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THIS INDEX is based on a consolidation of contents entries appearing in the January—June issues of the FEDERAL REGISTER together with broad subject references. The entries are arranged first under the name of the agency which issued the document. Under each agency, the entries are then listed alphabetically within the categories of Rules, Proposed Rules, and Notices. Executive Orders, Proclamations, and other documents from the President are listed under Presidential Documents. The number at the end of each entry gives the pages in the FEDERAL REGISTER where the document begins. Use the table of Federal Register Pages and Dates at the back of this index to locate the issue date for each page-number. This index is published monthly and is cumulated for 12 months.

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	Inspection Operations Manual: Standard operating inspectional and investigational procedures and instructions used by FDA investigational personnel	National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. Manual accession #PB88-913399, $55.95; subscription accession #PB88-913300, $65.00	
	Inspector Training Manual: Basic training manual for food and drug inspectors and inspection techniques	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $24.00. Payable to the Food and Drug Administration	
	Inspector's Manual for State Food and Drug Officials: Two-part manual—Part (1): operations section contains inspectional and investigational procedures, Part (2): program section outlines the specific recommended inspectional procedures applicable to a particular problem area, commodity or regulated industry. Similar in content to the Inspection Operations Manual, except for FDA administrative procedures which are not relevant to State Food and Drug Officials	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $71.00. Payable to the Food and Drug Administration	
	Inspector's Technical Guide: Technical information for FDA inspectors, not previously available on a broad scale	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $18.00. Payable to the Food and Drug Administration	

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Agency and subagency name	Index title: period covered, brief description of contents	Order from; price; make checks payable to—	For inspection, copying, or additional information contact
	Pesticide Analytical Manual: Procedures and methods used in FDA laboratories for surveillance of the extent and significance of contamination of man and his environment by pesticides and their metabolites	National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161. Volume I—Accession #PB88-911799, $62.95. Volume II—Accession #PB88-911999, $193.95. Entire Manual—Accession #PB86-911799, $230.00	
	Quantity of Contents Compendium: Contains information used to measure acceptance levels of shrinkage in food containers. Divided into two parts—(1) procedures for measuring fill-of-container, statistical evaluation acceptable common or usual declaration of quantity of contents; (2) information on sampling where special techniques are required	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $18.60. Payable to the Food and Drug Administration	
	Regulatory Procedures Manual: Guidance on regulatory policy and support processing procedures	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $142.80. Payable to the Food and Drug Administration	
	Staff Manual Guides—Organization and Delegations: Directives issued by FDA to establish policy, organization, procedures or responsibilities in the administrative area	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $259.00. Payable to the Food and Drug Administration	
	Supervisory Investigators Guide: Guidelines to assist supervisory inspectors in managing investigational groups	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $9.00. Payable to the Food and Drug Administration	
	Index to Administrative Staff Manuals: Current listing of all staff manuals with indexes and/or table of contents	Food and Drug Administration, Freedom of Information Staff, HFI-35, 5600 Fishers Lane, Rockville, MD 20857. Cost: $29.00 Payable to the Food and Drug Administration	
Department of Health and Human Services, Public Health Service, Health Services Administration (HHS/PHS/HSA)	HSA Freedom of Information Act (FOIA) Index: March 1975 to June 30, 1982. The HSA, FOIA index is a compilation of supplements to the departmental manual system, program level operations manuals, circulars, memoranda, notices and guides used by the components of HSA. All information included in this index is current as of June 30, 1982. The respective bureau level indexes are listed as follows: OA—OFFICE OF THE ADMINISTRATOR: OCPA—Public Affairs Management System Manual; OPEL—HSA forward plan, fiscal year 1979–83; OM/OCG—HSA procurement operating instructions; OM/OMP—HSA transmittal notices for supplements to HHS manuals; HSA Circulars; OM/OFS—policy decisions, procedures, and opinion. BMS—BUREAU OF MEDICAL SERVICES: Division of Hospitals and Clinics Operations Manual; BMS supplements to HHS manuals; Manual of Operations for PHS Health Unit, DFEH, BMS; BMS circulars; Contract Physician's Guide. IHS—INDIAN HEALTH SERVICES: IHS circulars; IHS supplements to HHS manuals; IHS Operations Manual; General Counsel opinions; policy and procedural manual and circulars. BCHS—BUREAU OF COMMUNITY HEALTH SERVICES: BCHS administrative guide system; BCHS Operations Manual; Emergency Medical Service Systems Program Guidelines; BCHS Regional Memorandum Series. BHPDS—BUREAU OF HEALTH PERSONNEL DEVELOPMENT AND SERVICE: BHPDS supplements to the HHS manuals; BHPDS operations manuals which include memoranda, guidelines, handbooks and procedures	Office of Communications and Public Affairs, HHS/PHS/HSA, Room 14A–39, 5600 Fishers Lane, Rockville, MD 20857. Checks payable to HHS/Public Health Service. Mail to HSA Collection Officer, HHS/PHS/HSA, Room 16–36, 5600 Fishers Lane, Rockville, MD 20857. Fees charged for research and reproduction of information are based upon the current departmental fee schedule for information under the FOI regulations (45 CFR part 5 subpart E)	Office of Communications and Public Affairs, HHS/PHS/HSA, Room 14A–39, 5600 Fishers Lane, Rockville, MD 20857

Agency and subagency name	Index title: period covered, brief description of contents	Order from; price; make checks payable to—	For inspection, copying, or additional information contact
Department of the Interior, Office of the Secretary	Departmental Manual Table of Contents, Checklist, and Subject Index dated May 31, 1989. Index of directives containing descriptions of central and field organizations of the Department, delegations of authority, internal policies, guidelines, procedures, and other administrative matters	Office of Information Resources Management, U.S. Department of the Interior, Washington, DC 20240 One copy only, no charge	Office of Information Resources Management, U.S. Department of the Interior, Washington, DC 20240
	Checklist and Subject Index of Departmental Manual Additions to the FPM dated June 3, 1988. Index of Departmental personnel management directives which supplement the Federal Personnel Manual	Chief, Division of Program Management and Evaluation, Office of Personnel, U.S. Department of the Interior, Washington, DC 20240 One copy only, no charge	Chief, Division of Program Management and Evaluation, Office of Personnel, U.S. Department of the Interior, Washington, DC 20240
	Listing of Secretary's Orders which are considered in effect with respect to current operations of the Department dated January 28, 1986	Office of Information Resources Management, U.S. Department of the Interior, Washington, DC 20240 One copy only, no charge	
Department of the Interior, Office of the Secretary, Office of Acquisition and Property Management	Departmental Manual Additions to the Federal Acquisition Regulation (FAR)	Division of Acquisition and Assistance, Office of Acquisition and Property Management, Department of the Interior, 18th & C Sts., NW., Room 5512, Washington, DC 20240 No charge	Division of Acquisition and Assistance, Office of Acquisition and Property Management, Department of the Interior, 18th & C Sts., NW., Room 5512, Washington, DC 20240 Telephone: (202) 343-6431
	400 DM - Departmental Manual Addition to the Interior Property Management Regulations (IPMR) Part 114-52	Division of Property Management, Office of Acquisition and Property Management, Department of the Interior, 18th & C Sts., NW., Room 5512, Washington, DC 20240 No charge	Division of Property Management, Office of Acquisition and Property Management, Department of the Interior, 18th & C Sts., NW., Room 5512, Washington, DC 20240 Telephone: (202) 343-3336
Department of the Interior, Office of the Secretary, Office of Aircraft Services	OAS Operational Procedures Memorandum No. 93-1, dated January 1, 1993. Subject: Index of Departmental Manual (Aviation Management) and Operational Procedures Memoranda Information.	Office of Aircraft Services, 3905 Vista Avenue, P.O. Box 15428, Boise, ID 83715-5428. No charge	Office of Aircraft Services, 3905 Vista Avenue, P.O. Box 15428, Boise, ID 83715–5428
Department of the Interior, Bureau of Indian Affairs	Bureau of Indian Affairs Manual Index and Table of Contents dated June 23, 1983	Division of Management Support, Bureau of Indian Affairs, 18th and C Streets, NW., Washington, DC 20245 No charge	Division of Management Support, Bureau of Indian Affairs, Room 334–Interior South, 1951 Constitution Ave., NW., Washington, DC 20240 Telephone: A.C.(202) 343-3577
Department of the Interior, Bureau of Land Management	Directives Digest Bulletin's dated – 1/31/90, 2/28/90, 3/31/90, 4/30/90, 5/31/90, 6/30/90, 7/31/90, 8/31/90, 9/31/90, 10/31/90, 11/30/90, 12/31/90	Department of the Interior, Bureau of Land Management, 1849 C Street, N.W., MIB 2454, Washington, DC 20240	Department of the Interior, Bureau of Land Management, 1849 C Street, N. W., MIB 2454, Washington, DC 20240 Telephone: (202) 208–6152
	Land Management Instructions and Manual Indexes	Department of the Interior, Bureau of Land Management, 1849 C Street, N. W., MIB 2454, Washington, DC 20240	Section for Directives and Records Operations (W0873) Room 2454, MIB Telephone: (202) 208–6152
Department of the Interior, Bureau of Mines	Basic Bureau of Mines Manual General Table of Contents and Checklist–July 6, 1976	Duplicate copies at 13 cents per page. in accordance with fee schedule in 43 CFR 2, Appendix A	Elizabeth Knorr, Chief, Branch of Management Analysis, 810 7th Street, NW., MS-2193, Washington, DC 20241 Telephone 202–501–9248
	Numeric and subject listing of internal policies and procedures by series, part, chapter, paragraph, and subordinate paragraph	Bureau of Mines	
Department of the Interior, Bureau of Reclamation	Reclamation Instructions Index dated July 7, 1983.	Supply and Services Division, D-7923, Bureau of Reclamation, P.O. Box 25007, Denver, CO 80225. No charge	Records Management Policy Staff, Bureau of Reclamation, D-7924, P.O. Box 25007, Denver, CO 80225-0007 Telephone: (303) 236-6494
Department of the Interior, U.S. Geological Survey	Table of Contents, Checklist, and Subject Index relating to the Geological Survey Manual	Paperwork Management Officer, U.S. Geological Survey, 208 National Center, Reston, VA 22092 No charge	Paperwork Management Officer; U.S. Geological Survey; 208 National Center, Reston, VA 22092 Telephone 703-648-7309
Department of the Interior, Minerals Management Service	Table of Contents and Checklist to Basic Minerals Management Service Manual. Listed numerically by part, series, chapter, release number, date, and pages.	In accordance with fee schedule in 43 CFR 2, Appendix A	Chief, Records and Mail Management Section, 381 Elden Street, MS 2050, Herndon, VA 22070 Telephone 703-787-1239
	Index of Director's appeal decisions	In accordance with fee schedule in 43 CFR 2, Appendix A	Chief, Appeals Division, Minerals Management Service, Office of Policy and Management Improvement, 381 Elden Street, MS 9110, Herndon, VA 22070, Telephone 703-787-1275
Department of the Interior, National Park Service	Checklist of the NPS Guidelines and Directives Dated January 1, 1993	U. S. Dept. of the Interior, National Park Service, P.O. Box 37127, Washington, DC 20013-7127 Attn: Management Services Division No charge	U. S. Dept. of the Interior, National Park Service, P.O. Box 37127, Washington, DC 20013-7127 Attn: Management Services Division Telephone 202-523-5043

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Agency and subagency name	Index title: period covered, brief description of contents	Order from; price; make checks payable to—	For inspection, copying, or additional information contact
Department of the Interior, Office of Hearings and Appeals	Index-Digest -- Index of synopses for all decisions decided by OHA Boards of Appeal and published Solicitor's decisions under specific topical headings. Useful in researching legal holdings of Department of the Interior. Published quarterly, annually and on 5-year basis.	Editorial Branch, Office of Hearings & Appeals, Room 1103, 4015 Wilson Blvd. Arlington, VA 22203.Telephone 703–235–3791 Price: $475.00 annually for quarterly issues and bound cumulative issue at end of calendar year. Checks made payable to "Department of the Interior." Price for photocopies as prescribed in Department fee schedule for FOIA information (43 CFR Part 2, Appendix A). Checks made payable to "Department of the Interior." Price on Quinquennial issue is set by Government Printing Office and available from that agency.	
	Indian Citator — Index of authorities cited in decisions of the Interior Board of Indian Appeals (IBCA). Initial publication covers volumes 1-15 of IBIA decisions. Annually.	Editorial Branch, Office of Hearings & Appeals, Room 1103, 4015 Wilson Blvd., Arlington, VA 22203. Telephone 703-235-3791 Price: $30.00 - initial cost Checks made payable to: "Department of the Interior". $15.00 – annual update	Editorial Branch, Office of Hearings & Appeals, Room 1103, 4015 Wilson Blvd., Arlington, VA 22203. Telephone 703-235-3791 Telephone (703) 235-3791
	Administrative Manual— Index related to administrative policies, procedures and standards as contained in the Administrative Manual	Editorial Branch, Office of Hearings & Appeals, Room 1103, 4015 Wilson Blvd., Arlington, VA 22203. Price for photocopies as prescribed in Department fee schedule for FOIA information (43 CFR Part 2, Appendix A): Checks payable to Department of the Interior.	Editorial Branch, OHA, 4015 Wilson Blvd., Arlington, VA 22203. Telephone: (703) 235-3791
Department of the Interior, Office of Inspector General	Inspector General Manual Index, December 17, 1992. Numeric and subject listing of internal policies and procedures by volume, chapter, section, and sub-section	In accordance with fee schedule in 43 CFR Part 2, Appendix A - Fees Office of Inspector General	Betty Foyes, Information Officer, Department of the Interior, Office of Inspector General, 18th and C Streets, NW., Washington, DC 20240 Telephone: 202–208–4356
Department of the Interior, Office of Surface Mining	Functional Index (OSMRE Directives Listed by Functions) dated October 22, 1986	Office of Surface Mining, Division of Management Services, 1951 Constitution Ave., NW., Washington, DC 20240 No charge	Office of Surface Mining, Division of Management Services, 1951 Constitution Ave., NW., Washington, DC 20240 Telephone: A.C. (202) 343-2210
Department of Labor	Department of Labor Freedom of Information Act Index Overview and Guide to DOL agencies and subagencies with information on how to obtain more detailed indexes to records maintained by each subagency; includes cross-reference to agencies by statute or executive order; 28 pages	Mail $4.20 check payable to DEPARTMENT OF LABOR to: FOIA Index Request, Counsel for Administrative Law, Division of Legislation and Legal Counsel, Office of the Solicitor, Department of Labor, 200 Constitution Avenue, NW., Room N2428, Washington, DC 20210.	Administrator, FOIA/PA, Counsel for Administrative Law, Division of Legislation and Legal Counsel, Office of the Solicitor, Department of Labor, 200 Constitution Avenue, NW., Room N2428, Washington, DC 20210 Phone (202) 523-9277
Department of Transportation, Federal Highway Administration (FHWA)	CrossReference Index of current directives, The index is alphabetical by subject and within each subject, applicable directives are identified. The index also includes a three-part cross-reference for the FHPM, 23 U.S.C. and 23 CFR. The index is updated semi-annually (March and September)	FOIA Program Officer, FHWA, 400 Seventh Street, SW., Washington, DC 20590. No charge	FOIA Program Officer, FHWA, 400 Seventh Street, SW., Washington, DC 20590
	Cease and Desist and Driver Disqualification Final Orders by the Federal Highway Administrator: 1969-1984; listing of cease and desist and driver disqualification final orders of the Federal Highway Administrator; items listed are identified by case docket number, name of carrier and date notice of investigation was mailed	FOIA Program Officer, FHWA, 400 Seventh Street, SW., Washington, DC 20590. No charge	FOIA Program Officer, FHWA, 400 Seventh Street, SW., Washington, DC 20590
	Opinions and Final Orders of the FHWA in Regard to the Regulation of Toll Bridges: 1968-1984 listing of opinions and final orders regarding regulation of toll bridges issued by the Federal Highway Administrator, which identifies the case and the date issued	FOIA Program Officer, FHWA, 400 Seventh Street, SW., Washington, DC 20590. No charge	FOIA Program Officer, FHWA, 400 Seventh Street, SW., Washington, DC 20590

Agency and subagency name	Index title: period covered, brief description of contents	Order from; price; make checks payable to—	For inspection, copying, or additional information contact
Department of the Treasury, Departmental Offices	Index of Selected Records, July 1967 to March 31, 1993. Index either contains the following information or indicates where the public may obtain information, decisions, statements of the general course and method by which functions are channeled and determined; a description of the central and field offices; rules of procedure, descriptions of forms; substantive rules and statements of general policy and interpretations adopted by the agency; and each amendment, revision, or repeal of the foregoing; final adjudications of cases; statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register; and administrative staff manuals and instructions to staff that affect a member of the public for the Departmental Offices, Internal Revenue Service, United States Customs Service, United States Secret Service, Bureau of Alcohol, Tobacco and Firearms, Bureau of Engraving and Printing, Financial Management Service, United States Mint, Bureau of the Public Debt, Office of the Comptroller of the Currency, United States Savings Bond Division, Federal Law Enforcement Training Center, Office of Thrift Supervision.	Library, Room 5010-MT, Department of the Treasury, Washington, DC 20220, Reproduced upon request; fees charged per page copied in accordance with fee schedule at 31 CFR 1.7. Make checks payable to Treasury of the United States	Treasury Department Library, Room 5010, Main Treasury Bldg., 15th and Pennsylvania Ave., NW., Washington, DC 20220 Telephone 202-622-0990
Architectural and Transportation Barriers Compliance Board	ATBCB Freedom of Information Index; June 1978 through November 1982: Final decisions made in adjudication of cases concerning alleged noncompliance to the Architectural Barriers Act of 1968; and a record of the final votes of each member of the Board in every Board proceeding. ATBCB annual reports; pamphlets describing the ATBCB, how to file complaints, and resource guides to literature in the area of creating an accessible environment	Freedom of Information Officer, ATBCB, Rm. 1010, 330 C St., SW., Washington, DC 20202. Reproduced upon request. Twenty cents per page, per copy. Make checks payable to the Department of Education Public Information Office, ATBCB, Rm. 1010, 330 C St., SW. Washington, DC 20202. No charge	Freedom of Information Officer, ATBCB, Rm. 1010, 330 C St., SW., Washington, DC Phone: 202-245-1591 Public Information Office, ATBCB, Rm. 1010, 330 C St., SW., Washington, DC 20202 Telephone: 202-245-1591
Committee for Purchase From the Blind and Other Severely Handicapped	Index of Additions and Deletions to the Procurement List: (a) Procurement List 1990 incorporates all additions and deletions through November 3, 1989; (b) Current index November 1989-December 1991.	Order from: Executive Director, Committee for Purchase From the Blind and Other Severely Handicapped, Crystal Square Building No. 5, 1755 Jefferson Davis Highway, Suite 1107, Arlington, VA 22202-3509. Price: Ten cents per page, per copy. Make checks payable to: Treasurer of the United States	Committee for Purchase From the Blind and Other Severely Handicapped, Attention: Freedom of Information Officer
Commodity Futures Trading Commission	Index of final Commission opinions, including concurring and dissenting opinions, and orders in the adjudication of cases. April 21, 1975 to date. (This index consists of separate chronological listings of final Commission opinions and orders in enforcement cases and reparations proceedings before the Commission) Index of statements of policy and interpretations adopted by the Commission and not published in the Federal Register. April 21, 1975 to date Index of Commission administrative manuals and instructions to staff that affect a member of the public. April 21, 1975 to date. (Commission instructions no longer in use are not included in this index)	Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581 Price: 10 cents per page	Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581 Telephone 202 254-6314

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General Services Administration (GSA)	GSA Freedom of Information Index; July 4, 1967 through June 30, 1984. Category A information which is final opinions, including concurring and dissenting opinions and orders, made in the adjudication of cases. Category B information which is those statements of policy and interpretations which have been adopted by GSA and are not published in the FEDERAL REGISTER. Category C information which is administrative staff manuals and instructions to staff that affect members of the public	GSA, Freedom of Information Officer (ATRAR), Washington, DC 20405. Price: $4.75. Make checks payable to: General Services Administration	GSA Central Office Library and the business service centers located in each regional office listed below: Central Office Library, 18th & F Sts., NW., Rm. 1033, Washington, DC 20405 Business Service Centers: National Capital Region: 7th & D Sts., SW., Washington, DC 20407 Region 1: John W. McCormack Post Office and Courthouse, Boston, Mass. 02109 Region 2: 26 Federal Plaza, New York, NY 10278 Region 3: 9th & Market Sts., Philadelphia, PA, 19107 Region 4: Richard B. Russell Bldg., 75 Spring St., Atlanta, GA 30303 Region 5: 230 So. Dearborn St., Chicago, IL, 60604 Region 6: 1500 East Bannister Rd., Kansas City, MO 64131 Region 7: 819 Taylor St., Ft. Worth, TX 76102 Region 8: Building 41, Denver Federal Center, Denver, CO 80225 Region 9: 525 Market St., San Francisco, CA 94105 Region 10: GSA Center, Auburn, WA 98002
International Boundary and Water Commission, United States and Mexico, U.S. Section	Brochure: Amistad Dam and Reservoir	Project Engineer, U.S. Section, IBWC, Route 2, Box 37, Highway 90 West, Del Rio, TX 78840. No charge	Project Engineer, U.S. Section, IBWC, Route 2, Box 37, Highway 90 West, Del Rio, TX 78840
	Brochure: Falcon Dam and Power Plant	Reservoirs Manager, U.S. Section, IBWC, P.O. Box 1, Falcon Village, TX 78545. No charge	Reservoirs Manager, U.S. Section, IBWC, P.O. Box 1, Falcon Village, TX 78545
	Water Bulletins: Containing data for 1 year covering flow of Rio Grande and related data from Elephant Butte, NM, to Gulf of Mexico, re storage in major reservoirs, diversions, suspended silt, chemical analyses, sanitary aspects of water quality, meteorologic data, and irrigated areas–for years 1931 through 1960	Division Engineer, Hydrographic Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902. Price: $4.50 per bulletin (data for 1 year). Payable to: International Boundary and Water Commission, U.S. Section	Division Engineer, Hydrographic Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902
	Water Bulletins: Containing data for 1 year covering flow of Colorado River and other Western Boundary streams, and related data (including Tijuana, Santa Cruz, and San Pedro Rivers, and Whitewater Draw) for years 1960 through 1980	Division Engineer, Hydrographic Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902. Price: $5.50 per bulletin (data for 1 year). Payable to: International Boundary and Water Commission, U.S. Section	Division Engineer, Hydrographic Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902
	Color print map – Lower Rio Grande Valley United States and Mexico	Division Engineer, Projects Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902. Prices: 14≥x36≥ $4.00 per map; 10≥x28≥ $3.00 per map. Payable to: International Boundary and Water Commission, U.S. Section	Division Engineer, Projects Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902
	Annual Report: Operation of Rio Grande Dams and Reservoirs. This report provides data concerning the operation of the international dams and reservoirs constructed by the Governments of the United States and Mexico on the reach of the Rio Grande which forms the boundary between the two countries	Division Engineer, Hydrographic Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902. No charge	Division Engineer, Hydrographic Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902
	Color print map: El Paso Rio Grande Projects, Canalization and Rectification Projects	Division Engineer, Projects Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902. Price: $10.00 per map. Payable to International Boundary and Water Commission, U.S. Section	Division Engineer, Projects Division, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902
	Brochure: Joint Projects of the United States and Mexico through the International Boundary and Water Commission	Section Secretry, U.S. Sec., IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902. Price: $6.00 per brochure. Payable to International Boundary and Water Commission, U.S. Section	Section Secretary, U.S. Section, IBWC, 4171 North Mesa, Suite C-310, El Paso, TX 79902

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National Archives and Records Administration (NARA)	NARA FOIA Index lists the following materials which have been adopted by NARA since April 1, 1985, and which are not published in the Federal Register: NARA final opinions and orders, statements of policy and interpretations, and administrative staff manuals and instructions to staff that affect a member of the public	Program Policy and Evaluation Division, National Archives (NAA), Washington, DC 20408	Program Policy and Evaluation Division, Room 409, National Archives Building, 8th and Pennsylvania Ave., NW., Washington, DC. Mailing address: National Archives (NAA), Washington, DC 20408. 202/523-3214
National Science Foundation (NSF)	Reviewer panelist, alphabetical listing contains name, State, and institution of individuals who have reviewed proposals for the National Science Foundation for the previously completed fiscal year		NSF Library, Room 245, 1800 G St., NW., Washington, DC 20550
	Numerical Index of the following NSF agency-wide issuances and Important Notices in effect as of January 24, 1986: (1) Office of the Director Staff Memoranda (O/D's); (2) NSF Bulletins; (3) NSF Manuals/Circulars; (4) NSF Handbooks; and (5) NSF Important Notices. O/D's are used by the NSF Director and Deputy Director to communicate information to the staff. O/D's also may be used to convey short-term policy statements or the initial statement of long-term policy. NSF Bulletins transmit approved changes to policy and convey administrative or "housekeeping" information. Significant NSF policy and procedure are located in NSF Manuals. NSF Circulars (historically used to communicate policies and procedures of a continuing nature) are being converted to Manuals and will be discontinued. Handbooks, less formal than Manuals, provide compendia of information concerning NSF programs, i.e., they do not establish NSF policy. Important Notices are the Director's primary means of communicating with organizations receiving or eligible for NSF support. Important Notices are issued over the Director's signature and convey information on NSF policies and procedures or other subjects determined to be of interest to the academic community and to other selected audiences.		
	Index of NSF regulations promulgated in the Code of Federal Regulations under Title 48, Public Contracts and Property Management; and Title 45, Public Welfare. A listing, by subject title, of current Foundation regulations with a brief description of the content of each		Office of the General Counsel, Room 501, 1800 G St., NW., Washington, DC 20550
	Publications of the National Science Foundation. An index by topical classification, as of April 1986, of current NSF publications issued and available to the public. Listing include annual reports, specific program announcements, and brochures, science resources studies pamphlets, special studies publications, and NSF periodicals. In addition to Titles, provides NSF publication numbers and copy prices. (NSF Publication 86-18)	NSF Forms and Publications Section, Room 232, 1800 G St., NW., Washington, DC 20550. One copy only (free)	For inspection or copying: NSF Library, Room 245, 1800 G St., NW., Washington, DC 20550. For additional information: Public Affairs Group, room 527, 1800 G St., NW., Washington, DC 20550
	NSF Guide to Programs, A composite listing of summary information about NSF support programs, as of October 1985. Provides general guidance and information describing the principal characteristics and basic purposes of each activity; eligibility requirements; closing dates (where applicable); and the address where more detailed information or applications may be obtained. (NSF Publication 85-40)	NSF Forms and Publications Section, Room 232, 1800 G St., NW., Washington, DC 20550. One copy gratis; or Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Stock No. 038-000-00458-1. Unit price $5.00	

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	NSF Grant Policy Manual. A compendium of basic NSF grant policies and procedures for use by the grantee community and NSF Staff. The Manual implements OMB Circular No. A-110, which is directed toward standardizing and simplifying the various accountability and reporting requirements amoung Federal granting agencies. (NSF Publication 77-47)	Superindendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Stock No. 038-000-81001-4. Unit Price $13.00	NSF Division of Grants and Contracts. Room 1150, 1800 G St., NW., Washington, DC 20550
Office of Personnel Management	Handbook of Publications, Periodicals, and FPM Issuances, OPM-AG-PSD-01. As of December 1991. A listing of publications, periodicals, and FPM issuances arranged in alphabetical order by title within each OPM issuing organization. This handbook contains some information formerly published in the Index to Information (no longer published).	Publishing Management Branch, Office of Personnel Management, Room B464, 1900 E St. NW, Washington, DC 20415-0001.	OPM Library or any OPM Office, including regional and area offices
Pennsylvania Avenue Development Corporation	PADC Freedom of Information Act (FOIA) Index; this index contains numeric and subject listings of PADC policy statements; public improvement policies; development guidelines; final opinions and cases interpreting PADC enabling legislation; and internal policies, guidelines and administrative procedures. Contains records originated since October 27, 1972, to date. The index is updated semi-annually (March and September).	PADC, Freedom of Information Officer, Suite 1220 North, 1331 Pennsylvania Avenue, NW, Washington, DC 20004-1703. Fees charged for research and reproduction of information are based upon the current Corporation fee schedule for information under FOI regulations (36 CFR Part 902, Subpart I).	PADC, Freedom of Information Officer, Suite 1220 North, 1331 Pennsylvania Avenue, NW, Washington, DC 20004-1703.
Pension Benefit Guaranty Corporation, Legal Department	Index to Pension Benefit Guaranty Corp. Opinion Manual; Sept. 2, 1974 to present; interpretive letters addressing the provisions of Title IV of the Employee Retirement Income Security Act (ERISA) plan termination insurance program	Disclosure Officer, Communications and Public Affairs Department, Pension Benefit Guaranty Corp., Room 7104, 2020 K St., NW., Washington, DC 20006; Charge $0.10 per page; payable to Pension Benefit Guaranty Corp.; or contact Disclosure Officer for information regarding a subscription to the Opinion Manual	Disclosure Officer, Communications and Public Affairs Department, 202–254–5527 (202–254–8010 for TTY and TDD), 2020 K St., NW., Washington, DC 20006
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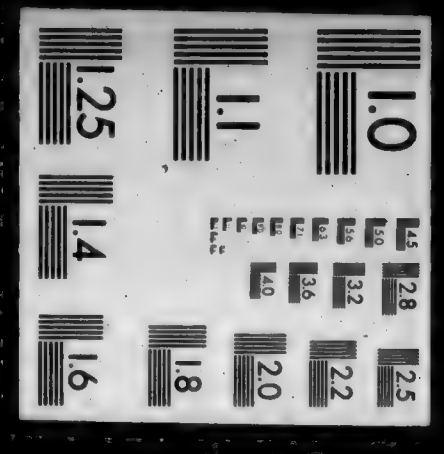
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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 422

Certified Seed Potato Option in Idaho

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Notice of exclusion for the 1993 crop year.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) herewith gives notice of its determination to exclude the Certified Seed Potato Option in Idaho for the 1993 crop year only.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Mari L. Dunleavy, Acting Director, Regulatory and Procedural Development, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (202) 254–8314.

SUPPLEMENTARY INFORMATION: Consistent with the FCIC's continuing commitment to limiting crop insurance programs that bear unreasonable risks to the taxpayer, the Corporation will exclude the Option in Idaho for the 1993 crop year only. Actuarial experience has dictated that the adverse risk associated with this option was in excess to the program's benefits. FCIC will further assess the option during the 1993 crop year for possible implementation in the 1994 crop year.

Authority: U.S.C. 1506, 1516.

Done in Washington, DC on December 23, 1992.

Jane A. Wittmeyer,

Deputy Manager, Federal Crop Insurance Corporation.

[FR Doc. 92–31724 Filed 12–31–92; 8:45 am]

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FEDERAL RESERVE SYSTEM

12 CFR Part 203

[Docket No. R–0790; Regulation C]

Home Mortgage Disclosure; Termination of Exemptions

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of order terminating state exemptions.

SUMMARY: Certain financial institutions in Connecticut and Massachusetts have been exempted from the Home Mortgage Disclosure Act because the Board determined that they were subject to substantially similar mortgage disclosure requirements under state law, and that these state laws contained adequate provisions for enforcement. After consultation with the banking commissioners of Connecticut and Massachusetts about the allocation of resources required for the processing and editing of the data, and the states' continued ability to enforce compliance with their state mortgage disclosure laws, the Board is terminating the exemptions as of January 1, 1993. The state officials concur with these terminations. The previously exempted institutions will submit their 1992 HMDA data to their federal regulatory agency rather than to the state.

DATES: This order is effective January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Jane Jensen Gell or W. Kurt Schumacher, Staff Attorneys, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, DC 20551, at (202) 452–2412 or (202) 452–3667. For the hearing impaired *only*, contact Dorothea Thompson, Telecommunications Device for the Deaf (TDD), at (202) 452–3544.

SUPPLEMENTARY INFORMATION:

(1) Introduction

The Board's Regulation C (12 CFR Part 203) implements the Home Mortgage Disclosure Act of 1975 (HMDA) (12 U.S.C. 2801 *et seq.*). HMDA requires certain depository institutions and other lenders located in metropolitan statistical areas to annually report information on the geographic distribution of their home mortgage and home improvement loans, and also to provide information on the race or national origin, sex, and income of applicants and borrowers for such loans. Under HMDA and Regulation C, the Board may grant exemptions to state-chartered or state-licensed financial institutions that are subject to state mortgage disclosure laws if those laws are substantially similar to the Federal law and contain adequate provisions for enforcement.

The Board previously determined that the laws of Connecticut and Massachusetts were substantially similar to federal law and that adequate provisions for enforcement existed. Therefore, the Board granted exemptions for state-chartered financial institutions subject to the state mortgage disclosure laws of the two states.

Following discussions and consultation with the banking commissioners' offices in each state, the Board is terminating these exemptions as of January 1, 1993. While the exemptions were in place, the states allocated resources to processing the HMDA data submissions from exempt institutions, and transmitted the data to the Federal Financial Institutions Examination Council (FFIEC) for compilation. Termination of the exemptions will shift the data processing responsibility back to the federal supervisory agencies. It will enable the states to reallocate their resources to analysis of the mortgage data, instead of to processing the raw data. Termination will also facilitate the processing of the HMDA data for the FFIEC by having all processing carried out directly by the federal agencies.

Because both states require the collection of the federally mandated HMDA data in a manner identical to the federal law, this termination will result in institutions sending their HMDA data to their federal supervisory agency and not to their state regulator. (Banking commission staff in the two states are expected to inform institutions shortly that they will not be required to send duplicate copies of their HMDA data to the state agency.) Given the absence of any apparent burden to affected institutions, the Board is issuing a final order terminating the exemption for state-chartered institutions in Connecticut and Massachusetts without providing a public comment period.

(2) Order of Termination

The Board granted exemptions from the federal Home Mortgage Disclosure Act to state-chartered financial institutions in Massachusetts and Connecticut in 1990 and 1991 respectively, based on the existence of substantially similiar requirements imposed by state law and on the states' provisions for their enforcement. The Board hereby terminates the exemptions for Connecticut and Massachusetts following consultation with, and the concurrence of, the banking commissioners of the two states. State-chartered financial institutions in Connecticut and Massachusetts that were previously exempt from the federal law shall be subject to the federal Home Mortgage Disclosure Act and Regulation C effective January 1, 1993. Accordingly, state-chartered institutions previously exempt from HMDA and Regulation C by virtue of the disclosure laws of Connecticut and Massachusetts shall submit their loan/application registers to their federal supervisory agency beginning with data collected for calendar year 1992, which are due to the supervisory agencies by March 1, 1993.

By order of the Board of Governors of the Federal Reserve System, December 28, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92-31872 Filed 12-31-92; 8:45 am]

BILLING CODE 6210-01-M

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12 CFR Part 229

[Regulation CC; Docket No. R-0783]

RIN 7100-AB01

Availability of Funds and Collection of Checks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; technical corrections.

SUMMARY: The Board is publishing technical corrections to Regulation CC. The corrections will conform the Uniform Commercial Code citations in Regulation CC and its Commentary to the 1990 version of Articles 3 and 4 of the UCC, as approved by the National Conference of Commissioners on Uniform State Laws and the American Law Institute, and to a recent realignment in Federal Reserve check processing regions. The amendments will provide updated cross-references between Regulation CC and the latest version of the UCC and will update the routing numbers in the appendices to the regulation.

EFFECTIVE DATE: January 5, 1993.

FOR FURTHER INFORMATION CONTACT: Oliver Ireland, Associate General Counsel (202/452-3625), or Stephanie Martin, Senior Attorney (202/452-3198), Legal Division. For the hearing impaired *only*: Telecommunications Device for the Deaf, Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The Board's Regulation CC (12 CFR part 229) and its accompanying Commentary (Appendix E to part 229) contains many citations and cross-references to the Uniform Commercial Code (UCC). Section 229.2(ii) of Regulation CC defines "Uniform Commercial Code" as the version of the UCC adopted by the individual states. The Commentary to this definition states that, for purposes of uniform citation, all citations to the UCC in the regulation and Commentary refer to the official text as approved by the National Conference of Commissioners on Uniform State Laws (NCCUSL) and the American Law Institute (ALI).

In 1990, the NCCUSL and the ALI approved new versions of UCC Articles 3 and 4, governing commercial transactions and bank deposits and collections, which have already been adopted in several states. Some sections of the new Articles 3 and 4 have been amended substantially and some only in form. The Board has amended the citations and cross-references in Regulation CC and its Commentary to conform to the new version of the UCC. The Board has also relocated two sentences in the Commentary to § 229.30(a) that were misplaced.

In addition, the Federal Reserve Bank of New York recently discontinued check processing at its head office and incorporated the former head office check processing region into the Jericho office check processing region. The Board has amended the routing number lists in Appendices A and B-2 to reflect this change.

The amendments adopted by the Board are technical changes that do not affect the substance of Regulation CC or its Commentary. The amendments will provide updated cross-references between Regulation CC and the latest version of the UCC and update the routing number lists in Appendices A and B-2. Accordingly, the Board, for good cause, finds that the notice and public comment procedure normally required is not necessary and would be contrary to the public interest under 5 U.S.C. 553(b)(B). The Board further finds that, for the same reasons, there is good cause under 5 U.S.C. 553(d)(3) to make the amendments effective immediately, without regard for the 30-day period provided for in 5 U.S.C. 553(d).

Final Regulatory Flexibility Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Board certifies that adoption of this final rule will not have a significant economic impact on a substantial number of small entities that are subject to the regulation. As noted above, the amendments impose no new requirements, but merely update UCC cross-references and appendices.

List of Subjects in 12 CFR Part 229

Banks, banking, Federal Reserve System, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 12 CFR part 229 is amended as follows:

1. The authority citation for part 229 continues to read as follows:

Authority: 12 U.S.C. 4001 *et seq.*

2. In section 229.2, in the second sentence of paragraph (cc), "U.C.C. 4-202(2)" is revised to read "UCC 4-202(b)".

3. In Appendix A to part 229, under the heading "SECOND FEDERAL RESERVE DISTRICT," the numbers appearing directly under the subheading "*Head Office*" are transferred in numerical order under the subheading "*Jericho Office*" and the subheading "*Head Office*" is removed.

4. In Appendix B-2 to part 229, the headings "*New York*" and "*Jericho*" and their corresponding entries are removed from the table.

5. In Appendix E under the Commentary to section 229.2, in the first sentence of the second paragraph of paragraphs (f) and (g), "U.C.C. § 4-104(1)(c)" is revised to read "UCC 4-104(a)(3)"; in the second sentence of paragraph (j), "U.C.C. §§ 3-410, 3-411" is revised to read "UCC 3-409"; in the first sentence of the third paragraph of paragraph (k), "U.C.C. § 3-120" is revised to read "UCC 4-106(a)"; the first sentence of the last paragraph of paragraph (bb) is revised as set forth below; and in the fourth sentence of paragraph (cc), "U.C.C. 4-202(2)" is revised to read "UCC 4-202(b)".

Appendix E to Part 229—[Amended]

* * * * *

Section 229.2 Definitions

* * * * *

(bb) *Qualified returned check.* * * *

* * * * *

A qualified returned check need not contain the elements of a check drawn on the

depositary bank, such as the name of the depositary bank. * * *

* * * * *

6. In Appendix E under the Commentary to section 229.11, in the fourth sentence of the last paragraph of paragraph (b) under the heading "*Time Period Adjustment for Withdrawal by Cash*", "U.C.C. § 4-107" is revised to read "UCC 4-108".

7. In Appendix E under the Commentary to paragraph (a) of section 229.14, in the fourth sentence of the first paragraph of footnote 3, "U.C.C. sections 4-211 and 4-213" is revised to read "UCC 4-214 and 4-215".

8. In Appendix E under the Commentary to section 229.19, in the last sentence of the last paragraph of paragraph (e), "U.C.C. 4-213(1)(a)" is revised to read "UCC 4-215(a)(1)".

9. In Appendix E under the Commentary to section 229.30:

a. In paragraph (a), the last two sentences of the seventh from the last paragraph are removed; two new sentences are added to the end of the fifth from the last paragraph as set out below; in footnote 4, "U.C.C. section 4-202(3)" is revised to read "UCC 4-202(c)"; in the third sentence of the sixth from the last paragraph, "U.C.C. sections 3-418 and 4-213(1)" is revised to read "UCC 3-418(c) and 4-215(a)"; the third from the last paragraph (numbered 1) is removed; the second from the last and the last paragraphs (numbered 2 and 3) are redesignated as 1 and 2, respectively; in newly-redesignated paragraph 1, "Section 4-301(4)" is revised to read "Section 4-301(d)"; and in newly-redesignated paragraph 2, "Section 4-301(1)" is revised to read "Section 4-301(a)";

b. In paragraph (b), in the last sentence of the last paragraph, "U.C.C. section 4-207" is revised to read "UCC 4-208"; and

c. In paragraph (f), in the first sentence of the second paragraph, "U.C.C. section 4-301(1)" is revised to read "UCC 4-301(a)".

Appendix E to Part 229—[Amended]

* * * * *

Section 229.30 Paying bank's responsibility for return of checks

* * * * *

(a) * * *

* * * Also, a paying bank is not responsible for failure to make expeditious return to a party that has breached a presentment warranty under UCC 4-208, notwithstanding that the paying bank has returned the check. (See Commentary to § 229.33(a).)

* * * * *

10. In Appendix E under the Commentary to section 229.31:

a. In paragraph (a), in the second sentence of the fifth from the last paragraph, "U.C.C. section 4-202(3)" is revised to read "UCC 4-202(c)"; the third from the last paragraph (numbered 1) is removed; the second from the last and the last paragraphs (numbered 2 and 3) are redesignated as 1 and 2, respectively; in newly-redesignated paragraph 1, "Section 4-202(2)" is revised to read "Section 4-202(b)", and in newly-redesignated paragraph 2, "Section 4-212(1)" is revised to read "Section 4-214(a)";

b. In paragraph (b), in the first sentence of the third paragraph, "U.C.C. section 4-202(2)" is revised to read "UCC 4-202(b)"; and

c. In paragraph (c), in the first sentence of the last paragraph, "U.C.C. section 4-212(1)" is revised to read "UCC 4-214(a)".

11. In Appendix E under the Commentary to section 229.32, in the fourth sentence of the first paragraph of paragraph (a), "U.C.C. section 3-504(2)" is revised to read "UCC 3-111", and in the second sentence of the second paragraph of paragraph (b), "U.C.C. section 4-107" is revised to read "UCC 4-108".

12. In Appendix E under the Commentary to paragraph (a) of section 229.33, in the second from the last sentence of the last paragraph, "U.C.C. 4-207(1)" is revised to read "UCC 4-208" and in the last sentence of the last paragraph, "U.C.C. 4-207(1) and 4-302" is revised to read "UCC 4-208 and 4-302".

13. In Appendix E under the Commentary to section 229.35:

a. In paragraph (a), the second sentence of the sixth paragraph is revised to read "(See UCC 4-207(a) and 4-208(a).)";

b. In paragraph (b), in the seventh sentence of the fifth paragraph, "U.C.C. sections 4-213(1) and 4-302" is revised to read "UCC 4-215(a) and 4-302"; in the eighth sentence of the fifth paragraph, "U.C.C. 4-211(2) and (3) and 4-213(3)" is revised to read "UCC 4-213 and 4-215(d)"; in the tenth sentence of the fifth paragraph, "U.C.C. 4-211, 4-212, and 4-213" is revised to read "UCC 4-213, 4-214, and 4-215"; in the first and second sentences of the second from the last paragraph (numbered 1), "Section 4-212(1)" is revised to read "Section 4-214(a)"; and the last paragraph (numbered 2) is revised as set out below; and

c. In paragraph (c), in the second sentence, "U.C.C. section 4-201(2)" is revised to read "UCC 4-201(b)".

Appendix E to Part 229—[Amended]

* * * * *

Section 229.35 Indorsements

* * * * *

(b) * * *

2. Section 3-415 and related provisions (such as section 3-503), in that such provisions would not apply as between banks, or as between the depositary bank and its customer.

* * * * *

14. In Appendix E under the Commentary to section 229.36:

a. In paragraph (b), in the fourth sentence of the third paragraph (numbered 1), "U.C.C. 4-204(3)" is revised to read "UCC 4-204(c)"; in the fourth sentence of the seventh paragraph (numbered 3), "U.C.C. 3-504(2)" is revised to read "UCC 3-111"; and in the last paragraph, "U.C.C. 3-504(2)(c)" is revised to read "UCC 3-111";

b. In paragraph (c), the third sentence is revised as set out below; and

c. In paragraph (d), in the fifth sentence, "U.C.C. § 4-213(b) or (d)" is revised to read "UCC 4-215(a)(2) or (3)".

Appendix E to Part 229—[Amended]

* * * * *

Section 229.36 Presentment and issuance of checks

* * * * *

(c) * * * This process has the potential to improve the efficiency of check processing, and express provision for truncation and electronic presentment is made in UCC 4-110 and 4-406(b). * * *

* * * * *

15. In Appendix E under the Commentary to section 229.37, before the parenthetical in the second sentence in the first paragraph, "U.C.C. 4-103(1)" is revised to read "UCC 4-103(a)", and in the first sentence in the second paragraph, "U.C.C. 4-103(2)" is revised to read "UCC 4-103(b)".

16. In Appendix E under the Commentary to section 229.38:

a. In paragraph (a), in the third sentence in the second paragraph, "U.C.C. sections 4-103(5) and 4-202(3)" is revised to read "UCC 4-103(e) and 4-202(c)";

b. In paragraph (b), in the last sentence, "sections 4-213 and 4-302" is revised to read "sections 4-215 and 4-302"; and

c. In paragraph (e), the second sentence is revised to read as follows:

Appendix E to Part 229—[Amended]

* * * * *

Section 229.38 Liability

* * * * *

(e) * * * It adopts the standard of UCC 4-109(b).

* * * * *

17. In Appendix E under the Commentary to section 229.39, in the introductory text, "U.C.C. section 4-214" is revised to read "UCC 4-216".

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By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority, December 29, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92-31933 Filed 12-31-92; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92-NM-100-AD; Amendment 39-8449; AD 92-27-14]

Airworthiness Directives; Airbus Industrie Model A320 Series Airplanes, Equipped With Garrett Auxiliary Power Unit (APU) GTCP36-300[A]

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Airbus Industrie Model A320 series airplanes, that currently requires a revision to the Limitations Section of the Airplane Flight Manual (AFM) and the installation of a placard in the cockpit prohibiting the use of the APU during flight or on the ground until the installation of an external secondary turbine containment shield assembly has been accomplished. This amendment requires replacement of the currently-installed external secondary turbine containment shield assembly with an assembly of an improved design. This amendment is prompted by a recent report of an APU turbine rotor that separated and several fragments were not contained. The actions specified by this AD are intended to prevent potential damage to the fuselage and flight controls, and subsequent reduced controllability of the airplane.

DATES: Effective February 8, 1993.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 8, 1993.

ADDRESSES: The service information referenced in this AD may be obtained from Garrett Airline Services Division, Technical Publications, Department 65-70, P.O. Box 52170, Phoenix, AZ 85072-2170. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Greg Holt, Aerospace Engineer, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2140; fax (206) 227-1320.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations by superseding AD 90-11-51 R1, Amendment 39-6635 (55 FR 24073, June 14, 1990), which is applicable to certain Airbus Industrie Model A320 series airplanes, was published in the **Federal Register** on July 6, 1992 (57 FR 29681). The action proposed to require replacement of the currently-installed external secondary turbine containment shield assembly with an assembly of an improved design.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the proposed rule.

One commenter objects to the wording in the Summary and Discussion sections of the proposal because it inaccurately depicts the incidents as they actually occurred. The proposal states that in a second incident of auxiliary power unit (APU) turbine rotor separation, several fragments were not contained. The commenter asserts that, in this incident, only low energy fragments were released, which resulted in minor damage to the APU fire enclosure and that the integrity of the fire enclosure was not breached. Furthermore, the commenter states that the safety of the aircraft was unaffected with respect to fire, the fuselage, and the flight controls. Therefore, the incident was considered contained by the APU manufacturer, the airplane manufacturer, the definition of TSO-C77a, and the FAA's Los Angeles Aircraft Certification Office. The commenter further maintains that the incident clearly demonstrated the capability of the containment system to contain high energy rotor bursts. Additionally, the commenter notes that the extended external shields were designed to provide additional protection against the escape of secondary low energy fragments, not because the original shield posed a potential safety problem. The FAA does not concur that the depiction of the incident needs to be clarified. The FAA has determined that since low energy fragments were released and caused damage to the APU fire enclosure, the possibility exists for high energy particles to be released in a worse case of rotor burst.

One commenter notes that the applicability of the proposal needs to be revised to exclude airplanes equipped with Garrett APU GTCP36-300[A], part number 3800278-2, having serial numbers P-453, P-454, and R-477 and subsequent; and APU's that have been modified in accordance with Garrett Service Bulletin GTCP36-49-6525; because the turbine plenum in these APU's incorporates a thicker wall. The FAA concurs. Paragraphs (a) and (b) and the applicability of the final rule have been revised accordingly.

Additionally, paragraph (c) has been revised to clarify that installation of an extended external secondary turbine containment shields assembly in accordance with Garrett Service Bulletin GTPC36-49-6549 terminates the requirements for paragraphs (a) and (b) of the final rule.

This same commenter states that the subject APU's are also installed on airplanes other than Airbus Model A320 series airplanes; therefore, the applicability of the rule should be revised to include these other airplanes. The FAA does not concur. The FAA has verified that the subject APU's were modified prior to installation on those other airplanes; therefore, they need not be included in this final rule.

One commenter requests that the proposed compliance time of 24 months be extended to compensate for a potential parts availability problem and the time required to perform the retrofit of the APU's. The FAA does not concur. In developing an appropriate compliance time for this action, the FAA considered not only the degree of urgency associated with addressing the subject unsafe condition, but the availability of required parts and the practical aspect of installing the required modification within a maximum interval of time allowable for all affected airplanes to continue to operate without compromising safety. The APU manufacturer has advised that an ample number of required parts will be available for modification of the U.S. fleet within the proposed compliance period. However, under the provisions of paragraph (d) of the final rule, the FAA may approve requests for adjustments to the compliance time, if data is submitted that substantiate that such an adjustment would provide an acceptable level of safety.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the

adoption of the rule with the changes previously described. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

The FAA estimates that 32 airplanes of U.S. registry will be affected by this AD, that it will take approximately 3 work hours per airplane to accomplish the required actions, and that the average labor rate is $55 per work hour. Required parts would be supplied by the manufacturer at no charge to operators. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $5,280, or $165 per airplane. This total cost figure assumes that no operator has yet accomplished the requirements of this AD.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–6635 (55 FR 24073, June 14, 1990), and by adding a new airworthiness directive (AD), amendment 39–8449, to read as follows:

92–27–14. Airbus Industrie: Amendment 39–8449. Docket 92–NM–100–AD. Supersedes AD 90–11–51 R1, Amendment 39–6635.

Applicability: Model A320 series airplanes; equipped with Garrett Auxiliary Power Unit (APU) GTCP36–300[A], Part No. 3800278–2, excluding serial numbers P–453, P–454, and R–477 and subsequent; and APU's modified in accordance with Garrett Service Bulletin GTCP36–49–6525, any revision; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent potential damage to the fuselage and flight controls, and subsequent reduced controllability of the airplane, accomplish the following:

(a) Within 72 hours (clock hours, not flight hours) after July 2, 1990 (the effective date of AD 90–11–51 R1, Amendment 39–6635), accomplish the procedures specified in paragraphs (a)(1) and (a)(2) of this AD:

(1) Revise the Limitations Section in the FAA-approved Airplane Flight Manual (AFM) to include the following statement. This may be accomplished by inserting a copy of this AD in the AFM Limitations Section.

"Operation of the APU on the ground is prohibited, and operation of the APU during flight is prohibited, except during an emergency."

(2) Install a placard next to the APU start switch in the cockpit to state:

"Operation of the APU on the ground is prohibited, and operation of the APU during flight is prohibited, except during an emergency."

(b) Within 30 days after July 2, 1990 (the effective date of AD 90–11–51 R1, Amendment 39–6635), install an external secondary turbine containment shield assembly, Part Number 3615644–1, in accordance with Garrett Alert Service Bulletin GTCP36–49–A5973, dated May 17, 1990; or Revision 1, dated May 22, 1990. Installation of this containment shield assembly constitutes terminating action for the requirements of paragraph (a) of this AD.

(c) Within 24 months after the effective date of this AD, remove the external secondary turbine containment shield assembly, Part No. 3615644–1, and install a new external secondary turbine containment shield assembly, Part Numbers 3615898–1 and 3615899–1, in accordance with Garrett Service Bulletin GTCP36–49–6549, dated February 28, 1992. Installation of this containment shield assembly constitutes terminating action for the requirements of paragraphs (a) and (b) of this AD.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Manager, Standardization Branch, ANM–113.

(e) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) The installation and replacement shall be done in accordance with the following Garrett service bulletins, which contain the specified effective pages:

Service Bulletin referenced and date	Page number	Revision level shown on page	Date shown on page
GTCP36–49–A5973, Revision 1, May 22, 1990	1, 3, 5, 7–8, 11–12	1	May 22, 1990.
	2, 4, 6, 9–10, 13–14	Original	May 17, 1990.
GTCP36–49–A5973, May 17, 1990	1–6, 9–14	Original	May 17, 1990.
	7–8	(Removed)	
GTCP36–49–6549, February 28, 1992	1–16	Original	February 28, 1992.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Garrett Airline Services Division, Technical Publications, Department 65–70, P.O. Box 52170, Phoenix, AZ 85072–2170. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North

Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on February 8, 1993.

Issued in Renton, Washington, on December 17, 1992.

Bill R. Boxwell,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92-31876 Filed 12-31-92; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 92-NM-137-AD; Amendment 39-8450; AD 92-27-15]

Airworthiness Directives; de Havilland, Inc., Model DHC-7 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to Model DHC-7 series airplanes, that requires installation of a water deflector over the elevator servo drum assembly. This amendment is prompted by a report of uncommanded pitch excursion that occurred during flight while the autopilot was engaged, apparently caused by ice accumulation in the elevator servo drum assembly. The actions specified by this AD are intended to prevent freezing of the elevator servo drum assembly, which could lead to an uncommanded pitch excursion with the autopilot engaged and reduced controllability of the aircraft.

DATES: Effective February 8, 1993.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 8, 1993.

ADDRESSES: The service information referenced in this AD may be obtained from de Havilland, Inc., Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 181 South Franklin Avenue, Room 202, Valley Stream, New York; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michele Maurer, Aerospace Engineer, Systems and Equipment Branch, ANE-173, New York Aircraft Certification Office, FAA, Engine and Propeller Directorate, 181 South Franklin Avenue, room 202, Valley Stream, New York 11581; telephone (516) 791-6427; fax (516) 791-9024.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations to include an airworthiness directive (AD) that is applicable to Model DHC-7 series airplanes was published in the **Federal Register** on August 17, 1992 (57 FR 36926). That action proposed to require installation of a water deflector over the elevator servo drum assembly.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter supports the rule as proposed.

One commenter requests a reduction of the compliance time for accomplishing the installation from the proposed 60 days to 30 days. The commenter feels that the compliance time as proposed will expose the affected airplanes, passengers, and flight crew to an increased risk of uncommanded pitch excursion as a result of ice accumulation in the elevator servo drum assembly. This is especially critical during the winter months. The FAA does not concur with the need for a shorter compliance time. In developing an appropriate compliance time for this action, the FAA considered not only the degree of urgency associated with addressing the subject unsafe condition, but the availability of required parts and the normal maintenance schedules for the majority of the affected fleet. In consideration of all of these items, the FAA determined that 60 days was reasonable and appropriate. In addition, the FAA determined that the probability of the occurrence of the unsafe condition is sufficiently low to warrant a compliance time of 60 days.

One commenter requests that the proposal be amended to include a provision to alert flight crews of the potential icing hazard during autopilot operation. The commenter notes that this could be accomplished by either adding a placard on the instrument panel, or incorporating the warning in the FAA-approved Airplane Flight Manual (AFM). The FAA does not concur. The FAA has determined that the probability of the occurrence of the subject unsafe condition is low and, if it occurs, it would be readily detected and corrected by standard flight crew procedures. Additionally, the modification that is required by this AD action is intended to prevent the unsafe condition (caused by water accumulation in the servo drum assembly) from occurring altogether.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

The FAA estimates that 50 airplanes of U.S. registry will be affected by this AD, that it will take approximately 5 work hours per airplane to accomplish the required actions, and that the average labor rate is $55 per work hour. Required parts will cost approximately $75 per airplane. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $17,500, or $350 per airplane. This total cost figure assumes that no operator has yet accomplished the requirements of this AD.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A final evaluation has been prepared for this action and it is contained in the Rules Docket. A copy of it may be obtained from the Rules Docket at the location provided under the caption "**ADDRESSES**."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

92-27-15. De Havilland, Inc.: Amendment 39-8450. Docket 92-NM-137-AD.

Applicability: All Model DHC-7 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent freezing of the elevator servo drum assembly, which could lead to an uncommanded pitch excursion with the autopilot engaged and reduced controllability of the aircraft, accomplish the following:

(a) Within 60 days after the effective date of this AD, install a water deflector onto the front spar of the vertical stabilizer, directly over the elevator servo assembly, Modification No. 7/2605, in accordance with paragraph III. of de Havilland Service Bulletin S.B. 7-55-10, dated October 25, 1991.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office (ACO), FAA, Engine and Propeller Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The installation shall be done in accordance with de Havilland Service Bulletin S.B. 7-55-10, dated October 25, 1991. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from de Havilland, Inc., Garratt Boulevard, Downsview, Ontario M3K 1Y5, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Engine and Propeller Directorate, New York Aircraft Certification Office, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on February 8, 1993.

Issued in Renton, Washington, on December 17, 1992.

Bill R. Boxwell,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 92-31877 Filed 12-31-92; 8:45 am]

BILLING CODE 4910-13-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 240, 241 and 276

[Release No. 34-31661; IA-1357]

RIN 3235-AE54

Registration of Successors to Broker-Dealers and Investment Advisers

AGENCY: Securities and Exchange Commission.

ACTION: Adoption of rule amendments; interpretive statement.

SUMMARY: The Commission is adopting amendments to the rules under the Securities Exchange Act of 1934 governing the registration of successors to registered broker-dealers. The Commission also is issuing interpretive guidance in this release regarding the registration of successors to broker-dealers and the registration of successors to investment advisers under the Investment Advisers Act of 1940. The amendments and interpretive statement are intended to clarify which entities may file as successors to registered broker-dealers and advisers, whether such filings should be in the form of an amendment to the predecessor's registration statement or in the form of a new application, and when such filings must be made.

EFFECTIVE DATES: The rule amendments will become effective on February 3, 1993. The interpretive positions become effective on December 28, 1992.

FOR FURTHER INFORMATION CONTACT: Robert L.D. Colby, Chief Counsel, or Belinda A. Blaine, Branch Chief, at (202) 504-2418, Office of Chief Counsel, Division of Market Regulation (with respect to broker-dealer successors); Eric C. Freed, Senior Counsel, at (202) 272-2107, Office of Disclosure and Investment Adviser Regulation, Division of Investment Management (with respect to investment adviser successors); Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Background

The Securities Exchange Act of 1934 ("Exchange Act") and the Investment Advisers Act of 1940 ("Advisers Act") respectively provide for the registration of "successors" to registered broker-dealers and investment advisers.[1] A successor is an unregistered entity that assumes and continues the business of a registered broker-dealer or adviser, which then ceases its broker-dealer or advisory activities. The purpose of the statutory provisions is to enable the successor to operate without an interruption of business by relying for a limited period of time on the registration of the predecessor broker-dealer or adviser. The Commission has adopted several rules to effectuate the statutory provisions of the Exchange Act and the Advisers Act.[2]

In general, the statutory provisions and rules provide that a successor may rely on the registration of the predecessor until such time as its own registration becomes effective if it files an application for registration within thirty days of the succession.[3] The successor rules also provide that, in certain limited circumstances, the successor may file an amendment to the predecessor's registration statement, instead of an original application for registration, within the prescribed time period.[4]

II. Amendments to Broker-Dealer Successor Rules

The Commission is adopting several technical amendments to the broker-dealer successor rules under the Exchange Act in order to address certain ambiguities in the rules.[5] As originally adopted, paragraph (a) of rule 15b1-3[6] allowed a broker-dealer that succeeded to and continued the business of a registered broker-dealer to operate

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[1] Section 15(b)(2) of the Exchange Act (15 U.S.C. 78o(b)(2)); section 203(g) of the Advisers Act (15 U.S.C. 80b-3(g)).

[2] Rules 15b1-3, 15Ba2-4, 15Ba2-6, and 15Ca2-3 under the Exchange Act (17 CFR 240.15b1-3, 15Ba2-4, 15Ba2-6, and 15Ca2-3); rule 203-1 under the Advisers Act (17 CFR 275.203-1).

[3] See, *e.g.*, paragraph (a) of rule 15b1-3 under the Exchange Act; section 203(g) of the Advisers Act.

[4] See, *e.g.*, paragraph (b) of rule 15b1-3 under the Exchange Act; paragraphs (b), (c) and (d) of rule 203-1 under the Advisers Act.

Currently, broker-dealers that are members of the National Association of Securities Dealers, Inc. ("NASD") must make all filings with both the Commission and the NASD. In a companion release published today, the Commission announced that it is joining the Central Registration Depository ("CRD"), a computer system operated by the NASD that maintains registration information regarding NASD member firms and their registered personnel. Thus, effective January 25, 1993, all broker-dealers filing for succession by application (or amendment) will be required to file with the Commission through the CRD. See Securities Exchange Act Release No. 31660 (Dec. 28, 1992). Investment advisers will continue to file directly with the Commission.

[5] These amendments, as well as an interpretive statement regarding the broker-dealer successor rules, were proposed for public comment in Securities Exchange Act Release No. 30959 (July 27, 1992), 57 FR 34046. No comments were submitted in connection with the proposed amendments or the interpretive statement.

[6] Rule 15b1-3 was adopted in 1985 pursuant to section 15(b)(2)(A) of the Exchange Act. See Securities Exchange Act Release No. 22468 (September 26, 1985), 50 FR 41867.

under the registration of the predecessor for seventy-five days if, within thirty days of the succession, it filed its own application for registration on Form BD.[7] Paragraph (b) of the rule permitted a successor broker-dealer to file an amendment to the predecessor's Form BD if the succession was based on a change in the date or state of incorporation, form of organization, or composition of a partnership.

In addition to minor revisions to the language of the rule, the amendments adopted today make two notable changes. First, paragraph (a) has been amended to provide that the predecessor's registration terminates forty-five days after the date on which the successor files its own application for registration on Form BD, rather than seventy-five days after the date of the succession.[8] This amendment is intended to address situations in which a successor broker-dealer submits an application within thirty days of the succession, but because the application is incomplete in certain minor respects, the seventy-five day period expires before the successor broker-dealer's registration becomes effective. Under the modified rule, the forty-five day period will not begin to run until a complete application has been filed with the Commission.[9]

Second, paragraph (b) of rule 15b1–3 has been revised to clarify that successors may register by filing an amendment to the predecessor's Form BD, rather than a complete application on Form BD, only in certain limited circumstances, discussed below in part III. Rule 15Ca2–3, which governs the registration of successors to government securities broker-dealers, and rules 15Ba2–4 and 15Ba2–6,[10] which govern the registration of successors to municipal securities dealers,[11] also have been revised to be consistent with amended rule 15b1–3.

III. Interpretive Position on Broker-Dealer and Investment Adviser Successions

A. General

As discussed above, the purpose of the successor rules under both the Exchange Act and the Advisers Act is to facilitate the legitimate transfer of business between two or more entities.[12] The successor rules therefore are intended to be used only where there is a direct and substantial business nexus between the predecessor and the successor. They are not designed to allow registered broker-dealers or advisers to sell their registrations, eliminate substantial liabilities, spin off personnel, or to facilitate the transfer of the registration of a "shell" organization that does not conduct any business.[13] To ensure that there is a legitimate connection between the predecessor and successor, no entity may rely on the successor rules unless it is acquiring or assuming substantially all of the assets and liabilities of the predecessor's broker-dealer or advisory business.[14] Although under this standard the successor need not acquire every asset and liability of the predecessor, it may not exclude any significant asset or liability.[15] Therefore, an entity that is not assuming substantially all of the assets and liabilities of its predecessor is not entitled to rely on the successor rules, and must wait until its own registration becomes effective before engaging in business as a broker-dealer or investment adviser.

Because the successor rules are intended to allow an unregistered successor to rely on the registration of its predecessor for a limited period of time, they do not apply to reorganizations that involve only registered entities. In those situations, the registered entities need not use the successor rules because they can continue to rely on their existing registrations. For instance, if two registered broker-dealers merge, the surviving broker-dealer would file an amendment to its Form BD, while the acquired broker-dealer would file to withdraw its registration on Form BDW.[16] Furthermore, if a person or entity acquires some or all of the shares of a registered adviser, or if one registered adviser purchases or otherwise assumes part or all of the business assets or personnel of another registered adviser, there would be no need to rely on the successor provisions.[17]

In addition, the successor rules do not apply to situations in which the predecessor intends to continue to engage in broker-dealer or advisory activities.[18] Otherwise, confusion may result as to the identities and registration statuses of the parties. Thus, if a registered broker-dealer or adviser shifts a portion of its business operations to a new unregistered entity,

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[7] 17 CFR 249.501.

[8] This 45-day period is consistent with section 15(b)(1)(B) of the Exchange Act, which provides that the Commission has 45 days in which to grant registration or to institute proceedings to determine if registration should be denied.

In addition, as discussed further below, the predecessor must file for withdrawal from registration.

[9] For further discussion of the timing requirements for successor filings, see discussion at part III.D, *infra*.

[10] Rule 15Ba2–6 also has been redesignated as rule 15Ba2–4(b).

[11] Specifically, these rules permit a municipal securities dealer that succeeds to and continues the business of a registered municipal securities dealer to rely on the registration of the predecessor if it files an application or an amendment for registration on Form MSD (17 CFR 249.1100) (for a municipal securities dealer that is a bank or a separately identifiable department or division of a bank), or Form BD (for all other municipal securities dealers).

[12] The interpretive positions set forth in this release apply to both broker-dealers and investment advisers. Comparable treatment of broker-dealers and advisers eases compliance burdens on registrants that maintain dual registrations, and simplifies the review of registration materials by Commission staff.

[13] See Securities Exchange Act Release No. 22468 (Sept. 28, 1985), 50 FR 41867.

[14] An entity's status under the successor rules, however, is not determinative of whether it will be held liable for the acts of its predecessor. See generally, *Ricciardello v. J.W. Gant & Co.*, [1989–1990] Fed. Sec. L. Rep. (CCH) ¶ 94,798 (July 7, 1989); Securities Exchange Act Release No. 25531 (March 30, 1988) (successor broker-dealer held liable for the predecessor's failure, prior to the succession, to maintain the required balance of cash or qualified securities in its reserve account for the exclusive benefit of customers); *Hutson Management Co.*, Investment Advisers Act Rel. No. 1078 (Aug. 17, 1987) (successor investment adviser held liable for predecessor's violations of section 10(f) of the Investment Company Act of 1940).

[15] The predecessor's liabilities, for example, may include: Customer claims, monies or securities due to customers or other broker-dealers or advisers, unsatisfied judgments, and outstanding fees or fines. In a few instances, the staff of the Commission has granted no-action relief to allow successors to rely on rule 15b1–3 without assuming a specific asset or liability of the predecessor. See, *e.g.*, *Alpha Management Inc.* (December 21, 1989) [available on LEXIS] (permitting a successor broker-dealer to file an application under paragraph (a) of Rule 15b1–3 without acquiring the shares of a subsidiary not engaged in broker-dealer activities); and *Franklin Financial Services, Inc.*, [1987–1988] Fed. Sec. L. Rep. (CCH) ¶ 78,529 (July 2, 1987) (allowing a successor to proceed under paragraph (a) without assuming unknown contingent liabilities of the predecessor. The predecessor represented that it would retain adequate funds in escrow to meet any such contingent liabilities).

[16] 17 CFR 249.501a.

[17] In the case of the purchase of the business assets or personnel of one registered adviser by another, the purchasing adviser would file an amendment to Form ADV (17 CFR 279.1) to reflect any changes in its operations, while the other adviser would file either Form ADV–W (17 CFR 279.3) or an amendment to its Form ADV, depending on whether it remained in the advisory business.

Of course, there is generally no difference in substance between the acquisition of an entity's shares and the acquisition of its assets, but in the latter case the presence of a new entity that will act as the broker-dealer or adviser necessitates reliance on the successor rules. The successor rules parallel state corporate laws in this regard, under which it is necessary to incorporate or register a new corporation, while no similar action is required if the ownership of an existing corporation changes.

[18] See generally *F.W. Horne & Co., Inc.* 38 S.E.C. 104 (1957) (finding that a broker-dealer did not succeed to the registration of another broker-dealer, where the first broker-dealer continued to exist as a corporate entity with the ability to resume business, and where the acquiring broker-dealer failed to acquire all of the assets of the first broker-dealer).

but remains in the broker-dealer or advisory business, the new entity must file a complete application for registration and refrain from doing business until its application is approved by the Commission pursuant to section 15(b)(1) of the Exchange Act or section 203(c)(2) of the Advisers Act.[19]

B. Succession by Amendment

In limited circumstances, the successor rules permit the successor to file an amendment to the predecessor's Form BD or Form ADV, rather than its own original application for registration.[20] The only successions that may be completed by filing an amendment are those that are the result of a formal change in the structure or legal status of the broker-dealer or adviser; *i.e.*, successions that involve the creation of a new legal entity, but no practical change in the control or operations of the broker-dealer or adviser.[21] Whether an actual change of control has occurred depends upon the facts and circumstances of the particular transaction. For purposes of the successor rules, however, the presumption of "control" in the instructions to Form BD and Form ADV offers some guidance.[22]

The types of successions that may be effected by filing an amendment are listed below. In all of these situations, the predecessor must cease operating as a broker-dealer or adviser.

1. Change in Form of Organization

An internal corporate reorganization or restructuring in which broker-dealer or advisory activities are transferred from one entity to another within the same organization, but that does not result in a change of control of the broker-dealer or adviser, would be filed by amendment.[23]

2. Change in Legal Status

A succession resulting from a change in the state of incorporation or a change in the form of business, such as from a partnership to a corporation, does not typically involve a change of control. Therefore, such a succession may generally be completed by amending the predecessor's Form BD or Form ADV promptly after the succession.[24]

3. Change in Composition of a Partnership

A change in the composition of a partnership (by death, withdrawal, or inclusion of a partner) that results in the dissolution of the partnership under local law, but does not result in a change in control of the partnership, would be completed by filing an amendment to the predecessor's Form BD or Form ADV in order to reflect the changes in the partnership.

C. Succession by Application

In all other successions, the successor may operate under the registration of the predecessor for a limited period of time only if it files its own complete application for registration on Form BD or Form ADV. The following are examples of the types of reorganizations that must be completed by filing an application.[25]

1. Acquisitions

In a typical succession, an unregistered entity purchases or assumes substantially all of the assets and liabilities of a registered broker-dealer or adviser, and the unregistered entity then operates the business of the broker-dealer or adviser.[26] Under the successor rules, the new entity must file a complete application within thirty days of the succession, while the predecessor must file for withdrawal from registration on Form BDW or Form ADV–W.[27]

2. Consolidations

If two or more registered entities consolidate their firms and conduct their business through a new unregistered entity, which assumes substantially all of the assets and liabilities of the predecessor entities, the new entity would be required to file a complete application on Form BD or Form ADV, while the predecessor firms would each be required to file for withdrawal from registration on the appropriate form.

3. Dual Successions[28]

Succesions in which one registered entity subdivides its business into two or more new unregistered entities are known as "dual successions," and may be effected by application under the successor rules. A dual succession may occur, for instance, when a clearing broker-dealer decides to separate its own retail broker functions from its clearing broker functions by creating two new entities. In that case, the successors in combination must acquire substantially all of the assets and liabilities of the predecessor. Each successor must then file a complete application on Form BD within thirty days of the succession, while the predecessor broker-dealer must file an application for withdrawal on Form BDW.[29]

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[19] 15 U.S.C. 78o(b)(1), 80b–3(c)(2). In addition, the registered broker-dealer or adviser would be required to promptly file an amendment on Form BD or Form ADV to reflect any changes in its operations. Like dual successions, discussed below, this type of reorganization is classified as a "partial acquisition" under the CRD system. See n.28, *infra*, and accompanying text.

[20] See, *e.g.*, Rule 15b1–3(b) under the Exchange Act, Rule 203–1(b)–(d) under the Advisers Act.

In the case of a broker-dealer, the amendment to Form BD would include page 1 (the execution page), page 2 (indicating that the applicant is a successor), Schedule D, and any other pages containing information that is no longer accurate as a result of the change in the form of organization of the broker-dealer. See rule 15b3–1(b) (17 CFR 240.15b3–1(b)) under the Exchange Act. In the case of an investment adviser, the amendment to Form ADV would include page 1, page 2, Schedule E and any other pages containing information required to be updated by rule 204–1(b) (17 CFR 275.204–1(b)) under the Advisers Act.

[21] The successor rules provide that a succession that is based solely upon certain events, such as a change in form of organization, may be effected by amendment. See, *e.g.*, rule 15b1–3(b) under the Exchange Act (as amended); Rule 203–1(d) under the Advisers Act. A succession that involves a change in control is not based solely upon an event enumerated in the rules, and therefore cannot be effected by amendment.

[22] Under the Advisers Act, a change of control of an adviser results in the "assignment" of its advisory contracts. Rule 202(a)(1)–1 under the Advisers Act (17 CFR 275.202(a)(1)–1). The adviser must obtain client consent to the assignment under section 205(a)(2) of the Advisers Act (15 U.S.C. 80b–5(a)(2)).

[23] For example, an unregistered entity that acquires substantially all of the assets and liabilities of a registered entity owned by the same parent corporation may file an amendment to its predecessor's registration, provided that it (the surviving entity) continues to be wholly-owned by the parent corporation. In contrast, a corporate reorganization involving a change of control, such as a change in the beneficial owners of the broker-dealer or advisory operation, must be filed by application, as discussed in part III.C, *infra*.

[24] Other changes in legal status that may be completed by filing an amendment include: (i) A change from general corporation to S corporation status under subchapter S of the Internal Revenue Code of 1986, as amended; and (ii) a change in a registered entity's name that results in the dissolution of the entity under local law. If a name change does not alter the entity's legal status, however, the successor rules do not apply. Instead, the registered entity would be required to promptly file an amendment to Form BD or Form ADV to reflect its new name. See rule 15b3–1(b) under the Exchange Act; rule 204–1(b) under the Advisers Act.

[25] Unless otherwise indicated, the titles below correspond to the classification of the succession under the CRD's "mass transfer" program, which determines whether registered representatives of a broker-dealer may have their registrations transferred to another entity.

[26] However, if no change in control occurs in connection with the transaction (*e.g.*, the beneficial owners of the adviser or broker-dealer remain the same), the succession could be effected by filing an amendment. See part III.B, *supra*.

[27] See rule 15b6–1 under the Exchange Act (17 CFR 240.15b6–1); rule 203–2 under the Advisers Act (17 CFR 275.203–2).

[28] Under the CRD's mass transfer program, this type of reorganization is classified as a "partial acquisition."

[29] Both successors in a dual succession must file original applications for registration, regardless of whether there is a change in control of the broker-dealer or advisory operation.

4. Division of Dual Registrants [30]

For business reasons, an entity registered as both an investment adviser and as a broker-dealer may wish to separate its services by transferring either the broker-dealer or advisory activities to a new unregistered entity. If that unregistered entity acquires substantially all of the assets and liabilities of the broker-dealer or advisory operation or division, and there is a change of control of that operation or division, the unregistered entity would be a successor required to file by application.[31]

D. Timing Requirements

In order to temporarily rely on its predecessor's registration, a successor must file the required application or amendment within thirty days of the succession.[32] Occasionally, situations arise in which a successor broker-dealer or adviser submits an application within thirty days of the succession, but because the application is incomplete in certain minor respects, the application is not considered "filed" until after the thirty-day period has expired.[33] Notwithstanding the fact that the filing requirements technically have not been met, the Commission would permit a successor that submits a substantially complete application or amendment within thirty days of the succession to rely on its predecessor's registration under the successor rules. A successor entity, however, will not be permitted to "lock in" the thirty-day window period by submitting an application that is incomplete in major respects, or by otherwise failing to file an application that represents a good faith attempt at compliance with the successor rules.[34]

[30] In the case of a division of dual registrants, the CRD category will be based on the type of broker-dealer reorganization.

[31] The predecessor also would be required to file Form BDW or ADV–W. See, e.g., *Alpha Management Inc.* (December 21, 1989) (available on LEXIS).

[32] Rule 15b1–3 under the Exchange Act; section 203(g) of the Advisers Act.

[33] Rule 0–3 under the Exchange Act (17 CFR 240.0–3) provides that a report or application is not "filed" for purposes of the Act until it fully complies with all of the requirements of the applicable rule or provision of the statute. While there is no comparable rule under the Advisers Act, the Commission likewise does not consider incomplete documents to be "filed" under the Advisers Act.

[34] As discussed above, the Commission is amending paragraph (a) of rule 15b1–3 under the Exchange Act to provide that the registration of a predecessor broker-dealer ceases to be effective as the registration of the successor broker-dealer forty-five days after the application for registration on Form BD is filed by the successor, rather than seventy-five days after the succession. Therefore, because the Commission must act on applications for registration within forty-five days (see note 8, *supra*), the registration of the predecessor will not expire during the period that the successor needs to rely on such registration. Neither the Advisers Act nor the rules thereunder specify when the registration of the predecessor expires. However, Form ADV–W must be filed to withdraw the registration of the predecessor, and Form ADV–W becomes effective on the 60th day after filing. See Rule 203–2(b) under the Advisers Act. Therefore, the predecessor's registration will expire only after the successor has established its own registration, which, as under the Exchange Act, will occur within forty-five days after the filing of the successor application. See section 203(c)(2) of the Advisers Act (15 U.S.C. 80b–3(c)(2)).

[35] 15 U.S.C. 78w(a)(2).

[36] 5 U.S.C. 603.

IV. Effects on Competition and Regulatory Flexibility Act Considerations

Section 23(a)(2) of the Exchange Act [35] requires the Commission, in adopting rules under the Exchange Act, to consider the anticompetitive effects of such rules, if any, and to balance any anticompetitive impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission believes that the clarifying amendments to the broker-dealer successor rules will not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.

In addition, the Commission has prepared a Final Regulatory Flexibility Analysis ("FRFA") pursuant to the requirements of the Regulatory Flexibility Act,[36] regarding the revisions to the rules. A copy of the FRFA may be obtained from Belinda Blaine, Branch Chief, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

List of Subjects

17 CFR Parts 240 and 241

Registration of brokers and dealers, Registration of government securities brokers and government securities dealers, Registration of non-bank municipal securities dealers; Reporting and recordkeeping requirements, Securities, Broker-Dealers.

17 CFR Part 276

Investment advisers, Reporting and recordkeeping requirements, Securities.

Statutory Basis and Text of Proposed Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78*o*, 78p, 78s, 78w, 78x, 78*ll*(d), 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, and 80b–11, unless otherwise noted.

2. By revising § 240.25b1–3 to read as follows:

§ 240.15b1–3 Registration of successor to registered broker or dealer.

(a) In the event that a broker or dealer succeeds to and continues the business of a broker or dealer registered pursuant to section 15(b) of the Act, the registration of the predecessor shall be deemed to remain effective as the registration of the successor if the successor, within 30 days after such succession, files an application for registration on Form BD, and the predecessor files a notice of withdrawal from registration on Form BDW; *Provided, however,* That the registration of the predecessor broker or dealer will cease to be effective as the registration of the successor broker or dealer 45 days after the application for registration on Form BD is filed by such successor.

(b) Notwithstanding paragraph (a) of this section, if a broker or dealer succeeds to and continues the business of a registered predecessor broker or dealer, and the succession is based solely on a change in the predecessor's date or state of incorporation, form of organization, or composition of a partnership, the successor may, within 30 days after the succession, amend the registration of the predecessor broker or dealer on Form BD to reflect these changes. This amendment shall be deemed an application for registration filed by the predecessor and adopted by the successor.

3. By revising § 240.15Ba2–4 to read as follows:

§ 240.15Ba2–4 Registration of successor to registered municipal securities dealer.

(a) In the event that a municipal securities dealer succeeds to and continues the business of a registered municipal securities dealer, the registration of the predecessor shall be deemed to remain effective as the registration of the successor if the successor, within 30 days after such succession, files an application for registration on Form MSD, in the case of a municipal securities dealer that is a bank or a separately identifiable department or division of a bank, or

Form BD, in the case of any other municipal securities dealer, and the predecessor files a notice of withdrawal from registration on Form MSDW or Form BDW, as the case may be; *Provided, however,* That the registration of the predecessor dealer will cease to be effective as the registration of the successor dealer 45 days after the application for registration on Form MSD or Form BD is filed by such successor.

(b) Notwithstanding paragraph (a) of this section, if a municipal securities dealer succeeds to and continues the business of a registered predecessor municipal securities dealer, and the succession is based solely on a change in the predecessor's date or state of incorporation, form of organization, or composition of a partnership, the successor may, within 30 days after the succession, amend the registration of the predecessor dealer on Form MSD, in the case of a predecessor municipal securities dealer that is a bank or a separately identifiable department or division of a bank, or on Form BD, in the case of any other municipal securities dealer, to reflect these changes. This amendment shall be deemed an application for registration filed by the predecessor and adopted by the successor.

§ 240.15Ba2–6 [Removed and reserved]

4. By removing and reserving § 240.15Ba2–6.

5. By revising § 240.15Ca2–3 to read as follows:

§ 240.15Ca2–3 Registration of successor to registered government securities broker or government securities dealer.

(a) In the event that a government securities broker or government securities dealer succeeds to and continues the business of a government securities broker or government securities dealer registered pursuant to section 15C(a)(1)(A) of the Act, the registration of the predecessor shall be deemed to remain effective as the registration of the successor if the successor, within 30 days after such succession, files an application for registration on Form BD, and the predecessor files a notice of withdrawal from registration on Form BDW; *Provided, however,* That the registration of the predecessor government securities broker or government securities dealer will cease to be effective as the registration of the successor government securities broker or government securities dealer 45 days after the application for registration on Form BD is filed by such successor.

(b) Notwithstanding paragraph (a) of this section, if a government securities broker or government securities dealer succeeds to and continues the business of a predecessor government securities broker or government securities dealer that is registered pursuant to section 15C(a)(1)(A) of the Act, and the succession is based solely on a change in the predecessor's date or state of incorporation, form of organization, or composition of a partnership, the successor may, within 30 days after the succession, amend the registration of the predecessor broker or dealer on Form BD to reflect these changes. This amendment shall be deemed an application for registration filed by the predecessor and adopted by the successor.

PART 241—INTERPRETIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

Part 241 is amended by adding this Interpretive Release [Release No. 34–31661] to the lists of Interpretive Releases.

PART 276—INTERPRETIVE RELEASES RELATING TO THE INVESTMENT ADVISERS ACT OF 1940 AND GENERAL RULES AND REGULATIONS THEREUNDER

Part 276 is amended by adding this Interpretive Release [Release No. IA–1357] to the lists of Interpretive Releases.

Dated: December 28, 1992.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92–31867 Filed 12–31–92; 8:45 am]

BILLING CODE 8010–01–M

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17 CFR Parts 240 and 249

[Release No. 34–31660]

RIN 3235–AE54

Broker-Dealer Registration and Reporting

AGENCY: Securities and Exchange Commission.

ACTION: Adoption of rule amendments.

SUMMARY: In order to coordinate the broker-dealer registration process with the Central Registration Depository, a computer system operated by the National Association of Securities Dealers, Inc., the Securities and Exchange Commission is adopting several amendments to the broker-dealer registration rules under the Securities Exchange Act of 1934. The amendments provide new instructions for filing Form BD, the uniform application form for broker-dealer registration, and Form BDW, the uniform request form for broker-dealer withdrawal, with the Central Registration Depository. The amendments also eliminate the requirement that applicants for broker-dealer registration file a statement of financial condition and representations regarding capital contributions, facilities, and financing, as part of their applications on Form BD.

EFFECTIVE DATE: January 25, 1993.

FOR FURTHER INFORMATION CONTACT: Robert L.D. Colby, Chief Counsel, or Belinda Blaine, Branch Chief, (202) 504–2418, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION:

I. Introduction

As part of its ongoing effort to reduce the costs associated with broker-dealer registration,[1] the Securities and Exchange Commission ("Commission") is preparing to participate in the Central Registration Depository ("CRD"). The CRD is a computerized filing and data processing system operated by the National Association of Securities Dealers, Inc. ("NASD") that maintains registration information regarding NASD member firms and their registered personnel for access by state regulators, certain self-regulatory organizations ("SROs"), and the Commission. The Commission's primary objective in joining the CRD system is to provide "one-stop filing" for broker-dealers. Currently, applicants for broker-dealer registration that also are applying for membership in the NASD are required to file separate applications on Form BD, the uniform form for broker-dealer registration, with both the Commission and the NASD. Under the new system, broker-dealers will only be required to file one application for registration on Form BD with the NASD, which will enter the information into the CRD system and then electronically forward the data to the Commission for review. Form BD amendments and withdrawals from

[1] The Commission recently adopted amendments to Form BD. See Securities and Exchange Act Release No. 30958 (July 27, 1992), 57 FR 34028; and Securities Exchange Act Release No. 31398 (November 4, 1992), 57 FR 53261. These amendments became effective on November 16, 1992.

registration on Form BDW also will be filed through the CRD system.

The Commission believes that its direct participation in the CRD system will improve the efficiency of the registration process by creating a comprehensive, centralized database of all registrants, and by giving the Commission more immediate access to current data in broker-dealer filings. The new system also will result in cost savings to registrants, who will no longer be required to make multiple filings with the Commission, the NASD, and state agencies.

To prepare for its entry into the CRD system, the Commission recently proposed several amendments to the broker-dealer registration rules under the Securities Exchange Act of 1934 ("Exchange Act"), as well as corresponding amendments to the registration filing instructions.[2] The Commission received one comment letter on the proposed amendments, which expressed support for the concept of "one-stop filing."[3] The Commission therefore is adopting the amendments as proposed, with the exception of one technical change to the filing instructions for non-NASD member broker-dealers, discussed below.

II. Filing Procedures

Rules 15b1–1, 15b3–1, and 15b6–1,[4] the Special Instructions for Completing or Amending Form BD, and the General Instructions to Form BDW, have been revised to implement the new procedures for filing registration materials through the CRD system, as follows.[5]

A. Form BD

1. New Applicants

All broker-dealers, including government securities broker-dealers,[6] applying for registration with the Commission on or after January 25, 1993, will file one executed original Form BD with the CRD in accordance with the instructions to the Form.[7] Foreign broker-dealers that are required to file a consent to service of process pursuant to Rule 15B1–5 or Rule 15Ca2–5 under the Exchange Act will continue to file the consent directly with the Commission, but will send a copy to the CRD with their Form BD application.[8]

2. Registered NASD Member Broker-Dealers

Registered broker-dealers that are members of the NASD will not be required to file a new Form BD when the Commission joins the CRD on January 25, 1993, because the system already contains Form BD information on NASD members. Any NASD member amending its Form BD filing on or after that date, however, will need to file the amended pages, together with the execution page, with the CRD in accordance with the instructions to the Form.[9]

3. Registered Non-NASD Member Broker-Dealers

In order to allow the CRD system to capture registration information on all broker-dealers, registered broker-dealers that are members of an SRO other than the NASD will be required to file a complete Form BD with the CRD over a period of nine months.[10] In the Proposing Release, the Commission suggested processing non-NASD member broker-dealers' filings by their SEC registration numbers. To facilitate the transition, these filings will now be processed according to both the broker-dealers' SEC registration numbers and their Designated Examining Authorities ("DEA").[11] Specifically, non-NASD member broker-dealers will be required to file a complete Form BD[12] during the week of:

(1) January 25, 1993, for all such broker-dealers whose DEA is the Boston Stock Exchange, the Cincinnati Stock Exchange, the Midwest Stock Exchange, or the Philadelphia Stock Exchange;

(2) February 1, 1993, for all such broker-dealers whose DEA is the Pacific Stock Exchange;

(3) May 3, 1993, for all such broker-dealers whose DEA is the New York Stock Exchange;

(4) June 1, 1993, for all such broker-dealers whose DEA is the American Stock Exchange;

(5) July 6, 1993, for all such broker-dealers whose DEA is the Chicago Board Options Exchange and whose SEC registration number is between 8–18117 and 8–34181;

(6) August 2, 1993, for all such broker-dealers whose DEA is the Chicago Board Options Exchange and whose SEC registration number is 8–34182 or above; and

(7) September 7, 1993, for all other non-NASD member broker-dealers.

Any subsequent amendments to these Form BD filings also must be submitted to the CRD. Registered non-NASD member broker-dealers that need to amend their Forms subsequent to January 25, 1993, but prior to their scheduled processing date, will be required to promptly file a complete amended Form BD with the CRD.[13]

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[2] Securities Exchange Act Release No. 30959 (July 27, 1992), 57 FR 34048 ("Proposing Release"). In the Proposing Release, the Commission also proposed structural amendments to the rules under the Exchange Act governing the registration of successors to broker-dealers. Those amendments are being adopted today in a separate release, which provides interpretive guidance with respect to the registration of successors to broker-dealers and the registration of successors to investment advisers under the Investment Advisers Act of 1940. See Securities Exchange Act Release No. 31661; Investment Advisers Act Release No. 1357 (Dec. 28, 1992).

[3] Letter from Jacqueline H. Hallihan, President, National Regulatory Services, Inc. ("NRS"), to Jonathan G. Katz, Secretary, SEC (August 27, 1992). NRS also expressed concern about the continued public availability of Form BD information once the Commission joins the CRD. The Commission wishes to emphasize that public access to Form BD and other registration information will not be affected by the CRD plan; such information will continue to be available directly from the Commission.

[4] 17 CFR 240.15b1–1, 240.15b3–1, and 240.15b6–1. Amendments also have been made to the analogous rules governing non-bank municipal securities dealers (whose business is exclusively intrastate) and government securities broker-dealers. See 17 CFR 240.15Ba2–2, 240.15Bc3–1, 240.15Ca1–1, 240.15Ca2–1, and 240.15Cc1–1.

[5] All applications, amendments, and withdrawals from registration that are filed with the CRD will be deemed to be filed with the Commission. However, the 45-day period under section 15(b)(1) of the Exchange Act (15 U.S.C 78o(b)(1)) (or any other relevant filing period) will not begin to run until the CRD has transmitted the form data to the Commission and the Commission has determined that the filing is complete.

[6] Non-bank municipal securities dealers whose business is exclusively intrastate also will file Form BD with the CRD. Municipal securities dealers that are banks or departments of banks, however, will continue to file Form MSD directly with the Commission pursuant to Rule 15Ba2–1 (17 CFR 240.15Ba2–1).

[7] As noted above, amendments to Form BD became effective on November 16, 1992. Accordingly, all new applicants for broker-dealer registration, as well as all registered non-NASD member broker-dealers filing a complete Form BD with the CRD in accordance with the schedule set forth in Part II.A.3 below, must file on the new revised Form BD.

[8] 17 CFR 240.15b1–5 and 17 CFR 240.15Ca2–5 require foreign broker-dealers to file consents to service of process on Form 7–M, 8–M, 9–M, or 10–M.

In addition, non-resident broker-dealers should continue to file the notice or undertaking required by Rule 17a–7 (17 CFR 240.17a–7) directly with the Commission, but send a copy with their applications to the CRD.

[9] The Commission will not accept filings directly from NASD members after January 25, 1993.

[10] Broker-Dealers that are members of both the NASD and an exchange will follow the procedures for NASD members set forth in Part II.A.2, *supra*.

[11] See generally section 15(b)(2)(C) of the Exchange Act (15 U.S.C. 78o(b)(2)(C)). For most non-NASD member broker-dealers, the DEA will be the national securities exchange of which they are a member.

[12] All broker-dealers should file using the version of Form BD that became effective on November 16, 1992. *See* discussion, *supra*.

[13] In addition, broker-dealers filing pursuant to Rule 15a–4 (17 CFR 240.15a–4) will be required to file with the CRD.

These broker-dealers will not be required to resubmit an application on their scheduled date.

B. Form BDW

NASD member broker-dealers requesting withdrawal from registration on or after January 25, 1993 will file one manually signed original Form BDW, the uniform request form for broker-dealer withdrawal, and a copy of the required sections of part II (or part IIA for non-clearing firms) of their FOCUS reports with the CRD.[14] *Non*-NASD member broker-dealers that have *not* previously filed a Form BD with the CRD will begin filing for withdrawal from registration with the CRD on September 30, 1993.[15] Non-NASD members, however, will continue to send a copy of Form BDW, together with the required attachments,[16] directly to the Commission's Office of Filings, Information, and Consumer Services.

III. Statement of Financial Condition and Representations

To facilitate the registration of broker-dealers through the CRD system, the Commission also is rescinding Rule 15b1–2 and related Rules 15Ba2–2(b) and 15Ca2–2, all under the Exchange Act.[17] Rule 15b1–2 originally required an applicant for broker-dealer registration to submit a statement of financial condition and other information regarding its financial resources as part of its application on Form BD.[18] Rules 15Ba2–2(b) and 15Ca2–2 contained similar reporting requirements for non-bank municipal securities dealers whose business is exclusively intrastate and government securities broker-dealers.

These filing requirements were intended to assist the Commission in determining whether applicants had the requisite amount of capital and the capacity to operate as a broker-dealer. As the Proposing Release noted, however, the rules of the SROs also require broker-dealers to file a statement of financial condition, or to otherwise demonstrate their ability to conduct business as a broker-dealer, with their applications for membership.[19] This information, as well as other registration information obtained by the SROs, is readily available to the Commission.

The Commission therefore is rescinding Rule 15b1–2, paragraph (b) of Rule 15Ba2–2, and rule 15Ca2–2 because the filing requirements under those rules duplicate SRO requirements and are not necessary to ensure that applicants for broker-dealer registration comply with the net capital and other requirements of the Exchange Act. Eliminating these requirements will result in savings to broker-dealers without affecting the Commission's ability to evaluate the financial condition of applicants. Moreover, it will simplify the Commission's entry into the CRD system, thereby facilitating the broker-dealer registration process.

IV. Effects on Competition and Regulatory Flexibility Act Considerations

Section 23(a)(2) of the Exchange Act[20] requires the Commission, in adopting rules under the Exchange Act, to consider the anticompetitive effects of such rules, if any, and to balance any anticompetitive impact against the regulatory benefits gained in terms of furthering the purposes of the Exchange Act. The Commission believes that the amendments to the broker-dealer registration rules and filing instructions will not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. On the contrary, the amendments should reduce the costs currently associated with broker-dealer registration.

In addition, the Commission has prepared a Final Regulatory Flexibility Analysis ("FRFA"), pursuant to the requirements of the Regulatory Flexibility Act,[21] regarding the amendments. A copy of the FRFA may be obtained from Belinda Blaine, Branch Chief, Office of Chief Counsel, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549; at (202) 504–2418.

V. Effective Date

Pursuant to Section 4(c) of the Administrative Procedure Act,[22] publication of the amendments to the broker-dealer registration rules may not be made less than thirty days before their effective date, absent good cause. As noted above, the Commission is joining the CRD system on January 25, 1993. In order to begin processing filings through the CRD by that date, the amendments to the registration rules shall become effective on January 25, 1993, based on the Commission's finding of good cause.

List of Subjects in 17 CFR Parts 240 and 249

Registration of brokers and dealers, Registration of government securities brokers and government securities dealers, Registration of non-bank municipal securities dealers; Reporting and recordkeeping requirements, Securities, Broker-dealers.

Statutory Basis and Text of Proposed Amendments

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78i, 78j, 78*l*, 78m, 78n, 78*o*, 78p, 78s, 78w, 78x, 78*ll*(d), 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, and 80b–11, unless otherwise noted.

2. By amending § 240.15b1–1 by revising the section heading, designating the current text as paragraph (a), and adding paragraphs (b) and (c) to read as follows:

Although the NASD is developing modifications to the CRD system that eventually will allow non-NASD members to file for registration with the states through the CRD, until further notice, all non-NASD members will need to file separately with the states in which they are registering.

[14] Form BDW instructs broker-dealers that file FOCUS reports to attach a copy of the "Statement of Financial Condition" and "Computation of Net Capital" sections of their FOCUS report. Broker-dealers that do not file FOCUS reports are required to attach a statement of financial condition giving the type and amount of the firm's net worth and assets and liabilities. Both the FOCUS report and the statement of financial condition must be dated no earlier than 10 days before the Form BDW is filed.

[15] Prior to September 30, 1993, non-NASD members should file Form BDW with the CRD *only* if they have already filed Form BD with the CRD. If they have *not* previously filed form BD with the CRD, they should continue to file Form BDW with the Commission.

[16] *See* n.14, *supra*.

[17] 17 CFR 240.15b1–2, 240.15Ba2–2(b), and 240.15Ca2–2.

[18] Specifically, the rule required the applicant to provide: (i) Information regarding its assets, liabilities, and net worth; (ii) a schedule listing its securities and, if readily marketable, their market value; (iii) a computation of aggregate indebtedness and net capital in compliance with Rule 15c3–1 under the Exchange Act (or the relevant rule of the national securities exchange of which the applicant is or will be a member); (iv) a statement describing the nature and source of capital, and representing that such capital has been and will continue to be contributed to the business; (v) a representation that adequate arrangements have been made for the establishment and maintenance of facilities, financing, and certain other aspects of its business; and (vi) a statement describing the arrangements made for obtaining the funds necessary to operate the business in the ensuing year, setting forth the anticipated expenses for that year, and providing information regarding arrangements made to obtain additional financing should it become necessary.

[19] See, e.g., NASD Schedules to the By-Laws, Schedule C, part I, §§ (1)(a), (C), NASD Manual (CCH) ¶ 1783.

[20] 15 U.S.C. 78w(a)(2).

[21] 5 U.S.C. 603.

[22] 5 U.S.C. 551 *et seq*.

§ 240.15b1–1 Application for registration of brokers or dealers.

* * * * *

(b) Every application for registration of a broker or dealer that is filed on or after January 25, 1993, shall be filed with the Central Registration Depository operated by the National Association of Securities Dealers, Inc.

(c) An application for registration that is filed with the Central Registration Depository pursuant to this section shall be considered filed with the Commission for purposes of Section 15(b) of the Act.

3. By removing and reserving § 240.15b1–2.

4. By revising § 240.15b3–1 to read as follows:

§ 240.15b3–1 Amendments to application.

(a) If the information contained in any application for registration as a broker or dealer, or in any amendment thereto, is or becomes inaccurate for any reason, the broker or dealer shall promptly file with the Central Registration Depository (operated by the National Association of Securities Dealers, Inc.) an amendment on Form BD correcting such information.

(b) *Temporary Filing Instructions.* (1) Every registered broker or dealer who is not a member of the National Association of Securities Dealers, Inc. shall file as an amendment to its application a complete Form BD (as revised November 16, 1992, and as amended), and any subsequent amendments thereto pursuant to paragraph (a) of this section, with the Central Registration Depository during:

(i) The week of January 25, 1993, in the case of a broker-dealer whose Designated Examining Authority (DEA) is the Boston Stock Exchange, the Cincinnati Stock Exchange, the Midwest Stock Exchange, or the Philadelphia Stock Exchange;

(ii) The week of February 1, 1993, in the case of a broker-dealer whose DEA is the Pacific Stock Exchange;

(iii) The week of May 3, 1993, in the case of a broker-dealer whose DEA is the New York Stock Exchange;

(iv) The week of June 1, 1993, in the case of a broker-dealer whose DEA is the American Stock Exchange;

(v) The week of July 6, 1993, in the case of a broker-dealer whose DEA is the Chicago Board Options Exchange and whose SEC registration number is between 8–18117 and 8–34181;

(vi) The week of August 2, 1993, in the case of a broker-dealer whose DEA is the Chicago Board Options Exchange and whose SEC registration number is 8–34182 or above; and

(vii) The week of September 7, 1993, in the case of all other broker-dealers.

(2) Notwithstanding paragraph (b)(1) of this section, if the information contained in any application for registration as a broker or dealer filed by a broker or dealer who is not a member of the National Association of Securities Dealers, Inc. is or becomes inaccurate for any reason prior to the applicable date set forth in paragraph (b)(1) of this section, the broker or dealer shall promptly file as an amendment to its application a complete Form BD (as revised November 16, 1992, and as amended) with the Central Registration Depository.

(c) Every amendment filed pursuant to this section shall constitute a "report" filed with the Commission within the meaning of sections 15(b), 17, 18, 32(a), and other applicable provisions of the Act.

5. By amending § 240.15b6–1 by redesignating paragraphs (b), (c), and (d), as paragraphs (c), (d), and (e), adding paragraph (b), and revising newly redesignated paragraph (e) to read as follows:

§ 240.15b6–1 Withdrawal from registration.

* * * * *

(b) Every notice of withdrawal from registration as a broker or dealer that is filed on or after January 25, 1993, by a broker or dealer who has previously filed an application for registration with the Central Registration Depository (operated by the National Association of Securities Dealers, Inc.) shall be filed with the Central Registration Depository. Every other notice of withdrawal from registration as a broker or dealer shall be filed with the Commission; except that such notice shall be filed with the Central Registration Depository beginning on September 30, 1993.

* * * * *

(e) Every notice of withdrawal filed pursuant to this section shall constitute a "report" filed with the Commission within the meaning of sections 15(b), 17(a), and other applicable provisions of the Act.

6. By revising § 240.15Ba2–2 to read as follows:

§ 240.15Ba2–2 Application for registration of non-bank municipal securities dealers whose business is exclusively intrastate.

(a) An application for registration, pursuant to section 15B(a) of the Act, of a municipal securities dealer who is not subject to the requirements of § 240.15Ba2–1, that is filed on or after January 25, 1993, shall be filed with the Central Registration Depository (operated by the National Association of Securities Dealers, Inc.) on Form BD in accordance with the instructions contained therein.

(b) Every applicant shall file with its application for registration a statement that such applicant is filing for registration as an intrastate dealer in accordance with the requirements of this section. Such statement shall be deemed a part of the application for registration.

(c) If the information contained in any application for registration filed pursuant to paragraph (a) of this section, or in any amendment to such application, is or becomes inaccurate for any reason, the dealer shall promptly file with the Central Registration Depository an amendment on Form BD correcting such information.

(d) Every application or amendment filed pursuant to this section shall constitute a "report" filed with the Commission within the meaning of Sections 15B, 17, 18, 32(a), and other applicable provisions of the Act.

7. By amending § 240.15Bc3–1 by redesignating paragraphs (b) and (c) as paragraphs (c) and (d), adding paragraph (b), and revising newly redesignated paragraph (d) to read as follows:

§ 240.15Bc3–1 Withdrawal from registration of municipal securities dealers.

* * * * *

(b) Every notice of withdrawal from registration as a municipal securities dealer that is filed on Form BDW on or after January 25, 1993, by a dealer who has previously filed an application for registration on Form BD with the Central Registration Depository (operated by the National Association of Securities Dealers, Inc.) shall be filed with the Central Registration Depository. Every other notice of withdrawal from registration as a dealer on Form BDW shall be filed with the Commission; except that such notice shall be filed with the Central Registration Depository beginning on September 30, 1993. Every notice of withdrawal on Form MSDW shall be filed with the Commission.

* * * * *

(d) Every notice of withdrawal filed pursuant to this section shall constitute a "report" filed with the Commission within the meaning of Sections 15B, 17(a), and other applicable provisions of the Act.

8. By amending § 240.15Ca1–1 by adding paragraph (c) to read as follows:

§ 240.15Ca1–1 Notice of government securities broker-dealer activities.

* * * * *

(c) Any notice required pursuant to this section shall be considered filed with the Commission if it is filed with

the Central Registration Depository operated by the National Association of Securities Dealers, Inc.

9. By revising § 240.15Ca2–1 to read as follows:

§ 240.15Ca2–1 Application for registration as a government securities broker or government securities dealer.

(a) An application for registration, pursuant to Section 15C(a)(1)(A) of the Act, of a government securities broker or government securities dealer that is filed on or after January 25, 1993, shall be filed with the Central Registration Depository (operated by the National Association of Securities Dealers, Inc.) on Form BD in accordance with the instructions contained therein.

(b) Temporary filing instructions. Every registered government securities broker or government securities dealer who is not a member of the National Association of Securities Dealers, Inc. shall file a complete Form BD (as revised November 16, 1992, and as amended) with the Central Registration Depository in accordance with the schedule set forth in § 240.15b3–1(b).

(c) Every application or amendment filed pursuant to this section shall constitute a "report" filed with the Commission within the meaning of Sections 15, 15C, 17(a), 18, 32(a), and other applicable provisions of the Act.

§ 240.15Ca2–2 [Removed and reserved]

10. By removing and reserving § 240.15Ca2–2.

§ 240.15Ca2–3 [Amended]

11. By removing the last sentence of paragraph (b) of § 240.15Ca2–3.

12. By amending § 240.15Cc1–1 by revising the section heading, redesignating paragraphs (b) and (c) as paragraphs (c) and (d), adding paragraph (b), and revising newly redesignated paragraph (d) to read as follows:

§ 240.15Cc1–1 Withdrawal from registration of government securities brokers or government securities dealers.

* * * * *

(b) Every notice of withdrawal from registration as a government securities broker or dealer that is filed on or after January 25, 1993, by a government securities broker or dealer who has previously filed an application for registration with the Central Registration Depository (operated by the National Association of Securities Dealers, Inc.) shall be filed with the Central Registration Depository. Every other notice of withdrawal from registration as a government securities broker or dealer shall be filed with the Commission; except that such notice shall be filed with the Central Registration Depository beginning on September 30, 1993.

* * * * *

(d) Every notice of withdrawal filed pursuant to this section shall constitute a "report" filed with the Commission within the meaning of sections 15, 15C, 32(a), and other applicable provisions of the Act.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

13. The authority citation for part 249 continues to read as follows:

Authority: 15 U.S.C. 78a, *et seq.*, unless otherwise noted.

Note: The following forms do not appear in the Code of Federal Regulations.

14. By revising the Special Instructions for Completing or Amending Form BD (§ 249.501), and the General Instructions to Form BDW (§ 249.501a) to read as follows:

Special Instructions for Completing or Amending Form BD, Uniform Application for Registration as a Broker-Dealer, With the U.S. Securities and Exchange Commission

How to File

File one manually signed and notarized Form BD (with the schedules). Keep a copy for your files. A copy may be filed if manually signed and notarized and on standard 8½ x 11 white paper, in the same size as the original.

To file an amendment to Form BD, complete all amended pages or schedules and file with page 1, the execution page.

Where to File

Broker-dealers that are applying for registration should file Form BD and its schedules with the Central Registration Depository (CRD), P.O. Box 9401, Gaithersburg, Maryland 20898–9401. Any subsequent amendments to Form BD also should be filed with the CRD.

All registered broker-dealers that are *not* members of the National Association of Securities Dealers, Inc. (NASD) should file a complete Form BD and its schedules with the CRD during the week of:

(1) January 25, 1993, in the case of all non-NASD member broker-dealers whose Designated Examining Authority (DEA) is the Boston Stock Exchange, the Cincinnati Stock Exchange, the Midwest Stock Exchange, or the Philadelphia Stock Exchange;

(2) February 1, 1993, for all such broker-dealers whose DEA is the Pacific Stock Exchange;

(3) May 3, 1993, for all such broker-dealers whose DEA is the New York Stock Exchange;

(4) June 1, 1993, for all such broker-dealers whose DEA is the American Stock Exchange;

(5) July 6, 1993, for all such broker-dealers whose DEA is the Chicago Board Options Exchange and whose SEC registration number is between 8–18117 and 8–34181;

(6) August 2, 1993, for all such broker-dealers whose DEA is the Chicago Board Options Exchange and whose SEC registration number is 8–34182 or above; and

(7) September 7, 1993, for all other non-NASD member broker-dealers.

Any subsequent amendments to these Form BD filings also should be filed with the CRD. Non-NASD members that need to file an amendment to their Form BD before their scheduled date should promptly file a complete Form BD with the CRD.

All non-NASD members must include their SEC 8-registration number in the appropriate box on page one of Form BD.

Foreign Broker-Dealers

Rules 15b1–5 and 15Ca2–5 require non-resident broker-dealers applying for registration to provide the Commission with a consent and power of attorney. This consent and power of attorney designate the Commission as agent for the service of process of any papers in connection with actions arising from the broker-dealer's business that are subject to the jurisdiction of the United States and that accrue while the broker-dealer is registered with the Commission. This consent and power of attorney, which is in addition to and separate from the consent to service of process provided on Form BD, should be filed directly with the Commission. A copy also should be filed with the CRD as part of the application on Form BD.

Successor Registration

A broker-dealer that assumes substantially all of the assets and liabilities, and that continues the business, of a registered predecessor broker-dealer is a successor broker-dealer. Rules 15b1–3, 15Ba2–4, and 15Ca2–3 require a successor broker-dealer to file a new Form BD (or, in special instances, to amend the predecessor broker-dealer's Form BD) within 30 days. The filing should indicate on page 2 of the form that the applicant is a successor. (*See* Securities Exchange Act Release No. 31661 (Dec. 28, 1992)).

Prohibited Broker-Dealer Names

United States Code Title 18 Section 709 makes it a criminal offense to use the words "National," "Federal," "United States," "Reserve," or "Deposit Insurance" in the name of a person or organization in the brokerage business, unless otherwise allowed by Federal law. If these words are used in the applicant's name, include an opinion of counsel with the Form BD explaining why the words are permitted. Send a copy of the opinion directly to the Commission.

Uniform Request for Broker-Dealer Withdrawal

General Instructions

- Each copy of this form must be *manually signed* by the proper individual.
- Type all information.
- Use only the Form BDW or a reproduction of it.
- *Filing Requirements*

Full Withdrawal

NASD Members: file Form BDW with the CRD beginning on January 25, 1993.

Non-NASD Members: file Form BDW with the CRD beginning on September 30, 1993. Prior to September 30, 1993, file Form BDW

with the CRD if Form BD has already been filed with the CRD; if not, file with the SEC.

Attach a copy of FOCUS Report Part II (or Part IIA for non-carrying or non-clearing firms) "Statement of Financial Condition" and "Computation of Net Capital" sections. Firms that are not required to file FOCUS Reports should attach a Statement of Financial Condition giving the type and amount of the firm's assets, liabilities, and net worth. The FOCUS Report and Statement of Financial Condition must reflect the finances of the firm no earlier than 10 days before Form BDW is filed.

Non-NASD Members only should send a copy of Form BDW and all attachments to the Office of Filings, Information, and Consumer Services, SEC, 450 5th St., NW., Washington, DC 20549.

Check with the States where registered for additional filing requirements.

Partial Withdrawal

File Form BDW with the CRD. Check with the States where registered for additional filing requirements. Amend Form BD and file with the CRD in accordance with the instructions to the form.

By the Commission.

Dated: December 28, 1992.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92-31868 Filed 12-31-92; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[T.D. 8466]

RIN 1545-AN45

21-Day Holding Period for Bank Accounts Subject to Levy

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations regarding the surrender of property subject to levy in the case of banks. Section 6236(e)(1) of the Technical and Miscellaneous Revenue Act of 1988 amended section 6332(c) of the Internal Revenue Code by adding a new paragraph (c), which provides that banks shall surrender deposits in taxpayers' accounts (including interest thereon) only after 21 days after service of a levy. The regulations set forth the rules for compliance by banks, and also contain conforming amendments reflecting the new provision.

DATES: These regulations are effective on January 4, 1993, and apply with respect to levies made on or after January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Kevin B. Connelly, 202-622-3640 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations amending the Procedure and Administration Regulations (26 CFR part 301) under section 6332 of the Internal Revenue Code (Code). The regulations reflect the amendment of section 6332 by section 6236(e)(1) of the Technical and Miscellaneous Revenue Act of 1988 (Pub. L. No. 100-647, 102 Stat. 3342) (TAMRA).

Explanation of Provisions

The Internal Revenue Service published a notice of proposed rulemaking in the **Federal Register** on May 1, 1991, (56 FR 19963). Numerous commentators submitted written comments concerning the proposed regulations. However, no request for a hearing was received and no hearing was held. Each of the issues raised in the comments was fully considered during the formulation of the final regulations. The principal comments received by the Internal Revenue Service are discussed below.

Section 6236(e)(1) of TAMRA amended section 6332 of the Code by redesignating paragraphs (c), (d), and (e) as paragraphs (d), (e), and (f), respectively, and by adding new paragraph (c). Under section 6332(c) banks (as defined in section 408(n) of the Code) shall surrender levied deposits, together with the interest accruing thereon, only after 21 days after a levy is made.

The regulations provide that a levy on a bank account applies to those funds on deposit at the time the levy is made, up to the amount of the levy. No withdrawals may be made against the funds reached by the levy during the 21-day holding period. The bank must surrender the deposits on the first business day following the 21st calendar day after the levy is made, unless the bank receives notification from the district director of a release of levy or unless the district director has requested an extension of the holding period. In addition, the bank must surrender any interest which accrued on the deposits under the terms of its agreement with its customer, but in no event must the bank surrender an amount greater than the amount of the levy. Any interest that accrues and is turned over to the Internal Revenue Service is considered to be paid to the bank's depositor. The depositor may waive the 21-day holding period by notifying the bank of his or her intention to do so. However, where more than one depositor is listed as the owner of an account, all of the listed owners must agree to a waiver of the holding period. The regulations set forth examples illustrating the requirements for compliance with section 6332(c) under various circumstances, and define the term "bank" pursuant to section 408(n) of the Code.

The regulations provide further that the bank's depositor may notify the district director to whom the assessment is charged of any errors with respect to the levied account by telephoning the telephone number listed on the face of the notice of levy. The district director may require any supporting documentation necessary to review an alleged error. Notification by telephone does not constitute or substitute for the filing by a third party of a written request for the return of wrongfully levied property.

With respect to imposing liability under section 6332(d) for refusal or failure to surrender property subject to levy, the 21-day rule effectively changes the date of the making of a levy on bank deposits to the date of the expiration of the 21-day holding period or any extension of the period granted by the Internal Revenue Service.

One commentator suggested that the regulations should discharge banks from liability to any third party that claims an interest in an attached account. This is beyond the narrow scope of section 6332(c) and these regulations. A bank's potential liability to the taxpayer or to third parties for surrendering deposits is governed generally by section 6332(e), which provides that any person who surrenders property or rights to property subject to levy to the Internal Revenue Service is discharged from any obligation or liability to the delinquent taxpayer or any other person. That section applies to banks that surrender deposits in accordance with section 6332(c) just as it applies to any other party that surrenders property pursuant to an Internal Revenue Service levy.

The proposed regulations provide that the district director may extend the holding period beyond the initial 21 days if more time is necessary for the district director to resolve alleged errors with respect to attached deposits before the deposits are surrendered. One commentator suggested that extensions of the 21-day holding period should be limited to two 21-day extensions. Although it will be in the best interest of the Internal Revenue Service to resolve as quickly as possible any issues concerning whether deposits should be turned over, the length of extensions of the holding period will vary depending

on the issues under consideration. Limiting the length or number of extensions could result in deposits being turned over before the district director has the time to resolve an alleged error, thereby defeating the purpose of section 6332(c).

One commentator suggested that the regulations should include the language that banks must use to indicate that depositors have waived the 21-day holding period. There is no specific language that a bank must use to inform the Internal Revenue Service that depositors have waived the holding period. As long as the bank indicates that each depositor to an account has agreed to a waiver, the waiver is sufficient with respect to that account.

Two commentators submitted questions concerning the effect of section 6332(c) on the terms of a bank's interest agreement with its depositor. The regulations provide that interest must be paid in accordance with the terms of a bank's agreement with its depositor. This provision is based on the fact that the Internal Revenue Service is entitled only to the amount to which the taxpayer would be entitled if the taxpayer withdrew the funds. If the taxpayer would not be entitled to interest, the Internal Revenue Service is not entitled to interest. This provision is illustrated by *Examples 5* and *6*, which deal with a certificate of deposit, the terms of which provide that the depositor must forfeit thirty days of interest in the event of early withdrawal.

Numerous commentators noted that the calculation of interest on levied funds poses a burden on banks and suggested that banks either should not have to pay any interest or that the regulations should set a floor—based on either the amount of interest due, the amount of the depositor's account balance, or the amount of the levy—below which the bank would not have to pay interest. A prescribed floor below which no interest would have to be paid would effectively reduce the amount of the depositor's liability that is satisfied by the levy. In light of the detrimental impact on the interests of the depositor and the Service, together with the statute's explicit reference to the payment of interest, the final regulations do not contain the suggested exceptions.

One commentator also suggested that a bank should be allowed to enforce against levied funds a contractual right to charge the depositor a fee for processing a levy or a garnishment. Again, the Internal Revenue Service is entitled to the amount to which the taxpayer is entitled. If the terms of the account do not allow the bank to charge a levy processing fee on a withdrawal by the depositor, the bank may not deduct such a fee from the amount subject to levy.

One commentator suggested that banks should be given an additional 10-day period after the 21-day period expires in which to turn over levied funds. Once a bank receives a levy the bank knows exactly when the 21-day period will expire and the funds will become due. An extra 10-day period in which to turn over levied funds is unnecessary.

Many comments that were submitted for consideration raise additional substantive issues that are unrelated to the 21-day rule or to procedural issues concerning the implementation of the 21-day rule. For example, a number of commentators submitted comments and questions concerning the types of accounts and deposits that are subject to an Internal Revenue Service levy. One commentator suggested that the regulations should describe the type of information that banks should and can legally divulge without violating financial privacy laws when informing the Service that a levy is unpostable, *e.g.*, the levy is on a closed account. These issues are outside the scope of the regulations. Section 6332(c) and these regulations neither address nor affect the priority of competing claims to a taxpayer's deposits, the type of property to which a levy attaches, the type of financial information that a bank may divulge about a depositor's account, or a bank's responsibilities with respect to deposits (other than to provide that the bank must hold deposits for 21 days). To reflect the limited scope of these regulations, the caption has been changed to "The 21-day holding period applicable to property held by banks."

Finally, one commentator suggested that the rule that interest surrendered to the district director is considered to be paid to the bank's customer and must be reported to the Internal Revenue Service, should be clarified to distinguish between the reporting of interest on IRA accounts and the reporting of interest on non-IRA accounts. While most interest paid to a depositor must be reported as interest, there are situations in which interest must be reported as some other type of payment. The purpose of this provision is to inform banks that the submission to the Internal Revenue Service of interest that accrues prior to and during the holding period should be treated as a payment to the bank's customer. Instead of accounting for each different characterization of interest in the Code and setting forth the different reporting requirements, the final regulation has been changed to provide simply that to the extent interest is accrued and surrendered such interest is considered to be paid to the bank's customer.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these proposed regulations is Kevin B. Connelly, Office of the Assistant Chief Counsel (General Litigation), Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 301

Administrative practice and procedure, Alimony, Bankruptcy, Child support, Continental shelf, Courts, Crime, Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Investigations, Law enforcement, Oil pollution, Penalties, Pensions, Reporting and recordkeeping requirements, Statistics, Taxes.

Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—[AMENDED]

Paragraph 1. The authority citation for part 301 continues to read in part:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 301.6332–1 is amended as follows:

1. In paragraph (a)(1) the language "and in § 301.6332–3, relating to property held by banks," is added immediately following the language "endowment contracts," and immediately before the language "any person."

2. The heading of paragraph (a)(2) is revised to read as set forth below.

3. In paragraph (b)(2), in the first sentence, the language "6332(c)(1)" is

removed and the language "6332(d)(1)" is added in its place.

§ 301.6332–1 Surrender of property subject to levy.

(a) * * *

(2) *Levy on bank deposits held in offices outside the United States.*

* * * * * *

Par. 3. Section 301.6332–3 is added to read as follows:

§ 301.6332–3 The 21-day holding period applicable to property held by banks.

(a) *In general.* This section provides special rules relating to the surrender, after 21 days, of deposits subject to levy which are held by banks. The provisions of § 301.6332–1 which relate generally to the surrender of property subject to levy apply, to the extent not inconsistent with the special rules set forth in this section, to a levy on property held by banks.

(b) *Definition of bank.* For purposes of this section, the term "bank" means—

(1) A bank or trust company or domestic building and loan association incorporated and doing business under the laws of the United States (including laws relating to the District of Columbia) or of any State, a substantial part of the business of which consists of receiving deposits and making loans and discounts, or of exercising fiduciary powers similar to those permitted to national banks under authority of the Comptroller of the Currency, and which is subject by law to supervision and examination by State or Federal authority having supervision over banking institutions;

(2) Any credit union the member accounts of which are insured in accordance with the provisions of title II of the Federal Credit Union Act, 12 U.S.C. 1781 et seq.; and

(3) A corporation which, under the laws of the State of its incorporation, is subject to supervision and examination by the Commissioner of Banking or other officer of such State in charge of the administration of the banking laws of such State.

(c) *21-day holding period*—(1) *In general.* When a levy is made on deposits held by a bank, the bank shall surrender such deposits (not otherwise subject to an attachment or execution under judicial process) only after 21 calendar days after the date the levy is made. The district director may request an extension of the 21-day holding period pursuant to paragraph (d)(2) of this section. During the prescribed holding period, or any extension thereof, the levy shall be released only upon notification to the bank by the district director of a decision by the Internal Revenue Service to release the levy. If the bank does not receive such notification from the district director within the prescribed holding period, or any extension thereof, the bank must surrender the deposits, including any interest thereon as determined in accordance with paragraph (c)(2) of this section (up to the amount of the levy), on the first business day after the holding period, or any extension thereof, expires. See § 301.6331–1(c) to determine when a levy served by mail is made.

(2) *Payment of interest on deposits.* When a bank surrenders levied deposits at the end of the 21-day holding period (or at the end of any longer period that has been requested by the district director), the bank must include any interest that has accrued on the deposits prior to and during the holding period, and any extension thereof, under the terms of the bank's agreement with its depositor, but the bank must not surrender an amount greater than the amount of the levy. If the deposits are held in a noninterest bearing account at the time the levy is made, the bank need not include any interest on the deposits at the end of the holding period, or any extension thereof, under this paragraph. Interest that accrues on deposits and is surrendered to the district director at the end of the holding period, or any extension thereof, is treated as a payment to the bank's customer.

(3) *Transactions affecting accounts.* A levy on deposits held by a bank applies to those funds on deposit at the time the levy is made, up to the amount of the levy, and is effective as of the time the levy is made. No withdrawals may be made on levied upon deposits during the 21-day holding period, or any extension thereof.

(4) *Waiver of 21-day holding period.* A depositor may waive the 21-day holding period by notifying the bank of the depositor's intention to do so. Where more than one depositor is listed as the owner of a levied account, all depositors listed as owners of the account must agree to a waiver of the 21-day holding period. If the 21-day holding period is waived, the bank must include with the surrendered deposits a notification to the district director of the waiver.

(5) *Examples.* The provisions of this paragraph (c) may be illustrated by the following examples:

Example 1. On April 2, 1992, a notice of levy for an unpaid income tax assessment due from A in the amount of $10,000 is served on X Bank with respect to A's savings account. At the time the notice of levy is served, X Bank holds $5,000 in A's interest-bearing savings account. On April 24, 1992, (the first business day after the 21-day holding period) X Bank must surrender $5,000 plus any interest that accrued on the account under the terms of A's contract with X Bank up through April 23, 1992, (the last day of the holding period).

Example 2. The facts are the same as in *Example 1* except that on April 3, 1992, A deposits an additional $5,000 into the account. On April 24, 1992, X Bank must still surrender only $5,000 plus the interest which accrued thereon until the end of the holding period, because the notice of levy served on April 2, 1992, attached only to those funds on deposit at the time the notice was served and not to any subsequent deposits.

Example 3. The facts are the same as in *Example 1* except that at the time the notice of levy is served on X Bank, A's savings account contains $50,000. On April 24, 1992, X Bank must surrender $10,000, which is the amount of the levy. The levy will not apply to any interest that accrues on the deposit during the 21-day holding period, because the entire amount of the levy is satisfied by the deposits existing at the time the levy is served.

Example 4. The facts are the same as in *Example 1* except that the amount of the levy is $5,002. Under the terms of A's contract with the bank, the account will earn more than $2 of interest during the 21-day holding period. On April 24, 1992, X Bank must surrender $5,002 to the district director. The remaining interest which accrued during the 21-day holding period is not subject to the levy.

Example 5. On September 3, 1992, A opens a $5,000 six-month certificate of deposit account with X Bank. Under the terms of the account, the depositor must forfeit up to 30 days of interest on the account in the event of early withdrawal. On January 4, 1993, a notice of levy for an unpaid income tax assessment due from A in the amount of $10,000 is served with respect to A's certificate of deposit account. On January 26, 1993, the bank must surrender $5,000 plus the interest which accrued on the account through January 25, 1993, minus the penalty of 30 days of interest as provided in the deposit agreement.

Example 6. Same facts as in *Example 5* except that the notice of levy is served on X Bank on February 15, 1993. The certificate matures on March 2, 1993. On March 8, X Bank must surrender $5,000 plus the interest that accrued on the certificate without any reduction for penalties.

(d) *Notification to the district director of errors with respect to levied upon bank accounts*—(1) *In general.* If a depositor believes that there is an error with respect to the levied upon account which the depositor wishes to have corrected, the depositor shall notify the district director to whom the assessment is charged by telephone to the telephone number listed on the face of the notice of levy in order to enable the district director to conduct an expeditious review of the alleged error. The district director may require any supporting documentation necessary to the review

of the alleged error. The notification by telephone provided for in this section does not constitute or substitute for the filing by a third party of a written request under § 301.6343–1(b)(2) for the return of property wrongfully levied upon.

(2) *Disputes regarding the merits of the underlying assessment.* This section does not constitute an additional procedure for an appeal regarding the merits of an underlying assessment. However, if in the judgment of the district director a genuine dispute regarding the merits of an underlying assessment appears to exist, the district director may request an extension of the 21-day holding period.

(3) *Notification of errors from sources other than the depositor.* The district director may take action to release the levy on the bank account based on information obtained from a source other than the depositor, including the bank in which the account is maintained.

(e) *Effective date.* These provisions are effective with respect to levies issued on or after January 4, 1993.

Shirley D. Peterson,

Commissioner of Internal Revenue.

Approved: December 15, 1992.

Alan J. Wilensky,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 92–31713 Filed 12–31–92; 8:45am]

BILLING CODE 4830–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 91–016]

RIN 2115–AD77

Drawbridge Operation Regulations, Emergency Situations

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: On August 7, 1991, the Coast Guard published a Notice of Proposed Rulemaking in the **Federal Register** to amend the regulations that govern the nation's drawbridges by requiring that emergency vessels, and vessels in an emergency situation, that have given the proper emergency signal, be passed through an attended draw at any time. This proposal was made because there is provision for the passage of emergency land vehicles, but nothing similar has been done to make allowance for the passage of emergency vessels or vessels in an emergency situation. This action will provide guidance for emergency situations both on land and water and should not seriously interfere with the needs of vehicular traffic, yet still provide for the reasonable needs of navigation in an emergency.

EFFECTIVE DATE: This rule is effective on February 3, 1993.

ADDRESSES: Unless otherwise indicated, documents referenced in this preamble are available for inspection and copying at the office of the Executive Secretary, Marine Safety Council (G–LRA–2/3406) (CGD 91–016), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001, room 3406, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477 for information.

FOR FURTHER INFORMATION CONTACT: Mr. Larry R. Tyssens, Alterations, Regulations and Systems Branch (G–NBR–1), at (202) 267–0376.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Mr. Larry R. Tyssens, Project Manager, and Lieutenant Ralph L. Hetzel, Project Counsel, Office of Chief Counsel.

Regulatory History

On August 7, 1991, the Coast Guard published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (56 FR 37504) to revise 33 CFR part 117 to allow for emergency passage of vessels. It was proposed that this amendment be incorporated in the Code of Federal Regulations (CFR) under a new § 117.29 entitled, "Opening of draw for emergency vessels and vessels in an emergency situation." Opportunity for comment on the proposal was provided until September 23, 1991. Since then, the decision has been made to combine the proposed amendment with existing § 117.31 "Closure of draw for emergency vehicles" and to revise the section title to read, "Operation of draw during emergency situations."

Two comments were received from a local government official in Jackson County, Mississippi, and a private individual in Houston, Texas. These comments, along with the views of pertinent Coast Guard officials, have been included in the public docket and are discussed below.

Background Information

An issue was raised by a member of the public concerning the lack of provisions in the regulations to allow for the passage of vessels in an emergency situation through a draw during a scheduled closure period. The Coast Guard agrees that provision should be made for emergency passage of vessels, and vessels in an emergency situation, as it is made for the passage of emergency land vehicles.

Discussion of Comments and Changes

The two comments objected to requiring draws to be opened for vessels seeking shelter from severe weather equivalent to Force 7 or greater on the Beaufort Wind Scale. As was pointed out by the individual from Texas, the "* * * severe weather operation of many bridges has already been discussed, and procedures accepted, by many of the Port Safety Committees which advise local Captains of the Port. These procedures reflect local [emergency management] considerations such as, highway routes for hurricane evacuation, the populace to be evacuated, the capability of the bridges to operate in high winds, and the availability of other areas for sheltering of vessels." Therefore, stipulating that draws should be opened for vessels seeking shelter from severe weather equivalent to Force 7 or greater on the Beaufort Wind Scale could be in conflict with local emergency management procedures. This is essentially the same concern that was expressed by a local government official in Jackson County, Mississippi. In addition, officials from different Coast Guard districts independently concurred with the fact that the same wind velocity can and does have different effects on different bodies of water based on the depth of the water body and its geographic location. Thus, the use of the Beaufort Wind Scale readings for this purpose is less than ideal. As a result of these comments, the Coast Guard has determined that requiring a draw to be opened at a specific wind velocity, irrespective of the geographic situation and local emergency management procedures, may be imprudent. Instead, the decision to open a draw during adverse weather conditions should rest with the drawtender and/or bridge owner in accordance with local emergency management procedures which have been approved by the cognizant Coast Guard Captain of the Port.

In addition, the decision was made to combine the amendment to open draws for vessels in an emergency situation as a part of the existing section 117.31 that allows for the closure of a draw for land vehicles responding to an emergency.

Regulatory Evaluation

This rulemaking is not major under Executive Order 12291 and

nonsignificant under the Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. There will be no cost to the general public other than that associated with the inconvenience to vehicular traffic occasioned by an opening of the draw for an emergency.

This rulemaking establishes emergency operating regulations for the nation's drawbridges across its navigable waters. The authority to regulate concerning drawbridge operation is committed to the Coast Guard by Federal statutes. Furthermore, since the regulated drawbridges are located nationwide, operating regulations concerning emergency situations should be consistent to avoid unreasonably burdensome variances. Therefore, the Coast Guard intends this rule to preempt state action addressing the same subject matter.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rulemaking will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

Because this final rule imposes no special expense on small business, and because the rule is expected to be infrequently used, the Coast Guard anticipates the economic impact of it to be minimal. No new equipment will be required. The delay to vehicular traffic will result in a minimal loss of time. The Coast Guard certifies under 5 U.S.C. 605(b) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rulemaking contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 12612 and has determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that under section 2.B.2. of Commandant Instruction M16475.1B, this rulemaking is categorically excluded from further environmental documentation because it is a Bridge Administration Program action involving the promulgation of operating requirements or procedures for drawbridges. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under "ADDRESSES."

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1(g); 49 CFR 1.46.

2. Section 117.31 is revised to read as follows:

§ 117.31 Operation of draw for emergency situations.

(a) When a drawtender is informed by a reliable source that an emergency vehicle is due to cross the draw, the drawtender shall take all reasonable measures to have the draw closed at the time the emergency vehicle arrives at the bridge.

(b) When a drawtender receives notice, or a proper signal as provided in § 117.15 of this part, the drawtender shall take all reasonable measures to have the draw opened, regardless of the operating schedule of the draw, for passage of the following, provided this opening does not conflict with local emergency management procedures which have been approved by the cognizant Coast Guard Captain of the Port:

(1) Federal, State, and local government vessels used for public safety;

(2) vessels in distress where a delay would endanger life or property;

(3) commercial vessels engaged in rescue or emergency salvage operations; and

(4) vessels seeking shelter from severe weather.

Dated: December 28, 1992.

W.J. Ecker,

Rear Admiral, U.S. Coast Guard, Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 92–31912 Filed 12–31–92; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 61

[FRL–4550–9]

Standards of Performance for New Stationary Sources; National Emission Standards for Hazardous Air Pollutants Supplemental Delegation of Authority to the State of Georgia

AGENCY: Environmental Protection Agency (EPA).

ACTION: Delegation of authority.

SUMMARY: On April 3, 1991, the Georgia Department of Natural Resources of the State of Georgia requested delegation of authority for the implementation and enforcement of additional categories of the New Source Performance Standards (NSPS) and the National Emission Standards for Hazardous Air Pollutants (NESHAPS). EPA's review of the State of Georgia's laws, rules, and regulations showed them to be adequate for the implementation and enforcement of these Federal standards. EPA granted the delegation as requested.

EFFECTIVE DATES: The effective date of delegation of authority is June 18, 1992 for the Asbestos NESHAPS, and August 23, 1991, for the other subparts in this notice.

ADDRESSES: Copies of the request for delegation of authority and EPA's letter of delegation are available for public inspection during normal business hours at the following locations:

Region IV Air Programs Branch, Environmental Protection Agency, 345 Courtland Street, Atlanta, Georgia 30365

Air Protection Branch, Georgia Environmental Protection Division, Georgia Department of Natural Resources, 205 Butler Street, Southeast, room 1162, East Tower, Atlanta, Georgia 30334

Effective immediately, all requests, applications, reports and other correspondence required pursuant to the newly delegated standards should not be submitted to the Region IV office, but should instead be submitted to the following address: Mr. Robert H. Collom, Chief, Air Protection Branch, Georgia Environmental Protection Division, Georgia Department of Natural

Resources, 205 Butler Street, SE., room 1162, East Tower, Atlanta, Georgia 30334.

FOR FURTHER INFORMATION CONTACT: Diane Altsman of the EPA Region IV Air Programs Branch at (404) 347–2864 and at the above EPA address.

SUPPLEMENTARY INFORMATION: Section 301, in conjunction with sections 110, 111(c)(1), and 112(d)(1) of the Clean Air Act as amended November 15, 1990, authorize the Administrator to delegate his authority to implement and enforce the standards set out in 40 CFR part 61, National Emission Standards for Hazardous Air Pollutants (NESHAPS), and to implement and enforce the standards set out in 40 CFR part 60, New Source Performance Standards (NSPS).

After a thorough review of the categories requested for delegation, the Regional Administrator determined that such delegation was appropriate for these source categories with the conditions set forth in the original delegation letter of May 3, 1976, and subsequent delegation letters of August 8, 1977, and June 17, 1985.

EPA, thereby, delegated its authority for 40 CFR part 60 and part 61 as follows:

40 CFR Part 60—New Categories for NSPS

Subpart BBB—Rubber Tire Manufacturing Industry, except § 60.543(c)(2)(ii)(B).
Subpart DDD—VOC Emissions From The Polymer Manufacturing Industry except § 60.562–2(c).
Subpart III—VOC Emissions From SOCMI Air Oxidation Unit Processes, except § 60.613(e).
Subpart KKK—Onshore Natural Gas Processing.
Subpart NNN—VOC Emissions From SOCMI Distillation Operations, except § 60.663(e).
Subpart QQQ—VOC Emissions From Petroleum Refinery Wastewater Systems.
Subpart SSS—Magnetic Tape Coating Facilities, except § 60.711(a)(16), § 60.713(b)(1)(i), § 60.713(b)(1)(ii), § 60.713(b)(5)(i), § 60.713(d), § 60.715(a) and § 60.716.
Subpart TTT—Plastic Parts For Business Machine Coating, except § 60.723(b)(1), § 60.723(b)(2)(i)(C), § 60.723(b)(2)(iv), § 60.724(e), § 60.725(b).
Subpart VVV—Polymeric Coating Of Supporting Substrates Facilities except § 60.743(a)(3)(v)(A) & (B), § 60.743(e), § 60.745(a) and § 60.746.

40 CFR Part 60—Revised Categories for NSPS

Subpart D—Fossil-Fuel Fired Steam Generators.
Subpart Da—Electric Utility Steam Generating Units.
Subpart E—Incinerators.
Subpart F—Portland Cement Plants.
Subpart G—Nitric Acid Plants.
Subpart H—Sulfuric Acid Plants.
Subpart I—Mix Asphalt Facilities.
Subpart L—Secondary Lead Smelters.
Subpart M—Secondary Brass and Bronze Ingot Production Plants.
Subpart N—Iron and Steel Plants.
Subpart Na—Secondary Emissions From Basic Oxygen Process Steel Facilities.
Subpart O—Sewage Treatment Plants, except § 60.153(e).
Subpart P—Primary Copper Smelters.
Subpart Q—Primary Zinc Smelters.
Subpart R—Primary Lead Smelters.
Subpart S—Primary Aluminum Reduction Plants.
Subpart T—Phosphate Fertilizer Industry: Wet Process Phosphoric Acid Plants.
Subpart U—Phosphate Fertilizer Industry: Superphosphoric Acid Plants.
Subpart V—Phosphate Fertilizer Industry: Diammonium Phosphate Plants.
Subpart W—Phosphate Fertilizer Industry: Triple Superphosphate Plants.
Subpart X—Phosphate Fertilizer Industry: Granular Triple Superphosphate.
Subpart Y—Coal Preparation Plants.
Subpart Z—Ferroalloy Production Facilities.
Subpart AA—Steel Plants: Electric Arc Furnaces.
Subpart AAa—Steel Plants: Electric Arc Furnaces and Argon-Oxygen Decarburization Vessels.
Subpart BB—Kraft Pulp Mills.
Subpart CC—Glass Manufacturing Plants.
Subpart DD—Grain Elevators.
Subpart GG—Stationary Gas Turbines, except § 60.334(b)(2) and § 60.335(f)(1).
Subpart HH—Lime Manufacturing Plants.
Subpart KK—Lead-Acid Battery Manufacturing Plants.
Subpart LL—Metallic Mineral Processing Plants.
Subpart NN—Phosphate Rock Plants.
Subpart PP—Ammonium Sulfate Manufacture.
Subpart UU—Asphalt Processing and Asphalt Roofing Manufacture, except § 60.474(g).
Subpart VV—Equipment Leaks of VOC in SOCMI, except § 60.482–1(c)(2) and § 60.484.
Subpart XX—Bulk Gasoline Terminals, except § 60.502(e)(6).
Subpart LLL—Onshore Natural Gas Processing.
Subpart OOO—Nonmetallic Mineral Processing Plants.
Subpart PPP—Wool Fiberglass Insulation.

40 CFR Part 61—New Categories for NESHAP

Subpart L—Benzene Emissions From Coke By-Product Recovery Plants, except § 61.136(d).
Subpart Y—Benzene Emissions From Benzene Storage Vessels, except § 61.273.
Subpart BB—Benzene Emissions From Benzene Transfer Operations.

40 CFR Part 61—Revised Categories for NESHAP

Subpart FF—Benzene Waste Operations, except § 61.353.

The Administrator retains the exclusive right to approve equivalent and alternative test methods, continuous monitoring procedures, and reporting requirements. Therefore, the noted sections of the requested NSPS and NESHAPS standards are among the sections which may not be delegated.

The EPA hereby notifies the public that it has delegated the authority over certain NSPS and NESHAP subparts to the State of Georgia.

The Office of Management and Budget exempted this rule from the requirements of Section 3 of Executive Order 12291.

This notice is issued under the authority of sections 101, 110, 111, 112, and 301 of the Clean Air Act, as amended (42 U.S.C. 7401, 7410, 74121, 7412, and 7601).

Patrick M. Tobin,
Acting Regional Administrator.

[FR Doc. 92–31748 Filed 12–31–92; 8:45 am]
BILLING CODE 6560–50–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 15

[CGD 89–061]
RIN 2115–AD38

Waiver of Crewmember Citizenship Requirements

AGENCY: Coast Guard, DOT.
ACTION: Final rule.

SUMMARY: In an interim final rule published on January 12, 1990, the Coast Guard amended the regulations concerning the use of non-U.S. citizens as licensed individuals and unlicensed seamen on U.S. documented vessels to provide a general waiver for offshore supply vessels (OSVs) operating out of foreign ports, and mobile offshore drilling units (MODUs) operating beyond the water above the U.S. Outer Continental Shelf. This action was necessary to allow these vessels to operate in areas subject to foreign jurisdiction where local citizenship requirements may apply and where recruitment of U.S. citizens may be impractical. The intent of this action was to allow these operations to be conducted without obligating the operators to request individual waivers for each situation in which a non-U.S.

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citizen may be employed or engaged. This rule adopts the interim final rule without change.

EFFECTIVE DATE: This rule is effective on February 3, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Young, Project Manager, Office of Marine Safety, Security and Environmental Protection (G–MVP), telephone (202) 267–0229.

SUPPLEMENTARY INFORMATION:

Drafting Information

The principal persons involved in drafting this document are Mr. Christopher Young, Project Manager, Office of Marine Safety, Security and Environmental Protection, and Mr. Nicholas Grasselli, Project Counsel, Office of Chief Counsel.

Regulatory History

On January 12, 1990, the Coast Guard published an interim final rule entitled "Waiver of Crewmember Citizenship Requirements" in the **Federal Register** (55 FR 1210). The Coast Guard received 11 letters commenting on the interim final rule. A public hearing was not requested and one was not held.

Background and Purpose

The Commercial Fishing Industry Vessel Anti-Reflagging Act of 1987 (Public Law 100–239, as amended in Public Law 100–255) authorized the Secretary of Transportation to waive, except with respect to the master, the requirement that the licensed individuals and 75 percent of the total number of unlicensed seamen on board a U.S. documented vessel must be citizens of the United States (46 U.S.C. 8103(b)(3)). This authority has been delegated to the Coast Guard (49 CFR 1.46(b)).

In accordance with 46 U.S.C. 8103(b)(3), a waiver may be granted with respect to the following:

(a) An offshore supply vessel or other similarly engaged vessel of less than 1600 gross tons that operates from a foreign port;

(b) A mobile offshore drilling unit or other vessel engaged in support of exploration, exploitation, or production of offshore mineral energy resources operating beyond the water above the Outer Continental Shelf; and

(c) Any other vessel if the Secretary of Transportation (Coast Guard) determines, after an investigation, that qualified seamen who are citizens of the United States are not available.

This regulatory action establishes a waiver only with respect to offshore supply vessels (OSVs) that operate from a foreign port, and mobile offshore drilling units (MODUs) operating beyond the water above the U.S. Outer Continental Shelf (as defined in 43 U.S.C. 1331(a)).

An OSV is defined in 46 U.S.C. 2101(19) as "a motor vessel of more than 15 gross tons but less than 500 gross tons that regularly carries goods, supplies, or equipment in support of exploration, exploitation, or production of offshore mineral orenergy resources and is not a small passenger vessel."

A MODU is defined in 46 U.S.C. 2101(15a) as "a vessel capable of engaging in drilling operations for the exploration or exploitation of subsea resources."

Waivers from citizenship requirements with respect to other vessels, including vessels engaged in operations similar to those of OSVs or MODUs, are not within the scope of this rulemaking. Waivers for these vessels are considered by the Coast Guard only on an individual basis.

Discussion of Comments and Changes

The 11 comments received expressed a division of opinions based on a variety of concerns. In most cases, opposition to the rule was qualified by comments on the appropriate use of a general waiver, and support for the rule was qualified by comments on the limited scope of the waiver. Three comments expressed general opposition to any waiver which allows the employment of non-U.S. citizens on U.S. documented vessels. Four comments were opposed to the use of a general waiver procedure to exempt certain U.S. vessels from citizenship requirements. Three comments expressed support for the rule but wanted it broadened to include additional vessels. One comment expressed concern regarding the availability of radio officers but did not take any position which was relevant to the present rulemaking.

The views expressed in the 11 comments related to the following general issues: (1) The consistency of the rule with congressional intent; (2) the use of a general as opposed to an individual waiver process; (3) the scope of the general waiver; (4) the responsibility of the master to determine whether non-U.S. citizens are qualified for crewmember positions; (5) the effect of foreign law on a U.S. vessel while it is operating in water subject to foreign jurisdiction; and (6) the amendment of 46 CFR 15.720(a) to reflect a statutory revision allowing substitution of U.S. crewmembers by non-U.S. citizens on a U.S. vessel on a foreign voyage until the vessel's return to a port where a U.S. citizen can be obtained expeditiously. Each of these issues is discussed below.

1. Congressional Intent

The interim final rule was described as inconsistent with the intent of Congress by both those who supported and those who opposed the rule. Several comments quoted sections of the House Report relating to the statutory provision which authorizes this regulation. The relevant paragraph states as follows:

> The Committee recognized that the practice of employing a limited number of American citizens on offshore supply vessels and mobile offshore drilling units when operating in foreign territorial waters or on the high seas or beyond the waters above our Outer Continental Shelf would have to be continued. Therefore, the Secretary of the Department in which the Coast Guard is operating (currently Transportation) has been granted authority to waive the citizenship requirement in specific and limited cases. The existing authority of the Secretary to authorize a reduction in citizenship requirements after an investigation shows that this authority cannot be used under normal circumstances and should only be used when a cause and effect shortage is adequately investigated and documented. For example, a sudden mobilization effort in which sufficient citizen seamen are not available, such as occurred in the Korean and Vietnam conflicts, might call for a reduction in citizenship requirements documented after an adequate investigation. (House Report 100–423, pages 10 and 11).

One comment said "these sentences establish beyond doubt that the Congress did not intend this waiver authority to be used in a general or blanket manner or without a case-by-case investigation."

Another comment expressed the same view and said the report language indicated that waiver authority was only to be used "in specific and limited cases" and "clearly shows that Congress never intended to allow citizenship requirements to be waived in a general manner, without a case-by-case investigation."

In contrast to this view, a comment supporting the general waiver cited this report language and the wording of the statute to argue that the limited scope of the waiver was inconsistent with congressional intent. Instead, according to this view, Congress intended for the waiver to be granted not only to OSVs but also to "other similarly engaged vessels." Restricting the waiver to OSVs as defined in 46 U.S.C. 2101(19) excluded other, similarly engaged vessels of less than 1600 gross tons which, in this person's opinion, Congress intended to be covered by the waiver. The comment said the regulations were "too restrictive, do not carry out the intent of Congress, and do

not sufficiently address the needs of our [offshore oil and gas] industry."

Two other comments said the wording of 46 U.S.C. 8103(b)(3) itself expressed the "intent" to include "other similarly engaged vessels of less than 1600 gross tons" and "other vessels engaged in support of exploration, exploitation, or production of offshore mineral energy resources operating beyond the water above the Outer Continental Shelf" in the general waiver. One of the comments said "clearly, Congress intended for [these other vessels] to be treated the same as OSVs and MODUs."

The Coast Guard interprets the paragraph from the House Report quoted above as describing two separate and distinct situations. First, the Committee on Merchant Marine and Fisheries recognized that the practice of employing non-U.S. citizens on OSVs and MODUs when operating in foreign territorial waters or on the high seas or beyond the waters above the U.S. Outer Continental Shelf, needed to be continued. "Therefore" authority was granted to waive the citizenship requirement "in specific and limited cases." The Coast Guard understands 46 U.S.C. 8103(b)(3) (A) and (B) codify the specific and limited cases in which waivers are intended to be granted. The operational criteria in those subsections are very specific and limited. The fact that the waiver in the present rule applies to a class of vessel rather than a specific ship does not render the rule incompatible with the report language: the report does not state that each vessel must be considered for a waiver individually; it states that the cases must be specific and limited, as they indeed are when the statutory criteria are applied.

The Coast Guard understands the second situation described in the Committee's report to include all other cases, where it can be determined that qualified U.S. citizens are not available. Authority to issue a wavier in this situation existed in 46 U.S.C. 8103(b) prior to the enactment of the 1987 Anti-Reflagging Act and is "retained" according to the report language. This authority, according to the report, "cannot be used under normal circumstances and should only be used when a cause and effect shortage is adequately investigated and documented." An example—sudden mobilization during a military conflict—is provided in the report. There is no indication that the Committee intended for this condition to be met before a waiver could be issued with respect to OSVs and MODUs in the specific and limited cases described in the first portion of the paragraph.

The wording and structure of 46 U.S.C. 8103(b)(3) is entirely consistent with the Coast Guard's understanding of the language in the House Report. Waivers may be issued in two specific and limited cases: OSVs or other similarly engaged vessels of less than 1600 gross tons when operating from a foreign port (subsection (A)); and MODUs or other vessels engaged in support of exploration, exploitation, or production of offshore mineral energy resources when operating beyond the water above the U.S. Outer Continental Shelf (Subsection (B)). Waivers may also be issued in a third category: "any other vessel" if the Coast Guard determines, after an investigation, that qualified seamen who are citizens of the United States are not available.

Therefore, it is the Coast Guard's view that Congress intended for waivers to be considered under three separate criteria, and the provisions of 46 U.S.C. 8103(b)(3) do not preclude the use of a general waiver when it is applied to the specific and limited cases described in 46 U.S.C. 8103(b)(3) (A) and (B).

2. Use of General Waiver Process

Three comments expressed opposition to granting any waiver of citizenship requirements to U.S. documented vessels, on the basis that this discouraged the employment of U.S. citizens or denied U.S. citizens certain career opportunities.

The Coast Guard must respect the statutory provisions which authorize waivers of citizenship requirements. As House Report 100–423 states: "the Committee recognized that the practice of employing a limited number of American citizens" on certain OSVs and MODUs "would have to be continued." The statutory provisions are very clear as to the criteria to be applied in granting waivers to these vessels. An individual request to waive a citizenship requirement for an OSV or MODU that met the operational conditions stated in 46 U.S.C. 8103(b)(3)(A) or (B) would automatically be granted a waiver request as long as there was no reason to doubt the vessel was actually operating from a foreign port or beyond the water above the U.S. Outer Continental Shelf. Therefore, the exercise of waiver authority in these conditions is considered to be strictly in accordance with the statutory provisions.

Three comments expressed opposition to the use of a general waiver procedure and believed a waiver should be issued only on a case-by-case basis. Representative of this view was one letter which said treating waivers "in an unlimited, general sense of whole classes of vessels without specific justification" would set a "bad precedent" and would lead to an expansion of general waivers "to other kinds of vessels, even, eventually, the entire U.S. flag fleet."

As explained above, the Coast Guard is convinced that Congress allowed for a general waiver process in 46 U.S.C. 8103(b)(3). The primary argument in favor of a general waiver for certain OSVs and MODUs was presented in the preamble to the interim final rule, as follows: "The Coast Guard is of the view that the operational conditions established in the Act for OSVs and MODUs are sufficiently clear that there is no need for a case-by-case evaluation of applications for waivers for vessels which meet these conditions." In other words, the criteria stated in 46 U.S.C. 8103(b)(3)(A) and (B) are specific and objective and can be described unambiguously for application of a general waiver to a limited class of vessels. Each vessel operator knows for certain whether or not non-U.S. citizens can be employed on a particular vessel under the general waiver, and approval does not require an exercise of agency discretion on a case-by-case basis.

In the view of one comment, this general waiver will set a precedent which will be broadened to include other classes of vessels in the future. The Coast Guard finds that a general waiver is only appropriate to the extent that specific and limited circumstances exist which justify this process. There are currently no plans to expand the general waiver procedure to any classes of vessel other than those identified in the present rule.

The Coast Guard does not agree with the view of one comment which asserted that a waiver should only be used when a shortage of qualified U.S. citizens is adequately investigated and documented. This is a separate statutory test which applies under 46 U.S.C. 8103(b)(3)(C) to vessels other than the OSV's and MODU's described in 46 U.S.C. 8103(b)(3) (A) and (B).

3. Scope of the General Waiver

Three comments expressed support for the general waiver but argued that it was too narrow and should be broadened to include vessels other than OSV's and MODUs which are engaged in similar activities, as provided in 46 U.S.C. 8103(b)(3) (A) and (B). These comments argued that Congress clearly intended for these vessels to be covered by the waiver. One comment said such a narrow waiver was "unfair" to

operators of the other similarly-engaged vessels which are faced with the same difficulties when operating under foreign jurisdiction.

In drafting the general waiver in this rule, the Coast Guard has selected the elements of 46 U.S.C. 8103(b)(3) which are clear and unambiguous and require no exercise of agency discretion to determine whether a particular vessel is operating under the conditions for which citizenship requirements are waived. This is entirely consistent with the congressional intent to apply the waiver in specific and limited cases. The terminology used in 46 U.S.C. 8103(b)(3) with respect to these "other vessels" is not as precise and unambiguous as the terms used with respect to OSVs and MODU's. In particular, the phrase "other similarly engaged vessel" in 46 U.S.C. 8103(b)(3)(A) is not as objective as the statutorily defined "offshore supply vessel"; and the phrase "other vessel engaged in support of exploration, exploitation, or production of offshore mineral energy resources" is not as precise as the statutorily defined term "Mobile Offshore Drilling Unit."

The use of a general waiver for OSVs and MODUs does not preclude the issuance of an individual waiver to any other vessel which is determined by the Coast Guard to meet the criteria described in 46 U.S.C. 8103(b)(3) (A) and (B). However, the Coast Guard has not had any requests for waivers for these vessels; and, until further information becomes available about the precise operational circumstances of these "other" vessels which could be used in drafting a specific and limited waiver, the Coast Guard will evaluate any such waiver requests only on a case-by-case basis.

4. Responsibility of the Master to Determine Equivalent Qualifications

One comment expressed concern that the Coast Guard was in effect delegating Coast Guard authority to vessel masters by requiring the master, under 46 CFR 15.720(d), to assure that any non-U.S. citizen replacement holds "a license or document which is equivalent in experience, training, and other qualifications to the U.S. license or document required for the position * * *." In the opinion of this comment, the responsibility for determining who is qualified should be performed by the Coast Guard on a case-by-case basis, and it is unreasonable, in the absence of a "world wide guide of equivalencies," to expect a master to determine that a foreign seaman is qualified to be engaged in a position on a U.S. ship.

As a note, 46 CFR 15.720(d) is only a renumbered and editorially revised version of an existing provision. This provision was first promulgated as an interim final rule in 1987 (52 FR 38654, October 16, 1987) after it had been proposed in a supplemental notice of proposed rulemaking (SNPRM) as part of a revision of the manning regulations previously contained in 46 CFR part 157 (50 FR 43363, October 24, 1985). There were no comments submitted on this provision at that time.

Section 15.720(d) should be understood not to delegate authority but to assign a responsibility to the master. The Coast Guard's authority to certify that an individual meets certain qualifications and to issue that individual a license or document has not been delegated. The master is required to ensure that non-U.S. citizen replacements have documentary evidence to indicate they are qualified to act in a certain capacity on the vessel (i.e., that their experience, training and other qualifications are equivalent to those required for a comparable U.S. license or document). The master's judgment is not used as a substitute for Coast Guard determinations of qualification or as the basis for certification of competence for any level of ability except for performing duties in a specific position on a specific vessel.

5. The Effect of Foreign Law on a U.S. Vessel While It Is Operating in Water Subject to Foreign Jurisdiction

Two different concerns were expressed by two comments on the influence of foreign law on a policy of waiving citizenship on U.S. ships which operate on waters subject to foreign jurisdiction. One comment said it was inappropriate for the Coast Guard to promulgate the waiver rule on the basis that U.S. vessels must operate in areas subject to foreign jurisdiction where local citizenship laws may apply, since under international law principles, the flag State of a ship has exclusive jurisdiction over shipboard matters relating to the internal order and economy of the vessel.

The Coast Guard is not convinced that the comment has identified a conflict between the waiver rule and international principles of flag State jurisdiction. The Coast Guard is convinced that these matters were taken into account when the statutory provision allowing for waivers was enacted by Congress. A foreign citizen who is engaged or employed on a U.S. flag ship in accordance with this general waiver should be subject to U.S. jurisdiction to the same extent as a foreign citizen employed, for example, to fill a vacancy in accordance with 46 U.S.C. 8103(e). The fact that a foreign country requires, as the point was expressed by another comment, employment of "indigenous crews as a condition of resource development" in their offshore areas, does not in itself alter the scope of flag State jurisdiction over shipboard matters.

Another comment expressed concern about the aspect of the general waiver, stating there were a number of "legal questions" which should be "thoroughly investigated" by the U.S. Coast Guard, such as "what disciplinary action will be available to the Masters aboard U.S.-flag OSVs and MODUs with foreign crews" and "can the U.S. Coast Guard prosecute non-U.S. citizens engaged in waters subject to foreign jurisdiction aboard U.S.-documented vessels?" While the Coast Guard agrees that there may be complicated legal issues in recruiting foreign citizens to work on a U.S. vessel which is operating in waters subject to the jurisdiction of a foreign country and subject to conditions imposed by that country, these questions are not unique to this rulemaking. Furthermore, in the absence of any specific factual scenario, any attempt to address these complicated questions would be vague and possibly misleading. In the most general terms, the Coast Guard is of the view that the master and crew on a U.S. documented vessel are subject to the full application of U.S. laws and regulations and any agreements which the U.S. has entered with countries which have jurisdiction over waters where that vessel is operating.

6. Revision of 46 CFR 15.720(a) to Reflect Statutory Change

The 1987 Anti-Reflagging Act revised 46 U.S.C. 8103(e) by allowing the recruitment of a non-U.S. citizen to fill the vacancy on a U.S. documented vessel on a foreign voyage only "until the vessel's return to a port at which in the most expeditious manner a replacement who is a citizen of the United States can be obtained." The previous version of 46 U.S.C. 8103(e) allowed the substitution by a non-U.S. crewmember "until the vessel's first return to a United States port at which a replacement who is a citizen of the United States can be obtained." The revision also allows the substitution with respect to every position "except the master and the radio officer" (whereas the prior language excepted only the master). Since the amendments bring the regulation in line with the current statutory language, the revision of 46 CFR 15.720 is considered editorial in nature. Two comments expressed

specific support for these changes in the rules.

Regulatory Evaluation

This rule is not major under the Executive Order 12291 and not significant under the Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979).

The Coast Guard expects the economic impact of this rule to be so minimal that further regulatory evaluation is unnecessary. In effect this rule is permitting vessels to continue to operate according to current industry practice.

Small Entities

Because this rule is essentially procedural and will permit the affected vessels to operate according to current, longstanding industry practice, the economic impact of this action is expected to be minimal. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This final rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard analyzed this rulemaking in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the action does not have sufficient federalism implications to warrant the preparation of a Federalism assessment. This final rule provides a general waiver for offshore supply vessels (OSVs) operating out of foreign ports, and mobile offshore drilling units (MODUs) operating beyond the water above the U.S. Outer Continental Shelf to use non-U.S. citizens as licensed individuals and unlicensed seamen on U.S. documented vessels. This action was necessary to allow these vessels to operate in areas subject to foreign jurisdiction where local citizenship requirements may apply and where recruitment of U.S. citizens may be impractical. Since this rule affects the manning of these specific vessels outside of State waters, the Coast Guard intends to preempt State action addressing the same subject matter. This rule adopts the interim final rule without change.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2.B.2 of Commandant Instruction M16475.1B, this proposal is categorically excluded from further environmental documentation. The rule is procedural in nature and permits the affected vessels to continue to operate according to current industry practice. Therefore, this is included in the categorical exclusion in subsection 2.B.2.1, "Administrative actions or procedural regulations and policies which clearly do not have any environmental impact." A Categorical Exclusion Determination has been placed in the docket.

List of Subjects in 46 CFR Part 15

Reporting and recordkeeping requirements, Seamen, Vessels.

In consideration of the foregoing, the interim rule amending 46 CFR part 15 which was published at 55 FR 1210 on January 12, 1990, is adopted as a final rule without change.

By direction of the Commandant.

Dated: October 30, 1992.

R.C. North,

Captain, U.S. Coast Guard, Deputy Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 92–31914 Filed 12–31–92; 8:45 am]

BILLING CODE 4910–14–M

FEDERAL MARITIME COMMISSION

46 CFR Part 514

[Docket No. 90–23]

Tariffs and Service Contracts; First Interim ATFI Amendments

AGENCY: Federal Maritime Commission.

ACTION: Interim rule.

SUMMARY: In order to implement the Federal Maritime Commission's ("Commission's" or "FMC's") Automated Tariff Filing and Information System, the Commission issued an interim rule on August 12, 1992. Several comments were filed to the interim rule, and these amendments address those comments. Additionally, Part 514's filing requirement for military rates (tenders) is noted as being the subject of a separate rulemaking proceeding.

DATES: Amendments are effective on February 3, 1993. Further written comments in response to this notice may be submitted by April 30, 1993, and again, by September 30, 1993.

ADDRESSES: Written comments (original and 15 copies) should be sent to Joseph C. Polking, Secretary, Federal Maritime Commission, 800 North Capitol Street, NW., Washington, DC 20573–0001.

FOR FURTHER INFORMATION CONTACT: John Robert Ewers, Deputy Managing Director, Federal Maritime Commission, 800 North Capitol Street, NW., Washington, DC 20573–0001, (202) 523–5800.

SUPPLEMENTARY INFORMATION: On August 12, 1992, the Federal Maritime Commission ("Commission" or "FMC") issued an interim rule to implement the Commission's Automated Tariff Filing and Information System ("ATFI" or "the system"). See the **Federal Register** of August 12, 1992, at 57 FR 36248–36311.[1] While the interim regulations were scheduled to go into effect by September 11, 1992, further comments were invited to be filed by September 30, 1992, especially on the format for filing the essential terms of service contracts under § 514.17.

Comments were submitted by:

Conferences: Asia North America Eastbound Rate Agreement (ANERA), jointly with the "8900" Lines, U.S. Atlantic & Gulf/Australia-New Zealand Conference, the South Europe/USA Freight Conference, and Transpacific Westbound Rate Agreement (TWRA),—the "Joint Conferences," and the Trans-Pacific Freight Conference of Japan and the Japan-Atlantic and Gulf Freight Conference ("TPFCJ/JAG");

Carriers: Farrell Lines, Inc. ("Farrell"), Sea-Land Service, Inc. ("Sea-Land"), and Zim-American Israeli Shipping Co., Inc. ("Zim");

Tariff Services: Pacific Coast Tariff Bureau ("PCTB"), and Rijnhaave Information Service, Inc. and World Tariff Services, Inc., a Rijnhaave Group Company ("Rijnhaave");

Others: Military Sealift Command ("MSC") within the Department of the Navy.

Several commenters suggested a "user-group" approach to technical problems (with periodic meetings). The Commission believes that, if the industry is interested in participating in a user group, it should take the

[1] Since the issuance of the interim rule on August 12, 1992, part 514 also has been amended in connection with other regulatory initiatives. See, for example, final rules in the **Federal Register** of September 28, 1992 (57 FR 44504); September 29, 1992 (57 FR 44697); and October 8, 1992 (57 FR 46318), which provide for, respectively, the reduction of notice for certain rate increases in the domestic offshore trades to 7 working days; relaxation of the requirements for filing of financial documents by non-vessel-operating common carriers in the domestic offshore trades; and the amendment of service contracts. The ATFI implementation schedule, as well as proposed amendments to part 514 to implement section 502 of Public Law 102–582, are being addressed separately.

appropriate steps to form such an entity without direct FMC involvement, other than, perhaps, an occasional invitation to address the group.

Section-by-Section Analysis

The following addresses other comments received and the resulting changes in Part 514, if any, in a sequence which tracks the affected sections of Part 514.

514.2—Definitions

As suggested by the Joint Conferences, the definition of "Alternate Port Service" is revised. As requested by Rijnhaave, the definitions of "Combination rate" and "Commodity description" are revised, and a new definition (cross reference) of "Intermodal service" is added. All suggested changes are improvements, leading to more accurate definitions and concepts within ATFI.

514.3—Exemptions and Exclusions

With regard to transportation in foreign commerce of U.S. Department of Defense cargo under terms and conditions negotiated and approved by MSC (see §§ 514.3(b)(4) and 514.9(b)(13)), MSC suggests that the rule delete the term, "American-flag" so that the continuing special permission (and electronic implementation thereof) applies to all common carriers, both U.S.- and foreign-flag. Farrell and Sea-Land propose that the rule be changed to eliminate ATFI filing and require only hard copy filing as at present. (See also discontinued Docket No. 92–25, *Regulation of Military Rates Under the Shipping Act of 1984.*)

Both suggestions are broader than the provisions of part 514, either as proposed or finalized. Accordingly, the filing of military tenders, including the above-described comments, will be addressed in a separate proceeding.

514.7—Tariffs and Service Contracts

Under § 514.7(k), where a service contract (and/or essential terms) has been allowed (directed) to be corrected, a me-too shipper can elect to continue with or without the changed essential term(s). This also would apply to amendments of service contracts and essential terms, now permitted under a rule promulgated in Docket No. 92–21. While ATFI would show the previous version of the essential terms (in history), it would not show that one or more shippers has elected to continue with the previous version unless the filer is required to enter this information (with, perhaps, a special ATFI field in which to put it). Rijnhaave urges the "filing of such data to keep ATFI as viable a system as possible to meet all contingency essential term applications." This information, while it could be helpful in administering me-too provisions, would be more than just the filing of essential terms and is, therefore, outside the scope of the proposed rule.

In paragraphs (f)(4), (l)(1) and (l)(2) of § 514.7, several cross reference citations to paragraphs in § 514.17 are revised to reflect the changes described in the analysis for that section.

Paragraphs (f)(3) and (h)(1)(iii) of § 514.7 are amended to require the insertion in a service contract of the "FMC File Number," which is generated by the system when essential terms are electronically filed and made available to the filer by electronic mail. See new § 514.17(d). This number facilitates FMC linkage of the electronically-filed essential terms and the later, physically-delivered-in-paper-form service contract itself. Paragraph (f)(3) also requires that filers of any service contract indicate in their transmittal that it is a "me-too" contract, if that is the case. Many filers do this at present.

514.8—Electronic Filing

The notice issue, including the interim rule becoming effective on 30-days (rather than 90-days) notice (similar to what originally appeared to be the notice period for implementation after the release of recent software upgrades), was raised by a commenter. The Commission will continue to give the industry as much notice as possible in order that they can be ready for implementation. The 30-day notice for the interim rule, for example, conforms to the guidelines set forth in the Administrative Procedure Act (5 U.S.C. 551, *et seq.*). However, because implementation under the interim rule will now not begin until at least 6 months after it was published, notice should be more than adequate.

Several commenters have raised technical, non-rulemaking issues, which either have been or will be addressed.

In § 514.8, paragraph (n)(1)(iii)(G) is revised to indicate that the system conformity checks will ensure that there is a 30-day availability date for both initial service contracts, as well as amendments thereto.

514.10—Other Items Used Throughout ATFI

As pointed out by the commenters, freight forwarder compensation is not an assessorial, and, therefore, is being deleted, as an example of an assessorial from paragraph (d)(1)(i)(B) of § 514.10.

Paragraph (d)(1)(ii) of § 514.10 provides that, when there may be a conflict between the text description and the algorithm formula of an assessorial, the algorithm shall take precedence. The Joint Conferences and TPFCJ/JAG request that the procedure should be reversed, i.e., the text should take precedence over algorithms.[2] Alternatively, TPFCJ/JAG argues that the provision should be suspended for 12 to 18 months. It is possible that paragraph (d)(1)(ii) has been confused with the "bottom-line calculation" provision, but the bottom-line total is not intended to be "official" because of (*inter alia*) non-predeterminable charges and operator discretion used in its calculation. See §§ 514.10(d) and 514.13(c). Otherwise, the commenters appear to be addressing the extent to which, if any, an assessorial can be expressed in mathematical terms (algorithm), *vis-a-vis* purely textual description. (The latter would seem to be more susceptible to error or ambiguity in the majority of cases.) In any event, the Commission has determined to make no changes to paragraph (d)(1)(ii). Any other approach would unduly dilute the importance of algorithms and the industry's duty to ensure clarity and unambiguity in tariff data.

514.12—Governing and General Reference Tariffs

As discussed below, the essential terms of service contracts will be filed substantially in "full-text" format, without the capability (requirement) of "linking" various tariff objects between types of tariffs, including the essential terms of service contracts. For these reasons, essential terms publications and tariffs of general applicability are deleted as types of "Governing tariffs (filed electronically)" under paragraph (a) of § 514.12, but are included as special types of governing tariffs under new paragraph (c) of that section.

514.15—Tariff Rules

The requirement in paragaph (b)(1)(iii)(A) of § 514.15 that a carrier state its liability to a shipper for each type of intermodal movement has been deleted as requested by the commenters. Additionally, paragraph (b)(2)(i) is amended to delete the reference to "inland rate tables."

514.17—Essential Terms of Service Contracts

ANERA continues to request that ETs be completely exempted from electronic filing. Alternatively, ANERA suggests

[2] The reverse approach, i.e., making the text version govern in case of conflict, would appear to be outside the scope of the proposed rule in any event.

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filing in "full text." TPFCJ also suggested this option. On the other hand, Rijnhaave stated that ETs fit the ATFI model and should be in database format, but it admitted that it would take several more rounds of comments to achieve that result. Zim suggested that because it is complicated to convert ETs to electronic format, the Commission should accept the service contract itself, with the converted ETs to follow four or five days later (the reverse of the current ATFI scheme).

In view of the difficulties in converting ETs to electronic form, the Commission has decided to adopt the full-text approach in these interim amendments, without prejudice to revisiting the database approach in the future.

While the rule change relaxes the electronic formatting of essential terms in order to facilitate filing into ATFI, certain standardization will be retained/required. Certain routine data will continue to be filed in data-element format, e.g., all relevant types of dates and identifying numbers. Location names will continue to be validated against the ATFI Locations Database, although full-text clarification may be given in "subterms." Additionally, the subjects of ten mandatory terms must be addressed for every essential term document by use of standardized numbering and titles. (If a term does not apply, such as the clause for liquidated damages or for later events causing deviation, the filer must use the number and title, but with the notation "NA.") A new mandatory term for "assessorials" is added, wherein the filer, in full text, sets forth all ET assessorials, either fully, or by cross-references to the places where the assessorial may be found. Preferably, a separate subterm will be used for each type of assessorial.

In addition to a new screen illustration, the interim amendments to § 514.17(d) provide for amendment numbers and symbols to accommodate the new regulations allowing amendment of service contracts, and an FMC File Number, generated by the system, which will facilitate FMC linkage of an essential terms to its associated service contract. See the analysis under § 514.7.

The Commission believes that the foregoing reflects a good compromise and should facilitate the first-time formatting and electronic filing of essential terms into the ATFI system.

514.21—User Charges

Section 514.21 is amended by the addition of routine billing and payment information, i.e., how and where payment for ATFI services may be made, and penalties for non-payment, which conform to penalties for non-payment for other services provided by the Commission and/or the U.S. Government.

Although the Commission, as an independent regulatory agency, is not subject to Executive Order 12291, dated February 17, 1981, it nonetheless has reviewed these amendments to 46 CFR part 514 in terms of this Order and has determined that they do not result in a "major rule," as defined in Executive Order 12291, because they will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions;

(3) Significant adverse effects on competition, employment, investment, productivity, innovations, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Federal Maritime Commission certifies, pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(n), that the interim amendments to 46 CFR part 514 will not have a significant economic impact on a substantial number of small entities, including small businesses, small organizational units and small government jurisdictions. Instead, most of the amendments result from the comments of the affected industry and, if anything, they will significantly reduce or inhibit any adverse economic impact on small entities.

The collection of information requirements contained in 46 CFR part 514 and Exhibit 1 to part 514 have been approved by the Office of Management and Budget (OMB) in accordance with 44 U.S.C. chapter 35 and have been assigned OMB control number 3072–0055. The amendments to part 514 contained in this rulemaking contain no significant, additional information collection requirements.

List of Subjects in 46 CFR Part 514

Barges, Cargo, Cargo vessels, Exports, Fees and user charges, Freight, Harbors, Imports, Maritime carriers, Motor carriers, Ports, Rates and fares, Reporting and recordkeeping requirements, Surety bonds, Trucks, Water carriers, Waterfront facilities, Water transportation.

Therefore, for the reasons set forth in the preamble, and pursuant to 5 U.S.C. 552 and 553; 31 U.S.C. 9701; 46 U.S.C. app. 804, 812, 814–817(a), 820, 833a, 841a, 843, 844, 845, 845a, 845b, 847, 1702–1712, 1714–1716, 1718, 1721 and 1722; and section 2(b) of Public Law 101–92; part 514 of title 46, Code of Federal Regulations, is amended as follows:

PART 514—TARIFFS AND SERVICE CONTRACTS

1. The authority citation for part 514 continues to read as follows:

Authority: 5 U.S.C. 552 and 553; 31 U.S.C. 9701; 46 U.S.C. app. 804, 812, 814–817(a), 820, 833a, 841a, 843, 844, 845, 845a, 845b, 847, 1702–1712, 1714–1716, 1718, 1721 and 1722; and sec. 2(b) of Pub. L. 101–92, 103 Stat. 601.

2. In § 514.2, the alphabetically listed definitions of "Alternate port service," "Combination rate," and "Commodity description" are revised, and, in alphabetical order, the definition of "Intermodal service," is added, to read as follows:

§ 514.2 Definitions.

* * * * *

Alternate port service means substituted service whereby the vessel-operating common carrier for whom the tariff object is filed uses someone else to perform the transportation between the point at which the cargo was tendered by the shipper and the port at which the cargo is actually loaded on the filing carrier's vessel, or between the port at which the cargo is discharged from the filing carrier's vessel and the point at which the cargo is to be tendered to the consignee.

* * * * *

Combination rate means a rate for a shipment moving under intermodal transportation which is computed by the addition of a TLI, and an inland rate(s) applicable from/to inland point(s) not covered by said TLI.

* * * * *

Commodity description means a comprehensive description of a commodity listed in a tariff, including a brief definition of the commodity, any applicable assessorial, related assessorial charges if any, and the commodity index entries by which the commodity is referenced.

* * * * *

Intermodal service. See "intermodal transportation."

* * * * *

3. In § 514.7, in paragraphs (f)(4), (l)(1) and (l)(2), change the cross reference citations "§ 514.17(d)(8)(v)" and "§ 514.17(d)(8)(vi)" to "§ 514.17(d)(7)(vii)" and "§ 514.17(d)(7)(viii)," respectively. Also in § 517.7, paragraphs (f)(3) and (h)(1)(iii) are revised to read as follows:

§ 514.7 Service contracts in foreign commerce.

* * * * *

(f) * * *

(3) *Filing of me-too contracts.* The service contract resulting from a request under this section may be implemented as described in paragraph (j)(3) of this section, and no additional statement of essential terms need be filed. The letter transmitting the service contract itself for filing, however, shall indicate that it is a "me-too" contract and reference the essential terms FMC File Number. See § 514 17(d)(4)(i).

* * * * *

(h) * * *

(1) * * *

(iii) A reference to the statement of essential terms numbers, as follows:

(A) "ET Number _____" as provided in § 514.17(d)(2)(i); and,

(B) "FMC File Number_____" as provided in § 514.17(d)(4)(i).

* * * * *

4. In § 514.8, paragraphs (d)(3) introductory text, and (n)(1)(iii)(G) are revised to read as follows:

§ 514.8 Electronic filing.

* * * * *

(d) * * *

(3) *"Batch Filing Guide."* The ATFI "Batch Filing Guide" is published and updated in Pike and Fischer, "Shipping Regulation," SR 329:501, and a copy of the Guide is available from BTCL. The "Batch Filing Guide" includes the following items:

* * * * *

(n) * * *

(1) * * *

(iii) * * *

(G) *Essential terms* (§ 514.17) must have:

(*1*) All mandatory terms (§ 514.17(d)).

(*2*) Availability date for initial service contracts and each amendment thereto at least 30 days greater than the filing date (§ 514.17(d)(3)).

* * * * *

5. In § 514.9, paragraph (a)(5) is revised to read as follows:

§ 514.9 Filing/Amendment codes and required notice periods.

(a) * * *

(5) *Essential terms and terminal tariffs.* Due to the absence of most of the notice requirements otherwise applicable to carrier or conference tariffs, the use of symbols under this section for terminal tariffs will be appropriate for the tariff objects employed and filing/maintenance. Symbols for essential terms of service contracts under § 514.17 will usually be "I" for initial filings, "S" for corrections, and the appropriate symbols for amendments to essential terms. See § 514.17(d)(5)(i).

* * * * *

6. In § 514.10, paragraph (d)(1)(i)(B) is removed and paragraphs (d)(1)(i) (C), (D), and (E), are redesignated (d)(1)(i) (B), (C), and (D), respectively; also, in § 514.10, paragraph (d)(1)(iii) is revised to read as follows:

§ 514.10 Other items used throughout ATFI.

* * * * *

(d) * * *

(1) * * *

(iii) *Predeterminable charges.* Assessorial charges which can be determined prior to shipment shall be expressed in algorithm form and may be contained in Tariff Rules of tariffs under § 514.15, as well as in commodity descriptions and TLIs of tariffs under § 514.13. Algorithms, including dummy algorithms under paragraph (d)(1)(iv) of this section, are not accommodated in essential terms publications or statements of essential terms under § 514.17.

7. In § 514.12, paragraphs (a)(1)(v) and (a)(1)(vi) are removed; and a new paragraph (c) is added, to read as follows:

§ 514.12 Governing and general reference tariffs.

* * * * *

(c) *Essential terms of service contracts.* To the extent possible under the special full-text format for electronic filing of the essential terms of service contracts under § 514.17, the following types of governing tariffs are permissible:

(1) Essential terms publications under § 514.17(b) (solely for essential terms documents); and

(2) Tariffs of general applicability under § 514.17(b)(2) (solely for essential terms publications).

8. In § 514.15, paragraphs (b)(1)(iii)(A) and (b)(2)(i) are revised to read as follows:

§ 514.15 Tariff Rules.

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(A) Tariff Rule 1 shall describe the modes of intermodal service provided (e.g., rail, truck, etc.).

* * * * *

(2) * * *

(i) All services provided to the shipper and covered by the TLIs, including the rate bases set forth in §§ 514.13(b)(17)(ii) and (b)(17)(iv)(A); and

* * * * *

9. In § 514.17, paragraphs (a)(1) and (d) are revised to read as follows:

§ 514.17 Essential terms of service contracts in foreign commerce.

(a) *General.* (1) A concise statement of the essential terms (ETs) of every initial service contract (which is filed in paper form under § 514.7) and appropriate amendments to ETs resulting from any amendment of the filed service contract, shall be filed with the Commission by authorized persons (see § 514.4(d)(5)) and made available to the general public in electronic tariff format. Unlike most other tariff data, ETs shall be filed largely in full text, with a minimum of database formatting (but with certain other standardization), as set forth in this section. Additionally, ETs are not subject to the algorithm or linkage requirements of § 514.10(d). Filing and maintenance of ETs are accomplished through an electronic essential terms publication (ETP) for each carrier or conference filer, which contains ETs for each of the carrier's or conference's service contracts.

* * * * *

(d) *Essential terms; specific requirements—(1) ATFI sample screen illustration.* The following ATFI simulated screen illustrates the elements required to be contained in essential terms filings and how they may appear in the ATFI system. The references in brackets in each line are to the subparagraphs of this paragraph which explain the requirements for the fields and the data contained therein. See paragraph (b)(1) of this section for provisions regarding the essential terms publication. On the screen, data above the double line, i.e., down through "Contract Termination," shall be entered in database format in the special fields provided; data beginning with Mandatory Term No. 3 ("Commodities") shall be entered in "full-text" format without the application of algorithms under § 514.10(d). However, the mandatory ETs (Nos. 1 to 10) shall bear the appropriate term number and exact mandatory term title, as set forth in this paragraph (and the screen). If the mandatory term does not apply (e.g., No. 7 or No. 8), the filer shall also enter the symbol "NA."

[§ 514.17(d)(1)] ATFI ESSENTIAL TERMS SEARCH

ET Num: 681		JKL Line Essential Terms Publication (XYZ 004)	[1]
SC Num: 765		Personal Computers from Taiwan	[2]
FMC File Num: 123456		Amendment Num: 3—Available until: 31 Jan 1992	[3]
Amendment Type: C		Contract Effective: 01 Dec 1992	[4]
Filing Date: 01 Jan 1992		Special Case: 123456—Contract Expiration: 15 Jan 1993	[5]
		Contract Termination: 15 Jan 1993	[6]

Term	(Amend)	List of essential terms titles	[7]
1	(0)	Origin	[I]
2	(0)	Destination	[II]
3	(0)	Commodities	[III]
4	(1)	Minimum Quantity	[IV]
4	A(0)	Minimum Quantity in 20ft containers	[A]
4	B(3)	Minimum Quantity in 40ft containers	[B]
5	(0)	Service Commitments	[V]
6	(0)	Contract Rates or Rate Schedules(s)	[VI]
7	(2)	Liquidated Damages for Non-Performance (if any)	[VII]
8	(0)	Later Events Causing Deviation From ET (if any)	[VIII]
9	(0)	Duration of the Contract (e.g., "46 days from 01 Dec. 1992 to 15 Jan. 1993")	[IX]
10	(0)	Accessorials	[X]
100	(0)	(Title and text—Optional)	[8]
101	(0)	(Title and text—Optional)	[8]
[999 zzz	(999)	Maximum term and amendment values]	

(2)(i) *ET Num (statement of essential terms number).* The "ET Num" is defined by the filer and shall be entered in the appropriate field. See § 514.7(h).

(ii) *ET Heading.* The filer's title of the ET document (e.g., "Personal Computers from Taiwan") is entered here and will appear in the ETP index to the included ETs.

(3)(i) *SC NUM (service contract number).* The "SC Num" is defined by the filer and shall be entered in the appropriate field. See § 514.7(h).

(ii) *Amendment Num.* Where feasible, ETs should be amended by amending only the affected specific term(s) or subterms, mandatory or optional. Each time any part of an ET is amended, the filer shall assign a consecutive ET amendment number (up to three digits), beginning with the number "1." (The amendment number field must be "0" or void for the initial ET filing.) Each time any part of the ET is amended, the ET "Filing Date" will be the date of filing of the amendment and the "Available Until Date" will be 30 days from the filing date, but the filer can enter a later date, making the availability period longer. See correction provisions under § 514.7(k) and paragraph (d)(5)(ii) of this section.

(iii) *Available until.* The period of availability of the essential terms to similarly situated shippers shall be no less than thirty (30) days, i.e., from the "Filing Date" (paragraph (d)(6)(i) of this section and § 514.10(a)(2)) of the initial filing or the latest amendment, to the "Available until" date (automatically defaulted to 30 days from the Filing Date by the interactive ATFI system, but the filer can enter a later date, making the availability period longer).

(4)(i) *FMC File Num.* The FMC File Numbers will be system assigned as initial ET filings are received/processed. The FMC File Numbers will be assigned sequentially and will start at a number designated by FMC at production start. The FMC File Number will be provided to filers in the acknowledge message (EMail) for filings so that they can put the number in the related service contract when it is filed in paper form. See § 514.7(h)(1)(iii)(B). This procedure will facilitate FMC linkage of the ET to its related service contract.

(ii) *Contract effective.* In addition to the period of availability of essential terms to similarly situated shippers, the service contract itself must have an effective date and an expiration date (see paragraph (d)(5)(iii) of this section and §§ 514.10 (a)(3) and (a)(4)), governing the duration of the contract between the original signatory parties. The duration must also be set forth in mandatory essential term No. 9, where the duration of the contract shall be stated as a specific fixed time period, with a beginning date (effective date) and an ending date (expiration date).

(5)(i) *Amendment type.* All ATFI amendment codes under § 514.9, except "G" and "S" (§§ 514.9(b)(7) and 514.9(b)(19)), may be used in any combination, with up to three amendment codes for amendments to ETs. No notice period is required for amendments to ETs, except that amendments to ETs require a new "Available until" date, which must be at least 30 days from the filing date. For the amendment code "S," see paragraph (d)(5)(ii) of this section.

(ii) *Special Case symbol and number.* The "S" amendment code (for special case under § 514.9(b)(19)(iii)) must be used singly, and in conjunction with a validated special case number for corrections to ETs. See correction provisions under § 514.7(k).

(iii) *Contract expiration.* See paragraph (d)(4)(ii) of this section.

(6)(i) *Filing date.* The filing date is automatically set by the system whenever an ET or amendment thereto is filed. See "Available until" in paragraph (d)(3)(iii) of this section.

(ii) *Contract termination date.* A statement of essential terms may not be canceled until after all of its associated service contracts, including any renewal or extension, have expired under the terms of the contract, or have been terminated for reasons not specifically set forth in the contract. See §§ 514.4(e)(2) and 514.7(l)(1)(ii). The contract termination date would, therefore, be the same as the contract expiration date under paragraph (d)(5)(iii) of this section, unless terminated sooner, in which case the filer would enter the earlier date when the termination event occurred.

(7) *Terms and subterms.* Mandatory essential terms Nos. 1 to 10 shall address the subjects and bear the terms' titles for the respective numbers exactly as provided in this section. If a subject is not included, such as No. 7 or No. 8, the number must be listed with the appropriate title and the designation "NA." All essential terms, mandatory and optional, may be subdivided into subterms (as illustrated for mandatory term No. 4) to facilitate retrieval and amendment. The mandatory terms are as follows:

(i) *Origin (No. 1).* "Origin" includes the origin port range(s) in the case of port-to-port movements, and the origin geographic area(s) in the case of through

intermodal movements, except that, in service contracts, the origin and destination of cargo moving under the contract need not be stated in the form of "port ranges" or "geographic areas," but shall reflect the actual locations agreed to by the contract parties. See § 514.10(b). Origin point and port locations will be validated against the ATFI Locations database. The validated names will be "inserted" by the system in Mandatory Term #1. The Mandatory Term may not contain text, but if the filer wishes to use full text to clarify or expand on the point/port entries in Term 1, full text may be used in subterms.

(ii) *Destination (No. 2).* "Destination" includes the destination port range(s) in the case of port-to-port movements, and the destination geographic area(s) in the case of through intermodal movements, except that, in service contracts, the origin and destination of cargo moving under the contract need not be stated in the form of "port ranges" or "geographic areas," but shall reflect the actual locations agreed to by the contract parties. See § 514.10(b). Destination point and port locations will be validated against the ATFI Locations database. The validated names will be "inserted" by the system in Mandatory Term #2. The Mandatory Term may not contain text, but if the filer wishes to use full text to clarify or expand on the point/port entries in Term 2, full text may be used in subterms.

(iii) *Commodities (No. 3).* Mandatory term No. 3 shall include commodities covered by the service contract, but these commodities may not be entered as described in § 514.13(a), i.e., commodities cannot be entered in data-element format, but the full-text format may incorporate the same elements of information, as desired. See § 514.7(c) for exempt commodities. For each commodity filed in this term, a separate formatted commodity index entry is required.

(iv) *Minimum quantity (No. 4).* Mandatory term No. 4 shall address the minimum quantity or volume of cargo and/or amount of freight revenue necessary to obtain the rate or rate schedule(s), except that the minimum quantity of cargo committed by the shipper may not be expressed as a fixed percentage of the shipper's cargo.

(A) *Subterm.* Example: Minimum quantity in 20FT Containers.

(B) *Subterm.* Example: Minimum quantity in 40FT Containers.

(v) *Service commitments (No. 5).* Mandatory term No. 5 shall address the service commitments of the carrier, conference or specific members of a conference, such as assured space, transit time, port rotation or similar service features.

(vi) *Contract rates or rate schedule(s) (No. 6).* Mandatory term No. 6 shall contain the contract rates or rate schedules, including any additional or other charges (i.e., general rate increases, surcharges, terminal handling charges, etc.) that apply, and any and all conditions and terms of service or operation or concessions which in any way affect such rates or charges; except that a contract may not permit the contract rate to be changed to meet a rate offer of another carrier or conference not published in a tariff or set forth in a service contract on file with the Commission.

(vii) *Liquidated damages for non-performance (if any) (No. 7).* Mandatory term No. 7 shall include liquidated damages for non-performance. See § 514.7(1).

(viii) *Later events causing deviation from ET (if any) (No. 8).* Where a contract clause provides that there can be a deviation from an original, essential term of a service contract, based upon any stated event occurring subsequent to the execution of the contract, mandatory term No. 8 shall include a clear and specific description of the event, the existence or occurrence of which shall be readily verifiable and objectively measurable. See § 514.7(1). This requirement applies to, *inter alia*, the following types of situations:

(A) Retroactive rate adjustments based upon experienced costs;

(B) Reductions in the quantity of cargo or amount of revenues required under the contract;

(C) Failure to meet a volume requirement during the contract duration, in which case the contract shall set forth a rate, charge, or rate basis which will be applied.

(D) Options for renewal or extension of the contract duration with or without any change in the contract rate or rate schedule;

(E) Discontinuance of the contract;

(F) Assignment of the contract; and

(G) Any other deviation from any original essential term of the contract.

(ix) *Duration of the Contract (No. 9).* The duration of the contract shall be stated as a specific fixed time period, with a beginning date (effective date) and an ending date (expiration date). See paragraph (d)(4)(ii) and (d)(5)(iii) of this section.

(x) *Assessorials (No. 10).* Mandatory Term 10 shall contain all ET assessorials, preferably using a separate subterm for each type of assessorial. For every assessorial, the filer shall set forth either:

(A) The full assessorial; or

(B) A complete cross-reference to the place(s) where it may be found.

(8) *Optional terms.* Any essential term of a service contract not otherwise specifically provided for in this section shall be entered after the mandatory terms and in numerical order, beginning with No. 100.

10. In § 514.18, change the cross reference citation in paragraph (c)(1) from "§ 514.7(d)" to "§ 514.4(d)."

11. In § 514.21, the introductory text is revised to read as follows:

§ 514.21 User charges.

In accordance with 5 U.S.C. 552 and 31 U.S.C. 9701, the user charges in this section are established for services under this part. Unless otherwise provided in this part, checks, drafts or money orders shall be remitted and made payable to "Federal Maritime Commission (OBFM)," 800 North Capitol Street, NW., Washington, DC 20573. Unless otherwise specified, overdue payments will be charged interest in accordance with the rate established by the Department of the Treasury for each 30-day period or portion thereof that the payment is overdue. In addition to any other remedy and penalty provided by law and regulation, if payment is overdue for 90 days, ATFI services will be denied:

* * * * *

By the Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 92–31889 Filed 12–31–92; 8:45 am]

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Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

FEDERAL RESERVE SYSTEM

12 CFR Part 203

[Docket No. R–0789; Regulation C]

Home Mortgage Disclosure; Proposed Regulatory Amendments

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule.

SUMMARY: The Board is publishing for comment a proposal to amend Regulation C, which implements the Home Mortgage Disclosure Act, to incorporate new statutory provisions. The Housing and Community Development Act of 1992 contains amendments that will require financial institutions to make their loan application register data available to the public beginning March 31, 1993; the register must be modified in accordance with Board regulations before release to the public. The act also requires institutions to make their disclosure statement—as compiled by the Federal Financial Institutions Examination Council—available to the public within three business days of receiving it from the Examination Council; they currently have 30 days to do so. The revised rules will apply to the disclosure of the loan and application data collected for calendar year 1992.

DATES: Comments must be received on or before January 31, 1993.

ADDRESSES: Comments should refer to Docket No. R–0789 and be mailed to William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551. They may also be delivered to the guard station in the Eccles Building Courtyard on 20th Street, NW. (between Constitution Avenue and C Street, NW.) between 8:45 a.m. and 5:15 p.m. weekdays. Except as provided in § 261.8 of the Board's rules regarding the availability of information (12 CFR 261.8), comments received will be available for inspection and copying by any member of the public in the Freedom of Information Office, room B–1122 of the Eccles Building, between 9 a.m. and 5 p.m. weekdays.

FOR FURTHER INFORMATION CONTACT: Jane Jensen Gell or W. Kurt Schumacher, Staff Attorneys, or John C. Wood, Senior Attorney, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, DC 20551, at (202) 452–2412 or (202) 452–3667. For the hearing impaired only, contact Dorothea Thompson, Telecommunications Device for the Deaf (TDD), at (202) 452–3544.

SUPPLEMENTARY INFORMATION:

(1) Background

The Home Mortgage Disclosure Act (HMDA) requires certain depository and nondepository mortgage lenders that have offices in metropolitan areas to disclose their housing-related lending activity each year. The Housing and Community Development Act of 1992 (Pub. L. 102–550, 106 Stat. 3672) amends HMDA in several respects. The statutory amendments require institutions to make modified versions of their loan application registers available to the public; the modified registers must be available before April 1 for requests made on or before March 1 following the year for which the data are compiled, and within 30 days for requests made after March 1. The amendments require the Board to specify deletions or modifications from institutions' registers needed to protect the privacy interest of any applicant or borrower, and to protect an institution from liability under federal or state privacy laws.

HMDA and Regulation C currently require financial institutions to make their mortgage loan disclosure statement publicly available no later than 30 calendar days after they receive the statement from their supervisory agency. The statutory revisions amend HMDA to require institutions to make the disclosure statement publicly available, upon request, within three business days after receiving it from the Federal Financial Institutions Examination Council (FFIEC).

The statutory provisions contain additional amendments relating to the time periods within which the federal supervisory agencies must make disclosure statements and aggregate tables available to financial institutions and the public. The statute requires that for data collected in 1993, disclosure statements must be publicly available for September 1, 1994. The aggregate data that are compiled by the FFIEC are to be publicly available (in central data depositories) before December 1, 1994. For data collected in 1994 and subsequent years, federal supervisory agencies must make every effort to ensure that disclosure statements are publicly available before July 1, and aggregate disclosure reports before September 1, following the year for which the data are compiled. In addition, the statutory revisions make various other amendments to HMDA that are discussed below.

The comment period ends on January 31, 1993. Because prompt implementation of the statutory amendments is in the public interest, the Board has set a 30-day comment period in place of the 60 days normally called for in the Board's policy statement on rulemaking (44 FR 3957, January 19, 1979). The Board believes an abbreviated comment period is necessary to ensure that a final rule is in place as quickly as possible to provide guidance to covered lenders.

In accordance with section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. ch. 35; 5 CFR 1320.13), the proposed revisions will be reviewed by the Board under the authority delegated to the Board by the Office of Management and Budget after consideration of the comments received during the public comment period.

(2) Summary of Proposed Regulatory Amendments

The following discussion summarizes the proposed amendments to Regulation C section by section. Heading changes and certain other changes that are self-evident are not discussed.

Section 203.5 Disclosure and Reporting

Section 203.5(a) Reporting to Agency

The Board proposes to revise this section to require institutions to retain copies of their complete loan application register for a minimum period of three years, not two years as presently required. This change is consistent with the provisions in the new law (see proposed § 203.5(d)).

Section 203.5(b) Public Disclosure of Statement

The statutory revisions require institutions to make their disclosure statement publicly available, upon request, no later than three business days after they receive the statement from the FFIEC. The Board proposes to incorporate this requirement into this subsection, in lieu of the current 30 calendar days for public data availability. However, the Board proposes to limit the three-business day requirement for availability to the institution's home office. Because of the need for duplication and distribution, many institutions could find it difficult to make disclosure statements available in a branch office in other MSAs within three business days after receipt. Therefore, the Board proposes that institutions have ten business days in which to make their disclosure statements available in these MSAs. The Board solicits comments on this proposed timing.

Section 203.5(c) Public Disclosure of Loan Application Register

The statutory revisions require institutions to make their loan application registers available to the public upon request, and require the Board to specify deletions or modifications from institutions' registers to protect the privacy interests of applicants and borrowers, and to protect institutions from liability under federal or state privacy laws. The Board proposes to add this new subsection to reflect this requirement. The three items to be deleted (application or loan number, date application received, and date of action taken) are specified in the instructions to the HMDA–LAR found in appendix A; they correspond to the items specified by the statutory amendments.

The proposed language also incorporates the statutorily mandated time periods by which an institution must make its modified register publicly available.

Section 203.5(d) Availability of Data

The proposed revisions to paragraph (d) reflect the amendments to the statute requiring that modified loan application register information be retained by institutions and made publicly available for a period of three years. The Board proposes to use the existing rule concerning the availability of disclosure statements at the branch office level as the rule governing the availability of an institution's modified register data.

The Board also proposes to incorporate language from the statutory amendments regarding the imposition of fees by an institution for providing or reproducing the modified loan application register or the disclosure statement.

Appendix A to Part 203—Form and Instructions for Completion of HMDA Loan/Application Register

III. Submission of HMDA–LAR and Public Release of Data

D. *Availability of disclosure statement.* The proposal would incorporate the new rule discussed above that an institution must make its disclosure statement available at its home office within three business days of receiving it from the FFIEC. The Board proposes to specify that disclosure statements must be made available in at least one branch office in each additional MSA within ten business days after receipt from the FFIEC. As mentioned above, the Board solicits comment on this proposed timing. As an alternative, the Board solicits comment on the feasibility of specifying that copies of disclosure statements must be made available at the applicable branch offices, upon request, within a "reasonable time" of an institution's receipt of the statements from the FFIEC.

E. *Availability of modified loan application register.* Paragraph 1 of this subsection would incorporate the requirement in the new provisions that the Board specify deletions or modifications from an institution's register to protect the privacy interests of applicants and borrowers. (See also the proposed revisions to § 203.5(c).) The deletions that the Board proposes to require are specified by the newly enacted statute. These items are those that the FFIEC presently deletes prior to the public release of the edited raw data that it makes available.

F. *Location and format of disclosed data.* The statutory amendments encourage institutions to make their modified register data available in census tract order, and allow the public release of this information (and of disclosure statements) in any media—including hard copy or in automated form—that is not prohibited by the Board. The statute makes clear, however, that aside from making the specified deletions, institutions are not required to change the format of the data from that used by institutions to internally maintain this information. The Board's proposed paragraph F. in the appendix reflects these statutory provisions.

Additionally, the revisions to HMDA require institutions' disclosure statements to be accompanied by a clear and conspicuous notice that the statement is subject to final review and revision, if necessary. Given that the FFIEC compiles the disclosure statements of financial institutions for public release by the institutions, the Board proposes that the FFIEC add this notice on the disclosure statements, thereby eliminating the need for financial institutions to supply the notice.

As mentioned in the supplementary information to § 203.5(d) above, the Board proposes to use the existing rule concerning the availability of disclosure statements at the branch office level as the rule for availability of an institution's modified register data.

(3) Form of Comment Letters

Comment letters should refer to Docket No. R–0789. The Board requests that, when possible, comments be prepared using a standard typeface with a type size of 10 or 12 characters per inch. This will enable the Board to convert the text into machine-readable form through electronic scanning, and will facilitate automated retrieval of comments for review. Comments may also be submitted on 3½ inch or 5¼ inch computer diskettes in any IBM-compatible DOS-based format, but must be accompanied by an original document in paper form.

(4) Regulatory Flexibility Analysis

HMDA does not cover small depository institutions (those with assets of $10 million or less), or small nondepository mortgage lenders (those with fewer than 100 home purchase loan originations and assets of $10 million or less). HMDA also exempts from coverage institutions that have neither a home nor a branch office in an MSA. Covered institutions currently must provide their loan/application registers to their supervisory agencies by March 1 for the preceding calendar year. Any incremental burden caused by this proposal would result from the requirement that these registers be modified prior to public release in the manner proposed by the Board. Small financial institutions will likely have fewer modifications to make to their registers (based on their fewer numbers of reportable transactions). This proposal is not expected to have a significant impact on the costs of small institutions.

(5) List of Subjects in 12 CFR Part 203

Banks, banking, Federal Reserve System, Mortgages, Reporting and recordkeeping requirements.

(6) Text of Proposed Revisions

For the reasons set forth in this proposed rule and pursuant to the Board's authority under section 305(a) of the Home Mortgage Disclosure Act (12 U.S.C. 2804(a)), the Board proposes to amend Regulation C, Home Mortgage Disclosure (12 CFR part 203), as set forth below.

Certain conventions have been used to highlight the proposed changes to the regulation and the instructions. Language to be added is shown inside bold-faced arrows, while language that would be removed appears within bold-faced brackets. The Board is publishing only those sections of the regulation and instructions that would be affected by the changes.

PART 203—HOME MORTGAGE DISCLOSURE

1. The authority citation for part 203 continues to read as follows:

Authority: 12 U.S.C. 2801–2810.

2. Section 203.5 would be amended by redesignating paragraphs (c) and (d) as (d) and (e), by adding a new paragraph (c), and by revising paragraphs (a) through (e) to read as follows:

§ 203.5 Disclosure and reporting.

(a) *Reporting to agency.* By March 1 following the calendar year for which the loan data are compiled, a financial institution shall send two copies of its complete **♦loan application♦** register to the agency office specified in appendix A of this regulation, and shall retain a copy for its records for a period of not less than **♦three♦** [two] years.

(b) **♦Public♦** disclosure **♦of statement♦** [*to the public*]. A financial institution shall make its mortgage loan disclosure statement (to be prepared by the Federal Financial Institutions Examination Council) available to the public **♦at its home office♦** no later than **♦three business♦** [30 calendar] days after the institution receives it from its supervisory agency **♦or from the Examination Council. The disclosure statement also shall be made available in at least one branch office in each additional MSA where the institution has offices, within ten business days after the institution receives it.♦** [The financial institution shall make the statement available to the public for a period of five years.]

♦(c) Public disclosure of loan application register. A financial institution shall make its loan application register available to the public at its home office after modifying it in accordance with appendix A. An institution shall make its modified register available following the calendar year for which the data are compiled, by March 31 for a request received on or before March 1, and within 30 days for a request received after March 1. The modified register also shall be made available in at least one branch office in each additional MSA where the institution has offices.♦

♦(d)♦ [(c)] *Availability of* **♦data♦** [disclosure statement]. A financial institution shall make **♦its modified register available for a period of three years and its disclosure statement available for a period of five years.♦** [the disclosure statement available at its home office. If it has a physical branch office in other MSAs, the institution shall also make a statement available in at least one branch office in each of those MSAs; the statement] **♦The statement and register♦** at a branch office need only contain data relating to property in the MSA where that branch office is located. An institution shall make the **♦data♦** [disclosure statement] available for inspection and copying during the hours the office is normally open to the public for business. It may impose a reasonable **♦fee for providing or reproducing the data♦** [charge for photocopying services].

♦(e)♦ [(d)] *Notice of availability.* A financial institution shall post a general notice about the availability of its disclosure statement in the lobbies of its home office and any physical branch offices located in an MSA. Upon request, it shall promptly provide the location of the institution's offices where the statement is available. At its option, an institution may include the location in its notice.

3. Appendix A to part 203 would be amended by revising the heading of section III., by revising subsection III.D., and by adding new subsections III.E., F., and G., to read as follows:

Appendix A to Part 203—Form and Instructions for Completion of HMDA Loan/Application Register

* * * * *

III. Submission of HMDA–LAR and **♦Public♦** Release of **♦Data♦** [Disclosure Statements]

* * * * *

♦D. Availability of disclosure statement. The Federal Financial Institutions Examination Council (FFIEC) will prepare a disclosure statement from the data you submit. Your disclosure statement will be returned to the name and address indicated on the transmittal sheet. Within three business days of receiving your disclosure statement, you must make a copy available at your home office for inspection by the public. You also must make your disclosure statement available, within ten business days after receipt of the statement from the FFIEC, in at least one branch office in each additional MSA where you have offices.

E. Availability of modified loan application register.

1. To protect the privacy of applicants and borrowers, an institution must modify its loan application register before release to the public by removing the following information: the application or loan number, date application received, and date of action taken.

2. A financial institution must make its modified register available following the calendar year for which the data are compiled, by March 31 for a request received on or before March 1, and within 30 days for a request received after March 1.

F. Location and format of disclosed data. You must make a complete copy of your disclosure statement and your modified register available to the public at your home office. You may make these data available in hard copy or in automated form (such as by floppy disk or computer tape). Although you are encouraged to make your modified loan application register available to the public in census-tract order, you are not required to do so. In addition, if you have physical branch offices in other MSAs, you must make available in at least one branch office in each of those MSAs either a complete copy of the disclosure statement and of the modified register, or the portion of each that relates to properties in that MSA.

G. Posters. Your agency can provide you with HMDA posters that you can use to inform the public of the availability of your disclosure statement, or you may print your own posters.♦

[D. The Federal Financial Institution Examination Council (FFIEC) will prepare a disclosure statement from the data you submit. Your disclosure statement will be returned to the name and address indicated on the transmittal sheet. When you receive that disclosure statement you must make a copy available for inspection by the public within 30 calendar days of the date the statement is received by your institution. You must make a complete copy available at your home office. If you have physical branch offices in other MSAs, you must make available, in at least one branch office in each of those MSAs, either the complete statement or the portion of the statement relating to that MSA.

Your agency can provide you with HMDA posters that you can use to inform the public of the availability of your disclosure statement, or you may print your own posters.]

* * * * *

By order of the Board of Governors of the Federal Reserve System, December 28, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92–31871 Filed 12–31–92; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 92-ANM-21]

Proposed Alteration of Jet Route J-151; WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to alter the description of Jet Route J-151 by extending the route segment between Whitehall, MT, VHF Omnidirectional Range/Tactical Air Navigation (VORTAC) direct to Spokane, WA, VORTAC. Currently, there is no jet route from Whitehall, MT, direct to Spokane, WA. This jet route extension would enhance traffic flow and reduce controller workload.

DATES: Comments must be received on or before February 18, 1993.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, ANM-500, Docket No. 92-ANM-21, Federal Aviation Administration, 1601 Line Avenue, Southwest, Renton, WA 98055-4056.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Norman W. Thomas, Airspace and Obstruction Evaluation Branch (ATP-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9230.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 92-ANM-21." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-220, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3485. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to alter Jet Route J-151 by extending this route from Whitehall, MT, to Spokane, WA. Currently, there is no direct jet route segment between these points. This extension would enhance traffic flow and reduce controller workload. Jet routes are published in Section 71.607 of FAA Order 7400.7A dated November 2, 1992, and effective November 27, 1992, which is incorporated by reference in 14 CFR 71.1. The jet route listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Incorporation by reference, Jet routes.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.7A, Compilation of Regulations, dated November 2, 1992, and effective November 27, 1992, is amended as follows:

Section 71.607 Jet routes.

* * * * *

J-151 [Revised]

From Cross City, FL; Vulcan, AL; INT Vulcan 335° and Farmington, MO, 139° radials; Farmington; St. Louis, MO; Des Moines, IA; O'Neill, NE; Rapid City, SD; Billings, MT; INT Billings 266° and Whitehall, MT, 103° radials; to Spokane, WA.

* * * * *

Issued in Washington, DC, on December 21, 1992.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 92-31908 Filed 12-31-92; 8:45 am]

BILLING CODE 4910-13-M

Office of the Secretary

14 CFR Part 241

[Docket No. 46597; Notice No. 92-34]

RIN 2137-AC08

Confidential Treatment of Aircraft Inventory Data

AGENCY: Office of the Secretary of Transportation, and Research and Special Programs Administration, DOT.

ACTION: Withdrawal of proposed rule and denial of petition for rulemaking.

SUMMARY: This document denies a petition for rulemaking, filed in Docket 46597, to amend part 241 of the Department's Economic Regulations to include a period of confidential treatment for aircraft inventory data reported on RSPA Form 41 Schedules B–7 and B–43, withdraws the rulemaking proceeding initiated based on the petition, and denies the motions filed in Docket 46597 for confidential treatment of aircraft inventory data reported on Schedules B–7 and B–43. This document is being issued because the Department has determined that withholding information reported on Schedules B–7 and B–43 is unwarranted under the Freedom of Information Act and the Department's regulations governing information that is exempt from public disclosure.

DATES: This document is effective on January 4, 1993.

FOR FURTHER INFORMATION CONTACT: M. Clay Moritz, Jr. or Jack M. Calloway, Office of Airline Statistics, DAI–10, Research and Special Programs Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001, (202) 366–4385 and 366–4383, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 10, 1991, the Department issued an Advanced Notice of Proposed Rulemaking (ANPRM) seeking public comments on the need for establishing a period of confidential treatment for Form 41 Schedules B–7, Airframe and Aircraft Engine Acquisitions and Retirements and B–43, Inventory of Airframes and Aircraft Engines (56 FR 32992; July 18, 1991). This rulemaking notice responds to the confidentiality issues raised in the ANPRM and the public comments entered into Docket 46597.

The issue of confidential treatment was first raised by the November 8, 1989 motion of United Air Lines (United), which requested the Department to withhold from public disclosure the acquisition costs and sales realization amounts for airframes and aircraft engines reported on its Schedule B–7, Airframe and Aircraft Engine Acquisitions and Retirements, for the quarter ended September 30, 1989 (Docket 46597). Subsequent motions were filed with every Schedule B–7 submitted since then (Dockets 46868, 46933, 47119 and 47254). On March 28, 1990, United also filed a motion for confidential treatment pertaining to the airframe and aircraft engine acquisition cost data reported on annual Schedule B–43, Inventory of Airframes and Aircraft Engines, its report covering calendar year 1989 (Docket 46869). In addition, American Airlines filed a motion dated August 9, 1990, for confidential treatment of its Schedule B–7 for the quarter ended June 30, 1990. All requests for confidential treatment were filed under 14 CFR 302.39, "Objections to Public Disclosure of Information."

The Director of the Research and Special Programs Administration's (RSPA's) Office of Airline Statistics, in a letter dated January 9, 1991, denied each of United's motions for confidential treatment. On February 1, 1991, United filed a response to the letter in the form of a petition for review of the staff action denying its motions. In its petition, United stated that it was not seeking exclusive confidentiality for its data, but rather, believes that aircraft acquisition costs and sales realization amounts should be held confidential for all carriers.

In urging the Department to review its staff action, United expressed its desire to have incorporated in the regulations governing the submission of Schedules B–7 and B–43 (14 CFR 241.23, Schedule B–7 and Schedule B–43) a provision for the confidential treatment of the reported data. United also indicated that it planned to submit a petition for rulemaking proposing to amend part 241 by providing for the confidential treatment of the equipment price data reported on both schedules.

Pending the filing of its rulemaking petition, United requested that the Department grant its motions to withhold from public disclosure along with those of any other carrier requesting such relief. By letter dated March 22, 1991, the Director, Office of Airline Statistics, granted United's request for a rulemaking to explore whether 14 CFR 241.23 of the Department's Economic Regulations should be amended to accord confidential treatment for the information reported on Form 41 Schedules B–7 and B–43. A copy of the March 22 letter is provided as Exhibit A.

In the letter, the Director, Office of Airline Statistics, overturned his earlier decision by granting United's motions, pending the outcome of this rulemaking proceeding. The Director also indicated that in order not to prejudge the outcome of the rulemaking process and to preclude United from enjoying an advantage over other carriers by having its data withheld from the public eye, the Department would look favorably upon individual air carrier motions for confidential treatment of Form 41 Schedule B–7 and/or Form 41 Schedule B–43. This offer applied to the information reported on Schedule B–7 for the fourth quarter of 1990 and Schedule B–43 for the calendar year 1990. At the same time, carriers were also apprised of their right to file, should they so desire, subsequent motions for confidential treatment for each successive filing of B–7 and B–43.

In order to simplify the administrative burden of responding to similar motions for confidential treatment filed in multiple dockets, the March 22 letter announced the Department's action to consolidate in Docket 46597 all previously filed motions for confidential treatment of Schedules B–7 and B–43. The Department's ANPRM (Notice 91–11) on the issue of confidentiality and this NPRM are also included in Docket 46597.

Advance Notice of Proposed Rulemaking

In order to provide the facts necessary to determine whether a grant of confidentiality to airframe and aircraft engine data is warranted, the Department, in the ANPRM, solicited answers to the following questions:

1. Is there a need to keep the information reported on Form 41 Schedule B–7 and/or Form 41 Schedule B–43 confidential? Please explain, in detail, why the information should or should not be held confidential. Identify, by specific data element, the information on Schedules B–7 and B–43 that you believe should or should not be held confidential. Explain how the information does or does not qualify for confidential treatment given the governing body of law and regulation, namely, the Freedom of Information Act (FOIA), 5 U.S.C. 552, and the Department's regulations, 49 CFR part 7.

2. For what length of time should the information be held confidential? Please explain the specific reasons, by data element if necessary, for selecting a particular period of time.

Public Comments

Twenty comments were received in response to the ANPRM. Six comments

were filed in support of a period of confidentiality for Form 41 Schedules B–7 and B–43 by American Airlines, Inc. (American); Delta Air Lines, Inc. (Delta); Northwest Airlines, Inc. (Northwest); United Air Lines, Inc. (United); United Parcel Service, Co. (UPS); and The Boeing Company (Boeing). Thirteen comments were filed in opposition to a grant of confidentiality by Federal Express Corporation (FedEx); McDonnell Douglas Corporation (MDC); Air Line Pilots Association International (ALPA); Air Cargo Management Group; Airt Services; BK Associates, Inc.; Avitas, Inc.; The CIT Group/Capital Equipment Financing; DCB Consultants; Jack B. Fair & Associates; Mack Aviation Company, Inc.; Simat, Helliesen & Eichner, Inc.; and York University. One Comment was filed, by Continental Air Lines, Inc. (Continental) suggesting an alternative course of action. In addition to these twenty comments, United States Leasing International, Inc. filed a late comment in opposition to granting confidentiality. A discussion of these comments follows:

Data Elements at Issue

In their comments, American, Delta, Northwest, United, and UPS identify the following data elements that they believe should be accorded confidential treatment.

Form 41 Schedule B–7	Form 41 Schedule B–43
1. Cost.	1. Acquired cost or capitalized value.
2. Amortized/ Depreciated cost.	2 Allowance for depreciation or amortization.
3. Realization.	3 Depreciated cost or amortized value.
	4. Estimated residual value.

UPS, in addition to these data elements, states that confidentiality should also be granted to the "Estimated Depreciable or Amortizable Life (Months)" on Schedule B–43. In its comments, Boeing, while not identifying specific data elements on Schedule B–7 and/or Schedule B–43 that it believes should be granted confidential treatment, does refer to "airframe acquisition costs" and "the negotiated price of aircraft."

FOIA and DOT Regulations

Having identified the data elements at issue, we will now turn to a discussion of the need for granting confidentiality. In order to reach a conclusion on whether or not to withhold the above information from public disclosure, we must examine the arguments made for and against confidentiality within the context of the Freedom of Information Act (FOIA) 5 U.S.C. 552. This section protects from public disclosure "trade secrets and commercial or financial information obtained from a person (which is) privileged or confidential" (5 U.S.C. 552 (b)(4)). This section is cited in each of the comments filed in support of confidentiality with the exception of Boeing, which does not address how the information at issue would fall within FOIA guidelines for exempting data from public disclosure. Boeing states: "This letter is furnished in strong support of the subject ANPRM to provide confidential treatment of the identified information. Confidential treatment is requested pursuant to Rule 39 of DOT's Rules of Practice." The "identified information" in its comments refers to the airframe acquisition cost reported on Schedule B–7 and Schedule B–43.

Since the data elements in question are not a trade secret, we have evaluated the information to see if it meets the requirements of the second category of commercial or financial information obtained from a person, which is privileged or confidential. Rule 39 of the Department's Procedural Regulations (14 CFR 302.39), which concerns the filing of objections to public disclosure of information, specifically states the 49 CFR part 7 governs the availability of the Department's records and documents to the public. Part 7 contains the Department's regulatory implementation of FOIA.

Rule 39 contains the procedures for objecting to the public disclosure of information. Section 302.39(e) states that information covered in reports filed with the Department need not be withheld from public disclosure unless a written motion objecting to such disclosure is filed with the Department. The motion must contain, among other things, a description of the information to be withheld and a statement explaining how and why the information falls within the FOIA exemptions (5 U.S.C. 552(b)(1)–(9)).

In addressing the issue of confidentiality in view of the provisions of FOIA and the Department's regulations, American, Delta, Northwest, United and UPS raise the following points:

- Public disclosure would impair the Department's ability to obtain the information at issue.
- Public disclosure would cause substantial competitive harm.
- Public disclosure is inconsistent with the grant of confidentiality to similar information by the Securities and Exchange Commission.
- Public disclosure would require the air carriers to violate a contract provision of equipment purchase agreements that bars release of the information.
- The information at issue is not customarily disclosed to the public.

In addition to these five points, United cites Civil Aeronautics Board Order 79–10–91, concerning the confidentiality of fuel price data, in its support for a grant of confidentiality. Each of these issues is addressed below under separate captions.

Impair the Ability to Collect the Data

American and UPS state in their comments that information should be treated as confidential if disclosure would impair the government's ability to obtain the information in the future or cause substantial harm to the competitive position of the person from whom the information is obtained. In support, both carriers cite *National Parks & Conservation Assn* v. *Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974). American also cites *Guerra* v. *Guajardo*, 466 F.Supp. 1046, 1059 (S.D. Tex. 1978) *aff'd without opinion*, 597 F.2d 769 (5th Cir. 1979); and *United Technologies Corp.* v. *Department of Health and Human Services*, 574 F.Supp. 86, 89 (D.Del. 1983).

All of the data elements at issue are submitted in accordance with the reporting requirements of 14 CFR part 241. Part 241 is applicable to all large certificated air carriers. A large certificated air carrier is defined as an air carrier operating under a certificate of public convenience and necessity issued under section 401 of the Federal Aviation Act of 1958, as amended, using aircraft with over 60 seats or over 18,000 pounds of payload capacity, or operating internationally (14 CFR 241.03). It is a mandatory condition for air carriers operating under a section 401 certificate to abide by the Department's regulations. Since all large certificated air carriers are required by regulation (14 CFR 241.23—Schedule B–7 and Schedule B–43) to provide the Department with the information contained in both Schedules B–7 and B–43, the Department believes that the ability of the government to obtain the information in the future will not be adversely affected by the issue of confidentiality. Since this test of confidentiality has not been met, we next examine the data elements under the test of substantial competitive harm.

Competitive Harm

Each air carrier filing in support of confidentiality cites competitive harm when addressing the need for the confidential treatment of the data at issue. Before discussing the carrier

comments on competitive harm, it should be noted that Boeing's comments support the need for confidentiality by stating that, in its opinion, disclosure of the information at issue would be competitively harmful to carriers filing Schedules B–7 and B–43. While remaining cognizant of Boeing's comment on behalf of the reporting carriers, the Department will weigh its decision as to potential for competitive harm based on the comments of the air carriers that are directly affected.

As to the affected carriers, American states: "It is not necessary to show actual competitive harm; actual competition and the likelihood of substantial injury is all that is necessary." *Professional Review Organization of Florida, Inc.* v. *U.S. Department of Health and Human Services*, 607, F.Supp. 423 (D.C. 1985) at 425–426.

Similarly, Delta states that information is considered confidential if disclosure of the information is likely to cause substantial harm to the competitive position of the person from whom the information was obtained. *National Parks & Conservation Assn* v. *Morton, supra.* Under this test, Delta quotes *National Parks and Conservation Assn* v. *Kleppe*, 547 F.2d. 673, 683 (D.C. Cir. 1976): "* * * No actual adverse effect on competition need be shown * * * The court need only exercise its judgment in view of the nature of the materials sought and the competitive circumstances [in which the person from whom the information was received does business], relying at least in part on relevant and credible opinion testimony."

Northwest also cites *National Parks & Conservation Assn* v. *Morton, supra*, as support that information is confidential if it could cause substantial harm to the competitive position of the person from whom the information was obtained. Northwest goes on to state that information from which competitors could deduce operating costs, profit margins, and competitive vulnerability is generally confidential and cites a number of cases in support: *Westinghouse Electric Corp.* v. *Schlesinger*, 392 F.Supp. 1246 (E.D. Va 1974), aff'd, 542 F.2d 1190 (4th Cir. 1976), *cert. denied*, 431 U.S. 924 (1977) (data describing a company's workforce held exempt from FOIA); *National Parks and Conservation Assn* v. *Kleppe, supra*, (agency records concerning concession operations at National Parks held exempt from FOIA); *Sterling Drug* v. *FTC*, 450 F.2d 698 (D.C. Cir. 1971) (disclosure of certain documents pertaining to corporate acquisition properly withheld by agency); *McCoy* v. *Weinberger*, 386 F.Supp. 504 (W.D. Ky. 1974) (cost report from nursing home held exempt from FOIA disclosure).

In arguing that public disclosure of the data elements at issue would cause substantial competitive harm, UPS states that the District of Columbia Circuit Court of Appeals acknowledged the implication of disclosure of similar information in *Worthington Compressors, Inc.* v. *Costle*, 213 U.S. App. D.C. 200, 662, F.2d 45, 51 (1981). In this case, the court rejected an argument that design and engineering specifications for air compressors were not entitled to confidential treatment because competitors could take the compressors apart and determine how they were made. UPS cites the court as stating:

> Because competition in business turns on the relative costs and opportunities faced by members of the same industry, there is a potential windfall for competitors to whom information is released under FOIA. If those competitors are charged only minimal FOIA retrieval costs for the information, rather than the considerable costs of private reproduction, they may be getting quite a bargain. Such bargains could easily have competitive consequences not contemplated as part of FOIA's principal aim of promoting openness in government.

As to competitive harm, UPS states that, unlike the *Worthington* case, the Department's Form 41 schedules are the sole means for competitors to obtain the information and the test under the case (Worthington at 51) becomes one of considering "how valuable the information will be to the requesting competitors and how much this gain will damage the submitter." UPS goes on to state: "There is little doubt as to how valuable purchase and sale prices of aircraft would be to a competitor who does not have the resources or abilities to negotiate the same type of arrangement. One should be entitled to the fruits of their labor."

We agree that actual harm need not be shown, only the likelihood of substantial competitive harm, in order to prevail on a grant of confidentiality. We now turn to the issue of substantial competitive harm, as addressed in the comments.

American states its belief that public disclosure would undermine its "* * * efforts to negotiate more favorable aircraft and engine purchase prices, as vendors would be far less willing to grant concessions knowing that other carriers would learn of and demand the same terms." Beyond this, American states that public disclosure would chill the willingness of vendors to engage in price negotiations.

Similarly, Delta states: "Aircraft and engine purchases form a continual stream of complex transactions that require a great deal of negotiating skill and experience to obtain the most favorable terms possible under the particular circumstances. Any advantages achieved by Delta through hard, arms-length bargaining with manufacturers would likely evaporate, if Delta's competitors are able to rely on information available in Delta's Schedules B–7 and B–43 to gain leverage in their own aircraft acquisition negotiations."

Northwest states that the need to keep the information at issue confidential relates directly to its ability to acquire aircraft at the lowest possible cost, and maximize resale value.

In a similar vein, United states that it applies considerable management resources in trying to obtain airframes and engines at the lowest possible acquisition cost and dispose of these assets at the highest possible sales price. As with Delta, United states that public release of the aircraft acquisition costs and sales realization amounts denies it the full benefit of its negotiating efforts.

UPS states "* * * the disclosure of aircraft price information will cause substantial harm to the competitive position of the submitter by revealing the fruits of the negotiation process leading to the agreement. There is a multitude of unique factors to be considered in arriving at the negotiated purchase price of an aircraft. Disclosure of this price information would be analogous to creating government-required tariffs on airline prices."

Delta, Northwest and United each comment that disclosure of the airframe and aircraft cost and sales price information leads to an unfair competitive advantage *vis a vis* foreign flag carriers, which are not required to report their equipment prices to the Department. United goes on to state that it is commercially damaging for U.S. carriers to have the fruits of their competitive efforts with manufacturers divulged to foreign flag competitors that will use the information to obtain the best possible purchase price.

By contrast, Northwest states that U.S. carriers have an advantage in that U.S. carriers can sometimes obtain more favorable volume discounts than relatively smaller foreign flag carriers. Northwest further states that disclosure tends to increase pressure on manufacturers to lessen the discount to a U.S. flag carrier to avoid the need to grant similar discounts to all purchasers.

ALPA and Airt Services both question the carriers' contention as to substantial

competitive harm. ALPA, in response to the Department's question as to how airframe and aircraft engine cost information would qualify for an exemption from FOIA, stated that, until United's motion for confidentiality was filed in 1989, the information contained in B–7 and B–43 has been routinely available and carriers, such as United, have nevertheless been fully capable of transacting business. ALPA goes on further to state that United and other carriers can claim only that it might be easier to transact business if this information was not available to its competitors, but such a claim does not meet the standard of substantial harm to its competitive position.

United states in its comments, that, if disclosed, its equipment costs can be used by its competitors to negotiate reductions in prices on ongoing flight equipment purchase contracts. United further states that once a carrier's costs are divulged, competitors can use the information to negotiate contract price adjustments from the same suppliers the carrier is using or from competing suppliers.

In its comments, Airt disputes the contention that disclosure of the financial data on B–7 and B–43 enables competitors to use the data as a starting point in their own negotiations to obtain equal or more favorable prices, allowing the carrier to enjoy lower capital costs and compete more efficiently. Airt states that aircraft acquisition contracts contain a large number of individual items and terms of purchase that affect the final price. Some examples of contract provisions, identified by Airt, that can affect the price of aircraft are the size of the order, delivery dates, inflation clauses, selected manufacturer or carrier supplied equipment, configuration, warranty, and financing. Airt states that in order to be useful in a competitive situation, a competitor would also need to know the full terms and conditions of the contract.

As to the "acquired cost or capitalized value" reported on Schedule B–43 for airframes and engines, AIRT points out that this amount may change from year to year as modifications are made to the aircraft. For used equipment, AIRT states that an important determinant of the cost of used aircraft reported on Schedule B–7 is the time between overhauls. The time between overhauls is not reported on Schedule B–7; therefore, its impact on the acquisition cost/sales price of used aircraft cannot be determined.

After considering the comments, the Department believes that the comments in support of confidentiality do not demonstrate that disclosure of the cost information reported on Form 41 Schedules B–7 and B–43 would likely result in substantial competitive harm to the carriers submitting the schedules. In assessing the potential for competitive harm, the Department has considered the impact that the availability of the information over the last several decades has had on competition. The Department is unaware of any instance where the public release of acquisition cost and/or sales realization data has substantially harmed the competitive position of an individual air carrier. Considering that airframe and aircraft engine acquisition costs and sales realization amounts have been publicly available for several decades, the Department believes that it would be reasonable to expect that historical evidence of substantial competitive harm would exist, given the history of public availability. None of the comments submitted in support of confidentiality has presented any evidence that substantial competitive harm has occurred.

In reaching this conclusion, the Department has also considered the changes that have occurred within the operating environment of the air transportation industry, namely the advent of deregulation and accompanying changes in carrier route structures and competition. This new evolution of the industry began with the passage of the Airline Deregulation Act of 1978, which phased in deregulation of the domestic sector. Domestic routes were deregulated beginning January 1, 1982 and the fares charged for domestic air transportation were deregulated as of January 1, 1983. Thus, deregulation has been evolving for almost fourteen years and the Department is unaware of any occurrence of substantial competitive harm that has resulted from the availability of Schedules B–7 and B–43.

As to Delta's, Northwest's and United's comment that disclosure of the airframe and aircraft cost and sales price information creates an unfair competitive advantage *vis a vis* foreign flag carriers, the Department is unaware of any evidence that U.S. carriers, in the international area, either have been or would be substantially harmed by the disclosure of Schedules B–7 and B–43.

The Department also notes that there is no consensus among the affected parties as to whether the information should be held confidential. Of the eleven largest air carriers (Group III air carriers, defined as having over $1 billion in total annual operating revenues), only five submitted comments in response to the ANPRM. Four filed in support of confidentiality, while one, Federal Express, filed comments in support of continuing the public availability of Form 41 Schedules B–7 and B–43.

In its comments, Federal Express, contends that the cost information reported on Schedules B–7 and B–43 provides the financial community, appraisers, aviation consultants, and buyers and sellers with reference points for evaluating fair market values on aircraft airframes and engines. Federal Express goes on to state that: "The elimination of such credible data on which to project fair market value could very well reduce the willingness of investors to invest in aircraft. This could have a detrimental impact on the ability of the airline industry to raise financing for the large number of aircraft needed to accommodate future traffic growth." In concluding, Federal Express states that "* * * airline disclosure of Form 41 Schedules B–7 and B–43 ensures a reasonable balance of investment information, and thus opportunity, for all air carriers, thereby enhancing competition. Federal Express' experience is that aircraft and engine manufacturers base their pricing on order size, support requirements, and credit worthiness. Those carriers who are in the best position to meet these factors are able to negotiate the best prices."

Of the sixteen air carriers classified as Group II (carriers with total annual operating revenues of between $100 million and $1 billion), only one carrier, UPS, filed a comment. UPS filed in opposition to the public disclosure of airframe and aircraft engine acquisition costs and sales realization amounts. None of the thirty-one Group I air carriers (defined as having total annual operating revenues between $0 and $100 million) filed comments regarding this rulemaking notice. As to each group's reporting obligation, Group III and Group II air carriers file both the quarterly report of airframe and aircraft engine acquisitions and retirements (Schedule B–7), and the annual inventory of airframes and engines (Schedule B–43). Group I air carriers file only the annual inventory of airframes and engines.

Before moving on to the issue of the Securities and Exchange Commission's grant of confidentiality, we want to address Boeing's comments regarding the competitive harm to aircraft manufacturers. In discussing competitive harm, Boeing cites four factors in support of its position that airframe acquisition costs should be kept confidential: (1) Boeing does not routinely make the information available and takes steps to maintain its confidentiality, (2) Boeing has recently

reminded its customers of the sensitive nature of this information, (3) Boeing has requested its customers to take appropriate actions to protect its confidentiality, and (4) the information is of the type and content which has in the past been treated as confidential by the Securities and Exchange Commission.

In claiming a competitive disadvantage, it must be kept in mind that, in order to remain confidential, the information at issue must, among other things, result in the likelihood of Boeing suffering substantial competitive harm.

Boeing is the only aircraft manufacturer to support confidential treatment. Neither of Boeing's main competitors, McDonnell Douglas (MDC) and Airbus Industrie, support confidentiality. MDC, on its own behalf, filed comments supporting the continued public availability of the cost information reported on Schedules B–7 and B–43. MDC's comments are discussed under the caption "Comments in Support of Public Access." While Airbus did not file a comment in support of confidential treatment in response to the ANPRM, it should be noted that the acquisition cost of Airbus aircraft is reported on Schedules B–7 and B–43 by those U.S. air carriers operating such aircraft. As of the quarter ended March 31, 1992, five (American, America West, Continental, Delta and Northwest) of the eleven major U.S. air carriers are operating over one hundred aircraft manufactured by Airbus and Airbus has not objected to the availability of this information.

The Department has concluded that Boeing would not be likely to suffer substantial competitive harm if the aircraft cost data reported on Schedules B–7 and B–43 were publicly available. As stated previously in discussing the comments of the air carriers that filed in support of confidential treatment, the information Boeing seeks to hold confidential has been publicly available for decades and, despite Boeing's comment that it does not routinely make such data available and takes steps to protect its confidentiality, this, to the Department's knowledge, is the first time Boeing has objected to the availability of any data reported on either Schedule B–7 or Schedule B–43; moreover, as stated previously, this is also the first time that the Department is aware of Boeing making an effort to "remind its customers of the sensitive nature of this information and request its customers to take appropriate action to protect its confidentiality."

As in the case of the carriers filing Schedules B–7 and B–43, the Department believes that, given the decades the data have been available, especially over the last decade during which the air transportation industry operated in a deregulated competitive environment, the existence of competitive harm affecting aircraft manufacturers would have surfaced. In reaching its conclusion, the Department notes that no evidence of competitive harm has been presented by any party arguing for confidential treatment. Based on the comments submitted into the docket, the Department concludes that it is unlikely that either the affected air carriers or Boeing would suffer substantial competitive harm through the public availability of Schedules B–7 and B–43.

Boeing's comment that the aircraft acquisition cost data reported on Schedules B–7 and B–43 are of the type and content which have in the past been granted confidential treatment by the Securities and Exchange Commission is discussed below.

SEC Confidentiality

American, Delta, United and Boeing, in support of a grant of confidentiality, state that the Securities and Exchange Commission (SEC) has granted confidential treatment to data that are of the type and content similar to the data at issue here. American and Delta both state that the SEC grants confidential treatment to air carriers' "aircraft acquisition costs and other sensitive financial information." Delta and Boeing go on to state that the SEC's grant of confidentiality occurs on a regular or routine basis. In support, Delta and United have cited, as examples of the SEC's grant of confidentiality, certain exhibits to their SEC Form 10K filings. Delta cites Exhibit 10.8 to its Form 10K for fiscal year ended June 30, 1990. United cites Exhibits (10)K and (10)L to UAL Corporation's Form 10K filing for the year ended December 31, 1989. United is a wholly-owned subsidiary of UAL Corporation. The request for confidential treatment filed with the SEC was submitted jointly by UAL and United.

In order to better understand this apparent anomaly in the application of FOIA regarding aircraft acquisition costs and sales realization amounts, we examined UAL's Exhibits (10)K and (10)L to its 1989 Form 10K report. The review has disclosed that both exhibits contain, in great detail, the specific contract terms and conditions regarding the purchase of Boeing 757–222 and 737–222 aircraft (Exhibit (10)K), and 767–322ER aircraft (Exhibit (10)L).

Similarly, we also examined Delta's Exhibit 10.8 to its SEC Form 10K for fiscal year ended June 30, 1990. Exhibit 10.8 is Purchase Agreement No. 1646, which was executed with the Boeing Company for the acquisition of Boeing Model 737–332 aircraft. As with United's purchase agreement, Delta's agreement also contains, in specific detail, the contract terms and conditions regarding the aircraft purchase.

In general, our review revealed that purchase agreements include the number of aircraft that are part of the basic order as well as the number of option aircraft. The schedule of aircraft deliveries, by month and year, is also included. As to acquisition cost, only base year prices are included along with a myriad of provisions that must be factored in to arrive at a "final price." Among these provisions are agreements as to buyer furnished equipment, excusable delays, customs duties, warranties, adjustment factors for economic fluctuations, post delivery support, accelerated delivery of options, cancellation of options, training of cockpit crews, and various credit memoranda. Any one of these provisions could have an impact on the price of each delivered aircraft. The final price can also be affected by changes required by law or government regulation that may be required to secure a standard airworthiness certificate. Beyond the basic contract, many side letter agreements are executed between the contracting parties, affecting the terms and possibly the cost of the contract. Another significant determinant of price is the quantity of aircraft covered by a specific purchase agreement, the volume of business transacted between buyer and seller and whether the aircraft order is a launch order for a new aircraft type.

Without the knowledge of the particular circumstances surrounding an agreement and the many detailed provisions of the contract, an individual could not deduce exactly how the price of a specific aircraft was computed and how the various factors were weighted in arriving at the final price. Further masking the connection of the acquisition cost reported on Schedule B–7 are any modifications that a carrier may make to an aircraft between the time it is delivered and placed in service. Any such modifications would be included in the reported cost.

As to the inventory of aircraft reported on Schedule B–43, the connection between buyer and seller is even more tenuous. Any modification or betterment that is made to the aircraft is included in the reported acquisition cost/capitalized value. For example any changes in avionics, noise abatement technology, cabin configuration, or

governmental regulation such as passenger exit requirements, are all included in the revised cost/capitalized value of the affected aircraft. As time passes, keeping in mind that Schedule B–43 is submitted annually, the probability increases that the "cost" initially reported on Schedule B–7 will not be the same as the cost reported on the latest filing of Schedule B–43.

As to used aircraft, an important factor in determining price is the amount of time between overhauls, which is not reported on either Schedule B–7 or Schedule B–43. Another factor in determining the reported cost of used aircraft is whether the aircraft is "equipped" as needed or requires modification before being placed in transport service.

In reviewing the comments, no evidence has been presented that would lead the Department to conclude that carriers are not able to engage in arm's-length negotiations to acquire and sell aircraft or would likely suffer substantial competitive harm due to the availability of Schedules B–7 and B–43. There also is no indication that any carrier has suffered substantial competitive harm in disposing of or purchasing used aircraft.

Absent the knowledge of the full terms and conditions contained in the purchase/sale agreement, the Department fails to see how the information reported on Schedules B–7 and B–43 can subject air carriers to the likelihood of suffering substantial competitive harm.

Contract Provisions

As a manufacturer/seller of aircraft, Boeing states that selling commercial aircraft is highly competitive and that premature disclosure of the financial data applicable to Boeing aircraft to purchasers of aircraft or to competing manufacturers would seriously impair Boeing's future sales of aircraft, and would put Boeing at a continuing disadvantage with respect to its domestic and foreign competitors. Boeing goes on to state that it does not routinely make such information public and takes steps to maintain its confidentiality. Boeing also states it has recently reminded its customers of the sensitive nature of the information and has requested its customers to take appropriate actions to protect its confidentiality. Boeing equates the airframe acquisition costs reported on Schedules B–7 and B–43 to the information that has in the past been treated as confidential by the SEC.

American, Delta, and UPS each commented that airframe and aircraft engine acquisition contracts contain confidentiality provisions that are overridden by the Department's public release of Schedules B–7 and B–43. As stated by UPS, "Normal business practice treats sales and purchasing negotiations as a confidential matter unless the parties involved choose to make the details of their negotiations public. As a result, confidentiality clauses are standard in these types of agreements and the parties are thus prohibited from disclosing price information, except where required by law." Boeing states that the contractual provisions provide for full compliance with all government filing requirements and that it has always relied on the agency to which the data are provided for reasonable protection from broad public disclosure.

It should be noted that, both before and after deregulation, the former Civil Aeronautics Board collected on recurrent Form 41 schedules, aircraft acquisition cost and sales realization data that were available for inspection in a public reports reference facility. Subsequent to the sunset of the CAB, the Department has continued this policy of public availability. As to the information filed on Schedules B–7 and B–43, this, to the best of the Department's knowledge, is the first time that Boeing has filed an objection to the disclosure of any data collected on these two schedules.

In sum, neither the former CAB nor the Department has changed the policy regarding the public availability of the airframe and aircraft engine cost data at issue and Boeing has never objected, until now, to the policy of public release. That inaction leads us to believe that Boeing was previously satisfied with the public information policies of the agency collecting the aircraft acquisition, retirement and inventory data. Because of these facts, the Department fails to see the relevance of Boeing's comment that it does not routinely make such information public and takes steps to maintain its confidentiality.

The Department assumes that the steps Boeing refers to relate to the filing of data with the SEC. The Department recognizes that there is a historical trail where the SEC has granted the confidential treatment requests of Boeing and its customers that address the disclosure of information contained in aircraft purchase agreements. However, Boeing's statement that the information at issue is of the type and content as that which is filed with the SEC has already been discussed and rejected under the preceding caption, "SEC Confidentiality."

As with the affected air carriers, the Department notes that there is no consensus among aircraft manufacturers as to the need for confidentiality. Boeing and McDonnell Douglas are the only two aircraft manufacturers that filed comments. McDonnell Douglas, on its behalf, filed comments supporting the continued public availability of the cost information reported on Schedules B–7 and B–43. Its comments are discussed under the caption "Comments in Support of Public Access."

Based on the preceding discussion, the Department concludes that it is unlikely that Boeing would suffer substantial competitive harm in its future sales of aircraft due to the public availability of Schedules B–7 and B–43.

Customary Disclosure

American states that it would not publicly disclose the cost and depreciation figures contained in Schedules B–7 and B–43 absent government compulsion to do so. Similarly, UPS states that normal business practice treats sales and purchasing negotiations as a confidential matter unless the parties involved choose to make the details of their negotiations public. Delta's position is that disclosure of aircraft acquisition costs and sales realization amounts reported on Schedules B–7 and B–43 is not required by the public interest.

Whether or not a carrier would have released the aircraft cost data on their own is not the issue here. The guiding principal of FOIA is that the Government's information belongs to the people, unless there is a justifiable reason to withhold. The justifiable reason would be FOIA exemption 4; however, the comments filed in support of confidentiality have failed to make a case that substantial competitive harm would likely result from disclosure.

Once again, the Department notes that the information at issue has been publicly available for several decades and is unaware of any objection to public disclosure until United's initial filing in 1989. Furthermore, no evidence has been presented that substantial competitive harm has occurred.

Confidentiality of Fuel Price Data

In its comments, United states that the aircraft inventory data at issue here are comparable in sensitivity to the price paid by air carriers for fuel. In support, United cites Civil Aeronautics Board Order 79–10–91, granting confidential treatment to submitted fuel price data. United quotes the order at 2: "Release of current detailed [fuel price] data and invoices could enable competing

purchasers of scarce fuel as well as fuel suppliers to anticipate [the reporting carrier's] attempts to secure fuel at the lowest possible price." United goes on to state that releasing equipment prices gives an unfair competitive advantage to competing purchasers and suppliers.

The Department believes the question of competitive harm has been adequately addressed under the caption "Competitive Harm." The Department also believes, however, that United's citation of Order 79–10–91 warrants comment.

The circumstances surrounding the grant of confidentiality in Order 79–10–91 are not the same. Order 79–10–91 dealt with the collection of, on a weekly basis, the average price of aviation fuel purchased plus fuel invoices for one day of each week. The situation in effect, at that time, was highly unusual and of limited duration. The collection of the fuel price data was conducted under delegated authority, not by regulation, and for a limited period of time. The request for special air carrier reports was in response to a crisis period of fuel scarcity and volatile fuel price changes brought about by conditions in the Middle East. The information collected was used by the Civil Aeronautics Board to update the Standard Industry Fare Level on the basis of the most current fuel information possible. Finally, the information collection was applicable to only a limited number (nine) of air carriers.

None of these circumstances are present in the Department's collection of aircraft inventory data, which has been a recurrent reporting requirement under 14 CFR part 241 for decades and is applicable to all large certificated air carriers.

In a similar vein, United had filed a motion with the Department to permanently withhold from public disclosure: (1) the fuel cost and consumption data it reports pursuant to 14 CFR part 241 on monthly RSPA Form 41 Schedule P–12(a), Fuel Consumption by Type of Service and Entity, and (2) the number of gallons of aircraft fuels issued and oils issued that are reported on quarterly RSPA Form 41 Schedule T–2, Traffic, Capacity, Aircraft Operations, and Miscellaneous Statistics by Type of Aircraft. United's original motion was filed in Docket 42882.

By letter dated July 26, 1990, the Department rejected United's motion for confidentiality stating it was not convinced that there was a likelihood of substantial competitive harm through the release of the fuel data. In reaching its conclusion, the Department noted that, while the average cost of fuel, by entity, was disclosed, the information collected lacked sufficient detail so as to cause the likelihood of substantial competitive harm. For example, the collected fuel data are not detailed to the extent they would permit a competing fuel supplier or airline to determine another airline's fuel cost or consumption at a particular location.

The situation surrounding the availability of airframe and aircraft engine transaction costs is similar to the above situation involving United's request for confidential treatment of the fuel data reported in its Form 41 reports. The Department believes, absent the availability of the purchase (sales) agreements' terms and conditions, substantial competitive harm would not likely occur.

Alternative Course of Action

Continental, in its comments, proposes an alternative course of action in lieu of amending part 241 to include a grant of confidentiality. Specifically, Continental proposes that the Department eliminate the following data elements: (1) Schedule B–7: Cost, Amortized/Depreciated Cost, and Realization; and (2) Schedule B–43: Acquired Cost, Allowance for Depreciation, Depreciated Cost, and Estimated Residual Value. The reason given for eliminating this information is that there is no direct link from any summarization of these elements to either the Balance Sheet (Schedule B–1), Statement of Operations (Schedule P–1.2), or Aircraft Operating Expenses (Schedule P–5.2). Continental questions the Department's need for the information.

The question of the Department's need for the data elements cited above is not at issue here. The need for the information has been addressed in other docketed forums, most recently as part of the President's Federal Regulatory Review, which concluded that the information cited by Continental is still required by the Department for the administration of its aviation responsibilities.

Comments in Support of Public Access

As noted above, fourteen of the comments filed, including the late comment, were in opposition to the grant of confidential treatment for the aircraft inventory data reported on Form 41 Schedules B–7 and B–43. FedEx, as previously pointed out, has stated that it believes the public availability of Schedules B–7 and B–43 enhances competition. Basically, the carrier contends that disclosure ensures a reasonable balance of investment information, and thus opportunity for all carriers to evaluate investment decisions. The B–7 and B–43 data provide the financial community, appraisers, aviation consultants and buyers and sellers with reference points for evaluating fair market values for airframes and aircraft engines. Eliminating the availability of such information could reduce the willingness of investors to invest in aircraft.

As a manufacturer of aircraft, the McDonnell Douglas Corporation (MDC) filed comments in support of the public availability of airframe and engine acquisition costs. MDC states that continued disclosure of the information would best serve the public interest and the U.S. aerospace industry.

In its comments, MDC states that it makes extensive use of Schedules B–7 and B–43 to support the design decisions of new and derivative aircraft. To quote MDC: "The results of these design efforts have provided the aerospace industry with efficient and modern aircraft. The improved efficiencies have led to new models with improved operating costs. As a result, the travelling public pays less for air travel, adjusted for inflation, than they did ten years ago."

The remaining ten comments (Air Cargo Management Group; BK Associates; Avitas; The CIT Group/ Capital Equipment Financing; DCB Consultants; Jack B. Feir & Associates; Mack Aviation; Simat, Helliesen & Eichner, Inc.; United States Leasing International and York University) come from air transportation industry analysts, researchers, consultants, and aircraft appraisers. (Two of the comments in opposition to confidentiality, ALPA's and Airt Services', have been discussed previously in this notice under the caption "Competitive Harm.")

The themes expressed in these ten comments are woven with several common threads. Among these are the shifting patterns of aircraft ownership within the air transportation industry to a trend towards sale and leaseback transactions, which require accurate valuations by banks and other financial institutions that provide debt and equity for the transaction. The comments generally also note the participation of income funds, limited partnerships, and equipment trusts in assisting air carriers in shifting to asset-based financing. As a consequence of this move away from a position of equity-financing to asset-based financing, buyers, sellers, and investors depend more on "appraisals." Without historical prices of new and used aircraft, it would be difficult, if not impossible, to develop a fair market

value of a leased aircraft in the "nth" year.

BK Associates comments that, without the data available on Schedules B–7 and B–43, lenders will be more restrictive in financing airframe and engine purchases. BK goes on to state that financially weaker airlines will have trouble in selling and leasing back aircraft to finance operations. Furthermore, airline requests for an appraiser to value aircraft for collateral purposes in establishing a line of credit would also be jeopardized by not having B–7 and B–43 data. In a similar vein, Mack Aviation notes that appraisers need the knowledge of used aircraft transactions to assist the trustee in airline bankruptcy cases.

York University states that data availability makes the markets for aircraft more efficient by facilitating the movement of aircraft and engines to their highest-valued users.

York goes on to state before granting confidentiality, a convincing case must be made that the carriers seeking confidentiality have been, and will continue to be, harmed significantly by such information being made public. The data at issue have been available for over 50 years and at no time has it been determined that individual carriers have been seriously harmed by the government's data access policies.

Federal Aviation Act of 1958, As Amended

The issue of confidential treatment has been discussed within the context of the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. section 552, and § 7.69, Trade Secrets and Commercial or Financial Information Obtained from a Person and Privileged or Confidential, of the Department's regulations (49 CFR part 7). Before concluding, we need to consider the sensitivity of the airframe and aircraft engine cost information reported on Schedules B–7 and B–43 within the context of section 1104, Withholding of Information, of the Federal Aviation Act of 1958, as amended. Section 1104 is referenced in paragraph (a)(13) of § 7.67, Records Exempted from Disclosure by Statute, of the Department's regulations (49 CFR 7.67).

Section 7.67 states that, under section 1104, information is exempted from public disclosure if it would prejudice the formulation and presentation of positions of the United States in international aviation negotiations or adversely affect the competitive position of any United States air carrier in foreign air transportation. Based on the decades of experience that the Department and the former Civil Aeronautics Board have in conducting bi-lateral and multi-lateral aviation negotiations, the Department concludes that the availability of Form 41 Schedules B–7 and B–43 would not adversely impact the development and presentation of U.S. positions in international negotiations. The information reported on both schedules has been publicly available for decades and the availability of the information has not adversely impacted U.S. international aviation policy or international aviation negotiations.

As to the potential for the information to adversely affect U.S. air carriers in foreign air transportation, the Department addressed this issue under the preceding caption: Competitive Harm.

Conclusion

After considering the comments submitted in response to the ANPRM, the Department has decided to withdraw the rulemaking proceeding started in Docket 46597. Furthermore, based on the preceding discussion of the comments, the Department has concluded that no further action is required and that the withholding of the Form 41 Schedules B–7 and B–43 from public disclosure is unwarranted.

This action also denies air carrier motions for confidential treatment of Form 41 Schedules B–7 and B–43 that have been filed in Dockets 46597, 46868, 46869, 46933, 47119 and 47254. This action also replies to United Air Lines' February 1, 1991, petition for review of staff action by reaffirming the January 9, 1991 denial of United's previous motions for confidentiality that were filed in the above listed dockets. Finally, this action further denies United's petition for rulemaking to modify 14 CFR part 241 to include a period of confidential treatment for Form 41 Schedule B–7 Airframe and Aircraft Engine Acquisitions and Retirements and Schedule B–43, Inventory of Airframes and Aircraft Engines.

Issued in Washington, DC on December 23, 1992.

James W. Mitchell,

Acting Associate Administrator for Research, Technology and Analysis, Research and Special Programs Administration.

Exhibit A

This Letter Was Sent to All Large Certificated Air Carriers

March 22, 1991.

Dear :

This letter concerns the confidentiality of information reported on quarterly Form 41 Schedule B–7, Airframe and Aircraft Engine Acquisitions and Retirements, and annual Form 41 Schedule B–43, Inventory of Airframes and Aircraft Engines.

The issue of confidential treatment was first raised by United Air Lines' motion of November 8, 1989, requesting the Department to withhold from public disclosure the acquisition costs and sales realization amounts for airframes and aircraft engines reported on its Schedule B–7 for the quarter ended September 30, 1989 (Docket 46597). Subsequent motions were filed with every Schedule B–7 submitted since then (Dockets 46868, 46933, 47119 and 47254). United also filed a motion on March 28, 1990, for confidential treatment pertaining to the airframe and aircraft engine acquisition cost data reported on Schedule B–43, the annual report covering calendar year 1989 (Docket 46869). In addition, American Airlines filed a motion dated August 9, 1990, for confidential treatment of its Schedule B–7 for the quarter ended June 30, 1990 (Docket 47273).

In my letter dated January 9, 1991, I denied each of United's motions for confidential treatment. United filed a petition for review of the staff action denying its motions on February 1, 1991. In its petition, United states that it is not seeking exclusive confidentiality for its data, but rather, believes that aircraft acquisition costs and sales realization amounts should be held confidential for all carriers.

In urging the Research and Special Programs Administration to review its staff action, United expresses its desire to have incorporated in the regulations governing the submission of B–7 and B–43 (14 CFR part 241, Schedule B–7 and Schedule B–43) a provision for the confidential treatment of the reported data. As stated in its petition, "To that end, United proposes in the near future to submit a petition for rulemaking requesting an amendment to part 241 to accord confidential treatment to the equipment price data on Schedules B–7 and B–43. Pending action on that rulemaking petition, United requests that its motions to withhold from public disclosure along with those of any other carrier requesting such relief be granted * * *"

Delta Air Lines filed an answer on February 8, 1991, in support of United's petition. In noting United's intention to file a rulemaking petition, Delta states its belief that the Department should conduct a thorough review of the important policies and interests which are at issue. Furthermore, Delta states: "Should the Department review and reverse the staff's denial of United's request, the equipment acquisition and sales data of all carriers must be accorded the same treatment as United's similar data."

To expedite the administrative process, I have decided to treat United's petition for review of staff action as a request for rulemaking to explore whether section 23 of part 241 of the Department's Economic Regulations (14 CFR part 241) should be amended to accord confidential treatment for the information reported on Form 41 Schedules B–7 and B–43. Pending the determination on the request for rulemaking, I am reversing my earlier decision and

granting confidential treatment to United's Schedule B–7 and Schedule B–43, as previously requested.

To preclude United from enjoying an advantage over other carriers by having its data withheld from the public eye, I will look favorably upon individual air carrier motions for confidential treatment of Form 41 Schedule B–7 and/or Form 41 Schedule B–43, which are submitted under the provisions of section 302.39 of the Department's Procedural Regulations (14 CFR part 302.39). Section 302.39 requires that a separate motion be filed along with each submission of data for which confidential treatment is requested. If Form 41 Schedules B–7 and B–43 are submitted at the same time, confidential treatment requests for both schedules may be combined into a single motion.

This opportunity to request confidential treatment under section 302.39 applies, initially, to the submission of the quarterly Schedule B–7 for the fourth quarter of 1990 and the annual filing of Schedule B–43 for calendar year 1990. The opportunity, of course, also applies to subsequent filings of both schedules pending the determination on the request for rulemaking.

For those air carriers that may have already filed their fourth quarter Schedule B–7 for 1990 and/or annual Schedule B–43 for calendar year 1990, we will maintain their schedules confidential until April 15, 1991 in order to afford sufficient time for any affected carrier to file a motion for confidentiality. If a motion is not filed by April 15, the affected schedules will then be placed in the Department's Reports Reference Room and be made available for public inspection.

For administrative convenience, we are consolidating all docketed motions of United (Dockets 46597, 46868, 46869, 46933, 47119, and 47254) and American (Docket 47273) into a single docket: Docket 46597. All motions for confidential treatment of Schedules B–7 and B–43 should be designated for Docket 46597. We further plan that any rulemaking action taken regarding United's request for confidentiality would also be placed in Docket 46597.

This action is taken under authority granted by 14 CFR 385.27 (a) and (i).

Sincerely,

Robin A. Caldwell,

Director, Office of Airline Statistics.

[FR Doc. 92–31704 Filed 12–31–92; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[EE–42–92]

RIN 1545–AQ77

Certain Cash or Deferred Arrangements Under Employee Plans

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend final regulations under section 401(k). The proposed amendments will affect sponsors of certain cash or deferred arrangements benefiting employees who are members of collective bargaining units.

DATES: Written comments and requests for a public hearing must be received by March 5, 1993.

ADDRESSES: Send written comments and requests for a public hearing to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attention: CC:CORP:T:R (EE–42–92), Washington, DC 20044. In the alternative, comments may be hand delivered to: Internal Revenue Building, room 5228, 1111 Constitution Ave., NW., attention: CC:CORP:T:R (EE–42–92), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Cheryl Press at 202–622–4688 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Final regulations under section 401(k) of the Internal Revenue Code (Code) were published in the **Federal Register** on August 15, 1991 (56 FR 40507). Amendments to the final regulations were published in the **Federal Register** on December 4, 1991 (56 FR 63420). Corrections to the final regulations were published in the **Federal Register** on March 25, 1992 (57 FR 10289).

Explanation of Provisions

This document proposes amendments to the final regulations under section 401(k) of the Code. The proposed amendments simplify the application of the regulations to certain plans benefiting employees who are members of collective bargaining units. The amendments modify the definition of the term "plan" to make optional, instead of mandatory, the disaggregation of a plan covering members of more than one collective bargaining unit.

Section 1.401(k)–1(g)(11)(iii)(A) of the final regulations provides that a plan that benefits employees who are included in a unit of employees covered by a collective bargaining agreement and employees who are not included in a collective bargaining unit is treated as comprising separate plans. Furthermore, employees of each collective bargaining unit benefiting under the plan must be treated as covered under a separate plan. Thus, for example, if a plan benefits employees in three categories, employees included in collective bargaining unit A, employees included in unit B, and those not included in any collective bargaining unit, the plan is treated as comprising three separate plans, each of which benefits only one category of employees. Many commentators have suggested that an employer be required instead to treat the portion of the plan that benefits employees included in collective bargaining units as a separate plan from the portion of the plan that benefits other employees.

The proposed amendments adopt the approach suggested by commentators. The portion of a plan that benefits employees who are included in collective bargaining units and the portion that benefits employees who are not included in collective bargaining units must be treated as comprising separate plans. However, further disaggregation of the plan by collective bargaining units is permissive, provided that the combinations of units are determined on a basis that is reasonable and reasonably consistent from year to year. An employer or plan administrator, as appropriate, may therefore treat the entire portion of a plan benefiting members of collective bargaining units as a single plan, may treat the portion benefiting members of each collective bargaining unit as separate plans, or may aggregate the portions benefiting members of any two or more collective bargaining units.

Section 1.401(k)–1(g)(11)(iii)(D) is similarly amended to make permissive the disaggregation of a multiemployer plan by collective bargaining unit. Under the final regulations, only the portion of a multiemployer plan benefiting employees under the same collective bargaining agreement and the same benefit computation formula is treated as a separate plan. Under the proposed amendments, the employer or plan administrator may choose to disaggregate this separate plan further on the basis of collective bargaining units.

Under §§ 1.401(k)–1(a)(7)(i) and 1.402(a)–1(d)(3)(iv) of the final regulations, a collectively bargained plan is only required to satisfy the actual deferral percentage test for plan years beginning after December 31, 1992. The proposed amendments are effective for the same plan years.

The proposed amendments to the regulations change the aggregation rules only for collectively bargained plans. Treasury and the Service anticipate further technical amendments to the regulations under section 401(k) and related provisions. No inference should be drawn from these proposed amendments concerning any other issue under the final regulations, including

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any other issue involving the treatment of collectively bargained or multiemployer plans.

Comments on the proposed amendments, and on any other issues or problems related to the testing of plans with participants who are members of collective bargaining units, are invited. In particular, comments are invited regarding the aggregation or disaggregation of multiemployer plans by collective bargaining agreement (as opposed to or in addition to collective bargaining unit) or by benefit computation formula.

Special Analyses

It has been determined that these proposed rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Written Comments

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted timely (preferably a signed original and eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying in their entirety.

Drafting Information

The principal author of these regulations is Cheryl Press, Office of the Associate Chief Counsel (Employee Benefits and Exempt Organizations), Internal Revenue Service. However, personnel from other offices of the Service and Treasury Department participated in their development.

List of Subjects in 26 CFR 1.401–0 Through 1.419A–2T

Bonds, Employee benefit plans, Income taxes, Pensions, Reporting and recordkeeping requirements, Securities, Trusts and trustees.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *.

Par. 2. Section 1.401(k)–1 is amended by revising paragraphs (g)(11)(iii)(A) and (g)(11)(iii)(D)(*2*) to read as follows:

§ 1.401(k)–1 Certain cash or deferred arrangements.

* * * * *

(g) * * *

(11) * * *

(iii) * * * (a) *Plans benefiting collective bargaining unit employees.* A plan that benefits employees who are included in a unit of employees covered by a collective bargaining agreement and employees who are not included in such a collective bargaining unit is treated as comprising separate plans. This paragraph (g)(11)(iii)(A) is generally applied separately with respect to each collective bargaining unit. At the option of the employer, however, two or more separate collective bargaining units can be treated as a single bargaining unit, provided that the combinations of units are determined on a basis that is reasonable and reasonably consistent from year to year. Thus, for example, if a plan benefits employees in three categories—employees included in collective bargaining unit A, employees included in collective bargaining unit B, and employees who are not included in any collective bargaining unit—the plan can be treated as comprising three separate plans, each of which benefits only one category of employees. However, if collective bargaining units A and B are treated as a single collective bargaining unit, the plan will be treated as comprising only two separate plans, one benefiting all employees who are included in a collective bargaining unit and another benefiting all other employees. Similarly, if a plan benefits only employees who are included in collective bargaining unit A and collective bargaining unit B, the plan can be treated as comprising two separate plans. However, if collective bargaining units A and B are treated as a single collective bargaining unit, the plan will be treated as a single plan.

* * * * *

(D) * * *

(*2*) *Multiemployer plans.* Consistent with section 413(b), the portion of the plan that is maintained pursuant to a collective bargaining agreement (within the meaning of § 1.415–1(a)(2)) is treated as a single plan maintained by a single employer that employs all the employees benefiting under the same benefit computation formula and covered pursuant to that collective bargaining agreement. The rules of paragraph (g)(11)(iii)(A) of this section (including the optional aggregation of collective bargaining units) apply to the resulting deemed single plan in the same manner as they would to a single employer plan, except that the plan administrator is substituted for the employer where appropriate and appropriate fiduciary obligations are taken into account. The non-collectively bargained portion of the plan is treated as maintained by one or more employers, depending on whether the non-collective bargaining unit employees who benefit under the plan are employed by one or more employers.

* * * * *

Shirley D. Peterson,

Commissioner of Internal Revenue.

[FR Doc. 92–31188 Filed 12–31–92; 8:45 am]

BILLING CODE 4830–01–M

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26 CFR Part 1

[PS–50–92]

RIN 1545–AS09

Rules to Carry Out the Purposes of Section 42 and for Correcting Administrative Errors and Omissions

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations concerning the Secretary's authority to provide guidance necessary or appropriate to carry out the purposes of section 42. This document also contains proposed regulations allowing State and local housing credit agencies to correct administrative errors and omissions made in connection with allocations of low-income housing credit dollar amounts and recordkeeping within a reasonable period after their discovery. The proposed regulations affect State and local housing credit agencies, owners of buildings or projects for which the low-income housing credit is allocated, and taxpayers claiming the low-income housing credit.

DATES: Written comments must be received by March 5, 1993. Requests to appear at a public hearing scheduled for April 5, 1993, and outlines of oral comments must be received by March 15, 1993. See notice of hearing

published elsewhere in this issue of the Federal Register.

ADDRESSES: Send comments, requests to appear at the public hearing, and outlines to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, (Attn: CC:CORP:T:R (PS–50–92), room 5228), Washington, DC 20044. In the alternative, comments, requests to appear at the public hearing, and outlines may be hand delivered to: CC:CORP:T:R (PS–50–92), Internal Revenue Service, room 5228, 1111 Constitution Avenue, NW., Washington, DC 20224. The public hearing will be held in the Internal Revenue Service Auditorium, Seventh Floor, 7400 Corridor, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Jeffrey A. Erickson, (202) 622–3040 (not a toll-free call). Concerning the hearing, Mike Slaughter, Regulations Unit, (202) 622–7190 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information requirement contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer T:FP, Washington, DC 20224.

The collection of information requirement in this proposed regulation is contained in § 1.42–13(b). This information is required by the Internal Revenue Service in order to ascertain the circumstances resulting in the administrative error or omission. The likely respondents are state and local housing credit agencies, individuals, business or other for-profit institutions, nonprofit institutions, and small businesses or organizations.

These estimates are an approximation of the average time expected to be necessary for the collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents may require greater or less time, depending on their particular circumstances. Estimated total annual reporting burden: 128 hours. Estimated average annual burden per respondent: 1.5 hours. Estimated number of respondents: 85. Estimated frequency of responses: on occasion.

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 42 of the Internal Revenue Code of 1986. These amendments are proposed to provide guidance under section 42(n). Under section 42(n), the Secretary of the Treasury may prescribe regulations as may be necessary or appropriate to carry out the purposes of section 42. Under section 42(n)(4), the Secretary may prescribe regulations providing housing credit agencies the opportunity to correct administrative errors and omissions with respect to allocations and recordkeeping within a reasonable period after their discovery.

Explanation of Provisions

Section 42 provides for a low-income housing credit that may be claimed as part of the general business credit under section 38. The credit determined under section 42 is allowable only to the extent the owner of a qualified low-income building receives a housing credit allocation from a State or local housing credit agency (Agency), unless the building is exempt from the allocation requirement by reason of section 42(h)(4)(B).

The proposed regulations incorporate the authority granted to the Secretary under section 42(n) to provide guidance necessary or appropriate to carry out the purposes of section 42. Thus, the proposed regulations establish that the Secretary may implement section 42(n) by issuing guidance in a form other than regulations.

The proposed regulations also permit an Agency to correct administrative errors and omissions with respect to allocations and recordkeeping within a reasonable period after their discovery. Under the regulations, an Agency must obtain the prior approval of the Secretary to correct an administrative error or omission if the correction is not made before the close of the calendar year of the error or omission and the correction: (1) Is a numerical change to the housing credit dollar amount allocated for the building or project; (2) affects the determination of any component of the housing credit ceiling of the State under section 42(h)(3)(C); or (3) affects the State's unused housing credit carryover that is assigned to the Secretary under section 42(h)(3)(D). In all other cases an Agency may correct an administrative error or omission without obtaining prior approval from the Secretary.

The proposed regulations specifically define what constitutes an administrative error or omission. Errors or omissions that are not within this definition, including misinterpretations of the applicable rules and regulations under section 42, are not covered by the proposed regulations and therefore may not be corrected as provided by the proposed regulations. However, relief may be granted by the Service under its general authority. The Service solicits comments as to other errors and omissions that should also be included in this section as administrative errors or omissions.

The guidance discussed in Notice 92–35, 1992–33 I.R.B. 18, relating to an Agency's ability to participate in the pool of unused housing credit carryovers, is not in these proposed regulations. However, that guidance will be provided in other proposed regulations that directly address State housing credit ceiling calculations.

Proposed Effective Date

These proposed regulations are proposed to be effective on March 5, 1993.

Special Analyses

It has been determined that these proposed rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, this notice of proposed rulemaking was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact on small business.

Comments and Requests to Appear at Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are timely submitted (preferably a signed original and eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying. A public hearing will be held on April 5, 1993. See notice of hearing published elsewhere in this issue of the Federal Register.

Drafting Information

The principal author of these regulations is Jeffrey A. Erickson, Office of the Assistant Chief Counsel

(Passthroughs and Special Industries), Internal Revenue Service. However, other personnel from the Internal Revenue Service and the Treasury Department participated in their development.

List of Subjects in 26 CFR 1.37–1 Through 1.44A–4

Credits, Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 is amended by adding the following citation:

Authority: 26 U.S.C. 7805 * * * § 1.42–13 also issued under 26 U.S.C. 42(n). * * *

Par. 2. New § 1.42–13 is added to read as follows:

§ 1.42–13 Rules necessary and appropriate; housing credit agencies' correction of administrative errors and omissions.

(a) *Publication of guidance.* Under section 42(n), the Secretary has authority to prescribe regulations as may be necessary or appropriate to carry out the purposes of section 42. The Secretary may also provide guidance through various publications in the Internal Revenue Bulletin. (See § 601.601(d)(2)(ii)(*b*) of this chapter.)

(b) *Correcting administrative errors and omissions*—(1) *In general.* An Agency may correct an administrative error or omission with respect to allocations and recordkeeping, as described in paragraph (b)(2) of this section, within a reasonable period after the Agency discovers the administrative error or omission. Whether a correction is made within a reasonable period depends on the facts and circumstances of each situation. Except as provided in paragraph (b)(3)(ii) of this section, an Agency need not obtain the prior approval of the Secretary to correct an administrative error or omission, if the correction is made in accordance with paragraph (b)(3)(i) of this section. The administrative errors and omissions to which this paragraph (b) applies are strictly limited to those described in paragraph (b)(2) of this section, and thus do not include, for example, any misinterpretation of the applicable rules and regulations under section 42. Accordingly, an Agency's allocation of a particular calendar year's low-income housing dollar credit amounts made after the close of that calendar year, or the use of an incorrect population amount in calculating a State's housing credit ceiling for a calendar year are not administrative errors that can be corrected under this paragraph (b).

(2) *Administrative errors and omissions described.* An administrative error or omission is a mistake that results in a document that inaccurately reflects the intent of the Agency at the time the document is originally completed or, if the mistake affects a taxpayer, a document that inaccurately reflects the intent of the Agency and the affected taxpayer at the time the document is originally completed. Administrative errors and omissions described in this paragraph (b)(2) include the following:

(i) A mathematical error;

(ii) An entry on a document that is inconsistent with another entry on the same or another document regarding the same property, or taxpayer;

(iii) An omission of information that is required on a document; and

(iv) Any other type of error or omission identified by guidance published in the Internal Revenue Bulletin (see § 601.601(d)(2)(ii)(*b*) of this chapter) as an administrative error or omission covered by this paragraph (b).

(3) *Procedures for correcting administrative errors or omissions*—(i) *In general.* An Agency's correction of an administrative error or omission, as described in paragraph (b)(2) of this section, must amend the document so that the corrected document reflects the original intent of the Agency, or the Agency and the affected taxpayer, and complies with applicable rules and regulations under section 42.

(ii) *Secretary's prior approval required.* An Agency must obtain the Secretary's prior approval to correct an administrative error or omission, as described in paragraph (b)(2) of this section, if the correction is not made before the close of the calendar year of the error or omission and the correction—

(A) Is a numerical change to the housing credit dollar amount allocated for the building or project;

(B) Affects the determination of any component of the State's housing credit ceiling under section 42(h)(3)(C); or

(C) Affects the State's unused housing credit carryover that is assigned to the Secretary under section 42(h)(3)(D).

(iii) *Requesting the Secretary's approval.* To obtain the Secretary's approval under paragraph (b)(3)(ii) of this section, an Agency must submit a request for the Secretary's approval within a reasonable period after discovering the administrative error or omission, and must agree to any conditions that may be required by the Secretary under paragraph (b)(3)(iv) of this section. When requesting the Secretary's approval, the Agency, or the Agency and the affected taxpayer, must file an application that complies with the requirements of this paragraph (b)(3)(iii) and Rev. Proc. 92–1, 1992–1 I.R.B. 9 (or any subsequent applicable revenue procedure). (See § 601.601(d)(2)(ii)(*b*) of this chapter). The application requesting the Secretary's approval must contain the following information—

(A) The name, address, and identification number of each affected taxpayer;

(B) The Building Identification Number (B.I.N.) and address of each building or project affected by the administrative error or omission;

(C) A statement explaining the administrative error or omission and the intent of the Agency, or of the Agency and the affected taxpayer, when the document was originally completed;

(D) Copies of any supporting documentation;

(E) A statement explaining the effect, if any, that a correction of the administrative error or omission would have on the housing credit dollar amount allocated for any building or project; and

(F) A statement explaining the effect, if any, that a correction of the administrative error or omission would have on the determination of the components of the State's housing credit ceiling under section 42(h)(3)(C) or on the State's unused housing credit carryover that is assigned to the Secretary under section 42(h)(3)(D).

(iv) *Agreement to conditions.* To obtain the Secretary's approval under paragraph (b)(3)(ii) of this section, an Agency, or the Agency and the affected taxpayer, must agree to the conditions the Secretary considers appropriate.

(c) *Examples.* The following examples illustrate the scope of this section:

Example 1. Individual B applied to Agency X for a reservation of low-income housing credits for a building that is part of a low-income housing project. When applying for the low-income housing credits, B informed Agency X that B intended to form Partnership Y to finance the project. After receiving the reservation letter and prior to receiving an allocation, B formed Partnership Y and sold partnership interests to a number of limited partners. B contributed the low-income housing project to Partnership Y in exchange for a partnership interest. B and Partnership Y informed Agency X of the ownership change. When actually allocating the credits, Agency X sent Partnership Y a document listing B, rather than Partnership

Y, as the building's owner. Partnership Y promptly notified Agency X of the error. After reviewing related documents, Agency X determined that it had incorrectly listed B as the building's owner on the allocation document. Since the parties originally intended that Partnership Y would receive the allocation as the owner of the building, Agency X may correct the error without obtaining the Secretary's approval, and insert Partnership Y as the building's owner on the allocation document.

Example 2. Agency Y allocated fewer low-income housing credits for a low-income housing building than Agency Y originally intended. After the close of the calendar year of the allocation, B, the building's owner, discovered the error and promptly notified Agency Y. Agency Y reviewed relevant documents and agreed that an error had occurred. Agency Y and B must apply, as provided in paragraph (b)(3)(iii) of this section, for the Secretary's approval before Agency Y may correct the error.

(d) *Effective date.* The rules set forth in this notice of proposed rulemaking are proposed to be effective on March 5, 1993.

Michael P. Dolan,

Acting Commissioner of Internal Revenue.

[FR Doc. 92-31189 Filed 12-31-92; 8:45 am]

BILLING CODE 4830-01-M

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26 CFR Part 1

[PS-50-92]

RIN 1545-AQ98

Rules to Carry Out the Purposes of Section 42 and for Correcting Administrative Errors and Omissions; Hearing

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of a public hearing on proposed Income Tax Regulations concerning the Secretary's authority to provide guidance necessary or appropriate to carry out the purposes of section 42 and allowing State and local housing credit agencies to correct administrative errors and omissions made in connection with allocations of low-income housing credit dollar amounts and recordkeeping within a reasonable period after their discovery.

DATES: The public hearing will be held on Monday, April 5, 1993, beginning at 10 a.m. Requests to speak and outlines of oral comments must be received by Monday, March 15, 1993.

ADDRESSES: The public hearing will be held in the IRS Commissioner's Conference Room, room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Requests to speak and outlines of oral comments should be submitted to the Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attn: CC:CORP:T:R [PS-50-92], room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), 202-622-7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 42 of the Internal Revenue Code of 1986.

The rules of § 601.601(a)(3) of the "Statement of Procedural Rules" (26 CFR part 601) shall apply with respect to the public hearing. Persons who have submitted written comments within the time prescribed in the notice of proposed rulemaking and who also desire to present oral comments at the hearing on the proposed regulations should submit not later than Monday, March 15, 1993, an outline of the oral comments/testimony to be presented at the hearing and the time they wish to devote to each subject.

Each speaker (or group of speakers representing a single entity) will be limited to 10 minutes for an oral presentation exclusive of the time consumed by the questions from the panel for the government and answers to these questions.

Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the persons testifying. Copies of the agenda will be available free of charge at the hearing.

By direction of the Commissioner of Internal Revenue:

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 92-31470 Filed 12-31-92; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD 92-015b]

RIN 2115-AE30

Temporary Deviations for Drawbridge Operation Requirements

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend drawbridge operation regulations to allow for temporary deviations for up to 90 days. Under current regulations, a Coast Guard District Commander may authorize a temporary deviation from a part 117 provision for a maximum of 60 days. The additional 30 days would better accommodate seasonal testing and public response surveys, and would provide additional time for a test regulation to be in effect before comments are due on the proposed change and its effectiveness.

DATES: Comments must be received on or before March 5, 1993.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council (G-LRA/3406)(CGD 92-015b), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001, or may be delivered to Room 3406 at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477.

The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at Room 3406, U.S. Coast Guard Headquarters.

FOR FURTHER INFORMATION CONTACT: Ms. Marcia L. Waples, Chief, Alterations, Drawbridges, and Systems Branch (G-NBR-1), at (202) 267-0375.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD 92-015b) and the specific section of this proposal to which each comment applies, and give a reason for each comment. The Coast Guard requests that all comments and attachments be submitted in an unbound format suitable for copying and electronic filing. If not practical, a second copy of any bound material is requested. Persons wanting acknowledgement of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Marine Safety

Council at the address under "ADDRESSES." The request should include reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the Federal Register.

Drafting Information

The principal persons involved in drafting this document are Ms. Marcia L. Waples, Project Manager, and Mr. Don Faleris, Project Counsel, Office of Chief Counsel.

Background and Purpose

Title 33, part 117 of the Code of Federal Regulations contains both general and specific requirements for drawbridge operations. In order to evaluate suggested changes to the drawbridge operation requirements, § 117.43 allows a Coast Guard District commander to authorize temporary deviations from the regulations contained in part 117, for up to 60 days. The authorized temporary deviation is meant to allow for regulations testing as a prelude to permanent regulation changes governing drawbridge operations and schedules. An issue has been raised regarding the need to revise § 117.43 because the maximum 60-day period does not consider the need to test a proposed regulation change over various lengths of seasonal periods in order to capture significant circumstances associated with seasonal waterborne traffic patterns. The 60-day limitation also does not allow for adequate public survey responses or commentary on proposed changes or other related problems not specifically addressed under part 117.

Discussion of Proposed Amendments

The proposed amendment would allow temporary deviations from drawbridge operation regulations to be authorized by a District Commander for up to 90 days, instead of the current 60 days. This will make the testing of proposed changes more effective and will increase the likelihood of more useful feedback from the affected public.

Regulatory Evaluation

This proposal is not major under Executive Order 12291 and not significant under the "Department of Transportation Regulatory Policies and Procedures" (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation is unnecessary. This proposal merely extends the allowable time for temporary changes in drawbridge operation requirements for regulatory purposes. There will be no cost to the general public. In fact, the ultimate purpose is to balance the needs of navigation and railroad and land transportation in the most effective and efficient manner possible, in order to minimize to the greatest extent practicable inconvenience and transportation and navigation costs which may be associated with delays caused by scheduling or other operating requirements in need of adjustment.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposal, if adopted, will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

This proposal is intended to provide greater flexibility in the regulation which allows for testing proposed changes in drawbridge operations or scheduling. This proposal is largely administrative in nature, and will be infrequently used. It imposes no special expense on small businesses. Because it expects the economic impacts of this proposal to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposal contains no additional collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501*et seq.*).

Federalism

The Coast Guard has analyzed this proposal under the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. Under Federal law, the primary jurisdiction to regulate drawbridges across the navigable waters of the United States is vested in the Secretary of Transportation and delegated to the Coast Guard. Therefore, if this rule becomes final, the Coast Guard intends it to preempt State action addressing this subject matter.

Environment

The Coast Guard considered the environmental impact of this proposal and concluded that under section 2.B.2.g.(5) of Commandant Instruction M16475.1B, this proposal is categorically excluded from further environmental documentation because it is a Bridge Administration Program action involving the promulgation of operating requirements or procedures for drawbridges. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under "ADDRESSES."

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g).

2. Section 117.43 is revised to read as follows:

§ 117.43 Changes in draw operation requirements for regulatory purposes.

In order to evaluate suggested changes to the drawbridge operation requirements, the District Commander may authorize temporary deviations from the regulations in this part for periods not to exceed 90 days. Notice of these deviations is disseminated in the Local Notices to Mariners and published in the **Federal Register**

Dated: Dec 28, 1992.

A. Cattalini,

Acting Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 92–31913 Filed 12–31–92; 8:45 am]

BILLING CODE 4910-14-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MM Docket No. 92–266, FCC 92–544]

Implementation of the Cable Television Consumer Protection and Competition Act of 1992; Rate Regulation

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this Notice of Proposed Rulemaking (NPRM), the Commission proposes to amend its rules to

implement sections 623, 612, and 622(c), of the Communications Act of 1934, 47 U.S.C. 543, 532 and 542(c) as amended by the Cable Television Consumer Protection and Competition Act of 1992, Pub. L. No. 102–385, §§ 3, 9, & 14, 106 Stat. 1460 (1992) (Cable Act of 1992). The Cable Act of 1992 directs the Commission to establish rules to govern rate regulation of cable service provided by cable systems not subject to effective competition and leased commercial access offered by cable systems to programmers.

DATES: Comments must be filed on or before January 27, 1993, and reply comments on or before February 11, 1993.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Patrick Donovan (202) 632–1295 or Nancy Boocker (202) 632–6917, Common Carrier Bureau; Regina Harrison or Alan Aronowitz, Policy and Rules Division, Mass Media, (202) 632–7792.

SUPPLEMENTARY INFORMATION:

I. Introduction

The FCC solicits comment to help it to craft a comprehensive regulatory model that will best fulfill statutory objectives related to rate regulation for the cable industry. The NPRM describes and proposes alternative procedural and substantive regulations through which the requirements of these statutory provisions could be implemented. It also discusses the advantages and disadvantages of each alternative. The NPRM tentatively concludes that the FCC should adopt a benchmark regulatory alternative for regulation of cable service rates under which the FCC would establish a benchmark rate, or a simple formula which could be used to derive such a rate. Rates above the benchmark would be presumed unreasonable. Cost-of-service regulation on an individual system basis would be applied to cable systems seeking to justify a rate above the benchmark. The FCC solicits comment generally on how the different rate regulation proposals presented in the NPRM would affect, and be affected by, other parts of the Cable Act of 1992 addressed in separate Commission proceedings.

II. Proposed Implementation

A. Regulation of Cable Service Rates

1. General Issues

The Cable Act of 1992 directs the Commission to establish rules to govern rate regulation of cable service tiers offered by cable systems not subject to effective competition. The Commission must establish regulations that assure that rates for the basic service tier are reasonable, and standards that permit identification, in individual cases, of rates for cable programming services that are unreasonable.

The Cable Act of 1992 states that since the rate deregulation triggered by the Cable Communications Policy Act of 1984, monthly rates for the lowest priced basic cable service have increased by 40 percent or more for 28 percent of cable subscribers. Acknowledging that since 1984 the average number of basic channels has increased from about 24 to 30, the Act still finds that average monthly rates have risen 29 percent during the same period and that the average monthly cable rate has grown almost three times as fast as the Consumer Price Index (CPI) since deregulation. The Cable Act of 1992 also requires that regulations governing rates for cable service be based on, among other factors, the rates charged by cable systems subject to effective competition. This leads to the basic question of whether the purpose and the terms of the Cable Act embody a congressional intent that our rules produce rates generally lower than those in effect when the Cable Act of 1992 was enacted (and if so, to what degree), or, rather a congressional intent that regulatory standards serve primarily as a check on prospective rate increases. To the extent Congress envisioned reductions in rates, the FCC solicits comment on the extent to which this should be accomplished for the basic service tier and/or for cable programming services. The FCC solicits comment generally on the impact of rate reductions, or of limits on prospective rate increases, on the ability of cable operators to provide service to subscribers on the basic or higher level service tiers.

The Cable Act of 1992 permits, and appears to require in some cases, a restructuring of service offerings. The FCC solicits comment on the impact of the rate regulation alternatives presented in the NPRM on the ability and incentive of cable operators to create packages of programming at different tier levels that will be useful and valuable to subscribers. The FCC also solicits comment on whether any regulatory alternative would, as a practical matter, unduly restrict the ability of cable operators to provide a full range of services on either the basic or higher level service tiers. In addition, the FCC seeks comment generally on the impact upon the cable industry, its investors, subscribers, future growth of services and of programming, and service quality of the different approaches to rate regulation that we present in the NPRM.

2. Standards and Procedures for Identification of Cable Systems Subject to Effective Competition

The Cable Act permits regulation of a cable system's subscriber rates only if this Commission finds that the cable system is "not subject to effective competition." Where effective competition does not exist, the Cable Act states that rates for the provision of "basic cable service" are to be regulated by the franchising authority (or by this Commission in circumstances discussed below), while rates for "cable programming services" shall be subject to regulation only by this Commission. The statute establishes three separate tests, any one of which, if satisfied, would determine that cable system is subject to effective competition. The first is satisfied if the households subscribing to a cable system constitute fewer than 30 percent of the households in the franchise area. The second test is met if: (i) There are at least two unaffiliated multichannel video programming distributors (one of which may be the cable system in question), each of which offers comparable video programming to at least 50 percent of the households in the franchise area, and (ii) the households subscribing to all but the largest multichannel video programming distributor exceed 15 percent of the households in the franchise area. The third way effective competition may arise is if the franchising authority in the subject franchise area is itself a multichannel video programming distributor and offers video programming to at least 50 percent of the households in that franchise area. The Commission seeks comment on the effective competition standards contained in the Cable Act.

The Commission also seeks comment on whether the standard for gauging whether households are "offered" video programming under the second and third tests should be that service is actually available to such households. The Commission plans to count "households" subscribing to or being offered cable or other video programming service on the basis of each separately billed or billable customer. The Commission seeks comment on this tentative view. Comments are also sought on sources for data needed to evaluate such criteria, and their current availability.

The Commission also seeks comment on who is "a multichannel video programming distributor" for purposes

of the second and third tests. The Cable Act defines multichannel video programming distributor as an entity who makes multiple channels of video programming available for purchase by subscribers or customers. As examples of such entities, section 602(12) of the Communications Act lists: A cable operator, a DBS satellite service provider, a television receive-only satellite program distributor, and an MMDS provider. In assessing cable competition, the Commission previously has considered whether to take into account alternative or substitute delivery services readily available to subscribers in the home. In this regard, the Commission seeks comment on whether a telephone company offering of "video dialtone" service or a television broadcast station offering multiplexed multichannel service would qualify as a "multichannel video programming distributor." A related issue on which the Commission sought comment is whether a leased access user offering compressed, multichannel service, or a leased access user or a franchising authority offering multichannel programming on the operator's leased access or PEG channels, on either a perchannel or a multiplexing basis, would be a "multichannel video programming distributor."

The Commission also seeks comment on its tentative view that it should measure penetration for purposes of the second test cumulatively, *i.e.*, by adding the subscribership of all alternative multichannel video programming distributors (other than the largest) together. In addition, the Commission ask parties to address whether any minimum amount of programming or minimum number of separate channels must be provided by an entity for it to quality as a "multichannel video programming distributor." With respect to "comparable video programming," the Commission might presume that such comparability exists under the second statutory test for effective competition if a competitor offers multiple channels of video programming and the numerical tests for the offering of and subscription to competitive service under the second test are met. The Commission seeks comment on this approach.

3. Regulation of the Basic Service Tier Rates

a. *Components of the basic service tier subject to regulation.* Under the Cable Act, each cable operator must offer its subscribers a separately available basic service tier to which subscription is required for access to "any other tier of service." Qualified franchising authorities are to be the primary regulators of rates for this basic tier of service, with the Commission regulating in certain circumstances. The statute provides that the basic service tier must include:

(1) All local commercial and noncommercial educational television and qualified low power station signals carried to meet carriage obligations imposed by sections 614 and 615 of the Cable Act;

(2) Any public, educational, and governmental access programming required by the system franchise to be provided to subscribers; and

(3) Any signal of any television broadcast station that the cable operator offers to any subscriber, unless it is a signal that is secondarily transmitted by a satellite carrier beyond the local service area of such a station.

Section 623(b)(7)(B) permits the operator to include additional video programming signals or services in the basic tier as long as the charges for their services conform to the Commission's rate regulations.

The statute requires that "must-carry" local television signals, as defined by sections 614 and 615 of the Communications Act, must be included in the basic service tier. However, the Cable Act authorizes local television stations to exercise "retransmission consent" rights in lieu of mandatory carriage. Parties are requested to comment on how the retransmission consent provisions will affect or shape the composition of the basic service tier. In particular, section 623(b)(7)(A)(iii) would appear to make any local signal carried pursuant to retransmission consent a basic tier channel. The Commission seeks comment on this tentative conclusion. The Commission also seeks comment on whether channels carried pursuant to retransmission consent would be classified as basic service channels, even if an operator had already satisfied his signal carriage obligations. The Commission also seeks comment on its tentative finding that cable operators may add any and as many video programming services to the basic tier as they wish, provided that such services are subject to basic rate regulation.

The statute defines basic service as a tier "to which subscription is required for access to any other tier of service." The Commission seeks comment on whether this language establishes a "basic buy-through" requirement, *i.e.*, whether it precludes the offering of video services completely "a la carte" and without prior subscription to the basic service tier. In particular, the Commission asks interested parties to comment on whether Congress intended to deprive consumers of the option of purchasing services, such as premium channels, or the services of a leased access programmer, on a stand-alone basis, especially in light of the plain language of the statute which limits any such "basic buy-through" to other tiers of service. In addition, the Commission interprets section 623(b)(8)(A) as precluding an operator's requiring the purchase of services in addition to the basic tier as a precondition for ordering other programming. Assuming *arguendo* that other alternative interpretations are possible, the Commission seeks comment on whether the Act would also preclude subscribers from purchasing a separate offering of a nonvideo or "institutional network" without first purchasing the basic tier.

The definition of what services are subject to rate regulation as part of the basic service tier appears to contemplate only a single tier, and to effectively amend the general "basic tier" definition that remains in the Communications Act from the 1984 Cable Act. Section 602(3) defines "basic cable service" as "*any* service tier which includes the retransmission of local television broadcast signals" (emphasis supplied). As *American Civil Liberties Union* v. *FCC*, 823 F.2d 1554 (D.C. Cir., 1987) held, under the 1984 Act, a tier of service that incorporates, in a marketing sense, the basic tier is itself also a basic tier service, although a tier added to a basic tier for a separate charge would not be considered a basic service. The Commission seeks comment on the effect of the 1992 Cable Act on the *ACLU* interpretation of basic service. In particular, it appears that the 1992 Cable Act contemplates that there be a single "basic tier" of service that is subject to local regulation and that includes the services defined in section 623(b)(7)(A) (i), (ii), (iii). If this were not the case, the anti-buy through provisions of section 623(b)(8) could be frustrated through the marketing of cumulative tiers of "basic" service. The Commission seeks comment on its tentative interpretation.

b. *Regulation of the basic service tier by local franchising authorities and the Commission.* The Cable Act of 1992 permits local franchising authorities or the Commission to regulate the rates for "basic cable service" only if effective competition does not exist. A franchising authority wishing to exert such regulatory jurisdiction must certify in writing to the Commission that: (1) The franchising authority will adopt and administer rules with respect to the

rates subject to regulation that are consistent with the regulations prescribed by the Commission; (2) the franchising authority has the legal authority to adopt, and the personnel to administer, such regulations; and (3) procedural laws and rules governing rate regulation proceedings by such authority provide a reasonable opportunity for consideration of the views of interested parties. Such a certification filed with this Commission by a franchising authority will become effective 30 days after filing unless the Commission finds, after notice and a reasonable opportunity for the authority to comment, that the franchising authority has not met one of the three criteria listed above. If the Commission disapproves the certification, this Commission must notify the franchise authority of any revisions or modifications necessary to obtain approval. Further, if the Commission disapproves or revokes a certification, section 623(a)(6) requires this Commission to exercise the franchise authority's regulatory jurisdiction until that authority becomes qualified by filing a new certification that meets the requirements. Such new certifications become effective upon approval by this Commission, which is required to act on them within 90 days.

aa. *Jurisdictional Division.* The Commission interprets Section 623 of the Communications Act, as amended by the Cable Act, to permit local franchising authorities to regulate the rates for basic cable service in areas that are not subject to effective competition unless the Commission disallows or revokes an authority's certification. The scope of the Commission's authority to regulate basic cable service rates under the statute is less clear. The Commission tentatively concludes that it has the power to regulate basic cable service rates only if the Commission has disallowed or revoked the franchise authority's certification. The Act states that rates for basic cable service "shall be subject to regulation by a franchising authority" *or* "by the Commission if the Commission exercises jurisdiction pursuant to paragraph (6)." Paragraph (6) of section 623(a) only permits this Commission to exercise "the franchising authority's regulatory jurisdiction" when a franchise authority's certification is disapproved or revoked, and then only until a new certification is approved. Thus, under the Commission's tentative interpretation, unless a local franchise authority seeks to assert regulatory jurisdiction over basic cable service and is unsuccessful, the Commission would have no independent authority to initiate regulation of basic service rates. The Commission seeks comment on this tentative interpretation.

Other interpretations may be possible, however. Section 623(b) mandates that the Commission ensure by regulation that the rates for the basic tier are reasonable. This section can be read as giving the Commission authority over basic cable rates in areas not subject to effective competition, including such areas in which local authorities have not sought certification from the Commission to regulate basic service rates. Under this interpretation, the Commission might exercise its jurisdiction over basic service rates through individual petitions or complaints. Alternatively, the Commission might regulate using procedures similar to those it proposes for local franchising authorities. The Commission seeks comment on this or any other alternative interpretation of the jurisdictional division established under the Cable Act. The Commission seeks comment on whether it should permit a local franchising authority to file a statement explaining why the authority cannot submit a certification, (*e.g.*, lack of personnel) and requesting that the Commission assert jurisdiction. Parties advocating this approach should explain how this is consistent with the jurisdictional framework of the Cable Act.

bb. *Finding of effective competition.* The Cable Act authorizes the Commission to "find" whether or not a cable system is subject to effective competition. The Commission proposes to base its independent findings on an initial determination of an absence of effective competition by the franchising authority. The Commission proposes to have the franchise authority submit its finding and the basis for this finding to the Commission as part of the process by which local authorities are certified to regulate basic service rates. Given the large number of franchise areas nationally and their varied competitive characteristics, this approach appears to be reasonable and realistic. First, the statute on its face states that local authorities may exercise regulatory jurisdiction over cable rates only if the authority certifies that it has "the legal authority to adopt * * * such regulations." Since the Cable Act makes the absence of effective competition a prerequisite to regulators' legal authority over basic cable rates, the Commission finds it reasonable to require that local franchising authorities provide evidence of the lack of effective competition as a threshold matter of jurisdiction. In addition, franchising authorities may be in a superior position to gather relevant local facts and to test the accuracy of operators' representations regarding competition. The Commission also expects that they will consider any data operators submit to the Commission as a result of data requests or reporting obligations. The Commission's proposal, it believes, would permit in many cases a more accurate and expeditious initial effective competition analysis than the Commission could undertake without local assistance. The Commission seeks comment on this proposal. Parties may also wish to comment on whether challenges to a determination of lack of effective competition may appropriately be made as part of a revocation proceeding under section 623(a)(5), or as part of the Commission's normal procedures for reconsideration and review. The Commission also seeks comment on whether multichannel video programming distributors who are competitors to cable systems should be required to disclose the number of their subscribers and any other data relevant to finding of effective competition; whether such information (*e.g.*, as to number of subscribers) is likely to be proprietary and subject to special protections, and if so, what that special protection should be.

The Commission also tentatively finds that the language of section 623(l)(1), which expresses the tests for the presence or absence of effective competition in terms of a "franchise area," implies that determinations that effective competition is absent should be made on a franchise-area basis. Thus, if a cable system serves more than one franchise area in a geographic region, separate effective competition determinations would have to be made for each distinct franchise area. Moreover, the Commission tentatively finds that if more than one cable system is authorized to operate in a given franchise area, the requisite effective competition analysis must be applied to each system. The Commission seeks comment on these tentative conclusions. The Commission also seeks comment on whether a determination of effective competition for cable programming services, which this Commission is charged primarily with regulating, could and should be made on a system-wide, as opposed to franchise-area, basis.

cc. *Filing of franchise authority certification.* The Commission proposes that a franchise authority intending to regulate the rates for basic cable service be required to submit a certification meeting the requirements of section 623(a)(3)(A–C), and additionally stating

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the basis for its finding that its franchisee is not subject to effective competition. The Commission tentatively concludes that a standardized and simple form can and should be used for certifying to the three criteria of section 623(a)(3), and that this form should include a section for the authority's statement and explanation of its initial finding that effective competition is lacking, with reference to documentable data, including any submissions made to the Commission. The Commission seeks comment on this tentative conclusion, as well as on the specific format for such a form. The Commission also invites comment on any other administratively efficient method for certification. Parties proposing such an alternative should also explain how their proposal is consistent with the goals of the Cable Act.

Section 623(a)(3) of the Communications Act, as amended, requires that a franchising authority be able legally to adopt regulations consistent with those the Commission establishes for basic cable rate regulation. The Communications Act, as amended by the 1984 Cable Act, appears to assume that a franchise authority derives its powers, including those to regulate rates, from state law. The legislative history of the Cable Act of 1992, however, suggests that the Act itself may abrogate franchise agreements in certain circumstances to permit rate regulation consistent with Commission rules. The Commission seeks comment on whether franchising authorities derive their powers to regulate from state and local laws alone, or whether the Cable Act may itself be an independent source of authority to regulate rates. To the extent the authority is not derived from state law, are there issues that need to be addressed as to which specific authorities within state and local government are entitled to exercise this authority? The Commission asks what Congress intended by enacting section 623(a)(3)(B), if the Cable Act in fact grants franchise authorities rate regulation powers irrespective of state law. The Commission also seeks comment on whether exercise by this Commission of basic service rate regulation authority in a state prohibiting rate regulation by local authorities would in fact constitute preemption of state law. If so, the Commission also ask whether such preemption would extend to giving franchising authorities the power to regulate rates where they otherwise would be without such power, or whether it would merely, under an alternative interpretation of section 623, authorize this Commission to do so.

The Commission seeks comment on whether two or more communities served by the same cable system could file a joint certification and exercise joint regulatory jurisdiction. The Commission asks whether there are actions it should take to provide incentives for local regulators to coordinate their activities and whether such coordination should be required as part of the certification process. The Commission seeks comment on the impact of franchising authorities' decisions to proceed independently on the Act's requirement that an operator's rate structure be uniform throughout a geographic area. The Commission also solicits comment on how, under such circumstances, a cable operator might fulfill the uniform rate structure requirement.

dd. *Approval of certification by the Commission.* The Cable Act states that the written certification submitted by a franchising authority to the Commission shall be effective 30 days after it is filed, unless the Commission finds, after notice to the authority and a reasonable opportunity for the authority to comment, that (1) the authority has adopted or is administering basic cable service rate regulations that are inconsistent with those the Commission prescribes, (2) the authority lacks the legal authority to adopt, or the personnel to administer, such regulations, or (3) procedural laws and regulations applicable to the authority's rate regulation proceedings do not provide a reasonable opportunity for consideration of the views of interested parties. The Act thus contemplates that unless the Commission takes explicit action within 30 days, a certification will be effective. The Act also appears to contemplate that any decision denying certification must be made within 30 days.

Given the expedited deadlines the Act imposes, the Commission assumes that Congress did not intend that the Commission establish a full-scale pleading cycle with opportunity for interested parties, including the cable operator, to comment prior to expiration of the initial 30-day period. Thus, although the Commission proposes that each certification application be served on the franchisee, the Commission proposes to base its decision on certification on the submission by the franchising authority alone. If a certification appears defective on its face, the franchise authority will be given notice, and the opportunity to submit additional information prior to the Commission's decision. Other interested parties, including cable operators, could subsequently challenge a certification by filing a petition for revocation once a certification is effective. The Commission seeks comment on this approach, and on whether, in addition to this avenue of relief, cable operators or other interested parties would be allowed to seek reconsideration of its decision regarding the existence of effective competition and certification. The Commission also ask interested parties to comment on what procedures it might adopt for the giving of notice and the submission of additional information by a franchise authority that would enable the Commission to render decisions within the 30-day statutory period. The Commission also seeks comment on whether it would be possible and consistent with legislative intent to establish a highly expedited pleading cycle permitting interested parties, including cable operators, to comment prior to the 30-day deadline.

The Commission proposes to reflect in its rules the Cable Act requirement that, in disapproving a franchising authority's certification, the FCC notify the authority of any revisions or modifications necessary to obtain approval. The Commission tentatively concludes that denial of certification would be subject to normal procedures for reconsideration, review and appeal. If the Commission certifies an authority, it proposes to require the authority to notify each franchisee within 10 days of this decision. The Commission seeks comment on these proposals and tentative conclusions.

ee. *Revocation of certification.* Subsection 623(a)(5) requires that "upon petition by a cable operator or other interested party," the Commission "review the regulation of cable system rates by a franchising authority." If the Commission finds that the franchising authority has acted inconsistently with the requirements of section 623(a)(3), the Commission is directed to "grant appropriate relief." If, after giving the franchising authority a reasonable opportunity to comment, the Commission finds the state and local laws and regulations do not conform to Commission rules governing basic service rate regulation, the Commission must revoke the jurisdiction of such authority. The Commission interprets this subsection to require it to revoke an authority's certification whenever local or state laws are inconsistent with its regulations concerning basic service rates. However, the statute appears to contemplate other lesser remedies where local and state laws may be

facially consistent with its regulations, but the authority has applied them inconsistently, or has otherwise departed from the terms of its certification. The Commission seeks comment on this interpretation. The Commission also asks parties to comment on how their analysis of the Commission's power to act where local or state regulations are inconsistent with its rate regulations harmonizes with their analysis of the FCC's preemptive powers. Does the 1992 Cable Act give the Commission the power to preempt specific state or local laws that may conflict with the rules that the Commission establish? Can actions other than inconsistent local and state laws, which would have caused the Commission to disallow a certification in the first instance, also be the basis for revocation, or should some lesser remedy be applied? The Commission also seeks comment on what types of relief, short of revocation, it could apply. Could the Commission, for example, suspend a certification, or impose a reporting requirement on a local authority? In cases of suspension, could the Commission, consistent with the Cable Act, assume the local authority's rate regulation authority and obligations?

The Commission also proposes that a petitioner for revocation or other relief against a franchising authority serve a copy of its petition on the franchising authority, as required by statute, and that the petition contain a statement that such service was made. The Commission also proposes to permit an authority 15 days in which to file an opposition to such a petition, and a cable operator or other party ten days in which to reply. The Commission seeks comment on these proposals.

The Commission seeks comment on what procedures should apply if an operator in a particular franchise area, once not subject to effective competition, becomes subject to it. The Commission tentatively finds that a cable operator should be required to petition a franchising authority for a change in its regulatory status. This petition should be subject to public comment. A franchising authority shall promptly inform the Commission that a cable operator had petitioned for a change in regulatory status and shall forward its findings to the Commission, including the basis for those findings. If the Commission ratifies the initial determination of the franchising authority, the franchising authority would then cease regulating basic cable service rates, and its regulation of cable programming services for this system in this franchise area would also cease. Cable operators denied a change in status by a franchising authority would be entitled to seek review of that determination with this Commission, with pleadings subject to the standard filing periods. The Commission seeks comment on these tentative conclusions. The Commission also seeks comment on whether a challenge to a denial of change in status regarding effective competition could or should be made as part of a petition for revocation.

ff. *Assumption of jurisdiction by the Commission.* The Act requires that if the Commission disapproves or revokes a franchise certification, the FCC exercise the franchising authority's regulatory jurisdiction until the authority qualifies to exercise that jurisdiction by filing a new certification, and that the Commission must act on such new certification within 90 days after it is filed. The Commission seeks comment on the procedures that it should employ when it assumes a franchising authority's jurisdiction over basic service rates.

c. *Regulations governing rates of the basic service tier.* The Act requires the Commission to ensure, by regulation, that rates for the basic service tier are reasonable. Such regulations are to be designed to protect subscribers of any cable system not subject to effective competition from paying rates higher than those that would be charged if the system were subject to effective competition. In establishing regulations governing rates for the basic service tier, the Commission must seek to reduce the administrative burdens on subscribers, cable operators, franchising authorities, and itself, and it may adopt formulas or other mechanisms and procedures to achieve this objective. the FCC's rate regulations must additionally take into account seven factors:

(1) The rates for cable systems that are subject to effective competition;

(2) The direct costs (and changes in such costs) of obtaining, transmitting, and providing signals carried on the basic tier including additional video programming signals or services beyond the "must carry" local broadcast television signals, and any public, educational, and governmental access programming required by the franchising authority;

(3) Only a reasonable and properly allocable portion, as determined by the Commission, of the joint and common costs of obtaining, transmitting, and providing signals on the basic service tier;

(4) Cable operator revenues from advertising on the basic tier or other consideration obtained in connection with the basic tier;

(5) The reasonably and properly allocable portion of taxes and fees imposed by any state or local authority on transactions between cable operators and subscribers or assessments of general applicability imposed by a governmental entity applied against cable operators or cable subscribers;

(6) The cost of satisfying franchise requirements to support public, educational, or governmental channels or the use of such channels or any other services required under the franchise; and

(7) A reasonable profit, as defined by the Commission consistent with the Commission's obligations to ensure that rates are reasonable and the goal of protecting subscribers of any cable system not subject to effective competition from paying more for basic tier service than subscribers would pay if the system were subject to effective competition.

The NPRM tentatively concludes that Congress intended the FCC to embody in its regulations a standard of reasonableness for basic tier rates that reflects a balancing of the statutory goals and enumerated factors. The NPRM further tentatively concludes that Congress intended to leave the FCC discretion to determine in its rulemaking process the comparative weight to be assigned to each of the seven factors.

The NPRM solicits comment on the extent to which Congress intended a low priced basic service tier, and the extent to which FCC rate regulations should seek to promote the availability of programming on the basic service tier beyond that minimum statutory components. If our regulations produce low rates for the basic service tier, would this in turn require us to permit more flexibility in pricing for higher tiers?

The FCC has identified two generic approaches for regulation of rates for basic tier service: benchmarking and cost-based. Because the Cable Act of 1992 directs the FCC to craft rules that will reduce burdens on cable operators, franchising authorities, the FCC, and consumers, the NPRM tentatively concludes that the FCC should not select a cost-of-service alternative as the primary mode of cable rate regulation unless it is unable to gather the information needed to develop a benchmarking alternative. The NPRM tentatively concludes that each of the benchmarking alternatives could achieve reasonable rates at lower costs and with less administrative burdens than could traditional cost-of-service regulation. The FCC nonetheless concludes that cost-of-service regulatory

principles could have a secondary role for cable operators seeking to justify the reasonableness of rates that do not meet the primary benchmarking standard.

Benchmarking. The NPRM describes a benchmark rate as a price against which a given cable system's basic tier rate would be compared. The system's rate would be presumed reasonable if it did not exceed the benchmark. Under a benchmarking approach to rate regulation, the FCC would establish a benchmark rate, or a simple formula which could be used to derive such a rate. Cable systems with rates above the benchmark price by an amount determined by the FCC would be required to reduce their rates to the benchmark level unless the system could justify a rate higher than the benchmark. The benchmark would permit identification of systems with presumptively unreasonable rates, while establishing a zone of reasonableness for systems with rates below the benchmark. The NPRM solicits comment on whether to include as a component of any benchmark alternative a price cap formula to limit how quickly systems with rates below the benchmark could raise their rates to that benchmark price.

The FCC recognizes the potential tension between the need, on the one hand, to establish an accurate benchmark using sound data collection processes and ratemaking methodologies, and the command of the Act, on the other hand, to simplify regulation. A simple formula, however, would protect consumers from excessive rates and, by eliminating the need for detailed cost-based regulation in many jurisdictions, would keep the costs of administration and compliance low. Allowing higher-cost systems to opt for cost-based regulation if the benchmark rate proved unreasonably low would provide a safety valve to prevent confiscatory rates.

Under a benchmark alternative, the FCC could separate cable systems into distinct classes based upon specified variables and then define a benchmark for each class of systems. The benchmarks might then be set forth in a matrix or table. The variables used to separate cable systems into distinct classes might include such cost-defining characteristics as: homes passed per mile, number of subscribers, number of channels, system age, miles of underground cable, terrain crossed, above average programming costs, or readily identifiable costs. Another variable could be the local price level in comparison to the national price level as measured by appropriate indexes. For each of the benchmarking alternatives discussed in the NPRM, the FCC solicits comment on what variables should be used for defining the classes of systems to which a different benchmark rate should apply. One effect of benchmarks could be to cause the rates of the systems subject to the same benchmark to converge over time to that benchmark. If we were to conclude that such a result would not be desirable, we could also permit some benchmark adjustment based upon individual system characteristics. The FCC solicits comment on whether we should permit individual system adjustment to otherwise widely applicable benchmarks and what measures should and could be established to permit such adjustments. The FCC solicits comment on appropriate indexes for local and national price levels that we could use as a variable in establishing benchmarks.

Another important adjustment factor is a general change in the cost of doing business. Such changes often are represented by the general consumer price index (CPI) or producer price index (PPI) compiled on a national or regional basis by the Bureau of the Census and Bureau of Labor Statistics. The FCC seeks comment on the tentative conclusion that a local service price index (SPI) would be more appropriate than the CPI or PPI for adjusting cable rate benchmarks, if such an index can be easily determined. The FCC also seeks comment on the composition of such a local SPI, how such an index would be created, what services should be included, where data would come from, and what geographical area is appropriate for comparison.

Cost-of-Service. Under a cost-of-service approach, the reasonableness of a cable system's rates would be determined by examination of the particular costs of the individual cable system using ratemaking principles set by the Commission. The primary advantage of a cost-based alternative is that it would permit close supervision of rates. A primary disadvantage is that it would be more burdensome on cable systems and regulatory authorities.

In addition to the benchmarking alternatives, the NPRM solicits comment on another alternative called the "Direct Cost of Signals Plus Nominal Contribution to Joint and Common Costs" for regulating basic service tier rates. The FCC solicits comment generally on which among these specific proposals should be incorporated in our comprehensive framework for regulating basic rates, and how they could be combined to govern rates for the basic service tier. The FCC also seeks comment on how these proposals might be modified to achieve more effectively the goals of section 623(b) of the Cable Act of 1992. The FCC discussed and solicited comment on several benchmark alternatives.

aa. *Benchmark alternatives—Rates charged by systems facing effective competition.* One potential benchmark would be defined using the average of rates currently charged by systems facing effective competition, as the Cable Act of 1992 defines that term. This benchmark would appear to meet the statutory goal of "protecting subscribers of any cable system that is not subject to effective competition from rates for the basic service tier that exceed the rates that would be charged for the basic service tier if such cable system were subject to effective competition." To use a benchmark based on rates charged by systems facing effective competition, however, the FCC would first have to identify those systems. Moreover, basic service tier rates of systems facing effective competition would reflect the different numbers of channels in different systems' basic tiers. To perform the necessary computations the FCC would thus need to know, at a minimum, the basic service tier rates and the number of channels in the basic tier for systems facing effective competition. This information would permit us to compute a single average rate.

To create benchmarks that more accurately reflect conditions facing individual systems, the FCC might seek to determine how rates vary with cost characteristics of the systems facing competition. If sufficient data were available, regression analysis or some other statistical technique could be used to determine how rates varied with such characteristics affecting costs as homes passed per mile, number of channels, number of subscribers, the relative mix of buried and overhead cable, and the factors described in section 623(b). With this information, we could create a benchmark formula based upon systems subject to effective competition that shared at least some of the regulated systems' underlying cost characteristics.

Past regulated rates. A second alternative would be to develop a benchmark for basic service tier rates based on rates charged in 1986 before the Cable Communications Policy Act of 1984 effectively prohibited local rate regulation of most cable systems. It may be acceptable to assume that rates in 1986 were reasonable because they resulted from a competitive bidding process for the franchise and subsequent rate adjustments made under local franchise authority oversight. Using

these data we could develop individual benchmark rates for systems operating in 1986 based upon the 1986 per-channel rate for their lowest tiers. Some adjustment might be made in individual cases for factors generally agreed to affect costs. For systems not operating in 1986 the FCC proposes a benchmark expressed on a per-channel basis to account for differences in the number of channels offered on the basic tier and based on the per channel rates of the systems operating in that year. The FCC requests comment on the advantages and disadvantages of using a benchmark based on past regulated rates.

Average rates of cable systems. A third alternative would use data for all cable systems operating in 1992 to develop a benchmark from the average per-channel rate for their lowest service tier. Per-channel rates would be considered reasonable if they did not exceed that average by more than some fixed amount. Systems whose rates exceeded the average rate for all systems by more than a specified amount, or by more than a specified percent, or systems which ranked among the highest few percent (*e.g.*, top 2–5%) in terms of rates would be assumed not to have rates that were reasonable. Thus, this benchmark would identify those systems whose rates were unusually high or substantially above the average.

This standard would have the advantage that data would be more readily available for calculating the benchmark, and consumers would be protected against rates far exceeding the general industry practice. Unadjusted, however, the benchmark would not reflect competition but merely average performance in the industry; if monopoly profits were reflected in the rates of at least some industry segments, they would be incorporated in the average rate. In addition, over time the average rates would be affected by regulation and would cease to be an independent measure of industry performance. The NPRM requests comment on the validity of a measure based on average industry rates. The FCC also inquires as to the best source of data for calculating the benchmark if such a standard were adopted.

Cost-of-Service Benchmark. Under this approach to developing a benchmark, the FCC would use engineering, operating, programming and other cost data gathered in this rulemaking to construct the costs of an "ideal" or "typical" cable system or systems, possibly on a per channel or per subscriber basis. This approach could produce a benchmark roughly related to cost without requiring detailed examination of actual costs of individual systems. For this reason, this approach might be a useful alternative if implementation of other benchmark alternatives prove infeasible to implement. We seek comment on the feasibility and desirability of developing and applying a benchmark based upon constructing "ideal" or "typical" system costs. Parties supporting this approach should submit specific and detailed cost data to be included in such a benchmark, along with detailed information about how the data were developed, including data sources, validity, and reliability.

Price Caps. A price cap benchmark would be a formula set by the FCC to define reasonable increases in rates for the basic tier. For this reason, we would not intend to use the price cap formula to assess initially whether a system's rates were reasonable. The price cap formula would instead govern changes to rates that have been found reasonable under some other alternative, either based upon cost-of-service or another benchmark alternative.

A price cap formula permits the regulated company to adjust its prices when certain variables contained in the price cap formula change. The price cap formula would apply to an existing rate and would control changes to the cable system's prices over time. The FCC solicits comment on the price cap alternative and whether it should make it a component of a comprehensive regulatory scheme for rates.

If we adopt a price cap alternative to govern rates for the basic tier, we would propose to define and to control rate changes permitted under this alternative. We will additionally need to determine how and when to revise the cap, and select an appropriate price index to include among permitted adjustments. The FCC seeks comment on whether and, if so, how a price cap formula might accommodate rate adjustments to reflect: changes in subscriber penetration, channel capacity, the nationwide level of prices, the relative contribution of regulated revenues to total cable revenues, franchise fees and requirements, and other factors relevant to the Act's regulatory objectives.

bb. *Individual system cost-based alternatives—Direct costs of signals plus nominal contribution to joint and common costs.* Under this alternative, the FCC would prescribe guidelines for basic service tier rate regulation by the local franchise authority that used an individual system's costs to define reasonable rates. Cable systems would be required to keep their accounting records according to generally accepted accounting principles (GAAP) and to provide those records, as requested, to the local franchising authority.

The franchise authority would be required to find reasonable basic service tier rates that allowed recovery of at least the direct costs of the channels in the basic tier. The FCC envisions that the major component of such direct costs would be programming costs, including both payments to cable networks and retransmission fees to broadcast stations. Allowing cable systems to pass the former costs through to subscribers might reduce operators' incentive to remove highly valued programming from the basic tier. Whatever equipment used and operating costs incurred to activate additional individual channels in this tier would also be covered.

In addition, the rates for the basic service tier would include a nominal contribution to the joint and common costs of the system as a whole. Under the statute, basic service tier rates can recover "only such portion of the joint and common costs * * * as is * * * reasonably and properly allocable to the basic service tier." This requirement would set an upper bound on basic service tier rates that could be considered reasonable under Commission guidelines. Within this limit, the FCC has several options for treatment of joint and common costs in basic service tier regulation. The FCC could set guidelines that resulted in rates that recovered far less than the fully distributed cost of providing the service in order to provide assurance of service for lower income viewers. Alternatively, the FCC could set guidelines that would permit higher basic service tier rates in order not to discourage offering of a broader basic service tier with a larger number of channels, including popular cable channels. This alternative would, however, require more elaborate cost allocation rules. Rules that the FCC might apply to the allocation of joint and common costs, and to the determination of allowable costs, are proposed in appendix A of the NPRM. The FCC might also leave to the franchise authority some discretion in setting the level of basic service tier rates. The FCC requests comment on the proposal to adopt FCC guidelines for cost-based basic service tier rate regulation.

Cost-of-Service. Under this alternative, a cable system's rates would be reviewed using the established standards of cost-of-service regulation traditionally applied to public utilities. The broad principles of cost-of-service regulation are well established. While these principles could be implemented

in a rigorous fashion with extensive cost-accounting requirements, the FCC believes such an approach would be inconsistent with legislative intent. For this reason, the FCC proposes to use simplified cost-accounting requirements described in appendix A of the NPRM if cost-of-service regulation becomes a component of our comprehensive model for regulating cable rates.

Under cost-of-service, companies can meet service demand because service revenues may be set to cover operating expenses and capital costs. Because cost-based rates only compensate for the cost of providing service, if the cost-of-service regulation is properly applied, companies cannot extract monopoly rents from consumers. Cost-of-service regulation also imposes high costs on the regulators and regulatees. The FCC is concerned that cost-of-service accounting may require a significant (and potentially expensive) departure from current industry accounting practices. The FCC seeks comment on the relative advantages and disadvantages of applying cost-of-service regulation to the basic tier.

The FCC additionally seeks comment on the impact of cost-of-service regulation on the cable industry. The NPRM asks how such regulation would affect the ability of cable operators to expand their channel capacity and program offerings. The FCC also seeks comment on the implications of cost-of-service ratemaking on the industry's ability to recover its investment, including goodwill, and to service its current capital debt. The FCC also requests comment on whether we would need to include transition mechanisms if we were to adopt a cost-of-service regulatory model.

If cost-of-service ratemaking is used as a "safety net" to allow cable operators to defend rates challenged under a benchmark test, the FCC believes that the efficiency of the appeal process could be greatly improved if we established standards for the showings that should be made in such an appeal process. The NPRM notes that cost-of-service regulation requires the regulatory authority to make determinations relating to four major cost components: Rate base, the cost of capital, depreciation, and operating expenses. It also generally requires rules to govern the design of rates once determinations have been made in these four areas. In order to establish standards for the showings that should be made by cable systems seeking to defend rates higher than the benchmark, the FCC proposes to adopt guidelines in each of these areas. The FCC solicits comment on what requirements it would need to adopt in these areas and on the impact on the cable industry and subscribers of those requirements. The NPRM sets forth in more detail in appendix B the issues in each of these four areas that would require resolution for cost-of-service regulation to be implemented.

d. *Regulation of rates for equipment.* The Cable Act of 1992 directs the FCC to establish standards for setting, on the basic of actual cost, the rate for installation and lease of equipment used by subscribers to receive the basic service tier, including converter boxes and remote control units, and installation and lease of monthly connections for additional television receivers.

Based on the language and legislative history of section 623(b)(3), the FCC tentatively concludes that Congress intended to separate rates for equipment and installations from other basic tier rates. The FCC also tentatively concludes that, to be consistent with the statute's intent, the rates for installation should not be bundled with rates for the lease of equipment. The FCC believes that this unbundling could help to establish an environment in which a competitive market for equipment and installation may develop. The NPRM seeks comment on these tentative conclusions, especially on the feasibility of a competitive market for installation services.

Although the FCC tentatively concludes that equipment covered under this section of the Act includes the converter box, remote control unit, connections for additional television receivers, and wiring other inside cabling, the NPRM seeks comment on the extent of this coverage. The FCC believes that our rules should clarify the relationship between section 623(b)(3), which requires regulating, on the basis of actual cost, "equipment used for the basic tier," and section 623(c), requiring regulations for cable programing services, which includes the installation or rental of equipment use for the receipt of such programming services. For the latter, the FCC must establish standards for determining whether the rates are unreasonable and, as for basic tier service, cost is to be only one of several factors to consider.

On the one hand, it appears that Congress may not have intended to limit regulation, on the basis of actual cost, to that equipment only used for basic tier service. On the other hand, the Act includes equipment and installation in the definition of cable programming services. If the FCC assumes that Congress intended different standards for determining the reasonableness of rates for equipment used to receive cable programming services, it is unclear how to treat equipment that is used for the provision of both basic tier service and cable programming services. Therefore, the FCC requests comment identifying any equipment not used for basic tier service and the extent to which the actual cost standard of section 623(b)(3) controls the rates charged for equipment used for more than just basic tier service. The FCC solicits comment on whether the only equipment that should be subject to section 623(b)(3) should be equipment that is necessary to receive basic service tier programming, and whether equipment, if any, use only to receive cable programming service would not be subject to section 623(b)(3).

The FCC proposes requiring operators to base charges for equipment covered by section 623(b)(3) on direct costs, and indirect cost allocations, including reasonable general administrative loading and a reasonable profit. Cable operators would amortize the cost of equipment over the average life of that equipment to determine the monthly equipment rate. The cost of maintaining and servicing equipment should be factored into leased rates for equipment. If the FCC adopts a cost-of-service showing requirement for basic tier rates, cable companies could allocate a share of the general administrative overhead expenses on the same basis that they allocate to basic tier services, which would simplify the rate setting process for equipment. If the FCC adopts the proposal that basic tier rates include only a nominal contribution to overhead, it is unclear whether the same loading should apply to equipment. It appears that Congress intended low rates for equipment and installation, but Congress might have intended actual costs to include a share of joint and common costs allocated using a fully distributed cost methodology. The NPRM seek comment on which allocation rule would more accurately reflect congressional intent concerning rates for equipment covered by section 623(b)(3).

Alternatively, cable operators may wish to sell equipment to their customers. The sale may occur as a one-time payment or over a period of time. The Act, however, appears to contemplate that cable operators would be limited to recovery of actual costs, however, the FCC defines that term. The FCC recognizes that actual costs may vary depending on the length of payment schedule. The purchaser would probably be independently responsible for repair of the equipment, unless a service contract were also

purchased. In addition, cable operators may have a competitive advantage as an alternative market for cable equipment develops because customers will not have or may not know of other equipment supplies. Therefore, the FCC asks whether customers purchasing on time from the cable operator should be permitted to change their minds and purchase equipment from an alternative source.

We propose determining the actual costs for installation on the same basis as for equipment. Because the FCC believes that this determination will require allocating many joint and common costs, it proposes not to prescribe any allocation rules but rather to require the cable operator to bear the burden of showing its implementation of those general allocation rules to be reasonable. To the extent that installation costs have traditionally been recovered through a one-time charge, and because the length of time a subscriber will continue service is unpredictable, it appears reasonable that companies be permitted to continue recovering these costs as one-time charges.

The FCC recognizes that costs for installation will vary depending on whether the dwelling has inside cabling already. It may thus be more reasonable to require two installation rates, one for previously wired dwellings and one rate for new inside cabling. This could encourage competition, especially for simple installations (or customers could do it themselves). The FCC requests comment on whether costs vary enough to reasonably require cable operators to develop two separate rates for installation or use an average rate and whether that decision should be left to the discretion of the local franchising authority.

Many operators charge less than actual costs for service installation as part of their marketing efforts. The FCC seeks comment on whether section 623(b)(3) reflects a legislative intent to prohibit such promotional offerings.

Section 623(b)(3)(B) also specifically directs the Commission to establish, on the basis of actual cost, rates for installation and monthly use of connections for additional television receivers. The FCC tentatively concludes that cable operators should use the same cost methodology they use for installation of other equipment to calculate the rates for installation of connections for additional receivers. If additional connections are installed at the same time a subscriber's initial service is installed, the FCC proposes that cable operators be limited to recovering the incremental costs of the additional installation.

e. *Costs of franchise requirements.* The statute requires that regulations governing the basic service tier shall include standards to identify costs attributable to satisfying franchise requirements to support public, educational, and governmental channels or the use of such channels or any other service required under the franchise.

The NPRM tentatively concludes that the purpose of this statutory requirement is to assure the establishment of standards that will permit the cable operator to identify on subscriber bills pursuant to section 622(c)(2) the amount of the bill attributable to franchise requirements. The FCC does not interpret this section as mandating that it establish separate cost-based charges apart from those for the basic service tier generally for either the customer or the users of public, educational, and governmental channels for costs attributable to franchise requirements. The NPRM solicits comment on this tentative conclusion. The NPRM further tentatively concludes that the FCC should require that the costs attributable to satisfying franchise requirements should include (1) any direct costs of providing any services required under the franchise, (2) the sum of per channel costs for the number of channels used to meet franchise requirements for public, educational, and governmental channels, and (3) a reasonable allocation of overhead.

f. *Customer changes.* The Cable Act of 1992 requires that regulations for the basic tier also include standards and procedures to prevent unreasonable charges for changing equipment or service tiers. Charges for changing the service tier must be based on cost.

The FCC tentatively concludes that Congress intended to broadly protect subscribers from unreasonable charges for changes in service tiers. The FCC tentatively concludes, therefore, that regulations adopted to implement section 623(b)(5)(C) should apply to any changes at the request of the subscriber in the number of service tiers received by the subscriber after installation of initial service. The NPRM tentatively proposes to require that charges for changing service tiers not exceed a nominal amount "when the system's configuration permits changes in service tier selection to be effected solely by coded entry on a computer terminal or by other similarly simple method." The FCC seeks comment on whether and, if so, at what level we should set the nominal amount when this condition is met.

To otherwise assure that subscribers do not pay unreasonable charges for changes in service tiers not effected by coded entry on a computer terminal or by other simple methods, the FCC solicits comment on two alternatives. First, the FCC could require that charges be based on the actual costs of making service tier changes at the subscriber's request including any direct costs and a reasonable allocation of indirect costs and overhead and a reasonable profit. Under the second alternative, as for changes effected by coded entry on a computer terminal, the FCC could require that charges for changes in services tiers effected by other means recover only nominal costs.

The FCC also solicits comment on applying these alternatives to define reasonable charges for changing equipment. The FCC seeks comment on our tentative conclusions and proposals relating to customer changes and on how best to implement them. In addition, the NPRM requests comment on whether the implementation of this rulemaking could encourage customers to change service tiers.

g. *Implementation and enforcement.* The Cable Act requires that the Commission's regulations regarding basic service rates include procedures for implementation by cable operators, for enforcement by franchising authorities, and for expeditious resolution of disputes between cable operators and franchising authorities. The Commission must also establish regulations to assure that subscribers are informed that basic service is available to them and that a cable operator notify franchising authorities 30 days in advance of any proposed increase in rates for the basic service tier. The Commission seeks comment on an expeditious way to trigger initial review of a cable operator's current basic tier rate once a local franchising authority has been certified to regulate those rates. One alternative would be to require that the operator file its schedule of basic tier rates with the franchising authority within a relatively brief period. The Commission believes that a deadline should apply to review of both an operator's initial filing and any later-filed proposed rate increases and service changes that involve rates increases. After expiration of the deadline, proposed rates would be presumed reasonable absent a negative finding. The Commission seeks comment on whether a deadline for a franchising authority to act on proposed rate increases would be appropriate, and if so, what time period would best balance the need for expiration with the need to

render an informed and judicious rate determination.

Another alternative would be to establish relatively brief notice periods (*e.g.*, 60 or 90 days) after which an increase would become effective unless a franchising authority had rejected it, but also to allow for the tolling of the franchising authority's deadline in particular circumstances. The disadvantage to this second alternative is that it might deprive the public of new services and the operator of a reasonable price increase for long periods of time. The Commission also observes that in some areas, a franchising authority's rate determination may be subject to review by a higher level of local or state authority, further delaying a final determination. A third possibility, might be to permit rate increases to go into effect automatically after the 30-day notice period expires. The Commission seeks comment on these various alternatives, on any other commenters suggest for implementing basic tier rate regulation, and particularly on the time constraints that should govern determinations on proposed rate increases. The Commission also seeks comment, depending on the ratemaking methodology adopted, on whether certain price changes caused by factors outside the operator's control, should not be deemed price "increases" subject to the notice requirement. Such increases might thus be permitted to be passed through without prior regulatory review. Those advocating such an approach should fully discuss its relationship to the ratemaking methodology they recommend.

The Commission seeks comment on how to achieve expedition in ratemaking procedures while at the same time ensuring that all parties received the due process to which they are entitled. To ensure that interested parties have an adequate opportunity to comment, the Commission proposes to require that an operator notify subscribers in writing of a proposed rate increase at approximately the same time it notifies the franchising authority, *i.e.*, at the billing cycle closest to 30 days before any proposed increase is effective. The Commission also proposes to permit any interested parties, including subscribers, to participate in the local authority's ratemaking decisions. The Commission seeks comment on this proposal, on what the appropriate pleading cycle might be, and on how such a cycle could be harmonized with the statutory goal that disputes between cable operators and franchising authorities be resolved expeditiously. The Commission also purposes to require the operator, for its initial filing and any subsequently proposed rate increase, to show that its submission complies with section 623 and the Commission's implementing regulations.

Given the statutory emphasis on expedition, the Commission does not propose to provide for formal hearings on proposed rate increases or rate-related disputes. The Commission also proposes to require the authority to issue a written initial decision explaining its disposition of each rate increase request. The Commission proposes also to adopt rules allowing local authorities to obtain additional information from operators requesting a rate increase and to establish proprietary information procedures analogous to those proposed below for cable programming service complaints. The Commission seeks comment on these tentative conclusions and proposals. The Commission also asks interested parties to comment on what oversight procedures franchising authorities may need to ensure compliance with the Cable Act.

When franchising authorities regulate rates for basic cable service consistent with the Act, they would be in the best position to monitor an operator's compliance with the Commission's regulations. Consequently, the Commission tentatively finds that enforcement of cable regulation should occur at the local level in these circumstances. The Commission seeks comment on whether a franchising authority has the power under the Cable Act, if it denies a rate increase, to set a rate for basic cable service itself, or whether formulation of a new rate should be left to the cable operator. The Commission also seeks comment on whether, in the event an operator should fail to comply with a rate decision, the Cable Act gives an authority the power to order refunds, or whether the authority must obtain an order from a court or other governmental entity with the power to order refunds. In order to obtain a refund, would an authority have to employ special procedures to ensure that the due process rights of an operator were not violated? The Commission also seeks comment on what forms of relief would be available under local law. For those authorities with franchise agreements that do not provide for rate regulation, could franchise agreements be revoked or not renewed for lack of compliance with rate decisions? The Commission seeks comment on whether other remedies, such as fines, would be available under state or local law. The Commission also seeks comment on whether it could impose forfeitures upon cable operators failing to comply with local authorities' determinations that were consistent with its basic service rate regulations.

The Commission invites interested parties to comment on the appropriate forum for appeals of local authorities' rate decisions. One approach would be to rely on the local courts, and not this Commission, to resolve what is essentially a local dispute between an operator or subscriber and a franchising authority. An alternative would be for this Commission to resolve such disputes. This approach might assure a more uniform interpretation of the standards and procedures adopted pursuant to the Cable Act. The Commission seeks comment on these alternatives. In particular, the Commission asks whether the jurisdictional framework of the Cable Act permits it exercise jurisdiction over an authority's decision in the absence of its disallowing or revoking its certification. The Commission has already asked whether the Cable Act gives it jurisdiction over basic cable service rates if franchising authorities do not seek certification. The Commission seeks comment here on whether, if it asserts jurisdiction over basic service rates in cases of disapproval or revocation of certification, the Commission should apply the same procedures to basic service rate petitions as those it would apply to cable programming services complaints, whether it should apply procedures more closely analogous to those proposed for local franchising authority's regulation of basic service rates (see below), or whether some combination of the two would be most appropriate.

The Cable Act also requires that the Commission establish rules to assure that operators inform subscribers that a basic service tier is available. The Commission tentatively concludes that it should require the operator to give initial written notice of basic tier availability to existing subscribers within 90 days or three billing cycles from the effective date of the Commission's rules governing cable rates. Additionally, the Commission proposes to require operators to notify subscribers in any sales information distributed prior to installation and hookup and at the time of installation. The Commission seeks comment on this proposal. The Commission also seeks comment on the appropriate format and content of any such notice. In addition, the Commission seeks comment on any other means by which it can ensure that

subscribers receive meaningful notice of basic tier availability.

4. Regulation of Cable Programming Services

a. *Regulations governing rates.* The Cable Act of 1992 requires that the FCC establish criteria for identifying, in individual cases, rates for the acquisition and distribution of cable programming services that are unreasonable. The statute provides that in establishing such criteria the FCC must consider:

(1) Rates for similarly situated systems taking into account similarities in costs and other relevant factors;

(2) Rates of systems subject to effective competition;

(3) The history of rates for the system including their relationship to changes in general consumer prices;

(4) The systems' rates as a whole for all cable services;

(5) Capital operating costs of the system; and

(6) Advertising revenues.

The statute also permits the FCC to consider other relevant factors.

The FCC tentatively concludes that the statute intends for the FCC to establish criteria to govern the determination in an individual case of whether rates for cable programming service are unreasonable based on a reasoned balancing of the factors enumerated in the statute and other factors that the FCC in its discretion may choose to consider.

With the exception of the "Direct Costs of Signals Nominal/Contribution to Joint and Common Costs" alternative, all previously described regulatory alternatives that could be used for the basic service tier could also be used to determine in individual cases whether rates for cable programming service are unreasonable. The FCC believes that the advantages and disadvantages of regulatory approaches and alternatives previously discussed for basic tier service are equally applicable to cable programming service. As with the basic service tier, the NPRM concludes that traditional cost-of-service regulation would not be the best alternative to select as the primary method of regulating rates for cable programming services. The FCC seeks comment on this tentative conclusion and on which alternatives it should incorporate in the comprehensive plan we will adopt for regulating cable programming service rates.

The FCC is aware that is must balance (a) the need to ensure that cable rates are relatively low and do not include monopoly rents, against (b) the need to ensure that cable systems earn a reasonable return so that they can continue to attract capital necessary to operate and to expand the services they provide to their subscribers. To the extent that local or state regulation of basic rates constrains the revenue and profits obtained from the basic tier, cable operators may seek to earn relatively more revenue and higher profits on their programming services beyond the basic tier. Hence, there may be a tradeoff between the severity of the restrictions that may be placed on basic tier rates and rates for other programming services. The FCC seeks comment on how this tradeoff can best be made in our cable rate regulations.

The Cable Act defines "cable programming service" as any video programming provided over a cable system, regardless of service tier, including installation or rental of equipment used for the receipt of such video programming, other than (A) video programming carried on the basic service tier, and (B) video programming offered on a per channel or per program basis.

Thus, cable programming service encompasses all video "tiered" programming, other than that included in the basic service tier, and would exclude all pay-per-channel or per-program material. As noted in the legislative history of the Cable Act, some cable systems are "experimenting with 'multiplexing'—the offering of multiple channels of commonly-identified video programming as a separate tier (*e.g.*, HBO1, HBO2 and HBO3)." The FCC thus proposes to exclude from the definition of "cable programming service," pay-per-channel or pay-per-program services offered on a multiplexed or time-shifted basis. The NPRM seeks comment on whether, for a tiered offering of a multiplexed premium service to be exempt from rate regulation, the multiple channels offered would have to consist of essentially the same programming offered on a time-shifted basis.

b. *Complaint procedures; rate reduction and refund procedures for rates found to be unreasonable.* The Cable Act requires that the Commission establish "fair and expeditious procedures" for receiving, considering and resolving complaints from "any subscriber, franchising authority, or other relevant State or local government entity" alleging that rates for cable programming services are unreasonable pursuant to our rules. The statute specifically states that the Commission must specify the minimum showing required for a complaint to obtain Commission consideration and resolution. A complaint is timely only if filed during the 180-day period following the effective date of the Commission's regulations governing unreasonable rates for cable programming services or within a reasonable period of time after the cable operator changes its rates. This time constraint on filing complaints also applies to complaints concerning changes in rates that result from changes in the system's service tiers.

The legislative history indicates that Congress intended the Commission's regulations not to be "so technical or complicated as to require subscribers to retain the services of a lawyer to file a complaint and obtain Commission consideration of the reasonableness of the rate in question." The Commission thus plans to devise procedures that are not only fair to all parties, but are also simple and expeditious. One alternative is to require that complaints concisely state facts showing how an operator has violated the Commission's rate regulations. The Commission recognizes, however, that the ratemaking methodology it adopts, even if very simple, may not be readily accessible to the ordinary subscriber. In addition, the legislative history indicates that Congress deliberately excluded the requirement that a complaint demonstrate a "prima facie case". Thus, if the Commission adopted this requirement, and a subscriber's complaint failed to conform, the Commission might, instead of dismissing it out of hand, send the subscriber an informational letter describing what a complaint should state, and permitting refiling within a set period, for example, 30 days. The filing of the first complaint would act to toll the time limit on complaints. On the other hand, although rigorous technical requirements should not be imposed, this Commission and cable operators need assurance that the Commission's procedures permit only genuine allegations of illegal rates to go forward, and do not permit complaints that are frivolous or lack any serious substantive allegation to proceed.

A second alternative, therefore, is to set an even simpler standard for a subscriber complaint, and to make this a minimum standard which would have to be met in order to avoid dismissal. We observe that if a straightforward benchmark approach is adopted, a statement of facts showing that rates were above the benchmark might be easily done by a layman. The complaint would have to allege that the complainant was a subscriber of a cable system named in the complaint, and also state the name of the franchising authority. The simplicity of this second approach would facilitate the filing of subscriber complaints. However, it

might not give the cable operator sufficient notice of the precise claims made, and might place greater demands on Commission staff seeking to determine the issues and resolve the dispute. It also might not adequately screen frivolous or unsubstantiated complaints. The Commission seeks comment on these two alternative standards for defining the minimum showing required for substantive complaints. The Commission also invites additional suggestions.

Interested parties are also asked to comment on specific forms or language that might be standardized for use by subscribers in filing rate-related complaints. The Commission also asks for comment on how such standardized information might be made widely available. For example, should it be given to local franchising authorities for local distribution? The Commission also seeks comment on whether complaints filed by franchising authorities or parties represented by counsel could or should be held to a different pleading standard, and if so, what that standard should be. The Commission also seeks comment on whether subscribers should be permitted, or required, to obtain a franchising authority's decision or concurrence as a precondition to the filing of a valid complaint. Parties advocating such an approach are asked to reconcile it with the specific provision in the Act permitting subscribers, as well as relevant governmental entities, to file complaints.

The Commission proposes to require that all complaints be served on both the cable operator and the franchising authority by the complaining parties. After a complaint is served, an operator would have a reasonable period of time in which to file a response. Based on the complaint and response, the Commission would make a determination of whether a complainant had made a minimum showing to permit the case to go forward. Once the Commission has determined, based on a review of the two documents, that a minimum showing of a violation of its rules had been established, the Commission would issue an order asking for further information from the operator, and setting a further pleading schedule, if necessary. At this point the operator would have the burden of producing evidence to disprove the allegations. This alternative should prove expeditious and easy for non-lawyers to use. The Commission seeks comment on these tentative conclusions and proposals. In particular, the Commission asks interested parties to comment on what the appropriate pleading cycle should be, taking into account the statute's dual objectives of expedition and fairness. Alternatively, the Commission seeks comment on whether it should require that cable operators answer complaints that the Commission has determined are in good faith and raise a genuine substantive issue. Under this approach, a cable operator would not be required to respond automatically to complaints. Rather, the Commission (or the subscriber) would notify the operator of a complaint after it had been initially reviewed by Commission staff and found to meet this minimum showing.

The Cable Act provides that, with one exception, the Commission's procedures for cable programming service complaints shall be available only to those filing within a "reasonable period" after a change in rates, including a change resulting from a tiering change. The Commission tentatively finds that a time limit of 30 days from the time that a subscriber receive notification of such a rate change would provide adequate opportunity for a subscriber to formulate a complaint under the simplified procedures the Commission contemplates. The Commission seeks comment on whether this would be a reasonable period of time within the meaning of the statute. The Commission also asks for comment on whether it should allow an additional 30 days if the Commission requires the concurrence of a franchising authority for the filing of a complaint. Section 623(c)(3) excepts from the "reasonable period of time" requirement complaints filed within 180 days following the effective date of the Commission's regulations concerning cable programming service rates. During this period, subscribers and other interested parties will have become familiar with the Commission's new regulations. The Commission thus interprets this exception to permit subscribers to complain of any cable programming services rates within that 180-day period, regardless of when those rates were initially effective. After this 180-day period passes, subscribers would be held to the 30-day time limitation. The Commission seeks comment on these tentative conclusions.

The Commission also seeks comment on how to treat information which may be necessary to a decision, but which the cable operator regards as proprietary. The Commission's existing rules authorize the withholding of trade secrets or confidential financial or commercial information from routine disclosure to the public. As a general matter, however, the Commission believes the burden should be firmly on the cable operator involved to demonstrate that significant competitive injury might result from any disclosure of information used in the rate regulation process and that as full a disclosure as is reasonably possible should be mandated. The Commission seeks comment on whether its existing rules would be adequate in a cable rate dispute, and whether they are sufficiently flexible to permit an opposing party to have access to the information necessary for its case. In particular, the Commission also asks whether it should devise procedures permitting the parties to a dispute limited access to proprietary information in specific cases, and in what cases such limited access would be appropriate. Should the Commission permit an operator to redact confidential information in the first instance, with Commission staff retaining the ability to seek further information if necessary? In such cases, should the Commission confine distribution of such information to designated representatives of parties and Commission staff? The Commission also invites comment on the types of information relevant to a cable rate determination which would likely be considered proprietary by any of the parties involved, and in particular, on any special problems that may arise from use of data proprietary to third parties.

Once a decision is made, the Commission seeks comment on what types of relief are available. The Commission assumes that its authority under the Cable Act to prevent unreasonable rates at a minimum authorizes it to order prospective reductions of rates it has found to be unreasonable. The Commission proposes to require operators to make such reduction promptly, such as, for example, within 30 days of a Commission decision finding existing rates unreasonable. The Commission seeks comment on this tentative conclusion and proposal. In addition, the Commission asks interested parties to comment on whether its ability to order prospective rate reductions would extend to prescription of specific rates.

The Commission tentatively finds that its authority under section 623(c)(2)(C) permits it to reduce rates determined to be unreasonable and to refund to subscribers the portion of such rates found to be unreasonable that subscribers paid after the filing of a complaint. The Commission proposes in the first instance to determine the amount of overcharge and to order a refund to the actual subscribers who paid this overage. It may, however, be

administratively infeasible or unreasonably burdensome to determine the actual subscribers who paid the unreasonable rate. In such cases, the Commission proposes to order a prospective percentage reduction in the unreasonable service rate to cover the cumulative overcharge, and to have that reduction made in the bills sent to the class of subscribers that had been unjustly charged. This reduction would be in addition to the rate reduction necessary to eliminate prospective overcharges, and would end when compensation for the overcharge had been made. The Commission interprets its authority under section 623(c) as permitting it to reduce rates for the class of subscribers who paid for a service the rate for which was determined to be unreasonable, even if this finding was based upon a complaint filed by a single subscriber. The Commission believes that this construction is necessary to fulfill the purposes of this statutory provision. The Commission seeks comment on these tentative findings and proposals.

The Commission seeks comment on how best to device procedures that will be simple and informal, while at the same time safeguarding the due process rights of all parties involved. One option would be to treat cable programming service complaints as informal adjudications, and apply the streamlined procedures outlined just above. If this option were adopted, would it also be advisable to adopt relaxed (*e.g.*, permit but disclose) *ex parte* rules to facilitate staff resolution of a dispute in which presumably non-lawyers were participating? Another approach might be to style cable programming services complaints as ratemaking proceedings, using procedures analogous to those followed in our tariff review process. These procedures would be the sole means by which the Cable Act empowers the Commission to regulate cable programming service rates, and would determine liability for overcharges on a prospective basis only (from the time the complaint was filed). They thus reasonably could be analogized to ratemaking proceedings. Under this option, the Commission would also consider cable programming service proceedings to be non-restricted proceedings under its *ex parte* rules, subject to "permit but disclose" *ex parte* obligations. This approach would give Commission staff maximum flexibility to gather relevant information, flexibility particularly helpful in disputes where one or more parties were not represented by counsel. This approach thus also serves the Commission's objective of crafting procedures which do not require parties to have professional representation. The Commission seeks comment on these proposed alternative approaches to complaint procedures and on whether they would adequately accommodate the various policy objectives and legal constraints just articulated. Should it be necessary to establish more formal proceedings in cases involving factual disputes or potential refund liability, the Commission seeks comment on how it might accomplish this and still make these proceedings accessible to non-lawyers and to parties located in areas distant from Commission offices in Washington, DC. The commission also seeks comment on whether alternative dispute resolution would be one possible solution, should the parties agree to employ it.

Once relief is ordered, the Commission must ensure that its decision is properly effectuated. The Commission seeks comment on whether operators should be required to certify that they have implemented the Commission's decision. The Commission tentatively finds that noncomplying operators would be subject to forfeitures. The Commission seeks comment on this tentative conclusion, and on other remedies, such as reporting requirements, that may be appropriate in specific circumstances.

5. Provisions Applicable to Cable Service Generally

a. *Geographically uniform rate structure.* The Cable Act of 1992 requires cable operators to "have a rate structure, for the provision of cable service, that is uniform throughout the geographic area in which cable service is provided over its cable system."

In accordance with the above provision of the Cable Act, the NPRM proposes to incorporate into implementing regulations a provision that cable systems must have a uniform rate structure throughout the geographic area served by the cable system. The NPRM solicits comment generally on the extent to which cable operators' ability to establish service categories with separate rates and terms and conditions of service is limited by the requirement for a geographically uniform rate structure. The NPRM also seeks information on the extent to which cable operators currently enter into special service arrangements with some customers or types of customers, such as long-term service contracts with certain types of customers with discounted rates and other special terms and conditions. In addition, the FCC solicits comment on whether cable operators should be afforded the flexibility to establish *bona fide* service categories with separate rates and service terms and conditions.

The FCC tentatively concludes that the statutory requirement of a geographically uniform rate structure does not prohibit establishment of reasonable categories of service with separate rates and terms and conditions of service. The FCC tentatively concludes that the requirement for a uniform rate structure should be read in conjunction with the amendments to section 623(e), which authorize regulatory authorities to prohibit discrimination, but do not require that they do so.

The NPRM seeks comment on the meaning of the term "geographic area" as used in this section of the Act. One possible interpretation is that Congress intended this phrase to mean a franchise area. The FCC recognizes, however, that many cable systems provide service for more than one franchise area. If Congress intended to limit the meaning of geographic area to a franchise area, it could have used the less ambiguous term.

If the FCC assumes that geographic area refers to an area greater than a franchise, the Act appears to limit the region to the contiguous area served by the cable system. Under this more inclusive interpretation, the FCC would require a uniform rate structure throughout a cable system. The NPRM requests comment on whether Congress intended to require or to permit cross-subsidization to maintain uniform rates within a cable system. The FCC solicits comment on the advantages and disadvantages generally of interpreting geographic area as synonymous with franchise area or as referring to a greater area.

b. *Discrimination.* The Cable Act permits local and federal authorities to prohibit discrimination in provision of cable service, except that (1) cable operators may establish reasonable discounts for senior citizens or other economically disadvantaged groups, and (2) local and federal authorities may regulate installation or rental of equipment for the hearing impaired. Based on this provision, the Commission tentatively concludes that it should explicitly permit the discounts contemplated in the statute. Local authorities would also be free to adopt anti-discrimination provisions consistent with the statute and the Commission's implementing regulations. The Commission seeks comment on these tentative conclusions. The Commission seeks

comment in particular on whether differences in rates among different classes of customers based on differences in costs of providing services should not be prohibited under this provision. The Commission also seeks comment on what economically disadvantaged groups other than senior citizens may be awarded reasonable discounts by cable operators. The Act does not preclude local authorities from adopting regulations concerning equipment and installation which facilitate reception by the hearing impaired that are consistent with the other provisions of the Cable Act. In addition, the Commission asks whether there is any need at this time to adopt specific rules at the federal level as well.

c. *Negative option billing.* The Cable Act provides that an operator may not charge a subscriber for "any service or equipment that the subscriber has not affirmatively requested by name." The Act further provides that a subscriber's failure to refuse a proposal to provide such service or equipment "shall not be deemed to be an affirmative request for such service or equipment." The legislative history indicates that Congress did not intend this section to apply to "changes in the mix of programming services that are included in various tiers of cable service." The Commission interprets this provision to mean that, in order to be billed for any cable service (either tiers or individually priced programs or channels) or equipment, a subscriber previously must have affirmatively requested that particular service or equipment. A cable operator may not take a subscriber's inaction following the operator's proposal to provide such service or equipment as an affirmative request for the same. The Commission tentatively concludes that an affirmative request for service or equipment may occur orally or in writing so that subscribers are given flexibility to order by either method. The Commission also tentatively concludes that an operator should not be permitted to charge for any service or equipment provided in violation of section 623(f) of the Act and the Commission's implementing rules. The Commission seeks comment on this tentative conclusion. The Commission also seeks comment on whether disputes between the operator and subscriber arising under this provision would primarily be subject to resolution in the local courts. This remedy would be in addition to the forfeiture provisions applicable to the operator that fails to comply with section 623(f) and the Commission's implementing rules. The Commission remains concerned, however, that its enforcement procedures be adequate to correct any practices or patterns on the part of operators that violate the Commission's rules, and seeks comment on how the Commission can ensure its ability to do so.

The legislative history states that section 623(f) does not apply to "changes in the mix of programming services that are included in various tiers of cable service." The Commission seeks comment on the types of tier changes that may be made without violating the negative option billing restriction and in particular, whether such tier changes must be revenue neutral. Can they involve additions or deletions of services? The Commission tentatively finds that a change in the composition of a tier that was accompanied by a price increase justified under its rate regulations would not be subject to the negative option billing prohibition. The Commission believes that this interpretation will avoid an undesirable stalemate in system offerings, to the public's detriment. The Commission also does not believe that Congress intended the negative option billing provision to apply to system-wide upgrades in equipment accompanied by a justified price increase. Otherwise the provision might discourage operators from making beneficial system improvements. However, the Commission also seeks comment on whether subscribers should be given 30-days notice of changes in tier composition or in system equipment, that are accompanied by a price increase. The Commission also seeks comment on the interplay between the negative option billing provision and the prohibition on evasions pursuant to section 623(h).

The Commission also seeks comment on how this provision should apply to initial implementation of the basic cable service rate structure. For example, an operator may have been offering a basic service consisting of more channels than are now required under the Cable Act's definition of basic service. It may now effectively be required to split its former basic service into the Act's formulation of basic service and an expanded basic tier. If some subscribers do not affirmatively request both basic and expanded basic, the Commission seeks comment on whether the operator may nevertheless continue to bill them at the old rate. What if the operator has also changed the rates?

d. *Collection of information.* The statute requires cable operators to file annually with the FCC or franchising authorities, as appropriate, beginning one year from the date of enactment, such financial information as is necessary to administer and enforce rate regulation.

The information that regulators will need to assure that they can effectively administer and enforce the requirements of section 623 will be determined by the alternative that we ultimately adopt. In order to assure that the FCC can adopt a collection of information requirement that will permit effective administration and enforcement of section 623, it is proposing to collect on an annual basis the information specified in appendix C of the NPRM and the information collected by the Commission in the Order, MM Docket No. 92–266, FCC 92–545, adopted December 10, 1992. The FCC will also need to collect information concerning rates of systems subject, and not subject, to effective competition to enable us to publish the annual reports on average prices required by section 623(k).

The FCC solicits comment generally on the appropriate scope of information that it should collect pursuant to section 623(k). The FCC solicits comment on the availability of the information specified in appendix C of the NPRM, on whether cable systems will ordinarily have developed this information, and the burdens that the collection of this information would impose. To the extent this information is not already developed by cable systems, the NPRM solicits comment on the extent to which the FCC should require that they develop it, and on time periods that the FCC should permit for its development. The FCC solicits comment on whether it should require the information specified in appendix C of the NPRM to be submitted by every cable system. Alternatively, the NPRM seeks comment on whether the FCC should rely instead on a sampling of systems, and, if so, what sampling methodology it should use. The NRPM also solicits comment on whether, in order to reduce burdens on systems with 1000 or fewer subscribers, the FCC should require less information, or no information, from such systems.

e. *Prevention of evasions.* The Cable Act requires the Commission to promulgate regulations that will prevent evasion of its rate regulation provisions and, specifically, evasions resulting from retiering. The statute requires that the Commission periodically review these regulations. The Commission proposes generally to prohibit evasion of its rate regulations by cable operators. The Commission proposes to allow interested parties to avail themselves of the expedited procedures the Commission establishes for rate relief to

seek redress of evasions of its rate regulations. The Commission plans to periodically review the standards it establishes pursuant to this subsection, with the first review occurring two years from the rules' effective date, and with periodic reviews every three years thereafter. The Commission seeks comment on these proposals.

As the legislative history contemplates, the Commission proposes to prohibit retiering that "shift[s] cable programs out of the basic service tier into other packages" and causes an unjustified increase in rates to subscribers for cable service. At the same time, the Cable Act of 1992 permits, and indeed appears to require in some cases, a restructuring of service offerings. Thus, the Commission proposes to prohibit retiering which actually results in an increase in regulated rates inconsistent with the regulations it establishes. Thus, retiering necessary to comply with basic tier requirements, retiering that did not change the ultimate price for the same mix of channels in issue to the subscriber, or retiering accompanied by a price change that complied with the Commission's rate regulations would not be deemed an evasion. The Commission seeks comment on this proposal. It is also possible that our substantive rate regulations will lessen the potential for evasions through retiering as well. Should the Commission adopt the same rate regulation regime for both the basic tier and cable programming services, this uniformity of approach might eliminate the incentive for operators to move services from basic to cable programming services tiers in order to evade rate regulation. The Commission seeks comment on the interplay between its substantive rate regulation responsibility and its obligation to adopt rules preventing evasions. The Commission also seeks comment on whether it needs to establish specific rules regarding evasions of rate regulation through charges for changes in equipment, particularly in light of the specific rules the Commission is adopting regarding such charges. Finally, the Commission seeks comment on other specific evasive acts and practices that should be prohibited. For example, the Commission seeks comment on whether retiering and repricing of cable services between the effective date of the Act and the implementation of these regulations could, if found to be unreasonable or evasive, raise specific concerns under the Commission's proposed enforcement scheme.

f. Small business burdens. The Cable Act requires that the Commission develop and prescribe cable rate regulations that reduce the administrative burdens and cost of compliance for cable systems that have 1000 or fewer subscribers. The Commission seeks comment on how best to effectuate this statutory requirement. The Commission's current rules exempt operators of cable systems of fewer than 1000 subscribers from certain administrative requirements. The Commission similarly could exempt cable systems of fewer than 1000 subscribers from certain administrative burdens associated with the rate regulations it establishes. Depending on the substantive ratemaking standard adopted, the Commission might, for example, exempt small systems from certain accounting requirements or the obligation to submit certain data. With respect to the data collection requirements of the Act, the Commission might rely on external sources of data or, if necessary, special studies instead of requiring individual reports from small systems. The Commission seeks comment on this general proposal, as well as on the specific requirements from which small systems might appropriately be exempted. Parties are also invited to comment on other alternatives, *e.g.*, the filing of abbreviated reports or other streamlining of administrative obligations that also might be appropriate. The Commission also seeks comment on ways it might coordinate any administrative requirements with the actual operations of small cable systems.

The Commission also seeks comment on whether it should exempt small systems from any substantive or procedural rate regulation requirements and, if so, which ones. The Commission's current rules exempt small systems from network non-duplication protection requirements, syndicated exclusivity rules, and from certain technical standards and performance testing requirements. A community unit having fewer than 1000 subscribers currently is exempt from the sports broadcast blackout rule. Are there requirements in the Commission's proposed rate regulation regime from which small systems may also appropriately be exempt? In this regard, the Commission also seeks comment on whether it should establish a presumption that systems with under 1000 subscribers are, because of the underlying costs involved and the small base over which these costs can be spread, unlikely to be earning returns or charging rates that could effectively be altered to the benefit of subscribers through detailed regulatory oversight. A second option might be to permit small companies to certify their compliance with the Commission's rate regulations. A third option might be to tailor the Commission's rate regulations specifically to small companies. The Commission might, for example, devise basic cable rate regulations that assure that high-cost small systems will be able to fully recover their costs. The Commission seeks comment on these substantive approaches to alleviating regulatory burdens on small systems and on whether they harmonize with the general objectives of the Cable Act. In addition, the Commission might exempt small systems from certain procedural requirements, including, for example, the filing of rate schedules. The Commission might also modify requirements such as burden of proof or information production for small systems in contested cases. The Commission seeks comment on these procedural approaches to alleviating regulatory burdens on small systems.

Finally, in making some or all of these small system exceptions, should the Commission distinguish between independently owned stand-alone systems of under 1000 subscribers and systems of under 1000 subscribers which are owned by a large MSO? Although the plain language of the statute makes no such distinction, the Commission questions whether systems in the latter case need such regulatory protection. A small cable system affiliated with an MSO may enjoy advantages such as program discounts or access to corporate resources that stand-alone small systems do not, and thus may not need the protection section 623(i) offers. It might also be appropriate to distinguish between larger and smaller MSOs if the Commission distinguished between MSO and independently-owned systems. For example, the Commission might distinguish a system directly or indirectly owned by a cable operator that directly or indirectly owns other cable systems, which altogether serve some specific number of subscribers. Parties advocating such an option are encouraged to suggest specific subscriber numbers that might serve to distinguish large from small MSOs.

With the exception of the sports blackout rule, the size of a cable system is determined under the Commission's current rules according to the number of subscribers served by a single integrated headend. In contrast, the community unit measurement used in the sports blackout rule defines a system in a

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narrower manner, according to what is essentially the cable franchise area. Use of the single integrated headend might help ensure that what is in practice a large system fully capable of meeting the Commission's requirements does not qualify merely because it covers numerous franchise areas, each under 1,000 subscribers. The Commission seeks comment on whether either of these two definitions might be appropriately applied in the context of rate regulation of small cable systems. The Commission also asks interested parties to suggest any alternative definitions they believe would be appropriate under the Cable Act. Finally, the Commission seeks comment on whether a system's qualifying for small system treatment should be based upon the average number of subscribers over a period of years, rather than the number of subscribers as of a specific date. The former standard would avoid abrupt or frequent changes in regulatory status resulting from seasonal or other brief fluctuations in the subscriber base.

g. *Grandfathering of rate agreements.* The Cable Act provides that the statute and its implementing regulations do not supersede franchising agreements made before July 1, 1990 that authorize regulation of basic cable service rates if there was not effective competition as of that date. The provision states that such agreements are to remain in effect "during the term" of such agreements. The Commission tentatively concludes that this provision authorizes a franchising authority with a franchise agreement executed before July 1, 1990, that was regulating basic cable rates at that time to continue regulating basic cable rates for the remaining term of that agreement without certification from this Commission. The Commission tentatively concludes that such franchising authorities (who are not required to apply for certification) should nevertheless be required to notify this Commission that they intend to continue to regulate basic cable rates under the provisions of section 623(j). This notification will give the Commission the information it needs to compile the annual reports on average prices required under the Cable Act. The Commission seeks comment on these tentative conclusions. The Commission also seeks comment on whether an agreement that falls within the terms of section 623(j) would supersede Commission regulations governing the rates for cable programming services that are not part of the basic tier as defined in the agreement and thus not subject to regulation under the agreement. The Commission also seeks comment on how franchising authorities now regulating rates and that are not covered by the grandfathering provision just discussed should make the transition to rate regulation under the Commission's new rules.

h. *Reports on average prices.* The statute requires the Commission to publish annual statistical reports comparing charges for the basic tier, cable programming services, and equipment by cable systems subject to, with those charges by systems not subject to effective competition. In order to comply with these requirements, the Commission will need to collect certain cable system data. These data include rates charged for basic cable service, expanded basic service, and other cable programming; and fees for converter boxes, remote control units, program guides, installation and disconnection charges, and any other charges for equipment or service. Because the Commission may wish to compare systems of similar sizes or other characteristics, the Commission proposes also to collect information on system size (measured by number of subscribers), system channel capacity, and possibly other characteristics such as percent of distribution plant above or below ground, length of distribution plant, and subscriber density per mile. The Commission envisions that the annual statistical report will consist of a compilation of the above data elements.

There are a number of possible ways to collect the specific data. Trade publications such as the Cable Fact Book collect much of the data we require, but such data are collected on a voluntary basis and are not always complete for each individual cable system. It appears to be necessary, therefore, to require cable operators to submit certain information directly to the Commission on a regular basis. Such information obtained directly from cable operators would be reliable, complete and comparable. The Commission requests comment on the specific data to be collected. For example, should the data submitted be on a per system rather than a per franchise basis? Further, the Commission notes that the data it proposes to collect for the annual report on rates may duplicate in part the data needed to carry out the ongoing rate regulations provisions of the Cable Act. In addition, depending on the particular rate standard the Commission ultimately adopts, the Commission may also need data on various costs and other financial information. The Commission tentatively concludes that it should combine all data requirements on a single form and requests comment on that conclusion.

The Commission realizes that annual collection of data will be costly for both the industry and the Commission. One option for minimizing these costs would be to collect data from a sample of cable systems rather than from the industry as a whole. The Commission seeks comment on how to identify systems subject to effective competition. The Commission seeks comment on this issue. Finally, commerters are invited to suggest other ways the Commission may obtain the data needed to fulfill the annual reporting requirements specified in section 623 (k).

i. *Definitions.* The statute includes definitions of effective competition, cable programming service, and multichannel video programming distributor. In order to implement the statutory definitions and rules to incorporate these terms, the NPRM proposes to adopt the definitions without change. The FCC solicits comment on this proposal. The FCC additionally solicit comment on whether it should establish any additional definitions in our rules.

j. *Effective date.* The statute provides that the amendments to section 623 establishing rate regulation of cable systems not subject to effective competition shall be effective 180 days from the date of enactment. The statute gives the FCC authority to prescribe regulations effective on the date of enactment. The statue expressly requires the FCC to establish regulations concerning rates for the basic service tier, rates for cable programming service, and prevention of evasions within 180 days of enactment.

In order to assure that the FCC meet the statutory deadline for implementing regulations, we propose to adopt implementing rules prior to April 3, 1993 and to make them effective as rapidly thereafter as is reasonably feasible. The NPRM seeks comment on this proposal and on what if any interim requirements may be necessary as the rules come into force. The FCC has tentatively concluded that, while its regulations must be in place 180 days from the date of enactment, the statute does not require that all implementing steps that cable systems must take to meet the obligations of the statute or our rules must be completed on that date.

D. Leased Commercial Access

1. Statutory Requirements

Section 612 of the Communication Act states that its purpose is to assure that the widest possible diversity of information sources is made available to

the public from cable systems in a manner consistent with growth and development of cable systems. The amendments to section 612 of the Communications Act contained in the Cable Act of 1992 add an additional purpose to the section: To promote competition in the delivery of diverse sources of video programming. Other amendments to section 612 grant the Commission authority: To determine the maximum allowable rates that a cable operator may establish for leased commercial access, including the rate charged for billing and collection services; to establish reasonable terms and conditions for commercial use of the system, including those to govern billing and collection; and to establish procedures for expedited resolution of disputes concerning rates or carriage. The FCC is required within 180 days of enactment to adopt regulations exercising authority in these areas.

2. Discussion

a. *Maximum reasonable rates.* The language of section 612, as amended by the Cable Act of 1992, that governs leased commercial access does not limit its application to only cable systems not subject to effective competition as the Act defines that term. Accordingly, the FCC tentatively concludes that our regulations governing the maximum reasonable rate for leased commercial access will apply to all cable systems. The NPRM also tentatively concludes that the Cable Act of 1992 does not necessarily require cable operators to provide billing and collection services. Rather, the FCC believes that Congress intended only that we establish regulations governing the maximum rate for such services if an operator chooses to offer them. The FCC also tentatively concludes that it should require that any charges for billing and collection services that a cable operator may elect to provide be unbundled from other charges for leased commercial access.

The FCC has initially identified three alternative standards for determining maximum reasonable rates for leased commercial access and for billing and collection services: Reliance on benchmark rates based on costs of typical cable systems, reliance on the cost-of-service principles, and reliance on the marketplace where effective competition exists. A fourth possibility, not explored in detail in the NPRM but on which comments are solicited, would be for the FCC to establish a mechanism or formula under which subscriber rates for the basic service tier and/or cable programming services could be used to compute a rate for leased commercial access. Additionally, the NPRM seeks comment on whether we should establish additional rate ceilings to govern rates for not-for-profit programmers.

Benchmark Based on Typical System Costs. Under this alternative, rates for leased commercial access would be governed by a benchmark based on costs incurred by a typical or ideal cable system for constructing and operating channel capacity. Such a benchmark would be particularly useful for cable systems whose rates for basic tier service and cable programming service were not subject to individual system cost-based regulation, possibly because they also met a benchmark.

Cost-of-Service. Under this alternative, the maximum reasonable rates for leased commercial access and for billing and collection services would be designed to recover the costs of providing those services. Under this alternative, the FCC would require that the maximum reasonable rate would be based on all direct costs, an allocation of the joint and common costs of access and of providing other cable services, an allocation of general and administrative overheads, and a reasonable profit determined under cost-of-service regulatory principles that were previously discussed. Should the FCC select the cost-of-service alternative, the NPRM solicits comment on whether the FCC should require a fully distributed cost methodology to identify the joint and common costs to be recovered through rates for leased channel access or for billing and collection services.

Marketplace Rates. Under this alternative, the FCC would determine that where a competitive market exists for leased commercial access or for billing and collection services there would be no prescribed price or ratemaking methodology. The FCC solicits comment on this approach generally and, in particular, on whether it is consistent with congressional intent and whether the Cable Act of 1992 authorizes us to rely on market forces to set such maximum rates. The NPRM also solicits comment on the extent to which a competitive market for leased commercial access currently exists. The NPRM solicits comment on whether the billing and collection services that were considered by the Commission in connection with telephone companies are the same as, or relevant to determining proper treatment of, the billing and collection services that cable systems might offer in connection with leased commercial access.

Special Rates for Not-for-Profit Programmers. The NPRM solicits comment generally on the need for special rates for not-for-profit programmers. The NPRM seeks comment on whether the Cable Act of 1992 empowers the FCC to set a lower maximum rate for leased commercial access for not-for-profit programmers, and ask whether this could help assure the diversity of programming sources on cable systems sought by the drafters of Section 612. The FCC asks to what extent it can permit costs of providing leased commercial access to not-for-profit programmers to be recovered from other leased access customers or from cable subscribers on all tiers generally.

In addition to the above proposals, the NPRM solicits comment on whether we need to take any measures to assure that our regulations governing maximum resale rates for leased commercial access are fulfilling the statutory objectives of section 612. The NPRM solicits comment on relying on the complaint process to monitor the effectiveness of our regulations. Alternatively, or in addition to the complaint process, the FCC could establish a reporting requirement that will enable us to track the use of leased commercial access and rates charged for that use.

b. *Reasonable terms and conditions of use.* Section 612(c)(4)(A)(ii) requires the Commission to "establish reasonable terms and conditions" for commercial use of leased access cable channels. In enacting this Section, Congress was particularly concerned that leased access programmers be offered a "genuine outlet" for their product. Thus, the Commission seeks comment on whether it needs to address in its rules tier location, channel position, and time scheduling for leased access use. The Commission also seeks comment on how such an alternative could be fashioned so that it intruded minimally upon programming decisions negotiated by private parties and on the discretion of the cable operator with respect to channel positioning and configuration of its system. However, the general prohibition on the cable operator's exercising editorial control over leased access remains intact, and Congress has expressed concern over providing leased access programmers "genuine outlet." Thus, the Commission seeks comment on the appropriate scope of the operator's discretion regarding tiering and channel location for leased access.

The Commission tentatively concludes that it should establish guidelines for technical standards and conditions for leased access. The Commission proposes to require that operators apply the same technical standards they apply to programs to be carried on public, educational, and governmental access channels to leased

access programs. Thus, an operator could not reject for technical reasons a program for leased access airing if it would not reject the program for the same reasons for airing on public, educational or governmental access channels. The Commission seeks comment on this proposal. The Commission also seeks comment on what, if any, technical and production facilities the cable operator should be expected to offer leased access users. The Commission also asks when the operator should be able to require posting of a bond or deposit, and what the impact of any bond or deposit requirement would be on programmers' ability to secure access to leased channels.

While the Communications Act does not give cable operators editorial control over leased access programming, the Cable Act does permit operators to prohibit or to channel indecent material on leased access channels. The Commission is presently considering how to implement these provisions of the Act. The Commission proposes generally to prohibit a cable operator from setting terms or conditions for leased access use based on content. The Commission proposes to except from this prohibition those terms and conditions relating to indecent material that would be consistent with the Cable Act and the implementing regulations the Commission ultimately adopts. In addition, as provided in existing section 612(c)(3) of the Communications Act, an operator may consider content "to the minimum extent necessary to establish a reasonable price for the commercial use of designated channel separately by an unaffiliated person." The Commission seeks comment on this approach.

Existing section 612(c)(1) provides that an operator shall establish prices, terms and conditions for leased access to an unaffiliated user at least sufficient to ensure that such use "not adversely affect the operation, financial condition, or market development of the cable system." The Commission seeks comment on how to ensure that regulations it establishes for leased access terms and conditions are consistent with this provision and do not undermine the financial condition of the cable system, while at the same time harmonizing with the statutory provisions governing the maximum rate for leased access. The legislative history of the 1984 Act indicates that Congress contemplated different treatment of leased access providers, who by definition are unaffiliated with the operator, and of affiliated entities who may also lease a channel or have an equivalent arrangement. It is unclear whether in passing the 1992 Cable Act, and requiring us to establish reasonable terms and conditions for leased access use, Congress intended to reinforce or reduce such differentiation. The Commission thus seeks comment on whether it has the authority to require and, if so, whether it should require operators to apply the same terms and conditions to the leasing of channel capacity by both affiliated and nonaffiliated users. If so, would this requirement extend to services such as billing and collection? The Commission also seeks comment on how its regulations might permit the beneficial discrimination which Congress considered might be necessary to establish terms and conditions that might be needed, for example, by non-profit program suppliers. The Commission also seeks comment on whether there is any need to reconcile the amendments made by the Cable Act of 1992 with the existing statute and its underlying objective of promoting diversity. For example, one may speculate that if rates for leased access are low enough, unaffiliated programmers may seek to move their program offerings from other channels to those set aside for leased access, thereby diminishing the number of channels available for leased access without adding to the diversity of programming offered on the system. The Commission seeks comment on the probability of such migration occurring, the likely impact of such actions, and whether there is any need to take regulatory action at this time to prevent it.

c. *Procedures for expedited resolution of disputes.* The Cable Act requires that the Commission establish procedures "for the expedited resolution of disputes concerning rates or carriage" of leased access. The legislative history of section 612(c)(4)(A) indicates that Congress believed that existing provisions of the Cable Act of 1984 entitling aggrieved leased access users to bring action in federal district court or file complaints at the Commission were too cumbersome. Congress believed these provisions, together with the imposition of a high burden of proof on access users, may have led to limited demand for leased access. One means of fulfilling Congressional intent to increase use of leased access channels would be to streamline this Commission's dispute resolution procedures for aggrieved leased access users. Thus, the Commission proposes to permit an aggrieved access user to file a petition for relief alleging that an operator's rates or terms and conditions for use of leased access capacity violate the Commission's rules. Should the Commission determine that a *prima facie* case of violation of its rules has been made, the burden of production would then shift to the operator to disprove the allegations. At this stage, the Commission might also issue an order requesting further information from the operator, under procedures analogous to those established for complaints of unreasonable rates. The Commission seeks comment on this approach.

The Commission proposes that if a petitioner has made out a *prima facie* case of a violation of its rules promulgated pursuant to Section 612(c), this case would be sufficient to rebut the presumption established in the 1984 Cable Act that the prices, terms and conditions for leased access are reasonable. If such allegations are proven, they would constitute clear and convincing evidence of unreasonable practices or rates and meet the burden of proof imposed under the Act. The Commission seeks comment on this proposal. The Commission also seeks comment on alternative approaches to reconciling the provisions of the 1984 Act (which presume that the operator's good faith prices, terms and conditions are reasonable) with the provisions of the 1992 Act (which require the Commission to establish reasonable terms and conditions and to determine maximum reasonable rates for leased access).

As a matter of general policy, the Commission also believes that parties should bring complaints to the Commission's attention in a timely manner. This policy will help to guard against determinations based on a stale record, as well as forestall development of any patterns of abuse. The Commission also proposes to give oral rulings in those situations in which time is of the essence, to be followed by a written formal ruling. The Commission seeks comment on what types of cases might be appropriate for such emergency treatment. The Commission tentatively finds that rate disputes, which are generally complex in nature, should not be the subject of emergency action at the Commission. The Commission believes that it would be possible in such cases to devise procedures that will enable a user to have access before a Commission decision is made. The Commission proposes to require that the user provide some form of security, *e.g.*, establish an escrow account, while the rate dispute is being determined, and seeks comment

on the fairness of this procedure to all parties involved.

The Commission seeks comment on the use of Alternative Dispute Resolution ("ADR") for leased access petitions filed at the Commission. The legislative history reflects concern that "cumbersome" administrative procedures may have limited usefulness for leased access. In light of this history, when the circumstances of a given case are fairly straightforward, the Commission tentatively concludes that ADR may be the most appropriate means of resolving conflicts by providing both expedition and cost-effectiveness. The Commission also assumes that it could be made available to parties in the franchise area in which they are located, adding the benefit of geographic convenience in such cases. The election of mediation by the parties would be purely voluntary under the Administrative Dispute Resolution Act, 5 U.S.C. 582(c) (1990). The Commission seeks comment on this approach, and on whether the Commission should encourage its use. The Commission also seeks comment on whether parties should be permitted to elect ADR at the outset of a dispute or whether election should take place only at the time the Commission rules that a *prima facie* case has been established. The Commission also seeks suggestions on what types of disputes would be most suitable for ADR. Specifically, the Commission seeks comment on whether conflicts concerning rates, credit terms, technical quality, or other terms or conditions would reasonably lend themselves to resolution by mediation, or whether certain categories of disputes would be better resolved by other means.

The Commission also seeks comment on whether and how it might enlist the assistance of local franchising authorities in resolving leased access disputes. The Commission thus asks whether parties should be permitted to seek resolution of leased access disputes by franchising authorities. The Commission seeks comment on whether this option should be voluntary, or possibly be required as a prerequisite to review by this Commission. On the latter point, the Commission seeks comment on whether such a requirement would be consistent with the language and intent of the Cable Act. Finally, the Commission seeks comment on what types of leased access disputes may be suitable for franchising authority resolution.

d. *Leased access for quality minority programming and qualified educational programming.* The Cable Act permits a cable operator to place programming from a qualified minority or educational programming source on up to 33 percent of the cable system's designated leased access channels. Programming already carried by a cable system as of July 1, 1990 does not qualify as minority or educational programming for purposes of this section. The Act defines a qualified minority programming source as one that devotes substantially all of its programming to coverage of minority viewpoints, or to programming directed at members of minority groups, and which is over 50 percent minority-owned, as the term minority is defined in section 309(i)(3)(C)(ii) of the Communications Act. The Act defines a qualified educational programming source as one that devotes substantially all of its programming to educational or instructional programming that promotes public understanding of mathematics, the sciences, the humanities, and the arts and has a documented annual expenditure on programming exceeding $15 million. The Commission proposes to adopt this subsection as part of its rules. The Cable Act defines "minority" with reference to section 309(i)(3)(C)(ii) of the Communications Act, which identifies Blacks, Hispanics, American Indians, Alaska Natives, Asians, and Pacific Islanders as minority groups. The Commission thus tentatively finds that, for purposes of the minority programming provision, programming that covers "minority viewpoints" or is "directed at members of minority groups" would have to cover the viewpoints of or be targeted to members of the above-listed groups. The Commission seeks comment on this proposal and tentative conclusion. The Commission also proposes to reflect the statutory definition of educational programming source described above in its rules. The Commission seeks comment on this proposal.

The Act qualifies minority and educational programming sources for leased access under this section if they devote "substantially all" of their programming to the coverage of minority viewpoints or to educational or instructional programming. The Commission seeks comment on the amount or proportion of programming necessary to fulfill this requirement.

C. Subscriber Bill Itemization

Section 622(c) of the Communications Act, as amended by the Cable Act, permits a cable operator to itemize, on separate lines on each regular subscriber bill, (1) the amount of that bill attributable to the franchise fee, together with the identity of the franchising authority to which the fee is paid, (2) the amount attributable to the support or use of public, educational, or governmental channels which is required under a franchise agreement, and (3) the amount of the total bill attributable to any other governmental assessments on transactions between the operator and the subscriber. The Conference Report states that an amendment was made to the legislation to clarify that itemization must be done in a manner consistent with the Commission's regulations implementing section 623. The House Report indicates that only direct and verifiable costs within the above-listed categories may be so itemized. Section 623 provides that rules governing basic service rates shall take into account "the reasonably and properly allocable portion" of amounts assessed as franchise fees, taxes, or governmental charges assessed on operator/subscriber transactions, and any amount required to satisfy franchise requirements to support public, educational, or governmental channels, or the use of such channels under a franchise. The Commission seeks comment on the possible differences and the interrelationships between section 622(c) and section 623. The House Report also indicates that Congress explicitly intended that such costs be itemized as part of the total bill, but not separately billed. The Commission proposes to reflect this Congressional intent in its rules incorporating section 622(c). The Commission seeks comment on this proposal, and on any other regulations that may be necessary to adequately implement this provision.

Initial Regulatory Flexibility Act Analysis

Pursuant to section 603 of the Regulatory Flexibility Act, the Commission has prepared the following initial regulatory flexibility analysis (IRFA) of the expected impact of these proposed policies and rules on small entities. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the regulatory flexibility analysis. The Secretary shall cause a copy of this Notice, including the initial regulatory flexibility analysis, to be sent to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, Public Law No. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981).

Reason for action. The Cable Television Consumer Protection and Competition Act of 1992 requires the Commission to prescribe rules and regulations for determining reasonable rates for basic tier cable service, including rates for equipment and installation, and procedures for implementation and enforcement of those rules. The Cable Act of 1992 also requires the Commission to establish criteria for identifying unreasonable rates for cable programming services, and procedures for resolving complaints regarding cable programming services. In addition, the statute requires the Commission to establish rules for determining the reasonable terms and conditions and maximum reasonable rates for leased commercial assess, including billing and collection.

Objectives. To propose rules to implement sections 3 and 14 and those portions of section 9 pertaining to rate regulation, of the Cable Television Consumer Protection and Competition Act of 1992. We also desire to adopt rules that will be easily interpreted and readily applicable and, whenever possible, minimize the regulatory burden on affected parties.

Legal basis. Action as proposed for this rulemaking is contained in sections 4(i), 4(j), 303(r), 612(c), 622(c) and 623 of the Communications Act of 1934, as amended.

Description, potential impact and number of small entities affected. Until we receive more data, we are unable to estimate the number of small cable systems that would be affected by any of the proposals discussed in the Notice of Proposed Rulemaking. We have, however, attempted to reduce the administrative burdens and cost of compliance for cable systems that have 1,000 or fewer subscribers as required by section 3(i) of the Cable Act of 1992.

Reporting, record keeping and other compliance requirements. The proposals under consideration in this Notice of Proposed Rulemaking include the possibility of new reporting and record keeping requirements for cable systems.

Federal rules which overlap, duplicate or conflict with this rule. None.

Any significant alternatives minimizing impact on small entities and consistent with stated objectives. Wherever possible, the Notice proposes general rules, or alternative rules for small systems, to reduce the administrative burdens and cost of compliance for cable systems that have 1,000 or fewer subscribers as required by Section 3(i) of the Cable Act of 1992.

Paperwork Reduction Act

The proposals contained herein have been analyzed with respect to the Paperwork Reduction Act of 1980 and found to impose new or modified information collection requirements on the public. Implementation of any new or modified requirement will be subject to approval by the Office of Management and Budget as prescribed by the Act.

Procedural Provisions

For purposes of this non-restricted informal rulemaking proceeding, members of the public are advised that *ex parte* contracts are permitted from the time of issuance of a notice of proposed rulemaking until the time a draft Order proposing a substantive disposition of the proceeding is placed on the Commission's Open Meeting Agenda. In general, an *ex parte* presentation is any written or oral communication (other than formal written comments or pleadings and oral arguments) between a person outside this Commission and a Commissioner or a member of this Commission's staff which addresses the merits of the proceeding. Any person who submits a written *ex parte* presentation must serve a copy of that presentation on this Commission's Secretary for inclusion in the public file. Any person who makes an oral *ex parte* presentation addressing matters not fully covered in any written comments previously filed in the proceeding must prepare a written summary of that presentation. On the day of the oral presentation, that written summary must be served on this Commission's Secretary for inclusion in the public file, with a copy to the Commission official receiving the oral presentation. Each *ex parte* presentation discussed above must state on its face that the Secretary has been served, and must also state by docket number the proceeding to which it relates. See generally § 1.1231 of the Commission's Rules, 47 CFR 1.1231.

Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 & 1.419, interested parties may file comments on or before January 27, 1993, and reply comments on or before February 11, 1993. To file formally in this proceeding, you must file an original plus four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should sent comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, room 239, Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

Ordering Clauses

Accordingly, *it is ordered*, That, pursuant to sections 4(i), 4(j), 303(r), 612(c), 622(c) and 623 of the Communications Act of 1934, 47 U.S.C. 154(i), 154(j), 303(r), 532(c), 543, notice is hereby given of adoption of proposed regulatory changes and amendments to the Commission's rules and regulations in accordance with the proposals, discussions, and statements of issues in this Notice of Proposed Rulemaking, and that comment is sought regarding such proposals, discussion, and statements of issues.

It is further ordered, That a rulemaking proceeding is instituted to implement sections 623, 612, and 622(c) of the Communications Act of 1934, as amended by the Cable Television Consumer Protection and Competition Act of 1992.

It is further ordered, That commenters shall address in a separate section of their comments issues concerning leased commercial access raised in paragraphs 144–73 of the NPRM.

List of Subjects for 47 CFR Part 76

Cable Television, Reporting and recordkeeping requirements.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 92–31839 Filed 12–31–92; 8:45 am]

BILLING CODE 6712–01–M

Notices

Federal Register
Vol. 58, No. 1
Monday, January 4, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Summer Food Service Program for Children; Program Reimbursement for 1993

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

SUMMARY: This notice informs the public of the annual adjustments to the reimbursement rates for meals served in the Summer Food Service Program for Children (SFSP). These adjustments reflect changes in the Consumer Price Index and are required by the statute governing the Program.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Robert M. Eadie, Chief, Policy and Program Development Branch, Child Nutrition Division, Food and Nutrition Service, U.S. Department of Agriculture, Alexandria, Virginia 22302, (703) 305–2620.

SUPPLEMENTARY INFORMATION: This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3507), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.559 and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local official (7 CFR part 3015, subpart V, and final rule related notice published at 48 FR 29114, June 24, 1983).

Definitions

The terms used in this Notice shall have the meaning ascribed to them in the regulations governing the Summer Food Service Program for Children (7 CFR part 225).

Background

Pursuant to section 13 of the National School Lunch Act (42 U.S.C. 1761) and the regulations governing the SFSP (7 CFR part 225), notice is hereby given of adjustments in Program payments for meals served to children participating in the SFSP during the 1993 Program. Adjustments are based on changes in the food away from home series of the Consumer Price Index for All Urban Consumers for the period November 1991 through November 1992.

The new 1993 reimbursement rates in dollars are as follows:

Maximum Per Meal Reimbursement Rates	
Breakfast	1.1375
Lunch or Supper	2.0425
Supplement	.5350
Administrative Costs:	
a. For meals served at rural or self-preparation sites:	
Breakfast	.1050
Lunch or Supper	.1950
Supplement	.0525
b. For meals served at other types of sites:	
Breakfast	.0825
Lunch or Supper	.1600
Supplement	.0425

The total amount of payments to State agencies for disbursement to Program sponsors will be based upon these Program reimbursement rates and the number of meals of each type served. The above reimbursement rates, before being rounded-off to the nearest quarter-cent, represent a 1.6 per cent increase during 1992 (from 139.3 in November 1991 to 141.5 in November 1992) in the food away from home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of Labor. Because of the relatively small adjustment, the Department points out that several of the new administrative rates are identical to the rates in effect for the 1992 Program.

Authority: Secs. 9, 13 and 14, National School Lunch Act, as amended (42 U.S.C. 1758, 1761 and 1762a).

Dated: December 24, 1992.

Robert E. Washington,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 92–31861 Filed 12–31–92; 8:45 am]
BILLING CODE 3410-30-M

DEPARTMENT OF COMMERCE

Bureau of the Census

[Docket No. 920695–2347]

Decision of the Director of the Bureau of the Census on Whether To Use Information From the 1990 Post-Enumeration Survey (PES) To Adjust the Base for the Intercensal Population Estimates Produced by the Bureau of the Census

December 29, 1992.

AGENCY: Bureau of the Census, Commerce.

ACTION: Notice of final decision.

SUMMARY: This is a notice of the final decision of the Director of the Census Bureau on the issue of whether to use information from the Post-Enumeration Survey (PES) to adjust the base for Intercensal Population Estimates produced by the Bureau of the Census.

DATES: The decision is effective on December 30, 1992.

FOR FURTHER INFORMATION CONTACT: Peter Bounpane, Assistant Director, Decennial Census, Bureau of the Census, Telephone (301) 763–5613.

SUPPLEMENTARY INFORMATION: Title 13, U.S. Code, section 181, states that: During the intervals between each census of population required under section 141 of this title, the Secretary, to the extent feasible, shall annually produce and publish for each State, county, and local unit of general purpose government which has a population of 50,000 or more, current data on total population and population characteristics and, to the extent feasible, shall biennially produce and publish for other local units of general purpose government current data on total population. Such data shall be produced and published for each State, country, and other local unit of general purpose government for which data are compiled in the most recent census of population taken under section 141 of this title. Such data may be produced by means of sampling or other methods, which the Secretary determines will produce current, comprehensive, and reliable data.

This authority is delegated by the Secretary of Commerce to the Director of the Bureau of the Census.

On August 10, 1992 and September 17, 1992, notices were published in the

Federal Register (57 FR, Nos. 154 and 181, pp. 35562–35564 and pp. 42939–42940), informing the public about alternatives available to the Director of the Census Bureau for potential improvement in the intercensal estimates of population and to seek comments on the alternative options on this issue. In addition, a public hearing was held on August 31, 1992 at the Bureau of the Census to provide the public the opportunity to present views on this matter and to give the Bureau of the Census the opportunity to hear the comments of interested parties.

The decision process was divided into several distinct phases:

Research Phase

A program of research was undertaken following the July 15, 1991, decision of former Secretary of Commerce Robert A. Mosbacher not to adjust the 1990 census, and continued through November 1992. Following his decision, Secretary Mosbacher urged the Bureau of the Census to continue the research that was started in 1990 to determine whether the census should be adjusted using data from a post-enumeration survey (PES) and a method of population estimation called the dual system estimate (DSE) which used both census and PES results. Although former Secretary Mosbacher determined the research results were not usable for adjustment of the census, he felt that—with continued work—results might be used to adjust the base of intercensal population estimates to improve those estimates. Intercensal estimates are not prepared for census tracts and blocks, or used for redistricting, as are census data. The additional research following former Secretary Mosbacker's decision was done under the direction of a senior level group of Bureau of the Census statisticians and demographers who made up the Committee on Adjustment of Postcensal Estimates (CAPE). The Director of the Bureau of the Census was present at virtually all meetings of the CAPE and examined carefully all research reports of CAPE during the July 1991-November 1992 period of its work.

Public Commentary Phase

The **Federal Register** notices of August 10, 1992, and September 17, 1992, invited comment from the public on the issue of whether to use data from the PES to adjust the base for intercensal population estimates, and on public preferences among five options available to the Director. 1,118 individuals and organizations responded by the end of a three month period of commentary which ended November 13, 1992.

Public Hearing

On August 31, 1992, 17 individuals, some representing organizations and coalitions, testified at a public hearing on the issue.

Evaluation

In making my decision, I relied on the results of research produced under the direction of the Committee on Adjustment of Postcensal Estimates (CAPE), advice from members of CAPE and senior Bureau of the Census officials, and from a panel of outside experts who studied the matter under the aegis of the CAPE and spent a day at the Bureau of the Census. In addition, I considered all public comments received by mail and at the public hearing. These comments, as well as the appendices, CAPE Report and Addendum, referred to in the following explanation of the decision, are available for public inspection in the U.S. Department of Commerce, Central Reference and Records Inspection Facility, room 6020 Herbert C. Hoover Building, 14th and Constitution Avenue, NW., Washington, DC 20230.

Following is a detailed discussion of the decision and the basis for the decision. The discussion is in six sections:

I. Summary Statement of the Decision
II. Uses of Intercensal Population Estimates
III. Research Input into the Decision
IV. Analysis of Options Available to the Director of the Bureau of the Census
V. Adjusted Population Estimates for Survey Controls but Official Unadjusted Estimates for Use in Administering Any Law in Which Population, or Population Characteristics, Are Used to Determine Benefits
VI. Summary of the Public Commentary and Public Hearing

Date: December 29, 1992.

Barbara Everitt Bryant,

Director, Bureau of the Census.

I. Summary Statement of the Decision

Intercensal population estimates using the 1990 census as their base will not be adjusted to correct for an undercount, currently estimated as 1.6 percent nationally, in the 1990 census.

The small overall undercount makes adjustment impossible to do accurately at all levels of places, counties and states at which intercensal estimates are produced. Intercensal population estimates are made by the Bureau of the Census for the United States, the 50 states and the District of Columbia, and for 44,055 substate areas.

This decision was difficult to make because it is the unanimous opinion of senior statisticians and demographers at the Bureau of the Census comprising the Committee on Adjustment of Postcensal Estimates (CAPE) that adjustment would improve the accuracy of the 1990 census base at the national level. There is substantial consensus, but not unanimity of opinion, among CAPE members that adjustment would improve the distribution of population shares among the states, but not necessarily the share of every single state. Below the large area level, the research does not show that adjustment improves the accuracy of population estimates.

Having made the decision not to adjust the official intercensal population estimates, I am making the decision that sponsors of Federal sample surveys conducted by the Bureau of the Census will be offered the option of having their surveys calibrated to adjusted population estimates. This is described in Section V. The national surveys conducted by the Bureau of the Census are calibrated at large, aggregate levels where Census Bureau research shows adjusted estimates are, on average, more accurate.

Although the 1990 undercount is estimated as only 1.6 percent for the United States, it is higher among certain demographic groups. At the national level, at which all CAPE members have confidence that the adjusted population estimate is an improvement on the census count, there are significant differences in the undercount between residents of owner-occupied housing and residents of rental housing. Undercount rates for Blacks, American Indians, and Hispanics, but not for Asians and Pacific Islanders, are statistically significantly different from those for non-Hispanic Whites.

UNDERCOUNT RATES

Subgroup	Undercount rate (357 post-strata PES) %	Standard error (%)
Total Population	1.58	0.20
Residents of:		
Owner occupied housing	0.07	0.21
Rental housing	4.32	0.39
Persons who are:		
Non-Hispanic Whites	1.18	0.20
Males	1.52	0.23
Females	0.85	0.21
Blacks	4.43	0.51
Males	4.90	0.53
Females	4.01	0.56
Asian or Pacific Islanders	2.33	1.35
Males	3.44	1.59
Females	1.25	1.50
American Indians	4.52	1.22
Males	5.18	1.23
Females	3.86	1.24
Hispanics	4.96	0.73

UNDERCOUNT RATES—Continued

Subgroup	Undercount rate (357 post-strata PES) %	Standard error (%)
Males	5.51	0.90
Females	4.39	0.71

*Not statistically significantly different from non-Hispanic Whites (.10 level).

The method of adjustment would correct for the differential undercount measured for these groups, and thus improve the measures of their distribution throughout the population. Thus, the decision not to adjust is made particularly difficult. Unfortunately, accurate correction of the many substate areas for which the Bureau of the Census produces population estimates is not achievable with the present adjustment modeling methodology.

In making the decision not to adjust, I want to acknowledge that the research on undercount and adjustment methodologies conducted at the Bureau of the Census over the past two and one-half years has advanced knowledge substantially on both the potentiality and the difficulty of using statistical techniques to improve the accuracy of enumeration. Results of the 1990 census show that the population of the United States is very diverse in demographic composition and living arrangements, and becoming increasingly so. It is unlikely that direct enumeration can ever approach 100 percent coverage of the population—achieving net coverage of over 98 percent in 1990 was an amazing feat. Looking toward the 2000 census, the Bureau of the Census will need to work closely with the Congress in deliberating over policy alternatives for developing a design for census taking which incorporates into the final count some type of statistical estimation of those who are missed, or choose to be missed, by all types of direct enumeration.

At large aggregate levels, one has more confidence in the use of a large scale survey to adjust the census than at the smaller aggregate levels. CAPE research shows that the national population estimate produced by the post-enumeration survey and dual system estimation of 252,712,821 is closer to the true population of the United States on April 1, 1990 than the census enumerated count of 248,709,873, although neither of these represents precisely true population count. At the national level, the population estimate can be tested by a third, independent method: Demographic Analysis. Demographic Analysis, using vital statistics and administrative records (births, deaths, immigration, Medicare and other current and historical administrative data), provides an estimate of 253,393,786—closer to the PES figure than to the census count. Demographic Analysis provides a higher figure than either of the other two methods because it is less subject to the bias of missed persons, which affects both the census and the post-enumeration survey.

Below the national level, the statistical test used by the Bureau of the Census to measure whether the census or the post-enumeration survey (PES)/dual system estimate produces the more accurate population shares is called loss function analysis. Loss function analysis depends upon first, building an estimate of the true population then comparing the census and the PES/dual system estimate to this estimate. Although the test indicates whether the PES or the census produces the more accurate distribution of population between states, it does not show which state estimates are improved or whether any are made less accurate.

As a check on the loss function analysis result, Census Bureau demographers and a demographer expert from outside the Census Bureau reviewed each state's estimated undercount to see if it made demographic sense, given what they know about the demographic composition of each state. For 44 states and the District of Columbia, the PES/dual system estimates of undercount appear logical. That is, given the proportions and concentrations of different demographic groups in each state, the mix of rental and owner-occupied housing, and measured undercount patterns for these, the undercount in relation to other states was what demographers might expect. For three states, however, the measured undercount was somewhat more than they would anticipate; for three it was somewhat less than they would anticipate.

From analysis of the extensive research CAPE produced, I conclude, with CAPE, that (a) adjustment would improve the accuracy of the national level count of the total population and of demographic groups by sex, race, Hispanic origin and tenure (residents of owner-occupied or rental housing) and that (b) adjustment would improve the overall distribution of population shares among the states.

At substate levels, however, CAPE was unable to conclude with reasonable certainty whether adjustment would improve or do harm to the estimates for counties and places. CAPE made no recommendation of whether or not to adjust for substate levels. While in some states loss function analysis provides statistical evidence that the population share of large places with high concentrations of those in undercounted demographic groups is improved versus the population share of the balance of their states, this is not the case within all states with such large places. Below the large area level, the research does not show that adjustment improves the accuracy of population estimates.

None of the options available to me—not adjusting, partial adjustment or full adjustment—is ideal. There is no perfect answer to, "What was the population of the United States on Census Day, April 1, 1990?" Any statistical and demographic research can only answer that question with some degree of uncertainty. After more than two years of Bureau of the Census research evaluating the 1990 census, the post-enumeration survey which followed it, and statistical models for making an adjustment, I must make a decision now. CAPE's recent work has solved some of the problems and criticisms which caused former Secretary Robert A. Mosbacher to decide not to use the PES/dual system estimate for adjustment of the 1990 census. Unfortunately many issues remain. Some sources of bias cannot be removed. Some of the concerns with the PES/dual system estimate expressed by CAPE and in the public commentary are not resolved and probably could not be with more time and research. While I strongly support continued research on these issues for the year 2000 census, I also feel strongly that the debate over adjustment of the 1990 census and related intercensal estimates should not continue further into the decade.

The CAPE work with the 1990 PES has been intensive for over two years. It has occupied the time and talent of the most senior statisticians and demographers within the Bureau of the Census. Their work suggests that no survey—either the high quality, well controlled and interviewed 1990 PES of 170,000 households or a larger one—can be used to make a post-census fine tuning of an average undercount as small as 1.6 percent in all types of places, counties and states at a level of accuracy beyond that by which surveys are usually judged. The preponderance of evidence suggests that adjustment would be a tradeoff of small errors in some states, counties and places for large overall improvements at the state and national level—but there would be errors. However, as the public commentary gives evidence, adjustment would not be acceptable to those localities harmed by such a decision. The stakes for communities and states

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in population figures are high, as the uses of intercensal estimates in the next section demonstrate.

Statisticians among those who made public comments, and members of CAPE express concerns about aspects of the PES/dual system estimate, about the total error model and loss function analysis used to evaluate it and about possible errors in the PES as a measurement tool compared to the level of undercounts and overcounts it seeks to measure. Given that there is little or no evidence adjustment would improve the quality of substate estimates, other than for a limited number of large places, the decision is not to adjust the base for intercensal population estimates.

II. Uses of Intercensal Population Estimates

The Bureau of the Census produces intercensal population estimates for the United States, metropolitan areas, states, counties, county subdivisions, places (cities, towns, townships, etc.), and consolidated cities. They are used by Federal, state, and local governments, and the public and private sectors in a variety of ways. The Bureau of the Census investigated Federal formula program uses and other major Federal uses [1] and identified five major Federal uses:

1. As the basis for Federal formula program funds allocations. Funding formulas are written by the Congress, not by the Bureau of the Census. Existing formulas were written over many years and incorporate population estimates as all, or part, of the variables used in these formulas in different ways. Some formula program funds allocations use population estimates while others use the decennial census throughout the decade. Title 13, U.S. Code, section 183(a) requires use of the current population estimate, which according to this decision will be the unadjusted estimate, for programs which provide Federal benefits, unless in section 183(b) the formula has been specifically tied to the decennial census.

Some formulas use population shares for all persons in states, or for particular age groups, or for those with particular characteristics as some portion of the formula; other formulas use per capita figures, such as per capita income, for which population estimates are the denominator, or a ratio of state to U.S. per capita income with state and national population estimates as the denominators. Some of these programs use the population estimates in several ways in their formulas. The largest of these funding programs is Medicaid, title XIX, which uses 50 percent of the ratio of state to U.S. per capita income as one part of its formula.

2. As the denominator for per capita, and incidence rates, such as per capita income; particular health conditions per 1,000 persons; number of crimes per 1,000 persons, etc.

3. As the determinant of the volume cap for tax-exempt private activity bonds issued within a state. Section 146 of the Internal Revenue Code mandates use of the most recent Bureau of the Census state population estimate issued before the beginning of the calendar year in which the bonds are issued for setting the cap for tax-exempt private activity bonds. Small states are guaranteed a minimum funding level, but states with over three (3) million population receive an additional $50 in bonding authority for each person in the population estimate. Unlike uses of population estimates in many Federal funding formulas, bonding authority for each state is based on the absolute size of the state's population, not on its proportional share.

4. As the basis for calibrating Federal government and other sample surveys. By calibrating sample survey estimates to independent estimates of the population, accuracy of survey estimates is improved. For Federal government surveys conducted by the Bureau of the Census, the current population estimate is used as the control total for the total population and population groups by sex, age, race, Hispanic origin. They are calibrated geographically by the population estimates for the 50 states, District of Columbia, New York City and Los Angeles. Because Federal surveys conducted by the Bureau of the Census are calibrated only to these large aggregated areas, at which CAPE considers adjusted population estimates an improvement over the unadjusted estimates, the Bureau of the Census will offer survey sponsors the option of having their surveys calibrated to adjusted population estimates beginning in 1993.

5. As descriptive statistics to provide the most current profile of the population of the Nation, state and substate areas, and as the numbers for determining population gains and losses compared to prior years.

III. Research Input Into the Decision

When former Secretary of Commerce Mosbacher made the decision not to adjust the 1990 census, he expressed several major concerns with the PES and dual system estimation model that would have been used for adjustment purposes. However, he did recognize that both the PES and Demographic Analysis showed an undercount and a continuation of the historical differential undercount of certain groups. He directed that research continue at the Bureau of the Census to determine the possibility of incorporating adjustment into the intercensal estimates, which are made with less geographic detail than the census.

The Bureau of the Census established the Committee on Adjustment of Postcensal Estimates (CAPE), comprising 13 statisticians and demographers, plus the Director and Deputy Director of the Bureau of the Census as ex-officio members. Eight of the 13 members had also served on the Undercount Steering Committee which directed the research prior to July 1991.

CAPE deliberations were not constrained by pre-specification of procedures and of the dual system estimating model. Such prespecifications were required pursuant to court order in considering whether to adjust the 1990 decennial census. CAPE also had the advantage that many of its members had worked extensively with PES data and gained insight on possible ways to improve the dual system estimate model.

CAPE determined that the necessary research could not be completed in time for potential incorporation into 1991 intercensal estimates. Instead, they scheduled this work in time to provide it for the Director's decision on whether or not to incorporate adjustment into the estimates to be released in late December 1992 for July 1, 1992.

CAPE research focused on five key areas of technical concern with the population estimate model as of July 1991. This research has been able to answer all of these concerns to some degree, but not all completely.[2]

Concern 1

Could the problems in the smoothing model, including lack of robustness, be resolved?

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[1] Sources: General Accounting Office, FEDERAL FORMULA PROGRAMS Outdated Population Data Used to Allocate Most Funds. (September 1990).

General Accounting Office, FEDERAL FORMULA PROGRAMS Adjusted Census Data Would Redistribute Small Percentage of Funds to States (November 1991).

General Accounting Office, Catalog of Federal Aid to States and Localities (1987).

Superintendent of Documents, CFDA (1988, 1990, 1991, 1992).

U.S. House of Representatives, United States Code (1988).

Conversations with grant administrators.

[2] This research is described in more detail in "Report of the Committee on Postcensal Estimates," August 7, 1992 and Addendum, November 1992 (Bureau of the Census, Washington, DC 20233)

Background

The pre-July 1991 modeling of the PES was done by dividing survey respondents into 1,392 post-strata, or groupings, based on census division, (geographic), type of place of residence, race, Hispanic origin, sex, age, and some post-strata by whether residents owned or rented their housing units. The rationale for each post-stratum is the assumption that persons within it have similar probability of having been counted in the census or the PES (although not necessarily the same in each). This is called the homogeneity, or synthetic, assumption. An undercount rate was computed for each post-stratum by matching names and characteristics of people enumerated in the PES to the census to determine who had been counted and who not, then producing an adjustment factor for each post-stratum to make the PES dual system estimate of the population. One problem in dividing the sample respondents into 1,392 post-strata was that sample sizes for some strata were very small. A statistical process known as "smoothing" had to be done to reduce variability from sampling error. Results varied by how some of the outliner post-strata (those with unusually high sampling error) were treated. Because of these variations, statisticians felt the model was not "robust" to changes in model specification and procedure.

Results

The PES and dual system estimate have been redesigned to used only 357 post-strata, thereby gaining enough sample size in each stratum to make smoothing unnecessary. Analysis of PES data showed some characteristics more important than others in identifying whether persons had been counted in the census. Besides race and Hispanic origin characteristics, living in owner occupied or rented housing proved to have an effect, as did living in an urbanized areas of 250,000 or more versus living in other urban or non-urban areas. A more effective division made it possible to reduce the number of post-strata. CAPE now considers the 357 post-strata model robust. Sampling error has been reduced as a source of error, with some loss of homogeneity. Both CAPE and I have used some caution in interpreting results of loss function analyses since these are highly dependent upon the homogeneity assumption (See discussion under Concern 4).

Concern 2

Could the estimated nonsampling error biases in the PES estimate of undercount be removed?

Background

In the research prior to July 1991, Bureau of the Census statisticians identified biases (nonsampling errors) that amounted to 0.7 percent of the then reported 2.1 percent undercount.

Results

Matching experts matched PES respondents to the census in the 104 blocks that had the most effect on undercount. This removed some bias and reduced the national estimate of undercount by 0.1 percentage points. During this analysis, the Bureau of the Census also found and corrected a computer error in the matching that had led to an overstated estimate of undercount. This correction reduced the undercount estimate an additional 0.4 percentage points. Matchers also rechecked matching in blocks with a preponderance of Hispanic surnames. These matches proved to have been done with the same apparent accuracy of the rest of the PES matching. Beyond these improvements, CAPE could find no reliable or expedient method to remove the balance of nonsampling error bias from the PES estimates. A significant amount of bias remains. The research estimates that, at the national level, removing all biases from the PES estimates would lower the estimated undercount from 1.6 to 1.3 percent. When the effect of correlation bias is not taken into account, (CAPE believes correlation bias should be considered) the estimated undercount would fall to 0.9 percent. Correlation bias is discussed under Concern 3.

Concern 3

Were all components of bias adequately reflected in the total error model, and was total error being accurately handled in loss function analysis?

Background

The total error model is used for building an estimate of the "true" population without bias, since the exact truth cannot be known. Loss function analysis is a statistical technique used to compare the census count and the PES/dual system estimate to this "true" target population to see which is closest to it (that is, has less "loss"). Loss functions can be run for various geographic levels.

Results

Two new components of error were added to those used in modeling prior to July 1991. With these additions, CAPE felt satisfied that all components of error were represented except for homogeneity bias. (The bias of all persons in a post-stratum not having the same probability of having been counted in the census or PES. This is discussed under Concern 4.) CAPE was concerned about the accuracy and variance of the estimates of bias and, therefore, used caution in evaluating the results of loss function analyses since the "true" target numbers are themselves dependent on levels of estimated bias.

The majority of CAPE members felt that correlation bias should be a component of total error. Correlation bias has two parts: (1) The dual system estimate assumes a person's participation in the PES is not affected by his or her participation in the census. Based on the evidence available to it, CAPE judged this was not a problem. The PES was conducted 4 months after the census and there were other controls. (2) The dual system estimate assumes people in each post-stratum have the same probability of being included in either the census or the survey. Some people may be virtually impossible to count, leading to a component of correlation bias. A national estimate was made of these people by comparing the PES estimate to the Demographic Analysis estimate, which is less subject to correlation bias. The difference was not added to the PES estimate, but included in the total error model and used to determine the target "true" target population to which the census and the PES estimate were compared. As mentioned, most CAPE members felt correlation bias should be a component of total error. However, concerns continue about measuring it and allocating it to the target "true" numbers. Loss functions, therefore, have been analyzed with and without correlation bias.

For use in loss function analysis, the "true" target population estimate was made by modifying the PES estimate by removing error in the PES identified in the total error model. A modeling system was used to allocate the direct estimates of bias from 10 evaluation post-strata (aggregated post-strata) to smaller levels of geography. Such modeling and error measurement obviously have errors themselves. CAPE decided to run loss functions in a variety of ways to judge results. CAPE ran loss functions using different ways of allocating bias to the target "true" numbers; with and without correlation

bias; using absolute and squared error, as well as variations of these to take account of variations in state (or other areas of interest) size. They looked at aggregate loss (difference from truth), then ran statistical hypothesis tests and reported the significance levels. These were run to look at whether the census or the PES estimate showed the greater or lesser difference from the "true" target population shares for a variety of levels of geography for places and counties by size and for states.

Using hypothesis tests with 10 percent significance, loss function analysis excluding correlation bias does not support adjustment. Including correlation bias, all but one of the loss function analyses favors adjustment at the state level when examining aggregate loss. These results show that the state level analysis is sensitive to assumptions about correlation bias. Below the state level, CAPE was generally unable to conclude that adjustment was better.

Concern 4

Could more be learned about whether or not the homogeneity assumption holds sufficiently to support adjustment?

Background

The homogeneity (or synthetic) assumption is that every person in a post-stratum has the same probability of having been counted in the census or PES (though not necessarily the same probability in both). There were 1,392 post-strata in the earlier model. There are 357 in the current model produced by CAPE.

Results

The PES data show clearly that the variables used for dividing the country into poststrata—particularly race, Hispanic origin, tenure (owner/renter), and type of place of residence—account for considerable variation in census coverage. The homogeneity assumption assumes, however, that there is no further variation in coverage within each poststratum separately, that is, that everyone within a poststratum has the same probability of being counted in the census. This assumption is central to the way that PES estimates have been produced for states, counties, towns, and all other units important in postcensal estimation. The PES data by themselves have not offered enough evidence to evaluate the homogeneity assumption adequately, especially to answer the most important question for me—does the assumption hold sufficiently so that our PES estimates based on it represent an actual improvement to the census?

Consequently, I have relied upon the available results on the homogeneity assumption from the analysis of the artificial populations, discussed extensively in the CAPE report and the Addendum to that report.[3] Because the artificial populations are based on known quantities (such as percent mail response, percent of multi-unit housing, percent in poverty, etc.), we can put the adjustment procedure based on 357 post-strata to a test. For every one of the eight surrogate variables that we examined, our results indicate that we can make adjustments that, on average, are closer to the truth than not adjusting. To represent the adjustment to the artificial population, we used the rates for the surrogate variable in each of the 357 post-strata and the homogeneity assumption to construct adjustments in the same way as the PES does for estimating undercount. I feel very confident about this finding for the artificial populations because we do know the actual values of the artificial population surrogate variables.

Any problem caused by departures from the homogeneity assumption, which we have called heterogeneity bias, would be less troublesome if we had been able to represent its effects in the loss function analysis. In fact, the loss function analysis for the PES data could not include heterogeneity bias because the PES data did not furnish adequate evidence on this question. Consequently, I have again relied on evidence from additional research on the artificial populations. I have considered the recent results discussed in the CAPE Addendum that compare 1) the loss function analysis as it is seen in the PES context, i.e., as the comparison of the census and PES values to targets based on the homogeneity assumption; to 2) the actual losses comparing adjusted population estimates and the census to the true values. I have been encouraged that, for 7 of the 8 surrogate variables available for study, the loss function analysis is robust. In other words, in all but one case, the loss function analysis understates or approximately correctly measures the level of improvement from adjustment, although the loss function also understates the true errors from non-adjustment and from adjustment.

The August CAPE report stated that research showed that the artificial population analysis supported the homogeneity assumption but, once 25 percent bias was introduced, the support for the assumption broke down. Furthermore, these results were then compared to estimated levels of bias in the PES, which were near the 25 percent level. Because of the clarification in the CAPE Addendum of the interpretation of these earlier findings for the artificial populations, one should not place so much weight on the results for 25 percent bias, since the comparisons were based on numeric accuracy whereas our primary focus has been on the accuracy of population shares. In August, with the information available to us, the results for 25 percent basis, reported in the manner that they were, represented a strong case against adjustment, but I now believe that the CAPE Addendum should alleviate many of the concerns about this issue.

Concern 5

Could CAPE resolve the inconsistencies between the PES and Demographic Analysis (DA) estimates of undercount?

Background

At the time of the July 1991 decision, there were differences in PES/DSE and Demographic Analysis estimates of population for some major subgroups. Also, at that time, the PES/DSE showed a higher undercount rate than Demographic Analysis, which was unexpected because Demographic Analysis accounts for people missed in both the census and the PES.

Results

The corrections to the PES and subsequent reduction of the PES estimate of undercount to 1.6 percent cleared up the major inconsistencies between the PES and DA estimates. Demographic Analysis which, as pointed out earlier, is less subject to correlation bias, should measure a somewhat higher undercount than the PES since it includes those who are missed or impossible to count. It now does, 1.8 percent undercount for Demographic Analysis compared to 1.6 percent for the PES/DSE. Comparisons of PES and DA for states and large areas (DA cannot go down to small areas) meet face validity expectations for most states. By "face validity" I mean that the patterns of high and low undercounts are logical demographically.

In summary, CAPE developed a new estimation model based on the modeling of the PES to 357 post-strata and a more thorough identification of biases resulting from sampling and nonsampling error.

The Bureau of the Census conducted a number of studies to evaluate and measure errors in the PES. A total error model was then used to combine the

[3] *Ibid.*

results from these studies to produce measures of net error on the estimated undercount rates. The estimated level of bias in the PES that was estimated from the total error model was –0.7%, without correlation bias, or –0.4% when the effects of correlation bias were taken into account. These estimates reflected the measures of bias in national estimates of undercount. Thus the national estimated undercount rate of 1.6% is, without bias, between 1.2% and 0.9%.

Both the unadjusted and adjusted census results are imperfect. The unadjusted census is subject to undercount, and the adjusted census is subject to the error in the PES—sampling error and bias. A key question to answer is which of these two imperfect systems will provide a more accurate base for use in the intercensal estimates program. This question is particularly relevant for population shares and was addressed through loss function analysis.[4] The loss function analysis accounts for both the sampling error and bias in the PES. The CAPE examined the results of the loss function analysis, and concluded that an adjustment would make the distribution of population shares for states more accurate. However, they could not reach consensus on substate areas.

An important issue associated with loss function analysis is the methodology associated with the creation of the target population (the estimates of the true unknown population). The measures of bias in the PES were used to "correct" the PES/dual system estimate to produce the target population. Unfortunately, the PES bias was not directly measured for each state, county or city. Models were used to allocate the directly measured bias at 10 sub-national levels to each state, county, and place to produce the target population. Questions have been raised regarding whether these models reflect an accurate distribution of the bias.

I am also concerned about this issue, as was the CAPE. The CAPE recognized that there were potential deficiencies in the modeling methodology. The CAPE therefore examined a number of different models for creating target populations. They concluded in August that the bias modeling methodology was sufficiently robust to conclude that at the state level, an adjustment would improve the state base for intercensal estimates. However, they could make no conclusion about the effects of adjustment at substate levels other than documenting in the November addendum to their August report that an adjustment would also improve the distribution of population shares for large places (100,000+) in aggregate compared to state balances in aggregate.

I have considered this modeling of bias issue at great length. There are certainly problems with the modeling methodology. In most statistical applications, we never know the true situation, and no model is perfect. Despite the extensive research, too many concerns remain about the level of bias; the estimate of the true population used as the target in loss function analyses; allocation of correlation bias; and whether the homogeneity assumption holds, given the levels of bias, to make a decision to adjust intercensal population estimates defensible across the board to all 44,055 substate areas.

IV. Analysis of Options Available to the Director, Bureau of the Census

A notice that the Bureau of the Census placed in the **Federal Register** August 10, 1992, and repeated on September 17, 1992, described five decision options available to the Director, Bureau of the Census.

Option One: Incorporate the results of the PES into the base for intercensal estimates at all levels of geography.

CAPE research, which provided much of the input to my decision, did not support adjustment below the state level. Although taking this option would have made some improvements at the state and national level, taking this option for all levels of geography is not defensible.

Option Two: Incorporate the PES results in the intercensal base at the national and state levels. At the substate level, use a simple synthetic estimate based on the percentage of state-level estimated undercount.

I rejected this option because the simple synthetic estimate would distort within state counts artificially. For example, a small city or county that had been well counted would have its population inflated because of the undercount in a large city in the same state. Conversely, the city with a large undercount would have its population understated because of low undercounts in other parts of the state.

Option Three: Incorporate the results of the PES into the intercensal base for national and state level estimates, but not for substate levels (counties, cities, etc.).

Although this is the level of adjustment which CAPE research very clearly supports, I rejected this option because it would not be additive at state levels; for example, the sum of the population of all counties within a state would not sum up to the state total. Public commentary from data users, user groups, Federal statistical agencies, and analysts within the Bureau of the Census said nonadditive population counts would be very difficult for them to use.

Option Four: The base for intercensal estimates for all levels of geography would be a simple average of the 1990 census count and an estimate incorporating the results of the PES.

I gave serious consideration to this option. CAPE conducted additional research on this option and a modification of it after the initial CAPE report of August 7, 1992. There is precedent in the statistical community for averaging two estimates. This would have had the effect of reducing the effect of biases in the PES, However, neither I as Director nor CAPE were comfortable with a "partial" correction at the national level. This option would have had the effect of raising the population by approximately two million when the undercount is a measured four million. CAPE considered the modification of averaging the census and PES, then ratio adjusting to the PES/dual system estimate total proportionally by eight racial, Hispanic, owner/renter subgroups (what CAPE refers to as a raked composite estimate in the November Addendum to the CAPE report). I decided against this modification because, according to CAPE, the "raking" to national totals introduced more dependence on the homogeneity assumption, possibly offsetting gains from reducing the effects of bias. This treatment of a census and an evaluation survey (the raked composite) is a treatment I hope the Bureau of the Census will continue to study in designing ways to make the 2000 census more accurate.

Option Five: Do not incorporate the PES results into the intercensal estimates for any jurisdiction.

This is the option I have chosen. While adjustment would make improvements at the national and state level, it is not defensible for all levels of geography. Concerns remain about the level of bias in the PES/dual system estimate and in whether the homogeneity assumption holds, i.e., whether all persons in a post-strata in the PES have, in fact, the same probability of having been counted in either the PES or the census. These concerns do not have answers nor are further research avenues available with which to answer them in the near future. This option is not ideal, as noted previously, because it foregoes the

[4] Loss function analysis is described in the August 7, 1992 CAPE report.

opportunity to improve estimates at national and state levels.

V. Adjusted Population Estimates for Survey Controls But Official Unadjusted Estimates for Use in Administering Any Law in Which Population, or Population Characteristics, Are Used To Determine Benefits

Having made the decision not to adjust intercensal population estimates, I am making the decision that sponsors of Federal sample surveys conducted by the Bureau of the Census will be offered the option of having their surveys calibrated to adjusted population estimates. Federal statistical surveys are calibrated at the level of national sex, age, race, Hispanic groups, and population totals for the 50 states, District of Columbia, New York City and Los Angeles. These are the levels at which CAPE judges the adjusted estimates are more accurate than the unadjusted estimates. Reaching the demographic groups undercounted in the census is a greater problem in taking surveys than in taking the census.

In the public commentary, Senator Herb Hohl of Wisconsin and Senator Arlen Specter of Pennsylvania suggested decoupling the official population estimate from the survey controls. This is what this decision does. Unadjusted population estimates are the official estimates, required to be reported by the Secretary to the President under title 13, U.S. Code section 183(a) for use in administering any law of the United States in which population or other population characteristics are used to determine the amount of benefit received by any State, county, or local units of general purpose government. Sponsors of surveys conducted by the Bureau of the Census will have the option of calibration to the adjusted estimates.

VI. Summary of the Public Commentary

As Director, Bureau of the Census, I received letters from 1,118 individuals or groups in response to our **Federal Register** notices of August 10 and September 17, 1992. I have personally read each of these.

Table 1 shows the distribution of the 1,118 responses—58 from Senators, 176 from Members of the U.S. House of Representatives, 37 from Governors, 349 from State Representatives, state and local government officials and agencies, 498 from all other respondents, including organizations, private citizens, and a small number from Federal agencies. Some individuals wrote a letter as well as co-signing a group letter, or wrote a second letter responding to the second **Federal Register** notice. Such persons are counted only once in Table 1.

Most responses stated a position for or against adjustment rather than responding to the five options of the Bureau of the Census' **Federal Register** notices. Preferences for the options, as well as positions for or against adjustment are summarized in Table 2. Overall, 995 favored adjustment; 123 opposed it.

In making my final decision, I considered this overwhelming preference for adjustment. However, I felt I should not use a "popular vote" as a determinant of a decision made on the basis of statistical and demographic criteria. With the exception of a few statisticians and a very few others, virtually everyone took the position which maximized the population estimate for his or her state or city rather than considering the merits of the issue. This is a problem which will persist in trying to make any adjustment after a census.

Fifteen to 20 letters had substantial statistical commentary. Some brought out issues that CAPE was already researching. Others presented new ideas that led to some additional CAPE research. I asked CAPE statisticians to analyze these letters for me, in addition to my reading each of these letters at least twice. A summary of the comments with statistical content is available as Appendix A: Discussion of Technical Issues Raised by Outside Comment. What follows is a more abbreviated summary.

The majority, but not all, of the technical comments came from those who oppose adjustment.

Homogeneity Assumption

Several reviewers were concerned about the critical nature of the dependence upon the homogeneity assumption, questioning whether persons living in post-strata which fell across several states had the same probability of being counted. CAPE agrees that this is one of the more vulnerable aspects of the PES/dual system estimate design and recognizes that each post-strata cannot be precisely homogeneous. The key issue is whether the assumption represents an adequate approximation to the distribution of undercount. While some of the concerns expressed with homogeneity were general comments, one commenter created a U.S. map showing the high degree of association between the adjustment at the state level and the groupings of states into the four census regions. The reviewer showed maps of other characteristics, such as poverty rate, which do not exhibit as marked a regional character as the undercount rates. Census Bureau researchers subsequently reexamined the series of characteristics employed in defining the 8 surrogate artificial populations. In varying degrees, the Census Bureau's investigations confirm that the adjustment methodology tends to emphasize regional aspects of the characteristic being estimated while missing or understating other aspects of state-to-state variation. However, among the variables defining post-strata, region captures some of the geographic variation. Others—race, Hispanic origin, tensure type of place of residence—are highly correlated with undercount.

Another reviewer provided calculations showing that it was possible that departures from the homogeneity assumption, that is heterogeneity, might account for more error in the PES adjustments of states than all the components of error estimated and included in the Bureau of the Census' total error model. Research on artificial populations continued after this commentary was received. These added investigations by the Bureau of the Census showed that the error due to heterogeneity tended to be large for the artificial populations. Applying these results to the PES itself, it is possible that errors due to heterogeneity in fact could be larger than all other sources of error in the adjustment. However, the investigations supported the premise that the PES adjustment could still, on average, make improvements to the overall state population shares. When heterogeneity bias is present, the results for artificial populations showed that the loss function tended to understate the errors of both the adjustment and non-adjustment. If it understated these by equal amounts, the net difference would be correct. In fact, the analyses showed that, for a majority of the 8 artificial populations (surrogate variables), the loss function would approximately correctly indicate or understate the net advantage from adjustment.

Sample Size

Some writers argued that the PES sample size was insufficient to permit an adjustment. These arguments were not reinforced by explicit calculations showing that the sample sizes were too small. The issue of sample size is linked directly to the level of sampling variance. The use of the 357-post-strata design reduced the effect of sampling variability considerably. Sampling error was a component of the total error model and was included in the loss function analysis. The loss function

analysis indicates that at the state level the adjustment results in an improvement.

Post-Stratification

Several comments were received applauding the revised post-stratification (357 post-strata compared to 1,392 in the original design). However, some of these reviewers claimed that the post-stratification was data-driven. The end result of this was that the estimates of sampling error would be too low, therefore, causing the loss function analysis to unduly favor the adjustment.

One reviewer found the new post-stratification acceptable but would have preferred the Bureau of the Census to continue to use "smoothing." Alternatively he proposed to control sampling variability by collapsing the original 1,392 post-strata to a smaller number to retain greater homogeneity within post-strata. However, this reviewer felt that the revised 357 post-stratification scheme for adjusting was superior to not adjusting.

These post-stratification ideas were discussed at various times by CAPE. The clear consensus of the CAPE was not to use "smoothing," and CAPE was pleased with the new post-stratification scheme. Members recognized the danger of post-stratification after data had been examined. This had some bearing on their general concerns regarding the loss function analysis.

Correlation Bias

Correlation bias was widely discussed both internally and externally. Some reviewers noted that an adjustment based on the Bureau of the Census estimate of correlation bias would be conservative; it would not go far enough in correcting the undercount.

Other reviewers noted that at the national level there was clear evidence of correlation bias. However, they claimed that problems resulted because there were no direct measures of correlation bias sub-nationally. It was not clear to these reviewers that the method of modeling correlation bias to produce sub-national estimates was appropriate. These reviewers were not convinced that the adjustment would improve the distribution of population shares subnationally. CAPE had previously expressed many of these same concerns. The general conclusion was that correlation bias should be a component of total error. However, there were concerns about the methods of estimating and allocating it. CAPE requested that loss function analysis be done with and without correlation bias.

Total Error Model

Some reviewers viewed the total error model as being complete, and when combined with the loss function analysis supportive of an adjustment. One reviewer felt that the total error measure of correlation bias was understated and a more accurate measurement would favor adjustment more than the current estimates.

There were others who did not believe that the total error model covered all sources of error. They cited sources of error they felt were omitted. They also felt many of the sources of error included in the total error model were not measured accurately, and cited specific ones. CAPE discussed the total error model at great length. Members felt that all components of error were included except for bias due to failure of the homogeneity assumption. However, CAPE could come to no agreement about the adequacy of the levels of error measured. CAPE concluded to use caution in evaluating the results of the loss function analysis since the target numbers used as truth were so dependent upon the levels of estimated bias. The uncertainty in the levels of estimated bias thus affects the measures of accuracy based on these target numbers.

Loss Function Analysis

Some reviewers viewed the loss function analysis as being very supportive of adjustment, and that the improvement indicated by the loss function analysis was an understatement because correlation bias was underestimated in the total error model.

Other reviewers generally had two major sources of concern regarding the loss function analysis: (1) There are components of error in the adjusted estimates that are not included in the loss function analysis, such as uncertainties from failure of the homogeneity assumption and from the choice of post-stratification. (2) There are concerns with the methods used to model the total error estimates of bias to create the target "truth" populations. One reviewer expressed concerns regarding the levels of significance for the loss function test.

CAPE discussed the loss function analysis in great detail. In particular, the comments regarding uncertainty due to failure of the homogeneity assumption led to some late research. In general, CAPE accepted the loss function results keeping in mind the caveats reflected in this report.

Other comments, which did not address the technical merits of this decision are summarized and available as Appendix B.

Public Hearing

Testimony at the public hearing August 31, 1992, came from individuals and groups, mostly groups, representing both those in favor of adjustment and those against it. All presented reasoned arguments that I listened to at the hearing and have read and weighed since. A summary of this testimony is available as Appendix C: Public Hearing, August 31, 1992, Summary of the Proceedings.

TABLE 1.—SUMMARY OF MAIL RESPONSE

Type of respondent	Pro	Con	Total
U.S. Senate—Total	31	27	58
U.S. House—Total	127	49	176
Governors—Total	20	17	37
State/Local Government—Total	332	17	349
Florida	205	.....	205
Texas	55	.....	55
California	37	.....	37
Other States	35	17	52
Others*—Total	485	13	498
Florida	462	.....	462
Other States	23	13	36
Total	995	123	1118

*Organizations, Individuals, and Federal Agencies.

TABLE 2.—SUMMARY BY OPTION

	Congress	State & local	Federal agencies	Organizations	Individuals	Total
PRO:						
Letters:						
Option 1	.....	43	1	5	2	51
Option 2	.....	.....	.....	.....	1	1
Option 3	.....	.....	.....	.....	.....	.....
Option 4	.....	1	.....	.....	.....	1
General	158	308	4	33	439	942

TABLE 2.—SUMMARY BY OPTION—Continued

	Congress	State & local	Federal agencies	Organizations	Individuals	Total
Total pro	158	352	5	36	442	995
CON:						
Letters:						
Option 5	76	34		1	12	123
Total Opinions	234	386	5	39	454	1118
General/Other	52	21	2	3	7	85

[FR Doc. 92-31890 Filed 12-29-92; 11:37 am]

BILLING CODE 3510-07-M

Foreign-Trade Zones Board

[Order No. 618]

Resolution and Order Approving the Application of the Indiana Port Commission for Special-Purpose Subzone Status

Pursuant to the authority under in the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the Indiana Port Commission, grantee of FTZ 177, filed with the Foreign-Trade Zones (FTZ) Board (the Board) on October 23, 1991, and amended on July 23, 1992, requesting special-purpose subzone status at the pharmaceutical manufacturing plant of Mead Johnson & Company, in Evansville and Mt. Vernon, Indiana, the Board, finding that the requirements of the Foreign-Trade Zones Act and the Board's regulations are satisfied, and that the proposal is in the public interest, approves the application, as amended.

Approval is subject to the FTZ Act and the FTZ Board's regulations (as revised, 56 FR 50790–50808, 10/8/91), including section 400.28. The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

Whereas, By an Act of Congress approved June 18, 1934, an Act To provide for the establishment of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes, as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized to grant to corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, The Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved;

Whereas, An application from the Indiana Port Commission, grantee of Foreign-Trade Zone 177, for authority to establish a special-purpose subzone for the pharmaceutical and nutritional products manufacturing plant (four sites) of Mead Johnson & Company, in Evansville and Mt. Vernon, Indiana, was filed by the Board on October 23, 1991, and notice was given in the **Federal Register** on November 1, 1991 (FTZ Docket 64–91, 56 FR 56186);

Whereas, The application was amended on July 23, 1992 (56 FR 33318, 7/28/92) to add two sites; and,

Whereas, The Board has found that the requirements of the Act and the Board's regulations are satisfied and that the proposal, as amended, is in the public interest;

Now, Therefore, The Board hereby authorizes the establishment of a subzone (Subzone 177A) for the manufacture of pharmaceutical and nutritional products at the Mead Johnson & Company facilities in Evansville and Mt. Vernon, Indiana, at the locations described in the application, as amended, subject to the FTZ Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including section 400.28.

Signed at Washington, DC, this 21st day of December 1992, pursuant to Order of the Board.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 92-31886 Filed 12-31-92; 8:45 am]

BILLING CODE 3510-05-M

[Order No. 610]

Resolution and Order Approving With Restrictions Extension of Subzone Status; Foreign-Trade Zone Subzones 44B, 44C, and 44D

Pursuant to the authority granted in the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Resolution and Order.

The Board, having considered the matter, hereby orders:

After consideration of the application of the Department of Commerce and Economic Development of the State of New Jersey, grantee of Foreign-Trade Zone 44, Mt. Olive, New Jersey, filed with the Foreign-Trade Zones (FTZ) Board (the Board) on October 23, 1992, requesting a time extension for FTZ Subzones 44B, 44C, and 44D (FTZ Board Order 366, 12/1/87), located in the northern New Jersey area, adjacent to the New York Customs port of entry, the Board, finding that the requirements of the FTZ Act and the Board's regulations would be satisfied and that the proposal would be in the public interest if the extension were approved for five years (to 12/1/97), subject to the conditions contained in Board Order 366, hereby approves a time extension for said subzones to December 1, 1997, subject to the conditions below.

The approval is subject to the FTZ Act and the FTZ Board's regulations (as revised, 56 FR 50790–50808, 10/8/91), including section 400.28, and further subject to the following conditions:

1. Authority for the subzones may be further extended after a review by the Board;

2. Foreign merchandise admitted into the subzones shall be monitored annually to ensure that zone procedures do not cause increased imports; and,

3. IFF shall provide the FTZ Board and the District Director of Customs annually with a list of merchandise admitted to the subzones in nonprivileged foreign status.

Signed at Washington, DC, this 21st day of December, 1992, pursuant to Order of the Board.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 92-31887 Filed 12-31-92; 8:45 am]

BILLING CODE 3510-DS-M

[Docket 37–92]

Foreign-Trade Zone 39—Dallas/Fort Worth, TX; Application for Subzone, Sanden International (U.S.A.), Inc., Auto Air Conditioner Manufacturing Plant, Wylie, TX

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the DFW International Airport Board, grantee of FTZ 39, requesting special-purpose subzone status for the automotive air conditioner manufacturing plant of Sanden International (U.S.A.), Inc. (Sanden) (subsidiary of Sanden Corporation,

Japan), located in Wylie, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on December 21, 1992.

The Sanden plant (437,000 sq.-ft. bldg. on 95 acres) is located at 601 South Sanden Boulevard in Wylie (Collin County), some 24 miles northeast of downtown Dallas. The Facility (345 employees) is used to produce air conditioning compressors, evaporator coils, and related components for use in motor vehicles and heavy equipment. The manufacturing process involves machining and assembly of compressors, clutches, and evaporator coils. Certain subcomponents are sourced from abroad, including clutch assemblies, heat insulators, electrical switches, coil covers, fan/motor assemblies, gaskets, and labels (duty rate range: 3.4%–6.2%). Such subcomponents represent some 54 percent of the finished compressors' value and 20 percent of the evaporator coils' value.

Zone procedures would exempt Sanden from Customs duty payments on the foreign parts used in export production. On its domestic sales, the firm would be able to choose the duty rate that applies to finished compressors (3.4%) and evaporator coils (2.2%) for the foreign material inputs noted above. If the products are shipped to auto assembly plants with subzone status, the compressors would be subject to the finished auto duty rate (2.5%). Foreign status merchandise and finished components made for export would also be exempt from certain state and local *ad valorem* taxes. The application indicates that the savings will help improve the plant's international competitiveness.

In accordance with the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), a member of the FTZ Staff has been appointed examiner to investigate the application and report to the Board.

Public comment on the application is invited from interested parties. Submissions (original and three copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is March 5, 1993. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period March 22, 1993.

A copy of the application and the accompanying exhibits will be available for public inspection at each of the following locations:

U.S. Department of Commerce District Office, World Trade Center, suite 170, 2050 N. Stemmons Freeway, Dallas, Texas 75242–0787.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, room 3716, 14th Street & Constitution Avenue, NW., Washington, DC 20230.

Dated: December 22, 1992.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 92–31888 Filed 12–31–92; 8:45 am]

BILLING CODE 3510-DS-M

International Trade Administration

[A–834–804, A–821–804, A–823–804]

Affirmative Preliminary Determinations of Critical Circumstances: Ferrosilicon From Kazakhstan, the Russian Federation, and Ukraine

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Kimberly Hardin, Office of Antidumping Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–0371.

PRELIMINARY DETERMINATION: On July 14, 1992, petitioners alleged that critical circumstances exist with respect to imports of ferrosilicon from Kazakhstan, the Russian Federation, and Ukraine. The Department of Commerce (the Department) published its preliminary determinations of sales at less than fair value in these investigations on December 29, 1992, but inadvertently omitted its critical circumstances analysis from those determinations.

Section 733(e)(1) of the Act provides that the Department will preliminarily determine that critical circumstances exist if we determine that there is a reasonable basis to believe or suspect that:

(A)(i) There is a history of dumping in the United States or elsewhere of the class or kind or merchandise which is the subject of the investigation, or

(ii) The person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the merchandise which is the subject of the investigation at less than its fair value, and

(B) There have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

Regarding criterion (A) above, we normally consider either an outstanding antidumping order in the United States or elsewhere on the subject merchandise, or margins of 25 percent or more in the case of purchase price, and 15 percent or more in the case of exporter sales price, comparisons sufficient to impute knowledge of dumping under section 733(e)(1)(A) of the Act. Since the preliminary dumping margins for all exporters of ferrosilicon from Kazakhstan, the Russian Federation, and Ukraine, are in excess of 25 percent, we can impute knowledge under section 733(e)(1)(A) of the Act.

Pursuant to 19 CFR 353.16(f), we generally consider the following factors in determining whether imports have been massive over a short period of time: (1) The volume and value of the imports; (2) seasonal trends (if applicable); and (3) the share of domestic consumption accounted for by imports.

Regarding criterion (B) above, because we did not receive adequate questionnaire responses from any party in Kazakhstan, the Russian Federation, or Ukraine, we based our preliminary determinations on best information available (BIA). Because we did not receive adequate questionnaire responses, we determine that imports were massive over a relatively short period of time based on BIA. Accordingly, we preliminarily find that critical circumstances do exist in these investigations.

We will announce the final determinations of critical circumstances along with the final antidumping determinations in these investigations on March 3, 1992.

Suspension of Liquidation

In accordance with section 733(e)(2) of the Act, we are instructing the Customs Service to suspend liquidation of all entries of ferrosilicon from Kazakhstan, the Russian Federation, and Ukraine, that are entered, or withdrawn on or after August 30, 1992, which is 90 days prior to December 29, 1992, the date of publication of the preliminary determinations.

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determinations.

Public Comment

Comments regarding these preliminary critical circumstances determinations, if any, should be

included in the case briefs, which are currently due on February 5, 1993.

These determinations are published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: December 24, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92-31924 Filed 12-31-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-423-602]

Industrial Phosphoric Acid From Belgium; Determination Not To Revoke the Antidumping Duty Order

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of determination not to revoke the antidumping order.

SUMMARY: The Department of Commerce is notifying the public of its determination not to revoke the antidumping duty order on industrial phosphoric acid from Belgium.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: John Kugelman, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC, 20230; telephone: (202) 482-3601.

SUPPLEMENTARY INFORMATION: The Department of Commerce (the Department) may revoke an antidumping duty order or finding, pursuant to § 353.25(d)(4) of the Department's regulations, if no interested party has requested an administrative review for five consecutive annual anniversary months and no interested party objects to the revocation (19 CFR 353.25(d)(4)(iii) (1992)). We had not received a request to conduct an administrative review of the antidumping duty order on industrial phosphoric acid from Belgium (52 FR 31439, August 20, 1987) for the last four consecutive annual anniversary months. Therefore, pursuant to § 353.25(d)(4)(i) of the Department's regulations, on November 27, 1992, we published in the **Federal Register** a notice of intent to revoke the order and served written notice of the intent to revoke to each interested party on the Department's service list.

On December 7, 1992, FMC Corporation and Monsanto Company, the petitioners in the original antidumping investigation, objected to our intent to revoke this antidumping duty order. Therefore, because interested parties have objected to the revocation, we no longer intend to revoke this antidumping duty order.

Dated: December 24, 1992.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 92-31925 Filed 12-31-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-791-602]

Low-Fuming Brazing Copper Wire and Rod From South Africa; Intent To Revoke Antidumping Duty Order

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of intent to revoke antidumping duty order.

SUMMARY: The Department of Commerce is notifying the public of its intent to revoke the antidumping duty order on low-fuming brazing copper wire and rod from South Africa. Interested parties who object to this revocation must submit their comments in writing no later than January 31, 1993.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: John Kugelman, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230, telephone: (202) 482-3601.

SUPPLEMENTARY INFORMATION:

Background

On January 29, 1986, the Department of Commerce (the Department) published an antidumping duty order on low-fuming brazing copper wire and rod from South Africa (51 FR 3640). The Department has not received a request to conduct an administrative review of this order for the most recent four consecutive annual anniversary months.

The Department may revoke an antidumping duty order or finding if the Secretary of Commerce concludes that it is no longer of interest to interested parties. Accordingly, as required by § 353.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke this antidumping duty order.

Opportunity to Object

No later than January 31, 1993, interested parties, as defined in § 353.2(k) of the Department's regulations, may object to the Department's intent to revoke this antidumping duty order.

Seven copies of any such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, room B-099, U.S. Department of Commerce, Washington, DC 20230.

If interested parties do not request an administrative review in accordance with the Department's notice of opportunity to request administrative review, or object to the Department's intent to revoke by January 31, 1993, we shall conclude that the order is no longer of interest to interested parties and shall proceed with the revocation.

This notice is in accordance with 19 CFR 353.25(d)(4)(i).

Dated: December 23, 1992.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 92-31882 Filed 12-31-92; 8:45 am]

BILLING CODE 3510-DS-M

[A-583-603]

Stainless Steel Cooking Ware From Taiwan; Intent to Revoke Antidumping Duty Order

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of intent to revoke antidumping duty order.

SUMMARY: The Department of Commerce is notifying the public of its intent to revoke the antidumping duty order on stainless steel cooking ware from Taiwan. Interested parties who object to this revocation must submit their comments in writing no later than January 31, 1993.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: John Kugelman, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230, telephone: (202) 482-3601.

SUPPLEMENTARY INFORMATION:

Background

On January 20, 1987, the Department of Commerce (the Department) published an antidumping duty order on stainless steel cooking ware from Taiwan (52 FR 2138). The Department has not received a request to conduct an administrative review of this order for the most recent four consecutive annual anniversary months.

The Department may revoke an antidumping duty order or finding if the Secretary of Commerce concludes that it is no longer of interest to interested parties. Accordingly, as required by § 353.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke this antidumping duty order.

Opportunity to Object

No later than January 31, 1993, interested parties, as defined in § 353.2(k) of the Department's regulations, may object to the Department's intent to revoke this antidumping duty order.

Seven copies of any such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, room B–099, U.S. Department of Commerce, Washington, DC 20230.

If interested parties do not request an administrative review in accordance with the Department's notice of opportunity to request administrative review, or object to the Department's intent to revoke by January 31, 1993, we shall conclude that the order is no longer of interest to interested parties and shall proceed with the revocation.

This notice is in accordance with 19 CFR 353.25(d)(4)(i).

Dated: December 23, 1992.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 92–31883 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DS–M

[A–588–823]

Preliminary Determinations of Sales at Less Than Fair Value and Postponement of Final Determinations of Sales at Less Than Fair Value: Professional Electric Cutting Tools and Professional Electric Sanding/Grinding Tools from Japan

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Brian Smith, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1766.

PRELIMINARY DETERMINATIONS: The Department of Commerce ("the Department") preliminarily determines that professional electric cutting tools (PECTs) and professional electric sanding/grinding tools (PESGTs) from Japan are being, or are likely to be, sold in the United States at less than fair value (LTFV), as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice. Also, the Department preliminarily finds that critical circumstances do not exist.

Case History

Since these investigations were initiated on June 18, 1992, (57 FR 28483 June 25, 1992), the following events have occurred:

On July 2, Ryobi, a Japanese exporter of subject merchandise, submitted a letter of appearance. On July 7, Hitachi did the same.

On July 13, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination.

On July 14, the Department presented Section A of the antidumping duty questionnaire to Makita Corporation, Makita U.S.A., Inc., and Makita Corporation of America (Makita). Makita accounted for at least 60 percent of the exports of PECTs and PESGTs to the United States.

On July 28, Makita submitted its Section A response. On July 31, Makita requested the Department to use third country sales as a basis for foreign market value (FMV). On August 10, the Department determined that the home market was viable and therefore denied Makita's request to use its third country sales as a basis for FMV.

Also on August 10, after considering comments submitted by two interested parties, we issued a decision memorandum regarding the instructions for selecting similar merchandise. These instructions were included with Sections B and C of the antidumping questionnaire which was presented to Makita on August 11, 1992. On August 20, we issued to Makita a Section A deficiency letter. On September 3, Makita submitted its deficiency response.

On September 30, the Department postponed the preliminary determinations until December 28, 1992 (57 FR 46148 October 7, 1992). On October 5, Makita submitted its response to Sections B and C of the antidumping questionnaire.

The Department issued supplemental sales questionnaires to Makita in October and November, 1992. Makita submitted the responses to these supplemental questionnaires in November 1992.

On December 2, petitioner, Black & Decker, alleged that critical circumstances exist with respect to imports of PECTs and PESGTs from Japan. Petitioner requested that the Department collect critical circumstances data from Makita, Ryobi, and Hitachi.

On December 8, the Department, in order to reach a critical circumstances determination, requested that Makita furnish shipment data concerning its exports of PECTs and PESGTs to the United States for the last two years. As only Makita is designated as a mandatory respondent in these investigations, we did not solicit this data from Ryobi and Hitachi. On December 9, the Department issued questions to Makita concerning some of its proposed model matches.

On December 10, Makita requested that, in the event of affirmative preliminary determinations in these investigations, the Department postpone the final determinations to 105 days after the date of the publication of the affirmative preliminary determinations. See the "Postponement of Final Determinations" section of this notice.

On December 14, Makita provided an explanation for those model matches identified in the Department's December 9, letter.

On December 16, Makita submitted replacement home market databases in response to a Department request. These databases were submitted too late to be considered in these preliminary determinations. In addition, petitioner submitted comments after December 4, which were not considered in the preliminary determinations.

On December 18, 1992, Makita alleged that petitioner did not have standing to seek on behalf of the U.S. industry relief from imports of the subject merchandise from Japan. This allegation was submitted too late to be considered in the preliminary determinations. On December 22, Makita submitted its shipment data.

Scope of Investigations

In the notice of initiations of these investigations, the Department invited interested parties to comment on their scope. We received comments from four parties, Makita, Ryobi, Hitachi, and Black & Decker, on September 4. On September 17, we requested additional information from the four parties. On October 13, we received their replies. On November 13, the Department requested product characteristic data from the three Japanese parties and certain clarifying information from Black & Decker. We received replies from the four parties by November 27.

Having considered the comments of all parties, the Department preliminarily defines the scopes of these proceedings as follows (See Memorandum to Richard W. Moreland, Acting Deputy Assistant Secretary, December 28, 1992, for more details). These investigations cover two classes or kinds of merchandise, PECTs and PESGTs. The tools may be

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assembled or unassembled and corded or cordless.

• The term "electric" encompasses electromechanical devices, including tools with electronic variable speed features.

• The term "assembled" includes unfinished or incomplete articles, which have the essential characteristics of the finished or complete tool.

• The term "unassembled" means components, which when taken as a whole, can be converted into the finished or unfinished or incomplete tool through simple assembly operations, *e.g.*, kits.

PECTs have blades or other cutting devices used for cutting wood, metal, and other materials. PECTs include chop saws, circular saws, jig saws, reciprocating saws, miter saws, portable band saws, cut-off machines, shears, nibblers, planers, routers, joiners, jointers, metal cutting saws, and similar cutting tools. PESGTs have moving abrasive surfaces used primarily for grinding, scraping, cleaning, deburring, and polishing wood, metal, and other materials. PESGTs include angle grinders, finishing sanders, disc sanders, orbital sanders, belt sanders, polishers, straight grinders, die grinders, and similar sanding/grinding tools.

The products subject to these investigations include all hand-held PECTs and PESGTs and certain bench-top, hand-operated PECTs.

• Hand-operated tools are designed so that only the functional or moving part is held and moved by hand while in use, the whole being designed to rest on a table top, bench, or other surface.

• Bench-top tools are small stationary tools that can be mounted or placed on a table or bench. They are generally distinguishable from other stationary tools by size and ease of movement.

The scope of the PECT investigation includes only the following bench-top, hand-operated tools: cut-off saws; PVC saws; chop saws; cut-off machines, currently classifiable under subheading 8461 of the *Harmonized Tariff Schedule of the United States* (HTSUS); all types of miter saws, including slide compound saws, currently classifiable under subheading 8465 of the HTSUS; and band saws with detachable bases, also currently classifiable under subheading 8465 of the HTSUS. The PECT and PESGT investigations do not include:

• Professional electric drilling/fastening tools;

• Lawn and garden tools;

• Heat guns;

• Paint and wallpaper strippers; and

• Chain saws, currently classifiable under subheading 8508 of the HTSUS.

Parts or components of PECTs and PESGTs when they are imported as kits, or as accessories imported together with covered tools are included within the scope of these investigations.

"Corded" and "cordless' consumer electric cutting tools and consumer electric sanding/grinding tools are not included within the scope of these investigations. "Corded" consumer electric power tools (CEPTs), which are driven by electrical current passed through a power cord, are, for purposes of these investigations, defined as power tools which have at least five of the following seven characteristics:

(1) The predominant use of sleeve or plain bearings (*i.e.*, a majority or greater number of the bearings in the tool are sleeve or plain bearings);

(2) Spur or straight bevel gearing;

(3) A thermo-plastic jacketed power supply cord with a length of less than eight feet;

(4) A power supply cord restrained by a molded-on cord protector;

(5) The absence of user-serviceable motor brushes;

(6) The predominant use of non-heat treated transmission parts (*i.e.*, a majority or greater number of the transmission parts in the tool are not heat treated); and

(7) The presence of only one coil per slot armature. If a "corded" CEPT possesses only six of the seven characteristics, then the tool must have at least four of the six characteristics.

"Cordless" CEPTS are distinguishable from professional electric "cordless" tools by voltage. We preliminarily find that the voltage of "cordless" CEPTs does not exceed 7.2 volts.

We have examined the comments of all parties in reaching these preliminary determinations. Nonetheless, given the complicated nature of these issues, we invite all parties to comment on our preliminary determination of the scope of these proceedings. We are especially interested in comments regarding criteria defining "corded" professional power tools, rather than "corded" CEPTs, and additional criteria that should be considered in distinguishing professional and consumer cordless tools. Such comments should be submitted to the Department not later than February 1, 1993.

PECTs are currently classifiable under the following subheadings of the HTSUS: 8508.20.00.20, 8508.20.00.70, 8508.20.00.90, 8461.50.00.20, 8465.91.00.35, 8508.80.00.55 and 8508.80.00.65. PESGTs are currently classifiable under the following subheadings of the HTSUS: 8508.80.00.10, 8508.80.00.15, 8508.80.00.25, 8508.80.00.35, and 8508.80.00.90. Although the HTSUS subheadings are provided for convenience and customs purposes, our written descriptions of the scopes of these proceedings are dispositive.

Period of Investigations

The period of these investigations (POI) is from December 1, 1991, through May 31, 1992.

Such or Similar Comparisons

We made fair value comparisons using the following such or similar categories for PECTs:

(1) Circular saws and hypoid saws;

(2) Hand-held jig saws and hand-held scroll saws;

(3) Hand-held reciprocating saws;

(4) Hand-operated cut-off saws, PVC saws, and chop saws;

(5) Hand-held band saws;

(6) Hand-held metal cutting saws;

(7) Hand-held cutter saws, angle cutters, and cut-off machines;

(8) Hand-held planers;

(9) Hand-held trimmers and routers;

(10) Hand-held shears and nibblers;

(11) and Hand-held joiners and jointers;

(12) Groove cutters; and

(13) Other miscellaneous groupings.

We made fair value comparisons using the following such or similar categories for PESGTs:

(1) Orbital and random orbit finishing sanders;

(2) Belt sanders;

(3) Wheel sanders;

(4) Disc sanders and disc polishers;

(5) Angle grinders, disc grinders, angle sanders, and angle polishers;

(6) Straight grinders and die grinders; and

(7) Other miscellaneous groupings.

We based all product comparisons in the U.S. and home markets on sales of similar merchandise only because identical merchandise was not sold in both markets. We selected similar merchandise by applying the following criteria in descending order of importance:

(1) Configuration;

(2) Corded vs. cordless;

(3) Capacity;

(4) Power;

(5) Speed;

(6) Housing material; and

(7) Size.

In examining Makita's model matches, we noted that they did not conform to the instructions contained in the questionnaire. On December 8, 1992, we informed Makita of these problems, and on December 14, 1992, Makita replied that it had applied the "Power" criteria using volts and amps, rather than the watts figure contained in their

catalogues. However, we continued to find mismatched products, unaffected by Makita's explanation. These mismatches are not great in number, nor do they follow a consistent pattern. We have matched these products correctly and this issue will be a focus of our verification.

In addition, we excluded sales made of one U.S. PESGT model from our analysis and certain other miscellaneous sales (*e.g.*, sample sales) from our price-to-price comparisons because they accounted for a small percentage of U.S. sales and we had adequate sales coverage. In performing its LTFV analysis, the Department is not required to examine every sales transaction made by a respondent during the POI. 19 CFR 353.42(b).

Fair Value Comparisons

To determine whether sales of PECTs and PESGTs from Japan to the United States were made at less than fair value, we compared the United States price (USP) to the FMV at the same levels of trade, as specified in the "United States Price" and "Foreign Market Value" sections of this notice. Although Makita did not propose any level of trade comparisons, we have determined that comparisons should be made at two levels of trade, wholesale and retail.

United States Price

We based USP on exporter sales price (ESP) in accordance with section 772(c) of the Act, because the subject merchandise was sold to unrelated purchasers in the United States after importation into the United States.

We calculated ESP based on packed, delivered and/or undelivered prices to unrelated customers in the United States. We made deductions, where appropriate, for discounts, rebates, foreign brokerage and handling, foreign inland freight, ocean freight, marine insurance, U.S. duties, U.S. brokerage and handling, and U.S. inland freight in accordance with section 772(d)(2) of the Act. We added to U.S. price payments Makita received for drop-ship fees.

In accordance with section 772(e) of the Act, we made additional deductions, where appropriate, for credit expenses, direct and indirect advertising expenses, warranty expenses, product liability premium expenses, and indirect selling expenses, including inventory carrying costs and bad debt expenses.

We disallowed an addition to U.S. price for handling fees associated with returned merchandise claimed by Makita. Makita did not adequately explain how this fee related to the sales being examined. If at verification, we find evidence that the returned merchandise should not be considered in our analysis, we will not include it in the final determinations.

In accordance with section 772(d)(1)(C) of the Act, we added to net unit price the amount of value-added tax (VAT) that is not collected by reason of exportation of the merchandise to the United States.

Foreign Market Value

In order to determine whether there were sufficient sales of PECTs and PESGTs in the home market to serve as viable bases for calculating FMV, we compared the volume of home market sales of PECTs to the volume of third party country sales of PECTs, and compared the volume of home market sales of PESGTs to the volume of third country sales of PESGTs, in accordance with 19 CFR 353.48(a). Makita had viable home markets with respect to sales of PECTs and PESGTs during the POI.

We excluded from our analysis certain home market sales claimed by Makita to be outside the ordinary course of trade.

We calculated FMV based on delivered prices to unrelated customers in the home market. We made deductions, where appropriate, for discounts, rebates, inland freight, post-sale warehousing expenses, credit expenses, and direct advertising expenses.

We also deducted from FMV the weighted-average home market indirect selling expenses, including, where appropriate, advertising and inventory carrying costs, up to the amount of indirect selling expenses and commissions incurred on U.S. sales, in accordance with 19 CFR 353.56(b).

We made a circumstance of sale adjustment for the difference between VAT on home market sales and that which would have been collected on U.S. sales if the export sales had been taxed.

We deducted home market packing costs and added U.S. packing costs.

Makita provided constructed value (CV) information for two cordless PECT models sold in the United States. In submitting the CV information, Makita did not follow the instructions in the August 11, 1992, questionnaire, which required Makita to request a CV questionnaire by contacting the "Official in Charge" if it was unable to make home market comparisons with a difference of merchandise adjustment within 20 percent. The Department requires that CV information be submitted in response to its own questionnaire so that the information can be efficiently used in its analysis. When informed that a questionnaire request would be required, Makita chose not to submit a request. Therefore, we did not analyze the data and have subsequently returned the CV information to Makita.

In addition, in submitting the CV information, Makita claimed that these two models represented an insignificant portion of its total U.S. sales made during the POI and requested that we exclude them from our analysis. However, after examining the total number of sales transactions of these two U.S. models during the POI, we find that these sales were not insignificant. Normally, we use the highest calculated rate but in this case it was aberrational. Therefore, as best information available (BIA) in accordance with 19 CFR 353.37, we used the average of the positive margins calculated for PECT transactions for these sales. *See, e.g., Preliminary Results and Termination in Part of Antidumping Duty Administrative Review: 3.5" Microdisks and Coated Media Thereof from Japan*, 56 FR 36768 (August 1, 1991).

Currency Conversion

We made currency conversions based on the official exchange rates in effect on the date of the U.S. sales as certified by the Federal Reserve Bank.

Verification

As provided in section 776(b) of the Act, we will verify the information used in making our final determinations.

Critical Circumstances

Petitioner alleges that "critical circumstances" exist with respect to imports of PECTs and PESGTs from Japan. Section 733(e)(1) of the Act provides that there is a reasonable basis to believe or suspect that critical circumstances exist if:

(A) (i) there is a history of dumping in the United States or elsewhere of the class or kind of the merchandise which is the subject of the investigation, or

(ii) the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the merchandise which is the subject of the investigation at less than its fair value, and

(B) there have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

Pursuant to 19 CFR 353.16(f), we generally consider the following factors in determining whether imports have been massive over a short period of time:

(1) The volume and value of the imports; (2) seasonal trends (if applicable); and (3) the share of

domestic consumption accounted for by imports. *See, e.g., Final Determination of Sales at Less Than Fair Value: Certain Internal-Combustion Industrial Forklift Trucks from Japan*, 53 FR 12552 (April 15, 1988). To determine whether imports have been massive, we normally compare the export volume for the base period, which is a period of not less than three months beginning with the month the petition was filed (provided that the petition was filed before the mid-way point in the month), with an immediately previous period of comparable duration. Since the petition was filed on May 29, 1992, we compared available U.S. Customs import data of PECTs and PESGTs from Japan, during the four month, not three month period after the filing of the petition (the comparison period), June through September 1992 (Customs data was not available after September 1992), to U.S. Customs import data during the four month period including the month the petition was filed, February through May 1992. Makita's company-specific shipment data was submitted too late to be considered for purposes of the preliminary determinations. It will, however, be verified and considered for the final determinations.

Under 19 CFR 353.16(f)(2), unless the imports in the comparison period have increased by at least 15 percent over the imports during the base period, we will not consider the imports "massive." Based on this analysis, we find that imports of the subject merchandise during the period subsequent to the receipt of the petition have not been massive.

Since we do not find that there have been massive imports, pursuant to section 733(e)(1)(B) of the Act, we need not consider whether there is a history of dumping or whether there is reason to believe or suspect that importers of this product knew or should have known that it is being sold at less than fair value.

Therefore, we preliminarily determine that there is not a reasonable basis to believe or suspect that critical circumstances exist with respect to imports of PECTs and PESGTs from Japan.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of PECTs and PESGTs from Japan that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice.

Producer/manufacturer/exporter	Weighted-average margin percentage	
	PECTs	PESGTs
Makita Corporation, Makita USA, Inc., and Makita Corporation of America	41.17	38.98
All Others	41.17	38.98

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determinations. If our final determinations are affirmative, the ITC will determine before the later of 120 days after the date of these preliminary determinations or 45 days after our final determinations whether imports of PECTs and PESGTs are materially injuring, or threaten material injury to, the U.S. industry.

Postponement of Final Determinations

As stated above, in accordance with 19 CFR 353.20(b), Makita, which accounts for a significant portion of the merchandise covered by these proceedings, has requested in writing that, in the event of affirmative determinations, the Department postpone the final determinations by 30 days. Accordingly, we are postponing the date of the final determinations until not later than 105 days after the date of publication of this notice.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments in at least ten copies must be submitted to the Assistant Secretary for Import Administration no later than March 12, 1993, and rebuttal briefs no later than March 17, 1993. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on March 22, 1993, at 9:30 a.m. at the U.S. Department of Commerce, room 3708, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled time.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, room B–099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

These determinations are published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: December 28, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 92–31926 Filed 12–31–92; 8:45 am]

BILLING CODE 3510-DS-M

[C–333–502]

Deformed Steel Concrete Reinforcing Bar From Peru; Determination Not To Revoke Countervailing Duty Order

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of determination not to revoke countervailing duty order.

SUMMARY: The Department of Commerce is notifying the public of its determination not to revoke the countervailing duty order on deformed steel concrete reinforcing bar from Peru.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Patricia W. Stroup or Maria MacKay, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 482–0983 or 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 1992, the Department of Commerce ("the Department") published in the **Federal Register** (57 FR 49691) its intent to revoke the countervailing duty order on deformed steel concrete reinforcing bar from Peru (50 FR 48819; November 27, 1985). Under 19 CFR 355.25(d)(4)(iii), the Secretary of Commerce will conclude that an order is no longer of interest to interested parties and will revoke the order if no interested party objects to revocation or requests an administrative review by the last day of the fifth anniversary month. We had not received a request for an administrative review of the order for more than four consecutive anniversary months.

On November 18, 1992, Chaparral Steel Company, a domestic producer of the subject merchandise and a petitioner in this proceeding, objected to our intent to revoke the order. On November

24, 1992, Florida Steel Corporation, also a domestic producer and a petitioner, submitted an objection to our intent to revoke the order. Because the requirements of 19 CFR 355.25(d)(4)(iii) have not been met, we will not revoke the order.

This notice is in accordance with 19 CFR 355.25(d).

Dated: December 23, 1992.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 92–31881 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DS–M

[C–351–812]

Rescheduling of Public Hearing: Certain Hot-Rolled Lead and Bismuth Carbon Steel Products From Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of rescheduling of a public hearing.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Phil Pia or Laurel Lynn, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW. room 4012, Washington, DC 20230; telephone (202) 482–2786.

NOTICE OF RESCHEDULING: In accordance with 19 CFR 355.38(f)(1992), we will hold a public hearing to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. The hearing will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., room 1412, Washington, DC, on January 5, 1993 at 1 p.m. Parties should confirm, by telephone, the time, date and place of the hearings 48 hours prior to the scheduled time.

The schedule for submission of briefs is as previously established with the parties.

This notice is published pursuant to 19 CFR 355.20(b).

Dated: December 22, 1992.

Rolf Th. Lundberg,

Acting Assistant Secretary for Import Administration.

[FR Doc. 92–31927 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DS–M

[C–580–602]

Certain Stainless Steel Cooking Ware From the Republic of Korea, Intent To Revoke Countervailing Duty Order

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of intent to revoke countervailing duty order.

SUMMARY: The Department of Commerce is notifying the public of its intent to revoke the countervailing duty order on certain stainless steel cooking ware from the Republic of Korea. Interested parties who object to this revocation must submit their comments in writing not later than January 31, 1993.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Patricia W. Stroup, Dana Mermelstein or Maria MacKay, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 482–0983 or 482–0984.

SUPPLEMENTARY INFORMATION:

Background

On January 20, 1987, the Department of Commerce ("the Department") published a countervailing duty order on certain stainless steel cooking ware from the Republic of Korea (52 FR 2140). The Department has not received a request to conduct an administrative review of this countervailing duty order for four consecutive annual anniversary months.

In accordance with 19 CFR 355.25(d)(4)(iii), the Secretary of Commerce will conclude that an order is no longer of interest to interested parties and will revoke the order if no interested party objects to revocation or requests an administrative review by the last day of the fifth anniversary month. Accordingly, as required by § 355.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke this order.

Opportunity to Object

Not later than January 31, 1993, interested parties, as defined in § 355.2(i) of the Department's regulations, may object to the Department's intent to revoke this countervailing duty order.

Seven copies of any such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, room B–099, U.S. Department of Commerce, Washington, DC 20230.

If interested parties neither request an administrative review (pursuant to the Department's notice of opportunity to request administrative review), nor object to the Department's intent to revoke by January 31, 1993, we shall conclude that the order is not longer of interest to interested parties and shall proceed with the revocation.

This notice is in accordance with 19 CFR 355.25(d)(4)(i).

Dated: December 24, 1992.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 92–31885 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DS–M

[C–583–604]

Stainless Steel Cooking Ware From Taiwan; Intent To Revoke Countervailing Duty Order

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of intent to revoke countervailing duty order.

SUMMARY: The Department of Commerce is notifying the public of its intent to revoke the countervailing duty order on stainless steel cooking ware from Taiwan. Interested parties who object to this revocation must submit their comments in writing not later than January 31, 1993.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Patricia W. Stroup, Lorenza Olivas or Maria MacKay, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 482-0983 or 482-2786.

SUPPLEMENTARY INFORMATION:

Background

On January 20, 1987, the Department of Commerce ("the Department") published a countervailing duty order on stainless steel cooking ware from Taiwan (52 FR 2141). The Department has not received a request to conduct an administrative review of this countervailing duty order for four consecutive annual anniversary months.

In accordance with 19 CFR 355.259d)(4)(iii), the Secretary of Commerce will conclude that an order is no longer of interest to interested parties and will revoke the order if no interested party objects to revocation or requests an administrative review by the last day of the fifth anniversary month. Accordingly, as required by § 355.25(d)(4) of the Department's regulations, we are notifying the public of our intent to revoke this order.

Opportunity to Object

Not later than January 31, 1993, interested parties, as defined in § 355.2(i) of the Department's regulations, may object to the Department's intent to revoke this countervailing duty order.

Seven copies of any such objections should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, room B–099, U.S. Department of Commerce, Washington, DC 20230.

If interested parties neither request an administrative review (pursuant to the Department's notice of opportunity to request administrative review), nor object to the Department's intent to revoke by January 31, 1993, we shall conclude that the order is no longer of interest to interested parties and shall proceed with the revocation.

This notice is in accordance with 19 CFR 355.25(d)(4)(i).

Dated: December 24, 1992.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 92–31884 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DS–M

[C–357–048]

Certain Textiles and Textile Products (Men's and Boys' Woolen Garments) From Argentina; Determination Not To Revoke Countervailing Duty Order

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of determination not to revoke countervailing duty order.

SUMMARY: The Department of Commerce is notifying the public of its determination not to revoke the countervailing duty order on certain textiles and textile products, specifically, men's and boys' woolen garments, from Argentina.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Patricia W. Stroup, Lorenza Olivas or Maria MacKay, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington DC 20230; telephone: (202) 482–0983 or 482–1775.

SUPPLEMENTARY INFORMATION:

Background

On November 3, 1992, the Department of Commerce published in the **Federal Register** (57 FR 49691) its intent to revoke the countervailing duty order on certain textiles and textile mill products from Argentina (43 FR 53421; November 16, 1978). Under 19 CFR 355.25(d)(4)(iii), the Secretary of Commerce will conclude that an order is no longer of interest to interested parties and will revoke the order if no interested party objects to revocation or requests an administrative review by the last day of the fifth anniversary month. We had not received a request for an administrative review of the order for more than four consecutive anniversary months.

On November 10, 1992, the Amalgamated Clothing and Textile Workers Union, AFL–CIO, a petitioner and an interested party in this proceeding, objected to our intent to revoke the order. Because the requirements of 19 CFR 355.25(d)(4)(iii) have not been met, we will not revoke the order.

This notice is in accordance with 19 CFR 355.25(d).

Dated: December 24, 1992.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 92–31880 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DS–M

National Oceanic and Atmospheric Administration

Coastal Zone Management; Federal Consistency Appeal by Robert E. Harris From an Objection by the New York State Department of State

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of decision.

On December 2, 1992, the Secretary of Commerce (Secretary) issued a decision in the consistency appeal of Robert E. Harris (Appellant). The Appellant had applied to the U.S. Army Corps of Engineers (Corps) for a permit to construct a dock with 18 slips behind his property on the shore of the Hudson River in Rensselaer, New York. In conjunction with the Federal permit application, the Appellant submitted to the Corps for review by the New York State Department of State (State), the State of New York's coastal management agency, under section 307(c)(3)(A) of the Coastal Zone Management Act of 1972, as amended (CZMA), 16 U.S.C. 1456(c)(3)(A), a certification that the proposed activity is consistent with the State's federally-approved Coastal Management Program (CMP).

On September 28, 1990, the State objected to the Appellant's consistency certification for the proposed project on numerous grounds including that the proposed project is not in accordance with the State's CMP policies and objectives of facilitating the siting of water dependent uses and facilitates on or adjacent to coastal waters. Under CZMA section 307(c)(3)(A) and 15 CFR 930.131, the State's consistency objection precludes the Corps from issuing a permit for the activity unless the Secretary finds that the activity is either consistent with the objectives or purposes of the CZMA (Ground I) or necessary in the interest of national security (Ground II). The Appellant based his appeal on Ground I.

Upon consideration of the information submitted by the Appellant, the State, and interested Federal agencies, the Secretary made the following findings pursuant to 15 CFR 930.121(d): The alternative proposed by the State of constructing a small dock with eight slips for the recreational use of the Appellant and his tenants was a reasonable, available alternative that would be consistent with the State's CMP. Accordingly, the proposed project is not consistent with the objectives or purposes of the CZMA. Because the Appellant's proposed project failed to satisfy all of the requirements of Ground I, the Secretary did not override the State's objection to the Appellant's consistency certification. Consequently, the proposed project may not be permitted by Federal agencies. Copies of the decision may be obtained from the contact person listed below.

FOR ADDITIONAL INFORMATION CONTACT: Angelica G. Fleites, Law Clerk, Office of the Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1825 Connecticut Avenue, NW., suite 603, Washington, DC 20235, (202) 606–4200.

Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance.

Dated: December 23, 1992.

Thomas A. Campbell,

General Counsel.

[FR Doc. 92–31896 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–08–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Bangladesh

December 29, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting limits.

EFFECTIVE DATE: December 29, 1992

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The current limits for certain categories are being adjusted, variously, for carryforward and swing.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 56 FR 60101, published on November 27, 1991). Also see 57 FR 1146, published on January 10, 1992.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

J. Hayden Boyd

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 29, 1992.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on January 7, 1992, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Bangladesh and exported during the twelve-month period which began on February 1, 1992 and extends through January 31, 1993.

Effective on December 29, 1992 , you are directed to amend further the directive dated January 7, 1992 to adjust the limits for the following categories, as provided under the terms of the current bilateral agreement between the Governments of the United States and People's Republic of Bangladesh:

Category	Adjusted twelve-month limit [1]
334	109,618 dozen.
638/639	1,293,950 dozen.
641	619,533 dozen.

[1] The limits have not been adjusted to account for any imports exported after January 31, 1992.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

J. Hayden Boyd

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 92–31921 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DR–F

Amendment of Export Visa Requirements for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Hong Kong

December 29, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs amending visa requirements.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Anne Novak, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce. (202) 482–4212.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The existing export visa arrangement between the Governments of the United States and Hong Kong is being amended to require a visa for women's and girls' cotton and man-made fiber trousers, breeches and shorts in part-Categories 348–K (knit), 348–W (woven), 648–K (knit) and 648–W (woven), produced or manufactured in Hong Kong and exported from Hong Kong on and after January 1, 1993.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 57 FR 54976, published on November 23, 1992). Also see 48 FR 2400, published on January 19, 1983 and 51 FR 27235, published on July 30, 1986.

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 29, 1992.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on January 14, 1983, as amended on July 25, 1986, by the Chairman, Committee for the Implementation of Textile Agreements. That directive directed you to prohibit entry of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced on manufactured in Hong Kong, for which the Government of Hong Kong has not issued an appropriate visa.

Effective on January 1, 1993, you are directed to amend further the January 14, 1983 directive to require an export visa for shipments of cotton and man-made fiber textile products in the following part-categories, produced or manufactured in Hong Kong and exported from Hong Kong on and after January 1, 1993:

Category	HTS numbers
348–K	Knit trousers, breeches and shorts—All HTS numbers in Category 348, except those in Category 348–W.
348–W	Woven trousers, breeches and shorts—Only 6204.12.0030, 6204.19.3030, 6204.22.3040, 6204.22.3050, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.62.4055, 6204.62.4065, 6204.69.3010, 6204.69.9010, 6210.50.2035, 6211.20.1550, 6211.20.6010, 6211.42.0030 and 6217.90.0050.
648–K	Knit trousers, breeches and shorts—All HTS numbers in Category 648, except those in Category 648–W
648–W	Woven trousers, breeches and shorts—Only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4308, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.60.2560, 6204.69.3030, 6204.69.9030, 6210.50.1035, 6211.20.1555, 6211.20.6030, 6211.43.0040 and 6217.90.0060.

Also effective January 1, 1993 the merged Category 347/348 visa shall no longer be accepted for goods produced or manufactured in Hong Kong and exported from Hong Kong on and after January 1, 1993. All shipments of goods in Category 347 and Category 348 produced or manufactured in Hong Kong and exported from Hong Kong on and after January 1, 1993 must be visaed as Category 347, 348–K or 348–W and not as merged Category 347/348.

Shipments entered or withdrawn from warehouse according to this directive which are not accompanied by an appropriate export visa shall be denied entry and a new visa must be obtained.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 92-31936 Filed 12-30-92; 10:46 am]

BILLING CODE 3510-DR-M

Announcement of Import Restraint Limits for Certainotton, Wool and Man-Made Fiber Textile Products Produced or Manufactured in the United Mexican States

December 28, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits for the new agreement year.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Anne Novak, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-6711. For information on embargoes and quota re-openings, call (202) 482-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of February 13, 1988, as amended and extended, establishes limits for the period beginning on January 1, 1993 and extending through December 31, 1993.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish limits for the 1993 agreement period, including certain categories subject to the Special Regime. Sublimits and separate limits for Normal Regime categories are established for products which are not subject to the terms of the Special Regime.

A copy of the current bilateral textile agreement is available from the Textiles Division, Bureau of Economic and Business Affairs, U.S. Department of State, (202) 647-3889.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 57 FR 54976, published on November 23, 1992).

Requirements for participation in the Special Regime Program are available in Federal Register notices 53 FR 15724, published on May 3, 1988; 53 FR 32421, published on August 25, 1988; 53 FR 49346, published on December 7, 1988; and FR 50425, published on December 6, 1989.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

J. Hayden Boyd

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 28, 1992.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on July 31, 1991; pursuant to the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of February 13, 1988, as amended and extended, between the Governments of the United States and the United Mexican States; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 1, 1993, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton, wool and man-made fiber textile products in the following categories, produced or manufactured in Mexico and exported during the twelve-month period beginning on January 1, 1993 and extending through December 31, 1993, in excess of the following levels of restraint:

Category	Twelve-month restraint limit
Group I	
218-220, 225-227, 313-326, 611-617 and 625-629, as a group.	53,595,720 square meters.
Sublevels in Group I	
218	1,118,925 square meters.
219	16,674,224 square meters.
313	29,775,400 square meters.
317	14,887,700 square meters.
326	1,118,925 square meters.
611	2,237,854 square meters.
Individual Limits not in a group	
300/301/607-Y[1]	6,337,112 kilograms of which not more than 4,525,861 kilograms shall be in Category 300.
334/634	150,000 dozen.
335 (Special Regime)	135,000 dozen.
336/636 (Special Regime).	476,408 dozen.
338/339/638/639 (Special Regime).	1,400,000 dozen.
340/640 (Special Regime).	481,762 dozen.
341/641 (Special Regime).	800,000 dozen.
342/642 (Special Regime).	300,000 dozen.
347/348/647/648 (Special Regime).	4,500,000 dozen.
351/651 (Special Regime).	350,000 dozen.
352/652 (Special Regime).	2,900,000 dozen.
359-C/659-C[2] (Special Regime).	1,800,000 kilograms.
363	5,500,000 numbers.
410	397,160 square meters.
433	11,809 dozen.
435 (Special Regime)	20,000 dozen.
443	118,485 numbers.
604-A[3]	2,006,867 kilograms.
604-O/607-O[4]	1,257,058 kilograms.
633 (Special Regime)	100,000 dozen.
635 (Special Regime)	300,000 dozen.
643	155,556 numbers.
669-B[5]	744,444 kilograms.
670	3,000,000 kilograms.
Normal Regime Category (Not subject to the Special Regime)	
335 (sublimit)	35,000 dozen.
336/636 (sublimit)	238,203 dozen.
338/339/638/639 (sublimit).	650,000 dozen.
340/640 (sublimit)	120,438 dozen.
341/641	700,000 dozen of which not more than 315,204 dozen shall be in Categories 341-Y/641-Y[6].
342/642	119,102 dozen.
347/348/647/648	650,000 dozen.
351/651	75,000 dozen.
352/652	1,905,826 dozen.
359-C/659-C (sublimit).	250,000 kilograms.
435	12,000 dozen.
633 (sublimit)	10,000 dozen.
635	153,896 dozen.

[1] Categories 300 and 301; Category 607-Y: only HTS numbers 5509.53.0030 and 5509.53.0060.

[2] Category 359-C: only HTS numbers 6103.42.2010, 6103.42.2025, 6103.49.3034, 6104.62.1010, 6104.62.1020, 6104.69.3010, 6114.20.0042, 6114.20.0048, 6114.20.0052, 6203.42.2005, 6203.42.2010, 6203.42.2090, 6204.62.2005, 6204.62.2010, 6211.32.0007, 6211.32.0010, 6211.32.0025, 6211.42.0007 and 6211.42.0010; Category 659-C: only HTS numbers 6103.23.0055, 6103.43.2015, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.3038, 6104.63.1010, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.3014, 6114.30.3044, 6114.30.3054, 6203.43.2005, 6203.43.2010, 6203.43.2090, 6203.49.1005, 6203.49.1010, 6203.49.1090, 6204.63.1505, 6204.63.1510, 6204.69.1005, 6204.69.1010, 6210.10.4015, 6211.33.0007, 6211.33.0010, 6211.33.0017, 6211.43.0007 and 6211.43.0010.

[3] Category 604-A: only HTS number 5509.32.0000.

[4] Category 604-O: all HTS numbers except 5509.32.0000 (Category 604-A); Category 607-O: all HTS numbers except 5509.53.0030 and 5509.53.0060 (Category 607-Y).

[5] Category 669-B: only HTS numbers 6305.31.0020 and 6305.39.0000.

[6] Category 341-Y: only HTS numbers 6204.22.3060, 6206.30.3010 and 6206.30.3030; Category 641-Y: only HTS numbers 6204.23.0050, 6204.29.2030, 6206.40.3010 and 6206.40.3025.

Imports charged to these category limits for the period January 1, 1992 through December 31, 1992 shall be charged against those levels

of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

The limits set forth above are subject to adjustment in the future pursuant to the provisions of the current bilateral agreement between the Governments of the United States and United Mexican States.

The bilateral agreement establishes separate treatment for products in certain categories. Those products which are made of U.S. formed and cut fabric are subject to the Special Regime and to the category limits listed in this directive. Those products which are exported from Mexico to the United States under provisions of the Special Regime on and after January 1, 1993 must be accompaniued by a properly certified Form ITA–370P.

Any shipment for entry under the Special Regime Program which is not accompanied by a valid and correct certification and Shippers Export Declaration (Form ITA–370P) in accordance with the provisions of the certification requirements established in the directive of August 22, 1988, as amended, shall be denied entry. Invoices visaed for Special Regime shall include only products that are subject to the Special Regime or entry will be denied.

Shipments of products in categories covered by the Special Regime, but that are not subject to the Special Regime, are subject to the applicable limits and sublimits listed in this directive.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

J. Hayden Boyd

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 92–31922 Filed 12–31–92; 8:45 am]

BILLING CODE 3510–DR–F

Soliciting Public Comment on Bilateral Negotiations During 1993

December 28, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Announcement.

SUPPLEMENTARY INFORMATION:

The U.S. Government anticipates holding negotiations during 1993 concerning expiring bilateral agreements covering certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and apparel from China (December 31, 1993), Colombia (December 31, 1993), Costa Rica (December 31, 1993), Czech and Slovak Federal Republic (May 31, 1993), Dominican Republic (December 31, 1993), Egypt (December 31, 1993), Guatemala (December 31, 1993—Categories 340/640 only), Hungary (December 31, 1993), India (December 31, 1993), Jamaica (December 31, 1993), Korea (December 31, 1993), Macau (December 31, 1993), Mauritius (September 30, 1993), Nepal (December 31, 1993), Pakistan (December 31, 1993), Poland (December 31, 1993), Philippines (December 31, 1993), Romania (December 31, 1993), Thailand (December 31, 1993), Turkey (December 31, 1993), United Arab Emirates (December 31, 1993) and Uruguay (June 30, 1993). (The dates noted in parenthesis are the expiration dates of the agreements.)

Anyone who wishes to comment or provide data or information regarding these agreements, or to comment on domestic production or availability of textiles and apparel affected by these agreements, is invited to submit such comments or information in 10 copies to J. Hayden Boyd, Acting Chairman, Committee for the Implementation of Textile Agreements, U.S. Department of Commerce, Washington, DC, 20230; ATTN: Helen L. LeGrande. The comments received will be considered in the context of the consultations held with respect to these agreements.

Because the exact timing of the consultations is not yet certain, comments should be submitted promptly. Comments or information submitted in response to this notice will be available for public inspection in the Office of Textiles and Apparel, room H3100, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC. Further comment may be invited regarding particular comments or information received from the public which the Committee for the Implementation of Textile Agreements considers appropriate for further consideration.

The solicitation of comments regarding any aspect of the agreements or the implementation thereof is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) relating to matters which constitute "a foreign affairs function of the United States."

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 93–31923 Filed 12–31–93; 8:45 am]

BILLING CODE 3510–DR–F

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to Procurement List.

SUMMARY: This action adds to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: February 3, 1993.

ADDRESSES: Committee for Purchase from People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On June 12, August 28, November 16 and 20, 1992, the Committee for Purchase from People Who Are Blind or Severely Disabled published notices (57 FR 25023, 39190, 54062 and 54774) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to produce the commodity and provide the services, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the commodity and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity or services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodity or services.

3. The action will result in authorizing small entities to furnish the commodity or services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity or

services proposed for addition to the Procurement List.

Accordingly, the following commodity and services are hereby added to the Procurement List:

Commodity

Cap, Knit, 8405–01–006–1074

Services

Commissary Shelf Stocking and Custodial, Naval Station, Treasure Island, California

Grounds Maintenance, U.S. Army Reserve Center, 6401 Imperial Drive, Waco, Texas

Janitorial/Custodial, Veterans Outreach Center, 500 Walnut Street, McKeesport, Pennsylvania

Janitorial/Custodial, Veterans Outreach Center, 954 Penn Avenue, Pittsburgh, Pennsylvania

Janitorial/Custodial, U.S. Army Reserve Center, 6401 Imperial Drive, Waco, Texas

Janitorial/Custodial, Army National Guard Readiness Center, 111 South George Mason Drive, Arlington, Virginia

Mailroom Operation, IRS Computing Center, Route 9 and Needy Road, Martinsburg, West Virginia

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 92–31928 Filed 12–31–92; 8:45 am]

BILLING CODE 6820-33-M

Additions to the Procurement List; Correction

In the document appearing on page 57423 of FR Doc. 92–29469 in the issue of December 4, 1992 under Supplementary Information: In the third paragraph the following sentence should be inserted after the first sentence: The contractor did not receive the previous contract for the pads, so it cannot be considered dependent on continuous Government contracts for them.

Beverly L. Milkman,

Executive Director.

[FR Doc. 92–31931 Filed 12–31–92; 8:45 am]

BILLING CODE 6820-33-M

Procurement List Proposed Additions

AGENCY: Committee for Purchase From People Who are Blind or Severely Disabled.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: February 3, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action does not appear to have a severe adverse impact on the current contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following commodities to the Procurement List for production by the nonprofit agency listed:

Commodities

Floorboard, Wood, 2510–01–067–2630; Nonprofit Agency: Hardeman County Developmental Services Center, Bolivar, Tennessee

Rail, Target Framing, 6920–01–E02–1996, (Requirements for the U.S. Marine Corps, Parris Island, SC); Nonprofit Agency: Walterboro Vocational Rehabilitation Center, Walterboro, South Carolina

Cradle, Military Fuel Can, 7240–01–318–5222; Nonprofit Agency: Knox County Association for Retarded Citizens, Knoxville, Tennessee

Yard News, GPO Program C101–S, 7690–00–NSH–0046 (Requirements for the Government Printing Office, Washington, DC only); Nonprofit Agency: Lt. Joseph P. Kennedy Institute, Washington, DC

Beverly L. Milkman,

Executive Director.

[FR Doc. 92–31929 Filed 12–31–92; 8:45 am]

BILLING CODE 6820-33-M

Procurement List; Proposed Addition

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed addition to procurement list.

SUMMARY: The Committee has received a proposal to add to the Procurement List a commodity to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: February 3, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed action.

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodity listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity to the Government.

2. The action will result in authorizing small entities to furnish the commodity to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following commodity to the Procurement List for production by the nonprofit agency listed:

Towel, Paper, Decomposable, 7930–00–NIB–0020; Nonprofit Agency: East Texas Lighthouse for the Blind, Tyler, Texas

Beverly L. Milkman,

Executive Director.

[FR Doc. 92–31930 Filed 12–31–92; 8:45 am]

BILLING CODE 6820-33-M

COMMODITY FUTURES TRADING COMMISSION

Chicago Board of Trade Proposal to Register Certain Non-Member Officials of Member Firms and To Require Membership of Certain Non-Member Parent Firms

AGENCY: Commodity Futures Trading Commission.

ACTION: Extension of comment period.

SUMMARY: On October 7, 1992, the Commission published in the **Federal Register** a notice of a proposed new Chicago Board of Trade ("CBT") Regulation 230.03 which would establish procedures requiring registration of certain non-member officials of member firms and application for membership by certain non-member parent firms. 57 FR 46151. The comment period on the proposed new regulation originally was scheduled to expire on November 6, 1992, however, on that date the Commission extended the comment period until December 21, 1992. 57 FR 53887 (November 13, 1992).

The Futures Industry Association ("FIA") and the CBT have both requested that the public comment period for CBT Regulation 230.03 be extended so that the FIA and CBT could fully address the issues raised by the proposal.

In order to ensure that all interested parties have an opportunity to submit meaningful comments, the Commission has determined to grant a 31-day extension of the comment period for the CBT's proposal.

DATES: Comments must be submitted by January 21, 1993.

FOR FURTHER INFORMATION CONTACT: David P. Van Wagner, Special Counsel, Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Telephone: (202) 254–8955.

Issued in Washington, DC on December 28, 1992 by the Commission.

Alan L. Seifert,

Deputy Director.

[FR Doc. 92–31897 Filed 12–31–92; 8:45 am]

BILLING CODE 6351-01-M

Chicago Board of Trade Proposal to Assign the Catastrophe Insurance Futures Contracts to the Agricultural and Associated Market Category

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed contract market rule changes.

SUMMARY: The Chicago Board of Trade ("CBT") has submitted proposed rule amendments which would assign the Catastrophe Insurance ("CI") futures contracts to the Agricultural and Associated Market ("AAM") category.[1] Acting pursuant to the authority delegated by Commission Regulations 140.96, the Director of the Division of Trading and Markets has determined to publish the CBT proposal for public comment. The Division believes that publication of the CBT proposal is in the public interest and will assist the Commission in considering the views of interested persons.

DATES: Comments must be received on or before February 3, 1992.

FOR FURTHER INFORMATION CONTACT: Clarence Sanders, Attorney, Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street NW, Washington, DC 20581. Telephone (202) 254–8955.

SUPPLEMENTARY INFORMATION:

I. Description of Proposed Rule Amendments

By a letter dated November 24, 1992, the CBT submitted proposed rule amendments pursuant to section 5a(12) of the Commodity Exchange Act ("Act") and Commission Regulation 1.41(c) which would assign the CI futures contracts to the AAM category. Each of the CI contractors is based upon and settled according to an index constructed from insurance loss data.

Under existing CBT Rule 290.00, each futures and options contract must be assigned to one of four market categories: the Index, Debt and Energy Market ("IDEM"), Government Instrument Market ("GIM"), Commodity Options Market ("COM"), and AAM categories. Assignment of a contract to one of these four market categories entitles holders of trading interests in that particular market category to trade the newly assigned contract. Thus, although CI futures contracts may be considered "index" contracts, under the CBT proposal the CI futures contracts would be assigned to the AAM category, and holders of IDEM interests would be ineligible to trade the CI futures contracts.

Upon assignment of the CI futures contracts to the AAM category, trading eligibility would be determined by reference to CBT rules governing trading rights of holders of voting membership interests—full and associate members. Full members are eligible to trade all CBT contracts and associate members are eligible to trade all contracts assigned to the IDEM, GIM, and COM market categories. However, because the CBT has not implemented the AAM market category, and there are no AAM interest holders, assignment of CI futures contracts to the AAM category ultimately would reserve the CI futures contracts exclusively for trading by full members. Assignment to the AAM category would not have any effect immediately because the CBT separately has granted temporary trading privileges in CI futures contracts to Associate Members for a period of five years and to IDEM, GIM and COM members for a period of three years.

II. Request for Comments

The Commission requests comments on any aspect of the CBT's proposed rule amendments that members of the public believe may raise issues under the Act or Commission regulations.

Copies of the proposed rule and related materials are available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581. Copies also may be obtained through the Office of the Secretariat at the above address or by telephoning (202) 254–6314. Some materials may be subject to confidential treatment pursuant to 17 CFR 145.5 or 145.9.

[1] On November 16, 1992, the Commission designated the CBT as a contract market in separate futures and options contracts in National Catastrophe Insurance, Eastern Catastrophe Insurance, Midwestern Catastrophe Insurance, and Western Catastrophe Insurance.

Any person interested in submitting written data, views, or arguments on the proposed amended rule should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street N.W., Washington, DC, 20581, by the specified date.

Issued in Washington, DC, on December 28, 1992.

Alan L. Seifert,

Deputy Director.

[FR Doc. 92–31898 Filed 12–31–92; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Public Information Collection Requirement Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title, Applicable Form, and Applicable OMB Control Number: Development of A DoD Interest Measure

Type of Request: New collection

Average Burden Hours/Minutes Per Response: 1.019 hours

Responses Per Respondent: 1

Number of Respondents: 4650

Annual Burden Hours: 4738

Annual Responses: 4650

Needs and Uses: By February of 1995, the DoD needs to replace a commercially purchased inventory that is now used in the DoD Student Testing Program. This data collection will allow for the development of an interest inventory according to professionally accepted development standards.

Affect Public: Individuals or households; state or local governments

Frequency: One time

Respondent's Obligation: Voluntary

OMB Desk Officer: Mr. Edward C. Springer. Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. William P. Pearce. Written request for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, suite 1204, Arlington, Virginia 22202–4302.

Dated: December 29, 1992.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 92–31904 Filed 12–31–92; 8:45 am]

BILLING CODE 3810–01–M

Office of the Secretary

Department of Defense Wage Committee; Closed Meetings

Pursuant to the provisions of section 10 of Public Law 92–463, the Federal Advisory Committee Act, notice is hereby given that a meeting of the Department of Defense Wage Committee will be held on Tuesday, February 2, 1993; Tuesday, February 9, 1993; Tuesday, February 16, 1993; and Tuesday, February 23, 1993, at 2 p.m. in room 800, Hoffman Building #1, Alexandria, Virginia.

The Committee's primary responsibility is to consider and submit recommendations to the Assistant Secretary of Defense (Force Management and Personnel) concerning all matters involved in the development and authorization of wage schedules for Federal prevailing rate employees pursuant to Public Law 92–392. At this meeting, the Committee will consider wage survey specifications, wage survey data, local wage survey committee reports and recommendations, and wage schedules derived therefrom.

Under the provisions of section 10(d) of Public Law 92–463, meetings may be closed to the public when they are "concerned with matters listed in 5 U.S.C. 552b." Two of the matters so listed are those "related solely to the internal personnel rules and practices of an agency," (5 U.S.C. 552b. (c) (2)), and those involving "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (5 U.S.C. 552b. (c) (4)).

Accordingly, the Deputy Assistant Secretary of Defense (Civilian Personnel Policy/Equal Opportunity) hereby determines that all portions of the meeting will be closed to the public because the matters considered are related to the internal rules and practices of the Department of Defense (5 U.S.C. 552b. (c) (2)), and the detailed wage data considered were obtained from officials of private establishments with a guarantee that the data will be held in confidence (5 U.S.C. 552b(c) (4)).

However, members of the public who may wish to do so are invited to submit material in writing to the chairman concerning matters believed to be deserving of the Committee's attention.

Additional information concerning this meeting may be obtained by writing the Chairman, Department of Defense Wage Committee, room 3D264, The Pentagon, Washington, DC. 20310.

Dated: December 29, 1992.

L.M. Bynum,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 92–31905 Filed 12–31–92; 8:45 am]

BILLING CODE 3810–01–M

Department of the Army

Army Science Board; Closed Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 20–22 January 1993.

Time of Meeting: 1200–1700, 20 January; and 0800–1700, 21–22 January.

Place: Ft. Monmouth, NJ.

Agenda: The Army Science Board Ad Hoc Panel on "Space Systems and Future Army Operations" will meet for discussions focussed on current operational concepts, the Army Long-range Plan for Space and associated technologies. This meeting will be closed to the public in accordance with section 552b.(c) of title 5, U.S.C., specifically subparagraph (1) thereof and title 5, U.S.C. Appendix 2, subsection 10(d). The classified and non-classified information to be discussed will be so inextricably intertwined so as to preclude opening any portion of the meeting. The ASB Administrative Officer, Sally Warner, may be contacted for further information (703)695–0781.

Sally A. Warner,

Administrative Officer, Army Science Board.

[FR Doc. 92–31878 Filed 12–31–92; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Management Service, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before February 3, 1993.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs,

Attention: Dan Chenok: Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place, NW., room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Cary Green, Department of Education, 400 Maryland Avenue, SW., room 5624, Regional Office Building 3, Washington, DC 20202–4651.

FOR FURTHER INFORMATION CONTACT: Cary Green (202) 708–5174.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Management Service, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Cary Green at the address specified above.

Dated: December 28, 1992.

Wallace McPherson,

Acting Director, Information Resources Management Service.

Office of Postsecondary Education

Type of Review: New
Title: Student Assistance General Provisions, Interlocutory Appeals
Frequency: On Occasion
Affected Public: Businesses or other for-profit; non-profit institutions; small businesses or organizations
Reporting Burden:
Responses: 30
Burden Hours: 240
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0

Abstract: The Department must provide an administrative appeal procedure for disputes regarding audit claims and enforcement actions against institutions of higher education in the student financial aid programs. The information will be used to consider appeals to the Secretary in these proceedings.

Office of Educational Research and Improvement

Type of Review: New
Title: Second Followup: Beginning Postsecondary Students Longitudinal Study Field Test and Full-Scale Survey
Frequency: Biennially
Affected Public: Individuals or households; businesses or others for profit; non-profit institutions; small businesses or organizations
Reporting Burden:
Responses: 1,345
Burden Hours: 859
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0

Abstract: This study will collect, analyze, and report data about first-time entering postsecondary students in academic year 1988–89 and 1989–90.

Office of Policy and Planning

Type of Review: Revision
Title: Even Start Evaluation
Frequency: Semi-annually
Affected Public: Individuals or households; state or local governments
Reporting Burden:
Responses: 22,717
Burden Hours: 15,276
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0

Abstract: This collection will analyze and report data on all Even Start local grantees that started their projects in 1989 or 1990. The Department will use the information for program analysis and to report to Congress.

[FR Doc. 92–31875 Filed 12–31–92; 8:45 am]
BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Office of Fossil Energy

[FE Docket No. 90–04–NG]

Rochester Gas and Electric Corp.; Final Authorization To Export and Import Natural Gas To and From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued a final order authorizing Rochester Gas and Electric Corporation (RG&E) to export up to 227.5 MMcf of natural gas per day to Canada near St. Clair, Michigan, and to import from Canada near Grand Island, New York, up to 227.5 MMcf per day. The term of the authorization is 15 years beginning on the date of RG&E's first export/import delivery on the proposed Empire State Pipeline system.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, room 3F–056, at 1000 Independence Avenue, SW., Washington, DC 20585. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on December 24, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 92–31916 Filed 12–31–92; 8:45 am]
BILLING CODE 6450–01–M

[FE DOCKET NO. 92–13–NG]

Selkirk Cogen Partners, L.P.; Long-Term Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting authorization to Selkirk Cogen Partners, L.P. to import up to 55,000 Mcf of natural gas per day over a 15-year period beginning on the date of first delivery for use at a new 252 megawatt cogeneration facility it is constructing in Selkirk, New York.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, room 3F–056 at the above address. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on December 24, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 92–31918 Filed 12–31–92; 8:45 am]
BILLING CODE 6450–01–M

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[Docket No. FE–R–79–43B]

Electric and Gas Utilities Covered in 1993 by Titles I and III of the Public Utility Regulatory Policies Act of 1978 and Requirements for State Regulatory Authorities to Notify the Department of Energy

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice.

SUMMARY: Sections 102(c) and 301(d) of the Public Utility Regulatory Policies Act of 1978 (PURPA) require the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each electric utility and gas utility to which titles I and III of PURPA apply during such calendar year. The 1993 list is published here as two separate tabulations. Appendix A lists the covered utilities by State and appendix B lists them alphabetically.

Each State regulatory authority is required, pursuant to sections 102(c) and 301(d) of PURPA, to notify the Secretary of Energy of each electric utility and gas utility on the list for which such State regulatory authority has ratemaking authority. In addition, written comments are requested on the accuracy of the list of electric utilities and gas utilities.

DATES: Notifications by State regulatory authorities and written comments must be received by no later than 4:30 p.m. on February 15, 1993.

ADDRESSES: Notifications and written comments should be forwarded to: Department of Energy, Office of Coal and Electricity, FE–52, 1000 Independence Avenue, SW., room 3F–070, Docket No. FE–R–79–43B, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Steven Mintz, Office of Coal and Electricity, Fossil Energy, Department of Energy, 1000 Independence Avenue, SW., room 3F–070, FE–52, Washington, DC 20585, Telephone 202/586–9506.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to sections 102(c) and 301(d) of PURPA, Public Law 95–617, 92 Stat. 3117, *et seq.* (16 U.S.C. 2601 *et seq.*, hereinafter referred to as the Act) the Department of Energy (DOE) is required to publish a list of utilities to which Titles I and III of PURPA apply in 1993.

State regulatory authorities are required by the Act to notify the Secretary of Energy as to their ratemaking authority over the listed utilities. The inclusion or exclusion of any utility on or from the list does not affect the legal obligations of such utility or the responsible authority under the Act.

The term "State regulatory authority" means any State, including the District of Columbia and Puerto Rico, or a political subdivision thereof, and any agency or instrumentality, which has authority to fix, modify, approve, or disapprove rates with respect to the sale of electric energy or natural gas by any utility (other than such State agency). In the case of a utility for which the Tennessee Valley Authority (TVA) has ratemaking authority, the term "State regulatory authority" means the TVA.

Title I of PURPA sets forth ratemaking and regulatory policy standards with respect to electric utilities. Section 102(c) of Title I requires the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each electric utility to which title I applies during such calendar year. An electric utility is defined as any person, State agency, or Federal agency that sells electric energy. An electric utility is covered by title I for any calendar year if it had total sales of electric energy for purposes other than resale in excess of 500 million kilowatt-hours during any calendar year beginning after December 31, 1975, and before the immediately preceding calendar year. An electric utility is covered in 1993 if it exceeded the threshold in any year from 1976 through 1991.

Title III of PURPA addresses ratemaking and other regulatory policy standards with respect to natural gas utilities. Section 301(d) of title III requires the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each gas utility to which title III applies during such calendar year. A gas utility is defined as any person, State agency, or Federal agency, engaged in the local distribution of natural gas and the sale of natural gas to any ultimate consumer of natural gas. A gas utility is covered by title III if it had total sales of natural gas for purposes other than resale in excess of 10 billion cubic feet during any calendar year beginning after December 31, 1975, and before the immediately preceding calendar year. A gas utility is covered in 1993 if it exceeded the threshold in any year from 1976 through 1991.

In compiling the list published today, the DOE revised the 1992 list (56 FR 66310, December 20, 1991) upon the assumption that all entities included on the 1992 list are properly included on the 1993 list unless the DOE has information to the contrary. In doing this, the DOE took into account information included in public documents regarding entities which exceed the PURPA thresholds for the first time in 1991. The DOE believes that it will become aware of any errors or omissions in the list published today by means of the comment process called for by this Notice. The DOE will, after consideration of any comment and other information available to the DOE, provide written notice of any further additions or deletions to the list.

II. Notification and Comment Procedures

No later than 4:30 p.m. on February 15, 1993, each State regulatory authority must notify the Department of Energy in writing of each utility on the list over which it has ratemaking authority. Five copies of such notification should be submitted to the address indicated in the "**ADDRESSES**" section of this Notice and should be identified on the outside of the envelope and on the document with the designation "Docket No. FE–R–79–43B." Such notification should include:

1. A complete list of electric utilities and gas utilities over which the State regulatory authority has ratemaking authority;
2. legal citations pertaining to the ratemaking authority of the State regulatory authority; and
3. for any listed utility known to be subject to other ratemaking authorities within the State for portions of its service area, a precise description of the portion to which such notification applies.

All interested persons, including State regulatory authorities, are invited to comment in writing, no later than 4:30 p.m. on February 15, 1993, on any errors or omission with respect to the list. Two copies of such comments should be sent to the address indicated in the "**ADDRESSES**" section of this Notice and should be identified on the outside of the envelope and on the document with the designation "Docket No. FE–R–79–43B." Written comments should include the commenter's name, address, and telephone number.

All notifications and comments received by the DOE will be made available, upon request, for public inspection in the Freedom of Information Reading Room, room 1E–190, 1000 Independence Avenue, SW., Washington, DC 20585, between the hours of 9 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

III. List of Electric Utilities and Gas Utilities

Appendices A and B contain two different tabulations of the utilities that meet PURPA coverage requirements. As

stated above, the inclusion or exclusion of any utility on or from the lists does not affect its legal obligations or those of the responsible State regulatory authority under PURPA.

Appendix A contains a list of utilities which are covered by PURPA. These utilities are grouped by State and by the regulatory authority within each State. Also included in this list are utilities which are covered by PURPA but which are not regulated by the State regulatory authority. This tabulation, including explanatory notes, is based on information provided to the DOE by State regulatory authorities in response to the December 20, 1991, **Federal Register** notice (56 FR 66310) requiring each State regulatory authority to notify the DOE of each utility on the list over which it has ratemaking authority, public comments received with respect to that notice, and information subsequently made available to the DOE.

The utilities classified in appendix A as not regulated by the State regulatory authority in fact may be regulated by local municipal authorities. These municipal authorities would be State agencies as defined by PURPA and thus have responsibilities under PURPA identical to those of the State regulatory authority. Therefore, each such municipality is to notify the DOE of each utility on the list over which it has ratemaking authority.

In appendix B, the utilities are listed alphabetically, subdivided into electric utilities and gas utilities, and further subdivided by type of ownership: investor-owned utilities, publicly-owned utilities, and rural cooperatives.

The changes to the 1992 list of electric and gas utilities are as follows:

Additions

Cap Rock Electric Cooperative, Inc. (TX)
Central Hudson Gas & Electric Corporation (NY)
Citizens Utilities Company (AZ)
Citizens Utilities Company (CO)
City of Fort Morgan Gas Department (CO)
ComFurT Gas, Incorporated (CO)
Dyersburg Electric System (TN)
Eastern Colorado Utility Company (CO)
Granite State Electric Company (NH)
Holy Cross Electric Association (CO)
Jonesboro Water & Light (AR)
Rocky Mountain Natural Gas, Division of K N Energy, Inc. (CO)
South Kentucky Rural Electric Cooperative (KY)
Town of Ignacio Municipal Utilities (CO)
Town of Rangley Gas Department (CO)

(Public Utility Regulatory Policies Act of 1978, Pub. L. 95–617, 92 Stat 3117 *et seq.* (16 U.S.C. 2601 *et seq.*)).

Issued in Washington, DC on December 24, 1992.

Charles F. Vacek,

Deputy Assistant Secretary, for Fuels Programs, Office of Fossil Energy.

Appendix A

All gas utilities listed below had natural gas sales, for purposes other than resale, in excess of 10 billion cubic feet in any year from 1976–1991.

All electric utilities listed below had electric energy sales, for purposes other than resale, in excess of 500 million kilowatt-hours in any year from 1976–1991.

State: Alabama

Regulatory Authority: Alabama Public Service Commission.

Gas Utilities

Investor-Owned:
Alabama Gas Corporation
Mobile Gas Service Corporation

Electric Utilities

Investor-Owned:
Alabama Power Company

The following covered utilities within the State of Alabama are not regulated by the Alabama Public Service Commission:

Electric Utilities

Publicly-Owned:
Athens Utilities
Decatur Electric Department
Dothan Electric Department
Florence Electric Department
Huntsvill Utilities
Rural Electric Cooperatives:
Cullman Electric Cooperative
Joe Wheeler Electric Membership Corporation
Rural Electric System

State: Alaska

Regulatory Authority: Alaska Public Utilities Commission.

Gas Utilities

Investor-Owned
Enstar Natural Gas Company

Electric Utilities

Rural Electric Cooperatives:
Chugach Electric Association
Publicly-Owned:
Anchorage Municipal Light & Power Department

State: Arizona

Regulatory Authority: Arizona Corporation Commission.

Gas Utilities

Investor-Owned:
Citizens Utilities Company
Southwest Gas Corporation

Electric Utilities

Investor-Owned:
Arizona Public Service Company
Tuscon Electric Power Company
Publicly-Owned:
Trico Electric Cooperative, Inc.
Rural Electric Cooperative:
Duncan Valley Electric Cooperative, Inc.

The following covered utilities within the State of Arizona are not regulated by the Arizona Corporation Commission:

Electric Utilities

Publicly-Owned:
Salt River Project Agricultural Improvement and Power District

State: Arkansas

Regulatory Authority: Arkansas Public Service Commission.

Gas Utilities

Investor-Owned:
Arkansas-Louisiana Gas Company
Arkansas-Oklahoma Gas Corporation
Arkansas Western Gas Company

Electric Utilities

Investor-Owned:
Arkansas Power and Light Company
Empire District Electric Company
Oklahoma Gas and Electric Company
Southwestern Electric Power Company
Rural Electric Cooperatives:
Arkansas Valley Electric Cooperative Corporation
Carroll Electric Cooperative Corporation
First Electric Cooperative Corporation
Mississippi County Electric Cooperative Corporation

The following covered utilities within the State of Arkansas are not regulated by the Arkansas Public Service Commission:

Electric Utilities

Publicly-Owned:
Jonesboro Water & Light
North Little Rock Electric Department

State: California

Regulatory Authority: California Public Utilities Commission.

Gas Utilities

Investor-Owned:
Pacific Gas and Electric Company
San Diego Gas and Electric Company
Southern California Gas Company
Southwest Gas Corporation

Electric Utilities

Investor-Owned:
Pacific Gas and Electric Company
Pacific Power and Light Company
San Diego Gas and Electric Company

Sierra Pacific Power Company
Southern California Edison Company

The following covered utilities within the State of California are not regulated by the California Public Utilities Commission:

Electric Utilities

Publicly-Owned:
Anaheim Public Utilities Department
Burbank Public Service Department
Glendale Public Service Department
Imperial Irrigation District
Los Angeles Department of Water and Power
Modesto Irrigation District
Palo Alto Electric Utility
Pasadena Water and Power Department
Riverside Public Utilities
Sacramento Municipal Utility District
Santa Clara Electric Department
Turlock Irrigation District
Vernon Municipal Light Department

Gas Utilities

Publicly-Owned:
Long Beach Gas Department

State: Colorado

Regulatory Authority: Colorado Public Utilities Commission.

Gas Utilities

Investor-Owned:
Citizens Utilities Company
ComFurT Gas, Incorporated
Eastern Colorado Utility Company
Greeley Gas Company
K N Energy, Incorporated
Peoples Natural Gas Company
Public Service Company of Colorado
Rocky Mountain Natural Gas Division of K N Energy, Inc.
Publicly-Owned:
City of Colorado Springs Department of Public Utilities
City of Fort Morgan Gas Department
Town of Ignacio Municipal Utilities
Town of Rangley Gas Department

Electric Utilities

Investor-Owned:
Public Service Company of Colorado
West Plains Energy

The following covered utilities within the State of Colorado are not regulated by the Colorado Public Utilities Commission:

Gas Utilities

Publicly-Owned:
Colorado Springs Department of Utilities (except sales to another gas utility)

Electric Utilities

Publicly-Owned:
Colorado Springs Department of Public Utilities
Rural Electric Cooperatives:
Holy Cross Electric Association
Intermountain Rural Association
Moon Lakes Electric Association

State: Connecticut

Regulatory Authority: Connecticut Department of Public Utility Control.

Gas Utilities

Investor-Owned:
Connecticut Natural Gas Corporation
Southern Connecticut Gas Company
Yankee Gas Service Company

Electric Utilities

Investor-Owned:
Connecticut Light and Power Company
United Illuminating Company
Publicly-Owned:
Groton Public Utilities

State: Delaware

Regulatory Authority: Delaware Public Service Commission.

Gas Utilities

Investor-Owned:
Delmarva Power and Light Company

Electric Utilities

Investor-Owned:
Delmarva Power and Light Company

State: District of Columbia

Regulatory Authority: Public Service Commission of the District of Columbia.

Gas Utilities

Investor-Owned:
Washington Gas Light Company

Electric Utilities

Investor-Owned:
Potomac Electric Power Company

State: Florida

Regulatory Authority: Florida Public Service Commission.

Gas Utilities

Investor-Owned:
City Gas Company of Florida
People Gas System

Electric Utilities

Investor-Owned:
Florida Power and Light Company
Florida Power Corporation
Gulf Power Company
Tampa Electric Company

The Florida Public Service Commission has rate structure jurisdiction over the following utilities:

Publicly-Owned:
Gainesville Regional Utilities
Jacksonville Electric Company
Kissimmee Utility Authority
Lakeland Department of Electric and Water
Ocala Electric Authority
Orlando Utilities Commission
Tallahassee, City of
Rural Electric Cooperatives:
Clay Electric Cooperative
Lee County Electric Cooperative
Sumter Electric Cooperative, Inc.
Withlacoochee River Electric Cooperative

State: Georgia

Regulatory Authority: Georgia Public Service Commission.

Gas Utilities

Investor-Owned:
Atlanta Gas Light Company
United Cities Gas Company

Electric Utilities

Investor-Owned:
Georgia Power Company
Savannah Electric and Power Company

The following utilities within the State of Georgia are not regulated by the Georgia Public Service Commission:

Electric Utilities

Publicly-Owned:
Albany Water, Gas & Light Commission
Dalton Water, Light & Sink
Rural Electric Cooperatives:
Cobb Electric Membership Corporation
Flint Electric Membership Corporation
GreyStone Power Electric Membership Corporation
Jackson Electric Membership Corporation
North Georgia Electric Membership Corporation
Sawnee Electric Membership Corporation
Walton Electric Membership Corporation

State: Hawaii

Regulatory Authority: Hawaii Public Utilities Commission.

Electric Utilities

Investor-Owned:
Hawaii Electric Light Company, Inc.
Hawaiian Electric Company, Inc.
Maui Electric Company, Ltd.

State: Idaho

Regulatory Authority: Idaho Public Utilities Commission.

Gas Utilities

Investor-Owned:
Intermountain Gas Company

Washington Water Power Company

Electric Utilities

Investor-Owned:
Idaho Power Company
Pacific Power and Light Company
Utah Power and Light Company
Washington Water Power Company

State: Illinois

Regulatory Authority: Illinois Commerce Commission.

Gas Utilities

Investor-Owned:
Central Illinois Light Company
Central Illinois Public Service Company
Illinois Power Company
Iowa-Illinois Gas and Electric Company
North Shore Gas Company
Northern Illinois Gas Company
Panhandle Eastern Pipeline Company
Peoples Gas, Light, and Coke Company

Electric Utilities

Investor-Owned:
Central Illinois Light Company
Central Illinois Public Service Company
Commonwealth Edison Company
Interstate Power Company
Iowa-Illinois Gas and Electric Company
Union Electric Company

The following covered utility within the State of Illinois is not regulated by the Illinois Commerce Commission:

Electric Utilities

Publicly-Owned:
Springfield Water, Light and Power Department

State: Indiana

Regulatory Authority: Indiana Utility Regulatory Commission.

Gas Utilities

Investor-Owned:
Indiana Gas Company
Northern Indiana Public Service Company
Southern Indiana Gas and Electric Company
Publicly-Owned:
Citizens Gas and Coke Utility

Electric Utilities

Investor-Owned:
Indiana and Michigan Power Company
Indianapolis Power and Light Company
Northern Indiana Public Service Company
PSI Energy
Southern Indiana Gas and Electric Company
Publicly-Owned:
Richmond Power and Light

State: Iowa

Regulatory Authority: Iowa Utilities Board.

Gas Utilities

Investor-Owned:
Interstate Power Company
Iowa-Electric Light and Power Company
Iowa-Illinois Gas and Electric Company
Iowa Southern Utilities Company
Midwest Gas, Division of Iowa Public Service Company
Peoples Natural Gas Company, Division of Utilicorp United, Inc.
United Cities Gas Company, Great River Division

Electric Utilities

Investor-Owned:
Interstate Power Company
Iowa Electric Light and Power Company
Iowa-Illinois Gas and Electric Company
Iowa Power Incorporated
Iowa Southern Utilities Company
IPS Electric, Division of Iowa Public Service Company
Union Electric Company
Rural Electric Cooperatives:
Linn County RECA

The Iowa Utilities Board has service and safety regulation over the following utilities:

Publicly-Owned
Muscatine Power and Water
Omaha Public Power District

State: Kansas

Regulatory Authority: Kansas State Corporation Commission.

Gas Utilities

Investor-Owned:
Anadarko Production Company
Arkansas-Louisiana Gas Company
Greeley Gas Company
KN Energy, Incorporated
KPL Gas Service
Panhandle Eastern Pipeline Company
Peoples Natural Gas Company, Division of UtiliCorp United
United Cities Gas Company

Electric Utilities

Investor-Owned:
Empire District Electric Company
Kansas City Power and Light Company
Kansas Gas and Electric Company
KPL Gas Service
Southwestern Public Service Company
West Plains Energy, Division of UtiliCorp United
Rural Electric Cooperatives:
Midwest Energy Incorporated

The following covered utility within the State of Kansas is not regulated by the Kansas State Corporation Commission:

Electric Utilities

Publicly-Owned:
Kansas City Board of Public Utilities

State: Kentucky

Regulatory Authority: Kentucky Public Service Commission.

Gas Utilities

Investor-Owned:
Columbia Gas of Kentucky, Inc.
Louisville Gas and Electric Company
Union Light, Heat and Power Company
Western Kentucky Gas Company

Electric Utilities

Investor-Owned:
Kentucky Power Company
Kentucky Utilities Company
Louisville Gas and Electric Company
Union Light, Heat and Power Company
Rural Electric Cooperatives:
Green River Electric Corporation
Henderson-Union Rural Electric Cooperative Corporation
South Kentucky Rural Electric Cooperative

The following covered utilities within the State of Kentucky are not regulated by the Kentucky Public Service Commission:

Electric Utilities

Bowling Green Municipal Utilities
Owensboro Municipal Utilities
Pennyrile Rural Electric Cooperative Corporation
Warren Rural Electric Cooperative Corporation
West Kentucky Rural Electric Cooperative Corporation

State: Louisiana

Regulatory Authority: Louisiana Public Service Commission.

Gas Utilities

Investor-Owned:
Arkansas-Louisiana Gas Company
Entex, Inc.
Gulf States Utilities Company
Louisiana Gas Service Company
Trans Louisiana Gas Company
Publicly-Owned:
New Orleans Public Service, Inc.

Electric Utilities

Investor-Owned:

Central Louisiana Electric Company
Gulf States Utilities Company
Louisiana Power and Light Company (West Bank)
Southwestern Electric Power Company
Rural Electric Cooperatives:
Cajun Electric Power Cooperative
Dixie Electric Membership Corporation
Southwest Louisiana Electric Membership Corporation

The following covered utilities within the State of Louisiana are not regulated by the Louisiana Public Service Commission:

Electric Utilities

Publicly-Owned:
Lafayette Utilities System
New Orleans Public Service, Inc.

State: Maine

Regulatory Authority: Maine Public Utilities Commission.

Electric Utilities

Investor-Owned:
Bangor Hydro-Electric Company
Central Maine Power Company

State: Maryland

Regulatory Authority: Maryland Public Service Commission.

Gas Utilities

Investor-Owned:
Baltimore Gas and Electric Company
Washington, Gas Light Company

Eectric Utilities

Investor-Owned:
Baltimore Gas and Electric Company
Conowingo Power Company
Delmarva Power and Light—Company of Maryland
Potomac Edison Company
Potomac Electric Power Company
Rural Electric Cooperatives:
Southern Maryland Electric Cooperative, Inc.

State: Massachusetts

Regulatory Authority: Massachusetts Department of Public Utilities.

Gas Utilities

Investor-Owned:
Bay State Gas Company
Boston Gas Company
Colonial Gas Energy System
Commonwealth Gas Company

Electric Utilities

Investor-Owned:
Boston Edison Company
Cambridge Electric Light Company
Commonwealth Electric Company
Eastern Electric Company
Western Massachusetts Electric Company

State: Michigan

Regulatory Authority: Michigan Public Service Commission.

Gas Utilities

Investor-Owned:
Consumers Power Company
Michigan Consolidated Gas Company
Michigan Gas Company
Southeastern Michigan Gas Company
Wisconsin Public Service Corporation

Electric Utilities

Investor-Owned:
Consumers Power Company
Detroit Edison Company
Indiana and Michigan Electric Company
Michigan Power Company
Northern States Power
Upper Peninsula Power Company
Wisconsin Electric Power Company
Wisconsin Public Service Corporation

The following covered utilities within the State of Michigan are not regulated by the Michigan Public Service Commission:

Gas Utilities

Investor-Owned:
Battle Creek Gas Company

Electric Utilities

Publicly-Owned:
Lansing Board of water and Light

State: Minnesota

Regulatory Authority: Minnesota Public Utility Commission.

Gas Utilities

Investor-Owned:
Interstate Power Company
Midwest Gas, Division of Iowa Public Service Company
Minnegasco—Division of Arkla, Inc.
Northern Minnesota Utilities—Division of UtiliCorp United, Inc.
Northern States Power Company
Peoples Natural Gas Company—Division of UtiliCorp United, Inc.

Electric Utilities

Investor-Owned:
Interstate Power Company
Minnesota Power and Light Company
Northern States Power Company
Otter Tail Power Company
Rural Electric Cooperative:
Dakota Electric Association

The following covered utilities within the State of Minnesota are not regulated by the Minnesota Public Utility Commission:

Electric Utilities

Publicly-Owned:
Rochester Department of Public Utilities
Rural Electric Cooperative:
Anoka Electric Cooperative

State: Mississippi

Regulatory Authority: Mississippi Public Service Commission.

Gas Utilities

Investor-Owned:
Entex, Inc.
Mississippi Valley Gas Company

Electric Utilities

Investor-Owned:
Mississippi Power and Light Company
Mississippi Power Company

The following covered utilities within the State of Mississippi are not regulated by the Mississippi Public Service Commission:

Electric Utilities

Publicly-Owned:
Tupelo Water & Light Department
Rural Electric Cooperatives:
Alcorn County Electric Power Association
Coast Electric Power Association
4-County Electric Power Association
Singing River Electric Power Association
Southern Pine Electric Power Association
Tombigbee Electric Power Association

State: Missouri

Regulatory Authority: Missouri Public Service Commission.

Gas Utilities

Investor-Owned:
Associated Natural Gas Company
Kansas Power & Light Company
Laclede Gas Company
Missouri Public Service Company
Union Electric Company

Electric Utilities

Investor-Owned:
Arkansas Power & Light Company
Citizens Electric Corporation
Empire District Electric Company
Kansas City Power and Light Company
Missouri Public Service Company
St. Joseph Light and Power Company
Union Electric Company

The following covered utilities within the State of Missouri are not regulated by the Missouri Public Service Commission:

Gas Utilities

Investor-Owned:
Williams Natural Gas Company
Publicly-Owned:

Springfield City Utilities

Electric Utilities

Publicly-Owned:
Independence Power and Light Department
Springfield City Utilities

State: Montana

Regulatory Authority: Montana Public Service Commission.

Gas Utilities

Investor-Owned:
Montana-Dakota Utilities Company
Montana Power Company

Electric Utilities

Investor-Owned:
Black Hills Power and Light Company
Montana-Dakota Utilities Company
Montana Power Company
Pacific Power and Light Company
Washington Water Power Company

State: Nebraska

Regulatory Authority—Nebraska Public Service Commission.

The Commission does not regulate the rates and service of the gas and electric utilities of the State of Nebraska.

The following covered utilities within the State of Nebraska are not regulated by the Nebraska Public Service Commission:

Gas Utilities

Investor-Owned:
Gas Service Company
Midwest Gas, Division of Iowa Public Service Company
Minnegasco—Division of Arkla, Inc.
Northwestern Public Service Company
Peoples Natural Gas Company, Division of Utilicorp United, Inc.

Electric Utilities

Publicly-Owned:
Lincoln Electric System
Nebraska Public Power District
Omaha Public Power District

The governing body of each Nebraska municipality exercises ratemaking jurisdiction over gas utility rates, operations, and services provided by a gas utility within its city or town limits. These municipal authorities would be State agencies as defined by PURPA, and thus have responsibilities under PURPA identical to those of the State regulatory authority.

Publicly-Owned:
Metropolitan Utilities District of Omaha

State: Nevada

Regulatory Authority: Nevada Public Service Commission.

Gas Utilities

Investor-Owned:
Southwest Gas Corporation

Electric Utilities

Investor-Owned:
Idaho Power Company
Nevada Power Company
Sierra Pacific Power Company

State: New Hampshire

Regulatory Authority: New Hampshire Public Utilities Commission.

Electric Utilities

Investor-Owned:
Granite State Electric Company
Public Service Company of New Hampshire
Rural Electric Cooperatives:
New Hampshire Electric Cooperative, Inc.

State: New Jersey

Regulatory Authority: New Jersey Board of Public Utilities.

Gas Utilities

Investor-Owned:
Elizabethtown Gas Company
New Jersey Natural Gas Company
Public Service Electric and Gas Company
South Jersey Gas Company

Electric Utilities

Investor-Owned:
Atlantic City Electric Company
Jersey Central Power and Light Company
Public Service Electric and Gas Company
Rockland Electric Company

State: New Mexico

Regulatory Authority: New Mexico Public Service Commission.

Gas Utilities

Investor-Owned:
Gas Company of New Mexico

Electric Utilities

Investor-Owned:
El Paso Electric Company
Public Service Company of New Mexico
Southwestern Public Service Company
Texas-New Mexico Power Company
Rural Electric Cooperatives:
Duncan Valley Electric Cooperative, Inc.
Lea County Electric Cooperative, Inc.

State: New York

Regulatory Authority: New York Public Service Commission.

Gas Utilities

Investor-Owned:
Brooklyn Union Gas Company
Central Hudson Gas and Electric Corporation
Consolidated Edison Company of New York
Long Island Lighting Company
National Fuel Gas Distribution Corporation
New York State Electric and Gas Corporation
Niagara Mohawk Power Corporation
Orange and Rockland Utilities
Rochester Gas and Electric Corporation

Electric Utilities

Investor-Owned:
Central Hudson Gas and Electric Corporation
Consolidated Edison Company of New York
Long Island Lighting Company
New York State Electric and Gas Corporation
Niagara Mohawk Power Corporation
Orange and Rockland Utilities
Rochester Gas and Electric Corporation

The following covered utility within the State of New York is not regulated by the New York Public Service Commission:

Electric Utilities

Publicly-Owned:
New York Power Authority

State: North Carolina

Regulatory Authority: North Carolina Utilities Commission.

Gas Utilities

Investor-Owned:
North Carolina Natural Gas Corporation
Piedmont Natural Gas Company
Public Service Company, Inc. of North Carolina

Electric Utilities

Investor-Owned:
Carolina Power and Light Company
Duke Power Company
Nantahala Power & Light Company
Virginia Electric and Power Company

The following covered utilities within the State of North Carolina are not regulated by the North Carolina Utilities Commission:

Electric Utilities

Publicly-Owned:
Fayetteville Public Works Commission
Greenville Utilities Commission
High Point Electric Utility Department
Rocky Mount Public Utilities
Wilson Utilities Department
Rural Electric Cooperatives:

Blue Ridge Electric Membership Corporation
Rutherford Electric Membership Corporation

State: North Dakota

Regulatory Authority: North Dakota Public Service Commission.

Gas Utilities

Investor-Owned:
Montana Dakota Utilities Company
Northern States Power Company

Electric Utilities

Investor-Owned:
Montana Dakota Utilities Company
Northern States Power Company
Otter Tail Power Company

State: Ohio

Regulatory Authority: Ohio Public Utilities Commission.

Gas Utilities

Investor-Owned:
Cincinnati Gas and Electric Company
Columbia Gas of Ohio, Inc.
Dayton Power and Light Company
East Ohio Gas Company
National Gas and Oil Company
West Ohio Gas Company

Electric Utilities

Investor-Owned:
Cincinnati Gas and Electric Company
Cleveland Electric Illuminating Company
Columbus and Southern Ohio Electric Company
Dayton Power and Light Company
Monongahela Power Company
Ohio Edison Company
Ohio Power Company
Toledo Edison Company

The following covered utilities within the State of Ohio are not regulated by the Ohio Public Utilities Commission:

Electric Utilities

Publicly-Owned:
Cleveland Division of Light and Power
Rural Electric Cooperative:
South Central Power Company

State: Oklahoma

Regulatory Authority: Oklahoma Corporation Commission.

Gas Utilities

Investor-Owned:
Arkansas-Louisiana Gas Company
Arkansas-Oklahoma Gas Corporation
KPL Gas Service Company
Oklahoma Natural Gas Company
Southern Union Gas Company

Electric Utilities

Investor-Owned:
Empire District Electric Company
Oklahoma Gas and Electric Company
Public Service Company of Oklahoma
Southwestern Public Service Company
Rural Electric Cooperative:
Cotton Electric Cooperative

State: Oregon

Regulatory Authority: Public Utility Commission of Oregon.

Gas Utilities

Investor-Owned:
Cascade Natural Gas Corporation
Northwest Natural Gas Company
Washington Water Power Company

Electric Utilities

Investor-Owned:
Idaho Power Company
Pacific Power and Light Company
Portland General Electric Company

The following covered utilities within the State of Oregon are not regulated by the Public Utility Commission of Oregon:

Electric Utilities

Publicly-Owned:
Central Lincoln People's Utility District
Clatskanie People's Utility District
Eugene Water and Electric Board
Springfield Utility Board
Rural Electric Cooperatives:
Oregon Trail Electric
Umatilla Electric Cooperative Association

State: Pennsylvania

Regulatory Authority: Pennsylvania Public Utility Commission.

Gas Utilities

Investor-Owned:
Carnegie Natural Gas Company
Columbia Gas of Pennsylvania, Inc.
Equitable Gas Company
National Fuel Gas Distribution Corporation
North Penn Gas Company
Pennsylvania Gas and Water Company
Peoples Natural Gas Company
Philadelphia Electric Company
T.W. Phillips Gas and Oil Company
UGI Corporation

Electric Utilities

Investor-Owned:
Duquesne Light Company
Metropolitan Edison Company
Pennsylvania Electric Company
Pennsylvania Power Company
Pennsylvania Power and Light Company
Philadelphia Electric Company
UGI—Luzerne Electric Company
West Penn Power Company

The following covered utility within the State of Pennsylvania is not regulated by the Pennsylvania Public Utility Commission:

Gas Utilities

Publicly-Owned:
Philadelphia Gas Works

State: Puerto Rico

Regulatory Authority: Puerto Rico Public Service Commission.

The following covered utility within Puerto Rico is not regulated by the Puerto Rico Public Service Commission:

Electric Utilities

Publicly-Owned:
Puerto Rico Electric Power Authority

State: Rhode Island

Regulatory Authority: Rhode Island Public Utilities Commission.

Gas Utilities

Investor-Owned:
Providence Gas Company

Electric Utilities

Investor-Owned:
Blackstone Valley Electric Company
Narragansett Electric Company

State: South Carolina

Regulatory Authority: South Carolina Public Service Commission.

Gas Utilities

Investor-Owned:
Carolina Pipeline Company
Piedmont Natural Gas Company
South Carolina Electric and Gas Company

Electric Utilities

Investor-Owned:
Carolina Power and Light Company
Duke Power Company
South Carolina Electric and Gas Company

The following covered utilities within the State of South Carolina are not regulated by the South Carolina Public Service Commission:

Electric Utilities

Publicly-Owned:
South Carolina Public Service Authority
Rural Electric Cooperatives:
Berkeley Electric Cooperatives, Inc.
Palmetto Electric Cooperatives, Inc.

State: South Dakota

Regulatory Authority: South Dakota Public Utilities Commission.

Gas Utilities

Investor-Owned:

Midwest Gas, Division of Iowa Public Service Company
Minnegasco, Inc.
Montana-Dakota Utilities Company
Northwestern Public Service Company

Electric Utilities

Investor-Owned:
Black Hills Power and Light Company
IPS Electric, Division of Iowa Public Service Company
Montana-Dakota Utilities Company
Northern States Power Company
Northwestern Public Service Company
Otter Tail Power Company

The following covered utility within the State of South Dakota is not regulated by the South Dakota Public Service Commission:

Electric Utilities

Publicly-Owned:
Nebraska Public Power District

State: Tennessee

Regulatory Authority: Tennessee Public Service Commission.

Gas Utilities

Investor-Owned:
Chattanooga Gas Company
Nashville Gas Company

Electric Utilities

Investor-Owned:
Kingsport Power Company

The following covered utilities within the State of Tennessee are not regulated by the Tennessee Public Service Commission.

Gas Utilities

Publicly-Owned:
Memphis Light, Gas and Water Division

Electric Utilities

Publicly-Owned:
Bristol Tennessee Electric System
Chattanooga Electric Power Board
Clarksville Department of Electricity
Cleveland Utilities
Greenville Light and Power System
Jackson Utility Division-Electric Department
Johnson City Power Board
Knoxville Utilities Board
Lenior City Utilities Board
Memphis Light, Gas and Water Division
Murfreesboro Electric Department
Nashville Electric Service
Sevier County Electric System
Rural Electric Cooperatives:
Appalachian Electric Cooperative
Cumberland Electric Membership Corporation
Duck River Electric Membership Cooperative
Gibson County Electric Membership Corporation
Meriwether Lewis Electric Cooperative
Middle Tennessee Electric Membership Corporation
Southwest Tennessee Electric Membership Corporation
Tri-County Electric Membership Corporation
Upper Cumberland Electric Membership Corporation
Volunteer Electric Cooperative
Regulatory Authority: Tennessee Valley Authority.

Electric Utilities

Publicly-Owned:
Athens Utilities
Bowling Green Municipal Utilities
Bristol Tennessee Electric System
Chattanooga Electric Power Board
Clarksville Department of Electricity
Cleveland Utilities
Clinton Utilities Board
Decatur Electric Department
Dyersburg Electric System
Florence Electric Department
Greeneville Light and Power System
Huntsville Utilities
Jackson Utility Division-Electric Department
Johnson City Power Board
Knoxville Utilities Board
Lenoir City Utilities Board
Memphis Light, Gas and Water Division
Morristown Power System
Murfreesboro Electric Department
Nashville Electric Service
Sevier County Electric System
Tupelo Water and Light Department
Rural Electric Cooperatives:
Alcorn County Electric Company Association
Appalachian Electric Cooperative
Cullman Electric Cooperative
Cumberland Electric Membership Corporation
Duck River Electric Membership Corporation
4-County Electric Power Association
Gibson County Electric Membership Corporation
Holston Electric Cooperative
Joe Wheeler Electric Membership Corporation
Meriwether Lewis Electric Cooperative
Middle Tennessee Electric Membership Corporation
North Georgia Electric Membership Corporation
Pennyrile Rural Electric Cooperative Corporation
Sequachee Valley Electric Cooperative
Southwest Tennessee Electric Membership Corporation
Tombigbee Electric Power Association
Tri-County Electric Membership Corporation
Upper Cumberland Electric Membership Corporation
Volunteer Electric Cooperative
Warren Rural Electric Cooperative Corporation
West Kentucky Rural Electric Cooperative Corporation

State: Texas

Regulatory Authority: Texas Public Utility Commission.

Electric Utilities

Investor-Owned:
Central Power and Light Company
El Paso Electric Company
Gulf States Utilities Company
Houston Lighting and Power Company
Southwestern Electric Power Company
Southwestern Electric Service Company
Southwestern Public Service Company
Texas-New Mexico Power Company
TU Electric
West Texas Utilities Company
Publicly-Owned:
Lower Colorado River Authority
Rural Electric Cooperatives:
Bluebonnet Electric Cooperative, Inc.
Cap Rock Electric Cooperative, Inc.
Guadalupe Valley Electric Cooperative, Inc.
Pedernales Electric Cooperative, Inc.
Sam Houston Electric Cooperative, Inc.
Tri-County Electric Cooperative, Inc.

The governing body of each Texas municipality exercises exclusive original jurisdiction over electric utility rates, operations, and services provided by an electric utility (whether privately owned or publicly owned) within its city or town limits, unless the municipality has surrendered this jurisdiction to the Texas Public Utility Commission. The Commission hears *de novo* appeals from the decision of such municipalities. These municipal authorities would be State agencies as defined by PURPA and, thus, have responsibilities under PURPA identical to those of a State regulatory authority.

The municipally owned utilities listed below are not under the commission's original ratemaking jurisdiction:

Electric Utilities

Publicly-Owned:
Austin Electric Department
Brownsville PUB
Bryan, City of

Carland Electric Department
Lubbock Power and Light
San Antonio City Public Service Board

Regulatory Authority: Railroad Commission of Texas.

Gas Utilities

Investor-Owned:
Atmos Energy Corporation
Entex, Inc.
Lone Star Gas Company, a division of ESERCH Corporation
Southern Union Company

The governing body of each Texas municipality exercises exclusive original ratemaking jurisdiction over gas utility rates, operations, and services provided by a gas utility within its city or town limits subject to appellate review by the Railroad Commission of Texas. These municipal authorities would be State agencies as defined by PURPA and, thus, have responsibilities under PURPA identical to those of a State regulatory authority.

The following covered utilities within the State of Texas are not regulated by the Railroad Commission of Texas. (The Railroad Commission's appellate authority does not extend to municipally owned gas utilities.)

Gas Utilities

Publicly-Owned
City Public Service Board (San Antonio)

State: Utah

Regulatory Authority: Utah Public Service Commission.

Gas Utilities

Investor-Owned:
Mountain Fuel Supply Company

Electric Utilities

Investor-Owned:
Utah Power and Light Company
Rural Electric Cooperatives:
Atmos Energy Corporation
Moon Lake Electric Association

State: Vermont

Regulatory Authority: Vermont Public Service Board.

Electric Utilities

Investor-Owned:
Central Vermont Public Service Corporation
Green Mountain Power Corporation
Public Service Company of New Hampshire

State: Virginia

Regulatory Authority: Virginia State Corporation Commission.

Gas Utilities

Investor-Owned:
Columbia Gas of Virginia, Inc.
Commonwealth Gas Services, Inc.
Northern Virginia Natural Gas
Virginia Natural Gas

Electric Utilities

Investor-Owned:
Appalachian Power Company
Delmarva Power and Light Company
Old Dominion Power Company
Potomac Edison Company
Virginia Electric and Power Company
Rural Electric Cooperatives:
Northern Virginia Electric Cooperative
Rappahannock Electric Cooperative

The following covered utilities within the State of Virginia are not regulated by the Virginia State Corporation Commission:

Gas Utilities

Publicly-Owned:
City of Richmond, Virginia, Department of Public Utilities

Electric Utilities

Publicly-Owned:
Danville Water, Gas & Electric

State: Washington

Regulatory Authority: Washington Utilities and Transportation Commission.

Gas Utilities

Investor-Owned:
Cascade Natural Gas Corporation
Northwest Natural Gas Company
Washington Natural Gas Company
Washington Water Power Company

Electric Utilities

Investor-Owned:
Pacific Power & Light Company
Puget Sound Power & Light Company
Washington Water Power Company

The following covered utilities within the State of Washington are not regulated by the Washington Utilities and Transportation Commission:

Electric Utilities

Publicly-Owned:
Port Angeles Light and Water Department
Public Utility District No. 1 of Benton County
Public Utility District No. 1 of Chelan County
Public Utility District No. 1 of Clark County
Public Utility District No. 1 of Cowlitz County
Public Utility District No. 1 of Douglas County
Public Utility District No. 1 of Franklin County
Public Utility District No. 1 of Grays County
Public Utility District No. 1 of Lewis County
Public Utility District No. 1 of Snohomish County
Public Utility District No. 2 of Grant County
Richland Energy Service Department
Seattle City Light Department
Tacoma Public Utilities—Light Division

State: West Virginia

Regulatory Authority: West Virginia Public Service Commission.

Gas Utilities

Investor-Owned:
Equitable Gas Company
Hope Gas Incorporated
Mountaineer Gas Company

Electric Utilities

Investor-Owned:
Appalachian Power Company
Monongahela Power Company
Potomac Edison Company
Wheeling Electric Company

State: Wisconsin

Regulatory Authority: Wisconsin Public Service Commission.

Gas Utilities

Investor-Owned:
Madison Gas and Electric Company
Northern States Power Company
Wisconsin Fuel and Light Company
Wisconsin Gas Company
Wisconsin Natural Gas Company
Wisconsin Power and Light Company
Wisconsin Public Service Corporation

Electric Utilities

Investor-Owned:
Madison Gas and Electric Company
Northern States Power Company
Wisconsin Electric Power Company
Wisconsin Power and Light Company
Wisconsin Public Service Corporation

State: Wyoming

Regulatory Authority: Wyoming Public Service Commission.

Gas Utilities

Investor-Owned:
Cheyenne Light, Fuel and Power Company
Kansas-Nebraska Natural Gas Company
Montana-Dakota Utilities Company
Mountain Fuel Supply Company

Electric Utilities

Investor-Owned:
Black Hills Power and Light Company
Montana-Dakota Utilities Company
Pacific Power and Light Company
Utah Power and Light Company

Rural Electric Cooperative:
Tri-County Electric Association, Inc.

Appendix B

Electric Utilities

All utilities listed below had electric energy sales, for purposes other than resale, in excess of 500 million kilowatt hours in any year from 1976–1991. The utilities listed more than once have sales in more than one State, and those States are indicated by abbreviations in parentheses.

Investor-Owned:
Alabama Power Company
Appalachian Power Company (VA)
Appalachian Power Company (WV)
Arizona Public Service Company
Arkansas Power & Light Company (AR)
Arkansas Power & Light Company (MO)
Atlantic City Electric Company
Baltimore Gas & Electric Company
Bangor Hydro-Electric Company
Black Hills Power & Light Company (MT)
Black Hills Power & Light Company (SD)
Black Hills Power & Light Company (WY)
Blackstone Valley Electric Company
Boston Edison Company
Cambridge Electric Light Company
Carolina Power & Light Company (NC)
Carolina Power & Light Company (SC)
Central Hudson Gas & Electric Corporation
Central Illinois Light Company
Central Illinois Public Service Company
Central Louisiana Electric Company
Central Maine Power Company
Central Power & Light Company
Central Vermont Public Service Corporation
Cincinnati Gas & Electric Company
Citizens Electric Corporation
Cleveland Electric Illuminating Company
Columbus and Southern Ohio Electric Company
Commonwealth Edison Company
Commonwealth Electric Company
Connecticut Light & Power Company
Conowingo Power Company
Consolidated Edison Company of New York
Consumers Power Company
Dayton Power & Light Company
Delmarva Power & Light Company (DE)
Delmarva Power & Light Company (VA)
Delmarva Power & Light Company of Maryland
Detroit Edison Company
Duke Power Company (NC)
Duke Power Company (SC)
Duquesne Light Company
Eastern Electric Company
El Paso Electric Company (NM)
El Paso Electric Company (TX)
Empire District Electric Company (AR)
Empire District Electric Company (KS)
Empire District Electric Company (MO)
Empire District Electric Company (OK)
Florida Power Corporation
Florida Power & Light Company
Georgia Power Company
Granite State Electric Company
Green Mountain Power Corporation
Gulf Power Company
Gulf States Utilities Company (LA)
Gulf States Utilities Company (TX)
Hawaii Electric Light Company, Inc.
Hawaiian Electric Company, Inc.
Houston Lighting and Power Company
Idaho Power Company (ID)
Idaho Power Company (NV)
Idaho Power Company (OR)
Illinois Power Company
Indiana & Michigan Power Company (IN)
Indiana & Michigan Power Company (MI)
Indianapolis Power & Light Company
Interstate Power Company (IA)
Interstate Power Company (IL)
Interstate Power Company (MN)
Iowa Electric Light & Power Company
Iowa-Illinois Gas & Electric Company (IA)
Iowa-Illinois Gas & Electric Company (IL)
Iowa Power Incorporated
Iowa Southern Utilities Company
IPS Electric, Division of Iowa Public Service Co. (IA)
IPS Electric, Division of Iowa Public Service Co. (SD)
Jersey Central Power & Light Company
Kansas City Power & Light Company (KS)
Kansas City Power & Light Company (MO)
Kansas Gas & Electric Company
Kentucky Electric Company
Kentucky Utilities Company
Kingsport Power Company
KPL Gas Service (KS)
Long Island Lighting Company
Louisiana Power & Light Company
Louisville Gas & Electric Company
Madison Gas & Electric Company
Massachusetts Electric Company
Maui Electric Company, Ltd.
Metropolitan Edison Company
Michigan Power Company
Minnesota Power & Light Company
Mississippi Power Company
Mississippi Power & Light Company
Missouri Public Service Company
Monongahela Power Company (OH)
Monongahela Power Company (WV)
Montana-Dakota Utilities Company (MT)
Montana-Dakota Utilities Company (ND)
Montana-Dakota Utilities Company (SD)
Montana-Dakota Utilities Company (WY)
Montana Power Company
Nantahala Power & Light Company
Narragansett Electric Company
Nevada Power Company
New Orleans Public Service, Inc.
New York State Electric & Gas Corporation
Niagara Mohawk Power Company
Northern Indiana Public Service Company
Northern States Power Company (MI)
Northern States Power Company (MN)
Northern States Power Company (ND)
Northern States Power Company (SD)
Northern States Power Company (WI)
Northwestern Public Service Company
Ohio Edison Company
Ohio Power Company
Oklahoma Gas & Electric Company (AR)
Oklahoma Gas & Electric Company (OK)
Old Dominion Power Company
Orange & Rockland Utilities
Otter Tail Power Company (MN)
Otter Tail Power Company (ND)
Otter Tail Power Company (SD)
Pacific Gas & Electric Company
Pacific Power & Light Company (CA)
Pacific Power & Light Company (ID)
Pacific Power & Light Company (MT)
Pacific Power & Light Company (OR)
Pacific Power & Light Company (WA)
Pacific Power & Light Company (WY)
Pennsylvania Electric Company
Pennsylvania Power & Light Company
Pennsylvania Power Company
Philadelphia Electric Company
Portland General Electric Company
Potomac Edison Company (MD)
Potomac Edison Company (VA)
Potomac Edison Company (WV)
Potomac Electric Power Company (DC)
Potomac Electric Power Company (MD)
PSI Energy (IN)
Public Service Company of Colorado
Public Service Company of New Hampshire (NH)
Public Service Company of New Hampshire (VT)
Public Service Company of New Mexico
Public Service Company of Oklahom

Public Service Electric and Gas Company
Puget Sound Power & Light Company
Rochester Gas & Electric Corporation
Rockland Electric Company
St. Joseph Light & Power Company
San Diego Gas & Electric Company
Savannah Electric & Power Company
Sierra Pacific Power Company (CA)
Sierra Pacific Power Company (NV)
South Carolina Electric & Gas Company
Southern California Edison Company
Southern Indiana Gas & Electric Company
Southwestern Electric Power Company (AR)
Southwestern Electric Power Company (LA)
Southwestern Electric Power Company (TX)
Southwestern Electric Service Company
Southwestern Public Service Company (KS)
Southwestern Public Service Company (NM)
Southwestern Public Service Company (OK)
Southwestern Public Service Company (TX)
Tampa Electric Company
Texas-New Mexico Power Company
Toledo Edison Company
TU Electric
Tucson Electric Power Company
UGI-Luzerne Electric Division
Union Electric Company (IA)
Union Electric Company (IL)
Union Electric Company (MO)
Union Light, Heat & Power Company
United Illuminating Company
Upper Peninsula Power Company
Utah Power & Light Company (ID)
Utah Power & Light Company (UT)
Utah Power & Light Company (WY)
Virginia Electric & Power Company (NC)
Virginia Electric & Power Company (VA)
Washington Water Power company (ID)
Washington Water Power Company (MT)
Washington Water Power Company (WA)
West Penn Power Company
West Plains Energy (CO)
West Texas Utilities Company
Western Massachusetts Electric Company
West Plains Energy, Division of UtiliCorp United (KS)
Wheeling Electric Company
Wisconsin Electric Power Company (MI)
Wisconsin Electric Power Company (WI)
Wisconsin Power & Light Company
Wisconsin Public Service Corporation (MI)
Wisconsin Public Service Corporation (WI)

Publicly-Owned:

Albany Water, Gas & Light Commission (GA)
Anaheim Public Utilities Department (CA)
Anchorage Municipal Light & Power Department (AK)
Athens Utilities (AL)
Austin Electric Department (TX)
Bowling Green Municipal Utilities (KY)
Bristol Tennessee Electric System (TN)
Brownsville Public Utility Board (TX)
Bryan, City of (TX)
Burbank Public Service Department (CA)
Central Lincoln People's Utility District (OR)
Chattanooga Electric Power Board (TN)
Clarksville Department of Electricity (TN)
Clatskanie People's Utility District (OR)
Cleveland Division of Light & Power (OH)
Cleveland Utilities (TN)
Clinton Utilities Board (TN)
Colorado Springs Department of Public Utilities (CO)
Dalton Water, Light & Sink (GA)
Danville Water, Gas & Electric (VA)
Decatur Electric Department (AL)
Dothan Electric Department (AL)
Dyersburg Electric System (TN)
Eugene Water & Electric Board (OR)
Fayetteville Public Works Commission (NC)
Florence Electric Department (AL)
Gainesville Regional Utilities (FL)
Garland Electric Department (TX)
Glendale Public Service Department (CA)
Greenville Light & Power System (TN)
Groton Public Utilities (CT)
High Point Electric Utility Dept. (NC)
Huntsville Utilities (AL)
Imperial Irrigation District (CA)
Independence Power & Light Department (MO)
Jackson Utility Division-Electric Department (TN)
Jacksonville Electric Authority (FL)
Johnson City Power Board (TN)
Jonesboro Water & Light (AR)
Kansas City Board of Public Utilities (KS)
Kissimmee Utility Authority (FL)
Knoxville Utilities Board (TN)
Lafayette Utilities System (LA)
Lakeland Department of Electric and Water (FL)
Lansing Board of Water & Light (MI)
Lenoir City Utilities Board (TN)
Lincoln Electric System (NE)
Los Angeles Department of Water and Power (CA)
Lower Colorado River Authority (TX)
Lubbock Power & Light (TX)
Memphis Light, Gas & Water Division (TN)
Modesto Irrigation District (CA)
Morristown Power System (TN)
Murfreesboro Electric Dept. (TN)
Muscatine Power & Water (IA)
Nashville Electric Service (TN)
Nebraska Public Power District (NE)
Nebraska Public Power District (SD)
New York Power Authority (NY)
North Little Rock Electric Department (AR)
Ocala Electric Authority (FL)
Omaha Public Power District (IA)
Omaha Public Power District (NE)
Orlando Utilities Commission (FL)
Owensboro Municipal Utilities (KY)
Palo Alto Electric Utility (CA)
Pasadena Water & Power Department (CA)
Port Angeles Light & Water Department (WA)
Public Utility District No. 1 of Benton County (WA)
Public Utility District No. 1 of Chelan County (WA)
Public Utility District No. 1 of Clark County (WA)
Public Utility District No. 1 of Cowlitz County (WA)
Public Utility District No. 1 of Douglas County (WA)
Public Utility District No. 1 of Franklin County (WA)
Public Utility District No. 1 of Grays Harbor County (WA)
Public Utility District No. 1 of Lewis County (WA)
Public Utility District No. 1 of Snohomish County (WA)
Public Utility District No. 2 of Grant County (WA)
Puerto Rico Electric Power Authority
Richland Energy Services Department (WA)
Richmond Power & Light (IN)
Riverside Public Utilities (CA)
Rochester Department of Public Utilities (MN)
Rocky Mount Public Utilities (NC)
Sacramento Municipal Utility District (CA)
Salt River Project Agricultural Improvement and Power District (AZ)
San Antonio City Public Service Board (TX)
Santa Clara Electric Department (CA)
Seattle City Light Department (WA)
Sevier County Electric System (TN)
South Carolina Public Service Authority
Springfield City Utilities (MO)
Springfield Utility Board (OR)

Springfield Water, Light & Power Department (IL)
Tacoma Public Utilities-Light Division (WA)
Trico Electric Cooperative, Inc. (AZ)
Tallahassee, City of (FL)
Tupelo Water & Light Department (MS)
Turlock Irrigation District (CA)
Vernon Municipal Light Department (CA)
Wilson Utilities Department (NC)
Rural Electric Cooperatives:
Alcorn County Electric Power Association (MS)
Anoka Electric Cooperative (MN)
Appalachian Electric Cooperative (TN)
Arkansas Valley Electric Cooperative Corporation (AR)
Berkeley Electric Cooperative (SC)
Bluebonnet Electric Cooperatives, Inc. (TX)
Blue Ridge Electric Membership Corporation (NC)
Cajun Electric Power Cooperative (LA)
Cap Rock Electric Cooperative, Inc. (TX)
Carroll Electric Cooperative Corporation (AR)
Chugach Electric Cooperative (AK)
Clay Electric Cooperative (FL)
Coast Electric Power Association (MS)
Cobb Electric Membership Corporation (GA)
Cotton Electric Cooperative (OK)
Cullman Electric Cooperative (AL)
Cumberland Electric Membership Corporation (TN)
Dakota Electric Association (MN)
Dixie Electric Membership Corporation (LA)
Duck River Electric Membership Corporation (TN)
Duncan Valley Electric Cooperative, Inc. (AZ, NM)
First Electric Cooperative Corporation (AR)
Flint Electric Membership Corporation (GA)
4-County Electric Power Association (MS)
Gibson County Electric Membership (TN)
Green River Electric Corporation (KY)
GreyStone Power Corporation (GA)
Guadalupe Valley Electric Cooperative, Inc. (TX)
Henderson-Union Rural Electric Cooperative Corporation
Holston Electric Cooperative (TN)
Holy Cross Electric Association (CO)
Intermountain Rural Electric (CO)
Jackson Electric Membership Corporation (GA)
Joe Wheeler Electric Membership Corporation (AL)
Lea County Electric Cooperative, Inc. (NM)
Lee County Electric Cooperative (FL)
Linn County Rural Electric Cooperative Association (IA)
Meriwether Lewis Electric Cooperative (TN)
Middle Tennessee Electric Membership Corporation (TN)
Midwest Energy Incorporated (KS)
Mississippi County ECC (AR)
Moon Lake Electric Association (CO)
New Hampshire Electric Cooperative, Inc. (NH)
Northern Virginia Electric Cooperative (VA)
North Georgia Electric Membership Corporation (GA)
Oregon Trail Electric
Palmetto Electric Cooperative, Inc. (SC)
Pedernales Electric Cooperative Corporation, Inc. (TX)
Pennyrile Rural Electric Cooperative Corporation (KY)
Rappahannock Electric Cooperative (VA)
Rural Electric System (AL)
Rutherford Electric Membership Corporation (NC)
Sam Houston Electric Cooperative, Inc. (TX)
Sawnee Electric Membership Corporation (GA)
Sequachee Valley Electric Cooperative (TN)
Singing River Electric Power Association (MS)
South Central Power Company (OH)
Southern Maryland Electric Cooperative, Inc. (MD)
Southern Pine Electric Power Association (MS)
South Kentucky Rural Electric Cooperative (KY)
Southwest Louisiana Electric Membership Corporation (LA)
Southwest Tennessee Electric Membership Corporation (TN)
Sumter Electric Cooperative (FL)
Tombigbee Electric Power Association (MS)
Tri-County Electric Association, Inc. (WY)
Tri-County Electric Cooperative, Inc. (TX)
Tri-County Electric Membership Corporation (TN)
Umatilla Electric Cooperative Association (OR)
Upper Cumberland Electric Membership Corporation (TN)
Volunteer Electric Cooperative (TN)
Walton Electric Membership Corporation (GA)
Warren Rural Electric Cooperative Corporation (KY)
West Kentucky Rural Electric Cooperative Corporation (KY)
Withlacoochee River Electric Cooperative (FL)
Federal Agencies:
Bonneville Power Administration (OR)
Tennessee Valley Authority (TN)
Western Area Power Administration (CO)

Gas Utilities

All gas utilities listed below had natural gas sales, for purposes other than resale, in excess of 10 billion cubic feet in any year from 1976–1991. The utilities listed more than once have sales in more than one State and those States are indicated by abbreviations in parentheses.

Investor-Owned:
Alabama Gas Corporation
Anadarko Production Company
Arkansas-Louisiana Gas Company (AR)
Arkansas-Louisiana Gas Company (KS)
Arkansas-Louisiana Gas Company (LA)
Arkansas-Oklahoma Gas Corporation (OK)
Arkansas-Oklahoma Gas Corporation (AR)
Arkansas Western Gas Company
Associated Natural Gas Company (MO)
Atlanta Gas Light Company
Atmos Energy Corporation
Baltimore Gas & Electric Company
Battle Creek Gas Company
Bay State Gas Company
Boston Gas Company
Brooklyn Union Gas Company
Carnegie Natural Gas Company
Carolina Pipeline Company
Cascade Natural Gas Corporation (OR)
Cascade Natural Gas Corporation (WA)
Central Hudson Gas and Electric Corporation (NY)
Central Illinois Light Company
Central Illinois Public Service Company
Chattanooga Gas Company (TN)
Cheyenne Light, Fuel and Power Company
Cincinnati Gas and Electric Company
Citizens Utilities Company (AZ)
Citizens Utilities Company (CO)
City Gas Company of Florida
Colonial Gas Energy System
Columbia Gas of Kentucky, Inc.
Columbia Gas of Ohio, Inc.
Columbia Gas of Pennsylvania, Inc.
Columbia Gas of Virginia, Inc.
ComFurt Gas Incorporated (CO)
Commonwealth Gas Company
Commonwealth Gas Service Incorporated
Commonwealth Gas Services, Incorporate
Connecticut Natural Gas Corporation

Consolidated Edison Company of New York, Inc.
Consumers Power Company
Dayton Power & Light Company
Delmarva Power & Light Company (DE)
East Ohio Gas Company
Eastern Colorado Utility Company
Elizabethtown Gas Company
Enstar Natural Gas Company
Entex Inc. (LA)
Entex Inc. (MS)
Entex Inc. (TX)
Equitable Gas Company (PA)
Equitable Gas Company (WV)
Gas Company of New Mexico
Gas Service Company (NE)
Greeley Gas Company (CO)
Greeley Gas Company (KS)
Gulf States Utilities Company
Hope Gas, Incorporated
Illinois Power Company
Indiana Gas Company
Intermountain Gas Company
Interstate Power Company (IA)
Interstate Power Company (MN)
Iowa Electric Light & Power Company
Iowa-Illinois Gas & Electric Company (IA)
Iowa-Illinois Gas & Electric Company (IL)
Iowa Southern Utilities Company
Kansas-Nebraska Natural Gas Company (WY)
Kansas Power & Light Company (MO)
K N Energy, Inc. (CO)
K N Energy, Inc. (KS)
KPL Gas Service Company (KS)
KPL Gas Service Company (OK)
Laclede Gas Company Consolidated
Lone Star Gas Company, a division of ENSERCH Corp. (TX)
Long Island Lighting Company
Louisiana Gas Service Company
Louisville Gas & Electric Company
Madison Gas & Electric Company
Michigan Consolidated Gas Company
Michigan Gas Company
Midwest Gas, Division of Iowa Public Service Company (IA)
Midwest Gas, Division of Iowa Public Service Company (MN)
Midwest Gas, Division of Iowa Public Service Company (NE)
Midwest Gas, Division of Iowa Public Service Company (SD)
Minnegasco—Division of Arkla, Inc. (MN)
Minnegasco—Division of Arkla, Inc. (NE)
Minnegasco—Division of Arkla, Inc. (SD)
Mississippi Valley Gas Company
Missouri Public Service Company
Mobile Gas Service Corporation
Montana-Dakota Utilities Company (MT)
Montana-Dakota Utilities Company (ND)
Montana-Dakota Utilities Company (SD)
Montana-Dakota Utilities Company (WY)
Montana Power Company
Mountaineer Gas Company
Mountain Fuel Supply Company (UT)
Mountain Fuel Supply Company (WY)
Nashville Gas Company
National Fuel Gas Distribution Corporation (NY)
National Fuel Gas Distribution Corporation (PA)
National Gas and Oil Company
New Jersey Natural Gas Company
New Orleans Public Service, Inc.
New York State Electric & Gas Corporation
Niagara Mohawk Power Company
North Carolina Natural Gas Corporation
North Shore Gas Company
Northern Illinois Gas Company
Northern Indiana Public Service Company
Northern Minnesota Utilities-Division of UtiliCorp United, Inc.
Northern Natural Gas Company (KS)
Northern Natural Gas Company (NE)
Northern States Power Company (MN)
Northern States Power Company (ND)
Northern States Power Company (WI)
North Penn Gas Company
Northwest Natural Gas Company (OR)
Northwest Natural Gas Company (WA)
Northwestern Public Service Company (NE)
Northwestern Public Service Company (SD)
Oklahoma Natural Gas Company
Orange & Rockland Utilities
Pacific Gas & Electric Company
Panhandle Eastern Pipeline Company (IL)
Panhandle Eastern Pipeline Company (KS)
Pennsylvania Gas & Water Company
Peoples Gas, Light and Coke Company
Peoples Gas System
Peoples Natural Gas Company
Peoples Natural Gas Company (CO)
Peoples Natural Gas Company, Division of UtiliCorp United, Inc. (IA)
Peoples Natural Gas Company, Division of UtiliCorp United, Inc. (KS)
Peoples Natural Gas Company, Division of UtiliCorp United, Inc. (MN)
Peoples Natural Gas Company, Division of UtiliCorp United, Inc. (NE)
Philadelphia Electric Company
Piedmont Natural Gas Company (NC)
Piedmont Natural Gas Company (SC)
Providence Gas Company
Public Service Company of Colorado
Public Service Company of North Carolina
Public Service Electric and Gas Company
Rochester Gas & Electric Corporation
Rocky Mountain Natural Gas Division of K N Energy, Inc.
San Diego Gas & Electric Company
South Carolina Gas & Electric Company
South Jersey Gas Company
Southwestern Michigan Gas Company
Southern California Gas Company
Southern Connecticut Gas Company
Southern Indiana Gas & Electric Company
Southern Union Company (TX)
Southern Union Gas Company (OK)
Southwest Gas Corporation (AZ)
Southwest Gas Corporation (CA)
Southwest Gas Corporation (NV)
Trans Louisiana Gas Company
T.W. Phillips Gas and Oil Company
UGI Corporation
Union Electric Company
Union Light, Heat & Power Company (KY)
United Cities Gas Company (KS)
United Cities Gas Company (GA)
United Cities Gas Company, Great River Division
Virginia Natural Gas
Washington Gas Light Company (DC)
Washington Gas Light Company (MD)
Washington Gas Light Company (VA)
Washington Natural Gas Company
Washington Water Power Company (ID)
Washington Water Power Company (OR)
Washington Water Power Company (WA)
West Ohio Gas Company
Western Kentucky Gas Company
Williams Natural Gas Company
Wisconsin Fuel & Light Company
Wisconsin Gas Company
Wisconsin Natural Gas Company
Wisconsin Power & Light Company
Wisconsin Public Service Corporation (MI)
Wisconsin Public Service Corporation (WI)
Yankee Gas Services Company (CT)

Publicly-Owned

Citizens Gas & Coke Utility (IN)
City of Fort Morgan Gas Dept. (CO)
City of Richmond, Department of Public Utilities (VA)
City Public Services Board (San Antonio, TX)
Colorado Springs, Department of Public Utilities (CO)
Long Beach Gas Department (CA)
Memphis Light, Gas & Water Division (TN)
Metropolitan Utilities District of Omaha (NE)

Philadelphia Gas Works (PA)
Springfield City Utilities (MO)
Town of Ignacio Municipal Utilities (CO)
Town of Rangley Gas Department (CO)

[FR Doc. 92-31915 Filed 12-31-92; 8:45 am]
BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4551-3]

Science Advisory Board Environmental Engineering Committee Modeling Project Subcommittee; Open Meeting

Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Science Advisory Board's (SAB's) Modeling Project Subcommittee (MPS) of the Environmental Engineering Committee (EEC), will meet on Thursday, January 14 through Friday, January 15, 1993. The meeting will be at the Howard Johnson National Airport Hotel, 2650 Jefferson Davis Highway, Arlington, VA 22202 (telephone number is (703) 684-7200). On Thursday, January 14, 1993 the MPS will meet from 9 a.m. to 5 p.m. On Friday, January 15, 1993 the MPS will meet starting at 8:30 a.m. and will adjourn no later than 4 p.m.

At this meeting, the MPS will be briefed on the Office of Solid Waste and Emergency Response (OSWER) Draft Policy on Modeling, with particular attention paid to OSWER's assessment framework for groundwater model applications. Specifically, the SAB is requested to review the draft guidance entitled "Assessment Framework for Ground-Water Model Applications," and to address the following questions: (1) Is the substance of the Framework scientifically correct?; (2) Does the Framework address groundwater model application activities with as much completeness as is acceptable and necessary?; (3) Does the Framework provide help from the project management perspective for managing model applications?; (4) Will the use of the Framework serve to aid the OSWER staff in improving the management of its modeling activities?; and (5) Is there additional information or direction which should be added to Project Management Requirements for Modeling teams, and the Model Code and Public Domain?

The meeting is open to the public and seating will be on a first come basis. Any member of the public wishing further information, such as a proposed agenda on the meeting should contact Dr. K. Jack Kooyoomjian, Designated Federal Official, or Mrs. Diana L. Pozun, Secretary, Science Advisory Board (A101F), U.S. Environmental Protection Agency, Washington, DC 20460, at (202) 260-6552. Anyone wishing copies of the draft report entitled "Assessment Framework for Ground-Water Model Applications," should contact Ms. Mary Lou Melley of OSWER's Information Management Staff at (202) 260-6860. Written comments received by January 4, 1993 will be mailed to the SAB's MPS; comments received after that date will be provided to the MPS at the meeting. Written comments of any length (at least 35 copies) may be provided to the Subcommittee up until the meeting.

Members of the public who wish to make a brief oral presentation should contact Dr. K. Jack Kooyoomjian no later than January 7, 1993. The Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously submitted oral or written statements. In general, each individual or group making an oral presentation will be limited to a total time of five minutes.

Dated: December 14, 1992.

A. Robert Flaak,

Acting, Staff Director, Science Advisory Board.

[FR Doc. 92-31907 Filed 12-31-92; 8:45 am]
BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary for Health; Statement of Organization, Functions and Delegations of Authority

Part H, Public Health Service (PHS), Chapter HA (Office of the Assistant Secretary for Health) of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (42 FR 61318, December 2, 1977, as amended most recently at 57 FR 47107-08, October 14, 1992), is amended to reflect changes to the functions of the Office on Women's Health (HAW) within the Office of the Assistant Secretary for Health to reflect more accurately current activities associated with women's health issues.

Office of the Assistant Secretary for Health

Under Part H, Chapter HA, Office of the Assistant Secretary for Health, Section HA-20, Functions, following the title and statement for the Division of Payment Management (HAU45), delete the title and statement for the Office on Women's Health (HAW) and add the following title and statement:

Office of Women's Health (HAW). The Director, Office on Women's Health, serves as the principal advisor to the Assistant Secretary for Health on scientific, legal, ethical, and policy issues relating to women's health. The issues cut across all PHS components which provide research, service, prevention, promotion, treatment, training, education, and dissemination of information. The crosscutting categories include the health priorities addressed in the PHS Action Plan on Women's Health, and the objectives outlined in Healthy People 2000 which specifically address women's health. The Office:

(1) Coordinates the programmatic aspects of PHS agencies in regard to issues relating to women's health;

(2) Serves as a locus within PHS to identify changing needs, to recommend new studies, and to assess new challenges to the health of women;

(3) Serves as a focal point within PHS to coordinate the continuing implementation of recommendations of the report of the PHS Task Force on Women's Health Issues in the context of the health objectives for the year 2000;

(4) Monitors the PHS Action Plan for Women's Health;

(5) Assures liaison with relevant PHS agencies and offices; and

(6) Provides staff support to the PHS Coordinating Committee on Women's Health Issues in furthering their charge;

(7) Facilitates the expansion of services and access to health care for all women, particularly women of low socioeconomic status and those who are socially or geographically isolated; and

(8) assesses the opportunities for woman in assuming leadership positions in the PHS.

Dated: December 16, 1992.

James O. Mason,

Assistant Secretary for Health.

[FR Doc. 92-31894 Filed 12-31-92; 8:45 am]
BILLING CODE 4160-17-M

Social Security Administration

Statement of Organization, Functions and Delegation of Authority

Part S of the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services covers the Social Security Administration (SSA). Chapter S4

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covers the Deputy Commissioner, Systems. Notice is hereby given that subchapter S4H, the Office of Systems Requirements, is being amended to reflect the realignment of the Office of Pre-Claims Requirements (S4HB). Notice is further given that subchapter S4J, the Office of Systems Planning and Integration, is being amended to reflect revised functions and division level title changes. Notice is further given that subchapter S4K, the Office of Information Management, is being amended to reflect the abolishment of the Division of Office Systems and to update functions in the remaining divisions. The changes are as follows:

Section S4H.10 *The Office of Systems Requirements*—(Organization)

E. The Office of Pre-Claims Requirements (S4HB).

Delete:

1. The Division of Enumeration and Employer Identification (S4HB1) in its entirety.

Retitle and Renumber:

2. The Division of Earnings Reporting and Maintenance (S4HB2) to: "1. The Division of Earnings Control and Processing (S4HB2)."

Renumber:

"3" to "2"."

Retitle and Renumber:

4. The Division of User Support and Interfaces (S4HB4) to: "3. The Division of Data Support and Enumeration (S4HB4)."

Renumber:

"5" to "4."

Section S4H.20 *The Office of Systems Requirements*—(Functions)

E. The Office of Pre-Claims Requirements (S4HB).

Delete:

1. The Division of Enumeration and Employer Identification (S4HB1) in its entirety.

Retitle and Renumber:

2. The Division of Earnings Reporting and Maintenance (S4HB2) to: "1. The Division of Earnings Control and Processing (S4HB2)."

Delete:

a. In its entirety.

Add:

a. Plans, develops, evaluates and implements organizational information requirements, functional specifications, procedures, instructions and standards, including those relating to security and fraud detection, for reporting private and public sector earnings data; for establishment, correction and maintenance of earnings records; for reconciling disagreements and resolving discrepancies; for the establishment and maintenance of employer identification information; for the classification of employers; for the employer reporting control and SSA/IRS reconciliation process; and for State and local reporting audit and reconciliation.

Delete:

c. thru f. In their entirety.

Add:

c. Develops and maintains a comprehensive, updated and integrated set of systems requirements specifications for the earnings reporting and maintenance process, State and local contribution and liability, and the employer identification and control process.

d. Performs requirements analyses and definition, conveying SSA-approved user needs and requirements in the areas of earnings reporting, State and local contributions and liability, and employer identification and control to the Office of Systems Design and Development (OSDD) for the development of ADP specifications and system design.

e. Evaluates legislative proposals, regulations and policy changes affecting the earnings reporting process, State and local contributions and liability, and the employer identification and control process.

f. Represents users in resolving systems discrepancies and errors relating to the existing earnings reporting and maintenance process, existing State and local contributions and liability, and employer identification and control processes with OSDD and the Office of Systems Operations' (OSO's) representatives.

Renumber:

3. The Division of Earnings Correction and Certification (S4HB3) to "2."

Delete:

c. thru f. In their entirety.

Add:

c. Develops and maintains a comprehensive, updated and integrated set of system requirements specifications for earnings data use and data accessing processes.

d. Performs requirements analyses and definition, conveying SSA-approved user needs and requirements in the area of earnings data use and data accessing processes to OSDD for the development of ADP specifications and systems design.

e. Evaluates legislative proposals, regulations and policy changes affecting use and maintenance of earnings data and data accessing processes.

f. Represents users in resolving system discrepancies and errors relating to earnings data uses and data accessing processes with OSDD and OSO representatives.

Retitle and Renumber:

4. The Division of User Support and Interface (S4HB4) to: "3. The Division of Data Support and Enumeration (S4HB4)."

Delete:

a. In its entirety.

Add:

a. Plans, develops, validates, evaluates and implements organizational information requirements, functional specifications, procedures, instructions and standards, including security and fraud detection for data exchanges between SSA systems and other Federal and State agencies; data bases; data base access for information, and teleprocessing; for the establishment, correction and maintenance of Social Security numbers; for the issuance of new or replacement cards; and for the Death Master, News and Tride files.

Delete:

c. thru f. In their entirety.

Add:

c. Develops and maintains a comprehensive, updated and integrated set of systems requirements specifications for the enumeration process and for interface and data base access processes.

d. Performs requirements analyses and definition, conveying SSA-approved user needs and requirements in the areas of enumeration, data base accesses and interfaces to OSDD for the development of ADP specifications and systems design.

e. Evaluates legislative proposals, regulations and policy changes affecting enumeration process and system interfaces.

f. Represents users in resolving system discrepancies and errors relating to the existing interface and enumeration process with OSDD and OSO representatives.

Renumber:

"5" to "4."

Section S4J.10 *The Office of Systems Planning and Integration*—(Organization)

C. The Immediate Office of the Director, Office of Systems Planning and Integration (S4J).

Delete:

1. The Data Administration Staff (S4J–1) in its entirety.

Retitle:

E. The Division of Systems Planning (S4JB) to: "The Division of Technology Assessment and Training (S4JB)."

Retitle:

F. The Division of Financial, Procurement and Information Management (S4JC) to: "The Division of Systems Planning and Budget (S4JC)."

Section S4J.20 *The Office of Systems Planning and Integration*—(Function)

C. The Immediate Office of the Director, Office of Systems Planning and Integration (S4J).

Delete:

1. The Data Administration Staff (S4J–1) in its entirety.

Delete:

D. The Division of Systems Engineering (S4JA) in its entirety.

Add:

D. The Division of Systems Engineering (S4JA) is responsible for SSA-wide data administration including responsibility for the overall operation of the SSA Data Resource Management Program. It is responsible for the development of Systems-wide policies, procedures and standards for all phases of the systems life cycle development process; development of methods to assure the quality of systems products; and development and maintenance of the Software Engineering Technology, which includes the policies, standards, guidelines, procedures, tools and training elements pertaining to the following software life cycle stages: Requirements definition and analysis, design, programming, validation, operation and review. The Division develops proposals and recommendations for new software engineering methods for use at SSA, based on extensive research into various methodologies utilized by other data processing installations. Develops and maintains quality assurance procedures and mechanisms to assure that software products satisfy user requirements and conform to the defined standards, guidelines and procedures of SSA systems.

Retitle:

E. The Division of Systems Planning (S4JB) to: "The Division of Technology Assessment and Training (S4JB)."

Revise in its entirety:

E. The Division of Technology Assessment and Training (S4JB) is responsible for assessment of new technologies and planning for and acquiring technical training for systems personnel. The Division analyzes the current SSA data processing environment, future systems requirements and technology forecasts to evaluate the applicability of new technologies to SSA processes. It develops pilot projects to evaluate technologies, particularly in the area of artificial intelligence and expert systems, for selected applications. The Division evaluates technical and nontechnical training needs for all Systems offices and coordinates and evaluates vendor provided and in-house training as applicable.

Retitle:

F. The Division of Financial, Procurement and Information Management (S4JC) to: "The Division of Systems Planning and Budget (S4JC)."

Revise in its entirety:

F. The Division of Systems Planning and Budget (S4JC) is responsible for development of SSA's Information Systems Plan (ISP) which sets forth SSA's major systems goals and objectives and the initiatives/projects to achieve them. It develops the Systems 5-year Information Technology Systems (ITS) plan and budget. It directs the fiscal management and tracking of ITS procurements and keeps management abreast of the status of all ITS acquisitions, systems life cycle costs and full-time equivalent utilization. The Division functions as an advisor and consultant to the Director, Office of Systems Planning and Integration, and the Deputy Commissioner for Systems, on all matters related to the development and execution of the ISP and the 5-year plan and budget. The Division is responsible for ongoing, formal change control procedures for the ISP and monitoring and reporting progress toward ISP project goals. It identifies major systems integration issues and develops alternative solutions and recommendations to the Deputy Commissioner for Systems. It also designs and maintains software systems and such as the Resource Accounting System to track and report on personnel and computer resource utilization. The Division operates the Systems Management Center, a fully-automated multimedia briefing center, and designs briefing material for SSA executive staff.

Section S4K.10 *The Office of Information Management*—(Organization)

Delete:

D. The Division of Office Systems (S4KA) in its entirety.

Reletter:

"E" to "D," "F" to "E," "G" to "F" and "H" to "G."

Section S4K.20 *The Office of Information Management*—(Functions)

Delete:

D. The Division of Office Systems (S4KA) in its entirety.

Reletter:

"E" to "D," "F" to "E," "G" to "F" and "H" to "G."

E. The Division of Information Resource Management (S4KB).

Delete:

1. In its entirety:

Add:

1. Coordinates with the staff components under the Deputy Commissioner for Systems on all areas within Division control. (e.g., ITS budget, management information systems design and delivery, ongoing user support.)

Add:

9. Plans, implements, integrates and controls Office Automation (OA) software functions at SSA and is responsible for development and dissemination of OA software acquisition and development policies, standards, guidelines and procedures.

10. Monitors technology trends and maintains current information on OA software products, development tools and techniques.

11. Works with SSA users to provide solutions to their OA requirements that are consistent with Agency OA policies.

12. Assists SSA users in refining OA requirements, configuring and engineering solutions, coordinating implementation and evaluating effectiveness.

13. Assists SSA users in determining OA applications, software and training needs, implementing solutions, planning for expansion.

14. Provides a full range of initial and follow-up OA applications, software and development support for SSA users in requirements analysis, system design, engineering, implementation and training.

15. Directs the preparation, acquisition and management of contracts for OA/end-user computing/MI hardware, software and support services.

F. The Division of Information Systems Policy and Administration (S4KC).

Add:

8. Responsible for formulating and maintaining the Information Systems Architecture supporting SSA's administrative and management information systems.

9. Responsible for developing systems requirements and validation in support of new automated management information systems.

10. Provides fourth and fifth generation computer language support to end-users and developers of Admin/MI systems.

Dated: December 15, 1992.

Ruth A. Pierce,

Deputy Commissioner for Human Resources.

[FR Doc. 92-31895 Filed 12-31-92; 8:45 am]

BILLING CODE 4190-29-M

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies and Laboratories That Have Withdrawn From the Program

AGENCY: Substance Abuse and Mental Health Services Administration, HHS. (Formerly: National Institute on Drug Abuse, ADAMHA, HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (53 FR 11979, 11986). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be identified as such at the end of the current list of certified laboratories, and will be omitted from the monthly listing thereafter.

FOR FURTHER INFORMATION CONTACT: Denise L. Goss, Program Assistant, Division of Workplace Programs, room 9-A-54, 5600 Fishers Lane, Rockville, Maryland 20857; Tel.: (301) 443-6014.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in an every-other-month performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of certification are not to be considered as meeting the minimum requirements expressed in the HHS Guidelines. A laboratory must have its letter of certification from SAMHSA, HHS (formerly: HHS/NIDA) which attests that it has met minimum standards.

In accordance with subpart C of the Guidelines, the following laboratories meet the minimum standards set forth in the Guidelines:

AccuTox Analytical Laboratories, 427 Fifth Avenue, NW., P.O. Box 770, Attalla, AL 35954-0770, 205-538-0012/800-247-3893
Aegis Analytical Laboratories, Inc., 624 Grassmere Park Road, Suite 21, Nashville, TN 37211, 615-331-5300
Alabama Reference Laboratories, Inc., 543 South Hull Street, Montgomery, AL 36103, 800-541-4931/205-263-5745
Allied Clinical Laboratories, 201 Plaza Boulevard, Hurst, TX 76053, 817-282-2257
American Medical Laboratories, Inc., 14225 Newbrook Drive, Chantilly, VA 22021, 703-802-6900
Associated Pathologists Laboratories, Inc., 4230 South Burnham Avenue, Suite 250, Las Vegas, NV 89119-5412, 702-733-7866
Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84108, 801-583-2787
Baptist Medical Center—Toxicology Laboratory, 9601 I-630, Exit 7, Little Rock, AR 72205-7299, 501-227-2783 (formerly: Forensic Toxicology Laboratory Baptist Medical Center)
Bayshore Clinical Laboratory, 4555 W. Schroeder Drive, Brown Deer, WI 53223, 414-355-4444/800-877-7016
Bellin Hospital—Toxicology Laboratory, 215 N. Webster Ave., Green Bay, WI 54301, 414-433-7485
Bioran Medical Laboratory, 415 Massachusetts Avenue, Cambridge, MA 02139, 617-547-8900
California Toxicology Services, 1925 East Dakota Avenue, suite 206, Fresno, CA 93726, 209-221-5655/800-448-7600
Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Avenue, Miami, FL 33136, 305-325-5810
Centinela Hospital Airport Toxicology Laboratory, 9601 S. Sepulveda Blvd., Los Angeles, CA 90045, 310-215-6020
Clinical Pathology Facility, Inc., 711 Bingham Street, Pittsburgh, PA 15203, 412-488-7500
Clinical Reference Lab, 11850 West 85th Street, Lenexa, KS 66214, 800-445-6917
CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory, 3308 Chapel Hill/Nelson Hwy., Research Triangle Park, NC 27709, 919-549-8263/800-833-3984
CompuChem Laboratories, Special Division, 3308 Chapel Hill/Nelson Hwy., Research Triangle Park, NC 27709, 919-549-8263
Cox Medical Centers, Department of Toxicology, 1423 North Jefferson Avenue, Springfield, MO 65802, 800-876-3652/417-836-3093
CPF MetPath Laboratories, 21007 Southgate Park Boulevard, Cleveland, OH 44137-3054 800-338-0166 (outside OH)/800-362-8913 (inside OH) (name changed: formerly Southgate Medical Laboratory; Southgate Medical Services, Inc.)
Damon Clinical Laboratories, 140 East Ryan Road, Oak Creek, WI 53154, 800-638-1100 (name changed: formerly Chem-Bio Corporation; CBC Clinilab)
Damon Clinical Laboratories, 8300 Esters Blvd., suite 900, Irving, TX 75063 214-929-0535
Doctors & Physicians Laboratory, 801 East Dixie Avenue, Leesburg, FL 32748, 904-787-9006
Drug Labs of Texas, 15201 I-10 East, suite 125, Channelview, TX 77530, 713-457-3784
DrugScan, Inc., P.O. Box 2969, 1119 Mearns Road, Warminster, PA 18974, 215-674-9310
Eagle Forensic Laboratory, Inc., 950 North Federal Highway, Suite 308, Pompano Beach, FL 33062, 305-946-4324
Eastern Laboratories, Ltd., 95 Seaview Boulevard, Port Washington, NY 11050, 516-625-9800
ElSohly Laboratories, Inc., 1215-1/2 Jackson Ave., Oxford, MS 38655, 601-236-2609
Employee Health Assurance Group, 405 Alderson Street, Schofield, WI 54476, 800-627-8200 (name change: formerly Alpha Medical Laboratory, Inc.)
General Medical Laboratories, 36 South Brooks Street, Madison, WI 53715, 608-267-6267
Harrison & Associates Forensic Laboratories, 606 N. Weatherford, P.O. Box 2788, Midland, TX 79702, 800-725-3784/915-687-6877
HealthCare/Preferred Laboratories, 24451 Telegraph Road, Southfield, MI 48034, 800-328-4142 (inside MI)/800-225-9414 (outside MI)
Hermann Hospital Toxicology Laboratory, Hermann Professional Building, 6410

Fannin, suite 354, Houston, TX 77030, 713–793–6080
IHC Laboratory Services Forensic Toxicology, 930 North 500 West, suite E, Provo, UT 84604 800–967–9766
Jewish Hospital of Cincinnati, Inc., 3200 Burnet Avenue, Cincinnati, Ohio 45229, 513–569–2051
Laboratory of Pathology of Seattle, Inc., 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206–386–2672
Laboratory Specialists, Inc., 113 Jarrell Drive, Belle Chasse, LA 70037, 504–392–7961
Marshfield Laboratories, 1000 North Oak Avenue, Marshfield, WI 54449, 715–389–3734/800–222–5835
Mayo Medical Laboratories, 200 S.W. First Street, Rochester, MN 55905, 507–284–3631
Med-Chek Laboratories, Inc., 4900 Perry Highway, Pittsburgh, PA 15229, 412–931–7200
MedExpress/National Laboratory Center, 4022 Willow Lake Boulevard, Memphis, TN 38175, 901–795–1515
MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc., 9176 Independence Avenue, Chatsworth, CA 91311, 818–718–0115/800–331–8670 (outside CA)/800–464–7081 (inside CA) (name changed: formerly Laboratory Specialists, Inc.; Abused Drug Laboratories)
MedTox Bio-Analytical, a Division of MedTox Laboratories, Inc., 2356 North Lincoln Avenue, Chicago, IL 60614, 312–880–6900 (name changed: formerly Bio-Analytical Technologies)
MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 800–832–3244/612–636–7466
Methodist Hospital of Indiana, Inc., Department of Pathology and Laboratory Medicine, 1701 N. Senate Boulevard, Indianapolis, IN 46202, 317–929–3587
Methodist Medical Center Toxicology Laboratory, 221 N.E. Glen Oak Avenue, Peoria, IL 61636, 800–752–1835/309–671–5199
MetPath, Inc., 1355 Mittel Boulevard, Wood Dale, IL 60191, 708–595–3888
MetPath, Inc., One Malcolm Avenue, Teterboro, NJ 07608, 201–393–5000
MetWest-BPL Toxicology Laboratory, 18700 Oxnard Street, Tarzana, CA 91356, 800–492–0800/818–343–8191
National Center for Forensic Science, 1901 Sulphur Spring Road, Baltimore, MD 21227, 410–536–1485 (name changed: formerly Maryland Medical Laboratory, Inc.)
National Drug Assessment Corporation, 5419 South Western, Oklahoma City, OK 73109, 800–749–3784 (name changed: formerly Med Arts Lab)
National Health Laboratories Incorporated, 2540 Empire Drive, Winston-Salem, NC 27103–6710, 919–760–4620/800–334–8627 (outside NC)/800–642–0894 (inside NC)
National Health Laboratories Incorporated, 75 Rod Smith Place, Cranford, NJ 07016–2843, 908–272–2511
National Health Laboratories Incorporated, d.b.a. National Reference Laboratory, Substance Abuse Division, 1400 Donelson Pike, Suite A–15, Nashville, TN 37217, 615–360–3992/800–800–4522
National Health Laboratories Incorporated, 13900 Park Center Road, Herndon, VA 22071, 703–742–3100/800–572–3734 (inside VA)/800–336–0391 (outside VA)
National Psychopharmacology Laboratory, Inc.,9320 Park W. Boulevard, Knoxville, TN 37923, 800–251–9492
National Toxicology Laboratories, Inc., 1100 California Avenue, Bakersfield, CA 93304, 805–322–4250
Nichols Institute Substance Abuse Testing (NISAT), 7470–A Mission Valley Road, San Diego, CA 92108–4406, 800–446–4728/619–686–3200 (name changed: formerly Nichols Institute)
Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800–322–3361
Occupational Toxicology Laboratories, Inc., 2002 20th Street, suite 204A, Kenner, LA 70062, 504–465–0751
Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Avenue, Eugene, OR 97440–0972, 503–687–2134
Parke DeWatt Laboratories, Division of Comprehensive Medical Systems, Inc., 1810 Frontage Rd., Northbrook, IL 60062, 708–480–4680
Pathology Associates Medical Laboratories, East 11604 Indiana, Spokane, WA 99206, 509–926–2400
PDLA, Inc. (Precision), 5 Industrial Park Drive, Oxford, MS 38655, 601–236–5600/800–237–7352
PDLA, Inc. (Princeton),100 Corporate Court, So. Plainfield, NJ 07080, 908–769–8500/800–237–7352
PharmChem Laboratories, Inc., 1505–A O'Brien Drive, Menlo Park, CA 94025, 415–328–6200/800–446–5177
PharmChem Laboratories, Inc., Texas Division, 7606 Pebble Drive, Fort Worth, TX 76118, 817–595–0294, (Formerly: Harris Medical Laboratory)
Physicians Reference Toxicology Laboratory, 7800 West 110th Street, Overland Park, KS 66210, 913–338–4070
Poisonlab, Inc., 7272 Clairemont Mesa Road, San Diego, CA 92111, 619–279–2600/800–882–7272
Precision Analytical Laboratories, Inc., 13300 Blanco Road, suite #150, San Antonio, TX 78216, 512–493–3211
Puckett Laboratory, 4200 Mamie Street, Hattiesburgh, MS 39402, 601–264–3856/800–844–8378
Regional Toxicology Services, 15305 N.E. 40th Street, Redmond, WA 98052, 206–882–3400
Resource One, Inc., Seven Pointe Circle, Greenville, SC 29615, 803–233–5639
Roche Biomedical Laboratories, 1801 First Avenue South, Birmingham, AL 35233, 205–581–4170
Roche Biomedical Laboratories, 1957 Lakeside Parkway, suite 542, Tucker, GA 30084, 404–939–4811
Roche Biomedical Laboratories, Inc., 1120 Stateline Road, Southaven, MS 38671, 601–342–1286
Roche Biomedical Laboratories, Inc., 69 First Avenue, Raritan, NJ 08869, 800–437–4986
Scott & White Drug Testing Laboratory, 600 S. 25th Street, Temple, TX 76504, 800–749–3788
S.E.D. Medical Laboratories, 500 Walter NE, suite 500, Albuquerque, NM 87102, 505–848–8800
Sierra Nevada Laboratories, Inc., 888 Willow Street, Reno, NV 89502, 800–648–5472
SmithKline Beecham Clinical Laboratories, 7600 Tyrone Avenue, Van Nuys, CA 91045, 818–376–2520
SmithKline Beecham Clinical Laboratories, 3175 Presidential Drive, Atlanta, GA 30340, 404–934–9205 (name changed: formerly SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 506 E. State Parkway, Schaumburg, IL 60173, 708–885–2010 (name changed: formerly International Toxicology Laboratories)
SmithKline Beecham Clinical Laboratories, 11636 Administration Drive, St. Louis, MO 63146, 314–567–3905
SmithKline Beecham Clinical Laboratories, 400 Egypt Road, Norristown, PA 19403, 800–523–5447 (name changed: formerly SmithKline Bio-Science Laboratories)
SmithKline Beecham Clinical Laboratories, 8000 Sovereign Row, Dallas, TX 75247, 214–638–1301 (name changed: formerly SmithKline Bio-Science Laboratories)
South Bend Medical Foundation, Inc., 530 N. Lafayette Boulevard, South Bend, IN 46601, 219–234–4176
St. Anthony Hospital (Toxicology Laboratory), P.O. Box 205, 1000 N. Lee Street, Oklahoma City, OK 73102, 405–272–7052
St. Louis University Forensic Toxicology Laboratory, 1205 Carr Lane, St. Louis, MO 63104, 314–577–8628
Toxicology & Drug Monitoring Laboratory, University of Missouri Hospital & Clinics, 301 Business Loop 70 West, suite 208, Columbia, MO 65203, 314–882–1273
Toxicology Testing Service, Inc., 5426 N.W. 79th Avenue, Miami, FL 33166, 305–593–2260

No laboratories have voluntarily withdrawn from the National Laboratory Certification Program.

Richard Kopanda,

Acting Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 92–31899 Filed 12–31–92; 8:45 am]

BILLING CODE 4160–20–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–921–08–4120–03; NDM 81582]

Coal Lease Application—NDM 81582—The Cotesu Properties Company; Intent To Hold Scoping Meetings To Solicit Comments for the Preparation of an Environmental Analysis for Federal Coal Resources Within the Fort Union Coal Production Region, North Dakota

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Notice of intent to hold scoping meetings to solicit comments for the

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preparation of an environmental analysis for the proposed lease tracts.

SUMMARY: On December 18, 1992, The Coteau Properties Company filed a lease application, NDM 81582, for federal coal resources within the Fort Union Coal Production Region.

The land included in Coal Lease Application NDM 81582 is located in Mercer County, North Dakota, and is described as follows:

T. 145 N., R. 86 W., 5th P.M.
Sec. 6: Lots 3,4,5, SE¼NW¼.
Sec. 8: E½E½, NW¼NW¼, SE¼NW¼, SE¼SW¼, SW¼SE¼.
Sec. 18: E½.
792.90 acres—Mercer County.

The application will be processed in accordance with the provisions of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181, *et seq.*), and the implementing regulations at 43 CFR Part 3400. A decision to allow leasing of the coal resources in said tract will result in a competitive lease sale to be held at a time and place to be announced through publication pursuant to 43 CFR Part 3422.

An environmental analysis will be prepared to analyze the proposed leasing of these federal coal resources and the reasonably foreseeable consequences of this action as well as the impacts of development of the coal.

All interested parties, including federal, state, and local agencies are invited to participate in the environmental analysis scoping process.

The scoping process used to collect issues and concerns on the proposed lease application will involve a public meeting and a written-comment period which will begin immediately and will close on January 15, 1993.

DATES: Written response and comments will be accepted now through January 15, 1993. A public meeting will be held on January 11, 1993, at 7 p.m. Mountain Standard Time at the Civic Center, 250 7th Street NE, Beulah, North Dakota.

SUPPLEMENTARY INFORMATION: The Coteau Properties Company submitted Coal Lease Application NDM 81582 as a result of the United States Department of the Interior's grant of a Category 5 Federal Royalty Rate Reduction for Coteau's federal lease numbers NDM 071813 and NDM 78697, situated within Coteau's Freedom Mine.

The tracts included in Coal Lease Application NDM 81582 are not presently scheduled to be mined. In the event Coteau is successful in obtaining a coal lease covering these tracts, a Category 5 Federal Royalty Rate Reduction Application will be submitted. Upon issuance of the reduction, Coteau will amend its mine plan and permits to provide for the mining of the coal underlying these tracts. In the absence of such a reduction, these tracts will remain bypassed.

Coteau is under contract with Dakota Coal Company which supplies coal to Dakota Gasification Company's synfuels plant, Basin Electric Power Cooperative's Antelope Valley Station and Leland Olds Station, and United Power Association's Stanton Station. The current annual coal production from the Freedom Mine is projected to range from 13.5 million tons in 1992 to 15.5 million tons in 1994, depending on the coal requirements of Dakota Coal Company.

The application is available for review between the hours of 9 a.m. to 4 p.m. at the Bureau of Land Management, Montana State Office, 222 North 32nd Street, Billings, Montana 59101, and at the Bureau of Land Management Dickinson District Office, whose address is 2933 Third Avenue West, Dickinson, North Dakota 58601–2619 between the hours of 7:45 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: For additional information regarding this application, please contact Jackie Samsal at (406) 255–2830, or Coal Coordinator Ed Hughes at (406) 255–2813, at the Bureau of Land Management, Montana State Office, 222 North 32nd Street, Billings, Montana 59107–6800.

All comments and requests for additional information concerning the scoping process should be addressed to Douglas J. Burger, District Manger, Bureau of Land Management, Dickinson District, 2933 Third Avenue West, Dickinson, North Dakota 58601–2619.

Douglas J. Burger,
District Manager.

[FR Doc. 92–31789 Filed 12–31–92; 8:45 am]
BILLING CODE 4310-DN-M

[CA–060–4350–06]

Intent To Prepare Chuckwalla Desert Tortoise Habitat Management Plan, To Amend the California Desert Conservation Area Plan and To Analyze Impacts in an Environmental Impact Statement; Invitation To Participate in the Identification of Issues

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the Bureau of Land Management (BLM), in cooperation with the California Department of Fish and Game under Sikes Act authority, intends to prepare a Chuckwalla Desert Tortoise Habitat Management Plan (HMP) and to analyze impacts in an associated Environmental Impact Statement (EIS). The HMP will constitute a proposed amendment to the California Desert Conservation Area (CDCA) Plan of 1980. This notice also constitutes the scoping notice required by the National Environmental Policy Act (40 CFR 1501.7). The HMP will provide guidelines for managing desert tortoise within the Colorado Desert by identifying zones within which the species will be managed for long-term viable, wild populations. The desert tortoise is on both the State and Federal lists of threatened species.

The planning effort will focus on the desert tortoise in the Colorado Desert of southern California. The 2.8 million acre planning area will include only public lands and will extend around Joshua Tree National Monument on the north to the Chocolate Mountains and the Coachella Valley on the south and from the San Gorgonio Pass below 4500 feet elevation on the west almost to the Colorado River on the east. This area includes the known range of wild desert tortoise on public land in the Colorado Desert region.

Agencies having land management responsibilities and/or regulatory jurisdiction affecting desert tortoise will be invited to participate in the planning effort. By addressing the issues of species protection in relation to resource development on a habitat-wide basis, the range of options for protection and development are increased.

DATES: Public scoping is initiated with publication of this notice and will continue until February 3, 1993. Public scoping workshops will be held to identify issues and concerns involving protection of desert tortoise and encourage and facilitate public participation in the planning process.

The workshops are scheduled as follows:

January 25, 1993, 7 p.m. at Blythe City Hall, 220 N. Spring, Blythe, CA.
January 26, 1993, 7 p.m. at the BLM office, 63–500 Garnet Ave., North Palm Springs, CA.
January 27, 1993, 7 p.m. at the Imperial Irrigation District's Auditorium, 1285 Broadway, El Centro, CA.
January 28, 1993, 7 p.m. at the BLM office, 3150 Winsor Avenue, Yuma, AZ.

ADDRESSES: Send your comments to the Bureau of Land Management, Palm Springs-South Coast Resource Area, Attn: Theodora Glenn, 63–500 Garnet Ave., P.O. Box 2000, North Palm Springs, CA 92258–2000.

FOR FURTHER INFORMATION CONTACT: Theodora Glenn at (619) 251–0812.

Dated: December 21, 1992.

David H. Eslinger,

Acting Area Manager.

[FR Doc. 92–31792 Filed 12–31–92; 8:45 am]

BILLING CODE 4310–40–M

[AZ–040–4320–01]

Safford District Grazing Advisory Board; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting.

SUMMARY: The Bureau of Land Management (BLM), Safford District announces a forthcoming meeting of the Safford District Grazing Advisory Board.

DATES: Friday, January 22, 1993; 9 a.m.

ADDRESSES: BLM Office, 711 14th Ave., Safford, Arizona 85546.

SUPPLEMENTARY INFORMATION: This meeting is held in accordance with Public Law 92–463. The agenda for the meeting will include:

1. Election of Treasurer.
2. Report on Permittee Water Rights.
3. Business from the floor:
   a. Oral statement from Mr. Wallace Klump.
   b. Requests for Advisory Board Funds.
4. Report on Reservation Fence.
5. Gila Box Riparian National Resource Conservation Area update.
6. BLM management update.

The meeting will be open to the public. Interested persons may make oral statements to the Board between 10 a.m. and 11 a.m. A written copy of the oral statement may be required to be provided at the conclusion of the presentation. Written statements may also be filed for the Board's consideration. Anyone wishing to make an oral statement must notify the District Manager, Bureau of Land Management, 711 14th Ave., Safford, AZ 85546, by 4:14 p.m., Thursday, January 21, 1993.

Summary minutes of the Board meeting will be maintained in the District Office and will be available for public inspection and reproduction (during regular business hours) within thirty (30) days following the meeting.

Dated: December 21, 1992.

Frank Rowley,

Acting District Manager.

[FR Doc. 92–31793 Filed 12–31–92; 8:45 am]

BILLING CODE 4310–32–M

[CA–020–4210–05; CACA–30745]

Sale of Public Land and Termination of Classification; Lassen County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management, Susanville District proposes to sell forty (40) acres of public land by means of direct sale to the Lassen Community College District, in order to resolve a hazardous materials trespass action. This notice of realty action terminates the existing Recreation and Public Purposes Act classification of the land and simultaneously closes the land to appropriation under the public land laws, including the mining laws, for up to 270 days from the date of publication of this document in the **Federal Register**.

DATES: Comments must be submitted by February 18, 1993.

ADDRESSES: Comments should be sent to the District Manager, Bureau of Land Management, 705 Hall St., Susanville, California 96130.

FOR FURTHER INFORMATION CONTACT: Peter Humm, Bureau of Land Management (BLM) Susanville District, 916–257–5381.

SUPPLEMENTARY INFORMATION: The following described public land has been examined and found suitable for sale under section 203 of the Federal Land Policy and Management Act of 1976 (FLPMA), and the regulations under title 43 Code of Federal Regulations (43 CFR), Part 2710.0–3(a)(3):

T 30 N., R. 12 E., Mt. Diablo Meridian, California
Section 28, SW¼SE¼.

The proposed sale to Lassen College is in conformance with the BLM's land use plan for the area, the Honey Lake Management Framework Plan (MFP), dated June 30, 1976. The Honey Lake Unit Land Use Guides for this area (Area #3) cover a total of 850 acres of public land adjacent to the College. The approved multiple-use recommendation from the MFP states: "National resource lands in this area will be used for college expansion and related use."

On February 1, 1982, the Bureau of Land Management (BLM) issued a twenty-five year lease with option to purchase this public land under the Recreation and Public Purposes (R&PP) Act of June 14, 1926 (as amended), to the Lassen Community College District. This lease, number CA–9273, authorized Lassen College to develop and eventually purchase this 40 acres of public land for use under the College's agricultural studies program. The land was classified for lease or sale under the R&PP Act, to be used by Lassen College for agricultural studies classes, livestock raising facilities, a rodeo arena and an environmental study area. During the first half of 1985, Lassen College generated fly ash and bottom ash from its nearby cogeneration plant, located on College property to the west of this parcel of public land. The College stored and disposed of the fly ash and bottom ash within the northeastern 10 to 15 acres of this 40 acre parcel of public land. Testing of the fly ash and bottom ash showed that the ash contained certain hazardous materials, primarily lead and other metals. This action by Lassen College constituted a violation of the College's Recreation and Public Purposes Lease on the parcel (CA–9273), a violation of federal and state solid waste disposal laws and regulations, and a trespass on the public land. During 1989, Lassen College removed the deposits of fly ash and bottom ash from the public land. Final testing of the site by an outside engineering firm indicated that total threshold limit concentrations for remaining contaminants (lead) were below the standards set forth in California Code of Regulations, title 22, Division 4, Article 11. The California Department of Health Services (DHS) determined that lead was the indicator parameter for site cleanup, and that the cleanup goal established in the site closure plan had been met. In a letter to the Bureau of Land Management dated October 10, 1990, the DHS determined that "the site poses no potential for environmental or public health threat".

Lassen College and the BLM have signed an Agreement, dated April 8, 1992, to resolve this situation on the parcel described above. A copy of the Agreement is available in the Susanville District Office. In accordance with the terms of the Agreement, the land will be sold by direct sale under 43 CFR 2711.3–3 to the Lassen Community College District, at the appraised fair market value. The sale will be conducted in accordance with section 120(h) of the Comprehensive Environmental Response Compensation and Liability Act as amended by the Superfund Amendments and Reauthorization Act of 1986, (CERCLA) (42 U.S.C. 9620(h)). In accordance with CERCLA, the patent for this land will contain a Notice Clause under section 120(h) of CERCLA, concerning the hazardous substances known to have been stored, released, or disposed of on

the property described in the patent, and describing the remediation measures taken on the land. The patent will contain an indemnification Clause to protect the United States from future liability on the parcel. The patent will also contain a reservation to the United States of a right-of-way thereon for ditches and canals constructed by the authority of the United States (Act of August 30, 1890, 43 U.S.C. 945).

The proposed sale of this parcel to Lassen College is necessary to resolve the pending trespass action against the College, to relieve the United States of future liability for the College's disposal of hazardous materials on this public land, and to provide Lassen College with the ability to use this parcel for College programs and development in the future. The BLM will not be able to sell the land to any other entity due to the disposal and temporary storage of hazardous materials on the site. The land may be sold to the Lassen Community College District without continuing liability to the United States, because the Lassen Community College District is the "potentially responsible party" (under CERCLA) for the generation and deposition of the hazardous materials.

The land in question was classified for lease or sale under the R&PP Act, for disposal to Lassen College. This classification is hereby revoked, and R&PP lease CA-9273 is hereby terminated at the request of the Lassen Community College District, to allow sale under section 203 of FLPMA. In accordance with 43 CFR 2711.1-2(d), the publication of this notice in the **Federal Register** shall segregate the public lands described herein to the extent that they will not be subject to appropriation under the public land laws, including the mining laws, for up to 270 days from the date of publication.

All minerals in this parcel will also be sold to the Lassen Community College District under section 209 of FLPMA and the regulations under 43 CFR part 2720. There are no grazing leases or permits on this parcel, and no other third-party rights or interests.

Dated: December 17, 1992.

Herrick E. Hanks,

District Manager.

[FR Doc. 92-31865 Filed 12-31-92; 8:45 am]

BILLING CODE 4310-

[CO-010-03-4210-04; COC-52964]

Realty Action: Exchange of Public and Private Lands in Grand and Jackson Counties, CO

AGENCY: Bureau of Land Management, Department of Interior.

ACTION: Notice of realty action.

SUMMARY: Pursuant to section 206 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1716), the Bureau of Land Management, Kremmling Resource Area is considering the following described land in Grand and Jackson Counties as suitable for disposal by exchange. This action is in response to a land exchange submitted by Daniel Ritchie, Grand River Ranch.

Selected Public Land

Sixth Principal Meridian, Colorado

Muddy Pass—4465.98 acres.

T. 4N., R. 81W.,
- Sec. 5, Lots 1 & 3, SE¼NE¼, NE¼SE¼,
- Sec. 7, Lots 3 & 4, SE¼NE¼, E½SE¼, SW¼SE¼,
- Sec. 8, NW¼NW¼, S½NW¼, W½SE¼, SW¼,
- Sec. 17, NW¼, NW¼NE¼, N½SW¼, SE¼SW¼
- Sec. 18, NE¼NE¼,

T. 4N., R. 82W.,
- Sec. 1, Lots 5-8;

T. 5N., R. 81W.,
- Sec. 7, Lots 12 & 13,
- Sec. 17, Lots 11-13,
- Sec. 18, Lots 7-10, 13, 19 & 20,
- Sec. 19, Lots 5, 6, 11-14, 19 & 20,
- Sec. 20, Lots 2-5, 11 & 12,
- Sec. 28, 5-9 & 11-15,
- Sec. 29, Lots 5-8,
- Sec. 30, Lots 5 & 8-12,
- Sec. 31, Lots 5-12, 15-18 & 20,
- Sec. 32, Lots 3 & 9,
- Sec. 33, Lots 4, 5 & 12;

T. 5N., R. 82W.,
- Sec. 24, Lots 3 & 14,
- Sec. 25, Lots 1 & 10.

Tyler Mtn.—385.04 acres.

T. 3N. R. 82W.,
- Sec. 24, Lots 3 & 4,
- Sec. 25, Lots 1, 2, 3 & 6,
- Sec. 36, Lots 1, 4, 5 & 11.

Mitchell—345.42 acres.

T. 3N., R. 80W.,
- Sec. 30, Lots 8 & 9,
- Sec. 31, Lot 6;

T. 3N., R. 81W.,
- Sec. 25, W½NE¼, E½NW¼, SW¼SE¼, SE¼SW¼.

The selected lands described above contain 5,196.44 acres, more or less. In exchange for these lands, the United States will acquire the following described lands from Daniel Ritchie, Grand River Ranch.

Offered Private land

Sixth Principal Meridian, Colorado

Williams Fork—2,628.03 acres more or less.

Metes and Bounds description in Sections 28, 29, 31, 32 and 33. T. 1S., R. 78W., and Sections 5, 6, 7, 8, 17, and 18, T. 2S., R. 78W., and Sections 12 and 13, T. 2S., R. 79W.; containing 2,628.03 acres more or less.

Red Dirt Reservior—603.16 acres.

T. 3N., R. 82W.,
- Tracts 48, 49 & 49A;

T. 2N., R. 82W..
- Tract 39A.

Diamond Creek—91.11 acres.

T. 5N., R. 81W.,
- Sec. 33, Lots 10 & 15.

Grizzly Creek—30 acres.

T. 5N., R. 82W.,
- Sec. 13, a portion of the SW¼,
- Sec. 14, a portion of the SE¼.

The Offered lands described above contain 3,352.3 acres more or less.

FOR FURTHER INFORMATION AND PUBLIC COMMENT: The environmental assessment and other information concerning this exchange, is available for review in the Kremmling Resource Area Office at 1116 Park Avenue, Kremmling, Colorado 80459. For a period of 45 days from the date of this notice, interested parties may submit comments to the District Manager, Craig District Office, Bureau of Land Management, 455 Emerson Street, Craig, Colorado 81625. Any adverse comments will be evaluated by the State Director, who may sustain, vacate or modify this realty action.

SUPPLEMENTARY INFORMATION: The purpose of this exchange is to facilitate improved resource management and to dispose of scattered, difficult to manage public land parcels while consolidating ownership of and establishing legal access to other public lands.

The exchange will be completed on an equal value basis. Full equalization of values will be achieved through acreage adjustment, or by cash payment in an amount not to exceed 25 percent of the value of the lands being transferred out of federal ownership.

The following reservations will be made in a patent issued for the public lands:

1. A reservation to the United States of a right-of-way for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

2. A reservation to the United States of all mineral deposits of known value.

3. A reservation of all existing and valid land uses, including grazing leases, unless waived.

Publication of this notice in the **Federal Register** segregates the public lands from operation of the public land laws and the mining law, except for mineral leasing and exchange under section 206 of FLPMA. For a period of 2 years from the date of publication of this notice in the **Federal Register**, the

land will be segregated as specified above unless the application is denied, canceled or the exchange is approved prior to that date.

Dated: December 14, 1992.

Robert Schneider,

Associate District Manager.

[FR Doc. 92-31801 Filed 12-31-92; 8:45 am]

BILLING CODE 4310-JB-M

[UT-050-03-4410-03]

Grand Resource Area Management Plan

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: The 1985 Grand Resource Management Plan (RMP) is being revised and an accompanying Environmental Impact Statement (EIS) is being prepared for the Grand Resource Area, Moab District, Bureau of Land Management. The revised RMP will provide overall management direction for the Resource Area. Necessary amendments to the approved plan will keep the document current and viable. This notice is intended to inform the public of the planning effort and to invite public participation in the identification of planning issues. Public comment will be solicited throughout the planning process. A call for nomination of Areas of Critical Environmental Concern (ACECs), and Wild and Scenic River (W&SR) is being made, along with a request for submission of technical mineral resource information.

FOR FURTHER INFORMATION CONTACT: Michael O'Donnell, Team Leader, Bureau of Land Management, Moab District Office, 82 East Dogwood, Moab, Utah 84532. Moab District Office hours are 7:45 a.m. to 4:30 p.m., Monday through Friday and the telephone number is (801) 259-6111.

SUPPLEMENTARY INFORMATION: The revised Grand RMP/EIS will be prepared under 43 CFR part 1610 to meet the requirements of section 202 of the Federal Land Policy and Management Act and section 102 of the National Environmental Policy Act. The revision is necessary to consolidate, modify, update, and expand the decisions in the existing Grand RMP.

Decisions generated during this planning process will supersede land use planning decisions presented in the 1985 Grand RMP. The RMP will bring forward valid existing decisions from the existing Grand RMP and other approved planning documents developed since 1985. The RMP/EIS will also incorporate needed decisions relating to policy and regulatory changes initiated or enacted since 1985.

The Grand Resource Area covers approximately 1.8 million acres in Grand and San Juan Counties, located in eastern Utah. Additionally, the Grand Resource Area manages mineral interests on other public lands, including the USDA Forest Service lands, and lands on the Uintah and Ouray Indian Reservation.

The revised RMP/EIS will provide a comprehensive land use plan that will coordinate management of all public resources in the Grand Resource Area. Coordination will take place with the State of Utah; the Ute Indian Tribe; Federal agencies such as the National Park Service, USDA Forest Service, and the Bureau of Indian Affairs; as well as other county and private entities. It will coordinate management of the Federal sub-surface mineral estate with the private or other surface owner. Coordination will also take place with adjoining BLM Districts in Utah and Colorado.

General planning issues to be addressed are: Access and transportation needs, livestock management, wildlife habitat management, watershed management, mineral activities, recreation management, cultural resource management, and threatened and endangered species recovery implementation plans.

As a part of the RMP/EIS process, requests for nominations for ACEC designations are encouraged. Nominations must include a map as well as a discussion on why an ACEC is necessary and what special management would be proposed. Nominations will be evaluated and final designations will be made through the RMP process. Nominations for Wild and Scenic River (W&SR) designations are also requested and will be evaluated through suitability. Opportunity is also provided at this time for submission of relevant technical information regarding mineral resources in the Grand Resource Area. This data will be used, along with other published information, in the evaluation of mineral resource potential and to assist in making resource allocation decisions.

Public participation is being sought at this initial state in the planning process to ensure the RMP/EIS addresses, all issues, problems, and concerns from those interested in the management of lands with the Grand Resource Area. The development of the RMP/EIS is a public process and the public is invited to assist in the identification of issues, the scope of the EIS, and the nomination of special designation areas. Public workshops will be held in January 1993 to discuss planning issues. The date, time, and location of these Scoping meetings will be announced at a later date in local newspapers. Additional public participation will be encouraged throughout this process; however, initial input on ACEC nominations and Wild and Scenic River nominations to be considered should be submitted to the team leader by September 30, 1993.

Formal public participation will be requested again for review of the draft RMP/EIS in 1995 and the proposed RMP/Final EIS in 1996. Notice of availability of these documents will be published at the appropriate times.

The RMP/EIS will be prepared by an interdisciplinary team which includes specialists in archaeological and paleontoligical resources, minerals, soil/water/air, range vegetation (including threatened and endangered plants), forestry, fire management, realty, recreation, and wildlife (including threatened and endangered animals). Other disciplines may be represented as necessary.

James M. Parker,

State Director.

[FR Doc. 92-31892 Filed 12-31-92; 8:45 am]

BILLING CODE 4310-DQ-M

Fish and Wildlife Service

Receipt of Applications for Permit

The following applicant has applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT-774973

Applicant: Embassy of the State of Qatar, 600 New Hampshire Ave, NW., Washington, DC

The applicant requests a permit to import and re-export one male captive-hatched Eurasian peregrine falcon (*Falco peregrine peregrinus*) from and to Jaber Muhammad Nasir Al Bureedi, Doha-Qatar, for enhancement of propagation and survival of the species through educational display at a Qatari Cultural Exhibition in Washington, DC.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, room 432, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with this application is available for review by any party who

submits a written request for a copy of such documents to, or by appointment during normal business hours (7:45–4:15) in, the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, room 432, Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: December 28, 1992.

Susan Jacobsen,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 92–31849 Filed 12–31–92; 8:45 am]

BILLING CODE 4310–55–M

Meeting; Klamath Fishery Management Council

AGENCY: U.S. Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. app. I), this notice announces a meeting of the Klamath Fishery Management Council, established under the authority of the Klamath River Basin Fishery Resources Restoration Act (16 U.S.C. 460ss *et seq.*). The meeting is open to the public.

DATES: The Klamath Fishery Management Council will meet from 10:30 am to 5:30 pm on Thursday, January 28, 1992, and from 8 am to 3:30 pm on Friday, January 29, 1992.

PLACE: The meeting will be held at the Quality Inn, 3535 Janes Road, Arcata, California.

FOR FURTHER INFORMATION CONTACT: Dr. Ronald A. Iverson, Project Leader, U.S. Fish and Wildlife Service, P.O. Box 1006, Yreka, California 96097–1006, telephone (916) 842–5763.

SUPPLEMENTARY INFORMATION: For background information on the Management Council, please refer to the notice of their initial meeting that appeared in the **Federal Register** on July 8, 1987 (52 FR 25639). The council will meet to hear technical reports on 1992 harvest and spawning escapement, and on projections of 1993 abundance of Klamath chinook salmon. The Council will decide how to proceed on a new harvest allocation agreement, and how to put the long term harvest management plan into action. Discussion will also include: Issues to be elevated for discussion by chairs of the three Klamath basin fishery advisory committees; recommendations on editorial policy for the Klamath Restoration News; and ways to make the Council more successful in reaching consensus on harvest management recommendations.

Dated: December 28, 1992.

William F. Shake,

Acting Regional Director, U.S. Fish and Wildlife Service.

[FR Doc. 92–31874 Filed 12–31–92; 8:45 am]

BILLING CODE 4310–55–M

National Park Service

Boundary Revision: Harpers Ferry National Historical Park

AGENCY: National Park Service, Interior.

ACTION: Notice of boundary revision.

SUMMARY: Notice is hereby given that the National Park Service is revising the boundary of Harpers Ferry National Historical Park to include three additional parcels within the Park.

EFFECTIVE DATE: December 31, 1992.

FOR FURTHER INFORMATION CONTACT: John G. Parsons, Associate Regional Director, Land Use Coordination, National Capital Region, National Park Service, 1100 Ohio Drive SW., Washington, DC 20242, (202) 619–7025; Gerald L. Kirwan, Chief, Land Resources Division, Mid-Atlantic Region, National Park Service, 143 South Third Street, Philadelphia, Pennsylvania 19106–2878, (215) 597–9939; and Donald W. Campbell, Superintendent, Harpers Ferry National Historical Park, Harpers Ferry, West Virginia 25425, (304) 535–6224.

SUPPLEMENTARY INFORMATION: The Act of June 30, 1944, c. 328, 58 Stat. 645 (codified as amended and supplemented, 16 U.S.C. 450bb–450bb–6),which established Harpers Ferry National Historical Park, provides the Secretary of the Interior with authority to make minor revisions in the boundary of the Park. Such boundary revisions may be made, when necessary, after advising the appropriate Congressional committees, and following publication of a revised boundary map drawing or other boundary description in the **Federal Register**.

In order to properly interpret and preserve the historic character of Harpers Ferry National Historical Park, it is necessary to revise the existing boundary of the Park to include three additional parcels of land comprising approximately 25.13 acres. The inclusion of the three parcels in the Park will bring Park acreage to just over 2300 acres. The acreage ceiling for the Park is 2505 acres. The parcels are being acquired by donation, exchange, and purchase as an economic remnant.

Notice is hereby given that the exterior boundary of Harpers Ferry National Historical Park is revised to include the following described parcels:

Parcel 1

All that parcel of Land, situated along the eastside of Hoffmaster Road approximately 0.56 miles Northeast from the intersection of the southernmost end of said Road with Harpers Ferry Road, in Election District No. II, Washington County, Maryland, and being more particularly described, according to a description prepared by J. Harold Seibert, Engineer and Surveyor, dated May 3, 1979 as follows:

Beginning at the intersection of the center line of Hoffmaster Road with the center of the culvert under it on an unnamed stream, said point of intersection being at the end of the South 82° 38′ East 51.72 foot line on the deed from Thomas B. Kern and Lillian Kern, his wife, to the said Andrea L. Steigman and Meryl F. Steigman, his wife, dated July 26, 1968, and recorded in Liber 474, folio 167, one of the Land Records of Washington County, Maryland, and running thence along Hoffmaster Road with one of the lines of said deed South 1° 40′ West, 93.43 feet to a point on the eastside thereof, thence leaving Hoffmaster Road but continuing with the lines of said deed and along the southern boundary of the 50 foot right of way conveyed by the heirs of Daisy Kern to the State of Maryland by deed dated January 17, 1962, and recorded in Liber 378, folio 195, another of said Land Records, South 72° 55′ East 200.0 feet to a point, thence correcting the next line, South 69° 20′ East 657.8 feet to a concrete monument marked NPS 12, thence South 69° 20′ East 1060.83 feet to a NPS monument 13, thence binding on the property of the United States of America North 20° 55′, East 536.64 feet to a monument marked USDI NPS 14, thence continuing along said property North 69° 20′ West 1692.93 feet to a monument marked USDI NPS 15 with an iron pin alongside it, and North 27° 33′ East 163.0 feet to a monument marked USDI NPS 16, thence leaving the lands of the United States of America and the lines of said deed and running North 62° 27′ West 17.5 feet into Hoffmaster Road, thence along or near the middle thereof South 31° 12′ West 155.82 feet to a point, thence South 64° 49′ West 234.35 feet to a point, and South 18° 36′ West 107.26 feet to a place of Beginning;

Containing 23.17 acres of land, more or less.

This parcel of Land is depicted as Tract 101–08 on Land Status Map Numbered 385/92002, Index and Segment 101, dated 30 June 1975.

Parcel 2

All that certain tract of land lying and being situated in the Town of Harpers Ferry, Jefferson County, West Virginia, and occupying a portion of Parcels 17, 19, and 33, as shown and designated on

the Baltimore and Ohio Railroad Company Right-of-Way and tract Map Number V–36. 1/1 and being more particularly described as follows:

Beginning at a point on the southerly shoreline of the Potomac River, at a corner common to the lands of the subject owner and a tract of land designated as Tract 101–04 in the Harpers Ferry National Historical Park, said corner being marked by a United States Monument numbered 148; thence from said point extending along the said shoreline (Being a stone retaining wall) South 40° 07′ 23″ East, 78.96 feet to a point; thence South 41° 27′ 09″ East, 262.33 feet to a point in the lines of a tract of land now or formerly owned by the Baltimore and Ohio Railroad Company; thence leaving the said shoreline and retaining wall and extending along the lands of the said Railroad Company South 38° 12′ 38″ East, 165.92 feet to a point; thence South 20° 34′ 57″ West, 15.00 feet to a point; thence along the arc of a curve to the right, having a radius of 1494.35 feet, a curve length of 760.00 feet and a chord bearing and distance of North 54° 50′ 52″ West, 751.84 feet to a point (the last mentioned course leaves the lands of the said railroad at an unknown distance and continues along the aforementioned Tract 101–04 to a point); thence continuing along the said Tract 101–04 the following bearings and distances:

North 49° 43′ 19″ East, 37.00 feet to a point;
South 45° 44′ 37″ East 228.15 feet to a point; and
North 44° 15′ 27″ East, 144.98 feet to the point of Beginning.

Containing 1.60 acres, more or less.

This parcel of land is depicted as Tract 106–28 on land Status Map numbered 385/92002, Segment 106, dated 30 June 1975.

Parcel 3

All those certain lots, tracts or parcels of land lying and being situated on Putnam Street in Block "W" in the Town of Harpers Ferry, Jefferson County, West Virginia, and being more particularly described as follows:

Lots 10 and 11 in Block "W" in said Town of Harpers Ferry.

Containing 0.36 of an acre, more or less.

This parcel of land is depicted as Tract 106–49 on Land Status Map Numbered 385/92002, Segment 106, dated 30 June 1975.

All maps referenced are on file and available for inspection in the offices of the National Park Service, Department of the Interior, listed above.

Dated: October 23, 1992.

John G. Parsons,

Acting Regional Director, National Capital Region.

[FR Doc. 92–31857 Filed 12–31–92; 8:45 am]

BILLING CODE 4310–70–M

Indiana Dunes National Lakeshore; Revision of Lakeshore Boundary

The Act of October 18, 1976, 90 Stat. 2532, 2533, 16 U.S.C. 460 u–19, following notice to Congress as provided therein, which has been satisfied, authorizes the United States to accept title to any lands, or interests in lands, located outside the boundaries of the Lakeshore which any private person, organization, or public or private corporation may offer to donate to the United States, if the Secretary finds that such lands would make a significant contribution to the purposes for which the Lakeshore was created; and he shall administer such lands as part of the Lakeshore following this publication. The Shirley Heinze Environmental Fund, a Charitable Trust, has offered to donate 2.37 acres of land for incorporation into the Lakeshore. Three tracts of land are being donated, one in LaPorte County, and two in Lake County, Indiana. The tracts contain a small wetlands, forest and flora species providing habitat for butterfly larva, and will preclude commercial development which would have an adverse impact on Lakeshore property. The tracts also afford recreational opportunities for the visiting public. It is considered that the recreational opportunities offered by this property, along with the biological resources on this 2.37 acres, will make a significant contribution to the Lakeshore. The specific lands proposed for addition are described as follows:

A tract of land situate in Section 31, Township 37 North, Range 7 West, Second Principal Meridian, Lake County, Indiana, described as follows:

Lots 1 through 5, the west half of Lot 6, and Lots 9 through 16 of Block 1; Lots 1 through 7 of Block 2; Lots 1 through 3, and Lot 9 of Block 3; all in Johnson-Kennedy Estates Fifth Subdivision in the City of Gary, as shown on Plat Book 16, Page 6, in the records of Lake County, Indiana.

Containing 2.19 acres of land, more or less.

A tract of land situate in Section 31, Township 38 North, Range 4 West, Second Principal Meridian, LaPorte County, Indiana, described as follows:

The north half of Lot 7 in Block 24 in Fred K. Bartlett's South Shore Acres Subdivision, as shown on Plat filed December 7, 1927 in Plat Book 6, Pages 26 and 27 in the records of LaPorte County, Indiana.

Containing 0.18 of an acre of land, more or less.

Aggregating 2.37 acres of land, more or less.

Therefore, notice is hereby given that in accordance with the Act of October 18, 1976, the boundary of the Indiana Dunes National Lakeshore is revised as described above, and as shown on Indiana Dunes National Lakeshore Segment Maps 14 and 98. These maps are on file and available for inspection in the Office of the National Park Service, Department of the Interior; the Office of the Midwest Region, National Park Service; and the Office of the Superintendent, Indiana Dunes National Lakeshore.

Dated: December 11, 1992.

Don H. Castleberry,

Regional Director, Midwest Region.

[FR Doc. 92–31856 Filed 12–31–92; 8:45 am]

BILLING CODE 4310–70–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32173 (Sub-No. 1)]

Riverside County Transportation Commission—Trackage Rights Exemption—The Atchison, Topeka and Santa Fe Railway Company

Two Los Angeles area transportation agencies, the Orange County Transportation Authority and the Riverside County Transportation Commission (County Agencies), have jointly filed a notice of exemption to acquire incidental trackage rights from The Atchison, Topeka and Santa Fe Railway Company (Santa Fe) over the property described in the footnote below, which totals about 57 miles.[1] The exemption became effective on December 17, 1992.[2] The parties intend to consummate the transaction as part of the transactions exempted in Finance Docket No. 32173, Orange County Transportation Authority, et al.—Acquisition Exemption—The Atchison, Topeka And Santa Fe Railway Company

[1] Between: (a) San Bernardino Subdivision mileposts 143.9 at Redondo Junction and 160.3 at the Orange County line in Los Angeles County, mileposts 160.3 and 30.6 at the Riverside County line in Orange County, mileposts 30.6 and 5.7 in Riverside County, and mileposts 5.7 and 0.34 in San Bernardino County; (b) Pasadena Subdivision mileposts 81.56 and 81.32 in San Bernardino County; and (c) Cajon Subdivision mileposts 81.32 and 81.19 in San Bernardino County.

Note: At Fullerton, the junction of two separate lines causes the milepost designations for the continued trackage rights to San Bernardino to change. Milepost 165.7 on the line from Mission Tower in Los Angeles to Fullerton is equivalent to milepost 45.3 on the line that continues from Fullerton east through Orange County towards Riverside and San Bernardino. Thus, the line segments involved on the San Bernardino Subdivision in Orange County are mileposts 160.3 to 165.7, a total of 5.4 miles and milepost 45.3 to 30.6, a total of 14.7 miles.

[2] Under 49 CFR 1150.32(b), the exemption is effective seven days after the notice is filed. The notice was stamped-in on December 8, 1992, but the filing fee was inadvertently omitted and was not paid until December 10, 1992.

(not printed), served November 20, 1992.

The County Agencies are acquiring these trackage rights to provide mass transit service. Santa Fe will continue to provide freight common carrier service on the line. As we noted in Finance Docket No. 32173, *supra*, we may lack jurisdiction over this acquisition of trackage rights because the provision of passenger service by the County Agencies may be exempt from our regulation.[3] If we subsequently find that jurisdiction is lacking, we will vacate this exemption.

This notice is filed under 49 CFR 1150.31(a)(4). If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction.

Pleadings must be filed with the Commission and served on: Charles A. Spitulnik, Hopkins & Sutter, Suite 700, 888 16th Street, NW., Washington, DC 20006.

Decided: December 28, 1992.

By the Commission, Julia M. Farr, Acting Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 92-31902 Filed 12-31-92; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Lodging of Stipulated Judgment Pursuant to Clean Air Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on December 18, 1992, a proposed Stipulated Judgment in *United States* v. *City of Chicago*, Civil Action No. 90-C-7544, was lodged with the United States District Court for the Northern District of Illinois. The proposed Stipulated Judgment requires the City of Chicago to continue to comply with the Federal Clean Air Act provisions concerning asbestos abatement operations and to pay a Clean Air Act civil penalty of $10,000.00 to the United States.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Stipulated Judgment. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *City of Chicago*, D.J. Ref. No. 90-5-2-1-1529.

The proposed Stipulated Judgment may be examined at the office of the United States Attorney, Northern District of Illinois, 219 South Dearborn Street, Chicago, Illinois 60604; at the Region 5 Office of the United States Environmental Protection Agency, Records Center, Seventh Floor, 77 West Jackson Boulevard, Chicago, Illinois 60604-3590; and at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue Building, Washington, DC 20044.

Copies of the proposed Stipulated Judgment may be obtained in person or by mail from the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW., Box 1097, Washington, DC 20004, (202) 347-2072. In requesting a copy, please refer to the case by name and D.J. Ref. No. 90-5-2-1-1529 and enclose a check in the amount of $1.50 (25 cents per page for reproduction cost), payable to the Consent Decree Library.

John C. Cruden,

Environment and Natural Resources Division.

[FR Doc. 92-31879 Filed 12-31-92; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determination in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wage payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classed engaged on contract work of the character and in the localities described therein. Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., room S-3014, Washington, DC 20210.

[3] This issue is pending before the Commission in a petition to reconsider Southern Pacific Transp. Co.—Abandonment, 8 I.C.C.2d 495 (1992).

Modification to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume, State, and page number(s). Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Connecticut:	
CT91–1 (Feb. 22, 1991.	p. all.
CT91–3 (Feb. 22, 1991.	p. all.
CT91–4 (Feb. 22, 1991.	p. all.
District of Columbia:	
DC91–1 (Feb. 22, 1991.	p. all.
Virginia:	
VA91–5 (Feb. 22, 1991.	p. all.
VA91–23 (Feb. 22, 1991.	p. all.
VA91–33 (Feb. 22, 1991.	p. all.
VA91–36 (Feb. 22, 1991.	p. all.
VA91–65 (Feb. 22, 1991.	p. all.
West Virginia:	
WV91–3 (Feb. 22, 1991.	p. 1445, pp. 1447–1458d.

Volume II

Texas:	
TX91–60 (Feb. 22, 1991.	p. all.

Volume III

Hawaii:	
HI91–1 (Feb. 22, 1991.	p. all.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 783–3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, this 28th day of December, 1992.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 92–31823 Filed 12–31–92; 8:45 am]

BILLING CODE 4510–27–M

NATIONAL SCIENCE FOUNDATION

Permit Application Received Under the Antarctic Conservation Act of 1978

December 28, 1992.

AGENCY: National Science Foundation.

ACTION: Notice of permit applications received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 2978. NSF has published regulations under the Antarctic Conservation Act of 1978 at title 45 part 670 of the Code of Federal Regulations. This is the required notice of permit application received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to this permit application by January 29, 1992. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, room 627, Division of Polar Programs, National Science Foundation, Washington, DC 20550.

FOR FURTHER INFORMATION CONTACT: John B. Talmadge at the above address or (202) 357–7817.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Public Law 95–541), has developed regulations that implement the "Agreed Measures for the Conservation of Antarctic Fauna and Flora" for all Untied States citizens. The Agreed Measures, developed by the Antarctic Treaty Consultative Parties, recommended establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection. The regulations establish such a permit system to designate Specially Protected Areas and Sites of Special Scientific Interest. The application received is as follows:

Applicant: Sean Turner, Department of Biological Sciences, University of Cincinnati, 878 La Fayette Avenue, #3, Cincinnati, OH 45221–0006

Activity for Which Permit Requested: Import Into USA-Port of Entry. Enter Site of Special Scientific Interest. Permit requested to visit Tramway Ridge on Mt. Erebus site of special scientific interest in order to collect samples for his project on cyanobacterial/algal communities peculiar to Antarctica. The objective on Mt. Erebus is to collect samples of these organisms, particulary in the vicinity of Tramway Ridge where the highest population densities occur. Samples will be returned to the Crary Science and Engineering Center at McMurdo Station for subsequent culturing and isolation of photosynthetic microorganisms using standard techniques. Equipment will be limited to sterile sampling spatulas, whirlpack bags, and sample containers.

Location: Tramway Ridge SSSI, Mt. Erebus; Ross Island access by helicopter to outside area, then travel by foot.

Dates: 01/01/93–01/15/93.

John B. Talmadge,

Permit Office, Division of Polar Programs.

[FR Doc. 92–31870 Filed 12–31–92; 8:45 am]

BILLING CODE 7555–01–M

Committee Management; Establishment

The Assistant Director for Computer and Information Science and Engineering has determined that the establishment of the Blue Ribbon Panel on High Performance Computing is necessary and in the public interest in connection with the performance of duties imposed upon the Director, National Science Foundation (NSF) by 42 U.S.C. 1861 *et seq.* This determination follows consultation with the Committee Management Secretariat, General Services Administration.

Name of Committee: Blue Ribbon Panel on High Performance Computing.

Purpose: To assess the contributions of high performance computing to scientific research and education; project future hardware, software and communication resource needs and means for providing them; and analyze possible cooperative relations between governmental agencies, the private sector and international entities.

Balanced Membership Plan: The Panel will be composed of 10–15 leading scientists and engineers representing relevant disciplines and knowledge of the field. Members will be drawn from academia, industry, and

government to insure representation across all appropriate dimensions, technical as well as policy.

Responsible NSF Official: Dr. A. Nico Habermann, Assistant Director, Computer and Information Science and Engineering, National Science Foundation, room 306, Washington, DC 20550, (202) 357–7936.

Dated: December 29, 1992.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 92–31919 Filed 12–31–92; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–6659]

Petrotomics Co.; Finding of No Significant Impact Regarding Issuance of an Amendment to Source Material License SUA–551 for the Petrotomics Co., Shirley Basin Mill, To Incorporate Reclamation Schedules, Carbon County, WY

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of a finding of no significant impact.

1. Proposed Action

The administrative action is issuance of a license amendment to incorporate an enforceable reclamation schedule for the Shirley Basin Mill in Carbon County, Wyoming.

2. Reasons for Finding of No Significant Impact

The proposed amendment is administrative, incorporating reclamation milestones into the license in accordance with the Memorandum of Understanding (MOU) between the Environmental Protection Agency (EPA) and the NRC which was published in the **Federal Register** on October 25, 1991. The Notice of Intent to Amend Source Material License SUA–551 for the Shirley Basin Mill to incorporate reclamation schedules was published in the **Federal Register** on October 19, 1992. The NRC accepted comments on this proposed licensing action for 45 days. No comments were received. In accordance with 10 CFR 51.22(c)(11)), the Commission has determined that no environmental analysis need be performed since no significant impacts will result from the proposed licensing actions.

3. Action

The Commission action is to amend Source Material License SUA–551 upon publication of this Notice. The action is based on this Finding of No Significant Impact and no comments being received to the Notice of Intent published on October 19, 1992.

This Notice, together with the Notice of Intent to Amend Source material License SUA–551, are available for public inspection and copying at the Commission's Uranium Recovery Field Office at 730 Simms Street, Golden, Colorado, and at the Commission's Public Document Room at 2120 L Street, NW., Washington, DC 20555.

Dated: at Denver, Colorado, this 23nd day of December 1992.

For the Nuclear Regulatory Commission.

Ramon E. Hall,

Director, Uranium Recovery Field Office.

[FR Doc. 92–31893 Filed 12–31–92; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Proposed Alteration of the Terminal Control Area at Tampa, FL; Public Meetings

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meetings.

SUMMARY: This notice announces two fact-finding informal airspace meetings to solicit information from airspace users and others concerning a proposal to modify the Tampa, FL, Terminal Control Area (TCA), and to provide interested persons an opportunity to discuss the proposal. All comments received during these meetings will be considered prior to the issuance of a Notice of Proposed Rulemaking.

TIMES AND DATES: These meetings will be held from 7 p.m. to 10 p.m., on Tuesday, February 16 and Wednesday, February 17, 1993. Comments must be received on or before April 19, 1993.

Date: Tuesday, February 16, 1993.

Place: University of South Florida—Bayboro Campus, MSL Auditorium, St. Petersburg, FL 33701, (Next to Albert-Whitted Airport).

Date: Wednesday, February 17, 1993.

Place: Armwood High School Auditorium, 1200 U.S. Hwy 92, Seffner, FL 33584.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, ASO–500, Federal Aviation Administration, P.O. Box 20636, Atlanta, GA 30320.

CONTACT PERSON FOR MORE INFORMATION: Kenneth Patterson; Manager, Airport Traffic Control Tower; Tampa International Airport; Tampa, FL 33607; telephone: (813) 872–1528.

SUPPLEMENTARY INFORMATION:

Meeting Procedures

(a) These meetings will be informal in nature and will be conducted by a representative of the Administrator, FAA Southern Region. Each participant will be given an opportunity to make a presentation, although a time limit may be imposed.

(b) These meetings will be open to all persons on a space-available basis. There will be no admission fee or other charge to attend and participate.

(c) Any person wishing to make a presentation to the panel will be asked to sign in and estimate the amount of time needed for such presentation so that timeframes can be established. This will permit the panel to allocate an appropriate amount of time for each presenter. The panel may allocate the time available for each presentation in order to accommodate all speakers. These meetings will not be adjourned until everyone on the list has had an opportunity to address the panel. These meetings may be adjourned at any time if all persons present have had the opportunity to speak.

(d) Position papers or other handout material relating to the substance of the meetings may be accepted. Participants wishing to submit handout material should present three copies to the presiding officer. There should be additional copies of each handout available for other attendees.

(e) These meetings will not be formally recorded. However, a summary of the comments made at these meetings will be filed in the docket.

Agenda for Each Meeting

Opening Remarks and Discussion of Meeting Procedures
Briefing on Background for Proposal
Public Presentations
Closing Comments

Issued in Washington, DC, on December 21, 1992.

Harold W. Becker,

Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 92–31909 Filed 12–31–92; 8:45 am]

BILLING CODE 4910-13-M

Pilot and Aviation Maintenance Technician Shortage Blue Ribbon Panel; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given of a meeting of the Pilot and Aviation Maintenance Technician Shortage Blue Ribbon Panel.

DATES: The meetings will be held February 9, 1993, from 1 p.m. to 4 p.m.

ADDRESSES: The meeting will be held at the FAA Center for Management Development, room C123, 4500 Palm Coast Parkway, Palm Coast, Florida 32137.

FOR FURTHER INFORMATION CONTACT: Daniel C. Beaudette, Executive Director, 800 Independence Ave., SW., Washington, DC, 20591; telephone (202) 267–7804.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463: 5 U.S.C., app. II), notice is hereby given of a meeting of the Pilot and Aviation Maintenance Technician Shortage Blue Ribbon Panel to be held February 9, 1993. The meeting agenda will include:

- Opening comments.
- Public comments.
- Panel deliberations.
- Future operations.

Attendance is open to the interested public but may be limited to the space available. The public must make arrangements on or before January 29, 1993, to present oral statements at the meeting. The public may present written statements to the committee at any time by providing 25 copies to the Executive Director. Arrangements may be made by contacting the person listed under the heading "**FOR FURTHER INFORMATION CONTACT.**"

Issued in Washington, DC, on December 23, 1992.

Daniel C. Beaudette,

Executive Director of the Pilot and Aviation Maintenance Technician Shortage Blue Ribbon Panel.

[FR Doc. 92–31911 Filed 12–31–92; 8:45 am]

BILLING CODE 4910–13–M

Notice of Intent To Rule on Application To Impose a Passenger Facility Charge (PFC) at Spokane International Airport and Use the Revenue at Spokane International Airport and Felts Field, Spokane, WA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose a PFC at Spokane International Airport and use the revenue at Spokane International Airport and Felts Field under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 3, 1993.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: J. Wade Bryant, Manager, Seattle Airports District Office, SEA–ADO, Federal Aviation Administration, 1601 Lind Avenue SW., suit 250, Renton, WA 98055–4056.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Paul Norman, Airport Director of the Spokane Airport Board, at the following address: Spokane International Airport, P.O. Box 19186, Spokane, Washington 99219–9186.

Air carriers and foreign air carriers may submit copies of written comments previously provided to Spokane Airport Board under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Paul Johnson (206) 227–2655; Seattle Airports District Office, SEA–ADO; Federal Aviation Administration; 1601 Lind Avenue SW., suite 250; Renton, Washington 98055–4056. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose a PFC at Spokane International Airport and use the revenues at Spokane International Airport and Felts Field Airport, under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On December 23, 1992, the FAA determined that the application to impose and use the revenue from a PFC submitted by Spokane Airport Board was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than March 24, 1993.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00

Proposed charge effective date: June 1, 1993

Proposed charge expiration date: October 31, 2000

Total estimated PFC revenue: $17,548,000.00

Brief description of proposed project: Spokane International Airport and Felts Field Airport have both listed projects to use PFC revenues—Spokane International has listed the following: Planning studies, construct airport perimeter road, purchase safety equipment, taxiway and apron improvements; runway safety improvements, public area safety improvements/Americans with Disabilities (ADA) compliance, access control improvements, airport airfield lighting and signage, access road improvements, ARFF training facility, aircraft deicing facility, airside infrastructure development, loading bridges and regional gate expansion.

Felts Field Airport has requested PFC revenue for safety improvements.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: Spokane Airport Authority requested that no air carriers be exempted from collection.

Any person may inspect the application in person at the FAA office listed above under "**FOR FURTHER INFORMATION CONTACT**" and at the FAA regional Airports office located at: Federal Aviation Administration, Northwest Mountain Region, Airports Division, ANM–600, 1601 Lind Avenue SW., suite 540, Renton, WA 98055–4056.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Spokane Airport Board at Spokane International Airport.

Issued in Renton, Washington on December 23, 1992.

Cecil C. Wagner,

Assistant Manager, Airports Division, Northwest Mountain Region.

[FR Doc. 92–31910 Filed 12–31–92; 8:45 am]

BILLING CODE 4910–13–M

Federal Highway Administration

Scenic Byways Advisory Committee; Public Meeting

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of public meeting.

SUMMARY: The FHWA announces a meeting of the Scenic Byways Advisory Committee. The focus of the meeting will be to develop and make recommendations regarding minimum criteria and standards for use by State and Federal agencies in designating highways as scenic byways and all-American roads for the purpose of a national scenic byways program. The national scenic byways program is authorized by section 1047(a)(3) of the

Intermodal Surface Transportation Efficiency Act of 1991.

DATES: January 28, 1993, 8:30 a.m. to 4:30 p.m. and January 29, 1993, 8:30 a.m. to 4:30 p.m. This meeting is open to the public.

ADDRESSES: The Ritz-Carlton Hotel, Pentagon City, 1250 S. Hayes Street, Board Room, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mr. Eugene Johnson, Federal Highway Administration, Intermodal Planning Division, HEP–50, room 3301, 400 Seventh St., SW., Washington, DC 20590, (202) 366–0150. Office hours are 7:30 a.m. to 4 p.m., e.t., Monday through Friday, except legal holidays.

Authority: 23 U.S.C. 315; 49 CFR 1.48; Sec. 1047, Public Law 102–240, 105 Stat. 1914, 1996.

Issued on: December 24, 1992.

T.D. Larson,

Administrator.

[FR Doc. 92–31900 Filed 12–31–92; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

December 28, 1992.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–0244
Form Number: IRS Form 6199
Type of Review: Extension
Title: Certification of Youth Participating in a Qualified Cooperative Education Program
Description: Internal Revenue Code (IRC) § 51(d)(8) requires that qualified school cooperative programs must certify their qualified students as youths participating in a qualified cooperative program in order that wages paid to the students by an employer be qualified for the jobs credit. Form 6199 provides for this certification.
Respondents: Farms, Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents/ Recordkeepers: 64,000
Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping	7 minutes.
Learning about the law or the form.	7 minutes.
Preparing the form	24 minutes.
Copying, assembling and sending the form to the IRS.	20 minutes.

Frequency of Response: On occasion
Estimated Total Reporting/ Recordkeeping Burden: 62,080 hours
OMB Number: 1545–0725
Form Number: IRS Form 928
Type of Review: Extension
Title: Fuel Bond
Description: Certain sellers of gasoline and diesel fuel may be required under § 4101 to post bond before they incur liability for gasoline and diesel fuel excise taxes imposed by § 4081 and 4091. This form is used by taxpayers to give bond and provide other information required by Regulations § 48.4101–2T.
Respondents: Individuals or households, Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents/ Recordkeepers: 500
Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping	1 hour, 55 minutes.
Learning about the law or the form.	18 minutes.
Preparing copying, assembling, and sending the form to the IRS.	20 minutes.

Frequency of Response: On occasion
Estimated Total Reporting/ Recordkeeping Burden: 1,280 hours
Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 92–31864 Filed 12–31–92; 8:45 am]

BILLING CODE 4830–01–M

Public Information Collection Requirements Submitted to OMB for Review

December 28, 1992.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: New
Form Number: None
Type of Review: New collection
Title: Focus Group Interviews Concerning Taxpayer Input on Forms 1099
Description: Focus group interviews are necessary to determine whether taxpayers experience problems with the 1099 family of forms and the various substitute forms to determine whether the information should be reported in a uniform fashion. Affected public is 50 participants.
Respondents: Individuals or households
Estimated Number of Respondents: 600
Estimated Burden Hours Per Respondent: 3 hours
Frequency of Response: Other (one-time focus groups)
Estimated Total Reporting Burden: 230 hours
Clearance Officer: Garrick Shear, (202) 535–4297, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 92–31891 Filed 12–31–92; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF VETERANS AFFAIRS

Information Collection Under OMB Review

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). This document lists the following information: (1) The title of the information collection, and the

Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer by February 3, 1993.

Dated: December 23, 1992.

By direction of the Secretary.

Frank E. Lalley,

Associate Deputy Assistant Secretary for Information Resources Policies and Oversight.

Extension

1. Nonsupervised Lender Nomination and Recommendation of Credit Underwriter, VA Form 26–8736a.

2. The form is submitted to VA by a nonsupervised lender with the initial application for authority to close loans on the automatic basis or in connection with nominations of additional or new credit underwriters. The information is used to determine whether or not the underwriter nominee is qualified.

3. 1,000 hours.

4. 20 minutes.

5. On occasion.

6. Businesses or other for-profit; Small businesses or organizations.

7. 3,000 respondents.

[FR Doc. 92–31858 Filed 12–31–92; 8:45 am]
BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
No. 1
Monday, January 4, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

December 29, 1992.

TIME AND DATE: 10.00 a.m., Tuesday, January 5, 1993.

PLACE: Room 600 1730, K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *Island Creek Coal Company,* Docket No. VA 91-47-R, etc. (Issues include whether the judge erred in vacating two imminent danger orders of withdrawal issued to Island Creek by the Secretary of Labor, pursuant to 30 U.S.C. § 817(a), alleging that the south gob at its mine contained an explosive level of methane and that Island Creek violated 30 C.F.R. § 75.316.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR § 2706.150(a)(3) and § 2706.160(e).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653-5629/(202) 708-9300 for TDD Relay/1-800-877-8339 for toll free.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 92-31944 Filed 12-30-92; 3:20 pm]

BILLING CODE 6735-01-M

FEDERAL RESERVE SYSTEM, BOARD OF GOVERNORS

TIME AND DATE: 10:00 a.m., Wednesday, January 6, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1 Publication for comment of proposed amendments to Regulation E (Electronic Fund Transfers) to cover Electronic Benefit Transfer (EBT) programs established by federal, state, or local government agencies.
2. Any items carried forward from a previously announced meeting.

Note.—This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-31937 Filed 12-30-92; 10:55 am]

BILLING CODE 6210-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Wednesday, January 6, 1993, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92-31938 Filed 12-30-92; 10:55 am]

BILLING CODE 6210-01-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of January 4, 11, 18, and 25, 1993.

PLACE: Commissioner's Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of January 4

Tuesday, January 5

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of January 11—Tentative

Monday, January 11

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of January 18—Tentative

Thursday, January 21

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of January 25—Tentative

Friday, January 29

10:00 a.m.
Briefing on Implementing Guidance for the Maintenance Rule and Industry Verification and Validation Effort (Public Meeting) (Contact: William Russell, 301-504-1274)

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note.—Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has yet been identified as requiring any Commission vote on this date.

TO VERIFY THE STATUS OF MEETING CALL (RECORDING): (301) 504-1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 504-1661.

Dated: December 29, 1992.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 92-31939 Filed 12-30-92; 10:56 am]

BILLING CODE 7590-01-M

OVERSEAS PRIVATE INVESTMENT CORPORATION

Meeting of the Board of Directors

TIME AND DATE: 1:00 p.m. (closed portion), 2:30 p.m. (open portion), Thursday, January 14, 1993.

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue, NW., Washington, DC.

STATUS: The first part of the meeting from 1:00 p.m. to 2:30 p.m. will be closed to the public. The open portion

of the meeting will commence at 2:30 p.m. (approximately).

MATTERS TO BE CONSIDERED: (Closed to the public 1:00 p.m. to 2:20 p.m.).

1. President's Report
2. Information Reports
3. Pending Major Projects
4. Finance Project in Argentina
5. Insurance Project in Tunisia
6. Insurance Project in Argentina
7. Approval of 9/22/92 Minutes (Closed Portion)

FURTHER MATTERS TO BE CONSIDERED: (Open to the public 2:30 p.m.).

1. Approval of 9/22/92 Minutes (Open Portion)
2. Information Reports
3. Recommendation for meeting schedule through end of September 1993

CONTACT PERSON FOR INFORMATION: Information with regard to the meeting may be obtained from the Corporation Secretary on (202) 336–8403.

Dated: December 30, 1992.

Dennis K. Dolan,

OPIC Corporate Secretary.

[FR Doc. 92–31942 Filed 12–30–92; 3:19 pm]

BILLING CODE 3210–01–M

VOL
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Corrections

Federal Register
No. 1
Monday, January 4, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 663

[Docket No. 920372–2072]

Pacific Coast Groundfish Fishery

Correction

In proposed rule document 92-27061 beginning on page 53313 in the issue of Monday, November 9, 1992, make the following correction: On page 53315, in the first column, in the first full paragraph, in the fourth line "16 U.S.C. 1810" should read "16 U.S.C. 1801".

BILLING CODE 1505-01-D

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Correction

In Sunshine Act Meetings notice document 92–31620 appearing on page 61965 in the issue of Tuesday, December 29, 1992, make the following corrections:

1. On page 61965, under the heading "Matters To Be Considered" in open session, item 4, "Waiver of 1992 EEO–3 Reporting Requirements," should be deleted.

2. On the same page, under the same heading, item 5 should be numbered as item 4.

BILLING CODE 1505-01-D

Federal Register

Monday
January 4, 1993

Part II

Department of Transportation

Federal Highway Administration

Intermodal Surface Transportation Efficiency Act of 1991; Implementation Guidance; Notice

VOL 58 ISS 1 JA 4 1993 UMI

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Intermodal Surface Transportation Efficiency Act of 1991; Implementation Guidance

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice.

SUMMARY: The FHWA, in order to assure widespread distribution of implementation guidance on the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) (Pub. L. 102–240, 105 Stat. 1914), (which it has issued to its regional and division offices) is publishing implementation materials that have been issued since the act was signed on December 18, 1991. Implementation guidance materials were first published in the **Federal Register** on April 23, 1992, at 57 FR 14880. In that notice of April 23, the FHWA stated it would continue to publish implementation guidance in future issues of the **Federal Register.** This notice is the second publication of ISTEA implementation guidance. Any changes to this implementation guidance will be published in future issues of the **Federal Register.**

The ISTEA implementation guidance published in this **Federal Register** notice is intended to be nonbinding except insofar as it references existing statutory requirements and should not be construed as rules of general applicability and legal effect or notices of proposed rulemaking.

On March 27, 1992, the FHWA issued a notice (57 FR 10691) advising members of the public that they may now dial into the FHWA Electronic Bulletin Board System (FEBBS) information conference using a microcomputer and modem and view informal questions and answers on how the agency intends to implement the provisions of the ISTEA. The FEBBS will also contain the implementation guidance published with this notice as well as future implementation guidance. This read-only facility is especially intended for use by the State and local transportation agencies. The telephone number for FEBBS is Area Code 202–366–3764. While the system supports 300, 1200 and 2400 baud line speeds, and a variety of terminal types and protocols, setting the modem for 2400 baud, 8 data bits, full duplex and no parity will give optimal performance. Once a connection has been established and the <R<egistration item completed, callers should select either <Q<uestions and Answers on ISTEA, or <I<nformation for more detailed help.

Specific questions on any of the material published with this notice should be directed to the contact person named in the particular guidance; if a contact is not included, calls should be directed to Frank Calhoun, Assistant Chief Counsel for Legislation and Regulations, Office of the Chief Counsel, (202) 366–0761, Federal Highway Administration, 400 Seventh Street, SW., room 4223 (HCC–10), Washington, DC 20590, for referral. Questions can also be directed to the FHWA Regional Offices or the FHWA Division Office in your State; updated addresses and phone numbers for these offices are listed in an attachment to this notice. Some of the materials reference attachments which are copies of sections of the ISTEA. These are not included. Copies can be obtained from the offices referred to herein.

FOR FURTHER INFORMATION CONTACT: Mr. Frank L. Calhoun, Office of the Chief Counsel, (202), 366–0761, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday except legal holidays.

For Technical Assistance Contact: FHWA Computer Help Desk, HMS–40, room 4401, 400 Seventh Street, SW., Washington, DC 20590. (202) 366–1120.

(23 U.S.C. 315; 49 CFR 1.48)

Issued on: December 10, 1992.

T.D. Larson,

Administrator.

Attachment—FHWA Regional Offices

Region 1 (HRA–01)—Headquarters, Hours of Duty: 7:30–4:00 EST

Location: Leo W. O'Brien Federal Building, Room 719, Clinton Avenue and North Pearl Street, Albany, New York 12207

Regional Federal Highway Administrator, John G. Bestgen, Jr., 518–472–6476

Region 3 (HRA–03)—Headquarters, Hours of Duty: 7:30–4:15 EST

Location: George H. Fallon Federal Office Building, 31 Hopkins Plaza, Room 1633, Baltimore, Maryland 21201

Regional Federal Highway Administrator, David S. Gendell, 410–962–0093

Region 4 (HRA–04)—Headquarters, Hours of Duty: 7:45–4:15 EST

Location: Suite 200, 1720 Peachtree Road, NW., Atlanta, Georgia 30367

Regional Federal Highway Administrator, Leon N. Larson, 404–347–4078

Region 5 (HRA–05)—Headquarters, Hours of Duty: 7:30–4:15 CST

Location: 18209 Dixie Highway, Homewood, Illinois 60430–2294

Regional Federal Highway Administrator, Herbert R. Teets, 708–206–3186

Region 6 (HRA–06)—Headquarters, Hours of Duty: 8:00–4:30 CST

Location: 819 Taylor Street, Room 8A00, P.O. Box 902003, Fort Worth, Texas 76102

Regional Federal Highway Administrator, Wesley S. Mendenhall, Jr., 817–334–4393

FHWA—Federal-Aid Division Offices

Alabama (HDA–AL)

7:15–4:30 CST

Division Administrator, Joe D. Wilkerson, 500 Eastern Boulevard, Suite 200, Montgomery, Alabama 36117–2018, 205–223–7370

Alaska (HDA–AK)

7:30–5:00 AST

Division Administrator, Robert E. Ruby, 709 W. Ninth Street, Room 851, Juneau, Alaska 99802–1648, 8+907–586–7180

Arizona (HDA–AZ)

7:30–4:15 MST

Division Administrator, Edward A. Wueste, 234 N. Central Avenue, Suite 300, Phoenix, Arizona 85004, 602–379–3646

Arkansas (HDA–AR)

7:30–4:00 CST

Division Administrator, William D. Richardson, Federal Office Building, Room 3128, 700 West Capitol Avenue, Little Rock, Arkansas 72201–3298, 8+501–324–5625

California (HDA–CA)

7:45–4:30 PST

Division Administrator, Roger E. Borg, Federal Building, 2d Floor, 801 I Street, Sacramento, California 95814, 916–551–1280

Colorado (HDA–CO)

7:45–4:15 MST

Division Administrator, George H. Osborne, 555 Zang Street, Room 250, Lakewood, Colorado 80228, 303–969–6730

Connecticut (HDA–CT)

7:30–4:00 EST

Division Administrator, Gary Hamby, Abraham A. Ribicoff Federal Building, 450 Main Street, Room 635, Hartford, Connecticut 06103, 203–240–3705

Region 7 (HRA–07)—Headquarters, Hours of Duty: 7:30–4:00 CST

Location: 6301 Rockhill Road, Kansas City, Missouri 64131

Mailing Address: P.O. Box 419715, Kansas City, Missouri 64141

Regional Federal Highway Administrator, Volmer K. Jensen, 816–926–7490

Region 8 (HRA–08)—Headquarters, Hours of Duty: 7:45–4:15 MST

Location: 555 Zang Street, Room 400, Lakewood, Colorado 80228

Regional Federal Highway Administrator, Louis N. MacDonald, 303–969–6722

Region 9 (HRA–09)—Headquarters, Hours of Duty: 7:45–4:15 PST

Location: 211 Main Street, Room 1100, San Francisco, California 94105

Regional Federal Highway Administrator, Edwin M. Wood, 415–744–2639

Region 10 (HRA–010)—Headquarters, Hours of Duty: 7:45–4:30 PST

Location: KOIN Center, Suite 600, 222 S.W., Columbia Street, Portland, Oregon 97201

Regional Federal Highway Administrator, Jerald P. Clark, 503–326–2053

Delaware (HDA–DE)

7:45–4:15 EST

Division Administrator, John J. Gilbert, 300 South New Street, Room 2101, Dover, Delaware 19901–6726, 302–734–5323

District of Columbia (HDA–DC)

8:00–4:30 EST

Division Administrator, Arthur J. Hill, Union Center Plaza, Suite 750, 820 First Street, NE., Washington, D.C. 20002, 202–523–0163

Florida (HDA–FL)

7:30–4:00 EST

Division Administrator, Jennings R. Skinner, 227 No. Bronough Street, Room 2015, Tallahassee, Florida 32301, 904–681–7223

Georgia (HDA–GA)

7:00–4:00 EST

Division Administrator, Larry Dreihaup, 1720 Peachtree Rd., NW., Suite 300, Atlanta, Georgia 30367, 404–347–4751

Hawaii (HDA–HI)

7:30–4:00 HST

Division Administrator, William R. Lake, Jr., Prince Jonah Kuhio Kalanianaole Federal Building, 300 Ala Moana Boulevard, Room 3202, Honolulu, Hawaii 96850, 808–541–2700

Mailing Address: Box 50206, Honolulu, Hawaii 96850

Idaho (HDA–ID)

7:30–4:00 MST

Division Administrator, Jack T. Coe, 3050 Lakeharbor Lane, Suite 126, Boise, Idaho 83703, 208–334–1690

Illinois (HDA–IL)

7:30–4:15 CST

Division Administrator, Lyle P. Renz, 3250 Executive Park Drive, Springfield, Illinois 62705, 217–492–4640

Indiana (HDA–IN)

7:30–4:00 EST

Division Administrator, Arthur A. Fendrick, 575 N. Pennsylvania Street, Room 254, Indianapolis, Indiana 46204, 317–226–7475

Iowa (HDA–IA)

7:45–4:30 CST

Division Administrator, Hubert A. Willard, 105 Sixth Street, Ames, Iowa 50010, 515–233–1664

Kansas (HDA–KS)

7:45–4:15 CST

Division Administrator, Robert J. Deatrick, 444 SE. Quincy Street, Room 240, Topeka, Kansas 66683, 913–267–7281

Kentucky (HDA–KY)

8:00–4:45 EST

Division Administrator, Paul E. Toussaint, John C. Watts Federal Building and U.S. Courthouse, 330 W. Broadway, Frankfort, Kentucky 40602, 502–582–5468

Mailing Address: P.O. Box 536, Frankfort, Kentucky 40602

Louisiana (HDA–LA)

7:30–4:00 CST

Division Administrator, William A. Sussman, Federal Building, Room 255, 750 Florida Street, Baton Rouge, Louisiana 70801, 504–389–0464

Mailing Address: P.O. Box 3929, Baton Rouge, Louisiana 70821

Maine (HDA–ME)

7:30–4:00 EST

Division Administrator, Vacant, Edmund S. Muskie Federal Building, 40 Western Avenue, Room 614, Augusta, Maine 04330, 207–622–8487

Maryland (HDA–MD)

7:45–4:15 EST

Division Administrator, A. Porter Barrows, The Rotunda, Suite 220, 711 West 40th Street, Baltimore, Maryland 21211, 410–962–4440

Massachusetts (HDA–MA)

7:45–4:15 EST

Division Administrator, Donald E. Hammer, 55 Broadway—10th Floor, Cambridge, Massachusetts 02142, 617–494–2416

Michigan (HDA–MI)

7:45–4:15 EST

Division Administrator, A George Ostensen, Federal Building, Room 211, 315 West Allegan Street, Lansing, Michigan 48933, 517–377–1844

Minnesota (HDA–MN)

7:30–4:00 CST

Division Administrator, Charles E. Foslien, Metro Square Building, Suite 490, Seventh & Robert Streets, St. Paul, Minnesota 55101, 612–290–3230

Mississippi (HDA–MS)

7:30–4:00 CST

Division Administrator, John F. Sullivan, Jr., 666 North Street, Suite 105, Jackson, Mississippi 39202–3199, 601–965–4215

Missouri (HDA–MO)

7:30–4:00 CST

Division Administrator, Gerald J. Reihsen, 209 Adams Street, Jefferson City, Missouri 65101, 314–636–7104

Mailing Address: P.O. Box 1787, Jefferson City, Missouri 65102

Montana (HDA–MT)

7:30–4:00 MST

Division Administrator, Henry D. Honeywell, Federal Office Building, 301 S. Park, Drawer 10056, Helena, Montana 59626–0056, 406–449–5306

Nebraska (HDA–NE)

7:30–4:15 CST

Division Administrator, Charles A. Culp, Federal Building, Room 220, 100 Centennial Mall North, Lincoln, Nebraska 68508–3851, 402–437–5521

Nevada (HDA–NV)

7:45–4:30 PST

Division Administrator, Frederick G. Wright, Jr., 1535 Hot Springs Road, Suite 100, Carson City, Nevada 89701–0602, 702–687–5320

New Hampshire (HDA–NH)

7:30–4:00 EST

Division Administrator, Gerald L. Eller, Federal Building, Room 204, 279 Pleasant Street, Concord, New Hampshire 03301, 603–225–1605

New Jersey (HDA–NJ)

8:00–4:30 EST

Division Administrator, Charles J. Nemmers, Suburban Square Building, 2nd Floor, 25 Scotch Road, Trenton, New Jersey 08628–2595, 609–989–2288

New Mexico (HDA–NM)

7:30–4:00 MST

Division Administrator, Reuben S. Thomas, 117 U.S. Courthouse, S. Federal Place, Santa Fe, New Mexico 87501–1963, 505–988–6569

New York (HDA–NY)

7:30–4:00 EST

Division Administrator, Harold J. Brown, Leo W. O'Brien Federal Building, 9th Floor, Clinton Avenue and North Pearl Street, Albany, New York 12207, 518–472–3616

North Carolina (HDA–NC)

7:45–4:15 EST

Division Administrator, Nicholas L. Graf, 310 New Bern Avenue, Suite 410, Raleigh, North Carolina 27611, 919–856–4346

North Dakota (HDA–ND)

7:45–4:30 CST

Division Administrator, George A. Jensen, Federal Building, P.O. Box 1755, 220 East Rosser Avenue, Bismarck, North Dakota 58502, 701–250–4204

Ohio (HDA–OH)

7:30–4:15 EST

Division Administrator, Fred J. Hempel, 200 North High Street, Room 328, Columbus, Ohio 43215, 614–469–6896

Oklahoma (HDA–OK)

7:30–4:00 CST

Division Administrator, Gary E. Larsen, Federal Office Building, Room 454, 200 NW. Fifth Street, Oklahoma City, Oklahoma 73102, 405–231–4624

Oregon (HDA–OR)

7:30–4:15 PST

Division Administrator, Robert G. Clour, The Equitable Center, Suite 100, 530 Center Street, NE., Salem, Oregon 97301, 503–399–5749

Pennsylvania (HDA–PA)

8:00–4:30 EST

Division Administrator, Manuel A. Marks, 228 Walnut Street, Harrisburg, Pennsylvania 17108, 717–782–2222

Mailing Address: P.O. Box 1086, Harrisburg, Pennsylvania 17108

Puerto Rico (HDA–PR)

7:30–4:00 AST

Division Administrator, Juan O. Cruz, Frederico Degetau Federal Building and U.S. Courthouse, Carlos Chardon Street, Room 329, Hato Rey, Puerto Rico 00918, 809–766–5600

Rhode Island (HDA–RI)

7:45–4:15 EST

Division Administrator, Gordon G. Hoxie, 380 Westminster Mall, Fifth Floor, Providence, Rhode Island 02903, 401–528–4541

South Carolina (HDA–SC)

7:45–4:15 EST

Division Administrator, Robert J. Probst, Strom Thurmond Federal Building, 1835 Assembly Street, Suite 758, Columbia, South Carolina 29201, 803–765–5194

South Dakota (HDA–SD)

8:00–4:30 CST

Division Administrator, Donald F. Kamnikar, Federal Building, Room 337, 225 South Pierre Street, P.O. Box 700, Pierre, South Dakota 57501, 605–224–8033

Tennessee (HDA–TN)

8:00–4:30 CST

Division Administrator, Dennis C. Cook, 249 Cumberland Bend Drive, Nashville, Tennessee 37228, 615–736–5394

Texas (HDA–TX)

7:30–4:15 CST

Division Administrator, Frank M. Mayer, Federal Office Building, 300 East Eighth Street, Room 826, Austin, Texas 78701, 512–482–5511

Utah (HDA–UT)

7:30–4:00 MST

Division Administrator, Donald P. Steinke, 2520 West 4700 South, Suite 9A, Salt Lake City, Utah 84118, 808–524–5141

Vermont (HDA–VT)

7:30–4:00 EST

Division Administrator, Karle L. Snyder, Federal Building, 87 State Street, Montpelier, Vermont 05602, 802–828–4423

Mailing Address: P.O. Box 568, Montpelier, Vermont 05601

Virginia (HDA–VA)

7:30–4:00 EST

Division Administrator, James M. Tumlin, Federal Building, 10th Floor, 400 N. 8th Street, Richmond, Virginia 23240, 804–771–2371

Mailing Address: P.O. Box 10045, Richmond, Virginia 23240

Washington (HDA—WA)

7:30–4:30 PST

Division Administrator, Barry F. Morehead, Suite 501, Evergreen Plaza, 711 South Capitol Way, Olympia, Washington 98501, 206–753–9480

West Virginia (HDA—WV)

8:00–4:30 EST

Division Administrator, Billy R. Higginbotham, 550 Eagan Street, Suite 300, Charleston, West Virginia 25301, 304–347–5928

Wisconsin (HDA–WI)

7:30–4:15 CST

Division Administrator, James E. St. John, 4502 Vernon Boulevard, Madison, Wisconsin 53705–4905, 608–264–5395

Wyoming (HDA–WY)

7:45–4:30 MST

Division Administrator, Frederick A. Behrens, 1916 Evans Avenue, Cheyenne, Wyoming 82001–3764, 307–772–2101

INDEX TO ISTEA OF 1991 IMPLEMENTATION GUIDANCE

Section of ISTEA	Date of guidance	Title
1001, 1021, 1012, 1020, 1100.	04/08/92	1991 ISTEA Implementation Interstate Construction Program.
1002	07/17/92	Revised Procedures for the Quarterly Obligation of Surface Transportation Funds.
1002, 1004, 1013	04/20/92	Fiscal Year 1992 Federal-aid Highway Program Obligations.
1002, 1003(c), 1004, 1007.	07/17/92	Comments on STP Quarterly Obligation Procedures.
1003(b)	10/19/92	Disadvantaged Business Enterprises (DBE) Program.
1006	06/12/92	Instructions for Developing the Proposed National Highway System.
1007	06/05/92 04/24/92	Transportation Enhancement Activities.
1007, 1008	03/05/92	Flexibility in the Intermodal Surface Transportation Efficiency Act (ISTEA).

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1007, 1009, 1020, 1021.	05/21/92	1991 ISTEA Implementation Interstate Maintenance Program.
1008	10/16/92	Further Guidance on the Congestion Mitigation and Air Quality Improvement Program.
1008	06/15/92	CMAQ and Transportation Enhancement Activities.
1008	07/30/92	Federal Transit Administration.
1008	07/30/92	Policy on Eligibility of PM–10 Projects for CMAQ funding.
1011, 3025	04/14/92	1991 Intermodal Surface Transportation Efficiency Act (ISTEA) Implementation of the Interstate Substitution Program.
1021, 1022	06/30/92	Federal Shares Established by Title 23, USC and the ISTEA of 1991.
1021	03/17/92	FHWA Notice (N 4540.12) Sliding Scale Rates in Public Land States—Rates Effective March 17, 1992.
1023, 4006, 4007	03/24/92	Longer Combination Vehicles and ISTEA.
1024	06/19/92	Fiscal Procedures for Federal Transit Projects Financed by Federal Highway Administration Funds.
1024, 1025	09/03/92	Public Involvement.
1025	06/24/92	Statewide Planning and Development of Transportation.
	06/30/92	Improvement Programs (TIP) for Federal Lands Highways.
1025	05/28/92	Interim Guidance 23 USC 135—Statewide Planning Requirement.
1025	10/09/92	Interim Measures to Meet STIP and TIP Requirements.
1027	05/20/92	Implementation Guidance on Section 1027 of 1991 ISTEA Public Transportation.

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1028	05/15/92	Highway Bridge Replacement and Rehabilitation Program (HBRRP) funds for Approach Roadway Construction.
1044	08/22/92	Section 1044 of the 1991 ISTEA Credit for Non-Federal Share.
1044	09/02/92	Section 1044—Credit for Non-Federal Share Implementation Q & A.
1100	08/26/92	Guidance in the Transfer Provisions contained in the ISTEA.
1301, 1302, 1303, 8003.	04/24/92	National Recreational Trails Program.
4002	09/04/92	MCSAP Final Rule Part 350.
4008	05/29/92	Information on Uniformity Grant Process.
6001	08/25/92	Implementation of ISTEA Minimum Expenditures on Research, Development and Technology Transfer Activities.
	05/22/92	Joint Memo on Implementation of the Intermodal Surface Transportation Efficiency Act.

MEMORANDUM

U.S. Department of Transportation

Federal Highway Administration

Date: April 8, 1992.
Reply to Attn of: HNG–13.
Subject: Information—1991 Intermodal Surface Transportation Efficiency Act (ISTEA) Implementation Interstate Construction Program.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

The purpose of this memorandum is to provide written guidance regarding the provisions in the 1991 ISTEA, which change or impact the Interstate construction program.

Authorizations—Section 1001

Section 1001(a) declares that the Interstate construction (IC) funds authorized by the act are the final authorizations of funding to complete construction of the Interstate System. The authorizations of $1.8 billion per year for fiscal years 1993 through 1996 are specified in section 1000(f). In some States, it may be necessary to supplement IC funds with other funds such as National Highway System (NHS) funds, or low priority work may be dropped from the Interstate program. An extension of the program or additional authorizations are not contemplated.

Apportionments—Section 1001

Section 1001(b) approved the 1991 Interstate Cost Estimate (ICE), and directed use of factors contained in the revised Table 5 of Committee Print 102–24, which were used in making apportionments for the FY 1993 funds. Section 1001(d) extends the administrative adjustment for FY 1994 through 1996. All previous credits, apportionments, lapses, withdrawals, discretionary allocations, and transfers of funds will be reflected as detailed in section 1001(d).

Prior to making apportionments from the $1.8 billion authorized each year, a separate allocation is made to Massachusetts in accordance with section 1001(e). Further, $20 million will be set aside each year to carry out the provisions of section 1006(h) of the act. Apportionments to Wisconsin will be made as specified in section 1045.

Section 1001(h) amends section 102(c) of the 1987 Surface Transportation and Uniform Relocation Assistance Act, and eliminates the provision that no State receive less than one-half percent minimum apportionment. The flexibility provided at the end of section 104(b)(5)(A) of title 23 was not altered by the ISTEA. Thus, if the Secretary and a State highway department agree that a part of the apportionment of IC funds is not needed for that fiscal year, the unneeded portion is not apportioned, but will be distributed under the Interstate discretionary program in accordance with section 118 of title 23. This agreement must be reached prior to the IC apportionment and so if any State is interested in this provision, inquiry should be made to the Program Analysis Division (HFS–30) well in advance of the scheduled IC apportionment.

Period of Availability—Section 1020

Section 1020(a) amends section 118 of title 23 and provides that IC funds, which are made available 1 year in advance, will be available until the last day of the fiscal year in which the funds are apportioned or allocated. This applies to all apportionments except the final apportionment, the FY 1996 funds, which will be apportioned on October 1, 1994, and will remain available until expended.

Federal Highway Administration Notice N4510.263, dated December 18, 1991, transmitted the certificate of apportionment of IC funds authorized for FY 1993. In a change to that notice issued February 27, 1992, paragraph 2b of the notice was revised to indicate that FY 1991 and 1992 IC apportionments are available until expended.

Federal Share—Section 1021

Section 1021 provides for a 90 percent Federal share for all IC funded projects, except for those that provide additional capacity, which will be funded at an 80-percent Federal share. The section provides for funding HOV and auxiliary lanes (truck climbing lanes, for example) at the 90 percent Federal share. It is believed that the Congress intended that all IC funded projects would retain the traditional 90 percent Federal share (with sliding scales up to 95 percent, where applicable). Technical correction language has been submitted to the Congressional committees to restore the 90 percent share. In the meantime, those portions of new IC funded projects that provide additional capacity (exclusive of HOV and auxiliary lanes) on existing Interstate routes shall be funded at an 80-percent Federal share.

Eligibility

The 1991 ISTEA did not change eligibility criteria for IC funds. Only work eligible under the provisions of the 1981 Federal-Aid Highway Act, and included in the 1981 ICE is eligible for IC funding.

Toll Roads, Bridges, and Tunnels—Section 1012

Section 1012(d) provides that existing toll agreements entered into under section 129 of title 23 prior to and in effect on the date of enactment of the 1991 ISTEA, shall continue in effect in accordance with the provisions of the agreement.

Federal participation in the initial construction of toll roads, bridges, tunnels or approaches thereto on the Interstate System is not allowed under section 129(a)(1)(A) where such facility was not covered by a section 129 agreement in effect on the date of enactment of the 1991 ISTEA.

Discretionary Funds—Section 1020

Section 1020 amends section 118(c) of title 23 by reducing the amount of funds set aside for the Interstate Discretionary (ID) Program from $300 million annually to $100 million annually. A separate memorandum will be issued by Headquarters near the end of each fiscal year to seek applications for ID allocations.

Section 1020 has eliminated the priorities (i.e. #1 for gaps, etc.) of section 118(b)(2)(B) of title 23 previously used in allocating ID funds. Any specific criteria to be used in considering future candidates for discretionary allocations will be included in the memorandum seeking applications each year.

All ID funds set aside for the current fiscal year have been allocated. Refer to Mr. Willett's memorandum dated December 23, 1991, for details.

Transferability

Section 119(d) of title 23, providing for the transfer of IC apportionments, is essentially unchanged, except that the transfers will be from IC funds to NHS or Interstate Maintenance funds. Requests to transfer IC funds are limited to the Federal share of the cost to complete open-to-traffic work included in the 1991 ICE, and must be made in writing to the Office of Fiscal Services (HFS–30). Upon approval of the transfer, the work on which the transfer is based will be removed from the 1991 ICE and will lose its IC fund eligibility.

Disposition of Unobligated Funds—Section 1100

Section 1100 (b) and (c) deal with the disposal of unobligated balances of funds apportioned prior to the act. The provision has been interpreted to apply to unobligated balances of FY 1991 and 1992 IC funds which were apportioned prior to September 30, 1991. The period of availability for these FY 1991 and 1992 apportionments will continue as prior to the act; available until expended. As a result, IC funds will lapse on September 30, 1992, (or 1993 or 1994) if the amount of unobligated IC funds is in excess of the total of FY 1991 and 1992 IC apportionments.

This guidance will be supplemented in the future if further clarifications are found necessary. Questions about any of these Interstate issues should be directed to the Interstate and Program Support Branch (HNG–13).

/s/ Kevin E. Heanue for Anthony R. Kane.

MEMORANDUM

Date: July 17, 1992.
Reply to Attn. of: HFS–30.
Subject: *Information*—Revised Procedures for the Quarterly Obligation of Surface Transportation Funds.
From: Director, Office of Fiscal Services, Washington, DC 20590.
To: Associate Administrators; Regional Administrators; Division Administrators.

Procedures for the obligation of funds for States that confirm that they wish to obligate Surface Transportation Program (STP) funds on a quarterly basis were provided in my March 24, 1992 memorandum. These procedures required that States which will obligate STP funds quarterly do so using one Federal-Aid project each quarter.

A number of States expressed concern about the effects that quarterly obligations will have on their internal accounting system and have requested that they be permitted to obligate STP funds on a project-by-project basis. Therefore, we have revised the procedures to provide States with the following options for obligating STP funds for projects not on the Interstate System or National Highway System (NHS), on a quarterly basis:

1. Using an annual project with obligations each quarter;
2. Using a single project for each quarter;
3. Obligating STP funds on a project-by-project basis each quarter.

It should be noted that in accordance with Mr. Carlson's memorandum of January 28, 1992, (Subj: Implementing Guidance—Project Review, Oversight and Administration under the ISTEA of 1991), STP funded projects located on the Interstate or NHS systems must be obligated on a project-by-project basis with all the normally required statistical data being reported on the FHWA–37.

In addition to the three methods of obligating on a quarterly basis, we have provided a method, which will allow those States using the single project or annual project option, to timely close STP projects.

States that wish to obligate STP funds for projects not on the Interstate System or NHS, on a quarterly basis, using any of the above options, must:

1. Request that the FHWA no longer review and approve plans, specifications, and estimates in accordance with 23 U.S.C. 106(b) or 23 U.S.C. 117. If a State makes this request they must utilize the quarterly obligation procedures for STP projects not located on the Interstate or NHS.

2. The Governor, or designee, is required by Statute to certify before the beginning of each quarter that the State will meet all the requirements of 23 U.S.C. 133; and the State must notify the FHWA Division Office of the amount of obligations expected to be incurred during the quarter, for STP projects coming under this provision.

Annual Project

If the State chooses to use the annual project option, Division offices are required to notify the Program Analysis Division (HFS–30) when the State's request for exemption from the FHWA PS&E review is processed so that the Fiscal Management Information System (FMIS) can be adjusted to permit the obligation on quarterly basis for that State.

States wishing to obligate STP funds on an annual project must establish a separate project for each year. The following are the procedures for obligating STP funds on a quarterly basis using the annual project option:

(a) The State must submit the required Certification (signed by the Governor or designee) and notify the Division Administrator of the amount the State will obligate in the next quarter. The amount obligated should be the total federal share for each state project included in the Annual Project. A Project Agreement (PR–2) or Modified Project Agreement (PR–2a) is to accompany the State's submission. The submission should reach the division prior to the beginning of the quarter. A new submission is required for each quarter.

(b) The Division Administrator will notify the State that the quarterly submission has been accepted and process the PR–2 or PR–2a. In the first quarter the Division's acceptance represents project authorization and project agreement. In the following quarters the Division's acceptance represents an amended authorization and modified project agreement.

(c) States must analyze the amounts obligated each quarter and make adjustments, as necessary, to reflect changes as a result of, delayed or additional projects, over-runs or underruns. A PR–2a may be used to make adjustments at any time during the quarter. The State must provide this analysis to the Division Office each quarter.

(d) In addition to the required certification the State's submission must contain, at a minimum, the following items:

1. Project number (A different project number must be used for each year).

2. Total Federal Funds to be obligated and a break-down by appropriation code. Additionally, if funds are to be obligated from appropriation code 33C (urbanized areas of 200,000 or more) the State must provide a break-down showing the amounts for each urbanized area.

3. The total cost of the project as it relates to the Federal Funds in item 2 above. This is also required to be broken-down by appropriation code.

The work authorized in a particular year will remain with that project until completed. However, to facilitate the closing of projects a State may elect to close the annual project at the end of the year and roll the uncompleted State projects into the next year's Annual project. If a State elects this option they must deobligate all the funds from all uncompleted old State projects and obligate them under the new Annual project. For example, if the Annual project was comprised of 4 State projects and only one was completed and ready to close at the end of the year, the total amount obligated for the 3 uncompleted projects would be deobligated and re-obligated under the next years annual project.

This process would also require a debit and credit on the Current Billing to move any expenditures from the old Federal project to the new one. Once the obligations and expenditures have been moved, the original annual project will contain only completed work and may therefore be closed and a final voucher submitted.

Each quarter the Division Office will enter into FMIS the quarterly obligation of the STP program. Only the amount needed for the next quarter may be obligated, when the next quarter's needs are ready to be obligated, it should be treated as a modification to the annual project. A separate FHWA–37, using the same project number, will have to be completed for each appropriation code. When entering the obligation and agreement into the FMIS the division will complete the following items on the FHWA–37:

a. Region and State Code.
b. Appropriation Code.
c. Project Number.
d. Prefix letters—Division Office may use any combination of letters.
e. Transaction Number.
f. Line number—enter as line 30—only one line is required except for appropriation code 33C. In this case a line is required for each urbanized area. See section 1 below.
g. County—enter as 999.
h. Agreement Date—enter the appropriate date.
i. Step, and Step Date—Enter step 6 when the funds are obligated. Move the project to step 8 when the final voucher is received and step 9 when paid. Normally, a division will not receive the necessary documentation to move a project to steps 7 or P.
j. Total Cost—enter the appropriate amount.
k. Federal Funds—enter the amount requested.
l. When entering data for appropriation code 33C, each urbanized area will have to be entered on a separate line with the urbanized area code being entered in the field "Urbanized Area—W08–082". The Urbanized Area field in the header record should be left blank.

Single Quarterly Project Option

If the State chooses to use the single quarterly project option, Division offices are required to notify the Program Analysis

Division (HFS–30) when the State's request for exemption from the FHWA PS&E review is processed so that the Fiscal Management Information System (FMIS) can be adjusted to permit quarterly obligations for that State.

States wishing to obligate STP funds on a single project must establish a separate project for each quarter. The following are the procedures for obligating STP funds on a quarterly basis using the single project option:

(a) The State must submit the required Certification (signed by the Governor or designee) and notify the Division Administrator of the amount the State will obligate in the next quarter. The amount obligated should be the total federal share for each state project included in the single project. A Project Agreement (PR–2) or Modified Project Agreement (PR–2a) is to accompany the State's submission. The submission should reach the division prior to the beginning of the quarter. A new submission is required for each quarter.

(b) The Division Administrator will notify the State that the quarterly submission has been accepted and process the PR–2 or PR–2a. The Division's acceptance represents project authorization and project agreement.

(c) States must analyze the amounts obligated each quarter and make adjustments, as necessary, to reflect changes as a result of, delayed or additional projects, over-runs or underruns. A PR–2a may be used to make adjustments at any time during the quarter. The State must provide this analysis to the Division Office each quarter.

(d) In addition to the required certification, the State's submission must contain, at a minimum, the following items:

1. Project number (a different project number must be used for each quarter).

2. Total Federal Funds to be obligated and a breakdown by appropriation code. Additionally, if funds are to be obligated from appropriation code 33C (urbanized areas of 200,000 or more) the State must provide a breakdown showing the amounts for each urbanized area.

3. The total cost of the project as it relates to the Federal Funds in item 2 above. This is also required to be brokendown by appropriation code.

The work authorized in a particular quarter will remain with that quarterly project until completed. However, to facilitate the closing of projects a State may elect to close a quarterly project at a specific point in time (for instance every December 31st) and roll the uncompleted State projects into a new Federal quarterly project. If a State elects this option they must deobligate the total amount obligated associated with uncompleted old State projects and obligate them under a new quarterly project. For example, if a quarterly project was comprised of 4 State projects and only one was completed and ready to close, the total amount obligated for the 3 uncompleted projects would be deobligated and re-obligated under a new quarterly project.

This process would also require a debit and credit on the Current Billing to move any expenditures from the old Federal project to the new one. Once the obligations and expenditures have been moved, the original quarterly project will contain only completed work and may therefore be closed and a final voucher submitted.

Each quarter the Division Office will enter into FMIS the quarterly obligation of the STP program. A new project number must be set up for each quarter. A separate FHWA–37, using the same project number, will have to be completed for each appropriation code. When entering the obligation and agreement into the FMIS, the division will complete the following items on the FHWA–37:

a. Region and State Code.

b. Appropriation Code.

c. Project Number.

d. Prefix letters—Division Office may use any combination of letters.

e. Transaction Number.

f. Line number—enter as line 30—only one line is required except for appropriation code 33C. In this case a line is required for each urbanized area. See section 1 below.

g. County—enter as 999.

h. Agreement Date—enter the appropriate date.

i. Step, and Step Date—Enter step 6 when the funds are obligated. Move the project to step 8 when the final voucher is received and step 9 when paid. Normally, a division will not receive the necessary documentation to move a project to steps 7 or P.

j. Total Cost—enter the appropriate amount.

k. Federal Funds—enter the amount requested.

l. When entering data for appropriation code 33C, each urbanized area will have to be entered on a separate line with the urbanized area code being entered in the field "Urbanized Area—W08—082". The Urbanized Area field in the header record should be left blank.

Project-by-Project Option

If the State chooses to use this option, Division offices are required to notify the Program Analysis Division (HPS–30) when the State's request for exemption from the FHWA PS&E review is processed so that the Fiscal Management Information System (FMIS) can be adjusted to permit quarterly obligations for that State.

States wishing to obligate STP funds on a project-by-project basis should obligate the funds at the beginning of each quarter for all projects expected to begin during the quarter. Changes to the quarterly package of projects, such as the addition of a project, may be made at any time during the quarter. The amounts obligated on each project must be adjusted as necessary due to over-runs, under-runs. As individual projects are completed, final vouchers should be prepared for each project using the final voucher procedures for non STP projects.

The following procedures should be utilized for obligating STP funds on a quarterly basis using this option:

(a) The State must submit the required certification (signed by the Governor or designee) and notify the Division Administrator of the projects the State will obligate for the quarter. A Project Agreement (PR–2) must be submitted for each project. The submission should reach the division prior to the beginning of the quarter. A new submission is required for each quarter.

(b) The Division Administrator will notify the State that the quarterly submission has been accepted and process the PR–2(s). The Division's acceptance represents project authorization and project agreement. Upon agreement between the Division and the State the PR–2 for construction projects may be delayed until the construction project is awarded.

(c) The State must adjust the amount obligated, as necessary due to overruns, underruns, etc. A PR–2a must be submitted to Division to modify the amounts obligated.

(d) In addition to the required certification the State's submission must contain for each project, at a minimum, the following items:

1. Project number—including the appropriation code.

2. Total Federal funds to be obligated.

3. The total cost of the project as it relates to the Federal funds above.

4. If the project is in an urbanized area over 200,000—the urbanized area name is required.

Each quarter the Division Office is to enter into FMIS the quarterly obligation of the STP program. A separate FHWA–37 is required for each project. When entering the obligation and agreement into the FMIS the division will complete the following items on the FHWA–37:

a. Region and State Code.

b. Appropriation Code.

c. Project Number.

d. Prefix letters—Division Office may use any combination of letters.

e. Transaction Number.

f. Line number—enter as line 30—only one line is required.

g. County—enter as 999.

h. Agreement Date—enter the appropriate date.

i. Step and Step Date—Enter step 6 when the funds are obligated. Move the project to step 8 when the final voucher is received and step 9 when paid. Normally, a division will not receive the necessary documentation to move a project to steps 7 or P.

j. Total Cost—enter the appropriate amount.

k. Federal Funds—enter the amount requested.

l. When entering data for appropriation code 33C, each urbanized area will have to be entered on a separate line with the urbanized area code being entered in the field "Urbanized Area—W08—082".

Division Offices should work with their State to determine which method best suits their local requirements. States may change from one method to another with the approval of the Division Office. Projects currently underway using non-quarterly procedures (ie., individual letters of authorization) should continue to be processed as an individual project.

When obligating STP funds, using quarterly obligation procedures, no additional program statistical data is necessary. However, the States will be required to provide data which will allow FHWA to monitor the program on a nationwide basis and respond to questions and requests for information about the STP program. The requirements for this additional data will be provided in the near future.

Only STP funds may be obligated using these procedures. All other programs, including Minimum Allocation and Donor State Bonus funds, are to be obligated using normal procedures. STP funds used for transit projects in conjunction with the Federal Transit Administration will follow procedures issued on June 19, 1992.

Should you have any questions concerning this matter, please contact Bruce Swinford or Tom Park (HFS–30) on 202–366–0673.

Peter J. Basso

MEMORANDUM

Date: April 20, 1992.
Reply to Attn. of: HFS–31.
Subject: *Action*—Fiscal Year 1992 Federal-aid Highway Program Obligations.
From: Administrator.
To: Regional Administrators; Division Administrators; Federal Lands Highway Program Administrator; Associate Administrators.

The Federal Highway Administration and the Department of Transportation are committed to the President's charge to use all available FY 1992 Federal-aid highway program funds as efficiently as possible as a means to stimulate the national economy and generate employment. The purpose of this memorandum is to provide direction and procedures for working with the state Transportation agencies to ensure that these benefits are realized by redistributing unneeded balances of FY 1992 obligation authority to those states that can use additional obligation authority beyond that presently available.This guidance pertains to obligations controlled by the Federal-aid obligation limitation as well as the obligation of minimum allocation funds that are exempt from the Federal-aid limitation, but are subject to separate obligation controls during fiscal year 1992 to ensure budget compliance.

The amounts released by, or redistributed to, states for both the formula and Minimum Allocation limitations, will have no bearing on the limitation that states receive in fiscal year 1993.

Background

The Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991 (Pub. L. 102–240) provides for redistribution, after August 1, 1992, of authority distributed to a state for FY 1992 if the state will not obligate the authority during FY 1992.

Of the total $15,686,364,000 obligation authority subject to the Federal-aid limitation, $378.9 million was reserved for the Federal Lands program, $449.6 million for administration, $5 million for the high-speed ground transportation program, and $508.6 million to support the obligation of FY 1992 allocations of special non-formula funds. The remainder, $14,344,347,430, was distributed by formula to the states.

The ISTEA of 1991 does not provide for additional FY 1992 obligation authority to those states that have obligated all authority distributed by formula. Therefore, any additional amounts to be made available in FY 1992 will be derived solely from the amount returned for redistribution. Thus, it is critical to determine as early as possible in the fiscal year those states that will not fully obligate available formula distribution.

In accordance with section 1004 (Budget Compliance) of the ISTEA of 1991, the obligation of FY 1992 section 157 Minimum Allocation funds may not exceed $1,092 million during FY 1992. The "limitation" on these obligations does not reduce a state's apportionment of these funds. The distribution to states of obligation authority under this "limitation" was based on each state's proportionate share of FY 1992 Minimum Allocation apportionments. Any unobligated balances of minimum allocation funds from previous fiscal years are also available for obligation during FY 1992. We are seeking at this time to determine whether states intend to fully obligate available minimum allocation "limitation" during FY 1992 and for those states that will not use their limitation to redistribute this "limitation."

Redistribution of Unobligated FY 1992 Authority Initially Distributed by Formula

To provide a basis for determining (1) the amount of FY 1992 obligation authority initially distributed by formula that will be available for redistribution among the other states after August 1, 1992, and (2) those states that are able to obligate amounts in addition to those previously distributed, each state shall submit a plan by May 18, 1992, to the Division Administrator showing:

(1) The projected July 31 unobligated balance of obligation authority.

(2) The projects and/or Federal funds that will be obligated, or could be obligated by the states by September 30, 1992, if additional authority is provided.

(3) The obligation authority that is excess to the needs of the state and is being released.

(4) Additional obligation authority required.

The Division Administrator shall review the plan submitted by the state and reach an agreement with the state on those projects which could be approved and authorized by the division office on or before September 30.

By May 26, 1992, Division Administrators shall report to their regional offices: (1) The amount of FY 1992 formula authority that is excess to the state's needs and is being released, or (2) that the state and Division Administrator have reached an agreement that the state's remaining unobligated FY 1992 formula authority will be obligated by September 30, 1992, and/or (3) the additional formula authority that could be obligated by September 30, 1991. The report shall be submitted to Washington Headquarters by June 1, 1992.

Redistribution of Unobligated FY 1992 Minimum Allocation Obligation Authority

To provide a basis for determining (1) the amount of FY 1992 obligation authority initially distributed for minimum allocation that will be available for redistribution among the other states after August 1, 1992, and (2) those states that are able to obligate amounts in addition to those previously distributed, each state shall submit a plan by May 18, 1992, to the Division Administrator showing:

(1) The projected July 31 unobligated balance of Minimum Allocation funds (Appropriation Codes 34A, 34B, 34C, and 34D).

(2) The projects and/or Federal funds that will be obligated, or could be obligated by the states by September 30, 1992, if additional authority is provided up to a maximum of the amount apportioned to the states in FHWA Notice 4510.271. The attached table provides the sub-allocations for the total minimum allocation apportionment for FY 1992.

(3) The Minimum Allocation obligation authority that is excess to the needs of the state and is being released.

(4) Additional obligation authority required.

The Division Administrator shall review the plan submitted by the state and reach an agreement with the state on those projects which could be approved and authorized by the Division Office on or before September 30. Care must be taken to ensure that the planned projects do not exceed the amounts available in the sub-allocations (see attached table).

By May 26, 1992, Division Administrators shall report to their region offices: (1) The amount of FY 1992 minimum allocation authority that is excess to the state's needs and is being released, or (2) that the state and Division Administrator have reached an agreement that the state's remaining unobligated FY 1992 minimum allocation authority will be obligated by September 30, 1992, and/or (3) the additional minimum allocation authority that could be obligated by September 30, 1992. The amounts requested in (1) and (3) above must be provided by appropriation code. The report shall be submitted to Washington Headquarters by June 1, 1992.

Release of Unobligated FY 1992 Authority Distributed To Support Obligations of Non-Formula Allocations (Except Federal Lands)

No state will be provided with special obligation authority in FY 1993 to cover any unobligated FY 1992 allocations carried over on September 30. Obligation in FY 1993 of any such carryover allocation must be charged to the state's share under the formula distribution.

The amount of FY 1992 obligation authority distributed to support obligations of allocations of non-formula funds that will not be obligated by September 30, 1992, should be determined by the Division Administrator in consultation with the state.

By May 18, 1992, Division Administrators shall report to their regional offices the amount of FY 1992 non-formula funds and authority allocated to the states, the amount that will be obligated as of September 30, 1992, and the amount of obligation authority which is being released.

Redistribution of FY 1992 Authority Reserved for Federal Lands and Other Headquarters Controlled Programs. Each respective Associate Administrator should report the balance, if any, of obligation authority reserved for their program(s) which will not be obligated as of September 30, 1992, to the Program Analysis Division (HFS–30) by May 26, 1992.

Reports From Regional Offices. Based on reports from division offices, regional offices shall submit reports in the attached format for each state in their region.

Redistribution of Excess FY 1992 Obligation Authority

A formula for redistribution of released obligation authority will be developed to implement the requirements of Public Law 102–240. Priority will be given to those states having large unobligated balances of funds apportioned under 23 U.S.C. 104 and 144. A final review of the reports submitted will be requested in early July to provide for any necessary revisions to the states' obligation plans.

The redistribution of released authority will be accomplished on August 3, 1992.

Program Monitoring. The Washington Headquarters will monitor the program on a national basis to insure that available authority is fully utilized.

T.D. Larson.

BILLING CODE 4910-22-M

Status of 1992 Obligational Authority Minimum Allocation
(Formula Minimum Allocation and Non-Formula) (RCS HFS-30-1)

State -

	Funds Allocated	Authority Provided	Balance of Available Obligational Authority as of 7/31/92	Projected Obligations August Available Authority Aug./Sept. 1992	Obligation Authority Release	Additional Authority Required
	(1)	(2)	(3)	(4)	(5)	(6)
Formula - Total for all funds subject to the obligation ceiling.	XXX	XXX	$	$	$	$
Minimum Allocation - List by Approp. Code 34A,B,C and D. Column (1) and (2) will be the same.						
"Non-Formula" and Federal Lands						
The projected obligation against the obligation authority (column 4) may not exceed the balance of available authority (column 3).*						
(a) List funds by title	$	$	$	$	$	$
(b) Please account for all 1992 allocations						
(c) Any amounts reported in column 5 should be footnoted to explain why.						
Non-Formula - Subtotal	$	$	$	$	$	$
State Total	$	$	$	$	$	$

* Obligation authority distributed with Section 149 Demonstration Projects is to be considered as formula authority.

BILLING CODE 4910-22-C

SUB-ALLOCATION OF FY 1992 TOTAL MINIMUM ALLOCATION APPORTIONMENT

State	Minimum allocation apportionment N4510.271 (1)	Urbanized areas of 200,000 plus population (2)	Areas of less than 200,000 population (3)	Areas of less than 5,000 population (4)	State flexibility (5)	Grand total (6)
Alabama	24,283,712	2,188,523	5,400,137	.....	16,695,052	24,283,712
Arizona	48,943,184	10,789,005	1,990,864	2,514,876	33,648,439	48,943,184
Arkansas	48,853,490	2,207,814	13,058,901	.....	33,586,775	48,853,490
California	135,126,746	32,368,742	9,858,366	.....	92,899,638	135,126,746
Florida	159,082,913	33,535,821	16,177,589	.....	109,369,503	159,082,913
Georgia	80,121,375	10,085,226	14,952,704	.....	55,083,445	80,121,375
Indiana	81,219,913	9,016,398	16,364,825	.....	55,838,690	81,219,913
Kentucky	10,551,973	994,847	2,302,644	.....	7,254,482	10,551,973
Louisiana	4,030,342	496,232	763,249	.....	2,770,861	4,030,342
Maine	1,209,959	.....	378,112	.....	831,847	1,209,959
Michigan	62,608,271	10,500,212	8,812,775	252,096	43,043,186	62,608,271
Mississippi	22,371,121	865,650	6,125,325	.....	15,380,146	22,371,121
Missouri	56,988,903	8,399,029	9,410,003	.....	39,179,871	56,988,903
North Carolina	65,949,471	3,757,803	16,851,407	.....	45,340,261	65,949,471
Ohio	98,837,335	17,201,510	13,685,157	.....	67,950,668	98,837,335
Oklahoma	36,377,321	4,550,269	6,817,644	.....	25,009,408	36,377,321
Oregon	1,257,963	138,954	254,159	.....	864,850	1,257,963
Tennessee	40,094,300	4,854,819	7,674,649	.....	27,564,832	40,094,300
Texas	125,464,106	20,513,302	18,694,231	.....	86,256,573	125,464,106
Wisconsin	56,615,426	5,318,901	12,373,419	.....	38,923,106	56,615,426
Total	1,159,987,824	177,783,057	181,946,160	2,766,974	797,491,633	1,159,987,824
Appropriation code	.....	34B	34C	34D	34A	

Note: Requests for additional authority may not exceed the above amounts by category.

MEMORANDUM

Date: July 17, 1992.
Reply to Attn. of: HFS–31.
Subject: Comments on STP Quarterly Obligation Procedures.
From: Director, Office of Fiscal Services, Washington, DC.
To: Regional Administrators, Division Administrators.

On June 12, 1992, we issued draft procedures for the quarterly obligation of STP funds. Comments were received from 23 Division Offices. Listed below is a summarization of the comments along with the action taken.

• Does the law require that a waiver of PS&E review under 23 U.S.C. 106(b) be complied with in order to process STP obligations on a quarterly basis?

Yes, the language in 23 U.S.C. 133(e)(2) allows quarterly obligations for STP projects not subject to review by the Secretary under chapter 1 of title 23. Only States operating under 106(b) and 117 meet this criteria.

• Clarify which STP projects are covered by quarterly procedures.

Clarification has been added to specifically exclude STP projects on the Interstate System and the National Highway System as provided in the memorandum providing, Implementing Guidance—Project Review, Oversight and Administration under the ISTEA of 1991, issued by the Executive Director on January 28, 1992. Because the principal Federal interest lies with the National Highway System and Interstate System, it was determined by the FHWA that its traditional process for obligating funds and tracking project accomplishments through FMIS would be retained for all Federal-aid projects on the NHS and Interstate System.

• Quarterly procedures will cause a lot more work for the State in project planning, record keeping and accounting.

The ISTEA established the concept of obligating STP on a quarterly basis. This will require a State to plan for the upcoming quarter. There is no change in record keeping requirements or in accounting for project costs. States which have systems that can take advantage of the annual or single project option can do so. The project-by-project option is very similar to business as usual with the one additional requirement that States must plan for the next quarter.

• New procedures could have significant impact on State systems and therefore, should be implemented formally, using the regulatory process.

The procedures for the annual and single project option can have an impact on State systems, however, they are optional. States that desire to obligate quarterly can do so using the project-by-project option. This would have an insignificant impact. For these reasons we do not feel that the formal regulatory process is necessary.

• States should be allowed to continue project-by-project until they are ready to begin quarterly.

States can obligate STP projects on a quarterly basis using the project-by-project option then switch to the annual or single project option, with the concurrence of the Division Office, when they are ready.

• Clarify how a State may change from one option to another as the States capabilities change.

Clarification has been added to state that the option may be changed with the approval of the Division Office. No headquarters action is necessary.

• Clarification is needed to indicate that a State can submit a PR–2a to adjust the quarterly obligation at any time during the quarter under any of the three options.

Clarification has been added to make this clear.

• Procedures are extremely complicated and we would recommend major simplification to incorporate efficiency into the program.

We have simplified the procedures as much as possible. One should note that procedures for each of the three options has been written such that each can stand on its own. This eliminates the need to refer back to another section of the procedures.

• The Credit and Debit process in closing projects will give the State major timing and paperwork problems. Suggested alternative—Keep the ongoing work under the existing and move the completed work to a new number.

We are attempting to provide a mechanism which will allow the State to close projects and reduce the number of Federal-aid projects that are open, the suggested alternative will not achieve this. Additionally, if a State chooses this option it should result in a review of the obligation to ensure that the amount obligated is still valid.

• Question the need for a final voucher on Annual Project. If final voucher is required the information required should be as simple as possible.

Final vouchers are required by 23 U.S.C. 121(b). The information required is contained in 23 CFR 140.107.

• The ISTEA requires only a notification of expected obligations at the beginning of the quarter and not the obligation of the expected amount at the beginning of the quarter. The State would prefer to obligate funds throughout the quarter and not at the beginning.

The ISTEA also states that acceptance of this notification shall be deemed a contractual obligation of the United States. This makes it very clear that the intent is to

obligate funds based on the notification. States should notify the Division of the funds to be obligated for the quarter at the beginning of the quarter. Adjustments to this amount may be made at any time during the quarter.

• The wording of option 3 implies a strict requirement for immediate adjustment for changes while the State believes the intent is for the use of judgment at the Division as to the timing of the adjustments.

The wording has been modified.

• Rewrite the first paragraph of Multiple Project Option as follows; "States wishing to obligate STP funds on a multiple project basis should obligate the funds at the beginning of each quarter for all projects expected to begin during the quarter. Changes to the quarterly package for projects, such as the addition of a project, may be made at other times during the quarter. The amounts * * *."

This wording has been incorporated in the procedures.

• State wants the mutiple project option without the quarterly requirement.

States which elect to utilize section 106(b) must obligate funds on a quarterly basis.

• State wants to hold the PR–2 until construction projects are awarded as opposed to placing the project in Agreement at the time of Obligation.

This flexibility has been added to the procedures.

• State wants to have STP projects go through step P as they use it for monitoring purposes.

Division Offices and States may agree to continue this practice. However, it should be noted that the criteria used to advance a project into Step P will not normally be available for STP projects.

• Need the requirement for any additional statistical data as soon as possible.

The Program Offices are developing the types of data and the mechanism to be used in collecting the data. Information will be provided as soon as it becomes available.

• State sees no need for a Quarterly Certification. State wants to certify annually.

The requirement contained in 23 U.S.C. 133(e)(2) is for a quarterly certification. Annual certifications would not meet the criteria established in law.

• Want the Details of the quarterly analysis required when obligating under the Annual Project.

• The analysis is simply a review of the amounts obligated during the quarter to ensure that necessary adjustments are made for delayed projects, over-runs, under-runs and projects which advanced quicker than expected.

• How should we handle the obligations at the beginning of the Fiscal Year. The Division is going to require the certification before the beginning of the quarter and obligate the funds after October 1, when funds become available.

This is the correct process.

• Need to clarify in option 3 para (b) that a PR–2 is required for each project. This can be done by putting a "(s)" after the PR–2.

This has been done.

• Need clarification on how the Projects already underway in STP will be handled when a State begins quarterly process. Are they mixed or does the State continue to process project-by-project when modifying existing projects.

Clarification has been added to state that projects authorized under non-quarterly procedures will continue to be processed under those procedures.

• The annual close out procedures will force the State to assume full responsibility for monitoring the 10 yr ROW AND PE requirements. Is this covered by the certification? and what is the Division's responsibility in this area?

For STP projects the State would assume full responsibility for the 10 year requirements.

• The requirement that the Division review the Governor's certification to ensure compliance with 23 USC 133 is very time consuming.

The requirement that the Division review the Governor's certification has been dropped. Divisions should accept the certification as evidence that State will comply with 23 U.S.C. 133.

• The procedures require a breakdown of the STP appropriation codes—What backup and details are intended.

No additional details or backup is required.

• STP funds have different funding ratios who will track these, i.e., 100% safety.

The funds will be obligated by appropriation code, each different funding ratio has a different appropriation code.

• Can the state authorize a large project and obligate only the amount of federal funds needed for the quarter.

Clarification has been added to explain that the amounts obligated must equal the total federal funds required for each state project included in the quarterly package.

• Rolling over uncompleted projects will result in the current quarterly project having multiple authorization dates. Since the State's system only allows for a single eligibility date, how should this be treated.

The rolling over of uncompleted projects is an option that States have to reduce the number of open Federal projects. If this is unworkable in a particular State we are willing to work with that State to develop another method.

As noted above we received a large number of comments and suggestions. A number of the comments were received from more than one Division. We attempted to accommodate as many of the comments as possible. I sincerely appreciate the level of interest and effort put into the responses to the draft. Should you have any other comments or questions please contact the Program Analysis Division at 202–366–2906.

Peter J. Basso.

MEMORANDUM

Date: October 19, 1992.
Reply to Attn. of: HCR–20.
Subject: *Information:* Section 1003(b) of the 1991 ISTEA—Disadvantaged Business Enterprise (DBE) Program.
From: Federal Highway Administrator.
To: Regional Federal Highway Administrators, Associate Administrators, Staff Office Directors, Federal Lands Highway Program Administrator.

Section 1003(b) of the ISTEA continued the DBE program. Section 1003(b) replaces section 106(c) of the 1987 STURRA as the statutory authority for the DBE program. A copy of section 1003(b) is attached for your information

Despite significant changes by the ISTEA to FHWA's program and its stewardship role under title 23, the agency's responsibility to oversee compliance with the DBE program has not changed. This is because the DBE program is a non-title 23 program. The legislation mandating the DBE program applies equally to several modes of the U.S. Department of Transportation other than FHWA, i.e., FTA and FAA. That is why the implementing regulations for the DBE program are published by the Department and contained in 49 CFR part 23, not 23 CFR. Therefore, all projects, regardless of whether they are on or off the National Highway System (NHS), continue to be subject to the legislative and regulatory DBE program requirements. Similarly, FHWA must continue to approve each State's DBE program and its annual goals, and to ensure compliance with all DBE program requirements.

Section 1003(b) retained all the basic DBE requirements of section 106(c) and added several requirements. The provisions retained and added are summarized in the following paragraphs.

Significant provisions retained from the 1987 STURRA include:

• Continuation of the requirement that not less than 10 percent of funds authorized in the act be expended with small business concerns owned and controlled by socially and economically disadvantaged individuals.

• Continuation of the inclusion of women in the presumptively disadvantaged category.

• Application of the DBE program to all categorical programs including demonstration projects.

• Application of the DBE program to all funds authorized by the 1987 STURRA that were unobligated prior to the passage of the act.

• Continuation of the requirement for an annual survey and listing by each State of the firms certified and their locations.

• Continuation of the requirement for minimum uniform certification criteria.

New/revised provisions of section 1003(b) of the ISTEA include:

• The size limitation for qualifying as a small business for purposes of the DBE program was modified by raising the threshold to $15,370,000 average annual gross receipts over 3 years. This is the same size standard established by the U.S. Department of Transportation (DOT) in the June 20, 1990, **Federal Register** notice.

• A requirement that the States annually report to the Secretary a detailed percentage breakdown of the socially and economically disadvantaged businesses participating in the DBE program. The annual report shall show the percentage (and number) of:

(1) White women business enterprises (WWBEs);

(2) Minority women business enterprises (MWBEs); and

(3) Minority business enterprises (MBEs).

See our memorandum dated April 22, that discusses these reporting requirements in more detail.

• Funds expended for contracts under Title V (Intermodal Transportation) and Title VI (Research) are now subject to the DBE requirement that not less than 10 percent of funds be expended with DBE firms. Consistent with current policy (see FHWA Administrator's August 23, 1983, memorandum, Attachment #2), the DBE program requirements are applicable to all funds expended in contracts (e.g., technical, professional, and management services) awarded by FHWA, States, or other federally funded recipients under these programs. We will be coordinating with each of the Associate Administrators to determine how this requirement will be implemented.

• A requirement that General Accounting Office (GAO) conduct a study of 10 areas of FHWA's DBE Program. These areas are described in Section 1003(b)(5).

Should you require additional clarification of the statutory requirements of the ISTEA, please contact Ms. Linda J. Brown (HCR–10) at (202) 366–0471 or Mr. George Duffy (HCR–20) at (202) 366–2925.

T.D. Larson.

MEMORANDUM

Date: June 12, 1992.
Reply to Attn of: HEP–12.
Subject: *Action:* Instructions for Developing the Proposed National Highway System (NHS).
From: Executive Director.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

The purpose of this memorandum is to provide instructions for use in developing the proposed NHS authorized by section 1006 of the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991. Copies should be made available to the States, metropolitan planning organizations (MPOs) and any other organizations, groups or stakeholders expressing an interest in the process.

The NHS is the centerpiece of the ISTEA, and the system is expected to be the major focus for the Federal-aid highway program into the 21st century. It is critically important, therefore, for the Federal Highway Administration (FHWA) to play a strong leadership role in the development of the proposed NHS to ensure that national objectives are achieved. Attachment 1 describes specific areas that require a strong Federal emphasis during the development of the proposed NHS. We are asking that you, the Division Administrators and appropriate regional and division office staffs work closely with the States and, where appropriate, with the MPOs and others in this effort. The successful completion of this important activity will depend on the combined efforts of the States, MPOs and FHWA.

Section 1006(a) directs the Secretary to submit a proposed NHS to the Congress for approval not later than December 18, 1993. This section establishes a limitation of 155,000 miles for the proposed NHS but permits the Secretary to increase or decrease the maximum mileage by up to 15 percent. Section 1006(a) also states that the illustrative NHS, submitted to the Congress in February 1991, "* * * shall serve as the basis for the States in proposing arterials and highways for designation to such system." Accordingly, the rural and urban mileage totals by State represented by the 150,000-mile illustrative NHS will be used as the starting point for developing the proposed NHS. Rural and urban mileage targets and related instructions for use by the States in proposing routes for the NHS are included in Attachments 1 through 6. Two copies of a map depicting the rural component of the illustrative NHS in each State are also attached.

We do not plan to conduct NHS workshops; however, if a region, or multiple regions, decide to schedule a workshop, Planning and Programming Branch staff members are available to participate. Requests for technical assistance or participation in workshops should be directed to Mr. Robert A. Gorman, (202) 366–5001.

Policy questions related to this memorandum and the attached instructions should be directed to Mr. Richard A. Torbik, Chief, Planning Programs Division (202) 366–0233 or Mr. Thomas R. Weeks, Chief, Planning and Programming Branch on (202) 366–5002. Technical questions should be directed to Mr. Gorman.

E. Dean Carlson

7 Attachments

Attachment 1—General Approach for Developing the Proposed National Highway System and Areas of Federal Emphasis

Section 1006 of the Intermodal Surface Transportation Assistance Act (ISTEA) of 1991 directs the Secretary to develop a proposed National Highway System (NHS) in cooperation with the States and local officials. This section establishes a limitation of 155,000 miles for the proposed NHS, but the Secretary is authorized to increase or decrease the maximum mileage by up to 15 percent. The broad criteria contained in the statement of purpose and the required components identified in Section 1006 provide the principal bases for developing the proposed NHS. Section 1006 also specifies that the routes on the map illustrating the NHS submitted to the Congress in February 1991, will serve as the basis for the States in proposing routes for the system. The proposed NHS must be submitted to the Congress for approval not later than December 18, 1993. No funds may be apportioned for the NHS or the Interstate maintenance program after September 30, 1995, unless the Congress approves a law designating the NHS.

Because of the national significance of the NHS, it is critical that the Federal Highway Administration play a strong role in its developing the proposed NHS in cooperation with the States and local officials. Accordingly, the instructions for developing the proposed NHS emphasize a cooperative Federal/State/local process.

Purpose (Objective) of the NHS (Section 1006 of the ISTEA)

"Provide an interconnected system of principal arterial routes which will serve major population centers, international border crossings, ports, airports, public transportation facilities, and other intermodal transportation facilities and other major travel destinations; meet national defense requirements; and serve interstate and interregional travel."

General Approach

The instructions contained in this and related attachments are intended to yield a 150,000- to 155,000-mile proposed NHS; however, the final mileage may vary. Mileage targets based on the 150,000-mile illustrative NHS, submitted to the Congress in February 1991, will serve as the starting point for developing the proposed NHS. This approach is consistent with the direction provided in Section 1006 that the illustrative NHS "* * * serve as the basis for the States in proposing arterials and highways for designation * * *." Rural and urban mileage targets are contained in Attachment 2. All components of the NHS identified in Attachments 3 and 4 must be satisfied with the mileage targets; however, the instructions provide an opportunity for the States and metropolitan planning organizations (MPOs) to propose routes, within certain constraints, which exceed the mileage targets. This approach will provide needed flexibility to achieve an equitable system that meets the objectives of section 1006.

Consistent with the traditional Federal/State relationship in administering the Federal-aid highway program, the States are expected to take the lead in working with the MPOs and other local officials to (1) identify routes for the proposed NHS, (2) coordinate with adjacent States to achieve an integrated system consistent with the objectives of the NHS, and (3) submit all required products to FHWA.

Because of the December 18, 1993, deadline established by the ISTEA for submitting the proposed NHS to the Congress, it may not be possible to fully integrate this effort with implementation of the statewide transportation planning requirements of 23 U.S.C. 135. Nevertheless, the States are encouraged to work within the framework of the requirements of 23 U.S.C. 135 to develop the proposed NHS. To the extent practicable, the public involvement processes established under 23 U.S.C. 135 should be utilized during the development of the proposed NHS.

The strategic highway network (STRAHNET) and major STRAHNET connectors are required components of the NHS. Specific instructions regarding these routes are included in Attachment 3. These routes must be included as a part of the proposed systems submitted by the States. If a State believes that there is a superior alternative to a STRAHNET corridor, or part of a corridor, or to a major STRAHNET connector, the reason(s) for the recommended change must be provided. Proposed changes to the STRAHNET corridors and major STRAHNET connectors will be coordinated by the Planning and

Programming Branch with the Military Traffic Management Command (MTMC). If the MTMC and FHWA concur with the proposed change, the Planning and Programming Branch will make appropriate adjustments to the proposed NHS and advise the affected State(s). In the event changes occur in the operational status of military installations served by major STRAHNET connectors during the development of the NHS, adjustments will be made to the proposed NHS in cooperation with the States.

Attachment 5 provides specific instructions covering a variety of issues and special cases affecting the development of the proposed NHS. Where appropriate, the States and MPOs are expected to work together and with the FHWA field offices to resolve conflicts and issues such as system connectivity, parallel routes in adjacent States, etc.

Federal Emphasis

It will be necessary for the regions and divisions to work closely with the States and the MPOs during the development of the proposed system. Specific areas of Federal emphasis are identified and discussed below.

• Multi-State corridors—Providing an interconnected system of arterial routes which serve major population centers and interstate and interregional travel is a major objective of the NHS. Each State (except Alaska, Hawaii, Puerto Rico) will need to work closely with adjacent States to achieve this objective. Likewise, the regions and divisions should place a strong emphasis on multi-state corridors in working with the States during the development of the proposed NHS. This area will also receive considerable emphasis in reviews by the Office of Environment and Planning.

• State connectivity—As with multi-state corridors, special attention must be given to achieving an integrated system. Each State will be expected to work closely with adjacent States to resolve any issues affecting connections at State lines. Where necessary, the regions and divisions should work with affected States to achieve an integrated system.

• Relationship to the Interstate System—The NHS will consist of the most important principal arterials and as such will serve as an extension of the Interstate System. In some cases the noninterstate NHS routes will be logical additions to the Interstate System; therefore, States are encouraged to propose NHS corridors that may provide logical future additions to the Interstate System and that provide service between existing Interstate corridors.

• Rural/urban connectivity—The proposed NHS must provide for system connectivity between rural and urban areas of the State; therefore the States must work closely with the MPOs during the development of the system to ensure system continuity across urban boundaries. Where necessary, the divisions should work with the States and MPO to achieve this objective.

• Role of local officials and the MPOs—Section 1006 of the ISTEA provides that "the States, in cooperation with local and regional officials, shall propose to the Secretary arterials and highways for designation to the National Highway System * * *." This section further states that "in urbanized areas, the local officials shall act through the metropolitan planning organizations designated for such areas under section 134 * * *." Clearly, the Congress intends for local officials to be actively involved in identifying proposed routes for the NHS. Accordingly, the States must seek, encourage and provide opportunities for the cooperative involvement of the MPOs and other local officials, including representatives from affected Indian tribal governments and land owning Federal agencies, in this process. The regions and divisions should be particularly aware of this requirement and assist the States, where appropriate, in establishing a process to obtain the cooperation of local officials in developing the proposed system.

• High priority corridors—Section 1105 of the ISTEA identifies 21 "high priority corridors" for inclusion in the NHS. Although section 1005 specifies that the high priority corridors must be included in the proposed NHS, affected States may have concerns about including certain corridors. The States should be asked to take a hard look at the high priority corridors and advise the FHWA if any are not logical or appropriate as NHS routes. If high priority corridors lack State support for inclusion in the proposed NHS and FHWA agrees, a recommendation will be included in the report to the Congress that the corridor(s) not be included in the final NHS. The regions and divisions are asked to work closely with the States in looking at these corridors, particularly those which involve more than one State.

Attachment 2—National Highway System Mileage Targets

Consistent with the direction provided in section 1006 that routes on the illustrative National Highway System (NHS) "* * * serve as the basis for the States in proposing arterials and highways for designation * * *", each State is provided an urban and a rural mileage target based on the 150,000-mile illustrative NHS submitted to the Congress in February 1991. These mileage targets are listed in Table 1. Because of changes in urban area boundaries and the need for flexibility to develop the proposed NHS, States are permitted to transfer up to 15 percent of the rural mileage to the urban category without FHWA approval. Likewise, the States and metropolitan planning organizations acting cooperatively may transfer 15 percent of the urban mileage to the rural category without FHWA approval. If a State desires to transfer more than 15 percent of the mileage from urban to rural or vice versa, the transfer must be approved by FHWA (Headquarters).

Although the States are required to use the urban mileage in urban areas (except as provided above), it is not necessary that each urban or urbanized area receive the same relative share of the mileage. The relative share of mileage in each urban area is expected to vary due to differences in size and configuration.

The mileage targets provide a starting point for developing the proposed NHS. The FHWA anticipates that some States will propose a system that is smaller than the combined mileage target (rural plus urban) while other States will propose a system that is larger than the combined mileage target. The FHWA feels that is important to maintain a national perspective on the overall size of the system; therefore, FHWA (Headquarters) will make the final determination, after consultation with affected States, on proposed routes that exceed the mileage targets. Attachment 4 provides instructions for justifying proposed routes that exceed the mileage targets.

Attachment 3—Required National Highway System Components

The following are required components of the National Highway System (NHS):

• Interstate routes. All Interstate routes including routes designated under 23 U.S.C. 139(a) and 139(c) shall be included. Future additions as to the Interstate System approved under 23 U.S.C. 139(b) should also be included.

• STRAHNET routes. Section 1006 of the ISTEA lists the strategic highway network (STRAHNET) as one of the components of the NHS. All STRAHNET routes contained in the Military Traffic Management Command (MTMC) report, Strategic Highway Corridor Network, MTMC Report SE 89–4b–27, January 1991 should be included; unless revisions are approved by HEP–12.

• Major STRAHNET Connectors. Section 1006 of the ISTEA also specifies major strategic highway connectors as a component of the NHS. Major STRAHNET connector routes are listed in the MTMC report, STRAHNET Connector Atlas, MTMCTEA Report SE 89–4b–59, September 1991. Major STRAHNET connectors are those providing connections to priority 1 and 2 installations. (Note: Two priority 3 installations—the Savanna Army Depot, Illinois and the Iowa Army Ammunition Plant, Iowa—have recently been upgraded to priority 2 and should also be included.) If more than one connection is identified, route A should be included, other routes *may* be included. Both routes A and B should be included for Fort Stewart, Georgia and Fort Drum, New York. Any deviations or revisions must be approved by the Planning and Programming Branch (HEP–12). (Some priority 1 and 2 installations may be scheduled for closing by the Department of Defense. If these bases are actually closed, some future adjustments to the proposed NHS may be necessary.)

Note: Although there has been considerable effort to establish and adjust the STRAHNET routes and the STRAHNET connectors in cooperation with MTMC, further refinements may be warranted. If a more suitable route exists that serves the same corridor, HEP–12 will work with the MTMC in evaluating such proposals. However, until changes are approved by FHWA and MTMC, the existing routes shall be included.

• Congressional High Priority Routes. These routes are listed in Section 1105 of the ISTEA. The following list is provided to clarify any ambiguities concerning the alignments of these routes:

1. North-South corridor from Kansas City, Missouri to Shreveport, Louisiana. This route

basically follows the US 71 route alignment. Refer to Section 1105(f) 3, 14, 15, 21.

2. Avenue of the Saints, St. Louis, Missouri to St. Paul, Minnesota. The Corridor B alignment is the preferred route.

3. East-West Transamerica Corridor. A feasibility study for this corridor authorized by the FY 1991 Department of Transportation Appropriations Act and Section 1105(f) is underway. No alignment will be specified until that study is complete.

4. Hoosier Heartland Industrial Corridor. This route follows In 25 and US 24 from Lafayette, Indiana to Ft. Wayne, Indiana, then US 24 from Ft. Wayne, Indiana to Toledo, Ohio.

5. I–73/74 North-South Corridor from Charleston, South Carolina through Winston-Salem, North Carolina to Portsmouth, Ohio to Cincinnati, Ohio and Detroit Michigan. This route connects Detroit, Michigan; Toledo, Ohio; Columbus, Ohio; Portsmouth, Ohio (a separate leg connects Cincinnati, Ohio to Portsmouth, Ohio). From Portsmouth Ohio, the route generally follows US 52 to Bluefield, West Virginia. Then the route proceeds in a southeast direction (west of Roanoke, Virginia and west of Fayetteville, North Carolina) to Myrtle Beach, South Carolina and then to Charleston, South Carolina. Also, refer to the three high priority segments of this corridor in West Virginia listed in Section 1105(f), numbers 10–12.

6. US 80 from Meridian, Mississippi to Savannah, Georgia. This route follows US 85 from Meridian, Mississippi to Montgomery, Alabama. East of Montgomery, it follows I–85 and US 80 and GA 96 to Macon, Georgia. East of Macon, it follows I–16 to Savannah, Georgia.

7. East-West Corridor from Memphis, Tennessee through Huntsville, Alabama to Atlanta, Georgia and Chattanooga, Tennessee. Section 1105(f) lists a high priority segment along US 72. This route follows US 72 from Memphis, Tennessee to Leighton, Alabama; US Alt 72 from Leighton, Alabama to Huntsville, Alabama (including I–565). The route forks at Huntsville, Alabama with one leg going to Chattanooga, Tennessee via US 72 and the other to Atlanta, Georgia via AL 35 from Scottsboro, Alabama to Cedar Bluff, Alabama; AL 9 from Cedar Bluff, Alabama to the Alabama–Georgia state line; GA 20 to Rome, Georgia and I–75 to Atlanta, Georgia.

8. Highway 412 East-West Corridor from Tulsa, Oklahoma through Arkansas along US 62/63/65 to Nashville, Tennessee. Refer to Section 1105(f), numbers 4, 5, and 29.

9. US route 220 and the Appalachian Thruway Corridor from Business 220 in Bedford, Pennsylvania to the vicinity of Corning, New York. Refer to Section 1105(f), numbers 1 and 6.

10. Appalachian Regional Corridor X.

11. Appalachian Regional Corridor V.

12. US route 25E corridor from Corbin, Kentucky to Morristown, Tennessee via Cumberland Gap including a portion of route 58 in Virginia which lies within the Cumberland Gap Historical Park.

13. Raleigh-Norfolk Corridor. Refer to Section 1105(f), number 13.

14. Heartland Expressway from Denver, Colorado through Scottsbluff, Nebraska to Rapid City, South Dakota. I–76 from Denver, Colorado to I–90 near Rapid City, South Dakota. Alignment to be determined, although potentially through Fort Morgan, Colorado; the Nebraska panhandle cities of Kimball, Scottsbluff-Gering, Alliance, Chadron; and north into South Dakota, skirting the Black Hills to the east and terminating at I–90. Also, refer to feasibility study authorized by Section 1105(f), number 7.

15. Urban Highway Corridor M–59 in Michigan. Follows M–59 from I–94 to I–96.

16. Economic Lifeline Corridor along I–15 and I–40 in California, Arizona, and Nevada. Refer to Section 1105(f), number 20.

17. Route 29 corridor from Greensboro, North Carolina to the District of Columbia.

18. Corridor from Indianapolis, Indiana to Memphis, Tennessee through Evansville, Indiana. Refer to Section 1105(f), number 26.

19. US 395 from Canadian border to Reno, Nevada.

20. US 59 from Laredo, Texas through Houston, Texas to vicinity of Texarkana, Texas.

21. US 219 from Buffalo, New York to intersection of US 17 in vicinity of Salamanca, New York.

• Other corridors: US 219 from I–68 in Maryland to Buffalo, New York. This corridor is specified in Section 1069 of the Intermodal Surface Transportation Efficiency Act of 1991.

Attachment 4—Other National Highway System Components

Attachment 3 describes the required elements of the National Highway System (NHS), i.e., Interstate, strategic highway network (STRAHNET), major STRAHNET connectors and high priority corridors. Additional routes are required to provide access between the NHS and major ports, airports, public transportation facilities, and other intermodal transportation facilities, and to adequately serve interstate and interregional travel. A process approach will be used to identify the additional routes required to complete the proposed NHS. In other words, specific criteria will not be provided by the FHWA on which ports, airports, etc., must be served and the level of access that must be provided. The FHWA has determined that these criteria can best be addressed by the States in cooperation with the metropolitan planning organizations (MPOs), the port and airport authorities, or other public organizations and agencies involved with public transportation facilities and intermodal transportation facilities.

Access Between the NHS and Major Ports, Airports, Public Transportation Facilities or Intermodal Transportation Facilities

Improved intermodal connectivity is a major objective of the NHS, and this area should be given special attention in identifying the proposed NHS. The States are expected to work closely with the MPOs and other affected agencies to identify which intermodal terminals and facilities should be served by the NHS and the level of access that is needed to meet the objectives of the NHS.

International Border Crossings

As with access to major ports, airports, etc., specific criteria will not be provided. The appropriate States should evaluate the relative importance of all border crossings to international travel and commerce in deciding which should be served by the proposed NHS. As a rule of thumb, only border crossings that are open 24 hours and allow access to commercial travel should be considered. Coordination with adjacent States may be necessary to ensure that spacing between routes serving international border crossings is consistent with the objectives of the NHS.

Other Rural and Urban Principal Arterials

Nationally, the required components of the NHS (i.e., Interstate System, STRAHNET, major STRAHNET connectors, and high priority corridors and routes providing access to major ports, airports, public transportation facilities and intermodal transportation facilities) are expected to account for 75,000 to 80,000 miles of the proposed NHS. The remaining routes—70,000 to 75,000 miles—must be comprised of routes functionally classified as rural and urban principal arterials. The States and MPOs have the flexibility to propose routes for the system within the remaining mileage that are consistent with the objectives of the NHS and that are responsive to the areas of Federal emphasis identified in Attachment 1. Consideration should also be given to principal arterial routes on the National Network for trucks and those that provide service to major travel generators such as National Parks, commercial recreation facilities, resorts, etc.

States may propose routes which exceed the mileage targets contained in Attachment 2; however, sufficient justification must be provided to permit FHWA to evaluate the relative importance of the routes and whether they meet the objectives of the NHS. The mileage for these routes should not exceed 15 percent of the total mileage target for the State. At a minimum, the following information should be provided:

1. Relationship of route(s) to adopted plans such as trunk highway system, arterial highway plan, long-range system plan, etc.

2. Amount of commercial vehicle travel.

3. Importance to State economic development plans and programs.

4. Importance to regional or interstate travel and relationship to routes in adjacent States to form multi-state corridors.

5. Relative priority of routes if more than one route is identified.

The FHWA will evaluate the information submitted by the States and, in consultation with the affected States, determine which routes meet the purpose and objectives of the NHS.

Attachment 5—Special Instructions

The following special instructions are provided to address a variety of issues that may arise during the development of the proposed National Highway System (NHS):

1. Toll Roads—States are strongly encouraged to identify all major toll

roads for the proposed NHS even if they do not intend to use NHS funds for improvements to the routes. If major toll roads are not included, a significant portion of the principal arterial mileage in a State could be excluded from the NHS, and it may be difficult to achieve a continuous interconnected system. The States are reminded that NHS funds may be used for improvements on toll facilities; however, if they do not use the funds in this manner, the funds may be used on other NHS routes or transferred to the STP program.

2. Regional Offices should monitor the development of the proposed NHS to ensure that there is close coordination among States, particularly for routes that cross State boundaries. If adjacent States identify parallel routes in the same corridor, FHWA expects the affected States to make every effort to decide on a single route for the corridor. For urbanized areas that extend across State lines, close coordination among the States and local jurisdictions involved will be required to insure that all proposed NHS routes connect across jurisdictional lines. In the absence of agreement among States or between a State and an MPO over which route should be included, FHWA will make the final determination.

3. Proposed NHS routes in urban and rural areas should connect with each other and provide a continuous interconnected system. However, there may be instances where a route serves a major travel generator and a stub connection cannot be avoided.

4. If parkways are identified for the NHS and trucks are excluded from the parkways, one parallel facility to accommodate trucks may be included without the State having to count that additional mileage against its mileage target. If the parkway is under the jurisdiction of the National Park Service, it should be consulted about the inclusion of parkway on the NHS.

5. If a route is functionally classified as a principal arterial and included in a short-range program (5–6 years) it may be included on the NHS even though the route is not yet constructed or open to traffic.

6. States should be encouraged to take a long-term, system perspective in identifying routes for the NHS. The functional classification should not be distorted so that less important routes could become eligible for inclusion on the NHS. States are encouraged to identify all important routes that meet the objectives of the NHS even if some are currently in good condition and may not need improvements in the foreseeable future.

7. The mileage for a proposed NHS route that passes through Federal lands must be counted against the State's mileage target if the route is under State jurisdiction. If the route is under the jurisdiction of a Federal agency, the mileage will not be counted against the State's mileage target. The Federal agency having jurisdiction over the route, must be consulted about including the route on the proposed NHS.

8. Ferry boat routes may be considered part of the NHS if they provide logical connections with other NHS routes. The ferry route mileage will not count against the State's mileage target.

9. Mileage for one-way pairs should only be counted once. The mileage for both routes should be added and then divided by 2 for reporting the mileage.

10. The Territories are not required to develop an NHS.

11. The illustrative NHS contains numerous stubs that were included in an attempt to provide service to all urban areas greater than 10,000 population (Access America). Since Access America is not a specific criteria for developing the proposed NHS, these stub connections should be reevaluated to determine whether they would make logical extensions of the NHS.

Attachment 8—Schedule and Products

Schedule

The proposed National Highway System should be submitted by the States to the FHWA division offices by April 30, 1993. After appropriate reviews by the divisions and regions, the proposed NHS for each State should be forwarded to the Planning and Programming Branch (HEP–12) by June 30, 1993, or sooner if possible. The proposed NHS must be submitted to the Congress by December 18, 1993.

Products

In order to ensure consistency in interpreting the results among States, uniform conventions have been established. The States are asked to adhere to these conventions in preparing the required products. States should submit 3 copies of a map depicting the proposed NHS in rural and urban areas to the FHWA division office. Inserts or separate maps for all urbanized areas should be included. The scale for the urbanized inserts should not be less than 1": 100,000". The following conventions should be adhered to:

1. Adjusted Census urban boundary or Census designated boundary—Black solid line
2. Interstate highways—Blue solid line
3. STRAHNET routes—Green solid line
4. Major STRAHNET Connectors—Purple solid line
5. Congressional high priority corridors—Orange solid line
6. Other principal arterial routes—Red solid line

(All future routes should be depicted with the appropriate color but should be shown as dashed lines.)

Symbols will be used to represent major airports, seaports, etc. The following convention should be used:

1. Major Airport—A
2. Major Seaport (River & Lake Ports)—P
3. Other Major Intermodal Terminal—T
4. Major International Border Crossings—B
5. Military Installations—M

The States are also requested to provide a list of all proposed NHS routes. This list should include the route number, total length, urban length, and a brief description. The list should basically follow a format similar to the former Federal-aid Primary list contained in 23 CFR part 470, appendix B. See example below.

Appendix B.—Primary Federal-Aid System

[State: Alpha]

Route No.		Route description and termini	County	Mileage[1]			
Fed. aid	State or local			Rural	Urbanized	Small urban	Total
1	S.R. 1	From the California-Nevada State line southwest of Verdi via Reno, Fernley, Lovelock, Winnemucca, Battle Mountain, Elko, and Wells to the Nevada-Utah State line at Wendover, Utah, with a spur from FAP Route 1 southerly along 17th St. to FAS Route 705 (Glendale Rd.) in Sparks. Approved Jan. 1, 1984, revised Dec. 7, 1984.	Washoe	41.5	5.4		46.9
			Storey	.2			.2
			Lyon	18.3			18.3
			Churchill	27.7			27.7
			Pershing	75.0			75.0
			Humboldt	61.3			61.3
			Lander	28.8			28.8
			Eureka	28.4			28.4
			Elko	131.3		3.2	134.5
			Total	408.5	5.4	3.2	415.1
2	C.R. and State Routes 2, 2a, 3, 19, and 24.	From the California-Nevada State line southwest of Glenbrook via Carson City, Dayton, Leeteville, Fallon, Austin, Eureka, and Ely to a junction with FA Route 1 near Wendover, Utah. Approved Jan. 1, 1984, revised July 27, 1987.	Churchill	104.8			104.8
			Douglas	15.3			15.3
			Elko	53.2			53.2
			Eureka	47.4			47.4
			Lander	59.0			59.0
			Lyon	35.3			35.3
			Ormsby	14.4		2.0	16.4
			White Pine	132.7			132.7
			Total	462.1		2.0	464.1
3	S.R. 3, 1, 70 and local road.	From the California-Nevada State line at Topaz Lake via Minden to a point on FA Route 2 south of Carson City via Reno to the Nevada-California State line northwest of Reno, with a spur in Reno from FAM Route 3 via East Plumb Lane to the Reno Municipal Airport. Approved Jan. 1, 1984, revised Aug. 25, 1985.	Douglas	34.1			34.1
			Ormsby	3.4		9.8	4.2
			Washoe	34.2	6.9		41.1
			Total	71.7	6.9	9.8	79.4

[1] For routes extending into or through 2 or more counties, show the mileage separately for each county. Show grand total for the system on last sheet.

Attachment 7 is not available for publication.

MEMORANDUM

Date: June 5, 1992.
Reply to Attn. of: HEP–32.
Subject: *Information:* Transportation Enhancement Activities.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators, Federal Lands Highway Program Administrator.

Our April 24 memorandum on this subject had an error which we would like to correct. The third sentence on page 4 should read:

In addition, 10 percent of half of the funds provided as (1) reimbursements for the segments of the Interstate System constructed without Federal assistance under 23 U.S.C. 160 and (2) apportionment adjustments made pursuant to subsections 1015(a)–(c) of ISTEA are available only for transportation enhancement activities.

As originally written, this sentence did not reflect that only half of the funds in the categories mentioned are subject to the 10 percent requirement.

Anthony R. Kane

MEMORANDUM

Date: April 24, 1992.
Reply to Attn. of: HEP–32.
Subject: Transportation Enhancement Activities.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators Federal Lands Highway Program Administrator.

Section 1007(a) of the ISTEA, adding 23 U.S.C. 133(d)(2), requires that 10 percent of the new Surface Transportation Program funds only be available for transportation enhancement activities. Section 1007(c), amending 23 U.S.C. 101(a), defines transportation enhancement activities. Section 1024, amending 23 U.S.C. 134(f)(5), specifies that the programming of transportation enhancement activities is a factor to be considered in the development of metropolitan transportation plans and programs. Section 1025, adding 23 U.S.C. 135, specifies that the statewide transportation improvement program shall reflect the priorities for programming and expenditure of funds, including transportation enhancements. This memorandum provides interim guidance concerning the interpretation of these provisions.

Qualifying Activities

Several field offices have asked whether the list of activities in section 1007(c) is exclusive or illustrative. It is exclusive. Only those activities listed in section 1007(c) are eligible to be accounted for as transportation enhancement activities. They are:

1. Provision of facilities for pedestrians and bicycles.
2. Acquisition of scenic easements and scenic or historic sites.
3. Scenic or historic highway programs.
4. Landscaping and other scenic beautification.
5. Historic preservation.
6. Rehabilitation and operation of historic transportation buildings, structures, or facilities (including historic railroad facilities and canals).
7. Preservation of abandoned railway corridors (including the conversion and use thereof for pedestrian or bicycle trails).
8. Control and removal of outdoor advertising.
9. Archaeological planning and research.
10. Mitigation of water pollution due to highway runoff.

Many projects are a mix of elements, some on the list and some not. Those project elements which are on the list may be counted as transportation enhancement activities. For example, a rest area might include a historic site purchased and developed as an interpretive site illustrating local history. The historic site purchase and development would qualify as a transportation enhancement activity.

Activities which are not explicitly on the list might qualify if they are an integral part of a larger qualifying activity. For example, if the rehabilitation of a historic railroad station required the construction of new drainage facilities, the entire project could be considered a transportation enhancement activity. Similarly, environmental analysis, project planning, design, land acquisition, and construction activities necessary for implementing qualifying transportation enhancement activities are eligible for funding and may be counted toward the 10 percent requirement.

Transportation Enhancement and Environmental Mitigation

The Congress included the language on transportation enhancements as a means of stimulating additional efforts in the activities listed. Enhancement measures in the activities listed that go beyond what is customarily provided as environmental mitigation can be considered as transportation enhancement. States may not use transportation enhancement funds to finance normal environmental mitigation work. We realize that the process of determining which activities will be considered as normal mitigation and which will be accounted for as transportation enhancement activities will be difficult. Initially, it will require close coordination between the State DOTs and their FHWA Division Offices on a case-by-case basis.

Project Linkage

The definition of transportation enhancement activities includes the phrase, "with respect to any project or the area served by the project." Given its overall context, we interpret this phrase to mean that the proposed transportation enhancement activity must have a direct relationship to the intermodal transportation system, but not necessarily to a currently planned highway project. This relationship may be one of function, proximity, or impact. For example, an independent bike path is a functional component of the intermodal transportation system. Removal of outdoor advertising in the viewshed of a highway is justified in light of its proximity. Retrofitting an existing highway by creating a wetland to filter runoff from the highway would qualify based on the impact of the highway in terms of water pollution.

Once a relationship to the intermodal transportation system is established, transportation enhancement activities can be implemented in a variety of ways. They can be developed as parts of larger transportation projects, as parts of larger joint development projects, or as stand-alone projects.

Planning Process

The metropolitan and Statewide planning processes should occupy a central role in the identification, planning, and funding of transportation enhancement activities. In particular, the planning processes are the appropriate mechanisms for determining funding priorities from among competing transportation enhancement activities, including those which are not part of larger transportation projects. FHWA field offices should strongly encourage the States and metropolitan planning organizations (MPOs) to seek out and fully integrate transportation enhancement activities into both their plan development and programming processes. To be funded, transportation enhancement activities must be included in the appropriate metropolitan and statewide transportation improvement programs.

Given the widespread public interest in transportation enhancement activities, they should be highlighted in public involvement activities implemented under the new metropolitan and statewide planning requirements. Procedures for planning, programming and developing transportation enhancement activities are of special interest to public interest organizations and members of the general public.

Project Development

Building on the work done in the planning process, State DOTs, MPOs, and FHWA field offices have a responsibility to actively pursue transportation enhancement opportunities during the development of individual transportation projects. Accordingly, future environmental approvals should specifically take into consideration the potential for implementing transportation enhancement activities as part of the overall projects. During their involvement on these projects, FHWA field offices should promote transportation enhancement activities as a means of more creatively integrating transportation facilities into their surrounding communities and the natural environment.

Where appropriate, transportation enhancement activities may be developed in cooperation with other State and local agencies and with private entities. However, the State DOT or other eligible transportation agency shall remain responsible to the FHWA for the enhancement project. Furthermore, transportation enhancement activities, including stand-alone transportation enhancement projects, must comply with all applicable environmental and other Federal requirements, even though the express purpose of the project is to enhance an element of the natural or cultural environment.

Financial Accounting

The funds made available only for transportation enhancement activities are derived from several sources. The main source is the STP, of which 10 percent is available only for transportation enhancement activities. In addition, 10 percent of (1) the funds resulting from reimbursements for segments of the Interstate system constructed without Federal assistance under 23 U.S.C. 160 and (2) the apportionment adjustments made pursuant to Subsection 1015(a)–(c) of ISTEA are available only for transportation enhancement activities.

The Office of Fiscal Services has already established an appropriation code for transportation enhancement activities and has notified you of the FY 1992 STP suballocation amounts available only for transportation enhancement activities. While 10 percent of each year's STP apportionment may be obligated only for transportation enhancement activities, there is no requirement that 10 percent of the funds for any given project be devoted to transportation enhancement activities, nor is there a requirement that 10 percent of the STP obligations made during a given fiscal year be devoted to transportation enhancement activities.

Section 1007 specifies that the 10 percent of STP funds for transportation enhancement activities is separate from the STP funds which are suballocated to the larger metropolitan areas and to other areas of the State. Accordingly, while the STP sub-State allocation funds can be used for transportation enhancement activities, any such use would not count toward the 10 percent requirement.

Monitoring Program Accomplishments

Guidance on reporting requirements will be forthcoming. It is very likely that States will need to prepare an annual report on overall STP obligations. To cover this contingency, States should maintain records on (1) the amounts obligated for transportation enhancement activities using the STP transportation enhancement appropriation code (counting toward the 10 percent requirement) and other STP funds (not counting toward the 10 percent requirement), and (2) how obligations for transportation enhancement activity are distributed among the 10 qualifying activities. A brief description of each specific transportation enhancement action for which STP funds have been obligated would also be very useful information.

Further Information

The transportation enhancement provisions offer exciting new opportunities to achieve the goals laid out in the National Transportation Policy, FHWA's Environmental Policy Statement, and FHWA's strategic planning process. This is an area that will undoubtedly evolve rapidly as we begin implementing projects under the new authority. We will be issuing additional guidance and sharing information on successful endeavors as the opportunities arise. In the meantime, please keep us informed about good examples of transportation enhancement efforts in your region. Our contact on transportation enhancement activities is Mr. Fred Skaer. He can be reached at FTS 366–2058.

Anthony R. Kane

MEMORANDUM

Date: March 5, 1992.
Reply to Attn of: HEP–23.
Subject: *Information:* Flexibility in the Intermodal Surface Transportation Efficiency Act (ISTEA).
From: Executive Director.
To: Regional Federal Highway Administrators Federal Lands Highway Program Administrator.

To highlight the flexibility in the use of highway and transit funds within the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991, the Federal Transit Administration (FTA) and the Federal Highway Administration sent out the attached letter to transportation professionals representing State Departments of Transportation, Metropolitan Planning Organizations (MPO's), and transit operators. I endorse this flexibility message and challenge you to take an active role in working with the States and MPO's in implementing multimodal transportation plans and programs.

I want this flexibility to work the way it was intended to, that is, for transportation investment decisions to be made on a level playing field, with no built-in biases or upfront advantages given to one mode over

another. This level playing field is supported by the equivalent cost sharing for highway and transit capital projects and the enhanced metropolitan planning provisions and the new requirement for statewide planning in ISTEA. The planning provisions provide the framework for evaluating multimodal transportation options and making cost effective transportation investment decisions.

I am committed to seeing a fair and unbiased evaluation of modal alternatives carried out through the statewide and metropolitan transportation planning and programming processes. To that end, I will continue to work with my colleagues in FTA and ask you to do the same with the States, MPO's and the FTA representatives in your Region.

E. Dean Carlson

Attachment

Federal Highway Administration

March 2, 1992.

Dear Colleague: One of the most important aspects of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) is the increased flexibility of Federal Highway Administration (FHWA) and Federal Transit Administration (FTA) funds. The purpose of this letter is to inform you of the funds available and to encourage you to take advantage of this flexibility as you plan and establish your project priorities.

ISTEA establishes a new FHWA Surface Transportation Program (STP) which provides block grant-type funding which can be used for any type of highway or transit capital project involving either mode. FTA Section 9 funds, capital-only, can be used for highway projects as long as certain specific requirements are met. Flexible funding is also available from the National Highway System (NHS) program and the Congestion Mitigation and Air Quality (CMAQ) program as well as a number of other program sources.

Congestion Mitigation and Air Quality program funds are available in ozone and carbon monoxide non-attainment areas for programs and projects, highway or transit, which contribute to attainment of a National Ambient Air Quality Standard. Projects such as transit capital improvements, high occupancy vehicle treatments and demand management projects are eligible, if they can be shown to help meet air quality standards. Enclosed is more detailed guidance on this program.

Under certain conditions, National Highway System program funds may be used for transit projects in NHS freeway corridors. In addition, NHS funds may be transferred to the STP program and used for all STP-eligible activities.

FTA and FHWA have reached agreement on procedures for handling transit projects funded with FHWA funds and vice versa. In the near future, we will be issuing guidance on these procedures.

We encourage State and local officials to consider use of these funds on the basis of the multi-modal transportation planning/programming process also outlined in the new legislation. The new transportation planning and programming process established by the ISTEA will provide the forum for making transportation investment decisions through a coordinated State and metropolitan area-wide process.

For your information, we have enclosed a table which shows the amount of STP funding which is allocated to each State, and how much of these funds are attributable to each urbanized area over 200,000 population within the States. In addition, the table includes the total amount of section 9 funds allocated to each urbanized area and how much of these funds are capital only, and thus available for highway projects in transportation management areas (urbanized areas over 200,000 population). The table also shows the amount of NHS and CMAQ funds available in each State.

We encourage you to use the flexibility provided through this landmark legislation. We will keep you informed of our progress in developing the details on implementing this important new aspect of our programs. Please do not hesitate to contact our field offices as specific questions arise.

Sincerely,

Brian W. Clymer,

Administrator, Federal Transit Administration.

Thomas D. Larson,

Administrator, Federal Highway Administration.

MEMORANDUM

Date: May 21, 1992.
Reply to Attn. of: HNG–13.
Subject: *Information:* 1991 Intermodal Surface Transportation Efficiency Act (ISTEA) Implementation Interstate Maintenance Program.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators Federal Lands Highway Program Administrators.

The purpose of this memorandum is to provide written guidance regarding the provisions in the 1991 ISTEA which created the Interstate maintenance (IM) program.

Authorizations—Section 1003

Section 1003(a)(1) establishes the first annual authorizations for the IM program for FY 1992 through FY 1997, in amounts ranging from $2.431 billion to $2.914 billion.

Apportionments—Section 1009

Section 1009 modified section 104(b)(5)(B) of title 23, which previously established the apportionment formula for the I–4R program. The formula remains based on the same factors, lane-mile (55 percent) and vehicular miles of travel (45 percent), for apportioning a IM funds, but the formula now includes those Interstate routes designated under sections 103 and 139(c) of Title 23 plus Interstate routes designated under 23 U.S.C., section 139(a) before March 9, 1984 (except toll roads not subject to a secretarial agreement as provided in section 105 of the Federal-Aid Highway Act of 1978). Section 104(b)(5)(B) of title 23 provides that no State shall receive less than one-half percent of the total IM funds apportioned annually.

The certificate of apportionment of FY 1992 funds was transmitted by the FHWA Notice N 4510.264 dated December 18, 1991.

Availability—Section 1020

Section 1020(a) rewrites 23 U.S.C. 118 and provides that IM funds shall remain available for obligation in a State for a period of 3 years after the last day of the fiscal year for which they are authorized. For example, FY 1992 funds were apportioned on December 18, 1991, and will lapse on September 30, 1995, and FY 1993 funds will be apportioned on October 1, 1992, and will lapse on September 30, 1996.

Federal Share—Section 1021

Section 1021(a) provides that the Federal share on all IM projects shall be 90 percent, except as modified in States with sliding scales.

Eligibility—Section 1009

Section 1009(e)(5) amends 23 U.S.C. 119(a) to permit the Secretary to approve IM funded projects for resurfacing, restoring, and rehabilitating routes on the Interstate System designated under sections 103 and 139(c) of title 23, and routes designated prior to March 9, 1984, under section 139(a) and (b) of title 23.

Section 1009(e)(3) amends section 119(c) of title 23 to establish types of work eligible for IM funding. The section has been interpreted to include as eligible, those work items which provide for 3R work on existing features on the Interstate route and its interchanges and grade separations within normal "touchdown limits." For example, the rehabilitation of existing roadside hardware may include IM funding for work such as bringing old guardrail up to current standards, maintenance of impact attenuators, refurbishing existing traffic control signs, pavement markings, and other devices, etc. However, excluded from eligibility for IM funding are all new work elements, such as new interchanges, new ramps, new rest areas, new noise walls, or other work which does not resurface, restore, or rehabilitate an existing element.

Existing bridges (including over crossing structures) may be replaced with IM funds, provided they meet the structurally deficient criteria of the bridge program. Bridges classified as functionally obsolete may also be replaced with IM funding, except that capacity expansion elements should be subject to the limitations discussed in the following paragraphs.

Section 1009(a) prohibits IM funding for the portion of the cost of any project attributable to the expansion of the capacity of any Interstate highway or bridge, except for the addition of high-occupancy vehicle lanes or auxiliary lanes (such as truck climbing lanes).

In determining what portion of a project is eligible for IM funding and what portion is capacity expansion (and, therefore, not eligible for IM funds), the basic purpose of the project should be considered. If the project is a combination of preservation and capacity expansion, the cost should be split with 3R items eligible for IM funding and capacity expansion items eligible for other funds. In determining the split, it may be helpful to visualize the project without the capacity expansion work (added lanes, bridge widening or extension for example) and allow IM funding for all necessary 3R items.

Section 1009(e)(4) amends 23 U.S.C. 119(e) to allow IM funding for preventative maintenance activities, which a State can demonstrate through its pavement management system, are a cost-effective means of extending Interstate pavement life. Preventative maintenance includes activities such as sealing joints and cracks, patching concrete pavement, shoulder repair, and restoration of drainage systems which are found to be cost-effective projects resulting in extending the service life of pavements.

This provision has been extended administratively to allow IM funding for other preventative maintenance activities. Examples may include structure work such as crack sealing, joint repair, seismic retrofit, scour countermeasures, and painting of steel members which are cost-effective in extending the service life of the structure.

Toll Roads, Bridges and Tunnels—Section 1012

Section 1012(d) provides that existing toll agreements entered into under section 119(e) or 129 of title 23 prior to and in effect on the date of enactment of the 1991 ISTEA, shall continue in effect. All new agreements must be executed in accordance with the provisions of the 1991 ISTEA. Guidance on the use of Federal-aid funds on toll roads has been provided by Mr. Kane's memorandum of March 12, 1992.

Discretionary Funds

There is no provision for set aside of funds from the IM program for discretionary purposes. Also there is no provision for reallocation of apportioned IM funds which lapse at the end of the availability period.

Section 1020 does provide for a continuation of the I–4R discretionary fund program that is separate and distinct from the IM program. The source of the I–4R discretionary funds is an annual set aside from National Highway System (NHS) funds. These I–4R discretionary funds may be used for IM-type projects or for other improvements on the Interstate including projects to provide additional Interstate capacity. A memorandum was issued on December 20, 1991, which outlined procedures for applying for FY 1992 I–4R discretionary funds. A similar memorandum will be issued annually.

Transferability—Section 1009

Section 1009(e)(5) (D) and (E) modifies 23 U.S.C. 119(f) to allow a State to unconditionally transfer an amount not to exceed 20 percent of its IM apportionment to its apportionments under 23 U.S.C. 104(b)(1) for the NHS, or 23 U.S.C. 104(b)(3) for the Surface Transportation Program (STP).

Section 1009(b) further amends 23 U.S.C. 119(f) to allow a State to transfer an amount in excess of the 20 percent unconditional IM fund transfer, if the State certifies to the Secretary that (1) the sums to be transferred are in excess of its needs for resurfacing, restoration or rehabilitating its Interstate System routes and (2) the State is adequately maintaining the Interstate System, and if the Secretary accepts the certification.

State requests to transfer IM funds should be submitted to the Division Administrator and may be approved by the Regional Federal Highway Administrator. Funds transferred into the STP will be transferred into the State Flexible Appropriation Code 33D.

Adequate Maintenance of the Interstate System

Requirements for the State to certify that it is adequately maintaining the Interstate System and that the Secretary develop criteria for determining what constitutes "adequate maintenance" were added by section 1009(c)(2).

We anticipate that formal rulemaking may be necessary to allow input from the States in the development of definitive guidance on what constitutes adequate maintenance. Therefore, for the purpose of evaluating State requests to transfer IM funds, in excess of the 20 percent unconditional amount, and until such time as these criteria are established, the guidance contained in the Federal-Aid Policy Guide, CFR 635E and its supplement (old FHPM 6–4–3–1) should be used for determining whether the State is adequately maintaining the Interstate System.

Headquarters Contacts

This guidance will be updated in the future if further clarifications are found necessary. Questions about what constitutes adequate maintenance of the Interstate System should be directed to the Construction and Maintenance Division (HNG–21). Pavement management systems are coordinated by the Pavement Division (HNG–41). Other questions about the IM program should be directed to the Interstate and Program Support Branch (HNG–13).

Anthony R. Kane

MEMORANDUM

Date: October 16, 1992.
Reply to Attn of: TGM–22/HEP–41; M. Savonis, x62080.
Subject: *Information:* Further Guidance on the Congestion Mitigation and Air Quality Improvement Program (CMAQ Program).
From: Federal Transit Associate Administrator for Grants Management; Federal Highway Associate Administrator for Program Development.
To: Regional Federal Transit Administrators; Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

This memorandum provides further guidance for the obligation of funds under the CMAQ program (CM funds), provided by the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991. Information contained in this memorandum supersedes the interim guidance of February 20, 1992, and incorporates the PM–10 policy memorandum of July 30, 1992. This guidance has been coordinated with the Environmental Protection Agency (EPA).

The first CMAQ apportionment was made in December 1991, and the last will not lapse until the end of fiscal year (FY) 2000. (See Figure 1 attached.) It is useful to view the CMAQ Program in three phases; pre-1995, 1995–1997, and post 1997. The pre-1995 phase is the start-up period. The amount of CMAQ funding will accumulate yearly, and obligation rates are expected to increase as the Program develops. The primary activities during this phase will be to get the program started by funding transportation control measures (TCMs) and other eligible projects, and develop and disseminate information on the effectiveness of various CMAQ activities. Program review may also be necessary during this period toward a possible mid-course correction in 1994.

The second phase, FY 1995 through FY 1997, will be a critical time for the Program. During FY 1995, the first CMAQ apportionment is subject to lapse, and activity in the Program will increase and reach its peak. Also during this period, moderate nonattainment areas for particulate matter (PM–10), carbon monoxide (CO) and ozone are scheduled to reach attainment, and the second triennial report to Congress on the effectiveness of transportation programs to improve air quality will be due, as required by the Clean Air Act Amendments (CAAA) of 1990. The best information on the effectiveness of the CMAQ Program will be crucial for this task. Finally, the last authorization for CMAQ funds under ISTEA is for FY 1997. During the post-1997 period of the Program, the most serious nonattainment areas are scheduled to reach attainment.

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CMAQ PROGRAM, Timeline of Important Events

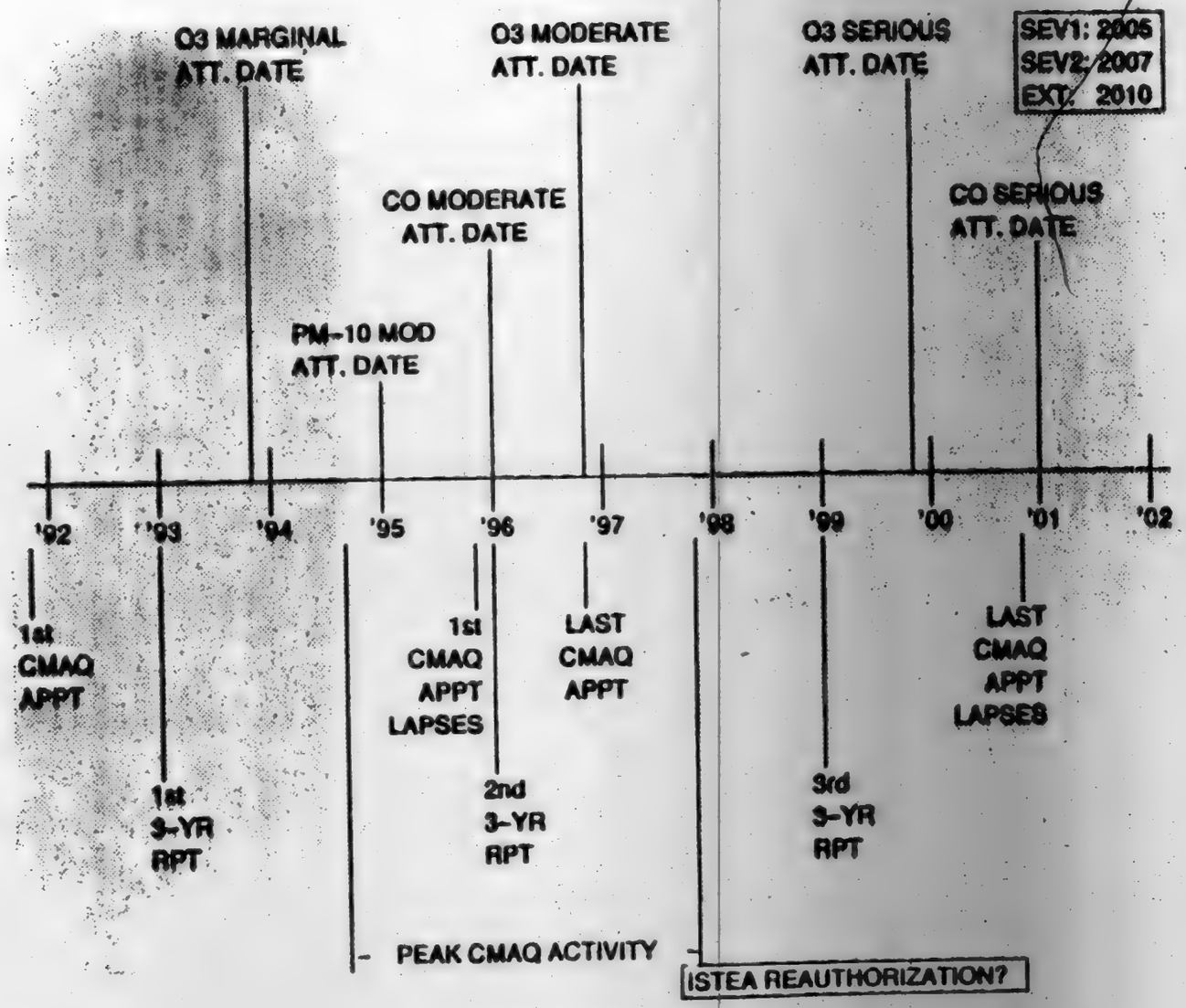

Figure 1

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I. Program Purpose and General Guidance

As established under the ISTEA, the purpose of the CMAQ program is to fund transportation projects or programs that will contribute to attainment of national ambient air quality standards (NAAQS) with a focus on ozone and CO. Under certain conditions, transportation projects and programs targeting PM–10 are also eligible.

Six billion dollars have been authorized by Congress for the CMAQ program for fiscal years 1992 through 1997. The greatest air quality benefit will accrue not solely from these funds but from a partnership of Federal, State and local efforts. In cases where specific guidance is not provided, either below or in other communications, the following should guide CMAQ eligibility decisions. Federal contributions to air quality improvements through CMAQ will be most effective if they are used for establishment of projects and programs that will result in tangible reductions in CO and ozone precursor emissions (and under certain conditions PM–10 pollution) and can be completed within the legislated timeframe for attainment as provided in the CAAA of 1990. Appropriate CMAQ projects and programs include those that would be approved as a TCM in a State Implementation Plan (SIP) and receive emission reduction credit by EPA.

The program is primarily focused on nonattainment areas for ozone and CO, and the guidance below is specific to States with these nonattainment areas. States with no CO or ozone nonattainment areas also receive a minimum apportionment of CMAQ funds, and guidance for these States is covered in section VIII.

The Federal share for most eligible activities and projects is 80 percent or 90 percent if used on certain activities on the Interstate System. Under certain conditions (including sliding scale rates), the Federal share can even be higher. Certain activities identified in section 120(c) of title 23 (see Attachment 1), including traffic control signalization, and commuter carpooling and vanpooling, may be funded at 100 percent Federal share if they meet the conditions of that section. Pedestrian and bicycle projects and programs, however, are limited to an 80 percent Federal share under ISTEA.

II. Program Focus: Ozone, CO and PM–10

States having ozone and/or CO nonattainment areas, which meet the nonattainment classifications contained in the CAAA of 1990, must use these apportioned funds in such nonattainment areas, except under certain conditions where they may also use them in PM–10 nonattainment areas. Under the CMAQ program, States which have ozone nonattainment areas that are classified as "marginal" or worse are apportioned funds based on the population in these areas and the severity of the ozone problem. Under the statute, if the ozone nonattainment area is also a CO nonattainment area, classified as "moderate" or worse, the State is apportioned additional CMAQ funds. If a State contains a CO nonattainment area that is not a nonattainment area for ozone as well, no additional funds are apportioned to the State.

Once apportioned, States generally must obligate these funds for projects and programs in CO or ozone nonattainment areas of the classifications noted above (marginal or worse for ozone, moderate or worse for CO). In certain cases, CMAQ funds may also be used in PM–10 nonattainment areas. States with ozone or CO nonattainment areas, but wishing to use CMAQ funds in PM–10 nonattainment areas, must meet the following requirements.

- The State must consult with, and consider the views of, the EPA regional office and the metropolitan planning organizations (MPOs) in all nonattainment areas for ozone, CO, and PM–10 within the State before programming CMAQ funds for a PM–10 project.
- Also, if the State contains any ozone or CO nonattainment areas, the EPA regional office must agree that the proposed use of CMAQ funds for PM–10 projects or programs will not detract from or delay efforts to attain the ozone or CO standards.

The CMAQ provisions in ISTEA recognize ozone and CO as the primary transportation pollutants. The requirements listed above will ensure proper consideration of the views of the agencies charged with controlling transportation emissions of ozone precursors, CO, and PM–10, especially their views on the most effective use of transportation funds in achieving the NAAQS. The CMAQ eligibility of PM–10 projects will not affect a State's CMAQ apportionment, but has the potential to spread the limited CMAQ funds over a greater number of nonattainment areas within the State.

The consultation and agreement with EPA will ensure that the proposed projects and programs effectively address PM–10 problems without exacerbating other pollution problems. For example, a project which reduces PM–10 emissions in a PM–10 and CO nonattainment area may cause an increase in CO emissions and be therefore less desirable than a project without this CO problem. Examples of projects and programs in a PM–10 nonattainment area eligible for CMAQ funds, if the above requirements are met, are paving dirt roads, diesel bus replacements, and purchase of more effective street sweeping equipment.

In an area which is nonattainment for both PM–10 and ozone or CO, projects and programs which reduce emissions of CO or ozone precursors in addition to reducing PM–10 emissions (e.g. transportation activities in approved State Implementation Plans and transportation control measures listed in Section 108(f)(1)(A) of the Clean Air Act) are not subject to the additional requirements listed above. The requirements apply only to projects and programs whose sole justification for CMAQ eligibility is the reduction in PM–10 emissions.

Except for cases that meet the above criteria, States cannot obligate funds in any other area of the State until all ozone and CO nonattainment areas have come into attainment.

III. CMAQ Programming Priorities

The Clean Air Act requires that FHWA and FTA give priority to the implementation of transportation portions of applicable SIPs, and TCMs from applicable SIPs are provided the highest priority for funding under the CMAQ Program. Some States have reached their ceiling on obligation authority with little use of CMAQ funds.

In view of the Clean Air Act priority requirement, this is inappropriate unless other sources of funds are being directed toward TCMs and transportation portions of SIPs. The SIPs and the control measures they contain are necessary to assist a State to attain and maintain the NAAQS. If States are failing to implement their stated TCMs, adverse consequences can ensue. A basic criterion for making conformity determinations is the timely implementation of TCMs in the SIP, and conformity determinations are necessary before transportation plans, programs, or projects can be adopted or approved. If States fail to give priority to such TCMs, their conformity determinations and transportation initiatives will be in jeopardy. In addition, failing to implement TCMs is also the basis for applying the Clean Air Act's highway funding sanctions. Under certain circumstances, sanctions may now be expanded even beyond the nonattainment areas to cover an entire State. Obviously, close coordination is needed between the State and MPO to assure that CMAQ funds are used appropriately and to maximize their effectiveness in meeting the Clean Air Act requirements.

States and MPOs must fulfill this responsibility so that nonattainment areas are able to meet their attainment dates established in the Clean Air Act. It is crucial that FHWA and FTA assist State and MPO actions to achieve the NAAQS which includes establishing an effective CMAQ Program. State and MPO actions should include consultation with air quality agencies at the State and local levels to develop an appropriate project list of CMAQ programming priorities which will have the greatest impact on air quality. (See VI.B. for a more complete discussion of this process.) Once CMAQ projects and programs are identified, States need to make sure that sufficient obligation authority is reserved to implement these projects and programs so that nonattainment areas make progress toward attainment of the NAAQS.

IV. Project Eligibility

All projects and programs eligible for CMAQ funds must come from a conforming transportation plan and TIP, and be consistent with the conformity provisions contained in section 176(c) of the Clean Air Act. Projects also need to complete the National Environmental Policy Act (NEPA) requirements and be included in the appropriate statewide program.

Transportation projects and programs are eligible for CMAQ Program funds only if they meet certain criteria spelled out in the ISTEA. The CMAQ provisions in the ISTEA are attached (see Attachment 2). In determining project eligibility under these criteria, priority should be given to implementing those projects and programs that are included in an approved SIP as a TCM and will have air quality benefits. Note that to enable FHWA and FTA to fulfill

statutory obligations, all CMAQ-funded projects and programs, whether explicitly covered in this guidance or not, require an assessment and documentation of air quality benefits by the State.

In all cases below, any reference to improving air quality means reducing ozone precursors in ozone nonattainment areas, CO emissions in CO nonattainment areas or, if applicable, transportation-related PM–10 pollution in PM–10 nonattainment areas.

A. Eligible Projects/Programs and Restrictions

The kinds of activities that are eligible for CMAQ funds are described below, together with any restrictions. All possible requests for funding are not covered; instead this section provides particular cases where guidance can be given and rules of thumb applied to assist decisions regarding CMAQ eligibility.

1. Transportation Activities in an Approved SIP

Transportation activities in approved SIPs are generally considered to be eligible activities and must be given the highest priority for CMAQ funding. Their air quality benefits will generally have already been documented. If not, such documentation is necessary before CMAQ funding can be approved. Further, the transportation activity must contribute to the specific emission reductions necessary to bring the area into attainment.

2. Transportation Control Measures

The TCMs included in section 108(f)(1)(A) of the CAAA of 1990 are the kinds of projects intended by the ISTEA for CMAQ funding, and generally fulfill the eligibility criteria. As above and consistent with the statute, air quality benefits for TCMs must be determined and documented before a project can be considered eligible. Two of the CAAA TCMs, however, are specifically excluded from the CMAQ Program by the ISTEA legislation. They are: xii—reducing emissions from extreme cold-start conditions, and xvi—programs to encourage removal of pre-1980 vehicles. Eligible TCMs are listed below as they appear in section 108.

(i) Programs for improved public transit;

(ii) Restriction of certain roads or lanes to, or construction of such roads or lanes for use by, passenger buses or high-occupancy vehicles (HOV);

(iii) Employer-based transportation management plans, including incentives;

(iv) Trip-reduction ordinances;

(v) Traffic flow improvement programs that achieve emission reductions;

(vi) Fringe and transportation corridor parking facilities serving multiple-occupancy vehicle programs or transit service;

(vii) Programs to limit or restrict vehicle use in downtown areas or other areas of emission concentration particularly during periods of peak use;

(viii) Programs for the provision of all forms of high-occupancy, shared-ride services;

(ix) Programs to limit portions of road surfaces or certain sections of the metropolitan area to the use of non-motorized vehicles or pedestrian use, both as to time and place;

(x) Programs for secure bicycle storage facilities and other facilities, including bicycle lanes, for the convenience and protection of bicyclists, in both public and private areas;

(xi) Programs to control extended idling of vehicles;

(xii) Excluded by ISTEA;

(xiii) Employer-sponsored programs to permit flexible work schedules;

(xiv) Programs and ordinances to facilitate non-automobile travel, provision and utilization of mass transit, and to generally reduce the need for single-occupant vehicle travel, as part of transportation planning and development efforts of a locality, including programs and ordinances applicable to new shopping centers, special events, and other centers of vehicle activity;

(xv) Programs for new construction and major reconstructions of paths, tracks or areas solely for the use by pedestrian or other non-motorized means of transportation when economically feasible and in the public interest. For purposes of this clause, the Administrator shall also consult with the Secretary of the Interior.

(xvi) Excluded by ISTEA.

3. Bicycle and Pedestrian Facilities and Programs

Bicycle and pedestrian facilities and programs are included as a TCM in Section 108 of the CAAA (ix, x, xiv and xv above). In addition, the ISTEA makes specific mention of the eligibility of bicycle and pedestrian facilities and programs under CMAQ (see 23 U.S.C. 217 (a)(d)). Included as eligible projects are:

- Construction of bicycle and pedestrian facilities,
- Nonconstruction projects related to safe bicycle use, and
- Establishment and funding of State bicycle/pedestrian coordinator positions, as established in the ISTEA, for promoting and facilitating the increased use of non-motorized modes of transportation. This includes public education, promotional, and safety programs for using such facilities.

4. Management Systems

The ISTEA requires that 6 management systems be established and implemented (see 23 U.S.C. 303 (a)(g)). Projects required to develop and establish 3 of these management systems (traffic congestion, public transportation facilities and equipment, and intermodal transportation facilities and systems), as well as implementation of projects contained in them, are eligible for CMAQ funds where it can be demonstrated that they are likely to contribute to the attainment of a NAAQS.

5. Traffic Monitoring, Management and Control Operations

The ISTEA also requires States to design and effect a traffic monitoring system for highways and public transportation facilities and equipment (see 23 U.S.C. 303(b)(g)). Note that the Interim Guidance of February 20 allowed operating expenses as an eligible CMAQ activity, provided that the operations contribute to achievement of a NAAQS and previous funding is not displaced. Under this guidance operating expenses for traffic monitoring, management or control, where they can be shown to have air quality benefits, are eligible for CMAQ funding, and as previously required, the expenses must be incurred from new or additional services. However, the operating expenses are now eligible only for a period of 2 years from the inception of the additional service. It should be noted that operating expenses for traffic management and control services are eligible under the Surface Transportation Program (STP) and that ISTEA provide flexibility to transfer other funding sources to STP if additional operating expenses are needed for traffic management systems. Capital expenses for air quality-related facilities and programs are still eligible where it can be shown that they will contribute to attainment of a NAAQS.

The reason for this is to use the CMAQ Program to gain the maximum reductions in emissions through new initiatives rather than through funding ongoing expenses that maintain the status quo. Similar guidance on the eligibility of operating expenses for transit and for Inspection and Maintenance (I/M) Programs has also been developed (see below). The same reasoning described above applies to these areas as well, and to establish a consistent policy, operating expenses to manage and control traffic are eligible under CMAQ only for the first 2 years after start-up of a new traffic operations project.

6. Emission I/M Programs

Emission I/M Programs show strong potential for improving air quality and appear to be a good use of CMAQ funds. To this end, construction of facilities and purchase of equipment for I/M stations in test-only networks are eligible. Projects necessary for the development of these I/M programs and one-time start-up activities, such as updating quality assurance software or developing a mechanic training curriculum, are also eligible. Operating expenses are eligible for CMAQ funding, but the same conditions described in "Traffic Monitoring, Management and Control Operations" apply here as well. The I/M services must be new or additional services, existing funding (including inspection fees) should not be displaced and operating expenses are only eligible for 2 years for the reasons described above.

While I/M programs show strong potential to improve air quality, implementation should be accomplished through a partnership of Federal, State and local agencies that shows the most promise for success.

7. Transit Projects

Improved public transit is one of the TCMs listed in section 108 of the CAAA. EPA's TCM Information Document describes a range of transit improvements under three broad types of actions: System/service expansions, operational improvements, and demand/market strategies. The emission reductions achieved with any of these measures can vary widely depending on project specifics as well as the existence of policies and actions that promote transit use, such as transit-supportive land use controls and single-occupant auto disincentives.

In general, the capital costs of system/service expansions are eligible for CMAQ funding because of the potential for attracting new transit riders and reducing trips by single-occupant vehicles. Examples are: new rail systems and extensions, new roadways or reserved lanes on existing roads for exclusive bus/HOV use, and capital costs of initiating commuter rail or ferry service. Capital projects that clearly enhance transit service are also eligible, such as new stations, terminals, transit malls, intermodal transfer facilities, and track and signalization improvements. New vehicles and equipment needed to provide the enhanced service are also eligible. Park-and-ride facilities related to transit systems are eligible for CMAQ funding since they generally contribute to ridesharing and transit use. It should be noted for these projects, in particular, that air quality analysis may subsequently be required during NEPA compliance to assure that no localized CO violations are likely to occur and that air quality conformity requirements are met.

One-for-one vehicle replacements of the existing bus or rail fleet, including locomotives, are eligible since the new vehicles are generally more reliable, less polluting, and make transit a more attractive option. However, the decision to use CMAQ funds for vehicle replacements should be made with consideration of the area's specific pollution problem and the project's capacity to reduce that pollution. For example, new buses are significantly cleaner than old buses with respect to small particulates; thus, the justification is strongest for using CMAQ funds for bus replacements in PM–10 nonattainment areas. One-for-one replacement of buses is also eligible in CO and ozone nonattainment areas but much smaller emission reductions can be expected for these pollutants.

In general, transit operating and maintenance costs are not eligible for CMAQ funds since they only maintain existing service. In limited cases, operating costs for new transit service are eligible for CMAQ funding. The main criterion is that it must be for new service which supports a discrete, new project or program having documented air quality benefits. CMAQ funds cannot be used to replace existing funding sources for transit operations and cannot be used to further subsidize existing operations. The intent is to assist in the start-up of various transit supply and travel demand management measures linked to transit which have been specifically designed to reduce mobile source emissions. As discussed in the preceding sections, transit operating costs meeting the above criteria are eligible for a maximum of two years. Examples of eligible costs are: new transit service to a major employer in support of an employer trip reduction program; new bus service in a community which presently lacks adequate transit service; or new transit service initiated on a HOV facility.

The TCM Information Document discusses a number of transit system operational improvements and marketing strategies which can lead to modest emission reductions, e.g., improving transfer policies and removal of on-street parking. Their mention in the TCM document should not be taken to mean that they are eligible for the CMAQ Program or even that they are improvements which typically receive Federal funding assistance. For the most part, these are policies or actions which evolve from local planning in an effort to make the most efficient use of existing resources. While they are not discrete projects or programs which receive Federal assistance, these types of operational improvements should not be overlooked in local air quality planning, particularly since they have the potential for reducing emissions at very little or no additional cost.

8. Highway and Transit Maintenance and Reconstruction Projects

Routine maintenance projects are ineligible for CMAQ funding. As above, routine maintenance on existing facilities maintains the existing levels of highway and transit service, and therefore maintains existing ambient air quality levels. Accordingly, progress toward the NAAQS is not achieved. Funding most simple reconstruction only serves to bring existing facilities back to acceptable levels of service. Other funding sources, like the STP funds, exist for reconstruction activities. Replacement in kind of track or other equipment, reconstruction of bridges, stations and other facilities, and repaving or repairing roads that do not improve air quality through upgraded levels of service are ineligible.

9. Planning and Air Quality Monitoring Projects

Project planning or other development activities that lead directly to construction of facilities or new services and programs that will have an air quality benefit, such as preliminary engineering or alternatives analysis for transportation/air quality projects are eligible. Also included are studies for the preparation of environmental or NEPA documents and related transportation/air quality project development activities. Project development studies would include planning directly related to a TCM or feasibility/developmental studies for any other eligible project or program. In the event that air quality monitoring is necessary to determine the air quality impacts of a proposed project, which is eligible for CMAQ funding, the costs of that monitoring are also eligible.

General planning activities, such as economic or demographic studies, that do not directly propose or support a transportation/air quality project are too far removed from project development to assure realization of any emission reductions. Preparation of NEPA or other environmental documents that are not related to a transportation project to improve air quality is also ineligible. Such activities should be funded with other appropriate title 23 or Federal Transit Act funds.

Region- or area-wide air quality monitoring is not eligible because such projects do nor themselves yield air quality improvements nor do they lead directly to projects that would yield air quality benefits. Air quality monitoring is normally a State air quality agency responsibility which is funded under section 105 of the Clean Air Act. If the MPO or State chooses, air quality monitoring could also be funded as a transportation planning activity and appropriate title 23 or Federal Transit Act funds used. However, it should be noted that regional air quality monitoring is subject to EPA guidance on siting and quality assurance.

10. Public/Private Initiatives

The CMAQ program may be used to fund projects or programs that are owned, operated or under the primary control of the public sector, including public/private joint ventures. A State may use CMAQ funds for initiatives that are privately owned and/or operated, including efforts developed and implemented by Transportation Management Associations, as long as the activity is one which: (1) Normally is a public sector responsibility (such as facility development for enhanced I/M programs in test-only networks), (2) private ownership or operation is shown to be cost-effective, and (3) the State is responsible for protecting the public interest and public investment inherent in the use of Federal funds.

Activities which are the mandated responsibility of the private sector under the Clean Air Act, such as vapor recovery systems at gas stations for example, are not eligible. Implementation of employer trip reduction programs, required for severe and extreme ozone nonattainment areas, are also a private responsibility, but general program assistance to employers to help them plan and promote these programs are eligible. Further public assistance to support trip reduction programs in the form of new or redirected public transportation services are also eligible.

11. Limitation on Construction of Single-Occupant Vehicle Capacity

Construction projects which will add new capacity for single-occupant vehicles are not eligible under this program unless the project consists of a HOV facility only available to single-occupant vehicles at off-peak travel times. For purposes of this program, construction of added capacity for single-occupant vehicles means the addition of general purpose through lanes to an existing facility, which are not HOV lanes, or a highway on new location.

12. Other Eligible Transportation Projects and Programs

Other transportation projects and programs, even if they are not included under one of the categories above may also be funded under CMAQ. Innovative activities based on promising technologies and feasible approaches to improve air quality will also be considered for funding. This would include such ventures as new efforts to identify and improve the emissions of gross emitters, vanpooling programs, planning and development of parking management programs, and preferential treatment for high-occupancy vehicles. Like all proposals, the State must provide documentation of air quality benefits, and FTA/FHWA, in consultation with EPA, must be satisfied that the project or program will help attain a NAAQS.

B. Levels of Analysis

Decisions regarding the level and type of air quality analysis, as well as the credibility of its results, are left to FTA and FWHA field staff, in consultation with EPA. Across the country, State and local transportation/air quality agencies have different approaches, analytical capabilities and technical expertise with respect to such analysis. At the national level, it is not feasible to specify a single method of analysis that would be applicable in all cases.

While no method is specified, every effort must be taken to ensure that determinations of air quality benefits are credible and based on a reproducible and logical analytical procedure that will yield quantitative results of emission reductions. In subsection VI.A. of this guidance, States are required to submit annual reports providing estimates of emission reductions for the CMAQ Program. Analysis of air quality benefits for individual project proposals will assist preparation of the annual reports. It also aids in the CMAQ project selection process. Of course, if an air quality analysis has been done for other reasons, it may also be used for this purpose.

Although quantitative analysis of air quality impacts is required whenever possible, some highway and transit improvements may not lend themselves to rigorous quantitative analysis because of the size or scope of the project or because practical experience is lacking to adequately analyze the project. In these cases, a qualitative assessment based on a reasoned and logical examination of how the project or program will decrease emissions and contribute to attainment of a NAAQS is appropriate and acceptable.

In some instances the appropriate focus of the analysis will not be the specific proposal submitted for CMAQ funding. In cases where CMAQ funds are to be used for planning studies, for example, the analysis should focus on the project emanating from the planning. In these cases, related projects should be grouped and the air quality benefits determined together.

In other situations, the appropriate analytical focus will be to examine the impacts of more comprehensive strategies to improve air quality by grouping TCMs. A stategy to reduce reliance on single-occupant vehicles in a travel corridor, for example, could include transit improvements coupled with demand management. The benefits of such a strategy should be evaluated together rather than as separate projects. Transit improvements, ridesharing programs or other TCMs affecting an entire region may be best analyzed in this fashion.

C. Responsibility for Project Management and Final Eligibility Decisions

Either the local FTA or FHWA office will be responsible for project management. In cases where the project is clearly related to transit, FTA will manage the project. Similarly, highway projects that improve air quality through traffic operational improvements would be managed by FHWA. For projects that include both highway and transit elements, such as park and ride lots and intermodal projects, the managing agency will be decided on case-by-case basis.

Following initial review by the managing agency and consultation with EPA, the managing agency makes the final determination on whether the project or program is likely to contribute to attainment of a NAAQS and is eligible for CMAQ funding.

V. Coordination With EPA

As noted in the February 20 interim guidance, the FTA and FHWA Regional Offices should establish a consultation and coordination process with their respective EPA Regional Offices for review of CMAQ funding proposals. EPA review is critical to assist the determination of whether a project will have air quality benefits and to assure that the most effective projects and programs are approved for CMAQ funding.

At the same time, the consultation process should be developed with the urgency of improving air quality and keeping the CAAA attainment schedules in mind. A process should be established for timely review and handling of CMAQ funding proposals. Also, a project category list should be developed for expedited funding under CMAQ without further review. As EPA will evaluate all TCMs in an approved SIP for the conformity determination, they can be included on such a list.

VI. MPO and State Authority/Responsibility

A. Annual Reports

To assist in meeting statutory obligations, States are required to prepare annual reports for FTA, FHWA and the general public that specifies how CMAQ funds have been spent and what the air quality benefits are expected to be. Annual reporting will serve to minimize funding questionable activities under CMAQ, and appropriately makes the States and local agencies accountable to the general public. Also, an annual report would enable FTA and FHWA to be responsive to the Congress on the utilization of the funds.

This report should be provided by the first day of February following the end of the previous Federal fiscal year (September 30) and cover all CMAQ obligations for that fiscal year. The report should include:

1. A list of projects funded under CMAQ, best categorized by one of the following six project types:
   - Transit: construction, equipment or operating expenses for new and improved services, and parking for transit services, etc.
   - Other shared-ride: vanpool and carpool programs, and parking for shared-ride services, etc.
   - Highway/road: traffic management and control services, signalization projects, intersection improvements, and construction or dedication of HOV lanes, etc.
   - Demand management: employer trip reduction programs, transportation management plans, flexible work schedule programs, vehicle restriction programs, etc.
   - Pedestrian/bike: trails, storage facilities, promotional activities, etc.
   - I/M and other TCMs (not covered by the above categories).

   Project planning and other developmental activities, eligible under CMAQ, should be categorized the same way as the project or program they support.

2. The amount of CMAQ funds obligated for the year, disaggregated by the type of project listed above; and

3. A tabulation of the estimated air quality benefits for the year summed from project-level analyses and expressed as reductions of ozone precursors (volatile organic compounds and nitrogen oxides), CO, or PM–10. These reductions should be expressed as kilograms per day removed from the atmosphere. This information will be important to monitoring and reporting to Congress on CMAQ Program effectiveness.

B. Fund Allocation and Project Selection

According to the ISTEA legislation, CMAQ funds are apportioned to the States based on the severity of their ozone pollution and the number of people affected by it. Additional funds are apportioned if a nonattainment area for ozone is classified as nonattainment for CO as well. Each State is guaranteed a minimum of 0.5 percent of the total yearly apportionment even if it has no nonattainment areas.

A State's apportionment can change from year-to-year. As some areas come into attainment, or as some areas whose air quality gets worse are classified as nonattainment, the distribution of the total yearly apportionment will change, affecting each State's apportionment to some degree. Further, EPA can adjust the boundaries of a nonattainment area which will in turn affect the number of people in the area and shift the distribution as well.

Despite the statutory formula for determining the apportionment amount, the State can use its CMAQ funds in any ozone, CO or PM–10 (under certain conditions) nonattainment area. It is under no statutory obligation to suballocate CMAQ funds in the same way as they were apportioned. States may retain funds for use in specific nonattainment areas or fund CMAQ projects on a case-by-case basis. We suggest, however, that the State consult with affected MPOs to determine CMAQ priorities and allocate funds accordingly.

The decision over which projects and programs to fund under CMAQ should be made through a cooperative process involving the State departments of transportation, affected MPOs, and State and local air quality agencies. This process serves to develop a pool of potential CMAQ projects to be considered for funding in a State's nonattainment areas. The programming of CMAQ projects should follow the procedures for TIP development and project selection noted below.

Projects to be funded with CMAQ funds must be included in the TIPs that are developed by the MPOs in cooperation with the State and transit operators. Under the metropolitan planning interim guidance of April 6, 1992, TIPs must contain a priority list of projects to be carried out in the 3-year period following adoption. For projects targeting CMAQ funds, priority in the TIP should be based on the projects' estimated air quality benefits.

Since the TIPs must be consistent with available funding, it is important that the State advise the MPOs of its proposed approach to utilize CMAQ funds in a timely

manner. Once CMAQ projects are included in a TIP (approved by the MPO and the Governor, and included in a FHWA/FTA-approved statewide transportation improvement program), they may be selected for implementation in accordance with the specified project selection procedures. In transportation management areas, CMAQ projects would be selected for implementation from the approved TIP by the MPO in consultation with the State. In all other areas CMAQ projects would be selected from the approved TIP by the State in cooperation with the MPO.

VII. States That Are in Attainment

States that do not have any ozone and CO nonattainment areas, which meet the nonattainment classifications contained in the CAAA, may use their funds for any eligible projects under the STP. We would encourage any of these States which also have PM–10 nonattainment areas, and those that achieve attainment of ozone and CO standards in the future, but still have PM–10 nonattainment areas, to give priority to the use of these funds for projects and programs that contribute to attainment of the PM–10 standard. This priority should be given only if mobile sources are considered major contributors of such nonattainment.

For States that are in attainment or achieve attainment of transportation-related NAAQS, we would further encourage them to give priority to the use of CMAQ program funds for the development of congestion management systems, public transportation facilities and equipment, and intermodal facilities and systems, as well as the implementation of projects and programs produced by those systems.

VIII. Further Information

If you have any questions on the CMAQ program or this guidance, please contact James M. Shrouds at (202) 366–2074, Michael J. Savonis at (202) 366–2080 or Abbe Marner at (202) 366–4317.

Anthony R. Kane

Robert H. McManus

2 Attachments

Attachments not available for publication

Attachment #1 is 23 U.S.C. 120.
Attachment #2 is Section 1008 of the Intermodal Surface Transportation Efficiency Act of 1991, Pub. L. 102–240, 105 Stat. 1914.

MEMORANDUM

Date: June 15, 1992.
Reply to Attn of: HEP–41/HEP–32.
Subject: *Information:* Congestion Mitigation and Air Quality (CMAQ) Improvement Program and Transportation Enhancement Activities.
From: Director, Office of Environment and Planning.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

Implementation of two of the new areas under the Intermodal Surface Transportation Efficiency Act (ISTEA) have created some concern at Headquarters. The CMAQ Improvement Program and Transportation Enhancement Activities (under the Surface Transportation Program) have shown rather slow rates of obligation to date. These activities represent completely new areas for FHWA, and some planning to determine how best to use these funds is not only expected, but desirable.

Our concern, however, is that States may also be slow to obligate these funds because of uncertainties over project eligibility and program structure. We need to address these uncertainties and remove the bottlenecks that may be interfering with the successful implementation of these programs.

CMAQ

Interim guidance on the CMAQ program was sent out on February 20. Still eligibility questions have continued to arise, most recently at a May 20 conference call with Regional Planning and Program Directors. These questions seem to be hindering program implementation. We need to insure that State Departments of Transportation (DOT) are fully aware of our positions on project eligibility and what is required under the ISTEA. Headquarters staff have already provided the most up-to-date information we have, and further guidance on project eligibility and procedures for coordination with the Federal Transit Administration (FTA) are being developed. These will be disseminated as soon possible.

In the interim, the divisions and regions should exercise their best judgement in making eligibility calls while keeping in mind the purpose of the CMAQ program—to fund projects and programs that will contribute to attainment of National Ambient Air Quality Standards for ozone and carbon monoxide. The interim guidance of February 20 and previous discussions with Headquarters will further serve to direct your decisions. It would be prudent to avoid making long-term commitments, such as funding operating expenses or capital projects that will extend far into the future, because final guidance may contradict some of these eligibility decisions.

You should be aware that the continuing development of State Implementation Plans may also play a role in the slow obligation rate for CMAQ. Some States seem to be waiting for their plans to more fully develop before expending these funds. In that 1992 CMAQ funds do not lapse for 4 years, this poses no significant threat to their funding and is within their prerogative.

Transportation Enhancement Activities

The April 24 memorandum on transportation enhancement activities provided guidelines for determining which activities qualified as transportation enhancements. Nevertheless, many State DOTs are grappling with enhancement proposals that are not definitively addressed by these guidelines. Some such proposals appear to qualify as transportation enhancements, but some State DOTs are unsure how these initial proposals will rank against transportation enhancement proposals that materialize as a broader group of interested parties seek to become involved in the Surface Transportation Program. State DOTs therefore find themselves in the position of balancing the immediate obligation of funds for transportation enhancement activities against taking the time to build a process which will serve them well over the longer term.

Given the newness of the transportation enhancement concept and the number of interested outside parties, one strategy that States should seriously consider is to develop separate short-term and longer-term approaches. Over the short term (the remainder of FY 92 and the beginning of FY 93), State DOTs could concentrate on incorporating clearly qualifying transportation enhancement measures into transportation projects that are currently in the project development pipeline and on advancing proposals for stand-alone projects which have indisputable merits. At the same time, State DOTs would be well-advised to immediately begin developing a longer term process for identifying candidate transportation enhancement proposals and for selecting which proposals will be funded. In developing the longer term process, State DOTs should consult with interested outside parties. Once developed, State DOTs should widely publicize the process in a way that interested members of the public can easily understand.

A few State DOTs have made substantial progress in developing strategies for implementing transportation enhancement activities. One State is establishing an interagency committee to screen enhancement proposals using published criteria and to advise the DOT Secretary of which proposals merit advancement. Another State DOT has decided to reserve some of the transportation enhancement funds for upgrading its own projects and will conduct a grant competition for the remaining funds. We will provide you with specifics as these processes are finalized and the State DOTs are willing to share the information.

Requested Followup

In order to relieve the uncertainties that may be interfering with the successful implementation of both the CMAQ program and transportation enhancement activities, we ask that Division Administrators meet with State DOTs as soon as possible to clarify any misunderstandings that exist. The FTA regional representatives should be invited to participate in these meetings because of the significant role they play in transportation enhancement activities and the CMAQ program.

If you need further information on these matters, contact the following members of my staff: CMAQ: James Shrouds, HEP–41 (202–366–2074), or Enhancements: Fred Skaer, HEP–32 (202–366–2058).

Kevin E. Heanue

Federal Transit Administration

July 30, 1992.

Dear Colleague: This is a followup letter to one we sent you on March 19 on the general subject of administrative procedures to be followed when Federal highway assistance is used for mass transit projects, or transit funds are used for highway projects. Both of these new options are authorized under the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA).

The March 19 letter primarily concerned itself with the Surface Transportation Program (STP) of the highway title, as well as the Section 9 Program of the transit title.

This letter, in an attachment, addresses the procedures that will be used when transferring funds to or from a highway program that is a companion of the STP, namely, the Congestion Mitigation and Air Quality Improvement Program (CMAQ). While generally similar to the procedures outlined in our March 19 letter, there are some difference, especially with respect to project eligibility.

A second attachment to this letter, an internal memorandum to the field staff of both the Federal Highway Administration (FHWA) and the Federal Transit Administration (FTA), outlines accounting procedures that will be used by our respective agencies for the fiscal management of transit projects financed by highway funds, either STP or CMAQ in origin.

It is expected that whatever the origin of the Federal funds involved, FTA will manage projects that are clearly transit in nature (e.g., the purchase of transit vehicles, the construction of transit facilities, etc.), while FHWA will manage projects that improve general road traffic and conditions.

Questions have arisen, however, about which agency will manage projects of an intermodal nature. Decisions on these will be made on a case-by-case basis. Sponsors of such intermodal projects should contact their field offices, both FTA and FHWA, as quickly as possible in the project development process. If at all possible, any preference that the project sponsor has will be honored.

At this point in the implementation of the ISTEA, we would like to express our appreciation for both the enthusiasm, and the patience, that we are finding among our grantees. The ISTEA is not just another reauthorization of two Federal assistance programs; it represents a major milestone in the partnership between Federal, State, and local interests on questions of transportation.

Sincerely yours,

Brian W. Clymer,

Administrator, Federal Transit Administration.

Thomas D. Larson,

Administrator, Federal Highway Administration.

2 Enclosures.

Transfer Procedures for Use of Title 23 Congestion Mitigation and Air Quality (CMAQ) Improvement Program Funds for Transit Projects and Programs

Funds from the CMAQ Improvement Program can be used for transportation projects and programs (for simplicity referred to as "projects" in these procedures) that will lead to attainment of National Ambient Air Quality Standards (NAAQS). The interim guidance of February 20 in combination with questions and answers on the Federal Electronic Bulletin Board System serve as the most current guide to what projects are eligible for CMAQ funding. Additional guidance is being developed and will be issued as soon as possible. The CMAQ funds may be used for either highway or transit projects. This paper outlines the steps which are to be taken in order to use these funds for a transit project.

Transportation Improvement Program (TIP) Development, Project Selection and Conformity Determinations

A transit project intended to use CMAQ funds, just as with highway projects, must contribute to the attainment of the NAAQS as defined by the Intermodal Surface Transportation Efficiency Act, the Clean Air Act Amendments of 1990 and the guidance referenced above. As in the case of projects selected to use Surface Transportation Program funds, the project must also be included in a conforming Transportation Plan and TIP developed by the Metropolitan Planning Organization (MPO). The TIP must be approved by the MPO and the Governor (or designate). Additionally, projects inside and outside the metropolitan areas must be included in the State Transportation Improvement Program (STIP). The STIP is to be approved by the Secretary no less frequently than biennially. Projects must then be selected for implementation in accordance with the requirements of section 8 of the Federal Transit Act and sections 134 and 135 of title 23, United States Code.

Once the project is selected for implementation, the recipient of the transit project funds (the "Grantee" as determined by State and local officials) completes all necessary preliminary steps. This includes preparation of necessary National Environmental Policy Act documentation.

Application

The Grantee submits a project application to the cognizant Federal Transit Administration (FTA) Regional Office which should include documentation on how the project will improve air quality. At the time of the application, the Grantee notifies the State that it has submitted an application to FTA which will require a transfer.

The application should specify under which Federal Transit Act section the funds will be utilized, and the application should be prepared in conformance with the requirements and procedures governing that section. Section 9 requirements and procedures will apply to urbanized area projects, Section 18 to non-urbanized area projects, and Section 16 to projects for the purposes of that section. Section 13(c) requirements will apply as may be called for under those programs.

The FTA Regional Office will receive and process the applications under the normal quarterly release process. Projects receive project numbers consistent with the purposes to which the funds will be applied.

Fund Obligation and Application Approval

If the project submitted for CMAQ funding is unambiguously a transit project, the FTA Regional Office will decide if the project is eligible for CMAQ funding and will manage the project. Similarly for a clearly-defined highway project, the Federal Highway Administration will be the responsible agency. In the case of an intermodal project or other projects which have elements of both highway and transit improvements, the FTA and FHWA Regional Offices will jointly decide if the project is eligible for CMAQ funding, if the application should be approved and which agency will manage the project. The remainder of this guidance applies if FTA is the managing agency.

If a State has not yet submitted a transfer request, the FTA Regional Office will notify the State and the Grantee that the project is ready for approval.

Project Execution

Once the project is approved, the Grantee executes the project using normal FTA program procedures appropriate to the project in question. The FTA Regional Office will manage the project in the same manner as typical transit projects. Requests for reimbursement are sent to FTA as for other FTA projects.

Project Amendments

Project Amendments which require the use of additional CMAQ funds will undergo the same processing as an original request for funding.

MEMORANDUM

Date: July 30, 1992.
Reply to Attn. of: HEP–41, M. Savonis, x62080, TGM–1.
Subject: *Action*—Policy on Eligibility of PM–10 Projects for CMAQ Funding.
From: Federal Highway Associate Administrator for Program Development; Federal Transit Associate Administrator for Grants Management.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator; Federal Transit Area Directors and Regional Administrators.

Officials in several small particulate matter (PM–10) nonattainment areas have requested that transportation projects and programs which reduce PM–10 emissions in a PM–10 nonattainment area be considered eligible for funding under the Congestion Mitigation and Air Quality Improvement Program (CMAQ). Such a request from Spokane, Washington is attached. We have concluded that projects and programs which reduce transportation-generated PM–10 emissions in a PM–10 nonattainment area should be considered eligible for CMAQ funding under the following additional conditions:

The State must consult with, and consider the views of, the EPA regional office and the metropolitan planning organizations (MPOs) in all nonattainment areas for ozone, carbon monoxide (CO), and PM–10 within the State before programming CMAQ funds for a PM–10 project.

If the State contains any ozone or CO nonattainment areas, the EPA regional office must agree that the proposed use of CMAQ funds for PM–10 projects or programs will not detract from or delay efforts to attain the ozone or CO standards.

The primary focus of a transportation program intended to improve air quality should be the primary transportation pollutants, ozone and CO. The CMAQ apportionment formula in the Intermodal Surface Transportation Efficiency Act recognizes ozone and CO as the primary transportation pollutants. The requirements listed above will ensure proper consideration of the views of the agencies charged with controlling transportation emissions of ozone precursors, CO, and PM–10, especially their views on the most effective use of transportation funds in achieving the National Ambient Air Quality Standards. The CMAQ eligibility of PM–10 projects will not affect a State's CMAQ apportionment, but has the potential to spread the limited CMAQ funds over a greater number of nonattainment areas within the State.

The consultation and agreement with EPA will ensure that the proposed projects and programs effectively address PM–10 problems without exacerbating other pollution problems. For example, a project which reduces PM–10 emissions in a PM–10 and CO nonattainment area may cause an increase in CO emissions and be therefore less desirable than a project without this CO problem.

Examples of projects and programs in a PM–10 nonattainment area that would be eligible for CMAQ funds if the above requirements are met are paving dirt roads, diesel bus replacements, and more effective street sweeping equipment. In an area which is nonattainment for both PM–10 and ozone or CO, projects and programs which reduce emissions of CO or ozone precursors in addition to reducing PM–10 emissions (e.g. transportation activities in approved State Implementation Plans and transportation control measures listed in section 108(f)(1)(A) of the Clean Air Act) are not subject to the additional requirements listed above. The requirements apply only to projects and programs whose sole justification for CMAQ eligibility is the reduction in PM–10 emissions.

These requirements have been coordinated with EPA and will be incorporated into more extensive guidance on CMAQ which will be issued soon. Please advise the States, MPOs, and transit agencies in your region of this PM–10 policy.

Robert H. McManus

Anthony R. Kane

Attachment

United States Senate
Washington, DC 20510–4701
June 23, 1992

William K. Reilly, Administrator,
Environmental Protection Agency, 401 M Street Southwest, #1200–W, Washington, D.C. 20460.

Dear Administrator Reilly: I understand that the Environmental Protection Agency will be working with the Department of Transportation as it reviews its interpretation of the Intermodal Surface Transportation Efficiency Act's Congestion Mitigation and Air Quality Improvement Program to include PM–10 (particulate micron material) reduction. Presently, DOT's interpretation only permits the funding of projects which reduce carbon monoxide and ozone levels.

In the State of Washington, the city of Spokane continually faces the threat of being labeled by the EPA as "serious" for PM–10 nonattainment. If labeled "serious" by the EPA, the city would face a barrage of restrictions on business and other activities vital to local commerce. Simply put, jobs and economic opportunities would be limited—if not lost—for Spokane's many families and communities.

After extensive research, EPA Region 10 and the Washington State Department of Ecology have targeted 4½ miles of unpaved roads which, if paved, will contribute to a substantial decrease in Spokane's PM–10 level. The Washington State Department of Transportation and regional Federal Highway Administration support the use of Congestion Mitigation funds for this project.

I encourage the EPA to consider the problems facing the city of Spokane when consulting with the DOT on its interpretation of the Congestion Mitigation and Air Quality Improvement Program. The threat which PM–10 poses to Spokane's citizens is great, and any measure which will reduce the pending threat of being labeled "serious" would greatly assist both the environmental and economic livability of this city.

Thank you for your consideration of this request. I look forward to your response.

Sincerely,

Slade Gorton,

United States Senator.

United States Senate
Washington, DC 20510–4701
June 23, 1992

The Honorable Andrew Card, Secretary,
Department of Transportation, 400 Seventh Street, Southwest, Washington, D.C. 20590.

Dear Secretary Card: I understand that the Department of Transportation is reviewing its interpretation of the Intermodal Surface Transportation Efficiency Act's Congestion Mitigation and Air Quality Improvement Program to include PM–10 (particulate micron material) reduction. Presently, DOT's interpretation only permits the funding of projects which reduce carbon monoxide and ozone levels.

In the State of Washington, the city of Spokane continually faces the threat of being labeled by the Environmental Protection Agency (EPA) as "serious" for PM–10 nonattainment. If labeled "serious" by the EPA, the city would face a barrage of restrictions on business and other activities vital to local commerce. Simply put, jobs and economic opportunities would be limited—if not lost—for Spokane's many families and communities.

After extensive research, EPA Region 10 and the Washington State Department of Ecology have targeted 4½ miles of unpaved roads which, if paved, will contribute to a substantial decrease in Spokane's PM–10 level. The Washington State Department of Transportation and regional Federal Highway Administration support the use of Congestion Mitigation funds for this project.

I urge your prompt review of the Department's interpretation of the Congestion Mitigation and Air Quality Improvement Program to include PM–10. The threat which PM–10 poses to Spokane's citizens is great, and any measure which will reduce the pending threat of being labeled "serious" would greatly assist both the environmental and economic livability of this city.

Thank you for your consideration of this request. I look forward to your response.

Sincerely,

Slade Gorton,

United States Senator.

MEMORANDUM

Date: April 14, 1992.
Reply to Attn of: HNG–13.
Subject: *Action*—1991 Intermodal Surface Transportation Efficiency Act (ISTEA) Implementation of Interstate Substitution Program.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators; Division Administrators; Federal Lands Highway Program Administrator.

This memorandum provides written guidance in the implementation of the provisions of the 1991 ISTEA accounting for changes and/or amendments made to the Interstate Substitution Program.

Authorizations—Sections 1011 and 3025

Section 1011(a)(1) authorizes $240,000,000 per fiscal year for each of fiscal years 1992, 1993, 1994 and 1995 for substitute highway projects. Substitute transit funds are authorized in section 3025 of the Act and the authorizations available when appropriated are $160,000,000 for fiscal year 1992 and $164,843,000 for fiscal year 1993. These substitute program authorizations will complete the withdrawal substitution program based on the remaining needs shown in the 1991 Interstate Substitute Cost Estimate (ISCE).

Distribution of Funds—Section 1011

Section 1011 amends title 23, United States Code 103(e)(4) (H) and (J) to provide that all funds made available for substitute highway and transit projects shall be apportioned in accordance with the estimates of the cost to complete. The substitute cost estimates shall be adjusted every year and used to calculate the apportionments for substitute highway projects for fiscal years 1992 and 1993.

In view of the changes to the substitution program by the 1991 Act, an update to the 1991 ISCE will be prepared in cooperation with the States involved in the program. The purpose of the update is to verify the splits (highway versus transit), in the consideration of the 1991 Act provisions, for use in apportioning substitute funds.

Period of Availability—Section 1011

Section 1011(c) amends 23 U.S.C. 103(e)(4)(E)(i) to provide that funds

authorized to be apportioned for substitute highway projects for fiscal year 1995 and for substitute transit projects for fiscal year 1993 shall remain available for obligation until expended. There is no change in the availability period for funds apportioned prior to those years. Unobligated funds at the end of the availability period in a State are subject to withdrawal and reapportionment to other States except when an amount by itself is not sufficient to pay the Federal share of the cost of a substitute project.

Eligibility

Projects eligible for funding remain as in 23 U.S.C. 103(e)(4)(B). However, Section 1011 now provides that substitute highway funds may be used for substitute transit projects.

If substitute highway funds are to be used for a transit project, a State will follow the uniform procedures established for the use of Surface Transportation Program funds and Interstate Substitute Highway funds for transit projects. These procedures are described in a March 19, 1992, letter signed jointly by Mr. Brian W. Clymer, FTA Administrator, and Mr. Thomas D. Larson, FHWA Administrator. A copy is attached for your ready reference.

Discretionary Funds—Section 1011

The 1991 Act eliminates the discretionary allocation of a portion of the substitute highway and substitute transit fund authorizations. In accordance with the Section 1011(a)(2) and (b)(2) amendments to Title 23, the funds authorized by the 1991 Act will be apportioned.

Federal Participation

The Federal share of each substitute project remains at 85 percent of the cost in accordance with 23 U.S.C. 103(e)(4)(D).

Anthony R. Kane

Attachments

Federal Highway Administration

March 19, 1992.

Dear Colleague: Recently, we wrote to you describing some of the new flexibility available in the use of Federal Highway Administration (FHWA) and Federal Transit Administration (FTA) funds. We remain fully committed to see that this new flexibility is fully realized. Consequently, we have been working together to develop procedures to permit all program funds which have flexible uses to be used as expeditiously as possible.

Enclosed are descriptions of the procedures we have put in place to govern use of FHWA Surface Transportation Program and Interstate Substitution—Highways Program funds used for transit projects and use of FTA Section 9 Program funds for highway projects. We will be issuing similar guidance on use of FHWA Congestion Mitigation and Air Quality program funds for transit projects shortly.

We believe that these procedures should provide States and transit operators the maximum flexibility permitted under the law. Please do not hesitate to contact our field offices as questions arise on these procedures.

Sincerely,

Brian W. Clymer,

Administrator, Federal Transit Administration.

Thomas D. Larson,

Administrator, Federal Highway Administration.

Enclosure.

Procedures for Use of Surface Transportation Program and Interstate Transfer—Highways Funds for Transit Projects

Surface Transportation Program (STP) funds may be used for a wide variety of surface transportation activities, including both highway and transit projects. Interstate Substitution—Highways (Ix) funds may be used for transit projects. Certain other FHWA funds, such as National Highway System Funds, may be transferred to the STP and then used for any STP-eligible activity. This paper outlines the steps which are to be taken in order to use these FHWA funds for a transit project.

TIP Development and Project Selection

A transit project intended to use STP or Ix funds must be included in a Transportation Improvement Program (TIP) developed by the Metropolitan Planning Organization (MPO) and approved by the MPO and the Governor. Projects must also be included in the State Transportation Improvement Program (STIP). Projects outside metropolitan areas must be included in the STIP. The STIP must be approved by the Secretary no less frequently than biennially. Projects must then be selected for implementation in accordance with the requirements of Section 8 of the Federal Transit Act and Section 135 of Title 23, United States Code.

Once the project is selected for implementation, the recipient of the transit project funds (the "Grantee," as determined by State and local officials) completes all necessary preliminary steps. This includes preparation of necessary National Environmental Policy Act documentation.

Application

The FTA Grantee submits an application for the project to the cognizant FTA Regional Office. The completed application must be submitted on or before the start of a quarter for the application to be approved at the end of that quarter. At the same time, the Grantee notifies the State that it has submitted an application to FTA which will require a transfer.

The application should specify under which Federal Transit Act section the funds will be utilized and the application should be prepared in conformance with the requirements and procedures governing that section. Section 9 requirements and procedures will apply to urbanized area projects, section 18 requirements and procedures to non-urbanized area projects and section 16 requirements and procedures to projects for the purposes of that Section. Section 13(c) requirements will apply as may be called for under those programs.

FTA Regional Offices will receive and process the applications under the normal quarterly release process. Projects receive project numbers consistent with the purposes to which the funds will be applied.

Fund Obligation and Application Approval

If the FTA Regional Office determines that the project can be approved and if a State has not yet submitted a transfer request, the FTA Regional Office will notify the State and the grantee that the project is ready for approval. In order for the project to be approved that quarter, the State must request the transfer no later than 10 working days prior to the end of the quarter.

Once all steps have been completed, the FTA Regional Office will award the grant at the end of the quarter.

Project Execution

Once the project is approved, the Grantee executes the project using normal FTA program procedures appropriate to the project in question. The FTA Regional Office will manage the project in the same manner as typical transit projects. Requests for reimbursement are sent to FTA as for other FTA projects.

Project Amendments

Project Amendments which require the use of additional STP or Ix funds will undergo the same processing as an original request for funding.

Procedures for Use of Section 9 Funds for Highway Projects

Section 9 capital-only funds may be used for highway projects in Transportation Management Areas if 1) such use is approved by the Metropolitan Planning Organization (MPO), 2) such funds are not needed for investments required by the Americans with Disabilities Act (ADA), and 3) the funds used for the State or local share of such a project are eligible to be used for either highway or transit projects. This paper outlines the steps which are to be taken in order to use FTA Section 9 funds for a highway project.

TIP Development and Project Selection

A highway project intended to use Section 9 funds must be included in a Transportation Improvement Program (TIP) developed by the MPO and approved by the MPO and the Governor. Projects must also be included in the State Transportation Improvement Program (STIP). The STIP must be approved by the Secretary no less frequently than biennially. The projects must then be selected for implementation in accordance with the requirements of Sections 134 and 135 of Title 23, United States Code.

Once the project is selected for implementation, the State completes all necessary preliminary steps including preparation of necessary National Environmental Policy Act documentation.

Once these steps are completed the State notifies the section 9 Designated Recipient that the project is ready to proceed. The Designated Recipient then sends a request to transfer to the FTA Regional Office. The request should include a certification by the MPO that ADA needs have been met. The FTA Regional Office will process the request and make the required determination that ADA needs have been met.

Request for Authority to Proceed

The State submits a request for PS&E approval or a request to obligate to the FHWA Division Office including a certification that the State or local matching funds are eligible to be used for either transit or highway projects. FHWA Division Offices will receive and process requests as for other highway projects.

Project Execution

Once the project is approved, the State executes the project and the FHWA Division Office will manage the project using FHWA program procedures. Requests for reimbursement are sent to FHWA as for other FHWA projects.

Project Amendments

Project amendments which require the use of additional section 9 funds will undergo the same processing as an original request for funding.

MEMORANDUM

Date: June 30, 1992.
Reply to Attn. of: HFS–21.
Subject: *Information*—Federal Shares Established by title 23 U.S.C. and the ISTEA of 1991.
From: Director, Office of Fiscal Services, Washington, DC 20590.
To: Regional Administrators, Division Administrators.

The following information, concerning Federal share, was furnished by the Executive Director's memorandum to Regional Administrators, dated December 6, 1991:

"For new projects advanced using old funds, the Federal share is governed by the provisions of title 23 in existence prior to enactment of the 1991 ISTEA.

For NHS, STP, or new Bridge funds used to cover overruns on previously authorized Federal-aid projects, the Federal share should be that originally authorized for the project.

For new projects advanced using the new Interstate Maintenance program, NHS, or STP funds, projects on the Interstate System would have a Federal share of 90 percent (including HOV or other auxiliary lanes but excluding any other added lanes). All other projects would be 80 percent."

The above information is still valid. The basic Federal share payable for Federal-aid highway projects, established by 23 U.S.C. 120, is 90 percent for Interstate system projects (including a project to add high occupancy vehicle lanes and a project to add auxiliary lanes but excluding a project to add any other lanes); 80 percent for Interstate—other added lanes, the National Highway System (NHS) and the Surface Transportation Program (STP); and 100 percent for certain safety projects, territorial projects, and emergency relief (for eligible emergency repairs to minimize damage, protect facilities or restore essential traffic accomplished within 180 days). The basic Federal share payable applies to all projects unless otherwise provided by title 23 or other legislation. The basic Federal share payable under sections 120(a) and 120(b) may be increased by the sliding scale rates for public land states, not to exceed 95 percent. A State may contribute an amount in excess of the non-Federal share of any project under title 23.

The attached exhibit provides a brief summary of section 120, other sections of title 23 that contain exceptions to section 120, and Federal share information from the ISTEA. The exceptions to 23 U.S.C. 120 and the Federal share information from the ISTEA are not subject to the sliding scale rates for public land states. Listed sections of 23 U.S.C. and the ISTEA should be referred to for program specifics.

Ten percent of the STP apportionments have been set aside to carry out sections 130, Railway-highway crossings; and 152, Hazard elimination (23 U.S.C. 133 (d)(1)). The Federal share for projects using the set-aside funds may not exceed 90 percent, unless qualified for the increased Federal share for safety work in accordance with section 120(c). The Federal share for other projects for these programs will be the same as source funds.

Categorical funding has been discontinued for several programs such as sections 131, Outdoor Advertising; 136, Junkyards; 147, Priority Primary; and 155, Access highways to certain lakes. The Federal share payable for new projects for these programs, using funds authorized by the ISTEA, will be the same as source funds.

The Appalachian Regional Commission provides funds for Appalachian development highways (ISTEA section 1069(y)). The Federal share payable for Appalachian development highway projects is 80 percent.

Any questions concerning the Federal share may be directed to Mr. Robert Sharples, HFS–21, on 202–366–2855.

Peter J. Basso

Attachment

Title 23 U.S.C.

Section	Not to exceed (percent)
Federal Share Payable—Section 120	
120(a) Interstate projects (including HOV and auxiliary lanes)	90
Subject to sliding scale rates	95
Interstate (other added lanes)	80
Subject to sliding scale rates	95
120(b) Other projects	80
Subject to sliding scale rates	95
120(c) Certain safety projects	100
120(e) Emergency Relief:	
For certain work (first 180 days)	100
Federal lands highways	100
120(h) Territories (all projects)	100
120(i) A State may increase the non-Federal share on any Federal-aid project under title 23.	
Exceptions To Section 120	
103 Interstate substitute	85
129 Toll roads, bridges, and tunnels	50/80
130 Railway-highway crossings (STP 10% set-aside)	90
143 Economic growth centers: engineering and economic surveys	100
144 Bridge replacement	80
152 Hazard elimination (STP 10% set-aside)	90
153 Safety belts and motorcycle helmets:	
First fiscal year	75
Second fiscal year	50
Third fiscal year	25
Funds transferred to section 402	100

Title 23 U.S.C.—Continued

Section	Not to exceed (percent)
217 Bicycle facilities and pedestrian walkways	80
307 Research and planning:	
Research and technology, R&D coop. agree (Secretary may approve a higher share)	50
State planning and research	80
Applied research and technology	80
320 Bridges on Federal dams:	
Portion within the limits of the dam	100
Other portions as determined	100
321 National Highway Institute: training for State and local employees	80
326 Education and training centers: for Indian tribal governments	100
402 Highway safety program: Indian tribes with insufficient match	100
403 Highway safety research: collaborative R&D coop. agreements	50
406 School bus driver training	75
408 Alcohol traffic safety programs:	
First fiscal year	75
Second fiscal year	50
Third, fourth, and fifth fiscal years	25
410 Alcohol-impaired driving countermeasures: Indian tribes with insufficient match	100
Intermodal Surface Transportation Efficiency Act—The following sections of the ISTEA contain Federal-share information (not subject to sliding scale rates):	
1012(b) Congestion pricing pilot program	80
1021(d) Projects under sections 1103 through 1108:	
Eligible for Federal lands funds	100
On Federally owned bridges	100
1039(d) Highway timber bridge research and demonstration program	80
1040(f) Highway use tax evasion projects	100
1047(c) Scenic byways program	80
1064(b) Ferry boats and terminal facilities	80
1103(d) High cost bridge projects	80
1104(d) Congestion relief projects	80
1105(g) High priority corridors on the NHS	80
1105(h) NHS high priority corridor feasibility	100
1106(a) Rural access projects	80
1106(b) Urban access and mobility projects	80
1107(d) Innovative projects	80
1108(d) Priority intermodal projects	80

NOTICE

Subject: Sliding Scale Rates in Public Land States—Rates Effective March 17, 1992

Classification Code—N 4540.12

Date: March 17, 1992.

1. *Purpose.* To provide tables which show sliding scale rates of Federal participation in public lands States.

2. *Authority.* a. Rates applicable to projects on the Interstate System were determined pursuant to 23 U.S.C. 120(a).

b. Rates applicable to any project not on the Interstate System were determined pursuant to 23 U.S.C. 120(b)(1) and (2).

3. *General.* a. The sliding scale rates provided herein apply to the costs of Federal-aid projects financed from the respective funds except for traffic control signalization projects, pavement marking projects, commuter carpooling and vanpooling projects, and installation of traffic signs, traffic lights, guardrails, impact attenuators, concrete barrier endtreatments, breakaway utility poles, or priority control systems projects for emergency vehicles at signalized intersection financed at greater than the regular participating ratio. The sliding scale rates initially determined shall be retained throughout the life of the project, except (1) the State may elect to revise active projects by modification of agreements to utilize revised sliding scale rates, and (2) at the final voucher stage the State may elect to utilize the sliding scale rate then in effect. However, this instruction does not permit revision from an initially established Federal/State pro rata (70/30) for a project to a different Federal/State pro rata (75/25), i.e., a sliding scale rate based on a 70/30 pro rata may be changed to the revised sliding scale rate based on the same 70/30 pro rata but not to a sliding scale rate based on a different pro rata (75/25).

b. For traffic control signalization, pavement marking, commuter carpooling and vanpooling, installation of traffic signs, traffic lights, guardrails, impact attenuators, concrete barrier endtreatments, breakaway utility poles, or priority control systems projects, the maximum rate of participation of Federal-aid funds is 100 percent of the cost of construction, except that not more than 50 percent is payable for right-of-way and property damage costs obligated prior to July 1, 1973; 70 percent is payable July 1, 1973 to November 6, 1978; and 75 percent is payable November 6, 1978 to December 18, 1991.

c. Projects financed with HPR funds pursuant to 23 U.S.C. 307 and bridge funds pursuant to 23 U.S.C. 144 are not subject to sliding scale rates.

d. The rate of Federal participation in projects financed with one percent metropolitan planning funds is 80 percent. The sliding scale rates may be applied to this program.

4. *Rates.* a. *Clause (1) Rates Applicable to Projects not subject to paragraph 4c below.* The rates shown in Table 1 are based on the ratio of the areas of nontaxable Indian lands and of public domain lands (reserved and unreserved) exclusive of national forests and national parks and monuments, to the total area of the State. Rates are available for States in which the designated public land area exceeds 5 percent of the total area of the State. The 50 percent Federal, 50 percent State rates apply to obligations incurred on projects from July 1, 1973. The 70 percent Federal, 30 percent State rates apply to obligations incurred on projects from July 1, 1973 to November 6, 1978. The 75 percent Federal, 25 percent State rates apply to obligations incurred on Federal-aid non-

Interstate projects on and after November 6, 1978.

b. *Clause (2) Rates Applicable to Projects not subject to paragraph 4c below.* These rates are shown in Table 2 and are based on the ratio of the area of nontaxable Indian land, public domain lands (reserved and unreserved), national forest, and national parks and monuments to the total area of the State. The 50 percent Federal, 50 percent State rates apply to obligations incurred on projects prior to July 1, 1973. The 70 percent Federal, 30 percent State rates apply to obligations incurred on projects from July 1, 1973 to November 6, 1978. The 75 percent Federal, 25 percent State rates apply to obligations incurred on Federal-aid non-Interstate projects November 6, 1978, and thereafter. The maximum rate of Federal participation is 95 percent. These rates are available for States that have signed agreements pursuant to 23 U.S.C. 120(b)(2).

c. *Rates Applicable to Projects on the Interstate System (including a project to add high occupancy vehicle lanes and a project to add auxiliary lanes but excluding a project to add any other lanes).* These rates are shown in Table 3 and are based on the ratio of the area of unappropriated and unreserved public lands and nontaxable Indian lands to the total area of the State. Rates are available for States in which the designated public land area exceeds 5 percent of the total area of the State. The maximum rate of Federal participation is 95 percent.

Peter J. Basso,

Director, Office of Fiscal Services.

Attachments.

TABLE 1.—U.S. DEPARTMENT OF TRANSPORTATION, FEDERAL HIGHWAY ADMINISTRATION

[Sliding scale rates of Federal-aid participation in public lands states—rates for projects not on interstate system—pursuant to 23 U.S.C. 120(b)(1)—effective March 17, 1992]

State	Ratio of designated public lands area [1] to total area of State	Percentage of cost of Federal-aid projects payable by Federal government				
		50% Federal 50% State	70% Federal 30% State	75% Federal 25% State	85% Federal 15% State	80% Federal 20% State
Alaska	0.5484	77.42	86.45	88.71	93.23	90.97
Arizona	0.5243	76.22	85.73	88.11	92.86	90.49
California	0.1786	58.93	75.36	79.47	87.68	83.57
Colorado	0.1397	56.99	74.19	78.49	87.10	82.79
Hawaii	0.0649	53.25	71.95	76.62	86.97	81.30
Idaho	0.2486	62.43	77.46	81.22	88.73	84.97
Montana	0.1376	56.88	74.13	78.44	87.06	82.75
Nevada	0.7444	87.22	92.33	93.61	[2] 95.00	94.89
New Mexico	0.2718	63.59	78.15	81.80	89.08	85.44
Oregon	0.2317	61.59	76.95	80.79	88.48	84.63
South Dakota	0.0976	54.88	72.93	77.44	86.46	81.95
Utah	0.4761	73.81	84.28	86.90	92.14	89.52
Washington	0.0711	53.56	72.13	76.78	86.07	81.42
Wyoming	0.3384	66.92	80.15	83.46	90.08	86.77

[1] Area of non-taxable Indian lands and reserved and unreserved public domain lands exclusive of national forests and national parks and monuments. Based on latest available data furnished by the Department of the Interior.
[2] Maximum amount.

TABLE 2.—U.S. DEPARTMENT OF TRANSPORTATION, FEDERAL HIGHWAY ADMINISTRATION

[Sliding scale rates of Federal-aid participation in public lands states—for projects not on the interstate system—pursuant to 23 U.S.C. 120(b)(2)—effective March 17, 1992]

State	Ratio of designated public lands area [1] to total area of State	Percentage of cost payable by Federal government			
		50% Federal 50% State	70% Federal 30% State	75% Federal 25% State	80% Federal 20% State
Alabama	0.0200	51.00	70.60	75.50	80.40
Alaska	0.7476	87.38	92.43	93.69	94.95
Arizona	0.7150	85.75	91.45	92.88	94.30
Arkansas	0.0773	53.87	72.32	76.93	81.55
California	0.4263	71.32	82.79	85.66	88.53
Colorado	0.3654	68.27	80.96	84.14	87.31
Connecticut	0.0020	50.10	70.06	75.05	80.04
Delaware	0.0000	.....	.....	.....	.....
Florida	0.0965	54.83	72.90	77.41	81.93
Georgia	0.0238	51.19	70.71	75.60	80.48
Hawaii	0.1241	56.21	73.72	78.10	82.48
Idaho	0.6329	81.65	88.99	90.82	92.66
Illinois	0.0073	50.37	70.22	75.18	80.15
Indiana	0.0065	50.43	70.26	75.21	80.17
Iowa	0.0002	50.01	70.01	75.01	80.00
Kansas	0.0027	50.14	70.08	75.07	80.05
Kentucky	0.0269	51.45	70.87	75.72	80.58
Louisiana	0.0207	51.04	70.62	75.52	80.41
Maine	0.0142	50.71	70.43	75.36	80.28
Maryland	0.0063	50.27	70.18	75.13	80.11
Massachusetts	0.0060	50.30	70.18	75.15	80.12
Michigan	0.0924	54.62	72.77	77.31	81.85
Minnesota	0.0709	53.55	72.13	76.77	81.42
Mississippi	0.0417	52.09	71.25	76.04	80.83
Missouri	0.0343	51.72	71.03	75.86	80.69
Montana	0.3290	66.45	79.87	83.23	86.58
Nebraska	0.0091	50.46	70.27	75.23	80.18
Nevada	0.8366	91.83	[2] 95.00	[2] 95.00	[2] 95.00
New Hampshire	0.1225	56.35	73.68	78.06	82.45
New Jersey	0.0070	50.13	70.21	75.18	80.14
New Mexico	0.3960	69.80	81.88	84.90	87.92

TABLE 2.—U.S. DEPARTMENT OF TRANSPORTATION, FEDERAL HIGHWAY ADMINISTRATION—Continued

[Sliding scale rates of Federal-aid participation in public lands states—for projects not on the Interstate system—pursuant to 23 U.S.C. 120(b)(2)—effective March 17, 1992]

State	Ratio of designated public lands area [1] to total area of State	Percentage of cost payable by Federal government			
		50% Federal 50% State	70% Federal 30% State	75% Federal 25% State	80% Federal 20% State
New York	0.0062	50.26	70.18	75.13	80.10
North Carolina	0.0486	52.44	71.46	76.22	80.98
North Dakota	0.0464	52.32	71.39	76.16	80.93
Ohio	0.0078	50.39	70.23	75.20	80.16
Oklahoma	0.0291	51.46	70.87	75.73	80.58
Oregon	0.4866	74.33	84.60	87.16	89.73
Pennsylvania	0.0192	50.96	70.58	75.48	80.38
Rhode Island	0.0023	50.12	70.07	75.06	80.05
South Carolina	0.0315	51.58	70.95	75.79	80.63
South Dakota	0.1410	57.05	74.23	78.53	82.82
Tennessee	0.0332	51.66	71.00	75.83	80.66
Texas	0.0112	50.56	70.34	75.28	80.22
Utah	0.6613	83.07	89.84	91.53	93.23
Vermont	0.0541	52.71	71.62	76.35	81.08
Virginia	0.0748	53.74	72.24	76.87	81.50
Washington	0.3250	66.25	79.75	83.13	86.50
West Virginia	0.0679	53.40	72.04	76.70	81.36
Wisconsin	0.0555	52.78	71.67	76.39	81.11
Wyoming	0.5244	76.22	85.73	88.11	90.49
District of Columbia	0.1574	57.87	74.72	78.94	83.15
Puerto Rico	0.0124	50.62	70.37	75.31	80.25

[1] Area of non-taxable Indian Lands and reserved and unreserved public domain lands inclusive of national forests and national parks and monuments. Based on latest available area data furnished by the Department of Interior.
[2] Maximum amount.

TABLE 3.—U.S. DEPARTMENT OF TRANSPORTATION, FEDERAL HIGHWAY ADMINISTRATION

[Sliding scale rates of Federal-aid participation in public lands states—rates for interstate programs—pursuant to 23 U.S.C. 120(c)—effective March 17, 1992]

State	Interstate Construction and Resurfacing Programs [1]	
	Ratio of designated public lands area [2] to total area of State	Percentage of cost of Federal-aid projects payable by Federal government—90% Federal/10% State
Alaska	0.3403	93.40
Arizona	0.4337	94.34
California	0.1574	91.57
Colorado	0.1206	91.21
Idaho	0.2269	92.27
Montana	0.1242	91.24
Nevada	0.6923	[3]95.00
New Mexico	0.2644	92.64
Oregon	0.2223	92.22
South Dakota	0.0972	90.97
Utah	0.4163	94.16
Washington	0.0660	90.66
Wyoming	0.2758	92.76

[1] a. These rates apply to all projects authorized on or after December 29, 1981, for resurfacing, restoring, rehabilitating and reconstructing routes of the Interstate System and all Interstate construction projects.
b. Pursuant to Section 120(c), Title 23 U.S.C., any project financed with primary funds on the Interstate System for resurfacing, restoring, rehabilitating and reconstructing shall be available for these rates.
[2] Area of unappropriated and unreserved public lands and non-taxable Indian Lands. Based on latest available data furnished by the Department of Interior.
[3] Maximum amount.

MEMORANDUM

Date: March 24, 1992.
Reply to Attn of: HIA–20.

Subject: Intermodal Surface Transportation Efficiency Act of 1991.
From: Director, Office of Motor Carrier Information Management and Analysis.
To: Regional Directors, Office of Motor Carriers *Thru:* Michael F. Trentacoste Director, Office of Motor Carrier Field Operations (HFO–1).

Reference is made to Mr. Landis' December 19, 1991, memorandum asking that you coordinate the collection of State responses regarding the longer combination vehicle (LCV) information required by the Intermodal Surface Transportation Efficiency Act (ISTEA). We appreciate the fine effort made by both the region and division offices in helping all of the States meet the initial 60-day information submission deadline.

The State responses have been processed and an initial Notice of Proposed Rulemaking (NPRM) was published Friday, March 20. Sufficient copies of the NPRM are included with this memorandum to provide one for your office and two for each division. Please have the divisions forward one copy to the State, along with a copy of the attached instructions.

The OMC division personnel are asked to work with the States to see that the "operational conditions" responses are subdivided by the indicated categories. As with any FHWA rulemaking, direct comments by our field offices should be sent to HIA–20 at Headquarters, attention Mr. Tom Klimek, not to the docket.

Again, we appreciate the effort you have made in coordinating the FHWA's efforts to comply with the ISTEA. If you have any questions, please contact Tom Klimek of my staff, at FTS 366–2212.

John F. Grimm

Attachment

Attachment 1—Instructions for State Review of the NPRM on Restrictions for LCV's and Combination Vehicles With Two or More Cargo Carrying Units

1. Have each State carefully review the information contained in the NPRM regarding the operation of LCV's and combination vehicles with two or more cargo carrying units in the State, and make any corrections needed.

2. On **Federal Register** (FR) page 9902, a misrepresentation contained in our original LCV questionnaire is explained. A straight truck-trailer combination can contain two cargo carrying units, but a State strictly following the LCV questionnaire instructions could easily have overlooked this combination. Any State which allows, but did not report, the operation of this combination should do so at this time, in accordance with cargo-carrying length determination guidelines described in the NPRM (page 9900). The operation of this combination *must* be reported by a State if the cargo carrying length exceeds 65 feet. A State should not report the operation of this combination with cargo carrying lengths less than or equal to 65 feet.

3. FR page 9902 also discusses the wide range of topics and level of detail with respect to "operational conditions" provided by the States in responding to the questionnaire. In an attempt to provide uniformity in this area, the NPRM is asking the States that allow LCV's and/or extra-length vehicles to provide initially, or resubmit, the condition information in a uniform manner for appendix C, and at least the first vehicle combination described in appendix D, using the following subject headings in the sequence indicated.

a. *Weight*—List the maximum single axle, tandem axle and gross weight; as well as any

axle spacing requirements for each combination vehicle.

b. *Driver*—Describe any special training or experience required to handle the combination vehicle described that is in addition to a commercial driver's license with appropriate endorsement(s).

c. *Vehicle*—Describe any special requirements that apply; such as horsepower, braking ability, off-tracking limits or order of trailers.

d. *Permit*—Indicate whether a permit is required and, if so, its duration, type, i.e., whether it is for a single or multiple trip and if a fee is charged (for purposes of this rule, the amount of the fee is irrelevant).

e. *Access*—Recognizing that approved operating routes are listed separately, describe any conditions which would restrict vehicle access between terminals and approved highways, i.e., describe what, if any, "reasonable access" conditions exist for the combination described.

For subsequent vehicle combinations described in appendix D, the information provided for the first vehicle may be referenced if it is the same. If different conditions apply to different vehicle combinations they must be listed.

In completing this information, the States are requested to restrict the response for each subject heading to one double-spaced typewritten page, if at all possible.

If the information for these subject headings is part of a booklet or other publication, or longer than the suggested one-page length, we ask that the States succinctly summarize the information for each heading and provide a copy of the source document. If the FHWA was provided a copy of the source document as part of the original LCV information response, the States do not have to submit another copy, they may simply reference the first. If no requirements exist for a subject heading please so indicate. The operational conditions described in appendices C and/or D are intended to be an informational summary of the major conditions for the public at large. They are not to be used as the basis for actual operations. Accordingly, the FHWA feels that summaries of regulatory documents and cross references to information provided elsewhere are appropriate to convey this information.

Information that is provided by any State in response to the foregoing instructions, or any other aspect of the NPRM including the general questions on cargo-carrying length determination (page 9900), and presentation format (page 9903), must be submitted to the docket by the date (May 4, 1992) contained in the NPRM.

MEMORANDUM

Date: June 19, 1992.
Reply to Attn. of: HPS–30, TBP–20.
Subject: *Information*: Fiscal Procedures for Federal Transit Projects Financed by Federal Highway Administration Funds.
From: Director, Office of Fiscal Services. Director, Office of Budget and Financial Management.
To: Federal Highway Administration Associate Administrators, Federal Highway Administration Regional Administrators, Federal Highway Administration Division Administrators, Federal Transit Administration Executive Staff, Federal Transit Administration Regional Administrators.

23 U.S.C. 134(k) provides, in part, that funds made available for a transit project by the Intermodal Surface Transportation and Efficiency Act of 1991 (ISTEA) shall be administered in accordance with the requirements of the Federal Transit Act. Therefore, the following are the procedures to be employed when using funds apportioned or allocated by the Federal Highway Administration for transit projects administered by the Federal Transit Administration (FTA):

Obligation of Funds

State Highway Agency—Notifies the FHWA Division Administrator to obligate funds to cover an initial project application submitted to the FTA Regional Office. The notification from the SHA must identify both the FTA and FHWA project numbers and amount to be obligated. A copy should be provided to the Local Transit Agency. Project overruns will be handled in the same manner. The submission of this letter is an indication that the SHA approves the use of its apportioned funds and forms the basis for the later transfer of cash by FHWA Headquarters, when requested by FTA.

FHWA Division Office—Division Administrator determines funds are available and obligates the funds in the FMIS. The Division notifies the SHA, FHWA Finance Division (HFS–20) and FTA Headquarters, Financial Management Division (TBF–23), of the date the funds were obligated, the amount, both FTA and FHWA project number, and the FHWA appropriation code.

The Division Office enters an FHWA–37, Step 8, "underway" and reports the project "under agreement".

The following are the Surface Transportation Program (STP), and Congestion Mitigation and Air Quality (CMAQ), appropriation codes and the corresponding subsidiary code to be used by FHWA when obligating funds for transit projects to be administered by FTA. The FTA Transit Code will be used by FTA in tracking the projects.

FHWA STP code	FHWA transit code	FTA transit code
3AA	3AY	AY
3AA	3AL	AL
3AB	3AM	AM
3AC	3AK	AK
3AD	3AN	AN
3AE	3AP	AP
3AM	3AR	AR
3AN	3AT	AT
3AP	3AW	AW

FHWA CMAQ code	FHWA transit code	FTA transit code
320	3AZ	AZ

Additional codes will be established as necessary.

FTA Headquarters—The FTA Office of Budget and Financial Management advises the FTA Regional Office of the availability of funds and to proceed with grant award.

FTA Regional Office—Awards the grant, records it in the FTA GMIS and notifies the grantee of the grant award.

Project Expenditures

Grantee—As work proceeds on the project, the grantee will request Federal funds through the FTA ECHO Payment System.

FTA Headquarters—FTA sends memorandum requesting current cash needs (monthly basis) to FHWA Finance Division (HPS–20).

FHWA Finance Division—Transfers cash to FTA (By SF–1151).

FTA Headquarters—Submits monthly reports to FHWA Finance Division as agreed to by FHWA and FTA.

FHWA Finance Division—Prepares FHWA–371, Code card (TT–98) reflecting the FTA expenditure by FHWA project number. Prepares a monthly reconciliation comparing project obligation and cost data with the "open" and "closed" project data submitted by FTA.

Project Closing

FTA Regional Office—Advises the State Highway Agency of project completion and of final project costs (total cost and Federal Funds).

SHA—Advises Division Office that the Project is complete.

FHWA Division Office—Enters an FHWA–37 project transaction advancing the project to a Step 8, closing status.

The use of these procedures should ensure that highway funds utilized for transit projects administered by FTA are obligated in a timely and efficient manner.

Peter J. Basso.

J.L. Wilson.

MEMORANDUM

Date: September 3, 1992.
Reply to Attn of: HEP–32.
Subject: Public Involvement.
From: Director, Office of Environment and Planning.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

Sections 1024 and 1025 of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) require opportunity for comment by the public on both long range transportation plans and Transportation Improvement Programs (TIP) for both the Metropolitan Planning processes and the statewide planning processes. By specifically identifying the intended public in each section (citizens, affected public agencies, etc.), the legislation clearly indicates the need for a broad outreach beyond the traditional focus of the most current programs. Our recent "Interim Guidance on the ISTEA Metropolitan Planning Requirements" and "Interim Guidance—23 U.S.C. 135 Statewide Planning Requirements" both specify that public involvement procedures include opportunities for interested parties to be

involved in the early stages of the plan development/update process. The somewhat more detailed Metropolitan Planning Organization (MPO) guidance adds early involvement in development of the TIP and provision for public information through publication or other dissemination of the long-range plan. The statewide planning guidance reiterates the requirement for public comment on the statewide TIP thereby implying public information and early involvement. Thus, at present, public involvement for both planning processes includes three elements: (1) Broad outreach, (2) early opportunity for involvement and comment continuing to adoption of the plan or TIP, and (3) public information.

There are, however, larger implications for public involvement than just two new, required public involvement processes. FHWA has long required public involvement for project development under National Environmental Policy Act (NEPA). The Environmental Protection Agency (EPA) intends to include a public involvement consultation as part of the air quality conformity regulations required by the Clean Air Act Amendments. All of these provisions result in the potential for four separate Federal public involvement requirements for highway project. There is considerable potential for public confusion and duplicate involvement opportunities. Here in Washington, we strongly believe that public involvement on air quality conformity issues should be conducted as part of the planning processes. I urge you to advocate with our partners in State and local governments that the public involvement processes at the planning and project development levels be coordinated with one another. Such efforts must respect the differences between individual States and between individual MPOs. Also, we need to institutionalize ways to assure that information received from public input during metropolitan or statewide planning reaches project development staff.

In addition to providing technical assistance on public involvement in project development, I have asked the Environmental Operations Division to assist the Metropolitan and Statewide Planning Divisions in providing technical assistance on public involvement in the metropolitan and statewide planning processes. As a basis for influencing FHWA policy, developing guidance and identifying research needs, we recently asked each region to provide information on good examples of public involvement procedures being used in the metropolitan planning process. As a result of this request, we received information from several regions as shown on the attachment. Since the response to our previous request was rather limited, we are now formally requesting the submission of information on any other examples of good public involvement procedures used in metropolitan planning that was not previously submitted. We would also like to receive information on any examples of good public involvement procedures being used in statewide planning. This information should be submitted by October 15 so we may use it in a report on good practices.

An informal telephone survey of the regions was conducted earlier this year to obtain an idea of the public involvement procedures being used in metropolitan and statewide planning prior to ISTEA. This information was useful and we appreciate the assistance of the Regional staff. To be able to respond to questions on the procedures and processes being used to address the ISTEA requirements and to develop a data base on public involvement, we would like to receive information on existing, new, or revised public involvement procedures that MPOs and States plan to use to satisfy these requirements. For statewide planning this should include involvement of the Indian Nations, where appropriate. We also would like any information on how States and MPOs are providing linkages between the new metropolitan and statewide public involvement processes and existing State public involvement/public hearing procedures for project development. A brief description of the procedures and techniques will be adequate.

Please send the information to Florence Mills, HEP–32. For additional information on this request, please contact Mrs. Mills at (202) 366–2062. Policy questions on public involvement in metropolitan planning should be directed to Sheldon Edner or Dean Smeins in HEP–21. Policy questions on public involvement in statewide planning should be directed to Martin Weiss or Tom Weeks in HEP–12.

Kevin E. Heanue.

Attachment

Responses Received From Field Survey

MPO Public Involvement Procedures

Region 4

Kentucky: brief summary for each MPO.

Alabama: table of MPO public involvement methods by MPO.

North Carolina: summary of State Action Plan and Winston-Salem procedures.

Florida: summary for State MPOs as a group plus relevant checklist items from Urbanized Area Transportation Planning Process Certification Procedure.

Region 5

Minnesota: section on Public Involvement from 1991 Transportation Unified Planning Work Program for the Twin Cities Metropolitan Area.

Region 8

Utah: copy of Certification Package for Salt Lake and Ogden including summary of public involvement activities 1985-present.

Region 9

Arizona: summary of Maricopa Association of Governments public involvement activities plus relevant excerpts from this MPO's 1991 Unified Planning Work Program.

California: excerpts of State requirement and guidelines for public involvement in preparing long range transportation plans and TIPs plus sample discussion of public involvement activities from San Diego.

Region 10

Oregon: brief summary of Portland procedures plus Bylaws of Transportation Policy Alternatives Committee (6 citizens, 13 local officials).

Washington: brief summary of Seattle procedures plus detailed description of public involvement for recent long range plan update by Puget Sound COG.

MEMORANDUM

Date: June 24, 1992.
Reply to Attn. of: HFL–11.
Subject: Statewide Planning and Development of Transportation Improvement Programs (TIP) for the Federal Lands Highway Program (Reply due July 20, 1992).
From: Federal Lands Highway Program Administrator; Federal Lands Highway Office.
To: Federal Lands Highway Division Engineers.

This memorandum and attachments explain the revised statewide transportation planning and programming requirements, processes, and your role. In section 1025 of the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991, Public Law 102–240, Congress established requirements for statewide planning. The Federal Highway Administration (FHWA) and the Federal Transit Administration jointly issued interim guidance on the ISTEA statewide transportation planning and programming requirements pending the issuance of formal guidance through the rulemaking process. A copy of the interim guidance along with the wording of Section 135, Statewide Planning, of title 23 U.S.C. are attached (Attachments 1 and 2).

The statutory requirements for statewide transportation planning and programming include:

—Implementation of a statewide transportation planning process that involves local officials and Indian tribal governments
—Increased coordination between Metropolitan Planning Organizations, States, Federal agencies, and Indian tribal governments
—A list of 20 factors that must be considered as part of the planning process
—Investment strategies to improve adjoining State and local roads that support rural economic growth and tourism development, Federal agency renewable resources management, and multipurpose land management practices, including recreational development
—Development of a long-range transportation plan for all areas of the State
—Development of a Statewide Transportation Improvement Program (STIP) that includes all projects funded under title 23 U.S.C.
—Project selection

All Federal Lands Highway Program (FLHP) projects must be in the appropriate State's STIP in order to be funded. In cooperation with our Office of Environment and Planning, we have developed interim statewide transportation planning and programming procedures for the Federal Lands Highway programs funded under 23 U.S.C. A copy of these procedures is also attached (Attachment 3).

Under these interim procedures, the Federal Lands Highway Office (FLHO) and its three divisions will:

1. Statewide Transportation Improvement Program: Develop a financially constrained transportation improvement program (TIP) for FY 93 and FY 94 (longer if the information is available) using available approved long-range programs in each FLHP category. The divisions will develop the Forest Highway TIPs for the Forest Highway programs for their respective States. The FLHO, in cooperation with the National Park Service (NPS), will develop the Park Roads and Parkways (PRP) TIP for the PRP program. The Bureau of Indian Affairs (BIA) will prepare its Indian Reservation Roads (IRR) TIP for the IRR program. All TIPs will be sent to the FLHO. The FLHO will assemble the TIPs for all FLHP categories by State and forward them to each FHWA region for inclusion in the appropriate STIPs.

2. Federal Land Management Agency Planning Information: Initiate efforts to have the Bureau of Land Management (BLM), BIA, Forest Service (FS), and NPS develop inventories of existing transportation plans and land and resource management plans, and have copies of all existing transportation plans provided to the appropriate State highway agency by October 1.

3. Federal Land Management Agency Planning Personnel: Develop directories of transportation planning personnel in the BIA, BLM, FS, and NPS. These directories will be distributed to all State highway agencies and appropriate Federal agencies by our Office of Environment and Planning later in the year.

Instructions and format for preparing the FLHP TIPs are attached (Attachment 4, Diskette). We would appreciate receiving the TIPs (paper and magnetic) on the Forest Highway portion of the program for your respective States by July 20.

We have written letters to the BIA, BLM, FS, and the NPS advising them of these statewide transportation planning and programming requirements and requesting assistance. If you have any questions, please call Mr. Paul Lee on 202–336–0487.

Thomas O. Edick.

4 Attachments
June 17, 1992

Interim Statewide Transportation Planning and Programming Procedures, Federal Lands Highway Programs Funded Under 23 U.S.C.

Focus of Interim Procedures

The purpose of this Interim Statewide Transportation Planning and Programming Procedures for the Federal Lands Highway Program (FLHP) is to provide detailed guidance for complying with the Statewide Transportation Improvement Program (STIP) and Project Selection requirements that were established in section 135, Statewide Planning, of title 23 U.S.C. by section 1025(a) of the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991, Public Law 102–240. It defines the responsibilities of the three Federal Lands Highway Divisions, the Bureau of Indian Affairs (BIA), the Bureau of Land Management (BLM), the Forest Service (FS), and the National Park Service (NPS) and provides procedures for preparing and transmitting FLHP and project selection information for inclusion into STIPs. These procedures are expected to remain in effect until the pending rulemaking by FHWA is completed.

Background

The new section 135(f) of title 23 requires:

1. Each State to develop a STIP for all areas of the State.

2. All projects within the boundaries of the State that are funded under title 23 to be included in the STIP.

3. Opportunity for public comment on the STIP.

4. The STIP to reflect the priorities for programming and expenditure of funds.

5. Investment strategies to improve adjoining State and local roads that support rural economic growth and tourism development, Federal agency renewable resources management, and multipurpose land management practices, including recreational development.

6. Biennial review and approval of the STIP by the Secretary of the U.S. Department of Transportation.

In addition, amended section 204 of title 23 U.S.C. requires Indian tribal governments in cooperation with the BIA and as may be appropriate with State, local government, or metropolitan planning organizations (MPOs), to develop a transportation improvement program that includes all Indian reservation road projects proposed for funding. Projects are to be selected by the Indian tribal government from the (IRR) transportation improvement program and shall be subject to the approval of the Secretaries of Interior (BIA) and Transportation (FHWA).

The amended section 204 of title 23 U.S.C. also requires that no public lands highway project may be undertaken in any State unless the State concurs in the selection and planning of the project.

Policy

The Federal Lands Highway Office (FLHO) is in full support of an integrated multimodal statewide transportation planning and programming process which is used to develop a multiyear STIP of projects. The process needs to satisfy the following criteria:

- An efficient and effective process is needed to provide timely and complete project information to State highway agencies for statewide transportation planning and development of a STIP.
- The process shall not stop the allocation of Federal Lands Highway (FLH) funds for the approved program of projects on the first workday of each Federal fiscal year.
- The FLHP Administrator (or as delegated) will continue to approve the annual and long-range priority program of projects, in accordance with Interagency Agreements and/or Regulations, for the Forest Highway portion of Public Lands Highways, IRR, and PRP.

We have reviewed the May 28, 1992, Interim Guidance on ISTEA Statewide Transportation Planning and Programming (HPD–1/TGM–1) which was prepared by the Office of Environment and Planning. The proposed guidance provides adequate flexibility. The following process is intended to detail the interim guidance with respect to the FLHP.

Statewide Planning Process

The FLHO will:

- Initiate efforts to have the BLM, BIA, FS, and NPS develop inventories of all existing transportation plans and land and resource management plans by September 1.
- Initiate efforts to have copies of all existing transportation plans provided to the appropriate State highway agency by October 1.
- Develop personnel directories of transportation planning personnel in the BIA, BLM, FS, and NPS, in cooperation with the Federal agencies.
- Work with the Federal agencies to modify the existing memorandums of agreement to incorporate transportation planning and other ISTEA requirements and procedures.
- Work with the Federal agencies to develop transportation planning and programming procedures to meet ISTEA requirements.

Federal agencies need to develop or revise their procedures to improve coordination in the transportation planning area with State highway agencies, local governments, Indian tribal governments, and MPOs. The only change anticipated by the FLHO to the tri-agency Forest Highway meetings is that the meetings will need to be held earlier in the fiscal year.

Fiscal Year 1992 Federal Lands Highway Projects

Under these interim procedures, Federal funds made available under title 23 for the FLHP may be obligated without being included in a STIP until October 1 provided they are in an approved program of projects.

Process for Developing a Statewide Transportation Improvement Program (STIP)

Under these interim procedures, the FLHO and its three divisions will develop financially constrained transportation improvement programs (TIPs) for FY 93 and FY 94 (longer if the information is available) using available approved long-range programs in each FLHP category. The divisions will develop the Forest Highway TIPs for the Forest Highway programs for their respective States. The FLHO, in cooperation with the NPS, will develop the financially constrained Park Roads and Parkway (PRP) TIP for the PRP program using the existing multiyear program of projects and the NPS-wide priority list. The BIA will prepare its financially constrained IRR TIP from information provided by the Indian tribes. All TIPs will be sent to FLHO. The FLHO will assemble the FLH TIP (including all FLHP categories) by State and forward them to each FHWA region by August 1 for inclusion in the appropriate STIPs. Copies of the FLH TIP will be also be provided to Office of Environment and Planning.

The FLH TIP will be divided by FLHP funding category, fiscal year, and by State. There should be one page per fiscal year when one or more projects are planned or programmed in that State. A copy of the required TIP page format is attached. The

divisions are to furnish their TIPS in both paper and magnetic form.

The TIP will have the following information on a project:

—County
—Route number
—Highway or bridge name/identification
—Project limits or termini
—Type of project
—Net construction amount to be funded
—Contracting agency
—Priority
—Source of funding
—Fiscal year to be funded

The costs for preliminary and construction engineering for all projects should be totaled and entered on the form. The FLHO or FHWA Federal Lands Highway Division Engineer shall approve the projects in the STIP.

A signature block is provided for the State official to indicate when this information is incorporated into the STIP.

Only those projects included in the list of projects will be eligible for funding beginning October 1, 1992.

Emergency projects (i.e., bridge failure, slide, etc.) may be advanced to funding even if they were not in the original STIP submission. A revised TIP must be prepared and forwarded to the FLHO for transmission to the appropriate State.

An updated TIP should be submitted by March 1 of each subsequent fiscal year. This earlier date is necessary to provide the States with adequate time to allow for public comment on their STIP.

Instructions for Entering Information on the FLH TIP

State: Enter the State name where the projects are located.

Fiscal Year: Enter the Federal fiscal year of funding.

County: Enter the county(s) where the project is located.

Route Number: Enter the State, U.S., or Federal route number.

Highway/Bridge Project Name: Enter the highway or bridge name. The National Forest, Park, or area name can also be entered here. The National Bridge Inspection System number can be entered here.

Project Limits/Termini: Enter the limit or project termini.

Type of Project: Enter the type of project such as grade, drain, base, pave, reconstruction, overlay, bridge, signing, etc.

Net Construction Program Funding Amount: Enter the amount of program funds to be used for actual construction. Construction engineering costs are not to be included.

Contracting Agency: Enter the name of the agency or organization that will administer the construction contract.

Priority: Enter the priority of the project. Priority can be High, Medium, Low, Back-up Project, or numeric.

Engineering Costs and Funding: The costs for preliminary and construction engineering for all projects should be totaled and entered on the form. The total program funds available for the fiscal year including any carryover should also be entered.

Signature Boxes: The FHWA Federal Lands Highway Division Engineer shall approve the Forest Highway projects in the STIP. The Federal Lands Highway Program Administrator will approve the IRR and PRP projects in the STIP.

BILLING CODE 4910-22-M

PARK ROADS AND PARKWAY (PRP) TRANSPORTATION IMPROVEMENT PROGRAM FOR FEDERAL FISCAL YEAR _____

FEDERAL LANDS HIGHWAY PROGRAM, 23 U.S.C 204

STATE: _____

County	Route Number	Highway/Bridge Project Name	Project Limits/Termini	Type of Project	Net Construction Program Funding Amount($000)	Contracting Agency	Priority
Statewide	Total of Preliminary and Construction Engineering for all projects:				0		

Cost and Funding Summary

Total Program Cost for fiscal year: 0
Program Funds Available: 0
Balance: 0

Federal Lands Highway Program Approval: _____ Date: _____

State inclusion in STIP: _____ Date: _____

A:STIP-PRP.WK1 Prepared by: _____ HFL-11 Date: 17-Jun-92

INDIAN RESERVATION ROAD (IRR) TRANSPORTATION IMPROVEMENT PROGRAM FOR FEDERAL FISCAL YEAR _____

FEDERAL LANDS HIGHWAY PROGRAM, 23 U.S.C 204

STATE: _____

County	Route Number	Highway/Bridge Project Name	Project Limits/Termini	Type of Project	Net Construction Program Funding Amount($000)	Contracting Agency	Priority
Statewide	Total of Preliminery and Construction Engineering for all projects:				0		

Cost and Funding Summary		
	Total Program Cost for fiscal year:	0
	Program Funds Available:	0
	Balance:	0

Federal Lands Highway Program Approval: _____ Date: _____

State Inclusion in STIP: _____ Date: _____

A:STIP-IRR.WK1 Prepared by: _____ Date: 17-Jun-92

FOREST HIGHWAY (FH) TRANSPORTATION IMPROVEMENT PROGRAM FOR FEDERAL FISCAL YEAR _____

FEDERAL LANDS HIGHWAY PROGRAM, 23 U.S.C 204

STATE: _____

County	Route Number	Highway/Bridge Project Name	Project Limits/Termini	Type of Project	Net Construction Program Funding Amount($000)	Contracting Agency	Priority
Statewide	Total of Preliminary and Construction Engineering for all projects:				0		

Cost and Funding Summary

Total Program Cost for fiscal year: 0
Program Funds Available: 0
Balance: 0

Federal Lands Highway Program Approval: _____ Date: _____

State inclusion in STIP: _____ Date: _____

A:STIP-FHE.WK1 Prepared by: _____ HFL-15 Date: 17-Jun-92

Page 1

BILLING CODE 4910-22-C

June 30, 1992.

The Honorable James M. Ridenour, Director,
National Park Service, Department of the Interior, Washington, DC 20240.

Dear Mr. Ridenour: The Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991, Public Law 102–240, made a number of changes to the park roads and parkways (PRP) program. During the past several months, our staffs have held a number of discussions on the procedures to implement the new provisions of the ISTEA. On May 19–21, the National Park Service (NPS) and the Federal Highway Administration (FHWA) held an interagency PRP program meeting. The enclosures provide the interim guidance for implementing 23 U.S.C. 204, Federal Lands Highway Program, as amended by the ISTEA.

The ISTEA of 1991 expands the list of items eligible for PRP program funding. In cooperation and coordination with your staff, we have updated the listing of eligible program items that was first issued in July 1983. The revised list identifies items that may be funded, items that will generally not be funded due to their low priority in relation to the large PRP backlog of needs, and items that will not be funded under the PRP program category.

We will continue working with your staff to finalize details for implementing the new program requirements. If there are any questions, please contact us.

Sincerely yours,

Allen W. Burden, for Thomas O. Edick, P.E.,
Federal Lands Highway Program Administrator, Federal Lands Highway Office.

FHWA Interim Guidance on Park Roads and Parkways Program (23 U.S.C. 101 and 23 U.S.C. 204)

June 30, 1992.

The purpose of this Interim Guidance on the Park Roads and Parkways Program is to provide guidance for complying with the requirements of 23 U.S.C. 101, 23 U.S.C. 202, and 23 U.S.C. 204, Federal Lands Highways Program, as stated and amended by section 1032 of the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991, Public Law 102–240.

Provision—The term "park road" means a public road, including a bridge built primarily for pedestrian use, but with capacity for use by emergency vehicles, that is located within or provides access to an area in the national park system with title and maintenance responsibilities vested in the United States, 23 U.S.C. 101.

Guidance—This provision redefines the temporary bridge between Ellis Island and Liberty State Park as a park road. A permanent replacement for the bridge is a project being executed jointly by the FHWA and the NPS. On March 20, a program schedule was developed. The design and construction of this bridge will be expedited upon approval of the Record of Decision in accordance with the National Environmental Policy Act.

Provision—The Secretary of Transportation, in cooperation with the Secretary of the Interior and the Secretary of Agriculture shall develop appropriate transportation planning procedures and safety, bridge, and pavement management systems for roads funded under the Federal Lands Highway Program, 23 U.S.C. 204(a).

Guidance—Current park roads and parkways (PRP) program transportation planning procedures will continue for the interim period. The NPS and FHWA will jointly prepare a Transportation Improvement Program (TIP) for the PRP program. The June 24, 1992, letter to the NPS describes the interim TIP procedures for roads funded under the Federal Lands Highway Program. The existing information system will be reviewed by NPS and FHWA to determine whether any enhancements are necessary to meet new management systems requirements and guidance will be jointly developed. Guidance on additional appropriate transportation planning procedures and management systems will be issued at later dates.

Provision—All appropriations for the construction and improvement of each class of Federal lands highways shall be administered in conformity with regulations and agreements jointly approved by the Secretary of Transportation and the Secretary of the appropriate Federal land managing agency, 23 U.S.C. 204(f).

Guidance—The Memorandum of Agreement signed by the NPS on May 3, 1983, and by the FHWA on May 19, 1983, remains in effect. A technical addendum updating and conforming legal references will be jointly developed by the NPS and FHWA, if necessary.

Funding of Program Items, Park Roads and Parkways Program

June 30, 1992.

Provision—The Secretary of Transportation shall allocate the sums authorized to be appropriated for such fiscal year for park roads and parkways each according to the relative needs of the various elements of the national park system, taking into consideration the need for access as identified through land use planning and the impact of such planning on existing transportation facilities, 23 U.S.C. 202(c)

Provision—Funds available for park roads, parkways, and Indian reservation roads shall be used by the Secretary of the Interior to pay for the cost of planning, research, engineering and construction thereof, 23 U.S.C. 204(b).

Provision—Funds available for each class of Federal lands highways shall be available for any kind of transportation project eligible for assistance under this title that is within or adjacent to or provides access to areas served by the particular class of Federal lands highways, 23 U.S.C. 204(b).

Provision—Funds available for each class of Federal lands highways may be available for the following: (1) Transportation planning for tourism and recreational travel including the National Forest Scenic Byways Program, Bureau of Land Management Back Country Byways Program, National Trails System Program, and similar Federal programs that benefit recreational development, (2) Adjacent vehicular parking areas, (3) Interpretive signage, (4) Acquisition of necessary easements and scenic or historic sites, (5) Provisions for pedestrians and bicycles, (6) Construction and reconstruction of roadside rest areas including sanitary and water facilities, (7) Other appropriate public road facilities such as visitor centers as determined by the Secretary of Transportation, 23 U.S.C. 204(h).

Guidance—The following updates the July 19, 1983, list of eligible park roads and parkways (PRP) program items. The list identifies items that may be funded, items that will generally not be funded, and items that will not be funded under the PRP program category. Funding for some items will be jointly determined by National Park Service (NPS) and Federal Highway Administration Headquarters based on overall relative PRP program priorities.

Items That May Be Funded

Project Support Items

- Transportation planning including planning for tourism and recreational travel that benefits recreational development.
- Research part of coordinated technology implementation program (CTIP).
- Traffic engineering and safety studies.
- Identification and surveillance of accident locations.
- Development of road and bridge standards.
- Bridge, pavement, and safety management.
- Selected preliminary engineering studies.
- Necessary interagency program/project formulation meetings.
- Interagency program review meetings (per interagency agreement).
- Necessary environmental studies and archeological investigation confined to the general roadway construction limits.
- Necessary architectural and landscape engineering services.
- Engineering design for roads and bridges.
- Necessary interagency project coordination.
- Project related revegetation.
- Construction engineering for contract administration, inspection and testing.

Construction and Improvements Items

- Engineered pavement overlays that add structural value, design life or improved skid resistance.
- Double bituminous surface treatments and chip seals that are part of predefined stage construction or form final surface on low volume roads.
- Engineered rehabilitation or reconstruction of pavement structures, bridges and bridge decks, and tunnels.
- Engineered spot safety improvements resulting from safety studies.
- Upgrading of substandard traffic barriers and bridge rails to current standards.
- Replacement of nonstandard traffic regulatory and guide signs.
- Upgrading substandard or nonconforming traffic markings (1-time only).
- Park entrance signs if the sign conforms to park standards, is in a safe location, is part of an adjacent park road project, and is of reasonable cost ($10,000 maximum).
- Handling traffic and pedestrians through construction zones.

- Public approach roads and interchange ramps which are under the jurisdiction and responsibility of the NPS.
- Installation of warranted roadway lighting.
- Adjustment of utilities directly related to roadway work.
- Conducts crossing under the roadway to accommodate future planned utilities.
- Landscaping and seeding of areas disturbed by PRP road construction.
- Landscaping required to meet EIS mitigation measures resulting from roadway construction.
- Construction of erosion control and environmental mitigation measures directly related to roadway construction.
- Experimental features where there is a planned monitoring evaluation schedule.
- Public parking lots or pull-offs to trail heads, interpretive areas, public lodging, visitor center, (including necessary supporting retaining walls, protective railings and adjacent perimeter sidewalk.
- Provisions for pedestrians within/adjacent to roadway prism when warranted for safety reasons.
- Restoration of burrow pits created by projects funded from the PRP program.
- Force account and day labor, including materials and equipment rental, being performed in accordance with approved plans and specifications, which has been determined to be cost-effective (public interest).

Funding Will Generally Not Be Made Available for the Following Items

(Funding will be determined on a case-by-case exception basis taking into consideration overall relative PRP program priorities.)

Project Support Items

- Acquisition of necessary scenic easements and scenic or historic sites.

Construction or Improvements Items

- Special use tram roads if in lieu of constructing a 2-lane public road and additional parking lots.
- Bike paths, unless they are part of the park's approved General Management Plan (GMP), constructed in conjunction with PRP projects, and are:
  - —part of a roadway prism necessary for safety reasons and if bike traffic warrants,
  - —independent paths used for transportation and safety reasons based on accident and traffic data analysis.
- Interpretive signage part of a roadway project.
- Construction of visitor information centers and related items.
- Construction of roadside rest area including sanitary and water facilities.
- Bridge painting work on structures (painting of major large structures considered on a case-by-case exception basis).
- Other public roads which provide access to areas under the jurisdiction and responsibility of the NPS.

Items That Will Not Be Funded

Project Support Items

- General park planning.
- Nonprogram specific conferences, field trips, or training conferences.
- Archeological investigations and work outside roadway construction limits.

Construction or Improvements Items

- Construction of campground roads and related parking pads (Reference NPS 3/28/89 Memorandum for relative PRP program priority funding).
- Cyclic roadway maintenance work including chip and slurry seals (seal coats), pavement patching, shoulder and ditch grading, cleaning culverts, snow removal, roadside mowing, normal sign repair and traffic markings.
- Seal coats on top of new asphalt concrete pavements.
- Cyclic bridge maintenance work including cleaning and repairing bridge joints, cleaning and repairing bridge drainage, and repairing other bridge appurtenances.
- Landscaping and irrigation systems of areas not disturbed by PRP road construction.
- Utilities and buildings not disturbed by construction.
- Sanitation facilities not disturbed by construction.
- Walls and erosion protection that are not part of or support the roadway prism.
- Recreational boat launching facilities and ramps.
- General park development project.
- Park road that serves only an administrative site such as park housing, maintenance areas, or park dormitory (or a combination of these).
- Park road that provides access to Park Headquarters which is not open to the general public (i.e., not a visitor center).
- Restoration of borrow pits (or portions of borrow pits) created by projects funded with non-PRP program funds.
- Repairs to or replacement of fences not disturbed by PRP road construction.
- Fences constructed for esthetics.

June 30, 1992.

Mr. Patrick A. Hayes, Deputy to the Assistant Secretary—Indian Affairs,
U.S. Department of the Interior, 1849 C Street, NW (Code 260 MS 4588), Washington, DC 20240.

Dear Mr. Hayes: The Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991, Public Law 102–240, made a number of changes to the Indian Reservation Road (IRR) program. During the past several months, our staffs have held a number of discussions on the procedures and policy to implement the new provisions of ISTEA. The enclosures provide the interim guidance for implementing section 204, Federal Lands Highway Program, of title 23 U.S.C. as amended by ISTEA.

The ISTEA has significantly increased the items that are eligible for IRR funding. The last list of eligible program items was issued in July 1983. The revised list of program items identifies items that may be funded, items that will generally not be funded due to their low priority in relation to the large IRR backlog of needs, and items that will not be funded under the IRR program category.

We will continue working with your staff on procedures and policy for implementing new program requirements from the ISTEA. If you have any questions, please call Mr. Paul R. Los on FTS 202–366–9487 or Mr. Salim Nassif on FTS 202–366–9490.

Sincerely yours,

Allen W. Burden for Thomas O. Edick.

FHWA Interim Guidance on Indian Reservation Roads Program (23 U.S.C. 204)

June 30, 1992.

Focus of Interim Guidance

The purpose of this Interim Guidance on the Indian Reservation Roads Program is to provide guidance for complying with the requirements of 23 U.S.C. 204, Federal Lands Highway Program, as amended by sections 1030 and 1032 of the Intermodal Surface Transportation Efficiency Act of 1991, Public Law 102–240.

Provision—The Secretary of Transportation in cooperation with the Secretary of the Interior, shall develop appropriate transportation planning procedures, and safety, bridge, and pavement management systems for roads funded under the Federal Lands Highway Program, 23 U.S.C. 204(a).

Guidance—The BIA will prepare a Transportation Improvement Program (TIP) for the Indian Reservation Road program in accordance with the May 28 Interim Guidance on 23 U.S.C. 135—Statewide Planning Requirements (HEP–12/TGM–21). The IRR TIP must be sent to FLHO. FLHO will assemble the TIPs by State and forward them to each FHWA region for inclusion in the appropriate Statewide Transportation Improvement Programs. Safety, bridge, pavement management systems are required for Indian Reservation Roads. Guidance on the management systems will be issued at later dates.

Provision—Notwithstanding any other provision of this title, Indian reservation roads under the jurisdiction of the Bureau of Indian Affairs of the Department of the Interior shall be eligible to expend not more than 15 percent funds appropriated from the Highway Trust Fund for the purpose of road sealing projects. The Bureau of Indian Affairs shall continue to retain responsibility, including annual request responsibility, for road maintenance programs on Indian Reservations, 23 U.S.C. 204(c).

Guidance—Prior to expenditures of these funds, the BIA shall submit to the Federal Highway Administration (FHWA) a list of proposed sealing projects (APL) for approval and an annual report of the amount expended on road sealing projects by State.

Provision—Up to 2 percent of funds made available to IRR roads for each fiscal year shall be allocated to those Indian tribal governments applying for transportation planning pursuant to the provisions of the Indian Self-Determination and Education Assistance Act. The Indian tribal government, in cooperation with the Secretary of the Interior, and, as may be appropriate, with a State, local government, or metropolitan planning organization, shall develop a transportation improvement program, that includes all Indian reservation road projects proposed for funding. Projects

shall be selected by Indian tribal government from the transportation improvement program and shall be subject to the approval of the Secretary of the Interior and the Secretary, 23 U.S.C. 204(j).

Guidance—Interim guidance and procedures were jointly developed and issued in Mr. Patrick A. Hayes' March 12 memorandum on Interim Guidelines and Procedures for Highway Trust Funds Transportation Planning Funds for Tribes.

Funding of Program Items, Indian Reservation Roads Program

June 30, 1992.

Provision—Funds available for each class of Federal Lands Highways shall be available for any kind of transportation project eligible for assistance under this title that is within or adjacent to or provides access to the areas served by the particular class of Federal Lands Highways, 23 U.S.C. 204(b).

Provision—The Secretary of the Interior may reserve funds from the Bureau of Indian Affairs' administrative funds associated with the Indian Reservation Road Program to finance the Indian technical centers authorized under section 326, 23 U.S.C. 204(b).

Provision—Funds available for each class of Federal Lands Highways shall be available for the following: (1) Transportation planning for tourism and recreational travel including the National Forest Scenic Byways Program, Bureau of Land Management Back Country Byways Program, Programs that benefit recreational development, (2) Adjacent vehicular parking areas, (3) Interpretive signage, (4) Acquisition of necessary scenic easements and scenic or historic sites, (5) Provision for pedestrians and bicycles, (6) Construction and reconstruction of roadside rest areas including sanitary and water facilities, (7) other appropriate public road facilities such as visitor centers as determined by the Secretary, 23 U.S.C. 204(h).

Guidance—The last list of eligible program items was issued in July 1983. The ISTEA has significantly increased the items that are eligible for IRR funding. The list identifies (1) items that may be funded, (2) items that will generally not be funded due to their low priority in relation to the large IRR backlog of needs, and (3) items that will not be funded under the IRR program category. The funding for items in (2) will be determined on a case-by case exception basis taking into consideration overall relative IRR program priorities.

Items That May Be Funded

Project Support Items

- Transportation planning procedures including planning for tourism and recreational travel that benefits recreational development.
- Management systems for bridges, pavements, and safety.
- Development of reservation transportation plans and priority list of projects.
- Research part of Coordinated Technology Implementation Program (CTIP).
- Traffic engineering and safety studies.
- Identification and surveillance of accident locations.
- Development of road and bridge standards.
- Selected preliminary engineering studies.
- Necessary interagency program/project formulation meetings.

MEMORANDUM

Date: 5/28/92.
Reply to Attn of: HEP–12, TGM–21.
Subject: *Action*—Interim Guidance—23 U.S.C. 135—Statewide Planning Requirements.
From: Federal Highway Associate Administrator for Program Development; Federal Transit Associate Administrator for Grants Management.
To: Regional Federal Highway Administrators; Federal Transit Area Directors and Regional Administrators.

The attached Interim Guidance on Statewide Transportation Planning and Programming addresses the requirements of the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991, pending the issuance of formal guidance through the rulemaking process. It clarifies phase-in operations where new processes and documents are required and provides target dates for State compliance.

The Interim Guidance does not provide the full detail of ISTEA provisions, but does include as suggestions, some fundamental elements that may well be added by rulemaking.

Copies of the Interim Guidance should be provided to the State transportation agency, the Governor's Office, county and municipal government associations, MPOs and other regional planning organizations and transit operators. In addition, it may be provided to other interested individuals or organizations.

We expect to formally publish the Interim Guidance in the **Federal Register** shortly. Questions on the Interim Guidance should be directed to Mr. Robert Kirkland (FTA, TGM–21, FTS 366–1612) or Mr. Thomas R. Weeks (FHWA, HEP–12, FTS 366–5002).

Robert H. McManus

Anthony R. Kane

Attachment

Interim Guidance on Statewide Transportation Planning and Programming (23 U.S.C. 135)

Focus of Interim Guidance

The purpose of this Interim Guidance on Statewide Transportation Planning and Programming is to provide guidance for complying with the requirements of 23 U.S.C. 135, in conjunction with the guidance on metropolitan transportation planning issued on April 6, 1992. In establishing this interim guidance, the Federal Highway Administration (FHWA) and the Federal Transit Administration (FTA) acknowledge the need for a phase-in period to fully comply with the requirements of section 135, and in particular the requirement for a statewide multi-modal transportation plan. Accordingly, this guidance is intended to provide sufficient flexibility to the States, transit operators, and local officials to maintain project authorizations within the spirit and intent of the legislation. The guidance identifies FHWA's and FTA's expectations concerning compliance with the statewide transportation improvement programming requirements during the phase-in period. The FHWA and FTA intend to issue regulations through formal rulemaking actions to establish permanent policies and procedures for implementing Section 135 and for administering revisions to planning funding.

Statewide Transportation Planning Process

Provision—A statewide transportation planning process is required that is coordinated with the transportation planning carried out in metropolitan areas and with the planning for all modes of transportation. Factors that the process must consider are specified. Included are requirements to determine transportation needs in nonmetropolitan areas in consultation with local elected officials having jurisdiction over transportation and to consider the concerns of Indian tribal governments having jurisdiction over lands within a State. [Section 135(c)]

Guidance—Pending rulemaking by the FHWA and the FTA, each State is encouraged to (1) review the requirements of 23 U.S.C. 135 and initiate steps to establish or modify its statewide transportation planning process to respond to these requirements and to include the management systems activities required by 23 U.S.C. 303, (2) review State/local legislative transportation and land use planning provisions and assess the adequacy of these provisions to comply with 23 U.S.C. 135, (3) review existing organizational arrangements affecting statewide transportation planning and programming and establish new processes as necessary, (4) initiate discussions with local officials and other State officials on nonmetropolitan multi-modal transportation needs, (5) coordinate with the metropolitan planning organizations (MPO) in the State on transportation needs and on the processes for integrating metropolitan plans and programs with statewide plans and programs, and (6) review existing public involvement procedures and identify changes necessary to meet the requirements of 23 U.S.C. 135. Where appropriate, discussions should be initiated with Indian tribal governments and appropriate Federal lands agencies to establish a cooperative process for planning and programming transportation improvements.

Statewide Transportation Plan

Provision—A long-range transportation plan for all areas of the State is required which provides for development of transportation facilities that will function as an intermodal State transportation system. With respect to metropolitan areas of the State, the land must be developed in cooperation with the MPOs. For areas of the State under the jurisdiction of an Indian tribal government, the plan needs to be developed in cooperation with the Indian tribal government and the Secretary of the Interior. Bicycle transportation and

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pedestrian walkway plans are required for appropriate areas of the State. There must be opportunity for public comment on the proposed transportation plan. Additionally, Section 1006 of the ISTEA provides for the identification of a proposed National Highway System (NHS) by the States in cooperation with local officials. The NHS must be based on a functional reclassification of highways and other criteria established by FHWA. A report on the proposed NHS must be submitted to the Congress by December 18, 1993. [Section 135(e)]

Guidance—Pending further guidance, each State, in cooperation with Indian tribal governments, MPOs and local officials, is encouraged to (1) conduct an inventory of transportation plans and policies for both metropolitan and nonmetropolitan areas which can serve as an interim basis for the development of the statewide transportation improvement program, (2) identify appropriate organizational structures for use in developing the long-range multi-modal transportation plan for all areas of the state, and (3) establish an overall approach and schedule for developing a multi-modal transportation plan.

By October 1, 1992, each State must establish or modify existing public involvement procedures so that citizens, affected public agencies, representatives of transportation agency employees, private providers of transportation, and other interested parties will have a reasonable opportunity to provide input during early stages and later key stages of the development of the long-range transportation plan.

By April 1, 1993, as an interim step in the plan development, each State, in cooperation with the MPOs, should identify a preliminary arterial highway component of the Statewide long-range multi-modal transportation plan to serve as the basis for developing the proposed NHS.

Pending rulemaking by the FHWA and the FTA, a statewide transportation plan for all areas of the State must (1) be approved by January 1, 1995, by the Governor (or designee), (2) include elements for all modes, including coordination of the plan elements, (3) include policies for implementation of projects based on the plan, and (4) be developed in cooperation with the MPOs for metropolitan areas of the State in accordance with 23 U.S.C. 134 and FTA Section 8(g). The FHWA and FTA anticipate that regulations to implement 23 U.S.C. 135 will include these requirements, as a minimum.

The Federal Lands Highway Office, FHWA, will arrange with appropriate Federal lands agencies for States to receive copies of existing transportation plans.

Statewide Transportation Improvement Program (STIP) and Project Selection

Provision—All highway and transit projects in the State funded under title 23 and the Federal Transit Act must be included in a federally approved STIP. Projects in the STIP must be consistent with the statewide long-range transportation plan and metropolitan transportation improvement program(s) (TIP), and the program must reflect expected funding and priorities for programming, including transportation enhancements. Additionally, in air quality nonattainment areas, only those projects that have been determined to conform under the requirements of the Clean Air Act Amendments of 1990 may be included in the STIP. There must be opportunity for public comment on the proposed improvement program. The STIP must be reviewed and approved at least biennially by the Secretary. [Section 135(f) (1), (2), and (4)]

Projects in rural areas and urban areas of less than 50,000 population (excluding projects on the NHS, and projects funded with Bridge and Interstate Maintenance funds) are selected by the State in cooperation with affected local officials. Projects on the NHS, and Bridge and Interstate Maintenance projects are selected by the State in consultation with affected local officials. [Section 135(f)(3)]

Guidance—The duplicate programming requirements of 23 U.S.C. 105 for projects funded under title 23 were not rescinded by the ISTEA. These requirements will be applicable during a transition period but will be satisfied by following the requirements of 23 U.S.C. 135 described herein and in subsequent regulations.

Each State should develop procedures, where appropriate, to work with Federal lands agencies to ensure that Federal lands highway projects selected for the STIP are consistent with plans for other transportation facilities in the State. For public lands highway projects (including forest highways), State concurrence in the selection of projects is required. The Federal Lands Highway Office, FHWA, will provide a multi-year list of projects selected for funding for the use of each State involved.

Suballocations of the flexible Surface Transportation Program (STP) funds and the STP funds allocated for use in areas less than 200,000 to individual jurisdictions or modes by predetermined percentages or formulas are discouraged. Such suballocations minimize the benefits of transportation planning, hinder the ability of States to respond to high priority problems identified through the transportation planning process, unduly constrain the programming process, and frustrate the flexibility provisions of the Intermodal Surface Transportation Efficiency Act of 1991. (See the interim metropolitan guidance issued by the FHWA and the FTA on April 6, 1992, for further information on suballocations of STP funds within the metropolitan areas.)

Until October 1, 1992, Federal funds made available under Title 23 and the Federal Transit Act may be obligated for projects contained in a federally approved section 105 highway program of projects, Federal lands highway program, section 9 transit program of projects, section 18 transit program or section 16(b)(2) transit program without further programming actions. For projects that are not included in the above programs, the State must certify that projects submitted to FHWA or FTA for obligation of Federal funds have been selected in accordance with the requirements for the specific funding programs (e.g., Federal-aid secondary, STP, public lands, section 18 transit, etc.). (For project selection in areas greater than 50,000 population, see the interim metropolitan guidance issued jointly by the FHWA and the FTA dated April 6, 1992.)

Effective October 1, 1992, a STIP approved by FHWA and FTA is required for the obligation of Federal funds made available to each State under title 23 and the Federal Transit Act. A multi-year STIP should be developed with proposed projects and funding identified for each year, or group of years. Highway and transit projects, including Federal lands highway projects, must be selected in accordance with the specific funding programs. For projects in areas less than 50,000 population, including rural areas, the project selection requirements for cooperation or consultation with affected local officials shall be satisfied for the first year of the STIP during the development of the STIP.

Information on project scheduling and funding sources must be provided to selecting officials, FHWA and FTA for each project or group of like projects that is selected for the first year of the STIP. Projects advanced for obligation of Federal funds from subsequent years of the STIP must again meet the project selection requirements. (For areas greater than 50,000 population, see the interim metropolitan guidance issued jointly by the FHWA and the FTA dated April 6, 1992.)

The STIP shall be based on an adopted statewide transportation plan but as an interim measure may be developed utilizing other existing transportation plans and policies, and for FY 1993, the existing section 105 and transit programming processes. The provisions of section 135(f) with respect to public involvement, priorities for programming, and expenditures of funds shall be addressed.

Since the Governor or the Governor's designee must approve each metropolitan area transportation improvement program (TIP), thereby indicating state-level concurrence in each metropolitan area TIP, it is expected that the TIP for each metropolitan area or part thereof within each State will be incorporated, either directly or by reference, into the STIP ultimately approved by the State and the Secretary. Because the metropolitan area TIPs and the STIP must be financially constrained, it is essential that the States work with the MPOs during the development of the metropolitan area TIPs to ensure that the TIPs reflect available Federal and State funding and that there is one State concurrence for the TIPs, whether prior to or simultaneous with adoption of the STIP. It is particularly important that there be one State concurrence for the TIPs developed for air quality nonattainment areas, as there must be a Federal determination that the metropolitan TIPs conform to the State implementation plan.

Effective October 1, 1993, pending rulemaking by the FHWA and the FTA, the STIP must meet all requirements of section 135(f); therefore, each State should immediately establish a process for the development of the STIP, including establishing or modifying existing public involvement procedures so that citizens, affected local and other public agencies, representatives of transportation agency

employees, private providers of transportation, and other interested parties have a reasonable opportunity to comment on the proposed STIP.

Preservation of Transportation Corridors—Report to Congress

Provision—Subsection 1017(c) of the ISTEA requires the Secretary to submit a report to the Congress by December 18, 1993, that contains a national list of rights-of-way identified for preservation under sections 134 and 135 of title 23. The report is to include the mileage involved, an estimate of total costs (rights-of-way), and a strategy for preventing further loss of rights-of-way including the desirability of creating a transportation right-of-way bank to preserve vital corridors.

Guidance—The FHWA Office of Right-of-Way is coordinating the development of this report and expects to issue detailed guidance by June 30. The States and the MPOs will be asked to develop the required information for the report through the section 134 and 135 transportation planning processes.

Funding

Provision—Funds apportioned to the States under 23 U.S.C. 307(c)(1) for planning and research (2 percent) and Section 26(a)(2) of the Federal Transit Act are available to carry out the statewide transportation planning requirements as well as metropolitan transportation planning requirements. Not less than 25 percent of funds apportioned under 23 U.S.C. 307(c)(1) must be used for research, development, and technology transfer activities, unless the State certifies to the Secretary that expenditures under statewide and metropolitan transportation planning will exceed 75 percent and the Secretary accepts the certification. (Section 307)

Guidance—Statewide transportation planning is an eligible activity under the Federal-aid highway NHS and STP programs and the Federal transit section 9, 18, and 26(a)(2) programs. Statewide transportation planning activities funded with NHS and STP funds must be treated as projects and identified in the STIP. All planning activities must be included in the annual statewide transportation planning program or, when appropriate, in a unified planning work program for a metropolitan area.

A State may request approval for the use of more than 75 percent of its annual amount of highway planning and research (HPR) funds for metropolitan and statewide transportation planning. Such requests must be submitted to FHWA Headquarters for approval. Additional guidance on this subject will be provided separately by the Office of Research and Development in cooperation with the Office of Environment and Planning.

MEMORANDUM

Date: October 9, 1992.
Reply to Attn. of: HEP–12 and 21, Attn of: TGM–21.
Subject: *Information*—Interim Measures To Meet the STIP and TIP Requirements.
From: Federal Highway Associate Administrator for Program Development; Federal Transit Associate Administrator for Grants Management.
To: Regional Federal Highway Administrators; Federal Transit Area Directors and Regional Administrators.

The joint FHWA/FTA interim guidance issued on May 28, 1992, requires that a STIP be jointly approved by FHWA and FTA as a condition to obligating funds authorized by Title 23 and the Federal Transit Act after October 1, 1992. Delays have occurred in the development of the STIP in some States due in part to difficulties in getting conformity determinations completed for the metropolitan TIPs and corresponding delays in getting approvals of the metropolitan TIPs by the MPOs and the Governor. To prevent all highway and transit projects from being delayed until the STIP is approved, two interim measures may be used for meeting the STIP requirement.

Interim Measures for Meeting STIP Requirement

1. *Use the existing Section 105 and transit programs approved by FHWA and FTA prior to October 1 as an interim STIP.* These programs would serve as the basis for FHWA and FTA project funding actions until the STIP prepared for FY 1993 is jointly approved by FHWA and FTA. Project authorizations would be limited to any remaining projects in these programs. Evidence must be provided that appropriate project selection procedures have been followed. A coordinated FHWA/FTA approval action would still be required.

2. *Approve parts of the STIP.* If the STIP cannot be approved in total, specific projects or groups of projects could be approved. For example, NHS, STP, Federal Lands, and Section 18 projects in non metropolitan areas could be approved even though TIPs for metropolitan areas have not been approved by the MPO and Governor. A coordinated FHWA/FTA approval action would still be required.

Interim Measures for Meeting TIP Requirement

A number of questions have been asked about using existing TIPs for all or part of the next fiscal year. The attached Questions and Answers provide guidance on the use of existing TIPs as an interim measure.

Questions on interim measures for STIPs should be directed to Mr. Robert Kirkland (FTA, TGM–21, FTS 366–1612) or Mr. Tom Weeks (FHWA, HEP–12, FTS 366–5002). Questions on interim TIP measures should also be directed to Mr. Robert Kirkland or Mr. Dean Smeins (FHWA, HEP–21, FTS 366–9227).

Robert H. McManus

Anthony R. Kane

Attachment

Questions and Answers Regarding Use of Existing Tips

Question: If a metropolitan area does not have a new TIP approved by the MPO and the Governor (and conformity determinations completed if applicable) by the beginning of the new FY, does the authority to obligate funds for new projects in that metropolitan area stop?

Answer: Yes, unless there are projects remaining in the annual/biennial element of the approved TIP (and these projects are also included in the approved 105 program for FHWA projects or the section 3, 9, 18, and 18 programs for FTA projects). Such projects may proceed subject to the concurrence of the MPO in the project(s) selected for implementation by the State or the transit operator. This assumes good faith efforts to meet the date for the start of the new FY. Further, we would not expect this situation to exist for more than a few months.

In addition to the above, if the MPO, the State, and the transit operator agree, projects in the outyears of the TIP could be advanced if these projects are included in the first three years of the pending new TIP, the appropriate project selection procedures are used and the STIP is amended to include these projects. Again, we would not expect this situation to continue for more than a few months.

Question: Can the MPO and the Governor simply approve the current TIP for one additional year in lieu of developing and approving a new TIP that includes additional projects? Would this require a new conformity determination if a nonattainment area is involved?

Answer: Yes, the MPO and the Governor could approve the existing TIP for another year, not to extend beyond 9/30/93, if the following conditions are met:

- The MPO, State and transit operator, after full consideration of the flexibility provisions, agree that no projects need to be added or deleted.
- A financial plan is prepared and it demonstrates that the TIP is financially constrained.
- The TIP, if necessary, is reformatted so projects are grouped and prioritized in accordance with the interim guidance and new funding categories.
- It includes all projects to be funded under Title 23 or the FT Act, including Federal Lands projects.
- The MPO provides a reasonable opportunity for comment on the TIP by the public and interested parties prior to approval.

A new conformity determination for such a TIP in a nonattainment area would not be required as long as there is no significant change in priorities, particularly for TCMs, that would affect attainment of the CAA standards.

Project advancement would be subject to these projects being included in an approved STIP.

Question: (Variation on the scenario for the above question) If the MPO and the Governor wish to approve a new TIP in a nonattainment area that includes the same projects that are in the existing TIP except for the addition of neutral projects is a new conformity analysis/determination necessary?

Answer: A new conformity determination would be necessary; however, since only neutral projects are being added, no additional analysis would be necessary.

MEMORANDUM

Date: May 20, 1992.
Reply to Attn of: HNG–12.
Subject: *Information*—Implementation Guidance on Section 1027 of the 1991 ISTEA—Public Transportation.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

Section 1027 of the 1991 ISTEA amends sections 142 and 156 of title 23, United States Code, covering the use of Federal-aid funds for transit activities and accommodation of transit facilities on highway right-of-way.

Pertinent modifications are:

1. In the past, only Federal-aid urban funds could be used for mass transit projects. Now, surface transportation program (STP) funds can be used for this purpose [23 U.S.C. 142(a)(2)].

2. Eligible work includes any capital transit project eligible for assistance under the Federal Transit Act. It has been further defined to include capital improvements to provide access and coordination between intercity and rural bus service and construction of facilities to provide connections between highways and other modes of transportation [23 U.S.C. 142(a)(2)].

3. Eligible work can now include modifications to existing highway facilities necessary to accommodate other modes of transportation provided these modifications will not adversely affect automotive safety [23 U.S.C. 142(c)].

4. Public transportation projects carried out under Section 142 in an urbanized area are subject to the metropolitan planning requirements of 23 U.S.C. 314 [23 U.S.C. 142(d)].

5. Prior to passage of the ISTEA, Federal-aid project right-of-way could only be made available without charge to publicly owned mass transit authorities. Now, a State may make Federal-aid project right-of-way available with or without charge to publicly or privately owned mass transit facilities. In addition to mass transit facilities, right-of-way can be made available to passenger and commuter rail facilities including those that are high speed rail and magnetic levitation lines [23 U.S.C. 142(f)]. Previously the criteria to be satisfied for allowing this use of highway right-of-way were that the accommodation would not adversely impair automotive safety or future highway improvements and such use was found to be in the public interest. The criteria now are that the accommodation will not adversely affect automotive safety [23 U.S.C. 142(f)].

Should a State desire to use STP funds for capital transit projects eligible for assistance under the Federal Transit Act, the procedures outlined in the March 19, letter to the States, transit operators and metropolitan planning organizations, jointly signed by FHWA Administrator Larson and FTA Administrator Clymer, should be followed.

Proposals to allow mass transit or other passenger and commuter rail facilities to use Federal-aid project right-of-way should continue to be processed following the procedures outlined in 23 CFR part 810, subpart C, except that the criteria for determining the acceptability of the proposed use should be that contained in amended 23 U.S.C. 142(f).

If you have any questions call Mr. Jerry Poston, Chief, Federal-Aid Program Branch at FTS 366–4652 or Mr. Robert Winans at FTS 366–4656.

Anthony R. Kane

MEMORANDUM

Date: May 15, 1992
Reply to Attn of: HNG–33
Subject: *Information*—Use of Highway Bridge Replacement and Rehabilitation Program (HBRRP) Funds for Approach Roadway Construction.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

Mr. Rex C. Leathers' memorandum of August 29, 1985, pertinent to the above subject described the concern of the Washington Headquarters for the State's use of HBRRP funds for improving deficient bridges as intended by Congress rather than for constructing long approach roadways. The guidance was to limit costs for approach roadways associated with the HBRRP project so that a nationwide average of no more than 10 percent of the total project costs would result. We felt the guidance provided sufficient flexibility to allow for a higher percentage for individual bridges in unusual or exceptional cases.

Application of the guidance since it was issued has resulted in a wide variety of projects with approach roadway costs greater than the targeted 10 percent. Typical examples have been cases where sight distance across a structure or improved underclearances require longer approach roadways to a HBRRP bridge project. Also a Division Administrator could determine th replacing a deficient bridge with a shorter span bridge and roadway fills is eligible for HBRRP funding, if this strategy is more cost-effective than replacing the deficient bridge with a similarly sized one.

The HBRRP project experience, coupled with revisions to section 104(g) of Title 23, which provides that 40 percent of HBRRP funds may be transferred to NHS or STP funds, indicates a need to ease our previous guidance regarding a 10 percent target. The eligible costs for approach roadway work for an HBRRP project should be limited to that necessary to render the replaced or rehabilitated bridge serviceable, and may exceed 10 percent of the total project cost within reasonable limits. Using HBRRP funds for an entire roadway project which happens to include an eligible deficient bridge is to be avoided.

Regarding the coding of HBRRP work items for the Fiscal Management Information System (FMIS), we are providing the attached guidelines for classification of project work items into specific work type codes. This is made necessary because of a 1991 HBRRP review conducted by the Office of Inspector General (OIG). The focus of the effort was to evaluate the FHWA's control over the use of HBRRP funds for non-bridge work items.

The OIG review concluded that the FHWA has adequate controls in place, but added guidance is required. When using HBRRP funds, inconsistencies were found in the FHWA Division Offices' coding of bridge, roadway, and miscellaneous work items in the FMIS. These inconsistencies do not impact eligibility of construction work for Federal funding, but do affect the accuracy in identifying approach roadway and bridge costs in the FMIS. Because of the many different bridge replacement and rehabilitation project situations and the engineering judgement required, it is not possible to eliminate all inconsistencies in data entry. However, this guidance should help to arrive at better uniformity in preparing the FHWA–37 and ultimately improve the validity of the FMIS data.

Anthony R. Kane

Attachment

Guidelines for Classification of HBRRP Project Work Items

A. Bridge Items

The following project work items can be classified using Bridge Work Type Codes=X—

1. Bridge Substructure and Superstructure Items
2. Structural Excavation—Required to construct bridge
3. Approach Railing—Transition sections, including approach guardrail
4. Approach Roadway—Bridge approach slab (that portion of the approach slab which spans the region of the abutment backfill)
5. Slope Protection—Concrete, rock, and other materials to protect the slopes at substructure units and abutment wingwalls
6. Rock Blankets—Necessary to protect substructure units from erosion or scour
7. Bridge Removal—Removal of substructure units and or superstructure elements
8. Mobilization—The percentage of this item attributable to bridge work
9. Traffic Control—Work items and devices, including temporary detour bridges, needed to direct traffic through the work zone or detour
16. Stream Channel Work—Bridge work codes may be used for all or part as deemed appropriate

MEMORANDUM

Date: June 22, 1992.
Reply to Attn. of: HNG–12.
Subject: *Information*—Section 1044 of the 1991 ISTEA—Credit for Non-Federal Share.
From: See Below.
To: Regional Federal Highway Administrators; Regional Federal Transit Administrators; Regional National Highway Traffic Safety Administrators; Federal Lands Highway Program Administrator.

Section 1044 permits a State to use certain toll revenue expenditures as a credit toward the non-Federal matching share of all programs authorized by Title 23 and the ISTEA. This is in essence a "soft match" provision that allows the Federal share to be

increased up to 100 percent to the extent credits are available.

The purpose of this memorandum is to provide initial guidance for implementing this provision. The following discussion covers determination of the credit amount, determination of the maintenance of effort test, and overall application of the credit.

1. Determination of Amount of Credit

The amount of credit earned is based on revenues generated by the toll authority (i.e., toll receipts, concession sales, right-of-way leases or interest) including borrowed funds (i.e., bonds, loans) supported by this revenue stream that are used by that authority to build, improve or maintain highways, bridges or tunnels that serve interstate commerce. The following requirements apply:

- The toll facility generating the revenue must be open to public travel.
- The toll authority may be a public, quasi-public or private entity.
- The amount of credit is based on expenditures (outlays) by a toll authority for capital improvements to build, improve, or maintain public highway facilities that carry vehicles involved in interstate commerce (the degree does not matter). It cannot include expenditures for items such as routine maintenance work (i.e., snow removal, mowing), debt service or costs of collecting tolls. Further, such expenditures must have been made for improvements paid for entirely without Federal funds. These improvements can be on facilities which have had prior Federal funding.
- The soft match opportunity begins with fiscal year (FY) 1992. The amount of soft match credit is based on the prior year's expenditures. A credit for any given FY can only be earned if a State's non-Federal transportation capital expenditures (as defined under Item 2 below) in the prior FY equal or exceed the average level of such expenditures for the 3 FYs preceding that prior FY. For example, to earn a credit for use in FY 1992 a State must first determine if it has qualifying toll authority expenditures in FY 1991. Then a State must also demonstrate that its FY 1991 non-Federal transportation capital expenditures equal or exceed the average of such expenditures for FYs 1988, 1989 and 1990.
- The State will have 4 FYs to use the credit amount established for any FY, these being the FY for which the credit amount was established plus the following 3 FYs. For example, if a State establishes a credit for FY 1992 based on the FY 1991 toll authority expenditures, the credit is available for projects authorized in FYs 1992, 1993, 1994 and 1995. However, any portion of this credit not used by the end of FY 1995 lapses. Accordingly, the State must establish a special account to track appropriate credit amounts and their subsequent use by FY.
- For chartered multi-State toll entities, the amount of credit must be divided equally among all the charter States.
- The State will provide the FHWA a certification that:

—The credit has been based on expenditures for improvements that met the above criteria.

—Lists the qualifying toll facilities generating the revenue and the total expenditures being proposed for use as credits along with the total non-Federal transportation capital expenditures for each of the last 4 FYs.

2. Maintenance of Effort (MOE) Determination

To be able to use the credit, a State's non-Federal transportation capital expenditures in the prior FY must have been at or above the average level of such expenditures for the 3 FYs preceding the prior FY.

The following requirements apply:

- The calculation of the non-Federal transportation capital expenditures must include expenditures to build, improve or maintain (but not routine maintenance) public highways, including toll facilities, and transit systems within the State. These would include expenditures on projects wholly funded by the State, plus the non-Federal shares of all federally funded highway and transit projects.
- The MOE determination is based on data for the previous FY compared to the preceding 3-year average. For example, if a State wants to use this credit provision in FY 1992, it would determine the amount of its non-Federal capital transportation expenditures for FYs 1988, 1989, and 1990, and compare the average of those 3 FYs with the FY 1991 expenditures. To satisfy the MOE test, FY 1991 expenditures must equal or exceed the average of FYs 1988, 1989, and 1990.
- The State will provide the FHWA a certification as to the total capital expenditures to demonstrate compliance with the MOE test.
- In addition to the certification of amount of credit (under Item 1 above) and the MOE amounts, a State must also certify that it has on file adequate documentation to support these amounts. These records will be available for audit or inspection.

3. Application

- The required certifications in Items 1 and 2 above are to be provided to the FHWA Division Office. The FHWA acceptance of a State's certifications must be accomplished prior to use of the soft match provision on any Federal-aid project. Until experience is gained in the operation of this new provision, the certifications shall be forwarded to FHWA Washington Headquarters for review prior to any field approval of a project with the increased Federal share. The FHWA Headquarters will notify FTA and NHTSA Headquarters when certifications are accepted.
- A request to use the soft match provision on a specific Federal-aid project should be submitted to the appropriate Federal Agency, FHWA, FTA or NHTSA, administering the project.
- The soft match provision is initiated at the time Federal funds are obligated and can only be used if the State has met the MOE test at that point in time. The State has the option of using amounts of credits to cover all or a portion of the non-Federal share of a project. The result is that the effective Federal share of an eligible project could be any value up to 100 percent.
- For eligible projects, whatever effective Federal share is established at the time of project authorization must be used throughout the life of the project. Subsequent overruns or underruns would be processed at this effective share provided a balance of credits are available.
- The State must establish a special account to track appropriate credits. The State may place into the special account the amount of credit that the FHWA has accepted under Item 1 above. When the State requests authorization of a project using the Section 1044 provisions, it shall request that all or a portion of the non-Federal share be credited from the special account. These projects will be processed and administered in accordance with normal procedures except the amount of funds authorized on the project and the Federal pro rata share will be increased. When the State submits a request to use credits from the special account, it will reduce the account in the same amount applied to the projects. The amount of non-Federal share credited will be deducted from the unobligated balance of Federal-aid funds available and charged to the State's obligation limitation.

Questions regarding determinations of credit and MOE or application on FHWA administered projects should be directed to Mr. Jerry Poston, HNG–12, (FTS 366–4852). Questions on application on FTA and NHTSA administered projects should be directed to Mr. Ed Fleischman, TGM–10, (FTS 366–1662) and Gary Butler, NRO–10, (FTS 366–2674) respectively.

Robert H. McManus,

Associate Administrator for Grant Management, Federal Transit Administration.

Anthony R. Kane,

Associate Administrator for Program Development, Federal Highway Administration.

Adele Derby,

Associate Administrator for Regional Operations, National Highway Traffic Safety Administration.

MEMORANDUM

Date: September 2, 1992.
Reply to Attn of: HNG–12.
Subject: Information—Section 1044 of the ISTEA, Credit for Non-Federal Share—Implementation Questions and Answers.
From: Associate Administrator for Program Development.
To: Regional Federal Highway Administrators.

Initial implementing guidance for section 1044 was provided to you by a June 22 memorandum issued jointly by the FHWA, FTA, and NHTSA. FHWA is serving as the lead agency in accepting a State's certification regarding determination of the credit and maintenance of effort (MOE) amounts.

One modification to this initial guidance is being implemented with this memorandum. The June 22 guidance did not allow the use of the soft match provision until FHWA acceptance of a State's credit and MOE certifications. Effective the date of this memorandum, Federal-aid projects may be conditionally authorized using the soft match

provisions subject to a State providing appropriate credit and MOE certifications and their subsequent acceptance by the FHWA.

Several questions have been raised by the division offices and States concerning the credit and MOE determinations and application of the soft match provisions. These questions and our responses follow.

Determination of Amount of Credit

Question 1: Do toll authority expenditures for capital improvements on public highway facilities need to be in the same year as the revenues are generated?

Answer: Toll authority expenditures are based on when the actual expenditures are made regardless of when the revenue was raised.

Question 2: A toll authority receives grant funds from the State DOT or State legislature. Can these funds, when expended by the toll authority, be included in the credit calculation?

Answer: No. Grants are not considered to be revenues generated by the toll authority.

Question 3: Does the Federal fiscal year have to be used for the credit calculation?

Answer: It is expected the Federal fiscal year will normally be used for both the credit and MOE calculation. However, if a State can demonstrate to the FHWA division office that data by Federal fiscal year is not readily available but is available by State fiscal year or on a calendar year basis, then these alternate 12-months periods can be used in making one or both of the calculations. For example, a State could use a calendar year in determining the credit amount, if that is the way toll authorities routinely keep their accounts, and then use the State's own June 30 FY in determining the MOE. If a State does use these alternate time periods, they must continue to use the same 12-month periods in future credit and MOE determinations. Notwithstanding this flexibility, the application year for use of the credit towards the non-Federal share of eligible Federal-aid projects must be the Federal fiscal year.

Question 4: For FY 92, when is the deadline for submitting the credit/MOE certifications?

Answer: The determination of credit earned for application beginning in FY 92 could theoretically be figured any time prior to that point in time the credit lapses. Lapse for the FY 92 determination would occur at the end of FY 95. Of course, the State would have to satisfy the MOE determination for FY 92 to earn the credit for the FY. In addition, for a State to be able to apply the credit in any given FY, a MOE determination for the application year must also be satisfied.

Question 5: Since funds spent by toll authorities on their own facilities are counted in the credit calculation and since those funds can be borrowed funds, can initial construction of a toll road be counted as credit even though the road is not open to traffic yet?

Answer: If the borrowed funds used to pay for initial construction are to be repaid by revenues generated by the toll authority, then the actual expenditures of these borrowed funds for initial construction in a given fiscal year can count in the credit calculation for that fiscal year.

Question 6: Can funds spent on preliminary engineering or right-of-way for future projects be counted in the credit calculation?

Answer: Yes, if they relate to construction projects that are eligible to be counted for the credit purpose.

MOE Determination

Question 1: Are expenditures actual cash outlays or are expenditures when funds are encumbered (obligated) for a contract?

Answer: Expenditures are based on actual cash outlays.

Question 2: Do non-Federal transportation expenditures include only the normal Title 23 highway construction costs or does it include the cost of computer design equipment, vehicles (ambulances and fire trucks) purchased under the 402 program, traffic monitoring equipment, etc.?

Answer: The MOE determination is based on expenditures for highways and transit systems. If data are available, the State could include expenditures for 402 program activities, traffic monitoring and computer equipment, etc., related to highways in the MOE determination. If these types of expenditures are included in the MOE determination, for consistency they should be provided for all years used in the MOE determination.

Question 3: Why were expenditures on airports excluded from MOE?

Answer: Since the soft match provision is limited in application to projects eligible for funding under Title 23 or the ISTEA, it can not be used for other DOT modal projects such as airports or maritime facilities. Accordingly, it was decided these other types of non-Title 23 or non-ISTEA projects would not be included in the MOE calculation.

Question 4: Does the Federal fiscal year have to be used for the MOE calculation?

Answer: Not necessarily (see Credit—Question 3).

Question 5: Is the MOE a "yes/no" decision or is use of soft match limited to the incremental amount of increase in the MOE.

Answer: The MOE is a determination of eligibility; either the State qualifies or does not. If the State qualifies, then it can use any or all of its credit amounts as soft match.

Question 6: Can funds spent on preliminary engineering and right-of-way for future projects be counted in the MOE calculation?

Answer: Yes, if they relate to construction projects that are eligible to be counted for MOE purposes.

Question 7: Do local government expenditures or those by toll authorities have to be included in the MOE calculation?

Answer: It is preferable that the MOE include local governmental and toll authority expenditures. However, we will accept a MOE calculation that does not. If a State excludes these types of expenditures in their initial calculation, then future MOE calculations by the State, for consistency, must also exclude these types of expenditures.

Question 8: If a toll authority receives grant funds from the State DOT or State legislature, can these funds, when expended by the authority, be included in the MOE calculation.

Answer: If the State is including toll authority expenditures in its MOE calculation (see Question 7 above), then that portion of a grant actually expended by a toll authority on construction can be included in the MOE.

Application

Question 1: If a State does not include local government expenditures in the MOE calculation, can the soft match credit be used on local government projects?

Answer: Regardless of which governmental units are included in the MOE, if a credit is approved for use, the soft match provision is available for all title 23 and ISTEA projects at the discretion of the State and with whatever conditions the State wishes to place on local entities.

Question 2: For Federal-aid highway funds, is soft match limited to only the formula funds?

Answer: No. Soft match can be used for all Federal-aid programs under title 23 or ISTEA.

Question 3: Can new projects be split funded with formula funds subject to obligation authority and other funds exempt from obligation authority?

Answer: Yes. The State has the option of applying the soft match provision to any or all of the funding sources eligible for soft match that are being used to finance the project.

Question 4: A State has an unused balance of credit at the end of FY 92 that is carried forward into FY 93. Is a new MOE determination needed before the State can use this carryover in FY 93?

Answer: Yes. A new MOE determination (for the next 12-month period the State is using) will need to be certified by the State for application of the credit (either the carryover balance or the next year's credit determination) in Federal FY 93. If this certification is not available, conditional authorization of projects using the soft match provisions may be approved subject to the State providing appropriate MOE and/or credit certification.

Question 5: Can a State which qualifies for soft match use the soft match credits on previously authorized projects?

Answer: No. However, use of conditional authorizations is allowed for work authorized on or after the date of this memorandum while a State is documenting its qualifying amounts.

Questions regarding this memorandum should be directed to Mr. Jerry Poston, Chief, Federal-Aid Program Branch, FTS 202–366–4652, or Mr. Jim Overton, FTS 202–366–4653, of his staff.

Thomas O. Willett,

for

Anthony R. Kane

MEMORANDUM

Date: June 26, 1992.
Reply to Attn of: HPS–31.

Subject: Guidance on Transfer Provisions Contained in the Intermodal Surface Transportation Act of 1991 (ISTEA).
From: Director, Office of Fiscal Services.
To: Associate Administrators, Regional Administrators, Division Administrators.

The ISTEA provides a significant amount of flexibility in the use of apportioned funds by permitting States to transfer funds between apportionments. Additionally Section 1100 provides that selected unobligated funds from prior Acts may be transferred to the new programs contained in ISTEA. It should be noted that funds may not be transferred both into and out of an appropriation within the same Fiscal Year. Guidance relating to the transfer provisions is provided below.

Transfer of Unobligated Balances

Section 1100 of the ISTEA provides that certain unobligated funds remaining from apportionments made before October 1, 1991 may be transferred to certain apportionments made after October 1, 1991. These are as follows:

- Primary System Funds may be transferred to the National Highway System (NHS) and/or the Surface Transportation Program (STP). Funds transferred into STP are not subject to sub-allocation and will be transferred into the state flexible appropriation code (33D).
- Secondary System Funds may be transferred to STP. These funds are not subject to sub-allocation and will be transferred into the state flexible appropriation code (33D).
- Urban System Funds, both attributable and non-attributable, may be transferred to STP. As required by 23 U.S.C. 150, the appropriate Metropolitan Planning Organization must approve the transfer of attributable funds. These funds are not subject to sub-allocation and will be transferred into the state flexible appropriation code (33D).

It should be noted that the lapse date for the transferred funds is 3 years after the Fiscal Year in which they were originally authorized.

Regional Administrators may approve these transfers (this may be delegated). A copy of the approval, the State's request, and the attached form must be provided to HFS–31.

Transfer of National Highway System Funds

- Up to 50% of a State's NHS funds may be transferred to STP upon the request of the State.

Regional Administrators may approve these transfers (this may be delegated). A copy of the approval, the State's request, and the attached form must be provided to HFS–31.

- Up to 100% of a State's NHS funds may be transferred to STP if approved by the Secretary of Transportation as being in the public interest. Additionally, States must provide notice to the public of the intent to request the transfer and give the public sufficient opportunity to comment.

The State's request, along with the attached form and the Regional Administrator's recommendation, should be forwarded to the Director, Office of Fiscal Services for coordination and submission to the Federal Highway Administrator for approval.

National Highway System funds transferred to STP are not subject to the sub-allocation and will be transferred to the state flexible appropriation code (33D).

Transfer of Bridge Replacement and Rehabilitation, Rail/Highway Crossing, Hazard Elimination Funds, and STP Safety Funds

- Up to 40% of a State's Bridge funds, apportioned under 23 U.S.C. 144 may be transferred to the NHS and/or STP. Funds transferred into STP are not subject to sub-allocation and will be transferred to the state flexible appropriation code (33D).

To comply with the requirements of 23 U.S.C. 144(g)(3), the funds provided under Appropriation Code 117, the 15% minimum for Off-system bridges, may not be transferred without a determination that the State has inadequate needs to justify such expenditures.

- For unobligated balances of funds from apportionments made before October 1, 1991, States may continue to transfer Bridge funds to the Rail/highway Crossing, and Hazard Elimination Programs (HES), however, the fiscal year identity must not be lost. That is, 1990 bridge funds may be transferred to the 1990 HES program but not into the 1991 HES program.
- The Rail/Highway Crossing and Hazard Elimination funds apportioned under 23 U.S.C. 130 and 23 U.S.C. 152 may continue to be transferred as in the past.
- Of the funds provided by 104(b)(3) for safety programs:
- 40% of the funds available for the Rail/highway Crossing Program and
- 40% of the funds provided for the Hazard Elimination Program safety programs.

may be transferred between the two safety programs or to the bridge apportionment. Funds transferred to bridge will be placed into appropriation 114 and be available for either on or off system bridges.

- Up to 100% of a State's safety funds may be transferred if approved as being in the public interest and with the assurance from the State that the purposes of the program have been met.

Regional Administrators may approve these transfers (this may be delegated). A copy of the approval, the State's request, and the attached form must be provided to HFS–31.

Interstate Maintenance

- Up to 20% of a State's Interstate Maintenance funds may be transferred to NHS and/or STP. Funds transferred into STP are not subject to sub-allocation and will be transferred to the state flexible appropriation code (33D).

Regional Administrators may approve these transfers (this may be delegated). A copy of the approval, the State's request, and the attached form must be provided to HFS–31.

- Up to 100% of a State's Interstate Maintenance funds may be transferred to NHS and/or STP if the State certifies that the funds are in excess of its needs for resurfacing, restoring or rehabilitating Interstate System routes and the State is adequately maintaining the Interstate System. The Secretary of Transportation must accept the certification before the transfer can be made. Funds transferred into STP are not subject to sub-allocation and will be transferred to the state flexible appropriation code (33D).

The State's request, along with the attached form and the Regional Administrator's recommendation, should be forwarded to the Director, Office of Fiscal Services for coordination and submission to the Secretary for approval.

Interstate Construction

- A State (other than Massachusetts) may transfer an amount equivalent to the Federal share of the cost to complete its open-to-traffic Interstate segments included in the 1991 Interstate Cost Estimate (ICE) from its Interstate construction funds to NHS and/or Interstate Maintenance apportionments. Upon approval of the transfer, the work on which the transfer is based will be removed from the 1991 ICE and will lose its IC fund eligibility.

The State's request, identifying the specific work to be removed from the ICE, along with the attached form and the Regional Administrator's recommendation, should be forwarded to the Director, Office of Fiscal Services for coordination and approval.

If you have any questions concerning these transfer provisions please contact the Program Analysis Division (HFS–30) on FTS 366–2906.

Peter J. Basso

Attachment

WORKSHEET FOR REVIEW OF FUND TRANSFERS—TRANSFER OF FEDERAL-AID HIGHWAY AND HIGHWAY SAFETY FUNDS

Fiscal year[1]	Funds[2]	Appropriation code[3]	Original apportionment[4]	Previous date[5]	Transfer amount[6]	Unobligated balance[6]	To be transferred[7]	Percent of original apportionment[8]
FROM:								
TO:								

[1] Enter the fiscal year of the apportionment involved. Transfers are permissible only between funds apportioned for the same fiscal year—i.e. transfers between FY 1990 rural primary and FY 1990 rural secondary are permitted but transfers between FY 1990 and FY 1991 are not. However, unobligated balances of funds apportioned prior to Oct. 1, 1991 may be transmitted to certain ISTEA categories.
[2] Enter name of funds involved.
[3] Enter appropriation codes of the funds involved.
[4] Enter original apportionment—the amount shown on the supplementary tables for the fiscal year exclusive of HPR.
[5] Enter any previous transfers involving the fiscal year fund for which the current request applies.
[6] Enter the unobligated balance of the fiscal year apportionment or apportionment segment from which funds are being transferred.
[7] Enter the amount to be transferred.
[8] Enter the percent of the orginal apportionment that is being transferred.

MEMORANDUM

Date: April 24, 1992.
Reply to Attn. of: HEP–50.
Subject: Information: National Recreational Trails Program.
From: Director, Office of Environment and Planning.
To: Regional Federal Highway Administrators Federal Lands Highway Program Administrator.

The Symms National Recreational Trails Act of 1991 (ISTEA sections 1301, 1302, 1303, and 8003) is intended to provide funds for recreational trails and trail-related projects. Dr. Larson sent a letter dated February 25, 1992, to each State Governor asking them to designate the State agency and official who would administer the Trails program in the State as required by the Symms Act. As of April 21, we have received responses from 27 States (see attached list). Please verify if the remaining States are planning to designate a State agency and official.

The Division offices should initiate contact with the State agency that will be administering the Recreational Trails Program. In most cases, it will not be the Department of Transportation. This is an opportunity to develop new State partnerships.

The Washington Headquarters Office would appreciate knowing who the contact person will be in each Regional and Division Office for the Recreational Trails Program. Please provide the name, telephone number, and routing code to Christopher B. Douwes, Recreation Trails Program Manager. He may be reached at (202) 366–5013, or FAX (202) 366–3713.

Finally, the Symms Act requires that Recreational Trail projects be identified in, or further a specific goal of, a trail plan included or referenced in a Statewide Comprehensive Outdoor Recreation Plan (SCORP) as required by the Land and Water Conservation Fund Act of 1965 (LWCF). All States have SCORPs. The National Park Service has asked each State to send three copies of their SCORPs to the Washington Headquarters Office. As they arrive, one copy will be sent directly to the Division Office. Copies for Regional offices will be held until SCORPs arrive from all States in that Region. Each SCORP mailing will include a copy of the Land and Water Conservation Fund Act. The last page will have excerpts from the LWCF Act referenced in the Symms Act.

B. Juhasz
for
Kevin E. Heanue
Attachment

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STATE
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Wyoming

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VOL 58 ISS 1 JA 4 1993 UMI

NATIONAL RECREATIONAL TRAILS PROGRAM
DESIGNATED STATE AGENCY

As of 10 December, 1992

STATE	OFFICIAL	AGENCY
Alabama	Gene Anderson	Department of Economic and Community Affairs
Alaska	Neil Johannsen	Department of Natural Resources; Div of Parks and Outdoor Recreation
Arizona	Kenneth E. Travous	Arizona State Parks
Arkansas	Maurice Smith	Department of Highways and Transportation; *coop with Dept of Parks and Tourism*
California	Douglas P. Wheeler	The Resources Agency; Department of Parks and Recreation
Colorado	Laurie A. Mathews	Department of Natural Resources; Div of Parks and Outdoor Recreation
Connecticut	Joseph Hickey	Department of Environmental Protection; Bureau of Outdoor Recreation
Delaware	Charles Salkin	Dept of Natural Resources & Environmental Control; Div of Parks & Recreation
Dist Columbia	Carol Hill Lowe	Department of Recreation and Parks
Florida	Fran P. Mainella	Department of Natural Resources; Division of Recreation and Parks
Georgia	Joe D. Tanner	Department of Natural Resources
Hawaii	Michael Buck, Christina Meller	Dept of Land and Natural Resources; Div Forestry and Wildlife; Na Ala Hele
Idaho	Yvonne S. Ferrell	Department of Parks and Recreation
Illinois	Kirk Brown	Dept of Transportation; *Dept of Conservation to select projects / administer program*
Indiana	Patrick R. Ralston	Department of Natural Resources
Iowa	Nancy J. Burns	Department of Transportation; Office of Project Planning
Kansas	Jack Lacey	Department of Wildlife and Parks
Kentucky	Bruce Ferguson	Department of Local Government
Louisiana	General Jude Patin	Department of Transportation and Development
Maine	Herbert W. Hartman	Department of Conservation; Bureau of Parks & Recreation
Maryland	O. James Lighthizer	Department of Transportation; Maryland Greenways Commission
Massachusetts	William Steffens	Massachusetts Highway Department
jointly	Richard Thibedeau	Massachusetts Department of Environmental Management
Michigan	Roland Harmes	Department of Natural Resources
Minnesota	R. Sando/Dennis Asmussen	Department of Natural Resources; Trails and Waterways Unit
Mississippi		***NO ACTION TAKEN***
Missouri	G. Tracy Mehan	Department of Natural Resources
Montana	Bob Walker	Department of Fish, Wildlife, and Parks; Parks Division; Trails Program
Nebraska	Rex Amack	Nebraska Game and Parks Commission
Nevada		***Contact person named, but FHWA has not received formal notification***
New Hampshire	Wilbur F. LaPage	Department of Resources and Economic Development; Div. of Parks and Recreation
New Jersey	John Weingart	Department of Environmental Protection and Energy
New Mexico	Anita Lockwood	Energy, Minerals, and Natural Resources Department
New York	Orin Lehman / Ivan Vamos	Office of Parks, Recreation, and Historic Preservation; *coordinate with NYS DOT*
North Carolina	William W. Cobey, Jr.	Department of Environment, Health, and Natural Resources; *coop with NC DOT*
North Dakota	Dr. Douglas K. Eiken	Department of Parks & Tourism; Parks and Outdoor Recreation Sites
Ohio	Frances S. Buchholzer	Dept of Natural Resources; *coordinate with Jerry Wray, Dept of Transportation*
Oklahoma	James Thomas	Tourism and Recreation Department
Oregon	David Talbot / Peter Bond	Parks and Recreation Department
Pennsylvania	James R. Grace	Department of Environmental Resources
Puerto Rico	Hon. Ibrahim Pérez	Department of Recreation and Sports
Rhode Island	Judith S. Benedict	Department of Environmental Management; Planning and Development Division
South Carolina	J.W. (Bill) Lawrence	Department of Parks, Recreation, and Tourism
South Dakota	Doug Hofer	Department of Game, Fish, and Parks; *in consultation with SD DOT*
Tennessee	J.W. Luna	Department of Environment and Conservation
Texas	Andrew Sansom	Texas Parks and Wildlife Department
Utah	Dee C. Hanson	Department of Natural Resources
Vermont	Jan Eastman / C. Motyka	Agency of Natural Resources; Forests, Parks, and Recreation
Virginia	J. Robert Hicks, Jr.	Department of Conservation and Recreation
Washington	L.D. Fairleigh	Interagency Committee for Outdoor Recreation
West Virginia		***NO ACTION TAKEN***
Wisconsin	Carroll D. Besadny	Department of Natural Resources
Wyoming	Gary Thorson	Department of Commerce; State Parks and Historic Sites

BILLING CODE 4910-22-C

MEMORANDUM

Date: September 4, 1992.
Reply to Attn of: HFO–30.
Subject: Motor Carrier Safety Assistance Program Final Rule Part 350 Reference Guide.
From: Director, Office of Motor Carrier Field Operations.
To: Regional Directors, Office of Motor Carriers.

The issuance of the final rule on September 8 marks a major milestone in our efforts to carry out the provisions of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA). Its provisions apply to all SEPs submitted for FY 1993. The advent of the final rule may raise questions as to how the new requirements are applied and how they will be implemented by the States. This reference guide was prepared to help answer some of these questions.

The preamble of the final rule also includes much information about the intent and rationale behind many of the new requirements. Therefore, the explanations in the preamble should help answer many of the questions that arise. The reference guide supplements the information in the preamble by expounding on issues that received limited coverage or are not addressed in the preamble. Both the preamble of the final rule and this reference guide will be made part of our policy memo. We hope that the "Q & A" format will help you to quickly pinpoint the answers to your questions.

If you need additional information, please call your Regional contact in Headquarters.

Michael F. Trentacoste

Motor Carrier Safety Assistance Program Final Rule

Reference Guide

Secondary Grant States

Question: The preamble (paragraph "e" of the Analysis of Comments) states that while the Secondary grant States are not accommodated in the formula, preference will be given to these States in the redistribution of funds and also that the funds will be reduced over the life of the authorization. In the rule this is addressed in 49 CFR 350.21(f). How will Secondary funding be reduced for the Secondary grant States (Colorado, Connecticut, Idaho, Louisiana, Massachusetts, Rhode Island, and Utah)?

Response: For FY '93, based upon availability of funds, Secondary grant States will receive 90 percent of the amount they received in Secondary funds for FY '92. The FHWA intends to gradually phase out these Secondary grants over the period of the authorization.

Question: May Secondary grant States receive additional grants in addition to their Basic formula allocation?

Response: Yes, Secondary grant States may receive Supplemental grants and Special grants above their Basic grants, i.e., Idaho's video center and Utah's drug/alcohol testing pilot project.

Question: May a State which is receiving Secondary funding request reallocated funds?

Response: Yes, a Secondary grant State may request reallocated funds for eligible activities. However, as with all States, the State should be discouraged from requesting funds to expand its work forces because additional reallocated funds may not be available in future years.

Maintenance of Effort (MOE)

Question: Must a State calculate its MOE and include it in the State Enforcement Plan (SEP)?

Response: Although the States are responsible for calculating their MOEs, the dollar amount is no longer included in the SEP. States will certify that they have calculated their MOE and are able to provide the supporting documentation if audited. This self-certification is included in 49 CFR part 350, appendix B, paragraph 8, "State Certification."

Question: Once a State has determined its new MOE based on the ISTEA, must the MOE ever be recalculated?

Response: Yes, a State would recalculate its MOE if it adds another MCSAP participating agency which has performed MCSAP eligible activities during the MOE period.

Question: For the purpose of a State determining its MOE, what is a "participating agency?"

Response: A participating agency is any jurisdiction—State or local—which receives MCSAP funding to perform MCSAP eligible activities. An agency, which employs officers who have been trained with MCSAP funds, but does not receive MCSAP funding to perform activities related to the training need not be considered a "participating agency."

Rollover Funds

Question: Section 350.21(g) provides that funds are available in the year they are obligated and the next full fiscal year. What is the procedure for a State to roll over funds to the next year's program?

Response: To ensure proper tracking of 2-year monies, a State must do the following:

1. Submit a final voucher (or a MCSAP–2A) within 90 days after the expiration of the grant for the amount expended during the fiscal year (projects to be broken out individually);

2. File a MCSAP–2A to increase the amount of the new fiscal year's grant program by the rolled over amount; and

3. Within 30 days after submitting the final voucher (or MCSAP–2A), amend the SEP to justify the higher total amount of funding now provided for the current year's grant program.

This process will deobligate the amount to be rolled over and reobligate the rolled over amount into the State's new grant program. This will then increase the current grant program by the rolled over amount. As stated in 49 CFR Section 350.21, the rollover funds must be expended before new money is used.

Question: How can rollover funds be used and tracked?

Response: Basic and Supplemental grant funding that is rolled over will be rolled over into the Basic grant and will "lose its identity." That is, rollover funding can be used for any eligible activity. Because the rolled over funds must be a part of an approved SEP, careful planning and program monitoring should keep unplanned rollover funds to a minimum.

Reallocated funds are awarded for specific high-priority activities. While these funds are generally Supplemental grants which can be rolled over for any eligible activity the following year, States are discouraged from applying for grants from reallocated funds with the desire to hold the funds in reserve in order to use them for other activities the following fiscal year. Reallocated funds should be closely monitored by the region and division to ensure the funds are used to the extent practicable for the original intent.

Rolled over funding for Special grants must be used for the same or substantially similar activities.

Question: May a State plan to reserve some funds to roll over to the next year?

Response: Yes. Now that funds are available for up to 2 years, a State may plan to combine Basic and/or Supplemental grant funds from two separate SEPs to cover large purchases. For example, a State needs to obtain computer equipment costing $20,000. Only $10,000 is available for this purchase in the present SEP. The State may include $10,000 in its present budget for rollover toward the purchase of $20,000 worth of computer equipment the next year.

SEP Guidelines

Question: What new format should be used in preparing SEPs to comply with the new activities and assurances that the ISTEA requires?

Response: The States are encouraged to submit one SEP, which includes their request for Basic, Supplemental, and Special grants, as well as requests for reallocated funds. This facilitates the Division and Region review of the State's overall safety program. Special and reallocated grant funds will be prioritized for funding if funds become available. Therefore, it is best to submit all requests in one submission, so that all applications can be evaluated at the same time. Special and reallocated grant requests may be submitted throughout the grant year, but States are encouraged to include these requests with the SEP so the requests will receive consideration in light of other requests.

Question: What is the current policy of submitting three quarterly reports in lieu of a narrative analysis?

Response: That policy is now rescinded. The new policy is to require a narrative analysis consistent with the provisions in appendix A to part 350 and based on the activities of the previous 12 months. A State may also base the analysis on the most current 12-month period in which it has complete program activities information. This analysis shall be submitted with the SEP, and is in addition to the quarterly reports, which are required to be submitted 30 days after the end of each quarter.

In-Kind Contributions

Question: A State may use either cash or non-cash contributions to satisfy the matching or cost-sharing requirements of the MCSAP. Non-cash contributions are more

commonly referred to as in-kind contributions. Please define "matching or cost sharing" contributions and "in-kind" contributions.

Response: Matching or Cost Sharing is the portion of a project or program costs not borne by the Federal Government.

In-kind contribution is the value of non-cash contributions provided by the recipient and non-Federal third parties. In-kind contributions are allowable costs valued as any other grantee cost in accordance with the cost principles. In-kind contributions may be in the form of charges for equipment, supplies and other services directly benefiting and specifically identifiable to the project or program.

For further information, reference the Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, commonly referred to as the Common Rule OMB Circular A–102 published in the March 11, 1988 Federal Register (see 53 FR 8034–8103) as codified in the Code of Federal Regulations 49 CFR Part 18.

Eligible Activities/Costs

Question: Section 350.29(c), Eligible Costs, provides for several new initiatives within the MCSAP such as size and weight enforcement, drug interdiction activities, and traffic enforcement. What conditions must be met for these activities to be eligible?

Response: These activities are eligible for reimbursement if they are performed in conjunction with a MCSAP inspection. Additionally, the following must be met:

Size and Weight activities are eligible for funding under limited circumstances. For example, they must be performed "in conjunction with" (as part of) an eligible MCSAP inspection. Further, for size and weight activities to be eligible, they must not be conducted at a fixed scale facility. A fixed scale facility includes weighing operations that could be anticipated by a driver of a commercial motor vehicle. The following are examples of fixed scale facilities:

(a) A permanent scale site;

(b) Portable equipment placed at a specific location, operating on regularly scheduled days of the week during specific times of the day; or

(c) Portable or semi-portable equipment used on a regular basis at fixed facilities. This includes, for example, facilities with a cement structure to cradle the semi-portable scales.

Size and weight activities, including fixed scale activities, are eligible when conducted at specific sites where the weight of the vehicle has a significant effect on safety, such as steep grades or at seaports where intermodal shipping containers enter and exit the U.S. These exceptions to using MCSAP funds for fixed scale activities are specifically limited by the ISTEA.

Drug Interdiction activities are restricted to those designed to detect and deter the use and transportation of controlled substances by the drivers or other occupants of commercial motor vehicles. Funding eligibility is extended only to those officers who have been specifically trained in commercial motor vehicle drug interdiction techniques.

Traffic Enforcement activities (and subsequent vehicle and/or driver inspection) are reimbursable provided the contact arose as a direct result of a safety-related traffic law violation, such as speeding, improper lane change, following too closely, etc.

Question: What costs associated with these activities are considered to be "eligible costs" under MCSAP?

Response: The officer's time spent on eligible activities and the pro-rated share of specialized equipment used to carry out these activities are eligible costs. For example, breathalyzers, speed control equipment, and portable scale equipment, are eligible costs. Some other examples of eligible costs for these new activities are:

Drug Interdiction: Field test kits and the purchase of dogs used to detect drugs.

Traffic Enforcement: Training related to equipment use. If a piece of equipment is used on commercial motor vehicle enforcement for 50 percent of the time, then the State may charge 50 percent of the cost of the training to use such equipment to the MCSAP. If a police officer spends 75 percent of the time on commercial motor vehicle enforcement activities, the State may charge 75 percent of the officer's time to MCSAP.

HM Training: Costs associated with attendance at appropriate hazardous materials training, including shipper and cargo tank training.

Local Enforcement: Costs associated with attendance at appropriate commercial motor vehicle enforcement training and time spent on conducting inspections in accordance with the North American Uniform Driver-Vehicle Inspection Standard.

HM Shipper Reviews: Time spent conducting shipper reviews to the same extent as safety and compliance reviews.

NGA Special Grants

Question: Up to $2 million a year is provided to the States to adopt and implement the 22 NGA recommended accident data elements. How may the States apply for NGA funds made available for FY 1993?

Response: The States may include proposals for their NGA grants in their FY 1993 SEPs or later as an amendment to the SEP. Funds have been allocated to each State as a Special grant. These funds will be distributed to the lead MCSAP agency to draft forms, train officers, evaluate data, etc. These funds are available to all States—whether they participate in the MCSAP or not—to provide full accident data collection nationwide.

MEMORANDUM

Date: May 29, 1992.
Reply to Attn of: HIA–20/HFO–1.
Subject: Information on Uniformity Grant Process (Section 4008, ISTEA).
From: Director, Office of Motor Carrier Information Management; Director, Office of Motor Carrier Field Operations.
To: Regional Directors, Office of Motor Carriers, Regions 1–10.

This memorandum requests your assistance in obligating and administering grants to the States as required by Section 4008(j) of the Intermodal Surface Transportation Efficiency Act (ISTEA) of 1991. Section 4008 of the ISTEA requires that all States join the International Registration Plan (IRP) and the International Fuel Tax Agreement (IFTA) by September 30, 1996. (See Attachment G for a copy of Section 4008 of the ISTEA.) States which participated in the Regional Fuel Tax Agreement (RFTA) as of January 1, 1991, are not required to join IFTA. The IRP is a base-State agreement for registering commercial trucks and buses operating in different States. Likewise, the IFTA and the RFTA are base-State agreements for reporting and paying State fuel taxes. (See Attachments H, I, and J for a more detailed description of IRP, IFTA and RFTA.)

To facilitate State participation in the IRP and IFTA agreements, Section 4008 also requires the establishment of a Working Group comprised of State officials to: (1) Recommend procedures for resolving disputes among IRP and IFTA member States, and (2) provide technical assistance to member States in their efforts to join IRP and IFTA. (See Attachment E and F for a list of members to the Base-State Working Group and State membership in the IRP, IFTA and RFTA.)

In fiscal years 1992 through 1997 Congress has authorized $5 million annually in grants to States for technical assistance, training, and equipment associated with participation in the IRP and IFTA. This memorandum and its attachments address the process and distribution of FY 1992 funds only.

Another uniformity provision is contained in Section 4003 of the ISTEA. This Section provides funds for the development of a Commercial Vehicle Information System (CVIS). These funds will be made available under a later solicitation once a lead State is identified for the CVIS project. We will provide details on the distribution of these funds next month.

The attached briefing package provides a schedule of dates, a description of the proposed grant process, sample forms, instructions for completing the work plan, a list of Working Group members, State membership lists, and background information on the IRP, IFTA and RFTA.

Attachment A: Schedule of Important Dates.

Attachment B: Description of the Grant Award Process.

Attachment C: Grant Agreement (pending).

Attachment D: Instructions for Completing a State Work Plan.

Attachment E: List of Members of the Base-State Working Group.

Attachment F: List of States in IRP, IFTA and RFTA.

Attachment G: Section 4008 of the ISTEA.

Attachment H: Description of IRP.

Attachment I: Description of IFTA.

Attachment J: Description of RFTA.

Attachment K: Description of the IRP and IFTA Repositories.

Please be advised that the lead agency for administering the Section 4008 funds will be identified by the Governor. We are requesting that he or she designate a lead agency and notify the Office of Motor Carriers (OMC)

State Director in the Federal Highway Administration's (FHWA) Division Office by mid-June. In addition, all State Work Plans should be received in the Division Office by July 15, 1992, so that grants can be awarded by August 31, 1992. (Attachment A provides a schedule of important dates related to the Section 4008 grant distribution process.)

We encourage OMC State Directors to initiate discussions with those State agencies that may be designated as the lead agency in this grant program. A copy of the letter from the FHWA Administrator to the Governors will be forwarded to you.

Note that Attachment C, the Grant Agreement is pending final clearances from our Office of Management Systems. We expect the grant agreement form to be approved by Management Systems within the near future. The approved grant agreement form will be sent to you at that time.

We will be sending you a package of section 4008 information materials to be forwarded onto the lead agencies within the States about mid-June. This informational package will inform the States about the availability of the Section 4008 grant funds and provide them with information about how and where to apply for the uniformity grants.

This is a proposed grant process. If you have any questions or suggestions pertaining to this process, please contact Nancy Emanuel at (202) 366–2948. If you have any technical questions pertaining to either IRP or IFTA or questions about State participation in the IRP or IFTA, please contact Bonnie Bass at (202) 366–0089.

Michael F. Trentacoste.

John F. Grimm.

Attachment.

Attachment A—FY '92 Uniformity Grants—Schedule of Important Dates

Late May—Briefing Package sent to OMC Regional Directors and Division Offices.

Early June—Letter from FHWA Administrator Sent to Governors Requesting the Designation of a Lead Agency to Administer Section 4008 Grant Funds.

Mid-June—OMC State Directors Notified of Lead Agency by Governor's Office.

Mid-June—Informational Package for the States Sent to Regional Directors and OMC State Directors for Distribution to Lead Agencies within the States.

July 15—State Work Plans Submitted to OMC State Directors for Review and Recommendation.

July 31—State Work Plans Submitted to OMC Regional Directors for Approval. Regional Directors Recommend to OMC Headquarters the Amounts to be Allocated to Each State.

Mid-August—OMC Headquarters Will Issue the Allocation Memo.

August 31—Grant Agreements Signed between Individual States and the FHWA Regional Director.

Attachment B—Uniformity Grants—Description of the Grant Award Process

The following narrative provides a description of the process for distributing FY '92 Section 4008 grant funds to States.

- Role of the Headquarters and Field Staff in Distributing Uniformity Grant Funds.

Headquarters: The State Programs Division (HFO–30) will oversee the allocation of section 4008 grant funds to the Regions for obligation to the States. Nancy Emanuel will be the official headquarter's contact for this activity. Ms. Emanuel can be reached on (202) 366–2948.

Regions: Regions provide guidance to the Divisions ensuring the timeliness and quality of reports. Regions support Divisions and States in achieving program status (reporting) and goals through the use of Highway Trust Fund and MCSAP funds. The Regional Directors will have final approval of State Work Plans and sign the agreement authorizing the grant award.

Divisions: Divisions work with the lead agency within the States to achieve uniformity goals developed in the State Work Plan. The Program Managers within the Division Offices will be primarily responsible for monitoring individual State activities and uniformity grant monies to the States.

- Amount of Uniformity Grant Funds to be Distributed to the States.

Although section 4008 provides $5 million in grant funds each fiscal year, only $3.5 million of the grant monies will be distributed directly to the States this fiscal year. The remaining $1.5 million will be used to fund the IRP and IFTA repositories and to provide training and technical assistance to the States. The $1.5 million will be administered by Headquarters staff through cooperative agreements with national associations such as the American Association of Motor Vehicle Administrators (AAMVA) and the IFTA Board of Directors.

- Deadline for Awarding Grants to States.

All State Work Plans should be received by the OMC Division Office no later than July 15 and all grants should be awarded by August 31, 1992. This money is available to the States for expenditure in the current fiscal year and one succeeding fiscal year.

- Criteria or Formula to be Used as a Basis for Awarding the Grants.

Because of the short time frame for awarding the grants before the end of the fiscal year, no special criteria, needs analysis or funding formula will be applied. Alaska and Hawaii are exempt from the mandate to join IRP and IFTA and so will not be eligible to receive grant funds. Therefore, the grant funds will be divided among the remaining 48 States and the District of Columbia. Under present projections, each of these States will get an equal share amounting to at least $71,000. State allocations for future fiscal years (1993–1997) may, however, be based upon special criteria or a formula.

As required by section 4008 of the ISTEA, FHWA has established a Base-State Working Group to facilitate participation in the IRP and IFTA. The Base-State Working Group will provide recommendations to FHWA on any formulas or criteria to be used in allocating future section 4008 grant funds. Because of the late distribution of these FY '92 funds, the State Work Plan should be developed to cover FY '92 and FY '93. We encourage the States to prepare this Work Plan for between $71,000 and $100,000 to be expended during FY '92 and FY '93. We are specifying up to $100,000 because some States may choose not to participate in the section 4008 grant program and their share of the funding may be redistributed to participating States. When the distribution of additional funds is decided the State can then amend the current State Work Plan to incorporate them and related activities.

- State Match Requirement.

Even though the section 4008 funds come out of the MCSAP authorization for fiscal years 1993–1997 no State match is required. These are 100% Federal grants.

- Lead Agency in the State.

At least three agencies within the State could potentially be interested in serving as the lead agency for administering the section 4008 grant funds. These agencies are: (1) The Department of Motor Vehicles; (2) the Department of Revenue; and (3) the Department of Transportation. We are requesting that the Governor's Office identify the lead agency within the State. The FHWA Administrator has sent a letter to each Governor and the Mayor of the District of Columbia requesting that the OMC State Directors be notified of a lead agency by mid-June 1992.

- Overview of the Grant Distribution Process.

The following describes the major aspects of the uniformity grant award process.

(1) The FHWA Administrator will contact the Governor's Office and request the Governors to designate a lead agency to administer the section 4008 grant funds and to notify the OMC State Directors of their decisions by mid-June.

(2) Around mid-June, OMC headquarters will send the OMC Regional Directors and State Directors an informational package to be forwarded to the State's lead agency. This informational package will notify the States about the availability of the section 4008 grant funds and provide them with information about how and where to apply for the uniformity grants.

(3) States interested in applying for the section 4008 grant funds must (a) develop a State Work Plan detailing how the grant funds will be spent; and (b) submit a completed State Work Plan to the OMC Division Office for review and recommendations. The Division Office will submit the State Work Plan to the Regional Office for approval.

(4) When the State Work Plan is approved, the authorized State representative will sign an agreement with the OMC Regional Director. (A copy of the pending grant agreement and instructions for completing the State Work Plan is attached.)

(5) A copy of the signed grant agreement and the State Work Plan will be sent to Headquarters for our records.

- State Reimbursement Procedures.

Reimbursement procedures, including the responsibility of review by the Division Office and concurrence by the Regional Director, will be the same as those used in administering the MCSAP.

A State may request periodic reimbursement for costs incurred for a project. The request shall be in the form of a voucher and shall be certified and accompanied by supporting data.

All claims by a State are to be made on Form PR–20 "Voucher for Work Performed under Provisions of the Federal-Aid and Federal Highway Acts, as amended." These vouchers are submitted to the FHWA's OMC Division Office for reimbursement after costs are incurred.

A final voucher represents the final claim and shall be submitted by a State to the FHWA within 90 days after the grant expires or the project is completed. The final voucher shows all final costs incurred, amount of Federal funds due on the project, previous Federal reimbursements, amount currently due, and a summary of project costs on the reverse side of the form. The final summary of the project costs shall contain, at a minimum, the types of costs incurred summarized by the primary functions performed under the grant.

• Reporting.

The lead agency within the State will be required to prepare a brief semiannual report within 30 days after each reporting period. For non-member States, the report shall contain a description of the State's progress in accomplishing the requirements of section 4008 over the past 6 months. For member States, the report shall contain a description of how section 4008 funds have been used to improve the operation of IRP and IFTA.

Attachment C (Pending)

_____

Project No.

International Registration Plan (IRP)/Base-State Fuel Tax Grant Agreement for Year 19____

Between: The Federal Highway Administration (FHWA) and

_____

(State Agency)

entered into in accordance with the Motor Carrier Act of 1991. (Pub. L. 102–240, Title IV, 105 Stat. 2140, December 18, 1991.)

Pursuant to Sections 4008 (e) and (j) of the Motor Carrier Act of 1991, the Federal Highway Administration hereby approves the grant request of the State of _____(State Agency) (hereinafter referred to as the State) dated _____, for Federal assistance funding in the amount of $_____for the Grant Program as described in the grant request.

These grant funds are provided to assist States in meeting the mandates of Section 4008 of the Motor Carrier Act of 1991. The Act requires that after September 30, 1996 (1) no State shall establish, maintain, or enforce any commercial motor vehicle registration law, regulation or agreement which limits the operation of any commercial motor vehicle within its borders which is not registered under the laws of the State if the vehicle is registered under the laws of any other State participating in the International Registration Plan [Section 4008(f)]; (2) no State shall establish, maintain or enforce any law or regulation which has fuel use tax reporting requirements (including tax reporting forms) which are not in conformity with the International Fuel Tax Agreement [Section 4008(g)(1)]; and (3) no State shall establish, maintain, or enforce any law or regulation which provides for the payment of fuel use tax unless such law or agreement is in conformity with the International Fuel Tax Agreement with respect to the collection of such a tax by a single base State and taxes so charged are shared proportionately among the States where a commercial motor vehicle is operated [Section 4008(g)(2)].

The State hereby agrees (1) to submit to the FHWA a semiannual report covering the progress of implementation and a final report; (2) to assure that accurate and auditable records to support the costs claimed are maintained and available for inspection by FHWA for a period of 3 years after the date of submission of the final expenditure report; (3) to limit interim and final claims to those costs incurred in accordance with this agreement; and (4) to comply with all laws, regulations and requirements relating to this program and with the provisions set forth on the reverse hereof.

This agreement is effective _____, and expires _____.

_____

(State Agency)

_____

(Authorized Representative, Title) Date

_____

(FHWA Regional Director) Date

Attachment D—Uniformity Grants—Instructions for Completing the Section 4008 Work Plan

To obtain grant monies under Section 4008 of the ISTEA, all States eligible for funding must complete a Work Plan to insure that the section 4008 grant funds will be spent properly. Submission of a Work Plan will also serve as the State's application for the grant. Individual State Work Plans will be submitted to the OMC Division Office for review and forwarded to OMC Regional Director for approval. An approved State Work Plan is a prerequisite for obtaining the uniformity grant funds. We anticipate these Work Plans to be approximately 2–5 pages in length. In preparing the plan, States should include the following information:

1. Name and address of the lead agency.

2. Name and address of the principal official within the lead agency responsible for the administration of the grant program.

3. Current Annual State Work Plan including:

(a) Total amount of funds requested.

(b) Percentage of funds to be used to facilitate participation in the International Registration Plan.

(c) Percentage of grant funds to be used to facilitate participation in the International Fuel Tax Agreement.

(d) Percentage of grant funds to be used to facilitate participation in the Regional Fuel Tax Agreement (RFTA).

(e) Narrative description of activities to be accomplished.

All proposed activities must facilitate State participation in the IRP and IFTA and be consistent with the eligible funding activities identified under section 4008(e) of the ISTEA. Those activities include: Providing technical assistance, personnel training, travel (e.g. technical assistance trips to other States, travel to attend IRP, IFTA or RFTA training sessions, travel to IRP, IFTA or RFTA meetings or seminars) costs, and technology and equipment associated with participation.

(f) Table which breaks down costs by activity.

(g) Detailed budget breakdown by line item.

(h) Schedule for accomplishing proposed activities.

Attachment E—List of Members to the Base State Working Group

Mr. Roger Tew (Chair), Commissioner, Utah State Tax Commission, 160 East 300 South, Salt Lake City, Utah 84134, (801) 530–6988

Mr. James Gentner (Vice Chair), Program Administrator, Arizona Department of Transportation, Motor Vehicle Division, 1801 W. Jefferson St., Drop 520M, Phoenix, Arizona 85001, (602) 255–8968

Ms. Patricia B. Adducci, Commissioner, New York State Department of Motor Vehicles, Empire State Plaza, Albany, New York 12228, (518) 474–0841

Mr. Timothy Byrnes, Program Administrator, Tax Processing Administration, Illinois Department of Revenue, 101 West Jefferson, Mail Code 3–200, Springfield, IL 62794

Mr. R. Gary Clark, Tax Administrator, Rhode Island Division of Taxation, 1 Capitol Hill, Providence, Rhode Island 02908–5800, (401) 277–3050

Mr. Ralph Craft, Transportation Analyst, New Jersey Governor's Office, 444 N. Capitol Street, NW., Suite 201, Washington, DC 20001, (202) 638–0631

Mr. Harley Duncan, Executive Director, Federation of Tax Administrators, 444 N. Capitol Street, NW., suite 348, Washington, DC 20001, (202) 624–5890

Mr. Dennis Foushee, Director, International Registration Plan, North Caroline Division of Motor Vehicles, IRP Unit, 1100 New Bern Ave., Raleigh, NC 27697–001, (919) 733–7458

Mr. Marc D. Guthrie, State Representative, Assistant Majority Whip Ohio House of Representatives, 77 South High Street, Columbus, Ohio 43215, (614) 466–4361

Mr. John LaFaver, State Tax Assessor, Bureau of Taxation, State House Station 24, Augusta, Maine 04333, (207) 289–4702

Mr. Clark Martin, Director, Motor Carrier Services, American Association of Motor Vehicle Administrators, 4200 Wilson Blvd., suite 1100, Arlington, VA 22203, (703) 522–4200

Ms. Linley Oberman, Area Manager, Customer Service Division, Bureau of Motor Vehicles, room 104, Transportation and Safety Building, Harrisburg, Pennsylvania 17120, (717) 787–2780

Mr. Joseph Pawlowski, Deputy Secretary of State, Michigan Department of State, Bureau of Driver and Vehicle Records, 7064 Crowner Drive, Lansing, Michigan 48918, (517) 322–1528

Mr. James Poe, Fuel Tax Administrator, Indiana Department of Revenue, Special Tax Division, 100 N. Senate Ave., room 218, Indianapolis, Indiana 46204, (317) 232–1862

Mr. Fred Porter, IRP Administrator, P.O. Box 1272 MV, Little Rock, Arkansas 72203, (501) 682–4630

Mr. James J. Scheiner, President, Benatec Associates, 101 Efford Road, Camp Hill, Pennsylvania 17011, (717) 763–7391
Mr. James Sizemore, Jr., Commissioner, Alabama Department of Revenue, Gordon Persons Building, 50 N. Ripley Street, Montgomery, Alabama 36130, (205) 242–1175
Ms. Ruth Skluzacek, Director, Office of Motor Carrier Services, Iowa Department of Transportation, 5238 NW. 2nd Avenue, Des Moines, Iowa 50313, (515) 237–1021
Mr. Ronald Snell, Program Director for Fiscal Affairs, National Conference of State Legislatures, 1560 Broadway, suite 700, Denver, Colorado 80202, (303) 830–2200
Mr. James Wetzler, Commissioner, New York State Department of Taxation and Finance, W.A. Harriman Campus, Albany, New York 12227–0125, (518) 457–2244

Federal Highway Administration Liaison (non-voting)

Mr. John F. Grimm, Director, Office of Motor Carrier Information Management and Analysis, U.S. Department of Transportation, 400 7th Street SW., Washington, DC 20590, (202) 366–4023

ATTACHMENT F.—STATE MEMBERSHIP IN IRP, IFTA AND RFTA AS OF MAY 15, 1992

	IRP	IFTA	RFTA
Alabama	X		
Alberta	X		
Arizona	X	X	
Arkansas	X	X	
California	X		
Colorado	X	X	
Connecticut	X		
Delaware			
District of Columbia			
Florida	X		
Georgia	X		
Idaho	X	X	
Illinois	X		
Indiana	X	X	
Iowa	X	X	
Kansas	X	X	
Kentucky	X		
Louisiana	X		
Maine	X		X
Maryland	X		
Massachusetts			
Michigan	X		
Minnesota	X	X	
Mississippi	X		
Missouri	X	X	
Montana	X	X	
Nebraska	X	X	
New Hampshire	X		X
New Jersey			
New Mexico	X		
New York	X		
Nevada	X	X	
North Carolina	X	X	
North Dakota	X	X	
Ohio	X		
Oklahoma	X	X	
Oregon	X		
Pennsylvania	X		
Rhode Island			
South Caroline	X		
South Dakota	X	X	
Tennessee	X		
Texas	X		
Utah	X	X	
Vermont	X		X
Virginia	X		

ATTACHMENT F.—STATE MEMBERSHIP IN IRP, IFTA AND RFTA AS OF MAY 15, 1992—Continued

	IRP	IFTA	RFTA
Washington	X	X	
West Virginia	X		
Wisconsin	X	X	
Wyoming	X	X	

Attachment G: See Section 4008 of the ISTEA

Attachments H, I, J: These attachments could not be reproduced without permission from the author.

Attachment K—Discussion of the IRP and IFTA Repositories

Both IRP and IFTA have established a Repository. The repositories are not policymaking bodies. Instead, they serve as information clearinghouses and provide technical assistance and administrative support to the States. The following represent examples of the kinds of activities performed by the repositories.

(1) Arrange for IRP/IFTA training to the States for:

(a) State motor vehicle and fuel tax administrators;

(b) State registration and fuel tax clerks.

(2) Arrange for on-site technical assistance visits.

(3) Perform clerical and administrative duties to support the agreements:

(a) Maintain historical files;

(b) Prepare and distribute ballots in accordance with the agreements;

(c) Report results in ballots to membership;

(d) Maintain current versions of the IRP and IFTA agreements, procedures, audit and compliance manuals;

(e) Maintain and distribute current registration fee schedules and fuel tax rates;

(f) Provide a focal point for collection of all relevant information;

(g) Establish and coordinate an annual schedule of Peer Reviews;

(h) Distribute minutes and agendas from conferences;

(i) Establish and maintain an accounting system, and;

(j) Prepare a proposed annual budget.

The IRP repository is the American Association of Motor Vehicle Administrators (AAMVA). The name of the contact person, the address and phone number of the IRP repository is as follows: Mr. Clark Martin, AAMVA, 4200 Wilson Blvd., suite 1100, Arlington, Va 22203, (703) 522–4200.

The IFTA repository is the Lockheed Management Service Co. The name of the contact person, the address and phone number of the IFTA Repository is as follows: Ms. Bonnie Anderson, Lockheed Management Service Co., 40 North Central Avenue, suite 2250, Phoenix, Arizona 85004, (602) 254–1687.

MEMORANDUM

Date: June 25, 1992.
Reply to Attn. of: HRD–10.
Subject: Information—Implementation of ISTEA—Minimum Expenditures on Research, Development, and Technology Transfer Activities.
From: Executive Director.
To: Associate Administrators; Regional Federal Highway Administrators.

Subsection (c) of section 307, title 23, as amended by the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), requires that not less than 25 percent of the State Planning and Research (SP&R) funds apportioned to a State for a fiscal year be expended for research, development, and technology transfer activities relating to highway, public transportation, and intermodal transportation systems. The legislation provides for an exception to this requirement when the Secretary accepts a State's certification that total expenditures by the State for transportation planning under Section 134 and 135 will exceed 75 percent of the amount apportioned for this program. We have received several inquires from field offices regarding this provision.

We believe it is the intent of the language in the ISTEA to ensure that no less than 25 percent of the SP&R funds be spent on research, development, and technology transfer, unless the need for a shift in balance toward planning is compelling. Any requests to use more than 75 percent of a State's annual apportionment of SP&R (formerly Highway Planning and Research) funds for metropolitan and Statewide planning should be carefully reviewed to ensure the additional planning activities are essential and there are no other reasonable options available for funding these planning activities (including the use of National Highway System, Surface Transportation Program, or Federal Transit Administration Section 26 (a)(2) funds) or deferring lower priority activities. It should be noted that some activities which have been funded under the planning portion of the State's work program may actually be research activities that could be included in the research portion of the work program. Prior to submitting a request for an exception to the 25 percent requirement, the State and field offices should:

1. Ensure the planning projects have a higher priority than research projects in overall needs of the State of given year.

2. Ensure the total level of effort by the State in research (using both Federal and State funds) is adequate.

3. Ensure the division Administrator has negotiated with the State and both parties are agreeable to the respective levels of funding for both planning and research.

Attached is a list of additional items which should be considered when a State is requesting an exemption. If a State wishes to pursue an exception, the request, along with supporting justification and FHWA field office recommendations, should be sent to Mr. Robert J. Betsold, Acting Associate Administrator for Research and Development (HRD–10). The response to the request will be coordinated with the Office of Environment and Planning.

E. Dean Carlson.

Attachment.

Items To Be Considered in Evaluating a State's Request for an Exception to the ISTEA Requirement for Minimum Expenditure on Research, Development, and Technology Transfer Activities

1. Does the State have a process for identifying research and technology transfer (RD&T) needs, and for implementing a viable RD&T program?

2. Is the State contributing to national programs such as the National Cooperative Highway Research Program, the Transportation Research Board's activities, the implementation of products coming out of the Strategic Highway Research Program, and pooled-fund studies? (Note: Funding contributed to these programs counts towards fulfillment of the 25 percent requirement.)

3. Is the State using SP&R funds for technology transfer and for transit or intermodal research and development that are now specifically permitted, or for planning research activities, to help meet the 25 percent minimum requirement?

4. What percentage of the State's Highway Planning and Research funds was used for planning and research respectively before the ISTEA and will the percentage of funds used for RD&T activities increase if the exception is approved?

5. If an exception is approved, can the State show that in following years it will meet the requirement, or substantially increase its research expenditures toward meeting the requirement over the 6-year period of the legislation? (Note: The approval of an exception is valid only for the fiscal year in which the exception is approved.)

6. Does the amount of Federal funds needed for planning for the program period exceed the total of the 75 percent limit for the fiscal year plus any unexpected (including unused funds that can be released from completed projects) planning funds from previous apportionments?

MEMORANDUM

Date: May 22, 1992.
Reply to Attn. of: HEP–31.
Subject: Action—Joint Memorandum on "Implementation of the Intermodal Surface Transportation Act."
From: Executive Director.
To: Regional Federal Highway Administrators; Federal Lands Highway Program Administrator.

On May 1, 1992, Secretary of Transportation Andrew H. Card, Jr., along with Administrator William K. Reilly of the Environmental Protection Agency (EPA) and Army Assistant Secretary Nancy P. Dorn, signed a joint memorandum on "Implementation of the Intermodal Surface Transportation Act." The memorandum is written as official policy to Regional Administrators and District/Division Engineers of the DOT, the EPA, and Department of the Army (DOA) to improve coordination, emphasize innovative and cost-effective approaches, and integrate the requirements of the National Environmental Policy Act (NEPA) and section 404 of the Clean Water Act. On May 1, I sent a copy of the joint memorandum to the field offices for information. Today, I am attaching copies of the May 1 memorandum plus the enclosure, which was not previously available, outlining additional initiatives to improve and streamline the regulation of transportation projects under Section 404) ("Protecting the Environment and Reducing Regulatory Inefficiencies").

Funding available under ISTEA is extremely important to our Nation's transportation infrastructure, as well as being a vital stimulus to our economy. The FHWA, EPA, and DOA are totally committed to the successful implementation of all elements of ISTEA, removal of any unnecessary delays, and expeditious development of highway projects in an environmentally sound manner.

As you know, the Executive Workshop for regional field office heads of FHWA, EPA, and the Corps of Engineers (COE) held on November 15–16, 1990, was designed to discuss wetlands and transportation issues. Participants discussed six basic issues: Project Purpose and Need; Practicable Alternative Analysis; Mitigation; Assessment of Functional Values; Wetlands Delineation; and Merging NEPA and Section 404. The workshop improved participants' understanding of the FHWA/NEPA process, wetland protection, and the Section 404 permit process. Participants also pledged commitment to early coordination and timely resolution of issues at the regional and field levels.

The attached joint memorandum, with its enclosures, illustrates the continuing high-level commitment to improved interagency coordination. Where problems exist, Regional and Division Administrators are urged to become personally involved in resolving issues causing project delays.

Mr. Eugene W. Cleckley, Chief of the Environmental Operations Division, is heading a team of Washington Headquarters officials of the EPA, the DOA, and the COE to expedite resolution of section 404 issues on highway projects potentially ready for construction by October 1, 1992. He will soon be calling each Regional Administrator regarding highway projects that fit this category. The Washington Headquarters team will assist efforts by FHWA Regional Administrators and/or arrange meetings in Washington or the field with officials of the FHWA, the State DOT's, the EPA, and the COE to resolve issues. The U.S. Fish and Wildlife Service and the National Marine Fisheries Service will be invited, where appropriate.

After October 1, the Washington Headquarters team will continue to conduct interagency workshops and meetings at the regional and/or State level with the aforementioned officials responsible for implementing the FHWA/NEPA and Section 404 permit processes. The purpose will be to resolve any misunderstandings about this policy, the initiatives, and the merger of NEPA and Section 404.

Implementation of the attached policy and initiatives is a top priority of the Administrator and Secretary Card. Every level of FHWA must do everything within its power to make the policy become a reality. Our goal is for all regions to develop measures to merge the common elements of NEPA and Section 404 by the end of fiscal year 1993. All environmental documents developed under those measures should demonstrate that the merger has been accomplished.

This policy is consistent with the National Transportation Policy, the FHWA's Environmental Policy Statement, FHWA 2000, and ISTEA. We must take full advantage of this great window of opportunity to renovate our transportation infrastructure, stimulate our economy, and provide environmentally sustainable transportation projects.

E. Dean Carlson

2 Attachments.

Department of Transportation, Environmental Protection Agency, Department of the Army

May 1, 1992

Memorandum for Regional Administrators and District/Division Engineers

Subject: Implementation of the Intermodal Surface Transportation Act

The Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) is landmark legislation. It sets new directions for the Nation's highway and transit programs in a post-interstate highway era.

Important provisions of the ISTEA include a new emphasis on comprehensive intermodal planning at the state and metropolitan area levels; greater flexibility in funding for both transit and highways, based on local needs and preferences; and increased attention to compatibility between transportation and environmental protection. Booklets summarizing key overall provisions of ISTEA and summarizing its environmental features are enclosed.

The rapid and successful implementation of ISTEA is a top priority for President Bush and for each one of us. The additional funding available under the Act is an important resource both for the renovation of our transportation infrastructure and as a vital stimulus to our economy. The Department of Transportation has taken steps to assure that the ISTEA funds are immediately made available to state and local agencies so the money can be put to work creating jobs and helping to jump-start the economy.

But making the funds available is only half the job. They have to be put to use on actual construction projects. All three of our agencies are firmly committed to removing any unnecessary impediments to such projects. Recognizing the importance of environmental protection and the necessity to comply with legal requirements, we believe that we can help accomplish the President's objective by, among other measures, streamlining and improving the efficiency of the environmental review and clearance process and taking prompt action on Section 404 permit applications. This is consistent with the President's comprehensive plan announced on August 9, 1991, to improve the protection of the Nation's wetlands and streamline the regulatory process.

In 1988, the Federal Highway Administration (FHWA), Army Corps of Engineers (COE), Environmental Protection Agency (EPA), Fish and Wildlife Service, and National Marine Fisheries Service jointly published as guidance the document "Applying the Section 404 Permit Process to Federal-aid Highway Projects." Better known as the "Red Book," this document provides numerous measures to improve coordination, emphasize innovative and cost-effective approaches, and integrate the NEPA and section 404 permit processes. Effective immediately, it will be the official policy of FHWA, the Corps, and EPA to fully implement the intent of the "Red Book."

Where there are interagency issues or problems delaying issuance of Section 404 permits, we urge you to become personally involved in settling disputes, assuring due protection of aquatic resources, and getting the projects moving. Please pass this message, with your personal endorsement, to each member of your staff who is working on transportation projects and permitting.

Even as we seek expedited treatment of Section 404 permit applications, we do not expect to see reduced protection and aquatic resources, including wetlands. Costs of avoiding, minimizing and compensating for wetland impacts are an eligible expense under ISTEA for projects and should be included wherever appropriate.

If there are issues on important projects which cannot be promptly resolved at the state or regional levels, please involve appropriate headquarters contacts promptly. They will arrange for review at headquarters level and, if appropriate, on site meetings with all appropriate participants to facilitate a permit decision. Headquarters contacts on this are:

Gene Cleckly (FHWA) (202) 366–0106
Greg Peck (EPA) (202) 260–8794
Michael Davis (OASA(CW)) (703) 695–1376

We appreciate your cooperation and assistance on this important initiative.

Sincerely,

Andrew H. Card, Jr.,

Secretary, Department of Transportation.

William K. Reilly,

Administrator, Environmental Protection Agency.

Nancy P. Dorn,

Assistant Secretary of the Army (Civil Works).

Enclosure.

Implementation of the Intermodal Surface Transportation Efficiency Act

Protecting the Environment and Reducing Regulatory Inefficiencies

Several initiatives currently underway or proposed by the Department of the Army (DA) will improve and streamline the regulation of Federally-aided transportation projects under section 404 of the Clean Water Act. The DA recognizes the important role that the Intermodal Surface Transportation Efficiency Act (ISTEA) can play in the Nation's economic recovery. It is the belief of the DA that significant administrative improvements in program efficiency can be accomplished without diminishing protection of the Nation's valuable aquatic resources.

To help accomplish the objectives of ISTEA in an environmentally sensitive manner, the action items listed below should be undertaken by the DA and the Department of Transportation, as well as other applicable Federal and state agencies. These items are divided into two categories: Those that are specifically designed to improve the regulation of transportation projects; and those that are components of the President's August 9, 1991, wetlands plan that will also benefit transportation projects.

Action Items Designed Specifically To Improve the Regulation of Transportation Projects

1. Effective immediately, it will be the official policy of the Federal Highway Administration (FHWA), the Army Corps of Engineers (Corps) and the Environmental Protection Agency (EPA) to implement fully the intent of the "Red Book."

2. To the extent practical, the NEPA environmental impact statement alternatives analysis and the Clean Water Act Section 404(b)(1) Guidelines alternative analysis will be consolidated.

3. The Corps will issue guidance to its field offices providing that, because of the infrastructure needs of the country and the positive impact on the economy of infrastructure development, evaluation of transportation projects be given high priority.

4. During the analysis of practicable alternatives under NEPA and Section 404, the Corps and EPA will make every effort to provide FHWA and states information on the impacts of various alternative road alignments.

5. The Corps will establish, where appropriate, additional general permits for the repair or replacement of roads and other projects which have only minimal impacts on wetlands.

6. The Corps, FHWA, EPA and other Federal agencies will work to establish wetlands mitigation banks for Federal and state highway projects.

7. The Corps and EPA will coordinate with FHWA and state DOTs to provide additional wetlands delineation training opportunities. The FHWA and state DOTs will request training and subsequently assist the Corps in conducting wetlands jurisdictional determinations.

8. The DA/Corps, FHWA, and EPA will convene, as necessary, a headquarters level team to assist in resolving controversies over NEPA and Section 404 issues. Other agencies such as the President's Council on Environmental Quality, the Fish and Wildlife Service and the National Marine Fisheries Service will be invited to participate as appropriate.

9. The Corps, FHWA and EPA will form regional interagency teams to identify the principal causes of delay during environmental review of transportation projects. Consistent with applicable law and regulation, the teams will propose specific measures to reduce identified delays.

10. The Corps, EPA, and FHWA will evaluate the need for guidance that clarifies that alternatives that would result in significant delays in project initiation will not be considered "practicable."

Components of the President's Wetlands Plan That Will Benefit Transportation Projects

1. By mid-May 1992, the Corps will issue a regulatory guidance letter which clearly articulates the role of the Corps as "project manager" and decision maker on section 404 permits. The guidance letter will also emphasize the need for effective and efficient coordination among prospective permittees, the Corps and Federal resource agencies. The need for project-related comments from the resource agencies will be emphasized.

2. By early summer 1992, the Section 404(q) Memoranda of Agreement between the Army and the Federal resource agencies will be revised to significantly streamline the agency appeal process. This will directly reduce applicant delays associated with interagency disagreements.

3. The Corps and EPA will issue guidance to their field personnel to use flexibility in requiring alternatives analysis when resource values are low (e.g., don't require a detailed alternatives analysis for a project proposed in low value wetlands).

In addition to the 13 items mentioned above, the Corps will complete in Fiscal Year 1993 a 25 percent increase in regulatory personnel. This will result in reduced permit evaluation times for highway projects. Implementation of all of the items noted will significantly streamline the permit evaluation process by minimizing delays and ensuring more timely decisions, while allowing for meaningful opportunity for substantive evaluation by the Corps and other Federal agencies. These streamlining measures are designed to maximize efficiency and are not inconsistent with reasonable environmental protection.

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Part III

Department of Transportation

Federal Highway Administration
National Highway Traffic Safety Administration

23 CFR Parts 659 and 1260
Certification of Speed Limit Enforcement; Revision of Procedures; Proposed Rule

VOL 58 ISS 1 JA 4 1993 UMI

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

National Highway Traffic Safety Administration

23 CFR Parts 659 and 1260

[Docket No. 93–6]

RIN 2125–0027

Certification of Speed Limit Enforcement; Revision of Procedures

AGENCY: Federal Highway Administration (FHWA) and National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to replace the National Maximum Speed Limit procedures contained in 23 CFR part 659 with new procedures as required by section 1029 of Public Law 102–240, the "Intermodal Surface Transportation Efficiency Act of 1991." It proposes that the speed limit compliance formula, the speed monitoring plan, and the penalty for non-compliance be modified in accordance with the requirements of this new legislation.

DATES: Comments must be received on or before February 3, 1993.

ADDRESSES: Comments should refer to the docket number set forth above and be submitted (preferably in 10 copies) to Docket 92–x, HCC–10, Federal Highway Administration, room 4232, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are from 8:30 a.m. to 3:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: In FHWA, Henry Sandhusen, Office of Highway Safety, Traffic Control Division, 202–366–2218. In NHTSA, J. Michael Sheehan, Chief, Policy Traffic Services Division, 202–366–4295.

SUPPLEMENTARY INFORMATION:

Background

The 55 mph national maximum speed limit (NMSL) was first instituted in 1974 as a temporary conservation measure in response to the oil embargo imposed by certain oil-producing nations. Because of the reduction in traffic fatalities that accompanied the institution of the speed limit, it was made permanent in 1975. The States were required to post 55 mph as their maximum speed limit, and to certify annually that they were enforcing the 55 mph limit, as a prerequisite for approval of Federal-aid highway projects.

In 1978, Congress amended the law to require that, in addition to posting and enforcing the speed limit, the States would have to achieve specific levels of compliance by their motorists or risk a reduction of up to ten percent in certain Federal-aid highway construction apportionments. The compliance level, originally enacted as a series of steps up to a final level of 70 percent, was reduced by a 1982 amendment to a level of 50 percent. The State certifications of compliance were submitted along with supporting data collected by State operated speed monitoring programs. Pursuant to regulations published in 23 CFR part 659, FHWA and NHTSA have shared responsibility for the enforcement of the national maximum speed limit since 1980.

In April 1987, Congress passed legislation which allowed States to post 65 mph maximum speed limits on rural Interstate highways. In December 1987, the President approved legislation enacting a limited demonstration program, which allowed the posting of speed limits as high as 65 mph on certain rural non-Interstate highways through the end of FY 1991.

The Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) made the demonstration program permanent, and allowed other rural non-Interstate highways that were not a part of the demonstration program to be posted at the 65 mph speed limit, provided they met the criteria applicable to the highways in the demonstration program.

ISTEA also required the Secretary of Transportation to publish a rule to establish speed limit compliance requirements on 65 mph roads, in addition to 55 mph roads, and to include a formula for determining compliance by the States with such requirements. The statute requires that the formula assign greater weight for violations of the applicable speed limits in proportion to the amount by which the speed of the motor vehicle exceeds the speed limit. The formula must also differentiate among the types of road on which the violations occur. In developing this formula, the Secretary has been directed to consider factors relating to the enforcement efforts made by the States, data concerning fatalities and serious injuries occurring on roads posted at the national maximum speed limits (NMSL), and any other factors relating to speed limit enforcement and speed-related highway safety trends which the Secretary determines appropriate.

The ISTEA also requires the Secretary to consider—

(1) The variability of speedometer readings;

(2) The speeds of all vehicles or a representative sample of all vehicles;

(3) The number of speeding citations, travel speeds and the posted speed limit for NMSL highways; and,

(4) The design characteristics for the NMSL highways.

In addition, the ISTEA mandates that:

(1) The data shall be collected from uniform monitoring programs; and,

(2) The data shall be obtained from devices and equipment placed at locations on NMSL highways on a scientifically random basis which takes into account the relative risk of motor vehicle accidents occurring considering the classes of highways and the speeds being attained on such highways.

Proposed Changes

The proposed rule would retain the format of the current rule, but modify it to reflect the changes mandated by ISTEA in the compliance formula, an increase in sample size required for reliability and a change in the sanctions for noncompliance.

Discussion of Proposed Compliance Formula

Two methods to determine States' compliance with the national maximum speed limit were examined. The first is a method that would compare an individual State's compliance only to itself. Under this proposal, compliance would be determined by comparing a State's compliance "score" with a baseline score determined for the State based upon a suitable data collection period, rather than measuring the State s score against a single national performance standard. However, all States would determine their compliance score using the same formula.

The second alternative is the development of a national compliance score. The former NMSL criterion, established in 1982, provided that a State would have to certify that it met a national performance standard by having at least 50 percent of its motorists on 55 mph roads travelling at or below 55 mph. The adoption of a national compliance score would continue this concept of a national compliance standard while incorporating the elements of ISTEA into the proposed formula.

State-by-State Individual Score Alternative

This method would select the first fiscal year following publication of the final rule as the initial baseline year for data collection. Data would be collected

in the identical manner for the next two fiscal years. The data for the three years would then be averaged to obtain the baseline. This computation of three years of data would determine the final baseline score each State could not exceed to maintain compliance.

To remain in compliance during the second year, States would be allowed to exceed the first year score by not more than 10 percent to account for disasters, economic anomalies, statistical variability, weather conditions, and other unforeseen circumstances that may not be reflected in one year's data. In year three, States would be allowed to exceed the average of the actual reported score of the years one and two by not more than 10 percent.

However, in the computation of the final baseline score, a State would be required to use the actual scores from years one, two and three. The basic formula, which is also used in the single national compliance score, would compute the score as the sum of multiple components, one for each highway type in question (55 mph freeways, 65 mph freeways and 55 mph nonfreeways). Each of the three highway components consists of three parts, one for each certification level: percentage exceeding 60 mph, 65 mph and 70 mph on 55 mph posted highways, and percentage exceeding 70 mph, 75 mph and 80 mph on 65 mph posted highways; i.e., 5 mph over the posted speed limit, 10 mph over the posted speed limit and 15 mph over the posted speed limit. (The rationale for these levels is discussed at greater length in the following section.)

Additionally, the score would have a "floor" to assist those States who are currently well within compliance to remain in compliance, and a "ceiling" to give a State having a very high score some incentive to improve, not to just maintain its high score.

Although this method might achieve the purposes of ISTEA, it is extremely complex in computation as well as application. The data collection would require three years of data to determine the baseline score and each State would have an individual score which would vary widely from State to State. Further examination revealed that this method would not only be extremely complicated, but would be perceived to be unfair because of the wide diversity of scoring permitted among the States. The agencies have therefore tentatively rejected it in favor of a more uniform national performance standard. Comments are nonetheless invited as to any revisions that might make this method more acceptable.

National Compliance Formula

The second alternative compliance formula would establish a national compliance score against which each State would be measured. The proposed compliance formula would assign greater weight to higher speed violations and would account for fatality risk and crash severity. It would require States to monitor traffic speeds at incremental levels on each of the three different highway categories: Freeways posted at 55 mph, freeways posted at 65 mph, and non-freeways posted at 55 mph.

Federal law permits the posting of speed limits lower than 65 mph on certain rural highways. To account for this in the proposed compliance formula, the speed limits that are higher than 55 mph but lower than 65 mph would be reported as 65 mph NMSL roads for the purposes of speed monitoring, data collection and compliance computation. Since there are so few miles posted in this range, the Department has determined that having to report additional speed limits would impose an undue burden on the States. Such additional reporting would also overly complicate the compliance formula and the monitoring plan.

For compliance purposes, speeds would be measured at 5, 10 and 15 mph over the 55 mph and 65 mph speed limits. To provide for statistical reporting and computational adjustments, two additional increments, one at the posted speed and the other at 20 mph over the posted speed limit respectively, would also be collected and reported.

The rationale to begin measuring speeds at 5 miles over the posted speed limit is based on several customs and practices generally accepted by the law enforcement community and motorists. As a general practice, police agencies do not apply the strict letter of the law to enforcement of minor speed infractions in any speed limit zone. It is unusual for motorists to be stopped or even warned if their speed is within five miles of the posted speed limit. In rare instances when enforcement action is taken for minor infractions, traffic courts generally do not reinforce the action by imposing sanctions. In essence, traffic courts expect application of reasonable judgment by police when enforcing traffic laws.

In speed ranges of 5–9 miles per hour above the limit, enforcement action is more likely. Violations in this range may be processed with either a verbal or written warning, or by issuance of a citation. Generally, all violations exceeding 10 mph over the maximum speed limit call for enforcement action, usually with the issuance of a citation.

In recognition of those enforcement practices many drivers now realize the police and courts tolerate moderate excesses of the 55 and 65 mph speed limits before applying enforcement and sanctions. The resulting average traffic speeds have slowly increased to this perceived tolerance level.

The proposed weighting scheme would encourage law enforcement agencies to focus enforcement efforts on higher speed violations on all categories of highways. These efforts should assist in controlling speed variance, which affects safety, and future increases in average travel speeds.

In sum, three speed increments (5 mph, 10 mph and 15 mph over the speed limit) account for the practical factors associated with speed enforcement and ISTEA requirements including generally accepted practices of law enforcement and courts, effects of speed variance, and giving greater weights to higher speeds.

Under this proposal, compliance would be determined based on a comparison of a State's compliance "score" with a national compliance score. Each State would determine its compliance score using data collected in a manner consistent with the monitoring plan appended to the rule. All States would use the same formula to determine compliance.

The compliance formula computes the "score" as the sum of nine components. Each of the three highway categories (freeways posted at 55 mph, freeways posted at 65 mph, and nonfreeways posted at 55 mph) has three speed levels (percentage exceeding 60 mph, 65 mph, and 70 mph on 55 posted highways, or percentage exceeding 70 mph, 75 mph, and 80 mph on 65 mph posted highways; i.e., 5 mph over the posted speed limit, 10 miles over the posted speed limit and 15 mph over the posted speed limit).

In addition, each component is weighted by a constant comprised of two factors: The relative risk of fatality per 100 million vehicle miles traveled on each highway category and a measure of crash severity.

The total urban freeway fatality rate (0.89) is used as the base for computing relative risk. The relative fatality risk on rural Interstates is computed to be 1.28 which is the rural Interstate fatality rate divided by the total urban freeway fatality rate (1.14/0.89). Similarly, using the total (2.23) fatality rate for other 55 mph roads (both arterials and collectors) and calculating the ratio to total urban freeways (both Interstate and non-Interstate [0.89]) yields 2.52 (2.23/0.89).

Thus, the relative risk of a fatality while driving on a rural freeway posted at 65 mph is 1.28 times the risk while driving on an urban freeway posted at 55 mph.

Similarly, the relative risk of a fatality while driving on a 55 mph nonfreeway road is 2.52 times as great as when driving on a 55 mph urban freeway.

The fatality rates and relative fatality risk, as explained above, are:

TABLE 1.—FATALITY RATE AND RELATIVE FATALITY RISK BY HIGHWAY TYPE

Highway type	Fatality rate 1990 fatal accident reporting system (FARS)			Relative fatality risk
	Urban	Rural	Total	
Freeway Type	.....	.....	0.97	.....
Interstate	0.70	1.14	.....	1.28
Non-Interstate	1.28	.....	.....	.....
Total	0.89	.....	.....	1.00
Other 55 mph Roads	.....	.....	2.23	2.52
Arterials	1.62	2.52	.....	.....
Collectors	.....	3.24	.....	.....

Second, to account for crash severity, 1989–1991 National Accident Sampling Survey (NASS) files at NHTSA were examined to determine the relationship between the change in velocity during a crash (a standard measure of crash severity, usually referred to as "Delta V") and the posted speed limit. Table 2 present these data for average Delta V. Delta V is related to the square of the posted speed limit. The resultant curve has an r^2 of .81. The formula is:

Predicted Delta V=$0.00144x^2+10.62838$

where x=posted speed limit.

Predicted Delta V from the formula is also presented in the table.

TABLE 2.—AVERAGE AND PREDICTED DELTA V

(NASS data 1989, 1990, 1991)

Posted speed limit	Average Delta V	Predicted Delta V
25	11.9266	11.529
30	12.0421	11.925
35	12.3215	12.393
40	12.1859	12.933
45	13.8243	13.545
50	15.1972	14.230
55	13.3791	14.986
60	.....	15.814
65	17.3789	16.715
70	.....	17.687
75	.....	18.731
80	.....	19.848

Dividing the predicted Delta V for 5, 10 and 15 mph over the speed limit by the Delta V for a baseline speed limit (55 mph or 65 mph) yields the following table, representing the relative crash severity for vehicles exceeding the posted speed limit by 5 mph, 10 mph and 15 mph.

TABLE 3.—MULTIPLIERS WITH DELTA V

Speed limit	MPH over speed limit		
	5	10	15
55	1.055	1.115	1.180
65	1.058	1.121	1.187

The two factors (relative fatality risk and relative crash severity) are combined for use in the final formula. The first factor, freeways at 55 mph, is the baseline (1.00) freeways at 65 mph have a multiplier of 1.28 and 55 mph nonfreeways have a multiplier of 2.52.

Table 4 provides the resultant factors.

TABLE 4.—RESULTANT FACTORS

Hwy Categ	5 MPH over speed limit			10 MPH over speed limit			15 MPH over speed limit		
	Rel fatty risk	Rel Delta V	Comb'd factor	Rel fatty risk	Rel Delta V	Comb'd factor	Rel fatty risk	Rel Delta V	Comb'd factor
55 FRW	1.000	1.055	1.055	1.000	1.115	1.115	1.000	1.180	1.180
65 FRW	1.280	1.058	1.354	1.280	1.121	1.434	1.280	1.187	1.520
55 NFR	2.520	1.055	2.659	2.520	1.115	2.811	2.520	1.180	2.974

Inserting the resultant constants the following:

Compliance score =

1.055 X (percentage >60 on 55 mph freeways)
+ 1.115 X (percentage >65 on 55 mph freeways)
+ 1.180 X (percentage >70 on 55 mph freeways)
+ 1.354 X (percentage >70 on 65 mph freeways)
+ 1.434 X (percentage >75 on 65 mph freeways)
+ 1.520 X (percentage >80 on 65 mph freeways)
+ 2.659 X (percentage >60 on 55 mph nonfreeways)
+ 2.811 X (percentage >65 on 55 mph nonfreeways)
+ 2.974 X (percentage >70 on 55 mph nonfreeways).

The percentage of vehicles exceeding a speed is expressed in percentage form. For example, 48.5% is expressed in the formula as 48.5, non 0.485. The multipliers of each of the nine components are indicative of the relative risks of fatality and crash severity on the three highway categories at each of the three certification speed levels.

When compliance is computed based on more than a single highway category, there is a possibility of trade-off. That is, compliance can improve on certain roads and decline on others. The proposed formulation weighs more dangerous roads and higher speeds more heavily. Poor speed compliance on these roads will have a grater influence on a State's score.

Calculation of the National Compliance Scores

As part of the process for certifying compliance with the 55 mph NMSL, States are required to provide quarterly travel speed data to FHWA for all roads posted at 55 mph. Information currently provided by States as part of the

certification process includes median speed, average or mean speed, 85th percentile travel speed, and the vehicle miles traveled (VMT) for each type of road posted at 55 mph. Historically, traffic studies have concluded that travel speeds follow an approximately normal, bell-shaped curve. Using this assumption, highway engineers can estimate the travel speed distribution from the average or mean speed and the 85th percentile speed. For a normal distribution, one standard deviation away from the mean contains approximately 34 percent on one side of the distribution. With this information, it is possible to estimate the standard deviation as the difference between the average speed and the 85th percentile travel speed (this difference contains 35 percent of the distribution).

Using the FY 1990 data provided by the States, unweighted national average speeds and national standard deviations were calculated for each of three highway categories: 55 mph freeways, 65 mph freeways and 55 mph nonfreeways. That is, for each highway category, each State providing data was counted exactly once, without weighting the State observations for the number of registered vehicles, vehicle miles traveled, etc. Data for both 55 mph freeways and 55 mph nonfreeways were provided by forty-nine States (one State has only 55 mph freeways and another State has only 55 mph nonfreeways and 60 mph freeways); eighteen States provided information on 65 mph freeways.

From the average speed, the standard deviation and the statistical properties of the normal distribution, it was possible to develop a normal, bell-shaped distribution for each of the three highway types. Using these three derived national normal distributions and a table of areas under the standard normal distribution, the estimated percentages of vehicles exceeding the posted speed limits by 5 mph, 10 mph, and 15 mph were determined for each of the three highway categories.

The results were:

PERCENTAGE EXCEEDING THE POSTED SPEED LIMIT

NMSL road category	5 mph	10 mph	15 mph
55 mph freeways	43	19	5
65 mph freeways	19	5	1
55 mph nonfreeways	27	9	2

Thus, it is estimated that an average 43 percent of the vehicles exceeded 60 mph on 55 mph freeways, 19 percent exceeded 65 mph on 55 mph freeways, and 5 percent exceeded 70 mph on 55 mph freeways.

These estimates are proposed for use in determining the national performance standard for speed compliance. There are four categories of States:

(1) Those with all three highway types;

(2) Those with 55 mph freeways and 55 mph nonfreeways;

(3) Those with only 55 mph nonfreeways and 60 mph freeways.

(4) Those with only 55 mph freeways; and,

Substituting these percentages into the compliance formula yields the following maximum scores, one for each of the four categories of States. The scores have been rounded up to the next whole number.

Maximum Allowable Compliance Scores

States with all highway categories	210
States with 55 mph freeways and 55 mph nonfreeways	176
States with only 55 mph nonfreeways and 60 mph freeways	138
States with only 55 mph freeways	73

Since the compliance formula is the sum of either nine, six, or three percentages (depending upon the presence of specific highway categories in each State) it is not necessary to be below the percentage exceeding each individual speed increment, but rather to be in compliance with the overall score. Thus, a State may exceed one or more of these individual percentages and still remain below the maximum score (in compliance) by having a lower percentage exceeding other speed intervals on the available highway categories.

The national performance score was established without using any of the previously allowed adjustments to the reported data, which included speedometer error, statistical error and speed monitoring equipment error. However, when a State certifies compliance, the data may be adjusted to take into account potential error sources. The current rule at 23 CFR 659.15 governing compliance with the 55 mph NMSL specifies the following areas: speedometer variability, sampling variability, and equipment error. If three separate adjustments were used, they would be applied to each of the nine, six, or three individual percentages exceeding, for a total of 27 possible adjustments. Instead of applying a maximum of 27 adjustments, this rule proposes a single adjustment.

The proposal is to use only the single adjustment which represents the average percentage in two consecutive 5 mph intervals. Thus, the single adjustment requires far fewer calculations overall (only one calculation for each percentage exceeding rather than three calculations). In addition, for the FY 1991 compliance certification, 44 States used the single adjustment, while only six States elected to use the individual adjustments for speedometer variability, sampling error and equipment error.

For example, if 45 percent of the vehicles were observed to be exceeding 60 mph on a 55 mph freeway and 35 percent were observed to be exceeding 65 mph, the single adjustment takes the average of the two estimates, yielding an adjusted 40 percent of the vehicles exceeding 60 mph. The adjustments are applied to each individual estimate of the percent exceeding a speed increment BEFORE being substituted into the compliance formula to determine the overall score.

Plan for the Collection of Monitoring Data

The monitoring of speeds remains a requirement for the States, and the proposed rule would require the States to continue to monitor speeds on national maximum speed limit roads. Each State would continue to certify to the Secretary of Transportation before January 1 of each year that it is enforcing the national maximum speed limits on all public highways in accordance with the criteria set forth in this rule. The certification shall be supported by information on activities and results achieved during the 12-month period ending on September 30 preceding the January 1 date by which certification is required.

Starting in FY 1994, the States would be required to revise their data collection procedures to conform to the new requirements. If the data a State collects under the new procedures shows that it is not in compliance, the State will be subject to a transfer of funds penalty for non-compliance in accordance with the requirements of the new rule.

It is proposed that each State develop a speed monitoring plan in accordance with the Speed Monitoring Program Procedural Manual, which is found in the Appendix to this rule. The speed monitoring plan is intended to provide reliable data to be included in a State's annual certification of NMSL enforcement.

Monitoring stations will be randomly selected from road segments in three highway categories: 55 mph freeways, 65 mph freeways (including freeways with speed limits that are higher than 55 mph but lower than 65 mph), and 55

mph nonfreeways. The number of monitoring stations required in each State will be a function of the number of different highway categories in the State, the variability in the number of vehicles using each highway category, and the number of vehicles exceeding the speed limit in each of three different speed levels (for highways posted at 55 mph the percent exceeding 60 mph, 65 mph and 70 mph; for freeways posted at 65 mph the percent exceeding 70 mph, 75 mph and 80 mph). Four times a year, once in each quarter, monitoring will occur at each monitoring station for a continuous 24-hour period.

A count of all vehicles and the speed of all vehicles in each 24-hour monitoring period must be recorded at each monitoring station. The speed data from the monitoring sessions will be summarized by each State by highway category. A State will then use the data summarized by highway category to calculate its compliance score.

The details on sampling, site selection, data collection, data analysis, and data submission can be found in the Speed Monitoring Program Procedural Manual.

Since FY 1994 would be the first year for speed monitoring, it would be advantageous to the States to initiate the selection and implementation of monitoring sites as soon as possible to ensure that data collection can commence on October 1, 1993. The FHWA division offices will work with the States in developing their monitoring plans, selecting sites, and approving deviations from the recommended procedures set forth in this NPRM.

Sanctions for Noncompliance

Statutory moratoria on sanctions against a State for non-compliance with the requirements of 23 CFR part 659 have been in effect since fiscal year FY 1986. There was no direction given in ISTEA regarding a moratorium beyond FY 1991. However, Congress required the Secretary of Transportation to develop a rule which makes it unnecessary to sanction for non-compliance until the rule becomes effective. Therefore, the effect of the proposed rule would be to continue the moratorium on sanctions for FY 1992 and FY 1993.

Section 1029(c)(1)(A) of ISTEA provides "* * * for the transfer of apportionments under section 104(b) of title 23, United States Code (other than paragraph (5)), if a State fails to enforce speed limits in accordance with this section, [and the rulemaking authorized by section 1029]." However, the legislation does not specify the amount of the apportionments to be transferred or designate the program area to which the apportionments would be transferred. The House bill had stated that the amount to be transferred would range from one to five percent of the designated apportionments for the first year of non-compliance and from two to ten percent for two or more consecutive years of non-compliance. The amounts were to be transferred to the highway safety grant programs of section 402 of title 23. The Senate bill did not provide for a transfer of apportionments.

In reviewing the ranges of the House bill for the purpose of proposing a reasonable amount to be utilized by a non-complying State, the Department determined that one and one-half percent of the designated apportionment for each State approximated the total amount of its 402 program. This amount was selected as the appropriate penalty because it represents a significant penalty and encourages the States to stay in compliance. A lesser amount may not have that effect. A greater amount, exceeding the total section 402 apportionments, would overburden a State's highway safety planning process and ability to expend the funds as intended.

In adopting the House's transfer penalty without the House language pertaining to amounts, the conferees included the following statement on page 328 of the report accompanying the conference bill:

The Conference Substitute applies that same reprogramming provision and Secretarial discretion with regard to the percentage transferred as in the House bill.

Consistent with this guidance, the agency proposes the following sanction provisions for a State having a compliance score exceeding the national compliance score:

1. One and one-half percent of the funds apportioned to the State for Federal-aid highways and highway safety construction programs under section 104(b) of title 23, United States Code (other than paragraph (5)) would be transferred to the State's apportionment under 23 U.S.C. 402 for the fiscal year, not to exceed the total section 402 apportionment for that year.

2. The funds reapportioned to section 402 Highway Safety Grant Programs would be used for section 402 highway safety programs with an emphasis on speed enforcement.

Credits in Mitigation of Noncompliance

Section 1029(c)(2) of ISTEA included the following statement:

In developing the compliance formula * * * the Secretary shall consider factors relating to the enforcement efforts made by the States and data concerning fatalities and serious injuries occurring on (NMSL) roads * * * and any other factors relating to speed limit enforcement and speed-related highway safety trends which the Secretary determines appropriate.

The Department examined a number of factors to recognize State efforts to reduce speed related crashes and to weigh highway safety trends. Considerations were based upon the relationship to speed enforcement and whether or not the specific item could be quantified and measured. The only factor considered to be appropriate for the proposed rule is whether a State has a fatality rate below the national average.

The primary goal of highway safety is to reduce the number of deaths and injuries occurring on our nation's highways. The Department has historically used the national fatality rate to gauge the success of highway safety programs. The fatality rate is an indicator of the success of a State's overall highway safety program, and thus reflects a number of specific safety efforts within a State. In order to provide for meaningful consideration of a State's fatality rate in accordance with the statutory requirement, the rule proposes a penalty reduction for States that exceed the national compliance score but have a low fatality rate. As discussed below, a State fatality rate, rounded to the nearest tenth, of at least twenty percent below the national fatality rate would result in a reduction in the amount of the apportionment being transferred.

A number of other specific factors, listed below, were considered and rejected for inclusion in the proposed rule. In each instance, there was no way to quantify the results of a specific activity or the particular factor was covered by other sections of the ISTEA. Those factors were:

- Public information and education campaigns that are speed enforcement related;
- Use of innovative technology such as photo-radar, laser speed measuring devices, drone radar, electronic speed display and signing, variable speed limits;
- Increased use of physical speed control techniques, such as speed bumps, and rumble strips; and psycho-perceptual techniques such as pavement markings;
- Point systems for speed limit violations, with higher speeds receiving more points that lead to the suspension or revocation of a driver's license;
- Increases in the number of speeding citations issued on NMSL highways;

- Presence of a Statewide front seat safety belt use law;
- 75 percent safety belt usage rate;
- Presence of 0.08 BAC law, and,
- Presence of an administrative per se law.

Penalty Reduction

A State in noncompliance would be eligible to have its penalty reduced by one-third if it has a fatality rate at least twenty percent below the national fatality rate. This rate is determined using fatality data contained in NHTSA's Fatal Accident Reporting System Annual Report and vehicle miles of travel data reported in FHWA's Annual Highway Statistics publication. The State's fatality rate would be based on data for the calendar year preceding the fiscal year of noncompliance. The previous calendar year fatality rate is used because the State vehicle miles of travel data are not available prior to the fiscal year in which the transfer of funds occurs.

A State having a fatality rate at least twenty percent below the national fatality rate demonstrates the benefit of a balanced highway safety program. The Department has selected this level of fatality reduction as a fair and reasonable measure of traffic safety efforts. Since the ultimate purpose of all highway safety programs, including speed enforcement, is to reduce traffic fatalities, injuries and crashes, a level of twenty percent below the national fatality rate provides meaningful evidence of such efforts. Further, this measure is consistent with the objectives of ISTEA.

The Department is proposing a penalty reduction of one-third to recognize overall highway safety accomplishments which resulted in reducing fatalities. Even with a reduction of one-third, the funds transfer remains a significant penalty. The purpose of the transfer is to aid a State to return to compliance by increasing the overall level of traffic safety programs. Any reduction of the penalty shall be applied in the fiscal year in which the transfer penalty is assessed.

Although the Department believes that the proposed penalty reduction level of one-third and the proposed fatality rate level of twenty percent below the national rate are fair and reasonable levels, comments are nonetheless invited regarding whether these percentages should be increased or reduced.

Notification of Noncompliance

Under the current regulation, the States are afforded the opportunity to request a meeting to discuss compliance status and the amount and timing of any reduction of apportionments. They are allowed to request a hardship deferral and/or request a reduction in the amount of reduction of apportionments. However, these procedures are unnecessary under the proposed rule.

The specific amount of the apportionments that must be transferred is set forth in the rule and therefore no procedure is necessary to challenge the results of compliance. The legislation does not provide for hardship considerations. There is no loss of funds, only a transfer from highway construction to highway safety programs.

Regulatory Analyses and Notices

Civil Justice Reform

This proposed rule would not have any preemptive or retroactive effect. It imposes no requirements on the States, but rather encourages States to consider enacting and enforcing legislation requiring speed limits and speed limit enforcement through the potential redesignation of Federal highway construction funds to safety programs. Any redesignation of funds would not take place until FY 1996. If a State (1) submits data showing that its highway speeds are below a certain national level, and (2) submits a certification from the Governor reporting that the State is enforcing the speed limits on public highways in accordance with 23 U.S.C. 154, then it shall not be subject to a redesignation of funds. The authorizing legislation for the proposed rule does not establish a procedure for judicial review of final rules promulgated under its provisions. There is no requirement that individuals submit a petition for reconsideration or other administrative proceedings before they may file suit in court.

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The agencies have analyzed the effect of this proposed action and determined that it is not "major" within the meaning of Executive Order 12291. However, because of the public's interest in the 55/65 MPH speed limit, it is considered to be "significant" within the meaning of Department of Transportation regulatory policies and procedures. The agencies have prepared a Preliminary Regulatory Evaluation (PRE) for this proposal, and made it available in the public docket. A copy of the PRE may be obtained by writing to the pubic docket at the address referenced above.

The PRE discusses the benefits of limiting excessive speed in general and estimates the costs of new speed monitoring devices to be $4.4 million. The PRE also presents estimated FY 1990 speed compliance data and finds that at least three States (Connecticut, Massachusetts and Wyoming) would have likely been out of compliance with the proposed maximum allowable compliance scores had they been in effect in FY 1990.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act, the agencies have evaluated the effects of this proposed action on small entities. Based on the evaluation, we certify that this action will not have a significant economic impact on a substantial number of small entities. The PRE concluded that there would be no significant impact on small businesses since the portion of the highway construction funds going to noncompliant States would not be lost, but only transferred to highway safety programs. Accordingly, the preparation of Regulatory Flexibility Analysis is unnecessary.

Paperwork Reduction Act

The requirement relating to this proposal, that each State must submit speed data and related certification information necessary to calculate its compliance score, is considered to be an information collection requirement, as that term is defined by the Office of Management and Budget (OMB) in 5 CFR part 1320. Accordingly, this information collection requirement has been previously submitted to and approved by OMB, pursuant to the provisions of the Paperwork Reduction Act (44 U.S.C. 3501, et seq.). The former requirement has been approved through March 31, 1993, and has been assigned control number OMB No. 2125–0027. A request for a revised information collection requirement under the proposed rule has been submitted to OMB for approval subject to the publication of a final rule.

This information collection requirement is specified in the Speed Monitoring Program Procedural Manual located in the appendix. The burden hours for quarterly data collection and annual certification is estimated at 93,024 hours for the respondent State Highway Departments on an annual basis. The average response time for this information collection is 364.8 hours. The FHWA will use this information to judge the effectiveness of each State's enforcement program.

The monitoring plan proposed is designed so the States collect the

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minimum amount of speed data to reliably measure compliance. The Department believes that the proposed information collection requirement, specifically the number of monitoring sites and the quarterly monitoring sessions, are the minimum needed to ensure statistically reliable estimates of annual compliance.

However, comments are invited regarding whether the amount of data collection could be reduced through statistical means. That is, could fewer than four quarterly observations be conducted and still ensure the availability of reliable unbiased estimates of annual speed limit compliance? Could this be achieved through the use of conducting observations during key time periods during the year which result in minimal information loss? Is it possible to identify particular times during the year which are indicative of annual travel speed trends? Can statistical models be developed that use the information collected during these key time periods to estimate annual travel speeds and hence, compliance, based on a reduced data collection effort?

The Department requests specific details on these methods and an indication of specific times during the year when such predictive information could be collected. For example, existing surveys of energy use patterns and agricultural commodities employ model-based methods of data collection and estimation that rely on measurements conducted during key periods of the year. The data collected during these key time periods are modeled to derive annual estimates without having to conduct surveys monthly or quarterly. These statistical models are based on relationships between the annual estimates and data collected during key time periods.

For further information one may contact the Information Requirements Division, M–34, Office of the Secretary of Transportation, 400 Seventh Street, SW., Washington, DC 20590, 202–266–4735. Comments on the proposed information collection requirements should be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, to the attention of the Desk Officer for the FHWA. It is requested that comments sent to OMB also be sent to the FHWA Docket for this proposed rule.

National Environmental Policy Act

The agencies have analyzed this proposed action for the purpose of compliance with the National Environmental Policy Act and have determined that it will not have a significant effect on the human environment.

Executive Order 12612 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. Since the Congress has directed the Secretary of Transportation to establish a rule for monitoring and promoting compliance with the National Maximum Speed Limits described in 23 U.S.C. 154, the federalism implications pursuant to Executive Order 12612 are minimal. Moreover, the proposed rule does not impose any requirements on the States, but rather encourages States to consider enacting and enforcing legislation requiring speed limits and speed limit enforcement through a potential redesignation of the purpose of certain Federal-aid highway funds. Under these circumstances, the preparation of Federalism Assessment is not warranted.

Comments to the Docket

The agencies are providing a 30-day comment period for interested parties to present data, views, and arguments on the proposed action. The agencies invite comments on the issues raised in this notice and any other issues commenters believe are relevant to this action. All comments must not exceed 15 pages in length (49 CFR 553.21). This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion. Necessary attachments may be appended to these submissions without regard to the 15-page limit.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule, if one is issued, will be considered as suggestions for further rulemaking action. The agencies will continue to file relevant information in the docket as it becomes available after the closing date and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified of receipt of their comments by the docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receipt of the comments, the docket supervisor will return the postcard by mail.

List of Subjects

23 CFR Part 659

Grant programs—transportation, Highway and roads, Motor vehicles, Reporting and recordkeeping requirements, Traffic regulations.

23 CFR Part 1260

Grant programs—transportation, Highway and roads, Motor vehicles, Reporting and recordkeeping requirements, Speed limit, Traffic regulations.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program).

In consideration of the foregoing, the FHWA and NHTSA hereby propose to remove part 659 of chapter I, subchapter G of title 23, Code of Federal Regulations (CFR), and to add part 1260 to chapter II, subchapter C of title 23, CFR, as set forth below.

Issued on: December 18, 1992.

Thomas D. Larson,

Administrator, Federal Highway Administration.

Marion C. Blakey,

Administrator, National Highway Traffic Safety Administration.

PART 1260—CERTIFICATION OF SPEED LIMIT ENFORCEMENT

Sec.

1260.1 Purpose.
1260.3 Objective.
1260.5 Definitions.
1260.7 Adoption of national maximum speed limits.
1260.9 Formulation of a plan for monitoring speeds.
1260.11 Guidelines and evaluations of operations.
1260.13 Certification requirement.
1260.15 Certification content.
1260.17 Certification and statistical submittal.
1260.19 Effect of failure to certify or to meet compliance standards.
1260.21 Penalty reduction and notification of noncompliance.
Appendix to Part 1260—Speed Monitoring Program Procedural Manual

Authority: 23 U.S.C. 118, 141, 154, 315 and delegations of authority at 49 CFR 1.48 and 1.50.

§ 1260.1 Purpose.

To prescribe requirements for administering a program for monitoring speeds on public highways in order to provide reliable data to be included in a State's annual certification of speed limit enforcement.

§ 1260.3 Objectives.

To establish a valid statistical method of measuring a sample of vehicle speeds on a sample of highways to estimate the percentage of vehicles exceeding the speed limit on highways posted at 55 mph and on highways posted at 65 mph with sufficient accuracy to support a determination of compliance by a State's motoring public with the National Maximum Speed Limits in accordance with 23 U.S.C. 154; to prescribe the compliance reporting requirements for the States; and to specify fund transfer provisions for non-compliance with the National Maximum Speed Limits.

§ 1260.5 Definitions.

As used in this part:

(a) *FHWA* means the Federal Highway Administration.

(b) *Fiscal year* means the Federal fiscal year, consisting of twelve months beginning each October 1 and ending the following September 30.

(c) *Governor* means the Governor of any of the fifty States, Puerto Rico or the Mayor of the District of Columbia.

(d) *Freeway* means a divided arterial highway for through traffic with full control of access and grade separated intersections.

(e) *Highway* means all streets, roads or parkways under the jurisdiction of a State, including its political subdivisions, open for use by the general public, and including toll facilities.

(f) *Interstate System* means the Interstate System as is described in 23 U.S.C. 103(e).

(g) *Motor vehicle* means any vehicle driven or drawn by mechanical power manufactured primarily for use on public highways, except any vehicle operated exclusively on a rail or rails.

(h) *National Maximum Speed Limits* mean the speed limits provided for the highways described in § 1260.7 of this part.

(i) *NHTSA* means the National Highway Traffic Safety Administration.

(j) *Roadway Segment* means a highway performance monitoring system (HPMS) sample section as defined by the States.

(k) *State* means any one of the 50 States, the District of Columbia, or Puerto Rico.

§ 1260.7 Adoption of national maximum speed limits.

The Secretary of Transportation shall not approve any Federal-aid projects under 23 U.S.C. 106 in a State which fails to adopt or maintain maximum speed limits as follows:

(a) The maximum speed limit shall be 65 mph or less on a highway located outside of an urbanized area of 50,000 population or more, either on the Interstate System, or on a highway:

(1) Which is constructed to Interstate standards in accordance with 23 U.S.C. 109(b) and connected to a highway on the Interstate System;

(2) Which is a divided 4-lane fully controlled access highway designed or constructed to connect to a highway on the Interstate System posted at 65 miles per hour and constructed to design and construction standards as determined by the Secretary which provide a facility adequate for a speed limit of 65 miles per hour; or

(3) Which is constructed to the geometric and construction standards adequate for current and probable future traffic demands and for the needs of the locality and is designated by the Secretary as part of the Interstate System in accordance with 23 U.S.C. 139(c).

The maximum speed limit on all other public highways in the State shall be 55 mph or less. Emergency and police motor vehicles may be authorized to operate at higher speeds when necessary to protect the public health and safety.

(b) Except as provided in paragraphs (c) and (d) of this section, the speed limit on any portion of a highway shall be uniformly applicable to all types of motor vehicles using such portion of highway, if on November 1, 1973, such portion of highway had a speed limit which was uniformly applicable to all types of vehicles using it.

(c) Notwithstanding the provisions of paragraph (b) of this section, a State may establish a lower speed limit for a motor vehicle operating under a special permit because of weight or dimension of such vehicle, including any load thereon.

(d) Notwithstanding the provisions of paragraph (b) of this section, a State may specify nonuniform speed limits on any portion of a highway when the condition of the highway, weather, a crash, or other condition creates a temporary hazard to the safety of traffic on such portion of a highway.

§ 1260.9 Formulation of a plan for monitoring speeds.

(a) Each State shall develop a speed sampling plan following the guidelines in the Speed Monitoring Program Procedural Manual (SMPPM), FHWA, 1992, which is set forth in the appendix.

(b) At a minimum, the plan shall discuss the following subjects:

(1) Miles of highway posted at the National Maximum Speed Limit (NMSL) classified as follows:

(i) Miles of freeways posted at 55 mph

(ii) Miles of freeways posted at 65 mph (including freeways with posted speed limits that are higher than 55 mph but lower than 65 mph)

(iii) Miles of nonfreeways posted at 55 mph

(2) Number of sampling locations and their distribution by highway classification (55 mph freeways, 65 mph freeways and 55 mph nonfreeways), all of which shall be determined in accordance with the SMPPM. The minimum sample size needed by each State for each highway classification shall be determined in accordance with the SMPPM.

(3) Location of monitoring stations. The discussion of the location or the monitoring sites must include information on the functional classification of the highway where the monitoring station is located.

(4) Type and capabilities of speed measuring equipment to be used.

(5) Data collection. (i) Schedule. Speed monitoring sessions shall be scheduled evenly among the three-month periods of the year ending December 31, March 31, June 30, and September 30. Each monitoring station must be monitored once per three-month period. The dates that monitoring is planned must be included in the schedule.

(ii) Field data collection. The choice of a data collection site within a given segment shall reflect the geometric design conditions of the segment. In addition, data will not be acceptable in determining compliance, if conditions at a site are such that the normal flow of traffic is substantially restricted by activities such as highway construction, maintenance operations, extreme weather conditions, temporary lane closings, or the presence of non-routine enforcement activity.

(iii) A 24-hour monitoring period shall be the duration of any individual speed monitoring session.

(6) Any deviation from the analysis methods described in the SMPPM.

§ 1260.11 Guidelines and evaluations of operations.

(a) The State shall submit its initial speed monitoring plan to the FHWA Division Administrator within 90 days after publication of the Final Rule. The plan shall be in accordance with the provisions of the SMPPM. The plan shall be evaluated annually and revised as conditions dictate. The plan may also be revised at any time during the 12-month data collection period ending September 30 if the State elects to change its speed limit on eligible roads.

(b) Annual evaluations of the State's speed monitoring plan shall be submitted to the FHWA Division Administrator by December 1 following

the close of the data collection period of each year beginning with December 1, 1993, so that changes to the plan called for by the evaluation can go into effect with the subsequent quarter beginning January 1. At a minimum, the evaluation shall discuss:

(1) Adjustments to the number of sampling locations in a State.

(2) Any other changes to the plan proposed by the State.

(c) Plan revisions called for during the data collection period due to a State changing its speed limit shall also be submitted to the FHWA Division Administrator for approval, and may take effect retroactively to the date on which the speed limit was changed if such approval is granted.

§ 1260.13 Certification requirement.

Each State shall certify to the Secretary of Transportation before January 1 of each year that it is enforcing the National Maximum Speed Limit on all public highways in accordance with 23 U.S.C. 154. The certification shall be supported by information on activities and results achieved during the 12-month period ending on September 30 preceding the January 1 date by which certification is required.

§ 1260.15 Certification content.

The certification shall consist of the following elements:

(a)(1) A statement by the Governor of the State, or an official designated by the Governor, that the National Maximum Speed Limits on public highways in the State are being enforced. The certifying statement shall be worded as follows:

(Name of the certifying official), (position title), of the (State or Commonwealth) of _____, do hereby certify that the (State or Commonwealth) of _____, is enforcing the National Maximum Speed Limits.

(2) If this statement is made by an official other than the Governor, a copy of the document designating the official, signed by the Governor, shall also be included in the certification made under this part.

(b) A copy of any State law, regulation, administrative order, statement of policy or any other written instruction relating to enforcement of the National Maximum Speed Limits shall be included with the initial certification required by this rule. If there has been no change in the applicable State law, regulation, administrative order, policy statement or written instruction concerning National Maximum Speed Limit enforcement, then a State may include a statement to that effect with the annual certification. If a change has occurred then a State need only submit a copy of the changed document with subsequent annual certifications. If a written enforcement policy on the National Maximum Speed Limits does not exist, a statement to that effect must also be included.

(c) Information relating to enforcement and monitoring as follows:

(1) Miles of highway with a 55 mph or 65 mph speed limit, by the following highway categories:

(i) Freeways posted at 55 mph;

(ii) Freeways posted at 65 mph (including freeways posted higher than 55 mph but lower than 65 mph); and

(iii) Nonfreeways posted at 55 mph.

(2) The number of speeding citations issued by all law enforcement agencies in the State with jurisdiction and responsibility to enforce speed limit violations on national maximum speed limit roads for violation of the 55 mph speed limit and 65 mph speed limit during each month of the 12-month period ending on September 30 before the date by which certification is required.

(3) Number of monitoring locations and monitoring sessions.

(4) Number of vehicles observed during monitoring sessions.

(5) Distribution of vehicles speed by each highway category listed in (c)(1).

(6) For freeways and nonfreeways posted at 55 mph. The percentage of vehicles exceeding each of the following speeds: 55, 60, 65, 70 and 75 mph.

(7) For freeways posted at 65 mph. The percentage of vehicles exceeding each of the following speeds: 65, 70, 75, 80 and 85 mph.

(8) The data must be reported as required in the SMPPM.

(d) The State's compliance score is determined by summing the product of relative fatality and a measure of crash severity, as derived from the 1989–1991 National Accident Sampling System data and 1990 Fatal Accident Reporting System data, and the percentage of vehicles exceeding 5 mph, 10 mph and 15 mph over the speed limit for each of the three highway categories. The compliance score formula is:

Compliance score =
- 1.055 X (percentage >60 on 55 mph freeways)
- + 1.155 X (percentage >65 on 55 mph freeways)
- + 1.180 X (percentage >70 on 55 mph freeways)
- + 1.354 X (percentage >70 on 65 mph freeways)
- + 1.434 X (percentage >75 on 65 mph freeways)
- + 1.520 X (percentage >80 on 65 mph freeways)
- + 2.659 X (percentage >60 on 55 mph nonfreeways)
- + 2.811 X (percentage >65 on 55 mph nonfreeways)
- + 2.974 X (percentage >70 on 55 mph nonfreeways)

The statewide percentage of vehicles exceeding 60, 65 and 70 mph on all 55 mph highways, and 70, 75 and 80 mph on all 65 mph highways, is derived from the speed sampling plan specified in § 1260.9, and adjusted using a single adjustment procedure to take into account potential error sources. The single adjustment formula is:

$$H = \frac{(A+B)}{2}$$

where:

H = The percent exceeding x mph after adjustment

A = the percent of vehicles exceeding x mph, and

B = the percent of vehicles exceeding x+5 mph

The adjusted percentages are then inserted into the compliance formula and the State's compliance score is calculated. The maximum allowable compliance scores are:

States with all highway categories	210
States with 55 mph freeways and 55 nonfreeways	176
States with only 55 mph nonfreeways and 60 mph freeways	138
States with only 55 mph freeways	73

The State must submit its compliance score in its annual certification statement.

§ 1260.17 Certification and statistical submittal.

(a) The Governor, or an official designated by the Governor, each year shall submit the certification to the FHWA Division Administrator. The FHWA Division Administrator shall retain the original and forward two copies each to the Regional Administrators of FHWA and NHTSA. The Regional Administrators shall each retain one copy and forward one copy of the submission, with any pertinent comments, to their respective Washington, DC headquarters, to the attention of the Chief Counsel.

(b) Any changes to the original certification or supplemental information necessitated by the review of the certifications as they are forwarded shall be submitted in the same manner as the original submission.

(c) The State is required to submit the information relating to enforcement, monitoring, and the compliance score as described in § 1260.15 (c) and (d).

(d) The data required for the annual certification under § 1260.15(c), with

the exception of the speeding citation data required under § 1260.15(c)(2), shall be submitted by each State to the FHWA Division Administrator on a quarterly basis for the 3-month periods ending December 31, March 31, June 30 and September 30 of each year. The submission of the July-September quarter shall, in addition to the quarterly report, include a summary report of the entire year's speed monitoring data (starting from the previous October 1).

§ 1260.19 Effect of failure to certify or to meet compliance standards.

(a) If a State fails to certify as required by § 1260.13, no Federal-aid highway project shall be approved under 23 U.S.C. 106 in that State.

(b) Notwithstanding the proper submission of the certification and information supporting the speed monitoring activities of any State, if the Secretary determines that a State's compliance score calculated pursuant to § 1260.15(d) is greater than the maximum allowable compliance score as provided in § 1260.15(d), one and one-half percent of the funds apportioned to that State under 23 U.S.C. 104(b)(1), 104(b)(2), 104(b)(3), 104(b)(4) and 104(b)(6) shall be transferred to such State's highway safety grant program fund under 23 U.S.C. 402 for the fiscal year subsequent to the fiscal year in which the compliance score is calculated to be greater than the maximum allowable compliance score.

§ 1260.21 Penalty reduction and notification of noncompliance.

(a) If the Administrators determine that a noncompliant State's fatality rate, rounded to the nearest tenth, is at least twenty percent below the national fatality rate, the Secretary shall reduce the amount of the apportionment transferred under § 1260.19 by one-third. The fatality rate is determined using fatality data contained in NHTSA's Fatal Accident Reporting System Annual Report and vehicle-miles of travel data reported in FHWA's Annual Highway Statistics publication. The State's fatality rate will be based on data for the calendar year preceding the fiscal year in which its compliance score is greater than the maximum allowable compliance score.

(b) On the basis of the information provided by the State and other information in the possession of the Department, the Secretary will notify the Governor of the State of the transfer of apportionments and direct the transfer of said apportionments. A copy of that notification will be transmitted promptly to the State by certified mail.

(c) The State shall expend any transferred funds pursuant to § 1260.19(b) for section 402 programs with an emphasis on speed enforcement programs within that State. In no instance shall such transfer exceed the total section 402 apportionment for that fiscal year, prior to any penalty reduction.

Appendix to Part 1260—Speed Monitoring Program Procedural Manual

Purpose

The speed monitoring program is intended to provide reliable data to be included in a State's annual certification of NMSL enforcement.

Development and Documentation of Sampling Plan

Following the requirements in the proposed rule, each State shall develop a Speed Sampling and Analysis Plan for approval by the FHWA Division Administrator. The plan shall be reviewed annually, and updated if there are changes in the number or location of monitoring stations, or in the dates that data collection is planned. At a minimum, the plan shall include:

- Grouping of highways by three highway categories:

—Freeways posted at 55 mph;
—Freeways posted at 65 mph (including freeways posted higher than 55 mph but lower than 65 mph); and,
—Nonfreeways posted at 55 mph.

- Number of miles of highway with a 55 or 65 mph speed limit, by above categories.
- Number of monitoring stations, sessions, location, and the direction that monitoring takes place (Northbound, Westbound, etc.).
- Any request for an exemption if a State proposes to limit the number of monitoring stations to a number no less than 30 percent higher than the maximum number of monitoring stations under the previous program. This request should include a justification as well as demonstrable assurances that the data integrity is being preserved.
- Type and capabilities of speed measuring equipment used.
- Functional classification of selected monitoring sites.
- Dates of planned data collection for each monitoring station.
- Any deviation from analysis methods recommended in this document.

Sampling Plan Prerequisites

The three types of data that must be assembled before a sampling plan can be developed are:

1. Miles of highway, by highway category, with a 55 or 65 mph speed limit.
2. Location of Highway Performance Monitoring System (HPMS) sample sections.
3. Location of monitoring stations under old program.

Miles of Highway, by Highway Category, With a 55 mph or 65 mph Speed Limit

Miles of highway, by highway category, with a 55 or 65 mph speed limit will be used in the random selection of monitoring stations.

Highways will be grouped into the following categories:

—Freeways posted at 55 mph;
—Freeways posted at 65 mph (including freeways posted speed limits that are higher than 55 mph but lower than 65 mph); and,
—Nonfreeways posted at 55 mph.

The monitoring category "nonfreeways posted at 55 mph" will NOT include any facilities classified as "local," any unpaved roads, and any rural minor collectors.

Location of HPMS Sample Sections

The location of the HPMS sample sections will assist in the selection of monitoring stations. HPMS sections average five miles in length. Monitoring stations will be randomly selected from among the HPMS sample sections where the entire section is posted at 55 or 65 mph.

Location of Monitoring Stations Under the Old Program

The location of existing monitoring stations must be known. Since the old monitoring stations were selected randomly, many of those stations can be retained, under the procedures discussed in the section "Selection of Sample Sites".

Sampling Guidelines

This is a sampling plan designed to monitor the speeds vehicles travel on highways posting with a 55 mph or 65 mph speed limit. Monitoring stations will be randomly selected from road segments in three highway categories:

—Freeways posted at 55 mph;
—Freeways posted at 65 mph (including freeways posted speed limits that are higher than 55 mph but lower than 65 mph); and,
—Nonfreeways posted at 55 mph.

The State shall be responsible for selecting the sites to be monitored in accordance with the procedures in this section. The following issues are addressed:

- Determination of sample sizes;
- Selection of sample sites;
- Number of sampling sessions and length of monitoring period.

Determination of Sample Sizes

The number of monitoring stations required in each State is a function of the number of different highway categories, the variability in the number of vehicles using each highway category, and the number of vehicles exceeding the speed limit in each of the three different levels (exceeding 60, 65, 70 etc). Data from past speed surveys indicate that speeds vary much more on 55 mph nonfreeways than on 55 or 65 mph freeways. In addition, most States have much more 55 mph nonfreeway mileage than 55 or 65 mph freeway mileage. Thus, most States will have more monitoring stations on nonfreeways than on freeways.

Three tables have been developed to assist the States in determining sample sizes. The tables were derived using speed data from previous surveys. Estimates of sampling errors were calculated for the 55 mph freeway and 55 mph nonfreeway monitoring categories. Since no data were available for 65 mph freeways, the assumption was made that the variability of speeds on this highway category were similar to the variability of speeds on the 55 mph freeways. An estimate of overall variance and percent of vehicles exceeding 55 mph were calculated using weighted averaging across the States examined. For the 55 mph freeways, the percent of vehicles exceeding 55 mph averaged 70.9 percent with an estimated population standard deviation of 21 percent. For the 55 mph nonfreeways, the percent of vehicles exceeding 55 mph averaged 51.8 percent with an estimated population standard deviation of 40 percent.

Using these figures the sample size tables were created. The tables show sample sizes for each highway category as a function of the required precision and the number of road segments in each category. The sample sizes given in each table at the 7.5 percent level of precision are the minimum necessary in each category to meet the precision requirement of these guidelines. Table 1 should be used to determine the number of monitoring stations for freeways with 55 mph speed limits. For example, in a State with 120 freeway road segments at 55 mph, seven monitoring stations would be required.

TABLE 1.—FREEWAYS WITH 55 MPH SPEED LIMIT

Number of road segments	Number of highway segments to be sampled*
1	1
2–3	2
4–6	3
7–10	4
11–18	5
19–36	6
37–141	7
142 or more	8

*Sample sizes are based on one standard error of 7.5 percent and the percentage of vehicles exceeding 55 equal to 70.9 percent.

Similarly, Table 2 should be used for determining the number of monitoring stations for 65 mph freeways and Table 3 for 55 mph nonfreeways. Continuing the example, if this State had 60 segments of 65 mph freeways then a sample of seven monitoring stations would be required on these roads. If the State had 1000 segments of 55 mph nonfreeways then 28 monitoring stations would be required on these roads.

TABLE 2.—FREEWAYS WITH 65 MPH SPEED LIMIT

Number of road segments	Number of highway segments to be sampled*
1	1
2–3	2
4–6	3
7–10	4
11–18	5
19–36	6
37–141	7
142 or more	8

*Sample sizes are based on data from 55 mph freeways and the assumption that the two roadway categories are similar in variation.

TABLE 3.—NONFREEWAYS WITH 55 MPH SPEED LIMIT

Number of road segments	Number of highway segments to be sampled*
1	1
2	2
3	3
4–5	4
6	5
7–8	6
9–10	7
11–12	8
13–14	9
15–16	10
17–19	11
20–22	12
23–25	13
26–29	14
30–34	15
35–39	16
40–45	17
46–53	18
54–62	19
63–74	20
75–88	21
89–109	22
110–137	23
138–180	24
181–253	25
254–406	26
407–950	27
951 or more	28

*Sample sizes are based on one standard error of 7.5 percent and the percentage of vehicles exceeding 55 mph equal to 51.8 percent.

If the total number of monitoring stations required by the above methodology is more than 30 percent higher than the maximum number of stations used on roads in the State's existing speed monitoring program, then the State can petition the Division Administrator for a reduced number of stations. The reduction in stations can be to a level no lower than 30 percent higher than the maximum number of stations under the old program. However, there can be no reduction in the number of stations required on freeways posted at 65 mph. Therefore, any reduction in the number of stations must come from the highway categories freeways posted at 55 mph and nonfreeways posted at 55 mph.

In lieu of the sample size tables, States can use their own data from past speed surveys to calculate sample sizes for each of the highway categories. However, the State must document in their sampling plan that their level of precision meets the precision requirements in each highway category. For 55 mph freeways and 65 mph freeways, a relative error of 11 percent for the total percent of vehicles exceeding the speed limit is required. For 55 mph nonfreeways, a 14 percent relative error for the total percent of vehicles exceeding the speed limit is required. Relative error is defined as one standard error divided by the estimate of the percent of vehicles exceeding the speed limit. For example, for 55 mph freeways, the percent of vehicles exceeding the speed limit was 71 percent. One standard error was estimated at 7.5 percent. The relative error would be calculated as:

Relative Error=Standard Error/Estimate,
Relative Error=7.5/71=11 percent.

If a State wishes to have a higher level of statistical reliability than a 7.5 percent level of precision, then the State can modify these monitoring requirements. The State can add monitoring stations or increase the number of days per year during which data are collected. The FHWA Division Administrator must accept the State's proposal before it can be implemented.

Selection of Sample Sizes

It is not feasible to select all new monitoring stations. Therefore, existing stations should be used to the maximum extent possible. States may either have too many or too few existing monitoring stations in each highway category. For example, many States may not have a sufficient number of stations on 65 mph freeways. Under the old monitoring program, all NMSL highways were divided into segments, an average of about five miles long, and monitoring stations were randomly selected from these. A similar process will be used under the new monitoring program.

- *Too few monitoring stations within a highway category:* If more stations are needed, road segments should be chosen at random from all road segments in that category that currently do not have a monitoring station.
- *Too many monitoring stations within a highway category:* If a State has more stations in a monitoring category than required in the previous section, the State can choose to eliminate stations. However, the stations to be eliminated must be selected at random from the existing stations.

A random selection procedure for either alternative is provided in Table 4. For all new stations one of the two directions of traffic should also be chosen at random. On existing monitoring stations, monitoring should take place in the same direction as under the old program. As under the old program, monitoring will take place on all lanes of the highway segment chosen as the monitoring station.

Each year, the number of monitoring stations should be reviewed to determine if any changes are required. Events that could precipitate changing the number of monitoring stations include:

- An increase or decrease in the number of HPMS sample sections in a highway category;
- The introduction or elimination of a 65 mph maximum speed limit in a State; and
- A significant increase or decrease in the amount of 55 mph highways.

Number and Length of Sessions

Each monitoring station will be monitored four times a year, once in each quarter. This is necessary to account for seasonal variation in traffic.

A 24-hour monitoring period will be used to account for varying hourly traffic conditions and to facilitate the scheduling of data collection. It is expected that the number of vehicles counted during the 24-hour monitoring period will vary.

Data Collection

This section summarizes guidelines for data collection in the speed monitoring program. It is a brief outline of basic procedures that should be expanded on by each State in developing its speed monitoring program.

Organization

The State program manager should be responsible for selection of monitoring sites, determining location of monitoring stations, obtaining necessary speed measurement equipment, scheduling equipment installation, scheduling data collection, managing data processing and analysis, and submission of required data and certifications. For the field operation, a detailed schedule should be developed that includes as a minimum:

- Selection and location of stations;
- Date of permanent station installation;
- Date/time of equipment setup at each location;
- Date/time of equipment takedown at each location;
- Travel time;
- Makeup time for equipment malfunction; bad weather, etc; and
- Transfer of recorded data to program manager.

This schedule should be as comprehensive as possible so that each member of the data collection team knows what work is expected. This schedule should be coordinated with district or local engineers, and law enforcement officials so that data collection does not occur during construction/maintenance activities and periods of intensive enforcement that might affect vehicle speeds.

Selection and Location of Stations

Selection and location of stations should be as described in the Speed Sampling and Analysis Plan. Once sites are selected, it must be determined which sites will be permanent monitoring stations and which ones temporary. Speed monitoring has been underway since the mid 1970s and is currently planned to extend at least until FY 1997. Thus, it may be cost effective to install permanent monitoring stations.

Installation of equipment at monitoring Stations—Segments which will have permanent monitoring stations should be surveyed to determine the optimum place for the installation of the monitoring station. The location of the monitoring station should be representative of typical conditions on the section. Situations to be avoided are:

- Near or at a sharp horizontal curve with a speed advisory plate less than the posted speed limit
- Steep grades (i.e. greater than 4%)
- Within 1000 feet of a significant at-grade intersection
- Within 1000 feet of an exit ramp on entrance ramp of an interchange
- Anywhere within the interchange (defined as the distance from the beginning of a deceleration lane through the end of an acceleration lane)
- Where other unusual features exist that might influence vehicle speeds (e.g. a narrow bridge or railroad crossing)

Temporary monitoring stations should be subjected to the same criteria as permanent stations. In this case, the field crew should drive the section (a minimum of twice) to become familiar with its characteristics and to identify any unusual conditions, in addition to those mentioned above, and any other criteria developed by the program manager. The criteria established for locating the monitoring station should be carefully followed since failure to do so may yield in speed data that could result in non-compliance due to data error and/or non-comparability.

Equipment Installation and Data Collection

Two common categories of detectors are available to be placed on the roadways for speed monitoring. The first is the standard loop detector. Loop detectors are permanently placed in the pavement. The second category includes temporary sensors (e.g., tape switch, cable sensors) and pneumatic tubes. These sensors must be placed on the pavement just before the start of each speed monitoring station. Extreme care is needed in placing the cables on the pavement since all traffic in one direction must be stopped to place the temporary sensors on the highway. The sensors are attached to the pavement by glue, tape, or both. There may be some problems installing the sensors during wet or cool weather. Both types of sensors perform well when properly placed on the highway. However, under heavy traffic conditions temporary sensors may be damaged.

Data recorders can be placed at a distance from the sensors where the recorder can be secured. The deployment of the data recorder and the temporary sensors can take up to four hours depending on traffic and weather conditions. A shorter deployment period would be needed if permanent loop detectors were already in place.

Review Highway Conditions

Prior to going to the monitoring site, the State should check with district and local engineers and local enforcement officials to determine if any maintenance/construction and/or enforcement activities are present or planned for the site. When the State personnel arrive at the designated site, they should determine the suitability of conditions at the site. Speed monitoring should not be attempted under the following conditions:

- Extreme weather conditions expected during the next 24-hour period (severe rainstorms, heavy snow accumulating or icy roadway);
- Presence of non-routine enforcement activity; or
- Construction/maintenance activity or other disruptive activities which affect the speed of vehicles passing the site.

If any of these conditions exist, the field personnel should immediately contact the program manager or his/her representative so that the session can be rescheduled.

1. Document Speed Monitoring Station. The field data collection crew document the exact location, equipment setup, and equipment used. The following information should be included in station documentation:

—Location of site;
—Station number;
—Session number;
—Equipment used;
—Field data collection crew names;
—Time of arrival at site;
—Sketch of site indicating
a. Location of speed monitoring equipment (sensor, recorder, etc.)
b. Direction of traffic monitored
c. Geometrics of highway (lane, width, shoulder width, etc.), and
d. Other physical features;
—Calibration of equipment checklist completed (check manufacturer's literature); and
—Time equipment is turned on.

Each manufacturer's recommended calibration procedures should be completed before the monitoring session begins. Any discrepancy should be reported to the program manager. No measurement should be taken with uncalibrated equipment.

2. End of Session Procedures. When the crew first arrives, they should determine if the equipment is still operating and run all calibration and data checks. Any temporary speed monitoring equipment and all data recorders should be removed from the road and stored.

Scheduling the Data Collection

Data collection must account for variations in speed by the hour of the day, day of the week, and time of the year. To account for the hourly variation, all data collection sessions should be 24 hours long. At all monitoring stations, one session of data will be obtained each quarter. All sessions should be evenly distributed by day of week. Data should not be collected on any monitoring station more than once on any day of the week in any one year.

Procedures for Obtaining and Recording Data

Data must be collected at each monitoring station to allow for the calculation of the following statistics:

- At monitoring stations on highways posted at 55 mph:

—Percent of vehicles exceeding 55 mph,
—Percent of vehicles exceeding 60 mph,
—Percent of vehicles exceeding 65 mph,
—Percent of vehicles exceeding 70 mph, and
—Percent of vehicles exceeding 75 mph.

- At monitoring stations on freeways posted at 65 mph:

—Percent of vehicles exceeding 65 mph,
—Percent of vehicles exceeding 70 mph,
—Percent of vehicles exceeding 75 mph,
—Percent of vehicles exceeding 80 mph, and
—Percent of vehicles exceeding 85 mph.

- The number of vehicles observed.

To determine the above statistics, each monitoring station must record a count of all vehicles and the speed of all vehicles that pass by the monitoring station in each 24-hour monitoring period.

Information on more categories of "percent exceeding" than is specified in the compliance formula is required to allow for the single adjustment to take into account potential error sources and to gather information on percent exceeding speed limit.

Data Analysis and Sample Design Evaluation

This section describes the procedures to be used in analyzing speed monitoring data. The main objective is to develop standard procedures applicable to all States. This section is divided into two parts:

- Computation of statistics related to the percentage of vehicles exceeding 55 mph, 60 mph, 65 mph, 70 mph, 75 mph, 80 mph, and 85 mph.
- Calculation of Compliance Score

Computation of Statistics

For monitoring stations on freeways and nonfreeways posted at 55 mph, it is necessary to compute the percentage of vehicles exceeding 55 mph, 60 mph, 65 mph, 70 mph, and 75 mph. For monitoring stations on freeways posted at 65 mph, it is necessary to compute the percentage of vehicles exceeding 65 mph, 70 mph, 75 mph, 80 mph, and 85 mph.

The data in each category is then adjusted to account for the various errors inherent in the process. As under the old program (FY 1981 to FY 1993), a single adjustment will be used to take into account the potential error sources. The single adjustment formula is:

$$H = \frac{(A+B)}{2}$$

where:

A=the percent of vehicles exceeding x mph
B=the percent of vehicles exceeding x+5 mph, and
H=The percent exceeding x mph after adjustment

The adjusted percentages are then inserted into the compliance formula and the State's compliance score is calculated. The following examples demonstrates these calculations.

Example

Part 1—Percent Exceeding at One Station

The first two parts presents a computation of statistics on the percentage of vehicles exceeding 70 mph on freeways posted at 55 mph. The same procedure is to be used to calculate the percentage of vehicles exceeding 55 mph, 60 mph, 65 mph, 70 mph, and 75 mph on highways posted at 55 mph, and the percent of vehicles exceeding 65 mph, 70 mph, 75 mph, 80 mph, and 85 mph on freeways posted at 65 mph.

For example, a monitoring station on a 65 mph highway, the proportion of vehicles exceeding 70 mph is computed by dividing the number of vehicles traveling in excess of 70 mph by the total number of vehicles measured during the four monitoring sessions.

The percentage of vehicles exceeding 70 mph is derived simply by multiplying the proportion by 100. For example:

Location number	Number of vehicles exceeding 70 mph	Total vehicles measured
1	2,936	9,786
2	3,473	11,875
3	3,616	12,429
4	3,229	11,064
Total	13,254	45,154

Percentage Exceeding 70 mph for Location Number 1:

$$100\left(\frac{13,254}{45,154}\right)=29.4$$

Part 2—Percent Exceeding for One Highway Category

The percentage exceeding 70 mph for each highway category is derived by summing the number of vehicles exceeding 70 mph for all the monitoring stations within the highway category, dividing this sum by the total number of vehicles measured in the highway category, and multiplying the result by 100.

FREEWAYS POSTED AT 65 MPH

Location number	Number of vehicles exceeding 70 mph	Total vehicles measured
1	13,254	45,154
2	15,519	56,549
3	8,410	35,831
4	18,374	61,143
5	14,291	48,784
Total	69,848	247,461

Percentage Exceeding 70 mph for Freeways Posted at 65 mph:

$$x=\frac{(38.0+19.5)}{2}$$

Part 3—Single Adjustment

This adjustment is to be taken for each of the nine percentages exceeding that go into base compliance score. Using the following percentages:

38.5 percent exceeding 60 mph on 55 mph freeways
19.0 percent exceeding 65 mph on 55 mph freeways

calculate the adjusted percent exceeding 60 mph on 55 mph freeways:

$$x=\frac{(38.0+19.5)}{2}$$

x=28.8, the adjusted percent exceeding 60 mph on 55 mph freeways.

Part 4—Calculation of Compliance Score

Assume a State with all three highway categories has collected the following data:

38.5 percent exceeding 60 mph on 55 mph freeways
19.0 percent exceeding 65 mph on 55 mph freeways
9.1 percent exceeding 70 mph on 55 mph freeways
1.5 percent exceeding 75 mph on 55 mph freeways
28.2 percent exceeding 70 mph on 65 mph freeways
10.2 percent exceeding 75 mph on 65 mph freeways
3.3 percent exceeding 80 mph on 65 mph freeways
0.9 percent exceeding 85 mph on 65 mph freeways
27.0 percent exceeding 60 mph on 55 mph nonfreeways
12.5 percent exceeding 65 mph on 55 mph nonfreeways
4.9 percent exceeding 70 mph on 55 mph nonfreeways
0.5 percent exceeding 75 mph on 55 mph nonfreeways

Applying the single adjustment to these figures yield:

28.8 percent exceeding 60 mph on 55 mph freeways
14.1 percent exceeding 65 mph on 55 mph freeways
5.3 percent exceeding 70 mph on 55 mph freeways
19.2 percent exceeding 70 mph on 65 mph freeways
6.8 percent exceeding 75 mph on 65 mph freeways
2.1 percent exceeding 80 mph on 65 mph freeways
19.8 percent exceeding 60 mph on 55 mph nonfreeways
8.7 percent exceeding 65 mph on 55 mph nonfreeways
2.7 percent exceeding 70 mph on 55 mph nonfreeways

These adjusted percent exceeding figures are used to calculate the compliance score as follows:

Compliance Score=
(1.055×28.8 percent exceeding 60 mph on 55 mph freeways)
+(1.115×14.1 percent exceeding 65 mph on 55 mph freeways)
+(1.180×5.3 percent exceeding 70 mph on 55 mph freeways)
+(1.354×19.2 percent exceeding 70 mph on 65 mph freeways)
+(1.434×6.8 percent exceeding 75 mph on 65 mph freeways)
+(1.520×2.1 percent exceeding 80 mph on 65 mph freeways)
+(2.659×19.8 percent exceeding 60 mph on 55 mph nonfreeways)
+(2.811×8.7 percent exceeding 65 mph on 55 mph nonfreeways)
+(2.974×2.7 percent exceeding 70 mph on 55 mph nonfreeways)

This calculation, without the verbiage, is:

Compliance score=
(1.055×28.8)+(1.115×14.1)+(1.180×5.3)
+(1.354×19.2)+(1.432×6.8)+(1.520×2.1)
+(2.659×19.8)+(2.811×8.7)+(2.974×2.7)

The sum of this multiplication=

30.87+15.72+6.25
+26.00+9.75+3.19
+52.65+24.46+8.03
The final score=176.9

Reporting Results

Summary speed statistics from each State's monitoring program are required to be submitted to the FHWA as part of the annual certification of NMSL enforcement. In addition, the current practice of submitting quarterly reports showing results of speed monitoring during the previous 3-month period will continue. The FHWA Speed Summary Report form is to be used for reporting both annual and quarterly speed summary data. The compliance score is to be calculated on the Speed Summary Report form. In the annual certification, the following data must be reported:

- For freeways and nonfreeways posted at 55 mph:

—Percent of vehicles exceeding 55 mph,
—Percent of vehicles exceeding 60 mph,
—Percent of vehicles exceeding 65 mph,
—Percent of vehicles exceeding 70 mph, and
—Percent of vehicles exceeding 75 mph.

- For freeways posted at 65 mph:

—Percent of vehicles exceeding 65 mph,
—Percent of vehicles exceeding 70 mph,
—Percent of vehicles exceeding 75 mph,
—Percent of vehicles exceeding 80 mph, and
—Percent of vehicles exceeding 85 mph.

- In addition to the above, the following must be determined for each highway category:

—Highway mileage posted at the NMSL,
—Number of vehicles observed,
—Number of monitoring locations, and
—Number of monitoring sessions.

Data on freeways posted at 55 mph and nonfreeways posted at 55 mph must be reported separately.

The data must be reported to the following precision:

- Number of Miles—Tenth of a Mile.
- Number of Vehicles Observed—Exact Number of Vehicles.
- Number of Locations—Exact Number of Locations.
- Number of Sessions—Exact Number of Sessions.
- Percent Exceeding 55 mph—Tenth of a Percent.
- Percent Exceeding 60 mph—Tenth of a Percent.
- Percent Exceeding 65 mph—Tenth of a Percent.
- Percent Exceeding 70 mph—Tenth of a Percent.
- Percent Exceeding 75 mph—Tenth of a Percent.
- Percent Exceeding 80 mph—Tenth of a Percent.
- Percent Exceeding 85 mph—Tenth of a Percent.
- Compliance Score—1 Decimal Place.

In addition, a distribution of vehicle speeds shall be reported for each highway category. The following categories shall be used in the reporting of the distribution of vehicle speeds:

- Number of vehicles at 30 mph and below;
- Number of vehicles from 31 to 35 mph;
- Number of vehicles from 36 to 40 mph;
- Number of vehicles from 41 to 45 mph;
- Number of vehicles from 46 to 50 mph;
- Number of vehicles from 51 to 55 mph;
- Number of vehicles from 56 to 60 mph;
- Number of vehicles from 61 to 65 mph;
- Number of vehicles from 66 to 70 mph;
- Number of vehicles from 71 to 75 mph;
- Number of vehicles from 76 to 80 mph;
- Number of vehicles from 81 to 85 mph; and,
- Number of vehicles at 86 mph and above.

These data should be reported on a formatted computer disk which will be provided to each State by the Division office.

SPEED SUMMARY REPORT

[Send quarterly report to office of Highway Information Management HPM—30]
[Send annual report to Office of Highway Safety HHS—32]
[Quarterly report annual report (Circle One)—quarter of year_____state_____]

Highway category	No. of miles	No. of vehicles observed	No. of locations	No. of sessions	Percent exceeding						
					55 mph	60 mph	65 mph	70 mph	75 mph	80 mph	85 mph
Freeways posted at 55 mph	____.__	_____	_____	_____	____.__	____.__	____.__	____.__	____.__	XXXX	XXXX
Freeways posted at 65 mph	____.__	_____	_____	_____	XXXX	XXXX	____.__	____.__	____.__	____.__	____.__
Non-freeways posted at 55 mph	____.__	_____	_____	_____	____.__	____.__	____.__	____.__	____.__	XXXX	XXXX

XXXX—Data not to be reported

CALCULATION OF COMPLIANCE SCORE

[Send annual report to Office of Highway Safety HHS–32]
[Annual Report—Year _____State _____]

Highway category	Adjusted percent exceeding				
	60 mph	65 mph	70 mph	75 mph	80 mph
Freeways Posted at 55 MPH	____.___	____.___	____.___	XXXX	XXXX
Freeways posted at 65 MPH	XXXX	XXXX	____.___	____.___	____.___
Non-freeways posted at 55 MPH	____.___	____.___	____.___	XXXX	XXXX

XXXX—Data not to be reported

Computation of Compliance Score:
Percent Exceeding 60 mph on 55 mph Freeways: _____.____times 1.055=_____.____
Percent Exceeding 65 mph on 55 mph Freeways: _____.____times 1.115=_____.____
Percent Exceeding 70 mph on 55 mph Freeways: _____.____times 1.180=_____.____
Percent Exceeding 70 mph on 65 mph Freeways: _____.____times 1.354=_____.____
Percent Exceeding 75 mph on 65 mph Freeways: _____.____times 1.434=_____.____
Percent Exceeding 80 mph on 65 mph Freeways: _____.____times 1.520=_____.____
Percent Exceeding 60 mph on 55 mph Non-Freeways: _____.____times 2.659=_____.____
Percent Exceeding 65 mph on 55 mph Non-Freeways: _____.____times 2.811=_____.____
Percent Exceeding 70 mph on 55 mph Non-Freeways: _____.____times 3.974=_____.____
Adjusted Compliance Score (sum of the scores for the nine highway categories) _____.____

DISTRIBUTION OF VEHICLE SPEEDS

[Send quarterly report to Office of Highway Information Statistics HPM–30, send annual report to Office of Highway Safety HHS–32]
[Quarterly Report Annual Report (circle one)—Quarter or Year _____State _____]

Recorded speeds	Number of vehicles measured							
	Freeways posted at 55 mph				Freeways Posted at 65 mph		Non-Freeways Posted at 55 mph	
	RI	RO	UI	UO	RI	RO	Rural	Urban
30 MPH and Below.								
31 to 35 MPH.								
36 to 40 MPH.								
41 to 45 MPH.								
46 to 50 MPH.								
51 to 55 MPH.								
56 to 60 MPH.								
61 to 65 MPH.								
66 to 70 MPH.								
71 to 75 MPH.								
76 to 80 MPH.								
81 to 85 MPH.								
86 MPH and Above.								

RI—Rural Interstate, RO—Rural Other, UI—Urban Interstate, UO—Urban Other.

Table 4

Table of Random Numbers

This table contains 2800 five-digit numbers organized in 200 rows by 14 columns. Numbers from this table may be selected by any random procedure. The procedure presented here consists of five steps:

1. Decide upon some arbitrary scheme of selecting the starting point (row, column) from the table. One method is to ask a person to select a number between 1 and 14. This will be the column number. Then ask a second person to select a number between 1 and 200. This will be the row number. You have now selected a point (number) to start in the table.

2. Assign numbers 1 to 99,999 to all items (highway sections within a highway category) in the population from which the random selection will be made.

3. Decide upon some arbitrary scheme of selecting positional digits for each number chosen. If 500 is the highest sequence number used, you may decide to use the first, third, and fourth digit of each entry selected, and as a consequence a three-digit number is created from each entry choice.

4. If the number selected from the random number table is less than the highest sequence number, one item has been selected from your population. If a number selected is greater than the highest sequence number or is a repeat of a number already selected, it should be passed over and the next number selected used. This process should continue until the desired number of random numbers have been selected.

5. A method should be designed to progress through the random number table from the starting point. Any method can be used, but you should decide before the

random numbers are selected. One method is to read down the column as far as you can. Then select one of the columns on either side and read up the next column. Continue this process until the desired number of random numbers has been selected.

The following is an example that puts this procedure into practice.

Example

The problem is to randomly select 10 highway segments to be monitored from a population of 500 segments.

- Select starting point in the Random Number Table.

a. Person one selected a number between 1 and 14, 7.

b. Person two selected a number between 1 and 200, 3.

- Therefore, the starting point selected is row 3, column 7, random number 15179.
- Assign number to highway segment population 1 to 500.
- Selection of Position of Digits.

a. Since the highest sequence number is 500, three digits should be selected.

b. The first three digits from the random number table will be used to construct the random number.

- The highest number that can be used is 500, therefore, a number greater than 500 will be passed over. If the number 600 represents 1,000, and if it is encountered it will not be used as it is greater than 500.
- If a number appears more than once in a selection, it will not be selected the second time (or third time, fourth time, etc.).
- Selection of Random Numbers

a. The progress through the random number table will be down the columns selected and up one of the columns on either side of the column used before.

b. Locate starting point row 3, column 7.

c. The first randomly selected number using the position of the digits in step 3 is 151. The next number is 394 (row 4, column 7). The next number, 604 (row 5, column 7), will not be used as it is greater than 500. Continue down the column selecting only numbers that are less than or equal to 500.

This process continues until all ten numbers have been selected. The result is the ten randomly selected highway segments listed below:

151, 394, 186, 388, 383, 473, 185, 458, 328, and 379.

RANDOM NUMBER TABLE

Line/col.	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
1	10480	15011	01536	02011	81647	91646	69179	14194	62590	36207	20969	99570	91291	90700
2	22368	46573	25595	85393	30995	89198	27982	53402	93965	34095	52666	19174	39615	99505
3	24130	48360	22527	97265	76393	64809	15179	24830	49340	32081	30680	19655	63348	58629
4	42167	93093	06243	61680	07856	16376	39440	53537	71341	57004	00849	74917	97758	16379
5	37570	39975	81837	16656	06121	91782	60468	81305	49684	60672	14110	06927	01263	54613
6	77921	06907	11008	42751	27756	53498	18602	70659	90655	15053	21916	81825	44394	42880
7	99562	72905	56420	69994	98872	31016	71194	18738	44013	48840	63213	21069	10634	12952
8	96301	91977	05463	07972	18876	20922	94595	56869	69014	60045	18425	84903	42508	32307
9	89579	14342	63661	10281	17453	18103	57740	84378	25331	12566	58678	44947	05585	56941
10	85475	36857	43342	53988	53060	59533	38867	62300	08158	17983	16439	11458	18593	64952
11	28918	69578	88231	33276	70997	79936	56865	05859	90106	31595	01547	85590	91610	78188
12	63553	40961	48235	03427	49626	69445	18663	72695	52180	20847	12234	90511	33703	90322
13	09429	93969	52636	92737	88974	33488	36320	17617	30015	08272	84115	27156	30613	74952
14	10365	61129	87529	85689	48237	52267	67689	93394	01511	26358	85104	20285	29975	89868
15	07119	97336	71048	08178	77233	13916	47564	81056	97735	85977	29372	74461	28551	90707
16	51085	12765	51821	51259	77452	16308	60756	92144	49442	53900	70960	63990	75601	40719
17	02368	21382	52404	60268	89368	19885	55322	44819	01188	65255	64835	44919	05944	55157
18	01011	54092	33362	94904	31273	04146	18594	29852	71585	85030	51132	01915	92747	64951
19	52162	53916	46369	58566	23216	14513	83149	98736	23495	64350	94736	17752	35156	35749
20	07056	97628	33787	09998	42698	06691	76988	13602	51851	46104	88916	19509	25625	58104
21	48663	91245	85828	14346	09172	30168	90229	04734	59193	22178	30421	61666	99904	32812
22	54164	58492	22421	74103	47070	25306	76468	26384	58151	06646	21524	15227	96909	44592
23	32639	32363	05597	24200	13363	38005	94342	28728	35806	06912	17012	64161	18296	22851
24	29334	27001	87637	87308	58731	00256	45834	15398	46557	41135	10367	07684	36188	18510
25	02488	33062	28834	07351	19731	92420	60952	61280	50001	67658	32586	86679	50720	94953
26	81525	72295	04839	96423	24878	82651	66566	14778	76797	14780	13300	87074	79666	95725
27	29676	20591	68086	26432	46901	20849	89768	81536	86645	12659	92259	57102	80428	25280
28	00742	57392	39064	66432	84673	40027	32832	61362	98947	96067	64760	64584	96096	98253
29	05366	04213	25669	26422	44407	44048	37937	63904	45766	66134	75470	66520	34693	90449
30	91921	26418	64117	94305	26766	25940	39972	22209	71500	64568	91402	42416	07844	69618
31	00582	04711	87917	77341	42206	35126	74087	99547	81817	42607	43808	76655	62028	76630
32	00725	69884	62797	56170	86324	88072	76222	36086	84637	93161	76038	65855	77919	88006
33	69011	65797	95876	55293	18988	27354	26575	08625	40801	59920	29841	80150	12777	48501
34	29976	57948	29888	88604	67917	48708	18912	82271	65424	69774	33611	54262	85963	03547
35	09763	83473	73577	12908	30883	18317	28290	35797	05998	41688	34952	37888	38917	88050
36	91567	42595	27958	30134	04024	86385	29880	99730	55536	84855	29080	09250	79888	73211
37	17955	56349	90999	49127	20044	59931	05115	20542	18059	02008	73708	83617	36109	42791
38	46503	18584	18845	49618	02304	51038	20655	58727	28168	15475	56942	53389	20562	87338
39	92157	89634	94824	78171	84610	82834	09922	25417	44137	48413	25555	21246	35509	20468
40	14577	62765	35605	81263	39667	47358	56873	56307	61607	49518	89656	20103	77490	18062
41	98427	07523	33362	64270	01638	92477	66969	98420	04880	45585	46585	04102	46880	45709
42	34914	63976	88720	82765	34476	17032	87589	40836	32427	70002	70663	88863	77775	69348
43	70060	28277	39475	46473	23219	53416	94970	25832	69975	94884	19661	72828	00102	66794
44	53976	54914	06990	67245	68350	82948	11398	42878	80287	88267	47363	46634	06541	97809
45	76072	29515	40980	07391	58745	25774	22987	80059	39911	96189	41151	14222	60697	59583
46	90725	52210	83974	29992	65831	38857	50490	83765	55657	14361	31720	57375	56228	41546
47	64364	67412	33339	31926	14883	24413	59744	92351	97473	89286	35931	04110	23726	51900
48	08962	00358	31662	25388	61642	34072	81249	36648	69882	40852	46373	46578	76547	81788
49	95012	68379	93526	70765	10699	04542	76463	54328	02349	17247	28805	14777	62738	92277
50	15664	10493	20492	38391	91132	21999	58916	81652	27195	48223	46751	22923	32261	85653
51	16408	81899	04153	53381	79401	21438	83035	92350	39693	31238	59849	91754	72772	02338
52	18629	81953	05520	91962	04739	13092	97662	24822	94730	06496	35090	04822	86772	98289
53	73115	35101	47498	87637	99016	71060	88824	71013	18735	20286	23153	72924	35165	43040
54	57491	16703	23167	49323	45021	33132	12544	41035	80780	45393	44812	12515	89831	91202
55	30405	83946	23792	14422	15059	45799	22716	19792	09983	74353	69958	30406	70735	25460
56	16631	35006	85900	98275	32388	52390	16815	69298	82732	38480	73817	32523	41916	44437
57	96773	20206	42559	78985	05300	22164	24369	54224	35083	19687	11052	91491	60383	18746
58	38935	64202	14349	82674	66523	44133	00697	35552	35970	19124	63318	29686	03387	59846
59	31624	76384	17403	53363	44167	64486	64758	75366	76554	31601	12614	33072	60332	92325

RANDOM NUMBER TABLE—Continued

Line/col.	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)
60	78919	19474	23632	27889	47914	02584	37680	20801	72152	39339	34806	08930	85001	87820
61	03931	33309	57047	74211	63445	17361	62825	39908	05607	91284	68833	25570	38818	46920
62	74426	33278	43972	10119	89817	15065	52872	73823	73144	88662	88970	74492	51805	99378
63	09066	00903	20795	95452	92648	45454	09552	88815	16553	51125	79375	97596	16296	66092
64	42238	12426	87025	14267	20979	04508	64535	31355	86064	29472	47689	05974	52468	16834
65	16153	08002	26504	41744	81959	65642	74240	56302	00033	67107	77510	70625	28725	34191
66	21457	40742	29820	96783	29400	21840	15035	34537	33310	06116	95240	15957	16572	06004
67	21581	57802	02050	89728	17937	37621	47075	42080	97403	48626	68995	43805	33386	21597
68	55612	78086	83197	33732	05810	24813	86902	60397	16409	03264	88525	42786	05269	92532
69	44657	06869	99324	51281	84463	60563	79312	93454	68876	25471	93911	25650	12682	73572
70	91340	84979	46949	81973	37949	61023	43997	15263	80644	43942	89203	71795	99533	50501
71	91227	21199	31935	27022	84067	05462	35216	14486	29891	68607	41867	14951	91696	85065
72	50001	38140	66321	19924	72163	09538	12151	06878	91903	18749	34405	56087	82790	70825
73	65390	05224	72958	28609	81406	39147	25549	48542	42627	45233	57202	94617	23772	07896
74	27504	96131	83944	41575	10573	08619	64482	73923	36152	05184	94142	25299	84387	34925
75	37169	94851	39117	89632	00959	16487	65536	49071	39782	17095	02330	74301	00275	48280
76	11508	70225	51111	38351	19444	66499	71945	05422	13442	78675	84081	66938	93654	59894
77	37449	30362	06694	54690	04052	53115	62757	95348	78662	11163	81651	50245	34971	52924
78	46515	70331	85922	38329	57015	15765	97161	17869	45349	61796	66345	81073	49106	79860
79	30986	81223	42416	58353	21532	30502	32305	86482	05174	07901	54339	58861	74818	46942
80	63798	64995	46583	09765	44160	78128	83991	42865	92520	83531	80377	35909	81250	54238
81	82486	84846	99254	67632	43218	50076	21361	64816	51202	88124	41870	52689	51275	83556
82	21885	32906	92431	09060	64297	51674	64126	62570	26123	05155	59194	52799	28225	85762
83	60336	98782	07408	53458	13564	59089	26445	29789	82505	41001	12535	12133	14845	23541
84	43937	46891	24010	25660	86355	33941	25786	54990	71899	15475	95434	98227	21824	19585
85	97656	63175	89303	16275	07100	92063	21942	18611	43748	20203	18534	03862	78095	50136
86	03299	01221	05418	38982	55758	92237	26759	86367	21216	98442	08303	56613	91511	75928
87	79626	06486	03574	17668	07785	76020	79924	25651	83325	88428	85076	72811	22717	50585
88	85636	68335	47539	03129	65651	11977	02510	26113	99447	68645	34327	15152	55230	93448
89	18039	14367	61337	06177	12143	46609	32989	74014	64708	00533	35398	58408	13261	47908
90	08362	15656	60627	36478	65648	16764	53412	09013	07832	41574	17639	82163	60859	75567
91	79556	29068	04142	16268	15387	12856	66227	38358	22478	73373	88732	09443	82558	05250
92	92608	82674	27072	32534	17075	27698	98204	63863	11951	34648	88022	56148	34925	57031
93	23982	25835	40055	67006	12293	02753	14827	22235	35071	99704	37543	11601	35503	85171
94	09915	96306	05908	97901	28395	14186	00821	80703	70426	75647	76310	88717	37890	40129
95	50937	33300	26695	62247	69927	76123	50842	43834	86654	70959	79725	93872	28117	19233
96	42488	78077	69882	61657	34136	79180	97526	43092	04098	73571	80799	76536	71255	64239
97	46764	86273	63003	93017	31204	36692	40202	35275	57306	55543	53203	18098	47625	88684
98	03237	45430	55417	63282	90816	17349	88298	90183	36600	78406	06216	95787	42579	90730
99	86591	81482	52667	61583	14972	90053	89534	76036	49199	43716	97548	04379	46370	28672
100	38534	01715	94964	87288	65680	43772	39560	12918	88537	62738	19636	51132	25739	56947
101	13284	16834	74151	92027	24670	36665	00770	22878	02179	51602	07270	76517	97275	45980
102	21224	00370	30420	03883	96648	89428	41583	17564	27395	63904	41548	49197	82277	24120
103	99052	47887	81085	64933	66279	80432	65793	83287	34142	13241	30590	97760	35848	91983
104	00199	50993	98603	38452	87890	94624	69721	57484	67501	77638	44331	11257	71131	11059
105	60578	06483	28733	37867	07936	98710	98539	27186	31237	80612	44488	97819	70401	95419
106	92140	18312	17441	01929	18163	68201	31211	54298	38296	37318	65724	90401	79017	62077
107	97458	14229	12063	59811	32249	90486	33216	19358	02591	54263	88449	01912	07436	50813
108	35249	38646	34475	72417	60514	69257	12489	51924	86871	92446	36607	11458	30440	52830
109	38080	46600	11759	11900	46743	27880	77940	39298	97636	95145	32378	68038	89351	37005
110	10750	52745	38749	87365	58959	53731	69295	59062	38404	13196	59960	70408	29812	83126
111	36247	27850	73958	20673	37800	63835	71051	84724	52492	22342	78071	17456	98104	18327
112	70994	66986	99744	72438	01174	42159	11392	20724	54322	36923	70009	23233	65438	59685
113	99638	94702	11463	18148	81396	80431	90628	52506	02016	85151	86598	47821	00265	82525
114	72055	15774	43857	99805	10419	76839	25993	03544	21560	83471	43989	90770	22965	44247
115	24038	65541	85788	55835	38835	59309	13790	35112	01324	39520	76210	22467	83275	32266
116	74976	14631	35908	28221	39470	91548	12854	30166	09073	75887	36782	00268	97121	57676
117	35553	71828	70189	26436	63407	91178	90348	55359	80392	41012	36270	77786	89578	21059
118	35676	12797	51434	82976	42010	26344	92920	92155	58807	54644	58581	95331	78629	73344
119	74815	67523	72985	23183	02446	63594	99924	20633	58842	85961	07648	70184	34994	67662
120	45246	88048	65173	50989	91060	89894	36063	32819	68559	99221	49475	50558	34696	71600
121	76509	47069	86378	41797	11910	49672	88575	97966	32466	10083	54728	81972	58975	30761
122	19689	90332	04315	21358	97248	11188	39062	63312	52496	07349	79178	33692	57352	72862
123	42751	35318	97513	61537	54955	08159	00337	80778	27507	95478	21252	12746	37554	80775
124	11946	22681	45045	13964	57517	59419	59045	44067	58716	58840	45557	96345	33271	53464
125	96518	48688	20996	11090	48396	57177	63867	86464	14342	21545	46717	72364	86954	55580
126	35726	58643	76869	84622	39098	36083	72505	92265	23107	60278	06822	46760	44294	07672
127	39737	42750	48968	70536	84864	64952	38404	94317	65402	13589	01055	79044	19308	83623
128	97025	66492	56177	04049	80312	48028	26408	43591	75528	65341	49044	95495	81256	53214
129	62814	08075	09788	56350	76787	51591	54509	49295	85230	59860	30883	89660	96142	18354
130	25578	22950	15227	83291	41737	79599	98191	71845	86899	70694	24290	01551	80092	82118
131	68763	69576	88991	49662	46704	63362	56625	00481	73323	91427	15264	06969	57048	54149
132	17900	00813	64361	60725	88974	61005	99709	30686	26451	11528	44323	34778	60342	60388
133	71944	60227	63551	71109	05624	43836	58254	26160	32116	63403	35404	57146	10909	07346
134	54684	93691	85132	64399	29182	44324	14491	55226	78793	34107	30374	48429	51376	09559
135	25946	27623	11258	65204	52832	50880	22273	05554	99521	73791	85744	29276	70326	60251
136	01353	39318	44961	44972	91766	90262	56073	06606	51826	18893	83448	31915	97764	75091
137	99083	88191	27662	99113	57174	35571	99884	13951	71057	53961	61448	74909	07322	80960
138	52021	45406	37945	75234	24327	86978	22644	87779	23753	99926	63898	54886	18051	96314
139	78755	47744	43776	83098	03225	14281	83637	55984	13300	52212	58781	14905	46502	04472
140	25282	69106	59180	16257	22810	43609	12224	25643	89884	31149	85423	32581	34374	70873

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141	11959	94202	02743	86847	79725	51811	12998	76844	05320	54236	53891	70226	38632	84776
142	11644	13792	98190	01424	30078	28197	55583	05197	47714	68440	22016	79204	06862	94451
143	06307	97912	68110	59812	95448	43244	31262	88880	13040	18458	43813	89416	42482	33939
144	76285	75714	89585	99296	52640	46518	55486	90754	88932	19937	57119	23251	55619	23679
145	55322	07589	39600	60886	63007	20007	66819	84184	61131	81429	60676	42807	78286	29015
146	78017	90028	90220	92503	83375	26986	74399	30850	88567	29169	72816	53357	15428	86932
147	44768	43342	20898	26331	43140	69744	82926	24988	94237	46138	77426	39039	55596	12655
148	25100	19336	14805	86603	51680	97678	24261	02464	86563	74812	60069	71674	15478	47642
149	83612	46623	62876	85197	07824	91392	58317	37726	84828	42221	10268	20692	15699	29167
150	41347	81666	82961	60413	71020	83658	02415	33322	66036	98712	46795	16308	28413	05417
151	38128	51178	75096	13609	16110	73533	42584	59870	29399	67834	91055	89917	51096	8901
152	60950	00455	73254	96067	50717	13878	03216	78274	65863	37011	91283	33914	91303	49326
153	90524	17320	29832	96116	75792	25326	22940	24904	80523	38928	91374	55597	97567	36914
154	49897	18278	67160	39408	97056	43517	84426	59650	20247	19293	02019	14790	02852	05819
155	18494	99209	81060	19486	65596	59787	47939	91225	98768	43688	00438	05548	09443	82897
156	65373	72984	30171	37741	70203	94094	87261	30056	58124	70133	18936	02138	59372	09075
157	40653	12843	04213	70925	95360	55774	76439	61768	52817	81151	52188	31940	54273	49032
158	51638	22238	56344	44587	83231	50317	74541	07719	25472	41602	77318	15145	57515	07633
159	69742	99303	62578	83575	30337	07488	51941	84316	42067	49692	28616	29101	03013	73449
160	58012	74072	67488	74580	47992	69482	58624	17106	47538	13452	22620	24260	40155	74716
161	18348	19655	42887	08279	43206	47077	42637	45606	00011	20662	14642	49984	94509	56380
162	59614	09193	58064	29086	44385	45740	70752	05663	49081	26960	57454	99264	24142	74648
163	75688	28630	39210	52897	62748	72658	98059	67202	72789	01869	13496	14863	87645	89713
164	13941	77802	69101	70061	35460	34576	15412	81304	58757	35498	94830	75521	00603	97701
165	96656	86420	96475	88458	54463	96419	55417	41375	76886	19008	66877	35934	59801	00497
166	03363	82042	15942	14549	38324	87094	19069	67590	11087	68570	22591	65232	85915	91499
167	70366	08390	69155	25496	13240	57407	91407	49160	07379	34444	94567	66035	38918	65708
168	47870	36605	12927	16043	53257	93796	52721	73120	48025	78074	95605	67422	41646	14557
169	79504	77606	22761	30518	28373	73898	30550	76684	77366	32276	04690	61667	64798	66276
170	46967	74841	50923	15339	37755	98995	40162	89561	69199	42257	11647	47803	48779	97907
171	14558	50769	35444	59030	87516	48193	02945	00922	48169	04724	21263	20892	92955	90251
172	12440	25057	01132	36611	28135	68089	10954	10097	54243	06460	50856	65435	79377	53890
173	32293	29938	68653	10497	98919	46587	77701	99119	93165	67788	17638	23097	21468	36992
174	10640	21875	72462	77981	56550	55999	87310	69643	45124	00349	25748	00844	96831	30651
175	47615	23169	39571	56972	20828	21788	51736	33133	72696	32605	41569	78148	91544	21121
176	16948	11128	71624	72754	49084	96303	27830	45817	67867	18062	87453	17226	72904	71474
177	21258	61092	66634	70335	92448	17354	83432	49608	66520	06442	59664	20420	39201	69549
178	15072	48853	15178	30730	47481	49490	41436	25015	49932	20474	53821	51015	79841	32405
179	99154	57412	09858	65671	60655	71479	63520	31357	56968	06729	34465	70685	04184	25250
180	08759	61089	23706	32994	35426	36666	63988	98844	37533	08269	27021	45886	22835	78451
181	67323	57839	61114	62192	47547	58023	64630	34886	98777	75442	95592	06141	45096	73117
182	09255	13986	84634	20764	72206	89393	34548	93438	88730	61805	78955	18952	46436	58740
183	36304	74712	00374	10107	85061	69228	81969	92216	03568	39630	81869	52824	50937	27954
184	15884	67429	66612	47367	10242	44880	12060	44309	46829	55105	66793	93173	00480	13311
185	18745	32031	35303	08134	33925	03044	59929	95418	04917	57596	24878	61733	92834	64454
186	72934	40086	88292	65728	38300	42323	64068	98373	48971	09049	59943	36538	05976	82118
187	17626	02944	20910	57662	80181	38579	24580	90529	52303	50436	29401	57824	86039	81062
188	27117	61399	50967	41399	81636	16863	15634	79717	94696	59240	25543	97989	63306	90946
189	93995	18678	90012	63645	85701	85269	62263	68331	00389	72571	15210	20769	44686	96176
190	67392	89421	09823	80725	62620	84162	87368	29560	00519	84545	06004	24526	41252	14521
191	04910	12261	37566	80016	21245	69377	50420	85658	55263	68667	78770	04533	14513	18099
192	81453	20283	79929	59839	23875	13245	46808	74124	74703	35769	95568	21014	37078	39170
193	19480	75790	48539	23703	15537	48885	02861	86587	74539	65227	90799	58789	96257	02708
194	21456	13162	74608	81011	55512	07481	93551	72189	76261	91206	89941	15132	37738	59284
195	89406	20912	46189	76376	25538	87212	20748	12831	57166	35026	16817	79121	18929	40628
196	09866	07414	55977	16419	01101	69343	13305	94302	80703	57910	36933	57771	42546	03003
197	66541	24681	23421	13521	28000	94917	07423	57523	97234	63951	42876	46829	09781	58160
198	10414	96941	06205	72222	57167	83902	07460	69507	10600	08858	07685	44472	64220	27040
199	49942	06683	41479	58982	56288	42853	92196	20632	62045	78812	35895	51851	83534	10689
200	23995	66882	42291	23374	24299	27024	67460	94783	40937	16961	26053	78749	46704	21983

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Monday
January 4, 1993

Part IV

The President

Proclamation 6519—To Implement Tariff Modifications on Certain Plywood Originating in the Territory of Canada and for Other Purposes

Executive Order 12827—Amendment to Executive Order No. 12792

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Presidential Documents

Title 3—

The President

Proclamation 6519 of December 30, 1992

To Implement Tariff Modifications on Certain Plywood Originating in the Territory of Canada and for Other Purposes

By the President of the United States of America

A Proclamation

1. Pursuant to section 201(c) of the United States-Canada Free-Trade Agreement Implementation Act of 1988 (Public Law 100–449) (the "CFTA Act"), the President is authorized to implement the tariff concessions described in article 2008 of the United States-Canada Free-Trade Agreement (the "CFTA") when he determines that common performance standards for the use of softwood plywood and other structural panels in construction applications have been incorporated into building codes in the United States and Canada. Article 2008 of the CFTA allowed the United States and Canada to delay implementation of tariff concessions on softwood plywood and on waferboard, oriented strand board, and particle-board of all species because a panel of experts from the two countries failed to resolve issues regarding the use of a particular grade of plywood by the date of entry into force of the CFTA.

2. Pursuant to section 201(c)(2) of the CFTA Act, the President reports to the Congress on the incorporation of common plywood performance standards into building codes in the two countries. Pursuant to section 201(c)(3) of the CFTA Act, any tariff reduction undertaken by the United States and commencing after January 1, 1991, need not be in equal annual increments.

3. Pursuant to section 201(c) of the CFTA Act, I have determined that common plywood performance standards have been incorporated into building codes in the United States and Canada and that the necessary conditions for implementing the tariff concessions under article 2008 of the CFTA have been met. Accordingly, I have reported to the Congress on such incorporation, and I have decided that the implementation by the United States of previously agreed staged reductions in duties on certain plywood originating in the territory of Canada should begin on January 1, 1993, and end on January 1, 1998.

4. Section 1204(b)(1)(C) of the Omnibus Trade and Competitiveness Act of 1988 (19 U.S.C. 3004(b)(1)(C)) (the "1988 Act") authorizes the President to proclaim modifications to the Harmonized Tariff Schedule of the United States ("HTS") as are necessary or appropriate to implement such technical rectifications as the President considers necessary. Pursuant to section 1204(b)(1)(C), I have determined that certain technical rectifications to the HTS are necessary to provide the proper tariff treatment to certain chemicals.

5. Section 604 of the Trade Act of 1974, as amended (19 U.S.C. 2483) (the "Trade Act"), authorizes the President to embody in the HTS the substance of the provisions of that Act, and of other acts affecting import treatment, and action thereunder, including the removal, modification, continuance, or imposition of any rate of duty or other import restriction.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, acting under the authority vested in me by the Constitution and the laws of the United States of America, including but not limited to section 201(c) of the CFTA Act, section 1204(b)(1)(C) of the 1988 Act, and section 604 of the Trade Act, do proclaim that:

(1) In order to implement, consistent with the provisions of article 2008 of the CFTA, the tariff concessions on certain plywood and on waferboard, oriented strand board, and particle-board of all species, the HTS is modified as set forth in Annex I to this proclamation.

(2) In order to make technical rectifications in the tariff treatment afforded to certain chemicals, the HTS is further modified as set forth in Annex II to this proclamation.

(3) Any provisions of previous proclamations inconsistent with the provisions of this proclamation are hereby superseded to the extent of such inconsistency.

(4)(a) The modifications made by Annex I to this proclamation shall be effective with respect to goods originating in the territory of Canada entered, or withdrawn from warehouse for consumption, on or after the dates set forth in Annex I

(b) The modifications made by Annex II to this proclamation shall be effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 1993.

IN WITNESS WHEREOF, I have hereunto set my hand this thirtieth day of December, in the year of our Lord nineteen hundred and ninety-two, and of the Independence of the United States of America the two hundred and seventeenth.

George Bush

Billing code 3195-01-M

Editorial note: For the President's letter to Congressional leaders on this modification, see issue no. 53 of the *Weekly Compilation of Presidential Documents*.

[FR Doc. 92-
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ANNEX I

IMPLEMENTATION OF STAGED TARIFF REDUCTIONS
ON CERTAIN PLYWOOD

(a) Effective with respect to goods originating in the territory of Canada entered, or withdrawn from warehouse for consumption, on or after January 1, 1993, HTS subheading 4410.10.00 is modified by inserting, in the parentheses following the "Free" duty rate in the Rates of Duty 1-Special subcolumn, the symbol "CA" in alphabetical order.

(b) Effective with respect to goods originating in the territory of Canada entered, or withdrawn from warehouse for consumption, on or after January 1 of each of the following years, for each of the enumerated HTS subheadings in the following table, the Rates of Duty 1-Special subcolumn in the HTS is modified (i) by inserting in such subcolumn for each such subheading the rate of duty specified for such subheading in the 1993 column followed by the sumbol "CA" in parentheses, and (ii) for each of the subsequent dated columns by deleting the rates of duty that are followed by the symbol "CA" in parentheses and by inserting the following rates of duty in such subheadings in lieu thereof.

HTS subheading	1993	1994	995	1996	1997	1998
4412.19.40	10%	8%	6%	4%	2%	Free
4412.99.40	10%	8%	6%	4%	2%	Free

ANNEX II

TECHNICAL RECTIFICATIONS TO THE
HARMONIZED TARIFF SCHEDULE OF THE UNITED STATES

Bracketed matter is included to assist in the understanding of the proclaimed modifications. The following supersedes matter now in the HTS. The subheadings and superior text are set forth in columnar format, and material in such columns is inserted in the columns of the HTS designated "Heading/Subheading", "Article Description", "Rates of Duty 1-General", "Rates of Duty 1-Special", and "Rates of Duty 2", respectively.

Effective with respect to articles entered, or withdrawn from warehouse for consumption, on or after January 1, 1993:

(a) HTS subheading 2922.29.23 is deleted.

(b) Subheading 2922.50 of the HTS is modified by inserting the following new subheading, in numerical sequence:

	[Oxygen-function amino-compounds:]			
	[Amino-alcohol-phenols,...:]			
	[Aromatic:]			
"2922.50.11	d(-)-p-Hydroxyphenylglycine and its salts.....	3.7¢/kg + 15.6%	Free (A*,CA,E, IL,J)	15.4¢/kg + 50%"

(c) General note 3(c)(ii)(D) to the HTS is modified by deleting "2922.29.23 India" and inserting, in numerical sequence, "2922.50.11 India" in lieu thereof.

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Presidential Documents

Executive Order 12827 of December 30, 1992

Amendment to Executive Order No. 12792

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2), and in order to extend the reporting period of the National Commission on America's Urban Families, it is hereby ordered that section 2(b) of Executive Order No. 12792 is amended by deleting the date "December 31, 1992" and inserting in lieu thereof the date "January 20, 1993".

George Bush

THE WHITE HOUSE,
December 30, 1992.

[FR Doc. 92-31946
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1120–1199	(869–017–00019–1)	9.50	Jan. 1, 1992
1200–1499	(869–017–00020–5)	22.00	Jan. 1, 1992
1500–1899	(869–017–00021–3)	15.00	Jan. 1, 1992
1900–1939	(869–017–00022–1)	11.00	Jan. 1, 1992
1940–1949	(869–017–00023–0)	23.00	Jan. 1, 1992
1950–1999	(869–017–00024–8)	26.00	Jan. 1, 1992
2000–End	(869–017–00025–6)	11.00	Jan. 1, 1992
8	(869–017–00026–4)	17.00	Jan. 1, 1992
9 Parts:			
1–199	(869–017–00027–2)	23.00	Jan. 1, 1992
200–End	(869–017–00028–1)	18.00	Jan. 1, 1992
10 Parts:			
0–50	(869–017–00029–9)	25.00	Jan. 1, 1992
51–199	(869–017–00030–2)	18.00	Jan. 1, 1992
200–399	(869–017–00031–1)	13.00	[4] Jan. 1, 1987
400–499	(869–017–00032–9)	20.00	Jan. 1, 1992
500–End	(869–017–00033–7)	28.00	Jan. 1, 1992
11	(869–017–00034–5)	12.00	Jan. 1, 1992
12 Parts:			
1–199	(869–017–00035–3)	13.00	Jan. 1, 1992
200–219	(869–017–00036–1)	13.00	Jan. 1, 1992
220–299	(869–017–00037–0)	22.00	Jan. 1, 1992
300–499	(869–017–00038–8)	18.00	Jan. 1, 1992
500–599	(869–017–00039–6)	17.00	Jan. 1, 1992
600–End	(869–017–00040–0)	19.00	Jan. 1, 1992
13	(869–017–00041–8)	25.00	Jan. 1, 1992
14 Parts:			
1–59	(869–017–00042–6)	25.00	Jan. 1, 1992
60–139	(869–017–00043–4)	22.00	Jan. 1, 1992
140–199	(869–017–00044–2)	11.00	Jan. 1, 1992
200–1199	(869–017–00045–1)	20.00	Jan. 1, 1992
1200–End	(869–017–00046–9)	14.00	Jan. 1, 1992
15 Parts:			
0–299	(869–017–00047–7)	13.00	Jan. 1, 1992
300–799	(869–017–00048–5)	21.00	Jan. 1, 1992
800–End	(869–017–00049–3)	17.00	Jan. 1, 1992
16 Parts:			
0–149	(869–017–00050–7)	6.00	Jan. 1, 1992
150–999	(869–017–00051–5)	14.00	Jan. 1, 1992
1000–End	(869–017–00052–3)	20.00	Jan. 1, 1992
17 Parts:			
1–199	(869–017–00054–0)	15.00	Apr. 1, 1992
200–239	(869–017–00055–8)	17.00	Apr. 1, 1992
240–End	(869–017–00056–6)	24.00	Apr. 1, 1992
18 Parts:			
1–149	(869–017–00057–4)	16.00	Apr. 1, 1992
150–279	(869–017–00058–2)	19.00	Apr. 1, 1992
280–399	(869–017–00059–1)	14.00	Apr. 1, 1992
400–End	(869–017–00060–4)	9.50	Apr. 1, 1992
19 Parts:			
1–199	(869–017–00061–2)	28.00	Apr. 1, 1992
200–End	(869–017–00062–1)	9.50	Apr. 1, 1992
20 Parts:			
1–399	(869–017–00063–9)	16.00	Apr. 1, 1992
400–499	(869–017–00064–7)	31.00	Apr. 1, 1992
500–End	(869–017–00065–5)	21.00	Apr. 1, 1992
21 Parts:			
1–99	(869–017–00066–3)	13.00	Apr. 1, 1992
100–169	(869–017–00067–1)	14.00	Apr. 1, 1992
170–199	(869–017–00068–0)	18.00	Apr. 1, 1992
200–299	(869–017–00069–8)	5.50	Apr. 1, 1992
300–499	(869–017–00070–1)	29.00	Apr. 1, 1992
500–599	(869–017–00071–0)	21.00	Apr. 1, 1992
600–799	(869–017–00072–8)	7.00	Apr. 1, 1992
800–1299	(869–017–00073–6)	18.00	Apr. 1, 1992
1300–End	(869–017–00074–4)	9.00	Apr. 1, 1992
22 Parts:			
1–299	(869–017–00075–2)	26.00	Apr. 1, 1992
300–End	(869–017–00076–1)	19.00	Apr. 1, 1992
23	(869–017–00077–9)	18.00	Apr. 1, 1992
24 Parts:			
0–199	(869–017–00078–7)	34.00	Apr. 1, 1992
200–499	(869–017–00079–5)	32.00	Apr. 1, 1992
500–699	(869–017–00080–9)	13.00	Apr. 1, 1992
700–1699	(869–017–00081–7)	34.00	Apr. 1, 1992
1700–End	(869–017–00082–5)	13.00	Apr. 1, 1992
25	(869–017–00083–3)	25.00	Apr. 1, 1992
26 Parts:			
§§ 1.0–1–1.60	(869–017–00084–1)	17.00	Apr. 1, 1992
§§ 1.61–1.169	(869–017–00085–0)	33.00	Apr. 1, 1992
§§ 1.170–1.300	(869–017–00086–8)	19.00	Apr. 1, 1992
§§ 1.301–1.400	(869–017–00087–6)	17.00	Apr. 1, 1992
§§ 1.401–1.500	(869–017–00088–4)	36.00	Apr. 1, 1992
§§ 1.501–1.640	(869–017–00089–2)	19.00	Apr. 1, 1992
§§ 1.641–1.850	(869–017–00090–6)	19.00	Apr. 1, 1992
§§ 1.851–1.907	(869–017–00091–4)	23.00	Apr. 1, 1992
§§ 1.908–1.1000	(869–017–00092–2)	26.00	Apr. 1, 1992
§§ 1.1001–1.1400	(869–017–00093–1)	19.00	Apr. 1, 1992
§§ 1.1401–End	(869–017–00094–9)	28.00	Apr. 1, 1992
2–29	(869–017–00095–7)	22.00	Apr. 1, 1992
30–39	(869–017–00096–5)	15.00	Apr. 1, 1992
40–49	(869–017–00097–3)	12.00	Apr. 1, 1992
50–299	(869–017–00098–1)	15.00	Apr. 1, 1992
300–499	(869–017–00099–0)	20.00	Apr. 1, 1992
500–599	(869–017–00100–7)	6.00	[5] Apr. 1, 1990
600–End	(869–017–00101–5)	6.50	Apr. 1, 1992

Title	Stock Number	Price	Revision Date
27 Parts:			
1–199	(869–017–00102–3)	23.00	Apr. 1, 1992
200–End	(869–017–00103–1)	13.00	Apr. 1, 1992
28	(869–017–00104–0)	28.00	July 1, 1992
29 Parts:			
0–99	(869–017–00105–8)	21.00	July 1, 1992
100–499	(869–017–00106–6)	9.50	July 1, 1992
500–899	(869–017–00107–4)	29.00	July 1, 1992
900–1899	(869–017–00108–2)	17.00	July 1, 1992
1900–1910 (§§ 1901.1 to 1910.999)	(869–017–00109–1)	28.00	July 1, 1992
1910 (§§ 1910.1000 to end)	(869–017–00110–4)	17.00	July 1, 1992
1911–1925	(869–017–00111–2)	11.00	July 1, 1992
1926	(869–017–00112–1)	17.00	July 1, 1992
1927–End	(869–017–00113–9)	28.00	July 1, 1992
30 Parts:			
1–199	(869–017–00114–7)	23.00	July 1, 1992
200–699	(869–017–00115–5)	18.00	July 1, 1992
700–End	(869–017–00116–3)	23.00	July 1, 1992
31 Parts:			
0–199	(869–017–00117–1)	15.00	July 1, 1992
200–End	(869–017–00118–0)	26.00	July 1, 1992
32 Parts:			
1–39, Vol. I	(869–017–00119–8)	15.00	[6] July 1, 1984
1–39, Vol. II	(869–017–00120–1)	19.00	[6] July 1, 1984
1–39, Vol. III	(869–017–00121–0)	18.00	[6] July 1, 1984
1–189	(869–017–00122–8)	24.00	July 1, 1992
190–399	(869–017–00123–6)	28.00	July 1, 1992
400–629	(869–017–00124–4)	25.00	July 1, 1992
630–699	(869–017–00125–2)	13.00	July 1, 1992
700–799	(869–017–00126–1)	20.00	July 1, 1992
800–End	(869–017–00127–9)	17.00	July 1, 1992
33 Parts:			
1–124	(869–017–00128–7)	19.00	July 1, 1992
125–199	(869–017–00129–5)	28.00	July 1, 1992
200–End	(869–017–00130–9)	23.00	July 1, 1992
34 Parts:			
1–299	(869–017–00131–7)	24.00	July 1, 1992
300–399	(869–017–00132–5)	13.00	July 1, 1992
400–End	(869–017–00133–3)	28.00	July 1, 1992
35	(869–017–00134–1)	10.00	July 1, 1992
36 Parts:			
1–199	(869–017–00135–0)	13.00	July 1, 1992
200–End	(869–017–00136–8)	24.00	July 1, 1992
37	(869–017–00137–6)	18.00	July 1, 1992
38 Parts:			
0–17	(869–017–00138–4)	23.00	July 1, 1992
18–End	(869–017–00139–2)	23.00	July 1, 1992
39	(869–017–00140–6)	13.00	July 1, 1992
40 Parts:			
1–51	(869–017–00141–4)	28.00	July 1, 1992
52	(869–017–00142–2)	28.00	July 1, 1992
53–60	(869–017–00143–1)	28.00	July 1, 1992
61–80	(869–017–00144–9)	13.00	July 1, 1992
81–85	(869–017–00145–7)	13.00	July 1, 1992
86–99	(869–017–00146–5)	28.00	July 1, 1992
100–149	(869–017–00147–3)	23.00	July 1, 1992
150–189	(869–017–00148–1)	18.00	July 1, 1992
190–259	(869–017–00149–0)	13.00	July 1, 1992
260–299	(869–017–00150–3)	28.00	July 1, 1992
300–399	(869–017–00151–1)	13.00	July 1, 1992
400–424	(869–017–00152–0)	23.00	July 1, 1992
425–699	(869–017–00153–8)	23.00	July 1, 1992
700–789	(869–017–00154–6)	28.00	July 1, 1992
790–End	(869–017–00155–4)	13.00	July 1, 1992
41 Chapters:			
1, 1–1 to 1–10		13.00	[7] July 1, 1984

Title	Stock Number	Price	Revision Date
27 Parts:			
1–199	(869–017–00102–3)	34.00	Apr. 1, 1992
200–End	(869–017–00103–1)	11.00	[6] Apr. 1, 1991
28	(869–017–00104–0)	37.00	July 1, 1992
29 Parts:			
0–99	(869–017–00105–8)	19.00	July 1, 1992
100–499	(869–013–00106–6)	9.00	July 1, 1992
500–899	(869–017–00107–4)	32.00	July 1, 1992
900–1899	(869–017–00108–2)	16.00	July 1, 1992
1900–1910 (§§ 1901.1 to 1910.999)	(869–017–00109–1)	29.00	July 1, 1992
1910 (§§ 1910.1000 to end)	(869–017–00110–4)	16.00	July 1, 1992
1911–1925	(869–017–00111–2)	9.00	[7] July 1, 1989
1926	(869–017–00112–1)	14.00	July 1, 1992
1927–End	(869–017–00113–9)	30.00	July 1, 1992
30 Parts:			
1–199	(869–017–00114–7)	25.00	July 1, 1992
200–699	(869–017–00115–5)	19.00	July 1, 1992
700–End	(869–017–00116–3)	25.00	July 1, 1992
31 Parts:			
0–199	(869–017–00117–1)	17.00	July 1, 1992
200–End	(869–017–00118–0)	25.00	July 1, 1992
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–189	(869–017–00119–8)	30.00	July 1, 1992
190–399	(869–017–00120–1)	33.00	July 1, 1992
400–629	(869–017–00121–0)	29.00	July 1, 1992
630–699	(869–017–00122–8)	14.00	[8] July 1, 1991
700–799	(869–017–00123–6)	20.00	July 1, 1992
800–End	(869–017–00124–4)	20.00	July 1, 1992
33 Parts:			
1–124	(869–017–00125–2)	18.00	July 1, 1992
125–199	(869–017–00126–1)	21.00	July 1, 1992
200–End	(869–017–00127–9)	23.00	July 1, 1992
34 Parts:			
1–299	(869–017–00128–7)	27.00	July 1, 1992
300–399	(869–017–00129–5)	19.00	July 1, 1992
400–End	(869–017–00130–9)	32.00	July 1, 1992
35	(869–017–00131–7)	12.00	July 1, 1992
36 Parts:			
1–199	(869–017–00132–5)	15.00	July 1, 1992
200–End	(869–017–00133–3)	32.00	July 1, 1992
37	(869–017–00134–1)	17.00	July 1, 1992
38 Parts:			
0–17	(869–013–00135–4)	24.00	July 1, 1991
18–End	(869–017–00136–8)	28.00	Sept. 1, 1992
39	(869–017–00137–6)	16.00	July 1, 1992
40 Parts:			
1–51	(869–017–00138–4)	31.00	July 1, 1992
52	(869–017–00139–2)	33.00	July 1, 1992
53–60	(869–017–00140–6)	36.00	July 1, 1992
61–80	(869–017–00141–4)	16.00	July 1, 1992
81–85	(869–017–00142–2)	17.00	July 1, 1992
86–99	(869–017–00143–1)	33.00	July 1, 1992
100–149	(869–017–00144–9)	34.00	July 1, 1992
150–189	(869–017–00145–7)	21.00	July 1, 1992
190–259	(869–017–00146–5)	16.00	July 1, 1992
260–299	(869–017–00147–3)	36.00	July 1, 1992
300–399	(869–017–00148–1)	15.00	July 1, 1992
400–424	(869–017–00149–0)	26.00	July 1, 1992
425–699	(869–017–00150–3)	26.00	July 1, 1992
700–789	(869–017–00151–1)	23.00	July 1, 1992
790–End	(869–017–00152–0)	25.00	July 1, 1992
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–017–00153–8)	9.50	July 1, 1992
101	(869–017–00154–6)	28.00	July 1, 1992
102–200	(869–017–00155–4)	11.00	[6] July 1, 1991
201–End	(869–017–00156–2)	11.00	July 1, 1992
42 Parts:			
1–60	(869–013–00157–5)	17.00	Oct. 1, 1991
61–399	(869–013–00158–3)	5.50	Oct. 1, 1991
400–429	(869–013–00159–1)	21.00	Oct. 1, 1991
430–End	(869–013–00160–5)	26.00	Oct. 1, 1991
43 Parts:			
1–999	(869–013–00161–3)	20.00	Oct. 1, 1991
1000–3999	(869–013–00162–1)	26.00	Oct. 1, 1991
4000–End	(869–013–00163–0)	12.00	Oct. 1, 1991
44	(869–017–00163–5)	26.00	Oct. 1, 1992
45 Parts:			
1–199	(869–013–00165–6)	16.00	Oct. 1, 1991
200–499	(869–013–00166–4)	12.00	Oct. 1, 1991
500–1199	(869–013–00167–2)	26.00	Oct. 1, 1991
1200–End	(869–017–00167–8)	20.00	Oct. 1, 1992
46 Parts:			
1–40	(869–013–00169–9)	15.00	Oct. 1, 1991
41–69	(869–017–00169–4)	16.00	Oct. 1, 1992
70–89	(869–013–00171–1)	7.00	Oct. 1, 1991
90–139	(869–013–00172–9)	12.00	Oct. 1, 1991
140–155	(869–013–00173–7)	10.00	Oct. 1, 1991
156–165	(869–017–00173–2)	14.00	[9] Oct. 1, 1991
166–199	(869–017–00174–1)	17.00	Oct. 1, 1992
200–499	(869–017–00175–9)	22.00	Oct. 1, 1992
500–End	(869–013–00177–0)	11.00	Oct. 1, 1991
47 Parts:			
0–19	(869–013–00178–8)	19.00	Oct. 1, 1991
20–39	(869–013–00179–6)	19.00	Oct. 1, 1991
40–69	(869–013–00180–0)	10.00	Oct. 1, 1991
70–79	(869–013–00181–8)	18.00	Oct. 1, 1991
80–End	(869–013–00182–6)	20.00	Oct. 1, 1991
48 Chapters:			
1 (Parts 1–51)	(869–013–00183–4)	31.00	Oct. 1, 1991
1 (Parts 52–99)	(869–017–00183–0)	22.00	Oct. 1, 1992
2 (Parts 201–251)	(869–017–00184–8)	15.00	Oct. 1, 1992
2 (Parts 252–299)	(869–017–00185–6)	12.00	Oct 1, 1992
3–6	(869–013–00187–7)	19.00	Oct. 1, 1991
7–14	(869–017–00187–2)	30.00	Oct. 1, 1992
15–End	(869–013–00189–3)	30.00	Oct. 1, 1991
49 Parts:			
1–99	(869–013–00190–7)	20.00	Oct. 1, 1991
100–177	(869–013–00191–5)	23.00	Dec. 31, 1991
178–199	(869–013–00192–3)	17.00	Dec. 31, 1991
200–399	(869–013–00193–1)	22.00	Oct. 1, 1991
400–999	(869–013–00194–0)	27.00	Oct. 1, 1991
1000–1199	(869–013–00195–8)	17.00	Oct. 1, 1991
1200–End	(869–013–00196–6)	19.00	Oct. 1, 1991
50 Parts:			
1–199	(869–013–00197–4)	21.00	Oct. 1, 1991
200–599	(869–017–00198–8)	20.00	Oct. 1, 1992
600–End	(869–013–00199–1)	17.00	Oct. 1, 1991
CFR Index and Findings Aids	(869–017–00053–1)	31.00	Jan. 1, 1992
Complete 1992 CFR set		775.00	1992
Microfiche CFR Edition:			
Complete set (one-time mailing)		188.00	1992

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Complete set (one-time mailing)		188.00	1991
Complete set (one-time mailing)		188.00	1992
Subscription (mailed as issued)		223.00	1993
Individual copies		2.00	1993

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Jan. 1, 1987 to Dec. 31, 1991. The CFR volume issued January 1, 1987, should be retained.

[5] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1991. The CFR volume issued April 1, 1990, should be retained.

[6] No amendments to this volume were promulgated during the period Apr. 1, 1991 to Mar. 30, 1992. The CFR volume issued April 1, 1991, should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 1989 to June 30, 1992. The CFR volume issued July 1, 1989, should be retained.

[8] No amendments to this volume were promulgated during the period July 1, 1991 to June 30, 1992. The CFR volume issued July 1, 1991, should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 1991 to September 30, 1992. The CFR volume issued October 1, 1991, should be retained.

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3 (Compil

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5 Parts:
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6 [Reserv

7 Parts:
0–26
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400–699
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1200–149
1500–189
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1950–199
2000–End

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9 Parts:

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Title

CFR ISSUANCES 1993
Complete Listing of 1992 Editions and Projected January, 1993 Editions

This list sets out the CFR issuances for the 1992 editions and projects the publication plans for the January, 1993 quarter. A projected schedule that will include the April, 1993 quarter will appear in the first Federal Register issue of April.

For pricing information on available 1992–1993 volumes consult the CFR checklist which appears every Monday in the Federal Register.

Pricing information is not available on projected issuances. The weekly CFR checklist and the monthly List of CFR Sections Affected will continue to provide a cumulative list of CFR titles and parts, revision date and price of each volume.

Normally, CFR volumes are revised according to the following schedule:

Titles 1–16—January 1
Titles 17–27—April 1
Titles 28–41—July 1
Titles 42–50—October 1

All volumes listed below will adhere to these scheduled revision dates unless a notation in the listing indicates a different revision date for a particular volume.

*Indicates volume is still in production.

Titles revised as of January 1, 1992 editions:

Title	
CFR Index	1–199
	200–End
1–2	
3 (Compilation)	
4	
5 Parts:	
1–699	
700–1199	
1200–End	
6 [Reserved]	
7 Parts:	
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When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

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January 6	January 21	February 5	February 22	March 8	April 6
January 7	January 22	February 8	February 22	March 8	April 7
January 8	January 25	February 8	February 22	March 9	April 8
January 11	January 26	February 10	February 25	March 12	April 12
January 12	January 27	February 11	February 26	March 15	April 12
January 13	January 28	February 12	March 1	March 15	April 13
January 14	January 29	February 16	March 1	March 15	April 14
January 15	February 1	February 16	March 1	March 16	April 15
January 19	February 3	February 18	March 5	March 22	April 19
January 21	February 5	February 22	March 8	March 22	April 21
January 22	February 8	February 22	March 8	March 23	April 22
January 25	February 9	February 24	March 11	March 26	April 26
January 26	February 10	February 25	March 12	March 29	April 26
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January 28	February 12	March 1	March 15	March 29	April 28
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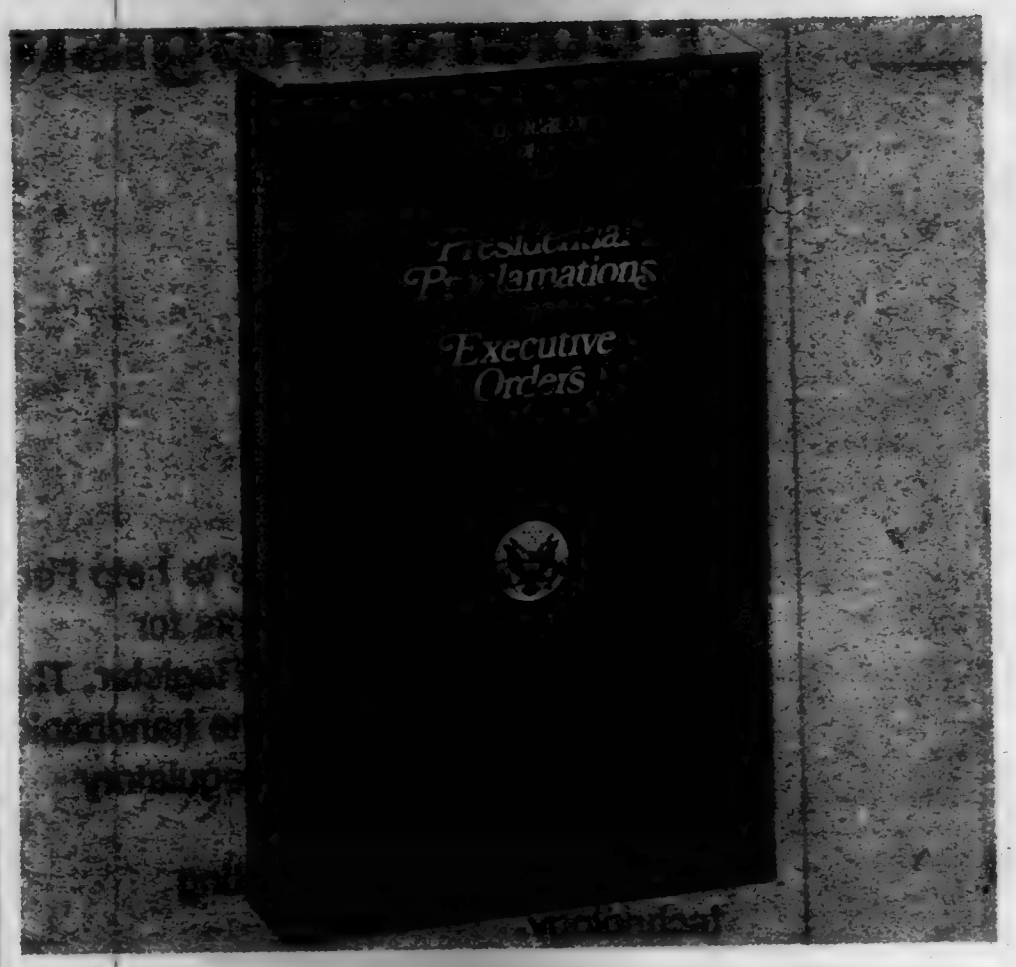

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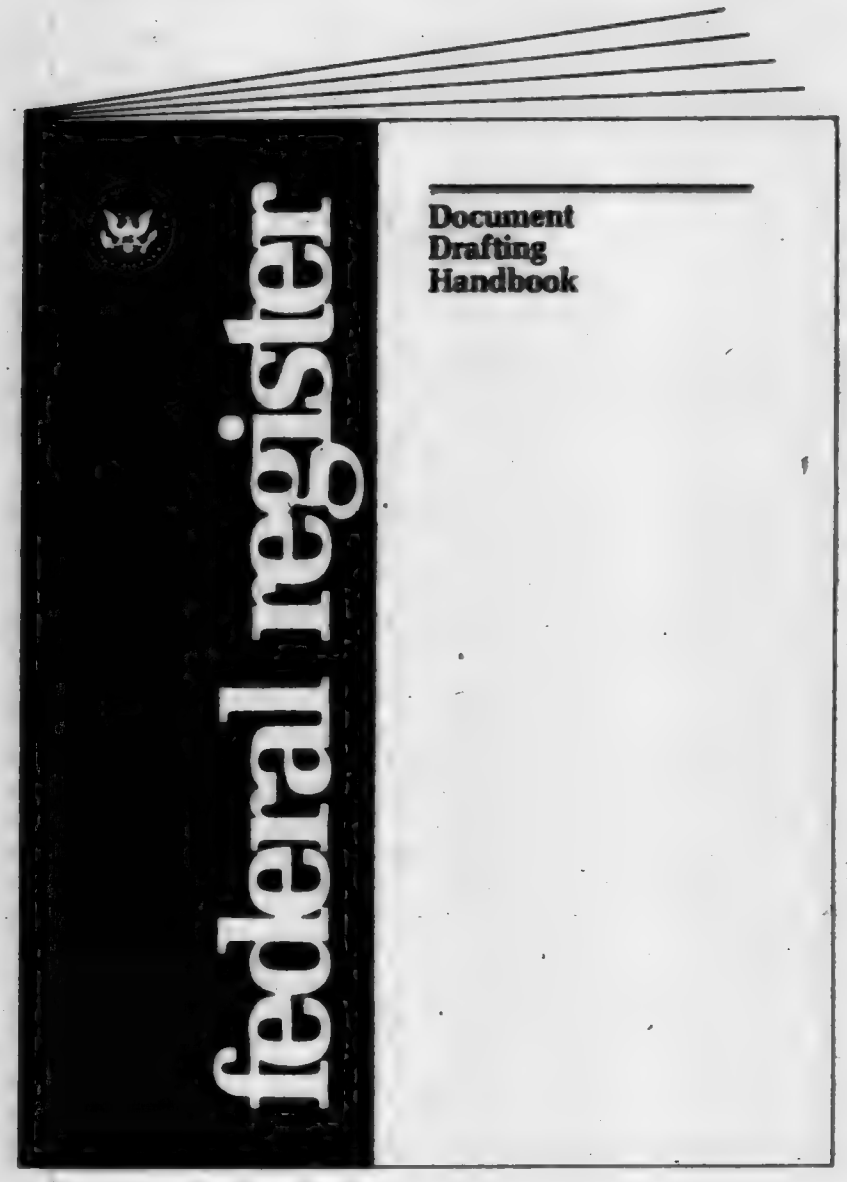

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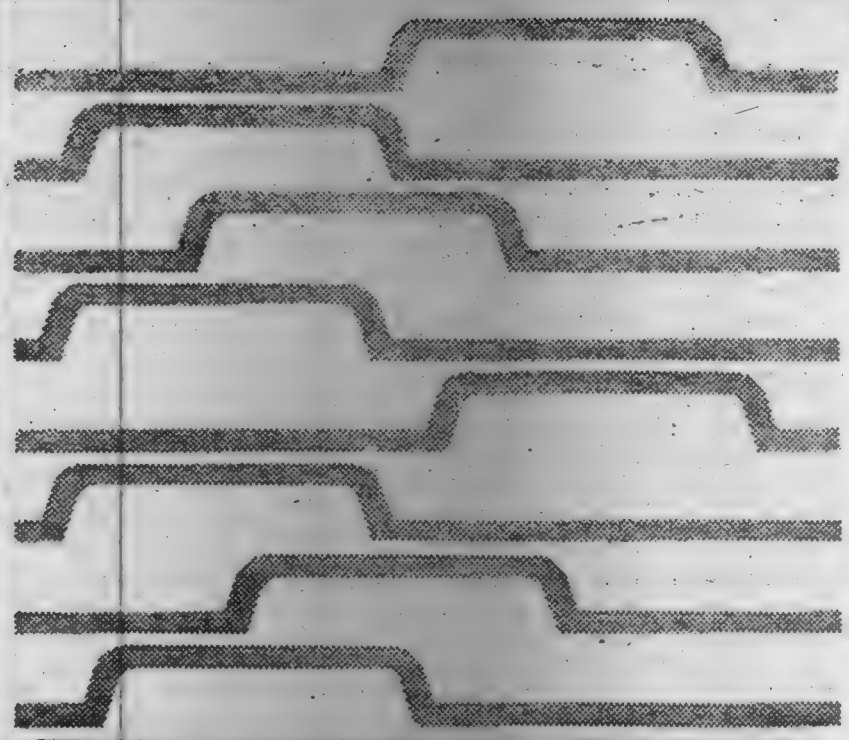

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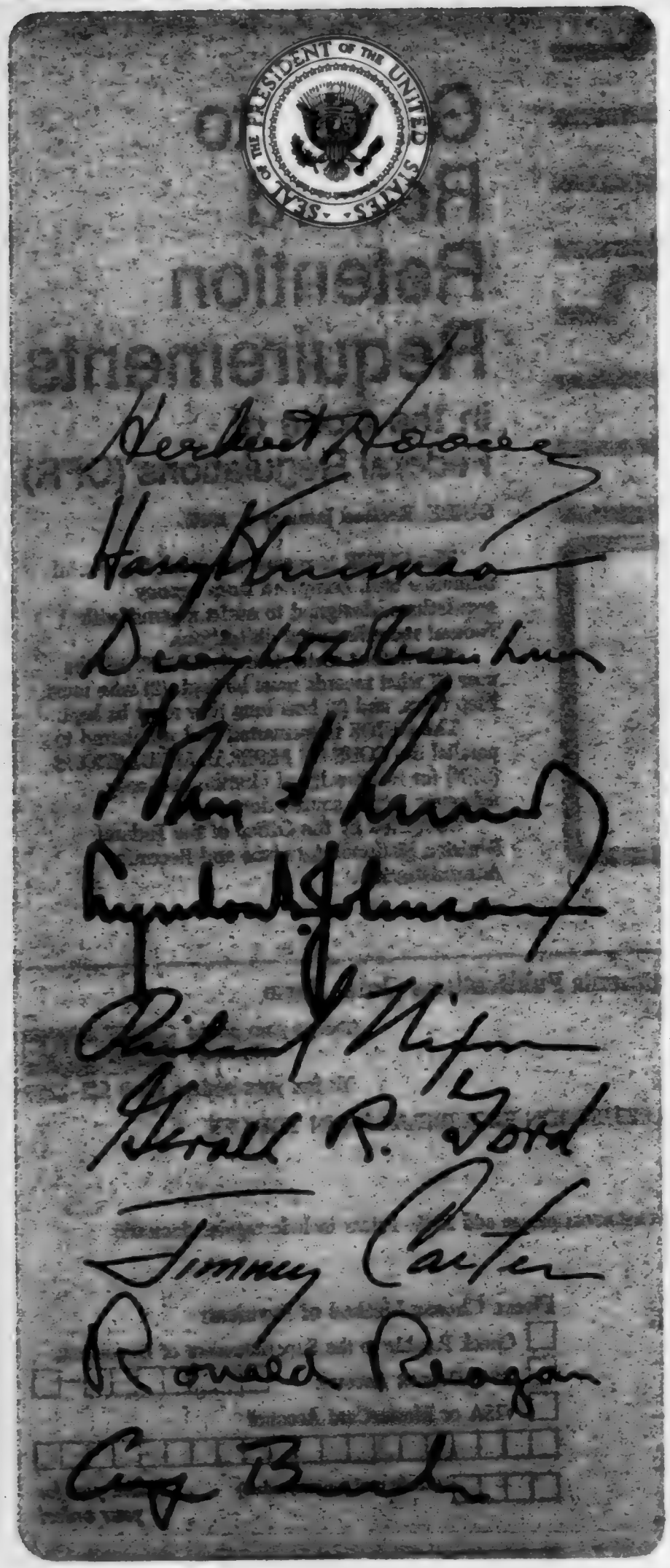

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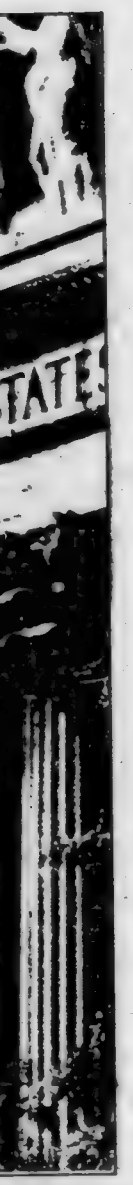

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 271, 272, 273, 274, 275, 276, 277, 278, 279, 280, 281, 282, 284, and 285

[Amdt. No. 330]

Food Stamp Program; Food Stamp Application and Income Exclusion Provisions of the 1990 Farm Bill

AGENCY: Food and Nutrition Service, USDA.

ACTION: Final rule.

SUMMARY: This action adopts as final the interim Food Stamp Program (FSP) rulemaking published March 28, 1991 (56 FR 12843). The interim regulation implemented several provisions of the Mickey Leland Memorial Domestic Hunger Relief Act (title XVII, Pub. L. 101–624, enacted November 28, 1990.) These provisions simplify FSP application requirements and exclude certain annual clothing allowances and general assistance (GA) vendor payments from being counted as income. The Department accepted comments on the interim rulemaking through June 26, 1991. This final action addresses relevant issues raised by commenters.

DATES: This action was effective and required to be implemented by State agencies on August 1, 1991.

FOR FURTHER INFORMATION CONTACT: Judith M. Seymour, Eligibility and Certification Rulemaking Section, Certification Policy Branch, Program Development Division, Food and Nutrition Service, USDA, 3101 Park Center Drive, Alexandria, Virginia, 22302. The telephone number is (703) 305–2496.

SUPPLEMENTARY INFORMATION:

Classification

Executive Order 12291

The Department has reviewed this rule under Executive Order 12291 and the Secretary of Agriculture's Memorandum No. 1512–1. The rule's effect on the economy will be less than $100 million, and it will have no effect on costs or prices. Competition, employment, investment, productivity, and innovation will remain unaffected. There will be no effect on the ability of United States-based enterprises to compete with foreign-based enterprises. Therefore, the Department has classified this rule as nonmajor.

Executive Order 12372

The Food Stamp Program is listed in the Catalog of Federal Domestic Assistance under No. 10.551. For the reasons set forth in the final rule and related Notice of 7-CFR part 3015, subpart V (48 FR 29115), this Program is excluded from the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless so specified in the "Effective Date" paragraph of this preamble. Prior to any judicial challenge to the provisions of this rule or the application of its provisions all applicable administrative procedures must be exhausted. In the Food Stamp Program the administrative procedures are as follows: (1) For program benefit recipients—State administrative procedures issued pursuant to 7 U.S.C. 2020(e)(10) and 7 CFR 273.15; (2) for State agencies—administrative procedures issued pursuant to 7 U.S.C. 2023 set out at 7 CFR 276.7 (for rules related to non-quality control (QC) liabilities) or part 284 (for rules related to QC liabilities); (3) for program retailers and wholesalers—administrative procedures issued pursuant to 7 U.S.C. 2023 set out at 7 CFR 278.8.

Regulatory Flexibility Act

The Department has also reviewed this rule in relation to the requirements of the Regulatory Flexibility Act of 1980 (Pub. L. 96–354, 94 Stat. 1164, September 19, 1980). Phyllis R. Gault, Acting Administrator of the Food and Nutrition Service (FNS), has certified that this rule does not have a significant economic impact on a substantial number of small entities. The requirements will affect food stamp applicants and recipients and the State and local agencies that administer the Program. The application process will be simplified, and some currently participating households will realize an increase in Program benefits.

Paperwork Reduction Act

The requirement of the Immigration Reform and Control Act of 1986 (Pub. L. 99–603) that applicants for food stamps attest to their alien or citizenship status was implemented in regulations issued October 7, 1988 (53 FR 39433). At that time, the Office of Management and Budget (OMB) approved the signature requirement under the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511) under OMB No. 0584–0064. Therefore, changes required to be made in the food stamp application as a result of the provisions in 7 CFR 273.2(b) of this action do not significantly alter the methodologies used to determine the burden estimates currently approved for the application under OMB No. 0584–0064.

Background

On March 28, 1991, the Department published an interim rulemaking (56 FR 12843) implementing several provisions of the Mickey Leland Memorial Domestic Hunger Relief Act, Public Law 101–624, 104 Stat. 3783, November 28, 1990 (Leland Act), which simplify application requirements, exclude GA vendor payments from income if no payments can be made in cash under State law, and exclude annual clothing allowances from consideration as income. The Department received five comment letters from State agencies, and reviewed and considered all comments. For a full understanding of the provisions of this final rule, the reader should refer to the preamble of the interim rule.

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Food Stamp Program Application Requirements—7 CFR 273.2(b)

The interim rule implemented the provision of section 1736 of the Leland Act allowing one adult representative of the household to attest, under penalty of perjury, to the truth of the information in the application, including information indicating that all members are citizens or aliens eligible for participation under the alien provisions of the Food Stamp Act. With one exception, the commenters were supportive of the change, which eliminated the requirement that each adult sign a declaration of alien or citizenship status and that an adult sign for each child in the household.

One commenter indicated that the change in food stamp procedures complicated the application process because the procedures for the Medicaid and the Aid to Families with Dependent Children (AFDC) programs still require that all adults sign a statement attesting to their citizenship or alien status. According to the commenter, this will require State agencies to provide two different sets of instructions for completing integrated applications. Also, since an individual household member who is not required to sign the food stamp application could be disqualified by the Medicaid or AFDC programs for failing to sign an alien/citizenship statement, the commenter believes a potential for error exists.

The Department had no discretion in this area. Therefore, the interim provision amending 7 CFR 273.2(b) is adopted as final without change.

Exclusion of General Assistance (GA) Payments When No Cash Payments May Be Made—7 CFR 273.9(c)(1)

Section 1722 of the Leland Act amended section 5(k)(2) of the Food Stamp Act to add an income exclusion for vendor payments provided under a State or local GA program, or another local basic assistance program comparable to GA. Under this provision, vendored GA assistance is excluded if, under State law, no assistance can be provided to the household in the form of cash. The payment may not be excluded if the prohibition against a cash payment is included only in the local law. The interim rule amended 7 CFR 273.9(c)(1) accordingly.

One commenter objected to the interim provision because it results in income being counted in one State and excluded in another. According to the commenter, households receiving GA are penalized if they live in a State that does not have a GA program which, under State law, is prohibited from providing cash benefits. The commenter also indicated that it is unfair to count as income payments from GA directly to a third party on behalf of a household when the same payments would be excluded from income if they were made by a private organization.

The Department has no discretion in implementing the GA vendor payment exclusion of the Leland Act. Therefore, the provisions of the interim rule are adopted as final. However, it should be noted that some GA vendor payments may be excluded under other parts of the Food Stamp Act and existing regulations. For example, rent or mortgage payments made to landlords or mortgage holders by State or local housing authorities and payments by a government agency to a child care institution are excluded under 7 CFR 273.9(c)(1)(i). GA vendor payments for energy assistance may be excluded, as provided in 7 CFR 273.9(c)(11). Child care assistance, medical assistance, temporary or emergency assistance to migrant or seasonal farmworkers in the job stream, and certain housing assistance may be excluded under 7 CFR 273.9(c)(1)(ii) (A) through (E). Assistance provided through vendor payments financed by State or local funds that are over and above the normal GA or public assistance grant or not normally provided as part of the grant is excluded under 7 CFR 273.9(c)(1)(iv)(B).

Another commenter suggested the regulation clarify how a GA vendor payment would be treated when only a portion of the GA grant is required by State law to be provided directly to a third party. For example, the State law may require that the shelter part of GA grant be paid directly to the landlord but provide for other household needs to be met by payments directly to the household. The language of section 1722 of the Leland Act which authorized this GA vendor payment exclusion provides that the exclusion applies only if, under State law, no assistance under the GA program may be provided in cash. Therefore, if a GA program provides some assistance in cash and some as a vendor payment, no amount may be excluded under this provision.

Exclusion of Annual Clothing Allowances—7 CFR 273.9(c)

Section 1716 of the Leland Act amended section 5(d)(5) of the Food Stamp Act to exclude from income any allowance a State agency provides no more frequently than annually to families with children for school clothes when the children enter or return to school or daycare. However, the allowance shall not be excluded if the State agency reduces the amount of monthly assistance provided by the Aid to Families with Dependent Children (AFDC) program in the month for which the allowance is provided. In accordance with the provision of section 1716, the interim rule amended 7 CFR 273.9(c)(5) to exclude from income annual school and daycare clothing allowances provided by a State agency regardless of whether they are paid in the form of cash, a voucher, or a two-party check. Annual clothing payments are excluded regardless of the age of the child or the correctness of the payment.

One commenter requested that annual clothing allowances made in the form of vendor payments also be excluded. Section 273.9(c)(5) applies to vendor payments as well as cash payments, so annual school clothing allowances provided as vendor payments are excluded. Further, the exclusion of annual (not monthly) clothing allowances made as vendor payments is allowed by regulations at 7 CFR 273.9(c)(1)(iv)(B) as assistance provided over and above the normal PA or GA grant. Therefore, the provisions of the interim rule are adopted as final without change.

Implementation

Section 1781 of the Leland Act required that the provisions of this rulemaking be effective and implemented the first day of the month beginning 120 days after publication of implementing regulations. The Department published implementing regulations March 28, 1991; therefore, the provisions of this rule were effective and State agencies were required to implement them on August 1, 1991. The implementation requirements of the interim rule at 7 CFR 272.1(g)(116) are adopted as final without change. Those requirements are: the provisions of the rule must be implemented for all households that newly apply on or after the required implementation date. The current caseload must be converted to the new provisions at recertification, at household request, or when the case is next reviewed, whichever occurs first, and the State agency must provide restored benefits back to the required implementation date. If for any reason a State agency failed to implement on the required effective date, restored benefits must be provided back to the required effective date or the date of the food stamp application, whichever is later.

The interim rule provided that any variance resulting from implementation of the provisions of this rule would be excluded from error analysis for 90 days from the required implementation date,

in accordance with 7 CFR 275.12(d)(2)(vii). One commenter requested that the final rule clarify the application of this provision when the regulations are implemented after the required implementation date. As indicated in the preamble to regulations published November 2, 1988 (53 FR 44172), a State agency is eligible for exclusion of implementation variances from the date of actual implementation by the agency through the 90th day of required implementation. Implementation at any time during the 90-day variance exclusion period entitles the State agency to exclude implementation variances for the remainder of the 90-day period. Therefore, a State agency is entitled to at least a partial exclusion if it implemented provisions of the interim rule prior to November 1, 1991.

Technical Amendment

The interim rule also revised the authority citation for parts 271 through 285 which appears after the Table of Contents for each part. The authority citation was revised to read "7 U.S.C. 2011–2031." The Department is taking this opportunity to again revise the authority citation to include an addition to the Food Stamp Act made by the Leland Act. This final rule revises the citation to read "7 U.S.C. 2011–2032."

Accordingly, the interim rule amending parts 271 through 285 which was published at 56 FR 12843–12845 on March 28, 1991, is adopted as final with the following change:

The authority citation for parts 271–285 is revised to read as follows:

Authority: 7 U.S.C. 2011–2032.

Dated: December 21, 1992.

Phyllis R. Gault,

Acting Administrator.

[FR Doc. 93–116 Filed 1–4–93; 8:45 am]

BILLING CODE 3410-30-M

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 92–097–1]

Witchweed Quarantine and Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are adding sorghum to the list of regulated articles whose interstate movement is restricted to prevent the artificial spread of witchweed. We are also amending the list of suppressive areas under the witchweed quarantine and regulations by adding and deleting specified areas in 10 counties in North Carolina and 1 county in South Carolina. These actions are necessary to impose certain restrictions on the interstate movement of regulated articles and to delete certain unnecessary restrictions on the interstate movement of regulated articles. The intended effect is to prevent the artificial spread of witchweed into noninfested areas of the United States.

DATES: Interim rule effective January 5, 1993. Consideration will be given only to comments received on or before March 8, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–097–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas G. Flanigan, Operations Officer, Domestic and Emergency Operations, PPQ, APHIS, USDA, room 646, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–8247.

SUPPLEMENTARY INFORMATION:

Background

Witchweed (*Striga* spp.), a parasitic plant that feeds off the roots of its host, causes degeneration of corn, sorghum, and other grassy crops. It has been found in the United States only in parts of North Carolina and South Carolina.

The witchweed quarantine and regulations (contained in 7 CFR 301.80 through 301.80–10, and referred to below as the regulations) quarantine the States of North Carolina and South Carolina and restrict the interstate movement of certain articles from regulated areas in the quarantined States for the purpose of preventing the artificial spread of witchweed.

Regulated articles cannot be moved interstate from any quarantined State except under conditions prescribed in the regulations. These conditions include certification, permit, and other requirements before moving certain farm products, commodities, and equipment from regulated areas.

Regulated areas for witchweed are designated as either suppressive areas or generally infested areas. Restrictions are imposed on the interstate movement of regulated articles from both types of areas to prevent the artificial movement of witchweed into noninfested areas. However, the eradication of witchweed is undertaken as an objective only in areas designated as suppressive areas. Therefore, restrictions are also imposed on the interstate movement of regulated articles from generally infested areas into suppressive areas. Currently, there are no areas designated as generally infested areas (any part of a regulated area not designated as a suppressive area in accordance with § 301.80–2).

Designation of Articles as Regulated Articles

We are amending § 301.80(b) by adding sorghum to the list of specified regulated articles.

We are taking this action because sorghum is a host of witchweed. Until recently, sorghum production was limited in North Carolina and negligible in South Carolina. The demand for sorghum as feed for poultry has increased due to the recent growth in the poultry industry in North Carolina and South Carolina. Production of sorghum has grown to match this increased demand. We expect that interstate and intrastate movement of sorghum will result from this increased production, presenting an unacceptable risk of introducing witchweed into noninfested areas.

Designation of Areas as Suppressive Areas

We are amending § 301.80–2a of the regulations, which lists generally infested and suppressive areas, by adding areas in two new counties, Harnett and Lenoir, in North Carolina to the list of suppressive areas. We are also adding areas in Craven, Cumberland, Greene, Pender, and Wayne counties in North Carolina, and areas in Horry County in South Carolina to the list of suppressive areas.

The rule portion of this document lists the suppressive areas for each county. Nonfarm areas, if any, are listed first; farms are then listed alphabetically.

We are taking this action because surveys conducted by the United States Department of Agriculture and State agencies of North Carolina and South Carolina have established that these areas meet one or more of the following conditions specified in § 301.80–2(a) of the regulations: (1) Witchweed has been found in these areas; (2) there is reason to believe that witchweed is present in these areas; (3) it is deemed necessary to regulate these areas because of their

proximity to infestation; or (4) these areas cannot be separated for quarantine enforcement purposes from infested localities. Designation of these areas as regulated areas imposes controls on the movement of regulated articles from these areas and prevents the spread of witchweed to noninfested areas.

Removal of Areas From List of Regulated Areas

We are also amending § 301.80–2a of the regulations by removing areas in Columbus, Cumberland, Duplin, Greene, Pender, Pitt, and Wayne Counties in North Carolina from the list of suppressive areas. There are no deletions for South Carolina.

We are taking this action because we have determined that witchweed no longer occurs in these areas, and there is no longer a basis to continue listing these areas as suppressive areas for the purpose of preventing the artificial spread of witchweed. This action removes unnecessary restrictions on the interstate movement of regulated articles from these areas.

Emergency Action

The Administrator of the Animal and Plant Health Inspection Service has determined that a situation exists that warrants publication of this rule without prior opportunity for public comment. Because of the possibility that witchweed could be spread artificially to noninfested areas of the United States, it is necessary to act immediately to control its spread by adding—(1) Sorghum to the list of regulated articles; and (2) specified areas to the list of suppressive areas in North Carolina and South Carolina. Also, where witchweed no longer occurs, immediate action is needed to delete unnecessary restrictions on the interstate movement of regulated articles.

Since prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest under these conditions, there is good cause under 5 U.S.C. 553 to make it effective upon publication in the **Federal Register**. We will consider comments received within 60 days of publication of this interim rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This interim rule affects the interstate movement of regulated articles from specified areas in North Carolina and South Carolina. Based on information compiled by the U.S. Department of Agriculture, we have determined that approximately 280,907 small entities move these articles interstate from North Carolina and South Carolina. However, this rule affects only 678 of these entities, by removing 593 entities from regulation and placing 85 new entities under regulation.

We have determined that the 593 deregulated entities will realize a combined annual dollar benefit of $39,731. Due, in part, to the reduction in regulatory and control costs, each deregulated entity will realize an average annual dollar benefit of $67. Approximately $40 of the $67 benefit represents increased revenue due to gained interstate markets.

Sixty-five of the newly-regulated small entities produce sorghum. The remaining 20 are affected as a result of additions to the list of suppressive areas. We estimate that the 85 newly-regulated entities will need to invest approximately $20 each, per year, in order to comply with our regulations. Implementation of this rule will also result in lost interstate markets for the newly-regulated entities. We estimate that annual income for each impacted entity will be reduced by about $40 annually. Therefore, the total cost for each of the 85 newly-regulated entities will be about $60 per year.

In the instances where this interim rule removes specified areas from the list of suppressive areas, this rule will enable freer movement of goods and services across State lines. Consumers will benefit from lower prices and quicker access to products from the 593 entities removed from the list of suppressed areas. Overall, we expect that this rule will enhance the ability of small entities to market products interstate.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 7 CFR part 301 is amended to read as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.17, 2.51, and 371.2(c).

2. In § 301.80, paragraph (b) is amended by redesignating paragraphs (b)(17) through (b)(21) as paragraphs (b)(18) through (b)(22) and adding a new paragraph (b)(17) to read as follows:

§ 301.80 Quarantine; restriction on interstate movement of specified regulated articles.

* * * * *

(b) * * *

(17) Sorghum.

* * * * *

3. In § 301.80–2a, the list of suppressive areas is amended by

adding, in alphabetical order, Hartnett and Lenoir Counties in North Carolina and the following areas in the counties of Craven, Cumberland, Greene, Pender, and Wayne in North Carolina and Horry in South Carolina:

§ 301.80–2a Regulated areas; generally infested and suppressive areas.

* * * * *

North Carolina

(1) * * *
(2) * * *

* * * * *

Craven County.

* * * * *

The Nobles, Jr., Jack, farm located on the west side of State Secondary Road 1262 and located 0.7 mile south of the intersection of State Secondary Road 1258 and State Secondary Road 1262.

* * * * *

Cumberland County.

* * * * *

The Lee, Jack, farm located on the west side of State Secondary Road 1716 and 0.1 mile north of its intersection with State Secondary Road 1717.

* * * * *

Greene County. The Alexander, Jenny, farm located on the west side of State Secondary Road 1419 and 0.3 mile south of its intersection with North Carolina Highway 903.

* * * * *

The Wood, Nina, farm located on the southwest side of the intersection of State Secondary Roads 1400 and 1418.

Harnett County. The Hicks, Vashti, farm located on the south side of State Secondary Road 2039 and 0.4 mile west of its intersection with State Secondary Road 2031.

The Jeter, James, farm located down a private lane off the south side of State Highway 27 at its intersection with State Secondary Road 1200.

The Womack, E.H., farm located on the east side of State Highway 27 and 1 mile north of its intersection with State Highway 24.

Lenoir County. The Dawson, Wayne, farm located on the east side of State Secondary Road 1318 and 0.25 mile north of its intersection with State Secondary Road 1316.

The Howell, Gregor, farm located on the northeast side of the intersection of State Secondary Roads 1310 and 1318.

The Pelletier, Roger, farm located on the northeast side of State Secondary Road 1316 and 0.3 mile northwest of its intersection with State Secondary Road 1318.

The Sutton, Nancy, farm located on the south side of State Secondary Road 1330 and 0.5 mile east of its intersection with State Secondary Road 1331.

The Waters, Thomas, Estate farm located on both sides of State Secondary Road 1318 and 0.3 mile north of its intersection with State Secondary Road 1317.

Pender County.

* * * * *

The Salomon, Gwendolyn S., farm located on a field road 1.7 miles east of U.S. Highway 117 and 0.3 mile south of its intersection with State Secondary Road 1411.

* * * * *

The Thompson, Dick, farm located on the south side of State Secondary Road 1108 and 0.5 mile northwest of its intersection with State Secondary Road 1107.

The Williams, Sidney, farm located on a field road 0.2 mile north of State Secondary Road 1102 and 1.0 mile northwest of its intersection with North Carolina Highway 210.

The Zibelin, John R., farm located 0.5 mile east of Secondary Road 1105 and 1.2 miles south of its intersection with State Secondary Road 1104.

* * * * *

Wayne County.

* * * * *

The Jones, Mary, farm located on the west side of State Secondary Road 1731 at its intersection with State Secondary Road 1730.

* * * * *

South Carolina

(1) * * *
(2) * * *

* * * * *

Horry County.

* * * * *

The Thomas, Fred, farm located on the west side of a dirt road and 0.1 mile northwest of State Primary Highway 90, this intersection being 3.2 miles south of the intersection of State Primary Road 90 with State Secondary Road 31.

The Thomas, Hubert, farm located on the west side of a dirt road and 0.3 mile northwest of State Primary Highway 90, this intersection being 3.2 miles south of the intersection of State Primary Road 90 with State Secondary Road 31.

The Thomas, J.R., farm located on the west side of a dirt road and 0.2 mile northwest of State Primary Highway 90, this intersection being 3.2 miles south of the intersection of State Primary Road 90 with State Secondary Road 31.

* * * * *

4. In § 301.80–2a, the list of suppressive areas is amended by removing the following areas in Columbus, Cumberland, Duplin, Greene, Pender, Pitt, and Wayne Counties in North Carolina:

a. In Columbus County, The Harmon,Thelma, (formerly the Lloyd Spaulding farm) and The Walters, Eugene, farm.

b. In Cumberland County, The McLaurin, McLaurin, farm; The Mclaurin, Octavious, farm; The Shirman, Harry, farm; and The Smith, Agnes, farm.

c. In Duplin County, The Holland, William, farm; The Lee, Daphne, farm; The Miller, O'Berry, farm; The Thomas, J.R., farm; and The Tyner, J.R., farm.

d. In Greene County, The Williams, Minnie, farm.

e. In Pender County, The Anderson, Julian W., farm; The Batson, Arthur, farm; The Dees, Betty, farm; The Hardie, George, farm; The Hicks, Carol, farm; The Larkins, C.E., farm; The Marshall, Crawford, farm; The Marshall, Milvin, farm; The Terrell, Nancy, farm; and The William, Leroy, farm.

f. In Pitt County, The Hodges, M.B., farm.

g. In Wayne County, The Daniels, Riley, farm; The George-Pacific Corp., farm; The Greenfield, Charlie, farm; The Greenfield, Mattie, farm; and The Humphrey, Josephine, farm.

5. In § 301.80–2a, in the list of suppressive areas for Greene County in North Carolina, the listing for "The Dun, Jo, Estate farm" is corrected to read "The Dunn, Joe, Estate farm".

Done in Washington, DC, this 30th day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–65 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–34–M

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7 CFR Part 301

[Docket 92–033–2]

Mexican Fruit Fly; Removal From the Quarantined Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: We are amending the Mexican fruit fly regulations by removing the quarantined area in Los Angeles County, CA, from the list of areas regulated because of the Mexican fruit fly, and by removing California from the list of States quarantined because of the Mexican fruit fly. We have determined that the Mexican fruit fly has been eradicated from California, and that restrictions are no longer necessary to prevent the spread of the Mexican fruit fly into noninfested areas of the United States. This action relieves unnecessary

restrictions on the interstate movement of regulated articles from the previously regulated area.

DATES: Interim rule effective December 30, 1992. Consideration will be given only to comments received on or before March 8, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–033–2. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Stefan, Operations Officer, Domestic and Emergency Operations, PPQ, APHIS, USDA, room 640, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–8247.

SUPPLEMENTARY INFORMATION:

Background

The Mexican fruit fly, *Anastrepha ludens* (Loew), is an extremely destructive pest of citrus and many other types of fruits. The short life cycle of the Mexican fruit fly allows rapid development of serious outbreaks that can cause severe economic losses in commercial citrus-producing areas. The Mexican fruit fly regulations, contained in 7 CFR 301.64 through 301.64–10 (referred to as the regulations), quarantine infested States, designate regulated areas, and restrict the interstate movement of regulated articles from regulated areas in order to prevent the spread of the Mexican fruit fly to noninfested areas.

In an interim rule effective December 31, 1991, and published in the **Federal Register** on January 7, 1992 (57 FR 519–522, Docket No. 91–174), we quarantined the State of California and designated a portion of Los Angeles County, near Maywood, as a regulated area because that area had been found to be infested with the Mexican fruit fly. In a document effective March 27, 1992, and published in the **Federal Register** on April 1, 1992 (57 FR 10973–10974, Docket No. 92–033), we expanded the regulated area in Los Angeles County to include an area of the county near Norwalk and Bellflower.

Based on insect trapping surveys by inspectors of California State and county agencies and by inspectors of the Animal and Plant Health Inspection Service, we have determined that the Mexican fruit fly has been eradicated from the regulated area in Los Angeles County, CA. The last finding of Mexican fruit fly thought to be associated with the infestation in this area was made on March 17, 1992.

Since then, no evidence of Mexican fruit fly infestations has been found in this area. We have determined that the Mexican fruit fly no longer exists in Los Angeles County, and we are therefore removing it from the list of areas in § 301.64–3(c) regulated because of the Mexican fruit fly. As a result of this action there is no longer an area in California regulated because of the Mexican fruit fly. Because we have determined that the Mexican fruit fly no longer exists in California, we are removing California from the list in § 301.64–3 of States quarantined because of the Mexican fruit fly.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. The area in California affected by this document was regulated due to the possibility that the Mexican fruit fly could be spread to noninfested areas of the United States. Since this situation no longer exists, and the continued regulated status of this area would impose unnecessary restrictions on the public, we are taking immediate action to remove the restrictions.

Since prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest under these conditions, there is good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments received within 60 days of publication of this interim rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**, including a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

This regulation removes restrictions on the interstate movement of regulated articles from a portion of Los Angeles County, CA. Within this regulated area there are approximately 835 entities that could be affected, including 270 fruit/produce markets, 113 nurseries, 6 flea markets, 3 processors, 430 mobile fruit vendors, 3 farmers' markets, 5 growers of lemons and oranges on 4 acres, and 5 wholesale distributors. These entities comprise less than 1 percent of the total number of similar entities operating in the State of California.

The effect of this rule on these entities should be insignificant since most of these small entities handle regulated articles primarily for local intrastate movement, not interstate movement, and the distribution of these articles was not affected by the regulatory provisions we are removing.

Many of these entities also handle other items in addition to the previously regulated articles so that the effect, if any, on these entities is minimal. Further, the conditions in the Mexican fruit regulations and treatments in the Plant Protection and Quarantine Treatment Manual, incorporated by reference in the regulations, allowed interstate movement of most articles without significant added costs.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings

before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This document contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 7 CFR part 301 is amended to read as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for 7 CFR part 301 continues to read as follows:

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.17, 2.51, and 371.2(c).

§ 301.64 [Amended]

2. In § 301.64, paragraph (a), the phrase "the States of California and Texas" is removed and the phrase "the State of Texas" is added in its place.

§ 301.64–3 [Amended]

3. In § 301.64–3, paragraph (c) is amended by removing the entry for "California" and the description of the regulated area for Los Angeles County, CA.

Done in Washington, DC, this 30th day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–64 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–34–M

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7 CFR Part 354

[Docket No. 92–175–1]

Commuted Traveltime Periods

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning overtime services provided by employees of Plant Protection and Quarantine (PPQ) by removing and adding commuted traveltime allowances for travel between Green Bay and Milwaukee, Wisconsin. Commuted traveltime allowances are the periods of time required for PPQ employees to travel from their dispatch points and return there from the places where they perform Sunday, holiday, or other overtime duty. The Government charges a fee for certain overtime services provided by PPQ employees and, under certain circumstances, the fee may include the cost of commuted traveltime. This action is necessary to inform the public of commuted traveltime for these locations.

EFFECTIVE DATE: January 5, 1993.

FOR FURTHER INFORMATION CONTACT: George H. McFadden, Jr., Director, Resource Management Support, PPQ, APHIS, USDA, room 458, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7764.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR, chapter III, and 9 CFR, chapter I, subchapter D, require inspection, laboratory testing, certification, or quarantine of certain plants, plant products, animals and animal byproducts, or other commodities intended for importation into, or exportation from, the United States. When these services must be provided by an employee of PPQ on a Sunday or holiday, or at any other time outside the PPQ employee's regular duty hours, the Government charges a fee for the services in accordance with 7 CFR part 354. Under circumstances described in § 354.1(a)(2), this fee may include the cost of commuted traveltime. Section 354.2 contains administrative instructions prescribing commuted traveltime allowances, which reflect, as nearly as practicable, the periods of time required for PPQ employees to travel from their dispatch points and return there from the places where they perform Sunday, holiday, or other overtime duty.

We are amending § 354.2 of the regulations by removing and adding commuted traveltime allowances for travel between Green Bay and Milwaukee, Wisconsin. The amendments are set forth in the rule portion of this document. This action is necessary to inform the public of the commuted traveltime between the dispatch and service locations.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The number of requests for overtime services of PPQ employee at the locations affected by our rule represents an insignificant portion of the total number of requests for these services in the United States.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Effective Date

The commuted travel time allowances appropriate for employees performing services at ports of entry, and the features of the reimbursement plan for recovering the cost of furnishing port of entry services, depend upon facts within the knowledge of the Department of Agriculture. It does not appear that public participation in this rulemaking proceeding would made additional relevant information available to the Department.

Accordingly, pursuant to the administrative procedure provisions in 5 U.S.C. 553, we find upon good cause that prior notice and other public procedure with respect to this rule are impracticable and unnecessary; we also find good cause for making this rule effective less than 30 days after publication of this document in the **Federal Register**.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule is intended to have preemptive effect with respect to any state or local laws, regulations, or policies that conflict with its provisions or that would otherwise impede its full implementation. This rule is not intended to have retroactive effect unless so specified in the "Effective Date" section of this preamble. There are no administrative procedures that must be exhausted prior to any judicial

challenge to the provisions of this rule or the application of its provisions.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 354

Exports, Government employees, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Travel and transportation expenses.

Accordingly, 7 CFR part 354 is amended as follows;

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS; AND USER FEES

1. The authority citation for part 354 continues to read as follows:

Authority: 7 U.S.C. 2260, 21 U.S.C. 136 and 136a; 49 U.S.C. 1741; 7 CFR 2.17, 2.51, and 371.2(c).

2. Section 354.2 is amended by removing or adding in the table, in alphabetical order, the information as shown below:

§ 354.2 Administrative instructions prescribing commuted traveltime.

* * * * *

COMMUTED TRAVELTIME ALLOWANCES

[In hours]

Location covered	Served from	Metropolitan area	
		Within	Outside
Remove:			
* * * * *			
Wisconsin:			
Green Bay	Milwaukee	.....	6
* * * * *			
Add:			
* * * * *			
Wisconsin:			
Green Bay	Milwaukee	.....	4
* * * * *			

Done in Washington, DC, this 30th day of December 1992.

Lennie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–66 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–34–M

Agricultural Marketing Service

7 CFR Part 921

[Docket No. FV92–921–1]

Suspension of Provisions of Marketing Order 921; Fresh Peaches Grown in Designated Counties in Washington

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Suspension and referendum order.

SUMMARY: This action suspends all provisions of Federal Marketing Order No. 921 for peaches grown in designated counties in Washington, and the rules and regulations issued thereunder. This action directs that a referendum be conducted among eligible growers to determine whether they favor continuance of the Federal marketing order regulating the handling of their fruit. This action is taken as a result of a recommendation for suspension made by the Washington Fresh Peach Marketing Committee (committee), the agency responsible for local administration of the order. The committee's recommendation was based on the Washington State Department of Agriculture's promulgation of handling regulations on fresh peaches comparable to those that are in place under the Federal marketing order. The committee believes that with the duplication of regulations, continuing to fund the Federal marketing order is an unnecessary expense.

EFFECTIVE DATE: March 31, 1993. The representative production period for the referendum is July 1–September 30, 1993. The referendum will be conducted during the period November 13–December 10, 1993.

FOR FURTHER INFORMATION CONTACT: Gary D. Olson, Northwest Marketing Field Office, 1220 SW. Third Avenue, room 369, Portland, Oregon 97204, telephone 503–326–2724, or Ken Johnson, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC 20090–6456, telephone 202–690–3670.

SUPPLEMENTARY INFORMATION: The Marketing Agreement and Order No. 921 (7 CFR part 921) regulates the handling of peaches grown in designated counties in Washington. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act." The suspension action is being taken under the provisions of section 8c(16)(A) of the Act.

The referendum will be conducted in accordance with the procedure for the conduct of referenda to determine whether continuation of the marketing order is favored by producers, who during the representative period were engaged in the production of peaches grown in designated counties in Washington. The procedure applicable to the referenda is the "Procedure for the Conduct of Referenda in Connection with Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended" (7 CFR 900.400 *et seq.*). The representative period for the conduct of such referendum is hereby determined to be July 1 through September 30, 1993.

This action has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This action has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This action will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has as his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are

brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 65 handlers of Washington peaches who are subject to regulation under the marketing order and approximately 890 peach producers. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000. Small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of these handlers and producers may be classified as small entities.

Marketing Order 921 has been in effect since 1960. The order provides for the establishment of grade, size, quality, maturity, pack and container, and inspection requirements. In addition, the order authorizes marketing research and development. It also provides for reporting and recordkeeping requirements on affected handlers. The production and marketing season runs from late July to early October.

The committee met on May 12, 1992, and by an 11 to 1 vote recommended that the marketing order be suspended at the end of the 1992–93 fiscal period. The recommendation was made to eliminate the expense of administering the marketing order. The committee's recommendation was based on the Washington State Department of Agriculture's (State) promulgation of handling regulations on intrastate shipments of fresh peaches. The State handling regulations are similar to those regulations that are in place under the Federal marketing order. With this duplication of regulations, the committee believes that continuing to fund the Federal program is an unnecessary expense. While the marketing order authorizes marketing research and development projects, this provision has been inactive for many years.

The committee recommended suspension, not termination, of the marketing order to allow the industry an opportunity to review the effectiveness of operating only under State handling regulations. If problems develop, the committee wants the industry to have the alternative of reactivating the Federal marketing order. Evidence indicates that the committee and the industry continue to support the need for grade, size, quality, maturity, pack and container, and inspection requirements.

The industry will have the opportunity to monitor the effectiveness of the State handling regulations, without Federal marketing order regulations in effect, during the next marketing season. After that season is completed, the Department will conduct a referendum of eligible growers to determine whether they favor continuance of the Federal marketing order.

Thus, it is determined that Federal Marketing Order 921 and the rules and regulations issued thereunder do not tend to effectuate the declared policy of the Act. This action suspends, effective March 31, 1993, for an indefinite period, provisions of Federal Marketing Order 921 and the rules and regulations issued thereunder, including:

(1) Provisions of the order dealing with the establishment and responsibilities of the committee and the administration of the order;

(2) The grade, size, quality, maturity, pack and container, and inspection requirements;

(3) The administrative rules and regulations related to special purpose shipments; and

(4) Information collection and reporting requirements (In compliance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), such requirements have been approved by the Office of Management and Budget and assigned OMB Control No. 0581–0097).

It is also found and determined, upon good cause, that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice or to engage in further public procedure with respect to this action because:

(1) This action relieves restrictions on handlers by suspending the requirements regulating the handling of peaches pursuant to M.O. 921;

(2) Handlers are aware of this action, which was discussed and recommended at public meetings held by the committee;

(3) A grower referendum will be conducted prior to deciding whether to continue or terminate the program; and

(4) No useful purpose would be served by delaying the suspension of the marketing order.

The committee shall, for the purpose of liquidating the affairs of the committee, continue as trustees of all the funds and property in its possession, or under its control, including claims for any funds unpaid or property not delivered.

The said trustees shall:

(1) Continue in such capacity until discharged by the Secretary;

(2) From time to time account for all receipts and disbursements and deliver all property on hand, together with all books and records of the committee and of the trustees, to such persons as the Secretary may direct; and

(3) Upon the request of the Secretary, execute such assignments or other instruments necessary or appropriate to vest in such person, full title and right to all of the funds, property, and claims vested in the committee or the trustees pursuant hereto.

Any person to whom funds, property, or claims have been transferred or delivered, shall be subject to the same obligation imposed upon the committee and upon the trustees.

After a statement of total claims and debts, remaining funds held in the reserve account will be returned, on a pro rata basis, to those handlers who paid assessments under M.O. 921 during one or more of the 1990–91, 1991–92 and 1992–93 fiscal years.

The Secretary of Agriculture (Secretary) has the authority to conduct a continuance referendum to determine whether growers affected by a marketing order favor continuance of their order. The Secretary has determined that continuance referenda are an effective means for ascertaining whether growers favor continuance of marketing order programs.

The Secretary would consider termination of the order if less than two thirds of the peach growers voting in the referendum and growers of less than two-thirds of the volume of such fruit represented in the referendum, favor continuance. In evaluating the merits of continuance versus termination, the Secretary would consider the results of the continuance referendum, other relevant information concerning the operation of the order, and the relative benefits and disadvantages to growers, handlers, and consumers. Through such analysis, the Secretary would determine whether continued existence of the order would tend to effectuate the declared policy of the Act.

In any event section 8c(16)(B) of the Act requires the Secretary to terminate an order whenever the Secretary finds that a majority of all growers favor termination, and that majority produced for market more than 50 percent of the commodity covered by the order.

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the ballot material that will be used in the referendum herein ordered has been submitted to and approved by the Office of Management and Budget (OMB) and has been assigned OMB No. 0581–0097. It has been estimated that it will take an average of 10 minutes to read and complete the ballot for each of the approximately 150 growers who elect to

participate in the voluntary referendum balloting.

It is hereby directed that a referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR 900.400 *et seq.*) to determine whether continuance of the marketing order regulating the handling of Washington peaches is approved or favored by producers who during the representative period were engaged in the production of peaches grown in designated counties in Washington.

The referendum agents of the Secretary to conduct the referendum are hereby designated as Gary D. Olson and Robert J. Curry, Northwest Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, 1220 SW. Third Ave., room 369, Portland, Oregon, 97204, telephone (503) 326–2724.

Ballots will be mailed to all growers of record. Ballots may also be obtained at County Extension Service Offices or by contacting the USDA Northwest Marketing Field Office.

Copies of the text of Marketing Order No. 921 may be obtained, at the above address, by contacting the referendum agents.

List of Subjects in 7 CFR Part 921

Marketing agreements, Peaches, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 921 is suspended as follows:

PART 921—FRESH PEACHES GROWN IN DESIGNATED COUNTIES IN WASHINGTON

1. The authority citation for 7 CFR part 921 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Part 921—Fresh Peaches Grown in Designated Counties in Washington (7 CFR part 921), and all provisions therein, is suspended effective March 31, 1993, for an indefinite period.

Dated: December 29, 1992.

John E. Frydenlund,

Deputy Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–63 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–02–M

Farmers Home Administration

7 CFR Parts 1822, 1823, 1900, 1901, 1910, 1941, 1942, 1943, 1944, 1945, 1948, 1951, and 1980

RIN 0575–AA64

Processing and Servicing FmHA Assistance to Employees, Relatives and Associates

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: Farmers Home Administration (FmHA) issues new regulations on processing and servicing FmHA assistance to FmHA employees, members of their families, known close relatives and associates. This action is taken to prevent employees from being directly involved in the processing or servicing of authorized FmHA program assistance to those with whom they have business or close personal associations. The intended effect is to reduce agency vulnerability to employee conflict of interest.

EFFECTIVE DATE: These rules become effective February 4, 1993.

FOR FURTHER INFORMATION CONTACT: Joyce M. Halasz, Senior Realty Specialist, Property Management Branch, Single Family Housing Servicing and Property Management Division, Room 5307–S, (202) 720–1452.

SUPPLEMENTARY INFORMATION: FmHA Instruction 2045–BB, Employee Responsibilities and Conduct (available in any FmHA office), requires the maintenance of high standards of honesty, integrity, and impartiality by FmHA employees. To reduce the potential for employee conflict of interest, any processing, approval, servicing or review activity, including access to automated information systems, is conducted only by authorized FmHA employees who (1) are not themselves the recipient; (2) are not members of the family or known close relatives of the recipient; (3) do not have an immediate working relationship with the recipient, the employee related to the recipient, or the employee who would normally conduct the activity; or (4) do not have a business or close personal association with the recipient. Nothing in the rule takes precedence over individual program requirements or restrictions. A reference to this rule and its requirements is added to the regulations of each of the programs affected.

Classification

This action has been reviewed under USDA procedures in Departmental Regulation 1512–1, which implements Executive Order 12291 and has been determined to be "nonmajor" since the annual effect on the economy is less than $100 million and there will be no significant increase in cost or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions. Furthermore, there will be no adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises to compete with foreign based enterprises in domestic or import markets. This action is not expected to substantially affect budget outlay or affect more than one agency or to be controversial.

Background/Discussion

On July 16, 1985, the Office of Inspector General (OIG) presented results of a FmHA Nationwide Audit of County Office Operations (04642–1–Te) which revealed that the agency's internal control process, a major administrative control, did not cover program assistance provided to close relatives of FmHA employees. OIG recommended changing regulations to prevent those with loan approval authority from approving loans to their close relatives. The agency determined the OIG finding and related areas of vulnerability should be addressed in single regulation governing all stages of processing and servicing any authorized program assistance provided to FmHA employees, members of their families, known close relatives and business or close personal associates.

On July 9, 1990, FmHA published a proposed rule (55 FR 28057) on processing and servicing FmHA assistance to employees, relatives and associates. Two comments were received. One comment from an employee requested an explanation of the reasons why an employee may or may not be permitted to obtain a particular type of FmHA loan or grant assistance and indicated that a closing agent's eligibility for FmHA program benefits should be discussed. This action does not in any way affect the eligibility of an employee or a closing agent for FmHA program benefits; therefore, the requested discussions are beyond the scope of this action. Comments from an employee organization requested clarification of certain administrative provisions which will be provided with instructions for program implementation. Other changes were made to the proposed rule as a result of more detailed analysis by program officials during the final rule clearance process. These changes:

—Revised the definition of employee to clarify the status of county or area committee members and closing agents.
—Added a reference to assure that prohibited processing and servicing activity also prohibited access to automated loan records.
—To simplify reporting and review procedures, provided that assistance usually processed and serviced at the County level would be reassigned only to another County Office, and at the District level only to another District Office. This necessitated removal of proposed provisions for default servicing.
—Clarified the responsible officials for assistance processed and serviced at a State Office and for assistance to relatives or associates of a State Director.
—Added a reference to clarify the source of funds to be obligated.
—Added provisions for handling acquired property case files.
—Replaced several ambiguous references to FmHA officials with the term "processing/servicing official."
—Made several minor editorial and grammatical changes which clarify but do not affect the proposed meaning or intent.

In addition, while the proposed rule published the entire FmHA Instruction, the final rule omits internal management and operating procedures. In the past, FmHA regulations published in the **Federal Register** and FmHA Instructions distributed to FmHA field offices have been identical, comprised of regulations as well as internal management and operating procedures. The agency has adopted a policy of publishing only FmHA regulations which confer an entitlement or benefit or impose an obligation on the public. FmHA Instructions distributed to FmHA field offices will include regulations and internal management and operating procedures and are available to the public on request.

Programs Affected

The programs affected are listed in the Catalog of Federal Domestic Assistance under:

10.404 Emergency Loans
10.405 Farm Labor Housing Loans and Grants
10.406 Farm Operating Loans
10.407 Farm Ownership Loans
10.410 Low Income Housing Loans
10.411 Rural Housing Site Development Loans
10.414 Resource Conservation and Development Loans
10.415 Rural Rental Housing Loans
10.416 Soil and Water Loans
10.417 Very Low-Income Housing Repair Loans and Grants
10.418 Water and Waste Disposal Systems for Rural Communities
10.419 Watershed Protection and Flood Prevention Loans
10.420 Rural Self-Help Housing Technical Assistance
10.421 Indian Tribes and Tribal Corporation Loans
10.422 Business and Industrial Loans
10.423 Community Facilities Loans
10.424 Rural Business Enterprise Grants and Television Demonstration Grants
10.427 Rural Rental Assistance Payments
10.428 Economic Emergency Loans
10.433 Housing Preservation Grants
10.434 Nonprofit National Corporation Loan and Grant Program
10.437 Rural Development Loan Fund
10.438 Intermediary Relending Program

Intergovernmental Consultation

This activity affects all FmHA financial assistance programs listed above which are subject to Executive Order 12372 which requires intergovernmental consultation with State and local officials (7 CFR 3015, subpart V).

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

List of Subjects

7 CFR Part 1822

Aged, Loan programs—Housing and community development, Low and moderate income housing, Mortgages, Nonprofit corporations, Rent subsidies, Rural housing.

7 CFR Part 1823

Credit, Indians.

7 CFR Part 1900

Administrative practice and procedure, Government employees, Conflict of interest, Federal aid programs, Rural areas, Low and moderate income housing, Loan programs—Housing and community development, Loan programs—Agriculture.

7 CFR Part 1901

Agriculture, Authority delegations.

7 CFR Part 1910

Applications, Credit, Loan programs—Agriculture, Loan programs—Housing and community development, Low and moderate income housing, Marital status discrimination, Sex discrimination.

7 CFR Part 1941

Crops, Livestock, Loan programs—Agriculture, Rural areas, Youth.

7 CFR Part 1942

Business and industry, Community development, Community facilities, Grant programs—Housing and community development, Industrial park, Loan programs—Housing and community development, Loan programs—Natural resources, Loan security, Rural areas, Soil conservation, Waste treatment and disposal—Domestic, Water supply—Domestic.

7 CFR Part 1943

Credit, Loan programs—Agriculture, Recreation, Water resources.

7 CFR Part 1944

Administrative practice and procedure, Aged, Farm labor housing, Grant programs—Housing and community development, Handicapped, Home improvement, Loan programs—Housing and community development, Low and moderate income housing—Rental, Migrant labor, Mobile homes, Mortgages, Nonprofit organizations, Public housing, Rent subsidies, Reporting and recordkeeping requirements, Rural housing, Subsidies.

7 CFR Part 1945

Agriculture, Disaster assistance, Intergovernmental relations, Livestock, Loan programs—Agriculture.

7 CFR Part 1948

Business and industry, coal, Community development, Community facilities, Energy, Grant programs—Housing and community development, Housing, Nuclear energy, Planning, Rural areas, Transportation, Credit, Economic development.

7 CFR Part 1951

Account servicing, Debt restructuring, Credit, Loan programs—Agriculture, Loan programs—Housing and community development, Low and moderate income housing loans—Servicing.

7 CFR Part 1980

Agriculture, Grant programs—Nonprofit corporations, Home improvement, Livestock, Loan programs—Agriculture, Loan programs—Housing and community development, Mortgage insurance, Mortgages, Rural areas, Loan

programs—Community programs—Rural development assistance.

Therefore, chapter XVIII, title 7, Code of Federal Regulations, is amended as follows:

PART 1822—RURAL HOUSING LOANS AND GRANTS

1. The authority citation for part 1822 continues to read as follows:

Authority: Sec. 510, 63 Stat. 437, 42 U.S.C. 1480; Orders of Secy. of Agr., 29 FR 16210, 32 FR 6650.

Subpart G—Rural Housing Site Loan Policies, Procedures, and Authorizations

2. Section 1822.261 is amended by adding new text after the sentence to read as follows:

§ 1822.261 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

PART 1823—ASSOCIATION LOANS AND GRANTS–COMMUNITY FACILITIES, DEVELOPMENT, CONSERVATION, UTILIZATION

3. The authority citation for part 1823 continues to read as follows:

Authority: 7 U.S.C. 1989; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart N—Loans to Indian Tribes and Tribal Corporations

4. Section 1823.401 is amended by adding new text after the first sentence to read as follows:

§ 1823.401 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

PART 1900—GENERAL

5. The authority citation for part 1900 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

6. Part 1900 is amended by adding subpart D to read as follows:

Subpart D—Processing and Servicing FmHA Assistance to Employees, Relatives, and Associates

Sec.

1900.151 General.
1900.152 Definitions.
1900.153 Identifying and reporting an employee relationship.
1900.154 Determining the need for special handling.
1900.155 Designating the processing/servicing official.
1900.156 Special handling-processing.
1900.157–1900.200 [Reserved]

PART 1900—GENERAL

Subpart D—Processing and Servicing FmHA Assistance to Employees, Relatives, and Associates

§ 1900.151 General.

(a) Farmers Home Administration (FmHA) Instruction 2045–BB (available in any FmHA office) requires the maintenance of high standards of honesty, integrity, and impartiality by employees. To reduce the potential for employee conflict of interest, any processing, approval, servicing or review activity, including access through automated information systems, is conducted only by authorized FmHA employees who:

(1) Are not themselves the recipient.

(2) Are not members of the family or known close relatives of the recipient.

(3) Do not have an immediate working relationship with the recipient, the employee related to the recipient, or the employee who would normally conduct the activity.

(4) Do not have a business or close personal association with the recipient.

(b) No provision of this subpart takes precedence over individual program requirements or restrictions, especially those restrictions found in FmHA Instruction 2045–BB (available in any FmHA office) relating to eligibility for FmHA assistance of FmHA employees, members of families of employees, close relatives, or business or close personal associates of employees.

(c) The determination of a case's need for special handling under the provisions of this subpart is not an adverse action and, therefore, is not subject to appeal.

§ 1900.152 Definitions.

Applicant or borrower. All persons or organizations, individually or collectively, applying for or receiving insured or guaranteed loan or grant assistance from or through FmHA. Referred to as recipient.

Assistance. Loans or grants made, insured or guaranteed, or serviced by FmHA.

Associates. All persons with whom an employee has a business or close personal association or immediate working relationship.

Business association. Business relationship between those with an identity of financial interest; including but not limited to a business partnership, being an officer, director, trustee, partner or employee of an organization, or other long-term contractual relationship.

Close personal association. Social relationship between unrelated residents of the same household.

Close relatives. The spouse, relatives and step-relatives of an employee or the employee's spouse, including Grandmother, Grandfather, Mother, Father, Aunt, Uncle, Sister, Brother, Daughter, Son, Niece, Nephew, Granddaughter, Grandson, and First Cousin.

Conflict of interest. A situation (or the appearance of one) in which one could reasonably conclude that an FmHA employee's private interest conflicts with his or her Government duties and responsibilities, even though there may not actually be a conflict.

Employee. All FmHA personnel, including gratuitous employees and those negotiating for or having arrangements for prospective employment, except as otherwise specifically stated. For the purposes of this instruction only, the term also refers to county or area committee members, elected or appointed, and to closing agents who, although they are not employees, have a special relationship to FmHA and therefore should be subject to these provisions.

Immediate working relationship. A relationship between a subordinate and a supervisor in a direct line, or between co-workers in the same office. For the purposes of this subpart, the relationships among a County Supervisor and members of the local County Committee are immediate working relationships.

Members of family. Blood and in-law relatives (such as by marriage or adoption) who are residents of the employee's household.

Recipient. One who has applied for or received FmHA financial assistance in the form of a loan or grant. See definition of applicant or borrower.

§ 1900.153 Identifying and reporting an employee relationship.

(a) *Responsiblity of applicant.* When an application for assistance is filed, the processing official asks if there is any

known relationship or association with an FmHA employee. The applicant is required to disclose the requested information under subpart A of part 1910 of this chapter and pertinent program regulations.

(b) *Responsibility of FmHA employee.* An FmHA employee who knows he or she is related to or associated with an applicant or recipient, regardless of whether the relationship or association is known to others, is required to notify the FmHA official who is processing or servicing the assistance, in writing. FmHA Guide Letter 1900–D–1 (available in any FmHA office) may be used as the notice. If the appropriate official is not known, the State Director should be notified. Regardless of whether the relationship or association is defined in § 1900.152 of this subpart, if the employee believes there may be a potential conflict of interest, the FmHA official who is processing or servicing the assistance may be notified and special handling requested. An employee's request that the case receive special handling is usually honored.

(c) *Responsibility of FmHA official.* When any relationship or association is identified, the FmHA official completes and submits FmHA Guide Letter 1900–D–2 (available in any FmHA office) to the State Director (or Administrator, under paragraph (e) of this section or § 1900.155(a) of this subpart). When completed FmHA Guide Letter 1900–D–3 (available in any FmHA office) is returned by the State Director, the processing official;

(1) [Reserved]

(2) [Reserved]

(3) notifies the recipient in writing of the change in responsibility and any other pertinent information,

(4) [Reserved]

(d) *Relationship or association established after application for FmHA assistance.* If a relationship or association is established after an application has been filed or assistance has been provided, both recipient and employee are required to notify the FmHA official who is processing or servicing the assistance. FmHA Guide Letter 1900–D–1 (available in any FmHA office) may be used for the notice.

(e) *Relationship or association with a State Office, Finance Office or National Office employee.* If an identified relationship or association is with an employee at a State Office (other than a State Director), Finance Office or National Office, the processing/servicing official completes and submits FmHA Guide Letter 1900–D–2 (available in any FmHA office) to the State Director in the normal manner. The State Director reviews the information, determines the need for special handling, designates the processing/servicing official, completes and submits FmHA Guide Letter 1900–D–3 (available in any FmHA office) to the Administrator for written concurrence. When the Administrator's concurrence is received, the State Director returns completed FmHA Guide Letter 1900–D–3 to the original official who completes the action described in paragraph (c) of this section.

(f) *Relationship or association with a State Director.* If an identified relationship or association is with a State Director, the processing/servicing official completes and submits FmHA Guide Letter 1900–D–2 (available in any FmHA office) to the Administrator. The Administrator reviews, determines the need for special handling, designates the processing/servicing official, completes and returns FmHA Guide Letter 1900–D–3 (available in any FmHA office) to the original official who completes the action described in paragraph (c) of this section.

(g) *Change in relationship or association, status of FmHA assistance, or employee's duty station.* If the relationship or association has changed, the application denied or the assistance otherwise terminated, or the FmHA employee's duty station changed, the designated processing/servicing official completes FmHA Guide Letter 1900–D–2 (available in any FmHA office) with the new information and submits it. The review process takes place as described in paragraphs (a) through (e) of this section to determine if processing/servicing activity may return to normal or requires another change. If the assistance is denied or otherwise terminated, the designated official notifies the original official.

§ 1900.154 Determining the need for special handling.

The State Director (or Administrator, under § 1900.153(e) or § 1900.155(a) of this subpart):

(a) [Reserved]

(b) determines whether the reported relationship or association is defined in § 1900.152 of this subpart and would violate the provisions of § 1900.151(a) of this subpart,

(c) [Reserved]

(d) [Reserved]

(e) [Reserved]

(f) [Reserved]

§ 1900.155 Designating the processing/servicing official.

(a) *Designating an official with equivalent authority.* The State Director (or Administrator, under § 1900.253(e) of this subpart or this paragraph) designates a nonrelated or nonassociated FmHA official authorized to conduct the activity under program regulations, established delegation of authority and approval authority under subpart A of part 1901 of this chapter, and whose duty station is most convenient to the recipient and to the security property. A type and/or amount of assistance processed or serviced by a County Supervisor or at a County Office should be assigned only to another County Supervisor or County Office. A type and/or amount of assistance processed or serviced by a District Director or at a District Office should be assigned only to another District Director or District Office.

(b) *County Committee.* For processing or servicing decisions to be made by a County Committee, if the recipient is a member, a different County Committee is designated. If the recipient is related to or associated with the member, notwithstanding the provisions of § 1900.151(a)(3) of this subpart, the State Director *may* permit the decision to be made by the local committee, if the related/associated member abstains.

(c) [Reserved]

§ 1900.156 Special handling—processing.

(a) [Reserved]

(b) *Eligibility determination.* The designated processing official reviews the application and develops additional data as necessary. Upon determination of whether the assistance will be provided, the designated processing official notifies the applicant of the decision in writing under program regulations, subpart A of part 1910 of this chapter, and subpart B of part 1900. If the determination is favorable, unless otherwise designated, the complete application is returned to the original processing official for docket preparation. If the determination is unfavorable, the designated processing official as decisionmaker participates in the appeal process to its conclusion.

(c) [Reserved]

(d) [Reserved]

(e) [Reserved]

(f) *Closing agent.* Unless there is a clear or apparent conflict of interest, closing will be at a location and by a closing agent chosen by the recipient.

(g) *Supervised bank account.* Unless there is a clear or apparent conflict of interest, any supervised bank account (or construction account) is established at a financial institution chosen by the recipient under supbart A of part 1902 of this chapter. Countersignature authority is delegated only to a nonrelated or nonassociated FmHA official.

(h) *Construction inspection.* Construction inspections are delegated to a nonrelated or nonassociated employee authorized to conduct inspections, whose duty station is nearest the construction site. The designated processing/servicing official notifies the builder (or architect/engineer) in writing of how and from whom to request inspections.

§§ 1900.157–1900.200 [Reserved]

PART 1901—PROGRAM-RELATED INSTRUCTIONS

Subpart A—Loan and Grant Approval Authorities

7. The authority citation for part 1901 continues to read as follows:

Authority: 42 U.S.C. 1480, 7 U.S.C. 1819, 5 U.S.C. 301; sec. 10, Pub.L. 93–357, 88 Stat. 392; Title II of the Emergency Agricultural Adjustment Act of 1978, 92 Stat. 429, 7 CFR 2.23; 7 CFR 2.70.

8. Section 1901.2 is amended by adding new text after the first sentence to read as follows:

§ 1901.2 Policy.

* * * Assistance to FmHA employees, members of their families, close relatives or business or close personal associates is subject to the provisions of subpart D of part 1900 of this chapter. * * *

PART 1910—GENERAL

9. The authority citation for part 1910 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Receiving and Processing Applications

10. Section 1910.3(a)(7) is added to read as follows:

§ 1910.3 Receiving applications.

* * * * *

(a) * * *

(7) Applicants are asked to identify any known relationship or association with an FmHA employee when completing the application. When there is a relationship or association, the processing official must complete the action required under subpart D of part 1900 of this chapter.

* * * * *

11. Section 1910.4 introductory text is amended by adding the following language at the end of the paragraph:

§ 1910.4 Processing applications.

* * * Applications of FmHA employees, members of their families, close relatives, or business or close personal associates are processed according to subpart D of part 1900 of this chapter.

* * * * *

PART 1941—OPERATING LOANS

12. The authority citation for part 1941 continues to read as follows:

Authority: 7 U.S.C. 1989; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Operating Loan Policies, Procedures, and Authorizations

13. Section 1941.1 is amended by adding new text after the fourth sentence to read as follows:

§ 1941.1 Introduction.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

PART 1942—ASSOCIATIONS

14. The authority citation for part 1942 continues to read as follows:

Authority: 7 U.S.C. 1989; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Community Facility Loans

15. Section 1942.1(a) is amended by adding the following language at the end of the paragraph:

§ 1942.1 General.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

* * * * *

Subpart C—Fire and Rescue Loans

16. Section 1942.101 if amended by adding new text after the first sentence to read as follows:

§ 1942.101 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

Subpart G—Rural Business Enterprise Grants and Television Demonstration Grants

17. Section 1942.301 is amended by adding the following language at the end of the paragraph:

§ 1942.301 Purposes.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

Subpart H—Development Grants for Community Domestic Water and Waste Disposal Systems

18. Section 1942.351(a) is amended by adding new text after the first sentence to read as follows:

§ 1942.351 General.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to Farmers Home Administration (FmHA) employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employe. * * *

* * * * *

Subpart I—Resource Conservation and Development (RCD) Loans and Watershed (WS) Loans and Watershed Advances

19. Section 1942.402(a) is amended by adding new second and third sentences to read as follows:

§ 1942.402 Policy.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify

any known relationship or association with an FmHA employee. * * *
* * * * * *

Subpart J—Technical Assistance and Training Grants

20. Section 1942.451 is amended by adding the following language at the end of the paragraph:

§ 1942.451 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to Farmers Home Administration (FmHA) employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

Subpart K—Emergency Community Water Assistance Grants

21. Section 1942.501(a) is amended by adding the following language at the end of the paragraph:

§ 1942.501 General.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.
* * * * * *

PART 1943—FARM OWNERSHIP, SOIL AND WATER AND RECREATION

22. The authority citation for part 1943 continues to read as follows:

Authority: 7 U.S.C. 1989; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart A—Insured Farm Ownership Loan Policies, Procedures and Authorizations

23. Section 1943.1 is amended by adding new text after the third sentence to read as follows:

§ 1943.1 Introduction.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

Subpart B—Insured Soil and Water Loan Policies, Procedures, and Authorizations

24. Section 1943.51 is amended by adding new text after the second sentence to read as follows:

§ 1943.51 Introduction.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

PART 1944—HOUSING

25. The authority citation for part 1944 is revised to read as follows:

Authority: 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart A—Section 502 Rural Housing Loan Policies, Procedures and Authorizations

26. Section 1944.1 is amended by adding the following language at the end of the paragraph:

§ 1944.1 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

§ 1944.37 [Amended]

27. In § 1944.37 paragraph (f) is amended by changing the reference "§ 1944.10(g)(4)" to "§ 1944.10(i)(4)," and paragraph (g) is amended by adding the words "of subpart G of part 1951" following "§ 1951.314."

28. Section 1944.39 is revised to read as follows:

§ 1944.39 RH loans to FmHA employees and loan closing officials.

FmHA employees, County Committee members, and loan closing agents, or members of their families may obtain a section 502 RH loan subject to the provisions of this subpart and the following conditions:

(a) Written evidence indicating the applicant's inability to obtain the needed credit elsewhere will be included in the application.

(b) Applications will be processed and loans will be serviced according to subpart D of part 1900 of this chapter.

(c) Loans, credit sales, or assumption agreements will not be approved for any of the following purposes:

(1) Buying FmHA inventory property.

(2) Buying FmHA security property from a borrower.

(3) Buying FmHA security property at foreclosure sale.

Subpart D—Farm Labor Housing Loan and Grant Policies, Procedures and Authorizations

29. Section 1944.151 is amended by adding the following language at the end of the paragraph:

§ 1944.151 Purpose.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

Subpart E—Rural Rental and Rural Cooperative Housing Loan Policies, Procedures and Authorizations

30. Section 1944.201 is amended by adding the following language at the end of the paragraph:

§ 1944.201 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

Subpart I—Self-Help Technical Assistance Grants

31. Section 1944.401 is amended by adding new text after the first sentence to read as follows:

§ 1944.401 Objective.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or

business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

Subpart J—Section 504 Rural Housing Loans and Grants

32. Section 1944.451 is amended by adding new second and third sentences to read as follows:

§ 1944.451 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

Subpart K—Technical and Supervisory Assistance Grants

33. Section 1944.501 is amended by adding new text after the first sentence to read as follows:

§ 1944.501 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

Subpart N—Housing Preservation Grants

34. Section 1944.651(a) is amended by adding new text after the first sentence to read as follows:

§ 1944.651 General.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to Farmers Home Administration (FmHA) employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

* * * * *

PART 1945—EMERGENCY

35. The authority citation for part 1945 continues to read as follows:

Authority: U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart C—Economic Emergency Loans

36. Section 1945.101(a) is amended by adding the following language at the end of the paragraph:

§ 1945.101 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

* * * * *

Subpart D—Emergency Loan Policies, Procedures and Authorizations

37. Section 1945.151(a) is amended by adding the following language at the end of the paragraph:

§ 1945.151 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

* * * * *

PART 1948—RURAL DEVELOPMENT

38. The authority citation for part 1948 continues to read as follows:

Authority: 7 U.S.C. 1989; 7 CFR 2.23; 7 CFR 2.70.

Subpart B—Section 601—Energy Impacted Area Development Assistance Program

39. Section 1948.51 is amended by adding the following language at the end of the paragraph:

§ 1948.51 General.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

Subpart C—Intermediary Relending Program (IRP)

40. Section 1948.101(a) is amended by adding the following language at the end of the paragraph:

§ 1948.101 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

* * * * *

PART 1951—SERVICING AND COLLECTIONS

41. The authority citation for part 1951 continues to read as follows:

Authority: 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 7 CFR 2.70.

Subpart S—Farmer Programs Account Servicing Policies

42. Section 1951.901 is amended by adding the following language at the end of the paragraph:

§ 1951.901 Purpose.

* * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

PART 1980—GENERAL

43. The authority citation for part 1980 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70; Pub. L. 100–387; Pub. L. 101–82.

Subpart B—Farmer Program Loans

44. Section 1980.101(a) is amended by adding new text after the fourth sentence to read as follows:

§ 1980.101 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this

subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

* * * * *

Subpart C—Emergency Livestock Loans

45. Section 1980.201(a) is amended by adding new text after the first sentence to read as follows:

§ 1980.201 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

* * * * *

46. In § 1980.207, the introductory text is revised to read as follows:

§ 1980.207 Definition.

The following general definitions are applicable to this subpart. Additional definitions may be found in § 1980.6 of subpart A of this part.

* * * * *

Subpart D—Rural Housing Loans

47. Section 1980.301(a) is amended by adding the following language at the end of the paragraph:

§ 1980.301 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

* * * * *

Subpart E—Business and Industrial Loan Program

48. Section 1980.401(a) is amended by adding the following language at the end of the paragraph:

§ 1980.401 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

* * * * *

Subpart F—Economic Emergency Loans

49. Section 1980.501(a) is amended by adding new text after the first sentence to read as follows:

§ 1980.501 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee. * * *

* * * * *

Subpart G—Nonprofit National Corporations Loan and Grant Program

50. Section 1980.601 is amended by adding the following language at the end of the paragraph:

§ 1980.601 Purpose.

* * *Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

Subpart I—Community Programs Guaranteed Loans

51. Section 1980.801(a) is amended by adding the following language at the end of the paragraph:

§ 1980.801 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

* * * * *

Subpart J—Agricultural Resource Conservation Demonstration Program

52. Section 1980.901(a) is amended by adding the following language at the end of the paragraph:

§ 1980.901 Introduction.

(a) * * * Any processing or servicing activity conducted pursuant to this subpart involving authorized assistance to FmHA employees, members of their families, known close relatives, or business or close personal associates, is subject to the provisions of subpart D of part 1900 of this chapter. Applicants for this assistance are required to identify any known relationship or association with an FmHA employee.

* * * * *

Dated: November 18, 1992.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 93–21 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–07–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 93

[Docket No. 27101]

High Density Traffic Airports; Slot Allocation and Transfer Methods

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Statement of policy; denial of petition for exemption.

SUMMARY: This policy statement and denial of petition are issued in response to a petition for exemption filed with the Federal Aviation Administration (FAA) on December 22, 1992, by the Air Transport Association (ATA) on behalf of 11 of its members. In its petition, ATA requests a 90-day exemption for its member air carriers operating at any of the high density traffic airports from the increased slot usage requirement or, in the alternative, a delay of the effective date of the final rule that will require the higher minimum slot usage of 80 percent effective January 1, 1993. This action denies ATA's petition to grant either a 90-day exemption or delay the effective date of the higher minimum slot usage requirement. Also, this action

explains the FAA's response to and treatment of requests for waivers submitted by air carriers or commuter operators that are predicated on the nonuse of slots due to the implementation of a deicing or ground delay program at any of the four high density traffic airports.

EFFECTIVE DATES: January 5, 1993.

FOR FURTHER INFORMATION CONTACT: Patricia R. Lane, Office of the Chief Counsel, AGC–230, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591. Telephone: (202) 267–3491.

SUPPLEMENTARY INFORMATION:

New Entrant Slot Final Rule

On August 12, 1992, the FAA issued a final rule (New Entrant Slot Final Rule) amending the Federal Aviation Regulations governing the allocation and transfer of air carrier and commuter slots effective November 1, 1992 (57 FR 37308; August 18, 1992). Congress subsequently passed a bill postponing the effective date of the rule until January 1, 1993. A "slot" is the authority to conduct an instrument flight rule (IFR) landing or takeoff during certain periods at four high density traffic airports: JFK International, LaGuardia, O'Hare International, and Washington National. The rule changes the slot lottery and withdrawal procedures to enhance the opportunities for carriers holding no or few slots at a high density traffic airport to obtain the necessary authority to conduct landings and takeoffs at such an airport. The rule also increases the minimum slot use requirements from 65 percent to 80 percent. Section 206 of the FAA reauthorization bill (H.R. 6168), passed by Congress on October 8, 1992, delayed the rule's effective date until January 1, 1993.

Deicing Rule

The Aircraft Ground Deicing and Anti-Icing Program interim final rule became effective on November 1, 1992. (57 FR 44924; September 29, 1992.) The rule requires part 121 certificate holders to develop and comply with an FAA-approved ground deicing/anti-icing program.

The FAA received a number of comments in response to the Aircraft Ground Deicing and Anti-Icing Program Notice of Proposed Rulemaking (NPRM), including comments relating to the roles of airport operators and air traffic control (ATC) and the delays resulting from deicing. Some commenters stated that ATC's role must be fully coordinated with the actions of air carriers and airports to ensure the proper use of holdover times and smooth traffic flows during icing conditions. Involvement of ATC and airport operators is essential for increasing safety in potential icing conditions. The FCC acknowledges that there may be delays affiliated with the new rule, especially if aircraft return for secondary deicing.

The FAA, in cooperation with the airports, engages in a national effort to manage departure delays during airline deicing operations. For example, at Washington National Airport, an objective of the airport deicing plan is to assist users to manage the flow of traffic from deicing through takeoff to minimize the time after deicing. ATC regulates the arrival flow at Washington National to accommodate timely departures of deiced aircraft. Similarly, JFK International Tower has developed a deicing plan to manage the time a deiced aircraft waits for departure. LaGuardia Tower has developed a deicing plan to ensure an effective departure flow from the aircraft ramps to the active departure runway. O'Hare International Tower has also established procedures to minimize departure delays during ground deicing operations.

ATA's Petition

On December 22, 1992, ATA filed with the FAA a petition for exemption on behalf of its carriers operating at any of the four high density traffic airports. In its petition, ATA requests the FAA to grant a 90-day exemption from the increased slot used requirement for 11 of its member carriers, i.e., American, American Trans Air, Continental, Delta, DHL, Federal Express, Northwest, TWA, United, UPS, and USAir. In the alternative, ATA is requesting a delay of the effective date of the New Entrant Slot Final Rule (57 FR 37308), which will require the higher minimum slot usage.

In support of its petition, ATA states that the juxtaposition of the interim deicing rule and the higher slot usage requirement places operators in an untenable position. On the one hand, the FAA will require that slots be used 80 percent of the time over a 2-month period. On the other hand, the deicing and ground delay programs will cause carriers to forego the use of some slots. The interaction among the deicing program, ground delay programs, and the higher minimum slot usage requirement, the ATA says, will force the carriers to operate slots that will "choke" the airport during these programs or to operate the slots in nonproductive times, i.e., the weekend. For this reason, ATA is requesting the specified relief.

In the interest of responding to ATA's urgent request as expeditiously as possible, the FAA has waived the requirements for publishing a summary of this petition in the **Federal Register**. Although comments were not solicited, America West submitted a response nonetheless, urging denial of the petition. The FAA's analysis of ATA's petition is set forth as follows.

Request for a Delay of the Effective Date

When the Department of Transportation (Department) issued the New Entrant Slot Final Rule, it considered the comments of air carriers, commuters, communities, and other interested parties concerning the minimum slot usage that should be required. In determining a slot usage minimum, the Department wanted to achieve a balance that would not jeopardize the viability of the smaller carriers and still promote the efficient use of slots. To that end, the Department considered the comments raising the potential problems of sporadic cancellations cased by weather, mechanical failure, or holiday schedule reductions in relation to the achievement of the goal of encouraging carriers to hold no more slots than their markets demand, potentially freeing up underutilized slots for use by other carriers without imposing impractically stringent use requirements.

The Department's objective of increasing the slot use efficiency and potentially freeing up underutilized slots has not changed. The Department still believes that the 80 percent usage requirement may accomplish the twin objectives of improving efficiency and increasing potential access for new entrants without substantially disrupting existing air service. The Department sees no benefit to be derived that warrants delaying the effective date of the final rule. The delay will not force operators to release underutilized slots to those operators that could use them, nor will it solve the relationship between slot usage and bad weather. (Operators have commented on that issue for almost every slot rule that has been published in the **Federal Register**.)

Request for a 90-Day Exemption

When the New Entrant Slot Final Rule was originally published for comment as an NPRM, some commenters mentioned the effect of weather and mechanical breakdowns on slot usage. After reviewing the comments, the FAA determined that the 80 percent usage requirement would allow for routine

nonuse of slots due to bad weather and mechanical difficulties without placing an undue burden on the operator. At the time that the NPRM was published, however, the FAA had not yet implemented the rule prescribing the deicing requirements (56 FR 44924; September 29, 1992). The FAA recognizes that there might be some inherent conflict between the need for the reduction of operations during a deicing program and the continued 80 percent operation of slots. But this potential can be adjusted without the need for a blanket 90-day exemption. Disagreeing with the contention in ATA's petition that differentiating the slots affected by deicing delays would not be practical or efficient, the FAA will adjust the slot usage for those operators affected by the implementation of a deicing program as described below.

Statement of Policy

When an operator submits its bimonthly use-or-lose report, it may designate those slots that were adversely affected by the implementation of a deicing program. The FAA Office of Chief Counsel, Slot Administration Office, will verify with the carrier that a deicing program was in effect that affected the carrier's operations. Upon sufficient verification that use of a slot was delayed or foregone because of a deicing program, the FAA will give credit for, i.e., treat as used, any slot that the holder-of-record or operator-of-record designates as either not used or used outside its allocated time as a result of the program's implementation. In this way, no operator will be in jeopardy of losing a slot merely because its use has been adversely affected by a deicing program. As a result, safety would remain unaffected and the public interest in maximizing to the extent feasible the efficient use of slots would also be served.

Conclusion

For the above stated reasons, the FAA is denying ATA's request for either a 90-day exemption from the minimum slot usage requirement or a delay of the effective date of the higher minimum slot usage. The FAA will consider an operator's request to give credit of usage for those slots that are either not used or used in a different time period due to the implementation of an airport deicing program that adversely affects usage of the slots in question.

Signed in Washington, DC, on December 30, 1992.

Thomas C. Richards,

Administrator.

[FR Doc. 92-31954 Filed 12-31-92; 12:54 pm]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8464]

RIN 1545-AQ44

Change in Functional Currency

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final Income Tax Regulations relating to adjustments and transition rules with respect to a change in functional currency. These regulations are issued under section 985 of the Internal Revenue Code of 1986 (Code), which was added to the Code by the Tax Reform Act of 1986. These regulations provide guidance for taxpayers with qualified business units (QBUs) that change functional currency and provide special rules for taxpayers with QBUs operating in a hyperinflationary environment that elect the dollar as their functional currency for their first post-1986 taxable year.

EFFECTIVE DATE: These regulations are effective February 4, 1993.

FOR FURTHER INFORMATION CONTACT: Jacob Feldman of the Office of Associate Chief Counsel (International), within the Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224 (202-622-3870, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

On September 20, 1989, proposed and temporary regulations §§ 1.985-5T and 1.985-6T were adopted (as part of T.D. 8263) and published in the **Federal Register** at 54 FR 38649 (September 20, 1989). No public hearing was requested, and none was held. Very few comments were received. The issues raised by these comments are discussed below. After consideration of the comments and related issues with respect to §§ 1.985-5T and 1.985-6T, these sections of the proposed regulations are adopted as a Treasury decision effective 30 days after publication, with the modifications discussed below. In addition, in an accompanying notice of proposed rulemaking, § 1.985-7 provides special rules for cases in which a QBU changes from the profit and loss method of accounting (P&L method) to the dollar approximate separate transactions method (DASTM). These revised rules are proposed to be effective in taxable years beginning 30 days after the publication of final regulations.

Explanation of Provisions

Section 1.985-5T, which contains adjustments required upon a change in functional currency, is finalized substantially as proposed. However, a new § 1.985-7 is being proposed to apply to a QBU that uses the P&L method in a post-1986 taxable year and that subsequently begins to use the dollar as its functional currency using DASTM accounting. The proposed regulation responds to taxpayers' comments and would permit the use of historical exchange rates to establish the QBU's DASTM balance sheet, rather than the spot rate provided under § 1.985-5, provided that the taxpayer makes a section 481 adjustment. The proposed regulation would permit taxpayers that elected DASTM in an open taxable year beginning before the proposed rule is finalized to use § 1.985-7 instead of the temporary or final versions of § 1.985-5 and § 1.985-6.

The final regulations contain several clarifying amendments to the temporary regulations. Section § 1.985-5T(e)(1), providing for translation of a corporation's earnings and profits into its new functional currency at the spot exchange rate, is expanded to clarify that pre-1987 creditable income taxes and accumulated profits of a foreign corporation maintained in foreign currency for purposes of section 902 also are translated at the spot rate when the foreign corporation changes its functional currency. Pre-1987 earnings and taxes must be translated at the same rate in order to implement the rule of section 902(c)(6) that the tax effects of distributions out of pre-1987 earnings are governed by pre-1987 law. See Bon Ami Co., 39 B.T.A. 825 (1939).

One taxpayer suggested that income or loss required to be recognized under the proposed regulations at the time a QBU changes functional currency should be taken into account over several years. See § 1.985-5(b) with respect to section 988 transactions denominated in the new functional currency, § 1.985-5(d)(2) with respect to a deemed branch termination when a branch changes to the taxpayer's functional currency, and § 1.985-5(e)(2)

with respect to a deemed distribution of previously taxed earnings and profits when a controlled foreign corporation changes its functional currency to the dollar. This suggestion was not adopted for several reasons.

In the case of the required section 988 adjustment to the subpart F income and earnings and profits of a foreign corporation changing functional currency, a multi-year spread period would be particularly difficult to implement because of the need for additional information reporting with respect to the foreign corporation, and the administrative complexity that would result from spreading a subpart F inclusion and associated deemed paid foreign tax credits at the shareholder level. Spreading the adjustments resulting from a deemed branch termination and a deemed distribution of previously taxed income also would be particularly complex because, for example, of their effect on the U.S. taxpayer's foreign tax credit. In addition, the Service is concerned that if a spread period were allowed taxpayers could use distributions in connection with a change in functional currency to manipulate the time these amounts are taken into account.

Section § 1.985–6T, which contains transition rules for QBUs that use DASTM accounting for their first taxable year beginning in 1987, is finalized essentially as proposed, except that a new paragraph (d)(1) provides for a spot exchange rate translation of pre-1987 section 902 accumulated profits and deficits as well as foreign income taxes attributable to such accumulated profits. In addition, new paragraph (d)(2) provides that only the translated amount of a pre-1987 section 902 deficit in accumulated profits is carried over into the foreign corporation's post-1986 undistributed earnings pool. The amount of any pre-1987 deficit in retained earnings determined under § 1.964–1(e) is not carried over. These rules are the same as those applicable under Notice 87–54, 1987–2 C.B. 363, and Notice 88–70, 1988–2 C.B. 369, to QBUs whose functional currency in 1987 is the same currency in which the taxpayer kept the QBU's books and records for purposes of section 902 prior to 1987.

One commentator suggested that in the case of a DASTM CFC, a pre-1987 section 964 accumulated deficit (and not a section 902 deficit) should be carried forward into the post-1986 undistributed earnings pool. This suggestion was not adopted because under section 902(c)(6) of the Internal Revenue Code the tax effects of distributions out of pre-1987 accumulated profits must be determined under pre-1987 law. Accordingly, the total amount of earnings and profits available for distribution as a dividend from a controlled foreign corporation that begins to use DASTM accounting in 1987 is the sum of (1) the pre-1987 accumulated profits (or deficits) computed in foreign currency under a P&L method in accordance with the rules of section 902 prior to amendment in 1986 and translated into dollars in 1987 in accordance with the principles of Notice 88–70, and (2) the post-1986 undistributed earnings pool, consisting of earnings and profits computed in dollars under the DASTM method in post-1986 years. The Service believes that reducing the post-1986 undistributed earnings pool (which is the denominator of the section 902 fraction) by a pre-1987 deficit computed in dollars for purposes of section 964 would contravene the rule that the pre-1987 section 964 amounts are not relevant for purposes of determining the tax effects of dividend inclusions. Similarly, excluding a pre-1987 section 902 deficit from the post-1986 undistributed earnings pool would be inconsistent with the rule referring to (positive) pre-1987 accumulated profits in determining the effect of a distribution in excess of the post-1986 pool.

A rule bringing forward a pre-1987 section 964 deficit into the post-1986 pool of a DASTM CFC would also create a difference in treatment between a DASTM CFC and a CFC with a dollar functional currency that uses a separate transactions profit and loss method. Finally, the commentators' proposed rule, to the extent it created a negative post-1986 pool, could increase the incidence of inclusions without credits should the foreign corporation realize subpart F income or pay a "nimble dividend" in a post-1986 year.

Paragraphs (d) and (e) of § 1.985–6T are renumbered as paragraphs (e) and (f), respectively, in the final regulations. An alternative transition rule for a branch that used a profit and loss method of accounting in pre-1987 taxable years and that now uses DASTM because the taxpayer elected to use the dollar as the branch's functional currency in its first post-1986 taxable year is provided in the accompanying notice of proposed rulemaking.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. Although this Treasury decision was preceded by a notice of proposed rulemaking that solicited public comments, it has been determined that the notice was not required by 5 U.S.C. 553 since the regulations proposed in that notice and adopted by this Treasury decision are interpretative. Therefore, a final Regulatory Flexibility Analysis is not required by the Regulatory Flexibility Act (5 U.S.C. chapter 6).

Drafting Information

Personnel from the Internal Revenue Service and Treasury Department participated in developing these regulations.

List of Subjects in 26 CFR 1.985–0 Through 1.989(c)–1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 is amended by removing the entry for "Sections 1.985–OT through 1.985–5T" and adding a citation to read as follows:

Authority: 26 U.S.C. 7805 * * * Sections 1.985–0 through 1.985–5 also issued under 26 U.S.C. 985. * * *

Par. 2. Section 1.985–5T and 1.985–6T are removed.

Par. 3. Section 1.985–0 is amended as follows:

1. The introductory text for section 1.985–0 is revised.

2. The section heading in the entry for § 1.985–5T is removed and a section heading for § 1.985–5 is added in its place.

3. The entry for § 1.985–6T is removed and an entry for § 1.985–6 is added.

4. The revisions and additions read as follows:

§ 1.985–0 Outline of regulations.

This section lists the paragraphs contained in § § 1.985–1 through 1.985–6.

* * * * *

Section 1.985–5 Adjustments required upon change in functional currency.

* * * * *

Section 1.985–6 Transition rules for a QBU that uses the dollar approximate separate transactions method for its first taxable year beginning in 1987.

(a) In general.

(b) Certain controlled foreign corporations.
(c) All other foreign corporations.
(d) Pre-1987 section 902 amounts.
(e) Net worth branch.
(f) Profit and loss branch.

Par. 4. New §§ 1.985–5 and 1.985–6 are added to read as follows:

§ 1.985–5 Adjustments required upon change in functional currency.

(a) *In general.* This section applies in the case of a QBU that changes from one functional currency (old functional currency) to another functional currency (new functional currency). A taxpayer or QBU subject to the rules of this section shall make the adjustments set forth in the 3-step procedure described in paragraphs (b) through (e) of this section. The adjustments shall be made on the last day of the taxable year ending before the year of change as defined in § 1.481–1(a)(1). Gain or loss required to be recognized under paragraphs (b), (d)(2), and (e)(2) of this section is not subject to section 481 and, therefore, the full amount of the gain or loss must be included in income or earnings and profits on the last day of the taxable year ending before the year of change. Except as provided in § 1.985–6, a QBU with a functional currency for its first taxable year beginning in 1987 that is different from the currency in which it had kept its books and records for United States accounting and tax accounting purposes for its prior taxable year shall apply the principles of this § 1.985–5 for purposes of computing the relevant functional currency items, such as earnings and profits, basis of an asset, and amount of a liability, as of the first day of a taxpayer's first taxable year beginning in 1987.

(b) *Step 1—Taking into account exchange gain or loss on certain section 988 transactions.* The QBU shall recognize or otherwise take into account for all purposes of the Code the amount of any unrealized exchange gain or loss attributable to a section 988 transaction (as defined in section 988(c)(1)(A), (B), and (C)) that, after applying section 988(d), is denominated in terms of or determined by reference to the new functional currency. The amount of such gain or loss shall be determined without regard to the limitations of section 988(b) (*i.e.*, whether any gain or loss would be realized on the transaction as a whole). The character and source of such gain or loss shall be determined under section 988.

(c) *Step 2—Determining the new functional currency basis of property and the new functional currency amount of liabilities and any other relevant items.* The new functional currency adjusted basis of property and the new functional currency amount of liabilities and any other relevant items (*e.g.*, items described in section 988(c)(1)(B)(iii)) shall equal the product of the amount of the old functional currency adjusted basis or amount multiplied by the new functional currency/old functional currency spot exchange rate on the last day of the taxable year ending before the year of change (spot rate).

(d) *Step 3A—Additional adjustments that are necessary when a branch changes functional currency*—(1) *Branch changing to a functional currency other than the taxpayer's functional currency*—(i) *Rule.* If a QBU that is a branch of a taxpayer changes to a functional currency other than the taxpayer's functional currency, the branch shall make the adjustments set forth in either paragraph (d)(1)(ii) or (d)(1)(iii) of this section for purposes of section 987. See § 1.987–5(d) for rules for computing the branch's equity pool and basis pool.

(ii) *Where prior to the change the branch and taxpayer had different functional currencies.* If the branch and the taxpayer had different functional currencies prior to the change, the branch's new functional currency equity pool shall equal the product of the old functional currency amount of the equity pool multiplied by the spot rate. No adjustment to the basis pool is necessary.

(iii) *Where prior to the change the branch and taxpayer had the same functional currency.* If the branch and the taxpayer had the same functional currency prior to the change, the branch's basis pool shall equal the difference between the branch's total old functional currency basis of its assets and its total old functional currency amount of its liabilities. The branch's equity pool shall equal the product of the basis pool multiplied by the spot rate.

(2) *Branch changing to the taxpayer's functional currency.* If a branch changes its functional currency to the taxpayer's functional currency, the branch shall be treated as if it terminated on the last day of the taxable year ending before the year of change. In such a case, the taxpayer shall realize gain or loss attributable to the branch's equity pool under the principles of section 987.

(e) *Step 3B—Additional adjustments that are necessary when a taxpayer changes functional currency*—(1) *Corporations.* The amount of a corporation's new functional currency earnings and profits and the amount of its new functional currency paid-in capital shall equal the product of the old functional currency amounts of such items multiplied by the spot rate. The foreign income taxes and accumulated profits or deficits in accumulated profits of a foreign corporation that were maintained in foreign currency for purposes of section 902 and that are attributable to taxable years of the foreign corporation beginning before January 1, 1987, also shall be translated into the new functional currency at the spot rate.

(2) *Collateral consequences to a United States shareholder of a corporation changing to the United States dollar as its functional currency.* A United States shareholder (within the meaning of section 951(b) or section 953(c)(1)(A)) of a controlled foreign corporation (within the meaning of section 957 or section 953(c)(1)(B)) changing its functional currency to the dollar shall recognize foreign currency gain or loss computed under section 986(c) as if all previously taxed earnings and profits, if any, (including amounts attributable to pre-1987 taxable years that were translated from dollars into functional currency in the foreign corporation's first post-1986 taxable year) were distributed immediately prior to the change. Such a shareholder shall also recognize gain or loss attributable to the corporation's paid-in capital to the same extent, if any, that such gain or loss would be recognized under the regulations under section 367(b) if the corporation was liquidated completely.

(3) *Taxpayers that are not corporations.* [Reserved]

(4) *Adjustments to a branch's accounts when a taxpayer changes functional currency*—(i) *Taxpayer changing to a functional currency other than the branch's functional currency.* If a taxpayer changes to a functional currency that differs from the functional currency of a branch of the taxpayer, the branch shall adjust its basis pool in the manner prescribed in paragraph (d)(1)(ii) of this section for adjusting the equity pool, if the taxpayer's old functional currency was different from the branch's functional currency. If the taxpayer's old functional currency was the same as the branch's functional currency, the branch shall determine its equity pool and basis pool in the manner set forth in paragraph (d)(1)(iii) of this section for determining the basis pool and equity pool, respectively.

(ii) *Taxpayer changing to the same functional currency as the branch.* If a taxpayer changes to the same functional currency as a branch of the taxpayer, the taxpayer shall realize gain or loss as set forth in paragraph (d)(2) of this section.

(f) *Examples.* The provisions of this section are illustrated by the following examples.

Example 1. S, a calendar year foreign corporation, is wholly owned by domestic corporation P. The Commissioner granted permission to change S's functional currency from the LC to the FC beginning January 1, 1993. The LC/FC exchange rate on December 31, 1992 is 1 LC/2 FC. The following shows how S must convert the items on its balance sheet from the LC to the FC.

	1:2	
	LC	FC
Assets:		
Cash on hand	40,000	80,000
Accounts Receivable	10,000	20,000
Inventory	100,000	200,000
100,000 FC Bond (100,000 LC historical basis) [1]	[1]50,000	100,000
Fixed assets:		
Property	200,000	400,000
Plant	500,000	1,000,000
Accumulated Depreciation	(200,000)	(400,000)
Equipment	1,00,000	2,000,000
Accumulated Depreciation	(400,000)	(800,000)
Total Assets	1,300,000	2,600,000
Liabilities:		
Accounts Payable	50,000	100,000
Long-term Liabilities	400,000	800,000
Paid-in-Capital	800,000	1,600,000
Retained Earnings	[2]50,000	100,000
Total Liabilities and Equity	1,300,000	2,600,000

[1] Under § 1.985–5(b), S will recognize a 50,000 LC loss (100,000 LC basis–50,000 LC value) on the bond resulting from the change in functional currency. Thus, immediately before the change, S's basis in the FC bond (taking into account the loss) is 50,000 LC.

[2] The amount of S's LC retained earnings reflects the 50,000 LC loss on the bond.

Example 2. P, a domestic corporation, operates a foreign branch, S. The Commissioner granted permission to change S's functional currency from the LC to the FC beginning January 1, 1993. As of December 31, 1992, S's equity pool was 2,000 LC and its basis pool was $4,000. The LC/FC exchange rate on December 31, 1992 is 1 LC/2 FC. On January 1, 1993, the new functional currency amount of S's equity pool is 4,000 FC. The basis pool is not affected.

§ 1.985–6 Transition rules for a QBU that uses the dollar approximate separate transactions method for its first taxable year beginning in 1987.

(a) *In general.* This section sets forth transition rules for a QBU that used the dollar approximate separate transactions method of accounting set forth in § 1.985–3 or § 1.985–3T (as contained in the April 1, 1989 edition of 26 CFR part 1 (1.908 to 1.1000)) for its first taxable year beginning in 1987 (DASTM QBU). A DASTM QBU must determine the dollar and hyperinflationary currency basis of its assets and the dollar and hyperinflationary currency amount of its liabilities that were acquired or incurred in taxable years beginning before January 1, 1987. In addition, a DASTM QBU must determine its net worth, including its retained earnings, at the end of the QBU's last taxable year beginning before January 1, 1987. This section provides rules for controlled foreign corporations (as defined in section 957 or section 953(c)(1)(B)), other foreign corporations, and branches of United States persons that must make these determinations.

(b) *Certain controlled foreign corporations.* If a DASTM QBU was a controlled foreign corporation for its last taxable year beginning before January 1, 1987, and it had a significant event as described in § 1.964–1(c)(6) in a taxable year beginning before January 1, 1987, then the rules of this paragraph (b) shall apply.

(1) *Basis in assets and amount of liabilities.* The hyperinflationary currency adjusted basis of the QBU's assets and the hyperinflationary currency amount of the QBU's liabilities acquired or incurred by the QBU in a taxable year beginning before January 1, 1987, shall be the basis or the amount as determined under § 1.964–1(e) prior to translation under § 1.964–1(e)(4). The dollar adjusted basis of such assets and the dollar amount of such liabilities shall be the adjusted basis or the amount as determined under the rules of § 1.964–1(e) after translation under § 1.964–1(e)(4).

(2) *Retained earnings.* The dollar amount of the QBU's retained earnings at the end of its last taxable year beginning before January 1, 1987, shall be the dollar amount determined under § 1.964–1(e)(3).

(c) *All other foreign corporations.* If a foreign corporation is a DASTM QBU that is not described in paragraph (b) of this section, then the hyperinflationary currency and dollar adjusted basis in the QBU's assets acquired in taxable years beginning before January 1, 1987, the hyperinflationary currency and dollar amount of the QBU's liabilities acquired or incurred in taxable years beginning before January 1, 1987, and the dollar amount of the QBU's net worth, including its retained earnings, at the end of its last taxable year beginning before January 1, 1987, shall be determined by applying the principles of § 1.985–3T or § 1.985–3. Thus, for example, the dollar basis of plant and equipment shall be determined using the appropriate historical exchange rate.

(d) *Pre-1987 section 902 amounts*—(1) *Translation of pre-1987 section 902 accumulated profits and taxes into United States dollars.* The foreign income taxes and accumulated profits or deficits in accumulated profits of a foreign corporation that were maintained in foreign currency for purposes of section 902 and that are attributable to taxable years of the foreign corporation beginning before January 1, 1987, shall be translated into dollars at the spot exchange rate on the first day of its first taxable year beginning after December 31, 1986. Once translated into dollars, these accumulated profits and taxes shall (absent a change in functional currency) remain in dollars for all federal income tax purposes.

(2) *Carryforward of accumulated deficits in accumulated profits from pre-1987 taxable years to post-1986 taxable years.* For purposes of sections 902 and 960, the post-1986 undistributed earnings of a foreign corporation that is subject to the rules of this section shall be reduced by the dollar amount of the corporation's deficit in accumulated profits, if any, determined under section 902 and the regulations thereunder, that was accumulated at the end of the corporation's last taxable year beginning before January 1, 1987. The dollar amount of the accumulated deficit shall be determined by multiplying the foreign currency amount of such deficit by the spot exchange rate on the last day of the corporation's last taxable year beginning before January 1, 1987, and shall be taken into account on the first day of the corporation's first taxable year beginning after December 31, 1986. Post-1986 undistributed earnings may not be reduced by the dollar amount of a pre-1987 deficit in retained earnings determined under § 1.964–1(e).

(e) *Net worth branch.* If a DASTM QBU is a branch of a United States person and the QBU used a net worth method of accounting for its last taxable year beginning before January 1, 1987, then the rules of this paragraph (e) shall apply. A net worth method of accounting is any method of accounting under which the taxpayer calculates the taxable income of a QBU based on the net change in the dollar value of the QBU's equity (assets minus liabilities) during the course of a taxable year, taking into account any contributions or remittances made during the year. See, *e.g.*, Rev. Rul. 75–106, 1975–1 C.B. 31. (See § 601.601(d)(2)(ii)(*b*) of this chapter).

(1) *Basis in assets and amount of liabilities*—(i) *Hyperinflationary amounts.* For the first taxable year beginning in 1987, the hyperinflationary currency adjusted basis of a QBU's assets or the hyperinflationary currency amounts of its liabilities acquired or incurred in a taxable year beginning before January 1, 1987 is the

hyperinflationary currency basis or amount at the date when acquired or incurred, as adjusted according to United States generally accepted accounting and tax accounting principles. If a hyperinflationary currency basis or amount was not determined at such date, the dollar basis or amount, as adjusted according to United States generally accepted accounting and tax accounting principles, shall be translated into hyperinflationary currency at the spot exchange rate on the date when the asset or liability was acquired or incurred.

(ii) *Dollar amounts.* For the first taxable year beginning in 1987, the dollar adjusted basis of the QBU's assets and the amounts of its liabilities shall be those amounts reflected on the QBU's dollar books and records at the end of the taxpayer's last taxable year beginning before January 1, 1987, after adjusting the books and records according to United States generally accepted accounting and tax accounting principles.

(2) *Ending net worth.* The dollar amount of the QBU's net worth at the end of its last taxable year beginning before January 1, 1987 shall equal the QBU's net worth at that date as determined under paragraph (e)(1)(ii) of this section.

(f) *Profit and loss branch.* If a DASTM QBU is a branch of a United States person and the QBU used a profit and loss method of accounting for its last taxable year beginning before January 1, 1987, then the United States person shall first apply the transition rules of § 1.987–5 in order to determine the beginning amount and dollar basis of the branch's EQ pool, the hyperinflationary currency basis of the branch's assets, and the hyperinflationary currency amounts of its liabilities. A profit and loss method of accounting is any method of accounting under which the taxpayer calculates the profits of a QBU by computing the QBU's profits in its functional currency and translating the net result into dollars. See *e.g.*, Rev. Rul. 75–107, 1975–1 C.B. 32. (See § 601.601(d)(2)(ii)(*b*) of this chapter). The QBU and the taxpayer must then make the adjustments required by § 1.985–5, *e.g.*, the QBU must take into account unrealized exchange gain or loss on dollar-denominated section 988 transactions, the taxpayer must account for the deemed termination of the branch, and the taxpayer must translate the QBU's balance sheet items from hyperinflationary currency into dollars at the spot rate.

Michael P. Dolan,

Acting Commissioner of Internal Revenue.

Approved: November 30, 1992.

Alan J. Wilensky,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 92–31467 Filed 12–31–92; 8:45 am]

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26 CFR Part 1

[T.D. 8465]

RIN 1545–AN83

Deduction of Amounts Owed To Related Foreign Persons

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final Income Tax Regulations describing when an otherwise deductible amount owed to a related foreign person may be deducted. Changes to the applicable tax law were made by the Tax Reform Act of 1984 and the Tax Reform Act of 1986. These final regulations provide guidance needed to comply with these changes and affect persons that owe otherwise deductible amounts to a related foreign person.

EFFECTIVE DATES: January 5, 1993.

FOR FURTHER INFORMATION CONTACT: Lisa G. Sams of the Office of Associate Chief Counsel (International), within the Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224, Attention: CC:CORP:T:R (INTL–625–89) (202–622–3840, not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

On March 19, 1991, the Internal Revenue Service published in the **Federal Register** proposed amendments (56 FR 11531) to the Income Tax Regulations (26 CFR part 1) under sections 163 and 267 of the Internal Revenue Code (Code). Written comments responding to this notice were received. The significant points raised by these comments and the changes made to the proposed amendments are discussed in the following sections of this preamble.

Discussion of Major Comments and Revisions to Proposed Regulations

Section 163(a)(3) generally requires a taxpayer to use the cash method of accounting with respect to the deduction of original issue discount owed to a related foreign person. Section 1.163–12 of the proposed regulations describes this general rule, and provides certain exceptions. In response to comments received, special rules are provided for original issue discount owed to a related foreign person that is a foreign personal holding company, a controlled foreign corporation, or a passive foreign investment company. These special rules are appropriate because there is a proper matching of income and deduction with respect to original issue discount owed to a related foreign corporation that is required to compute its taxable income and earnings and profits for United States tax purposes pursuant to the foreign personal holding company, subpart F, or passive foreign investment company provisions.

Section 267(a)(3) also generally requires a taxpayer to use the cash method of accounting with respect to the deduction of amounts owed to a related foreign person. Section 1.267(a)–3 of the proposed regulations describes this general rule and the amounts covered, and also provides certain exceptions. Stated broadly, the exceptions apply to certain amounts treated as income effectively connected with the conduct of a trade or business in the United States by the recipient of the income, and to certain amounts reported as income of the related foreign person pursuant to the foreign personal holding company, controlled foreign corporation, and passive foreign investment company provisions of the Code. Amounts excepted under the regulations generally remain subject to the rules described in section 267(a)(2), however.

A commentator stated that sections 267(a) (2) and (3) does not provide authority to place a taxpayer on the cash method of accounting with respect to amounts owed to related foreign persons, arguing that the rules announced in the proposed regulations exceed the direction of Congress to apply the principles of section 267(a)(2). This comment is rejected, since the legislative history of section 267(a)(3) states clearly that a taxpayer may be placed on the cash method of accounting with respect to amounts owed to a related foreign person. See H.R. Rept. No. 426, 99th Cong., 2d Sess. 939–940 (1985).

A related foreign person, for purposes of sections 163(e)(3) and 267(a) (2) and (3), is defined as any person that is not a United States person within the meaning of section 7701(a)(30) that has a relationship with the issuer described in section 267(b). Pursuant to section 267(b)(3), two corporations are related if they are members of the same

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"controlled group" within the meaning of section 1563(a), subject to certain modifications. The final regulations clarify that this definition applies without regard to any of the limitations under section 1563(b).

Several commentators argued that the regulations under section 267(a)(3) governing the treatment of interest should be applied only prospectively, contending that the public had no notice that the statute would be applied in the manner described in the regulations. This comment also was rejected. Section 267(a)(2) provides generally that an otherwise deductible amount may not be deducted by the payor until the amount is includible in the gross income of the recipient. The legislative history makes clear that its provisions apply to otherwise deductible amounts owed to related foreign persons, and that regulations under section 267 (a)(3) would be necessary only to clarify the application of the matching principle of section 267(a) (2) and (3) to amounts not includible in the gross income of the recipient for United States tax purposes. See H.R. Rept. No. 426, 99th Cong., 2d Sess. 939–940 (1985).

Therefore, it was determined that the general principles of section 267(a)(2) should be applied to interest amounts from the effective date of its provisions. The effective dates for the application of the rules governing stated interest thus are consistent with those under section 163(e)(3) governing the treatment of original issue discount, ensuring general uniformity of treatment of items of stated interest and original issue discount.

A commentator argued that these regulations may violate the non-discrimination provisions of certain income tax treaties. The Service rejects this comment, since domestic tax principles are applied uniformly to determine the timing of a deduction for otherwise deductible amounts owed by a taxpayer to a related person (whether domestic or foreign) under sections 163(e)(3) and 267(a) (2) and (3).

Lastly, an amount owed to a foreign sales corporation that is exempt foreign trade income of the foreign sales corporation for purposes of section 921 *et seq.*, is not an amount to which these regulations apply, because the amount is treated as foreign source income of the foreign sales corporation that is not effectively connected with the conduct of a trade or business within the United States. Pursuant to section 924(f)(2), foreign trading gross receipts do not include interest and other investment income. Interest and other investment income is never characterized as exempt foreign trade income. For this reason, the special rule in the proposed regulations excluding from the application of these regulations interest owed to a foreign sales corporation is not necessary. Accordingly, the rule described in § 1.267(a)–3(c)(4) of the proposed regulations is removed. No contrary inference is intended.

Additional clarifying or editorial changes also have been made. For example, the special rule described in §§ 1.163–12(b)(3)(iii) and 1.267(a)–3(c)(4)(iii) governing amounts owed to a related foreign person that is a passive foreign investment company applies if the person that owes the amount to the related foreign person has made and has in effect an election under section 1295 (and not section 1291) with respect to the passive foreign investment company to which the amount is owed.

Change in Method of Accounting

A revenue procedure is issued contemporaneously with the issuance of these final regulations that describes the procedures for a change in method of accounting to conform with these rules. See § 601.601(d)(2)(ii)(*b*) of this chapter.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and thus a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking for the regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is James K. Sams formerly of the Office of Associate Chief Counsel (International), within the Office of Chief Counsel, Internal Revenue Service. Other personnel from the Internal Revenue Service and Treasury Department participated in developing the regulations.

List of Subjects in 26 CFR 1.161–1 Through 1.280H–1T

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 is amended by adding the following citation:

Authority: 26 U.S.C. 7805 * * * Section 1.267(a)–3 issued under 26 U.S.C. 267(a)(3). * * *

Par. 2. Section 1.163–12 is added to read as follows:

§ 1.163–12 Deduction of original issue discount on instrument held by related foreign person.

(a) *General rules*—(1) *Deferral of deduction.* Except as provided in paragraph (b) of this section, section 163(e)(3) requires a taxpayer to use the cash method of accounting with respect to the deduction of original issue discount owed to a related foreign person. A deduction for an otherwise deductible portion of original issue discount with respect to a debt instrument will not be allowable as a deduction to the issuer until paid if, at the close of the issuer's taxable year in which such amount would otherwise be deductible, the person holding the debt instrument is a related foreign person. For purposes of this section, a related foreign person is any person that is not a United States person within the meaning of section 7701(a)(30), and that is related (within the meaning of section 267(b)) to the issuer at the close of the taxable year in which the amount incurred by the taxpayer would otherwise be deductible. Section 267(f) defines "controlled group" for purposes of section 267(b) without regard to the limitations of section 1563(b). An amount is treated as paid for purposes of this section if the amount is considered paid for purposes of section 1441 or section 1442 (including an amount taken into account pursuant to section 871(a)(1)(C), section 881(a)(3), or section 884(f)). The rules of this paragraph (a) apply even if the original issue discount is not subject to United States tax, or is subject to a reduced rate of tax, pursuant to a provision of the Internal Revenue Code or a treaty obligation of the United States. For purposes of this section, original issue discount is an amount described in section 1273, whether from sources inside or outside the United States.

(2) *Change in method of accounting.* A taxpayer that uses a method of accounting other than that required by

the rules of this section must change its method of accounting to conform its method to the rules of this section. The taxpayer's change in method must be made pursuant to the rules of section 446(e), the regulations thereunder, and any applicable administrative procedures prescribed by the Commissioner. Because the rules of this section prescribe a method of accounting, these rules apply in the determination of a taxpayer's earnings and profits pursuant to § 1.312–6(a).

(b) *Exceptions and special rules*—(1) *Effectively connected income.* The provisions of section 267(a)(2) and the regulations thereunder, and not the provisions of paragraph (a) of this section, apply to an amount of original issue discount that is income of the related foreign person that is effectively connected with the conduct of a United States trade or business of such related foreign person. An amount described in this paragraph (b)(1) thus is allowable as a deduction as of the day on which the amount is includable in the gross income of the related foreign person as effectively connected income under sections 872(a)(2) or 882(b) (or, if later, as of the day on which the deduction would be so allowable but for section 267(a)(2)). However, this paragraph (b)(1) does not apply if the related foreign person is exempt from United States income tax on the amount owed, or is subject to a reduced rate of tax, pursuant to a treaty obligation of the United States (such as under an article relating to the taxation of business profits).

(2) *Certain obligations issued by natural persons.* This section does not apply to any debt instrument described in section 163(e)(4) (relating to obligations issued by natural persons before March 2, 1984, and to loans between natural persons).

(3) *Amounts owed to a foreign personal holding company, controlled foreign corporation, or passive foreign investment company*—(i) *Foreign personal holding companies.* If an amount to which paragraph (a) of this section otherwise applies is owed to a related foreign person that is a foreign personal holding company within the meaning of section 552, then the amount is allowable as a deduction as of the day on which the amount is includible in the income of the foreign personal holding company. The day on which the amount is includible in income is determined with reference to the method of accounting under which the foreign personal holding company computes its taxable income and earnings and profits for purposes of sections 551 through 558. See section 551(c) and the regulations thereunder for the reporting requirements of the foreign personal holding company provisions (sections 551 through 558).

(ii) *Controlled foreign corporations.* If an amount to which paragraph (a) of this section otherwise applies is owed to a related foreign person that is a controlled foreign corporation within the meaning of section 957, then the amount is allowable as a deduction as of the day on which the amount is includible in the income of the controlled foreign corporation. The day on which the amount is includible in income is determined with reference to the method of accounting under which the controlled foreign corporation computes its taxable income and earnings and profits for purposes of sections 951 through 964. See section 6038 and the regulations thereunder for the reporting requirements of the controlled foreign corporation provisions (sections 951 through 964).

(iii) *Passive foreign investment companies.* If an amount to which paragraph (a) of this section otherwise applies is owed to a related foreign person that is a passive foreign investment company within the meaning of section 1296, then the amount is allowable as a deduction as of the day on which amount is includible in the income of the passive foreign investment company. The day on which the amount is includible in income is determined with reference to the method of accounting under which the earnings and profits of the passive foreign investment company are computed for purposes of sections 1291 through 1297. See sections 1291 through 1297 and the regulations thereunder for the reporting requirements of the passive foreign investment company provisions. This exception shall apply, however, only if the person that owes the amount at issue has made and has in effect an election pursuant to section 1295 with respect to the passive foreign investment company to which the amount at issue is owed.

(c) *Application of section 267.* Except as limited in paragraph (b)(1) of this section, the provisions of section 267 and the regulations thereunder shall apply to any amount of original issue discount to which the provisions of this section do not apply.

(d) *Effective date.* The rules of this section are effective with respect to all original issue discount on debt instruments issued after June 9, 1984.

Par. 3. Section 1.267(a)–3 is added to read as follows:

§ 1.267(a)–3 Deduction of amounts owed to related foreign persons.

(a) *Purpose and scope.* This section provides rules under section 267(a) (2) and (3) governing when an amount owed to a related foreign person that is otherwise deductible under Chapter 1 may be deducted. Paragraph (b) of this section provides the general rules, and paragraph (c) of this section provides exceptions and special rules.

(b) *Deduction of amount owed to related foreign person*—(1) *In general.* Except as provided in paragraph (c) of this section, section 267(a)(3) requires a taxpayer to use the cash method of accounting with respect to the deduction of amounts owed to a related foreign person. An amount that is owed to a related foreign person and that is otherwise deductible under Chapter 1 thus may not be deducted by the taxpayer until such amount is paid to the related foreign person. For purposes of this section, a related foreign person is any person that is not a United States person within the meaning of section 7701(a)(30), and that is related (within the meaning of section 267(b)) to the taxpayer at the close of the taxable year in which the amount incurred by the taxpayer would otherwise be deductible. Section 267(f) defines "controlled group" for purposes of section 267(b) without regard to the limitations of section 1563(b). An amount is treated as paid for purposes of this section if the amount is considered paid for purposes of section 1441 or section 1442 (including an amount taken into account pursuant to section 884(f)).

(2) *Amounts covered.* This section applies to otherwise deductible amounts that are of a type described in section 871(a)(1) (A), (B) or (D), or in section 881(a) (1), (2) or (4). The rules of this section also apply to interest that is from sources outside the United States. Amounts other than interest that are from sources outside the United States, and that are not income of a related foreign person effectively connected with the conduct by such related foreign person of a trade or business within the United States, are not subject to the rules of section 267(a) (2) or (3) or this section. See paragraph (c) of this section for rules governing the treatment of amounts that are income of a related foreign person effectively connected with the conduct of a trade or business within the United States by such related foreign person.

(3) *Change in method of accounting.* A taxpayer that uses a method of accounting other than that required by the rules of this section must change its method of accounting to conform its

method to the rules of this section. The taxpayer's change in method must be made pursuant to the rules of section 446(e), the regulations thereunder, and any applicable administrative procedures prescribed by the Commissioner. Because the rules of this section prescribe a method of accounting, these rules apply in the determination of taxpayer's earnings and profits pursuant to § 1.1312–6(a).

(4) *Examples.* The provisions of this paragraph (b) may be illustrated by the following examples:

Example 1. (i) FC, a corporation incorporated in Country X, owns 100 percent of the stock of C, a domestic corporation. C uses the accrual method of accounting in computing its income and deductions, and is a calendar year taxpayer. In Year 1, C accrues an amount owed to FC for interest. C makes an actual payment of the amount owed to FC in Year 2.

(ii) Regardless of its source, the interest owed to FC is an amount to which this section applies. Pursuant to the rules of this paragraph (b), the amount owed to FC by C will not be allowable as a deduction in Year 1. Section 267 does not preclude the deduction of this amount in Year 2.

Example 2. (i) RS, a domestic corporation, is the sole shareholder of FSC, a foreign sales corporation. Both RS and FSC use the accrual method of accounting. In Year 1, RS accrues $z owed to FSC for commissions earned by FSC in Year 1. Pursuant to the foreign sales company provisions, sections 921 through 927, a portion of this amount, $x, is treated as effectively connected income of FSC from sources outside the United States. Accordingly, the rules of section 267(a)(3) and paragraph (b) of this section do not apply. See paragraph (c) of this section for the rules governing the treatment of amounts that are effectively connected income of FSC.

(ii) The remaining amount of the commission, $y, is classified as exempt foreign trade income under section 923(a)(3) and is treated as income of FSC from sources outside the United States that is not effectively connected income. This amount is one to which the provisions of this section do not apply, since it is an amount other than interest from sources outside the United States and is not effectively connected income. Therefore, a deduction for $y is allowable to RS as of the day on which it accrues the otherwise deductible amount, without regard to section 267 (a)(2) and (a)(3) and the regulations thereunder.

(c) *Exceptions and special rules*—(1) *Effectively connected income subject to United States tax.* The provisions of section 267(a)(2) and the regulations thereunder, and not the provisions of paragraph (b) of this section, apply to an amount that is income of the related foreign person that is effectively connected with the conduct of a United States trade or business of such related foreign person. An amount described in this paragraph (c)(1) thus is allowable as a deduction as of the day on which the amount is includible in the gross income of the related foreign person as effectively connected income under sections 872(a)(2) or 882(b) (or, if later, as of the day on which the deduction would be so allowable but for section 267(a)(2)). However, this paragraph (c)(1) does not apply if the related foreign person is exempt from United States income tax on the amount owed, or is subject to a reduced rate of tax, pursuant to a treaty obligation of the United States (such as under an article relating to the taxation of business profits).

(2) *Items exempt from tax by treaty.* Except with respect to interest, neither paragraph (b) of this section nor section 267 (a)(2) or (a)(3) applies to any amount that is income of a related foreign person with respect to which the related foreign person is exempt from United States taxation on the amount owed pursuant to a treaty obligation of the United States (such as under an article relating to the taxation of business profits). Interest that is effectively connected income of the related foreign person under sections 872(a)(2) or 882(b) is an amount covered by paragraph (c)(1) of this section. Interest that is not effectively connected income of the related foreign person is an amount covered by paragraph (b) of this section, regardless of whether the related foreign person is exempt from United States taxation on the amount owed pursuant to a treaty obligation of the United States.

(3) *Items subject to reduced rate of tax by treaty.* Paragraph (b) of this section applies to amounts that are income of a related foreign person with respect to which the related foreign person claims a reduced rate of United States income tax on the amount owed pursuant to a treaty obligation of the United States (such as under an article relating to the taxation of royalties).

(4) *Amounts owed to a foreign personal holding company, controlled foreign corporation, or passive foreign investment company*—(i) *Foreign personal holding companies.* If an amount to which paragraph (b) of this section otherwise applies is owed to a related foreign person that is a foreign personal holding company within the meaning of section 552, then the amount is allowable as a deduction as of the day on which the amount is includible in the income of the foreign personal holding company. The day on which the amount is includible in income is determined with reference to the method of accounting under which the foreign personal holding company computes its taxable income and earnings and profits for purposes of sections 551 through 558. See section 551(c) and the regulations thereunder for the reporting requirements of the foreign personal holding company provisions (sections 551 through 558).

(ii) *Controlled foreign corporations.* If an amount to which paragraph (b) of this section otherwise applies is owed to a related foreign person that is a controlled foreign corporation within the meaning of section 957, then the amount is allowable as a deduction as of the day on which the amount is includible in the income of the controlled foreign corporation. The day on which the amount is includible in income is determined with reference to the method of accounting under which the controlled foreign corporation computes its taxable income and earnings and profits for purposes of sections 951 through 964. See section 6038 and the regulations thereunder for the reporting requirements of the controlled foreign corporation provisions (sections 951 through 964).

(iii) *Passive foreign investment companies.* If an amount to which paragraph (b) of this section otherwise applies is owed to a related foreign person that is a passive foreign investment company within the meaning of section 1296, then the amount is allowable as a deduction as of the day on which amount is includible in the income of the passive foreign investment company. The day on which the amount is includible in income is determined with reference to the method of accounting under which the earnings and profits of the passive foreign investment company are computed for purposes of sections 1291 through 1297. See sections 1291 through 1297 and the regulations thereunder for the reporting requirements of the passive foreign investment company provisions. This exception shall apply, however, only if the person that owes the amount at issue has made and has in effect an election pursuant to section 1295 with respect to the passive foreign investment company to which the amount at issue is owed.

(iv) *Examples.* The rules of this paragraph (c)(4) may be illustrated by the following examples. Application of the provisions of sections 951 through 964 are provided for illustration only, and do not provide substantive rules concerning the operation of those provisions. The principles of these examples apply equally to the provisions of paragraphs (c)(4) (i) through (iii) of this section.

Example 1. P, a domestic corporation, owns 100 percent of the total combined

voting power and value of the stock of both FC1 and FC2. P is a calendar year taxpayer that uses the accrual method of accounting in computing its income and deductions. FC1 is incorporated in Country X, and FC2 is incorporated in Country Y. FC1 and FC2 are controlled foreign corporations within the meaning of section 957, and are both calendar year taxpayers. FC1 computes its taxable income and earnings and profits, for purposes of sections 951 through 964, using the accrual method of accounting, while FC2 uses the cash method. In Year 1 FC1 has gross income of $10,000 that is described in section 952 (a) ("subpart F income"), and which includes interest owed to FC1 by P that is described in paragraph (b) of this section and that is otherwise allowable as a deduction to P under chapter 1. The interest owed to FC1 is allowable as a deduction to P in Year 1.

Example 2. The facts are the same as in *Example 1*, except that in Year 1 FC1 reports no subpart F income because of the application of section 954 (b)(3)(A) (the subpart F de minimis rule). Because the amount owed to FC1 by P is includible in FC1's gross income in Year 1, the interest owed to FC1 is allowable as a deduction to P in Year 1.

Example 3. The facts are the same as in *Example 1*. In Year 1, FC1 accrues interest owed to FC2 that would be allowable as a deduction by FC1 under chapter 1 if FC1 were a domestic corporation. The interest owed to FC2 by FC1 is paid by FC1 in Year 2. Because FC2 uses the cash method of accounting in computing its taxable income for purposes of subpart F, the interest owed by FC1 is allowable as a deduction by FC1 in Year 2, and not in Year 1.

(d) *Effective date.* The rules of this section are effective with respect to interest that is allowable as a deduction under chapter 1 (without regard to the rules of this section) in taxable years beginning after December 31, 1983, but are not effective with respect to interest that is incurred with respect to indebtedness incurred on or before September 29, 1983, or incurred after that date pursuant to a contract that was binding on that date and at all times thereafter (unless the indebtedness or the contract was renegotiated, extended, renewed, or revised after that date). The regulations in this section issued under section 267 apply to all other deductible amounts that are incurred after July 31, 1989, but do not apply to amounts that are incurred pursuant to a contract that was binding on September 29, 1983 and at all times thereafter (unless the contract was renegotiated, extended, renewed, or revised after that date).

Michael P. Dolan,

Acting Commissioner of Internal Revenue.

Approved: December 17, 1992.

Alan J. Wilensky,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 92–31618 Filed 12–31–92; 8:45 am]

BILLING CODE 4830–01–M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1602

Records and Reports for Local Unions.

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of Extension of deadline for filing report.

SUMMARY: Notice is hereby given that the deadline for filing the 1992 Local Union report (EEO–3) required by 29 CFR 1602.22 is extended from December 31, 1992 to February 28, 1993. The two month period required to report certain information in Schedule I of that report may be any consecutive period of two months beginning no earlier than August 1, 1992 and ending no later than November 30, 1992.

EFFECTIVE DATE: January 5, 1993.

FOR FURTHER INFORMATION CONTACT: Joachim Neckere, Director, Program Research and Surveys Division at (202) 663–4958 (voice) or (202) 663–4593 (TDD).

For the Commission:

Evan J. Kemp, Jr.,

Chairman.

[FR Doc. 93–7 Filed 1–4–93; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 40a

Defense Contracting; Reporting Procedures on Defense Related Employment

AGENCY: Office of the Secretary, DoD.

ACTION: Final rule.

SUMMARY: This rule is the fiscal year 1992 revision of the section listing DoD contractors receiving contract awards of $10 million or more. This part is published to comply with the provisions of section 1 of the Public Law on Employees or Former Employees of Defense Contractors: Reports.

EFFECTIVE DATE: September 30, 1992.

FOR FURTHER INFORMATION CONTACT: Mr. J.R. Sungenis, Director, Directorate for Information Operations and Reports, Washington Headquarters Services, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA, 22202–4302. Telephone (703) 746–0334.

SUPPLEMENTARY INFORMATION:

List of Subjects in 32 CFR Part 40a

Armed Forces, Conflict of interests, Government employees, Government procurement, Reporting and recordkeeping requirements.

Accordingly, 32 CFR part 40a is revised to read as follows:

PART 40a—DEFENSE CONTRACTING: REPORTING PROCEDURES ON DEFENSE RELATED EMPLOYMENT

Authority: 10 U.S.C. 2397.

40a.1—Department of Defense contractors receiving awards of $10 million or more.

Fiscal Year 1992

3D/International, Inc.
3M
A&E Industries, Inc.
AAI Corp.
AAR Allen Airmotive Inc.
AAR Brooks & Perkins Corp.
ABB Flakt, Inc.
ACC Construction Co. Inc.
AEL Defense Corp.
AIL Systems, Inc.
AM General Corp.
AMCA International Construction Corp.
AT&T Communications, Inc.
AW & Associates Inc.
Abacus Technology Corp.
Abbott Laboratories
Accudyne Corp.
Actus Corp. & Sundt Corp. JV
Advanced Marine Enterprises
Advanced Research & Applications
Aepco, Inc.
Aerojet
Aeromet, Inc.
Aeroquip Corp.
Aerospace Corp., The
Aframe Lines, Ltd., USA
Age Marketing Co.
Agip Petroli SPA
Ahntech, Inc.
Air Treads, Inc.
Aksarben Foods, Inc.
Alascom, Inc.
Alberici, J.S. Construction Co.
Alisud Handling SPA
All Bann Enterprises, Inc.
All Star Maintenance, Inc.
Alliant Techsystems, Inc.
Allied Signal Aerospace Co.
Allied Signal, Inc.
Altama Delta Corp.
Amerada Hess Corp.
American Auto Carriers
American Engineer Corp.
American Fuel Cell & Coated Fabrics
American International Contractors
American Management Systems, Inc.
American President Lines, Ltd.
American Systems Corp.
American Systems Engineering Corp.

American Telephone & Telegraph Co.
American Trans Air & Connie Kalitta Services JV
American Transport Lines, Ltd.
American Vision Systems, Inc.
Amerind, Inc.
Ametek, Inc.
Amoco Oil Corp.
Amron Corp.
Amtec Corp.
Anadac, Inc.
Analysis & Technology, Inc.
Analytic Science Corp., The
Analytic Services, Inc.
Analytical Systems Engineering Corp.
Andrulis Research Corp.
Applied Data Technology, Inc.
Applied Research Associates, Inc.
Applied Technology Associates, Inc.
Arcata Associates, Inc.
Arco Power Technologies, Inc.
Arinc, Inc.
Arinc Research Corp.
Armtec Defense Products Co.
Arrow Construction, Inc.
Association Momentanee Entre
Assurance Technology Corp.
Astronautics Corp. of America
Atherton Construction
Atlantic Dry Dock Corp.
Atlantic Industries, Inc.
Atlantic Research Corp.
Atlantic Richfield Co.
Atlas Processing Co.
Autec Range Services
Automated Sciences Group, Inc.
Automation Research Systems, Ltd.
Avco Corp.
Avondale Industries, Inc.
BAMSI, Inc.
BBDO Worldwide, Inc.
BBN Communications Corp.
BDM International, Inc.
BDM Management Services Co.
BEI Electronics, Inc.
BFM Aerospace Corp.
BP Oil Co.
BT Marine, Ltd
Babcock & Wilcox Co., The
Bahrain National Oil Co.
Baker TSA, Inc.
Balimoy Mfg. Co. of Venice
Ball Corp.
Baltimore Gas & Electric Co.
Barnhart, Douglas E., Inc.
Barrett Refining Corp.
Basil & Trataros JV
Basil, Frank E., Inc.
Bateson, J.W. Co., Inc.
Bath Iron Works Corp.
Battelle Memorial Institute
Bay Tankers, Inc.
Bean Dredging Corp.
Bechtel National, Inc.
Beech Aerospace Services, Inc.
Beech Aircraft Corp.
Bell Atlantic Corp.
Bell Helicopter Textron & Boeing Co., JV
Bell Helicopter Textron, Inc.
Belleville Shoe Mfg. Co.
Bender, Allen L., Inc.
Bender, Shipbuilding & Repair Co.
Beneco Enterprises, Inc.
Beretta U.S.A. Corp.
Betac Corp.
Bethlehem Steel Corp.
Biehn Construction, Inc.
Big Bear Oil Co., Inc.
Bionetics Corp.
Black & Decker Corp.
Black & Veatch
Black River Constructors
Blake Construction Co., Inc.
Blount, Inc.
Blount/Universal City Construction JV
Blue Cross & Blue Shield of South Carolina
Boeing Aerospace Operations
Boeing Co. & Sikorsky Aircraft JV
Boeing Co., The
Boland, David, Inc.
Bolt Beranek & Newman, Inc.
Booz Allen & Hamilton, Inc.
Braintree Maritime Corp.
Braswell Services Group, Inc.
Brazos Roofing International
British Aerospace PLC
Broughton, T.T. & Sons
Brown & Root, Inc.
Brown & Root International, Inc.
Brown & Root Services Corp.
Browning Construction Co.
Brunswick Corp.
Buckner & Moore, Inc.
Bulova Technologies Inc.
Bundesamt Fuer Wehrtechnik
Burgos Fred Construction Co.
Burns & Roe Services Corp.
Burnside Ott Aviation Training Center
C3, Inc.
CACI, Inc.
CACI International, Inc.
CAE Link Corp.
CAS, Inc.
CBC Enterprises, Inc.
CFM International, Inc.
CFS Aircargo, Inc.
CRS Sirrine Metcalf & Eddy JV
CTA, Inc.
Cabot Corp.
Caddell Construction Co., Inc.
Calcasieu Refining Co.
California Microwave, Inc.
California Pacific Associates
Calspan Corp.
Caltex Oil Products Co.
Campbell Industries
Canon USA, Inc.
Cargill Petroleum, Inc.
Carnegie Mellon University
Carolina Power & Light Co.
Carothers Construction, Inc.
Casde Corp.
Case, J.I. Co.
Caterpillar, Inc.
Celikcilik San Ve Tic As
Center For Naval Analyses
Central Gulf Lines, Inc.
Centre Mfg. Co., Inc.
Century Technologies, Inc.
Ceridian Corp.
Chamberlain Mfg. Corp.
Chem-Nuclear Systems, Inc.
Chemical Waste Management, Inc.
Chesapeake & Potomac Tel Co VA
Chevron USA, Inc.
Childers Construction Co.
Chrysler Technologies Airborne Systems
Cincinnati Gear Co., The
Cincinnati Milacron Mktg Co.
Coastal Aruba Refining NV
Coastal Eagle Point Oil Co.
Coastal Group, Inc.
Coastal Refining & Marketing
Cobro Corp.
Codar Technology, Inc.
Codex Corp.
Coleman Research Corp.
Collins International Service Co.
Colsa, Inc.
Columbia Research Corp.
Comarco, Inc.
Comcon, Inc.
Communications Satellite Corp.
Compania Espanola De Petroleos
Compliance Corp.
Comprehensive Technologies International
Comptek Research, Inc.
Computer Associates International
Computer Dynamics, Inc.
Computer Sciences Corp.
Conagra, Inc.
Condor Systems, Inc.
Conoco, Inc.
Consolidated Electronics, ITT & Westinghouse JV
Consolidated Services, Inc.
Contel Corp.
Continental Maritime of San Diego
Contraves Goerz Corp.
Control Data Corp.
Cormorant Shipholding Corp.
Cortana Corp.
Cox Construction Co.
Craddock, Terry, Inc.
Craft Machine Works, Inc.
Crowley Marine Services, Inc.
Crysen Refining Inc.
Cubic Corp.
Cummins Engine Co., Inc.
Curtis Wright Corp.
DBA Systems, Inc.
DCS Corp.
Dames & Moore
Dataproducts News England, Inc.
Day & Zimmerman, Inc.
Day & Zimmerman/Basil Corp. JV
De Bra, Fred B. Co., The
De Filippis
Del Jen, Inc.
Delta Air Lines, Inc.
Delta Dental Plan of California
Detroit Diesel Corp.
Detyens Shipyards, Inc.
Deutsche Bundespost

Deval Corp.
Diagnostic Retrieval Systems
Diamond Shamrock Refining
Digital Equipment Corp.
Digital Systems Research, Inc.
Dillingham Construction Corp.
Dipl Ing Hans Schiebel
Dock Express Contractors, Inc.
Douglas Aircraft Co.
Draper, Charles Stark Laboratories, Inc.
Dreyfus Louis Corp.
Du Pont, E.I. De Nemours & Co.
Dual & Associates, Inc.
Dycom Industries, Inc.
Dynamic Science, Inc.
Dynamics Research Corp.
Dyncorp
Dynetics, Inc.
EA Engineering & Science Technology
EC III JV
ECC International Corp.
ECI Construction, Inc.
EDP Enterprises, Inc.
EER Systems Corp.
EG&G, Inc.
EG&G Management Systems
EG&G Riticon
EG&G Washington Analytical Services Center
EOS Technologies, Inc.
ERC Environmental & Energy Service
ESL, Inc.
E Systems, Inc.
Eagle Technology, Inc.
Earl Industries, Inc.
Earth Technology Corp.
East Penn Mfg. Co.
Eastman Kodak Co.
Eaton Corp.
Ebasco Constrs Gust Newberg JV
Ebasco Services, Inc.
Eberharter Construction Group, Inc.
Economics Technology Associates
El Paso Refining Co., Ltd.
Elbit Computers, Ltd.
Eldyne, Inc.
Electro Methods, Inc.
Electronic Data Systems Corp.
Electronics & Space Corp.
Electrospace Systems, Inc.
Elkem Metals Co.
Emco, Inc.
Emergency Medical Services Assoc.
Engineered Air Systems, Inc.
Engineering & Economics Research
Engineering Science, Inc.
Ensco, Inc.
Environmental Research Institute of Michigan
Environmental Technologies Group
Equa Industries, Inc.
Esso Nederland BV
Ex Cell O Corp.
Executive Resource Associates
Exide Electronics Corp.
Expeditor Transport Corp.
Exporter Transport Corp.
Expressor Transport Corp.
Exxon Co., USA
Exxon Corp.
F2M, Inc.
FEL Corp.
FKW, Inc.
FMC Corp.
FMS Corp.
FN Mfg., Inc.
Face, Edward W., Co., Inc.
Fairchild Aircraft Corp.
Fairchild Industries, Inc.
Fairchild Space & Defense Corp.
Falcon Microsystems, Inc.
Farrell Lines, Inc.
Federal Express, Northwest Airlines, PanAm World Airways, Tower Air & United Parcel Service JV
Federal Computer Corp.
Federal Data Corp.
Federal Hoffman, Inc.
Felec Services, Inc.
Ferguson Williams, Inc.
First Hospital Corp.
Flight International Group, Inc.
Flightsafety International, Inc.
Flightsafety Service Co.
Flintco, Inc.
Fluke, John Mfg. Co., Inc.
Fluor Engineers, Inc.
Foley Co.
Fordice Construction Co.
Foundation Health Corp.
Freightliner Corp.
Frito Lay, Inc.
Frontier Engineering, Inc.
Fuller, George A. Co.
G&C Enterprises, Inc.
G&F Co.
GEC Avionics, Ltd.
GEC Marconi Electronic Systems
GLR Constructors JV
GNB Industrial Battery Co.
GTE Government Systems Corp.
Garcia, Luis E., Inc.
Gaskins, L.C., Construction Co.
General Atomics
General Dynamics Corp.
General Dynamics & FMC Corp. JV
General Dynamics & Westinghouse JV
General Electric Co.
General Foods USA
General Mills, Inc.
General Motors Corp.
General Physics Corp.
General Research Corp.
General Ship Corp.
Gentex Corp.
Geo Centers, Inc.
Georgia Power Co.
Georgia Tech Research Corp.
Giant Refining Co.
Gibbs & Cox, Inc.
Giddings & Lewis, Inc.
Gilbert Corp of Delaware
Gold Line Refining, Ltd.
Golden Mfg Co., Inc.
Goodrich, B.F. Co., The
Goodyear Tire & Rubber Co., The
Government Micro Resources
Government Systems, Inc.
Government Technology Services
Granite Construction Co.
Great Lakes Dredge & Dock Co.
Greenbrier Industries, Inc.
Greenwich Air Services, Inc.
Grimberg, John C. Co., Inc.
Grumman Aerospace Corp.
Grumman Corp.
Grumman Data Systems Corp.
Grumman Technical Services, Inc.
Gulf Coast Trailing Co.
Gulfstream Aerospace Corp.
Guyco Engineering Co.
HFSI, Inc.
Halifax Engineering, Inc.
Halter Marine, Inc.
Harbert International, Inc.
Harcon, Inc.
Hardaway Co., Inc., The
Harnischfeger Corp.
Harris Corp.
Harsco Corp.
Hawaiian Airlines, Inc.
Hawaiian Electric Co., Inc.
Hawaiian Independent Refinery
Haworth, Inc.
Hazeltine Corp.
Health Strategies International
Hellenic Fuels & Lubricants
Hensel Phelps Construction Co.
Hercules Construction Corp.
Hercules Engines, Inc.
Hercules, Inc.
Hermes Consolidated, Inc.
Heroux, Inc.
Hewlett Packard Co.
Hilton Systems, Inc.
Hitt Electric Corp.
Hoffman La Roche, Inc.
Holmes & Narver Inc.
Holston Defense Corp.
Honam Oil Refinery Co., Ltd.
Honeywell, Inc.
Hooks, Mike, Inc.
Horizons Technology, Inc.
Horst Mosolf International Sped
Hospital Klean
Howmet Corp.
Hubbard Construction Co.
Hughes Aircraft & Raytheon Co. JV
Hughes Aircraft Co.
Hughes Data Systems & BTG, Inc. JV
Hughes Danbury Optical Systems
Hughes Electronic Technologies
Hughes Training Systems, Inc.
Hunt Building Corp.
Huttenbauer, E. & Son, Inc.
Hyman, George Construction Co.
Hyster Co.
I Net, Inc.
IBP, Inc.
ICF, Inc.
ICI Americas, Inc.
IIT Research Institute
ILC Dover
ILC Industries, Inc.
IPAC
IRISS Co.
IT Corp.

ITT Corp.
ITT Federal Services Corp.
Illinois Glove Co.
Imo Industries, Inc.
Industrial Acoustics Co., Inc.
Industrial Data Link Corp.
Information Handling Services Group
Information Spectrum, Inc.
Information Technology, Inc.
Infotec Development, Inc.
Ingalls Shipbuilding, Inc.
Institute for Defense Analyses
Integrated Systems Analysts
Intel Corp.
Intelcom Support Services, Inc.
Intergraph Corp.
Intermarine, USA
Intermetrics, Inc.
International Business Machines Corp.
International Marine
International Technology Corp.
International Terminal Operating Co.
Interstate Electronics Corp.
Interstate Landscaping Co., Inc.
Ireco, Inc.
Irvin Industries, Inc.
Israel Aircraft Industries, Ltd.
Israeli Military Industries
Isratex, Inc.
Itek Corp.
J&J Maintenance, Inc.
JT Construction Co., Inc.
JWK International Corp.
Jacobs Engineering Group, Inc.
James, T.L. & Co., Inc.
Japan Aircraft MFG Co., Ltd
Jaycor
Jered Brown Brothers, Inc.
Jersey Central Power & Light Co.
Joeris, Inc.
Johns Hopkins University
Johnson, Al Construction Co.
Johnson Controls World Service
Johnson G.E. Construction Co.
Johnson Technology, Inc.
Jonathan Corp., The
Jones Group, Inc., The
Jones, John T. Construction Co.
Jordan, W.M. Co., Inc.
Jowett, Inc.
Junghans Feinwerktechik
K&K Industries, Inc.
K&M Maintenance Services
Kaiser Aerospace & Electronics Corp.
Kaman Aerospace Corp
Kaman Sciences Corp.
Kay & associates, Inc.
Kearfott Guidance & Navigation Corp.
Keco Industries, Inc.
Kidde, Inc.
Kiewit & Johnson, Al JV
Kilgallon Construction Co.
Kilgore Corp.
Koch Fuels, Inc.
Koh Systems, Inc.
Kokosing Construction Co., Inc.
Kollmorgen Corp.
Korea Electric Power Corp.
Korean Air Lines Co., Ltd.
Kraft General Foods, Inc.
Krempp Lumber Co.
Krystal Gas Marketing Co.
Kvaas Construction Co.
Kyung IN Energy Co.
La Barge Products, Inc.
Ladd, Roy E., Inc.
Laguna Industries, Inc.
Laidlaw Environmental Services
Laketon Refining, Inc.
Lane Construction Corp.
Law Co., Inc., The
Law Environmental, Inc.
Lawrence Associates, Inc.
Lear Astronics Corp.
Lear Siegler Management Services
Learjet Corp.
Leland Electrosystems, Inc.
Lewis, Lee General Contractor
Libby Corp.
Life Cycle Engineering, Inc.
Light Helicopter Turbine Engine Co.
Lilly, David B. Co., Inc.
Lilly, Eli & Co.
Little, Arthur D., Inc.
Litton Industries, Inc.
Litton Systems, Inc.
Lockheed Aeromod Center, Inc.
Lockheed Aeronautical Systems Co.
Lockheed Aircraft Service Co.
Lockheed Corp.
Lockheed Missiles & Space Co.
Lockheed Sanders, Inc.
Locus, Inc.
Loggins Meat Co., Inc.
Logicon, Inc.
Logistics Management Institute
Loral Aerospace Corp.
Loral Corp.
Loral Training & Tech Svcs.
Loral Vought Systems
Lott Constructors, Inc.
Louisville Gas & Electric Co.
Luhr Brothers, Inc.
Lykes Brothers Steamship Co., Inc.
MCC Construction Corp.
MCI Constructors, Inc.
MCI International, Inc.
MCI Telecommunications Corp.
MG Refining & Marketing
MK Ferguson Group
MW Builders
Mac H.B., Inc.
Macalloy Corp.
Macaulay Brown, Inc.
Maden Tech Consulting, Inc.
Maersk, Inc.
Maersk Stevedoring Co.
Magann, W.F. Corp.
Magnavox Government & Industrial Electronics Co.
Mandex, Inc.
Manson Construction & Engineering Co.
Mantech International Corp.
Mantech, VSE, & Potomac Research JV
Mar Ship Operators, Inc.
Marconi Command & Control Systems, Ltd.
Marine Hydraulics International
Mark Diversified, Inc.
Martech USA, Inc.
Martin Baker Aircraft Co., Ltd
Martin Electronics, Inc.
Martin Marietta Corp.
Martin Marietta, Diehl Co's., Thorn & Thompson JV
Martin Marietta Corp. & Westinghouse Electric Co. JV
Marvin Engineering Co., Inc.
Maryland Air International, Inc.
Mason Hanger Silas Mason, Inc.
Massachusetts Institute of Technology
Maxima Corp.
Maxwell Laboratories, Inc.
Mayer, Oscar Foods Corp.
McCarthy Construction Co.
McDonnell Douglas Corp.
McDonnell Douglas Electronic Systems
McDonnell Douglas Helicopter Co.
McDonnell Douglas Missile & Space Systems Co.
McDonnell Douglas Space Systems Co.
McDonnell Douglas Training Systems, Inc.
McKnight Construction Co., Inc.
McLaghlin Research Corp.
McMaster Construction Inc.
McMullan, Robert & Son, Inc.
McMullen, John J. Associates, Inc.
Mercer University
Merchants National Corp.
Merck & Co., Inc.
Meredith, W.B., II., Inc.
Metal Trades, Inc.
Metcalf & Eddy, Inc.
Metric Construction Co., Inc.
Metric Constructors, Inc.
Metric Systems Corp.
Metro Machine Corp.
Metters Industries, Inc.
Mevatec Corp.
Michelin Tire Corp.
Micro Lithics, Inc.
Midgard DSAG ,
Milcom Systems Corp.
Miles Biological Laboratories
Miller Herman, Inc.
Mills Mfg. Corp.
Miltope Corp.
Mine Safety Appliances Co.
Mip Instandsetzungsbetric
Misener Marine Construction
Mission Research Corp.
Mitre Corp.
Mobil Corp.
Mobility, Inc.
Modern Technologies Corp.
Modular Computer Systems, Inc.
Mohamed A. Kharafi
Monarch Construction Co.
Montgomery, J.M., Consulting Engineers
Moon Engineering Co., Inc.
Morrison Knudsen Co., Inc.
Mortenson, M.A. Companies
Motor Oils Hellas Corinth Refinery
Motorola Communications & Electronics
Motorola, Inc.
NASP National Contractor Team

NCR Comten, Inc.
NUS Corp.
Natco Limited Partnership
National Academy of Sciences
National Airmotive Corp.
National Apparel, Inc.
National Beef Packing Co.
National Forge Co.
National Steel & Shipbuilding Co.
National Systems & Research Co.
Navcom Defense Electronics, Inc.
Navcom Systems, Inc.
Navistar International Transportation
Nero & Associates, Inc.
Net Fed, Inc.
New Mexico State University
Newport News Shipbuilding & Dry Dock Co.
Ni Industries, Inc.
Nichols Research Corp.
Nomura Enterprise, Inc.
Norden Systems, Inc.
Norfolk Dredging Co., Inc.
Norfolk Shipbuilding & Dry Dock Corp.
North American Mechanical Services
North Atlantic Industries, Inc.
North Carolina Dept. of Human Resources
Northeast Construction Co.
Northern Telecom, Inc.
Northrop Corp.
Northrop Worldwide Aircraft Services, Inc.
Northwest Enviro Service, Inc.
Nova Group, Inc.
Nuclear Research Corp.
OH Materials Corp.
Ocean Star Shipping, Inc.
Ohbayashi Corp.
Oil Refineries, Ltd.
Okinawa Electric Power Co.
Olin Corp.
Olin Ordnance
Olmos Equipment Co., Inc.
Oracle Complex System Corp.
Oregon Iron Works, Inc.
Orincon Corp.
Oshkosh Truck Corp.
Owl International, Inc.
PAE GMBH
PCC Technical Industries, Inc.
PCL Construction Associates, Inc.
PHH Homequity Corp.
PHP Healthcare Corp.
PRC Environmental Management
PRC, Inc.
Pacer Systems, Inc.
Pacific Architects & Engineers, Inc.
Pacific Ship Repair & Fabrication
Pacific Sierra Research Corp.
Pacifica Services, Inc.
Paramax Systems Corp.
Parker Hannifin Corp.
Parsons, Ralph M. Co., The
Patrol Ofisi A S Genel Mud
Patton Tully Transportation Co.
Peat Marwick Mitchell & Co.
Peerless Petrochemicals, Inc.
Pemco Aeroplex, Inc.
Pence, Howard W., Inc.
Pennsylvania State University
Pentastar Electronics, Inc.
Perini Corp. & O&G Industries JV
Perland Environmental
Peterson Builders, Inc.
Philip Morris, Inc.
Phillips & Jordan, Inc.
Phillips Petroleum Co.
Phoenix Construction Services
Physics International Co.
Picker International, Inc.
Pile Foundation, Inc.
Pillsbury Co., The
Pine Bluff Sand & Gravel Co.
Pinner Construction Co., Inc.
Pioneer Recovery Systems, Inc.
Piquniq Management Corp.
Pizzagalli Construction Co.
Placid Oil Co.
Planning Systems, Inc.
Pneumo Abex Corp.
Potomac Electric Power Co.
Potomac Systems Engineering
Power Conversion, Inc.
Powertronic Systems, Inc.
Prestolite Electric, Inc.
Pride Pipeline Co.
Proctor & Gamble Co., The
Producto Electronic Industries
Propellex Corp.
Puerto Rico Sun Oil Co., Inc.
Puget Sound Tug & Barge Co.
Pulau Electronics Corp.
QED Systems, Inc.
Questech, Inc.
Quintron Corp.
R&D Associates
RJO Enterprises, Inc.
Racal Communications, Inc.
Racal Tacticom, Ltd.
Radian Corp.
Rados, Steve P., Inc.
Rafael Armaments Development
Ram Systems GMBH
Rand Corp., The
Rasmussen, C.A., Inc.
Raymond Engineering, Inc.
Raytheon Co.
Raytheon Service Co.
Raytheon Support Services, Co.
Red River Carriers
Refinery Associates of Texas
Reflectone, Inc.
Research Analysis & Maintenance
Resource Consultants, Inc.
Rexon Technology Corp.
Reynolds Metals Co.
Rich International Airways
River City Construction Co.
Riverside Research Institute
Robbins Gioia, Inc.
Rockwell International Corp.
Rockwell Power Systems
Rolls Royce, PLC
Roofing Constructors, Inc.
Rooney, Frank J., Inc.
Rosenblatt, M. & Son, Inc.
Ross, R.G., Construction Co., Inc.
Royal Norwegian Naval Material
Ryan Co., Inc.
Ryan Walsh, Inc.
S Systems Corp.
S&H Mechanical Contractors
S&M Sakamoto, Inc.
SAIC Engineering, Inc.
SCI Systems, Inc.
SCI Technology, Inc.
SFA, Inc.
SMS Data Products Group, Inc.
SPSA Southeastern Public Service
SRA Technologies, Inc.
SRI International
SRS Technologies
Saab Training Systems AB
Sabreliner Corp.
Saco Defense, Inc.
Sacramento Municipal Utility
Sadelmi New York, Inc.
Saft America, Inc.
Salk Institute for Biological Studies
Salomon, Inc.
San Diego Community College District
Sargent Fletcher Co.
Saudi Operations & Maintenance Co.
Schafer, W.J. Associates, Inc.
Schneider, Inc.
Science & Technology, Inc.
Science Applications International Corp.
Scientific Atlanta, Inc.
Scientific Research Corp.
Sea Land Service, Inc.
Sealift, Inc.
Sears Roebuck & Co.
Sechan Electronics, Inc.
Semcor, Inc.
Sequa Corp.
Serv Air, Inc.
Service Engineering Co., Inc.
Sevenson Construction Corp.
Shadrock Petroleum Products
Sharp Construction Co., Inc.
Sharp, George G., Inc.
Shell Oil Co.
Sherikon, Inc.
Shin Cheon Co., Ltd.
Shirley Construction Corp.
Short Brothers PLC
Short, John & Associates
Siemens Elektrogeraete GMBH
Sierra Nevada Corp.
Silicon Graphics, Inc.
Silverton Construction Co., Inc.
Simms Industries, Inc.
Simplex Wire & Cable Co.
Sippican, Inc.
Sisters of Charity
Sligsby Aviation, Ltd.
Smiths Industries, Inc., USA
Sohio Oil Co.
Sonalysts, Inc.
Sony Corporation of America
South Carolina Research Authority
Southeast Atlantic Cargo Operators
Southern Air Transport, Inc.
Southern California Edison Co.
Southern Systems, Inc.

Southfork Systems, Inc.
Southwest Marine, Inc.
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Southwest Research Institute
Space & Sensors Associates
Space Applications Corp.
Space Data Corp.
Sparta, Inc.
Sparton Corp.
Sparton Electronics Florida
Spectrum Emergency Care, Inc.
Sperry Marine, Inc.
Ssangyong Oil Refining Co., Ltd.
Standard Technology, Inc.
Stanford Telecommunications
Stanford University
Statoil North America, Inc.
Sterling Federal Systems, Inc.
Stewart & Stevenson Services, Inc.
Storage Technology Corp.
Strand, Inc.
Strong Bill Enterprises, Inc.
Sumaria Systems, Inc.
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Summa Technology, Inc.
Sun Microsystems, Inc.
Sun Refining & Marketing Co.
Sundstrand Corp.
Sundt Corp.
Sunkyoung, Ltd.
Superfos A/S
Supreme Beef Processors, Inc.
Sverdrup Corp.
Sverdrup Technology, Inc.
Synetics Corp.
Syscon Corp.
System Planning Corp.
System Resources Corp.
Systems & Electronics, Inc.
Systems Control Technology
Systems Engineering & Management Associates
Systems Engineering & Management Co.
Systems Engineering Associates
Systems Planning & Analysis
Systems Research & Applications Corp.
Systems Research Laboratories
TDS, Inc.
TGS Technology, Inc.
TSC, Inc.
TRW, Inc.
Tadiran Israel Electronic Industries
Talley Defense Systems, Inc.
Tampa Shipyards, Inc.
Techmatics, Inc.
Technical & Management Services Corp.
Technology Applications, Inc.
Technology Scientific Services
Tecolote Research, Inc.
Tecom, Inc.
Tektronix, Inc.
Teledyne Industries, Inc.
Telephonics Corp.
Telos Corp.
Tennessee Apparel Corp.
Tennier Industries, Inc.
Texaco Caribbean, Inc.
Texaco International Trader, Inc.
Texaco Instruments & Martin Marietta JV
Texas Instruments Inc.
Texas Utilities Electric Co.
Texcom, Inc.
Textron, Inc.
Thermo Electronic Technologies Corp.
Thiokol Corp.
Thomasville Furniture Industries
Thompson, J. Walter Co.
Tilley Constructors & Engineers
Titan Corp.
Titan Wheel International
Todd Pacific Shipyards Corp.
Tohoku Denryoku KK
Tokyo Denryoku KK
Tracor Aerospace, Inc.
Tracor Applied Sciences, Inc.
Tracor, Inc.
Trans World Airlines, Inc.
Translant, Inc.
Trescomp, Inc.
Tri State Design, Inc.
Trinity Industries, Inc.
Trinity Marine Group
Triton Marine Construction
Tucson Electric Power Co.
Turtle Mountain Mfg. Co.
Tyger Construction Co., Inc.
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U.S. Sprint Communications Co.
UNC, Inc.
URS Corp.
Unified Industries, Inc.
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Uniroyal Chemical Co., Inc.
Unisys Corp.
United Engineers & Constructors
United International Engineers
United Technologies Corp.
United Telecontrol Electronics
Universal Maritime Service
University of California
University of Dayton
University of Florida
University of Minnesota
University of Pennsylvania
University of Pittsburgh
University of Southern California
University of Texas System
University of Washington
Utah Power & Light Co.
Utah State University
VSE Corp.
Valentec International Corp.
Valmac Industries, Inc.
Varian Associates, Inc.
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Vector Research, Inc.
Veda, Inc.
Viereck Co., Inc.
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Vinnell Corp., & Brown & Root JV
Virtexco Corp.
Vitro Corp.
Vitronics, Inc.
Vought Aircraft
WMP Security Service Co.
Wang Laboratories, Inc.
Waterman Steamship Corp.
Wellco Enterprises, Inc.
Western Gear Corp.
Western Petroleum Co.
Westinghouse Electric Corp.
Westmont Industries
Weston, Roy F., Inc.
Wheeler Brothers, Inc.
Whitesell Green, Inc.
Whittaker Corp.
Willbros Butler Engineers, Inc.
Williams International Corp.
Wisconsin Physicians Service Insurance
Woodward, Clyde Consultants
World Airways, Rosenbalm Aviation, Key Airlines, American Airlines, Evergreen International & Emery Worldwide JV
Wyle Laboratories
Wynn Construction Co.
Xerox Corp.
Xontech, Inc.
Yates, W.G. & Sons Construction Co.
Yeager, E.L. Construction Co.
Young & Rubicam, Inc.
Zachry, H.B. Co.
Zodiac of North America Inc.

Dated: December 28, 1992.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–12 Filed 1–4–93; 8:45 am]

BILLING CODE 3810–01–M

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Part 194

[Docket No. PS–130]

RIN 2137–AC30

Response Plans for Onshore Oil Pipelines

December 28, 1992.

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule establishes regulations requiring response plans for certain pipelines that transport oil. These regulations are mandated by the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990 (OPA 90). The purpose of these requirements is to improve response capabilities and minimize the environmental impact of oil discharges from pipelines. Although RSPA is issuing an interim final rule, it invites comments and will, if appropriate, make changes to the rule.

DATES: The effective date of this interim final rule is January 5, 1993. Comments must be received on or before February 19, 1993.

ADDRESSES: The RSPA Dockets Unit maintains the public docket for this rulemaking. Written comments must be submitted in duplicate and mailed or hand-delivered to: RSPA Dockets Unit, room 8421, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001. Comments will become part of this docket and will be available for inspection or copying at the Dockets Unit in room 8421, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590–0001.

All comments and docketed material will be available for inspection and copying each business day between 8:30 a.m. and 5 p.m. in room 8421. For information concerning comments or copies of this interim final rule, the telephone number of the Dockets Unit is 202–366–5046.

FOR FURTHER INFORMATION CONTACT: Mr. Lloyd W. Ulrich, Office of Pipeline Safety Regulatory Programs, RSPA, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001, 202–366–4556, or Mr. Robert A. Monniere, Office of the Chief Counsel, RSPA, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001, 202–366–4400, regarding the contents of this interim final rule; or the RSPA Dockets Unit, room 8421, 400 Seventh Street, SW., Washington, DC 20590–0001, 202–366–5046, regarding copies of this interim final rule or other information in the docket.

SUPPLEMENTARY INFORMATION:

Introduction

In accordance with 5 U.S.C. 553(b)(3)(B), this interim final rule is being issued without a prior notice of proposed rulemaking and opportunity to comment. The Oil Pollution Act of 1990, Pub. L. No. 101–380, 104 Stat. 484, (OPA 90) which amends the Federal Water Pollution Control Act, 33 U.S.C. 1251 *et seq.*, contains statutory deadlines for the preparation and submission of response plans for onshore pipelines. After these deadlines, a pipeline operator whose pipeline is not in compliance with the statutory requirements would be prohibited from using that pipeline to handle, store, or transport oil.

In order to allow the timely implementation of OPA 90, RSPA has determined that good cause exists for finding that notice and comment is impracticable and contrary to public interest. RSPA believes that any further delay in issuing these regulations would create an undue hardship on the regulated community and have the potential to disrupt the sale and delivery of oil. In order to encourage the prompt filing of response plans and thus avoid the disruptive effect this rule could have on the oil industry, this rule is effective on its publication date.

Although an opportunity for public comment has not been provided prior to issuing this interim final rule, RSPA seeks public comment to assure that the rule is feasible and workable. If appropriate, RSPA will amend the provisions of this rule. RSPA will consider holding public hearings to obtain comments at a later date, if needed. As an interim final rule, this regulation is fully in effect and binding upon publication in the **Federal Register.**

Although no further regulatory action by RSPA is essential to implement this rule, RSPA encourages interested persons to participate in this rulemaking by submitting written views, data, or information on this interim final rule. Persons submitting comments should include their names and addresses, identify this rulemaking by the docket number stated in the heading of this rule and the specific section of the rule to which each comment applies, and give the basis for each comment. RSPA will consider all public comments and will make changes to this rule if public comments indicate a change is necessary.

Prior to the issuance of this rule, the Department engaged in preliminary data-gathering from various sources in order to define such terms as "substantial harm," "significant and substantial harm" and "worst case discharge." A summary of these contacts has been placed in the docket.

Background and Purpose

In recent years, several catastrophic oil spills have damaged the marine environment of the United States. These spills had extensive environmental impact, including the loss of fish and wildlife. In response to these catastrophic spills, Congress passed OPA 90 to establish a new national planning and response system. This system includes the development of facility response plans.

On October 18, 1991, the President, in Executive Order (E.O.) 12777, 56 FR 54757 (October 22, 1991) delegated authority to the Secretary of Transportation (the Secretary) to establish procedures, methods, and requirements for equipment to prevent and contain discharges of oil from pipelines.

The Secretary delegated certain OPA 90 prevention authority to the Administrator, Research and Special Programs Administration (RSPA), 57 FR 8581 (March 11, 1992). Specifically, the Secretary granted the RSPA Administrator (Administrator) authority to establish "procedures, methods, and equipment and other requirements for equipment to prevent discharges from, and to contain oil and hazardous substances in, pipelines, motor carriers, and railways." 33 U.S.C. 1321(j)(1)(C). RSPA believes that, with respect to pipelines, these prevention concerns have been addressed and satisfied by the existing regulations in 49 CFR part 195 (e.g., 49 CFR 195.402, 195.416, 195.418, 195.428, and 195.430). In a subsequent rulemaking, the Secretary also delegated to the appropriate modal administrators the authority to require, review, and approve response plans for pipelines, motor carriers, and railroads. Under a delegation from RSPA's Administrator, the Office of the Associate Administrator for Pipeline Safety will implement this regulation. This rule implements OPA 90 requirements as they apply to response planning for oil discharges from pipelines. Response planning for hazardous substance discharges from pipelines will be the subject of a separate rulemaking.

This rule applies to all oil pipelines whether or not such pipelines are exempt from existing Federal pipeline safety regulations or statutes (e.g., 49 CFR part 195 currently exempts pipelines operating at a stress level of 20 percent or less of specified minimum yield strength (SMYS), onshore gathering lines in rural areas, and pipelines operated by gravity).

This rule implements section 4202(a) and section 4202(b) of OPA 90. Section 4202(a) amended section 311(j) of the FWPCA, 33 U.S.C. 1321(j), and sets out in paragraph (j)(5) response planning requirements relating to pipelines. Section 4202(b) of OPA established the implementation schedule for these provisions. These requirements include the preparation and submission of a response plan addressing a worst case discharge or a substantial threat of a worst case discharge of oil or a hazardous substance.

Definitions

The OPA 90 defines "facility" as "any structure, group of structures, equipment, or device (other than a vessel) which is used for one or more of the following purposes: exploring for, drilling for, producing, storing,

handling, transferring, processing, or transporting oil. This term includes any motor vehicle, rolling stock, or pipeline used for one or more of these purposes." 33 U.S.C. 2701(9). In addition, "onshore facility" is defined as "any facility (including, but not limited to, motor vehicles and rolling stock) of any kind located in, on, or under, any land within the United States other than submerged land." 33 U.S.C. 2701(24).

As defined in this rule, oil includes but is not limited to petroleum, fuel oil, sludge, oil refuse, and oil mixed with waste other than dredge spoils. This definition includes animal, vegetable, and mineral oils in addition to petroleum oil. In addition, the term "navigable waters," as used in section 1001 of FWPCA and this rule, means the waters of the United States, including the territorial sea. This would include such waters as lakes, rivers, streams, waters which are used for public drinking water supplies, recreation, and waters from which fish or shellfish are taken and sold in interstate or foreign commerce. The term "worst case discharge" is defined as the largest foreseeable discharge in adverse weather conditions. 33 U.S.C. 1321(a)(24)(B).

Recommendations of Oil Spill Response Plan Negotiated Rulemaking Committee

The Coast Guard has been drafting regulations requiring response plans for tank vessels and onshore marine transportation-related facilities. To assist with the development of its rules, the Coast Guard established the Oil Spill Response Plan Negotiated Rulemaking Committee. (57 FR 1139, January 10, 1992).

Many of the recommendations developed through the negotiated rulemaking process are relevant to pipeline transportation and have been included in this rule. These include recommendations on definitions of "adverse weather" and "maximum extent practicable."

A copy of the final Committee report is available in the RSPA public docket (Docket No. PS–130).

Response Plans for Onshore Oil Pipelines

Section 4202(b)(4) of OPA 90 establishes statutory deadlines for the submission and approval of response plans regarding onshore oil pipelines. After February 18, 1993, a pipeline for which a response plan is required to be submitted may not be used to handle, store, or transport oil unless a plan for the pipeline has been submitted to RSPA. After August 18, 1993, a pipeline for which a response plan is required, may not handle, store, or transport oil unless the facility is operating in compliance with the applicable response plan.

For those plans addressing "significant and substantial harm" caused by an oil discharge and thus requiring RSPA approval, RSPA may authorize the operation of an onshore oil pipeline for up to two years after the operator has submitted a response plan. The two year authorization is based on the operator certifying, no later than July 18, 1993, that it has obtained sufficient private personnel and equipment to respond to a worst case discharge or a substantial threat of a worst case discharge. RSPA has set the July 18, 1993 deadline for receipt of certifications to allow adequate processing time prior to the statutory deadline. The terms "respond" and "response" include the containment and removal of oil from water and shorelines, the temporary storage and disposal of recovered oil, and other actions needed to minimize or mitigate damage to the environment.

In the vast majority of cases, the operator's response plan will consist of a core plan covering the entire company's pipeline facilities and separate response zone appendices. Each appendix will address a response zone which is a geographic area along a length of pipeline, containing one or more adjacent line sections, for which the operator must provide response capabilities. The size of the response zone is determined by the operator after considering available spill response capability, resources, and geographic characteristics, including number and location of navigable waters, public drinking water intakes and environmentally sensitive areas in or adjacent to navigable waters. An operator must provide sufficient response equipment and response personnel, either by the operator's organization or through contract, to reach a worst case discharge, or a substantial threat of such a discharge, within the times prescribed in this rule. RSPA requires operators to ensure by their response plans that resources can be deployed in required time frames. RSPA requests comments on the definition for response zone.

RSPA believes that many operators already have in place response plans that satisfy, or substantially satisfy, the intent of OPA 90. RSPA intends that the definition for "response zone," as proposed in this rule, will conform with those planning areas already delineated in the operators' existing plans. RSPA's purpose in asking for appendices applicable to separate response zones is to: (1) Allow the operator to add incrementally to the existing plans the information elements required by OPA 90 and (2) provide the operator the convenience of grouping appropriate line sections for which a common set of planning elements would apply in one response zone.

A major objective of OPA 90 is to utilize effective response planning to reduce the likelihood that an accidental oil discharge will reach navigable waters. OPA 90 emphasized facility location as a key element in determining the environmental threat posed by a facility. Therefore, this interim final rule requires operators to identify, within a response zone, areas of greatest vulnerability to an oil discharge, including navigable waters, public drinking water intakes, and environmentally sensitive areas.

RSPA is requiring operators of onshore pipelines that handle, store or transport oil and could reasonably be expected to cause either "substantial harm" or "significant and substantial harm" to the environment by discharging oil into or on the navigable waters or adjoining shorelines, to prepare and submit response plans for a worst case discharge or the substantial threat of a worst case discharge.

In the event of a worst case discharge, or a substantial threat of such a discharge, operators must then take action to protect these navigable waters, public drinking water intakes, and environmentally sensitive areas in accordance with a response plan. Soon after the discovery of a discharge, an operator must determine whether or not it is a substantial threat of becoming a worst case discharge, based on pipe diameter, operating pressure, flow rate, topography, weather conditions and shut down capability. By activating its response plan, the operator can reduce the likelihood that the discharge will become a "worst case" discharge. In determining the adequacy of equipment and personnel involved in responding to such a discharge in vulnerable areas, an operator must consider the range of geographic factors.

This rule requires operators to compute a "worst case discharge" as a basis for response planning. This hypothetical discharge is the largest volume of oil that could reasonably be expected to be discharged in a single event within a response zone, regardless of spill location in that zone. This rule includes factors the operator must use to determine a worst case discharge for each response zone. This computation is a way of measuring discharge volume to ensure the necessary response capability for any location in the response zone.

Since the computation of worst case discharge is hypothetical, operators must consider the need to respond in vulnerable environmentally sensitive areas within the zone, whether or not the worst case discharge is calculated for that specific location.

RSPA encourages operators to plan for responses to discharges that are less severe than the worst case discharge. Although OPA 90 does not require submission of plans for less than worst case discharge, the Coast Guard (USCG) and the Environmental Protection Agency (EPA) are proposing response planning that specifies three separate and distinct planning levels. RSPA is not requiring response planning for less than a worst case discharge; however, an operator may benefit by planning responses to smaller discharges since they are more likely to occur and would likely require different types and quantities of response equipment.

OPA 90 requires that response plans must: (1) Identify the qualified individual with full authority to implement response actions, including liaison with the Federal On-Scene Coordinator (OSC) and response contractors; (2) identify and ensure, by contract or other approved means, the availability of private personnel and equipment sufficient to remove, to the maximum extent practicable, a worst case discharge and to mitigate or prevent a substantial threat of such a discharge from the facility; (3) describe the training, equipment testing, periodic unannounced drills, and response activities of persons at the facility to ensure the safety of the facility and mitigate the effects of an oil discharge; (4) include procedures for periodically updating or resubmitting the response plan for approval when significant changes occur; and (5) be consistent with the National Contingency Plan (NCP) and any Area Contingency Plan (ACP) for the geographic area in which the facility operates.

The NCP provides general organizational structure and procedures for addressing discharges of oil and hazardous substances and specifies responsibilities among all levels of government, resources available for response, emergency planning requirements and procedures for undertaking removal actions. ACPs are prepared by Area Committees, composed of Federal, state and local personnel, under the direction of the Federal OSC for each area, who is either a Captain of the Port for coastal areas, or an EPA regional administrator for inland areas.

ACPs address the removal of a worst case discharge from a facility operating in or near the area covered by the plan and the mitigation and prevention of such a discharge. Further, they describe areas of environmental importance; responsibilities of operators and agencies in removing, mitigating and preventing discharges; equipment available to an operator to ensure effective removal, mitigation or prevention of a discharge, or a threat of such a discharge; procedures for decisions on use of dispersants; and other operating procedures.

ACPs are in early stages of development. As these plans evolve, OPA 90 requires operators to update their facility plans so as to be consistent with corresponding procedures and activities, including any response equipment limitations identified by the Area Committee.

As noted above, OPA 90 requires that response plans identify and ensure the availability of private personnel and equipment necessary to remove, to the maximum extent practicable, a worst case discharge, including a discharge resulting from fire or explosion. For the purposes of this rule, this requirement applies to each response zone covered by a response plan.

Although the intent of OPA 90 is to create a system in which private parties supply the bulk of any equipment and personnel needed for oil spill response in a given area, in the event of a worst case discharge, the private resources are likely to be supplemented by public response resources. Therefore, this rule requires that the response plan identify private resources, either maintained by the operator or other approved means, and the names and telephone numbers of any government agencies expected to assume pollution control responsibilities. The integration and coordination of public and private response resources will be addressed in the applicable ACP. As prescribed in OPA 90, this rule requires that the response plans be consistent with the ACP and the NCP. An operator must certify that it has reviewed the NCP and each applicable ACP and that its response plan is consistent with the NCP and applicable ACPs.

Statutory Criteria: "Substantial Harm" and "Significant and Substantial Harm"

OPA 90 requires that operators of onshore oil pipelines that may reasonably be expected to cause "substantial harm" or "significant and substantial harm," prepare and submit response plans. It also requires RSPA to review and approve those response plans for any onshore oil pipeline that may reasonably be expected to cause "significant and substantial harm."

OPA 90 does not define "substantial harm" or "significant and substantial harm." The OPA 90 Conference Report (H.R. Conf. Report No. 653, 101st Cong., 2d Sess., 101, reprinted in 1990 U.S. Code Cong. & Admin. News 779) states that the President should develop nationwide criteria to determine those facilities which could reasonably be expected to cause "substantial harm" and are therefore required to submit response plans. (OPA Conference Report, p. 829) The report indicates that the criteria should result in a broad requirement for facility owners and operators to prepare and submit plans, but that only a subset of these plans (i.e., those addressing significant and substantial harm) will actually be reviewed and approved. (OPA Conference Report, p. 829)

Substantial Harm; Significant and Substantial Harm

Section 4202(b)(4) of OPA 90 established statutory deadlines for the submission and approval of response plans regarding onshore oil pipelines. After February 18, 1993, a pipeline for which a response plan is required to be submitted may not be used to handle, store, or transport oil unless a response plan for the pipeline has been submitted to RSPA. After August 18, 1993, a pipeline for which a response plan is required, may not handle, store, or transport oil unless the facility is operating in compliance with the applicable response plan.

RSPA has determined that most onshore oil pipelines, because of their locations, could reasonably be expected to cause substantial harm to the environment by discharging oil into or on the navigable waters or adjoining shorelines. This determination is based on the volume of oil transported by pipelines and the fact that they often cross, or are located adjacent to, navigable waters. Thus, most onshore oil pipeline operators will be required to prepare and submit response plans.

Because of varying environmental conditions along the route of a pipeline, RSPA is requiring, in addition to a company-wide core plan, submission of response zone appendices which address geographic variables. Operators will compute a worst case discharge for each response zone. A response zone may include one or more adjacent line sections.

A "line section" is defined in this rule as "a continuous run of pipe that is contained between adjacent pressure pump stations, between a pressure pump station and a terminal or breakout

tank, between a pressure pump station and a block valve, or between adjacent block valves."

Under the rule, the operator must make a determination of whether a response zone contains a line section that may reasonably be expected to cause "significant and substantial harm." The operator must provide this information in the response plan's information summary.

This rule provides exceptions from the requirement to submit plans to certain pipelines operators and establishes criteria developed by RSPA for operators to use in determining which onshore oil pipelines may reasonably be expected to cause "significant and substantial harm" to the environment. If any line section within a response zone is determined to be likely to cause "significant and substantial harm", then, for the purpose of plan review and approval, RSPA will consider all of the operator's pipelines contained in that particular response zone as likely to cause "significant and substantial harm" in the event of a discharge. The operator must be able to deliver response resources adequate for a worse case discharge to any location in that zone.

RSPA will review and approve only those response plans for response zones which include a line section that may reasonably be expected to cause "significant and substantial harm" to the environment. The prohibition on operation of a pipeline without an approved response plan applies only to those pipelines within a response zone containing one or more "significant and substantial harm" line sections.

Exceptions and Requirements for "Small" Pipelines and "Distant" Pipelines

Some pipelines, based on their length and size, are too small to transport a large volume of oil and, consequently, do not have the capacity to discharge a volume of oil large enough to cause substantial harm to the environment. RSPA believes there is no reasonable expectation that these pipelines will cause substantial harm to the environment in the event of a discharge. Therefore, RSPA has created an exception from the response plan submission requirements under this regulation for certain pipelines, unless an OSC recommends otherwise, or they are in proximity to navigable waters, public drinking water intakes or environmentally sensitive areas which are in or adjacent to navigable waters. For the purposes of this rule, "in proximity" means the pipeline is within a distance of navigable waters, public drinking water intakes or environmentally sensitive areas which are in or adjacent to navigable waters such that a discharge could cause substantial harm, even though the pipeline is transporting a "small" volume of oil.

The "small pipeline" exception applies only to a pipeline which is 6⅝ inches or less in outside nominal diameter, is 10 miles or less in length, and meets all of the following conditions:

(1) The pipeline has not experienced a release greater than 1,000 barrels within the previous five years;

(2) The pipeline has not experienced two or more reportable releases, as defined in 49 CFR 195.50, within the previous five years;

(3) A pipeline containing any electric resistance welded pipe, manufactured prior to 1970, does not operate at a maximum operating pressure established under § 195.406 that corresponds to a stress level greater than 50 percent of the specified minimum yield strength of the pipe as defined in this rule; and

(4) The pipeline is not in proximity to public drinking water intakes, navigable waters, or environmentally sensitive areas as defined in this rule.

If the small pipeline meets all of these conditions, it qualifies for the exception, and the operator does not have to submit a response plan. RSPA has determined that even a "small" pipeline can cause "substantial harm" to the environment in the event of a discharge, when it is in proximity to navigable waters, public drinking water intakes or environmentally sensitive areas. Environmentally sensitive areas are those areas of environmental importance which are in or adjacent to navigable waters. These areas may include, wetlands, national parks, wilderness and recreational areas, wildlife refuges marine sanctuaries, and conservation areas. As required by statute, an ACP must describe those areas covered by the ACP that are of environmental importance. The statute also requires that an operator's response plan be consistent with the ACP. Thus, an operator must compare its response plan with the applicable ACP(s) to ensure consistency.

Some other pipelines are located at a distance far enough away from any navigable waters, public drinking water intakes or environmentally sensitive areas that it is not reasonable to expect that a discharge at any point on the pipeline would have an adverse affect within 12 hours after the time of release. RSPA believes it is reasonable to except these "distant" pipelines or line sections of pipelines from the requirement to submit response plans. RSPA encourages an operator to plan a response to such a discharge within 12 hours, so as to prevent it from reaching navigable waters, public drinking water intakes or environmentally sensitive areas.

RSPA believes that a similar distance exception should apply for small pipelines. Therefore, where it is not reasonable to expect that a distance at any point on the small pipeline would have an adverse affect within 4 hours after the time of release, RSPA is not requiring the submission of a response plan.

RSPA was unable to develop specific procedures for determining whether a pipeline would meet this distance exception. Therefore, RSPA is requesting comments on procedures for determining the time it takes for oil to travel from a release site to navigable waters, public drinking water intakes or environmentally sensitive areas and whether the travel time of 4 hours for small pipelines or 12 hours for other pipelines from the time of release to navigable waters is an appropriate criteria for determining "distant" pipelines.

If after February 18, 1993, an operator determines that an exception no longer applies to a previously excepted pipeline, then the operator must prepare and submit a response plan for that pipeline.

While this rule provides exceptions from the requirement to submit response plans for certain pipeline operators, it does not relieve operators from their responsibilities under 49 CFR 195.402 which requires operators to have procedures to provide safety when an emergency condition occurs.

Requirements for All Other Pipelines

Onshore oil pipelines not qualifying for the "small pipeline" or "distant pipeline" exceptions are expected to cause "substantial harm" in the event of a discharge, and the operators of those pipelines must submit response plans to RSPA. Each plan must identify each response zone covered by the plan, and the operator must determine if any line section within a response zone could reasonably be expected to cause "significant and substantial harm" to the environment. If a response zone contains a line section that is expected to cause significant and substantial harm, then the entire response zone must, for response plan approval purposes, be treated as if it is expected to cause significant and substantial harm.

As adopted in the rule, a line section can reasonably be expected to cause "significant and substantial harm" if the pipeline is greater than 6⅝ inches in outside nominal diameter, greater than 10 miles in length, and any of the following conditions exist:

(1) The line section has experienced a release greater than 1,000 barrels within the previous five years;

(2) The line section has experienced at least two reportable releases, as defined in § 195.50, within the previous five years;

(3) A line section containing any electric resistance-welded pipe, manufactured prior to 1970, operates at a maximum operating pressure established under § 195.406 that corresponds to a stress level greater than 50 percent of the specified minimum yield strength of the pipe as defined in this rule;

(4) The line section is located within a five-mile radius of potentially affected public drinking water intakes and could reasonably be expected to reach public drinking water intakes; or

(5) The line section is located within a one-mile radius of potentially affected environmentally sensitive areas, as defined in this rule, and could reasonably be expected to reach these areas.

Potentially affected means that an oil discharge could reach a public drinking water intake or environmentally sensitive area by moving downstream or downhill from the pipeline.

In determining the proximity of a line section to public drinking water intakes and environmentally sensitive areas, until the ACPs are developed, the operator should use its regional knowledge and the existing Local Contingency Plan (LCP), developed by the OSC, for its area of operation.

RSPA requests comments on the criteria it has established to determine which line sections could reasonably be expected to cause significant and substantial harm to the environment. RSPA specifically requests comments on whether it should consider additional facility characteristics and the appropriateness of using the specified distances from navigable waters, public drinking water intakes and environmentally sensitive areas, as criteria.

As a result of new information, changing circumstances, the recommendation of an OSC, and the development of ACPs, RSPA may in the future identify facilities as having the potential to cause either "substantial harm" or "significant and substantial harm".

Requirements for Information Summary

In order to facilitate RSPA's review and approval of response plans, this rule requires all operators to submit an information summary as part of its response plans. The information summary will provide RSPA with the necessary information to determine which response plans require review and approval by RSPA.

The information summary for a core plan must include:

- The name and address of the operator; and
- A listing and description of all response zones, including county(s) and state(s), in which a worst case discharge could cause significant and substantial harm to the environment.

The information summary for a response zone appendix must include:

- The name and telephone number of the qualified individual, available on a 24-hour basis;
- A description of the response zone, including county(s) and state(s), in which a worst case discharge could cause substantial harm to the environment;
- A listing of the line sections in the zone, identified by milepost or survey station number or other operator designation;
- The basis on which the operator determined that the zone meets the criteria for "significant and substantial harm"; and
- The type of oil and volume of the worst case discharge.

Additionally, operators must provide a duplicate copy of the information summary sheet from the core plan with each response zone appendix to assure availability of complete information during the review of the response zone appendices.

Certification

OPA 90 provides the opportunity for an operator, with response zones that contain line sections which can reasonably be expected to cause significant and substantial harm, to seek a waiver from the requirement to have an approved response plan by August 18, 1993. In order to receive a waiver, the operator must submit to RSPA a certification by the qualified individual or appropriate corporate officer that the operator has obtained, through contract or other approved means, the necessary private personnel and equipment to respond, to the maximum extent practicable, to a worst case discharge, or the substantial threat of such a discharge, in each of its response zones.

Given the large number of plans requiring review and approval which RSPA expects to receive in February 1993, RSPA may not complete all the required approvals by August 18, 1993. Therefore, operators may choose to provide a certification at the time of submission of the plan, or up until July 18, 1993. Operators who opt to provide certification are granted an automatic extension for up to two years after plan submission or until the date RSPA approves or disapproves the plan, whichever occurs first. During this period they may operate without response plan approval. Operators who choose this option may provide the certification with the information summary sheet for their core plans.

General Response Plan Requirements

1. Immediate Communications Procedures

Each response plan must provide the name and telephone number of a qualified individual for each response zone and describe a communications network, such as a spill response telephone list, to identify those parties (i.e., Federal, state, and local officials, contractors, and company personnel) who must be immediately contacted in the event of any discharge.

2. Planning for Worst Case Discharge

Each response plan must describe the means by which an operator will respond, to the maximum extent practicable, to its worst case discharge in each response zone. Response to a worst case discharge includes planning for a discharge of the largest foreseeable volume in environmentally sensitive areas.

The definition of "maximum extent practicable," as used in this rule, is based on a recommendation made by the USCG's negotiated rulemaking committee. "Maximum extent practicable" means the limits of available technology and the practical and technical limits on an individual pipeline operator in planning the response resources required to provide the on-water recovery capability and the shoreline protection and cleanup capability to conduct response activities for a worst case discharge from a pipeline in adverse weather.

As used in this rule, a worst case discharge is the largest foreseeable discharge in adverse weather conditions that a pipeline could discharge in a response zone. It is based on a comparison between several factors. First, it could result from the calculation of the rate of flow times the maximum time to detect the spill, plus the rate of flow times the time to shut-down the pipeline, plus the drainage volume after shutdown of the pipeline. The operator must determine and utilize a realistic shut down time based on the pipeline's

operating and design characteristics, including leak detection and shut down capability.

Second, the worst case discharge could be the largest foreseeable discharge for the line section(s) within a response zone, expressed in barrels, based on the maximum historic discharge, if one exists, adjusted for any subsequent corrective or preventive action taken. Subsequent corrective or preventive action may include installation of a Supervisory Control and Data Acquisition (SCADA) based leak detection subsystem, replacement of defective pipe, or the installation of block valves.

Third, if a response zone contains breakout tanks, it could be the total volume of the single largest breakout tank or battery of breakout tanks within a single containment system, adjusted for the capacity of the containment system.

An operator must select the largest of these numbers as the volume for a worst case discharge.

If the worst case discharge is based on one or more breakout tanks, an adjustment or credit can be applied to the capacity of the tank or tanks. This credit in reducing the worst case discharge volume is permissible if the tank is protected by a secondary containment system providing containment of a minimum of 110% of the capacity of the tank. This credit is granted based on the fact that it is unlikely that a facility, with adequate secondary containment, will discharge its entire contents since the secondary containment system will retain a substantial portion of the discharge.

RSPA requests comments on the worst case discharge for pipeline breakout tanks, including the credit adjustment for an adequate secondary containment system. In addition, what other criteria are appropriate for the definition of worst case discharge? Should there be one definition used for pipelines or should there be a separate definition based on each pipeline's unique set of operating conditions and equipment installed? Should there be a tiered approach to the worst case discharge with consideration given to a pipeline having in place a Supervisory and Data Acquisition (SCADA) system with a SCADA-based leak detection subsystem? Should RSPA consider other criteria on the types and locations of valves, the operating parameters of a leak detection systems, and, in the case of breakout tanks, secondary containment?

As stated earlier, the computation of worst case discharge is a method of measuring response capability needed for any location in a response zone. In planning response capabilities and strategies, operators must consider the need to respond in vulnerable areas, where greatest damage could occur, whether or not the worst case discharge could occur in that location.

Several reasons exist for RSPA requiring operators to provide their computation of worst case discharge with the summary of response plan information. In the operator's preparation of plans and in RSPA's review of plans, the operator and RSPA must consider the unique set of variables that determine the potential volume, including line drainage volume after shutdown, which might be discharged at any location along the pipeline. Pipe diameter, operating pressure, flow rate and the topography surrounding the pipeline are among the factors which RSPA believes are most critical in planning and determining the need for personnel and equipment. Operator submission of these data will allow RSPA to effectively assess the operator's leak detection and control measures and other aspects of discharge prevention and mitigation, and thereby improve the response planning process.

Additionally, under this rule, RSPA retains discretion to consider, on a case-by-case basis, the above-mentioned and other risk-based factors in making final determinations of which line sections in response zones could cause significant and substantial harm to the environment, and therefore require review and approval. RSPA believes that the amount of a worst case discharge is a relevant factor for future consideration in determining which zones require review and approval.

3. Consistency with the NCP and ACPs

The rule requires response plans to be consistent with requirements in the NCP and ACPs, as these plans evolve. An operator must certify that it has reviewed the NCP and each applicable ACP and its response plan is consistent with the NCP and ACPs.

Because revisions to the NCP were not completed by the EPA and the USCG prior to August 18, 1992, response plans should be based on the existing NCP published in 40 CFR part 300. ACPs are in various stages of development and, in most cases, will not be completed in time for operators to consult when developing their response plans. Until the applicable ACPs are completed, response plans submitted to meet the February 18, 1993 deadline should be consistent with the LCP or ACP in effect on August 18, 1992.

A response plan submitted after February 18, 1993 must be consistent with the applicable contingency plan (LCP or ACP) in effect when the response plan is submitted. If the NCP or ACP has been revised within six months of the date of submission, the operator's response plan may conform to the prior NCP or ACP.

4. Requirement for Updates

Unless a change in the NCP or an ACP has significant impact on equipment appropriate for response or other geographic-specific considerations, approved response plans will not be required to be resubmitted for approval based solely on a subsequent revision of ACP or an NCP. However, the OPA 90 requires that the operators update their plans "periodically." This rule requires that after a plan is submitted, an operator must perform a periodic update every three years. RSPA believes that significant changes in procedures are not likely to occur once the operator has completed the response planning to comply with the requirements of this regulation. In exercising its enforcement authority for comparable situations (e.g., 49 CFR part 195), OPS has adopted this triennial requirement.

Consistent with the statute, however, an operator must resubmit a response plan in the event of a significant change that affects the response plan's implementation. Significant changes include:

- Change in the type of oil transported,
- Relocation or replacement of a pipeline or a line section in a manner that operationally affects the response plan or the worst case discharge,
- Change in the person(s) qualified to activate the response plan,
- Contracting with new cleanup operators, or
- Any change to information relating to circumstances likely to affect full implementation of the plan.

RSPA may also request a pipeline operator to revise and resubmit a response plan based on the agency's review of the plan, due to a recent discharge from the facility, or at the request of the OSC.

5. Availability of Response Resources

Operators must identify and ensure, by contract or other acceptable means, the availability of private personnel and equipment necessary to respond, to the maximum extent practicable, to a worst case discharge (including a discharge resulting from fire or explosion), and to mitigate or prevent a substantial threat of such a discharge.

Operators may find it advantageous to place cleanup contractors or spill cooperatives on retainer to ensure their response services are available.

(Operators are reminded that cleanup contractors who may be hired to perform an emergency response function regulated by 49 CFR part 195 may be subject to the drug testing requirements of 49 CFR part 199.)

In order to ensure the availability of private personnel and equipment necessary to remove a worst case discharge, operators need to determine the capabilities of response resources needed for the specific operating environments. Limitations for particular response zones will be identified in the ACPs, including types of equipment permissible for response. Response resources should include sufficient boom, oil recovery devices and storage capacity to recover a worst case discharge. RSPA encourages operators, as part of the planning process, to identify storage location and the make, model and effective daily recovery rate of oil recovery devices.

The USCG, in its Navigation and Vessel Inspection Circular (NVIC) No. 7–92 issued September 15, 1992, provided an appendix with guidelines on what type and amount of equipment are required for a specific discharge volume from a facility based on its capacity. A copy of this NVIC is available in the public docket for this rulemaking. Operators may use this as a reference for determining equipment requirements. Other factors such as the facility's location, the environmental sensitivity of the area, the facility's proximity to public drinking water intakes, and the type of oil transported by the facility (i.e., persistent or non-persistent) need to be considered by the operator in determining the type and amount of required response equipment.

Tiering Response Resources for On Water Recovery

RSPA has structured the requirements for responding, to the maximum extent practicable, to a worst case discharge in a tier system. RSPA has specified the times by which certain response equipment must be present at discharge sites. This rule establishes three tiers to allow the operator to identify response resources from outside a facility's specific geographic location to satisfy its response requirements.

Some fraction of the personnel and equipment necessary to respond to a worst case discharge must be available for each tier standard. For instance, it might be appropriate for the resources to arrive in the first tier to be prepared to address immediate requirements to keep the maximum amount of oil from getting into the water. The second tier might address containment equipment to prevent the discharge from disbursing. The third tier might concentrate on cleanup and storage of the discharge. The intent is to provide the operator latitude in staging resources most efficiently.

The tier approach recognizes two levels of concern based on the areas traversed by pipelines. "High volume areas" means those areas where an oil pipeline having a nominal outside diameter of 20 inches or more crosses a major river or other navigable waters, which, because of the velocity of the river flow and vessel traffic on the river, would require a more rapid response in case of a worst case discharge or substantial threat of such a discharge. "All other areas" include smaller rivers, canals, inland and nearshore areas. The list of "high volume" areas, provided in Appendix B, may not be complete for the purposes of this regulation. Operators should determine, based on their regional knowledge, if there are other areas that contain rivers or other navigable waters which, because of their velocity or traffic, would, in case of discharge, require a more rapid response.

On-scene arrival times in hours for each tier are as follows:

	Tier 1	Tier 2	Tier 3
High volume areas	6	30	54
All other areas	12	36	60

Tier 1 response activities must begin after discovery of a worst case discharge or substantial threat of such a discharge and be completed within the hours prescribed. Response activities must be operational by the tier 3 time. As required by OPA 90, the response plan must identify and ensure the availability of personnel and equipment necessary to remove, to the maximum extent practicable, a worst case discharge. RSPA believes this should include consideration of mobilization and travel time. In calculating the travel time for personnel and equipment, an on-water speed of 10 knots and a land speed of 35 miles per hour is assumed unless the operator can demonstrate otherwise. RSPA is requesting comments on this approach to tiering response resources.

Recognizing the diversity of situations to be addressed, RSPA has not specified the equipment and personnel to be provided. The operator needs to determine the amount of response resources that need to be mobilized and delivered to respond to a worst case discharge, consistent with the times established in this rule. USCG's NVIC 7–92 lists the response resource mobilization factors.

These factors reflect the organization of on-water oil recovery capacity to be mobilized and delivered within the response times for each tier in order to maximize the oil recovery potential.

The operator is responsible for ensuring that sufficient numbers of trained personnel, boats, aerial spotting aircraft, sorbent materials, boom anchoring materials and other supplies are available to sustain response operations. The operator needs to evaluate the availability of adequate temporary storage capacity to sustain effective daily recovery rates. Based on USCG guidance in NVIC 7–92, temporary storage should be equivalent to twice the daily oil recovery rate due to inefficiency of oil recovery devices which collect approximately equal amounts of oil and water. Since the water is contaminated, storage must be provided for the contaminated water. This capacity may be reduced if the operator can demonstrate a better efficiency rate. The operator needs to also arrange for disposal of recovered oil products, consistent with specifications of the ACP.

6. Training, Equipment Testing, Drills and Response Actions

Each response plan must address training, equipment testing, periodic unannounced drills, and the response actions of operator personnel. This rule establishes levels of training. The amount of training required depends on the complexity of functions performed. Additionally, Occupational Safety and Health Administration (OSHA) rules require that all personnel who are expected to respond to, and control, hazardous discharges will undergo formal worker health and safety training before starting work. These rules also apply to personnel, including volunteers and casual laborers employed during a response, that are subject to those standards pursuant to 40 CFR part 311. Personnel are required to receive refresher training at regular intervals. OSHA considers petroleum products and gases to be hazardous materials.

The response plan must describe equipment testing and the type, schedule, and procedure for drills. It must describe response actions under the plan that ensure the safety of facilities and mitigate or prevent the worst case discharge or the substantial threat of such a discharge. Appropriate types of drills and frequencies need to be selected by the operator. Equipment and procedures used in drills must be consistent with requirements of the ACP.

When the operator is deciding the equipment to test and the drill schedule, the operator should consider drills or

exercises of: (1) Manned pipeline facilities, emergency procedures, and qualified individual notification; (2) emergency actions by assigned operating or maintenance personnel and notification of the qualified individual on pipeline facilities which are normally unmanned; (3) spill management team tabletop exercises; (4) oil spill removal organization field equipment deployment; and (5) exercises of the entire response zone organization.

Operators need to evaluate drills and correct any problems identified. OPA 90 requires operators to participate in any unannounced drills conducted by the appropriate OSC, including the activation of the appropriate oil spill removal organization and spill management team identified in the response plan.

OPA 90 requires operators to describe response actions of assigned personnel in the response plan. In Appendix A, Guidelines for the Preparation of Response Plans, RSPA has provided information to assist operators. Operators are encouraged to consider the information in the guidelines. RSPA considers the following factors priorities in response planning: containment and cleanup activities; assessment of proximity to environmentally sensitive areas; assessment of potential impact of worst case discharge; precautions for worker health and safety; and assessment of the threat to public health and safety from the worst case discharge.

Submission of State Plans

RSPA is aware that many operators are developing response plans that comply with state law or regulation requiring preparation of an oil spill response plan which provides equivalent or greater response capabilities than required in this rule. RSPA believes that the response planning process an operator completes to comply with state requirements will serve to ensure that operators plan for responding to the maximum extent practicable to a worst case discharge. A response plan meeting state law requirements and submitted to RSPA must name the qualified individual and ensure, through contract or other approved means, the necessary private personnel and equipment to respond to a worse case discharge or a substantial threat of such a discharge.

If, to satisfy the requirements of this rule, an operator submits a plan developed to comply with state requirements, an operator must provide an information summary sheet identifying critical information as specified in this rule, as required in 49 CFR 194.113. After review of those plans, RSPA may determine that additional amendments are necessary to ensure adequate response resources for worst case discharge.

Multi-Agency Jurisdiction

Most oil storage facilities are composed of both transportation-related and non-transportation-related facilities as defined in the 1971 Memorandum of Understanding between the Environmental Protection Agency and Department of Transportation (36 FR 24080; December 18, 1971). This combination of transportation-related and non-transportation-related facilities will be subject to multi-agency jurisdiction. The USCG, EPA, and RSPA are discussing how a response plan from such a facility will be reviewed and approved.

Summary of Public Comments Requested

RSPA requests public comment on a variety of issues. As a convenience to the reader, those issues are summarized below:

(1) The definition of "response zone",

(2) The criteria for "distant" pipelines and procedures for determining the time it takes for oil to travel from a release site to navigable waters, public drinking water intakes or environmentally sensitive areas,

(3) The selection criteria used in determining which line sections in response zones could reasonably be expected to cause "significant and substantial harm" to the environment,

(4) The selection criteria and additional facility characteristics, including a facility's location in relation to navigable waters, public drinking water intakes and proximity to environmentally sensitive areas,

(5) The definition of worst case discharge for pipeline breakout tanks,

(6) Other criteria appropriate for the definition of worst case discharge,

(7) The tiered approach to the worst case discharge, with consideration given to a pipeline having in place a Supervisory and Data Acquisition (SCADA) system with a SCADA-based leak detection subsystem,

(8) Other criteria on the types and locations of valves, the operating parameters of leak detection systems, and, in the case of break out tanks, secondary containment, and

(9) The tiered approach to determine the necessary response resources.

Regulatory Analyses and Notices

A. Impact Assessment

This rule does not meet the criteria specified in section 1(b) of Executive Order 12291 and is not, therefore, a major rule, but it is considered a significant rule under the section 5(a)(2)(f) of DOT's Regulatory Policies and Procedures ("the Procedures") (44 FR 11034; February 26, 1979) because of significant public and congressional interest. This rule does not require a Regulatory Impact Analysis. A regulatory evaluation is under development. It will include an analysis of the economic consequences of the regulation and an analysis of its anticipated benefits and impacts.

RSPA has tentatively determined the incremental unit costs of the rule, above and beyond existing response planning costs. They are as follows:

RESPONSE PLAN INCREMENTAL UNIT COST ESTIMATES FOR PIPELINE COMPANIES

Response plan elements	Small	Medium	Large
General information	$70	$110	$190
Emergency response procedures	749	2,838	5,667
Spill detection and mitigation procedures	327	1,447	2,814
Training and drills	18,033	24,754	39,757
Response zone appendices (per zone)	4,291	12,948	19,794
Response capability	10,000	30,000	100,000
Total first-year cost	33,470	71,898	168,222
Plan review and update	399	1,074	1,449
Training and drills	18,033	24,754	39,757

RESPONSE PLAN INCREMENTAL UNIT COST ESTIMATES FOR PIPELINE COMPANIES—Continued

Response plan elements	Small	Medium	Large
Response capability	10,000	30,000	100,000
Subsequent-year cost	28,432	55,828	141,206

Note: Small company model: operates about 275 miles of pipeline and has 7 pipeline facilities; Medium company model: operates about 900 miles of pipeline and has 20 pipeline facilities; and Large company model: operates about 5,300 miles of pipeline and has 128 pipeline facilities.

Comments are requested on these costs so that RSPA may finalize the regulatory evaluation. RSPA specifically requests comments on the cost that operators will incur for retainers associated with response capability.

B. Regulatory Flexibility Act

A majority of the entities composing the regulated pipeline industry are large corporations with both sales and revenue in the million of dollars. For the majority of small businesses that are subject to this interim final rule, the regulatory evaluation under development indicates they should be able to absorb the estimated regulatory compliance costs without experiencing significant adverse economic effects.

Thus, based on information available concerning the size and nature of entities likely affected by this rule, I certify this regulation will not have a significant economic impact on a substantial number of small entities under criteria of the Regulatory Flexibility Act.

However, RSPA specifically requests comments on the impact of this rule on small business concerns and this certification is subject to modification as a result of a review of comments received in response to this regulation. The rule will have no direct impact on small units of government.

C. Federalism Assessment

RSPA has analyzed this regulation in accordance with Executive Order 12612 and has determined that it does not have sufficient Federalism implications to warrant preparing a Federalism Assessment. The regulations have no substantial effects on the states, on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various levels of government. Nothing in this rule shall be construed as preempting any State or a political subdivision of a State from imposing any additional requirement or liability with respect to the discharge of oil into any waters within the State, or with respect to any removal activities related to such a discharge. (33 U.S.C. 2718 Supp. II 1990).

D. Paperwork Reduction Act

The reporting and recordkeeping requirement associated with this rule is being submitted to the Office of Management and Budget for approval in accordance with 44 U.S.C. chapter 35. OMB NO. New;

Administration: Research and Special Programs Administration. **Title:** Response Plans for Onshore Pipelines;

Need for Information: The Oil Pollution Act of 1990 requires an operator of a pipeline transporting oil to submit a plan for responding to a worst case discharge or the threat of such a discharge; *Proposed Use of Information:* RSPA will use this information to review and approve certain response plans; *Frequency:* one time submission with plan updates every three years;

Burden Estimate: 26,400 hours; *Respondents:* 300 oil pipeline operators; *Forms:* none; *Average Burden Hours per Respondent:* 11.5 hours.

For further information contact: The Information Requirements Division, M–34, Office of the Secretary of Transportation, 400 Seventh Street, SW., Washington, DC 20590 or Edward Clarke or Ron Minsk, Office of Management and Budget, New Executive Office Building, room 3228, Washington, DC 20503.

E. National Environmental Policy Act

RSPA has reviewed these regulations in accordance with its procedures for ensuring full consideration of the environmental impacts of RSPA actions as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, executive orders, and DOT Order 5610.1c. RSPA has determined that the rules are not a major Federal action for which an Environmental Impact Statement must be prepared.

List of Subjects in 49 CFR Part 194

Oil pollution, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Administrator, RSPA, adds part 194 to chapter I of title 49 of the Code of Federal Regulations as follows:

Part 194—RESPONSE PLANS FOR ONSHORE OIL PIPELINES

Subpart A—General

Sec.
194.1 Purpose.
194.3 Applicability.
194.5 Definitions.
194.7 Operating restrictions and interim operating authorization.

Subpart B—Response Plans

194.101 Operators required to submit plans.
194.103 Significant and substantial harm; operator's statement.
194.105 Worst case discharge.
194.107 General response plan requirements.
194.109 Submission of state response plans.
194.111 Response plan retention.
194.113 Information summary.
194.115 Response resources.
194.117 Training.
194.119 Submission and approval procedures.
194.121 Response plan review and update procedures.

Appendix A to Part 194—Guidelines for the Preparation of Response Plans

Appendix B to Part 194—High Volume Areas

Authority: 33 U.S.C. 1231, 1321(j)(1)(C), (j)(5) and (j)(6); sec. 2, E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; 49 CFR 1.53.

Subpart A—General

§ 194.1 Purpose.

This part contains requirements for oil spill response plans to reduce the environmental impact of oil discharged from onshore oil pipelines.

§ 194.3 Applicability.

This part applies to an operator of an onshore oil pipeline that, because of its location, could reasonably be expected to cause substantial harm, or significant and substantial harm to the environment by discharging oil into or on any navigable waters of the United States or adjoining shorelines.

§ 194.5 Definitions.

Adverse weather means the weather conditions considered by the operator in identifying the response systems and equipment to be deployed in accordance with a response plan, including wave height, ice, temperature, visibility, and currents within the inland or Coastal Response Zone (defined in the National

Contingency Plan (40 CFR part 300)) in which those systems or equipment are intended to function.

Barrel means 42 United States gallons at 60 degrees Fahrenheit.

Breakout tank means a tank used to:

(1) relieve surges in an oil pipeline system or

(2) receive and store oil transported by a pipeline for reinjection and continued transportation by pipeline.

Coastal zone means all United States waters subject to the tide, United States waters of the Great Lakes and Lake Champlain, specified ports and harbors on inland rivers, waters of the contiguous zone, other waters of the high seas subject to the National Contingency Plan, and the land surface or land substrate, ground waters, and ambient air proximal to those waters. (The term "coastal zone" delineates an area of federal responsibility for response action. Precise boundaries are determined by agreements between the Environmental Protection Agency (EPA) and the U.S. Coast Guard (USCG), and are identified in Federal Regional Contingency Plans and Area Contingency Plans.)

Contract or other approved means is:

(1) A written contract or other legally binding agreement between the operator and a response contractor or other spill response organization identifying and ensuring the availability of the specified personnel and equipment within stipulated response times for a specified geographic area;

(2) Certification that specified equipment is owned or operated by the pipeline operator, and operator personnel and equipment are available within stipulated response times for a specified geographic area; or

(3) Active membership in a local or regional oil spill removal organization that has identified specified personnel and equipment to be available within stipulated response times for a specified geographic area.

Environmentally sensitive area means an area of environmental importance which is in or adjacent to navigable waters.

High volume area means an area which an oil pipeline having a nominal outside diameter of 20 inches or more crosses a major river or other navigable waters, which, because of the velocity of the river flow and vessel traffic on the river, would require a more rapid response in case of a worst case discharge or substantial threat of such a discharge. Appendix B to this part contains a list of some of the high volume areas in the United States.

Inland area means the area shoreward of the boundary lines defined in 46 CFR part 7, except that in the Gulf of Mexico, it means the area shoreward of the lines of demarcation (COLREG lines) defined in 33 CFR 80.740–80.850. The inland area does not include the Great Lakes.

Inland zone means the environment inland of the coastal zone excluding the Great Lakes, Lake Champlain, and specified ports and harbors on inland rivers. (The term inland zone delineates an area of federal responsibilities for response actions. Precise boundaries are determined by agreements between the EPA and the USCG and are identified in Federal Regional Contingency Plans.)

Line section means a continuous run of pipe that is contained between adjacent pressure pump stations, between a pressure pump station and a terminal or breakout tank, between a pressure pump station and a block valve, or between adjacent block valves.

Major river means a river that, because of its velocity and vessel traffic, would require a more rapid response in case of a worst case discharge. For a list of rivers see "*Rolling Rivers, An Encyclopedia of America's Rivers,*" Richard A. Bartlett, Editor, McGraw-Hill Book Company, 1984.

Maximum extent practicable means the limits of available technology and the practical and technical limits on a pipeline operator in planning the response resources required to provide the on-water recovery capability and the shoreline protection and cleanup capability to conduct response activities for a worst case discharge from a pipeline in adverse weather.

Navigable waters means the waters of the United States, including the territorial sea and such waters as lakes, rivers, streams; waters which are used for recreation; and waters from which fish or shellfish are taken and sold in interstate or foreign commerce.

Oil means oil of any kind or in any form, including, but not limited to, petroleum, fuel oil, vegetable oil, animal oil, sludge, oil refuse, oil mixed with wastes other than dredged spoil.

Oil spill removal organization means an entity that provides response resources.

On-Scene Coordinator (OSC) means the federal official designated by the Administrator of the EPA or by the Commandant of the USCG to coordinate and direct federal response under subpart D of the National Contingency Plan (40 CFR part 300).

Onshore oil pipeline facilities means new and existing pipe, rights-of-way and any equipment, facility, or building used in the transportation of oil located in, on, or under, any land within the United States other than submerged land.

Operator means a person who owns or operates onshore oil pipeline facilities.

Pipeline means all parts of an onshore pipeline facility through which oil moves including, but not limited to, line pipe, valves, and other appurtenances connected to line pipe, pumping units, fabricated assemblies associated with pumping units, metering and delivery stations and fabricated assemblies therein, and breakout tanks.

Qualified individual means an English-speaking representative of an operator, located in the United States, available on a 24-hour basis, with full authority to: activate and contract with required oil spill removal organization(s); activate personnel and equipment maintained by the operator; act as liaison with the OSC; and obligate any funds required to carry out all required or directed oil response activities.

Response activities means the containment and removal of oil from the water and shorelines, the temporary storage and disposal of recovered oil, or the taking of other actions as necessary to minimize or mitigate damage to the environment.

Response area means the inland zone or coastal zone, as defined in the National Contingency Plan (40 CFR part 300), in which the response activity is occurring.

Response plan means the operator's core plan and the response zone appendices for responding, to the maximum extent practicable, to a worse case discharge of oil, or the substantial threat of such a discharge.

Response resources means the personnel, equipment, supplies, and other resources necessary to conduct response activities.

Response zone means a geographic area either along a length of pipeline or including multiple pipelines, containing one or more adjacent line sections, for which the operator must plan for the deployment of, and provide, spill response capabilities. The size of the zone is determined by the operator after considering available capability, resources, and geographic characteristics.

Specified minimum yield strength means the minimum yield strength, expressed in pounds per square inch, prescribed by the specification under which the material is purchased from the manufacturer.

Stress level means the level of tangential or hoop stress, usually expressed as a percentage of specified minimum yield strength.

Worst case discharge means the largest foreseeable discharge of oil,

including a discharge from fire or explosion, in adverse weather conditions. This volume will be determined by each pipeline operator for each response zone and is calculated according to § 194.105.

§ 194.7 Operating restrictions and interim operating authorization.

(a) After February 18, 1993, an operator of a pipeline for which a response plan is required under § 194.101, may not handle, store, or transport oil in that pipeline unless the operator has submitted a response plan meeting the requirements of this part.

(b) After August 18, 1993, an operator must operate its onshore pipeline facilities in accordance with the applicable response plan.

(c) After August 18, 1993, the operator of a pipeline line section described in § 194.103(c), may continue to operate the pipeline for two years after the date of submission of a response plan, pending approval or disapproval of that plan, only if the operator has submitted the certification required by § 194.119(e).

Subpart B—Response Plans

§ 194.101 Operators required to submit plans.

(a) Except as provided in paragraph (b) of this section, or unless RSPA grants a request from the OSC to require an operator of the following pipelines to submit a response plan or the pipeline is covered by § 194.103, each operator of an onshore pipeline facility shall prepare a response plan and submit the response plan to RSPA, as provided in § 194.119.

(b) *Exception.* An operator need not submit a response plan for:

(1) A pipeline that is 6⅝ inches or less in outside nominal diameter, is 10 miles or less in length, and all of the following conditions apply to the pipeline:

(i) The pipeline has not experienced a release greater than 1,000 barrels within the previous five years,

(ii) The pipeline has not experienced at least two reportable releases, as defined in § 195.50, within the previous five years,

(iii) A pipeline containing any electric resistance welded pipe, manufactured prior to 1970, does not operate at a maximum operating pressure established under § 195.406 that corresponds to a stress level greater than 50 percent of the specified minimum yield strength of the pipe, and

(iv) The pipeline is not in proximity to navigable waters, public drinking water intakes, or environmentally sensitive areas.

(2)(i) A line section that is greater than 6⅝ inches in outside nominal diameter and is greater than 10 miles in length, where the operator determines that it is unlikely that the worst case discharge from any point on the line section would adversely affect, within 12 hours after the initiation of the discharge, any navigable waters, public drinking water intake, or environmentally sensitive areas.

(ii) A line section that is 6⅝ inches or less in outside nominal diameter and is 10 miles or less in length, where the operator determines that it is unlikely that the worst case discharge from any point on the line section would adversely affect, within 4 hours after the initiation of the discharge, any navigable waters, public drinking water intake, or environmentally sensitive areas.

§ 194.103 Significant and substantial harm; operator's statement.

(a) Each operator shall submit a statement with its response plan, as required by §§ 194.107 and 194.113, identifying which line sections in a response zone can be expected to cause significant and substantial harm to the environment in the event of a discharge of oil into or on the navigable waters or adjoining shorelines.

(b) If an operator expects a line section in a response zone to cause significant and substantial harm, then the entire response zone must, for the purpose of response plan review and approval, be treated as if it is expected to cause significant and substantial harm. However, an operator will not have to submit separate plans for each line section.

(c) A line section can be expected to cause significant and substantial harm to the environment in the event of a discharge of oil into or on the navigable waters or adjoining shorelines if; the pipeline is greater than 6⅝ inches in outside nominal diameter, greater than 10 miles in length, and the line section—

(1) Has experienced a release greater than 1,000 barrels within the previous five years,

(2) Has experienced two or more reportable releases, as defined in § 195.50, within the previous five years,

(3) Containing any electric resistance welded pipe, manufactured prior to 1970, operates at a maximum operating pressure established under § 195.406 that corresponds to a stress level greater than 50 percent of the specified minimum yield strength of the pipe,

(4) Is located within a five-mile radius of potentially affected public drinking water intakes and could reasonably be expected to reach public drinking water intakes, or

(5) Is located within a one-mile radius of potentially affected environmentally sensitive areas, and could reasonably be expected to reach these areas.

§ 194.105 Worst case discharge.

(a) Each operator shall determine the worst case discharge for each of its response zones and provide the methodology, including calculations, used to arrive at the volume.

(b) The worst case discharge is the largest volume, in barrels, of the following:

(1) The pipeline's maximum release time in hours, plus the maximum shutdown response time in hours (based on historic discharge data or in the absence of such historic data, the operator's best estimate), multiplied by the maximum flow rate expressed in barrels per hour (based on the maximum daily capacity of the pipeline), plus the largest line drainage volume after shutdown of the line section(s) in the response zone expressed in barrels; or

(2) The largest foreseeable discharge for the line section(s) within a response zone, expressed in barrels, based on the maximum historic discharge, if one exists, adjusted for any subsequent corrective or preventive action taken; or

(3) If the response zone contains one or more breakout tanks, the capacity of the single largest tank or battery of tanks within a single secondary containment system, adjusted for the capacity or size of the secondary containment system, expressed in barrels.

§ 194.107 General response plan requirements.

(a) Each response plan must plan for resources for responding, to the maximum extent practicable, to a worst case discharge, and to a substantial threat of such a discharge.

(b) Each response plan must be written in English and also, if applicable, in a language that is understood by the personnel responsible for carrying out the plan.

(c) Each response plan must be consistent with the National Contingency Plan (NCP) (40 CFR part 300) and each applicable Area Contingency Plan (ACP). An operator must certify that it has reviewed the NCP and each applicable ACP and that its response plan is consistent with the existing NCP and each existing applicable ACP.

(d) Each response plan must include:

(1) A core plan consisting of—

(i) An information summary as required in § 194.113,

(ii) Immediate notification procedures,

(iii) Spill detection and mitigation procedures,

(iv) The name, address, and telephone number of the oil spill response organization, if appropriate,

(v) Response activities and response resources,

(vi) Names and telephone numbers of Federal, state and local agencies which the operator expects to have pollution control responsibilities or support,

(vii) Training procedures,

(viii) Equipment testing,

(ix) Drill types, schedules, and procedures, and

(x) Plan review and update procedures; and

(2) An appendix for each response zone. Each response zone appendix must include the information required in paragraph (d)(1) (i)–(ix) of this section that is specific to the response zone and the worst case discharge calculations.

§ 194.109 Submission of state response plans.

(a) In lieu of submitting a response plan required by § 194.103, an operator may submit a response plan that complies with a state law or regulation, if the state law or regulation requires a plan that provides equivalent or greater spill protection than a plan required under this part.

(b) A plan submitted under this section must

(1) Have an information summary required by § 194.113;

(2) Name the qualified individual; and

(3) Ensure through contract or other approved means the necessary private personnel and equipment to respond to a worst case discharge or a substantial threat of such a discharge.

§ 194.111 Response plan retention.

(a) Each operator shall maintain relevant portions of its response plan at the following locations:

(1) The response plan at the operator's headquarters;

(2) The core plan and relevant response zone appendices for each line section whose pressure may be affected by the operation of a particular pump station, at that pump station; and

(3) The core plan and relevant response zone appendices at any other locations where response activities may be conducted.

(b) Each operator shall provide a copy of its response plan to each qualified individual.

§ 194.113 Information summary.

(a) The information summary for the core plan, required by § 194.107, must include:

(1) The name and address of the operator; and

(2) For each response zone which contains one or more line sections that meet the criteria for determining significant and substantial harm as described in § 194.103, a listing and description of the response zones, including county(s) and state(s).

(b) The information summary for the response zone appendix, required in § 194.107, must include:

(1) The information summary for the core plan;

(2) The name and telephone number of the qualified individual available on a 24-hour basis;

(3) The description of the response zone, including county(s) and state(s), for those zones in which a worst case discharge could cause substantial harm to the environment;

(4) A list of line sections for each pipeline contained in the response zone, identified by milepost or survey station number, or other operator designation;

(5) The basis for the operator's determination of significant and substantial harm; and

(6) The type of oil and volume of the worst case discharge.

§ 194.115 Response resources.

(a) Each operator shall identify and ensure, by contract or other approved means, the resources necessary to remove, to the maximum extent practicable, a worst case discharge and to mitigate or prevent a substantial threat of a worst case discharge.

(b) An operator shall identify in the response plan the response resources which are available to respond within the time specified, after discovery of a worst case discharge, or to mitigate the substantial threat of such a discharge, as follows:

	Tier 1	Tier 2	Tier 3
High volume area	6 hrs	30 hrs ...	54 hrs.
All other areas	12 hrs ...	36 hrs ...	60 hrs.

§ 194.117 Training.

(a) Each operator shall conduct training to ensure that:

(1) All personnel know—

(i) Their responsibilities under the response plan,

(ii) The name and address of, and the procedure for contacting, the operator on a 24-hour basis, and

(iii) The name of, and procedures for contacting, the qualified individual on a 24-hour basis;

(2) Reporting personnel know—

(i) The content of the information summary of the response plan,

(ii) The toll-free telephone number of the National Response Center, and

(iii) The notification process; and

(3) Personnel engaged in response activities know—

(i) The characteristics and hazards of the oil discharged,

(ii) The conditions that are likely to worsen emergencies, including the consequences of facility malfunctions or failures, and the appropriate corrective actions,

(iii) The steps necessary to control any accidental discharge of oil and to minimize the potential for fire, explosion, toxicity, or environmental damage, and

(iv) The proper firefighting procedures and use of equipment, fire suits, and breathing apparatus.

(b) Each operator shall maintain a training record for each individual that has been trained as required by this section. These records must be maintained in the following manner as long as the individual is assigned duties under the response plan:

(1) Records for operator personnel must be maintained at the operator's headquarters; and

(2) Records for personnel engaged in response, other than operator personnel, shall be maintained as determined by the operator.

(c) Nothing in this section relieves an operator from the responsibility to ensure that all response personnel are trained to meet the Occupational Safety and Health Administration (OSHA) standards for emergency response operations in 29 CFR 1910.120, including volunteers or casual laborers employed during a response who are subject to those standards pursuant to 40 CFR part 311.

§ 194.119 Submission and approval procedures.

(a) Each operator shall submit two copies of the response plan required by this part. Copies of the response plan shall be submitted to: Pipeline Response Plans Officer, Research and Special Programs Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001.

(b) If RSPA determines that a response plan requiring approval does not meet all the requirements of this part, RSPA will notify the operator of any alleged deficiencies, and to provide the operator an opportunity to respond, including the opportunity for an informal conference, on any proposed plan revisions and an opportunity to correct any deficiencies.

(c) An operator who disagrees with the RSPA determination that a plan contains alleged deficiencies may petition RSPA for reconsideration within 30 days from the date of receipt

of RSPA's notice. After considering all relevant material presented in writing or at an informal conference, RSPA will notify the operator of its final decision. The operator must comply with the final decision within 30 days of issuance unless RSPA allows additional time.

(d) For those response zones of pipelines, described in § 194.103(c), that could reasonably be expected to cause significant and substantial harm, RSPA will approve the response plan if RSPA determines that the response plan meets all requirements of this part, and the OSC raises no objection.

(e) If RSPA has not approved a response plan for a pipeline described in § 194.103(c), the operator may submit a certification to RSPA by July 18, 1993, that the operator has obtained, through contract or other approved means, the necessary private personnel and equipment to respond, to the maximum extent practicable, to a worst case discharge or a substantial threat of such a discharge. The certificate must be signed by the qualified individual or an appropriate corporate officer.

(f) If RSPA receives a request from an OSC to review a response plan, RSPA may require an operator to provide a copy of the response plan to the OSC. If an OSC recommends that an operator not previously required to submit a plan to RSPA, should submit one, RSPA will require the operator to prepare and submit a response plan and send a copy to the OSC.

§ 194.121 Response plan review and update procedures.

(a) Each operator shall review its response plan at least every three years from the date of submission and modify the plan to address new or different operating conditions or information included in the plan.

(b) If a new or different operating condition or information would substantially affect the implementation of a response plan, the operator must immediately modify its response plan to address such a change and, within 30 days of making such a change, submit the change to RSPA. Examples of changes in operating conditions that would cause a significant change to an operator's response plan are:

(1) An extension of the existing pipeline or construction of a new pipeline in a response zone not covered by the previously approved plan;

(2) Relocation or replacement of the pipeline in a way that substantially affects the information included in the response plan, such as a change to the worst case discharge volume;

(3) The type of oil transported, if the type affects the required response resources, such as a change from crude oil to gasoline;

(4) The name of the oil spill removal organization;

(5) Emergency response procedures;

(6) The qualified individual;

(7) A change in the NCP or an ACP that has significant impact on the equipment appropriate for response activities; and

(8) Any other information relating to circumstances that may affect full implementation of the plan.

(c) If RSPA determines that a change to a response plan does not meet the requirements of this part, RSPA will notify the operator of any alleged deficiencies, and provide the operator an opportunity to respond, including an opportunity for an informal conference, to any proposed plan revisions and an opportunity to correct any deficiencies.

(d) An operator who disagrees with a determination that proposed revisions to a plan are deficient may petition RSPA for reconsideration, within 30 days from the date of receipt of RSPA's notice. After considering all relevant material presented in writing or at the conference, RSPA will notify the operator of its final decision. The operator must comply with the final decision within 30 days of issuance unless RSPA allows additional time.

Appendix A to Part 194—Guidelines for the Preparation of Response Plans

This appendix provides a recommended form for the preparation and submission of response plans required by 49 CFR part 194. Operators may use other forms provided the form chosen provides the information required by 49 CFR part 194.

Response Plan: Section 1. Information Summary

Section 1 would include the following:

(a) For the core plan:

(1) The name and address of the operator; and

(2) For each response zone which contains one or more line sections that meet the criteria for determining significant and substantial harm as described in § 194.103, a listing and description of the response zones, including county(s) and state(s).

(b) For each response zone appendix:

(1) The information summary for the core plan;

(2) The name and telephone number of the qualified individual, available on a 24-hour basis;

(3) A description of the response zone, including county(s) and state(s) in which a worst case discharge could cause substantial harm to the environment;

(4) A list of line sections contained in the response zone, identified by milepost or survey station number or other operator designation.

(5) The basis for the operator's determination of significant and substantial harm; and

(6) The type of oil and volume of the worst case discharge.

(c) The certification that the operator has obtained, through contract or other approved means, the necessary private personnel and equipment to respond, to the maximum extent practicable, to a worst case discharge or a substantial threat of such a discharge.

Response Plan: Section 2. Notification Procedures

Section 2 would include the following:

(a) Notification requirements that apply in each area of operation of pipelines covered by the plan, including applicable State or local requirements;

(b) A checklist of notifications the operator or qualified individual is required to make under the response plan, listed in the order of priority;

(c) Names of persons (individuals or organizations) to be notified of a discharge, indicating whether notification is to be performed by operating personnel or other personnel;

(d) Procedures for notifying qualified individuals;

(e) The primary and secondary communication methods by which notifications can be made; and

(f) The information to be provided in the initial and each follow-up notification, including the following:

(1) Name of pipeline;

(2) Time of discharge;

(3) Location of discharge;

(4) Name of oil involved;

(5) Reason for discharge (e.g., material failure, excavation damage, corrosion);

(6) Estimated volume of oil discharged;

(7) Weather conditions on scene; and

(8) Actions taken or planned by persons on scene.

Response Plan: Section 3. Spill Detection and On-Scene Spill Mitigation Procedures

Section 3 would include the following:

(a) Methods of initial discharge detection;

(b) Procedures, listed in the order of priority, that personnel are required to follow in responding to a pipeline emergency to mitigate or prevent any discharge from the pipeline;

(c) A list of equipment that may be needed in response activities on land and navigable waters, including—

(1) Transfer hoses and connection equipment;

(2) Portable pumps and ancillary equipment; and

(3) Facilities available to transport and receive oil from a leaking pipeline;

(d) Identification of the availability, location, and contact telephone numbers to obtain equipment for response activities on a 24-hour basis; and

(e) Identification of personnel and their location, telephone numbers, and responsibilities for use of equipment in response activities on a 24-hour basis.

Response Plan: Section 4. Response Activities

Section 4 would include the following:

(a) Responsibilities of, and actions to be taken by, operating personnel to initiate and supervise response actions pending the arrival of the qualified individual or other

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response resources identified in the response plan;

(b) The qualified individual's responsibilities and authority, including notification of the response resources identified in the plan;

(c) Procedures for coordinating the actions of the operator or qualified individual with the action of the OSC responsible for monitoring or directing those actions;

(d) Oil spill response organizations available, through contract or other approved means, to respond to a worst case discharge to the maximum extent practicable; and

(e) For each organization identified under paragraph (d) of this section, a listing of:

(1) Equipment and supplies available; and

(2) Trained personnel necessary to continue operation of the equipment and staff the oil spill removal organization for the first 7 days of the response.

Response Plan: Section 5. List of Contacts

Section 5 would include the names and addresses of the following individuals or organizations, with telephone numbers at which they can be contacted on a 24-hour basis:

(a) A list of persons the plan requires the operator to contact;

(b) Qualified individuals for the operator's areas of operation;

(c) Applicable insurance representatives or surveyors for the operator's areas of operation; and

(d) Persons or organizations to notify for activation of response resources.

Response plan: Section 6. Training Procedures

Section 6 would include a description of the training procedures and programs of the operator.

Response plan: Section 7. Drill Procedures

Section 7 would include a description of the drill procedures and programs the operator uses to assess whether its response plan will function as planned. It would include:

(a) Announced and unannounced drills;

(b) The types of drills and their frequencies. For example, drills could be described as follows:

(1) Manned pipeline emergency procedures and qualified individual notification drills conducted quarterly.

(2) Drills involving emergency actions by assigned operating or maintenance personnel and notification of the qualified individual on pipeline facilities which are normally unmanned, conducted quarterly.

(3) Shore-based spill management team tabletop drills conducted yearly.

(4) Oil spill removal organization field equipment deployment drills conducted yearly.

(5) A drill that exercises the entire response plan for each response zone, would be conducted at least once every 3 years.

Response plan: Section 8. Response Plan Review and Update Procedures

Section 8 would include the following:

(a) Procedures to meet § 194.121; and

(b) Procedures to review the plan after a worst case discharge and to evaluate and record the plan's effectiveness.

Response plan: Section 9. Response Zone Appendices.

Each response zone appendix would provide the following information:

(a) The name and telephone number of the qualified individual;

(b) Notification procedures;

(c) Spill detection and mitigation procedures;

(d) Name, address, and telephone number of oil spill response organization;

(e) Response activities and response resources including—

(1) Equipment and supplies necessary to meet § 194.115, and

(2) The trained personnel necessary to sustain operation of the equipment and to staff the oil spill removal organization and spill management team for the first 7 days of the response;

(f) Names and telephone numbers of Federal, state and local agencies which the operator expects to assume pollution response responsibilities;

(g) The worst case discharge volume;

(h) The method used to determine the worst case discharge volume, with calculations;

(i) A map that clearly shows—

(1) The location of the worst case discharge, and

(2) The distance between each line section in the response zone and—

(i) Each potentially affected public drinking water intake, lake, river, and stream within a radius of five miles of the line section, and

(ii) Each potentially affected environmentally sensitive area within a radius of one mile of the line section;

(j) A piping diagram and plan-profile drawing of each line section, which may be kept separate from the response plan if the location is identified; and

(k) For every oil transported by each pipeline in the response zone, emergency response data that—

(1) Include the name, description, physical and chemical characteristics, health and safety hazards, and initial spill-handling and firefighting methods; and

(2) Meet 29 CFR 1910.1200 or 49 CFR 172.602.

Appendix B to Part 194—High Volume Areas

As of January 5, 1993 the following areas are high volume areas:

Major rivers	Nearest town and state
Arkansas River	N. Little Rock, AR.
Arkansas River	Jenks, OK.
Arkansas River	Little Rock, AR.
Black Warrior River	Moundville, AL.
Black Warrior River	Akron, AL.
Brazos River	Glen Rose, TX.
Brazos River	Sealy, TX.
Catawba River	Mount Holly, NC.
Chattahoochee River	Sandy Springs, GA.
Colorado River	Yuma, AZ.
Colorado River	LaPaz, AZ.
Connecticut River	Lancaster, NH.
Coosa River	Vincent, AL.
Cumberland River	Clarksville, TN.
Delaware River	Frenchtown, NJ.
Delaware River	Lower Chichester, NJ.
Gila River	Gila Bend, AZ.
Grand River	Bosworth, MO.
Illinois River	Chillicothe, IL.
Illinois River	Havanna, IL.
James River	Arvonia, VA.
Kankakee River	Kankakee, IL.
Kankakee River	South Bend, IN.
Kankakee River	Wilmington, IL.
Kentucky River	Salvisa, KY.
Kentucky River	Worthville, KY
Maumee River	Defiance, OH.
Maumee River	Toledo, OH.
Mississippi River	Myrtle Grove, LA.
Mississippi River	Woodriver, IL.
Mississippi River	Chester, IL.
Mississippi River	Cape Girardeau, MO.
Mississippi River	Woodriver, IL.
Mississippi River	St. James, LA.
Mississippi River	New Roads, LA.
Mississippi River	Ball Club, MN.
Mississippi River	Mayersville, MS.
Mississippi River	New Roads, LA.
Mississippi River	Quincy, IL.
Mississippi River	Ft. Madison, IA.
Missouri River	Waverly, MO.
Missouri River	St. Joseph, MO.
Missouri River	Weldon Springs, MO.
Missouri River	New Franklort, MO.
Naches River	Beaumont, TX.
Ohio River	Joppa, IL.
Ohio River	Cincinnati, OH.
Ohio River	Owensboro, KY.
Pascagoula River	Lucedale, MS.
Pascagoula River	Wiggins, MS.
Pearl River	Columbia, MS.
Pearl River	Orla, TX.
Platte River	Ogallala, NE.
Potomac River	Reston, VA.
Rappahannock River	Midland, VA.
Raritan River	South Bound Brook, NJ.
Raritan River	Highland Park, NJ.
Red River (of the South)	Hanna, LA.
Red River (of the South)	Bonham, TX.
Red River (of the South)	Dekalb, TX.
Red River (of the South)	Sentell Plantation, LA.
Red River (of the North)	Wahpeton, ND.
Rio Grande	Anthony, NM.
Sabine River	Edgewood, TX.
Sabine River	Leesville, LA.
Sabine River	Orange, TX.
Sabine River	Echo, TX.
Savannah River	Hartwell, GA.
Smokey Hill River	Abilene, KS.
Susquehanna River	Darlington, MD.
Tenessee River	New Johnsonville, TN.
Wabash River	Harmony, IN.
Wabash River	Terre Haute, IN.
Wabash River	Mt. Carmel, IL.
White River	Batesville, AR.
White River	Grand Glaise, AR.
Wisconsin River	Wisconsin Rapids, WI.
Yukon River	Fairbanks, AK.

Other Navigable Waters
Arthur Kill Channel, NY
Cook Inlet, AK
Freeport, TX
Los Angeles/Long Beach Harbor, CA
Port Lavaca, TX
San Fransico/San Pablo Bay, CA

Issued in Washington, DC, on December 28, 1992.

Alan I. Roberts,

Acting Administrator, Research and Special Programs Administration.

[FR Doc. 92–31866 Filed 12–30–92; 9:34 am]

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Proposed Rules

Federal Register
Vol. 58, No. 2
Tuesday, January 5, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 354

[Docket No. 92-157-1]

User Fees—Calculation of Fees Charged by States for Issuance of Phytosanitary Certificates

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations concerning user fees for export certification of plants and plant products, by providing an alternative method of calculating the fees States may charge when States issue Federal phytosanitary certificates. The regulations currently provide guidelines for States to calculate a "cost per certificate" fee. Some States have brought it to our attention that they would prefer to calculate fees on a "cost per hour" basis. We believe that a "cost per hour" fee is also an appropriate way of charging for the issuance of phytosanitary certificates. We are therefore proposing to add guidelines for States to calculate a "cost per hour" fee for the issuance of Federal phytosanitary certificates.

DATES: Consideration will be given only to comments received on or before March 8, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92-157-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Don R. Thompson, Operations Officer, Port Operations, PPQ, APHIS, USDA, room 638, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782; (301) 436-8646.

SUPPLEMENTARY INFORMATION:

Background

In a final rule published in the **Federal Register** on January 9, 1992, and effective on February 9, 1992 (57 FR 755-773, Docket No. 91-135), we amended the regulations in 7 CFR part 354 (referred to below as the regulations) to, among other things, impose user fees for the issuance of phytosanitary certificates for the export of plants and plant products. Phytosanitary certificates are issued in accordance with 7 U.S.C. 147a and regulations in 7 CFR part 353, and they certify agricultural products as being free from plant pests, according to the phytosanitary requirements of the foreign countries to which the plants or plant products may be exported or to the freedom from exposure to plant pests while in transit through the United States. These certificates must be issued in accordance with 7 CFR part 353 to be accepted in international commerce.

The proposed rule on which that final rule was based was published on August 7, 1991 (56 FR 37481-37499, Docket No. 91-021). In that proposal, we explained that in some States certain State employees are designated to issue Federal phytosanitary certificates. Designated State employees issue approximately 47 percent of all phytosanitary certificates issued in the United States for the export of plants and plant products. These State inspectors are vital to the success of our certification program. There are more State inspectors than Animal and Plant Health Inspection Service (APHIS) inspectors, and in many instances, including in remote portions of the country, they are able to provide services more efficiently.

As provided in the regulations, when an APHIS employee conducts the inspection and signs the phytosanitary certificate, the user is required to pay the applicable APHIS user fee. However, if a designated State employee conducts the inspection and signs the phytosanitary certificate, we do not charge the APHIS user fee because APHIS is not providing any service to the user. The State, if it wishes, may charge a State fee to cover the cost of providing its services. The regulations include guidelines which the State must follow in order to establish such fees. These guidelines require States to calculate a "cost per certificate" fee for the issuance of phytosanitary certificates, and are the same guidelines used in the calculation of APHIS fees. To calculate a "cost per certificate" fee, the States must:

(1) Estimate the annual number of certificates to be issued;

(2) Determine the total cost of issuing certificates; and

(3) Divide the cost of issuing certificates by the estimated number of certificates to be issued to obtain a "raw" fee.

The State may round the "raw" fee up to the nearest quarter, if necessary, for ease of calculation, collection, or billing.

When determining the total cost of issuing certificates, States may include delivery, support, and administrative costs. Delivery costs are costs such as employee salary and benefits, transportation, per diem, travel, purchases of specialized equipment, and user fee costs associated with maintaining field offices. Support costs are similar costs at supervisory levels, and user fee costs such as training, automated data processing, public affairs, enforcement, legal services, communications, postage, budget and accounting services, and payroll purchasing, billing, and collection services. Administration costs are any additional costs the States incur as a direct result of collecting and monitoring Federal certificates.

At the time that we proposed guidelines for calculating the "cost per certificate" fee, we did not receive any comments alerting us that another method of calculation is preferred by some States. However, since the regulations have been in effect, it has come to our attention that certain States prefer to use a different method of calculating fees than the "cost per certificate" method provided in the regulations. This method is not the same as that used by APHIS in the calculation of APHIS fees. However, in some cases, States were charging a "cost per hour" fee prior to the implementation of the regulations, and it would be helpful for them to be able to do so. APHIS believes that the "cost per hour" calculation is also appropriate for the establishment of

user fees. We are therefore proposing to add, as an alternative, guidelines for the calculation of a "cost per hour" fee, according to the fee-setting method preferred by some States that issue Federal phytosanitary certificates.

To establish the "cost per hour" fee, the States would have to:

(1) Estimate the annual number of hours taken to issue phytosanitary certificates;

(2) Determine the total cost of issuing phytosanitary certificates; and

(3) Divide the cost of issuing phytosanitary certificates by the estimated number of hours taken to issue phytosanitary certificates, to obtain a "cost per hour" fee.

The State could round the "cost per hour" fee up to the nearest quarter, if necessary for ease of calculation, collection, or billing.

When determining the total cost of issuing certificates, States could include delivery, support, and administrative costs. Delivery, support, and administrative costs would be the same as those used in the calculation of a "cost per certificate" fee. Likewise, when calculating the total number of hours taken to issue phytosanitary certificates, States could include delivery, support, and administrative hours. Delivery hours are hours taken by the inspector to issue the certificate, including travel time, inspection time, and time taken to complete paperwork. Support hours are similar hours taken at supervisory levels, as well as hours taken in training, automated data processing, enforcement, legal services, communications, budgeting and accounting, payroll purchasing, billing, and collecting. Administrative hours are any additional hours taken as a direct result of collecting and monitoring Federal certificates.

As explained above, the States' participation in this program is vital to its success. To ensure that United States plants and plant products move in international commerce, it is in the public's interest that APHIS cooperate with States to ensure that phytosanitary certificates are issued. For this reason, we believe that offering States an additional option for the calculation of user fees for the issuance of phytosanitary certificates is warranted, as the addition would encourage States to continue participating in the program. Therefore, we are proposing to amend § 354.3(g)(4) to provide, as a alternative, guidelines for the calculation of a "cost per hour" fee that States may charge when States issue Federal phytosanitary certificates.

In addition, we are proposing to make a nonsubstantive editorial change in § 354.4, paragraph (a)(3), by redesignating footnote 2 and the reference to it as footnote 1.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule, if adopted, would have an effect on the economy of less that $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed rule, if adopted, would provide guidelines for the establishment of fees on a "cost per hour" basis for States which wish to charge a fee for issuance of Federal phytosanitary certificates. As explained above, the regulations already allow States to charge user fees for the issuance of Federal phytosanitary certificates on a "cost per certificate" basis.

APHIS estimates that only approximately five States would opt to use the "cost per hour" fee. In these States, the fees collected from each exporter may differ from the present fee collected, depending on the scenario. For example, the time taken by an inspector to issue a block of phytosanitary certificates is not significantly longer than the time taken by an inspector to issue a single phytosanitary certificate. Therefore, the cost per hour fee for the exporter receiving a block of phytosanitary certificates would be less than the fee on a cost per certificate basis. As another example, it might happen that an inspector would have to travel a considerable distance to inspect a shipment and issue a single phytosanitary certificate. The cost per hour fee for this service would be greater than the cost per hour fee for a shipment located closer to the inspector's workplace. According to these scenarios, the fee charged may be lower in some instances and may be higher in other instances.

However, APHIS does not believe that calculation on a "cost per hour" basis would significantly change the total fees collected by each State, because the same delivery, support, and administrative factors would be used to calculate the fee. In the end, we estimate that the total fees collected annually would be approximately the same.

Most small entities that currently pay user fees to States for the issuance of Federal phytosanitary certificates are exporters of non-commercial and low value shipments, and would not likely be affected by this proposed rule. Issuing a phytosanitary certificate for a commercial shipment generally requires inspectors to travel to the inspection site. It also generally requires them to inspect larger shipments, which takes more time. Because exporters of non-commercial and low value shipments usually bring their items to the office to be inspected, they would not be charged for any travel time. Also, their shipments usually take less time to inspect than a commercial shipment. Therefore, their fees would remain lower than the fees charged for inspection of commercial shipments, to reflect the amount of services they would receive.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted: (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This document contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion

permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 7 CFR Part 354

Exports, Government employees, Imports, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Travel and transportation expenses.

Accordingly, we propose to amend 7 CFR part 354 as follows:

PART 354—OVERTIME SERVICES RELATING TO IMPORTS AND EXPORTS; AND USER FEES

1. The authority citation for part 354 would continue to read as follows:

Authority: 7 U.S.C. 2260, 21 U.S.C. 136 and 136a; 49 U.S.C. 1741; 7 CFR 2.17, 2.51, and 371.2(c).

2. In § 354.3, paragraph (g)(4) would be revised to read as follows:

§ 354.3 User fees for certain international services.

* * * * *

(g) * * *

(4) Any State which wishes to charge a fee for services it provides to issue certificates must establish fees in accordance with one of the following guidelines:

(i) *Calculation of a "cost per certificate" fee.* The State must:

(A) Estimate the annual number of certificates to be issued;

(B) Determine the total cost of issuing certificates by adding together delivery,[2] support,[3] and administrative[4] costs; and

(C) Divide the cost of issuing certificates by the estimated number of certificates to be issued to obtain a "raw" fee. The State may round the "raw" fee up to the nearest quarter, if necessary for ease of calculation, collection, or billing; or

(ii) *Calculation of a "cost per hour" fee.* The State must:

(A) Estimate the annual number of hours taken to issue certificates by adding together delivery, support, and administrative hours;

(B) Determine the total cost of issuing certificates by adding together delivery, support, and administrative costs; and

(C) Divide the cost of issuing certificates by the estimated number of hours taken to issue certificates to obtain a "cost per hour" fee. The State may round the "cost per hour" fee up to the nearest quarter, if necessary for ease of calculation, collection, or billing.

* * * * *

§ 354.4 [Amended]

3. In § 354.4, paragraph (a)(3), footnote 2 and the reference to it would be redesignated as footnote 1.

Done in Washington, DC, this 30th day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–67 Filed 1–4–93; 8:45 am]

BILLING CODE 3410-34-M

[2] Delivery costs are costs such as employee salary and benefits, transportation, per diem, travel, purchase of specialized equipment, and user fee costs associated with maintaining field offices. Delivery hours are similar hours taken by inspectors, including travel time, inspection time, and time taken to complete paperwork.

[3] Support costs are costs at supervisory levels which are similar to delivery costs, and user fee costs such as training, automated data processing, public affairs, enforcement, legal services, communications, postage, budget and accounting services, and payroll, purchasing, billing, and collecting services. Support hours are similar hours taken at supervisory levels, as well as hours taken in training, automated data processing, enforcement, legal services, communication, budgeting and accounting, payroll purchasing, billing, and collecting.

[4] Administrative costs are costs incurred as a direct result of collecting and monitoring Federal phytosanitary certificates. Administrative hours are hours taken as a direct result of collecting and monitoring Federal phytosanitary certificates.

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9 CFR Part 91

[Docket No. 92–120–1]

Ports Designated for the Exportation of Animals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the "Inspection and Handling of Livestock for Exportation" regulations by designating Tacoma, WA, as a port of embarkation and Pacific Rim Livestock Quarantine as an export inspection facility for that port. Tacoma, WA, and Pacific Rim Livestock Quarantine appear to meet the requirements of the regulations for designation as a port of embarkation and an animal export inspection facility, respectively. We are also proposing to remove the listings for three export inspection facilities that are no longer operating and to revise the listings for two others that have changed operators or locations. These actions would add a port of embarkation and an inspection facility through which animals may be processed for export and would update the regulations.

DATES: Consideration will be given only to comments received on or before February 4, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–120–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Najam Faizi, Senior Staff Veterinarian, Import-Export Animals Staff, VS, APHIS, USDA, room 762, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–8383.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 91, "Inspection and Handling of Livestock for Exportation" (referred to below as the regulations), prescribe conditions for exporting animals from the United States. The regulations state, among other things, that all animals, except animals being exported to Mexico or Canada, shall be exported through designated ports of embarkation.

To receive designation as a port of embarkation, a port must have export inspection facilities available for the inspection, holding, feeding, and watering of animals prior to exportation to ensure that the animals meet certain requirements specified in the regulations. To receive approval as an export inspection facility, the regulations provide that a facility must

meet specified standards in § 91.14(c) concerning materials, size, inspection implements, cleaning and disinfection, feed and water, access, testing and treatment, location, disposal of animal wastes, lighting, and office and rest room facilities.

It appears that Pacific Rim Livestock Quarantine, 17835 Highway 507 SE., Yelm, WA, (206) 458–1762, meets the requirements of § 91.14(c). Yelm is located approximately 20 miles south of Tacoma, so the facility is available to exporters using Tacoma's airport and harbor. Therefore, we propose to add Tacoma, WA, to the regulations as a port of embarkation and Pacific Rim Livestock Quarantine as an export inspection facility for that port.

We are further proposing to delete Stewart Airport in Newburgh, NY, Northwest Quarantine Station in Portland, OR, and S&W Export Ltd. in Seattle, WA, from the list of animal export inspection facilities. These three facilities are no longer operating as animal export inspection facilities, so their deletion is necessary to keep the list current. In the cases of Stewart Airport and Northwest Quarantine Station, the facilities were the sole animal export inspection facilities available for the ports of Newburgh, NY, and Portland, OR, respectively. As discussed above, a port must have export inspection facilities available in order to qualify for designation as a port of embarkation. Because neither Newburgh nor Portland has an export inspection facility available, we would delete both ports from the list of ports of embarkation for animals.

Miscellaneous

The export inspection facility for the port of embarkation at the John F. Kennedy International Airport in Jamaica, NY, is no longer operated by the American Society for the Prevention of Cruelty to Animals (ASPCA). The facility is now operated by Vetport, Inc. We propose to revise the facility's entry on the list of export inspection facilities to reflect this change.

The street address and telephone number for the export inspection facility operated by Stevedoring Service of America in Seattle, WA, have changed. We propose to change the facility's entry on the list of export inspection facilities to reflect these changes.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule, if adopted, would have an effect on the economy of less than $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Currently, the State of Washington is served by designated ports of embarkation in Seattle, Olympia, and Moses Lake. Our proposal to add Tacoma as a fourth port of embarkation for the State of Washington would facilitate the export of animals from this part of the United States. We believe that adding this fourth port of embarkation would have little or no economic impact on animal exporters, the majority of which are small businesses, because it would not significantly change the cost of doing business. Although animal exporters based in the Tacoma area would realize some savings from reduced transportation costs, the primary impact on these animal exporters would be the increased convenience of having an additional port of embarkation from which to choose.

The three export inspection facilities that we are proposing to delete from the list have already ceased operating as animal export inspection facilities. Therefore, we do not believe that their deletion from the regulations will have any economic impact. The port of embarkation at John F. Kennedy International Airport, located approximately 60 miles south of Newburgh, NY, is available to animal exporters who had used the Stewart Airport animal export inspection facility. Similarly, animal exporters who used the Northwest Quarantine Station in Portland, OR, can use the animal export inspection facility located at the port of Olympia, WA, approximately 150 miles to the north. Animal exporters in Seattle, WA, still have a local animal export inspection facility available, despite the closing of S&W Export Ltd.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted:

(1) All State and local laws and regulations that are in conflict with this rule will be preempted;

(2) No retroactive effect will be given to this rule; and

(3) Administrative proceedings will not be required before parties may file suite in court challenging any provision of this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 9 CFR Part 91

Animal diseases, Animal welfare, Exports, Livestock, Reporting and recordkeeping requirements, Transportation.

Accordingly, we propose to amend 9 CFR part 91 as follows:

PART 91—INSPECTION AND HANDLING OF LIVESTOCK FOR EXPORTATION

1. The authority citation for part 91 would continue to read as follows:

Authority: 21 U.S.C. 105, 112, 113, 114a, 120, 121, 134b, 134f, 612, 613, 614, 618; 46 U.S.C. 466a, 466b; 49 U.S.C. 1509(d); 7 CFR 2.17, 2.51, and 371.2(d).

§ 91.14 [Amended]

2. Section 91.14 would be amended as follows:

a. Paragraph (a)(10)(i) would be removed and paragraph (a)(10)(ii) would be redesignated as paragraph (a)(10)(i).

b. In newly designated paragraph (a)(10)(i)(A), the word "ASPCA" would be removed and "Vetport, Inc." would be added in its place.

c. Paragraph (a)(13) would be removed and paragraphs (a)(14) through (a)(17) would be redesignated as paragraphs (a)(13) through (a)(16).

d. Newly designated paragraph (a)(16)(ii)(A) would be removed and paragraph (a)(16)(ii)(B) would be redesignated as paragraph (a)(16)(ii)(A) and revised as set forth below.

e. A new paragraph (a)(16)(iv) would be added to read as follows:

§ 91.14 Ports of embarkation and export inspection facilities.

(a) * * *

(16) * * *

(ii * * *

(A) Stevedoring Service of America, 3415 11th Avenue SW., Seattle, WA 98134, (800) 422–3505.

* * * * *

(iv) Tacoma—airport and ocean port.

(A) Pacific Rim Livestock Quarantine, 17835 Highway 507 SE., Yelm, WA 98507, (206) 458–1762.

* * * * *

Done in Washington, DC, this 30th day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–68 Filed 1–4–93; 8:45 am]

BILLING CODE 3410-34-M

9 CFR Part 94

[Docket No. 92–154–1]

Change in Disease Status of the Netherlands Because of Rinderpest and Foot-and-Mouth Disease

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to declare The Netherlands free of rinderpest and foot-and-mouth disease. There have been no outbreaks of foot-and-mouth disease in The Netherlands since 1984, and we have determined that rinderpest has not existed there since 1870. We are also proposing to add The Netherlands to a list of countries that, although declared free of rinderpest and foot-and-mouth disease, are subject to special restrictions on the importation of their meat and other animal products into the United States. This proposed revision would relieve certain prohibitions and restrictions on the importation into the United States, from The Netherlands, of ruminants and fresh, chilled, and frozen meat from ruminants.

The Netherlands is not declared to be free of hog cholera and swine vesicular disease. Therefore, even if this proposal is adopted, the importation from The Netherlands of swine and fresh, chilled, and frozen meat from swine would continue to be restricted because of these diseases. We are also proposing to add The Netherlands and Poland to the list of countries whose importation into the United States of llamas and alpacas is restricted.

DATES: Consideration will be given only to comments received on or before March 8, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–154–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Harvey A. Kryder, Chief Staff Veterinarian, Import-Export Products Staff, VS, APHIS, USDA, room 753, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7885.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation into the United States of specified animals and animal products in order to prevent the introduction into the United States of various diseases, including rinderpest, foot-and-mouth disease, bovine spongiform encephalopathy, African swine fever, hog cholera, and swine vesicular disease. These are dangerous and destructive communicable diseases of ruminants and swine.

Section 94.1(a)(1) of the regulations provides that rinderpest or foot-and-mouth disease exists in all countries of the world except those listed in § 94.1(a)(2), which are declared to be free of these diseases. We are proposing to add The Netherlands to this list.

We will consider declaring a country to be free of rinderpest and foot-and-mouth disease if there have been no cases of these diseases reported there for at least the previous 1-year period. Rinderpest has not existed in The Netherlands since 1870, and there have been no outbreaks of foot-and-mouth disease in The Netherlands since 1984. The Netherlands has applied to the U.S. Department of Agriculture to be recognized as free of rinderpest and foot-and-mouth disease. The Animal and Plant Health Inspection Service (APHIS) has reviewed the documentation submitted by the government of The Netherlands in support of its request. In addition, a team of APHIS officials recently conducted an on-site evaluation of the animal health program in The Netherlands in regard to the foot-and-mouth disease situation in that country. The evaluation consisted of a review of the capability of The Netherlands' veterinary services, laboratory and diagnostic procedures, vaccination practices, and the administration of laws and regulations to ensure against the introduction into The Netherlands of foot-and-mouth disease through the importation of animals, meats, and animal products. The team of APHIS officials conducting the on-site evaluation concluded that The Netherlands is free of foot-and-mouth disease. Details concerning the on-site evaluation are available upon written request to the person listed under **FOR FURTHER INFORMATION CONTACT.**

Based on the information discussed above, we believe that The Netherlands qualifies for listing in § 94.1(a)(2) of the regulations as a country declared free of rinderpest and foot-and-mouth disease. This action would remove the

prohibition on the importation of live ruminants and fresh, chilled, and frozen meat from ruminants. Importations of live swine and fresh, chilled, or frozen meat from swine would continue to be restricted under 9 CFR part 94, since The Netherlands has not been declared free of hog cholera and swine vesicular disease.

Special Restrictions

We also propose to add The Netherlands to the list in § 94.11(a) of countries free of rinderpest and foot-and-mouth disease that are subject to special restrictions on the importation of their meat and other animal products into the United States. The countries listed in § 94.11(a) are subject to these special restrictions because they: (1) Supplement their national meat supply by importing fresh, chilled, or frozen meat of ruminants or swine from countries that are designated in § 94.1(a) as infected with rinderpest or foot-and-mouth disease; (2) have a common land border with countries designated as infected with rinderpest or foot-and-mouth disease; or (3) import ruminants or swine from countries designated as infected with rinderpest or foot-and-mouth disease under conditions less restrictive than would be acceptable for importation into the United States.

The special restrictions placed on meat and meat products of ruminants and swine in § 94.11 generally require that the meat be: (1) Prepared in an inspected establishment that is eligible to have its products imported into the United States under the Federal Meat Inspection Act; and (2) accompanied by an additional certificate, issued by an animal health official of the national government of the country declared free of the disease, assuring that the meat and meat products have not been commingled with or exposed to meat or other meat products originating in, imported from, or transported through a country infected with rinderpest or foot-and-mouth disease, and are otherwise handled in accordance with the requirements of § 94.11.

The Netherlands has common land borders with Germany and Belgium, which are designated in § 94.1(a)(1) as countries in which rinderpest or foot-and-mouth disease exists. In addition, The Netherlands imports live ruminants and swine from countries not recognized as free of foot-and-mouth disease under conditions less restrictive than would be acceptable for importation into the United States. Further, The Netherlands supplements its national meat supply by the importation of fresh, chilled, and frozen meat of ruminants and swine from countries designated in § 94.1(a)(1) as countries in which rinderpest or foot-and-mouth disease exists. As a result, even though we propose to designate The Netherlands as free of rinderpest and foot-and-mouth disease, the meat and other animal products produced in The Netherlands may be commingled with the fresh, chilled, or frozen meat of animals from a country in which rinderpest and foot-and-mouth disease exists, resulting in an undue risk of introducing rinderpest or foot-and-mouth disease into the United States.

Therefore, we are proposing that meat and other animal products of ruminants and swine, and the ship stores, airplane meals, and baggage containing these meat or animal products imported into the United States from The Netherlands be subject to the restrictions specified in § 94.11 of the regulations, in addition to other applicable requirements of title 9, chapter III.

We also propose to add The Netherlands to the list in § 94.1(d)(1) of countries in which rinderpest or foot-and-mouth disease has been known to exist and that are declared free of rinderpest and foot-and-mouth disease on or after September 28, 1990. All countries declared free of rinderpest and foot-and-mouth disease on or after September 28, 1990, must be added to this list. Adding The Netherlands to this list would restrict the importation of llamas and alpacas from The Netherlands into the United States, unless in accordance with 9 CFR 92.435.

Miscellaneous

We also propose to add Poland to the list in § 94.1(d)(1). We declared Poland free of rinderpest and foot-and-mouth disease in a final rule published in the **Federal Register** on April 24, 1992 (57 FR 15002–15004, Docket No. 91–200). However, in that document, we neglected to add Poland to the list in § 94.1(d)(1). We are now proposing to add Poland to the list in order to correct our oversight. Adding Poland to the list would likewise restrict the importation of llamas and alpacas from Poland into the United States.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule, if adopted, would have an effect on the economy of less than $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed rule, if adopted, would add The Netherlands to the list in part 94 of countries declared to be free of rinderpest and foot-and-mouth disease. This action would relieve restrictions imposed on the importation of live ruminants and fresh, chilled, and frozen meat of ruminants from The Netherlands into the United States. This action would not relieve restrictions on the importation of live swine and fresh, chilled, and frozen meat of swine because The Netherlands is still considered to be affected with hog cholera and swine vesicular disease.

Based on available information, the Department does not anticipate a major increase in exports of fresh, chilled, or frozen meat of ruminants from The Netherlands into the United States as a result of this proposed rule. In 1990, total meat production in the United States (excluding pork) was just over 10.6 million metric tons. In comparison, in 1990, total meat production (excluding pork) in The Netherlands was only 554,000 metric tons, which amounts to about 5 percent of U.S. production. Since The Netherlands' cattle industry is relatively small, it is unlikely that The Netherlands would export a significant portion of its meat production exclusively to the United States. Therefore, any effect on domestic prices or supplies would be insignificant. Increases in imports of live ruminants from The Netherlands are also unlikely because of high transportation costs.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

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Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted and approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0015.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), VELOGENIC VISCEROTROPIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

§ 94.1 [Amended]

2. In § 94.1, paragraph (a)(2) would be amended by adding "The Netherlands," immediately after "Mexico,".

3. In § 94.1, paragraph (d)(1) would be amended by adding ", The Netherlands, and Poland" immediately after "Chile".

§ 94.11 [Amended]

4. In § 94.11, the first sentence in paragraph (a) would be amended by adding "The Netherlands," immediately after "Japan,".

Done in Washington, DC, this 30th day of December 1992.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–69 Filed 1–4–93 8:45 am]

BILLING CODE 3410-34-M

9 CFR Part 98

[Docket No. 92–128–1]

Importation of Certain Animal Semen

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations concerning the importation of certain animal semen by: Adding a provision requiring that all imported animal semen be accompanied by a health certificate; restoring the exemption from the requirement for an import permit for animal semen being imported into the United States from Canada through a land border port; and restoring the list of ports of entry so that it includes all of the ports designated for the importation of animal semen into the United States. These actions would help to prevent disease from entering the United States and correct omissions that resulted from the reorganization of the regulations.

DATES: Consideration will be given only to comments received on or before February 4, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–128–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Joyce Bowling, Staff Veterinarian, Import-Export Animals Staff, VS, APHIS, USDA, room 766, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–8170.

SUPPLEMENTARY INFORMATION:

Background

The regulations contained in "Subpart C—Certain Animal Semen" of 9 CFR part 98 (referred to below as "the regulations") concern the importation of certain animal semen into the United States. We are proposing to amend or revise several sections of subpart C to help prevent disease from entering the United States and correct omissions that resulted from the reorganization of the regulations.

We are proposing to add a requirement that all animal semen imported into the United States be accompanied by a health certificate. A health certificate would help the Animal and Plant Health Inspection Service (APHIS) to determine if animal semen being offered for importation into the United States meets the collection, identification, and testing requirements of § 98.34. A health certificate would not only help to ensure the disease-free status of animal semen entering the United States, but it would also provide a means of tracing the animal semen back to its source if necessary.

We would require that the health certificate state where the animal semen was collected, who collected the animal semen, the date of collection, the identification and breed of the donor animal, the number of ampules or straws and the identification number or code used on each, the dates and results of all examinations and tests required by the regulations, and the names and addresses of the consignor and the consignee. The health certificate would also have to state that the animal semen was being imported in accordance with the regulations in subpart C of 9 CFR part 98.

We would further require that the health certificate be issued by a full-time salaried veterinary officer of the national government of the exporting country, or issued by a veterinarian authorized by the national government of the exporting country and endorsed by a full-time salaried veterinary officer of the national government of that country. We believe that a full-time salaried veterinary officer of the national government of the exporting country would be best qualified to certify to the accuracy of the information provided on the health certificate. However, we would accept a certificate issued by a veterinarian who is not a salaried veterinary officer of the national government of the exporting country if the certificate were endorsed by a salaried veterinary officer of the national government of the exporting country. The endorsement would ensure that the veterinarian issuing the certificate was authorized to do so.

The remainder of our proposed changes are needed to rectify errors that occurred when 9 CFR part 92 was reorganized by a final rule published in the **Federal Register** on August 2, 1990 (55 FR 31484–31562, Docket No. 90–023). Originally, part 92 was a mixture of general provisions that applied to all types of animals and specific rules that applied only to some types of animals. To eliminate the need to search through all of part 92 to find all the regulations for one type of animal, part 92 was divided into seven subparts, with each subpart containing all the regulations for a given type of animal. If a section in the original part 92 applies to more than one type of animal, that section was repeated in each subpart to which it applied. The reorganization of part 92 was undertaken to make the regulations easier to use rather than to make any substantive changes to the requirements, so care was taken to avoid omitting provisions that might apply to a given subpart.

During the reorganization of 9 CFR part 92, the animal semen importation regulations were assembled into their own subpart and moved to 9 CFR part 98. When the animal semen importation regulations were moved, some provisions that should have been copied from part 92 were unintentionally omitted, and some provisions that did not apply to the subpart were copied from part 92. These errors are the subject of our remaining proposed changes.

Section 98.33 of the regulations contains a list of limited ports that are designated for the importation of animal semen. Although the ports listed are correct, the list is incomplete. The limited ports paragraph was the only paragraph in the original part 92 that specifically mentioned animal semen; so when the animal semen importation subpart was assembled, the paragraphs listing air and ocean ports, Canadian border ports, and Mexican border ports were not included. The ports that were omitted do have adequate inspection facilities for the entry of animal semen and should have been included in the list of designated ports in § 98.33. Therefore, we propose to change the section heading of § 98.33 to the more specific title of "Ports designated for the importation of certain animal semen" and restore the paragraphs listing air and ocean ports, Canadian border ports, and Mexican border ports.

Section 98.36 of the regulations contains requirements for import permits and declarations for animal semen imported from Canada. In the original part 92, that section contained a provision that exempted animal semen collected from certain donor animals in Canada from the requirement for an import permit when the animal semen is imported into the United States through a land border port on the United States-Canada border. When the animal semen importation subpart was assembled, the exemption was inadvertently omitted. Applications for import permits help APHIS to project its future workload and schedule qualified personnel to be at ports of entry to inspect shipments upon their arrival. Because APHIS veterinarians are already assigned on a full-time basis to each of the land border ports on the United States-Canada border, the advance notice provided by the import permit process is not necessary to ensure that qualified personnel are present at the port of entry at the time of importation. Moreover, the previous regulations required the animal semen to be from donor animals born in Canada or the United States, or to have been legally imported into Canada and unconditionally released into Canada; such semen presents an insignificant risk of carrying communicable diseases into the United States. Therefore, we propose to restore the provision that exempts animal semen collected from certain donor animals in Canada from the requirement for an import permit when the animal semen is imported into the United States through a land border port on the United States-Canada border.

In the original part 92, §§ 92.19 to 92.42 were divided into three categories: Canada, Countries of Central America and West Indies, and Mexico. Each category contained regulations specific to the importation of animals from each country or group of countries. When the animal semen importation subpart was assembled, the three categories were retained; they now appear in part 98 as §§ 98.36 to 98.39. However, § 98.37, which concerns the countries of Central America and the West Indies, and §§ 98.38 and 98.39, which concern Mexico, contain nothing that differs from the general provisions contained elsewhere in the subpart. To eliminate any confusion that this duplication might cause, we propose to remove the category headings before §§ 98.37 and 98.38, their footnotes, and §§ 98.37 through 98.39.

Finally, we are proposing to amend §§ 98.31 and 98.35(a) by removing references to "this part," a term that had been used before the animal semen importation regulations were placed in their own subpart, and replacing them with references to "this subpart." We are also proposing to amend § 98.34(a) by removing an outdated, inaccurate reference to §§ 98.26, 98.27, and 98.28 and replacing it with a reference to § 98.36.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule, if adopted, would have an effect on the economy of less than $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, States, or local government agencies, or geographic regions; and would not cause a significant adverse affect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We anticipate that the provisions of this proposed rule, if adopted, would have little or no economic effect. We believe that the proposed requirement for a health certificate to accompany each shipment of animal semen being imported into the United States would not have any significant impact on importers. The health certificate would not require any additional tests or examinations to be conducted on the donor animal; rather, the health certificate would merely document the identification, collection, and examination activities that are already required by the regulations.

The remainder of our proposed changes are either non-substantive in

nature or would simply restore language that was mistakenly omitted from the regulations. We believe, therefore, that this rule would have little or no economic impact on importers of animal semen because it would not significantly increase or decrease the cost of doing business.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted:.

(1) All State and local laws and regulations that are in conflict with this rule will be preempted;

(2) No retroactive effect will be given to this rule; and.

(3) Administrative proceedings will not be required before parties may file suite in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule will be submitted for approval to the Office of Management and Budget. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please send a copy of your comments to (1) Chief, Regulatory Analysis and Development, PPD, APHIS, SUDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782 and (2) Clearance Officer, OIRM, USDA, room 404–W, 14th Street and Independence Avenue SW., Washington, DC 20250.

Regulatory Reform: Less Burdensome or More Efficient Alternatives.

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 9 CFR Part 98

Animal diseases, Imports.

Accordingly, we propose to amend 9 CFR part 98 as follows:

PART 98—IMPORTATION OF CERTAIN ANIMAL EMBRYOS AND ANIMAL SEMEN

1. The authority citation for part 98 would continue to read as follows:

Authority: 7 U.S.C. 1622; 21 U.S.C. 103, 104, 105, 111, 134a, 134b, 134c, 134d, 134f; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(d).

2. In §§ 98.31 and 98.35(a), the words "this part" would be removed and the words "this subpart" would be added in their place each time the words appear.

3. Section 98.33 would be amended by revising the section heading, revising paragraph (a) and redesignating it as paragraph (d), redesignating paragraph (b) as paragraph (e), and adding new paragraphs (a), (b), and (c) to read as follows:

§ 98.33 Ports designated for the importation of certain animal semen.

(a) *Air and ocean ports.* The following air and ocean ports are designated as having inspection facilities for the entry of animal semen: Los Angeles, California; Miami, Florida; Honolulu, Hawaii; and Newburgh, New York.

(b) *Canadian border ports.* The following land border ports are designated as having inspection facilities for the entry of animal semen from Canada: Eastport, Idaho; Houlton and Jackman, Maine; Detroit, Port Huron, and Sault Ste. Marie, Michigan; Opheim, Raymond, and Sweetgrass, Montana; Alexandria Bay, Buffalo, and Champlain, New York; Dunseith, Pembina, and Portal, North Dakota; Derby Line and Highgate Springs, Vermont; Blaine, Lynden, Oroville, and Sumas, Washington.

(c) *Mexican border ports.* The following land border ports are designated as having inspection facilities for the entry of animal semen from Mexico: Douglas, Naco, Nogales, San Luis, and Sasabe, Arizona; Calexico and San Ysidro, California; Antelope Wells, Columbus, and Santa Teresa, New Mexico; Brownsville, Del Rio, Eagle Pass, El Paso, Hidalgo, Laredo, and Presidio, Texas.

(d) *Limited ports.* The following limited ports are designated as having inspection facilities for the entry of animal semen: Anchorage and Fairbanks, Alaska; San Diego, California; Denver, Colorado; Jacksonville, St. Petersburg-Clearwater, and Tampa, Florida; Atlanta, Georgia; Chicago, Illinois; New Orleans, Louisiana; Portland, Maine; Baltimore, Maryland; Boston, Massachusetts; International Falls and Minneapolis, Minnesota; Great Falls, Montana; Portland, Oregon; San Juan, Puerto Rico; Galveston and Houston, Texas; Seattle, Spokane, and Tacoma, Washington.

* * * * *

§ 98.34 [Amended]

4. In § 98.34, paragraph (a)(1), the designations "§§ 98.26, 98.27, and 98.28," would be removed and the designation "§ 98.36," would be added in their place.

5. In § 98.35, paragraph (a), the words "this part" would be removed and the words "this subpart" would be added in their place.

5. In § 98.35, the section heading would be revised and two new paragraphs, (c) and (d), would be added to read as follows:

§ 98.35 Declaration, health certificate, and other documents for animal semen.

* * * * *

(c) All animal semen offered for importation into the United States shall be accompanied by a health certificate issued by:

(1) A full-time salaried veterinarian of the national government of the country of origin; or

(2) Any veterinarian authorized by the national government of the country of origin, provided that the health certificate is endorsed by a full-time salaried veterinarian of the national government of the country of origin.

(d) The health certificate must state:

(1) The name and address of the place where the semen was collected;

(2) The name and address of the veterinarian who collected the semen;

(3) The date of semen collection;

(4) The identification and breed of the donor animal;

(5) The number of ampules or straws covered by the health certificate and the

identification number or code on each ampule or straw;

(6) The dates, types, and results of all examinations and tests performed on the donor animal as a condition for importing the semen;

(7) The names and addresses of the consignor and consignee; and

(8) That the semen is being imported into the United States in accordance with subpart C of 9 CFR part 98.

6. Section 98.36, including the undesignated center-heading, "CANADA[3]", would be revised (and footnote 3 removed) to read as follows:

CANADA

§ 98.36 Import permit, declaration, and health certificate for animal semen.

(a) For animal semen intended for importation from Canada, the importer shall first apply for and obtain from APHIS an import permit as provided in § 98.34: *Provided*, that an import permit is not required for animal semen offered for entry at a land border port designated in § 98.33(b) if the donor animal:

(1) Was born in Canada or the United States, and has been in no country other than Canada or the United States; or

(2) Has been legally imported into Canada from some other country and unconditionally released in Canada so as to be eligible to move freely within that country without restriction of any kind and has been in Canada after such release for 60 days or longer.

(b) For all animal semen offered for importation from Canada, the importer or his or her agent shall present two copies of a declaration and a copy of a health certificate as provided in § 98.35.

§§ 98.37 through 98.39 [Removed]

7. The undesignated center-headings "Countries of Central America and West Indies[4]" and "Mexico[5]"and §§ 98.37 through 98.39 and (footnotes 4 and 5) would be removed.

Done in Washington, DC, this 30th day of December 1992.

Lennie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–70 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–34–M

Food Safety and Inspection Service

9 CFR Part 318

[Docket No. 89–033P]

RIN 0583–AB20

Use of Citric Acid as a Color Preserver on Cured Pork Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat inspection regulations to permit the use of citric acid as a color preserver on cured pork products during storage. It is proposed that a solution consisting of citric acid, at levels not to exceed 30 percent in water, be allowed as a spray applied to the surfaces of cured pork cuts, prior to packaging. Use of the citric acid in water solution would be limited to a one-time application. This proposed rule is in response to a petition submitted by the Better Marketing Company, East Rutherford, New Jersey.

DATES: Comments must be received on or before February 4, 1993.

ADDRESSES: Written comments to: Policy Office, Attn: Linda Carey, FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. (See also "Comments" under "SUPPLEMENTARY INFORMATION.")

FOR FURTHER INFORMATION CONTACT: Charles Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 205–0080.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Agency has determined that this proposed rule is not a major rule under Executive Order 12291. It would not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under section 408 of the Federal Meat Inspection Act (FMIA) (21 U.S.C. 678) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat products that are in addition to, or different than, those imposed under the FMIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat products that are outside official establishments for the purpose of preventing the distribution of meat products that are misbranded or adulterated under the FMIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA, States that maintain meat inspection programs must impose requirements on State inspected products and establishments that are at least equal to those required under the FMIA. The States may, however, impose more stringent requirements on such State inspected products and establishments.

This rule is not intended to have retroactive effect. However, the administrative procedures specified in 9 CFR 306.5 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an inspector relating to inspection services provided under the FMIA. The administrative procedures specified in 9 CFR part 335 must be exhausted prior to any judicial challenge to the application of the provisions of this rule with respect to labeling decisions.

Effects on Small Entities

The Administrator, FSIS, has made an initial determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. The proposal would permit the use of citric acid, applied as a spray prior to packaging, as a color preserver on cured pork cuts during storage. Manufacturers, both large and small, opting to use such substance in the proposed manner would be required to revise the ingredient statements on product labels to show the presence of citric acid. However, the use of citric acid would be voluntary and any costs associated with new label applications would be covered under existing approved paperwork requirements of FSIS's prior label approval system. Decisions by individual manufacturers on whether to use citric acid on cured pork cuts would be based on their conclusions that the benefits would outweigh the costs.

Comments

Interested persons are invited to submit written comments concerning this proposed rule. Written comments should be sent to the Policy Office at the address shown above and should refer to Docket Number 89–033P. All comments submitted in response to this proposal will be available for public inspection in the Policy Office from 9 a.m. to 12:30 p.m. and from 1:30 p.m. to 4 p.m., Monday through Friday.

Background

Better Marketing Company Petition

FSIS has been petitioned by Better Marketing Company, East Rutherford, New Jersey, to approve the use of a solution consisting of citric acid, at a level of 30 percent in water, to be applied to cut surfaces of cured meat products, prior to packaging, to preserve the product's cured color for up to 3 days.[1] According to the petitioner, a color retention of 3 days is considered essential for retail merchandising of cured meat cuts such as slices and end pieces of smoked hams and picnics. After cured meat is cut, the cut surface begins to fade from pink to a light gray, resulting in economic loss to meat merchandisers, who either trim and rewrap the product or reduce the price.

The petitioner contends that a one-time spraying of a solution containing 30 percent citric acid and water, to the surfaces of cured pork cuts will not preserve the product's cure color beyond 3 days nor reverse gray-colored meat to a pink color. Supporting data submitted by the petitioner was based on a series of tests using citric acid alone and in combination with ascorbic acid in solution levels ranging from 10 percent to 30 percent on surfaces of cured pork cuts. The data show that only the solution consisting of 30 percent citric acid in water provides a cure color retention of up to but no more than 3 days. The data also show that a 30 percent citric acid level is the lowest level sufficient for up to 3-day color preservation without a concern for masking any indicators of spoilage.

Current Regulations

Section 318.7(c)(4) of the Federal meat inspection regulations (9 CFR 318.7(c)(4)) currently allows the use of citric acid as a curing accelerator to accelerate color fixing or preserve color during storage of cured pork and beef cuts, and cured comminuted meat food products. Citric acid may be used in cured products or in a 10 percent solution to spray surfaces of cured cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate or sodium erythorbate that is used (9 CFR 318.7(c)(4)). Citric acid may also be used as an acidifier, an anticoagulant, a flavoring agent, and a synergist at various levels in various meat food products (9 CFR 318.7(c)(4)). The Food and Drug Administration lists citric acid as generally recognized as safe (GRAS) for use in foods in 21 CFR 182.1033, when used in accordance with good manufacturing practices.

The Proposal

After reviewing the petitioner's data and information, FSIS has determined that a one-time spray application of a solution containing citric acid, at levels up to 30 percent in water, to surfaces of cured pork cuts would not affect the wholesomeness of the products and would be in accordance with the requirements of the Federal Meat Inspection Act. Therefore, FSIS is proposing to amend the chart of approved substances in 9 CFR 318.7(c)(4) to allow the use of citric acid to preserve the color on surfaces of cured pork cuts. This proposal would permit the one-time spray application of a solution consisting of citric acid, at levels not to exceed 30 percent in water, to the surfaces of cured pork cuts. Although the petitioner requested use of the citric acid and water solution on cut surfaces of "cured meat products," the petitioner's supporting data was based on tests done on cured pork products only. Therefore, this proposal is limited to the use of a citric acid in water solution on the surfaces of cured pork cuts. Further, although the data submitted by the petitioner shows that the 30 percent citric acid level is the lowest level sufficient for up to a 3-day color preservation, FSIS will allow use levels up to 30 percent because some manufacturers may want to use lower levels to preserve the cured color for less than 3 days.

List of Subjects in 9 CFR Part 318

Food additives, Meat inspection.

Proposed Rule

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR part 318 of the Federal meat inspection regulations to read as follows:

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. In the chart in § 318.7(c)(4), the Class of substance "Miscellaneous" would be amended by adding at the end thereof the following:

§ 318.7 Approval of substances for use in the preparation of products.

* * * * *

(c) * * *

(4) * * *

Class of substance	Substance	Purpose	Products	Amount
•	•	•	•	•
Miscellaneous	• • •			
	Citric acid	To preserve cured color during storage	Cured pork cuts	Not to exceed 30 percent, in water solution used to spray surfaces of cured cuts, prior to packaging, in accordance with 21 CFR 182.1033. (The use of such solution shall not result in the addition of a significant amount of moisture to the product and shall be applied only once to the product.)

[1] A copy of this petition is available for public review in the FSIS Hearing Clerk's Office.

* * * * *

Done at Washington, DC, on December 16, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 93–57 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–DM–M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50, 52 and 100

RIN 3150–AD93

Reactor Site Criteria; Including Seismic and Earthquake Engineering Criteria for Nuclear Power Plants and Proposed Denial of Petition From Free Environment, Inc. et al.

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Extension of comment period.

SUMMARY: On October 20, 1992 (57 FR 47802), the NRC published for public comment a proposed rule to update the criteria used in decisions regarding power reactor siting, including geologic, seismic, and earthquake engineering considerations for future nuclear power plants. The comment period for this proposed rule was to have expired on February 17, 1993. The availability of the five draft regulatory guides and the standard review plan section that were developed to provide guidance on meeting the proposed regulations was published on November 25, 1992 (57 FR 55601). Because the proposed rule would move the detailed guidance from the regulation and place it into a regulatory guide, a critical evaluation of the proposed rule could not be performed until the draft regulatory guides and standard review plan section were available. The NRC has stated that comments on the draft regulatory guides and standard review plan section would be most helpful if received by March 24, 1993. In view of the importance of the proposed rule and the differences in the comment period, the NRC has decided to extend the comment period on the proposed rule for an additional thirty six days. The extended comment period now expires March 24, 1993.

DATES: The comment period has been extended and now expires March 24, 1993. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to 11555 Rockville, Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m., Federal workdays.

Copies of the regulatory analysis, the environmental assessment and finding of no significant impact, and comments received may be examined at the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dr. Andrew J. Murphy, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–3860, concerning the seismic and earthquake engineering aspects and Mr. Leonard Soffer, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–3916, concerning other siting aspects.

Dated at Rockville, Maryland, this 29th day of December, 1992.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93–48 Filed 1–4–93; 8:45 am]

BILLING CODE 7590–01–M

FEDERAL RESERVE SYSTEM

12 CFR Part 230

[Regulation DD; Docket No. R–0791]

Truth in Savings; Proposed Regulatory Amendments

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule.

SUMMARY: The Board is publishing for comment proposed amendments to Regulation DD (Truth in Savings) to implement recent changes made to the Truth in Savings Act by the Housing and Community Development Act of 1992. The law extends the mandatory date for compliance with the requirements of the Truth in Savings Act by three months, so that institutions must comply by June 21, 1993, rather than March 21, 1993. The law also modifies the advertising rules relating to signs in an institution's lobby, and makes a technical change to the provision dealing with notices required to be given to existing account holders. In addition, the Board is proposing to make a minor change to the regulation and clarify and provide additional guidance on a few issues that have been raised by institutions since publication of the final regulation on September 21, 1992.

DATES: Comments must be received on or before February 1, 1993.

ADDRESSES: Comments should refer to Docket No. R–0791, and may be mailed to Mr. William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551. Comments also may be delivered to room B–2222 of the Eccles Building between 8:45 a.m. and 5:15 p.m. weekdays, or to the guard station in the Eccles Building courtyard on 20th Street, NW (between Constitution Avenue and C Street) any time. Comments may be inspected in Room B–1122 between 9 a.m. and 5 p.m. weekdays, except as provided in 12 CFR 261.8 of the Board's rules regarding the availability of information.

FOR FURTHER INFORMATION CONTACT: Jane Ahrens, Kyung Cho, Kurt Schumacher, or Mary Jane Seebach, Staff Attorneys, Division of Consumer and Community Affairs, at (202) 736–5500; for the hearing impaired only contact Dorothea Thompson, Telecommunications Device for the Deaf, at (202) 452–3544, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

(1) Background

The Truth in Savings Act (act) (contained in the Federal Deposit Insurance Corporation Improvement Act of 1991) was enacted in December 1991. The Board published proposed rules to implement the act on April 13, 1992 (57 FR 12735), and published a final regulation, Regulation DD, on September 21, 1992 (57 FR 43337) (correction notice at 57 FR 46480, October 9, 1992).

The Housing and Community Development Act (HCDA) was enacted in October 1992 (Pub. L. 102–550, 106 Stat. 3672). The law contains three provisions that amend the Truth in Savings Act. The provisions extend the effective date for compliance with the act by three months, reduce the requirements that apply to some advertisements on the premises of a depository institution, and modify the provision that requires a notice to be given to existing account holders alerting them to the availability of account disclosures.

To implement the changes, the Board is proposing regulations for comment, and expects to adopt final amendments before March 21, 1993—the compliance date currently set forth in Regulation DD. In light of the minor nature of the

amendments and in order to ensure that amendments are adopted by March 21, the Board is providing only a 30-day comment period. In addition to proposing rules to implement the statutory changes, the Board is proposing to make one minor change to the regulation and to provide guidance on a few other issues that have been raised by institutions since adoption of the final rules. Due to a significant number of questions raised about these issues, the Board proposes to provide guidance at this time, rather than delaying until the Official Staff Commentary is proposed for comment in the fall of 1993.

(2) Proposed Regulatory Provisions

Mandatory Compliance Date

The final regulation referred to March 21, 1993, as the mandatory date for complying with the requirements of the regulation. The definition of "account" under § 230.2(a) states that existing accounts held by an unincorporated nonbusiness association of natural persons prior to March 21, 1993 are not included in the term.

As discussed above, the mandatory date for compliance with the requirements of the Truth in Savings Act was extended by the HCDA for three months. (Section 957(b) of the HCDA amended section 269(a)(2) of the Truth in Savings Act.) The Board proposes to replace the reference to "March 21" with "June 21" in § 230.2(a).

In several places, the supplementary information accompanying the final regulation referred to an effective date of March 21, 1993. The proposed change to the regulation supersedes all such references.

In conjunction with the final regulation, the Board had deleted the existing advertisement and disclosure rules in Regulation Q (12 CFR part 217) as of March 21, 1993, when the requirements in Regulation DD would become mandatory. Consistent with the change to Regulation DD, the Board will make a technical amendment to Regulation Q so that the requirements in Regulation Q will remain in effect until June 21, 1993. As stated in the supplementary information accompanying the final regulation, however, institutions may begin complying solely with the advertising provisions in Regulation DD prior to the date for mandatory compliance, instead of the advertising and disclosures provisions in Regulation Q.

Section 230.4—Account Disclosures

(c) *Notice to existing account holders—(1) Notice of availability of disclosures.* As enacted in December 1991, section 266(e) of the act would have required institutions to include a notice of disclosure availability on or with any regularly scheduled periodic statement sent to existing consumer account holders within 180 days of adoption of the Board's final rule. In implementing this provision, the Board's regulation specified that this notice to existing account holders did not have to be sent prior to the mandatory compliance date of March 21, 1993. Instead, the notice was to be included on or with the first periodic statement sent on or after March 21, 1993 (or the first periodic statement for a statement cycle beginning on or after that date).

As stated above, section 957(b) of the HCDA extended the mandatory compliance date from 6 months to 9 months after the Board's issuance of a final rule. In addition, section 1604(e) of the HCDA amended section 266(e) of the Truth in Savings Act to require that the notice to existing account holders be sent "on or with the first regularly scheduled mailing sent after the end of the *6 month period* beginning on the date of publication" of the Board's implementing regulations (emphasis added).

If the revisions to statutory sections 957(b) and 1604(e) were taken literally, the amended act could be read to require institutions to provide the notice to existing consumer account holders on or with the first periodic statement sent after March 21, 1993. The Board believes that the Congress did not intend for institutions to have to comply with this disclosure duty prior to the new compliance data, but rather intended to grant institutions an additional three-month period to comply. Therefore, the Board is proposing to amend § 230.4(c) of Regulation DD to require the notice of account disclosure availability to be included on or with the first periodic statement sent on or after the mandatory compliance date of June 21, 1993 (or the first periodic statement for a statement cycle beginning on or after that date). The Board solicits comments on this proposal.

Section 230.5—Subsequent Disclosures

(a) *Change in terms—(2) No notice required—(ii) Check printing fees.* The act and regulation require institutions to provide a 30-day advance notice to consumers of any change in a previously disclosed term that may adversely affect the consumer. In the final rule the Board used its exception authority, pursuant to section 269(a)(3) of the act, to create a limited exception to the notice requirements for changes in check printing fees "assessed by third parties."

Since release of the final rule, the Board has received numerous inquiries about the scope of this exception. For example, institutions have asked whether they can take advantage of the exception if the check-printing vendor directly bills the institution which adds a "mark-up" and passes the fee on to the consumer. Institutions have asked whether the exception applies if the third party originates a debit to the account, but the institution is involved in determining the fee.

In order to simplify the requirement and avoid further confusion, the Board proposes to clarify the exception so that an institution does not have to provide a change in terms notice for check printing fees—regardless of whether the fee is assessed by a third party or by the depository institution itself. The Board solicits comment on whether it is necessary to broaden the current exception in this manner.

The imposition of check printing fees by a third party was referred to in the supplementary information to section 230.8(a) that accompanied the final regulation. That section prohibits institutions from advertising an account as "free" or "no cost" if a "maintenance or activity" fee might be imposed on the account. The supplementary information specified that fees imposed by a third party to print checks are not considered maintenance or activity fees imposed on the account. Consistent with the proposed amendment to the regulation and in light of the concerns discussed above, the Board proposes to clarify that check printing fees are not maintenance or activity fees, regardless of who imposes them. Thus, an institution that imposes check printing fees could state that an account is free, if no maintenance or activity fees are imposed.

Section 230.8—Advertising

(e) *Exemption for certain advertisements.* Section 263(a) of the act provides that a reference to a specific interest rate, yield, or rate of earnings in an advertisement triggers a duty to state certain additional information, including the annual percentage yield. The HCDA amendment to section 263(c) of the advertising rules provides that if a rate is displayed on a sign (including a rate board) designed to be viewed only from the interior of an institution, the disclosure requirements of section 263 do not apply. Instead, only the annual percentage yield and a statement advising consumers to ask employees about fees and terms applicable to the

advertised account are required to be stated.

The regulation currently exempts lobby signs from some advertising disclosure requirements. The Board's proposal would amend the regulation by reorganizing § 230.8(e). A new subparagraph (2) would be added to address disclosure requirements for lobby signs.

The proposal does not define the term "lobby sign." The Board believes that lobby signs would include signs such as preprinted posters and chalk or peg boards, whether affixed to a wall or displayed on an easel or a counter. The Board also proposes that a lobby sign include any advertisement "facing inside" an institution, including computer screens and electronic media. The Board believes, however, that a lobby sign does *not* include a document that can be retained by a consumer (such as a print-out from a computer or a brochure). Thus, such a document would be subject to all of the advertising rules. The Board requests comment on whether "lobby signs" should be defined, and if so, how the term should be defined.

Under the act, the exception applies to lobby signs designed to be viewed only from the interior of a depository institution (or the premises of a deposit broker). The Board proposes to use the term "facing inside" the lobby rather than using an "intent" standard. The Board believes this will provide a simpler test for determining if a sign is exempt under section 230.8(e) or not. Since the act creates an exemption only for lobby signs designed to be viewed from inside an institution, lobby signs that do not face inside a depository institution (or the premises of a deposit broker) would remain subject to the normal disclosure requirements of this section.

Technically, the statute could be read to exempt from the disclosure rules only those lobby signs that state a rate. The Board believes the Congress intended to except these media from the disclosure provisions in section 263(a) and 263(c) regardless of whether a rate of return is stated. Lobby signs would be exempt from the disclosure requirements under paragraphs (b), (c) and (d) of § 230.8 if the signs face inside a depository institution or the premises of a deposit broker. This would exempt such lobby signs from the disclosure rules dealing with bonuses in § 230.8(d); thus, a lobby sign could state a "bonus" without stating any additional disclosures.

Section 263(c) of the act excepts lobby signs from the "disclosure provisions" of section 263. A second amendment to the act exempts lobby signs from paragraph (a) of section 263, which deals specifically with "disclosures" required when rates of earnings are mentioned in advertisements. The proposal would exempt lobby signs from the disclosure provisions of section 263, but they would remain subject to the prohibition on misleading or inaccurate advertisements. The Board believes that if a broader exemption were intended, the Congress would have exempted the lobby signs described in section 263(c) of the act from section 263 entirely. Thus, the Board believes that lobby signs facing inside an institution (or the premises of a deposit broker) are subject to the act's prohibitions against the use of misleading or inaccurate statements in advertisements, and against the description of accounts as "free" if a regular service fee is imposed. As a result, lobby signs facing inside a depository institution would be covered by paragraph (a) of § 230.8. The Board solicits comment on this proposal.

The amendment to section 263(c) of the act requires that if any rate is displayed, the annual percentage yield must also be stated (but does not expressly require that the figure be described as the "annual percentage yield"). The regulation currently provides that in all cases, if any rate of return is advertised, it must be stated as the annual percentage yield, using that term or the abbreviation "APY." The Board solicits comment on this issue.

(3) Proposed Additional Guidance

Section 230.2(q)—Periodic Statement

The regulation defines a periodic statement as one sent to a consumer "on a regular basis four or more times a year." The supplementary information accompanying the final regulation stated that if an institution provides a statement to meet other legal requirements (for example, if an electronic fund transfer takes place and the transaction is covered by the Board's Regulation E), such a statement is a periodic statement for purposes of Regulation DD.

Many institutions have asked whether every statement sent to meet requirements of Regulation E is considered a periodic statement for purposes of Regulation DD. For example, Regulation E requires a statement to be sent for each monthly or shorter cycle in which an electronic fund transfer has occurred, but at least quarterly if no transfer has occurred (12 CFR 205.9(b)). Institutions that provide regular quarterly statements, and only provide monthly statements if a transfer has occurred, have asked whether the monthly statement is a periodic statement for Regulation DD purposes.

The Board does not believe this monthly statement is a periodic statement for Regulation DD. The statement may or may not be sent on a monthly basis, depending on whether an electronic fund transfer actually occurs that month. Unlike a statement sent every quarter—or a policy of an institution in which it sends a statement on a monthly or other regular basis—the statement is not sent on a "regular" basis since an institution may send the statement one month but not every month. Thus, the Board believes that such a statement need not include any of the disclosures in § 230.6, since it does not meet the definition of "periodic statement."

In such a circumstance discussed above, however, the quarterly statement is a periodic statement, and the disclosures in § 230.6 would have to be provided for that statement period. The Board solicits comments on whether institutions should be exempt from disclosing fees for a quarterly statement if they have reflected those fees in the prior monthly statement, in accordance with Regulation E.

Appendix A to Part 230—Annual Percentage Yield Calculation.

Proposed Alternative Formula for Certain Accounts

Part II of appendix A provides institutions with a single formula to calculate the annual percentage yield earned for periodic statements. The Board has received several inquiries from institutions about whether this formula should be used in all situations. Institutions that use the daily balance method to accrue interest have noted that if a periodic statement is sent more frequently than the period for which interest is compounded, the annual percentage yield earned may be higher than the annual percentage yield. Institutions have stated that consumers could be confused or mislead by the annual percentage yield earned figure. By way of illustration, an institution that pays a 5% interest rate and compounds annually would state an annual percentage yield of 5%. The same institution would show $4.11 of interest accrued on $1,000 of principal on a monthly periodic statement (reflecting 30 days). In such a case, the annual percentage yield earned shown on that statement would be 5.12%. Institutions have urged the Board not to require use of a formula that produces such a result.

The Board solicits comment on whether an additional formula should

be added to Appendix A, Part II, to calculate the annual percentage yield earned for those accounts in which institutions provide periodic statements more often than they compound interest. The Board also requests comment on whether use of any additional formula should be optional or required. The definitions that apply to the existing formula in Appendix A, Part II would apply to the new formula, although a definition of "compounding" would be added, where "compounding" is the frequency with which interest is compounded, expressed as a number of days. (For example, quarterly compounding would be expressed as 91.25; semi-annual compounding would be expressed as 182.5; and annual compounding would be expressed as 365.) The Board requests comment on whether the following formula should be added:

$$APY\ Earned = 100\left\{\left[1+\frac{(Interest\ earned/Balance)}{Days\ in\ period}\right]^{(Days/Compounding)}-1\right\}$$

To illustrate, in the example discussed above, if a consumer earned $4.11 in interest for a 30-day period on a $1,000 deposit, the annual percentage yield earned under the proposed formula would be 5%.

$$APY\ Earned = 100\left\{\left[1+\left(\frac{4.11/1,000}{30}\right)\right]^{(365)}-1\right\}$$

$$APY\ Earned = 5\%$$

The Board believes that this second annual percentage yield earned formula would be used under fairly narrow circumstances. First, the additional formula could be used only by those institutions that calculate interest by using a daily balance method. (Section 230.6(b) of the regulation provides a special rule for calculating the annual percentage yield earned if institutions use the average daily balance method to calculate interest.) Second, only accounts that provide periodic statements more often than the frequency for which interest is compounded would be affected. Evidence indicates that the vast majority of NOW and money market accounts—typically accounts that provide periodic statements on a monthly or quarterly basis—compound on a daily or monthly basis. Third, given the proposed position regarding the definition of a periodic statement discussed earlier in this notice, there may be few cases in which an institution provides a periodic statement more frequently than it compounds interest. (See the discussion under § 230.2(q) above, in which the Board proposes that a statement sent on a nonregular basis, to meet Regulation E requirements, is not a periodic statement for purposes of Regulation DD.) Finally, several factors may cause the annual percentage yield earned that is disclosed on the periodic statement to be lower than the annual percentage yield, such as the failure to meet a daily minimum balance requirement, a decrease in the interest rate, and use of a collected balance method of accruing interest.

Use of "Ledger" and "Collected" Balance To Calculate the Annual Percentage Yield Earned

The Board proposes to address a second issue in Part II of Appendix A. The supplementary information accompanying the final regulation state that the annual percentage yield earned reflects the relation between the amount of interest and the "*account balance for the period reflected on the statement.*" (Emphasis added.) The Board has received numerous questions regarding how the balance figure is determined when an institution uses a "collected" balance method of accruing interest. (As was stated in the supplementary information accompanying the final regulation, institutions may accrue interest using either the collected or ledger balance method.) Regardless of which method is used to accrue interest, the Board intends for institutions to use the ledger balance in the account, for the period reflected on the statement, for calculating the annual percentage yield earned.

The Board believes using the ledger balance for the periodic statement cycle provides a more accurate yield figure since it demonstrates the difference between institutions that accrue interest using a collected balance compared to those that use a ledger balance. (Assuming that the interest rate and other conditions remain the same, an institution using the ledger balance method of accruing interest would disclose a higher annual percentage yield earned on the periodic statement than an institution using a collected balance method.) The Board believes it is essential that the annual percentage yield earned be calculated in a standardized way to ensure that consumers are able to compare returns on deposit accounts. In addition, the Board believes requiring use of a ledger balance to calculate the annual percentage yield earned will minimize compliance costs and burdens on institutions.

(4) Form of Comment Letters

As discussed above, comment letters should refer to Docket No. R–0791. The Board requests that, when possible, comments be prepared using a standard typeface with a type size of 10 or 12 characters per inch. This will enable the Board to convert the text into machine-readable form through electronic scanning, and will facilitate automated retrieval of comments for review. Comments may also be submitted on 3½ inch or 5¼ inch computer diskettes in any IBM-compatible DOS-based format, if accompanied by an original document in paper form.

(5) Economic Impact Statement

The proposed change to the regulation is not likely to have a significant impact on institutions' costs, including those of small institutions.

List of Subjects in 12 CFR Part 230

Advertising, Banks, Banking, Consumer protection, Deposit accounts, Interest, Interest rates, Federal Reserve System, Truth in savings.

Certain conventions have been used to highlight the proposed revisions to the regulation. New language is shown inside bold-faced arrows, while language that would be deleted is set off with bold-faced brackets.

For the reasons set forth in the preamble, 12 CFR part 230 is proposed to be amended as follows:

PART 230—TRUTH IN SAVINGS

1. The authority citation for part 230 continues to read as follows:

Authority: 12 U.S.C. 4301 *et seq.*

2. Section 230.2 would be amended by revising the last sentence of paragraph (a) to read as follows:

§ 230.2 Definitions.

* * * * *

(a) *Account* * * * The term does not include an existing account held by an unincorporated nonbusiness association of natural persons prior to [March 21] ♦June 21♦, 1993, unless the association notifies the institution that it meets the definition of "consumer."

* * * * *

3. Section 230.4 would be amended by revising the first and second sentences of paragraph (c)(1) to read as follows:

§ 230.4 Account disclosures.

* * * * *

(c) *Notice to existing account holders*—(1) *Notice of availability of*

disclosures. Depository institutions shall provide a notice to consumers who receive periodic statements and who hold existing accounts of the type offered by the institution on [March 21] ♦June 21♦, 1993. The notice shall be included on or with the first periodic statement sent on or after [March 21] ♦June 21♦, 1993 (or on or with the first periodic statement for a statement cycle beginning on or after that date). * * *

* * * * *

4. Section 230.5 would be amended by revising paragraph (a)(2)(ii) to read as follows:

§ 230.5 Subsequent disclosures.

* * * * *

(a) * * *

(2) * * *

(ii) *Check printing fees.* Changes in fees assessed [by third parties] for check printing.

* * * * *

5. Section 230.8 would be amended by revising paragraph (e) and by adding a new paragraph (e)(2) to read as follows:

§ 230.8 Advertising.

* * * * *

(e) *Exemption for certain advertisements.* ♦(1) *Certain media.*♦ If an advertisement is made through one of the following media, it need not contain the information in paragraphs (c)(1), (c)(2), (c)(4), (c)(5), (c)(6)(ii), (d)(4), and (d)(5) of this section:

♦(i)♦ [(1)] Broadcast or electronic media, such as television or radio;

♦(ii)♦ [(2)] Outdoor media, such as billboards; ♦or♦

♦(iii)♦ [(3)] Telephone response machines♦.♦ [; or

[(4) Lobby boards inside a depository institution or deposit broker (provided they contain a notice advising consumers to contact an employee for further information).]

♦(2) *Lobby signs.* Lobby signs facing inside a depository institution (or facing inside the premises of a deposit broker) are not subject to paragraphs (b), (c), or (d) of this section. If a lobby sign states a rate of return, it shall:

(i) State the rate as an "annual percentage yield," using that term or the term "APY." The advertisement shall not state any other rate, except that the interest rate may be stated in conjunction with the annual percentage yield to which it relates.

(ii) Contain a statement advising consumers to contact an employee for further information about applicable fees and terms.♦

By order of the Board of Governors of the Federal Reserve System, December 29, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93–54 Filed 1–4–93; 8:45 am]

BILLING CODE 6210–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91–ANE–51]

Airworthiness Directives; Pratt & Whitney JT9D Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Pratt & Whitney JT9D series turbofan engines. This proposal would require a one-time modification and overhaul of engine control system accessories. This proposal is prompted by multiple engine surge and power loss events caused by deterioration of internal components of engine control system accessories. The actions specified by the proposed AD are intended to prevent the loss of engine compressor surge margin caused by the deterioration of engine control system accessories, resulting in an engine surge, and subsequent power loss or inflight engine shutdown.

DATES: Comments must be received by February 4, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91–ANE–51, 12 New England Executive Park, Burlington, Massachusetts 01803–5299. Comments may be inspected at this location between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Pratt & Whitney, Publications Department, 400 Main Street, East Hartford, Connecticut 06108. This information may be examined at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, Massachusetts.

FOR FURTHER INFORMATION CONTACT: Daniel Kerman, Engine Certification Branch, ANE–141, FAA, New England Region, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, Massachusetts 01803–5299, telephone (617) 270–2410; fax (617) 270–2412.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 91–ANE–51." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 91–ANE–51, 12 New England Executive Park, Burlington, Massachusetts 01803–5299.

Discussion

The FAA has conducted an extensive fleet-wide study of Pratt & Whitney (PW) JT9D series turbofan engines for incidents of engine surge and subsequent power loss or inflight engine shutdown. The FAA received operators' responses to a request from the engine manufacturer for data on incorporation of recommended modifications and frequency of overhauls. The FAA has concluded from the above data that engine control system accessory reliability is a predominant contributing factor to insufficient engine compressor

surge margin. Further analysis shows that PW JT9D series turbofan engines have a heightened susceptibility to engine surges, and subsequent power loss or inflight engine shutdown when engine control system accessories have not incorporated certain recommended modifications and have not undergone periodic overhaul. This situation allows these components to deteriorate beyond acceptable levels, thus greatly increasing the likelihood of engine surge, and subsequent power loss or inflight engine shutdown.

Some of the incidents of engine surge the FAA studied involved more than one engine during the same flight. There have been 12 incidents over the past two years where more than one engine on the same aircraft simultaneously surged, resulting in loss of power or inflight shutdown of multiple engines. During certain phases of flight, such as takeoff or climb-out, a loss of power on more than one engine adversely affects aircraft control. The FAA has concluded that there is a greatly increased risk of more than one engine surging on the same flight when engine control system accessories have not been modified and have not undergone periodic overhaul. This condition, if not corrected, could result in the loss of engine compressor surge margin caused by the deterioration of engine control system accessories, resulting in an engine surge, and subsequent power loss or inflight engine shutdown.

The FAA has reviewed and approved the technical contents of the following TRW, Argo-Tech (AT), Hamilton Standard (HS), and Pratt & Whitney (PW) service bulletins (SB):

SB No.	Revision	Date
Main Fuel Gear Pump:		
TRW SB No. 73-28	2	4-15-77
TRW SB No. 73-29	1	9-1-80
TRW SB No. 73-31	Original	9-1-79
TRW SB No. 73-32	3	4-1-85
AT SB No. 73-38	1	10-1-88
AT SB No. 73-43	Original	12-15-89
TRW SB No. 73-6	Original	9-1-82
PW SB No. 5889	3	10-4-91
TRW SB No. 73-5	Original	4-30-81
Engine Vane Bleed Control GTA 9:		
HS SB No. 75-26	1	8-21-91
HS SB No. 75-19	1	8-21-91
HS SB No. 75-17	Original	3-31-88
HS SB No. 75-16	Original	3-20-88
HS SB No. 75-9	2	8-21-91
Engine Vane Control 3-5:		
HS SB No. 75-9	2	8-21-91
HS SB No. 75-6	1	8-20-91
HS SB No. 75-5	Original	3-31-88
HS SB No. 75-4	2	8-20-91
HS SB No. 75-2	1	11-8-79
Engine Vane Control 3-4:		
HS SB No. 75-28	Original	5-13-91
HS SB No. 75-27	1	8-19-91
HS SB No. 75-24	1	8-19-91
HS SB No. 75-23	Original	3-31-88
HS SB No. 75-22	1	8-19-91
HS SB No. 75-19	3	8-19-91
HS SB No. 75-20	Original	9-1-78
HS SB No. 75-14	Original	5-23-75
HS SB No. 75-11	Original	1-3-75
HS SB No. 75-10	Original	9-10-74
Engine Vane Control 3-2:		
HS SB No. 75-48	Original	5-13-91
HS SB No. 75-46	1	8-16-91
HS SB No. 75-45	1	8-16-91
HS SB No. 75-43	2	4-25-91
HS SB No. 75-42	1	8-16-91
HS SB No. 75-41	3	8-16-91
HS SB No. 75-37	3	8-16-91
HS SB No. 75-36	Original	1-31-78
HS SB No. 75-31	Original	5-23-75
HS SB No. 75-28	Original	1-3-75
HS SB No. 75-27	Original	9-10-74
Fuel Control 68-6:		
HS SB No. 73-19	1	9-20-86
HS SB No. 73-27	1	9-27-82
HS SB No. 73-23	1	8-15-81
HS SB No. 73-3	Original	1-7-77
Fuel Control 68-4:		
HS SB 73-19	1	9-20-86
HS SB No. 73-50	1	8-15-79
HS SB No. 73-42	Original	2-27-76
HS SB No. 73-36	3	7-1-77
HS SB No. 73-35	1	8-29-75
HS SB No. 73-33	2	10-31-78
HS SB No. 73-29	1	9-27-77
HS SB No. 73-26	Original	5-29-74
HS SB No. 73-24	2	10-15-74
HS SB No. 73-21	1	10-27-76
Fuel Control 68-3:		
HS SB No. 73-19	1	9-20-86
HS SB No. 73-150	Original	4-30-81
HS SB No. 73-139	Original	2-27-76
HS SB No. 73-129	3	7-1-77
HS SB No. 73-128	1	8-29-75
HS SB No. 73-127	1	3-5-76
HS SB No. 73-122	1	9-27-77
HS SB No. 73-121	Original	5-29-75
HS SB No. 73-117	3	10-15-74
HS SB No. 73-111	1	10-27-76

These SB's describe the procedures for modifying certain critical engine control system accessories.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require a one-time modification and overhaul of engine control system accessories to prevent loss of engine compressor surge margin caused by the deterioration of engine control system accessories, resulting in an engine surge, and subsequent power loss or inflight engine shutdown. The actions would be required to be accomplished in accordance with the service bulletins described previously.

The FAA estimates that 300 engines of the affected design installed on aircraft of U.S. registry would be affected by this AD, that it would take approximately 30 work hours per engine to accomplish the required actions, and that the average labor rate would be $55 per work hour. The cost of required parts is estimated to be $13,100 per engine. Based on these figures, the total cost impact of the AD on U.S. operators is estimated to be $4,425,000.

The regulations proposed herein would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) Is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Pratt & Whitney: Docket No. 91-ANE-51

Applicability: Pratt & Whitney (PW) Model JT9D-3A, -7, -7A, -7AH, -7H, -7F, -7J, -20, -20J, -59A, -70A, and -7Q turbofan engines installed on but not limited to Boeing 747 series, McDonnell Douglas DC10 series, and Airbus A300 series aircraft.

Compliance: Required as indicated, unless accomplished previously.

To prevent the loss of engine compressor surge margin caused by the deterioration of engine control system accessories, resulting in an engine surge, and subsequent power

loss or inflight engine shutdown, accomplish the following:

(a) Overhaul and modify the main fuel controls as follows:

(1) For main fuel controls with either 12,000 hours or more time since overhaul (TSO) on the effective date of this AD or with an undocumented TSO, or for those main fuel controls that have never been overhauled and have either 12,000 hours or more time since new (TSN) on the effective date of this AD or an undocumented TSN, overhaul in accordance with the applicable Hamilton Standard (HS) Maintenance Manual (MM) listed in Table 1 of this AD, and modify in accordance with the applicable HS Service Bulletins (SB) listed in Table 2 of this AD, at the earliest of: the next shop visit; 3,000 hours time in service (TIS) after the effective date of this AD; or January 31, 1995.

(2) For main fuel controls with more than 10,000 hours but less than 12,000 hours TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with the HS MM listed in Table 1 of this AD, and modify in accordance with the applicable HS SB's listed in Table 2 of this AD, not later than 3,000 hours TIS after the effective date of this AD, or by January 31, 1995, whichever occurs first.

(3) For main fuel controls with 10,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with the HS MM listed in Table 1 of this AD, not later than 12,000 hours TSO or TSN, or by January 31, 1995, whichever occurs later.

(4) For main fuel controls with 10,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, modify in accordance with the applicable HS SB's listed in Table 2 of this AD, not later than 12,000 hours TSO or TSN, or by January 31, 1995, whichever occurs first.

TABLE 1.—ENGINE ACCESSORY OVERHAUL REFERENCE LIST

Accessory description	Hamilton standard maintenance manual No.	Temporary revision No.
Main fuel controls:		
JFC68–3	73–21–01, Revision 19, dated June 15, 1991	73–54, dated June 15, 1992.
JFC68–4	73–21–02, Revision 10, dated Jan. 15, 1992	73–31, dated June 15, 1992.
JFC68–6	73–21–03, Revision 9, dated Jan. 15, 1992	73–25, dated June 15, 1992.
Engine vane controls:		
EVC3–2 and EVC3–4	75–31–01, Revision 20, dated July 1, 1992	N/A.
EVC3–5	75–32–01, Revision 9, dated June 15, 1986	75–5, dated July 1, 1992.
Engine vane and bleed controls:		
GTA9–1 and GTA9–2	75–34–01, Revision 10, dated Jan.1, 1992	75–11, dated June 15, 1992.

TABLE 2.—HAMILTON STANDARD MAIN FUEL CONTROL UNIT (FCU) SERVICE BULLETIN INCORPORATION LIST

Series engines		
FCU model, JFC68–3, JT9D–3A, –7	FCU model, JFC68–4, JT9D–20, –20J	FCU model, JFC68–6, JT9D–59A, –70A, –7Q
73–150 (L160), Original, dated 4–30–81	73–50 (L94), Revision 1, dated 8–15–79	73–23 (L30), Revision 1, dated 8–15–91.
73–139 (L152), Original, dated 2–27–76	73–42 (L87), Original, dated 2–27–76	N/A.
73–129 (L143), Revision 3, dated 7–1–77	73–36 (L81), Revision 3, dated 7–1–77	73–3 (L14), Original, dated 7–1–77.
73–128 (L142), Revision 1, dated 8–29–75	73–35 (L80), Revision 1, dated 8–29–75	N/A.
73–127 (L141), Revision 1, dated 3–5–76	73–33 (L79), Revision 2, dated 10–31–78	N/A.
73–122 (L137), Revision 1, dated 9–27–77	73–29 (L75), Revision 1, dated 9–27–77	N/A.
73–121 (L136), Original, dated 5–29–75	73–28 (L74), Original, dated 5–29–74	N/A.
73–117 (L133)	73–24 (L71)	N/A.
73–111 (L126)	73–21 (L69)	N/A.
N/A	N/A	73–27 (L33), Revision 1, dated 9–27–82.
73–19, Revision 1, dated 9–20–86	73–19, Revision 1, dated 9–20–86	73–19, Revision 1, dated 9–20–86.

(b) Overhaul and modify engine vane controls as follows:

(1) For engine vane controls with either 12,000 hours or more TSO on the effective date of this AD or with an undocumented TSO, or for those engine vane controls that have never been overhauled and have either 12,000 hours or more TSN on the effective date of this AD or an undocumented TSN, overhaul in accordance with the applicable HS MM listed in Table 1 of this AD, and modify in accordance with the applicable HS SB's listed in Table 3 of this AD, at the earliest of: the next shop visit; 3,000 hours time in service (TIS) after the effective date of this AD; or January 31, 1995.

(2) For engine vane controls with more than 10,000 hours but less than 12,000 hours TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with the applicable HS MM listed in Table 1 of this AD, and modify in accordance with the applicable HS SB's listed in Table 3 of this AD, not later than 3,000 hours TIS after the effective date of this AD, or by January 31, 1995, whichever occurs first.

(3) For engine vane controls with 10,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with the applicable HS MM listed in Table 1 of this AD, not later than 12,000 hours TSO or TSN, or by January 31, 1995, whichever occurs later.

(4) For engine vane controls with 10,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, modify in accordance with the applicable HS SB's listed in Table 3 of this AD not later than 12,000 hours TSO or TSN, or by January 31, 1995, whichever occurs first.

TABLE 3.—HAMILTON STANDARD ENGINE VANE CONTROL (EVC) RECOMMENDED SERVICE BULLETIN INCORPORATION LIST

Series engines		
EVC3–2 model, JT9D–3A, –7	EVC3–4 model, JT9D–20, –20J	EVC3–5 model, JT9D–59A, 70A, –7Q
75–48 (L46), Revision 1, dated 8–6–91	75–27 (L33), Revision 1, dated 8–19–91	75–9 (L10), Revision 2, dated 8–21–91.
75–45 (L43), Revision 1, dated 8–16–91	75–24 (L30), Revision 1, dated 8–19–91	75–6 (L7), Revision 1, dated 8–20–91.
75–43 (L42), Revision 2, dated 4–25–91	75–23 (L29), Original, dated 3–31–88	75–5, Original, dated 3–31–88.
75–41 (L41), Revision 3, dated 8–16–91	75–22 (L28), Revision 1, dated 8–19–91	75–4 (L5), Revision 2, dated 8–20–91.
75–42, Revision 1 dated 8–16–91	N/A	N/A.
75–37 (L40), Revision 3, dated 8–16–91	75–19 (L27), Revision 3, dated 8–19–91	75–2 (L4), Revision 1, dated 11–8–79.

TABLE 3.—HAMILTON STANDARD ENGINE VANE CONTROL (EVC) RECOMMENDED SERVICE BULLETIN INCORPORATION LIST—Continued

Series engines		
EVC3–2 model, JT9D–3A, –7	EVC3–4 model, JT9D–20, –20J	EVC3–5 model, JT9D–59A, 70A, –7Q
75–36, Original, dated 1–31–78	75–20, Original, dated 9–1–78	N/A.
75–31 (L35), Original, dated 5–23–75	75–14 (L22), Original, dated 5–23–75	N/A.
75–28 (L33), Original, dated 5–13–81	75–11 (L20), Original, dated 1–3–75	N/A.
75–27 (L32), Revision 1, dated 8–19–91	75–10 (L19), Original, dated 9–10–74	N/A.
75–49 (L30), Original, dated 5–13–91	75–28 (L34) Original, dated 5–13–81	N/A.

(c) Overhaul and modify engine vane and bleed controls as follows:

(1) For engine vane and bleed controls with either 10,000 hours or more TSO on the effective date of this AD or with an undocumented TSO, or for those engine vane and bleed controls that have never been overhauled and have either 10,000 hours or more TSN on the effective date of this AD or an undocumented TSN, overhaul in accordance with the applicable HS MM listed in Table 1 of this AD, and modify in accordance with the applicable HS SB's listed in Table 4 of this AD, at the earliest of: the next shop visit; 3,000 hours TIS after the effective date of this AD; or January 31, 1995.

(2) For engine vane and bleed controls with more than 8,000 hours but less than 10,000 hours TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with the applicable HS MM listed in Table 1 of this AD, and modify in accordance with the applicable HS SB's listed in Table 4 of this AD, not later than 3,000 hours TIS after the effective date of this AD, or by January 31, 1995, whichever occurs first.

(3) For engine vane and bleed controls with 8,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with the applicable HS MM listed in Table 1 of this AD, not later than 10,000 hours TSO or TSN, or by January 31, 1995, whichever occurs later.

(4) For engine vane and bleed controls with 8,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, modify in accordance with the applicable HS SB's listed in Table 4 of this AD, not later than 10,000 hours TSO or TSN, or by January 31, 1995, whichever occurs first.

TABLE 4.—HAMILTON STANDARD ENGINE VAN BLEED CONTROL (EVBC) (GTA9) REQUIRED SERVICE BULLETIN INCORPORATION LIST

JT9D–59A, –70A, –7Q, Series Engines		
Service bulletin	Revision	Date
75–26 (L21)	1	8–21–91
75–19 (L14)	1	8–21–91
75–17 (L13)	Original	3–31–88
75–16 (L12)	Original	3–20–88
75–9 (L8)	2	8–21–91

(d) Overhaul and modify main fuel gear pumps as follows:

(1) For main fuel gear pumps with either 8,000 hours or more TSO on the effective date of this AD or with an undocumented TSO, or for those main fuel gear pumps that have never been overhauled and have either 8,000 hours or more TSN on the effective date of this AD or an undocumented TSN, overhaul in accordance with either Argo-Tech (AT) Overhaul Manual (OM) No. 73–11–01 or No. 73–11–02, as applicable, and modify in accordance with the applicable TRW, AT, and Pratt & Whitney (PW) SB's listed in Table 5 of this AD, at the earliest of: the next shop visit; 3,000 hours TIS after the effective date of this AD; or January 31, 1995.

(2) For main fuel gear pumps with more than 6,000 hours but less than 8,000 hours TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with either AT OM No. 73–11–01 or No. 73–11–02, as applicable, and modify in accordance with the applicable TRW, AT, and PW SB's listed in Table 5 of this AD, not later than 3,000 hours TIS after the effective date of this AD, or by January 31, 1995, whichever occurs first.

(3) For main fuel gear pumps with 6,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, overhaul in accordance with either AT OM No. 73–11–01 or No. 73–11–02, as applicable, not later than 8,000 hours TSO or TSN, or by January 31, 1995, whichever occurs later.

(4) For main fuel gear pumps with 6,000 hours or less TSO, or TSN if never overhauled, on the effective date of this AD, modify in accordance with the applicable TRW, AT and PW SB's listed in Table 5 of this AD, not later than 8,000 hours TSO or TSN, or by January 31, 1995, whichever occurs first.

TABLE 5.—TRW, AT, AND PW MAIN FUEL GEAR PUMP REQUIRED SERVICE BULLETIN INCORPORATION LIST

Series engines	
JT9D–3A, –7, –20, –20J	JT9D–59A, –70A, –7Q
TRW 73–28 (–26), Revision 2, dated 4–15–77.	N/A.
TRW 73–29 (–27), Revision 1, dated 9–1–80.	TRW 73–5 (–9), Original, dated 4–30–81.
TRW 73–31 (–29), Original, dated 9–1–79.	N/A.
TRW 73–32 (–30), Revision 3, dated 4–1–85.	N/A.
AT 73–36 (–32), Revision 1, dated 10–1–88.	N/A.
AT 73–43, Original, dated 12–15–89.	N/A.
N/A	TRW 73–8 (–12), Original, dated 9–1–82.
PW 5869, Revision 3, dated 10–4–91.	N/A.

(e) For the purpose of this AD, a shop visit is defined as an engine removal where engine maintenance entails separation of pairs of mating engine flanges or the removal of a disk, hub, or spool.

(f) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety, may be used if approved by the Manager, Engine Certification Office. The request should be forwarded through an FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(g) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on December 14, 1992.

Jack A. Sain,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 93–42 Filed 1–4–93; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 92–ANE–21]

Airworthiness Directives; Wytwornia Sprzetu Komunikacyjnego "PZL–RZESZOW" PZL–3S Second Series Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to Wytwornia Sprzetu Komunikacyjnego "PZL–RZESZOW" PZL–3S Second Series engines, that currently requires removal from service certain modified pistons, inspection of the propeller to engine propeller-flange attachment bolts, inspection of the engine propeller-flange retaining nut, and inspection of the rear crankshaft counterweight system. This action would remove the repetitive

inspection requirements of the existing AD, but retains the requirement to remove from service certain modified pistons. This proposal is prompted by test results that have indicated that PZL–3S Second Series engines not configured with modified pistons are not susceptible to excessive vibration. The actions specified by the proposed AD are intended to prevent separation of the propeller and loss of the aircraft.

DATES: Comments must be received by March 8, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Assistant Chief Counsel, Attention: Rules Docket No. 92–ANE–21, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803–5299. Comments may be inspected at this location between 8:30 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Wytwornia Sprzetu Komunikacyjnego "PZL–RZESZOW", ul. Hetmanska 120, 35–078 Rzeszow, Poland. This information may be examined at the FAA, New England Region, Office of the Assistant Chief Counsel, 12 New England Executive Park, Burlington, Massachusetts.

FOR FURTHER INFORMATION CONTACT: Robert J. Ganley, Engine Certification Office, ANE–140, Engine and Propeller Directorate, Aircraft Certification Service, FAA, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803–5299; telephone (617) 272–5047; fax (617) 270–2412.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92–ANE–21." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 92–ANE–21, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803–5299.

Discussion

On December 16, 1991, the Federal Aviation Administration (FAA) issued AD 91–18–12, Amendment 39–8120 (57 FR 5378, February 14, 1992), applicable to Wytwornia Sprzetu Komunikacyjnego "PZL–RZESZOW" PZL–3S Second Series engines, to require removal from service of certain modified pistons, inspection of the propeller to engine propeller-flange attachment bolts, inspection of the engine propeller-flange retaining nut, and inspection of the rear crankshaft counterweight system. That action was prompted by two reported occurrences of propeller to engine propeller-flange attachment bolts found to have cracked or failed. That condition, if not corrected, could result in separation of the propeller and loss of the aircraft.

Since the issuance of that AD, additional engine testing with modified and standard pistons has been completed. The results indicate that excessive engine vibration that could result in cracking or failure of the propeller to engine propeller-flange attachment bolts occurs in those engines which incorporate pistons modified and assembled with certain compression ring, scraper ring, and oil ring components. Engines that have not incorporated pistons modified and assembled with these components have acceptable engine vibratory characteristics, and no longer must be inspected as required by AD 91–18–12.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would supersede AD 91–18–12 to require removal from service certain PZL–3S Second Series engine pistons which have been modified and assembled with certain compression ring, scraper ring, and oil control ring components.

There are approximately 11 PZL–3S Second Series engines of the affected design in the worldwide fleet. The FAA estimates that 3 engines of the affected design are installed on aircraft of U.S. registry, that it would take approximately 5 work hours per engine to accomplish the proposed actions, and that the average labor rate is $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $825.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "**ADDRESSES.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8120 (57 FR

5378, February 14, 1992), and by adding the following new airworthiness directive, Amendment 39–XXXX to read as follows:

Wytwornia Sprzetu Komunikacyjnego "PZL–RZESZOW": Docket No. 92–ANE–21. Supersedes AD 91–18–12, Amendment 39–8120.

Applicability: Wytwornia Sprzetu Komunikacyjnego "PZL–RZESZOW" PZL–3S Second Serjes piston engines installed on but not limited to Grumman AG CAT aircraft.

Compliance: Required as indicated, unless accomplished previously.

To prevent separation of the propeller and loss of the aircraft, accomplish the following:

(a) For pistons that have been modified and assembled with compression ring, part number (P/N) JRS 123421, scraper ring, P/N JRS 123423, and oil control ring, P/N JRS 123424, prior to further flight:

(1) Remove these pistons from service and replace with serviceable parts.

(2) Remove, clean, and visually inspect using 10x magnification the propeller to engine propeller-flange attachment bolts for evidence of cracking or failure, and perform the following:

(i) For engines with bolts found to be cracked or broken, replace with new bolts and disassemble and visually inspect for distress of the rear crankshaft, rear counterweight, and rear counterweight pins.

(A) If any distress is found in the rear crankshaft, rear counterweight, or rear counterweight pins, replace distressed parts with new parts.

(B) Distress is defined as any evidence of wear, galling, pitting, or scoring, and includes discoloration (blue color) of the counterweight pins.

(ii) For engines with bolts found not to be cracked, inspect the engine propeller-flange retaining nut for looseness and perform the following:

(A) Retorque the propeller-flange retaining nut if found loose in accordance with Section 3.3.4 of the PZL–3S Engine Servicing Instructions, revised March 1984.

(B) Replace all propeller to engine propeller-flange attachment bolts with new bolts.

(b) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Engine Certification Office. The request should be forwarded through an FAA Maintenance Inspector, who may concur or comment and then send it to the Manager, Engine Certification Office.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on December 9, 1992.

Diane S. Romanosky,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 93–43 Filed 1–4–93; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 93

[Docket No. 27106 Notice No. 92–20]

RIN 2120–AE78

Operation of Jet Aircraft in Commuter Slots at O'Hare International Airport

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This proposed rule would amend the regulations pertaining to the definition and allocation of commuter operator slots (*i.e.*, allocated instrument flight rules (IFR) takeoff and landing reservations) at O'Hare International Airport (O'Hare). The FAA proposes to eliminate the provision that limits the use of larger aircraft in commuter slots at O'Hare to a temporary 2-year trial period. It further proposes to permit an air carrier to use larger aircraft in up to 50 percent of its commuter slot holdings at O'Hare, expand the category of aircraft that may be used in those slots, and remove the restriction on the maximum number of larger aircraft operations in commuter slots per half hour or consecutive half hour periods. This proposed rule would neither increase the number of operations at O'Hare, nor necessarily bring about additional jet service to some smaller communities. The proposed rule would preserve the class of commuter slots as distinct from air carrier slots. This NPRM is in response to a petition for rulemaking by American Airlines and the comments on that petition.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attention: Rules Docket, Docket No. 27106, 800 Independence Avenue, SW., Washington, DC 20591; or deliver comments in triplicate to: Federal Aviation Administration, Rules Docket, room 915G, 800 Independence Avenue, SW., Washington, DC 20591. Comments may be examined in the rules docket weekdays, except Federal holidays, between 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Patricia R. Lane, Office of the Chief Counsel, AGC–230, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–3491.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the proposal by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned decisions on the proposals. Comments are specifically invited on the overall economic, energy, environmental, reporting, and recordkeeping aspects of the proposals. Communications should identify the docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 27106." Communications received on or before the specified closing date for comments will be considered before taking any further action on the proposal. The proposals contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this proposal will be filed in the docket.

Availability of NPRM

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA–430, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–3484. Communications must identify the docket number of this NPRM. Persons interested in being placed on a mailing list for future notices should also request a copy of Advisory Circular NO. 11–2A, "Notice of Proposed Rulemaking Distribution System," which describes the application procedures.

Background

The High Density Traffic Airport Rule, or "High Density Rule," 14 CFR part 93, subpart K, was promulgated in 1969 to reduce delays at five congested airports: JFK International, LaGuardia, O'Hare International, Washington National, and Newark International (33 FR 17896, December 3, 1968). The regulation limits the number of IFR operations at each airport, by hour or half hour (by half hour at O'Hare), during certain hours of the day. It provides for the allocation to carriers of operational authority, or a "slot," for each IFR landing or takeoff during a specific 30- or 60-minute period. The

restrictions were lifted at Newark in the early 1970's.

On August 19, 1991, the Department published Amendment No. 93–62 which, among other changes, revised the definition of "commuter" aircraft in the High Density Rule to include turboprop or reciprocating aircraft having less than 75 passenger seats or turbojet aircraft having less than 56 seats (56 FR 41200). In that same amendment, the FAA changed the slot rules, effective for a 2 year period beginning September 20, 1991, to allow carriers at O'Hare to use up to 25 percent of their commuter slots for operations with aircraft having a maximum certificated seating capacity of no more than 110 passengers.

The American Airlines Petition

Summary of the Petition

On February 18, 1992, American Airlines (AAL) filed a petition for rulemaking to (1) Suspend the 30- and 60-minute slot restrictions at O'Hare; (2) eliminate the category of commuter slots at O'Hare or increase from 25 percent to 45 percent the number of commuter slots for which larger aircraft may be used under Amendment No. 93–62; (3) impose slot restrictions at Midway Airport or establish a Chicago area slot system incorporating O'Hare and Midway; (4) permit AAL to revise its selection of commuter slot times for operations with larger aircraft under Amendment No. 92–62; and (5) make Amendment No. 93–62 permanent. The FAA published a summary of the petition on March 31, 1992, with a 60-day comment period (57 FR 10836).

Comments on the Petition

More than 200 comments were received, most of which supported AAL's petition. Supporting commenters include government officials, community leaders, business owners or managers, and other residents of regions that have received Fokker 100 (F–100) jet service by AAL since the promulgation of Amendment No. 93–62, or that anticipate such service. Comments in support came predominantly from the communities of Fargo, ND; Sioux Falls, SD; and Peoria and Springfield, IL. Although pilots of Simmons Airlines, an AAL subsidiary, commented that Decatur, IL, and Madison, WI, may lose service if more commuter slot conversions are allowed, some commenters from those two areas support the petition, ostensibly expecting an upgrade rather than cessation of air service.

Supporting comments are not limited to communities within Chicago's commuter circumference. Raleigh-Durham, NC, and Nashville, TN, now have F–100 service non-stop into O'Hare. Several North Carolina and Tennessee commenters support making Amendment No. 93–62 permanent to continue that service. Commenters from Louisville, KY, also support the petition.

Commenters from Vail, Colorado, anticipate benefiting from a rule change. Three officers of Vail Associates wrote in support of AAL's petition, saying that adoption of the proposal would allow AAL to add service to Vail, improving the competitive position of Vail and Beaver Creek resorts in the European marketplace. Aspen Skiing Company submitted a similar comment.

Commenters opposing the petition include government officials, community leaders, business owners or managers, and other residents of regions that have suffered or fear a reduction or elimination of air service by AAL's subsidiary commuter airlines, AMR Eagle and Simmons. These communities include Mattoon, IL; Bloomington, Lafayette, and Terre Haute, IN; Dubuque, Ames, and Waterloo, IA; Lansing, MI; and Madison, WI. Pointing to the loss of a daily flight since Amendment No. 93–62 went into effect, the Madison writers opposing the petition do not share the optimism of the Madison commenters supporting the position and would rather see the 1991 amendment terminated. AAL has since announced plans to add a flight to Madison, causing one commenter to submit a second comment reversing his position.

Also opposing AAL's petition are the Simmons pilots and AAL's competitors. One commenter stated that Simmons has announced a 20 percent cutback in pilot staffing as a result of the transfer of slots from Simmons to AAL. Numerous commenters said that AAL will train new hires rather than Simmons pilots as it substitutes jets for turboprops in the commuter slots.

The supporting and opposing comments exhibit little common ground. Supporters of the petition generally urged eliminating the commuter restrictions or increasing the slots eligible for use with larger aircraft to 45 percent of a carrier's commuter slot base, making the recent amendment permanent, imposing slots at Midway, and giving carriers greater scheduling flexibility at O'Hare. A common theme is that allowing airlines to match equipment with market demand will improve service to small communities and bring about economic growth and opportunities. Many commented on the enhanced competition AAL has brought; one commenter observed that Sioux Falls, SD, is now served by seven commercial airlines. Another commenter observed that upgraded jet service has enhanced connections to other cities in the region. Other commenters spoke about the perception of extra safety, comfort, and convenience that jet service provides. The Fort Wayne Chamber of Commerce and the Assistant General Counsel for Caterpillar Inc., Peoria, mentioned reduced noise.

Those opposing AAL's petition said that Amendment No. 93–62 should be allowed to expire in September 1993. Any further relaxation of the commuter restrictions, they argued, will lead to air service only in major markets, small communities will lose access to O'Hare and its connections to the rest of the nation and the world, and much of the rural Midwest will be placed at a severe competitive disadvantage. Some commenters saw the recent amendment as a measure to enhance the competitive position of one carrier, American Airlines.

United Air Lines, USAir, Delta Air Lines, Air Wisconsin, Continental Airlines, and Pan Am Express also opposed the petition on grounds of diminishing air service to small communities, the exclusive benefit and windfall to AAL, and the resulting increase in air and ground congestion at O'Hare. The City of Chicago foresees, however, a reduction in parking ramp congestion as jet aircraft replace commuter turboprops.

The City of Chicago also suggested, as did Great Lakes Aviation, that the slot category for general aviation and non-scheduled operators is underutilized and should in part be made available for carrier use. Among the other comments were that certain slots should be attached to secondary hubs through which connections would be provided to outlying communities, that AAL has used most of its subsidiaries' commuter slots designated for use with larger aircraft to serve major long-haul markets, and that increased use of commuter slots with larger jets will require additional Essential Air Service awards to replace discontinued service to small communities.

Discussion of Comments

A. Suspend 30- and 60-Minute Slot Restrictions

AAL proposed to expand the air carrier slot restriction periods to 2-hour blocks. It claimed that the 30- and 60-minute restrictions concentrate arrival and departure banks. The City of Chicago agreed and suggested

conducting a demonstration program suspending the limits during one 2-hour period. The Mayor of Chicago stated that airlines at other hub airports have been able to adjust their schedules to avoid congestion and delays. United Air Lines suggested extending each slot period to include the 15 minutes before and after the designated period and permitting slides of slot times to less congested periods. Delta Air Lines disagreed that any expansion will reduce the bunching of operations, citing AAL's practice of concentrating banks at its Dallas, Raleigh-Durham, and Nashville hubs. The Michigan Department of Transportation (MDOT) asserted that expanding the slot restriction periods might reduce the opportunities for smaller communities to gain access to O'Hare.

The FAA is not persuaded that expanding the slot restriction periods will ameliorate the concentration of flight operations since airlines appear to schedule their operations based primarily on marketing strategy. At O'Hare, voluntary schedule agreements have been used several times since 1984 to reduce concentrations of operations. These agreements authorized the participating airlines to operate outside their allocated slot times on the condition that the major hub operators diffused the concentrations of their arrival and departure banks. These agreements served to reduce congestion and delays in the short term, but carriers quickly made schedule adjustments and peaked operations, leapfrogging their schedules to precede immediately a competitor's banks.

The purpose of the slot restriction periods is to force carriers to spread their operations throughout the day and avoid concentrated operations within discrete, peak periods. AAL argues that the 30-minute restriction on scheduling within a slot period causes peaking because carriers tend to bunch flights at the beginning and end of the 30-minute slot period. Scheduled flights at O'Hare show periods of compressed scheduling throughout the day, however, and not just at the beginning and end of a slot period. Adoption of AAL's proposal to substitute 2-hour limits for the current 30- and 60-minute totals would merely raise the ceiling on the number of operations that carriers might bunch within the same peak times. The practice of peaking schedules would likely be exacerbated at O'Hare if the slot periods were expanded.

The timing of current operations at O'Hare is largely determined by the number of slots held by the major hub carriers during half-hour periods. The 30-minute slot restrictions and the distribution of a slot holdings prevent large overlapping of banks during most periods of the day. This notice does not propose, therefore, to adopt the suspension that AAL seeks.

B. Eliminate the Commuter Slot Category

AAL proposed to eliminate the seating capacity restrictions applicable to commuter slots or to raise to 45 percent the percentage of commuter slots in which aircraft with up to 110 seats may be operated under Amendment No. 93–62. The City of Chicago would support this proposal if the larger jets operate below 24,000 feet mean sea level (MSL) and added that the substitute aircraft should meet Stage 3 noise standards. MDOT would concur with the proposed change if small and medium communities were guaranteed access to O'Hare, a view shared by the Wisconsin Department of Transportation (WDOT) and the Director of the Monroe County Airport, Bloomington, IN.

The FAA is proposing to retain the category of commuter slots to preserve slots for use by commuter aircraft serving smaller communities. Where feasible, however, the FAA endeavors to reduce or remove burdens on slot use. Increasing the percentage of commuter slots that could be used with larger aircraft is consistent with that objective and could be accommodated without exacerbating air traffic congestion. The FAA proposes, therefore, to retain the commuter slot restrictions but to increase the number of slots that may be used for operations with non-commuter aircraft to 50 percent of a carrier's commuter slot holdings. In proposing 50 percent, the FAA is seeking to achieve a fair balance among competing interests and operational practicalities at O'Hare and would appreciate comments on whether 50 percent is the appropriate level considering the potential impact on service to small communities.

Amendment No. 93–62 limits the aircraft size to 110 maximum passenger seats according to the aircraft series' type certificate, regardless of the actual seating configuration. To reduce the restrictive burden of this limit, the FAA proposes to modify the 110-seat restriction and allow the use of any aircraft having an actual seating configuration of 110 or fewer passengers as reflected in the type certificate or any supplemental type certificate for the aircraft in up to 50 percent of a carrier's commuter slot holdings at O'Hare.

The use of the actual seating configuration of an aircraft as based on the limitations set forth in the type certificate or supplemental type certificate would be a change to the existing rule. Under current procedures, the maximum number of passengers seats as reflected in the original type certificate for the aircraft series is controlling for the purpose of determining the size of aircraft permitted to be operated in commuter slots pursuant to the definitions found in 14 CFR part 93, subpart K. The FAA incorporated the use of the original type certificate as a way of limiting the overall size of the aircraft. The original type certificates show maximum seating in excess of 110 passengers, however, for several models of aircraft that are comparable in size, i.e., fuselage length and wing span, to the aircraft envisioned by the FAA for use in commuter slots, but their actual seating is configured for less than 110 passengers.

The number of type certificated passenger seats does not necessarily relate directly to the overall size of the aircraft. Therefore, the FAA is proposing to change the current procedures and use the seating configuration approved for the operator's airplane, rather than the original type certificate for the aircraft series. The FAA is proposing to use the most recent certification (original, amended, or supplemental) for the operator's airplane as the basis for determining whether an aircraft complies with the 110-seat maximum limit. Comments are welcome on whether using the most recent certificate might compel an operator to seek to amend or supplement a type certificate just to enable it to use the aircraft in commuter slots at O'Hare under this proposed rule.

The FAA recognizes that even wide-body aircraft might be configured to hold less than 110 seats. To ensure that the larger aircraft used in the commuter slots would be comparable in size, the FAA proposes, in conjunction with the seat limit, a maximum takeoff weight limit of 126,000 pounds. This limitation would also make the aircraft being used in commuter slots more likely to fit into the short- and medium-haul categories. Several comments received while Amendment No. 93–62 was under consideration suggested using weight, wake turbulence, or performance criteria to determine the appropriate class of aircraft. In Amendment No. 93–62, the FAA acknowledged that, from an air traffic standpoint, no significant differences separated aircraft in the 100 to 110 seat range, such as the F–100, from the slightly larger jets such as certain Boeing 737 and DC–9 series. The FAA went on to say that expanding the rule to include slightly larger aircraft

would be considered in future rule changes. (56 FR 41201.)

Upon reviewing the performance data of aircraft currently in service in the United States, the FAA concludes that, as a complement to the 110-seat restriction, a maximum certificated takeoff weight limit of 126,000 pounds would further inhibit the use of long-range aircraft in commuter slots. The FAA recognizes that some aircraft meeting this weight limit may have long-range capability, but they are unlikely to have as few as 110 passenger seats. Thus, the combination of 110 seats and 126,000 pounds maximum takeoff weight should effectively limit the aircraft being used in commuter slots to short- and medium-haul capability. Moreover, the weight limit would preclude heavy jets that would require greater in-flight separation, which could lead to air traffic congestion and delays.

In response to the City of Chicago's comments concerning the possible environmental effects of the use of the larger aircraft, the FAA is seriously considering limiting in a subsequent final rule the types of larger aircraft that may operate in commuter slots to those that meet Stage 3 noise levels. Without a Stage 3 restriction on the larger aircraft, the Day Night Average Sound Level 65 dB contour could increase up to 5 percent. The Stage 3 restriction would reduce this potential increase to less than 1 percent. While the use of the larger aircraft may improve service to smaller communities, that improvement should not be compromised by any environmental degradation at O'Hare or the surrounding communities if it can be avoided. A Stage 3 restriction should not prove burdensome to the carriers wishing to use larger jets in commuter slots, because those carriers are already using, are planning to use, or have available to use Stage 3 aircraft in their fleets.

Under this proposal, therefore, a carrier would be allowed to use, in half of its commuter slot holdings at O'Hare, any aircraft with a certificated seating configuration of 110 or fewer passengers, so long as the aircraft has a maximum certificated takeoff weight less than 126,000 pounds. Even though a Stage 3 requirement is not specifically stated in this Notice, the FAA may consider in any subsequent final rule requiring that any larger aircraft using the commuter slots meets the Stage 3 noise levels as defined in 14 CFR part 36. For that reason, the FAA is specifically requesting comments on the Stage 3 limitation.

As mentioned previously, the City of Chicago supported AAL's petition if the larger jet aircraft operating in commuter slots were restricted to an operational ceiling of 24,000 feet MSL. The proposed ceiling restriction ostensibly seeks to address concerns about delays in traffic at higher altitudes, where jets normally operate, as jets are substituted for turboprops, which normally operate at lower altitudes.

A similar 24,000 foot MSL restriction was proposed by AAL and supported by the City of Chicago as part of the rulemaking proceedings for the last amendment of the High Density Rule. As the agency observed in promulgating Amendment No. 93–62, a significant amount of enroute traffic uses altitudes below 24,000 feet MSL, and the Chicago Center controls aircraft beginning at 12,000 feet MSL on handoff from Chicago Radar Approach Control in the O'Hare area and at lower altitudes elsewhere. Operations below, as well as above, 24,000 feet MSL affect the efficiency of enroute, arrival, and departure operations at and in the vicinity of O'Hare.

By September 1, 1992, AAL had increased its F–100 jet operations in commuter slots to 47. Many of these flights have been operating above 24,000 feet MSL in the Chicago Center airspace. No air traffic control operational problems have resulted due to the addition of these turbojet operations. Air traffic data (collected under the "OPSNET" system) indicate that delays have been decreasing at O'Hare, notwithstanding jet substitutions under Amendment No. 93–62. While favorable weather conditions account partly for the lack of negative impact, also contributing are the FAA's efforts to enhance traffic management resources to improve efficiency in the air traffic control system.

A ceiling restriction thus offers no meaningful benefit to the air traffic control system; instead, it would create unwarranted complications. AAL and other carriers use jet equipment at O'Hare that meet the current and proposed criteria for use with commuter slots. These operations are conducted using air carrier slots that would not be subject to the proposed 24,000 foot ceiling. If the ceiling restriction were adopted, some aircraft would then be subject to flight restrictions that identical aircraft of the same company would not be, complicating the operating environment for airline pilots, dispatchers, and air traffic controllers. The controller would be burdened with the responsibility of knowing which aircraft are subject to the restriction and, constrained by the ceiling for those operations, lose flexibility in assigning altitudes for aircraft.

No operating restrictions would be needed if two requirements are retained that have helped avoid exacerbating congestion at O'Hare in the implementation of Amendment No. 93–62. The first requirement is that carriers wishing to use larger aircraft in commuter slots submit their proposed schedules to Air Traffic Control (ATC) for its approval. ATC's review of these requests has included an analysis of all scheduled operations during the specific 5-minute period within which each operation is proposed. ATC has denied requests for an operation during a period when scheduled operations were so compressed that they exceeded airport capacity. So long as ATC retains this authority and exercises it as necessary, permitting up to 50 percent of the commuter slots to be used with larger aircraft and eliminating the 30- and 60-minute restrictions on the number of commuter slots that could be used for larger aircraft currently contained in 14 CFR part 93, Appendix B, should not result in additional delays at O'Hare. Therefore, the FAA proposes to retain the approval authority of ATC and eliminate the hourly and half-hourly restrictions found in 14 CFR part 93, Appendix B.

The second requirement is that an arrival gate be available without any planned waiting time. If an aircraft arrives without having a gate available, the ground controller typically must direct the aircraft to a holding area located away from the gate area and then clear the aircraft back into the gate area when a gate becomes available. Depending on the area used, this process may involve directing the aircraft across active runways and taxiways, further increasing controller workload and impeding other operations. Additionally, holding areas at O'Hare are limited and will be further limited when certain holding areas are designated for use as secondary deicing facilities, as currently planned.

The advance notice and certification of gate availability requirements contained in Amendment No. 93–62 have helped prevent the bunching of additional operations at peak periods. These requirements are integral elements of the proposal to increase to 50 percent the number of commuter slots for which larger aircraft could be used. Therefore, the FAA proposes to retain the requirement that gates be available to service these operations.

Finally, one commenter suggested dedicating certain slots for service to secondary hubs with connections to outlying small communities in their region. Most of the service to small communities out of O'Hare is short-

haul, raising a question as to how useful access to O'Hare via a connecting point would be in these short-haul markets. Except for slots that are expressly designated for Essential Air Service at the direction of the Department of Transportation, the FAA does not require or restrict the use of a slot for service to a specific market. Therefore, the FAA is not proposing to establish a secondary hub slot requirement.

C. Make Amendment 93–62 "Permanent"

All of the comments in support of AAL's proposal to eliminate unconditionally the commuter slot restrictions also support its proposal to "make Amendment No. 93–62 a permanent rule." MDOT comments that the decision to revoke the temporary trail provision contained in the amendment should wait until an evaluation can be performed toward the end of the trial period. United and Delta similarly assert that AAL's proposal is premature and lacks supporting data.

AAL has incrementally added F–100 service at O'Hare in place of turboprop operations in commuter slots. These jets were being operated in 47 commuter slots as of September 1, 1992; no other carrier had substituted larger jet equipment for turboprops in commuter slots. AAL's additional F–100 operations have caused no additional delays or congestion. In fact, air traffic data indicate that the incidence of delays at O'Hare has been decreasing slightly, despite the substitution of jets for some turborprop operations.

Experience in implementing and working with Amendment No. 93–62 indicates that the agency can remove the trial basis provision the amendment contained. The use of commuter slots as proposed herein should not exacerbate delays because ATC would retain its authority under the notice provisions of existing 14 CFR 93.223 (e)(5); that authority permits ATC to ensure that the scheduling of additional arrivals and departures with larger aircraft will be distributed to avoid bunching of operations with resulting congestion and delays. If further experience indicates a need for adjustment, however, the rule can be amended to resolve any unforeseen circumstance that may arise.

Removing the expiration date of 14 CFR 93.221 (e)(8) would subject any future changes to notice and comment procedures. This would provide some stability upon which the airlines can rely in developing their long-term schedules to maximize the use of O'Hare's capacity.

D. Establish Slots at Midway

AAL's proposal to bring Midway Airport under the High Density Rule gathered no support beyond those commenters supporting all aspects of the petition. Of the commenters—other than AAL—addressing this point specifically, only the Mayor of Chicago declines to oppose it, saving that it deserves further study. The Airplane Owners and Pilots Association (AOPA), the National Business Aircraft Association (NBAA), the City of Kansas City, Southwest Airlines, and Trans World Airlines submitted comments that opposed this proposal and spoke to little or nothing else. MDOT and WDOT also oppose imposing slots at Midway.

The FAA sees no public benefit from this proposal. Although O'Hare and Midway do share some of the same enroute structure, the arrival and departure routes are distinct and O'Hare's ground congestion is totally unaffected by Midway's operations. The FAA proposes to deny this part of AAL's petition.

E. Revise AAL's Selection of Commuter Slot Times

In its petition, AAL asks that it be allowed to shift its "conversion slot authorities" to different time periods. AAL's request to shift its slot times seeks relief specific to AAL and is inappropriate for general rulemaking. The requested action is also inconsistent with the general purpose of the existing rule to control distribution of additional operations with larger aircraft throughout the day. This proposal would, however, relax the hourly restrictions on the use of the larger aircraft but retain the approval by ATC and gate availability requirements. The FAA does not propose rulemaking, therefore, to implement this aspect of AAL's petition.

The Proposal

For the reasons mentioned above, the FAA proposes to amend part 93 of the Federal Aviation Regulations (14 CFR), subpart S, to permit, in up to 50 percent of each carrier's commuter slot holdings at O'Hare International Airport, the operation of aircraft satisfying the following three criteria: (1) Having an actual seating configuration of 110 or fewer passengers; and (2) having a maximum certificated takeoff weight of less than 126,000 pounds. The cap would limit potential effects on airport operations and preserve at least 50 percent of existing commuter slots for operation with smaller aircraft that might include service to small communities. No matter which carriers held or operated commuter slots, no more than 50 percent of any carrier's commuter slot base or of the total number of commuter slots at O'Hare could be used for larger aircraft. The FAA also proposes to remove the limits on the number of operations per half hour and consecutive half hour periods set forth in 14 CFR 93.221(e)(3) and (e)(5) and 14 CFR part 93, appendix B, and allow the continued use of larger aircraft in commuter slots by removing the trial period provision of 14 CFR 93.221(e)(8).

The FAA anticipates a substantial increase in requests to use larger aircraft in commuter slots if this proposed rule is adopted. This increase would add to the workload of ATC in analyzing each requested operation's impact on air traffic movement and would require more time to process the requests. Since the carriers have informed the FAA that they need as much notice as possible to schedule aircraft and crews, the FAA proposes to amend the notice provision of 14 CFR 93.221(e)(4) to require that a carrier notify ATC 75 days in advance of the planned operation of a larger aircraft in a commuter slot, enlarging by 15 days the current advance notice requirement. ATC would have the authority to disapprove a request based on actual conditions at the time of the request or anticipated at the planned start date. As under the current rule, ATC's approval, conditional approval, or disapproval would be issued more than 45 calendar days before the planned start date stated in the notice to allow requesting carriers time to make operational and marketing preparations. ATC approval for a specific operation would be valid for 30 days after the planned start date, and then would expire if the operation had not commenced.

The proposed amendment would also add to the notice provision the requirement to provide the series, type, and actual seating configuration of the aircraft to be used in the commuter slots. This information would be needed to ensure that the seat and weight limits are being met.

In making this proposal, the FAA emphasizes two areas of concern. The first concern is gate availability. The proposed amendment would not change the current requirement that any carrier intending to operate commuter slots with larger aircraft have sufficient gates available for those operations, to prevent ramp and taxiway congestion which could result from additional jet operations. This requirement appears to have helped avoid any adverse impact on ground congestion that might have resulted from Amendment No. 93–62.

The second concern is the potential effect of the proposed rule on service to small communities. The majority of support for the petition came from representatives or residents of small and mid-size cities for which AAL has promised to continue or add jet service. Contrary to the belief of many of those commenters, no current government regulation prevents AAL or any other carrier from providing jet service to their communities, and this proposed rule would not require any carrier to fly to their cities, much less dictate the type of equipment to be used.

From the time Amendment No. 93–62 was adopted in August 1991 until September 1, 1992, only AAL had substituted larger jet equipment for turboprops in commuter slots. As of September 1, 1992, AAL was using larger jet equipment (F–100's) in place of turboprops in 47 commuter slots. Although AAL has filed two notices to discontinue Essential Air Services (one notice has since been withdrawn) during the period the amendment has been in effect, the FAA's analysis of AAL's pre-and post-Amendment No. 93–62 service pattern to small communities revealed no trend suggesting a general change in service to small communities since the amendment.

The Department of Transportation seeks to promote access by all communities to the air transportation system. The Department ensures that Essential Air Service is provided to eligible points and supports the availability of air service to other small communities. At the same time, the Department recognizes that the greatest utility of the finite capacity of high density airports such as O'Hare may favor the use of larger aircraft in higher density markets. To balance the interests of maximum economic use of a limited resource, on the one hand, and the Department's interest in preserving feeder service to smaller markets in the Chicago region, on the other, the FAA proposes to increase the number of commuter slots that can be operated with larger aircraft to 50 percent of the commuter lots held by each carrier at O'Hare, rather than eliminate the commuter slot restrictions entirely. Limiting seating to 110 passengers and maximum takeoff weight to 126,000 pounds would prevent the use of commuter slots with long-haul aircraft designated for higher demand markets. These limitations would preserve the category of commuter slots and mitigate the impact on commuter markets generally.

The Department will continue to monitor the use of commuter slots at O'Hare. Further comments on the use of commuter slots with larger aircraft since the promulgation of Amendment No. 93–62 would be welcome. Should the use of commuter slots under Amendment No. 93–62 and this proposed rule, if promulgated, lead to unacceptable reductions in service to smaller communities in the region, the Department will reevaluate the use of larger aircraft in commuter slots.

This proposal raises a potential issue relating to slot withdrawals for international operations under 14 CFR 93.217. To date, no commuter slots have been withdrawn at O'Hare for international operations. The proposed expansion of the types of aircraft that may be used in certain commuter slots would include airplanes capable of being flown in international/transborder operations, and the number of slots in which they could be used would be substantially increased. Although these aircraft could be use in commuter slots under this proposed rule, under current practice only air carrier slots would be withdrawn for their use in international operations. The FAA is soliciting comments on whether and how commuter slots that a carrier designates for use with larger aircraft should be treated for withdrawal purposes or be merged with the air carrier slot withdrawal priorities.

This proposed action represents a partial grant of the petition for rulemaking filed by American Airlines on February 18, 1992.

Environmental Review

In conjunction with Amendment No. 93–62, the FAA analyzed the environmental impact of allowing 25 percent of the 435 commuter slots at O'Hare to be used for operations with jet aircraft certificated to hold a maximum of 110 passengers. The FAA calculated that if all 108 commuter slots were used with turbojets, turbojet activity at O'Hare would increase by 6 percent during slot restricted hours. Using the Area Equivalent Method (AEM) computer model, the agency determined that the use of 25 percent of the commuter slots for turbojet operations would result in a 0.2 percent increase in the size of the Day Night Average Sound Level 65 dB contour at O'Hare. The agency concluded that permitting turbojet operations in 25 percant of the commuter slots at O'Hare was consistent with existing national environmental policies and objectives as set forth in section 101(a) of the National Environmental Policy Act (NEPA) and that it would not significantly affect the quality of the human environment or otherwise include any condition requiring consultation pursuant to section 102(2)(c) of NEPA.

The FAA has conducted preliminary analyses of the potential environmental impact of this proposal using the AEM computer model. The first analysis factored in the use of larger aircraft in 50 percent of the commuter slots without any Stage 3 restriction. As a worst possible case scenario, it assumed that all of the affected slots would be used with B737–200's or DC–9–30's; these are Stage 2 aircraft that generate the most noise among the aircraft that the proposed rule, absent a Stage 3 restriction, would allow to operate in commuter slots. The analysis indicated a worst scenario increase of 5 percent in the Day Night Average Sound Level 65 dB contour.

The second analysis added the Stage 3 restriction. The added restriction brought the Day Night Average Sound Level 65 dB contour increase down to less than 1 percent. The FAA has therefore determined that this proposal, even without the Stage 3 requirement, is consistent with existing national environmental policies and objectives as set forth in section 101(a) of NEPA and would not significantly affect the quality of the human environment or otherwise include any condition requiring consultation pursuant to section 102(2)(c) of NEPA.

Comments on the potential environmental effects, if any, of the proposed rule are invited.

Initial Regulatory Evaluation

Executive Order 12291, dated February 17, 1981, directs Federal agencies to promulgate new regulations or modify existing regulations only if potential benefits to society for each regulatory change outweigh potential costs. The order also requires the preparation of a Regulatory Impact Analysis of all "major" rules except those responding to emergency situations or other narrowly defined exigencies. A "major" rule is one that is likely to result in an annual effect on the economy of $100 million or more, a major increase in consumer costs, a significant adverse effect on competition, or is highly controversial.

The FAA has determined that this proposed rule is not "major" as defined in the Executive Order; therefore, a full regulatory analysis, which includes the identification and evaluation of cost reducing alternatives to this proposed rule, has not been prepared. Instead, the agency has prepared a more concise document termed an initial regulatory evaluation that analyzes only this proposal without identifying alternatives.

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Costs

This proposal is voluntary and would not impose any additional costs on Part 121 or Part 135 air carriers. This rule would allow them to use some of their commuter slots (up to 50 percent) at O'Hare Airport for operations with larger aircraft. The decision whether to use the larger aircraft rests, however, strictly with the operators, not the FAA. An increase from 108 to a maximum of 217 operations per day using larger aircraft would be permitted in commuter slots under this proposal.

The proposal would not significantly alter the operating environment at O'Hare for scheduled Part 121 or Part 135 air carriers. It is not expected that ground operations and departure and arrival procedures would be significantly affected if the rule's existing conditions are met.

This proposed regulation would have no effect on the safety of either air or ground operations. ATC would retain the ability to disapprove proposed arrival or departure schedules of additional larger airplane operations at O'Hare. ATC procedures will continue to maintain a high level of safety and efficiency.

Because AAL speaks in its petition about improving, not reducing, air service to small communities, the FAA assumes that promulgation of the rule as proposed would not diminish such service below current levels. This proposal would allow air carrier operators to substitute larger turbojet airplanes for turboprops and, thereby, improve service. However, the FAA recognizes that the ability to use jets in commuter slots may serve as an incentive to remove those slots from use in markets that cannot support jet service, and the FAA solicits public comment regarding this assumption. Especially helpful would be comments reflecting an analysis of the net national economic impact if service to small communities should decrease as a result of the use of the limited resource of slots for higher demand, and perhaps more profitable, routes.

Benefits

This proposal would reduce some of the current restrictions on the use of commuter slots at O'Hare and would permit air carriers holding commuter slots additional flexibility in the use of those slots. To the extent jet aircraft are substituted for commuter turboprops, the rule would benefit passengers flying in those aircraft to and from Chicago.

The proposed rule could save time for the traveling public. For most commuter flights, which are short-range, turbojets would not provide any significant time savings. Passengers on long commuter flights, however, would save time. The FAA estimates that about 20 minutes could be saved on a long commuter flight by using turbojet airplanes instead of turboprop airplanes. The FAA estimates that approximately 50 passengers would be on each turbojet commuter flight. The estimated passenger time saved is, therefore, 16.7 passenger-hours per commuter flight. The FAA estimates that the value of passenger time is $42 per hour for 1992. Allowing turbojet airplanes to be used on long commuter flights would save $701 in passenger time for each long commuter trip. This proposed regulation would allow an additional 109 commuter slots to be used in this way. Assuming half of the slots would be used for long commuter flights with turbojet equipment, this proposal would save about $38,200 per day in passenger time. The FAA solicits public comment regarding the assumptions used in estimating the benefits of this proposal.

One commenter mentions that AAL's introduction of jet service of Fargo, ND, has increased competition resulting in lower fares. This benefit is not readily quantifiable, but similar results might be expected in other markets as a result of the promulgation of this proposed rule.

Some indirect benefits and costs have been suggested that cannot be considered because (1) The results are uncertain and (2) their realization is not dependent on any rule change. AAL supported its petition by saying that granting the petition would create 1650 jobs having an annual payroll over $95 million and a positive economic impact of more than $280 million in the Chicago area alone. It said that Amendment No. 93–62 has enabled it to create 550 jobs, and further relaxation of the commuter slot restrictions would bring about 1100 more jobs. AAL also said that more Fokker 100 service at O'Hare would translate to more opportunities for students at its Maintenance Academy at Midway Airport. As similar, indirect, and somewhat offsetting results, various Simmons pilots claimed they will lose their jobs if AAL's petition is granted. The FAA declines to consider these benefits and costs because they are not direct results of the proposed rule that are appropriate for consideration in this analysis.

The FAA invites comments, however, on the costs and benefits of any job loss or job creation that a commenter perceives as resulting directly from a rule change.

Comparison of Benefits and Costs

The FAA finds that there would be no significant costs to this proposed regulation. However, there are measurable benefits. As a result, the FAA has determined that the proposed regulation would be cost-beneficial.

Initial Regulatory Flexibility Determination

The Regulatory Flexibility Act (RFA) of 1980 requires Federal agencies to review rules that may have a "significant economic impact on a substantial number of small entities." The FAA has adopted criteria and guidelines for determining if a proposed or existing rule has any significant economic impact on a substantial number of small entities.

The FAA defines a small entity as an operator who owns, but does not necessarily operate, nine or fewer airplanes. A substantial number of small entities is one-third of the small entities provided 11 or more small entities are substantially impacted. The FAA defines a significant economic impact as $4,000 per year for unscheduled operators, $57,000 per year for scheduled operators, and $101,000 per year for scheduled operators with aircraft containing no less than 60 passenger seats.

No small entity owning or operating nine or fewer airplanes holds commuter slots at O'Hare. Thus, the FAA determines that this proposed rule would have no significant economic impact on a substantial number of small entities.

International Trade Impact Assessment

The proposed regulation would only affect domestic operations at Chicago O'Hare Airport. Thus, it would not provide either an advantage or disadvantage to foreign air carriers providing service to and from the United States, nor would it provide either a trade advantage or disadvantage to United States air carriers providing foreign service.

Paperwork Reduction Act

This proposal, if adopted, provides for no changes to the required reporting of information by air carrier and commuter operators to the FAA. Under the requirements of the Federal Paperwork Reduction Act, the Office of Management and Budget has approved the information collection provision of subpart S through August 31, 1995. OMB Approval Number 2120–0524 has been assigned to subpart S.

Federalism Implications

The proposal set forth herein would not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this regulation, if adopted, would not have federalism implications warranting the preparation of a Federalism Assessment.

Conclusion

For the reasons set forth above, the FAA has determined that this proposal (1) Would not be a "major rule" under Executive Order 12291; and (2) would be a "significant rule" under Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). Further, I certify that under the criteria of the Regulatory Flexibility Act, this proposal would not have a significant economic impact on a substantial number of small entities.

List of Subjects in 14 CFR Part 93

Air traffic control, Airports, Alaska, Navigation (air), Reporting and recordkeeping.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, I propose to amend part 93 of the Federal Aviation Regulations (14 CFR part 93) as follows:

PART 93—SPECIAL AIR TRAFFIC RULES AND AIRPORT TRAFFIC PATTERNS

1. The authority citation for part 93 continues to read as follows:

Authority: 49 U.S.C. App. 1302, 1303, 1348, 1354(a), 1421(a), 1424, 2451 *et seq.*; 49 U.S.C. 106(g).

§ 93.221 [Amended]

2. Section 93.221(e)(1) and (e)(2) are revised to read as follows:

§ 93.221 Transfer of slots.

* * * * *

(e) * * *

(1) Air carrier aircraft that may be operated under this paragraph are limited to aircraft:

(i) Having an actual seating configuration of 110 or fewer passengers; and

(ii) Having a maximum certificated takeoff weight of less than 126,000 pounds.

(2) No more than 50 percent of the total number of commuter slots held by a slot holder at O'Hare International Airport may be used with aircraft described in paragraph (e)(1) of this section.

3. Section 93.221(e)(3), (e)(5), and (e)(8) are removed.

4. Section 93.221(e)(4) is designated as (e)(3) and amended by removing, in the fifth line, the number "60" and inserting in its place the number "75", and in the ninth line, after the words "aircraft type" inserting ", aircraft series, actual aircraft seating configuration".

5. Section 93.221(e)(6) and (e)(7) are redesignated as (e)(4) and (e)(5), respectively.

Appendix B—[Removed]

6. Appendix B to part 93 is removed.

Issued in Washington, DC, on December 29, 1992.

Thomas C. Richards,

Administrator.

[FR Doc. 92–31941 Filed 12–30–92; 4:01 pm]

BILLING CODE 4910–13–M

Research and Special Programs Administration

14 CFR Parts 221 and 389

[Docket No. 48379; 48385; Notice 92–35]

RIN 2137–AC18

Electronic Filing of Property and Passenger Tariffs; Extension of Comment Period

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Reopening of comment period; notice of public meeting; request for comments on petition for rulemaking.

SUMMARY: On October 15, 1992, RSPA published a notice of proposed rulemaking (NPRM) in the **Federal Register** inviting comment on electronic filing of property and passenger tariffs. Improvements were proposed to the procedures for electronic filing of passenger fares that were implemented on December 18, 1989, that, among other changes, would allow electronic text submissions in addition to electronic price submissions. The electronic text would include price conditions or limitations. RSPA has received several requests asking for an extension of the comment period from the current 30 days to 90 days. RSPA concurs, in part, and has concluded that additional time for public comment and a public meeting should contribute to the public understanding of the proposals. RSPA is reopening the comment period, will hold a public meeting, and will accept comments until March 5, 1993. RSPA also requests comments on a related petition for rulemaking.

DATES: *Comments.* The comment period is reopened, and comments will be accepted until March 5, 1993. *Public Meeting.* A public meeting will be held on February 3, 1993, at 10 a.m.

ADDRESSES: *Comments.* Five copies of any comments to this docket should be sent to the Documentary Services Division, C–55, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, and should refer to this Docket. Receipt of comments will be acknowledged if the commenter includes a stamped, self-addressed postcard, which the Docket Clerk will time- and date-stamp and return. *Public meeting.* A public meeting on the proposed electronic cargo and passenger tariff filing procedures will be held at the Department of Transportation NASSIF Building, 400 Seventh Street, SW., Washington, DC 20590, on February 3, 1993, at a room number to be provided later. The meeting will be transcribed. Those planning to attend should notify RSPA, by telephone or in writing, no later than January 22, 1993. To confirm plans to attend, and obtain the meeting room number, contact Mr. Dean L. Johnson or Mrs. Rita B. Clowes at (202) 366–2414.

FOR FURTHER INFORMATION CONTACT: Mr. Donald W. Bright or Mr. Dean L. Johnson, Office of Automated Tariffs, Research and Special Programs Administration (RSPA), Department of Transportation, at the address above. Telephone: (202) 366–4080.

SUPPLEMENTARY INFORMATION: On October 15, 1992, RSPA published a notice of proposed rulemaking (NPRM) in the **Federal Register** inviting comment on electronic filing of property and passenger tariffs (Docket 48385, Notice 92–19, 57 FR 47303). Improvements were proposed to the procedures for electronic filing of passenger fares that were implemented on December 18, 1989. The NPRM proposed to allow an air carrier to submit an all-electronic tariff filing that includes not only an electronic price, but also the conditions of service and limitations on the application of the price for travel and other purposes.

RSPA also proposed to eliminate excess filing of tariff information; prescribe the form and content of electronic fare rules; require a finished electronic tariff arrangement or format in addition to the existing subscription service for electronic raw tariff data; allow the filer to charge a fee to reproduce electronic tariffs in a finished

construction; clarify the tariff regulations affecting the filer's proposed effective date of an electronic tariff filing; and revise the user fee regulations to reflect current costs and to clarify the initial exclusion from electronic user fees for electronic filers.

RSPA received several requests asking for an extension of the comment period from the current 30 days to 90 days. RSPA concurs, in part, with these requests in that additional time for public comment and a public meeting should contribute to the public understanding of the proposals. RSPA is reopening the comment period, will hold a public meeting, and will accept comments until March 5, 1993.

On October 28, 1992, the Airline Tariff Publishing Company (ATPCO) requested a delay in response date, a public meeting, and disclosure of cost studies. Comments in support of ATPCO's request were received from Japan Airlines Company, Swissair, Varig, S.A., American Airlines, Delta Air Lines, Northwest Airlines, United Air Lines, and USAir.

ATPCO is concerned about the potential costs of the proposal and its impact on electronic rules, which are the electronic text provisions that contain the relevant conditions for application of the tariff, and conditions or limitations on specific prices in the tariff. ATPCO stated that fare files are maintained separately from rules files and footnote files, and the proposal would require each of the fares to be integrated with its conditions. ATPCO believes this proposal to be potentially very costly, because "marriage of the footnote and rule to the fare" would require "republication of the fares each time the footnote or rule is changed."

ATPCO questioned the need for a hierarchy of electronic rules information as proposed in the NPRM. Finally, ATPCO stated that the proposed RSPA fee increases for fare filings are double current levels, and the fee for rules filings may be three times more than current levels, and it asked that relevant cost studies be placed in the docket.

On October 1, 1992, ATPCO submitted a petition for rulemaking to allow air carriers to initiate fare action at any time and the Department to accept those filings as of the time they are filed. RSPA invites public comment on the petition during the comment period, and will consider the merits of the petition as part of this rulemaking.

RSPA agrees that additional time should be provided for public comment and public discussion of the proposals in the NPRM. Therefore, RSPA is reopening the comment period and will accept additional public comments. RSPA also will hold a public meeting to discuss the NPRM. A regulatory evaluation is available for review in the docket.

Issued in Washington, DC on December 29, 1992.

Elaine E. Joost,

Acting Associate Administrator for Research, Technology and Analysis, Research and Special Programs Administration.

[FR Doc. 93–8 Filed 1–4–93; 8:45 am]

BILLING CODE 4910–62–M

Federal Highway Administration

23 CFR Part 655

[FHWA Docket No. 89–1, Notice No. 6]

RIN 2125–AC83

National Standards for Traffic Control Devices; Manual on Uniform Traffic Control Devices; Work Zone Traffic Control Standards Revision

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of proposed amendments to the Manual on Uniform Traffic Control Devices (MUTCD); request for comments.

SUMMARY: The MUTCD is incorporated by reference in 23 CFR 655, subpart F, and recognized as the national standard for traffic control devices on all public roads open to public travel. The FHWA has been considering options for rewriting part VI of the MUTCD with the objective of improving safety through more uniform application of effective traffic control and traffic control devices in work zones. Initial recommendations from this effort were made available for review and comment on December 23, 1988, at 53 FR 51826 through a Public Information Package followed by recommendations in a second Public Information Package on June 5, 1989, at 54 FR 23990. The comment period for the second Public Information Package was reopened on April 26, 1990, at 55 FR 17634, and again reopened from August 15, 1990, to March 31, 1991, at 55 FR 33325. The FHWA invited review and comments on reformatting the MUTCD on January 10, 1992, at 57 FR 1134 (Docket No. 89–1, Notice No. 5). The FHWA has decided not to reformat part VI at this time. The FHWA has evaluated the information received concerning the technical aspects of part VI and combined many of the suggestions into this notice of proposed amendments to part VI of the MUTCD. Interested persons are invited to review and comment on this rewrite of part VI. Persons who furnished comments concerning the technical aspects of part VI as a part of their comments to Docket No. 89–1, Notice No. 5, need not resubmit the comments.

This proposal is specifically intended to improve the safety of workers, pedestrians, and motorists in work zones. This proposal is also intended to expedite implementations of the Intermodal Surface Transportation Efficiency Act of 1991, and improve traffic operations by providing more uniform application of traffic control devices in work zones.

DATES: Comments concerning these proposed amendments must be received on or before March 8, 1993.

ADDRESSES: Submit written, signed comments to FHWA Docket No. 89–1, Notice No. 6, Federal Highway Administration, room 4232, HCC–10, 400 Seventh Street, SW., Washington, DC 20590. All comments received will be available for examination at the above address between 8:30 a.m. and 3:30 p.m., e.t., Monday through Friday except legal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Rudolph M. Umbs, Office of Highway Safety, (202) 366–0411, or Mr. Wilbert Baccus, Office of Chief Counsel, (202) 366–0780, Department of Transportation, 400 Seventh Street, NW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: The MUTCD is approved by the FHWA as the National Standard for all streets and highways open to public travel. The MUTCD is available for inspection and copying as prescribed in 49 CFR part 7, appendix D. It may be purchased for $22.00 from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, stock No. 050–001–00308–2. Each amendment is assigned an identification number which indicates, by Roman numeral, the primary organizational part of the MUTCD affected and, by Arabic numeral, the order in which the request was received (e.g., Request VIII–9).

The FHWA enlisted the services of an engineering consultant to solicit comments from Federal, State, local, and other highway agencies regarding the design, administration, and operation of highway work zones in anticipation of rewriting part VI of the MUTCD. The consultant's initial findings were made available for review and comment on December 23, 1988, at 53 FR 51826, through a Public Information Package followed by revised findings in a second Public

Information Package on June 5, 1989, at 54 FR 23990. The comment period for the second Public Information Package was reopened on April 26, 1990, at 55 FR 17634, and again reopened from August 15, 1990, to March 31, 1991, at 55 FR 33325. The FHWA's advance notice of proposed rulemaking (ANPRM) on January 10, 1992, at 57 FR 1134, was issued to: (1) Provide an opportunity to the public to comment on the desirability of the proposed amendments to part VI of the MUTCD, and (2) address alternative formats for the MUTCD. The ANPRM is identified as FHWA Docket No. 89–1, Notice No. 5. The public docket on Notice No. 5 closed on July 30, 1992.

The FHWA received 100 comments in response to the public docket 89–1, Notice Nos. 1 through 4. The large majority of comments supported the following conclusions:

(1) There is a need to retain most of the traffic control device design and application standards that are presently contained in the current MUTCD;

(2) There is a need for a few new traffic control devices; and

(3) There is a need to provide users with the new guidance information presented in the public information packages.

Many comments to Notice No. 5 echoed the above conclusions, and have encouraged the FHWA to publish part VI:

(1) As a stand alone document;

(2) In the same format as the 1988 Edition of the MUTCD; and

(3) As soon as possible.

In response to these early comments, and in order to expedite the part VI rulemaking process, the FHWA has developed this NPRM.

The proposed amendments in this rulemaking, *Request VI–72(C) Total Revision of Part VI*, concern part VI of the MUTCD "Traffic Controls for Street and Highway Construction, Maintenance, Utility, and Emergency Operations" in its entirety. Part VI sets forth basic principles and prescribes standards for traffic control during work zone operations on streets and highways in the United States. With the current emphasis on repairing the Nation's highways and improving safety in work zone areas, an update of part VI would better serve the highway community.

The document containing the text changes for this proposed amendment to the MUTCD has been titled: 1988 MUTCD Proposed Revision 3, dated August 1, 1992. It is available from the Federal Highway Administration, Office of Highway Safety, HHS–31, 400 Seventh Street SW., Washington, DC 20590. Everyone currently appearing on the FHWA **Federal Register** mailing list will automatically be sent a copy.

Discussion of Amendments

The following items are the more important part VI revisions.

Pedestrian and Worker Safety

To focus attention on pedestrian and worker safety, new sections 6D–1 and 6D–2 have been developed. These sections would consolidated the standards, guidance, and information on these subjects that were previously scattered throughout part VI.

New Symbol Signs

The study, "Motorists' Comprehension of Regulatory, Warning, and Symbol Signs,"[1] raised serious doubts about the continuing process of converting word legend signs to symbol signs. The FHWA has adopted very few new symbols since this report was completed. There are no new symbol designs proposed for inclusion in the rewrite of Part VI. There are, however, several new combinations of existing symbols to form new symbol messages. As an example, in Figure VI–8a, Sign W1–4c shows a three-lane shift. This sign uses three lane shift symbols from the current standard W1–4 sign (Figure 6–13a of the 1988 MUTCD).

New Word Message Signs

The rewrite of part VI includes some new word message warning signs. These signs, like any word legend warning sign, are currently allowed by section 6C–41. The warning signs that are proposed for inclusion in the rewrite of Part VI are commonly used by many State and local highway agencies.

Portable Changeable Message Signs

Standards, guides, and information regarding changeable message signs would be added to section 6F–2, Portable Changeable Message Signs. This change would be made to improve application uniformity and make the standards, guides, and information regarding these signs, found elsewhere in the MUTCD (part II), more readily available to those who administer, design, and operate work zones.

Channelizing Devices

The minimum diameter of drums and the materials used to make drums have been somewhat controversial over the past several years. As in the current standards, drums would be required to have a minimum diameter of 18 inches. Other shapes of drums would also be required to have at least 18 inches minimum width regardless of orientation.

There are other channelizing devices, such as the rectangular drum, light-weight plastic barrier, and the "Road Hog," which may have specialized applications. Contracting procedures are in place in all highway agencies to specify the use of these devices for such specialized applications without their being recognized as standard channelizing devices in part VI of the MUTCD. This notice recognizes the existence of specialized applications to encourage the continued development of and experimentation with such devices.

Research studies have repeatedly shown that a steel drum poses severe hazards to pedestrians, workers, and motorists when the drum is struck. Therefore, the use of steel drums as a channelizing or other traffic control device would be specifically prohibited.

Interim (Short-term) Traffic Control Marking Standards

The MUTCD interim pavement marking standards and guides, that are found in section 6F–6, have been somewhat controversial over the past several years. The text that is currently in the 1988 edition of the MUTCD has not been changed in this proposal. The results of the recent FHWA contract research[2] confirm the continuation of these standards. Under section 1A–6 of the MUTCD, the FHWA has also authorized two States to conduct experimentation with abbreviated no-passing zone markings. The results of the experimentation will be incorporated into the decisionmaking process regarding interim no-passing zone pavement marking standards.

Additional Guidance for the use of Various Traffic Control Devices

Additional guidance concerning the use of tubular markers would be added at 6F–5c, drums at 6F–5e, temporary raised islands at 6F–5h, impact attenuators at 6F–8a, rumble strips at 6F–8d, and glare screens at 6F–8e.

Description of Distinct Work Zone Time Durations

To assist users of the MUTCD part VI in the selection of traffic control devices and typical application of these devices, section 6G-2, Selection of Typical Application, would be added to

[1] Motorists' Comprehension of Regulatory, Warning, and Symbol Signs, November 1985, Report Nos. FHWA–RD–86–111, 112, and 113. It is available for inspection and copying as prescribed in 49 CFR part 7, appendix D.

[2] Non-Permanent Pavement Markings in Work Zones, February 1992, Report No. FHWA–RD–92–007. It is available for inspection and copying as prescribed in 49 CFR part 7, appendix D.

describe five distinct work zone time durations. These time durations are: Long-Term Stationary, Intermediate-Term Stationary, Short-Term Stationary, Short Duration, and Mobile.

New Typical Application Diagrams

Many engineering practitioners have requested that the part VI standards and guidelines be supplemented with typical application diagrams. The existing part VI includes a small number of such diagrams. In the rewrite of part VI, it is proposed to incorporate a substantially larger number of new or improved typical application figures.

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The FHWA has determined that this document contains neither a major rule under Executive Order 12291 nor a significant regulation under the regulatory policies and procedures of the DOT. It is anticipated that the economic impact of this rulemaking will be minimal. Therefore, a full regulatory evaluation is not required. The need to further evaluate economic consequences will be reviewed on the basis of the comments submitted in response to this notice.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act (Pub. L. 96–345; 5 U.S.C. 601–612, the FHWA has evaluated the effects of this rule on small entities. Based upon this evaluation, the FHWA hereby certifies that this action will not have a significant economic impact on a substantial number of small entities. The need to further evaluate economic consequences will be reviewed on the basis of the comments submitted in response to this notice.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The MUTCD is incorporated by reference in 23 CFR Part 655, subpart F, which requires that changes to the National Standards issued by the FHWA shall be adopted by the States or other Federal agencies within 2 years of issuance. This proposed amendment is in keeping with the Secretary of Transportation's authority under 23 U.S.C. 109(d) and 315 to promulgate uniform guidelines to promote the safe and efficient utilization of the highways. Therefore, nothing in the proposed rule preempts any State laws, regulations or requirements.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act

The FHWA has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.) and has determined that this action would not have any effect on the quality of the environment.

Regulatory Identification Number

A regulatory identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 655

Design standards, Grant programs-transportation, Highways and roads, Incorporation by reference, Signs, Traffic regulations.

(23 U.S.C. 315; 49 CFR 1.48)

Issued on: December 30, 1992.

T. D. Larson,

Administrator.

[FR Doc. 93–88 Filed 1–4–93; 8:45 am]

BILLING CODE 4910-22-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[INTL–0848–89]

RIN 1545–A022

Taxable Year of Certain Foreign Corporations Beginning After July 10, 1989

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed Income Tax Regulations setting forth the required taxable year for specified foreign corporations for taxable years of those foreign corporations beginning after July 10, 1989. This action is necessary because of changes to the applicable tax law made by the Omnibus Budget Reconciliation Act of 1989, which added section 898 to the Internal Revenue Code. The regulations will give guidance on which foreign corporations must change their taxable year and how to effect the change in taxable year.

DATES: Written comments and requests for a public hearing must be received by March 8, 1993.

ADDRESSES: Send written comments and requests for a public hearing to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attention: CC:CORP:T:R (INTL–0848–89), room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Bill Lundeen of the Office of Associate Chief Counsel (International), within the Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20224 (Attention: CC:CORP:T:R (202–622–3870 (INTL–0848–89), not a toll-free call).

SUPPLEMENTARY INFORMATION:

A. Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224.

The collection of information in these proposed regulations is in §§ 1.563–3, 1.898–3 and 1.898–4. The Internal Revenue Service requires this information to verify compliance with section 898 of the Internal Revenue Code. The respondents will be certain United States shareholders of specified foreign corporations.

The estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on information as is available to the Internal Revenue Service. Individual respondents may require greater or lesser time, depending on their particular circumstances.

Estimated total annual reporting burden: 600 hours.

Estimated burden per respondent varies from 5 hours to 1.5 hour, depending on individual circumstances, with an estimated average of 1 hour.

Estimated number of respondents: 600.

Estimated frequency of responses: Once every three years.

B. Background

This document contains proposed regulations under sections 441, 442, 563 and 898 of the Internal Revenue Code (Code). Sections 1.898–1 through 1.898–4 are proposed to be effective for taxable years of specified foreign corporations beginning after July 10, 1989. However, §§ 1.898–3(a)(4) (regarding situations in which inconsistent majority U.S. shareholder years exist) and 1.898–3(a)(5)(iii) (regarding situations in which additional testing days are required) are proposed to be effective for taxable years beginning after [Insert Date 120 Days After Date of Publication of Final Regulations in the **Federal Register**], and section 1.898–4(b) is proposed to be effective for changes in the required year of a specified foreign corporation subsequent to its first taxable year beginning after July 10, 1989.

C. Explanation of Provisions

Introduction

Section 7401(a) of the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101–239, 103 Stat. 2106 ("the Act"), added section 898 to the Code. The purpose of section 898 is to eliminate the deferral of income and, therefore, the understatement in income, by United States shareholders of certain controlled foreign corporations and foreign personal holding companies, referred to in the statute as specified foreign corporations. Deferral results when certain income earned by these corporations is subject to United States income tax in a taxable year of the United States shareholder subsequent to the taxable year during which it was earned. The elimination of deferral is accomplished by requiring a specified foreign corporation to conform its taxable year to the required year, which is generally the majority U.S. shareholder year, for taxable years of specified foreign corporations beginning after July 10, 1989.

Section 1.898–1

Section 1.898–1 provides the general rule that, for purposes of the Internal Revenue Code, the taxable year of any specified foreign corporation shall be the required year determined under section 898 (c) and § 1.898–3. In addition, § 1.898–1(b) sets forth the effective dates of the regulations under section 898.

The regulations at paragraph (c) exempt certain specified foreign corporations from section 898 in three circumstances. First, a specified foreign corporation is exempt from section 898 so long as its United States shareholders do not have any amount includible in gross income pursuant to section 951(a) and do not receive any actual or deemed distributions attributable to amounts described in section 553 with respect to that corporation. Once any United States shareholder has such amounts, however, section 898 applies to the specified foreign corporation. Second, a specified foreign corporation that is a foreign insurance company and elects to be treated as a domestic corporation pursuant to section 953(d) is exempt from section 898. Likewise, a specified foreign corporation described in section 1504(d) for which an election has been made to treat it as a domestic corporation is exempt from section 898.

Section 1.898–2

Section 1.898–2(a) defines specified foreign corporation. Generally, a specified foreign corporation is defined to include controlled foreign corporations and foreign personal holding companies. However, specified foreign corporations include only those controlled foreign corporations and foreign personal holding companies that meet certain ownership requirements. Paragraphs (b)(1) and (b)(2) set forth the ownership requirements of a specified foreign corporation and paragraph (b)(3) defines United States shareholder for purposes of these rules. Paragraph (c) provides a special rule for foreign personal holding companies that are specified foreign corporations.

There is an inconsistency in the legislative history of section 898 between the Senate Print and the Conference Report. The conference agreement generally follows the Senate amendment, but misstates the Senate amendment in reporting that section 898 applies only to a controlled foreign corporation or foreign personal holding company, more than 50 percent of the total voting power or value of the U.S.-owned stock of which is treated as owned by a United States shareholder, and that section 898 takes into account only the taxable years of those United States shareholders (and certain related persons) in determining the majority U.S. shareholder year. The words "U.S.-owned" did not appear in the Senate amendment, which is the version of the bill that Congress enacted and which became public law. Accordingly, specified foreign corporations include controlled foreign corporations and foreign personal holding companies in which a United States shareholder owns (or is considered to own) more than 50 percent of the voting power of all classes of stock of the corporation entitled to vote, or more than 50 percent of the total value of all classes of stock of the corporation.

Section 1.898–3

Section 1.898–3(a)(1) provides the general rule that the required year of a specified foreign corporation means the majority U.S. shareholder year. Paragraph (a)(2) provides that a specified foreign corporation that is a controlled foreign corporation may elect, in lieu of the required year, a taxable year beginning one month earlier than the majority U.S. shareholder year. Paragraph (a)(3) defines majority U.S. shareholder year, and paragraph (a)(4) provides rules for situations in which more than one majority U.S. shareholder year exists. Paragraph (a)(5) defines testing days which are the days on which a specified foreign corporation must determine whether it is using the required year. Paragraph (b) provides special rules for foreign personal holding companies that are specified foreign corporations.

Section 1.898–4

Section 1.898–4 provides special rules applicable to specified foreign corporations. Paragraph (a) sets forth rules for changes to the required year of a specified foreign corporation for its first taxable year beginning after July 10, 1989, and paragraph (b) provides rules for changes in the required year of a specified foreign corporation during a taxable year subsequent to its first taxable year beginning after July 10, 1989.

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Paragraph (c) provides rules for situations in which a specified foreign corporation maintains a foreign taxable year (for purposes of computing income tax liabilities due a foreign country) that is different from its required year, including rules relating to the computation of income and earnings and profits of the corporation and rules for the situation in which the U.S. majority shareholder year is a 52–53-week taxable year and the specified foreign corporation's taxable year is not, or in which the specified foreign corporation's taxable year is a 52–53-week taxable year and the U.S. majority shareholder year is not.

A foreign income tax accrues only when the liability for it is fixed and the amount of the liability can be determined. This event generally occurs at the end of the foreign taxable year with respect to a foreign income tax that is imposed on that year's income. Consequently, with the enactment of section 898, a mismatch may arise between the income that comprises a subpart F or foreign personal holding company inclusion and the creditable foreign taxes related to the inclusion when the foreign taxable year of a specified foreign corporation ends later than the corporation's United States taxable year.

Adherence to the foreign tax accrual rule in the context of section 898 may result in income being taxed under subpart F without the associated foreign income taxes being available as a credit under section 960. While we considered several options to address the effect of the foreign tax accrual rule in this context, we believe that adherence to the foreign tax accrual rule is justified for several reasons. First, unlike section 338 (i), there is no direct authority in section 898 to modify the rule. Second, rules that require the pooling of post-1986 undistributed earnings and foreign taxes mitigate the effect of the foreign tax accrual rule. Third, determining the foreign taxes on a specified foreign corporation's taxable income prior to the end of the foreign taxable year may not be possible, especially where that foreign taxable year has not ended by the filing date of the applicable U.S. tax return.

Accordingly, modifying the foreign tax accrual rule for specified foreign corporations that have foreign taxable years which differ from their required year would result in speculative foreign tax accruals, necessitating a corrective mechanism, and would result in a set of highly complex rules which would be difficult to administer. Such an approach would place additional pressure on the foreign tax credit rules, in particular, on the section 905(c) rules. Finally, the potential mismatch resulting from adherence to the foreign tax accrual rule is mitigated by the rule, discussed below, that applies to the first taxable year after section 898 was enacted and that spreads over four taxable years the recognition of certain income otherwise required to be recognized in one year as a result of section 898.

Section 1.898–4(d) provides rules to implement section 7401(d)(2)(C) of the Act. That section of the Act provides that if, because of the change in taxable year, any United States person would be required to include in gross income for its taxable year amounts attributable to two taxable years of the specified foreign corporation, the amount of income reported for the short taxable year of the specified foreign corporation shall be included in the United States person's gross income ratably over its next four taxable years beginning with its taxable year in which amounts attributable to two taxable years of the specified foreign corporation would have been included.

The foregoing four-year rule applies only when a United States person would otherwise be required to include deemed distributions of income from more than one taxable year of the specified foreign corporation in any one of its own taxable years, and only if the short taxable year of the specified foreign corporation was its first taxable year beginning after July 10, 1989. If a specified foreign corporation that changed its taxable year in accordance with section 898 derived subpart F income in its first taxable year, but not in its second (short) taxable year, which ended within the one taxable year of the United States person, then the ratable four-year inclusion would not be applicable. Finally, any United States person who would otherwise be subject to the four-year rule may not waive that rule and accelerate an income inclusion due to the application of section 898.

Section 1.563–3

Section 7401(b)(1) of the Act amended section 563 of the Code by adding a new subsection (c) which generally requires that, in determining the dividends paid deduction for purposes of the foreign personal holding company provisions of the Code, a dividend paid after the close of any taxable year, and on or before the 15th day of the third month following the close of that taxable year, will be considered as paid during that taxable year to the extent the foreign personal holding company designates the dividend as being taken into account under section 563(c). Section 1.563–3 provides rules to implement section 7401(b)(1).

D. Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on the impact of the rules on small business.

E. Comments and Requests for a Public Hearing

Before adopting these regulations, consideration will be given to any written comments that are submitted (preferably a signed original and eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying. A public hearing will be held upon written request by any person who submits timely written comments on the proposed rules. Notice of the time, place and date for the hearing will be published in the **Federal Register**.

F. Drafting Information

The principal author of this regulation is Bill Lundeen of the Office of Associate Chief Counsel (International), within the Office of Chief Counsel, Internal Revenue Service. Other personnel from the Internal Revenue Service and Treasury Department participated in developing the regulations.

List of Subjects

§§ 1.441–1 Through 1.444–3T

Accounting, Income Taxes, Reporting and recordkeeping requirements.

§§ 1.561–1 Through 1.565–6

Income taxes, Reporting and recordkeeping requirements.

§§ 1.891–1 Through 1.907(f)–1A

Aliens, Foreign investments in United States, Income Taxes, Reporting and recordkeeping requirements, United States investments abroad.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for 26 CFR part 1 is amended by adding the following citations:

Authority: 26 U.S.C. 7805 * * * Sections 1.898–1 through 1.898–4 also issued under 26 U.S.C. 898. * * *

Par. 2. Section 1.441–1T is amended by adding paragraph (b)(1)(ii)(I) to read as follows:

§ 1.441–1T Period for computation of taxable income (temporary).

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(I) In the case of any controlled foreign corporation or foreign personal holding company that is a specified foreign corporation, within the meaning of section 898 and § 1.898–2, the applicable rules are contained in section 898 and the regulations under that section.

* * * * *

Par. 3. Section 1.442–1 is amended by adding a sentence to the end of paragraphs (a)(1), (b)(3) and (c)(5), to read as follows:

§ 1.442–1 Change of annual accounting period.

(a) * * *

(1) * * * For special rules relating to controlled foreign corporations and foreign personal holding companies that are specified foreign corporations, within the meaning of section 898 and § 1.898–2, see section 898 and the regulations under that section.

* * * * *

(b) * * *

(3) * * * For special rules relating to controlled foreign corporations and foreign personal holding companies that are specified foreign corporations, within the meaning of section 898 and § 1.898–2, see section 898 and the regulations under that section.

* * * * *

(c) * * *

(5) * * * For special rules relating to controlled foreign corporations and foreign personal holding companies that are specified foreign corporations, within the meaning of section 898 and § 1.898–2, see section 898 and the regulations under that section.

* * * * *

Par. 4. Section 1.442–2T is amended by adding paragraph (a)(9) to read as follows:

§ 1.442–2T Special limitations on certain changes of annual accounting period (Temporary).

(a) * * *

(9) Any specified foreign corporation, within the meaning of section 898 and § 1.898–2, that is required to change its taxable year to the required year under section 898 and the regulations under that section.

* * * * *

Par. 5. Section 1.563–3 is redesignated as § 1.563–4 and new § 1.563–3 is added to read as follows:

§ 1.563–3 Foreign personal holding company tax; Procedure for designation of a dividend as being taken into account under section 563(c).

In determining the deduction for dividends paid under section 561, a foreign personal holding company may designate a dividend paid after the close of any taxable year beginning after July 10, 1989, and on or before the 15th day of the third month following the close of that taxable year, as being taken into account under section 563(c) and this section by making the designation on an attachment to Schedule N of Form 5471. The designation must set forth the date of the distribution and a statement indicating the extent to which the distribution is being taken into account under section 563(c), and any other information required by Form 5471 and the instructions to that form. The designation must be signed and dated by a duly authorized corporate officer of the foreign personal holding company. If a foreign personal holding company took a dividend paid into account under section 563(c) for any taxable year beginning after July 10, 1989, and ending prior to [Insert date that is 120 days after date of publication of Final Regulations in the **Federal Register**] but did not follow the procedures set forth in this paragraph, then a designation on an attachment to Schedule N of Form 5471 setting forth the information required above should be signed in a manner set forth above and attached to the first Form 5471 and, if applicable, Form 1120F, to be filed after [Insert date that is 120 days after date of publication of Final Regulations in the **Federal Register**.]

Par. 6. Sections 1.898–0 through 1.898–4 are added under the heading "miscellaneous provisions" to read as follows:

§ 1.898–0 Outline of regulations for section 898.

This section lists the major paragraphs contained in §§ 1.898–1 through 1.898–4.

§ 1.898–1 Taxable year of certain foreign corporations.

(a) In general.
(b) Effective dates.
(c) Exceptions to section 898.
(1) Specified foreign corporations with no section 951(a) or foreign personal holding company income.
(2) Elections to be treated as domestic corporations.

§ 1.898–2 Definition of specified foreign corporation.

(a) In general.
(b) Ownership requirements.
(1) In general.
(2) Ownership by attribution.
(3) Definition of United States shareholder.
(i) In general.
(ii) Certain captive insurance companies.
(iii) Foreign personal holding companies.
(4) Illustrations.
(c) Special rule for foreign personal holding companies that are not controlled foreign corporations.
(1) In general.
(2) Illustrations.

§ 1.898–3 Determining the required year.

(a) Controlled foreign corporations.
(1) In general.
(2) One-month deferral election.
(3) Majority U.S. shareholder year.
(i) In general.
(ii) Passthrough entities.
(4) Inconsistent majority U.S. shareholder years.
(i) In general.
(ii) Formula for determining least aggregate deferral.
(iii) Illustrations.
(iv) Procedural requirements and effective date.
(5) Testing days.
(i) In general.
(ii) Illustration.
(iii) Additional testing days.
(iv) Illustration.
(v) Anti-abuse rule.
(b) Foreign personal holding companies.
(1) In general.
(2) One-month deferral election not available.
(3) Testing days.

§ 1.898–4 Special rules.

(a) Changes in the required year of a specified foreign corporation for its first taxable year beginning after July 10, 1989.
(1) In general.
(2) Procedure for a specified foreign corporation to conform to the required year for the first taxable year beginning after July 10, 1989.
(i) No section 898(c)(1)(B) election.
(ii) With section 898 (c)(1)(B) election.
(iii) Filing requirement.
(b) Changes in the required year of a specified foreign corporation during a taxable year of a specified foreign corporation subsequent to its first taxable year beginning after July 10, 1989.
(1) In general.
(2) Procedure for the change to a new required year of a specified foreign corporation for taxable years subsequent

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to its first taxable year beginning after July 10, 1989.
(i) Different majority U.S. shareholder year.
(ii) Election under section 898(c)(1)(B).
(iii) Procedure for prior years.
(iv) Making a second election under section 898(c)(1)(B).
(v) Procedure for obtaining the consent of the Commissioner to change the required year of specified foreign corporations.
(3) Short period.
(i) In general.
(ii) Illustrations.
(4) Conforming changes in the majority U.S. shareholder year.
(c) Nonconforming foreign and United States taxable years of a specified foreign corporation.
(1) In general.
(2) Computation of income and earnings and profits of a specified foreign corporation.
(i) Separate books of account.
(ii) Income and earnings and profits computation in lieu of separate books.
(iii) Illustration.
(3) 52–53-week taxable year.
(i) In general.
(ii) Majority United States shareholder with 52–53-week taxable year.
(iii) Specified foreign corporation with a 52–53-week taxable year.
(iv) Illustrations.
(4) Certain captive insurance companies that elect to treat their related person insurance income as income effectively connected with the conduct of a United States trade or business.
(d) Four-year income spread.

§ 1.898–1 Taxable year of certain foreign corporations.

(a) *In general.* Pursuant to section 898(a), the taxable year of a specified foreign corporation is the required year. The required year is generally the majority U.S. shareholder year. These regulations define specified foreign corporation and United States shareholder, for purposes of these rules, at § 1.898–2 (a) and (b)(3), respectively. The ownership requirements of a specified foreign corporation, which are a part of the definition of specified foreign corporation, are set forth at § 1.898–2(b) (1) and (2). A special rule for determining whether a foreign corporation that meets the ownership requirements of a foreign personal holding company is a specified foreign corporation as located at § 1.898–2 (c). Section 1.898–3 sets forth the rules for the determination of the required year, including rules by which a specified foreign corporation that is a controlled foreign corporation may elect a taxable year beginning one month earlier than the majority U.S. shareholder year. Section 1.898–4 sets forth special rules including rules at paragraphs (a) and (b) of that section on changes in the required year, rules at paragraph (c) of that section covering situations where the required year under section 898 is different from the specified foreign corporation's foreign taxable year (the taxable year for purposes of computing income tax liabilities due a foreign country), and rules at paragraph (d) of that section regarding the four-year spread of certain income.

(b) *Effective dates.* Sections 1.898–1 through 1.898–4 are effective for taxable years of specified foreign corporations beginning after July 10, 1989. However, §§ 1.898–3(a)(4) (regarding situations in which inconsistent majority U.S. shareholder years exist) and 1.898–3(a)(5)(iii) (regarding situations in which additional testing days are required) are effective for taxable years beginning after [Insert Date 120 Days After Date of Publication of Final Regulations in the **Federal Register**], and section 1.898–4(b) is effective for changes in the required year of a specified foreign corporation subsequent to its first taxable year beginning after July 10, 1989.

(c) *Exceptions to section 898*—(1) *Specified foreign corporations with no section 951(a) or foreign personal holding company income.* A specified foreign corporation is not required to conform its taxable year to the required year so long as its United States shareholders do not have any amount includible in gross income pursuant to section 951(a) and do not receive any actual or deemed distributions attributable to amounts described in section 553 with respect to that corporation. Once any United States shareholder of that specified foreign corporation has any amount includible in gross income pursuant to section 951(a) or receives any actual or deemed distributions attributable to amounts described in section 553 with respect to that corporation, then the specified foreign corporation must comply with section 898 and §§ 1.898–3 and 1.898–4 beginning with its first taxable year subsequent to the taxable year to which that shareholder's income is attributable. Once the specified foreign corporation is required to conform its taxable year to the required year, the fact that the shareholders of the corporation cease to have any such amount includible in gross income pursuant to section 951(a) or section 553 is not relevant. Section 898 continues to apply.

(2) *Elections to be treated as domestic corporations.* A foreign corporation that is a foreign insurance company and that elects to be treated as a domestic corporation pursuant to section 953(d) is treated as a domestic corporation for all purposes of the Code and, thus, is not subject to section 898. Likewise, a foreign corporation organized under the laws of a contiguous foreign country and described in section 1504(d) is not subject to section 898 if the foreign corporation is treated as a domestic corporation in accordance with section 1504(d).

§ 1.898–2 Definition of specified foreign corporation.

(a) *In general.* For purposes of section 898 and §§ 1.898–1 through 1.898–4, a specified foreign corporation means any foreign corporation with respect to which the ownership requirements of section 898(b)(2) and paragraph (b) of this section are met and which either is treated as a controlled foreign corporation for any purpose under sections 951 through 964 of the Code (including sections 957(a), 957(b) and 953(c)), or is a foreign personal holding company, as defined in section 552.

(b) *Ownership requirements*—(1) *In general.* The ownership requirements of section 898(b)(2) and this paragraph (b)(1) are met with respect to any foreign corporation if a United States shareholder owns, or is considered to own by applying the attribution rules set forth in paragraph (b)(2) of this section, on each testing day, more than 50 percent of the total voting power of all classes of stock of the foreign corporation entitled to vote, or more than 50 percent of the total value of all classes of stock of the foreign corporation.

(2) *Ownership by attribution.* For purposes of section 898(b)(2)(A) and paragraph (b)(1) of this section, the rules contained in the following sections of the Internal Revenue Code apply in determining ownership—

(i) Section 958 (a) and (b) for determining direct, indirect, and constructive stock ownership of a controlled foreign corporation;

(ii) Section 551(f) pertaining to the stock of a foreign personal holding company held through a foreign entity; and,

(iii) Section 554 for determining stock ownership of a foreign personal holding company.

(3) *Definition of United States shareholder*—(i) *In general.* For purposes of §§ 1.898–1 through 1.898–4, United States shareholder has the meaning given to it by section 951(b), except that, in the case of a foreign corporation having related person insurance income, as defined in section 953(c)(2), a person will be treated as a United States shareholder for purposes of section 898 if that person is treated as a United States shareholder under section 953(c)(1). *See* section 898(b)(3)(A).

(ii) *Certain captive insurance companies.* The determination of whether certain shareholders are United States shareholders under section 953(c)(1) and, consequently, whether the foreign corporation is a controlled foreign corporation for a particular taxable year, depends on the proportion of related person insurance income to total insurance income earned by the foreign corporation during the taxable year. If the related person insurance income of the foreign corporation is less than 20 percent of its total insurance income for the year, then the special rules of section 953(c) for captive insurance companies will not apply. The determination of whether the related person insurance income of a foreign corporation is less than 20 percent of its total insurance income for a particular taxable year cannot be made until the end of that year. Consequently, a foreign corporation that derives related person insurance income generally will not be required to consider non-10 percent United States shareholders (*i.e.*, persons who are United States shareholders only because of the special captive insurance rules) in determining whether it is a controlled foreign corporation on the first day of the foreign corporation's taxable year to determine further whether it is a specified foreign corporation and, therefore, subject to section 898, unless the foreign corporation was treated as a controlled foreign corporation because of the special captive insurance rules for the immediately preceding taxable year. When a foreign corporation is both a captive insurance company and a specified foreign corporation, it must consider all persons who are United States shareholders under both sections 951(b) and 953(c) in determining its required year.

(iii) *Foreign personal holding companies.* In the case of any foreign personal holding company as defined in section 552, which is not also a specified foreign corporation by reason of being a controlled foreign corporation under section 898(b)(1)(A)(i), United States shareholder means any person who is treated as a United States shareholder under section 551(a).

(4) *Illustrations.* The application of this paragraph (b) may be illustrated by the following examples:

Example 1. Z is a publicly traded United States corporation that owns all of the outstanding stock of FY, a foreign corporation. FY is not a foreign personal holding company. FY owns 51 percent (of both voting power and value) of all of the outstanding stock of FX, which is also a foreign corporation. The remainder of the stock is owned by an unrelated foreign corporation. FY is a controlled foreign corporation and a specified foreign corporation. In addition, pursuant to section 958(a)(2), Z is considered to own its proportionate share (*i.e.*, 51 percent) of the stock of FX which is owned by FY. Thus, FX is also both a controlled foreign corporation and specified foreign corporation, as defined in section 898(b) and this section.

Example 2. Z is a United States citizen who owns 51 percent of the value, but none of the voting stock, of FY, a foreign corporation. The remaining 49 percent of the value of FY, as well as all of FY's voting stock, is owned by a nonresident alien individual who is not related to Z. FY owns 51 percent (of both voting power and value) of all of the outstanding stock of FX, which is also a foreign corporation. FY is not a controlled foreign corporation because it does not have a United States shareholder within the meaning of section 951(b) (although if FY had related person insurance income it may be a controlled foreign corporation under the rules of section 953(c)). FY was a foreign personal holding company for its prior year. FY is a foreign personal holding company and a specified foreign corporation for the current year for purposes of section 898 because Z is a United States shareholder within the meaning of section 551(a) who owns 51 percent of the total value of the stock of FY. *See* section 552(a)(2)(B). Under section 551(f), however, the stock of FX owned by FY is not treated as being owned proportionately by Z. Accordingly, FX is not subject to section 898.

Example 3. FX has 20 equal shareholders, all of whom are related United States persons. Thus, FX does not qualify as a controlled foreign corporation under the general subpart F rules applicable to insurance companies because none of the United States persons are United States shareholders. However, if FX earns related person insurance income in a particular taxable year, then it will be considered a controlled foreign corporation for that year, unless the amount of the related person insurance income was less than 20 percent of its total insurance income for that year. If, in its taxable year ending December 31, 1990, FX earns related person insurance income in an amount that is less than 20 percent of its total insurance income and, thus, is not considered a controlled foreign corporation, then FX would not be required to determine its required year on January 1, 1991. Alternatively, if FX earns related person insurance income in its taxable year ending December 31, 1990, in excess of the 20 percent *de minimis* amount and, thus, is considered a controlled foreign corporation, FX would be required to determine whether it is a specified foreign corporation on January 1, 1991, and in making that determination, would be required to treat all United States persons owning its stock as United States shareholders.

(c) *Special rule for foreign personal holding companies that are not controlled foreign corporations*—(1) *In general.* A foreign corporation that is not a controlled foreign corporation for 30 days or more during the current taxable year will be required to determine whether it is a specified foreign corporation on any testing day during the current year only if the foreign corporation—

(i) meets the ownership requirements of section 552(a)(2) (ownership requirements for a foreign personal holding company) for the current taxable year, and

(ii) was a foreign personal holding company for its taxable year immediately preceding the current taxable year.

(2) *Illustrations.* The application of this paragraph (c) may be illustrated by the following examples:

Example 1. (i) FX is a foreign corporation that uses the calendar year as its taxable year. For calendar year 1989, its last taxable year beginning before the effective date of section 898, FX met the stock ownership requirements of section 552(a)(2) for a foreign personal holding company. More than 50 percent of the total value of all classes of stock of FX is owned by Y, a United States shareholder with a taxable year ending June 30. The remaining value of FX stock, and all of FX's voting stock, is owned by Z, a nonresident alien individual who is unrelated to Y. FX is not a controlled foreign corporation.

(ii) On January 1, 1990 (FX's first testing day after the effective date of section 898), FX examined its gross income for the taxable year ending December 31, 1989. FX met the gross income requirement of section 552(a)(1) for a foreign personal holding company for that year. Therefore, under the rules of this paragraph (c), FX was deemed to be a foreign personal holding company, for purposes of section 898, for the current taxable year beginning January 1, 1990. Accordingly, FX was required to determine whether it was a specified foreign corporation on January 1, 1990. FX was a specified foreign corporation on that date and, therefore, was required to change its taxable year to the required year ending on June 30.

Example 2. The facts are the same as in *Example 1*, with the additional fact that FX did not meet the gross income requirement for a foreign personal holding company for the short taxable year beginning January 1, 1990, and ending June 30, 1990. Nevertheless, FX will be required to maintain a taxable year beginning July 1, 1990, as its required year under section 898(c).

§ 1.898–3 Determining the required year.

(a) *Controlled foreign corporations*—(1) *In general.* The required year is the majority U.S. shareholder year prescribed in section 898 (c)(1)(C) and paragraph (a)(3) of this section. If, however, there are inconsistent majority U.S. shareholder years, then the required year is the taxable year prescribed in section 898(c)(1)(A)(ii) and paragraph (a)(4) of this section.

(2) *One-month deferral election.* A specified foreign corporation that is a controlled foreign corporation may elect

under section 898(c)(1)(B) and § 1.898–4(a)(2)(ii) and (b)(2)(ii) of this section a taxable year beginning one month earlier than the majority U.S. shareholder year. The specified foreign corporation may revoke this election; see § 1.898–4(b). If the specified foreign corporation revokes the election, it may re-elect the one-month deferral only if it follows the procedures set forth in § 2.898–4(b)(2) (iv) and (v). A specified foreign corporation that is a foreign personal holding company, but is not a controlled foreign corporation, may not make this election. Also, this election may not be made by a specified foreign corporation that is a controlled foreign corporation, but whose required year is the taxable year prescribed by section 898(c)(1)(A)(ii) and paragraph (a)(4) of this section because there are inconsistent majority U.S. shareholder years.

(3) *Majority U.S. shareholder year*—(i) *In general.* For the purpose of determining the required year of a specified foreign corporation, the majority U.S. shareholder year under section 898(c)(1)(C)(i) means the taxable year (if any) which, on each testing day as defined in paragraph (a)(5) of this section, constitutes the taxable year of a United States shareholder described in either paragraph (a)(3)(i) (A) or (B) of this section.

(A) Each United States shareholders, as defined in sections 898(b)(3)(A) and 1.898–2(b)(3),that owns more than 50 percent of the voting power of all classes of stock of the specified foreign corporation entitled to vote, or more than 50 percent of the total value of all classes of stock of the specified foreign corporation, after application of the attribution rules of section 898(b)(2)(B). This shareholder is described in section 898(b)(2)(A) and is referred to in this section as a "more than 50 percent United States shareholder."

(B) Each United States shareholder, as defined in section 898(b)(3)(A) and § 1.898–2(b)(3), that is not a more than 50 percent United States shareholder and whose stock was treated as owned under section 898(b)(2)(B) (the attribution rules) by a more than 50 percent United States shareholder.

(ii) *Passthrough entities.* For the purpose of determining the required year of a specified foreign corporation, if each United States shareholder described in paragraph (a)(3)(i)(A) or (B) of this section is a passthrough entity, such as an S corporation, partnership, trust, or estate, then the majority U.S. shareholder year is the taxable year which, on a testing day, constitutes the taxable year of the passthrough entity and not the taxable year or years of the passthrough entity's shareholders, partners, or beneficiaries.

(4) *Inconsistent majority U.S. shareholder years*—(i) *In general.* There may exist more than one majority U.S. shareholder year under section 898(c)(1)(C)(i) and paragraph (a)(3) of this section because the taxable years of shareholders described in paragraph (a)(3)(i)(A) or (B) of this section may be different taxable years. If the majority U.S. shareholder years are inconsistent, then the specified foreign corporation must adopt the taxable year that results in the least aggregate deferral of income to all United States shareholders of the specified foreign corporation, even if that taxable year is not a majority U.S. shareholder year. See paragraph (a)(4)(iii), *Example* 2, of this section. If the required year is the taxable year prescribed by this paragraph (a)(4) because there are inconsistent majority U.S. shareholder years, then the one-month deferral election under section 898(c)(1)(B) and paragraph (a)(2) of this section is not available.

(ii) *Formula for determining least aggregate deferral.* The aggregate deferral of income for a particular year is equal to the sum of the products determined by multiplying, on each testing day as defined in paragraph (a)(5) of this section, the number of month(s) of deferral for each United States shareholder, that are shareholders on the testing day, that would be generated by that year end by that United States shareholder's percentage interest in deemed distributions from the specified foreign corporation. The United States shareholder's taxable year that produces the lowest sum when compared to the other United States shareholders' taxable years is the taxable year that results in the least aggregate deferral of income to the United States shareholders. For purposes of this section, the number of months of deferral for a United States shareholder of a specified foreign corporation is measured by the number of months from the end of the taxable year of the specified foreign corporation to the end of the taxable year of the United States shareholder. Part of a month is treated as a month. If the calculation results in more than one taxable year qualifying as the taxable year with the least aggregate deferral, the specified foreign corporation may select any one of such taxable years as its required year. However, if one of such qualifying taxable years is also the specified foreign corporation's existing taxable year, the specified foreign corporation must maintain its existing taxable year.

(iii) *Illustrations.* The application of this paragraph (a)(4) may be illustrated by the following examples:

Example 1. (i) FX is a foreign corporation with two classes of stock, only one of which is voting stock. Each class of stock shares equally in distributions. FX has a June 30 taxable year. FX's shareholders, A, B and C are U.S. citizens. A owns 45 percent of each class of stock, B owns 35 percent of each class of stock, and C owns the remaining 20 percent of each class of stock. A is B's grandfather and C is unrelated to A and B. A and C are calendar year taxpayers. B's taxable year ends on June 30. Under sections 958(b)(1) and 318(a)(1)(A), A is considered to own the stock owned by B. Under section 898(c)(1)(C)(i)(I), A is a more than 50 percent United States shareholder and under section 898(c)(1)(C)(i)(II), B is a United States shareholder whose stock is considered to be owned by a more than 50 percent United States shareholder. Accordingly, FX has two majority U.S. shareholder years, the calendar year and the fiscal year ending June 30. These majority U.S. shareholder years are inconsistent.

(ii) Beginning July 1, 1990, the first day of FX's first taxable year beginning after July 10, 1989, FX must conform its taxable year to the required year by adopting the taxable year that results in the least aggregate deferral of income, taking into consideration the taxable year of each United States shareholder, including C. The taxable year ending December 31 produces .35×6 (B's percentage share of distributions from FX multiplied by the number of months of deferral if December 31 is the required year), or a product of 2.1. The taxable year ending June 30 produces [.45×6] plus [.20×6] (A and C's percentage shares of distributions from FX multiplied by the number of months of deferral if June 30 is the required year), or a product of 3.9. Accordingly, the taxable year ending December 31 is the required year. However, if C's year end were also June 30, or if only the nonvoting stock shared in distributions and B owned all of the nonvoting stock, then the taxable year ending June 30 would produce the least aggregate deferral of income, and would be the required year.

Example 2. (i) LX is a calendar year foreign corporation with one class of stock. LX's shareholders, A, B and C are U.S. citizens. A is B's grandfather and C is unrelated to A and B. A owns 10 percent of LX's stock and has a taxable year ending June 30. B owns 45 percent of LX's stock and has a taxable year ending March 31. C owns the remaining 45 percent of LX and has a September 30 taxable year. Under sections 958(b)(1) and 318(a)(1)(A), A is considered to own the stock owned by B. Under section 898(c)(1)(C)(i)(I), A is a more than 50 percent United States shareholder and under section 898(c)(1)(C)(i)(II), B is a United States shareholder whose stock is considered to be owned by a more than 50 percent United States shareholder. Accordingly, LX has two inconsistent majority U.S. shareholder years, the fiscal year ending June 30 and the fiscal year ending March 31.

(ii) Beginning January 1, 1990, the first day of LX's first taxable year beginning after July

10, 1989, LX must conform its taxable year to the required year by adopting the taxable year that results in the least aggregate deferral of income, taking into consideration the taxable year of each United States shareholder. The taxable year ending June 30 produces [.45×3] plus [.45×9] (B and C's, respective percentage shares of distributions multiplied by the number of months of deferral), or a product of 5.4. The taxable year ending March 31 produces [.1×9] plus [.45×6] (A and C's percentage shares of distributions multiplied by the number of months of deferral), or a product of 3.6. The taxable year ending September 30 produces [.1×3] plus [.45×6] (A and B's percentage shares of distributions multiplied by the number of months of deferral), or a product of 3.0. Accordingly, September 30 is the required year.

(iv) *Procedural requirements and effective date.* This paragraph (a)(4) is effective for taxable years beginning after [Insert Date 120 Days After Date of Publication of Final Regulations in the **Federal Register**]. In order to show that the requirements of this paragraph (a)(4) are satisfied, a statement setting forth the computations required to establish the taxable year that results in the least aggregate deferral of income to the United States shareholders of the specified foreign corporation must be attached to Form 5471 and, if applicable, to Form 1120F, and must indicate the following at the top of page one of the statement: "FILED UNDER § 1.898–3(a)(4)."

(5) *Testing days*—(i) *In general.* A specified foreign corporation must identify its majority U.S. shareholder year(s), if any, for the purpose of determining its required year. The specified foreign corporation must determine its majority U.S. shareholder year on each testing day. In general, the testing day is the first day of the specified foreign corporation's taxable year for U.S. tax purposes, determined without regard to section 898. *See* section 898(c)(1)(C)(ii).

(ii) *Illustration.* The application of paragraph (a)(5)(i) of this section may be illustrated by the following example:

Example. FX is a foreign corporation that, prior to the effective date of section 898, used the calendar year as its taxable year. Thus, on January 1, 1990, the first day of FX's first taxable year beginning after July 10, 1989, FX determined whether it was a specified foreign corporation and, thus, required to change its taxable year to the required year under section 898(c). Based on this test, FX changed to a taxable year ending on June 30 (because FX was a specified foreign corporation and its majority U.S. shareholder year ends on June 30). Accordingly, FX had a short period taxable year for the period beginning January 1, 1990, and ending June 30, 1990. On July 1, 1990, the first day of its new taxable year, FX again tested to determine whether it was using the required year.

(iii) *Additional testing days.* For taxable years of specified foreign corporations beginning after [Insert date that is 120 days after final regulations are published in the **Federal Register**], a specified foreign corporation must determine its majority U.S. shareholder year on each day, since the most recent testing day described in paragraph (a)(5)(i) of this section, on which a substantial change occurs in the United States ownership of the stock of the specified foreign corporation. A substantial change in the United States ownership of the stock of a specified foreign corporation is a change that results in a new more than 50 percent United States shareholder of the foreign corporation.

(iv) *Illustration.* The application of paragraph (a)(5)(iii) of this section may be illustrated by the following example:

Example. FX is a controlled foreign corporation with one class of stock and a taxable year ending on June 30. Y, the majority United States shareholder of FX, owns 51 percent of the stock of FX. Y also has a taxable year ending June 30. Thus, FX is a specified foreign corporation subject to section 898. On May 1, 1994, Y sold 10 percent of the stock in FX to Z, an unrelated United States corporation that owned 41 percent of the stock of FX before the sale. Z obtained, therefore, a sufficient amount of FX stock to qualify as a "more than 50 percent United States shareholder" of FX. Z has a taxable year ending on April 30. Consequently, on May 1, 1994, FX determined that its new required year was a taxable year ending April 30. FX has a taxable year ending June 30, 1994, and a short taxable year beginning July 1, 1994, and ending April 30, 1995. *See § 1.898–4 (b)(3).*

(v) *Anti-abuse rule.* The district director may require the use of a testing day other than that identified in paragraph (a)(5)(i) or (iii) of this section that will reflect more accurately the ownership of the specified foreign corporation and thereby the aggregate deferral of income to the United States shareholders of the specified foreign corporation where the United States shareholders engage in a transaction (or transactions) that has as its principal purpose the avoidance of the principles of this section. Thus, the anti-abuse rule of the preceding sentence would apply, for example, when there is a transfer of an interest in a specified foreign corporation that results in a temporary transfer of that interest principally for the purpose of qualifying for a specific taxable year under the principles of this section.

(b) *Foreign personal holding companies*—(1) *In general.* The required year is the majority U.S. shareholder year prescribed by section 898(c)(1)(A) and paragraph (a)(3) of this section. If, however, there are inconsistent majority U.S. shareholder years, then the required year is the taxable year determined under the provisions of paragraph (a)(4) of this section.

(2) *One-month deferral election not available.* A specified foreign corporation that is a foreign personal holding company, but is not a controlled foreign corporation, may not make the one-month deferral election of paragraph (a)(2) of this section.

(3) *Testing days. See* paragraph (a)(5) of this section.

§ 1.898–4 Special rules.

(a) *Changes in the required year of a specified foreign corporation for its first taxable year beginning after July 10, 1989*—(1) *In general.* A specified foreign corporation must conform its taxable year to the required year as defined in section 898(c) for taxable years beginning after July 10, 1989. In addition, section 898(c)(1)(B) permits a specified foreign corporation that is a controlled foreign corporation to elect a taxable year beginning one month earlier than the majority U.S. shareholder year.

(2) *Procedure for a specified foreign corporation to conform to the required year for the first taxable year beginning after July 10, 1989*—(i) *No section 898(c)(1)(B) election.* If no election under section 898(c)(1)(B) can be made because the specified foreign corporation is a foreign personal holding company, or no election is being made for a specified foreign corporation that is a controlled foreign corporation, but the specified foreign corporation is changing its first taxable year beginning after July 10, 1989, to conform to the required year, then unless the instructions to the forms provide otherwise, the words "Change in Taxable Year" must be placed in the upper left hand corner of the first page of Form 5471 and, if applicable, on Form 1120F, with respect to the specified foreign corporation for the taxable year for which the change is made. If a specified foreign corporation is not required to change its taxable year, then no notation concerning this fact need appear on Form 5471 and, if applicable, on Form 1120F.

(ii) *With section 898(c)(1)(B) election.* The election under section 898(c)(1)(B) may be made for a specified foreign corporation that is a controlled foreign corporation for its first taxable year beginning after July 10, 1989, by indicating on Form 5471 and, if applicable, on Form 1120F, that the taxable year shown on the form with

respect to the controlled foreign corporation was determined in accordance with section 898(c)(1)(B). The following words must be used unless the instructions to the forms provide otherwise:

(A) If the election involves a change in the taxable year of the controlled foreign corporation, the words "Section 898(c)(1)(B) Election—Change in Taxable Year" must be placed in the upper left hand corner of the first page of Form 5471 and, if applicable, on Form 1120F; and

(B) If the election does not involve a change in the taxable year of the controlled foreign corporation, the words, "Section 898(c)(1)(B) Election" must be placed in the upper left hand corner of the first page of Form 5471 and, if applicable, on Form 1120.

(iii) *Filing requirement.* If a specified foreign corporation changed its required year for its first taxable year beginning after July 10, 1989, to conform to the requirements of section 898 and § 1.898–3 but did not follow the procedures set forth in Rev. Proc. 90–26 and this paragraph (a)(2), a statement must be attached to the first Form 5471 and, if applicable, Form 1120F, to be filed after [Insert Date That is 120 Days After Date of Publication of Final Regulations in the **Federal Register**] indicating that the corporation's taxable year was changed to conform to the requirements of section 898. If a specified foreign corporation has not conformed its first taxable year beginning after July 10, 1989, to the taxable year required by section 898 and § 1.898–3, an amended return with an amended Form 5471 (or Form 1120F) must be filed to satisfy the requirements of section 898, § 1.898–3 and this paragraph (a)(2).

(b) *Changes in the required year of a specified foreign corporation during a taxable year of a specified foreign corporation subsequent to its first taxable year beginning after July 10, 1989*—(1) *In general.* A specified foreign corporation must conform its taxable year to a different required year should circumstances arise in which the required year changes under the rules of § 1.898–3, such as when a substantial change in ownership of a specified foreign corporation results in a new more than 50 percent United States shareholder with a different majority U.S. shareholder year. The change in taxable year of a specified foreign corporation made to conform to a different required year shall be treated as initiated by the taxpayer and as having been made with the consent of the Commissioner. The requirements set forth in this paragraph (b) are effective for taxable years subsequent to a specified foreign corporation's first taxable year beginning after July 10, 1989.

(2) *Procedure for the change to a new required year of a specified foreign corporation for taxable years subsequent to its first taxable year beginning after July 10, 1989*—(i) *Different majority U.S. shareholder year.* If the specified foreign corporation is changing its taxable year to conform to a different required year under paragraph (b)(1) of this section, unless the instructions to the forms provide otherwise, the words "Change in Taxable Year" must be placed in the upper left hand corner of the first page of Form 5471 and, if applicable, on Form 1120F, with respect to the specified foreign corporation for the taxable year for which the change is made. This paragraph covers terminations of prior elections under section 898(c)(1)(B) made in conjunction with that change.

(ii) *Election under section 898(c)(1)(B).* If the specified foreign corporation that is a controlled foreign corporation is changing its taxable year to conform to a different required year under paragraph (b) of this section and an election under section 898(c)(1)(B) is made, the change in taxable year and the election under section 898(c)(1)(B) are to be noted on Form 5471 and, if applicable, on Form 1120F, with respect to that corporation for the taxable year for which the change and election are made. Unless the instructions to the forms provide otherwise, the words "Section 898(c)(1)(B) Election—Change in Taxable Year" must be placed in the upper left hand corner of the first page of each form. This paragraph covers terminations of prior elections under section 898(c)(1)(B) made in conjunction with that election.

(iii) *Procedure for prior years.* If a specified foreign corporation conformed its taxable year to that required by section 898 and § 1.898–3 prior to [Insert Date That is 120 Days After Date of Publication of Final Regulations in the **Federal Register**] but did not follow the procedures set forth in this paragraph (b)(2), a statement must be attached to the first Form 5471 and, if applicable, Form 1120F, to be filed after [Insert Date That is 120 Days After Date of Publication of Final Regulations in the **Federal Register**] indicating that the corporation's taxable year was changed to conform to the requirements of section 898 and § 1.898–3. If a specified foreign corporation has not conformed a taxable year subsequent to its first taxable year beginning after July 10, 1989, to the taxable year required by section 898 and § 1.898–3, an amended return, with an amended Form 5471 (or Form 1120F) must be filed to satisfy the requirements of section 898, § 1.898–3 and this paragraph (b)(2).

(iv) *Making a second election under section 898(c)(1)(B).* Except for an election under section 898(c)(1)(B) that is made in conjunction with a change in its taxable year to conform to a different required year under paragraph (b)(2)(ii) of this section, a specified foreign corporation that has elected the one-month deferral under section 898(c)(1)(B) and subsequently revoked that election shall not be eligible to make an election under section 898(c)(1)(B) for any taxable year before its fifth taxable year which begins after the first taxable year for which the revocation is effective, unless the consent of the Commissioner pursuant to the procedures set forth in paragraph (b)(2)(v) of this section is obtained.

(v) *Procedure for obtaining the consent of the Commissioner to change the required year of specified foreign corporations.* In the circumstance described in paragraph (b)(2)(iv) of this section, a specified foreign corporation must request the approval of the Commissioner for a change in taxable year by completing and filing Form 1128 (Application for Change in Accounting Period) with the Commissioner of Internal Revenue. The application may be filed either by the majority United States shareholder on behalf of the specified foreign corporation or by the specified foreign corporation. The application must be filed on or before the 15th day of the second calendar month following the close of the short period for which a return is required to effect the change in taxable year. Reference to this regulation must be made part of the application by placing the following statement at the top of page one of the application: "FILED UNDER § 1.898–4." Approval of a change in taxable year described in paragraph (b)(2)(iv) of this section will not be granted unless the taxpayer agrees to the terms, conditions, and adjustments, as set forth by the Commissioner, under which the change will be effected. Unless the instructions to the forms indicate otherwise, re-election of section 898(c)(1)(B) must be noted on Form 5471 and, if applicable, on Form 1120F, for the taxable year for which the re-election is made. Unless the instructions to the forms indicate otherwise, the words "Re-elected Section 898(c)(1)(B) Election—Change in Taxable Year" must be placed in the upper left hand corner of the first page of each form.

(3) *Short period*—(i) *In general.* Any short period required for a specified foreign corporation to effect the change in taxable year described in paragraph (b)(1) of this section will begin on the first day of the specified foreign corporation's current taxable year and will end on the last day of the new required year within which the change in ownership of the specified foreign corporation (or other event that necessitates a change in taxable year) occurs. If, however, the last day of the specified foreign corporation's current taxable year occurs prior to the last day of the new required year within which the change in ownership of the specified foreign corporation (or other event resulting in a new required year) occurs, then the short period will begin the day following the last day of the specified foreign corporation's current taxable year and end on the last day of the new required year subsequent to the required year within which the change in ownership of the specified foreign corporation (or other event resulting in a new required year) occurred. In no case shall the taxable year of the specified foreign corporation be in excess of one year.

(ii) *Illustrations.* The application of this paragraph (b)(3) may be illustrated by the following examples:

Example 1. FX is a foreign corporation that is a specified foreign corporation within the meaning of section 898(b). FX had been a calendar year taxpayer. On July 1, 1991, FX was purchased by a United States shareholder with a September 30 fiscal year. Accordingly, the short period required to change the taxable year of FX to the required year began on January 1, 1991, the first day of FX's current taxable year, and ended on September 30, 1991, the last day of the new required year within which the change in ownership of FX occurred.

Example 2. The facts are the same as in *Example 1* except that on July 1, 1991, FX was purchased by a United States shareholder with a June 30 fiscal year. Accordingly, the short period required to change the taxable year of FX to the required year did not begin until January 1, 1992, the day following the last day of FX's current taxable year because the last day of FX's current taxable year occurs prior to the last day of the new required year within which the change in ownership occurred. The short period will begin January 1, 1992, and will end June 30, 1992.

(4) *Conforming changes in the majority U.S. shareholder year.* The requirements of section 898 and §§ 1.898–3 and 1.898–4 may be satisfied by a majority United States shareholder of a specified foreign corporation changing its taxable year to conform to the taxable year of the specified foreign corporation. However, any change to the United States shareholder's taxable year requires the approval of the Commissioner, and must be made in accordance with section 442 and the regulations under that section, relating to changes of annual accounting period.

(c) *Nonconforming foreign and United States taxable years of a specified foreign corporation*—(1) *In general.* If a specified foreign corporation's foreign taxable year (for purposes of computing income tax liabilities due a foreign country) does not conform to the required year pursuant to section 898(c) and § 1.898–3, then the United States shareholders must compute any income inclusion relating to the specified foreign corporation including, but not limited to, subpart F income, increase in earnings invested in United States property, foreign personal holding company income, and section 864(d) income in accordance with the rules set forth in paragraphs (c)(2) and (3) of this section. However, see section 338 and the regulations under that section for rules applicable to certain domestic and foreign corporations, and the shareholders of those corporations where an election under that section is made.

(2) *Computation of income and earnings and profits of a specified foreign corporation*—(i) *Separate books of account.* A specified foreign corporation that has a foreign taxable year different from its required year, as determined under section 898(c) and § 1.898–3, will have portions of two foreign annual accounting periods in each required year. In this case, either separate books of account for the specified foreign corporation based upon the required year may be maintained, or income (and earnings and profits) shall be computed as set forth in paragraph (c)(2)(ii) of this section. Books of account must be maintained on a consistent basis for each foreign annual accounting period.

(ii) *Income and earnings and profits computation in lieu of separate books.* In lieu of maintaining separate books of account, income and earnings and profits shall be computed in two steps. First, for the foreign annual accounting period of the specified foreign corporation which ends within its required year, the income (and earnings and profits) of the specified foreign corporation is the entire income (or earnings and profits) of the foreign annual accounting period, less the income (or earnings and profits), if any, of that foreign annual accounting period properly allocable to the preceding taxable year, determined under a consistent application of the principles of section 964 and the regulations under that section. Second, for the foreign annual accounting period of the specified foreign corporation which ends after its required year, the income (and earnings and profits) of the specified foreign corporation is the income (and earnings and profits) of each month (or quarter) which has ended within the required year determined on the basis of interim actual book closings and computed by a consistent application of the principles of section 964 and the regulations under that section. If the amount of income properly includable in the gross income of United States shareholders in the preceding taxable year is different from the amount of income actually included by United States shareholders in the preceding taxable year, then an adjustment must be made by each United States person affected by means of an amended return for that preceding taxable year.

(iii) *Illustration.* The application of this paragraph (c)(2) may be illustrated by the following example:

Example. (i) FX is a specified foreign corporation organized in foreign country, FC. FX's annual accounting period and taxable year, for FC purposes, end March 31. FX's required year is the calendar year. FX did not conform its FC taxable year to the required year. Separate books for United States tax purposes are not maintained. Accordingly, FX's required year, Calendar Year 1, will include portions of two FC annual accounting periods and FC taxable years.

(ii) For the FC period ending March 31, during Calendar Year 1, FX's income (in U.S. dollars) was $1,000, all of which was foreign personal holding company income. This amount was determined on the basis of FX's annual March 31, FC financial reports, adjusted in accordance with section 964 and the regulations under that section. Of the $1,000, it was determined from the annual financial reports that $350 was earned during the months ending in Calendar Year 1. For the period April 1, during Calendar Year 1, to the end of Calendar Year 1, FX's income was $1,200, determined on the basis of FX's monthly interim FC books of account. Accordingly, the income of FX subject to inclusion in the gross income of United States shareholders for Calendar Year 1, is $1,550. However, based on FX's annual March 31, Year 2, financial reports (adjusted in accordance with section 964 and the regulations under that section), FX's income for the period April 1, during Calendar Year 1, to the end of Calendar Year 1 was $1,300, not $1,200. Accordingly, each United States shareholder of FX must file an amended return for Calendar Year 1 showing its portion of the additional $100 of income.

(3) *52–53-week taxable year*—(i) *Majority United States shareholder with a 52–53-week taxable year.* If a majority United States shareholder elects to follow a 52–53-week taxable year (determined under section 441(f) and the regulations under that section), and

the specified foreign corporation does not intend to follow a 52–53-week taxable year, then the required year of the specified foreign corporation, as determined under section 898(c) and § 1.898–3, shall be a 12-month taxable year, which must end on the last day of the same month used in determining the 52–53-week taxable year of its majority United States shareholder. If the election of the one-month deferral under section 898(c)(1)(B) and § 1.898–3(a)(2) is made, the election will be valid, and the specified foreign corporation may retain a 12-month taxable year, subject to the condition that the 12-month taxable year must end on the last day of the month which immediately precedes the month used in determining the 52–53-week taxable year of its majority United States shareholder.

(ii) *Specified foreign corporation with a 52–53-week taxable year.* If a specified foreign corporation elects to follow a 52–53-week taxable year, and the majority United States shareholder does not intend to follow a 52–53-week taxable year, then the required year, as determined under section 898(c) and § 1.898–3, of the specified foreign corporation shall be a 52–53-week taxable year, which must end within a seven-day period from the last day of the 12-month taxable year of its majority United States shareholder. If the election of the one-month deferral under section 898(c)(1)(B) and § 1.898–3(a)(2) is made, the election will be valid and the specified foreign corporation may retain a 52–53-week taxable year, subject to the condition that the 52–53-week taxable year must end within a seven-day period from the last day of the month which immediately precedes the 12-month taxable year of its majority United States shareholder.

(iii) *Illustrations.* The application of this paragraph (c)(3) may be illustrated by the following examples:

Example 1. X is a United States corporation created on January 1, 1990, that elected to follow a 52–53-week taxable year which ends on the Friday nearest the end of December. Thus, X's first United States taxable year began on Monday, January 1, 1990, and ended on Friday, December 28, 1990; its next taxable year began on Saturday, December 29, 1990, and ended on Friday, January 3, 1992. X owns 100 percent of FY, a specified foreign corporation that is a controlled foreign corporation which follows a 12-month taxable year ending on November 30. In these circumstances, X's taxable year may end either earlier or later than one month after the end of FY's taxable year. Nonetheless, an election under section 898(c)(1)(B), which would permit FY to retain its current taxable year, will be effective because FY's taxable year ends on the last day of the month which immediately precedes the same month used in determining the 52–53-week taxable year of X, its majority United States shareholder.

Example 2. Y is a United States person with a taxable year ending September 30. Y also is the majority United States shareholder of FX, a specified foreign corporation which is a controlled foreign corporation that wishes to make the one-month deferral election under section 898(c)(1)(B). FX follows a 52–53-week taxable year that ends on the Monday closest to the last day of August. In 1990, the last day of August fell on a Friday. Thus, FX's taxable year ended on Monday, September 3, 1990, a date within a seven-day period from the last day of the month which immediately precedes the 12-month taxable year of its majority United States shareholder, Y. In 1994, FX's taxable year will end on Monday, August 29, and its next taxable year will begin on August 30, 1994. Thus, in 1994, FX's taxable year will begin more than one month before the beginning of Y's United States taxable year. Nevertheless, the election made under section 898(c)(1)(B) will be effective because FX's taxable year will end within a seven-day period from the last day of the month which immediately precedes the 12-month taxable year of its majority United States shareholder.

(4) *Certain captive insurance companies that elect to treat their related person insurance income as income effectively connected with the conduct of a United States trade or business.* Section 953(c)(3)(C) permits a foreign corporation to elect to treat its related person insurance income as income effectively connected with the conduct of a trade or business in the United States. Under § 1.953–7(c)(3) of proposed regulations, such a foreign corporation must utilize the calendar year as its annual accounting period for United States tax purposes, as required by section 843. Further, if an election is made for the first taxable year beginning after December 31, 1987, or any subsequent taxable year, the election is effective from the first day of the taxable year for which the election is made (and all subsequent taxable years). Therefore, a foreign corporation that has a fiscal taxable year prior to making the election must file a short-year return for the period from the first day the election becomes effective to the last day of the calendar year in which the election is made. The rules under section 953(c)(3)(C) and § 1.953–7 will prevail over the rules under section 898 and this section. Thus, if a captive insurance company that is a specified foreign corporation makes an election pursuant to section 953(c)(3)(C) and § 1.953–7(c), it must use the calendar year as its annual accounting period for United States tax purposes, regardless of the taxable year of its majority United States shareholder. However, if a captive insurance company that is a specified foreign corporation does not make the election pursuant to section 953(c)(3)(C) and the regulations thereunder, it must conform its United States taxable year to that of its majority United States shareholder.

(d) *Four-year income spread.* For its first taxable year beginning after July 10, 1989, if, because of the change necessitated by section 898 in the taxable year of the specified foreign corporation, any United States person was required to include in gross income for one taxable year amounts attributable to two taxable years of the specified foreign corporation, the amount that the United States person would otherwise have included in gross income for the one taxable year by reason of the short taxable year of the specified foreign corporation resulting from the change shall be included in that person's gross income ratably over a four-taxable-year period beginning with that one taxable year. A United States person who is required by reason of section 898 to include in gross income amounts attributable to two taxable years of a specified foreign corporation may not waive the four-year ratable inclusion of such gross income.

Shirley D. Peterson,

Commissioner of Internal Revenue.

[FR Doc. 92–31469 Filed 12–31–92; 8:45 am]

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26 CFR Part 1

[INTL–0045–92]

RIN 1545–AL24

Change From Profit and Loss Method to DASTM

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed Income Tax Regulations relating to adjustments required when a qualified business unit (QBU) that used the profit and loss method of accounting in a post-1986 taxable year begins to use the dollar approximate separate transactions method of accounting (DASTM). The regulations provide rules for taxpayers to construct an opening dollar balance sheet for the QBU and require certain income adjustments in connection with this change in accounting method.

DATES: Comments and requests for a public hearing must be received by March 8, 1993.

ADDRESSES: Send comments and requests for a public hearing to: Internal

Revenue Service, P.O. Box 7604, Ben Franklin Station, Attention: CC:CORP:T:R (INTL–0045–92), room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Jacob Feldman at (202) 622–3870 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 985 of the Internal Revenue Code of 1986. These amendments are proposed to change the applicable rules with respect to a QBU that changes to the dollar approximate separate transactions method of accounting (DASTM).

General rules providing for adjustments for QBUs changing functional currency are provided in § 1.985–5. Transition rules for a QBU that uses DASTM for its first taxable year beginning in 1987 are provided in § 1.985–6. Those regulations were published as temporary and proposed regulations in the Federal Register on September 20, 1989 (54 FR 38649) and are finalized with minor changes in the accompanying Treasury decision. These proposed regulations are in response to taxpayer comments that the spot exchange rate translation convention of § 1.985–5 produces inappropriate results when a QBU changes to DASTM in a post-1987 taxable year. These regulations would replace § 1.985–5 for taxpayers with a QBU that begins to use DASTM in a taxable year beginning 30 days after the regulations are finalized and for taxpayers that elect to apply the regulations retroactively.

For post-1986 taxable years, sections 986(b) and 987 generally require taxpayers to compute the taxable income or loss of a QBU that is a foreign branch, and the earnings and profits (E&P) of a QBU that is a foreign corporation, in the QBU's functional currency using a profit and loss (P&L) method.[1] Under the P&L method, exchange gain or loss on earnings resulting from exchange-rate fluctuations that occur after earnings are included in income generally is deferred until the earnings are remitted. When earnings are remitted from a branch, or when a controlled foreign corporation (CFC) makes a distribution of previously taxed earnings and profits, exchange gain or loss is recognized to the extent that the dollar value of the remittance differs from the dollar value of the earlier income inclusion.

The deferral of exchange gain and loss that the P&L method allows may create significant distortions relative to the dollar when a QBU makes its income tax determinations using a hyperinflationary currency. One such distortion is the overstatement of income and E&P for QBUs with substantial depreciable assets. This occurs because, in terms of the hyperinflationary currency, sales revenues increase as the currency inflates, but depreciation and amortization deductions, which are based on hyperinflationary currency cost bases, remain constant.

Income and expense derived from financial assets and liabilities also may be distorted in dollar terms. For example, a QBU that borrows in a hyperinflationary currency pays a high nominal rate of interest, which is offset by an exchange gain (relative to the dollar) on the principal amount of the liability when it is repaid in depreciated local currency. Under the P&L method, however, recognition of the offsetting exchange gain on the QBU's hyperinflationary currency liabilities is deferred. Thus, under the P&L method, large interest deductions shelter other income of QBUs that are net borrowers, and income tends to be understated. Conversely, the income of QBUs that hold net financial assets in the hyperinflationary currency tends to be overstated under the P&L method, because such QBUs accrue large amounts of interest income while deferring the offsetting exchange losses on the loan principal.

Because in these situations use of the P&L method does not clearly reflect income, the regulations under section 985 permit QBUs that would otherwise have a hyperinflationary functional currency to elect to use the dollar and to compute income and E&P using a version of the net worth method of accounting,[2] the dollar approximate separate transactions method (DASTM). Proposed amendments to the regulations under § 1.985–3 published on July 17, 1991 would make DASTM mandatory for these QBUs.

DASTM uses historical exchange rates to translate into dollars the hyperinflationary currency basis of fixed assets and accumulated depreciation, which preserves the dollar value of depreciation deductions. Spot exchange rates are used to revalue the hyperinflationary currency basis or amount of certain of the QBU's financial assets and liabilities in determining the closing dollar balance sheet, which results in the current recognition of exchange gain or loss that offsets the overstatement of interest income or expense.

Under § 1.985–6, a QBU that elects DASTM for its first post-1986 taxable year may use its 1986 year-end dollar tax balance sheet, if any, as the starting point for its DASTM computations beginning in 1987. Generally, a U.S. taxpayer that used a net worth method in computing the pre-1987 income or loss of a foreign branch, and a U.S. taxpayer owning an interest in a controlled foreign corporation that had had a "significant event" requiring the preparation of a dollar balance sheet under § 1.964–1 prior to 1987, will have these records. Such a dollar balance sheet generally reflects the use of historical exchange rates to translate the foreign currency basis of fixed assets and long-term liabilities and the use of current exchange rates to translate the basis or amount of certain short-term financial and other assets and liabilities. Sections 1.985–6(b) and (e). U.S. shareholders of foreign corporations that begin using DASTM in 1987 but had not been required to compute earnings and profits in dollars prior to 1987 must use similar rules to set up an opening dollar balance sheet. Section 1.985–6(c).

In contrast, U.S. taxpayers that used a P&L method to account for the income or loss of a foreign branch prior to 1987 and that elect DASTM in 1987 must translate each item on the hyperinflationary currency balance sheet into dollars using the exchange rate in effect at the time the dollar election is made. See § 1.985–6(f). Use of spot (rather than historical) exchange rates also is required under the general

[1] Under the P&L method, the QBU maintains an income statement in foreign currency and translates the relevant amounts into dollars when such amounts are included in income for U.S. tax purposes. Section 989(b) provides translation rules for converting the foreign functional currency amounts into dollars.

[2] A net worth method uses a dollar balance sheet, rather than a foreign currency income statement, to measure earnings. Under this method the income or loss (or earnings and profits) of a QBU for the taxable year is the difference between the QBU's dollar net worth (assets minus liabilities) at the end of the year and its dollar net worth at the beginning of the year, adjusted for capital contributions and distributions.

A version of the net worth method was mandatory under pre-1987 law for computing the E&P of a CFC for purposes of subpart F unless the CFC kept dollar books using a separate transactions approach. See § 1.964–1. However, for purposes of measuring income inclusions and foreign tax credits under section 902 with respect to an actual dividend distribution, earnings and profits of a foreign corporation were computed in foreign currency using a P&L method. Taxpayers could elect to use either a P&L method or a net worth method to compute the taxable income or loss of a foreign branch in pre-1987 years. See generally Rev. Rul. 75–106, 1975–1 C.B. 31, and Rev. Rul. 75–107, 1975–1 C.B. 32.

rule of § 1.985–5 when a QBU branch or foreign corporation that used the P&L method in a post-1986 taxable year changes to DASTM.

The translation convention adopted by § 1.985–5 and § 1.985–6(f) (translation of the balance sheet into the new functional currency deferral of unrealized exchange gains and losses that were not recognized while the QBU used the P&L method. (However, certain income adjustments are required under § 1.985–5(b), (d)(2), and (e)(2) in connection with the spot rate rule.) The Service adopted the spot rate translation rule because it is relatively easy to apply and avoids the need, discussed in more detail below, for additional income adjustments in connection with the change in method.

One commenter objected to the application of different translation conventions depending on whether a foreign corporation that is a QBU begins to use DASTM in 1987 or in a later year. The use of historical exchange rates to determine the dollar basis of fixed assets will preserve the dollar value of depreciation deductions in determining the dollar earnings and profits of the foreign corporation, an attribute that is lost if the hyperinflationary currency cost basis is translated at the current spot exchange rate. Another taxpayer suggested that the use of historical exchange rates would permit increased reliance on financial accounting data in determining depreciation deductions and other tax accounting adjustments under DASTM. Closer conformity to financial accounting records is an important simplifying objective of the proposed amendments to § 1.985–3 and other proposed amendments to regulations under section 964 governing book-to-tax adjustments that are required in computing earnings and profits.

These proposed regulations are in response to the suggestion in these comments that equitable and administrative concerns that favor some use of historical exchange rates combined with an income adjustment outweigh the simplification benefits of the spot rate transition rule. The following discussion explains why income adjustments are necessary when historical exchange rates are used to translate certain balance sheet items from a hyperinflationary currency into dollars in the case of (1) a QBU branch that computed income or loss under the P&L method and that begins to use DASTM in any post-1986 taxable year, and (2) a CFC that used the P&L method in a post-1986 taxable year and subsequently begins to use DASTM.

In the case of a foreign branch, use of a combination of current and historical exchange rates to translate balance sheet items into dollars requires an income adjustment to the extent the equity reflected on the dollar balance sheet differs from the taxpayer's dollar basis in the branch determined under the P&L method. This adjustment is necessary because the effect of using DASTM translation rules is to step up (or down) the dollar basis of the branch's net assets to reflect amounts that would have been included in income in prior years under DASTM but were not taxed under the P&L method.

For example, a taxpayer with a QBU branch that is financed with short-term hyperinflationary debt would have recognized exchange gains with respect to the principal of the debt under DASTM but not under the P&L method. The DASTM balance sheet (which translates the basis of the fixed asset at the historical exchange rate and the amount of the short-term liability at the current spot rate) will reflect these previously unrecognized exchange gains in equity. An income adjustment is required to ensure that the taxpayer's dollar equity in the branch reflects only previously-taxed amounts.

In the case of a foreign corporation that used the P&L method in a post-1986 taxable year, use of historical exchange rates to translate certain balance sheet items also results in a different dollar amount of retained earnings than would result from a spot rate translation of the foreign functional currency retained earnings accumulated under the P&L method. In the case of a noncontrolled foreign corporation, such an adjustment to undistributed earnings and profits would not necessarily result in current Federal income tax consequences because such earnings are subject to tax only on distribution. However, in the case of a CFC, where E&P computed under DASTM would have differed from E&P computed under the P&L method, an income adjustment at the shareholder level is appropriate to the extent a different amount of subpart F income would have been recognized under DASTM.

For purposes of subpart F in pre-1987 taxable years, earnings and profits and subpart F income were required to be computed under a net worth method similar to DASTM. Therefore, the Service believes that no subpart F income adjustment should be required with respect to pre-1987 taxable years in the case of a U.S. shareholder of a foreign corporation that uses DASTM beginning in 1987 or in any subsequent year. Such adjustments are necessary only in the case of branch earnings and post-1986 subpart F income, where the use of the P&L method resulted in a different income inclusion than would have resulted under DASTM.

For purposes of section 902 in pre-1987 taxable years, accumulated profits were computed using a P&L method. It might be argued that pre-1987 accumulated profits should be restated in dollars computed under a net worth method when a foreign corporation begins to use DASTM in a post-1986 taxable year, so that the corporation's total earnings and profits would be computed using a single method. However, the Service believes that such a rule would be inconsistent with the requirement of section 902(c)(6) that the tax effect of dividends paid out of pre-1987 earnings be determined under old law (using a P&L method) and also would be extraordinarily complex for taxpayers to implement. In addition, use of a net worth method rather than a P&L method to compute earnings generally would not alter the amount of a dividend inclusion with respect to a distribution out of pre-1987 earnings and profits (although it might alter the available foreign tax credit). Accordingly, the Service believes that use of DASTM translation conventions necessitates an income adjustment at the shareholder level only with respect to post-1986 subpart F income amounts.

Explanation of Provisions

The proposed regulations would amend the transition rules applicable to a QBU branch or foreign corporation that begins to use DASTM in a taxable year beginning after the proposed regulations are finalized. In addition, taxpayers may choose to apply the proposed rule retroactively as an alternative to applying the spot rate translation rule of § 1.985–5 (or § 1.985–5T) and § 1.985–6T(e). (For the text of the temporary regulations, see the April 1, 1992 edition of 26 CFR part 1 (1.908 to 1.1000)). Thus, U.S. shareholders who elect DASTM on behalf of a foreign corporation in an open post-1987 taxable year, but before the effective date of the proposed regulations, may apply the proposed rule to all prior open years instead of complying with the rules of § 1.985–5T. The proposed rule also may be applied retroactively to any open post-1986 year for which a U.S. taxpayer makes the DASTM election with respect to a QBU branch.

In the case of a foreign corporation that is not a CFC, the general rule would require the preparation of opening and closing dollar balance sheets for the year of change under the rules of § 1.985–3(c). Earnings and profits would be adjusted in the year of change. The

opening balance in the post-1986 undistributed earnings pool for the year of change would be determined by subtracting the accumulated earnings and profits determined under DASTM principles at the end of the foreign corporation's last taxable year beginning before 1987 (or, if section 902(c)(3)(A) applies, the last pre-acquisition year) from the accumulated earnings and profits determined under DASTM at the end of the taxable year ending before the year of change. No adjustments to income at either the corporate level or the shareholder level would be required.

Comments are requested as to whether this method of determining post-1986 earnings is an appropriate substitute for making annual DASTM computations for each post-1986 year, and in particular whether there is any need to compute the amount of DASTM earnings in each section 904(d) separate category for a foreign corporation that is not a CFC. Suggestions as to alternative methods are invited. Note that since the retained earnings on the dollar balance sheet for the year of change reflects both pre-1987 and post-1986 earnings computed in dollars under DASTM, subtracting the pre-1987 accumulated profits (translated from the old functional currency into dollars at the appropriate spot exchange rate) from the total retained earnings reflected on the dollar balance sheet for the year of change will not accurately reflect post-1986 earnings computed under DASTM.

In the case of a CFC or a noncontrolled foreign corporation subject to the special rules of § 1.904–6(a)(2), the proposed rule would apply the rules of § 1.985–3 in determining the opening dollars balance sheet for the year of change. The post-1986 undistributed earnings pool would be determined under DASTM for each post-1986 year (or later pre-acquisition year) prior to the year of change. An adjustment to income would be required at the shareholder level to the extent the aggregate amount of subpart F income in any section 904(d) separate category that was realized during the post-1986 period when the CFC had a foreign functional currency differs from the aggregate amount of subpart F income that would have been realized if the CFC had used DASTM for such years. Any excess of subpart F income determined under DASTM over that determined under the P&L method is deemed distributed to the CFC's United States shareholder(s) as subpart F income (along with associated deemed-paid foreign income taxes, if any) in the year of the change to DASTM. Generally, any positive or negative adjustment to income would be accounted for ratably over three years.

For taxpayers who choose to apply the revised transition rule to DASTM elections made in prior years, the Service believes that this adjustment with respect to subpart F income is necessary to avoid creating an opportunity for taxpayers to choose whether to elect DASTM in a prior, open year and compute subpart F income under DASTM for the intervening years, or to elect DASTM prospectively while avoiding any increased subpart F inclusions attributable to prior years. However, the Service is concerned that computation of the shareholder-level income adjustment may impose substantial administrative burdens in future years, should a CFC's functional currency become hyperinflationary after its earnings have been computed in a non-dollar functional currency using the P&L method for a number of post-1986 taxable years. Comments are requested as to whether a simpler method of approximately the appropriate adjustment to previously reported subpart F income might be utilized. Options being considered include requiring separate year DASTM computations for a limited period prior to the year of the change, such as the shorter of all post-1986 taxable years or the base years used to determined that the old functional currency becomes hyperinflationary, in which case the rules of § 1.985–5 would apply in preparing the opening balance sheet for the first year of the look-back period. Another possible method would treat a portion of the retained earnings on the historic dollar balance sheet as subpart F income based on an average historical ratio of subpart F income to total earnings and profits.

Alternatively, the Service is considering whether it might be preferable to retain the general rule of § 1.985–5 to use current spot exchange rates to translate balance sheet items, including earnings, with a special provision to allow the use of historical exchange rates to step up the basis of fixed assets to the extent of the dollar amount of the shareholder's unrealized exchange losses on paid-in capital. This approach would avoid the "disappearing plant" problem to the extent assets were funded with capital contributions, while denying a basis step-up (that must be accounted for by an income adjustment) to the extent assets were funded with hyperinflationary currency liabilities with respect to which exchange gains on repayment were not recognized under the P&L method. Comments are requested on these issues.

Under the proposed rule, in the case of a QBU branch, the taxpayer prepares an opening dollar balance sheet for the year of change in accordance with the rules of § 1.985–3. Any difference between the dollar amount of retained earnings reflected on this balance sheet and the taxpayer's dollar basis pool with respect to the branch must be included in income, generally over three years beginning with the year of change. This income or loss is characterized and sourced in the same manner as exchange gain or loss determined under section 987(3). Comments are requested as to the appropriateness of these character and source rules.

Special Analysis

It has been determined that these proposed rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Request for Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are timely submitted (preferably a signed original and eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying. A public hearing will be held upon written request by any person who submits written comments on the proposed rules. Notice of the time, place, and date for the hearing will be published in the Federal Register.

Drafting Information

The principal author of these proposed regulations is Barbara Felker of the Office of the Associate Chief Counsel (International), Office of Chief Counsel, Internal Revenue Service. Other personnel from the Internal Revenue Service and Treasury Department participated in developing the regulations.

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List of Subjects in 26 CFR 1.985–0 through 1.989(c)–1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendment to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 1.985–7 is added to read as follows:

§ 1.985–7 Adjustments required in connection with a change to DASTM.

(a) *In general.* If a QBU begins to use the dollar approximate separate transactions method of accounting set forth in § 1.985–3 (DASTM) in a taxable year beginning after [Date 30 days after the date final regulations are published in the **Federal Register**], the rules of § 1.985–3 shall apply in determining the QBU's opening and closing dollar balance sheets for the year of change as defined in § 1.481–1(a)(1). In addition, an adjustment to income shall be made to the extent required by this section. See paragraph (b) of this section for transition rules regarding earnings and profits adjustments, paragraph (c) of this section for rules with respect to adjustments to the income of United States shareholders of controlled foreign corporations, paragraph (d) of this section for rules with respect to adjustments to income with respect to QBU branches, and paragraph (e) of this section for the effective date of this section. For rules applicable to a QBU that used DASTM for its first taxable year beginning in 1987, see § 1.985–6.

(b) *Earnings and profits adjustments*—(1) *Pre-1987 accumulated profits.* The foreign income taxes and accumulated profits or deficits in accumulated profits of a foreign corporation that are attributable to taxable years of the foreign corporation beginning before January 1, 1987, and that were maintained for purposes of section 902 in the old functional currency, shall be translated into dollars at the spot exchange rate in effect on the first day of the foreign corporation's first taxable year beginning after December 31, 1986. Once translated into dollars, these pre-1987 taxes and accumulated profits or deficits in accumulated profits shall (absent a change in functional currency) remain in dollars for all federal income tax purposes.

(2) *Post-1986 undistributed earnings.* In the case of a controlled foreign corporation (within the meaning of section 957 or section 953(c)(1)(B)) (CFC) or a foreign corporation subject to the rules of § 1.904–6(a)(2), the corporation's post-1986 undistributed earnings in each separate category as defined in § 1.904–5(a)(1) as of the first day of the taxable year of change (and prior to adjustment under paragraph (c)(1) of this section) shall equal the sum of the earnings and profits (or deficit in earnings and profits) in such separate category determined under § 1.985–3 for each post-1986 taxable year (or such later year determined under section 902(c)(3)(A)) prior to the year of change, reduced by the aggregate dollar amount (translated from functional currency in accordance with the rules of section 989(b)) attributable to earnings and profits (including previously taxed earnings and profits within the meaning of sections 959 and 1293(c)) that were distributed or treated as distributed in prior years out of post-1986 earnings and profits in such separate category. In the case of all other foreign corporations, post-1986 undistributed earnings shall be determined by subtracting the accumulated earnings and profits determined under the principles of § 1.985–3 at the end of the foreign corporation's last taxable year beginning before January 1, 1987, or such later year determined under section 902(c)(3)(A), from the accumulated earnings and profits determined under § 1.985–3 at the end of the taxable year ending before the year of change.

(c) *United States shareholders of controlled foreign corporations*—(1) *Income adjustment*—(i) *Computation.* A United States shareholder (within the meaning of section 951(b) or section 953(c)(1)(A)) of a CFC that changes to DASTM shall adjust gross income in accordance with the rules of this paragraph (c)(1) to the extent that its pro rata share of the CFC's subpart F income in post-1986 years as determined under DASTM differs from the CFC's subpart F income as previously determined. The shareholder first shall compute, in each separate category, the sum of the CFC's subpart F income in post-1986 years as determined under DASTM for each post-1986 taxable year prior to the year of change (post-1986 DASTM subpart F income). The shareholder next shall compute, in each separate category, the sum of the CFC's subpart F income in post-1986 years as determined under the profit and loss method using the old functional currency and translated into dollars in accordance with section 989(b) for each post-1986 taxable year prior to the year of change (post-1986 P&L subpart F income). The shareholder then shall determine the difference, for each separate category in the post-1986 period, between the post-1986 DASTM subpart F income and the post-1986 P&L subpart F income.

(ii) *Manner of adjustment.* An excess of post-1986 DASTM subpart F income over post-1986 P&L subpart F income in any separate category shall be deemed distributed pro rata to the CFC's United States shareholder(s) on the first day of the taxable year of change. Any such deemed distribution shall be accounted for as an amount included in income under section 951(a)(1) for all federal income tax purposes (including sections 902, 959, 960, 961, 1248, and 6038). In addition, the CFC's United States shareholder(s) shall reduce gross income in a separate category to reflect a pro rata share of an excess of post-1986 P&L subpart F income over post-1986 DASTM subpart F income in that separate category. See section 904(f) and the regulations thereunder for rules applicable if an adjustment under this section results in a loss for the taxable year in a separate category. Adjustments under this section shall be taken into account by the shareholder ratably over three taxable years, beginning with the year of change, or any applicable shorter period. An appropriate adjustment shall be made to the basis of the shareholder's stock under section 961. Similar rules shall apply in determining adjustments to income of United States persons who have made an election under section 1295 to treat a passive foreign investment company as a qualified electing fund.

(2) *Foreign tax credit.* A United States shareholder of a CFC shall compute an amount of foreign taxes deemed paid under section 960 with respect to any deemed distribution determined under paragraph (c)(1) of this section. The amount of foreign taxes deemed paid shall be computed with reference to the full amount of the deemed distribution and to the post-1986 undistributed earnings determined under paragraph (b)(2) of this section and the post-1986 foreign income taxes of the CFC on the first day of the taxable year of change (*i.e.*, without taking into account earnings and taxes for the year of change). For purposes of section 960, the associated taxes in each separate category shall be allocated pro rata among, and deemed paid in, the shareholder's taxable year or years in which the income is taken into account. (No adjustment to foreign taxes deemed paid in prior years is required solely by

reason of a negative adjustment to income under paragraph (c)(1) of this section.)

(d) *QBU branches.* The adjustment required when a QBU branch of a taxpayer changes to DASTM shall be determined by subtracting the dollar amount of the taxpayer's basis pool with respect to the branch on the last day of the taxable year prior to the year of change from the dollar equity reflected on the branch's opening dollar balance sheet for the year of change, as determined under paragraph (a) of this section. The adjustment shall be taken into account by the taxpayer ratably over three taxable years, beginning with the year of change, or any applicable shorter period. The adjustment shall be characterized and sourced in the same manner as section 987 gain or loss.

(e) *Effective date.* This section is effective for taxable years beginning after [Date that is 30 days after the publication of final regulations in the **Federal Register**]. However, a taxpayer may choose to apply this section to all open taxable years beginning after December 31, 1986, provided each person, and each QBU branch of a person, that is related (within the meaning of § 1.985–2(d)(3)) to the taxpayer also applies these rules.

Michael P. Dolan,

Acting Commissioner of Internal Revenue.

[FR Doc. 92–31468 Filed 12–31–92; 8:45 am]

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26 CFR Parts 1, 20 and 25

[PS–102–88]

RIN 1455–AM85

Income, Gift and Estate Tax

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to income tax imposed under chapter 1, the estate tax imposed under chapter 11 and the gift tax imposed under chapter 12 of the Internal Revenue Code of 1986. Changes to the marital deduction provisions of the estate and gift tax chapters were made by the Technical and Miscellaneous Revenue Act of 1988. Further amendments were made by the Revenue Reconciliation Act of 1989, and the Revenue Reconciliation Act of 1990. The proposed regulations will provide the guidance needed to comply with the changes to the marital deduction provisions of the estate and gift tax chapters.

DATES: Written comments, requests to appear, and outlines of oral comments to be presented at the public hearing scheduled for March 2, 1993, must be received by February 16, 1993.

ADDRESSES: Send comments, requests to appear, and outlines to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attention: CC:CORP:T:R (PS 102–88), Room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the regulation, Susan Hurwitz or George Masnik at (202) 622–3090 (not a toll free call); concerning the hearing, Michael Slaughter, (202) 622–7190 (not a toll free call).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information requirements contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collection of information requirements and suggestions for reducing the burden should be sent to the Office of Management and Budget, Attention: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attention: IRS Reports Clearance Officer T:FP, Washington, DC 20224.

The collection of information requirements contained in these regulations are in §§ 20.2056A–2, 20.2056A–4, 20.2056A–10(a) and 20.2056A–10(b). This information is required by the Internal Revenue Service in order to administer the qualified domestic trust provisions in section 2056(d) and section 2056A. This information will be used to monitor qualified domestic trusts regarding their compliance with the statutory and regulatory requirements. The likely respondents are trustees and executors.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents may require greater or less time, depending on their particular circumstances. Estimated total annual reporting and recordkeeping burden: 7,650 hours. The estimated burden per respondent varies from 30 minutes to 3 hours, with an estimated average of 2 hours. Estimated number of respondents: 3,000. Estimated annual frequency of responses: one.

Background

This document contains proposed additions to the Income, Estate and Gift Tax Regulations (26 CFR parts 1, 20 and 25) under sections 1015, 2056, 2056A, 2101, 2102, 2106, 2503, and 2523 of the Code. The Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100–647) (the 1988 Act) added section 2056A to the Code and amended sections 2056, 2523, 2101, 2102, and 2106. Some of these sections have been further amended by the Revenue Reconciliation Act of 1989 (Pub. L. 101–239) (the 1989 Act), and the Revenue Reconciliation Act of 1990 (Pub. L. 101–508) (the 1990 Act). The 1988, 1989, and 1990 Acts place restrictions on the allowance of the estate and gift tax marital deduction where the surviving spouse (in the case of a transfer at death) or the donee spouse (in the case of a lifetime transfer) is not a citizen of the United States. In addition, the gift tax annual exclusion allowable in the case of a transfer to a noncitizen spouse was increased to $100,000. The statutory amendments also changed the tax rate and the amount of the unified credit applicable in the case of the estate of a decedent nonresident not a citizen of the United States (nonresident alien). The terms "resident" and "nonresident" are used in this document to refer to residence status for estate tax purposes only, and not for income tax purposes.

Explanation of Provisions

Overview

Prior to the enactment of the 1988 Act, section 2056 of the Code provided an unlimited estate tax marital deduction for estates of United States citizens or residents regardless of the citizenship of the surviving spouse. Similarly, under section 2523, the gift tax marital deduction was allowable for transfers by a United States citizen or resident to a spouse, regardless of the citizenship of the spouse. The 1988 Act placed restrictions on the availability of the estate tax marital deduction if the surviving spouse is not a United States citizen and eliminated the gift tax marital deduction if the donee spouse is not a United States citizen. These new rules are generally effective with respect to estates of decedents dying after November 10, 1988, and for gifts made on or after July 14, 1988. However, the 1989 Act (as amended by the 1990 Act) limited the application of these rules in the case of certain estate and gift tax transfers otherwise covered by certain tax treaties.

With respect to the estate tax, in the case of decedents dying after November 10, 1988, the marital deduction is

allowable for property passing to a noncitizen spouse only if the property passes (or is deemed to have passed) in a "Qualified Domestic Trust" (QDOT). An exception to this rule is provided if the surviving spouse becomes a citizen of the United States before the estate tax return is filed and the spouse was a resident of the United States (as defined for estate tax and not for income tax purposes) at all times after the date of the decedent's death and before becoming a United States citizen. Further, with certain exceptions, a deferred estate tax under section 2056A(b) of the Code is imposed on distributions of corpus from the QDOT during the spouse's lifetime and on the balance of the corpus held in the trust at the spouse's death.

Under section 2056(d) of the Code, property passing to a trust that does not satisfy the requirements for a QDOT may be reformed to qualify under section 2056A. Similarly, where an interest in property passes outright to a noncitizen surviving spouse, either by testamentary bequest or by operation of law, the property is treated as passing to the surviving spouse in a QDOT if the spouse (or the executor of the decedent's estate) transfers the property to a QDOT before the estate tax return is filed and during the time the QDOT election may be made. Alternatively, the spouse can assign the property to a QDOT under an enforceable and irrevocable assignment made on or before the date on which the return is filed and during the time that the QDOT election may be made. The spouse must thereafter transfer the property to the QDOT in a timely manner.

If the surviving spouse becomes a citizen of the United States after the establishment of a QDOT, special rules apply. If the surviving spouse has been a United States resident from the date of the death of the decedent or if no taxable distributions have been made from the QDOT prior to such time, the deferred estate tax no longer applies. If neither of these conditions is satisfied, the surviving spouse must make certain elections in order to avoid the future application of the deferred estate tax.

Where property is held by a United States citizen or resident decedent and a noncitizen surviving spouse as joint tenants or as tenants by the entirety, the joint property is subject to inclusion in the decedent's gross estate under section 2040(a) of the Code, based on the relative contribution of the decedent towards the purchase of the property and section 2040(b) (which provides for the inclusion of only one-half of the value of the property in the case of joint interests of husbands and wives) does not apply. A limited transition rule may apply to treat prior gifts to the spouse as the spouse's contributions for this purpose. In accordance with sections 2103, 2031, and 2040(a) of the Code, similar rules apply if the decedent was a nonresident alien and the spouse is not a United States citizen.

These new provisions are contained in sections 2056(d) and 2056A of the Code. In order to ensure that the new regulations are readily accessible, all of the proposed regulations are promulgated under section 2056A.

With respect to the gift tax, the statutory amendments eliminated the marital deduction for gifts made by a United States citizen or resident donor to a noncitizen spouse, effective for gifts made on or after July 14, 1988. However, the gift tax annual exclusion was increased to $100,000 for qualifying transfers to a noncitizen spouse. The statutory amendments also reinstated the principles of sections 2515 and 2515A (as such sections were in effect before their repeal by the Economic Recovery Tax Act of 1981) with respect to the creation of joint tenancies and tenancies by the entirety where the donee spouse is not a United States citizen, except that the provisions of section 2515 providing for an election to treat the creation of the tenancy as a gift do not apply.

The statutory amendments also substantially revised the estate and gift tax provisions previously applicable to nonresident aliens in a number of ways. First, the estate tax rates applicable to United States citizen and resident decedents are made applicable to estates of nonresident aliens. Second, the allowable unified credit is increased to $13,000. Where permitted by treaty, however, the estate of a nonresident alien is allowed the unified credit applicable to estates of United States citizen or resident decedents multiplied by the proportion of the total gross estate situated in the United States (compared to the entire gross estate, wherever situated).

The statutory amendments also provided, for the first time, that a nonresident alien decedent or donor is allowed the estate and gift tax marital deduction for qualifying transfers to a surviving or donee spouse on the same basis as a United States citizen or resident donor or decedent. Thus, a transfer to the surviving spouse of a nonresident alien decedent will qualify for the estate tax marital deduction if the requirements of section 2056 (including, subject to the special rules for treaties, the QDOT requirements) are satisfied. Similarly, a transfer by a nonresident alien donor to a spouse who is a United States citizen will qualify for the gift tax marital deduction if the requirements of section 2523 are satisfied. The statutory amendments also clarified that the increased $100,000 annual exclusion is available to a nonresident alien donor whose spouse is not a United States citizen. The changes made with respect to joint tenancy property between spouses are also made applicable to nonresident alien decedents and donors.

Qualified Domestic Trust

A QDOT is a trust that otherwise qualifies for the marital deduction under section 2056(b)(5) (life estate with power of appointment), section 2056(b)(7) (qualified terminable interest property), § 20.2056(e)–2(b)(1)(i)–(iii) of the Estate Tax Regulations (estate trust), or section 2056(b)(8) (lifetime beneficiary of a charitable remainder trust described in section 664), and that also meets the requirements of section 2056A(a). Those requirements are: (1) The trust must require that at least one trustee of the trust be an individual citizen of the United States or a domestic corporation; (2) the trust must provide that no distribution, other than a distribution of income, may be made from the trust unless a trustee who is an individual citizen of the United States or a domestic corporation has the right to withhold from the distribution the tax imposed by section 2056A(b) on the distribution; (3) the trust must meet any additional requirements as prescribed by regulations to ensure collection of any tax imposed; and (4) the executor must elect on the decedent's estate tax return to treat the trust as a QDOT. Even though the requirements for qualifying as a QDOT have been modified several times since the 1988 Act, the requirements as provided above are applicable for all decedents dying after November 10, 1988.

The legislative history underlying the 1988 Act expresses Congress' concern that insufficient assets might be subject to United States tax jurisdiction when the deferred estate tax imposed under section 2056A(b) becomes due, thus jeopardizing collection of the tax deferred upon the death of the first decedent. See H.R. Rep. No. 1104, 100th Cong., 2d Sess. 115 (1988). To protect against this possibility, section 2056A(a)(2) specifically authorizes the Secretary to promulgate regulations to ensure collection of the tax. These proposed regulations are issued pursuant to that authority. Under the proposed regulations, if the fair market value of the assets of the QDOT at the death of the first decedent exceeds $2 million, the trust instrument must

require that: (1) At least one trustee be a bank as defined in section 581, or (2) the trustee furnish a bond or security to the Service in an amount equal to 65 percent of the fair market value of the trust corpus, determined as of the date of the decedent's death, and subject to review. If the fair market value of the QDOT assets at the first decedent's death is $2 million or less, the QDOT need not meet the foregoing trustee or security requirements to qualify as a QDOT (although it may electively do so). As an alternative, if the trustee or security arrangements are not elected, the trust instrument of these smaller trusts must expressly provide that no more than 35 percent of the fair market value of the trust assets, determined annually, may be invested in real property that is not located in the United States.

In arriving at the $2 million dollar threshold, the Service weighed various factors including administrative burden, impact of institutional trustees' fees, and the need to ensure the collectability of the deferred estate tax. The Service believes that the $2 million threshold for requiring an institutional trustee appropriately balances these considerations. The Service requests comments as to whether a monetary threshold for imposing stricter trust requirements designed to provide greater assurance for collection of the tax is appropriate and if so, whether $2 million is the appropriate threshold.

The proposed regulations also contain an anti-abuse rule that provides for disqualification of a QDOT if the trust uses any device or arrangement that has as a principal purpose the avoidance of liability for the deferred estate tax. The regulations also require that the trustee report annually (by statement attached to the Form 1041 filed for the trust) regrading the trust's compliance with these regulatory requirements. Certain restrictions are also imposed on U.S. citizens who act as a trustee of the QDOT.

The Service will publish guidance in the Internal Revenue Bulletin pursuant to which either larger or smaller trusts can request approval for an alternate plan to assure collection of the deferred estate tax.

Section 20.2056A–13 contains a special effective date rule for implementing these requirements.

Election of Treat Trust as a QDOT

The QDOT election must be made by the executor on the last estate tax return filed before the due date or, if a timely return is not filed, on the first return filed after the due date. If the election is made on a late-filed return, it must be made no later than one year after the due date (including extensions).

The proposed regulations allow an executor to make a protective QDOT election if there is a bona fide legal controversy that would render the making of the election at the time the return is filed not feasible; for example, a controversy as to whether property otherwise eligible for the deduction is includable in the gross estate. However, due to the time-period restrictions imposed by the statute on the making of the election, a return must be filed making the protective election within the time period prescribed by the statute.

The proposed regulations do not permit an executor to make a partial QDOT election; that is, an election with respect to less than all of the property held in the QDOT (or deemed to be so held under the nonassignable annuity rules discussed below). Partial elections are not authorized by the statute and would present computational difficulties in determining the deferred estate tax in the event of a distribution of corpus from the trust.

Imposition of Deferred Estate Tax

Under section 2056A(b), a deferred estate tax is imposed in the case of certain "taxable events." In general, distributions from the trust during the spouse's lifetime constitute taxable events. However, distributions of income to the spouse and distributions of principal to the surviving spouse on account of hardship are exempted from the deferred tax. The tax is also imposed on the value of the trust corpus (1) at the time of the noncitizen surviving spouse's death, or (2) if the trust ceases to meet the requirements of a QDOT (including the requirements proposed by these regulations to ensure collection of the tax).

Regarding the exemption for lifetime distributions of income, section 2056A(c)(2) provides that except as provided by regulations, the term "income" has the same meaning as provided in section 643(b). This definition generally allocates items between principal and income based on local law and the terms of the governing instrument. However, the section 643(b) definition of income is modified under the proposed regulations to prevent the characterization as income of items that would normally be viewed as corpus, such as gain realized on the sale of a trust asset. In the absence of this modification, such items could be allocated to income under the terms of the trust and, thus, possibly be distributed without incurring a deferred estate tax. Accordingly, under the proposed regulations, items that would ordinarily be allocated to principal by applicable local law, such as capital gains, are treated as principal for purposes of determining whether the distribution is tax exempt, regardless of how the item is allocated under the terms of the trust. Items of income in respect of a decedent (IRD), described in section 691 of the Code, are treated as income or principal in accordance with the foregoing standards. Although the legislative history gives no indication of providing special treatment for IRD items, comments are requested as to the treatment of IRD for these purposes.

Regarding the hardship exemption, the proposed regulations define "hardship" generally in the same manner as does § 1.401(k)–1(d)(2)(i) (involving permissible distributions from certain deferred compensation plans). A distribution is made on account of hardship under the proposed regulations if the distribution is in response to an immediate and heavy financial need relating to the noncitizen surviving spouse's health, maintenance, or support. A distribution is not considered made on account of hardship to the extent that the amount distributed may be obtained from other sources that are reasonably available to the noncitizen surviving spouse or if the conditions of section 2056A(b)(2)(C), pertaining to the appointment of a designated filer in the case of multiple QDOTs, are not satisfied.

In the case of a taxable event, the deferred estate tax is the amount of tax that would have been imposed under section 2001 had the property subject to the tax been included in the first decedent's taxable estate. These proposed regulations define "the tax which would have been imposed" on a net basis (*i.e.*, after all applicable credits).

Generally, in computing the deferred estate tax, the rate of tax is determined by reference to the actual size of the first decedent's estate, as increased by the amount involved in the taxable event. However, the highest estate tax rate must be used if the tax imposed on the first decedent's estate has not been finally determined at the time of the taxable event, or if there is more than one QDOT with respect to the first decedent and the designated filer provisions of these proposed regulations are not complied with. Use of the highest rate of tax may be avoided in the case of multiple QDOTs if a designated filer is appointed to file the Form 706QDT and to pay the tax for all of the QDOTs.

The deferred estate tax imposed on lifetime distributions under section

2056A(b)(1)(A) is due on April 15th of the calendar year following the end of the taxable year in which the taxable event occurs, except for taxable events which occur during the calendar year in which the surviving spouse dies. In the latter case and for purposes of the tax imposed on the surviving spouse's death under section 2056A(b)(1)(B), the tax is due no later than 9 months after the date of the surviving spouse's death, unless an extension of time for payment is granted. The trustee of a QDOT is personally liable for the deferred estate tax and may make written application to the Service for a determination of the final deferred estate tax and for a discharge of personal liability. Under section 2056A(b)(8), the deferred estate tax is treated as an estate tax for purposes of the section 6324 estate tax lien provisions.

The proposed regulations impose certain limitations on the use of the section 2011 and section 2014 credits and extend the benefits allowed to the estate of a nonresident alien surviving spouse under section 2106(a)(2) (charitable deduction) and section 2106(a)(3) (marital deduction).

Credit for Tax on Prior Transfers

Section 2056(d)(3) provides two special rules for the application of the credit for tax on prior transfers provided under section 2013. First, if a marital deduction is allowed to the estate of the first spouse to die (the transferor) for QDOT property passing to the surviving spouse (the transferee), the deferred estate tax imposed is treated as an estate tax paid by the estate of the transferor spouse with respect to the QDOT property. Accordingly, if the transferee spouse's estate is subject to U.S. estate tax under sections 2001 or 2101, the deferred estate tax, whether imposed on distributions during the transferee spouse's lifetime under section 2056A(b)(1)(A) or on the transferee spouse's death under section 2056A(b)(1)(B), is creditable within the section 2013 framework against the transferee spouse's estate tax. The proposed regulations provide that the "first limitation" in determining the allowable credit is deemed to be the deferred estate tax imposed under section 2056A(b)(1). The Service considered a rule which would require that the first limitation be determined based on the methodology described in section 2013(b) and § 20.2013–2, with certain modifications. This approach was rejected because it would require complex computations and would raise difficult interpretative problems.

Section 2056(d)(3) provides a second special rule affecting the application of the section 2013 credit where property included in the transferor spouse's gross estate is not deducted under section 2056(a), solely because the property does not satisfy the alien spouse requirements under sections 2056(d) and 2056A (*e.g.*, the transferee spouse elects not to transfer an outright bequest to a QDOT). Under these circumstances, on the death of the transferee spouse, if the transferee's estate is subject to the estate tax under chapter 11, the allowable section 2013 credit is determined without any percentage reduction otherwise required under section 2013(a). The proposed regulations clarify that the credit is computed in accordance with the Code and applicable regulations, except that the percentage reductions contained in section 2013(a) do not apply.

Assignment or Transfer by Surviving Spouse to QDOT

Under section 2056(d)(2)(B), probate and nonprobate property that passes from the decedent to the noncitizen surviving spouse outside of a QDOT is treated as passing from the decedent to a QDOT if the noncitizen spouse either actually transfers the property to a QDOT or irrevocably assigns the property to a QDOT pursuant to an assignment that is enforceable under local law before the estate tax return is filed and at a time when the QDOT election may still be made. Property that is assigned or transferred to a QDOT is treated as passing from the decedent in a QDOT solely for purposes of qualifying for the marital deduction. For all other purposes (*e.g.*, income, gift, estate, generation-skipping transfer tax, and section 1491 excise tax), the proposed regulations treat the surviving spouse as the transferor of the property to the QDOT. This result comports with section 2056(d)(2)(B), which provides that property transferred or assigned by the spouse to a QDOT is treated as passing from the decedent to the QDOT solely for purposes of section 2056(d)(2)(A), and not for purposes of the income and transfer tax provisions of the Code. The Service invites comments on the treatment for income, estate, gift, generation-skipping transfer and excise tax purposes of a transfer or assignment of property by the surviving spouse to a QDOT.

The proposed regulations also generally impose restrictions on the time period during which an actual transfer of property passing outside of a QDOT to a noncitizen surviving spouse must be made to the QDOT in the case of an irrevocable timely assignment.

Nonassignable Annuities or Other Similar Payments

Post-death transfer or assignment relief provided under the statute is not available in the case of survivor benefits payable under qualified pension and profit-sharing plans and annuity contracts described in sections 401(a) and 403(b), because under federal law these benefits cannot be assigned or transferred prior to the time distributions are received under the plan. Similarly, many annuity contracts payable by insurance companies, state lotteries, and other obligors contain provisions that prevent assignment or transfer. Accordingly, section 2056A(e) and the Conference Report accompanying the 1989 Act, H.R. Rep. No. 386, 101st Cong., 1st Sess. 670 (1989), authorize the Secretary to promulgate regulations that provide QDOT treatment for survivor annuities payable under these arrangements.

Section 20.2056A–4(c) provides the surviving spouse with two options for qualifying a nonassignable survivor annuity or similar payment for the marital deduction. Under the first option, the noncitizen surviving spouse must agree to pay a deferred estate tax under section 2056A(b)(1)(A), on an annual basis, on the "corpus portion" (as defined in the regulations) of such payment received. A detailed information statement must be filed with the QDOT return and the noncitizen surviving spouse must execute an agreement acknowledging, *inter alia*, the obligation to pay this annual tax, and agreeing to the imposition of the deferred estate tax under section 2056A(b)(1)(B), on the entire value of the annuity or similar nonassignable payment, if the tax is not paid when due (as if the surviving spouse had died on that date).

Under the second option for these nonassignable arrangements, the noncitizen surviving spouse must agree to transfer or "roll over" to a QDOT, within 60 days of receipt, that portion of each such payment received that constitutes the "corpus portion" of the distribution. As is the case with the first option, a specific information statement must be filed with the QDOT return, and the noncitizen surviving spouse must execute an agreement acknowledging the obligation to make the transfer to the QDOT on an annual basis and in a timely manner, and agreeing to the imposition of the deferred estate tax under section 2056A(b)(1)(B) on the entire value of the annuity or similar nonassignable payment if the noncitizen surviving spouse fails to make any required

transfer (as if the surviving spouse had died on that date). In some cases, all or a portion of the distribution may constitute taxable income on receipt by the spouse. Under section 2056A(b)(15) and § 20.2056A–5(c)(3) of the proposed regulations, any amounts distributed to the spouse from the QDOT, reimbursing the spouse for income taxes paid by the spouse with respect to the receipt of the annuity or similar payment (by actual payment of the spouse's income tax or through withholding), are not subject to the deferred estate tax. This should alleviate any undue burden arising from the imposition of income tax on funds the spouse agrees to transfer to the QDOT.

The rollover option is intended to approximate the same result as if the present value of the survivor benefit were transferred to a QDOT in a lump sum and, thereafter, the noncitizen surviving spouse received the income from the QDOT. Similarly, the tax-payment option is intended to approximate the result that would occur if the plan or annuity arrangement itself constituted a QDOT (which it could not unless it is an explicit trust as defined in § 301.7701–4(a)), and distributed a portion of corpus to the spouse annually. Under either option, a portion of each payment is deemed to constitute income and may be received and retained by the noncitizen surviving spouse without imposition of the deferred estate tax. The corpus portion of each payment will either be transferred to a QDOT, thereby ensuring the collection of the appropriate amount of tax on the occurrence of a taxable event (such as the death of the spouse), or will immediately be subject to tax on receipt as a corpus distribution (except in the case of hardship).

The Service recognizes that the rules regarding treatment of nonassignable annuity or similar payments impact on a significant number of estates subject to the QDOT rules. It is also recognized that the proposed regulations define a QDOT as an "explicit trust", thereby preventing annuity or other trust-equivalent arrangements from qualifying as a QDOT as a separate entity. In the case of annuities or similar arrangements not subject to transfer restrictions (and, thus, not eligible for the elections described above), the proposed regulations authorize the assignment of the spouse's rights under such plans to a QDOT without the actual transfer of the plan assets to a QDOT. The Service invites comments on the proposed rules, as well as suggested revisions that will facilitate the payment of these benefits but, nevertheless, will ensure collection of the appropriate deferred estate tax when due.

Special Rules for Treaties

Several estate and gift tax treaties entered into by the United States were negotiated on the assumption that the United States estate and gift tax marital deduction was not available in the case of an estate of, or transfer by, a nonresident alien. Section 7815(d)(14) of the 1989 Act added a special rule under which the statutory amendments affecting the estate and gift tax marital deduction do not apply when the decedent or donor is not a United States citizen or resident and is a resident of a country with which the United States has an estate, gift or inheritance tax treaty, to the extent such amendments would be inconsistent with the treaty provisions.

Similarly, the United States negotiated several treaties on the basis that the United States marital deduction was allowable in cases involving transfers by United States citizen or resident decedents and donors. Section 7815(d)(14) of the 1989 Act exempts estates of United States citizen or resident decedents, and United States citizen or resident donors, from the statutory amendments for a three-year transition period ending December 18, 1992, if the transfer comes within the purview of a treaty and the estate and gift tax provisions of the treaty are inconsistent with the statutory amendments. This three-year delay was intended to allow renegotiation of the treaties.

The Treasury may conclude treaty negotiations that may supplement the rules contained in these regulations. Further, the Service is considering issuing additional guidance on the application of these special treaty rules on or prior to the issuance of these regulations as final regulations. Comments are requested as to the scope and extent of this guidance.

Special Analyses

It has been determined that these proposed rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has been determined that section 553(b) of the Administrative Procedures Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations; therefore, an initial Regulatory Flexibility Analysis is not required.

Comments and Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted timely (preferably nine copies) to the Internal Revenue Service. All comments will be made available for public inspection and copying in their entirety. A public hearing is scheduled for March 2, 1993. See the notice of public hearing published elsewhere in this issue of the **Federal Register**.

Drafting Information

The principal author of these regulations is Susan B. Hurwitz, Office of Chief Counsel, Internal Revenue Service. Other personnel from the Internal Revenue Service and Treasury Department participated in developing these regulations.

List of Subjects

26 CFR 1.1011–1 through 1.1021–1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 20

Estate taxes, Reporting and recordkeeping requirements.

26 CFR Part 25

Gift taxes, Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR parts 1, 20 and 25 are proposed to be amended as follows:

PART 1—INCOME TAX REGULATIONS; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 continues to read in part:

Authority: 26 U.S.C. 7805 * * *

Par. 2. § 1.1015–5 is amended by adding paragraph (d) to read as follows:

§ 1.1015–5 Increased basis for gift tax paid.

* * * * *

(d) *Special rule for increased basis for gift tax paid.* Section 1015(d) provides for an increase in basis with respect to a gift for which a gift tax is paid under chapter 12.

(1) *Amount of gift.* For purposes of section 1015(d)(6)(A)(ii), the amount of the gift is the amount included with respect to the gift in determining (for purposes of section 2503(a)) the total amount of gifts made during the calendar year, reduced by the amount of any deduction allowed with respect to the gift under section 2522 (relating to the charitable deduction) or under section 2523 (relating to the marital deduction).

(2) *Special rules.* For purposes of section 1015(d)(6), it is immaterial whether the gift tax is paid by the donor or the donee. Where more than one gift of a present interest in property is made to the same donee during a calendar year, the annual exclusion applies to the earliest of such gifts in point of time. Where the donor and the donor's spouse elect under section 2513 to have any gifts made by either of them considered as made one-half by each, the amount of gift tax paid with respect to the gift is the sum of the amounts of tax paid (computed separately) with respect to each half of the gift by the donor and the donor's spouse.

(3) *Qualified domestic trusts.* In the case of a qualified domestic trust (QDOT) described in section 2056A(a), any distribution during the noncitizen surviving spouse's lifetime on which a tax is imposed under section 2056A(b)(1)(A) is treated as a transfer by gift, and any tax paid on the distribution under section 2056A(b)(1)(A) is treated as a gift tax for purposes of section 1015(d)(6). The rules under this section apply for purposes of determining the extent to which basis is increased by the section 2056A(b)(1)(A) tax paid in the case of a taxable distribution from a QDOT.

(4) *Examples.* The method provided in section 1015(d)(6) and this paragraph (d) for computing the increased basis with respect to any gift tax paid may be illustrated by the following examples:

Example 1. (i) Prior to 1993, *X* exhausts *X*'s unified credit against gift tax under section 2505. In 1994, *X* makes a gift to *Y*, an unrelated third party, of a parcel of real estate having a value for gift tax purposes of $100,000. *X*'s adjusted basis in the real estate immediately before making the gift was $70,000. *X* also makes a gift the same year to *Z*, an unrelated third party, of a painting having a value for gift tax purposes of $70,000. *X* files a timely gift tax return for 1994 with respect to which *X* paid gift tax in the amount of $55,500 computed as follows:

Value of real estate given to *Y*	$100,000	
Less: Annual exclusion	10,000	
Included amount of gift (C)		$90,000
Value of painting given to *Z*	70,000	
Less: annual exclusion	10,000	
Included amount of gift		60,000
Total included gifts (D)		150,000
Total gift tax liability for 1994 gifts (B)		55,500

(ii) In determining the gift tax paid with respect to the real estate given to *Y*, the amount of gift tax paid with respect to the gift of $100,000 is determined as follows:

$$\frac{\$90,000\ (C)}{\$150,000\ (D)} \times \$55,500\ (B) = \$33,300$$

(iii) (A) The amount by which *Y*'s basis in the real property is increased is determined as follows:

$$\frac{\$30,000\ (\text{net appreciation})}{\$90,000\ (\text{amount of gift})} \times \$33,300 = \$11,100$$

(B) *Y*'s basis in the real property is $70,000 plus $11,100, or $81,100.

Example 2. (i) *X* dies in 1993. *X*'s spouse, *Y*, is not a United States citizen. In order to obtain the marital deduction for property passing to *X*'s spouse, *X* established a QDOT in *X*'s will. In 1996, the trustee of the QDOT makes a distribution of principal from the QDOT in the form of shares of stock having a value of $70,000 and a basis of $50,000. The distribution is not made on account of hardship. No previous taxable distributions from the QDOT have been made. A deferred estate tax under section 2056A(b)(1)(A) is imposed and paid in the amount of $38,500 on the distribution. The amount by which *Y*'s basis in the shares of stock is increased is determined as follows:

$$\frac{\$20,000\ (\text{net appreciation})}{\$70,000\ (\text{amount of distribution})} \times \$38,500 = \$11,000$$

(ii) *Y*'s basis in the stock is $50,000 plus $11,000, or $61,000.

(5) *Effective date.* The provisions of § 1.1015–5(d) are effective in the case of any gift made after the date these regulations are published in the Federal Register as final regulations.

PART 20—ESTATE TAX; ESTATES OF DECEDENTS DYING AFTER AUGUST 16, 1954

Par. 3. The authority citation for part 20 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 4. Section 20.2056(d)–1 is revised to read as follows:

§ 20.2056(d)–1 Marital deduction; special rules for marital deduction if surviving spouse is not a United States citizen.

Rules pertaining to the application of section 2056(d), including certain transition rules, are contained in §§ 20.2056A–1 through 20.2056A–13.

Par. 5. Sections 20.2056A–0 through 20.2056A–13 are added to read as follows:

§ 20.2056A–0 Table of contents.

This section lists the captions that appear in the regulations under §§ 20.2056A–1 through 20.2056A–13

Section 20.2056A–1 Restrictions on allowance of marital deduction if surviving spouse is not United States citizen.

(a) General rule.
(b) Marital deduction allowed if resident spouse becomes citizen.
(c) Special rules in the case of certain transfers subject to estate and gift tax treaties.

Section 20.2056A–2 Requirements for qualified domestic trust.

(a) In general.
(b) Qualified marital interest requirements.
(1) Property passing to QDOT.
(2) Property passing outright to spouse.
(3) Property passing under a nontransferable plan or arrangement.
(c) Statutory requirements.
(d) Additional requirements to ensure collection of the deferred estate tax.
(1) Security and other arrangements for payment of tax imposed under section 2056A(b)(1).
(2) Individual trustees.
(3) Tangible personal property and intangible personal property.
(4) Annual reporting requirements.
(5) Request for alternate arrangement or waiver.

Section 20.2056A–3 QDOT election.

(a) General rule.
(b) No partial elections.
(c) Protective elections.
(d) Manner of election.

Section 20.2056A–4 Procedures for conforming marital trusts and nontrust marital transfers to the requirements of a qualified domestic trust.

(a) Marital trusts.
(1) In general.
(2) Time for commencing reformation.
(3) Tolling of statutory assessment period.

(b) Nontrust marital transfers.
(1) In general.
(2) Form of assignment.
(3) Assets eligible for assignment.
(4) Pecuniary assignment—special rules.
(5) Transfer tax treatment of assignment.
(6) Period for completion of transfer.
(7) Protective assignment.
(c) Nonassignable annuities and other arrangements.
(1) Definition and general rule.
(2) Agreement to remit deferred estate tax on corpus portion of each annuity payment.
(3) Agreement to roll over corpus portion of annuity payment to QDOT.
(4) Determination of corpus portion.
(5) Information statement.
(6) Agreement to pay deferred estate tax.
(7) Agreement to roll over annuity Payments.
(d) Examples.

Section 20.2056A–5 Imposition of deferred estate tax.

(a) In general.
(b) Amounts subject to tax.
(1) Distribution of principal during the spouse's lifetime.
(2) Death of surviving spouse.
(3) Trust ceases to qualify as QDOT.
(c) Distributions and dispositions not subject to tax.
(1) Distributions of principal on account of hardship.
(2) Distributions of income to the surviving spouse.
(3) Certain miscellaneous distributions and dispositions.

Section 20.2056A–6 Amount of tax.

(a) Definition of tax.
(b) Example.
(c) Benefits allowed in determining amount of deferred estate tax.
(1) General rule.
(2) Presumption of residency.
(3) Special rule in the case of trusts described in section 2056(b)(8).
(4) Credit for state and foreign death taxes.
(5) Alternate valuation and special use valuation.
(d) Miscellaneous rules.

Section 20.2056A–7 Allowance of prior transfer credit under section 2013.

(a) Property subject to QDOT election.
(b) Property not subject to QDOT election.

Section 20.2056A–8 Special rules for joint property.

(a) Inclusion in gross estate.
(1) General rule.
(2) Consideration furnished by surviving spouse.
(3) Amount required to be transferred to QDOT.
(b) Surviving spouse becomes citizen.
(c) Example.

Section 20.2056A–9 Designated filer.

Section 20.2056A–10 Surviving spouse becomes citizen after QDOT established.

(a) Deferred estate tax no longer imposed under certain circumstances.
(1) General rule.
(2) [Reserved].
(b) Special election by spouse.
(1) In general.
(2) [Reserved].

Section 20.2056A–11 Filing requirements and payment of the deferred estate tax.

(a) Distributions during surviving spouse's life.
(b) Tax at death of surviving spouse.
(c) Extension of time for paying deferred estate tax.
(1) Extension of time for paying tax under section 6161(a)(2).
(2) Extension of time for paying tax under section 6161(a)(1).
(d) Liability for tax.

Section 20.2056A–12 Increased basis for deferred estate tax paid with respect to distribution from a QDOT.

Section 20.2056A–13 Effective dates.

(a) In general.
(b) Transition rules for reporting and paying the deferred estate tax.

§ 20.2056A–1 Restrictions on allowance of marital deduction if surviving spouse is not United States citizen.

(a) *General rule.* Subject to the special rules provided in section 7815(d)(14) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239; 103 Stat. 2106), in the case of a decedent who dies after November 10, 1988, the federal estate tax marital deduction is not allowed for property passing to or for the benefit of a surviving spouse who is not a United States citizen at the date of the decedent's death (whether or not the surviving spouse is a resident of the United States) unless—

(1) The property passes from the decedent to (or pursuant to)—

(i) A "qualified domestic trust" (QDOT) described in section 2056A and § 20.2056A–2;

(ii) A trust that, although not meeting all of the requirements for a QDOT, is reformed after the decedent's death to meet the requirements of a QDOT (see § 20.2056A–4(a));

(iii) The surviving spouse not in trust (*e.g.*, by outright bequest or devise, by operation of law, or pursuant to the terms of a plan or arrangement) and, prior to the date that the estate tax return is filed and during the time that the QDOT election may be made, the surviving spouse either actually transfers the property to a QDOT or irrevocably assigns the property to a QDOT (see § 20.2056A–4(b)); or

(iv) A plan or other arrangement that would have qualified for the marital deduction but for section 2056(d)(1)(A), and whose payments are not assignable or transferable to a QDOT (see § 20.2056A–4(c)); and

(2) The executor makes a timely QDOT election under § 20.2056A–3.

(b) *Marital deduction allowed if resident spouse becomes citizen.* The marital deduction is determined as if the surviving spouse is a citizen of the United States if the requirements of section 2056(d)(4) are satisfied. For purposes of section 2056(d)(4)(A) and notwithstanding § 20.2056A–3(a), a return filed prior to the due date (including extensions) is considered filed on the last date that the return is required to be filed (including extensions), and a late return filed at any time after the due date is considered filed on the date that it is actually filed. A surviving spouse is a "resident" only if the spouse is a resident under chapter 11 of the Internal Revenue Code. See § 20.0–1(b)(1). The status of the spouse as a resident under section 7701(b) is not relevant to this determination.

(c) *Special rules in the case of certain transfers subject to estate and gift tax treaties.* See section 7815(d)(14) of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239) for certain rules applicable in the case of transfers governed by certain estate and gift tax treaties to which the United States is a party.

§ 20.2056A–2 Requirements for qualified domestic trust.

(a) *In general.* In order to qualify as a "qualified domestic trust" (QDOT), the requirements of § 20.2056A–2 (b), (c), and (d) must be satisfied. In addition, the trust must be created and maintained under the laws of the United States or any state or the District of Columbia and must constitute an "explicit trust," as defined in § 301.7701–4(a) of this chapter, and not any other type of entity.

(b) *Qualified marital interest requirements*—(1) *Property passing to QDOT.* If property passes from a decedent to a QDOT, the trust must qualify for the federal estate tax marital deduction under section 2056(b)(5) (life estate with power of appointment), section 2056(b)(7) (qualified terminable interest property, including joint and survivor annuities under section 2056(b)(7)(C), or section 2056(b)(8) (surviving spouse is the only noncharitable beneficiary of a charitable remainder trust), or meet the requirements of an estate trust as defined in § 20.2056(e)–2(b)(1)(i)–(iii).

(2) *Property passing outright to spouse.* If property does not pass from a decedent to a QDOT, but passes to a noncitizen surviving spouse in a form that meets the requirements for a marital deduction without regard to section 2056(d)(1)(A), and that is not described in paragraph (b)(1) of this section, the surviving spouse must either actually transfer the property, or irrevocably assign the property, to a trust (whether

created by the decedent, the decedent's executor or by the surviving spouse) that meets the requirements of paragraphs (c) and (d) of this section (pertaining, respectively, to statutory requirements and regulatory requirements imposed to ensure collection of tax) prior to the filing of the estate tax return for the decedent's estate and before the due date of the QDOT election (see § 20.2056A–3(a)).

(3) *Property passing under a nontransferable plan or arrangement.* If property does not pass from a decedent to a QDOT, but passes under a plan or other arrangement that meets the requirements for a marital deduction without regard to section 2056(d)(1)(A) and whose payments are not assignable or transferable (see § 20.2056A–4(c)), the property is treated as meeting the requirements of § 20.2056A–2(b), (c) and (d), if the requirements of § 20.2056A–4(c) are satisfied. In addition, where an annuity or similar arrangement is described above except that it is assignable or transferable, see § 20.2056A–4(b)(6).

(c) *Statutory requirements.* The requirements of section 2056A(a)(1)(A) and (B) must be satisfied. For purposes of that section, a domestic corporation is a corporation that is created or organized under the laws of the United States or under the laws of any state or the District of Columbia. The trustee required under that section is referred to herein as the "United States Trustee".

(d) *Additional requirements to ensure collection of the deferred estate tax—(1) Security and other arrangements for payment of tax imposed under section 2056A(b)(1)—(i) QDOTs with assets in excess of $2 million.* If the fair market value of the assets passing or deemed to have passed to the QDOT, determined as of the date of the decedent's death, exceeds $2,000,000, the trust instrument must also require that either—

(A) At least one United States Trustee be a bank, as defined in section 581; or

(B) The United States Trustee furnish a bond or security in an amount equal to 65 percent of the fair market value of the trust corpus determined as of the date of the decedent's death. The bond or security shall be made on the appropriate form and with satisfactory surety, as prescribed under section 7101 and § 301.7101–1 of this chapter (Regulations on Procedure and Administration), and subject to such review as may be prescribed.

(ii) *QDOTs with assets of $2 million or less.* If the fair market value of assets passing or deemed to have passed to the QDOT, determined as of the date of the decedent's death, is $2,000,000 or less, the trust instrument must either meet the requirements prescribed by paragraph (d)(1)(i)(A) or (d)(1)(i)(B) of this section, or require that no more than 35 percent of the fair market value of the trust assets, determined annually on the last day of the taxable year of the trust, may consist of real property located outside of the United States that is owned by the trust.

(A) For purposes of paragraph (d)(1)(ii) of this section, if more than one QDOT is established for the benefit of the surviving spouse, the fair market value of all trusts is aggregated in determining whether the $2,000,000 threshold under paragraph (d)(1)(ii) of this section is exceeded.

(B) For purposes of paragraph (d)(1)(ii) of this section, all assets owned by a corporation with 15 or fewer shareholders, or by a partnership with 15 or fewer partners, are deemed to be owned directly by a QDOT that owns stock in the corporation, or an interest in the profits or capital of the partnership, to the extent of the QDOT's pro rata share of the assets of the corporation or partnership. All stock in the corporations, or interests in the partnerships, as the case may be, owned or held for the benefit of the surviving spouse or any members of the surviving spouse's family (within the meaning of section 267(c)(4)) are treated as owned by one person solely for purposes of determining the number of partners or shareholders in the entity.

(C) Interests owned by the QDOT in other entities (such as an interest in a trust) are accorded treatment consistent with that described in paragraph (d)(1)(ii)(B) of this section.

(iii) *Anti-abuse rule.* Regardless of whether the QDOT designates a bank as the United States Trustee under paragraph (d)(1)(i)(A) of this section, furnishes security under paragraph (d)(1)(i)(B), or is subject to the foreign real property requirements of paragraph (d)(1)(ii) of this section, the trust immediately ceases to qualify as a QDOT if the trust utilizes any device or arrangement that has, as a principal purpose, the avoidance of liability for the deferred estate tax under section 2056A(b)(1), or the prevention of the collection of the tax. For example, the trust may become subject to this paragraph (d)(1)(iii) of this section if the United States Trustee that is selected is a domestic corporation established with insubstantial capitalization by the surviving spouse or members of the spouse's family.

(2) *Individual trustees.* If the United States Trustee is an individual United States citizen, the individual must have a tax home (as defined in section 911(d)(3)) in the United States.

(3) *Tangible personal property and intangible personal property.* Except when either paragraph (d)(1)(i) or (d)(5) of this section apply, the trust instrument must provide that all other trust assets (including tangible personal property, written evidence of intangible property, stock certificates, bonds, notes, and similar property) must be physically located in the United States at all times during the term of the trust. Securities held in a brokerage account must be held in an account established with a domestic corporation (as defined in § 20.2056A–2(c)).

(4) *Annual reporting requirements—* (i) *In general.* The United States Trustee must file a statement annually with the Internal Revenue Service, setting forth the information described in § 20.2056A–2(d)(4)(ii). Such statement must be attached to Form 1041—U.S. Fiduciary Income Tax Return, filed by the QDOT.

(ii) The statement filed with the Form 1041 must contain the following information—

(A) The name, address, and taxpayer identification number of the United States Trustee and of the QDOT; and

(B) A list summarizing the assets held by the QDOT, together with the fair market value of each listed QDOT asset, determined as of the last day of the taxable year for which the Form 1041 is filed. If a QDOT subject to paragraph (d)(1)(ii) of this section holds stock of a corporation with 15 or fewer shareholders, or an interest in the profits or capital of a partnership with 15 or fewer partners, or an interest in a trust or other entity, the partnership, corporation, trust or other entity must be identified and the QDOT's pro rata share of the assets owned by that entity must be listed on the statement as if directly owned by the QDOT. Failure to timely file the statement may subject the QDOT to the rules of paragraph (d)(1)(iii) of this section.

(5) *Request for alternate arrangement or waiver.* The Commissioner will provide guidance published in the Internal Revenue Bulletin pursuant to which a testator, executor, or the United States Trustee may submit a request for approval of an alternate plan or arrangement to assure collection of the deferred estate tax.

§ 20.2056A–3 QDOT election.

(a) *General rule.* Subject to the time period prescribed in section 2056A(d), the election to treat a trust as a QDOT must be made on the last federal estate tax return filed before the due date (including extensions of time to file actually granted) or, if a timely return is

not filed, on the first federal estate tax return filed after the due date.

(b) *No partial elections.* An election to treat a trust as a QDOT may not be made with respect to a specific portion of an entire trust that would otherwise qualify for the marital deduction but for the application of section 2056(d). However, if the trust is actually severed in accordance with the applicable requirements of section 2056(b)(7), a QDOT election may be made separately for each separate trust.

(c) *Protective elections.* A protective election may be made to treat property as a QDOT only if there is a bona fide controversy at the time the federal estate tax return is filed as to the property includible in the decedent's gross estate or the property the surviving spouse is entitled to receive; *e.g.*, in the case of a bona fide will contest, or controversy regarding the inclusion in the gross estate of an asset which, if includible, would be eligible for the QDOT election. The protective election is in addition to, and is not in lieu of, the requirements set forth in § 20.2056A–4. The protective election must identify the specific assets to which the protective election refers and the specific reason for the protective election, but may otherwise be defined by means of a formula. Once made, the protective election cannot be revoked. For example, if a protective election is made because a bona fide question exists as to the includibility of an asset in the decedent's gross estate and if it is later determined that the asset is so includible, the protective election becomes effective with respect to the asset and cannot be revoked.

(d) *Manner of election.* The QDOT election is made in the form and manner as set forth in the decedent's estate tax return, including applicable instructions.

§ 20.2056A–4 Procedures for conforming marital trusts and nontrust marital transfers to the requirements of a qualified domestic trust.

(a) *Marital trusts*—(1) *In general.* If an interest in property passes from the decedent to a trust for the benefit of a noncitizen surviving spouse and if the trust otherwise qualifies for a marital deduction but for the provisions of section 2056(d)(1)(A), the property interest is treated as passing to the surviving spouse in a QDOT if the trust is reformed, either in accordance with the terms of the decedent's will or trust agreement, or pursuant to a judicial proceeding to meet the requirements of a QDOT.

(2) *Time for commencing reformation.* In general, a reformation pursuant to a judicial proceeding is permitted under this section if the reformation is commenced on or before the due date (determined with regard to extensions actually granted) for filing the return of tax imposed by chapter 11 of the Internal Revenue Code. The reformation (either pursuant to a judicial proceeding or otherwise) must result in a trust that is effective and irrevocable under local law.

(3) *Tolling of statutory assessment period.* For the tolling of the statute of limitations in the case of a judicial reformation, see section 2056(d)(5)(B).

(b) *Nontrust marital transfers*—(1) *In general.* Under section 2056(d)(2)(B), if an interest in property passes outright from a decedent to a noncitizen surviving spouse either by testamentary bequest or devise, by operation of law, or pursuant to an annuity or other similar plan or arrangement, and such property interest otherwise qualifies for a marital deduction except that it does not pass in a QDOT, solely for purposes of section 2056(d)(2)(A), the property is treated as passing to the surviving spouse in a QDOT if the property interest is either actually transferred to a QDOT before the estate tax return is filed and during the time that the QDOT election may be made, or is assigned to a QDOT under an enforceable and irrevocable assignment made on or before the date on which the return is filed and during the time that the QDOT election may be made. For purposes of section 2056(d)(2)(B), the terms of the QDOT are not required to meet the qualified marital interest requirements under § 20.2056A–2(b)(1). See § 20.2056A–3(a) with respect to the time limitations for making the QDOT election.

(2) *Form of assignment.* A transfer or assignment of property to a QDOT must be in writing. The transfer or assignment may be of a specific asset or a group of assets, or a fractional share of either, or may be of a pecuniary amount. A transfer or assignment of less than an entire interest in an asset or a group of assets may be expressed as a formula (such as the minimum amount necessary to reduce the estate tax to zero).

(3) *Assets eligible for assignment.* If a transfer or assignment is of a specific asset or group of assets, only assets passing from the decedent to the spouse and included in the decedent's gross estate (or the proceeds from the sale, exchange or conversion of such assets) may be transferred or assigned to the QDOT. The noncitizen surviving spouse may not fund the QDOT with property initially owned by the surviving spouse.

(4) *Pecuniary assignment—special rules.* If the transfer or assignment is expressed in the form of a pecuniary amount (such as a fixed dollar amount or a formula designed to reduce the decedent's estate tax to zero), the transfer or assignment must specify that:

(i) Assets actually transferred to the QDOT in satisfaction of the transfer or assignment have an aggregate fair market value on the date of actual transfer to the QDOT amounting to no less than the amount of the pecuniary transfer or assignment; or

(ii) The assets actually transferred to the QDOT be fairly representative of appreciation or depreciation in the value of all property available for transfer to the QDOT between the valuation date and the date of actual transfer to the QDOT, if the assignment is to be satisfied by accounting for the assets on the basis of their fair market value as of some date before the date of actual transfer to the QDOT.

(5) *Transfer tax treatment of assignment.* Property assigned or transferred to a QDOT pursuant to section 2056(d)(2)(B) is treated as passing from the decedent in a QDOT solely for purposes of section 2056(d)(2)(A). For all other purposes (*e.g.*, income, gift, estate, generation-skipping transfer tax, and section 1491 excise tax), the surviving spouse is treated as the transferor of the property to the QDOT.

(6) *Period for completion of transfer.* Property irrevocably assigned but not actually transferred to the QDOT before the estate tax return is filed must actually be conveyed and transferred to the QDOT under applicable local law before the administration of the decedent's estate is completed. If an actual transfer to the QDOT is not timely made, section 2056(d)(1)(A) applies and the marital deduction is not allowed. The executor of the decedent's estate may request a private letter ruling from the Internal Revenue Service extending the time for completing the conveyance or waiving the actual conveyance under specified circumstances. For purposes of this § 20.2056A–4(b)(6), an assignment in compliance with this paragraph (b) of rights under annuities or other similar arrangements which are assignable or transferable under § 20.2056A–4(c)(1) is treated as having been actually transferred (regardless of the method of payment actually elected under such annuity or plan) to the QDOT.

(7) *Protective assignment.* A protective assignment of property to a QDOT may be made if there is a bona fide controversy at the time the federal estate tax return is filed as to the extent

to which property passing to the surviving spouse is includible in the decedent's gross estate. For example, a bona fide question may be presented regarding the extent to which the decedent contributed towards the purchase of joint property held with the spouse, thereby affecting the extent to which the property is included in the gross estate under section 2040(a) and the portion of the property the spouse must assign to the QDOT. The protective assignment must identify the specific assets to which the assignment refers and the reason for the protective assignment, but may otherwise be defined by means of a formula (such as the minimum amount necessary to reduce the estate tax to zero). Once made, the protective assignment cannot be revoked. For example, if a protective assignment is made because a question exists as to the includibility of an asset in the decedent's gross estate and it is later determined that the asset is so includible, the protective assignment becomes effective with respect to the asset and cannot be revoked. Protective assignments are, in all events, subject to § 20.2056A–4(b)(6).

(c) *Nonassignable annuities and other arrangements*—(1) *Definition and general rule.* For purposes of this section, a "nonassignable annuity or other payment" means a plan, annuity, or other arrangement (whether qualified or not qualified under part I of subchapter D of chapter 1 of subtitle A of the Internal Revenue Code) that qualifies for the marital deduction but for section 2056(d)(1)(A), and whose payments are not assignable or transferable to the QDOT under either federal law (*see, e.g.*, section 401(a)(13)), state law, foreign law, or the terms of the plan or arrangement itself. In the case of a plan, annuity, or other arrangement which is not so assignable or transferable, the property passing under the plan from the decedent is treated as meeting the requirements of § 20.2056A–2(b), (c) and (d) (pertaining, respectively, to qualified marital interest requirements, statutory requirements, and requirements to ensure collection of the tax). Thus, the property is treated as passing in the form of a QDOT, notwithstanding that the spouse does not irrevocably transfer or assign the annuity or other payment to the QDOT as provided in § 20.2056A–4(b), but only if the requirements of § 20.2056A–4(c) (2) or (3) are satisfied.

(2) *Agreement to remit deferred estate tax on corpus portion of each annuity payment.* The requirements of this paragraph (c)(2) are satisfied if—

(i) The noncitizen surviving spouse agrees to pay the deferred estate tax under section 2056A(b)(1) due on the "corpus portion," as defined in paragraph (c)(4) of this section, of each nonassignable annuity or other payment received under the plan or arrangement;

(ii) The executor of the decedent's estate files with the estate tax return the Information Statement described in paragraph (c)(5) of this section;

(iii) The executor files with the estate tax return the Agreement To Pay Deferred Estate Tax described in paragraph (c)(6) of this section; and

(iv) The executor makes the election under § 20.2056A–3 with respect to the nonassignable annuity or other payment.

(3) *Agreement to roll over corpus portion of annuity payment to QDOT.* The requirements of this paragraph (c)(3) are satisfied if—

(i) The noncitizen surviving spouse agrees to roll over and transfer the corpus portion of each annuity payment to a QDOT, whether the QDOT is created by the decedent's will, the executor of the decedent's estate, or the surviving spouse;

(ii) A QDOT for the benefit of the surviving spouse is established prior to the date that the estate tax return is filed and during the time that the QDOT election may be made;

(iii) The executor of the decedent's estate files with the estate tax return the Information Statement described in paragraph (c)(5) of this section;

(iv) The executor files with the estate tax return the Agreement To Roll Over Annuity Payments described in paragraph (c)(7) of this section; and

(v) The executor makes the election under § 20.2056A–3 with respect to the nonassignable annuity or other payment. See § 20.2056A–5(c)(3)(iv) regarding distributions from the QDOT reimbursing the spouse for income taxes paid (either by actual payment or withholding) by the spouse with respect to amounts transferred to the QDOT pursuant to this § 20.2056A–4(c)(3).

(4) *Determination of corpus portion*—(i) *Corpus portion.* For purposes of this § 20.2056A–4(c), the "corpus portion" of each nonassignable annuity or other payment is the "corpus amount" of the annual payment divided by the total annual payment.

(ii) *Corpus amount.* (A) The "corpus amount" of the annual payment is determined in accordance with the following formula:

$$\text{Corpus Amount} = \frac{\text{Total present value of annuity or other payment}}{\text{Expected annuity term}}$$

(B) The "total present value of the annuity or other payment" is the present value of the nonassignable annuity or other payment as of the date of the decedent's death, determined in accordance with the interest rates and mortality data prescribed by section 7520. The "expected annuity term" is the number of years that would be required for the scheduled payments to exhaust a hypothetical fund equal to the present value of the scheduled payments. This is determined by first dividing the total present value of the payments by the annual payment. From the quotient so obtained, the expected annuity term is derived by identifying the term of years that corresponds to the annuity factor equal to the quotient. This is determined by using column 1 of Table B, for the applicable interest rate, contained in Internal Revenue Service Publication 1457, "Actuarial Values, Alpha Volume" (8–89), which is available for purchase from the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402. If the quotient obtained falls between two terms, the longer term is used.

(5) *Information Statement*—(i) *In general.* In order for a nonassignable annuity or other payment described in this § 20.2056A–4(c) to qualify under either paragraph (c)(2) or (c)(3) of this section, the Information Statement described in paragraph (c)(5)(ii) of this section must be filed with the decedent's federal estate tax return. The Information Statement must be signed under penalties of perjury by both the executor of the decedent's estate and by the surviving spouse of the decedent. The Statement must contain all of the information prescribed by this paragraph (c)(5).

(ii) *Annuity source information*—(A) *Employment-related annuity.* If the nonassignable annuity or other payment is employment-related, the following information must be provided:

(*1*) The name and address of the employer;

(*2*) The date of retirement or other separation from employment of the decedent;

(*3*) The name and address of the pension fund, insurance company, or other obligor that is paying the annuity (or similar payment); and

(*4*) The identification number that the obligor has assigned to the annuity or other payment.

(B) *Annuity not employment-related.* If the nonassignable annuity or other payment is not employment-related, the following information must be provided:

(*1*) The name and address of the person or entity paying the

nonassignable annuity or other payment;

(2) The date of acquisition of the nonassignable annuity contract by the decedent or by the decedent and the surviving spouse; and

(3) The identification number, if any, that the obligor has assigned to the nonassignable annuity or other payment.

(iii) *The total annuity amount payable each year.* The total amount payable annually under the nonassignable annuity or other arrangement, including a description of whether the annuity is payable on a monthly, quarterly, or other interval and a description of any scheduled changes in the annuity payout amount.

(iv) *The duration of the annuity.* A description of the term of the nonassignable annuity or other payment in years, if it is determined by a term certain, and the name, address, and birthdate of any measuring life if the nonassignable annuity or other payment is determined by one or more lives.

(v) *The market interest rate under section 7520.* The applicable interest rate as determined under section 7520.

(vi) *Determination of corpus portion of each payment (in accordance with paragraph (c)(4) of this section).* (A) The present value of the nonassignable annuity or other payment as of the decedent's death;

(B) The expected annuity term;

(C) The corpus amount of the annual annuity payments ((A) divided by (B));

(D) The corpus portion of the annual payments ((C) divided by the total amount payable annually).

(vii) *The recipient QDOT* (applicable only in the case of an agreement to rollover under paragraph (c)(3) of this section).

(A) The name and address of the trustee of the QDOT who is the United States Trustee;

(B) The name and taxpayer identification number of the QDOT.

(viii) *Certification statement.* The executor of the decedent's estate and the surviving spouse of the decedent must each sign a Certification Statement as follows:

Under penalties of perjury, I hereby certify that, to the best of my knowledge and belief, the information reported in this Information Statement is true, correct and complete.

(6) *Agreement To Pay Deferred Estate Tax.* In order for a nonassignable annuity or other payment described in this § 20.2056A–4(c) to qualify under paragraph (c)(2) of this section, the executor of the decedent's estate must file with the estate tax return the following Agreement To Pay Deferred Estate Tax, which must be signed by the surviving spouse of the decedent.

I [*name*] hereby agree that I will report all annuity payments received under the [*name of plan or arrangement*] on Form 706QDT for the calendar year and remit, on an annual basis, to the Internal Revenue Service the deferred estate tax that is imposed under section 2056A(b)(1) of the Internal Revenue Code on the corpus portion of each annuity payment (as defined in section 20.2056A–4(c)(4) of the Estate Tax Regulations) received under the plan during the calendar year. I also agree that form 706QDT is to be filed no later than April 15th of the year following the calendar year in which any annuity payments are received except in the year of my death, in which case it must be filed no later than the date my estate tax return is filed (or if no return is filed, no later than 9 months from the date of my death). I further agree that if I fail to timely file Form 706QDT or pay the tax imposed on the corpus portion of any annuity payment, I will become immediately liable to pay the tax imposed by section 2056A(b)(1) on the full remaining present value of the annuity, calculated as of the beginning of the calendar year in which the payment was received with respect to which I failed to report or remit payment of the tax imposed under section 2056A(b)(1). I agree, at the request of the District Director, to enter into a security agreement to secure my undertakings under this agreement.

(7) *Agreement To Roll Over Annuity Payments.* In order for a nonassignable annuity or other payment described in this § 20.2056A–4(c) to qualify under paragraph (c)(3) of this section, the executor of the decedent's estate must file with the estate tax return the following Agreement To Roll Over Annuity Payments, which must be signed by the surviving spouse of the decedent.

I [*name*] hereby agree that within 60 days of receipt of each annuity payment paid under the [*name of plan or arrangement*], I will transfer an amount equal to _____ percent (the corpus portion determined under section 20.2056A–4(c)(4) of the Estate Tax Regulations) of each annuity payment to [*identify the QDOT*]. Further, I will report all annuity payments received during the calendar year under the [*name of plan or arrangement*] on Form 706QDT including a schedule of transfers to the [*identify the QDOT*]. I also agree that Form 706QDT is to be filed no later than April 15th of the year following the year in which any annuity payments are received except in the year of my death, in which case it must be filed no later than the date my estate tax return is filed (or if no such return is filed, no later than 9 months from the date of my death). I further agree that if I fail to timely transfer any required amount with respect to any annuity payment, or fail to timely file Form 706QDT reporting the transfers for any year, I will become immediately liable to pay the amount of the tax determined by application of section 2056A(b)(1) on the entire remaining present value of the annuity, calculated as of the beginning of the year in which the payment was received with respect to which I failed to make the transfer or file a return. I agree, at the request of the District Director, to enter into a security agreement to secure my undertakings under this agreement.

(d) *Examples.* The provisions of this section are illustrated by the following examples. In each of the following examples the decedent, *D*, a citizen of the United States, died after the date these regulations are published as final regulations and *D*'s surviving spouse, *S*, is not a United States citizen at the time of *D*'s death.

Example 1. Transfer and assignment of probate and nonprobate property to QDOT. (i) *S* is the beneficiary of the following probate and nonprobate assets included in *D*'s gross estate:

Pecuniary bequest under will	$400,000
Proceeds of life insurance	200,000
D's interest in property owned jointly with *S* includible in the gross estate under § 2040 (a)	300,000
Devise of real property under will	100,000
Total	1,000,000

(ii) Before the estate tax return for *D*'s estate is filed and before the date that the QDOT election must be made, *S* creates a QDOT pursuant to which all income is payable to *S* for life and the remainder is distributable to *S*'s children. *S* retains a power of appointment over the disposition of the remainder to ensure that *S* does not make an immediate gift of the remainder of the trust. Also, before the estate tax return is filed and before the date that the QDOT election must be made, *S* transfers the life insurance proceeds and the specifically devised real property to the QDOT. *S* decides not to transfer the property that had been jointly owned to the QDOT. Because *S* has not received distribution of the pecuniary bequest before *D*'s estate tax return is filed and before the QDOT election must be made, *S* irrevocably assigns the interest in the pecuniary bequest to the QDOT. Assume that the pecuniary bequest is in fact transferred by *S* to the QDOT before the estate administration is concluded. *D*'s executor makes a QDOT election on the estate tax return for the $700,000 in property that *S* has transferred and assigned to the QDOT. A marital deduction of $700,000 is allowed to *D*'s estate assuming the estate tax return is filed and the QDOT election is made within the time limitation prescribed in § 20.2056A-3 (a). No marital deduction is allowed for the $300,000 interest in jointly-owned property not transferred to the QDOT.

Example 2. Formula assignment. Under the terms of *D*'s will, the entire probate estate passes outright to *S*. Prior to the date *D*'s estate tax return is filed and before the date that the QDOT election must be made, *S* establishes a QDOT and irrevocably assigns to the QDOT that portion of the gross estate necessary to reduce the estate tax to zero, taking into account all available credits and deductions. The assignment meets the requirements of § 20.2056A-4 (b), assuming that the QDOT is funded by the time that administration of *D*'s estate is completed.

Example 3. Jointly owned property. At the time of *D*'s death, *D* and *S* hold real property as joint tenants with right of survivorship. In accordance with section 2056(d) (1) (B), section 2040(a), and § 20.2056A-8, 60 percent of the value of the property is included in *D*'s gross estate. *S* establishes a QDOT and, prior to the date the estate tax return is filed and before the QDOT election must be made, *S* transfers a 60 percent interest in the real property to the QDOT. The transfer satisfies the requirements of § 20.2056A-4(b).

Example 4. Computation of corpus portion of annuity payment. (i) At the time of *D*'s death in October 1994, *D* is a participant in an employee's pension plan described in section 401(a). On *D*'s death, *D*'s spouse *S*, a resident of the United States, becomes entitled to receive a survivor's annuity of $72,000 per year, payable monthly, for life. At the time of *D*'s death, *S* is age 60. Assume that under section 7520, the appropriate discount rate to be used for valuing annuities in the case of a decedent who dies in October 1994, is 9 percent. The annuity factor at 9 percent for a person age 60 is 8.3031. The adjustment factor at 9 percent for monthly payments is 1.0406. Accordingly, the right to receive $72,000 a year on a monthly basis is equal to the right to receive $74,923 ($72,000×1.0406) on an annual basis.

(ii) The corpus portion of each annuity payment received by *S* is determined as follows. The first step is to determine the annuity factor for the number of years that would be required to exhaust a hypothetical fund that has a present value and a payout corresponding to *S*'s interest in the payment under the plan, determined as follows:

(A) Present value of *S*'s annuity:
$74,923×8.3031=$622,093

(B) Annuity Factor for Expected Annuity Term: $622,093/$74,923=8.3031

(iii) The second step is to determine the number of years that would be required for *S*'s annuity to exhaust a hypothetical fund of $622,093. The term certain annuity factors for 8.3031 falls between the annuity factors for 15 and 16 years in a 9 percent term certain annuity table (Column 1 of Table B, Publication 1457—Alpha Volume). Accordingly, the expected annuity term is 16 years.

(iv) The third step is to determine the corpus amount by dividing the expected term of 16 years into the present value of the hypothetical fund as follows:

Corpus amount of annual payment:
$622,093/16=$38,881

(v) In the fourth step, the corpus portion of each annuity payment is determined by dividing the corpus amount of each annual payment by the annual annuity payment as follows:

Corpus portion of each annuity payment:
$38,881/$74,923=.52

(vi) Accordingly, 52 percent of each payment to *S* is deemed to be a distribution of corpus. A marital deduction is allowed for $622,093, the present value of the annuity as of *D*'s date of death, if either: *S* agrees to roll over the corpus portion of each payment to a QDOT and the executor files the Information Statement described in § 20.2056A–4(c)(5) and the Roll Over Agreement described in § 20.2056A–4(c)(7); or *S* agrees to pay the tax due on the corpus portion of each payment and the executor files the Information Statement described in § 20.2056A–4(c)(5) and the payment Agreement described in § 20.2056A–4(c)(6).

Example 5. Transfer to QDOT subject to gift tax. D dies on April 1, 1994. *D*'s will bequeaths $700,000 outright to *S*. The bequest qualifies for a marital deduction under section 2056(a) except that it does not pass in a QDOT. On September 1, 1994, *S* creates an irrevocable trust that meets the requirements for a QDOT and transfers the $700,000 to the QDOT. The QDOT instrument provides that *S* is entitled to all the income from the QDOT payable at least annually and that, upon the death of *S*, the property remaining in the QDOT is to be distributed to the grandchildren of *D* and *S* in equal shares. The trust instrument contains all other provisions required to qualify as a QDOT. On *D*'s estate tax return, *D*'s executor makes a QDOT election under section 2056A(a)(3). Solely for purposes of the marital deduction, the property is deemed to pass from *D* to the QDOT trust. *D*'s estate is entitled to a marital deduction for the $700,000 value of the property passing from *D* to *S*. *S*'s transfer of property to the QDOT is treated as a gift of the remainder interest for gift tax purposes because *S*'s transfer creates a vested remainder interest in the grandchildren of *D* and *S*. Accordingly, as of the date that *S* transfers the property to the QDOT, a gift tax is imposed on the present value of the remainder interest. Since *S* made the transfer after October 8, 1990, *S* is deemed to make a gift with a value equal to the entire value of the property under section 2702. In addition, at *S*'s death, *S* is treated as the transferor of the property into the trust for estate tax and generation-skipping transfer tax purposes. *See, e.g.*, sections 2036 and 2652(a)(1). The trust is not eligible for a reverse QTIP election by *D*'s estate under section 2652(a)(3) because a QTIP election cannot be made for the QDOT. This is so because the marital deduction is allowed under section 2056(a) for the outright bequest to the spouse and the spouse is then separately treated as the transferor of the property to the QDOT.

§ 20.2056A–5 Imposition of deferred estate tax.

(a) *In general.* A deferred estate tax is imposed under section 2056A(b)(1) on the occurrence of a "taxable event," as defined in section 2056A(b)(9). The tax is generally equal to the amount of estate tax that would have been imposed if the amount involved in the taxable event had been included in the decedent's taxable estate and had not been deductible under section 2056. See section 2056A(b)(3) and § 20.2056A–5(c) for certain exceptions from taxable events.

(b) *Amounts subject to tax*—(1) *Distributions of principal during the spouse's lifetime.* If a taxable event occurs during the noncitizen surviving spouse's lifetime, the amount subject to tax is the amount of the distribution including any amount withheld from the distribution by the United States Trustee to pay the deferred estate tax. If, however, the tax is not withheld by the United States Trustee but is paid by the Trustee out of other assets of the QDOT, an amount equal to the tax so paid is treated as an additional distribution to the spouse in the year that the tax is paid.

(2) *Death of surviving spouse.* If a taxable event occurs as a result of the death of the surviving spouse, the amount subject to tax is the value of the trust corpus on the date of the spouse's death (or alternate valuation date if applicable). *See also* section 2032A.

(3) *Trust ceases to qualify as QDOT.* If a taxable event occurs as a result of the trust ceasing to qualify as a QDOT (for example, the trust ceases to have at least one United States Trustee), the amount subject to tax is the value of the trust corpus on the date of disqualification.

(c) *Distributions and dispositions not subject to tax*—(1) *Distributions of principal on account of hardship.* Section 2056A(b)(3)(B) provides an exemption from the deferred estate tax for distributions to the surviving spouse on account of hardship. A distribution of principal is made on account of hardship if the distribution is made to the spouse from the QDOT in response to an immediate and substantial financial need relating to the spouse's health, maintenance, or support. A distribution is not considered made on account of hardship if the amount distributed may be obtained from other sources that are reasonably available to the surviving spouse; *e.g.*, the sale by the surviving spouse of personally owned, publicly traded stock or the cashing in of a certificate of deposit owned by the surviving spouse. Although a hardship distribution of principal is exempt from the deferred estate tax, it must be reported on Form 706QDT even if it is the only distribution that occurred during the filing period. See § 20.2056A–11 regarding filing requirements for the Form 706QDT.

(2) *Distributions of income to the surviving spouse.* Section 2056A(b)(3)(A) provides an exemption from the deferred estate tax for distributions of income to the surviving spouse. For purposes of section 2056A(b)(3)(A), "income" refers to income as defined in section 643(b), except that income does not include capital gains or other items that would be allocated to corpus under applicable local law governing the administration

of trusts without regard to any specific trust provision to the contrary.

(3) *Certain miscellaneous distributions and dispositions.* Certain additional miscellaneous distributions and dispositions of trust assets are exempt from the deferred estate tax, including but not limited to the following—

(i) Payments for ordinary and necessary expenses of the QDOT;

(ii) Payments to applicable governmental authorities for income tax or any other applicable tax imposed on the QDOT (other than a payment of the deferred estate tax due on the occurrence of a taxable event as described in paragraph (b) of this section);

(iii) Dispositions of trust assets by the trustees (such as sales, exchanges, or pledging as collateral) for full and adequate consideration in money or money's worth; and

(iv) Amounts paid from the QDOT to reimburse the spouse for income taxes paid by the spouse (either by actual payment or through withholding) with respect to amounts received from a nonassignable annuity or other arrangement that are transferred by the spouse to a QDOT pursuant to § 20.2056A–4(c)(3).

§ 20.2056A–6 Amount of tax.

(a) *Definition of tax.* Section 2056A(b)(2) provides for the computation of the deferred estate tax. For purposes of section 2056A(b)(2)(A)(i) and (ii), except as provided in § 20.2056A–6(d), in determining the tax that would have been imposed under section 2001 on the estate of the first decedent, the rates in effect on the date of the first decedent's death are used. In addition, for purposes of section 2056A(b)(2)(A)(i) and (ii), "the tax which would have been imposed by section 2001 on the estate of the decedent" means the net tax after allowance of any allowable credits, including the unified credit allowable under section 2010, the credit for state death taxes under section 2011, the credit for tax on prior transfers under section 2013, and the credit for foreign death taxes under section 2014. In the case of a decedent nonresident not a citizen of the United States, the applicable credits are determined under section 2102.

(b) *Example.* The rules of § 20.2056A–6 are illustrated as follows:

Example. (i) *D*, a United States citizen, dies in 1994 with a gross estate of $1,200,000. Under *D*'s will, a pecuniary bequest of $700,000 passes to a QDOT for the benefit of *D*'s spouse *S*, who is a resident but not a citizen of the United States. *D*'s estate tax is computed as follows:

Gross estate	$1,200,000	
Marital Deduction	(700,000)	
Taxable Estate	500,000	
Gross Tax		$155,800
Less: $192,800 Unified Credit		(155,800)
Net Tax		0

(ii) *S* dies in 1996 at which time the value of the corpus of the QDOT is $700,000. Assuming there were no taxable events during *S*'s lifetime with respect to the QDOT, the tax imposed under section 2056A(b)(1)(B) is $235,000, computed as follows:

D's actual taxable estate	$500,000	
QDOT property	700,000	
Total	1,200,000	
Gross Tax		$427,800
Less: Unified Credit		(192,800)
Net Tax		235,000
Less: Tax that would have been imposed on *D*'s actual taxable estate of $500,000		0
Deferred Estate Tax		235,000

(c) *Benefits allowed in determining amount of deferred estate tax*—(1) *General rule.* Section 2056A(b)(10) provides for the allowance of certain benefits in computing the deferred estate tax. Except as provided in this paragraph, the rules of each of the credit, deduction and deferral provisions referred to therein must be complied with.

(2) *Presumption of residency.* For purposes of section 2056A(b)(10)(A), it is presumed that the noncitizen spouse is a resident of the United States for purposes of determining whether the QDOT property is includible in the spouse's gross estate under chapter 11 and for purposes of determining whether any of the credits, deductions or deferral provisions are allowable with respect to the QDOT property to the estate of the spouse.

(3) *Special rule in the case of trusts described in section 2056(b)(8).* In the case of a QDOT in which the spouse's interest qualifies for a marital deduction under section 2056(b)(8), the provisions of section 2056A(b)(10)(A) apply in determining the allowance of a charitable deduction in computing the deferred estate tax, notwithstanding that the QDOT is not includible in the spouse's gross estate.

(4) *Credit for state and foreign death taxes.* In order for a credit to be finally allowed for either state death taxes under section 2011 or foreign death taxes under section 2014, the state or foreign jurisdiction must actually impose death taxes on the property subject to the section 2056A(b)(1) tax and those taxes must actually be paid to the state or foreign jurisdiction. The credit allowable cannot exceed the state or foreign death taxes previously paid at the time of death of the first decedent, and any additional state or foreign taxes imposed on the surviving spouse's death on the QDOT property, other than taxes imposed on property includible in the spouse's gross estate.

(5) *Alternate valuation and special use valuation*—(i) *In general.* In order to claim the benefits of alternate valuation under section 2032, or special use valuation under section 2032A, for purposes of computing the deferred estate tax, an election must be made on the Form 706QDT that is filed with respect to the balance remaining in the QDOT upon the death of the surviving spouse. In addition, the separate requirements for making the section 2032 and/or section 2032A elections under those sections and the regulations thereunder must be complied with except that, for this purpose, the surviving spouse is treated as a resident of the United States regardless of the surviving spouse's actual residency status. Solely for purposes of this paragraph (d)(5), the citizenship of the first decedent is immaterial.

(ii) *Alternate valuation.* For purposes of the alternate valuation election under section 2032, the election may not be made unless the election decreases both the value of the property remaining in the QDOT upon the death of the surviving spouse and the net amount of deferred estate tax due. Once made, the election is irrevocable.

(iii) *Special valuation.* For purposes of section 2032A, the Designated Filer (in the case of multiple QDOTs) or the United States Trustee may elect to value certain farm and closely held business real property at its farm or business use value, rather than its fair market value, if all of the requirements under section 2032A and the applicable regulations are met, except that, for this purpose, the surviving spouse is treated as a resident of the United States regardless of the spouse's actual residency status. The total value of property valued under section 2032A in the QDOT cannot be decreased from fair market value by more than $750,000.

(d) *Miscellaneous rules.* See sections 2056A(b)(2)(B)(i) and 2056A(b)(2)(C) for special rules regarding the appropriate rate of tax. See section 2056A(b)(2)(B)(ii) for provisions regarding a credit or refund with respect to the deferred estate tax.

§ 20.2056A–7 Allowance of prior transfer credit under section 2013.

(a) *Property subject to QDOT election.* Section 2056(d)(3) provides special rules for computing the section 2013 credit allowed with respect to property subject to a QDOT election. In computing the credit under section 2013, the amount of the credit is determined under section 2013 and the regulations thereunder, except that:

(1) The "first limitation" as described in section 2013(b) and § 20.2013–2 is the amount of the deferred estate tax imposed under section 2056A(b)(1)(A), with respect to distributions during the spouse's life, and under section 2056A(b)(1)(B), with respect to the value of the trust corpus on the spouse's death; and

(2) The amount of the credit is determined without regard to the percentage limitations contained in section 2013(a).

(b) *Property not subject to QDOT election.* If property includible in a decedent's gross estate passes to a noncitizen surviving spouse (the transferee) and no deduction is allowed to the decedent's estate for the property under section 2056(a) solely because the requirements of section 2056(d)(2) are not satisfied, and the transferee spouse dies with an estate that is subject to tax under section 2001 or section 2101, as the case may be, any credit for tax on prior transfers allowable to the estate of the transferee spouse under section 2013 with respect to such property is determined in accordance with the rules of section 2013 and the regulations thereunder, except that the amount of the credit is determined without regard to the percentage limitations contained in section 2013(a).

§ 20.2056A–8 Special rules for joint property.

(a) *Inclusion in gross estate*—(1) *General rule.* If property is held by the decedent and the surviving spouse of the decedent as joint tenants with right of survivorship, or as tenants by the entirety, and the surviving spouse is not a United States citizen at the time of the decedent's death, the property is subject to inclusion in the decedent's gross estate in accordance with the rules of section 2040(a) (general rule for includibility of joint interests), and section 2040(b) (special rule for includibility of certain joint interests of husbands and wives) does not apply. Accordingly, the rules contained in section 2040(a) and § 20.2040–1 govern the extent to which such joint interests are includible in the gross estate of a decedent who was a citizen or resident of the United States. If the decedent is a nonresident not a citizen of the United States, the foregoing rule applies pursuant to sections 2103, 2031, 2040(a), and 2056(c)(1)(B).

(2) *Consideration furnished by surviving spouse.* For purposes of applying section 2040(a), in determining the amount of consideration furnished by the surviving spouse, any consideration furnished by the decedent with respect to the property before July 14, 1988, is treated as consideration furnished by the surviving spouse to the extent that the consideration was treated as a gift under section 2511, or to the extent that the decedent elected to treat the transfer as a gift to the spouse under section 2515 (to the extent applicable). For purposes of determining whether the consideration was a gift by the decedent under section 2511, it is presumed that the decedent was a citizen of the United States at the time the consideration was so furnished to the spouse. The special rule of this § 20.2056A–8(a)(2) is applicable only if the donor spouse predeceases the donee spouse and not if the donee spouse predeceases the donor spouse.

(3) *Amount required to be transferred to QDOT.* If, as a result of the application of the rules described above, only a portion of the value of a jointly-held property interest is includible in a decedent's gross estate, only that portion that is so includible must be transferred to a QDOT in order to obtain the estate tax marital deduction for the property. See § 20.2056A–4(d), *Example 3.*

(b) *Surviving spouse becomes citizen.* Paragraph (a) of this section does not apply if the surviving spouse meets the requirements of section 2056(d)(4). For the definition of resident in applying section 2056(d)(4), see § 20.0–1(b).

(c) *Example.* The provisions of § 20.2056A–8 are illustrated by the following example:

Example. In 1987, *D*, a United States citizen, purchases real property and takes title in the names of *D* and *S*, *D*'s spouse (a noncitizen, but a United States resident), as joint tenants with right of survivorship. In accordance with § 25.2511–1(h)(5), one-half the value of the property is a gift to *S*. *D* dies in 1993. Because *S* is not a United States citizen, the provisions of section 2040(a) are determinative of the extent to which the real property is includible in *D*'s gross estate. Because the joint tenancy was established before July 14, 1988, and under the applicable provisions of the Internal Revenue Code and regulations the transfer was treated as a gift of one-half the property, one-half of the value of the property is deemed attributable to consideration furnished by *S* for purposes of section 2040(a). Accordingly, only one-half of the value of the property is includible in *D*'s gross estate under section 2040(a).

§ 20.2056A–9 Designated Filer.

Section 2056A(b)(2)(C) provides special rules where more than one QDOT is established with respect to a decedent. The designation of a person responsible for filing a return under section 2056A(b)(2)(C)(i) (the Designated Filer) must be made on the decedent's federal estate tax return, or on the first 706QDT that is due and is filed by its prescribed date, including extensions. The Designated Filer must be a United States Trustee of the QDOT. If the United States Trustee is an individual United States Trustee, the individual must have a tax home (as defined in section 911(d)(3)) in the United States. At least thirty days before the due date for filing the tax returns for all of the QDOTs, the United States Trustee(s) of each of the QDOTs must provide to the Designated Filer all of the necessary information relating to distributions from their respective QDOTs. The Designated Filer may allocate the deferred estate tax due from each QDOT in the Designated Filer's discretion.

§ 20.2056A–10 Surviving spouse becomes citizen after QDOT established.

(a) *Deferred estate tax no longer imposed under certain circumstances*—(1) *General rule.* Section 2056A(b)(12) provides that a QDOT is no longer subject to the imposition of the deferred estate tax if the spouse becomes a citizen of the United States and the following conditions are satisfied—

(i) The spouse either was a United States resident (for the definition of resident for this purpose, see § 20.2056A–1(b)) at all times after the death of the decedent and before becoming a United States citizen, or no taxable distributions are made from the QDOT before the spouse became a United States citizen (regardless of the residency status of the spouse); and

(ii) The United States Trustee(s) of the QDOT notifies the Internal Revenue Service and certifies in writing that the surviving spouse has become a United States citizen. Notice is to be made by filing a final Form 706QDT on or before April 15th of the year following the year in which the surviving spouse becomes a United States citizen, unless an extension of time for filing is granted under section 6081.

(2) [Reserved].

(b) *Special election by spouse*—(1) *In general.* If the surviving spouse becomes a United States citizen and the spouse is not a United States resident (see § 20.2056A–1(b)) at all times after the death of the decedent and before becoming a United States citizen, and a tax was previously imposed under

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section 2056A(b)(1)(A) with respect to any distribution from the QDOT before the surviving spouse becomes a United States citizen, the deferred estate tax under section 2056A(b)(1) does not apply to distributions after the spouse becomes a citizen if:

(i) The spouse elects to treat any taxable distribution from a QDOT prior to the spouse's election as a taxable gift made by the spouse for purposes of section 2001(b)(1)(B) (referring to adjusted taxable gifts) and for purposes of determining the amount of the tax imposed by section 2501 on actual taxable gifts made by the spouse during the year in which the spouse becomes a citizen or in any subsequent year;

(ii) The spouse elects to treat any previous reduction in the tax by reason of the decedent's unified credit (under either section 2010 or section 2102(c)) as a reduction in the spouse's unified credit under section 2505 for purposes of determining the amount of the credit allowable with respect to taxable gifts made by the surviving spouse during the taxable year in which the spouse becomes a citizen, or in any subsequent year; and

(iii) The elections referred to in § 20.2056A–10(b)(1)(i) and (ii) are made by timely filing a Form 706QDT on or before April 15th of the year following the year in which the surviving spouse becomes a citizen (unless an extension of time for filing is granted under section 6081) and attaching notification of the election to the return.

(2) [Reserved].

§ 20.2056A–11 Filing requirements and payment of the deferred estate tax.

(a) *Distributions during surviving spouse's life.* Section 2056A(b)(5)(A) provides the due date for the deferred estate tax due on distributions during the spouse's lifetime. An extension of not more than 6 months may be obtained for the filing of Form 706QDT under section 6081(a) if the conditions specified therein are satisfied. See also § 20.2056A–5(c)(1) regarding the requirements for filing a Form 706QDT in the case of a distribution on account of hardship.

(b) *Tax at death of surviving spouse.* Section 2056A(b)(5)(B) provides the due date for payment of the deferred estate tax imposed on the death of the spouse under section 2056A(b)(1)(B). An extension of not more than 6 months may be obtained for the filing of the Form 706QDT under section 6081(a), if the conditions specified therein are satisfied.

(c) *Extension of time for paying deferred estate tax—(1) Extension of time for paying tax under section 6161(a)(2).* Pursuant to sections 2056A(b)(10)(C) and 6161(a)(2), upon a showing of reasonable cause, an extension of time beyond the due date to pay any part of the deferred estate tax that is imposed upon the surviving spouse's death under section 2056A(b)(1)(B) and shown on the final Form 706QDT, or any part of any installments of such tax under section 6166 (including any part of a deficiency prorated to any installment under such section), may be granted for a reasonable period of time, not to exceed 10 years from the date prescribed for payment of the tax (or in the case of an installment or part of a deficiency prorated to an installment, if later, not beyond the date that is 12 months after the due date for the last installment), by the district director or the director of the service center where the Form 706QDT is filed.

(2) *Extension of time for paying tax under section 6161(a)(1).* An extension of time beyond the due date to pay any part of the deferred estate tax imposed on lifetime distributions under section 2056A(b)(1)(A), or imposed at the death of the surviving spouse under section 2056A(b)(1)(B), may be granted for a reasonable period of time, not to exceed 6 months (12 months in the case of the tax imposed under section 2056A(b)(1)(B) at the surviving spouse's death), by the district director or the director of the service center where the Form 706QDT is filed.

(d) *Liability for tax.* Under section 2056A(b)(6), each trustee (and not solely the United States Trustee(s)) of a QDOT is personally liable for the amount of the deferred estate tax imposed in the case of any taxable event under section 2056A(b)(1). In the case of multiple QDOTs with respect to the same decedent, the trustee(s) of each trust are jointly and severally liable to the extent of the assets within the trustee's control notwithstanding the appointment of a Designated Filer under § 20.2056A–9. The trustee may also be personally liable as a withholding agent under section 1461 or other applicable provisions of the Internal Revenue Code.

§ 20.2056A–12 Increased basis for deferred estate tax paid with respect to distribution from a QDOT.

Under section 2056A(b)(13), in the case of any distribution from a QDOT on which a tax is imposed under section 2056A(b)(1)(A), the distribution is treated as a transfer by gift for purposes of section 1015, and any deferred estate tax paid under section 2056A(b)(1)(A) is treated as a gift tax. See § 1.1015–5(d) for rules for determining the amount by which the basis of the distributed property is increased.

§ 20.2056A–13 Effective dates.

(a) *In general.* Except as provided below, the provisions of §§ 20.2056A–1 through 20.2056A–12 are effective with respect to estates of decedents dying after the date these regulations are published as final regulations in the **Federal Register**. With respect to estates of decedents dying on or before such date, taxpayers may rely on any reasonable interpretation of the statutory provisions. The provisions of § 20.2056A–2(d), pertaining to the additional QDOT qualification requirements, are effective in the case of estates of decedents dying 180 days after the date these regulations are published as final regulations in the **Federal Register**. With respect to estates of decedents dying before such date, taxpayers may rely on any reasonable interpretation of the statutory provisions.

(b) *Transition rules for reporting and paying the deferred estate tax.* For certain transition rules for reporting and paying the tax imposed under section 2056A(b)(1), see Announcement 90–39, 1990–12 I.R.B. 26, and Announcement 91–58, 1991–15 I.R.B. 39 (See § 601.601(d)(2)(ii)(*b*) of this chapter for the availability of the I.R.B.).

Par. 6. Section 20.2101–1 is revised to read as follows:

§ 20.2101–1 Estates of nonresidents not citizens; tax imposed.

(a) *Imposition of tax.* Section 2101 imposes a tax on the transfer of the taxable estate of a nonresident who is not a citizen of the United States at the time of death. In the case of an estate of a decedent dying after November 10, 1988, the tax is computed at the same rates as the tax that is imposed on the transfer of the taxable estate of a citizen or resident of the United States in accordance with the provisions of section 2101 (b) and (c). For the meaning of the terms "resident," "nonresident," and "United States," as applied to a decedent for purposes of the estate tax, see paragraphs (b) (1) and (2) of § 20.0–1. For the liability of the executor for the payment of the tax, see section 2002.

(b) *Special rates in the case of certain decedents.* In the case of an estate of a nonresident who was not a citizen of the United States and who died after December 31, 1976, and on or before November 10, 1988, the tax on the nonresident's taxable estate is computed using the formula provided under section 2102(b), except that the rate schedule in paragraph (c) of this section

is to be used in lieu of the rate schedule in section 2001(c).

(c) *Rate schedule for decedents dying after 12/31/76 and on or before 11/10/88.*

If the amount for which the tentative tax to be computed is:	The tentative tax is:
Not over $100,000	6% of such amount.
Over $100,000 but not over $500,000.	$6,000, plus 12% of excess over $100,000.
Over $500,000 but not over $1,000,000.	$54,000, plus 18% of excess over $500,000.
Over $1,000,000 but not over $2,000,000.	$144,000 plus 24% of excess over $1,000,000.
Over $2,000,000	$384,000, plus 30% of excess over $2,000,000.

(d) *Effective date.* The provisions of § 20.2101–1 are effective with respect to estates of decedents dying after the date these regulations are published as final regulations in the **Federal Register**. With respect to estates of decedents dying on or before such date, taxpayers may rely on any reasonable interpretation of the statutory provisions.

Par. 7. § 20.2102–1 is amended by adding a new paragraph (c) to read as follows:

§ 20.2102–1 Estates of nonresidents not citizens; credits against tax.

* * * * *

(c) *Unified credit*—(1) *In general.* Subject to paragraph (c)(2) of this section, in the case of decedents dying after November 10, 1988, a unified credit of $13,000 is allowed against the tax imposed by section 2101 subject to the limitations of section 2102(c).

(2) *When treaty is applicable.* To the extent required under any treaty obligation of the United States, the estate of a nonresident not a citizen of the United States is allowed the unified credit permitted to a United States citizen or resident of $192,800 multiplied by the proportion that the total gross estate of the decedent situated in the United States bears to the decedent's total gross estate wherever situated.

(3) *Certain residents of possessions.* In the case of a decedent who is considered to be a "nonresident not a citizen of the United States" under section 2209, there is allowed a unified credit equal to the greater of $13,000, or $46,800 multiplied by the proportion that the decedent's gross estate situated in the United States bears to the total gross estate of the decedent wherever situated.

(4) *Effective date.* The provisions of § 20.2102–1(c) are effective with respect to estates of decedents dying after the date these regulations are published as final regulations in the **Federal Register**. With respect to estates of decedents dying on or before such date, taxpayers may rely on any reasonable interpretation of the statutory provisions.

Par. 8. § 20.2106–1 is amended by revising paragraph (a)(3) (including concluding text following paragraph (a)(3)(ii)(*b*)), adding paragraph (a)(4), and removing paragraph (c) to read as follows:

§ 20.2106–1 Estates of nonresidents not citizens; taxable estate; deductions in general.

(a) * * *

(3) Subject to the special rules set forth at § 20.2056A–1(c), the amount which would be deductible with respect to property situated in the United States at the time of the decedent's death under the principles of section 2056. Thus, if the surviving spouse of the decedent is a citizen of the United States at the time of the decedent's death, a marital deduction is allowed with respect to the estate of the decedent if all other applicable requirements of section 2056 are satisfied. If the surviving spouse of the decedent is not a citizen of the United States at the time of the decedent's death, the provisions of section 2056, including specifically the provisions of section 2056(d) and (unless section 2056(d)(4) applies) the provisions of section 2056A (QDOTs) must be satisfied.

(4) *Effective date.* The provisions of § 20.2106–1(a)(3) are effective with respect to estates of decedents dying after the date these regulations are published as final regulations in the **Federal Register**. With respect to estates of decedents dying on or before such date, taxpayers may rely on any reasonable interpretation of the statutory provisions.

* * * * *

PART 25—GIFT TAX; GIFTS MADE AFTER DECEMBER 31, 1954

Par. 9. The authority citation for part 25 is revised to read as follows:

Authority: 26 U.S.C. 7805.

Par. 10. Section 25.2503–2 is amended as follows:

1. The first sentence in paragraph (a) is revised to read as set forth below.

2. New paragraph (f) is added to read as set forth below.

§ 25.2503–2 Exclusion from gifts.

(a) * * * Except as provided in paragraph (f) of this section (involving gifts to a noncitizen spouse), the first $10,000 of gifts made to any one donee during the calendar year 1982 or any calendar year thereafter, except gifts of future interests in property as defined in §§ 25.2503–3 and 25.2503–4, is excluded in determining the total amount of gifts for the calendar year.

* * *

* * * * *

(f) *Special rule in the case of gifts made on or after July 14, 1988, to a spouse who is not a United States citizen*—(1) *In general.* Subject to the special rules set forth at § 20.2056A–1(c) of this chapter, in the case of gifts made on or after July 14, 1988, if the donee of the gift is the donor's spouse and the donee spouse is not a citizen of the United States at the time of the gift, the first $100,000 of gifts made during the calendar year to the donee spouse (except gifts of future interests) is excludable in determining the total amount of gifts for the calendar year. It is not relevant for purposes of this paragraph (f) whether the donor is a citizen or resident of the United States for purposes of chapter 12.

(2) *Gifts made after June 29, 1989.* In the case of gifts made after June 29, 1989, the $100,000 exclusion provided in paragraph (f)(1) of this section applies only if the gift in excess of the otherwise applicable annual exclusion is in a form that qualifies for the gift tax marital deduction under section 2523(a) but for the provisions of section 2523(i)(1) (disallowing the marital deduction if the donee spouse is not a United States citizen.)

(3) *Effective date.* The provisions of § 25.2503–2(f) (1) and (2) are effective with respect to gifts made after the date these regulations are published as final regulations in the **Federal Register.** With respect to gifts made on or before such date, donors may rely on any reasonable interpretation of the statutory provisions.

Par. 11. Sections 25.2523(i)–1, 25.2523(i)–2 and 25.2523(i)–3 are added to read as follows:

§ 25.2523(i)–1 Disallowance of marital deduction when spouse is not a United States citizen.

(a) *In general.* Subject to § 20.2056A–1(c) of this chapter, section 2523(i)(1) disallows the marital deduction if the spouse of the donor is not a citizen of the United States at the time of the gift. If the spouse of the donor is a citizen of the United States at the time of the gift, the gift tax marital deduction under section 2523(a) is allowed regardless of whether the donor is a citizen or resident of the United States at the time of the gift, subject to the otherwise applicable rules of section 2523.

(b) *Exception for certain joint and survivor annuities.* Paragraph (a) does not apply to disallow the marital deduction with respect to any transfer resulting in the acquisition of rights by a noncitizen spouse under a joint and survivor annuity described in section 2523(f)(6).

(c) *Increased annual exclusion*—(1) *In general.* In the case of gifts made from a donor to the donor's spouse for which a marital deduction is not allowable under this section, if the gift otherwise qualifies for the gift tax annual exclusion under section 2503(b), the amount of the annual exclusion under section 2503(b) is $100,000 in lieu of $10,000. In the case of gifts made after June 29, 1989, in order for the increased annual exclusion to apply, the gift in excess of the otherwise applicable annual exclusion under section 2503(b) must be in a form that qualifies for the marital deduction but for the disallowance provision of section 2523(i)(1).

(2) *Status of donor.* The $100,000 annual exclusion for gifts to a noncitizen spouse is available regardless of the status of the donor. Accordingly, it is immaterial whether the donor is a citizen, resident or a nonresident not a citizen of the United States as long as the spouse of the donor is not a citizen of the United States at the time of the gift. See § 25.2503–2(f).

(d) *Examples.* The principles outlined in the preceding paragraphs are illustrated in the following examples. Assume in each of the examples that the donee, *S*, is *D*'s spouse and is not a United States citizen at the time of the gift.

Example 1. Outright transfer of present interest. In 1993, *D*, a United States citizen, transfers to *S*, outright, 100 shares of *X* corporation stock valued for federal gift tax purposes at $130,000. The transfer is a gift of a present interest in property under section 2503(b). Additionally, the gift qualifies for the gift tax marital deduction except for the disallowance provision of section 2523(i)(1). Accordingly, $100,000 of the $130,000 gift is excluded from the total amount of gifts made during the calendar year by *D* for gift tax purposes.

Example 2. Transfer of survivor benefits. In 1993, *D*, a United States citizen, retires from employment in the United States and elects to receive a reduced retirement annuity in order to provide *S* with a survivor annuity upon *D*'s death. The transfer of rights to *S* in the joint and survivor annuity is a gift by *D* for gift tax purposes. However, under § 25.2523(i)–1(b), the gift qualifies for the gift tax marital deduction even though *S* is not a United States citizen.

Example 3. Transfer of present interest in trust property. In 1993, *D*, a resident alien, transfers property valued at $500,000 in trust to *S*, who is also a resident alien. The trust instrument provides that the trust income is payable to *S* at least quarterly and *S* has a testamentary general power to appoint the trust corpus. The transfer to *S* qualifies for the marital deduction under section 2523 but for the provisions of section 2523(i)(1). Because *S* has a life income interest in the trust, *S* has a present interest in a portion of the trust. Accordingly, *D* may exclude the present value of *S*'s income interest (up to $100,000) from *D*'s total 1993 calendar year gifts.

Example 4. Transfer of present interest in trust property. The facts are the same as in *Example 3*, except that *S* does not have a testamentary general power to appoint the trust corpus. Instead, *D*'s child, *C*, has a remainder interest in the trust. If *S* were a United States citizen, the transfer would qualify for the gift tax marital deduction if a qualified terminable interest property election is made under section 2523(f)(4). Accordingly, the gift qualifies for the gift tax marital deduction but for the disallowance provision of section 2523(i)(1). The annual exclusion under section 2523(i)(2) is available with respect to *D*'s transfer in trust and *D* may exclude the present value of *S*'s income interest (up to $100,000) from *D*'s total 1993 calendar year gifts.

Example 5. Spouse becomes citizen after transfer. D, a United States citizen, transfers a residence valued at $350,000 on December 20, 1993, to *D*'s spouse, *S*, a resident alien. On January 31, 1994, *S* becomes a naturalized United States citizen. On *D*'s federal gift tax return for 1993, *D* must include $250,000 as a gift ($350,000 transfer less $100,000 exclusion). Although *S* becomes a citizen in January, 1994, *S* is not a citizen of the United States at the time the transfer is made. Therefore, no gift tax marital deduction is allowable. However, the transfer does qualify for the $100,000 annual exclusion.

§ 25.2523(i)–2 Treatment of spousal joint tenancy property where one spouse is not a United States citizen.

(a) *In general.* In the case of the creation of a joint tenancy with right of survivorship between spouses, or a tenancy by the entirety, where the donee spouse is not a United States citizen at the time of the creation of the tenancy, the gift tax treatment of the creation and termination of the tenancy (regardless of whether the donor is a citizen, resident or nonresident not a citizen of the United States at such time), is governed by the principles of sections 2515 and 2515A (as such sections were in effect before their repeal by the Economic Recovery Tax Act of 1981). However, in applying these principles, the donor spouse cannot elect to treat the creation of a tenancy in real property as a gift, as provided in section 2515(c) prior to its repeal by the Economic Recovery Tax Act of 1981.

(b) *Tenancies by the entirety and joint tenancies in real property*—(1) *In general.* Under the principles of section 2515, the creation of a tenancy by the entirety (or joint tenancy) in real property (either by one spouse alone or by both spouses) and any additions to the value of the tenancy in the form of improvements, reductions in indebtedness thereon, or otherwise, are not deemed to be transfers of property for purposes of the gift tax, regardless of the proportion of the consideration furnished by each spouse, but only if the creation of the tenancy otherwise is a gift to the donee spouse who is not a citizen of the United States at the time of the gift.

(2) *Termination.* When a tenancy described in paragraph (b)(1) of this section is terminated, other than by reason of the death of a spouse, a spouse is deemed to have made a gift to the extent that the proportion of the total consideration furnished by the spouse multiplied by the proceeds of the termination (whether in the form of cash, property, or interests in property) exceeds the value of the proceeds of termination received by the spouse. See section 2523(i), and §§ 25.2523(i)–1 and 25.2503–2(f) as to certain of the tax consequences that may result upon termination of the tenancy.

(3) *Tenancy by the entirety.* For purposes of this section, "tenancy by the entirety" includes a joint tenancy between husband and wife with right of survivorship.

(4) *Section 2515 regulations.* The regulations under section 2515 are applicable for purposes of determining the amount of consideration furnished by each spouse, whether a termination has occurred, the extent of the termination, and the amount of the gift upon termination.

(5) *No election to treat as gift.* The regulations under section 2515 that relate to the election to treat the creation of a tenancy by the entirety as constituting a gift and the consequences of such an election upon termination of the tenancy (§§ 25.2515–2 and 25.2515–4) do not apply for purposes of section 2523(i)(3).

(c) *Tenancies by the entirety in personal property where one spouse is not a United States citizen*—(1) *In general.* In the case of the creation (either by one spouse alone or by both spouses where at least one of the spouses is not a United States citizen) of a joint interest in personal property with right of survivorship, or additions to the value thereof in the form of improvements, reductions in the indebtedness thereof, or otherwise, the retained interest of each spouse, solely for purposes of determining whether there has been a gift by the donor to the spouse who is not a citizen of the

United States at the time of the gift, is treated as one-half the value of the joint interest. See section 2523(i) and §§ 25.2523(i)–1 and 25.2503–2(f) as to certain of the tax consequences that may result upon creation and termination of the tenancy.

(2) *Exception.* The rule provided in paragraph (c)(1) of this section does not apply with respect to any joint interest in property if the fair market value of the interest in property (determined as if each spouse had a right to sever) cannot reasonably be ascertained except by reference to the life expectancy of one or both spouses. In these cases, actuarial principles may need to be resorted to in determining the gift tax consequences of the transaction.

§ 25.2523(i)–3 Effective date.

The provisions of §§ 25.2523(i)–1 and 25.2523(i)–2 are effective in the case of gifts made after the date that these regulations are published in the **Federal Register** as final regulations.

Shirley D. Peterson,

Commissioner of Internal Revenue.

[FR Doc. 92–31190 Filed 12–31–92; 8:45 am]

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26 CFR Part 1, 20 and 25

[PS–102–88]

RIN 1545–AM85

Income, Gift and Estate Tax; Hearing

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of a public hearing on proposed Income Tax Regulations relating to income tax imposed under chapter 1, the estate tax imposed under chapter 11 and the gift tax imposed under chapter 12 of the Internal Revenue Code of 1986.

DATES: The public hearing will be held on Tuesday, March 2, 1993, beginning at 10:00 a.m. Requests to speak and outlines of oral comments must be received by Tuesday, February 16, 1993.

ADDRESSES: The public hearing will be held in the IRS Auditorium, Seventh floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Requests to speak and outlines of oral comments should be submitted to the Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attn: CC:CORP:T:R [PS–102–88], room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), 202–622–7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations that would provide guidance needed to comply with the changes to the marital deduction provisions of the estate and gift tax chapters.

The rules of § 601.601(a)(3) of the "Statement of Procedural Rules" (26 CFR part 601) shall apply with respect to the public hearing. Persons who have submitted written comments within the time prescribed in the notice of proposed rulemaking and who also desire to present oral comments at the hearing on the proposed regulations should submit not later than Tuesday, February 16, 1993, an outline of the oral comments/testimony to be presented at the hearing and the time they wish to devote to each subject.

Each speaker (or group of speakers representing a single entity) will be limited to 10 minutes for an oral presentation exclusive of the time consumed by the questions from the panel for the government and answers to these questions.

Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the persons testifying. Copies of the agenda will be available free of charge at the hearing.

By direction of the Commissioner of Internal Revenue:

Dale D. Goode,

Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 92–31935 Filed 12–31–92; 8:45 am]

BILLING CODE 4830–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA–37–1–5617; FRL–4551–8]

Approval and Promulgation of Implementation Plans, California State Implementation Plan Revision; San Bernardino County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA is proposing a limited approval and limited disapproval of a new rule submitted to revise the California State Implementation Plan (SIP) adopted by the San Bernardino County Air Pollution Control District (San Bernardino County APCD) on March 2, 1992. The California Air Resources Board (CARB) submitted this new rule to EPA on June 19, 1992. The new rule concerns San Bernardino County APCD Rule 1115, Metal Parts and Products Coating Operations, which controls the emission of volatile organic compounds (VOCs) from metal coating operations. EPA has evaluated Rule 1115 and is proposing a limited approval under sections 110(k)(3) and 301(a) of the Clean Air Act, as amended in 1990 (CAA or the Act) because the rule will strengthen the SIP. At the same time, EPA is proposing a limited disapproval under sections 110(k)(3) and 301(a) of the CAA because the rule does not meet the Part D, section 182(a)(2)(A) requirement of the CAA.

DATES: Comments must be received on or before February 4, 1993.

ADDRESSES: Comments may be mailed to: Daniel A. Meer, Rulemaking Section II (A–5–3), Air and Toxics Division, Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the new rule and EPA's evaluation report of the rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 1219 "K" Street, Sacramento, CA 95814.

San Bernardino County Air Pollution Control District, 15428 Civic Drive, Victorville, California 92392.

FOR FURTHER INFORMATION CONTACT: Christine D. Vineyard, Rulemaking Section II (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1195, FTS: (415) 744–1076.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 1978 EPA promulgated a list of ozone nonattainment areas under the provisions of the 1977 Clean Air Act (1977 CAA or pre-amended Act) that included the San Bernardino Area. 43 FR 8964; 40 CFR 81.305. Because the San Bernardino Area was unable to reach attainment by the statutory attainment date of December 31, 1982, California requested under pre-amended section 172 (a)(2), and EPA approved, an extension of the attainment date to December 31, 1987.40 CFR 52.238. The

San Bernardino Area did not attain the ozone standard by the approved attainment date. On May 26, 1988, EPA notified the Governor of California that the San Bernardino County APCD's portion of the SIP was inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, amendments to the 1977 CAA were enacted. Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 74401–7671q. In amended § 182 (a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182 (a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the date of enactment. It requires such areas to adopt and correct RACT rules pursuant to pre-amended section 172(b) as interpreted in pre-amended guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The San Bernardino Area is classified as severe;[2] therefore, this area is subject to the RACT fix-up requirement and the May 15, 1991 deadline.

The State of California submitted many revised RACT rules to EPA for incorporation into its SIP on June 19, 1992, including the rule being acted on in this notice. This notice addresses EPA's proposed action for Rule 1115, Metal Parts and Products Coating Operations. This submitted rule was found to be complete on August 27, 1992 pursuant to EPA's completeness criteria adopted on August 26, 1991 (56 FR 42216) and set forth in 40 CFR part 51, appendix V and is being proposed for limited approval and limited disapproval.

Rule 1115 controls the emission of volatile organic compounds (VOCs) from metal coating operations. VOCs contribute to the production of ground level ozone and smog. Rule 1115 is a new rule which has been adopted to meet EPA's SIP-Call and the section 182 (a)(2)(A) CAA requirement. The following is EPA's evaluation and proposed action for San Bernardino County APCD's Rule 1115.

EPA Evaluation and Proposed Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 1. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the preamended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to "fix-up" their RACT rules. See section 182(a)(2)(A). The CTG applicable to Rule 1115, Metal parts and Products Coating Operations is entitled, "Control of Volatile Organic Emissions from Existing Stationary Sources (Volume VI: Surface Coating of Miscellaneous Metal Parts and Products)", EPA–450/2–78–015. Further interpretations of EPA policy are found in the Blue Book. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

San Bernardino County APCD's Rule 1115, Metal Parts and Products Coating Operations, is a new rule which was adopted to reduce the amount of VOC's emitted by metal coating operations. EPA has evaluated San Bernardino County APCD's submitted Rule 1115 for consistency with the CAA, EPA regulations, and EPA policy and has found that the submitted rule will strengthen the SIP by providing emission limits, recordkeeping for coatings and solvents used, and test methods for the determination of compliance.

Although the approval of San Bernardino County APCD's Rule 1115 will strengthen the SIP, this rule still contains deficiencies which were required to be corrected pursuant to the section 182(a)(2)(A) requirement of part D of the CAA. The rule allows the Air Pollution Control Officer discretion in choosing equivalent test methods for determination of compliance, it contains specialty coatings which exceed the CTG limits, and lacks recordkeeping requirements for add-on control equipment. A detailed description of the deficiencies is contained in the technical support document (TSD) for Rule 1115. Because of these deficiencies, the rule is not approvable pursuant to the section 182(a)(2)(A) of the CAA because it is not consistent with the interpretation of section 172 of the 1977 CAA as found in the Blue Book and may lead to rule enforceability problems.

Because of the above deficiencies, EPA cannot grant full approval of this rule under section 110(k)(3) and part D. Also, because the submitted rule is not composed of separable parts which meet all the applicable requirements of the CAA, EPA cannot grant partial approval of the rule under section 110(k)(3). However, EPA may grant a limited approval of the submitted rule under section 110(k)(3) in light of EPA's authority pursuant to section 301(a) to adopt regulations necessary to further air quality by strengthening the SIP. The approval is limited because EPA's action also contains a simultaneous limited disapproval. In order to strengthen the SIP, EPA is proposing a limited approval of San Bernardino County APCD's submitted Rule 1115 under section 110(k)(3) and 301(a) of the CAA.

At the same time, EPA is also proposing a limited disapproval of this rule because it contains deficiencies that have not been corrected as required by section 182(a)(2)(A) of the CAA and, as such, the rule does not fully meet the requirements of part D of the Act. Under section 179(a)(2), if the Administrator disapproves a submission under section 110(k) for an area designated nonattainment, based on the submission's failure to meet one or more of the elements required by the Act, the Administrator must apply one of the sanctions set forth in section 179(b) unless the deficiency has been corrected within 18 months of such disapproval. Section 179(b) provides two sanctions available to the Administrator: highway funding and offsets. The 18 months period referred to in section 179(a) will begin at the time EPA publishes final notice of this disapproval. Moreover, the

[1] Among other things, the pre-amended guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** Notice" (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).

[2] San Bernardino County APCD retained its designation and was classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 56 FR 56694 (November 6, 1991).

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final disapproval triggers the federal implementation plan (FIP) requirement under section 110(c). It should be noted that the rule covered by this notice of proposed rulemaking has been adopted by the San Bernardino County APCD and is currently in effect in the San Bernardino Country district. EPA's limited disapproval action in the notice of proposed rulemaking does not prevent the San Bernardino County APCD from fully enforcing this rule.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Regulatory Process

Under the Regulatory Flexibility Act, 5 U.S.C. section 600 et. seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises and government entities with jurisdiction over populations of less than 50,000.

Limited approvals under sections 110 and 301 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPS on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.ct. 1976); 42 U.S.C. 7410(a)(2).

EPA's limited approval of the State request under sections 110 and 301 and subchapter I, part D of the CAA does not affect any existing requirements applicable to small entities. Any pre-existing federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect its state-enforceability. Moreover, EPA's disapproval of the submittal does not impose any new federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements nor does it impose any new federal requirements.

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and Table 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of two years. EPA has submitted a request for a permanent waiver for Table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and recordkeeping requirements.

Authority: 42 U.S.C. §§ 7401–7671q.

Dated: December 22, 1992.

David P. Howekamp,

Acting Regional Administrator.

[FR Doc. 93–73 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–01–M

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40 CFR Part 52

[CA 12–6–5606; FRL–4551–9]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision; San Diego County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA is proposing to approve a revision to the California State Implementation Plan (SIP) adopted by the San Diego County Air Pollution Control District (San Diego County APCD) on October 16, 1990. The California Air Resources Board submitted this revision to EPA on April 5, 1991. The revision concerns the adoption of San Diego County APCD's Rule 67.5, Paper, Fabric and Film Coating Operations. This rule regulates volatile organic compound (VOC) emissions from paper, fabric and film operations. EPA has evaluated this rule and is proposing to approve it under section 110(k)(3) as meeting the requirements of section 110(a) and part D of the Clean Air Act, as amended in 1990 (CAA or the Act).

DATES: Comments must be received on or before [February 4, 1993].

ADDRESSES: Comments may be mailed to: Daniel Meer, Rulemaking Section II (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105.

Copies of the rule revision and EPA's evaluation report of the rule are available for public inspection at EPA's Region 9 office during normal business hours. Copies of the submitted rule revision are also available for inspection at the following locations:

California Air Resources Board, Stationary Source Division, Rule Evaluation, 1219 "K" Street, Sacramento, CA 95814.

San Diego County Air Pollution Control District; 9150 Chesapeake Drive, San Diego, CA 92123–1095.

FOR FURTHER INFORMATION CONTACT: Christine Vineyard, Rulemaking Section II (A–5–3), Air and Toxics Division, U.S. Environmental Protection Agency, Region IX; 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744–1195, FAX: (415) 744–1076.

SUPPLEMENTARY INFORMATION:

Background

On March 3, 1978, EPA promulgated a list of ozone nonattainment areas under the provisions of the Clean Air Act, as amended in 1977 (1977 CAA or pre-amended Act), that included the San Diego Area. 43 FR 8964, 40 CFR 81.305. Because this area was unable to meet the statutory attainment date of December 31, 1982, California requested under section 172(a)(2), and EPA approved, an extension of the attainment date to December 31, 1987. 40 CFR 52.238. On May 26, 1988, EPA notified the Governor of California, pursuant to section 110(a)(2)(H) of the pre-amended Act, that the above district's portion of the California SIP was inadequate to attain and maintain the ozone standard and requested that deficiencies in the existing SIP be corrected (EPA's SIP-Call). On November 15, 1990, the Clean Air Act Amendments of 1990 were enacted. Public Law 101–549, 104 Stat. 2399, codified at 42 U.S.C. 7401.7671q. In amended § 182(a)(2)(A) of the CAA, Congress statutorily adopted the requirement that nonattainment areas fix their deficient reasonably available control technology (RACT) rules for ozone and established a deadline of May 15, 1991 for states to submit corrections of those deficiencies.

Section 182(a)(2)(A) applies to areas designated as nonattainment prior to enactment of the amendments and classified as marginal or above as of the

date of enactment. It requires such areas to adopt and correct RACT rules pursuant to preamended section 172(b) as interpreted in pre-amended guidance.[1] EPA's SIP-Call used that guidance to indicate the necessary corrections for specific nonattainment areas. The San Diego Area is classified as a severe ozone area; therefore, this area is subject to the RACT fix-up requirement and the May 15, 1991 deadline.[2]

The State of California submitted many revised RACT rules for incorporation into its SIP on May 30, 1991, including the rule being acted on in this notice. This notice addresses EPA's proposed action for San Diego County APCD, Rule 67.5, Paper, Fabric and Film Coating Operations. This submitted rule was found to be complete on May 21, 1991 pursuant to EPA's completeness criteria adopted on February 26, 1990 (55 FR 5830) and set forth in 40 CFR part 51 appendix V.[3] Today, EPA is proposing approval of the rule into the federally-enforceable SIP.

Rule 67.5 regulates volatile organic compound (VOC) emissions from coatings used in paper, fabric and film operations. VOCs contribute to the production of ground level ozone and smog. The rule was adopted as part of each district's effort to achieve the National Ambient Air Quality Standard (NAAQS) for ozone and in response to EPA's SIP-Call and the section 182(a)(2)(A) CAA requirement. The following is EPA's evaluation and proposed action for this rule.

EPA Evaluation and Proposed Action

In determining the approvability of a VOC rule, EPA must evaluate the rule for consistency with the requirements of the CAA and EPA regulations, as found in section 110 and part D of the CAA and 40 CFR part 51 (Requirements for Preparation, Adoption, and Submittal of Implementation Plans). The EPA interpretation of these requirements, which forms the basis for today's action, appears in the various EPA policy guidance documents listed in footnote 1. Among those provisions is the requirement that a VOC rule must, at a minimum, provide for the implementation of RACT for stationary sources of VOC emissions. This requirement was carried forth from the pre-amended Act.

For the purpose of assisting state and local agencies in developing RACT rules, EPA prepared a series of Control Technique Guideline (CTG) documents. The CTGs are based on the underlying requirements of the Act and specify the presumptive norms for what is RACT for specific source categories. Under the CAA, Congress ratified EPA's use of these documents, as well as other Agency policy, for requiring States to "fix-up" their RACT rules. See section 182(a)(2)(A). The CTG applicable to this rule is entitled, "Control of Volatile Organic Emissions from Existing Stationary Sources (Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light-Duty Trucks)", EPA–450/2–77–008. Further interpretations of EPA policy are found in the Blue Book, referred to in footnote 1. In general, these guidance documents have been set forth to ensure that VOC rules are fully enforceable and strengthen or maintain the SIP.

San Diego County APCD's Rule 67.5, Paper Fabric and Film Coating Operations, includes the following significant changes from the current SIP approved rule (for more detailed information please refer to the Technical Support Document):

- The scope of the rule has been expanded to include reverse osmosis membrane manufacturing.
- Several new definitions were added to clarify the revisions of the rule.
- The emissions limit was revised to 265 grams of VOC per liter of coating as applied.
- A provision was added to emissions from noncompliant coatings to be controlled by an emission control system with combined collection and abatement efficiency of at least 90 percent on a mass basis at all times during operation.
- Specific operating requirements were added for cleaning equipment using VOC containing materials.
- Daily recordkeeping requirements were added to reflect compliance of day-to-day operations.
- Test methods were added for determination of compliance.
- A revised compliance schedule was added to reflect the new time frame for achieving compliance.
- A low solvent usage exemption was added for laboratory equipment.

EPA has evaluated the submitted rule and has determined that it is consistent with the CAA, EPA regulations, and EPA policy. Therefore, San Diego APCD's Rule 67.5, Paper, Fabric and Film Coating Operations, is being proposed for approval under section 110(k)(3) of the CAA as meeting the requirements of section 110(a) and part D.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Regulatory Process

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et. seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under sections 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S.E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and Table 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of two years. EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. OMB has

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[1] Among other things, the pre-amended guidance consists of those portions of the proposed Post-1987 ozone and carbon monoxide policy that concern RACT, 52 FR 45044 (November 24, 1987); "Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations, Clarification to Appendix D of November 24, 1987 **Federal Register** Notice" (Blue Book) (notice of availability was published in the **Federal Register** on May 25, 1988); and the existing control technique guidelines (CTGs).

[2] The San Diego Area was redesignated nonattainment and classified by operation of law pursuant to sections 107(d) and 181(a) upon the date of enactment of the CAA. See 55 FR 56694 (November 6, 1991).

[3] EPA has since adopted completeness criteria pursuant to section 110(k)(1)(A) of the CAA to be codified at 40 CFR part 51, Appendix V. See 56 FR 42216 (August 26, 1991).

agreed to continue the temporary waiver until such time as it rules on EPA's request.

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Hydrocarbons, Intergovernmental relations, Reporting and Recordkeeping requirements.

Authority: 42 U.S.C. 7401–7671q.

Dated: December 22, 1992.

David P. Howekamp,

Acting Regional Administrator.

[FR Doc. 93–74 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–60–M

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40 CFR Part 52

[WI 13–1–5278; FRL–4551–6]

Approval and Promulgation of Implementation Plans; Wisconsin, Rhinelander Sulfur Dioxide Maintenance Plan

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: USEPA is proposing to disapprove rule S. NR 418.07: Rhinelander Reasonably Available Control Technology (RACT) Sulfur Limitations, Wis. Adm. Code, (NR 418.07) as a revision to Wisconsin's State Implementation Plan (SIP) for sulfur dioxide.

USEPA's action is based upon a SIP revision request which was submitted by the State on April 28, 1989, to satisfy the requirements of the Clean Air Act.

DATES: Comments on this revision and on the proposed USEPA action must be received by February 4, 1993.

ADDRESSES: Copies of the SIP revision request and USEPA's analysis are available for inspection at the following address: (It is recommended that you telephone Sheila Breen at (312) 886–6053, before visiting the Region 5 Office.)

U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Written comments should be sent to: Carlton Nash, Chief, Regulation Development Section, Air Toxics and Radiation Branch (AT–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Sheila Breen, Regulation Development Section, Air Toxics and Radiation Branch (AT–18J), U.S. Environmental Protection Agency, Region 5, Chicago, Illinois 60604, (312) 886–6053.

SUPPLEMENTARY INFORMATION:

I. Summary of State Submittal

A. Reasons for SIP Submittal

On April 26, 1984, USEPA notified the Governor of Wisconsin, pursuant to section 110(a)(2)(H) of the Clean Air Act, that the Wisconsin sulfur dioxide (SO_2) SIP was inadequate to achieve the primary and secondary national ambient air quality standards (NAAQS). This finding of SIP inadequacy applied statewide, except for certain sources and areas which are not subject to this proposed rulemaking. USEPA found that the Wisconsin SIP did not contain sufficient specific SO_2 emission limitations and timetables for compliance with such limitation as required by section 110(a)(2)(B) of the Clean Air Act in order to ensure attainment and maintenance of the SO_2 NAAQS. Wisconsin has responded to the notice of SIP deficiency with numerous submittals to USEPA, including NR 418.07: Rhinelander RACT Sulfur Limitations, which is the focus of today's proposed rulemaking.

Additionally, section 191(b) of the Clean Air Act, as amended in 1990, required States with areas designated primary nonattainment for sulfur dioxide that lacked fully approved SIPs prior to November 15, 1990, to submit to USEPA by May 15, 1992, a SIP revision meeting the requirements of part D of the Act for the applicable area. USEPA promulgated a nonattainment designation for a subportion of the city of Rhinelander in Oneida County on October 9, 1985, (50 FR 41139). The Wisconsin Department of Natural Resources (WDNR) submitted to USEPA on April 28, 1989, a part D SIP revision for the Rhinelander nonattainment area. The SIP revision consists of NR 418.07 which regulates SO_2 emissions from the Rhinelander Paper Company.

B. Historical Information

In 1981 and 1983, exceedances of the primary SO_2 NAAQS were monitored in Rhinelander. After further investigation, it was determined that the Rhinelander Paper Company, the only significant SO_2 source in the city, was responsible for the violations. WDNR performed a modeling analysis, using the USEPA guideline model: Industrial Source Complex Short Term (ISCST), to determine the appropriate emission limits for this source. As a result of this analysis, the State adopted a rule, effective on April 1, 1985, s. NR 154.12(9), Wis. Adm. Code which prescribed specific emission limits for boilers and process sources at Rhinelander Paper Company.

During the second half of 1985, three more exceedances were monitored in Rhinelander from a monitor 0.6 kilometers to the north-northeast of the paper mill. WDNR performed a field investigation, which identified the facility's boiler stacks as the culpable sources. As noted above, the emission limits at which the source was operating at the time of the violations were based upon an air dispersion modeling analysis using a USEPA guideline model (ISCST). It was subsequently determined that the volumetric flow rates originally modeled were higher than the actual volumetric flow rates as identified in a stack test, possibly resulting in the underprediction of SO_2 concentrations by ISCST. A subsequent analysis, using ISCST and the correct flow rates still underpredicted the ambient data. USEPA modeling guidelines counsel that in the event of an independently performing guideline model, ambient data (i.e., a rollback analysis) may be used to determine appropriate emission limits.

A rollback analysis is a simple model that assumes that if emissions from each source affecting a given receptor are decreased by the same percentage, ambient air quality concentrations decrease proportionately. A rollback takes a monitored ambient exeedance recorded during a specific set of facility operating conditions, determines the amount of exceedance due to each SO_2 source at the facility, and then determines how much the emissions from any given SO_2 source must be linearly scaled back to provide for attainment of the NAAQS under that set of operating conditions.

Using the results of a rollback calculation, WDNR issued an administrative order for Rhinelander Paper Company on October 2, 1986, which limited its five fossil fuel fired steam generating stoker boilers to a maximum of 1.25 pounds of SO_2 per million British Thermal Units (lbs. SO_2/mmBTU) and limited its one fossil fuel fired steam generating cyclone boiler to a maxium of 3.50 lbs. SO_2/mmBTU.

WDNR met with the Rhinelander Paper Company on December 8, 1987, regarding the administrative order. The source proposed to WDNR that the stoker boiler limit be relaxed to 1.60 lbs. SO_2/mmBTU. This stoker boiler limit and the other limits from the administrative order were incorporated into NR 418.07. Along with the SIP revisions submittal, WDNR submitted to USEPA an ISCST analysis that shows the NAAQS are attained at these rollback-relaxed stoker boiler limits.

C. Proposed SIP Regulations

The revised Rhinelander SO_2 rule regulations the emission of sulfur dioxide within the corporate boundaries of Rhinelander, Wisconsin, from sources constructed before April 1, 1985. A paper mill (Rhinelander Paper Company) is the only source affected by the rule limits. The limits for each SO_2 source in the proposed SIP revision and its other provisions are summarized below.

NR 418.07(1)(a)(1): Fossil fuel fired stoker boilers—1.60 lbs. SO_2/mmBTU.
NR 418.07(1)(a)(2): Fossil fuel fired cyclone boilers—3.50 lbs. SO_2/mmBTU.
NR 418.07(1)(a)(3): Surface condenser—0.40 lbs./hour and 7.92 lbs./24 hours.
NR 418.07(1)(a)(4): Yeast dryer—4.20 lbs./hour and 88.1 lbs./24 hours.
NR 418.07(1)(a)(5): Liquor dryer—2.10 lbs./hour and 44.9 lbs./24 hours.
NR 418.07(1)(c)(1): Vacuum compression evaporator—28.8 lbs./hour and 600.0 lbs./24 hours.
NR 418.07(1)(c)(2): All other sources: 0.0 lbs./hour.
NR 418.07(2): Requires source subject to above limits to achieve compliance by April 1, 1985.
NR 418.07(3): Requires source subject to above limits to submit a plan by May 1, 1985, demonstrating continuous compliance with the above limits.
NR 418.07(4): Prohibits source subject to above limits from lowering the heights of SO_2 emission releases from those that existed on December 1, 1983, without permission by WDNR.
NR 418.07(5): Requires source subject to above limits to notify WDNR in writing 30 days prior to resumption of pulp manufacturing.

II. Analysis of State Submittal

USEPA has reviewed the technical analyses that were submitted in conjunction with the Rhinelander SO_2 rule and is proposing to disapprove the SIP revision for the following reasons:

A. Inappropriate Use of Underpredicting Model

In order to technically support the relaxed emission limits in s. NR 418.07(1)(a)(1), Wis. Adm. Code, for the stoker boilers that were requested by Rhinelander Paper Company (i.e., 1.60 lbs. SO_2/mmBTU), WDNR submitted a dispersion modeling analysis using ISCST. This is the same model that has twice been shown to be underpredicting ambient sulfur dioxide concentrations in the Rhinelander area. According to USEPA modeling policy in the "Guideline on Air Quality Models (revised)", in all cases the model applied to a given situation should be the one that provides the most accurate representation of atmospheric conditions in the area. USEPA has concluded that ISCST-derived limits do not adequately ensure the NAAQS will be attained in Rhinelander.

B. Inappropriate Use of Rollback Analysis

USEPA has determined that the rollback analysis used by WDNR to technically support all of the limits in NR 418.07 (except (1)(a)(1), which was supported by a dispersion modeling analysis) does not adequately ensure that the NAAQS will be attained at these emission limitations.

Wisconsin's analysis was based on the second-highest 24 hour rolling average concentration monitored in 1985: 453 micrograms per cubic meter, recorded from 8 a.m. on September 16, to 8 a.m. on September 17. The 24 hour sulfur dioxide NAAQS is 365 micrograms per cubic meter. The background SO_2 concentration in Rhinelander was estimated to be 20 micrograms per cubic meter. Thus, the emission sources at the Rhinelander Paper Company must not cause concentrations greater than 345 micrograms per cubic meter (365–20 = 345). The next step in the analysis is to determine which process sources were operating during the time of the exceedance. According to operating data from the Rhinelander Paper Company and an eyewitness account, WDNR determined that the stack emissions from the cyclone boilers and two stoker boilers were impacting the monitor during the time of the exceedance. The facility's other three stoker boilers and the surface condenser were not operating during the period. The plant's other SO_2 sources (the liquor dryer, the yeast dryer, and the vacuum compression evaporator) were in operation but were judged not to be impacting the monitor, and therefore, were not accounted for in the State's analysis.

According to the State's analysis, the cyclone boiler was responsible for 93.50 percent of the exceedance and each of the two stoker boilers operating were responsible for 3.25 percent of the ambient value. Due to the age and nature of the stoker boilers, a minimum emissions limit of 1.25 lbs. SO_2/mmBTU was set for the stoker boilers. The State's rollback then concluded that a cyclone boiler emission limit of 3.50 lbs. SO_2 /mmBTU would be necessary to attain the NAAQS. A more detailed account of the State's rollback analysis exists in the technical support document of this notice of proposed rulemaking.

The limitation in S. NR 418.07(1) (a) and (c), Wis. Adm. Code, rely upon this analysis. The major deficiency in the State's rollback is that it sets limits for sources (the other three stoker boilers and the surface condenser) that were not operating during the exceedance period. It is expected that if all the facility's potential SO_2 sources had been operating, the ambient value being scaled back would have been higher than 453 micrograms per cubic meter, and consequently, the emission limits would have to be more stringent. In effect, Wisconsin's analysis guarantees that the NAAQS will be attained when a cyclone boiler and two stoker boilers are operated at NR 418.07's limits at the Rhinelander Paper Company, but the proposed SIP revision allows the source to operate more SO_2 sources (all five stoker boilers) at the same limits. No acceptable demonstration of attainment was provided for this second scenario. WDNR's rollback analysis would be acceptable only if those sources that were not operating during the exceedance period were "zeroed out". A minor deficiency in the State's rollback, given their slight contribution to the exceedance, is not considering the other non-boiler sources that were operating during the exceedance.

USEPA believes an acceptable rollback analysis would involve accounting for the sources that were not operating on the rollback days by mandating in the rule that, along with the cyclone boiler, no more than two stoker boilers can be operated by any given time at the affected facility. This proposal makes two assumptions: (1) Emissions from one stoker boiler have the same impact as any other stoker boiler at the same limits and (2) that the surface condenser is a negligible contributor to the exceedance and need not be considered as a part of the rollback.

It should be noted that while USEPA is proposing to disapprove the limitation of 1.60 lbs. SO_2/mmBTU for the stoker boilers in s. NR 418.07(1)(a)(1), Wis. Adm. Code, because of the use of an inappropriate dispersion model analysis, the earlier stoker boiler limit of 1.25 lbs. SO_2/mmBTU in Wisconsin's 1986 administrative order would also be proposed for disapproval based on its inadequate rollback analysis.

III. Proposed Rulemaking Action

USEPA is proposing to disapprove NR 418.07: Rhinelander RACT Sulfur Limitations as a revision to Wisconsin's State Implementation Plan because the State rule cannot be shown to provide for attainment and maintenance of the

SO_2 NAAQS consistent with all applicable requirements of the Clean Air Act. This proposed disapproval affects the following source: Rhinelander Paper Company.

USEPA has provided WDNR with a potential solution to the deficiencies which currently exist in NR 418.07 and its associated technical support. It is USEPA's understanding that WDNR may submit a revised Rhinelander SIP before the Agency completes final rulemaking on this action. If USEPA receives a new Rhinelander SIP revision which conforms to the approach outlined in section II(b) of this notice and this notice's technical support document, the Agency is prepared to approve the Rhinelander SIP in the final rulemaking on this action.

Nothing in this action should be construed as permitting, allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

This action has been classified as a Table Two action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989, (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table Two and Three SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of 2 years. USEPA has submitted a request for a permanent waiver for Table Two and Three SIP revisions. The OMB has agreed to continue the temporary waiver until such time as it rules on USEPA's request.

Under 5 U.S.C. 605(b), the Administrator certifies that SIP approvals under sections 107, 110, and 172 of the Clean Air Act will not have a significant economic impact on a substantial number of small entities. SIP approvals (or redesignations) do not create any new requirements, but simply approve requirements that are already State law. SIP approvals (or redesignations), therefore, do not add any additional requirements for small entities. Moreover, due to the nature of the Federal-State relationship under the Clean Air Act, preparation of a flexibility analysis for a SIP approval would constitute Federal inquiry into the economic reasonableness of the State actions. The Clean Air Act forbids USEPA to base its actions concerning SIPs on such grounds.

Public comments are solicited on the requested SIP revision and on USEPA's proposal to disapprove NR 418.07. Public comments received by (30 days from date of publication) will be considered in the development of USEPA's final rulemaking action.

The Agency has reviewed this request for revision of the federally approved State Implementation Plan for conformance with the provisions of the 1990 Amendments, enacted on November 15, 1990. The Agency has determined that this action does not conform with those requirements irrespective of the fact that the submittal preceded the date of enactment.

List of Subjects in 40 CFR Part 52

Air pollution control, Reporting and recordkeeping requirements, Sulfur oxides.

Authority: 42 U.S.C. 7401–7671(q).

Dated: December 22, 1992.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 93–75 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 63

[FRL–4552–6]

National Emission Standards for Hazardous Air Pollutants; Coke Oven Batteries

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public hearing.

SUMMARY: On December 4, 1992, EPA proposed national emission standards which would limit emissions from new and existing coke oven batteries (57 FR 57534). In response to requests by environmental and citizens groups, a public hearing to hear oral testimony concerning this standard will be held in Philadelphia, Pennsylvania.

DATES: Public Hearing. A public hearing will be held on January 15, 1993 beginning at 10 a.m.

Request to Speak at Hearing: Persons wishing to present oral testimony must contact Ms. Amada Agnew by January 11, 1993 at (919) 541–5268.

ADDRESSES: Public Hearing. A public hearing will be held at U.S. Environmental Protection Agency, Region 3, 841 Chestnut Building, 8th Floor, Conference Room 8A, Philadelphia, Pennsylvania 19107.

FOR FURTHER INFORMATION CONTACT: Mr. Fred Dimmick or Ms. Amanda Agnew, Standards Development Branch Emission Standards Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, telephone number (919) 541–5625 or (919) 541–5268.

Michael Shapiro,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. 93–193 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[MM Docket No. 92–265; FCC 92–543]

Cable Act of 1992—Program Distribution and Carriage Agreements

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In response to the Cable Television Consumer Protection and Competition Act of 1992, the Commission initiates this Notice of Proposed Rule Making ("Notice") seeking comment on the Commission's implementation of Sections 12 and 19 of the 1992 Cable Act governing access to multichannel video programming. The Notice addresses the provisions regarding unfair or discriminatory practices in the sale of cable programming. The Notice also addresses carriage agreements between cable systems and the programming services they distribute.

DATES: Comments are due on or before January 25, 1993 and reply comments are due on or before February 16, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jim Coltharp, Policy and Rules Division, Mass Media Bureau, (202) 632–6302; Diane Hofbauer, Office of the General Counsel (202) 632–6990.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, in MM Docket No. 92–265 adopted December 10, 1992, and released December 24, 1992. The complete text of this Notice of Proposed Rule Making is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission's copy contract, Downtown Copy Center, (202) 452–1422, 1990 M Street, NW., suite 640, Washington, DC 20036.

Synopsis of Notice of Proposed Rule Making

1. On October 5, 1992, Congress enacted the Cable Television Consumer

Protection and Competition Act of 1992 ("1992 Cable Act"). This Notice of Proposed Rule Making seeks comment on the Commission's implementation of Sections 19 and 12 of the 1992 Cable Act, which amend the Communications Act of 1934 by adding new Sections 628 and 616, respectively. First, the Notice addresses the provisions of Section 628 regarding unfair or discriminatory practices in the sale of cable programming. Section 628 is intended to foster the development of competition to traditional cable systems by prescribing regulations that govern the access by competing multichannel systems to cable programming services. The Notice then addresses the provisions of Section 616 that require the Commission to adopt regulations that govern agreement between cable systems—or other multichannel video programming distributors—and the programming services they distribute. These regulations on programming carriage agreements are intended to prevent cable systems from taking undue advantage of programming vendors through various practices, including coercing the vendors to exchange ownership interests or exclusive distribution rights in exchange for carriage. In this proceeding, as the Commission develops regulations pertaining to program access and carriage agreements, the Commission seeks to serve the congressional intent to prohibit unfair or anticompetitive actions with restraining the amount of multichannel programming available by precluding legitimate business practices common to a competitive marketplace.

2. In drafting the 1992 Cable Act, Congress was concerned that increased horizontal concentration and vertical integration in the cable industry have created an imbalance of power, both between cable operators and program vendors and between cable operators and their multichannel competitors. Therefore, Congress has concluded that vertically integrated program suppliers have the incentive and ability to favor their affiliated cable operators over other multichannel programming distributors. Congress concluded that the programming provisions of the 1992 Act are necessary to prevent cable operators from abusing their market power to the detriment of programs and competitors. Congress has also concluded that vertically integrated cable operators have the incentive and ability to favor affiliated programmers over unaffiliated programmers with respect to granting carriage on their systems. Congress also has found that non-affiliated programmers are sometimes required to grant cable operators exclusive rights to programming, a financial interest in the programming, or some other additional consideration in return for carriage on the cable system.

3. Section 19 of the 1992 Cable Act amends Title VI of the Communications Act of 1934 by creating section 628, which was promulgated for the purpose of: (1) Promoting the public interest by increasing competition and diversity in the multichannel video programming market; (2) increasing the availability of satellite cable and broadcast programming to persons in rural and other areas that are not currently able to receive such programming; and (3) encouraging the development of communications technologies. To accomplish these purposes, Section 628(b) makes it unlawful for a cable operator, a satellite cable programming vendor in which a cable operator has an attributable interest, or a satellite broadcast programming vendor to engage in unfair methods of competition or unfair or deceptive acts or practices whose purpose or effect is to "hinder significantly" or to "prevent" delivery of programming by multichannel video programming distributors.[1] The law provides greater specificity in the subsections that follow and instructs the Commission to adopt implementing regulations "to specify particular conduct that is prohibited" under this section. At the outset, in developing a proper interpretation of this provision and in implementing the regulations required, the Commission emphasizes the importance of arriving at a correct understanding of the Congressional objectives. Accordingly, this is the first matter on which the Commission seeks comment.

4. From the structure of section 628 as well as the legislative history, it appears that Congress' concerns were particularly focused on vertical ownership relationships in the cable industry and the extent to which they may restrict the availability and increase the cost of programming. At the same time, Congress recognized that common ownership of cable systems and programming suppliers can benefit the public. In particular, the legislative history shows that substantial investment by cable operators "stimulated the development of programming that was necessary to flesh out the promise of cable." This Commission has also recognized that MSO investment has enabled certain programming services to remain in operation, while such investment and a ready subscriber base have also promoted the introduction of innovative programming services focused upon narrow audiences. Vertical integration also contributes to an enriched quality of existing programming services, given that a cable operator has a strong incentive to increase its penetration by making the programming that it offers more attractive to potential subscribers. Section 628, however, reflects a Congressional concern with the enhanced market power that emanates from the integration of large MSOs with programming vendors. Specifically, firms that are vertically integrated could have incentives to favor their own affiliates and to unfairly discriminate against alternative distributors, which could restrain competition in program distribution.

5. With respect to the intended objectives and scope of Section 628, the Commission believes that the proscriptions for program access pertaining to satellite cable programming vendors are apparently focused on practices that are pursued by vertically integrated entities. The Commission seeks comment on this interpretation, as well as on whether the section covers conduct beyond those actions that are related to discriminatory incentives caused by vertical integration. Also, given the section's emphasis on vertically integrated entities, the Commission asks whether Section 628 is intended to require vertically integrated firms to conduct themselves in a manner similar to nonintegrated firms, thereby minimizing the anticompetitive potential of integration. Alternatively, the Commission asks whether the regulations should cause vertically integrated firms to function differently than nonintegrated firms. In contrast to satellite cable programming vendors, the 1992 Cable Act appears to require that the Commission's implementing regulations should prevent all "satellite broadcast programming vendors,"

[1] Section 2 of the 1992 Cable Act amends section 602 of the Communications Act to define "multichannel video programming distributor" as a person such as, but not limited to, a cable operator, a multichannel multipoint distribution service, a direct broadcast satellite service, or a television receive-only satellite program distributor, who makes available for purchase, by subscribers or customers, multiple channels of video programming. The Commission notes that the scope of this definition is unclear, and that this issue was raised in the Notice implementing the must-carry and retransmission consent provisions of the 1992 Cable Act. See Notice of Proposed Rulemaking in MM Docket No. 92–259, FCC 92–499, released November 19, 1992. Given that the current proceeding raises similar concerns, we seek comment similar to those solicited in the must-carry proceeding on the scope of the definition of a "multichannel video programming distributor."

regardless of vertical relationships, from pursuing unfair or deceptive actions that would unduly favor cable television systems as compared to other multichannel program outlets. Therefore, the Commission seeks comment on appropriate implementing regulations pertaining to satellite broadcast programming vendors.

6. In order to determine whether a cable operation is vertically integrated under the 1992 Cable Act, the Commission must establish a threshold at which an ownership interest will be considered attributable. The Senate Report states that "[i]n determining what is an attributable interest, it is the intent of the Committee that the FCC use the attribution criteria set forth in 47 CFR 73.3555 (notes) or other criteria the FCC may deem appropriate." The Senate version of the programming access provisions was not adopted. The House version, which was adopted with amendments, uses the term "attributable interest" but does not define an attributable benchmark. Therefore, the Commission seeks comment on whether it should define "attributable interest" with reference to the attribution threshold generally applicable to the broadcasting industry. The Commission notes that the five-percent threshold for outstanding voting stock from the broadcast attribution standard has been followed in the cable-telco cross-ownership proceeding. If the basic broadcast standard is used, should the single majority shareholder rule and the other provisions of the broadcast attribution rules also apply? As an alternative, the Commission asks whether it should use some other attribution standard.

7. Commenters should address the rationale underlying the attribution benchmarks adopted for broadcast ownership rules, and discuss the level of influence and control that need to be attributed in order to effectuate any rules adopted in this proceeding. Moreover, the Commission asks whether an attribution benchmark by itself is sufficient to determine whether an entity actually controls another entity, or whether it should establish behavioral guidelines to determine control irrespective of the attribution threshold? If so, what guidelines should be developed? In addition, should the Commission use the broadcast reporting requirement or some other standard to keep track of transfers of control of cable distributors and programmers over time?

8. Section 628 is limited to conduct for which the purpose or effect is to hinder significantly or prevent any multichannel video programming distributor from providing satellite cable programming or satellite broadcast programming to subscribers or consumers. The Commission seeks comment on how this component of the conduct that section 628 would address, which is a critical threshold requirement under the statute, interacts with the remainder of section 628 in proscribing specific practices or conduct. The plain language of section 628(b) suggests that the Commission's regulation should only implicate practices that are both (i) "unfair," "deceptive," or "discriminatory," and (ii) could significantly hinder multichannel video programming distributors from providing satellite programming. This analysis is particularly significant to the extent that conduct might be considered unfair or discriminatory from the vantage point of a particular competitor, yet does not significantly harm competition in multichannel video programming distribution. As a result, the precise showing of harm that the Commission should require to meet the statute's threshold requirement is a critical issue. Thus, the Commission seeks comment on whether, when adjudicating complaints filed pursuant to the implementing regulations for section 628, its analysis should consider harm to (i) consumers, as measured by the availability of, or quantity of, programming to consumers in the relevant market; or (ii) to other multichannel video distributors in the relevant market; or (iii) to both consumers and other multichannel competitors. The Commission seeks comment on this interpretation of the statute and approach to implementing section 628.

9. Regarding issues related to establishing the existence of "harm" under section 628, the Commission questions what geographic market would be relevant to determining whether a proscribed behavior, such as an unjustified price differential by one program vendor between two programming distributors, causes anticompetitive harm in the market. As a general matter, the Commission seeks comment on how to define the relevant market to the extent that the purposes of the prohibitions are intended to address conduct associated with vertical integration. The Commission further questions whether "harm" should be measured within a local market or across different local markets, and whether any prohibitions should apply only in local markets where an entity is, in fact, vertically integrated. The Commission also seeks comment on whether its standard for establishing "harm" should exclude certain entities that lack significant anticompetitive potential due to their limited size or negligible market share as programming vendors or cable operators, such that the degree of vertical integration might be deemed *de minimis*.

10. The Commission also asks commenters to address how it can best accomplish section 628's objectives in a manner that is faithful to the policy of Congress in the 1992 Cable Act to rely on the marketplace, to the maximum extent feasible in promoting the availability of programming to the public through cable television and other video distribution media. Furthermore, the Commission seeks comment on whether its proposals on enhancing programming access—including the proposed standards for determining discriminatory behavior as detailed below—fulfill the Congressional intent as expressed in the 1992 Cable Act and the legislative history. The Commission also solicits detailed allegations or evidence regarding unfair practices for distributing cable programming, as well as analysis of the potential consequences, to assist the Commission in prescribing regulations governing particular conduct by cable operators and programming vendors.

11. Section 628 directs the Commission to prescribe specific regulations related to: (1) Undue or improper influence by a cable operator on an affiliated satellite programming service in selling programming to unaffiliated multichannel video programming distribution services; (2) discrimination in the prices, terms, and conditions of sale or delivery of satellite programming among or between cable systems, other multichannel video distributors, or their agents; and (3) contractual exclusivity between cable operators and programming vendors in the sale of satellite programming.[3] In addition, the Commission is directed to establish an adjudicatory process for resolving disputes under section 628, to report annually to Congress on the state of competition in the delivery of video programming, and to provide penalties for the filing of frivolous complaints. The following discussion focuses on issues for comment and proposed

[3] The Commission seeks comment on whether Congress intended for the Commission to regulate any additional unfair methods of competition or unfair or deceptive acts or practices beyond those specified in section 628(c). In particular, it asks whether other practices that are precluded by the various antitrust laws—such as refusals to deal or "tying" arrangements—are encompassed within the terms of section 628 and warrant regulation.

standards relating to specific concerns, such as "undue influence," price discrimination, and exclusive agreements.

12. Section 628(c)(2)(A) specifically directs the Commission to prohibit a cable operator that is vertically integrated with a satellite cable a satellite broadcast programming vendor from unduly or improperly influencing the vendor's decision to sell programming, or the prices or terms of sale of that programming, to an unaffiliated multichannel programming distributor. The Commission seeks comment on the scope of activities or practices that should be considered "undue influence" by a cable operator upon such a programming vendor's decisions in selling programming. The Commission also requests comment on standards to apply in distinguished practices that would constitute "undue influence" from other actions that may occur during the normal course of negotiations over the prices and conditions of programming sales. In addition, the Commission asks how to distinguish a cable operator's influence from a program vendor's independent conduct.

13. Section 628(c)(2)(B) requires the Commission to prohibit a programming vendor that is vertically integrated with a cable operator from discriminating in the prices, terms, and conditions of sale or delivery of satellite programming among or between cabled systems, other multichannel video distributors, or their agents or buying groups. The Commission asks commenters to identify such practices that should be considered "discriminatory." The Commission asks for specific evidence of discriminatory practices. The Commission seeks comment on objective standards that may be applied to distinguished discriminatory behavior—with respect to pricing or other practices—from legitimate business behavior that may occur in the video program distribution marketplace. The Commission notes interest in examples of pricing practices for certain types of programming that may employ a graduated pricing structure in order to facilitate broad program distribution. Moreover, it seeks comment on specific situations in which a "uniform" pricing requirement could reduce the amount of programming available to subscribers.

14. The Commission proposes to determine whether certain programming vendors have pursued discriminatory actions against unaffiliated multichannel video distributors through the enforcement process for resolving complaints. This process requires a compliant to establish a *prima facie* case. The Commission proposes a resolve complaints of alleged instances of discrimination by using a system of presumptions that will be developed in this proceeding. The Commission seeks comment on whether it should utilize a two step approach for evaluating allegations of discriminatory behavior that determines (i) whether price differentials are justifiable or "discriminatory" and (ii) if "discriminatory," whether the discriminatory practice has prevented or hindered significantly any multichannel video programming distributor from providing satellite programming to subscribers or consumers. In this regard the Commission observes that the 1992 Cable Act appears to mandate that it consider second component of this approach regarding the harm or hindrance resulting from an alleged discriminatory practice. The Commission requests that commenters address the merits of this approach as well as any system of presumptions it could incorporate.

15. Section 628 of the 1992 Cable Act states that programming vendors are not prohibited from (1) imposing reasonable requirements to account for differences in (a) creditworthiness, (b) offering of service, (c) financial stability, (d) character, and (e) technical quality; (2) accounting for actual and reasonable differences in the cost of creation, sale, or delivery of programming; and (3) accounting for economies of scale, cost savings, or other direct and legitimate economic benefits that are reasonably attributable to the number of subscribers served by the distributor. The Commission seeks comment on an appropriate means of defining and measuring each of these factors, as well as on the types of data that vendors should be required to submit when relying on one or more of the factors to explain a price differential.[3] In particular, the Commission asks commenters to suggest how to distinguish and measure considerations of "creditworthiness," "financial stability," or other factors. For instance, the Commission notes that substantial cash flow may enable highly leveraged cable operators or other multichannel video distributions that are not otherwise considered "creditworthy," to become "financially stable." With respect to costs, the Commission recognizes that delivery of an encrypted signal to individual home satellite dish (HSD) subscribers may be more expensive—and less secure from piracy—than delivery to the head end of a cable system. The Commission seeks information on the actual expense differentials of these two delivery modes. With respect to accounting for economies of scale and economic benefits reasonably attributable to size, the Commission asks commenters to address the extend to which it should consider such factors beyond volume discounts for distributing programming. It also seeks comment on how to allow for differences in negotiations between a programming vendor and various multichannel vido programming distributions, particularly as individual distributions might be willing to exchange particular terms for pricing changes. The Commission seeks comment on an appropriate method of comparing the "technical quality" of envolving multichannel video services, particularly in instances where only prototype models are available for a prospective service. In such cases, can program vendors be expected to enter distribution contracts, subject to conditions of a pre-determined level of objective technical quality in actual operation? In addition, the Commission asks commenters to recommend any measures that could be employed as proxies for the various permissible causes of pricing differentials.

16. The Commission also asks whether the statute permits it to consider other factors that could cause price differences, including certain factors that are related to costs such as the volume of subscribers served or the direct costs of delivery, particularly if these aspects would increase the availability of programming. If so, it asks commenters to discuss any other legitimate factors that are relevant and permissible under the statute. For instance, the Commission seeks comment on whether it should consider the extent that a programming service is sold with certain conditions or arrangements—such as discounts for prepayment or for performance in marketing a service to subscribers, or an allowance for serving as a marketing agent—for particular purchasers. The Commission asks commenters to address the question of whether it can assign an appropriate magnitude of price differential that we could attribute to each factor to avoid resorting to an *ad hoc* justification in every case based on demonstrations of specific costs and circumstances. The Commission seeks to develop standards that it could apply

[3] With respect to the factor that specifies the cost of "creation, sale, delivery or transmission" of programming, the Commission seeks comment on the appropriate definition or type of costs that it should consider in evaluating a given price differential. See colloquy between Senators Kerry and Inouye found in Congressional Record, United States Senate, October 5, 1992, at S16671.

to distinguish between justifiable and discriminatory price differences, and proposes four options below for developing such objective standards. In addition to the issues and questions for comment that are presented with each option, the Commission seeks comment on any other standards that parties consider appropriate, including combinatons of the following options.

17. An initial standard for determining price discrimination could be derived from information gathered in this proceeding that would allow for a "reasonable region" of price differentials, depending upon the factors involved, within which the Commission would rebuttably presume that a disparity in price is not discriminatory, although that presumption could be rebutted. Conversely, it would presume that a price differential of a magnitude that exceeds the established "reasonable region" is due to a discriminatory practice, but a showing of significant legitimate factors could rebut the presumption and cause the Commission to consider the price difference acceptable. The Commission believes that this approach is appropriate because of section 628's explicit allowance for permissible factors for price differentials. Furthermore, to the extent that adequate data on the magnitude—and the contributing factors—of current differentials is available through the record and enforcement process, the Commission believes that a sufficiently broad region or allowance might reduce the administrative burden in resolving complaints. The Commission seeks comment both on the merits of such an approach relative to its potential burden for the Commission and the industry, as well as on the appropriate method for determining the parameters for the "reasonable region." Similarly, it asks commenters to address whether different thresholds are necessary for different technologies. Finally, in order to apply this approach, the Commission seeks comment on the nature of appropriate evidence and sufficient showings required to rebut the proposed presumptions related to price discrimination complaints.

18. Another option for defining "discrimination" as prohibited by section 628 of the 1992 Cable Act is to use a standard similar to that developed to implement section 202(a) of the Communications Act. Under section 202's standard, it is unlawful for a common carrier to engage in "unjust or unreasonable discrimination" in the provision of "like" communications services or to give any "unreasonable preference or advantage" to any person. In order to prove a violation of section 202(a), a complainant must show that (1) the services in question are "like," (2) discrimination has occurred, and (3) such discrimination is not just or reasonable. Although the Commission recognizes that the entities that Congress intended to regulate in section 628 of the 1992 Cable Act would not be subject to the current provisions of section 202 if they are not providing common carrier services, it could adopt a standard similar to section 202 as a basis of a definition of discrimination in these new regulations. The Commission notes that it has used this standard in another proceeding to evaluate the existence and extent of discrimination in some aspects of the video programming distribution market. Section 202 could offer the most appropriate standard because it addresses the term "unlawful discrimination" in providing communications services, and therefore, may be more relevant than other laws that do not specifically regulate telecommunications entities. The Commission requests comment on whether a standard similar to section 202 of the Communications Act is an appropriate basis for judging discriminatory practices by vertically integrated cable operators and programming distributors in violation of section 628. It also seeks comment on suggested modifications to the standards used to enforce section 202 that could facilitate its use as a discrimination standard in the context of the cable industry.

19. Section 2 of the Clayton Act as amended by the Robinson-Patman Act prohibits any person engaged in commerce from discriminating in price between different purchasers of commodities of like grade or quality where the effect of such discrimination may be to substantially lessen competition or tend to create a monopoly in any line of commerce. Under the Robinson-Patman Act, price differences may reflect either cost differences or changes in market conditions, thus allowing price differences by a firm where the lower price is intended to meet the equally low price of a competitor. In addition, under this analysis, price discrimination is prohibited only where the effect may be to substantially lessen competition, and thus price differences that do not harm competition are permissible. Although the Robinson-Patman Act is generally applied to the pricing of goods or commodities rather than services, the Commission believes that the 1992 Cable Act and the price discrimination provisions in section 628 provide ample authority for it to apply appropriate standards to program pricing for the cable industry and other multichannel competitors. It also recognizes that questions have been raised regarding the Robinson-Patman Act's treatment of price discrimination cases and whether the standard may conflict with particular aspects of economic theory. Accordingly, the Commission seeks comment on the extent that it may apply any of the related antitrust standards for price discrimination, or at least certain useful principles from the legislation. The Commission also asks comments to consider whether an anticompetitive or "predatory" harm to competition in distributing programming is necessary to find discrimination. Also, given that the Robinson-Patman Act governs price differences for "goods of like grade or quality," the Commission asks parties to comment on how this standard might apply to cable programming. Similarly, if a particular programming service is sold under different conditions or arrangements for various customers, should sufficiently dissimilar conditions cause us to consider the services "distinct in grade or quality?"

20. The Commission also asks commenters to consider the applicability of principles for price comparison from other areas of federal regulation. For example, the Commission questions whether principles underlying the regulations and policies utilized by the International Trade Administration of the Commerce Department ("ITA") in anti-dumping analysis can be used to develop FCC regulations to implement section 628 of the 1992 Cable Act. In anti-dumping cases, U.S. product manufacturers challenge the pricing policies of foreign competitors, alleging that such foreign competitors charge prices that are below the market level in the U.S. in order to gain unfair competitive advantages over U.S. manufacturers. When evaluating such challenges, the ITA must compare the prices charged by the foreign manufacturer or distributor in the U.S. with the price charged in the manufacturer's home market, or a third country market if there are no home market sales, to determine whether the foreign company is engaging in unfair sales practices in the U.S. The ITA has developed detailed regulations that govern the price comparison process.

21. The Commission recognizes that price discrimination complaints concerning video programming filed pursuant to section 628 raise allegations of unfair overpricing. The Commission

also recognizes that dumping cases involve pricing comparisons for manufactured goods, rather than services, which could thus involve costs relevant only to manufactured goods. However, the Commission suggests that the underlying principles used for ITA's price comparisons may remain applicable. For example, the ITA recognizes the need for various types of adjustments to the actual prices charged to allow fair comparisons between the pricing practices used by the foreign manufacturer in different markets. Thus, the ITA has established specific classes of pricing adjustments. These include adjustments for circumstances of sale (related to costs associated with differing credit terms, guarantees, warranties, commissions, and product-specific advertising directed at the purchasers of the product), differences in quantities (volume discounts), and level of trade (sales to wholesalers vs. sales to retailers). The Commission seeks comment on how to apply any, or some combination, of the above options to develop regulations that (i) take into account relevant differences between the programming distributor's customers that are necessary to make fair pricing comparisons, and (ii) will enable the Commission to determine whether price differentials are legitimate or are the result of unfair practices. Furthermore, the Commission asks whether to permit certain practices that cause price differentials upon a showing that non-vertically integrated programming vendors also employ such a practice. The Commission also seeks comment on how to easily identify the appropriate video programming sales agreements that should be used to make the price comparisons necessary to resolve particular discrimination complaints. The Commission also seeks comment on how, to the extent possible, it can expedite the complaint process by developing standardized formulas, possibly utilizing objective values for the types of price adjustments contemplated above, to minimize disputes between the parties relating to specific computations. Finally, in addition to distinguishing between reasonable price differentials and those that are discriminatory, the Commission seeks comment on what factors should be considered in the second component of any analysis that would consider whether a discriminatory price differential causes anticompetitive "harm" to multichannel programming distributors or consumers.

22. Section 628(c)(2)(B) states that the 1992 Cable Act's protections against price discrimination apply to "agents" and "buying groups" of cable systems and other multichannel video distributors. The Commission seeks comment on issues relevant to defining the class of "agents" or "buying groups" covered by this provision. Are there any circumstances under which it would be appropriate to establish parameters for such protected "agents" or "groups"? For example, would it ever be appropriate to establish limits concerning the size of individual entities permitted to aggregate for purposes of purchasing programming under regulated pricing policies?

23. The Commission notes that the statute is silent concerning enforcement of antidiscrimination rules with respect to existing contracts. Its initial view is that any pricing policies or restrictions developed to implement section 628 should not be applied retroactively against existing contracts. The Commission requests comment on this interpretation, and asks commenters how to implement section 628 with respect to exiting contracts. For example, if the policies are applied prospecively only, waiting for existing contracts to expire, the results Congress envisioned from the requirements of section 628 may not be achieved in a timely fashion, given the long term nature of many programming agreements. The Commission seeks comment on whether to establish a prospective deadline for compliance that will give parties to long term programming contracts sufficient notice and time for renegotiation, and if so, what appropriate compliance deadline would be for existing contracts. The Commission seeks further comment on the current duration of existing programming contracts to gauge the practical effects of any proposed deadlines. In addition, it seeks comment on whether to require that any renewals of existing contracts subsequent to the adoption of this Notice comply with the new rules, or whether to require compliance only in contracts signed after the effective date of any rules adopted.

24. Another statutory provision aimed at promoting competition and increased access to video programming is the requirement contained in section 628(c)(2)(C) that the Commission develop rules that prohibit practices, understandings, arrangements, and activities, including exclusive contracts for satellite cable programming or satellite broadcast programming between a cable operator and a satellite cable programming vendor or a satellite broadcast programming vendor, that prevent a multichannel video programming distributor from obtaining such programming from any satellite cable programming vendor in which a cable operator has an attributable interest or any satellite broadcast programming vendor in which a cable operator has an attributable interest for distribution to persons in areas not served by a cable operator as of the date of enactment of this section.

Similarly, section 628(c)(2)(D) requires the Commission to prohibit exclusive contracts in areas "served by a cable operator" unless it determines that the exclusive contract is in the public interest pursuant to section 628(c)(4). The Commission seeks comment on whether the lack of reference to the public interest finding of section 628(c)(4) for contracts in areas "not served by a cable operator" means that section 628(c)(2)(C) makes exclusive contract in such areas a *per se* violation.

25. In implementing these provisions, the Commission first seeks comment on the appropriate determination of whether an area is served by a cable operator. The Conference Report states, "[f]or purposes of this section,the conferees intend that an area 'served' by a cable system be defined as an area actually passed by a cable system and which can be connected for standard connection fee." How should the Commission define "area"? The language in the Conference Report suggests that this should be a local market determination related to a particular cable system. Alternative multichannel video program distributors, however, may serve a somewhat different market than an individual cable operator. Thus, the Commission seeks comment on the appropriate definition of "area" for purposes of this provision.

26. The Commission notes that section 628(c)(2)(C) prohibits "practices, understandings, arrangements and activities, *including exclusive contracts*" (emphasis added) in areas not served by a cable operator, while section 628(c)(2)(D) only prohibits "exclusive contracts" (unless deemed to be in the public interest) in areas served by a cable operator. The Commission asks commenters to consider the significance of this distinction, as well as how it might identify other "practices, understandings, arrangements and activities" that should be prohibited pursuant to section 628(c)(2)(C).

27. In the Commission's 1990 Cable Report, it noted various types of apparent contractual restrictions on program access, such as (i) prohibitions against or restrictions on a multichannel video programming vendor's

distribution into areas served by a wired cable operator; (ii) requirements to renegotiate agreements once the multichannel distributor reached a stated penetration level; and (iii) time-delay requirements. Did Congress intend that such practices be prohibited? Are there other similar practices that restrict access to programming that should be prohibited pursuant to this section?

28. In the Commission's 1990 Cable Report, it also noted that programming vendors sometimes required that a multichannel competitor purchase programming from a local cable operator to whom the programming vendor had given subdistribution rights for its franchise area. While such agreements do not necessarily "prevent" another multichannel video programming distributor from obtaining programming, they create the potential for disparate, and perhaps unfair, access treatment. What limits, if any, should be imposed on such subdistribution arrangements? The Commission also seeks comment on what data should be required to demonstrate that an exclusive contract in violation of these provisions has been made. For administrative reasons, the Commission does not believe it practical to require prior approval of exclusive arrangements. Thus, it proposes to enforce regulations adopted pursuant to this section through the complaint process, and seeks comment on this approach. If it is nonetheless urged to require prior approval of exclusive agreements, the Commission seeks comment on how to develop practical, expeditious procedures to evaluate requests for approval of exclusive agreements. For example, how will a multichannel competitor establish the existence of an "exclusive" contract if it does not have access to the contract? What if the contract is not written? What will be required to establish a *prima facie* case that any exclusivity "practice, understanding, arrangements" exists? How can a program distributor likely to be aggrieved by such practices obtain the evidence necessary to substantiate a complaint to the Commission?

29. The Commission further notes that section 628(c)(2)(C) specifically prohibits actions that prevent a multichannel video programming distributor from obtaining programming. Thus, it appears that an analysis of anticompetitive harm, such as restricted or inhibited access to programming, is required to find violations of this provision. What evidence should the Commission consider when determining whether specific practices, understandings, arrangements, or activities restrict, inhibit or otherwise limit access to programming? The Commission also asks whether this provision imposes any duty on a programmer to deal with non-affiliated programming distributors. With respect to exclusive contracts, section 628(c)(4) sets forth the criteria to be considered by the Commission when determining whether an exclusive contract is in the public interest, and thus not prohibited by section 628(c)(2)(D). In addition, the Commission is to consider the duration of the exclusive contract and seeks comment on objective standards or benchmarks that can be developed as consulted to assess each of the criteria set forth in the statute. Moreover, are these the only factors that the Commission is permitted to consider? If not, what other factors are relevant to such a determination? Are there benefits to exclusivity that should be considered?

30. The Commission also asks commenters to identify, where possible, specific instances where it could establish in advance by rule that limited exclusive distribution agreements are permitted under section 628(c)(4). For example, the Commission recognizes that exclusive distribution rights are often given to encourage distributors to carry new program services. Such exclusive rights may well be essential to the introduction of new services, and thus should be permitted to the extent necessary to ensure continued program diversity. Therefore, it may be in the public interest to define, at the outset, a rule that would permit exclusive distribution contracts for new program services. Such contracts would be deemed to meet the public interest test of section 628(c)(4) if they were limited to a specific duration, such as two years, that would facilitate the launch of the new service. The Commission seeks comment on this proposal and the appropriate limitations on such contracts. Commenters are also asked to provide other examples of contracts that could be presumed to serve the public interest. Finally, the Commission notes that section 628(c)(4)(D) refers to the effect on diversity of an exclusive contract on the "multichannel video programming distribution market." Given section 628(c)(4)(B)'s reference to "local and national" markets, should it infer a similar local and national market focus to interpret section 628(c)(4)(D), or should it employ some other type of market analysis?

31. Section 628(d) of the 1992 Cable Act provides that any multichannel video programming distributor aggrieved by conduct that it alleges to violate section 628(b) or (c) may commence an adjudicatory proceeding at the Commission. Section 628(f) requires the Commission to prescribe regulations to implement this section, including provisions for expedited review by the Commission, procedures for data collection, and provision for penalties against any person filing a frivolous complaint. The Commission proposes to adopt rules governing a formal complaint process that would resolve disputes without a hearing unless there are substantial and material issues of fact that cannot be resolved by the staff or through stipulation by the parties. The Commission proposes to develop a complaint process based on certain procedures used in complaint cases regarding the lowest unit charges filed under section 315(b) of the Communications Act and those used in processing common carrier complaints under section 208 of the Communications Act. In developing this process, it proposes to limit the pleading cycle to encourage substantive discussions of the issues in dispute, and to expedite complaint resolution by eliminating unnecessary pleadings. The Commission proposes to permit a complaint and response. Replies would not be permitted, and parties against whom a complaint is filed would not be permitted to file separate motions to dismiss or motions for summary judgment—any such requests should be included in the answer. The Commission seeks comment on these proposals.

32. The Commission proposes to require that complaints set forth specific allegations of misconduct and include affidavits by knowledgeable persons, or other tangible evidence, to support each allegation made in the complaint. Failure to plead each claim with specificity or to include supporting factual evidence for each allegation will result in dismissal of that portion of the complaint. The Commission proposes to require defendants to respond in 20 days, noting that answers should provide substantive support of all factual allegations or denials, and seeks comment on these proposals. After the staff has reviewed the pleadings, it would determine whether the complainant has established a *prima facie* case. At this point, if a *prima facie* case has been made, the Commission tentatively believes that the staff should hold a status conference to attempt to resolve any factual disputes and to determine whether early resolution is possible based on the staff's preliminary determinations. Given the statutory directive for expeditious resolution of section 628 complaints, the Commission

proposes to allow the parties to elect to utilize our Alternative Dispute Resolution ("ADR") process. The Commission seeks comment on whether it would be required to implement specific procedures for ADR in this area, and if so, what those procedures should encompass. It also seeks comment on ways to encourage parties to elect to resolve disputes through ADR. For example, should ADR for program access disputes include specific provisions for discovery, when appropriate, to provide an incentive for complainants to agree to ADR?

33. The Commission also seeks comment on what standard it should employ to determine whether a *prima facie* case has been made, and whether a single standard can be used for all complaints brought under section 628, or whether different standards must be developed for different types of claims, *e.g.*, a price discrimination claim as opposed to another type of unfair practices claim. In addition, it questions whether the information necessary to establish a *prima facie* case is readily available to potential complainants aggrieved by violations of regulations adopted to implement section 628. If not, what minimum threshold showing can be made with available information that would be appropriately required to establish a *prima facie* case? The Commission also seeks comment on what sorts of presumptions could be established for evaluating whether a complainant has made a *prima facie* case. Could objective criteria be developed? Could specific benchmarks be used as an evidentiary factor in complaint cases, such as specified program penetration levels that shift the burdens of proof for the complaint proceedings prescribed by section 628? The Commission asks whether penetration benchmarks could provide a useful tool for measuring the availability of programming, and thus ascertaining whether the behavior complained of violates section 628. For example, if a specific MMDS operator files a complaint against a program service alleging unfair behavior that impedes its access to programming, it may be relevant to consider whether other MMDS operators are, in fact, distributing the same programming. If so, and the penetration level of the programming on MMDS systems meets the designated benchmark, would this be relevant evidence that the programmer is not engaging in behavior in violation of section 628? Are these circumstances under which such evidence could reach a level to warrant a presumption that would require the complainant to meet a higher burden of proof to establish a *prima facie* case? Or, are there too many other factors affecting such penetration levels to permit a fair inference of discrimination based on any such disparity?

34. Similarly, the Commission asks whether there are any circumstances under which it would be appropriate to consider the relationship between the volume of programming sold by a vertically integrated program supplier to alternative delivery media, such as MMDS or TVROs, and the volume of programming sold by that program supplier to its affiliated cable systems. For example, what would be the relevance, if any, of a showing by a vertically integrated programming supplier that it sold the majority of its programming, or some substantial volume of sales, to such alternative delivery media, but sold a comparatively small volume of programming to its affiliated cable systems, in a complaint case alleging that the programmer is engaging in anticompetitive behavior? What sales volumes or comparative relationship between the sales volumes could be relevant? Again, the Commission asks whether there are too many other factors affecting such sales volumes to permit a fair inference of discrimination based on any disparity. The Commission seeks comment on, and encourages commenters to propose, other benchmarks or objective criteria relevant to determining whether a *prima facie* case has been made.

35. After the status conference with the Commission staff, if the parties elected to continue to pursue a formal proceeding, and if discovery were required, the Commission proposes that the staff issue a discovery order setting forth the procedures for, and limitations on, discovery. Should a complainant routinely be entitled to a specified number of interrogatories and document production requests as a matter of right, with depositions permitted only upon a special showing, or should the staff determine the parameters of discovery on a case by case basis? The Commission seeks comment on what, if any, self-executing discovery could be adopted. For example, could particular documents be identified in this proceeding, in addition to those set forth in section 628(f)(2), that would be clearly relevant to resolving the various kinds of complaints that could arise under section 628? The Commission seeks comment on practical, expeditious ways for the staff to resolve discovery disputes. In addition, it seeks comment on what period of time, such as 60 days, would be appropriate within which to require completion of discovery.

36. The Commission also proposes that the staff discovery order include a protective order with respect to document production that limits examination of the documents produced to parties designated in the order (and the Commission), and prohibits further dissemination of the information revealed therein. The Commission further proposes to permit defendants to redact proprietary information not relevant to the resolution of the complaint, such as the specific identity of a customer (but not the type of multichannel video programming distributor involved), so long as the defendant provided a general description of the nature of the redacted information. The Commission invites other suggestions for protecting proprietary information without undermining legitimate discovery. The Commission proposes to adopt a specific rule that requires the parties to abide by the terms of the staff protective order. Within 30 days after completion of discovery, the complainant would be required to file an amended complaint based on the information discovered. The defendant would have 15 days to respond. The parties would again be given the opportunity to elect ADR. If ADR is not selected, the staff would impose an appropriate sanction where it finds that our rules have been violated, or it would dismiss the complaint. In appropriate circumstances, the dispute may be referred to an administrative law judge ("ALJ") for resolution. Any decision rendered by the staff or an ALJ may be appealed directly to the full Commission.

37. Section 628(e)(1) provides that the Commission has the power to order appropriate remedies, including, if necessary, the power to establish prices, terms and conditions of sale of programming to an aggrieved multichannel video programming distributor. The Commission seeks comment on what additional remedies would be deemed "appropriate" for section 628 violations. In addition, section 628(e)(2) specifically states that any such remedies are in addition to and not in lieu of the Commission's authority to impose forfeitures pursuant to title V of the Communications Act for violations of its regulations. The Commission seeks comment on the appropriate application of our forfeiture guidelines to section 628 violations.

38. Section 628(c)(3)(A) of the 1992 Cable Act specifies that the program distribution rules do not require a national or regional distributor of video programming to make that programming

available outside of the geographic area in which it is authorized or licensed to distribute such programming. The Commission seeks comment on implementation of this provision. What parameters should be established for determining whether a change in the geographic area in which an operator is authorized or licensed has occurred? In addition, section 628(c)(3)(B)(i) provides that these carriage rules do not apply to the signal of a television network affiliate or other television signal that is retransmitted by satellite but that does not constitute "satellite broadcast programming" because it is retransmitted by the broadcaster or someone authorized by the broadcaster. Similarly, section 628(c)(3)(B)(ii) provides that these carriage rules do not apply to internal satellite communications of broadcast or cable networks that would not be considered "satellite broadcast programming." The Commission seeks comment on the appropriate interpretation of these provisions.

39. Section 628(f)(2) directs the Commission to prescribe regulations to establish procedures for collecting necessary data, including the right to obtain copies of all contracts and documents reflecting arrangements and understandings that allegedly violate the provisions of Section 628. The Commission believes that necessary data will include contracts or other documents that offer information on past practices, prices and conditions for program sales, levels of programming penetration, as well as evidence to justify permissible cause for price differentials. Accordingly, the Commission seeks comment on the type of data that may become necessary during the course of a section 628 proceeding, and how it may obtain such information. Also, what if any additional procedures must be developed to protect proprietary information?

40. Section 628(g) directs the Commission, beginning no later than 18 months after promulgating the regulations, to annually report to Congress on the state of competition for the delivery of video programming. It is the Commission's tentative view that the annual report should consist of an analysis of section 628 complaints filed at the Commission and generally available industry information relating to the status of competition in the satellite cable and broadcast programming marketplace. The Commission seeks comment on this approach and the nature of any additional information that the Commission could obtain to contribute to its report. The Commission emphasizes that detailed information on pricing and sales of programming would enhance its ability to monitor changes in the programming marketplace. For example, the Commission could survey the industry or require that parties submit information about (1) the number of independently owned cable operators and programming distributors; (2) the degree of vertical integration between cable operators and programming distributors; (3) the penetration or availability of programming to competing multichannel services; and (4) the levels of pricing differentials for programming, including the range and average of volume-related discounts and other permissible factors for price differentials. The Commission asks commenters to consider the extent to which any information in the Report to Congress may be similar to information collected for other proceedings related to the 1992 Cable Act to avoid duplication. The Commission also requests comment on the level of detailed information required to serve the Commission's interest without overburdening its resources, as well as those required to provide such information.

41. Section 628(f)(3) requires the Commission to provide for penalties to be assessed against any person filing a frivolous complaint regarding programming practices. The Commission seeks comment on implementation of this provision. It also proposes to assess monetary forfeitures for frivolous complaints, and seeks comment on the relationship between the penalties that Congress has indicated that the Commission may assess under section 628 as well as the more general monetary forfeiture provisions of section 503 of the Communications Act. Also, what factors should determine whether a complaint is frivolous? What guidelines should determine forfeiture amounts? Should the forfeiture amount be based on the resources expended by the Commission in considering the claim as well as by the party in defending against the claim?

42. The provisions of the 1992 Cable Act discussed above primarily restrict the activities of programming vendors with respect to cable operators and other multichannel programming distributors. Section 12 of the 1992 Cable Act restricts the activities of cable operators and other multichannel programming distributors with respect to programming vendors. Section 12 amends the Communications Act by adding new section 616, which addresses regulation of carriage agreements between multichannel video programming distributors and video program vendors.

43. Section 616(a) directs the Commission to establish regulations that prevent multichannel programming distributors from entering into carriage agreements that condition carriage of a vendor's programming on particular consessions. Specifically, the Commission must adopt regulations that prevent a multichannel distributor from requiring a programming vendor to provide it with a financial interest in the programming service in return for carrying the program service on its system. The new rules must also prohibit a multichannel distributor from coercing a programming vendor to provide it with exclusive rights as a condition of carriage, from retaliating against such a vendor for failing to provide exclusive rights, or from otherwise engaging in conduct that discriminates on the basis of affiliation of vendors in the selection, terms or conditions for carriage of video programming. In addition, the statute specifies procedures the Commission must adopt for implementation of the above provisions, including expedited review of compaints made by a programming vendor and assessment of appropriate penalties for violation of the carriage agreement rules as well as for the filing of frivolous claims.

44. The Commission seeks comment on how best to implement these provisions. First, section 616(a)(1) of the 1992 Cable Act provides that the Commission must adopt rules to prevent a cable operator or other multichannel video programming distributor from requiring a financial interest in a program service as a condition for carriage on the operator's systems. Because the statute does not prohibit multichannel distributors from holding a financial interest in a programming service, the Commission anticipates that it will not always be clear whether an operator has "required" the programming vendor to provide it with a financial interest in return for carriage of a particular programming service. What factors should determine whether such is the case? Second, section 616(a)(2) directs the Commission to adopt rules that prohibit a cable operator or other multichannel video programming distributor from coercing a video programming vendor to provide, and from retaliating against such a vendor for failing to provide, exclusive rights against other multichannel video programming distributors as a condition of carriage. What types of activities would constitute indicia of coercion?

Also, the Commission asks how it can clearly distinguish between "coercion" and "negotiation" and whether it could conceivably construe certain mutually acceptable arrangements that would otherwise comply with section 628 as "coercion." Further, the above provision makes clear that exclusive arrangements may exist other than as a condition of carriage. Section 616 thus does not specifically prohibit exclusive arrangements, but the Commission believes that section 616 must be read together with section 628(c), which limits certain exclusive arrangements and establishes standards for determining whether exclusive contracts are in the public interest, and seeks comment on this interpretation.

45. Third, section 616(a)(3) provides that the new rules must prevent a multichannel video programming distributor from engaging in conduct that unreasonably restrains the ability of an unaffiliated video programming vendor to compete fairly, by discriminating in video programming distribution on the basis of affiliation or nonaffiliation of vendors in the selection, terms or conditions for carriage of video programming. What specific conduct should be considered a violation of this section? The Commission proposes that an "unaffiliated programming vendor" is a video programming vendor or service in which the multichannel distributor does not have an attributable interest, as defined by the broadcast attribution criteria of § 73.3555 of the Commission's Rules. In addition, section 616(a)(3) prohibits multichannel video programming distributors from discriminating in video programming distribution on the basis of affiliation or nonaffiliation of vendors. The Commission believes that a practice of discriminating in the context of carriage agreements involves different activities than those discussed with respect to section 628 regarding programming access, and thus seeks comment on how to define "discrimination" in the context of section 616. Additionally, the Commission also believes section 628(h) is clear with respect to exclusive distribution arrangements, i.e., such agreements in areas served by cable are grandfathered if they were entered into on or before June 1, 1990; if the area is not served by cable, exclusive programming agreements are nullified. With respect to matters other than exclusive programming arrangements, it proposes to afford distributors and vendors six months from the date of adoption of these carriage agreement rules to bring their agreements into compliance. The Commission seeks comment on these proposals and on any other issues regarding implementation of this provision that commenters may deem relevant.

46. The Commission also seeks comment on the procedures to be established for review of complaints, and on the appropriate penalties and remedies to be ordered. Section 616(a)(4) provides for expedited review of any complaints made by a video programming vendor pursuant to this section. Should the Commission follow the same review process as was discussed above with respect to Section 628(d), or should different complaint procedures be adopted? Should carriage agreements be afforded confidential treatment in full, or rather, should the Commission permit only confidential or proprietary information to be redacted? Section 616(a)(5) provides that the Commission must adopt appropriate penalties and remedies for violations of this subsection, including requiring the multichannel video programming distributor to carry the unaffiliated program vendor. What procedures should be established for mandatory carriage? The Commission does not intend to require the multichannel distributor to carry the programming service indefinitely. How long should mandatory carriage last? The Commission also intends to assess forfeitures against violators. What guidelines should determine forfeiture amounts? Should the Commission also consider remedies other than forfeiture or mandatory carriage, such as establishment of prices, terms and conditions of sale, similar to the remedies specified in section 628(e)(1), as discussed above? In addition, section 616(a)(6) provides that the Commission must delineate penalties to be assessed against any person filing a frivolous complaint pursuant to this section. The Commission proposes to assess monetary forfeitures for frivolous complaints and it asks for comment on the factors that should determine whether a compliant is frivolous. Likewise, what guidelines should determine forfeiture amounts? Should the Commission base the forfeiture amount on the resources it expends in considering the claim and by the party defending against the claim?

Initial Regulatory Flexibility Analysis

47. Pursuant to the Regulatory Flexibility Act of 2980, the Commission finds:

I. Reason for Action

This action is taken to implement certain provisions of the Cable Television Consumer Protection and Competition Act of 1992.

II. Objectives

The Cable Act of 1992 and the subsequent Commission actions to implement it are intended to set forth a regulatory scheme for cable systems in the area of programming distribution and carriage agreements. Congress adopted the statute to address its concerns regarding the performance of the cable industry in these areas since the 1984 Cable Act was enacted. The program access provisions of this act are intended to (i) promote the public interest by increasing competition and diversity in the multichannel video programming market, (ii) increase the availability of satellite cable and broadcast programming, and (iii) encourage the development of communications technologies. The carriage agreements provisions restricts the activities of cable operators and other multichannel programming distributors with respect programming vendors.

III. Legal Basis

Action as proposed for this rule making is contained in sections 4 (i) and (j), and 303 of the Communications Act of 1934, as amended, and the Cable Television Consumer Protection and Competition Act of 1992.

IV. Reporting, Recordkeeping and Other Compliance Requirements

In order to implement the 1992 Cable Act, the Commission might require that multichannel video distributors and cable operators submit data regarding the prices, conditions, and level of program sales.

V. Federal Rules which Overlap, Duplicate or Conflict with this rule

Sherman Act, Clayton, Act, and Robinson-Patman Act.

VI. Description, Potential Impact and Number of Small Entities Affected

In order to implement the Cable Television Consumer Protection and Competition Act of 1992, the Commission has proposed to add new rules and modify others. Depending on the extent of such actions, different cable systems may be affected in different ways. For example, certain cable operators or programming distributors may find it necessary to alter pricing or contracting practices as related to programming distribution, while other cable operators or other muiltichannel video distributors may enjoy increased access to programming.

VII. Any significant Alternatives Minimizing Impact on Small Entities and Consistent With Stated Objective

None.

48. As required by section 603 of the Regulatory Flexibility Act, the FCC has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected impact of these proposed policies and rules on small entities. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice of Proposed Rule Making, but they must have a separate and distinct heading designating them as responses to the regulatory flexibility analysis. The Secretary shall cause of a copy of this Notice of Proposed Rule Making, including the Initial Regulatory Flexibility Analysis, to be sent to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of the Regulatory Flexibility Act, Pub. L. No. 96–354, 94 Stat. 1164, 5 U.S.C. section 601 *et seq.* (1981).

Ex Parte

49. This is a non-restricted notice and comment rule-making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's rule. See generally, 47 CFR 1.1202, 1.203, and 1.206(a).

Comment Dates

50. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 and 1.149, interested parties may file comments on or before January 25, 1993, and reply comments on or before February 16, 1993. To file formally in this proceeding, you must file an original plus four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center (room 239) of the Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

51. Authority for this proposed Rule Making is contained in Sections 4(i) and (j), and 303 of the Communications Act of 1934, as amended.

List of Subjects in 47 CFR Part 76

Cable Television.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93–5 Filed 1–4–93; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

49 CFR Part 213

[FRA Docket No. RST–90–1, Notice No. 2]

RIN 2130–AA75

Track Safety Standards; Public Workshops on Miscellaneous Proposed Revisions

AGENCY: Federal Railroad Administration.

ACTION: Notice of public workshops.

SUMMARY: This document contains information supplementing that of Notice No. 1 (November 16, 1992 (57 FR 54038)) which proposed to identify those sections of the present Track Safety Standards that FRA is considering for amendment, including the introduction of performance-based standards in two significant areas. This action is being undertaken by FRA in an effort to improve its safety regulatory program by ensuring that provisions governing track safety are necessary, effective, and suitably flexible. The information contained in this document covers:

Date changes;
Identification of city-specific public workshop locations (including one city change) and times;
A description of the format within which the public workshops will be conducted.

DATES: New workshop dates are:

Denver (Lakewood) on February 23, 1993; Chicago on February 25, 1993.

Any person desiring to participate in one or more of the workshops will now have until January 15, 1993 to notify the Docket Clerk. FRA will accept written comments from February 26, 1993 through April 1, 1993.

ADDRESSES:

(1) *Written comments:* Comments should identify the docket number and the notice number and should be submitted in triplicate to: Docket clerk, Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, SW., Washington, DC 20590. Persons desiring to be notified that their written comments have been received by FRA should include a stamped, self-addressed postcard with their comments. The Docket Clerk will indicate on the postcard the date on which the comments were received and will return the card to the addressee. Written comments will be available for examination during regular business hours in room 8201 of the Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

(2) *Public workshops:* One-day workshops to discuss particular issues will be held at these locations:

January 26, 1993—Newark, New Jersey.
Radisson Hotel Newark Airport, 128 Frontage Road, Newark, New Jersey, (201) 690–5500.

Topics: Responsibility of track owners; Inspector qualifications; Restoration/Renewal of track; and 30-day period under § 213.9.

January 28, 1993—Atlanta, Georgia.
Peachtree Summit Building—Rooms 10A and 10B, 401 West Peachtree Street, NW., Atlanta, Georgia 30365.

Topics: Continuous welded rail/ Lateral track resistance; Gage restraint measurement; and Vehicle track interaction.

February 23, 1993—Denver (Lakewood), Colorado.
Lehigh Building, Third Floor Conference Room, 555 Zang Street, Lakewood, Colorado 80228.

Topics: Defective rails/remedial action; Internal rail inspection frequency; System tolerances and reliability; and Torch cut rail.

February 25, 1993—Chicago, Illinois.
12th Floor Conference Room, U.S. Army Corps of Engineers, 1111 North Canal Street, Chicago, Illinois 60606.

Topics: Excepted track; Inspection requirements; Definitions; and Other issues significantly affecting track or related structures.

Each of the four workshops will start at 8 a.m.

Persons desiring to participate in any of the workshops should notify the Docket Clerk by writing to: Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT:

Principal program person: Allison H. MacDowell, Office of Safety Enforcement, Federal Railroad Administration, 400 Seventh Street, SW., Washington, DC 20590. Telephone: (202) 366–6081.

Principal attorney: Nancy Lummen Lewis, Office of Chief Counsel, Federal Railroad Administration, 400 Seventh Street, SW., Washington, DC 20590. Telephone: (202) 366–0635.

SUPPLEMENTARY INFORMATION: Notice No. 1 states that "* * * workshops are designed so that technically experienced persons may express their views about the track safety standards and those related issues in which they have a personal interest." FRA intends to follow that format. These discussions, associated as they are with an advance notice of proposed rulemaking, are intended to be fact finding sessions involving informal give-and-take exchanges between industry and government professionals who are charged with the administration of the track safety standards on a day-to-day basis. The discussion at each workshop will be focused on the specific topics to which the particular workshop has been dedicated. However, should time remain following conclusion of the workshop discussion, any party wishing to read a prepared statement into the record will be permitted to do so. Parties wishing to provide formal comments on any matter within the scope of this rulemaking are encouraged to do so in writing, not later than the comment closing date announced in this notice.

Issued in Washington, DC on December 29, 1992.

S. Mark Lindsey,

Acting Administrator, Federal Railroad Administration.

[FR Doc. 93–37 Filed 1–4–93; 8:45 am]

BILLING CODE 4910–06–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AB 83

Endangered and Threatened Wildlife and Plants; Proposed Endangered Status for "Myrcia paganii" and "Calyptranthes thomasiana"

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes to determine *Myrcia paganii* (no common name) and *Calyptranthes thomasiana* (no common name) to be endangered species pursuant to the Endangered Species Act (Act) of 1973, as amended. *Myrcia paganii*, a small tree, is endemic to Puerto Rico and known from only three locations in the limestone hills of the northwestern part of the island. *Calyptranthes thomasiana*, a small tree, is only known from one area on the island of Vieques in Puerto Rico, one area in St. John, U.S. Virgin Islands, and from Gorda Peak, Virgin Gorda, British Virgin Islands. Habitat loss and modification are the primary threats to these species. This proposal, if made final, would implement the Federal protection and recovery provisions afforded by the Act for *Myrcia paganii* and *Calyptranthes thomasiana*. The Service seeks data and comments from the public on this proposal.

DATES: Comments from all interested parties must be received by March 8, 1993. Public hearing requests must be received by February 19, 1993.

ADDRESSES: Comments and materials concerning this proposal should be sent to the Field Supervisor, Caribbean Field Office, U.S. Fish and Wildlife Service, P.O. Box 491, Boquero, Puerto Rico 00622. Comments and materials received will be available for public inspection, by appointment, during normal business hours at this office, and at the Service's Southeast Regional Office, suite 1282, 75 Spring Street, SW., Atlanta, Georgia 30303.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Silander at the Caribbean Field Office address (809/851–7297).

SUPPLEMENTARY INFORMATION:

Background

Myrcia paganii, a small evergreen tree, was first collected by Paul Sintenis during the last part of the nineteenth century. The species was named for Juan Bianchi Pagán, who collected the species with Krug. However, the type specimen was destroyed during World War II and no duplicates are known to exist. *Myrcia paganii* was not collected again until Roy Woodbury rediscovered the species in 1959 in the Biafara-Arrozal area to the south of the city of Arecibo, located in northern Puerto Rico. Six individuals are known from this privately owned site (Vivaldi and Woodbury 1981). The species has been reported more recently from two locations, one individual at each, in the Quebradillas area of northwestern Puerto Rico (Department of Natural Resources 1992).

Myrcia paganii is an evergreen tree which may reach 9 meters (30 feet) and 13 centimeters (5 inches) in diameter. The bark is mottled and flaky and the inner bark is orange-brown. Young twigs are flattened and have numerous soft brownish hairs. The leaves are opposite, simple, entire, coriaceous, aromatic, and glandular punctate below. The leaf blade is elliptic to elliptic-oblong, villous when young but glabrescent, 10 to 16 centimeters (4 to 6¼ inches) long, and 4 to 9 centimeters (1½ to 3½ inches) wide. The leaf base is acute, the apex obtuse, and the midvein is clearly impressed above. Petioles are 4 to 5 millimeters long. The flowers and fruit have not been described.

Calyptranthes thomasiana was described in 1855 from specimens collected from St. Thomas, U.S. Virgin Islands. Although collected from St. Thomas, it has not been reported from the island in recent years. It was previously thought to be endemic to Puerto Rico and the U.S. Virgin Islands, but was recently reported from Virgin Gorda, British Virgin Islands, where it occurs within the National Park (Center for Plant Conservation 1992; G. Proctor, pers. comm.). It is currently known from only three locations: Monte Pirata on the island of Vieques in Puerto Rico; Bordeaux Mountain on the island of St. John, U.S. Virgin Islands; and Gorda Peak in Virgin Gorda, British Virgin Islands.

Calyptranthes thomasiana is an evergreen shrub or small tree which may reach 9 meters (30 feet) in height and 13 centimeters (5 inches) in diameter. Leaves are opposite, obovate to oblong, 2 to 4 centimeters (¾ to 1¾ inches) long, blunt at the apex, and short pointed at the base. The leaves are coriaceous, with gland dots, shiny on the upper surface, and dull on the lower surface. Flowers and fruit have not been described.

Calyptranthes thomasiana is found only at three localities. Only 10 to 12 individuals are now known from Monte Pirata, where it is located on U.S. Navy property. However, additional individuals may have been eliminated by the construction of Navy facilities on this peak (Department of Natural Resources 1992). This area was severely affected by Hurricane Hugo in 1989. As many as 100 mature individuals are known from a small area on Bordeaux Mountain of St. John, part of the National Park and managed by the National Park Service, U.S. Department of the Interior (G. Ray, pers. comm.; Woodbury and Weaver 1987). Although on Virgin Gorda the species is found within the National Park of the British Virgin Islands Government, it is rare and localized and may be impacted by park management practices (Center for Plant Conservation 1992; G. Proctor, pers. comm.).

Myrcia paganii and *Calyptranthes thomasiana* were recommended for Federal listing by the Smithsonian Institution (Ayensu and DeFilipps 1978). The species were included among the plants being considered as endangered or threatened by the Service, as published in the **Federal Register** notice of review dated December 15, 1980 (45 FR 82480); the November 28, 1983 update (48 FR

53680), the revised notice of September 27, 1985 (50 FR 39526), and the February 21, 1990 (55 FR 6184) notice of review. Both species were designated as category 1 species (species for which the Service has substantial information supporting the appropriateness of proposing to list them as endangered or threatened) in the notice of review published on February 21, 1990.

In a notice published in the **Federal Register** on February 15, 1983 (48 FR 6752), the Service reported the earlier acceptance of the new taxa in the Smithsonian's 1978 book as under petition within the context of section 4(b)(3)(A) of the Act, as amended in 1982. Beginning in October 1983, and in each October thereafter, the Service found that listing *Myrcia paganii* and *Calyptranthes thomasiana* was warranted but precluded by other pending listing actions of a higher priority, and that additional data on vulnerability and threats were still being gathered. This proposed rule constitutes the final 1-year finding in accordance with section 4(b)(3)(B)(ii) of the Act.

Summary of Factors Affecting the Species

Section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be endangered or threatened due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Myrcia paganii* Krug & Urban and *Calyptranthes thomasiana* Berg. are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Two populations of *Myrcia paganii* are found on privately owned land currently subject to intense pressure for agricultural, rural and tourist development. Adjacent land is currently being cleared for grazing by cattle and goats. One individual has been reported from the Guajataca Commonwealth Forest, where it may be affected by forest management practices. Although on Vieques Island *Calyptranthes thomasiana* is found on U.S. Navy property, this area has been severely modified for the construction of Navy facilities. Expansion of the facilities may result in the elimination of individual plants. Although known individuals on St. John are found within the National Park, these may be affected by park management practices and the presence of feral pigs and donkeys.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Taking for these purposes has not been a documented factor in the decline of these species.

C. Disease or Predation

Disease and predation have not been documented as factors in the decline of these species.

D. The Inadequacy of Existing Regulatory Mechanisms

The Commonwealth of Puerto Rico has adopted a regulation that recognizes and provides protection for certain Commonwealth listed species. However, *Myrcia paganii* and *Calyptranthes thomasiana* are not yet on the Commonwealth list. Federal listing would provide immediate protection and, if the species are ultimately placed on the Commonwealth list, enhance their protection and possibilities for funding needed research.

E. Other Natural or Manmade Factors Affecting its Continued Existence

One of the most important factors affecting the continued survival of these species is their limited distribution. Because so few individuals are known to occur in a limited area, the risk of extinction is extremely high. Hurricane Hugo in 1989 dramatically affected the Monte Pirata area of Vieques, felling large trees and creating numerous canopy gaps.

The Service has carefully assessed the best scientific and commercial information available regarding the past, present, and future threats faced by these species in determining to propose this rule. Based on this evaluation, the preferred action is to list *Myrcia paganii* and *Calyptranthes thomasiana* as endangered. Both *Myrcia paganii* and *Calyptranthes thomasiana* are each known from only three locations. Deforestation for rural, agricultural, residential, and tourist development are imminent threats to the survival of the species. Therefore, endangered rather than threatened status seems an accurate assessment of the species' condition. The reasons for not proposing critical habitat for these species are discussed below in the "Critical Habitat" section.

Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that, to the maximum extent prudent and determinable, the Secretary propose critical habitat at the time the species is proposed to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for this species at this time. The number of individuals of *Myrcia paganii* and *Calyptranthes thomasiana* is so sufficiently small that vandalism and collection could seriously affect the survival of the species. Publication of critical habitat descriptions and maps in the **Federal Register** would increase the likelihood of such activities. The Service believes that Federal involvement in the areas where these plants occur can be identified without the designation of critical habitat. All involved parties and landowners have been notified of the location and importance of protecting these species' habitats.

Protection of these species' habitats will also be addressed through the recovery process and through the section 7 consultation process.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Endangered Species Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages and results in conservation actions by Federal, Commonwealth, and private agencies, groups and individuals. The Endangered Species Act provides for possible land acquisition and cooperation with the Commonwealth, and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act, as amended, required Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is subsequently listed, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or

to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat is being proposed for these two species, as discussed above. Federal involvement is anticipated for the population of *Calyptranthes thomasiana* located on Monte Pirata in Vieques, U.S. Navy property, and for the population located in the Virgin Island National Park in St. John.

The Act and its implementing regulations found at 50 CFR 17.61, 17.62, and 17.63 set forth a series of general prohibitions and exceptions that apply to all endangered plants. All trade prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.61, would apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export any endangered plant, transport it in interstate or foreign commerce, or remove it from areas under Federal jurisdiction and reduce it to possession. In addition, for endangered plants, the 1988 amendments (Pub. L. 100–478) to the Act prohibit the malicious damage or destruction on Federal lands and the removal, cutting, digging up, or damaging or destroying of endangered plants in knowing violation of any State law or regulation, including State criminal trespass law. Certain exceptions can apply to agents of the Service and State conservation agencies. The Act and 50 CFR 17.62 and 17.63 also provide for the issuance of permits to carry out otherwise prohibited activities involving endangered species under certain circumstances. It is anticipated that few trade permits for these three species will ever be sought or issued, since the species are not known to be in cultivation and are uncommon in the wild. Requests for copies of the regulations on listed plants and inquiries regarding prohibitions and permits may be addressed to the Office of Management Authority, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, room 432, Arlington, Virginia 22203 (703/358–2104).

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, any comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning any aspect of this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to *Myrcia paganii* and *Calyptranthes thomasiana;*

(2) The location of any additional populations of these three species, and the reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act;

(3) Additional information concerning the range and distribution of these species; and

(4) Current or planned activities in the subject areas and their possible impacts on these three species.

Final promulgation of the regulation on *Myrcia paganii* and *Calyptranthes thomasiana* will take into consideration the comments and any additional information received by the Service, and such communications may lead to adoption of a final regulation that differs from this proposal.

The Endangered Species Act provides for a public hearing on this proposal, if requested. Requests must be filed within 45 days of the proposal. Such requests must be made in writing and addressed to the Field Supervisor, Caribbean Field Office, U.S. Fish and Wildlife Service, P.O. Box 491, Boqueron, Puerto Rico 00622.

National Environmental Policy Act

The Fish and Wildlife Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

References Cited

Ayensu, E.S. and R.A Defilipps. 1978. Endangered and threatened plant of the United States. Smithsonian Institution and World Wildlife Fund, Washington, D.C. xv + 403 pp.

Center for Plant Conservation. 1992. Report on the rare plants of Puerto Rico. Missouri Botanical Garden, St. Louis, Missouri.

Department of Natural Resources. 1992. Natural Heritage Program status information of *Myrcia paganii* and *Calyptranthes thomasiana*, San Juan, Puerto Rico.

Vivaldi, J.L. and R.O. Woodbury. 1981. Status report on *Myrcia paganii* Krug & Urban. Unpublished report submitted to the U.S. Fish and Wildlife Service, Atlanta, Georgia. 24 pp.

Woodbury, R.O., and P.L. Weaver. 1987. The vegetation of St. John and Hassel Island, U.S. Virgin Islands. U.S. Department of the Interior, National Park Service, Southeast Regional Office, Research/Resources Management Report SER–83. 103 pp.

Author

The primary author of this proposed rule is Ms. Susan Silander, Caribbean Field Office, U.S. Fish and Wildlife Service, P.O. Box 491, Boqueron, Puerto Rico 00622 (809/8512–7297).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and record-keeping requirements, and Transportation.

Proposed Regulation Promulgation

Accordingly, it is hereby proposed to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. It is proposed to amend § 17.12(h) by adding the following, in alphabetical order, to the list of Endangered and Threatened Plants:

§ 17.12 Endangered and Threatened Plants.

* * * * *

(h) * * *

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
• • •	•	• •	•	•	•	
Myrtaceae—Myrtle family:						
Calyptranthes thomasiana	None	U.S.A. (PR,VI),	E		NA	NA

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
Myrcia paganii	None	British VI U.S.A. (PR)	E		NA	NA

Dated: December 15, 1992.

Richard N. Smith,

Deputy Director, Fish and Wildlife Service.

[FR Doc. 93–80 Filed 1–4–93; 8:45 am]

BILLING CODE 4310–55–M

VOL 58 ISS 2 JA 5 1993 UMI

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AGENCY:

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Notices

Federal Register
Vol. 58, No. 2
Tuesday, January 5, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Types and Quantities of Agricultural Commodities Available for Donation Overseas

AGENCY: Office of the Secretary, USDA.

ACTION: Notice.

SUMMARY: This notice sets forth the determination that an additional quantity of corn, sorghum and butter/butteroil may be made available for donation overseas under section 416(b) of the Agricultural Act of 1949, as amended, during fiscal year 1993.

FOR FURTHER INFORMATION CONTACT: Charles T. Delaplane, Director, Program Analysis Division, Office of the General Sales Manager, FAS, USDA (202) 720–3573.

SUPPLEMENTARY INFORMATION: It has previously been determined that a total of 2,181,000 metric tons of grains and 80,000 metric tons of dairy products may be made available for donation under section 416(b) during fiscal year 1993. This determination was published in the **Federal Register** on October 2, 1992. The purpose of this Notice is to inform the public that such previous determination is revised by adding 600,000 metric tons of corn, 70,000 metric tons of sorghum, and 20,000 metric tons of butter/butteroil.

Determination

Accordingly, a total of 2,851,000 metric tons of grains and 100,000 metric tons of dairy products may be made available for donation overseas pursuant to section 416(b) during fiscal year 1993.

The total kinds and quantities of commodities that may be made available for donation are as follows:

	Commodity	Quantity (Metric Tons)
Grains	Corn	981,000
	Wheat (feed quality)	1,800,000
	Sorghum	70,000
Total		2,851,000
Dairy products	Butter/Butteroil*	100,000
Total		100,000

*At least 40,000 metric tons must be butter.

Done at Washington, DC, this 29th day of December 1992.

Ann M. Veneman,

Acting Secretary of Agriculture.

[FR Doc. 93–55 Filed 1–4–93; 8:45 am]

BILLING CODE 3410–10–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Subcommittee on Export Administration of the President's Export Council; Closed Meeting

A meeting of the President's Export Council Subcommittee on Export Administration will be held January 11, 1993, 2:30 p.m., in the Herbert C. Hoover Building, room 3407, 14th Streets & Constitution Avenue, NW., Washington, DC. The Subcommittee provides advice on matters pertinent to those portions of the Export Administration Act, as amended, that deal with United States policies of encouraging trade with all countries with which the United States has diplomatic or trading relations, and of controlling trade for national security and foreign policy reasons. This meeting is called on short notice because of difficulty in coordinating schedules of PECSEA members and meeting participants.

The Subcommittee will meet only in Executive Session to discuss matters properly classified under Executive Order 12610, pertaining to the control of exports for national security, foreign policy or short supply reasons under the Export Administration Act of 1979, as amended. A Notice of Determination to close meetings, or portions of meetings, of the Subcommittee to the public on the basis of 5 U.S.C. 522(c)(1) was approved September 27, 1991, in accordance with the Federal Advisory Committee Act. A copy of the Notice of Determination is available for public inspection and copying in the Central Reference and Records Inspection Facility, room 6628, U.S. Department of Commerce, Washington, DC. For further information, contact Ms. Betty A. Ferrell (202) 482–2583.

Dated: December 29, 1992.

James M. LeMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93–35 Filed 1–4–93; 8:45 a.m.]

BILLING CODE 3510–DT–M

National Oceanic and Atmospheric Administration

Atlantic Tuna Fisheries; Atlantic Bluefin Tuna

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of extension of deadline for submitting written comments on the preparation of an Environmental Impact Statement (EIS) for western Atlantic bluefin tuna.

SUMMARY: A previous **Federal Register** notice (Volume 57, No. 214) announced NMFS's intent to prepare an EIS for western Atlantic bluefin tuna and requested written comments on or before January 15, 1993. NMFS received a request from a Fishery Management Council to extend the comment period beyond January 21, 1993 in order to allow its pelagic species committee to make comments and the full Council (during its January 19–21 meeting) to adopt recommendations and submit them to the Agency. Since this would not delay any action planned, NMFS announces an extension of the deadline for submitting written comments on the preparation of the EIS for bluefin tuna. The new deadline is January 31, 1993.

ADDRESSES: Comments on the proposal to prepare an EIS must be sent to: Richard H. Schaefer, Director, Office of Fisheries Conservation and Management (F/CM), National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Richard B. Stone at 310–713–2347.

SUPPLEMENTARY INFORMATION: NMFS is responsible for managing the Atlantic bluefin tuna fishery and implementing recommendations of the International Commission for the Conservation of Atlantic Tunas (ICCAT). Further

background information, including management rules and scheduled public hearings, are published in the November 4, 1992, **Federal Register** notice (Vol. 57, No. 214), as well as the December 11, 1992, **Federal Register** notice (Vol. 57, No. 239).

Dated: December 29, 1992.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–31 Filed 1–4–93; 8:45 am]

BILLING CODE 3510–22–M

National Weather Service; Proposed Modernization

AGENCY: National Weather Service, NOAA, Commerce.

ACTION: Notice and request for comments.

SUMMARY: The National Weather Service (NWS) must prepare a report on the proposed modernization of the Weather Service as required by section 708 of the Weather Service Modernization Act. In doing so the NWS must consult with local aviation groups in areas uniquely dependent on aviation. The NWS is requesting comments from any groups in areas of the Country other than Alaska who believe they should be consulted.

DATES: Comments should be received by March 8, 1993.

ADDRESSES: Send comments to: Dr. Ronald Lavoie, 1325 East-West Highway, 14348, Silver Spring, MD 20910, (301) 713–0700.

SUPPLEMENTARY INFORMATION: Section 708 of Public Law 102–567 requires the Secretary of Commerce to prepare a report on the proposed modernization of the NWS within 6 months of enactment of the Act (by April 29, 1993). This report must identify the geographic area of responsibility of each proposed Weather Forecast Office, describe the number and type of personnel involved, and explain the reasons for assigning a geographic area of responsibility to any office that exceeds twice the national average and the reasons for assigning responsibility for more than one next generation radar to an office.

That section also requires the Secretary to consult with local aviation groups "in areas of the Nation that are uniquely dependent on general aviation as a means of transportation."

The NWS believes that all such areas are located in the State of Alaska. However, persons who believe that such areas exist outside Alaska, particularly local aviation groups who wish to be consulted, are requested to identify these areas.

Dated: December 23, 1992.

Louis J. Boezi,

Deputy Assistant Administrator for Modernization.

[FR Doc. 93–30 Filed 1–4–93; 8:45 am]

BILLING CODE 3510–12–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Establishment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in the United Arab Emirates

December 29, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing limits.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715. For information on categories on which consultations have been requested, call (202) 482-3740.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

Inasmuch as consultations have not yet been held on a mutually satisfactory solution on Categories 326, 335/635 and 369–S, the United States Government has decided to control imports in these categories for the twelve-month period beginning on October 28, 1992 and extending through October 27, 1993.

The United States remains committed to finding a solution concerning these categories. Should such a solution be reached in consultations with the Government of the United Arab Emirates, further notice will be published in the **Federal Register**.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 56 FR 60101, published on November 27, 1991; and 57 FR 54976, published on November 23, 1992). Also see 57 FR 54061, published on November 16, 1992.

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

December 29, 1992

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on December 30, 1992, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton and man-made fiber textile products in the following categories, produced or manufactured in the United Arab Emirates and exported during the twelve-month period beginning on October 28, 1992 and extending through October 27, 1993, in excess of the following limits:

Category	Restraint limit [1]
326	980,188 square meters.
335/635	82,745 dozen.
369–S [2]	131,323 kilograms.

[1] The limits have not been adjusted to account for any imports exported after October 27, 1992.
[2] Category 369–S: only HTS number 6307.10.2005.

Textile products in Categories 326, 335/635 and 369–S which have been exported to the United States prior to October 28, 1992 shall not be subject to the limits established in this directive.

Textile products in Categories 326, 335/635 and 369–S which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1) prior to the effective date of this directive shall not be denied entry under this directive.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 93–36 Filed 1–4–93; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF ENERGY

Office of Conservation and Renewable Energy

Energy conservation Program for Consumer Products Representative Average Unit Costs of Energy

AGENCY: Office of Conservation and Renewable Energy, Department of Energy.

ACTION: Notice.

SUMMARY: In this notice, the Department of Energy (DOE) is forecasting the representative average unit costs of five residential energy sources for the year 1993. The five sources are electricity, natural gas, No. 2 heating oil, propane, and kerosene. The representative unit cost of these energy sources is used in the Energy Conservation Program for Consumer Products established by the Energy Policy and Conservation Act (EPCA), Public Law No. 94–163, 89 Stat. 871 (1975), as amended.

EFFECTIVE DATE: The representative average unit cost of energy contained in this notice will become effective February 4, 1993, and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT:

Michael J. McCabe, U.S. Department of Energy, Office of Conservation and Renewable Energy, Forrestal Building, Mail Station CE–43, 1000 Independence Avenue, SW, Washington, DC 20585, (202) 586–9127.

Eugene Margolis, Esq., U.S. Department of Energy, Office of General Counsel, Forrestal Building, Mail Station GC–41, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9507.

SUPPLEMENTARY INFORMATION: Section 323 of the EPCA (Act) [1], as amended, requires that the DOE prescribe test procedures for the determination of the estimated annual operating costs and other measures of energy consumption for certain consumer products specified in the Act. These test procedures are found in 10 CFR part 430, subpart B.

Section 323(b) of the Act requires that the estimated annual operating costs of a covered product be computed from measurements of energy use in a representative average-use cycle and from representative average unit costs of energy needed to operate such product during such cycle. The section further requires DOE to provide information regarding the representative average unit costs of energy for use wherever such costs are needed to perform calculations in accordance with the test procedures. Most notably, these costs are used under the Federal Trade Commission appliance labeling program established by section 324 of the Act and in connection with advertisements of appliance energy use and energy costs which are covered by section 323(c) of the Act.

DOE last published representative average unit costs of residential energy for use in the Conservation Program for Consumer Products on January 30, 1991. (56 FR 3455). Effective February 4, 1993, the cost figures published on January 30, 1991, will be superseded by the cost figures set forth in this notice.

The DOE Energy Information Administration (EIA) has developed the 1992 representative average unit costs of electricity, natural gas, and No. 2 heating oil found in this notice. These costs were taken from the EIA fourth quarter 1991 Short-Term Energy Outlook (Outlook), DOE/EIA–0202 (91/4Q), which forecasts the retail cost of selected energy products based on changes in world oil prices, natural gas wellhead prices, seasonal patterns in retail prices, and established trends in margins and operating expenses. The development of these costs is discussed in detail in the fourth quarter 1992 issue of this report which is the EIA quarterly publication of historical and forecasted energy consumption and prices. The kerosene and propane prices developed here were generated by the computer models used by Outlook but were not published in that specific report. Table 5 of the EIA Outlook contains forecasts for residential electricity, natural gas, and heating oil prices. Copies of this report are available at the National Energy Information Center, Forrestal Building, room 1F–048, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–8800.

The 1993 representative average unit costs stated in Table 1 are provided pursuant to Section 323(b)(4) of the Act and will become effective February 4, 1993. They will remain in effect until further notice.

Issued in Washington, DC, December 29, 1992.

J. Michael Davis,

Assistant Secretary, Conservation and Renewable Energy.

TABLE 1.—REPRESENTATIVE AVERAGE UNIT COSTS OF ENERGY FOR FIVE RESIDENTIAL ENERGY SOURCES

[1993]

Type of energy	In common terms	As required by test procedure	Dollars per million Btu[1]
Electricity	8.30 ¢/kWh[2,3]	$0.0830/kWh	$24.33
Natural gas	59.46 ¢/therm[4] or $6.13/MCF[5,6]	0.00000595/Btu	5.95
No. 2 Heating Oil	$1.00/gallon[7]	0.00000721/Btu	7.21
Propane	$0.73/gallon[8]	0.00000799/Btu	7.99
Kerosene	$0.82/gallon[9]	0.00000607/Btu	6.07

[1] Btu stands for British thermal units.
[2] kWh stands for kilowatt hour.
[3] 1kWh=3,412 Btu.
[4] 1 therm=100,000 Btu. Natural gas prices include taxes.
[5] MCF stands for 1,000 cubic feet.
[6] For the purposes of this table, one cubic foot of natural gas has an energy equivalence of 1,031 Btu.
[7] For the purposes of this table, one gallon of No. 2 heating oil has an energy equivalence of 138,690 Btu.
[8] For the purposes of this table, one gallon of liquid propane has an energy equivalence of 91,333 Btu.
[9] For the purposes of this table, one gallon of kerosene has an energy equivalence of 135,000 Btu.

[FR Doc. 93–81 Filed 1–4–93; 8:45 am]

BILLING CODE 7450–01–1–M

[1] References to the "Act" refer to the Energy Policy and Conservation Act, as amended by the National Energy Conservation Policy Act, by the National Appliance Energy Conservation Act of 1987, and by the National Appliance Energy Conservation Amendments of 1988.

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Federal Energy Regulatory Commission

[Docket No. TQ93-3-23-000]

Eastern Shore Natural Gas Co.; Proposed Changes in FERC Gas Tariff

December 28, 1992.

Take notice that Eastern Shore Natural Gas Company (ESNG) tendered for filing on December 22, 1992 certain revised tariff sheets included in appendix A attached to the filing. Such sheets are proposed to be effective February 1, 1993.

ESNG notes that the above referenced tariff sheets are being filed pursuant to § 154.308 of the Commission's regulations and §§ 21.2 and 21.4 of the General Terms and Conditions of ESNG's FERC Gas Tariff to reflect changes in ESNG's jurisdictional rates. The sales rates set forth thereon reflect a decrease of $0.5908 per dt in the Commodity Charge and a decrease of $0.1352 per dt in the Demand Charge, all as measured against ESNG's Out-Of-Cycle Purchased Gas Adjustment in Doc. No. TQ93-2-23-000, as filed on October 30, 1992 and requested to be effective November 1, 1992.

ESNG states that copies of the filing have been served upon its jurisdictional customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 and Rule 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 5, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25 Filed 1-4-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-48-000]

Northwest Pipeline Corp.; Proposed Change in FERC Gas Tariff

December 28, 1992.

Take notice that on December 15, 1992, Northwest Pipeline Corporation ("Northwest") tendered for filing and acceptance Second Revised Fourteenth Revised Sheet No. 13 to become a part of its FERC Gas Tariff, Second Revised Volume No. 1.

Northwest states that the purpose of this filing is to file its Annual Report and Cost-of-Service Study to establish a revised Facility Charge and an Amortizing Adjustment relating to Rate Schedule T-1.

Northwest requests an effective date of February 1, 1993.

Northwest states that copies of the filing is being served upon PITCO and upon all jurisdictional sales customers and affected state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 4, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93-24 Filed 1-4-93; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2984-022]

S.D. Warren Co.; Complaints

(December 28, 1992)

Take notice that on September 3, 1992, Friends of Sebago Lake filed a complaint in which it contends that S.D. Warren Company has violated and continues to violate certain terms of the license for the Eel Weir Hydroelectric Project No. 2984, located in Cumberland County, Maine, at the outlet of Sebago Lake into the Presumpscot River. Additional complaints contending similar license violations were filed on September 22, 1992, by Charles Tranter and Rita M. Tranter; on October 15, 1992, by Anthony DeSalvo, Gerald A. Cole and Kevin T. Cole; on October 27, 1992, by Roger D. Wheeler; and on December 14, 1992, by Frank St. Pierre and Pauline St. Pierre.

The complaints concern S.D. Warren Company's practice, since 1987, of reducing outflows from Sebago Lake during the summer and fall months in order to increase outflows, and thereby electric generation, during the winter. The complainants contend that the reduced seasonal outflows have raised Sebago Lake's level annually above normal historical lake levels, which has caused previously stable beach and shoreline soils to erode severely. The erosion, complainants allege, has damaged the beaches and the trees and bushes around Sebago Lake, and has produced algae and macrophytes that detrimentally affect the lake waters. The complainants maintain that the licensee's actions violate Articles 3 and 19 of the license for the Eel Weir Project.[1]

Any person may submit comments regarding these complaints with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211. The respondent, S.D. Warren Company, shall file an answer to these complaints pursuant to Rules 206 and 213, 18 CFR 385.206 and 385.213. No replies to respondent's answer will be accepted. In determining the appropriate action to take, the Commission will consider all comments filed. Copies of the complaints are on file with the Commission and are available for public inspection.

Comments and the answer to the complaints are due on or before March 1, 1993.

For further information, contact Rachel Hecht at (202) 208-2138.

Lois D. Cashell,

Secretary.

[FR Doc. 93-27 Filed 1-4-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM93-6-29-000]

Transcontinental Gas Pipe Line Corp.; Proposed Changes in FERC Gas Tariff

December 28, 1992.

Take notice that Transcontinental Gas Pipe Line Corporation (TGPL) tendered for filing on December 22, 1992 certain revised tariff sheets to Third Revised Volume No. 1 of its FERC Gas Tariff included in appendix A attached to the filing.

TGPL states that the purpose of the filing is to track rate changes

[1] Article 3 requires the licensee to obtain prior Commission approval for substantial alterations to its use of project lands and waters. Article 19 makes the licensee responsible for, and requires the taking of reasonable measures to prevent, soil erosion due to project operation on lands adjacent to streams or other waters.

attributable to storage services purchased from North Penn Gas Company (North Penn) under its Rate Schedule SS the costs of which are included in the rates and charges payable under TGPL's Rate Schedule SS–1 and storage services purchased from Texas Eastern Transmission Corporation (TETCO) under its Rate Schedule X–28 the costs of which are included in the rates and charges payable under TGPL's Rate Schedule S–2. The tracking filing is being made pursuant to section 5 of TGPL's Rate Schedule SS–1 and section 26 of the General Terms and Conditions of Volume No. 1 of TGPL's FERC Gas Tariff.

Included in the appendices B and C attached to the filing are explanations of each of the tracking rate changes, the proposed effective date of such changes and details regarding the computation of the revised rates under Rate Schedules SS–1 and S–2.

Also included therein for filing are revised tariff sheets which incorporate the Rate Schedule SS–1 and S–2 rate changes proposed therein into subsequent intervening rate filings which have been accepted by the Commission to be effective on the dates reflected thereon.

TGPL states that copies of the filing are being mailed to each of its SS–1 and S–2 customers and interested State Commissions.

Any person desiring to be heard or to protests said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 5, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–26 Filed 1–4–93; 8:45 am]

BILLING CODE 6717–01–M

Post-Licensing Filing With the Commission; Turlock and Modesto Irrigation Districts

December 29, 1992.

Take notice that the following material has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. Type of action: Notice of Proceeding.

b. Project number: 2299–024.

c. License issued: March 10, 1964.

d. Licensees: Turlock and Modesto Irrigation Districts.

e. Name of project: New Don Pedro Project.

f. Location: Tuolumne County, California.

g. Authorization: Article 37 of the project license.

h. Licensee contact: Mr. Ernest Geddes, P.O. Box 949, Turlock, CA 95380.

i. FERC contact: John A. Schnagl (202) 219–2661.

j. Comment date: February 10, 1993.

k. Description of proceeding: On March 9, 1992, Turlock and Modesto Irrigation Districts (licensees) filed and supplemented on March 19 the results of studies required by article 39 of the license for the New Don Pedro Project. The filing includes a memorandum of agreement with the California Department of Fish and Game whereby the licensees agree to a modified minimum flow schedule that would generally increase the amount of water released from the project for fish protection. The City and County of San Francisco (City) and San Francisco Bay Area Water Users Association object to the proposed agreement, citing the effect of the agreement on their principal water supply. In addition, the City recommended alternative flows for the protection of the fishery resources in the Tuolumne River. The Commission will conduct an independent evaluation to determine what change of flows, if any, is necessary to proctect the fishery resources in the Tuolumne River. The results of the evaluation will be presented in an environmental assessment that will also discuss the environmental impacts of any proposed changes.

l. This notice also consists of the following standard paragraphs: B, C, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.210, 385.211, 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "RECOMMENDATIONS FOR TERMS AND CONDITIONS," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATIONS," "PROTEST" or "MOTION TO INTERVENE," as applicable, and the project number of the particular application to which the filing is in response. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to: The Director, Office of Hydropower Licensing, Division of Project Compliance and Administration, Federal Energy Regulatory Commission, ATTN: HL–21, room 1148 UCP, at the above address. A notice of intent, competing application, or motion to intervene must also be served upon each representative of the applicant specified in the particular application.

D2. Agency Comments—The Commission invites federal, state, and local agencies to file comments on the described application. (Agencies may obtain a copy of the application directly from the applicant.) If an agency does not file comments within the time specified for filing comments, the Commission will presume that the agency has none. One copy of an agency's comments must also be sent to the applicant's representatives.

Lois D. Cashell,

Secretary.

[FR Doc. 93–22 Filed 1–4–93; 8:45 am]

BILLING CODE 6717–01–M

Office of Fossil Energy

[FE Docket No. 92–154–NG]

Gas Company of New Mexico, a Division of Public Service Company of New Mexico; Application for Blanket Authorization to Export Natural Gas to Mexico

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on December 7, 1992, of an application filed by Gas Company of New Mexico (GCNM), a division of Public Service Company of New Mexico, to export up to 8 Bcf of natural gas from the United States to Mexico over a two-year period commencing on the date of first delivery. The proposed exports would take place at a border crossing to be constructed at or near Santa Teresa, New Mexico.

The application is filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204–111 and 0204–127. Protests, motions to intervene, notices of intervention, and written comments are invited. A copy of GCNM's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, at the above address. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., eastern time, February 4, 1993.

ADDRESSES: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–056, FE–50, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION:

Peter Lagiovane, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–056, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–8116.

Lot Cooke, Office of Assistant General Counsel for Fossil Energy, U.S. Department of Energy, Forrestal Building, room 6E–042, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–0503.

SUPPLEMENTARY INFORMATION: GCNM is a division of the Public Service Company of New Mexico, a corporation organized and existing under the laws of the State of New Mexico with its principal place of business in Albuquerque. The exported gas would come from production areas in the United States with surplus supplies of natural gas and will be sold in Mexico to residential and industrial users in and around the Santa Teresa International Industrial Park being developed on both sides of the U.S.-Mexico border near Santa Teresa, New Mexico. GCNM has advised DOE that all sales of exported gas would result from arms-length negotiations and the prices would be determined by market conditions. The exported gas will be transported to the industrial park through existing pipeline facilities and twenty-two miles of natural gas pipeline to be constructed between the park and the El Paso Natural Gas California main line. GCNM will also construct, connect, operate, and maintain export facilities at the U.S.-Mexico border and has applied to the Federal Energy Regulatory Commission (FERC) for a Presidential Permit authorizing the construction of these facilities.

The decision on the application for export authority will be made consistent with DOE's gas export policy guidelines, under which DOE considers the domestic need for the gas to be exported and any other issues determined to be appropriate, including whether the arrangement is consistent with the DOE policy of promoting competition in the natural gas marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties, especially those that may oppose the application, should comment on these issues as they relate to the requested export authority.

NEPA Compliance. The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.*, requires DOE to give appropriate consideration to the environmental effects of its proposed actions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures. In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have their written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the address listed above.

It is intended that a decisional record on the application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

Issued in Washington, DC, on December 29, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 93–83 Filed 1–4–93; 8:45 am]

BILLING CODE 6450–01–M

[FE Docket No. 92–04–NG]

Kamine/Besicorp Natural Dam L.P.; Authorization To Import Natural Gas From Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting authorization to Kamine/Besicorp Natural Dam L.P. to import up to 12,500 Mcf per day of Canadian natural gas and up to a total of 114.1 Bcf over a period of 15 years. the gas will be used as fuel in a new 58-megawatt cogeneration facility under construction near

Gouverneur, New York. The term of the authorization begins at the time of the first import delivery or June 1993, whichever is earlier.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, room 3F–056 at the above address. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on December 18, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs; Office of Fossil Energy.

[FR Doc. 93–84 Filed 1–4–93; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL 4551–5]

Revised Hours for Public Access to the Headquarters Library and INFOTERRA

AGENCY: U.S. Environmental Protection Agency.

SUMMARY: Notice is hereby given that beginning January 4, 1993, the Headquarters Library and INFOTERRA will be open to the public from 10 a.m. to 4 p.m. This constitutes a reduction in hours.

FOR FURTHER INFORMATION CONTACT: Jonda Byrd, National Library Network Program Manager at 513/569–7183 or Emma McNamara, INFOTERRA Manager at 202/260–1522.

Mike Miller,

Acting Chief, Information Access Branch.

[FR Doc. 93–62 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–50–M

[FRL–4551–7]

Meeting of the Ozone Transport Commission for the Northeast United States

AGENCY: Environmental Protection Agency.

ACTION: Notice of meeting.

SUMMARY: The United States Environmental Protection Agency is announcing a meeting of the Ozone Transport Commission to be held on Friday, January 8, 1993.

The Commission will deal with appropriate matters within the transport region, as provided for under the Clean Air Act Amendments of 1990. This meeting is not subject to the provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended.

DATES: The meeting will be held on January 8, 1993.

ADDRESSES: The meeting will be held at: Sheraton National Hotel, Columbia Pike and Washington Boulevard, Arlington, VA 22204, (202) 508–3840.

FOR FURTHER INFORMATION OR PRESS INQUIRIES CONTACT: Bruce Carhart, Executive Director, Ozone Transport Commission, 444 North Capitol Street NW., Suite 604, Washington, DC 20001, (202) 508–3840.

SUPPLEMENTARY INFORMATION: The Clean Air Act Amendments of 1990 contain at Section 184 new provisions for the "Control of Interstate Ozone Air Pollution." Section 184(a) establishes an ozone transport region comprised of the States of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, parts of Virginia and the District of Columbia. The purpose of the Transport Commission is to deal with appropriate matters within the ozone transport region.

The purpose of this notice is to announce that this Commission will meet on January 8, 1993. The meeting will be held at the address noted earlier in this notice.

Section 176Á(b)(2) of the Clean Air Act Amendments of 1990 specifies that the meetings of Transport Commissions are not subject to the provisions of the Federal Advisory Committee Act. This meeting will be open to the public as space permits.

TYPE OF MEETING: Open.

AGENDA: The meeting begins at 9 a.m. and is expected to last until 4:30 p.m. The Commission will review the 1993 work plan, and receive reports from its committees, particularly on (1) Rules and plans for Inspection and Maintenance (I/M) programs, (2) Results of Regional Oxidant Model (ROM) simulations, (3) Design of an Ozone Transport Commission logo, and (4) Discussion of Emissions Offset Programs.

A complete agenda is available from the Ozone Transport Commission at the address given for the information contact person.

Dated: December 21, 1992.

Julie Belaga,

Regional Administrator, EPA Region I.

[FR Doc. 93–76 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–50–M

[FRL–4552–8]

Meeting of the Grand Canyon Visibility Transport Commission Work Plan Committees

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of meeting.

SUMMARY: The United States Environmental Protection Agency (U.S. EPA) is announcing meetings of the Operations, Technical, Alternatives Assessment, and Communications Committees of the Grand Canyon Visibility Transport Commission (Commission) on January 12, 13, and 14, 1993, in San Diego, California. The meetings will be held at the Pan Pacific Hotel, 400 West Broadway, San Diego, California, beginning at 1:30 p.m. (p.s.t.) on January 12. The committees were established by the Commission by approval of work plan at its June 21, 1992 meeting (see 56 FR 24790, June 11, 1992, and 56 FR 38633, August 26, 1992). The Commission was established by the EPA on November 13, 1991 (see 56 FR 57522, November 12, 1991).

This will be the first meeting for the Public Advisory Committee which was recently appointed by the Commission. The Public Advisory Committee membership represents a broad range of interests in addressing the issue of regional haze and was established to advise the Commission and Operations Committee on technical and policy matters.

Central to these meetings will be presentations by the National Academy of Sciences (NAS) and the Environmental Protection Agency (EPA). The NAS will be reporting on its recent study on haze in national parks. The EPA will be giving a preliminary report on future impacts of the Clear Air Act Amendments of 1990 on regional haze in the southwest. In addition, the committees will review tasks in progress and will assign additional work plan tasks to participating State, Federal, private and nongovernmental organizations. All meetings are open to the public. These meetings are not subject to provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended.

DATES: The meetings will be held as follows (all times p.s.t.):

Public Advisory Steering Committee:

Tuesday, January 12, 4 p.m.–5:30 p.m.

Public Advisory Committee:

Wednesday, January 13, 2:30 p.m.–4:30 p.m.

All Committees (NAS and EPA Presentations):

Wednesday, January 13, 8:30 a.m.–2 p.m.

Operations Committee:

Tuesday, January 12, 1:30 p.m.–3:30 p.m.
Wednesday, January 13, 4:30 p.m.–5:30 p.m.
Thursday, January 14, 8:30 a.m.–noon.

Technical Committee (Aerosol Subcommittee only):

Tuesday, January 12, 9 a.m.–noon.

Technical Committee (Joint Subcommittees):

Wednesday, January 13, 7:30 p.m.–9:30 p.m.

Technical Committee (Concurrent Subcommittees):

Thursday, January 14, 12:30 p.m.–2:30 p.m.

Alternatives Assessment Committee:

Thursday, January 14, 2:30 p.m.–4:30 p.m.

Communications Committee:

Tuesday, January 12, 9 a.m.–noon.
Wednesday, January 13, 4:45 p.m.–6 p.m.

ADDRESSES: The meetings will be held in San Diego, California, at the Pan Pacific Hotel, 400 West Broadway, San Diego, California, 92101.

FOR FURTHER INFORMATION CONTACT: Mr. John T. Leary, Project Manager for the Grand Canyon Visibility Transport Commission, Western Governors' Association, 600 17th Street, Suite 1705, South Tower, Denver, Colorado 80202. Telephone number (303) 623–9378. Facsimile machine number (303) 534–7309.

Dated: December 30, 1992

Michael Shapiro,

Assistant Administrator for Air and Radiation.

[FR Doc. 93–194 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–01–M

[FRL–4552–4]

Proposed Settlement, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended ("Act"), notice is hereby given of a proposed consent order in the following case:

Nelson v. *Reilly*, No. 92–6260–HO (D. Ore.). This citizen suit was filed under section 304(a) of the Act, 42 U.S.C. 7604, and alleges that EPA failed to meet a mandatory deadline for revision of the regulations promulgated under section 206(a)(4)(A) of the Act with regard to certain certification test procedures for light-duty vehicles and trucks. The proposd consent order would require EPA to propose such regulations by December 15, 1992, and to promulgate final regulations by 10 months thereafter.

For a period of thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the proposed consent order from persons who were not named as parties to the litigation in question. EPA or the Department of Justice may withhold or withdraw consent to the proposed order if the comments disclose facts or circumstances that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with requirements of the Act.

A copy of the proposed order has been lodged with the clerk of the United States District Court for the District of Oregon. Copies are also available from Betty S. Mobley, Air and Radiation Division (LE–132A), Office of General Counsel, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, (202) 260–7606. Written comments should be sent to Steven E. Silverman, Esq. at the above address and must be submitted on or before February 4, 1993.

Dated: December 9, 1992.

Raymond B. Ludwiszewski,

Acting General Counsel.

[FR Doc. 93–78 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–50–M

[OPPTS–44594; FRL–4181–9]

TSCA Chemical Testing; Receipt of Test Data

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the receipt of test data on crotonaldehyde (CAS No. 4170–30–3), submitted pursuant to a testing consent order under the Toxic Substances Control Act (TSCA). Publication of this notice is in compliance with section 4(d) of TSCA.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS–799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–543B, 401 M St., SW., Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: Under 40 CFR 790.60, all TSCA section 4 consent orders must contain a statement that results of testing conducted pursuant to these testing consent orders will be announced to the public in accordance with section 4(d).

I. Test Data Submissions

Test data for crotonaldehyde were submitted by Eastman Chemical Company pursuant to a testing consent order at 40 CFR 799.5000. They were received by EPA on December 1, 1992. The submissions describe the chronic toxicity to *daphnia magna* under flow-through conditions and the toxicity to fathead minnow (Pimephales promelas) during an early life-stage exposure. Environmental effects testing is required by this testing consent order. This chemical is used as an intermediate to produce crotonic acid, sorbic acid, 3-methoxybutanol and *n*-butanol.

EPA has initiated its review and evaluation process for these data submissions. At this time, the Agency is unable to provide any determination as to the completeness of the submissions.

II. Public Record

EPA has established a public record for this TSCA section 4(d) receipt of data notice (docket number OPPTS–44594). This record includes copies of all studies reported in this notice. The record is available for inspection from 8 a.m. to 12 noon, and 1 p.m. to 4 p.m., Monday through Friday, except legal holidays, in the TSCA Public Docket Office, Rm. NE–G004, 401 M St., SW., Washington, DC 20460.

Authority: 15 U.S.C. 2603.

Dated: December 16, 1992.

Charles M. Auer,

Director, Chemical Control Division, Office Pollution Prevention and Toxics.

[FR Doc. 93–77 Filed 1–4–93; 8:45 am]

BILLING CODE 6560–50–F

FEDERAL MARITIME COMMISSION

Agreement(s) Filed: Ecuador Discussion Agreements et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC office of the Federal

Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 203–010999–012.

Title: Ecuador Discussion Agreement.

Parties: United States Atlantic and Gulf/Ecuador Freight Conference, Naviera Consolidada S.A., Empresa Naviera Santa, S.A., Transportes Navieros Ecuatorianos, Empremar/MSC.

Synopsis: The proposed agreement will permit the parties to agree on the sharing of expenses and the conduct of any collective administrative matters.

Agreement No.: 224–200690–001.

Title: Port of Oakland and Stevedoring Services of America Marine Terminal Agreement.

Parties: The Port of Oakland ("Port"), Stevedoring Services of America ("SSA").

Synopsis: The modification amends the basic Agreement by identifying certain reimbursement obligations of the Port to SSA for certain extraordinary labor costs incurred during the repairs by the Port to the Charles P. Howard Terminal as a result of earthquake damage.

Agreement No.: 224–200709.

Title: Port of Galveston/SeaTruck Texas, Incorporated Terminal Agreement.

Parties: The Board of Trustees of the Galveston Wharves SeaTruck Texas, Incorporated ("SeaTruck").

Synopsis: The Agreement provides for SeaTruck to have exclusive use of the leased premises, and preferential berthing at adjacent pier 34, for the development and operation of a truck-trailer Ro-Ro terminal. The Agreement's term is 25 years.

Agreement No.: 224–200710.

Title: Port of Oakland and Canadian Transport Co., Ltd., Marine Terminal Agreement.

Parties: The Port of Oakland ("Port"), Canadian Transport Co., Ltd. ("CTCO").

Synopsis: The Agreement provides for CTCO to have the nonexclusive right to certain assigned premises at the Port's Charles P. Howard Terminal for berthing, loading and discharging of vessels and related operations. The term of the Agreement is for three years.

By Order of the Federal Maritime Commission.

Dated: December 29, 1992.

Joseph C. Polking,

Secretary.

[FR Doc. 93–19 Filed 1–4–93; 8:45 am]

BILLING CODE 6730–01–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ES–030–3–4210–05; MIES–043236]

Realty Actions, Sales, Leases, etc.; Michigan

AGENCY: Bureau of Land Management, Interior.

ACTION: Sale of public land in Chippewa County, Michigan—modified competitive method.

SUMMARY: The following public land has been found suitable for sale under section 203 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701, 1713), at not less than the estimated fair market value (FMV) of $4,800.00. The public land will not be offered for sale for at least 60 days following the date of this notice. The public land is described as follows:

MIES–043236

T. 41N., R. 7E., Sec. 30, Lot 3, Michigan Meridian, Drummond Township, Chippewa County, Michigan (containing approximately 2.50 acres);

The public land described above is hereby segregated from appropriation under the public land laws, including the mining laws, pending disposition of this action, or 270 days from the date of publication of this notice in the **Federal Register**, whichever occurs first.

The public land will be offered for sale at a public auction beginning at 10 a.m. CST, on March 15, 1993 at Reuss Federal Plaza, Suite 225, West Tower, 310 West Wisconsin Avenue, Milwaukee, Wisconsin 53203. This sale will be by modified competitive procedures. Mr. Thomas A. McCaskill will be given the opportunity to meet the highest bid received at public auction. Sale will be by sealed bid only.

All sealed bids must be submitted to the BLM's Milwaukee District Office at Reuss Federal Plaza, Suite 225, West Tower, 310 West Wisconsin Avenue, Milwaukee, Wisconsin 53203, no later than 3 p.m. CST on March 12, 1993. Bid envelopes must be marked on the left front corner with MIES–043236 and March 15, 1993. Bids must be for not less than the appraised FMV specified in this notice. Each sealed bid shall be accompanied by a certified check, postal money order, bank draft, or cashier's check made payable to the U.S. Department of the Interior, BLM for not less than 10 percent of the amount bid.

The terms and conditions applicable to the sale: (1) All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove the minerals. A more detailed description of this reservation, which will be incorporated in the patent document, is available for review at the Milwaukee District Office; and

(2) There is no legal access to the parcel because it is landlocked by the adjacent parcel to the north. There is physical access to the parcel by boat.

Federal law requires that all bidders must be U.S. citizens, 18 years or older, or in the case of corporations, be subject to the laws of any State of the United States. Proof of these requirements must accompany the bid.

Under modified competitive sale procedures, an apparent high bid will be declared at public auction. The apparent high bidder and the designated bidder (Mr. Thomas A. McCaskill) will be notified. The designated bidder shall have fifteen (15) days from the date of notification to exercise the preference consideration given to meet the high bid. Should the designated bidder fail to submit a bid that matches the apparent high bid within the specified time period, the apparent high bidder shall be declared high bidder. The total purchase price for the land shall be paid with 180 days of the date of the sale.

Detailed information concerning the sale, including the reservations, procedures for and conditions of sale, planning and environmental documents, are available at the Milwaukee District Office.

DATES: On or before February 19, 1993, interested parties may submit comments to the District Manager, Bureau of Land Management, P.O. Box 631, Milwaukee, Wisconsin 53201–0631. In the absence of objections, this proposal shall become the final determination of the Department of the Interior.

FOR FURTHER INFORMATION CONTACT:

Duane Marti, Realty Specialist, Bureau of Land Management, P.O. Box 631, Milwaukee, Wisconsin 53201–0631; telephone number (414) 297–4429.

Gary D. Bauer,

District Manager.

[FR Doc. 93–6 Filed 1–4–93; 8:45 am]

BILLING CODE 4310–GJ–M

VOL 58 ISS 2 JA 5 1993 UMI

Minerals Management Service

Outer Continental Shelf (OCS) Oil and Gas Information Program

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that the Minerals Management Service has recently released a publication entitled "Accidents Associated with Oil and Gas Operations, Outer Continental Shelf, 1956–1990, OCS Report MMS 92–0058." This 324-page report is a compilation of descriptions of all blowouts, explosions and fires, pipeline breaks or leaks, significant pollution incidents, and major accidents that occurred on federally leased offshore lands for 1956 through 1990.

The report identifies accidents by area, block number, lease number, platform number, well number, and operator. It describes the type of accident, corrective action taken, and the amount of pollution. It provides figures on fatalities, injuries, and property and environmental damage.

ADDRESSES: This OCS REPORT, MMS 92–0058, is available for inspection at the Technical Communication Services; Document Distribution Center; Minerals Management Service, Mail Stop 4530; 381 Elden Street, room 1317; Herndon, Virginia 22070–4817, telephone (703) 787–1080. Copies of this report can be obtained from the same address.

FOR FURTHER INFORMATION CONTACT: Lloyd M. Tracey; Engineering and Standards Branch; Minerals Management Service, Mail Stop 4700; 381 Elden Street; Herndon, Virginia 22070–4817, telephone (703) 787–1600.

SUPPLEMENTARY INFORMATION: This report is published pursuant to 30 CFR part 252—OCS Oil and Gas Information Program, 44 FR 46408, August 7, 1979. An outline of the contents of the report is set forth below.

Accidents Associated with Oil and Gas Operations in the OCS.

I. Introduction

II. Gulf of Mexico (GOM) OCS Region

Table 1, Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS—GOM.

Table 2–A, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Blowouts.

Table 2–B, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Explosions and Fires.

Table 2–C, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Pipeline Breaks or Leaks.

Table 2–D, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Significant Pollution Incidents, 50 bbl (2,100 gal) or More.

Table 2–E, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Major Accidents.

III. Pacific OCS Region

Table 3, Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS—Pacific.

Table 4–A, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Blowouts.

Table 4–B, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Explosions and Fires.

Table 4–C, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Pipeline Breaks or Leaks.

Table 4–D, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Significant Pollution Incidents, 50 bbl (2,100 gal) or More.

Table 4–E, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Major Accidents.

IV. Alaska OCS Region

Table 5–E, Accidents Associated with Oil and Gas Operations on the OCS, Alaska, Major Accidents.

V. Atlantic OCS Region

Table 6–E, Accidents Associated with Oil and Gas Operations on the OCS, Atlantic, Major Accidents.

VI. Summary Tables for the Entire OCS

Table 7, Summary of Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS.

Table 8, Summary of Accidents Associated with Oil and Gas Operations on the OCS, 1956–1990.

VII. Graphs of Data Pertaining to Accidents Associated With Oil and Gas Operations on the OCS

Figure 1, Crude & Condensate Spills≥200 bbl, OCS—GOM.

Figure 2, Crude & Condensate Spills≥200 bbl, OCS—Pacific.

Figure 3, Volume of Crude & Condensate Spilled, OCS—GOM.

National Park Services

Cape Cod National Seashore; South Wellfleet, MA; Cape Cod National Seashore Advisory Commission; Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App 1 10), that meetings of the Cape Cod National Seashore Advisory Commission will be held on Friday, January 22, 1993.

The Commission was reestablished pursuant to Public Law 99–349, Amendment 24. The purpose of the Commission is to consult with the Secretary of the Interior, of his designee, with respect to matters relating to the development of the Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The commission members will meet at 1 p.m. on Friday, January 22, 1993, for a regular business meeting which will convene at Park Headquarters for the following reasons:

1. Adoption of Agenda.
2. Approval of Minutes of Previous Meeting.
3. Reports of Officers.
4. Superintendent's Report.
5. Water Resources on the Lower Cape.
6. Land Acquisition Program.
7. New Business.
8. Agenda for Next Meeting.
9. Date for Next Meeting.
10. Communications/public comment.
11. Adjournment.

The business meetings are open to the public. It is expected that 15 persons will be able to attend each meeting in addition to the Commission members.

Interested persons may make oral/written presentations to the Commission during the business meetings or file written statements. Such requests should be made to the park superintendent at lease seven days prior to the meeting. Further information concerning these meetings may be obtained from the Superintendent, Cape Cod National Seashore, South Wellfleet, MA 02663.

Dated: December 23, 1992.

John J. Burchill,

Acting Regional Director.

[FR Doc. 93–17 Filed 1–4–93; 8:45 am]

BILLING CODE 4310–70–M

National Register of Historic Places; Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before December 26, 1992. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013–7127. Written comments

should be submitted by January 21, 1993.

Antionette J. Lee,

Acting Chief of Registration, National Register.

ALABAMA

Cullman County

Greene, Ernest Edward, House, 105 6th Ave. SE., Cullman, 92001828

Dallas County

Plattenburg, Wesley, House, 601 Washington St., 92001827

Jefferson County

Rickwood Field, 1137 2nd Ave. W., Birmingham, 92001826

Perry County

Judson College Historic District, Roughly bounded by E. Lafayette, Curb, Mason and Washington Sts., Marion, 92001825

Randolph County

Roanoke Downtown Historic District, Roughly, jct. of Main, West Point, Chestnut, Louina and Knight, and Main E to Trammell and West Point E to Church, Roanoke, 92001829

Tuscaloosa County

Murphy—Collins House, 2601 Paul Bryant Dr., Tuscaloosa, 92001824

ARIZONA

Maricopa County

Story, F. O., Neighborhood Historic District (Boundary Increase), Roughly bounded by 17th Ave., Culver St., 15th Ave. and Lynwood St., also lots on Roosevelt St. and McDowell Rd., Phoenix, , 92001834

ARKANSAS

Johnson County

Science Hall, University of the Ozarks, University of the Ozarks campus, W of AR 103, Clarksville, 92001830

FLORIDA

Orange County

Huttig, John N., Estate, 435 Peachtree Rd., Orlando, 92001776

LOUISIANA

East Baton Rouge Parish

Les Chenes Verts (Louisiana's French Creole Architecture MPS). Jct. Highland Rd. and Jean Lafitte Ave., Baton Rouge, 92001831

Ory House (Louisiana's French Creole Architecture MPS). Jct. of Highland Rd. and Jean Lafitte Ave., Baton Rouge, 92001818

St. Tammany Parish

Salmen, Albert, House, 213 Cleveland Ave., Slidell, 92001822

Tangipahoa Parish

Reed Farmstead Log Dependencies, LA 445, Husser vicinity, 92001821

West Feliciana Parish

3 V Tourist Court, 111 E. Commerce St., St. Francisville, 92001832

NEW MEXICO

Dona Ana County

San Jose Church, 317 Josephine St., La Mesa, 92001817

McKinley County

Vogt. Evon Zartman, Ranch House, 1 mi; S of Ramah, 500 ft. E of NM 53, Ramah vicinity, 92001819

NORTH CAROLINA

Dare County

First Colony Inn, 6720 S. Virginia Dare Trail, Nags Head, 92001835

OKLAHOMA

Garfield County

Champlin, N. H., House, 612 S. Tyler, Enid, 92001833

PENNSYLVANIA

Blair County

Tyrone Borough Historic District, Roughly bounded by W. 14th St., Logan Ave., Bald Eagle Ave., the Little Juniata R., W. 8th St. and Jefferson Ave., Tyrone, 92001823

TENNESSEE

Monroe County

Scott Mansion, Scott Mansion Rd., about 1¼ mi. E of TN 68, Tellico Plains, 92001816

TEXAS

Kleberg County

Ragland, John B., Mercantile Company Building, 201 E. Kleberg Ave., Kingsville, 92001820

[FR Doc. 93–13 Filed 1–4–93; 8:45 am]

BILLING CODE 4310–70–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–560 (Final)]

Sulfanilic Acid From Hungary

AGENCY: United States International Trade Commission.

ACTION: Revised schedule for the subject investigation.

EFFECTIVE DATE: December 23, 1992.

FOR FURTHER INFORMATION CONTACT: Debra Baker (202–205–3180), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION: Effective October 22, 1992, the Commission instituted the subject investigation and established a schedule for its conduct (57 FR 54420, November 18, 1992). Subsequently, the Department of Commerce extended the date for its final determination in the investigation from December 29, 1992 to February 3, 1993 (57 FR 57729, December 7, 1992). The Commission, therefore, is revising its schedule in the investigation to conform with Commerce's new schedule.

The Commission's schedule for the investigation is revised as follows: a supplemental brief addressing only the final antidumping determination of the Department of Commerce is due on February 8, 1993; the brief may not exceed five (5) pages in length. The other dates announced in the Commission's notice of investigation cited above are unchanged.

For further information concerning this investigation see the Commission's notice of investigation cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR party 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.20 of the Commission's rules.

Issued: December 28, 1992.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–34 Filed 1–4–93; 8:45 am]

BILLING CODE 7020–02–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32212]

Soo Line Railroad Co.; Trackage Rights Exemption; Indiana Harbor Belt Railroad Co.

Indiana Harbor Belt Railroad Company (IHB) has agreed to grant overhead trackage rights to Soo Line Railroad Company over IHB's line extending between IHB's connection with Baltimore and Ohio Chicago Terminal Railroad Company (B&OCT) at GTW Tower, in Blue Island, and IHB's connection with B&OCT at CP Calumet Park, in Calumet City, IL. The trackage rights were to become effective on December 18, 1992.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Larry D. Starns, 1000 Soo Line Building,

105 South Fifth Street, Minneapolis, MN 55402.

As a condition to the use of this exemption, any employees adversely affected by the trackage rights will be protected under *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: December 28, 1992.

By the Commission, Julia M. Farr, Acting Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–58 Filed 1–4–93; 8:45 am]

BILLING CODE 7035–01–M

JUDICIAL CONFERENCE OF THE UNITED STATES

Meeting of the Judicial Conference Advisory Committee on Bankruptcy Rules

AGENCY: Judicial Conference of the United States.

SUBAGENCY: Advisory committee on bankruptcy rules.

ACTION: Notice of open meeting.

SUMMARY: There will be a two-day meeting of the Judicial Conference Advisory Committee on Bankruptcy Rules. The meeting will be open to public observation but not participation. The meeting will commence at 9 a.m.

DATES: February 18–19, 1993.

ADDRESSES: Innisbrook Hotel, Tarpon Springs, Florida 34688–1088.

FOR FURTHER INFORMATION CONTACT: Peter G. McCabe, Secretary, Committee on Rules of Practice and Procedure, Administrative Office of the United States Courts, Washington, DC 20544, telephone (202) 273–1820.

Dated: December 16, 1992.

John K. Rabiej,

Chief, Rules Committee Support Office.

[FR Doc. 93–23 Filed 1–3–93; 8:45 am]

BILLING CODE 2210–01–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D–7603]

Metropolitan Life Insurance Co.; Located in New York, NY

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of proposed exemption.

SUMMARY: This document contains a notice of pendency before the Department of Labor (the Department) of a proposed exemption from certain of the prohibited transaction restrictions of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) and the Internal Revenue Code of 1986 (the Code). The proposed exemption relates to the establishment and operation by Metropolitan Life Insurance Company (Met) of an open-ended commingled real estate equity separate account (the Separate Account) in which certain plans (the Participating Plan or Participating Plans) invest.

EFFECTIVE DATE: If granted, this exemption would be effective as of September 21, 1989, the first date a transaction described in Section I(a) herein occurred.

DATES: Written comments and requests for a public hearing must be received by the Department on or before February 19, 1993.

ADDRESSES: All written comments and requests for a hearing (at least three copies) should be sent to the Office of Exemption Determinations, Pension and Welfare Benefits Administration, room N–5649, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Application No. D–7603. The application for exemption and the comments received will be available for public inspection in the Public Documents Room of the Pension and Welfare Benefits Administration, U.S. Department of Labor, room N–5507, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Angelena C. Le Blanc of the Department, telephone (202) 523–8883. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of an application for exemption from the restrictions of sections 406(a), 406(b)(1), and 406(b)(2) of the Act and from the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code. The proposed exemption was requested in an application filed by Met pursuant to section 408(a) of the Act and section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, this notice of pendency is issued solely by the Department.[1]

Summary of Facts and Representations

1. Met is a mutual life insurance company organized under the laws of the State of New York. Met represents that it is the second largest life insurance company in the United States and that it provides insurance products and asset management and other services for numerous employee benefit plans subject to the provisions of title I of the Act. As of December 31, 1991, Met had under management in its general account (the General Account) and all of its separate accounts, a portfolio of mortgage loans and real estate equities of approximately $28.1 billion. During 1991, approximately $900 million was invested in real estate investments. As of December 31, 1991, real estate investments comprised approximately 29% of all the assets of Met.

2. The Separate Account is an open-ended commingled real estate equity separate account which had a net asset value of $104.8 million, as of May 31, 1992. It is represented that the Separate Account is marketed primarily as an investment for defined contribution plans. Met believes that there is significant need for a pooled investment which can provide interests in equity real estate investments to participants in defined contribution plans, but believes that liquidity requirements have largely restricted the utilization of such pools to defined benefit plans. Met, however, has developed a mechanism which Met represents permits the Separate Account to offer an undiluted real estate equity return to defined contribution plans without sacrificing the ability of individual participants of such plans to contribute to, or withdraw investments from, such Separate Account on a daily basis.

Met represents that the cash to facilitate the liquidity needs of the Separate Account is obtained from the following sources: (a) The contributions to the Separate Account by Participating Plans either directly or on behalf of the individual participants in Participating Plans; and (b) the amounts attributable to transfers of balances from other investment funds in such plans to the Separate Account by individuals in Participating Plans pursuant to individual participant direction. When amounts from sources (a) and (b), described above, are inadequate to

[1] For purposes of this proposed exemption references to specific provisions of title I of the Act, unless otherwise specified, refer also to the corresponding provisions of the Code.

satisfy net withdrawal requests from Participating Plans or from individual participants, Met's General Account proposes to provide liquidity to the Separate Account by purchasing units from the Separate Account (the Units). Transactions involving purchases of the Units by Met's General Account are discussed in paragraphs #5 and #6 below.

It is represented that the operation of the Separate Account may generate cash, either as a result of income from rents from real estate investments, from other temporary investments, or from receipts from the sale of such investments, prior to reinvestment of such earnings and proceeds by the Separate Account. From such sources of cash, the Separate Account may, as needed from time to time, reserve amounts for payment of projected operating expenses and other liabilities on the real estate investments held in the Separate Account. However, for the purposes of responding to requests from any of the Participating Plans to withdraw all investments from the Separate Account or from individual participants in any of the Participating Plans to transfer amounts from the Separate Account to other investment vehicles, Met does not maintain a reserve in the Separate Account. Met represents that such a reserve would dilute the rate of return from the real estate assets of the Separate Account.

3. In order to optimize the efficient operation of the Separate Account and to assure that an appropriately diversified portfolio of properties (the Property or Properties) was available to offer to plans interested in participating, Met believed that initially the Separate Account needed an investment pool of approximately $100 million dollars. Met represents that when newly established, the Separate Account could not rely on obtaining such an amount from Participating Plans within a short period of time in order to commence operation with an appropriately diversified portfolio. As a result, prior to the first purchase of any Units in the Separate Account by Participating Plans, Met's General Account contributed certain amounts as seed money (the Seed Money) to the Separate Account, during a start up period (the Start Up Period) in order to provide for such a portfolio of Properties.

In exchange for its initial contribution of Seed Money, Met received Units of the Separate Account representing 100% of the value of the Separate Account at that time. Thereafter, as Properties[2] were identified as investments for the Separate Account, Met continued to contribute Seed Money and receive Units.[3] Each time money was generated by incoming net contributions from Participating Plans or from subscriptions paid by plans choosing to participate in the Separate Account, Met withdrew portions of its Seed Money from the Separate Account. Such withdrawals of Seed Money were accomplished by the redemption of Met's Units in the Separate Account at the value of such Units on the date when redeemed. Met represents that it will continue to withdraw Seed Money until the total amount of Seed Money ultimately returned to Met will equal the lesser of: (1) The amount (not to exceed $100 million) actually contributed by Met to the Separate Account in order to acquire the Properties, or (2) the amount received by Met when the Units it acquired in exchange for its contributions of Seed Money are redeemed at their then current value. It is anticipated that following the return of the Seed Money, by means of sufficient redemptions of Met's Units, Met would have little, if any, interest in the Separate Account.[4]

Whenever net participant contributions are received from Participating Plans, such net contributions are automatically applied to redeem the Units which were obtained by Met as discussed in paragraph #3 above. It is represented that until all of Met's Units, both those acquired upon contributions of Seed Money and those acquired from time to time in order to provide liquidity to the Separate Account, are redeemed, Met has no discretion to cause new net participant contributions to be invested in additional Properties.

4. The Start Up Period for the Separate Account began on December 21, 1988, the date on which Properties were first acquired by the Separate Account using Seed Money. The Start Up Period will end on the earliest to occur of: (a) The expiration of four years following the beginning of the Start Up Period, or (b) the first date, after the total value of the Separate Account has reached $100 million, and on which the percentage of the total number of Units owned by Met in the Separate Account is ten percent (10%) or less. Met represents that in December 1988, it began operation of the Separate Account under the rules and procedures of the Separate Account which are consistent with the terms and conditions as set forth in this proposed exemption, even though no plans were participating in the Separate Account at that time and even though Met then owned 100% of the Units in the Separate Account.

5. During the operation of the Separate Account, it is represented that Met's ownership of Units rises and falls essentially on an automatic basis, as either: (1) Met sells Units when there is a net contribution amount in the Separate Account, or (2) Met purchases Units to provide liquidity to the Separate Account to the extent requests for withdrawals from Participating Plans or from individual participants exceed new contributions or transfers. Although Met's Unit share may increase during the Start Up Period by reason of Met's continuing contributions of Seed Money or by its acquisition of Units in order to provide liquidity to the Separate Account, it is represented that such share in the Separate Account will not be increased by a purchase of Units

[2] It is represented that the Properties purchased by Met for the Separate Account are small- to medium-sized retail and office buildings, light industrial facilities, and residential apartment space which range in value up to $15 million and which have good operating income. It is represented that the Properties reflect geographical and investment diversification. Met believes that these types of Properties as investments for the Separate Account are appropriately acquired on a fee interest basis with the ownership of the Properties to be held entirely in the Separate Account.

[3] Met represents that as of June, 1991, its General Account had contributed Seed Money of approximately $100 million to the Separate Account.

[4] Met believes that the analysis contained in Advisory Opinion 83–38A (July 22, 1983) is applicable to Met's transfer of the Seed Money to the Separate Account, and to the Separate Account's redemption of Units from Met which were acquired when Met contributed Seed Money to the Separate Account. This opinion held that seed money allocated to separate accounts by an insurance company in order to aid in the start-up and management of those accounts would not be treated as assets of the plans which invested in the separate accounts, and that the redemption by the insurance company of participation units in the separate accounts would not constitute a violation of the prohibited transaction provisions of the Act, solely by reason of the transfer of seed money from the separate accounts to the insurance company's general account. In this regard, Met maintains that similar transfers of seed money between its Separate Account and its General Account do not violate section 406(a)(1) (A) and (D) or section 406 (b)(1) and (b)(2) of the Act. Thus, the Department is offering no relief, herein, for the transfer of the Seed Money into the Separate Account or the redemption by the Separate Account of Met's Units acquired with the Seed Money, as above described. The Department notes that Advisory Opinion 83–38A did not address the situation involving the redemption of units of the separate account by the insurance company, when, at the same time, there were outstanding requests for redemption by participating plans. As a result, the Department has determined to propose exemptive relief from September 21, 1989, the date, according to Met, when it first purchased Units of the Separate Account to satisfy net withdrawal requests from Participating Plans. (See Section I(a) of the proposed exemption, as set forth below, which provides an exemption for certain transactions involving the purchase of Units of the Separate Account by Met.)

by Met for any other reason. Met recognizes the potential that, through the purchases of Units to provide liquidity, Met may retain an unanticipated level of ownership in the Separate Account. As the result of such purchases, Met's interest in the Separate Account may at any time after the end of the Start Up Period increase beyond a certain stated percentage of the total value of the Separate Account Units (the Trigger Point).[5]

In the event of such an increase beyond the Trigger Point through liquidity purchases of Units by Met from the Separate Account, Met proposes to reduce its percentage of ownership in the Separate Account: (a) Through the use of cash available in the Separate Account (Available Cash), or (b) through the use of monies generated by the sale of Properties from the Separate Account. In this regard, Available Cash is defined as the income and other amounts received by the Separate Account from rents and from other sources, such as temporary investments, that are not required to be held for projected expenses with respect to the Separate Account. It is represented that net contributions from Participating Plans would not be deemed Available Cash for this purpose. As discussed in paragraph #6 below, such net contributions from Participating Plans would have automatically been applied when received to redeem the Units held by Met.

These methods of reducing Met's ownership in the Separate Account to a percentage equal to or below the Trigger Point and the process of increasing and decreasing Met's interest in the Separate Account through purchases and sales of Units, involve transactions between the Separate Account and the General Account of Met. Further, because cash flows to and from the Separate Account, as a result of contributions, transfers or withdrawals by Participating Plans or by individual plan participants, are offset either on a plan by plan basis or will be aggregated for all Participating Plans before there is an acquisition or a disposition by Met of the Units it holds in the Separate Account, such acquisitions or dispositions could be viewed as indirect transactions between Met and the Participating Plans. Accordingly, Met has requested prohibited transaction relief for the above described transactions.

6. It is represented that Met offsets daily the amounts requested to be withdrawn or transferred by the Participating Plans and/or by individual participants against the amounts, during the same period, contributed by plans entering the Separate Account and/or transferred into the Separate Account from other investment vehicles. Met represents that the determination of whether there is a net contribution or net withdrawal in the Separate Account is a non-discretionary calculation that the Met pension administration group makes on the basis of aggregate cash flow information provided directly to them by various plan fiduciaries (the Plan Fiduciaries or Plan Fiduciary) of Participating Plans which hold Units in the Separate Account. It is represented that during the Start Up Period, any net withdrawals or contributions from the Separate Account on a given valuation date are determined separately for each Participating Plan. After the Start Up Period is completed, it is anticipated that the withdrawals and contributions for all Participating Plans will be aggregated for purposes of this determination.

In order to provide liquidity to the Separate Account, whenever a net withdrawal occurs, Met purchases additional Units sufficient to provide the cash needed to meet the amount of the withdrawal requests. Whenever a net contribution results after withdrawal requests are satisfied, such net contribution amounts are applied to the sale of Units held by Met for the purpose of reducing Met's ownership interest in the Separate Account. If, at that time, Met owns no Units, then any net contribution creates new Units at the current Unit value and the net cash inflows into the Separate Account accumulate until sufficient to purchase additional Properties.[6]

Cash amounts necessary to provide liquidity to the Separate Account or to reduce Met's ownership in the Separate Account are transferred into and out of the Separate Account and are converted into and out of Units daily. In this regard, Met guarantees liquidity to the individual participants in Participating Plans invested in the Separate Account at the current daily value of the Units of the Separate Account. It is represented that payouts to such individual participants are made in accordance with any limitations on the timing or frequency of such payouts which may be imposed under applicable plan provisions.

Notwithstanding guaranteed liquidity to individual participants, it is represented that under certain circumstances limitations on the timing or frequency of payouts are imposed by Met upon requests for transfers and withdrawals which are initiated by the sponsor of a Participating Plan. However, such limitations apply only if: (1) The sponsor initiated transfer or withdrawal exceeds $5 million for each Participating Plan that is transferring or withdrawing, and (2) individual participants in such Participating Plans will not be receiving the amounts transferred or withdrawn. In such event, on the last business day of each succeeding month until the full amount is distributed, Met proposes to make monthly payments in installments of about $5 million to each Participating Plan that is transferring or withdrawing. If the total amount transferred or withdrawn by a Participating Plan is $60 million or more, Met represents that payments of approximately equal installments will be made on the last business day of the month over a period of twelve (12) months. However, it is represented that, regardless of the dollar limitations imposed on distribution amounts when the sponsor of a Participating Plan initiates a transfer or withdrawal, if the money is intended for distribution to the individual participants in a Participating Plan, Met will immediately make payments in full.

Met represents that all payouts will be at the prevailing value of the Units on the date the payout is made. Met states that any other method for fixing the value of payments would result either in the Participating Plans that remain in the Separate Account subsidizing the transferring or withdrawing plans, if the value of the Units has fallen, or, conversely, obtaining a windfall at the expense of the transferring or withdrawing plans, if the value of Units has risen. Met represents that these rules should not result in any inequities with respect to the transferring or withdrawing plans because: (1) The Plan Fiduciary prior to investing in the Separate Account is informed of the rules governing all distributions of this type, and (2) the participants in

[5] It is represented that the Trigger Point is the point at which Met's ownership in the Separate Account may be decreased with the approval of or as required by an independent fiduciary (the Independent Fiduciary). The Independent Fiduciary, acting on behalf of the Plans in the proposed transactions sets the percentage of Met's ownership of Units in the Separate Account which serves as the Trigger Point. See paragraph (d) of Section IV, herein, for a description of the independence, qualifications, and duties of the Independent Fiduciary. It is represented that the Trigger Point will arise only after the end of the Start Up Period. It is anticipated that following the end of the Start Up Period, the Trigger Point will not exceed ten percent (10%).

[6] In this regard, if one of the Properties were sold during the Start Up Period, it is represented that the proceeds of such sale also would be accumulated in the Separate Account and be used for reinvestment in new Properties, but would not be used to reduce Met's ownership in the Separate Account.

transferring or withdrawing plans always have the opportunity, as individuals, to transfer or withdraw from the Separate Account on any date. Although it is acknowledged that such individual participant action, as described in item (2) above, could not be effected for sponsor initiated transfers or withdrawals from the Separate Account by Participating Plans which maintain balanced funds, Met believes that the prior disclosure of the rules to the Plan Fiduciaries of such plans provides sufficient protection.

7. It is represented that when the Separate Account was first established, the initial value of each of the Units in the Separate Account was set at $100. Thereafter, the value of one of the Units equals the total value of the net assets of the Separate Account divided by the number of outstanding Units in the Separate Account divided by the number of outstanding Units in the Separate Account. It is represented that establishing the initial value for the Units at $100 afforded a reasonable starting point for determinations of Unit value and provided a basis for applying appropriate earnings factors, obtained through periodic valuations of the Properties in the Separate Account. It is represented that such $100 initial value has been a standard initial unit value for pooled separate accounts established by Met.

Met represents that the specified valuation rules and procedures, which are more fully described below, have been used by Met and the Independent Fiduciary in the operation of the Separate Account. In order to calculate the value of the Units, each of the Properties held in the Separate Account was valued initially at the price at which it was acquired. Thereafter, an independent qualified appraiser designated by Met and approved by the Independent Fiduciary has appraised and will appraise each of the Properties at least annually (the Annual Appraisals) on the anniversary date of purchase.[7] It is represented that replacement cost, comparable sales, discounted cash flow, current and projected occupancy levels, market conditions, and the condition of the Properties have been and will be considered by the independent qualified appraiser in the Annual Appraisals of the Properties. It is represented that the cost of the Annual Appraisals, such other appraisals as are necessary, and the cost of hiring the Independent Fiduciary were and will be charged to the Separate Account as a direct operating expense.

It is represented that Met's staff, in addition to the independent qualified appraiser, has conducted and will conduct an appraisal, as of December 31, of each year, for each of the Properties in the Separate Account. As more fully described in paragraphs #9 and #10 below, the Independent Fiduciary, as final determinant of value, selects the appropriate estimate from among conflicting values for any of the Properties, if any exists between Met's annual appraisals or the Annual Appraisals prepared by the independent qualified appraisers.

8. This annual value approved by the Independent Fiduciary for any of the Properties may be updated by Met every three months (the Quarterly Updates). In making Quarterly Updates, Met's staff reviews its own December 31st appraisal of each of the Properties, as well as the Annual Appraisals prepared by the independent qualified appraisers, and, if necessary, updates of both these appraisals. Met represents that these Quarterly Updates are performed on the quarterly anniversary of the property purchase date (See, footnote 7), and are not matched to the calendar quarter. Met represents that it takes into consideration in the Quarterly Updates the current rate of interest and inflation, occupancy levels, cash flow, regional and local market conditions, and other relevant factors, such as the availability of comparable space and whether there have been changes in access roads or other transportation facilities. As described more fully in paragraphs #9 and #10 below, the Independent Fiduciary has a substantial role in approving these adjustments to the value of the Properties.

In addition, Met has reviewed and will review the value of any of the Properties at the end of every month (the Monthly Reviews) where such Properties are not otherwise subject to Annual Appraisals, Quarterly Updates, or the yearly appraisals performed by Met on December 31. The purpose of the Monthly Reviews is to note whether there has been a material change in the value of any of the Properties resulting from a change, for example, in occupancy rate or leasing activity, rather than from fluctuations in general economic conditions. Met represents that in the operation of the Separate Account it rarely has changed the value of the Properties during these Monthly Reviews.

In addition to appraising, updating, and reviewing the value of the Properties, Met has calculated and will calculate the daily accrued value of the Units (the Daily Accruals). It is represented that the accrued value of a single Unit is based daily on the projected aggregate net monthly income of the Properties divided by the number of days in the month and by the number of Units outstanding for the Separate Account. Met compares this process to one employed with a fixed income obligation where interest is credited on a daily basis but is not distributed. Actual aggregate income and expense figures for the Properties, as determined in each prior month, are used to set income and expense projections for the succeeding month. It is represented that the amount of these monthly projections are communicated to, monitored by, and, where necessary, adjusted by the Independent Fiduciary. Met represents that because these Daily Accruals are based on net income, increases in the value of the Separate Account may occur. However, unlike the Annual Appraisals, Quarterly Updates, and Monthly Reviews, the Daily Accruals generally do not change the value of underlying Properties in the Separate Account. However, Met recognizes that certain events such as natural disasters may cause immediate and significant change to the value of the Properties which would be reflected in the Daily Accruals of the value of the Units. To date, Met represents that no such adjustment has occurred.

It is represented that Met has determined and will determine the value of all assets besides real estate in the Separate Account in a manner similar to the way such values would be determined if they were held in a non-real estate account in which group contract holders participate. It is represented that pending permanent investment in real estate, assets of the Separate Account (other than cash reserved to pay projected operating expenses) are invested in short-term securities, such as discount notes and interest-bearing notes. Met represents

[7] It is represented that when the Separate Account began Met: (1) Expected the Separate Account to acquire Properties in an evenly distributed fashion throughout the calendar year, and (2) intended the cycle of Annual Appraisals to cause Properties comprising different portions of the Separate Account and approximately 25% of the value of the Separate Account to be appraised by an independent qualified appraiser every three months. However, based on the dates when the Separate Account actually acquired Properties, Met represents that it may be necessary to adjust the timing of the Annual Appraisals for certain Properties in order to achieve a better balance of Annual Appraisal dates throughout the year. Met represents that any adjustments which may be made to the timing of the Annual Appraisals will be effected by accelerating the date when such Annual Appraisals are due, rather than by deferring them. Further, Met's adjustments to the timing of the Annual Appraisals would not cause the appraisals of the Properties prepared by the independent qualified appraisers to occur any less frequently than annually.

that the daily market value for both of these types of securities is done through an automated security accounting system. It is represented that all valuation procedures utilized by Met regarding property values in the Separate Account are approved and supervised by an Independent Fiduciary, as more fully described in paragraphs #9 and #10 below.

9. Following a procedure outlined in paragraph #14 below, Met appointed an Independent Fiduciary who assumed full fiduciary responsibilities under ERISA with respect to certain specified activities of the Separate Account. The Independent Fiduciary approved, prior to their adoption, the investment guidelines and valuation procedures of the Separate Account under which the day-to-day investment or valuation decisions by Met for the Separate Account have been made. Thereafter, the Independent Fiduciary is also responsible for approving any changes to such investment guidelines and valuation procedures.

In connection with the valuation of the Properties in the Separate Account, the Independent Fiduciary is responsible for approving Met's selection of the independent qualified appraisers who perform the Annual Appraisals of the Properties and for removing any names from the list of previously approved appraisers.

10. It is represented that Met cannot alter through any of its review methods, without the prior approval of the Independent Fiduciary, the value of any one or more of the Properties, if such would either: (a) Result in a six percent (6%) increase or decrease in the value of any of the Properties, since the last Annual Appraisal by a independent qualified appraiser; or (b) result in a greater than two percent (2%) increase or decrease in the value of the Separate Account, as determined in the prior month. As a further limitation, Met represents that within any quarter the aggregate increase or decrease in the value of the Separate Account, as a result of alterations in the valuation of Properties in the Separate Account by Met, will in no event exceed, without the approval of the Independent Fiduciary, four percent (4%). It is represented that any changes in value which exceed such percentage limitations and all independent appraisals have been and will be approved by the Independent Fiduciary prior to inclusion in a calculation of a value for the Units of the Separate Account.

In addition to the percentage limitations discussed above, it is represented that any adjustments, which are made by Met to the value of the Properties during the first three months after receipt of an Annual Appraisal prepared by an independent qualified appraiser, are made only after discussion with and approval by the Independent Fiduciary. Further, it is represented that the Independent Fiduciary has the discretion at any time: (a) To adjust the appraised value for any of the Properties in the Separate Account, if in the Independent Fiduciary's judgment and experience the characteristics of any of the Properties have changed, or (b) to order an additional independent appraisal of any of the Properties, if the Independent Fiduciary deems such to be necessary or appropriate to assure a correct value of such Properties or of the Separate Account.

11. It is represented that because Met acts as investment manager of the Separate Account, the Independent Fiduciary is not primarily responsible for the management of the Separate Account's assets it terms either of policy or operation. However, while the Independent Fiduciary is not ordinarily involved in the day-to-day investment management of the assets of the Separate Account, the Independent Fiduciary will be directly involved in the management and disposition of the Properties in the Separate Account at two points in time. The first point, the Trigger Point, occurs at any time after the end of the Start Up Period where the value of Met's Unit participation in the Separate Account exceeds a certain percentage of the total value of the Separate Account Units, as agreed upon between Met and the Independent Fiduciary. The second point occurs upon termination of the Separate Account.

As noted earlier, it is intended that Met's interest in the Separate Account after the Start Up Period will not exceed a certain percentage (anticipated to be ten percent (10%) or less) established as the Trigger Period by the Independent Fiduciary. However, it is recognized that if plans do not participate in the Separate Account to a sufficient degree during the Start Up Period, and/or if the Separate Account experiences a period of substantial net withdrawals, Met may retain or obtain more than ten percent (10%) interest in the Separate Account and such interest may exceed the percentage established as the Trigger Point. In this event, Met proposes after the end of the Start Up Period to reduce its percentage of ownership in the Separate Account through the use of: (a) Available Cash, as defined in Section IV(c), in the Separate Account; or (b) monies generated by the sale of Properties from the Separate Account.

It is represented that the Independent Fiduciary has the authority to: (1) Set the percentage of the Trigger Point, (2) establish a method to implement any changes in the Trigger Point, and (3) adjust the percentage for specified periods of time and to a specified extent, if the Independent Fiduciary believed such is in the best interest of the Separate Account. The Independent Fiduciary at the Trigger Point also has authority to approve or to require the reduction of Met's interest in the Separate Account, if, in the view of the Independent Fiduciary, such reduction is in the best interest of the Participating Plans in the Separate Account. Before Met's participation may be reduced by the use of Available Cash in the Separate Account, it is represented that Met will consult and agree with the Independent Fiduciary as to whether such method is appropriate. if, rather than use the Available Cash in the Separate Account, a sale of assets from the Separate Account is necessary in the opinion of Met and the Independent Fiduciary in order to reduce Met's ownership below the Trigger Point, the Independent Fiduciary will participate in the planning of any such program of sales, including the selection of the Properties to be sold and the determination of the guidelines to be followed in making such sales. If a difference of opinion arises between Met and the Independent Fiduciary, the decision of the Independent Fiduciary controls. It is represented that the Independent Fiduciary may require independent appraisals at the time any Properties are sold.

12. In addition to controlling the Trigger Point, the Independent Fiduciary is responsible for the activity of the Separate Account in the event of its termination and during the subsequent liquidation of its assets. During such liquidation, it is represented that the Independent Fiduciary has the ability to supervise the operation of the Separate Account, to approve all sales of Properties in the Separate Account, to approve the order in which such Properties are sold by the Separate Account, to set the price for such Properties, and to determine the timing of the disposition of those Properties.

Met, however, retains the authority to terminate the Separate Account. This decision would result in the wind-down of the operations of the Separate Account (the Wind Down). The Wind Down will begin on the date on which Met notifies all Participating Plans of its decision to terminate the Separate

Account and will conclude on the date on which no Units are held by any of the Participating Plans. Such notification of termination must be provided to the Participating Plans one year in advance of the termination of the Separate Account. During this one year period, Met will accept new investment money from Participating Plans but will not allow new plans to participate in the Separate Account. It is represented that during this one year period the Separate Account would continue to function as described in this proposed exemption, would honor withdrawal requests, and would accept contributions and transfers from Participating Plans and from individual participants. After this one year period has ended, no new money from any source would be taken by the Separate Account.

The Separate Account provides rules and procedures applicable during the Wind Down for the orderly redemption of the Units under two different circumstances: (a) Those applicable to redemptions of Units held by individual participants, and (b) those applicable to redemption of all of the Units owned by participating Plans. Both sets of rules and procedures are disclosed to and reviewed by the Plan Fiduciaries before any plan invests in the Separate Account. It is represented that the application of either set of rules and procedures does not involve the exercise of discretion by Met. Met has no authority with respect to the operation of the Separate Account that would permit Met to require any individual participant or any Participating Plan to leave the Separate Account or to reduce any individual's or any Participating Plan's level of participation in the Separate Account. It is represented that to the extent necessary to provide liquidity in either circumstance, Met's General Account will be required to acquire Units from the Separate Account.

Under the rules applicable to the redemption of Units held by individual participants, it is represented that such participants in any Participating Plan may continue to withdraw without limitation from the Separate Account during the Wind Down under the Separate Account procedures described in paragraph #6 of this proposed exemption.

On the other hand, Met represents that the rules applicable to redemptions of the Units held by Participating Plans during the Wind Down are a function of the size of the Participating Plans' interests in the Separate Account and are similar to the limitations imposed upon sponsor initiated transfers and withdrawals, as described above in paragraph #6 of this proposed exemption. Under these rules, if the value of the Units held by a Participating Plan on the effective date of the termination of the Separate Account (i.e. at least one year after notice of termination has been provided by Met), is less than $5 million, the entire interest of each such Participating plan will be redeemed. If the value of a Participating Plan's interest in the Separate Account is in excess of $5 million on the effective date of the termination, the distribution of the value of such Units shall be made pro rata over no longer than a twelve month period. Under these rules, each monthly payment over the course of the twelve month period (apart from the final payment) will be at least $5 million. During the Wind Down period in order to provide further flexibility for Participating Plans, the Separate Account provides that any Participating Plan may elect to defer redemption with respect to its Units in the Separate Account and maintain its participation in the final distribution of money in the Separate Account to the Participating Plans who choose to remain will occur only after all the Properties have been sold. Under this procedure, the rules discussed above for the orderly redemption of Units in the event the Separate Account is terminated would not be applied to a Participating Plan that elects to continue its investment in the Separate Account. However, any Participating Plan which elects to stay invested in the Separate Account could, at any time prior to the final distribution, begin the redemption of its Units in accordance with the rules discussed above which govern redemption of Units during the Wind Down. Upon termination and liquidation of the Separate Account, any Units held by Met will be the last Units redeemed.

13. In order to fulfill its responsibilities with respect to the Separate Account, the Independent Fiduciary receives a variety of written reports on a monthly basis (the Monthly Reports) which detail the activity in the Separate Account. The information contained in the Monthly Reports includes, but is not limited to, descriptions of investment decisions made by the Met portfolio manager of the Separate Account, operating results from the Properties (including variances from projections), as well as information with respect to the daily values, of Units, cash flow in and out of the Separate Account, and the percentage of Units held by Met in the Separate Account, as of the end of each month. The Reports provide information with respect to current values of the Properties reflected in the Quarterly Updates, and the Monthly Reviews, and such incremental adjustments in the value of the Units, as is reflected in the Daily Accruals of income and expenses.It is represented that the Independent Fiduciary also receives copies of: (a) Annual audits of the Separate Account prepared by independent auditors, (b) Annual Appraisals prepared by independent appraisers and by Met, and (c) any other reasonably available information or materials which Met believes to be necessary or which are requested by the Independent Fiduciary. It is represented that the format of the Monthly Reports are developed by Met with assistance and approval of the Independent Fiduciary, and that the materials in the Monthly Reports are reviewed in regularly scheduled meetings between the Met portfolio manager and the Independent Fiduciary.

14. Landauer Associates, Inc. (Landauer) has been appointed by Met to serve as Independent Fiduciary. In this regard, Landauer has acknowledged in writing that it has assumed fiduciary responsibility on behalf of the assets of the Participating Plans invested in the Separate Account. Landauer represents that it has undertaken to perform the duties of the Independent Fiduciary described in this proposed exemption for the exclusive benefit of the individual participants in the Participating Plans and their beneficiaries.

Landauer states that they are independent in that the gross income received by Landauer (or any partnership or corporation of which Landauer is a ten percent (10%) or more partner or shareholder) from Met and its affiliates (the Affiliates) for any fiscal year ending during the term of its agreement to serve as Independent Fiduciary shall not exceed five percent (5%) of its annual gross income from all sources for the preceding fiscal year. Such income limitation includes fees for services rendered to the Separate Account as the Independent Fiduciary for the proposed transactions. Further, Landauer states that it shall not (a) acquire any property from, sell any property to, or borrow any funds from, Met or any of its Affiliates during the period for which it serves as Independent Fiduciary, or (b) negotiate any such transaction during the period that Landauer serves as the Independent Fiduciary.

Landauer states that it is qualified in that it has at least five years of experience with respect to commercial

real estate investment. Landauer also represents that it has seven fully-staffed offices in the United States providing professional real estate counseling services nationwide. In addition, Landauer has provided teams of specialists who advise, appraise, negotiate, buy, sell, lease, finance, and manage portfolios for business, financial, and non-profit institutions.

It is represented that each of the Participating Plans was informed of the appointment of Landauer as the Independent Fiduciary for the Separate Account, and information regarding the role of the Independent Fiduciary was provided to the Plan Fiduciaries, prior to their decision to offer the Separate Account as an investment option under each respective plan. Further, it is represented that similar information with respect to Landauer or any successor Independent Fiduciary will be disclosed to the fiduciaries of plans prior to the investment in the Separate Account by plans in the future. A decision by a Plan Fiduciary on behalf of a plan to participate in the Separate Account after full disclosure has been made by Met will constitute approval and acceptance of Landauer or any successor Independent Fiduciary.

Landauer has been appointed by Met to a three (3) year term of office which is renewable for three (3) year terms from time to time without limitation. The renewal of Landauer's appointment is subject to the approval of the Plan Fiduciaries of Participating Plans in the Separate Account. It is represented that Landauer's appointment will not be renewed, if twenty-five percent (25%) of the Plan Fiduciaries of Participating Plans in the Separate Account disapprove.

It is further represented that Landauer will be subject to removal annually, with or without cause, if a majority of the Units held by Participating Plans in the Separate Account vote in favor of such removal, following receipt by the Participating Plans of an annual report on the Separate Account which details such procedure for removal. Met may terminate Landauer's appointment only "for cause," as set forth in the contract between Met and Landauer.

In addition, Landauer's appointment as Independent Fiduciary shall terminate by Landauer giving Met not less than 180 days notice of resignation from office in writing. In the event that Landauer resigns, Landauer's three (3) year appointment is not renewed, or Landauer is removed from its responsibilities as Independent Fiduciary, Met will nominate a successor and will seek approval of such nomination from the Plan Fiduciaries, other than Met acting in its individual capacity. It is represented that the nominee will not be appointed to serve as the Independent Fiduciary, if such nominee is disapproved by 25% of the Plan Fiduciaries. In the event of the disapproval of a nomination, a new nomination will be made and approval sought in the same manner as described above.

15. Landauer represents that it understands the Separate Account valuation procedure, as described in paragraphs #7 and #8 above. In Landauer's opinion, it is completely informed and understands the need for independence in the essential valuation structure and has scrupulously maintained an independent position with regard to Met and its staff. The operating experience which Landauer has had with the Separate Account, since it was established, has satisfied Landauer that the basic concept and the structuring of the relationship between Met, as investment manager, and Landauer, as Independent Fiduciary, protects against any manipulation of the Separate Account by Met.

Landauer has pointed out, however, that the valuation process is not a completely mechanical one. Landauer represents that the Daily Accruals of Unit values and, only to a slightly lesser extent, the Monthly Reviews of the values of the Properties may be considered somewhat mechanical, as such amounts are calculated by computer based upon information supplied by third party managers of the Properties and by the appraisers. With respect to the Quarterly Updates and Annual Appraisals performed by Met and by independent appraisers, Landauer represents that the judgment and perspective of the appraisers play a major role in the final estimation of value, even though a disciplined methodology, which is mathematical in nature, is used consisting of different approaches to value. Subject only to Landauer's discretion and judgment on the facts and circumstances in a particular situation, there are no restrictions, standards, or limitations on Landauer's right, as Independent Fiduciary, to alter valuations received from independent qualified appraisers and to obtain a new independent appraisal of any of the Properties at any time. Landauer represents that, over the period of time since the Separate Account was established, it has asked various independent appraisers for re-consideration of their valuation results and required additions, clarifications, and modifications. It is further represented that whenever there has been a difference of opinion about any particular valuation, Met has accepted and acceded to Landauer's judgment.[8]

It is represented that a written record is being maintained by Landauer of its appraisal functions and the rationale employed in estimating market value. Landauer also represents that it believes its monitoring process protects Unit holders to the maximum extent possible. While carrying out its responsibilities as Independent Fiduciary since the establishment of the Separate Account, as described above in paragraphs #9 and #10, Landauer represents that it has overseen the quality of the appraisal functions performed by Met and by outside independent qualified appraisers. Landauer states that it has physically observed the computer methodology employed by Met in arriving at Unit values set by the Daily Accruals and Monthly Reviews and has analyzed the mechanical calculations. In fulfilling its monitoring function, Landauer has also conducted surprise visits and scheduled visits to Separate Account Properties. With regard to monitoring the real estate valuation process, Landauer represents that it has also been and will be in contact with managing agents and account personnel.

16. Met, the investment manager of the Separate Account, acknowledges its status as a fiduciary pursuant to section 3(21) of the Act with respect to the assets of the Participating Plans which are invested in the Separate Account.[9]

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[8] In the application file Landauer provides an example of one such occasion where Landauer believed that neither the appraisals prepared by Met nor the Annual Appraisals prepared by an independent qualified appraiser gave sufficient weight to the limited income growth potential inherent in the subject's long-term net lease and its impact on the value of the asset to other like-minded investors. In that instance, in the opinion of Landauer, the returns produced by Met's and the independent qualified appraiser's values, were not sufficiently attractive to market the property within a reasonable time framework. As a result, Landauer represents that it applied a moderately higher income capitalization rate to generate a slightly lower, yet more realistic estimate of market value for that property.

[9] The Department is not providing any relief herein with respect to the fees charged by Met to the Separate Account. In this regard, Met notes that its fee for serving as investment manager for the Separate Account is based upon 1.25% of the first $25 million of the net asset value of the holdings in the Separate Account and 1.00% of any amount in excess of $25 million. For purposes of determining the net asset value of holdings in the Separate Account, the amount of any indebtedness of the Separate Account reduces the value of the Separate Account upon which Met's fee is based. All fees are determined and withdrawn monthly from the Separate Account by Met and are reflected as a reduction in the return on the interests of the Participating Plans in the Separate Account. Such fees (including contingency charges) are apportioned among all the Participating Plans in the Separate Account, based upon each of the Participants Plans' dollar amount of investment.

As the investment manager of the Separate Account, Met acquires and disposes of the individual real estate Properties which comprise the assets of the Separate Account. In addition to being empowered as real estate manager, Met has authority to modify the property selection criteria, consistent with the diversification requirements of the Separate Account. Met also has the power: (a) To leverage Properties with loans from third-party lenders to the extent that it is consistent with prudent management of the Separate Account; or (b) to cause the Separate Account to participate in transactions where an unrelated joint venture partner may be involved. Met maintains that such transactions do not require separate relief under this proposed exemption.[10] Met also represents that the following transactions have not been and will not be permitted in the Separate Account:

(a) Participation by Met, any Affiliate of Met, the General Account of Met, or any other Met separate account in any joint venture with the Separate Account or in the ownership of any of the Properties in the Separate Account either along or together with a joint venture partner;

(b) Loans by Met's General Account to the Separate Account in order to leverage any purchases of the Properties or otherwise; and

(c) Acquisition of Properties from, or sale to, Met's General Account or any other separate account over which Met has investment control.

It is represented that sales or purchases of Properties in the Separate Account (other than at a Trigger Point or termination of the Separate Account, as previously described) do not cause funds to flow to or from Met's General Account or other separate accounts over which Met has investment control. Rather, the proceeds of any sale of Properties are reinvested in the Separate Account in accordance with the investment guidelines of the Separate Account, as established by the Independent Fiduciary. (In the event that the Trigger Point is reached or in the event the Separate Account is terminated, Landauer, as the Independent Fiduciary, has confirmed its understanding and acknowledged acceptance of its responsibilities, as discussed above in paragraphs #11 and #12.)

17. It is represented that the Separate Account is a separate account within the contemplation of section 3(17) of the Act. The Separate Account was established and is operated in accordance with the requirements of section 4240 of the New York Insurance Law. Further, Met's attorney's review all sales materials and disclosures used in connection with annuity and insurance products to assure compliance with the laws and regulations of New York and other states. The Separate Account is not registered with the Securities and Exchange Commission, because Met represents that it relies on applicable exemptions from the registration requirements of the Investment Company Act of 1940 and the Securities Act of 1933.

18. Plans first began participating in the Separate Account on September 8, 1989 It is represented that the decision to acquire Units by the Participating Plans in the Separate Account has been and will be made by independent Plan Fiduciaries without influence or control by Met. It is represented that the initial members of the Separate Account were tax qualified plans. Specifically, Met notes that the Separate Account was designed for defined contribution plans (the D.C. Plans) which are qualified under section 401(a) of the Code. The Metropolitan Savings and Investment Plan and similar plans of Met's subsidiaries (the Met Savings Plans) also participate in the Separate Account. As of May 31, 1992, the Met Savings Plans' Units in the Separate Account represented approximately 11.15% of the net asset value of the Separate Account. As of December 31, 1991, participation in the Separate Account represented approximately .9% of the total assets of the Met Savings Plans. It is represented that this portion of the Separate Account held by the Met Savings Plans is not anticipated to increase greatly.[11]

Also included in the category of qualified plans eligible to invest in the Separate Account are certain teachers' plans which comply with the requirements of section 403(b) of the Code. In addition to qualified ERISA plans, Met believes that non-ERISA plans, such as government sponsored plans, which meet the requirements of section 414(d) of the Code and which have long been participants in separate accounts maintained by Met and other insurance carriers, also should be afforded the opportunity to participate in the Separate Account. Met has represented its understanding that this proposed exemption, if granted, will apply only to those Participating Plans that are subject to section 406 of the Act and/or section 4975 of the Code.

It is anticipated that the principal investors in the Separate Account will be D.C. Plans under which individual participants, subject to the respective limitations set forth by such plans, are afforded the opportunity to direct the investment of their account balances among a series of investment alternatives. However, Met believes that the Separate Account can also be useful to D.C. Plans that maintain "balanced funds", also subject to participant election, where the Plan Fiduciary for the balanced fund determines to acquire an interest in the Separate Account. Although participants in such "balanced funds" would not have the direct authority to contribute to or withdraw contributions from the Separate Account, their ability to direct investments with respect to a "balanced fund" which includes an interest in the Separate Account gives rise to the same requirements for liquidity as exist in participant directed D.C. Plans. It is represented that contribution and withdrawal requests with respect to the Separate Account will be received by Met periodically with respect to each of the Participating Plans at the direction of Plan Fiduciaries or authorized recordkeepers. It is represented that the individual records for each participant in each of the Participating Plans is the responsibility of the Plan Fiduciaries. However, Met represents that it retains the right to audit such records.

Met represents that, as of June 30, 1992, there were a total of forty-nine (49) plans participating in the Separate Account. Of this number, it is represented that there were twenty-seven (27) Participating Plans in the Separate Account, as of the end of 1990. In addition, eleven (11) plans began participating in 1991, and fifteen (15) more began participating by the middle of July 1992. The net asset value of the Units held by all the plans participating in the Separate Account, as of May 31, 1992, was $17.1 million. This amount represented approximately 16.3% of the total net assets of the Separate Account.

[10] The Department is expressing no opinion whether any such transactions would violate section 406 of the Act and is offering no relief for transactions other than those proposed.

[11] Met represents that the acquisition by the Met Savings Plans of Units in the Separate Account should not violate section 406 (a) and (b) of the Act, by reason of the statutory exemption contained in section 408(b)(5) of the Act. In this regard, Met also notes, that Advisory Opinion No. 79–79A, dated November 7, 1979, held that the amendment of an annuity contract and the concomitant transfer of assets from one separate account to another would be exempt from the prohibited transaction provisions of section 406(a)(1), and 406(b)(1) and (406(b)(2) under section 408(b)(5), if the conditions of section 408(b)(5) are met, including the condition that no more than adequate consideration is charged. The Department, is offering no view herein as to whether the acquisition by the Met Savings Plans of Units in the Separate Account is covered by the statutory exemption provided in section 408(b)(5).

The remaining portion of the assets of the Separate Account is held by Met's General Account.

It is represented that none of the Participating Plans had withdrawn from the Separate Account prior to February 1991; however, since that time, Met represents that four plans have done so. The dates of withdrawals and the amounts involved are represented to be as follows:

1. February, 1991—$504,382
2. September, 1991—$89,430
3. September, 1991—$2,746
4. February, 1991—$838

In addition to the above withdrawals by Participating Plans, it is represented that on several occasions during the operation of the Separate Account net withdrawals by individual participants of Participating Plans on a given date have exceeded net contributions to the Separate Account, such that Met has been required to acquire Units of the Separate Account in order to provide liquidity to fund such withdrawals. Met represents that the first instance of such occurred on September 21, 1989, and for this reason, Met has requested retroactive exemption relief to become effective as of that date.

It is represented that Met maintains a separate record of the Units it acquired as a result of providing liquidity to fund such withdrawals and intends to redeem such Units from the Separate Account only after the Units which Met acquired from contributions of Seed Money have been redeemed as a result of net contributions from Participating Plans.

19. Before electing to establish the Separate Account as an investment alternative, it is represented that the Plan Fiduciaries of any plans interested in participating in the Separate Account were and are provided with a full disclosure concerning the investment guidelines, structure, the manner of operation and administration of the Separate Account, and the procedures for withdrawal, transfer, distribution, and payout applicable to the Separate Account. Plan Fiduciaries were and are provided with the expense and fee provisions of the Separate Account, (including but not limited to a description of the services provided by Met and an estimate of the amount of the fees), together with appropriate financial statements, (including but not limited to the most recent audited annual report, income statement, and balance sheet), and as of the end of the most recent fiscal period of the Separate Account, a schedule of fees paid, a list of the buy/sells of Properties, and a list of the assets in the Separate Account. Thereafter, such Plan Fiduciaries have received and will receive monthly valuation reports and quarterly reports on the Separate Account which include a financial statement of the Separate Account and a list of current holdings. In addition, the Plan Fiduciaries receive any reasonably available information which Met reasonably believes to be necessary or which the Plans Fiduciaries reasonably request in order to determine whether any plan should purchase, sell, or continue to hold Units in the Separate Account.

Notice to Interested Persons

Those persons who may be interested in the pendency of the requested exemption include Plan Fiduciaries and individual participants of Participating Plans which have invested or may invest in the Separate Account. Because it is represented that Met does not know which plans or participants may choose from time to time in the future to invest in the Separate Account, and because some Participating Plans and some individual participants have invested in the Separate Account and have withdrawn, Met does not know the number of plans or individual participants and beneficiaries which therefore may be affected by the requested exemption. In addition, because the maintenance of an account of the type such as the Separate Account requires a substantial pool of assets and a correspondingly large participant base, it would be expected and intended that many thousands of individuals may have invested or may be invested, or may ultimately invest in the Separate Account. Accordingly, the Department has determined that the only practical form of providing notice to interested persons is the distribution, by Met, of a copy of the notice of pendency of this proposed exemption (the Notice), within fifteen (15) days of the date of the publication of such Notice in the **Federal Register** to: (1) The Plan Fiduciaries of any Participating Plans which in the past have participated in the Separate Account but which are no longer invested in the Separate Account; and (2) to the Plan Fiduciaries of Participating Plans which are invested in the Separate Account on the date of the publication of the Notice in the **Federal Register**. Such distribution to interested persons shall inform interested persons of their right to comment and to request a hearing, and shall include a copy of the Notice, as published in the **Federal Register**. Further, with respect to all plans which in the future contemplate investing in the Separate Account, distribution of a copy of the Notice and, if the exemption has been granted, a copy of the grant, as published in the **Federal Register**, will occur at least thirty (30) days prior to the investment of any such plan in the Separate Account.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest or disqualified person from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) The proposed exemption, if granted, will not extend to transactions prohibited under section 406(b)(3) of the Act and section 4975(c)(1)(F) of the Code;

(3) Before an exemption may be granted under section 408(a) of the Act and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interest of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(4) The proposed exemption, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and the Code, including statutory or administrative exemptions. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or requests for a hearing on the pending exemption to the address above, within the time period set forth above.

All comments will be made a part of the record. Comments received will be available for public inspection with the

application for exemption at the address set forth above.

Proposed Exemption

Based on the facts and representations set forth in the application, the Department is considering granting the requested exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975).

Section I—Exemption for Certain Transactions Involving the Purchase and Sale of Units of the Separate Account by Met

If the exemption is granted, the restrictions of section 406(a), 406(b)(1), and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the following transactions described below, if each of the conditions set forth in Section III is met.

(a) The purchase of Units of the Separate Account by Met, during the Start Up Period, in the event of net withdrawals from the Separate Account;

(b) The sale of Units by Met, during the Start Up Period, following any purchases described in Section I(a) above, in the event of net contributions to the Separate Account; and

(c) The purchase and sale of Units of the Separate Account by Met in the event of new withdrawals from the Separate Account or net contributions to the Separate Account, following the termination of the Start Up Period.

Section II—Exemption for Certain Transactions Involving Sales of Properties in the Separate Account and the Purchase of Met's Units of the Separate Account

If the exemption is granted, the restrictions of sections 406(a), 406(b)(1), and 406(b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to the use of Available Cash in the Separate Account, or to the sale of Properties owned by the Separate Account, for the purpose of the Separate Account's purchasing Units held by Met in connection with a decrease in Met's participation in the Separate Account after the Trigger Point has been met or during the Wind Down of the Separate Account; provided that the conditions set forth in Section III are met.

Section III—General Conditions

The exemption is conditioned upon Met's adherence to the material facts and representations described in this Notice and upon satisfaction of the following requirements:

(a) The decision to participate in the Separate Account by a plan, other than the Met Savings Plans, has been and will be made by Plan Fiduciaries who are unrelated to Met and its Affiliates;

(b) Each Property in the Separate Account has been and will be valued at least annually by an independent appraiser;

(c) No Properties have been or will be purchased for the Separate Account during the Start Up Period with plan contributions or monies other than Met's Seed Money, and neither Available Cash nor the proceeds from sales of Properties in the Separate Account have been or will be used to redeem Met's Units during the Start Up Period;

(d) Prior to investment in the Separate Account by any plan, except as otherwise specified below in paragraph (d)(9) of this Section III, Met will furnish the Plan Fiduciaries with:

(1) Full disclosure concerning the investment guidelines, structure, manner of operation, administration of the Separate Account, the method of valuation applicable to the Units, and the method of valuation applicable to the assets of the Separate Account,

(2) A written description of potential conflicts of interest that may result from Met's acquisition, purchase, retention, redemption, or sale of Units in the Separate Account,

(3) The rules and procedures for withdrawal, transfer, redemption, distribution, and payout applicable throughout the term of the Separate Account to Met, to the Participating Plans in the Separate Account, and to individual participants of the Participating Plans,

(4) The expense and fee provisions of the Separate Account, (including but not limited to a description of any services rendered by Met, a schedule of fees for such services, and an estimate of the amount of fees paid by the Separate Account annually),

(5) A list of all assets in the Separate Account, as of the end of the most recent fiscal period of the Separate Account, and a list of the Properties which the Separate Account has bought or has sold within twelve months prior to the end of the most recent fiscal period of the Separate Account,

(6) The appropriate financial statements pertaining to the Separate Account, (including but not limited to the most recent audited annual report, an income statement, and a balance sheet),

(7) Copies of the most recent monthly reports on the Separate Account and the most recent monthly reviews and the quarterly updates of the valuation of the Separate Account (including a list of the holdings of the Separate Account during those periods),

(8) Any reasonably available information which Met believes to be necessary or which the Plan Fiduciaries reasonably request in order to determine whether any plan should acquire Units in the Separate Account, and

(9) Upon publication of this Notice, a copy of such Notice, as it appears in the **Federal Register**, shall be provided to Plan Fiduciaries for all Participating Plans which were invested or are at the time invested in the Separate Account. If this proposed exemption is granted, the Plan Fiduciaries of all Participating Plans which were invested or which are at the time invested in the Separate Account shall receive upon publication of the grant a copy of such grant, as it appears in the **Federal Register**. If subsequent to the grant, any plans choose to invest in the Separate Account, such plans will be provided, at least thirty (30) days prior to the investment in the Separate Account by such plans, with copies of both the Notice and the grant, as such documents appeared upon publication in the **Federal Register**.

(e) Met periodically makes available information which Met reasonably believes to be necessary or which the Plan Fiduciaries reasonably request in order to determine whether any plan should buy, sell or continue to hold Units in the Separate Account.

(f) An Independent Fiduciary has been appointed coincident with the start of operations of the Separate Account. The Independent Fiduciary's responsibilities include but are not limited to:

(1) Reviewing and approving investment guidelines established by Met for the Separate Account and approving any changes to such guidelines;

(2) Monitoring the conformity of the Properties acquired for the Separate Account to the requirements of such guidelines;

(3) Reviewing and approving the valuation procedures for the Separate Account and approving changes in such procedures;

(4) Reviewing and approving the valuation of the Units in the Separate Account and of the Properties held in the Separate Account, as described in

the summary of facts and representations;

(5) Approving the appointment of all independent appraisers retained by Met to perform periodic valuations of the Properties in the Separate Account;

(6) Requiring appraisals in addition to those normally conducted whenever the Independent Fiduciary believes that the characteristics of any of the Properties have changed materially, or with respect to any of the Properties, whenever it deems an additional appraisal to be necessary or appropriate in order to assure the correct valuation of the Separate Account;

(7) Reviewing the purchases and sales of Units by Met and the Participating Plans in the Separate Account to assure that the correct values of the Units and of the Separate Account are applied;

(8) Following the termination of the Start Up Period, determining the appropriate Trigger Point with respect to Met's ongoing ownership of Units, establishing a method to implement any changes in such Trigger Point, adjusting the percentage which serves as the Trigger Point, approving or requiring any reduction of Met's interest in the Separate Account, and approving the manner in which such reduction of Met's participation in the Separate Account in excess of the Trigger Point is to be effected;

(9) In the event the Trigger Point is reached, participating in the planning of any program of sales of the assets of the Separate Account, including the selection of the Properties to be sold, the guidelines to be followed in making such sales, and the approval of such sales, if in the opinion of the Independent Fiduciary, such sales are desirable at the Trigger Point to reduce Met's ownership of Units in the Separate Account or to facilitate the Wind Down;

(10) Supervising the operation of the Separate Account during the Wind Down;

(11) During the Wind Down, planning any program of sales of the assets of the Separate Account, including the selection of the Properties to be sold, the guidelines to be followed in making such sales, and approving the sale of the Properties in the Separate Account, in the event of the termination of the Separate Account, if in the opinion of the Independent Fiduciary, such sales are desirable to facilitate the Wind Down; and

(12) Reviewing any other transactions or matters involving the Separate Account that are submitted to the Independent Fiduciary by Met and determining whether such transactions or matters are fair to the Separate Account and in the best interest of the Separate Account.

(g) The proposed exemption is also subject to the condition that the following transactions involving the Separate Account have not occurred and will not occur:

(1) Participation by Met, any Affiliate of Met, Met's General Account, or any other separate account over which Met has investment control in any joint venture with the Separate Account, or in the ownership of any of the Properties of the Separate Account, either alone or together with a joint venture partner.

(2) Lending of funds by Met's General Account to the Separate Account in order to leverage any purchase of any of the Properties, or otherwise.

(3) Acquisition of any Properties from or sale of any Properties to Met's General Account or any other separate account over which Met has investment control.

(h) Met must maintain for a period of six (6) years from the date of any transaction, the records necessary to enable the persons described in paragraph (i) of this Section III to determine whether the conditions of this exemption have been met. However, a prohibited transaction will not be considered to have occurred if, due to circumstances beyond the control of Met or its Affiliates, the records are lost or destroyed prior to the end of the six-year period, and no parties in interest, other than Met and its Affiliates, shall be subject to the civil penalty that may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975 (a) and (b) of the Code, if the records are not maintained, or are not available for examination as required by paragraph (i) below.

(i)(1) Except as provided in subparagraph (2) of this subsection (i) and notwithstanding any provisions of subsection (a)(2) and (b) of section 504 of the Act, the records referred to in paragraph (h) of this Section III are unconditionally available at their customary location for examination during normal business hours by:

(A) Any duly authorized employee or representative of the Department or the Internal Revenue Service,

(B) Any Plan Fiduciary of a Participating Plan in the Separate Account who has authority to acquire or dispose of the interest of such Participating Plan, or any duly authorized employee or representative of such Plan Fiduciary,

(C) Any contributing employer to any Participating Plan in the Separate Account or any duly authorized employee or representative of such employer, and

(D) Any participant or beneficiary of any Participating Plan in the Separate Account, or any duly authorized employee or representative of such participant or beneficiary.

(2) None of the persons described in subparagraphs (B) through (D) of this paragraph (i) shall be authorized to examine trade secrets of Met, any of its Affiliates, or commercial or financial information which is privileged or confidential.

Section IV—Definitions

For purposes of this exemption:

(a) "Affiliate" of Met includes:

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with Met,

(2) Any officer, director or employee of Met, or of a person described above in paragraph (a)(1) of Section IV, and

(3) Any partnership in which Met is a partner.

(b) "Control" means the power to exercise a controlling influence over the management or policies or a person other than an individual.

(c) "Available Cash" means the income and other amounts received by the Separate Account from rents and other sources, such as temporary investments, that are not required to be held for projected expenses with respect to the Separate Account. Such term does not include net contributions from Participating Plans.

(d) "Independent Fiduciary" means a person who:

(1) Is not an Affiliate of Met, as defined in Section IV(a);

(2) Does not have an ownership interest in Met or its Affiliates;

(3) Is not a corporation or partnership in which Met or any of its Affiliates has an ownership interest;

(4) Is not a fiduciary with respect to any Participating Plan in the Separate Account;

(5) Has acknowledged in writing acceptance of fiduciary responsibility; and

(6) Is either:

(i) a business organization which has at least five (5) years of experience with respect to commercial real estate investments or other appropriate experience;

(ii) a committee comprised of three to five individuals who each have had at least five (5) years of experience with respect to commercial real estate investments or other appropriate experience, or

(iii) a committee comprised both of a business organization or organizations

and individuals have the qualifications described in paragraphs (d)(1–5) of Section IV above.

For purposes of this definition, no organization or individual may serve as an Independent Fiduciary for the Separate Account for any fiscal year, if the gross income received from Met or its Affiliates by such organization or individual (or by any partnership or corporation of which such organization or individual is an officer, director, or ten percent (10%) or more partner or shareholder) for that fiscal year exceeds five percent (5%) of its or his annual gross income from all sources for the prior fiscal year. If such organization or individual had no income for the prior fiscal year, the 5% limitation shall be applied with reference to the fiscal year in which such organization or individual serves as an Independent Fiduciary. The income limitation will include services rendered to the Separate Account as Independent Fiduciary, as described in this proposed exemption.

In addition, no organization or individual who is an Independent Fiduciary, and no partnership or corporation of which such organization or individual is an officer, director, or ten percent (10%) or more partner or shareholder, may:

(1) Acquire any property from, sell any property to, or borrow any funds from, Met, its Affiliates, or any separate account maintained by Met or its Affiliates, during the period that such organization or individual serves as an independent fiduciary and continuing for a period of six (6) months after such organization or individual ceases to be an Independent Fiduciary; or

(2) Negotiate any such transaction, described above in paragraph (d)(1) of Section IV during the period that such organization or individual serves as Independent Fiduciary.

No Plan Fiduciary or sponsor of a Participating Plan or a designee of such Plan Fiduciary, sponsor, or Participating Plan may serve as the Independent Fiduciary with respect to the Separate Account.

(e) "Met Savings Plans" means the Metropolitan Savings and Investment Plan sponsored by Met and similar defined contribution plans sponsored by Met's subsidiaries.

(f) "Participating Plan" or "Participating Plans" means a plan qualified pursuant to section 401(a) or 403(b) of the Code which may participate in ownerships of Units in the Separate Account and which are subject to section 406 of the Act and section 4975 of the Code.

(g) "Plan Fiduciary" or "Plan Fiduciaries" means the individual fiduciary or fiduciaries acting on behalf of each of the Participating Plans that invest in the Separate Account.

(h) "Properties" means the geographically dispersed small- to medium-sized retail and office buildings, light industrial facilities, and residential apartment space, ranging in value up to $15 million with good operating income which Met has acquired or will acquire on behalf of the Participating Plans which invest in the Separate Account.

(i) "Seed Money" means the total amount (not to exceed $100 million) actually contributed by Met to the Separate Account for the purpose of acquiring Properties.

(j) "Separate Account" means the real estate equity pooled separate account invested in by plans, as described herein.

(k) "Start Up Period" means a period which began on December 21, 1988, the date on which Properties were first acquired by the Separate Account; and will end on the earliest to occur of: (1) The expiration of four years following the beginning of the Start Up Period; or (2) the first date, after the total value of the Separate Account has reached $100 million, on which the percentage of the total number of Units in the Separate Account owned by Met is 10% or less.

(l) "Trigger Point" means the point at which Met's ownership in the Separate Account may be decreased with the approval of or as required by the Independent Fiduciary. The Independent Fiduciary, acting on behalf of the Plans in the proposed transactions, sets the percentage of Met's ownership of Units in the Separate Account which serves as the Trigger Point. In this regard, the Trigger Point will arise only after the end of the Start Up Period.

(m) "Units" means the units of interest into which equity participation in the Separate Account is divided.

(n) "Wind Down" means the period which begins on the date on which Met notifies all the Participating Plans in the Separate Account that it has decided to terminate the Separate Account and concludes on the date on which no Units are held by any of the Participating Plans.

The proposed exemption, if granted, will be subject to the express conditions that the material facts and representations contained in the application are true and complete, and that the application accurately describes all material terms of the transaction to be consummated pursuant to the proposed exemption.

Signed at Washington, DC, this 30th day of December, 1992.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 93–79 Filed 1–4–93; 8:45 am]

BILLING CODE 4510–29–M

NATIONAL SCIENCE FOUNDATION

Blue Ribbon Panel on High Performance Computing; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Date and Time: January 21, 1993; 8:30 a.m. to 5:30 p.m. January 22, 1993; 8:30 a.m. to 1:30 p.m.

Place: Room 540, 1800 G Street, NW., Washington, DC 20550.

Type of Meeting: Open.

Contact Person: Odessa Dyson, Administrative Officer, Office of the Assistant Director, Directorate for Computer and Information Science and Engineering, National Science Foundation, 1800 G St., NW., Washington, DC 20550. Telephone: (202) 357–7936.

Minutes: May be obtained from the contact person listed above.

Purpose of Meeting: To provide current knowledge on the state of supercomputing to the National Science Board; to assess the contributions of high performance computing to scientific research and education; to help project changes required by developments in this rapidly evolving field; and to provide recommendations on NSF's possible future role in supercomputing.

Agenda:

(1) Discuss charter
(2) Identify issues to be addressed
(3) Identify needed inputs and sources
(4) Establish Issue Working Groups
(5) Discuss timetable and plan future meetings

Dated: December 30, 1992.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–61 Filed 1–4–93; 8:45 am]

BILLING CODE 7555–01–M

Permit Issued; J. Ward Testa

AGENCY: National Science Foundation.

ACTION: Notice of permit issued under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Thomas F. Forhan, Permit Office,

Division of Polar Programs, National Science Foundation, Washington, DC 20550.

SUPPLEMENTARY INFORMATION: On November 30, 1992 the National Science Foundation published a notice in the **Federal Register** of permit applications received. A permit was issued to J. Ward Testa on December 30, 1992.

Thomas F. Forhan,

Permit Office, Division of Polar Programs.

[FR Doc. 93–45 Filed 1–4–93; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of OMB review of information collection.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. Type of submission, new, revision, or extension: Revision.

2. The title of the information collection:

10 CFR part 35—Medical Use of Byproduct Material

3. The form number if applicable: Not applicable.

4. How often the collection is required: Required reports are collected and evaluated on a continuing basis as events occur. Applications for new licenses or amendments may be submitted at any time. Applications for renewal of licenses are submitted every five years.

5. Who will be required or asked to report: Physicians and medical institutions who are applicants for or holders of an NRC license authorizing the administration of byproduct material or its radiation to humans for medical use.

6. An estimate of the number of responses annually: 3,220,707.

7. An estimate of the total number of hours needed to complete the requirement or request: An average of 0.01 hours per response, plus approximately 162.44 hours per recordkeeper. The total industry burden is approximately 330,201 hours annually.

8. An indication of whether section 3504(h), Public Law 96–511 applies: Not applicable.

9. Abstract: 10 CFR part 35, Medical Use of Byproduct Material, contains requirements that apply to NRC licensees who are authorized to administer byproduct material or its radiation to humans for medical use. The information in the required reports, applications and records is used by NRC to ensure that the health and safety of the public is protected and that licensee possession and use of byproduct material is in compliance with license and regulatory requirements. The revision is a net increase adjustment in burden resulting primarily from a reevaluation of the time required to perform individual activities and the number of times those activities are performed.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

Comments and questions may be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs (3150–0010), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments may also be communicated by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 28th day of December 1992.

For the Nuclear Regulatory Commission.

George H. Messenger,

Acting Designated Senior Official for Information Resources Management.

[FR Doc. 92–49 Filed 1–4–93; 8:45 am]

BILLING CODE 7590–01–M

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget (OMB) Review

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection.

SUMMARY: The NRC has recently submitted to the OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

1. Type of submission, new, revision, or extension: Revision (Expedited Review—OMB approval is requested within 30 days of receipt of the "Request for OMB Review").

2. The title of the information collection: Requalification Examination Feedback Form.

3. The form number if applicable: Not applicable

4. How often the collection is required: Once per year at each power reactor facility during the NRC-conducted requalification examination.

5. Who will be required or asked to report: All operators, evaluators and facility licensee representatives (including facility licensee managers) participating in the NRC requalification examination at a power reactor will be asked to report on a voluntary basis.

6. An estimate of the number of annual responses: Approximately 675 facility personnel consisting of 450 operators, 175 facility representatives and evaluators, and 50 facility managers.

7. An estimate of average burden per response: Approximately 30 minutes.

8. An estimate of the total number of hours needed annually to complete the requirement or request: Approximately 340 hours (30 minutes per questionnaire ×675 personnel).

9. An indication of whether section 3504(h), Public Law 96–511 applies: Not applicable.

10. Abstract: Industry is concerned that failure to pass requalification examinations may be a result of high levels of stress experienced by the operators rather than a lack of knowledge. In SECY–91–391, "Results of the Study of Requalification Examination Stress," the U.S. NRC staff evaluated the issue of undue examination stress and reported its findings and planned actions. The Operator Licensing Branch of the Office of Nuclear Reactor Regulation, U.S. NRC, will monitor the success of the actions put in place to reduce undue examination stress through the use of the requested requalification examination feedback form.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW., (Lower Level), Washington, DC 20555–0001.

Comments and questions should be directed to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs, (3150–0159), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda Jo. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 28th day of December 1992.

For the Nuclear Regulatory Commission.
George H. Messenger,
Acting Designated Senior Official for Information Resources Management.
[FR Doc. 93–47 Filed 1–4–93 8:45 am]
BILLING CODE 7590–01–M

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB review of information collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to OMB for review the following proposal for collection of information under the provision of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. Type of submission, new, revision, or extension: Revision.

2. The title of the information collection: 10 CFR parts 30, 40, 70, and 72, Timeliness in Decommissioning of Materials Facilities.

3. The form number if applicable: NRC Form 314.

4. How often is the collection required: A one-time notification is required within 60 days of the licensee's decision to terminate all activities involving materials authorized under the license and within 60 days of terminating licensed activities at a portion of a licensed site. In addition, the licensee may request a delay in initiating decommissioning at least 1 month before the deadline for notification submittal.

5. Who will be required or asked to report: Part 30, 40, 70 and 72 NRC and Agreement State licensees terminating licensed activities at all or portions of their licensed sites.

6. An estimate of the number of responses: 2747 per year.

7. An estimate of the number of hours needed annually to complete the requirement or request: 2073.

8. An indication of whether section 3504(h), Public Law 96–511 applies: Applicable.

9. Abstract: The proposed rule would require licensees to make timely notification to the Commission when all or portions of the licensee's facilities are no longer being used for licensed activities. Requirements are also included to ensure timely submittal of decommissioning plans and completion of decommissioning.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555.

Comments and questions can be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs, (3150–0009, 3150–0017, 3150–0020, 3150–0028, and 3150–0132), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments can also be submitted by telephone at (202) 395–3084.

The NRC Clearance Officer is Brenda J. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 28th day of December, 1992.

For the Nuclear Regulatory Commission.
George H. Messenger,
Acting Designated Senior Official for Information Resources Management.
[FR Doc. 93–46 Filed 1–4–93; 8:45 am]
BILLING CODE 7590–01–M

[Doc. Nos. 50–528, 50–529, and 50–530]

Arizona Public Service Co., Et Al.; Palo Verde Nuclear Generating Station; Unit Nos. 1, 2, and 3; Receipt of Petition for Director's Decision

Notice is hereby given that by petition dated October 23, 1992, Thomas J. Saporito, Jr. (petitioner) requested that the Commission take action with regard to Arizona Public Service Company's (APS or licensee) Palo Verde Nuclear Generating Station Units 1, 2, and 3. Specifically, the petitioner requests that the Commission institute a show cause proceeding to modify, suspend, or revoke the operating licenses of the three Palo Verde units and order their immediate shutdown until such time as a nuclear safety evaluation can be performed on approximately 72 safety valves currently installed at the nuclear station.

As a basis for the request, the petitioner states that APS and the NRC cannot be sure whether the 72 safety valves will operate within their design bases and setpoint tolerances to mitigate an overpressurization event in any of the Palo Verde units. In support of this assertion, the petitioner provides the following reasons: (a) An APS request of November 13, 1990, to revise the technical specifications of its operating licenses for Palo Verde Units 1, 2, and 3 to increase the allowable setpoint tolerances for the main steam safety valves was signed by a person who was not technically qualified to provide safety commitments for this or any license amendment request and 56 persons in engineering positions at Palo Verde hold those positions without having a bachelor of science degree in engineering. (b) The licensee's interoffice memorandum of March 22, 1991, responds to an employee who stated a concern that the amendment request to increase the allowable setpoint tolerance for the safety valves indicates that the peak analyzed pressure for the loss of condenser vacuum transient is 2740.9 pounds per square inch absolute (psia), leaving only a 9.1 psia margin to the safety limit of 2750 psia. (c) The NRC staff's interoffice memorandum of December 4, 1991, stated it was not prudent to entertain the licensee's request to revise its technical specifications at this time. (d) APS's June 1992 Condition Report Disposition Request (CRDR No. 1–2–0139) documented the following inadequacies in safety valves: certain valves were found with blowdown rings out of their required position; there is an industrial history of these valves on set pressure drifting; actual experience with safety valves in nuclear applications is that frequently they neither lift at the required setpoint nor reseat tightly without leaking; the variation of the setpoint from the requirements often exceeds not only ±1 percent but also ±3 percent; this is the first time that Unit 1 valves have been tested at their required temperature profile; preventive maintenance has not been performed on Unit 1 valves since 1984; exercising the valves has no useful effect on preventing valve setpoint drift and could result in result in failure to reseat and in seat leakage, damage to the valve seating surface, and ultimately erratic set pressure causing premature lift and failure to lift. (e) One of the authors of CRDR No. 1–2–0139 testified to NRC officials that the licensee falsified documents related to its request to revise the technical specifications. (f) A person told the petitioner that two investigators from the NRC Office of Investigations told her that they had documents demonstrating that licensee officials falsified documents related to the licensee's request to revise its technical specifications. (g) On October 8, 1991, one of the licensee's engineers willfully violated a safety-related procedure by intentionally adjusting PSV–574 contrary to the requirements of the procedure.

The request is being treated pursuant to § 2.206 of the Commission's regulations (10 CFR 2.206). The petition has been referred to the Director, Office of Nuclear Reactor Regulation. As provided by § 2.206, appropriate action will be taken on this petition within a reasonable time. By letter dated December 29, 1992, the Director denied

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the petitioner's request for an immediate shutdown of Units 1, 2, and 3.

A copy of the petition and letter dated December 29, 1992 are available for inspection at the Commission's Public Document Room at 2120 L Street, NW., Washington, DC 20555 and at the Phoenix Public Library, Business and Science Division, 12 East McDowell Road, Phoenix, Arizona 85004.

Dated at Rockville, Maryland this 29th day of December 1992.

For the Nuclear Regulatory Commission.

Thomas E. Murley,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 93–51 Filed 1–4–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–220]

Niagara Mohawk Power Corp.; (Nine Mile Point Nuclear Station Unit No. 1); Exemption.

I

Niagara Mohawk Power Corporation (NMPC or the licensee) is the holder of Facility Operating License No. DPR–63, which authorizes operation of Nine Mile Point Nuclear Station Unit No. 1 (the facility or NMP1), at a steady-state reactor power level not in excess of 1850 megawatts thermal. The facility is a boiling water reactor located at the licensee's site in Oswego County, New York. The license provides among other things, that it is subject to all rules, regulations, and Orders of the U.S. Nuclear Regulatory Commission (the Commission or NRC) now or hereafter in effect.

II

Section III of appendix J to 10 CFR part 50 requires the development of a program to conduct periodic leak testing of the primary reactor containment and related systems and components, and components penetrating the primary containment pressure boundary. The interval between local leak rate tests for containment isolation valves (Type C tests) is specified by Section III.D.3 to be no greater than 2 years.

III

By letter dated November 3, 1992, NMPC requested a one-time only exemption (for a maximum of 7 weeks) from the requirements of 10 CFR part 50, appendix J, Section III.D.3, regarding periodic retest schedules for 39 Type C tests. This letter superseded an application from NMPC dated October 14, 1992. The requested exemption would permit continued operation of the facility until its next refueling outage, which will begin no later than February 19, 1993. Otherwise, the required testing would require a plant shutdown 7 weeks before the end of the current fuel cycle.

IV

Section III.D.3 of appendix J to 10 CFR part 50 states that Type C tests shall be performed during reactor shutdowns for refueling, at an interval not to exceed 2 years. The licensee has requested a one-time exemption from the regulations.

The 2-year interval requirement for Type C testing is intended to be often enough to preclude significant deterioration between tests and long enough to permit the tests to be performed during routine plant outages. Leak rate testing of containment isolation valves during plant shutdown is preferable because of the lower radiation exposures to plant personnel. Furthermore, some containment isolation valves cannot be tested at power. For those valves that cannot be tested during power operation, or for which testing at power would yield unnecessary radiation exposure of personnel, the Commission staff believes the increase in confidence of containment integrity following a successful test is not significant enough to justify the hardships and costs associated with a plant shutdown specifically to perform the tests within the 2-year time period.

V

The Commission has determined the pursuant to 10 CFR 50.12(a)(1) this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further determines that special circumstances, as provided in 10 CFR 50.12(a)(2)(ii), are present justifying the exemption; namely, that application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of Section III.D.3 of appendix J to 10 CFR part 50 is to provide an interval short enough to prevent serious deterioration from occurring between tests and long enough to permit testing to be performed during regular plant outages. For containment isolation valves that cannot be tested at power, or for containment isolation valves where testing at power involves unreasonable risk to personnel and equipment, the increased confidence in containment integrity following successful testing is not significant enough to justify a plant outage merely to perform the tests within the 2-year interval. The licensee has presented information accepted by the Commission, which gives a high degree of confidence that the components affected by this exemption will not degrade to an unacceptable extent. Acceptable leakage limits are defined in Sections III.B.3(a) and III.C.3 of appendix J to 10 CFR part 50.

Pursuant to 10 CFR 51.32, the Commission has determined that granting this Exemption will not have a significant impact on the environment (57 FR 54621).

This Exemption is effective upon issuance and shall expire on February 20, 1993.

Dated at Rockville, Maryland, this 24th day of December 1992.

For the Nuclear Regulatory Commission.

Steven A. Varga,

Director, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93–50 Filed 1–4–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–344]

Portland General Electric Co. et. al. (Trojan Nuclear Plant); Exemption.

I

On November 21, 1975, the Commission issued Facility Operating License No. NPF–1 to Portland General Electric Company, *et al.*, (the licensee), for operation of the Trojan Nuclear Plant located in Columbia County, Oregon. The licensee provided, among other things, that the facility is subject to all rules, regulations, and Orders of the Commission now or hereafter in effect.

II

Section 50.54(q) of 10 CFR part 50 requires a licensee authorized to operate a nuclear power reactor to follow and maintain in effect emergency plans which meet the standards of 10 CFR 50.47(b) and the requirements of appendix E to 10 CFR part 50. Section IV.F.2 of appendix E requires that each licensee annually exercise its emergency plan. The licensee was scheduled to conduct the 1992 annual exercise on December 15, 1992. The last annual exercise was conducted on September 24–25, 1991.

By letter dated December 11, 1992, the licensee requested an exemption from 10 CFR part 50, appendix E, (IV)(F)(2) which would defer conducting its annual emergency plan exercise scheduled for December 15, 1992, until the first quarter of 1993. The licensee stated that conducting the exercise on December 15, 1992, was impractical due to the continued forced outage resulting from a steam generator tube leak.

Ongoing outage activities would be hampered by the conduct of an exercise at this time. The licensee does not expect the plant to startup until after January 1, 1993. The one time schedular exemption will allow the annual emergency plan exercise to be deferred until the first quarter of 1993.

III

The NRC staff has reviewed the licensee's request for a one time extension of the Trojan Nuclear Plant emergency plan exercise completion date. The most recent Systematic Assessment of Licensee Performance (SALP) Report, covering the period from April 1, 1991 through May 31, 1992, indicated that resources are adequate and reasonably allocated so that good plant performance is being achieved in the area of emergency preparedness. The licensee was rated to be in Performance Category 2 for the functional area of emergency preparedness. In addition, evaluation of the licensee's performance during their 1991 annual exercise indicated that the licensee was fully capable and prepared to take actions necessary to protect the public's health and safety.

Due to difficulties in coordinating schedules of all involved parties to exercises (NRC, FEMA, Licensee, State governments, local governments, and volunteer agencies) the time frame of annual has been interpreted to be met as long as an exercise is conducted during the calendar year. Hypothetically, a licensee could conduct an exercise on January 1 one year and December 31 the following year and still meet the requirement of 10 CFR part 50 appendix E.IV.F.2., even though a period of 24 months had elapsed. In this instance, the licensee conducted an exercise in September of 1991 and is proposing to conduct an exercise some time between January and March of 1993, a period of 16 to 18 months. The licensee is also scheduled to conduct another exercise in November 1993, a period of 8 to 10 months. Approving deferment of the 1992 exercise to the first quarter of 1993 will not create an unacceptable lapse in time between exercises.

The licensee has made a good faith effort to conduct the exercise within the calendar year. The scope and objectives for the 1992 exercise were submitted to the NRC for review on August 12, 1992. The exercise was originally scheduled for November 17, 1992, but was rescheduled for December 15, 1992 due to the steam generator tube leak and forced outage at the plant. The licensee undertook the necessary preparatory actions to conduct the annual exercise on this date, in an effort to comply with 10 CFR part 50 appendix E, (IV)(F)(2). However, as a result of the continued forced outage, the 1992 annual exercise could not be practicably performed on December 15, 1992.

The current forced outage for steam generator eddy current inspection requires the reactor coolant system to be operated in a reduced inventory condition. The licensee's request not to conduct an exercise while plant staff is involved in a major outage is prudent. This allows for the focusing of resources to accomplish complicated outage tasks without unnecessary distractions or delays. The licensee does not expect the plant to restart until after January 1, 1993. The one time exemption from the annual requirement will allow the licensee to defer the exercise until the first quarter of 1993. This exemption applies to the 1992 annual exercise and does not defer the licensee's 1993 annual exercise which is currently scheduled for the fourth quarter of 1993. Therefore, the requested one time schedular exemption from 10 CFR part 50, appendix E, (IV)(F)(2) is acceptable.

IV

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a)(1), this exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. The Commission further determines that special circumstances, as provided in 10 CFR 50.12(a)(2)(v), are present justifying the exemption. The exemption would provide only temporary relief from the applicable regulation and the licensee has made good faith efforts to comply with the regulation in that the licensee has deferred the 1992 annual exercise until the first quarter of 1993 to allow for the completion of activities associated with the forced outage.

Accordingly, the Commission hereby grants an exemption as described in Section III above from 10 CFR part 50, appendix E, (IV)(F)(2) to defer the completion date of the emergency plan exercise until the first quarter of 1993. This exemption is effective until the end of March 1993.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of the Exemption will have no significant impact on the environment (57 FR 61934).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 29th day of December 1992.

For the Nuclear Regulatory Commission.

Martin J. Virgilio,

Acting Director, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 93–52 Filed 1–4–93; 8:45 am]

BILLING CODE 7590–01–M

PROSPECTIVE PAYMENT ASSESSMENT COMMISSION

Meetings

Notice is hereby given of the meetings of the Prospective Payment Assessment Commission on Thursday and Friday, January 14 and 15, 1993, at the Madison Hotel, 15th & M Streets, NW., Washington, DC.

The full Commission will convene on Thursday at 9 a.m. until 5 p.m., and on Friday from 9 a.m. to approximately 3:30 p.m., in Executive Chambers 1, 2 and 3.

All meetings are open to the public.

Donald A. Young,

Executive Director.

[FR Doc. 93–10 Filed 1–4–93; 8:45 am]

BILLING CODE 6820–BW–M

SECURITIES AND EXCHANGE COMMISSION

Forms Under Review by Office of Management and Budget

Agency Clearance Officer: John J. Lane, (202) 272–5407.

Upon Written Request, Copy Available From: Securities and Exchange Commission, Office of Filings, Information and Consumer Services, 450 Fifth Street, NW., Washington, DC 20549.

Amendments

File No.	Rule/Form
270–128	Form U–1.
270–129	Rule 50.
270–79	Rules 93 and 94, Form U–13–60 and 17 CFR part 256 and 256(a).
270–161	Rule 71(a), Forms U–12(I)–A and U–12(I)–B.
270–168	Rule 1(c) and Form U5S.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission has submitted for OMB approval amendments to rule 71 and Forms U5S, U–12(I)–A, U–12(I)–B and U–13–60; and the rescission of rule 50 under the Public Utility Holding Company Act of 1935 ("Act") (15 U.S.C. 79 *et seq.*).

The amendments would change the reporting burdens associated with rules 24 and 50(d) and Forms U5S, U–12(I)–

B and U–13–60. Although the reporting burden associated with Form U–1 would not change, the amendments would have the effect of reducing the number of applications and/or declarations on Form U–1. The Commission anticipates that the amendments would eliminate the necessity for 14 filings on Form U–1 per year so the total annual burden would be 27,125 hours. The amendments would also reduce the number of statements required under rule 24 which must be filed with the Commission. The Commission anticipates a reduction of 90 burden hours for complying with the requirements of rules 24 and 50(d) so the total annual burden would be 340 hours.

Form U5S would be amended to require annual reporting of investments under rule 40(a)(5). The 14 filers on Form U5S will incur an increase of one hour in the time spent preparing the form as a result of the proposed amendments, which corresponds to a total annual burden of approximately 132.4 hours. Form U–13–60 would be amended to comport with changes to the Federal Energy Regulatory Commission's standard of accounts for utility companies. The 16 companies who file on Form U–13–60 will incur an increase of 3 hours, bringing the total time to 14.5 hours per response, to complete Form U–13–60 as a result of the proposed amendments, which corresponds to a total annual burden of 232 hours. Finally, the proposed amendments would permit the 785 filers anticipated to file annually on Form U–12(I)–B to file once every three years rather than once a year, as is the current practice. The annual burden for all filers would then be 174.5 hours. These estimates of average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of SEC rules and forms.

Direct general comments to Gary Waxman at the address below. Direct any comments concerning the accuracy of the estimated average burden hours for compliance with SEC rules and forms to John J. Lane, Associate Executive Director, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549, and Gary Waxman, Clearance Officer, Office of Management and Budget (Paperwork Reduction Projects 3235–0126) [Rules 24 and 50], 3235–0125 [Form U–1], 3235–0164 [Form U5S], 3235–0153 [Form U–13–60], and 3235–0173 [Forms U–12(I)–A and U–12(I)–B], Room 3208 New Executive Office Building, Washington, DC 20503.

Dated: December 11, 1992.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–59 Filed 1–4–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–31662; File No. SR–NASD–92–40]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to the Payment of Gratuities or Anything of Value by Members to Others

December 28, 1992.

On November 2, 1992 the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] a proposed rule change consisting of amendments to Article III, Section 10(a) of the Rules of Fair Practice.

The proposed rule change was published for comment in Securities Exchange Act Release No. 31486 (November 19, 1992), 57 FR 55607 (November 25, 1992). No comments were received.

Article III, Section 10(a) of the NASD's Rules of Fair Practice currently sets a limit of $50 per person per year for the payment of anything of value, including gifts and gratuities, by a member or associated person of a member to another person where the payment is in relation to the business of the employer of the person receiving the payment or gratuity. The rule protects against improprieties which might arise in connection with the giving by members or associated persons of substantial gifts or monetary payments to certain persons without their employer's knowledge.

Prior to 1969, Section 10 completely prohibited the payment of gratuities or anything of value to employees of others. The current $50 limitation was increased from $25 in 1984.[3] Because of the amount of time that has elapsed since the dollar limitation was last adjusted, the NASD is proposing to increase the dollar limitation for the payment of gratuities or anything of value to $100 per person per year.

The NASD states that the proposed rule change is consistent with the recently approved Rule 350(a) of the New York Stock Exchange ("NYSE"), which raised the value limit on the amount of a gratuity from $50 to $100 that an Exchange member may give to another without obtaining the prior written consent of the recipient's employer.[4] The proposed rule would simplify compliance obligations of NASD member firms that are also members of the NYSE.

The Commission finds that the proposed rule change will only revise the dollar limitation in the rule and will neither change the categories of persons covered by the rule nor the other requirements under Section 10 concerning prior written agreements and record-keeping relating to such compensation for services. The Commission believes that, even with the proposed increase, the dollar amounts are relatively low and will neither compromise the intent, nor reduce the ability, of the rule to prevent fraudulent acts and practices which might arise in connection with the giving of valuable gifts or payments to persons without their employer's knowledge.

The Commission finds that the proposal is consistent with the provisions of section 15A(b)(6) of the Act,[5] which require that the rules of the Association be designed to prevent fraudulent and manipulative acts and promote just and equitable principles of trade. The proposed rule change adjusts the dollar limit under Article III, Section 10 to be consistent with NYSE Rule 350(a); the Commission believes that increasing the dollar amount is reasonable given the amount of time that has elapsed since the last increase. In addition, the Commission believes that even with the increase, the dollar values are relatively low, and that it is appropriate to take into account the effects of inflation.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act, that the proposed rule change (SR–NASD–92–40) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–60 Filed 1–4–93; 8:45 am]

BILLING CODE 8010–01–M

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[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1992).

[3] See Securities Exchange Act Release No. 21074 (June 20, 1984), 49 FR 26330 (June 26, 1984).

[4] See Securities Exchange Act Release No. 30877 (June 30, 1992), 57 FR 30283 (July 8, 1992).

[5] 15 U.S.C. 78o–3.

[6] 17 CFR 200.30–3(a)(12) (1992).

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD 92-079]

Chemical Transportation Advisory Committee (CTAC) and CTAC Subcommittee on the Revision of the Regulations for Barges Carrying Bulk Liquid Hazardous Materials Cargoes

AGENCY: Coast Guard, DOT.

ACTION: Notice of meetings.

SUMMARY: A. The Chemical Transportation Advisory Committee will hold a meeting on Tuesday, February 23, 1993 in room 2415, U.S. Coast Guard Headquarters, 2100 2nd Street, SW., Washington, DC 20593. The meeting is scheduled to begin at 9:30 a.m. and end at 2 p.m.

The agenda for the meeting follows:

1. Opening remarks—RADM Henn,
2. U.S. Coast Guard remarks,
3. Chairman's remarks and general interest topics,
4. Issue briefs:
   Tankerman regulations,
   Tank Filling Limits,
   Static Discharge During Gauging,
5. Subcommittee reports:
   Fire fighting media review; final report,
   46 CFR part 151 revision; interim report,
6. New tasks and initiatives:
   Applicability of OPA-90 to Chemical Tankships,
   Chemical Compatibility Table,
   Marine Occupational Safety and Health Subcommittee,
7. International activities update,
8. Other business:
   Coast Guard human factors initiatives—domestic/international,
   Chemical carriers initiative for assessment and management of bulk chemical and gas shipping operations,
9. Closing.

B. The Subcommittee on the Revision of the Regulations for Barges Carrying Bulk Liquid Hazardous Materials Cargoes, title 46 Code of Federal Regulations (CFR) part 151, of the Chemical Transportation Advisory Committee will meet on Monday, February 22, 1992 in room 6103 at 0930 at Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593. Following the Subcommittee meeting, the Subcommittee's working groups will meet as follows. The Cargo Classification Working Group and the Construction, Design and Equipment Working Group will meet in rooms 6103 and 6319, respectively, until 12 noon. The Liquefied Flammable Gases Working Group and the Operations, Administrative and Inspection Working Group will meet in Rooms 6103 and 6319, respectively, from 12:30 a.m. until 3:30 p.m. The purpose of these meetings is to continue work to fulfill the tasking of the Subcommittee which is to review 46 CFR part 151, determine areas in need of updating and revision, and make recommended changes.

Attendance at the above meetings is open to the public. Members of the public may present oral statements at the meetings. Persons wishing to present oral statements should notify the Executive Director of CTAC no later than the day before the meetings. Any member of the public may present a written statement to the Committee at any time.

FOR FURTHER INFORMATION CONTACT: Commander K. J. Eldridge or Mr. F. K. Thompson, U.S. Coast Guard Headquarters (G-MTH-1), 2100 2nd Street, SW., Washington, DC 20593, (202) 267-1217.

Dated: December 29, 1992.

A. E. Henn,

Rear Admiral, U.S. Coast Guard Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 93-85 Filed 1-4-93; 8:45 am]

BILLING CODE 4910-14-M

Federal Aviation Administration

Advisory Circulars: Small Airplanes Airworthiness Standards

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Publication of Advisory Circulars; part 21 (Airships) and part 23 Airplanes.

SUMMARY: The purpose of this notice is to advise the public of advisory circulars (AC's) issued by the Small Airplane Directorate since January 1992. The AC's listed below relate to part 21 of the Federal Aviation Regulations (FAR) regarding Airships, part 23 of the FAR, and/or part 3 of the Civil Air Regulations (CAR). They were issued to inform the aviation public of acceptable means of showing compliance with the Airworthiness Standards in the FAR and/or CAR, but the material is neither mandatory nor regulatory in nature.

FOR FURTHER INFORMATION CONTACT: Ms. Julea Bell, Standards Staff (ACE-110), Small Airplane Directorate, Aircraft Certification Service, Federal Aviation Administration, 601 East 12th Street, Kansas City, Missouri 64106; telephone number (816) 426-6941.

SUPPLEMENTARY INFORMATION:

Background

These AC's were developed to update existing policy information for small airplane certification programs.

Comments

Interested parties were given the opportunity to review and comment on each AC during the development phase. At that time, notices were published in the **Federal Register** to announce the availability of, and request written comments, to each proposed AC. Each comment was reviewed and resolved. Appropriate comments were incorporated in the AC.

Distribution

The published AC's are available upon request through the U.S. Department of Transportation, Utilization and Storage Section, M-443.2, Washington, DC 20590.

ADVISORY CIRCULARS PUBLISHED

AC number	Date	Title
23.1419-2	1/3/92	Certification of Part 23 Airplanes for Flight in Icing Conditions.
23.1309-1A	6/3/92	Equipment, Systems, and Installations in Part 23 Airplanes.
23.1309-1A, CHG 1	8/5/92	Equipment, Systems, and Installations in Part 23 Airplanes.
21.17-1A	9/25/92	Type Certification—Airships.
21.17-1A, CHG 1	10/30/92	Type Certification—Airships.
23.701-1	11/13/92	Flap Interconnections in Part 23 Airplanes.
23.11	12/2/92	Type Certification of Very Light Airplanes with Powerplants and Propellers Certificated to Parts 33 and 35 of the Federal Aviation Regulations.

In addition to the AC's listed above, change 1 to FAA Report FAA P-8110-2, Airship Design Criteria, was issued 7/24/92. This change updated the design criteria for type certification of airships.

Note: Appendix 3 to AC 23-11 contains the Joint Aviation Requirements for Very Light Airplanes (JAR-VLA). For recipients of this AC to keep abreast of changes to the JAR-VLA, subscriptions may be forwarded to: Printing & Publishing Services, Civil

Aviation Authority, 37 Gratton Road, Cheltenham GL50 2BN England.

Barry D. Clements,

Manager, Small Airplane Directorate, Aircraft Certification Service.

Federal Highway Administration

[FHWA Docket No. MC–92–5]

Parts and Accessories Necessary for Safe Operation; Limited Waiver for Domino's Pizza Distribution Co.

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Grant of petition of waiver.

SUMMARY: The FHWA is granting, in part, Domino's Pizza Distribution Corporation's petition for a waiver from the requirements of 49 CFR 393.25(e) of the Federal Motor Carrier Safety Regulations (FMCSRs). This waiver will permit Domino's Pizza Distribution Corporation to use a strobe warning lamp on the rear of its semi-trailers, which would be operated when the vehicle is being driven in reverse and when the vehicle is being unloaded. The FHWA is granting the waiver to permit Domino's Pizza to use the strobe lamps on certain of its semi-trailer fleet during a 3-year trial period, subject to the conditions imposed by the FHWA in this notice.

EFFECTIVE DATE: January 5, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Larry W. Minor, Office of Motor Carrier Standards, HCS–10, (202) 366–2981; or Mr. Charles Medalen, Office of the Chief Counsel, HCC–20, (202) 366–0834, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal holidays.

SUPPLEMENTARY INFORMATION: On January 21, 1992, the FHWA published a notice of petition in the **Federal Register** (57 FR 2308) requesting comments on a petition received from Domino's Pizza Distribution Corporation (Domino's Pizza). The petitioner uses tractor-semi-trailer combination vehicles to distribute supplies to its stores. Approximately 65 to 75 percent of the trailers in the Domino's Pizza fleet are navy blue, and most deliveries are made during night-time, non-business hours. Delivery locations are within or in close proximity to "highly marqueed" strip malls. Domino's Pizza has indicated that their vehicles are equipped with all lighting and reflective devices required under the Federal Motor Vehicle Safety Standards (FMVSSs) and the FMCSRs. However, Domino's Pizza has a problem with front-to-rear collisions; motorists are driving into the rear of their semi-trailers. Domino's Pizza believes that merchants' advertising methods and local weather conditions have an adverse effect on the visibility of its vehicles to drivers of other vehicles. The advertising methods include signs and lights which, depending on the position of the Domino's vehicle and the time of day, may decrease motorists' ability to recognize the presence of the semi-trailers. To address this problem, Domino's Pizza began studying the possibility of using auxiliary non-steady-burning lamps on the rear of its semi-trailers.

However, § 393.25(e) of the FMCSRs requires, in part, that all exterior lighting devices be steady-burning, except turn signals and stop lamps when used as turn signals. Strobe lamps are not included amount the lighting devices which are excepted from the steady-burning requirement (i.e., turn signals, warning lamps on service vehicles authorized by State and local authorities, or vehicular hazard warning flashers as required by § 392.22 or permitted by § 392.18). The noncompliance of the proposed lighting device necessitated that petition for a waiver.

The waiver is being granted under section 206(f) of the Motor Carrier Safety Act of 1984 (Pub. L. 98–554, 98 Stat. 2829, 2835, 49 U.S.C. app. 2505(f)) which authorizes waivers of any regulation issued under the authority of that Act upon a determination that the waiver is not contrary to the public interest and is consistent with the safe operation of commercial motor vehicles. In accordance with section 206(f), the FHWA published a notice seeking public comment on Domino's requires for a waiver on January 21, 1992 (57 FR 2308).

Discussion of Comments to the Docket

The FHWA received one comment to the notice of petition—from the Virginia State Police (State police). The State police were opposed to the waiver. "We feel the use of [retroreflective] material or reflex reflectors as proposed by [the National Highway Traffic Safety Administration (NHTSA) on December 4, 1991, (56 FR 63474)] would be far more likely to increase vehicle conspicuity and in turn reduce crashes than the use of a single warning lamp as Domino's Pizza suggests." The State police mentioned that the Virginia Department of Transportation is presently using retroreflective material on "a number of vehicles in its fleet" with favorable results.

The State police also indicated that "the intensity of the strobe warning lamp is much less than other lighting on the rear of such vehicles." Amber rear turn signals have an intensity of approximately 750 candela compared to an effective intensity of 165 candela for the strobe warning lamp.

The FHWA is familiar with the NHTSA's rulemaking on trailer conspicuity and does not believe the current rulemaking should serve as a basis for denying Domino's petition for a waiver. While the proposed conspicuity treatment has been proven effective in the NHTSA's fleet study, the 15 percent effectiveness in reducing accidents in which a trailer is struck by another vehicle is not sufficient to preclude the evaluation of other devices. The FHWA believes that a study on the use of strobe warning lamps may provide useful information concerning the prevention of collisions with trailers.

In response to the State police's comment on the effective intensity of the strobe lamp, the FHWA believes the 165-candela limit is appropriate. The 165-candela limit is within the range of photometric values allowed by FMVSS No. 108 for stop lamps and turn signals. Under a worst-case scenario, the effective intensity of the strobe lamp would be greater than the photometric values of stop lamps and turn signals with performance levels which are at or slightly above the minimum acceptable levels of FMVSS No. 108. The FHWA believes this restriction will ensure that the strobe lamp does not decrease the effectiveness of the required lighting devices.

Conditions of the Waiver

The conditions of the waiver listed below, with the exception of the removal of the requirement to submit a copy of the accident report form (MCS–50T) and the modification of the requirements for an annual report on the results of the use of the strobe lamp and the reporting of accidents within certain distances of Domino's vehicles, are as published in the January 21 notices. The decision to remove the requirement for the submittal of the MCS–50T is based on the FHWA's proposed elimination of the requirement that motor carriers submit accident reports (57 FR 33712, July 30, 1992).

The accident history monitoring requirement in the conditions of the waiver has been modified to include an annual assessment on the effectiveness of the strobe lamp. Although the annual assessment was implied by the wording proposed in the January 21, 1992, notice, the FHWA believes the

requirement should be clearly stated in the conditions of the waiver. Also, the requirement that Domino's Pizza provide information about motor vehicle accidents within 150 feet of the Domino's vehicles equipped with the strobe lamp has been modified to include only those accidents that occur within 25 feet to the rear of Domino's vehicles. The FHWA does not believe that information about all motor vehicle accidents occurring beyond 25 feet to the rear of the Domino's vehicle will provide meaningful data. The FHWA does not believe these changes will result in less stringent conditions than those proposed in the notice of petition.

I. Effective Intensity of the Strobe

The FHWA is limiting the maximum effective intensity of the strobe lamp to no more than 165 candela. The 165-candela limit for the strobe lamp allows for manufacturing tolerances in the production of the 150-candela strobe lamp. A measurement of effective intensity shall be made using the strobe lamp under operational conditions and the measurement procedure in "Emergency Vehicle Warning Lights: State of the Art," U.S. Department of Commerce, National Institute of Standards and Technology (formerly National Bureau of Standards), Special Publication 480–16, September 1978, pp. 100–105. Domino's Pizza Distribution Corporation is required to ensure that the effective intensity of the proposed strobe lamp is measured using the method prescribed or by comparable measurement procedures or obtain a written statement from the manufacturer of the strobe lamp indicating the lamp has been tested using comparable measurement procedures. The voltage to be used for the testing of the strobe lamp shall be equal to the maximum voltage to be used when the strobe lamp is mounted on the vehicle. Also, the strobe lamp's effective intensity shall be measured using an amber lens (the color of the lens to be used during the 3-year trial period). The effective color of the light emitted by the strobe lamp is required to conform to the definition of yellow (amber) found in the Society of Automotive Engineers (SAE) standard J578, Color Specification, May 1988. Domino's Pizza shall provide written notification to the FHWA that the measurement of the effective intensity of the proposed strobe lamp was made under operational conditions. Domino's Pizza shall also provide: the date(s) the measurement was performed; the location of the measurement; certification that the effective color of the strobe lamp conforms to the definition of yellow (amber) in SAE J578; the voltage used during testing and the effective intensity determined at that voltage; the individual(s) or company performing the measurement; and the measurement procedure used.

II. Installation of the Strobe

The strobe lamp shall be installed in such a way that it can only be operated when the transmission of the tractor is in the reverse or when the vehicle is parked. The strobe lamp shall be mounted approximately on the vertical centerline of the rear of the trailer, at a height between 35 and 60 inches above the surface of the road (measured with the vehicle unloaded). Domino's Pizza shall obtain the approval of the FHWA for the installation of the lamp in other locations on the rear of the trailer. The diameter of the lens shall not exceed 4 inches, and the color of the lens is restricted to amber. The flash rate for the strobe shall not exceed 80 flashes per minute.

III. Compliance With Lighting and Wiring Requirements of the FMCSRs

The installation of the strobe lights shall be in compliance with § 393.25, except paragraph (e); § 393.27, Wiring specifications; § 393.29, Grounds; § 393.31, Overload protective devices; and § 393.33, Wiring, installation.

IV. Duration of Waiver; Accident History Monitoring

The FHWA is granting the waiver for a 3-year period. The 3-year period begins with the publication of this notice in the Federal Register Domino's Pizza shall provide the FHWA with an annual report on the result of the use of the strobe lamps so that the accident history of the vehicles equipped with the strobe lamp and those vehicles which are not equipped with the lamp can be closely monitored. The annual report shall include an assessment, by Domino's Pizza, of the effectiveness of the strobe lamp in reducing accidents (distinguishing between accidents on private property versus public roads). The assessment shall make reference to any specific incidents in which Domino's Pizza believes the strobe lamp may have prevented an accident.

Domino's Pizza shall report accident information and data on all accidents that occur to the vehicles equipped with the strobe lamp, including those which do not involve front-to-rear collisions with Domino's vehicles. In addition, all motor vehicles accidents that occur within 25 feet to the rear of Domino's vehicles equipped with the strobe lamp, but not necessarily involving the Domino's vehicles, are to be reported. All front-to-rear collisions with Domino's vehicles which are not equipped with the strobe lamp are also to be reported. Three copies of the information listed below shall be forwarded to the Office of Motor Carrier Standards on a monthly basis:

1. The position of the vehicles engaged in the accident (description and diagram of the accident scene).
2. Color photographs of the surrounding environment.
3. Environmental conditions (i.e., background environment, time of day, light conditions, weather, roadway type).
4. Interview information with the driver/occupants of the striking vehicle (specifically, what the driver/occupants saw).
5. Copy of police report (if one is prepared) for the accident. In the case of motor vehicle accidents that occur within 25 feet to the rear of Dominos's vehicles equipped with the strobe lamp, but not necessarily involving the Domino's vehicles, the police report is not required.
6. Cost damage to each of the involved vehicles. In the case of accidents that occur within 25 feet to the rear of Domino's vehicles equipped with the strobe lamp, but not necessarily involving the Domino's vehicles, the cost of damage is not required.
7. Description of injuries/fatalities.

V. Maintenance History

As part of the periodic review of this waiver, Domino's Pizza Distribution Corporation shall develop a test and maintenance program to ensure that the operation of the strobes is consistent with the conditions of the waiver, and keep a maintenance history of the strobe lamps. A copy of the maintenance history shall be forwarded to the Office of Motor Carrier Standards on a quarterly basis, each year, for the duration of the waiver. In addition the maintenance history for the strobe lamps shall be maintained at the location at which the vehicles are garaged or maintained, or the principal place of business.

VI. State and Local Laws

The use of the strobe lamps must be in compliance with State and local safety regulations or must be approved by the State or local authorities in the jurisdictions in which the strobe lamp will be used. A list of States in which the vehicles will be operated and copies of State approvals shall be provided to the FHWA. The FHWA strongly encourages State and local authorities with safety regulations which would prohibit the use of the proposed lamps to accept the terms of the waiver. It is

not the intention of the FHWA to preempt State or local requirements which would preclude the use of the strobe lamps. For jurisdictions in which the safety regulations preclude the use of the strobe lamps, a copy of the approval granted by the States or local authorities shall be provided to the FHWA by Domino's Pizza.

VII. Number of Vehicles To Be Equipped With Strobe Lamps

The number of semi-trailers that may be equipped with the strobe lamps shall not exceed 50 percent of the number of semi-trailers per Domino's Pizza Distribution Corporation terminal. The total number of semi-trailers per terminal, along with the total number of vehicles equipped with the strobe lights, shall be provided to the FHWA.

VIII. Termination of Waiver

Domino's Pizza shall discontinue the use of the strobe lamps (1) upon the completion of the 3-year trial period or (20 when instructed to do so by the FHWA at either the completion of an annual review or at any time it is determined by the FHWA that the continued use of the strobe lamps decreases the safety of operation of the vehicles on which the lamps are used.

In consideration of the comments of the Virginia State police, and under the conditions provided above, the FHWA hereby grants Domino's Pizza Distribution Corporation's petition for a waiver from the requirements of § 393.25(e).

Authority: 49 U.S.C. 3102; 49 U.S.C. app. 2505; 23 U.S.C. 315; 49 CFR 1.48.

Issued on: December 21, 1992.

T.D. Larson,

Administrator.

[FR Doc. 93–33 Filed 1–4–93 8:45 am]

BILLING CODE 4910–22–M

Federal Railroad Administration

[FRA Docket No. H–92–1]

Petition for Waiver for Test Program; National Railroad Passenger Corporation

On July 14, 1992, the Federal Railroad Administration (FRA) published in the **Federal Register** (57 FR 31228) notice of a petition from the National Railroad Passenger Corporation (Amtrak) and Metro North Commuter Railroad (MCNW) for waiver from FRA rail safety regulations for a program to conduct a test and provide a limited revenue service demonstration of a passenger trainset imported from Sweden, the "X2000".

By January 15, 1993, the test phase of this program will have been completed and the start of the limited revenue service demonstration will be imminent. Amtrak submitted an additional petition (to which MCNW is not a part) requesting waiver of compliance with § 213.9 of the Federal track safety standards in order to operate the X2000 trainset at speeds above 110 mph. For convenience sake, this new petition is included within the scope of the initial petition, Docket No. H–92–1.

Certain sections of the Northeast Corridor main tracks between Washington, DC and New York City are now approved for revenue passenger train speeds of up to 125 mph. The railroad has in effect for these track segments a rigorous inspection and maintenance program. Amtrak wants to operate the X2000 equipment at 135 mph over a portion of these high speed tracks. The demonstration period, commencing February 1, 1993, is scheduled to be not longer than four months.

Interested parties may submit written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request. All communications concerning this proceeding should identify the appropriate docket number (e.g., Waiver Petition Docket No. H–92–1) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. Communications received before February 1, 1993 will be considered by FRA before final action is taken. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) in room 8201, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

Issued in Washington, DC on December 28, 1992.

Edward R. English,

Acting Associate Administrator for Safety.

[FR Doc. 93–9 Filed 1–4–93; 8:45 am]

BILLING CODE 4910–06–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 2
Tuesday, January 5, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Thursday, January 14, 1993.

PLACE: 2033 K St., NW., Washington, DC, Lower Lobby Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED:

—Regulation of Hybrid Instruments—final rules
—Exemption of Certain Swap Agreements—final rules

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92–31449 Filed 12–31–92; 11:35 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10:30 a.m., Thursday, January 14, 1993.

PLACE: 2033 K St., NW., Washington, DC, 8th Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Enforcement Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean W. Webb,

Secretary of the Commission.

[FR Doc. 92–31950 Filed 12–31–92; 8:45 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Thursday, January 21, 1993.

PLACE: 2033 K St., NW., Washington, DC, Lower Lobby Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED: Floor Trader Registration and Ethics Training Rules—proposed rules.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92–31951 Filed 12–31–92; 11:35 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10 a.m., Thursday, January 26, 1993.

PLACE: 2033 K St., NW., Washington, DC, Lower Lobby Hearing Room.

STATUS: Open.

MATTERS TO BE CONSIDERED: Contract Market Emergency Actions—proposed rules.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92–31952 Filed 12–31–92; 11:35 am]

BILLING CODE 6351–01–M

COMMODITY FUTURES TRADING COMMISSION

TIME AND DATE: 10:30 a.m., Thursday, January 26, 1993.

PLACE: 2033 K St., NW., Washington, DC, 8th Floor Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Rule enforcement review.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 92–31953 Filed 12–31–92; 11:35 am]

BILLING CODE 6351–01–M

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given of the continuation of the following meeting of the Board:

TIME AND DATE: 9 a.m., January 5, 1993.

PLACE: Public Hearing Room, Suite 700, 625 Indiana Avenue, NW., Washington, DC 20004.

STATUS: Closed. Exemption 3. Portions of the meeting may also be closed under Exemption 1; Exemption 7; and Exemption 9.

MATTERS TO BE CONSIDERED: The Board will reconvene and continue the closed meeting conducted on December 17 to deliberate upon safety issues related to the HB-Line, Savannah River Site, South Carolina, including, but not limited to, consideration of testimony and documents received at the public meeting and public hearing conducted in Aiken, South Carolina, on December 15, 1992, regarding the Department of Energy's Operational Readiness Review and other matters related to the proposed restart of the HB-Line.

FOR MORE INFORMATION CONTACT: Kenneth M. Pusateri, General Manager, Defense Nuclear Facilities Safety Board, or Carole J. Council, 625 Indiana Avenue, NW., Suite 700, Washington, DC 20004, (202) 208–6400.

SUPPLEMENTARY INFORMATION: The Board specifically reserves its right to further schedule and otherwise regulate the course of the meeting, to recess, reconvene, postpone, or adjourn the meeting, and otherwise exercise its powers under the Atomic Energy Act of 1954, as amended.

Dated: December 30, 1992.

Kenneth M. Pusateri,

General Manager.

[FR Doc. 92–31945 Filed 12–30–92; 4:35 pm]

BILLING CODE 6820–KD–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 11:00 a.m., Monday, January 11, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: December 31, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 92–31955 Filed 12–31–92; 2:37 am]

BILLING CODE 6210–01–M

Corrections

Federal Register
Vol. 58, No. 2
Tuesday, January 5, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[PR Docket No. 91-295; RM-7182, FCC 92-534]

Private Land Mobile Radio Services; Additional 72-76 MHz Frequencies

Correction

In rule document 92-30727 beginning on page 60132 in the issue of Friday, December 18, 1992, make the following correction:

§ 90.63 [Corrected]

On page 60134, in the first column, in § 90.63(c), in the table, the last two entries, "73.37" and "73.39" should read "75.37" and "75.39".

BILLING CODE 1505-01-D

FEDERAL EMERGENCY MANAGEMENT AGENCY

Changes to the Hotel and Motel Fire Safety Act National Master List

Correction

In notice document 92-31111 beginning on page 61234 in the issue of Wednesday, December 23, 1992 make the following corrections:

1. On pages 61234—61238, in the heading for the table, "[Additions]" should be removed.

2. On page 61234, in the table, in the first column, "Additions:" should appear above "Alabama:".

3. Please make note of the following in the table:

a. "Additions" begin on page 61234 and continue through page 61235, ending with "Spokane—Shilo Inn".

b. "Corrections/Changes" begin on page 61235 and continue through page 61238, ending with "Innkeeper".

c. "Deletions" are on page 61238.

BILLING CODE 1505-01-D

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1230

RIN 3095-AA22

Micrographic Records Management

Correction

In proposed rule document 92-28944 beginning on page 57042 in the issue of Wednesday, December 2, 1992, make the following correction:

§ 1230.14 [Corrected]

On page 57044, in § 1230.14, in the third column, the table should have appeared as follows:

Paragraph	Remove	Add
1230.14(c)	ANSI IT9.1-1989 MS23-1983.	ANSI IT9.1-1991 MS23-1991
1230.14(d)(1)(i)	ANSI/AIIM MS23-1983 ISO 3334-1989.	ANSI/AIIM MS23-1991 ISO 3334-1991
1230.14(d)(2)	ANSI/AIIM MS23-1983 ANSI/ISO 5/2-1985.	ANSI/AIIM MS23-1991 ANSI IT2.19-1990

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-92-37]

Petitions for Exemption; Summary of Petitions Received, Dispositions of Petitions Issued

Correction

In notice document 92-30879 beginning on page 60553 in the issue of Monday, December 21, 1992, make the following correction:

On page 60554, in the second column, in the seventh line, the *Docket No.:* should read "112CE.".

BILLING CODE 1505-01-D

Federal Register

Tuesday
January 5, 1993

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 103

Quality Standards for Foods With No Identity Standards; Bottled Water; Final Rule and Proposed Rules

VOL 58 ISS 2 JA 5 1993 UMI

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 103

[Docket No. 89N-0469]

Quality Standards for Foods With No Identity Standards; Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the quality standards for bottled water by establishing allowable levels for the following seven synthetic volatile organic chemicals (VOC's): Benzene (not to exceed 0.005 milligrams per liter(mg/L); carbon tetrachloride (not to exceed 0.005 mg/L); 1,2-dichloroethane (not to exceed 0.005 mg/L); 1,1-dichloroethylene (not to exceed 0.007 mg/L); 1,1,1-trichloroethane (not to exceed 0.20 mg/L); trichloroethylene (TCE) (not to exceed 0.005 mg/L); and vinyl chloride (not to exceed 0.002 mg/L). FDA is taking this action to amend the quality standard for bottled water following rulemaking by the Environmental Protection Agency (EPA) that established maximum contaminant levels (MCL's) for these seven compounds in public drinking water. This rulemaking will ensure that the minimum quality of bottled water remains comparable with the quality of public drinking water meeting EPA standards.

DATES: Effective July 6, 1993. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 103.35(d)(3), effective July 6, 1993.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS-306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

Section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349) requires that whenever EPA prescribes interim or revised National Primary Drinking Water Regulations (NPDWR's) under the Safe Drinking Water Act (SDWA), FDA consult with EPA and either amend its regulations for bottled drinking water (21 CFR 103.35) or publish in the **Federal Register** its reasons for not making such amendments.

In the **Federal Register** of July 8, 1987 (52 FR 25690), EPA issued a final rule establishing NPDWR's consisting of MCL's for eight VOC's. In accordance with section 410 of the act, FDA published a proposal in the **Federal Register** of July 6, 1990 (55 FR 27831) announcing the agency's intent to adopt the MCL's of EPA as quality standards for seven of the VOC's addressed in EPA's final rule, as follows: benzene—0.005 mg/L; carbon tetrachloride—0.005 mg/L; 1,2-dichloroethane—0.005 mg/L; 1,1-dichloroethylene—0.007 mg/L; 1,1,1-trichloroethane—0.20 mg/L; trichloroethylene—0.005 mg/L; and vinyl chloride—0.002 mg/L. FDA summarized the toxicological evidence relied upon by EPA for each of the seven VOC's in establishing MCL's (55 FR 27831 and 27832) and discussed the reasons for the agency's tentative determination to adopt the MCL's as the allowable levels for these chemical contaminants in bottled water (55 FR 27832 through 27833). FDA did not propose to adopt an allowable level for the eighth VOC covered by EPA's proposal, *para*-dichlorobenzene (*p*-dichlorobenzene), because EPA was in the midst of a second rulemaking on this chemical contaminant, and FDA felt that it was appropriate to postpone action with respect to this substance (55 FR 27831).

Following publication of this proposal, FDA reopened the 60-day comment period for an additional 30 days by a notice published in the **Federal Register** of March 21, 1991 (56 FR 11979). That notice announced that: (1) The enactment on November 8, 1990, of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) removed the rulemaking procedures for quality standards for foods from the formal rulemaking provision of section 701(e) of the act (21 U.S.C. 371(e)), and (2) FDA was therefore redesignating the VOC rulemaking as a notice and comment rulemaking that would proceed under the provisions of section 701(a) of the act (21 U.S.C. 371(a)). As a result of the change announced by FDA on March 21, 1991, and in the interest of fairness, the comment period was reopened to provide an additional opportunity for public comment because the 701(a) procedures do not provide an opportunity to submit objections to the final rule as do the formal rulemaking provisions under which this action was initiated.

II. Summary of and Response to Comments

A. Summary of Comments

FDA received 13 comments in response to the July 6, 1990, proposal. The comments represented the views of a foreign government's office for General Agreement for Tariffs and Trade (GATT) Enquiry Point, a chemical supply company, three State water districts, a consortium of State water districts, four trade associations representing the interests of both public water and bottled water providers, a State health department, a bulk water company, and one individual. Eleven of the 13 comments agreed that FDA should adopt the proposed VOC levels based on EPA requirements for public drinking water and the public's expectation that bottled water should at least meet the standards set by EPA for public drinking water.

The comment from the foreign GATT Enquiry Point stated that their country had not set contaminant level standards for VOC's because they believe VOC contaminants are unacceptable in bottled water. The remaining comment, while concurring that FDA should consider MCL's when adopting quality standards, stated that FDA should establish maximum VOC levels on the basis of its own toxicological assessment of appropriate and permissible levels of contaminants in drinking water.

B. Response to Comments

1. In response to the foreign government's comment objecting to the acceptability of VOC contaminants in bottled water, the agency notes that FDA and EPA recognize that in certain instances, the presence of VOC's and other undesirable substances in drinking water sources may be unavoidable. These substances are widely dispersed in the environment and have been found in some public and bottled water sources. The legally prescribed course of action under the SDWA and the act with respect to such contaminants is for EPA to establish limits for them that provide for the protection of the public health and, when appropriate, for FDA to adopt limits for these contaminants in bottled water. It has been FDA's policy to fulfill its legal obligation under the act by amending the quality standard for bottled water to include allowable limits for contaminants that EPA has regulated under the SDWA.

Acceptable, health-based limits for such substances in public drinking water are set by EPA by determining a lifetime exposure level at which no known or anticipated adverse health

effects occur and that will provide an adequate margin of safety. EPA uses these criteria to establish maximum contaminant level goals (MCLG's) and then sets the MCL's as close as feasible to the MCLG's.

Under the SDWA, "feasible" means possible with the use of the best technology, treatment techniques, and other means that are found to be practical under actual field conditions for removal or reduction of the contaminant to a level that protects the public health (52 FR 25690 at 25097). For example, EPA set the MCL's for the carcinogenic VOC's addressed in this rulemaking (0.002 mg/L for vinyl chloride and 0.005 mg/L for benzene, carbon tetrachloride, 1,1-dichloroethane, and trichloroethylene) as close as is feasible to the MCLG's of zero, that is, at the practical quantitation limits (PQL's) of the analytical methods used to measure each of these contaminants (52 FR 25690 at 25700).

Given these considerations, FDA believes that the MCL's for these seven VOC's are appropriate as maximum allowable levels for these contaminants in bottled drinking water. By adopting limits on these VOC's, FDA is not condoning their presence in bottled water, as implied by the comment, but is instead acting to protect the public by limiting potentially harmful levels of exposure to these contaminants that may occur.

2. The comment that suggested that FDA should conduct its own assessment of drinking water contaminant levels argued that such an assessment was especially important because the MCLG's set by EPA for the substances that are the subject of this rulemaking were based on EPA policy and not on the science at issue. This comment questioned the scientific basis upon which EPA assigned MCLG's of zero to all carcinogens which EPA categorized as Group B (Probable Human), because B2 substances, that is, substances that have been shown to be carcinogens in animal testing but for which there is no evidence of human cancer risk, should not be assigned MCLG's of zero. In particular, the comment contended, and provided documents to support its contention, that TCE was misclassified by EPA as a B2-probable human carcinogen. The comment concluded that FDA should review the scientific basis for EPA's drinking water standards and reevaluate the proposed bottled water quality standard for TCE, considering that it should be classified as a Group C-possible human carcinogen.

To avoid any misunderstanding, FDA notes that it does not have authority to set standards for public drinking water. Under the provisions of the SDWA of 1974, EPA is charged with ensuring that the public is provided with safe drinking water and with establishing standards for contaminants (as MCL's) in public drinking water sources. FDA, under a memorandum of understanding between EPA and FDA (44 FR 42775, July 20, 1979), is responsible for water, and substances in water, used in food and for food processing and for bottled drinking water.

In the case of bottled water, it has been FDA's policy to fulfill its charge under section 410 of the act by adopting EPA drinking water standards as maximum allowable levels for contaminants in bottled water unless there exist reasons for FDA to conclude that certain EPA standards are not applicable to bottled water. For example, an EPA standard for drinking water may be inappropriate as an allowable level for a contaminant in bottled water if it is reasonable to expect that lower levels of the contaminant will be present in bottled water because the presence of the contaminant in drinking water is the result of circumstances peculiar to public water systems that can be avoided by bottlers, e.g., lead in pipes, solder, or brass fittings.

As explained in the July 6, 1990, proposal, FDA tentatively decided to adopt the EPA's health-based MCL's for seven of the eight VOC's under section 410 of the act because some sources for bottled drinking water may be expected to contain these VOC contaminants. In addition, the agency noted that in some cases bottled water may be consumed daily in amounts similar to the consumption of water from public water supplies. In cases where bottled water is subject to the same source contaminants as public water supplies, FDA believes that to ensure the quality of bottled water, the allowable levels for contaminants should normally correspond to the levels set by EPA as the MCL's for public water supplies. FDA proposals that respond to EPA rulemaking under the SDWA generally have not duplicated the efforts of EPA in judging the adequacy of NPDWR's for the protection of the public health. In most cases, (except as noted in the previous paragraph) FDA will propose to adopt EPA's MCL's as quality standards for bottled water.

It would clearly be inappropriate for FDA to reevaluate or revise the drinking water standards duly prescribed by another Federal agency. For FDA to reexamine, as suggested in the comment, the full scope of the toxicological issues for each contaminant after EPA has done so, and after EPA has established MCL's under notice and comment rulemaking procedures, would be redundant and inconsistent with the intent of section 410 of the act.

However, before proposing to adopt the MCL's for the seven VOC's, FDA did in fact review the overall results of the toxicological studies conducted with the VOC's. As a result, FDA found that it agreed completely with EPA's conclusions. These conclusions were, in part, based on studies showing that TCE causes liver tumors in mice when administered orally at high doses over the lifetime of the animals. Considering these data and the possible chronic human exposure to this contaminant from daily water consumption, FDA believes that EPA's MCL for TCE is a reasonable health-based drinking water contaminant level limit. Therefore, FDA rejects the comment's suggestion that it conduct its own assessment of drinking water contaminant levels for bottled water and reevaluate the carcinogenic potential of TCE in humans and is adopting the 0.005 mg/L MCL for TCE as the allowable level for this substance in the quality standard for bottled water.

However, should new data or a reexamination of the toxicological status of TCE lead EPA to conclude that TCE is not a potential human carcinogen, or that it has otherwise misclassified this substance, FDA will consider amending the bottled water quality standards to reflect any significant revision in the MCL by EPA.

3. The comments received from trade associations and State water officials uniformly urged that FDA adopt the VOC standards as proposed and stressed a need for more stringent regulation of the bottled water industry. The comments called for more frequent inspections and analyses of water samples, better coordination of recalls, labeling on bottled water products that identifies the source and purity of the water, a national registry for bottled waters, the use of only certified State or Federal testing laboratories for required water analyses, and limits for other organic and inorganic contaminants. One comment encouraged FDA to define the terms used in the labeling of bottled water, to adopt a program to provide guidance to States for approving and protecting bottled water sources, and to develop a regular testing and monitoring program to be funded by user fees based on production volume.

Other comments from State water officials cited recent experiences with bottled waters found to contain chlorodifluoromethane (a Freon), xylene, toluene, and lead contaminants and suggested that FDA regulate the

levels of these compounds in bottled water. These comments requested that FDA eliminate the current exemption for bottled mineral waters from compliance with the quality standard for bottled water, citing recent experience with contaminated mineral waters and noting that mineral water sources are subject to some of the same contaminants as are other bottled water sources. All of these comments requested that FDA adopt the MCL for p-dichlorobenzene. As noted above, FDA stated in the July 6, 1990, proposal that it would delay adoption of the allowable level of this chemical until EPA completes rulemaking on the secondary MCL that it proposed for this chemical on May 22, 1989 (54 FR 22062). EPA has since stated (56 FR 3526, January 30, 1991) that it is deferring promulgation of a secondary MCL for p-dichlorobenzene.

Most of the issues raised in these comments are outside the scope of this rulemaking, which addresses only the adoption of the quality standards for seven VOC's. It is inappropriate for FDA to respond here to issues that were not raised by the proposal. However, many of the concerns expressed in the comments either are the subject of separate rulemakings by the agency in response to EPA's promulgation of NPDWR's for 38 contaminants in drinking water, including toluene, xylenes, and p-dichlorobenzene (56 FR 3526, January 30, 1991 and 56 FR 30266, July 1, 1991), to EPA's promulgation of NPDWR's for lead and copper in drinking water (56 FR 26460, June 7, 1991) , or to a petition filed by the International Bottled Water Association (IBWA) (see proposals published elsewhere in this issue of the Federal Register).

Revision of the agency's required frequency of testing for contaminants in bottled water, as advocated in the comments received from trade associations and State water officials, while not the subject of this rulemaking, was discussed in the proposal in relation to the required minimum annual testing for chemical contaminants in the source water and in bottled water products under the provisions of current good manufacturing practice (CGMP) regulations (21 CFR 129.35). FDA continues to believe that it is not necessary to revise the frequency requirements for the analysis of bottled water at this time. In particular, the agency reminds bottlers that they are responsible for ensuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard set forth in § 103.35. Bottled water that does not comply with a requirement in § 103.35 must bear a label statement that the water is of substandard quality (§ 103.35(f)). Moreover, any bottled water that contains a substance that presents a health concern may be subject to regulatory action under section 402(a)(1) of the act, even if the bottled water bears a label statement of substandard quality (§ 103.35(g)).

III. Conclusions

EPA's drinking water regulations promulgated under the SDWA are extensive and address several distinct types of chemical contaminants in drinking water. To facilitate the understanding and use of § 103.35 after FDA makes the anticipated extensive amendments to this regulation in response to EPA rulemakings, FDA has reorganized § 103.35(d) (the paragraph of the bottled water quality standard that contains allowable levels for individual chemical contaminants) by listing levels for chemical contaminants established pursuant to section 410 of the act in new paragraph (d)(3), which is divided to reflect the different categories of chemical contaminants addressed by EPA in its regulations. Specifically, paragraph (d)(3) contains: (1) The allowable levels for inorganic contaminants in § 103.35(d)(3)(i); (2) the allowable levels for VOC's in paragraph (d)(3)(ii); (3) the allowable levels for pesticides and other synthetic organic chemicals in paragraph (d)(3)(iii); and (4) the allowable levels for chemicals for which EPA has established secondary maximum contaminant levels in paragraph (d)(3)(iv). In addition, § 103.35(d)(3)(vi) contains provisions concerning analytical methodology to be used in determining compliance with the allowable levels.

Because this reorganization of § 103.35(d) is not a substantive change, under 5 U.S.C. 553(b) and 21 CFR 10.40(d), FDA finds that rulemaking is unnecessary. FDA is codifying the provisions of this final rule in the reorganized format for § 103.35(d). Specifically, FDA is listing the maximum allowable levels for the seven VOC's in bottled water in § 103.35(d)(3)(ii) and the methodologies for analyzing for these contaminants in § 103.35(d)(3)(vi). Furthermore, at this time, FDA is reserving sections of § 103.35(d)(3) that will list the allowable levels and appropriate methods for chemical contaminants other than VOC's (e.g., inorganic chemicals, pesticides, and synthetic organic chemicals).

Therefore, upon the effective date of this rule, July 6, 1993, any bottled water that contains an amount of any of these contaminants that exceeds the allowable levels will be misbranded under section 403(h)(1) of the act (21 U.S.C. 343(h)(1)) unless it bears a statement of substandard quality as provided by § 103.35(f)(2)(ii).

FDA has made two minor changes in the final rule concerning the analytical methods for the determination of the seven VOC's. First, the § 103.35(d)(3)(vi) of the final rule cites an updated version of the EPA publication that contains the analytical methods ("Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, Environmental Monitoring Systems Laboratory, EPA/600/4–88/039, December 1988) that are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Second, the source for these methods will be the National Technical Information Service rather than FDA. This change is consistent with the agency's practice of relying on readily available commercial sources for incorporated materials when possible.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (55 FR 27831, July 6, 1990). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Economic Impact

FDA has examined the economic implications of this final rule to amend 21 CFR part 103 as required by Executive Orders 12291 and 12612 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12291 compels agencies to use a cost-benefit analysis as a component of decisionmaking, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. FDA has received no new information or comments that would alter its tentative finding in the proposal that there is no substantive economic issue, and that this rule is not a major rule as defined by either Executive Order 12291 or the Regulatory Flexibility Act. Finally, because this regulation applies to food

for interstate trade, and individual State regulations would hinder interstate trade, FDA finds that there is no substantial Federalism issue that would require an analysis under Executive Order 12612.

List of Subjects in 21 CFR Part 103

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 103 is amended as follows:

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

1. The authority citation for 21 CFR part 103 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 410, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 349, 371, 376).

2. Section 103.35 is amended by adding new paragraph (d)(3) to read as follows:

§ 103.35 Bottled water.

* * * * *

(d) * * *

(3) Having consulted with the U.S. Environmental Protection Agency (EPA) as required by section 410 of the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration has determined that bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraph (d)(3)(vi) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraph (d)(3)(ii) of this section.

(i) [Reserved]

(ii) The allowable levels for volatile organic chemicals (VOC's) are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Benzene (71–43–2)	0.005
Carbon tetrachloride (56–23–5)	0.005
1,2-Dichloroethane (107–06–2)	0.005
1,1-Dichloroethylene (75–35–4)	0.007
1,1,1-Trichloroethane (71–55–6)	0.20
Trichloroethylene (79–01–6)	0.005
Vinyl chloride (75–01–4)	0.002

(iii)—(v) [Reserved]

(vi) Analyses conducted to determine compliance with paragraph (d)(3)(ii) of this section shall be conducted in accordance with a relevant method contained in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, Environmental Monitoring Systems Laboratory, EPA/600/4–88/039, December 1988, and listed separately in paragraphs (d)(3)(vi)(A) through (d)(3)(vi)(E) of this section, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Except as otherwise indicated below, copies are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(A) Method 502.1—"Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography" (applicable to VOC's).

(B) Method 502.2—"Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series" (applicable to VOC's).

(C) Method 503.1—"Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography" (applicable to VOC's).

(D) Method 524.1—"Measurement of Purgeable Organic Compounds in Water by Purged Column Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(E) Method 524.2—"Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(vii) [Reserved]

* * * * *

Dated: April 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

Editorial Note: This document was received in the Office of the Federal Register December 28, 1992.

[FR Doc. 92–31850 Filed 12–30–92; 9:00 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 103

[Docket No. 91N–0141]

Quality Standards for Foods With No Identity Standards; Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its bottled water quality standard to establish or modify the allowable levels for 10 inorganic chemicals (IOC's) and 28 synthetic organic chemicals (SOC's), including 10 synthetic volatile organic chemicals (VOC's), 17 pesticides, and polychlorinated biphenyls (PCB's). FDA is also proposing to affirm the existing allowable levels in the bottled water quality standard for mercury and nitrate. These actions follow rulemakings by the Environmental Protection Agency (EPA) that resulted in the promulgation of regulations establishing maximum contaminant levels (MCL's) for the 28 SOC's and 8 IOC's, treatment techniques for 2 SOC's, and secondary maximum contaminant levels (SMCL's) for 2 IOC's. FDA is not proposing to establish allowable levels for the two SOC's for which EPA established treatment techniques because EPA determined that it was not feasible to establish MCL's for these substances. FDA is also proposing to adopt the current EPA MCL for *para*-dichlorobenzene (*p*-dichlorobenzene) as the allowable level for this chemical.

DATES: Written comments by March 8, 1993. The agency intends to make any final rule based upon this proposal effective 180 days following the date of publication of the final rule in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5229.

SUPPLEMENTARY INFORMATION:

I. Background

National primary drinking water regulations (NPDWR's) are promulgated by EPA to protect the public health from the adverse effects of contaminants in drinking water. National secondary drinking water regulations (NSDWR's) are promulgated by EPA to protect the public welfare from the adverse aesthetic effects, such as odor, taste, and color, of contaminants in drinking water. In addition, at the time that it promulgates NPDWR's, EPA promulgates maximum contaminant level goals (MCLG's), which are health goals that are based solely on considerations of protecting the public from adverse effects of drinking water contamination.

In the **Federal Register** of January 30, 1991 (56 FR 3526), EPA published a final rule promulgating NPDWR's consisting of MCL's or treatment techniques for 26 SOC's and 7 IOC's. In that final rule EPA also established NSDWR's consisting of SMCL's for two IOC's. Also in the **Federal Register** of July 1, 1991 (56 FR 30266), EPA published a final rule promulgating NPDWR's consisting of MCL's for one IOC (barium) and four SOC's (aldicarb, aldicarb sulfoxide, aldicarb sulfone, and pentachlorophenol). EPA initiated these rulemakings with a proposal that it published in the **Federal Register** of May 22, 1989 (54 FR 22062). However, the MCL's for the 5 contaminants promulgated in EPA's July 1, 1991 final rule were reproposed by EPA on January 30, 1991 (56 FR 3600) at different levels based on information that EPA received or analyzed after it published its May 22, 1989 proposal.

Under section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349), whenever EPA prescribes interim or revised NPDWR's under section 1412 of the Public Health Service Act (The Safe Drinking Water Act (SDWA) (42 U.S.C. 300f through 300j–9)), FDA is required to consult with EPA and, within 180 days after EPA promulgates the drinking water regulations, "* * * either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the **Federal Register** * * * reasons for not making such amendments." In accordance with section 410 of the act, FDA has consulted with EPA and is proposing to adopt as allowable levels in the quality standard for bottled water the MCL's that EPA established in the rulemakings of January 30, 1991 (56 FR 3526) and July 1, 1991 (56 FR 30266). FDA is also proposing to adopt as allowable levels the two SMCL's that EPA established in January 1991.

II. EPA Standards

Under section 1412(b) of the SDWA, as amended in 1986, EPA is required to promulgate NPDWR's for 83 contaminants, including those substances that were the subject of the final rules of January 30, 1991 (56 FR 3526) and July 1, 1991 (56 FR 30266). Further, EPA must regulate an additional 25 contaminants every 3 years after 1989 (54 FR 22062 at 22066, May 22, 1989). NPDWR's, which are enforceable standards, consist of either an MCL or a treatment technique regulation for each contaminant. EPA sets MCL's for contaminants as close as feasible (with the use of the best technology or other means available, taking costs into consideration) to the maximum contaminant level goal (MCLG), the level at which no known or anticipated adverse health effects occur and that provides an adequate margin of safety. When it is not feasible to establish an MCL for a specific contaminant, EPA can establish a treatment technique requirement to protect the public health from the adverse health effects of that contaminant.

EPA adopted treatment technique requirements, rather than MCL's, for the contaminants acrylamide and epichlorohydrin, because standardized analytical methods with adequate limits of detection were not available for analyzing drinking water for these contaminants. Both occur as residual monomers in polymers used as flocculents in water treatment and migrate to the water from the flocculating agents. EPA estimated that approximately 90 percent of the acrylamide and epichlorohydrin that is found in treated water gets into the water in this way.

Based on this fact, EPA in its final rule of January 30, 1991 (56 FR 3526), established a standard that requires certification by the public water system that flocculents containing residual amounts of these monomers are used only within specified levels to treat water, and that the levels of monomers in the flocculents do not exceed other specified levels.

EPA's January 30, 1991 final rule (56 FR 3526) established an SMCL of 0.1 milligram per liter (mg/L) for silver to protect the general public from the adverse cosmetic effect of argyria (a discoloration of the skin) from lifetime exposure to this metal. EPA considers argyria to be a cosmetic effect because it does not impair body function.

EPA's January 30, 1991 final rule (56 FR 3526) established an SMCL for aluminum as a range of from 0.05 to 0.2

mg/L. EPA based this SMCL on the possibility that the aluminum that remains in some drinking waters after treatment could increase the water's turbidity (cloudiness) and, when the aluminum level exceeds 0.1 mg/L, could discolor the water. While EPA encouraged water systems to meet a level of 0.05 mg/L, it recognized that some systems could experience difficulty in meeting this level in certain situations. Thus, EPA established a range for the SMCL of from 0.05 mg/L to 0.2 mg/L, with the appropriate level for each system determined by the state agency having primacy.

In EPA's May 22, 1989 proposal (54 FR 22062), it proposed SMCL's for seven organic chemicals, including *p*-dichlorobenzene. These organic chemicals could reportedly affect the taste or odor of the water at lower levels than those that EPA had either proposed or adopted as MCL's for these chemicals. EPA considered it appropriate to set SMCL's for these compounds because of their aesthetic effects.

In the final rule of January 30, 1991 (56 FR 3526), however, EPA announced that it had decided to defer promulgating SMCL's for these seven organic chemicals. Comments to EPA's proposal had opposed the SMCL's on the grounds that there was an inadequate experimental basis for such levels for four of the chemicals. The proposed SMCL's were based on a theoretical extrapolation from air odor thresholds. EPA stated that the determination of a level for a chemical that has a perceived aesthetic effect in drinking water presents a difficult and currently unresolved problem. EPA further stated that minimum detection levels, although different in different waters, could be identified, but that the point for each chemical, in different waters, at which consumers complain required more study and research. EPA stated that it may establish a national task force of experts to review and assess the data, information, and opinions available with respect to taste and odor problems in public water supplies, including development of one or more SMCL's. Even though it deferred adopting specific SMCL's for the seven organic chemicals, EPA pointed out that it was retaining the existing odor SMCL of 3 Total Odor Number, which is also the bottled water odor quality standard.

III. FDA Proposal

A. Introduction

FDA has traditionally fulfilled its obligation under section 410 of the act to respond to EPA's issuance of NPDWR's by amending the quality standard for bottled water introduced or delivered for introduction into interstate commerce to maintain compatibility with EPA's drinking water regulations. In general, FDA believes that, with few exceptions, the EPA standards for drinking water are appropriate as allowable levels for the chemicals in the quality standard for bottled water.

FDA proposals that respond to EPA rulemaking under the SDWA generally have not duplicated the efforts of EPA in judging the adequacy of NPDWR's for the protection of the public health, nor have they duplicated that agency's efforts in judging the adequacy of NSDWR's for control of aesthetic characteristics affecting consumer acceptance of drinking water. FDA does not intend to change this approach. Because bottled water is increasingly used in some households as a replacement for tap water, consumption patterns considered by EPA for tap water can be used as a conservative estimate for the maximum expected consumption of bottled water. In cases where bottled water is subject to the same source contaminants as tap water (e.g., when obtained from the same sources used by public water systems), allowable levels for contaminants to ensure the safety of bottled water, and levels to ensure its aesthetic quality, should normally correspond to the levels set by EPA as the NPDWR's and NSDWR's for tap water. Therefore, FDA intends to rely on EPA's determinations that the MCL's or treatment technique requirements are adequate to protect the public health, and that the SMCL's are adequate to control other quality defects such as those of an aesthetic nature. In most cases, FDA will propose to adopt EPA's MCL's and SMCL's as allowable levels in the quality standard for bottled water. Furthermore, in most cases, FDA intends to rely on EPA's determinations as to the appropriate analytical methods for determining levels of these contaminants in water and to incorporate such methods by reference in the proposed amendment of its quality standard for bottled water (56 FR 3526, January 30, 1991; 54 FR 22062, May 22, 1989; 52 FR 25690, July 8, 1987; 52 FR 12876, April 17, 1987; 50 FR 46902, November 13, 1985).

FDA will, however, make its own determination as to whether it is appropriate to have an allowable level in the quality standard for bottled water for a chemical for which EPA has promulgated an NPDWR and, assuming that establishing an allowable level is appropriate, as to what amount it should be. For example, when EPA establishes or revises an NPDWR that includes an MCL for a particular contaminant, FDA will consider whether any quality defects (e.g., effects of an aesthetic nature) occur at levels below that at which EPA has established the MCL. FDA will also consider whether the contaminant is present in the source water or is added as a result of the production or distribution of the bottled water, and whether the contaminant is likely to be removed during bottled water manufacturing. If the presence of a contaminant is the result of circumstances peculiar to public water systems, for example, lead in pipes, solder, or brass fittings, and if it can be avoided by bottlers, FDA may decide to propose a lower allowable level than the MCL for that contaminant.

In the past, bottled water quality standard rulemakings have been subject to the formal rulemaking procedure in section 701(e) of the act (21 U.S.C. 371(e)). However, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), enacted November 8, 1990, removed standard of quality rulemakings from the coverage of that section. FDA is therefore proposing these amendments to the quality standards under section 701(a) of the act, which involves notice and comment rulemaking.

B. Modifications in § 103.35 (21 CFR 103.35)

EPA's drinking water regulations promulgated under the SDWA are extensive and address several distinct types of chemical contaminants in drinking water. To facilitate the understanding and use of § 103.35 after FDA makes the anticipated extensive amendments to this regulation in response to EPA rulemakings, FDA, in a final rule establishing allowable levels for seven VOC's published elsewhere in this issue of the **Federal Register**, has reorganized § 103.35(d) (the paragraph of the bottled water quality standard that contains allowable levels for individual chemical contaminants) by listing levels for chemical contaminants established pursuant to section 410 of the act in new § 103.35(d)(3), which is divided to reflect the different categories of chemical contaminants addressed by EPA in regulations. Specifically, § 103.35(d)(3) contains: (1) The allowable levels for IOC's in paragraph (d)(3)(i); (2) the allowable levels for VOC's in paragraph (d)(3)(ii); (3) the allowable levels for pesticides and other SOC's in paragraph (d)(3)(iii); and (4) the allowable levels for chemicals for which EPA has established SMCL's in paragraph (d)(3)(iv). In addition,

§ 103.35(d)(3)(v) through (d)(3)(vii) contains provisions concerning analytical methodology to be used in determining compliance with the allowable levels. The amendments to the bottled water quality standard that FDA is proposing in this document follow the reorganized format for § 103.35(d).

Some of the IOC's and pesticides addressed in this proposal are the subject of previously established allowable levels listed in § 103.35(d)(1). FDA intends to delete the entries for these IOC's and pesticides from § 103.35(d)(1) and list the levels for these contaminants in § 103.35(d)(3).

FDA is proposing to establish or modify allowable levels for bottled water, based on the MCL's that EPA has established (January 30, 1991, 56 FR 3526 and July 1, 1991, 56 FR 30266), for the following six IOC contaminants in § 103.35(d)(3)(i): Asbestos, barium, cadmium, chromium, nitrite, and selenium. In § 103.35(d)(3)(v), FDA is proposing to adopt the methodologies for determining levels of these contaminants that EPA has adopted.

Although EPA evaluated the available toxicology data on mercury and nitrate, it determined that the existing MCL's were still appropriate. Based on EPA's determination, FDA is retaining the existing allowable levels for these chemicals. As noted above, the agency is transferring the listings for these chemicals to § 103.35(d)(3)(i) so that the allowable levels for mercury and nitrate are listed with those for the other inorganic contaminants. FDA is also proposing to adopt analytical methodologies that EPA has adopted for analyzing for mercury and nitrate, as listed in § 103.35(d)(3)(v).

In listing appropriate analytical methods for IOC's in its January 30, 1991 and July 1, 1991 rules, EPA, in many instances, cited its own developed version, and equivalent versions published by other organizations, of a specific method. (For example, for determining nitrate by the manual cadmium reduction method, EPA cited its own developed version, the version published by the American Society for Testing Materials, and the version published jointly by the American Public Health Association, the American Water Works Association, and the Water Pollution Control Federation.) To minimize the resource burden on FDA associated with periodic updating of methods incorporated by reference (as is required by 5 U.S.C. 552(a) and 1 CFR part 51), where an EPA version of a method exists for an IOC, FDA is proposing to incorporate by reference in § 103.35(d)(3)(v) only that version of the method. When conducting analyses for these IOC's in bottled water for compliance purposes, FDA will use the method incorporated by reference (i.e., the EPA version).

In § 103.35(d)(3)(ii), FDA is proposing to establish allowable levels for bottled water based upon the MCL's that EPA has established for the following 10 VOC's: *ortho*-dichlorobenzene (*o*-dichlorobenzene), *cis*-1,2-dichloroethylene, *trans*-1,2-dichloroethylene, 1,2-dichloropropane, ethylbenzene, monochlorobenzene, styrene, tetrachloroethylene, toluene, and xylenes. In § 103.35(d)(3)(vi), FDA is proposing to adopt methodologies that EPA has cited for determining levels of these contaminants.

In § 103.35(d)(3)(ii), FDA is also proposing to establish an allowable level of 0.075 mg/L for *para*-dichlorobenzene (*p*-dichlorobenzene) in bottled water. EPA established an MCL of 0.075 mg/L for this VOC in a final rule promulgating NPDWR's published in the **Federal Register** of July 8, 1987 (52 FR 25960). FDA had originally intended to adopt EPA's proposed SMCL of 0.005 mg/L for this contaminant (54 FR 22062 at 22138, May 22, 1989) based on a reported odor detection level of 0.003 mg/L. However, because EPA deferred establishing an SMCL for this chemical, FDA is proposing to adopt EPA's MCL for this chemical as an allowable level. In § 103.35(d)(3)(vi), FDA is proposing to adopt analytical methods that EPA has cited for determining the level of *p*-dichlorobenzene. FDA notes that although it is not proposing an odor-based quality standard for *p*-dichlorobenzene at this time, bottled water must still comply with the physical quality standards in § 103.35(c)(3), which provide that the odor shall not exceed threshold odor no. 3.

In § 103.35(d)(3)(iii), FDA is proposing to establish or modify allowable levels for polychlorinated biphenyls (PCB's) and for the following 17 pesticides: alachlor, aldicarb, aldicarb sulfoxide, aldicarb sulfone, atrazine, carbofuran, chlordane, 1,2-dibromo-3-chloropropane, 2,4–D, ethylene dibromide, heptachlor, heptachlor epoxide, lindane, methoxychlor, pentachlorophenol, toxaphene, and 2,4,5–TP (Silvex). The allowable levels are based on the MCL's that EPA has established for these contaminants. In § 103.35(d)(3)(vi), FDA is proposing to adopt the methodologies for determining levels of these contaminants that EPA has adopted.

FDA is not proposing to establish allowable levels for the two contaminants for which EPA established treatment techniques, acrylamide and epichlorohydrin. As discussed in Section II of this document, EPA's treatment techniques set limits on the use levels of flocculents containing acrylamide or epichlorohydrin polymers for treating drinking water and on residual acrylamide and epichlorohydrin monomer levels in the flocculents. However, flocculents may not be used in the manufacture of bottled water unless a food additive regulation or other appropriate authorization (such as a generally recognized as safe affirmation regulation) exists prescribing conditions under which such additives may be safely used. Similarly, food-contact materials, such as paints and adhesives, that may be used on equipment used in bottled water manufacturing processing must also be prescribed in food additive regulations or other appropriate authorizations unless there is no reasonable expectation of migration of components of such materials into the bottled water. Therefore, because EPA has determined that it is not feasible to establish MCL's for acrylamide and epichlorohydrin, and because it is unnecessary, and it would be duplicative to adopt EPA's treatment techniques when the Food Additives Amendment of 1958 (Pub. L. 85–929) and regulations that the agency has issued thereunder prohibit unsafe use of flocculents and other food-contact materials in the manufacture of bottled water, FDA has decided not to propose an allowable level for these chemicals in the quality standard for bottled water.

In § 103.35(d)(3)(iv), FDA is proposing to adopt allowable levels for silver (0.1 mg/L) and aluminum (0.2 mg/L) based on EPA's SMCL's for these contaminants. In § 103.35(d)(3)(vii), FDA is proposing to adopt analytical methodologies that EPA has cited for determining levels of these contaminants.

As discussed in section II above, EPA established an SMCL for aluminum that consisted of a range from 0.05 mg/L to 0.2 mg/L and allowed State water officials to decide the appropriate level for each water distribution system on a case-by-case basis.

Aluminum is a common constituent of ground water, which is used as source water both by bottled water manufacturers and by public water systems. Comments to the EPA rule of January 30, 1991 (56 FR 3256), cited a 1987 American Water Works Association Research Foundation Survey of more than 90 water utilities that found an average aluminum concentration of 0.09 mg/L in finished

water. Furthermore, the International Bottled Water Association (IBWA) found that: "* * * a review of literature shows ranges (of aluminum) from 0.07 mg/L to 0.13 mg/L with one sample at 0.70 mg/L. The information listed the products as spring water" (Ref. 2).

FDA has considered EPA's SMCL range and the reasons given by EPA for its approach and has tentatively determined that 0.2 mg/L is the appropriate allowable level for aluminum in the quality standard for bottled water for several reasons.

First, FDA believes that single values should be used as the allowable level for chemicals in the quality standard for bottled water because bottled water, unlike tap water, is a packaged food product that may be shipped far from where it is bottled. If a range were used with the applicable allowable level to be determined by the State agency having primacy, it could be difficult for authorities in localities where the bottled water is to be sold to determine whether it meets the applicable standards.

Secondly, FDA has considered that EPA's standard was set not to address adverse health effects but to address possible post-treatment precipitation discoloration of the water. Therefore, selection of the higher level as the quality standard for aluminum in bottled water would not pose a greater health risk than selection of the lower level.

Thirdly, because bottled water could have more than 0.05 mg/L aluminum and still be acceptable, it would be inappropriate to set the allowable level at that amount.

Finally, the World Health Organization has established a guideline level for aluminum in drinking water at 0.2 mg/L (56 FR 3526 at page 3573). Therefore, adoption of 0.2 mg/L as the allowable level would further international harmonization of food regulations.

Based on these four factors FDA is proposing 0.2 mg/L as the allowable level for aluminum in bottled water.

In Table 1, FDA is listing, for convenience, the chemical contaminants for which it is proposing to modify the allowable levels in the bottled water quality standard. The chart permits comparison of the existing and the proposed maximum allowable levels.

TABLE 1

Proposed Revisions to Existing Allowable Levels in Bottled Water Quality Standard

Contaminant	Existing level in milligrams per liter	Proposed level in milligrams per liter
Barium	1.0	2.0
Cadmium	0.01	0.005
Chromium	0.05	0.1
Selenium	0.01	0.05
Silver	0.05	0.1
Lindane	0.004	0.0002
Methoxychlor	0.1	0.04
Toxaphene	0.005	0.003
2,4–D	0.1	0.07
2,4,5–TP (Silvex)	0.01	0.05

FDA reminds water bottlers that they are responsible for ensuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard set forth in § 103.35. Bottled water that does not comply with any requirement in § 103.35 must bear a label statement that the water is of substandard quality (§ 103.35(f)). Moreover, any bottled water that contains a substance that presents a health concern may be subject to regulatory action under section 402(a)(1) of the act, even if the bottled water bears a label statement of substandard quality (§ 103.35(g)).

FDA has established current good manufacturing practice (CGMP) regulations for bottled water, including mineral water, in 21 CFR part 129. The CGMP regulations require sampling and analysis of source water, and of each bottled water product, for chemical contaminants at least once each year. The CGMP regulations also provide for the sampling and analysis, as often as necessary, of water taken after processing but before bottling, to assure uniformity and effectiveness of the processing performed by the plant.

These CGMP regulations will apply to the contaminants that FDA is proposing to add to the list of chemical contaminants in § 103.35. However, compliance with CGMP requirements of 21 CFR part 129 does not exempt a firm from regulatory action if its bottled water products do not meet the quality standard for bottled water.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Economic Impact

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act and Executive Order 12291 and 12612. The Regulatory Flexibility Act requires relief for small businesses where feasible. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because this proposed regulation applies to food for interstate trade, and because State regulations would hinder interstate trade, FDA finds that there is no substantial federalism issue which would require an analysis under Executive Order 12612.

A. Costs

The bottled water industry consists of 475 bottling plants with 600 brands (Ref. 1). Of the 250 bottling plants that are members of the IBWA, about half are considered small, 113.5 L (30 gallons) per minute, 25 percent medium, 227.1 L (60 gallons) per minute, and 25 percent large, 378.5 L (100 gallons) per minute. Most bottlers who are not members of IBWA are probably small. For this analysis, FDA assumes that the bottled water industry consists of 295 small bottling plants, 120 medium bottling plants, and 60 large bottling plants. FDA also assumes that each small bottler markets one brand of water, each medium bottler markets an average of one and a half brands, and each large plant markets two different brands of water.

If this proposal becomes a final rule, bottlers will be required to test the source water and product water to ensure that the potential chemical contaminants in source and product water are below the allowable levels. Some of the testing that would be required is required by existing regulations. Thus, it is likely that the incremental testing cost of source and product water required by this regulation would be incurred by a relatively small proportion of the industry.

FDA estimates that between 9 and 40 brands of bottled water will be required to be tested for contaminants. The estimated incremental annual testing cost per brand of bottled water is $2,430. Therefore, the total incremental annual testing cost would be between $22,000 and $97,000.

In addition to these estimated testing costs, FDA assumes that all bottlers must incur an annual cost of $6 per brand to keep records of the testing for inspections. This results in a total industry cost of $3,600 per year ($6 multiplied by 600 brands).

Approximately 75 percent of the bottled water brands are from natural sources, either wells or natural springs (Ref. 1). It is highly unlikely that any of these natural sources would include levels of the chemical contaminants above the proposed allowable levels for bottled water because of the protected, proprietary nature of the sites of this source water. Therefore, waters from these sources are unlikely to require additional treatment to comply with the allowable levels that the agency has proposed.

Bottled waters produced from municipal water sources that are in compliance with EPA's MCL's for chemical contaminants in public drinking water should comply with most of the proposed allowable levels for chemical contaminants in bottled water. Bottlers using source waters that contain chemical contaminants above the proposed allowable levels could treat the water to reduce the contaminant, use an alternative water source, or revise product labels to bear a statement of substandard quality. If one or more bottlers are using source water from a municipal system that does not comply with the allowable levels stated in the proposed regulation, it may be necessary for the bottler to temporarily use an alternative water source or treat the water to achieve compliance until the municipal water system fully complies with EPA drinking water regulations. The estimated incremental one-time cost to bottlers of treating source water that is out of compliance would range from $25,300 to $109,200. Annual incremental treatment costs are expected to range between $13,400 and $36,200.

B. Benefits

FDA has no information to quantify the benefits of this proposed regulation. However, as the costs are minimal, FDA expects that benefits will exceed costs.

C. Summary

FDA has determined that this proposed rule is not a major rule as defined by Executive Order 12291. The establishment of allowable levels for 39 chemical contaminants in bottled water would result in a one-time treatment cost of between $25,000 to $109,000. Annual treatment, testing, and record keeping costs are estimated to be between $39,000 and $136,000. Therefore, total costs of this proposed regulation, if it becomes a final rule, are estimated to be between $64,000 and $245,000. Although FDA is not able to quantify the benefits of this regulation, benefits are expected to exceed costs.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. "Twenty Questions Concerning Bottled Water," International Bottled Water Association, 1990.

2. IBWA letter dated February 16, 1991.

VII. Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Effective Date

The agency intends to make any final rule based upon this proposal effective 180 days following the date of publication of the final rule. The agency is providing this time period to permit affected firms adequate time to take appropriate steps to bring their product into compliance with the standard imposed by the new rule. The agency is requesting comments on the proposed effective date. All comments concerning the effective date should be accompanied by data to support or justify any change in the proposed effective date.

List of Subjects in 21 CFR Part 103

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 103 be amended as follows:

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

1. The authority citation for 21 CFR part 103 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 410, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 349, 371, 376).

2. Section 103.35 is amended in the table in paragraph (d)(1)(i) by removing the entries for "Barium," "Cadmium," "Chromium," "Mercury," "Nitrate (N)," "Selenium," "Silver," and under "Organics:" by removing the entries "Lindane * * *," "Methoxychlor * * *," "Toxaphene * * *," "2,4-D (2,4-dichlorophenoxyacetic acid)," and "2,4,5–TP (Silvex) * * *," and in paragraph (d)(3) by adding new paragraphs (d)(3)(i), (d)(3)(iii), (d)(3)(iv), (d)(3)(v), and (d)(3)(vii), by adding new entries in the table in paragraph (d)(3)(ii), and by revising paragraph (d)(3)(vi) to read as follows:

§ 103.35 Bottled water.

* * * * *

(d) * * *

(3) * * *

(i) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter (or as specified)
Asbestos	$7X10^6$ fibers/L (longer than 10 μM)
Barium	2.0
Cadmium	0.005
Chromium	0.1
Mercury	0.002
Nitrate	10 (as nitrogen)
Nitrite	1 (as nitrogen)
Total Nitrate and Nitrite	10 (as nitrogen)
Selenium	0.05

(ii) The allowable levels for volatile organic chemicals are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
o-Dichlorobenzene (95–50–1)	0.6
p-Dichlorobenzene (106–46–7)	0.075
cis-1,2-Dichloroethylene (156–59–2)	0.07
trans-1,2-Dichloroethylene (156–60–5)	0.1
1,2-Dichloropropane (78–87–5)	0.005
Ethylbenzene (100–41–4)	0.7
Monochlorobenzene (108–90–7)	0.1
Styrene (100–42–5)	0.1
Tetrachloroethylene (127–18–4)	0.005
Toluene (108–88–3)	1
Xylenes (1330–20–7)	10

(iii) The allowable levels for pesticides and other synthetic organic chemicals are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Alachlor (15972–60–8)	0.002
Aldicarb (116–06–3)	0.003
Aldicarb sulfoxide (1646–87–3)	0.004
Aldicarb sulfone (1646–87–4)	0.002
Atrazine (1912–24–9)	0.003
Carbofuran (1563–66–2)	0.04
Chlordane (57–74–9)	0.002
1,2-Dibromo-3-chloropropane (96–12–8)	0.0002
2,4-D (94–75–7)	0.07
Ethylene dibromide (106–93–4)	0.00005
Heptachlor (76–44–8)	0.0004
Heptachlor epoxide (1024–57–3)	0.0002
Lindane (58–89–9)	0.0002
Methoxychlor (72–43–5)	0.04
Pentachlorophenol (87–86–5)	0.001
PCB's (as decachlorbiphenyl) (1336–36–3)	0.0005
Toxaphene (8001–35–2)	0.003
2,4,5–TP (Silvex) (93–72–1)	0.05

(iv) The allowable levels for certain chemicals for which EPA has established secondary maximum contaminant levels in its drinking water regulations are as follows:

Contaminant	Concentration in milligrams per liter
Aluminum	0.2
Silver	0.1

(v) Analyses to determine compliance with the requirements of paragraph (d)(3)(i) of this section shall be conducted in accordance with an applicable method or applicable revisions to the methods listed in paragraphs (d)(3)(v)(A) through (d)(3)(v)(G) of this section and described (unless otherwise noted) in "Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268 (EPA–600/4–79–020), March 1983, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Except as otherwise indicated below, copies are available from ORD Publications, CERI, EPA, Cincinnati, OH 45268, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(A) Asbestos—"Analytical Method for Determination of Asbestos Fibers in Water" EPA–600/4–83–043, available from the EPA Environmental Research Laboratory, Athens, GA 30613.

(B) Barium—The following methods are from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 208.2—Atomic absorption; furnace technique.

(*2*) Method 208.1—Atomic absorption; direct aspiration, and

(*3*) Method 207—Inductively coupled plasma with Method 200.7A—"Inductively Coupled Plasma Atomic Emission Analysis of Drinking Water," Appendix to Method 200.7, March 1987, available from the EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268.

(C) Cadmium—The following methods are from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 213.2—Atomic absorption; furnace technique, and

(*2*) Method 200.7A—"Inductively Coupled Plasma Atomic Emission Analysis of Drinking Water," Appendix to Method 200.7, March 1987, available from the EPA, Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268.

(D) Chromium—The following methods are from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 218.2—Atomic absorption; furnace technique.

(*2*) Method 207—Inductively coupled plasma with Method 200.7A—"Inductively Coupled Plasma Atomic Emission Analysis of Drinking Water," Appendix to Method 200.7, March 1987 available from the EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268.

(E) Mercury—The following methods are from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 245.1—Manual cold vapor technique.

(*2*) Method 245.2—Automated cold vapor technique.

(F) Nitrate and/or nitrite—The following methods are from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 353.3—Manual cadmium reduction, for both nitrate and nitrite.

(*2*) Method 353.2—Automated cadmium reduction, for both nitrate and nitrite.

(*3*) Method 300.0—Ion chromatography, for both nitrate and nitrite.

(*4*) Method 353.1—Automated hydrazine reduction, for nitrate only, and

(*5*) Method from "Orion Guide to Water and Wastewater Analysis", Form WeWWG/5880, p. 5, 1985. Orion Research, Inc., Cambridge, MA, nitrate only.

(G) Selenium—The following methods are from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 270.2—Atomic absorption; furnace technique.

(*2*) Method 270.3—Atomic absorption; gaseous hydride.

(vi) Analyses conducted to determine compliance with paragraphs (d)(3)(ii) and (d)(3)(iii) of this section shall be conducted in accordance with a relevant method contained in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, Environmental Monitoring Systems Laboratory, EPA/600/4–88/039, December 1988, and listed separately in paragraphs (d)(3)(vi)(A) through (d)(3)(vi)(M) of this section, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Except as otherwise indicated below, copies are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(A) Method 502.1—"Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography" (applicable to VOC's).

(B) Method 502.2—"Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series" (applicable to VOC's).

(C) Method 503.1—"Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Gas Chromatography" (applicable to VOC's).

(D) Method 524.1—"Measurement of Purgeable Organic Compounds in Water by Purged Column Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(E) Method 524.2—"Measurement of Purgeable Organic Compounds in Water by Capillary Column Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(F) Method 504—"1,2-Dibromoethane (EDB) and 1,2-Dibromo-3-Chloropropane (DBCP) in Water by Microextraction and Gas Chromatography" (applicable to dibromochloropropane (DBCP) and ethylene dibromide (EDB)).

(G) Method 505—"Analysis of Organohalide Pesticides and Commercial Polychlorinated Biphenyl Products in Water by Micro-Extraction and Gas Chromatography" (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene and as a screen for PCB's).

(H) Method 507—"Determination of Nitrogen- and Phosphorus-Containing Pesticides in Ground Water by Gas Chromatography with a Nitrogen-Phosphorus Detector" (applicable to alachlor and atrazine).

(I) Method 508—"Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector" (applicable to chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, toxaphene, and as a screen for PCB's).

(J) Method 508A—"Screening for Polychlorinated Biphenyls by Perchlorination and Gas Chromatography." (used to quantitate PCB's as decachlorobiphenyl if detected in methods 505 or 508).

(K) Method 515.1, Revision 5.0—"Determination of Chlorinated Acids in Water by Gas Chromatography with an Electron Capture Detector" as revised May 1991 (applicable to 2,4–D, 2,4,5–TP (Silvex) and pentachlorophenol).

(L) Method 525.1, Revision 3.0—"Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry" as revised May 1991 (applicable to alachlor, atrazine, chlordane, heptachlor, heptachlor epoxide, lindane, methoxychlor, and pentachlorophenol).

(M) Method 531.1—"Measurement of N-Methylcarbamoyloximes and N-Methylcarbamates in Water by Direct Aqueous Injection HPLC with Post Column Derivatization" (applicable to aldicarb, aldicarb sulfoxide, aldicarb sulfone, and carbofuran).

(vii) Analyses to determine compliance with the requirements of paragraph (d)(3)(iv) of this section shall be conducted in accordance with an applicable method listed in this paragraph and described (unless otherwise noted) in "Methods of Chemical Analysis of Water and Wastes," EPA Environmental Monitoring and Support Laboratory, Cincinnati, OH 45268 (EPA–600/4–79–020), March 1983. The "Methods of Chemical Analysis of Water and Wastes," other analytical methods, and applicable revisions to the methods described in "Methods of Chemical Analysis of Water and Wastes," listed in this paragraph are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Except as otherwise indicated below, copies are available from ORD Publications, CERI, EPA, Cincinnati, OH 45268 or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(A) Aluminum—The following methods are from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 202.1—Atomic absorption technique; direct aspiration.

(*2*) Method 200.2—Atomic absorption; graphite furnace technique, and

(*3*) Method 200.7—"Determination of Metals and Trace Elements by Inductively Coupled Plasma-Atomic Emission Spectrometry," version 3.2, August 1990, available from the EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268, and

(*4*) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," version 4.3, August 1990, EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268, available from ORD Publications, CERI, EPA, Cincinnati, OH 45268, and

(*5*) Method 200.9—"Determination of Metals and Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," version 1.1, August 1990, available from EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268.

(B) Silver—The following method from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 272.1—Atomic absorption technique; direct aspiration.

(*2*) Method 272.2—Atomic absorption; graphite furnace technique, and

(*3*) Method 200.7—"Determination of Metals and Trace Elements by Inductively Coupled Plasma-Atomic Emission Spectrometry," version 3.2, August 1990, available from the EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268, and

(*4*) Method 200.8—"Determination of Trace Elements in Water and Wastes by Inductively Coupled Plasma-Mass Spectrometry," version 4.3, August 1990, EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268, available from ORD Publications, CERI, EPA, Cincinnati, OH 45268, and

(*5*) Method 200.9—"Determination of Metals and Trace Elements by Stabilized Temperature Graphite Furnace Atomic Absorption Spectrometry," version 1.1, August 1990, available from EPA, Environmental Monitoring and Systems Laboratory, Cincinnati, OH 45268.

Dated: April 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

Editorial Note: This document was received at the Federal Register December 28, 1992.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 103

[Docket No. 92N–0059]

Quality Standards for Foods With No Identity Standards; Bottled Water; Chemical Quality Standards for Copper and Lead

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its standard of quality regulations for bottled water to establish a maximum level of 0.005 milligram per liter (mg/L) as the quality standard for lead in bottled water. FDA also is proposing to retain the existing quality standard for copper in bottled water that specifies a maximum level for this contaminant of 1.0 mg/L. These proposed actions, in accordance with section 410 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 349) (the act), are in response to rulemakings by the Environmental Protection Agency (EPA) that resulted in the promulgation of regulations that established treatment technique requirements for controlling lead and copper contamination of public drinking water.

DATES: Written comments by March 8, 1993. The agency intends to make any final rule based upon this proposal effective 180 days following the date of publication of the final rule in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michael E. Kashtock, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5229.

SUPPLEMENTARY INFORMATION:

I. Background

National primary drinking water regulations (NPDWR's) are promulgated by EPA to protect the public health from the adverse effects of contaminants in public drinking water. In the **Federal Register** of June 7, 1991 (56 FR 26460), EPA published a final rule promulgating NPDWR's consisting of required treatment techniques for controlling copper and lead contamination. In establishing the NPDWR's for copper and lead, EPA stated that source waters used for public drinking water systems were not the primary source of copper and lead contamination. Rather, EPA said lead contamination results primarily from the corrosion of lead-containing materials located throughout public water distribution systems, while copper contamination results primarily from the corrosion of copper pipes used for interior plumbing in residences and buildings in the United States. At the same time that it established NPDWR's for copper and lead, EPA also established maximum contaminant level goals (MCLG's) for both substances in public drinking water.

Under section 410 of the act, whenever EPA prescribes an interim or revised NPDWR under section 1412 of title XIV of the Public Health Service Act (The Safe Drinking Water Act (SDWA) (42 U.S.C. 300f–300j–9)), FDA is required to consult with EPA and within 180 days after the promulgation of such drinking water regulations "* * * either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the **Federal Register** * * * reasons for not making such amendments." FDA has consulted with EPA and is proposing to amend the quality standard for lead in bottled water. The quality standard that FDA is proposing to establish for lead represents a level for this contaminant that the agency expects will not be exceeded in source waters that have not been exposed to the significant lead contamination that results from corrosion of materials in public water distribution systems. FDA also has consulted with EPA and has determined, for the reasons stated below, that it will retain the existing quality standard for copper in bottled water.

II. EPA Standards

Under section 1412(b) of the SDWA, as amended in 1986, EPA is required to promulgate NPDWR's for 83 contaminants, including lead and copper. Further, EPA must regulate an additional 25 contaminants every 3 years after 1989 (54 FR 22062 at 22066, May 22, 1989). NPDWR's, which are enforceable standards, consist of either a maximum contaminant level (MCL) or a treatment technique requirement for each contaminant. EPA sets MCL's for contaminants as close as feasible to the MCLG, the level at which no known or anticipated adverse health effects occur and that provides an adequate margin of safety. When it is not feasible to establish an MCL for a specific contaminant, EPA can establish a treatment technique requirement to reduce the level of the contaminant and thus protect the public from the adverse health effects of the contaminant.

The SDWA requires that EPA promulgate MCLG's at the time that it promulgates NPDWR's. However, MCLG's do not constitute regulatory requirements but rather are health goals that are based solely on considerations of protecting the public from adverse health effects of drinking water contamination.

EPA also establishes National Secondary Drinking Water Regulations (NSDWR's), consisting of secondary maximum contaminant levels (SMCL's) under the SDWA. SMCL's are established to control water color, odor, appearance, and other characteristics affecting consumer acceptance of drinking water. NSDWR's are not federally enforceable but are considered to be guidelines for the States (section 1401(2) of the SDWA).

EPA has established MCLG's of zero and 1.3 mg/L for lead and copper, respectively (56 FR 26460, June 7, 1991). The MCLG for lead was based upon: (1) The occurrence of a variety of low level health effects for which it is currently difficult to identify clear threshold exposure levels below which these effects do not occur, (2) EPA's policy that drinking water should contribute minimal lead to total lead exposures because a substantial portion of the sensitive population already exceeds acceptable blood lead levels, and (3) EPA's classification of lead as a probable human carcinogen. The MCLG for copper was based upon the protection of the public from gastrointestinal effects such as nausea and diarrhea resulting from acute exposure to copper.

However, EPA concluded that setting MCL's for lead and copper would not be feasible under the SDWA because such action could result in a large number of public water systems being out of compliance with these levels because of circumstances beyond the direct control of the system, e.g., corrosion in service lines not owned by the system and in the plumbing of residences and buildings. Instead, EPA chose to establish treatment technique requirements rather than MCL's as the enforceable standards for achieving the objective of the SDWA (i.e., reducing consumers' exposure to drinking water contaminants to the maximum extent feasible) because it found treatment techniques to be more appropriate when contamination was largely the result of circumstances beyond the direct control of the system (56 FR 26460 at 26477

EPA's treatment technique requirements consist of corrosion control, source water treatment, lead service line replacement, and public education. These requirements are triggered in large part if the 90th percentile lead or copper levels of the targeted tap water samples exceed 0.015 mg/L for lead and 1.3 mg/L for copper (except that large systems may be required to install optimal corrosion control even if initial levels at the tap do not exceed these trigger levels). In its final rule, EPA noted that its trigger level for lead of 0.015 mg/L at the 90th percentile corresponds to an average level of 0.005 mg/L lead in water, is associated with substantial public health protection, and is expected to trigger treatment among large numbers of systems nationwide, thereby substantially reducing public exposure to lead from drinking water.

III. Reorganization of Quality Standard for Chemical Contaminants

EPA's drinking water regulations promulgated under the SDWA are extensive and address several distinct types of chemical contaminants in drinking water. To facilitate the understanding and use of § 103.35 (21 CFR 103.35) after FDA makes the anticipated extensive amendments to this regulation in response to EPA rulemakings, FDA, in a final rule establishing allowable levels for seven volatile organic chemicals (VOC's) published elsewhere in this issue of the **Federal Register**, has reorganized § 103.35(d) (the paragraph of the bottled water quality standard that contains allowable levels for individual chemical contaminants) by listing levels for chemical contaminants established pursuant to section 410 of the act in new § 103.35(d)(3), which is divided to reflect the different categories of chemical contaminants addressed by EPA in regulations. Specifically, § 103.35(d)(3) contains: (1) The allowable levels for inorganic chemicals in § 103.35(d)(3)(i); (2) the allowable levels for VOC's in paragraph (d)(3)(ii); (3) the allowable levels for pesticides and other synthetic organic chemicals in paragraph (d)(3)(iii); and (4) the allowable levels for chemicals for which EPA has established SMCL's in paragraph (d)(3)(iv). In addition, § 103.35(d)(3)(v) through (d)(3)(vii) contains provisions concerning analytical methodology to be used in determining compliance with the allowable levels. The amendments to the bottled water quality standard that FDA is proposing in this document follow the reorganized format for § 103.35(d).

IV. FDA Proposal

A. Agency Approach to Bottled Water Quality Standards Established Under Section 410 of the Act

Under section 401 of the act (21 U.S.C. 341), the agency may promulgate a regulation establishing a standard of quality for a food under its common or usual name, when in the judgment of the agency such action will promote honesty and fair dealing in the interest of consumers. The current quality standard for bottled water is set forth in § 103.35. Producers of bottled water are responsible for assuring, through appropriate manufacturing techniques and sufficient quality control procedures, that all bottled water products introduced or delivered for introduction into interstate commerce comply with the quality standard. Bottled water that is of a quality that is below the prescribed standard is required by § 103.35(f) to be labeled with a statement of substandard quality. Moreover, any bottled water containing a substance at a level that causes the food to be adulterated under section 402 of the act (21 U.S.C. 342) is subject to regulatory action, even if the bottled water bears a label statement of substandard quality.

FDA has traditionally fulfilled its obligation under section 410 of the act to respond to EPA's issuance of NPDWR's by amending the quality standard regulations for bottled water introduced or delivered for introduction into interstate commerce to maintain compatibility with EPA's drinking water regulations. In general, FDA believes that EPA's standards for chemical contaminants in drinking water are appropriate as allowable levels for chemicals in the quality standard for bottled water when bottled water may be expected to contain the same contaminants.

FDA proposals that respond to EPA rulemaking under the SDWA generally have not duplicated the efforts of EPA in judging the adequacy of NPDWR's for the protection of the public health, nor have they duplicated EPA's efforts in judging the adequacy of NSDWR's for control of other characteristics affecting consumer acceptance of drinking water. FDA does not intend to change this approach. Because bottled water is increasingly used in some households as a replacement for tap water, consumption patterns considered by EPA for tap water can be used as a conservative estimate for the maximum expected consumption of bottled water. In cases where bottled water is subject to the same source contaminants as tap water (e.g., when obtained from the same sources used by public water systems), allowable levels for contaminants to ensure the safety of bottled water, and levels to ensure its aesthetic quality, should normally correspond to the levels set by EPA as the NPDWR's and NSDWR's for tap water. Therefore, FDA intends to rely on EPA's determinations that the MCL's or treatment technique requirements are adequate to protect the public health, and that the SMCL's are adequate to control other quality defects such as those of an aesthetic nature. In most cases, FDA will adopt EPA's MCL's and SMCL's as quality standards for bottled water. Furthermore, FDA intends to rely, in most cases, on EPA's determinations as to the appropriate analytical methods for testing for these contaminants in water and to incorporate those methods by reference in proposed amendments of its quality standard for bottled water (56 FR 3526, January 30, 1991; 54 FR 22062, May 22, 1989; 52 FR 25690, July 8, 1987; 52 FR 12876, April 17, 1987; 50 FR 46902, November 13, 1985).

FDA will, however, make its own determination as to whether it is appropriate to have an allowable level in the quality standard for bottled water for a chemical for which EPA has promulgated an NPDWR and, assuming that establishing an allowable level is appropriate, as to what amount it should be. For example, when EPA establishes or revises an NPDWR for a particular contaminant, FDA will consider whether the contaminant is present in the source water or is added as a result of the production or distribution of the bottled water. If the contaminant is present in the source water, when FDA establishes a quality standard for the contaminant, it will consider whether the contaminant is likely to be removed during bottled water processing. Further, if the presence of a contaminant in tap water is the result of circumstances peculiar to public water systems, for example, lead derived from service lines, plumbing pipes, solder, or fixtures encountered in drinking water distribution systems, and if it can be avoided by bottlers, FDA may decide to propose a lower allowable level than the MCL for that contaminant.

B. Quality Standards for Lead and Copper

The current quality standard for bottled water as set forth in § 103.35 prescribes that bottled water shall not contain lead in excess of 0.05 mg/L and shall not contain copper in excess of 1.0 mg/L. FDA has reviewed these levels in light of EPA's recent action.

1. Lead

FDA has evaluated the NPDWR that EPA has promulgated for controlling lead contamination in public drinking water and has tentatively decided not to adopt the trigger level at which EPA requires initiation of treatments, 0.015 mg/L, as an allowable level for lead in bottled water.

The EPA treatment technique requirements, which seek to attain a level of lead in public drinking water as close to the MCLG of zero as is feasible, are primarily intended to control the significant lead contamination that can occur in public water distribution systems because of corrosion of lead containing materials such as service lines, pipes, solder, and fixtures. However, EPA stated that source waters generally contain much less than 0.015 mg/L of lead. In fact, EPA estimates that only 1 percent of all public water systems have lead levels in their source water exceeding 0.005 mg/L.

In a 1990 survey of bottled water conducted by FDA (Ref. 1), 48 domestic and 58 imported bottled water samples were analyzed for their lead content using a method with a practical quantitation limit of 0.005 mg/L. The results revealed that the average lead level was substantially below 0.005 mg/L, with only eight samples (two domestic and six imported) above 0.005 mg/L. FDA's 1990 bottled water survey was limited in scope and was not designed to obtain results that are statistically representative of the entire bottled water industry. Nevertheless, FDA believes that the survey evidences that bottlers are generally using sources of water that are free of significant lead contamination. Thus, FDA tentatively concludes that it is both reasonable and desirable, for quality as well as for public health purposes, to establish a standard that ensures that bottlers will continue to use sources of water that are free of significant lead contamination. FDA requests comments on whether bottlers can readily produce bottled water with lead levels below the proposed allowable level of 0.005 mg/L, or whether bottlers will experience undue hardship in complying with the proposed standard. If the comments provide convincing evidence that complying with the proposed allowable level for lead in bottled water will cause undue hardship for bottlers, the agency may then consider establishing a higher allowable level for lead in its final rule. FDA requests comments on what that higher level should be.

When FDA proposes to establish a quality standard for a chemical contaminant, as a practical matter, it must also consider the reliable quantitation capabilities of the methods it proposes to use for determining compliance with the standard. FDA concurs with EPA (56 FR 26460, June 7, 1991) that the best methods available for the determination of lead in water have 0.005 mg/L as their practical quantitation limit (Ref. 2). Thus 0.005 mg/L is the lowest level at which FDA could enforce an allowable level for lead in bottled water. FDA believes that a quality standard specifying that the concentration of lead in bottled water shall not exceed 0.005 mg/L would be appropriate because it would provide public health protection at least equivalent to that provided by EPA's NPDWR and ensure that bottlers produce water that is free of significant lead contamination. Therefore, FDA is proposing in § 103.35(d)(3)(i) to establish 0.005 mg/L as the allowable level for lead in bottled water.

2. Copper

As noted above, the current allowable level for copper in bottled water is 1.0 mg/L. In addition, EPA has established a SMCL for copper in 40 CFR 143.3 of 1.0 mg/L (44 FR 42198, July 19, 1979). Therefore, FDA's existing allowable level for copper in bottled water is below EPA's MCLG for this contaminant of 1.3 mg/L and is equivalent to EPA's SMCL. On the basis of EPA's MCLG of 1.3 mg/L (which constitutes a level that will protect the public from adverse health effects with an adequate margin of safety) and its SMCL of 1.0 mg/L (which constitutes a level that will protect the public from aesthetic defects), FDA tentatively concludes that it will retain the existing allowable level for copper in bottled water of 1.0 mg/L. By doing so, the levels of copper in bottled water will meet both the safety and aesthetic criteria that EPA has established for public drinking water. However, FDA will move the existing quality standard for copper from § 103.35(d)(1) to § 103.35(d)(3)(i), consistent with the reorganization of § 103.35 discussed above.

3. Analytical Methods for Lead and Copper

In its final NPDWR's for lead and copper, EPA provided in 40 CFR 141.89 that analyses for these contaminants in drinking water shall be performed by any of three basic methods that it judged to be suitable for the analysis of lead, and by any of five basic methods that it judged to be suitable for the analysis of copper. FDA concurs that the eight analytical methods cited by EPA (56 FR 26460 at 26510, June 7, 1991) are appropriate for the analysis of lead and copper in water, and it has incorporated the versions of these methods that are available through EPA in the proposed rule for testing for these contaminants in bottled water. Thus, when conducting analyses for compliance purposes, FDA may use any of the incorporated methods.

C. Informal Rulemaking Procedure

In the past, bottled water quality standard rulemakings have been subject to the formal rulemaking procedure in section 701(e) of the act (21 U.S.C. 371(e)). However, the Nutrition Labeling and Education Act of 1990, enacted November 8, 1990, removed standard of quality rulemakings from the coverage of that section. FDA is therefore proposing these amendments to the quality standards under section 701(a) of the act, which involves notice and comment rulemaking.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA FY 90 Bottled Water Survey, 1990.

2. FDA internal memorandum of meeting, Discussions on the Analytical Methods for Determination of Lead in Bottled Water, December 26, 1991.

3. "Twenty Questions Concerning Bottled Water," International Bottled Water Association, 1990.

VI. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VII. Economic Impact

FDA has examined the economic implications of the proposed rule amending 21 CFR part 103 as required by the Regulatory Flexibility Act and Executive Orders 12291 and 12612. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking and Executive Order 12612 requires Federal agencies to

ensure that Federal solutions, rather than State or local solutions, are necessary. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because this proposed regulation applies to food for interstate trade, and because State regulations would hinder interstate trade, FDA finds that there is no substantial federalism issue which would require an analysis under Executive Order 12612.

A. Costs

FDA's proposal to retain the existing quality standard for copper in bottled water has little economic impact on the bottled water industry because no change in processing will be needed to meet the existing quality standard. Therefore, the remainder of this economic assessment will focus on the potential economic impact of the proposal to amend the quality standard for lead in bottled water.

FDA believes that the costs of meeting the proposed allowable level of 0.005 mg/L for lead in bottled water will be minimal because most bottled waters (excluding mineral water) already meet the proposed allowable level. Approximately 75 percent of domestic bottled water is produced from private water sources (Ref. 3). Such sources are protected and are not exposed to distribution systems (such as residential plumbing) which are the major source for lead contamination in public drinking water. FDA data from the 1990 bottled water survey (Ref. 1) showed that approximately 4 percent of domestic bottled water (excluding mineral water) samples exceeded the proposed limit of 0.005 mg/L.

If this proposal becomes a final rule, bottlers will be required to test each lot of bottled water to ensure that their respective lead levels are below 0.005 mg/L. Testing and treatment is currently being conducted by most of the industry in order to meet present FDA standards. Thus, it is likely that the incremental testing cost required by this proposed rule would be incurred by a relatively small proportion of the industry.

B. International Impact

According to data from the International Bottled Water Association, the 75 brands of imported bottled water are mostly mineral water and constitute only 3.6 percent of all bottled water consumed in the United States. Mineral water is not subject to this proposed quality standard. Thus, imported water will not be considered in this analysis.

C. Benefits

FDA has no information to quantify the benefits of this proposed regulation. However, as the costs are minimal, FDA expects that benefits, which are also small, will be greater than costs.

D. Summary

FDA has determined that this proposed rule is not a major rule as defined by Executive Order 12291. Little additional costs are expected from establishing a maximum allowable level of 0.005 mg/L for lead in bottled water. Although FDA is not able to quantify the benefits of this regulation, benefits are expected to exceed costs.

VIII. Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. Effective Date

The agency is proposing to make any final rule based on this proposal effective 180 days following the date of publication of the final rule in the **Federal Register**. The agency is providing this time period to permit affected firms adequate time to take appropriate steps to bring their product into compliance with the standard imposed by the new rule. The agency is requesting comments on the proposed effective date. All comments concerning the effective date should be accompanied by data to support or justify any change in the proposed effective date.

List of Subjects in 21 CFR Part 103

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 103 be amended as follows:

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

1. The authority citation for 21 CFR part 103 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 410, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 349, 371, 376).

2. Section 103.35 is amended by removing the entries for "Copper" and "Lead" from the table in paragraph (d)(1)(i), by adding them alphabetically to the table in paragraph (d)(3)(i) (which is proposed to be added in a document published elsewhere in this separate part), and by adding new paragraphs (d)(3)(v)(H) and (d)(3)(v)(I) to read as follows:

§ 103.35 Bottled water.

* * * * *

(d) * * *

(3) * * *

(i) The allowable levels for inorganic substances are as follows:

Contaminant	Concentration in milligrams per liter (or as specified)
* * * * *	
Copper	1.0
Lead	0.005
* * * * *	

* * * * *

(v) * * *

* * * * *

(H) Copper shall be measured as total recoverable metal without filtration using the following methods from "Methods of Chemical Analysis of Water and Wastes."

(*1*) Method 220.2—Atomic absorption; furnace technique.

(*2*) Method 220.1—Atomic absorption; direct aspiration.

(*3*) Method 200.7—Inductively coupled plasma, with "Determination of Metals and Trace Elements in Water and Wastes by Inductively-Coupled Plasma Atomic Emission Spectrometry," Revision 3.3, April 1991, U.S. Environmental Protection Agency, Environmental Monitoring and Support Laboratory (EMSL). The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the manual are available from U.S. Environmental Protection Agency, EMSL, Cincinnati, OH 45268, or available for inspection at the Office of

the Federal Register, 1100 L St. NW., Washington, DC.

(4) Method 200.8—Inductively coupled plasma; mass spectrometry, with "Determination of Trace Elements in Water and Wastes by Inductively-Coupled Plasma-Mass Spectrometry," Method 200.8, April 1991, Revision 4.4, U.S. Environmental Protection Agency, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the manual are available from U.S. Environmental Protection Agency, EMSL, Cincinnati, OH 45268, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(5) Method 200.9—Atomic absorption; platform furnace, with "Determination of Trace Elements in Stabilized Temperature Graphite Furnace Atomic Absorption, Spectrometry," Method 200.9, April 1991, Revision 1.2, U.S. Environmental Protection Agency, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the manual are available from U.S. EPA, EMSL, Cincinnati, OH 45268, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(l) Lead shall be measured as total recoverable metal without filtration using the following method from "Methods of Chemical Analysis of Water and Wastes."

(1) Method 239.2—Atomic absorption; furnace technique.

(2) Method 200.8—Inductively coupled plasma; mass spectrometry, with "Determination of Trace Elements in Water and Wastes by Inductively-Coupled Plasma-Mass Spectrometry," Method 200.8, April 1991, Revision 4.4, U.S. Environmental Protection Agency, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the manual are available from U.S. EPA, EMSL, Cincinnati, OH 45268, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(3) Method 200.9—Atomic absorption; platform furnace, with "Determination of Trace Elements in Stabilized Temperature Graphite Furnace Atomic Absorption, Spectrometry," Method 200.9, April 1991, Revision 1.2, U.S. Environmental Protection Agency, EMSL. The revision is contained in the manual entitled "Methods for the Determination of Metals in Environmental Samples," Office of Research and Development, Washington, DC 20460, (EPA/600/4–91/010), June 1991, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the manual are available from U.S. EPA, EMSL, Cincinnati, OH 45268, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

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Dated: April 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

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21 CFR Parts 103, 129, 165, and 184

[Docket No. 88P–0030]

Beverages: Bottled Water

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to: Establish a standard of identity for bottled water; recodify the standard of quality for bottled water; revise the definition for bottled water in the quality standard to include mineral water and ingredient uses of this product; and define "artesian water," "distilled water," "mineral water," "purified water," "spring water," and "well water." As proposed, the regulations will exempt mineral water from certain maximum allowable levels of physical and chemical contaminants if the mineral water contains total dissolved solids (TDS) in excess of 500 parts per million (ppm). These actions are being proposed, in part, in response to a petition submitted by the International Bottled Water Association (IBWA). Moreover, FDA believes that the proposed regulations will promote honesty and fair dealing in the interest of consumers, as well as the interests of the regulated industry.

DATES: Written comments by March 8, 1993. The agency is proposing that any final rule that may issue based upon this proposal become effective 180 days following the date of publication of the final rule.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5112.

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA's Regulatory Scheme

FDA regulations pertaining to bottled water appear in parts 103 and 129 (21 CFR parts 103 and 129). Section 103.35 sets forth microbiological, physical, chemical, and radiological quality standards for bottled water. In § 103.35(a)(1), "bottled water" is defined as "water that is sealed in bottles or other containers and intended for human consumption." However, specifically excluded from this definition are mineral water and any type of soft drink, including that commonly known as "soda water," that is made by absorbing carbon dioxide into potable water.

Generally, the bottled water quality standards, where practicable, follow the Environmental Protection Agency's (EPA's) requirements for drinking water. Section 410 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 349) obligates FDA, whenever EPA prescribes interim or revised national primary drinking water regulations under section 1412 of the Public Health Service Act (the Safe Drinking Water Act (42 U.S.C. 300f through 300j–9)), to consult with EPA concerning those regulations. In 21 U.S.C. 349, the act further requires that within 180 days after EPA promulgates the drinking water regulations, FDA either promulgate amendments to its regulations applicable to bottled water or publish in the **Federal Register** its reasons for not amending the regulations. To comply with 21 U.S.C. 349, FDA reviews new EPA regulations and determines whether the new or revised primary drinking water regulations (issued by EPA as maximum contaminant levels (MCL's) or treatment

technology regulations) can be incorporated into FDA's quality standards without further modification.

Part 129 contains current good manufacturing practice (CGMP) requirements for the processing and bottling of "bottled drinking water." In § 129.3(b), FDA defines bottled drinking water to include "all water which is sealed in bottles, packages, or other containers and offered for sale for human consumption, including [in a departure from § 103.35(a)(1)] bottled mineral water." (Emphasis added.)

B. The International Bottled Water Association Petition

On January 20, 1988, IBWA submitted a petition under § 10.30 (21 CFR 10.30), requesting that FDA revise the standards of quality for bottled water in § 103.35 and the bottled water CGMP regulations in part 129 to expand the scope of these regulations to include mineral water in the standards of quality and to more closely regulate the labeling, production, and distribution of bottled water. IBWA subsequently amended its petition through submissions of March 25, 1988, September 12, 1990, and May 17, 1991. (The IBWA petition and its supplements will hereinafter be referred to as "the IBWA petition.")

At the time that IBWA submitted its petition, the quality standards for bottled water were subject to the formal rulemaking procedures of section 701(e) of the act (21 U.S.C. 371(e)). However, in November of 1990, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) was signed into law. The 1990 amendments removed rulemaking under the authority of section 401 of the act (21 U.S.C. 341), including standards of quality, from the procedural requirements of 21 U.S.C. 371(e) with the exception of rulemaking for the amendment or repeal of food standards of identity for dairy products or maple syrup. Therefore, any action on the IBWA petition is subject to informal, notice and comment rulemaking under 21 U.S.C. 371(a) instead of the formal rulemaking procedures of 21 U.S.C. 371(e).

FDA has completed a thorough review of the IBWA petition in accordance with 21 CFR part 10 and has reached a number of tentative conclusions concerning the requested revisions of agency regulations. A complete discussion of the requested revisions and the agency's tentative conclusions follow.

II. The Standard of Identity

A. Justification

In its petition, IBWA requested that FDA amend the standard of quality for bottled water in § 103.35 to include mineral water and to provide definitions for "artesian water," "distilled water," "mineral water," "purified water," "spring water," and "well water." IBWA stated that given the steady increases in the types and brands of bottled drinking water, the American public should be made aware of the various distinctions in the types of bottled water. It stated that labels complying with precise definitions for bottle contents would foster public awareness. IBWA stated that the public deserves to be able to make an informed decision regarding the purchase of bottled drinking water.

On January 6, 1989 (54 FR 398), FDA published a final rule repealing the soda water standard of identity. In response to a comment that requested that FDA amend § 103.35 to include definitions for "carbonated spring water," "artesian water," and "mineral water" as a means of distinguishing various bottled waters, FDA stated:

> The agency does not believe it necessary to include definitions for bottled waters from various water sources and produced by different treatments in the standard of quality for bottled water at this time. Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) provides that a food will be deemed to be misbranded if its labeling is false or misleading in any particular. Accordingly, if a manufacturer decides to provide information in the labeling regarding the source of the water or special treatment that the water has received, such information must be truthful, factual, and not misleading in any respect. For example, a product labeled "carbonated spring water" would have to have been obtained from a spring and had carbonation added in some form. FDA concludes that existing statutory authority is sufficient to provide for regulatory action in instances where false and misleading statements concerning the source or treatment of the bottled water are made, and that it is not necessary to include specific statements to this effect in § 103.35.

However, FDA no longer believes that the position in this comment is appropriate. Based on the information that has become available to it over the last 3 years, FDA has tentatively concluded that it will promote honesty and fair dealing in the interest of consumers, as well as the interests of the regulated industry, if the agency adopts a standard of identity for bottled water as well as definitions for the various types of bottled water products.

FDA recognizes that standards of identity are often viewed as discouraging innovation. However, as discussed in greater detail below, a number of States have established differing labeling definitions for bottled water. A Federal standard of identity would provide a uniform definition for bottled water products, and it would provide an established framework in which innovation could occur. Thus, given the current state of the regulation of bottled water, the agency finds that innovation is more likely if the agency acts in the way that it is proposing than if the current situation is allowed to persist.

FDA's tentative conclusion is based in part on several reports that it has received. The first is a report from the Food and Nutrition Board of the Institute of Medicine, National Academy of Sciences (IOM). In response to section 6 of the 1990 amendments, FDA contracted with IOM to conduct a study of State and local laws that require food labeling of the type required by certain misbranding provisions of the act. The study was to consider whether FDA has adequately implemented these sections. After an information-gathering process that included a public meeting, requests to the States, and communications with several organizations representing food and drug officials, IOM issued a report (Ref. 1).

This report noted that the Attorneys General of 7 States (California, Iowa, Minnesota, Missouri, New York, Texas, and Wisconsin) suggested in their submission to the IOM that States often respond to the public's needs well in advance of the Federal government. They stated that the States' actions ultimately stimulate the Federal government to act and provide a template for any national standard. One of the examples cited by the Attorneys General of matters on which the States have provided leadership was the labeling of bottled water.

In communications with IOM during the preparation of the report, a number of States expressed discontent with FDA's inaction in the face of false and misleading labeling claims for bottled water products. IOM reported that a total of 23 States have expressed their dissatisfaction with FDA's regulation of bottled water by adopting laws or regulations to provide additional controls. While these State laws vary, one of the main problems that they address is the nomenclature for various types of bottled water. For example, nearly half the States have established definitions for the different types of bottled and mineral water on the market.

IOM also reported that many States expressed particular concern that the

opportunity for public confusion has been increased by virtue of the increased number of products on the market and the increasingly aggressive claims made for these products. For example, even though FDA stated in the **Federal Register** of January 8, 1973 (38 FR 1019), that bottled water was not any better or purer than tap water, and that there is reason to believe that this is still the case, IOM found that it is questionable whether that view is held by consumers after years of exposure to advertising that claimed superiority for bottled and mineral water.

Thus, the IOM has described a situation in which in response to proliferating claims and statements on bottled water, the States are responding with proliferating regulations. In such a situation, the possibility of inconsistent State regulation grows, and the IBWA petition makes clear that such inconsistency is in fact what has occurred.

The bottled water industry has stated that there is a need for uniform labeling standards to prevent or eliminate inconsistent State labeling requirements that significantly limit interstate commerce in bottled water (Ref. 2). For example, North Carolina (Ref. 3) defines "spring water" as water taken from "a natural orifice in the earth's surface through which water freely flows without the aid of mechanical means." California (Ref. 4), on the other hand, defines "spring water" as water that issues by natural forces out of the earth at a particular place. According to the California definition, however, spring water may be derived from the natural orifice or from a bore hole adjacent to the natural orifice. Therefore, water collected from a bore hole adjacent to the spring could be called "spring water" in California but could not be called "spring water" in North Carolina.

FDA has received comments from bottled water manufacturers who are not members of IBWA that urge the agency to enact labeling requirements for bottled water (Refs. 5 and 6) that will supersede State requirements. One of these manufacturers stated that it spent approximately $80,000 for label changes in 1990 because of requests from various States concerning labeling requirements (Ref. 6).

The bottled water segment of the beverage industry is growing at a strong pace. In 1981, bottled water had a comparative market share of 1.8 percent. In 1991, the comparative market share had tripled to 5.4 percent. In 1981, the per capita consumption of bottled water did not exceed that of juices, tea, or powdered drinks. However, in 1991, bottled water consumption exceeded that of each of these drinks (Ref. 7).

The agency realizes that there is an increasing number of bottled water products on the market, and that the labels on these products may be misleading to consumers (Ref. 8). FDA also realizes that there may be a significant difference in price for bottled water products depending on the representations made or implied by the product labeling. Often marketing and advertising associated with bottled water suggest that the "water comes from a tranquil, distant, utopian source" (Ref. 9). For example, a picture of a blue-green mountain spring on a label of a bottled water product may indicate to consumers that the water comes from a mountain spring. Such a label is misleading to consumers if the water actually comes from the municipal water supply of an urban area located far from any mountains.

Therefore, FDA agrees that there is a need to define the various types of bottled water products because such information is of material interest to consumers. FDA tentatively concludes that defining the bottled water sources, as IBWA requested in its petition, will provide a definition and standard of identity for bottled water products that will promote honesty and fair dealing in the interest of consumers.

For the reasons set forth above, FDA tentatively concludes that the different State requirements for labeling and testing bottled water impose a significant burden on interstate commerce. A uniform Federal definition will ensure that consumers will be able to purchase bottled water products that are informatively and consistently labeled throughout the country. Therefore, FDA is proposing to establish a standard of identity for bottled water in proposed § 165.110(a). Under the 1990 amendments, such a standard will preempt any State standards that are not identical to it (21 U.S.C. 343A(a)(1)).

Section 103.5(c) (21 CFR 103.5(c)) of FDA's regulations states that should a standard of identity be established for any of the foods defined by a standard of quality in Part 103, the standard of quality will be recodified to appear in the same part of the regulations as the standard of identity. Therefore, the agency is proposing to move the standard of quality for bottled water from § 103.35 to proposed § 165.110.

B. Coverage

The common or usual name of a food that has been defined by a standard of identity under 21 U.S.C. 341 is the name prescribed by the standard. Whenever an ingredient in a food purports to be a standardized food, the ingredient must conform to the standard of identity even though the finished food is not a standardized product (21 U.S.C. 343(g)). In addition, if a standard of quality exists for a food, the food also must conform to that quality standard when used as an ingredient or must be labeled as substandard (21 U.S.C. 343(h)).

Specialty waters are significant ingredients in some types of beverages such as flavored waters and diluted juice drinks. For example, there are numerous flavored water products that claim to use spring or mineral water as the water ingredient and that include this information on their label. Other beverages are labeled to indicate that the water ingredient possesses a specific characteristic or has received a specific treatment (e.g., "sparkling" water).

FDA believes that highlighting the water component of these products in this manner is effectively a claim that the water ingredient in the beverage has particular value, and that consumers are likely to purchase these beverages in large measure because of the claim concerning the water ingredient. Therefore, these products should be treated as part of the general category of bottled water products, and the quality of the water ingredient in these beverages should be at least as good as the quality of bottled water. Consequently, FDA is proposing to include water used as an ingredient in these types of beverages (e.g., flavored bottled waters) in the definition for "bottled water" (proposed § 165.110(a)(1)).

The same type of claim is not made, however, on beverages labeled as containing "carbonated water," "seltzer water," "soda water," and "tonic water." These beverages have historically been considered to be soft drinks and not bottled water. Moreover, labels of foods that claim to contain "water" as an ingredient do not claim or imply any particular properties or characteristics for that ingredient.

Use of the terms "disinfected" and "filtered" in describing the water ingredient in beverages also does not imply any particular characteristic of the water other than that it has been subjected to a commonly used treatment. Municipal water is subject to these processes. Therefore, FDA tentatively concludes that consumers understand that these terms do not make a special claim about the water ingredient, and that they will not confuse water described in these ways with bottled water.

Accordingly, FDA is proposing in § 165.110(a)(1) to exempt an ingredient from the definition of bottled water if it

is declared in the ingredient listing using the terms "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," or "tonic water." FDA is requesting comments from interested persons concerning the appropriateness of the proposed exemption, and whether there are other water ingredients that should also be exempted.

C. Mineral Water

1. Inclusion of Mineral Water in the Coverage of the Standard of Identity

In the **Federal Register** of January 8, 1973 (38 FR 1019), FDA published a proposed rule to establish bottled water quality standards. In that proposal, FDA defined "bottled water" as water that is sealed in bottles or other containers and intended for human consumption but excluded mineral water and soda water from the definition. FDA received several comments in response to the proposal suggesting that the standard of quality should also apply to bottled mineral water. The agency concluded in the final rule (38 FR 32558, November 26, 1973) that mineral water was a product inherently different from bottled water. FDA stated that it intended to develop a separate standard of quality for mineral water. However, the agency has not issued such a standard.

IBWA requested in its petition that the definition for "bottled water" in § 103.35(a)(1) be amended to delete the exemption for mineral water.

FDA believes that the significance of the differences between water subject to the provisions of the quality standards and mineral water has been lessened by the wide diversity of the mineral water products that are now found in the marketplace. Bottled water and mineral water may be displayed for sale side by side, and water with lower mineral content than many tap waters is sometimes labeled as "mineral water." In recent years, the production of bottled mineral water has so dramatically increased that the agency believes that this product may be replacing tap water consumption for some consumers. In response to increased marketing of bottled mineral water products, many States have established definitions for "mineral water."

Accordingly, FDA has tentatively concluded that mineral water should be included in the standard for bottled water. Including mineral water in the standard for bottled water will subject it to the requirements of the quality standard for bottled water. FDA is proposing to delete the exclusion for mineral water from the definition of "bottled water" in § 165.110(a)(1).

FDA is proposing this action because mineral water is now being as widely consumed as other bottled waters. This action will ensure that consumers who drink mineral water will be afforded the same level of protection as those who drink other bottled water products or tap water. If the mineral water is substandard, that information will be presented on the label of the product, just as it is presented on the label of other bottled water products if they are substandard. Therefore, FDA tentatively finds that it will promote honesty and fair dealing in the interest of consumers to include mineral water in the definition for "bottled water."

2. Definition of Mineral Water

FDA has also tentatively decided to define "mineral water."

IBWA originally defined "mineral water" in its January 20, 1988, petition as bottled water that contains not less than 500 ppm TDS. In an amendment to its petition, dated May 17, 1991, IBWA redefined "mineral water" as bottled water coming from an approved source tapped at one or more bore holes or natural springs, originating from a geologically and physically protected underground water source. IBWA stated that the definition of "mineral water" should provide that it is clearly distinguishable from other types of water because of the constant level of minerals and trace elements in the water as it emerges from its source. However, IBWA did not include a minimum mineral content in its amended definition.

The European Regional Codex Standard (Ref. 10) defines "natural mineral water" as a water clearly distinguishable from ordinary drinking water because

(1) It is characterized by its content of certain mineral salts and their relative proportions and by the presence of trace elements or of other constituents;

(2) It is obtained directly from natural or drilled sources from underground water bearing strata;

(3) Of the constancy of its composition, the stability of its discharge, and its temperature, due account being taken of the cycles of natural fluctuations;

(4) It is collected under conditions that guarantee the original bacteriological purity;

(5) It is bottled close to the point of emergence of the source with particular hygienic precautions;

(6) It is not subjected to any treatment other than that permitted by the standard; and

(7) It is in conformity with all the provisions laid down in the standard.

Several States have adopted standards for mineral water. For example, Texas' standard (Ref. 11) states that mineral water is not derived from a public system and is unmodified by blending with water from another source or by mineral addition or deletion, except as it relates to ozonation or equivalent disinfection and filtration. Texas' standard does not include a minimum mineral content.

California (Ref. 4) defines "mineral water" as containing more than 500 ppm TDS and originating entirely from an underground source, which may be a well, artesian well, or spring. California regulations further state that mineral water may not be altered by the addition or deletion of minerals or by blending with water from another source, except that mineral water may be filtered and shall be treated with ozone or an equivalent disinfection process approved by the appropriate regulatory agency.

The Association of Food and Drug Officials (AFDO) (Ref. 12) defines "mineral water" as water that is impregnated with mineral solids and that has been obtained entirely from an approved source. AFDO has defined "light mineral water" as containing not less than 250 ppm nor more than 500 ppm of dissolved solids and "mineral water" as containing not less than 500 ppm of dissolved mineral solids. AFDO defines "mineralized water" as water that meets the requirements for mineral water, except that the water contains added mineral solids.

FDA received several comments on the IBWA petition that maintained that the originally suggested level of 500 ppm TDS would be inappropriate because there are many mineral waters being marketed that have less than 500 ppm TDS. The comments maintained that these waters should not be prohibited from using the term "mineral water" in their statements of identity. One comment discussed various classifications of mineral water using the following criteria: (1) Up to 500 ppm for "mineral light," (2) 500 to 1,000 ppm for "mineral water," and (3) 1,000 ppm and up for "heavy mineral water." The European Community (Ref. 13) has adopted the following labeling criteria: (1) Low mineral content—mineral salt content not greater than 500 ppm; (2) very low mineral content—mineral salt content not greater than 50 ppm; and (3) rich in mineral salts—mineral salt content greater than 1,500 ppm.

Mineral waters may have very different flavors depending on the mineral content and types of minerals

and trace elements present in the water (Ref. 14). Consumers may purchase a particular mineral water from a particular source because of the flavor contributed by the mineral content. It is important to consumers that the mineral content (e.g., flavor) of a particular source remain constant. Most international and State regulations concerning mineral water require that it come from an underground source, such as a spring or a well, and that it have a fairly stable mineral composition characteristic of the source. Based on these definitions, FDA considers that industry and consumers have come to expect that mineral water is from an underground source and has a fairly stable mineral composition. In addition, the IBWA definition for mineral water is to a large extent a geological definition.

FDA tentatively concludes that the IBWA amended definition for mineral water has merit, in part, because this definition (1) is what industry and consumers have come to expect in a product called "mineral water;" (2) agrees with other established definitions for mineral water (e.g., Texas' standard, the European Regional Codex Standard); (3) will not hinder international trade; and (4) will not exclude all water containing less than 500 ppm TDS that is currently being marketed as mineral water. Therefore, FDA is proposing in § 165.110(a)(2)(ii) that water coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source, may be called "mineral water." FDA is further proposing in § 165.110(a)(2)(ii) that mineral water shall be distinguished from other types of water by its constant level of minerals and trace elements in the water as it emerges from its source.

All water contains some minerals unless it has been demineralized (Ref. 14). Thus, the agency surmises that consumers expect that a product identified as "mineral water" would contain a minimum level of minerals. As mentioned above, consumers may purchase a particular mineral water because of the flavor contributed by the mineral content. Therefore, FDA tentatively concludes that it would be contradictory for bottled water that has essentially no minerals and does not perform (e.g., taste) like mineral water to be labeled as mineral water. Consistent with this tentative conclusion, FDA is proposing in § 165.110(a)(2)(ii) that "mineral water" be defined as water containing not less than 250 ppm TDS. This level is in agreement with the AFDO definition (Ref. 12) for light mineral water and mineral water.

FDA is requesting comments on the proposed minimum level of 250 ppm TDS in mineral water. If FDA receives substantive data to support another minimum level, it will consider issuing a final rule with a different minimum level.

3. Mineral Content of Mineral Water

IBWA stated in its May 17, 1991, amendment to its petition that the TDS of mineral water should appear on a label of the bottle and be stated in milligrams per liter (mg/L).

FDA does not object to the optional label declaration of TDS because FDA believes that such information is useful to some consumers. However, many consumers may not understand the relevance of a specific TDS (Ref. 14). Therefore, FDA tentatively concludes that there is no substantive basis on which to require that this information appear on the label.

Because FDA is proposing a definition of mineral water that provides for a wide range of mineral contents of mineral water, and because the mineral content can change the character of the product by affecting the flavor and therefore the use of mineral water by consumers, FDA tentatively concludes that the listing of relative mineral content is useful to consumers to characterize a given mineral water product.

As discussed above, most definitions of "mineral water" describe mineral water that contains less than 500 ppm TDS as being low in mineral content. Therefore, to ensure that consumers are not misled as to the characteristics of the mineral water, FDA is proposing in § 165.110(a)(3)(i) to require that if the TDS is below 500 ppm, the statement "low mineral content" appear on the label.

A mineral content of more than 1,500 ppm greatly affects the flavor of the water. This level is consistent with the European Community definition of "mineral water—rich in mineral salts" (Ref. 13) and will not hinder international trade. Therefore, to ensure that consumers know that the product that they are purchasing is high in mineral content, FDA is also proposing in § 165.110(a)(3)(i) to require that the label of mineral water containing more than 1,500 ppm TDS include the statement "high mineral content."

FDA is not proposing to define the term "light" or other descriptive terms other than "low" and "high" as they apply to mineral water at this time. In the Federal Register of November 27, 1991 (56 FR 60421 at 60450), FDA stated that because of the potential for misuse of the term "light," its tentative view is that use of the term must be limited to foods that, compared to other products in their class, contribute substantially to the reduction of calories and, in certain circumstances, fat in the diet. Use of the term "light" on mineral water would refer to the mineral content and not to a reduction in calories. Use of this term with respect to mineral water could be confusing to consumers if, for example, the mineral water is used as an ingredient in a beverage that would not qualify for use of the caloric descriptor (e.g., mineral water flavored with fruit juice). Therefore, FDA tentatively concludes that the use of the statements "low mineral content" or "high mineral content," as applicable, instead of using terms such as "light" will be less confusing to consumers.

Under 21 U.S.C. 343(f), FDA is proposing to require that the statement of "low" or "high" mineral content appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by consumers under customary conditions of purchase and use. To ensure that consumers will know where to find this information, the statement needs to appear in the same area of the label as the statement "mineral water." Therefore, FDA is proposing in § 165.110(a)(3)(i) to require that the statement of mineral content appear on the principal display panel following the statement of identity in type at least one-half the size of the type used for the statement of identity but in no case of less than one-sixteenth of an inch.

The agency also tentatively concludes that the information about mineral content is a material fact under section 201(n) of the act (21 U.S.C. 321(n)) because it bears on the consequences of the use of the article. The mineral content can change the character of the product by affecting the flavor and therefore the use of mineral water by consumers. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading. The product would consequently be misbranded under 21 U.S.C. 343(a). FDA is requesting comments concerning the proposed levels defining high or low mineral content.

D. Nomenclature for Other Types of Bottled Water

FDA is proposing in § 165.110(a)(2) that the name of the standardized food is "bottled water." However, as discussed previously concerning the need to establish a standard of identity for bottled water, FDA believes that certain types of bottled water need to be

defined. Therefore, in addition to "mineral water," FDA is proposing to define "artesian water," "distilled water," "purified water," "spring water," and "well water" in proposed § 165.110(a)(2). The agency has considered State regulations, international regulations, and dictionary definitions in deriving these proposed definitions. In this manner, FDA has attempted to ensure that the proposed definitions comport with consumers' understanding of these terms. Therefore, the agency views this action as one that will promote honesty and fair dealing in the interest of consumers. FDA is requesting comments from interested persons on these definitions and on other terms that need to be defined.

1. Artesian Water

The IBWA petition states that "artesian water" means bottled water from a well tapping a confined aquifer in which the water level stands above the natural table. AFDO (Ref. 12) defines "artesian water" in its model bottled water regulation as water that is forced from below the ground to the surface through a well by natural underground pressure.

The U.S. Geological Survey (USGS) (Ref. 15) defines "confined aquifers" as geological units (aquifers) completely filled with water and overlain by a confining bed that restricts the movement of water either into or out of adjacent aquifers. USGS defines "artesian wells" as wells drilled into confined aquifers where the water level stands at some height above the top of the natural water table but not necessarily above the land surface. Therefore, water obtained from a drilled well tapping a confined aquifer located 300 feet below the surface with a natural hydraulic pressure that makes the water rise in the well to 150 feet below the surface could be called "artesian water" under the geological definition.

The IBWA definition for "artesian water" is thus in agreement with the geologic definition. It is also consistent with the definitions of this type of water that have been adopted by California (Ref. 4) and by Texas (Ref. 11), but it is less restrictive than the AFDO definition. Therefore, FDA is proposing in § 165.110(a)(2)(i) that bottled water that is drawn from a well tapping a confined aquifer in which the water level stands above the natural water table may be called "artesian water."

IBWA requested in its petition that § 129.20 (21 CFR 129.20) be amended by adding provisions addressing appropriate collection procedures for artesian waters. IBWA stated that artesian water may be collected with the assistance of external force to enhance the natural underground pressure so long as such measures do not alter the physical properties, composition, and quality of the water.

FDA agrees that it may be necessary to use external force to collect the water because the water may not reach the land surface. However, use of external force can alter the physical properties, composition, and quality of the water. The water obtained would then be different from artesian water from that particular artesian well. Consequently, FDA tentatively concludes that use of external force is acceptable only so long as such measures do not change the physical properties, composition, and quality of the water.

Therefore, FDA is proposing in § 165.110(a)(2)(i) to provide for the collection of artesian water with the assistance of external force to enhance the natural underground pressure so long as such measures do not alter the physical properties, composition, and quality of the water. FDA is including this provision in the definition of "artesian water" and, therefore, finds that an amendment of § 129.20 is not needed.

2. Purified Water

The IBWA petition defines "distilled water" as bottled water that has been produced by a process of distillation and "purified water" as bottled water produced by distillation, deionization, reverse osmosis, or other suitable process. IBWA stated that both terms refer to bottled water that meets the definition of "purified water" in the most recent edition of the United States Pharmacopeia (U.S.P.) (Ref. 16). IBWA further stated that distilled water may be alternatively named "purified water."

Purified water, as defined in the 21st revision of the U.S.P. (1985), is water obtained by distillation, ion-exchange treatment, reverse osmosis, or other suitable process and contains no added substance. U.S.P. specifications for purified water include pH, chloride, sulfate, ammonia, calcium, carbon dioxide, heavy metals, oxidizable substances, total solids, and bacteriological purity.

The IBWA definition for "purified water" is consistent with that established by AFDO (Ref. 12). AFDO has not established a definition for "distilled water." The IBWA definition for "distilled water" agrees with the definition established by the State of Texas (Ref. 11).

FDA believes that the IBWA definitions have merit because they agree with established U.S.P. standards, and consumers would be assured of purchasing a water product that has in fact been purified. Therefore, FDA is proposing in § 165.110(a)(2)(iii) that water that is produced by distillation, deionization, reverse osmosis, or other suitable processes, and that meets the definition of "purified water" in the most recent edition of the U.S.P., can be "purified water." If the water is produced by distillation and meets the U.S.P. standard, alternatively it may be called "distilled water."

3. Spring Water

In its petition, IBWA stated that "spring water" is water that is derived from an underground formation from which water flows naturally to the surface of the earth. IBWA asked FDA to provide that the water may be collected through a bore hole that is adjacent to the point of emergence but also to require that the water retain all the physical properties, and be of the same composition and quality, as the water that flows naturally to the surface of the earth. IBWA also requested that § 129.20 be amended by adding provisions addressing appropriate collection procedures for spring waters.

The AFDO definition of "spring water" (Ref. 12) permits the use of a bore hole. Some States have definitions of "spring water" similar to the definition submitted by IBWA, although others do not allow the use of a bore hole adjacent to the spring to collect the water. The California definition (Ref. 4) specifically states that if spring water is derived from the natural orifice by external force or from a bore hole adjacent to the natural orifice, the water shall be from the same underground stratum and be of the same quality and composition as the water derived from the natural orifice without external force.

A typical dictionary definition of a spring is "a flow of water from the ground" (Ref. 19).

Hydrogeologists and groundwater hydrologists generally consider that springs represent a natural discharge or flow of ground water at the land surface (Ref. 17). They do not consider ground water extracted from a well or bore hole to be water from a spring. Water is subject to higher pressures and temperatures underneath the ground, and consequently its composition may be significantly altered upon emerging at the surface (Ref. 18).

FDA realizes that some bottled water manufacturers currently collect spring water through a bore hole to avoid impurities at the surface of the earth (Ref. 5). The agency recognizes that the geological definition for spring water

does not provide for use of a bore hole. However, because use of a bore hole will reduce the possibility of contamination and is an aid in the sanitary bottling of the water, FDA is proposing to permit water collected by such means to be called "spring water" as long as such measures do not change the physical properties, composition, and quality of the water. When ground water reaches the surface its environment is greatly changed. Ground water may then be exposed to oxygen, algae and other organisms, and surface water of a different composition (Ref. 18). Therefore, FDA tentatively concludes that the definition for spring water should provide for the tapping of the source in a way that will ensure sanitation. FDA is proposing in § 165.110(a)(2)(iv) that bottled water derived from an underground formation from which water flows naturally to the surface of the earth, or would flow naturally to the surface of the earth if not for its collection below the earth's surface, may be called "spring water."

IBWA stated that the bore hole must be adjacent to the spring. FDA interprets this statement to mean that the definition for spring water should allow for the tapping of the source from a point near the mouth of the spring (Ref. 20).

Some States consider water derived from an underground source through use of a bore hole as well water. Thus, to avoid confusion there is a need to distinguish spring water obtained through use of a bore hole from well water. The California (Ref. 4) definition requires that for water to be called "spring water," it must be from the same underground stratum as the water derived from the natural orifice without external force. Water obtained through a bore hole tapping a different underground stratum is not spring water because it comes from a different underground source. Water that is different in composition from the spring water that flows to the surface or would flow naturally to the surface of the earth if not for its collection below the earth's surface is not "spring water" because use of the bore hole has altered the composition of the water.

Therefore, FDA is proposing in § 165.110(a)(2)(iv) to provide for the collection of spring water only at the spring or through a bore hole adjacent to the point of emergence. FDA is also proposing in § 165.110(a)(2)(iv) that spring water collected with the assistance of a bore hole to protect the water shall be from the same underground stratum as the spring and shall retain all the physical properties, and be of the same composition and quality, as the water that flows naturally to the surface of the earth or would flow naturally to the surface of the earth if not for its collection below the earth's surface. Because FDA is including this provision in the definition of spring water, it finds that an amendment of § 129.20 is not needed. FDA is requesting comments from interested persons concerning the definition for "spring water" and on the use of a bore hole adjacent to the point of emergence of the spring to facilitate collection of the water.

4. Well Water

IBWA stated in its petition that "well water" means water from a hole bored, drilled, or otherwise constructed in the ground that taps the water of an aquifer. The AFDO (Ref. 12) definition is similar to the IBWA definition.

A typical dictionary definition of a well is a hole sunk into the earth to get water (Ref. 19). Thus, the IBWA definition is descriptive of the common meaning of well water. Therefore, FDA is proposing in § 165.110(a)(2)(v) that the name of bottled water from a hole bored, drilled, or otherwise constructed in the ground that taps the water of an aquifer may alternatively be "well water."

E. Other Label Statements

1. Water from a Municipal Supply

IBWA stated in its petition that any bottler, distributor, or vendor of bottled water whose corporate name, brand name, or trademark confains the words "spring," "well," "artesian," "mineral," or any derivative of these terms should be required to label each bottle with the type of bottled water contained in the product, in typeface at least equal to the size of the typeface of the corporate name, brand name, or trademark, if the type of the bottled water is different from the type stated or implied in the corporate name, brand name, or trademark.

FDA agrees that the use of certain corporate names, brand names, and trademarks may be misleading to consumers if the source of the water is different from the source stated or implied. In 21 U.S.C. 343(a), the act specifically states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. In addition, misleading labeling is not limited to use of the terms "artesian," "mineral," "spring," or "well" but may include other terms and vignettes as well. For example, a bottled water product labeled with a vignette showing water from a mountain spring would purport to be spring water and would be misleading unless the product met the definition for "spring water," or there was an appropriate qualifying statement that made clear that the product was not spring water.

In a significant number of situations, the labeling of products currently being marketed states or implies that the water originates from a source such as a spring or a well, when the water is actually obtained from a municipal source (Ref. 8). Such labeling is misleading.

Therefore, FDA is proposing to require in § 165.110(a)(3)(ii) that the phrase "from a municipal source" appear on the principal display panel or panels as a part of the name of the food if the water is obtained from a municipal water supply, except if the water has been treated to meet the definitions of distilled water or purified water and is labeled as such. Information about the actual source of a bottled water product is a material fact in light of the either explicit (e.g., use of terms such as "spring" or "well") or implied (the presentation of the product in a bottle) representation made by a bottled water product that it is not tap water. Information about the source of the water is necessary to ensure that consumers do not incorrectly assume that because water is sold in a bottle, it does not come from a municipal water supply.

FDA is exempting municipal water that has been treated to meet the definition of "purified" or "distilled water" and is labeled as such because consumers purchase this water because of its treatment and subsequent purity rather than because of its source. In addition, there are no significant compositional differences among purified and distilled waters, regardless of the source of the water.

Under 21 U.S.C. 343(f), FDA is proposing to require that the statement appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by consumers under customary conditions of purchase and use. FDA considers the statement as information necessary to ensure that the labeling is not misleading. To ensure that consumers will know where to find this information, the statement needs to appear in the same area of the label as the name of the food. The statement of identity is the most critical information on the package. Therefore, FDA is proposing to require in § 165.110(a)(3)(ii) that the statement "from a municipal source," appear on the principal display panel following the statement of identity in type at least one-half the size of the type in which the statement of identity appears but in no case of less than one-sixteenth of an

inch. The agency is proposing to require that the statement immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by proposed § 165.110(c).

2. Water for Infant Use

Bottled water is not free of all microorganisms unless it has been specifically treated to make it sterile and to maintain its sterility throughout its shelf-life. At this time, some bottled water products that are not sterile are being promoted for use in feeding infants. FDA conducted a limited survey of domestic bottled water manufacturers and imported bottled water products in 1990. FDA found that several firms specifically labeled their products for use in the preparation of infant formulas (Ref. 21). Other firms labeled their product as "nursery drinking water" or "infant drinking water." One firm provided a brochure indicating use of their product for "baby formulas (healthier)." The label of one imported product stated that the water "needs no filtering or sterilization," and that it was ideal for infant drinks. The label of another imported product stated that the product can be used for "baby feeding (very pure, ideal for use with powdered milk, straight from the bottle)." Analyses of this product showed a heterotrophic plate count of 8,200 organisms per milliliter (mL).

Representations of bottled water for infant use without further label instructions reasonably may be interpreted by consumers to mean that the product is ready to use in infant formula and needs no additional preparation. In fact, these products are not sterile and should be treated similarly to tap water before being used to reconstitute or dilute infant formula. Therefore, labeling that promotes bottled water products that are not sterile for infant use will misbrand the products under provisions of 21 U.S.C. 343(a)(1). Accordingly, FDA on its own initiative is proposing in § 165.110(a)(3)(iii) to require notice on the principal display panel of the bottled water products that are promoted for infant use that such products are not sterile (if such is in fact the case), and that they should be used as directed by a physician or by infant formula preparation instructions.

3. Method of Preparation of Purified Water

IBWA stated in their petition that the method of preparation of purified water should be stated on the label. As discussed above concerning the proposed definition for "purified water," purified water may be produced by distillation, deionization, reverse osmosis, or other suitable process as long as it meets U.S.P. purity specifications.

The IBWA petition did not provide any explanation for why the method of preparation should be required on the label of purified water. Although this information may be useful for some consumers, FDA tentatively concludes that there is no substantive basis on which to require that this information appear on the label. Therefore, FDA is not proposing to require that the method of preparation be stated on the label of purified water, although a manufacturer may include this information on the label if it so desires. FDA is requesting comments from interested persons on the need to include this information on the label.

III. Standard of Quality

A. General Changes

FDA is proposing to move the definition for bottled water from § 103.35(a)(1) to proposed § 165.110(a)(1). As discussed above, FDA is also proposing to move the standard of quality for bottled water from § 103.35 to proposed § 165.110. Section 103.35 will thus be recodified as follows:

Old section	New section
103.35(a)(1)	165.110(a)(1)
103.35(a)(2)	165.110(b)(1)(i)
103.35(a)(3)	165.110(b)(1)(ii)
103.35(b)	165.110(b)(2)
103.35(b)(1)	165.110(b)(2)(i)
103.35(b)(2)	165.110(b)(2)(ii)
103.35(c)	165.110(b)(3)
103.35(c)(1)	165.110(b)(3)(i)
103.35(c)(2)	165.100(b)(3)(ii)
103.35(c)(3)	165.110(b)(3)(iii)
103.35(d)(1)(i)	165.110(b)(4)(i)(A)
103.35(d)(1)(ii)	165.110(b)(4)(i)(B)
103.35(d)(2)(i)	165.110(b)(4)(ii)(A)
103.35(d)(2)(ii)	165.110(b)(4)(ii)(B)
103.35(d)(2)(iii)	165.110(b)(4)(ii)(C)
103.35(d)(2)(iv)	165.110(b)(4)(ii)(D)
103.35(d)(3)	165.110(b)(4)(iii)
103.35(d)(3)(i)	165.110(b)(4)(iii)(A)
103.35(d)(3)(ii)	165.110(b)(4)(iii)(B)
103.35(d)(3)(iii)	165.110(b)(4)(iii)(C)
103.35(d)(3)(iv)	165.110(b)(4)(iii)(D)
103.35(d)(3)(v)	165.110(b)(4)(iii)(E)
103.35(d)(3)(vi)	165.110(b)(4)(iii)(F)
103.35(d)(3)(vi)(A)	165.110(b)(4)(iii)(F)(*1*)
103.35(d)(3)(vi)(B)	165.110(b)(4)(iii)(F)(*2*)
103.35(d)(3)(vi)(C)	165.110(b)(4)(iii)(F)(*3*)
103.35(d)(3)(vi)(D)	165.110(b)(4)(iii)(F)(*4*)
103.35(d)(3)(vi)(E)	165.110(b)(4)(iii)(F)(*5*)
103.35(d)(3)(vii)	165.110(b)(4)(iii)(G)
103.35(e)(1)	165.110(b)(5)(i)
103.35(e)(1)(i)	165.110(b)(5)(i)(A)
103.35(e)(1)(ii)	165.110(b)(5)(i)(B)
103.35(e)(1)(iii)	165.110(b)(5)(i)(C)
103.35(e)(2)	165.110(b)(5)(ii)
103.35(f)	165.110(c)
103.35(f)(1)	165.110(c)(1)
103.35(f)(2)	165.110(c)(2)
103.35(f)(2)(i)	165.110(c)(2)(i)
103.35(f)(2)(ii)	165.110(c)(2)(ii) and 165.110(c)(2)(iii)
103.35(f)(2)(iii)	165.110(c)(2)(iv)
103.35(g)	165.110(d)

FDA points out that it has published (see the **Federal Register** of September 16, 1988 (53 FR 36063)) and is publishing (see elsewhere in this issue of the **Federal Register**) several proposed rules to revise the chemical and microbiological quality standards of § 103.35 to provide for establishment of new standards and updating of existing standards.

FDA advises that all water included in the definition of bottled water will be subject to the quality standard for bottled water.

Section 103.3 defines "lot," "sample," and "analytical unit," and current § 103.35 refers to these terms. Because FDA is removing the quality standard from § 103.35 and including it in proposed § 165.110, FDA believes that these terms must also be defined in proposed Part 165. Therefore, FDA is proposing to establish § 165.3 to reference definitions for the terms "lot," "sample," and "analytical unit" found in § 103.3.

B. Exemptions for Mineral Water

As discussed above, FDA is proposing that mineral water be subject to the quality standard for bottled water. However, some allowable levels in the quality standard are based on EPA secondary maximum contaminant levels (SMCL's) for color, odor, TDS, chloride, iron, manganese, sulfate, and zinc. These allowable levels were established for aesthetic reasons and not for consumer safety. Mineral water with a high mineral content may not meet the allowable levels for odor and color because of the types of minerals that may be present. For example, chloride at high levels may be undesirable organoleptically, and excess iron may precipitate, producing a brown color (Ref. 22). The agency tentatively concludes that certain aesthetically based allowable levels should not apply to waters with more than 500 ppm TDS.

Accordingly, the agency is proposing to add a footnote to the list of allowable levels in § 165.110(b)(4)(i)(A) to provide that when water is labeled as "mineral water," it will be exempt from the allowable levels for color, odor, TDS, chloride, iron, manganese, sulfate, and zinc. FDA is not proposing to include bottled waters that are not conspicuously identified with the term "mineral" or that are identified as "mineral water, low mineral content" in

this exemption because consumers will not generally expect to encounter flavors affected by high mineral content in these bottled water products.

FDA is not, however, proposing to exempt mineral water from the allowable levels for copper, fluoride, and silver. FDA proposed a revised allowable level for fluoride in the **Federal Register** of September 16, 1988 (53 FR 36063 at 36067). Elsewhere in this issue of the **Federal Register**, FDA is proposing a new allowable level for silver and is proposing to affirm its existing level for copper. The allowable levels for fluoride and silver are intended not merely to protect the flavor and color of the water but to ensure that significant adverse aesthetic effects to consumers are avoided. In the case of fluoride, FDA has proposed the allowable level to ensure that consumers are not subject to dental fluorosis (characterized chiefly by mottling of the teeth) from bottled water. In the case of silver, FDA has proposed the allowable level to prevent argyria (a discoloration of the skin). FDA believes that the quality standard for mineral water should protect consumers from any adverse effects on the body, even those that may be characterized as aesthetic.

In the **Federal Register** of June 7, 1991 (56 FR 26460), EPA published a final rule to establish a maximum contaminant level goal (MCLG) of 1.3 mg/L for copper. This value was based on short-term gastrointestinal disturbances and other acute toxic effects of copper on humans at relatively high doses (50 FR 46936 at 46968, November 13, 1985). However, as EPA stated in the final rule, the maximum copper level found in groundwater supplies "was 0.47 mg/L and the mean of the positive measurements (i.e., those exceeding the detection limit of 0.010 mg/L) was 0.075 mg/L." These values are well below the present quality standard limit of 1.0 mg/L. Therefore, FDA believes that the proposed regulation should not exempt mineral water from the existing quality standard for copper. Elsewhere in this issue of the **Federal Register**, FDA is proposing to retain the existing allowable level for copper in bottled water of 1.0 mg/L.

EPA has recently established a secondary MCL for aluminum, and FDA is proposing elsewhere in this issue of the **Federal Register** to adopt an allowable level for this chemical. If FDA establishes an allowable level for aluminum, the agency will propose to exempt mineral water (except low mineral content type mineral waters) from that standard because the standard is intended to control aesthetic properties of the water (turbidity), and not its effect on the body. However, if the agency exempts mineral water from the allowable level for aluminum, the water will still have to comply with the quality standard with respect to turbidity. FDA is not proposing at this time to exempt mineral water from the allowable level for turbidity because high turbidity may interfere with disinfection and microbiological determinations. The agency requests comment from interested persons concerning the need to establish a separate turbidity level for mineral water.

C. Substandard Chemical Quality Labeling

Current § 103.35(f)(2)(ii) permits the general phrase "Contains Excessive Chemical Substances" to be used where bottled water fails to meet an allowable level for a chemical in § 103.35(d), with a listing of the specific chemical that exceeds the allowable level being optional. However, the agency is proposing to include mineral water in the definition of bottled water and to exempt it from certain allowable levels in the quality standard when it contains more than 500 ppm TDS. Mineral water with TDS greater than 500 ppm may contain significant levels of chemical substances that are not considered excessive for mineral water. Mineral water is marketed for its mineral content, especially when it contains significant levels of minerals such as fluoride or calcium. Therefore, the general phrase, "Contains Excessive Chemical Substances," on mineral water that contains a level of a substance that exceeds the allowable level for mineral water may mislead consumers because they may assume that mineral water ordinarily contains considerable amounts of chemical substances. In view of this possibility, the agency tentatively concludes that the general phrase may not be adequate for mineral water and is therefore proposing in § 165.110(c)(2)(ii) that the label or labeling of mineral water list the specific names of any substances present in amounts that exceed the allowable levels to which mineral water is subject (e.g., "Contains Excessive Arsenic," "Contains Excessive Trihalomethanes"). However, FDA points out that current § 103.35(g) (which FDA is proposing to recodify as § 165.110(d)) provides that regardless of whether the bottled water bears a statement of substandard quality, the product is adulterated if it contains a substance (e.g., arsenic) at a level considered injurious to health under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)).

Current § 103.35(f) references § 103.5(b), which sets forth general principles for how statements of substandard quality are to be made on foods that are defined by a quality standard but for which there is no identity standard. Because the agency is proposing to establish a standard of identity and move the standard of quality for bottled water to § 165.110, FDA is proposing to amend current § 103.35(f) (which will be recodified as § 165.110(c)) to reference 130.14(a) (in § 165.110(c) (1) and (2)). This section sets forth general statements of substandard quality for use on foods for which a standard of identity has been established.

D. Chemical Quality Standards

The IBWA petition requested revision of chemical quality standards for total trihalomethanes (TTHM) from 100 parts per billion (ppb) to 10 ppb and for lead from 50 ppb to 5 ppb.

EPA has the primary responsibility for determining appropriate safety standards for drinking water. As stated above, under 21 U.S.C. 349, FDA is obligated to follow EPA's lead by revising bottled water regulations after EPA promulgates interim or revised primary drinking water regulations or by publishing its reasons for not doing so. EPA published a final rule in the **Federal Register** of June 7, 1991 (56 FR 26460) on national primary drinking water regulations for lead in drinking water. FDA published a proposal to lower the lead quality standard to 5 ppb elsewhere in this issue of the **Federal Register** in response to EPA's revised lead standards. EPA is currently reviewing drinking water standards for TTHM. Therefore, FDA is not proposing any action on the IBWA request concerning TTHM.

IV. CGMP'S

A. Product Water, Operations Water, and Compliance Procedures

1. Conforming Amendment

Because the agency is moving the quality standard from § 103.35 to proposed § 165.110(b), the reference in § 129.35 needs to be updated to reflect this change. Therefore, FDA is amending § 129.35(a)(3)(ii) to reference proposed § 165.110 instead of § 103.35.

2. Testing of Mineral Water

The IBWA petition requested that § 129.80(g) be revised by deleting the exclusion for mineral water from testing requirements to reflect the inclusion of mineral water in the definition of

"bottled water." Because FDA is proposing to grant the latter request in proposed § 165.110(a)(1) and to subject this commodity to the quality standards in proposed § 165.110(b), FDA is proposing to revise § 129.80(g) as requested and to delete the exclusion for mineral water from the testing requirements.

3. Use of Public Water Certificate in Lieu of Monitoring

IBWA requested in its petition that § 129.35(a)(3) be amended to provide bottlers that use a public water source with the alternative of obtaining and displaying a certificate from the public water system (demonstrating that the public water system conducts the monitoring required by paragraph 129.35(a)(3)) in lieu of conducting all source monitoring required by this paragraph for chemical contaminants. The petition also requested that FDA reduce the frequency or scope of source monitoring, provided that the source does not contain the substances for which monitoring is required and is not vulnerable to contamination.

FDA realizes that it would be redundant to require bottlers of water from municipal sources that meet all EPA standards to retest source water for the contaminants that are covered by the bottled water quality standards. The only possible source of contamination of such water would be the water distribution system itself, and it is unlikely that this system would act as a source of most of the regulated chemical contaminants. Moreover, protection from chemical contamination is provided by § 129.80(g)(2), which requires that a plant analyze a representative sample of each type of bottled drinking water produced at least annually for chemical contaminants.

Therefore, FDA is proposing in § 129.35(a)(4)(i) to permit firms that use a municipal water system as the source of their water to substitute municipal testing results showing full compliance with the EPA primary and secondary drinking water regulations (or a certificate to this effect) for the source water chemical contaminant testing required in § 129.35(a)(3).

The EPA final rule of January 30, 1991 (56 FR 3526), allows States to grant areawide or statewide waivers of pesticide testing requirements based on pesticide use information. The rule also provides States with the discretion to set subsequent testing frequencies in systems that did not detect volatile synthetic organic chemicals in the initial round of samples and that are assessed and designated as not vulnerable. EPA stated in adopting this rule that for all contaminants for which levels are established in the rule, minimum monitoring requirements may be increased or decreased by States based on analytical results or the results of a vulnerability assessment. EPA monitoring requirements are designed to ensure that compliance with the MCL's is met and to efficiently utilize State and utility resources (56 FR 3526 at 3559, January 30, 1991).

FDA realizes that it would be unreasonable to require bottlers using nonmunicipal sources to test source water for each and every contaminant regardless of the chances of finding a particular contaminant. Such testing can be quite costly, and it makes no sense to require testing for a pesticide or other synthetic organic chemical that is not used in the source water recharge basin. Thus, in certain cases, there is justification for reducing both the frequency and scope of testing for chemical contaminants and for providing exemptions from testing requirements under carefully controlled conditions. Because EPA regulations currently permit State regulatory agencies to modify testing requirements under appropriate circumstances, FDA tentatively concludes that it is reasonable to recognize appropriate testing exemptions from EPA requirements granted by State agencies that have jurisdiction over approval of source water under EPA regulations. Therefore, FDA is proposing in § 129.35(a)(4)(ii) to permit firms that use a nonmunicipal water source as the source of their water to reduce the frequency of testing and the number of chemical contaminants for which they test source water if they can document that such reduction is consistent with a waiver that the State has issued under EPA regulations.

FDA emphasizes however that, irrespective of the minimum testing requirements specified in the CGMP regulations (part 129) for source water or finished products, every lot of bottled water products introduced or delivered into interstate commerce must comply with the bottled water quality standards (proposed § 165.110(b)) and is subject to the act, including the provisions of 21 U.S.C. 342 on the circumstances in which food is adulterated. Therefore, FDA is proposing in § 129.35(a)(4)(iii) that the finished bottled water must comply with bottled water quality standards (proposed § 165.110(b)) and 21 U.S.C. 342(a)(1) dealing with adulterated foods.

B. Additional Definitions

IBWA requested revision of the definitions in § 129.3 to include new definitions for "bottled water plant," "plant operator," "water dealer," and a revised definition for "bottled drinking water."

IBWA did not provide any explanation for why these provisions are needed, and FDA has no information to support the requested revisions. Therefore, FDA is not proposing at this time to establish definitions for "bottled water plant," "plant operator," or "water dealer" or to revise the definition for "bottled drinking water." FDA is requesting comment from interested persons concerning the need to define or amend the definitions of these terms.

C. Unregulated Contaminants

IBWA requested revision of part 129 to provide for additional source and final product testing requirements in § 129.35 to detect and control specific unregulated contaminants. No explanation was provided for why these additional provisions are needed.

Part 129 does not limit testing to only those contaminants listed in the quality standards. Bottled water that contains a poisonous or deleterious substance is subject to the adulteration provisions of 21 U.S.C. 342(a)(1) and therefore to regulatory action. Further, all food firms, including bottled water producers, are subject to the CGMP regulations in part 110 (21 CFR part 110). Section 110.80 (21 CFR 110.80) states that appropriate quality control procedures are to be employed to ensure that food is suitable for human consumption. This section also states that all food that has become contaminated, to the extent that it is adulterated within the meaning of the act, is to be rejected or, if permissible, treated or processed to eliminate the contamination. Thus, bottled water producers are already obligated to monitor their source water for contaminants that may not be the subject of specific provisions in FDA's regulations. If these producers knowingly produce and distribute adulterated bottled water, they may be subject to the criminal penalties of the act.

D. Microbiological Control Standards

The petition requested revision of § 129.40 to include microbiological control standards that include prohibitions from processing and bottling water with equipment that has been used to produce milk, fruit juice, or any other food product "likely to contribute nutrients for microbiological growth." In its March 25, 1988, amendment to its petition, IBWA submitted a report on dual filling lines

prepared by Harold Wainess & Associates (HWA).

The Milk Industry Foundation (MIF) submitted comments on the IBWA petition opposing a requirement for the use of dedicated equipment for bottling water. MIF stated that milk processors are experienced in sanitation and related procedures that are necessary for the production of safe, high quality foods, both dairy and nondairy. MIF also stated that the adoption of the IBWA request for dedicated equipment would: (1) Eliminate many milk processors from the bottled water market or impose substantial additional costs on companies, (2) increase costs to consumers, and (3) not provide health or safety benefits to the public.

FDA believes that dedicated equipment will not ensure that the goal of production of foods with a low probability of microbiological contamination will be met. Only good sanitation will ensure that this goal is achieved. As the HWA report points out, milk is more sensitive to microbiological contamination than water. Because of this fact, the milk industry has had to develop and achieve very high sanitary standards to meet regulatory agencies' requirements for safety. In addition, the Pasteurized Milk Ordinance, which is used as a model by most States, includes strict standards of operation in dairy plants. The agency believes that the bottled water recall data included in the HWA report to establish the need for the requested revision do not refute that high sanitary standards are met by the milk industry. Only a few of the recalls cited involved dairy plants, and the number of such recalls cited was far too few to draw any conclusions concerning problems with the lack of dedicated equipment.

Microbiological standards already exist for bottled water in § 103.35(b) (which FDA is proposing to recodify as § 165.110(b)(2)). The agency will propose additional microbiological quality standards as necessary to protect consumers from microbiological hazards. Regardless of the type of plant processing the water, the water must meet these standards or bear appropriate labeling advising that it is of substandard quality. In addition, FDA advises that the water is also subject to regulatory sanctions under 21 U.S.C. 342(a)(1) if deviations from these standards result in a product that may be injurious to health.

FDA tentatively finds that IBWA has not provided adequate support to justify proposing an amendment to § 129.40 to require processing and bottling water with dedicated equipment. FDA is not persuaded that the HWA report establishes that the revision is needed.

E. Production and Process Controls

IBWA requested revision of certain requirements in Part 129 pertaining to filtration and germicidal treatment. Specifically, IBWA requested that the agency add a new paragraph in § 129.40, to require that bottled water that originates from a surface water source that is not protected from surface contamination be subject to ozonation, filtration, or another effective process that removes or destroys the cysts of the parasite *Giardia lamblia*.

In 1989, EPA revised its regulations concerning processes to remove or destroy the cysts of this parasite (54 FR 27486, June 29, 1989). FDA is preparing a response to EPA's final rule.

IBWA also requested that the agency amend the treatment requirements for bottled water to require "* * * filtration, and effective germicidal treatment by ozonation, carbonation * * * or equivalent disinfection * * *" in accordance with the food additive requirements. The amendment would replace the current provisions of § 129.80(a) which require that certain specified treatments of bottled water be in accord with the food additive requirements but do not require filtration and germicidal treatment.

IBWA did not provide a basis to support this revision. EPA is currently considering the need for disinfection treatment of ground waters, and FDA is awaiting EPA's determination.

F. Laboratory and Personnel Approval

IBWA requested that the CGMP regulations in Part 129 be revised to include requirements for certification of laboratories analyzing water and for supervisory personnel.

IBWA did not provide a basis to justify the need for these approvals. Moreover, the act does not provide authority to the agency to require such approval. Further, even if such authority were provided by the act, FDA lacks the resources to monitor analytical laboratories and personnel in the absence of a significant public health problem. In § 129.35(a)(3)(iii), FDA states that analysis of samples may be performed for the plant by competent commercial laboratories. Such laboratories may include EPA certified or other competent laboratories, and no further requirements appear to be necessary.

G. Annual Plant Inspection

IBWA requested that FDA revise the CGMP regulations in Part 129 to include a requirement for annual plant inspections to ensure compliance with the regulations.

FDA finds that IBWA has not presented an adequate basis for it to propose this revision. Annual plant inspections are not required for any other food products within FDA's jurisdiction, either by statute or by regulation. Thus, without a clear indication of a significant public health problem that could not be corrected by other means, there is no basis for FDA to adopt such a requirement for bottled water. The agency does not believe that the petition establishes that there is a significant public health problem with bottled water. FDA lacks the resources to conduct annual plant inspections for manufacturers of bottled water in the absence of such a problem. FDA recognizes, however, that IBWA requires third party inspection of its member firms, and FDA encourages such self-regulated programs within industry.

H. Recall Procedures

The IBWA petition requested that FDA establish specific recall procedures for bottlers and dealers in the CGMP regulations in part 129.

FDA finds no basis for this requested revision. Recall procedures for FDA regulated products are already set forth in 21 CFR part 7, subpart C. These procedures are voluntary. The IBWA petition does not explain why special recall procedures for bottled water products are necessary. IBWA did not point to any circumstances that establish that there is a unique problem with bottled water.

V. Other Matters

A. Ozone

In the **Federal Register** of November 5, 1982 (47 FR 50209), FDA affirmed that ozone is generally recognized as safe (GRAS), with specific limitations, for use as a antimicrobial agent in bottled water. Mineral water having TDS greater than 500 ppm was not included within the definition of "bottled water" at the time that this use of ozone was affirmed as GRAS. Therefore, the agency is proposing to specify in § 184.1563(d) that the term "bottled water," for purposes of this section, does not include mineral water with TDS greater than 500 ppm. This action will ensure that FDA's rulemaking on the definition of bottled water in § 165.110 will not inadvertently have the effect of expanding the permitted uses of ozone.

Anyone wishing to petition for food additive listing or GRAS affirmation for the use of ozone in mineral water with

TDS greater than 500 ppm may do so following the procedure set out in 21 CFR 171.1 or 170.35, respectively.

B. Nutrition Labeling

In the **Federal Register** on November 27, 1991 (56 FR 60394 at 60418), FDA proposed that the serving size of carbonated beverages, wine coolers, and all types of water be 240 mL. This proposal was published as part of FDA's food labeling initiative to implement the provisions of the 1990 amendments and replaced FDA's serving size proposal of July 19, 1990 (55 FR 29517).

In response to the 1990 amendments, FDA also published a proposed rule on November 27, 1991 (56 FR 60366) concerning nutrition labeling. FDA proposed the circumstances in which a simplified form of nutrition labeling could be used. In this proposal, FDA stated that beverages such as soft drinks could bear the simplified nutrition information format.

Final regulations for nutrition labeling of foods, including bottled water, are expected to be published in the **Federal Register** by early 1993. The following is a brief discussion of relevant provisions in the November 27, 1991, proposal and the agency's tentative position regarding the nutrition labeling of mineral water.

FDA proposed that nutrition information relating to food must be provided for all products that contain more than insignificant amounts of any of the nutrients or food components that are required to be listed, or whose label, labeling, or advertising contains a nutrient content claim or any other nutrition information. FDA proposed that an insignificant amount of a nutrient or a food component is that amount that allows a declaration of zero in nutrition labeling. A nutrient content claim or any other nutrition information in any context, and in any form of expression, implicit as well as explicit, will subject a food to the nutrition labeling provisions.

Nutrients likely to be present in bottled water products include calcium, sodium, and iron. If any of these minerals are present in more than insignificant amounts in the product, nutrition labeling will be required under the act. According to the proposed regulations, a significant amount of calcium is 18 milligrams (mg) or more per serving, a significant amount of sodium is 5 mg or more per serving, and a significant amount of iron is 0.24 mg or more per serving. It is unlikely that many products will contain a significant quantity of iron, but some products may contain a significant amount of calcium or sodium or both.

In the November 27, 1991, proposal FDA further stated that if manufacturers voluntarily choose to declare additional nutrients or food components that are not among the 15 required nutrients (e.g., magnesium and potassium), they will be required to use the statement "Not a significant source of ———," with the blank filled in with the name of any of the 15 required nutrients or food components that are missing or present in insignificant amounts. The agency also proposed that if a product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared within the simplified format and followed by the above statement. The agency stated that it considered such voluntary addition of nutrients an effort to market the food as a significant source of nutrients.

FDA believes that nutrition labeling should appear on bottled water labeled as "mineral water, high mineral content" because consumers may assume that water with a high mineral content would be of nutritional benefit. However, FDA realizes that mineral water with a high mineral content could contain enough sodium, calcium, and iron to make nutrition labeling mandatory.

FDA is aware that some foreign producers of bottled water products state or imply on products sold in their domestic markets that their products may provide some health benefit. In response to the 1990 amendments, FDA proposed in the **Federal Register** of November 27, 1991 (56 FR 60537), general requirements pertaining to the use of health claims that characterize the relationship of a food component to a disease or health-related condition on the labels and in labeling of foods. These requirements, if adopted, will apply to health claims made on bottled water products.

C. Ingredient Declaration

If ingredients are added to the water, including carbon dioxide, each must be declared on the label as required by applicable regulations in part 101 (21 CFR part 101). According to § 101.4, all ingredients must be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24 that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

The proposed recodification of § 103.35 to new § 165.110 and the proposed conforming reference changes in Part 129 and in § 184.1563 are excluded under § 25.24(a)(9). The proposed amendments to part 129 pertaining to the CGMP's of the bottled water industry are excluded under § 25.24(a)(10). The action proposing new definitions and requirements in § 165.110 is excluded under § 25.24(b)(1).

VII. Economic Impact and Federalism Assessment

FDA has examined the economic implications of the proposed rule to establish a standard of identity for bottled water, recodify the standard of quality for bottled water, and define various types of bottled water, as required by Executive Orders 12291, 12612, and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis when making decisions, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses.

There are two options associated with this proposed rule: (1) Make the proposed changes in standards of identity and quality and in the definitions applicable to bottled water, or (2) take no action.

Option two is the baseline case and will be considered to have neither costs nor benefits. Potential compliance costs under option one include the cost of new analytical testing for mineral water and the cost of label changes for all types of bottled water. Potential benefits under option one include labeling cost savings and the value of increased interstate commerce and competition in the bottled water industry from the elimination of conflicting State regulations.

Mineral water testing is done by brand rather than by bottling plant or firm. The exact number of brands of mineral water currently sold in the United States is unknown; however, this

number is probably less than 100.[1] As an example of the costs involved, the agency assumes there are 85 brands of mineral water sold in the United States at this time. The compliance cost of new analytical testing for mineral water depends on the type and amount of testing currently being done on mineral water. Based on the testing requirements contained in the CGMP's for drinking water, including mineral water, the agency believes that many mineral water bottlers are already testing for the substances specified in the proposed regulation. For example, FDA believes that no new testing for microbiological contaminants will occur as a result of the proposed regulation. In addition, many States probably have testing requirements for mineral water.

If State regulations do not require testing for any substances specified in Federal bottled water regulations, then the estimated compliance cost of subjecting mineral water to testing requirements for bottled water would be about $3,000 per brand per year for chemical contaminants and about $1,400 per brand every 4 years for radiological testing, based on the cost of required testing at a private testing laboratory. Over 20 years at a discount rate of 5 percent, these testing costs would amount to about $44,000 per brand or about $3 million for all brands. If State regulations already require testing for all substances specified in Federal bottled water regulations, then the estimated compliance cost of subjecting mineral water to testing requirements for bottled water would be zero. FDA requests information on the cost of any mineral water testing required by the proposed regulation that is not already being performed.

A number of provisions in the regulation proposed below affect the labeling of bottled water. One bottled water firm reported that label changes cost between $40,000 and $50,000.[2] Some bottled water firms would ordinarily change their labels in the allotted compliance period. In general, the length of time between ordinarily scheduled label changes varies considerably, from less than 1 year up to 10 years. Smaller firms typically change their labels less frequently than larger firms. As an example of the costs involved: (1) If all bottled water firms have labeling costs of about $45,000 per label change, (2) if all bottled water firms make one label change as a result of Federal standards, and (3) if the average bottled water plant ordinarily changes its labels once every 6 years, then the total cost of the label changes proposed below would be about $18 million. FDA requests information on the labeling costs imposed by this proposal.

Standards of identity for various types of bottled water have the potential to reduce the number of firms and thus competition in the markets for particular types of bottled water. However, FDA believes the proposed standard is more general than any State's existing standard, and that no firm legally selling a given type of bottled water will be unable to do so because of the proposed regulation. FDA requests information on any bottling plant legally producing bottled water that will be required to rename its product as a result of the current proposal.

Other than the costs of labeling, which may be passed on, no costs should accrue to consumers since FDA does not believe that Federal standards defining certain types of bottled water, namely, artesian, spring, and well water, will contribute to the belief that the composition or properties of bottled water from different geological sources varies in any systematic way. In addition, FDA does not believe that a Federal standard defining mineral water involving both the mineral content of the water and its geological source will contribute to the belief that the properties or composition of mineral water necessarily differ from that of other types of water to which minerals may be added. Although Federal food standards generally deal with issues that affect the properties of the finished product, it should be clear that the proposed standards for artesian, spring, and well water do not. In addition, it should be clear that the standard for mineral water involves both the geological source and the properties and composition of that water. FDA believes that consumers are interested in the geological source of bottled water as such and will not use this information to infer differences in the composition or properties of water where none exist.

The potential benefits of option one include savings on labeling costs which now result from conflicting State definitions for the terms used to describe bottled water. States can be divided into three categories with respect to their labeling regulations for bottled water: (1) Twenty States use only bottled water regulations found in the Code of Federal Regulations, (2) seventeen States use the International Bottled Water Association's Model Code labeling provisions, as a supplement either to the Code of Federal Regulations or to their own bottled water regulations, and (3) thirteen States have adopted their own labeling provisions as a supplement to the bottled water regulations in the Code of Federal Regulations.[3]

One bottled mineral water firm reported making 4 label changes costing between $40,000 and $50,000 per change in the last 6 years to keep their labels in conformance with State regulations.[4] Approximately six States in which this firm sells bottled water adopted their own labeling provisions in this time period. As an example of the costs involved, if one label change would ordinarily have taken place in the last 6 years, then the average labeling cost due to the adoption of the potentially conflicting State standards for bottled water for this one firm would be about $23,000 per year. If labeling changes would ordinarily take place more frequently than once every 6 years, then the cost of responding to State labeling regulations would be lower.

Labeling costs resulting from changing State regulations for most bottled water firms are probably less, because the reporting firm is in the upper twenty-fifth percentile of bottled water firms in terms of the number of employees. The number of States to which water is shipped is probably a function of firm size, which in turn is a function of the number of employees. In addition, many States have already promulgated bottled water regulations, and the rate at which States adopt and change labeling regulations for bottled water will probably decline significantly over time. Finally, this firm produces mineral water, and State regulations concerning the labeling of mineral water are more likely to change than regulations concerning other types of bottled water. As an example of the costs involved: (1) If the average bottled water firm has additional labeling costs of $12,000 per year because of changing State definitions, and (2) the average yearly rate of change of bottled water regulations over the next 20 years is half the current rate (so that the total number of States having their own potentially unique labeling provisions triples in 20 years), then Federal bottled water standards would save bottling plants approximately $35 million in labeling costs over 20 years. FDA requests information on labeling costs

[1] Phone call between Terry Troxell, FDA, and Carol Kinkade, IBWA, May 26, 1992.

[2] Memorandum of phone call between Ed Puro, FDA, and Bruno Rolando, Quibell Corp., May 19, 1992.

[3] Information submitted by Lisa Prats, IBWA, May 15, 1992.

[4] Memorandum of phone call between Ed Puro, FDA, and Bruno Rolando, Quibell Corp., May 19, 1992.

attributable to conflicting State standards for bottled water.

If one label cannot comply with all relevant State regulations concerning the labeling of bottled water, then bottled water plants may have to maintain different labels for different States. This could add to the manufacturing, storage, and shipping costs for the affected products. FDA requests cost information from any bottled water producer currently maintaining different labels for different States.

Finally, eliminating inconsistent State standards for bottled water should stimulate interstate commerce and competition within this industry. FDA requests information on the probable effects of this proposal on the degree of competition within this industry.

In summary, the agency estimates that the compliance costs of this proposal are between $18 million and $21 million, depending on the proportion of proposed Federal testing requirements for mineral water that are already included in State testing requirements, and the number of plants that will have to relabel their bottled water products. The agency estimates that benefits are about $35 million, depending on the frequency with which firms ordinarily change their labels and the rate at which States adopt potentially unique labeling regulations, plus the value of any increase in interstate commerce which may occur. Net benefits over 20 years will range from $14 million to $17 million plus the value of any increase in interstate commerce in bottled water.

Finally, this proposal has sufficient federalism implications so that FDA has assessed its effects in light of the principles, criteria, and requirements stated in sections 2 through 4 of Executive Order 12612. The proposal is fully consistent with those principles, criteria, and requirements. As discussed in sections II. and VII. of this document, States have developed their own policies to regulate bottled water, and FDA until this time has refrained from establishing a standard of identity. However, because the States have developed inconsistent provisions, FDA finds that a national standard of identity is necessary. The evidence compelling this tentative conclusion is found in sections II. and III. of this document. FDA has consulted with a number of States about this situation and the agency's tentative conclusions. With this notice, FDA is providing an opportunity for States to participate in the process by which the agency will make a final decision in this matter. This policy will impose no additional costs or burdens on the States. They will be free to continue to perform their traditional functions. However, if this proposal is found necessary and adopted, those States that have regulatory provisions that are not identical to those set forth in the document will have to conform their regulatory provisions to those set forth here. (See 21 U.S.C. 343–1(a).)

VIII. Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

IX. Effective Date

The agency is proposing that any final rule that may be issued based upon this proposal becomes effective 180 days following its publication in the **Federal Register**. The agency is providing this time period to permit affected firms adequate time to take appropriate steps to bring their products into compliance with the standards imposed by the new rules. The agency solicits comments on whether a different effective date is appropriate to make the effective date consistent with the date on which other labeling changes will be required under such recent legislation as the 1990 amendments or the amendments to the Fair Packaging and Labeling Act, enacted as part of the American Technology Preeminence Act of 1991.

X. References

The following references have been placed on display in the Dockets Management Branch (address above), and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. Committee on State Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Food Labeling: Toward National Uniformity," National Academy Press, Washington DC, 1992.

2. Deal, W.F., "Remarks before the Congressional Office of Technology Assessment," Proceedings of the Bottled Water Workshop, A Report Prepared for the Use of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, U.S. Government Printing Office, Washington, DC, 1990.

3. North Carolina Department of Agriculture, Food and Drug Protection Division, 2 NCAC 9C .0700—Bottled water.

4. State of California, Chapter 639, Assembly Bill No. 170, September 15, 1987.

5. Timothy, A.R., Coors Brewing Co., letter to Fred Shank, March 16, 1992.

6. Quibell, R.S., Quibell Corp., letter to Terry C. Troxell, May 6, 1991.

7. Maxwell, J.C., Jr., Wheat First Securities as quoted in Beverage Industry, February 1992.

8. Cech, I., "Bottled Water: Truth in Advertising and Selected Water Quality Issues," Proceedings of the Bottled Water Workshop, A Report Prepared for the Use of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, U.S. Government Printing Office, Washington, DC, 1990.

9. Ferstandig, R., "Consumers & Bottled Water," Proceedings of the Bottled Water Workshop, A Report Prepared for the Use of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, U.S. Government Printing Office, Washington, DC, 1990.

10. Codex Alimentarius, Volume XII, "Codex Standards for Natural Mineral Waters and Edible Ices and Ice Mixes," Food and Agriculture Organization of the United Nations, World Health Organization, Rome, 1982.

11. Texas Department of Health, Division of Food And Drugs, Rules for Bottled and Vended Water, August 20, 1988.

12. Association of Food and Drug Officials, "AFDO Model Bottled Water Regulation," 1986.

13. The Council of the European Communities, "Council Directive of 15 July, 1980 on the Approximation of the Laws of the Member States Relating to the Exploitation and Marketing of Natural Mineral Waters," *Official Journal of the European Communities*, No. L. 229/1, 1980.

14. O'Donnell, W.J., "Sanpellegrino," Proceedings of the Bottled Water Workshop, A Report Prepared for the Use of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, U.S. Government Printing Office, Washington, DC, 1990.

15. Heath, R.C., United States Geological Survey, "Basic Ground-Water Hydrology," Water-Supply Paper 2220, United States Government Printing Office, 1989.

16. The United States Pharmacopeia, United States Pharmacopeial Convention, Inc., Rockville, MD, 1985.

17. Konikow, L.F., U.S. Geological Survey letter to Terry Troxell, January 14, 1992.

18. Meinzer, O.E., "Ground Water," *Hydrology*, Dover Publications, Inc., New York, 1942.

19. Guralnik, D.B., "Webster's New World Dictionary of the American Language," Warner Books, Inc., 1983.

20. Sowards, R.D., Texas Department of Health, letter to Janice F. Oliver, July 30, 1991.

21. Lipnicki, J.D., Field Programs Branch (HFF–26), Center for Food Safety and

Applied Nutrition, Food and Drug Administration, memo to Nick Duy, December 12, 1990.

22. Allen, H.E., "Chemical Quality of Bottled Water," Proceedings of the Bottled Water Workshop, A Report Prepared for the Use of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, U.S. Government Printing Office, Washington, DC, 1990.

List of Subjects in 21 CFR

Part 103

Beverages, Bottled water, Food grades and standards.

Part 129

Beverages, Bottled water, Food packaging, Reporting and recordkeeping requirements.

Part 165

Beverages, Bottled water, Food grades and standards, Incorporation by reference.

Part 184

Food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 103, 129, 165, and 184 be amended as follows:

PART 103—QUALITY STANDARDS FOR FOODS WITH NO IDENTITY STANDARDS

1. The authority citation for 21 CFR part 103 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 410, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 349, 371, 376).

Subpart B—[Removed and Reserved]

2. Subpart B, consisting of § 103.35 is removed and reserved.

PART 129—PROCESSING AND BOTTLING OF BOTTLED DRINKING WATER

3. The authority citation for 21 CFR part 129 continues to read as follows:

Authority: Secs. 402, 409, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342, 348, 371, 374); sec. 361 of the Public Health Service Act (42 U.S.C. 264).

4. Section 129.35 is amended in paragraph (a)(3)(ii) by removing "§ 103.35" and adding in its place "§ 165.110" and by adding new paragraph (a)(4) to read as follows:

§ 129.35 Sanitary facilities.

* * * * *

(a) * * *

(4) *Source water testing exemptions.* (i) Firms that use a municipal water system for source water may substitute municipal testing results, or certificates showing full compliance with all provisions of EPA National Primary and Secondary Drinking Water Regulations pertaining to chemical contaminants, for the testing requirements of § 129.35(a)(3).

(ii) Firms that use a nonmunicipal water source as the source of their water may reduce the frequency of testing and the number of chemical contaminants for which they test source water if they can document that such reduction is consistent with a State issued waiver under EPA regulations.

(iii) The finished bottled water must comply with bottled water quality standards (21 CFR 165.110(b) of this chapter) and section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act dealing with adulterated foods.

* * * * *

5. Section 129.80 is amended by revising the introductory text of paragraph (g) to read as follows:

§ 129.80 Processes and controls.

* * * * *

(g) *Compliance procedures.* A quality standard for bottled drinking water is established in § 165.110(b) of this chapter. To ensure that the plant's production of bottled drinking water complies with the applicable standards, laws, and regulations of the government agency or agencies having jurisdiction, the plant will analyze product samples as follows:

* * * * *

6. Part 165 is added to read as follows:

PART 165—BEVERAGES

Subpart A—General Provisions

Sec.

165.3 Definitions.

Subpart B—Requirements for Specific Standardized Beverages

165.110 Bottled water.

Authority: Secs. 201, 401, 403, 403A, 409, 410, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 343A, 348, 349, 371, 376).

Subpart A—General Provisions

§ 165.3 Definitions.

(a) A *lot* is:

(1) For purposes of determining quality factors related to manufacture, processing, or packing, a collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible and usually designated by a common container code or marking, or in the absence of any common container code or marking, a day's production.

(2) For purposes of determining quality factors related to distribution and storage, a collection of primary containers or units transported, stored, or held under conditions as nearly uniform as possible.

(b) A *sample* consists of 10 subsamples (consumer units), taken one from each of 10 different randomly chosen shipping cases to be representative of a given lot, unless otherwise specified in a specific standard in this part.

(c) An *analytical unit* is the portion(s) of food taken from a subsample of a sample for the purpose of analysis.

Subpart B—Requirements for Specific Standardized Beverages

§ 165.110 Bottled water.

(a) *Identity*—(1) *Description.* Bottled water is water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except it may optionally contain safe and suitable antimicrobial agents. Bottled water may be used as an ingredient in beverages (e.g., diluted juices, flavored bottled waters). It does not include those food ingredients that are declared in ingredient labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," and "tonic water." The processing and bottling of bottled water shall comply with applicable regulations in part 129 of this chapter.

(2) *Nomenclature.* The name of the food is "bottled water" or alternatively one of the following terms as appropriate:

(i) The name of water from a well tapping a confined aquifer in which the water level stands above the natural water table may be "artesian water." Artesian water may be collected with the assistance of external force to enhance the natural underground pressure so long as such measures do not alter the physical properties, composition, and quality of the water.

(ii) The name of water containing not less than 250 parts per million (ppm) total dissolved solids, coming from a source tapped at one or more bore holes or springs, originating from a geologically and physically protected underground water source may be "mineral water." Mineral water shall be distinguished from other types of water by its constant level of minerals and trace elements at the point of emergence from the source.

(iii) The name of water that has been produced by distillation, deionization, reverse osmosis, or other suitable processes and that meets the definition of purified water in the most recent edition of the United States Pharmacopeia may be "purified water." Alternatively, the water may be called "distilled water" if it is produced by distillation.

(iv) The name of water derived from an underground formation from which water flows naturally to the surface of the earth or would flow naturally to the surface of the earth if not for its collection below the earth's surface may be "spring water." Spring water shall be collected only at the spring or through a bore hole that is adjacent to the point of emergence. Spring water collected with the assistance of external force to protect the water shall be from the same underground stratum as the spring and shall retain all the physical properties, and be of the same composition and quality, as the water that would flow naturally to the surface of the earth if not for its collection below the earth's surface.

(v) The name of water from a hole bored, drilled, or otherwise constructed in the ground which taps the water of an aquifer may be "well water."

(3) *Other label statements.* (i) If the total dissolved solids (TDS) content is below 500 ppm, or if the TDS is greater than 1,500 ppm, the statement "low mineral content" or the statement "high mineral content", respectively, shall appear on the principal display panel following the statement of identity in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.

(ii) When bottled water comes from a municipal source and has not been treated to meet the definition of distilled water or purified water as defined in paragraph (a)(2) of this section, the label shall state "from a municipal source" on the principal display panel or panels. This statement shall immediately and conspicuously precede or follow the name of the food without intervening written, printed, or graphic matter, other than statements required by paragraph (c) of this section in type size at least one-half the size of the statement of identity but in no case of less than one-sixteenth of an inch.

(iii) When the label or labeling characterizes the bottled water in any manner (e.g., through label statements or vignettes with references to infants) as for use in feeding infants, and the product is not sterile, the principal display panel shall bear conspicuously the phrase "not sterile, use as directed by physician or by labeling directions for use of infant formula."

(b) *Quality.* The standard of quality for bottled water including water for use as an ingredient in beverages (except those described in the labeling as "water," "carbonated water," "disinfected water," "filtered water," "seltzer water," "soda water," and "tonic water") is as follows:

(1) *Definitions.* (i) *Trihalomethane* means one of the family of organic compounds, named as derivatives of methane, wherein three of the four hydrogen atoms in methane are each substituted by a halogen atom in the molecular structure.

(ii) *Total trihalomethane* means the sum of the concentration in milligrams per liter of the trihalomethane compounds (trichloromethane, dibromochloromethane, bromodichloromethane and tribromomethane), rounded to two significant figures.

(2) *Microbiological quality.* Bottled water shall, when a sample consisting of analytical units of equal volume is examined by the methods described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 17th ed. (1989), American Public Health Association, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (copies are available from the American Public Health Association, 1015 15th St. NW., Washington, DC 20005, or may be inspected at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC), meet the following standards of microbiological quality:

(i) *Multiple-tube fermentation method.* Not more than one of the analytical units in the sample shall have a most probable number (MPN) of 2.2 or more coliform organisms per 100 milliliters and no analytical unit shall have an MPN of 9.2 or more coliform organisms per 100 milliliters; or

(ii) *Membrane filter method.* Not more than one of the analytical units in the sample shall have 4.0 or more coliform organisms per 100 milliliters and the arithmetic mean of the coliform density of the sample shall not exceed one coliform organism per 100 milliliters.

(3) *Physical quality.* Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the method described in applicable sections of "Standard Methods for the Examination of Water and Wastewater," 17th ed. (1989), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (b)(2) of this section), meet the following standards of physical quality:

(i) The turbidity shall not exceed 5 units.

(ii) The color shall not exceed 15 units.[1]

(iii) The odor shall not exceed threshold odor No. 3.[1]

(4) *Chemical quality.* (i)(A) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (4)(i)(B) of this section, meet standards of chemical quality and shall not contain chemical substances in excess of the following concentrations:

Substance	Concentration in Milligrams per Liter
Arsenic	0.05
Barium	1.0
Cadmium	0.01
Chloride[1]	250.0
Chromium	0.05
Copper	1.0
Iron[1]	0.3
Lead	0.05
Manganese[1]	0.05
Mercury	0.002
Nitrate (N)	10.0
Phenols	0.001
Selenium	0.01
Silver	0.05
Sulfate[1]	250.0
Total dissolved solids[1]	500.0
Zinc[1]	5.0
Organics:	
Endrin (1,2,3,4,10,10-hexachloro - 6,7 - epoxy - 1,4,4a,5,6,7,8,8a - octa - hydro - 1,4 - endo, endo - 5,8 - dimethane naphthalene)	0.0002
Lindane (1,2,3,4,5,6 - hexachloro - cyclohexane, gamma isomer)	0.004
Methoxychlor (1,1,1 - trichloro - 2,2 - bis[p - methoxy - phenyl] ethane)	0.1
Total Trihalomethanes	0.10
Toxaphene ($C_{10}H_{10}Cl_8$-technical chlorinated camphene, 67–69 percent chlorine)	0.005
2,4-D (2,4-dichlorophenoxyacetic acid)	0.1
2,4,5-TP Silvex (2,4,5-trichlorophenoxypropionic acid)	0.01

(B) Analyses conducted to determine compliance with paragraph (4)(i)(A) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 17th ed. (1989), or "Methods for Chemical Analysis of Water and Wastes," Environmental Monitoring and Support Laboratory, EPA–600/4–82–055, March 1983, U.S. Environmental Protection Agency, both of which are incorporated by reference

[1] Mineral water is exempt from standard where product contains more than 500 milligrams per liter total dissolved solids.

in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(C) Analyses for organic substances shall be determined by appropriate methods described in "Methods for Organochlorine Pesticides in Industrial Effluents" and "Methods for Chlorinated Phenoxy Acid Herbicides in Industrial Effluents," November 28, 1973, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and "Part I: The Analysis of Trihalomethanes in Finished Waters by the Purge and Trap Method," Method 501.1 and "Part II: The Analysis of Trihalomethanes in Drinking Water by Liquid/Liquid Extraction," Method 501.2 in 40 CFR part 141, Appendix C (45 FR 68672, November 29, 1979). The availability of these incorporations by reference are given in paragraph (b)(2) of this section.

(ii)(A) Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	2.4
53.8–58.3	2.2
58.4–63.8	2.0
63.9–70.6	1.8
70.7–79.2	1.6
79.3–90.5	1.4

(B) Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

(C) Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

Annual average of maximum daily air temperatures (°F)	Fluoride concentration in milligrams per liter
53.7 and below	1.7
53.8–58.3	1.5
58.4–63.8	1.3
63.9–70.6	1.2
70.7–79.2	1.0
79.3–90.5	0.8

(D) Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.

(iii) Bottled water, when a composite of analytical units of equal volume from a sample is examined by the methods listed in paragraphs (b)(4)(iii)(E) through (b)(4)(iii)(F) of this section, shall not contain the following chemical contaminants in excess of the concentrations specified in paragraphs (b)(4)(iii)(A) through (b)(4)(iii)(D) of this section.

(A) [Reserved]

(B) The permitted levels for volatile organic chemicals are as follows:

Contaminant (CAS Reg. No.)	Concentration in milligrams per liter
Benzene (71–43–2)	0.005
Carbon tetrachloride (56–23–5)	0.005
1,2-Dichloroethane (107–06–2)	0.005
1,1-Dichloroethylene (75–35–4)	0.007
1,1,1-Trichloroethane (71–55–6)	0.20
Trichloroethylene (79–01–6)	0.005
Vinyl chloride (75–01–4)	0.002

(C) through (E) [Reserved]

(F) Analyses conducted to determine compliance with paragraphs (b)(4)(iii)(B) and (b)(4)(iii)(C) of this section shall be made in accordance with a relevant method contained in "Methods for the Determination of Organic Compounds in Drinking Water," Office of Research and Development, Environmental Monitoring Systems Laboratory, EPA/600/4–88/039, December 1988, and listed separately in paragraphs (b)(4)(iii)(F)*(1)* through (b)(4)(iii)(F)*(5)* of this section, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Except as otherwise indicated below, copies are available from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Rd., Springfield, VA 22161, or available for inspection at the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC.

(1) Method 502.1—"Volatile Halogenated Organic Compounds in Water by Purge and Trap Gas Chromatography" (applicable to VOC's).

(2) Method 502.2—"Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography with Photoionization and Electrolytic Conductivity Detectors in Series" (applicable to VOC's).

(3) Method 503.1—"Volatile Aromatic and Unsaturated Organic Compounds in Water by Purge and Trap Column Gas Chromatography" (applicable to VOC's).

(4) Method 524.1—"Volatile Organic Compounds in Water by Purge and Trap Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(5) Method 524.2—"Volatile Organic Compounds in Water by Purge and Trap Capillary Column Gas Chromatography/Mass Spectrometry" (applicable to VOC's).

(G) [Reserved]

(5) *Radiological quality.* (i) Bottled water shall, when a composite of analytical units of equal volume from a sample is examined by the methods described in paragraph (b)(5)(ii) of this section, meet standards of radiological quality as follows:

(A) The bottled water shall not contain a combined radium-226 and radium-228 activity in excess of 5 picocuries per liter of water.

(B) The bottled water shall not contain a gross alpha particle activity (including radium-226, but excluding radon and uranium) in excess of 15 picocuries per liter of water.

(C) The bottled water shall not contain beta particle and photon radioactivity from manmade radionuclides in excess of that which would produce an annual dose equivalent to the total body or any internal organ of 4 millirems per year calculated on the basis of an intake of 2 liters of the water per day. If two or more beta or photon-emitting radionuclides are present, the sum of their annual dose equivalent to the total body or to any internal organ shall not exceed 4 millirems per year.

(ii) Analyses conducted to determine compliance with paragraph (b)(5)(i) of this section shall be made in accordance with the methods described in the applicable sections of "Standard Methods for the Examination of Water and Wastewater," 17th ed. (1989), and "Interim Radiochemical Methodology for Drinking Water," Environmental Monitoring and Support Laboratory, EPA–600/4–75–008 (Revised), March 1976, U.S. Environmental Protection Agency, both of which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of these incorporations by reference is given in paragraph (b)(2) of this section.

(c) *Label statements.* Bottled water, the quality of which is below that prescribed by this section, shall be labeled with a statement of substandard quality as follows:

(1) When the microbiological quality of bottled water is below that prescribed by paragraph (b)(2) of this section, the label shall bear the statement of substandard quality specified in § 130.14(a) of this chapter.

(2) When the physical, chemical, or radiological quality of bottled water is below that prescribed by paragraphs (b)(3) through (b)(5) respectively of this

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section, the label shall bear the statement of substandard quality specified in § 130.14(a) of this chapter except that, as appropriate, instead of or in addition to the words "Contains Excessive Bacteria" the following statement(s) shall be used:

(i) "Excessively Turbid", "Abnormal Color", and/or "Abnormal Odor" if the bottled water fails to meet the requirements of paragraph (b)(3)(i), (b)(3)(ii), or (b)(3)(iii), respectively, of this section.

(ii) "Contains Excessive ———," with the blank filled in with the name of the chemical for which a maximum contaminant level in paragraph (b)(4) of this section is exceeded (e.g., "Contains Excessive Arsenic," "Contains Excessive Trihalomethanes").

(iii) "Contains Excessive Chemical Substances" may be used in lieu of the statement in paragraph (c)(2)(ii) if the bottled water is not mineral water.

(iv) "Excessively Radioactive" if the bottled water fails to meet the requirements of paragraph (b)(5) of this section.

(d) Adulteration. Bottled water containing a substance at a level considered injurious to health under section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act is deemed to be adulterated, regardless of whether or not the water bears a label statement of substandard quality prescribed by paragraph (c) for this section.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

7. The authority citation for 21 CFR Part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

8. Section 184.1563 is amended in the table in paragraph (c), under the heading "Category of food" by removing "§ 103.35(b) through (e)" and adding in its place "§ 165.110(b)(2) through (b)(5)" and by adding new paragraph (d) to read as follows:

§ 184.1563 Ozone.

* * * * *

(d) The term "bottled water," for purposes of this section, does not include mineral water with total dissolved solids greater than 500 parts per million.

Dated: June 23, 1992.

Douglas L. Archer,

Acting Director, Center for Food Safety and Applied Nutrition.

Editorial note: This document was received at the Office of the Federal Register December 28, 1992.

[FR Doc. 92–31855 Filed 12–30–92; 9:00 am]

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January 5, 1993

Part III

Department of the Treasury

Fiscal Service

31 CFR Parts 349 and 356

Sale and Issue of Marketable Book-Entry Treasury Bills, Notes, and Bonds; Final Rule

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DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Parts 349 and 356

[Department of the Treasury Circular, Public Debt Series No. 1–93]

Sale and Issue of Marketable Book-Entry Treasury Bills, Notes, and Bonds

AGENCY: Bureau of the Public Debt, Fiscal Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury hereby publishes a final rule setting out the terms and conditions for the sale and issue by the Department to the public of marketable book-entry Treasury bills, notes, and bonds. This rule, also referred to as the uniform offering circular, applies to securities held in the book-entry system established by the Department and maintained through the Federal Reserve Banks, commonly referred to as the commercial book-entry system, as well as to those held in the TREASURY DIRECT system. This final rule, for the most part, consolidates into one document the terms and conditions which are currently found in a variety of other documents. It replaces 31 CFR part 349, relating to the offering of Treasury bills. In addition, individual offering circulars for Treasury notes and bonds will no longer be published as of the effective date of this rule.

EFFECTIVE DATE: March 1, 1993.

FOR FURTHER INFORMATION CONTACT: Michael W. Sunner, Deputy Assistant Commissioner, Office of Financing, Bureau of the Public Debt (202) 219–3350, or Margaret Marquette, Attorney-Adviser, Office of the Chief Counsel, Bureau of the Public Debt (202) 219–3320.

SUPPLEMENTARY INFORMATION:

I. Background

On January 31, 1992, the Department of the Treasury published a proposed rule setting out the terms and conditions governing the sale and issue of marketable book-entry Treasury bills, notes, and bonds (57 FR 3870). Sixteen written comment letters were received in response to that proposed rule. A revised proposed rule was published on September 30, 1992 (57 FR 45116). Five commenters responded to that proposed rule. The Department found the comments extremely useful in making the revisions described herein. Although some minor comments are not addressed here, all comments have been considered in the formulation of this final rule.

The comments were primarily in the following areas: Submission of bids by computer, net long position reporting, customer confirmations, investment advisers as bidders, and certifications for separate bidder status. The comments and other changes to the rule are discussed, as appropriate, in the following Section-by-Section Analysis.

II. Section-by-Section Analysis

Section 356.2 Definitions

The term "intermediary" has been added to the listing of definitions. This term refers to a depository institution or dealer that forwards bids for customers through another depository institution or dealer. An intermediary is distinguishable from a submitter in that a submitter submits bids directly to a Federal Reserve Bank or the Bureau of the Public Debt. An intermediary forwards bids to another intermediary or to a submitter rather than directly to a Federal Reserve Bank or the Bureau of the Public Debt. Other minor changes have been made throughout the rule to clarify the obligations of the intermediary depository institution or dealer.

Section 356.10 Offering Announcement

Two comments were received on this section. The commenters were pleased that the Department had revised the offering circular to include specific terms and conditions that, under the first proposed rule, were to be as specified in the offering announcement. The commenters were concerned, however, about the provision that allows changes to be made in the terms and conditions for the sale and issue of securities by other than an amendment to the offering circular. One of those commenters was concerned likewise with the provision that gives the offering announcement control over the offering circular in the event of any inconsistencies between the offering circular and the offering announcement.

No changes have been made to this section. The Department is sensitive to the commenters' concerns about monitoring and compliance burdens. It intends that the offering circular will be a comprehensive document, and that, whenever possible, changes will be made by means of an amendment to the offering circular. It reserves the right, however, to modify any terms and conditions of any new securities offerings without first publishing such changes for public comment. When a change is not temporary and is announced by means other than an amendment to the offering circular, the circular will be amended to reflect such change.

Section 356.11 Submission of Bids

One commenter commented generally that requirements contained on tender forms and in certifications or representations should be consistent with the requirements of the uniform offering circular, and should not go beyond the requirements of the circular. The Department will be revising tender forms and other agreements in accordance with this final rule.

Two comments were received on § 356.11(c)(5). This section provided that if disruptions or failures in the operation of the Federal Reserve Bank's computer or communications facilities result in the nonreceipt or untimely receipt of tenders otherwise timely submitted, the Department at its option may accept or reject such tenders. The commenters objected to this provision. The Department has deleted § 356.11(c)(5).

Section 356.13 Net Long Position

Commenters expressed concern about the proposed requirement contained in § 356.13(b) that if the person making the bidding decision knows of an increase in the bidder's net long position of $200 million or more after the designated position reporting time, the larger amount must be reported. Commenters felt that, to comply with this requirement in practice, those bidders would have to monitor and calculate their positions right up to the time their bids are submitted. The commenters stated that this would be difficult if not impossible to achieve, particularly for those bidders that must aggregate their positions across a range of affiliates.

The Department has decided not to include the proposed requirement for bidders to update net long position information after the designated reporting time. Instead, it will continue its current practice of requiring a bidder to determine its net long position one-half hour prior to the closing time for receipt of competitive bids.

In connection with clarifying the treatment of investment advisers under the Bidder Definitions, discussed below, the Department has revised § 356.13(a)(2) to clarify when net long positions must be aggregated for reporting purposes. This section provides for aggregating net long positions and competitive bids of different persons or entities, even though they might otherwise be considered separate bidders, if the investment or bidding decisions for

those persons or entities are centralized—as in the case of a single investment adviser. This section provides specific direction on which net long positions and bids must be taken into account, and it permits the exclusion of certain net long positions of less than $500 million.

It should be noted that § 356.22(b) of this Part provides that when the net long positions and competitive bids of more than one person or entity must be combined under § 356.13(a)(2), such combined amount will be used for the purpose of the 35% award limitation.

Section 356.14 Submitting Bids for Customers

One commenter recommended that the threshold for requiring that a submitter inform a customer of the customer's net long reporting obligation be raised from $10 million to $100 million. The commenter suggested that the higher amount was more in keeping with the $2 billion threshold for net long position reporting.

The Department concurs with that recommendation. Section 356.14(c)(1) has been changed to require a submitter or intermediary to inform its customer of the customer's net long reporting obligation when the customer bids competitively through that submitter for $100 million or more.

Two comments were received on the requirement, in § 356.14(c)(3), that if the submitter knows that the position information provided by the customer is incorrect, the submitter shall not submit the customer's bid. The commenters were concerned that the phrase "if the submitter knows" carries potential liability in cases where employees are assumed to have knowledge that they did not, in fact, have. They felt that, in order to avoid such liability, the submitter would be required to conduct a data search when a customer chooses to report its position through that submitter. The commenters suggested that a precise definition of "knowledge" be given or that the term "submitter" be narrowed.

Based on the above, § 356.14(c)(3) has been revised to narrow the circumstances under which a submitter or intermediary would be required to withhold a bid. That section now provides that a customer's bid shall not be submitted if the personnel directly involved in receiving or forwarding a customer's bid have actual knowledge that the position information provided by the customer is incorrect.

Section 356.24 Notice of Awards; Confirmations

Two commenters commented on the requirement, contained in § 356.24(d), that any customer awarded $100 million or more must furnish a written statement confirming its net long position. The commenters expressed concern that the obligation to file at the $100 million level might discourage customers from participating in auctions. One commenter felt also that using a $100 million threshold for net long position confirmations and a $500 million threshold for bid confirmations was unnecessarily confusing. Both commenters recommended that the net long position confirmation requirement and the bid confirmation requirement be combined.

The Department has modified the customer confirmation requirements. Section 356.24(d) has been deleted. Section 356.24(e) has been renumbered § 356.24(d) and includes provisions for both bid and net long position confirmations. Under the new § 356.24(d), any customer awarded $500 million or more in an auction must furnish a written statement confirming its bid and net long position. This statement must be provided to the Federal Reserve Bank where the bid was submitted no later than 10:00 a.m. on the day following the auction. The provisions requiring a submitter submitting a customer bid to notify its customer of the bid confirmation and net long position confirmation requirements have likewise been combined.

Appendix A—Bidder Definitions

Commenters commended the Department for its revisions to the Bidder Definitions, especially the provision that has been made for a major organizational component to obtain recognition as a separate bidder.

The commenters requested clarification, however, regarding the treatment of investment advisers and others who bid on behalf of their managed investment accounts or other clients (hereafter referred to as "investment advisers"). They expressed concern that, without a bidder category for advisers that manage accounts, it is not clear that such entities may submit bids on behalf of their managed accounts.

The Bidder Definitions do not include a separate category for investment advisers. Under the Bidder Definitions, however, if an investment adviser meets the corporation, partnership, or individual category definition, such person or entity may be considered a bidder within that category. The investment adviser may then bid in its own name and may include in its bid amounts that it is investing for clients. In that case, the adviser is considered to be the bidder for all purposes of this rule.

In the alternative, an investment adviser, when authorized by a client or principal, may place bids for the client in the name of such client, provided the client meets one of the Bidder Definitions. In that case, the client or principal is considered to be the bidder for all purposes of this rule.

It should be noted that regardless of whether the investment adviser or the client is named the bidder, §§ 356.13(a)(2) and 356.22(b) apply. Section 356.13(a)(2) provides for the aggregation of net long positions and competitive bids when one person or entity is exercising control over the net long positions or competitive bids of one or more other persons or entities. This requirement is described more fully in the section of this preamble discussing the net long position reporting requirements. Section 356.22(b) provides that the aggregate amount referred to above will be used for the purpose of the 35% award limitation.

One commenter expressed concern about the language contained in the sample certification to be used in requesting recognition as a separate bidder. The commenter suggested that the Department provide a carve-out, in the certification, for communication among support staff, e.g., legal or compliance, as distinct from information communicated among traders or business managers. The Department has not made this change. It believes that the language which refers to yields, rates, amounts, positions, and strategies related to a specific auction is integral to the certification and is not unnecessarily restrictive.

Finally, one commenter pointed out that, as proposed, a bidder must certify that it will not exchange any investment strategies that it plans to follow with any other part of its corporate structure. The commenter suggested that this provision be narrowed to prohibit the exchange of investment strategies regarding the security being auctioned. The Department has adopted this suggestion.

Procedural Requirements

It has been determined that this document is not a major regulation as defined in E.O. 12291 and a regulatory impact analysis is not required.

Although this rule was issued in proposed form to secure the benefit of

public comment, the notice and public procedures requirements of the Administrative Procedure Act are inapplicable, pursuant to 5 U.S.C. 553(a)(2). As no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) do not apply.

The collections of information contained in this rule have been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)) under control number 1535–0112. The estimated annual burden per respondent varies from 20 minutes to 40 minutes, depending on individual circumstances, with an estimated average of 30 minutes.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to Bureau of the Public Debt, Forms Management Officer, Washington, DC 20239–1300 and to the Office of Management and Budget, Paperwork Reduction Project (1535–0112), Washington, DC 20503.

List of Subjects

31 CFR Part 349

Federal Reserve System, Government securities, Securities.

31 CFR Part 356

Bonds, Federal Reserve System, Government securities, Securities.

For the reasons set forth in the preamble, 31 CFR Chapter II, subchapter B, is amended as follows:

PART 349—[REMOVED]

Part 349 is removed.

Part 356 is added to read as follows:

PART 356—SALE AND ISSUE OF MARKETABLE BOOK-ENTRY TREASURY BILLS, NOTES, AND BONDS (DEPARTMENT OF THE TREASURY CIRCULAR, PUBLIC DEBT SERIES NO. 1–92)

Subpart A—General Information

Sec.

356.0 Authority for sale and issue.
356.1 Applicability.
356.2 Definitions.
356.3 Book-entry securities and systems.
356.4 Functions of Federal Reserve Banks.
356.5 Description of securities.

Subpart B—Bidding, Certifications, and Payment

356.10 Offering announcement.
356.11 Submission of bids.
356.12 Noncompetitive and competitive bidding.
356.13 Net long position.
356.14 Submitting bids for customers.
356.15 Certifications.
356.16 Responsibility for payment.

Subpart C—Determination of Auction Awards; Settlement

356.20 Determination of auction awards.
356.21 Proration of awards.
356.22 Limitation on auction awards.
356.23 Announcing auction results.
356.24 Notice of awards; confirmations.
356.25 Payment for awarded securities.

Subpart D—Miscellaneous Provisions

356.30 Payment of principal and interest on notes and bonds.
356.31 STRIPS.
356.32 Taxation.
356.33 Reservation of rights.
356.34 Remedies.
356.35 Reservations as to terms of offerings.
356.36 Paperwork Reduction Act approval.

Appendix A to Part 356—Bidder Definitions

Appendix B to Part 356—Formulas and Tables

Exhibit A to Part 356—Sample Announcements of Treasury Offerings to the Public

Exhibit B to Part 356—Sample Autocharge Agreement to Deliver and Charge for Securities Awarded in Department of the Treasury Auctions

Exhibit C to Part 356—Minimum Par Amounts for Strips

Authority: 5 U.S.C. 301; 31 U.S.C. 3102, *et seq.*

Subpart A—General Information

§ 356.0 Authority for sale and issue.

The Secretary of the Treasury is authorized under chapter 31 of title 31, United States Code, to issue United States obligations and to offer them for sale under such terms and conditions as the Secretary may prescribe.

§ 356.1 Applicability.

Unless otherwise specified in an offering announcement, the provisions in this part, including the appendices, govern the sale and issuance of all marketable Treasury securities and any other obligations issued by the Secretary that, by the terms of the offering announcement, are made subject to this part.

§ 356.2 Definitions.

In this part, unless the context indicates otherwise:

Accrued interest means an amount payable to the Department for such part of the next semiannual interest payment that represents interest income attributed to the period prior to the date of issue. (See appendix B.)

Auction means a bidding process by which the Department sells marketable Treasury securities to the public.

Autocharge agreement means a written agreement between a submitter and a depository institution, acknowledged by a Federal Reserve Bank, which authorizes a Federal Reserve Bank to deliver securities awarded to the submitter and its customers at auction to the book-entry account of the depository institution or, when authorized, to a TREASURY DIRECT account, and to charge a funds account of the depository institution for the settlement amount of the securities. (See Exhibit B for a sample autocharge agreement.)

Bid means an offer to purchase a stated par amount of securities, either competitively or noncompetitively, in an auction.

Bidder, as further defined in appendix A, means a person or an entity that bids either directly or through an entity authorized to submit bids for customers in an auction. In some cases, two or more persons or entities are considered to be one bidder based on their relationship or their actions in participating in an auction.

Book-entry security means a security the issuance and maintenance of which are represented by an accounting entry or electronic record and not by a certificate.

Call means the redemption, pursuant to the terms specified in its offering announcement, of a security, in whole or in part, prior to maturity, at the option of the Secretary.

Competitive bid means a bid to purchase a stated par amount of securities at a specified yield or discount rate.

Corpus means the principal component of a stripped security and future callable semiannual interest payments, if any.

CUSIP means Committee on Uniform Securities Identification Procedures.

CUSIP number means the unique identifying number assigned to each separate security issue and each separate STRIPS component. CUSIP numbers are provided by the CUSIP Service Bureau of Standard & Poor's Corporation.

Customer means a bidder on whose behalf a depository institution or dealer has been directed to submit or forward a competitive or noncompetitive bid for a specified amount of securities in a specific auction. Only depository institutions and dealers may submit or forward bids for customers, whether directly at a Federal Reserve Bank or the Bureau of the Public Debt, or through an intermediary depository institution or dealer.

Dated date means the date from which interest accrues. The dated date

and issue date are the same except when the date from which interest accrues is prior to the issue date.

Dealer means an entity that is registered or has given notice of its status as a government securities broker or government securities dealer, pursuant to Section 15C(a)(1) of the Securities Exchange Act of 1934.

Department means the United States Department of the Treasury.

Depository institution means:

(1) An entity described in section 19(b)(1)(A), excluding subparagraph (vii), of the Federal Reserve Act (12 U.S.C. 461(b)(1)(A)). Under section 19(b)(1)(A) of the Federal Reserve Act, the term *depository institution* includes:

(i) Any insured bank as defined in 12 U.S.C. 1813 or any bank which is eligible to make application to become an insured bank under 12 U.S.C. 1815;

(ii) Any mutual savings bank as defined in 12 U.S.C. 1813 or any bank which is eligible to make application to become an insured bank under 12 U.S.C. 1815;

(iii) Any savings bank as defined in 12 U.S.C. 1813 or any bank which is eligible to make application to become an insured bank under 12 U.S.C. 1815;

(iv) Any insured credit union as defined in 12 U.S.C. 1752 or any credit union which is eligible to make application to become an insured credit union under 12 U.S.C. 1781;

(v) Any member as defined in 12 U.S.C. 1422; and

(vi) Any savings association (as defined in 12 U.S.C. 1813) which is an insured depository institution (as defined in the Federal Deposit Insurance Act, 12 U.S.C. 1811, et seq.) or is eligible to apply to become an insured depository institution under such Act.

(2) Any agency or branch of a foreign bank as defined by the International Banking Act of 1978, as amended (12 U.S.C. 3101).

Discount means the difference between par and the price of the security, when the price is less than par.

Discount amount means the discount divided by 100 and multiplied by the par amount.

Discount rate, also referred to as "bank discount rate," means an annualized rate of return to maturity on bills, expressed in percentage terms and based on a 360-day year. [See appendix B for formulas and examples.]

Federal Reserve Bank means a Federal Reserve Bank or a branch of a Federal Reserve Bank.

Funds account means a cash account maintained by a depository institution at a Federal Reserve Bank.

Interest rate means the annual percentage rate of interest paid on the par amount of a specific issue of notes or bonds. [See appendix B for methods and examples of interest calculations on notes and bonds.]

Intermediary means a depository institution or dealer that forwards bids for customers to another depository institution or dealer and not directly to a Federal Reserve Bank or the Bureau of the Public Debt.

Issue date means the date specified in the offering announcement on which a security is issued as an obligation of the United States, and from which interest normally begins to accrue.

Marketable security means a security that is negotiable and transferable, i.e., may be bought and sold in the secondary market.

Maturity date means the date specified in the offering announcement on which a security becomes due and payable, and ceases to earn interest.

Minimum to hold means the smallest amount of a security that will be issued to a bidder and may be held in any book-entry account. Unless otherwise stated in the offering announcement, the minimum to hold is the same as the minimum bid amount given in the offering announcement.

Multiple-price auction means an auction in which each successful bidder pays the price equivalent to the yield or rate that it bid.

Multiple to hold means the smallest additional amount of a security that will be issued to a bidder and may be held in any book-entry account above the minimum to hold. Unless otherwise stated in the offering announcement, the multiple to hold is the same as the multiple to bid amount given in the offering announcement.

Noncompetitive bid means a bid to purchase securities at the weighted average yield or discount rate of awards to competitive bidders.

Par means a price of 100. [See appendix B.]

Par amount means the stated value of a security that will be paid at maturity.

Person means a natural person.

Premium means the difference between par and the price of the security, when the price is greater than par.

Premium amount means the premium divided by 100 and multiplied by the par amount.

Price means the price of a security as calculated using the formulas in appendix B.

Public offering means the par amount of securities offered to the public for purchase in an auction. For all bills except cash management bills, the public offering is the amount specified in the offering announcement, less securities awarded in the auction to the Federal Reserve Banks for their own account (up to the amount of maturing securities held by the Federal Reserve) and for the account of foreign and international monetary authorities (up to the amount of maturing securities held by foreign and international accounts). For notes, bonds, and cash management bills, the public offering is the same as the amount specified in the offering announcement.

Reopening means the auction of an additional amount of an outstanding security.

Secretary means Secretary of the Treasury.

Security means a Treasury bill, note, or bond, each as described in this part, and any other obligation issued by the Secretary that, by the terms of the applicable offering announcement, is made subject to this part. Security includes an interest or principal component under the STRIPS program (see below).

Settlement means final and complete payment for securities awarded in an auction.

Settlement amount means the par amount of securities awarded less any discount amount and plus any premium amount and accrued interest.

Single-price auction means an auction in which all successful bidders pay the same price regardless of the yields or rates they each bid.

STRIPS (Separate Trading of Registered Interest and Principal of Securities) means the Department's program under which eligible securities are authorized to be separated into principal and interest components, and traded separately. These components are maintained in book-entry form on the books of a Federal Reserve Bank.

Submitter means the person or entity submitting bids directly to a Federal Reserve Bank or the Bureau of the Public Debt for its own account, for the account of others, or both. The only submitters that are permitted to submit bids for the account of others are depository institutions and dealers.

Tender means the document or computer transmission submitted to a Federal Reserve Bank or the Bureau of the Public Debt by which a bidder bids for securities.

TINT means an interest component from a stripped security.

TREASURY DIRECT means the TREASURY DIRECT Book-Entry Securities System. [See 31 CFR 357, subpart C.]

Weighted average means the average of the yields or discount rates at which securities are awarded to competitive bidders weighted by the par amount of

securities allotted at each yield or discount rate.

Yield, also referred to as "yield to maturity," means the annualized rate of return to maturity on a note or bond expressed as a percentage. (See appendix B.)

§ 356.3 Book-entry securities and systems.

Securities issued subject to this part shall be held in either of two systems for maintaining book-entry securities, described. Securities may be transferred from one system to the other in accordance with Treasury regulations governing book-entry Treasury bills, notes, and bonds. See Department of the Treasury Circular No. 300, as currently revised, and Department of the Treasury Circular, Public Debt Series No. 2–86, as amended (31 CFR parts 306 and 357).

(a) *Commercial book-entry system.*[1] The commercial book-entry system is established, maintained, and operated by the Federal Reserve Banks, acting as fiscal agents of the United States, pursuant to 12 U.S.C. 391. The Federal Reserve Banks maintain book-entry accounts for themselves, depository institutions, and other authorized entities, such as government and international agencies and foreign central banks. In their accounts, depository institutions maintain securities held for their own account and for the accounts of others, including other depository institutions and dealers, which may, in turn, maintain accounts for others.

(b) *TREASURY DIRECT.* TREASURY DIRECT is a system in which the book-entry securities of account holders are identified and maintained directly on the records of the Bureau of the Public Debt, Department of the Treasury.

§ 356.4 Functions of Federal Reserve Banks.

Federal Reserve Banks, as fiscal agents of the United States, are authorized to perform all activities necessary to carry out the provisions of this part, any offering announcements, and applicable regulations.

§ 356.5 Description of securities.

Securities offered pursuant to this part are offered exclusively in book-entry form and are direct obligations of the United States, issued under chapter 31 of title 31 of the United States Code. The securities are subject to the terms and conditions set forth in this part, as well as the general regulations governing United States securities (31 CFR part 306), the regulations governing book-entry Treasury bills, notes, and bonds (31 CFR part 357), and the offering announcements, all to the extent applicable. When the Department issues additional securities with the same CUSIP number as outstanding securities, all securities with the same CUSIP number are considered the same security.

(a) *Treasury bills.* Treasury bills are issued at a discount, are redeemed at their par amount at maturity, and have maturities of not more than one year.

(b) *Treasury notes.* Treasury notes are issued with a stated rate of interest, earn interest semiannually, and are redeemed at their par amount at maturity. They are sold at discount, par, or premium, depending upon the auction results. They have maturities of at least one year, but of not more than ten years.

(c) *Treasury bonds.* Treasury bonds are issued with a stated rate of interest, earn interest semiannually, and are redeemed at their par amount at maturity. They are sold at discount, par, or premium, depending upon the auction results. They typically have maturities of more than ten years.

Subpart B—Bidding, Certifications, and Payment

§ 356.10 Offering announcement.

The Department provides public notice of the sale of bills, notes, and bonds by issuing an offering announcement. The offering announcement lists the specifics of each offering, e.g., offering amount, term and type of security, CUSIP number, and issue and maturity dates. The offering announcement and this part, including the Appendices, specify the terms and conditions of sale. To the extent that the provisions of an offering announcement are inconsistent with the provisions of this part, the provisions of the offering announcement will control. (See Exhibit A for sample announcements.)

§ 356.11 Submission of bids.

(a) *General.* (1) Bids may be submitted directly to a Federal Reserve Bank that is authorized to accept tenders or to the Bureau of the Public Debt, Washington, DC, or through a depository institution or dealer that is authorized, pursuant to § 356.14, to submit bids on behalf of customers. Except as otherwise provided in this section, tenders must be submitted in an approved format. Competitive and noncompetitive bids must be received prior to the respective closing times specified in the offering announcement, except as provided in paragraph (b)(2) of this section. Bids not received timely will not be recognized in the auction. Bids for securities are binding on the bidder after the closing time specified in the offering announcement.

(2) If the awarded securities are to be issued in the commercial book-entry system, a submitter must have on file at a Federal Reserve Bank a certificate listing those persons who are authorized to submit tenders on its behalf. The certificate must be duly executed by an authorized person on behalf of the submitter. A tender will not be recognized if the person submitting the tender is not listed on the certificate. The submitter is responsible for any tenders submitted for the submitter by persons who are designated on the certificate as authorized to submit tenders on its behalf.

(b) *Submission of paper tenders.* (1) Paper tenders should be on preprinted forms provided by the Federal Reserve Bank to which the tender is submitted or preprinted forms of the Bureau of the Public Debt, and should provide the information requested on the form. Paper tenders in any other form or incomplete tenders may be accepted or rejected at the option of the Department.

(2) The submitter is responsible for ensuring that the paper tender is received timely at the Federal Reserve Bank or the Bureau of the Public Debt, Washington, DC. A noncompetitive bid is considered timely if received prior to the deadline for the receipt of noncompetitive tenders. Further, a noncompetitive bid received after the deadline for the receipt of noncompetitive tenders is considered timely only if it was submitted by mail and only if the envelope containing the tender bears a U.S. Postal Service cancellation date prior to the auction date and the tender is received on or before the issue date.

(3) Neither the Federal Reserve Bank nor the Department shall be, in any way, responsible for any unauthorized paper tender submissions or for any delays, errors, or omissions in the submission of paper tenders.

(c) *Submission of tenders by computer.* Competitive and noncompetitive tenders may be submitted by computer transmission to a Federal Reserve Bank. Tenders may be submitted by computer only by those submitters that have previously arranged with a Federal Reserve Bank for such submission.

(1) For computer tenders, the submitter must comply with computer communications and electronic access standards and requirements for Treasury auctions. Incomplete tenders or transmissions that do not comply with

[1] Upon the adoption of a final rule therefor, the commercial book-entry system will be referred to as the Treasury/Reserve Automated Debt Entry System (TRADES).

such standards and requirements may be accepted or rejected at the option of the Department.

(2) All tenders submitted by computer are binding on the submitter to the same extent as if they had been paper tenders. No paper tender should be submitted that duplicates a tender submitted by computer.

(3) Tenders submitted by computer must be received by the applicable closing time; the Federal Reserve Bank's computer time stamp will establish the time of receipt.

(4) The submitter bears sole risk for any disruption or failure in the operation of its own computer, any electronic-based communications facilities, or any communications lines between the submitter and the Federal Reserve Bank.

(5) The submitter is responsible for tenders submitted using computer equipment on its premises, whether or not such tenders are authorized.

(6) Neither the Federal Reserve Bank nor the Department shall be, in any way, responsible for any delays, errors, or omissions in the submission of tenders.

§ 356.12 Noncompetitive and competitive bidding.

(a) *General.* All bids must state the par amount of securities bid for and must equal or exceed the minimum bid amount stated in the offering announcement. Bids that exceed the minimum bid amount must be in the multiple stated in the offering announcement.

(b) *Noncompetitive.* A bidder bidding competitively for its own account may not bid noncompetitively for its own account in the same auction. A request for reinvestment of securities maturing in TREASURY DIRECT is a noncompetitive bid.

(1) *Maximum bid.* A bidder may not bid noncompetitively for more than $1 million in a bill auction or more than $5 million in a note or bond auction. The maximum bid limitation does not apply to bidders who are bidding solely through TREASURY DIRECT reinvestment requests.

(2) *Additional restrictions.* A bidder may not bid noncompetitively for its own account if, in the security being auctioned, it holds a position in when-issued trading or in futures or forward contracts between the date of the offering announcement and the designated closing time for the receipt of competitive tenders. Prior to the designated closing time for receipt of competitive tenders, a noncompetitive bidder may not enter into any agreement to purchase or sell or otherwise dispose of the securities it is acquiring in the auction.

(c) *Competitive.* A bidder bidding noncompetitively for its own account may not bid competitively for its own account in the same auction.

(1) *Bid format.* A competitive bid must show the yield or discount rate bid, expressed with two decimals. Fractions may not be used.

(2) *Maximum recognized bid.* There is no limitation on the maximum dollar amount that a bidder may bid for competitively, either at one yield or discount rate, or at different yields or discount rates. However, a competitive bid by a bidder at a single yield or discount rate that exceeds 35% of the public offering amount will be reduced to that amount. For example, if the public offering is $10 billion, the maximum bid amount that will be recognized at any one yield or discount rate from any bidder is $3.5 billion. (See § 356.22 for award limitations.)

§ 356.13 Net long position.

(a) *Reporting net long positions.* (1) When bidding competitively, a bidder must report the amount of its net long position when the total of all of its bids in an auction plus the bidder's net long position in the security being auctioned equals or exceeds $2 billion. If the bidder either has no position or has a net short position and the total of all of its bids equals or exceeds $2 billion, a net long position of zero must be reported. In cases where a bidder that is required to report the amount of its net long position bids through more than one submitter or Federal Reserve Bank, the bidder's total net long position should be reported through only one submitter or Federal Reserve Bank to which a bid was submitted. A bidder that is a customer must report its net long position through one depository institution or dealer. (See § 356.14(c).)

(2) If a person or entity (such as an investment adviser) is exercising control over the net long positions or competitive bids of one or more other persons or entities, then such net long positions and bids, as well as its own net long positions and competitive bids, must be combined for purposes of this paragraph (a)(2). If the combined amount of those net long positions and bids equals or exceeds $2 billion, then the person or entity exercising control must report: (i) A combined net long position that aggregates its own net long position with the other net long positions under its control; and (ii) the name of each person or entity in whose name it is placing competitive bids in the auction. The person or entity exercising control need not include in the combined amount any net long position less than $500 million of any person or entity in whose name it is not placing a competitive bid. The report required by this paragraph (a)(2) must be provided, prior to the closing time for receipt of competitive tenders, to a Federal Reserve Bank to which a competitive bid is being submitted.

(b) *Determination of net long position.* The net long position must be determined as of the designated reporting time, which is one-half hour prior to the closing time for receipt of competitive bids. A net long position includes the par amount of:

(1) Holdings of outstanding securities with the same CUSIP number as the security being auctioned;

(2) Positions, in the security being auctioned, in

(i) When-issued trading,

(ii) Futures contracts that require delivery of the specific security being auctioned (but not futures contracts for which the security being auctioned is one of several securities that may be delivered, and not futures contracts that are cash-settled), and

(iii) Forward contracts; and

(3) Holdings of STRIPS principal components of the security being auctioned, including when-issued trading positions of such principal components.

§ 356.14 Submitting bids for customers.

Depository institutions and dealers may submit bids for their own account, for their customers, or for customers of intermediaries, subject to the requirements set out in paragraphs (a), (b), and (c) of this section. Others are permitted to submit bids only for their own account.

(a) *Payment.* By submitting a bid on behalf of its customer or a customer of any intermediary, a submitter agrees to remit payment for securities awarded as a result of such bid.

(b) *Customer lists.* A customer list must be submitted or be available, as provided in paragraphs (b) (1), (2) and (3), whenever bids for more than one customer are included on the same tender. The customer list must include direct customers of the submitter as well as customers of any intermediaries who are forwarding customer bids to the submitter.

(1) For competitive bids submitted by paper tender, the submitter must provide a separate tender for each yield or discount rate at which a bid is submitted. As a part of such tender, the submitter must provide a list that includes the full name of each customer and the amount bid by each customer. For competitive bids submitted by

computer, the submitter may submit bids at multiple yields or discount rates on the same tender. On each such tender, the submitter must submit the full name of each customer and the amount bid at each yield or discount rate by each customer.

(2) For noncompetitive bids, a list must be provided that includes the full name of each customer and the amount bid by each customer. For mailed tenders, the customer list must be submitted with the tender. For other than mailed tenders, the customer list should accompany the tender. If the customer list is not submitted with the tender, information for the list must be complete and available for review by the deadline for submission of noncompetitive tenders, and must be received by the Federal Reserve Bank to which the tender was submitted by close of business on the auction day.

(3) Bids submitted on behalf of trusts or other fiduciary estates must identify on the customer list the full name or title of the trustee or fiduciary; a reference to the document creating the trust or fiduciary estate with date of execution; and the employer identification number of the trust or fiduciary estate.

(c) *Net long position of customers.* (1) A submitter or intermediary, when submitting or forwarding a competitive bid of $100 million or more for its customer, must inform that customer of the customer's net long position reporting obligation as described in § 356.13.

(2) A submitter or intermediary, when submitting or forwarding a competitive bid for a customer, must report the net long position amount if such amount is provided by the customer.

(3) If personnel of a submitter or intermediary who are directly involved in receiving or forwarding a customer's bid know that the position information provided by a customer is incorrect, the customer's bid shall not be submitted or forwarded by the submitter or intermediary.

(4) If the amount of a customer's net long position is to be reported by the submitter by paper tender, a separate tender must be submitted for that customer that includes the amount of the net long position.

§ 356.15 Certifications.

(a) *Submitters.* By submitting a tender for a security, a submitter is deemed to have certified that it is in compliance with this part and the offering announcement governing the sale and issue of the security. Further, the submitter is deemed to have certified that the information provided on the tender with regard to bids for its own account is accurate and complete, and that the information provided on the tender with regard to bids for customers accurately and completely reflects information provided to it by its customers or intermediaries. Prior to submitting a computer tender, a submitter must have on file a written certification that the submitter is certifying, each time it submits a computer tender, that it is in compliance with this part and the applicable offering announcement. The certification must be signed and dated by an authorized person on behalf of the submitter, be filed with the Federal Reserve Bank to which the computer tender is submitted, and be renewed at least annually.

(b) *Intermediaries.* By forwarding a bid, an intermediary is deemed to have certified that it is in compliance with this part and the offering announcement governing the sale and issue of the security. Further, the intermediary is deemed to have certified that the information provided to a submitter or other intermediary with regard to bids for its own account is accurate and complete, and that the information provided to a submitter or other intermediary with regard to bids for customers accurately and completely reflects information provided to it by its customers or intermediaries.

(c) *Customers.* By bidding for a security, a customer is deemed to have certified that it is in compliance with this part and the offering announcement governing the sale and issue of the security and that the information it provided to the submitter or intermediary in connection with the bid is accurate and complete.

§ 356.16 Responsibility for payment.

A bidder agrees to pay the settlement amount for any securities awarded to it in the auction. (See § 356.25.) In addition, certain payments or provisions for payment are required at the time a tender is submitted. The specific requirements, outlined in this section, depend on whether awarded securities will be delivered to TREASURY DIRECT or the commercial book-entry system.

(a) *TREASURY DIRECT.* For securities to be held in TREASURY DIRECT, payment of the par amount and announced accrued interest, if any, must be submitted with the tender unless other provision has been made, such as provision for payment by charge to the funds account of a depository institution.

(1) *Payment with tender.* For bills, payment must be by cash, depository institution (cashier's or teller's) check, certified check, currently dated Treasury or fiscal agency check made payable to the bidder, or definitive Treasury securities maturing on or before the issue date of the securities being auctioned, but which are not overdue as defined in the general regulations governing United States securities (31 CFR 306.25). Also, maturing securities held in TREASURY DIRECT may be used as payment for new securities that are being offered, provided that the appropriate transaction request is received timely. For notes or bonds, payment must be in one of the forms described above for bills, or by personal check. Checks submitted to a Federal Reserve Bank must be made payable to that Bank and checks submitted to the Bureau of the Public Debt must be made payable to the Bureau of the Public Debt.

(2) *Authorized charge to a funds account.* If a depository institution or dealer submits a tender for a TREASURY DIRECT bidder and payment is not submitted with the tender, an authorization from a depository institution to charge the institution's funds account at a Federal Reserve Bank must be submitted with the tender.

(b) *Commercial book-entry system.* For securities to be held in the commercial book-entry system, payment of the par amount and announced accrued interest, if any, must be submitted with the tender unless provision has been made for payment by charge to the funds account of a depository institution.

(1) *Payment with tender.* Where payment is submitted with the tender, payment must be by one of the means specified under paragraph (a)(1) of this section.

(2) *Authorized charge to a funds account.* Where payment is not submitted with the tender, an authorization to charge the funds account of a depository institution must be provided as follows.

(i) A depository institution with a funds account submitting tenders directly to a Federal Reserve Bank may authorize the Bank to charge its funds account upon delivery of the securities.

(ii) A submitter that chooses not to pay by charge to its funds account or a submitter that does not have a funds account must, prior to the submission of a tender, have an approved autocharge agreement on file at the Federal Reserve Bank to which the tender is submitted. By submitting a tender for securities to be paid for under such autocharge agreement, the submitter authorizes the Federal Reserve Bank to provide, to the depository institution whose funds

account will be charged under the agreement, notice of the total par amount of, and price to be charged for, securities awarded as a result of the submitter's tender.

Subpart C—Determination of Auction Awards; Settlement

§ 356.20 Determination of auction awards.

(a) *Determining the range and amount of accepted competitive bids.*—(1) *Accepting bids.* Determinations of awards in auctions are made at the Bureau of the Public Debt after the closing time for receipt of bids. In determining auction awards, the Bureau of the Public Debt first accepts in full all noncompetitive bids received by the closing time specified in the offering announcement. Then competitive bids are accepted, starting with those at the lowest yields or discount rates through successively higher yields or discount rates, up to the amount required to meet the public offering. Bids at the highest accepted yield or discount rate will be prorated (as described in paragraph (a)(2) of this section), if necessary. If the amount of noncompetitive bids would absorb most or all of the public offering, competitive bids will be accepted in an amount determined by the Department to be sufficient to provide a fair determination of the yield or discount rate for the securities being auctioned.

(2) *Accepting bids at the high yield or discount rate.* When the total amount of bids at the highest accepted yield or discount rate exceeds the amount of the public offering remaining after acceptance of noncompetitive bids and competitive bids at the lower yields or discount rates, a percentage of the bids received at the highest accepted yield or discount rate will be awarded. This proration is performed for the purpose of awarding a par amount of securities close to the public offering amount. The percentage is derived by dividing the remaining par amount needed to fill the public offering by the par amount of the bids recognized at the high yield or rate and rounding up to the next whole percentage point.

(b) *Determining the interest rate for new note and bond issues.* The interest rate established as a result of the auction will generally be set at the ⅛ of one percent increment that produces the price closest to, but not above, par when evaluated at the weighted average yield of awards to competitive bidders.

(c) *Determining purchase prices for awarded securities.* (See Appendix B for formulas and tables. Price calculations will be rounded to three decimal places on the basis of price per hundred, e.g., 99.954.)

(1) *Multiple-price auctions*—(i) *Competitive bids.* The price of securities awarded to competitive bidders is the price equivalent to each yield or discount rate at which their bids were accepted.

(ii) *Noncompetitive bids.* The price of securities awarded to noncompetitive bidders is the price equivalent to the weighted average yield or discount rate of accepted competitive bids.

(2) *Single-price auctions.* The price of securities awarded to both competitive and noncompetitive bidders is the price equivalent to the highest yield or discount rate at which bids were accepted.

§ 356.21 Proration of awards.

(a) *Awards to submitters.* In auctions where bids at the highest accepted yield or discount rate are prorated under § 356.20(a)(2), the Federal Reserve Banks are responsible for prorating awards for submitters at the percentage announced by the Department. For example, if 80% is the announced percentage at the highest yield or discount rate, then each bid at that rate or yield shall be awarded 80% of the amount bid. Hence, a bid for $100,000 at the highest accepted yield or discount rate would be awarded $80,000. In all cases, awards will be for, at least, the minimum to hold, and awards must be in an appropriate multiple to hold. For example, Treasury bills may be issued with a minimum to hold of $10,000 and multiples to hold of $5,000. Where a $100,000 bid is accepted at the high discount rate, and the percent awarded at the high discount rate was 11%, the award to that bidder would be $15,000, because bills cannot be held in an amount of $11,000. Awards at the highest accepted yield or rate are adjusted upwards, if necessary, to an appropriate multiple to hold. If tenders at the highest accepted rate were prorated at, for example, a rate of 4%, the award for a $100,000 bid would be $10,000, instead of $4,000, in order to meet the minimum to hold for a bill issue.

(b) *Awards to customers.* In auctions where bids at the highest accepted yield or discount rate are prorated under § 356.20(a)(2), depository institutions and dealers, whether submitters or intermediaries, are responsible for prorating awards for their customers at the same percentage as that announced by the Department. For example, if 80% is the announced percentage at the highest yield or discount rate, then each customer bid at that rate or yield shall be awarded 80%. The same prorating rules apply to customers as apply to submitters.

§ 356.22 Limitation on auction awards.

(a) *Awards to noncompetitive bidders.* The maximum award that will be made to any bidder is $1 million for bills and $5 million for notes and bonds. This does not apply to bidders bidding solely through TREASURY DIRECT reinvestment requests.

(b) *Awards to competitive bidders.* The maximum award that will be made to any bidder is 35% of the public offering less the bidder's net long position as reportable under § 356.13. For example, in a note auction with a $10 billion public offering, a bidder with a reported net long position of $1 billion could receive a maximum auction award of $2.5 billion. When the bids and net long positions of more than one person or entity must be combined as required by § 356.13(a)(2), such combined amount will be used for the purpose of this award limitation.

§ 356.23 Announcing auction results.

After the conclusion of the auction, the Department will make an official announcement of the auction results through a press release. The press release will include such information as the amounts of bids recognized and accepted, the range of yields or discount rates at which securities were awarded, noncompetitive yield or discount rate, proration percentage, the interest rate for a note or bond, a breakdown of the amounts of noncompetitive and competitive bids recognized and accepted from the public, the amounts recognized and accepted from the Federal Reserve Banks for their own accounts and for foreign and international monetary authorities, and the minimum par amount required to strip a STRIPS-eligible note or bond.

§ 356.24 Notice of awards; confirmations.

(a) *Notice of awards.* Notice of awards will be provided by a Federal Reserve Bank or the Department to submitters of successful competitive bids. Submitters of noncompetitive bids will be notified only when the price to be paid by noncompetitive bidders is over par or if noncompetitive bids are not accepted in full.

(b) *Confirmation of award to customer.* A submitter submitting a bid for customers is responsible for notifying its customers and intermediaries that forwarded bids to it of the awards. Similarly, an intermediary is responsible for notifying its customers and any intermediaries that forwarded bids to it of the awards.

(c) *Confirmation of award and settlement amount to a depository institution having an autocharge agreement with a submitter.* Not later

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than the day after each auction, the appropriate Federal Reserve Bank will notify each depository institution that has entered into an autocharge agreement with a submitter as to the amount to be charged to the institution's funds account at the Federal Reserve Bank on the issue date.

(d) *Customer confirmation.* Any customer awarded a par amount of $500 million or more in an auction must furnish a confirmation including the information in paragraphs (d) (1) and (2) of this section to the Federal Reserve Bank to which the bid was submitted, no later than 10:00 a.m. on the day following the auction. The confirmation must be signed by the customer or authorized representative and must include the capacity in which such representative is acting. A submitter or intermediary submitting or forwarding a customer bid is responsible for notifying its customer of this requirement if the customer is awarded a par amount of $500 million or more as a result of bids submitted by the submitter or forwarded by the intermediary.

(1) A written confirmation of its bid, and

(2) A written statement indicating whether it had a reportable net long position as defined in § 356.13, and, if a position had to be reported, the amount of any such position and the name of the depository institution or dealer through which the customer requested that the position be reported.

§ 356.25 Payment for awarded securities.

Payment for securities is to be accomplished by the issue date. Payment will be accomplished as follows:

(a) *Payment with tender.* When payment is made with the tender as provided for in § 356.16 (a)(1) and (b)(1), settlement is accomplished as follows:

(1) *When an amount is due the submitter.* When the payment previously remitted by the submitter exceeds the settlement amount, the balance will be refunded to the submitter following the auction.

(2) *When the submitter must remit an additional amount.* When the settlement amount exceeds the payment previously remitted by the submitter, the submitter will be notified of the additional amount due and is responsible for remitting it immediately. Such additional amount may be due if the auction calculations result in a premium or if accrued interest is due.

(b) *Payment by authorized charge to a funds account.* Where the submitter's method of payment is an authorized charge to the funds account of a depository institution as provided for in §§ 356.16 (a)(2) and (b)(2), the settlement amount will be charged to the specified funds account on the issue date.

Subpart D—Miscellaneous Provisions

§ 356.30 Payment of principal and interest on notes and bonds.

Principal on notes and bonds will be paid on the maturity date as specified in the offering announcement unless the security is called pursuant to its terms and in accordance with appropriate public notice. Interest on notes and bonds accrues from the dated date. Interest is payable on a semiannual basis on the interest payment dates specified in the offering announcement through the date that the principal becomes payable. In the event any principal or interest payment date is a Saturday, Sunday, or other day on which the Federal Reserve Banks are not open for business, the amount is payable (without additional interest) on the next business day.

§ 356.31 STRIPS.

(a) *General.* A note or bond may be designated in the offering announcement as eligible for the STRIPS program. At the option of the holder, and generally at any time from its issue date until its call or maturity, any such security may be "stripped," i.e., divided into separate principal and interest components maintained in the commercial book-entry system. The principal components of such stripped security have a single CUSIP number that is different from the CUSIP number of the fully-constituted (unstripped) security. When an interest payment is stripped, an interest component is created and the interest payment date becomes the maturity date for the component. A short or long first interest payment and all interest payments within a callable period are not eligible to be stripped from the principal component. All interest components with the same maturity date have the same CUSIP number, regardless of the underlying security from which the interest payments were stripped. The CUSIP numbers of all interest components are different from the CUSIP number of any fully-constituted security and any principal component. The CUSIP numbers and payment dates for the principal and interest components are provided in the offering announcement if not previously announced.

(b) *Minimum par amounts required for STRIPS.* For a note or bond to be stripped into the components described in paragraph (a) of this section, the par amount of the note or bond must be in an amount that, based on its interest rate, will produce a semiannual interest payment in a multiple of $1,000. Exhibit C to this part provides the minimum par amounts required to strip a note or bond at various interest rates, as well as the corresponding interest payments. Amounts greater than the minimum par amount must be in multiples of that amount. The minimum par amount required to strip a particular security will be provided in the press release announcing the auction results.

(c) *Reconstituting a security.* Stripped interest and principal components may be reconstituted, i.e., restored to their fully-constituted form, and maintained in the commercial book-entry system. A principal component and all related unmatured interest components, in the appropriate minimum or multiple amounts, must be submitted together for reconstitution.

(d) *Applicable regulations.* Unless otherwise provided in this part, the Department's general regulations governing United States securities (31 CFR part 306) apply to notes and bonds separated into their STRIPS components.

§ 356.32 Taxation.

Securities issued under this part are subject to all applicable taxes imposed under the Internal Revenue Code of 1986. Under section 3124 of title 31, United States Code, the securities are exempt from taxation by a State or political subdivision of a State, except for State estate or inheritance taxes and other exceptions as provided in that section.

§ 356.33 Reservation of rights.

The Secretary reserves the right to accept or reject or refuse to recognize any or all bids or tenders submitted under this part. The Secretary also reserves the right to award more or less securities than the amount of securities specified in the offering announcement. The Secretary further reserves the right to waive any provision or provisions of this part for any or all bidders or submitters. Decisions of the Secretary under this section shall be final.

§ 356.34 Remedies.

(a) *General.* When a person or an entity fails to comply with the requirements of this part, the Secretary will consider the circumstances of such failure and determine an appropriate remedy. Such remedy may include prohibiting the person or entity from participating in future auctions for its own account, for the account of others, or both. The Secretary may refer such

occurrences to the appropriate regulatory agency for enforcement action.

(b) *Liquidated damages.* A bidder agrees to pay liquidated damages of 1% of the par amount of securities awarded the bidder in an auction if the bidder fails to pay for the awarded securities in a timely manner. The Secretary may waive, in whole or in part, the payment of liquidated damages. This liquidated damages provision shall not preclude the use of any other available remedy.

§ 356.35 Reservations as to terms of offerings.

The Secretary reserves the right to supplement or amend provisions of this part. The Secretary further reserves the right to modify the terms and conditions of new securities and to depart from the customary pattern of securities offerings at any time. Public notice of any such changes will be provided.

§ 356.36 Paperwork Reduction Act approval.

The collections of information contained in §§ 356.11, 356.12, 356.13, and 356.14, and in appendix A of this part have been approved by the Office of Management and Budget under control number 1535–0112.

Appendix A to Part 356—Bidder Definitions

For the purpose of this part, the definitions set forth in this appendix describe all of the categories of bidders eligible to bid in Treasury auctions. These definitions are to be used by persons and entities in determining whether they are considered one bidder or more than one bidder for the purpose of bidding in auctions and for the purpose of complying with the requirements of this part. Notwithstanding these definitions, any persons or entities that intentionally act together with respect to bidding in a Treasury auction are considered, collectively, to be one bidder.

The following definitions will be used by the Department in applying competitive and noncompetitive award limitations and related requirements, as described in this part.

(a) *Corporation*—A corporation and all affiliates, whether persons, partnerships, or other entities, hereinafter referred to as a corporate structure, are considered, collectively, to be one bidder.

An affiliate is any: entity that is more than 50% owned, directly or indirectly, by the corporation; entity that is more than 50% owned, directly or indirectly, by any other affiliate of the corporation; person or entity that owns, directly or indirectly, more than 50% of the corporation; person or entity that owns, directly or indirectly, more than 50% of any other affiliate of the corporation; or entity, a majority of whose board of directors or a majority of whose general partners are directors or officers of the corporation or of any affiliate of the corporation.

Under certain circumstances, one or more major organizational components (e.g., the parent or a subsidiary) in a corporate structure, either separately or together with one or more other organizational components in the corporate structure, may be recognized as a bidder separate from the larger corporate structure. All of the following criteria must be met for such component or components to qualify for recognition as a separate bidder:

(1) Such component or components must be prohibited by law or regulation from exchanging, or must have established written internal procedures (i.e., Chinese walls) designed to prevent the exchange of, information related to bidding in Treasury auctions with any other component in the corporate structure;

(2) Such component or components must not be created for the purpose of circumventing the Department's bidding and award limitations;

(3) Decisions related to purchasing Treasury securities at auction and participation in specific auctions must be made by employees of such component or components. Employees of such component or components that make decisions to purchase or dispose of Treasury securities must not perform the same function for other components within the corporate structure; and

(4) The records of such component or components related to the bidding for, acquisition of, and disposition of Treasury securities must be maintained by such component or components. Those records must be identifiable—separate and apart from similar records for other components within the corporate structure.

To obtain recognition as a separate bidder, each component or group of components must request such recognition from the Department, provide a description of the component or group and its position within the corporate structure, and provide the following certification:

[Name of the bidder] hereby certifies that to the best of its knowledge and belief it meets the criteria for a separate bidder as described in appendix A to 31 CFR part 356. The above-named bidder also certifies that it has established written policies or procedures, including ongoing compliance monitoring processes, that are designed to prevent the component or group of components from:

(1) Exchanging any of the following information with any other part of the corporate structure: (a) Yields or rates at which it plans to bid; (b) amounts of securities for which it plans to bid; (c) positions that it holds or plans to acquire in a security being auctioned; and (d) investment strategies that it plans to follow regarding the security being auctioned, or

(2) In any way intentionally acting together with any other part of the corporate structure with respect to formulating or entering bids in a Treasury auction.

The above-named bidder agrees that it will promptly notify the Department in writing when any of the information provided to obtain separate bidder status changes or when this certification is no longer valid.

(b) *Partnership*—A partnership for which the Internal Revenue Service has assigned a tax-identification number; general partners acting on behalf of the partnership; and all affiliates, whether persons, corporations, or other entities; hereinafter referred to as a partnership structure, are considered, collectively, to be one bidder. A partnership structure that contains one or more corporations is considered one bidder under either this "partnership" category or the "corporation" category, but not both.

An affiliate is any: Entity that is more than 50% owned, directly or indirectly, by the partnership; entity that is more than 50% owned, directly or indirectly, by any other affiliate of the partnership; person or entity that owns, directly or indirectly, more than 50% of the partnership; person or entity that owns, directly or indirectly, more than 50% of any other affiliate of the partnership; or entity, a majority of whose general partners or a majority of whose board of directors are general partners or directors of the partnership or of any affiliate of the partnership.

Under certain circumstances, one or more major organizational components (e.g., the partnership or a subsidiary) in a partnership structure, either separately or together with one or more other organizational components in the partnership structure, may be recognized as a bidder separate from the larger partnership structure. All of the following criteria must be met for such component or components to qualify for recognition as a separate bidder:

(1) Such component or components must be prohibited by law or regulation from exchanging, or must have established written internal procedures (i.e., Chinese walls) designed to prevent the exchange of, information related to bidding in Treasury auctions with any other component in the partnership structure;

(2) Such component or components must not be created for the purpose of circumventing the Department's bidding and award limitations;

(3) Decisions related to purchasing Treasury securities at auction and participation in specific auctions must be made by employees of such component or components. Employees of such component or components that make decisions to purchase or dispose of Treasury securities must not perform the same function for other components within the partnership structure; and

(4) The records of such component or components related to the bidding for, acquisition of, and disposition of Treasury securities must be maintained by such component or components. Those records must be identifiable—separate and apart from similar records for other components within the partnership structure.

To obtain recognition as a separate bidder, each component or group of components must request such recognition from the Department, provide a description of the component or group and its position within the partnership structure, and provide the following certification:

[Name of the bidder] hereby certifies that to the best of its knowledge and belief it meets the criteria for a separate bidder as described in appendix A to 31 CFR part 356. The above-named bidder also certifies that it has established written policies or procedures, including ongoing compliance monitoring processes, that are designed to prevent the component or group of components from:

(1) Exchanging any of the following information with any other part of the partnership structure: (a) Yields or rates at which it plans to bid; (b) amounts of securities for which it plans to bid; (c) positions that it holds or plans to acquire in a security being auctioned; and (d) investment strategies that it plans to follow regarding the security being auctioned, or

(2) In any way intentionally acting together with any other part of the partnership structure with respect to formulating or entering bids in a Treasury auction.

The above-named bidder agrees that it will promptly notify the Department in writing when any of the information provided to obtain separate bidder status changes or when this certification is no longer valid.

(c) *Government-related entity*—(1) The government of each of the 50 states and of the District of Columbia is considered to be one bidder.

(2) A unit of local government, including any county, city, municipality, or township, or other unit of general government, as defined by the Bureau of the Census for statistical purposes, is considered to be one bidder.

(3) The government of a commonwealth, territory, or possession of the United States is considered to be one bidder.

(4) A governmental entity, body, or corporation established under Federal, State, or local law is considered to be one bidder.

(5) A foreign central bank, the government of a foreign state, or an international organization in which the United States holds membership is considered to be one bidder.

An investment, reserve, or other fund of one of the above government-related entities, not otherwise meeting the definition of the "trust or other fiduciary estate" category, is considered part of that entity and not a separate bidder unless applicable law requires that the investments of such fund be made separately.

(d) *Trust or other fiduciary estate*—A legal entity created under a valid trust instrument, court order, or other legal authority that designates a trustee or fiduciary to act for the benefit of a named beneficiary may be considered a bidder. To be considered a bidder, such legal entity must be able to be identified by the name or title of the trustee or fiduciary; specific reference to the trust instrument, court order, or legal authority under which the trustee or fiduciary is acting; and the unique IRS-assigned employer identification number (not social security number) for the entity. Further, it must be the trustee or fiduciary who makes the decisions related to participation in auctions on behalf of the trust or fiduciary estate.

(e) *Individual*—A person, whether acting in his or her individual capacity, as a sole proprietor, for any entity not otherwise defined as a bidder, or in more than one such capacity, is considered to be one bidder. When a person meets the definition of an affiliate within a corporate or partnership structure as defined above, such person may only be considered a bidder in this "individual" category when the bidder of which they are a part is not bidding in the same auction. A person acting in an official capacity as an employee or other representative of a bidder defined in any other category is not considered an "individual" bidder when acting in such capacity. A person, his or her spouse, and any children under the age of 21 having a common household are considered, collectively, to be one "individual" bidder.

(f) *Other bidder*—A bidder defined by any of the above categories is not considered a bidder in this category. A bidder not defined by any of the above categories may possibly be considered a bidder in this category. For purposes of this definition, "other bidder" means an institution or organization with a unique IRS-assigned employer identification number. This definition of other bidder includes such entities as an association, church, university, union, or club. This category does not include any person or entity acting in a fiduciary or investment management capacity, a sole proprietorship, an investment account, an investment fund, a form of registration, or investment ownership designation.

Notwithstanding the definitions in this appendix, it is the intent of the Department that no auction participant receive a larger auction award by acquiring securities through others than it could have received had it been considered a bidder under these definitions.

Appendix B to Part 356—Formulas and Tables

I. Computation of Interest on Treasury Bonds and Notes.

II. Formulas for Conversion of Bond and Note Yields to Equivalent Prices.

III. Computation of Purchase Price, Discount Rate, and Investment Rate for Treasury Bills.

I. Computation of Interest on Treasury Bonds and Notes

A. Regular Half-Year Payment Period

Interest on marketable Treasury bonds and notes is payable on a semiannual basis. The regular interest payment period is a full half-year of six calendar months. Examples of half-year periods are: (1) February 15 to August 15, (2) May 31 to November 30, and (3) February 29 to August 31 (in a leap year). Calculation of an interest payment for a note with a par amount of $1,000 and an interest rate of 8% is made in this manner: ($1,000 × .08) ÷ 2 = $40. Specifically, a semiannual interest payment represents one half of one year's interest, and is computed on this basis regardless of the actual number of days in the half-year.

B. Daily Interest Decimal

In cases where an interest payment period is shorter or longer than six months or where accrued interest is payable by an investor, a daily interest decimal, based on the actual number of days in the half-year or half-years involved, must be computed. The number of days in any half-year period is shown in Table 1.

TABLE 1

Interest period	Beginning and ending days are 1st or 15th of the months listed under interest period (number of days)		Beginning and ending days are the last days of the months listed under interest period (number of days)	
	Regular year	Leap year	Regular year	Leap year
January to July	181	182	181	182
February to August	181	182	184	184
March to September	184	184	183	183
April to October	183	183	184	184
May to November	184	184	183	183
June to December	183	183	184	184
July to January	184	184	184	184
August to February	184	184	181	182
September to March	181	182	182	183
October to April	182	183	181	182
November to May	181	182	182	183
December to June	182	183	181	182

Table 2 below sets forth the daily interest decimals covering interest from ⅛% to 20% on $1,000 for one day in increments of ⅛ of one percent. These decimals represent 1/181, 1/182, 1/183, or 1/184 of a full semiannual interest payment, depending on which half-year is applicable.

TABLE 2.—DECIMAL FOR ONE DAY'S INTEREST ON $1,000 AT VARIOUS RATES OF INTEREST, PAYABLE SEMIANNUALLY OR ON A SEMIANNUAL BASIS, IN REGULAR YEARS OF 365 DAYS AND IN YEARS OF 366 DAYS (TO DETERMINE APPLICABLE NUMBER OF DAYS, SEE TABLE 1).

Rate per annum (percent)	Half-year of 184 days	Half-year of 183 days	Half-year of 182 days	Half-year of 181 days
⅛	0.003396739	0.003415301	0.003434066	0.003453039
¼	0.006793478	0.006830601	0.006868132	0.006906077
⅜	0.010190217	0.010245902	0.010302198	0.010359116
½	0.013586957	0.013661202	0.013736264	0.013812155
⅝	0.016983696	0.017076503	0.017170330	0.017265193
¾	0.020380435	0.020491803	0.020604396	0.020718232
⅞	0.023777174	0.023907104	0.024038462	0.024171271
1	0.027173913	0.027322404	0.027472527	0.027624309
1⅛	0.030570652	0.030737705	0.030906593	0.031077348
1¼	0.033967391	0.034153005	0.034340659	0.034530387
1⅜	0.037364130	0.037568306	0.037774725	0.037983425
1½	0.040760870	0.040983607	0.041208791	0.041436464
1⅝	0.044157609	0.044398907	0.044642857	0.044889503
1¾	0.047554348	0.047814208	0.048076923	0.048342541
1⅞	0.050951087	0.051229508	0.051510989	0.051795580
2	0.054347826	0.054644809	0.054945055	0.055248619
2⅛	0.057744565	0.058060109	0.058379121	0.058701657
2¼	0.061141304	0.061475410	0.061813187	0.062154696
2⅜	0.064538043	0.064890710	0.065247253	0.065607735
2½	0.067934783	0.068306011	0.068681319	0.069060773
2⅝	0.071331522	0.071721311	0.072115385	0.072513812
2¾	0.074728261	0.075136612	0.075549451	0.075966851
2⅞	0.078125000	0.078551913	0.078983516	0.079419890
3	0.081521739	0.081967213	0.082417582	0.082872928
3⅛	0.084918478	0.085382514	0.085851648	0.086325967
3¼	0.088315217	0.088797814	0.089285714	0.089779006
3⅜	0.091711957	0.092213115	0.092719780	0.093232044
3½	0.095108696	0.095628415	0.096153846	0.096685083
3⅝	0.098505435	0.099043716	0.099587912	0.100138122
3¾	0.101902174	0.102459016	0.103021978	0.103591160
3⅞	0.105298913	0.105874317	0.106456044	0.107044199
4	0.108695652	0.109289617	0.109890110	0.110497238
4⅛	0.112092391	0.112704918	0.113324176	0.113950276
4¼	0.115489130	0.116120219	0.116758242	0.117403315
4⅜	0.118885870	0.119535519	0.120192308	0.120856354
4½	0.122282609	0.122950820	0.123626374	0.124309392
4⅝	0.125679348	0.126366120	0.127060440	0.127762431
4¾	0.129076087	0.129781421	0.130494505	0.131215470
4⅞	0.132472826	0.133196721	0.133928571	0.134668508
5	0.135869565	0.136612022	0.137362637	0.138121547
5⅛	0.139266304	0.140027322	0.140796703	0.141574586
5¼	0.142663043	0.143442623	0.144230769	0.145027624
5⅜	0.146059783	0.146857923	0.147664835	0.148480663
5½	0.149456522	0.150273224	0.151098901	0.151933702
5⅝	0.152853261	0.153688525	0.154532967	0.155386740
5¾	0.156250000	0.157103825	0.157967033	0.158839779
5⅞	0.159646739	0.160519126	0.161401099	0.162292818
6	0.163043478	0.163934426	0.164835165	0.165745856
6⅛	0.166440217	0.167349727	0.168269231	0.169198895
6¼	0.169836957	0.170765027	0.171703297	0.172651934
6⅜	0.173233696	0.174180328	0.175137363	0.176104972
6½	0.176630435	0.177595628	0.178571429	0.179558011
6⅝	0.180027174	0.181010929	0.182005495	0.183011050
6¾	0.183423913	0.184426230	0.185439560	0.186464088

TABLE 2.—DECIMAL FOR ONE DAY'S INTEREST ON $1,000 AT VARIOUS RATES OF INTEREST, PAYABLE SEMIANNUALLY OR ON A SEMIANNUAL BASIS, IN REGULAR YEARS OF 365 DAYS AND IN YEARS OF 366 DAYS (TO DETERMINE APPLICABLE NUMBER OF DAYS, SEE TABLE 1).—Continued

Rate per annum (percent)	Half-year of 184 days	Half-year of 183 days	Half-year of 182 days	Half-year of 181 days
6⅞	0.186820652	0.187841530	0.188873626	0.189917127
7	0.190217391	0.191256831	0.192307692	0.193370166
7⅛	0.193614130	0.194672131	0.195741758	0.196823204
7¼	0.197010870	0.198087432	0.199175824	0.200276243
7⅜	0.200407609	0.201502732	0.202609890	0.203729282
7½	0.203804348	0.204918033	0.206043956	0.207182320
7⅝	0.207201087	0.208333333	0.209478022	0.210635359
7¾	0.210597826	0.211748634	0.212912088	0.214088398
7⅞	0.213994565	0.215163934	0.216346154	0.217541436
8	0.217391304	0.218579235	0.219780220	0.220994475
8⅛	0.220788043	0.221994536	0.223214286	0.224447514
8¼	0.224184783	0.225409836	0.226648352	0.227900552
8⅜	0.227581522	0.228825137	0.230082418	0.231353591
8½	0.230978261	0.232240437	0.233516484	0.234806630
8⅝	0.234375000	0.235655738	0.236950549	0.238259669
8¾	0.237771739	0.239071038	0.240384615	0.241712707
8⅞	0.241168478	0.242486339	0.243818681	0.245165746
9	0.244565217	0.245901639	0.247252747	0.248618785
9⅛	0.247961957	0.249316940	0.250686813	0.252071823
9¼	0.251358696	0.252732240	0.254120879	0.255524862
9⅜	0.254755435	0.256147541	0.257554945	0.258977901
9½	0.258152174	0.259562842	0.260989011	0.262430939
9⅝	0.261548913	0.262978142	0.264423077	0.265883978
9¾	0.264945652	0.266393443	0.267857143	0.269337017
9⅞	0.268342391	0.269808743	0.271291209	0.272790055
10	0.271739130	0.273224044	0.274725275	0.276243094
10⅛	0.275135870	0.276639344	0.278159341	0.279696133
10¼	0.278532609	0.280054645	0.281593407	0.283149171
10⅜	0.281929348	0.283469945	0.285027473	0.286602210
10½	0.285326087	0.286885246	0.288461538	0.290055249
10⅝	0.288722826	0.290300546	0.291895604	0.293508287
10¾	0.292119565	0.293715847	0.295329670	0.296961326
10⅞	0.295516304	0.297131148	0.298763736	0.300414365
11	0.298913043	0.300546448	0.302197802	0.303867403
11⅛	0.302309783	0.303961749	0.305631868	0.307320442
11¼	0.305706522	0.307377049	0.309065934	0.310773481
11⅜	0.309103261	0.310792350	0.312500000	0.314226519
11½	0.312500000	0.314207650	0.315934066	0.317679558
11⅝	0.315896739	0.317622951	0.319368132	0.321132597
11¾	0.319293478	0.321038251	0.322802198	0.324585635
11⅞	0.322690217	0.324453552	0.326236264	0.328038674
12	0.326086957	0.327868852	0.329670330	0.331491713
12⅛	0.329483696	0.331284153	0.333104396	0.334944751
12¼	0.332880435	0.334699454	0.336538462	0.338397790
12⅜	0.336277174	0.338114754	0.339972527	0.341850829
12½	0.339673913	0.341530055	0.343406593	0.345303867
12⅝	0.343070652	0.344945355	0.346840659	0.348756906
12¾	0.346467391	0.348360656	0.350274725	0.352209945
12⅞	0.349864130	0.351775956	0.353708791	0.355662983
13	0.353260870	0.355191257	0.357142857	0.359116022
13⅛	0.356657609	0.358606557	0.360576923	0.362569061
13¼	0.360054348	0.362021858	0.364010989	0.366022099
13⅜	0.363451087	0.365437158	0.367445055	0.369475138
13½	0.366847826	0.368852459	0.370879121	0.372928177
13⅝	0.370244565	0.372267760	0.374313187	0.376381215
13¾	0.373641304	0.375683060	0.377747253	0.379834254
13⅞	0.377038043	0.379098361	0.381181319	0.383287293
14	0.380434783	0.382513661	0.384615385	0.386740331
14⅛	0.383831522	0.385928962	0.388049451	0.390193370
14¼	0.387228261	0.389344262	0.391483516	0.393646409
14⅜	0.390625000	0.392759563	0.394917582	0.397099448
14½	0.394021739	0.396174863	0.398351648	0.400552486
14⅝	0.397418478	0.399590164	0.401785714	0.404005525
14¾	0.400815217	0.403005464	0.405219780	0.407458564
14⅞	0.404211957	0.406420765	0.408653846	0.410911602
15	0.407608696	0.409836066	0.412087912	0.414364641
15⅛	0.411005435	0.413251366	0.415521978	0.417817680
15¼	0.414402174	0.416666667	0.418956044	0.421270718
15⅜	0.417798913	0.420081967	0.422390110	0.424723757
15½	0.421195652	0.423497268	0.425824176	0.428176796
15⅝	0.424592391	0.426912568	0.429258242	0.431629834
15¾	0.427989130	0.430327869	0.432692308	0.435082873
15⅞	0.431385870	0.433743169	0.436126374	0.438535912
16	0.434782609	0.437158470	0.439560440	0.441988950
16⅛	0.438179348	0.440573770	0.442994505	0.445441989
16¼	0.441576087	0.443989071	0.446428571	0.448895028
16⅜	0.444972826	0.447404372	0.449862637	0.452348066
16½	0.448369565	0.450819672	0.453296703	0.455801105

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TABLE 2.—DECIMAL FOR ONE DAY'S INTEREST ON $1,000 AT VARIOUS RATES OF INTEREST, PAYABLE SEMIANNUALLY OR ON A SEMIANNUAL BASIS, IN REGULAR YEARS OF 365 DAYS AND IN YEARS OF 366 DAYS (TO DETERMINE APPLICABLE NUMBER OF DAYS, SEE TABLE 1).—Continued

Rate per annum (percent)	Half-year of 184 days	Half-year of 183 days	Half-year of 182 days	Half-year of 181 days
16⅝	0.451766304	0.454234973	0.456730769	0.459254144
16¾	0.455163043	0.457650273	0.460164835	0.462707182
16⅞	0.458559783	0.461065574	0.463598901	0.466160221
17	0.461956522	0.464480874	0.467032967	0.469613260
17⅛	0.465353261	0.467896175	0.470467033	0.473066298
17¼	0.468750000	0.471311475	0.473901099	0.476519337
17⅜	0.472146739	0.474726776	0.477335165	0.479972376
17½	0.475543478	0.478142077	0.480769231	0.483425414
17⅝	0.478940217	0.481557377	0.484203297	0.486878453
17¾	0.482336957	0.484972678	0.487637363	0.490331492
17⅞	0.485733696	0.488387978	0.491071429	0.493784530
18	0.489130435	0.491803279	0.494505495	0.497237569
18⅛	0.492527174	0.495218579	0.497939560	0.500690808
18¼	0.495923913	0.498633880	0.501373626	0.504143646
18⅜	0.499320652	0.502049180	0.504807692	0.507596685
18½	0.502717391	0.505464481	0.508241758	0.511049724
18⅝	0.506114130	0.508879781	0.511675824	0.514502762
18¾	0.509510870	0.512295082	0.515109890	0.517955801
18⅞	0.512907609	0.515710383	0.518543956	0.521408840
19	0.516304348	0.519125683	0.521978022	0.524861878
19⅛	0.519701087	0.522540984	0.525412088	0.528314917
19¼	0.523097826	0.525956284	0.528846154	0.531767956
19⅜	0.526494565	0.529371585	0.532280220	0.535220994
19½	0.529891304	0.532786885	0.535714286	0.538674033
19⅝	0.533288043	0.536202186	0.539148352	0.542127072
19¾	0.536684783	0.539617486	0.542582418	0.545580110
19⅞	0.540081522	0.543032787	0.546016484	0.549033149
20	0.543478261	0.546448087	0.549450549	0.552486188

C. Short First Payment Period

In cases where the first interest payment period for a bond or note covers less than a full half-year period (a "short coupon"), the daily interest decimal is multiplied by the number of days from, but not including, the issue date to, and including, the first interest payment date, resulting in the amount of the interest payable per $1,000 par amount. In cases where the par amount of securities is greater than $1,000, the appropriate multiple should be multiplied by the unrounded interest payment amount for $1,000 par amount.

Example. A 2-year note paying 8⅜% interest was issued on July 2, 1990, with the first interest payment on December 31, 1990. The number of days in the full half-year period of June 30 to December 31, 1990, was 184 (see Table 1). The number of days for which interest actually accrued was 182 (not including July 2, but including December 31). The daily interest decimal, $0.227581522 (see Table 2, line for 8⅜%, under the column for half-year of 184 days), was multiplied by 182, resulting in a payment of $41.419837004 per $1,000. Because the note was issued in a minimum denomination of $5,000, $41.419837004 was multiplied by 5, resulting in a payment of $207.099185020, or $207.10, for a $5,000 note. For $20,000 of these notes, $41.419837004 would be multiplied by 20, resulting in a payment of $828.39674008 ($828.40).

D. Long First Payment Period

In cases where the first interest payment period for a bond or note covers more than a full half-year period (a "long coupon"), the daily interest decimal is multiplied by the number of days from, but not including, the issue date to, and including, the last day of the fractional period that ends one full half-year before the interest payment date. That amount is added to the regular interest amount for the full half-year ending on the first interest payment date, resulting in the amount of interest payable for $1,000 par amount. In cases where the par amount of securities is greater than $1,000, the appropriate multiple should be applied to the unrounded interest payment amount for $1,000 par amount.

Example. A 5-year 2-month note paying 7⅞% interest was issued on December 3, 1990, with the first interest payment due on August 15, 1991. Interest for the regular half-year portion of the payment was computed to be $39.375 per $1,000 par amount. The fractional portion of the payment, from December 3 to February 15, fell in a 184-day half-year (August 15, 1990, to February 15, 1991). Accordingly, the daily interest decimal for 7⅞% was $0.213994565. This decimal, multiplied by 74 (the number of days from but not including December 3, 1990, to and including February 15), resulted in interest for the fractional portion of $15.835597810. When added to $39.375 (the normal interest payment portion ending on August 15, 1991), this produced a first interest payment of $55.210597810, or $55.21 per $1,000 par amount. For $7,000 par amount of these notes, $55.210597810 would be multiplied by 7, resulting in an interest payment of $386.474184670 ($386.47).

E. Accrued Interest

Accrued interest will be payable by the purchaser of a Treasury bond or note when interest accrues prior to the issue date of the security. Because the purchaser receives a full interest payment despite having held the security for only a portion of the interest payment period, the Department is compensated through the payment of accrued interest at settlement.

If accrued interest covers a fractional portion of a full half-year period, the number of days in the full half-year period and the stated interest rate will determine the daily interest decimal to be used in computing the accrued interest. The decimal is multiplied by the number of days for which interest has accrued. If a reopened bond or note has a long first interest payment period (a "long coupon"), and the dated date for the reopened issue is less than six full months before the first interest payment, the accrued interest will fall into two separate half-year periods, and a separate daily interest decimal must be multiplied by the respective number of days in each half-year period during which interest has accrued. All accrued interest computations are rounded to five decimal places for a $1,000 par amount, using normal rounding procedures. Accrued interest for a par amount of securities greater than $1,000

is calculated by applying the appropriate multiple to accrued interest payable for $1,000 par amount, taken to five decimal places.

Examples. (1) *Involving One Half-Year:* A bond paying interest at a rate of 8¼%, originally issued on August 15, 1990, as a 30-year bond with a first interest payment date of February 15, 1991, was reopened as a 29-year 9-month bond on November 15, 1990. Interest had accrued for 92 days, from August 15 to November 15. The regular interest period from August 15 to February 15, 1991, covered 184 days. Accordingly, the daily interest decimal, $0.237771739, multiplied by 92, resulted in accrued interest payable of $21.874999988, or $21.87500, for each $1,000 bond purchased. If the bonds have a par amount of $150,000, then 150 is multiplied by $21.87500, resulting in an amount payable of $3,281.25.

(2) *Involving Two Half-Years:* A 10¼% bond, originally issued on July 2, 1985, as a 20-year 1-month bond, with a first interest payment date of February 15, 1986, was reopened as a 19-year 10-month bond on November 4, 1985. Interest had accrued for 44 days, from July 2 to August 15, 1985, during a 181-day half-year (February 15 to August 15); and for 81 days, from August 15 to November 4, during a 184-day half-year (August 15, 1985, to February 15, 1986). Accordingly, $0.296961326 was multiplied by 44, and $0.292119565 was multiplied by 81, resulting in products of $13.066298344 and $23.661684765 which, added together, resulted in accrued interest payable of $36.727983109, or $36.72798, for each $1,000 bond purchased. If the bonds have a par amount of $11,000, then 11 is multiplied by $36.72798, resulting in an amount payable of $404.00778 ($404.01).

II. Formulas for Conversion of Bond and Note Yields to Equivalent Prices [1]

Definitions

P=price per 100 (dollars), rounded to three places, using normal rounding procedures

C=the regular annual interest per $100, payable semiannually, e.g., 10.125 (the decimal equivalent of a 10⅛% interest rate)

i=nominal annual rate of return or yield to maturity, based on semiannual interest payments and expressed in decimals, e.g., .0719

n=number of full semiannual periods from the issue date to maturity, except that, if the issue date is a coupon frequency date, n will be one less than the number of full semiannual periods remaining to maturity. Coupon frequency dates are the two semiannual dates based on the maturity date of each note or bond issue. For example, a security maturing on November 15, 1995, would have coupon frequency dates of May 15 and November 15.

[1] In the following examples, intermediate rounding is used to allow the reader to follow the calculations. In actual practice, the Department does not round prior to determining the final result.

r=(1) number of days from the issue date to the first interest payment (regular or short first payment period), or (2) number of days in fractional portion (or "initial short period") of long first payment period

s=(1) number of days in the full semiannual period ending on the first interest payment date (regular or short first payment period), or (2) number of days in the full semiannual period in which the fractional portion of a long first payment period falls, ending at the onset of the regular portion of the first interest payment

$v^n=1/[1+(i/2)]^n$=present value of 1 due at the end of n periods

$a_{\overline{n}|}=(1-v^n)/(i/2)=v+v^2+v^3+\ldots+v^n$=present value of 1 per period for n periods

A=accrued interest

A. *For bonds and notes with a regular first interest payment period:*

Formula:

$P[1+(r/s)(i/2)]=(C/2)(r/s)+(C/2)a_{\overline{n}|}+100\ v^n$

Example:

For an 8¼% 30-year bond, issued May 15, 1990, due May 15, 2020, with interest payments on November 15 and May 15, solve for the price per 100 (P) at a yield of 8.84%.

Definitions:

C=8.75
i=.0884
r=184 (May 15 to November 15, 1990)
s=184 (May 15 to November 15, 1990)
n=59 (There are 60 full semiannual periods, but n is reduced by 1 because the issue date is a coupon frequency date.)
$v^n=1/[(1+.0884/2)]^{59}$, or .077940
$a_{\overline{n}|}=(1-.077940)/.0442$, or 20.861086

Resolution:

$P[1+(r/s)(i/2)]=(C/2)(r/s)+(C/2)a^n+100\ v^n$ or
$P[1+(184/184)(.0884/2)]=(8.75/2)(184/184)+(8.75/2)(20.861086)+100(.077940)$
(1) P[1+.0442]=4.375+91.267251+7.7940
(2) P[1.0442]=103.436251
(3) P=103.436251÷1.0442
(4) P=99.057892
(5) P=99.058

B. *For bonds and notes with a short first interest payment period:*

Formula:

$P[1+(r/s)(i/2)]=(C/2)(r/s)+(C/2)a_{\overline{n}|}+100\ v^n$

Example:

For an 8½% 2-year note, issued April 2, 1990, due March 31, 1992, with interest payments on September 30 and March 31, solve for the price per 100 (P) at a yield of 8.59%.

Definitions:

C=8.50
i=.0859
n=3
r=181 (April 2 to September 30, 1990)
s=183 (March 31 to September 30, 1990)
$v^n=1/[(1+.0859/2)]^3$, or .881474
$a_{\overline{n}|}=(1-.881474)/.04295$, or 2.759627

Resolution:

$P[1+(r/s)(i/2)]=(C/2)(r/s)+(C/2)a_{\overline{n}|}+100\ v^n$ or
$P[1+(181/183)(.0859/2)]=(8.50/2)(181/183)+(8.50/2)(2.759627)+100(.881474)$
(1) P[1+.042481]=4.203552+11.728415+88.1474
(2) P[1.042481]=104.079367
(3) P=104.079367÷1.042481
(4) P=99.838143
(5) P=99.838

C. *For bonds and notes with a long first interest payment period:*

Formula:

$P[1+(r/s)(i/2)]=[(C/2)(r/s)]v+(C/2)a_{\overline{n}|}+100\ v^n$

Example:

For an 8½% 5-year 2-month note, issued March 1, 1990, due May 15, 1995, with interest payments on November 15 and May 15 (first payment on November 15, 1990), solve for the price per 100 (P) at a yield of 8.53%.

Definitions:

C=8.50
i=.0853
n=10
r=75 (March 1 to May 15, 1990, which is the fractional portion of the first interest payment)
s=181 (November 15, 1989, to May 15, 1990)
v=1/(1+.0853/2), or .959095
$v^n=1/(1+.0853/2)^{10}$, or .658589
$a_{\overline{n}|}=(1-.658589)/.04265$, or 8.004947

Resolution:

$P[1+(r/s)(i/2)]=[(C/2)(r/s)]v+(C/2)a_{\overline{n}|}+100\ v^n$ or
$P[1+(75/181)(.0853/2)]=[(8.50/2)(75/181)].959095+(8.50/2)(8.004947)+100(.658589)$
(1) P[1+.017673]=1.689014+34.021025+65.8589
(2) P[1.017673]=101.568939
(3) P=101.568939÷1.017673
(4) P=99.805084
(5) P=99.805

D. (1) *For bonds and notes reopened during a regular interest period where the purchase price includes predetermined accrued interest.*

(2) *For new bond and note issues accruing interest from the coupon frequency date immediately preceding the issue date, with the interest rate established in the auction being used to determine the accrued interest payable on the issue date.*

Formula:

$(P+A)[1+(r/s)(i/2)]=C/2+(C/2)a_{\overline{n}|}+100\ v^n$

Where: $A=[(s-r)/s](C/2)$

Example:

For a 9½% 10-year note, interest accruing from November 15, 1985, issued November 29, 1985, due November 15, 1995, with interest payments on May 15 and November 15, solve for the price per 100 (P) at a yield of 9.54%. Accrued interest is from November 15 to November 29 (14 days).

Definitions:

C=9.50
i=.0954
n=19
r=167 (November 29, 1985, to May 15, 1986)
s=181 (November 15, 1985, to May 15, 1986)
$v^n=1/[(1+.0954/2)]^{19}$, or .412570400
$a_{\overline{n}|}=(1-.412570)/.0477$, or 12.315094
A=[181−167)/181](9.50/2), or .367403

Resolution:
$(P+A)[1+(r/s)(i/2)]=C/2+(C/2)a_n+100\ v^n$ or
$(P+.367403)[1+(167/181)(.0954/2)]=(9.50/2)+(9.50/2)(12.315094)+100(.412570)$
(1) $(P+.367403)[1+.044011]=4.75+58.496697+41.2570$
(2) $(P+.367403)[1.044011]=104.503697$
(3) $(P+.367403)=104.503697+1.044011$
(4) $(P+.367403)=100.098272$
(5) $P=100.098272-.367403$
(6) $P=99.730869$
(7) $P=99.731$

E. *For bonds and notes reopened during the regular portion of a long first payment period:*

Formula:
$(P+A)[1+(r/s)(i/2)]=(r'/s'')(C/2)+C/2+(C/2)a_n+100\ v^n$
Where:
$A=AI'+AI$
$AI'=(r'/s'')(C/2)$
$AI=[(s-r)/s](C/2)$
and
r=number of days from the reopening date to the first interest payment date
s=number of days in the semiannual period for the regular portion of the first interest payment period
r'=number of days in the fractional portion (or "initial short period") of the first interest payment period
s''=number of days in the semiannual period ending with the commencement date of the regular portion of the first interest payment period

Example:

A 10¾% 19-year 9-month bond due August 15, 2005, is issued on July 2, 1985, and reopened on November 4, 1985, with interest payments on February 15 and August 15 (first payment on February 15, 1986), solve for the price per 100 (P) at a yield of 10.47%. Accrued interest is calculated from July 2 to November 4.

Definitions:
C=10.75
i=.1047
n=39
r=103 (November 4, 1985, to February 15, 1986)
s=184 (August 15, 1985, to February 15, 1986)
r'=44 (July 2 to August 15, 1985)
s''=181 (February 15 to August 15, 1985)
$v^n=1/[(1+.1047/2)]^{39}$, or .136695
$a_n=(1-.136695)/.05235$, or 16.491022
$AI'=(44/181)(10.75/2)$, or 1.306630
$AI'=[(184-103)/184](10.75/2)$, or 2.366168
$A=AI'+AI$, or 3.672798
Resolution:
$(P+A)[1+(r/s)(i/2)]=(r'/s'')(C/2)+C/2+(C/2)a_n+100v^n$ or
$(P+3.672798)[1+(103/184)(.1047/2)]=(44/181)(10.75/2)+10.75/2+(10.75/2)(16.491022)+100(.136695)$
(1) $(P+3.672798)[1+.029305]=1.306630+5.375+88.639243+13.6695$
(2) $(P+3.672798)[1.029305]=108.990373$
(3) $(P+3.672798)=108.990373+1.029305$
(4) $(P+3.672798)=105.887344$
(5) $P=105.887344-3.672798$
(6) $P=102.214546$
(7) $P=102.215$

F. *For bonds and notes reopened during a short first payment period:*

Formula:
$(P+A)[1+(r/s)(i/2)]=(r''/s)(C/2)+(C/2)a_n+100\ v_n$
Where:
$A=[(r''-r)/s](C/2)$
and
r''=number of days from the original issue date to the first interest payment date

Example:

For a 10½% 8-year note due May 15, 1991, originally issued on May 16, 1983, and reopened on August 15, 1983, with interest payments on November 15 and May 15 (first payment on November 15, 1983), solve for the price per 100 (P) at a yield of 10.53%. Accrued interest is calculated from May 16 to August 15.

Definitions:
C=10.50
i=.1053
n=15
r=92 (August 15, 1983, to November 15, 1983)
s=184 (May 15, 1983, to November 15, 1983)
r''=183 (May 16, 1983, to November 15, 1983)
$v_n=1/[(1+.1053/2)]^{15}$, or .463170
$a_n=(1-.463170)/.05265$, or 10.196201
$A=[(183-92)/184](10.50/2)$, or 2.596467
Resolution:
$(P+A)[1+(r/s)(i/2)]=(r''/s)(C/2)+(C/2)a_n+100\ v_n$ or
$(P+2.596467)[1+(92/184)(.1053/2)]=(183/184)(10.50/2)+(10.50/2)(10.196201)+100(.463170)$
(1) $(P+2.596467)[1+.026325]=5.221467+53.530055+46.3170$
(2) $(P+2.596467)[1.026325]=105.068522$
(3) $(P+2.596467)+105.068522-1.026325$
(4) $(P+2.596467)=102.373539$
(5) $P=102.373539-2.596467$
(6) $P=99.777072$
(7) $P=99.777$

G. *For bonds and notes reopened during the fractional portion (initial short period) of a long first payment period:*

Formula:
$(P+A)[1+(r/s)(i/2)]=[(r'/s)(C/2)]v+(C/2)a_n+100\ v^n$
Where:
$A=[(r'-r)/s](C/2)$
and
r=number of days from the reopening date to the end of the short period
r'=number of days in the short period
s=number of days in the semiannual period ending with the end of the short period

Example:

For a 9¼% 6-year 2-month note due December 15, 1994, originally issued on October 15, 1988, and reopened on November 15, 1988, with interest payments on June 15 and December 15 (first payment on June 15, 1989), solve for the price per 100 (P) at a yield of 9.79%. Accrued interest is calculated from October 15 to November 15.

Definitions:
C=9.75
i=.0979
n=12
r=30 (November 15, 1988, to December 15, 1988)
s=183 (June 15, 1988, to December 15, 1988)
r'=61 (October 15, 1988, to December 15, 1988)
v=1/(1+.0979/2), or .953334
$v^n=[1/(1+.0979/2)]^{12}$, or .563563
$a_n=(1-.563563)/.04895$, or 8.915975
$A=[(61-30)/183](9.75/2)$, or .825820
Resolution:
$(P+A)[1+(r/s)(i/2)]=[(r'/s)(C/2)]v+(C/2)a_n+100\ v^n$ or
$(P+.825820)[1+(30/183)(.0979/2)]=[(61/183)(9.75/2)](.953334)+(9.75/2)(8.915975)+100(.563563)$
(1) $(P+.825820)[1+.008025]=1.549168+43.465378+56.3563$
(2) $(P+.825820)[1.008025]=101.370846$
(3) $(P+.825820)=101.370846+1.008025$
(4) $(P+.825820)=100.563821$
(5) $P=100.563821-.825820$
(6) $P=99.738001$
(7) $P=99.738$

III. Computation of Purchase Price, Discount Rate, and Investment Rate (Coupon-Equivalent Yield) for Treasury Bills

A. *Conversion of the discount rate to a purchase price for Treasury bills of all maturities:*

Formula:
$P=100\ [(1-dr)/360]$
Where:
d=discount rate, in decimals
r=number of days remaining to maturity
P=price per 100 dollars

Example:

For a bill issued November 24, 1989, due February 22, 1990, at a discount rate of 7.61%, solve for price per 100 (P).

Definitions:
d=.0761
r=90 (November 24, 1989 to February 22, 1990)
Resolution:
$P=100\ (1-dr/360)$
(1) $P=100\ [1-(.0761)(90)/360]$
(2) $P=100\ (1-.019025)$
(3) $P=100\ (.980975)$
(4) $P=98.0975$
(5) $P=98.098$

Note: Purchase prices per $100 are rounded to three decimal places, using normal rounding procedures.

B. *Computation of purchase prices and discount amounts based on price per $100, for Treasury bills of all maturities:*

1. To determine the purchase price of any bill, divide the par amount by 100 and multiply the resulting quotient by the price per $100.

Example. To compute the purchase price of a $10,000 13-week bill sold at a price of $98.098 per $100, divide the par amount

($10,000) by 100 to obtain the multiple (100). That multiple times 98.098 results in a purchase price of $9,809.80.

2. To determine the discount amount for any bill, subtract the purchase price from the par amount of the bill.

Example. For a $10,000 bill with a purchase price of $9,809.80, the discount amount would be $190.20, or $10,000–$9,809.80.

C. *Conversion of prices to discount rates for Treasury bills of all maturities:*

Formula:

$$d = \left[\frac{100-P}{100} \times \frac{360}{r}\right]$$

Where:

P=price per 100 (dollars)
d=discount rate
r=number of days remaining to maturity

Example:

For a 26-week bill issued December 30, 1982, due June 30, 1983, with a price of $95.930, solve for the discount rate (d).

Definitions:

P=95.930
r=182 (December 30, 1982, to June 30, 1983)

Resolution:

$$d = \left[\frac{100-P}{100} \times \frac{360}{r}\right]$$

1) $$d = \left[\frac{100-95.930}{100} \times \frac{360}{182}\right]$$

(2) d=[.0407×1.978022]
(3) d=.080506
(4) d=8.051%

Note: Since April 18, 1983, bills have been sold only on a discount rate basis, where the discount rates bid are submitted with two decimals, e.g., 7.32%. In price-basis auctions, discount rates calculated from prices were rounded to three places, using normal rounding procedures.

D. *Calculation of investment rate (coupon-equivalent yield) for Treasury bills:*

1. For bills of not more than one half-year to maturity:

Formula:

$$i = \left[\frac{100-P}{P} \times \frac{y}{r}\right]$$

Where:

i=investment rate, in decimals
P=price per 100 (dollars)
r=number of days remaining to maturity
y=number of days in year following the issue date; normally 365 but, if the year following the issue date includes February 29, then y is 366.

Example:

For a cash management bill issued June 1, 1990, due June 21, 1990, with a price of $99.559 (computed from a discount rate of 7.93%), solve for the investment rate (i).

Definitions:

P=99.559
r=20 (June 1, 1990, to June 21, 1990)
y=365

Resolution:

$$i = \left[\frac{100-P}{P} \times \frac{y}{r}\right]$$

1) $$i = \left[\frac{100-99.559}{99.559} \times \frac{365}{20}\right]$$

(2) i=[.004430×18.25]
(3) i=.080848
(4) i=8.08%

2. For bills of more than one half-year to maturity:

Formula: $P[1+(r-y/2)(i/y)](1+i/2) = 100$;

This formula must be solved by using the quadratic equation, which is:

$ax^2+bx+c=0$

Therefore, rewriting the bill formula in the quadratic equation form gives:

$$\left[\frac{r}{2y} - .25\right]i^2 + \left[\frac{r}{y}\right]i + \left[\frac{P-100}{P}\right] = 0$$

and solving for "i" produces:

$$i = \frac{-b + \sqrt{b^2 - 4ac}}{2a}$$

Where:

i=investment rate in decimals
b=r/y
a=(r/2y)–.25
c=(P–100)/P
P=price per 100 (dollars)
r=number of days remaining to maturity
y=number of days in year following the issue date; normally 365, but if the year following the issue date includes February 29, then y is 366.

Example:

For a 52-week bill issued June 7, 1990, due June 6, 1991, with a price of $92.265 (computed from a discount rate of 7.65%), solve for the investment rate (i).

Definitions:

r=364 (June 7, 1990, to June 6, 1991)
y=365
P=92.265
b=364/365, or .997260
a=(364/730)–.25, or .24863
c=(92.265–100)/92.265, or –.083835

Resolution:

$$i = \frac{-b + \sqrt{b^2 - 4ac}}{2a}$$

$$(1)\ i = \frac{-.997260 + \sqrt{(.997260)^2 - 4[(.24863)(-.083835)]}}{2(.248630)}$$

$$(2)\ i = \frac{-.997260 + \sqrt{.994528 + .083376}}{.497260}$$

(3)i=(−.997260 + 1.038222)/.497260
(4)i=.040962/.497260
(5)i=.082375 or
(6)i=8.24%

Exhibit A to Part 356—Sample Announcements of Treasury Offerings to the Public

I. Treasury Quarterly Financing Announcement.
II. Treasury Weekly Bill Announcement.
III. Treasury Cash Management Bill Announcement.

I. Treasury Quarterly Financing Announcement

For Release When Authorized at Press Conference
May 1, 19XX
Contact: Office of Financing, 202/219–3350

Treasury May Quarterly Financing

The Treasury will auction two notes and one bond totaling approximately $37,000 million, to be issued May 15, 19XX. This offering will provide about $18,025 million of new cash and will refund $18,976 million of securities maturing that date.

In addition to the public holdings, Federal Reserve Banks hold $3,662 million of the maturing securities for their own accounts, which may be refunded by issuing additional amounts of the new securities at the average yield of accepted competitive tenders.

The maturing securities held by the public include $1,099 million held by Federal Reserve Banks as agents for foreign and international monetary authorities. Amounts bid for these accounts by Federal Reserve Banks will be added to the offering. Bids for such accounts will be accepted at the average yield of accepted competitive tenders.

The 9¾-year note and 30-year bond being offered today will be eligible for the STRIPS program.

Tenders will be received at Federal Reserve Banks and Branches and at the Bureau of the Public Debt, Washington, DC.

Details about each of the new securities are given in the attached offering highlights and in the Treasury Department's Uniform Offering Circular.

Highlights of Treasury Offerings May 19XX Quarterly Financing

[May 1, 19XX]

Offering Amount	$13,500	$11,750 million	$11,750 million.
Description of Offering:			
Term and type of security	3-year notes	9¾ year notes	30-year bonds of 20XX.
Series	Series S–19XX	Series A–20XX	Bonds of May 20XX.
CUSIP number	912827 A7 7	912827 ZX 3	912810 EJ 3.
Auction date	May 7, 19XX	May 8, 19XX	May 9, 19XX.
Issue date	May 15, 19XX	May 15, 19XX	May 15, 19XX.
Dated date	May 15, 19XX	Feb. 15, 19XX	May 15, 19XX.
Maturity date	May 15, 19XX	Feb. 15, 20XX	May 15, 20XX.
Interest rate	Determined based on the average of accepted competitive bids.	7¾%	Determined based on the average of accepted competitive bids.
Yield	Determined at auction	Determined at auction	Determined at auction.
Interest payment dates	Nov. 15 and May 15	August 15 and February 15	Nov. 15 and May 15.
Minimum bid amount	$5,000	$1,000	$1,000.
Multiples	5,000	$1,000	$1,000.
Accrued interest payable by investor	None	$19.05387 per $1,000	None.
Premium or discount	Determined at auction	Determined at auction	Determined at auction.
STRIPS Information:			
Minimum amount required	Not applicable	$800,000	Determined at auction.
Corpus CUSIP number	Not applicable	912820 AZ 0	912803 AW 3.
New TINT CUSIP number	Not applicable	Not applicable	912833 LD 0.
New TINT due date	Not applicable	Not applicable	May 15, 20XX.

The following rules apply to all securities mentioned above:

Submission of Bids:	
Noncompetitive bids	Accepted in full up to $5,000,000 at the weighted average yield of accepted competitive bids.
Competitive bids	(1) Must be expressed as an annual yield with two decimals, e.g., 7.10%.

	(2) Net long position for each bidder must be reported when the sum of the total bid amount, at all yields, and the net long position is $2 billion or greater. (3) The net long position must be determined as of one-half hour prior to the closing time for receipt of competitive tenders.
Maximum Recognized Bid at a Single Yield.	35% of offering amount.
Maximum Award	35% of offering amount.
Receipt of Tenders:	
Noncompetitive tenders	Prior to 12:00 noon Eastern time on auction day.
Competitive tenders	Prior to 1:00 p.m. Eastern time on auction day.
Payment Terms	Full payment with tender or by charge to a funds account on issue date.

II. Treasury Weekly Bill Announcement

For Release at 2:30 p.m., October 9, 19XX

Contact: Office of Financing, 202/219–3350

Treasury's Weekly Bill Offering

The Treasury will auction two series of Treasury bills totaling approximately $18,800 million, to be issued October 18, 19XX. This offering will provide about $1,375 million of new cash, as the maturing weekly bills are currently outstanding in the amount of $17,421 million.

Federal Reserve Banks hold $4,294 million of the maturing bills for their own accounts, which may be refunded within the offering amount at the weighted average discount rate of accepted competitive tenders.

Federal Reserve Banks hold $1,104 million as agents for foreign and international monetary authorities, which may be refunded within the offering amount at the weighted average discount rate of accepted competitive tenders. Additional amounts may be issued for such accounts if the aggregate amount of new bids exceeds the aggregate amount of maturing bills.

Tenders for the bills will be received at Federal Reserve Banks and Branches and at the Bureau of the Public Debt, Washington, DC.

Details about each of the new securities are given in the attached offering highlights and in the Treasury Department's Uniform Offering Circular.

Highlights of Treasury Offerings of Weekly Bills

[October 9, 19XX]

Offering Amount	$9,400 million	$9,400 million.
Description of Offering:		
Term and type of security	91-day bill	182-day bill.
CUSIP number	912794 VR 2	912794 WE 0.
Auction date	Oct. 15, 19XX	Oct. 15, 19XX.
Issue date	Oct. 18, 19XX	Oct. 18, 19XX.
Maturity date	Jan. 17, 19XX	Apr. 18, 19XX.
Original issue date	Jan. 18, 19XX	Oct. 18, 19XX.
Currently outstanding	$19,127 million	
Minimum bid amount	$10,000	$10,000.
Multiples	$5,000	$5,000.

The following rules apply to all securities mentioned above:

Submission of Bids:	
Noncompetitive bids	Accepted in full up to $1,000,000 at the weighted average discount rate of accepted competitive bids.
Competitive bids	(1) Must be expressed as a discount rate with two decimals, e.g., 7.10%. (2) Net long position for each bidder must be reported when the sum of the total bid amount, at all discount rates, and the net long position is $2 billion or greater. (3) The net long position must be determined as of one-half hour prior to the closing time for receipt of competitive tenders.
Maximum Recognized Bid at a Single Yield.	35% of public offering.
Maximum Award	35% of public offering.
Receipt of Tenders:	
Noncompetitive tenders	Prior to 12:00 noon Eastern time on auction day.
Competitive tenders	Prior to 1:00 p.m. Eastern time on auction day.
Payment Terms	Full payment with tender or by charge to a funds account on issue date.

III. Treasury Cash Management Bill Announcement

For Release at 2:30 p.m.August 27, 19XX

Contact: Office of Financing, 202/219–3350

Treasury To Auction Cash Management Bills

The Treasury will auction approximately $5,000 million of 16-day Treasury cash management bills to be issued September 3, 19XX.

Competitive tenders will be received at all Federal Reserve Banks and Branches. Noncompetitive tenders will not be accepted. Tenders will not be received at the Bureau of the Public Debt, Washington, DC.

Details about the new security are given in the attached offering highlights and in the Treasury Department's Uniform Offering Circular.

Highlights of Treasury Offering of 16-Day Cash Management Bill

[August 27, 19XX]

Offering Amount	$5,000 million.
Description of Offering:	
Term and type of security	16-day Cash Management Bill.
CUSIP number	912794 XG 4.
Auction date	Aug. 29, 19XX.
Issue date	Sept. 3, 19XX.
Maturity date	Sept. 19, 19XX.
Original issue date	Mar. 21, 19XX.
Currently outstanding	$20,125 million.
Minimum bid amount	$1,000,000.
Multiples	$1,000,000.
Minimum to hold amount	$10,000.
Multiples	$5,000.
Submission of Bids:	
Noncompetitive bids	Not accepted.
Competitive bids	(1) Must be expressed as a discount rate with two decimals, e.g., 7.10%. (2) Net long position for each bidder must be reported when the sum of the total bid amount, at all discount rates, and the net long position is $2 billion or greater. (3) The net long position must be determined as of one-half hour prior to the closing time for receipt of competitive tenders.
Maximum Recognized Bid at a Single Yield	35% of offering amount.
Maximum Award	35% of offering amount.
Receipt of Tenders:	
Noncompetitive tenders	Not accepted.
Competitive tenders	Prior to 1 p.m. Eastern time on auction day.
Payment Terms	Full payment with tender or by charge to a funds account on issue date.

Exhibit B to Part 356—Sample Autocharge Agreement To Deliver and Charge for Securities Awarded in Department of Treasury Auctions

Federal Reserve Bank of

_____

Attention: (Name of Fiscal Officer)
(Address)
(Address)

To Whom It May Concern:

I. The depository institution ("DI") and the submitting entity ("Submitter"), as identified below, agree that

(a) The Submitter is authorized to submit tenders to the Federal Reserve Bank of _____("Bank");

(b) The Bank is authorized to deliver, as provided herein, Treasury securities awarded to the Submitter through the auction process;

(c) The Bank, or other Federal Reserve Bank identified in Section II below, is authorized to charge the DI's funds account for payment of awarded securities that are delivered by the Bank hereunder. Such charge is to be made at the same time the securities are delivered;

(d) The Submitter [ ] is, [ ] is not authorized to submit TREASURY DIRECT tenders. Where such tenders are authorized, the Bank is instructed to deliver awarded securities to the TREASURY DIRECT Book-Entry System and charge the DI's funds account for the securities delivered; and

(e) The Bank [ ] is, [ ] is not authorized to deliver the awarded securities to the DI's securities account at a Federal Reserve Bank other than the Bank.

The above authorizations apply to:

[ ] bills
[ ] notes
[ ] bonds

II. For securities to be delivered to a Federal Reserve Bank other than the Bank receiving the tender, the Submitter must complete the following:

Awarded securities are to be delivered hereunder by the Bank to the DI's securities account at the Federal Reserve Bank of _____.

III. The following wire instructions are to be used by the Bank to deliver securities to the DI:

Wire Instructions: _____.

IV. General Provisions.

This agreement is effective on the date it is received by the Bank, although the Bank normally will not act under the agreement until it has acknowledged receipt of such.

The Submitter hereunder is the entity submitting bids to a Bank for its own account or for the account of others. The Submitter is responsible to the Treasury for full payment of all securities awarded, including any securities awarded under customer bids submitted by the Submitter.

Any Federal Reserve Bank identified herein is authorized to act on information in any tender in the name of the Submitter that reasonably appears to be valid and genuine. The DI, by executing this agreement, guarantees the authority and signature of the person signing this agreement on behalf of the Submitter.

This agreement will remain in effect until written notice is received by the Bank from either the DI or the Submitter that the agreement has been terminated, provided that if securities are scheduled to be delivered hereunder, such notice must be received in accordance with the termination procedures hereafter described.

As to termination action by the DI, notice of termination will not be effective unless received in writing by a Fiscal/Securities Department officer by the later of (i) 5 p.m. (the Bank's time) on the business day prior to the issue date of the securities scheduled to be delivered hereunder or (ii) if the submitter has authorized the Bank to advise the DI of securities to be delivered, two hours after such advice is sent by the Bank. Such termination action by the DI shall not affect the Submitter's responsibility to make full payment for the securities awarded. A DI may, at any time, waive in writing its right to terminate hereunder.

As to termination action by the Submitter after an auction but prior to delivery of awarded securities, the written notice of termination will not be effective, and this agreement shall remain in full force and effect, unless the Submitter has provided to the Bank, and the latter has acknowledged, a new autocharge agreement executed by a DI having a funds account at a Federal Reserve Bank.

Written notices to be sent hereunder in connection with the termination of this autocharge agreement shall be sent by either the Submitter or the DI to the Bank authorized to receive tenders hereunder.

In the event that this autocharge agreement is terminated, it is the sole responsibility of the party terminating the agreement to notify the other party hereto.

AGREED TO BY _____
(Full DI Name and ABA #)
Signature: _____
Name: _____
Title: _____
Date: _____

AGREED TO BY _____
(Full name of Submitter)
Signature: _____
Name: _____
Title: _____
Date: _____

ACKNOWLEDGED BY: Federal Reserve Bank of _____
("Bank"):
Signature: _____
Name: _____
Title: _____
Date: _____

DI'S SIGNATURE AND WIRE INSTRUCTIONS VERIFIED BY:
(For use only by Federal Reserve Bank named in Section II above)
Signature: _____
Name: _____
Title: _____
Date: _____
Federal Reserve Bank of _____

Instructions for Completing the Autocharge Agreement

1. DEPOSITORY INSTITUTION: This is the DI whose funds account at a Federal Reserve Bank will be debited, under this autocharge agreement, for the price of Treasury securities awarded at auction to the Submitter. Also, this DI must have a book-entry securities account at the Federal Reserve Bank to which securities will be delivered against payment on settlement day pursuant to the autocharge agreement and the Submitter's tender submission.

2. SUBMITTER: The Submitter must identify the full name of the entity that is submitting bids under this autocharge agreement. The name shown on the autocharge agreement should be the same as that appearing on related tender forms.

3. BANK: This is the Federal Reserve Bank to which the Submitter will be submitting tenders in Treasury auctions.

4. SIGNATURE FOR DI: This is the signature of an officer of the DI having authority to enter into or terminate this autocharge agreement, and whose signature is on file at the Federal Reserve Bank where the DI has a funds account.

5. SIGNATURE FOR SUBMITTER: This is the signature of an officer of the Submitter having authority to enter into or terminate the autocharge agreement.

6. SIGNATURE FOR BANK: This is the signature of an officer of the Bank having authority to acknowledge this autocharge agreement.

Exhibit C to Part 356—Minimum Par Amounts for STRIPS

Minimum face amounts which are multiples of $1000 required in order to produce interest payments that are multiples of $1000.

Coupon (%)	Minimum face ($)	Interest payment ($)
0.125	1600000.00	1000.00
0.250	800000.00	1000.00
0.375	1600000.00	3000.00
0.500	400000.00	1000.00
0.625	320000.00	1000.00
0.750	800000.00	3000.00
0.875	1600000.00	7000.00
1.000	200000.00	1000.00
1.125	1600000.00	9000.00
1.250	160000.00	1000.00
1.375	1600000.00	11000.00
1.500	400000.00	3000.00
1.625	1600000.00	13000.00
1.750	800000.00	7000.00
1.875	320000.00	3000.00
2.000	100000.00	1000.00
2.125	1600000.00	17000.00
2.250	800000.00	9000.00
2.375	1600000.00	19000.00
2.500	80000.00	1000.00
2.625	1600000.00	21000.00
2.750	800000.00	11000.00
2.875	1600000.00	23000.00
3.000	200000.00	3000.00
3.125	64000.00	1000.00
3.250	800000.00	13000.00
3.375	1600000.00	27000.00
3.500	400000.00	7000.00
3.625	1600000.00	29000.00
3.750	160000.00	3000.00
3.875	1600000.00	31000.00
4.000	50000.00	1000.00
4.125	1600000.00	33000.00
4.250	800000.00	17000.00
4.375	320000.00	7000.00
4.500	400000.00	9000.00
4.625	1600000.00	37000.00
4.750	800000.00	19000.00
4.875	1600000.00	39000.00
5.000	40000.00	1000.00
5.125	1600000.00	41000.00
5.250	800000.00	21000.00
5.375	1600000.00	43000.00
5.500	400000.00	11000.00
5.625	320000.00	9000.00
5.750	800000.00	23000.00
5.875	1600000.00	47000.00
6.000	100000.00	3000.00
6.125	1600000.00	49000.00
6.250	32000.00	1000.00
6.375	1600000.00	51000.00
6.500	400000.00	13000.00
6.625	1600000.00	53000.00
6.750	800000.00	27000.00
6.875	320000.00	11000.00
7.000	200000.00	7000.00
7.125	1600000.00	57000.00
7.250	800000.00	29000.00
7.375	1600000.00	59000.00
7.500	80000.00	3000.00
7.625	1600000.00	61000.00
7.750	800000.00	31000.00
7.875	1600000.00	63000.00
8.000	25000.00	1000.00
8.125	320000.00	13000.00
8.250	800000.00	33000.00
8.375	1600000.00	67000.00
8.500	400000.00	17000.00
8.625	1600000.00	69000.00
8.750	160000.00	7000.00
8.875	1600000.00	71000.00
9.000	200000.00	9000.00
9.125	1600000.00	73000.00
9.250	800000.00	37000.00
9.375	64000.00	3000.00
9.500	400000.00	19000.00
9.625	1600000.00	77000.00
9.750	800000.00	39000.00
9.875	1600000.00	79000.00
10.000	20000.00	1000.00
10.125	1600000.00	81000.00
10.250	800000.00	41000.00
10.375	1600000.00	83000.00
10.500	400000.00	21000.00
10.625	320000.00	17000.00
10.750	800000.00	43000.00
10.875	1600000.00	87000.00
11.000	200000.00	11000.00
11.125	1600000.00	89000.00
11.250	160000.00	9000.00
11.375	1600000.00	91000.00
11.500	400000.00	23000.00
11.625	1600000.00	93000.00
11.750	800000.00	47000.00
11.875	320000.00	19000.00
12.000	50000.00	3000.00
12.125	1600000.00	97000.00
12.250	800000.00	49000.00
12.375	1600000.00	99000.00
12.500	16000.00	1000.00
12.625	1600000.00	101000.00
12.750	800000.00	51000.00
12.875	1600000.00	103000.00
13.000	200000.00	13000.00
13.125	320000.00	21000.00
13.250	800000.00	53000.00
13.375	1600000.00	107000.00
13.500	400000.00	27000.00
13.625	1600000.00	109000.00
13.750	160000.00	11000.00
13.875	1600000.00	111000.00
14.000	100000.00	7000.00
14.125	1600000.00	113000.00
14.250	800000.00	57000.00
14.375	320000.00	23000.00
14.500	400000.00	29000.00
14.625	1600000.00	117000.00
14.750	800000.00	59000.00
14.875	1600000.00	119000.00
15.000	40000.00	3000.00
15.125	1600000.00	121000.00
15.250	800000.00	61000.00
15.375	1600000.00	123000.00
15.500	400000.00	31000.00
15.625	64000.00	5000.00
15.750	800000.00	63000.00
15.875	1600000.00	127000.00
16.000	25000.00	2000.00
16.125	1600000.00	129000.00
16.250	160000.00	13000.00
16.375	1600000.00	131000.00
16.500	400000.00	33000.00
16.625	1600000.00	133000.00
16.750	800000.00	67000.00
16.875	320000.00	27000.00
17.000	200000.00	17000.00
17.125	1600000.00	137000.00
17.250	800000.00	69000.00
17.375	1600000.00	139000.00
17.500	80000.00	7000.00
17.625	1600000.00	141000.00
17.750	800000.00	71000.00
17.875	1600000.00	143000.00
18.000	100000.00	9000.00
18.125	320000.00	29000.00
18.250	800000.00	73000.00
18.375	1600000.00	147000.00
18.500	400000.00	37000.00
18.625	1600000.00	149000.00
18.750	32000.00	3000.00
18.875	1600000.00	151000.00
19.000	200000.00	19000.00

Coupon (%)	Minimum face ($)	Interest payment ($)
19.125	1600000.00	153000.00
19.250	800000.00	77000.00
19.375	320000.00	31000.00
19.500	400000.00	39000.00
19.625	1600000.00	157000.00
19.750	800000.00	79000.00
19.875	1600000.00	159000.00
20.000	10000.00	1000.00

Dated: December 24, 1992.

Marcus W. Page,

Deputy Fiscal Assistant Secretary.

[FR Doc. 93–14 Filed 1–4–93; 8:45 am]

BILLING CODE 4810–35–M

Interest payment ($)

71000.00
9000.00
73000.00
37000.00
3000.00
19000.00
77000.00
39000.00
79000.00
1000.00
81000.00
41000.00
83000.00
21000.00
17000.00
43000.00
87000.00
11000.00
89000.00
9000.00
91000.00
23000.00
93000.00
47000.00
19000.00
3000.00
97000.00
49000.00
99000.00
1000.00
101000.00
51000.00
103000.00
13000.00
21000.00
53000.00
107000.00
27000.00
109000.00
11000.00
111000.00
7000.00
113000.00
57000.00
23000.00
29000.00
117000.00
59000.00
119000.00
3000.00
121000.00
61000.00
123000.00
31000.00
5000.00
63000.00
127000.00
2000.00
129000.00
13000.00
131000.00
33000.00
133000.00
67000.00
27000.00
17000.00
137000.00
69000.00
139000.00
7000.00
141000.00
71000.00
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19000.00

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Part IV

Department of Housing and Urban Development

Office of the Assistant Secretary for Public and Indian Housing

Funding Availability for Urban Revitalization Demonstration; Notice

VOL 58 ISS 2 JA 5 1993 UMI

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-93-3557; FR-3412-N-01]

Funding Availability (NOFA) for Urban Revitalization Demonstration

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, Department of Housing and Urban Development (HUD, or the Department).

ACTION: Notice of funding availability for Fiscal Year 1993.

SUMMARY: This NOFA announces the availability of $300 million in funding for implementation and planning grants under the Urban Revitalization Demonstration (URD), which is authorized by the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1993 (the 1993 Appropriations Act) (Pub. L. 102–389, approved October 6, 1992.) The Urban Revitalization Demonstration was created for the purpose of revitalizing severely distressed or obsolete public housing developments. The activities in the program include funding of the capital costs of major reconstruction, rehabilitation and other physical improvements, the provision of replacement housing, management improvements, planning and technical assistance, implementation of community service programs and supportive services or the planning of such activities.

This Notice contains information on: eligible applicants, program requirements, rating factors, selection criteria, and contents of applications. In carrying out this demonstration, the Department of Housing and Urban Development (HUD) has chosen to exercise the authority granted in the 1993 Appropriations Act to conform certain program standards and criteria with those set forth in subsequent authorization legislation. For this purpose, the Department has chosen to incorporate certain provisions of sec. 24 of the 1937 Housing Act, as added by sec. 120 of the Housing and Community Development Act of 1992 (Pub. L. 102–550, approved October 28, 1992) (Revitalization of Severely Distressed Public Housing). The Demonstration is limited to public housing agencies (PHAs) in up to 15 cities, which will be chosen in accordance with the requirements set forth in this NOFA.

DATES: Applications must be received on or before 4 P.M. Eastern Standard Time on April 5, 1993, at the HUD Headquarters Office, 451 Seventh St., SW., room 4138, Washington, DC 20410. Attention: Director, Office of Construction, Rehabilitation, and Maintenance. Applications may be hand-delivered or mailed to the above address. Applications sent by facsimile will not be accepted. HUD will not waive this deadline for any reason.

ADDRESSES: An original and two copies of the completed application must be submitted to the HUD Headquarters office at the address indicated under "**DATES**" above. Failure to submit an application to the HUD Headquarters office so that it is received by the deadline date and time will result in the application being disqualified.

FOR FURTHER INFORMATION CONTACT: Janice D. Rattley, Director, Office of Construction, Rehabilitation and Maintenance, Department of Housing and Urban Development, 451 Seventh Street, SW., room 4138, Washington, DC 20410. Telephone (202) 708–1800 (This is not a toll free number). Hearing or speech impaired individuals may call HUD's TDD number 1–800–877–TDDY, which is a toll-free number.

SUPPLEMENTARY INFORMATION:

Background

The challenge of successfully revitalizing the Nation's most severely distressed public housing is a very difficult one. In launching this demonstration, the Department recognizes that there is no one prescription for the ills that affect these developments, and each development will require its own solution. It is the intent of this demonstration to allow the greatest degree of flexibility on the part of the PHA in determining the approach likely to be most successful in treating the development it has selected. The approach selected must be consistent with the overall mandate of providing modestly designed housing for low-income persons and cost-effectiveness in the management of such housing, but should incorporate boldness and creativity in addressing difficult issues such as high density, crime, poor structural design, and oppressive social and economic conditions. PHAs are encouraged to seek a broad spectrum of participation and assistance from local and state governments, neighborhood organizations, business, nonprofit corporations, social service agencies, and residents of the developments.

Paperwork Reduction Act Statement

The information collection requirements contained in this document have been submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501–3520). No person may be subjected to a penalty for failure to comply with these information collection requirements until they have been approved and assigned on OMB control number. The OMB control number, when assigned, will be announced by separate notice in the **Federal Register.**

Public reporting burden for the collection of information requirements contained in this document are estimated to include the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Information on the estimated public reporting burden is provided under the heading, Other Matters. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Department of Housing and Urban Development, Rules Docket Clerk 451 Seventh Street, SW., room 10276, Washington, DC 20410–0500; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for HUD, Washington, DC 20503.

I. Purpose and Substantive Description

A. Authority

The funding made available under this NOFA is authorized by the 1993 Appropriations Act (Pub. L. 102–389 approved on October 6, 1991).

B. Allocation Amounts

The 1993 Appropriations Act made available $300,000,000 of budget authority for this Program.

C. Definitions

1. Targeted Units

The units for which funds are requested by a single applicant in a single city, whether they represent a part of a development, all of a development, or more than one development.

2. Revitalization Plan

All the activities described in the application which are necessary to address the distress in the targeted units and distress in the surrounding area which has a significant effect on the targeted units, whether those activities are proposed to be funded from the grant or from other sources.

D. Eligible Applicants

Applications may be filed by the following PHAs (See appendix A):

1. PHAs located in the 40 most populous United States cities based on 1990 Census data; or

2. PHAs on the Department's Troubled Housing Authority list as of 3/31/92, except that any such PHA will not be eligible if the Secretary certifies to the Congress that the PHA is not making substantial progress to eliminate its troubled status in accordance with section 6(j) of the Housing Act of 1937. The following troubled PHAs will be considered to have made substantial progress:

a. PHAs which have been removed from the troubled list after 3/31/92, or

b. PHAs which have made improvement of at least 5 nonhandicapped points (on a zero-to-one-hundred point scale) in their most recent assessment under the Public Housing Management Assessment Program (PHMAP), as compared to their assessment completed on April 16, 1992,

c. If PHAs have not made at least 5 nonhandicapped points (on a zero-to-one-hundred point scale) improvement in their PHMAP scores, PHAs which can demonstrate to the satisfaction of the Secretary, that they are making substantial progress by a narrative describing actions that have been taken to address deficiencies identified by PHMAP, by the PHA's Memorandum of Agreement with the Department, or by Departmental reviews, audits or surveys, or

d. PHAs which have a binding commitment from another public or private entity to act as administrator of the grant on behalf of the PHA. The alternative administrator must be deemed acceptable by the Department.

E. Program Requirements

1. Severely Distressed

a. Required documentation.

i. Documentation that a development in which the targeted units are located is both severely distressed (as compared to citywide information) and among the most severely distressed developments in the PHA's inventory must be based upon the four categories below which were set forth in The Final Report of the National Commission on Severely Distressed Public Housing, dated August 10, 1992: families living in distress, incidence of serious crimes in the development, barriers to managing the environment, and physical deterioration of buildings. The serious lack of data on some of the specific indicators in the extensive and detailed definition of severely distressed public housing found in the Commission's report precludes use of the full Commission definition and rating system. Further, the Commission itself recognized the need for further examination of the definition, modification or discard of some measures based on the availability of data, and use of narrative justifications based on qualitative information where quantitative data is lacking.

ii. Applicants must determine that the development in which the targeted units are located is a severely distressed development and is among the most severely distressed developments in the PHA's inventory, and must document this finding by comparing information about the development to comparable information about the PHA's general occupancy (family) developments and about the city as a whole. Such justification must be made by means of a narrative description containing qualitative information on the categories below and must include specific supporting data relevant to the category where such data is reasonably available to the PHA. HUD fully recognizes that the relevant data may not be available in all cases. Information should be presented in real numbers or percentages as well as percentages of PHA-wide or citywide data, wherever possible. Examples of relevant data are presented below under each category.

iii. The PHA must list in its application all of the developments in its inventory which the PHA regards as severely distressed. No documentation is required, however, unless funding is requested for a development.

iv. If there is severe distress in one category, that is sufficient to determine a development as severely distressed.

v. HUD will review the documentation provided and will accept the PHA's determination unless:

(a) The facts and data presented are clearly inconsistent with available facts and data on the development in the official records of the Department or the PHA, or

(b) The facts and data presented describe conditions which either are no more distressed than the majority of the family developments in the PHA's inventory or indicate levels of distress that are below average for the city as a whole.

vi. *Categories of distress*—(a) *Families living in distress.* Information and data on barriers to self-sufficiency for the families in the development, such as percentage with no earned income, level of average income in the development as a percentage of area median income, or educational data.

(b) *Incidence of serious crime.* Information and data on the frequency of criminal acts of various types (drug-related, violent crime, thefts, etc.) or total crimes such as data from Federal, State or local law enforcement agencies, or information from the applicant's records on crime in the development including number of lease terminations or evictions for criminal activity, number of police calls to the development, incidence of vandalism or opinions and observations of individuals having direct knowledge of the nature and frequency of crime in the development as compared to the PHA's family developments and the city as a whole. These individuals may include law enforcement officials, youth anti-crime workers, and security personnel.

(c) *Barriers to managing the environment.* Information and data which reflect lack of management control of the site or failure of the development to meet the needs of residents or would-be applicants, such as the vacancy rate in the development, the turnover rate, the percent of rent collected monthly, and the rate of units rejected by applicants.

(d) *Physical deterioration of buildings and sites.* Information and data which shows the extent of physical problems at the development, such as the cost of rehabilitation/reconstruction as a percent of Total Development Cost, the density of the development as measured in units per acre, the level of deferred maintenance as measured by annual average work order backlog and number of units that do not meet Housing Quality Standards (HQS) pursuant to 24 CFR 882.109 as amended by the Lead Based Paint regulation at 24 CFR part 35, major system deficiencies, including peeling and chipping lead-based paint in greater than 20% of units, lack of reliable and reasonably efficient heat and hot water, major structural deficiencies, electrical system under code, poor site conditions, leaking roof, deteriorated laterals and sewers, and high number of plumbing leaks.

2. Funding Limitations

a. The maximum number of units for which funds may be provided in any one grant award is 500; however, developments of more than 500 units may be funded by providing funds from a grant for only a portion of the units. No more than three areas of a city, containing the community's most severely distressed developments, may be funded.

b. No more than 15 grants will be awarded. The Department intends to fund both planning and implementation grants. For planning grants, each city

may receive no more than $500,000. For implementation grants, HUD will provide no more than $50 million per city. No city may receive more than one grant under the URD from FY 1993 funds.

c. Only one application for an implementation grant may be made in any one city. The application may not cover more than 500 units in three areas and may not request more then $50 million. A PHA which has within its jurisdiction more than one eligible city may make a separate application for each city. A PHA may apply for a planning grant in the same city for which an implementation grant is requested, but it must be for a different development.

3. Matching Requirement

The City in which the PHA applicant is located must provide contributions for supportive services in an amount equal to at least 15% of the implementation grant funds requested by the PHA for supportive services. This contribution must be from non-federal sources, which may include funding under the Community Development Block Grant Program. Amounts contributed to the match shall be used for eligible supportive services under the URD under section III.A.2.b. and c. Contributions may only be in the form of cash contributions, administrative costs, and the reasonable value of in-kind contributions.

4. Sustainability

The targeted units under an implementation grant must be expected to be sustainable over the long term regardless of whether the application covers an entire development or a portion of a development. In determining sustainability, the Department will consider social and physical problems in the unfunded portion of the development, if any, and in the surrounding neighborhood, the degree to which those problems affect the units to be funded, and the extent to which actions are being taken to ameliorate those problems.

5. Replacement Housing

a. Units to be demolished or disposed of under the demonstration must be replaced on a one-for-one basis. Where the replacement housing need is to be met through conventional public housing units in ii (a), (b) or (c) below, such funds must be provided through this Urban Revitalization Grant. Other forms of replacement housing, e.g., Section 8 Certificates, may be provided from these grant funds. Replacement housing is not required for units lost through reconfiguration of interior space without demolition. Section 18 of the U.S. Housing Act of 1937 applies to demolition, disposition and replacement housing under this demonstration. The 1993 Appropriation Act, however, creates an alternative for sections 18(b)(3) (A) and (B), which describe the types of housing that may be used as replacement housing and the circumstances under which Section 8 certificates may be used. In this demonstration, replacement housing may be accomplished by the following programs or as otherwise permitted under section 18 of the Act:

i. One-third by certificates under section 8(b),

ii. The remaining two-thirds by any combination of:

(a) Conventional public housing units consistent with 24 CFR part 941.

(b) Units acquired or otherwise provided for homeownership under section 5(h) of the Act,

(c) Units made available through homeownership programs involving construction or substantial rehabilitation of homes and meeting essentially the same eligibility requirements as those established pursuant to the Nehemiah Housing Opportunity Program, (section 603–607 of the Housing and Community Development Act of 1987, Pub. L. 100–242) or under the HOPE II or III programs as established under sections 421 and 441 of the Cranston-Gonzalez National Affordable Housing Act (NAHA).

b. Within six months of the date of grant approval, the PHA must submit an approvable application prepared in accordance with Handbook 7485.1 for any demolition or disposition which is to be funded under the URD grant.

6. Cost Requirements

a. For implementation grants, the average per unit hard costs (as defined in 24 CFR 968.105) must equal or exceed 62.5 percent of Total Development Costs.

b. For all implementation grants, average per unit hard costs for units to be reconstructed or rehabilitated may not exceed 100 percent of the published Total Development Costs, except that the Department may approve exceptions to this requirement for applications achieving a standard of modest design which include an adequate justification of the higher costs based on:

i. An analysis of the costs, separately identifying costs of lead paint testing and abatement, above average infrastructure replacement, accessibility improvements to meet 504 requirements, asbestos removal, major reconfiguration of streets and sidewalks and other significant improvements; and

ii. An analysis of the cost and feasibility of alternative courses of action, showing that there are no feasible, less expensive alternatives. The alternatives may include demolition of all or a portion of the development with replacement of units on-site, off-site, or a combination. The analysis should describe all the factors that went into the PHA's decision-making and should include evaluation of alternative designs and the feasibility in time and effort of acquiring units or land off-site for replacement housing.

7. Resident Consultation

In consultation with the residents, the PHA shall develop a process which assures that residents are fully briefed and meaningfully involved in developing, implementing, and monitoring the urban revitalization program. The PHA shall give full consideration to the comments and concerns of residents. The process shall include:

a. Consultation with representative residents or resident organizations throughout the PHA in the selection of the units for which funds will be requested in this application.

b. Consultation with the residents of the selected development or, if the development is vacant, with representative residents or resident organizations throughout the PHA, regarding the preparation of the plan under a planning grant or the implementation application under an implementation grant. Such consultation shall include, but not be limited to, identification of the nature and causes of distress, design of appropriate remedies for the causes of distress, the overall redesign, units to be demolished, community service opportunities, supportive services and empowerment opportunities, and replacement housing.

c. Once a draft plan has been developed under a planning grant or a draft application has been prepared under an implementation grant, the PHA shall make a copy available for reading in the management office; provide copies of the draft to any resident organization representing the residents of the development; and provide adequate opportunity for comment by the residents of the development and their representative organizations prior to making the plan or the application final.

d. Provide to HUD and any resident organization representing the development a summary of the resident comments and its response to them; and

notify residents of the development that this summary and response are available for reading in the management office.

e. For implementation grants in which demolition or disposition is planned, the applicant must comply with Section 412 of the National Affordable Housing Act, 1990, as amended, which requires a PHA to afford the opportunity to purchase to existing PHA-wide resident councils, and to the resident management corporation, resident council or resident cooperative of the development that is to be demolished or disposed of, under certain limited conditions, including total demolition or disposition. A Notice containing procedures for implementation of this requirement is found in the Federal Register dated October 6, 1992, 57 FR 46074. The requirements of the Notice are not applicable to demolition of selected portions of the development in order to reduce density which is essential to ensure the long-term viability of the development or the housing agency, except that this inapplicability should not be used cumulatively to avoid Section 412 requirements. In cases where the requirements of the Notice are applicable, applications including plans for demolition or disposition must include a certification of lack of resident interest in acquiring the property in the form required by Section VII.C. of the Notice.

f. After HUD approval of a grant, notify residents of the development and any representative organizations of the approval of the grant, provide the resident organization with a copy of the HUD-approved Project Implementation Schedule; and notify the residents of the availability of the schedule in the management office for reading.

8. Local Government Certifications

The public official, or his or her authorized representative, who submits the Comprehensive Housing Affordability Strategy (CHAS), under section 105 of NAHA, must certify that the proposed activities are consistent with the CHAS. The local governing body must approve the application and must certify that they will permit replacement, in accordance with Section 18 of the Act and the 1993 Appropriations Act, of any units to be demolished or disposed of.

9. Community Service Component

Each application for an implementation grant must include a community service component as described in III.A.2.a. below and in Appendix B.

10. Displaced Persons

Under implementation grants, persons displaced by the reconstruction activities funded by URD must be eligible under the plan for occupancy of the replacement units.

11. Planned Use of Comprehensive Grant Program Funds

Any planned use of Comprehensive Grant Program Funds in connection with activities funded under the Urban Revitalization Demonstration must be shown in the Annual Statement and revised Five-Year Action Plan submitted in anticipation of FY 1994 funding.

12. Non-duplication

Grant funds may not be used to duplicate work which is funded under any other Federal program, and the PHA shall establish controls to assure non-duplication of funding.

13. Applicability of Program Regulations

The following activities that may be undertaken with grant funds shall be subject to the cited program requirements, consistent with the 1993 Appropriation Act and this NOFA. If the revitalization plan requires any deviation from these cited requirements, such as local programs for replacement housing through housing opportunity programs of construction or substantial rehabilitation of homes meeting essentially the same eligibility requirements as the Nehemiah Program or HOPE II or III must be approved by the Department.

a. Demolition and disposition activity under the grant will be governed by 24 CFR part 970;

b. Public housing development activity (including on-site reconstruction as well as off-site replacement housing) will be governed by 24 CFR part 941;

c. Replacement housing activity using section 8 rental certificates will be governed by 24 CFR part 882;

d. Replacement housing activity with units acquired or otherwise provided for homeownership under section 5(h) will be governed by 24 CFR part 906;

e. Replacement housing activities provided through housing opportunity programs of construction or substantial rehabilitation of homes will be governed by 24 CFR part 280 (the Nehemiah Program);

f. Replacement housing activities under HOPE II shall be governed by 24 CFR subtitle A, appendix B;

g. Replacement housing activities under HOPE III shall be governed by 24 CFR subtitle A, appendix C;

h. Rehabilitation and physical improvement activities will be governed by 24 CFR 968.310 (Eligible costs), and 24 CFR 968.335 (Conduct of modernization activity.)

F. Other Program Characteristics

1. Waiver of Departmental Regulations

PHAs may request, for the revitalized development, a waiver of Departmental regulations (not statutory provisions) governing rents, income eligibility, or other areas of public housing management to permit a PHA to undertake measures that enhance the long-term viability of a severely distressed project revitalized under this demonstration. If the application requests a waiver which would permit a separate waiting list for the development, the PHA must adopt a strategy for affirmatively marketing the development, which shall include specific steps to inform potential applicants and solicit applications from eligible families in the housing market area who are least likely to apply for the program without special outreach.

2. Preferences Applicable to Selection of Tenants

PHAs may choose to utilize a local system of preferences for the selection of tenants for the revitalized development. Such preferences shall be established in writing and shall respond to local housing needs and priorities as determined by the PHA after one or more public hearings to obtain the views of low-income residents and other interested parties.

3. Use of Other Sources of Funds

Funds made available under the URD may be used in conjunction with, but not in lieu of, funding provided under the head "Modernization of Low-Income Housing Projects" for the modernization of existing public housing pursuant to section 14 of the Act (42 U.S.C. 14371); for construction or major reconstruction of obsolete public housing, other than for Indian families; for the replacement of public housing units pursuant to section 18 of the Act; and for the HOPE for Public and Indian Housing Homeownership Program as authorized under title III of the Act. (See III.B.3.g.)

4. Failure To Proceed

In the event that an applicant selected to receive URD funding does not proceed in a manner consistent with the approved plan and requirements of this NOFA, HUD may withdraw any unobligated balances of funding.

5. Grant Agreement

After HUD approves an application for a planning or an implementation grant, it shall enter into a grant agreement with the recipient setting forth the amount of the grant and applicable terms and conditions, including sanctions for violation of the agreement. Among other things, the grant agreement will provide that the recipient agrees:

a. To carry out the program in accordance with the provisions of this NOFA, applicable law, the approved application, and all other applicable requirements;

b. To comply with such other terms and conditions, including recordkeeping and reports, as HUD may establish for the purposes of administering, monitoring and evaluating the program in an effective and efficient manner; and

c. That HUD may withhold, withdraw, or recapture any portion of a grant, terminate the grant agreement, or take other appropriate action authorized under the grant agreement, if HUD determines that the recipient is failing to carry out the approved revitalization program in accordance with the terms of the approved application and this NOFA, including failure to provide the contribution towards the match.

II. Planning Grants

A. Eligible Activities

A planning grant may be used to plan for the revitalization of severely distressed developments consistent with the requirements of this NOFA, including:

1. Studies of the different options for revitalization, including the feasibility, costs and neighborhood impact of such options;

2. Providing technical or organizational support to ensure resident involvement in all phases of the planning and implementation processes;

3. Conducting workshops to ascertain the attitudes and concerns of the neighboring community;

4. Preliminary architectural and engineering work;

5. Planning for supportive services, including economic development, job training and self-sufficiency activities that promote the economic self-sufficiency of residents under the revitalization program;

6. Planning for community service opportunities;

7. Designing a suitable replacement housing plan, in situations where partial or total demolition is considered;

8. Planning for necessary management improvements; and

9. Conducting environmental studies.

B. Application Submission Requirements

An application for a planning grant shall contain:

1. A request for a planning grant, specifying a plan for the activities proposed, the schedule for completing the activities, the personnel necessary to complete the activities and the amount of the grant requested;

2. Identification and description of the development and the targeted units involved, and a description of the composition of the residents, including family size and income;

3. Demonstration that the development meets the description of severely distressed as described in section I.E.1. of this NOFA;

4. A description of the extent of resident interest and involvement in the development of the planning application and the plan for resident involvement during the planning period; and evidence of resident involvement consistent with the program requirements as stated in I.E.7. above to the extent applicable;

5. A description of the extent of involvement of local public and private entities in the development of the planning application and the plan for involvement of local public and private entities during the planning period;

6. A description of the process to be used in the development of the community service component;

7. If the PHA is listed on the attached March 31, 1992 list of troubled housing agencies, documentation necessary to demonstrate that the PHA has made substantial progress to eliminate their troubled status as defined in section I.D.2. of this NOFA;

8. A certification by the public official responsible for submitting the CHAS under section 105 of NAHA that the proposed activities are consistent with the approved housing strategy of the State or unit of general local government within which the targeted units are located;

9. A certification that the applicant will comply with the requirements of the Fair Housing Act, title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975, and will affirmatively further fair housing;

10. Form HUD–52825, Comprehensive Assessment/Program Budget (Parts I and II).

11. A narrative statement addressing each of the rating factors.

12. Form HUD–50070, Certification for a Drug-Free Workplace.

13. Form HUD–52820, PHA Board Resolution Approving URD Application.

14. Anti-Lobbying Certification for Contracts, Grants, Loans and Cooperative Agreements if request for grant exceeds $100,000.

15. SF–LLL, Disclosure of Lobbying Activities only where any funds, other than federally appropriated funds, will be or have been used to lobby the Executive or Legislative branches of the Federal government regarding specific grants or contracts.

16. Disclosures required by section 102 of the HUD Reform Act of 1989.

17. A certification that the applicant has not and will not receive assistance from the Federal government, a State, or a unit of local government, or any agency or instrumentality thereof, for the specific activities for which funding is requested in the application.

C. Rating and Selection Process

1. Rating Factors

Applications will not be rated until they have been determined to be eligible under section I.D. of this NOFA and to meet the program requirements under I.E. 1, 2, 7, and 12. If an application fails to have an adequate plan for the development of the community service component, rating may proceed. However, a revised plan must be approved by the Commission on National and Community Service (CNCS) before any funds may be disbursed. HUD Headquarters review staff will rate factors "a. through e." below. CNCS will rate factor "f." below and provide the rating to HUD for incorporation into the total score.

a. The extent of the need for the revitalization program as defined in III.C.1.a.

b. The capability of the applicant as defined in III.C.1.c;

c. The potential of the applicant for developing a successful and affordable revitalization program as determined by the quality of the plan for the planning process, and the suitability of the development for such a program;

d. The extent of resident interest and involvement in the development of the planning application and the extent of resident involvement planned for the planning period;

e. The extent of involvement of local public and private entities in the development of the planning application and the extent of involvement of local public and private entities planned for the planning period;

f. The likely effectiveness of the process described for the development of the community service component.

2. Selection Criteria

a. Points awarded under section II.C. 3. below for the rating factors.

b. National geographic diversity. The Department, in its discretion, may choose to select a lower-rated, approvable application over a higher-rated application in order to increase the level of national geographic diversity of applications approved under this NOFA.

c. Diversity of development types. HUD may, in its discretion, choose to select to lower-rated, approvable application over a higher-rated application in order to increase the diversity of development types (developments which include family high-rise buildings of five or more stories and those which include only low rise buildings) approved under this NOFA.

3. Rating Values

The following point assignments will be used to rate planning grant applications in accordance with the criteria listed in section II.C.1. above. The Department shall examine the ratings, and where it determines that applications falling below a certain point total are not suitable or not feasible for planning grants, it may establish a minimum number of points for an application to be selected. The Department shall then select the highest rated applications, unless it exercises its discretion to select lower rated, approvable applications in order to promote national geographic diversity and/or diversity of project types in accordance with Section II.C.2. of this NOFA.

Rating factors	Point range
Extent of Need	0–30
Capability	0–30
Applicant Potential for Success	0–20
Extent of Resident Interest and Involvement	0–15
Extent of Involvement of Local Public and Private Entities	0–10
Likely Effectiveness of Plan for Community Service Component	0–15
Total Maximum Score	120

4. Funding Decisions

After rating, Headquarters will select approvable applications for funding in accordance with the selection criteria set forth in section II.C.2. above. If any selected applications include plans for the development of community service components which have not been approved by the CNCS, the applicants may conform their applications to CNCS requirements after selection in order to obtain release of funds. HUD may approve an application for an amount lower than the amount requested if the application includes an ineligible activity, or if insufficient funds are available to fund the full amount requested and HUD determines that partial funding is a viable option.

5. Duration

Activities funded under planning grants shall be completed within 18 months of the effective date of the planning grant agreement.

III. Implementation Grants

A. Eligible Activities

1. At least 80% of funding awarded in each grant must be used for any combination of the following activities: capital costs of major reconstruction, rehabilitation and other physical improvements, including energy retrofit, capital costs of replacement units, certificates under section 8(b) used for replacement, management improvements for the reconstructed development and planning and technical assistance. Funds may be used for total or partial demolition and/or disposition of units. The following costs may be included:

a. Capital costs may include related administrative costs and temporary relocation necessary for reconstruction, rehabilitation, demolition or disposition.

b. Administrative costs may include the annual premium of LBP insurance incident to approved URD work.

2. Not more than 20% of funding awarded in each grant may be used for any combination of the following activities and the related administrative expenses:

a. Community service programs, as defined by the Commission on National and Community Service for the URD, specifically, programs organized, administered, overseen or funded by a public housing agency, or its designated representative, engaging individuals in meaningful service on a volunteer basis or through limited stipends to address unmet human, environmental, educational, and/or public safety needs through youth service and conservation corps, residents' associations, community-based organization, K–12 schools, institutions of higher education, churches or other religious entities and other such similar organizations. Such programs must comply with the requirements stated in appendix B.

b. Supportive services, including but not limited to, resident capacity building, literacy training, day care, youth activities, economic development, and resident employment and job training activities such as the Step-Up apprenticeship program (see **Federal Register** Notice, October 8, 1992, 57 FR 46398);

c. Economic development costs may include a setaside for a revolving loan fund, established and operated in accordance with 25 CFR part 85 (with specific reference to §§ 85.21 and 85.25), and

d. The following services authorized under the Gateway Program: outreach and information services designed to make eligible individuals aware of available services, literacy and bilingual education services, remedial education and basic skills training, employment training and personal management skill development or referrals for such services, child care or dependent care for dependents of eligible individuals during those times when training services are being provided, pre-employment skills training, employment counsel and application assistance, job development services, job training, Federal employment-related activity services, completion of high school or GED program services, transitional assistance, including child care for up to 6 months to enable such individual to successfully secure unsubsidized employment, substance abuse prevention and education, and other support services deemed to be important by the Secretary of Health and Human Services.

B. Application Submission Requirements

Each application must include a request for an implementation grant containing a description of the development and the proposed activities, information relevant to rating the application, submissions to demonstrate compliance with various program requirements, and various required certifications, as follows:

1. A description of the development and the proposed activities, including:

a. A description of the number of units, by unit size, a site plan, and a statement of the number and location of vacant units; identification of the units to be targeted, if less than the entire development; a description of socio-economic and demographic characteristics of the residents.

b. A description of the proposed treatment of the units, including a narrative description of the extent of rehabilitation/reconstruction of existing units, extent of demolition, description of changes in the sizes and shapes of units and other changes in the use of interior space; any reduction in the number of units due to reconfiguration

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or changes in the utilization of interior space.

c. Description of community space alterations, improvements, and/or additions.

d. A description of the changes in the use of the site, and a post-revitalization site plan.

e. A description of proposed management improvements.

f. Description of the surrounding neighborhood, including strengths and weaknesses; proposed treatment of any neighborhood problems, including physical, economic, and security.

g. Description of proposed supportive services.

h. A description of any revolving loan fund for economic development, as permitted under Section III.A.2.c. hereof, including but not limited to the purpose of the loans, borrower eligibility, and the entity which will administer the fund.

i. Description of proposed community service component.

j. Where the demonstration grant is requested for a vacant development, identification of the residents who will receive the supportive services and participate in community service, and a statement of the reasons why this resident group is appropriate, how residents will be selected to participate and how this plan relates to the physical work planned to be undertaken in connection with this demonstration.

k. A description of the resident involvement in the development of the application and in the execution, implementation and monitoring of the revitalization plan.

l. A description of the number of replacement units to be funded, the nature of the programs to be used, including type and size of unit, tenure, and program descriptions.

m. Management plans describing the management of the revitalization activity and proposed management of the development after revitalization. The post-revitalization management plan must state whether additional or reduced management and maintenance costs will result from the revitalization and how the proposed management differs from the management process utilized prior to revitalization; e.g., resident selection, rent collection, and maintenance.

n. Form HUD–52825, Comprehensive Assessment/Program Budget (Parts I and II), covering units for which funding is requested in the current fiscal year, evidencing that the applicant has not exceeded the cost limits or exceptions granted pursuant to section I.E.6. above.

o. Statement of the percentage of the funding to be used for items listed in III.A.1. and in III.A.2. of this NOFA.

p. Modernization Organization and Staffing Plan, stating the proposed organization, staffing and inspection of the modernization program.

q. Implementation schedule for all revitalization activities for the development to be funded, whether those activities will be funded by URD or other sources.

2. The following information relevant to rating the application, which is not otherwise requested:

a. Documentation of the extent of need as required by III.C.1.a.

b. An assessment of the causes of distress; an explanation of how the proposed physical changes, management improvements, supportive services, and community service component will remedy the distress; an explanation of how the plan for management after revitalization will correct previous problems; a discussion of why the proposed revitalization plan is likely to be successful.

c. Data necessary for rating of section III.C.1.a.

d. Description of the involvement and commitment of local public and private entities sufficient to assess Section III.C.1.e.

3. The following submissions to demonstrate compliance with various program requirements:

a. Demonstration that the development meets the description of severely distressed as described in section I.E.1. of this NOFA.

b. A list of all severely distressed developments under the PHA's jurisdiction.

c. A certification by the PHA that the targeted units are located in not more than 3 separately defined areas containing the community's most severely distressed projects.

d. Description of the amount and nature of the supportive service funding from non-federal sources to be provided by the city in which the PHA is located and the percentage of the total supportive services funding that this represents; a commitment from the city to provide the contribution for supportive services required under section I.E.3.

e. If the PHA is proposing to revitalize only a portion of the development, a description of the actions to be taken to revitalize the portions which will not be funded under this application, including alternate sources of funding which may be utilized (e.g. Comprehensive Grant Program funds or reprogrammed Comprehensive Improvement Assistance Programs funds); and the basis for the conclusion that the revitalization of the targeted units will be sustainable over the long term.

f. Where average per unit costs for all hard costs will exceed 100% of TDC, a justification of the need for higher costs as required in I.E.6.

g. In order to assure that URD funds are not used in lieu of otherwise available modernization funds, a demonstration that the funds reasonably expected to be available to the PHA over the period of the CGP Five-Year Action Plan are not adequate to address the total modernization needs of the PHA.

h. If the PHA is listed on the attached March 31, 1992 list of troubled housing agencies, documentation necessary to demonstrate that the PHA has made substantial progress to eliminate their troubled status as defined in section I.D.2. of this NOFA.

4. The following submissions which are necessary only in certain circumstances:

a. Any request for waiver of Departmental regulations governing rents, income eligibility, or other areas of public housing management which will enhance the long term viability of the development, if the PHA desires such waivers. The request must:

i. Identify the specific provisions requested to be waived,

ii. State how the waiver will contribute to the success of the revitalization plan, and

iii. State specifically how the PHA wishes to manage any function for which a waiver is sought, pursuant to applicable law.

b. Narrative description of the local preferences applicable to the selection of tenants for the revitalized development if they are different from the approved tenant selection plan for the entire PHA jurisdiction, and a certification by the PHA that at least one public hearing was held to discuss the proposed local preferences.

5. The following required certifications:

a. Where demolition or disposition of units is contemplated in the application, the PHA and the city must certify that each unit will be replaced in accordance with Section 18 of the Act, as modified by the Appropriations Act of 1993 (see I.E.5.) and that they will take all necessary steps to assure that replacement units will be provided within 6 years of approval of the demolition application. In demolition/disposition cases where the requirements of the Section 412 Notice (57 FR 44074) are applicable, applications including plans for demolition or disposition must include

a certification of lack of resident interest in acquiring the property in the form required by Section VII.C. of the Notice.

b. Commitment from any other public or private entity other than the PHA for any contribution to the development or the surrounding neighborhood which is a part of the revitalization plan.

c. A certification by the public official responsible for submitting the comprehensive housing affordability strategy under section 105 of NAHA that the proposed activities are consistent with the approved housing strategy of the State or unit of general local government within which the targeted units are located.

d. Disclosures required by section 102 of the HUD Reform Act of 1989.

e. Form HUD–50070, Certification for a Drug-Free Workplace.

f. Form HUD–52820, PHA Board Resolution Approving URD Application and PHA certification of compliance with minimum resident consultation requirements.

g. Anti-Lobbying Certification for Contracts, Grants, Loans and Cooperative Agreements for grants exceeding $100,000.

h. SF–LLL, Disclosure of Lobbying Activities only where any funds, other than federally appropriated funds, will be or have been used to lobby the Executive or Legislative branches of the Federal government regarding specific grants or contracts.

i. A certification that the applicant has not and will not receive assistance from the Federal government, a State, or a unit of local government, or any agency or instrumentality thereof, for the specific activities for which funding is requested in the application.

j. A certification that the applicant will comply with the requirements of the Fair Housing Act, Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975, and will affirmatively further fair housing.

C. Rating and Selection

1. Rating Factors

Applications will not be rated until they have been determined to be eligible under section I.D. of this NOFA. Further, prior to ranking, all applications must meet program requirements I.E.1, 2, 4, 6, 7, 8, and 12. Where applicable, the applications must also meet the following program requirements: I.E.3, 5, 10, and 11. If an application fails to meet the requirements for the community service component found in III.A.2.a. and Appendix B, rating may proceed. However, a revised community service component must be approved by the Commission on National and Community Service (CNCS) before any funds will be disbursed. HUD Headquarters review staff will rate factors "a"–"e" below. The CNCS will rate factor "f" below. The Department may establish a panel of experts with whom to consult for advice on elements of the applications which are within their expertise. Such experts will be advisors and will not conduct any part of the rating or selection of grantees.

a. *Extent of need for revitalization.* Points will be awarded for evidence of distress in the development and distress in the surrounding neighborhood that has a significant impact on the development as measured by the information listed below and any qualitative information submitted pursuant to the categories identified in I.E.1. In determining rating points, applicants will be compared to each other. The following information must be submitted for the development:

i. *Families living in distress.* Percentage of households with no earned income, average income as a percentage of area median.

ii. *Incidence of serious crime.* Such statistical information as is available on the following: frequency of criminal acts of various types or all criminal acts, number of lease terminations or evictions for criminal activity, average number of police calls to the development monthly, average monthly incidence of vandalism to PHA property in dollars.

iii. *Barriers to managing the environment.* Vacancy rate, percentage of new residents per year, percent of rent collected monthly.

iv. *Physical deterioration.* Cost of rehabilitation/reconstruction per unit as a percentage of TDC, density as measured in units per acre, average work order backlog, number of units that do not meet HQS, and major system deficiencies, including peeling and chipping lead-based paint, lack of reliable and reasonably efficient heat and hot water, major structural deficiencies, electrical system under code, poor site conditions, leaking roof, deteriorated laterals and sewers, high number of plumbing leaks.

b. *Potential impact of the plan.* Points will be awarded to the extent the revitalization plan developed by the PHA appropriately addresses the causes of distress and seems likely to produce fully occupied units providing a satisfactory living environment, both in terms of the physical problems of the units to be funded and the social, educational, and income problems affecting the residents. In making a determination under this factor, the Department will consider the evidence of distress identified in the application, as well as other information available to HUD from previous applications to the Department, site visits, monitoring, and other information in the Department's files. Specifically, the application must demonstrate:

i. That the PHA has accurately assessed the causes of physical, social, educational and economic distress in the targeted units, the development, and the surrounding neighborhood,

ii. That the PHA has designed appropriate remedies to ameliorate the physical, social, educational and economic distress, including appropriate supportive services and service opportunities,

iii. That the plan for management of the development after revitalization will correct previous problems and contribute to the success of the development, and

iv. That, taken together, the sum of all the actions to be taken, whether funded by the grant or by other sources is highly likely to be successful in revitalizing the targeted units, resulting in full occupancy and in the provision of decent, safe, and sanitary housing to the residents over the long term.

c. *Capabilities of the applicant.* Points will be awarded based upon the PHA's capabilities, as measured by the following indicators:

i. Overall PHA capability.

(a) The PHA's total score under the Public Housing Management Assessment Program (PHMAP), 24 CFR Part 901

(b) The PHA's most recent fiscal audit

(c) Outstanding HUD monitoring findings

(d) For PHAs which were on the 3/31/92 Troubled PHA List, any submission pursuant to I.D.2.

ii. Modernization capability.

(a) The PHA's score for Indicator 2, Modernization, (24 CFR 901.10(b)(2)) under PHMAP

(b) Ability to carry out the implementation schedule in current and previous modernization except for delays beyond the control of the PHA

iii. Quality of management plan for carrying out revitalization activity.

d. *Extent of resident involvement.* Points will be awarded based upon the extent of resident involvement, as measured by the following indicators and demonstrated in the plan:

i. Extent of resident consultation in preparation of the application;

ii. Degree of resident training, employment and contracting planned during execution of the revitalization plan (for example, as part of a Step-Up apprenticeship program); and

iii. Level of planned resident involvement in implementation and monitoring progress.

e. *Extent of involvement of local public and private entities.* Points will be awarded based upon the extent of involvement of local public and private entities, as measured by the following indicators and demonstrated in the plan:

i. Extent of involvement in the development of the application;

ii. Extent of commitment to the provision of supportive services to residents of the development to be revitalized;

iii. Level of commitment of local, non-federal funds to the physical improvement of the development and the surrounding neighborhood; and

iv. Extent of commitment to improvement of supportive services and economic activity in the immediate vicinity surrounding the development to be revitalized.

f. *Community service component.* Points will be awarded by the Commission based upon the community services component, as provided below, measured by the following indicators:

i. Quality based on:

(a) The program's ability to offer valuable services in the areas where they are needed most and where programs do not exist or where existing service opportunities are too limited to meet community needs;

(b) The program's ability to involve participants, particularly youth, in the design and operation of the program;

(c) The program's ability to involve individuals from diverse backgrounds (including diversity of gender, race, ethnic background, economic background, educational background, age, physical ability) who will serve together;

(d) The leadership and management, as measured by the qualifications of the principal leaders of the program; and

(e) The extent to which the applicant proposes specific and concrete plans for achieving its stated objectives.

ii. Cost effectiveness based on the reasonableness of the budget request relative to the perceived impact of the proposed activity.

iii. Sustainability based on:

(a) Strong and broad-based community support for involvement in the program; and

(b) Evidence that the best efforts will be made to obtain the financial resources necessary to continue the program beyond the term of the revitalization project.

iv. Innovation based on the ability of the program to advance knowledge about creative and effective community service.

v. Replicability based on the degree to which program design can be broadly applicable in areas beyond program location.

vi. The following rating points will be used by CNCS to create the score for the community service component which will then be incorporated into the overall selection and rating scores assigned in section III.C.3. below:

2. Selection Criteria

a. Points awarded under section III.C.3. below for the rating factors.

Rating factors	Point range
Quality	7.5 points.
Cost-effectiveness	2.25 points.
Sustainability	2.25 points.
Innovation	1.5 point.
Replicability	1.5 point.

b. National geographic diversity. The Department, in its discretion, may choose to select a lower-rated, approvable application over a higher-rated application in order to increase the level of national geographic diversity of applications approved under this NOFA.

c. Diversity of development types. HUD may, in its discretion, choose to select a lower-rated, approvable application over a higher-rated application in order to increase the diversity of development types (developments which include family high-rise buildings of five or more stories and those which include only low rise buildings) approved under this NOFA.

3. Rating Values

The following point assignments will be used to rate applications in accordance with the criteria listed in section III.C.1. above. The Department shall examine the rating, and where it determines that applications falling below a certain point total are not suitable or not feasible for demonstration of successful revitalization of severely distressed developments, it may establish a minimum number of points for an application to be selected.

Rating factors	Point range
Extent of need for revitalization	0–30
Potential impact of the plan	0–30
Capabilities of the applicant	0–20
Extent of resident involvement	0–15
Extent of involvement of local public and private entities	0–10
Community service component	0–15
Total maximum score	120

4. Funding Decisions

After rating, Headquarters will select approvable applications for funding in accordance with the selection criteria set forth in section III.C.1. above. If any selected applications include community service components which have not been approved by the CNCS, the applicants may conform their applications to CNCS requirements after selection in order to obtain release of funds. HUD may approve an application for an amount lower than the amount required if the application includes an ineligible activity, or if insufficient funds are available to fund the full amount requested and HUD determines that partial funding is a viable option.

IV. Application Processing

A. Schedule for Submission and Approval

Applications must be received on or before 4 p.m. E.S.T. on April 5, 1993. HUD will select grantees by [insert date 180 days from date of publication].

B. Corrections to Deficient Applications

1. Immediately after the deadline for submission of applications, Headquarters will screen each application to determine whether all items were submitted.

2. If the PHA fails to submit the technical items listed below or the application contains a technical mistake such as an incorrect signatory, the Department shall immediately notify the PHA in writing that the PHA has 14 calendar days from the date of HUD's written notification to submit or correct any of the specified items. The PHA will have no opportunity to correct deficiencies not identified in HUD's written notification. If the items listed below are missing, and the PHA does not submit them within the required time period, the application will be ineligible for further processing.

a. PHA Report on Cooperation Agreement;

b. Form HUD–50070, Certification for a Drug-Free Workplace;

c. Form HUD–52820, PHA Board Resolution Approving URD Application;

d. Certification for Contracts, Grants, Loans and Cooperative Agreements;

e. SF–LL, Disclosure of Lobbying Activities;

f. Report on Project Implementation Schedule(s);

g. Modernization Organization Staffing Plan.

V. Applicability of Other Federal Requirements

A. Flood Insurance

Pursuant to the Flood Disaster Protection Act of 1973 (42 U.S.C. 4001–4128), HUD will not approve applications for grants providing financial assistance for acquisition or rehabilitation of properties located in an area identified by the Federal Emergency Management Agency (FEMA) as having special flood hazards, unless—

1. The community in which the area is situated is participating in the National Flood Insurance program (see 44 CFR Parts 59 through 79), or less than one year has passed since FEMA notification regarding such hazards; and

2. Flood insurance is obtained as a condition of approval of the application.

B. Coastal Barriers Resources Act

Pursuant to the Coastal Barrier Resources Act (16 U.S.C. 3601), HUD will not approve grant applications for properties in the Coastal Barrier Resources System.

C. Fair Housing Requirements

The requirements of the Fair Housing Act (42 U.S.C. 3601–19) and regulations pursuant thereto (24 CFR part 100); Executive Order 11063 (Equal Opportunity in Housing) and regulations pursuant thereto (24 CFR part 107); the fair housing poster regulations (24 CFR part 110) and advertising guidelines (24 CFR part 109).

D. Nondiscrimination in Housing

Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) and regulations pursuant thereto (24 CFR part 1).

E. Discrimination on the Basis of Age or Handicap

The prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975 (42 U.S.C. 6101–07) and regulations issued pursuant thereto (24 CFR part 146), the prohibitions against discrimination against handicapped individuals under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and regulations issued pursuant thereto (24 CFR part 8) and the Americans with Disabilities Act (Public Law 101–336) and its implementing regulation at 28 CFR part 36.

F. Employment Opportunities

The requirements of section 3 of the Housing and Urban Development Act of 1968 (12 U.S.C. 1701u) (Employment Opportunities for Lower Income Persons in Connection with Assisted Projects) and its implementing regulation at 24 CFR part 135.

G. Minority and Womens' Business Enterprises

The requirements of Executive Orders 11246, 11625, 12432, and 12138. Consistent with HUD's responsibilities under these Orders, recipients must make efforts to encourage the use of minority and women's business enterprises in connection with funded activities.

H. Disability Requirements

Fair Housing Act and section 504. The recipient must comply with the reasonable modification and accommodation requirements of the Fair Housing Act and the accessibility requirements of the Fair Housing Act and section 504 of the Rehabilitation Act of 1973, as amended.

I. OMB Circulars

The policies, guidelines, and requirements of OMB Circular Nos. A–87 (Cost Principles Applicable to Grants, Contracts and Other Agreements with State and Local Governments) and 24 CFR part 85 (Administrative Requirements for Grants and Cooperative Agreements to State, Local and Federally Recognized Indian Tribal Governments) apply to the award, acceptance, and use of assistance under the program by PHAs, and to the remedies for non-compliance, except when inconsistent with the provisions of the Appropriations Act, other Federal statutes, or this notice. Recipients are also subject to the audit requirements of OMB Circular A–128 implemented at 24 CFR part 44. Copies of OMB Circulars may be obtained from E.O.P. Publications, room 2200, New Executive Office Building, Washington, DC 20503, telephone (202) 395–7332 (this is not a toll-free number). There is a limit of two free copies.

J. Drug-Free Workplace

Applicants shall certify that they will provide a drug-free workplace, in accordance with the Drug-free Workplace Act of 1988 and HUD's implementing regulations at 24 CFR part 24, subpart F.

K. Anti-Lobbying Certification

Section 319 of Public Law 101–121 prohibits recipients of Federal contracts, grants, and loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government. A government-wide common rule governing the restrictions on lobbying was published as an interim rule on February 26, 1990 (55 FR 6736) and supplemented by a notice published June 15, 1990 (55 FR 24540). For HUD, this rule is found at 24 CFR part 87. The rule requires applicants for and recipients of assistance exceeding $100,000 to certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance. The rule also requires disclosures from applicants and recipients if nonappropriated funds have been spent or committed for lobbying activities if those activities would be prohibited if paid with appropriated funds. The law provides substantial monetary penalties for failure to file the required certification or disclosure.

L. Section 102 of HUD Reform Act of 1989

On March 14, 1991, the Department published in the **Federal Register** a final rule to implement section 102 of the Department of Housing and Urban Development Reform Act of 1989 (24 CFR part 12, 56 FR 11032). Section 102 contains a number of provisions that are designed to ensure greater accountability and integrity in the provision of certain types of assistance administered by the Department.

M. Documentation and disclosures

Since HUD makes assistance under the program available on a competitive basis, 24 CFR part 12 requires HUD to:

1. Ensure that documentation and other information regarding each application submitted to the Department are sufficient to indicate the basis upon which assistance was provided or denied. HUD must make this material available for public inspection for a five-year period (§ 12.14(b).) HUD will provide further guidance on how this material may be accessed in a later Notice published in the **Federal Register**.

2. Publish a Notice in the **Federal Register** at least quarterly indicating the recipients of the assistance (24 CFR 12.16(a).)

3. Subpart C of part 12 requires applicants that seek assistance from HUD for a specific project or activity must make the disclosures required under § 12.32. Each applicant must complete form HUD 2880, Applicant/Recipient Disclosure/Update Report, and submit the completed form with its application.

N. Section 103 HUD Reform Act of 1989

HUD's regulation implementing section 103 of the Department of Housing and Urban Development Reform Act of 1989 was published May

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13, 1991 (56 FR 22088) and became effective on June 12, 1991. That regulation, codified as 24 CFR part 4, applies to the funding competition announced today. The requirements of the rule continue to apply until the announcement of the selection of successful applicants. HUD employees involved in the review of applications and in the making of funding decisions are limited by part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted under 24 CFR part 4. Applicants who have questions should contact the HUD Office of Ethics (202) 708–2815; TDD (202) 708–1112. (These are not toll-free numbers.)

O. Section 112 HUD Reform Act of 1989

Section 13 of the Department of Housing and Urban Development Act contains two provisions dealing with efforts to influence HUD's decisions with respect to financial assistance. The first imposes disclosure requirements on those who are typically involved in these efforts—those who pay others to influence the award of assistance or the taking of a management action by the Department and those who are paid to provide the influence. The second prohibits the payment of fees to those who are paid to influence the award of HUD assistance, if the fees are tied to the number of housing units received or are based on the amount of assistance received, or if they are contingent upon the receipt of the assistance. Section 13 was implemented by final rule (24 CFR part 86) published in the **Federal Register** on May 17, 1991 (56 FR 22912). If readers are involved in any efforts to influence the department in these ways, they are urged to read the final rule, particularly the examples contained in appendix A 24 CFR part 86. Any questions regarding the rule should be directed to Director, Office of Ethics, room 2158, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Telephone: (202) 708–3815; TDD: (202) 708–1112. (These are not toll-free numbers.) Forms necessary for compliance with the rule may be obtained from the local HUD office.

P. Debarred or Suspended Contractors

The provisions of 24 CFR part 24 apply to the employment, engagement of services, awarding of contracts, subgrants, or funding of any recipients, or contractors or subcontractors, during any period of debarment, suspension, or placement in ineligibility status.

Q. Conflict of Interest

1. In addition to the conflict of interest requirements in 24 CFR part 85, no person who is an employee, agent, consultant, officer, or elected or appointed official of the PHA and who exercises or has exercised any functions or responsibilities with respect to activities assisted under an URD grant, or who is in a position to participate in a decision-making process or gain inside information with regard to such activities, may obtain a financial interest or benefit from the activity, or have an interest in any contract, subcontract, or agreement with respect thereto, or the proceeds thereunder, either for himself or herself or for those with whom he or she has family or business ties, during his or her tenure or for one year thereafter.

2. HUD may grant an exception to the exclusion in paragraph (1) of this section on a case-by-case basis when it determines that such an exception will serve to further the purposes of the revitalization demonstration and the effective and efficient administration of the revitalization program. An exception may be considered only after the applicant or recipient has provided a disclosure of the nature of the conflict, accompanied by an assurance that there has been public disclosure of the conflict and a description of how the public disclosure was made and an opinion of the applicant's or recipient's attorney that the interest for which the exception is sought would not violate State or local laws. In determining whether to grant a requested exception, HUD shall consider the cumulative effect of the following factors, where applicable:

a. Whether the exception would provide a significant cost benefit or an essential degree of expertise to the revitalization program that would otherwise not be available;

b. Whether an opportunity was provided for open competitive bidding or negotiation;

c. Whether the person affected is a member of a group or class intended to be the beneficiaries of the activity and the exception will permit such person to receive generally the same interest or benefits as are being made available or provided to the group or class;

d. Whether the affected person has withdrawn from his or her functions or responsibilities, or the decisionmaking process, with respect to the specific activity in question;

e. Whether the interest or benefit was present before the affected person was in a position as described in paragraph (1) of this section;

f. Whether undue hardship will result either to the applicant, recipient, or the person affected when weighed against the public interest served by avoiding the prohibited conflict; and

g. Any other relevant considerations.

R. Labor Standards

Pursuant to section 12 of the 1937 Act, Davis-Bacon or HUD-determined prevailing wage rates shall apply to activities under this demonstration program. The wage rate requirements do not apply to individuals who perform services for which they volunteered; do not receive compensation for those services or are paid expenses, reasonable benefits, or a nominal fee for the services; and are not otherwise employed in the work involved (24 CFR part 70). In addition, if other Federal programs are used in connection with the revitalization program, labor standards requirements apply to the extent required by such other Federal programs. For example, if the CDBG program is used in connection with the revitalization program, the labor standards requirements of those programs would apply to the extent required by them.

S. Lead-Based Paint Testing and Abatement

Any property assisted under the revitalization program established under this notice constitutes HUD-associated housing for the purpose of the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. 4821, *et seq.*) and is, therefore, subject to 24 CFR part 35, and 24 CFR part 965 (subpart H). Unless otherwise provided, recipients shall be responsible for testing and abatement activities.

T. Relocation

1. The requirements of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 and government-wide implementing regulations at 49 CFR part 24 are applicable to this program.

2. Temporary Relocation

The recipient shall provide each resident of an eligible property, who is required to relocate temporarily to permit work to be carried out, with suitable, decent, safe, and sanitary housing for the temporary period and shall reimburse the resident for all reasonable out-of-pocket expenses incurred in connection with the temporary relocation, including the

costs of moving to and from the temporarily occupied housing and any increase in monthly costs of rent and utilities.

U. Records, Reports, and Audit of Recipients

1. General Records

Each recipient shall keep records that will facilitate an effective audit to determine compliance with program requirements and that fully disclose—

a. The amount and disposition of funds received under this notice, including sufficient records that document the reasonableness and necessity of each expenditure;

b. The amount and nature of any other assistance, including cash, services, or other items contributed as a condition of receiving a grant;

c. The cost or other value of all in-kind non-Federal contributions towards the supportive services match required by Section I.E.3.; and

d. Any other proceeds received for, or otherwise used in connection with, the revitalization program.

2. Reports

The PHA shall submit Form HUD–52826, Schedule/Report of Modernization Expenditures (approved by the Office of Management and Budget under control number 2577–0049) no later than 45 calendar days after the end of the quarter. The first report is due 45 calendar days after the end of the quarter in which the ACC amendment is executed.

The PHA shall also submit a quarterly narrative report describing the current status of the work activities in the revitalization plan, including community service or supportive services set forth on Form HUD–52825, Comprehensive Assessment/Program Budget. In this narrative, the PHA shall describe any actions taken during the quarter towards accomplishment of its stated goals and explain any lack of progress or actions.

V. Access by HUD

For the purpose of audit, examination, monitoring, and evaluation each recipient shall give HUD (including any duly authorized representatives and the Inspector General) access to any books, documents, papers, and records of the recipient that are pertinent to assistance received under this notice, including all records required to be kept by paragraph (1) of this section.

W. Environmental Requirements

Before HUD approves applications under this demonstration, HUD will assess the environmental effects of each application in accordance with the provisions of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) (NEPA) and HUD's implementation regulations at 24 CFR part 50 and the compliance requirements of the related environmental laws and authorities listed in 24 CFR 50.4.

Other Matters

Information Collections

The estimated information collection requirements contained in this NOFA have been sent to the Office of Management and Budget. Information on these requirements is provided as follows:

URBAN REVITALIZATION NOFA—BURDEN HOURS

Submission requirements	No. of respondents	No. responses per respondent	Total annual responses	Hours per response	Total hours
Planning Grant:					
Application (Sec. II(b))	50	1	50	40	2,000
Resident Consultation (Sec. II(d)(7))	50	1	50	10	500
Reporting Requirements (Sec. IV(s)(2))	9	4	36	4	144
Recordkeeping (Sec. IV(s)(1))	9	1	9	1	9
Implementation Grant:					
Application (Sec. III(c))	50	1	50	275	13,750
Resident Consultation (Sec. II(d)(7))	50	1	50	20	1,000
Reporting Requirements (Sec. IV(s)(2))	6	4	24	10	240
Recordkeeping (Sec. IV(s)(1))	6	1	6	2	12
Total Burden					17,655

Environmental Review

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969. The Finding is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays in the Office of the Rules Docket Clerk, Office of the General Counsel, Department of Housing and Urban Development, room 10276, 451 7th St., SW., Washington, DC 20410.

Impact on the Family

The General Counsel, as the designated official under Executive Order 12606, The Family, has determined that the provisions of this NOFA do not have a potential significant impact on the formation, maintenance, and general well-being of the family. To the extent that there is an impact on the family, revitalization of severely distressed public housing developments under the demonstration can be expected to support family values by enabling low-income families to live in decent, safe, and sanitary housing.

Federalism Impact

The General Counsel has also determined, as the Designated Official for HUD under section 6(a) of Executive Order 12612, Federalism, that the provisions of this NOFA are closely based on statutory requirements and impose no significant additional burdens on States or other public bodies. The notice does not affect the relationship between the Federal government and the States and other public bodies or the distribution of power and responsibilities among various levels of government. Therefore, the policy is not subject to review under Executive Order 12612.

Dated: December 30, 1992.

Michael B. Janis,

General Deputy Assistant Secretary for Public and Indian Housing.

Appendix A

Forty Most Populous U.S. Cities

Cities

New York, NY
Los Angeles, CA
Chicago, IL
Houston, TX
Philadelphia, PA
San Diego, CA
Detroit, MI

Dallas, TX
Phoenix, AZ
San Antonio, TX
San Jose, CA
Baltimore, MD
Indianapolis, IN
San Francisco, CA
Jacksonville, FL
Columbus, OH
Milwaukee, WI
Memphis, TN
Washington, DC
Boston, MA
Seattle, WA
El Paso, TX
Cleveland, OH
New Orleans, LA
Nashville-Davidson, TN
Denver, CO
Austin, TX
Fort Worth, TX
Oklahoma City, OK
Portland, OR
Kansas City, MO
Long Beach, CA
Tucson, AZ
St. Louis, MO
Charlotte, NC
Atlanta, GA
Virginia Beach, VA
Albuquerque, NM
Oakland, CA
Pittsburgh, PA

PHAS on the Troubled PHA List as of 3/31/92

Boston, MA
Bridgeport, CT
New Haven, CT
Camden, NJ
Newark, NJ
D.C. Department of Public and Assisted Housing
Philadelphia, PA
Chester, PA
Atlanta, GA
Birmingham, AL
Jacksonville, FL
Puerto Rico
Virgin Islands
Cuyahoga, OH
Detroit, MI
Indianapolis, IN
Lucas County, OH
East St. Louis, IL
Chicago, IL
Springfield, IL
New Orleans, LA
Kansas City, MO
Los Angeles, CA
San Francisco, CA

Appendix B

Program Requirements for Community Service Component

Background

The legislation creating the HUD Urban Revitalization Demonstration Program requires that each plan submitted for funding include a community service component to be approved by the Commission on National and Community Service (CNCS). By requiring a community service component in each plan for urban revitalization, the legislation presents HUD and CNCS with a unique opportunity to create a strong and lasting union between physical urban revitalization and community service. Physical urban revitalization cannot be sustained without a revitalization of the spirit of the people of the community such that the people begin to view themselves as collective owners of the community. A sense of collective ownership of the community engenders not only concern for people who live in the community but also caring for and pride in the physical structures in the community. Through community service, the sense of collective ownership of the community can be developed, thereby revitalizing the spirit of the people of the community. Thus, beyond the bricks and mortar of the physical structures, community service can be the glue that holds an urban revitalization program together, sustains it, and nourishes it.

To assist applicants for urban revitalization funds in designing their community service programs, CNCS has set forth below a definition for "community service program" followed by guidance on program requirements, allowable program activities, application content, selection criteria and ranking factors.

I. Definition

For purposes of the HUD Urban Revitalization Demonstration Program, "community service program" is defined as:

A program organized, administered, overseen or funded by a public housing authority or its designated representative, engaging individuals in meaningful service on a volunteer basis or through limited stipends to address unmet human, environmental, educational, and/or public safety needs through youth service and conservation corps, residents' associations, community-based organizations, K–12 schools, institutions of higher education, churches or other religious entities (but see paragraph II.(13) below) and other such similar organizations.

II. Program Requirements

(1) An applicant that receives assistance under the revitalization program may administer the community service program or may contract with a nonprofit organization or a unit of state or local government, subject to the limitations contained in paragraph 13 below to administer such program.

(2) Each applicant intending to administer a community service program itself, and any organization contracted to administer a community service program by an applicant shall secure the services of a community service coordinator who will have primary responsibility for the design and administration of the applicant's community service program.

(3) In designing a community service program, each applicant shall solicit input from residents of the development to be revitalized—particularly youth—community-based organizations, local businesses, school representatives, representatives of religious organizations, and other interested parties. In order to maximize this level of input, each applicant is encouraged to establish a Community Service Advisory Board comprised of the parties listed in the preceding sentence.

(4) With the assistance of the parties listed in paragraph (3), each applicant shall determine the human, environmental, educational, and/or public safety needs of the housing development to be revitalized as well as the surrounding neighborhood. An applicant may also determine the human, environmental, educational, and/or public safety needs of the city at large.

(5) In light of the determination required in paragraph (4), and in conjunction with the parties listed in paragraph (3), each applicant shall devise strategies or service opportunities for addressing the greatest needs identified and provide a justification for choosing those particular strategies.

(6) Programs may, but are not required to provide, in-service stipends or post-service benefits for participants. If post-service benefits are provided, they shall only be paid at the end of the term of service and shall only be used for education, training, or apprenticeships. In-service stipends and post-service benefits are subject to the following limitations:

(a) *Full-time service.* (i) In-service stipends shall not exceed 100 percent of the poverty line for a family of two (as defined in 42 USC section 9902(2)); and

(ii) Post-service benefits shall not exceed $100 per week of service or $5,000 per year of service, whichever is less.

(b) *Part-time service.* (i) In-service stipends shall not exceed an amount equal to a share of such stipend offered to full-time participant under paragraph (a)(i) above, that has been prorated according to the number of hours such part-time participant serves in the program.

(ii) Post-service benefits shall not exceed an amount equal to a share of

such post-service benefit offered to a full-time participant under paragraph (a)(ii) above, that has been prorated according to the number of hours worked per week of service or $2000 per year of service, whichever is less.

(c) A participant in a community service program who receives an in-service stipend and/or post-service benefit shall not be considered a Federal employee and shall not be subject to the provisions of law relating to Federal employment.

(7) Each applicant shall give preference for participation in service opportunities included in the community service program to residents of the housing development to be revitalized.

(8) Each community service program shall be for a term of no less than the term of the revitalization project. Each applicant shall exercise best efforts to continue the community service plan beyond the term of the revitalization project.

(9) Each applicant shall collect such data as the Commission on National and Community Service (CNCS) directs to enable CNCS to conduct an evaluation of the community service program.

(10) To reflect the importance of the community service component of each application, we recommend that each applicant use between 7 percent and 10 percent of the funds made available under the revitalization program for its community service program. Of the amount of funds reserved for the community service program:

(a) No more than 10 percent may be expended for administrative expenses related to such program; and

(b) No more than 10 percent may be expended for the purchase of major capital equipment related to such program.

(11) Prior to the placement of a participant in a service opportunity, the applicant shall consult with any local labor organization representing employees in the area who are engaged in the same or similar work as that proposed to be carried out under the community service program.

(12) Each applicant shall ensure that individuals do not drop out of school for the purpose of participating in the community service program.

(13) Applicants shall not contract with any of the following organizations to administer or carry out, in whole or in part, any community service program funded under the demonstration program, neither may any organization selected to carry out service activities use the funds provided to conduct any of the types of activities carried out by any of the organizations listed below:

(a) Business organized for profit;

(b) Labor union;

(c) Partisan political organization;

(d) Organization engaged in religious activities, unless such activities do not involve the use of funds provided under the demonstration program by program participants and program staff to give religious instruction, conduct worship services, or engage in any form of proselytization; or

(e) Domestic or personal service company or organization.

(14) Participants in the community service program shall be citizens or nationals of the United States or lawful permanent resident aliens of the United States.

(15) *Supplementation, nonduplication, and nondisplacement*—(a) *Supplementation.* (i) Applicants are advised that funds received for the community service program are to be used only to supplement, not supplant, State and local public funds expended for services of the type assisted under this grant in the previous fiscal year.

(ii) Paragraph (i) of this section shall be satisfied, with respect to a particular program, if the aggregate expenditure for such program for the fiscal year in which services are to be provided will not be less than the aggregate expenditure for such program in the previous fiscal year, excluding the amount of Federal assistance provided and any other amounts used to pay the remainder of the costs of programs assisted under this grant.

(b) *Nonduplication.* (i) In general, funds may be used only for a program that does not duplicate, and is in addition to, an activity performed by paid employees in the locality being served by the program; this requirement shall not be construed to bar the replication of an exemplary volunteer or community service program; and

(ii) Funds made available under this grant for the community service program shall not be provided to a private nonprofit entity to conduct activities that are the same or substantially equivalent to activities provided by a State or local government agency that such entity resides in, unless the requirements of paragraph (c) of this section are met.

(c) *Nondisplacement.* (i) An employer shall not displace an employee or position, including partial displacement such as reduction in hours, wages, or employment benefits, as a result of the assistance used by the employer of a participant in a program funded under this grant.

(ii) A service opportunity may not infringe in any manner on the promotional opportunity of an employed individual.

(iii) A participant in a program receiving assistance under this grant shall not perform any services or duties or engage in activities that would otherwise be performed by an employee as part of the assigned duties of such employee.

(iv) Services may not be performed that would supplant the hiring of employed workers or would otherwise be performed by an employee, including an employed worker who recently resigned or was discharged; an employee who is subject to a reduction in force; an employee who is on leave (terminal, temporary, vacation, emergency, or sick); or an employee who is on strike or who is being locked out.

III. Allowable Program Activities

(1) An applicant's community service program shall consist of any activities that directly address the unmet needs identified through the determination required in paragraph (4) above, including, but not limited to, crime prevention, victim assistance, drug abatement, after school programs, tutoring/mentoring programs, community gardens, day care for children and elderly, housing rehabilitation, and community health centers.

(2) Applicants are encouraged to develop programs which combine support services (as defined in section III.A.2.b of this notice) and community service. For example, an applicant may support a youth corps as a means of involving youth in meaningful community service while at the same time such youth can benefit from the education and job training service provided by the youth corps.

(3) Applicants are encouraged to develop service opportunities in connection with the physical revitalization plan. For example, program participants could be involved in rehabilitation activities, planting community gardens, or painting murals.

IV. Application Content

The community service program component of each application shall include:

(1) A description of the objectives of the program;

(2) The experience, accomplishments, and qualifications of the community service coordinator, particularly his/her community service experience.

(3) For a public housing agency that contracts with another organization to administer the community service program, a description of that

organization's capacity to administer such program, including the amount and quality of staff time committed to the program, and experience in the area of community service;

(4) The manner in which the program will be coordinated with and build upon existing community service programs;

(5) The process for soliciting community input—particularly from youth—in the planning of the program;

(6) A description of youth involvement in the operation of the program, including leadership roles;

(7) The process for determining the human, environmental, educational and/or public safety needs of the housing development to be revitalized and the findings of such determination;

(8) The service opportunities proposed and how those opportunities will address unmet needs;

(9) The particular target group, if any, of the program, e.g., youth, the elderly. If any particular group is targeted either as providers of service or receivers of service, provide justification for targeting such group;

(10) A plan for recruiting participants for service opportunities;

(11) A plan for placing participants in service opportunities and preparing participants for their placements;

(12) An estimate of the number of participants expected to be involved in the program;

(13) A discussion of whether participants will serve on a volunteer basis of whether some or all will receive in-service stipends and/or post service monetary benefits out of grant proceeds. If stipends and/or post-service benefits will be paid, describe how amounts will be determined;

(14) A discussion of whether the program will offer full-time and/or part-time service opportunities;

(15) A discussion of efforts to create service opportunities that place residents in locations in the community or city at large;

(16) Any efforts to involve non-residents from the surrounding neighborhood or the city at large as co-providers of service with residents of the development to be revitalized;

(17) The extent to which the community service program will be combined with supportive services, and describe such services;

(18) A budget accompanied by a narrative setting forth the grant amounts to be expended in the administration (and, where applicable, the operation) of a community service program.

(19) Such other information as CNCS shall require.

V. Review and Approval

The community service component of each application must be reviewed and approved by the Commission on National and Community Service prior to any final funding determinations.

VI. Selection Criteria

In approving the community service components of applications for funding, CNCS will use the following criteria and ranking factors:

(1) Quality based on:

(a) The program's ability to offer valuable services in the areas where they are needed most and where programs do not exist or where existing service opportunities are too limited to meet community needs;

(b) The program's ability to involve participants—particularly youth—in the design and operation of the program;

(c) The program's ability to involve individuals from diverse backgrounds (including diversity of gender, race, ethnic background, economic background, educational background, age, physical ability) who will serve together;

(d) The leadership and management, as measured by the qualifications of the principal leaders of the program; and

(e) The extent to which the applicant proposes specific and concrete plans for achieving its stated objectives.

(2) Cost-effectiveness based on the reasonableness of the budget request relative to the perceived impact of the proposed activities.

(3) Sustainability based on:

(a) Strong and broad-based community support for and involvement in the program; and

(b) Evidence that best efforts will be made to obtain the financial resources necessary to continue the program beyond the term of the revitalization project.

(4) Innovation based on the ability of the program to advance knowledge about creative and effective community service.

(5) Replicability based on the degree to which program design can be broadly applicable in areas beyond program location.

VII. Ranking Factors

The following point assignment will be used to rank the community service component of applications in accordance with the criteria listed above.

Quality	7.50 points.
Cost-effectiveness	2.25 points.
Sustainability	2.25 points.
Innovation	1.50 points.
Replicability	1.50 points.
Total Maximum Score	15 points.

[FR Doc. 93–82 Filed 1–4–93; 8:45 am]

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Part V

Department of Transportation

Coast Guard

33 CFR Parts 151, et al.
Requirements for Cargo Lightering Operations; Notice of Proposed Rulemaking

VOL 58 ISS 2 JA 5 1993 UMI

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 151, 155, and 156

[CGD 90–052]

RIN 2115–AD68

Requirements for Cargo Lightering Operations

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend the applicability sections of the safety and pollution prevention regulations issued under section 311(j) of the Federal Water Pollution Control Act (FWPCA) to make it clear that section 311(j) requirements apply to offshore lightering operations. The Coast Guard further proposes to establish what constitutes acceptable evidence of compliance with section 311(j). The purpose of the proposed amendments is to clarify the applicability of regulations issued under 311(j). The Coast Guard expects the amendments to codify existing practice and assist mariners in complying with the requirements of section 311(j).

DATES: Comments must be received on or before February 19, 1993.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council (G–LRA/3406) (CGD 90–052), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001, or may be delivered to room 3406 at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477. Comments on collection of information requirements must be mailed also to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of this docket, and will be available for inspection and copying in room 3406, U.S. Coast Guard Headquarters.

FOR FURTHER INFORMATION CONTACT: Ms. Joan Tilghman, Project Counsel and Project Manager, Oil Pollution Act (OPA 90) Staff (G–MS), (202) 267–6401, between 9 a.m. and 5:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD 90–052), the specific section of this proposal to which each comment applies, and the reason for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope. The Coast Guard will consider all comments received during the comment period.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Marine Safety Council at the address listed under "ADDRESSES." If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the Federal Register.

Drafting Information

The principal person involved in drafting this document is Ms. Joan Tilghman, Project Counsel and Project Manager.

Background and Purpose

Even prior to the Oil Pollution Act of 1990 (OPA 90), the Coast Guard had the authority under 46 U.S.C. 3715(b) to regulate, in accordance with 46 U.S.C. 3715(a), lightering operations occurring in the marine environment involving oil or hazardous material, if the lightered cargo was destined for a port or place subject to the jurisdiction of the United States. Section 4115(d) of the Oil Pollution Act of 1990 (OPA 90) (Pub. L. 101–380), however, amended section 3715(a) and added three new requirements for these lightering operations. As amended, 46 U.S.C. 3715(a) requires the delivering and receiving lightering vessels to meet five conditions.

First, the transfer must be conducted consistent with regulations prescribed by the Secretary.

Second, at the time of transfer, both the delivering and receiving vessel must have on board a Certificate of Inspection or a Certificate of Compliance as would have been required under 46 U.S.C. 3710 or 3711, had the transfer taken place in a port or place subject to the jurisdiction of the United States.

Third, at the time of transfer, each vessel must have on board a Certificate of Financial Responsibility (COFR) as would have been required under section 1016 of OPA 90 (33 U.S.C. 2716), had the transfer taken place in a port or place subject to the jurisdiction of the United States.

Fourth, at the time of transfer, each vessel must have on board evidence that it is operating in compliance with section 311(j) of the FWPCA (33 U.S.C. 1321(j)). Section 311(j) requires the owner or operator of a tank vessel to prepare and submit an emergency response plan to the President. Also, the Coast Guard issues safety and pollution prevention regulations under authority of this provision.

Fifth, each vessel must operate in compliance with 46 U.S.C. 3703a concerning tank vessel construction standards. Section 3703a requires double hulls on newly built tankers, and sets out a phase-in schedule for implementing this requirement. A note to this section also directs the Coast Guard to establish interim measures that certain existing vessels must take to provide substantial protection to the environment.

The first two conditions predate the OPA 90 amendments, and the last three conditions reflect the new requirements added by OPA 90. Regulatory action to implement the COFR and double hull statutory provisions are the subjects of separate rulemaking projects.

The purpose of this rulemaking is to clarify the applicability provisions of the provisions of the pollution prevention regulations and to define what constitutes "evidence" that the vessel is operating in compliance with section 311(j) requirements.

In 1979, the Coast Guard issued a notice of proposed rulemaking (NPRM) to impose the same regulatory requirements on offshore lightering as those imposed on vessels and facilities engaged in similar operations in the navigable waters of the United States and the contiguous zone. (44 FR 31486, May 31, 1979.) The Coast Guard intended to make offshore lightering operations subject to then-existing safety and pollution prevention regulations for similar operations near shore and in ports. The 1979 NPRM set out personnel, operating, and notice requirements for offshore lightering, including a requirement for a transfer plan and a contingency plan.

Responding to comments on this proposal, the Coast Guard issued a supplemental notice of proposed rulemaking (SNPRM). (48 FR 40741, September 9, 1983.) In the SNPRM, the Coast Guard stated that decreases in the frequency of offshore lightering made the 1979 proposed regulations "too restrictive or inappropriate," and opted to "simplify" the NPRM.

The final rule, which was published March 26, 1984 (49 FR 11170), largely codified the SNPRM. It required both the delivering and receiving vessels

engaged in an offshore lightering operation where the lightered cargo was destined for a port or place subject to the jurisdiction of the United States, to have a valid Certificate of Inspection or, alternatively, either a Certificate of Compliance or a Tank Vessel Examination Letter (TVEL).

The preamble to the final rule stated that these regulations "are required by 46 U.S.C. 3715, and supported by the need to prevent substandard tank vessels from lightering beyond the contiguous zone." The Coast Guard's objective was to construct offshore lightering requirements "as simply as possible, without sacrificing essential pollution prevention requirements." The preamble further provided that the rulemaking was amended to apply to "vessels which engage in oil and other hazardous materials lightering in the marine environment."

Current pollution prevention regulations issued under section 311(j) of the FWPCA are found in 33 CFR part 151, Vessels Carrying Oil, Noxious Liquid Substances, Garbage and Municipal or Commercial Waste; part 153, Control of Pollution by Oil and Hazardous Substances, Discharge Removal; part 155, Oil or Hazardous Material Pollution Prevention Regulations for Vessels; part 156, Oil and Hazardous Material Transfer Operations; and part 157, Rules for the Protection of the Marine Environment Relating to Tank Vessels Carrying Oil in Bulk.

The existing applicability provisions in 33 CFR parts 151, 155, and 156 use ambiguous language regarding offshore lightering operations. It is clear that the lightering regulations were intended to so apply. Further, Coast Guard Marine Safety Officers currently apply pollution prevention operating regulations to offshore lightering through the TVEL and Certificate of Inspection requirements. As a condition of receiving and maintaining a valid TVEL required by 33 CFR 156.201(a)(2), a foreign flag vessel lightering offshore must meet applicable U.S. pollution prevention requirements. (See Volume II, Marine Safety Manual, Chapter 20, Section 20B). Similarly, a U.S. flag vessel must meet those requirements to receive and maintain the required Certificate of Inspection. (See 46 CFR chapter I, subchapter D).

Because OPA 90 amendments to 46 U.S.C. 3715(a) focused attention on offshore lightering again, and because the Coast Guard anticipates an overall increase in offshore lightering operations as oil imports from the Middle East increase [1], the Coast Guard proposes to clarify the applicability provisions and certain other provisions in 33 CFR parts 151, 155, and 156. The Coast Guard further proposes that the Declaration of Inspection required under 33 CFR 156.150 and an approved vessel response plan constitute acceptable "evidence" that a vessel meets the section 311(j) requirements.

Discussion of Proposed Amendments

First, the Coast Guard proposes amending 33 CFR 151.05 and 156.205 to incorporate the definition of "marine environment" stated in 46 U.S.C. 2101. This is a technical amendment to keep the wording of the regulations consistent with the wording of the recently amended statute.

Second, the Coast Guard is proposing to amend the applicability sections in 33 CFR parts 151, 155, and 156 to expressly state that vessels lightering in the marine environment must meet the conditions set out in 46 U.S.C. 3715(a) regarding operating requirements for lightering vessels.

Third, the Coast Guard proposes to amend 33 CFR 151.23 to reflect the requirement that vessels lightering in the marine environment under the conditions set out in 46 U.S.C. 3715(a) have on board the evidence of compliance with section 311(j) of FWPCA required by proposed 33 CFR 156.217. These vessels also must have a Certificate of Inspection, a Certificate of Compliance, or a Tank Vessel Examination Letter; and a Certificate of Financial Responsibility.

Fourth, under its authority in 46 U.S.C. 3715(b), the Coast Guard proposes to amend 33 CFR 156.215 to require that lightering vessels include the amount of cargo involved in the transfer in the prearrival notice to the Captain of the Port (COTP) nearest the lightering location or zone, prior to arrival in the lightering location or zone. The Coast Guard is proposing this change to alert COTPs to important risk factors associated with lightering operations so that the COTP can plan for emergency circumstances. This requirement should not add costs to lightering operations because operators already know the amount of cargo to be lightered as a planning matter.

Finally, the Coast Guard proposes adding a new § 156.217 to establish what documents constitute "evidence" that a vessel is complying with the section 311(j) requirements (including the requirement for a vessel response plan) and applicable regulations issued under the authority of section 311(j). This evidence will be in the form of the Declaration of Inspection (DOI) or Tank Vessel Examination Letter (TVEL), and an approved vessel response plan. (The vessel response plan requirements are the subject of a separate NPRM (CGD 91–034), published in the Federal Register at 57 FR 27514, on June 19, 1992).

Regulatory Evaluation

The Coast Guard has determined that this proposal is not major under Executive Order 12291. This proposal is not significant under the Department of Transportation Regulatory Policies and Procedures (DOT Order 2100.5) because it does not meet any of the criteria listed in paragraph 6(a)(2) of the Order. The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation is unnecessary.

Vessels currently lightering in the marine environment already are required by 33 CFR 156.210 to have a Certificate of Inspection or a Tank Vessel Examination Letter. To receive and maintain a valid COI or TVEL, vessels must be in compliance with 33 CFR parts 151, 155, and 156. Furthermore, because lightering vessels already must document, with a Declaration of Inspection, that they comply with operating requirements applicable to lightering, and because tank vessels will be required by a separate rulemaking to have a vessel response plan, the Coast Guard anticipates no new costs associated with showing evidence of compliance with section 311(j) of the FWPCA. Therefore, this proposal will not result in annual costs of $100 million or more; will have no significant adverse effects on competition, employment, or other aspects of the economy; and will not result in a major increase in costs and prices.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposal will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses which are not dominant in their field and which otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632). "Small entities" also includes small not-for-

[1] U.S. Congress. Office of Technology Assessment. Competition in Coastal Seas: An Evaluation of Foreign Maritime Activities in the 200 Mile EEZ, Background Paper. OTA–BP–O–55 (Washington, DC: United States Government Printing Office, July, 1989).

profit organizations and small governmental jurisdictions.

Because the Coast Guard expects no new costs to be associated with this rule, the Coast Guard anticipates the economic impact of this proposal to be minimal. Therefore, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposed rule contains a provision that would direct the master, owner, or agent of each vessel to be lightered to include a new piece of data in a report required under 33 CFR 156.215, Pre-arrival notices. This required report will be incorporated into an approved collection of information (OMB control number 2115–0539) that expires March 31, 1993. The proposed addition is minor, and is being included in a request to OMB for extension of the existing collection of information described above.

Federalism

The Coast Guard has analyzed this proposal in accordance with the principles and criteria contained in Executive Order 12612, and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This proposed rule would clarify that pollution prevention regulations do apply to vessels lightering in the marine environment when the cargo lightered is destined for a port or place subject to the jurisdiction of the United States. The Coast Guard intends these regulations to provide uniform, national standards for conducting lightering operations. These standards will be uniform throughout the marine environment.

Environmental Impact

The Coast Guard considered the environmental impact of this proposal and concluded that, under section 2.B.2 of Commandant Instruction M16475.1B, this proposal is categorically excluded from further environmental documentation. This proposal is not expected to result in significant impact on the quality of the human environment, as defined by the National Environmental Policy Act, because the proposed is administrative in nature. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under "ADDRESSES."

List of Subjects

33 CFR Part 151

Administrative practice and procedure, Oil pollution, Penalties, Reporting and recordkeeping requirements, Water pollution control.

33 CFR Part 155

Hazardous substances, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 156

Hazardous substances, Oil pollution, Reporting and recordkeeping requirements, Water pollution control.

For the reasons stated in the preamble, the Coast Guard proposes to amend 33 CFR parts 151, 155, and 156 as follows:

PART 151—VESSELS CARRYING OIL, NOXIOUS LIQUID SUBSTANCES, GARBAGE AND MUNICIPAL OR COMMERCIAL WASTE

1. The authority citation for subpart A of part 151 is revised or read as follows:

Authority: 33 U.S.C. 1321(j)(1)(C) and 1903(b); 46 U.S.C. 3715; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; 49 CFR 1.46.

2. Section 151.05 is amended by adding a new definition in alphabetical order to read as follows:

§ 151.05 Definitions.

* * * * *

Marine environment means—

(1) The navigable waters of the United States and the land and resources under those waters;

(2) The waters and fishery resources of an area over which the United States asserts exclusive fishery management authority;

(3) The seabed and subsoil of the Outer Continental Shelf of the United States, the resources of the Shelf, and the waters superadjacent to the Shelf; and

(4) The recreational, economic, and scenic values of the waters and resources referred to in paragraphs (1), (2), and (3) of this definition.

* * * * *

3. In § 151.09, paragraph (a) is revised to read as follows:

§ 151.09 Applicability.

(a) Except as provided in paragraph (b) of this section, §§ 151.09 through 151.25 apply to—

(1) Each ship that is operated under the authority of the United States and engages in international voyages;

(2) Each ship that is operated under the authority of the United States and is certificated for ocean service;

(3) Each ship that is operated under the authority of the United States and is certificated for coastwise service beyond 3 nautical miles from land;

(4) Each ship that is operated under the authority of the United States and operates at any time seaward of the outermost boundary of the territorial sea of the United States as defined in § 2.05–10 of this chapter;

(5) Each ship that is operated under the authority of a country other than the United States while in the navigable waters of the United States, or while at a port or terminal under the jurisdiction of the United States; or

(6) Each delivering and receiving ship engaged in a lightering operation in the marine environment when the oil or hazardous material lightered is destined for a port or place subject to the jurisdiction of the United States.

* * * * *

4. Section 151.23 is amended by redesigning existing paragraphs (b) and (c) as paragraphs (c) and (d), respectively, and by adding a new paragraph (b) to read as follows:

§ 151.23 Inspection for compliance and enforcement.

* * * * *

(b) While engaged in a lightering operation in the marine environment, a vessel is subject to inspection by the Coast Guard to determine if the vessel has on board—

(1) Evidence of compliance with section 311(j) of the Federal Water Pollution Control Act (33 U.S.C. 1321(j)) and applicable regulations issued under the authority of section 311(j), as required under § 156.217 of this chapter;

(2) A Certificate of Inspection, a Certificate of Compliance, or a Tank Vessel Examination Letter, as required under § 156.210 of this chapter; and

(3) A Certificate of Financial Responsibility as required under part 130 of this chapter.

* * * * *

5. In § 151.30, paragraph (a) is revised to read as follows:

§ 151.30 Applicability.

(a) Except as provided in paragraph (b) of this section, §§ 151.30 through 151.49 apply to—

(1) Each ship that is operated under the authority of the United States and engages in international voyages;

(2) Each ship that is operated under the authority of the United States and is certificated for ocean service;

(3) Each ship that is operated under the authority of the United States and is certificated for coastwise service beyond 3 nautical miles from land;

(4) Each ship that is operated under the authority of the United States and

operates at any time seaward of the outermost boundary of the territorial sea of the United States as defined in § 2.05–10 of this chapter;

(5) Each ship that is operated under the authority of a country other than the United States while in the navigable waters of the United States, or while at a port or terminal under the jurisdiction of the United States; or

(6) Each delivering and receiving ship engaged in a lightering operation in the marine environment when the oil or hazardous material lightered is destined for a port or place subject to the jurisdiction of the United States.

* * * * *

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

6. The authority citation for part 155 is revised to read as follows:

Authority: 33 U.S.C. 1231, 1321(j)(1)(C); 46 U.S.C. 3715; sec. 2, E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; 49 CFR 1.46. Sections 155.100 through 155.130, 155.350 through 155.400, 155.430, 155.440, and 155.470 also issued under 33 U.S.C. 1903(b). Sections 155.340 and 155.750(e) are issued under section 4110, Pub. L. 101–380, 104 Stat. 515.

7. In § 155.100, paragraph (a) is revised to read as follows:

§ 155.100 Applicability.

(a) Subject to the exceptions provided for in paragraph (b) of this section, this part applies to—

(1) Each ship that is operated under the authority of the United States, wherever located;

(2) Each ship that is operated under the authority of a country other than the United States while in the navigable waters of the United States, or while at a port or terminal under the jurisdiction of the United States; or

(3) Each delivering and receiving ship engaged in a lightering operation in the marine environment when the oil or hazardous material lightered is destined for a port or place subject to the jurisdiction of the United States.

* * * * *

PART 156—OIL AND HAZARDOUS MATERIAL TRANSFER OPERATIONS

8. The authority citation for part 156 is revised to read as follows:

Authority: 33 U.S.C. 1231, 1321(j)(1)(C) and (D); 46 U.S.C. 3715; sec. 2, E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; 49 CFR 1.46.

9. Section 156.100 is revised to read as follows:

§ 156.100 Applicability.

This subpart applies to the transfer of oil or hazardous material on the navigable waters, the contiguous zone, or in the marine environment of the United States to, from, or within each vessel with a capacity of 250 barrels or more; except that this subpart does not apply to transfer operations involving public vessels.

10. Section 156.200 is revised to read as follows:

§ 156.200 Applicability.

This subpart applies to each vessel to be lightered and the service vessel engaged in a lightering operation in the marine environment when the oil or hazardous material lightered is destined for a port or place subject to the jurisdiction of the United States. This subpart does not apply to lightering operations involving public vessels. These rules are in addition to the rules of subpart A of this part, as well as the rules in the applicable sections of parts 151, 153, 155, 156, and 157 of this chapter.

11. In paragraph (b) of § 156.205, the definition for "Marine environment" is revised to read as follows:

§ 156.205 Definitions.

* * * * *

(b) * * *

Marine environment means—

(1) The navigable waters of the United States and the land and resources under those waters;

(2) The waters and fishery resources of an area over which the United States asserts exclusive fishery management authority;

(3) The seabed and subsoil of the Outer Continental Shelf of the United States, the resources of the Shelf, and the waters superadjacent to the Shelf.

(4) The recreational, economic, and scenic values of the waters and resources referred to in paragraphs (1), (2), and (3) of this definition.

* * * * *

12. In § 156.215, paragraph (a)(3) is revised to read as follows:

§ 156.215 Pre-arrival notices.

(a) * * *

(3) The number of transfers expected and the amount of cargo expected to be transferred during each transfer;

* * * * *

13. A new § 156.217 is added to read as follows:

§ 156.217 Lightering.

(a) If in a lightering operation, a vessel delivers or receives oil or hazardous material in the marine environment, the receiving vessel may transfer that oil or hazardous material in a port or place subject to the jurisdiction of the United States only if—

(1) The transfer was in accordance with applicable regulations in parts 151, 153, 155, 156, and 157 of this chapter; and

(2) The delivering and receiving vessels have on board at the time of transfer, evidence that each vessel is operating in compliance with section 311(j) of the Federal Water Pollution Control Act (33 U.S.C. 1321(j)) and applicable regulations issued under the authority of section 311(j) in the form of a Declaration of Inspection as required by § 156.150 of this chapter and a vessel response plan approved under part 155 of this chapter.

Dated: December 29, 1992.

A.E. Henn,

Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 93–86 Filed 1–4–93; 8:45 am]

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40 CFR Part 2
Disclosure of Confidential Data; Interim Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 2

[FRL–4552–1]

Disclosure of Confidential Data to Authorized Representatives of the United States and to Potentially Responsible Parties

AGENCY: Environmental Protection Agency.

ACTION: Interim rule with request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is issuing interim regulations modifying certain of EPA's regulations at 40 CFR part 2, subpart B governing confidential business information. This rule updates statutory references to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) pursuant to changes made by the Superfund Amendments and Reauthorization Act of 1986, corrects erroneous citations to CERCLA and the Clean Air Act (CAA) in these regulations, authorizes disclosure of confidential data submitted by contractors, pursuant to CERCLA section 104, to authorized representatives of the United States and to potentially responsible parties (PRPs) in actions under CERCLA section 107 for recovery of EPA's response costs, and authorizes disclosure of confidential data to contractors of other Federal agencies.

DATES: This rule is effective January 5, 1993. Comments will be accepted until March 8, 1993.

ADDRESSES: Send or deliver written comments to Donald A. Sadowsky, Contracts, Information General Law Division (LE–132K), Office of General Counsel, Environmental Protection Agency, 401 M Street, SW., Washington, DC 24060.

FOR FURTHER INFORMATION CONTACT: Donald A. Sadowsky, Office of General Counsel. Telephone 202/260–5469.

SUPPLEMENTARY INFORMATION:

On May 20, 1975, EPA published in the **Federal Register** (40 FR 21987) a proposed rule concerning procedures for the treatment of confidential business information (CBI) submitted under various environmental statutes, including the Clean Air Act (CAA), 42 U.S.C. 7401 *et seq.* This rule was made final on September 1, 1976 (41 FR 36902), codified as 40 CFR part 2, subpart B.

On December 18, 1985, EPA published in the **Federal Register** (50 FR 51654) a rule establishing procedures for the treatment of confidential business information (CBI) submitted pursuant to section 104 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9604. This rule was codified as 40 CFR 2.310.

A. Information Collected Pursuant to Sections 115 and 211 of the Clean Air Act

EPA's special rules governing CBI submitted pursuant to the Clean Air Act are codified at 40 CFR 2.301. Paragraph (B)(6) of § 2.301 provides that § 2.301 does not apply to information obtained under section 115(j) or 211(b) of the Clean Air Act, 42 U.S.C. 7415(j) or 7545(b). Both statutory references are inappropriate, and paragraph (b)(6) will therefore be eliminated, for the following reasons.

First, section 115(j) is no longer a part of the Clean Air Act. Second, EPA's intent with respect to section 211 was to effectuate the section's limitation on CBI claims for results of health and safety tests on fuels and additives performed pursuant to section 211(b)(2)(A). However, 40 CFR 2.30(b)(6) as currently written exempts information submitted under any part of section 211(b) from § 2.301 coverage. EPA is hereby correcting the regulation by eliminating paragraph (b)(6) and modifying § 2.301(e) (Substantive Criteria for Use in Confidentiality Determinations) to make clear that section 211(b)(2)(A) information is not entitled to confidential treatment.

B. Disclosure to Contracts of Other Federal Agencies

Under sections 114, 208 and 307(a) of the Clean Air Act (42 U.S.C. 7414, 7542, and 7607), sections 308 and 509(a) of the Clean Water Act (33 U.S.C. 1318, and 1369(a)), 1445(d) of the Safe Drinking Water Act (42 U.S.C. 300j–4), sections 3001(b)(3)(B), 3007(b), and 9005(b) of the Solid Waste Disposal Act (42 U.S.C. 6921(b)(3)(B), 6927(b), and 6995(b)), and section 104(e)(7) of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9604(e)(7), EPA may disclose CBI to authorized representatives of the United States. Similarly, under section 10(e) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136h(e)) and section 14(a)(2) of the Toxic Substances Control Act (15 U.S.C. 2613(a)(2)) EPA may disclose CBI to contractors with the United States.

Although Congress did not require that contractors which are authorized representatives of the United States have a direct contractual relationship with EPA, the Agency so chose to limit its authority when it first proposed and promulgated regulations governing disclosure of CBI to contractors. See 40 FR 21990, 40 CFR 2.301(h)(2)(i). At the time it was not contemplated that there would be occasion to disclose CBI to contractors of other Federal agencies. (Special provision was later made in 40 CFR 2.306(j)(1) for disclosure to contractors of other agencies of CBI submitted pursuant to the Toxic Substances Control Act.)

However, the Agency may find it in the interests of the Government to enter into arrangements with another Federal agency where a contractor of that agency performs work to support the mission of EPA. Having clear authority to allow such access, EPA is hereby amending its regulations accordingly.

C. Information Obtained From Superfund Contractors

1. Applicability of 40 CFR 2.310

In the preamble to the rule promulgating 40 CFR 2.310, the Agency stated that § 2.310 was intended to be "applicable to information obtained under any provision of section 104 of (CERCLA)." 50 FR 51656. However, the rule as written did not apply to all information submitted under section 104. The rule applied "only to information provided to or obtained by EPA under section 104 of (CERCLA), 42 U.S.C. 9604, by or from any person who stores, treats, or disposes of hazardous wastes; or where necessary to ascertain facts not available at the facility where such hazardous substances are located, by or from any person who generates, transports, or otherwise handles or has handled hazardous substances." 40 CFR 2.310(b).

Section 2.310 as written does not cover contractor information submitted pursuant to section 104. Section 104(a)(1) authorizes EPA, *inter alia*, to respond to hazardous conditions at Superfund sites. In particular, the Government "is authorized to act, consistent with the national contingency plan, to remove or arrange for the removal of, and provide for remedial action relating to" hazardous substances at a site. CERCLA section 104(a)(1), 42 U.S.C. 9603(a)(1). The language in section 104(a)(1) ("remove or arrange for the removal"; "provide for remedial action") serves as authority for the Agency to enter into contracts for removal and remediation.

"Removal" is defined in CERCLA section 101(23) to include not only "the cleanup or removal of released hazardous substances" but also "such

actions as may be necessary to monitor, assess, and evaluate the release or threat of release of hazardous substances." "Remedial action" is defined in section 101(24) to include "those actions consistent with the permanent remedy taken" and "any monitoring reasonably required to assure that such actions protect the public health and welfare and the environment." Moreover, removal and remedial actions include related enforcement activities. CERCLA section 101(25). Thus, "removal" and "remedial action" are defined broadly enough to include all contracts at issue, and information submitted to EPA pursuant to these contracts constitutes information submitted under CERCLA section 104.

Therefore EPA is today modifying 40 CFR 2.310 to effectuate the original intent of the Agency, i.e., to make the rule applicable to all information submitted under CERCLA section 104.

2. Disclosure to Authorized Representatives

Information obtained by the Agency under CERCLA section 104 may be disclosed to authorized representatives of the United States. CERCLA section 104(e)(7). EPA regulations at 40 CFR 2.310(h) define authorized representative to include Agency contractors and subcontractors. Thus, this amendment to 40 CFR 2.310 makes clear that confidential information from a Superfund contractor may be disclosed to another Agency contractor.

EPA recognizes that information submitted to the Agency by its contractors can be of potential value to other businesses competing for contracts with EPA, other agencies, or the private sector. Contractors typically assert that information pertaining to costs such as labor, overhead and profit rates are entitled to confidential treatment because release of this information to the public would allow competitors to underbid that contractor in future procurements. EPA has generally accorded confidential treatment to these rates where public release of the information is likely to cause substantial competitive harm.

The Agency does not intend to disclose to the public sensitive information obtained from a contractor. However, the Agency needs to utilize authorized representatives to support various functions involved in the administration of CERCLA and which involve access to contractor CBI, such as records management, data processing, and cost recovery.

By disclosing to an authorized representative information obtained from a Superfund contractor, EPA does not compromise the confidentiality of the information. 40 CFR 2.310(h) provides procedures for the protection of confidential data submitted under CERCLA section 104. These include a bar from disclosure of confidential information to a contractor or subcontractor unless the contract or subcontract provides that:

a. The employees of the contractor or subcontractor shall use the information only for the purpose of carrying out the work required by the contract or subcontract;

b. The employees of the contractor or subcontractor shall refrain from disclosing the information to anyone other than EPA (or another Federal agency, as appropriate) without prior written approval of each affected business or of an EPA legal office;

c. The employees of the contractor or subcontractor shall return to EPA (or another Federal agency, as appropriate) all copies of such information (and any abstracts or extracts therefrom) upon request by the EPA program office, whenever the information is no longer required for performance of the work required under the contract or subcontract, or upon completion of the contract or subcontract;

d. The contractor or subcontractor shall obtain a written agreement to honor such terms of the contract from each of the contractor's or subcontractor's employees who will have access to such information, before such employee is allowed access; and

e. The contractor or subcontractor acknowledges and agrees that the contract or subcontract provisions concerning the use and disclosure of business information supplied to the contractor or subcontractor by EPA (or another Federal agency, as appropriate) under the contract or subcontract are included for the benefit of, and shall be enforceable by, both the United States Government and any affected business having an interest in information concerning the business.

In addition, before such disclosure is made, the Agency must notify the submitter (either by letter or via notice in the **Federal Register** of the information to be disclosed, the identity of the contractor or subcontractor, and the purposes to be served by the disclosure, and give the submitter an opportunity to comment on the disclosure. Moreover, because Superfund contractor information is submitted pursuant to CERCLA Section 104, persons outside the Federal Government who improperly disclose the information are subject to criminal prosecution under Section 104(e)(7)(B).

This rule is by its nature retroactive, in that it authorizes disclosure of information already obtained by EPA. The retroactivity is inherent in the authority granted by Section 104 to disclose information to authorized representatives and pursuant to a proceeding. Moreover, the public interest in efficient operation of the Agency weighs in favor of such a result, while the restrictions on further use and disclosure of the information discussed above ensure that there is no adverse effect on persons who have submitted confidential information to EPA.

D. Disclosure to Potentially Responsible Parties

CERCLA gives the United States authority to respond directly to releases or threats of releases of hazardous substances into the environment or releases or threats of releases into the environment of any pollutant or contaminant which may present an imminent and substantial danger to the public health or welfare. CERCLA also authorizes EPA to recover response action costs from those responsible for releases or threats of releases of hazardous substances. Voluntary settlement of cost recovery cases with responsible parties under CERCLA enables the United States to recover the costs of response actions without engaging in lengthy and costly litigation.

Over the years, EPA has encountered a serious obstacle in attempting to release some of its contractor documents to responsible parties to encourage and expedite settlements. As discussed above, these documents may contain information that the contractors claim is entitled to confidential treatment.

Currently, before EPA releases to responsible parties information that may be entitled to confidential treatment, EPA seeks to obtain the consent of the submitter of the information pursuant to 40 CFR 2.209(f). EPA's experience is that it is extremely time-consuming and occasionally impossible to obtain the consent from its contractors to release their CBI to responsible parties in pre-litigation negotiations or under a protective order in litigation. It has taken as long as 18 months at one site for EPA to obtain the consent of all of its contractors to disclose information under a protective order and over a year at several other sites. The primary reason for this delay results from each contractor's desire to participate in preparing the scope of the protective order. With 35 or more contractors at a site, negotiating confidentiality agreements, stipulations, and protective orders has become a major impediment

in obtaining expeditious cost recovery settlements.

This regulation amends 40 CFR 2.310 to provide for limited releases of CBI to responsible parties under a contractual agreement in pre-litigation negotiations and under a stipulation and protective order during litigation. Generally, EPA would make a limited release to responsible parties of all CBI information maintained by EPA pursuant to 40 CFR 300.160 of the national contingency plan. This limited disclosure would be made without the prior consent of the contractors and applies to documents submitted to EPA since the inception of the Superfund program in 1980.

The basis for this regulation is found in Section 104 of CERCLA, and promulgation of the regulation will assist EPA in implementing Sections 107 and 122 of the Act. Section 107 authorizes the recovery of federal costs expended on site cleanups financed by the Superfund. If the Agency elects to pursue these costs through litigation, EPA (through the Department of Justice) brings lawsuits against responsible parties in order to recover costs it has expended in cleaning up a site. In such lawsuits, responsible parties frequently make discovery requests for information which may be entitled to confidential treatment. EPA may ultimately be required be court order to release cost documents containing such information in response to these discovery requests. CBI, although not privileged under the Federal Rules of Civil Procedure, is routinely granted protection from unlimited disclosure through the use of a protective order. Accordingly, EPA will seek the entry of a stipulation and protective order before releasing CBI to defendants. (See Appendix B for a Model Stipulation and Protective Order).

EPA requires the discretion to make a limited release of CBI to responsible parties in pre-litigation negotiations, in order to recover the costs of site cleanups more efficiently and expeditiously. Such a release clearly furthers the goal, envisioned by Congress in section 107, of a Superfund replenished through successful cost recoveries.

Section 122 encourages the Agency to facilitate settlements where possible. EPA believes that the limited release of cost information, including information potentially entitled to confidential treatment, would greatly facilitate settlements in cost recovery cases. The regulation clarifies EPA's authority to release CBI during pre-litigation negotiations under a contractual agreement, and during litigation through a stipulation and protective order. In doing so, the Agency will continue to afford protection to its contractors' information while at the same time facilitating settlements and minimizing litigation.

Congress recognized in section 104 that some trade secret information might need to be released "when relevant in any proceeding under this chapter." 42 U.S.C. 9604(e)(7)(A). Congress was willing to allow for the release of trade secret and confidential business information where the release would advance the purposes of the statute. Neither the statute nor the legislative history of CERCLA define "proceeding." A definition of "proceeding" can be found in the Administrative Procedure Act (APA), 5 U.S.C. 551.

The APA, 5 U.S.C. 551(12), defines "agency proceeding" as "an agency process as defined by paragraphs (5) [rulemaking], (7) [adjudication], and (9) [licensing] of this section." Paragraph (7) defines "adjudication" as an "agency process for the formulation of an order." "Order" is defined in paragraph (6) as "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing." In order words, an agency process which results in a final agency disposition may be considered adjudication, and thus a proceeding, under the APA.

Settlements under CERCLA section 107 or 122 fall into this definition of adjudication. The Agency negotiates a settlement with a PRP, and, after notice and comment, files the agreement in district court as a consent decree. CERCLA section 122. EPA thus reaches a disposition as to the appropriate liability of the PRP, and finalizes it through notice and comment and through entry as a consent decree, enforceable by the court against all parties.

The regulation published today amends the definition of "proceeding" in 40 CFR 2.310(a) to authorize EPA to release potential CBI to appropriate persons that EPA has determined to be PRPs at a particular site. This would not be a public release of information. The regulation allows a limited release of confidential business information to a discrete group with a need to review the information if EPA believes the release would encourage and expedite settlement. This limited disclosure would not subject this information to release under the Freedom of Information Act (FOIA), 5 U.S.C. 552. EPA would continue to deny all FOIA requests for information in cost documents that EPA determines to be CBI pursuant to exemption 4 of FOIA.

EPA believes that the use of contractual agreements and protective orders would maintain the confidential nature of the information and adequately protect it from improper release and misuse. Courts routinely afford this type of protection in other contexts and find it to be sufficiently protective. In addition, as noted above, because Superfund contractor information is submitted pursuant to CERCLA section 104, persons outside the Federal Government who improperly disclose the information are subject to criminal prosecution under section 104(e)(7)(B). (Federal employees are similarly subject to the Trade Secrets Act, 18 U.S.C. 1905.) Absent the applicability of a privilege or other litigation consideration to the disclosure, EPA believes that a limited release is necessary in order to fulfill its responsibility to expeditiously recover the costs of site cleanup. See section B., above, for a discussion of retroactivity.

The regulation does not address the release of information subject to the Privacy Act of 1974, 5 U.S.C. 552(a). EPA regulations at 40 CFR part 16 govern information that is subject to the Privacy Act and Part 16 would not be affected by the proposal.

Appendices to the preamble of today's rule set forth model documents, for illustrative purposes, that provide for the limited disclosure of certain business information that may be entitled to confidential treatment. They detail the protections EPA contemplates providing to contractors' CBI.

If a case has not been filed in federal district court, the "Agreement Regarding Confidentiality of Information" would apply (Appendix A). This document would also be appropriate for use in negotiations leading to administrative settlements with responsible parties. If an action has been filed in federal District Court, the government would seek entry by the court of the "Stipulation and Protective Order" (Appendix B). In this document defendants would stipulate that the documents released to them may contain information entitled to confidential treatment and agree to specified procedures to maintain confidentiality.

All documents released under the agreement or order would be used only in preparation for either settlement negotiations or trial. All persons to whom the information is subsequently disclosed would have to agree to be bound by the terms of the agreement or order by signing the "Confidentiality Agreement" annexed to the above

agreement and protective order. EPA and the submitter of the information would receive copies of all executed "Confidentiality Agreements" five days prior to the disclosure.

E. Statutory References to CERCLA Section 104

The Superfund Amendments and Reauthorization Act of 1986 (SARA) added several paragraphs to section 104 of CERCLA which pertain to information gathering. Subparagraph (e)(2) of section 104 was redesignated by SARA as subparagraph (e)(7). This rule amends the statutory references in 40 CFR 2.310 accordingly.

F. Correction of Citation to 40 CFR 2.310

40 CFR 2.211 requires contractors who are furnished business information by EPA to properly safeguard such information. Paragraph (d) of 2.211 erroneously cites § 2.310(i) as the provision authorizing disclosure to authorized representatives of information collected pursuant to CERCLA section 104; the correct reference is to § 2.310(h). This regulation corrects that reference.

Waiver of Notice of Proposed Rulemaking and Delay in Effective Date

With respect to the changes affecting CERCLA CBI and CAA CBI, this rule is interpretive in nature, as opposed to legislative. As such it may be promulgated without prior opportunity for notice and comment, pursuant to the Administrative Procedures Act, 5 U.S.C. 553(b)(A), and may be made effective immediately, without a 30-day delay, pursuant to section 553(d)(2). With respect to information disclosed to contractors of other Federal agencies, I find that prior notice is unnecessary and that good cause exists for making the rule effective immediately, for the following reason: contractors of other Federal agencies will be required by regulation and contract to have the same protections against unauthorized use and disclosure of CBI as are EPA contractors, so that the rights of CBI submitters are unaffected.

Executive Order 12291

Executive Order (E.O.) 12291 requires the preparation of a regulatory impact analysis for major rules, defined by the order as those likely to result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic industries; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

EPA has determined that this regulation does not meet the definition of a major rule under E.O. 12291 and has therefore not prepared a regulatory impact analysis.

Paperwork Reduction Act

Information collection requirements in a rule must be submitted for approval to the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* No reporting or recordkeeping requirements are included as part of this regulation. Therefore, no Information Collection Request document has been prepared.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule authorizes the disclosure to authorized representatives of the United States of confidential information and disclosure pursuant to a proceeding. The persons receiving the confidential information are bound by agreement, court order, or criminal statute not to disclose the information except where authorized or to use the information for unauthorized purposes. These restrictions ensure that such disclosure does not affect the competitive position of the submitters of the information. Thus, there is no economic impact on small entities.

List of Subjects in 40 CFR Part 2

Administrative practice and procedure, Confidential business information, Courts, Freedom of information, Government employees.

Dated: December 23, 1992.

William K. Reilly,

Administrator.

Therefore EPA amends 40 CFR part 2 as follows:

PART 2—[AMENDED]

1. The authority citation for part 2 is revised to read as follows:

Authority: 5 U.S.C. 301, 552 (as amended), 553; secs. 114, 205, 208, 301, and 307, Clean Air Act, as amended (42 U.S.C. 7414, 7525, 7542, 7601, 7607); secs. 308, 501 and 509(a), Clean Water Act, as amended (33 U.S.C. 1318, 1361, 1369(a)); sec. 13, Noise Control Act of 1972 (42 U.S.C. 4912); secs. 1445 and 1450, Safe Drinking Water Act (42 U.S.C. 300j–4, 300j–9); secs. 2002, 3007, and 9005, Solid Waste Disposal Act, as amended (42 U.S.C. 6912, 6927, 6995); secs. 8(c), 11, and 14, Toxic Substances Control Act (15 U.S.C. 2607(c), 2610, 2613); secs. 10, 12, and 25, Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136h, 136j, 136w); sec. 408(f), Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 346(f)); secs. 104(f) and 108, Marine Protection Research and Sanctuaries Act of 1972 (33 U.S.C. 1414(f), 1418); secs. 104 and 115, Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (42 U.S.C. 9604 and 9615); sec. 505, Motor Vehicle Information and Cost Savings Act, as amended (15 U.S.C. 2005).

PART 2—PUBLIC INFORMATION

§ 2.211 [Amended]

2. In section 2.211(d), remove "contractor or subcontractor with EPA" and substitute "contractor or subcontractor with the United States Government".

3. In § 2.211(d) revise "2.310(i)" to read "2.310(h)".

4. Section 2.301(b)(6) is removed.

5 Section 2.301 is amended by revising the first sentence of paragraph (e); and by revising paragraphs (h)(2)(i), (h)(2)(ii)(A) and (h)(2)(ii)(C) to read as follows:

§ 2.301 Special rules governing certain information obtained under the Clean Air Act.

* * * * *

§ 2.208 [Amended]

(e) * * * Section 2.208 applied to information to which this section applies, except that information which is emission data, a standard or limitation, or is collected pursuant to section 211(b)(2)(A) of the Act is not eligible for confidential treat. * * *

* * * * *

(h) * * *

(2)(i) A person under contract or subcontract to the United States government to perform work in support of EPA in connection with the Act or regulations which implement the Act may be considered an authorized representative of the United States for purposes of this paragraph (h). Subject to the limitations in this paragraph (h)(2), information to which this section applies may be disclosed:

(A) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract; or

(B) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the

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information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary in order that the contractor or subcontractor may carry out the work required by the contract or subcontract.

(ii) * * *

(A) That the contractor or subcontractor and the contractor's or subcontractor's employees shall use the information only for the purpose of carrying out the work required by the contract or subcontract, shall refrain from disclosing the information to anyone other than EPA without the prior written approval of each affected business or of an EPA legal office and shall return to EPA all copies of the information (and any abstracts or extracts therefrom) upon request by the EPA program office, whenever the information is no longer required by the contractor or subcontractor for the performance of the work required under the contract or subcontract, or upon completion of the contract or subcontract (where the information was provided to the contractor or subcontractor by an agency other than EPA, the contractor may disclose or return the information to that agency);

(B) * * *

(C) That the contractor or subcontractor acknowledges and agrees that the contract or subcontract provisions concerning the use and disclosure of business information are included for the benefit of, and shall be enforceable by, both the United States government and any affected business having an interest in information concerning it supplied to the contractor or subcontractor by the United States government under the contract or subcontract.

* * * * *

6. Section 2.306 is amended by revising the second sentence of paragraph (j)(1); and by adding paragraphs (j)(1)(i) and (ii) to read as follows:

§ 2.306 Special rules governing certain information obtained under the Toxic Substances Control Act.

* * * * *

(j) * * * (1) * * * Subject to the limitations in this paragraph (j), information to which this section applies may be disclosed:

(i) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract; or

(ii) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract.

* * * * *

7. Section 2.310 is amended by revising the section heading; by revising paragraphs (a)(1), (a)(6), (b), (g)(1), (g)(3), (g)(4), (h)(1), and (h)(4); and by adding paragraphs (g)(5) and (g)(6), to read as follows:

§ 2.310 Special rules governing certain information obtained under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

(a) * * *

(1) *Act* means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, including amendments made by the Superfund Amendments and Reauthorization Act of 1986, 42 U.S.C. 9601, et seq.

* * * * *

(6) *Proceeding* means any rulemaking or adjudication conducted by EPA under the Act or under regulations which implement the Act (including the issuance of administrative orders under section 106 of the Act and cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act), any cost recovery litigation under section 107 of the Act, or any administrative determination made under section 104 of the Act, but not including determinations under this subpart.

(b) *Applicability.* This section applies only to information provided to or obtained by EPA under section 104 of the Act, 42 U.S.C. 9604, by or from any person who stores, treats, or disposes of hazardous wastes; or where necessary to ascertain facts not available at the facility where such hazardous substances are located, by or from any person who generates, transports, or otherwise handles or has handled hazardous substances, or by or from any person who performs or supports removal or remedial actions pursuant to section 104(a) of the Act. Information will be considered to have been provided or obtained under section 104 of the Act if it was provided in response to a request from EPA or a representative of EPA made for any of the purposes stated in section 104, if it was provided pursuant to the terms of a contract, grant or other agreement to perform work pursuant to section 104, or if its submission could have been required under section 104, regardless of whether section 104 was cited as authority for any request for the information or whether the information was provided directly to EPA or through some third person.

* * * * *

(g)(1) Under section 104(e)(7)(A) of the Act (42 U.S.C. 9604(e)(7)(A)) any information to which this section applies may be disclosed by EPA because of the relevance of the information in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (g).

* * * * *

(3) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to the public, or to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(3). An EPA office proposing disclosure of information under this paragraph (g)(3) shall so notify the presiding officer in writing. Upon receipt of such a notification, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(3) has been proposed, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed under this paragraph (g)(3) only if, after consideration of any timely comments submitted by the business, the EPA office determines in writing that, for reasons directly associated with the conduct of the proceeding, the contemplated disclosure would serve the public interest, and the presiding officer determines in writing that the information is relevant to a matter in controversy in the proceeding. The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of

information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to the public or to one or more of the parties of record to the proceeding.

(4) In connection with any proceeding involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, except with respect to litigation conducted by a Federal court, information to which this section applies which may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon request of a party, under this paragraph (g)(4). A party of record seeking disclosure of information shall direct his request to the presiding officer. Upon receipt of such a request, the presiding officer shall notify each affected business that disclosure under this paragraph (g)(4) has been requested, and shall afford each such business a period for comment found by the presiding officer to be reasonable under the circumstances. Information may be disclosed to a party of record under this paragraph (g)(4) only if, after consideration of any timely comments submitted by the business, the presiding officer determines in writing that:

(i) The party of record has satisfactorily shown that with respect to a significant matter which is in controversy in the proceeding, the party's ability to participate effectively in the proceeding will be significantly impaired unless the information is disclosed to him; and

(ii) Any harm to an affected business that would result from the disclosure is likely to be outweighed by the benefit to the proceeding and the public interest that would result from the disclosure.

The presiding officer may condition disclosure of the information to a party of record on the making of such protective arrangements and commitments as he finds to be warranted. Disclosure to one or more parties of record, under protective arrangements or commitments, shall not, of itself, affect the eligibility of information for confidential treatment under the other provisions of this subpart. Any affected business shall be given at least 5 days notice by the presiding officer prior to making the information available to one or more of the parties of record to the proceeding.

(5) In connection with cost recovery pre-litigation settlement negotiations under sections 107 or 122 of the Act (42 U.S.C. 9607, 9622), any information to which this section applies that may be entitled to confidential treatment may be made available to potentially responsible parties pursuant to a contractual agreement to protect the information.

(6) In connection with any cost recovery proceeding under section 107 of the Act involving a decision by a presiding officer after an evidentiary or adjudicatory hearing, any information to which this section applies that may be entitled to confidential treatment may be made available to one or more parties of record to the proceeding, upon EPA's initiative, under this paragraph (g)(6). Such disclosure must be made pursuant to a stipulation and protective order signed by all parties to whom disclosure is made and by the presiding officer.

(h) * * * (1) Under section 104(e)(7) of the Act (42 U.S.C. 9604(e)(7)), EPA possesses authority to disclose to any authorized representative of the Untied States any information to which this section applies, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

* * * * *

(h)(4) At the time any information is furnished to a contractor, subcontractor, or state or local government under this paragraph (h), the EPA office furnishing the information to the contractor, subcontractor, or state or local government agency shall notify the contractor, subcontractor, or state or local government agency that the information may be entitled to confidential treatment and that any knowing and willful disclosure of the information may subject the contractor, subcontractor, or state or local government agency and its employees to penalties in section 104(e)(7)(B) of the Act (42 U.S.C. 9604(e)(7)(B)).

Note: The remainder of text will not appear in the Code of Federal Regulations.

Appendix A to Preamble—Agreement Regarding Confidentiality of Information and Annexes

These documents would provide for limited disclosure of certain business information pertaining to costs that may be entitled to confidential treatment pursuant to 40 CFR part 2 in the situation where the Department of Justice has not filed an action on behalf of EPA in a United States District Court. The documents would also apply in circumstances where EPA is negotiating with responsible parties outside of a litigation context using CERCLA section 122 administrative settlement authorities.

Agreement Regarding Confidentiality of Business Information

EPA and the potentially responsible party (PRP) hereby agree that settlement of the Government's claim concerning the _____ Superfund site will involve the production of documents which have been submitted to the United States Environmental Protection Agency (EPA) by various contractors (listed in Annex 1) (hereinafter "submitters") containing certain information which may be entitled to confidential treatment under 40 CFR part 2. Furthermore, the parties herein agree that the limitation on the disclosure of the documents subject to this Agreement is necessary in order to protect the interests of the submitters in the confidentiality of their business information.

The terms of the Agreement Regarding Confidentiality of Business Information (hereinafter "Agreement") are as follows:

1. EPA shall provide the document(s) containing information which may be entitled to confidential treatment to the PRP and such document(s) shall be handled in accordance with the terms of this Agreement.

2. As used in this Agreement, the term "confidential information" means trade secrets or commercial or financial information submitted by a person to EPA and which may be entitled to confidential treatment under 40 CFR part 2. This information has not been determined by EPA under 40 CFR part 2, subpart B not to be entitled to confidential treatment.

3. Any information to be produced by EPA pursuant to this Agreement shall be stamped conspicuously with the word "CONFIDENTIAL" by EPA on the top of each page of each document prior to production to the PRP. The transmittal of information designated as confidential shall be done by letter from EPA stating that the information designated as confidential is subject to this Agreement.

4. Information designated as confidential under this Agreement shall not be used or disclosed by the PRP or any other person subject to paragraph 7 below for any purpose other than the preparation for negotiation of a settlement.

5. The PRP and PRP's counsel who obtain information designated as confidential hereunder, and any nonparty subject to this Agreement, shall not disclose or permit disclosure of this information to any other person, including without limitation any officer, director, employee, agent, or representative of the PRP, the PRP's counsel, or any nonparty, except in the following circumstances:

a. Disclosure may be made to employees of the PRP or of the PRP's counsel who have responsibility for settlement negotiations involving the _____ Superfund site. Any employee to whom disclosure is made shall be advised of, and become subject to, the provisions of this Agreement prior to such disclosure by executing the Confidentiality Agreement (Annex 2) annexed hereto. Employees do not include persons, firms or corporations engaged by the PRP or the PRP's counsel on a contract basis, who shall be subject to the requirements of subparagraph (b) of this paragraph.

b. Disclosure may be made to consultants, witnesses, experts, or employees of experts

("Expert(s)") employed or otherwise engaged by the PRP or PRP's counsel to assist in the preparation for negotiations. Prior to disclosure to any Expert, the Expert must agree to be bound by the terms of this Agreement by executing the Confidentiality Agreement annexed hereto. A copy of each executed Confidentiality Agreement shall be furnished to EPA and submitter not less than five (5) business days prior to disclosure to the Expert of the business information.

6. The PRP, PRP's counsel and any other person subject to this Agreement who obtains information designated as confidential hereunder, shall take all necessary and appropriate measures to maintain the confidential nature of the information, shall share such information only with persons authorized to receive it pursuant to this Agreement, and shall retain the information in a secure manner. Except as provided in paragraph 5 above, no other person shall be permitted access to the information.

7. Any person who obtains access to information designated as confidential under this Agreement may make copies, duplicates, extracts, summaries, or descriptions of the information or any portion thereof *only* for the purpose of preparation for settlement negotiations for cost recovery at the_____Superfund site. All copies, duplicates, extracts, etc. shall be subject to terms of this Agreement to the same extent and manner as original documents.

8. Any unauthorized disclosure of information designated as confidential under this Agreement shall not result in a waiver of any submitter's claim of confidentiality.

9. Within 60 days after termination of negotiations, or as determined by EPA, any person who obtained information designated as confidential under this Agreement shall assemble and return such information to EPA, including all copies, extracts, summaries, or descriptions of the information or portions thereof. Such return shall be certified in writing by the person who obtained the information from EPA. All such information covered by this Agreement which constitutes the work product of counsel or the PRP shall be destroyed. However, if before the expiration of the 60 days the United States has filed in Federal court a cost recovery action for the _____ Superfund site, naming the PRP as a party, the PRP may retain the information. Such retention shall be governed by the provisions of this Agreement until entry of a protective order governing the information.

Dated: _____

_____

For the PRP

Dated: _____

_____

For EPA

Annex 1—List of Contractors

Annex 2—Business Information Confidentiality Agreement

The undersigned is currently working at _____ __ which is located at _____. During the past year the undersigned has been employed or other-wise engaged as a consultant or contractor by the following companies located at the corresponding address:

(1) _____

(2) _____

The undersigned hereby acknowledges that he/she has read the foregoing Agreement Regarding Confidentiality of Business Information ("Agreement") executed by the attorneys for the parties involved in settlement of the Government's claim concerning the _____Superfund site, understands the terms thereof, and agrees to be bound by such terms. The undersigned understands that disclosure of information which has been designated as confidential by the submitter of that information may cause substantial harm to the affected business' competitive position. Accordingly, among other responsibilities, the undersigned shall only share such information with persons specifically authorized to receive the information pursuant to the Agreement, shall retain the information in a secure manner, and shall use such information only for the purposes authorized by the Agreement. The undersigned understands that the pledge of confidentiality under this Confidentiality Agreement continues after any lawsuit associated with the settlement negotiations is over. Furthermore, the undersigned understands that a breach of the Agreement may subject him/her to civil claims for damages and to criminal prosecution under 42 U.S.C. 9604(e)(7)(B).

Dated: _____

Signed: _____

Appendix B to Preamble—Stipulation and Protective Order and Annexes

These documents would provide for limited disclosure of certain business information pertaining to costs that may be entitled to confidential treatment pursuant to 40 CFR part 2 after the Department of Justice has filed an action on behalf of EPA and the matter is subject to the jurisdiction of a United States District Court.

In The United States District Court

For the _____ District of _____.

United States of America, Plaintiff, v.

_____

Defendant. Civil Action No. _____.

Stipulation and Protective Order

Plaintiff, United States of America, on behalf of the United States Environmental Protection Agency (EPA), and Defendant *(name)* have hereby stipulated that discovery in this case will involve the production of documents which have been submitted to EPA by various contractors (listed in Annex 1) (hereinafter "submitter(s)") containing information which may be entitled to confidential treatment. In view of this stipulation, the Court finds that good cause exists for issuance of an order requiring limited disclosure of such information. Upon consideration of the joint motion for such an order filed by the parties hereto and pursuant to Rule 26(c), Federal Rules of Civil Procedure, *It is Hereby Ordered:*

1. Plaintiff shall submit the document(s) containing information which may be entitled to confidential treatment to the Defendant and such document(s) shall be handled in accordance with the terms of this Stipulation and Protective Order ("Protective Order")

2. As used in this Protective Order, the term "confidential information" means trade secrets or commercial or financial information submitted by a person to Plaintiff and which may be entitled to confidential treatment under 40 CFR part 2. This information has not been determined by Plaintiff under 40 CFR part 2, subpart B not to be entitled to confidential treatment.

3. Any information to be produced by Plaintiff pursuant to this Protective Order shall be stamped conspicuously with the word "CONFIDENTIAL" by the Plaintiff on the top of each page of each document prior to production to the Defendant. The transmittal of information designated as confidential shall be done by letter from the Plaintiff stating that the information designated as confidential is subject to this Protective Order.

4. Information designated as confidential under this Protective Order shall not be used or disclosed by the Defendant or any other person subject to Paragraph 7 below for any purpose other than the preparation for, and trial of, this action and any appeal therein.

5. The Defendant and Defendant's counsel who obtain information designated as confidential hereunder, and any nonparty subject to this Protective Order, shall not disclose or permit disclosure of this information to any other person, including without limitation any officer, director, employee, agent, or representative of Defendant, Defendant's counsel, or any nonparty, except in the following circumstances:

a. Disclosure may be made to employees of Defendant or of Defendant's counsel who have responsibility for the preparation and trial of this action or any appeal therein. Any employee to whom disclosure is made shall be advised of, and become subject to, the provisions of this Protective Order prior to such disclosure by executing the Confidentiality Agreement annexed hereto. Employees do not include persons, firms or corporations engaged by Defendant or Defendant's counsel on a contract basis, who shall be subject to the requirements of subparagraph (b) of this Paragraph.

b. Disclosure may be made to consultants, witnesses, experts, or employees of experts ("Expert(s)") employed or otherwise engaged by any party or counsel to any party to assist in the preparation and trial of this litigation. Prior to disclosure to any Expert, the Expert must agree to be bound by the terms of this Protective Order by executing the Confidentiality Agreement annexed hereto. A copy of each executed Confidentiality Agreement shall be furnished to the Plaintiff and submitter not less than five (5) business days prior to disclosure to the Expert.

6. Defendant, Defendant's counsel, and any other person subject to this Protective Order who obtains information designated as confidential hereunder, shall take all necessary and appropriate measures to maintain the confidentiality of the information, shall share such information only with persons authorized to receive it

pursuant to this Protective Order, and shall retain the information in a secure manner. Except as provided in Paragraph 5 above, no other person shall be permitted access to the information.

7. Any person who obtains access to information designated as confidential under this Protective Order may make copies, duplicates, extracts, summaries, or descriptions of the information or any portion thereof *only* for the purpose of preparation for litigation in this matter. All copies, duplicates, extracts, etc. shall be subject to the terms of this Protective Order to the same extent and manner as original documents.

8. Any information designated as confidential under this Protective Order shall be filed with the Court in sealed envelopes or other appropriate sealed containers on which shall be endorsed the caption of this litigation, an indication of the nature of the contents of such sealed envelope or container, the word "CONFIDENTIAL", and a statement substantially in the following form:

"This envelope, containing documents which are filed in this case by _____ ("the producing party") is not to be opened and the contents are not to be displayed or revealed except by order of the Court or consent of the producing party."

In addition, if such documents have been sealed and filed with the Court, the submitter shall be informed of this by the filing party at the time of filing.

9. Any unauthorized disclosure of information designated as confidential under this Protective Order shall not result in a waiver of any submitter's claim of confidentiality.

10. If Plaintiff desires to add contractors to the list in Annex 1, Plaintiff may file written notice with the Court and the Defendant of the identities of such contractors. If the Defendant does not object within three days of receipt of such notice, the contractors will be added to Annex 1.

11. Within 60 days after termination of this action by judgment, settlement or otherwise, or as may be determined by the court or EPA:

a. Any person who obtained information designated as confidential hereunder shall assemble and return such information to Plaintiff, including all copies, duplicates, extracts, summaries, or descriptions of the information or portions thereof. Such return shall be certified in writing by the person who obtained the information from EPA. All such information covered by this Protective Order which constitutes the work product of counsel for the Defendant shall be destroyed; and,

b. The Clerk of the Court shall maintain under seal all papers filed under seal until the Court orders otherwise.

Dated: _____

_____

For: Defendant(s)

Dated: _____

_____

For: United States of America

So Ordered this _____ day of _____, 199_____.:

_____

United States District Court Judge

_____ District of _____.

Annex 1—List of Contractors

Annex 2—Stipulation and Protective Order Confidentiality Agreement

The undersigned currently working at _____ which is located at _____. During the past year the undersigned has been employed or otherwise engaged as a consultant or contractor by the following company located at the following address:

The undersigned hereby acknowledges that he/she has read the foregoing Stipulation and Protective Order ("Protective Order") executed by the attorneys of record for the parties in the action presently pending in the U.S. District Court for the District of _____, entitled *United States* v. *[name]*, understands the terms thereof, and agrees, upon threat of penalty of contempt, to be bound by such terms. The undersigned understands that disclosure of information which has been designated as confidential by the submitter of that information may cause substantial harm to the affected business' competitive position. Accordingly, among other responsibilities, the undersigned shall only share such information with persons specifically authorized to receive the information pursuant to the Protective Order, shall retain the information in a secure manner, and shall use such information only for the purposes authorized by the Protective Order. The undersigned understands that the pledge of confidentiality under this Agreement continues after the lawsuit is over. Furthermore, the undersigned understands that a breach of the Protective Order may subject him/her to civil claims for damages and to criminal prosecution under 42 U.S.C. 9604(e)(7)(B).

Dated: _____

Signed:. _____

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Presidential Documents

Title 3—

The President

Proclamation 6520 of December 23, 1992

National Good Teen Day, 1993

By the President of the United States of America

A Proclamation

The passage between childhood and adulthood constitutes one of the most eventful stages of our life's journey. The teen years are as challenging as they are exciting, and at a time when young Americans are facing more serious pressures than ever before—from substance abuse and violence to sexual promiscuity and dropping out of school—it is fitting that we set aside this day to reaffirm the unique, God-given potential of every teenager.

Today millions of American teenagers are setting examples for others by demonstrating love and respect for their parents, by meeting their responsibilities at home and in school, by participating in their places of worship, and by showing consideration and concern for their classmates and neighbors. They are also enjoying the rewards of voluntary service to others, thereby contributing to our communities and Nation as Points of Light. These teens are making the most of their talents and opportunities and, through their determination and hard work, are building the foundation for a bright future.

It is vital that we recognize and reinforce good behavior among teens and instill in every child a positive sense of responsibility, self-control, and self-worth. The pursuit of freedom and independence is characteristic of adolescence. Yet, while most adolescents demand increasing autonomy, they also continue to need and seek their parents' reassurance, guidance, and support. For teenagers who are struggling to cope with the many physical and emotional changes of adolescence, as well as the external pressures that weigh so heavily on young people today, such encouragement and guidance are essential. We must provide our teens with opportunity and hope, with firm yet loving moral guidance and discipline, and—most important—with clear, consistent examples of personal responsibility and virtue.

No child is destined to become a "bad teen." Through loving, responsible parenting and through the support of schools, churches, and communities that set high standards of character and conduct for people of all ages, we can help every young American to recognize and attain his or her fullest potential. On this occasion, let us resolve to do exactly that.

The Congress, by House Joint Resolution 409, has designated January 16, 1993, as "National Good Teen Day" and has authorized and requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim January 16, 1993, as National Good Teen Day. I invite all Americans to observe this day with appropriate programs and activities in honor of America's teenaged citizens.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-third day of December, in the year of our Lord nineteen hundred and ninety-two, and of the Independence of the United States of America the two hundred and seventeenth.

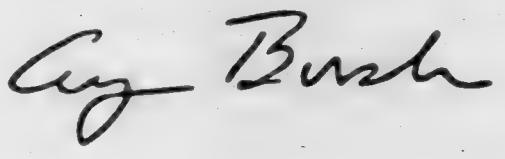

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Presidential Documents

Proclamation 6521 of January 4, 1993

National Sanctity of Human Life Day, 1993

By the President of the United States of America

A Proclamation

Americans have demonstrated their commitment to the belief "that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness." This tradition of generosity and reverence for human life stands in marked contrast with the prevalence of abortion in America today—some 1.5 million children lost each year; more than 4,000 each day. This is shocking evidence of just how far we have strayed from our Nation's most cherished values and beliefs. Thus we pause on this National Sanctity of Human Life Day to call attention to the tragedy of abortion and to recognize the many individuals who are working to restore respect for human life in our Nation.

Advances in science and technology have offered us tremendous new insight on life in the womb: parents can now hear their unborn child's heartbeat as early as 8 weeks of age; physicians can monitor the baby's development using high-resolution sonography; and they may even diagnose and treat abnormalities before birth. How terribly ironic it is that, at one hospital or clinic, an unborn child may be carefully treated as a patient, while at another facility—perhaps just a few blocks away—another innocent child may become a victim of abortion.

Recognizing the tragedy of abortion and the feelings of desperation that lead some women to make such a painful, devastating choice, concerned individuals throughout the United States are working to help women choose life for their unborn children. On this occasion we recognize the many generous Americans who—with nothing to gain for themselves—reach out to women in need through crisis pregnancy centers, residential facilities, mentoring programs, and a host of other support services. We also recognize the many social services professionals, attorneys, and counselors who assist in promoting the adoption option, and we salute each of the courageous women who make this unselfish choice for their children. Such works of generosity and compassion are saving lives and, yes, slowly but surely turning hearts—one woman, one couple, one community at a time.

The struggle to overcome abortion in the United States—to educate individuals about life in the womb, to restore reverence for the miracle of creation, and to expand alternatives for women in need—is far from ended. While the struggle may be a long and difficult one, many Americans know that it is a cause from which we cannot retreat. And because it is a cause that appeals directly to the conscience of the Nation—a Nation that has, time and again, demonstrated its capacity to rediscover its highest ideals, ideals rooted in our belief in the God-given rights and dignity of every human being—it is a cause that cannot fail.

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NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim Sunday, January 17, 1993, as National Sanctity of Human Life Day. I call on all Americans to reflect on the sanctity of human life in all its stages and to gather in homes and places of worship to give thanks for the gift of life and to reaffirm our commitment to respect the life and dignity of every human being.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of January, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

George Bush

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Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 100

[INS No. 1511–92]

RIN 1115–AC95

Statement of Organization; Name Change for Border Patrol Stations in Sector Number 2

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rule amends 8 CFR 100.4 by revising the names of stations located in Border Patrol sector headquarter's number 2 from "Malone, New York" to "Burke, New York", from "Rouses Point, New York" to "Champlain, New York", and from "Derby Line, Vermont" to "Newport, Vermont". These changes are necessary to show the actual city in which these Border Patrol stations are physically located.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Marion E. Moody, Assistant Chief Patrol Agent, Border Patrol, Immigration and Naturalization Service, 425 I Street, NW., room 7227, Washington, DC 20536, telephone (202) 514–1109.

SUPPLEMENTARY INFORMATION: 8 CFR 100.4 is being amended to change the names of three Border Patrol stations located in sector headquarters number 2 from "Malone, New York" to "Burke, New York", from "Rouses Point, New York" to "Champlain, New York", and from "Derby Line, Vermont" to "Newport, Vermont", to show the actual city in which these Border Patrol stations are located.

The Service's implementation of this rule as a final rule is based upon 5 U.S.C. 553 (b)(A) as it is a rule of agency organization. The immediate implementation of this final rule is based upon the "good cause" exception found at 5 U.S.C. 553 (d) in that the usual notice provisions are unnecessary because the rule will benefit the public by showing the actual city in which these Border Patrol stations are physically located.

In accordance with 5 U.S.C. 605(b), the Commissioner of the Immigration and Naturalization Service certifies that this rule does not have a significant adverse economic impact on a substantial number of small entities. This rule is not considered to be a major rule within the meaning of section 1(b) of E.O. 12291, nor does this rule have Federalism implications warranting the preparation of a Federalism Assessment in accordance with E.O. 12612.

List of Subjects in 8 CFR Part 100

Authority delegation (Government agencies), Organization and functions (Government agencies).

Accordingly, part 100 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 100—STATEMENT OF ORGANIZATION

1. The authority citation for part 100 continues to read as follows:

Authority: 8 U.S.C. 1103; 8 CFR part 2.

§ 100.4 [Amended]

2. In § 100.4, paragraph (d) is amended by revising the border patrol station names in Sector No. 2:

a. From "Derby Line, VT" to read: "Newport, VT";

b. From "Malone, NY" to read: "Burke, NY"; and

c. From "Rouses Point, NY" to read: "Champlain, NY".

Dated: December 21, 1992.

Gene McNary,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 93–108 Filed 1–5–93; 8:45 am]

BILLING CODE 4410–10–M

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R–0755]

Review Criteria for Bank Holding Company Applications

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is amending its Regulation Y to implement certain regulatory improvements contained in sections 202(d) and 210 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA). The final rule specifies additional factors that the Federal Reserve System must consider in acting on applications by bank holding companies to acquire banks under section 3 of the Bank Holding Company Act. The intended effect of the amendment is to conform the Board's regulations to the statutory changes.

EFFECTIVE DATE: February 4, 1993.

FOR FURTHER INFORMATION CONTACT: Scott G. Alvarez, Associate General Counsel (202–452–3583), or Brian E.J. Lam, Attorney (202–452–2067), Legal Division; or Sidney M. Sussan, Assistant Director (202–452–2638), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For the hearing impaired only, Telecommunications Device for the Deaf (TDD), Dorothea Thompson (202–452–3544), Board of Governors of the Federal Reserve System, 20th and C Street, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: The Board is adopting a final rule that revises its Regulation Y to include new supervisory factors that FDICIA requires the Board to consider in reviewing and acting on applications by bank holding companies to acquire banks under section 3 of the Bank Holding Company Act (BHC Act). These changes are required by sections 202(d) and 210 of FDICIA, Public Law 102–242, 105 Stat. 2237, 2290, 2298. On April 15, 1992, the Board adopted an interim rule that implemented sections 202(d) and 210 of FDICIA, and requested public comment on the revision to Regulation Y. 57 FR 13002, April 15, 1992. The public comment period expired on June 15, 1992.

Section 202(d) of FDICIA provides that the Board must disapprove an application under section 3 of the BHC Act if:

(1) The bank holding company fails to provide the Board with adequate assurances that it will make available to the Board such information on its operations or activities, and the operations or activities of any affiliates, as the Board deems appropriate to determine and enforce compliance with BHC Act; or

(2) In the case of an application involving a foreign bank, the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in the bank's home country. Public Law 102–242, 105 Stat. 2237, 2290. Section 210 of FDICIA also provides that the Board's consideration of the managerial resources of a bank holding company or bank shall include consideration of the competence, experience and integrity of the officers, directors and principal shareholders of the bank holding company or bank. Public Law 102–242, 105 Stat. 2237, 2298.

The Board is adopting a final rule substantially as proposed. The final rule adopts the statutory language contained in sections 202(d) and 210 of FDICIA, specifying that, in deciding applications under section 3 of the BHC Act, the Board will consider the competence, experience, and integrity of the officers, directors, and principal shareholders of the applicant, and of the banks and bank holding companies concerned, their record of compliance with applicable laws and regulations, and the record of the applicant and its affiliates of fulfilling any commitments to, and any conditions imposed by, the Board in connection with prior applications.[1] In addition, the final rule adopts a definition of "principal shareholder."[2]

The Board will also consider whether the applicant has provided the Board with adequate assurances that it will make available such information on its operations or activities, and the operations or activities of any affiliate of the applicant, that the Board deems appropriate to determine and enforce compliance with the BHC Act and other applicable federal banking statutes, and any regulations thereunder. Moreover, in the case of an application involving a foreign banking organization, the Board will consider whether the organization is subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in the organization's home country.

The final rule is being adopted in conjunction with the Board's implementation of the Foreign Bank Supervision Enhancement Act of 1991 (FBSEA), subtitle A of title II of FDICIA, which changed the authority of the Board under the International Banking Act of 1978. FBSEA provided the Board with new authority to approve the establishment of U.S. offices by a foreign bank, and to regulate and supervise the operations of a foreign bank with U.S. offices.

The Board anticipates that the final rule will not impose any significant additional burdens on domestic banking organizations or financial institutions because the Board currently seeks, and has generally been able to obtain, from domestic applicants all of the information needed to consider section 3 applications. The Board is not proposing to seek any additional types or quantities of information from domestic applicants by virtue of the final rule. The final rule ensures that the Board is able to obtain from all applicants, especially foreign applicants operating in jurisdictions that limit or prohibit the disclosure of financial information outside of the jurisdiction, the same type of information that the Board now seeks and typically obtains from domestic applicants.

Comments

In response to its request, the Board received four comments. Two commenters, a Federal Reserve Bank and a banking organization, favor the adoption of the interim rule as a final rule. Another commenter, a foreign bank, supports the goal of strengthening the applications process under the BHC Act, and agrees that the competence, experience and integrity of the officers and directors of banks and bank holding companies should be considered, as required by section 210 of FDICIA. This commenter, however, suggests that the Board should not consider the competence and experience of shareholders where such shareholders are passive investors that do not anticipate any significant involvement in the management of the bank or the bank holding company.

Section 210 expressly provides that the Board's consideration of the managerial resources of a bank or bank holding company include consideration of the competence, experience, and integrity of the officers, directors, and principal shareholders of the company or bank. Thus, the text of section 210 directs the Board to consider all three managerial factors with respect to all three groups of individuals.

However, the Board believes that the statutory language does not prevent the Board from considering the extent of the role a principal shareholder may play in the management of a bank or a bank holding company when evaluating the competence or experience of the shareholder. An underlying purpose of section 210 is to permit the Board to consider the abilities of the principal shareholders of banks and bank holding companies in appropriate situations, including situations where a principal shareholder has or could have a significant effect on the financial and managerial resources, future prospects, or safety and soundness of a bank or bank holding company. Thus, the Board could consider whether a shareholder proposes to be a passive investor in weighing the shareholder's banking experience and competence.

The final commenter, a banking association, suggests that, in reviewing applications submitted by domestic bank holding companies, the Board not

[1] The Board's regulations currently provide that, in considering applications under section 3 of the BHC Act, the Board will consider the records of the applicant, its subsidiaries, any banks related to the applicant through common ownership or management, and the bank or banks to be acquired, of complying with applicable laws and regulations, and their record of fulfilling any commitments to, and any conditions imposed by, the Board in connection with prior applications. *See* 12 CFR 225.13(b)(2). These provisions will remain unchanged in the final rule.

[2] Regulation Y currently includes a definition of "principal shareholder" that is used in determining the Board's presumption of control of a financial institution or banking organization, and in the Board's Capital Adequacy Guidelines. In order to avoid confusion and to maintain consistency between the statutory language of FDICIA and the implementing provisions of Regulation Y, the Board has redesignated the current term "principal shareholder" as "controlling shareholder", and has added a new definition of the term "principal shareholder" that applies strictly to the standards the Board must review under the FDICIA amendments to the BHC Act. Thus, in the final rule, the term "controlling shareholder" means any person that owns or controls, directly or indirectly, 25 percent or more of any class of voting securities of a bank or other company. Corresponding changes have been made in the Board's regulations regarding presumptions of control, and in the Board's Capital Adequacy Guidelines. The term "principal shareholder" has been redefined for purposes of implementing the FDICIA provisions to mean any person that owns or controls, directly or indirectly, 10 percent or more of any class of voting securities of a bank or other company, or any person that the Board determines has the power to exercise, directly or indirectly, a controlling influence over the management or policies of a bank or other company. The Board believes that the managerial qualities of all major shareholders (*i.e.*, shareholders controlling 10 percent or more of any class of voting securities) should be considered in appropriate situations. This is the level of ownership at which shareholder review is conducted under the Change in Bank Control Act, 12 U.S.C. 1817(j). As discussed in the preamble, the Board will consider the actual or anticipated role of a principal shareholder in the management of a bank in evaluating the competence, experience and integrity of that individual.

require domestic applicants to provide information on their respective operations and activities, and the operations and activities of their affiliates. This commenter asserts that the text and placement of section 202(d) of FDICIA, its legislative history, and other legal and practical considerations all support exempting domestic banks and bank holding companies from this requirement.

The Board has considered these comments and concluded that domestic bank holding companies should not be exempted from the requirement that, when submitting section 3 applications, they provide the Board with adequate assurances that they will make available appropriate information to the Board. By its express terms, section 202(d) requires the Board to disapprove *any* application by *any* bank holding company under section 3 of the BHC Act if the company fails to provide adequate assurances that the company will make available to the Board such information on the operations or activities of the company or any affiliate of the company. In drafting section 202(d), Congress expressly limited the application of certain other provisions of that section to foreign banks, without imposing a similar limitation on the "availability of information" provision. Moreover, the legislative history of section 202(d) expressly indicates that this requirement is applicable to domestic bank holding companies.[3] Thus, in light of the statutory language and the legislative history of section 202(d), the Board has concluded that the availability of information provision should apply to domestic bank holding companies.

[S]ection 202(d) amends the BHC Act to permit the Board to disapprove *any application* to acquire a U.S. bank unless the Board is given adequate assurances that it will have access to information on the operations or activities of a company or companies, or any affiliates, making application to acquire a U.S. bank that the Board deems necessary to fulfill the requirements of the [International Banking Act], the BHC Act, or the [Financial Institutions Supervisory Act of 1966]. *This requirement applies to applications by both foreign banking organizations and domestic bank holding companies.*

H.R. Rep. No. 157, 102nd Cong., 1st Sess. 159 (1991) (emphasis added); *see also* Section-By-Section Analysis Of S. 543 As Reported By The Senate Banking Committee, *reprinted in* 138 Cong. Rec. 2059, 2094 (February 21, 1992) (noting that the availability of information provision "applies to applications by both foreign banking organizations and domestic bank holding companies").

The Board does not believe, however, that the final rule will impose a significant additional burden on domestic applicants because the Board currently seeks and typically is able to obtain from such applicants all of the information needed to consider section 3 applications. The Board does not expect or propose, following adoption of this final rule, to seek additional types or quantities of information from domestic applicants than the Board currently seeks from these applicants.

The commenter also suggests that the Board should require domestic banks and bank holding companies to provide information on an affiliate only if the affiliate either transacts business with the bank that goes beyond ordinary deposit or loan services, or exposes the bank to substantial risk. Based on the express language and legislative history of section 202(d), which both refer to "any affiliates" of the applicant, the Board also has concluded that applicants should provide the necessary assurances with regard to all affiliates, not just affiliates that transact business with a bank that goes beyond ordinary deposit or loan services or that exposes a bank to substantial risk.

However, under section 202(d) and the final rule, the Board retains discretion to determine on a case-by-case basis the extent that assurances are needed for affiliates under common control of individuals. The Board does not believe that, in light of the language and purpose of section 202(d) of FDICIA, it is appropriate to provide a general regulatory exemption for all or most companies affiliated through individual owners.

Finally, the commenter urges the Board not to require banks, bank holding companies and their affiliates to provide information that is deemed to be privileged or confidential under applicable federal or state laws. No such exception appears to have been contemplated by section 202(d). The Board believes that, in certain circumstances, it may be appropriate for the Board to request, and for applicants to provide, information which may be deemed privileged or confidential. The Board can and will, however, afford this information confidential treatment as provided in the Freedom of Information Act. Accordingly, the Board believes that it is not appropriate to adopt a regulatory provision limiting the Board's ability to request or obtain relevant confidential or privileged information.

For all of the foregoing reasons, the Board has concluded that the availability of information provision of the interim rule should remain unchanged in the final rule.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, the Board hereby certifies that the final rule will not have a significant impact on a substantial number of small entities.

The final rule imposes the minimum burdens necessary to implement the provisions of sections 202(d) and 210 of FDICIA for all banks and bank holding companies subject to the regulation, regardless of size. The regulation specifies additional factors which the Board must consider in acting on applications by bank holding companies to acquire banks under section 3 of the BHC Act. The final rule does not impose any additional regular recordkeeping, reporting or other similar requirements on banks.

List of Subjects in 12 CFR Part 225

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, and pursuant to the Board's authority under section 5(b) of the Bank Holding Company Act of 1956, 12 U.S.C. 1844(b), the Board amends part 225 of Chapter II of Title 12 of the Code of Federal Regulations as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. Section 225.2 is amended by revising the text of paragraph (k) as follows:

§ 225.2 Definitions.

* * * * *

(k)(1) *Controlling shareholder* means a person that owns or controls, directly or indirectly, 25 percent or more of any class of voting securities of a bank or other company.

(2) *Principal shareholder* means a person that owns or controls, directly or indirectly, 10 percent or more of any class of voting securities of a bank or other company, or any person that the Board determines has the power, directly or indirectly, to exercise a controlling influence over the management or policies of a bank or other company.

* * * * *

[3] For example, the Report of the House Committee on Banking, Finance and Urban Affairs states:

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2. Section 225.13 is amended by revising paragraphs (a) and (b)(2) to read as follows:

§ 225.13 Factors considered in acting on bank applications.

(a) *Prohibited anticompetitive transactions.* As specified in section 3(c) of the BHC Act, the Board may not approve any application under this subpart if:

(1) The transaction would result in a monopoly or would further any combination or conspiracy to monopolize, or to attempt to monopolize, the business of banking in any part of the United States;

(2) The effect of the transaction may be substantially to lessen competition in any section of the country, tend to create a monopoly, or in any other manner be in restraint of trade, unless the Board finds that the transaction's anticompetitive effects are clearly outweighed by its probable effect in meeting the convenience and needs of the community;

(3) The applicant has failed to provide the Board with adequate assurances that it will make available such information on its operations or activities, and the operations or activities of any affiliate of the applicant, that the Board deems appropriate to determine and enforce compliance with the BHC Act and other applicable federal banking statutes, and any regulations thereunder; or

(4) In the case of an application involving a foreign bank, the foreign bank is not subject to comprehensive supervision or regulation on a consolidated basis by the appropriate authorities in its home country, as provided in § 211.24(c)(1)(ii) of the Board's Regulation K (12 CFR 211.24(c)(1)(ii)).

(b) * * *

(2) *Managerial Resources.* The competence, experience, and integrity of the officers, directors, and principal shareholders of the applicant, its subsidiaries, and the banks and bank holding companies concerned; their record of compliance with laws and regulations; and the record of the applicant and its affiliates of fulfilling any commitments to, and any conditions imposed by, the Board in connection with prior applications.

* * * * *

3. Section 225.31 is amended by revising paragraph (d)(2)(ii) to read as follows:

§ 225.31 Control proceedings.

(d) * * *

(2) * * *

(ii) *Shares controlled by company and associated individuals.* A company that, together with its management officials or controlling shareholders (including members of the immediate families of either as defined in 12 CFR 206.2(k)), owns, controls, or holds with power to vote 25 percent or more of the outstanding shares of any class of voting securities of a bank or other company controls the bank or other company, if the first company owns, controls, or holds with power to vote more than 5 percent of the outstanding shares of any class of voting securities of the bank or other company.

* * * * *

4. Appendix B is amended by revising footnote 1 to read as follows:

Appendix B to Part 225—Capital Adequacy Guidelines for Bank Holding Companies and State Member Banks: Leverage Measure

* * * * *

[1] The guidelines will apply to bank holding companies with less than $150 million in consolidated assets on a bank-only basis unless:

(1) The holding company or any nonbank subsidiary is engaged directly or indirectly in any nonbank activity involving significant leverage or

(2) The holding company or any nonbank subsidiary has outstanding significant debt held by the general public. Debt held by the general public is defined to mean debt held by parties other than financial institutions, officers, directors, and controlling shareholders of the banking organization or their related interests.

* * * * *

By order of the Board of Governors of the Federal Reserve System, December 29, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 92-32 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Part 567

[No. 92-539]

RIN 1550-AA50

Valuation and Regulatory Capital Treatment of Foreclosed Assets

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Thrift Supervision (OTS) is revising its policy guidance to require savings associations to use fair value rather than net realizable value (NRV) for valuing foreclosed assets subsequent to acquisition. The OTS is also amending its capital regulation to place all assets previously assigned to the 200 percent risk-weight category, including foreclosed assets, into the 100 percent risk-weight category. The accounting change will make the accounting treatment of foreclosed assets consistent with generally accepted accounting principles as applied by the other Federal banking agencies. The capital rule change will make the capital treatment of certain items, including foreclosed assets, consistent with the new accounting treatment and with the treatment accorded these assets by the other Federal banking agencies.

EFFECTIVE DATE: December 31, 1992.

FOR FURTHER INFORMATION CONTACT: Robert J. Fishman, Program Manager, (202) 906-5672, Deidre G. Kvartunas, Program Analyst, (202) 906-7933, Timothy J. Stier, Deputy Chief Accountant (202) 906-5699, Policy; Catherine A. Shepard, Senior Attorney, Regulations and Legislation Division, Office of Chief Counsel (202) 906-7275; Office of Thrift Supervision, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

I. Background and Summary of Proposal

On October 7, 1992, the OTS published a proposal to modify its classification, valuation, and regulatory capital treatment of troubled, collateral-dependent loans and foreclosed assets.[1] The OTS proposed three new policies:

(a) The use of fair value instead of net realizable value for the valuation of troubled, collateral-dependent loans and foreclosed assets;

(b) A requirement to use charge-offs instead of specific valuation allowances (SVAs) for amounts classified "loss"; and

(c) The removal of the 200 percent risk-weight category, and the reassignment of items formerly in that category to the 100 percent risk-weight category for capital purposes.[2]

The purposes of the proposal were to conform OTS's accounting treatment for troubled, collateral-dependent loans and foreclosed assets with that of the other Federal banking agencies and to amend its capital regulations to be consistent with the change in valuation

[1] 57 FR 46,098 (Oct. 7, 1992).

[2] Three types of assets are currently placed in the 200 percent risk-weight category under the OTS's risk-based capital rule: (1) Repossessed (or foreclosed) assets; (2) assets that are more than 90 days past due (except 1-4 family residential real estate that is more than 90 days past due, which is placed in the 100 percent risk-weight category); and (3) equity investments that OTS determines to have the same risk characteristics as real estate owned. 12 CFR 567.6(a)(1)(v).

methodology. The OTS intended that the proposed changes in valuation methodology would be reflected in agency guidance such as a Thrift Bulletin or instructions to the Thrift Financial Report. The requirement that charge-offs be used instead of SVAs and the removal of the 200 percent risk-weight category were to be accomplished through amendment of the agency's regulations.

II. Summary of Comments

The OTS received thirty-one comment letters on its proposal. Commenters included twenty-three savings associations, five financial institution trade associations, a bank holding company with a savings bank subsidiary, an accounting trade association, and an individual. As discussed in Section III below, today's final action addresses only the accounting treatment for foreclosed assets and the accompanying amendment to the capital rule. Comments addressing the use of fair value for troubled, collateral-dependent loans will be summarized and discussed when the agency issues its final guidance on that issue. Similarly, comments addressing the use of charge-offs instead of SVAs will be summarized and discussed in any final regulation on that issue.

Only ten commenters addressed whether the OTS should revise its guidance on foreclosed assets to require savings associations to value such assets at their fair value. All ten commenters supported the proposed change. Twenty of the commenters discussed the OTS's proposal to amend the risk-based capital rules by eliminating the 200 percent risk-weight category and placing foreclosed assets in the 100 percent risk-weight category. In light of the proposed changes in valuation for these assets, all twenty commenters supported this portion of the proposal without modification.

III. Description of Final Guidance and Regulation

The OTS has decided to finalize only part of its October proposal. First, the OTS is requiring that, as of December 31, 1992, savings associations use fair value for the valuation of all foreclosed assets. Second, today's final rule removes the 200 percent risk-weight category and reassigns all assets in that category to the 100 percent risk-weight category. The OTS is postponing to a later date final action on the application of fair value to troubled collateral-dependent loans and on revising its regulations on the use of charge-offs instead of SVAs. Final guidance will address both troubled collateral-dependent loans and foreclosed assets.[3]

A. Foreclosed Assets

The OTS is revising its policy on foreclosed assets, including repossessed real estate. Under the new policy, after foreclosure, foreclosed assets must be carried at the lower of cost or fair value,[4] based on the presumption that such assets are held for sale. The cost of such assets at the time of foreclosure is the fair value of the assets foreclosed. This policy also applies to in-substance foreclosures.

This policy accords with the Statement of Position (SOP) 92–3, "Accounting for Foreclosed Assets," issued by the American Institute of Certified Public Accountants. Under the SOP, there is a rebuttable presumption that foreclosed assets are held for sale. The SOP recommends that foreclosed assets held for sale be carried at the lower of: (a) Fair value minus estimated costs to sell, or (b) cost. While the SOP mandates the use of fair value for foreclosed assets in annual financial statements for periods ending on or after December 15, 1992, all savings associations, regardless of when their fiscal years end, must use the fair value method in all regulatory reports prepared for periods ending on or after December 31, 1992.

B. Removal of 200 Percent Risk-Weight Category

The OTS is also amending its risk-based capital rule, 12 CFR 567.6(a)(1)(v), to lower from 200 percent to 100 percent the risk-weight on all assets currently assigned to the 200 percent category. This amendment is consistent with the fair value accounting treatment adopted today. When the capital rules were promulgated in 1989, repossessed assets were assigned a 200 percent risk-weight because a savings association could carry such assets at the lower of cost or NRV.[5] Since the OTS is today eliminating the use of NRV in favor of fair value, it is appropriate to remove foreclosed assets from the 200 percent risk-weight category. Accordingly, foreclosed assets will be assigned a risk-weight of 100 percent.

The OTS's current capital rule also places all loans that are 90 days or more past due in the 200 percent risk-weight category except for 1 to 4 family residential mortgages, which are in the 100 percent risk-weight category. This risk-weighting treatment was intended to minimize any disincentive under the capital rules for thrifts to foreclose on properties. In recognition of the change in the risk-weight category for foreclosed assets, the OTS is also revising its capital rule to place loans 90 days or more past due in the 100 percent risk-weight category.[6]

C. Effective Date

Both of the actions taken today—the risk-weighting change to the OTS's capital regulations and the revision to OTS guidance on the valuation of foreclosed assets—are effective as of December 31, 1992. Regulatory reports prepared for periods ending on or after December 31, 1992, must, accordingly, reflect both changes. Neither of these actions is subject to the delayed effective date provision of the Administrative Procedure Act (APA).

The APA permits a regulation that relieves a restriction to become effective without a 30-day delay in its effective date. 5 U.S.C. 553(d)(1). The placement of assets formerly in the 200 percent risk-weight category into the 100 percent category falls within this exception. Accordingly, its effective date will not be delayed.

The OTS's revisions to its policy governing the valuation of foreclosed assets are subject to the APA provision authorizing interpretive rules and statements of policy to become effective without delay. 5 U.S.C. 553(d)(2). In addition, the OTS finds that good cause exists for its guidance on the valuation of foreclosed assets to take immediate effect.[7] SOP 92–3, "Accounting for Foreclosed Assets," must be applied by savings associations in preparing their annual financial statements for periods ending on or after December 15, 1992. The majority of, but not all, savings associations have calendar year-end fiscal years and, thus, will be required by GAAP to follow this SOP in

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[3] The Financial Accounting Standards Board (FASB) has issued an exposure draft on accounting for impaired loans. "Proposed Statement of Financial Accounting Standards: Accounting by Creditors for Impairment of a Loan", File Reference No. 116–B, June 30, 1992. The OTS will address any final FASB action on this issue when it issues final guidance of the regulation of troubled, collateral-dependent loans.

[4] Fair value is to include a reduction for the seller's disposition costs.

[5] *See* 54 FR 46845, 46853 (Nov. 8, 1989).

[6] Given its decision to lower the risk-weight for the first two types of assets currently placed in the 200 percent category, that is, repossessed (or foreclosed) assets and assets more than 90 days past due, OTS has concluded that it is inappropriate to retain a 200 percent risk-weighting for the third type of asset—equity investments with the same risk characteristics as REO. If REO is risk-weighted at 100 percent, then assets having similar risk characteristics should carry the same risk-weight. Since no other assets are risk-weighted at 200 percent, it is appropriate to remove that risk-weighting category.

[7] *See* 5 U.S.C. 553(d)(3) (an agency may dispense with a delay in effective date for "good cause").

preparing their December 31, 1992 financial statements. An immediate effective date for the implementation of the fair value policy will cause the regulatory reports filed with the OTS by all savings associations to be consistent both with GAAP and with the treatment of these assets by the other federal banking regulatory agencies. A lack of uniformity would impede OTS's supervision of savings associations.

IV. Executive Order 12291

The OTS has determined that this regulation does not constitute a "major rule" and, therefore, the preparation of a regulatory impact analysis is not required. The impact on affected savings associations that results from the more stringent valuation methodology required for foreclosed assets will be substantially offset by removal of the 200 percent risk-weight category.

V. Regulatory Flexibility Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act, it is certified that this regulation will not have a significant impact on a substantial number of small savings associations. Any impact on small associations that results from the more stringent valuation methodology required for foreclosed assets will be substantially offset by removal of the 200 percent risk-weight category. Any impact on small savings associations will, accordingly, not be significant.

List of Subjects in 12 CFR Part 567

Capital, Reporting and recordkeeping requirements, Savings associations.

Accordingly, the Office of Thrift Supervision hereby amends part 567, chapter V, title 12, Code of Federal Regulations as set forth below.

SUBCHAPTER D—REGULATIONS APPLICABLE TO ALL SAVINGS ASSOCIATIONS

PART 567—CAPITAL

1. The authority citation for part 567 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1476a.

2. Section 567.6 is amended by revising the section heading; by removing the period located at the end of paragraph (a)(1)(iv)(Q) and by adding in lieu thereof a semicolon; by adding new paragraphs (a)(1)(iv)(R) and (a)(1)(iv)(S); and by removing and reserving paragraph (a)(1)(v) to read as follows:

§ 567.6 Risk-based capital credit risk-weight categories.

(a) *Risk-weighted Assets.* * * *

(1) *On-balance Sheet Assets:* * * *

(iv) *100 percent Risk Weight (Category 4).* * * *

(R) All repossessed assets or assets that are more than 90 days past due; and

(S) Equity investments that the Office determines have the same risk characteristics as foreclosed real estate by the savings association.

* * * * *

Dated: December 28, 1992.

By the Office of Thrift Supervision.

John F. Robinson,

Acting Director.

[FR Doc. 92-31948 Filed 12-31-92; 11:42 am]

BILLING CODE 6720-01-M

RESOLUTION TRUST CORPORATION

12 CFR Part 1616

RIN 3205-AA14

Privacy Act Regulations

AGENCY: Resolution Trust Corporation.

ACTION: Final rule.

SUMMARY: The Resolution Trust Corporation (RTC or Corporation) is adopting a rule for the processing of requests for access to or amendment of records, other than the records of the RTC Inspector General, pursuant to the Privacy Act of 1974 (5 U.S.C. 552a). An interim rule with request for comments was published on September 22, 1992 (57 FR 43607).

EFFECTIVE DATES: This final rule is effective December 21, 1992.

FOR FURTHER INFORMATION CONTACT: Richard White, Privacy Act Program Officer, Office of the Secretary, FOIA/PA Branch, (703) 908-6137. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: This rule governs release of all Corporate records, with the exception of the Office of Inspector General of the RTC, pursuant to the Privacy Act of 1974, as amended. This rule sets forth the procedures to be used in requesting records from the RTC, appealing the decision to deny, in whole or in part, access to Corporate records, the procedures for contesting the content of Corporate records, and the identification of systems of records that are exempt from the access, amendment, and disclosure accounting provisions of the Privacy Act. It also establishes a fee schedule for the duplication of Corporate records, and establishes a minimum amount under which fees will not be charged. No comments from members of the public were received. Appendix A of the rule has been amended to reflect the most current addresses of RTC field office locations.

List of Subjects in 12 CFR Part 1616

Privacy.

Accordingly, the interim rule adding part 1616 to title 12, chapter XVI, of the Code of Federal Regulations is amended and adopted as a final rule to read as follows:

PART 1616—PRIVACY ACT REGULATIONS

Sec.

1616.1 Purpose and scope.
1616.2 Definitions.
1616.3 Procedures for requests pertaining to individual records in a system of records.
1616.4 Times, places and requirements for identification of individuals making requests.
1616.5 Disclosure of requested information to individuals.
1616.6 Special procedures for medical records.
1616.7 Requests for amendment of records.
1616.8 Agency reviews of requests for amendment of records.
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Appendix A—RTC Field Offices

Authority: 5 U.S.C. 552a.

§ 1616.1 Purpose and scope.

This part sets forth the basic policies of the Resolution Trust Corporation (RTC or Corporation), with the exception of the Office of Inspector General of the RTC, that implement the provisions of the Privacy Act of 1974 (5 U.S.C. 552a) regarding the protection of the privacy of individuals on whom the Corporation maintains information which is retrieved by reference to an individual's name or an identifying particular assigned to the individual. This part also sets forth the procedures by which an individual may seek access under the Privacy Act to records pertaining to him/her, may request amendment of such records, or may seek an accounting of disclosures of such records maintained by the Corporation.

§ 1616.2 Definitions.

For the purposes of this part:

(a) *Corporation* means the Resolution Trust Corporation operating in its Corporate capacity.

(b) *Individual* means a natural person who is either a citizen of the United States of America or an alien lawfully admitted for permanent residence.

(c) *Maintain* includes maintain, collect, use, disseminate, or control.

(d) *Record* means any item, collection or grouping of information about an individual that is maintained by the RTC in its Corporate capacity and contains his/her name, or an identifying number, symbol, or other identifying particular assigned to the individual.

(e) *System of records* means a group of any records under the control of the Corporation from which information is retrieved by the name of the individual or some identifying number, symbol or other identifying particular assigned to the individual.

(f) *Designated system of records* means a system of records which has been listed and summarized in the **Federal Register** pursuant to the requirements of 5 U.S.C. 552a(e).

(g) *Routine use* means, with respect to disclosure of a record, the use of such record for a purpose which is compatible with the purpose for which it was created.

(h) *Amend* and *amendment* mean any correction of, addition to or deletion from a record.

(i) *System manager* means the agency official responsible for a designated system of records, as denominated in the **Federal Register** publication of "Systems of Records Maintained by the Resolution Trust Corporation."

§ 1616.3 Procedures for requests pertaining to individual records in a system of records.

(a) Any present or former employee of the Federal Deposit Insurance Corporation (FDIC) who is working for or has worked for the RTC and who is seeking access to his/her official personnel folder or other U.S. Office of Personnel Management government-wide personnel-type record, including compensation, training, medical information, time and attendance and performance, maintained by the RTC in Corporation offices should submit his/her request in such a manner as prescribed by the U.S. Office of Personnel Management in part 297 of its rules and regulations (5 CFR 297.101 through 297.501). Such requests should be submitted to the Office of the Secretary, RTC, FOIA/PA Branch, International Place, 1735 North Lynn Street, Rosslyn, VA 22209. An FDIC employee who is presently working for the RTC may also gain access to his/her unofficial personnel folder, and other personnel-type record, by visiting, either in person or with an authorized representative, the RTC Corporate office in which the folder is maintained.

(b) Written requests by individuals for access to records pertaining to them, other than official personnel folders, and maintained within one of the Corporation's designated system of records should be submitted to the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209. Each such request should contain a reasonable description of the record(s) sought, identify the system or systems in which such records may be contained, and any additional identifying information, as specified in the Corporation's **Federal Register** "Notice of Systems of Records" for that particular system, copies of which are available upon request from the FOIA/PA Branch, Office of the Secretary.

§ 1616.4 Times, places and requirements for identification of individuals making requests.

(a) Individuals may request access to records pertaining to themselves as provided in § 1616.3 by submitting a written request by mail or in person to the office in which the records are maintained or the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209. Before access to records is granted, pursuant to this part, reasonable identification, as specified in § 1616.4(b), of the person making the request is required to ensure that information is given and records are disclosed only to the proper individual.

(b) Employees appearing in person at RTC offices seeking access to or amendment of personnel records pertaining to themselves shall present two forms of reasonable identification, such as employment identification cards, driver's licenses, passports, or credit cards. One piece of identification shall contain the individual's photograph and signature.

(c) Individuals submitting written requests seeking access to or amendment of records pertaining to themselves shall include copies of two forms of identification which contain the signatures of the individuals. Except for records that must be publicly disclosed pursuant to the Freedom of Information Act (5 U.S.C. 552), where the Corporation determines it to be necessary for the individual's protection, a certification of a duly commissioned notary public, of any state or territory, attesting to the requesting individual's identity may be required before a written request seeking access to or amendment of a record will be honored. Identification, as described in this section, will be required of any individuals visiting RTC offices to inspect records after submission of written requests.

§ 1616.5 Disclosure of requested information to individuals.

(a) Except to the extent that Corporation records in a system of records pertaining to an individual:

(1) Are exempt from disclosure under § 1616.14, or

(2) May require special procedures for medical records under § 1616.6, or

(3) Were compiled in reasonable anticipation of a civil action or proceeding, the Corporation will make such records available upon request for purposes of inspection and copying by the individual about whom the information is maintained or, upon the individual's request and written authorization, by another person of the individual's own choosing (after proper identity verification as provided in § 1616.4).

(b) The Secretary, or designee, will acknowledge receipt of a request submitted under this rule within ten (10) working days, and notify, in writing, the individual making a request, whenever practicable within ten business days following receipt of the request, whether any specified, designated system of records maintained by the Corporation contains a record pertaining to the individual. Where such a record does exist, the Secretary, or designee, with the advice of the System Manager, will inform the individual of the decision whether to grant or deny, in whole or in part, the request for access. In the event existing records are determined not to be disclosable, the notification will inform the individual of the reason(s) for which disclosure will not be made and will provide a description of the individual's right to appeal the denial, as more fully set forth in § 1616.9.

(c) Individuals will be granted access to records disclosable under this part 1616 as soon as is practicable. The Secretary, or designee, will give written notification of a reasonable period within which individuals may inspect disclosable records pertaining to themselves at the Office of the Secretary (FOIA/PA Branch) or the appropriate Headquarters, or field offices during normal business hours. Alternatively, the Corporation may mail copies of requested records to the individual. Fees for copying such records will be assessed as provided in § 1616.12.

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§ 1616.6 Special procedures for medical records.

Medical records in a system of records shall be disclosed on request to individuals to whom they pertain, except, if in the judgment of the Corporation, the transmission of the medical information directly to the requesting individual could have an adverse effect upon such individual. In the event medical information is withheld from a requesting individual because of any possible adverse effect such information may have upon the individual, the Corporation shall transmit such information to a licensed medical doctor named by the requesting individual.

§ 1616.7 Requests for amendment of records.

The Corporation will maintain all records it uses in making any determination about any individual with such accuracy, relevance, timeliness, and completeness as is reasonably necessary to assure fairness to the individual in the determination. An individual may request that the Corporation amend any portion of a record pertaining to that individual which the Corporation maintains in a designated system of records. Such a request should be submitted in writing to the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209, and should contain the individual's reason for requesting the amendment and a description of the record (including the name of the appropriate designated system of records) sufficient to enable the Corporation to identify the particular record or portion thereof with respect to which amendment is sought. If an individual has a copy of the record he/she wishes to have amended, it should be attached to the request for amendment and the specific portion of the record sought to be amended should be clearly identified. The individual making the request may be required to provide the information specified in § 1616.4 to permit verification of the identify of the individual making the request for amendment.

§ 1616.8 Agency reviews of requests for amendment of records.

(a) Requests by individuals for the amendment of records will be acknowledged by the Secretary, or designee, within ten (10) business days following receipt of such requests and referred to the System Manager of the system of records in which the record is contained for an analysis of the request to amend. Promptly thereafter, the Secretary, or designee, with the advice of the System Manager, will notify the individual of the decision to grant or deny the request to amend. If the request to amend is granted in whole or in part, the Secretary, or designee, will effect the appropriate amendment.

(b) If the Secretary, or designee, denies a request to amend a record, the notification of such denial shall contain the reason(s) for the denial, a description of the individual's right to appeal the denial as more fully set forth in § 1616.9, and the address of the Corporation officer to whom the appeal should be sent.

§ 1616.9 Appeals of adverse initial agency determinations of access or amendment of records and Statements of Disagreement.

(a) For RTC records contained within a system of records, the initial denial of an individual's request for access to or amendment of a record pertaining to him/her may be appealed to the RTC's General Counsel within 30 business days following receipt of notification of the denial. Such appeals should be mailed to the Office of the Secretary, FOIA/PA Branch, RTC, International Place, 1735 North Lynn Street, Rosslyn, VA 22209, and contain all the information specified for requests for access in § 1616.3 or for initial requests to amend in § 1616.7, as well as any other additional information the individual deems relevant for the consideration by the General Counsel, or designee, of the appeal. Both the envelope and the appeal letter should have written on them "Privacy Act Appeal." The appeal letter should also enclose a copy of the initial denial letter.

(b) The General Counsel, or designee, will normally make a final determination with respect to an appeal made under this part within 30 business days following receipt of the appeal by the Office of the Secretary. The General Counsel, or designee may, however, extend this 30-day time period for good cause shown. When such an extension is required, the individual making the appeal will be notified of the reason for the extension and the expected date upon which a final decision will be given.

(c) If the General Counsel, or designee, affirms the initial denial of a request for access or amendment, he/she will inform the individual affected by the decision, the reason(s) therefore and the right of judicial review of the decision. With respect to a decision to sustain the initial refusal to amend a record, the General Counsel, or designee, will also inform the individual of the right to submit a Statement of Disagreement under paragraph (d) of this section.

(d) Upon receipt of a determination to affirm the initial denial of a request to amend a record, the individual may submit to the Corporation a concise statement (Statement of Disagreement) setting forth his or reasons for disagreeing with the Corporation's determination not to amend. Such a Statement of Disagreement will be attached to the record which was the subject of the request to amend. The General Counsel, or designee may, if deemed appropriate, prepare a concise statement (Statement of Explanation) of the reason(s) why the requested amendment was not made. Any RTC Statement of Explanation will be included in the system of records in the same manner as the Statement of Disagreement. A copy of the Statement of Explanation and the notation of the dispute as marked on the original record will be provided to the individual who requested an amendment of the record.

(e) When a record has been amended or when a Statement of Disagreement has been filed, the Secretary, or designee, will provide all prior recipients of the affected record, whose identities may be determined pursuant to the disclosure accountings required by the Privacy Act (5 U.S.C. 552a(c)) or any other accounting previously made, a copy of the amended or corrected record or the Statement of Disagreement. Any disclosure of disputed information occurring after a Statement of Disagreement has been filed will clearly identify the specific information disputed and be accompanied by a copy of the Statement of Disagreement and a copy of any RTC Statement of Explanation.

§ 1616.10 Preservation of records.

The Corporation will preserve all correspondence relating to the written requests it receives under this part, and all records processed pursuant to such requests, in accordance with the records retention provisions of General Records Schedule 14, Informational Services Records. Under no circumstances will records be destroyed while they are subject to a pending request for access, amendment, appeal, or lawsuit pursuant to the Privacy Act.

§ 1616.11 Disclosure of a record to a person other than the individual to whom the record pertains.

(a) Except as provided in paragraph (b) of this section, the Corporation will not disclose any record contained in a designated system of records to any person or agency except without the

prior written consent of the individual to whom the record pertains.

(b) The restrictions on disclosure in paragraph (a) of this section do not apply to any disclosures:

(1) To those officers and employees of the Corporation who have a need for the record in the performance of their duties;

(2) Required under the Freedom of Information Act (5 U.S.C. 552);

(3) For a routine use, as defined in § 1616.2(g), listed with respect to a designated system of records and described in the **Federal Register** notice of the system;

(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of title 13 of the United States Code;

(5) To a recipient who has provided the Corporation with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

(6) To the National Archives and Records Administration as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Archivist of the United States, or designee, to determine whether the record has such value;

(7) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the Corporation specifying the particular portion desired and the law enforcement activity for which the record is sought;

(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of the individual to whom the record pertains;

(9) To either House of Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

(10) To the Comptroller General, or any of his/her authorized representatives, in the course of the performance of the duties of the General Accounting Office;

(11) Pursuant to the order of a court of competent jurisdiction; or

(12) To a consumer reporting agency in accordance with 31 U.S.C. 3711(f)

(c) Any Statement of Disagreement with the Corporation's determination not to amend a record, filed with the Corporation by an individual pursuant to § 1616.9(d) will be included in the disclosure of the record under authority of paragraph (b) of this section. The Corporation may, in its discretion, also include a copy of the Corporation's Statement of Explanation.

(d) The Corporation, with respect to each system of records under its control shall:

(1) Except for disclosures made under paragraphs (b)(1) or (b)(2) of this section, keep an accurate accounting of:

(i) The date, nature, and purpose of each disclosure of a record to any person or to another agency made under paragraph (b) of this section; and

(ii) The name and address of the person or agency to whom the disclosure is made; and

(2) Retain the accounting made under paragraph (d)(1) of this section for at least five years or the life of the record, whichever is longer, after the disclosure for which the accounting is made;

(3) Except for disclosures made under paragraph (b)(7) of this section, make the accounting made under paragraph (d)(1) of this section available to the individual named in the record at his/her request; and

(4) Inform any person or other agency about any correction or Statement of Dispute made by an individual in accordance with § 1616.9(d), of any record that has been disclosed to the person or agency if an accounting of the disclosure was made.

§ 1616.12 Fees.

The Corporation, upon a request for records disclosable pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), shall charge a fee of $0.20 per page for duplicating, except as follows:

(a) If the Corporation determines that it can grant access to a record only by providing a copy of the record, no fee will be charged for providing the first copy of the record or any portion thereof; and

(b) Whenever the aggregate fees computed under this section do not exceed $25.00 for any one request, the fee will be deemed waived by the Corporation.

§ 1616.13 Penalties.

Any person who knowingly and willfully requests or obtains any record concerning an individual from the RTC under false pretenses shall be guilty of a misdemeanor and fined not more than $5,000.

§ 1616.14 Exemptions.

The following information is exempt from disclosure: (a) Investigatory material compiled for law enforcement purposes is exempt from §§ 1616.3 through 1616.9 and § 1616.11(d)(3), *Provided, however,* that if any individual is denied any right, privilege, or benefit to which he/she would otherwise be entitled under Federal law, or for which he/she would otherwise be eligible, as a result of the maintenance of such material, such material shall be disclosed to such individual, except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence;

(b) Investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Corporation employment to the extent that disclosure of such material would reveal the identity of a source who furnished information to the Corporation under an express promise that the identity of the source would be held in confidence, is exempt from §§ 1616.3 through 1616.9 and § 1616.11(d)(3); and

(c) Testing or examination material used solely to determine or assess individual qualifications for appointment or promotion in the Corporation's service, the disclosure of which would compromise the objectivity or fairness of the testing, evaluation, or examination process is exempt from §§ 1616.3 through 1616.9 and § 1616.11(d)(3).

Appendix A—RTC Field Offices

1. Atlanta Office, 100 Colony Square, Atlanta, GA 30361;

2. Kansas City Office, 4900 Main Street, Kansas City, MO 64112;

3. Dallas Office, 3500 Maple Avenue, Dallas, TX 75219;

4. Denver Office, 1225 17th Street, Denver, CO 80202;

5. Costa Mesa Office, 4000 MacArthur Boulevard, Newport Beach, CA 92660;

6. Valley Forge Office, 1000 Adams Avenue, Norristown, PA 19403.

By order of the Chief Executive Officer.

Dated at Washington, D.C., this 30th day of December, 1992.

Resolution Trust Corporation

William J. Tricarico,

Assistant Secretary.

[FR Doc. 93–100 Filed 1–5–93; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92-NM-235-AD; Amendment 39-8459; AD 93-01-05]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes two existing airworthiness directives (AD), applicable to certain Boeing Model 747 series airplanes, that currently require repetitive inspections to detect cracks in forward and aft bottle bore fuse pins in the diagonal braces of the inboard engine struts, and replacement of cracked pins. Those AD's also provided for installation of forward 15-5 steel fuse pins or aft bulkhead fuse pins as optional terminating actions for the repetitive inspections. This amendment adds repetitive inspections of forward and aft bottle bore fuse pins in the outboard engine strut, and aft bulkhead fuse pins in the inboard and outboard engine struts. This AD also provides optional terminating action for certain repetitive inspections and adds airplanes to the applicability statement of the AD. This amendment is prompted by numerous reports of cracks and corrosion in certain fuse pins in the diagonal braces of the inboard and outboard engine struts. The actions specified in this AD are intended to prevent failure of the engine support structure and the inability of the strut to carry required engine operational loads.

DATES: Effective February 5, 1993.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 5, 1993.

Comments for inclusion in the Rules Docket must be received on or before March 8, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 92-NM-235-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Tim Beckman, Aerospace Engineer, Seattle Aircraft Certification Office, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2776; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: On August 5, 1981, the FAA issued AD 79-22-03 R3, Amendment 39-4176 (46 FR 38343, July 27, 1981), applicable to certain Model 747 series airplanes, to require:

1. Repetitive visual inspections at intervals of 350 landings, or ultrasonic inspections at intervals of 1,200 landings, to detect cracks and corrosion in forward bottle bore fuse pins in the diagonal braces of the inboard engine struts, and replacement of cracked pins; and

2. Application of corrosion preventive compound, and removal of any corrosion found.

That action also provided for installation of forward 15-5 steel fuse pins as an optional terminating action for the requirements of that AD. That action was prompted by a report of a completely fractured forward bottle bore fuse pin. The actions required by that AD are intended to prevent failure of the forward bottle bore fuse pins in the diagonal braces of the inboard engine struts.

Since the issuance of AD 79-22-03 R3, the FAA has received a total of 39 reports of cracking and two reports of complete fractures of forward bottle bore fuse pins. Boeing's analysis of several cracked forward bottle bore fuse pins indicates that cracking initiated at a sharp, circumferential machining groove in the fuse pin bore internal recess and was propagated by fatigue. The FAA notes that the same forward bottle bore fuse pin design is used on both inboard and outboard struts. In addition, these fuse pins operate in similar loads environments. Therefore, the FAA concludes that forward bottle bore fuse pins on the outboard struts, as well as the inboard struts, are subject to the same fatigue cracking.

One of the cracks discussed previously was found in a forward bottle bore fuse pin on an airplane that had accumulated only 192 landings since its last visual inspection. Critical crack length in these fuse pins is short; therefore, cracks cannot be detected using visual techniques before the pins would become fractured. Consequently, the FAA has determined that the option of performing visual inspections that is specified in the existing AD must be deleted, and repetitive ultrasonic inspections of these pins must be required.

On January 9, 1984, the FAA issued AD 83-24-05, Amendment 39-4775 (48 FR 54476, December 5, 1983), applicable to certain Model 747 series airplanes, to require repetitive visual inspections at intervals of 350 landings, or ultrasonic inspections at intervals of 1,200 landings, to detect cracks in aft bottle bore fuse pins in the diagonal braces of the inboard engine struts, and replacement of cracked pins. That AD also provided for installation of aft bulkhead fuse pins as an optional terminating action for the repetitive inspections. That AD was prompted by two reports of cracked aft bottle bore fuse pins. The actions required by that AD are intended to prevent failure of the aft bottle bore fuse pins in the diagonal braces of the inboard engine struts.

Since the issuance of AD 83-24-05, the FAA has received additional reports of cracks in aft fuse pins on the inboard and outboard engine struts. These reports involve both bottle bore and bulkhead fuse pins. Additionally, the FAA has received four reports of completely fractured aft bulkhead fuse pins.

Since cracks have been found on aft bulkhead fuse pins, as well as on aft bottle bore fuse pins, the FAA has determined that the installation of bulkhead fuse pins does not provide terminating action for the repetitive inspection requirements of AD 83-24-05. In addition, the FAA concludes that aft bulkhead fuse pins must be inspected to detect cracks and corrosion. Further, for reasons explained previously regarding AD 79-22-03 R3, both forward and aft bottle bore fuse pins must be inspected using ultrasonic, rather than visual, techniques. The applicability statement of this AD is expanded to include those airplanes equipped with bulkhead fuse pins. Additionally, since cracks in aft bottle bore fuse pins located in the outboard engine strut have been reported, inspections of both inboard and outboard struts are included in this AD.

The FAA has also determined that the repetitive ultrasonic inspection interval of 1,200 landings that is specified currently in both existing AD's must be reduced to 1,000 landings. This finding is based on an evaluation of additional crack growth data supplied by the manufacturer.

Cracks in these fuse pins could result in failure of the engine support structure

and the inability of the strut to carry required engine operational loads.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747–54A2153, dated December 23, 1992, that describes procedures for repetitive inspections to detect cracks and corrosion in the forward and aft bottle bore fuse pins and the aft bulkhead fuse pins in the inboard and outboard engine struts; and replacement, if necessary. The service bulletin also describes procedures for installing a forward 15–5 steel fuse pin, which, if accomplished, eliminates the need for the repetitive inspections of the forward bottle bore fuse pins.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of this same type design, this AD supersedes AD 79–22–03 R3 and AD 83–24–05 to require repetitive inspections to detect cracks and corrosion in (1) forward and aft bottle bore fuse pins, and (2) aft bulkhead fuse pins in the diagonal braces of the inboard and outboard engine struts; and replacement of pins, if necessary. This AD also provides terminating action for the repetitive inspections of forward bottle bore fuse pins in the diagonal braces of the inboard and outboard engine struts. The actions are required to be accomplished in accordance with the service bulletin described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption "ADDRESSES." All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92–NM–235–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–4176 (46 FR 38343, July 27, 1981) and amendment 39–4775 (48 FR 54476, December 5, 1983), and by adding a new airworthiness directive (AD), amendment 39–8459, to read as follows:

93–01–03 Boeing: Amendment 39–8459. Docket 92–NM–235–AD. Supersedes AD 79–22–03 R3, Amendment 39–4176; and AD 83–24–05, Amendment 39–4775.

Applicability: All Model 747 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the engine support structure and the inability of the strut to carry required engine operational loads, accomplish the following:

(a) For all Model 747 series airplanes, except JT9D–70-equipped airplanes: Inspect the forward bottle bore fuse pins in the rear diagonal brace of the inboard nacelle struts in accordance with paragraph (a)(1) or (a)(2) of this AD.

(1) Within 100 landings after August 5, 1981 (the effective date of AD 79–22–03 R3, Amendment 39–4176), unless accomplished already within the last 250 landings, but not to exceed 1,200 landings from the previous inspection: Remove the retainer bolt and end caps from the fuse pins, part numbers 65B94182–3, 69B904010–1, –3, –4, –600, and 69B89612–3, and perform a visual inspection of the fuse pins to detect cracks in the machined shear section, in accordance with Boeing Service Bulletin 747–54–2066, dated November 7, 1979; Revision 1, dated October 10, 1980; or Revision 2, dated July 16, 1982. Repeat that inspection thereafter at intervals not to exceed 350 landings until the inspection required by paragraph (e) of this AD is accomplished.

(2) Within 100 landings after August 5, 1981 (the effective date of AD 79–22–03 R3, Amendment 39–4176), unless accomplished already within the last 1,100 landings, but not to exceed 1,200 landings from the previous inspection: Remove the retainer bolt and end caps from the fuse pins, part numbers 65B94182–3, 69B904010–1, –3, –4, –600, and 69B89612–3, and perform an ultrasonic inspection of the fuse pins to detect cracks in the machined shear section, in accordance with Boeing Service Bulletin 747–54–2066, dated November 7, 1979; Revision 1, dated October 10, 1980; or Revision 2, dated July 16, 1982. Repeat that inspection thereafter at intervals not to exceed 1,200 landings until the inspection required by paragraph (e) of this AD is accomplished.

(b) After the effective date of this AD, perform the repetitive inspections required

by paragraph (a) of this AD only in accordance with the ultrasonic inspection method referenced in paragraph (a) of this AD.

(c) For Model 747 series airplanes listed in Boeing Service Bulletin 747–54–2101, dated April 11, 1983: Prior to the accumulation of 5,000 landings, or within 350 landings after January 9, 1984 (the effective date of AD 83–24–05, Amendment 39–4775), whichever occurs later, perform a visual or an ultrasonic inspection for cracks in the aft bottle bore fuse pin bore in recessed shear plane areas, in accordance with Boeing Service Bulletin 747–54–2101, dated April 11, 1983; or Revision 1, dated June 1, 1984. Repeat that inspection thereafter at intervals not to exceed 350 landings (if the previous inspection was visual) or 1,200 landings (if the previous inspection was ultrasonic) until the inspection required by paragraph (f) of this AD is accomplished.

(d) After the effective date of this AD, perform the repetitive inspections required by paragraph (b) of this AD only in accordance with the ultrasonic inspection method referenced in paragraph (b).

(e) For diagonal brace forward bottle bore fuse pins: Perform an ultrasonic inspection to detect cracks and a detailed visual inspection to detect corrosion in the forward bottle bore fuse pins located in the diagonal braces on the inboard and outboard engine struts from each end of the pin, in accordance with Boeing Alert Service Bulletin 747–54A2153, dated December 23, 1992, at the time specified in paragraph (e)(1) of this AD. Accomplishment of this inspection terminates the repetitive inspection requirements of paragraph (a) of this AD. Thereafter, repeat these inspections at intervals not to exceed 1,000 landings.

(1) Inspect all engine positions at the later of the times specified in paragraphs (e)(1)(i) and (e)(1)(ii) of this AD:

(i) Prior to the accumulation of 3,000 landings after the effective date of this AD, or within 3 years since pin installation, whichever occurs first, or

(ii) Within 90 days after the effective date of this AD.

Note: This AD does not require that these inspections be performed on forward 15–5 steel fuse pins or forward H–11 steel bolts in the diagonal brace.

(2) If any crack or corrosion is found as a result of the inspections required by paragraph (e) of this AD, prior to further flight, replace the cracked or corroded pin with a forward 15–5 steel fuse pin, in accordance with Boeing Alert Service Bulletin 747–54A2153, dated December 23, 1992. Installation of a forward 15–5 steel fuse pin constitutes terminating action for the repetitive inspections required by paragraph (e) of this AD.

(f) For diagonal brace aft bottle bore fuse pins and aft bulkhead fuse pins: Perform an ultrasonic inspection to detect cracks, and a detailed visual inspection to detect corrosion, in the aft bottle bore and aft bulkhead fuse pins in the diagonal brace on the inboard and outboard engine struts from each end of the pin, in accordance with Boeing Alert Service Bulletin 747–54A2153, dated December 23, 1992, at the time specified in paragraph (f)(1) of this AD. Accomplishment of this inspection terminates the repetitive inspection requirements of paragraph (c) of this AD.

(1) Inspect all engine positions at the later of the times specified in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD:

(i) Prior to the accumulation of 3,000 landings after the effective date of this AD, or within 3 years since pin installation, whichever occurs first, or

(ii) Within 90 days after the effective date of this AD.

(2) If any crack is found as a result of the inspections required by paragraph (f) of this AD, prior to further flight, replace the cracked pin with an aft bulkhead fuse pin, in accordance with Boeing Alert Service Bulletin 747–54A2153, dated December 23, 1992. Thereafter, accomplish the initial inspection required by paragraph (f) of this AD on the newly installed aft bulkhead fuse pin.

(3) If any corrosion is found as a result of the inspections required by paragraph (f) of this AD, prior to further flight, accomplish paragraph (f)(3)(i) or (f)(3)(ii) of this AD, as applicable.

(i) If corrosion is found in any aft bottle bore fuse pin: Replace with an aft bulkhead fuse pin, in accordance with Boeing Alert Service Bulletin 747–54A2153, dated December 23, 1992.

(ii) If corrosion is found in any aft bulkhead fuse pin: Accomplish paragraph (f)(3)(ii)(A), (f)(3)(ii)(B), or (f)(3)(ii)(C) of this AD, as applicable.

(A) If the amount of corroded material that must be removed exceeds the limit specified in Figure 8 of the service bulletin, replace the corroded fuse pin with an aft bulkhead fuse pin, in accordance with the service bulletin. Thereafter, accomplish the initial inspection required by paragraph (f) of this AD on the newly-installed aft bulkhead fuse pin.

(B) If the amount of corroded material that must be removed is more than light, and equal to or less than the limit specified in Figure 8 of the service bulletin, rework the corroded fuse pin, or replace the corroded fuse pin with an aft bulkhead fuse pin, in accordance with the service bulletin. "Light" corrosion is characterized by discoloration or pitting to a depth of not more than 0.001-inch maximum. This type of corrosion can be removed normally by light hand sanding. A fuse pin that has been reworked in accordance with Figure 8 of the service bulletin must be replaced with an aft bulkhead fuse pin prior to the accumulation of 3,000 landings on the pin, or 3 years since the pin was reworked and reinstalled, whichever occurs first.

(C) If the corrosion is light, remove the corroded material from the fuse pin in accordance with the service bulletin. Thereafter, accomplish the repetitive inspections required by paragraph (f)(4) of this AD.

(4) Repeat the inspections required by paragraph (f) of this AD at the intervals specified in paragraph (f)(4)(i) or (f)(4)(ii) of this AD, as applicable:

(i) For aft bottle bore fuse pins: Repeat at intervals not to exceed 1,000 landings.

(ii) For aft bulkhead fuse pins: Repeat at intervals not to exceed 2,000 landings.

(g) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(h) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(i) The inspections, replacement, and repair shall be done in accordance with the following Boeing service bulletins, as applicable, which contain the specified effective pages:

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
747–54–2006, November 7, 1979	1–7	Original	November 7, 1979.
747–54–2086, Revision 1, October 10, 1980	1–27	1	October 10, 1980.
747–54–2086, Revision 2, July 16, 1982	1–17, 20, 27	2	July 16, 1982.
	18–19, 21–16	1	October 10, 1980.
747–54–2101, April 11, 1983	1–27	Original	April 11, 1983.
747–54–2101, Revision 1, June 1, 1984	1–23	1	June 1, 1984.
747–54A2153, December 23, 1992	1–56	Original	December 23, 1992.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the

Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(j) This amendment becomes effective on February 5, 1993.

Issued in Renton, Washington, on December 24, 1992.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93-175 Filed 1-5-93; 8:45 am]

BILLING CODE 4910-13-U

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14 CFR Part 39

[Docket No. 92-NM-234-AD; Amendment 39-8458; AD 93-01-04]

Airworthiness Directives; Boeing Model 747 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing airworthiness directive (AD), applicable to certain Boeing Model 747 series airplanes, that currently requires repetitive ultrasonic inspections to detect cracks in the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. This amendment reduces certain inspection intervals, removes the optional terminating action for repetitive inspections of the lugs, and adds airplanes to the applicability of the AD. This amendment is prompted by seven reports of fatigue cracking on lugs and numerous reports of lug bushing migration. The actions specified in this AD are intended to prevent failure of the engine support structure and the inability of the strut to carry required engine support loads.

DATES: Effective February 5, 1993.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 5, 1993.

Comments for inclusion in the Rules Docket must be received on or before March 8, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 92-NM-234-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

The service information referenced in this AD may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Tim Backman, Aerospace Engineer, Seattle Aircraft Certification Office, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2776; fax (206) 227-1181.

SUPPLEMENTARY INFORMATION: On October 10, 1985, the FAA issued AD 85-22-07, Amendment 39-5153 (50 FR 42146, October 18, 1985), to require repetitive ultrasonic inspections to detect cracks in the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. That action was prompted by a report of the failure of both lugs on the inboard midspar fitting of an inboard strut on a Boeing Model 747 series airplane that had accumulated approximately 44,000 flight hours and 11,300 landings. The actions required by that AD are intended to prevent failure of the strut midspar fitting lugs or spring beam aft lugs.

Since the issuance of that AD, the FAA has received seven reports of fatigue cracking on lugs. One of these reports involved a failed lug that was found on the inboard midspar fitting of an inboard strut on a Model 747 series airplane that had accumulated 1,724 landings since its last ultrasonic inspection accomplished in accordance with AD 85-22-07. The FAA concludes that the repetitive inspection interval must be reduced from the currently required 3,000 landings to 1,000 landings in order to adequately address cracking of the midspar fitting lugs.

Although the operational loads environment of the spring beam aft lugs is similar to that of the midspar fitting lugs, there have been no reports of cracks in the spring beam aft lugs. Therefore, the FAA concludes that the existing inspection interval of 3,000 landings is adequate to address cracking of these spring beam aft lugs.

Two types of bushings are installed currently on Model 747 series airplanes: (1) Press-fit bushings, and (2) roller-swaged, shrink-fitted bushings. Recently, the FAA has received numerous reports of migration of press-fit and roller-swaged, shrink-fitted bushings. The FAA has determined that migration of the bushings could result in moisture ingression and subsequent corrosion of the lugs. Operator reports indicate that lug cracking initiated from corrosion pits. Cracking of the lugs, if not detected and corrected, could result in failure of the engine support structure and the inability of the strut to carry required engine support loads.

The FAA has reviewed and approved Boeing Alert Service Bulletin 747-54A2152, dated December 23, 1992, which describes procedures for repetitive ultrasonic inspections to detect cracks on the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. The service bulletin also describes repetitive detailed visual inspections of the inboard and outboard struts to detect bushing migration and corrosion, and repair, if necessary.

In light of the recent reports discussed previously, the FAA has determined that the initial and repetitive inspection intervals for ultrasonic inspections of the midspar fitting lugs, as specified currently in AD 85-22-07, must be reduced.

That AD also specifies that installation of roller-swaged, shrink-fitted bushings constitutes terminating action for repetitive ultrasonic inspections of the lugs. However, since reports of the migration of roller-swaged, shrink-fitted bushings have been received, the FAA has determined that a detailed visual inspection to detect migration of these bushings is necessary.

Roller-swaged, shrink-fitted bushings that have migrated are susceptible to the addressed unsafe condition and are subject to the requirements of this AD. Therefore, those airplanes equipped with roller-swaged, shrink-fitted bushings are included in the applicability statement of this AD.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of this same type design, this AD supersedes AD 85-22-07 to require repetitive ultrasonic inspections to detect cracks on the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut, and replacement of midspar fittings or spring beams, if necessary. This AD also requires repetitive detailed visual inspections of the inboard and outboard struts to detect bushing migration and corrosion, and repair, if necessary.

Currently, the FAA is conducting a review of the wing-to-strut attachment structure on Boeing Model 747 series airplanes and may consider further rulemaking as additional data becomes available.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified under the caption "ADDRESSES." All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92–NM–234–AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–5153 (50 FR 42146, October 10, 1985), and by adding a new airworthiness directive (AD), amendment 39–8458, to read as follows:

93–01–04 Boeing: Amendment 39–8458. Docket 92–NM–234–AD. Supersedes AD 85–22–07, Amendment 39–5153.

Applicability: All Model 747 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

Note: Paragraph (a) of this AD restates the inspection requirements of AD 85–22–07, Amendment 39–5153. As allowed by the phrase, "unless accomplished previously," if the initial inspection requirements of AD 85–22–07 have been accomplished previously, paragraph (a) of this AD does not require the initial inspection to be repeated.

To prevent failure of the engine support structure and the inability of the strut to carry required engine support loads, accomplish the following:

(a) For Model 747 series airplanes listed in Boeing Service Bulletin 747–54–2100, dated June 20, 1983: Perform an ultrasonic inspection of the inboard and outboard midspar fitting lugs or spring beam aft lugs of each strut for cracks, in accordance with Boeing Service Bulletin 747–54–2100, dated June 20, 1983; Revision 1, dated August 25, 1988; Revision 2, dated July 20, 1989; or Revision 3, dated November 16, 1989; at the time specified in paragraph (a)(1), (a)(2), (a)(3), or (a)(4) of this AD. Repeat that inspection thereafter at intervals not to exceed 3,000 landings until the inspection required by paragraph (b) of this AD is accomplished.

(1) For airplanes that have accumulated less than 30,000 flight hours as of November 24, 1985 (the effective date of AD 85–22–07, Amendment 39–5153), inspect within 18 months after November 24, 1985, or prior to the accumulation of 25,000 flight hours, whichever occurs later.

(2) For airplanes that have accumulated 30,000 or more flight hours, but less than 40,000 flight hours, as of November 24, 1985 (the effective date of AD 85–22–07, Amendment 39–5153), inspect within 12 months after November 24, 1985.

(3) For airplanes that have accumulated 40,000 or more flight hours as of November 24, 1985 (the effective date of AD 85–22–07, Amendment 39–5153), inspect within 6 months after November 24, 1985.

(4) For airplanes on which the midspar fitting or its lug bushings have been replaced, or on which the spring beam or its aft lug bushings have been replaced, inspect those lugs within 18 months after November 24, 1985 (the effective date of AD 85–22–07, Amendment 39–5153), or within 25,000 flight hours after such replacement, whichever occurs later.

(b) For airplanes equipped with midspar fittings with press-fit bushings; and for airplanes equipped with spring beam lugs with press-fit bushings, as listed in Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992: Perform an ultrasonic inspection of the midspar fitting lugs or spring beam aft lugs of each strut for cracks, and a detailed visual inspection for corrosion of the lugs and bushing migration, in accordance with Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992, at the applicable times specified in paragraphs (b)(1) and (b)(2) of this AD. Accomplishment of this inspection terminates the repetitive inspection requirement of paragraph (a) of this AD.

(1) Inspect inboard engine positions 2 and 3 at the later of the times specified in paragraph (b)(1)(i) or (b)(1)(ii) of this AD:

(i) Prior to the accumulation of 5,000 landings on the midspar fitting lugs or spring beam, or within 5 years since installation, whichever occurs first. Or

(ii) Within 60 days after the effective date of this AD.

(2) Inspect outboard engine positions 1 and 4 at the later of the times specified in paragraph (b)(2)(i) or (b)(2)(ii) of this AD:

(i) Prior to the accumulation of 5,000 landings on the midspar fitting lugs or spring beam, or within 5 years since installation, whichever occurs first. Or

(ii) Within 90 days after the effective date of this AD.

(c) For airplanes having midspar fittings or spring beam lugs delivered with roller-

swaged, shrink-fitted bushings, as listed in Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992, or installed in accordance with Boeing Service Bulletin 747–54–2100, dated June 20, 1983; Revision 1, dated August 25, 1988; Revision 2, dated July 20, 1989; or Revision 3, dated November 16, 1989: Perform a detailed visual inspection of the midspar fitting lugs or spring beam aft lugs of each strut for corrosion of the lugs and bushing migration, in accordance with Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992, at the later of the times specified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Prior to the accumulation of 5,000 landings on the midspar fitting lugs or spring beam, or within 5 years since installation, whichever occurs first. Or

(2) Within 90 days after the effective date of this AD.

(d) If any migrated bushing is found as a result of the inspection of lugs with roller-swaged, shrink-fitted bushings required by paragraph (c) of this AD, prior to further flight, perform an ultrasonic inspection of the midspar fitting lugs or spring beam aft lugs for cracks, in accordance with Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992.

(e) If any crack is found in the lugs as a result of any inspection required by paragraph (b), (c), or (d) of this AD, prior to further flight, replace the affected midspar fitting or spring beam in accordance with Boeing Service Bulletin 747–54–2100, dated June 20, 1983; Revision 1, dated August 25, 1988; Revision 2, dated July 20, 1989; or Revision 3, dated November 16, 1989.

(f) If any migrated bushing is found as a result of any inspection required by paragraph (b) or (c) of this AD, prior to further flight, re-seal the bushing in accordance with Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992. Prior to the accumulation of 1,000 additional landings after detecting the migrated bushing, re-work the fitting in accordance with Figure 5 of the service bulletin.

(g) If any corrosion is found as a result of any inspection required by paragraph (b) or (c) of this AD, prior to further flight, remove the corrosion in accordance with Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992.

(h) Repeat the inspections required by paragraphs (b) and (c) of this AD at the applicable time specified in paragraph (h)(1) or (h)(2) of this AD.

(1) For midspar fitting lugs, as listed in Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992: At intervals not to exceed 1,000 landings. Or

(2) For spring beam aft lugs, as listed in Boeing Alert Service Bulletin 747–54A2152, dated December 23, 1992: At intervals not to exceed 3,000 landings.

(i) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(j) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(k) The inspections, replacement, and repair shall be done in accordance with the following Boeing service bulletins, as applicable, which contain the specified effective pages:

Service bulletin referenced and date	Page No.	Revision level shown on page	Date shown on page
747–54–2100, June 20, 1983	1–153	Original	June 20, 1983.
747–54–2100, Revision 1, August 25, 1988	1–6, 8–9, 24, 27, 33, 70	1	August 25, 1988.
	7, 10–23, 25–26, 28–32, 34–69, 71–153.	Original	June 20, 1983.
747–54–2100, Revision 2, July 20, 1989	1–6, 8–11, 16, 21	2	July 20, 1989.
	24, 27, 33, 70	1	August 25, 1988.
	7, 12–15, 17–20, 22–23, 25–26, 28–32, 34–69, 71–153.	Original	June 20, 1983.
747–54–2100, Revision 3, November 16, 1989	1–6, 8–11, 16, 26–27, 32	3	November 16, 1989.
	21	2	July 20, 1989.
	24, 33, 70	1	August 25, 1988.
	7, 12–15, 17–20, 22–23, 25, 28–31, 34–69, 71–153.	Original	June 20, 1983.
747–54A2152, December 23, 1992	1–49	Original	December 23, 1992.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(l) This amendment becomes effective on February 5, 1993.

Issued in Renton, Washington, on December 24, 1992.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–176 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 771, 773, 774, 776, 779, and 785

[Docket No. 921082–2282]

Exports to Afghanistan; Special Country Policies

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: On June 3, 1980, the Department of Commerce announced that in response to the Soviet invasion of Afghanistan, applications for licenses to export to Afghanistan were being reviewed on the assumption that commodities and technical data sent to that country would be available to the U.S.S.R. (45 FR 37415). Validated licensing requirements for Afghanistan were therefore made virtually identical to those in force for the U.S.S.R. However, since that time the Soviet military withdrew from Afghanistan, and the Department of State has determined that there is no longer a need for this special treatment of Afghanistan. The Bureau of Export Administration is therefore amending the Export Administration Regulations (EAR) to correctly reflect this change in policy.

EFFECTIVE DATE: This rule is effective on January 6, 1993.

FOR FURTHER INFORMATION CONTACT:

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David Schlechty, Foreign Policy Branch, Office of Technology and Policy Analysis, Bureau of Export Administration, Telephone: (202) 482–4252.

SUPPLEMENTARY INFORMATION:

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0694–0005 and 0694–0010. This rule may slightly increase the number of export license applications.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a military or foreign affairs function of the United States. No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Nancy Crowe, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, room 4054, 14th Street and Pennsylvania Ave., NW., Washington, DC 20230.

List of Subjects

15 CFR Parts 771, 773, 774, 776

Exports, Reporting and recordkeeping requirements.

15 CFR Part 779

Computer technology, Exports, Reporting and recordkeeping requirements, Science and technology.

15 CFR Part 785

Exports.

PARTS 771, 773, 774, 776, 779, and 785—[AMENDED]

Accordingly, parts 771, 773, 774, 776, 779, and 785 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

1. The authority citation for 15 CFR parts 771 and 774 continues to read as follows:

Authority: Public Law 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Public Law 93–153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Public Law 94–163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Public Law 94–258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Public Law 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Public Law 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Public Law 95–372, 92 Stat. 668 (43 U.S.C. 1354); Public Law 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; sec. 125, Public Law 99–64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

2. The authority citation for 15 CFR parts 773, 779 and 785 continues to read as follows:

Authority: Public Law 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; Public Law 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Public Law 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); Public Law 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 2, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

3. The authority citation for 15 CFR part 776 continues to read as follows:

Authority: Public Law 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; Public Law 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Public Law 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); Public Law 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; sec. 125, Public Law 99–64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

4. The term "Afghanistan" is removed from the following places:

Sec.
773.7(d)(2)(ii) heading and introductory text
773.7(d)(2)(ii)(A)
773.7(d)(2)(ii)(C)
773.7(h)(1)(ii)
773.7(i) heading and introductory text
773.7(i)(2)
773.7(i)(6)
773.7(k) introductory text
773.7(k) concluding text

5. The phrase "Afghanistan," is removed from the following places:

Sec.
771.23(b)
773.3(a)(1)(ii)
773.3(d)(3)(iii)(D)
776.8(b)(1)(ii)
776.8(b)(1)(iii)
776.10(a)(1)

6. The phrase "or Afghanistan" is removed from the following places:

Sec.
773.7(i)(1)
774.5(a)
779.4(f)(1)(i)
779.4(f)(1)(iii)
779.4(f)(2)(i)
779.4(f)(2)(iii)
779.5(e)(1)(vii)

7. The phrase "Afghanistan, Iran, and" is revised to read "Iran and" in the following places:

Sec.
773.7(d)(1) introductory text
773.7(d)(2)(i) [three references]
773.7(d)(2)(ii) introductory text
773.7(d)(3) introductory text [two references]
773.7(h)(1)(ii)

PART 773—[AMENDED]

8. Section 773.3 is amended by removing the phrase ", Afghanistan" from paragraph (e)(1)(ix)(I).

§ 773.7 [Amended]

9. Section 773.7 is amended:

a. By removing the phrase "Afghanistan and" from paragraph (c)(2) heading and text [two references];

b. By removing the phrase ", and Afghanistan" from paragraph (d)(1), introductory text;

c. By removing the phrase "and Afghanistan" from paragraph from footnote no. 2 to paragraph (h)(1)(i); and

d. By removing the phrase ", or to Afghanistan" from paragraph (i)(4).

§ 773.8 [Amended]

10. Section 773.8 is amended by removing the phrase "or Afghanistan," from paragraph (a)(2), introductory text.

§ 773.8 [Amended]

11. Section 773.8 is amended by removing the phrase ", Afghanistan" from paragraph (c)(1).

PART 779—[AMENDED]

12. Section 779.5 is amended:

a. By revising the phrase "the People's Republic of China, or Afghanistan" in paragraph (e)(2) the first place it appears to read "or the People's Republic of China"; and

b. By removing the phrase ", or Afghanistan" from the end of the first sentence in paragraph (e)(2).

PART 785—[AMENDED]

13. Section 785.4 is amended:

a. By removing paragraph (f); and

b. By redesignating paragraph (g) as paragraph (f).

Dated: December 31, 1992.

James M. LeMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93–161 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DT–M

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15 CFR Parts 771 and 777

[Docket No. 910480–2266]

Western Red Cedar

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) by adding a new General License GLOG, which authorizes exports of unprocessed western red cedar, and by revising the short supply provisions of the EAR to remove the individual validated licensing requirements for exports of unprocessed western red cedar harvested from: Federal, State, and other public lands in Alaska, lands held in trust by any Federal or State official or agency for a recognized Indian tribe, or private lands. In addition, this rule amends the short supply provisions of the EAR by revising the licensing procedures and recordkeeping requirements for exports of unprocessed western red cedar.

Unprocessed western red cedar harvested from Federal or State lands (except lands in the State of Alaska and lands held in trust for recognized Indian tribes by Federal or State agencies) continues to require a validated license. Applications to export unprocessed western red cedar harvested from these public lands will be reviewed with a presumption of denial.

This rule also revises the definition of processed western red cedar to exclude any individual piece of western red cedar having a cross section that exceeds 2,000 square centimeters (310 square inches), regardless of grade.

BXA expects the new General License GLOG to eliminate individual validated licensing for approximately $78 million of annual exports.

EFFECTIVE DATE: This rule is effective January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Bernard Kritzer, Office of Foreign Availability (OFA), Bureau of Export Administration, Telephone: (202) 482–0074.

SUPPLEMENTARY INFORMATION:

Background

The Department of Commerce administers export controls, under section 7(i) of the Export Administration Act [1] (EAA), as amended, on western red cedar. Section 777.7 of the Export Administration Regulations (EAR) formerly required an individual validated license to export all unprocessed western red cedar (WRC) timber, with a presumption of denial for WRC timber harvested from public lands located outside the state of Alaska. This final rule amends the EAR:

(1) By revising § 777.7 to remove the individual validated licensing requirements for exports of unprocessed western red cedar harvested from private lands, Indian lands, or Federal, State, and other public lands in Alaska;

(2) By adding § 771.7, which authorizes exports of this unprocessed western red cedar under a new General License GLOG; and

(3) By revising, in § 777.7, certain licensing procedures and recordkeeping requirements for exports of unprocessed red cedar.

These changes are consistent with those contained in the proposed rule on western red cedar that BXA published in the **Federal Register** on June 3, 1991 (56 FR 25054).

Exports of unprocessed western red cedar harvested from Federal and State lands (except lands in the State of Alaska and lands held in trust for recognized Indian tribes by Federal or State agencies) continue to require a validated license. A presumption of denial exists for such timber if it was harvested under harvest contracts entered into after September 30, 1979.

This rule also revises the definition of processed western red cedar. Previously, the licensing requirements of § 777.7 did not apply to WRC timber that had been processed into lumber of American Lumber Standards, Grades of Number 3 or better, or Pacific Lumber Inspection Bureau of Export R-List Grades of Number 3 dimension common or better. This rule revises the definition of processed western red cedar in § 777.7 to limit the maximum cross section for any individual piece of western red cedar that may be exported as processed lumber to 2,000 square centimeters (310 square inches), regardless of grade.

This clarification conforms with the comments submitted by the U.S. Department of Agriculture's Forest Service Pacific Northwest Region (Forest Service) on the June 3, 1991, proposed rule. The Forest Service comments, which were the only comments received on the proposed rule, supported the establishment of a limit, based on product size (2,000 square centimeter or 310 square inch cross section), to distinguish between processed and unprocessed western red cedar, but indicated that the proposed rule was unclear as to whether the 310 square-inch cross section limitation applied to "Number 3 Common or Better" lumber as a single grade, or "Number 3 Common" and all higher (or better) grades of lumber. The Forest Service suggested that the size limitation apply to any piece of timber, regardless of grade. BXA agrees with this interpretation and believes that it is consistent with the intent of the statute to restrict the maximum size, with or without wane, that can be considered to be processed western red cedar lumber and, therefor, not subject to the licensing requirements described in § 777.7.

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). This collection has been approved by the Office of Management and Budget under control number 0694–0005. This rule also contains a collection of information that has been approved by OMB under control number 0694–0025 and new recordkeeping requirements for

[1] Although the Export Administration Act of 1979 (EAA), as amended, expired on September 30, 1990, the President invoked the International Emergency Economic Powers Act and continued in effect, to the extent permitted by law, the provisions of the EAA and the Export Administration Regulations in Executive Order 12730 of September 30, 1990.

exporters using the General License GLOG that have been approved by OMB under control number 0694–0065. Public burden hours for these information collection and recordkeeping requirements is estimated to average 30 minutes for the collection of information under 0694–0025 and 1 hour for the new recordkeeping requirement 0694–0065. This includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding these burden estimates or any other aspect of the data requirements, including suggestions for reducing these burdens, to the Office of Security and Management Support, Bureau of Export Administration, U.S. Department of Commerce, Washington, DC 20230; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (ATTN: Paperwork Reduction Project—0694–0025 and/or 0694–0065).

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. The General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. The establishment of General License GLOG is expected to result in the export licensing decontrol of approximately $75 million to $80 million (extrapolated from 1989 data) of unprocessed western red cedar harvested from private lands and Indian lands, as well as Federal, State, and other public lands in Alaska. This amount represents approximately one to one and one-half percent of the $6 billion dollar value of United States exports of forest products during 1990. As a result, no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking and the opportunity for public participation have been satisfied because this rule was issued in proposed form and comments were considered in the development of this final rule. Moreover, because this rule relieves certain licensing burdens on exporters, there is good cause for making it effective immediately.

Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Willard Fisher, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR Part 771

Exports, Reporting and recordkeeping requirements.

15 CFR Part 777

Administrative practice and procedure, Exports, Forest and forest products, Petroleum, Reporting and recordkeeping requirements.

Accordingly, parts 771 and 777 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

1. The authority citation for 15 CFR part 771 is revised to read as follows:

Authority: Pub. L. 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Pub. L. 93–153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Pub. L. 94–163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Pub. L. 94–258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Pub. L. 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Pub. L. 95–372, 92 Stat. 668 (43 U.S.C. 1354); Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; sec. 125, Pub. L. 99–64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978; E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

2. The authority citation for 15 CFR part 777 is revised to read as follows:

Authority: Pub. 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Pub. L. 93–153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Pub. L. 94–163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Pub. L. 94–258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Pub. L. 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Pub. L. 95–372, 92 Stat. 668 (43 U.S.C. 1354); Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12058 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

PART 771—[AMENDED]

3. Section 771.7 (formerly reserved) is added to read as follows:

§ 771.7 General License GLOG; Unprocessed western red cedar timber harvested from public lands in Alaska, private lands, and Indian lands.

(a) *Scope.* A General License GLOG is established, subject to the provisions of this section (including the recordkeeping requirements described in paragraph (b)), authorizing the export of unprocessed western red cedar timber harvested from Federal, State and other public lands in Alaska, all private lands, and lands held in trust for recognized Indian tribes by Federal or State agencies.

(b) *Recordkeeping requirements.* Exporters who use General License GLOG must obtain and retain on file the documents described in paragraphs (b)(1) and (b)(2) of this section. These documents must be maintained in accordance with the recordkeeping requirements of § 787.13 of this subchapter.

(1) A statement by the exporter (or other appropriate documentation) indicating that the unprocessed western red cedar timber exported under GLOG was not harvested from State or Federal lands outside the State of Alaska, and did not become available for export through substitution of commodities so harvested or produced. If the exporter did not harvest or produce the timber, the records or statement must identify the harvester or producer and must be accompanied by an identical statement from the harvester or producer. If any intermediate party or parties held title to the timber between harvesting and purchase, the exporter must also obtain such a statement, or equivalent documentation, from the intermediate party or parties and retain it on file. The exporter shall retain this documentation in the files for the period prescribed in § 787.13(e).

(2) A certificate of inspection issued by a third party log scaling and grading organization, approved by the United States Forest Service, that:

(i) Specifies the quantity in cubic meters or board feet, scribner rule, of unprocessed western red cedar timber to be exported; and

(ii) Lists each type of brand, tag, and/or paint marking that appears on any log

or unprocessed lumber in the export shipment or, alternatively, on the logs from which the unprocessed timber was produced.

Note: See § 777.7 for the definition of unprocessed red cedar.

PART 777—[AMENDED]

4. Section 777.7 is revised to read as follows:

§ 777.7 Unprocessed western red cedar.

(a) *General.* The export of unprocessed western red cedar timber, as defined in paragraph (b) of this section, from the United States to any destination, including Canada, is prohibited, except pursuant to a validated license issued by the Office of Export Licensing, unless the timber was harvested from public lands in the State of Alaska, private lands, or Indian lands, and otherwise meets the requirements for export under General License GLOG (see § 771.7 of this subchapter).

(b) *Licensing policy.* (1) The Office of Export Licensing will generally deny applications for individual validated licenses to export unprocessed western red cedar harvested from Federal or State lands under harvest contracts entered into after September 30, 1979.

(2) The Office of Export Licensing will consider, on a case-by-case basis, applications for individual validated licenses to export unprocessed western red cedar harvested from Federal or State lands under harvest contracts entered into prior to October 1, 1979.

(c) *Definitions.* When used in this section, the following terms have the meaning indicated:

(1) *Unprocessed western red cedar* means western red cedar (thuja plicata) timber, logs, cants, flitches, and processed lumber containing wane on one or more sides, as defined in ECCN 1C88D, that has not been processed into:

(i) Lumber of American Lumber Standards Grades of Number 3 dimension or better, or Pacific Lumber Inspection Bureau Export R-List Grades of Number 3 common or better grades, with a maximum cross section of 2,000 square centimeters (310 square inches) for any individual piece of processed western red cedar (WRC) being exported, regardless of grade;

(ii) Chips, pulp, and pulp products;

(iii) Veneer and plywood;

(iv) Poles, posts, or pilings cut or treated with preservative for use as such and not intended to be further processed; and

(v) Shakes and shingles.

(2) *Federal and State lands* means Federal and State lands, excluding lands in the State of Alaska and lands held in trust by any Federal or State official or agency for a recognized Indian tribe or for any member of such tribe.

(3) *Contract harvester* means any person who, on October 1, 1979, had an outstanding contractual commitment to harvest western red cedar timber from State and Federal lands and who can show by previous business practice or other means that the contractual commitment was made with the intent of exporting or selling for export in unprocessed form all or part of the commodities to be harvested.

(4) *Producer* means any person engaged in a process that transforms an unprocessed western red cedar commodity (e.g., western red cedar timber) into another unprocessed western red cedar commodity (e.g., cants) primarily through a saw mill.

(d) *Application for export license.* (1) Applicants to export unprocessed western red cedar must submit a properly completed Form BXA-622P, Application for Export License, other documents as may be required by the Office of Export Licensing, and a signed statement from an authorized representative of the exporter, reading as follows:

I, _____
(Name)

_____
(Title)

of _____
(Exporter)

Hereby Certify that to the best of my knowledge and belief the

_____
(Quantity)

(cubic meters or board feet scribner) of unprocessed western red cedar timber that

_____
(Exporter)

proposes to export was not harvested from State or Federal lands under contracts entered into after October 1, 1979.

_____
(Signature)

_____
(Date)

(2) For Items 6 and 7 on Form BXA-622P, "Various" may be entered when there is more that one purchaser or ultimate consignee.

(e) *Supporting documentation.* For each Form BXA-622P submitted, and for each export shipment made under the authority of a validated export license, the exporter must assemble and retain for the period prescribed in § 787.13(e) of this subchapter, and produce or make available for inspection as provided in § 787.13(f), the following:

(1) A signed statement(s) by the harvester or producer, and each subsequent party having held title to the commodities, that the commodities in question were harvested under a contract to harvest unprocessed western red cedar from State or Federal lands, entered into before October 1, 1979; and

(2) A copy of the Shipper's Export Declaration.

(f) *Shipping tolerance.* A shipping tolerance of 5 percent in cubic feet or board feet scribner is allowed on the unshipped balance of a commodity listed on an individual validated license. This tolerance applies only to the final quantity remaining unshipped on a license against which more than one shipment is made and not to the original quantity authorized by such license. (See § 786.7 of this subchapter.)

(g) *Communications.* Questions concerning applications to export unprocessed western red cedar under this section, and the specific documentation requirements, should be directed to the Bureau of Export Administration at the address provided in § 772.1(e) of this subchapter.

Dated: December 30, 1992.

James M. DeMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93-231 Filed 1-5-93; 8:45 am]

BILLING CODE 3510-DT-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 2

[Docket No. FA88-62-001]

Order Denying Interlocutory Appeal and Amending Policy Statement Concerning Disclosure of Documents and Information Obtained in Staff Audits

Issued December 28, 1992.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule; policy statement.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending its regulations which authorized disclosure of information in cases under the Natural Gas Act scheduled for formal hearing if the information is relevant to the case. The Commission is extending the provisions of those regulations to Commission

proceedings under the Federal Power Act and under the Interstate Commerce Act as it applies to the regulation of oil pipelines. The Commission found that the authorization of the release of information specified in a prior policy statement for natural gas proceedings and the underlying rationale are equally applicable in other Commission proceedings.

EFFECTIVE DATE: This final rule is effective December 28, 1992.

FOR FURTHER INFORMATION CONTACT: Kasha Cieglo, Office of General Counsel, Federal Energy Regulatory Commission, 825 North Capitol St., NE., Washington, DC 20426, Telephone: (202) 208–2165.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the Federal Register, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in the Commission's Public Reference Room, room 3104, 941 North Capitol St., NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this final rule will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, LaDorn Systems Corporation, also located in room 3104, 941 North Capitol St., NE., Washington, DC 20426.

I. Background

On November 16, 1992, Wisconsin Electric Power Company (Company) filed an interlocutory appeal of the presiding judge's denial of a motion to permit appeal rendered on November 9, 1992. On November 23, 1992, the Chairman, as the Motions Commissioner, determined, pursuant to Rule 715 of the Commission's Rules of Practice and Procedure, 18 CFR 385.715, that extraordinary circumstances existed which made prompt Commission review of the contested rulings necessary to prevent detriment to the public interest or irreparable harm to any person, warranting referral to the Commission of the Company's interlocutory appeal.

A. The Case

On February 4, 1992, the Chief Accountant issued an audit report under delegated authority summarizing the results of an audit performed by the Office of Chief Accountant's Division of Audits. Wisconsin Electric Power Company, 58 FERC ¶ 62,121 (1992). The Chief Accountant noted the Company's disagreement with one item included in the report, regarding the accounting and fuel adjustment clause billings for coal mine reclamation costs. 58 FERC at 63,350, 63,357–60. In response to a request from the Chief Accountant regarding disposition of the question, the Company initially advised the Commission that it consented to the shortened procedures provided under section 41.3 of the Commission's regulations. 18 CFR 41.3. Accordingly, on March 30, 1992, the Commission issued an Order Instituting Proceedings under part 41 of the Commission's Regulations. Wisconsin Electric Power Company, 58 FERC ¶ 61,332 (1992). On April 22, 1992, the Company filed a motion for termination of the shortened procedures under part 41 and for a hearing under part 385. Accordingly, on May 14, 1992, the Commission set the accounting issue for evidentiary hearing. Wisconsin Electric Power Company, 59 FERC ¶ 61,184 (1992). On August 19, 1992, the Commission issued an order expanding the scope of the hearing to include prudence issues. Wisconsin Electric Power Company, 60 FERC ¶ 61,181 (1992).

1. The Legal Opinions at Issue

In October 1990, at the request of audit staff, the Company provided a copy of four opinions rendered by its in-house and outside legal counsel concerning the coal mine reclamation costs dispute. In a letter to the audit staff dated October 25, 1990, the Company asserted that the opinions involved factual and legal analysis by its attorneys and so constituted privileged working papers and attorney-client communications. Nonetheless, "in order to resolve the issue," the Company provided the opinions to audit staff, "on the condition that the opinions be kept confidential, not reproduced, and returned to the Company when [the] audit is closed." The Company requested privileged and confidential treatment of the documents under 18 CFR 388.112.[1]

When trial staff advised the Company that it proposed to use the documents in evidence and under seal, the Company asserted that trial staff had no right to use the documents.[2]

2. The Presiding Judge's Orders

On September 29, 1992, trial staff filed a motion requesting a conference to resolve the status of the four opinions. Trial staff argued that the Company's voluntary disclosure of the documents to the audit staff waived any attorney-client or work product privilege that might apply to the documents. On October 9, 1992, the Company filed an answer opposing trial staff's request to use the privileged documents, arguing that the Company waived neither the attorney-client nor work product privilege and that the documents should not be used in the trial staff's prudence evidence.

At a prehearing conference on October 15, 1992, the presiding judge granted the relief requested in the trial staff's motion. The judge adopted what he called the "majority view" that, once the documents were voluntarily disclosed, the privilege is waived, even if the third-party agrees not to disclose the information to anyone else. The judge cited as support cases from the District of Columbia and Third Circuits: *Permian Corporation* v. *United States*, 665 F.2d 1214 (D.C. Cir. 1981) (Permian) and *Westinghouse Electric Corporation* v. *Republic of the Philippines*, 951 F.2d 1414 (3d Cir. 1991) (*Westinghouse*). Tr. 20, 21. The judge considered the rejected the Eighth Circuit's limited waiver analysis relied upon by the Company: *Diversified Industries, Inc.* v. *Meredith*, 572 F.2d 596 (8th Cir. 1977) (Diversified). Tr. 21.[3]

The judge declined to follow Diversified for two reasons. First, in the case at bar, there was no agreement on the part of trial staff to keep the information confidential. The Company merely requested confidential treatment pursuant to section 388.112, which does not insure a document's confidentiality. Tr. 21. The judge added that, although section 388.112 provides that the Commission will place materials it receives under a request for privileged

[1] Section 388.112 provides that a party submitting a document to the Commission may request privileged treatment by claiming that all or part of the information is exempt from Freedom of Information Act (FOIA) requirements and should be withheld from public disclosure.

[2] The Company also objected to an intervenor's discovery requests seeking the legal opinions.

[3] In Diversified, the company voluntarily surrendered privileged material to the Securities and Exchange Commission (SEC). The court concluded that only a limited waiver of the attorney-client privilege had occurred, reasoning that to hold otherwise may have the effect of thwarting the developing procedure of corporations to employ independent outside counsel to investigate and advise them in order to protect stockholders, potential stockholders and customers. Diversified, 572 F.2d at 612.

treatment in a non-public file, it also provides that this is not a determination on any claim or privilege and that the "Commission retains the right to make determinations with regard to any claim or privilege, and the discretion to release information as necessary to carry out its jurisdictional responsibilities." *Id.*, discussing and quoting 18 CFR 388.112.

Second, the judge followed the Permian and Westinghouse line of cases which specifically reject Diversified's "limited" or "selective" waiver theory. Tr. 22. The judge noted that, the Permian court rejected Diversified's selective waiver because it has little to do with the purpose of the attorney-client privilege, and because voluntary cooperation with government investigations does not improve the attorney-client relationship. Permian, 665 F. 2d at 1220–21. Tr. 22. The judge found that, once the attorney-client privilege is waived, it is waived for all purposes. As a Permian, the Company may not pick and choose as to the issues to which the privilege still attaches. *Id.*

The presiding judge also rejected the Company's argument that section 301(b) of the Federal Power Act (FPA), 16 U.S.C. § 825(b) (1988), prohibits release of the documents. The judge explained that section 301(b) provides that information received by staff in the course of an audit shall be kept confidential unless ordered to be disclosed by a Commission or court order. Tr. 22–23. The judge reasoned that the Commission's two hearing orders in this case are sufficient to satisfy the requirements of section 301(b) and to authorize the use of the documents received by audit staff in this investigation. Tr. 22–24, 26. The judge relied on the Federal Power Commission decision in Availability of Information Acquired By Staff Investigation, Order No. 509–A, 52 FPC 389 (1974), involving a statement of policy that the Commission was not going to assume a case-by-case determination of when information garnered by staff in various investigations should be released, but was authorizing as a matter of policy that the information can be released and not kept confidential. The judge noted that, while this statement of policy was issued under the National Gas Act, in adopting this statement of policy the Commission has relied on the legislative history of section 301(b) of the Federal Power Act. Tr. 23–24.

The judge added that he was willing to proceed with use of the information pursuant to a protective order, but would retain his right to re-examine the question of whether the information should be protected once he had viewed the documents. TR 24–25.

On October 30, 1992, the Company filed a motion to permit an interlocutory appeal to the Commission, from the presiding judge's rulings, under 18 CFR 385.715. On November 5, 1992 trial staff filed an answer opposing the Company's motion. On November 9, 1992, the presiding judge issued an order which denied the Company's motion. The judge stated that, based on the applicable case law and the rationale in his October 15, 1992 ruling, the Company had not demonstrated the extraordinary circumstances which would warrant prompt Commission review.

B. The Company's Interlocutory Appeal

In its November 16, 1992 interlocutory appeal, the Company objected to the judge's interlocutory rulings that: (1) The Company has waived the attorney-client and work product privileges attached to legal opinions by providing them to audit staff under an express claim of privilege and on the condition that they be given confidential treatment; and (2) the Commission's hearing orders implicitly authorize the release of the opinions under section 301(b) of the FPA, which prohibits a Commission employee from divulging information required in an audit except as directed by the Commission or a court. The Company claims that the first ruling would discourage utilities from providing privileged documents to the audit staff in audits. According to the Company, the second ruling would violate the prohibition against disclosure; the documents cannot be released absent a Commission order without violating section 301(b).

With respect to the claim of privilege, the Company argues that there is well-reasoned precedent for a "limited waiver" theory under which disclosure of privileged documents to an agency for one purpose does not result in a waiver for other purposes, citing Diversified. The Company claims that Diversified applies here because legal opinions were disclosed to audit staff in a confidential audit and the presiding judge ruled that the confidential disclosure entitled trial staff and an intervenor access to documents on the separate prudence issue. The Company argues that requiring such disclosure here would thwart full disclosure in audits. The Company also argues that the "unlimited waiver" theory adopted by the D.C. Circuit was adopted without intending to deprive an agency of the power to adopt a "limited waiver" approach, citing In Re Sealed Case, 676 F.2d 793 (D.C. Cir. 1982). The Company believes that the Commission is free to adopt a "limited waiver" policy as best serving full disclosure in audits.

With regard to the claim that section 301(b) protects the confidentiality of information obtained by the audit staff, the Company criticizes the judge's finding that the hearing orders in this proceeding may be construed as lifting the requirement that the documents be kept confidential. The Company notes that the judge's finding was based on Order No. 509–A, which is a statement of policy under the Natural Gas Act. The Company contends that there is no comparable statement of policy under the FPA. In addition, the Company argues that Order No. 509–A did not provide that hearing orders implicitly authorize the release of documents. Consequently, the necessary legal authorization for release of the documents at issue here is missing.

II. Discussion

There are essentially two issues to be resolved in this proceeding: First, whether the Company waived the attorney-client and work product privileges for all purposes when it voluntarily disclosed certain documents to the audit staff; and second, whether the Commission's hearing orders authorized the release of the documents under section 301(b) of the FPA.

A. Waiver of Attorney-Client and Work Product Privileges

As an initial matter, the Commission notes that the Company requests privileged treatment of the documents under section 388.112 of the Commission's regulations, but argues that the staff would violate attorney-client and work product privileges by releasing these documents. Section 388.112 has nothing to do with attorney-client communications or work product Rather, it provides procedures under which a party may request that a document be exempt from FOIA requirements and be withheld from public disclosure. As noted above, and discussed further *infra*, the presiding judge agreed to use the documents under a protective order, which would be consistent with section 388.112. However, that provision also allows protected information to be released, subject to certain notice and comment procedures.

In addition, staff has, to this point, kept the documents confidential. Tr. 26–30. Trial staff has proposed a procedure that would ensure that the documents would be provided to the decisionmaker and at the same time would protect any rights that the

Company may have under FOIA. Trial staff would offer the documents in evidence in this proceeding by filing a sealed copy of trial staff's testimony with the presiding judge and placing only a redacted copy in the public files. Other parties to the case would be granted access to the sealed portion of staff's testimony if they executed a protective agreement preventing public disclosure. The Commission finds this proposal reasonable and in compliance with the Company's request for privileged treatment under § 388.112. We will leave to the presiding judge's sound discretion whether the documents should later be released or made public, pursuant to the requirements in § 388.112.

The Commission believes that the Company's appeal raises various issues regarding the Commission's policy regarding attorney-client communications and work product that should be addressed and clarified.

As noted above, there are two schools of thought regarding voluntary disclosure and subsequent waiver. One school, following Diversified, recognizes the "limited" or "selective" waiver theory under which disclosure of privileged documents for one purpose does not result in waiver for other purposes. The other school, following Permian and Westinghouse, recognizes the "unlimited" waiver theory that, once the attorney-client or work product privilege is voluntarily waived for any purpose, it is waived for all purposes. The Commission believes that the presiding judge ruled correctly in following the "unlimited" waiver theory in this proceeding and rejecting the "selective" waiver theory. In this regard, the Commission specifically adopts the presiding judge's rationale from the October 15, 1992 prehearing conference, discussed above, in support of the unlimited waiver theory.

The Commission believes that the better approach is to reject creating a special exception to the waiver doctrine for the purpose of encouraging voluntary disclosure to government agencies. Westinghouse, 951 F.2d at 1424.[4] The Commission disagrees that adopting the theory of unlimited waiver will discourage utilities from providing the audit staff with confidential information. The unlimited waiver rule does not affect a utility's right to protect legitimate attorney-client communications and work product. The utility may still assert the privileges, even in audits. However, once the utility has opted to surrender the privileges because the utility believes it to be in its interest to do so, the utility cannot reassert the privileges at a later date when it believes it better to conceal what it earlier revealed. Additionally, we have not seen natural gas companies refuse to provide confidential data to staff as a result of the statement of policy announced in Order No. 509–A, making information acquired by staff investigation available in contested cases.

The Commission also believes that the Company's voluntary disclosure waived the work product privilege that may apply to these documents. In contrast to the attorney-client privilege, the work product privilege exists not to protect a confidential relationship, but rather to promote the adversary system by safeguarding the fruits of an attorney's trial preparation from the discovery attempts of an opponent. Permian, 665 F.2d at 1219, *citing United States* v. *AT&T*, 642 F.2d 1285, 1299 (D.C. Cir. 1980). Hence, the work product privilege is not automatically waived by any disclosure to a third party. *Id.*[5]

The D.C. Circuit has identified three factors that lead to a waiver of work product privilege:[6] (1) "the party claiming the privilege seeks to use it in a way that is not consistent with the purpose of the privilege," citing In Re Sealed Case, 676 F.2d at 818; (2) the party had no reasonable basis for believing that the disclosed materials would be kept confidential by the agency; and (3) waiver of the privilege would not trench on any policy inherent in the privilege. In Re Subpoena Duces Tecum, 738 F.2d at 1372.

Concerning the first factor, the court reasoned that fairness and consistency require that the party not be allowed to gain substantial advantages resulting from voluntary disclosure of work product to one adversary—in that case, SEC—while being able to maintain another advantage in protecting the same work product from other adversaries. In Re Subpoena Duces Tecum, 738 F.2d at 1372, citing In Re Sealed Case, 676 F.2d at 818–21. The court added that, in that instance, it was unreasonable not to anticipate litigation with other adversaries at the time of disclosure to the SEC. *Id.* Here, the Company disclosed the documents to gain advantage with the audit staff and then asserted work product privilege for those documents in a later trial-type evidentiary hearing that resulted from that investigation. The Company cannot be allowed to disclose the documents selectively within the Commission.

With regard to the second factor, concerning confidentiality, the court found no common interest between the company and the regulatory agency in that case, and declined to find in the SEC's procedures any proper expectations of confidentiality that the company claimed. In Re Subpoena Duces Tecum, 738 F.2d at 1372–74. Similarly, the Company's request for confidentiality under FOIA and the Commission's FOIA regulations, given the circumstances of its disclosure; does not justify the expectation of confidentiality that the D.C. Circuit found necessary to maintain the privilege. The Company could have no reasonable expectations that its disclosure in an attempt to influence the audit staff could be limited so as to preclude disclosure to the parties, trial staff and presiding judge (and ultimately the Commission) later in the same case.[7]

With regard to the third factor, as to policy concerns, the court believed there was no policy inherent in the work product privilege that required a special exception for the SEC's voluntary disclosure program or similar governmental projects. The court stated that the privilege does not protect against the manipulation of selecting a particular opponent for selective disclosure, most probably for the discloser's own benefit. In Re Subpoena Duces Tecum, 738 F.2d at 1374–75. Here also there is no policy inherent in the work product privilege which calls for a special waiver exemption. The Company "voluntarily and deliberately made disclosures to" the Commission "undoubtedly in the hope and expectation of receiving a benefit * * *." *Id.* at 1375. While such disclosure is certainly not improper, it is inconsistent with a later assertion of a work product privilege.

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[4] The Company's request that the documents be kept confidential under section 388.112 of the Commission's regulations does not reinstate the Company's waived privilege. Westinghouse, 951 F.2d at 1427. In Westinghouse, the Department of Justice (DOJ) had apparently agreed not to disclose the information and SEC regulations provided that the SEC would maintain confidentiality. *Id.* Nonetheless, the court found that voluntary disclosures to the SEC and the DOJ still waived the attorney-client privilege. *Id.*

[5] See also In Re Sealed Case, 676 F.2d at 809; In re Subpoena Duces Tecum, 738 F.2d 1367, 1371 (D.C. Cir. 1984); and Westinghouse, 951 F.2d at 1428.

[6] In Westinghouse, the court stated: "Most courts hold that to waive the protection of the work-product doctrine, the disclosure must enable an *adversary* to gain access to the information. . . . [and] the purpose of the work-product doctrine requires [the court] to distinguish between disclosure to adversaries and disclosures to non-adversaries." Westinghouse, 951 F.2d at 1428 (emphasis added). When, as is the case here, the company is the target of an investigation conducted by the agency, the courts have found that the agency is the company's adversary. *Id.* Subpoena Duces Tecum, 738 F.2d at 1372.

[7] *Cf. infra* note 12.

The Company would also fail the Third Circuit's test in Westinghouse. Under the Third Circuit's standard, a party who discloses documents protected by the work product doctrine may continue to assert the doctrine's protection only when the disclosure furthers the doctrine's underlying goal. Westinghouse, 951 F.2d at 1429. According to the court:

> When a party discloses protected materials to a government agency investigating allegations against it, it uses those materials to forestall prosecution (if the charges are unfounded) or to obtain lenient treatment (in the case of well-founded allegations). These objectives, however rational, are foreign to the objectives underlying the work-product doctrine.

Id. Like Westinghouse, the Company disclosed the documents to the Commission's audit staff "to resolve the issue." Again, this objective is certainly not improper, but it is inconsistent with the objectives underlying the work product privilege.[9]

In summary, the Commission believes that the Company waived both the attorney-client and the work product privileges in this proceeding. The Company provided the documents in this case "in order to resolve the issue." However, the evidentiary hearing that the Commission ordered is likewise for the precise purpose of resolving the issue. The question here is whether, having provided the documents to audit staff early in the proceeding to help resolve the issue, the Company may later in the proceeding assert a privilege with regard to those documents. The answer is no.[9]

We also note that our position regarding disclosures of privileged materials here is consistent with our prior rulings: a disclosure of privileged material waives the privileges as to that material; once it is disclosed, the confidentiality is breached.[10]

B. Release of Documents Under Section 301(b) of the FPA

The second issue in this proceeding pertains to whether the two hearing orders issued by the Commission—one to initiate the audit investigation and the other to initiate the prudence inquiry—authority staff's release of the documents pursuant to section 301(b) of the FPA.

Under section 301(b),

> No member, officer, or employee of the Commission shall divulge any fact or information which may come to his knowledge during the course of examination of books or other accounts, as hereinbefore provided, except insofar as he may be directed by the Commission or by a court.

The Company argues that this provision protects the confidentiality of *any* information which the audit staff uncovers, unless the Commission or a court requires that it be divulged. As noted above, the presiding judge found that the two hearing orders issued in this case are sufficient to remove the requirements that the documents be kept confidential. Tr. 23. The judge based his finding on Order No. 509–A, announcing a statement of policy under the Natural Gas Act.[11] Order No. 509–A provides that the Natural Gas Act's section 8(b) restraint on disclosing information—the counterpart of the Federal Power Act's section 301(b)—did not prohibit the Commission's blanket authorization of disclosure of information in cases scheduled for formal hearings if the information is relevant to the case. order No. 509–A cites the legislative history of section 301(b) as the basis for a blanket authorization to disclose information. 52 FPC at 391. The presiding judge reasoned that because the Commission in Order No. 509–A found that section 8(b) of the Natural Gas Act originated in the legislative history of section 301(b), the statement of policy in Order No. 509–A regarding gas proceedings may also be applied to electric proceedings. He concluded that the Commission's issuance of the two orders in this proceeding authorizes use of the documents in this proceeding and their release from the confidential status they may previously have had, and thus, satisfies section 301(b). Tr. 24.

In Order No. 509–A, while the Commission cited the legislative history of section 301(b) as basis for its blanket authorization under the Natural Gas Act, the Commission did not specifically extend that statement of policy to proceedings under the FPA. However, the Commission believes that the authorization of the release of information specified in Order No. 509–A for natural gas proceedings and the underlying rationale are equally applicable in other Commission proceedings, *i.e.*, in proceedings under the FPA, and should be applied in this case.[12] Thus, section 301(b)'s restraint on disclosing information does not prohibit the Commission's authorization of disclosure of information in cases, such as this, which are set for formal hearing if the information is relevant to the case. Rather, section 301(b) merely provides that information cannot be released without authorization.

We believe that hearing orders, such as the hearing orders in this proceeding, should be read to authorize the release of information obtained during the course of an audit, such as the documents in question, in those cases set for formal hearing.[13] However, to the extent that an additional order under the FPA is necessary, this order authorizes the release of the information at issue in this proceeding.

In addition, to avoid any future misunderstandings, this order specifically extends the policy statement in Order No. 509–A to jurisdictional proceedings under the FPA, as well as to proceedings under the Interstate Commerce Act as it applies to the regulation of oil pipelines. Thus, we will amend 18 CFR 2.72, as set forth below. This revised statement of policy is effective December 28, 1992.

The Commission Orders:

The Company's interlocutory appeal is hereby denied, as discussed in the body of this order.

List of Subjects in 18 CFR Part 2

Administrative practice and procedure, Electric power, Natural gas, Pipelines, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission is amending part 2, chapter I, title 18, Code of Federal Regulations, as set forth below.

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[9] The Third Circuit specifically rejected the argument that the work product privilege was not waived because the company reasonably expected the agencies to keep the documents confidential. Westinghouse, 951 F.2d at 1430.

[9] Contrary to the Company's suggestion, ordering an evidentiary hearing does not make this a different proceeding.

[10] *See* Consolidated Gas Supply Corporation, 16 FERC ¶ 61,234 at 61,502 (1981) (citing and quoting from *Permian* approvingly). *Accord,* Tenneco, Inc., *et al.*, Opinion No. 41, 7 FERC ¶ 61,258 at 61,541–42 (1979). *See also* Pennzoil Louisiana and Texas Offshore Co., Inc., *et al.*, 3 FERC ¶ 61,133 at 61,382 & 61,396 n.1 (1988).

[11] This policy was codified in 18 CFR 2.72, which provides that: Pursuant to the Commission's authority under the Natural Gas Act, particularly subsection (b) of section 8 thereof, upon request by a party to the proceedings, or as required in conjunction with the presentation of a Commission staff case or staff's cross-examination of any other presentation therein, all relevant information acquired by Commission staff, including workpapers pursuant to any staff investigation conducted under sections 8, 10, or 14 of the Natural Gas Act shall, without further order of the Commission, be free from the restraints of said subsection (b) of section 8 regarding the divulgence of information, with respect to any matter hereafter set for formal hearing.

[12] See 52 FPC at 390, 391–92; Availability of Information Acquired by Staff Investigation, Order No. 509, 51 FPC 1439, 1439–40, *order on reh'g,* Order No. 509–A, 52 FPC 389 (1974). Accord, 7 FERC at 61,541–42 & 61,549 n.51; 3 FERC at 61,382.

[13] See 51 FPC at 1440; 52 FPC at 391–92. Accord, 7 FERC at 61,541–42 & 61,549 n.51; 3 FERC at 61,382.

By the Commission.

Lois D. Cashell,

Secretary.

PART 2—GENERAL POLICY AND INTERPRETATIONS

1. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C. 717–717w, 3301–3432; 16 U.S.C. 792–825r, 2601–2545; 42 U.S.C. 4321–4361, 7101–7352.

2. Section 2.72 is redesignated as section 2.1b and is revised to read as follows:

§ 2.1b Availability in contested cases of information acquired by staff investigation.

Pursuant to the Commission's authority under the Natural Gas Act, particularly subsection (b) of section 8 thereof, under the Federal Power Act, particularly subsection (b) of section 301 thereof, and under the Interstate Commerce Act as it applies to regulation of oil pipelines, particularly subsection (7)(f) of section 20 thereof, upon request by a party to the proceedings, or as required in conjunction with the presentation of a Commission staff case or staff's cross-examination of any other presentation therein, all relevant information acquired by Commission staff, including workpapers pursuant to any staff investigation conducted under sections 8, 10, or 14 of the Natural Gas Act, sections 301, 304 or 307 of the Federal Power Act, and sections 12 and 20 of the Interstate Commerce Act as it applies to regulation of oil pipelines shall, without further order of the Commission, be free from the restraints of said subsection (b) of section 8 of the Natural Gas Act, subsection (b) of section 301 of the Federal Power Act, and subsection (7)(f) of section 20 of the Interstate Commerce Act as it applies to regulation of oil pipelines regarding the divulgence of information with respect to any matter hereafter set for formal hearing.

[FR Doc. 93–111 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Counterfeit Drugs Enforcement Activities

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority relating to enforcement activities concerning counterfeit drugs. The amendment clarifies the authority of FDA criminal investigators and the description of the official credentials issued to them.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Ellen Rawlings, Division of Management Systems and Policy (HFA–340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4976.

SUPPLEMENTARY INFORMATION: In a May 24, 1991, **Federal Register** notice (56 FR 23788), FDA amended the regulations for delegations of authority for § 5.35 *Enforcement activities* (21 CFR 5.35). FDA added to the authorities delegated to officers and employees of FDA-issued official credentials by delegating authority to criminal investigators to conduct certain activities under section 702(e)(1) through (e)(5) of the Federal Food, Drug, and Cosmetic Act (the act), as amended (21 U.S.C. 372(e)(1) through (e)(5)). This amendment clarifies the authority of the criminal investigators to perform other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe. This amendment also clarifies the description of the official credentials, consisting of a two part Form FDA–200D, Special Authority for Criminal Investigations, issued to the criminal investigators.

List of Subjects in 21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 5 is amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.35 is amended by revising the introductory text of paragraph (b), by redesignating paragraphs (b)(1) through (b)(5) as (b)(1)(i) through (b)(1)(v), by adding new paragraphs (b)(1) introductory text and (b)(2), and by revising paragraph (c)(3) to read as follows:

§ 5.35 Enforcement activities.

(a) * * *

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA–200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act:

* * * * *

(2) Perform such other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe.

(c) * * *

(3) Form FDA–200D, entitled "Special Authority for Criminal Investigators," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under 21 U.S.C. 334 and 372 and other duties as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigator's badge with blue imprint.

Dated: December 30, 1992.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 93–244 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Food and Drug Administration

21 CFR Part 291

[Docket No. 88N–0444]

Methadone in Maintenance Treatment of Narcotic Addicts; Joint Revision of Conditions for Use; Interim Maintenance Treatment; Human Immunodeficiency Virus Disease Counseling

AGENCIES: Food and Drug Administration and Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) and the Substance Abuse and Mental Health Services Administration (SAMHSA) formerly the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) are revising the conditions for the use of methadone in the maintenance treatment of narcotic addicts. The final rule allows, contingent on FDA and State approval, public and nonprofit private narcotic treatment programs to provide interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment and to require all narcotic treatment programs to provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV) disease.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8046.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary of the Proposal

In the **Federal Register** of March 2, 1989 (54 FR 8973) (corrected in the **Federal Register** of March 27, 1989 (57 FR 12531)), FDA and the National Institute on Drug Abuse (NIDA) jointly published a proposed regulation to revise the conditions for the use of methadone in the maintenance treatment of narcotic addicts. The proposal would allow narcotic treatment programs to provide interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment and require such programs to provide counseling on avoidance and transmission of HIV disease. Prompted by the HIV epidemic in the intravenous (IV) drug abuser population and evidence that methadone treatment is an effective method of limiting the transmission of HIV among this population, the proposal was intended to allow narcotic treatment programs greater flexibility in admitting narcotic addicts into treatment. The proposal specifically solicited comments on several unresolved issues that are important to the successful implementation of interim maintenance treatment. Those issues included: (1) The elements of a policy for transferring patients from interim maintenance treatment to comprehensive maintenance treatment, (2) the question of requiring mandatory HIV testing in methadone treatment programs, (3) the utility of requiring random urine testing of interimcare patients, (4) the question of allowing "stand alone" interim maintenance clinics, and (5) other limitations (allowable number of interim patients, ratio of interim patients to comprehensive patients) on the interim maintenance treatment modality.

In the **Federal Register** of April 6, 1989 (54 FR 13897), FDA and NIDA extended the comment period on the proposal until May 3, 1989. This action was based on several requests for extension of the comment period.

B. Administrative Record

FDA and NIDA received over 80 comments on the proposal. These comments represented many interests—members of Congress; Federal, State, and local government authorities; narcotic treatment programs and counseling services; professional associations representing administrators, physicians, and treatment programs; and national organizations for HIV prevention and treatment research. Comments on the proposed interim maintenance provisions revealed large differences of opinion both on the desirability of adopting the interim maintenance provisions and on a number of related issues as well. Some comments were concerned with the possible detrimental effect proposed interim maintenance treatment would have on comprehensive maintenance treatment. Other comments questioned the existence of an extensive, nationwide, or regional waiting list problem associated with methadone maintenance programs. Because of these differing views and in light of comments urging that an expert meeting be convened to addressed the complex issues posed by the proposal, the agencies concluded that it was necessary to solicit additional information before making a final decision. Therefore, FDA and NIDA jointly published a notice in the **Federal Register** of December 4, 1989 (54 FR 50226), announcing a public hearing to be convened on February 28, 1990, to obtain further public comment and factual information on the unresolved issues. The December 4, 1989, notice specifically sought comments on the likely success of the interim maintenance treatment approach to decrease the spread of HIV infection among IV drug abusers. In addition, the agencies sought help in assessing the extent to which demand for methadone maintenance treatment exceeds current treatment resources, and the likely impact that interim maintenance treatment would have in shortening the waiting lists for entry into methadone treatment programs. Finally, the agencies sought help in developing standards for interim maintenance treatment should interim maintenance rules be adopted.

At the February 28, 1990, public hearing, 28 individuals representing 20 organizations made oral presentations on these and related issues before a panel composed of representatives from FDA, NIDA, and other Public Health Service organizations. A transcript of the hearing and additional written information were placed in the administrative record.

FDA and NIDA evaluated the data, evidence, and testimony submitted as part of the February 28, 1990, public hearing, together with the written comments submitted in response to the March 2, 1989, proposed rule. Several comments stressed the potential importance of interim maintenance in checking the spread of AIDS. Representatives of an interim program, operating under a § 291.505(d)(11) exemption (21 CFR 291.505(d)(11)), indicated that they had witnessed a substantial decline in high risk heroin use among those participating in the program. While submissions indicated some regional shortages of methadone treatment capacity, the administrative record does not disclose significant national shortages in the availability of methadone maintenance treatment slots. Several comments noted that the exemption process currently provided for in § 291.505(d)(11), and described in the preamble of the public hearing notice that was published December 4, 1989 (54 FR 50226 at 50227), would provide for treatment modifications similar to the proposed interim maintenance approach. The comments suggested that this exemption process could be applied on a case-by-case basis

to relieve regional or State overcrowding.

Extensive information was presented in the administrative record regarding the current "poly-drug abuse" profile of IV narcotic addicts and the concomitant need to focus counseling and other rehabilitative services available in comprehensive maintenance treatment on narcotic addicts with multiple addictions entering treatment. Many comments contended that the resources and funding that participating methadone treatment programs would have to provide to offer the proposed interim maintenance treatment would be at the expense of the current comprehensive maintenance treatment and would therefore diminish the role of comprehensive narcotic treatment programs in reducing IV drug abuse. In light of this concern, a considerable number of comments concluded that interim maintenance would fail to decrease the incidence of IV drug abuse and the transmission of HIV disease nationwide.

In addition, the agencies have also considered reports regarding the effectiveness of drug abuse treatment prepared in 1990 by the General Accounting Office (GAO) and the Office of Technology Assessment (OTA). The GAO report concluded that its research findings did not support the effectiveness of proposed interim maintenance in reducing IV drug use and in reducing the corresponding risk of Acquired Immunodeficiency Syndrome (AIDS). The OTA report stated that interim methadone maintenance programs may be more appropriate for certain geographical areas, such as those with large numbers of IV drug users and long waiting lists.

C. ADAMHA Reorganization Act

On July 10, 1992, the ADAMHA Reorganization Act (the Act) became law (Pub. L. 102–321). Pursuant to the reorganization provisions of Title I of the Act, ADAMHA has been restructured to transfer its substance abuse and mental health research institutes, including NIDA, to the National Institutes of Health and to establish SAMHSA to administer substance abuse and mental health prevention and treatment services programs. Thus, unless specifically provided otherwise by the Act, all service-related functions formerly exercised by ADAMHA or its entities, including NIDA, have been transferred to SAMHSA. The reorganization provisions under Title I of the Act were effective on October 1, 1992.

The Act amended the PHS Act and requires the Secretary of Health and Human Services (the Secretary), after consultation with the National Commission or Acquired Immunodeficiency Syndrome (NCAIDS), to issue a final rule establishing interim maintenance treatment regulations and the conditions for public and nonprofit private programs to obtain authorization from the Secretary to provide such treatment. Section 1976(b)(1) of the PHS Act, as amended by section 202 of the ADAMHA Reorganization Act, provides that interim maintenance treatment regulations do not need to be promulgated if the Secretary finds that one or more of three conditions exist. These conditions are that:

(1) "The preponderance of scientific research indicates that the risk of transmission of HIV disease pursuant to the intravenous abuse of drugs is minimal;" (2) "the preponderance of scientific research indicates that the medically supervised dispensing of methadone is not an effective method of reducing the extent of dependence on heroin and other morphine-like drugs;" or (3) "the preponderance of available data indicates that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs." Further, section 1976(b)(2) of the PHS Act requires the Secretary to consult with NCAIDS to determine one or more of those conditions have been met.

With the concurrence of NCAIDS, the Secretary has determined that none of these conditions has been met. First, the Secretary has determined that the preponderance of scientific research indicates that IV abuse of drugs is, in fact, a primary pathway for HIV disease transmission and as such constitutes a major public health problem. Second, the Secretary has determined that the preponderance of scientific research indicates that the medically supervised dispensing of methadone continues to be an effective method of reducing dependence on heroin and other morphine-like drugs.

Finally, the Secretary has determined that the preponderance of available data does not indicate that, of treatment programs that dispense methadone as part of comprehensive treatment, a substantial majority admit all individuals seeking services to the programs not later than 14 days after the individuals seek admission to the programs. Because waiting lists are currently not an accurate measure of the number of individuals seeking treatment services or in need of treatment services, the Secretary does not believe that the available data could support a finding of inapplicability for this condition. Therefore, the Secretary, after consultation with NCAIDS, has determined that the conditions for the use of methadone should be revised to allow public and nonprofit private narcotic treatment programs to provide interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment. Further, to provide HIV disease counseling to all individuals seeking treatment, the Secretary has decided the methadone regulations should be revised in § 291.505(d)(4)(i)(C) to require all narcotic treatment programs offering maintenance and detoxification treatment to provide counseling to each patient on exposure to, and the transmission of, HIV disease.

Current narcotic treatment regulations require a tuberculin skin test to be included in each patient's initial medical evaluation. In view of the recent increase in tuberculosis cases, the agencies emphasize the importance of the tuberculin skin test required under § 291.505(d)(3) as part of the medical evaluation given each patient at the time of admission. Programs are also encouraged to periodically retest patients who had negative tuberculin skin tests on admission. In addition, the agencies encourage programs to routinely perform tuberculin skin tests for all program personnel at the start of employment and all current employees who have not recently received a tuberculin skin test. Programs are encouraged to periodically retest all program employees with negative skin tests. Programs are encouraged to maintain records on the tuberculin skin testing results of both patients and staff. All tuberculin skin tests should be administered intradermally using the Mantoux technique, or, when available, a procedure of equal or better sensitivity.

Any patient or staff member with a positive skin test or clinical evidence of possible tuberculosis disease needs a prompt medical evaluation and appropriate treatment.

Methadone treatment programs should report all patients or staff who have tuberculosis disease to State and local health departments.

II. Interim Maintenance Treatment

Section 1976(c)(1) of the PHS Act requires the Secretary, after consultation with NCAIDS, to issue regulations containing the conditions for public and nonprofit private narcotic treatment programs to obtain authorization from

the Secretary and the chief public health officer of the State to provide interim maintenance treatment. Such conditions shall include conditions for preventing the unauthorized use of methadone. In addition, the Secretary expects that the State public health officer will consult with the State Alcohol and Drug Abuse Director. Section 1976(c)(4) of the PHS Act also requires the Secretary to issue a final rule providing for interim maintenance treatment not later than 180 days after enactment. If a final rule is not promulgated by that time, the proposed rule of March 2, 1989, and the mandated provisions of the Act will take effect as a final rule. Therefore, under section 1976(c)(4) of the PHS Act, FDA and SAMHSA are promulgating this final rule that is based on the proposed rule of March 2, 1989, and mandated provisions of the PHS Act.

Provisions of the ADAMHA Reorganization Act other than those requiring interim maintenance treatment, such as the substance abuse block grant provisions, also affect interim maintenance treatment. Consistent with the PHS Act, the interim maintenance treatment provisions proposed in 1989 are being finalized with changes to incorporate all of the requirements of the Act. These are as follows: First, § 291.505(b)(1)(v) the applicability of interim maintenance treatment regulations is limited to public and nonprofit private narcotic treatment programs that are approved in accordance with § 291.505(c). Secondly, § 291.505(d)(7) provides that a public or nonprofit private narcotic treatment program may place a patient, otherwise eligible for admission to comprehensive maintenance treatment, in interim maintenance only if the program is unable to place the patient in comprehensive treatment in a public or nonprofit private program within a reasonable geographic area within 14 days of seeking admission. Thirdly, § 291.505(b)(2)(vi) provides that a public or nonprofit private narcotic treatment program, to provide interim maintenance treatment, must obtain authorization from FDA and the chief public health officer of the State. Before such authorization is granted by FDA, the program must provide FDA with written certification from the chief public health officer of the State that he or she does not object to interim maintenance treatment in the State and that interim maintenance treatment programs will not reduce the capacity or fiscal support of comprehensive maintenance treatment programs to admit individuals (relative to the date on which such officer so certifies). The Secretary expects that the States will ensure that interim maintenance programs are given appropriate guidance in order to assure that, before admitting a patient, comprehensive treatment in a public or nonprofit private program was not available to the patient within a reasonable geographic area. The Secretary also expects that, as part of the certification process, a State's chief public health officer will consult with the State agency charged with oversight of substance abuse programs utilizing methadone. If a State certifies interim maintenance treatment the State must establish appropriate and reasonable criteria to ensure that interim care is provided in a manner consistent with Federal law and that no individual continues in such a program for more than a total of 120 days for a 12-month period.

Fourth, consistent with section 1923 of the PHS Act, a State must make comprehensive treatment available to any individual who requests and is in need of treatment for intravenous drug abuse within 120 days of the date of such request. Thus, patients may only be admitted to, and treated with, interim maintenance for a period up to and including 120 days per 12-month period. After 120 days, patients must be transferred to a comprehensive program if they are still in need of treatment. The program must notify the State health officer both when interim treatment begins and before the 120-day period expires and document these notifications.

Fifth, § 291.505(d)(7) provides that consistent with section 1927(a) of the PHS Act, a State must ensure that programs within the State providing interim maintenance services give preference in admission to interim care and transfer to comprehensive care to pregnant women who seek or are referred to and would benefit from such services. The Department of Health and Human Services (DHHS) will monitor closely interim maintenance treatment programs.

The final regulation does not require programs to maintain a specific counselor to patient ratio. However, programs are required to provide a number of services (e.g., referrals to such services as medical services, prenatal care, HIV counseling). Accordingly, programs should assure that sufficient counseling staff is available to provide these services. In addition, programs should assure that counseling staff is available to respond to patient emergency situations.

The Secretary advises that, in addition to the initial drug screening, interim programs should perform a minimum of two additional drug screenings. The Secretary recommends that programs perform more frequent tests to assist in assessing patient needs and priorities for transfer to comprehensive programs.

III. HIV Disease Counseling

Section 1976(c)(2) of the PHS Act requires that the Secretary not authorize the provision of interim maintenance unless the public and nonprofit private program provides patients with counseling on preventing exposure to, and the transmission of, HIV disease. Additionally, the March 2, 1989, interim maintenance treatment proposal included a provision requiring all narcotic treatment programs offering maintenance or detoxification treatment to provide counseling on avoiding the transmission of HIV disease. This requirement was uniformly supported by received comments. Therefore, FDA and SAMHSA, in § 291.505(d)(4)(i)(C) are also finalizing that portion of the March 2, 1989, proposal requiring all narcotic treatment programs to provide counseling to each patient on preventing exposure to, and transmission of, HIV disease. This counseling shall be provided upon entrance to all types of maintenance and detoxification treatment. Counseling should be repeated as necessary.

Although HIV testing is not required by this regulation, HIV testing is an important element in reducing the risk of HIV transmission. Accordingly, the agencies believe that HIV testing must be made accessible to patients who request it. If a program does not provide HIV testing on site, then the program shall counsel patients on other opportunities where availability of testing is assured through agreements with HIV testing facilities to make HIV testing accessible to patients who request it.

The final rule also amends the narcotic treatment regulations in § 291.505(a)(10) to include a definition for the term "HIV disease" as defined under section 1976(d)(2) of the PHS Act and a conforming amendment in § 291.505(d)(8)(i)(F) to include a requirement inadvertently omitted from the March 2, 1989, proposal requiring HIV disease counseling in the provisions for short-term detoxification.

IV. Environmental Impact

FDA has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

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nor an environmental impact statement is required.

V. Economic Impact

FDA and SAMHSA have examined the regulatory impact and regulatory flexibility implications of the final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). The final rule will allow methadone treatment programs to provide minimum service (interim) maintenance treatment to patients awaiting placement in comprehensive treatment. This will allow narcotic addicts into treatment more quickly, thereby decreasing the incidence of intravenous drug abuse and the transmission of HIV. The agencies find that the final rule is not a major rule inasmuch as these revisions will not result in any significant increase in cost to narcotic treatment programs or to State and local authorities. In fact, this final rule will allow maintenance treatment of narcotic drug addicts at a lower cost per patient. In addition, the final rule establishes a provision requiring treatment programs to provide counseling on preventing exposure to, and the transmission of, HIV disease for each patient seeking admission and readmission to a treatment program.

The agencies estimated the costs of providing HIV disease counseling for a range of patients because of varying estimates of the census of patients under treatment nationally. The GAO report, "Methadone Maintenance" (March 1990), and SAMHSA estimate 100,000 patients are under treatment nationally, while other experts offered a higher estimate of 350,000 patients. In response to the proposed rule, one comment suggested an incremental cost of 80 cents per patient per day, but did not present information on the components of this cost.

For its cost analysis, the agencies have assumed that counselors earn $13 per hour and that patients on average would receive 1 hour of counseling. Based on these assumptions, the annual cost of providing HIV-disease counseling would be between $1,300,000 ($13/hour × 100,000 patients) and $4,550,000 ($13/hour × 350,000 patients). This cost estimate assumes that no narcotic treatment programs currently offer HIV-disease counseling. However, because some narcotic treatment programs currently already provide disease counseling, the actual costs will be less than the agencies' estimates. The requirements for referrals for other services already exist for providers of comprehensive services; thus, minimum incremental costs will be incurred in the provision of these referrals. In areas where there is a shortage of drug treatment slots, interim methadone maintenance provides a bridge to comprehensive treatment, thus reducing both HIV transmission and continued use of opiates. Even if interim methadone maintenance changes the behavior of only a few addicts, the potential savings from reducing the spread of HIV and reducing illicit drug use by facilitating entrance to a proven treatment modality, thereby reducing illicit drug use, are substantial.

For these reasons, therefore, the agencies have determined that this rule is not a major rule as defined in Executive order 12291. Further, FDA and SAMHSA certify that the rule will not have a significant impact on a substantial number of small entities as defined by the Regulatory Flexibility Act.

VI. Paperwork Reduction Act of 1980

The final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the paperwork reduction Act of 1980. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Methadone, HIV Disease Counseling, Transfer Priority Criteria Evaluation Notation.

Description: FDA and SAMHSA are requiring this notation to ensure that a record exists of the transfer criteria evaluation, which is designed to help prevent interim maintenance treatment from becoming a long-term treatment modality for any patient.

Description of Respondents: State or local governments, businesses, or other organizations; nonprofit institutions.

Estimated Annual Reporting and Recordkeeping Burden:

Section 291.505(d)(7).
Annual number of respondents: 20.
Annual frequency: 200.
Average burden per response: 5 minutes.
Annual burden hours: 333.

The agencies received no public comments on the estimated public reporting burden, and it remains the same as that contained in the proposed rule.

VII. Effective Date

This final rule is effective on January 6, 1993. The ADAMHA Reorganization Act requires that a final rule be effective not later than 180 days after its enactment (by January 6, 1993) or the proposed rule issued on March 2, 1989 (54 FR 8973) is deemed to take effect. The final rule also relieves a restriction, in that it will provide conditions for interim maintenance treatment to patients awaiting placement in comprehensive maintenance treatment programs. Therefore, the agencies find that the final rule is within the exemption to the Administrative Procedure Act (5 U.S.C. 553d) so that it can be made effective in less than 30 days.

List of Subjects in 21 CFR Part 291

Health professions, Methadone, Reporting and recordkeeping requirements.

Therefore, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, the Narcotic Addict Treatment Act of 1974, and applicable delegations of authority thereunder, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 291 is amended as follows:

PART 291—DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

1. The authority citation for 21 CFR part 291 is revised to read as follows:

Authority: Secs. 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; secs. 301(d), 548, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290ee–3, 300y–11); 42 U.S.C. 257a.

2. Section 291.505 is amended by inserting the word "comprehensive" before the word "maintenance" everywhere it appears in paragraphs (d)(1)(i), (d)(1)(iii), (d)(1)(iv), (d)(2)(i), (d)(3)(v)(D), (d)(4)(i)(B)*2*), (d)(5)(ii), (d)(6)(iv)(B)(*6*), (d)(6)(v)(A)(*1*) and (d)(6)(v)(A)(*3*), (d)(6)(v)(C), (d)(8)(i) introductory text and (d)(8)(i)(E), (d)(9)(i) introductory text and (d)(9)(i)(F), and by revising paragraph (a)(2), by adding paragraphs (a)(10), (b)(1)(v), (b)(2)(vi), (d)(4)(i)(C), and (d)(7), and by revising paragraph (d)(8)(i)(F) to read as follows:

§ 291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

(a) * * *

(2) *Maintenance treatment* means the dispensing of a narcotic drug, at relatively stable dosage levels, in the treatment of an individual for dependence on heroin or other morphine-like drug. There are two types of maintenance treatment:

comprehensive maintenance treatment and interim maintenance treatment.

(i) *Comprehenisve maintenance treatment* is maintenance treatment provided in conjunction with a comprehensive range of appropriate medical and rehabilitative services.

(ii) *Interim maintenance treatment* is maintenance treatment provided in conjunction with appropriate medical services while a patient is awaiting transfer to comprehensive maintenance treatment.

* * * * *

(10) The term *HIV disease* means infection with the etiologic agent for acquired immunodeficiency syndrome.

* * * * *

(b) * * *

(1) * * *

(v) *Interim maintenance treatment.* A public or nonprofit private narcotic treatment program may provide interim maintenance treatment only if the program also provides comprehensive maintenance treatment to which interim maintenance treatment patients may be transferred.

(2) * * *

(vi) *Interim maintenance treatment program approval.* Before a public or nonprofit private narcotic treatment program may provide interim maintenance treatment, the program must receive approval of both the Food and Drug Administration and the chief public health officer of the State. Before such approval is granted, the program must provide the Food and Drug Administration with certification from the chief public health officer of the State that:

(A) Such officer does not object to the authorization of programs providing interim maintenance treatment in the State and that programs seeking such authorization are unable to place patients in a public or nonprofit private comprehensive treatment program within a reasonable geographic area within 14 days of the time patients seek admission to such programs;

(B) The authorization of programs providing interim maintenance treatment in the State will not reduce the capacity of comprehensive programs in the State to admit individuals to these programs (relative to the date on which such officer so certifies);

(C) The State guarantees that individuals enrolled in interim maintenance treatment will be transferred to comprehensive programs not later than 120 days, as provided by section 1923 of the Public Health Service Act (the PHS Act) and applicable regulations; and

(D) Requests for authorization should be submitted to the address specified in § 291.505(k).

* * * * *

(d) * * *

(4) * * *

(i) * * *

(C) *Counseling on HIV disease.* A narcotic treatment program shall provide counseling on preventing exposure to, and the transmission of, HIV disease for each patient admitted or readmitted to maintenance or detoxification treatment. Although HIV testing is not required, an interim program shall inform patients of the availability of HIV testing. The program sponsor shall also ensure that HIV testing is accessible to patients who request such testing either on site or by the programs entering into agreements with HIV testing facilities to make HIV testing accessible to those patients who request it.

* * * * *

(7) *Minimum standards for interim maintenance treatment.* The person(s) responsible for a program may place an individual, who is eligible for admission to comprehensive maintenance treatment, in interim maintenance treatment if the individual cannot be placed in a public or nonprofit private comprehensive program within a reasonable geographic area and within 14 days of the individual's application for admission. An initial and at least two other urine screens shall be taken from interim patients during the maximum of 120 days permitted for such treatment. A program shall establish and follow reasonable criteria for establishing priorities for transferring patients from interim maintenance to comprehensive maintenance treatment. These transfer criteria shall be in writing and available for inspection and shall include, at a minimum, a preference for pregnant women in admitting patients to interim maintenance and in transferring patients from interim maintenance to comprehensive maintenance treatment. Interim maintenance shall be provided in a manner consistent with all applicable Federal and State laws including sections 1923 (mandatory transfer) and 1927(a) (pregnant patients) of the PHS Act. The program shall notify the State health officer when a patient begins interim treatment, when a patient leaves interim treatment, and before the date of mandatory transfer to a comprehensive program, and shall document such notifications. Programs in States not in compliance with provisions of this regulation risk loss of authorization for interim maintenance. All requirements for comprehensive maintenance treatment apply to interim maintenance treatment with the following exceptions:

(i) The narcotic drug is required to be administered daily under observation;

(ii) Take-home medication is not allowed;

(iii) The initial treatment plan and periodic treatment plan evaluation are not required;

(iv) A primary counselor is not required to be assigned to a patient;

(v) Interim maintenance cannot be provided for longer than 120 days in any 12 month-period; and

(vi) The requirements and exceptions in paragraphs (b)(2)(iii) (as apply to rehabilitative services), in paragraphs (b)(3)(iv)(B) and (d)(4)(i)(A) (as apply to rehabilitative services), and in paragraphs (d)(4)(ii)(E), (d)(4)(ii)(F), (d)(4)(iv), (d)(6)(iv), (d)(6)(v), (d)(6)(vi), and (d)(6)(vii) of this section do not apply.

* * * * *

(8) * * *

(i) * * *

(F) The requirements of paragraph (d)(4) of this section, except paragraphs (d)(4)(i)(C), (d)(4)(ii)(A) through (d)(4)(ii)(D), and (d)(4)(iii) of this section, do not apply to short-term detoxification treatment.

* * * * *

Elaine Johnson,

Acting Administrator, Substance Abuse and Mental Health Services Administration.

David A. Kessler,

Commissioner of Food and Drugs.

Dated: January 4, 1993.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 93–266 Filed 1–4–93; 12:33 pm]

BILLING CODE 4160–17–M

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Diazepam Injection

AGENCY: Food and Drug Administration. HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Hoffmann-La Roche Inc. The NADA provides for the use of diazepam injection as a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia in dogs.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Marcia K. Larkins, Center for Veterinary Medicine (HFV–112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8614.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, filed NADA 140–848 which provides for intravenous use of Veteeze® (diazepam) injection for dogs as a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia. The NADA is approved as of December 17, 1992, and the regulations are amended by adding new § 522.575 (21 CFR 522.575) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning December 17, 1992, because no active ingredient (including any ester or salt thereof) has been approved previously in any other NADA.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 522.575 is added to read as follows:

§ 522.575 Diazepam injection.

(a) *Specification.* Each milliliter of sterile solution contains 5 milligrams of diazepam.

(b) *Sponsor.* See 000004 in § 510.600(c) of this chapter.

(c) *Conditions of use. Dogs*—(1) *Indications for use.* As a preanesthetic agent to reduce the amount of barbiturate required for short duration anesthesia.

(2) *Dosage.* Intravenously, 0.2 milligram per kilogram of body weight 3–5 minutes before anesthesia is to be induced using a short acting barbiturate.

(3) *Limitations.* Not for use in dogs with known sensitivity to benzodiazepines. Safety in animals intended for breeding and pregnant animals has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 17, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93–99 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 526

Intramammary Dosage Forms; Penicillin G Procaine in Oil

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove that portion reflecting approval of new animal drug application (NADA) held by Boehringer Ingelheim Animal Health, Inc., for procaine penicillin G for treatment of bovine mastitis. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADA.

EFFECTIVE DATE: January 19, 1993.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8749.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of NADA 65–466 held by Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506, for procaine penicillin G bovine mastitis treatment. This final rule removes 21 CFR 526.1696a(f) to reflect the withdrawal of approval of the NADA.

List of Subjects in 21 CFR Part 526

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

1. The authority citation for 21 CFR part 526 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 526.1696a [Amended]

2. Section 526.1696a *Penicillin G procaine in oil* is amended by removing paragraph (f).

Dated: December 16, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93–95 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[FRL–4552–5]

Minnesota: Schedule of Compliance for Modification of Minnesota's Hazardous Waste Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of Minnesota's Compliance Schedule to adopt program modifications.

SUMMARY: On September 26, 1986, U.S. EPA promulgated amendments to the deadlines for State program modifications and published requirements for States to be placed on a compliance schedule to adopt necessary program modifications. U.S. EPA is today publishing a compliance schedule for Minnesota to modify its program, in accordance with § 271.21(g) to adopt Federal program modifications.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Christine Klemme, Minnesota Regulatory Specialist, Office of RCRA, U.S. EPA, Region V, 77 W. Jackson, HRM–7J, Chicago, Illinois 60604, (312) 886–3715, [FTS (312) 886–3715].

SUPPLEMENTARY INFORMATION:

A. Background

Final authorization to implement the Federal hazardous waste program within the State is granted by U.S. EPA if the Agency finds that the State program: (1) Is "equivalent" to the Federal program, (2) is "consistent" with the Federal program and other State programs, and (3) provides for adequate enforcement (section 3006(b), 42 U.S.C. 6926(b)). U.S. EPA regulations for final authorization appear at 40 CFR 271.1–271.25. In order to retain authorization, a State must revise its program to adopt new Federal requirements by the cluster deadlines and procedures specified in 40 CFR 271.21. See 51 FR 33712, September 22, 1986, for a complete discussion of these procedures and deadlines.

B. Minnesota

Minnesota received final authorization of its base hazardous waste program on February 11, 1985 (see 49 FR 226). The State received authorization for program revisions effective on September 18, 1987, June 23, 1989, August 14, 1990, August 23, 1991, and May 18, 1992. Today U.S. EPA is publishing a compliance schedule for Minnesota to complete a program revision on two Federal regulations, the Burning of Hazardous Waste in Industrial Furnaces (56 FR 7134, February 21, 1991), and, the Petroleum Refinery Primary and Secondary Oil/Water/Solids Separation Sludge Listing (55 FR 46354, November 2, 1990). The adoption deadline under 40 CFR 271.21 for these Federal regulations was July 1,1992. Minnesota has been granted a six-month extension to address these rules.

Minnesota has determined that, due to resource constraints, a one year delay to address these rules is necessary. On September 23, 1992, a letter from the State was received requesting an extension. Therefore, U.S. EPA is granting a one year extension of time until January 1, 1994, to address these two rules.

Authority

This notice is issued under authority of sections 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended by the RCRA of 1976, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

Dated: December 17, 1992.

David A. Ullrich,

Acting Regional Administrator.

[FR Doc. 93–195 Filed 1–5–93, 8:45 am]

BILLING CODE 6560–50–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7559]

Suspension of Community Eligibility

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Final rule.

SUMMARY: This rule identifies communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If FEMA receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the Federal Register.

EFFECTIVE DATES: The effective date of each community's suspension is the third date ("Susp.") listed in the fourth column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, 500 C Street, SW., room 417, Washington, DC 20472, (202) 646–2717.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 et seq., unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR Part 59 *et seq.* Accordingly, the communities will be suspended on the effective date in the fourth column. As of that date, flood insurance will no longer be available in the community. However, some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the Federal Register.

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM if one has been published, is indicated in the fifth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Federal Insurance Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and, after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

Regulatory Impact Analysis

This rule is not a major rule under Executive Order 12291, Federal Regulation, February 17, 1981, 3 CFR, 1981 Comp., p. 127. No regulatory impact analysis has been prepared.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 64.6 [Amended]

2. The tables published under the authority § 64.6 are amended as follows:

State and Location	Community No	Effective date of authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in special flood hazard areas
Suspensions				
Region III				
Virginia: Clinchport, town of Scott County	510143	Mar. 11, 1974, Emerg; Sept. 29, 1978, Reg; Jan. 6, 1993, susp.	Sept. 29, 1978	Jan. 6, 1993
Region II				
New Jersey: Stow Creek, township of Cumberland County	340174	July 1, 1975, Emerg; June 15, 1979, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Jan. 20, 1993
New York: Busti, town of Chautauqua County	361106	Aug. 8, 1975, Emerg; Mar. 18, 1980, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do
Elizabethtown, town of Essex County	361388	Apr. 30, 1976, Emerg; July 20, 1984, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do
Morristown, town of St. Lawrence County	360706	July, 30, 1980, Emerg; Aug. 6, 1982, Reg; Jan. 20, 1993, Susp.	Aug. 6, 1982	Do
Region III				
West Virginia: Ranson, city of Jefferson County	540068	Apr. 2, 1975, Emerg; June 15, 1979, Reg; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do

Code for reading fourth column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Issued: December 30, 1992.

C.M. "Bud" Schauerte,

Administrator, Federal Insurance Administration.

[FR Doc. 93–188 Filed 1–5–93; 8:45 am]

BILLING CODE 6718–21–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 1

[OST Docket No. 1; Amdt. 1–252]

Organization and Delegation of Powers and Duties; Delegation of Authority to the Federal Highway Administrator

AGENCY: Office of the Secretary, DOT.

ACTION: Final rule.

SUMMARY: This document delegates to the Federal Highway Administrator the authority vested in the Secretary of Transportation by section 601 of the Pipeline Safety Act of 1992, Public Law 102–508, concerning the construction of the Page Avenue Extension Project in St. Charles and St. Louis Counties, Missouri. The purpose of this rulemaking is to amend 49 CFR part 1 to reflect this delegation.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: John Kraybill, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590 (202) 366–1367, or Steve Farbman, Office of the Assistant General Counsel for

Regulations and Enforcement, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590 (202) 366–9306.

SUPPLEMENTARY INFORMATION: The Secretary has determined that the authority vested in the Secretary by section 601 of the Pipeline Safety Act of 1992, Pub. L. 102–508, concerning the authority to waive the requirements of section 138 of title 23, United States Code, and section 303 of title 49, United States Code, and other authority relating to construction of the Page Avenue Extension Project in the State of Missouri should be delegated to the Federal Highway Administrator. Since this rule relates to Departmental management, organization, procedure, and practice, notice and comment on it are unnecessary and it may be made effective in fewer than 30 days after publication in the **Federal Register**.

List of Subjects in 49 CFR Part 1

Authority delegations (government agencies), Organizations and functions (government agencies).

PART 1—[AMENDED]

In consideration of the foregoing, part 1 of title 49, Code of Federal Regulations, is amended as follows:

1. The authority citation for 49 CFR part 1 continues to read as follows:

Authority: 49 U.S.C. 322.

2. Section 1.48 is amended by adding a new paragraph (jj), and the introductory text of the section is reprinted for the convenience of the reader, to read as follows:

§ 1.48 Delegations to Federal Highway Administrator.

The Federal Highway Administrator is delegated authority to—

* * * * *

(jj) Carry out the functions vested in the Secretary of Transportation by section 601 of the Pipeline Safety Act of 1992, Public Law 102–508, relating to construction of the Page Avenue Extension Project in Missouri.

Issued on: December 30, 1992.

Andrew H. Card, Jr.,

Secretary.

[FR Doc. 93–224 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 672

[Docket No. 921240–2340]

RIN 0648–AE90

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: NMFS announces a final rule to remove a provision from the regulations acting to define "pelagic trawl gear" for purposes of the time/area closures authorized by Amendment 18 to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). Amendment 18 expires on December 31, 1992. New time/area closure authority is provided by Amendment 26 to the FMP, which uses the definition of "pelagic trawl gear" appearing in 50 CFR 672.2.

EFFECTIVE DATE: Effective January 1, 1993.

ADDRESSES: Copies of the environmental assessment/regulatory impact review (EA/RIR) may be obtained from the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510 (telephone 907–271–2809).

FOR FURTHER INFORMATION CONTACT: Susan J. Salveson, Fisheries Management Division, Alaska Region, NMFS, 907–586–7230.

SUPPLEMENTARY INFORMATION:

Background

The domestic and foreign groundfish fisheries in the exclusive economic zone (EEZ) of the Gulf of Alaska (GOA) are managed by the Secretary of Commerce (Secretary) in accordance with the FMP. The FMP was prepared by the North Pacific Fishery Management Council (Council) under the Magnuson Fishery Conservation and Management Act (Magnuson Act). The FMP is implemented by regulations appearing at 50 CFR part 611 for the foreign fishery and at 50 CFR part 672 for the U.S. fishery. General regulations that also pertain to U.S. fisheries appear at 50 CFR part 620.

Amendment 18 to the FMP, which expires December 31, 1992, authorizes time/area closures around Kodiak Island. paragraph (d) of 50 CFR 672.24 implements that authority.

A notice of proposed rulemaking was published in the **Federal Register** on October 15, 1992 (57 FR 47321) that invited comment on the continuation of time/area closures around Kodiak Island to protect sensitive king and Tanner crab habitat areas from on-bottom trawl operations as recommended by the Council under Amendment 26 to the FMP. The intent of that notice was to propose to implement the time/area closure authority of Amendment 26 by maintaining, without change paragraphs (d) (1) and (2) of 50 CFR 672.24 and removing paragraphs (d) (3) and (4), which act to define pelagic trawl gear for the sole purpose of time/area closures authorized by Amendment 18. Paragraphs (d) (3) and (4) require that each person using pelagic trawl gear in the Kodiak Island time/area closures maintain a working net-sonde device on the trawl, retain all net-sonde recordings on board the vessel, and maintain contact between the footrope and the seabed 10 percent or less of the period of any tow as indicated by the net-sonde device. Amendment 26 provides authority for time/area closures but uses the definition of pelagic trawl gear appearing in § 672.2. This definition defines pelagic trawl gear based on gear configuration rather than net-sonde device recordings (56 FR 2700, January 24, 1991). Unfortunately, because of a drafting error, the proposed amendatory language failed to propose removal of paragraphs (d) (3) and (4).

Response to Comments

Two letters of comment were received during the comment period. Comments are summarized and responded to below.

Comment 1: Regulations implementing Amendment 26 and its predecessor, Amendment 18, exemplify a wise approach to the conservation of the crab resource without unnecessarily impacting commercial fishing operations.

Response: NMFS notes this comment.

Comment 2: NMFS invited comment on the enforcement concerns about aerial monitoring of the time/area closures to non-pelagic trawl gear when pelagic trawl gear could still be deployed in the closed areas. These concerns are unfounded in the Gulf of Alaska (GOA). Pollock is the only pelagic trawl fishery in the GOA. All other groundfish trawl fisheries are prosecuted with non-pelagic trawl gear. Additionally, all non-pelagic groundfish fisheries are restricted by a single halibut bycatch limit that is apportioned into seasonal allowances. When a seasonal allowance is reached, the GOA is closed to directed fishing for groundfish by vessels using trawl gear, except that fishing for pollock with pelagic trawl gear may continue when directed fishing for pollock is open. The only time pelagic and non-pelagic trawl

gear operations simultaneously occur in the GOA is when directed fisheries for pollock and other groundfish are both open. The trawl fleet normally fishes for pollock at the beginning of each quarterly reporting period when quarterly apportionments of the annual pollock quota become available. Quarterly apportionments are harvested within a short time period and the trawl fleet typically shifts to other groundfish species during the remainder of the quarter. Therefore, monitoring of the non-pelagic trawl gear closures around Kodiak Island may only be complicated during the seasonal openings of the pollock fishery. NMFS enforcement need not resort to aerial monitoring in this case, but could simply confirm a vessel's participation in the pelagic trawl pollock fishery by checking observer reports, landings documents, or vessel logbooks.

Response: NMFS concurs that enforcement of the Kodiak Island closures to trawl gear other than pelagic trawl gear is possible. However, aerial surveillance of areas closed to specified gear types is the most effective and least costly and intrusive means to monitor such closures. NMFS may pursue an FMP amendment in the future that would prohibit the deployment of all trawl gear in the Kodiak Island time/area closures implemented under Amendment 26.

Comment 3: Fisheries enforcement would be enhanced if the time/area closures implemented under Amendment 26 applied to all trawl operations. Allowing only pelagic trawls in the closed areas renders aerial enforcement ineffective. As a result, enforcement of these closures will continue to require air/sea coordination to board and verify whether pelagic or non-pelagic trawl gear activity is occurring. The U.S. Coast Guard does not object to the regulations implementing Amendment 26 because they continue current practices and minimize impacts on pelagic trawl fisheries in the Kodiak Island area.

Response: NMFS notes this comment. Also, see response to Comment 2.

Final Rule

For the reasons set forth above, the final rule maintains paragraphs (d) (1) and (2) of 50 CFR 672.24 but removes paragraphs (d) (3) and (4).

Classification

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has determined that this action is necessary for conservation and management of the groundfish fishery in the Gulf of Alaska and that it is consistent with the Magnuson Act and other applicable laws.

This final rule deletes a more restrictive definition for a gear exemption from regulatory time/area closures around Kodiak Island. As a substantive rule that relieves a restriction, under 5 U.S.C. 553(d)(1) it can and is being made effective without a 30-day delay in effective date.

The Council prepared an EA for this rule and the Assistant Administrator concluded that no significant impact on the environment would result from its implementation. The public may obtain a copy of the EA (see ADDRESSES).

The Assistant Administrator determined that this rule is not a major rule requiring a regulatory impact analysis under E.O. 12291. This determination is based on the socioeconomic impact discussed in the EA/RIR prepared by the Council.

NMFS has determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management program of the State of Alaska. This determination has been submitted for review by the responsible State agency under section 307 of the Coastal Zone Management Act. The State agency declined to comment on the consistency determination within the statutory time period and consistency is inferred.

This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612, and does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Dated: December 30, 1992.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 672 is amended as follows:

PART 672—GROUNDFISH OF THE GULF OF ALASKA

1. The authority citation for 50 CFR part 672 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

§ 672.24 [Amended]

2. In § 672.24, paragraphs (d)(3) and (d)(4) are removed.

[FR Doc. 93–209 Filed 1–5–93; 8:45 am]
BILLING CODE 3510–22–M

50 CFR Parts 672 and 675

[Docket No. 920531–2221]

Groundfish of the Gulf of Alaska; Groundfish Fishery of the Bering Sea and Aleutian Islands Area

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Pacific halibut and red king crab bycatch rate standards; request for comments.

SUMMARY: NMFS announces Pacific halibut and red king crab bycatch rate standards for the first half of 1993. Publication of these bycatch rate standards and the schedule for the 1993 fishing months is necessary for purposes of the vessel incentive program. This action is necessary to implement the bycatch rate standards under this program that must be met by individual trawl vessel operators who participate in the groundfish fisheries. The intent of this action is to reduce prohibited species bycatch rates and promote conservation of groundfish and other fishery resources.

DATES: Effective 12:01 a.m., Alaska local time (A.l.t.), January 20, 1993, through 12 midnight, A.l.t., June 30, 1993. Comments on this action must be received at the following address no later than 4:30 p.m., A.l.t., January 19, 1993.

ADDRESSES: Comments should be mailed to Ronald J. Berg, Chief, Fisheries Management Division, NMFS, P.O. Box 21668, Juneau, Alaska 99802–1668, Attn: Lori Gravel, or be delivered to 9109 Mendenhall Mall Road, Federal Building Annex, Suite 6, Juneau, Alaska.

FOR FURTHER INFORMATION CONTACT: Susan J. Salveson, Fisheries Management Division, Alaska Region, NMFS, 907–586–7228.

SUPPLEMENTARY INFORMATION: The domestic and foreign groundfish fisheries in the exclusive economic zone of the Bering Sea and Aleutian Islands Area (BSAI) and Gulf of Alaska (GOA) are managed by the Secretary of Commerce (Secretary) according to the Fishery Management Plan (FMP) for the Groundfish Fishery of the BSAI and the FMP for Groundfish of the GOA. The FMPs were prepared by the North Pacific Fishery Management Council (Council) under the authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). The FMPs are implemented by regulations for the foreign fishery at 50 CFR part 611 and for the U.S. fishery at 50 CFR parts 672 and 675. General regulations

that also pertain to the U.S. fishery appear at 50 CFR part 620.

Regulations at §§ 672.26 and 675.26 implement a vessel incentive program to reduce halibut and red king crab bycatch rates in the groundfish trawl fisheries. The vessel incentive program was expanded to include all GOA and BSAI groundfish trawl fisheries under a final rule effective January 20, 1993 (57 FR 43926, September 23, 1992). Under the expanded incentive program, operators of trawl vessels must comply with Pacific halibut bycatch rate standards specified for the BSAI and GOA midwater pollock and "other trawl" fisheries, and the BSAI yellowfin sole and "bottom pollock" fisheries. Vessel operators must also comply with red king crab bycatch standards specified for the BSAI yellowfin sole and "other trawl" fisheries in Bycatch Limitation Zone 1 (defined at § 675.2). The fisheries included under the incentive program are defined in regulations at §§ 672.26(b) and 675.26(b).

Regulations at §§ 672.26(c) and 675.26(c) require that halibut and red king crab bycatch rate standards for each fishery monitored under the incentive program be published in the **Federal Register.** Any vessel operator whose monthly bycatch rate exceeds the bycatch rate standard is in violation of the regulations implementing the incentive program. The standards are in effect for specified seasons within the 6-month periods of January 1 through June 30, and July 1 through December 31. Given that the amended vessel incentive program becomes effective January 20, 1993, and the GOA and BSAI fisheries are closed to trawling until that date (§§ 672.23(e) and 675.23(d), respectively), NMFS is implementing bycatch rate standards for the first half of 1993 effective from January 20, 1993, through June 30, 1993.

At its December 8–13, 1992 meeting, the Council reviewed updated analyses comparing 1991 and 1992 bycatch rates experienced by vessels participating in the fisheries under the incentive program. Based on this and other information presented below, the Council recommended halibut and red king crab bycatch rate standards for the first half of 1993. These standards are set forth in Table 1. As required by §§ 672.26(c) and 675.26(c), the Council's recommended bycatch rate standards for January through June are based on the following information:

(A) Previous years' average observed bycatch rates;

(B) Immediately preceding season's average observed bycatch rates;

(C) The bycatch allowances and associated fishery closures specified under §§ 672.20(f) and 675.21;

(D) Anticipated groundfish harvests;

(E) Anticipated seasonal distribution of fishing effort for groundfish; and

(F) Other information and criteria deemed relevant by the Regional Director.

Bycatch Rate Standards for Pacific Halibut

The Council's Pacific halibut bycatch rate standards for the BSAI and GOA trawl fisheries are based largely on anticipated seasonal fishing effort for groundfish species and historic halibut bycatch rates observed in specified trawl fisheries. Council deliberations on seasonal bycatch rate standards recognized that the 1993 trawl fisheries do not start until January 20 and that the BSAI yellowfin sole fishery is further delayed until May 1 under regulations at § 675.23(c).

The recommended halibut bycatch rate standards for the BSAI yellowfin sole, "bottom pollock," and "other trawl" fisheries approximate the average rates observed on trawl vessels participating in these fisheries during the past 2 years.

The halibut bycatch rate standard recommended for the BSAI and GOA midwater pollock fisheries (1 kilogram (kg) halibut/metric ton (mt) of groundfish) is higher than the bycatch rates normally experienced by vessels participating in these fisheries. The recommended standard is intended to encourage vessel operators to maintain off-bottom trawl operations during their participation in the midwater pollock fisheries. Vessel operators/owners who exceed the halibut bycatch rate standard are subject to prosecution under the incentive program.

The recommended standard for the BSAI "bottom pollock" fishery during the first quarter of 1993 (7.5 kg halibut/mt of groundfish) is set at a level that approximates the average halibut bycatch rate experienced by vessels participating in the "bottom pollock" fishery during the first quarter of 1992 (7.58 kg halibut/mt of groundfish. The recommended bycatch rate standard for the first quarter of 1993 is higher than the standard recommended for the second quarter (5.0 kg halibut/mt of groundfish). The Council anticipates that fishing effort for pollock by the inshore and offshore components will occur during the first quarter of 1993 and that directed fishing allowances specified for the pollock "A" season will be reached before the end of the "A" season (April 15). Directed fishing for pollock by vessels participating in the inshore and offshore component fisheries is prohibited from the end of the pollock "A" season until the beginning of the pollock "B" season (June 1). During its December meeting, the Council took action to delay the opening of the pollock "B" season until August 15. If the Secretary approves the "B" season delay, it could be implemented in 1993. Vessels fishing under the Community Development Quota (CDQ) program (50 CFR § 675.27) could participate in a directed fishery for pollock between the "A" and "B" seasons, subject to other provisions governing the groundfish fisheries.

The 5.0 kg halibut/mt of groundfish bycatch rate standard recommended by the Council for the second quarter of 1993 approximates the average halibut bycatch rate experienced by vessels participating in the "bottom pollock" fishery during the second quarter of 1992 (4.3 kg halibut/mt of groundfish). This bycatch rate standard is intended to accommodate any CDQ fishery that may occur after the first quarter of 1993. This standard also would apply to the inshore and offshore pollock fisheries during the month of June should the Secretary not approve the Council's proposed delay of the pollock "B" season.

The Council recommended a 50 Kg halibut/mt of groundfish bycatch rate standard for the GOA "other trawl" fishery. This standard is unchanged from 1992 and is based on Council intent to simplify the GOA incentive program by specifying a single bycatch rate standard for the fisheries under the incentive program, yet maintain the Council's objective of reducing halibut bycatch rates in the GOA trawl fisheries. Observer data collected from the 1991 GOA trawl fisheries (excluding the midwater pollock fishery) show first and second quarter halibut bycatch rates of 24 and 66 kg halibut/mt of groundfish, respectively. First and second quarter rates from 1992 were lower at 20 and 22 kg/mt of groundfish, respectively. In spite of the apparent reduction in average bycatch rates from 1991 to 1992, the Council determined that a halibut bycatch rate standard of 50 kg halibut/mt of groundfish would continue to provide an incentive to vessel operators to reduce halibut bycatch rates while participating in the GOA trawl fisheries.

Bycatch Rate Standard for Red King Crab

The Council's recommended red king crab bycatch rate standard for the yellowfin sole and "other trawl" fisheries in Zone 1 of the Bering Sea subarea is 2.5 crab/mt of groundfish

during the first half of 1993. This standard is the same as that recommended for 1992.

Little fishing effort for flatfish occurred in Zone 1 during 1991 because commercial concentrations of yellowfin sole normally occur north of this area by the time the fishery opens May 1. As such, limited observer data exist for the 1991 and 1992 yellowfin sole fishery in Zone 1. These data indicate average quarterly red king crab bycatch rates between 1.3 and 1.4 crab/mt of groundfish. During this same period, vessels participating in the "other trawl" fishery experienced average red king crab bycatch rates ranging between 0.8 and 1.7 crab/mt of groundfish. During 1991 and 1992, some fishermen experienced relatively high bycatch rates of halibut north of Zone 1 and expressed a desire to explore fishing grounds in Zone 1 that may have lower halibut bycatch rates. Fishermen were reluctant to fish in Zone 1, however, because of possibly exceeding the red king crab bycatch rate standard. The total bycatch of red king crab by vessels participating in the 1992 trawl fisheries is estimated at 111,325 crab, or about 56 percent of the 200,000 crab bycatch limit established for the trawl fisheries in Zone 1. Recognizing that the red king crab bycatch limit will restrict bycatch amounts to specified levels, the Council maintained the 2.5 red king crab/mt of groundfish bycatch rate standard to support those fishermen who actively pursue alternative fishing grounds in an attempt to reduce halibut bycatch rates.

The Regional Director has determined that Council recommendations for bycatch rate standards are appropriately based on the information and considerations necessary for such determinations under §§ 672.26(c) and 675.26(c). Therefore, the Regional Director concurs in the Council's determinations and recommendations for halibut and red king crab bycatch rate standards for the first half of 1993 as set forth in Table 1. These bycatch rate standards may be revised and published in the **Federal Register** when deemed appropriate by the Regional Director pending his consideration of the information set forth at §§ 672.26(c) and 675.26(c).

Fishing Months

As required in regulations at §§ 672.26(a)(2)(iii) and 675.26(a)(2)(iii), the 1993 fishing months are specified as the following periods for purposes of calculating vessel bycatch rates under the incentive program:

Month 1: January 1 through January 30;
Month 2: January 31 through February 27;
Month 3: February 28 through April 3;
Month 4: April 4 through May 1;
Month 5: May 2 through May 29;
Month 6: May 30 through July 3;
Month 7: July 4 through July 31;
Month 8: August 1 through August 28;
Month 9: August 29 through October 2;
Month 10: October 3 through October 30;
Month 11: October 31 through November 27; and
Month 12: November 28 through December 31.

Classification

This action is taken under 50 CFR 672.26 and 675.26 and complies with E.O. 12291.

Information upon which the recommended bycatch rate standards are based was not available prior to the Council's December 1992 meeting. These standards must be effective by the start of the 1993 trawl season on January 20, to avoid a lapse in vessel accountability under the vessel incentive program. Without this accountability, prohibited species bycatch rates could increase in the groundfish trawl fisheries, prohibited species bycatch allowances could be reached sooner, specified groundfish trawl fisheries could be closed prematurely, and owners and operators of groundfish trawl vessels could incur additional foregone revenues. Therefore, the Assistant Administrator for Fisheries, NOAA, finds for good cause that it is impractical and contrary to the public interest to extend prior notice and comment on this notice beyond the start of the 1993 trawl season, or to delay its effective date.

List of Subjects in 50 CFR Parts 672 and 675

Fisheries, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated December 31, 1992.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

TABLE 1.—BYCATCH RATE STANDARDS, BY FISHERY AND QUARTER, FOR THE FIRST HALF OF 1993 FOR PURPOSES OF THE VESSEL INCENTIVE PROGRAM IN THE BSAI AND GOA.

Fishery and quarter	1993 bycatch standard
Halibut bycatch as kg of halibut/mt of allocated groundfish catch	
BSAI Midwater pollock:	
Qt 1	1.0
Qt 2	1.0
BSAI Bottom pollock:	
Qt 1	7.5
Qt 2	5.0
BSAI Yellowfin sole:	
Qt 1	5.0
Qt 2	5.0
BSAI Other trawl:	
Qt 1	30.0
Qt 2	30.0
GOA Midwater pollock:	
Qt 1	1.0
Qt 2	1.0
GOA Other trawl:	
Qt 1	50.0
Qt 2	50.0
Zone 1 red king crab bycatch rates (number of crab/mt of allocated groundfish)	
BSAI Yellowfin sole:	
Qt 1	2.5
Qt 2	2.5
BSAI Other trawl:	
Qt 1	2.5
Qt 2	2.5

[FR Doc. 92–31956 Filed 12–31–92; 2:59 pm]

BILLING CODE 3510–22–M

Proposed Rules

Federal Register
Vol. 58, No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1944

RIN 0575–AB16

Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend its Single Family Rural Housing loan making regulation. The following actions are taken: The definition of income is being revised pursuant to the Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, which excludes "any earned income tax credit to the extent it exceeds tax liability" from being counted in the annual income; The interests of individual Indians in trust or restricted lands and payments made from the Agent Orange Settlement Fund or any other exempted Federal statutes cannot be used for the purposes of determining eligibility for an FmHA loan, nor can they be considered in determining the amount of interest credit assistance for which a borrower is eligible; Exclusion from the definition of annual income of pay of a member of the Armed Forces stationed in the Operation Desert Storm Combat Zone; FmHA will no longer post the selected Rural Housing applicants' names on the FmHA County Office's bulletin boards; FmHA will require applicants/borrowers to submit Federal income tax returns as part of a completed loan application; and the interest credit regulation is updated and discrepancies with previously published regulations are removed.

DATES: Comments must be received on or before March 5, 1993.

ADDRESSES: Submit written comments, in duplicate, to the Office of the Chief, Regulations Analysis and Control Branch, Farmers Home Administration, U.S. Department of Agriculture, room 6348, South Agriculture Building, 14th and Independence SW., Washington, DC 20250. All written comments will be available for public inspection during regular working hours at the above address.

FOR FURTHER INFORMATION CONTACT: Gloria L. Denson, Loan Specialist, Farmers Home Administration, USDA, room 5334–S, South Agriculture Building, 14th and Independence SW., Washington, DC 20250, Telephone (202) 720–1487.

SUPPLEMENTARY INFORMATION:

Classification

These actions have been reviewed under USDA procedures established in Departmental Regulation 1512–1 which implements Executive Order 12291, and has been determined to be a nonmajor because there is no substantial change from practices under existing rules that would have an annual effect on the economy of $100 million or more. There is no major increase in cost or prices for consumers, individual industries, Federal, State, or local Government agencies, or geographic regions, or significant adverse effects on competition, employment, productivity, innovation, or in the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets. These actions are not expected to substantially affect budget outlay or affect more than one Agency or to be controversial. The net result is expected to provide better service to rural residents.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, Environmental Program. It is the determination of FmHA that the proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Policy Act of 1949, Public Law 91–90, an Environmental Impact Statement is not required.

Intergovernmental Consultation

For the reason set forth in the final rule related notice to 7 CFR part 3015, subpart V, 48 FR 29115, June 24, 1983, this program/activity is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials.

Program Affected

This program is listed in the catalog of Federal Assistance under 10.410, Low-Income Housing Loans.

Regulatory Flexibility Act

This final rule has been reviewed with respect to the Regulatory Flexibility Act (5 U.S.C. 601–612). The undersigned has determined that this action will not have a significant economic impact on a substantial number of small entities since this rulemaking action does not involve a new or expanded program.

Background/Discussion

FmHA's existing regulations require any earned income tax credit to the extent it exceeds income tax liability to be included in the applicant/borrower's annual income. The Omnibus Budget Reconciliation Act of 1990, Public Law 101–508, excluded the earned income tax credit refund from being considered as income for purposes of FmHA housing programs. This exclusion was effective January 1, 1991. Therefore, the current regulations are being amended to exclude this requirement from the annual income definition.

FmHA is revising its regulations defining income for housing programs to clarify that the interests of individual Indians in trust or restricted lands shall not be considered a resource in determining eligibility for assistance. This change is consistent with 25 U.S.C. 1408.

Revisions are being made to FmHA regulations to exclude payments from the Agent Orange Settlement Fund or any other fund established pursuant to the settlement in the In re Agent Orange product liability litigation as means or resources for purposes of determining eligibility for an FmHA housing loan or interest credit. These changes are required by Public Law 101–201.

Section 501(b)(5) of the Housing Act of 1949 provides that for the purposes of the Housing Act of 1949 the "terms 'income' and 'adjusted income' have the meanings given by sections 3(b)(4) and 3(b)(5), respectively, of the United States Housing Act of 1937." Section 3(b)(4) of the United States Housing Act of 1937, 42 U.S.C. 1437a(b)(4), provides that the "term 'income' means income

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from all sources of each member of the household, as determined in accordance with criteria prescribed by the Secretary of [of HUD], in consultation with the Secretary of Agriculture, except that any amounts not actually received by the family may not be considered as income under this paragraph." On January 29, 1991, the HUD Assistant Secretary for Public and Assisted Housing issued Notice H 91-11 which, among other things, waives HUD regulations which required annual income to include "all regular pay, special pay and allowances of a member of the Armed Forces." Thus, for the duration of Operation Desert Storm HUD's definition of annual income does not include military pay of military personnel stationed in the combat zone as defined in Presidential Executive Order 12744 (January 21, 1991). This revision in the definition of annual income is added to the FmHA definition of income for housing programs.

Current regulations require the County Supervisor to post on the County Office bulletin board after each selection period a list of the names of those applicants who have been selected and notified of the processing of their application. Based on recent Supreme Court decisions under the Freedom of Information Act (FOIA), FmHA is deleting this public posting requirement.

Current FmHA regulations do not require the County Supervisor to have the applicants submit, during the application process, audited and/or certified financial statements and income tax returns. The regulations are being revised to require the FmHA County Supervisor to review the Single Family Housing applicants' audited and/or certified financial statements and/or most recent Federal income tax returns as a part of the application process.

In an earlier rule change, FmHA implemented a provision of the Housing and Community Development Act of 1987 that provided for borrowers receiving interest credit assistance to continue their interest credit subsidies even though their incomes exceeded the moderate income level. To eliminate inconsistencies, the Agency proposes to revise the limitation on new interest credits for existing loans to allow borrowers with income not exceeding moderate to receive interest credit. In the past, a borrower had to have a low income to initially receive interest credit, although interest credit could continue to the borrower when the adjusted family income exceeded the moderate income limit. The change will allow existing borrowers who have moderate incomes to qualify to receive interest credit.

A change in the effective period of the Interest Credit Agreement is proposed in situations where the borrower is unemployed. Currently, the Interest Credit Agreement is processed for 12 months based on the borrower's present verified income. When a borrower receives unemployment income, there is potential for confusion about how to estimate the borrower's income for the next 12 months. The Agency proposes to extend the Interest Credit Agreement only for the known period of unemployment benefits or six months. The borrower's income will be reviewed prior to the end of this period and the interest credit agreement revised accordingly.

A change is being made to ensure that the Agency handles a reduction in income consistently between the servicing regulations (7 CFR part 1951 subpart G) and the credit regulations. Currently, married borrowers must be separated for a period of at least six months before additional interest credit assistance can be considered. An income reduction of at least 30 percent within three months of the anniversary date was not considered for additional interest credit assistance until the anniversary date. FmHA servicing regulations permit an account to be accelerated when it is three monthly payments delinquent provided the account has been serviced. Thus it was possible to accelerate a borrower's account before reaching the prescribed eligibility for additional interest credit assistance. Revisions have been made to correct this problem and to allow consideration of interest credit benefits at the end of three months instead of six months. In addition, borrowers may qualify for a reduction in payments at any time, provided the verified change in income results in a payment reduction of at least 15 percent.

The Agency proposes to remove the provision for cancelling interest credit benefits to a family who has improved its property beyond what is considered to be modest for the area. This provision was untenable because the lack of interest credit would make many of these families unable to afford the costs of home ownership.

The Agency proposes to add a District Director review of a representative sample of interest credit agreements in each County Office. The incomes reported on these agreements will be verified with the State Employment Agency, or similar agency, to ensure that all family income has been counted.

Paperwork Reduction Act

The collection of information requirements contained in this regulation have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980. Public reporting burden for this collection of information is estimated to vary from 15 minutes to 1.5 hours per response, with an average of 30 minutes per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, 404–W, Washington, DC 20250; and to the Office of Management and Budget, Attention: Desk Officer for the Farmers Home Administration, Washington, DC 20503.

Civil Justice Reform

The proposed regulation has been reviewed in light of Executive Order (EO) 12778 and meets the applicable standards provided in section 2(a) and (2)(b)(2) of that Order. Provisions within this part which are inconsistent with state law are controlling. All administrative remedies pursuant to 7 CFR part 1900 subpart B must be exhausted prior to filing suit.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992 memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is

minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this Notice.

List of Subjects in 7 CFR Part 1944

Home improvement, Loan programs—Housing and community development, Low and moderate income housing—Rental, Mobile homes, Mortgages, Subsidies.

Therefore, as proposed, part 1944, chapter XVIII, title 7, Code of Federal Regulations, is amended as follows:

PART 1944—HOUSING

1. The authority citation for part 1944 continues to read as follows:

Authority: 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart A—Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

2. Section 1944.5 is amended by removing paragraph (d)(8) and redesignating current paragraphs (d)(9), (10), and (11), as paragraphs (d)(8), (9), and (10), respectively; and by revising paragraphs (e)(8), (e)(12), and (e)(17) to read as follows:

§ 1944.5 Annual income.

* * * * *

(e) * * *

(8) The hazard duty pay to a service person applicant/borrower or spouse away from home and exposed to hostile fire. The imminent danger duty pay to a service person applicant/borrower or spouse away from home and exposed to hostile fire. Amounts of imminent danger pay for Military personnel stationed in the Combat Zone are excluded from annual income effective August 2, 1990. Any military pay received by persons serving in the Combat Zone received on or after January 17, 1991 is excluded from annual income. The Combat Zone, as defined by the Presidential Executive Order 12744 dated January 21, 1991, consists of the Persian Gulf, the Red Sea, the Gulf of Oman, that portion of the Arabian Sea that lies north of 10 degrees north latitude and west of 68 degrees east longitude, the Gulf of Aden, the total land areas of Iraq, Kuwait, Saudi Arabia, Oman, Bahrain, Qatar, and the United Arab Emirates. Immediately upon notification by the family or based on information from a knowledgeable source that a member of the household is or was serving in the Combat Zone, the County Supervisor shall redetermine the household income retroactive to January 17, 1991, and adjust the borrower's interest credit accordingly.

* * * * *

(12) Any earned income tax credit to the extent it exceeds income tax liability will not be counted as part of annual income, but will remain part of the applicant's income for purposes of repayment ability.

* * * * *

(17) Payments received from the Agent Orange Settlement Fund, income from interests of individual Indians in trust or restricted land, and any funds which a Federal statute specifies must not be used as the basis for denying or reducing Federal financial assistance or benefits to which the recipient would otherwise be entitled.

3. Section 1944.26 is amended by removing paragraph (c) (2) and redesignating paragraphs (c) (3), (4), and (5) as (c) (2), and (3) and (4), respectively; and by adding a paragraph (a) (7) to read as follows:

§ 1944.26 Application processing.

* * * * *

(a) * * *

(7) The applicant must submit a certified financial statement and/or a copy of the applicant's most recently filed Federal income return as part of the completed loan application. The applicant will be advised of this requirement during the application interview.

* * * * *

4. Section 1944.34 is revised to read as follows:

§ 1944.34 Interest credit.

(a) *General.* It is the policy of FmHA to grant interest credit on loans to qualified borrowers to assist them in obtaining and retaining decent, safe, and sanitary dwellings and related facilities. When FmHA contracts out servicing, all actions assigned to the County Supervisor may be performed by the contractor, except approval or cancellation of interest credit.

(b) *Definition.*—(1) *Annual payment borrowers.* Borrowers who signed promissory notes providing for annual payments, including borrowers converted to monthly payments through the use of Form 1951–34, Direct Plan Change.

(2) *Monthly payment borrowers.* Borrowers who signed promissory notes providing for monthly payments.

(3) *Review period.* The review period for an annual payment borrower will be the months of October and November. The review period for a monthly payment borrower will be the second and third months prior to the scheduled expiration date of the borrower's current Interest Credit Agreement.

(4) *Real estate taxes.* Real estate taxes for interest credit purposes means the amount of real estate taxes and assessments that will actually be due and payable on the dwelling and the dwelling site during the interest credit period, reduced by the amount of any tax exemption available to the borrower, regardless of whether such exemption is actually claimed. Tax exemptions may include such things as homestead exemptions, special exemptions for low-income families, senior citizens, veterans, and others.

(c) *Approval authority.* Those FmHA officials who are authorized to approve Section 502 loans are also authorized to approve the Interest Credit Agreement.

(d) *Amount of interest credit.* (1) Loans other than FmHA loans qualified to be considered in the interest credit calculation include only those loans made for authorized Section 502 RH purposes and which are a lien against the FmHA security by virtue of a prior mortgage. Except as provided in paragraph (d)(2) of this section, the amount of interest credit granted will be the lesser of:

(i) The difference between 20 percent of the borrower's adjusted annual income and the sum of the annual installments due at the note interest rate on qualified loans plus the cost of real estate taxes and insurance, or

(ii) The difference between the annual installment due on the FmHA promissory notes eligible for interest credit and the amount the borrower would pay if the loan(s) was amortized at an interest rate of 1 percent.

(2) For repair and rehabilitation loans which meet the requirements of paragraph (f)(6) of this section, interest credit will be granted in an amount to achieve the following effective interest rates:

(i) For borrowers whose adjusted annual income is not more than $5,000, interest credit will be calculated using the amortization factor for 1 percent.

(ii) For borrowers whose adjusted annual income is more than $5,000 but not more than $7,000, interest credit will be calculated using the amortization factor for 2 percent.

(iii) For borrowers whose adjusted annual income is more than $7,000 but not more than $10,000, interest credit will be calculated using the amortization factor for 3 percent.

(3) Borrowers qualifying for interest credit assistance under both paragraphs (d) (1) and (2) of this section will be granted only the one type of interest credit assistance that is most beneficial to them. Interest credit on initial and subsequent loans will always be the same type. There is no provision for switching from one type of interest credit to the other.

(e) *Recapture.* At the applicant interview, FmHA will advise all Section 502 RH applicants that interest credit is subject to recapture.

(f) *Eligibility.* To be eligible for interest credit, a borrower must qualify for a Section 502 loan, must personally occupy the dwelling, and must meet the following additional requirements:

(1) *Initial loans including credit sales.* Interest credit may be granted at loan closing if:

(i) The borrower's adjusted annual income at time of loan approval did not exceed the applicable low-income limit in Exhibit C of this subpart. (Available in any FmHA office).

(ii) The borrower's net family assets do not exceed $7,500, (maximum as defined in § 1944.2(n) of this subpart) (net family assets of $10,000 will be allowed for an elderly family as defined in § 1944.2(d) of this subpart) unless an exception is authorized. The calculation of net family assets will exclude the value of the dwelling and a minimum adequate dwelling site, cash on hand which will be used to reduce the amount of the loan, and household goods and personal automobile(s) and the debts against them.

(iii) The term of the loan will be determined in accordance with § 1944.25 of this subpart. Interest credit will not be granted on loans with a term of less than 25 years, except as provided in paragraphs (f) (4) and (6) of this section.

(iv) The loan was approved on or after August 1, 1968, and

(v) The amount of interest credit will be $5 or more per month or $60 or more annually.

(2) *Subsequent loans.* Interest credit may be granted on subsequent loans which meet the requirements of paragraph (f)(1) of this section. If interest credit is presently being granted on the initial loan and the borrower's adjusted income does not exceed the moderate-income limit, it may also be granted on the subsequent loan if the term of the subsequent loan is 25 years or more.

(3) *Assumptions.* Interest credit may be granted to a borrower assuming a RH loan provided the assuming party(ies) qualifies according to paragraph (f)(1) of this section.

(4) *Reamortization.* Interest credit may be granted on loans made as low- and moderate-income loans after reamortization:

(i) If the loan was eligible for interest credit prior to reamortization, interest credit may continue to be granted regardless of the remaining reamortization period.

(ii) If the loan was not eligible for interest credit prior to reamortization, the reamortized term of the loan must be 25 or more years and all other conditions of paragraph (f)(1) of this section must be met.

(5) *Existing loans.* Interest credit may be granted at any time after loan closing if:

(i) the requirements of paragraphs (f)(1) (ii), (iii), and (v) of this section are met;

(ii) the loan was approved as a "low or moderate" Section 502 loan on or after August 1, 1968;

(iii) the borrower's adjusted annual income does not exceed the moderate income limit in Exhibit C of this subpart (available in any FmHA Office).

(iv) Due to a change in circumstances, the borrower requests interest credit, or FmHA determines that interest credit is needed to enable the borrower to repay the loan. In the case of co-borrowers, when one co-borrower has left the dwelling due to domestic discord, interest credit based on the remaining co-borrower's income may be extended to the remaining co-borrower if:

(A) the remaining co-borrower is occupying the dwelling, owns a legal interest in the property, and is liable for the debt;

(B) legal papers have been filed with the appropriate court to commence divorce or legal separation proceedings, or one co-borrower has not been living in the dwelling for at least three months. Interest credit will not be granted if separation is due only to work assignment or military order; and

(C) The remaining co-borrower is informed and agrees that should the co-borrower return to live in the dwelling, that co-borrower's income will then be counted toward annual income and interest credit may be reduced or cancelled.

(6) *Repair and rehabilitation loans.* Interest credit may be granted on Section 502 RH loans made to repair or rehabilitate a dwelling already owned by the applicant provided the following conditions are met:

(i) The initial interest will be granted at the time of loan closing and the loan will be secured by a real estate mortgage;

(ii) The dwelling is, or will be, occupied by an eligible borrower after the loan is made;

(iii) The amount of the loan will not exceed $10,000, or be amortized for not more than 25 years;

(iv) The applicant's adjusted annual income does not exceed $10,000;

(v) The repairs will be made to bring a substandard dwelling up to the standards outlined in Section 1944.16(j); and

(vi) The net family asset requirements in paragraph (f)(1)(ii) of this section are met.

(g) *Processing interest credit*—(1) *General.* The amount of interest credit for which a borrower may be eligible will be determined by use of Form FmHA 1944–6 or Form 1944–A6, "Interest Credit Agreement," as outlined in paragraph (d) of this section.

(i) *Determination of Income.* The County Supervisor is responsible for determining the borrower's annual and adjusted annual income as defined in § 1944.2, paragraphs (b) and (c) respectively, of this subpart. A borrower interview will be conducted in all cases for granting initial interest credit. Form FmHA 1910–5 will be used to verify the earning from employment of all persons whose income is included in "Annual Income."

(ii) *Effective period.* Interest Credit Agreements on loans made to monthly payment borrowers will be for a 12-month period. For annual payment borrowers and annual converted to monthly borrowers, the agreements will be in effect until January 1 after the effective date. For an unemployed borrower receiving unemployment benefits, the agreement will be effective for the period during which the borrower will receive unemployment benefits, or if the period if unknown, no longer than 6 months. The expiration date will be established by FmHA.

(iii) *Partial year interest credit.* For an annual payment borrower with an initial installment less than a regular installment, and who will receive less than a full year of interest credit assistance, the interest credit granted will be pro rata portion calculated on the number of months left in the current calendar year, including the month in which the loan is closed.

(iv) *Advance from the RHIF.* The repayment schedule for advances made from the Rural Housing Insurance Fund will be computed at the interest rate shown on the promissory note.

(v) *Preparation of the transaction record.* For borrowers receiving interest credit in Western Pacific Territory field offices, the following changes will be shown on Form 451–26, Transaction

Record, when prepared by the Finance Office:

(A) *Interest rate field.* The interest rate field of the form will continue to show the interest rate on the note. The Finance Office will compute the effective interest rate charged the borrower based on the amount of interest credit granted. The computed rate, rounded to the nearest ⅛ of a percent, will be shown as a footnote on the form as "Interest Rate reduced to ____%." Subsequent transactions will be applied to the loan by the Finance Office at the reduced interest rate until such time as renewal, change, or cancellation occurs.

(B) *Daily interest accrual field.* The daily interest accrual will be shown at the reduced interest rate and the interest will accrue at the same interest rate until such time as the interest credit is renewed, changed, or cancelled.

(C) *Application of credit field.* The initial transaction record form will not have an entry in the "Application of Credit" field. The Interest Credit Transaction Code for this method of processing interest credit will be 4 Z.

(D) Payment status field. The payment status field will not reflect the dollar amount of the interest credit granted. No entry will be made for monthly payment borrowers.

(E) Minimum amount due by date show field. For annual payment borrowers, the amount of the installment, reduced by the amount of interest credit granted, will be shown. For monthly payment borrowers the word "monthly" will be entered in the space provided.

(2) *Initial and subsequent loans*—(i) *County Office action.* The County Supervisor will:

(A) Determine the borrower's adjusted annual income and document the calculations in the case file running record.

(B) Enter on Form FmHA 1940–1 the adjusted annual income, the estimated real estate taxes that will become due and payable during the first and second years of the agreement, and the amount of the annual property insurance premium for the dwelling.

(C) For initial loans approved with interest credit and closed under the multiple advance feature of the loan disbursement system outlined in Subpart A of Part 1902 of this Chapter, further review of the borrower's financial status is not required unless the Interest Credit Agreement will be approved more than 90 days after the last "Verification of Employment" or there is evidence which indicates the borrower's financial status has changed significantly. If prior to the approval of the Interest Credit Agreement, the County Supervisor finds that the adjusted income has increased, interest credit will be granted on the basis of the borrower's new circumstances.

(D) Complete a corrected Interest Credit Agreement when the loan is closed or at the amortization effective date if the borrower's circumstances have changed do that the amount of interest credit would be increased or decreased by at least $5 monthly or $60 annually.

(3) *Reamortization, credit sales and transfers.* Interest credit to a borrower whose loan(s) is being reamortized, or a borrower who assumes an RH loan or purchases property from inventory will be calculated by the County Office on Form FmHA 1944–6.

(4) *Existing loans.* Interest credit granted in accordance with paragraph (f)(5) of this section can be processed at any time in the same manner as interest credit on initial loans, except that the County Office will complete Form FmHA 1944–6 and calculate the amount of interest credit assistance the borrower will receive.

(h) *Interest credit modification*—(1) *Before expiration.* When approving a change in interest credit assistance before the expiration of a current Interest Credit Agreement in accordance with paragraph (i)(3) of this section, FmHA will interview the borrower and determine the borrower's adjusted annual income.

(2) *Correction of Interest Credit Agreement.* When an error by a FmHA employee results in granting at least $5 per month ($60 per year) less interest credit than the borrower was eligible to receive, a corrected agreement will be prepared. The effective date of the corrected agreement will be the same as the agreement in error. Payments made under the previous agreement will be reapplied according to the terms of the new Interest Credit Agreement.

(3) *Interest credit renewal.* Pursuant to delegations of procurement authority included in FmHA Instruction 2024–A (available in any FmHA Office), FmHA is authorized to enter into contracts for the processing of interest credit renewals. Contractors will not be given the authority to approve or disapprove Interest Credit Agreements.

(i) *Borrower responsibility.* The interest credit renewal packages are issued annually to determine the borrower's eligibility for interest credit assistance and to verify the earnings or incomes of all persons whose incomes are included in the annual income. Upon receipt of the package, the borrower's responsibility will to give one copy of the Verification of Employment (Form FmHA 1910–5) to the employer or employers of each member of the household who has income to be considered. An envelope will be provided each employer to facilitate the mailing of the form directly to the County Office or to the contractor, if applicable. The borrower will also complete Part II of the interest form, sign the original form and bring the original and all copies to the FmHA or the interest credit contractor. Postage for these envelopes will be provided as set forth in § 1944.26(a)(5) of this subpart.

(ii) *County Office actions.* The County Supervisor, or designee will:

(A) One month prior to the interest credit agreement expiration date, Transaction Code (T/C) IC will become available for a borrower and the county office will access the workfile to enter the required renewal information using Transaction Code T/C IC, Interest Credit Workfile, via the Automated Discrepancy Processing System (ADPS). At this time, the County Office may input the necessary data which will be updated to the borrower's account on the expiration date. The county office should not attempt to change the process code, this will be taken care of systemically.

(B) Conduct an interview with the borrower to review the information on Forms FmHA 1944–A6 and FmHA 1910–5 for completeness and accuracy. The interview should, when possible, be face to face contact. After discussing the interest credit renewal with the borrower, a typewriter should be used to complete actions III and V on the Form FmHA 1944–A6. All amounts should be rounded in accordance with the Forms Manual Insert and shown in dollars only.

(C) Determine the adjusted annual income and document the calculations in the case file running record. After completion and verification of the information on Form FmHA 1944–A6, retain the original in the County Office for use in processing the renewal to the IC workfile and as part of the borrower's official record. Return the last copy to the borrower. Do not return Form 1944–A6, Interest Credit Agreement, for monthly borrowers to the Finance Office.

(D) If the borrower is no longer eligible for interest credit, notify the borrower by using Exhibit B 1 to 7 CFR part 1900, subpart B. The letter must notify the borrower of the right to appeal as outlined in 7 CFR part 1900, subpart B. A new Form FmHA 440–9 will be obtained when needed.

(E) Effective with the processing of interest renewal information to the workfile, annotate on the Form 1944–A6

and the list the name of the employee entering the data, date information entered, and related ADPS block number of T/C IC. FmHA Instruction 2033–A, Exhibit C, provides the program records retention requirements for source/input documents processed to ADPS via the Field office terminal system.

(iii) *Finance Office actions.* The Finance Office will update automated monthly interest credit renewals daily, based upon the effective date. Direct payment coupons will be mailed in time to ensure that borrowers are provided their new payment packet in sufficient time to make their next payment as scheduled.

(iv) *Processing interest credit renewals not received during the interview period.* Interest credit agreements not updated via the Interest Credit Workfile will automatically be canceled as of the expiration date. To ensure continued interest credit, it is imperative that renewals are processed to the workfile before the agreement effective date.

(v) *Renewals not updated before the expiration date.* If a renewal was not updated before the expiration date, perform the following:

(A) Access and verify that the renewal record for the applicable borrower's case number is not on the Automated Discrepancy Processing System (ADPS) recap and resequence screen.

(B) If the renewal is on the ADPS, enter the renewal information.

(C) If the renewal is not on the ADPS, verify that the borrower's interest credit has been canceled by viewing the related on-line history information.

(D) If interest credit was canceled, verify that there is no later activity (transactions) that has processed and process the renewal through the field office terminal system.

(E) If later activity has processed, manuscript and route the renewal transaction to the Finance Office servicing team.

(i) *Eligibility review.* The eligibility reviews of borrowers currently receiving interest credits are based on verified earnings or incomes of all persons whose incomes are included in the annual income. The eligibility of those borrowers will be reviewed as follows:

(1) *Annual review.* The eligibility of borrowers will be reviewed annually during the review period.

(i) If the value of the borrower's net family assets increases above the applicable eligibility limit, interest credit will be renewed unless the increase is sufficient to enable the borrower to graduate to another source of credit.

(ii) Interest credit will not be renewed if the amount of interest credit for which the borrower qualifies is less than $5 monthly or $60 annually.

(2) *Renewal not completed during the review period.* When the borrower's renewal Interest Credit Agreement is not completed during the review period, it will be processed in accordance with § 1944.34(h)(3)(v).

(3) *Change in borrower's circumstances.* FmHA is not responsible for monitoring whether a borrower's income, family size, real estate taxes, or insurance costs have changed after an Interest Credit Agreement is approved. If, however, it becomes known that the borrower's circumstances have changed significantly, FmHA will take action in accordance with the following:

(i) Increased adjusted income outside the regular review period. If FmHA determines that the borrower's adjusted income has increased to the level where the interest credit is less than $5 monthly or $60 annually, the interest credit will be cancelled effective the date FmHA becomes aware of the situation. The borrower will be notified in accordance with paragraph (l) of this section.

(ii) Decreased adjusted income. Changes in interest credit will not be made unless the borrower's payment would be reduced by at least 15 percent.

(iii) FmHA will not count any military pay received by persons serving in the Combat Zone. If such income was counted, the FmHA County Supervisors should process a revised interest credit agreement, if not counting such pay would result in a change in the amount of interest credit. After the County Supervisor becomes aware that a borrower has entered active military duty after the loan is closed, the servicing of the account should be handled under § 1951.317 of Subpart G of Part 1951 of this chapter.

(j) *Unauthorized interest credit.* When it is determined that a borrower has received interest credit to which he/she was not entitled (unauthorized interest credit), the case will be serviced according to Subpart M of Part 1951 of this chapter.

(k) *Cancellation of interest credit agreements*—(1) *Reasons for cancellation.* An existing Interest Credit Agreement will be cancelled whenever:

(i) The borrower does not physically occupy the dwelling as his/her primary residence. Nursing homes and specialized care facilities are considered full time residences. The following may be indicators of non-occupancy:

(A) The borrower does not physically occupy the property more than half of the year

(B) The borrower's children are enrolled in a day school that is not considered within commuting distance of the dwelling

(C) The borrower's primary source of year round employment is not within commuting distance of the dwelling and/or

(D) The borrower routinely stays at another residence.

(ii) The borrower rents, leases, sells or conveys the title to the property.

(iii) The borrower has received improper interest credit as outlined in subpart M of part 1951 of this chapter and a corrected Interest Credit Agreement will not be submitted.

(iv) The borrower has an increase in income as outlined in § 1994.34(i)(3)(i) and is no longer eligible for interest credit.

(v) The security property is acquired by FmHA.

(vi) The borrower provides fraudulent or materially inaccurate financial information in connection with an interest credit application/renewal.

(2) *Effective date of cancellation.* The effective date of cancellation if the borrower has never occupied the property will be the date of loan closing. The effective date of cancellation for paragraphs (k)(1) (i), (ii), (iii), (iv) and (vi) of this section will be the date on which the earliest action occurs which causes the cancellation. If the date cannot be determined, the date on which FmHA became aware of the situation will be used. The effective date of cancellation for paragraph (k)(1)(v) of this section will be the date the property is acquired by FmHA. When an account has been accelerated and one of the conditions outlined in paragraph (k)(1) of this section exists, the Interest Credit Agreement will remain in effect until it expires. No interest credit renewals will be processed on accounts that are under acceleration. If foreclosure action is dismissed, withdrawn or terminates without sale of the property or payment of the loan in full, a renewal agreement will be prepared with an effective date as of the expiration of the previous agreement.

(l) *Applicant or borrower notice of right to appeal.* All applicants or borrowers who request and are denied interest credit or whose interest credits are reduced, cancelled, or not renewed, will be notified of their appeal rights. If a decision is not appealable, such as decisions based on verified income, or clear and objective statutory or regulatory requirements, the applicant or borrower will receive review rights.

5. Exhibit D of Subpart A is amended by redesignating paragraphs 5 through

21 as 6 through 22 and adding a new paragraph 5 to read as follows:

Exhibit D—Rural Housing Applicant Interview

5. *Review of Federal Tax Returns and/or Audited or Certified Financial Statements:* The County Supervisor will review the applicant/borrower's most recently filed Federal income tax return and/or certified financial statement as part of the completed loan application during the application processing/interview.

* * * * *

Dated: November 24, 1992.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 93–20 Filed 1–5–93; 8:45 am]

BILLING CODE 3410–07–M

FEDERAL RESERVE SYSTEM

12 CFR Part 211

[Regulation K; Docket No. R-0793]

International Banking Operations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule.

SUMMARY: The Board is proposing an amendment to part 211 of its regulations concerning the permissible activities of state-licensed branches and agencies of foreign banks. Section 202(a) of the Federal Deposit Insurance Corporation Improvement Act of 1991 provides that after December 19, 1992, a state-licensed branch or agency of a foreign bank may not engage in any activity that is not permissible for a federal branch of a foreign bank unless the Board has determined that the activity is consistent with sound banking practice, and in the case of an insured branch, the Federal Deposit Insurance Corporation (FDIC) has determined that the activity would pose no significant risk to the deposit insurance fund. This proposed amendment to Regulation K sets forth the application procedures that state-licensed branches and agencies of foreign banks will be required to follow in order to request the Board's permission to engage in or continue to engage in an activity that is not permissible for a federal branch of a foreign bank and the requirements of divestiture and cessation plans. Insured branches are also required to seek the approval of the FDIC to engage in or to continue to engage in such an activity.

DATES: Comments must be received by March 5, 1993.

ADDRESSES: Comments, which should refer to Docket No. R-0793, may be mailed to the Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551, to the attention of Mr. William W. Wiles, Secretary. Comments addressed to the attention to Mr. Wiles may be delivered to the Board's mailroom between the 8:45 am and 5:15 pm, and to the security control room outside of those hours. Both the mailroom and the security control room are accessible from the courtyard entrance on 20th Street between Constitution Avenue and C Street, NW. Comments may be inspected in room B-1122 between 9 am and 5 pm, except as provided in § 261.8 of the Board's Rules Regarding the Availability of Information, 12 CFR 261.8.

FOR FURTHER INFORMATION CONTACT: Kathleen M. O'Day, Associate General Counsel (202/452-3786), Ann E. Misback, Senior Attorney (202/452-3788), Margaret E. Miniter, Attorney (202/452-3900), John W. Rogers, Attorney (202/452-2798), Legal Division; Michael G. Martinson, Assistant Director (202/452-3640), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Street, NW., Washington, DC 20551.

SUPPLEMENTARY INFORMATION: Section 202 of the Act amended section 7 of the IBA by adding several new subsections concerning the establishment and termination of foreign bank branches in the United States. New subsection 7(h) of the IBA provides that after December 19, 1992, a state branch or state agency may not engage in any type of activity that is not permissible for a federal branch unless the Federal Reserve Board has determined that such activity is consistent with sound banking practice; and, in the case of an insured branch, the FDIC has determined that the activity would pose no significant risk to the deposit insurance fund. 12 U.S.C. 3105(h)(1).

In order to implement this provision, the Board is proposing to amend Regulation K (12 CFR part 211) concerning international banking operations by adding a new section to Subpart B entitled "Applications by State-Licensed Branches and Agencies to Conduct Activities Not Permissible for Federal Branches." This proposed new section provides that a foreign bank operating a state-licensed branch or agency in the United States, which desires to engage in or continue to engage in an activity that is not permissible for a federal branch, pursuant to statute, regulation or order or interpretation issued by the Comptroller of the Currency (OCC), shall file an application for permission to conduct or to continue conducting such activity with the Board.

Contents of Application

Section 211.29(b) of the proposed regulation provides that the application shall be in letter form and shall contain certain information, including among other things, a description of the activity in which the branch or agency desires to engage or in which it is already engaged, the foreign bank's financial condition, the assets and liabilities of the branch or agency, the projected effect of the proposed activity on the financial condition of the foreign bank and the branch or agency, and in the case of an application by a state-licensed insured branch, a statement of why the proposed activity will pose no significant risk to the deposit insurance fund.

In view of the fact that section 202(h) of the Act became effective on December 19, 1992, a foreign bank with a state branch or agency that currently is conducting an activity that is determined to be impermissible for a federal branch will not be able to obtain the Board's permission to continue the activity prior to that effective date. In such cases, the Board may permit any such branch or agency to continue to conduct the activity in question (at existing levels) until such time as the Board acts on its application. The Board expects any foreign bank engaged in an impermissible activity in a state-licensed branch or agency to file the required application promptly.

The Board and the FDIC have consulted concerning the type of information that each agency will need in order to make an informed judgment, and have agreed on a common list of information in order that applicants will need to prepare only one application which, in the case of insured branches, may be submitted to both agencies. It is contemplated that the Board and the FDIC will review such applications simultaneously. Moreover, the Board and the FDIC have attempted to balance their need for information on which to base their decisions with the cost to the applicant of gathering, organizing and submitting an application.

The Board is particularly interested in receiving comments concerning the amount and type of information requested pursuant to § 211.29(b) of the proposed regulation. Comment is also requested on whether there are certain

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classes of activities that, even though not permitted for federal branches, nonetheless are consistent with sound banking practices, and whether a more limited prior written notice rather than a letter application could be utilized in connection with these types of activities. With respect to the activities described in the preceding sentence, commenters are requested to describe the activity in detail and to explain why its conduct by a state-licensed branch or agency would be consistent with sound banking practice.

In addition, the Board requests comment concerning whether the conduct by a state-licensed branch or agency of activities permitted by the OCC pursuant to informal interpretation, opinion or advice rather than by formal interpretation or opinion should require the filing of an application. In this regard, the Board will initiate consultations with the OCC on any questions of whether a particular activity is or is not permissible for a federal branch. The Board also seeks comment on potential coordination between applications to the Board and the FDIC as a way to make this process as efficient as possible.

Finally, the Board requests comment on whether an application should be required when a foreign bank wishes to convert a federally-licensed branch or agency to a state-licensed branch or agency. When the Board approved the final amendments to Regulation K concerning establishment of branches and agencies, the Board decided that an application would *not* be required when a foreign bank wished to convert from a state license to a federal license, because it would be converting from a less restrictive to a more restrictive regime. In light of the statutory provision limiting state office powers to those of a federal branch unless the Board and, in the case of an insured branch, the FDIC approve the activities, the Board is requesting comment on whether it is necessary to require an application when a foreign bank seeks to convert from a federal to a state license.

Standards to be Examined

Section 211.29(c) sets forth the standards that the Board will examine in order to determine whether a particular practice in consistent with sound banking practice. These factors are:

(1) What types of risks, if any, the activity poses to the foreign banking organization;

(2) If the activity poses any such risks, the magnitude of each risk; and

(3) If a risk is not *de minimis*, the actual or proposed procedures to control and minimize such risk.

Each of these factors shall be evaluated in light of the financial condition of the foreign bank in general and the branch or agency in particular and the volume of the proposed activity. The Board may also determine that a particular activity, after consideration of the above factors and subject to any conditions or limits imposed by the Board, may be conducted by any state-licensed branch or agency without further application to the Board.

Divestiture or Cessation

In the event that a state branch or agency is required to cease conducting an activity pursuant to the proposed regulation, § 211.29(e) of the proposed regulation sets forth the guidelines that must be followed to divest or cease the impermissible activity. Generally, this section provides that the state branch or agency shall submit a written plan of divestiture or cessation within 60 days of

(1) Being notified by the Board or the FDIC that an application to continue to conduct the activity has been denied;

(2) The effective date of the regulation in the event that the foreign bank elects not to apply for permission to continue to conduct the activity; and

(3) Any change in statute, regulation, order or OCC interpretation that renders the activity impermissible.

Divestiture or cessation shall be completed within one year, or sooner if the Board so directs. The Board requests comment on whether this period of time should be longer or shorter.

Application Not Required in Certain Instances.

The Board has determined that an application under this section normally shall not be required where an activity is permissible to a federal branch, but the OCC imposes a quantitative restriction on the conduct of such activity by the federal branch. As described in further detail above, the Board is requesting comment on whether there are any other classes of activities for which more limited prior notice would suffice.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*), it is certified that the proposed rule would not have a significant impact on a substantial number of small entities.

List of Subjects in 12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

For the reasons outlined above, the Board is proposing to amend 12 CFR part 211 as set forth below:

PART 211—INTERNATIONAL BANKING OPERATIONS

1. The authority citation for part 211 continues to read as follows:

Authority: Federal Reserve Act (12 U.S.C. 221 *et seq.*); Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841 *et seq.*); the International Banking Act of 1978, (Pub. L. 95-369; 92 Stat. 607; 12 U.S.C. 3101 *et seq.*); the Bank Export Services Act (Title II, Pub. L. 97-290, 96 Stat. 1235); the International Lending Supervision Act (Title IX, Pub. L. 96181, 97 Stat. 1153, 12 U.S.C. 3901 *et seq.*); and the Export Trading Company Act Amendments of 1988 (Title III, Pub. L. 100-418, 102 Stat 1384 (1988)).

2. Part 211 is amended by revising § 211.29 to subpart B to read as follows:

§ 211.29 Applications by state-licensed branches and agencies to conduct activities not permissible for federal branches.

(a) *Scope.* Any state-licensed branch or agency that desires to engage in or continue to engage, after December 19, 1992, in any type of activity that is not permissible for a federal branch, pursuant to statute, regulation or order or interpretation issued by the Comptroller, shall file a prior written application for permission to conduct such activity with the Board pursuant to this section.

(b) *Content of application.* An application submitted pursuant to paragraph (a) of this section shall be in letter form and shall contain the following information:

(1) A brief description of the activity, including the manner in which it will be conducted and an estimate of the expected dollar value;

(2) A discussion by management of its analysis regarding the impact of the proposed activity on the applicant's earnings, capital adequacy, and general condition, and on the balance sheet, earnings and condition of the branch or agency, including a copy, if available, of any feasibility study, management plan, financial projections, business plan, or similar document concerning the conduct of the activity;

(3) A current statement of the applicant's assets, liabilities, and capital;

(4) A current statement of the assets and liabilities of the branch or agency;

(5) A copy of applicant's most recent audited financial statements;

(6) A resolution by the applicant's board of directors or, if a resolution is not required pursuant to the applicant's organizational documents, evidence of approval by senior management, authorizing the conduct of such activity and the filing of this application;

(7) In the case of an insured branch, a statement by the applicant of whether or not it is in compliance with §§ 346.19 and 346.20, Pledge of Assets and Asset Maintenance, respectively, of 12 CFR part 346;

(8) In the case of an insured branch, a statement by the applicant that it has complied with all requirements of the Federal Deposit Insurance Corporation concerning applications to conduct the activity in question and the status of such application, including a copy of the FDIC's disposition of such application, if applicable;

(9) In the case of an insured branch, a statement of why the activity will pose no significant risk to the deposit insurance fund; and

(10) Any other information that the Reserve Bank deems appropriate.

(c) *Factors to be considered in determination.*

(1) The Board may consider the following factors in order to determine whether a proposed activity is consistent with sound banking practice:

(i) The types of risks, if any, the activity poses to the foreign banking organization;

(ii) If the activity poses any such risks, the magnitude of each risk; and

(iii) If a risk is not de minimis, the actual or proposed procedures to control and minimize such risk.

(2) Each of the factors set forth in paragraph (c)(1) of this section, shall be evaluated in light of the financial condition of the foreign bank in general and the branch or agency in particular and the volume of the activity.

(d) *Application procedures.* Applications pursuant to this section shall be filed with the responsible Reserve Bank for the foreign bank. An application shall not be deemed complete until it contains all the information requested by the Reserve Bank and has been accepted. Approval of such an application may be conditioned on the applicant's agreement to conduct the activity subject to specific conditions or limitations.

(e) *Divestiture or Cessation.*

(1) In the event that an applicant's application for permission to continue to conduct an activity is not approved by the Board or the FDIC, the applicant shall submit a detailed written plan of divestiture or cessation of the activity to the responsible Reserve Bank within 60 days of the disapproval. The divestiture or cessation plan shall describe in detail the manner in which the applicant will divest itself of or cease the activity in question and shall include a projected timetable describing how long the divestiture or cessation is expected to take. Divestitures or cessation shall be complete within one year from the date of the disapproval, or within such shorter period of time as the Board shall direct.

(2) In the event that a foreign bank operating a state branch or agency chooses not to apply to the Board for permission to continue to conduct an activity that is not permissible for a federal branch or which is rendered impermissible due to a subsequent change in statute, regulation, order or interpretation, the foreign bank shall submit a written plan of divestiture or cessation, in conformance with § 211.29(d)(1) of this part, within 60 days of the effective date of this rule or of such change in statute, regulation, order or interpretation, respectively.

By order of the Board of Governors of the Federal Reserve System, December 30, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93–163 Filed 1–5–93; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92–NM–215–AD]

Airworthiness Directives; Airbus Industrie Model A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Airbus Model A320 series airplanes. This proposal would require modification of the inner rear spar web. This proposal is prompted by reports that cracking was found in the inner rear spar web during fatigue testing. The actions specified by the proposed AD are intended to prevent fatigue cracking, which may lead to reduced structural integrity of the main landing gear.

DATES: Comments must be received by March 2, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 92–NM–215–Ad, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, Airbus Support Division, Avenue Didier Daurat, 31700 Blagnac, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Greg Holt, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2140; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92–NM–215–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the

FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 92–NM–215–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on Airbus Model A320 series airplanes. The DGAC advises that during fatigue testing, cracking was found in the inner rear spar adjacent to 10 bolt holes. Cracking adjacent to two of the holes was located at rib 5 of the main landing gear (MLG) support. Cracking adjacent to the other eight holes was located at the anchorage of the MLG actuating cylinder. This cracking occurred at 64,120 simulated flights. Fatigue cracking, if not detected and corrected, could result in reduced structural integrity of the main landing gear.

Airbus Industrie has issued Service Bulletin A320–57–1004, Revision 1, dated September 24, 1992, which describes procedures for modification of the inner rear spar web. This modification consists of cold working the 10 bolt holes in which cracking was found during fatigue testing of an Airbus Model A320 series airplane. The French DGAC classified this service bulletin as mandatory and issued Airworthiness Directive 92–202–031(B), dated September 30, 1992, in order to assure the continued airworthiness of these airplanes in France.

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. pursuant to this bilateral airworthiness agreement, the French DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the French DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require modification of the inner rear spar web. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Currently, no airplanes of U.S. registry would be affected by this AD. However, should one of the affected airplanes be imported and placed on the U.S. register, it would take approximately 60 work hours per airplane to accomplish the required actions, and the average labor cost would be $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $3,300 per airplane.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "**ADDRESSES**."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR Part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus Industrie: Docket 92–NM–215–AD.

Applicability: Model A320 series airplanes, manufacturer's serial numbers (MSN) 003 through 008, inclusive; MSN's 018 through 021, inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent fatigue cracking, which may lead to reduced structural integrity of the main landing gear, accomplish the following:

(a) Prior to the accumulation of 12,000 landings, or within 500 landings after the effective date of this AD, whichever occurs later, modify the inner rear spar web in accordance with Airbus Industrie Service Bulletin A320–57–1004, Revision 1, dated September 24, 1992.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and the sent it to the Manager, Standardization Branch.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 29, 1992.

David Hmiel,

Acting Manager.

[FR Doc. 93–92 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–13–M

Office of the Secretary

14 CFR Part 300

[Docket 4852, Notice No. 92–36]

RIN 2105–AB89

Rules of Conduct in DOT Proceedings

AGENCY: Department of Transportation, Office of the Secretary.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Transportation is proposing amendments to its procedural regulations to permit Department staff to communicate informally with applicants and any objectors or other commenters in the initial investigation stage of air carrier initial certificate application and continuing fitness cases (collectively referred to as "fitness cases") where the issues are limited solely to fitness and/or U.S. citizenship. Under this proposal, once either a show cause order or an order instituting a formal proceeding is issued, the Department's current *ex parte* restrictions would apply. In several fitness proceedings, processing of those cases has been delayed unnecessarily or made more difficult because of the Department's inability under the current procedural regulations to discuss

informally aspects of the cases, in oral or written communications, with either the applicant carrier or objecting parties or other commenters. The proposed amendment would give the Department an added degree of flexibility in seeking information from all interested parties and would decrease the burden on applicants as well as objectors and other comments. However, it would still provide those parties a fair and complete opportunity to be heard and ensure an adequate record for the proceeding.

DATES: Comments must be submitted on or before February 22, 1993. Comments received after this date will be considered to the extent practicable. If adopted as a final rule, these amendments would take effect 30 days after publication of the final rule in the Federal Register.

ADDRESSES: Comments should refer to Docket 48582, and be submitted to: Docket Section (C–55), room 4107, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. The Docket Section is open from 9 a.m. to 5 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Patricia T. Szrom, Chief, Air Carrier Fitness Division (P–56), Office of the Secretary, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–9721.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in this rulemaking proceeding by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions. Communications should identify the regulatory docket number and be submitted in duplicate to the address listed above. Commenters wishing the Department to acknowledge receipt of their comments must submit with those comments a self-addressed stamped postcard on which the following statement is made: "Comments on Docket 48582." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date will be considered by the Assistant Secretary for Policy and International Affairs before taking action on any further rulemaking. Also, this proposal may be changed in light of comments received. All comments submitted will be available for examination in Docket 48528. A report summarizing each substantive public contact with DOT personnel concerned with this rulemaking will be filed in the docket.

Background

Under section 401(a) of the Federal Aviation Act (the Act), a Certificate of Public Convenience and Necessity (certificate) must be obtained from the Department of Transportation (the Department) before an air carrier may engage in any air transportation operations (49 U.S.C. app. 1371(a)).[1] Section 418 of the Act contains a similar certification requirement for air carriers proposing to engage in domestic all-cargo air service (49 U.S.C. app. 1388). Following an investigation, if the Department finds that an applicant for authority under section 401 or 418 is a U.S. citizen that is "fit, willing, and able" to engage in air transportation operations and comply with the Act and the Department's regulations, a certificate is issued. The Department's "fitness" requirement is a continuing one for carriers; that is, once a carrier is found fit initially, it must remain fit in order to continue to hold its authority section 401(r) of the Act, 49 U.S.C. app. 1371(r)).

Carriers that apply for fitness determinations must comply with the Department's regulations concerning specific and general requirements for certificate applications (14 CFR part 201), including providing supporting data (14 CFR part 204). The Department's regulations allow any person to file an answer in support of or in opposition to the application within 28 days of the filing date of the application (14 CFR 302.1720(d)). If the application is opposed, the Department's regulations concerning prohibited communications come into play.

Part 300 of the Department's aviation economic regulations establishes the terms and conditions governing the rules of conduct for Department proceedings under Chapter II of Title 14 of the Code of Federal Regulations (14 CFR part 300). Among other provisions, part 300 generally prohibits oral or written communications relevant to the merits of a public proceeding between any concerned Department employee and any interested person outside the Department until after the Department's final disposition of the proceeding (the *ex parte* rule) (14 CFR 300.2). For purposes of the Department's review of the fitness of applicants for certificate authority or its consideration of docketed petitions for review of an air carrier's continuing fitness, the *ex parte* rules are triggered by the filing in the docket of an identifiable written opposition to the initiating document (14 CFR 300.2(b)(4)).

The Department's *ex parte* rules in fitness cases are more restrictive than the *ex parte* requirements established by the Administrative Procedure Act, 5 U.S.C. 557(d). Those requirements cover only proceedings for which a formal hearing is required by statute. Since section 401 of the Act gives us the discretion to determine whether an oral evidentiary hearing should be held in fitness cases, the Administrative Procedure Act's *ex parte* requirements do not apply to applications for certificate authority.

Proposed Rules

As described above, the *ex parte* rules, with a limited exception,[2] require that once a written opposition to an application for certificate authority is filed all substantive communications between the Department and either the applicant or the opposing party or other commenters be made through documents that are filed in the docket and distributed to all the parties. In practice, the Department has found that the *ex parte* provisions of part 300 often unnecessarily delay the processing of fitness cases or make the processing unduly difficult.

The Department believes that application of the *ex parte* rules to all stages of fitness cases is often counter-productive. Many complex issues relating to the application and the objections to the application could more readily be resolved through informal investigative-type discussions with the applicant, the objectors, or any other interested parties. However, that informal type of inquiry is prohibited by the current rules.

Instead, the Department's staff must go through the burdensome task of putting all of its questions in writing, filing them in the docket, and serving them on all parties. The applicant must likewise respond in writing through the docket, with copies to all parties. Often responses to staff questions need clarification or spawn further inquiries. Moreover, questions asked by the Department's staff of the applicant may

[1] The Department has the authority under section 416(b) of the Act (49 U.S.C. 1386(b)) to exempt carriers from the certification requirement when doing so would be consistent with the public interest. For example, under 14 CFR 298.11, air taxi operators are exempt from the certification requirement.

[2] The exception concerns documents placed in the correspondence section of the docket per 14 CFR 300.3.

themselves require clarification before a proper response can be made. As a result, often matters that could be cleared up in minutes by telephone or in a meeting can drag on for days or weeks solely due to the tedious procedures of on-the-record communications required under the current rules. Overall, the process is often cumbersome and time-consuming.

Carrier applicants are not the only persons who suffer as a result. For example, the Department's staff cannot under present *ex parte* rules ask simple questions of an objector in an effort to verify the facts contained in the filing objecting to the application without a similarly unwieldy and protracted written procedure.

The fact-finding nature of the initial phase of fitness cases lends itself to an informal, rather than a formal, on-the-record investigative procedure. The Act requires that the Department find an applicant "fit, willing, and able." In fitness cases where the issues are limited to determinations of fitness and/or U.S. citizenship, the Act does not require that the Department choose the best applicant; there are no comparative rights at issue.[3] The Department believes that for fitness cases where the issues are thus limited, the intensive fact-finding required in the initial phase of those cases is best achieved by unobstructed lines of communication between the Department, the applicant, and other interested persons.

The Department continues to believe that the *ex parte* restrictions are appropriate once a show cause order or an order instituting a formal proceeding is issued to ensure due process for all applicants and informed, on-the-record decisionmaking. Therefore, the Department would retain the benefits offered by the *ex parte* restrictions where they are most appropriate to on-the-record decisionmaking: after issuance of a show cause order or other order instituting a formal proceeding. Moreover, the Department's orders ruling on the merits of a certificate application will set forth the factual basis for the Department's tentative and final conclusions on the applicant's fitness and citizenship, if the Department uses show-cause procedures for considering the application. Parties will therefore know what information is being relied upon by the Department in its analysis and will have an opportunity to comment on the findings of fact. If the Department determines to hold an oral evidentiary hearing on an application, the Department's ultimate decision will be based on the record developed in the formal hearing proceeding. As a result, the proposed rule will not deny any party ability to participate fully and fairly in a fitness proceeding.

In line with the action proposed here, where expedition and an unfettered ability to gather information is in the public interest, part 300 already provides for several exceptions to the prohibition against substantive *ex parte* communications (14 CFR 300.2(c)). For example, part 300 permits communications made in the course of an investigation to determine whether formal enforcement action should be taken (14 CFR 300.2(c)(3)). The initial review phase of a fitness case is very similar to an investigation conducted to determine whether reasonable cause exists to institute a formal enforcement proceeding, with the issuance of a show cause order in a fitness proceeding the equivalent of the issuance of a Notice of Enforcement Proceeding and filing of an accompanying formal complaint in the enforcement context.[4]

Accordingly, the Department proposes to amend section 300.2, *Prohibited communications*, by adding paragraph (c)(10) that would create an exception to the prohibition of *ex parte* communications made in the course of docketed cases where the issues are limited to determinations of fitness and/or U.S. citizenship, prior to the issuance of a show cause order or an order instituting a formal proceeding. Once either type of order is issued, the *ex parte* communications prohibitions would apply. This proposal would facilitate the collection of information needed for consideration of cases, minimize the time and resources necessary for parties to process cases, yet continue to ensure procedural fairness for all parties.

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The Department has analyzed the economic and other effects of this proposal and has determined that they are neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department's regulatory policies and procedures. The Department has also determined that the economic effects of the proposed amendments are so minimal that a full regulatory evaluation is not required. If these amendments are adopted, fitness application costs to carriers and costs to opposing parties should be slightly lower due to the less formal procedures that would replace the current procedures.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, the Department has evaluated the effects of this proposed action on small entities. Based upon this evaluation, the Department certifies that the proposed amendments would not have a significant economic impact on a substantial number of small entities. As stated above, the Department believes that the proposed amendments would create a slight economic benefit for parties in fitness cases.

Executive Order 12612 (Federalism)

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. The Department has determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This proposed rule would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Naitonal Environmental Policy Act

The Department has also analyzed this proposed rule for the purpose of the National Environmental Policy Act. The Department has determined that the proposed rule would not have any significant impact on the quality of the human environment.

List of Subjects in 14 CFR Part 300

Administration practice and procedure, Conflict of interests, Rules of conduct, Prohibited communications.

For the reasons set out in the Supplementary Information, title 14, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 would continue to read as follows:

Authority: 49 U.S.C. 1324, 1371–1389, 1471, 1473, 1481, 1482, and 1487, 18 U.S.C. 20(b)(c); 49 U.S.C. Subtitle I.

2. Section 300.2 would be amended by adding new paragraph (c)(10) to read as follows:

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[3] In cases where comparative rights are at issue, such as where the authority sought includes a market or markets where entry is limited by a bilateral agreement and there are competing proposals, the current *ex parte* rules would continue to apply.

[4] Indeed, certain continuing fitness proceedings may be more akin to enforcement investigations than to initial fitness proceedings.

§ 300.2 Prohibited communications.

* * * * *

(c) * * *

(10) Docketed proceedings involving determinations of fitness and/or U.S. citizenship only, for that portion of the proceeding that precedes the issuance of a show cause order or an order instituting a formal proceeding.

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Issued in Washington, DC, on December 30, 1992.

Jeffrey N. Shane,

Assistant Secretary for Policy and International Affairs.

[FR Doc. 93-225 Filed 1-5-93; 8:45 am]

BILLING CODE 4910-62-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 35 and 290

[Docket No. RM85-17-000]

Regulation of Electricity Sales-for-Resale and Transmission Service

Issued December 28, 1992

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Order Terminating Docket.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is terminating this proceeding because the Notices of Inquiry accomplished their purpose by generating public comments on the Commission's pricing and other regulatory policies, and because the information collected has since been overtaken by events.

FOR FURTHER INFORMATION CONTACT: Lawrence R. Greenfield, Deputy Assistant General Counsel, Office of the General Counsel, Federal Energy Regulatory Commission, 825 N. Capitol St., NE., Washington, DC 20426, Telephone: (202) 208-0415.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208-1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this document will be available on CIPS for 10 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Order Terminating Docket

On May 30, 1985 and June 28, 1985, the Commission issued two Notices of Inquiry in this proceeding to evaluate its then-present policies toward wholesale electricity transactions and transmission service, and to evaluate whether those policies promoted or impeded efficiency in electricity markets and whether there were alternatives or possible revisions that would further promote efficiency in the electric utility industry.[1] For the reasons given below, we are terminating this docket.

Background

As noted, in mid-1985, the Commission issued two Notices of Inquiry in a "broad inquiry into the regulation of electric utilities selling in wholesale markets."[2]

In the first Notice of Inquiry, the Commission addressed its regulation of coordination transactions and transmission service. With respect to such coordination transactions, the Commission reviewed its pricing policies, summarizing its then-current policies and asking commenters to address both those policies as well as possible alternatives.[3] With respect to transmission service, the Commission reviewed both pricing and availability, again summarizing its then-current policies and asking commenters to address those policies and possible alternatives.[4]

In the second Notice of Inquiry, the Commission addressed its regulation of requirements service. The Commission reviewed its then-current pricing practices and possible alternatives, as well as questions concerning the allocation of risk, and asked commenters to address these matters.[5]

Comments were filed as to both Notices of Inquiry by a broad cross-section of those involved in the electric utility industry—Federal and state governmental bodies (including the United States Department of Energy and various state commissions), electric utilities, customers and customer groups, and consultants and other persons active in the industry. In addition, the Commission held public conferences at which the matters raised by the Commission and commented upon by the various commenters were discussed.

Discussion

The Commission issued the two Notices of Inquiry, solicited comments, and held public conferences to learn whether the various segments of the electric utility industry—including utilities, customers, and regulations—believed the Commission's pricing and other regulatory policies were promoting or impeding efficiency, and what alternatives or changes might better promote efficiency.[6] Having received comments and having held the public conferences, that purpose was accomplished.

Moreover, much has changed since 1985. The Energy Policy Act of 1992, Public Law No. 102-486, 106 Stat. 2776 (1992), has been enacted. That Act, *inter alia*, provides for a new category of power producers, exempt wholesale generators or EWGs, which are exempt from regulation by the Securities and Exchange Commission under the Public Utility Holding Company Act of 1935, 15 U.S.C. 79a *et seq.* (1988). That Act also expands the Commission's ability to order transmission. Additionally, the Commission itself has, for example, accepted non-cost-based, market-based rates for service,[7] and has permitted public utilities to price their power and energy to respond to competitive pressures.[8]

In sum, the information sought by the Commission in its NOI's, and provided

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[1] Regulation of Electricity Sales-for-Resale and Transmission Service, Notice of Inquiry, 50 FR 23445 (June 4, 1985), IV FERC Stats. & Regs. ¶35,516 (1985) (*NOI I*); Regulation of Electricity Sales-for-Resale and Transmission Service, Notice of Inquiry, 50 FR 27604 (July 5, 1985), IV FERC Stats. & Regs. ¶35,519 (1985) (*NOI II*).

[2] *NOI II*, IV FERC Stats. & Regs. at 35,637.

[3] *NOI I*, IV FERC Stats. & Regs. at 35,628-33.

[4] *Id.* at 35,633-35.

[5] *NOI II*, IV FERC Stats. & Regs. at 35,637-53.

[6] See Pacific Gas & Electric Company, 38 FERC ¶61,242 at 61,781 (1987) (NOI's were issued "to gather information to be used to evaluate [Commission's] policies toward wholesale electricity transactions and transmission service").

[7] *E.g.*, Commonwealth Atlantic Limited Partnership, 54 FERC § 61,268 (1991); Commonwealth Atlantic Limited Partnership, 51 FERC ¶61,368 (1990); Public Service Company of Indiana, Inc., Opinion No. 349, 51 FERC ¶61,367, *order on reh'g sub nom.* PSI Energy, Inc., Opinion No. 349-A, 52 FERC ¶61,280, *clarified*, 53 FERC ¶61,131 (1990), *appeal dismissed sub nom. Northern Indiana Public Service Company* v. *FERC*, *954 F.2d 736 (D.C. Cir. 1992)*.

[8] *E.g.*, Public Service Company of Oklahoma, 54 FERC ¶61,021 (1991); Oklahoma Gas & Electric Company, 54 FERC ¶61,212, *reh'g denied*, 55 FERC ¶61,142 (1992).

in the comments and public conferences, served to educate the Commission. In many respects, however, that information has been overtaken by events and is now, quite simply, stale. Accordingly, as a matter of "administrative housekeeping", the Commission will terminate the docket.*

The Commission Orders:

Docket No. RM85-17-000 is hereby terminated.

By the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 92-110 Filed 1-5-92; 8:45 am]

BILLING CODE 6717-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 135

[Docket No. 88P-0251]

Frozen Desserts: Removal of Standards of Identity for Ice Milk and Goat's Milk Ice Milk; Amendment of Standards of Identity for Ice Cream and Frozen Custard and Goat's Milk Ice Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing: (1) To remove the standard of identity for ice milk, and (2) to amend the standard of identity for ice cream and frozen custard to provide for the use of safe and suitable sweeteners and to allow for the use of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure, in the food. To ensure consistency with the removal of the standard of identity for ice milk and the proposed changes in the standard of identity for ice cream and frozen custard, FDA is also proposing to remove the standard of identity for goat's milk ice milk and to make comparable changes in the standard of identity for goat's milk ice cream which cross-references the standard of identity for ice cream and frozen custard. FDA tentatively finds that these actions will promote honesty and fair dealing in the interest of consumers.

DATES: Comments by March 8, 1993. FDA proposes that any final rule that may issue based on this proposal, unless stayed by the filing of proper objections, become effective 1 year following the date of publication of the final rule in the **Federal Register**.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Margaret E. Cole, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4745.

SUPPLEMENTARY INFORMATION:

I. Background

A. The 1991 Advance Notice of Proposed Rulemaking

In the **Federal Register** of January 22, 1991 (56 FR 2149), FDA announced, in an advance notice of proposed rulemaking (ANPRM), that petitions had been filed in Docket No. 88P-0251 by the International Ice Cream Association (IICA), 888 16th St. NW., Washington, DC 20006, a trade association representing manufacturers and distributors of ice cream and other frozen desserts (petition dated February 23, 1990, and amended March 29, 1990); Public Voice for Food and Health Policy (Public Voice), 1001 Connecticut Ave. NW., Suite 522, Washington, DC 20036, a national nonprofit consumer research, education, and advocacy organization (petition dated March 30, 1990); The Calorie Control Council (the Council), 5775 Peachtree-Dunwoody Rd., Atlanta, GA 30342, an international association of manufacturers of low calorie and diet foods and beverages, including manufacturers of a variety of sweeteners and other low calorie ingredients (petition dated March 5, 1990); and Kraft General Foods (KGF), 1880 JFK Blvd., Philadelphia, PA 19103, a manufacturer and distributor of a broad range of food products within the United States (petition dated October 16, 1989, and submitted on March 14, 1990). The petitioners requested that the agency: (1) Amend the standard of identity for ice milk (§ 135.120 (21 CFR 135.120)) to change the name of the food from "ice milk" to "reduced fat ice cream;" (2) establish new standards of identity for "lowfat ice cream" and "nonfat ice cream;" (3) provide for the use of any safe and suitable sweeteners in the new or revised standards for "reduced fat," "lowfat," and "nonfat" ice cream products; and (4) amend the standard of identity for ice cream (135.110 (21 CFR 135.110)) to provide for the use of any safe and suitable sweeteners. Interested persons were given until March 25, 1991, to comment.

In the ANPRM, FDA specifically requested comments on whether the suggested names "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream" would be misleading to consumers. The agency also requested data and information concerning the need for, and appropriateness of, such new or revised standards, as well as on a number of factors including, but not limited to:

(1) The minimum weight per gallon requirement;

(2) The minimum total nonfat milk solids requirement;

(3) The milkfat content requirements;

(4) The use of "nonfat" on a product that may contain up to 0.5 percent milkfat;

(5) The use of "lowfat" on a product that may contain 2 percent milkfat;

(6) Whether the limitations on fat content should apply to the milkfat content of the basic mix or to the total fat content of the product including the fat contributed by characterizing flavoring ingredients (e.g., milk chocolate, butterscotch, and nuts) that may be added to the basic ice cream mix;

(7) Nutritional equivalency, i.e., whether these products should contain added vitamins and minerals;

(8) The suitability of, need for, and conditions of use of any safe and suitable sweeteners, including alternative sweeteners such as saccharin and aspartame;

(9) The need to amend the goat's milk ice cream and goat's milk ice milk standards of identity (§§ 135.115 and 135.125 (21 CFR 135.115 and 135.125)) to be consistent with any changes made in the ice cream and ice milk standards of identity (§§ 135.110 and 135.120);

(10) Alternative ways of addressing the underlying issue raised by the petitions, i.e., providing for lower fat ice cream products under the name "ice cream;"

(11) The alternative language, suggested by FDA, to describe the

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*As to an agency's considerable discretion not to initiate a rulemaking and its discretion not to promulgate a final rule after a notice of proposed rulemaking has been issued, see, e.g., Western Fuels-Illinois, Inc. v. ICC, 878 F.2d 1023, 1027, 1031 (7th Cir. 1989); Williams Natural Gas Company v. FERC, 872 F.2d 436, 443-44, 450 (D.C. Cir. 1989); Arkansas Power & Light Company v. ICC, 725 F.2d 716, 723 (D.C. Cir. 1984); Professional Drivers Council v. Bureau of Motor Carrier Safety, 700 F.2d 1218, 1220-21 (D.C. Cir. 1983).

These decisions involve situations different than the facts here—*i.e.*, decisions not to institute rulemaking proceedings at all or not to promulgate final rules after notices of proposed rulemaking, as compared to terminating a proceeding involving a notice of inquiry. However, the deference accorded to administrative agencies in the former circumstances (and especially the considerable deference accorded if the agency's decision is not to institute rulemaking proceedings) is no less appropriate here.

permitted optional sweeteners as "any sweetener that has been affirmed as generally recognized as safe (GRAS) or approved as a food additive for this use by the FDA" instead of the phrase "any safe and suitable sweeteners," as suggested by the petitioners; and

(12) The impact on small businesses if proposals, as suggested by the petitioners, were adopted.

B. The 1991 Proposals

On November 8, 1990, the President signed into law the Nutrition Labeling and Education Act of 1990 (1990 amendments) (Pub. L. 101–535). Section 3(b)(1)(A) of the 1990 amendments (21 U.S.C. 343) requires FDA to issue regulations that define claims characterizing the level of any nutrient that is of a type required to be declared in nutrition labeling. Specifically, the 1990 amendments direct FDA to promulgate regulations prescribing the use of the terms "free," "low," "light" or "lite," "reduced," "less," and "high" to characterize the level of these nutrients, unless the Secretary of Health and Human Services finds that the use of any such term would be misleading (section 3(b)(1)(A)(iii) of the 1990 amendments).

In its implementation of the 1990 amendments, FDA published a number of food labeling proposals in the November 27, 1991, **Federal Register**. In one document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (56 FR 60421), FDA proposed to establish regulations that define specific nutrient content claims including the terms "low," "free," "reduced," "light" or "lite," "source," and "high." Further, in the November 27, 1991, document the agency proposed to provide for comparative claims that use the terms "less," "fewer,"and "more." In another document entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" (56 FR 60478), FDA proposed to establish definitions for fat, fatty acid, and cholesterol claims as well as requirements for the proper use of such terms as "reduced fat," "lowfat," and "nonfat" on food labels.

In the November 27, 1991, **Federal Register**, FDA also published a proposal entitled "Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (hereinafter referred to as the general standard proposal) (56 FR 60512). In that document, FDA proposed to amend the general provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (21 CFR part 101) (such as "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (e.g., "reduced fat ice cream").

After consulting with Public Voice and KGF about the course of action that should be taken in light of the general standard proposal (56 FR 60512), IICA, in a letter dated January 15, 1992, amended its petitions of February 23, 1990, and March 29, 1990. IICA's amended petition withdrew its February 23, 1990, petition as it related to the establishment of standards of identity for "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream" and requested that the standard of identity for ice milk be removed. Subsequently, in a letter dated March 12, 1992, KGF withdrew its petition to establish a new standard of identity for nonfat ice cream. Shortly thereafter, on April 10, 1992, Public Voice withdrew its petition. Both KGF and Public Voice supported IICA's request that the standard of identity for ice milk be removed. KGF also supported IICA's petition for the use of safe and suitable sweeteners. Public Voice stated that it neither supported nor opposed IICA's recommendation on this issue.

C. The 1992 Final Rules

Elsewhere in this issue of the **Federal Register**, FDA is publishing two related final rules to implement section 3(b)(1)(A) of the 1990 amendments. They are: (1) "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule); and (2) "Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (hereinafter referred to as the general standard final rule).

In the nutrient content claims final rule, FDA is establishing in part 101 definitions for nutrient content claims together with general principles and procedures governing their use. Nutrient content claims for the fat content of foods are defined in new § 101.62 and include: "nonfat" (new § 101.62(b)(1)), "lowfat" (new § 101.62(b)(2)), and "reduced fat" (new § 101.62(b)(4)). The term "light" (or "lite") is defined in new § 101.56.

In the general standard final rule, FDA is establishing a general definition and standard of identity in new § 130.10 for modified versions of standardized foods. Specifically, the new general standard final rule, in new § 130.10, permits the use of FDA-defined nutrient content claims for fat content, such as "reduced fat," "lowfat," and "nonfat," in conjunction with the names of traditional standardized foods in parts 131 through 169 (21 CFR parts 131 through 169) in naming these new foods that have been specially formulated to reduce the level of fat in the product in new § 130.10(a). For example, the general standard final rule establishes conditions whereby the terms "reduced fat," "lowfat," and "nonfat" can be used with the standardized term "ice cream" for foods that resemble and substitute for ice cream but contain less milkfat than regular ice cream.

Under the general standard final rule, the modified version of the traditional product must not be nutritionally inferior to the traditional food that it resembles and for which it is intended to substitute (new § 130.10(b)). In addition, the food must possess similar performance properties and organoleptic characteristics (new § 130.10(c)), and it must be prepared from the same ingredients as the traditional standardized food, except that safe and suitable ingredients to improve texture, add flavor, add sweetness, prevent syneresis, extend shelf life, or improve appearance are allowed (new § 130.10(d)(1)). Further, to replace fat and calories, appropriate fat analogs and water may be added to modified versions of the traditional standardized foods defined in parts 131 through 169 (new § 130.10(d)(5)). Ingredients not provided for by the standard of identity, and ingredients used in excess of those provided for by the standard e.g., water to replace fat, must be identified as such in the ingredient statement (new § 130.10(f)(2)).

Thus, terms such as "reduced fat," "lowfat," and "nonfat" can be used in conjunction with the name "ice cream" as long as their use complies with new § 130.10 and is not false or misleading to consumers, and as long as the modified version does not purport to be a food to which another standard of identity applies. For example, without the changes proposed below, a reduced fat ice cream product that complies with the existing standard of identity for ice milk must be labeled as "ice milk."

II. Frozen Desserts—Legal Authority

Section 8 of the 1990 amendments removes food standards from the coverage of section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)) except for:

> * * * any action for the amendment or repeal of any definition and standard of identity under section 401 of the act for any dairy products (including products regulated under parts 131, 133, and 135 of title 21,

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Code of Federal Regulations) or maple sirup (regulated under § 168.140 of title 21, Code of Federal Regulations).

In this document, FDA is proposing to remove (i.e., repeal) the standards of identity for ice milk (§ 135.120) and goat's milk ice milk (§ 135.125) and to amend the standards of identity for ice cream (§ 135.110 (21 CFR 135.110)) and goat's milk ice cream (§ 135.115 (21 CFR 135.115)). Because these proposed actions are to remove and to amend standards for dairy products, they are subject to the formal rulemaking procedures of section 701(e) of the act. Section 701(e) of the act, unlike the informal rulemaking procedures of section 701(a) of the act, requires that the agency hold a formal evidentiary hearing if objections that raise issues of material fact are filed in response to final rules to establish, amend, or remove a food standard.

III. IICA's and the Council's Statement of Grounds and Review of Comments

A. IICA's and the Council's Statement of Grounds

FDA summarized in the ANPRM the statements of grounds submitted by IICA and the Council in support of their suggested changes concerning safe and suitable sweeteners. In that ANPRM, FDA noted that the petitioners had argued that permitting the use of safe and suitable sweeteners in frozen desserts would help consumers to meet national nutritional goals and would ultimately enhance the public health by increasing the availability in the marketplace of ice cream products low in calories and sugars. Further, the agency noted that the petitioners had asserted that the provision concerning safe and suitable sweeteners would create consistency in the naming of new ice cream products and would provide label information about sweeteners to consumers.

B. Summary of Comments

FDA received and reviewed 65 letters, each containing one or more comments, from consumers, the food industry, academia, trade associations, and consumer organizations in response to the ANPRM on the standards for ice cream and ice milk and the need to establish standards for reduced fat, lowfat, and nonfat ice creams. The comments generally supported the petitioners' requests as published in the ANPRM.

Some comments addressed issues unrelated to the establishment of standards of identity for "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream." However, many comments specifically addressed the need to establish such standards. With regard to the need to establish such standards, FDA received one or more comments addressing each of the following issues:

(1) Percentage declaration of milkfat content;

(2) Minimum weight per gallon;

(3) Total solids requirement for lowfat and nonfat ice cream;

(4) Establishment of 5 percent milkfat, as compared to 7 percent milkfat, as the maximum milkfat content of reduced fat ice cream;

(5) Maximum fat level in nonfat ice cream and the contribution of high fat flavoring ingredients;

(6) Nutritional equivalency;

(7) Declaration of the fat content to include flavoring ingredients; and

(8) "Reduced fat" labeling on products with a 50 percent reduction in fat.

The agency believes that the new requirements that it has established in the general standard final rule in new § 130.10 for modified foods named by use of a nutrient content claim and a standardized term (e.g., reduced fat ice cream) eliminate the need for individual standards of identity for these lower fat ice cream products. Moreover, in that document, FDA responds to many of the comments on the need for such standards. For example, among other issues, the preamble to the general standard final rule addresses the issues of minimum weight per gallon, the total solids requirement, the definition of "reduced fat ice cream," the definition of "nonfat ice cream," and nutritional equivalency. Therefore, in light of: (1) New § 130.10 in the general standard final rule; and (2) the petitioners' concurrence that individual standards are no longer necessary, as evidenced by the withdrawal of their petitions for establishing such individual standards, FDA believes that further regulatory action to establish standards for reduced fat, lowfat, and nonfat ice cream products is unnecessary. Therefore, FDA has fully addressed the comments relating to this issue, and there is no need to address them any further.

The agency will describe the relevant comments as they relate to the removal of the ice milk standard and to the amendment of the ice cream standard in the discussion of the proposed regulation that follows.

IV. The Proposal

A. Ice Milk

Comments received by the agency in response to the ANPRM did not specifically address the issue of removing the standard of identity for ice milk. However, the amended petitions from IICA, Public Voice, and KGF supported the removal of the ice milk standard so as to provide for lower fat ice cream products such as "reduced fat ice cream."

If FDA removes the "ice milk" standard, then under the general standard final rule, manufacturers will be free to label as "reduced fat ice cream" those frozen desserts that meet the agency's definition of "reduced fat" in new § 101.62(a)(4) of the nutrient content claim final rule and that comply with the definition and standard of identity for ice cream in § 135.110 except for those deviations from that standard that are provided for in new § 130.10 of the general standard final rule. The agency is defining "reduced fat" to mean a total fat content at least 25 percent less than the total fat content of an appropriate reference food (new § 101.62(b)(4)). Many products that now bear the name "ice milk" on their labels could, without reformulation, be redesignated as "reduced fat ice cream" under the general standard of identity (new § 130.10) if the ice milk standard is removed.

However, reduced fat ice cream must also contain less than the minimum 10 percent milkfat provided for in traditional standardized ice cream in accordance with § 135.110(a)(2). Frozen dessert products that meet the standard for ice cream (i.e., that contain a minimum of 10 percent milkfat or a minimum of 8 percent milkfat in products where bulky flavors are used) must be labeled as ice cream. Thus, a manufacturer that reduces the fat level in the company's "super premium" product (e.g., vanilla ice cream with a milkfat content of 14 percent) by 25 percent would not be able to designate the product as "reduced fat ice cream." In this instance, because the product would contain a level of milkfat that is consistent with the minimum milkfat level for ice cream in § 135.110(a)(2), the product would still be ice cream and would have to be named accordingly. However, the product could bear on its label a truthful statement explaining that the product contains 25 percent less fat than the company's "super premium" product.

Moreover, Public Voice mentioned in its petition that the use of the name "ice milk" reduces the marketability of a food that is similar to ice cream but that contains less fat. Thus, redesignation of the product as "reduced fat ice cream" may improve the marketability of the product and consequently may promote its consumption in place of full fat ice cream. Replacement of regular full fat ice cream in the diet with a lower fat version of ice cream will help

consumers to achieve one of the recommended national nutritional goals (i.e., to reduce dietary fat levels).

Therefore, the agency is proposing to remove the standard of identity for ice milk in § 135.120.

B. Safe and Suitable Sweeteners

In their petitions, IICA and the Council requested that FDA provide for the use of any safe and suitable sweeteners in ice cream products. In the ANPRM, the agency asked whether the language in the current standards that requires that all ingredients used in the food be "safe and suitable" should be expanded to provide for the use of "any safe and suitable sweeteners." FDA notes that the standard of identity in § 135.110 now provides only for the use of safe and suitable nutritive carbohydrate sweeteners in ice cream. Further, to ensure that the use of sweeteners that have not been determined by FDA to be safe is prohibited in these foods, the agency suggested that the permitted optional sweeteners be described in the standards as "any sweetener that has been affirmed as GRAS or approved as a food additive for this use by the FDA."

The majority of the comments addressing this issue supported the use of alternative sweeteners (i.e., sweeteners other than nutritive carbohydrate sweeteners), such as aspartame and saccharin, in new food products because the use of these sweeteners would increase the availability of lower calorie frozen desserts. Many of these comments also approved of the language, suggested by FDA, that the sweeteners used in the ice cream products be either "affirmed as GRAS or approved for this use by FDA" instead of the usual "safe and suitable" language. Several persons maintained that this language would ensure that the sweeteners used would be safe for this use. Other comments believed that either statement is acceptable.

A few comments, however, were concerned that the proposed FDA language would create a mandatory safety evaluation system for all optional sweeteners in ice cream products irrespective of their possible GRAS status. The comments contended that such a requirement would be an inappropriate use of food standards and would use standards as a vehicle for circumventing the safety review procedures established by the act. A trade association was concerned that the FDA suggested language was a return to the pre-1974 practice of defining acceptable ingredients for each food standard.

A comment from the Council stated that FDA's concern about the use of unapproved food additives is fully addressed by the use of the term "safe and suitable," which the agency already has defined in § 130.3(d)(21 CFR 130.3(d). The comment pointed out that the purpose of FDA's codification of the definition of "safe and suitable" was to avoid repeating the same definition in each individual standard. The comment concluded that a change in the "safe and suitable" language of the standards is not necessary.

Although the "safe and suitable" language does not directly cite GRAS substances, the agency acknowledges that this language includes them because safe and suitable ingredients include substances that are not unapproved food additives. The agency acknowledges that the suggested alternative FDA language could be interpreted as eliminating from use in ice cream products certain sweetening ingredients whose use is not specifically provided for in current FDA regulations. The agency also notes that the general provisions for food standards in § 130.3(c) strengthen the safety requirements of § 130.3(d). These general provisions provide that no provisions of food standards may be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding. Thus, § 130.3(c) of the general provisions for food standards reinforces the requirement that sweetening additives must be safe and in compliance with sections 201(s) and 409 of the act (21 U.S.C. 321(s) and 348). Therefore, FDA has decided to use the safe and suitable language in describing the sweetening ingredients permitted in ice cream products in this proposal.

However, this tentative decision should not be construed as agency concurrence with independent GRAS determinations. The agency points out that it cannot agree that a sweetener is GRAS for some intended use in a food until it has reviewed all pertinent data on the ingredient and made a determination that it is safe for such use. FDA cautions that, without appropriate authorization, companies or individuals who make a GRAS determination on an ingredient take the risk that the agency will disagree with them and take regulatory action against the use of the substance.

One comment stated that the agency should reject the petition to add a provision to permit the use of "any safe and suitable sweeteners" in these products. It expressed the opinion that more information is needed on the long-term safety of some alternative sweeteners that may be used in foods.

FDA advises that any safe and suitable sweetener, whether GRAS or an approved food additive, presumably is viewed as safe for its intended use by experts, qualified by scientific training and experience, to evaluate the safety of such substances. In addition, traditional sweeteners, such as honey which has been used for many years for this purpose, were not intended to be excluded from use in ice cream products by the suggested language that referred to the GRAS status of the sweetener (§ 170.30(d) 21 CFR 170.30(d)). Therefore, as discussed above, FDA is proposing to provide in § 135.110(a)(1) for the use of both nutritive and nonnutritive safe and suitable sweeteners in the standards set forth below.

FDA points out that another option is to retain the provision in § 135.110(a)(1) that requires the use of "nutritive carbohydrate sweeteners" as mandatory ingredients in ice cream and to allow ice cream products containing alternative sweeteners to be subject to the general standard of identity in new § 130.10, as has been done with other standardized foods. FDA notes, however, that new § 130.10(d)(4) of the general standard final rule requires that an ingredient that is specifically required by the standard (e.g., nutritive carbohydrate sweetener in ice cream) must be present in the product in a significant amount (i.e., at least that amount that is required to achieve the technical effect of that ingredient in the food). Thus, this option would prevent manufacturers from replacing all of the nutritive carbohydrate sweetener in such a product with one or more alternative sweeteners unless they called the product by a name other than the standardized name of the food.

The agency is requesting comments on the need for, and appropriateness of, the proposed change in § 135.110(a)(1) and proposed § 135.110(e)(7) with respect to the use of "safe and suitable sweeteners" in ice cream products as opposed to the general provision of new § 130.10.

One comment requested that the standards for ice cream products require that the artificial sweeteners used in these foods be declared on the principal display panel.

FDA recognizes that some consumers want to avoid frozen dessert products that contain the alternative sweeteners for which the standard of identity for ice cream does not now provide. In § 102.5 (21 CFR 102.5), FDA has established general principles for establishing common or usual names for

nonstandardized foods when the presence of a characterizing ingredient or component of an ingredient in such foods has a material bearing on consumer acceptance. However, there are no similar requirements for standardized foods unless specifically provided for in the standard of identity for a given food. FDA believes that ice cream made in compliance with § 135.110, but that is sweetened with an alternative sweetener, is a distinctly different product than that sweetened with a nutritive carbohydrate sweetener as the standard for this food now permits and accordingly should be clearly distinguished from the traditional food. Therefore, FDA tentatively concludes that it is necessary to inform consumers of this fact in sections 201(n) and 403(a) (21 U.S.C. 343) of the act. Under new § 130.10 in the general standard final rule, a product containing an alternative sweetener would be distinguished from the traditional product by naming the product using such nutrient content claims as "reduced sugar" defined in new § 101.60(c)(4) or "reduced calorie" defined in new § 101.60(b)(4), provided that the requirements for the use of these terms on the food label are otherwise met.

FDA also notes that foods that are sweetened with one or more artificial sweeteners, whether nutritive or nonnutritive, are foods for special dietary use under § 105.3(a)(2) (21 CFR 105.3(a)(2). Therefore, they must be labeled to comply with the requirements of § 105.66 (21 CFR 105.66). A final rule revising § 105.66 to conform with the requirements of the 1990 amendments is published elsewhere in this issue of the **Federal Register**. In accordance with new § 105.66, the food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false or misleading to consumers, and the food is labeled "low calorie" or "reduced calorie" or bears another comparative caloric claim.

Therefore, to distinguish standardized ice cream products sweetened with alternative sweeteners (i.e., sweeteners other than nutritive carbohydrate sweeteners) from products sweetened with traditional sweeteners (i.e., nutritive carbohydrate sweeteners), FDA is proposing to add a requirement in the ice cream standard in proposed § 135.110(e)(7), and in the goat's milk ice cream standard in proposed § 135.115(c)(2), that the presence of such alternative sweeteners be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters of no less than one-half the size of the type used in the product name (e.g., "ice cream") but no smaller than one-sixteenth of an inch.

FDA is also providing in these proposed provisions that, as discussed above, ice cream products sweetened with such sweeteners must comply with the applicable provisions of new § 105.66. Thus, in addition to having to declare the presence of alternative sweeteners as a part of their statements of identity, such products will have to be labeled as "low calorie" or "reduced calorie" or bear another comparative caloric claim in compliance with part 101. The agency notes that modified ice cream products made in conformity with the provisions of new § 130.10 in the general standard final rule will also have to comply with the labeling requirements for sweeteners if they are finalized as in proposed § 135.110(e)(7). New § 130.10(e) requires that the name of a modified version of a standardized food that complies with the general standard in new § 130.10 is the appropriate expressed nutrient content claim e.g., "reduced fat" and the applicable standardized term e.g., "ice cream sweetened with aspartame." The agency specifically requests comments on the need to declare alternative sweeteners in ice cream as discussed above.

C. Skim Milk with Part or All of the Lactose Removed by Alternate Technologies

One comment stated that recently developed technologies will permit increases in the amount of milk protein used in ice cream and related products without the quality problems normally associated with lactose in the dairy ingredients. To address the use of ultrafiltration and other lactose-reduction technologies, the comment requested that FDA revise § 135.110(b) to replace the phrase "skim milk that has been concentrated and from which part of the lactose has been removed by crystallization" with "skim milk [that] may be concentrated and from which part of the lactose has been removed by crystallization, ultrafiltration, or other approved technologies."

FDA tentatively finds that it would be appropriate for the standard to permit addition of concentrated skim milk from which part of the lactose has been removed by ultrafiltration. The agency believes that it should also provide for the removal of part or all of the lactose by any safe and suitable procedure. These actions will give manufacturers the opportunity to use state-of-the-art processing technologies. However, manufacturers must ensure that the nutritional quality of the resulting food is not detrimentally affected. Accordingly, FDA is amending the ice cream standard in proposed § 135.110(b) to provide for the addition of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure, in the food. This approach will minimize the need to revise the standard should other acceptable procedures be developed for lactose reduction or removal at a later date.

D. Goat's Milk Ice Cream and Goat's Milk Ice Milk

In the ANPRM, FDA asked whether the goat's milk ice cream and goat's milk ice milk standards of identity in §§ 135.115 and 135.125 should be amended to achieve consistency with any changes in the ice cream and ice milk standards of identity §§ 135.110 and 135.120. The goat's milk ice cream and goat's milk ice milk standards of identity cross-reference the ice cream and ice milk standards of identity with respect to the use of optional ingredients excluding caseinates, weight per gallon, weight of total food solids, and labeling requirements.

FDA received one comment from a consumer advocacy organization in support of changes in the goat's milk ice cream and goat's milk ice milk standards. The comment stated that, in the interest of consistency and for the same basic reasons given in the petitions, corresponding changes in the standards of identity for goat's milk ice cream and goat's milk ice milk should be proposed.

FDA agrees with this comment. The agency believes that the suggested actions relating to the standards for goat's milk ice milk and goat's milk ice cream will foster uniformity in the labeling of ice cream products. In addition, making changes in the standard for goat's milk ice cream in § 135.115 will permit this product to be formulated similarly to ice cream in § 135.110. Accordingly, the agency is proposing to remove the standard for goat's milk ice milk and to make changes in the standard for goat's milk ice cream similar to the proposed changes in the standard for ice cream and frozen custard, as discussed above.

E. Additional Comments

FDA received several comments on the use of "any safe and suitable dairy ingredient;" the use of safe and suitable milk-derived protein ingredients other than caseinates; the use of vegetable proteins; and the use of fat substitutes, such as microparticulated protein, in ice cream products. As discussed below,

FDA finds that the issues raised by these comments are appropriate for agency consideration. However, as a resource matter, given the demands of the formal rulemaking process, FDA concludes that it is not appropriate for the agency at this time to institute formal rulemaking procedures on most of these matters.

One comment requested that FDA revise § 135.110(b) to provide for "any safe and suitable dairy ingredient." It stated that the listing of optional dairy ingredients by name or by the process by which they are derived effectively prohibits the use of some new or novel materials (e.g., concentrated skim milk with the lactose removed by a process other than crystallization).

In view of the wide range of optional dairy ingredients listed by name or by the process by which they are derived in § 135.110(b) of the standard for ice cream, FDA requests comments on whether the specific names should be deleted from § 135.110(b), and whether the standard should be amended to provide for the use of any safe and suitable dairy ingredients, as suggested by the comment. If a comment supports use of a collective term such as "dairy ingredient," the agency asks that the comment provide a definition of the term so as to facilitate proper interpretation of the regulation.

One comment suggested that FDA provide for safe and suitable milk-derived protein ingredients other than caseinates where the milk solids content minimums required by the standard for ice cream in § 135.110 are otherwise met. The comment stated that these "other milk protein ingredients" include milk protein hydrolysates (enzyme-modified milk protein) and milk protein isolates (caseinates and whey protein co-isolates). The comment maintained that the use of milk proteins other than caseinates contributes to aeration of frozen lowfat dairy desserts, thereby improving the body and texture of these products, and that their use will not reduce the nutritional value of standardized dairy products. It further stated that these ingredients are safe and suitable for use in other nonstandardized foods such as frozen yogurt, coffee whiteners, infant formulas, fortified cereals, and medical foods. The comment requested that the standards proposed in the ANPRM be amended by replacing the optional caseinates with the term "safe and suitable milk-derived proteins."

FDA acknowledges that milk protein hydrolysates are GRAS and are now used in many foods. These hydrolysates vary in the degree of hydrolysis that they have undergone depending on the manufacturing process They also vary in their functional characteristics depending on their intended use. However, before the agency extends the category of milk-derived protein components that may be used in these foods, it would like additional information on the nature of and need for these ingredients in ice cream, the proposed levels of use, and their suitability in performing technical functions in the food, such as aeration, as suggested by the comment, as well as information on any possible adverse effects of their use. If the comments on this issue adequately support the need for such ingredients, FDA will consider providing for their use in the final regulation that results from this proposal.

One comment suggested that the standards provide for the addition of vegetable proteins in addition to milk-derived protein sources. It maintained that vegetable proteins could provide consumers and manufacturers with new nutritional, economic, and quality advantages in these products.

FDA does not agree that the standards for ice cream products should provide for the addition of vegetable proteins. Ice cream and ice milk products are traditionally considered to be dairy products, and, as such, neither vegetable proteins nor vegetable fats or oils are considered to be suitable ingredients of these foods. When vegetable proteins or vegetable fats or oils are used in frozen dessert products resembling ice cream, FDA considers these foods to be nonstandardized substitute foods provided that they are nutritionally equivalent to ice cream or ice milk. As such, these products should bear a common or usual name that is not misleading.

For example, coffee whiteners containing ingredients of vegetable origin do not purport to be cream or dry cream products. Rather, they are products that bear their own common or usual name. In a like manner, the agency believes that frozen dessert products, made in the semblance of ice cream and containing vegetable proteins or vegetable fats or oils, must be properly identified under their own common or usual name. Therefore, FDA is not providing for vegetable proteins in the proposed amendment of the standard of identity for ice cream set forth below. However, the agency notes that nonmilk-derived protein-containing ingredients may be included in frozen dessert products labeled as "mellorine" in § 135.130 (21 CFR 135.130).

One comment from an ingredient supplier asked whether fat substitutes, such as microparticulated protein, could be used in ice cream products. The comment stated that microparticulated protein, prepared from egg white and skim milk (or, alternatively, from whey protein concentrate), is used in products complying with the IICA proposed standards.

A comment from a consumer stated that fat substitutes do not belong in traditional ice cream products covered by standards of identity. The comment stated that these ingredients should be used only in the "frozen desserts" category. The comment contended that the preservation of tradition overrides governmental, medical, and consumer interests in reducing fat intake and providing alternative, healthful products.

FDA does not agree with the consumer comment in its entirety. FDA notes that § 135.110(a) provides for the use of "safe and suitable nonmilk-derived ingredients." In the **Federal Register** of April 12, 1977 (42 FR 19127), in an amendment of the standard for ice cream that provided for "safe and suitable nonmilk derived ingredients," the agency stated that it deems as unsuitable those ingredients that change the basic character of the food or that do not perform an appropriate function in the food. In this regard, the use of fat substitutes to replace milkfat in ice cream is suitable if the minimum compositional levels for milkfat and nonfat milk solids for ice cream in § 135.110(a)(2) are met, and if the fat substitutes are made from ingredients permitted by the standard of identity for ice cream. FDA believes that this approach is reasonable in order to give consumers the option to purchase products that simulate the characteristics of traditional ice cream but that contain less fat.

F. Summary of Proposal

On the basis of the information mentioned above, FDA is proposing to remove the standard of identity for ice milk (§ 135.120) and to make several requested changes in the standard of identity for ice cream. The requested changes in the ice cream standard deal with provisions for: (1) The use of safe and suitable sweeteners; and (2) the use of skim milk that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure, in the food.

FDA considers it reasonable to propose to remove the standard of identity for ice milk because this action will allow for the use of the "reduced fat" nutrient content claim in conjunction with the name "ice cream." Such use will be consistent with the use of the terms "lowfat" and "nonfat" on ice cream products made in compliance

with new § 130.10. Until the ice milk standard has been removed, frozen desserts that have a milkfat content between 2 and 7 percent and that otherwise comply with the standard in § 135.120 cannot be called "reduced fat ice cream."

FDA also considers it reasonable to amend the standard of identity for ice cream to provide for the use of safe and suitable sweeteners, including alternative sweeteners such as aspartame or saccharin; and to allow for the use of skim milk that may be concentrated, and from which part or all of the lactose has been removed by any safe and suitable procedure, in ice cream. FDA tentatively finds that these changes will permit manufacturers to develop nutritious, wholesome frozen dessert products containing alternative sweeteners or sweetening systems. The proposed amendment of the ice cream standard will increase flexibility and give manufacturers the latitude to develop new, innovative products in response to consumer interest in and desire for lower calorie dairy products.

The goat's milk ice cream (§ 135.115) and goat's milk ice milk (§ 135.125) standards of identity cross-reference the ice cream and ice milk standards of identity. Thus, FDA considers it appropriate to propose comparable changes in the goat's milk ice cream and goat's milk ice milk standards to reflect the proposed changes in the ice cream and ice milk standards. Therefore, the agency is also proposing to remove the goat's milk ice milk standard and to amend the goat's milk ice cream standard with respect to the use of sweeteners and with respect to the use of skim milk with part or all of the lactose removed by any safe and suitable procedure as discussed above for the cross-referenced ice cream standard.

FDA is also making certain minor editorial changes in the standards of identity for ice cream and goat's milk ice cream for clarity.

FDA believes that these actions are necessary to ensure the integrity of these foods, to minimize any confusion regarding the types of acceptable ingredients that may be used in the foods, and to promote honesty and fair dealing in the interest of consumers.

V. Economic Impact

FDA has examined the economic implications of the proposed rule to remove the standards of identity for ice milk and goat's milk ice milk and to amend the standards of identity for ice cream and goat's milk ice cream in part 135 as required by Executive Order 12291 and the Regulatory Flexibility Act. Executive Order 12291 compels Federal agencies to use cost-benefit analysis as a component of decisionmaking. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. Because no marginal costs are expected to be incurred to comply with this proposed regulation, the agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act Pub. L. 96–354, FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses.

FDA has tentatively determined that, because the effect of the actions that the agency is proposing is to permit increased flexibility in the processing of frozen desserts and because a reasonable amount of time will be provided to use existing supplies of labels, the proposed actions will not result in a significant impact on a substantial number of small entities. FDA has not received any information or comments on the ANPRM that would cause it to reach a different determination.

FDA considered several options in arriving at this proposal. One option considered was to take no action. Under this option, manufacturers of ice cream products would be limited in the types of skim milk ingredients that may be used in ice cream products. Thus, consumers' choices would also be limited. In addition, removal of the standard of identity for ice milk will provide for more informative labeling of the lower fat ice cream products and help consumers to achieve recommended nutritional goals.

Another option considered was to remove the ice cream standard and goat's milk ice cream standard, as well as the standards for ice milk and goat's milk ice milk, and allow manufacturers to use any combination of types and levels of ingredients in these foods. While this option would appear to provide flexibility in the selection of ingredients, it would not be in the best interest of consumers or manufacturers. In the absence of Federal standards for these foods, the states could establish standards with different requirements which could hinder interstate commerce. Uniform standards protect consumers from unfair trade practices and also enable manufacturers to compete in an equitable manner.

Under the selected option set forth below, i.e., removing the standard of identity for ice milk and amending the standard of identity for ice cream, as requested by the petitioners, as well as removing the goat's milk ice milk standard and amending the goat's milk ice cream standard that cross-references the ice cream standard, manufacturers will be able to provide consumers with ice cream products that reflect the traditional food and that are labeled in a uniform manner. In addition, the removal of the ice milk standard will provide manufacturers with increased flexibility to use names more acceptable to the public in designating ice cream products that contain reduced levels of calories and fat.

If FDA adopts this proposal, firms that produce ice milk products will have to revise their labels. Some firms may also wish to reformulate their ice milk products so as to be able to take advantage of the increased flexibility in product formulation provided for under new § 130.10. However, FDA believes that any additional costs for label changes will be offset by the increased consumer recognition of the benefits of the resulting reduced calorie and reduced fat ice cream products. FDA will also allow an appropriate period of time (1 year) for manufacturers to use up labels so as not to cause a hardship on manufacturers of ice milk products. The proposed amendments to the ice cream and goat's milk ice cream standards will also allow the use of additional optional ingredients. The agency does not anticipate that there will be any increased cost from these changes because there is no requirement that these new optional ingredients be used in ice cream products.

Therefore, FDA finds that marginal costs if any, will be small for the proposed amendment because FDA is providing sufficient time for most ice cream manufacturers to incorporate label changes into normal label stock reordering. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Effective Date

FDA proposes that any final rule that may issue based on this proposal, unless stayed by the filing of proper objections, become effective 1 year following the date publication of the final rule in the

Federal Register. Because of the formal rulemaking procedures that apply to the amendment and removal of standards for products regulated under part 135, the agency notes that the effective date for any final rule that may issue from this proposal may not coincide with the effective date for the food labeling final rules that were issued in response to the 1990 amendments and that are published elsewhere in this issue of the **Federal Register**. Except as to any provisions that may be stayed by the filing of proper objections, compliance with any final rule that may issue based on this proposal (including any required labeling changes) may begin immediately upon publication of such a final rule in the **Federal Register**. Notice of the filing of objections or lack thereof will be published in the **Federal Register**.

VIII. References

The following information has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Nutrition and Your Health, Dietary Guidelines for Americans," 2d ed., Washington, DC, 1985.

2. U.S. Department of Health and Human Services, "The Surgeon General's Report on Nutrition and Health." DHHS (PHS) Publication No. 88–50210, Washington, DC, U.S. Government Printing Office, GPO Stock No. 017–001–00465–1, 1988.

3. Committee on Technological Options to Improve Nutritional Attributes of Animal Products, Board of Agriculture, National Research Council, "Designing Foods: Animal Product Options in the Marketplace," National Academy Press, Washington, DC, 1988.

IX. Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, it is proposed that 21 CFR part 135 be amended as follows:

PART 135—FROZEN DESSERTS

1. The authority citation for 21 CFR part 135 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

2. Section 135.110 is amended by revising paragraphs (a)(1) and (b), and by adding paragraph (e)(7) to read as follows:

§ 135.110 Ice cream and frozen custard.

(a) *Description.* (1) Ice cream is a food produced by freezing, while stirring, a pasteurized mix consisting of one or more of the optional dairy ingredients specified in paragraph (b) of this section, and may contain one or more of the optional caseinates specified in paragraph (c) of this section subject to the conditions hereinafter set forth, and other safe and suitable nonmilk-derived ingredients; and excluding other food fats, except such as are natural components of flavoring ingredients used or are added in incidental amounts to accomplish specific functions. Ice cream is sweetened with safe and suitable sweeteners and may or may not be characterized by the addition of flavoring ingredients.

* * * * *

(b) *Optional dairy ingredients.* The optional dairy ingredients referred to in paragraph (a) of this section are: Cream; dried cream; plastic cream (sometimes known as concentrated milkfat); butter; butter oil; milk; concentrated milk; evaporated milk; sweetened condensed milk; superheated condensed milk; dried milk; skim milk; concentrated skim milk; evaporated skim milk; condensed skim milk; superheated condensed skim milk; sweetened condensed skim milk; sweetened condensed part-skim milk; nonfat dry milk; sweet cream buttermilk; condensed sweet cream buttermilk; dried sweet cream buttermilk; skim milk, that may be concentrated, and from which part or all of the lactose has been removed by a safe and suitable procedure; skim milk in concentrated or dried form that has been modified by treating the concentrated skim milk with calcium hydroxide and disodium phosphate; and whey and those modified whey products (e.g., reduced lactose whey, reduced minerals whey, and whey protein concentrate) that have been determined by FDA to be generally recognized as safe (GRAS) for use in this type of food. Water may be added, or water may be evaporated from the mix. The sweet cream buttermilk and the concentrated sweet cream buttermilk or dried sweet cream buttermilk, when adjusted with water to a total solids content of 8.5 percent, has a titratable acidity of not more than 0.17 percent, calculated as lactic acid. The term "milk" as used in this section means cow's milk. Any whey and modified whey products used contribute, singly or in combination, not more than 25 percent by weight of the total nonfat milk solids content of the finished food. The modified skim milk, when adjusted with water to a total solids content of 9 percent, is substantially free of lactic acid as determined by titration with 0.1*N* NaOH, and it has a pH value in the range of 8.0 to 8.3.

* * * * *

(e) * * *

(7) When safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "ice cream" but in any case no smaller than one-sixteenth of an inch. Further, the use of such sweeteners in the food shall comply with the requirements of § 105.66 of this chapter.

* * * * *

3. Section 135.115 is amended by revising paragraph (a), by redesignating the text of paragraph (c) as paragraph (c)(1), and by adding new paragraph (c)(2) to read as follows:

§ 135.115 Goat's milk ice cream.

(a) *Description.* Goat's milk ice cream is the food prepared in the same manner prescribed in § 135.110 for ice cream, and complies with all the provisions of § 135.110, except that the only optional dairy ingredients that may be used are those in paragraph (b) of this section; caseinates may not be used; and paragraphs (e)(1) and (f) of § 135.110 shall not apply.

* * * * *

(c) * * *

(2) When safe and suitable sweeteners other than nutritive carbohydrate sweeteners are used in the food, their presence shall be declared by their common or usual name on the principal display panel of the label as part of the statement of identity in letters that shall be no less than one-half the size of the type used in the term "goat's milk ice cream" but in any case no smaller than one-sixteenth of an inch. Further, the use of such sweeteners in the food shall

comply with the requirements of § 105.66 of this chapter.

* * * * *

§ 135.120 [Removed]

4. Section 135.120 *Ice milk* is removed from subpart B.

§ 135.125 [Removed]

5. Section 135.125 *Goat's milk ice milk* is removed from subpart B.

Dated: October 23, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-31529 Filed 12-28-92; 8:45 a.m.]

BILLING CODE 4160-01-F

DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. 921118-2318]

RIN 0651-AA63

Patent Interference Practice Burden of Proof

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Patent and Trademark Office (PTO) proposes to amend its rules of practice in patent interference cases. As a result of issues arising in some recent cases, it is apparent that parties in interference cases would be helped if the interference rules explicitly stated which party has the burden of proof when a motion is filed. There is also some confusion with respect to the nature of the evidence that should be submitted with a preliminary motion, particularly when testimony is needed to support or oppose the preliminary motion. PTO proposes to specify that a party filing a motion has the burden of proof. PTO also proposes to more clearly specify the nature of expert witness and factual witness evidence that must accompany a preliminary motion. Finally, PTO proposes to add a definition of an interlocutory order, as contrasted with a final decision, in order to clarify the meaning of an interlocutory order.

DATES: Comments must be submitted on or before March 8, 1993. A public hearing will not be held.

ADDRESSES: Address written comments to Box 8, Commissioner of Patents and Trademarks, Washington, DC 20231, marked to the attention of Fred E. McKelvey, Solicitor. Written comments will be available for public inspection in suite 918, on the 9th floor of Crystal Park II, located at 2121 Crystal Drive, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Fred E. McKelvey by telephone at (703) 305-9035 or by mail marked to his attention and addressed to Box 8, Commissioner of Patents and Trademarks, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: The PTO conducts interference proceedings to determine who, as between two or more applicants for patent or one or more applicants and one or more patentees, is the first inventor of a patentable invention. In the course of interference proceedings, the Board of Patent Appeals and Interferences enters two kinds of decisions, interlocutory orders and final decisions. There has been some confusion as to what orders are interlocutory orders. The PTO is proposing to add subsection (q) to 37 CFR 1.601 to define an interlocutory order and to contrast interlocutory orders with the final decision. The presumption of correctness of an interlocutory order, which is presently in 37 CFR 1.655(a), is proposed to be moved to proposed new subsection 1.601(q), and to be deleted from § 1.655(a). The definition of interlocutory order would include the decision represented by the notice declaring the interference.

Under the interference rules, a party in an interference is authorized to file motions, including preliminary motions (37 CFR 1.633), motions to correct inventorship (37 CFR 1.634) and miscellaneous motions (37 CFR 1.635). When necessary, a preliminary motion should be accompanied by evidence (37 CFR 1.639). Recently there has been confusion as to who has the burden of proof when a motion is filed. For example, when transmitting papers to the Board for declaration of an interference, the Primary Examiner determines in the first instance the extent, if any, to which a party is entitled to the filing date of an earlier domestic or foreign application. 37 CFR 1.609(b)(4). The interference is then declared by an examiner-in-chief and an indication is given that a party has been accorded the benefit of the filing date of an earlier application. 37 CFR 1.611(c)(5). An opponent, however, is authorized to challenge the initial decision of the Primary Examiner and the examiner-in-chief to accord benefit. The challenge is made through a preliminary motion. 37 CFR 1.633(g). It is the PTO's position that the party filing the motion bears the burden of proof to show that its opponent should not have been accorded the benefit of the filing date of an earlier application. If adopted, the proposed rules would make explicit in 37 CFR 1.637(a) that a party filing a motion has the burden of proving why it is entitled to the relief sought in the motion.

Another difficulty in interference cases has been compliance with 37 CFR 1.639 with respect to evidence that must accompany a preliminary motion. In 1990, a decision was entered in *Hanagan* v. *Kimura*, 16 USPQ2d 1791, 1794 (Comm'r Pat. 1990), that provided the following guidance:

> To the extent it may prove useful, the following guidance is provided. When expert testimony is needed in support of, or in opposition to, a preliminary motion, a party should:
>
> (1) Identify the person whom it expects to call as an expert;
>
> (2) State the field in which the person is alleged to be an expert; and
>
> (3) State in a declaration signed by the person
>
> (a) the subject matter on which the person is expected to testify,
>
> (b) the facts and opinions to which the person is expected to testify, and
>
> (c) a summary of the grounds and basis for each opinion.
>
> If a person is to be called as a fact witness, a declaration by that person stating the facts should be filed.
>
> If the other party is to be called, or if evidence in the possession of the other party is necessary, an explanation of the evidence sought, what it will show, and why it is needed must be supplied.
>
> When inter partes tests are to be performed, a description of the tests stating what they will show must be presented.
>
> The nature of the showing under § 1.639(c) will vary from case to case.

Nothing in the rule change being proposed would alter the need to supply evidence in support of, or in opposition to, a preliminary motion. The rules being proposed would codify the *Hanagan* guidelines. Subsection (c) of § 1.639 is proposed to be amended to refer to "additional evidence in the form of testimony" so as to distinguish the evidence in the form of testimony" so as to distinguish the evidence needed under subsection (c) from that which may be submitted under subsections (a) and (b).

Proposed subsection (d) to 37 CFR 1.639 would specify the nature of evidence that must be submitted when an opinion of an expert is needed. The statement which would be required under proposed subsection (d) would be essentially the same as discovery required under Rule 26(b)(4)(A)(i) of the Federal Rules of Civil Procedures.

Proposed subsection (e) would specify the nature of evidence that must be

submitted when a statement of a fact witness is to be relied upon.

Proposed subsection (f) would specify the nature of a showing which should be made when a statement of an opponent is needed or evidence in possession of an opponent is needed.

Proposed subsection (g) would specify the nature of evidence that must be supplied if inter partes tests are to be conducted.

The party filing the preliminary motion would be expected to supply all necessary evidence with the preliminary motion. Likewise, a party opposing a preliminary motion should supply with the opposition all needed evidence in support of the opposition. Normally, if a party cannot obtain all necessary evidence to support or oppose a preliminary motion, and can show good cause, the party should seek an extension of time to file or oppose the preliminary motion. In an unusual situation, the guidance may not apply in the case of a party opposing a preliminary motion. In a recent interference, an examiner-in-chief deferred to final hearing consideration of a preliminary motion which had been accompanied by considerable evidence. The opponent had requested leave to take testimony. Based on the amount of evidence submitted with the preliminary motion, it was the examiner-in-chief's view that it would have been manifestly unfair to require the opponent to have prepared a full case in opposition to the preliminary motion in the 20-day period set for filing oppositions. As noted by the examiner-in-chief in the instance mentioned above, more leeway as to the evidence, and when it is supplied, can properly be granted to a party opposing a preliminary motion than a party filing a preliminary motion. The party filing the preliminary motion knows what must be proved. A party opposing the preliminary motion may or may not have time to fully respond with evidence accompanying an opposition. If an examiner-in-chief finds in a particular case that a party, during the time allowed for filing an opposition to a preliminary motion, could not reasonably have fully marshalled its evidence for presentation along with the opposition to a preliminary motion, a testimony period may be set. Alternatively, the examiner-in-chief, *sua sponte* or on motion of the opponent, may grant an extension of time to gather and supply the evidence. The action to be taken is a matter within the discretion of the examiner-in-chief.

Present 37 CFR 1.655(a) is proposed to be amended by deleting the last sentence, which would be moved to and be included in the proposed definition of interlocutory order in proposed subsection 1.601(q). The burden of showing error in entry of an interlocutory order is on the party challenging the order. If the order involved a procedural matter, the challenger must show that an examiner-in-chief or a panel abused discretion in entering the order. If the order involved a non-procedural matter (i.e., granting a motion for judgment based on unpatentability), the challenger must show legal error.

In some instances, two or more interlocutory orders may involve the same issue. For example, a notice declaring an interference may accord a party benefit of an earlier application. A preliminary motion may result in the party being denied benefit. When there are two or more interlocutory orders involving the same issue, the latest interlocutory order is presumed to be correct in further proceedings in the interference.

Other Considerations

The proposed rule changes are in conformity with the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), Executive Orders 12291 and 12612 and the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

The General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that these proposed rule changes will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The principal impact of these proposed changes would be to clarify procedure in patent interference and thereby eliminate any ambiguity which might exist in current rules.

The Office has determined that this proposed rule change is not a major rule under Executive Order 12291. The annual effect on the economy will be less than $100 million. There will be no major increase in costs or prices for consumers; individuals; industries; Federal, state or local government agencies; or geographic regions. There will be no significant effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Office has also determined that this notice has no Federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

The rule change will not impose a burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, since no recordkeeping or reporting requirements within the coverage of the Act are placed upon the public.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Inventions and patents.

PART 1—RULES OF PRACTICE IN PATENT CASES

For the reasons set out in the preamble, it is proposed to amend 37 CFR part 1 wherein removals are indicated by brackets ([ ]) and additions by arrows (⧫ ⧫):

1. The authority citation for 37 CFR part 1 would continue to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.601 is proposed to be amended by adding paragraph (q) to read as follows:

§ 1.601 Scope of rules, definitions.

* * * * *

⧫(q) A *final decision* is a decision awarding judgment as to all counts. An *interlocutory order* is any other action taken by an examiner-in-chief or a panel of the Board in an interference, including the notice declaring an interference. All interlocutory orders shall be presumed to have been correct and the burden of showing error or an abuse of discretion shall be on the party attacking the order. When two or more interlocutory orders involve the same issue, the last entered order shall be presumed to have been correct.⧫

3. Section 1.637 is proposed to be amended by revising paragraph (a) to read as follows:

§ 1.637 Content of motions.

(a) ⧫A party filing a motion has the burden of proof to show that it is entitled to the relief sought in the motion.⧫ Every motion shall include (1) a statement of the material facts in support of the motion, and (3) a full statement of the reasons why the relief requested should be granted.

* * * * *

4. Section 1.639 is proposed to be amended by revising paragraph (c) and by adding paragraphs (d) through (g) as follows:

§ 1.639 Evidence in support of motion, opposition, or reply.

* * * * *

(c) When a party believes that ⧫additional evidence in the form of⧫

testimony is necessary to support or oppose a preliminary motion under § 1.633 or a motion to correct inventorship under § 1.634, the party shall describe the nature of any proposed testimony ❙in the manner specified in subsections (d) through (g) of this section❙. If the examiner-in-chief finds that testimony is needed to decide the motion, the examiner-in-chief may grant appropriate interlocutory relief and enter an order authorizing the taking of testimony and deferring a decision on the motion to final hearing.

❙(d) When the testimony is needed in support of or opposition to a preliminary motion is expert testimony, the moving party or opponent should:

(1) Identify the person whom it expects to call as an expert;

(2) State the field in which the person is alleged to be an expert; and

(3) State:

(i) The subject matter on which the person is expected to testify;

(ii) The facts and opinions to which the person is expected to testify; and

(iii) A summary of the grounds and basis for each opinion.

(e) If a fact witness is to be relied upon, state the facts to which the witness will testify.

(f) If the opponent is to be called, or if evidence in the possession of the opponent is necessary, explain the evidence sought, what it will show, and why it is needed.

(g) When inter partes tests are to be performed, describe the tests stating what they will be expected to show.❙

5. Section 1.655 is proposed to be amended by removing the last sentence of paragraph (a) as follows:

§ 1.655 Matters considered in rendering a final decision.

(a) In rendering a final decision, the Board may consider any properly raised issue including (1) priority of invention, (2) derivation by an opponent from a party who filed a preliminary statement under § 1.625, (3) patentability of the invention, (4) admissibility of evidence, (5) any interlocutory matter deferred to final hearing, and (6) any other matter necessary to resolve the interference. The Board may also consider whether any interlocutory order was erroneous or an abuse of discretion. (All interlocutory orders shall be presumed to have been correct and the burden of showing manifest error or an abuse of discretion shall be on the party attacking the order.)

* * * * *

Dated: December 30, 1992.

Edward E. Kubasiewicz,

Assistant Commissioner for Patents.

[FR Doc. 93–210 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–16–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 43

[CC Docket No. 92–296; FCC 92–537]

Simplification of the Depreciation Prescription Process

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Communications Commission (the Commission) has adopted a Notice of Proposed Rulemaking (Notice) proposing to simplify its depreciation prescription process. In a continuing effort to reduce unnecessary regulatory burdens and their associated costs, the Commission seeks comment on proposals that would simplify procedures and reduce associated costs in the depreciation prescription process.

DATES: Comments must be filed on or before March 10, 1993 and reply comments must be filed on or before April 13, 1993.

ADDRESSES: Federal Communications Commission, 1919 M St., NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Sonja J. Rifken or Fatina K. Franklin, Common Carrier Bureau, Accounting and Audits Division, (202) 632–7500.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rulemaking in Simplification of the Depreciation Prescription Process, CC Docket No. 92–296, FCC 92–537, adopted December 10, 1992 and released December 29, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M St., NW., Washington, DC. The full text will be published in the FCC Record and may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1990 M Street, NW., suite 640, Washington, DC 20036.

Summary

1. In this Notice of Proposed Rulemaking (Notice), we continue our efforts to reduce unnecessary regulatory burdens and their associated costs by undertaking simplification of our depreciation prescription process. Under our current depreciation prescription process, we prescribe depreciation rates by plant account for individual carriers. In this Notice, we seek comment on proposals that would simplify procedures and reduce associated costs in our depreciation prescription process.

2. This Commission determines depreciation rates by using a formula. This formula contains two parameters which must be estimated: future net salvage (FNS) and average remaining life (ARL). Once the parameters are determined, a depreciation rate is computed. The carriers then apply the depreciation rate to the average plant account balance to calculate the depreciation expense for that account. The ultimate purpose of continually estimating depreciation rates is to develop rates, using the most current information, that most accurately allocate plant costs to expense at a rate representative of the actual consumption of the plant.

3. Because the basic factors composing the ARL, projection life and survivor curve, as well as the FNS, are estimates, they are the subject of detailed analyses. Carriers submit detailed studies to prove the merit of their estimates, as required by our rules. A typical carrier submits studies totalling approximately 600 pages and averaging 20–25 pages of analysis per account. It is this part of the depreciation process we seek to simplify in this Notice.

4. In this Notice, we propose four options for simplifying the determination of depreciation expense: the basic factor range option, the range of rates option, the depreciation schedule option, and the price cap carrier option. The first proposal, the basic factor range option, would simplify the depreciation process by establishing ranges for the basic factors that determine the parameters used in the depreciation rate formula; the FNS, and the projection life and survivor curve (the basic factors that determine the ARL). This would eliminate the need for carriers to submit detailed studies in support of their proposed factors. Under this proposal, we would continue to prescribe depreciation rates using the current depreciation rate formula. Carriers would then apply the rates to their plant account balances to determine their depreciation expense.

5. The second proposal, the range of rates options, would simplify the depreciation process by establishing ranges for depreciation rates. Under this option, we would no longer focus on the basic factors used to derive the

parameters for the depreciation rate formula, and more importantly, we would not use the depreciation rate formula to derive depreciation rates. However, carriers would continue to apply depreciation rates to their plant account balances to determine their depreciation expense.

6. The third proposal, the depreciation schedule option, would simplify the depreciation process by establishing a depreciation schedule for each plant account. Essentially, the schedule would be based upon a Commission-specified service life, retirement pattern, and salvage value for a particular account. Carriers would then apply the schedule to their investment by vintage.

7. The final proposal would affect only price cap carriers. The price cap carrier option would simplify the depreciation process by allowing price cap carriers to file depreciation rates with no supporting data, but continuing Commission prescription of depreciation rates. Price cap carriers would file their proposed depreciation rates, and the Commission would issue a Public Notice seeking comment on the proposed rates. The Commission would then prescribe depreciation rates based on the price cap carriers' proposals and the comments submitted thereon.

8. The current depreciation process, and the four simplification options we seek comment on, include net salvage as a part of the depreciation process. In furtherance of simplification, we seek comment on whether we should, independent of those options, change our approach to salvage and not consider it in the depreciation process. This simplification option would require carriers to remove salvage from their depreciation process and require them to book the cost of removal and salvage as current period charges and credits. In addressing this proposal, commenters should quantify the effects this change would have on carriers' income statement and the administrative costs savings associated with the change. Also, we ask whether this changed treatment of salvage would be contrary to Generally Accepted Accounting Principles (GAAP).

9. We certify that the Regulatory Flexibility Act of 1980 does not apply to this rulemaking proceeding because if the proposed rule amendments are promulgated, there will not be a significant economic impact on a substantial number of small business entities, as defined by Section 601(3) of the Regulatory Flexibility Act. 5 U.S.C. 603(a). Because of the nature of local exchange and access service, the Commission has concluded that small telephone companies are dominant in their fields of operation and therefore are not "small entities" as defined by that act. The Secretary shall send a copy of this Notice of Proposed Rulemaking, including the certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of that act.

10. Accordingly, it is ordered that, pursuant to sections 1, 4(i), 4(j), 220, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 220(b), and 403, notice is hereby given of proposed amendments to § 43.43 of the Commission's Rules, 47 CFR 43.43 as described in this Notice of Proposed Rulemaking.

List of Subjects in 47 CFR Part 43

Communications common carriers, Reporting and recordkeeping requirements, Telephone.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–104 Filed 1–5–93; 8:45 am]

BILLING CODE 6712–01–M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1007

[Ex Parte No. 514(B)]

Privacy Act: New System of Records—Exemption; Office of Inspector General Complaint and Investigative Files

AGENCY: Interstate Commerce Commission.

ACTION: Proposed rule.

SUMMARY: The Commission (ICC) proposes here to exempt a new system of records due to the law enforcement nature of those records. That system of records which the Commission today proposed to establish in another proceeding under the Privacy Act of 1974, as amended (5 U.S.C. 552a), will consist of the complaint and investigatory files of the ICC's Office of Inspector General (OIG). This proposed rule amendment is required in order to invoke the relevant exemptions. By relieving the OIG of certain restrictions, the exemption will help ensure that the OIG may efficiently and effectively perform investigations and other authorized duties and activities.

DATES: Comments are due February 5, 1993.

ADDRESSES: An original and two copies of comments, referring to Ex Parte No. 514(B), should be submitted to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: S. Arnold Smith, Freedom of Information/Privacy Officer, (202) 927–6317 [TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: In the notice section of today's **Federal Register**, the ICC is publishing a notice proposing to establish a new system of records, "Office of Inspector General Complaint and Investigative Files," under the Privacy Act, as amended, 5 U.S.C. 552a. The following proposed amendment of ICC Rule 49 CFR 1007.12 is necessary to exempt the new system of records from certain provisions of the Act. These provisions require, among other things, that the ICC provide notice when collecting information, account for certain disclosures, permit individuals access to their records, and allow them to request that the records be amended. These provisions would interfere with the conduct of OIG investigations if applied to the OIG's maintenance of the proposed system of records.

Accordingly, the ICC proposes to exempt the system of records under sections (j)(2) and (k)(2) of the Privacy Act. Section (j)(2), 5 U.S.C. 552a(j)(2), exempts a system of records maintained by "the agency or component thereof which performs as its principal function any activity pertaining to enforcement of criminal laws * * *" Section (k)(2), 5 U.S.C. 552a(k)(2), exempts a system of records consisting of "investigatory materials compiled for law enforcement purposes," where such materials are not within the scope of the (j)(2) exemption pertaining to criminal law enforcement.

Where applicable, section (j)(2) may be invoked to exempt a system of records from any Privacy Act provision except: 5 U.S.C. 552(b) (conditions of disclosure); (c) (1) and (2) (accounting of disclosures and retention of accounting, respectively); (e)(4) (A) through (F) (system notice requirements); (e) (6), (7), (9), (10), and (11) (certain agency requirements relating to system maintenance); and (i) (criminal penalties). Section (k)(2) may be invoked to exempt a system of records from 5 U.S.C. 552(c)(3) (making accounting of disclosures available to the subject individual); (d) (access to record); (e)(1) (G), (H) and (I) (notice of certain procedures); and (f) (promulgation of certain Privacy Act rules).

The proposed system of records consists of information covered by the (j)(2) and (k)(2) exemptions. The OIG complaint and investigatory files are maintained pursuant to official

investigatory and law enforcement functions of the ICC's OIG under the authority of the Inspector General Act Amendments of 1988, Public Law 100–504, 102 Stat. 251 (amending 5 U.S.C. App. 3 (1978)). Furthermore, the OIG constitutes an ICC component that performs as one of its principal functions activities pertaining to the enforcement of criminal laws. See 5 U.S.C. 552a(j)(2). Information covered under the (j)(2) exemption includes, but is not limited to, information compiled for the purpose of identifying criminal offenders and alleged offenders and consisting of identifying data and notations of arrests, and the nature and disposition of criminal charges, sentencing, confinement, release, and parole and probation status; information compiled for the purpose of a criminal investigation, including reports of informants and investigators, that is associated with an identifiable individual; or reports of enforcement of the criminal laws from arrest or indictment through release from supervision. Information contained in OIG complaint and investigative files under the (k)(2) exemption relates to non-criminal law enforcement matters, such as information pertaining to the investigation of civil, administrative, or regulatory violations and similar wrongdoing.

Access by subject individuals, among others, to this system of records; including the names of persons or agencies to whom the information has been transmitted, would substantially compromise the effectiveness of OIG investigations. Knowledge of such investigations could enable suspects to take action to prevent detection of unlawful activities, conceal or destroy evidence, or escape prosecution. Disclosure of this information could lead to the intimidation of, or harm to, informants, witnesses, and their families and could jeopardize the safety and well-being of investigative and related personnel and their families. The imposition of certain restrictions on the manner in which investigative information is collected, verified, or retained would significantly impede the effectiveness of OIG investigatory activities and, in addition, could preclude the apprehension and successful prosecution or discipline of persons engaged in fraud or other illegal activity.

For these reasons, the ICC proposes to exempt the proposed system of records containing the OIG complaint and investigative files under exemptions (j)(2) and (k)(2) of the Privacy Act by amending 490 CFR 1007.12. Under this rule, the ICC specifies its system of records that are exempt from the Privacy Act.

This proposed rule amendment will become effective 30 days after its final publication in the **Federal Register**. This date may be postponed if the Director of the Office of Management and Budget (OMB) declines, in whole or part, the ICC's request to waive the 60-day period prescribed by OMB for advance notice to OMB and Congress. See OMB Circular No. A–130, App. 1 at 4b.(c)(4).

Regulatory Flexibility Certification

Pursuant to the Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), the Commission certifies that the proposed amendment to its regulations, if adopted, would not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. The purpose of that amendment, which is proposed pursuant to the Privacy Act, is solely to exempt from disclosure certain files of the ICC's OIG that would be kept in a new system of records within the ICC. The proposed amendment imposes no new regulatory requirements either directly or indirectly on anyone, including small entities. Moreover, because the Privacy Act applies only to "individuals," and the RFA defines "small entities" as having the same meaning as 'small business', 'small organization' and 'small government jurisdiction' as defined in section 601(3), (4) and (5) respectively, the "individuals" who may be affected by the new rule do not appear to come within the meaning of "small entity" as defined by the RFA.

Energy and Environment Considerations

We preliminarily conclude that this action will not significantly affect either the quality of the human environment or the conservation of energy resources.

List of Subjects in 49 CFR Part 1007

Administrative practice and procedure, Privacy.

Decided: December 31, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

For the reasons set forth in the preamble, title 49, chapter X, part 1007 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1007—RECORDS CONTAINING INFORMATION ABOUT INDIVIDUALS

1. The authority citation for part 1007 continues to read as follows:

Authority: 5 U.S.C. 552, 553, and 559.

2. Section 1007.12 is proposed to be amended by adding a new paragraph (c) as follows:

§ 1007.12 Exemptions.

* * * * *

(c) Complaints and investigatory materials compiled by the Commission's Office of Inspector General are exempt from the provisions of 5 U.S.C. 552a and the regulations in this part, pursuant to 5 U.S.C. 552a(j)(2), except subsections (b), (c)(1) and (2), (e)(4) (A) through (F), (e)(6), (7), (9), (10), and (11) and (i) to the extent that the system of records pertains to the enforcement of criminal laws. Complaint and investigatory materials compiled by the Commission's Office of Inspector General for law enforcement purposes also are exempt from the provisions of 5 U.S.C. 5552a and the regulations of this part, pursuant to 5 U.S.C. 552a(k)(2), except subsections (c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f).

[FR Doc. 93–250 Filed 1–5–93; 8:45 am]

BILLING CODE 7535–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 672

[Docket No. 921226–2326]

Groundfish of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to delay the opening of the second quarter for pollock fishing in the Combined Western and Central Regulatory Areas (W/C) of the Gulf of Alaska (GOA) from the beginning of the second quarterly reporting period (around April 1) until the first day of the weekly reporting period closest to June 1. This action is necessary to increase revenues from the GOA pollock harvest by avoiding a second quarter directed fishery at a time when pollock have recently spawned and flesh yield is low. Additionally, NMFS anticipates this action would reduce discards of undersized pollock, and of incidental bycatch amounts of chinook salmon in the pollock fishery.

By increasing the value of the pollock harvest, this action would foster economic growth. This action is intended to promote the goals and objectives of the North Pacific Fishery Management Council (Council) with respect to groundfish management off Alaska.

DATES: Comments must be received at the following address no later than 4:30 p.m., Alaska local time, February 5, 1993.

ADDRESSES: Comments may be sent to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, Box 21668, Juneau, AK 99802, Attention: Lori Gravel. Copies of the environmental assessment/regulatory impact review/initial regulatory flexibility analysis (EA/RIR/IRFA) prepared for the proposed action may be obtained from the same address.

FOR FURTHER INFORMATION CONTACT: Jessica A. Gharrett, Fisheries Management Division, (907) 586–7229.

SUPPLEMENTARY INFORMATION:

Background

The domestic and foreign groundfish fisheries in the exclusive economic zone of the GOA are managed by the Secretary of Commerce (Secretary) under the Fishery Management Plan for Groundfish of the GOA (FMP). The FMP was prepared by the Council under the Magnuson Fishery Conservation and Management Act (Magnuson Act) and is implemented by regulations for the foreign fishery at 50 CFR Part 611 and for the U.S. fishery at 50 CFR part 672. General regulations that also pertain to the U.S. fishery appear at 50 CFR part 620.

Under regulations at § 672.20(a)(2)(iv), the total allowable catch (TAC) for pollock in the W/C GOA is apportioned among statistical areas Shumagin (61), Chirikof (62), and Kodiak 63 in proportion to known distribution of the pollock biomass. Each apportionment is divided equally into the four quarterly reporting periods of the fishing year. Under § 672.2, a "quarterly reporting period" means one of four successive 3-month periods during a calendar year. Under § 672.20(c)(1)(ii)(A), directed fishing for pollock in the W/C GOA will commence on dates that coincide with anticipated quarterly reporting periods for 1993. Pollock fishing quarters in the W/C GOA for 1993 commence on the first day of each of the four quarterly reporting periods: January 1, March 29, June 28, and October 4.

At its September 22–27, 1992, meeting, the Council considered an industry proposal to delay the opening of the second quarter pollock fishery in the W/C GOA from the first day of the second quarterly reporting period until the first day of the weekly reporting period nearest June 1. Under § 672.2, a "weekly reporting period" means from 0001 hours Monday morning until 2400 hours the following Sunday night, Alaska local time. For the 1993 fishing year, this date falls on May 31. For the reason given below, the Council found the industry proposal would provide economic benefits to pollock harvesters and processors and recommended that NMFS prepare a proposed rule delaying the opening of the second quarter pollock fishery in the W/C GOA. Pending approval by NMFS, this action would be implemented prior to the start of the second 1993 W/C GOA pollock quarter, currently scheduled for March 29.

The most recent year in which a W/C GOA directed pollock fishery occurred in April was 1990; in 1991 and 1992, the opening of the second quarter was delayed until June. In 1991, the second quarter directed pollock fishery commence on June 13. This change was the result of a delay in approval of the pollock harvest specification to complete additional analyses and a Section 7 consultation for Steller sea lions under the Endangered Species Act (ESA) (56 FR 28112, June 19, 1991). In 1992, the opening of the second quarter was delayed until June 1, under an emergency rule (57 FR 11272, April 2, 1992). This emergency rule was intended to prevent preemption of the inshore component by the offshore component until allocations of pollock under a final rule implementing Amendment 23 to the FMP were effective (57 FR 23321, June 3, 1992). Adoption of this proposed rule would maintain the second quarter pollock fishing and processing seasons as they occurred in 1993 and 1992.

The allocation of pollock into quarters and among several areas has resulted in small quarterly pollock allowances for pollock. Because the domestic groundfish industry has more than adequate capacity to harvest and process the pollock TAC in the W/C GOA, the resultant directed fishery is of short duration; the number of days directed fishing for pollock was open during the second quarter in 1992 was: 2 days for area 61; 16 days for area 62; and 11 days for area 63. This proposed delay is not anticipated to alter effort, and would not be likely to change the length of the directed fishery. The opening of the second quarter directed fishery for pollock would be displaced by approximately 2 months, from the beginning of April to the beginning of June. The opening of the third pollock quarter in the W/C GOA would not be altered by this proposed rule.

The allocation of the W/C GOA pollock TAC to 3 areas will ensure that the harvest remains distributed spatially. Harvesters may be able to fish closer to ports and make shorter trips if searching time to avoid encounters with young and undersized pollock is reduced, and if pollock are not as dispersed as they are in early spring just after spawning.

If the opening of the second quarter pollock fishery is delayed, the same individuals would likely participate in the harvesting and processing of GOA pollock as in 1992, including some processors in close proximity to the Bering Sea and Aleutian Islands Area (BSAI) who also participate in BSAI pollock fisheries. GOA pollock harvesters and processors who participate both in the pollock fishery and in June salmon fisheries may not be able to participate fully in the second quarter fishery if the opening is delayed until June. Participation would depend on the starting dates of the salmon fisheries. In 1992, operators of more than 300 vessels held Federal groundfish permits for trawl gear in the GOA. While this number of vessels is considered substantial, this regulatory measure would only affect the portion of the fleet that participates in the second quarter pollock fishing season. processors who intend to participate in fisheries for pollock as well as other species in the second quarter may experience labor and/or equipment conflicts. These costs, or the extent to which pollock fishing would be foregone, are not quantifiable at this time. Although some processing operations may incur additional labor costs, most operators would realize net benefits resulting from increased yields.

Delaying the opening of the second quarter pollock fishery could result in a fishery that is conducted with pelagic, rather than with non-pelagic, trawl gear, although no additional costs to the industry are anticipated. Under § 672.20(f), an annual halibut bycatch limit is specified for trawl gear. When the limit, or seasonal apportionment thereof, is reached, all GOA groundfish trawl fisheries are closed with the exception of trawling for pollock with pelagic trawl gear. Delay of the opening of the second quarter pollock fishery to around June 1 would increase the likelihood that a seasonable trawl bycatch allowance is taken in other trawl fisheries prior to the start of the second quarter pollock fishery. This situation occurred in the past 2 years and, because trawl closures typically occur in other seasons as well, many

pollock fishermen have acquired pelagic trawl gear. Therefore, any additional costs to harvesters to purchase pelagic nets under the proposed rule are expected to be minimal.

NMFS anticipates that under this proposed action, pollock fishery conducted with pelagic trawl gear would accrue negligible amounts of additional halibut bycatch. Any savings in halibut bycatch experienced by the pollock fishery because of a prohibition on the use of non-pelagic trawl gear may support additional catches of other groundfish species during the second quarter and result in a higher overall groundfish harvest.

NMFS also anticipates that a delayed opening of the second quarter pollock fishery could result in a substantial decrease in the bycatch rates of chinook salmon. Data from 1991 and 1992 indicate that bycatch rates (number of salmon/metric ton (mt) of groundfish) in the pelagic trawl pollock fishery are significantly lower in June than at the end of the first quarter (0.02 and 0.20, respectively). In contract, bycatch rates for salmon other than chinook salmon and for herring may be higher. Bycatch rates of crabs in June are very low and would likely not be different from earlier in the quarter.

The proposed delay of the second quarter opening is anticipated to increase the first wholesale value of the pollock harvest during the second quarter by allowing harvest when recovery of flesh is higher, and to result in potentially higher value products, such as larger fillets and higher grades of surimi. Because the amount of pollock harvest would not be altered under the proposed season delay, an estimate of the increased value is dependent on improved yields, product mix, and wholesale prices. Information on product recovery rates indicates that the increase in flesh yield between pollock harvested in April, when fish have recently spawned, and June, is about 3 percent for fillets, and 4 percent for surimi. Based on 1991 first wholesale values, the value increase would likely be between $2.6 million and $3.6 million for 1993. In addition to increased product value, harvesters and processors also would benefit from decreased fishing, sorting, processing, and storage time, and from decreased disposal of unsuitable fish.

NMFS preliminarily concurs with the Council's recommendation and proposes to delay the opening of the second quarter pollock fishery until the first day of the weekly reporting period nearest June 1.

Classification

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has initially determined that this rule is necessary for the conservation and management of the groundfish fishery off Alaska and that it is consistent with the Magnuson Act and other applicable law.

NMFS prepared an EA for this proposed rule that discusses the impact on the environment as a result of this rule. The public may obtain a copy of the EA from the Regional Director (see **ADDRESSES**).

The Assistant Administrator determined that this proposed rule is not a "major rule" requiring a regulatory impact analysis under Executive Order 12291. This determination is based on the socioeconomic impacts discussed in the EA/RIR/IRFA prepared by the NMFS. This proposed rule, if adopted, is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

NMFS prepared an IRFA that concludes that this proposed rule, if adopted, would have significant effects on small entities. In 1992, operators of over 300 vessels were issued permits to fish for GOA groundfish with trawl gear. While this number of vessels is considered substantial, this regulatory measure would affect only the portion of the fleet that participates in the second quarter pollock fishing season. In addition, 14 processors processed pollock during the second quarter pollock fishing of 1992. The proposed action to delay the opening of the second quarter pollock fishery in the W/C GOA is superior to the status quo alternative, because economic benefits will be gained by allowing harvest of pollock when flesh recovery is improved in June as opposed to April. Based on 1991 first wholesale prices, the value increase under the proposed rule is estimated to be between $2.6 and $3.6 million for 1993. Additionally, costs to harvesters and processors may be lower due to decreased time required for fishing, sorting, processing, and product storage. The bycatch and discard of young and undersized pollock, and of chinook salmon, are likely to be lower. Conservation of groundfish and salmon resources would be improved to the extent that these bycatch rates would be reduced. A copy of this analysis is available from the Regional Director (see **ADDRESSES**).

This rule does not include a collection-of-information requirement subject to the Paperwork Reduction Act.

Pursuant to the requirements of the ESA, the Regional Director has determined that this action is not likely to adversely affect any endangered or threatened species or critical habitat within NMFS' jurisdiction.

NFMS has determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal management program of the State of Alaska. This determination has been submitted for review by the responsible State agency under Section 307 of the Coastal Zone Management Act.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under E.O. 12612.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

Dated: December 30, 1992.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 672 is proposed to be amended as follows:

PART 672—GROUNDFISH OF THE GULF OF ALASKA

1. The authority citation for 50 CFR part 672 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

2. In § 672.23, paragraph (a) is revised and a new paragraph (f) is added to read as follows:

§ 672.23 Seasons.

(a) Fishing for groundfish in the regulatory areas and districts of the Gulf of Alaska is authorized from 00:01 a.m., Alaska local time (A.l.t), January 1, through 12 midnight, A.l.t., December 31, subject to the other provisions of this part, except as provided in paragraphs (c) through (f) of this section

* * * * *

(f) Directed fishing for pollock in the Western and Central Regulatory Areas of the Gulf of Alaska is authorized from 12 noon, A.l.t., on the first day of each quarterly reporting period through the end of that quarterly reporting period, subject to other provisions of this part, except that directed fishing for pollock during the second quarterly reporting

period is authorized from 12 noon, A.l.t., on the first day of the weekly reporting period closest to June 1, through the end of the second quarterly reporting period, subject to other provisions of this part.

[FR Doc. 93–135 Filed 1–5–93; 8:45 am]
BILLING CODE 3510-22-M

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Notices

Federal Register
Vol. 58, No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Meat Import Limitations; First Quarterly Estimate

Public Law 88–482, enacted August 22, 1964, as amended by Public Law 96–177, Public Law 100–418, and Public Law 100–449 (hereinafter referred to as the "Act"), provides for limiting the quantity of fresh, chilled, or frozen meat of bovine, sheep except lamb, and goats; and processed meat of beef or veal (Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.20, 0201.20.40, 0201.20.60, 0201.30.20, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.20, 0202.20.40, 0202.20.60, 0202.30.20, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, and 0204.50.00), which may be imported, other than products of Canada, into the United States in any calendar year. Such limitations are to be imposed when the Secretary of Agriculture estimates that imports of articles, other than products of Canada, provided for in Harmonized Tariff Schedule of the United States subheadings 0201.10.00, 0201.20.40, 0201.20.60, 0201.30.40, 0201.30.60, 0202.10.00, 0202.20.40, 0202.20.60, 0202.30.40, 0202.30.60, 0204.21.00, 0204.22.40, 0204.23.40, 0204.41.00, 0204.42.40, 0204.43.40, and 0204.50.00), (hereinafter referred to as "meat articles"), in the absence of limitations under the Act during such calendar year, would equal or exceed 110 percent of the estimated aggregate quantity of meat articles prescribed for calendar year 1993 by section 2(c) as adjusted under section 2(d) of the Act.

In accordance with the requirements of the Act, I have made the following estimates:

1. The estimated aggregate quantity of meat articles prescribed by section 2(c) as adjusted by section 2(d) of the Act for calendar year 1993 is 1,144.7 million pounds.

2. The first quarterly estimate of the aggregate quantity of meat articles which would, in the absence of limitations under the Act, be imported during calendar year 1993 is 1,259.1 million pounds.

Done at Washington, DC this 31st day of December, 1992.

Edward Madigan,

Secretary of Agriculture.

[FR Doc. 93–213 Filed 1–5–93; 8:45 am]

BILLING CODE 3410–10–M

COMMISSION ON CIVIL RIGHTS

Maine State Advisory Committee; Public Meetings

Notice is hereby given, pursuant to the provisions of the Rules and Regulations of the U.S. Commission on Civil Rights, that a meeting of the Maine State Advisory Committee will be convened at 2 p.m. and adjourn at 5 p.m. on Thursday, January 21, 1993, in suite 212, Civic Center Comfort Inn, 282 Civic Center Drive, Augusta, ME 04330. The purpose of the meeting is (1) to update Committee members and the public on the Commission; (2) to provide an orientation for new Committee members; and (3) to plan future activities.

Persons desiring additional information, or planning a presentation to the Committee, should contact Grayce E. Studley (207–563–3610) or John I. Binkley, Director, ERO (202–376–7533), or TDD (202–376–8116). Hearing impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the regional office at least (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, December 22, 1992.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 93–190 Filed 1–5–93; 8:45 am]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 619]

Expansion of Foreign-Trade Zone 162; New Haven, Connecticut

Pursuant to its authority under the Foreign-Trade Zones (FTZ) Act of June 18, 1934, as amended (19 U.S.C. 81a–81u) (the Act), and the FTZ Board Regulations (15 CFR part 400), the FTZ Board (the Board) adopts the following Resolution and Order:

Whereas, an application from the Greater New Haven Chamber of Commerce, grantee of Foreign-Trade Zone No. 162, for authority to relocate its general-purpose zone to a larger site at the Port of New Haven, New Haven, Connecticut, within the New Haven Customs port of entry, was filed by the Board on October 31, 1991, and notice inviting public comment was given in the **Federal Register** on November 15, 1991 (Docket 70–91, 56 FR 58030);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the expansion is necessary to improve and expand zone services in the New Haven area; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations are satisfied, and that approval is in the public interest;

Now, therefore, the Board hereby orders;

That the grantee is authorized to relocate and expand its zone in accordance with the application filed on October 31, 1991, subject to the Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including section 400.28.

Signed at Washington, DC, this 29th day of December, 1992.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternatives, Foreign-Trade Zones Board.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–232 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DS–M

[Order No. 623]

Expansion of Foreign-Trade Zone 101; Clinton County, Ohio

Pursuant to its authority under the Foreign-Trade Zones (FTZ) Act of June 18, 1934, as amended (19 U.S.C. 81a–81u) (the Act), and the FTZ Board Regulations (15 CFR part 400), the FTZ Board (the Board) adopts the following Resolution and Order:

Whereas, an application from the Airborne FTZ, Inc., grantee of Foreign-Trade Zone No. 101, for authority to expand its general-purpose zone at the Airborne Commerce Park in Clinton County, Ohio, adjacent to the Dayton Customs port of entry, was filed by the Board on April 27, 1992, and notice inviting public comment was given in the **Federal Register** on May 7, 1992 (Docket 13–92, 57 FR 19597);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the expansion is necessary to improve and expand zone services in the Clinton County area; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations are satisfied, and that approval is in the public interest;

Now, therefore, the Board hereby orders:

That the grantee is authorized to expand its zone in accordance with the application filed on April 27, 1992, subject to the Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including § 400.28.

Signed at Washington, DC, this 29th day of December, 1992.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates, Foreign-Trade Zones Board.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–234 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DS–M

[Order No. 621]

Resolution and Order Approving the Application of the Port of Portland (Oregon) for Special-Purpose Subzone Status for Export Activity Tofle U.S.A., Inc. (Stainless Steel Tubing) Tualatin, OR

Proceedings of the Foreign-Trade Zones Board, Washington, D.C.

Resolution and Order

Pursuant to the authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board (the Board) adopts the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the Port of Portland, grantee of Foreign-Trade Zone 45, filed with the Foreign-Trade Zones (FTZ) Board (the Board) on November 6, 1991, requesting special-purpose subzone status for export activity at the stainless steel tubing plant of Tofle U.S.A., Inc., in Tualatin, Oregon, adjacent to the Portland Customs port of entry, the Board, finding that the requirements of the Foreign-Trade Zones Act and the Board's regulations are satisfied, and that the proposal is in the public interest, approves the application.

The approval is subject to the FTZ Act and the FTZ Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including Section 400.28. The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

Whereas, by an Act of Congress approved June 18, 1934, an Act, "To provide for the establishment * * * of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized to grant to corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of special-purpose subzones when existing zone facilities cannot serve the specific use involved;

Whereas, an application from the Port of Portland (Oregon), grantee of Foreign-Trade Zone 45, for authority to establish a special-purpose subzone for export activity at the stainless steel tubing plant of Tofle U.S.A., Inc., located in Tualatin, Oregon, was filed by the Board on November 6, 1991, and notice was given in the **Federal Register** on November 27, 1992 inviting public comment (FTZ Docket 75–91, 56 FR 60087); and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations are satisfied and that the proposal is in the public interest;

Now, Therefore, the Board hereby authorizes the establishment of a subzone (Subzone 45E) for export activity at the stainless steel tubing plant of Tofle U.S.A., Inc., in Tualatin, Oregon, at the location described in the application, subject to the FTZ Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91), including Section 400.28.

Signed at Washington, DC, this 29th day of December, 1992, pursuant to Order of the Board.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates Foreign-Trade Zones Board.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–233 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DS–M

National Oceanic and Atmospheric Administration

Gulf of Mexico Fishery Management Council; Revision to Public Meeting Agenda

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

A notice of, and the agenda for, public meetings of the Gulf of Mexico Fishery Management Council and its Committees were published in the **Federal Register** at 57 FR 61050–61051 on December 23, 1992. Recent actions require a revision to the prior notice as noted below. All other information originally published on December 23, 1992, remains unchanged.

REVISION: Committees: The Budget, Law Enforcement, Habitat and Shrimp Committees will meet on January 18, 1993, from 11 a.m. to 5:30 p.m.

FOR MORE INFORMATION CONTACT: Wayne E. Swingle, Gulf of Mexico Fishery Management Council, 5401 West Kennedy Boulevard, Suite 331, Tampa, FL; telephone: (813) 228–2815.

Dated: December 30, 1992.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–136 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–22–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcing 1993 Agreement Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Hong Kong

December 30, 1992.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Notice.

FOR FURTHER INFORMATION CONTACT: Anne Novak, International Trade

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Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Bilateral Textile Agreement of August 4, 1986, as amended and extended, and Memoranda of Understanding (MOUs) dated July 29, 1992, August 18, 1992 and November 23, 1992 between the Governments of the United States and Hong Kong establishes limits for the period January 1, 1993 through December 31, 1993. A complete list of the limits is published below.

A copy of the current bilateral agreement is available from the Textiles Division, Bureau of Economic and Business Affairs, U.S. Department of State, (202) 647–3889.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 57 FR 54976, published on November 23, 1992).

Category	Twelve-month limit
Group I	
200–229, 300–326, 360–369, 400–414, 464–469, 600–629 and 665–670, as a group.	212,057,104 square meters equivalent.
Sublevels in Group I	
200	288,725 kilograms.
219	33,488,449 square meters.
218/225/317/326	82,654,035 square meters of which not more than 3,450,739 square meters shall be in Category 218(1)—yarn dyed fabric other than denim and jacquard [1].
226/313	60,071,085 square meters.
314	18,200,451 square meters.
315	8,009,558 square meters.
369(1) [2] (shoptowels)	658,223 kilograms.
604	198,190 kilograms.
611	5,279,905 square meters.
617	3,331,250 square meters.
Group II	
237, 239, 330–359, 431–459, 630–659 and 843/844(1), as a group.	771,903,427 square meters equivalent.
Sublevels in Group II	
237	968,395 dozen.
239	4,439,251 kilograms.
331	3,768,184 dozen pairs.
333/334	259,205 dozen.
335	312,833 dozen.
336	187,035 dozen.
338/339 [3] (shirts and blouses other than tank tops and tops, knit).	2,658,990 dozen.
338/339(1) [4] (tank tops and knit tops).	1,997,712 dozen.
340	2,546,264 dozen.
341	2,577,404 dozen.
342	481,971 dozen.
345	394,291 dozen.
347/348	6,086,317 dozen of which not more than 2,985,454 dozen shall be in Category 347; not more than 4,612,442 dozen shall be in Category 348; not more than 6,086,317 dozen shall be in Categories 347–W/348–W [5] of which not more than 4,612,442 dozen shall be in Category 348–W.
350	119,067 dozen.
351	1,088,580 dozen.
352	5,695,971 dozen.
359(1) [6] (coveralls, overalls and jumpsuits).	514,982 kilograms.
359(2) [7] (outer vests)	1,073,329 kilograms.
433	9,090 dozen.
434	9,758 dozen.
435	70,000 dozen.
436	91,170 dozen.
438	748,772 dozen.
442	80,626 dozen.
443	57,523 numbers.
443/444/643/644/843/844(1) (made-to-measure suits).	51,462 numbers.
444	36,506 numbers.
445/446	1,237,621 dozen.
447/448	62,240 dozen.
631	537,473 dozen pairs.
633/634/635	1,162,865 dozen of which not more than 434,862 dozen shall be in Categories 633/634 and not more than 892,796 dozen shall be in Category 635.
636	251,718 dozen.
638/639	4,463,894 dozen.
640	801,977 dozen.
641	771,342 dozen.
642	200,176 dozen.
644	36,455 numbers.
645/646	1,283,443 dozen.
647	447,106 dozen.
648	976,355 dozen of which not more than 976,355 dozen shall be in Category 648–W [8].
649	668,364 dozen.
650	142,351 dozen.
651	272,605 dozen.
652	4,144,252 dozen.
659(1) [9] (coveralls, overalls and jumpsuits).	569,190 kilograms.
659(2) [10] (swimsuits)	227,316 kilograms.
Group III	
831–842, 843/844 (excluding made-to-measure suits), and 847–859, as a group.	43,071,306 square meters equivalent.
Sublevels in Group III	
835	101,129 dozen.
836	136,342 dozen.
840	600,714 dozen.
842	224,421 dozen.
847	322,604 dozen.
Limits not in a group	
845(1) [11] (sweaters made in Hong Kong).	1,100,777 dozen.
845(2) [12] (sweaters assembled in Hong Kong from knit-to-shape component parts knitted elsewhere).	2,634,842 dozen.
846(1) [13] (sweaters made in Hong Kong).	178,006 dozen.
846(2) [14] (sweaters assembled in Hong Kong from knit-to-shape component parts knitted elsewhere).	426,927 dozen.

[1] Category 218(1): The Government of Hong Kong will continue to use these products as 218.

[2] Category 369(1): only HTS number 6307.10.2005.

[3] Categories 338/339: all HTS numbers except 6109.10.0018, 6109.10.0023, 6109.10.0060, 6109.10.0065, 6114.20.0005 and 6114.20.0010.

[4] Categories 338/339(1): only HTS numbers 6109.10.0018, 6109.10.0023, 6109.10.0060, 6109.10.0065, 6114.20.0005 and 6114.20.0010.

[5] Category 347–W: only HTS numbers 6203.19.1020, 6203.19.4020, 6203.22.3020, 6203.22.3030, 6203.42.4005, 6203.42.4010, 6203.42.4015, 6203.42.4025, 6203.42.4035, 6203.42.4045, 6203.42.4050, 6203.42.4060, 6203.49.3020, 6210.40.2035, 6211.20.1520, 6211.20.3010 and 6211.32.0040; Category 348–W: only HTS numbers 6204.12.0030, 6204.19.3030, 6204.22.3040, 6204.22.3050, 6204.29.4034, 6204.62.3000, 6204.62.4005, 6204.62.4010, 6204.62.4020, 6204.62.4030, 6204.62.4040, 6204.62.4050, 6204.62.4055, 6204.62.4065, 6204.69.3010, 6204.69.9010, 6210.50.2035, 6211.20.1550, 6211.20.6010, 6211.42.0030 and 6217.90.0050.

[6] Category 359(1): only HTS numbers 6103.42.2025, 6103.49.3034, 6104.62.1020, 6104.69.3010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010.

[7] Category 359(2): only HTS numbers 6103.19.2030, 6103.19.4030, 6104.12.0040, 6104.19.2040, 6110.20.1022, 6110.20.1024, 6110.20.2030, 6110.20.2035, 6110.90.0044, 6110.90.0046, 6201.92.2010, 6202.92.2020, 6203.19.1030, 6203.19.4030, 6204.12.0049, 6204.19.3040, 6211.32.0070 and 6211.42.0070.

[8] Category 648–W: only HTS numbers 6204.23.0040, 6204.23.0045, 6204.29.2020, 6204.29.2025, 6204.29.4038, 6204.63.2000, 6204.63.3000, 6204.63.3510, 6204.63.3530, 6204.63.3532, 6204.63.3540, 6204.69.2510, 6204.69.2530, 6204.69.2540, 6204.69.2560, 6204.69.3030, 6204.69.9030, 6210.50.1035, 6211.20.1555, 6211.20.6030, 6211.43.0040 and 6217.90.0060.

[9] Category 659(1): only HTS numbers 6103.23.0055, 6103.43.2025, 6103.43.2050, 6103.49.2000, 6103.49.3038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.3014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.4015, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[10] Category 659(2): only HTS numbers 6112.31.0010, 6112.31.0020, 6112.41.0010, 6112.41.0020, 6112.41.0030, 6112.41.0040, 6211.11.1010, 6211.11.1020, 6211.12.1010 and 6211.12.1020.

[11] Category 845(1): only HTS numbers 6103.29.2074, 6104.29.2076, 6110.90.0024, 6110.90.0042 and 6117.90.0021.

[12] Category 845(2): only HTS numbers 6103.29.2078, 6104.29.2077, 6110.90.0022 and 6110.90.0040.

[13] Category 846(1): only HTS numbers 6103.29.2068, 6104.29.2075, 6110.90.0020, 6110.90.0038 and 6117.90.0018.

[14] Category 846(2): only HTS numbers 6103.29.2066, 6104.29.2073, 6110.90.0018 and 6110.90.0036.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Donald R. Foote,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 93–162 Filed 1–5–93; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0101]

Clearance Request Regarding Drug-Free Workplace

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance (9000–0101).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning Drug-Free Workplace.

FOR FURTHER INFORMATION CONTACT: Edward Loeb, Office of Federal Acquisition Policy, GSA (202) 501–4547.

SUPPLEMENTARY INFORMATION:

A. Purpose

Public Law 100–690, the Drug-Free Workplace Act of 1988, mandates that: (1) Government contract employees notify their employer of any criminal drug statute conviction for a violation occurring in the workplace; and (2) Government contractors, after receiving notice of such conviction, must notify the Government contracting officer. These requirements are effective as of March 18, 1989.

The information provided to the Government will be used to determine contractor compliance with the statutory requirements to maintain a drug-free workplace.

B. Annual Reporting Burden

The annual reporting burden is estimated as follows: Respondents, 600; responses per respondent, 1; total annual responses, 600; preparation hours per response, .17; and total response burden hours, 102.

C. Annual Recordkeeping Burden

The annual recordkeeping burden is estimated as follows: Recordkeepers, 600; hours per recordkeeper, .5; and total recordkeeping burden hours, 300.

OBTAINING COPIES OF PROPOSALS: Requester may obtain copies of OMB applications or justifications from the General Services Administration, FAR Secretariat (VRS), room 4037, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0101, Drug-Free Workplace, in all correspondence.

Dated: December 28, 1992.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 93–101 Filed 1–5–93; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0108]

Clearance Request Regarding Bankruptcy

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for an extension to an existing OMB clearance (9000–0108).

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 35), the Federal Acquisition Regulation (FAR) Secretariat has submitted to the Office of Management and Budget (OMB) a request to review and approve an extension of a currently approved information collection requirement concerning bankruptcy.

FOR FURTHER INFORMATION CONTACT: Edward Loeb, Office of Federal Acquisition Policy, GSA, (202) 501–4547.

SUPPLEMENTARY INFORMATION:

A. Purpose

Under statute, contractors may enter into bankruptcy which may have a significant impact on the contractor's ability to perform its Government contract. The Government often does not receive adequate and timely notice of this event. The subject contract clause requires contractors to notify the contracting officer within five days after the contractor enters into bankruptcy.

B. Annual Reporting Burden

The annual reporting burden is estimated as follows: Respondents, *1,000*; responses per respondent, *1*; total annual responses, *1,000*; preparation hours per response, *1*; and total response burden hours, *1,000*.

C. Annual Recordkeeping Burden

The annual recordkeeping burden is estimated as follows: Recordkeepers, *1,000*; hours per recordkeeper, *.25*; and total recordkeeping burden hours, *250*.

OBTAINING COPIES OF PROPOSALS: Requester may obtain copies of OMB applications or justifications from the General Services Administration, FAR Secretariat (VRS), room 4037, Washington, DC 20405, telephone (202) 501–4755. Please cite OMB Control No. 9000–0108, Bankruptcy, in all correspondence.

Dated: December 28, 1992.

Beverly Fayson,

FAR Secretariat.

[FR Doc. 93–102 Filed 1–5–93; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF ENERGY

Energy Information Administration

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration, DOE.

ACTION: Notice of request submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Public Law 96–511, 44 U.S.C. 3501 *et seq.*). The listing does not include collections of information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection (a DOE component, which term includes the Federal Energy Regulatory Commission); (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours

per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed by February 5, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.)

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Jay Casselberry, Office of Statistical Standards (EI–73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254–5348.

SUPPLEMENTARY INFORMATION: The energy information collection submitted to OMB for review was:

1. Energy Information Administration
2. EIA–1, 3, 3A, 4, 5, 5A, 6, 7A, and 20
3. 1905–0167
4. Coal Program Package
5. Revision
6. Quarterly, Annually, Other (Standby)
7. Mandatory
8. Businesses or other for-profit
9. 6,133 respondents
10. 2.06 responses per respondent
11. 1.53 hours per response
12. 19,390 hours
13. The coal surveys collect data on coal production, consumption, stock prices, imports and exports. Data are published in various EIA publications. Respondents are manufacturing plants, producers of coke, purchasers and distributors of coal, coal mining operators, and coal-consuming electric utilities.

Authority: Sec. 5(a), 5(b), 13(b), and 52, Public Law 93–275, Federal Energy Administration Act of 1974, 15 U.S.C. 764(a), 764(b), 772(b), and 790a.

Issued in Washington DC, December 30, 1992.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–205 Filed 1–5–93; 8:45 am]

BILLING CODE 6450–01–M

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration.

ACTION: Notice of request submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Pub. L. No. 96–511, 44 U.S.C. 3501 *et seq.*). The listing does not include collections of information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection (a DOE component which term includes the Federal Energy Regulatory Commission (FERC)); (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public; (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed by February 5, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.)

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Jay Casselberry, Office of Statistical Standards, (EI–73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254–5348.

SUPPLEMENTARY INFORMATION: The energy information collection submitted to OMB for review was:

1. Energy Information Administration
2. EIA–800–804, 807, 810–814, 816–818, 819M, 819A, 820, 822A/D, and 825
3. 1905–0165
4. Petroleum Supply Reporting System Surveys
5. Revision
6. On occasion, Weekly, Monthly, Annually, and Triennially
7. Mandatory
8. Businesses or other for-profit
9. 5,350 respondents
10. 10.305 responses per respondent
11. 1.145 hours per response
12. 63,134 hours
13. The Petroleum Supply Reporting System collects information needed for determining the supply and disposition of crude petroleum, petroleum products, and natural gas liquids. These data are published by the EIA. Respondents are producers of oxygenates, operators of petroleum refining facilities, blending plants, bulk terminals, crude oil and product pipelines, natural gas plant facilities, tanker and barge operators, and oil importers.

Authority: Sec. 5(a), 5(b), 13(b), and 52, Public Law 93–275, Federal Energy Administration Act of 1974, 15 U.S.C. 764(a), 764(b), 772(b), and 790a.

Issued in Washington, DC, Dec. 30, 1992.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–203 Filed 1–5–93; 8:45 am]

BILLING CODE 6450–01–M

Agency Information Collections Under Review by the Office of Management and Budget

AGENCY: Energy Information Administration, DOE.

ACTION: Notice of request submitted for review by the Office of Management and Budget.

SUMMARY: The Energy Information Administration (EIA) has submitted the energy information collection(s) listed at the end of this notice to the Office of Management and Budget (OMB) for review under provisions of the Paperwork Reduction Act (Pub. L. No. 96–511, 44 U.S.C. 3501 *et seq.*). The listing does not include collections of

information contained in new or revised regulations which are to be submitted under section 3504(h) of the Paperwork Reduction Act, nor management and procurement assistance requirements collected by the Department of Energy (DOE).

Each entry contains the following information: (1) The sponsor of the collection (a DOE component, which term includes the Federal Energy Regulatory Commission); (2) Collection number(s); (3) Current OMB docket number (if applicable); (4) Collection title; (5) Type of request, e.g., new, revision, extension, or reinstatement; (6) Frequency of collection; (7) Response obligation, i.e., mandatory, voluntary, or required to obtain or retain benefit; (8) Affected public; (9) An estimate of the number of respondents per report period; (10) An estimate of the number of responses per respondent annually; (11) An estimate of the average hours per response; (12) The estimated total annual respondent burden; and (13) A brief abstract describing the proposed collection and the respondents.

DATES: Comments must be filed by February 5, 1993. If you anticipate that you will be submitting comments but find it difficult to do so within the time allowed by this notice, you should advise the OMB DOE Desk Officer listed below of your intention to do so, as soon as possible. The Desk Officer may be telephoned at (202) 395–3084. (Also, please notify the EIA contact listed below.)

ADDRESSES: Address comments to the Department of Energy Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW., Washington, DC 20503. (Comments should also be addressed to the Office of Statistical Standards at the address below.

FOR FURTHER INFORMATION AND COPIES OF RELEVANT MATERIALS CONTACT: Jay Casselberry, Office of Statistical Standards, (EI–73), Forrestal Building, U.S. Department of Energy, Washington, DC 20585. Mr. Casselberry may be telephoned at (202) 254–5348.

SUPPLEMENTARY INFORMATION: The energy information collection submitted to OMB for review was:

1. Federal Energy Regulatory Commission
2. FERC–520
3. 1902–0083
4. Application for Authority to Hold Interlocking Directorate Position
5. Extension
6. On occasion
7. Mandatory
8. Businesses or other
9. 25 respondents
10. 1 response per respondent
11. 51.8 hours per response
12. 1,296 hours
13. The Federal Power Act requires each person that desires to hold public utility interlocking directorate positions to submit an application to the FERC for authority to do so. The supporting information describes the interlocking positions the applicant seeks to hold, the applicant's financial interest, other officers and nature of the business relationships among the firms.

Authority: Sec. 5(a), 5(b), 13(b), and 52, Public Law 93–275, Federal Energy Administration Act of 1974, 15 U.S.C. 764(a), 764(b), 772(b), and 790a.

Issued in Washington, DC., December 30, 1992.

Yvonne M. Bishop,

Director, Statistical Standards, Energy Information Administration.

[FR Doc. 93–204 Filed 1–5–93; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket Nos. EC93–6–000, et al.]

Cincinnati Gas & Electric Co. and PSI Energy, Inc., et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Take notice that the following filings have been made with the Commission:

1. Cincinnati Gas & Electric Co. and PSI Energy, Inc.

[Docket No. EC93–6–000]

December 28, 1992.

Take notice that on December 23, 1992, Cincinnati Gas & Electric Co. ("CG&E"), on behalf of itself (and its subsidiaries, Union Light, Heat and Power Co. and Miami Power Corp.) and PSI Energy, Inc. (together, "Applicants") filed, pursuant to section 203 of the Federal Power Act and Part 33 of the Commission's regulations, a Joint Application requesting authorization to merge and reorganize Applicants' utility operations and to dispose of Applicants' jurisdictional facilities.

Pursuant to an Agreement and Plan to Reorganization, PSI Resources Inc., PSI Energy and CG&E will merge into a new corporation, CINergy, and PSI Energy and CG&E will operate as separate utility divisions of CINergy. The subsidiaries of CG&E and PSI Resources (excluding PSI Energy, but including PSI Energy's subsidiaries) will become subsidiaries of CINergy. The merger will be effected through an exchange of stock, with PSI Resources and CG&E shareholders exchanging their shares for shares in CINergy.

Applicants have submitted the direct testimony of eleven witnesses who provide, *inter alia*, a description of the merger and the projected benefits for ratepayers and shareholders and an analysis of the effects of the merger on competition in the relevant markets. Applicants also have submitted a *pro forma* open access transmission tariff for Applicants' integrated system, which provides a range of services for a single rate.

Applicants have requested that the Commission expedite consideration of the Joint Application and approve it without an evidentiary hearing.

Comment date: January 27, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Northern States Power Co.

[Docket No. ER92–551–001]

December 30, 1992.

Take notice that on November 23, 1992, Northern States Power Company tendered for filing its compliance filing in response to a Commission letter order dated October 23, 1992.

Comment date: January 8, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Ogden Martin Systems of San Bernardino, Inc.

[Docket No. ER93–281–000]

December 30, 1992.

Take notice that on December 15, 1992, Odgen Martin Systems of San Bernardino, Inc. (Ogden-San Bernardino) tendered for filing a Notice of Termination of Rate Schedule FERC No. 1 of Ogden Martin Systems of San Bernardino, Inc. with the Federal Energy Regulatory Commission (FERC or the Commission).

On September 23, 1987, the Commission accepted for filing an electric power purchase agreement between Ogden-San Bernardino and Southern California Edison Company for the sale of capacity and energy from a proposed 42.5 MW solid waste, biomass-fueled small power production facility (the Facility) and designated the agreement as Rate Schedule FERC No. 1. Due to the decision of San Bernardino County, California, to not proceed with the construction of the Facility, Ogden-San Bernardino will not sell capacity and energy to Southern California Edison Company pursuant to Rate Schedule FERC No. 1 and, accordingly, seeks to terminate Rate Schedule FERC No.1.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. Entergy Power, Inc.

[Docket Nos. ER92–611–000; ER92–664–000; ER92–843–000 and ER93–45–000]

December 30, 1992.

Take notice that on December 17, 1992, Entergy Power, Inc. submitted an amendment to its rate schedule filings originally submitted in the above dockets on June 3, 1992, June 26, 1992, August 14, 1992, September 18, 1992, and October 27, 1992.

The amendment responds to a deficiency letter from the Director of the Division of Applications dated November 17, 1992 and issued in the above referenced proceedings.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Gulf States Utilities Co.

[Docket No. ER93–292–000]

December 30, 1992.

Take notice that, pursuant to section 205 of the Federal Power Act and part 35 of the Commission's regulations, Gulf States Utilities Company (Gulf States), on December 22, 1992, tendered for filing rate schedule changes with respect to Gulf States' provision of wholesale and transmission service to Sam Rayburn Dam Electric Cooperative, Inc. (SRDE) and Sam Rayburn Municipal Power Agency (SRMA), and an initial Power Interconnection Agreement between Gulf States and the Vinton Public Power Authority (VPPA). Gulf States states that its filing amends the Power Interconnection Agreement and the Power Supply Agreement among Gulf States, SRDE, and SRMA to account for the sale of SRMA's interest in the jointly-owned Nelson 6 generating station to VPPA.

Gulf States requests a waiver of the prior notice requirements of the Federal Power Act and the Commission's regulations to allow an effective date for its filings of December 18, 1992.

Copies of the filing were served upon SRDE, SRMA, VPPA, the Public Utility Commission of Texas, and the Louisiana Public Service Commission.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

6. Florida Power Corp.

[Docket No. ER93–299–000]

December 30, 1992.

Take notice that Florida Power Corporation (Florida Power), on December 24, 1992, tendered for filing a wholesale rate change in its full requirements, partial requirements and transmission rates. The amount of the rate change, either an increase or a decrease, depends on the rates to which the current ones are compared. If compared to the presently effective rates, the filed rates accomplish a rate decrease in the amount of $8.2 million or 5.6% on a 1993 calendar-year basis. If the rates filed herein are compared to the rates negotiated in settlement of Florida Power's last filing, (Consolidated Docket Nos. ER92–436–000 and EL92–29–000), an increase of $8.4 million per year or 6.8% on a 1993 calendar-year basis results.

Florida Power requests that the rate change be permitted to become effective on February 22, 1993, and that it be made effective without suspension if the compliance rates are in effect or be suspended for the minimum one-day period if the settlement rates are in effect. Florida Power states that it has served copies of its filing on the affected customers and the Florida Public Service Commission.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

7. Public Service Company of New Mexico

[Docket No. ER93–300–000]

December 30, 1992.

Take notice that on December 28, 1992, Public Service Company of New Mexico (PNM) tendered for filing a Notice of Termination of the Interconnection Agreement (PNM Rate Schedule FPC No. 8 and supplements thereto) between PNM and The Western Colorado Power Company (WCP), as subsequently assigned to WCP's successor, Colorado-Ute Electric Association (CUEA) and since CUEA's bankruptcy to Public Service Company of Colorado (PSCo) and Tri-State Generation and Transmission Association, Inc. (Tri-State).

PNM requests that the Commission's notice requirements be waived to permit the Interconnection Agreement to be terminated effective upon the contract termination date of November 13, 1992.

Copies of the filing have been served upon PSCo, Tri-State and the New Mexico Public Service Commission.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. Idaho Power Co.

[Docket No. ER93–69–000]

December 30, 1992.

Take notice that on December 22, 1992, Idaho Power Company (IPC) tendered for filing an amendment to its filing of its Agreement for the Sale and Purchase of Firm Energy dated August 31, 1992 with Oregon Trail Electric Consumers Cooperative, Inc.

IPC has requested waiver of the notice provisions § 35.3 of the Commission's regulations in order to permit the Agreement to become effective on January 1, 1993, as requested in the original filing of this Agreement.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

9. G. Alex Bernhardt

[Docket No. ID–2541–001]

December 30, 1992.

Take notice that on December 24, 1992, G. Alex Bernhardt (Applicant) tendered for filing a supplemental application under section 305(b) of the Federal Power Act to hold the following positions:

Director Duke Power Company
Director First Union Corporation

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. Entergy Power Development Corp.

[Docket No. EG93–9–000]

December 30, 1992.

Take notice that on December 23, 1992, Entergy Power Development Corporation (Entergy Development) filed an application under section 32 of the Public Utility Holding Company Act of 1935, as amended by section 711 of the Energy Policy Act of 1992, seeking a determination by the Commission that Entergy Development is an exempt wholesale generator. Entergy Development owns an interest in a 250 MW electric generating facility located in Richmond, Virginia.

Comment date: January 19, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. Long Island Lighting Co.

[Docket No. ER93–298–000]

December 30, 1992.

Take notice that on December 24, 1992, Long Island Lighting Company (LILCO) tendered for filing an Agreement between LILCO and the Suffolk County Electrical Agency (SCEA) dated November 12, 1992, for the delivery of certain New York Power Authority power and energy to eligible customers within LILCO's service territory in Suffolk County, New York, together with a supplement thereto which consists of a Letter Agreement between LILCO and the New York Power Authority (NYPA) dated October 29, 1992. LILCO has requested a waiver

so that this filing can become effective on January 1, 1993.

Notice is further given that upon acceptance for filing or approval of the instant filing, LILCO–FERC Rate Schedule No. 42, including Supplement Nos. 1 and 2, and those portions of LILCO–FERC Rate Schedule No. 40 that govern delivery of NYPA economic development power to SCEA's economic development customers are hereby cancelled.

LILCO states that this filing has been served upon the New York State Public Service Commission, NYPA, and SCEA.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

12. Richmond Power Enterprise, L.P.

[Docket No. EG93–7–000]

December 30, 1992.

Take notice that on December 23, 1992, Richmond Power Enterprise, L.P. (Richmond Power) filed an application under Section 32 of the Public Utility Holding Company Act of 1935, as amended by section 711 of the Energy Policy Act of 1992, seeking a determination by the Commission that Richmond Power is an exempt wholesale generator. Richmond Power owns and operates a 250 MW electric generating facility located in Richmond, Virginia.

Comment date: January 19, 1993, in accordance with Standard Paragraph E at the end of this notice.

13. Entergy Richmond Power Corp.

[Docket No. EG93–8–000]

December 30, 1992.

Take notice that on December 23, 1992, Entergy Richmond Power Corporation (Entergy Richmond) filed an application under section 32 of the Public Utility Holding Company Act of 1935, as amended by section 711 of the Energy Policy Act of 1992, seeking a determination by the Commission that Entergy Richmond is an exempt wholesale generator. Entergy Richmond owns an interest in a 250 MW electric generating facility located in Richmond, Virginia.

Comment date: January 19, 1993, in accordance with Standard Paragraph E at the end of this notice.

14. Northeast Utilities Service Co.

[Docket No. ER93–297–000]

December 30, 1992.

Take notice that on December 23, 1992, Northeast Utilities Service Company (NUSCO) on behalf of The Connecticut Light and Power Company (CL&P), Western Massachusetts Electric Company (WMECO), and Public Service Company of New Hampshire (PSNH) tendered for filing a Capacity, Transmission and Energy Service Agreement between CL&P and Green Mountain Power Corporation (GMP), a Bulk Power Service Agreement between CL&P and Bozrah Light and Power Company and a Firm Transmission Service Agreement Between CL&P, WMECO, and PSNH and GMP.

NUSCO requests that the Commission waive its standard notice periods and filing regulations to the extent necessary to permit the rate schedule change to become effective as early as January 1, 1993, but no later than February 1, 1993.

NUSCO states that copies of this rate schedule have been mailed or delivered to each of the parties.

NUSCO further states that the filing is in accordance with section 35 of the Commission's regulations.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

15. Green Mountain Power Corp.

[Docket No. ER93–296–000]

December 30, 1992.

Take notice that on December 23, 1992, Green Mountain Power Corporation (GMP) tendered for filing a Notice of Cancellation of Power Sales Agreement between GMP and Bozrah Light and Power Company (Bozrah) (GMP Rate Schedule FERC No. 104).

GMP states that the Notice of Cancellation is part of a comprehensive arrangement under which Bozrah will discontinue the purchase of its bulk power requirements from GMP and commence the purchase of its bulk power requirements from The Connecticut Light and Power Company. GMP has requested the Commission to waive any applicable requirements in order to make each of the agreements included in this arrangement effective on January 1, 1993.

Comment date: January 13, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–230 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Beaver City Canyon, Plant No. 2 Project, FERC No. 1858–002]

Beaver City Corp.; Availability of Environmental Assessment

December 30, 1992.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing together with the USDA Forest Service (FS) have reviewed the application for new minor license for the existing Beaver City Canyon Plant No. 2 Hydroelectric Project, located on the Beaver River, in Beaver County, near Beaver, Utah, and have prepared a joint environmental assessment (EA) for the relicense proposal. In the EA, the FS and the Commission staff analyze the potential environmental impacts of the project and conclude that approval of the project, with appropriate environmental measures, would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, room 3104, of the Commission's offices at 941 North Capitol Street, NW., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 93–217 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. CP93–108–000, et al.]

Texas Eastern Transmission Corp., et al.; Natural Gas Certificate Filings

Take notice that the following filings have been made with the Commission:

1. Texas Eastern Transmission Corporation

[Docket No. CP93–108–000]

December 28, 1992.

Take notice that on December 14, 1992, Texas Eastern Transmission Corporation (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056–5310 filed in Docket No. CP93–

108–000 an application pursuant to section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing it to provide a new incremental firm transportation service pursuant to Rate Schedule FTS–11 and to construct and operate the associated incremental facilities required to perform the proposed transportation service, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Texas Eastern requests authorization to construct, install, own and operate the following facilities required to provide the proposed transportation service:

(a) 3.0 miles of 30-inch diameter pipeline in Warren County, Ohio;

(b) 1.4 miles of 36-inch diameter pipeline in Monroe County, Ohio;

(c) 0.96 mile of 36-inch diameter pipeline loop in Greene County, Pennsylvania;

(d) Replace approximately 1.07 miles of 24-inch diameter pipeline with 36-inch diameter pipeline at the Uniontown Compressor Station discharge in Somerset County, Pennsylvania;

(e) Replace approximately 1.00 mile of 24-inch diameter pipeline with 36-inch diameter pipeline at the Bedford Compressor Station discharge in Fulton County, Pennsylvania; and

(f) Replace approximately 1.21 miles of 20-inch diameter pipeline with 36-inch diameter pipeline at the discharge of Eagle Compressor Station in Bucks County, Pennsylvania.

Texas Eastern indicates that the proposed facilities would be used to render firm incremental transportation service for Staten Island Cogeneration Corporation (Staten Island) from the existing point of interconnection between Texas Eastern and ANR Pipeline Company (ANR) near Lebanon, Ohio to an existing point of interconnection between the facilities of Texas Eastern and the Brooklyn Union Gas Company (BUG) at Goethals Bridge, New York. Texas Eastern proposes to transport and make delivery of up to 11,600 Dth equivalent of natural gas per day to Staten Island.

Texas Eastern states that the estimated total capital cost of the proposed facilities is $14,598,000. Texas Eastern indicates that the proposed facilities will be financed initially by Texas Eastern with funds on hand, borrowing under Texas Eastern's revolving credit arrangements or short-term financing.

Comment date: January 19, 1993, in accordance with Standard Paragraph F at the end of this notice.

2. Arkla Energy Resources a division of Arkla, Inc.

[Docket No. CP93–128–000]

December 29, 1992.

Take notice that on December 22, 1992, Arkla Energy Resources, a division of Arkla, Inc., (AER), P.O. Box 21734, Shreveport, Louisiana 71151, filed in Docket No. CP93–128–000 a request pursuant to §§ 157.205, 157.211 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211, 157.212) for authorization to construct and operate certain facilities under AER's blanket certificate issued in Docket No. CP82–384–000, *et al.*, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

AER proposes to:

(1) Construct and operate two new sales taps and related facilities in Coal County, Oklahoma, for delivery of natural gas to Arkansas Louisiana Gas Company (ALG) for resale to two domestic customers, Stephen J. Burge, and Frank Whitt. It is projected that each customer would use approximately 1 Mcf on a peak day and 85 Mcf annually. AER states that each of the tap facilities would cost approximately $1,389.

(2) Operate an existing 1-inch tap on AER's Line OT–23 in Sebastian County, Arkansas, for delivery of natural gas for resale to ALG's domestic customer, Thomas Goodin, who is projected to use 1 Mcf on a peak day and 85 Mcf annually. AER states that this customer would manifold onto an existing tap installed for right-of-way grantor Terrell Jones in 1974.

AER states that the facilities would be financed with internally generated capital.

Comment date: February 12, 1993, in accordance with Standard Paragraph G at the end of this notice.

3. Northern Natural Gas Company

[Docket No. CP93–88–000]

December 29, 1992.

Take notice that on December 3, 1992, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP93–88–000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon six individually certificated transportation and exchange agreements between Northern and EL Paso Natural Gas Company (EL Paso), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Specifically, Northern proposes to abandon its Rate Schedules T–1, T–3, T–25, X–21, X–58 and X–68 contained in its FERC Gas Tariff, Original Volume No. 2. Northern indicates that proper notice was given by Northern and El Paso for the termination of the service under these agreements are no longer required and the abandonment requested will not impact the remaining service of Northern of EL Paso. Finally, Northern states that EL Paso has received authorization from the Commission to abandon the certificates issued to EL Paso for two of these agreements and is filing in a separate application to abandon its certificates issued for the remaining four agreements.

Comment date: January 19, 1993, in accordance with Standard Paragraph F at the end of this notice.

4. Panhandle Eastern Pipe Line Co.

[Docket No. CP93–110–000]

December 30, 1992.

Take notice that on December 14, 1992, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP93–110–000 a request under Section 7(b) of the Commission's Regulations under the Natural Gas Act for a certificate permitting and approving abandonment of sales service provided to the City of Hazelton, Kansas (Hazelton), an existing jurisdictional customer under Panhandle's Rate Schedule SSS–3, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Panhandle states that it is requesting authorization to abandon firm sales service provided to Hazelton under Rate Schedule SSS–3, effective January 1, 1993, as a result of Hazelton's election to terminate its firm sales service with Panhandle effective January 1, 1993. Panhandle states that Hazelton will convert to firm transportation service provided under Panhandle's Rate Schedule SCT effective January 1, 1993. No facilities are proposed to be abandoned herein.

Comment date: January 21, 1993, in accordance with Standard Paragraph F at the end of this notice.

5. Panhandle Eastern Pipe Line Co.

[Docket No. CP93–115–000]

December 30, 1992.

Take notice that on December 17, 1992, panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP93–115–000 a request under section 7(b) of the Commission's

Regulations under the Natural Gas Act for a certificate permitting and approving abandonment of sales services provided to Associated Natural Gas Company (Associated), under Panhandle's Rate Schedules SSS–2 to be effective January 1, 1993, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Panhandle states it is requesting authorization to abandon firm sales service provided to Associated under Rate Schedule SSS–2, effective January 1, 1993, as a result of Associated's election to terminate its firm sales service with Panhandle effective January 1, 1993. Panhandles states that Associated will convert to firm transportation service provided under Panhandle's Rate Schedule SCT effective January 1, 1993. No facilities are proposed to be abandoned herein.

Comment date: January 21, 1993, in accordance with Standard Paragraph F at the end of this notice.

6. Panhandle Eastern Pipe Line Co.

[Docket No. CP93–112–000]

December 30, 1992.

Take notice that on December 15, 1992, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77251–1642, filed in Docket No. CP93–112–000 a request under section 7(b) of the Commission's Regulations under the Natural Gas Act for a certificate permitting and approving abandonment of transportation and sales services provided to Kansas-Nebraska Natural Gas Company (KN), under Panhandle's Rate Schedules T–41, T–61, and TT–1 to be effective October 31, 1992, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Panhandle states that by letters dated October 19, 1992, Panhandle and KN have mutually agreed to terminate Rate Schedules TT–1, T–41 and T–61 effective October 31, 1992. Panhandle further states that the existing interconnections with KN will continue to be available for open access transportation service. No facilities are proposed to be abandoned herein.

Comment date: January 21, 1993, in accordance with Standard Paragraph F at the end of this notice.

7. United Gas Pipe Line Co.

[Docket No. CP93–131–000]

December 30, 1992.

Take notice that on December 2, 1992, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251–1478, filed a request with the Commission in Docket No. CP93–131–000 pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (NGA) for authorization of facilities previously constructed under section 311(a) of the Natural Gas Policy Act (NGPA) and § 284.3(c) of the Commission's regulations, under United's blanket certificate issued in Docket No. CP88–6–000, all as more fully set forth in the request which is open to public inspection.

United states that the proposed facilities will enable United to provide transportation services under its blanket transportation certificate through all of its facilities to all current and potential shippers. United also states that it has sufficient capacity to provide the proposed service without detriment to its other existing customers.

Comment date: February 16, 1993, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said file with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93–229 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. TA93–1–20–000 and TM93–3–20–000]

Algonquin Gas Transmission Co.; Notice of Proposed Changes in FERC Gas Tariff

December 30, 1992.

Take notice that Algonquin Gas Transmission Company ("Algonquin") on December 23, 1992, tendered for filing proposed changes in its FERC Gas Tariff, Third Revised Volume No. 1, as set forth in the revised tariff sheets:

Proposed to be effective February 1, 1993

6 Rev Sheet No. 63

Proposed to be effective March 1, 1993

2 Rev 16 Rev Sheet No. 21
2 Rev 16 Rev Sheet No. 22
2 Rev 16 Rev Sheet No. 25
2 Rev 16 Rev Sheet No. 26
2 Rev 16 Rev Sheet No. 27
2 Rev 16 Rev Sheet No. 28
2 Rev 16 Rev Sheet No. 29

Algonquin states that the revised tariff Sheet Nos. 21 through 29, listed above, are being filed as part of Algonquin's regularly scheduled Annual Purchased Gas Adjustment ("PGA") and Transportation Cost Adjustment ("TCA") to reflect the standby service costs to be charged by Texas Eastern Transmission Corporation ("Texas Eastern"), Transportation and Compression by Others' Costs ("T&C Costs") from Texas Eastern and Transcontinental Gas Pipe Line Corporation and purchased gas costs to be charged by its various suppliers.

Algonquin states that the effect of the change in rates in the listed sheets is to

decrease the demand charges by $0.4400 per MMBtu and to decrease the commodity charges by $0.4373 per MMBtu under all of Algonquin's firm sales rate schedules from those rates contained in Algonquin's last quarterly PGA and TCA filing, made October 29, 1992 in Docket Nos. TQ93–2–20–001 and TM93–5–20–000 and revised December 9, 1992 per Commission Letter Order of November 24, 1992.

Algonquin states that the proposed effective date for the listed tariff sheets is March 1, 1993 with the exception of 6 Rev Sheet No. 63.

Algonquin further states that it is filing Sheet No. 63 to concurrently track the change made by Texas Eastern in the underlying rates. Pursuant to section 4.2(c) of Rate Schedule ATAP, the proposed effective date of Sheet No. 63 is February 1, 1993 to coincide with the effective date of Texas Eastern's filing. The effect of the revision in rates in Rate Schedule ATAP is to decrease the demand rate by $0.7600 per MMBtu and decrease the maximum commodity rates by $0.0241 per MMBtu.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–221 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–53–000]

Carnegie Natural Gas Co.; Petition for Temporary Waiver of Regulations and Tariff, and for Expedited Action

December 30, 1992.

Take notice that on December 23, 1992, Carnegie Natural Gas Company (Carnegie) filed a petition for waiver of § 154.305(i) (1) (iii) of the Commission's regulations and Section 23.9 of the General Terms and Conditions of Carnegie's FERC Gas Tariff to permit Carnegie to retain the balance in the refund subaccount of its Account No. 191 until such time as the Account No. 191 settlement proposal filed in Carnegie's restructuring proceeding in Docket No. RS92–30–000 becomes subject to a final Commission order.

Carnegie requests that the Commission grant temporary waiver of the requirement that it disburse to its customers within 90 days, or before January 30, 1993, the demand portion of the refund received by Carnegie from Texas Eastern Transmission Corporation (Texas Eastern) on October 30, 1992. Carnegie states that waiver is requested only for the limited period pending the outcome of the issues in Docket No. RS92–30–000 concerning the treatment upon restructuring of Carnegie's remaining unrecovered gas costs.

Carnegie states that copies of the filing have been served upon all affected customers of Carnegie and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–216 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM93–8–4–000]

Granite State Gas Transmission, Inc.; Notice of Proposed Changes in Rates

December 30, 1992.

Take notice that on December 28, 1992, Granite State Gas Transmission, Inc. (Granite State), 300 Friberg Parkway, Westborough, Massachusetts 01581 filed Sixth Revised Sheet No. 24 in its FERC Gas Tariff, Second Revised Volume No. 1, proposing changes in rates for effectiveness on January 28, 1993.

According to Granite State, its filing is submitted to passthrough to its customers the take-or-pay buydown and buyout costs directly billed to Granite State by Tennessee Gas Pipeline Company (Tennessee).

Granite State states that, on December 1, 1992, Tennessee filed revised tariff sheets to recover additional transition costs in Docket Nos. RP93–37–000 and TM93–2–9–000. According to Granite State, its tariff sheet reflects the changes in Tennessee's allocation of take-or-pay costs to Granite State and also complies with the requirements of the reallocation of costs to small customers pursuant to Order No. 528–A.

According to Granite State the proposed rate changes are applicable to its jurisdictional sales services rendered to Bay State Gas Company and Northern Utilities, Inc. and to a sale to a direct customer, Pease Air Force Base. Granite State further states that copies of its filing were served upon its customers and the regulatory commissions of the States of Maine, New Hampshire and Massachusetts.

Any person desiring to be heard or to make any protest with reference to said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–218 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM93–7–4–000]

Granite State Gas Transmission, Inc.; Notice of Proposed Changes in Rates

December 30, 1992.

Take notice that on December 28, 1992, Granite State Gas Transmission, Inc. (Granite State) 300 Friberg Parkway, Westborough, Massachusetts 01581 tendered for filing the revised tariff sheets listed below in its FERC Gas Tariff, Second Revised Volume No. 1,

containing changes in rates for effectiveness on December 1, 1992:

Eighteenth Revised Sheet No. 25
Second Revised Sheet No. 66

According to Granite State, it provides storage services for Bay State Gas Company and Northern Utilities, Inc., under its Rate Schedule S–1 with storage capacity provided in a facility operated by Penn-York Energy Corporation (Penn-York) pursuant to Penn-York's Rate Schedule SS–1.

Granite State further states that Penn-York filed proposed changes in its rates for storage service under Rate Schedule SS–1 in Docket No. RP92–161–000 which were suspended until December 1, 1992. According to Granite State, Penn-York moved its suspended rate changes into effect on December 1, 1992.

Granite State states that its filing tracks in its Rate Schedule S–1 the revised rates made effective on December 1, 1992 by the motion filed by Penn-York in Docket No. RP92–161–000.

Granite State states that copies of its filing were served on its storage service customers, Bay State Gas Company and Northern Utilities, Inc. and also on the regulatory commissions of the states of Maine, Massachusetts and New Hampshire.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with sections 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–222 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Project No. 1855–006]

New England Power Co.; Notice Dismissing Complaint

December 29, 1992.

New England Power Company is the licensee for the Bellows Falls Project No. 1855, located on the Connecticut River in Cheshire and Sullivan Counties, New Hampshire, and in Windham and Windsor Counties, Vermont.[1] Horace A. and Betty B. Bezanson, and their daughter Marcia S. Calloway (collectively, the Bezansons), own property within the project boundary over which New England Power has flowage rights.[2] On December 28, 1989, the Bezansons filed a complaint [3] alleging that New England Power [4] intended to convey certain property rights with respect to land within the project boundary and adjacent to the Bezansons' to facilitate the construction of a wood chip storage and transfer facility adjacent to the Bezanson's property. The wood chip facility was to be developed by Woodland Fiber, Inc. on land owned by Cersosimo Lumber Company over which New England Power has flowage rights.

On October 7, 1992, the Director, Division of Project Compliance and Administration (Director), sent a status request letter to the parties. The letter noted that during its preliminary investigation of the complaint the Commission staff had received informal indications that Woodland Fiber, Inc. may no longer be planning to construct the contemplated wood chip storage and transfer facility, such that the complaint may be moot. The letter asked the parties to advise the Commission of the current status of the matter, including any recommendations the parties might have with respect to future proceedings on the complaint.

Both parties responded to the Director's letter.[5] Marcia Calloway, on behalf of the Bezansons, responded first, indicating that she is "not privy to the plans" of either Woodland Fiber, Inc. or Cersosimo Lumber Company, and is "therefore unable to tell you the exact status of their intention * * *." Her letter refers to a recent application by Cersosimo for an access right-of-way permit, from which "complainants can only assume that the Woodland Fiber project is still viable." Accordingly, "complainants request the Commission to consider this matter as open and continue the proceeding pending definite withdrawal of the Woodland Fiber, Inc. wood chip storage and transfer facility project."

New England Power contends, in its response to the Director, that the complaint has been rendered moot and should therefore be dismissed. New England Power's response includes a letter to New England Power [6] from Ramsey, McLaren, the firm that had been retained by Woodland Fiber, Inc. to secure the permits and approvals necessary for the construction of the wood chip facility. That letter describes the current status of the proposed wood chip facility as follows:

3. In May 1991 the property owner advised Woodland Fiber that no further land lease extensions would be granted and that the purchase option had to be exercised if Woodland Fiber wanted to continue with its permit and approval process. Woodland Fiber did not exercise the purchase option.

4. The state Land Use Permit application was terminated at that time and the local site plan and zoning approvals subsequently expired due to an absence of activity within the statutory time period.

5. To the best of our knowledge, Woodland Fiber has no intention of resuming any activities necessary for the establishment of a wood fiber storage and transfer facility at this site and we have therefore closed the file. [Emphasis in original.]

New England sent a copy of its response to Marcia Calloway. No response to New England Power's letter was filed.

Based on the above-described correspondence in the record, there appears to be no present plans to construct and operate the proposed wood chip storage and transfer facility. Inasmuch as the complaint was predicated on the development of that facility, the complaint does not present a current controversy. Therefore, the complaint is dismissed, but without prejudice to refiling in the event that the proposal to construct the wood chip facility is revived.

This notice constitutes final agency action. Requests for rehearing by the Commission may be filed within 30

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[1] 8 FERC ¶61,122 (1979).

[2] The Bellows Falls Project includes a 2,604-acre reservoir that extends approximately 26 miles upstream from the project's dam. The project boundary includes land along the shoreline that New England Power needs for the operation and maintenance of the project. New England Power has title in fee to only a small portion of this land, and has flowage easements over the rest.

[3] Notice of the complaint was published in the Federal Register (55 *FR* 19979, May 14, 1990).

[4] The complaint was filed against New England Power Service Company, an affiliate of New England Power Company, which is the licensee. New England Power filed an answer on June 13, 1990.

[5] See letter from Marcia S. Calloway, dated October 14 and filed October 19, 1992, and letter from Mark E. Slade, attorney for New England Power, dated November 6 and filed November 9, 1992, both addressed to the Commission's Secretary.

[6] See letter from Hal J. Wilkins to Mark Slade, dated November 4, 1992.

days of the issuance of this notice, pursuant to 18 CFR 385.713.

Lois D. Cashell,

Secretary.

[FR Doc. 93–109 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–52–000]

Northern Natural Gas Co.; Notice of Proposed Changes in FERC Gas Tariff

December 30, 1992.

Take notice that Northern Natural Gas Company (Northern) on December 23, 1992, tendered for filing to become part of Northern's FERC Gas Tariff, the following tariff sheets, proposed to become effective January 1, 1993:

Fourth Revised Volume No. 1

Third Revised Sheet No. 56
Third Revised Sheet No. 57
Third Revised Sheet No. 58
Substitute Third Revised Sheet No. 56
Substitute Third Revised Sheet No. 57
Substitute Third Revised Sheet No. 58

Original Volume No. 2

One Hundred Twenty-Third Revised Sheet No. 1C
Substitute 123 Revised Sheet No. 1C

Northern states that the filing of the revised tariff sheets reflects notice to Northern's customers of the potential shifting of costs from the IGIC to the PGA. The Northern Distributor Group has challenged the inclusion of certain Pre-July 1991 costs in the IGIC and alleged that those costs should be more appropriately recovered through the PGA. Pursuant to this filing, Northern's Reconciliation Adjustment would increase $.057 to $.118. Northern states that it would defer collection of the $.057 increase pending resolution of the Northern Distributor Group's protest of Northern's IGIC Reconciliation Report filed April 30, 1992. Northern requests, at a minimum, that the Commission find the filing constitutes sufficient legal notice to the customers that if the Pre-July 1991 IGIC costs are to be recovered in the PGA, then the Reconciliation Adjustment will be modified accordingly.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214 and 385.211). All such petitions or protests must be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–220 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–51–000]

Northwest Pipeline Corp.; Petition for Limited Waiver of Tariff Provisions

December 30, 1992.

Take notice that on December 21, 1992, Northwest Pipeline Corporation (Northwest) petitions the Commission for a limited waiver of the Commission's first-come, first-served policy as reflected in Section 1 of Northwest's TF–1 Rate Schedule and in the Priority Date provisions of section 12 of First Revised Volume 1–A of Northwest's FERC approved tariff, in order to allow the permanent assignment of firm transportation capacity presently held by Kern River Gas Supply Corporation (KRGS) to KRGS' producer-suppliers who have entered into "buy/sell" agreements with KRGS.

Northwest seeks waiver of the Commission's first-come, first-served policy in order to implement replacement firm transportation agreements with Petro-Canada, Salmon, CHMI, and WRI, who will each succeed to a portion of KRGS' interests under the Transportation Agreement pursuant to proposed assignments.

Northwest states that by providing firm transportation service directly to Salmon, Petro-Canada, CHMI, and WRI instead of indirectly through KRGS, simply eliminates KRGS as an unnecessary conduit in these suppliers securing transportation services on the Northwest system.

Northwest requests that the Commission grant any necessary waivers of the Commission's first-come, first-served policy and Northwest's applicable tariff provisions to permit KRGS' permanent assignment of its firm capacity on Northwest to Salmon, Petro-Canada, CHMI, and WRI.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–215 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP89–137–010]

Northwest Pipeline Corp.; Notice of Compliance Filing

December 30, 1992.

Take notice that on December 8, 1992, Northwest Pipeline Corporation (Northwest) made a filing to comply with Ordering Paragraph (B) of Federal Energy Regulatory Commission order issued September 24, 1992, in the above docket. Northwest provided justification of Order No. 500/528 recovery of a certain amount associated with transportation discounts included in five of Northwest's take-or-pay buyout/buydown settlements.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–219 Filed 1–5–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–120–000]

Panhandle Eastern Pipe Line Co.; Informal Settlement Conference

December 30, 1992.

Take notice that an informal settlement conference will be convened in this proceeding on Wednesday, January 13, 1993, at 10 a.m. The conference will be held at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE.,

Washington, DC, for the purpose of exploring the possible settlement of all issues raised in the above-referenced docket.

Any party, as defined in 18 CFR 385.102(c) or any participant, as defined in 18 CFR 385.102(b) is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations, 18 CFR 385.214.

For additional information, contact Carmen Gastilo at (202) 208–2182 or Joanne Leveque at (202) 208-5705.

Lois D. Cashell,

Secretary.

[FR Doc. 93–214 Filed 1–5–93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93–23–001]

Transcontinental Gas Pipe Line Corp.; Notice of Proposed Change in FERC Gas Tariff

December 30, 1992.

Take notice that Transcontinental Gas Pipe Line Corporation (TGPL) on December 21, 1992, tendered for filing a certain tariff sheets to Third Revised Volume No. 1 of its FERC Gas Tariff (Tariff). The proposed effective date of the revised tariff sheets is December 13, 1992.

On November 12, 1992, TGPL filed Third Revised Sheet No. 62 to the Tariff to permit TGPL to discount its Commodity Producer Settlement Payment (PSP) charge for quantities of gas received and redelivered by TGPL in its Rate Zones 1, 2 or 3 under its Rate Schedules IT and FT. By order issued on December 11, 1992 in the referenced proceeding (Order), the Commission accepted and suspended effective December 13, 1992 Third Revised Sheet No. 62 subject to refund and subject to modifications and conditions.

Specifically, the Order required TGPL to file tariff sheets including language permitting TGPL to discount all of its take-or-pay commodity surcharges, including those for transportation in Zones 4, 5 and 6, in a non-discriminatory manner. The Order further required TGPL's filing to include the appropriate rate sheets reflecting maximum and minimum rates for all of TGPL's take-or-pay surcharges not already filed. TGPL states that the purpose of the instant filing is to comply with the Order.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 7, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–223 Filed 1–5–93; 8:45 am]

BILLING CODE 6717-01-M

Office of Fossil Energy

[FE Docket No. 92–159–NG]

CanWest Gas Supply U.S.A., Inc.; Order Granting Blanket Authorization To Import and Export Natural Gas From and to Canada

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting CanWest Gas Supply U.S.A., Inc. blanket authorization to import and/or export a cumulative maximum of 400 Bcf of natural gas from and to Canada over a two-year term beginning on the date of the first import or export after February 28, 1993.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 29, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 93–202 Filed 1–5–93; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–4552–7]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden.

DATES: Comments must be submitted on or before February 5, 1993. For further information, or to obtain a copy of this ICR, contact Sandy Farmer at EPA (202) 206–2740.

SUPPLEMENTARY INFORMATION:

Office of Pesticides and Toxic Substances

Title: Section 12(b) Notification of Chemical Exports (EPA ICR No.: 0795.07; OMB No.: 2070–0030). This is a reinstatement of a previously approved collection.

Abstract: Under section 12(b)(2) of the Toxic Substances Control Act (TSCA), those who export or intend to export federally regulated chemical substances (or mixtures) must notify the EPA Administrator annually of the export or intent to export. EPA will then notify the government of the importing country of the Agency's action concerning the regulated chemical. Respondents submit to EPA one annual notice per chemical, or list of chemicals, for each country to which they are intending to export. A notice consists of: the name and the address of the exporter, the name (or list) of the chemical(s) to be exported, the country of import, the date of export, and the citation of the TSCA section (4, 5, 6, or 7) requiring the chemicals to be reviewed for export.

Burden Statement: The estimated public reporting burden for this collection of information is 38 hours per respondent annually. On average a respondent will prepare 74 export notices each requiring 0.5 hour. This estimate includes the time to read the instructions, gather existing information, prepare the chemical lists and submit the annual notice.

Respondents: Exporters of TSCA 12(b) chemicals.

Estimated No. of Respondents: 162.

Estimated No. of Responses per Respondent: 74.

Estimated Total Annual Burden on Respondents: 6,162 hours.

Frequency of Collection: Annually and on occasion.

Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden to: Sandy Farmer, U.S. Environmental Protection Agency, Information Policy

Branch (PM 223Y), 401 M Street, SW, Washington, DC 20460.

and

Matthew Mitchell, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20503.

Dated: December 30, 1992.

Paul Lapsley,

Director, Regulatory Management Division.

[FR Doc. 93–197 Filed 1–5–93; 8:45 am]

BILLING CODE 6560-60-M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirements Submitted to Office of Management and Budget for Review

December 28, 1992.

The Federal Communications Commission has submitted the following information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of these submissions may be purchased from the Commission's copy contractor, Downtown Copy Center, 1990 M Street, NW., suite 640, Washington, DC 20036, (202) 452–1422. For further information on these submissions contact Judy Boley, Federal Communications Commission, (202) 632–7513. Persons wishing to comment on these information collections should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395–4814.

OMB Number: 3060–0054.
Title: Application for Exemption From Ship Station Requirements
Form Number: FCC Form 820
Action: Revision of a currently approved collection
Respondents: Individuals or households and business or other for-profit (including small businesses)
Frequency of Response: On occasion reporting
Estimated Annual Burden: 200 responses; 1.166 hours average burden per response; 233 hours total annual burden
Needs and Uses: Applicants are required to complete FCC Form 820 to apply for exemption from radio provisions of statute, treaty, or international agreement. The forms is being revised to remove data elements that are no longer necessary and to re-word and reformat questions to simplify completion of the form.

OMB Number: 3060–0184.
Title: Section 73.1740, Minimum Operating Schedule
Action: Extension of a currently approved collection
Respondents: Businesses or other for-profit (including small businesses)
Frequency of Response: On occasion reporting
Estimated Annual Burden: 330 responses; 0.5 hours average burden per response; 165 hours total annual burden
Needs and Uses: Section 73.1740 requires licensees of commercial broadcast stations to notify the FCC in Washington, DC when events beyond their control make it impossible to continue operation or to adhere to the required operating schedules set forth in this section. In addition, the FCC must be notified when normal operation is resumed. No further authority is needed for limited operation or discontinued operation for a period not exceeding 30 days. Should events beyond the licensees control make it impossible for compliance within the required 30-day time period, an informal written request shall be submitted to the FCC requesting the amount of additional time that the licensee deems necessary. The data are used by FCC staff to authorized temporarily a limited operation or a discontinuance of operation.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–103 Filed 1–5–93; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–966–DR]

Florida; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Florida (FEMA–966–DR), dated October 8, 1992, and related determinations.

EFFECTIVE DATE: November 23, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective October 4, 1992.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93–185 Filed 1–5–93; 8:45 am]

BILLING CODE 6718-02-M

[FEMA–975–DR]

Massachusetts; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Massachusetts (FEMA–975–DR), dated December 21, 1992, and related determinations.

EFFECTIVE DATE: December 23, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Massachusetts, dated December 21, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 21, 1992:

The counties of Duke, Nantucket, Norfolk, and Worcester for Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93–184 Filed 1–5–93; 8:45 am]

BILLING CODE 6718-02-M

[FEMA–973–DR]

New Jersey; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New Jersey (FEMA–973–DR), dated December 18, 1992, and related determinations.

EFFECTIVE DATE: December 22, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New Jersey, dated December 18, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 18, 1992:

The counties of Essex, Hudson, Middlesex, Somerset, and Union for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93–186 Filed 1–5–93; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–973–DR]

New Jersey; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New Jersey (FEMA–973–DR), dated December 18, 1992, and related determinations.

EFFECTIVE DATE: December 18, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New Jersey, dated December 18, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 18, 1992:

The counties of Bergen, Cape May, and Cumberland for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93–187 Filed 1–5–93; 8:45 am]

BILLING CODE 6718–02–M

[FEMA–974–DR]

New York; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of New York (FEMA–974–DR), dated December 21, 1992, and related determinations.

EFFECTIVE DATE: December 21, 1992.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of New York, dated December 21, 1992, is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 21, 1992:

The counties of Rockland and Westchester for Individual Assistance and Public Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

Grant C. Peterson,

Associate Director, State and Local Programs and Support.

[FR Doc. 93–183 Filed 1–5–93; 8:45 am]

BILLING CODE 6718–02–M

FEDERAL FINANCIAL INSTITUTIONS EXAMINATION COUNCIL

Appraisal Subcommittee; Interim Order Granting Commonwealth of the Northern Mariana Islands Emergency Temporary Waiver Relief and Request for Comments

[Docket No. AS92–5]

AGENCY: Appraisal Subcommittee, Federal Financial Institutions Examination Council.

ACTION: Interim order granting Commonwealth of the Northern Mariana Islands ("CNMI") emergency temporary waiver relief from State appraiser certification and licensure requirements and request for comments.

SUMMARY: The Appraisal Subcommittee ("ASC") of the Federal Financial Institutions Examination Council ("FFIEC"), with the FFIEC's approval, is issuing an interim Order granting CNMI emergency temporary waiver relief under section 1119(b) [1] of title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 ("FIRREA"), as amended.[2] This interim relief will run from January 1, 1993, until the effective date of the ASC's final Order on this matter. The ASC also is soliciting comments from interested members of the public regarding CNMI's temporary waiver request.

DATES: Effective date of interim Order is January 1, 1993. Written comments on this Notice must be submitted on or before the close of business on February 5, 1993.

ADDRESSES: Copies of the request for temporary waiver relief and supporting documentation are available for public inspection at: Appraisal Subcommittee, 2100 Pennsylvania Avenue, NW., suite 200, Washington, DC 20037. Written comments may be mailed to the Appraisal Subcommittee at this location, and those comments also will be made available for public inspection.

FOR FURTHER INFORMATION CONTACT: Edwin W. Baker, Executive Director, or Marc L. Weinberg, General Counsel, at (202) 634–6520, Appraisal Subcommittee, 2100 Pennsylvania Avenue, NW., suite 200, Washington, DC 20037.

SUPPLEMENTARY INFORMATION:

I. Background

After December 31, 1992, all federally regulated financial institutions must use State licensed or certified appraisers, as appropriate, in federally related transactions.[3] Thus, each State should have in place at that time its entire regulatory scheme for certifying, licensing and supervising real estate appraisers.

Section 1119(b) of title XI provides the ASC and the States with a degree of flexibility in dealing with extraordinary circumstances that may occur at any time at December 31st. This Section enables the ASC to waive, on a temporary basis and with the FFIEC's approval,[4] any State certification or licensing requirement on a written finding that: (1) "There is a scarcity of certified or licensed appraisers to perform appraisals in connection with federally related transactions"; and (2) that the scarcity is "leading to significant delays in the performance of such appraisals." Either a State in compliance with title XI or the ASC can make a written "scarcity/delay" finding. A State, however, cannot grant or deny a waiver under section 1119(b); that authority belongs only to the ASC.

[1] 12 U.S.C. 3348(b).

[2] Public Law 101–73, 103 Stat. 183 (1989), as amended by Public Law 102–233, 105 Stat. 1761, 1792 (1991), Public Law 102–242, 105 Stat. 2330, 2386 (1991), Public Law 102–550, 106 Stat. 3672 (1992), and Public Law 102–485, 106 Stat. 2771 (1992).

[3] See Section 1119(a) of title XI, 12 U.S.C. 3348(a).

[4] On December 30, 1992, the Chairman of the FFIEC has approved this action pursuant to authority delegated by the Council.

Congress intended that the ASC exercise this waiver authority "cautiously."[5] Temporary waivers terminate when the ASC "determines that such * * * delays have been eliminated."

In April 1992, the ASC adopted rules governing the handling of temporary waiver requests.[6] In order for a waiver request to be received by the ASC for processing, ASC Rule 1102.2 requires a State appraiser regulatory agency to include in its request:

(a) * * * a written, duly authorized determination by the * * * Agency that there is a scarcity of State licensed or State certified appraisers leading to significant delays in obtaining appraisals in federally related transactions;

(b) The requirement or requirements of State law from which relief is being sought;

(c) A description of all significant problems currently being encountered in efforts to comply with title XI;

(d) The nature of the scarcity of certified or licensed appraisers (including supporting documentation);

(e) The extent of the delays anticipated or experienced in obtaining the services of certified or licensed appraisers (including supporting documentation);

(f) The reasons why the requester believes that the requirement or requirements are causing the scarcity of certified or licensed appraisers and the service delays; and

(g) A specific plan for expeditiously alleviating the scarcity and the service delays.

Rule 1102.4 requires the ASC to publish a notice promptly in the **Federal Register** respecting the received request which must "contain a concise general statement of the nature and basis for the action and (must) give interested persons 30 calendar days from its publication in which to submit written data, views and arguments." The ASC then, under Rule 1102.5, must "either grant or deny a waiver in whole, in part, and upon specified terms and conditions" within "45 calendar days of the date of publication of the notice * * * in the **Federal Register**." The ASC retains significant flexibility in the case of an emergency. If the ASC determines that an emergency exists, "the ASC may issue an interim approval Order simultaneously with its action" publishing the Rule 1102.4 notice in the **Federal Register**.

II. CNMI's Request

On December 21, 1992, the ASC received a letter dated December 16, 1992, from Lorenzo I. De Leon Guerrero, the Governor of CNMI. The letter requested a one-year waiver, i.e., from January 1 through December 31, 1993, from the requirement to use certified or licensed real estate appraisers within CNMI. CNMI stated that, while it has made "substantial, documented progress," it continues "to encounter significant problems in [its] efforts to comply with Title XI" and has "a serious shortage of [certified or licensed] appraisers."

More specifically, CNMI stated that only four appraisers in CNMI "theoretically qualify for appraisal work" and that, "[d]espite good faith efforts * * *, we still can't qualify the people we have available. In practice, we have only one person who might be able to meet Title XI requirements. This person must complete required courses." However, no appraisal education providers are situated on CNMI, and the closest educational provider is on the island of Guam, 120 miles south by air. CNMI concluded that "[e]ducation is our dilemma. It relates directly to our present scarcity of appraisers."

CNMI further represented that this scarcity of appraisers causes "inordinate delays in connection with federally related transactions. Six retail banks operate in CNMI.* * * Many people seek federally guaranteed home loans. Business loan applications are brisk. We have significant appraiser business and presently no local qualified appraisers to serve it." CNMI concedes that appraisers who are licensed or certified in Guam are willing to come to CNMI to perform appraisals. The use of such appraisers, however, "means delay" and "significant and burdensome costs to loan applicants."

CNMI noted that it has a specific plan for resolving the scarcity and delays. A one-year waiver will "allow our local appraisers time to finish the required appraisal courses. At least one of our local appraisers has started the course work, presently only available on Guam." CNMI also is "working on getting the qualified Guam instructors to come to the CNMI to teach appraisal courses." In sum, CNMI promised to "work hard to make the plan a success."

III. Finding of an Emergency Under Rule 1102.5

On the basis of the foregoing representations of CNMI's Governor, the ASC finds that an emergency exists in CNMI. Absent emergency interim relief, CNMI's appraisers who have not been licensed or certified would be unable to perform appraisals in connection with federally related transactions for federally regulated lenders during the period of January 1, 1993, until the time that the ASC makes a final determination respecting CNMI's temporary waiver request under Rule 1102.5. Those lenders would be forced to fly into CNMI State certified or licensed appraisers from elsewhere, *e.g.*, Guam, Hawaii or the United States mainland. In the worst case, such appraisers would not be available and real estate loans in federally related transactions could not be made in compliance with federal law. And, in the best case, significant delays and additional costs would likely result.

IV. Order

On the basis of the foregoing and with the concurrence of the FFIEC, the ASC finds that an emergency exists in CNMI under section 1119(b) of title XI and 12 CFR part 1102, subpart A, thereunder, and orders temporary interim waiver relief under those provisions for CNMI for the period beginning on January 1, 1993, through the date on which the ASC will make a final determination respecting CNMI's temporary waiver request, not to exceed February 22, 1993. Thus, during the time that this Order is effective within CNMI, the federally regulated lenders specified in section 1120 of Title XI[7] may use appraisers who are not licensed or certified so long as appraisals are performed in a manner that is consistent with the appraisal regulations, requirements, guidelines and standards of the appropriate federal financial institution regulatory agency.[8] By the Appraisal Subcommittee of the Federal Financial Institutions Examination Council.

Dated: December 30, 1992.

Fred D. Finke,

Chairman.

[FR Doc. 93–182 Filed 1–5–93; 8:45 am]

BILLING CODE 6210–01–M

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[5] House Comm. on Banking, Finance and Urban Affairs, Report Together With Additional, Supplemental, Minority, Individual, and Dissenting Views, Financial Institutions Reform, Recovery, and Enforcement Act of 1989, H.R. Rep. No. 101–54 Part 1, 101st Cong., 1st Sess., at 482–83.

[6] 12 CFR part 1102, subpart A (57 FR 10979 (April 1, 1992)).

[7] 12 U.S.C. 3349.

[8] These agencies are the Board of Governors of the Federal Reserve System ("FRS"), the Federal Deposit Insurance Corporation ("FDIC"), the Office of the Comptroller of the Currency ("OCC"), the Office of Thrift Supervision ("OTS"), and the National Credit Union Administration ("NCUA"). *See* section 1122(6) of title XI, 12 U.S.C. 3350(6). Their appraisal regulations can be found at 12 CFR: part 225, subpart G (FRS); part 323 (FDIC); part 34 (OCC); part 564 (OTS); and part 722 (NCUA).

FEDERAL RESERVE SYSTEM

Barnett Merger Corp., et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than January 26, 1993.

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Barnett Merger Corp., Jacksonville, Florida; to acquire Barnett Banks Trust Company, N.A., Jacksonville, Florida, and thereby engage in trust company functions pursuant to § 225.25(b)(3) of the Board's Regulation Y.

2. Main Street Banks Incorporated, Covington, Georgia; to acquire First Federal Savings Bank of Georgia, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

B. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Union Planters Corporation, Memphis, Tennessee; to acquire First Federal Savings Bank of Maryville, Maryville, Tennessee, and thereby engage in operating a savings association pursuant to § 225.25(b)(9); and in the sale of credit life, accident, and health insurance as principal, agent, or broker, directly related to the extensions of credit by First Federal and limited to assuring the repayment of the outstanding balance due on the extension of credit in the event of the death, disability, or involuntary unemployment of the debt pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–164 Filed 1–5–93; 8:45 am]

BILLING CODE 6210–01–F

Robert H. and Norma J. Garwood, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than January 20, 1993.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Robert H. and Norma J. Garwood, Miami, Oklahoma; to acquire 100 percent of the voting shares of Nine Tribes Bancshares, Inc., Quapaw, Oklahoma, and thereby indirectly acquire The Bank of Quapaw, Quapaw, Oklahoma.

2. Dr. James M. Plate, Kimball, Nebraska; to acquire an additional 26.49 percent of the voting shares of Banner County Ban Corporation, Harrisburg, Nebraska, for a total of 36.42 percent and thereby indirectly acquire Banner County Bank, Harrisburg, Nebraska.

3. Donald L. Sturm, Omaha, Nebraska; to acquire up to 100 percent of the voting shares of Bank of Laramie, Laramie, Wyoming.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–165 Filed 1–5–93; 8:45 am]

BILLING CODE 6210–01–F

Merchants New York Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than January 26, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. Merchants New York Bancorp, Inc., New York, New York; to become a bank holding company by acquiring 100 percent of the voting shares of The Merchants Bank of New York, New York.

B. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104

Marietta Street, N.W., Atlanta, Georgia 30303:

1. F & M Bancorporation, Birmingham, Alabama; to become a bank holding company by acquiring 100 percent of the voting shares of The Farmers & Merchants Bank, Centre, Alabama.

C. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Minowa Bancshares, Inc., Decorah, Iowa; to acquire 100 percent of the voting shares of Minnesota Bank, National Association, Caledonia, Minnesota.

D. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Citizens Financial Corporation and Citizens Financial Corporation Employee Stock Ownership Plan, Belzoni, Mississippi; to acquire 100 percent of the voting shares of Flora Financial Corporation, Flora, Mississippi, and thereby indirectly acquire Bank of Flora, Flora, Mississippi.

2. West Tennessee Financial Corporation, Selmer, Tennessee; to become a bank holding company by acquiring 100 percent of the voting shares of Community Bank of West Tennessee, Selmer, Tennessee, through the conversion of the existing savings association, First Federal Savings Bank of West Tennessee, Selmer, Tennessee.

E. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. LNB Financial Corporation, Austin, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of LNB Financial-Delaware, Inc., Wilmington, Delaware, and thereby indirectly acquire Liberty National Bank, Austin, Texas. In connection with this application, LNB Financial-Delaware, Inc., Wilmington, Delaware, has applied to become a bank holding company by acquiring 100 percent of the voting shares of Liberty National Bank, Austin, Texas.

F. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. American Marine Bank Employee Stock Ownership Plan, Bainbridge Island, Washington; to become a bank holding company by acquiring 48.58 percent of the voting shares of American Marine Bank, Winslow, Washington.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-166 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

U.S. Trust Corporation, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 20, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. U.S. Trust Corporation, New York, New York; to engage *de novo* through its subsidiary, U.S. Trust Company of Connecticut, Stamford, Connecticut, in trust company activities, including activities of a fiduciary, investment advisory, agency and custodial nature pursuant to §§ 225.25(b)(3) and (b)(4) of the Board's Regulation Y.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. Victoria Bankshares, Inc., Victoria, Texas; to engage *de novo* through its subsidiary, Victoria Securities Corporation, Victoria, Texas, in full service brokerage activities and advisory services pursuant to §§ 225.25(b)(4) and (b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, December 30, 1992.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-167 Filed 1-5-93; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL TRADE COMMISSION

[Dkt 9254]

Alliant Techsystems Inc.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require, among other things, a Minnesota-based defense systems contractor that provides ammunition, for a 10-year period, to obtain Commission approval before: acquiring the assets or stock of any company engaged in systems contracting for certain tank or lightweight ammunition; or selling or transferring Alliant's stock or assets to a company engaged in systems contracting for certain types of ammunition. In addition, the respondent would be required to terminate its proposed acquisition of Olin.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Laura Wilkinson, FTC/S-2308, Washington, DC 20580. (202) 326-2830.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C.

46 and § 3.25(f) of the Commission's Rules of Practice (16 CFR 3.25(f)), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order

In the matter of Alliant Techsystems Inc., a corporation.

The agreement herein, by and between Alliant Techsystems Inc. ("Alliant"), a corporation, by its duly authorized officer and its attorney, and counsel for the Federal Trade Commission ("the Commission"), is entered into in accordance with the Commission's Rule governing consent order procedures. In accordance therewith the parties hereby agree that:

1. Alliant is a corporation organized, existing and doing business under the laws of the State of Delaware, with its office and principal place of business located at 5901 Lincoln Drive, Edina, Minnesota 55436.

2. Alliant has been served with a copy of the complaint issued by the Federal Trade Commission charging it with violations of section 7 of the Clayton Act, as amended, and section 5 of the Federal Trade Commission Act, as amended. Alliant denies said charges.

3. Alliant admits all the jurisdictional facts set forth in the Commission's complaint in this proceeding.

4. Alliant waives:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. All rights to seek judicial review or otherwise challenge or contest the validity of the Order entered pursuant to this agreement; and,

d. All rights under the Equal Access to Justice Act.

5. This agreement shall not become part of the public record unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify Alliant, in which event it will take such action as it may consider appropriate, or issue and serve its decision, in disposition of the proceeding.

6. This agreement is for settlement purposes only and does not constitute an admission by Alliant that the law has been violated as alleged in the complaint issued by the Commission.

7. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 3.25(f) of the Commission's Rules, the Commission may, without further notice to Alliant, 1) issue its decision containing the following Order in disposition of the proceeding, and 2) make information public with respect thereto. When so entered, this Order shall have the same force and effect, and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. This Order shall become final upon service. Delivery by the U.S. Postal Service of the decision containing the agreed to Order to Alliant's address as stated in this agreement shall constitute service. Alliant waives any right it may have to any other manner of service. The complaint may be used in construing the terms of this Order, and no agreement, understanding, representation or interpretation not contained in the Order or this agreement may be used to vary or contradict the terms of the Order.

8. Alliant has read the complaint and Order contemplated hereby. Alliant understands that it may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

Order

I.

For purposes of this Order, the following definitions shall apply:

"Alliant" means Alliant Techsystems Inc., as well as its directors, officers, employees, representatives, agents, parents, divisions, subsidiaries, successors, and assigns, as well as the directors, officers, employees and agents of its parents, divisions and subsidiaries, successors, and assigns.

"Olin" means Olin Corporation, as well as its directors, officers, employees, representatives, agents, parents, divisions, subsidiaries, successors, and assigns, as well as the directors, officers, employees and agents of its parents, divisions and subsidiaries, successors, and assigns.

"Systems contractor for 30mm lightweight ammunition or 120mm tank ammunition" means any company that supplies or has supplied completed rounds of 30mm lightweight ammunition or completed rounds of 120mm tank ammunition to any customer in the United States, including but not limited to the United States Army, or that is developing completed rounds of 30mm lightweight ammunition or completed rounds of 120mm tank ammunition for any customer in the United States, including but not limited to the United States Army.

II.

It is ordered That, for a period commencing on the date this Order becomes final and continuing for ten (10) years, Alliant shall not, without the prior approval of the Commission, directly or indirectly, through subsidiaries or otherwise, acquire: (1) Any interest in the whole or any part of the stock, share capital, or equity of any systems contractor for 33mm lightweight ammunition or 120mm tank ammunition; or (2) any assets of a systems contractor for 30mm lightweight ammunition or 120mm tank ammunition. *Provided,* however, that this Paragraph II shall not apply to the acquisition of products or services in the ordinary course of business.

III.

It is further ordered That, for a period commencing on the date this Order becomes final and continuing for ten (10) years, Alliant shall not, without the prior approval of the Commission, directly or indirectly, through subsidiaries or otherwise, sell or otherwise transfer to any systems contractor for 30mm lightweight ammunition or 120mm tank ammunition: (1) Any interest in or any part of the stock, share capital, or equity of Alliant, or (2) any assets used for or previously used for (and still suitable for use for) systems contracting of 30mm lightweight ammunition or 120mm tank ammunition. *Provided,* however, that this Paragraph III shall not apply to the sale of products or services in the ordinary course of business.

IV.

It is further ordered That, for a period commencing on the date this Order becomes final and continuing for ten (10) years, Alliant shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation that may affect compliance obligations arising out of the Order, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or

dissolution of any subsidiary engaged as systems contractor for 30mm lightweight ammunition or 120mm tank ammunition, or any other change that may affect compliance obligations arising out of the Order.

V.

It is further ordered That, unless Alliant has already done so, it will, not later than fourteen (14) days after this Order becomes final: (1) Terminate any agreement that provides for or contemplates the acquisition of, or exchange of stock for, Olin's Ordnance Division and/or its Physics International Subsidiary, including but not limited to the transaction agreement signed on or about August 4, 1992; (2) return or destroy all documents containing or recording confidential information provided to Alliant by Olin in connection with acquisition negotiations or agreements; and (3) recover from Olin or have Olin destroy all documents containing or recording confidential information provided by Olin by Alliant in connection with acquisition negotiations or agreements. Nothing herein contained shall relieve Alliant from any obligation of confidentiality imposed by agreement among Alliant and Olin.

VI.

It is further ordered That Alliant shall, within sixty (60) days after the date this Order becomes final, file with the Commission a report, in writing, setting forth in detail the manner and form in which it has complied with this Order. Within one year after the Order becomes final, and annually for the next nine years, Alliant shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, or has complied with the Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted provisionally an agreement containing a proposed consent order from Alliant Techsystems Inc. ("Alliant"), concerning Alliant's proposed acquisition of Olin Corporation's ("Olin") Ordnance Division and Physics International Company. Olin is Alliant's only competitor in systems contracting for 120mm tank ammunition and 30 mm lightweight ammunition in the United States. The proposed order requires Alliant to seek prior approval for certain mergers or acquisitions for a period of ten (10) years.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

On or about August 4, 1992, Alliant and Olin signed a definitive agreement under which Olin would exchange its Ordnance Division and Physics International subsidiary for approximately 2.82 million shares of newly issued Alliant common stock plus Alliant's assumption of $65 million of Olin debt. On November 6, 1992, the Federal Trade Commission filed a preliminary injunction action against Alliant in the United States District Court for the District of Columbia to enjoin the proposed acquisition. The Commission won a preliminary injunction on November 18, 1992; the district court's supplemental opinion supporting the injunction was issued on November 23, 1992. The court found that the merger would preclude the Army from conducting a competitive bid for an upcoming multiyear contract, and that the anticompetitive effects of the merger were not counterbalanced by competing efficiency and other considerations alleged by defendants. *FTC* v. *Alliant Techsystems Inc.*, Civ. Action No. 92–2499–LFO, Supplemental Memorandum at 6–7, 21–22, 25–28 (November 23, 1992).

On December 7, 1992, the Commission issued an administrative complaint against Alliant which alleges that Alliant's proposed acquisition of Olin violates section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, as amended, and that, if consummated, such acquisition would violate section 7 of the Clayton Act, 15 U.S.C. 18, as amended, and section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, as amended. The complaint alleges that both Alliant and Olin are competitors in systems contracting for 120mm tank ammunition and 30mm lightweight ammunition in the United States. The complaint alleges that these markets are highly concentrated and that entry into the markets is difficult or unlikely. The complaint alleges that the effect of the proposed acquisition may be substantially to lessen competition or tend to create a monopoly in the relevant markets in the United States.

The first paragraph of the proposed order defines the terms "Alliant," "Olin" and "system contractor for 30mm lightweight ammunition or 120mm tank ammunition" as used in the order. Paragraph II bans Alliant from acquiring, directly or indirectly, without the prior approval of the Federal Trade Commission, any stock or assets of any company engaged in systems contracting for 30mm lightweight or 120mm tank ammunition in the United States. Paragraph III bans Alliant from selling or transferring its stock or assets to a company engaged in systems contracting for 30mm lightweight or 120mm tank ammunition without the prior approval of the Federal Trade Commission. These bans last for a period of ten (10) years from the date the order becomes final.

Paragraph IV of the proposed order requires that Alliant notify the Commission at least thirty (30) days prior to any proposed change in the corporation, such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of any subsidiary engaged in systems contracting for 30mm lightweight or 120mm tank ammunition in the United States, or any other change that may affect compliance obligations arising out of the Order.

Paragraph V of the proposed order requires that within fourteen (14) days after the order becomes final, Alliant must terminate its proposed acquisition of Olin. Additionally, Alliant must return or destroy any documents containing confidential information obtained from Olin and recover or have Olin destroy any confidential documents Alliant supplied to Olin.

Paragraph VI of the proposed order requires Alliant to file with the Commission, within sixty (60) days after service of the order, a report, in writing, setting for in detail the manner and form in which it has complied with this order. Alliant is also required to file with the Commission annual reports detailing its compliance with the order.

The agreement is for settlement purposes only and does not constitute an admission by Alliant that the law has been violated as alleged in the complaint issued by the Commission.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93–115 Filed 1–5–93; 8:45 am]

BILLING CODE 6750–01–M

[Docket C-3406]

American Psychological Association; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a Washington, DC association from restricting the dissemination of truthful, non-deceptive information by its members. In addition, the respondent is prohibited from banning payments by psychologists to patient-referral services. Finally, the respondent must cease its affiliation with any state, regional or other psychological association that imposes similar restrictions.

DATES: Complaint and Order issued December 16, 1992. [1]

FOR FURTHER INFORMATION CONTACT: Elizabeth R. Hilder, FTC/S-3115, Washington, DC 20580. (202) 326-2545.

SUPPLEMENTARY INFORMATION: On Tuesday, October 6, 1992, there was published in the **Federal Register**, 57 FR 46028, a proposed consent agreement with analysis In the Matter of American Psychological Association, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93-112 Filed 1-5-93; 8:45 am]

BILLING CODE 6750-01-M

[1] Copies of the Complaint and the Decision and Order and the separate statement of Commissioner Mary L. Azcuenaga, concurring in part and dissenting in part, are available from the Commission's Public Reference Branch, H-130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

[File No. 902 3145]

CC Pollen Company, et al.; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of Federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit, among other things, a Phoenix-based firm, and its owners, from making false claims about the effect consumption of their bee pollen products has in regard to allergies, aging, impotence, sexual disfunction, weight loss and antibiotic treatment, and require that they have scientific evidence to support any other health-benefit claims they make about any food or other product for human consumption, in the future. In addition, the respondents would be prohibited from producing or distributing any advertisement that is represented to be something other than a paid ad, and required to prominently disclose in all future infomercials they create that the programs are paid ads. Finally, the respondents would be required to pay $200,000 as disgorgement of profits.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Brinley Williams, Cleveland Regional Office, Federal Trade Commission, 668 Euclid Avenue, Suite 520-A, Cleveland, OH 44114, (216) 522-4210.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order To Cease and Desist

The Federal Trade Commission having initiated an investigation of certain acts and practices of C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, hereinafter sometimes referred to as proposed respondents, and it now appearing that proposed respondents are willing to enter into an agreement containing an Order to Cease and Desist from the use of the acts or practices being investigated.

It is hereby agreed by and between proposed respondents and their attorney and counsel for the Federal Trade Commission that:

1. Proposed respondents C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, have an office or principal place of business located at 3627 East Indian School Road, Suite 209, Phoenix, Arizona 85018.

2. Proposed respondents admit all the jurisdictional facts set forth in the draft Compliant here attached.

3. Proposed respondent waive:

(a) Any further procedural steps;

(b) The requirement that the Commission's Decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the Order entered pursuant to this Agreement; and

(d) All claims under the Equal Access to Justice Act.

4. This Agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission, it, together with the draft Complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information with respect thereto publicly released. The Commission thereafter may either withdrew its acceptance of this Agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its Complaint (in such form as the circumstances may require) and Decision, in disposition of the proceeding.

5. This Agreement is for settlement purposes only and does not constitute an admission by proposed respondents of facts other than jurisdictional facts, or of violations of law as alleged in the draft Complaint here attached.

6. This Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the

Commission's Rules, the Commission may, without further notice to proposed respondents, (1) issue its Complaint corresponding in form and substance with the draft Complaint and its Decision containing the following Order to Cease and Desist in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the Order to Cease and Desist shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The Order shall become final upon service. Delivery by the United States Postal Service of the Complaint and Decision containing the agreed-to Order to proposed respondents' address as stated in this Agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The Complaint attached thereto may be used in construing the terms of the Order. No agreement, understanding, representation, or interpretation not contained in the Order or the Agreement may be used to vary or contradict the terms of the Order.

7. Proposed respondents have read the proposed Complaint and Order contemplated hereby. They understand that once the Order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the Order. Proposed respondents further understand that they may be liable for civil penalties in the amount provided by law for each violation of the Order after it becomes final.

Order

The following definition shall apply throughout this Order:

Bee pollen product means any product(s) intended for human consumption or use consisting in whole or in part of bee pollen, bee propolis, and/or royal jelly in any form.

I

It is Ordered That respondents CC Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device in connection with the advertising, packaging, labeling, promotion, offering for sale, sale or distribution of any product or service in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from creating, producing, selling or disseminating:

(A) Any advertisement that misrepresents, directly or by implication, that is not a paid advertisement; and

(B) Any commercial or other video advertisement fifteen (15) minutes in length or longer, or intended to fill a broadcasting or cablecasting time slot of fifteen (15) minutes in length or longer, that does not display visually, in a clear and prominent manner and for a length of time sufficient for an ordinary consumer to read, within the first thirty (30) seconds of the commercial and immediately before each presentation of ordering instructions for the product or service, the following disclosure:

The program you are watching is a paid advertisement for [the product or service].

Provided that, for the purposes of this provision, the oral or visual presentation of a telephone number or address for viewers to contact to place an order for the product or service shall be deemed a presentation of ordering instructions so as to require the display of the disclosure provided herein.

Provided further That should the Federal Trade Commission adopt a trade regulation rule requiring different disclosures or a different frequency of making such disclosures than that required by subpart I(B), above, compliance with such trade regulation rule shall be deemed compliance with subpart I(B).

II

It is further ordered That respondents C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, their successors and assigns, and their officers agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any bee pollen product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that:

(A) Consumption of any been pollen product cannot or will not result in an allergic reaction;

(B) Consumption of any bee pollen product will permanently alleviate all pollen allergy symptoms;

(C) Consumption of any bee pollen product slows or prevents or reverse the aging process;

(D) Consumption of any bee pollen product can cure, or prevent, or alleviate impotence and/or sexual dysfunction;

(E) Consumption of any been pollen product can cause weight loss;

(F) Any bee pollen product is an effective antibiotic for human use.

Provided, however, That use of any statement approved by the United States Food and Drug Administration ("FDA") for inclusion on the above label of the product will be deemed not to violate this part when its use is consistent with the FDA approval.

III

It is further ordered That respondents C C Pollen Company, a corporation, and Bruce R. Brown, Carol M. Brown, and Royden Brown, individually and as officers of said corporation, their successors and assigns, and their officers, agents, representatives and employees, directly or through any partnership, corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of any product or service for human consumption or use, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, directly or by implication, that any such product or service will have any effect on the user's health or physical condition unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of this Order, "competent and reliable scientific evidence" shall mean tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted by others in the profession to yield accurate and reliable results.

IV

It is further ordered That respondents, their successors and assigns, shall pay Two Hundred Thousand Dollars ($200,000) to the United States Treasury as disgorgement. Such payment shall be by two cashier's checks or certified checks made payable to the Treasurer of the United States, the first such check, in the amount of One Hundred Thousand Dollars ($100,000), to be tendered within five (5) days of the date of service of this Order, and the second, also in the amount of One Hundred Thousand Dollars ($100,000), to be tendered no later than one year to the day after this Agreement becomes final. Respondents shall provide security for the second payment in a manner agreed to by the parties before provisional acceptance of this Order by the Federal Trade Commission. In the event of any default in payment, which default continues for more than ten (10) days beyond the due date of payment, respondents shall also pay interest as computed under 28 U.S.C. 1961, which shall accrue on the unpaid balance from the date of default until the date the balance is fully paid.

V

It is further ordered That for a period of three (3) years from the date that a representation covered by this Order is last disseminated, respondents shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

(A) All materials that were relied upon by respondents in disseminating any representation covered by this Order; and

(B) All reports, tests, studies, surveys, demonstrations or other evidence in any respondent's possession or control that contradict, qualify or call into question such representation or the basis upon which respondents relied for such representation, including complaints from consumers.

VI

It is further ordered That respondent CC Pollen Company shall:

(A) Within thirty (30) days after service of this Order, provide a copy of this Order to each of respondent's current principals,

officers, directors and managers, and provide a complete copy of Parts I through III of this Order to all personnel, agents and representatives having advertising or policy responsibility with respect to the subject matter of this Order, and to each employee of CC Pollen Company who is engaged in the sale of CC Pollen products; and

(B) For a period of seven (7) years from the date of entry of this Order, provide a copy of this Order to each of respondent's principals, officers, directors and managers, and provide a complete copy of Parts I through III of this Order to all personnel, agents and representatives having advertising or policy responsibility with respect to the subject matter of this Order, and to each employee of CC Pollen Company who is engaged in the sale of CC Pollen products, within three (3) days after the person assumes his or her position.

VII

It is further ordered That respondent CC Pollen Company shall notify the Commission at least thirty (30) days prior to the effective date of any proposed change in the corporate respondent such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in the corporation which may affect compliance obligations arising out of this Order.

VIII

It is further ordered That respondents Bruce R. Brown, Carol M. Brown, and Royden Brown shall, for a period of seven (7) years from the date of entry of this Order, notify the Federal Trade Commission within thirty (30) days of the discontinuance of his or her present business or employment and of his or her affiliation with any new business or employment. Each notice of affiliation with any new business or employment shall include the respondent's new business address and telephone number, current home address, and a statement describing the nature of the business or employment and his or her duties and responsibilities.

IX

It is further ordered That respondents shall, for at least three (3) years after service of this Order, maintain and make available to the Federal Trade Commission upon request, for inspection and copying, complete records regarding respondents' compliance with this Order.

X

It is further ordered That respondents shall, within sixty (60) days after service of this Order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, an agreement to a proposed Consent Order from C C Pollen Company and its principals, Royden Brown, Bruce Brown and Carol Brown.

The proposed Consent Order has been placed on the public record for sixty (60) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action, or make final the proposed Order contained in the agreement.

This matter concerns two program-length television advertisements for C C Pollen's bee pollen products, *TV Insiders* and *The Search for the Fountain of Youth*, as well as C C Pollen's print advertisements for these products.

The Complaint alleges that C C Pollen Company engaged in deceptive advertising in violation of section 5 of the Federal Trade Commission Act by falsely claiming that the television advertisements were not paid-for advertisements but rather were independent and objective documentary or news programs.

The Complaint also alleges that C C Pollen violated sections 5 and 12 of the FTC Act by making false and unsubstantiated claims that consumption of any bee pollen product cannot result in an allergic reaction; that consumption of C C Pollen Company's bee pollen products will permanently alleviate all of the consumer's pollen allergy symptoms; that consumption of bee pollen products slows or prevents or reverses the aging process; that consumption of bee pollen products can cure, or prevent, or alleviate impotence and/or sexual dysfunction; that consumption of bee pollen products causes weight loss; and that bee pollen projects, such as those advertised by C C Pollen Company, are an effective antibiotic for human use.

The Complaint further alleges that C C Pollen falsely implied that it had a reasonable basis for each of these claims. According to the Complaint, C C Pollen did not have a reasonable basis for making these claims.

The Consent Order contains provisions designed to prevent future misrepresentations concerning the nature of C C Pollen's program-length advertisements. Paragraph I of the Order prohibits C C Pollen and the three named officers of the company from misrepresenting that any advertisement is an independent program, and not an advertisement. Paragraph I also provides that any television advertisement 15 minutes or more in length must contain a clear and prominent visual message which states that the program is a paid advertisement. The disclosure must be made at the beginning of the advertisement and prior to any ordering instructions.

Paragraph II of the Order prohibits respondents from claiming that consumption of any bee pollen product cannot or will not result in an allergic reaction; that consumption of any bee pollen product will permanently alleviate all pollen allergy symptoms; that consumption of any bee pollen product slows or prevents or reverses the aging process; that consumption of any bee pollen product can cure, or prevent, or alleviate impotence and/or sexual dysfunction; that consumption of any bee pollen product can cause weight loss; and that any bee pollen product is an effective antibiotic for human use.

Paragraph III requires substantiation consisting of competent and reliable scientific evidence for all future claims concerning any product for human use or consumption having any effect on the user's health or physical condition.

Paragraph IV requires the respondents to pay to the United States Treasury Two Hundred-Thousand Dollars ($200,000) as disgorgement, with $100,000 to be paid within five days of the date of service of the Order and the remaining $100,000 to be paid within one year after the Order becomes final.

The remainder of the Order contains standard record-retention and notification provisions.

The purpose of this analysis is to facilitate public comment on the proposed Order. It is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93–119 Filed 1–5–93; 8:45 am]

BILLING CODE 6750–01–M

[File No. 922 3155]

Alan V. Phan, d/b/a Harcourt Companies; Proposed Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would prohibit,

among other things, a California marketer of "Jazz cigarettes", a non-tobacco product, from representing that smoking such products poses no health risk, that smoking such products does not pose any of the health risks associated with smoking cigarettes, and that the smoke contains no tar. In addition, the respondent would be prohibited from making any representations about the comparative or absolute health or safety attributes, benefits or risks of any cigarette or smoking product, unless it is substantiated by reliable scientific evidence.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Jeffrey Klurfeld or Kerry O'Brien, San Francisco Regional Office, Federal Trade Commission, 901 Market St., Suite 570, San Francisco, CA 94103. (415) 744-7920.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and § 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order To Cease and Desist

In the Matter of Alan V. Phan, a/k/a Alan V. Pasqualle, an individual trading and doing business as Harcourt Companies.

The Federal Trade Commission having initiated an investigation of certain acts and practices of Alan V. Phan, an individual trading and doing business as Harcourt Companies ("proposed respondent"), and it is now appearing that proposed respondent is willing to enter into an agreement containing an order to cease and desist from the acts and practices being investigated,

It is hereby agreed By and between Alan V. Phan and counsel for the Federal Trade Commission that:

1. Proposed respondent Alan V. Phan is the owner of Harcourt Companies, a California sole proprietorship. His principal office and place of business is located at 10915 Bloomfield Avenue, Los Alamitos, CA 90720.

2. Proposed respondent admits all the jurisidictional facts set forth in the draft complaint here attached.

3. Proposed respondent waives:

a. Any further procedural steps;

b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and

d. All claims under the Equal Access to Justice Act, 5 U.S.C. 504.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent of facts, other than jurisdictional facts, or of violations of law as alleged in the draft of complaint here attached.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of § 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (a) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to cease and desist in disposition of the proceeding and (b) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this agreement shall constitute service. Proposed respondent waives any right he may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondent has read the proposed complaint and order contemplated hereby. Proposed respondent understands that once the order has been issued, he will be required to file one or more compliance reports showing that he has fully complied with the order. Proposed respondent further understands that he may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

I.

It is ordered That respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of Jazz or any product containing substantially similar ingredients, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that:

A. Smoking such product poses no health risk for the user.

B. Smoking such product does not pose any of the health risks associated with smoking tobacco cigarettes.

C. Such product's smoke contains no "tar."

It is further ordered That respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of any smoking product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any misrepresentation, in any manner, directly or by implication, regarding the display of health warnings required by the Federal Cigarette Labeling and Advertising Act.

III.

It is further ordered That respondent Alan V. Phan, an individual trading and

doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of any cigarette, as defined in 15 U.S.C. 1332, or any other smoking product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, the comparative or absolute health or safety attributes, benefits, or risks associated with smoking such product, unless such representation is true and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation. For purposes of this Order, "competent and reliable scientific evidence" shall mean tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

IV.

It is further ordered That respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies, and his successors and assigns, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale, or distribution of any product in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, that using such product is effective in aiding people to quit smoking tobacco products, unless, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

V.

It is further ordered That respondent shall:

A. Within thirty (30) days from the date of service of this Order, distribute a copy of the Complaint and Order to each past or present distributor of Jazz.

B. Distribute a copy of the Complaint and Order to each new distributor of Jazz within thirty (30) days of the date that individual or entity becomes a distributor;

C. Distribute a copy of the Complaint and Order to each future purchaser of Jazz, or any other transferee, who acquires, with or without valuable consideration, more than thirty (30) cartons of Jazz.

D. For ten (10) years from the date of service of this Order, distribute a copy of the Complaint and Order to each managerial employee of respondent, and to each salesperson of respondent's products, whether they are independent sales agents or employees of respondent.

E. Within ten (10) days from the date of service of this Order, distribute a copy of the Complaint and Order to any individual or entity who is involved in the preparation and placement of advertisements or promotional materials, or communicates with customers or prospective customers regarding the efficacy or safety of any product covered by this Order.

VI.

It is further ordered That for five (5) years after the last date of dissemination of any representation covered by this Order, respondent, or his successors and assigns, shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials that were relied upon in disseminating such representation; and

B. All test, reports, studies, surveys, demonstrations or other evidence in his possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

VII.

It is further ordered That respondent shall, for a period of ten (10) years after the date of service of this Order upon him, promptly notify the Commission, in writing, of his discontinuance of his present business or employment and of his affiliation with a new business or employment. For each such new affiliation, the notice shall include the name and address of the new business or employment, a statement of the nature of the new business or employment, and a description of respondent's duties and responsibilities in connection with the new business or employment.

VIII.

It is further ordered That respondent shall, within sixty (60) days from the date of service of this Order upon them, and at such other times as the Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this Order.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent Alan V. Phan, an individual trading and doing business as Harcourt Companies.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

This matter concerns the advertising of "Jazz Cigarettes" ("Jazz"), a nontobacco product. Because Jazz does not contain tobacco, it is not a "cigarette," as that term is defined in the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. 1332. The Commission's complaint charges that respondent's advertising contained false and unsubstantiated representations concerning the health risks associated with smoking Jazz, and Jazz's efficacy in helping people to quit smoking tobacco products.

Specifically, the complaint alleges that respondent falsely represented that: (1) Smoking Jazz poses no health risk for the user; (2) smoking Jazz does not pose any of the health risks associated with smoking tobacco cigarettes; (3) Jazz smoke contains no tar; and (4) Jazz packages do not display the Surgeon General's health warnings because smoking Jazz does not pose the health and safety risks that have been associated with smoking tobacco cigarettes. The complaint also alleges that respondent lacked substantiation for his claim that smoking Jazz is effective in aiding people to quit smoking tobacco products.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent from engaging in similar acts and practices in the future.

Part I of the proposed order prohibits respondent from representing that (1) smoking Jazz poses no health risk for the user; (2) smoking Jazz does not pose any of the health risks associated with smoking tobacco cigarettes; and (3) Jazz's smoke contains no tar. Part I of the proposed order also covers these representations when made about a product that contains substantially similar ingredients as those contained in Jazz.

Part II of the proposed order prohibits respondent from making any misrepresentation regarding the display of health warnings required by the Federal Cigarettes Labeling and Advertising Act on any smoking product.

As fencing-in relief, Part III of the proposed order provides that if respondent represents that comparative or absolute health or safety attributes, benefits, or risks associated with smoking any cigarette or any other smoking product, the representation must be true and respondent must possess competent and reliable scientific evidence that substantiates the representation.

Part IV of the proposed order provides that if respondent represents that a product helps people to quit smoking tobacco products, respondent must possess competent and reliable scientific evidence that substantiates the representation.

The proposed order also requires respondent to maintain materials relied upon to substantiate claims covered by the order, to distribute copies of the order to past, present and future distributors of Jazz, to distribute copies of the order to certain future purchasers of Jazz, to notify the Commission of certain changes in respondent's business or employment, and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93–114 Filed 1–5–93; 8:45 am]

BILLING CODE 6750–01–M

[Docket No. 9247]

Phone Programs, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent order prohibits, among other things, a New York corporation from misrepresenting the ease with which a premium is obtainable and the content of any telephone information service message to children aged twelve and under. In addition, the respondent is required to include a clear statement at the beginning of each children's message giving the child a chance to hand up without charge, and is required to provide a means for parents to prevent, or not be charged for, unauthorized calls by their children.

DATES: Complaint issued May 7, 1991. order issued December 10, 1992.[1]

FOR FURTHER INFORMATION CONTACT: Richard Cleland, FTC/S–4002, Washington, DC 20580. (202) 326–3088.

SUPPLEMENTARY INFORMATION: On Tuesday, September 29, 1992, there was published in the **Federal Register**, 57 FR 44744, a proposed consent agreement with analysis In the Matter of Phone Programs, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93–113 Filed 1–5–93; 8:45 am]

BILLING CODE 6750–01–M

[File No. 931 0023]

S.C. Johnson & Son, Inc.; Proposed Consent Agreement with Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would require, among other things, a Wisconsin-based manufacturer of home care products to divest its assets used in the production, manufacture and sale of continuous action and aerosol air freshener products and furniture care products, in order to acquire certain assets of the Drackett Company, a subsidiary of Bristol-Myers Squibb Company. In addition, for a 10-year period, Johnson must obtain Commission approval before acquiring any interest in any air freshener or furniture care product manufacturer or distributor.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, room 159, 6th St. and Pa. Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Steven A. Newborn, FTC/S–2308, Washington, DC 20580. (202) 326–2682.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46 and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with § 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

Agreement Containing Consent Order

In the matter of S.C. Johnson & Son, Inc. a corporation.

The Federal Trade Commission ("Commission") having initiated an investigation of the proposed acquisition by S.C. Johnson & Son, Inc. ("Johnson"), a corporation, of all the voting securities of The Drackett Company ("Drackett"), from Bristol-Myers Squibb Company ("BMS"), a corporation, and certain assets of BMS relating to Drackett's international business, and it now appearing that Johnson, hereinafter sometimes referred to as "proposed respondent", is willing to enter into an Agreement Containing Consent Order ("Agreement") to divest certain assets, to cease and desist from certain acts, and to provide for certain other relief.

It is Hereby Agreed by and between Johnson, by its duly authorized officers and its attorneys, and counsel for the Commission that:

1. Proposed respondent Johnson is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Wisconsin, with its office and principal place of business located at 1525 Howe Street, Racine, Wisconsin 53403–5011.

2. BMS is a corporation, organized, existing, and doing business under and by virtue of the laws of the State of

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, NW., Washington, DC 20580.

Delaware, with its office and principal place of business located at 345 Park Avenue, New York, New York 10154–0037.

3. Drackett is a corporation, organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 201 East Fourth Street, Cincinnati, Ohio 45202.

4. Proposed respondent admits all the jurisdictional facts set forth in the draft of complaint here attached.

5. Proposed respondent waives:

(a) Any further procedural steps;

(b) The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;

(c) All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this Agreement; and

(d) Any claim under the Equal Access to Justice Act.

6. This Agreement shall not become part of the public record of the proceedings unless and until it is accepted by the Commission. If this Agreement is accepted by the Commission it, together with the draft of complaint contemplated thereby, will be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this Agreement and so notify the proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

7. This Agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft of complaint here attached.

8. This Agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the draft of complaint here attached and its decision containing the following order to divest and cease and desist, and for other relief in disposition of the proceeding, and (2) make information public with respect thereto. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the United States Postal Service of the complaint and decision containing the agreed-to order to proposed respondent's address as stated in this Agreement shall constitute service. Proposed respondent waives any right it may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the Agreement or the order may be used to vary or contradict the terms of the order.

9. Proposed respondent has read the proposed complaint and order contemplated hereby. Johnson understands that once the order has been issued, it will be required to file one or more compliance reports showing it has fully complied with the order. Proposed respondent further understands that it may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

I.

As used in this order, the following definitions shall apply:

A. "Johnson" means S.C. Johnson & Son, Inc., its predecessors, successors and assigns, divisions, subsidiaries, affiliates, companies, groups, partnerships and joint ventures that S.C. Johnson & Son, Inc. controls, directly or indirectly, and their directors, officers, employees, agents and representatives, and their respective successors and assigns.

B. "BMS" means Bristol-Myers Squibb Company, its predecessors, successors and assigns, divisions, subsidiaries, affiliates, companies, groups, partnerships and joint ventures that Bristol-Myers Squibb Company controls, directly or indirectly, and their directors, officers, employees, agents and representatives, and their respective successors and assigns.

C. "Drackett" means The Drackett Company, its predecessors, successors and assigns, divisions, subsidiaries, affiliates, companies, groups, partnerships and joint ventures that The Druckett Company controls, directly or indirectly, the their directors, officers, employees, agents and representatives, and their respective successors and assigns.

D. "Acquisition" means the acquisition by Johnson from BMS of all the voting securities of Drackett, a wholly-owned subsidiary of BMS, and certain assets of BMS relating to Drackett's international business.

E. "Air freshener products" means products designed to combat and eliminate offensive odors in the home that are applied by aerosol spray, or in liquid, solid, wick or other forms and that are distributed to consumers primarily through grocery, drug, and mass merchandise stores.

F. "Furniture care products" means household polishes and dusting aids designed to clean, shine, and protect furniture and other household surfaces, which are applied by aerosol spray or in cream, paste, liquid and other forms and that are distributed to consumers primarily through grocery, drug, and mass merchandise stores.

G. "Renuzit Assets" means all of Drackett's rights, title and interest in and to:

(1) Air freshener products, including, but not limited to, the brands and trademarks "Renuzit", "Renuzit Adjustable", "Renuzit Roommate", "Renuzit Freshell", "Renuzit Fragrance Jar", "Renuzit Aerosol", and "Renuzit Fresh 'n Dry";

(2) Furniture care products, including, but not limited to, the brands and trademarks "Endust" and "Behold", but excluding the brand and trademark "Jr. Muscle" outside the United States; and

(3) All of Drackett's assets and businesses associated with the development, production, distribution, and sale for resale of air freshener products and furniture care products and as further delineated in the subparagraphs of Schedule A, attached hereto and made a part hereof.

II.

It is ordered That:

A. Johnson shall divest, absolutely and in good faith, within twelve (12) months of the date this order becomes final, the Renuzit Assets; provided, however, Johnson is not required to divest any of the Renuzit Assets identified in Schedule A, Part 2, if such assets are not needed by the acquirer or acquirers ("acquirer(s)") in connection with the development, production, distribution, and sale for resale of air freshener products or furniture care products.

B. Johnson shall divest the Renuzit Assets only to an acquirer or acquirers ("acquirer(s)") that receive the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission. The purpose of the divestiture of the Renuzit Assets is to ensure the continuation of the assets as an ongoing, viable enterprise engaged in the same businesses in which the Renuzit Assets

presently are employed, and to remedy the lessening of competition resulting from the proposed Acquisition as alleged in the Commission's complaint.

C. At the time of divestiture, Johnson shall make available to the acquirer(s) such Johnson personnel, assistance and training as the acquirer(s) might reasonably need to transfer Drackett technology and know-how included in the Renuzit Assets, and shall continue providing such personnel, assistance and training at Johnson's cost for a period of time (not to exceed six (6) months) sufficient to satisfy the acquirer(s)' management that its personnel are appropriately trained in the technology and know-how. At the time of divestiture, Johnson shall also divest any additional, incidental assets of Drackett and make any further arrangements for administrative services within the first six (6) months after divestiture that may be reasonably necessary to assure the viability and competitiveness of the Renuzit Assets.

D. Johnson shall ensure that substantially the same services that BMS agreed to provide Johnson pursuant to the Acquisition Agreement dated October 26, 1992, between Johnson and BMS covering Johnson's acquisition of Drackett ("Acquisition Agreement"), shall be provided to the acquirer(s), upon the acquirer's request and on the same terms as such services are provided to Johnson, during the period that BMS has agreed to provide Johnson such services pursuant to the Acquisition Agreement.

E. Johnson will provide and ensure that BMS also provides reasonable cooperation and assistance to the acquirer(s) in obtaining approvals for the transfer of all registrations, leases, licenses, certifications, permits, or similar documents relating to the Renuzit Assets.

F. Johnson shall comply with all terms of the Agreement to Hold Separate, attached hereto and made a part hereof. The Agreement to Hold Separate shall continue in effect until such time as Johnson has divested the Renuzit Assets or until such other time as the Agreement to Hold Separate provides.

G. Johnson shall take such actions as are necessary to maintain the viability and marketability of the Renuzit Assets and to prevent the destruction, removal, wasting, deterioration or impairment of any of the Renuzit Assets except in the ordinary course of business and except for ordinary wear and tear that does not affect the viability and marketability of the Renuzit Assets.

III.

It is further ordered That:

A. If Johnson has not divested, absolutely and in good faith and with the Commission's prior approval, the Renuzit Assets within twelve (12) months of the date this order becomes final, Johnson shall consent to the appointment by the Commission of a trustee to divest the Renuzit Assets. In the event the Commission or the Attorney General brings an action pursuant to section 5(1) of the Federal Trade Commission Act, 15 U.S.C. 45(1), or any other statute enforced by the Commission, Johnson shall consent to the appointment of a trustee in such action. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to section 5(1) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Johnson to comply with this order.

B. If a trustee is appointed by the Commission or a court pursuant to Paragraph III.A. of this order, Johnson shall consent to the following terms and conditions regarding the trustee's power, duties, authorities, and responsibilities:

1. The Commission shall select the trustee, subject to the consent of Johnson, which consent shall not be unreasonably withheld. The trustee shall be a person with experience and expertise in acquisitions and divestitures.

2. The trustee shall, subject to the prior approval of the Commission, have the exclusive power and authority to divest the Renuzit Assets, and in addition, after a period of six (6) months, to divest the trademark "Vanish" along with the Renuzit Assets, together with any additional, incidental assets of Johnson, including those relating to the "Vanish" trademark, and make any further arrangements for administrative services that may be reasonably necessary to assure the viability and competitiveness of the Renuzit Assets and the "Vanish" trademark.

3. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described in Paragraph B.8. to accomplish the divestiture. If, however, at the end of the twelve-month period, the trustee has submitted a plan of divestiture or believes that divestiture can be accomplished within a reasonable time, the divestiture period may be extended by the Commission or by the court (in the case of a court-appointed trustee). Provided, however, the Commission may only extend the divestiture period two (2) times.

4. The trustee shall have full and complete access to the personnel, books, records, and facilities related to the Renuzit Assets, or any other relevant information, as the trustee may reasonably request. Johnson shall develop such financial or other information as such trustee may reasonably request and shall cooperate with any reasonable request of the trustee. Johnson shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Johnson shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or the court for a court-appointed trustee.

5. Subject to Johnson's absolute and unconditional obligation to divest at no minimum price and the purpose of the divestiture as stated in Paragraph II.B. of this order, the trustee shall use his or her best efforts to negotiate the most favorable price and terms available with each acquirer for the divestiture. The divestiture shall be made in the manner set out in Paragraph II; provided, however, if the trustee receives bona fide offers from more than one acquirer, and if the Commission determines to approve more than one such acquirer, the trustee shall divest to the acquirer(s) selected by Johnson from among those approved by the Commission.

6. The trustee shall serve, without bond or other security, at the cost and expense of Johnson, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have authority to employ, at the cost and expense of Johnson, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are reasonably necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the sale and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for his or her services, all remaining monies shall be paid at the direction of Johnson and the trustee's power shall be terminated. The trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the trustee's divesting the Renuzit Assets.

7. Johnson shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trusteeship, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, claims, or expenses result from misfeasance, negligence, willful or wanton acts, or bad faith by the trustee.

8. Within thirty (30) days after appointment of the trustee, and subject to the prior approval of the Commission and, in the case of a court-appointed trustee, of the court, Johnson shall execute a trust agreement that transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestiture required by this order.

9. If the trustee ceases to act or fails to act diligently, a substitute trustee shall be appointed in the same manner as provided in Paragraph III.A. of this order.

10. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this order.

11. The trustee shall have no obligation or authority to operate or maintain either the Renuzit Assets or those assets associated with the "Vanish" trademark.

12. The trustee shall report in writing to Johnson and to the Commission every thirty (30) days concerning the trustee's efforts to accomplish divestiture.

IV.

It is further ordered That Johnson shall maintain the viability and marketability of the "Vanish" trademark together with any additional, incidental assets of Johnson relating to the "Vanish" trademark, and shall not sell, transfer, encumber (other than in the normal course of business), or otherwise impair their marketability or viability, pending divestiture without the prior approval of the Commission.

V.

It is further ordered That, within sixty (60) days after the date this order becomes final and every sixty (60) days thereafter until Johnson has fully complied with the provisions of Paragraphs II and III of this order, Johnson shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, or has complied with those provisions. Johnson shall include in its compliance reports, among other things that are required from time to time, a full description of all substantive contacts or negotiations for the divestiture, including the identity of all parties contacted. Johnson also shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

VI.

It is further ordered That, for a ten (10) year period commencing on the date this order becomes final, Johnson shall cease and desist from acquiring, without the prior approval of the Federal Trade Commission, directly or indirectly, through subsidiaries, partnerships or otherwise.

(1) Any equity or other interest in, or the whole or any part of the stock or share capital of, any person or business that is engaged in the development, production, distribution, and sale for resale of air freshener products or furniture care products in the United States; provided, however, that individual employees of Johnson and each pension, benefit or welfare plan or trust controlled by Johnson may acquire, for investment purposes only, an interest of not more than two (2) percent of the stock or share capital of such person or business;

(2) Any equity or other interest in, or the whole or any part of the stock or share capital of, any person or business that owns or licenses a brand or trademark used in connection with the sale of air freshener products or furniture care products in the United States; provided, however, that individual employees of Johnson and each pension, benefit or welfare plan or trust controlled by Johnson may acquire, for investment purposes only, an interest of not more than two (2) percent of the stock or share capital of such person or business; or

(3) Any assets used or previously used (and still suitable for use) in the manufacture or production of air freshener products or furniture care products; provided, however, that Johnson may, in the ordinary course of business, make purchases of used equipment suitable for manufacturing air freshener products and/or furniture care products totalling not more than $1 million per year.

One (1) year from the date this order becomes final and annually thereafter for nine (9) years on the anniversary date of this order, Johnson shall file with the Secretary of the Federal Trade Commission a verified written report of its compliance with this Paragraph.

VII.

It is further ordered That, for the purposes of determining or securing compliance with this order, and subject to any legally recognized privilege, upon written request and on reasonable notice to Johnson, Johnson shall permit any duly authorized representatives of the Commission:

A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Johnson relating to any matters contained in this consent order; and

B. Upon five (5) days notice to Johnson, and without restraint or interference from Johnson, to interview officers or employees of Johnson, who may have counsel present, regarding such matters.

VIII.

It is further ordered That Johnson shall notify the Commission at least thirty (30) days prior to any change that may affect compliance obligations arising out of the order, including but not limited to, any change in Johnson such as dissolution, assignment, or sale resulting in the emergency of a successor, the creation or dissolution of subsidiaries, or any other change.

Schedule A

Johnson shall divest all of the Renuzit Assets pursuant to the terms of this order. The associated assets identified in Paragraph I.G.(3) of this order shall include all assets, properties, business and goodwill, tangible and intangible, utilized by Drackett in the development, production, distribution and sale of air freshener products and furniture care products, including, without limitation, the following:

Part 1

(1) All customer lists, vendor lists, catalogs, sales promotion literature, advertising materials, marketing information, product development information, research materials, technical information, management information systems, software, inventions, trade secrets, technology, know-how, specifications, designs, drawings, processes and quality control data;

(2) Intellectual property rights, patents and patent applications and the

formulas, copyrights, trademarks and trade names, service marks:

(3) All rights, title and interest in and to the contracts entered in the ordinary course of business with customers (together with associated bid and performance bonds), suppliers, sales representatives, brokers and distributors, agents, inventors, product testing and laboratory research institutions, providers of electronic data exchange services, personal property lessors, personal property lessees, licensors, licensees, consignors and consignees;

(4) All rights under warranties and guarantees, express or implied;

(5) All books, records, files, financial statements and supporting documents;

(6) All items of prepaid expense.

Part 2

(1) The Franklin, Kentucky plant, all machinery, fixtures, equipment, vehicles, furniture, tools and all other tangible personal property;

(2) Inventory;

(3) Accounts and notes receivable;

(4) All Environmental Protection Agency and all other federal and state regulatory agency registrations and applications, and all documents related thereto; and

(5) All rights, title and interest in and to owned or leased real property, together with appurtenances, licenses and permits.

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission ("Commission") has accepted provisionally a proposed Consent Order and Agreement to Hold Separate from S.C. Johnson & Son, Inc. ("SCJ").

The proposed Consent Order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

On October 26, 1992, SCJ entered into an agreement with Bristol-Myers Squibb Company ("BMS") to buy all of the voting securities of the Drackett Company ("Drackett"), a wholly-owned subsidiary of BMS, and certain assets of BMS relating to Drackett's international business. The proposed complaint alleges that the proposed acquisition, if consummated, would constitute a violation of section 7 of the Clayton Act, as amended, 15 U.S.C. 18 and section 5 of the FTC Act, as amended, 15 U.S.C. 45 in the markets for the manufacturer and sale of air freshener products and furniture care products in the United States.

The proposed Consent Order provides that SCJ shall divest all of the assets relating to Drackett's air freshener products and furniture care products businesses (the "Renuzit Assets") within twelve (12) months of the Order becoming final. If the divestiture is not completed within twelve (12) months, the Commission will appoint a trustee to complete the divestiture. If the Renuzit Assets are not divested by the trustee after an additional six (6) months, the proposed Order provides that all of the assets relating to Drackett's toilet bowl cleaning products the "Vanish Assets", shall also be divested with the Renuzit Assets.

The Hold Separate Agreement provides that pending divestiture, the Renuzit Assets shall be operated independently of SCJ. Under the provisions of the proposed Order, SCJ is also required to provide the Commission with a report of its compliance with the divestiture provisions of the Order within sixty (60) days following the date this Order becomes final, and every sixty (60) days thereafter until SCJ has completely divested the Renuzit Assets. The proposed Order will also require SCJ to cease and desist for ten (10) years from acquiring, without Federal Trade Commission approval, any interest in assets suitable for the manufacture, sale, or distribution of air freshener products or furniture care products in the United States. SCJ will also be required to file with the Commission annual reports of its compliance with the Order.

The purpose of this analysis is to facilitate public comment on the proposed Order, and it is not intended to constitute an official interpretation of the agreement and proposed Order or to modify in any way their terms.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 93–117 Filed 1–5–93; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N–0448]

Boehringer Ingelheim Animal Health, Inc., Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) held by Boehringer Ingelheim Animal Health, Inc. The NADA provides for the use of True Antibiotic 10 Lactating Cow Mastitis Treatment (procaine penicillin G). The firm requested the withdrawal of approval. In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending the regulations by removing the entry that reflects the approval.

EFFECTIVE DATE: January 19, 1993.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8749.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Highway, St. Joseph, MO 64506, is the sponsor of NADA 65–466 which provides for the use of True Antibiotic 10 Lactating Cow Mastitis Treatment. In its letter dated August 10, 1992, the sponsor requested the withdrawal of approval of the NADA.

Therefore, under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 65–466 and all supplements and amendments thereto is hereby withdrawn, effective January 19, 1993.

In a final rule published elsewhere in this issue of the **Federal Register**, FDA is amending 21 CFR 526.1696a(f) to reflect the withdrawal of approval of this NADA.

Dated: December 16, 1992.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 93–94 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket Nos. 91N–0429 and 91P–0325]

Alpha Therapeutic Corp.; Revocation of U.S. License No. 744–071

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the establishment license (U.S. License No. 744–071) and the product license issued to Alpha

Therapeutic Corp. (doing business as Alpha Plasma Center) for the manufacture of Source Plasma. Alpha Therapeutic Corp. has multiple Centers at various locations under its licenses. Only the Alpha Plasma Center in Odessa, TX, is affected by this revocation. A notice of opportunity for a hearing (NOOH) on a proposal to revoke the licenses was published in the **Federal Register** of January 21, 1992 (57 FR 2281). On February 14, 1992, Alpha Therapeutic Corp. requested a hearing. On March 20, 1992, Alpha Therapeutic Corp. withdrew its request for a hearing. On March 20, 1992, Alpha Therapeutic Corp. also withdrew a petition (Docket No. 91P–0325) requesting reconsideration of FDA's decision to institute proceedings for the revocation of U.S. License No. 744–071.

DATES: The revocation of the above establishment and product license is effective on January 6, 1993.

FOR FURTHER INFORMATION CONTACT: JoAnn M. Minor, Center for Biologics Evaluation and Research (HFB–132), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–295–8188.

SUPPLEMENTARY INFORMATION: FDA is revoking the establishment license (U.S. License No. 744–071) and the product license issued to Alpha Therapeutic Corp., doing business as Alpha Plasma Center, located at 2100 Andrews Hwy., Odessa, TX 79761, for the manufacture of Source Plasma. Other locations under the Alpha Therapeutic Corp. license are not affected by this revocation.

By letter dated April 26, 1991, FDA advised Alpha Therapeutic Corp. that FDA intended to initiate proceedings to revoke the licenses. In the **Federal Register** of January 21, 1992 (57 FR 2281), FDA published a NOOH on the proposed revocation of the licenses pursuant to 21 CFR 12.21(b), as provided in 21 CFR 601.5(b). As described in the NOOH, the grounds for the proposed license revocation included the following: (1) The results of the most recent FDA inspections of Alpha Plasma Center in February 1991, (2) the results of an FDA investigation of Alpha Plasma Center conducted concurrently with the February 1991 inspections, (3) a determination by FDA that the deviations documented during the February 1991 inspections and investigation of Alpha Plasma Center showed significant and continued noncompliance with the applicable Federal regulations and the provisions of the establishment's license, and (4) a determination by FDA that the violations at the Alpha Plasma Center were significant and willful. FDA noted that documentation in support of the proposed revocations had been placed on file for public examination with Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

The NOOH provided 30 days for Alpha Therapeutic Corp. to submit any written request for a hearing, as specified in 21 CFR 12.21(b), and 60 days to submit any written data justifying a hearing. The NOOH further provided 60 days for other interested persons to submit written comments on the proposed revocations. FDA advised Alpha Therapeutic Corp., by telephone, that the NOOH had been published, and forwarded a copy of the NOOH to Alpha Therapeutic Corp., by facsimile transmission, on February 3, 1992.

Alpha Therapeutic Corp. responded to the NOOH by letter dated February 14, 1992. The letter requested a hearing concerning the proposal to revoke the establishment and the product licenses issued for the Alpha Plasma Center location. The letter also stated that data justifying a hearing would be submitted by March 23, 1992. By letter dated March 20, 1992, the firm informed FDA that after further consideration, and in light of the financial impact, Alpha Therapeutics Corp. was withdrawing its request for a hearing. By a separate letter dated March 20, 1992, Alpha Therapeutic Corp. also withdrew a petition (Docket No. 91N–0325) that requested reconsideration of FDA's decision to institute proceedings for the revocation of U.S. License No. 744–071.

No other written comments on the proposed revocations were received within the prescribed 60 days specified in the NOOH. Accordingly, under 21 CFR 12.38(a)(1), 601.7, 601.8, and the Public Health Service Act (sec. 351 (42 U.S.C. 262)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director and Deputy Director, Center for Biologics Evaluation and Research (21 CFR 5.67(d)), the establishment license (U.S. License No. 744–071) and the product license issued to Alpha Therapeutic Corp. for the manufacture of Source Plasma are revoked, effective January 6, 1993.

Dated: December 15, 1992.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 93–96 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0501]

Lyphomed, et al.; Withdrawal of Approval of 30 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 30 abbreviated new drug applications (ANDA's). The holders of the ANDA's notified the agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's listed in the table in this document have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

ANDA No.	Drug	Applicant
70–522	Aminocaproic Acid Injection, USP, 250 milligrams (mg)/milliliters (mL)	Lyphomed, 2045 North Comell Ave., Melrose Park, IL 60160–1002.
70–652	Methyldopate Hydrochloride Injection, USP, 50 mg/mL	Do.
70–661	Naloxone Hydrochloride Injection, USP, 0.02 mg/mL	Do.
83–136	Niacin Tablets, 500 mg	Bolar Pharmaceutical Co., Inc., 33 Ralph Ave., P.O. Box 30, Copiague, NY 11726–0030.
83–150	Propoxyphene Hydrochloride Capsules, 65 mg	Do.
83–172	Butabarbital Sodium Tablets, 15 mg	Do.
83–204	Promethazine Hydrochloride Tablets, 25 mg	Do.
83–636	Phentermine Hydrochloride Tablets, 8 mg	Do.
83–645	Butabarbital Sodium Tablets, 100 mg	Do.

ANDA No.	Drug	Applicant
83–646	Butabarbital Sodium Tablets, 30 mg	Do.
83–797	Diphenhydramine Hydrochloride Capsules, 25 and 50 mg	Do.
84–911	Chlorpromazine Hydrochloride Injection, 25 mg/mL	Lyphomed, 2045 North Cornell Ave., Melrose Park, IL 60160–1002.
84–964	Sulfasalazine Tablets, 500 mg	Bolar Pharmaceutical Co., Inc., 33 Ralph Ave., P.O. Box 30, Copiague, NY 11726–0030.
85–485	Chlorothiazide Tablets, 250 mg	Eon Labs Manufacturing, Inc., 227–15 North Conduit Ave., Laurelton, NY 11413.
86–761	Lidocaine Hydrochloride Injection, 1 percent and 2 percent	Lyphomed, 2045 North Cornell Ave., Melrose Park, IL 60160–1002.
88–290	Nandrolone Decanoate Injection, USP	Do.
88–317	Nandrolone Decanoate Injection, USP	Do.
89–143	Methylprednisolone Sodium Succinate for Injection, USP, 40 mg/mL	Do.
89–144	Methylprednisolone Sodium Succinate for Injection, USP, 125 mg/mL	Do.
89–157	Methylprednisolone Sodium Succinate for Injection, USP, 500 mg/8 mL	Do.
89–159	Methylprednisolone Sodium Succinate for Injection, USP, 1,000 mg/10 mL	Do.
89–194	Cyclophosphamide for Injection, USP, 100 mg/vial	Do.
89–195	Cyclophosphamide for Injection, USP, 200 mg/vial	Do.
89–196	Cyclophosphamide for Injection, USP, 500 mg/vial	Do.
89–263	Methotrexate Sodium Injection, USP, 25 mg/mL	Do.
89–322	Methotrexate Sodium Injection, USP, 25 mg/mL	Do.
89–323	Methotrexate Sodium Injection, USP, 2.5 mg/mL	Do.
89–373	Calcium Gluceptate Injection, USP, 90 mg Calcium/5 mL	Do.
89–415	Procainamide Hydrochloride Injection, USP, 100 mg/mL	Do.
89–416	Procainamide Hydrochloride Injection, USP, 500 mg/mL	Do.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the ANDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective February 5, 1993.

Dated: December 16, 1992.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 93–174 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 91E–0491]

Determination of Regulatory Review Period for Purposes of Patent Extension; Pravachol®; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent term extension for Pravachol® (pravastatin sodium) that appeared in the Federal Register of March 10, 1992 (57 FR 8461). The notice incorrectly identified the applicant for patent term extension as "E. R. Squibb & Sons, Inc." The notice should have identified the applicant as "Sankyo Co., Ltd." In addition, the notice incorrectly stated: "[T]he applicable regulatory review period for Pravachol® is 2,189 days. Of this time, 1,040 days occurred during the testing phase of the regulatory review period, while 1,149 days occurred during the approval phase." The notice should have stated: "[T]he applicable regulatory review period for Pravachol® is 2,191 days. Of this time, 1,187 days occurred during the testing phase of the regulatory review period, while 1,004 days occurred during the approval phase." A correction to the March 10, 1992, notice was published in the Federal Register of April 24, 1992 (57 FR 15090); the latter notice contained errors and should be disregarded.

FOR FURTHER INFORMATION CONTACT: John S. Ensign, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

1. In FR Doc. 92–5596, appearing on page 8461 in the Federal Register of Tuesday, March 10, 1992, the following corrections are made:

On page 8462, in the first column, under the caption "SUPPLEMENTARY INFORMATION:", in the third complete paragraph, in line 14, "E. R. Squibb & Sons, Inc." is corrected to read "Sankyo Co., Ltd."; on the same page, in the second column, in the first complete paragraph, in line 3, "2,189" is corrected to read "2,191"; in line 4, "1,040" is corrected to read "1,187"; and in line 6, "1,149" is corrected to read "1,004".

Dated: December 17, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 93–97 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Vaccines and Related Biological Products Advisory Committee

Date, time, and place. January 26, 1993, 8:30 a.m., Conference rms. D and E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Jack Gertzog, Center for Biologics Evaluation and Research (HFB–5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8226.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of vaccines intended for use in the diagnosis, prevention, or treatment of human diseases.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 20, 1993, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed

participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss: (1) The influenza virus vaccine formulation for the 1993 through 1994 influenza season, (2) a live oral cholera vaccine (Swiss Serum and Vaccine Institute), and (3) the reorganization of the Center for Biologics Evaluation and Research.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: December 21, 1992.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–98 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–01–F

Indian Health Service

National Environmental Policy Act; Categorical Exclusions

AGENCY: Indian Health Service (IHS), HHS.

ACTION: List of IHS program actions that are categorically excluded from the requirement to conduct further evaluation under the National Environmental Policy Act (NEPA).

SUMMARY: This notice provides a list of classes of IHS actions that normally do not have a significant impact on the environment and, therefore, do not require environmental impact statements (EIS) or environmental assessments (EA) under Council on Environmental Quality (CEQ) regulations (40 CFR parts 1500–1508) or Department of Health and Human Services (HHS) procedures (HHS General Administration Manual Part 30). All actions involving construction are reviewed to determine if extraordinary or exceptional circumstances exist that prevent the action from meeting the criteria established for this listing.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Director, Division of Environmental Health (DEH), Office of Environmental Health and Engineering (OEHE), IHS, Public Health Service (PHS), HHS, room 5A–39, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; or telephone (301) 443–1043.

SUPPLEMENTARY INFORMATION: Regulations of the CEQ at 40 CFR parts 1500–1508 require Federal agencies to adopt procedures to supplement and implement their regulations. The HHS, by giving notice in the **Federal Register** (45 FR 76519), has adopted such procedures and included them in the HHS General Administration Manual Part 30. The CEQ approved the HHS procedures on October 2, 1980. Paragraphs 1507.3 and 1508.4 of the CEQ regulations provide for the definition of categories of actions that do not individually or cumulatively have a significant effect on the human environment and therefore, do not require the preparation of an EIS or an EA. Paragraph 30–20–40 of the HHS General Administration Manual establishes categories of exclusion for Departmental actions and provides for the listing of actions by Operating Divisions within the Department. The IHS, as an agency of the PHS, hereby gives notice of its listing of actions which normally can be categorically excluded from further environmental review.

If a proposed action belongs to an excluded category but one or more extraordinary or exceptional circumstances (as defined in Part K) apply, then an EA must be prepared for the purpose of determining whether an EIS is warranted.

The IHS provides comprehensive health care services to more than 1 million American Indians and Alaska Natives. The goal of the IHS program is to raise the health status of American Indians and Alaska Natives to the highest level possible. In carrying out this goal, the program has three main objectives: (1) To deliver the highest quality health services possible; (2) to assist tribes and native corporations to develop their capacity to manage health programs; and (3) to serve as an advocate for American Indians and Alaska Natives in health related matters.

The IHS program is carried out through a health services delivery system, designed to provide a broad mix of preventive, curative, rehabilitative, and environmental services. The type of health services delivery system

employed varies from Area to Area. Population, health indices, and facilities and services available from sources other than the IHS are evaluated to determine the methods IHS uses to provide services.

The IHS program consists of two major systems: (1) A Federal health care delivery system, administered by Federal employees, and (2) a tribal health delivery system, administered by tribes and tribal groups under grants, contracts or cooperative agreements. The categorical exclusions apply to IHS program actions whether carried out directly by the IHS, or funded or otherwise sponsored by the IHS. The IHS contracts, grants, and cooperative agreements are actions defined in NEPA and are subject to the IHS review procedures established to ensure NEPA compliance, including provisions covering extraordinary and exceptional circumstances. The NEPA compliance for the tribal health care delivery system is ensured through IHS administrative procedures for contracts, grants, and cooperative agreements.

The selection of IHS program actions to list as categorical exclusions has been determined, in part, by agency experience in complying with NEPA, during the past 10 years. Actions required to provide health care services will not have significant impact on the environment except when exceptional or extraordinary circumstances exist. The IHS has categorically excluded these actions, since enactment of NEPA; however, actions involving construction normally have required completion of an environmental review/assessment.

The IHS administers programs for the construction of domestic sanitation facilities (water, wastewater, and solid waste) for Indian homes and communities, construction of new or replacement health care facilities and staff quarters, and renovations to existing health care facilities and quarters units.

Environmental reviews/assessments of construction projects undertaken during the past 10 years have concluded that an EIS was not required for any of them. Approximately 2,300 sanitation facilities construction projects and fewer than 60 health care facilities/staff quarters construction projects have been approved during this time.

The type of program and procedures employed to administer the construction of sanitation facilities for Indian homes and communities, and the consistent determinations that these projects do not have a significant impact on the environment, are the basis for the decision to list most sanitation facilities projects are categorically excluded. Factors considered in making this determination include:

1. Projects are undertaken to improve health and/or environment.

2. Projects are untaken at the request and with approval of the tribal governing body, which provides for discussion and evaluation of the project and its impacts.

3. Projects are normally constructed on tribally owned or individually owned tribal land within reservation boundaries.

4. Projects are constructed to comply with all current applicable environmental regulations and plans and specifications are submitted to State and Federal agencies as necessary for review and comment.

5. Projects are constructed to provide utilities (water, sewer, solid waste) either for existing American Indian or Alaska Native homes or for new homes constructed with Federal, tribal, State or other resources. New homes are constructed at sites and locations approved by the Tribal Governing Board. Utilities are not provided for future development or undeveloped parcels, and capacity provided is limited to that routinely provided by standard engineering practice for the current design population.

6. The IHS projects fall into the category of minor construction projects based on cost. During the last 10 years, 85 of the 2,300 projects exceeded $1 million, and the average estimated cost was $250,000.

7. Standard IHS procedures require documentation of an environmental review of each construction project to identify any exceptional or extraordinary circumstances and to ensure compliance with all environmental laws, regulations, and executive orders; e.g., those concerning floodplains, wetlands, endangered species, etc. This review is required early in the project planning process.

The categorical exclusion for construction of health care facilities and staff quarters has been limited to renovation or new construction at existing health care delivery sites, and construction or development of relatively small facilities at new locations. The procedures noted in item 7 above for sanitation facilities construction projects also apply to all health care facility and staff quarters construction projects. Most health care facility and staff quarters renovation projects can be classified as minor construction projects based on cost. Fewer than 200 major renovation projects have been undertaken and only a few were funded at a level exceeding $1 million.

Categorical Exclusions

A. Health Services

Direct delivery of medical, dental, nursing, and other related health services; e.g., patient care/counseling administered from hospitals, health centers, health stations, satellite clinics, and in private homes by IHS staff or contract providers to authorized recipients.

B. Research

Research activities that are consistent with the mission of IHS including: (a) Biological and behavioral studies conducted in laboratories, clinics, and the field; (b) studies on the development and delivery of prevention and treatment services and their administration and financing; and (c) evaluations of prevention and treatment.

C. Pesticides

Application of pesticides which are not classified for restricted use under provisions of the Federal Insecticide, Fungicide and Rodenticide Act when used for routine pest control purposes.

D. Contracts, Grants, and Cooperative Agreements

Contracts, grants, and cooperative agreements and continuations, supplements, extensions, and amendments of these documents for IHS programs or actions that are categorically excluded. (Includes Self-Determination Act contracts, Contract Health Care contracts, etc.)

E. Technical Assistance

Action involving the provision of technical assistance to American Indian and Alaska Native tribes and groups, other Federal agencies, State and local governments, and non-profit organizations are excluded. These actions include but are not limited to:

1. The provision of technical assistance to American Indian and Alaska Native tribes and groups for the purpose of developing management capabilities needed to enable eventual tribal assumption of health program operation;

2. The provision of technical assistance to American Indian and Alaska Native tribes and groups for the purpose of developing capabilities in the areas of epidemiology, disease reduction, injury prevention, environmental improvement, and the operation and maintenance of sanitation facilities; and

3. The assignment of IHS personnel to agencies/organizations for the purpose of providing technical expertise (e.g.,

investigation, diagnosis, consultation, counseling) in health programs.

F. Management and Administrative Support

Routine management and administrative support actions.

G. Training, Education, and Manpower Development

The award of training grants, scholarships, and the provision of other types of training and educational assistance are excluded. These actions include:

1. Support for development of professional and paraprofessional health competencies;
2. Support for development of American Indian and Alaskan Natives health management capabilities;
3. Support for development of tribal and community capabilities in the areas of environmental improvement, disease reduction, injury control, and operation and maintenance of sanitation facilities;
4. Support for training and education of IHS personnel necessary for the efficient accomplishment of the IHS program; and
5. Educational activities including development of disease prevention and treatment and presentation of such material to American Indian and Alaskan Natives.

H. Statistics, Data Processing, and Information Gathering

Actions associated with statistics and information collection and dissemination are excluded. These actions typically involve:

1. Collection of demographic or morbidity data and analysis for program management and budget justification purposes;
2. Epidemiologic studies;
3. Environmental surveillance activities (e.g., sample collection, analysis, and monitoring of air, food, water, and wastewater) to determine quality as a basis for ensuring necessary corrective action;
4. Engineering studies and investigations including soil boring and test well drilling to gather data for the purpose of determining engineering feasibility and to permit facility design;
5. Updating existing data bases and data processing;
6. Printing and distributing reports; and
7. Developing new/redesignating existing data systems to meet specific program needs.

I. Indian Health Service Owned and Leased Facilities

Actions related to the IHS owned and leased facilities, or actions funded by IHS at tribally owned (or leased) and managed facilities as listed below, are excluded:

1. Maintenance and day-to-day operation of the physical plant and repairs to plant and equipment, or replacement-in-kind of utilities and building components;
2. Acquisition of equipment, provided all requirements for permits, registrations, and licenses are met, and provided the equipment involves use of generally accepted technology;
3. Building alteration or renovation that does not substantially change the function or general appearance of existing buildings;
4. Construction or lease of new facilities (including portable facilities and trailers) where such lease or construction:

(a) Is at the site of an existing health care facility and the facility capacity is not substantially increased,

(b) Is for buildings of less than 12,000 square feet of useable space when less than five acres of surface land area are involved at a new site, or

(c) Is for projects other than buildings when less than five acres of surface land area are involved at a new site;

5. Facility planning and design including funding of such activities;
6. Acquisition of space by lease, use agreement, transfer, gift or similar arrangement for which:

(a) The intended use of the space is consistent with the functional design of the building, and

(b) The acquisition is consistent with an applicable master plan, if such plan exists;

7. The acquisition, sale, release, abandonment, closure or transfer of real property, provided the action:

(a) Is consistent with any applicable master plan, if such a plan exists,

(b) Conforms to local zoning and land use ordinances, if such ordinances exist,

(c) Is consistent with the functional design of the facility,

(d) Would not violate applicable Federal, State, or local environmental protection or historic preservation laws, and

(e) Satisfies the requirements of applicable comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 120 (h) provisions.

J. Construction of Sanitation Facilities

Actions associated with construction of sanitation facilities to serve Indian homes and communities, except that the following actions are not excluded:

(1) Construction of a sanitary landfill at a new solid waste disposal site, and

(2) Construction of a new wastewater treatment facility with direct discharge of treated sewage to surface waters.

K. Extraordinary or Exceptional Circumstances

Under extraordinary circumstances, the normally excluded actions described above may have a significant environmental effect; such actions are not categorically excluded. Actions that can be characterized by, or may cause any of, the conditions described below are examples of actions that are not categorically excluded:

1. Those with potential to change the existing environment where such change violates directives or other controls that are imposed by any governmental body having jurisdiction, for the purpose of protecting or otherwise affecting that environment;
2. Those with potential or real threat of violation, or continued violation, of an applicable Federal, State, or local law or requirement imposed for protection of the environment or to ensure public health and safety;
3. Those likely to cause controversy with respect to the types or extent of the resulting environmental effects where such controversy is based on pertinent and substantial issues;
4. Those involving the use of technology where the possible effects are highly uncertain or involve unique or unknown risks and where such technology has not been assessed previously for environmental impact;
5. Those which have adverse effects on unique geographic characteristics (e.g., historic, archeological, or cultural resources, park recreation or refuge lands, wilderness areas, wild or scenic rivers, sole or principal drinking water aquifers, prime farmlands, wetlands, floodplains, coastal management zones or ecological or critical areas including those listed on the Department of Interiors National Register of National Landmarks);
6. Those which establish a precedent for future action or represent a decision in principle about future actions with potentially significant environmental effects;
7. Those which have adverse effects on properties listed or eligible for listing on the National Register of Historic Places;
8. Those which have adverse effects on species listed by the Federal Government as endangered or Threatened Species, or which have adverse effects on any designated critical habitat for these species;
9. Those which require assessment in accordance with Executive Order 11988 (Floodplain Management), or Executive

Order 11990 (Protection of Wetlands), or the Fish and Wildlife Coordination Act; and

10. Those which involve the use, transfer, or lease of real property which has been determined, after investigation in accordance with the provisions of CERCLA 120 (h), to have been used as a storage facility for hazardous waste for more than 1 year; and

11. Construction projects which are significantly greater in scope or size than normally experienced for a particular category of action.

Dated: December 29, 1992.

Michel E. Lincoln,

Deputy Director.

[FR Doc. 93–173 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–16–M

National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences; Meeting of the Fogarty International Center Advisory Board

Pursuant to Public Law 92–463, notice is hereby given of the twenty-third meeting of the Fogarty International Center (FIC) Advisory Board, February 9, 1993, in the Lawton Chiles International House (Building 16), at the National Institutes of Health.

The meeting will be open to the public from 8:30 a.m. to 2:30 p.m. The morning agenda will include a report by the Director, FIC; a report of the meeting of the NIH Director's Advisory Committee; and a status report on FIC's long-range planning.

The afternoon agenda will be a report on a minority scientists international training initiative and a report on emerging infections.

In accordance with the provisions of sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public from 2:30 p.m. to adjournment for the review of applications for International Research Fellowships, Senior International Fellowships, Fogarty International Research Collaboration Awards, AIDS International Research Training Program, nominations for Scholars-in-Residence award, and proposals for Scholars Conferences.

Myra Halem, Committee Management Assistant, Fogarty International Center, Building 31, room B2C08, National Institutes of Health, Bethesda, Maryland 20892 (301–496–1491), will provide a summary of the meeting and a roster of the committee members upon request.

Dr. Coralie Farlee, Assistant Director for International Legislation and Advisory Activities, Fogarty International Center (Executive Secretary), Building 31, Room B2C08, telephone 301–496–1491, will provide substantive program information.

Catalog of Federal Domestic Assistance Program No. 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome and No. 93.989, Senior International Awards program.

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–142 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

Notice of Meeting of the National Advisory Council for Human Genome Research

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council for Human Genome Research, National Center for Human Genome Research, January 24 and 25, 1993, in Chevy Chase I & II, Embassy Suites Hotel, Chevy Chase Pavilion, 4300 Military Road, NW., Wisconsin at Western Avenue, Washington, DC.

This meeting will be open to the public on January 25, 1993, from 8:30 a.m. to 10 a.m. to discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on January 24 from 7 p.m. to recess and on January 25, 1993, from 10 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Elke Jordan, Deputy Director, National Center for Human Genome Research, National Institutes of Health, Building 38A, room 605, Bethesda, Maryland 20892, (301) 496–0844, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request.

(Catalogue of Federal Domestic Assistance Program No. 93.172, Human Genome Research.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–150 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Cancer Institute; Meeting of the Cancer Biology-Immunology Contracts Review Committee (Subcommittees B&D)

Pursuant to Public Law 92–463, notice is hereby given of a meeting of Subcommittees B&D, of the Cancer Biology-Immunology Contracts Review Committee, National Cancer Institute, National Institutes of Health, January 15, 1993, at the Executive Plaza North Building, in Conference Room "G", 6130 Executive Boulevard, Bethesda, Maryland 20892.

This meeting will be open to the public on January 15 from 8:30 a.m. to 9:30 a.m. to discuss administrative details. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on January 15 from 9:30 a.m. to adjournment for the review, discussion, and evaluation of individual contract proposals. These proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposals, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Committee Management Officer, National Cancer Institute, Building 31, room 10A06, National Institutes of Health, Bethesda, Maryland 20892, Tel. 301/496–5708, will provide summaries of the meeting and rosters of committee members upon request.

Dr. Lalita D. Palekar, Scientific Review Administrator, Cancer Biology-Immunology Contracts Review Subcommittee G, 5333 Westbard Avenue, room 805, Bethesda, Maryland 20892, Tel. 301/496–7575, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower 93.399, Cancer Control.)

Dated: December 24, 1992.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 93–152 Filed 1–5–93; 8:45 am]
BILLING CODE 4140–01–M

National Center for Nursing Research; Meeting: National Advisory Council for Nursing Research and its Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Advisory Council for Nursing Research, National Center for Nursing Research; and its Subcommittees, February 1–3, 1993, Building 31C, Conference Room 6, National Institutes of Health, Bethesda, Maryland 20892.

Meetings of the full Council and its Subcommittees will be held at times and places listed below. Attendance by the public will be limited to space available.

The full Council will meet in open session on February 2, from 8:30 a.m. to 4 p.m. and on February 3, from approximately 11 a.m. to adjournment. Agenda items will include the NCNR Director's Report, Molecular Biology Task Force and Interface for the Biological Studies Plan with NIH Strategic Plan, National Nursing Research Agenda Phase II Priorities, and Report on the Division of Extramural Programs.

The Planning Subcommittee will meet in open session February 1, in Building 31B, NCNR Conference Room (5B–03), from 12 noon to 2:30 p.m. to discuss long-term and strategic planning and policy issues.

The Nursing Resources and Health Policy Subcommittee will meet in open session February 1, in Building 31C, Conference Room 6, from 12 noon to 2 p.m. to discuss nursing resources and health policy as they relate to nursing science and the achievement of quality and effective outcomes in patient care.

The Communications Subcommittee will meet in open session February 1, in Building 31C, Conference Room 6, from 2:30 p.m. to 4:30 p.m. to discuss goals and strategies for enhancing communications with specific audiences.

The National Nursing Research Agenda Subcommittee will meet in open session February 1, in Building 31B, NCNR Conference Room (5B–03), from 9 a.m. to 11:30 a.m. to discuss the National Nursing Research Agenda in general and the Priority Expert Panels in particular.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S. Code and section 10(d)) of Public Law 92–463, the meeting of the Research Subcommittee will be closed to the public on February 1, from 2:30 p.m. to 4:30 p.m., and the meeting of the full Council on February 3, from 8:30 a.m. to approximately 11 a.m. for the review, discussion, and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Ethel Jackson, Executive Secretary, National Advisory Council for Nursing Research, National Institutes of Health, Building 31, room 5B25, Bethesda, Maryland 20892, (301) 496–0472, will provide a summary of the meeting, roster of committee members, and substantive program information upon request.

(Catalog of Federal Domestic Assistance Program No. 93.361, Nursing Research, National Institutes of Health.)

Dated: December 23, 1992.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 93–141 Filed 1–5–93; 8:45 am]
BILLING CODE 4140–01–M

National Eye Institute; Meeting of the National Advisory Eye Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Eye Council (NAEC) on February 4 and 5, 1993, in Building 31C, Conference Room 6, National Institutes of Health, Bethesda, Maryland.

The NAEC meeting will be open to the public from 8:30 a.m. until approximately 11:30 a.m. on Thursday, February 4, 1993. Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs and policies. Attendance by the public at the open sessions will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the NAEC will be closed to the public from approximately 11:30 a.m. on Thursday, February 4 until adjournment on Friday, February 5 for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Lois DeNinno, Committee Management Officer, National Eye Institute, Building 31, room 6A04, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–9110, will provide a summary of the meeting, roster of committee members, and substantive program information upon request.

(Catalog of Federal Domestic Assistance Programs, Nos. 93.867, Retinal and Choroidal Disease Research; 93.868, Anterior Segment Diseases Research; and 93.871, Strabismus, Amblyopia and Visual Processing; National Institutes of Health.)

Dated: December 23, 1992.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 93–143 Filed 1–5–93; 8:45 am]
BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Heart, Lung, and Blood Special Emphasis Panels Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the following Heart, Lung, and Blood Special Emphasis Panels.

These meetings will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: NHLBI SEP on The Framingham Study: Physical Examination, Testing and Surveillance.
Scientific Review Administrator: Dr. C. James Scheirer.
Telephone Number: 301–496–7363.
Dates of Meeting: January 4–6, 1993.
Place of Meeting: Newton Marriott Hotel, Newton, Massachusetts.
Time of Meeting: 7:30 p.m.
Reason for Closure: To review contract proposals.

Name of Panel: NHLBI SEP review for Predictors of Perioperative Cardiac Morbidity (Telephone Conference Call)

Scientific Review Administrator: Dr. David Monsees.

Telephone Number: 301–496–7361.

Dates of Meeting: January 6, 1993.

Place of Meeting: 5333 Westbard Avenue, room 550, Bethesda, MD 20892.

Time of Meeting: 2 p.m. (e.s.t.)

Reason for Closure: To review grant applications.

(Catalog of Federal Domestic Assistance Program Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–145 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Meeting Heart, Lung, and Blood Special Emphasis Panel

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the following Heart, Lung, and Blood Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant application, contract proposals, and/or cooperative agreements. These applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: NHLBI SEP on Production Characterization of Adenovirus Vector for Cystic Fibrosis Gene Therapy (Telephone Conference Call)

Dates of Meeting: January 19, 1993.

Time of Meeting: 2 p.m.

Place of Meeting: 5333 Westbard Avenue, room 5A10.

Agenda: To review and evaluate contract proposals.

Contact Person: Dr. Dennis Lang, Scientific Review Administrator, 5333 Westbard Avenue, room 5A10, Bethesda, Maryland 20892, (301) 496–5965.

(Catalog of Federal Domestic Assistance Program Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–146 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Heart, Lung, and Blood Institute; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the following Heart, Lung, and Blood Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These applications and/or proposal and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: NHLBI SEP on the Review of Program Project Grant Applications.

Date of Meeting: January 5, 1993

Time of Meeting: 8 a.m.

Place of Meeting: Holiday Inn Chevy Chase, Chevy Chase, Maryland.

Agenda: To review grant applications.

Contact Person: Dr. Louis M. Ouellette, (301) 496–7915.

(Catalog of Federal Domestic Assistance Program Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health.)

Dated: December 22, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–151 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Environmental Health Services; Notice of Meeting of National Advisory Environmental Health Sciences Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Environmental Health Services Council, January 25–26, 1993, at the National Institute of Environmental Health Services, Building 101 Conference Room, South Campus, Research Triangle Park, North Carolina. This meeting will be open to the public on January 25 from 9 a.m. to approximately 2 p.m. and 8:30 a.m. to 10 a.m. on January 26 for the report of the Director, NIEHS, and for discussion of the NIEHS budget, program policies and issues, recent legislation, and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. section 10(d) of Public Law 92–463, the meeting will be closed to the public on January 25, from approximately 2 p.m. to 5 p.m. and on January 26 from 10 a.m. to adjournment, for the review, discussion and evaluation of individual grant applications.

These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Winona Herrell, Committee Management Officer, NIEHS, Bldg. 31, Rm. B1C02, NIH, Bethesda, Md. 20892 (301) 496–3511, will provide summaries of the meeting and rosters of council members. Dr. Anne Sassaman, Director, Division of Extramural Research and Training, NIEHS, P.O. Box 12233, Research Triangle Park, North Carolina 27709, (919) 541–7723, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos 93.113, Biological Response to Environmental Agents; 93.114, Applied Toxicological Research and Testing; 93.115, Biometry and Risk Estimation; 93.894, Resource and Manpower Development, National Institutes of Health)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–149 Filed 1–5–93; 8:45 am]

BILLING CODE 4410–01–M

National Institute of General Medical Sciences; Notices of Meeting of the National Advisory General Medical Sciences Council

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory General Medical Sciences Council, National Institute of General Medical Sciences, National Institutes of Health, on February 1–2, 1993, Building 1, Wilson Hall, Bethesda, Maryland.

This meeting will be open to the public on February 1, from 8:30 a.m. to 11 a.m. for opening remarks; report of the Director, NIGMS; and other business of the Council. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on February 1 from 11 a.m. to 6 p.m., and on February 2 from 8:30 a.m. until adjournment, for the review, discussion, and evaluation of individual grant applications. The discussions of these applications could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Ann Dieffenbach, Public Information Officer, National Institute of General Medical Sciences, National Institutes of Health, Building 31, room 4A52, Bethesda, Maryland 20892, Telephone: 301–496–7301 will provide a summary of the meeting and a roster of council members. Dr. W. Sue Shafer, Executive Secretary, NAGMS Council, National Institutes of Health, Westwood Building, room 938, Bethesda, Maryland 20892, Telephone: 301–496–7061 will provide substantive program information upon request.

(Catalog of Federal Domestic Assistance Program Nos. 93.821, Biophysics and Physiological Sciences; 93.859, Pharmacological Sciences; 93.862, Genetics Research; 93.863, Cellular and Molecular Basis of Disease Research; 93.880, Minority Access Research Careers [MARC]; and 93.375, Minority Biomedical Research Support [MBRS]).

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–148 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Advisory Committee Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of an advisory committee of the National Institute of Mental Health for January 1993.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, room 9–105, 5600 Fishers Lane, Rockville, MD 20857, Area Code (301) 443–4333, will provide a summary of the meeting and a roster of committee members.

Other information pertaining to the meeting may be obtained from the contact indicated.

Committee Name: Neuroscience Subcommittee, Mental Health Special Projects Review Committee.

Meeting Date: January 10–12, 1993.

Place: Hyatt Hotel, 4290 El Camino Real, Palo Alto, CA 94306.

Open: January 10, 8–9 a.m.

Closed: January 10, 9 a.m., to adjournment on January 12.

Contact: Helen D. Craig, room 9C–18, Parklawn Building, Telephone (301) 443–3857.

(Catalog of Federal Domestic Assistance Program Numbers 93.126, Small Business Innovation Research; 93.176, ADAMHA Small Instrumentation Program Grants; 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training; and 93.921, ADAMHA Science Education Partnership Award.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–144 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Mental Health; Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Advisory Mental Health Council and the review committees of the National Institute of Mental Health for February 1993.

These meetings will be open to the public as indicated below for the discussion of NIMH policy issues and will include current administrative, legislative, and program developments.

All meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Joanna L. Kieffer, Committee Management Officer, National Institute of Mental Health, Parklawn Building, room 9–105, 5600 Fisher Lane, Rockville, MD 20857, Area Code 301, 443–4333, will provide a summary of the meeting and a roster of committee members.

Other information pertaining to the meetings may be obtained from the contact person indicated.

Committee Name: Mental Disorders of Aging Review Committee.

Contact: Pyllis L. Zusman, room 9C–02, Parklawn Building, Telephone: 301–443–1340.

Meeting Date: February 3–5, 1993.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Open: February 3, 1993, 9 a.m.–10 a.m.

Closed: February 3, 1993, 10 a.m.–5 p.m., February 4, 1993, 9 a.m.–5 p.m., February 5, 1993, 9 a.m.–adjournment.

Committee Name: Neuropharmacology and Neurochemistry Review Committee.

Contact: William H. Radcliff, room 9C–18, Parklawn Building, Telephone: 301–443–3857.

Meeting Date: February 4–5, 1993.

Place: Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Open: February 4, 1993, 8:30 a.m.–9:30 a.m.

Closed: February 4, 1993, 9:30 a.m.–5 p.m., February 5, 1993, 8:30 a.m.–adjournment.

Committee Name: Perception and Cognition Review Committee.

Contact: Debra D. Woods, room 9C–23, Parklawn Building, Telephone: 301–443–1177.

Meeting Date: February 4–6, 1993.

Place: Dupont Plaza Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Open: February 4, 1993, 9 a.m.–10 a.m.

Closed: February 4, 1993, 10 a.m.–5 p.m., February 5, 1993, 9 a.m.–5 p.m., February 6, 1993, 9 a.m.–adjournment.

Committee Name: National Advisory Mental Health Council.

Contact: Carolyn Strete, Ph.D., room 9–105, Parklawn Building, Telephone: 301, 443–3367.

Meeting Date: February 8–9, 1993.

Place: February 8—Conference Rooms D and E, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

February 9—Wilson Hall, Building 1, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Open: February 9, 8:30 a.m. to adjournment.

Closed: February 8, 8:30 a.m. to 5 p.m.

Committee Name: Behavioral Neuroscience Review Committee.

Contact: William H. Radcliffe, room 9C–18, Parklawn Building, Telephone: 301, 443–3857.

Meeting Date: February 11–12, 1993.

Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.
Open: February 11, 1993, 8:30 a.m.–9:30 a.m.
Closed: February 11, 1993, 9:30 a.m.–5 p.m., February 12, 1993, 8:30 a.m.–adjournment.
Committee Name: Social and Group Processes Review Committee.
Contact: Bernice R. Cherry, room 9C–15, Parklawn Building, Telephone: 301, 443–6470.
Meeting Date: February 11–13, 1993.
Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Open: February 11, 1993, 9 a.m.–10 a.m.
Closed: February 11, 1993, 10 a.m.–5 p.m., Februrary 12, 1993, 9 a.m.–5 p.m., February 13, 1993, 9 a.m.–adjournment.
Committee Name: Clinical Psychopathology Review Committee.
Contact: Doris Lee-Robb, Room 9C–08, Parklawn Building, Telephone: 301, 443–1340.
Meeting Date: February 17–19, 1993.
Place: Embassy Suites Hotel, 4300 Military Road, NW., Washington, DC 20015.
Open: February 17, 1993, 9 a.m.–10 a.m.
Closed: February 17, 1993, 10 a.m.–5 p.m., February 18, 1993, 9 a.m.–5 p.m., February 19, 1993, 9 a.m.–adjournment.
Committee Name: Health Behavior and Prevention Review Committee.
Contact: Monica F. Woodfork, room 9C–05, Parklawn Building, Telephone: 301, 443–4843.
Meeting Date: February 17–19, 1993.
Place: Chevy Chase Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.
Open: February 17, 1993, 8:30 a.m.–9:30 a.m.
Closed: February 17, 1993, 9:30 a.m.–5 p.m., February 18, 1993, 8:30 a.m.–5 p.m., February 19, 1993, 8:30 a.m.–adjournment.
Committee Name: Clincial Neuroscience Review Committee.
Contact: Maurine L. Eister, room 9C–18, Parklawn Building., Telephone: 301, 443–3936.
Meeting Date: February 17–19, 1993.
Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Open: February 17, 1993, 9 a.m.–10 a.m.
Closed: February 17, 1993, 10 a.m.–5 p.m., February 18, 1993, 9 a.m.–5 p.m., February 19, 1993, 9 a.m.–adjournment.
Committee Name: Violence and Traumatic Stress Review Committee.
Contact: Phyllis D. Artis, room 9C–15, Parklawn Building, Telephone: 301, 443–6470.
Meeting Date: February 17–19, 1993.
Place: The River Inn Inn, 924 25th Street, NW., Washington, DC 20037.
Open: February 17, 1993, 8:30 a.m.–9:30 a.m.
Closed: February 17, 1993, 9:30 a.m.–5 p.m., February 18, 1993, 8:30 a.m.–5 p.m., February 19, 1993, 8:30 a.m.–adjournment.
Committee Name: Molecular, Cellular, and Developmental Neurobiology Review Committee.
Contact: Shirley H. Maltz, room 9C–18, Parklawn Building, Telephone: 301, 443–3857.
Meeting Date: February 18–19, 1993.
Place: Crowne Plaza Holiday Inn, 1750 Rockville Pike, Rockville, MD 20852.
Open: February 18, 1993, 8 a.m.–9 a.m.
Closed: February 18, 1993, 9 a.m.–5 p.m., February 19, 1993, 9 a.m.–adjournment.
Committee Name: Cognitive Functional Neuroscience Review Committee.
Contact: Shirley H. Maltz, room 9C–18, Parklawn Building, Telephone: 301, 443–3936.
Meeting Date: February 18–20, 1993.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.
Open: February 18, 1993, 9 a.m.–10 a.m.
Closed: February 18, 1993, 10 a.m.–5 p.m., February 19, 1993, 9 a.m.–5 p.m., February 20, 1993, 9 a.m.–adjournment.
Committee Name: Mental Health Small Business Research Review Committee.
Contact: Wm. Gregory Zimmerman, 9C–14, Parklawn Building, Telephone: 301, 443–1367.
Meeting Date: February 22–23, 1993.
Place: Washington Marriott Hotel, 1221 22nd Street, NW., Washington, DC 20037.
Open: February 22, 1993, 9 a.m.–10 a.m.
Closed: February 22, 1993, 10 a.m.–5 p.m., February 23, 1993, 9 a.m.–adjournment.
Committee Name: Child Psychopathology and Treatment Review Committee.
Contact: Tammye M. Cross, room 9C–14, Parklawn Building, Telephone: 301, 443–1367.
Meeting Date: February 24–26, 1993.
Place: Omni Georgetown Hotel, 2121 P Street, NW., Washington, DC 20037.
Open: February 24, 1993, 9 a.m.–10 a.m.
Closed: February 24, 1993, 10 a.m.–5 p.m., February 25, 1993, 9 a.m.–5 p.m., February 26, 1993, 9 a.m.–adjournment.
Committee Name: Services Research Review Committee.
Contact: Wm. Gregory Zimmerman, room 9C–14, Parklawn Building, Telephone: 301, 443–1367.
Meeting Date: February 24–26, 1993.
Place: Washington Marriott, 1221 22nd Street, NW., Washington, DC 20037.
Open: February 24, 1993, 9 a.m.–10 a.m.
Closed: February 24, 1993, 10 a.m.–5 p.m., February 25, 1993, 9 a.m.–5 p.m., February 26, 1993, 9 a.m.–adjournment.
Committee Name: Emotion and Personality Review Committee.
Contact. Sheri L. Schwartzbeck, room 9C–05, Parklawn Building, Telephone: 301, 443–4843.
Meeting Date: February 25–26, 1993.
Place: Georgetown Holiday Inn, 2101 Wisconsin Avenue, NW., Washington, DC 20007.
Open: February 25, 1993, 8:30 a.m.–9 a.m.
Closed: February 25, 1993, 9 a.m.–5 p.m., February 26, 1993, 8:30 a.m.–adjournment.
Committee Name: Child/Adolescent Risk and Prevention Review Committee.
Contact: Michele D. Campbell, room 9C–23, Parklawn Building, Telephone: 301, 443–1177.
Meeting Date: February 25–27, 1993.
Place: Marriott Residence Inn, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Open: February 25, 1993, 9 a.m.–10 a.m.
Closed: February 25, 1993, 10 a.m.–5 p.m., February 26, 1993, 9 a.m.–5 p.m., February 27, 1993, 9 a.m.–adjournment.

(Catalog of Federal Domestic Assistance Program Numbers 93.126, Small Business Innovation Research; 93.176, ADAMHA Small Instrumentation Program Grants; 93.242, Mental Health Research Grants; 93.281, Mental Research Scientist Development Award and Research Scientist Development Award for Clinicians; 93.282, Mental Health Research Service Awards for Research Training; and 93.921, ADAMHA Science Education Partnership Award.)

Dated; December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–147 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Neurological Disorders and Stroke; Meeting

Pursuant to Public Law 92–463, notice is hereby given of meetings of committees of the National Institute of Neurological Disorders and Stroke (NINDS). These meetings will be open to the public to discuss program planning, program accomplishments and special reports or other issues relating to committee business as indicated in the notice.

The Council meeting will be open to the public on February 4, 1993, as listed below. The agenda includes a report by the Director, NINDS, and a report by the Director, Division of Intramural Research, NINDS. Attendance by the public will be limited to space available.

These meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sections 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of meetings, rosters of committee members, and other information pertaining to the meetings can be obtained from the Executive Secretary or the Scientific Review Administrator indicated.

Name of Committee: The Planning Subcommittee of the National Advisory Neurological Disorders and Stroke Council.
Date: February 3, 1993.
Place: National Institutes of Health, Building 31, Conference Room 8A28, 9000 Rockville Pike, Bethesda, MD 20892.

Open: 1 p.m.–3 p.m.
Closed: 3 p.m.–recess.

Name of Committee: National Advisory Neurological Disorders and Stroke Council.
Dates: February 4–5, 1993.
Place: National Institutes of Health, Shannon Building—Wilson Hall, Bethesda, MD 20892.
Open: February 4, 9 a.m.–1 p.m.
Closed: February 4, 1 p.m.–recess, February 5, 8:30 a.m.–adjournment.
Executive Secretary: Constance W. Atwell, Ph.D. Special Assistant for Extramural Activities, NINDS, National Institutes of Health Bethesda, MD 20892, Telephone: (301) 496–9248.

Name of Committee. Neurological Disorders Program Project Review A Committee.
Dates: February 13–15, 1993.
Place: Pier 66 Resort and Marina, 2301 S.E. 17th Causeway, Fort Lauderdale, FL 33316.
Open: February 13, 7:30 p.m.–8 p.m.
Closed. February 13, 8 p.m.–recess, February 14, 8:30 a.m.–recess, February 15, 8:30 a.m–adjournment.
Scientific Review Administrator: Dr. Katherine Woodbury, Federal Building, room 9C–14, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496–9223.

Name of Committee: Training Grant and Career Development Review Committee.
Dates: February 22–23, 1993.
Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.
Open: February 22, 8:30 a.m.–9 a.m.
Closed. February 22, 9 a.m.–recess, February 23, 8 a.m.–adjournment.
Scientific Review Administrator: Dr. Herbert Yellin, Federal Building, room 9C–10, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496–9223.

Name of Committee: Neurological Disorders Program Project Review B Committee.
Dates. February 25–27, 1993.
Place: Holiday Inn Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.
Open February 25, 7 p.m.–7:30 p.m.
Closed: February 25, 7:30 p.m.–recess, February 26, 8:30 a.m.–recess, February 27, 8:30 a.m.–adjournment.
Scientific Review Administrator: Dr. Paul Sheehy, Federal Building, room 9C–14, National Institutes of Health, Bethesda, MD 20892, Telephone: (301) 496–9223.

(Catalog of Federal Domestic Assistance Program No. 93.853, Clinical Research Related to Neurological Disorders; No. 93.854, Biological Basis Research in the Neurosciences).

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–137 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Meetings of the National Deafness and Other Communication Disorders Advisory Council and its Research Subcommittee

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the National Deafness and Other Communication Disorders Advisory Council and its Training Subcommittee and Research Subcommittee on January 27–29, 1993, at the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland. The meeting of the full Council will be held in Conference Room 6, Building 31C, and those of the subcommittees in Conference Room 7, Building 31C.

The meeting of the Training Subcommittee will be open to the public on January 27 from 12:30 pm to adjournment at approximately 2:30 pm. The meeting of the Research Subcommittee will be open to the public on January 27 from 2:30 pm until 3:30 pm for the discussion of policy issues. The meeting of the full Council will be open to the public on January 28 from 8:30 am until recess for a report from the Institute Director and discussion of extramural policies and procedures at the National Institutes of Health and the National Institute on Deafness and Other Communication Disorders and on January 29 from 8:30 am to approximately 9 a.m. for a report on extramural programs of the Division of Communication Sciences and Disorders.

In accordance with the provisions set forth in section 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the Research Subcommittee on January 27 will be closed to the public from 3:30 p.m. to adjournment. The meeting of the full Council will be closed to the public on January 29 from 9 a.m. until adjournment. The closed portions of the meetings will be for the review, discussion, and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concerning the Council and Subcommittee meetings may be obtained from Dr. John C. Dalton, Executive Secretary, National Deafness and Other Communication Disorders Advisory Council, National Institute on Deafness and Other Communication Disorders, Executive Plaza South, room 400B, National Institutes of Health, Bethesda, Maryland 20892, 301–496–8693. A summary of the meetings and rosters of the members may also be obtained from his office.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Other Communicative Disorders)

Dated: December 3, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–140 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

National Library of Medicine; Meetings of the Board of Regents and Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Regents of the National Library of Medicine on February 11–12, 1993, in the Board Room of the National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland. The Subcommittee will meet on February 10 as follows:

The Extramural Programs Subcommittee, 5th-floor Conference Room, Building 38A, 2 to approximately 3:30 p.m., and the Planning Subcommittee in Conference Room B, Building 38, 4 to approximately 5 p.m. The Extramural Programs Subcommittee will be closed to the public.

The meeting of the Board will be open to the public from 3 to approximately 4 p.m. on February 11 and from 9 a.m. to adjournment on February 12 for administrative reports and program discussions. Attendance will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4), 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the entire meeting of the Extramural Programs Subcommittee on February 10 will be closed to the public, and the regular Board meeting on February 11 will be closed from approximately 4 to adjournment for the review, discussion, and evaluation of individual grant applications. These applications and the discussion could reveal confidential trade secrets or commercial property, such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mr. Robert B. Mehnert, Chief, Office of Inquiries and Publications Management, National Library of

Medicine, 8600 Rockville Pike, Bethesda, Maryland 20894, Telephone Number: 301–496–6308, will furnish a summary of the meeting, rosters of Board members, and other information pertaining to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.879—Medical Library Assistance, National Institutes of Health.)

Dated: December 23, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–138 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

Prospective Grant of Exclusive Patent License

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: This is notice in accordance with 15 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i) that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive license in a limited field of use to practice the inventions embodies in U.S. Patent Application 07/010,424 (now U.S. Patent Application 07/445,131), entitled "Vector for Recombinant Poxvirus Expressing Rabies Virus Glycoprotein," and U.S. Patent Application 07/198,213 (now U.S. Patent Application 07/829,597), entitled "Raccoon Poxvirus As a Gene Expression and Vaccine Vector for Genes of Rabies and Other Organisms" to Fort Dodge Laboratories Inc. having a place of business at Fort Dodge, Iowa. The patent rights in these inventions have been assigned to the United States of America.

The prospective exclusive license will be for the field of veterinary biologicals. It will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

These inventions relate to a novel plasmid containing a recombinant infectious vaccinia poxvirus for use in the production of rabies vaccine and production of rabies virus glycoprotein antigen, antibody, and related reagents. The inventions also relate to a recombinant vector containing raccoon poxvirus as a method for inducing protective immunity against rabies virus and other organisms.

The availability of U.S. Patent Application 07/010,424, for licensing was published in the April 30, 1987 edition of the **Federal Register**. The availability of U.S. Patent Application 07/198,213 for licensing was published in the June 28, 1988 edition of the **Federal Register**. Requests for a copy of the above identified patent applications, inquiries, comments and other materials relating to the contemplated license should be directed to: Mr. Mark Hankins, J.D., Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, Maryland 20892 (telephone: (301) 496–7735; FAX: (301) 402–0220). Properly filed competing applications for a license filed in response to this notice will be treated as objections to the grant of the contemplated license. Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer within sixty (60) days of this notice will be considered.

Dated: December 23, 1992.

Reid G. Adler,

Director, Office of Technology Transfer

[FR Doc. 93–153 Filed 1–5–93; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

Treasury, Postal Service and General Government Appropriations Act of 1992; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of authority of November 19, 1992, by the Secretary of Health and Human Services to the Assistant Secretary for Health, I have delegated to Director, Centers for Disease Control and Prevention, with authority to redelegate, all the authorities vested in the Assistant Secretary for Health under section 633 of the Treasury, Postal Service and General Government Act of 1992, Public Law 102–141, as amended hereafter. This delegation excludes the authority to promulgate regulations and to submit reports to Congress.

This delegation became effective upon date of signature. In addition, I have affirmed and ratified any actions taken by the Director, Centers for Disease Control and Prevention or his subordinates which, in effect, involved the exercise of the authorities delegated herein prior to the effective date of the delegation.

Dated: December 22, 1992.

James O. Mason,

Assistant Secretary for Health.

[FR Doc. 93–93 Filed 1–5–93; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Education Facilities Construction Priority List as of FY 1993

December 31, 1992.

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Indian Affairs (BIA) is publishing an Education Facilities Construction Policy List as of FY 1993. Publication of the Priority List in the **Federal Register** is required by statute. The Priority List includes those projects that were on the New School Construction Priority List for FY 1992 along with additions that have been made to the list. This Priority List is being published "as of FY 1993." Construction funding is not currently available for all of the Education Facilities Construction projects listed on the Priority List. As appropriations become available, Education Facilities Construction projects will be funded for construction in the order in which they are ranked.

FOR FURTHER INFORMATION CONTACT: W. "Buck" Martin, Director, Office of Construction Management, Department of the Interior, Mail Stop 2417 MIB, 1849 C Street, NW., Washington, DC 20240, telephone number (202) 208–3403.

SUPPLEMENTARY INFORMATION: The BIA is publishing the Priority List of Education Facilities Construction projects to satisfy 25 U.S.C. 2005(c) that provides: "At the time any budget request for school construction is presented, the Secretary shall publish in the **Federal Register** and submit with the budget request the current list of all school construction priorities."

The current priority ranking process is in accordance with the "Construction of School Facilities for Indian Children; School Construction Applications and Procedures" that were published in the **Federal Register** on May 22, 1979, at 44 FR 29864. Amended criteria to be used in the priority ranking of new school construction projects were published in the **Federal Register** on April 14, 1988, at 53 FR 12470.

On October 19, 1990, at 55 FR 42497, a notice was published that contained the "New School Construction Priority

List for FY 1992." The notice established a deadline of December 15, 1990, for filing applications to be considered for the FY 1993 priority ranking list.

The Conference Report for the Fiscal Year 1992 Interior and Related Agencies Appropriation Act, House Report No. 256, 102d Cong., 1st Sess., p. 46 (1991) (Conference Report) froze the "New School Construction Priority List for FY 1992." Under the current procedures, the priority list published each year has been a proposed list and subject to the availability of appropriated funds. Not all projects listed received construction funding. Those projects not funded had to file a new or updated application the next year to be considered for priority ranking. Applications were evaluated and a new list was prepared each year.

Congress provided funding for planning and design "for the top ten schools contained on the fiscal year [1992] priority list, to the extent that funds are available." Schools not funded for planning and design in FY 1992 would be funded for planning and design in FY 1993.

"[S]tarting at the top of the fiscal year 1992 list and including Pyramid Lake," construction funding was to be made available after completion of the necessary validations, planning and design. It was recognized by Congress that appropriations for FY 1992 were insufficient to provide construction funding for the ten schools listed on the New School construction Priority List of FY 1992 plus Pyramid Lake. The Conference Report stated that additional funds would be provided to complete these projects in FY 1993 and outyears.

The Conference Report further directed the Department "to review applications and prepare a new school construction priority list for fiscal year 1993, with these schools eligible for planning and design and construction funding, subject to budget constraints in fiscal year 1993 and beyond, in addition to any remaining fiscal year 1992 schools."

The Department published a notice in the **Federal Register** on December 6, 1991, at 56 FR 64185, that new applications and/or additional, supplemental materials in support of existing new school applications on file could be submitted for consideration for priority ranking in FY 1993. The notice established a deadline of January 31, 1992, for filing new or updated applications.

The applications submitted for inclusion on the FY 1993 list have been evaluated and priority ranked. Five (5) schools have been selected for inclusion on the new school priority list for FY 1993. Because Congress has created a continuous multi-year priority ranking list for new school construction, it is misleading to refer to the list as the priority list for FY 1993. Although some planning and design funding is available, construction funding has not been appropriated. Construction funding will not become available until funding has been provided for all the ten (10) schools on the New School Construction Priority List for FY 1992 plus the Congressional add-on, Pyramid Lake.

To prevent any confusion or misunderstanding, the Department is consolidating the FY 1992 and FY 1993 new school construction priority lists into one continuous multi-year list. For reference purposes, the list set out below is entitled: "Education Facilities Construction Priority List as of FY 1993." The list contains: The ten (10) new schools which were included on the "New School Construction Priority List for FY 1992," Nos. 1 through 10; plus Pyramid Lake, which was added by Congress, No. 11; and, the five (5) schools priority ranked for FY 1993, Nos. 12 through 16.

The priority ranking process under current procedures has been subject to criticism, primarily because of the uncertainty of the process, by Indian tribes and Indian organizations, as well as Congress. A decision had been made by the Department, prior to the FY 1992 Interior Appropriations Act, to promulgate regulations to govern the priority ranking process.

The Conference Report acknowledged the actions and directed the Department to continue efforts to revise the priority ranking process for new school construction. The Conference Report stated that emphasis should be given to tribal consultation and to improving the objectivity of the ranking process, to providing continuity to the priority ranking list and to providing procedures for handling emergency needs.

Tribal consultation meetings were held on a draft of a proposed rulemaking document in December 1991 and a proposed rule adding a new Part 294 Education Facilities Construction to title 25 of the Code of Federal Regulations should be published in the **Federal Register** in the near future.

Because of the current efforts to promulgate regulations and the action by Congress to create a continuous multi-year priority list, the Department does not intend to call for the filing of applications for new school construction under the current process, again. However, once the regulations are published as a final rule and are in effect, the Department will provide for the filing of applications.

As the regulations are currently drafted, not only will a notice be published in the **Federal Register**, but also mailed directly to all federally-recognized tribes and BIA-funded schools, whether BIA-operated, contract, or grant. The notice will advise individuals of the relevant procedures to be followed as well as the deadline for filing applications. Publication of a final rule is not anticipated until the end of 1993. Schools listed on the "Education Facilities Construction Priority List of FY 1993" will not have to reapply, but will be retained, in order, on the list. School construction projects priority ranked under the regulations will be added at the end of any schools remaining from the Education Facilities Construction Priority List as of FY 1993.

The "Education Facilities Construction Priority List as of FY 1993" is as follows:

Education Facilities Construction Priority List as of FY 1993

1. Pinon Community School Dorm
2. Eastern Cheyenne River Consolidated School
3. Rock Point Community School
4. Many Farms High School
5. Tucker Day School
6. Shoshone-Bannock/Fort Hall School
7. Standing Pine Day School
8. Chief Leschi School Complex
9. Seba Delkai Boarding School
10. Sac and Fox Settlement School
11. Pyramid Lake
12. Shiprock Alternative School
13. Tuba City Boarding School
14. Fond du Lac Ojibway School
15. Second Mesa Day School
16. Zia Day School

Eddie F. Brown,

Assistant Secretary—Indian Affairs.

[FR Doc. 93–192 Filed 1–5–93; 8:45 am]

BILLING CODE 4310–02–M

National Park Service

Completion of Inventory of Native American Human Remains From Hawaii in the Possession of the Peabody & Essex Museum

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is hereby given in accordance with provisions of the Native American Graves Protection and Repartriation Act, 25 U.S.C. 3003(d), of the completion of the inventory of human remains from Hawaii in the possession of the Peabody & Essex Museum. Representatives of

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culturally affiliated Native Hawaiian organizations are advised that these human remains will be retained by the museum until February 5, 1993, after which they may be repatriated to the culturally affiliated group.

The detailed inventory and assessment of these human remains has been made by the Peabody & Essex Museum curatorial staff, specialists in physical anthropology and prehistoric archeology from the Bernice Pauahi Bishop Museum, Honolulu, HI, and representatives of Hui Mālama I Nā Kūpuna 'O Hawai'i Nei, a nonprofit, Native Hawaiian organization incorporated under the laws of the State of Hawaii and recognized under 25 U.S.C. 3001 (6) to provide guidance and expertise in decisions dealing with Native Hawaiian cultural issues, particularly burial issues.

The human remains consist of a cranium collected by Charles Derby in the Sandwich (now Hawaiian) Islands in the 19th Century. The cranium was accessioned by the Essex Institute prior to 1867 and catalogued as Hawaiian. Osteological documentation revealed a "rocker jaw" and upper palate typical of Polynesian individuals. The crania is believed to be of Hawaiian cultural affiliation based on this morphology and collection history.

Based on the above mentioned information, officials of the Peabody & Essex Museum have determined pursuant to 25 U.S.C. 3001 (2) that there is a relationship of shared group identity which can be reasonably traced between these remains and present-day Native Hawaiian organizations.

This notice has been sent to officials of Hui Mālama I Nā Kūpuna 'O Hawai'i Nei and the Office of Hawaiian Affairs. Representatives of any other Native Hawaiian organization which believes itself to be culturally affiliated with these human remains should contact John R. Grimes, Curator of Archeology, Peabody & Essex Museum, East India Square, Salem MA 01970, (508) 745–1876, before February 5, 1993.

Dated: December 31, 1992.

Francis P. McManamon,

Departmental Consulting Archeologist Chief, Archeological Assistance Division.

[FR Doc 93–139 Filed 1–5–93: 8:45 am]

BILLING CODE 4310–70–M

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 514 (A)]

Privacy Act: Establishment of a System of Records; Office of Inspector General Complaint and Investigative Files

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposed new system of records and request for comments.

SUMMARY: The Commission (ICC) is establishing a new system of records under the Privacy Act of 1974, as amended (5 U.S.C. 552a), Pub. L. 93–579, to consist of the complaint and investigatory file of the ICC's Office of Inspector General (OIG). The new system of records facilitates the OIG's ability to collect, maintain, use and disclose information pertaining to individuals, thus helping to ensure that the OIG may efficiently and effectively perform its investigations and other authorized duties and activities.

DATES: Comments are due February 5, 1993.

ADDRESSES: An original and two copies of comments referring to Ex Parte No. 514 (A) should be submitted to: Office of the Secretary, Case Control Branch, room 1324, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: S. Arnold Smith, Freedom of Information/Privacy Officer (202) 927–6317. [TDD for hearing impaired: (202) 927–5721.

SUPPLEMENTARY INFORMATION: As required by 5 U.S.C. 552a(e)(4), the ICC is notifying the public of the establishment of a new system of records in its OIG (32–20–0015). This system is being established as part of the formal creation of an OIG within the ICC under the authority of the 1988 amendments to the Inspector General Act of 1978. See Pub. L. No. 100–504, 102 Stat.251 (amending 5 U.S.C. App. 3 1978)). Among the OIG's statutory duties are the prevention and detection of fraud, waste, and abuse relating to the ICC's programs and operations through the conduct of audits and investigations and the preparation of reports to the ICC's Chairman and to Congress.

The system of records being established consists of complaint and investigatory files compiled and maintained by the OIG. Due to the law enforcement nature of these records, the proposed system may be exempted by the ICC from certain provisions of the Privacy Act including disclosure to individuals who are the subject of a record in the system. See 5 U.S.C. 552a(j)(2) and (k)(2). The exemption of the system is the subject of a companion notice of proposed rulemaking to amend ICC Rule 49 CFR 1007.12. That notice is published in the proposed rule section of today's **Federal Register.** Pursuant to 5 U.S.C. 552a(o) and OMB Circular No. A–130, the ICC has submitted its report on the proposed establishment of this system of records to both Houses of Congress and to OMB.

Unless changes are made in response to comments received from the public, this action will become effective 30 days after final publication of the proposed amendment to ICC Rule 49 CFR 1007.12. The effective date may be extended if the Director of the Office of Management and Budget (OMB) declines, in whole or in part, the ICC's request to waive the 60 day period prescribed by OMB for advance notice to it and Congress. See OMB Circular No. A–130, App.1 at section 4b.(c)(4).

Accordingly, the ICC proposes to establish the following system of records.

32–20–0015

SYSTEM NAME:

OIG Complaint and Investigative Files.

SYSTEM LOCATION:

OIG, ICC. Room 2121, Washington, DC 20423.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals involved in complaints reported to and investigations conducted by the OIG relating to the programs and operations of the ICC.

CATEGORIES OF RECORDS IN THE SYSTEM:

Files containing information relevant to complaints and investigations. Files include all relevant correspondence, internal staff memoranda, copies of all subpoenas issued, affidavits, witness statements, transcripts of testimony and accompanying exhibits, working papers of the staff, and any other reports, documents, and records. These records are used as a basis for the issuance of subpoenas, suitability determinations, and civil, criminal, and administrative actions.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The authority for maintenance of the system is found under the Inspector General Act Amendments of 1988, Public Law 100–504, 102 Stat. 251 (amending 5 U.S.C. App. 3 (1978)).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to the disclosures generally permitted under 5 U.S.C. 552a(b), these records or information in these records may specifically be disclosed pursuant to 5 U.S.C. 552a(b)(3) as follows, provided that no routine use specified herein shall be construed to limit or waive any other routine use specified herein:

(1) To other agencies, offices, establishments, and authorities, whether federal, state, local, foreign, or self-regulatory (including, but not limited to, organizations such as professional associations or licensing boards), authorized or with the responsibility to investigate, litigate, prosecute, enforce, or implement a statute, rule, regulation, or order, where the record or information, by itself or in connection with other records or information:

(a) Indicates a violation or potential violation of law, whether criminal, civil, administrative, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or order issued pursuant thereto, or

(b) Indicates a violation or potential violation of a professional, licensing, or similar regulation, rule or order, or otherwise reflects on the qualifications or fitness of an individual who is licensed or seeking to be licensed;

(2) To any source, private or governmental, to the extent necessary to secure from such source information relevant to and sought in furtherance of a legitimate investigation or audit;

(3) To agencies, offices, or establishments of the executive, legislative, or judicial branches of the federal or state government:

(a) Where such agency, office, or establishment has an interest in the individual for employment purposes, including a security clearance or determination as to access to classified information, and needs to evaluate the individual's qualifications, suitability, or loyalty to the United States Government, or

(b) Where an agency, office, or establishment conducts an investigation of the individual for purposes of granting a security clearance, or making a determination of qualifications, suitability, or loyalty to the United States Government or access to classified information or restricted areas, or

(c) Where the records or information in those records are relevant and necessary to a decision with regard to the hiring or retention of an employee or disciplinary or other administrative action concerning the employee, or

(d) Where disclosure is requested in connection with the award of a contract or other determination relating to a government procurement, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter, including but not limited to, disclosure to any Federal agency responsible for considering suspension or debarment action where such record would be germane to a determination of the propriety or necessity of such action, or disclosure to the United States General Accounting Office, the General Services Administration Board of Contract Appeals, or any other Federal contract board of appeals in cases relating to an agency procurement;

(4) To the Office of Personnel Management, the Office of Government Ethics, the Merit Systems Protection Board, the Office of Special Counsel, the Equal Employment Opportunity Commission, or the Federal Labor Relations Authority or its General Counsel, of records or portions thereof relevant and necessary to carry out their authorized functions, such as, but not limited to, rendering advice requested by the OIG, investigations of alleged or prohibited personnel practices (including unfair labor or discriminatory practices), appeals before official agencies, offices, panels or boards, and authorized studies or reviews of civil service or merit systems or affirmative action programs;

(5) To independent auditors or other private firms with which the OIG has contracted to carry out an independent audit or investigation, or to analyze, collate, aggregate or otherwise refine data collected in the system of records, subject to the requirement that such contractors shall maintain Privacy Act safeguards with respect to such records;

(6) To any authorized component of the ICC, the Department of Justice, or other law enforcement authority, and for disclosure by such parties:

(a) To the extent relevant and necessary in connection with litigation in proceedings before a court or other adjudicative body, where (i) the United States is a party to or has an interest in the litigation, including where the ICC, or an ICC component, or an ICC official or employee in his or her official capacity, or an individual ICC official or employee whom the Department of Justice has agreed to represent, is or may likely become a party, and (ii) the ligation is likely to affect the agency or any component thereof, or

(b) For purposes of obtaining advice, including advice concerning the accessibility of a record or information under the Privacy Act or the Freedom of Information Act;

(7) To the National Archives and Record Administration for records management inspections conducted under authority of 44 U.S.C. 2904 and 2096;

(8) To a Congressional office from the record of a subject individual in response to an inquiry from the Congressional office made at the request of the individual, but only to the extent that the record would be legally accessible to that individual;

(9) To any direct recipient of federal funds, such as a contractor, where such record reflects serious inadequacies with a recipient's personnel and disclosure of the record is for purpose of permitting a recipient to take corrective action beneficial to the Government;

(10) To debt collection contractors for the purposes of collecting debts owed to the Government, as authorized under the Debt Collection Act of 1982, 31 U.S.C. 3718, and subject to applicable Privacy Act safeguards;

(11) To a grand jury pursuant either to a federal or state grand jury subpoena, or to a prosecution request that such record be released for the purposes of its introduction to a grand jury where subpoena or request has been specifically approved by a court;

(12) To OMB for the purposes of obtaining advice regarding ICC obligations under the Privacy Act; or

(13) To the Secretary of the ICC for purpose of placing any ex parte communication, which has not already been reported to the Secretary pursuant to 49 CFR 1102.2(e), in the correspondence section of the appropriate public docket.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The OIG files consist of paper records maintained in binders or folders, and on automated data storage devices. Files are secured at all times.

RETRIEVABILITY:

Indexed on disk by case number. Paper records are filed numerically by case number. At this time, records are not cross-indexed by name and/or by subject but are expected to be retrieved in this fashion in the near future.

ACCESS CONTROL:

Access to the records is limited to authorized staff in OIG and to other

authorized officials or employees of ICC on a need-to-know basis as determined by the OIG. All records are kept in limited access areas during duty hours and in locked files at all other times.

RETENTION AND DISPOSAL:

To be retained for an unlimited period of time.

SYSTEM MANAGER AND ADDRESS:

Inspector General, OIG, ICC, room 2121, Washington, DC 20423.

NOTIFICATION PROCEDURE:

See 49 CFR Part 1007.

RECORD ACCESS PROCEDURE:

Same as above.

CONTESTING RECORD PROCEDURE:

Same as above.

RECORD SOURCE CATEGORIES:

Information in these records is obtained from all individuals and entities who may assist OIG in evaluating complaints and conducting investigations authorized by Pub. L. 100–504.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

This system is exempted from 5 U.S.C. 552a, except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11) and (i), under 552a(j)(2) to the extent the system of records pertains to the enforcement of criminal laws; and is exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f) under 5 U.S.C. 552a(k)(2), to the extent the system of records consists of investigatory materials compiled for law enforcement purposes, other than that material within the scope of the exemption at 5 U.S.C. 552a(j)(2).

5 U.S.C. App. 3 (1978) prohibits disclosure by the OIG of the identity of any employee, without the consent of the employee, who submits a complaint or provides information concerning the possible existence of an activity constituting a violation of law, rules or regulations, or mismanagement, gross waste of funds, abuse of authority, or a substantial and specific danger to the public health or safety.

Decided: December 21, 1992.

By the Commission, S. Arnold Smith, Freedom of Information/Privacy Officer.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–251 Filed 1–5–93; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 32189]

The Broe Cos., Inc.; Continuance in Control Exemption; Central Kansas Railway, Inc.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission, under 49 U.S.C. 10505, exempts The Broe Companies, Inc. from the regulatory requirements of 49 U.S.C. 11343, *et seq.*, for its continuance in control of Central Kansas Railway, Inc. (CKR) once CKR becomes a rail carrier.[1]

DATES: This exemption is effective on December 31, 1992. Petitions to reopen must be filed by January 26, 1993.

ADDRESSES: Send pleadings referring to Finance Docket No. 32189 to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioners' representatives: Louis E. Gitomer, Suite 210, 919 18th Street, NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder, (202) 927–5610.

[TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721].

Decided: December 23, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–179 Filed 1–5–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–3 (Sub-No. 104X)]

Missouri Pacific Railroad Co., Abandonment Exemption; In Muskogee, McIntosh and Haskell Counties, OK

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from the prior approval requirements of 49 U.S.C. 10903–10904 the Abandonment by Missouri Pacific Railroad Company of 43.0 miles of its Midland Valley Branch between Shopton and Kerr McGee, OK, subject to standard labor protective conditions, environmental and historic preservation conditions, and a public use condition. In addition, interim trail use has been approved.

DATES: Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on February 5, 1993. Formal expressions of intent to file an offer[1] of financial assistance under 49 CFR 1152.27(c)(2) must be filed by January 16, 1993; petitions to stay must be filed by January 19, 1993; and petitions to reopen must be filed by February 1, 1993.

ADDRESSES: Send pleadings referring to Docket No. AB–3 (Sub-No. 104X) to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423, and

(2) Petitioner's representatives: Joseph D. Anthofer, Jeanna L. Regier, 1416 Dodge Street, #830, Omaha, NE 68179.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder (202) 927–5610, [TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5271.]

Decided: December 29, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–277 Filed 1–5–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–12 (Sub-No. 148X)]

Southern Pacific Transportation Company—Abandonment Exemption—In Tyler, Jasper, and Angelina Counties, TX

Southern Pacific Transportation Company (SP) has filed a notice of exemption under 49 CFR part 1152

[1] CKR is acquiring approximately 890 miles of railroad from The Atchison, Topeka and Santa Fe Railway Company. See Finance Docket No. 32190, Central Kansas Railway, Inc.—Acquisition and Operation Exemption—Certain Lines of The Atchison, Topeka and Santa Fe Railway Company (notice of exemption filed December 10, 1992).

[1] *See Exempt. of Rail Abandonment—Offers of Finan. Assist.*, 4 I.C.C.2d 164 (1987).

Subpart F—Exempt Abandonments to abandon a 32.05-mile portion of its Rockland Branch rail line in Tyler, Jasper, and Angelina Counties, TX, between milepost 76.85, at or near the Hillister rail station, and milepost 108.90, at or near the Dolan rail station.

SP has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic has been rerouted over other lines; and (3) no formal complaint filed by a user of rail service on the line (or a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or any U.S. District Court or has been decided in favor of a complainant within the 2-year period. SP also has been certified that it has complied with the requirements at 49 CFR 1152.50(d)(1) (notice to government agencies), 49 CFR 1105.12 (newspaper publication), 49 CFR 1105.7, and 49 CFR 1105.8.

As a condition to this exemption, any employee affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 6, 1993, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking statements under 49 CFR 1152.29 must be filed by January 19, 1993.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 27, 1993 with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Gary A. Laakso, Southern Pacific Building, One Market Plaza, room 846, San Francisco, CA 94105.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

Applicant has filed an environmental report which addresses the abandonment's effects, if any, on the environmental or historic resources.

The Section of Energy and Environment (SEE) will issue an environmental assessment (EA) by January 12, 1993. Interested persons may obtain a copy of the EA from SEE by writing to it (Room 3219, Interstate Commerce Commission Building, Washington, DC 20423) or by calling Elaine Kaiser, Chief, SEE, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: December 28, 1992.

By the Commission, Julia M. Farr, Acting Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–178 Filed 1–5–93; 8:45 am]

BILLING CODE 7035–01–M

[1] A stay will be routinely issued by the Commission in these proceedings where an informed decision on environmental issues (whether raised by a party or by the Section of Energy and Environment in its independent investigation) cannot be made prior to the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible to permit this Commission to review and act on the request before the effective date of this exemption.

[2] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[3] The Commission will accept late-filed trail use statements so long as it retains jurisdiction to do so.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Registration

By Notice dated November 16, 1992, and published in the **Federal Register** on November 23, 1992, (57 FR 55000), North Pacific Trading Company, 1505 SE Gideon Street, Portland, Oregon 97202, made application to the Drug Enforcement Administration to be registered as an importer of Marihuana (7370), a basic class of controlled substance listed in Schedule I.

No comments or objections have been received. Therefore, pursuant to section 1008(a) of the Controlled Substances Import and Export Act and in accordance with title 21 Code of Federal Regulations § 1311.42, the above firm is granted registration as a importer of the basic class of controlled substance listed above.

Dated: December 29, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93–236 Filed 1–5–93; 8:45 am]

BILLING CODE 4410–09–M

Importation of Controlled Substances; Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958(i)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 1311.42 of title 21, Code of Federal Regulations (CFR), notice is hereby given that on December 3, 1992, Research Biochemicals Inc., One Strathmore Road, Natick, Massachusetts 01760, made a written request to the Drug Enforcement Administration to be registered as an importer of Morphine (9300) a basic class of controlled substance in Schedule II. The firm plans to import 2 grams of morphine-6 glucuronide for research purposes.

Any manufacturer holding, or applying for, registration as a bulk manufacturer of this basic class of controlled substance may file written comments on or objections to the application described above and may, at the same time, file a written request for a hearing on such application in accordance with 21 CFR 1301.54 in such form as prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR), and must be filed no later than February 5, 1993.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1311.42(b), (c), (d), (e), and (f). As noted in a previous notice at 40 FR 43745–46 (September 23, 1975), all applicants for registration to import a basic class of any controlled substance in Schedule I or II are and will continue to be required to demonstrate to the Deputy Assistant

Administrator of the Drug Enforcement Administration that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1311.42(a), (b), (c), (d), (e), and (f) are satisfied.

Dated: December 28, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93–235 Filed 1–5–93; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Registration

By notice dated November 16, 1992, and published in the **Federal Register** on November 23, 1992, (57 FR 55002), Toxi-Lab, Inc., 2 Goodyear, Irvine, California 92718, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Phencyclidine (7471)	II
1-Piperidinocyclohexanecarbonitrile (8603).	II
Benzoylecgonine (9180)	II

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations § 1301.54(e), the Deputy Assistant Administrator hereby orders that the application for registration submitted by the above firm for registration as a bulk manufacturer of the basic classes of controlled substances listed above is granted.

Dated: December 29, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93–238 Filed 1–5–93; 8:45 am]

BILLING CODE 4410-09-M

Manufacturer of Controlled Substances; Registration

By Notice dated November 16, 1992, and published in the **Federal Register** on November 23, 1992, (57 FR 52002), Upjohn Company, 7171 Portage Road, Kalamazoo, Michigan 49001, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of 2,5-Dimethoxyamphetamine (7396), a basic class of controlled substance listed in Schedule I.

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations § 1301.54(e), the Deputy Assistant Administrator hereby orders that the application for registration submitted by the above firm for registration as a bulk manufacturer of the basic class of controlled substance listed above is granted.

Dated: December 29, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93–237 Filed 1–5–93; 8:45 am]

BILLING CODE 4410-09-M

Office of Justice Programs

Office for Victims of Crime; FY 1993 Assistance to Victims of Federal Crime in Indian Country Discretionary Grant Program Application Kit

AGENCY: Office of Justice Programs, Office for Victims of Crime, DOJ.

ACTION: Public announcement of the availability of the FY 1993 Assistance to Victims of Federal Crime in Indian Country Discretionary Grant Program Application Kit for first-time applicants.

SUMMARY: The Office for Victims of Crime (OVC) is publishing this Notice of availability of the FY 1993 Discretionary Grant Application Kit for the State agencies appointed by the Governors in Alabama, Colorado, Iowa, Louisiana, Mississippi, Nebraska, North Carolina, and Texas.

DATES: Applications must be submitted to the Office for Victims of Crime by the due date indicated in the Application Kit.

ADDRESSES: Applications should be addressed to the Office for Victims of Crime, Federal Crime Victims Division, room 1386, 633 Indiana Avenue, NW., Washington, DC 20531. To obtain a copy of the Application Kit, call (202) 616–3579.

FOR FURTHER INFORMATION CONTACT: Toni Thomas, Program Specialist, at the above address. Telephone: (202) 514–6444.

SUPPLEMENTARY INFORMATION:

Authority

The action is authorized under Sec. 1404(c)(1)(B) of the Victims of Crime Act of 1984 (VOCA), as amended, 42 U.S.C. 10603(c)(1)(B).

Background

In 1988 OVC initiated a program of making grants to State victim assistance programs for the purpose of awarding subgrants to Indian tribes or tribal organizations. This has resulted in the expansion of victim assistance programs in tribal communities in 15 different States. These States are working with Indian tribes to enhance the network of services developed by using a combination of Federal, State and tribal funds. OVC now plans to extend this successful program so that other tribes in areas of Federal jurisdiction can work with State victim assistance programs to establish victim assistance services in their communities.

On November 4, 1992, the Office for Victims of Crime, published a Notice in the **Federal Register**, 57 FR 52639, announcing the FY 1993 Comprehensive Discretionary Program Plan. That publication announced the availability of $250,000 to eligible States for Assistance to Victims of Federal Crime in Indian Country. The Assistance to Victims of Federal Crime in Indian Country Discretionary Grant Application Kit, announced herein, expands upon information provided in the program plan and defines specific application requirements and deadlines.

Brenda G. Meister,

Acting Director, Office for Victims of Crime.

[FR Doc. 93–91 Filed 1–5–93; 8:45 am]

BILLING CODE 4410-18-M

DEPARTMENT OF LABOR

Office of the Secretary

Glass Ceiling Commission; Open Meeting

SUMMARY: Pursuant to title II of the Civil Rights Act of 1991 (Pub. L. 102–166) and section 9 of the Federal Advisory Committee Act (FACA) (Pub. L. 92–462, 5 U.S.C. app. II) a Notice of Establishment of the Glass Ceiling Commission was published in the **Federal Register** on March 30, 1992 (57 FR 10776). Pursuant to section 10(a) of FACA, this is to announce a meeting of the Commission which is to take place on Monday, January 25, 1993.

The purpose of the Commission is to, among other things, focus greater attention on the importance of eliminating artificial barriers to the advancement of minorities and women to management and decision making positions in business. The Commission has the practical task of:

(a) Conducting basic research into the practices, policies and manner in which

management and decision making positions in business are filled;

(b) Conducting comparative research of businesses and industries in which minorities and women are promoted to management and decision making positions, and businesses and industries in which minorities and women are not promoted to such positions; and

(c) Recommending measures designed to enhance opportunities for and the elimination of artificial barriers to the advancement of minorities and women to management and decision making positions.

TIME AND PLACE: The meeting will be held on Monday, January 25, 1993 from 10 a.m. to 5 p.m. at the U.S. Department of Labor, 200 Constitution Avenue, NW., room C–2313, Washington, DC.

AGENDA: The agenda for the meeting is as follows:

(a) Introduction of Commission Members;

(b) Discussion of procedures to be followed in conducting Commission business;

(c) Discussion of Commission objectives including, to the extent practicable, a delineation of specific tasks and projected time frames for achieving such objectives; and

(d) Ancillary considerations attendant to ongoing Commission activities.

PUBLIC PARTICIPATION: The meeting will be open to the public. Seating will be available to the public on a first-come, first-served basis. Seats will be reserved for the media. Handicapped individuals should contact the Commission if special accommodations are needed. Individuals or organizations wishing to submit written statements should send thirty (30) copies to Mrs. Elizabeth Leonard, Executive Director, Glass Ceiling Commission, U.S. Department of Labor, 200 Constitution Avenue, NW., room S–2018, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mrs. Elizabeth Leonard, Executive Director, Glass Ceiling Commission, U.S. Department of Labor, 200 Constitution Avenue, NW., room S–2018, Washington, DC 20210, (202) 219–8271.

Signed at Washington, DC this 30th day of December, 1992.

Lynn Martin,

Secretary of Labor.

[FR Doc. 93–160 Filed 1–5–93; 8:45 am]

BILLING CODE 4510–23–M

Employment and Training Administration

[TA–W–27,816, TA–W–27,817, TA–W–27,818]

Lally Manufacturing Corp.; Adams, New York, New York Mill, NY and Port Leyden, NY; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18 an application for administrative reconsideration was filed with the Director of the Office of Trade Adjustment Assistance for workers at Lally Manufacturing Corporation, Adams, New York, New York Mill, New York and Port Leyden, New York. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–27,816, TA–W–27,817, TA–W–27,818; Lally Manufacturing Corporation, Adams, New York, New York Mill, New York and Port Leyden, New York (December 30, 1992)

Signed at Washington, DC this 30th day of December, 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93–159 Filed 1–5–93; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 211(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 18, 1993.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 18, 1993.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC this 21st day of December, 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition number	Artices produced
Philips Consumer (workers)	Jefferson City, TN	12/21/92	12/08/92	28,109	TV cabinets.
Superior Technology, Inc (IBEW)	Paris, TX	12/21/92	12/03/92	28,110	Meter boxes.
West Tech, Inc./Van Dale, Inc. (workers)	Long Lake, MN	12/21/92	12/11/92	28,111	Farm machinery.
General Atronics Corp., cathode ray (workers)	Philadelphia, PA	12/21/92	12/15/92	28,112	Cathode ray tubes.
Air City Models and Tools (IAMAW)	Dayton, OH	12/21/92	12/12/92	28,113	Dasnboard foam for GM autos.
General Motors-Inland Fisher Guide (workers)	Syracuse, NY	12/21/92	12/09/92	28,114	Plastic auto trim.
The Bargman Company (GMP)	Coldwater, MI	12/21/92	12/10/92	28,115	RV accessories.
Hitachi Zosen Clearing, Inc. (workers)	Chicago, IL	12/21/92	12/07/92	28,116	Metal stamping presses, etc.
Oil Dynamics, Inc. (workers)	Tulsa, OK	12/21/92	12/10/92	28,117	Submersible pumping systems.
Struthers-Dunn (IUE)	Pitman, NJ	12/21/92	12/04/92	28,118	Electrical mechanical relays.
Hercules, Inc. (OCAW)	Burlington, NJ	12/21/92	11/30/92	28,119	Modified resins and plasticizers.
Accessories Unlimited of Maine (workers)	Cornish, ME	12/21/92	12/07/92	28,120	Luggage and handbags.
Moline Corp. (GMPPA)	Belvidere, IL	12/21/92	12/09/92	28,121	Cast, malleable iron products.
Moline Corp. (GMPPA)	St. Charles, IL	12/21/92	12/09/92	28,122	Cast, malleable iron products.
Klasic Div. of KLA (workers)	San Jose, CA	12/21/92	12/04/92	28,123	Servicing equipment.
Valeo Climate Control Corp. (UAW)	Fort Worth, TX	12/21/92	12/04/92	28,124	Auto air conditioners & component parts.

APPENDIX—Continued

Petitioner (union/workers/firm)	Location	Date received	Date of petition	Petition number	Artices produced
Florsheim Shoe Co. (UFCW)	Anna, IL	12/21/92	11/17/92	28,125	Men's dress shoes.
General Electric Co., OH Lamp Plant (workers)	Warren, OH	12/21/92	11/09/92	28,126	Decorative lamps.
E.G. & G Vactec Optoelectronics (UAW)	St. Louis, MO	12/21/92	12/11/92	28,127	Optoelectronic devices.
Mona Lisa Coat (ILGWU)	Hoboken, NJ	12/21/92	12/09/92	28,128	Coats and suits.
Felters Company (workers)	Millbury, MA	12/21/92	12/08/92	28,129	Wet processing goods.
Wells Oilfield Specialties, Inc. (workers)	Coalinga, CA	12/21/92	11/30/92	28,130	Oil and gas.
Wells Oilfield Specialties, Inc. (workers)	Bakersfield, CA	12/21/92	11/30/92	28,131	Downhold oilfield pumps.
Teledyne Vasco (USWA)	Latrobe, PA	12/21/92	12/07/92	28,132	Specialty steel.
Distel Tool & Machine Co. (UAW)	Warren, MI	12/21/92	12/08/92	28,133	Large stamping dies.
AT & T Technologies (workers)	Oklahoma City, OK	12/21/92	12/07/92	28,134	Cables.
Allied Tube & Conduit (Co.)	Liberty, TX	12/21/92	10/29/92	28,135	Steel pipe & tubing.
Goodyear Tire & Rubber Co. (URW)	Logan, OH	12/21/92	12/09/92	28,136	Instrument panels for autos.
Coca-Cola Bottling Co. of NY (IBT)	Paterson, NJ	12/21/92	12/08/92	28,137	Carbonated beverages.
JIK Ltd. (workers)	Allentown, PA	12/21/92	11/27/92	28,138	Women's sportswear.
GTE (workers)	Potosi, MO	12/21/92	12/01/92	28,139	Public telephone services.
Paterson Canning Co. (IBT)	Paterson, NJ	12/21/92	12/08/92	28,140	Carbonated beverages.
Cleaver Brooks (LIU)	Lebanon, PA	12/21/92	12/08/92	28,141	Steam and hot water generated boilers.
HOMCO International, Inc. (workers)	Bakersfield, CA	12/21/92	11/01/92	28,142	Oil.

Job Training Partnership Act; Announcement of Proposed Noncompetitive Grant Awards

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of intent to award a noncompetitive grant.

SUMMARY: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to The Association for Manufacturing Technology, McLean, Virginia, for the provision of specialized services under the authority of the Job Training Partnership Act (JTPA).

DATES: It is anticipated that this grant award will be executed by January 29, 1993, and will be funded for twelve months. Submit comments by 4:45 p.m. (Eastern Time), on January 21, 1993.

ADDRESSES: Submit comments regarding this proposed assistance award to: U.S. Department of Labor, Employment and Training Administration, room C–4305, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Reda Harrison: Reference FR–DAA–008–92.

SUPPLEMENTARY INFORMATION: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to The Association for Manufacturing Technology (AMT) of McLean, Virginia, in accordance with the Department of Labor Manual Series (DLMS), Volume No. 2, section 836(g)(5). AMT will produce a series of national satellite teleconferencing programs on state of the art manufacturing technology designed to accelerate the implementation of advanced manufacturing technology methods for U.S. machine tool manufacturers. In line with DOL's Technical & Education Assistance for Mid- and Small-sized firms (TEAMS) initiative, AMT will test teleconferencing as a methodology for building small firm networks to train workers for high performance. The majority of member companies which will participate in the downlink broadcasts employs less than 70 persons. AMT's ultimate goal through the BETA series broadcast is to establish highly replicable outcomes for the U.S. machine tool and other industries in need of increasing the skills of their workforce.

Funds for this activity are authorized by the Job Training Partnership Act, as amended, Title IV—Federally Administered Programs. The proposed funding is approximately $100,000 for twelve months.

Signed at Washington, DC on December 17, 1992.

Robert D. Parker,

ETA Grant Officer.

[FR Doc. 93–157 Filed 1–5–93; 8:45 am]

BILLING CODE 4510–30–M

Job Training Partnership Act; Announcement of Proposed Noncompetitive Grant Award

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of intent to award a noncompetitive grant.

SUMMARY: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the Bay State Center for Applied Technology of Boston, Massachusetts to participate in the development and operation of a comprehensive network of small machine shops in Western Massachusetts.

DATES: It is anticipated that this grant award will be executed by January 29, 1993, and will be funded for twenty-four months. Submit comments by 4:45 p.m. (Eastern Time), on January 21, 1993.

ADDRESSES: Submit comments regarding this proposed assistance award to: U.S. Department of Labor, Employment and Training Administration, room C–4305, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Laura Cesario; Reference FR–DAA–010–92.

SUPPLEMENTAL INFORMATION: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the Bay State Center for Applied Technology, in accordance with the Department of Labor Manual Series (DLMS), Volume No. 2, section 836(g)(4). The Bay State Center for Applied Technology will be part of a partnership to develop a comprehensive skills upgrading program that will be combined with industrial modernization strategies for small and mid-sized firms. The partnership will consist of the State of Massachusetts, the Western Massachusetts National Tooling and Machining Association, and the Western Massachusetts Precision Institute. This project will support the Department of Labor Technical and Education Assistance for Mid- and Small-sized firms (TEAMS) goal to support the provision of a broad range of services in the areas of technical training and work restructuring. The partnership with the Bay State Center for Applied Technology supports the goals of TEAMS in its development and operation of a comprehensive network of small machine shops in Western Massachusetts.

Funds for this activity are authorized by the Job Training Partnership Act, as amended, Title IV—Federally Administered Programs. The proposed funding is approximately $200,000 for twenty-four months.

Signed at Washington, DC on December 17, 1992.

Robert D. Parker,

ETA Grant Officer.

[FR Doc. 93–155 Filed 1–5–93; 8:45 am]

BILLING CODE 4510-30-M

Job Training Partnership Act; Announcement of Proposed Noncompetitive Grant Award

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of intent to award a noncompetitive grant.

SUMMARY: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the United Auto Workers Labor Employment and Training Company of New York, New York to develop a model approach for training and human resource development for small and mid-size firms in the international trade and financial sectors.

DATES: It is anticipated that this grant award will be executed by January 29, 1993, and will be funded for six months. Submit comments by 4:45 p.m. (Eastern Time), on January 21, 1993.

ADDRESSES: Submit comments regarding this proposed assistance award to: U.S. Department of Labor, Employment and Training Administration, room C–4305, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Laura Cesario; Reference FR–DAA–011–92.

SUPPLEMENTARY INFORMATION: The Employment and Training Administration (ETA) announces its intent to award a noncompetitive grant to the United Auto Workers Labor and Employment Company (UAW–LETC), in accordance with the Department of Labor Manual Series (DLMS), Volume No. 2, section 836(g)(4). In cooperation with the Port Authority of New York and the UAW–LETC, a model approach for training and human resource development for small and mid-size firms in the international trade and financial sectors would be developed. The partnership will assist World Trade Center companies in meeting their human resource needs by offering placement, training and other human resource services, specifically tailored to the needs of those companies. This project will support the Department of Labor Technical and Education Assistance for Mid- and Small-sized firms (TEAMS) goal to support the provision of a broad range of services in the areas of technical training and work restructuring. The partnership with the UAW–LETC presents a unique opportunity to develop worker skill assessment tools for use on a national basis in the service sector of the economy, an area of significant importance to the TEAMS outreach program, and one in which TEAMS needs to develop technical assistance tools.

Funds for this activity are authorized by the Job Training Partnership Act, as amended, Title IV—Federally Administered Programs. The proposed funding is approximately $75,000 for six months.

Signed at Washington, DC on December 17, 1992.

Robert D. Parker,

ETA Grant Officer.

[FR Doc. 93–156 Filed 1–5–93; 8:45 am]

BILLING CODE 4510-30-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 92–79]

Landsat Advisory Process

AGENCY: National Aeronautics and Space Administration.

ACTION: Request for public advice and comments.

SUMMARY: This request for public advice and comments is issued pursuant to Public Law 102–555, the Land Remote Sensing Policy Act of 1992, dated October 1992. Section 101(e) of this Law requires the Landsat Program Management to seek impartial advice and comments regarding the status, effectiveness, and diversity of the program plans from individuals who represent a broad range of public and private sector perspectives and a full spectrum of interest in the Landsat program and other data and services it provides. Those wishing to provide such advice and comments, via a survey which will be used as input for a report to Congress, can obtain further information on the Landsat advisory process by contacting Stanley R. Schneider, Landsat Advisory Process Coordinator, National Aeronautics and Space Administration, Code SED, 300 E Street, SW., Washington, DC 20546. Fax: (202) 358–3098.

DATES: Comments must be received on or before February 1, 1993.

FOR FURTHER INFORMATION CONTACT: Stanley R. Schneider at the address above.

Dated: December 30, 1992.

L.A. Fisk,

Associate Administrator for Space Science and Applications.

[FR Doc. 93–191 Filed 1–5–93; 8:45 am]

BILLING CODE 7510-01-M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–269, 50–270, and 50–287]

Duke Power Co.; Oconee Nuclear Station, Unit Nos. 1, 2, and 3; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility Operating License Nos. DPR–38, DPR–47, and DPR–55 issued to the Duke Power Company (the licensee), for operation of the Oconee Nuclear Station, Units 1, 2, 3, located in Oconee County, South Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would revise the limitations on concentrations of radioactive material released in liquid effluents and the limitations on the dose rate resulting from radioactive material released in gaseous effluents, and reflect the relocation of the prior 10 CFR 20.106 requirements to the new 10 CFR 20.1302. These changes are in response to the new 10 CFR part 20. The review of an additional item, to revise the BASES for the liquid holdup tank TS, was not completed and consequently is not included in the amendment. It will be addressed by separate correspondence.

The Need for the Proposed Action

The proposed action is needed in order to retain operational flexibility consistent with 10 CFR part 50, Appendix I, concurrent with the implementation of the revised 10 CFR part 20.

Environmental Impacts of the Proposed Action

The proposed revision does not change the actual release rates as referenced in the TS as a dose rate to the maximally exposed member of the public. Therefore, there will be no increase in the types or amounts of effluents that may be released offsite, nor an increase in individual or cumulative occupational radiation exposures. Therefore, the Commission

concludes that there are no significant radiological environmental impacts associated with the proposed changes.

With regard to potential nonradiological impacts, the proposed changes do not affect nonradiological effluent and have no other environmental impact. Therefore, the Commission concludes that there are no significant non-radiological impacts associated with the proposed changes.

Alternative to the Proposed Action

Since the Commission's staff has concluded that there is no significant environmental impact associated with the proposed changes to the TS, any alternative to the amendments will have either no significantly different environmental impact or greater environmental impact. The principal alternative would be to deny the requested amendments. This would not reduce environmental impacts as a result of plant operation.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in connection with the Final Environmental Statement related to the operation of the Oconee Nuclear Station, Units 1, 2, and 3, dated March 1972.

Agencies and Persons Consulted

The Commission's staff did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendments.

Based on the above environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further information with respect to this action, see the application dated November 5, 1992, as supplemented December 9 and 18, 1992, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC and at the Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina.

Dated at Rockville, Maryland, this 30th day of December 1992.

For the Nuclear Regulatory Commission.

Timothy A. Reed,

Acting Director, Project Directorate II–3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93–170 Filed 1–5–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–369 and 50–370]

Duke Power Co., McGuire Nuclear Station, Unit Nos. 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility Operating License Nos. NPF–9 and NPF–17 issued to the Duke Power Company (the licensee), for operation of the McGuire Nuclear Station, Units 1 and 2, located in Mecklenburg County, North Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would revise the limitations on concentrations of radioactive material released in liquid effluents and the limitations on the dose rate resulting from radioactive material released in gaseous effluents, and reflect the relocation of the prior 10 CFR 20.106 requirements to the new 10 CFR 20.1302. These changes are in response to the new 10 CFR part 20. The review of an additional item, to revise the BASES for the liquid holdup tank TS, was not completed and consequently is not included in the amendment. It will be addressed by separate correspondence.

The Need for the Proposed Action

The proposed action is needed in order to retain operational flexibility consistent with 10 CFR part 50, appendix I, concurrent with the implementation of the revised 10 CFR part 20.

Environmental Impacts of the Proposed Action

The proposed revision does not change the actual release rates as referenced in the TS as a dose rate to the maximally exposed member of the public. Therefore, there will be no increase in the types or amounts of effluents that may be released offsite, nor an increase in individual or cumulative occupational radiation exposures. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed changes.

With regard to potential nonradiological impacts, the proposed changes do not affect nonradiological effluent and have no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological impacts associated with the proposed changes.

Alternative to the Proposed Action

Since the Commission's staff has concluded that there is no significant environmental impact associated with the proposed changes to the TS, any alternative to the amendments will have either no significantly different environmental impact or greater environmental impact. The principal alternative would be to deny the requested amendments. This would not reduce environmental impacts as a result of plant operation.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in connection with the Final Environmental Statement related to the operation of William B. McGuire Nuclear Station, Units 1 and 2 dated April 1976, and its addendum dated January 1981.

Agencies and Persons Consulted

The Commission's staff did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendments.

Based on the above environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further information with respect to this action, see the application dated November 5, 1992, as supplemented December 9 and 18, 1992, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC and at the Atkins Library, University of North Carolina (UNCC Station), North Carolina 28223.

Dated at Rockville, Maryland, this 30th day of December, 1992.

For the Nuclear Regulatory Commission.

Timothy A. Reed,

Acting Director, Project Directorate II–3, Division of Reactor Projects—I/II Office of the Nuclear Reactor Regulation.

[FR Doc. 93–169 Filed 1–5–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–413 and 50–414]

Duke Power Co., et al., Catawba Nuclear Station, Unit Nos. 1 and 2; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of amendments to Facility

Operating License Nos. NPF–35 and NPF–52 issued to the Duke Power Company (the licensee), for operation of the Catawba Nuclear Station, Units 1 and 2, located in York County, South Carolina.

Environmental Assessment

Identification of Proposed Action

The proposed action would revise the limitations on concentrations of radioactive material released in liquid effluents and the limitations on the dose rate resulting from radioactive material released in gaseous effluents, and reflect the relocation of the prior 10 CFR 20.106 requirements to the new 10 CFR 20.1302. These change are in response to the new 10 CFR part 20. The review of an additional item, to revise the BASES for the liquid holdup tank TS, was not completed and consequently is not included in the amendment. It will be addressed by separate correspondence.

The Need for the Proposed Action

The proposed action is needed in order to retain operational flexibility consistent with 10 CFR part 50, appendix I, concurrent with the implementation of the revised 10 CFR part 20.

Environmental Impacts of the Proposed Action

The proposed revision does not change the actual release rates as referenced in the TS as a dose rate to the maximally exposed member of the public. Therefore, there will be no increase in the types or amounts of effluents that may be released offsite, nor an increase in individual or cumulative occupational radiation exposures. Therefore, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed changes.

With regard to potential nonradiological impacts, the proposed changes do not affect nonradiological effluent and have no other environmental impact. Therefore, the Commission concludes that there are no significant nonradiological impacts associated with the proposed changes.

Alternative to the Proposed Action

Since the Commission's staff has concluded that there is no significant environmental impact associated with the proposed changes to the TS, any alternative to the amendments will have either no significantly different environmental impact or greater environmental impact. The principal alternative would be to deny the requested amendments. This would not reduce environmental impacts as a result of plant operation.

Alternative Use of Resources

This action does not involve the use of resources not previously considered in connection with the Final Environmental Statement related to the operation of the Catawba Nuclear Station, Units 1 and 2, dated January 1983.

Agencies and Persons Consulted

The Commission's staff did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the proposed license amendments.

Based on the above environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment.

For further information with respect to this action, see the application dated November 5, 1992, as supplemented December 9 and 18, 1992, which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC and at the York County Library, 138 East Black Street, Rock Hill, South Carolina.

Dated at Rockville, Maryland, this 30th day of December, 1992.

For the Nuclear Regulatory Commission.

Timothy A. Reed,

Acting Director, Project Directorate II–3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93–168 Filed 1–5–93; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–245]

Northeast Nuclear Energy Co., Millstone Nuclear Power Station, Unit 1; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of a one-time exemption from 10 CFR 50, appendix J, paragraph III.A.6(b) to the Northeast Nuclear Energy Company (NNECO or the licensee) for Millstone Nuclear Power Station, Unit 1, located in New London County, Connecticut.

Environmental Assessment

Identification of the Proposed Action

The proposed action would grant a one-time exemption to provide relief from the accelerated Type A containment integrated leak rate test frequency required by appendix J to 10 CFR part 50 when two consecutive Type A tests have failed to meet their acceptance criteria.

The Need for the Proposed Action

One of the conditions of all operating licenses for water-cooled power reactors, as specified in 10 CFR 50.54(o), is that primary reactor containments shall meet the containment leakage test requirements set forth in 10 CFR part 50, appendix J.

Appendix J to 10 CFR part 50, paragraph III.A.6(b), requires, in part, that if two consecutive periodic Type A tests fail to meet the applicable acceptance criteria in III.A.5(b), a Type A test shall be performed at each plant shutdown for refueling or approximately 18 months, whichever occurs first, until two consecutive Type A tests meet the acceptance criteria in III.A.5(b), after which time the normal retest schedule specified in III.D (three tests in 10 years) may be resumed.

NRC Information Notice (IN) No. 85–71 states that licensees may submit a Corrective Action Plan (CAP) with an alternate leakage test program proposal as an exemption request for NRC staff review if it is determined that Type B and C leakage rates constitute the identified contributor to the failure of the two Type A tests. If the CAP and alternate leakage rate test program is approved, the licensee is allowed to implement the corrective action and alternate leakage rate test program in lieu of the required increase in Type A test frequency.

Millstone Unit 1 experienced failures of the "As-Found" Type A tests in 1987 and 1991, therefore, a test is required to be performed during the present operating cycle in late December 1992 or January 1993. In order to perform this required Type A test, Millstone Unit 1 would have to undergo a forced shutdown. Such a shutdown would result in an increase in occupational radiation exposure and an additional transient on the plant.

Because the licensee determined that Type C local leakage rates were the reason for the "As-Found" Type A test failures, NNECO submitted a CAP with an alternate leakage test program proposal in lieu of the required accelerated testing and a request for exemption from 10 CFR 50, Appendix J, Paragraph III.A.6(b).

Environmental Impacts of the Proposed Action

The proposed action would provide a one-time exemption from the accelerated Type A containment integrated leak rate test frequency

required by appendix J to 10 CFR part 50 when two consecutive Type A tests have failed to meet their acceptance criteria. The NRC staff has reviewed the proposed exemption and concluded that the licensee's CAP and alternate leakage rate test program are acceptable. The NRC staff finds that the CAP and alternate leakage rate test program are an acceptable alternative to the increased Type A test frequency (every 18 months) and that there is reasonable assurance that the containment leakage-limiting function will be maintained. Therefore, the subject exemption is acceptable and the licensee will return to the normal test schedule of three tests in 10 years. With the normal test schedule, Type A tests would be scheduled to be performed at the next two plant shutdowns for refueling (currently expected to be in 1994 and 1996).

Thus, radiological releases will not differ from those determined previously and the proposed exemption does not otherwise affect facility radiological effluent or occupational exposures. With regard to potential nonradiological impacts, the proposed exemption does not affect plant nonradiological effluents and have no other environmental impact. Therefore, the Commission concludes there are no measurable radiological or nonradiological environmental impacts associated with the proposed exemption.

Alternatives to the Proposed Action

Since the Commission has concluded there is no measurable environmental impact associated with the proposed exemptions, any alternatives with equal or greater environmental impact need not be evaluated. The principal alternative to the exemptions would be to deny the exemptions requested. Such action would not enhance the protection of the environment.

Alternative Use of Resources

This action does not involve the use of resources not considered previously in the Final Environmental Statement for Millstone Nuclear Power Station, Unit 1.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

Finding of No Significant Impact

Based on the foregoing environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed exemptions.

For further details with respect to this proposed action, see the licensee's letter dated November 4, 1992, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room located at the Learning Resources Center, Thames Valley State Technical College, 574 New London Turnpike, Norwich, Connecticut 06360.

Dated at Rockville, Maryland this 30th day of December, 1992.

For the Nuclear Regulatory Commission.

John F. Stolz,

Director, Project Directorate I–4, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93–172 Filed 1–5–93; 8:45 am]

BILLING CODE 7590–01–M

Biweekly Notice

Applications and Amendments to Operating Licenses Involving No Significant Hazards Considerations

I. Background

Pursuant to Public Law (P.L.) 97-415, the Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly notice. P.L. 97-415 revised section 189 of the Atomic Energy Act of 1954, as amended (the Act), to require the Commission to publish notice of any amendments issued, or proposed to be issued, under a new provision of section 189 of the Act. This provision grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from December 12, 1992, through December 23, 1992. The last biweekly notice was published on December 23, 1992 (57 FR 61105).

Notice Of Consideration Of Issuance Of Amendment To Facility Operating License, Proposed No Significant Hazards Consideration Determination, And Opportunity For a Hearing

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P-223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By February 5, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room for the particular facility involved. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the

Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) the nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received before action is taken. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1-(800) 325-6000 (in Missouri 1-(800) 342-6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to (Project Director): petitioner's name and telephone number, date petition was mailed, plant name, and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of factors specified in 10 CFR 2.714(a)(1)(i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room for the particular facility involved.

Arizona Public Service Company, et al., Docket Nos. STN 50-528, STN 50-529, and STN 50-530, Palo Verde Nuclear Generating Station, Unit Nos. 1, 2, and 3, Maricopa County, Arizona

Date of amendment requests: November 20, 1992

Description of amendment requests: The amendment requests propose to increase the allowable out-of-service time for the Core Operating Limit Supervisory System (COLSS) from one hour to four hours before the more restrictive limits based on the Core Protection Calculators (CPCs) must be applied.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensees have provided their analysis about the issue of no significant hazards consideration, which is presented below:

Standard 1 -- Involve a significant increase in the probability or consequences of an accident previously evaluated.

This proposed amendment distinguishes between the ACTION requirements applicable when COLSS is either in service or out of service. If COLSS is in service the ACTIONs and time requirements remain unchanged. When COLSS is out of service the requirement for initiating corrective action within 15 minutes is replaced with the requirement to restore linear heat rate (LHR)

and departure from nucleate boiling ratio (DNBR) within 4 hours. The purpose of the proposed amendment is to provide a reasonable opportunity for appropriate corrective actions when the COLSS becomes inoperable.

The technical specification (TS) Limiting Conditions for Operation (LCOs) for DNBR margin and LHR are more restrictive when operating without the COLSS due to the uncertainties associated with the CPCs. Consequently, when the COLSS becomes inoperable, the existing LHR and DNBR limits based on CPC information can only be satisfied by either a power reduction or by restoring the COLSS to service. By itself, a loss of the COLSS or returning the COLSS to service does not affect plant operation and does not affect the actual DNBR or the LHR. In addition, a loss of the COLSS does not constitute a change in actual core power distribution. Therefore, during normal operation within the COLSS power operating limits (POLs), if there are no indications that the actual DNBR margin or LHR has degraded, a power reduction will not significantly improve the level of confidence that the existing margin is below the required margin discussed in Chapter 15 of the Updated Final Safety Analysis Report (UFSAR).

When either TS 3.2.1 or TS 3.2.4 is not satisfied, compensatory actions will provide additional assurance that the actual DNBR margin and LHR do not exceed the safety limits stated in the UFSAR. Compensatory actions will be provided in a revision to the surveillance test procedure for monitoring LHR and DNBR while in the 4-hour ACTION for COLSS out of service. The revised procedure will allow continued full power operation after COLSS becomes unavailable, consistent with the revised TS ACTIONs. In addition, the revised procedure will require LHR and DNBR to be monitored at least every 15 minutes for the 4-hour ACTION period when COLSS is out of service and the more restrictive CPC limits are not met as required by the LHR and DNBR TS LCOs.

The primary consideration in extending the COLSS out-of-service time limit is the remote possibility of a slow, undetectable transient that degrades the DNBR margin or LHR within the 4-hour ACTION time which is then followed by an anticipated operational occurrence or accident. The plant parameters monitored by COLSS which could affect DNBR margin and LHR include RCS flow rate, axial and radial power distribution, cold leg temperature, reactor core power, RCS pressure, and azimuthal tilt. Cold leg temperature, core power, and RCS pressure are monitored by operators using redundant, safety grade control room indications. Operating experience indicates that changes in RCS flow rate are rare and involve only large obvious step changes. Therefore, any change in RCS flow rate will be quickly identified by operators using other redundant, safety-grade instrumentation.

Azimuthal tilt variations occur either slowly over the entire cycle due to burnup variations or due to asymmetric events such as an inadvertent drop or misalignment of a Control Element Assembly (CEA). The probability of dropping or misaligning a CEA is remote, and it is very unlikely that a CEA would drop within a given 4-hour period. In the unlikely event this were to occur, the safety related Control Element Assembly Calculators (CEACs) would alert operators that corrective action was required. A large temperature difference (i.e. an asymmetric steam generator transient) could also produce a core tilt variation but the CPCs have been specifically designed to detect this type of event and ultimately provide the appropriate protection system response. Thus, during the proposed 4-hour ACTION statement any degradation of azimuthal tilt is very unlikely when the plant is operating at steady state conditions and would be quickly and positively identified. Additionally, an adverse change in azimuthal tilt would result in a degradation in the CPC monitored LHR and DNBR margin.

Axial xenon oscillations are a normal consequence of the Palo Verde core designs, particularly near the end of a fuel cycle. The resultant axial core power fluctuations are strictly controlled to ensure efficient and even fuel burnup. As a result, axial power shape is strictly maintained by existing procedures well within the limits assumed in the safety analysis. Typically, one full xenon oscillation will take approximately 26 hours. It is unlikely that a change in axial shape index (ASI) during the 4-hour ACTION period of steady state plant operation would either be undetected or lead to a condition outside the range of initial conditions assumed in the safety analysis since a change would have to be initiated by either a power transient or CEA movement. In the event of an inadvertent power transient or CEA movement, the CPCs would provide the appropriate protection system response. Additionally, any adverse change in ASI would result in a degradation in the CPC monitored LHR and DNBR margin.

The proposed amendment does not modify either the LHR or DNBR LCOs. The core power distribution during all phases of normal operation and anticipated operational occurrences will remain bounded by the initial conditions assumed in Chapter 15 of the UFSAR. The COLSS calculated POLs and the CPC-based LHR and DNBR operating limits will remain unchanged. Increasing the time to 4 hours for restoration of LHR and DNBR to within limits would reduce the number and rate of power reductions. While decreasing the potential for RPS actuation, the proposed change would not significantly increase the probability of exceeding the core power operating limits based on LHR and DNBR. Therefore, this proposed change will not significantly increase the probability or consequences of an accident previously evaluated.

Standard 2 – Create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed amendment is limited to changing administrative limits and does not involve any physical change to plant systems or to the COLSS and CPC software. These changes will not affect any safety-related equipment used in the mitigation of anticipated operational occurrences or design basis accidents. The only change resulting from this amendment will be to the procedure for operating when COLSS is out of service. The procedural changes will be reviewed and implemented in accordance with 10 CFR 50.59 and TS Administrative Controls. The DNBR and LHR LCOs are not affected by these changes. Therefore, this change will not create the possibility of a new or different kind of accident from any accident previously evaluated.

Standard 3 – Involve a significant reduction in a margin of safety.

TS LCOs 3.2.1 and 3.2.4 ensure that operation of the reactor is within the range of conditions assumed in the Safety Analysis. Therefore, maintaining LHR and DNBR within the existing LCOs will ensure that no anticipated operational occurrence or postulated accident will result in core conditions exceeding Specified Acceptable Fuel Design Limits or the maximum peak cladding temperature of 2200°F specified by 10 CFR 50.46. The UFSAR Chapter 15 analysis remains bounding because there has been no change to the LHR and DNBR limits. Administrative limits will be in place to provide additional assurance that potential reductions in core thermal margin, while in the extended 4-hour ACTION, will be quickly detected, and should it prove necessary, result in a decrease in reactor power and subsequent compliance with the LCOs. Therefore, this change will not result in a significant reduction in a margin of safety.

The NRC staff has reviewed the licensees' analysis and, based on that review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Local Public Document Room location: Phoenix Public Library, 12 East McDowell Road, Phoenix, Arizona 85004

Attorney for licensees: Nancy C. Loftin, Esq., Corporate Secretary and Counsel, Arizona Public Service Company, P.O. Box 53999, Mail Station 9068, Phoenix, Arizona 85072-3999

NRC Project Director: Theodore R. Quay

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson Steam Electric Plant, Unit No. 2, Darlington County, South Carolina

Date of amendment request: November 20, 1992

Description of amendment request: The proposed amendment would revise the Technical Specifications to add a requirement for a refueling interval calibration of the Auxiliary Feedwater (AFW) flow instrumentation and delete the separate requirement for a refueling interval functional test. A change in the type of instrumentation used to monitor AFW flow resulted in a change in the method of operability verification required. The new instrumentation, installed by a plant modification, can be

calibrated; whereas, the old instrumentation could only be functionally tested.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated because the proposed amendment only provides a means of calibration for this equipment. Since the AFW flow indication system provides the operator sufficient information to allow for the recognition and isolation of faulted AFW supply piping to the steam generators, the increase in accuracy and reliability of this indication resulting from its calibration would not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Since the AFW flow indication system does not interface with any system involved in an accident initiation sequence, the possibility of a new or different kind of accident cannot be created by introduction of a new required calibration of that system. Therefore, the proposed changes do not create the possibility of a new or difference kind of accident from any accident previously evaluated.

3. The proposed amendment does not involve a significant reduction in the margin of safety.

The subject instrumentation calibration has no impact on accident sequences. The improved reliability and accuracy of the subject instrumentation, as a result of its calibration, serve to improve the operator's ability to respond to AFW flow failure events. This potentially improved response to events does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29550

Attorney for licensee: R. E. Jones, General Counsel, Carolina Power & Light Company, P. O. Box 1551, Raleigh, North Carolina 27602

NRC Project Director: Elinor G. Adensam

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: May 27, 1992, as supplemented December 7, 1992

Description of amendment request: The proposed amendments would revise Sections 3.0 and 4.0 of the Vogtle Electric Generating Plant Units 1 and 2 Technical Specifications (TS) to incorporate the changes recommended in NRC's Generic Letter 87-09, "Sections 3.0 and 4.0 of the Standard Technical Specifications (STS) on the Applicability of Limiting Conditions for Operation and Surveillance Requirements." In this letter the NRC has concluded that certain recommended modifications to TSs 3.0.4, 4.0.3, and 4.0.4 would clarify the intent of these TSs and would resolve three problems associated with the existing requirements, as follows: (1) TS 3.0.4 would be revised to remove any unnecessary restrictions on operational mode changes in those cases where conformance with Action Statement requirements provides an acceptable level of safety for continued operation for an unlimited period of time; (2) TS 4.0.3 would be revised to provide a 24-hour delay before implementing TS Action Statement requirements due to a missed surveillance, in those cases where the allowed time to perform the missed surveillance is less than 24 hours; and (3) TS 4.0.4 would be revised to assure that its Surveillance Requirements do not prevent the plant's passage through or to Operational Modes as required to comply with TS Action Statement requirements.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Revision to Specification 3.0.4 and associated bases

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated because the change simply recognizes those cases where conformance to the action requirements associated with an LCO establishes an acceptable level of safety for continued operation of the facility for an unlimited period of time. Generally, individual specifications that have action requirements which allow continued operation note that Specification 3.0.4 does not apply. However, exceptions to Specification 3.0.4 have not been consistently applied. Rather than applying individual exceptions to Specification 3.0.4 (except in those cases where an exception to Specification 3.0.4 exists and the specification does not satisfy the provisions under which mode changes are permitted by the revision to Specification 3.0.4) the revision to Specification 3.0.4 defines the conditions under which the requirements do apply. Furthermore, Georgia Power Company concurs with the NRC staff position that good practice dictates that plant startup should normally be initiated only when all required equipment is operable, and that startup with inoperable equipment must be the exception rather than the rule. Therefore, since the proposed change will ensure consistent application of Specification 3.0.4 while continuing to ensure an acceptable level of safety for continued operation of the facility, the probability or consequences of an accident previously evaluated will not be significantly increased.

b. This change does not create the possibility of a new or different kind of accident from any accident previously evaluated. If an LCO has action requirements that permit continued operation for an unlimited period of time, it follows that an acceptable level of safety is provided by conformance to those action requirements. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

c. The proposed change will not involve a significant reduction in a margin of safety. As previously stated, the proposed revision to Specification 3.0.4 defines the conditions under which Specification 3.0.4 applies. The fact that the action requirements allow for continued operation of the facility for an unlimited period of time implies that an acceptable level of safety is provided for and maintained by conformance to the action requirements. Therefore, it follows that the proposed change does not involve a significant reduction in a margin of safety.

2. Deletion...of individual exceptions to Specification 3.0.4. Where individual specifications satisfy the provisions of revised Specification 3.0.4 under which mode changes would be allowed, the individual exemption statements have been deleted or added, as necessary. The following specifications and tables are affected by this change:

Specification

3.1.3.2, 3.2.4, 3.3.3.1, 3.3.3.2, 3.3.3.3, 3.3.3.4, 3.3.3.9, 3.3.3.10, 3.3.3.11, 3.4.10, 3.7.1.5, 3.7.9, 3.7.10, 3.8.4.1, 3.9.7, 3.9.9, 3.9.11, 3.9.12, 3.11.1.1, 3.11.1.2, 3.11.1.3, 3.11.1.4, 3.11.2.1, 3.11.2.2, 3.11.2.3, 3.11.2.4, 3.11.2.5, 3.11.2.6, 3.11.3, 3.11.4, 3.12.1, 3.12.2, 3.12.3

Table

3.3-1, 3.3-2, 3.3-8

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated. Each specification listed above...presently contains an exception to the provisions of Specification 3.0.4. Georgia Power Company has determined that all...or part of these specifications listed above satisfy the provisions of revised Specification 3.0.4 under which mode changes would be

allowed. In other words, each specification has action requirements which provide an acceptable level of safety for continued operation of the facility for an unlimited period of time. Therefore, in accordance with Generic Letter 87-09 the individual exceptions to Specifications 3.0.4 are no longer required and should be deleted in order to avoid confusion about the applicability of Specification 3.0.4. The net effect is that there is no change in the requirements. The individual exceptions to Specification 3.0.4 will be replaced by revised Specification 3.0.4. The exception to 3.0.4 is being added to Specification 3.7.1.2 to clarify that mode changes are not allowed with these auxiliary feedwater pumps inoperable. Since there is no net change in the requirements, it follows that the proposed change will not significantly increase the probability or consequences of an accident previously evaluated.

b. This change does not create the possibility of a new or different kind of accident from any accident previously evaluated. Since there is no net change in the requirements, it follows that there is no possibility of a new or different kind of accident as a result of this change.

c. The proposed change will not involve a significant reduction in the margin of safety because there is no net change in the requirements.

3. Revision to Specification 4.0.3 and associated bases

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated. The existing...Technical Specifications state that the allowable outage time limits apply upon discovery that a required surveillance has been inadvertently omitted. Therefore, the only change in requirements associated with adopting the wording of Generic Letter 87-09 for Specification 4.0.3 and its associated bases involves the addition of a 24-hour interval for performing a missed surveillance if the allowable outage time is less than 24 hours.

Generic Letter 87-09 states that it is overly conservative to assume that systems or components are inoperable when a surveillance requirement has not been performed. The letter further states that the majority of surveillances demonstrate that systems or components in fact are operable, and when a surveillance is missed it is primarily a question of verification of operability by the performance of the required surveillance. In some cases, the condition of a missed surveillance could force a plant shutdown which would be unnecessary if in fact the system or component in question was operable. If a plant shutdown is required before a missed surveillance is completed, it is likely that it would be conducted while the plant is being shut down because completion of a missed surveillance could terminate the shutdown requirement. This is undesirable since it increases the risks to the plant and public safety for two reasons. First, the plant would be in a transient state involving changing plant conditions that offer the potential for an upset that could lead to a demand for the system or component being tested. Secondly, a shutdown would increase the pressure on the plant staff to expeditiously complete the required surveillance so that the plant could be returned to power operation. This would further increase the potential for a plant upset when both the shutdown and surveillance activities place a demand on the plant operations. The NRC staff has concluded that, based on consideration of plant conditions, adequate planning, availability of personnel, time required to perform the missed surveillance, and the safety significance of the delay in completion of the surveillance, 24 hours would be an acceptable time limit for completing a missed surveillance when the allowable outage time limit is less than 24 hours or when shutdown action requirements apply. Furthermore, the NRC staff concludes that the 24-hour time limit would balance the risks associated with an allowance for completing the surveillance within this period against the risks associated with the potential for a plant upset and challenge to safety systems when the alternative is a shutdown to comply with action requirements before the surveillance can be completed. Finally, the deletion of the statement that exceptions to Specification 4.0.3 are noted in individual specifications is an administrative change since the implied exceptions do not exist. Specification 4.0.3 always applies.

Georgia Power Company agrees with the evaluation of the NRC staff as presented in Generic Letter 87-09 and therefore concludes that this aspect of the revision to Specification 4.0.3 will not involve a significant increase in the probability or consequences of an accident previously evaluated.

b. This change does not create the possibility of a new or different kind of accident from any accident previously evaluated. As stated in item 3a above, the proposed revision should minimize the potential for a plant upset due to efforts to comply with an LCO in the event of a missed surveillance. The deletion of the statement regarding noted exceptions to Specification 4.0.3 is an administrative change since the noted exceptions do not exist. Therefore, this change does not create the possibility of a new or different kind of accident.

c. The proposed change does not involve a significant reduction in the margin of safety. Equipment operability will continue to be verified as required by the Technical Specifications. The proposed revision should minimize the potential for plant upset due to efforts to meet an LCO in the event of a missed surveillance. The deletion of the statement regarding noted exceptions to Specification 4.0.3 is administrative since the noted exceptions do not exist. Therefore, this change does not involve a significant reduction in the margin of safety.

4. Revision to Specification 4.0.4 and associated bases

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated. As discussed in item 3a, the potential for a plant upset and challenge to safety systems is heightened if surveillances are performed during the transition to shutdown to comply with action requirements, and it should not apply when mode changes are imposed by action requirements. Since the proposed change should reduce the potential for plant upset and challenge to safety systems, there is no significant increase in the probability or consequences of an accident previously evaluated.

b. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated. As stated in item 4a, this change should reduce the potential for plant upset and challenge to safety systems. This change is a clarification which will facilitate conformance to action requirements when mode changes are required. Therefore, the change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

c. The proposed change does not involve a significant reduction in the margin of safety. The proposed change is a clarification which will facilitate compliance with action requirements when mode changes are required. The result should be an enhancement to plant safety in the event that inoperable equipment or an out of limit condition requires a plant shutdown. Therefore, there is not significant reduction in the margin of safety.

5. Revision of the bases for Specifications 3.0.1, 3.0.2, 3.0.3, 3.0.4, 4.0.1, 4.0.2, 4.0.3, 4.0.4, and 4.0.5

a. The proposed change will not significantly increase the probability or consequences of an accident previously evaluated because the Technical Specification requirements have not changed (i.e., Specifications 3.0.1, 3.0.2, 3.0.3, 3.0.4, 4.0.1, 4.0.2, 4.0.3, 4.0.4, and 4.0.5). The bases associated with these requirements have simply been rewritten for clarity. Therefore, there will be no significant increase in the probability or consequences of an accident previously evaluated.

b. The proposed change will not create the possibility of a new or different kind of accident from any accident previously evaluated. As stated in item 5a, there are no changes to the requirements proposed. The proposed change will result in improved bases for the subject specifications. Therefore, there is no possibility of a new or different kind of accident from any previously evaluated.

c. The proposed change will not involve a significant reduction in the margin of safety because the requirements have not changed.

The staff has reviewed the licensee's no significant hazards analysis given above. Based on this review and the consistency of the proposed changes with those recommended in Generic Letter 87-09, the staff proposes to determine that the proposed amendments meet the three 10 CFR 50.92(c) standards and do not involve a significant hazards consideration.

Local Public Document Room location: Burke County Public Library, 412 Fourth Street, Waynesboro, Georgia 30830.

Attorney for licensee: Mr. Arthur H. Domby, Troutman, Sanders.

NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia 30308-2210.

NRC Project Director: David B. Matthews

Georgia Power Company, Oglethorpe Power Corporation, Municipal Electric Authority of Georgia, City of Dalton, Georgia, Docket Nos. 50-424 and 50-425, Vogtle Electric Generating Plant, Units 1 and 2, Burke County, Georgia

Date of amendment request: December 7, 1992

Description of amendment request: The proposed amendments would revise the Technical Specifications (TS) to change the frequency of reporting the quantity of each of the principal radionuclides released from the plant site to unrestricted areas in liquid and in gaseous effluents from semiannual to annual. These changes would be implemented by further modifying certain related changes (TS Sections 1.19, 6.8.1, and 6.13.2) proposed by the licensee with respect to NRC Generic Letter (GL) 89-19 on March 4, 1992, that were noticed in the **Federal Register** on August 19, 1992 (57 FR 37565). Specifically, the title "Annual Radioactive Effluent Release Report" would be used instead of "Semiannual Radioactive Effluent Release Report." This title appears in TSs 1.19, 6.8.1, 6.13.2, and TS Index page XXIII.

The proposed change for TS 6.8.1 would also require that the Annual Radioactive Effluent Release Report covering the operation of the unit during the previous calendar year be submitted before May 1 of each year, and that the quantity of solid waste releases be reported on an annual, rather than a semiannual, basis.

Basis for proposed no significant hazards consideration determination: As noticed in the **Federal Register** on August 31, 1992 (57 FR 39353), the NRC has amended 10 CFR 50.36a to reduce the required frequency of reporting the quantity of each principal radionuclide released to unrestricted areas in liquid and gaseous effluents from semiannual to annual. The proposed amendments would revise the TS to be consistent with the revised regulation. The reporting requirement for solid wastes is not addressed by the revised 10 CFR 50.36a. However, to be consistent with the proposed changes for liquid and gaseous effluents, the licensee proposes that the quantity of solid waste releases also be reported on an annual basis.

As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated. The proposed changes are administrative in nature and do not involve any change to the configuration or method of operation of any plant equipment that is used to mitigate the consequences of an accident. Also, the proposed changes do not alter the conditions or assumptions in any of the Final Safety Analysis Report (FSAR) accident analyses. Since the FSAR accident analyses remain bounding, the radiological consequences previously evaluated are not adversely affected by the proposed changes. Therefore, it can be concluded that the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated. The proposed changes are administrative in nature and do not involve any change to the configuration or method of operation of any plant equipment that is used to mitigate the consequences of an accident. Accordingly, no new failure modes have been defined for any plant system or component important to safety nor has any new limiting failure been identified as a result of the proposed changes. Also, there will be no change in the types or increase in the amount of effluents released offsite. Therefore, it can be concluded that the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. The proposed changes do not involve a significant reduction in a margin of safety. The proposed changes are administrative in nature and do not adversely impact the plant's ability to meet applicable regulatory requirements related to liquid and gaseous effluents, and solid waste releases. The proposed change[s] would also eliminate an unnecessary burden of governmental regulation without reducing protection for public health and safety. Therefore, it can be concluded that the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Burke County Public Library, 412 Fourth Street, Waynesboro, Georgia 30830.

Attorney for licensee: Mr. Arthur H. Domby, Esquire, Troutman, Sanders, NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, Georgia 30308-2210.

NRC Project Director: David B. Matthews

Houston Lighting & Power Company, City Public Service Board of San Antonio,Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: September 28, 1992, as supplemented on November 12, 1992.

Description of amendment request: Two proposed changes to the Technical Specification (TSs) were included in the submittal. The first change is to replace the variable shutdown margin requirements for Modes 1 and 2 with a constant value for all values of boron concentration. The second change is intended to clarify when an overall reactivity balance is to be performed to confirm core design predictions, and hence validate shutdown margin.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

1. The proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

Figure 3.1-1 of the TSs presently requires that shutdown margin be maintained as a function of boron concentration for Modes 1, 2, 3, and 4. The shutdown margin is a constant value of 1.75 percent $\Delta k/k$ up to a boron concentration of 900 ppm and then increases linearly with boron concentration. The presence of the variable shutdown requirement for Modes 1 and 2 may place the plant in a condition that is more restrictive than required in order to meet its safety analysis. The use of longer fuel cycles will cause the reactor core to be more reactive at beginning of life (BOL). This, in turn causes the "all rods in" critical boron concentration to increase at BOL. Use of the current Figure 3.1-1 of TS 3.1.1.1 requires additional shutdown margin over the 1.75 percent $\Delta k/k$ for the higher boron concentrations. For Modes 1 and 2, the safety analyses were performed using a constant value of 1.75 percent $\Delta k/k$, so any shutdown margin above that is more than is required to meet the safety analysis.

The licensee is also requesting that the surveillance requirement as stated in TS 4.1.1.1.2 be exempt from the requirements of TS 4.0.4. TS 4.1.1.1.2 requires that "the overall core reactivity balance shall be compared to predicted

values to demonstrate agreement within +1 percent $\Delta k/k$ at least once per 31 Effective Full Power Days." The TS is applicable in Modes 1, 2, 3, and 4. There is no exemption from TS 4.0.4. TS 4.0.4 prevents a mode change unless all surveillance requirements are met. Therefore, as written, TS 4.1.1.1.2 would have to be satisfied before entry into Mode 4 and each succeeding mode. However, performing a reactivity balance prior to criticality is not possible. As part of a normal reactor startup process, an estimated critical condition (ECC) is performed. If the ECC is in error by a specified amount, plant procedures are followed to ascertain the source of the error and to take appropriate action.

For the above stated reasons, the proposed TS changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed changes do not create the possibility of a new or different kind of accident from any previously stated.

The design basis for the shutdown margin in Modes 1 and 2 is unchanged.

The proposed change in the applicability of surveillance requirement (TS 4.1.1.1.2) does not affect the accuracy of the parameters used in the shutdown margin calculation performed for compliance with TS 3.1.1.1.

For the above reasons, the proposed changes do not create the possibility of a new or different accident from any previously stated.

3. The proposed changes do not involve a significant reduction in a margin of safety.

The design basis for the shutdown margin in Modes 1 and 2 remains unchanged.

The proposed change in the surveillance requirement does not affect the accuracy of the parameters used in the shutdown margin calculation performed for compliance with TS 3.1.1.1.

For the above reasons, the proposed changes do not involve a significant reduction in the margin of safety.

Based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the request for amendments involves no significant hazards consideration.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488.

Attorney for licensee: Jack R. Newman, Esq., Newman & Holtzinger, P.C., 1615 L Street, N.W., Washington, D.C. 20036

NRC Project Director: Suzanne C. Black

Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of amendment request: February 12, 1992

Description of amendment request: The proposed amendments would change Technical Specifications to reflect the addition of clean water tanks and associated pumps, piping, and valves to the fire suppression water system in Units 1 and 2.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Involve a significant increase in the probability or consequences of an accident previously evaluated.

[The proposed amendment does not involve a significant increase in the probability or consequences of an accident previously evaluated.] The newly installed fire water storage tanks and their three associated pumps will supply enough water and pumping capability to be able to put out the largest single fire hazard even if one of the three pumps fail, which is in accordance with Branch Technical Position APSCB 9.5-1. Maintaining two of the existing pumps that take suction off of Lake Michigan is an added conservatism that results in Cook Nuclear Plant having two completely separate and independent sources of fire suppression water. Consequently, the proposed changes to the Cook Nuclear Plant design and Technical Specifications will not involve a significant increase in the probability or consequences of an accident previously evaluated.

(2) Create the possibility of a new or different kind of accident from any previously analyzed.

[The proposed amendment does not create the possibility of a new or different kind of accident from any previously analyzed.] The proposed system is designed in accordance with 10CFR50 Appendix A General Design Criterion 3. As such, no new potential fire hazards will be located in the vicinity of any structures, systems, or components important to safety. In addition, the effects of the fire water storage tanks rupturing have been analyzed to ensure that the safety capability of structures, systems, or components important to safety is not impaired.

In addition, by having the two pumps that take suction from Lake Michigan, we will still have a readily available source of fire suppression water in the event that the tanks fail. Consequently, the proposed changes will not create the possibility of a new or different kind of accident from any previously analyzed.

(3) Involve a significant reduction in a margin of safety.

[The proposed amendment does not involve a significant reduction in the margin of safety.] The margin of safety was carefully considered in the design of the proposed system. It was realized early in the design process that if we did not maintain the capability to obtain water from [the] Lake Michigan then the overall margin of safety would be reduced for two reasons.

First, Lake Michigan is essentially an infinite source of water and the tanks are not. Second, if both tanks catastrophically failed, no fire suppression water would exist until an alternate source was established.

The number of pumps is also important to the margin of safety. Although only three pumps are needed to meet the requirements of Branch Technical Position APSCB 9.5-1, a reduction in the number of pumps from four in the existing system to three in the new system would also reduce the margin of safety.

However, zebra mussel infestation of the existing system also poses the potential to reduce the margin of safety. Therefore, it was decided to install a new system with clean water stored in tanks and to also maintain two of the existing diesel-engine-driven lake pumps in the new system design. In this manner we address the zebra mussel problem and maintain the capability of obtaining water from Lake Michigan. We also increase the number of pumps from four in the existing system to five in the new system. By keeping the lake pumps isolated we eliminate any concern that the new portion of the system will become infested with zebra mussels. Periodically starting the lake pumps and flushing their discharge piping per the proposed T/Ss requirements, and chemically treating the pumps and discharge piping will help to ensure that they will be kept operational and free of zebra mussels. By increasing the number of pumps, having diversity in our available water sources, and addressing the zebra mussel problem, we have not only addressed the design issues that may have potentially reduced the margin of safety, but have actually increased the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Maude Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, NW, Washington, DC 20037.

NRC Project Director: L. B. Marsh.

Niagara Mohawk Power Corporation, Docket No. 50-410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York

Date of amendment request: November 24, 1992

Description of amendment request: The proposed amendment would revise Section 6.0, "Administrative Controls," of the Technical Specifications (TS). TS 6.5.1 would be revised to reflect changes in the size and composition of the Station Operations Review Committee (SORC) that are intended to improve the efficiency of the station review function. TS 6.5.3.6 would be revised to change the quorum requirements for the Safety Review and Audit Board (SRAB) to ensure membership continuity during scheduled meetings. TS 6.3 and 6.4 would be revised to delete several references and thereby improve consistency with 10 CFR Part 55.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The operation of NMP2 [Nine Mile Point Nuclear Station, Unit 2], in accordance with the proposed amendment, will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes to Technical Specification 6.5.1 are consistent with STS [Standard Technical Specifications] guidelines regarding number of members associated with a "Unit Review Group", designated at NMP2 as the "Station Operations Review Committee (SORC)". Proposed changes to the SORC quorum requirements incorporate BWR [boiling-water reactor] STS guidelines combined with later operating BWR plant provisions regarding establishment of a SORC Vice-Chairman position. The SORC Vice-Chairman position, with duties, responsibilities and qualifications similar to those of the SORC Chairman, is adopted from later operating BWR plant provisions found acceptable to the NRC. In addition, the authority presently granted to the SORC Chairman to appoint alternate SORC members and to convene SORC, is extended to the Vice-Chairman.

These changes provide a flexibility in the implementation of the SORC review process which should enhance the timeliness of response to routine activities as well as to emerging circumstances requiring SORC review. During SORC Chairman absence, the Vice-Chairman position assures the continuity required for effective implementation of the day-to-day SORC functions. Continued technical adequacy of the process is assured by retention of existing procedural controls requiring verification that SORC members or alternates present have appropriate technical background necessary for an adequate safety review of agenda items, as well as the requirements to designate other personnel, as necessary, for attendance at meetings where additional information or expertise is needed.

The SORC function of advising the Plant Manager on all matters related to nuclear safety, as stated in TS 6.5.1.1, remains unchanged. Similarly, the specific SORC responsibilities detailed in TS 6.5.1.6 are not affected by the proposed changes. The number of alternates permitted by TS 6.5.1.3 remains unchanged thereby maintaining the present condition that there always be at least a majority at each SORC meeting who are permanent SORC members.

The proposed change to the SRAB quorum meets the requirements of ANSI [American National Standards Institute] N18.7-1976 Sections 4.3.2.1 and 4.3.2.3. These require that the committee consist of no less than five (5) persons and that the quorum consist of not less than a majority of the principles or duly appointed alternates. This will ensure membership continuity during scheduled meetings. The proposed changes are consistent with STS guidelines, ANSI N18.7-1976 and the SRAB charter.

The proposed changes to TS 6.3 and 6.4 are administrative in nature and since no changes will be made to the Operator and Senior Operator license training programs, there is no impact on nuclear safety.

The proposed changes do not affect any accident precursors and do not alter or modify existing limitations on the function, use of alternates, and responsibilities of the SORC. Addition of STS and later operating BWR plant provisions applicable to NMP2 assures retention of an adequate level and quality of review of matters related to nuclear safety, and therefore does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The operation of NMP2, in accordance with the proposed amendment, will not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes for NMP2 Technical Specification Section 6.0 are based on STS guidelines and on later operating BWR plant provisions found acceptable to the NRC. These proposed changes have been reviewed for acceptability at NMP2 considering similarity of NMP2 nuclear safety review processes versus the STS and later operating BWRs. No new conditions of operation are introduced by the proposed changes. The proposed changes do not modify existing setpoints or design assumptions for system operation.

Since the proposed changes do not alter the functions and responsibilities of SORC and SRAB to review matters related to nuclear safety, do not modify the present level of plant system operability, and do not affect the Operator and Senior Operator license training programs, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The operation of NMP2, in accordance with the proposed amendment, will not involve a significant reduction in a margin of safety.

The proposed changes to Technical Specification Section 6.0 represent a combination of present requirements, STS guidelines and provisions that have been found acceptable for use on other operating BWRs with review processes similar to those at NMP2. The proposed SORC changes are intended to provide the flexibility required for continued timely SORC review of routine activities as well as review of emergent conditions, without compromising the technical adequacy of the process. The proposed SRAB quorum requirements will ensure membership continuity during scheduled SRAB meetings.

Existing procedural administrative controls requiring verification that SORC members or alternates present have appropriate technical background necessary for an adequate safety review of agenda items, as well as the requirements to designate other personnel, as necessary, for attendance at meetings where additional information or expertise is needed, remain in effect.

Since the proposed changes are based on STS guidelines and NRC accepted provisions at other operating plants that are applicable at NMP2, and since procedural administrative controls remain in place to assure presence of adequate technical expertise during the SORC review process, the proposed changes do not involve a significant reduction in a margin of safety.

Therefore, based on the above evaluation, Niagara Mohawk has concluded that these changes do not involve significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Attorney for licensee: Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005-3502.

NRC Project Director: Robert A. Capra

Northern States Power Company, Docket Nos. 50-282 and 50-306, Prairie Island Nuclear Generating Plant, Unit Nos. 1 and 2, Goodhue County, Minnesota

Date of amendments request: January 21, 1992

Description of amendments request: The amendments revise surveillance tests intervals for engineered safety feature systems pump and valves to be consistent with the standard technical specifications.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the

licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed amendment will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The decrease in the number of equipment operational transients will increase reliability more than the delay in problem identification. The net effect of this change will have a positive effect on equipment availability. These changes are consistent with Standard Technical Specifications. Therefore, these changes will not effect the probability or consequences of previously analyzed accidents.

2. The proposed amendment will not create the possibility of a new or different kind of accident from any accident previously analyzed.

These changes only affect the equipment testing frequency, and therefore will not create the possibility of a new kind of accident or different kind of accident.

3. The proposed amendment will not involve a significant reduction in the margin of safety.

These changes will improve the performance of equipment and are intended to reduce the potential for equipment failures due to unnecessary testing. No safety margins will be affected.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts, and Trowbridge, 2300 N Street, NW, Washington, DC 20037.

NRC Project Director: L. B. Marsh

Pacific Gas and Electric Company, Docket Nos. 50-275 and 50-323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California

Date of amendment requests: October 27, 1992 (Reference LAR 92-06)

Description of amendment requests: The proposed amendment would revise the combined Technical Specifications (TS) for the Diablo Canyon Power Plant (DCPP) Units 1 and 2 to relocate Table 3.8-1, "Motor-Operated Valves (MOVs) Thermal Overload Protection and Bypass Devices," to Diablo Canyon Power Plant procedures. The relocation is proposed in accordance with the guidance provided in Generic Letter (GL) 91-08, "Removal of Component Lists from Technical Specifications," dated May 6, 1991. TS 3/4.8.4 would be revised by removing reference to TS Table 3.8-1 and rewording in accordance with GL 91-08. The associated Bases would also be appropriately revised.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the change involve a significant increase in the probability or consequences of an accident previously evaluated?

The proposed changes simplify the TS, meet the regulatory requirements for control of MOV thermal overload and bypass devices, and are consistent with the recommendations of NUREG 1024 and GL 91-08. The procedural details of the MOV thermal overload protection and bypass devices table have not been changed, only relocated to a different controlling document. The proposed change is administrative in nature, should result in improved administrative practices, and does not affect plant operations.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the change create the possibility of a new or different kind of accident from any accident previously evaluated?

The proposed changes are administrative in nature, do not result in physical alterations or changes to the operation of the plant, and cause no change in the method by which any safety-related system performs its function.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the change involve a significant reduction in a margin of safety?

The administrative change to relocate TS Table 3.8-1 to DCPP plant procedures does not alter basic regulatory requirements and does not affect any safety analyses. Adequate control of the content of the table is assured by existing administrative procedures.

The proposed relocation of TS Table 3.8-1 does not alter the requirements for MOV thermal overload protection and bypass devices operability currently in the TS. The LCO and surveillance requirements would be retained in the revised TS. Therefore, the proposed change would not affect the meaning, application, and function of the TS requirements.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Local Public Document Room location: California Polytechnic State University, Robert E. Kennedy Library, Government Documents and Maps Department, San Luis Obispo, California 93407

Attorney for licensee: Christopher J. Warner, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120

NRC Project Director: Theodore R. Quay

The Cleveland Electric Illuminating Company, Centerior Service Company, Duquesne Light Company, Ohio Edison Company, Pennsylvania Power Company, Toledo Edison Company, Docket No. 50-440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of amendment request: September 28, 1992

Description of amendment request: The proposed amendment would revise the Technical Specifications by removing the Reactor Protection System (RPS) trip and the Main Steam Line (MSL) Isolation Actuation signal requirements from the Main Steam Line Radiation Monitors (MSLRMs). This Technical Specification (TS) change requires revisions to TS 2.2.1 "Reactor Protection System Instrumentation Setpoints," TS 3.3.1 "Reactor Protection System Instrumentation," and TS 3.3.2 "Isolation Actuation Instrumentation."

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. These changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change does not involve any increase in the probability of a previously evaluated accident. The RPS trips and Main Steam Line isolations being deleted were in place only to react to a previously evaluated accident, the Control Rod Drop Accident (CRDA). The elimination of the trips/isolations will not change the probability of occurrence of the CRDA, and thus has no affect [sic] on the probability of occurrence of previously evaluated accidents.

The consequences of previously evaluated accidents are also not increased as result of the proposed changes. No credit was ever taken for the RPS trip from the Main Steam Line radiation monitors (MSLRMs) in the Control Rod Drop Accident (CRDA) accident sequence description or in the associated radiological assessment (the scram signal assumed in the CRDA is the APRM Upscale signal). At PNPP, the CRDA accident sequence description also does not depend upon the Main Steam Line isolation signals from the MSLRMs. The plant will continue to be operated in compliance with the Banked Position Withdrawal Sequence (BPWS) analysis criteria, which are unchanged by this proposed amendment.

These criteria are enforced by the Rod Pattern Controller portion of the Rod Pattern Control System (RPCS), whose design and Technical Specification controls are also unchanged by this amendment, and conformance to the BPWS criteria ensure that an individual control rod's worth is such that if it is dropped during rod withdrawals, the enthalpy rise will continue to be less than the acceptance criteria for such scenarios. A CRDA event would not result in any significant radiological release, and the magnitude of any such release would continue to be less than any level which would have caused an isolation signal from the MSLRMs. As noted in the Bases for Specification 3.1.4.2, during power reductions below the LPSP [Low Power Setpoint], the Rod Pattern Controller portion of RPCS provides automatic supervision to assure that out-of-sequence rods will not be withdrawn or inserted. If this condition is not correctable in a manner consistent with the BPWS analysis, controls are in place to scram the plant. If the Rod Pattern Controller portion of RPCS is inoperable when thermal power is below the Low Power Setpoint, Technical Specification 3.1.4.2, Rod Pattern Control System, requires that no control rod be moved except by scram. Therefore, enforcement of the BPWS/RPCS requirements assures that the CRDA is of no significance at PNPP, and that the Main Steam Line isolation signal from the MSLRMs is not required.

Even though the BPWS/RPCS is designed to minimize the consequences of the CRDA, a hypothetical radiological assessment of a CRDA was performed which assumed that the BPWS/RPCS and their corresponding requirements do not exist in order to evaluate the radiological consequences without subsequent main steam line isolation, as compared to previous design basis assessments. This assessment was performed consistent with the BWR Owners Group Topical Report NEDO-31400 "Safety Evaluation for Eliminating the Boiling Water Reactor Main Steam Line Isolation Valve Closure Function and Scram Function of the Main Steam Line Radiation Monitor," which has been reviewed and generically accepted by the NRC staff in a Safety Evaluation Report (SER) dated May 15, 1991.

The NEDO-31400 submittal and the NRC's SER analyzed the proposed changes and both concluded that as long as the individual utilities met certain conditions the changes would not significantly affect the consequences of a previously evaluated accident. This amendment request documents how PNPP meets the conditions imposed by the NRC's SER, and that the PNPP design is in fact bounded by the NEDO-31400 radiological analysis. Thus this assessment also shows that there is no significant increase in the consequences of any previously evaluated accident.

2 The proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes request the removal of the Technical Specification requirements for the RPS trips and main steam line isolation signals generated by the MSLRMs. The original reason for the signals was to respond to a CRDA as discussed above. The elimination of these signals, which served only in a mitigative function, do not create the possibility of a new or different kind of accident from those previously evaluated. Also, radiation monitors with alarm functions will remain installed in the plant to warn the operators of a high radiation condition in the main steam lines, or in the offgas system. In addition, the trip signal from the MSLRMs to the mechanical vacuum pump line isolation valves will remain installed in the plant, and will be addressed in the Technical Specifications. As such, the condenser release path through the mechanical vacuum pump line will still be isolated on a high Main Steam Line Radiation condition. Thus no new or different accident can be postulated by the proposed changes.

3. The proposed changes do not involve a significant reduction in the margin of safety.

A reliability assessment of the elimination of the MSLRM scram function on reactivity control failure frequency and core damage frequency was performed as part of the NEDO analysis. The results of the analysis indicated a negligible increase in reactivity control failure frequency with deletion of the MSLRM scram function. However, this increase is offset by the reduction in the transient initiating events (inadvertent scrams). This reduction in transient initiating events represents a reduction in core damage frequency. The final result was determined to be a net improvement to safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Perry Public Library, 3753 Main Street, Perry, Ohio 44081

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, NW., Washington, DC 20037

NRC Project Director: John N. Hannon

Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: July 28, 1992

Description of amendment request: The proposed amendment wouldddelete Technical Specification (TS) 3/4.9.9, "Refueling Operations - Containment Purge and Exhaust Isolation System," and its bases, because of its redundancy to other TS that address the operability requirements of the containment purge and exhaust isolation system. Also, the proposed amendment would revise TS 3/4.3.2, "Safety System Instrumentation - Safety Features Actuation System Instrumentation," and TS 3/4.9.4, "Refueling Operations - Containment Penetrations," and its bases. The effect of this proposed change would be to allow the bypass of the safety features actuation system in Mode 6, "Refueling," by the use of the containment purge and exhaust system noble gas monitor in conjunction with manual closure of the containment purge and exhaust isolation valves instead of automatic closure.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Toledo Edison had reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the DBNPS in accordance with the changes would:

1a. Not involve a significant increase in the probability of an accident previously evaluated because the initiators regarding the fuel handling accident (USAR Section 15.4.7.3) are not affected by the deletion of TS 3/4.9.9 or the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain any release in progress.

1b. Not involve a significant increase in the consequences of an accident previously evaluated because the assumptions discussed in the fuel handling accident (USAR Section 15.4.7.3) are not affected by the deletion of TS 3/4.9.9 or allowing the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain a release in progress. Furthermore, manual operator action can be taken to isolate containment in lieu of the SFAS area radiation monitors' automatic containment isolation function. No credit is taken in the assumptions for the containment isolation. Thus, the deletion of TS 3/4.9.9 and the use of the containment purge and exhaust system noble gas monitor (RE5052C) and manual operator action does not involve a significant increase in the consequences of an accident previously evaluated. There is no significant change in the ability of DBNPS to contain a release of radioactivity.

2b. Not create the possibility of a different kind of accident from any accident previously evaluated because the operability requirements of the containment purge and exhaust isolation system contained in the TS 3/4.9.9 are adequately addressed by SR 4.3.2, SR 4.6.3, and TS 3/4.9.4. Thus, deletion of TS 3/4.9.9 does not affect the operability of the containment purge and exhaust isolation system and, therefore, does not create the possibility of a different kind of accident from any accident previously evaluated.

Allowing the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain a release in progress in lieu of the SFAS area radiation monitors' automatic containment isolation function does not introduce any different accident initiators. Furthermore, manual

operator action can be taken to isolate containment. Thus, it does not create the possibility of a different kind of accident from any accident previously evaluated.

3. Not involve a significant reduction in a margin of safety because neither the purpose nor the function of the containment purge and exhaust isolation system is being changed by the deletion of TS 3/4.9.9. The operability requirements of TS 3/4.9.9 are adequately addressed in SR 4.3.2, SR 4.6.3, and TS 3/4.9.4.

Allowing the use of the containment purge and exhaust system noble gas monitor (RE5052C) to automatically contain a release in progress in lieu of the SFAS area radiation monitors automatic isolation function is acceptable based on the accident analysis assuming no isolation or filtration for the fuel handling accident in containment. Furthermore, manual operator action can be taken to isolate containment. Thus, it does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606

Attorney for licensee: Jay E. Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Toledo Edison Company, Centerior Service Company, and The Cleveland Electric Illuminating Company, Docket No. 50-346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of amendment request: September 11, 1992

Description of amendment request: The proposed amendment would delete Technical Specification (TS) Figures 5.1-1, 5.1-2, 5.1-3, and 5.1-4 regarding the Davis-Besse Nuclear Power Station exclusion area, low population zone, unrestricted area boundary for liquid effluents, and unrestricted area boundary for gaseous effluents, respectively. Also, TS 5.1,"Site," would be revised to reference 10 CFR Part 100, "Reactor Site Criteria," and TS Section 1.0, "Definitions," instead of the four figures.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

Toledo Edison has reviewed the proposed changes and determined that a significant hazards consideration does not exist because operation of the Davis-Besse Nuclear Power Station, Unit Number 1, in accordance with the proposed changes would:

1a. Not involve a significant increase in the probability of an accident previously evaluated because this is strictly an administrative change to delete from the Davis-Besse Nuclear Power Station (DBNPS) Technical Specifications (TS) information that is already maintained in the DBNPS Updated Safety Analysis Report (USAR). There are no accident initiators or assumptions affected by the proposed changes.

1b. Not involve a significant increase in the consequences of an accident previously evaluated because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR. There is no effect on the source term or containment isolation, and no increase in radiological effluents.

2a. Not create the possibility of a new kind of accident from any accident previously evaluated because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR.

2b. Not create the possibility of a different kind of accident from any accident previously evaluated because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR.

3. Not involve a significant reduction in a margin of safety because this is strictly an administrative change to delete from the DBNPS TS information that is already maintained in the DBNPS USAR.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: University of Toledo Library, Documents Department, 2801 Bancroft Avenue, Toledo, Ohio 43606

Attorney for licensee: Jay E. Silberg, Esquire, Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: November 3, 1992 and December 1, 1992

Description of amendment request: This proposed amendment would revise Technical Specification (TS) 3.3.2 "Engineered Safety Features Actuation System (ESFAS) Instrumentation," TS 3.8.1 "Alternating Current (AC) Sources," and their associated surveillances. These TS revisions would require the Load Shedder Emergency Load Sequencer (LSELS) and the supplying 4KV Bus undervoltage devices to be operable during plant modes 5 and 6.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change does not involve a significant hazards consideration because operation of Callaway Plant with this change would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated. The Callaway Safety Analysis Report has been reviewed and been found to be unaffected by this proposed change. This change will not increase the probability or consequences of any accident or malfunction of equipment because the LSELS will be required to be operable in modes 5 and 6 which enhances plant operabilily

2. Create the possibility of a new or different kind of accident from any previously evaluated. This change increases the operability requirement for the LSELS. There is no new type of accident or malfunction created and the method and manner of plant operation will only change by adding OPERABILITY requirements for LSELS in MODES 5 & 6, which enhances plant safety in shutdown modes.

3. Involve a significant reduction in a margin of safety. The margin of safety remains unaffected since no design change is made and plant operation remains the same.

As discussed above, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated or create the possibility of a new or different kind of accident from any previously evaluated. This change does not result in a significant reduction in a margin of safety. Therefore, it has been determined that the proposed change does not involve a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of amendment request: November 3, 1992 and December 4, 1992

Description of amendment request: This proposed amendment would revise Table 4.3-1 "Reactor Trip System Instrumentation Surveillance Requirements," Note 5, to reflect that integral bias curves, rather than detector plateau curves, are used to calibrate the source range instrumentation. The low-noise preamplifiers, provided for the Callaway Nuclear Instrumentation System, do not accommodate the use of the traditional detector plateau curves to calibrate the source range.

The integral bias curve is considered to be a more inclusive calibration than the detector plateau curves. The intermediate range and power range channels will continue to be calibrated by using the detector plateau curves.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

The proposed change to Technical Specification Table [4.3-1] does not involve a significant hazard consideration because operation of the Callaway Plant with this change would not:

1. Involve a significant increase in the probability or consequences of an accident previously evaluated.

Plant equipment is not modified by calibrating the NIS [Nuclear Instrumentation System] source range instrumentation using the integral bias curve. Using the integral bias curve is a more inclusive calibration than the plateau curve and provides the same information, i.e., the high voltage operating point. The change does not affect accident initiators or assumptions. The consequences due to accidents previously evaluated are not being changed.

2. Create the possibility of a new or different kind of accident from any previously evaluated.

No new accidents are created by the changes being made. No new equipment is being added. No new modes of operation or means of control are being made. The probability of a malfunction of equipment important to safety is unchanged since the calibration of the NIS source range instrumentation using the integral bias curve, rather than the plateau curve, provides the same information. The consequences of malfunctions of equipment important to safety are not changed. No new malfunctions are being created. No new controlling modes or equipment operations are being created.

3. Involve a significant reduction in a margin of safety.

Using the integral bias curve is a more inclusive calibration than the plateau curve and provides the same information, i.e., the high voltage operating point. As discussed above, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated, create the possibility of a new or different kind of accident from any previously evaluated, or result in a significant reduction in a margin of safety. Therefore, it has been determined that the proposed change does not involve a significant hazards consideration.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Attorney for licensee: Gerald Charnoff, Esq., Shaw, Pittman, Potts & Trowbridge, 2300 N Street, N.W., Washington, DC 20037

NRC Project Director: John N. Hannon

Washington Public Power Supply System, Docket No. 50-397, Nuclear Project No. 2, Benton County, Washington

Date of amendment request: November 25, 1992

Description of amendment request: The amendment proposes to change Section 6 (Administrative Controls) of the Technical Specifications (TS) to: (1) modify the title of the Nuclear Safety Assurance Group (NSAG) to the Nuclear Safety Assurance Division (NSAD), and Director of Licensing and Assurance to Director of Quality Assurance, (2) modify the titles of the members on the Plant Operations Committee (POC), (3) delete the position of Assistant Plant Manager as Vice Chairman of the POC, and allow the Plant Manager to designate a Vice Chairman from the POC membership, and record the designation in the POC meeting minutes, and (4) add the Engineering Services Division Manager as a POC member. One title change involves splitting the current combined responsibilities for Chemistry/Radiation Protection into two different management positions responsible for their respective activities. The Radiation Protection Manager will remain as a member of the POC.

The proposed changes are needed to implement a reorganization of plant management to make the various divisions of station operation more responsive to plant issues and events.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

The changes are administrative in nature and involve no physical alteration of the plant, or changes to setpoints, operating conditions, or operating parameters. The response of the plant to previously evaluated accidents thus is not affected. Therefore, the proposed change will not involve a significant increase in the probability or consequences of an accident previously evaluated.

The administrative nature of the proposed changes do not affect the design, operation, maintenance, or testing of the plant. Thus no new modes of failure are created. Therefore, these changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed changes reflect a planned organizational change that do not change the qualification requirements or competence of the members of the POC. The same technical level of Plant Management Staff is still required to constitute a quorum. The addition of the Engineering Services Division Manager to POC membership expands the capability to more completely cover appropriate aspects of station operation. Thus, the capability of POC to meet its responsibilities is not diminished. Therefore, these changes do not involve a significant reduction in a margin to safety.

Based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Local Public Document Room location: Richland Public Library, 955 Northgate Street, Richland, Washington 99352

Attorney for licensee: Nicholas S. Reynolds, Esq., Winston & Strawn, 1400 L Street, N.W., Washington, D.C. 20005-3502

NRC Project Director: Theodore R. Quay

Wolf Creek Nuclear Operating Corporation, Docket No. 50-482, Wolf CreekGenerating Station, Coffey County, Kansas

Date of amendment request: October 28, 1992

Description of amendment request: The proposed technical specification revisions are being made to various parameter values, limiting conditions

for operation, and surveillance requirements as a result of analyses performed to support Cycle 7 operation, including the introduction of the VANTAGE 5H fuel design. Although the analyses were also performed assuming an increased power level, the proposed Cycle 7 changes do not include an increase in the rated thermal power defined by the facility operating license. Specific changes proposed include the incorporation of a Core Operating Limits Report in accordance with Generic Letter 88-16, increases in allowable peaking factors, changes to power distribution monitoring to reflect a change to the licensee's nuclear design methodology, increase in the most positive moderator temperature coefficient, changes to several reactor protection system setpoints, decrease in the reactor coolant system thermal design flow, increase in the allowable tolerance on the main steam safety valve setpoints, and an increase in the required shutdown margin in Mode 5, Cold Shutdown.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration. The NRC staff has reviewed the licensee's analysis against the standards of 10 CFR 50.92(c). The NRC staff's review is presented below.

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes do not significantly change the actual operation of plant systems, structures or components. The changes in fuel assembly design, power distribution monitoring, and reactivity parameter values have been evaluated and determined to be acceptable. These changes have been analyzed in accordance with methodologies which have been approved by or are currently under review by the NRC staff. Since the changes do not significamtly revise plant hardware or operating practices, no increase in the probability of an accident has been introduced. The changes, including those involving changes in setpoints, setpoint tolerances, or other analysis assumptions have been analyzed and determined to have minimal impact on the consequences of any previously evaluated accident.

2. Do the proposed changes create the possibility of a new or different kind of accident from any previously evaluated.

The proposed changes do not introduce any significant changes to the performance requirements for or mode of operation of any systems or components and therefore, do not introduce any new failure modes. Changes to specific parameter values or tolerances have been analyzed utilizing methodologies either approved by or currently under review by the NRC and the plant has been determined to remain within established operating limits. Therefore, there is no possibility of the creation of a new or different kind of accident from those previously evaluated.

3. Do the proposed changes involve a significant reduction in the margin of safety.

The analyses performed to justify Cycle 7 operation, including all of the proposed changes, demonstrated that applicable design and safety limits continue to be satisfied. The proposed changes to various parameter values, limiting conditions for operation, and surveillance requirements reflect changes in the core design methodology and selected analysis assumptions. However, the analyses methodologies utilized have either been approved or are currently under review by the NRC. These reviews and the specific analysis results associated with the proposed changes have demonstrated that the margin of safety is not significantly reduced.

Local Public Document Room Locations: Emporia State University, William Allen White Library, 1200 Commercial Street, Emporia, Kansas 66801 and Washburn University School of Law Library, Topeka, Kansas 66621

Attorney for licensee: Jay Silberg, Esq., Shaw, Pittman, Potts and Trowbridge, 2300 N Street, N.W., Washington, D. C. 20037

NRC Project Director: Suzanne C. Black, Director

Previously Published Notices Of Consideration Of Issuance Of Amendments To Operating Licenses, Proposed No Significant Hazards Consideration Determination, And Opportunity For A Hearing

The following notices were previously published as separate individual notices. The notice content was the same as above. They were published as individual notices either because time did not allow the Commission to wait for this biweekly notice or because the action involved exigent circumstances. They are repeated here because the biweekly notice lists all amendments issued or proposed to be issued involving no significant hazards consideration.

For details, see the individual notice in the **Federal Register** on the day and page cited. This notice does not extend the notice period of the original notice.

Pennsylvania Power and Light Company, Docket No. 50-387 Susquehanna Steam Electric Station, Unit 1, Luzerne County, Pennsylvania

Date of amendment request: November 30, 1992

Brief description of amendment request: The amendment would revise the Technical Specifications to authorize operation of the Reactor Water Cleanup (RWCU) system in the current fuel cycle (Cycle 6) with the RWCU system non-regenerative heat exchanger discharge high temperature channel substituting for the inoperable 'B' RWCU high flow isolation trip channel.Date of publication of individual notice in **Federal Register:** December 15, 1992, (57 FR 59363)

Expiration date of individual notice: January 14, 1993

Local Public Document Room location: Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.Notice Of Issuance Of Amendment To Facility Operating License

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing in connection with these actions was published in the **Federal Register** as indicated. No request for a hearing or petition for leave to intervene was filed following this notice.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has

made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendments, (2) the amendments, and (3) the Commission's related letters, Safety Evaluations and/or Environmental Assessments as indicated. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, D.C., and at the local public document rooms for the particular facilities involved. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects.

Baltimore Gas and Electric Company, Docket Nos. 50-317 and 50-318, Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland

Date of application for amendments: September 1, 1992, as supplemented on November 11, 1992.

Brief description of amendments: The amendments revise the Unit Nos. 1 and 2 spent fuel pool enrichment limit. The enrichment limit is decreased from 5.0 weight percent (w/o) U-235 to a value of 4.52 w/o U-235.

Date of issuance: December 22, 1992

Effective date: December 22, 1992

Amendment Nos.: 176 and 153

Facility Operating License Nos. DPR-53 and DPR-69: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 30, 1992 (57 FR 45075)The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated December 22, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Calvert County Library, Prince Frederick, Maryland 20678.

Boston Edison Company, Docket No. 50-293, Pilgrim Nuclear Power Station,Plymouth County, Massachusetts

Date of application for amendment: October 8, 1992

Brief description of amendment: This amendment revises Technical Specifications to incorporate an asterisk referencing a footnote granting relief to allow only one train of SGTS and CRHEAF system operable prior to and during refueling activities during RFO No. 9.

Date of issuance. December 16, 1992

Effective date: December 16, 1992

Amendment No.: 144

Facility Operating License No. DPR-35: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 28, 1992 (57 FR 48813) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 16, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Plymouth Public Library, 11 North Street, Plymouth, Massachusetts 02360.

Carolina Power & Light Company, Docket No. 50-261, H. B. Robinson SteamElectric Plant, Unit No. 2, Darlington County, South Carolina

Date of application for amendment: June 5, 1992

Brief description of amendment: The amendment clarifies Item 44 of Technical Specification Table 4.1-1, which specifies the minimum frequencies for checks, calibrations and tests of the containment vessel high-range monitors (R-32A and B) by revising the footnote so that the calibration method is clearly identified as an acceptable alternative to the NRC-preferred calibration technique described in NUREG-0737, but which does not preclude the use of the NUREG-0737 methodology.

Date of issuance: December 10, 1992

Effective date: December 10, 1992

Amendment No. 143

Facility Operating License No. DPR-23. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** June 24, 1992 (57 FR 28196) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 10, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Hartsville Memorial Library, Home and Fifth Avenues, Hartsville, South Carolina 29550

Consumers Power Company, Docket No. 50-255, Palisades Plant, Van Buren County, Michigan

Date of application for amendment: October 13, 1989 and August 27, 1992.

Brief description of amendment: This amendment would modify the Palisades Plant Technical Specification (TS) Section te incorporate the guidance provided in NRC Generic Letter (GL) 89-01 for implementation of programmatic controls for Radiological Effluent Technical Specifications (RETS) in the Administrative Controls Section of the TS and the relocation of procedural details of RETS to the Offsite Dose Calculation Manual (ODCM) or to the Process Control Program (PCP). This amendment also changes the reporting requirement for major modifications to radioactive liquid, gaseous, and solid waste treatment systems from a special report to a 10 CFR 50.59 report.

Date of issuance: December 18, 1992

Effective date: December 18, 1992

Amendment No.: 154

Facility Operating License No. DPR-20. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** February 7, 1990 (55 FR 4262)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 18, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Van Wylen Library, Hope College, Holland, Michigan 49423.

Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One,Unit No. 2, Pope County, Arkansas

Date of application for amendment: October 15, 1991

Brief description of amendment: The amendment deleted two inboard containment purge isolation valves from Technical Specification Table 3.6-1.

Date of issuance: December 14, 1992

Effective date: December 14, 1992

Amendment No.: 140

Facility Operating License No. NPF-6. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 2, 1992 (57 FR 40211)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 14, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Entergy Operations, Inc., Docket No. 50-368, Arkansas Nuclear One,Unit No. 2, Pope County, Arkansas

Date of application for amendment: October 9, 1990, as supplemented by letters dated May 12, and September 28, 1992

Brief description of amendment: The amendment revised TS 3/4.8.1, "A.C. Sources," to achieve consistency with Generic Letter 84-15, "Proposed Staff Actions to Improve and Maintain Diesel Generator Reliability." The changes were intended to reduce testing of the emergency diesel generators and

improve their reliability. Editorial changes were also made.

Date of issuance: December 15, 1992

Effective date: 30 days from the date of issuance

Amendment No.: 141

Facility Operating License No. NPF-6. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** November 28, 1990 (55 FR 494500). The additional information contained in the supplemental letters dated May 12, and September 28, 1992, was clarifying in nature and, thus, within the scope of the initial notice and did not affect the staff's proposed no significant hazards consideration determination.The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 15, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Tomlinson Library, Arkansas Tech University, Russellville, Arkansas 72801

Houston Lighting & Power Company, City Public Service Board of San Antonio, Central Power and Light Company, City of Austin, Texas, Docket Nos. 50-498 and 50-499, South Texas Project, Units 1 and 2, Matagorda County, Texas

Date of amendment request: June 26, 1991, as supplemented by letters dated January 24, 1992 and June 24, 1992.

Brief description of amendments: The amendments make changes to the Technical Specifications in accordance with the guidance provided in Generic Letter 89-01. The changes consist of relocating the procedural details of Radiological Effluent Technical Specifications (RETS) into the Offsite Dose Calculation Manual (ODCM) or the Process Control Program (PCP) in a manner that ensures these details are incorporated into plant operating procedures. In addition, programmatic controls would be added to the Administrative Controls section of Technical Specifications to satisfy the regulatory requirements and control changes to the procedural details of ODCM or PCP.

Date of issuance: December 21, 1992

Effective date: December 21, 1992, to be implemented within 15 days of issuance.

Amendment Nos.: Amendment Nos. 47 and 36

Facility Operating License Nos. NPF-76 and NPF-80: Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 18 1991 and September 30, 1992 (56 FR 47238 and 57 FR 45085). The Commission'srelated evaluation of the amendments is contained in a Safety Evaluation dated December 21, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Wharton County Junior College, J. M. Hodges Learning Center, 911 Boling Highway, Wharton, Texas 77488

Indiana Michigan Power Company, Docket Nos. 50-315 and 50-316, Donald C. Cook Nuclear Plant, Unit Nos. 1 and 2, Berrien County, Michigan

Date of application for amendments: February 15, 1991 as supplemented September 13, 1991.

Brief description of amendments: The amendments make administrative changes to the TS for both units. Four items in the proposed change were not purely administrative in nature. The changes dealt with operability of the automatic trip logic, engineered safety featured system instrumentation, containment air lock, and the physical stops on the Auxiliary Building Crane. These changes will be evaluated under a separate cover.

Date of issuance: November 13, 1992

Effective date: November 13, 1992

Amendments Nos.: 168 and 151Facility Operating Licenses Nos. DPR-58 and DPR-74. Amendments revised theTechnical Specifications.

Date of initial notice in **Federal Register:** July 10, 1991 (56 FR 31435) and November 13, 1991 (56 FR 57697).The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated November 13, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Maude Preston Palenske Memorial Library, 500 Market Street, St. Joseph, Michigan 49085.

Nebraska Public Power District, Docket No. 50-298, Cooper Nuclear Station, Nemaha County, Nebraska

Date of amendment request: November 15, 1991

Brief description of amendment: The amendment modified the technical specifications to remove the Rod Sequence Control System, and reduce the Rod Worth Minimizer Low Power Setpoint from 20 percent to 10 percent.

Date of issuance: December 22, 1992

Effective date: December 22, 1992

Amendment No.: 156

Facility Operating License No. DPR-46 Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 8, 1992 (57 FR 30251)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 22, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Auburn Public Library, 118 15th Street, Auburn, Nebraska 68305.

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile Point Nuclear Station Unit No. 1, Oswego County, New York

Date of application for amendment: October 16, 1992

Brief description of amendment: The amendment revises Technical Specification Surveillance Requirement 4.1.4.b. to extend the current quarterly pump surveillance test interval for Core Spray System 11 from January 10, 1993, until February 20, 1993.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment No.: 135

Facility Operating License No. DPR-63: Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** November 12, 1992 (57 FR 53787)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 17, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Niagara Mohawk Power Corporation, Docket No. 50-220, Nine Mile Point Nuclear Station Unit No. 1, Oswego County, New York

Date of application for amendment: September 17, 1992

Brief description of amendment: The amendment revises Technical Specification 3.6.12/4.6.12, "Reactor Protection System Motor Generator Set Monitoring," and associated Bases to reflect the replacement of Motor Generator Sets 162 and 172 with Static Uninterruptible Power Supplies. The amendment also makes conforming changes to the Table of Contents and a minor editorial change to Technical Specification 4.6.12.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment No.: 136

Facility Operating License No. DPR-63: Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** October 14, 1992 (57 FR

47140)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 17, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Northeast Nuclear Energy Company, et al., Docket No. 50-336, Millstone Nuclear Power Station, Unit No. 2, New London County, Connecticut

Date of application for amendment: August 5, 1992, as supplemented October 20, 1992

Brief description of amendment: The amendment incorporates into the Technical Specifications the addition of two containment isolation valves to the auxiliary feedwater system and changes to Technical Specification Table 3.6-2, "Containment Isolation Valves."

Date of issuance: December 14, 1992

Effective date: December 14, 1992

Amendment No.: 166

Facility Operating License No. DPR-65. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 2, 1992 (57 FR 40216) The October 20, 1992, submittal provided additional clarifying information that did not change the initial no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 14, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Learning Resources Center, Thames Valley State Technical College, 574 New London Turnpike, Norwich, Connecticut 06360.

Northern States Power Company, Docket Nos. 50-282 and 50-306, Prairie Island Nuclear Generating Plant, Unit Nos. 1 and 2, Goodhue County, Minnesota

Date of application for amendments: March 20, 1992 as revised July 23 and November 6, 1992. The July 23 and November 6, 1992 letters contained clarifying information to the amendment application. This information did not change the scope of the amendment request or the proposed determination of no significant hazards consideration.

Brief description of amendments: The amendments add and revise limiting conditions for operation and surveillance requirements to reflect the facility station blackout project modifications that will be complete upon startup of the Prairie Island units from the Fall 1992 outages.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment Nos.: 103 and 96

Facility Operating License Nos. DPR-42 and DPR-60. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 15, 1992 (57 FR 13135) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 17, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: Minneapolis Public Library, Technology and Science Department, 300 Nicollet Mall, Minneapolis, Minnesota 55401.

Power Authority of the State of New York, Docket No. 50-333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of application for amendment: November 20, 1992

Brief description of amendment: The amendment revises Technical Specification (TS) 3.0.D and its associated Bases to incorporate recommendations of NRC Generic Letter (GL) 87-09, "Sections 3 0 And 4.0 Of The Standard Technical Specifications (STS) On The Applicability Of Limiting Conditions For Operation And Surveillance Requirements." Specifically, GL 87-09 provides guidance to address unnecessary restrictions on mode changes by TS 3.0.4 (FitzPatrick TS 3.0.D) and inconsistent application of exceptions.

Date of issuance: December 17, 1992

Effective date: December 17, 1992

Amendment No.: 184

Facility Operating License No. DPR-59: Amendment revised the Technical Specifications.Public comments requested as to proposed no significant hazards consideration: Yes (57 FR 56430, dated November 27, 1992). That notice provided an opportunity to submit comments on the Commission's proposed no significant hazards consideration determination. No comments have been received. The notice published November 27, 1992, also provided for an opportunity to request a hearing by December 28, 1992, but indicated that if the Commission makes a final no significant hazards consideration determination any such hearing would take place after issuance of the amendment.

The Commission's related evaluation of the amendment, finding of exigent circumstances, and final no significant hazards consideration determination are contained in a Safety Evaluation dated December 17, 1992.

Local Public Document Room location: Reference and Documents Department, Penfield Library, State University of New York, Oswego, New York 13126.

Public Service Electric & Gas Company, Docket No. 50-354, Hope Creek Generating Station, Salem County, New Jersey

Date of application for amendment: June 4, 1992 and July 8, 1992, as supplemented by letters dated September 1, 1992, October 6, 1992, and November 16, 1992.

Brief description of amendment: This amendment changes Technical Specification 6.3 to delete the Operations Manager as a position requiring a Senior Reactor Operator (SRO) license and delineate the requirements for the Operations Manager position, and changes TS 6.3.1 and 6.4.1 to delete existing licensed operator qualification and training requirements that are superseded based on 1) INPO accreditation of Hope Creek's licensed operator training programs, and 2) promulgation of the revised 10 CFR Part 55.

Date of issuance: December 21, 1992

Effective date: December 21, 1992

Amendment No.: 56

Facility Operating License No. NPF-57: This amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** July 22, 1992 (57 FR 32576) and August 19, 1992 (57 FR 37571)The Commission's related evaluation of the amendment is contained in aSafety Evaluation dated December 21, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Pennsville Public Library, 190 S. Broadway, Pennsville, New Jersey 08070

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Docket No. 50-395, Virgil C. Summer Nuclear Station, Unit No. 1, Fairfield County, South Carolina

Date of application for amendment: April 15, 1992

Brief description of amendment: The amendment changes the Technical Specifications to revise Engineered Safety Features response times to account for sequential stroking of the outlet isolation valves on the refueling water storage tank and volume control tank.

Date of issuance: December 15, 1992

Effective date: December 15, 1992

Amendment No.: 108

Facility Operating License No. NPF-12. Amendment revises the Technical Specifications.

Date of initial notice in **Federal Register:** June 10, 1992 (57 FR 24679)The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 15, 1992, No significant hazards consideration comments received: No

Local Public Document Room location: Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: December 20, 1991 and October 30, 1992

Brief description of amendment: The amendment revised Technical Specification Table 3 3-4, "Engineered Safety Features Actuation System Instrumentation Trip Setpoint," Functional Unit 8.b, to change the trip setpoint, the allowable value, total allowance, sensor error, and "Z" value for the "4 KV Undervoltage-Grid Degraded Voltage" protection function to agree with the required design values.

Date of issuance: December 16, 1992

Effective date: December 16, 1992

Amendment No.: 74

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** April 29, 1992 (57 FR 18179)The October 30, 1992, letter provided clarifying information only and did not affect the staff's proposed no significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 16, 1992. No significant hazards consideration comments received: No.Sholly

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Union Electric Company, Docket No. 50-483, Callaway Plant, Unit 1, Callaway County, Missouri

Date of application for amendment: March 15, 1991, December 13, 1991, September 16, 1992 and October 30, 1992.

Brief description of amendment: The amendment revised Technical Specification (TS) ACTION statement 3.6.1.2, and the surveillance criteria in TS 4.6.1.2.b to establish two conditions for determining the acceptability of the periodic Type A tests conducted pursuant to Appendix J to 10 CFR Part 50. These conditions are the "as found" and the "as left" conditions; each has separate acceptance criteria.

Date of issuance: December 16, 1992

Effective date: December 16, 1992

Amendment No.: 75

Facility Operating License No. NPF-30. Amendment revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 4, 1991 (56 FR 43816)The December 13, 1991, September 16, 1992 and October 30, 1992 submittals provided additional clarifying information that did not change the initial proposed significant hazards consideration determination. The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 16, 12992. No significant hazards consideration comments received: No.

Local Public Document Room location: Callaway County Public Library, 710 Court Street, Fulton, Missouri 65251.

Virginia Electric and Power Company, et al., Docket Nos. 50-338 and 50-339, North Anna Power Station, Units No. 1 and No. 2, Louisa County, Virginia

Date of application for amendments: September 4, 1992

Brief description of amendments: The amendments revise the current NA-1&2 TS pertaining to the monitoring program for secondary waiver chemistry. The revised TS are consistent with the Steam Generator Owners' Group and Electric Power Research Institute guidelines and NUREG-0452, Revision 4, "Standard Technical Specifications for Westinghouse Pressurized Water Reactors."

Date of issuance: December 9, 1992

Effective date: December 9, 1992

Amendment Nos.: 169, 148

Facility Operating License Nos. NPF-4 and NPF-7. Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** October 14, 1992 (57 FR 47141)The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated December 9, 1992. No significant hazards consideration comments received: No.

Local Public Document Room location: The Alderman Library, Special Collections Department, University of Virginia, Charlottesville, Virginia 22903-2498.

Virginia Electric and Power Company, Docket Nos. 50-280 and 50-281, Surry Power Station, Unit Nos. 1 and 2, Surry County, Virginia.

Date of application for amendments. July 28, 1992

Brief description of amendments: These amendments delete the operability and surveillance requirements for the hydrogen monitor from the explosive gas monitoring instrumentation requirements for the waste gas holdup system. In addition, a requirement is added to submit a special report to the NRC if the oxygen concentration in a waste gas decay tank exceeds the TS limit and is not returned to below that limit in a specified time. Finally, administrative changes were made to achieve consistency with the Standard Technical Specifications.

Date of issuance: December 14, 1992

Effective date: December 14, 1992

Amendment Nos. 171, 170

Facility Operating License Nos. DPR-32 and DPR-37: Amendments revised the Technical Specifications.

Date of initial notice in **Federal Register:** September 2, 1992 (57 FR 40223) The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated December 14, 1992. No significant hazards consideration comments received: No

Local Public Document Room location: Swem Library, College of William and Mary, Williamsburg, Virginia 23185

Dated at Rockville, Maryland, this 29th day of December 1992.

For the Nuclear Regulatory Commission

Martin J. Virgilio,

Acting Director, Division of Reactor Projects III/IV/V, Office of Nuclear Reactor Regulation

[Doc. 93–44 Filed 1–5–93; 8:45 am]

BILLING CODE 7590–01–F

[Docket No. 50–373]

Commonwealth Edison Co.; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–11, issued to Commonwealth Edison Company (CECo, the licensee), for operation of the LaSalle County Station, Unit 1, located in LaSalle County, Illinois.

The proposed amendment requests changes to Technical Specification 5.0.

"Design Features" to address the planned rerack of the spent fuel pool at the LaSalle County Station. The proposed rerack would increase the spent fuel pool storage capacity from 1080 to 3986 storage cells. The added capacity would extend the projected loss of the full core discharge capability date from 2002 to 2013.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

(1) Would operation of the facility in accordance with the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

In the course of the analysis, CECo has considered the following potential accident scenarios:

1. A fuel assembly drop in the spent fuel pool.
2. Tool drops from the elevated worktable.
3. Loss of spent fuel pool cooling system flow.
4. A seismic event.
5. Rack (heavy load) drop during [rack installation].

It has been concluded that the proposed modification to the spent fuel pool does not increase the probability of accident scenarios 1–4 since the increase in storage capacity is not assumed to be an initiator of events involving the loss of spent fuel pool cooling, a dropped spent fuel assembly in the spent fuel pool, or a seismic event. A tool drop from the elevated worktable, although not a previously analyzed accident, is bounded by the consequences of the fuel drop accident.

CECo has also considered the probability of an accident resulting from a postulated rack (heavy load) drop during the [installation] process. LaSalle Technical Specification 3.9.7.b. restricts movement of loads heavier than the weight of a single spent fuel assembly from being carried over fuel stored in the spent fuel pool. All work in the spent fuel pool area will be controlled and performed in strict accordance with specific written procedures and administrative controls to prevent the movement of a rack directly over any fuel, all of which will be stored in the Unit 2 Spent Fuel Storage Pool. Therefore the probability of an accident resulting from the drop of a rack module on spent fuel is [very low].

* * * * *

Accordingly, the proposed Technical Specification and the associated modification does not involve an increase in the probability of an accident previously evaluated, or an accident of a different type.

CECo has evaluated the consequences of a fuel assembly drop in the spent fuel pool and determined that the criticality acceptance criterion, $k_{eff} \leq 0.95$, is not violated. In addition, CECo determined that the radiological consequences of a fuel assembly drop are bounded by the [Updated Final Safety Analysis Report] UFSAR analyses. Analyses demonstrate that the calculated doses are well within 10 CFR part 100 guidelines. The results of an analysis show that a dropped fuel assembly on the racks will not distort the racks such that stored fuel assemblies would be impacted. Thus, the consequences of this type of accident are not significantly changed from the previously evaluated spent fuel assembly drops.

The spent fuel pool system is a passive system with the exception of the Fuel Pool Cooling and Cleanup system and HVAC equipment. The redundancies in the cooling system and the HVAC hardware are not reduced by the planned storage densification. The extent of active hardware in these systems is only marginally changed. Therefore, the probability of occurrence or malfunction of safety equipment leading to loss of spent fuel pool cooling flow is not increased.

The consequences of a loss of spent fuel pool cooling system flow have been evaluated and it was determined that sufficient time remains available to provide an alternate means for cooling in the event of a complete failure of the cooling system. Thus, the consequences of this type of accident are not increased from previously evaluated loss of cooling system flow accidents.

The consequences of a seismic event have been evaluated. The new racks are designed and will be fabricated to meet the requirements of applicable portions of the NRC Regulatory Guides and published standards. The new free-standing racks are designed so that the integrity of both the racks and the pool structure is maintained during and after a seismic event with no resultant damage to stored fuel. Thus, the consequences of a seismic event are not increased from previously evaluated events.

The probability and consequences of a spent fuel cask drop will not be affected by the replacement of the racks. LaSalle Technical Specification 3.9.7. restricts movement of spent fuel casks from traveling over any region of the spent fuel pool. During the reracking of the Unit 1 Spent Fuel Storage Pool, all spent fuel will be stored in the Unit 2 Spent Fuel Storage Pool.

The consequences of a rack (heavy load) drop during [installation] have been considered. There is no equipment which is essential to the safe shutdown of the reactor or employed to mitigate the consequences of an accident which is beneath, adjacent to or otherwise within the area of influence of any loads that will be handled during the expansion modification. An analysis was also performed to determine the effect on the integrity of the spent fuel pool structure following the free fall of the heaviest rack module. The analysis concluded that the maximum load due to the rack drop event is well below the cumulative impact load produced during the seismic event, and as such is bounded by the seismic analysis. Therefore, the consequences of a rack (heavy load) drop during construction are not increased from previously evaluated events.

In summary, it is concluded that the proposed amendment to replace the spent fuel racks in the Unit 1 spent fuel pool does not involve an increase in the probability or consequences of an accident previously evaluated.

(2) Would operation of the facility in accordance with the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

CECo has evaluated the proposed modification in accordance with the guidance of the NRC Position Paper, "OT Position for Review and Acceptance of Spent Fuel Storage and Handling Applications," appropriate NRC Regulatory Guides, appropriate NRC Standard Review Plans, and appropriate Industry codes and standards. In addition, CECo has reviewed several previous NRC Safety Evaluation Reports for rerack applications similar to this proposed modification.

No unproven technology will be utilized either in the construction process or in the analytical techniques necessary to justify the planned fuel storage expansion. The basic reracking technology in this instance has been developed and demonstrated in other applications for fuel pool capacity increases previously approved by the NRC.

Based upon the foregoing, CECo concludes that the proposed Technical Specification and associated reracking modification does not create the possibility of a new or different kind of accident from any accident previously evaluated.

(3) Would operation of the facility in accordance with the proposed amendment involved a significant reduction in the margin of safety?

* * * * *

The established acceptance criterion for criticality is that the neutron multiplication factor in spent fuel pools shall be less than or equal to 0.95, including all uncertainties, under all conditions. This margin of safety has been adhered to in the criticality analysis methods for the new rack design.

The methods used in the criticality analysis conform to the applicable portions of the appropriate NRC guidance and industry codes, standards, and specifications. In meeting the acceptance criteria for criticality in the spent fuel pool, the analyses showed that k_{eff} is always less than 0.95, including uncertainties at a 95% confidence and 95% probability. Therefore, the proposed amendment does not involve a reduction in the margin of safety for nuclear criticality, as defined in the UFSAR.

The K-infinity criticality approach for allowing storage of advanced fuel designs in the new Unit 1 fuel racks includes the same type of conservatisms that were used in the original analysis performed for the new spent fuel storage racks. Therefore, the use of the K-infinity analysis does not involve a reduction in the margin of safety for nuclear criticality.

Conservative methods were used to calculate the maximum fuel cladding temperature and the increase in temperature of the water in the spent fuel pool. The thermal-hydraulic evaluation used the methods previously employed for evaluations of previously licensed high density spent fuel racks to demonstrate that adequate temperature margin is maintained. The proposed modification will increase the heat load in the spent fuel pool. However, the evaluation shows that the existing spent fuel cooling system will maintain the bulk pool water temperature at or below 140 degrees Fahrenheit with both cooling trains in operation. Thus, it is demonstrated that the peak value of the pool bulk temperature is lower than the temperature guidelines for both normal and abnormal conditions specified in the Standard Review Plan, section 9.1.3. The evaluation also shows that maximum local water temperatures along the hottest fuel assembly are below the nucleate boiling condition value. Thus, there is no reduction in the margin of safety for thermal hydraulic or spent fuel cooling concerns as defined in the UFSAR.

The main safety function of the spent fuel pool and the racks is to maintain the spent fuel assemblies in a safe configuration through all normal or abnormal loadings. Abnormal loadings which have been considered are the effect of an earthquake and the impact due to the drop of a spent fuel assembly. The mechanical, material, and structural design of the new spent fuel racks is in accordance with applicable portions of "NRC OT Position for Review and Acceptance of Spent Fuel Storage and Handling Applications," dated April 14, 1978, as modified January 18, 1979 and other applicable NRC guidance and industry codes. The rack materials used are comparable with the spent fuel pool and spent fuel assemblies. The structural considerations of the new racks address margins of safety against tilting and deflection or movement, such that the racks, if they do impact each other during the postulated seismic events, will only come in contact with each other at locations designed for that purpose. In addition the spent fuel assemblies remain intact and no criticality concerns exist. Thus the margins of safety as defined in the UFSAR are not reduced by the proposed rerack.

The Finite Element Method was used to evaluate the margins of the spent fuel pool concrete structure. The evaluation demonstrates that the strength margin of safety of the fuel pool structure is maintained.

From the foregoing, it is concluded that the margin of safety against nuclear criticality, structural integrity and material compatibility are consistent with the provision of the LaSalle UFSAR and USNRC regulations. The new worse case maximum bulk pool water temperature is 140 degrees Fahrenheit. This is found to result in a negligible decrease in the time-to-boil stated in the UFSAR. The margin of safety in the pool structure due to thermal loadings is well within the UFSAR specifications.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within thirty (30) days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Written comments may be submitted by mail to the Rules and Directives Review Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room P–223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the NRC Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555. The filing of requests for hearing and petitions for leave to intervene is discussed below.

By February 5, 1993, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555 and at the local public document room located at the Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board Panel, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board Panel will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The

contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period, such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Services Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800)–325–6000 (in Missouri 1–(800)–342–6700). The Western Union operator should be given Datagram Identification Number N1023 and the following message addressed to Richard J. Barrett: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Michael I. Miller, Esquire; Sidley and Austin, One First National Plaza, Chicago, Illinois 60690, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board Panel that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

The Commission hereby provides notice that this is a proceeding on an application for a license amendment falling within the scope of section 134 of the Nuclear Waste Policy Act of 1982 (NWPA), 42 U.S.C. 10154. Under section 134 of the NWPA, the Commission, at the request of any party to the proceeding, must use hybrid hearing procedures with respect to "any matter which the Commission determines to be in controversy among the parties." The hybrid procedures in section 134 provide for oral argument on matters in controversy, preceded by discovery under the Commission's rules, and the designation, following argument, of only those factual issues that involve a genuine and substantial dispute, together with any remaining questions of law, to be resolved in an adjudicatory hearing. Actual adjudicatory hearings are to be held on only those issues found to meet the criteria of section 134 and set for hearing after oral argument.

The Commission's rules implementing section 134 of the NWPA are found in 10 CFR part 2, Subpart K, "Hybrid Hearing Procedures for Expansion of Spent Nuclear Fuel Storage Capacity at Civilian Nuclear Power Reactors" (published at 50 FR 41670, October 15, 1985), and 10 CFR 2.1101 *et seq.* Under those rules, any party to the proceeding may invoke the hybrid hearing procedures by filing with the presiding officer a written request for oral argument under 10 CFR 2.1109. To be timely, the request must be filed within 10 days of an order granting a request for hearing or petition to intervene. (As outlined above, the Commission's rules in 10 CFR part 2, subpart G, and 2.714 in particular, continue to govern the filing of requests for a hearing or petitions to intervene, as well as the admission of contentions.) The presiding officer shall grant a timely request for oral argument. The presiding officer may grant an untimely request for oral argument only upon showing of good cause by the requesting party for the failure to file on time and after providing the other parties an opportunity to respond to the untimely request. If the presiding officer grants a request for oral argument, any hearing held on the application shall be conducted in accordance with the hybrid hearing procedures. In essence, those procedures limit the time available for discovery and require that an oral argument be held to determine whether any contentions must be resolved in adjudicatory hearing. If no party to the proceedings requests oral argument, or if all untimely requests for oral argument are denied, then the usual procedures in 10 CFR part 2, subpart G, apply.

For further details with respect to this action, see the application for amendment dated June 5, 1992, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the local public document room, located at the Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Dated at Rockville, Maryland, this 29th day of December 1992.

For the Nuclear Regulatory Commission.

Robert J. Stransky,

Project Manager, Project Directorate III–2, Division of Reactor Projects—III/IV/V, Office of Nuclear Reactor Regulation.

[FR Doc. 93–171 Filed 1–5–93; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF SPECIAL COUNSEL

Complaints and Disclosures Submitted Under the Whistleblower Protection Act

AGENCY: U.S. Office of Special Counsel.

ACTION: Extension of the expiration date of a currently approved collection.

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act.

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SUMMARY: The U.S. Office of Special Counsel has submitted the following proposal for the collection of information to the Office of Management and Budget for approval under provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

OMB APPROVAL NUMBER: 3255–0002.

SUPPLEMENTARY INFORMATION: To fulfill the requirements of 5 U.S.C. 1212(a) of the Whistleblower Protection Act of 1989, the Office of Special Counsel (OSC) must receive complaints of prohibited personnel practices, Hatch Act violations and other matters under the Special Counsel's jurisdiction; whistleblower disclosures must also be received.

Affected Public

Individuals and Federal, State, and local government employees.

Respondent's Obligations

Required to obtain or retain a benefit.

Frequency

One time per complaint or disclosure.

Estimated Completion Time

1 hour.

Annual Responses

1600.

FOR FURTHER INFORMATION CONTACT: Copies of the information collection proposal can be obtained by calling or writing Cathleen M. Sadlo, (202) 653–6005, U.S. Office of Special Counsel, 1730 M Street, NW., suite 300, Washington, DC 20036–4505. Written comments and recommendations for the proposed information collection should be sent to Ms. Sadlo and Joe Lackey, OMB Desk Officer, Office of Management and Budget, room 3002, 725 17th Street, NW., Washington, DC 20503.

Signed on this 30th day of December, 1992.

Leonard M. Dribinsky,

Deputy Associate Special Counsel for Prosecution.

[FR Doc. 93–121 Filed 1–5–93; 8:45 am]

BILLING CODE 7405–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301–90]

Determination Concerning Section 301 Investigation of Indonesian Acts, Policies, and Practices Regarding Pencil Slat

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of determination pursuant to section 304(a) of the Trade Act of 1974, as amended (Trade Act), that acts, policies, and practices of Indonesia concerning pencil slat are not imposing a burden or restriction upon United States commerce within the meaning of section 301(b)(1) of the Trade Act. In light of this determination, the United States Trade Representative (USTR) has terminated this investigation.

SUMMARY: On October 2, 1992, pursuant to section 302(a) of the Trade Act, the USTR initiated an investigation of Indonesia's acts, policies, and practices concerning pencil slat, in response to a petition filed by P&M Cedar Products, Inc. and Hudson ICS. 57 FR 46609 (Oct. 9, 1992). Since the investigation was initiated, the interagency Section 301 Committee has reviewed information submitted by the petitioners, the Government of Indonesia, and interested persons, as well as information already in the United States's possession and obtained from public sources. Additionally, in coordination with the Section 301 Committee, an interagency team led by USTR officials has conducted three rounds of consultations with Indonesian Government officials concerning the allegations set forth in the petition.

Based upon the results of these investigative efforts and the recommendations of the Section 301 Committee, the USTR has determined pursuant to sections 301(b)(1) and 304(a) of the Trade Act that the alleged acts, policies and practices are not imposing a burden or restriction upon United States commerce. Accordingly, the USTR has terminated this investigation.

EFFECTIVE DATE: This investigation is terminated effective December 31, 1992.

ADDRESSES: Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Peter Collins, Director, Southeast Asian Affairs (202) 395–6813; Joseph Papovich, Deputy Assistant United States Trade Representative for Industry and Labor (202) 395–6160; or Dorothy Balaban, Special Assistant to the Section 301 Committee (202) 395–3432, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION:

Summary of the Investigation

On August 18, 1992, P&M Cedar Products, Inc. and Hudson ICS filed a petition pursuant to section 302(a) of the Trade Act alleging that various Indonesian practices concerning pencil slat are unreasonable and burden or restrict United States commerce. Petitioners manufacture pencil slat from incense cedar. Indonesian pencil slat is manufactured from Jelutong, a less expensive and lower quality product.

The petition alleges that the following practices by Indonesia enhance exports of Indonesian pencil slat to third-country markets and are actionable under section 301(b): (1) The imposition of differential export taxes, with a high tax imposed on logs and no tax imposed on finished products such as pencil slat; (2) underpricing of government-owned timber stock; and (3) failure to enforce the terms of timber concession arrangements. The petition contends that these actions are part of Indonesia's plan to target exports of wood products, including pencil slat, a practice which is actionable under section 301(d)(3)(E) of the Trade Act. According to the petition, the combined effect of these practices has resulted in a substantial decline in petitioner' sales in third-country markets.

On October 2, 1992, the USTR initiated an investigation to determine whether the petition's allegations warranted action pursuant to section 301. 57 FR 46609 (Oct. 9, 1992). Immediately thereafter, USTR requested consultations with the Government of Indonesia, as required by section 303(a) of the Trade Act. Additionally, USTR invited comments from interested persons, 57 FR 46609–10, and obtained information and advice from the petitioners in preparing for the consultations. USTR also considered documents already in the possession of the United States concerning the possibility that Indonesia has engaged in or tolerated anticompetitive activities involving wood products.

In coordination with the Section 301 Committee, an interagency team led by USTR officials conducted three rounds of consultations with Indonesian government officials. Two of these rounds were held in Jakarta. On November 15 and 16, 1992, senior USTR officials and the Section 301 Committee met with petitioners and their counsel to discuss the petition's allegations, Indonesia's responses, submissions by interested persons, data gathered during the investigation, and legal and policy issues raised by the petition. The Section 301 Committee and the interagency investigative team also reviewed all available information concerning the practices alleged by the petition, including all comments submitted by interested persons and information obtained from international organizations.

Results of the Investigation

1. Indonesia's Log Export Tax

The investigation revealed that Indonesia maintains high export taxes on virtually all unprocessed and semi-processed wood products. The export tax on Jelutong logs is US$500 per cubic meter, and the export tax on Jelutong lumber is US$250 per cubic meter. The petition alleges that these export taxes "artificially inflate the domestic supply of materials used to make pencil slat, and thus depress their prices within Indonesia. Indonesian pencil slat producers thus obtain far cheaper raw materials."

No evidence was submitted to or uncovered by USTR or the Section 301 Committee during the investigation substantiating that the export tax has resulted in lower prices for Jelutong logs and lumber. In fact, as explained below, the data shows just the opposite—that Indonesian prices for Jelutong logs and lumber have increased notwithstanding the export tax.

2. Pricing of Government-Owned Timber

The petition also alleges that "Indonesia deliberately undervalues its forests, thereby reducing the cost of logging to artificially low levels," and that this undervaluation is evidenced by Indonesia's capture of only one-third of the actual economic "rent" on government-owned timber. Further, the petition claims that, because of extensive vertical integration in this industry, the benefits of any undervaluation flow directly to pencil slat producers. According to the petition, Indonesia captures less rent than the Malaysian state of Sabah. While Sabah captures over three-quarters of its timber rent, Indonesia captures only one-third.

Data obtained during the investigation demonstrates, however, that Indonesia's capture of rent compares favorably with that of a number of other similarly-situated, major timber producing states. These include the Malaysian state of Sarawak, Peninsular Malaysia, and the Philippines, which capture only 18.4 percent, 21.8 percent, and 11 percent, respectfully. This information indicates that Indonesia captures timber rent at a rate comparable to other similarly-situated countries.

3. Enforcement of Terms of Timber Concessions

The petition alleges that Indonesia charges "fire sale" prices for its timber and "turns a blind eye to widespread and notorious smuggling, poaching, early cutting, high grading, and tax evasion with respect to such timber harvests."

During the investigation, the Section 301 Committee obtained the following information concerning these allegations:

- A 1989 Ministerial Decree specifies the types of fines levied on Indonesian concessionaires who violate concession regulations. Out of the 581 concessionaires, 371 have had some type of fine levied against them since 1988; 607 violations have been recorded, for which approximately $21 million (at current exchange rates) in fines have been levied. Since 1988, 66 concession licenses have been revoked.
- In August 1992, Indonesia adopted a new procedure to track trees through the harvesting process to increase collected fees and deter poaching. The form used for this purpose is difficult to forge. If a log arrives at a mill without the required form, a fine of 10 times the royalty fee is assessed.
- Indonesia is making greater use of remote sensing information from satellites to monitor the rate of harvest and the presence of logging roads. An aerial survey is performed of the concession prior to its award, and thereafter an aerial survey is performed annually.
- Both the reforestation and license fees charged to Indonesian concessionaires have been increased.

USTR currently is unaware of any reason to question the validity of this information, which suggests that Indonesia has taken steps in recent years to enforce timber concession terms.

4. Trade Effects of the Alleged Practices

All available data indicates that prices of Jelutong logs in Indonesia actually have increased since the imposition of the export tax. In fact, prices for Jelutong logs appear to have increased more rapidly than other prices in the Indonesian economy. Factors other than the practices alleged in the petition appear to have had a much greater impact on prices than the three practices alleged by petitioners if, in fact, those practices have affected Indonesian prices of Jelutong logs. These factors include (1) exchange rate fluctuations since 1985; and (2) labor and transportation cost advantages enjoyed by Indonesian producers.

Thus, the alleged practices do not appear to be suppressing Jelutong log prices in Indonesia. The petition acknowledges that elimination of the export taxes on Jelutong logs and lumber "would have neither a direct nor an immediate impact on the export prices of Indonesian Jelutong slat." Accordingly, the remedy proposed by the petition is the imposition of an offsetting export tax on pencil slat, rather than the elimination of the export tax on Jelutong logs.

Comments Received From Interested Persons

Comments submitted by interested persons during the investigation suggest that the alleged practices do not exist, are not unreasonable, or are not harming United States commerce. Dixon-Ticonderoga, a United States pencil manufacturer that uses both cedar slat produced domestically and Jelutong slat from Indonesia, claims that Indonesia's ability to produce export-quality pencil slat is largely due to technical assistance provided by Dixon in order to develop an alternative to cedar slat. Dixon further claims that Indonesian Jelutong slat is used to produce lower-quality pencils for sale in markets that do not require the more expensive, higher-quality cedar slat.

According to Dixon, even if Indonesia eliminated all of the practices alleged in the petition, Dixon would continue to purchase Jelutong slat from Indonesia because there would still be a price difference between cedar and Jelutong slat. Thus, Dixon contends that elimination of the Indonesian practices would have no impact on the current mix of pencil slat sales in third-country markets. Accordingly, Dixon asserts that the practices alleged in the petition impose no burden or restriction on U.S. commerce.

The International Hardwood Products Association (IHPA) also submitted comments during the investigation. IHPA is comprised of importers of primarily tropical hardwoods, as well as some foreign exporters and end users. IHPA claims that the petitioners enjoyed a monopolistic position in the pencil slat market until Jelutong became available as an alternative to cedar. IHPA further claims that Indonesia will enjoy a comparative advantage in the pencil slat market as long as U.S. producers use more expensive raw materials (*i.e.*, cedar).

Determination

Section 301(b) of the Trade Act authorizes discretionary action if the USTR determines that an act, policy or practice of a foreign government is unreasonable and burdens or restricts United States commerce. Section 304(a)(1) of the Trade Act requires the USTR to determine whether any act, policy or practice described in section 301(b) exists and, if so, what action, if any, the USTR should take.

The petition contends that the three alleged practices together constitute export targeting, which Congress has specifically defined as an "unreasonable" practice within the meaning of section 301(b) The legislative history indicates that a determination of export targeting under section 301(b) concerns three elements:

(1) There must be a government scheme or plan involving coordinated actions;

(2) Export targeting practices must be involved; and

(3) The targeting must have the effect of assisting a discrete class of companies or industries to become more competitive in their export activities.

Based upon the results of this intensive investigation, and the recommendations of the interagency Section 301 Committee, the USTR has determined that there is no evidence that the alleged practices are having the adverse trade effects asserted by the petition. Thus, even assuming that the alleged practices exist and would otherwise be considered actionable under section 301(b), there is no basis for concluding that they are burdening or restricting United States commerce. Accordingly, the USTR has determined that no action is appropriate in this investigation and that it should be terminated.

The United States will continue to pursue improvements in international trade of wood and wood products through multilateral negotiations with Indonesia and other countries. In terminating this investigation, the USTR has strongly urged the Government of Indonesia to support these initiatives.

Additional information submitted to or obtained by USTR during this investigation is contained in the public file, which is available for public inspection in the USTR Reading Room: Room 101, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20506. An appointment to review the file (Docket No. 301–90) may be made by calling Brenda Webb (202) 395–6186. The USTR Reading Room is open to the public from 10 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday.

Jeanne E. Davidson,

Chairman, Section 301 Committee.,

[FR Doc. 93–180 Filed 1–5–93; 8:45 am]

BILLING CODE 3190–01–M

Identification of Priority Foreign Countries; Request for Public Comment

AGENCY: Office of the United States Trade Representative.

ACTION: Request for written submissions from the public concerning acts, policies to be considered with respect to identification of countries under section 182 the Trade Act of 1974, as amended (Trade Act).

SUMMARY: Section 182 of the Trade Act requires the United States Trade Representative (USTR) to identify countries that deny adequate and effective protection of intellectual property rights or deny fair and equitable market access to U.S. persons that rely on intellectual property protection. (19 U.S.C. 2242.) In addition, the USTR is required to determine which of those countries identified are priority foreign countries. Such priority countries would be subject to initiation of a "special" 301 investigation.

The USTR requests written submissions from the public concerning foreign countries' acts, policies, and practices that are relevant to the decision whether that country partner should be identified under section 182 of the Trade Act.

DATES: Submissions must be received on or before 12 noon on Friday, February 12, 1993.

FOR FURTHER INFORMATION CONTACT: Emery Simon, Deputy Assistant USTR for Intellectual Property (202) 395–6864; Gilbert Donahue at (202) 395–7320; or Catherine Field, Associate General Counsel (202) 395–3432, Office of the United States Trade Representative.

SUPPLEMENTARY INFORMATION: Pursuant to section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988, the USTR must identify those countries that deny adequate and effective protection for intellectual property rights or deny fair and equitable market access to U.S. persons that rely on intellectual property protection. Those countries that have the most onerous or egregious acts, policies, or practices and whose acts, policies or practices have the greatest adverse impact (actual or potential) on relevant U.S. products are to be identified as priority foreign countries.

The USTR may not identify a country as a priority foreign country if it is entering into good faith negotiations, or making significant progress in bilateral or multilateral negotiations, to provide adequate and effective protection of intellectual property rights.

The USTR must decide whether to identify countries as priority foreign countries each year and issue a decision within 30 days after publication of the National Trade Estimate (NTE) report, i.e., no later than April 30, 1993. Priority foreign countries are potentially subject to initiation of an investigation under section 301 of the Trade Act.

Requirements for Submissions

Submissions should include a description of the problems experienced and the effect of the acts, policies, and practices on U.S. industry. Submissions should be as detailed as possible and should provide as a much information on methodology for assessing the effect of the acts, policies and practices. Comments must be filed in accordance with the requirements set forth in 15 CFR 2006.8(b) (55 FR 20593) and must be sent to Dorothy Balaban, Special Assistant to the Section 301 Committee, room 223, 600 17th Street, NW., Washington, DC 20506, no later than 12 noon on Friday, February 12, 1993. Because submissions will be placed in a file open to public inspection at USTR, business-confidential information should not be submitted.

Public Inspection of Submissions

Within one business day of receipt, submissions will be placed in a public file, open for inspection at the USTR Reading Room, in room 101, Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC. An appointment to review the file may be made by calling Brenda Webb, (202) 395–6186. The USTR Reading Room is open to the public from 10 a.m. to 12 noon and from 1 p.m. to 4 p.m., Monday through Friday.

Carmen Suro-Bredie,

Assistant USTR for Intellectual Property and the Environment.

[FR Doc. 93–181 Filed 1–5–93; 8:45 am]

BILLING CODE 3190–01–M

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the Railroad Retirement Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) *Collection title:* Financial Disclosure Statement

(2) *Form(s) submitted:* G–423

(3) *OMB Number:* 3220–0127

(4) *Expiration date of current OMB clearance:* Three years from date of OMB approval

(5) *Type of request:* Extension of the expiration date of a currently

approved collection without any change in the substance or in the method of collection
(6) *Frequence of response:* On Occasion
(7) *Respondents:* Individuals or households
(8) *Estimated annual number of respondents:* 2,100
(9) *Total annual responses:* 2,100
(10) *Average time per response:* 1.4166 hours
(11) *Total annual reporting hours:* 2,975
(12) *Collection description:* Under the Railroad Retirement and Railroad Unemployment Insurance Acts, the Railroad Retirement Board has authority to secure from an overpaid beneficiary a statement of the individual's assets and liabilities if waiver of the overpayment is requested.

Additional Information or Comments: Copies of the form and supporting documents can be obtained from Dennis Eagan, the agency clearance officer (312–751–4693). Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092 and the OMB reviewer, Laura Oliven (202–395–7316), Office of Management and Budget, room 3002, New Executive Office Building, Washington, DC 20503.

Dennis Eagan,

Clearance Officer.

[FR Doc. 93–177 Filed 1–5–93; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

Forms Under Review by Office of Management and Budget

Agency Clearance Officer—John J. Lane (202) 272–5407.

Upon written request copy available from: Securities and Exchange Commission Office of Filings, Information, and Consumer Services, Washington, DC 20549.

Extension:

Rules 701, 702, 703 and Form 701—File No. 270–306, Form 8—File No. 270–158, Regulation B—File No. 270–102, Rule 236—File No. 270–118.

Notice is hereby given pursuant to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*), that the Securities and Exchange Commission ("Commission") has submitted for OMB approval extension of the following: Rules 701, 702, 703, and Form 701, Form 8, Regulation B, and Rule 236.

Filings on Form 701 and pursuant to the rules and regulation provide limited exemptions from the registration requirements of the Securities Act of 1933. Form 701 is filed by approximately 500 respondents annually at an estimated one burden hour per response.

Form 8 is used to file amendments to applications for registration of securities pursuant to section 12 of the Securities Exchange Act of 1934, or amendments to annual reports and other reports filed pursuant to sections 13 and 15(d) of that Act. There are approximately 6,856 Form 8 filings annually at an estimated 12 burden hours per response.

It is estimated that approximately five respondents file schedules and forms under Regulation B annually at an estimated 41 burden hours per response.

Approximately 10 respondents make filings pursuant to Rule 236 annually at an estimated 1.5 burden hours per response.

The estimated average burden hours are made solely for purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even a representative survey or study of the costs of Commission rules or forms. General comments regarding the estimated burden hours should be directed to Gary Waxman at the address below. Any comments concerning the accuracy of the estimated average burden hours for compliance with Commission rules and forms should be directed to John J. Lane, Associate Executive Director, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549 and Gary Waxman, (PRA Project Nos. 3235–0093, 3235–0095; 3235–0141 and 3235–0347), Clearance Officer, Office of Management and Budget, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: December 29, 1992.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–126 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–31668; File No. SR–NYSE–92–34]

Self-Regulatory Organizations; Proposed Rule Change by the New York Stock Exchange, Inc., Relating to Annual Regulatory Fee

December 29, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 11, 1992, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The New York Stock Exchange is proposing to extend the applicability of the annual regulatory fee imposed pursuant to Rule 129 to all members and member organizations.[2]

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in section (A), (B) and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to permit the Exchange to extend the regulatory fee imposed pursuant to Rule 129 to all members and member organizations. The fee was established to help offset expenses incurred by the Exchange for Financial/Operational ("FIN/OP") examinations and surveillance performed pursuant to its responsibilities under the Act.[3] The regulatory fee is presently collected only from members and member organizations for which the Exchange has been appointed the Designated Examining Authority ("DEA") by the

[1] The NYSE has amended the proposed rule change to clarify that the regulatory fee at issue is presently collected from members and member organizations for which the Exchange is the designated examining authority pursuant to Rule 17d–1 rather than 17d–2 of the Act. *See* letter from Mary Furlong, Director of Rule and Interpretive Standards, NYSE, to Cheryl Evans-Dunfee, Staff Attorney, Exchange Branch, Division of Market Regulation, SEC, dated December 29, 1992. See also note 4, infra.

[2] NYSE Rule 129 provides that is Board of Governors may impose charges on members to reimburse the Exchange, in whole or in part, for regulatory oversight services provided for the membership by the Exchange.

[3] *See* Securities Exchange Act Release Nos. 20277 (October 19, 1983), 48 FR 48562, and 20337 (October 31, 1983), 48 FR 51188 (File Nos. SR–NYSE–83–33 and SR–NYSE–83–34).

Commission under Rule 17d–1 of the Act.[4]

Exchange policy is to surveil and examine all members and member organizations irrespective of DEA designation. There are currently 536 Exchange member organizations of which all but 21 have been designated to the Exchange. Imposition of the regulatory fee on the 21 member organizations that have been designated to other SROs will help offset the costs incurred by the Exchange in performing FIN/OP functions for these organizations. These functions include: Field examinations; monthly review and analysis of FOCUS; review of year-end outside audits; preparation of risk assessment packages; and response to interpretive questions.

The NYSE believes that the proposed rule change is consistent with the requirement under section 6(b)(4) of the Act that an exchange have rules that provide for the equitable allocation of reasonable dues, fees and other charges among its members and issuers and other persons using its facilities. The NYSE also believes that the imposition of the regulatory fee to non-DEA organizations will provide for a more equitable allocation among all members and member organizations of regulatory related expenses.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will impose no burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments regarding the proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR–NYSE–92–34 and should be submitted by January 27, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–130 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[4] 17 CFR 240.17d–1 (1991). Exchange Act Rule 17d–1 provides that where a member of SIPC is a member of more than one self-regulatory organization ("SRO"), the Commission shall designate responsibility for examining such member for compliance with applicable financial responsibility rules.

[Rel. No. IC–19191; 812–8156]

American Capital Government Target Series, et al.; Application

December 29, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: American Capital Government Target Series ("Trust") and American Capital Asset Management, Inc. ("Adviser").

RELEVANT ACT SECTIONS: Order requested under section 17(b) for an exemption from section 17(a), and under rule 17d–1(b) to permit a joint transaction otherwise prohibited by section 17(d) and rule 17d–1(a).

SUMMARY OF APPLICATION: Applicants seek an order that would permit one of the Trust's two portfolios to acquire all of the assets and assume all of the liabilities of the Trust's other portfolio.

FILING DATE: The application was filed on November 10, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, c/o American Capital Asset Management, Inc., 2800 Post Oak Blvd., Houston, Texas 77056.

FOR FURTHER INFORMATION CONTACT: Barry A. Mendelson, Senior Attorney, at (202) 504–2284, or C. David Messman, Branch Chief, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. The Trust was organized on June 24, 1990 as a Massachusetts business trust. The Trust is registered under the Act as an open-end, diversified, management investment company. The Trust is comprised of two investment portfolios: Portfolio '97 and Portfolio '98 (the "Portfolios"). The Adviser provides investment advisory, administrative, and management services to the Portfolios.

2. Portfolio '97 and Portfolio '98 have the same investment objectives and policies, the same fee structure, and similar investment portfolios. Both Portfolios invest at least 80% of their assets in obligations issued or guaranteed by the United States government or its agencies or instrumentalities. The only substantive

difference between the two Portfolios is the liquidation date. Portfolio '97 is scheduled to liquidate on December 16, 1997; Portfolio '98 is scheduled to liquidate on May 1, 1998.

3. In its capacity as custodian of the Portfolios, Amalgamated Bank of New York ("Amalgamated") owned of record, as of October 30, 1992, approximately 21% of the outstanding shares of Portfolio '97 and approximately 47% of the outstanding shares of Portfolio '98.

4. The trustees of the Trust, including a majority of those trustees who are not "interested persons" (as defined in the Act) of the Trust ("Disinterested Trustees") have approved a Plan of Reorganization ("Plan") pursuant to which Portfolio '97 will acquire all of the assets and assume all of the liabilities of Portfolio '98. The net asset value of the shares Portfolio '97 issues in the exchange will equal the net asset value of the shares of Portfolio '98 then outstanding. Each shareholder of Portfolio '98 will receive that number of full and fractional shares of Portfolio '97 equal in value as of the date of the exchange to the value of such shareholder's shares of Portfolio '98.

5. The Trust will submit the proposed Plan to the shareholders of Portfolio '98 for their approval at a meeting called for that purpose to be held on or about March 31, 1993. A majority of the outstanding shares of Portfolio '98 will be required to approve the acquisition.

6. The proposed reorganization will result in an increase in the asset size of Portfolio '97. The Trust expects that, to the extent expenses remain relatively fixed and do not vary with asset size, this increase will result in economies of scale to the benefit of all shareholders of the combined Portfolio. Management will be facilitated by having fewer Portfolios and certain expenses, including brokerage and research costs, audit fees, and general administrative costs, are expected to decrease as a result.

7. The proposed transaction will not have adverse tax consequences for the shareholders. No gain or loss will be recognized by Portfolio '98 or its shareholders as a result of the reorganization, and applicants will receive an opinion of tax counsel to this effect before consummating the reorganization.

8. The Adviser will pay all of the direct and indirect expenses of the proposed transaction.

Applicants' Legal Analysis

1. Section 2(a)(3) of the Act defines the term "affiliated person," in relevant part, as:

> (A) any person directly or indirectly owning, controlling, or holding with power to vote, 5 per centum or more of the outstanding voting securities of such other person; (B) any person 5 per centum or more of whose outstanding voting securities are directly or indirectly owned, controlled, or held with power to vote, by such person; (C) any person directly or indirectly controlled by or under common control with, such other person * * *.

The Portfolios would be considered affiliated persons of one another if they are deemed to be under "common control." In this regard, since the Portfolios are part of the same investment company, they have common trustees and officers, and a common investment adviser. In addition, by virtue of its ownership of the Portfolios' stock, Amalgamated, the Portfolios' custodian, arguably is a "5% affiliate" of each Portfolio. If so, Portfolio '97 would be an affiliated person of an affiliated person (*i.e.*, Amalgamated) of Portfolio '98, and vice-versa.

2. Section 17(a) of the Act, in relevant part, prohibits any affiliated person of a registered investment company, or any affiliated person of such a person, from knowingly selling to or purchasing from such investment company any security or other property.

3. Rule 17a–8 under the act exempts from the prohibitions of section 17(a) mergers, consolidations, or purchases or sales of substantially all of the assets involving registered investment companies which may be affiliated persons, or affiliated persons of an affiliated person, solely by reason of having a common investment adviser, common directors, and/or common officers. Because the Portfolios may be affiliated with one another other than through their adviser, directors, and officers, applicants may not rely on rule 17a–8. Nevertheless, applicants have agreed to comply with the substantive requirements of the rule. Specifically, the trustees of the Trust, including a majority of the Disinterested Trustees, have determined that the proposed reorganization will be in the best interests of the shareholders of each Portfolio and will not result in the dilution of the current interests of any such shareholder.

4. Section 17(b) of the Act authorizes the SEC to exempt any transaction from the provisions of section 17(a) if the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned; the transaction is consistent with the policy of each registered investment company concerned; and the transaction is consistent with the general purposes of the Act.

5. Applicants contend that the proposed reorganization meets the standards of section 17(b). Among other things, applicants assert that (a) the shareholders of both Portfolios will benefit from the reorganization (as discussed above), (b) the Adviser will bear all costs of the reorganization, (c) the reorganization is subject to approval of the shareholders of Portfolio '98, who will receive a proxy statement containing information about the transaction, (d) the reorganization will have no adverse tax consequences for shareholders of either Portfolio, and (e) the exchange will be made at net asset value and will not result in dilution of the current interests of any shareholder.

6. Section 17(d) and rule 17d–1(a), taken together, prohibit an affiliated person of a registered investment company, or an affiliated person of such a person, acting as principal, from participating in, or effecting any transaction in connection with, any joint enterprise or joint arrangement in which such registered company is a paricipant, unless an application relating thereto has been filed with the SEC and an order approving the joint transaction has been entered.

7. Rule 17d–1(b) provides that in determining whether to grant an order, the SEC must consider whether participation of each Portfolio in the reorganization is consistent with the provisions, policies and purposes of the Act, and the extent to which each Portfolio's participation is on a basis different from or less advantageous than that of other participants.

8. Applicants contend that the proposed reorganization meets the standards of rule 17d–1(b). In particular, they note that each Portfolio will participate in the reorganization on a basis not different from or less advantageous than that of the other Portfolio. Moreover, applicants submit that the participation of Amalgamated (as a shareholder of each Portfolio) in the organization is consistent with rule 17d–1 because Amalgamated will receive no benefit different from an other Portfolio '98 shareholder. Finally, applicants note that although the Adviser and its affiliates may receive some benefits from the reorganization, the Adviser will bear all of the costs thereof.

For the SEC, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–125 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–19185; 812–7498]

First Prairie Money Market Fund et al.; Application

December 29, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: First Prairie Money Market Fund (the "Fund") and The First National Bank of Chicago ("FNBC").

RELEVANT ACT SECTIONS: Exemption requested pursuant to sections 6(c) and 17(b) from section 17(a).

SUMMARY OF APPLICATION: Applicants seek an order to permit the Fund to enter into repurchase agreements with FNBC or an affiliate of FNBC.

FILING DATE: The application was filed March 22, 1990 and amended on January 10, 1992, August 7, 1992, and November 27, 1992. Counsel for the applicants has represented by letter dated December 24, 1992, that another amendment, the substance of which is incorporated herein, will be filed during the notice period.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicants, First Prairie Money Market Fund, 144 Glenn Curtiss Boulevard, Uniondale, New York 11556–0144; The First National Bank of Chicago, One First National Plaza, Chicago, Illinois 60670–0120.

FOR FURTHER INFORMATION CONTACT: Marilyn Mann, Special Counsel, at (202) 504–2259, or Barry Miller, Senior Special Counsel, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicants' Representations

1. The Fund is an open-end, diversified management investment company. It is a money market fund that maintains a net asset value of $1.00 per share for purchases and redemptions and, pursuant to rule 2a–7 under the Act, uses the amortized cost method of valuing its securities.

2. FNBC is the Fund's investment adviser. FNBC, a wholly owned subsidiary of First Chicago Corporation, a registered bank holding company, is a commercial bank offering a range of banking and investment services. The Bank of New York acts as the Fund's custodian.

3. The Fund is divided into two separate portfolios, the Money Market Series and the Government Series (each, a "Series"). The Money Market Series invests in short-term money market obligations, including repurchase agreements with banks or primary government securities dealers reporting to the Federal Reserve Bank of New York. The Government Series invests only in short-term securities issued or guaranteed as to principal and interest by the U.S. Government, and repurchase agreements with respect to such securities with banks that have total assets in excess of $1 billion or securities dealers that have issued securities rated at least A–1 by Standard & Poor's Corporation.

4. The Fund's shares are purchased primarily by clients of FNBC and its affiliates, including qualified custody, agency, and trust accounts, through their accounts with FNBC and its affiliates. The Fund's shares may be purchased through automatic investment transactions. In these transactions, FNBC, as agent, follows the standing instructions of such clients and automatically invests excess cash balances in the clients' accounts in shares of the Money Market Series or the Government Series.[1] Currently, these "sweep" transactions are effected automatically by computer each Fund business day as of the next determined net asset value (currently, 12 noon, New York time). The machine processing required to tabulate the day's transactions in such clients' accounts and other shareholder accounts, however, is completed later in the day (normally no earlier than 11 p.m., New York time) when the daily processing for FNBC's accounting system is completed (the "Completion Time"). Therefore, total assets to be invested in each Series through the "sweep" program each day are not known until that evening and are invested in each Series at the respective net asset values determined on the following day.

5. The current operation of the "sweep" program makes the Fund materially less attractive to FNBC's clients because they lose a day's income on funds invested through the program and, for "sweeps" accomplished on a Friday, lose a weekend's income.

6. To permit FNBC, as the Fund's investment adviser, to invest anticipated net assets attributable to the "sweep" program on the same day that they are available for investment (despite the fact that the exact amount thereof will not be known until after the time for investment that day), FNBC or an affiliate proposes to enter into overnight repurchase agreements with each Series. Such assets would be invested in Fund shares as of the time the relevant Series determined its net asset value (the "Pricing Time") on the same day the sweep occurs.

7. The Fund proposes to enter into a master repurchase agreement with FNBC or one of its affiliates, which is substantially the same as the industry standard master repurchase agreement promulgated by the Public Securities Association, covering all repurchase agreement transactions (the "Master Repurchase Agreement").

8. Applicants intend to limit the amount of each Series' net assets that may be invested pursuant to the order with FNBC or its affiliates to a percentage upon which applicants from time to time may agree (the "Maximum Purchase Amount"), which percentage may fluctuate but shall not exceed 15%.

9. To facilitate the repurchase transaction where the exact amount of the overnight repurchase agreement and, consequently, the required collateral is not known until the following day, FNBC, at no cost to the Fund, will maintain at all times in a segregated sub-custodian account in the name of the relevant Series collateral at least equal to 102% of the Maximum Purchase Amount. The Fund will promptly notify FNBC of any increase or decrease in a Series' net asset value and

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[1] In accordance with the standing instructions of FNBC's clients, the computer program also provides for the automatic redemption of Fund shares held in an account as of the next determined net asset value if the cash balance in the account is less than the minimum balance specified by the client.

FNBC will adjust the amount of collateral maintained in the segregated account daily so that it at least equals 102% of the Maximum Purchase Amount. The relevant Series will have a perfected security interest in the repurchase agreement collateral held in such account.

10. FNBC's Trust Department would act as the Fund's sub-custodian pursuant to a sub-custodian agreement approved by the Fund's Board of Trustees, including a majority of the Trustees who are not "interested persons," as defined in the Act, of either FNBC or the Fund.[2] The Fund's assets held by FNBC's Trust Department would be maintained in a segregated custodial account established on its behalf in accordance with the rules and standards of the Comptroller of the Currency and the Act. FNBC's Trust Department would receive the eligible securities transferred to it in its capacity as sub-custodian for the relevant Series and hold them in a manner complying with the requirements of section 17(f) of the Act. After the Completion Time that evening, for a particular Series, the records maintained by FNBC for its client's accounts and by FNBC's Trust Department in its capacity as the Series' sub-custodian would show:

(i) For FNBC's client accounts, a cash entry for the amount of Series shares purchased or redeemed and a corresponding entry to the client accounts for the number of Series shares purchased or redeemed as of the Pricing Time through operation of the computer "sweep" program; and

(ii) For the Fund's sub-custodian account, all purchase and sale transactions and the net cash proceeds, if any, received by the Series through the operation of the "sweep" (or, conversely, the net redemption proceeds paid or payable by the Series if there were net redemptions). In addition, the relevant Series' sub-custodian account would reflect the specific amount in fact invested in the particular transaction (including the ownership of the securities securing the repurchase agreement). If the "sweep" had resulted in unanticipated net redemptions for the Series, the relevant sub-custodian account would reflect this fact and show no ownership of any of such securities transferred by FNBC or its affiliates to the account, since (contrary to expectations) none of the Fund's assets had been used to purchase the securities. To the extent that transferred securities exceeded the relevant Series' assets that were available for investment (as shown by the results of the day's computer processing), FNBC or the appropriate affiliate would be shown to be the owner of such securities.

11. After the Completion Time, FNBC would transmit to the Fund's transfer agent records relating to these automatic investment transactions. The transfer agent's records would show an entry to each of the corresponding shareholder accounts for the number of Fund shares automatically purchased or redeemed as of the Pricing Time through operation of the "sweep."

12. Each Series will purchase only securities in which it may invest as described in its prospectus and statement of additional information and as limited by rule 2a-7 under the Act. The Master Repurchase Agreement into which the Fund, on behalf of each Series, proposes to enter will be collateralized only by U.S. Treasury Bills, Notes, and Bonds, with a remaining maturity of one year or less and value at least equal to 102% of the repurchase price (including accrued interest). The transactions will comply with the guidelines set forth in Investment Company Act Release No. 13005 (February 2, 1983). The Master Repurchase Agreement will be subject to annual approval by the Fund's Board of Trustees, including a majority of the Trustees who are not "interested persons" (as defined in the Act) of the Fund or FNBC or its affiliates.

13. The transactions would be "repurchase agreements" for purposes of Chapter 11 of the United States Bankruptcy Code and the Financial Institutions Reform, Recovery and Enforcement Act of 1989. These statutes provide that, if the bankruptcy of the counterparty occurs, the repurchase agreement can be liquidated without being subject to the potential delay associated with the automatic stay or similar provisions of those statutes. If the transactions were not "repurchase agreements" as defined under those statutes, the Fund might encounter significant liquidity problems if a large percentage of its assets were invested in repurchase agreements with a bankrupt counterparty.

14. Each of the Money Market Series and the Government Series currently invests a substantial amount of their respective net assets on an overnight basis. The Fund's average daily portfolio maturity customarily is between 20 and 40 days for the Money Market Series and 15 and 25 days for the Government Series. Applicants intend to limit the Maximum Purchase Amount at a level that they believe should avoid reducing average daily portfolio maturity and thus the yield for the Fund.[3]

15. FNBC will continue to solicit independent quotes from third parties for the proposed "sweep" transactions, but to date FNBC has been unable to find any unaffiliated entity willing to engage in such transactions on a basis as favorable to the Fund as the proposed arrangement with FNBC. The repurchase agreement counter-party will not know until the next day the amount, if any, of such transactions. This delay results because the daily processing for FNBC's accounting system normally is completed well into the night of the day the order is placed and the actual amount to be invested in the repurchase transaction is not known and, thus, monies in respect thereof cannot be transmitted until the next morning. Unaffiliated third parties will not agree to operate in this "look back" manner with the Fund on a basis as favorable to the Fund as the proposed arrangement with FNBC.

16. Before any repurchase agreements are entered into pursuant to the exemption, the Fund or FNBC must obtain and document competitive quotations from at least two other dealers with respect to repurchase agreements that are comparable in terms of size, maturity, and collateral, except that if quotations are unavailable from two such dealers only one other competitive quotation is required. In addition, the transactions for which quotations are sought will be conventional overnight repurchase agreements in which the funds would be transferred by the Fund on the same day that the transaction is entered into, and then returned by the counterparty on the following day. Before entering into a transaction pursuant to the exemption, a determination will be required that the income to be earned from the repurchase agreement is at least equal to that available from the other dealers from which quotes were obtained. As set forth in the application, applicants enter into repurchase agreements on an ongoing basis and, therefore, believe they are capable of obtaining such quotes.

Applicants' Legal Analysis

1. Section 17(a) of the Act, among other things, generally prohibits certain entities affiliated with an registered investment company, when acting as principal, from knowingly selling to or purchasing from the investment

[2] The sub-custodian account may be maintained with FNBC's Trust Department or a nominee qualified to act as a custodian pursuant to section 17(f) of the Act and references herein to FNBC's Trust Department shall mean either entity.

[3] Applicants point out that, not infrequently, the overnight rate is as favorable as and, in certain cases, may exceed the rate available for securities with longer maturities.

company any security. Among the entities precluded from dealing as principal with a registered investment company under section 17(a) are any affiliated person of the investment company and any affiliated person of an affiliated person of the investment company. Section 2(a)(3) of the Act defines any investment adviser of such company. Therefore, FNBC, as the Fund's investment adviser, and its affiliates are subject to the prohibitions contained in section 17(a) with respect to the Fund.

2. Section 6(c) of the Act provides in relevant part that "the Commission, * * * by order upon application, may * * * exempt any person, security, or transaction * * * from any provision or provisions of [the Act] or of any rule or regulation thereunder, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of [the Act]."

3. Section 17(b) of the Act provides that "notwithstanding [section 17(a)], any person may file with the Commission an application for an order exempting a proposed transaction * * * from one or more provisions of that subsection. The Commission shall grant such application and issue such order of exemption if evidence establishes that * * * (1) the terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned; (2) the proposed transaction is consistent with the policy of each registered investment company concerned, as recited in its registration statement and reports filed under [the Act]; and (3) the proposed transaction is consistent with the general purposes of [the Act]."

4. The Fund believes that the relief requested is appropriate and in the public interest because it will permit the Fund to invest at a favorable price net assets attributable to the "sweep" program on the same day that such assets are available for investment. Applicants believe that a more attractive "sweep" program will result in increased assets for the Fund. A larger asset base for the Fund will benefit all Fund shareholders by reducing the amount of Fund expenses indirectly borne by each shareholder, thereby increasing investors' returns.

5. FNBC and its affiliates are aware of the potential conflict of interest inherent in the operation of the "sweep" program if the proposed relief is granted. FNBC, therefore, has established procedures and conditions to be followed by its employees and agents to prevent any overreaching on the part of any person that could act to the detriment of the Fund and to ensure that each transaction is effected on a reasonable and fair basis.

6. The Fund's overnight position should not necessarily reduce its yield. If the operation of the proposed "sweep" program shortens the Fund's average daily portfolio maturity, the effect of such reduction would be minimal because: (i) The Fund currently maintains a relatively short average daily portfolio maturity; (ii) as FNBC develops more experience operating the "sweep" program, FNBC will be able to manage the maturity of that portion of the Fund's assets held outside the sub-custodian account for the program so as to provide optimal liquidity levels; and (iii) upon receipt of such assets currently, the Fund has invested such assets in overnight or very short-term obligations in any event, but such investment occurs one day later. Thus, applicants believe that any effect on yield as a result of the proposed relief would be negligible. In addition, operation pursuant to the independent pricing mechanism set forth in condition 8 should provide yields from "sweep" investments that are no lower than similar non-sweep Fund investments.

7. Based on the arguments set forth above, applicants believe that the requested relief is necessary and appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants also believe that the terms of the proposed transactions, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, that the proposed transactions are consistent with the policy of each Series, as set forth in the Fund's registration statement and reports filed under the Act, and that the proposed transactions are consistent with the general purposes of the Act.

Applicants' Conditions

Applicants agree that the order of the Commission granting the requested relief shall be subject to the following conditions:

1. No FNBC or affiliate "sweep" account client will be permitted to affect a transaction after the sweep has occurred and the Fund's net asset value has been computed for that day.

2. The legal or compliance department of, and internal and outside auditors for, FNBC or its affiliates will prepare guidelines for FNBC and affiliate personnel to ensure that the transactions described herein comply with the conditions set forth herein and that the integrity of the program is maintained. The Fund's independent public accountants will verify assets held in each sub-custodian account in accordance with rule 17f–2 under the Act. The legal or compliance department and auditors will periodically monitor the activities of FNBC and its affiliates in connection with the operation of the "sweep" program to ensure that the conditions set forth in the application are adhered to.

3. If granted, the terms of the relief would be disclosed fully in the Fund's prospectus and statement of additional information. A schedule of all transactions with FNBC and its affiliates will be filed with each semi-annual report filed by the Fund with the Commission pursuant to sections 30(a) and 30(b)(1) of the Act. FNBC will provide the Fund's Board of Trustees with a full report of the transactions under the "sweep" program, as described herein, no less frequently than quarterly. FNBC also will provide the Board of Trustees with a statement that, as the Fund's investment adviser, it determined the principal transactions to be necessary and appropriate under the circumstances.

4. The Fund and FNBC will maintain such records with respect to those transactions conducted pursuant to the exemption as may be necessary to confirm compliance with the conditions to the requested relief. In this regard, the Fund will maintain an itemized daily record of repurchase agreement transactions entered into pursuant to the exemption, showing for each transaction: the Series that entered into the transaction; the entity with which the Series entered into the transaction; the purchase and repurchase prices; the type and amount of collateral; the date fixed for termination of the transaction; and the time and date of the transaction. For each transaction, such records also shall document the quotations received from other dealers in accordance with condition no. 8, including: The names of the dealers; the prices quoted; and the times and dates the quotations were received. The records required by this condition will be maintained and preserved in the same manner as records required under rule 31a–1(b)(1).

5. The Maximum Purchase Amount will be the percentage of each Series' net assets upon which the applicants from time to time may agree, which percentage may fluctuate but shall not

exceed 15%. As to a particular Series on a particular day, the amount invested pursuant to the exemption will not exceed the amount swept into such Series on such day.

6. All records pertaining to the sweep program will be preserved for a period of not less than six years, the first two years in an easily accessible place, from the end of the fiscal year in which any sweep transaction occurred.

7. In connection with overnight repurchase agreement transactions pursuant to the Master Repurchase Agreement, FNBC will maintain at all times during operation of the "sweep" program in a segregated sub-custodian account in the name of each Series collateral comprised only of U.S. Treasury Bills, Notes or Bonds, with remaining maturities of one year or less, and valued at least equal to 102% of the Maximum Purchase Amount. In addition, FNBC or its affiliates would transfer such collateral through the book entry system of the Federal Reserve and, in connection therewith, the relevant Series' sub-custodian account with FNBC's Trust Department will be designated by Fedwire as the recipient of such securities and FNBC's internal records and written confirmations will indicate that the collateral is being held on behalf and in such Series' name. The relevant Series thereby would acquire a security interest in the collateral.

8. Before any transaction may be conducted pursuant to the exemption, the Fund or FNBC must obtain such information as it deems necessary to determine that the price test set forth below has been satisfied. Before any repurchase agreements are entered into pursuant to the exemption, the Fund or FNBC must obtain and document competitive quotations from at least two other dealers with respect to repurchase agreements comparable to the type of repurchase agreement involved (including size, which would be at least equal to the Maximum Purchase Amount, maturity and collateral), except that if quotations are unavailable from two such dealers only one other competitive quotation is required. In addition, the transactions for which quotations are sought will be conventional overnight repurchase agreements in which the funds would be transferred by the Fund on the same day that the transaction is entered into, and then returned by the counterparty on the following day. Before entering into a transaction pursuant to the exemption, a determination will be required in each instance, based upon the information available to the Fund and FNBC, that the income to be earned from the repurchase agreement is at least equal to that available from the other dealers from which quotes were obtained.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–127 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Rel. No. 19187; International Series Rel. No. 515; 812–8222]

The Park Avenue Portfolio; Notice of Application

December 29, 1992.

AGENCY: Securities and Exchange Commission (the "SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "Act").

APPLICANT: The Park Avenue Portfolio.

RELEVANT ACT SECTIONS: Order requested under section 6(c) for an exemption from the provisions of section 12(d)(3).

SUMMARY OF APPLICATION: Applicant seeks a conditional order permitting it to invest in equity and convertible debt securities of foreign issuers that, in each of their most recent fiscal years, derived more than 15% of their gross revenue from their activities as a broker, dealer, underwriter, or investment adviser ("Foreign Securities Companies"), provided that such investments comply with the provisions of proposed amended rule 12d3–1 under the Act.

FILING DATE: The application was filed on December 17, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicant, 201 Park Avenue South, New York, New York 10003.

FOR FURTHER INFORMATION CONTACT: James J. Dwyer, Staff Attorney, at (202) 504–2920, or Elizabeth G. Osterman, Branch Chief, at (202) 272–3016 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant, a Massachusetts business trust, is registered as a diversified open-end management investment company under the Act. Applicant will consist of seven series upon the effectiveness of a post-effective amendment to its registration statement filed with the SEC on November 20, 1992. Only one of these funds, The Guardian Baillie Gifford International Fund (the "International Fund"), currently intends to invest in equity or convertible debt securities of foreign issuers. Guardian Baillie Gifford Limited acts as the investment adviser for the International Fund. Baillie Gifford Overseas Limited will serve as sub-adviser for the International Fund.

2. Applicant seeks to invest in equity securities and convertible debt securities of Foreign Securities Companies. Applicant seeks conditional relief from section 12(d)(3) of the Act to invest in equity and convertible debt securities of Foreign Securities Companies to the extent permitted in proposed amended rule 12d3–1 under the Act. See Investment Company Act Release No. 17096 (Aug. 3, 1989).

Applicant's Legal Conclusions

1. Section 12(d)(3) prohibits an investment company from acquiring any security issued by any person who is a broker, a dealer, an underwriter, or an investment adviser. Rule 12d3–1 provides an exemption from section 12(d)(3) for investment companies acquiring securities of an issuer that derived more than 15% of its gross revenues in its most recent fiscal year from securities-related activities, provided that these investments comply with certain conditions set forth in the rule.

2. Under rule 12d–1, an equity security of a Foreign Securities Company must be a "margin security" as defined in Regulation T promulgated by the Board of Governors of the Federal Reserve (the "Board") in order for the acquisition of such security by an investment company to be exempt from the prohibition of section 12(d)(3). Accordingly, Applicant may not invest in equity securities of a Foreign Securities Company that are comparable in quality to "margin securities," but

which do not fall within the definition of "margin securities" under Regulation T, because they are not registered in the United States, are not traded in United States over-the-counter markets, and are not included in the List of Foreign Margin Stocks published by the Board.

3. Proposed amended rule 12d3–1 provides that the "margin securities" requirement will be excused if the acquiring company purchases equity securities of Foreign Securities Companies that meet the qualitative criteria comparable to criteria applicable to equity securities of United States securities-related businesses.

Applicant's Condition

Applicant agrees that the proposed exemptive order will be subject to the following condition:

Applicant will comply with the proposed amendments to rule 12d3–1, Investment Company Act Release No. 17096 (Aug. 3, 1989), as they are currently proposed, or as they maybe reproposed, adopted, or amended.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Security.

[FR Doc. 93–129 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–25722]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

December 29, 1992.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The applications(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by January 22, 1993 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

General Public Utilities Corp. (70–7473)

General Public Utilities Corporation ("GPU"), 100 Interpace Parkway, Parsippany, New Jersey 07054, a registered holding company, has filed a post-effective amendment to its application-declaration pursuant to sections 9(a), 10 and 12(c) of the Act and Rule 42 thereunder.

By orders dated December 29, 1987, (HCAR No. 24550), March 31, 1988 (HCAR No. 24612), August 5, 1988 (HCAR No. 24691) and September 11, 1989 (HCAR No. 24949), the Commission, among other things, authorized GPU to repurchase from time-to-time through December 31, 1992 up to 11 million shares of its common stock, par value $2.50 per share, in the open market, through odd-lot tender offers and/or from shares held under GPU's Tax Credit Act Employee Stock Ownership Plans upon their termination. The timing of those repurchases depends upon existing market conditions and the anticipated capital needs of GPU and its subsidiaries. At December 3, 1992, GPU had repurchased 7,491,432 shares of its common stock, all of which were repurchased prior to a two-for-one stock split effective May 29, 1991. GPU does not expect to repurchase any additional shares during the remainder of 1992.

GPU now requests authority to repurchase up to five million shares of its common stock in the open market, through privately negotiated transactions and/or through odd-lot tender offers from time-to-time from the effective date of the order herein through December 31, 1995. GPU has determined that the current cost of common stock equity is higher than the current cost of borrowed funds used to effect such repurchases. In all other respects, the transactions as previously authorized by the Commission would remain unchanged.

At September 30, 1992, GPU's equity ratio, on a consolidated basis, was 46%. If GPU were to repurchase the entire five million shares of common stock for which authority is requested, GPU's consolidated equity ratio would be reduced to 45%, assuming an average purchase price of $26.00 per share.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–124 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Rel. No. 19183; 812–8088]

Technology Funding Medical Partners I, L.P., et al.; Application

December 28, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 ("Act").

APPLICANTS: Technology Funding Medical Partners I, L.P. (the "Partnership"); and Technology Funding Inc. and Technology Funding Ltd. (the "Managing General Partners").

RELEVANT ACT SECTIONS: Order requested under section 6(c) granting an exemption from sections 2(a)(19) and 2(a)(3)(D).

SUMMARY OF APPLICATION: Applicants seek a conditional order determining that: (a) The Independent General Partners (as hereinafter defined) are not "interested persons" of the Partnership, the other general partners, or the principal underwriter of the Partnership solely by reason of their status as general partners of the Partnership and co-partners of the other general partners; and (b) no limited partner owning less than five percent of the units of limited partnership interest in the Partnership is an "affiliated person" of the Partnership or any of its partners solely by reason of being a limited partner of the Partnership and a co-partner of the other limited partners and the general partners.

FILING DATE: The application was filed on September 14, 1992 and amended on December 1, 1992, December 23, 1992, and December 24, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 22, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the

request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, 2000 Alameda de las Pulgas, suite 250, San Mateo, California 94403.

FOR FURTHER INFORMATION CONTACT: James E. Anderson, Staff Attorney, at (202) 272–7027, or C. David Messman, Branch Chief, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Partnership, organized as a Delaware limited partnership on September 3, 1992, will be governed by an Amended and Restated Limited Partnership Agreement (the "Partnership Agreement"). The Partnership has elected to be a business development company pursuant to section 54(a) of the Act. As a business development company, the Partnership will be subject to sections 55 through 65 of the Act and to those sections of the Act made applicable to business development companies. The Partnership will terminate-no later than December 31, 2006. The Partnership has organized as a limited partnership because applicants believe that the partnership form is a more appropriate investment vehicle for a closed-end entity of limited duration seeking long-term capital appreciation by making venture capital investments.

2. On October 30, 1992 the Partnership filed a registration statement on Form N–2 under the Securities Act of 1933 with respect o a proposed public offering of up to 300,000 units of limited partnership interest in the Partnership (the "Units"). The maximum proceeds from the offering will be $30 million.

3. The general partners of the partnership initially will consist of three individual general partners (the "Individual General Partners") and the Managing General Partners. The initial Individual General Partners will act as independent general partners (the "Independent General Partners") (defined to be individuals who are not "interested persons" of the Partnership within the meaning of the Act). The number of Individual General Partners may not be less than three nor more than nine, and a majority of the Individual General Partners must be Independent General Partners. Only natural persons may serve as Individual General Partners. The Partnership Agreement provides that if at any time the number of Independent General Partners is reduced to less than a majority of the Individual General Partners, the remaining Independent General Partners must, within 90 days, designate one or more successor Independent General Partners so as to restore the number of Independent General Partners to a majority.

4. The Individual General Partners will provide overall guidance and supervision with respect to the operations of the Partnership. The Individual General Partners will perform the same functions and have the same duties and responsibilities that the Act imposes on the boards of directors of business development companies organized in corporate form. The Independent General Partners will assume the responsibilities and obligations imposed by the Act upon disinterested directors of a business development company organized in corporate form. In addition to fiduciary duties, the Individual General Partners will, among other things, have responsibilities with respect to the management and underwriting arrangements of the Partnership, the custody arrangements with respect to portfolio securities, fidelity bonding, and transactions with affiliates.

5. The Managing General Partners, Technology Funding Inc. and Technology Funding Ltd., are a California corporation and a California limited partnership, respectively. Both Managing General Partners are registered investment advisers under the Investment Advisers Act of 1940. Under the Partnership Agreement, the Managing General Partners, subject to the guidance and supervision of the Individual General Partners, are responsible for the management of the Partnership's investments and will provide other management and administrative services.

6. As compensation for their services, the Managing General Partners will receive an allocation of 20% of the Partnership's net profits (as defined in the Partnership Agreement, as well as the following fees: a fee equal to 2% of total limited partner capital contributions for each year of partnership operations until six years after the completion of the public offering of Units, and thereafter declining by 10% per year, as compensation for partnership overhead; reimbursement for organizational and offering expenses and operational costs (as defined in the Partnership Agreement) up to a maximum of 5% of total limited partner capital contributions; [1] and a sales commission of up to 8% of the gross proceeds of the offering, of which up to 7% will be reallowed to unaffiliated broker-dealers. The sales commission will be paid to Technology Funding Securities Corporation, a wholly-owned subsidiary of Technology Funding Inc.

7. The limited partners of the Partnership have no right to participate in the control of the Partnership's business. The Partnership Agreement, consistent with the Act, authorizes the limited partners to vote on certain matters, including the election or removal of general partners, approval or termination of certain arrangements with affiliates of the Managing General Partners, ratification or rejection of the appointment of the independent certified public accountants of the Partnership, approval of the sale of all or substantially all of the Partnership's assets, and amendments to the Partnership Agreement. The Partnership will obtain an opinion of counsel that the possession or exercise of these voting rights does not cause the limited partners to be participating in the control of the Partnership's business under the Delaware Revised Uniform Limited Partnership Act. The Partnership does not have an insurance policy which would provide coverage to persons who become limited partners. The Independent General Partners will periodically review the question of the appropriateness of obtaining an errors and omissions insurance policy for the Partnership.

8. The Partnership Agreement provides that any Individual General Partner may be removed either: (a) for cause by the action of two-thirds of the remaining Individual General Partners, including a majority of the remaining Independent General Partners; or (b) with the consent of a majority in interest of the limited partners. The Managing General Partners may be removed either: (a) By a majority of the Independent General Partners, with or without cause; or (b) with the consent of the majority in interest of the limited partners.

9. The Partnership Agreement provides that the Managing General Partners will not resign or withdraw from the Partnership unless a successor managing general partner or partners have been appointed and consented to

[1] Under the Partnership Agreement, overhead, organizational and offering expenses, and operational costs are each distinct categories and do not overlap.

by the limited partners. The Managing General Partners may resign or withdraw voluntarily only if: (a) At least 120 days prior to such withdrawal, all partners are given notice that the Managing General Partners propose to withdraw and that there will be substituted in their place a person or persons designated and described in such notification; (b) each of the proposed successor managing general partners represents that it is experienced in performing the functions that a managing general partner is required to perform under the Partnership Agreement, that it has the net worth required by the Partnership Agreement, and that it is willing to become a managing general partner under the Partnership Agreement and will assume all duties and responsibilities thereunder, without receiving any compensation for services from the Partnership in excess of that payable under the Partnership Agreement to the withdrawing Managing General Partners and without receiving any participation in the withdrawing Managing General Partners' interests other than that agreed upon by the withdrawing Managing General Partner and its successor; (c) there is on file at the principal office of the Partnership certified audited financial statements of each proposed successor managing general partner; (d) a majority in interest of the limited partners consent to the appointment of the successor; (e) the withdrawing Managing General Partner cooperates with the successor managing general partners so that the responsibilities of the withdrawing Managing General Partner may be transferred with as little disruption of the Partnership's business and affairs as practicable; and (f) the withdrawing Managing General Partner pays all expenses incurred as a result of its withdrawal.

Applicants' Legal Conclusions

1. Applicants request that the Independent General Partners be exempted from the provisions of section 2(a)(19) to the extent that the Independent General Partners would otherwise be deemed "interested persons" of the Partnership, the other general partners, or the principal underwriter of the Partnership solely because such Independent General Partners are general partners of the Partnership and co-partners of the Managing General Partners. Section 2(a)(19) excludes from the definition of "interested person" those individuals who would be "interested persons" solely because they are directors of an investment company. The Partnership has been structured so that the Independent General Partners are the functional equivalents of, and will assume the responsibilities and obligations imposed by the Act and the regulations thereunder on, the non-interested directors of an incorporated investment company. Granting the requested exemption from the provisions of section 2(a)(19) is consistent with the purposes, policies, and provisions of the Act.

2. Applicants request further that the SEC exempt all limited partners of the Partnership who own less than 5% of the Units of the Partnership from being deemed under section 2(a)(3)(D) of the Act to be "affiliated persons" of the Partnership or any of its other partners solely because such limited partner is a partner of the Partnership and any of such other persons are partners with one another in the Partnership. Section 2(a)(3)(D) of the Act provides that an "affiliated person" of an entity includes, *inter alia*, any partner or co-partner of such entity. Under section 2(a)(3), persons investing in a corporate entity as mere shareholders would have substantially the same rights to vote on the affairs of the entity as the rights that are accorded to the limited partners under the Partnership Agreement, but would not be thereby deemed "affiliated persons" of the corporate entity unless they held more than 5% of such entity's outstanding voting securities. Granting the requested exemption from the provisions of section 2(a)(3)(D) is consistent with the purposes, policies, and provisions of the Act and places investments in the Partnership on a more equal footing with investments in business development companies organized in corporate form.

Applicants' Conditions

If the requested order is granted, applicants agree to the following conditions:

1. The general partners of the Partnership, except the Managing General Partners, will be natural persons, and a majority of the Individual General Partners will not be interested persons of the Partnership.

2. The Individual General Partners will assume the responsibilities and obligations imposed by the Investment Company Act on directors of a business development company organized in corporate form. The Independent General Partners, all of whom will be Individual General Partners, will assume the responsibilities and obligations imposed by the Investment Company Act on non-interested directors of a business development company organized in corporate form.

3. Neither Managing General Partners will resign or withdraw as a Managing General Partner of the Partnership without two years prior notice unless a successor Managing General Partner has been appointed in accordance with the Partnership Agreement and the provisions of section 15(a), 15(c), and 15(f) of the Investment Company Act.

4. The limited partners will have the right to vote on all matters which would require their approval under the Investment Company Act if they were shareholders of a business development company organized in corporate form, including the right to elect or remove general partners, the right to approve any new or amended investment advisory contract, the right to approve proposed changes in the Partnership's fundamental policies, and the right to ratify or reject the appointment of auditors.

5. If a limited partner transfers his or her units in a manner which is effective under the Partnership Agreement, the general partners will ensure that such assignee, transferee or successor has all of the rights afforded a shareholder under the Investment Company Act.

6. The Partnership will obtain an opinion of counsel stating that the voting rights provided the Limited Partners do not subject the limited partners to liability as general partners under Delaware law.

7. The Partnership will obtain an opinion of counsel that the Partnership should be classified and treated as a partnership for federal income tax purposes.

8. The Partnership will obtain an opinion of counsel that the distributions and allocations provided for in the Partnership Agreement are permissible under section 205 and rule 205–3 under the Investment Advisers Act and under section 15(a) of the Investment Company Act.

9. If, under the Partnership Agreement, the Partnership is or becomes authorized to make in-kind distributions of portfolio securities to its Partners, no such in-kind distributions will be made until such time as the Partnership has obtained a no-action letter from the staff of the SEC or, alternatively, has obtained an order pursuant to section 206A of the Investment Advisers Act of 1940 permitting such distribution.

10. Under the Partnership Agreement, upon the removal of the Managing General Partners, all unrealized gains and losses are deemed realized for purposes of making a final allocation to the Managing General Partners. However, applicants will not deem such unrealized gains and losses realized

until they have received a no-action letter from the staff of the SEC confirming the Partnership's interpretation of section 205 of the Investment Advisers Act (i.e., that such treatment of unrealized gains and losses is appropriate) or, in the alternative, the Partnership has obtained an exemption from section 205 by SEC order issued pursuant to section 206A of the Investment Advisers Act, permitting the Partnership to deem such gains or losses to be realized.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–131 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. IC–19188; File No. 812–8172]

Travelers Growth and Income Stock Account for Variable Annuities, et al.; Application

December 29, 1992.

AGENCY: Securities and Exchange Commission (the "Commission" or "SEC").

ACTION: Notice of Application for Exemption under the Investment Company Act of 1940 (the "1940 Act").

APPLICANTS: The Travelers Growth and Income Stock Account for Variable Annuities ("Account GS"), The Travelers Quality Bond Account for Variable Annuities ("Account QB"), The Travelers Fund B for Variable Contracts ("Fund B") and The Travelers Fund B–1 for Variable Contracts ("Fund B–1") (referred to collectively as the "Applicants").

RELEVANT 1940 ACT SECTIONS: Order requested under section 17(b) of the 1940 Act for exemption from section 17(a).

SUMMARY OF APPLICATION: Applicants request an Order of the Commission under section 17(b) of the Investment Company Act of 1940 (the "1940 Act") granting an exemption from the provisions of section 17(a) of the 1940 Act to permit the transfer of portfolio securities from Fund B to Account GS and from Fund B–1 to Account QB.

FILING DATE: The Application was filed on August 19, 1992 and amended on November 9, 1992. Applicants will file another amendment during the notice period to delete references to in kind redemptions by Contract Owners.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving the Applicants with copies of the request, personally or by mail. Hearing requests must be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on the Applicants in the form of an affidavit, or, for lawyers, by certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, One Tower Square, Hartford, Connecticut 06183–1050, Attention: Thomas A. Klee, Secretary.

FOR FURTHER INFORMATION CONTACT: Cindy J. Rose, Staff Accountant, or Wendell M. Faria, Deputy Chief, at (202) 272–2060, Office of Insurance Products, Division of Investment Management.

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from the Commission's Public Reference Branch.

Applicant's Statements and Representations

1. Accounts GS and QB and Funds B and B–1 are open-end diversified management investment companies, registered under the 1940 Act on Form N–3 (File Nos. 811–1539, 811–2571, 811–1671 and 811–2583, respectively). The Travelers Investment Management Company serves as the investment adviser for Account GS and Fund B. Travelers Asset Management International Corporation serves as the investment adviser for Account QB and Fund B–1.

2. Funds B and B–1 currently serve as the underlying investment vehicles for certain variable annuity contracts (the "old Contracts") issued by the Travelers Insurance Company ("Travelers"). Due to the small asset size of Fund B and Fund B–1, which adversely affects the Funds' ability to diversify, Travelers intends to offer to Contract Owners of the old Contracts the opportunity to exchange their old Contracts for new variable annuity contracts (the "new Contracts") for which Accounts GS and QB serve as the underlying investment vehicles. The exchange offer will be made in compliance with Rule 11a–2 under the 1940 Act (the "Exchange Offer").

3. The proposed transactions will be executed on the effective date of the Exchange Offer if there is 100% participation in the Exchange Offer or all units are otherwise exchanged by the effective date. The transactions will be effectuated by exchanging all units in Funds B and B–1 held under the old Contracts for units of equal value in Accounts GS and QB under the new Contracts. The transactions will be settled by the transfer of all portfolio securities valued on the basis of net asset values as of the date of transfer from Fund B to Account GS and from Fund B–1 to Account QB. Net asset values will be determined in accordance with the methods set forth in the Statement of Additional Information of each of the Applicants. Funds B and B–1 will cease operations when the Exchange Offer and the proposed transactions have been completed.

Applicants' Legal Analysis and Conditions

1. Section 17(a)(1) of the 1940 Act prohibits any affiliated person of a registered investment company, or an affiliated person of an affiliated person, from selling any security or other property to such registered investment company. Section 17(a)(2) of the 1940 Act prohibits any of the persons described above from purchasing any security or other property from such registered investment company.

2. Each Applicant may be deemed to be an affiliated person or affiliated person of an affiliated person of each other Applicant under section 2(a)(3) of the 1940 Act, and the proposed transactions may be deemed to entail one or more purchases or sales of securities or property between the respective Applicants. Therefore, an exemption from section 17(a) of the 1940 Act, pursuant to section 17(b) of the 1940 Act, may be required.

3. Section 17(b) of the 1940 Act provides that the Commission may grant an Order exempting transactions prohibited by section 17(a) of the 1940 Act upon application if evidence establishes that: (a) The terms of the proposed transactions, including the consideration to be paid or received, are reasonable and fair and do not involve over-reaching on the part of any person concerned; (b) the proposed transactions are consistent with the investment policy of each registered investment company concerned, as recited in the registration statements and reports filed under the 1940 Act, and (c) the proposed transactions are consistent with the general purposes of the 1940 Act.

4. Applicants represent that the terms of the proposed transactions and the Exchange Offer, including consideration paid or received, are reasonable and fair and do not involve over-reaching on the

part of any person. Applicants will not pay any of the expenses of the Exchange Offer, as they will be borne entirely by Travelers. The new Contracts will have terms at least as favorable, and in certain respects more favorable, than the old Contracts. There will be no surrender charges or sales charges imposed in connection with the exchange of the old Contracts for the new Contracts, in as much as neither the old Contracts nor the new Contracts provide for a contingent deferred sales charge and the front-end sales charge on the new Contracts has been waived for amounts exchanged in connection with the Exchange Offer. The proposed transactions will be effectuated by exchanging all units in Funds B and B–1 for units in Accounts GS and QB, respectively, and making a corresponding transfer of all portfolio securities from Funds B and B–1 to Accounts GS and QB. The proposed transactions will not be completed if there is not 100% participation by Contract Owners. Without full participation, the Applicants will not be in the position of determining which portfolio securities are to remain in Funds B or B–1 and which are to be transferred to Accounts GS or QB, respectively. The Applicants believe that the proposed transactions are reasonable and fair since they will avoid any transaction costs for any of the Applicants. The portfolio securities will be valued for the purposes of the transfer in the same manner utilized by the Applicants for determining net asset value. Valuing the portfolio securities in this manner will result in consistent values for purposes of the proposed transactions and for determining the net asset values of Accounts GS and QB upon the completion of the proposed transactions.

5. The Exchange Offer will not be a taxable transaction for participants pursuant to section 1035 of the Internal Revenue Code and Revenue procedure 92–26. Deposits made under the old Contracts prior to August 14, 1982 will continue to retain their favorable tax status under the new Contracts.

6. The assets of Funds B and B–1 are declining in size because the old Contracts have not been offered to new customers since 1983. Applicants represent that if Contract Owners exchange their old Contracts for the new Contracts, and their assets are thereby invested in Accounts GS and QB, they will benefit from greater diversification in the portfolios and greater stability as assets are withdrawn.

7. The investment objectives, polices and restrictions of the respective Applicants involved in the proposed transactions are identical. Thus, the transfer of the portfolio securities which will occur between the corresponding funds are consistent with the objectives, policies and restrictions of Accounts GS and QB. Moreover, Accounts GS and QB will be able to retain the portfolio securities received from Funds B and B–1 upon completion of the proposed transactions.

8. Applicants represent that the proposed transactions are consistent with the general purposes of the 1940 Act, as enunciated in the findings and Declaration of Policy in Section 1 of the 1940 Act. Applicants assert that the proposed transactions do not present any of the issues or abuses that the 1940 Act is designed to prevent. Moreover, Applicants represent that the proposed transactions and the Exchange Offer will be effected in a manner consistent with the public interest and the protection of investors. The owners of the old Contracts will be fully informed of the terms of the Exchange Offer through the Prospectus for the new Contracts and explanatory correspondence, including an Exchange Authorization Form. Contract Owners will benefit from increased diversity in the portfolios underlying their new Contracts, and, if the Order is granted, will not incur any expenses in the transfer of portfolio securities.

9. Applicants also note that the proposed transactions fall within the intent of, but not the literal requirements of, Rule 17a–7 under the 1940 Act. Rule 17a–7 generally exempts from section 17(a) certain purchase and sale transactions between registered investment companies which are affiliated persons of each other, provided certain enumerated conditions are met. Applicants represent that, as a condition to any Order under section 17(b), they will comply with the conditions set forth in sub-paragraphs (c), (d), and (e) of Rule 17a–7, namely, that: (c) the proposed transactions are consistent with the policy of the Applicants and the old and new Contracts participating in the Exchange Offer, as recited in the applicable registration statements and reports filed under the 1940 Act; (d) no brokerage commissions, fees (except for customary transfer fees), or other remuneration will be paid in connection with the transactions; and (e) the Boards of Managers, including a majority of the members of the Boards who are not interested persons, have adopted procedures pursuant to which the proposed transactions may be effected, which are reasonably designed to provide that the conditions of paragraphs (c) and (d) of Rule 17a–7 are complied with, and will determine that the proposed transactions are effected in compliance with such procedures.

10. Applicants will not, however, meet the conditions of subparagraphs (a), (b) and (f) of Rule 17a–7. Applicants cannot comply with subparagraph (a) because no cash will be involved in the proposed transactions. Subparagraph (b) will not be complied with since the proposed transactions will be made on the basis of the relative net asset values of the securities to be exchanged, rather than on the basis of "current market price" as defined in subparagraph (b). Subparagraph (f) requires that Funds B and B–1 maintain and preserve permanently in an easily accessible place a written copy of the procedures (and any modifications thereto) described in paragraph (e) of Rule 17a–7, and maintain and preserve for at least six years a written record of each such transaction setting forth a description of the security purchased or sold, the identity of the person on the other side of the transaction, the terms of the purchase or sale transaction, and the information or materials upon which the determinations described in paragraph (e) of Rule 17a–7 were made. Since subparagraph (f) contemplates that each party will have continuing operations after a transaction pursuant to Rule 17a–7 (in order to be able to satisfy the recordkeeping requirements), Funds B and B–1 may not be able to comply if they cease operations upon the completion of the Exchange Offer. However, Accounts GS and QB represent that they will comply with such requirements. Moreover, the records of Funds B and B–1 will be maintained by Travelers for the required periods.

11. Applicants submit that because the proposed transactions involve a transfer of portfolio securities on the basis of net asset values, and because Funds B and B–1 may discontinue operations after the Exchange Offer is complete, the type of potential abuse which Rule 17a–7 was designed to guard against is not present. Applicants state that Rule 17a–7 was designed to permit investment companies to sell securities between themselves at a fairly determined price based on current market prices without incurring costs, including brokerage costs, to the detriment of Contract Owners. Applicants assert that the proposed transactions will be effected at fair market prices, and in substance, are of the type ordinarily exempted by Rule 17a–7

Conclusion

Applicants submit, for all of the reasons stated herein, that their exemptive request meets the standards set forth in section 17(b) of the 1940 Act and that an Order should therefore be granted.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–128 Filed 1–5–93; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF STATE

Bureau of Oceans and International Environmental and Scientific Affairs

[Public Notice 1749]

United States Man and the Biosphere Program; Request for Proposals for Tropical Ecosystems Directorate

The Tropical Ecosystems Directorate (TED) of the U.S. Man and the Biosphere Program (U.S. MAB) announces a call for proposals addressing the theme of sustainable use of tropical forest resources. A small number of research grants in the range of $5,000 to $12,000 will be awarded in mid–1993. Preference will be given to proposals focusing on the Maya Tri-National Region of Belize, Guatemala, and/or Mexico.

Funding Objectives

U.S. MAB funding should assist research teams to: Add a national researcher to their effort; better integrate conservation and sustainable development; add a particular discipline to an ongoing research project; or explore the application of ongoing site-specific research to an additional site in the Maya Tri-National region. U.S. MAB funding will not be provided for planning purposes.

Focal Issues

Within the broad thematic focus of sustainable use of tropical forest resources in the Maya Tri-National Region, U.S. MAB/TED encourages research projects addressing focal issues such as community-based production systems, tropical forest management for timber and/or non-timber forest products, economic valuation and accounting of tropical forest products and services, benefits and costs of low impact uses such as ecotourism, or integration of biodiversity conservation with production forestry.

Proposal Content

Each proposal should have a title page, a one page synopsis of the existing research project, two pages detailing the proposed use of U.S. MAB/TED funds that would be complementary to the TED core program, and a one-page budget with justification. No funds are available for institutional overhead; only direct costs can be supported.

Evaluation and Review Process

Because of limited available funding, U.S. MAB/TED will give greatest preference to those proposals that directly complement the objectives of the directorate's core program. Proposals will be evaluated for the intrinsic merit of the research, its policy relevance, applicability to promoting sustainable use of tropical forest resources in the May Tri-National Region, and the quality and demonstrated productivity of the principals. All potential proposers are encouraged to contact the Secretariat of the U.S. Man and the Biosphere Program, OES/EGC/MAB, U.S. Department of State, Washington, DC 20522–3706. Tel. (703) 235–2946, to request a description of the TED core program.

Complete proposals must be received by the U.S. MAB Secretariat by close of business February 19, 1993. The U.S. MAB Secretariat will notify all principals of the Directorate's final decisions by the first week of April, 1993. Funds will be committed to the managing institutions identified in the proposals during July, 1993. Principals will receive from the U.S. MAB Secretariat copies of all U.S. MAB/TED review evaluations of their proposal and a written notification of the Directorate's decision on their project.

Submission of Proposals

Mail proposals to: U.S. MAB Secretariat, OES/EGC/MAB, room 608, SA–37, U.S. Department of State, Washington, DC 20522–3706.

Individuals choosing to submit their proposals by Express Mail, Federal Express, UPS, etc., must use the following address: U.S. MAB Secretariat, rm. 608, 1555 Wilson Boulevard, Rosslyn, Virginia 22209.

Deadline for Proposals: 19 February 1993.

Page Limit: 5 pages, single-spaced.

Dated: December 22, 1992.

Roger E. Soles,

Executive Director, U.S. Man and the Biosphere Program, Office of Global Change.

[FR Doc. 93–189 Filed 1–5–93; 8:45 am]

BILLING CODE 4710–09–M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings; Agreements Filed During the Week Ended December 25, 1992

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: 48568.
Date filed: December 22, 1992.
Parties: Members of the International Air Transport Association.
Subject: Comp Reso/P0810 dated November 10, 1992; Composite Resolutions R–1 to R–15.
Proposed Effective Date: April 1, 1993.

Docket Number: 48569.
Date filed: December 22, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC2 Reso/P 1327 dated November 13, 1992. Within Europe (Some EC Applicability) r–1 to r–4 TC2 Reso/P 1328 dated November 13, 1992. Within Europe (Some EC Applicability) r–5 to r–18 TC2 Reso/P 1329 dated November 13, 1992. Within Europe (No EC Applicability) r–19 to r–41.
Proposed Effective Date: April 1, 1993.

Docket Number: 48570.
Date filed: December 22, 1992.
Parties: Members of the International Air Transport Association.
Subject: Comp Telex—Resolution 024f—Norway.
Proposed Effective Date: January 7, 1993.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 93–227 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–62–M

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week Ended December 25, 1992

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases

a final order without further proceedings.

Docket Number: 48562.
Date filed: December 21, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 19, 1993.
Description: Application of American Trans Air, Inc., pursuant to section 401 of the Act and subpart Q of the Regulations, applies for a certificate of public convenience and necessity authorizing it to provide scheduled foreign air transportation of persons, property and mail between Indianapolis, Indiana, and Cancun, Mexico.

Docket Number: 48565.
Date filed: December 21, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 5, 1993.
Description: Application of Morris Air Service, Inc. request the Department for disclaimer of jurisdiction under section 401(h) and issue a new certificate in the name of Morris Air Corporation, pursuant to part 215 of the Department's Regulations.

Docket Number: 48566.
Date filed: December 22, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 20, 1993.
Description: Application of Lineas Aereas Allegro, S.A. de C.V., pursuant to section 402 of the Act and subpart Q of the Regulations, applies for a foreign air carrier permit for authority to provide charter foreign air transportation of persons and accompanying baggage between points in the United States and points in Mexico.

Docket Number: 48571.
Date filed: December 23, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 21, 1993.
Description: Application of Skybus, Inc., pursuant to section 401(d)(1) of the Act and subpart Q of the Regulations, applies for a certificate of public convenience and necessity authorizing it to engage in scheduled interstate and overseas air transportation of persons, property and mail between any point in any State of the United States or the District of Columbia, or any territory or possession of the United States, and any other point in any State of the United States or the District of Columbia, or any territory or possession of the United States.

Docket Number: 48572.
Date filed: December 23, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 20, 1993.
Description: Application of Biman Bangladesh Airlines, pursuant to section 402 of the Act and subpart Q of the Regulations, applies for a Foreign Air Carrier Permit to permit it to commence on March 1, 1993, the transportation of passengers, general cargo, and mail between Dhaka, Bangladesh, and New York, New York, and Newark, New Jersey, and points in between.

Docket Number: 48574.
Date filed: December 23, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 20, 1993.
Description: Application of American Trans Air, Inc. pursuant to section 401 of the Act and subpart Q of the Regulations, requests a certificate of public convenience and necessity to authorize scheduled foreign air transportation of persons, property, and mail between New York, New York and Riga, Latvia, both nonstop and via the intermediate point of Shannon, Republic of Ireland.

Phyllis T. Kaylor,
Chief, Documentary Services Division.
[FR Doc. 93-226 Filed 1-5-93; 8:45 am]
BILLING CODE 4910-62-M

Federal Railroad Administration

[FRA Docket No. H-92-9]

Petition for Waiver for Test Program; CSX Transportation

In accordance with 49 CFR part 211, notice is hereby given that CSX Transportation (CSXT) has submitted a petition dated November 2, 1992, for a temporary waiver of compliance with specific requirements of certain parts of title 49 Code of Federal Regulations in order to conduct a test of a performance-based method for determining the gage restraint capacity of the track structure, and to further develop this method as a possible alternative to sections of the existing Track Safety Standards.

The proposed test program is designed to evaluate a performance-based method of objectively determining the gage restraint capacity of the crossties and rail fasteners under continuous lateral and vertical loading of the track structure. The applied loads would sufficiently engage and exercise the rail fasteners, but would not permanently damage the track structure. The test program and associated procedures are meant to further develop this approach as an alternative to the present methods of determining adequate gage restraint capacity which are contained in § 213.109, "Crossties" and § 213.127, "Rail Fastenings", of the existing Track Safety Standards (49 CFR part 213).

CSXT and FRA recognize the desirability of improving present methods of determining the adequacy of gage restraint capacity. Present methods rely on visual and manual inspections by both railroad and FRA inspectors. These methods require an inspector to determine the gage restraint capacity of crossties and rail fasteners by observing indications of relative motion and by estimating component strength based on visual appearance. The proposed test program will evaluate a technique which provides a means of testing and objectively measuring the gage restraint capacity by applying controlled loads at the wheel/rail interface and then measuring the resulting deflections. Use of this technique is expected to maintain and enhance safety by detecting and marking safety critical locations so that immediate corrective action can be taken, while simultaneously producing a continuous, objective record of gage restraint capacity.

The test program is proposed to be conducted on the following track segments of the CSXT Florence Division: Aberdeen Subdivision; Hamlet Subdivision; Columbia Subdivision; and Andrews Subdivision. The Aberdeen, Hamlet, and Columbia Subdivisions form a through route between Raleigh, North Carolina and Savannah, Georgia via Hamlet, NC. The Andrews Subdivision is a route between Charleston, South Carolina and Hamlet, NC. The test program is expected to continue for at least three years unless terminated earlier for reasons not foreseen at the present time.

For the purposes of this test program, CSXT Transportation requests temporary relief from the following paragraphs of § 213.109: (b)(1)(i), (b)(2), (b)(3), (c), and (d); and from § 123.127.

FRA is seeking comments on this proposed test program from interested parties. FRA will take these comments into account in arriving at a final specification of conditions governing the conduct of the proposed test program, if conditional approval is granted by FRA'S Railroad Safety Board. Such comments may also have value in supporting FRA's consideration of modifications to the existing Track Safety Standards to incorporate performance-based alternatives.

Interested parties are invited to participate in this proceeding by submitting written views, data, or

comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

Communications received before February 1, 1993, will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) in room 8201, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

Issued in Washington, DC on December 30, 1992.

Edward R. English,

Acting Associate Administrator for Safety.

[FR Doc. 93–105 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–06–M

[Waiver Petition Docket Number H–92–7]

Public Hearing

The Union Pacific Railroad Company (UP) has requested a waiver of compliance from certain provisions of the Railroad Power Brakes Regulations (49 CFR part 232) (see FR 59197, December 12, 1992). The UP is seeking a waiver of compliance with § 232.12(b), which stipulates, "Each carrier shall designate additional inspection points not more than 1,000 miles apart where intermediate inspections will be made to determine that—

(1) Brake pipe leakage does not exceed five pounds per minute;

(2) Brakes apply on each car in response to a 20-pound service brake pipe pressure reduction; and

(3) Brake rigging is properly secured and does not bind or foul.

The UP is seeking the waiver for a six (6) month test period.

The FRA has received a request that a public hearing be held. Accordingly a public hearing is hereby set for 10 a.m. on January 15, 1993, in room 8236 of the Nassif Building located at 400 7th Street, SW., in Washington, DC.

The hearing will be an informal one and will be conducted in accordance with Rule 25 of the FRA Rules of Practice (49 CFR 211.25), by a representative designated by the FRA.

The hearing will be a nonadversary proceeding and, therefore, there will be no cross-examination of persons presenting statements. The FRA representative will make an opening statement outlining the scope of the hearing. After all initial statements have been completed, those persons wishing to make brief rebuttal statements will be given the opportunity to do so in the same order in which they made their initial statements. Additional procedures, if necessary for the conduct of the hearing, will be announced at the hearing.

Issued in Washington, DC on December 30, 1992.

Edward R. English,

Acting Associate Administrator for Safety.

[FR Doc. 93–106 Filed 1–5–93; 8:45 am]

BILLING CODE 4910–06–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Dated: December 29, 1992.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515–0082
Form Number: CF 226
Type of Review: Extension
Title: Record of Vessel Foreign Repair or Equipment Purchase
Description: A 50-percent duty exists on equipment purchases for and repairs made to U.S. flag vessels in foreign ports. Arriving at its first U.S. port, the owner or master of a vessel is required to declare all equipment, parts, or materials purchased, and repairs made outside the U.S.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 2,000
Estimated Burden Hours Per Respondent: 30 minutes
Frequency of Response: On occasion
Estimated Total Reporting/Recordkeeping Burden: 4,000 hours
Clearance Officer: Ralph Meyer, (202) 927–1552, U.S. Customs Service, Paperwork Management Branch, Room 6316, 1301 Constitution Avenue, NW., Washington, DC 20229.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–122 Filed 1–5–93; 8:45 am]

BILLING CODE 4820–02–M

Public Information Collection Requirements Submitted to OMB for Review

December 30, 1992.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–1012
Form Number: IRS Form 5305A–SEP
Type of Review: Revision
Title: Salary Reduction and Other Elective Simplified Employee Pension-Individual Retirement Accounts Contribution Agreement
Description: This form is used by an employer to make an agreement to provide benefits to all employees under a salary reduction Simplified Employee Pension (SEP) described in section 408(k). This form is not to be filed with IRS but is to be retained in the employer's records as proof of establishing such a plan, thereby justifying a reduction for contributions made to this SEP. The data is used to verify the deduction.
Respondents: Businesses or other for-profit
Estimated Number of Respondents/Recordkeepers: 100,000
Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping—40 minutes
Learning about the law or the form—56 minutes
Preparing the form—1 hour, 6 minutes
Frequency of Response: On occasion
Estimated Total Reporting/Recordkeeping Burden: 270,000 hours
Clearance Officer: Garrick Shear, (202) 622–3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports Management Officer.
[FR Doc. 93–123 Filed 1–5–93; 8:45 am]
BILLING CODE 4830–01–M

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Environmental Hazards; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 that a meeting of the Veteran's Advisory Subcommittee on Environmental Hazards will be held on Monday, January 25, 1993, in room 401 at 801 I Street, NW., Washington, DC 20004. The meeting will convene at 9 a.m. and adjourn at 5 p.m.

A full Committee meeting will be held on February 1–2, 1993, in room 946 at 801 I Street, NW., Washington, DC 20004. The meetings will convene at 9 a.m. and adjourn at 5 p.m.

The purpose of the meetings is to review information relating to activities during which significant numbers of veterans were exposed to ionizing radiation before January 1, 1970 (this includes activities other than participation in an atmospheric nuclear test or service with the occupation forces of Hiroshima, or Nagasaki, Japan.)

The meeting is open to the public to the capacity of the room. For those wishing to attend, contact Mrs. Leney Holohan, Department of Veterans Affairs Central Office (026B), 810 Vermont Avenue, NW., Washington, DC 20420, phone (202) 523–3911, prior to January 18, 1993.

Members of the public may direct questions or submit prepared statements for review by the Committee in advance of the meeting, in writing only, to Mr. Frederic L. Conway, Deputy Assistant General Counsel, (026B), Department of Veterans Affairs Central Office, 810 Vermont Avenue, NW., Washington, DC 20420. Submitted material must be received at least five days prior to the meeting. Such members of the public may be asked to clarify submitted material prior to consideration by the Committee.

Dated: December 21, 1992.

Diane H. Landis,
Committee Management Officer.
[FR Doc. 93–107 Filed 1–5–93; 8:45 am]
BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 57 FR 61965, Tuesday, December 29, 1992.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 2:00 p.m. (eastern time) Tuesday, January 12, 1993.

CHANGE IN THE MEETING:

Open Session

The meeting time will change to 10:00 a.m. (eastern time) Tuesday, January 12, 1993.

CONTACT PERSON FOR MORE INFORMATION: Frances M. Hart, Executive Officer, on (202) 663-4070.

Dated: January 4, 1993.

Frances M. Hart,

Executive Officer, Executive Secretariat.

This Notice Issued January 4, 1993.

[FR Doc. 93-319 Filed 1-4-93; 3:14 pm]

BILLING CODE 6750-06-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 57 FR 61966, December 29, 1992.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11:00 a.m., Monday, January 4, 1993.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting: Federal Reserve Bank and Branch director appointments.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: January 4, 1993.

Jenifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-314 Filed 1-4-93; 2:27 pm]

BILLING CODE 6210-01-M

SECURITIES AND EXCHANGE COMMISSION

Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meeting during the week of January 4, 1993.

A closed meeting will be held on Tuesday, January 5, 1993, at 1:30 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Schapiro, as duty officer, voted to consider the items listed for the closed meeting in a closed session.

The subject matter of the closed meeting scheduled for Tuesday, January 5, 1993, at 1:30 p.m., will be:

Settlement of injunctive actions.
Institution of injunctive actions.
Regulatory matter bearing enforcement implications.
Institution of administrative proceedings of an enforcement nature.
Settlement of administrative proceeding of an enforcement nature.
Opinions.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Paul Atkins at (202) 272-2000.

Dated: January 4, 1993.

Jonathan G. Katz,

Secretary.

[FR Doc. 93-290 Filed 1-4-93; 12:47 pm]

BILLING CODE 8010-01-M

VOL 58 ISS 3 JA 6 1993 UMI

Corrections

Federal Register
Vol. 58 No. 3
Wednesday, January 6, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[OACT-042-N]

RIN 0938-AF94

Medicare Program; Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for 1993

Correction

In notice document 92-28717 beginning on page 56345 in the issue of Friday, November 27, 1992, make the following corrections:

1. On page 56346, in the 1st column, in the 21st line, "recognizes" should read "recognize".

2. On the same page, in the same column, in the 28th line, "any" should read "may".

BILLING CODE 1505-01-D

POSTAL RATE COMMISSION

[Docket No. C93-2 and Order No. 953]

Parcel Post Rate Complaint: Notice and Order on Filing of Complaint of United Parcel Service

Correction

In notice document 92-29727 appearing on page 58033 in the issue of Tuesday, December 8, 1992, the Docket No. should read as set forth above.

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-31601; File No. SR-NSCC-92-08]

Self-Regulatory Organization; National Securities Clearing Corporation; Order Approving a Proposed Rule Change Relating to Index Receipts

Correction

In notice document 92-31051 beginning on page 61136 in the issue of Wednesday, December 23, 1992, make the following correction: On page 61136, in the heading, "File No. SR-NSCC-92-09" should read "File No. SR-NSCC-92-08".

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 28

[CGD 88-079a]

RIN 2115-AD12

Commercial Fishing Industry Vessel Regulations

Correction

In proposed rule document 92-25895 beginning on page 48670 in the issue of Tuesday, October 27, 1992, make the following corrections:

1. On page 48670, in the 1st column, in the 16th and 17th lines, delete "and outside the Boundary Line".

2. On page 48672, in the second column, in the fourth paragraph, in the eighth line, several words of text were omitted. The eighth and subsequent lines, after "trade", should read "before September 8, 1990, and enters into that service before June 1, 1992, and it has not had a load line assigned at any time before November 16, 1990."

3. On page 48676, in the third column, in the third full paragraph, in the second line, "requirement" should read "requirements".

4. On page 48677, in the first column, in the first line, "codified" should read "modified".

5. On the same page, in the 3rd column, in the 13th line, "pat" should read "part".

6. On page 48678, in the 2nd column, in the 2nd full paragraph, in the 29th line, insert the word "a" between "of" and "bulkhead's".

§ 28.65 [Corrected]

7. On page 48681, in the third column, in § 28.65(b)(1)(ii), in the first line, "of" should read "or".

§ 28.600 [Corrected]

8. On page 48685, in the third column, in § 28.600(d)(1), in the third line a numerical notation was omitted. The third line should read "(2) Flooding through these hatches does".

BILLING CODE 1505-01-D

Federal Register

Wednesday
January 6, 1993

Part II

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 317, 320, and 381
Nutrition Labeling of Meat and Poultry Products; Final Rule

VOL 58 ISS 3 JA 6 1993 UMI

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 320, and 381

[Docket No. 91–006F]

RIN 0583–AB34

Nutrition Labeling of Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations by permitting voluntary nutrition labeling on single-ingredient, raw meat and poultry products, and by establishing mandatory nutrition labeling for all other meat and poultry products, with certain exceptions. FSIS is committed to providing consumers with the most informative labeling system possible. FSIS's nutrition labeling final regulations for meat and poultry products will parallel to the extent possible, as authorized by the Federal Meat Inspection Act and the Poultry Products Inspection Act, FDA's nutrition labeling regulations promulgated under the Nutrition Labeling and Education Act (NLEA).

EFFECTIVE DATE: July 6, 1994. The incorporation by reference of the "Official Methods of Analysis" of the Association of Analytical Chemists (AOAC) International, contained in this regulation, is approved by the Director of the Federal Register as of July 6, 1994.

FOR FURTHER INFORMATION CONTACT: Charles Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 205–0080. Copies (printed or on 3.5" high-density diskettes) of the final rule may be obtained from the Policy Office, Linda Carey, FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 720–7163.

SUPPLEMENTARY INFORMATION:

Executive Order 12291 and Effects on Small Entities

This final rule has been reviewed under USDA procedures established to implement Executive Order 12291 and has been classified as a major rule pursuant to section 1(b)(1) of that order because it is likely to result in an annual effect on the economy of $100 million or more. The Department reported its review in its Final Regulatory Impact Analysis (FRIA), which includes an analysis of the costs and benefits of nutrition labeling. FSIS estimates that the final rule will result in net societal benefits of $1.5 billion during the first 20 years after required nutrition labeling is available to consumers. For the purpose of this rule, net societal benefits are the estimated health benefits minus the compliance costs. The $1.5 billion represents the present value of net benefits, recognizing that changes in nutrition labeling requirements generate both costs and benefits that will occur in future years. All costs and benefits have been converted to a present value using a discount rate of 7 percent. Total 20-year health benefits were estimated to be $1.75 billion. Total 20-year compliance costs were estimated to range from $218 to $272 million.

To estimate future costs and benefits, it is necessary to use a specific time frame. The optimum time period is unknown. The Department selected 20 years, recognizing that 15 years or 25 years may also have been appropriate.

The final rule exempts products from required labeling if annual production of the product is less than 100,000 pounds and the producing firm has 500 or fewer employees. The Small Business Administration's definition of a small meat and poultry processing firm is one having 500 or fewer employees (13 CFR part 121). Thus, products produced by small businesses are exempt if they are produced at levels below 100,000 pounds. Without the small business and 100,000 pound exemption, 20-year costs would rise to $767 to $999 million. The exemption reduces benefits by $138 million. Thus, without the exemption, total benefits would be $1,892 million and estimated net benefits would range from $0.9 to $1.1 billion. The reduction in benefits is based on the estimate that the exemption applies to 7.3 percent of the volume of meat and poultry products that would require nutrition labeling without the exemption. Benefit estimates are directly related to the volume of products that are labeled. Therefore, the exemption reduces estimated benefits by 7.3 percent.

Without the exemption, the estimated compliance cost increases of $767 to $999 million are not the only type of costs that would be incurred. The Department believes that without the exemption many small businesses would have to close or substantially reduce the variety of products they now offer. Reductions in purchase options are a cost to consumers that could not be quantified for the Department's analysis.

The final rule allows processors of meat and poultry products the flexibility to base labeling information on laboratory analyses, recipe analyses using nutrition information from available data bases, or any combination of both. The rule does require that firms maintain a record of supporting information. The net benefit estimates are based on an assumption that 30 percent of the required nutrition information will be based on recipe analyses using data base values. The 30 percent estimate reflects concerns that (1) products using proprietary mixes as ingredients may not be able to make use of recipe analysis, and (2) some manufacturers might feel greater confidence in using laboratory analysis. The final 20-year cost estimates are reduced by from $32 to $50 million based on the estimate that 30 percent of required information will be supported by recipe analyses using data base values. When the predicted use of recipe analyses varied from 15 to 60 percent, the cost savings ranged from $16 to $100 million. Thus, if 60 percent of the required nutrition information was supported by recipe analyses, net benefits could increase by as much as $50 million.

Three alternatives to the final rule were considered. The first alternative was to allow for the voluntary nutrition labeling of all meat and poultry products. All voluntary labeling would have to be consistent with the regulations that FDA issues to implement the NLEA.

Based on responses to a 1992 survey of federally inspected firms, the Department now believes that earlier estimates that 40 percent of packaged processed products have nutrition labeling were high. It is possible that 40 percent of products in large supermarkets have nutrition labeling, but the overall level for all grocery stores is now estimated to be far lower. The Department has three serious concerns with the option of voluntary nutrition labeling on processed products. First, the analytical costs are going up substantially because of the nutrients/food components that will be required. Today, a large portion of voluntary labeling consists of an abbreviated format. The average cost of single laboratory analysis is estimated to be $231. To be consistent with revised FDA regulations, the average cost would rise to $406 per analysis. This voluntary option would not include the testing requirements associated with the current Nutrition Labeling Verification (NLV) program. The NLV program requires 26 analyses over a 20-year period. Based on public comments, the

cost estimates for both mandatory or voluntary labeling use a range of 7 to 13 total analyses per product over the 20-year period. Since the type and amount of testing will be determined by the producer, there is no reason to believe that analytical costs would differ between voluntary labeling and mandatory labeling.

The Department has three major reservations concerning the viability of the voluntary alternative. First, if all nutrition labeling were voluntary, the Department is concerned that higher analytical costs per analysis could result in fewer products having voluntary labeling than currently exists, a level that is already far lower than previously believed. Second, the Department has always been concerned that under a voluntary program, products containing large amounts of fat, saturated fat, cholesterol, or sodium are less likely to be labeled. Third, firms with relatively low levels of nutrition labeling responding to the USDA survey conducted in 1992, did not indicate that, under a voluntary program, they would be increasing nutrition labeling for the new products they plan to introduce over the next three years. These same firms indicate they have substantially more nutrition information on file than they are currently providing on product labels.

The second alternative was to change the exemption criterion on production per product. One variation would lower the exemption criterion on production to 50,000 pounds per year. The change in the 20-year estimated costs when including these products is very close to the change in 20-year projected benefits, thus, including these products between 50,000 and 100,000 pounds results in a minimal change in net benefits. When the impact on individual products and small businesses was considered, the Department decided against lowering the exemption level. Requiring nutrition labeling on the many small-firm products having between 50,000 and 100,000 pounds in annual production would most likely lead to many of those products no longer being produced, with a consequent loss of benefits to consumers. In small firms, these are not generally new or developmental products. They are more likely to represent stable, low production levels for limited markets.

On considering whether to raise the level of exemption from 100,000 to 250,000 pounds, the analysis also indicates little change in net benefits. However, as production increases, the lower relative impact on individual products greatly reduces the possibility that product lines will be unprofitable. The Department has chosen to allow extra time to implement nutrition labeling on products produced at levels between 100,000 and 250,000 pounds. The extra time reduced 20-year compliance costs by $8 to $10 million.

The third alternative was to remove the exemption criterion for employees and exempt all products produced at levels under 100,000 pounds. This option reduces estimated total benefits by $32 million to $1,722 million. Estimated total costs are reduced by from $39 to $47 million to a revised level of from $179 to $225 million. Net benefits remain at $1.5 billion, no change after rounding. To decide whether or not to accept this alternative, the Department had to look beyond the estimates of net benefits.

In developing a comprehensive economic impact for the final analysis, it is useful to view the meat and poultry processing industry as two separate industry sectors. There are medium to large firms that distribute most products regionally and nationally to supermarkets and other grocery stores. There are also a far larger number of small processors that sell most of their products in small specialty stores, locker plants, and butcher shops. Many also sell products through retail counters at production facilities. These small producers, however, market very little product through grocery stores and supermarket chains. In contrast, the Department believes that most products from firms with more than 500 employees are marketed through supermarkets.

This third alternative would result in a substantial increase in the number of exempt products sold in supermarkets. This becomes a concern when viewed in the context of the methodology used to estimate benefits. With the methodology used, overall health benefits come from having a high portion of volume labeled. There is, however, an implicit assumption that a sufficient number of products are labeled so that consumers are able to transfer information to like products. While the analysis cannot explicitly account for the reduction in the prevalence of labels in benefit estimates, each additional exemption weakens their reliability. The Department rejected this alternative in order to assure that both a high volume of products are labeled and the number of labeled products is above a subjective threshold that assures that consumers have sufficient information. Because compliance costs are a very small portion of total production costs for large firms, rejecting this alternative is not viewed as creating an economic hardship for large firms.

The Department developed the final rule with the goal of providing nutrition labeling on the maximum volume of packaged, processed retail product while assuring that small businesses producing small volumes of specialty products for limited markets are not at risk of going out of business or materially reducing the variety of products they deliver to their customers. Ensuring that a high percentage of total production is subject to nutrition labeling is important because that is what accounts for consumer purchases, consumption, and potential health effects.

This final rule achieves the goal. The Department estimates that 99 percent of the pounds of processed products distributed through approximately 24,000 supermarkets will be labeled. Likewise, approximately 95 percent of the volume of processed product marketed through an estimated 170,000 total supermarkets, grocery stores, and smaller convenience stores will be labeled. Finally, over 90 percent of the total production of packaged, processed product marketed through all retail outlets will include nutrition labeling for consumers.

The Department acknowledges that the benefit estimates are based on the total contribution of meat and poultry products to dietary fat, saturated fat, and cholesterol. Labeling will be required on most processed products purchased by consumers in retail stores. Together, with the voluntary program for retail store information on fresh products, consumers will have nutrition information on most of the meat and poultry products purchased for consumption at home. The Department believes that over time consumers will be able to transfer their knowledge gained through such labeling to meals eaten away from home. For that reason, benefits have not been reduced to account for the portion of meat and poultry consumed away from home.

The costs developed for the final analysis are the costs required to comply with the final rule. This analysis does not address the opportunity costs of alternative labeling schemes which would require different label information. It also excludes an analysis of the economic impact if firms choose to reformulate products or produce alternative products rather than comply with the labeling requirements of the rule.

The FRIA is available for public review in the office of the FSIS Hearing Clerk, room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Copies are available from the

Hearing Clerk, without charge. The FRIA also satisfies the analysis requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), which deals with the effect on small entities.

Executive Order 12778

This final rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. This rule provides provisions for: (1) Voluntary nutrition labeling on single-ingredient, raw meat and poultry products; and (2) mandatory nutrition labeling for all other meat and poultry products, with the exceptions of (a) certain products produced by small businesses; (b) products used for further processing; (c) products that are not for sale to consumers; (d) products in small packages weighing less than ½ ounce; (e) products custom slaughtered or prepared; (f) products intended solely for export; (g) ready-to-eat products packaged at the retail level; and (h) multi-ingredient products processed at the retail level.

This final rule concerns labeling of meat and poultry products. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat or poultry products that are in addition to, or different from, those imposed under the FMIA or the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and the PPIA, States that maintain meat and poultry inspection programs must impose requirements on State inspected products and establishments that are at least equal to those required under the FMIA or PPIA. These States may, however, impose more stringent requirements on such State inspected products and establishments.

Upon its adoption, no retroactive effect will be given to this final rule, and applicable administrative procedures must be exhausted before any judicial challenge to its provisions or their application. Those administrative procedures are set forth in the rules of practice governing proceedings for labeling determinations at 9 CFR parts 335 and 381, subpart W.

Paperwork Requirements

This final rule requires manufacturers to maintain records supporting the validity of nutrient information on the labels of meat and poultry products, and to make such records available to FSIS upon request. This final rule requires most currently approved labels for all meat and poultry products, except for single-ingredient, raw products, to be revised and submitted to FSIS for approval, which will impact substantially on all such manufacturers. Manufacturers of single-ingredient, raw meat and poultry products opting to use nutrition labeling on the label will also be required to revise their labels and comply with requirements of the mandatory program.

The final rule also requires that manufacturers desiring to use (1) a new nutrient content claim not currently provided in the regulations, (2) a synonymous term to a term defined by regulation, or (3) an implied nutrient content claim in a brand name, or to amend the table for Product Categories and Reference Amounts, to submit to FSIS a standard labeling application, along with additional supporting information. The supporting information includes statements that (1) identify the term, (2) explain why the term is not false or misleading, (3) set forth the importance of the term and its relation to consumer nutrition or health, and (4) analyze the potential effect of the use of the proposed term on food consumption. The supporting information required to accompany the labeling application is a new paperwork burden being imposed upon manufacturers.

The paperwork requirements contained in this final rule have been submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). If you wish to comment on the paperwork burden of this proposed rule, send your comments to: Office of Management and Budget, Desk Officer for FSIS, Office of Information and Regulatory Affairs, room 3208, New Executive Office Building, Washington, DC 20503 and to the Clearance Office, room 404–W, Administration Building, Washington, DC 20250.

Background

Introduction

The FMIA (U.S.C. 601 *et seq.*) and the PPIA (21 U.S.C. 451 *et seq.*) authorize the Secretary of Agriculture to establish and maintain inspection programs designed to assure consumers that meat and poultry products distributed in commerce or within designated States are wholesome, not adulterated, and are properly marked, labeled, and packaged.

FSIS regulates the labeling of meat and poultry products while FDA has responsibility for all other food labeling. FSIS conducts a prior label approval program under which labeling to be used on, or in conjunction with, meat and poultry products must be approved by the Agency prior to their use. FDA, on the other hand, relies primarily upon food manufacturers to comply with prescribed labeling regulations and to ensure that information contained on food labels is truthful and not misleading.

FSIS also develops standards of identity or composition for certain meat and poultry products under section 7(c) of the FMIA (21 U.S.C. 607(c)) and section 8(b) of the PPIA (21 U.S.C. 457 (b)). Under these authorities, FSIS has promulgated regulations prescribing definitions and standards of identity or composition (9 CFR part 319 and § 381.155 *et seq.*). FSIS also has promulgated regulations prescribing the content and design of labels (9 CFR part 317 and § 381.115 *et seq.*).

In 1973, FDA adopted a regulation, recodified in 1977 as 21 CFR 101.9, prescribing a specific labeling format to be included on food product labels when voluntary or mandatory nutrition information is provided. Currently required components that must be addressed include: calories, protein, carbohydrates, fat, sodium, two mineral elements (calcium and iron), and five vitamins (vitamin A, vitamin C, thiamin, riboflavin, and niacin). FSIS disseminates its nutrition labeling guidelines for meat and poultry products through the issuance by its Food Labeling Division of various policy memoranda. Copies of FSIS policy memoranda on nutrition labeling are available for public review in the FSIS Hearing Clerk's office.

The policy memos that relate in whole or in part to nutrition related issues will need to be rescinded or revised because of this final rule. Policy Memo 74A, dated November 1986, Exemptions from Nutrition Label Verification (NLV) Procedures or Partial Quality Control (PQC) Programs, and Policy Memo 85B, dated January 1988, NLV Procedures will no longer be in effect upon publication of this final rule. The following policy memoranda will remain in effect during the 18-month period between the date of publication and the effective date of this final rule, except that the provisions relating to data requirements and requirements for

an NLV procedure or PQC Program will not be enforced: Policy Memo 86, dated May 1985, Nutrition Labeling; Policy Memo 49C, dated June 1984, Sodium Labeling Guidelines; Policy Memo 70B, dated November 1987, Fat and Lean Claims; Policy Memo 71A, dated March 1986, Lite and Similar Terms; and Policy Memo 78, dated November 1984, Potassium Labeling Guidelines. These memoranda will be rescinded upon the effective date of this final rule. Policy Memo 16A, dated March 1981, Combinations of Ground Beef or Hamburger and Soy Products; Policy Memo 46, dated April 1982, Percent Fat Free Label Declarations; Policy Memo 7, dated August 1980, Information Panel; Policy Memo 39, dated January 1982 Caloric Claims/Weight Reduction; and Policy Memo 121, dated May 1991, Low Fat Ground Beef and Low Fat Hamburger with Added Ingredients, will remain in effect during the interim period but will be rescinded upon the effective date of this final rule. Policy Memo 69, dated March 1984, Labeling for Substitute Products; Policy Memo 19A, dated May 1987 Negative Labeling; and Policy Memo 114, dated July 1988, Point of Purchase Materials, will remain in effect during the interim period but will be revised upon the effective date of this final rule. Thus, companies desiring to continue declaring nutrition related information on labels in accordance with existing policy memoranda may do so until the effective date of this final rule. During this interim period, labels must conform either to policies established in the cited policy memorandum or these regulations, but not both. No combinations will be allowed. The policy memoranda discussed in this section reflect those listed in the proposal, and the addition of Policy Memo 7, Policy Memo 16A, Policy Memo 19A, and Policy Memo 121. These latter two policy memoranda have been added because FSIS agrees with the comments that stated these policy memoranda would also be impacted by the regulation.

Marketing Trends

Consumers are becoming increasingly aware of diet, health, and nutrition, and are concerned about the nutrient content of their foods. As a result, food manufacturers are adding nutrient content claims to allow consumers to make more informed food purchases. Claims such as "lean," "low fat," and "low cholesterol" have become common in today's marketplace. The use of such terms is subject to various interpretations and may mislead the consumer when purchasing products so labeled.

Nutrition Labeling Endeavors

The issue of providing consumers with more accurate and informative labeling prompted a series of undertakings by various segments of the Federal government to provide more nutrition information on the labels of all foods.

1. Congressional Action

On November 8, 1990, the Nutrition Labeling and Education Act of 1990 (NLEA), which amended certain provisions of the Federal Food, Drug, and Cosmetic Act, was enacted (Pub L. 101.535; 104 Stat. 2353). The NLEA requires mandatory nutrition labeling for most FDA-regulated packaged food products. It also requires FDA to issue voluntary nutrition guidelines to food retailers for providing nutrition information on 20 of each most frequently consumed, during a year, varieties of raw vegetables, raw fruits, and raw fish. Should food retailers fail to comply substantially with the guidelines, the NLEA requires FDA to issue mandatory requirements for these commodities.

2. FDA Regulatory Initiatives

In August 1989, FDA issued an advance notice of proposed rulemaking (ANPR) requesting comments on a wide range of labeling issues to determine what changes, if any, should be made on the labeling of foods regulated by FDA (54 FR 32610). In September 1989, FDA issued a notice of an extension of the comment period on the ANPR and announced a series of public hearings to be held throughout the Nation on food labeling (54 FR 38806). FSIS participated in these hearings, which were conducted by FDA in the fall of 1989. Issues discussed at the hearings related to nutrition labeling, ingredient labeling, descriptions of food, health messages, and nutrition label format.

After consideration of various comments received, FDA published a reproposed rule on February 13, 1990, on health messages (55 FR 5176), and three proposed rules on July 19, 1990, that would establish provisions on daily values for use in declaring nutrient content in nutrition labeling (55 FR 29476), require mandatory nutrition labeling on most food products that are meaningful sources of calories or nutrients (55 FR 29487), and define serving and portion sizes (55 FR 29517). FDA also published a tentative final rule on July 19, 1990 (55 FR 29456), prescribing regulations that define and provide for the use of the terms "cholesterol free," "low cholesterol," and "reduced cholesterol" in the labeling of foods.

The NLEA, as previously discussed, was enacted in November 1990, several months after FDA published its proposed rules and tentative final rule on food labeling. As a result, on January 11, 1991, FDA published a notice in the **Federal Register** (56 FR 1151) recognizing the impact of the NLEA on its pending rulemaking proceedings dealing with food labeling. FDA announced its plans to obtain comments in some form, or issue reproposals or supplemental proposals in some form, to ensure that all such regulations are consistent with the NLEA. These reproposals and supplemental proposals are discussed throughout this document.

3. NAS Study

In 1989, FSIS and the Public Health Service, U.S. Department of Health and Human Services (HHS), which includes FDA, jointly sponsored a study by the Institute of Medicine of the National Academy of Sciences (NAS) to provide options for improving food labeling. In its 1990 final report, NAS recommended that FSIS and FDA mandate nutrition labeling for all packaged foods under their respective jurisdictions, except for certain exemptions.[1] In addition, NAS presented recommendations on various facets of nutrition labeling including: Nutrition label content, serving sizes, U.S. Recommended Daily Allowances, adjectival descriptors, and ingredient labeling.

4. Advance Notice of Proposed Rulemaking (ANPR)

On April 2, 1991, FSIS published an ANPR in the **Federal Register** to solicit comments and recommendations from consumers, industry, public health officials, and other interested parties to assist the Agency in developing proposed regulations for nutrition labeling of meat and poultry products (56 FR 13564). In the ANPR, the Agency announced its intent to propose mandatory nutrition labeling regulations for most processed meat and poultry products and a voluntary program for fresh meat and poultry products. FSIS identified the following eight major food labeling issues that are of particular concern to the Agency: (1) Mandatory nutrition labeling, (2) nutrition label content, (3) U.S. Recommended Daily

[1] The NAS final report titled "Nutrition Labeling: Issues and Directions for the 1990s" is available for public review in the FSIS Hearing Clerk's office. Copies of the report are available for sale from the National Academy Press, 2101 Constitution Avenue, NW., Washington, DC 20418.

Allowances, (4) serving size, (5) descriptors and health messages, (6) food ingredients and standards of identity, (7) compliance and analytical methods, and (8) economic impact.

FSIS received 197 comments in response to the ANPR. After review and consideration of the comments received on the ANPR, FSIS issued a proposed rule in the **Federal Register** (56 FR 60302) on November 27, 1991, which is discussed in the following section.

5. Proposed Rules

On November 27, 1991, FSIS published a proposed rule in the **Federal Register** (56 FR 60302) to solicit comments and recommendations from consumers, industry, public health officials, and other interested parties to assist the Agency in developing the final regulations for nutrition labeling of meat and poultry products. In the proposed rule, the Agency announced its intent to amend the Federal meat and poultry products inspection regulations by permitting voluntary nutrition labeling on single-ingredient, raw meat and poultry products, and by establishing mandatory nutrition labeling for all other meat and poultry products, with the exception of products used for further processing.

FSIS received 1109 comments in response to the proposed rule. The majority of these comments (586) were submitted by food manufacturers and distributors, while 296 comments were received from consumers and consumer groups; 94 from trade associations; 24 from State governments; 15 from congressional offices on behalf of small businesses; 15 from food retailers; 10 from expediters and consultants; 10 from academia; 9 from the Federal Government; 9 from health professionals; 8 from foreign governments; 4 from professional organizations; 4 from financial institutions; 4 from meat and poultry associated industries; 4 from computerized database companies; 3 from food service organizations; 3 from health promotional groups; 2 from local governments; 2 from food ingredient developers; 2 from food industry technical advisors; and 1 each from a weight loss service, laboratory, oven and smokehouse supplier, and pharmaceutical official. One comment received did not address the scope of the proposed regulations. All comments submitted with respect to the proposed regulation were given due consideration and are discussed further in this document.

On March 25, 1992, FSIS published a supplemental (57 FR 10298) to the November 1991 proposed rule in the **Federal Register** regarding nutrition labeling of meat and poultry products. This supplemental proposed rule would (1) allow for the use of data bases and recipe analyses using data bases, as well as the proposed laboratory analyses, on which to base the nutrition information on processed meat and poultry product labels, and (2) provide a small business exemption from mandatory nutrition labeling. This action was taken because of the Agency's concern that its proposed rule not impose undue cost burdens and that its proposal be implemented in the most cost-effective manner possible while providing consumers with the same high quality nutritional information. FSIS received 247 comments in response to the supplemental proposed rule. The majority of these comments (161) were submitted by food manufacturers/distributors, while 29 comments were received from trade associations; 14 from congressional members; 13 from State governments; 10 from academia; 9 from consumers and consumer groups; 2 from labeling consultants; and 1 each from a health professional, professional organization, food retailer, Federal Government Agency, and a computerized database company. Full and careful consideration was given to all written comments received. In view of these comments and the comments received at the public forums, the Agency is providing a small business exemption and the use of databases which are discussed later in this document.

On August 28, 1992, FSIS published a proposed rule in the **Federal Register** (57 FR 39332) regarding the adoption of a standard format for use in presenting nutrition information on the labels of meat and poultry products. In its proposal, FSIS proposed to establish the CONTROL WITH DIETARY GUIDANCE or the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE as the standard format. The Agency also requested comments on the proposed formats, as well as other options. A discussion of the comments received is provided later in this document.

6. Implementation Date

On March 25, 1992, FSIS published a notice in the **Federal Register** (57 FR 10298) announcing the intended implementation date of its rulemaking for nutrition labeling of meat and poultry products. FSIS advised that, based upon a careful review of the comments received from the proposed rule (56 FR 60302) published on November 27, 1991, the Agency has decided that the nutrition labeling regulations concerning meat and poultry products will be implemented 18 months from the date of publication of the final rule. Thus, the nutrition labeling regulations shall become effective on July 6, 1994.

7. Public Forums

a. On April 4, 1991, FSIS participated in a FDA public meeting on food labeling to discuss issues related to serving size: (1) The basis for determining serving size, (2) units of measure to be used, (3) deviation allowed from standard serving sizes, (4) dual nutrition labeling with the second column on the basis of uniform weight, and (5) the definition of single-serving container. One recommendation expressed by all the participants was that USDA and FDA should work in harmony to establish uniform serving sizes for the foods the agencies regulate. In response to this, FSIS participated as a member of an Interagency Committee on Serving Sizes formed by FDA to ensure consistency in serving size requirements for all foods. The committee's recommendations and objectives are discussed in this document under section VI, Serving Sizes;

b. On January 23, 1992, FSIS published a notice in the **Federal Register** (57 FR 2692) announcing its participation in FDA's "Food Labeling Hearing" on January 30 and 31, 1992, in Bethesda, MD. The hearing provided an additional opportunity for interested persons to present their views on the proposed rulemaking entitled, "Nutrition Labeling of Meat and Poultry Products" (56 FR 60302). The hearing addressed several subject areas including mandatory nutrition labeling, nutrient content claims, and health claims;

c. In April 1992, FSIS issued a notice in the **Federal Register** (57 FR 14499) announcing three public forums on the small business exemption issues raised in its nutrition labeling supplemental proposed rule published March 25, 1992, as well as other issues of public concern specific to exempting small businesses from nutrition labeling. The public forums were held May 12 in Kansas City, MO; May 14 in Atlanta, GA; and May 21 in San Francisco, CA. Issues discussed at the hearings related to defining a small business, criteria for a small business exemption, the potential economic impact of nutrition labeling on small businesses, and the ramifications of exempting small businesses from nutrition labeling regulations;

d. On July 23, 1992, FDA issued a notice in the **Federal Register** (57 FR

32750) announcing a public hearing on the notice of proposed rulemaking on the format for the nutrition label that it published in the **Federal Register** of July 20, 1992. The public hearing, held on August 17 and 18, 1992, in Bethesda, MD, provided an opportunity for interested persons to present their views on the issues raised by the proposal. FSIS participated in the hearing.

Major Issues

The following discussion provides background information on the major issues of nutrition labeling and a summary of the comments received on FSIS's proposed rule, the supplemental rule, the format proposal, and the small business forums, and highlights of the Agency's final rule on nutrition labeling.

I. Codified Language

In response to the proposed rule, FSIS received many comments that suggested that the Agency should include all the codified language for meat and poultry products in the regulations under 9 CFR parts 317 and 381. The commenters stated that it is very difficult to go back and forth between FDA and FSIS regulations to look up different provisions for the nutrition labeling regulations.

FSIS agrees with the comments. However, FSIS and FDA desire to ensure as much harmonization as possible of the nutrition labels for all food products, including simultaneous publication of final regulations. Harmonization will ensure consistency of format and content for consumers and, thereby, will encourage the use of the new labels, while minimizing the cost of compliance on the food industry.

The NLEA dictates for FDA the timeframe for publication of the final regulation. In order for FSIS to issue nutrition labeling regulations simultaneously with FDA, FSIS must meet this same publication timeframe. The codified portion of FSIS's final regulations will cross reference all the provisions of FDA's regulations where the provisions are identical, and provide codified language only for those provisions where there are variations from FDA because of the different products that FSIS regulates. FDA's final rule on nutrition labeling, portions of which are cross referenced in this final rule, is published elsewhere in this issue of the **Federal Register**. FSIS plans to publish, in the near future, the codified language as it applies to meat and poultry products in its entirety in 9 CFR parts 317 and 381.

The implementation date for FSIS's regulations is July 6, 1994. The future codification of the regulations for nutrition labeling of meat and poultry products into 9 CFR part 317 and 381 does not postpone the implementation of nutrition labeling set by this final rule.

II. Mandatory Nutrition Labeling

FSIS requires food manufacturers to obtain prior approval for the content and design of labeling for meat and poultry products before the products may be marketed. FSIS permits and encourages voluntary nutrition labeling using formats set forth in Agency policy memoranda. Many processed, packaged meat and poultry products currently bear nutrition labeling. FSIS requires manufacturers to provide nutrition data to substantiate nutrition claims. Additional information, when necessary to facilitate consumer understanding of these claims, is required.

NAS recommended that FSIS promulgate regulations which would require nutrition labeling for most packaged foods under FSIS's jurisdiction, including institutional-size packages and commodities distributed through USDA food programs, and the 20 to 30 top items of fresh/frozen meat and poultry products. NAS suggested that values for the latter be provided by using point-of-purchase information developed from data base values.

FSIS's rulemaking activities addressed several issues surrounding mandatory nutrition labeling, such as: (1) Statutory authority, (2) exemptions from mandatory nutrition labeling, and (3) voluntary nutrition labeling for single-ingredient, raw meat and poultry products.

1. *Statutory Authority.* In the proposed rule, FSIS stated that it had statutory authority to require nutrition labeling based on the Secretary of Agriculture's determination that meat and poultry products, other than single-ingredient, raw products, would be misbranded in the absence of such information under section 1(n) of the FMIA (21 U.S.C. 601(n) (1)) and section 4(h) of the PPIA (21 U.S.C. 453 (h) (4)).

There was considerable opposition to mandatory nutrition labeling from food manufacturers and trade associations. Much of the opposition centered around anticipated increased costs. These commenters indicated that they preferred a strictly voluntary program, citing that supply and demand in the marketplace would provide the nutrition information wanted by consumers.

FSIS has concluded that consumers should be provided nutrition labeled products to the extent possible for all foods. Because the nutrient values of single-ingredient, raw meat and poultry products are not modified through various stages of preparation, such as cooking and heat processing, FSIS believes that consumers have reasonable expectations as to the nutritional qualities of such products. Therefore, FSIS is establishing mandatory nutrition labeling for most processed meat and poultry products, such as pumped turkey, chicken franks, corned beef and meat burritos. FSIS addresses cost concerns in the following section with provisions for a small business exemption and allowance for the use of data bases.

2. *Exemptions.* Many comments on the Agency's November 1991 proposal supported the need for nutrition labeling of meat and poultry products, but had concerns about the absence of an exemption from mandatory nutrition labeling for small businesses for which the cost impact may be excessive. Therefore, FSIS published a supplemental proposed rule in the March 25, 1992, **Federal Register**, which asked for comments on small business exemptions and on the use of data bases and recipe analyses using data bases. In the supplemental proposal, FSIS sought input on the appropriate criteria for determining a small business exemption for meat and poultry product manufacturers, such as annual sales by dollars, pounds of product, or units of product, and the relationship between the level of exempted meat and poultry products.

On April 21, 1992, FSIS published a notice in the **Federal Register** (57 FR 14499) asking for participation in three public forums on the small business exemption issues raised in the March 25 supplemental proposal. Forum participants were asked to focus on specific issues regarding viable criteria for a small business exemption, the feasibility of compliance with various exemption criteria, and the effect of specific exemption criteria on nutrition labeling of the total food supply. Participants were free to also comment on other relevant issues relating to a small business exemption.

Public comments have indicated that, without an exemption, the cost burden for small businesses would be excessive. Some manufacturers have contended that unless an exemption is established for meat and poultry products, they will be forced out of business or will be forced to drop unprofitable product lines. These manufacturers further stated that their volume of sales or the size of their product lines do not make it feasible for them to incur the additional costs of nutrition labeling.

The majority of trade association and industry representatives responding to the supplemental rule advocated a small business exemption based on pounds of product, with 100,000 pounds as the suggested amount. Also, most commenters favored an exemption that would be implemented on a product-by-product basis to allow a company to stay diverse and to encourage production of unique and innovative products.

Numerous commenters also suggested that each official establishment be considered a separate business. Many trade associations and industry comments defined a product as one that is approved on a single label request. However, identical products with different weights would be considered the same product. The majority of comments suggested that the daily production records be used to evaluate a company's eligibility.

In addition, commenters suggested that an average of 2 years of data be used to establish eligibility. Numerous commenters suggested that the time period allowed to implement the nutrition labeling requirement, when a company exceeds the exemption limits, should be 6 months to 1 year.

In May 1992, public meetings were held in Kansas City, MO, Atlanta, GA, and San Francisco, CA. At the Kansas City forum, the consensus of the group was that the exemption should be based on pounds of product. The most important factor in favor of the pounds per product option is that a product will be exempted based on each product's contribution to the diet; the level of the exemption may be tied directly to the percentage of the diet that may not be nutrition labeled. Furthermore, each exempted product is likely to be a small part of an individual's annual diet.

In Atlanta, the concept of a unit-based exemption was introduced. The unit concept is similar to the pound-per-product option and may be better for FDA-regulated products because of their wide variation in weight.

In San Francisco, a representative of the Small Business Administration suggested using an exemption that included a pound/unit concept in combination with the small business definition of 500 employees or less. The majority of people attending the meeting contended the exemption should be based on pounds and/or units.

FSIS believes an exemption for small business is necessary because mandatory nutrition labeling requirements will create undue economic hardship and serve as a disincentive for development of more nutritious food products. Furthermore, the burden of mandatory nutrition labeling may force some small firms to drop product lines that would become unprofitable because of the cost of nutrition labeling and eventually force some small firms out of business. Therefore, after reviewing comments received in response to the 1990 amendment proposal, comments at the nutrition labeling hearings, the public forums held for the small business exemption, and written comments supplied to the Agency, FSIS is establishing a small business exemption for meat and poultry processing firms based on the volume of production in combination with the number of employees working at a firm. To qualify for the small business exemption, a processor must produce less than the annual production poundage level of a single food product and must employ no more than a specified number of employees. For purposes of the small business exemption, a "food product" is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

FSIS evaluated several options in establishing a poundage limit for the small business exemption, as discussed in the Agency's FRIA. This evaluation was based on two objectives: (1) Setting the limit high enough so that the risk that any small business would have to close would be minimal, and (2) setting the limit low enough so that the maximum volume of total production would bear nutrition labeling. FSIS believes that a maximum annual production poundage level between 100,000 and 250,000 pounds appears to best satisfy these two stated objectives.

Accordingly, FSIS has determined that the cutoff for the annual production level should be 100,000 pounds, phased in over a 3-year period. The 3-year phase-in period will minimize the impact of compliance costs to the industry, while also minimizing the impact of additional purchasing costs to consumers. The maximum annual production poundage level is set at 250,000 pounds per food product for the first year of implementation of nutrition labeling, lowered to 175,000 pounds per food product for the second year of implementation, and lowered finally to 100,000 pounds per food product for the third and subsequent years. The 3-year phase-in period ultimately achieves the 100,000-pound limit suggested by industry and trade association representatives. In addition, FSIS estimates an average food product line has a 3-year life. Therefore, the 3-year phase-in period will accommodate the many firms that will be relabeling their products during the normal course of business because of changed formulations.

The limit on the number of employees at a firm is set at 500 or fewer employees, which is the Small Business Administration's definition of a small meat or poultry processing firm. This approach will allow the Small Business Administration to assist in determining which firms would qualify for exemption based on the number of employees.

For purposes of a small business exemption, FSIS defines "business" as a single-plant facility or a company that owns multiple facilities. Although most meat and poultry firms are single-plant facilities, a significant number of firms are multi-plant companies. These multi-plant companies tend to make labeling decisions for all facilities under their ownership or management in a centralized manner. The qualification of a multi-plant company for exemption from nutrition labeling entails the total annual production and the total number of employees for all facilities under that multi-plant company, not for each individual facility. Thus, if a multi-plant company as a whole meets both criteria set forth in the small business exemption, all facilities under that centralized company may be exempt from nutrition labeling. Conversely, if the multi-plant company does not meet both criteria in the small business exemption, no facility under that company qualifies for exemption from nutrition labeling.

Given this combination approach for exemption from nutrition labeling, FSIS estimates that over 90 percent of all meat and poultry products, under the mandatory nutrition labeling provisions, will bear nutrition labeling after the 3-year phase-in, when the maximum annual production level has reached 100,000 pounds. FSIS further expects, that nutrition labeling will be included on as much as 99 percent of all nationally distributed meat and poultry products available to consumers through supermarkets. Again, this figure takes into account all products that are regulated under the mandatory nutrition labeling regulations, and do not include single-ingredient raw meat and poultry products that are under voluntary nutrition labeling.

In its November 1991 proposal, FSIS proposed to exempt from nutrition labeling foods used for further processing. For very small packages (less than ½ ounce) and other than consumer-size packages, FSIS proposed to allow nutrition information to be provided by labeling means other than a nutrition panel on the package.

Although there were relatively few comments addressing this issue, the majority of those that did comment on exemptions supported a blanket exemption for foods used in further processing and other than consumer-size packages.

FSIS believes that there is little value in requiring nutrition information where the consumer will not see it. Since other than consumer-size packages can be purchased by the consumer at the retail level, FSIS believes it is more appropriate to exempt products that are not for sale to consumers, regardless of size, and allow industry to determine when the product is to be used for further processing and not to be sold, at that point, to consumers. (The term "consumers", as used throughout this document refers only to household consumers.) Since consumers will not see the nutrition information on products used for further processing or products that are not for sale to consumers, these products are exempt from nutrition labeling.

For very small packages, some commenters recommended a blanket exemption, while others recommended an increase in the net weight for small package exemptions. Several commenters recommended that FSIS follow FDA's definition for very small packages (i.e., surface area available to bear labeling of less than 12 square inches). FSIS believes that it is appropriate to retain the definition of very small packages as individually wrapped packages of less than ½ ounce net weight. The Agency does not currently require packages of meat or poultry products weighing less than ½ ounce to bear a net weight statement (9 CFR 317.2(h)(9)(ii) and 381.121(c)(9)(ii)). In order to provide consistency with this net weight labeling policy, FSIS is adopting the proposed definition of very small packages as individually wrapped packages of less than ½ ounce net weight. However, since these products are such an insignificant part of the diet, FSIS is exempting very small packages from nutrition labeling requirements, provided that no nutrition claim is made on the labeling. If a nutrition claim is made on the label of very small packages, all nutrition labeling requirements must be satisfied by printing the information on the labeling.

Based on comments it received on its proposal, FDA concluded that there was adequate justification for allowing some flexibility for food in an intermediate size package group of between 12 and 40 square inches. In this intermediate size package range, FDA is allowing for the use of a linear format, making the daily reference values (DRV's) optional, allowing for abbreviations, and allowing for required information to appear on other label panels adjoining the principal display panel or the information panel. FSIS has reviewed FDA's summary of the comments received on this issue, and agrees that there may be situations that warrant a modified nutrition label. Accordingly, FSIS will allow a modified nutrition label for packages with a total surface area available to bear labeling of 40 or less square inches. In addition, on a case-by-case basis, FSIS will consider allowing a modified nutrition label for packages larger than 40 square inches that have a surface area which precludes the presentation of the full nutrition label.

Numerous commenters raised the issue of custom services and were concerned about the status of these services with respect to nutrition labeling products. FSIS has determined that custom services, such as custom slaughter or custom processing, should be exempt from nutrition labeling requirements since such services are performed solely for individuals.

Several commenters stated that products intended for export should be exempt from nutrition labeling requirements. Such products are not covered under this final rule because they are labeled according to the requirements of the country where the product is to be exported. This final rule sets forth this exception to mandatory nutrition labeling.

Although the FSIS proposal did not specifically address the issue of food products served in restaurants, the Agency did receive several comments from trade associations and retailers. Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

FSIS has historically provided for certain retail exemptions, as prescribed in 9 CFR 303.1 and 381.10. However, the adulteration and misbranding provisions of the FMIA and PPIA, as well as related regulations, still apply to such retail exempted product. FSIS has determined, based on experience and on comments, that it would be impractical to enforce nutrition labeling requirements on products prepared or served at retail. In addition, FSIS has concluded, based on review of National Food Consumption Survey (NFCS) data, the average person's diet consists of an insignificant proportion of ready-to-eat, retail packaged or processed products.

Accordingly, FSIS is exempting from mandatory nutrition labeling (1) ready-to-eat products, such as sliced bologna, that are packaged or portioned at a retail store or similar retail-type establishment; and (2) multi-ingredient products, such as sausage, that are processed at a retail store or similar retail-type establishment, provided the labels or the labeling of these products bear no nutrition claims or nutrition information.

FSIS anticipates that most meat and poultry products in gift packs will fall under the small business exemption. FSIS also believes that gift packs play a very minor role in the overall diet. Although FSIS does not agree with those commenters who stated that gift packs should be exempt from nutrition labeling, this final rule provides that nutrition information for gift packs may be shown at a location other than on the gift pack label, unless a nutrition claim is made on the labeling of such products. For example, nutrition information may be provided on a package insert.

3. *Voluntary Nutrition Labeling.* FSIS proposed to permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products, including those that have been previously frozen. Products such as ground beef, chicken breasts, and whole turkeys would be in the voluntary program. Under the proposed rule, manufacturers electing to provide nutrition information on the label of these products would be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling for the voluntary program could be declared on the basis of "as consumed" or "as packaged", rather than required to be declared on an "as packaged" basis as is the case for products under the mandatory nutrition labeling program.

Several commenters requested clarification of whether single-ingredient, raw kosher meat and poultry products would be included in the voluntary program. These products are considered to fall within the definition of single-ingredient, raw products, and, thus, are included in the voluntary program. Commenters tended to support a voluntary program similar to FDA's voluntary program for raw fruit, raw vegetables, and raw fish. After reviewing the various comments received, FSIS believes that a voluntary nutrition labeling program for single-ingredient, raw meat and poultry products is the best approach.

Commenters supported the Agency's proposal to incorporate point-of-purchase materials in the voluntary program. Examples of the use of point-of-purchase materials to display nutrition information may include large placards (e.g., wall posters, signs, and aisle hangings). The nutrition

information may be supplemented by videos, live demonstrations or other media. If a nutrition claim is made on point-of-purchase materials that are labeled under the FMIA and the PPIA, all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials: (a) The requirements of the mandatory nutrition labeling program, apply but the nutrition information may be supplied on "as packaged" or "as consumed" basis; (b) the listing of DRV's is voluntary; and (c) the point-of-purchase materials are not subject to any of the format requirements. FSIS will not require the listing of DRV's on point-of-purchase materials which do not make nutrition claims because there will be limited space in grocery stores and supermarkets to display such nutrition information. Also, the Agency does not believe there is one most effective format for the presentation of nutrition information in point-of-purchase materials. Currently point-of-purchase nutrition information materials have many different formats. The Agency is not aware of any studies that show one format to be more effective than another.

FSIS proposed to survey food retailers on actions taken to provide consumers with nutrition information on products described in the voluntary program. FSIS will survey for "significant participation" rather than follow FDA's review of "substantial compliance" of the voluntary guidelines. Because FSIS does not have a statutory mandate as provided to FDA under the NLEA, FSIS proposed different terminology to refer to its review of the voluntary program. FSIS will follow FDA's planned 2-year evaluation cycle of the voluntary program, and will issue its first report of survey findings on the voluntary program by May 1995. FSIS initially proposed to implement both the voluntary and the mandatory nutrition labeling programs in May of 1993. However, FSIS has delayed the effective date of the nutrition labeling programs until 18 months from publication of this final rule. Therefore, FSIS will not begin surveying for significant participation until the effective date of this final rule. FSIS will reevaluate for significant participation every 2 years thereafter. If the Agency determines, during any evaluation of its voluntary guidelines, that significant participation does not exist, the Agency will initiate proposed rulemaking to determine whether it would be beneficial to require nutrition labeling on single-ingredient, raw meat and poultry products. The guidelines will remain in effect, however, as long as significant participation exists.

Individual stores selected for evaluation of the guidelines will be found to be participating at a significant level if (1) the store provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat and poultry products that it sells, such as those listed in Table 1, including those that have been previously frozen; and (2) nutrition labeling information is in accordance with the guidelines described in the regulations.

FSIS will use a representative sample of stores to obtain the information necessary to assess participation. The distribution of the sample of stores shall cover all chain companies and a representative sample of independent companies. FSIS further proposed that significant participation by food retailers exists if at least 60 percent of the companies that are evaluated are participating in accordance with the guidelines.

There were few comments addressing the proposal for measuring significant participation. Several commenters supported the Agency's proposal, while those that disagreed with the proposal did not support measuring for significant participation. Two consumer groups that disagreed with the proposal expressed a different viewpoint, i.e., the Agency should require a higher percentage of participation than the proposed 60 percent.

FSIS believes it is important to provide nutrition information to consumers and, to the extent possible, harmonize with FDA's voluntary program for raw fruit, raw vegetables, and raw fish. To meet the 60 percent criterion, over half of the covered stores will provide nutrition information. In addition, FSIS believes that, by allowing for the use of point-of-purchase materials, retailers will be able to provide consumers with the necessary nutrition information. Therefore, FSIS is adopting the proposed standard for significant participation.

The FSIS proposal identified 45 major cuts of meat and poultry that would be used to measure significant participation in the voluntary program and requested comments on the list. Very few commenters addressed this issue. However, those that commented generally supported the proposed list. One commenter that generally disagreed with the proposed list suggested that the list omitted several of the more popular, fattier cuts and included leaner, less popular cuts of meats. FSIS attempted to identify representative cuts based on USDA nutritional studies, Poultry Nutri-Facts and Meat Nutri-Facts programs. The list in no way restricts retailers from providing additional nutrition information on other cuts of meat and poultry. FSIS encourages retailers to provide nutrition information on other cuts of meat and poultry to meet changing consumer needs.

One company requested that necks and giblets be excluded from the whole bird nutrient profile listing, stating that consumers frequently do not prepare these items nor do they consume them as part of the bird. In addition, it was requested that, at the manufacturer's option, the whole bird nutrient profile for turkeys be listed as white and dark meat.

Manufacturers currently label turkeys with two nutrient panels—one for white meat and one for dark meat. FSIS believes it is reasonable to exclude the necks and giblets from the whole bird when listing the nutrient profile. FSIS will permit manufacturers to continue the option of labeling turkeys with two panels. These minor revisions are reflected in Table 1 and in the final rule.

TABLE 1.—MAJOR CUTS OF MEAT AND POULTRY

1. Whole Chicken [1]
2. Chicken Breast
3. Chicken Wing
4. Chicken Drumstick
5. Chicken Thigh
6. Whole Turkey [2]
7. Turkey Breast
8. Turkey Wing
9. Turkey Drumstick
10. Turkey Thigh
11. Beef Chuck Blade Roast
12. Beef Loin Top Loin Steak
13. Beef Rib Roast Large End
14. Beef Round Eye Round Steak
15. Beef Round Top Round Steak
16. Beef Round Tip Roast
17. Beef Chuck Arm Pot Roast
18. Beef Loin Sirloin Steak
19. Beef Round Bottom Round Steak
20. Beef Brisket (Whole, Flat Half, or Point Half)
21. Beef Rib Steak Small End
22. Beef Loin Tenderloin Steak
23. Ground Beef Regular, w/o added seasoning
24. Ground Beef Extra Lean, w/o added seasoning
25. Pork Loin Chop
26. Pork Loin Country Style Ribs
27. Pork Loin Top Loin Chop Boneless
28. Pork Loin Rib Chop
29. Pork Spareribs
30. Pork Loin Tenderloin
31. Pork Loin Sirloin Roast
32. Pork Shoulder Blade Steak
33. Pork Loin Top Roast Boneless
34. Ground Pork
35. Lamb Shank
36. Lamb Shoulder Arm Chop
37. Lamb Shoulder Blade Chop
38. Lamb Rib Roast
39. Lamb Loin Chop
40. Lamb Leg (Whole, Sirloin Half, or Shank Half)
41. Veal Shoulder Arm Steak
42. Veal Shoulder Blade Steak
43 Veal Rib Roast

TABLE 1.—MAJOR CUTS OF MEAT AND POULTRY—Continued

44 Veal Loin Chop	
45. Veal Cutlets	

[1] Without neck and giblets.
[2] Without neck and giblets. Separate nutrient panels for white and dark meat permitted as an option.

III. Nutrition Label Content

The NLEA mandates that the amount of the following food constituents be included on the labeling of nonexempted food products: Calories derived from any source, calories derived from the total fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrates, sugars, dietary fiber, protein, and sodium. Also required to be included is any mineral, vitamin, or other nutrient required to be placed on the label or labeling before October 1, 1990, if the Secretary of Health and Human Services (HHS) determines that such information will assist consumers in maintaining healthy dietary practices. The NLEA allows FDA, by regulation, to add other nutrients to the list of nutrients that should be included on the labeling of foods subject to the NLEA, if this will help consumers to maintain healthy dietary practices. It allows FDA, by regulation, to remove nutrients required to be listed, if the Secretary of HHS determines that the information relating to the nutrient is not necessary to assist consumers in maintaining healthy dietary practices. The NLEA specifies that a simplified nutrition label format is to be used when a food contains insignificant amounts of more than one-half of the nutrients required to be listed.

In its November 1991 proposal, FSIS proposed to establish a list of 15 required nutrients which are: Calories, calories from total fat, total fat, saturated fat, cholesterol, total carbohydrate, complex carbohydrate, sugars, dietary fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. In addition, FSIS proposed to adopt FDA's proposed list of nutrients as mandatory or voluntary components of nutrition labeling, definition of nutrients, definition of insignificant amounts, and increments for declaring nutrients, in the interest of harmonizing with FDA. FSIS and FDA received numerous comments on these issues. Both agencies reviewed and discussed all comments, and after consideration, based their decisions regarding the list of nutrients on the agencies' discussion of comments. The following discussion addresses comments received concerning various nutrients.

1. *Saturated fat.* In the proposal, FSIS defined saturated fat as the sum of lauric (C12), myristic (C14), palmitic (C16), and stearic (C18) acids. FSIS requested comments on the inclusion of stearic acid in the definition of saturated fat.

Most of the comments received on the definition of saturated fat supported excluding stearic acid, stating that the proposed definition would be detrimental to red meat products and would serve no health benefit to consumers. A manufacturer supporting the inclusion of stearic acid in the definition of saturated fat stated that it has not been confirmed that stearic acid lowers serum cholesterol.

FDA also received a number of comments concerning the definition of saturated fat. There is substantial evidence that diets low in saturated fatty acids are associated with decreased levels of blood cholesterol, reduced risks of coronary heart disease and atherosclerotic disease and may help to lower total fat intake, which may be associated with risks of cancer and obesity. For these reasons, FSIS and FDA agreed with the comments supporting the definition of saturated fat as the sum of all fatty acids, including stearic acid, without double bonds. Although the definition for saturated fat includes stearic acid, a near consensus has been reached that stearic acid does not have the same serum cholesterol-raising effect as the three other saturated fatty acids—myristic, palmitic, and lauric acids. To provide consumers with factual information concerning saturated fats that do not have a cholesterol-raising effect, FSIS is allowing for the voluntary declaration of stearic acid as a subcomponent of saturated fat.

2. *Dietary fiber.* Food manufacturers and trade associations strongly objected to requiring the declaration of dietary fiber content. These commenters contended that, because meat and poultry products are generally not meaningful sources of dietary fiber, disclosure would be of limited value to consumers.

While whole muscle cuts may contain no dietary fiber, FSIS believes that some breaded and meal-type products may contain substantial amounts of dietary fiber. FSIS is requiring the declaration of total dietary fiber content, based on the well documented role of dietary fiber in maintaining normal bowel function. Different physiological effects are associated with soluble and insoluble dietary fibers, and consumers have expressed an interest in knowing these types of fibers in foods. However, no quantitative guidelines for daily intakes of soluble and insoluble fiber components have been provided. Therefore, FSIS is permitting the voluntary declaration of insoluble and soluble fiber components unless a nutrient content claim on fiber is made.

3. *Total carbohydrate.* FSIS proposed to define total carbohydrate to exclude dietary fiber. Because dietary fiber includes components of carbohydrate that cannot be digested by humans, the proposed definition of total carbohydrate did not include the components of carbohydrate that generally do not contribute calories to the diet. One comment stated that there was no justification for excluding dietary fiber from total carbohydrate values.

Based on comments, FSIS and FDA concluded that excluding dietary fiber from carbohydrate is inconsistent with established methods of reporting food composition, confuses the issue of calculating energy content, and will decrease consumer understanding of label information. Therefore, dietary fiber is included in the definition of total carbohydrate.

4. *Complex carbohydrate and sugars.* Food manufacturers and trade associations opposed the mandatory listing of complex carbohydrate and sugars (including sugar alcohols) on the label. These commenters stated that in most meat and poultry products, complex carbohydrate and sugars are present in small amounts or not at all.

In the interest of harmonization with FDA, FSIS is requiring the declaration of grams of sugars. Additionally, FSIS is limiting the definition of sugars to free mono- and disaccharides.

FSIS proposed that complex carbohydrate be defined as the sum of dextrins and starches. Thus, complex carbohydrate, as defined, includes those carbohydrate components that contain 10 or more saccharide units (exclusive of dietary fiber).

There was opposition to the proposed definition of complex carbohydrate. One manufacturer commented that excluding dietary fiber from the definition of complex carbohydrate has no scientific rationale, since dietary fiber is, by chemical composition, a complex carbohydrate. Several commenters were concerned that currently there is insufficient methodology for determining sugars and complex carbohydrates.

FSIS believes that the inclusion of dextrins and saccharide units of 10 or more within the definition of complex carbohydrate may inappropriately classify the relatively low molecular weight carbohydrates in some nutritive sweeteners as complex carbohydrate.

Additionally, from a compliance perspective, available and widely used laboratory methods provide for the analysis of carbohydrate in foods in a manner that may not be sufficiently specific for regulatory purposes.

Based on review of the comments submitted, FSIS concurs with FDA that it is more appropriate to replace the term "complex carbohydrate" with the term "other carbohydrate" which would be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars, or if sugar alcohol is declared, the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol. In harmonization with FDA, FSIS is allowing for the declaration of other carbohydrate on a voluntary basis.

FSIS proposed to define "sugars," including sugar alcohol, as free mono- and oligosaccharides (and their derivatives) that contain four or fewer saccharide units. This definition includes tri- and tetrasaccharides. Most of the comments on this issue objected to the proposed definition of sugars, stating that sugars should be defined to include only mono- and disaccharides. One opposing commenter stated that the definition differed from that used by Canada, the Codex Alimentarius Commission and the European Economic Community. Two commenters suggested that including sugar alcohols in the definition of sugars is inappropriate because sugar alcohols do not have the nutritional and metabolic effects of sugars, such as glucose.

FSIS is aware that the proposed definition differs from that used by Canada, the Codex Alimentarius Commission, and the European Economic Community, all of which limit the definition of sugars to mono- and disaccharides. FSIS agrees that it is more appropriate to exclude sugar alcohols from the definition of sugars. FSIS is allowing, on a voluntary basis, the separate declaration of the number of grams of sugar alcohols or, alternatively, if only one sugar alcohol is present in the food, the name of the specific sugar alcohol. If sugar alcohols are present but not listed, they are included in other carbohydrates. Declaration of sugar alcohols is mandatory when claims are made relative to sugar alcohols or to sugars when sugar alcohols are present.

5. *Protein.* FSIS proposed to require that the label for any food contain the statement "not a significant source of protein" immediately adjacent to the protein content regardless of the actual amount of protein present if the food (a) intended for adults and children 4 or more years of age, has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, (b) intended for children greater than 1 but less than 4 years of age, has a protein digestibility-corrected amino acid score of less than 40 percent of casein, or (c) intended for infants, has a protein quality, as measured by protein efficiency ratio, of less than 40 percent of the reference standard (casein).

Based on comments received, FDA concluded that the amino acid pattern for children 1 to 4 years of age should be the same as the amino acid reference pattern for 2- to 5-year old children. FSIS agrees, and is removing casein as a reference standard for foods intended to be for children older than 1 year but younger than 4 years of age.

One commenter stated that it was important to harmonize with FDA on protein quality. Another company opposed use of the statement "not a significant source of protein" citing that there is no evidence of protein malnutrition in the United States.

The Agency is retaining this requirement because there is a need to protect the consumer, especially a young child, from inadequate nutrition from the use of poor quality protein.

FSIS proposed that declaration of protein content calculated as a percent of the recommended daily intake (RDI) be voluntary for foods intended for consumption by adults and children 4 or more years of age unless a protein claim is made for the food. However, the Agency also proposed that nutrition labeling on foods intended for infants and children less than 4 years of age contain a mandatory statement of protein content expressed as a percent of the RDI.

The label reference value for protein for adults and children 4 or more years of age has been established as a DRV rather than a RDI because the label reference value for protein for this age group is now being based on percent of calories. However, because FDA did not propose DRV's for infants, children less than 4 years of age, pregnant and lactating women, the protein label reference values for these groups remain as RDI's.

One commenter recommended that protein expressed as a percentage of RDI be voluntary for all foods unless a protein claim is made. Another commenter disagreed stating that the mandatory listing of protein as a percent of RDI would provide consumers with knowledge of when protein requirements are met and also exceeded.

Because current evidence suggests that the diet typically within the U.S. provides for an adequate intake of protein of sufficiently high biological quality, FSIS is allowing but not requiring the voluntary declaration of protein content calculated as a percent of the DRV for foods represented for consumption by adults and children 4 or more years of age unless a protein claim is made for the food. Furthermore, the Agency is requiring that nutrition labeling on foods represented for use by infants and children less than 4 years of age contain a mandatory statement of protein content expressed as a percent of the RDI.

6. *Vitamins and minerals.* Public concern for thiamin, riboflavin, and niacin has lessened considerably in the last 20 years. The Agency received only one comment stating that these vitamins should be required. Therefore, the Agency is making the declaration of thiamin, riboflavin and niacin voluntary, unless a claim is made for them.

7. *Nutrient components.* FSIS and FDA received numerous comments on a variety of issues concerning nutrient components. Both agencies have carefully reviewed and assessed the comments and discussed the merit of these comments. Accordingly, FDA has made changes in its final rule published elsewhere in this issue of the **Federal Register**. FSIS is adopting the agreed upon changes since both agencies are committed to providing consumers with the most consistent food labeling system possible. The following tables list the voluntary and mandatory nutrient components.

TABLE 2.—MANDATORY/VOLUNTARY NUTRIENTS

Nutrients	Mandatory (M), Voluntary (V)	Core nutrient	Units	Increments rounding	Insignificant amount	Definition	Other
Calories	M	X	Calories	5 cal <=50 cal 10 cal >50 cal	<5 cal		May be listed on label as kilojules (kj) or (energy) in addition to calories.
Calories from fat	M		Calories	5 cal <=50 cal 10 cal > 50 cal	<5 cal		
Calories from sat fat.	V		Calories	5 cal <=50 cal 10 cal > 50 cal	<5 cal		
Total Fat	M	X	gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm	Total lipid fatty acids	
Saturated Fat	M		gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm	Sum of all fatty acids without double bonds.	
Stearic Acid	V		gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm		
Polyunsaturated fat and monounsaturated fat.	V		gm	Nearest .5 gram below 3 grams nearest gram above 3 grams.	<.5 gm		
Cholesterol	M		mg	Nearest .5 mg	<2 mg		2–5 mg may state "Less than 5 mg".
Sodium	M	X	mg	5 mg <=140 mg 10 mg>140 mg	<5 mg		
Potassium	V		mg	5 mg <=140 mg 10 mg >140 mg	5 mg		
Total Carbohydrate.	M	X	gm	Nearest gram	<1 gm	All carbohydrates including dietary fiber.	
Dietary Fiber	M		gm	Nearest gram	<1 gm	Sum of soluble and insoluble fiber.	
Soluble Fiber	V		gm	Nearest gram	<.5 gm		
Insoluble Fiber	V		gm	Nearest gram	<.5 gm		
Sugars	M		gm	Nearest gram	<.5 gm	Sum of all free mono and disaccharides.	
Sugar Alcohols	V		gm	Nearest gram	<.5 gm	Sum of all approved sugar alcohols.	
Other Carbohydrates.	V		gm	Nearest gram	<.5 gm	All carbohydrates except sugars, sugar alcohols (if not declared), and dietary fiber.	
Protein	M	X	gm	Nearest gm	<1 gm	Voluntarily state as % of RDI or DRV, becomes mandatory for foods for infants and children less than 4 years.	
Vitamin A	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		
Vitamin C	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		
Calcium	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		
Iron	M		% RDI	Nearest 2% <=10% Nearest 5% > 10% <=50% Nearest 10% >50%	<2% RDI		

Note: All voluntary nutrients become mandatory if a claim is made regarding the nutrient or one of its subcomponents.

TABLE 3.— MANDATORY/VOLUNTARY RDI CHART

Nutrient	Mandatory (M), voluntary (V)	Unit of measurement	RDI
Vitamin A	M	International Units	5000
Vitamin C	M	Milligrams	60
Calcium	M	Gram	1.0
Iron	M	Milligrams	18
Vitamin D	V	International Units	400
Vitamin E	V	do	30
Thiamin	V	Milligrams	1.5
Riboflavin	V	do	1.7
Niacin	V	do	20
Vitamin B6	V	do	2.0

TABLE 3.— MANDATORY/VOLUNTARY RDI CHART—Continued

Nutrient	Mandatory (M), voluntary (V)	Unit of measurement	RDI
Folate	V	do	0.4
Vitamin B12	V	Micrograms	6.0
Biotin	V	Milligrams	0.3
Pantothenic Acid	V	do	10
Phosphorus	V	Gram	1.0
Magnesium	V	Milligrams	400
Zinc	V	do	15
Iodine	V	Micrograms	150
Copper	V	Milligrams	2.0

Notes:
- All voluntary nutrients are required if a claim is made regarding that nutrient.
- The declaration of all vitamins and minerals will be as a percent of the RDI.

IV. Nutrition Label Format

In its November 27, 1991, proposal, FSIS announced its intent to issue a separate proposed rule on format. At that time, FDA had initiated a pilot program to test alternative nutrition label formats. On July 20, 1992, FDA proposed to adopt a new nutrition label format. Its proposal was based on the findings of four consumer research studies, and other label research being conducted by industry. FDA described its intent in revising the current nutrition label so that the information included in the nutrition panel would enable consumers to understand its relative significance in the context of a total daily diet.

On August 28, 1992, FSIS issued a separate proposed rule adopting a standard format for use in presenting nutrition information on the labels of meat and poultry products. FSIS proposed to establish the CONTROL WITH DIETARY GUIDANCE or the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE as the standard format. The Agency tentatively concluded that these formats would: (1) Enable consumers to select foods that fit into a healthier diet that meets their individual needs; (2) provide consumers with the most accurate information on which to base their dietary decisions; (3) promote and reinforce a nutrition education message that is familiar to consumers and well accepted by health professionals; and (4) allow the Agency flexibility to adapt to ever changing scientific findings without publishing new regulations. FSIS requested comments on whether the CONTROL WITH DIETARY GUIDANCE or the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE format enables consumers to apply the nutrition information in the context of a total daily diet. FSIS also requested comments on certain label format elements, such as changes in terminology, graphic presentation, and highlighting.

To be consistent with FDA, FSIS proposed the use of an abbreviated format in its November 1991 proposal. The proposed abbreviated format was to be used if a meat or poultry product contained insignificant amounts of more than one-half of the nutrients required in the full nutrition label format. The term "insignificant amount" was proposed as meaning "that amount which may be rounded to zero in nutrition labeling."

Trade associations and food manufacturers expressed opposition to the requirements for use of an abbreviated format stating that virtually every meat and poultry product will have significant amounts of more than one-half of the required nutrients. Many commenters supported some type of shortened format for which meat and poultry products could qualify.

In the August 28, 1992, proposal on format, the Agency stated that it was unable to find meat or poultry products that would qualify for the proposed simplified format ("abbreviated" format was changed to "simplified" format). Therefore, FSIS did not propose FDA's simplified format. FSIS requested comments on a simplified format, with differing criteria for meat and poultry products. When any of the required nutrients, other than the core nutrients or food components, are present in insignificant amounts, FSIS proposed that they may be omitted from the tabular listing, provided that the following statement is included within the nutrition label: "Not a significant source of _____." The blank would be filled in with the appropriate nutrient or food component. In addition, at a minimum, the simplified format would include calories, total fat, total carbohydrate, protein, and sodium.

FSIS received 70 comments on the format proposal from trade associations (25), food manufacturers and distributors (22), consumers (5), colleges and universities (4), consumer advocacy organizations (3), foreign governments (2), professional organizations (2), a health promotion organization (1), and others (3).

Although there was some support for both the CONTROL WITH DIETARY GUIDANCE and the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE formats, commenters thought, in general, that these formats needed testing prior to any consideration for adopting them. There was general agreement among those opposing FSIS's proposed formats that these formats do not meet the NLEA provision which requires that nutrition information be provided in a manner that is understandable and informative. (Although FSIS is not bound by the NLEA, as FDA is, nutrition labeling is a harmonization effort on the part of both agencies.)

Strong objections were voiced on the CONTROL WITH DIETARY GUIDANCE format, suggesting that the dietary guidance would be too general to be informative or would require too much label space. Further objections included: (1) Consumers would not have time to calculate the dietary guidance into meaningful information; (2) the dietary guidance offered no frame of reference; and (3) the order of ingredients should reflect the CONTROL format.

Those opposing the CONTROL WITH RECOMMENDED DAILY INTAKE RANGE format did not believe consumers would be able to apply the information to their individual needs. Many believed that nutrition education would be needed in order for consumers to understand this format, and that this format also utilizes too much label space.

Commenters opposed the CONTROL WITH DAILY GUIDE FOR MEN AND WOMEN format because they thought consumers would focus on one number for each nutrient and assume that this number would be right for them. This format was also criticized for not allowing space for other groups, such as children.

Many commenters voiced support for the CONTROL format. These

commenters cited simplicity, minimal label cutter, and consumer familiarity to support their viewpoint. Several companies commented that the CONTROL format should be required as a base, but allow the expansion of the CONTROL format to include recommended daily intake ranges and expanded dietary guidance on a voluntary basis.

There was some support for the CONTROL/DRV, PERCENT DV WITH DRV, and PERCENT DV WITHOUT DRV formats. Commenters contended that the DRV's represent an estimate of the daily needs for the average consumer or that DRV's provide consumers a framework based on the total daily diet.

No comments supported the ADJECTIVE, HIGHLIGHTING, and GROUPING formats.

Commenters repeatedly stressed that, whatever format is ultimately selected, it is critical for FSIS and FDA to adopt a uniform format. They believed that consistency in labeling format should be the main concern to achieve the ultimate goal of providing useful nutrition information to consumers for all foods.

FSIS and FDA have extensively reviewed and discussed all comments submitted, and have determined that the PERCENT DV WITH DRV format best meets the intent of the NLEA and serves the needs of consumers. The required elements of the nutrition label format include: the fourteen mandatory nutrients and their quantitative amounts, the percent of the daily value based on a 2,000 calorie diet, the DRV's for both a 2,000 calorie and a 2,500 calorie diet, and caloric conversion information. Both FSIS and FDA believe that establishing one uniform format for all foods is in the consumers' best interest. Accordingly, FSIS is adopting all of the mandatory and voluntary elements of the PERCENT DV WITH DRV format.

Commenters expressed strong support for the simplified format with differing criteria for meat and poultry products. Commenters agreed that the FSIS proposed simplified format was appropriate for meat and poultry products. Therefore, FSIS is adopting the simplified format as proposed.

V. U.S. Recommended Daily Allowances

In its November 1991 proposed rule, FSIS proposed to require that daily reference values (DRV's) become part of nutrition labeling. FSIS also proposed to adopt FDA's proposed format for the "daily value", as presented in the proposed 21 CFR 101.9(c)(12)(i).

The majority of commenters opposed the use of DRV's on the label because they believe that:

(1) DRV's are based on an extremely high calorie intake that is not a representative sample of the average population;

(2) DRV's would only serve to confuse consumers;

(3) DRV's do not have universal acceptance by health professionals, and are not in common usage by the scientific and academic communities;

(4) DRV's will not apply uniformly to all consumers due to variations in individual diets; and

(5) DRV's would clutter the food label.

Those commenters that supported the use of DRV's on the label believe that using DRV's gives consumers a gauge for the nutrient amounts on the label and aids consumers in understanding how individual foods fit into the total diet. Most of the supporters of the DRV concept believe that its use should be voluntary.

There were varying opinions among commenters regarding the Agency's proposal to head the list of vitamins and minerals with the single term "Daily Value." Some commenters were concerned that the term "Daily Value" could be interpreted as goals to be achieved rather than reference levels. Other commenters agreed with the FSIS proposal, while others said Daily Value intakes should be eliminated or postponed until they are better defined, justified by a consensus of the scientific community, and understood by industry and consumers. The terms "Percent of Daily Values" and "Reference Value" were suggested as alternatives to the proposed "Daily Value" term. Some commenters thought "Daily Value" should be voluntary and recommended that it be allowed as an additional column in the main nutritional panel.

The majority of the commenters opposed the adoption of the Recommended Daily Intakes (RDI's) and supported the continued use of the U.S. Recommended Daily Allowances (RDA's). Commenters opposed the adoption of RDI's because they believe RDI's would mislead and confuse consumers and understate or ignore the nutritional needs of many population groups. Some commenters suggested that the method used to derive the RDI's and DRV's undermines the usefulness and effective accuracy of the nutrition panel for most consumers. Another commenter believes that the 2,350 calories level would be misinterpreted by consumers as goals to achieve.

Those commenters supporting the continued use of U.S. RDA's believe that U.S. RDA's are currently accepted as the established and up-to-date reference standard for vitamins and minerals for healthy Americans. Also, there is a history of recognition and use of the U.S. RDA's by consumers.

Some commenters concurred with FSIS's decision to adopt FDA's RDI's and stated that the current U.S. RDA's are the appropriate standards to use in developing the RDI's. The commenters suggested that the age adjusted mean is a reasonable method for establishing the level for each nutrient and food component. Commenters also stated that the five sets of RDI's that FDA proposed should provide adequate standards for foods specifically designed for infants, children, and pregnant and lactating women.

Several commenters addressed the issue of updating RDI's and RDA's. The commenters pointed out that the current proposal makes no provision for incorporating a mechanism to update the RDI's at regular intervals as the population changes and as new evidence for recommended nutrient requirements (RDA's) changes. Another commenter supported updating of the U.S. RDA's to reflect the 10th edition of the RDA's.

Most of the commenters suggested that FSIS and FDA be consistent in the use of RDI's and DRV's.

FSIS will parallel FDA and adopt the format for the "Daily Value." "Daily Value" will be the means of placing the nutrition information on the label in the context of a total daily diet. As the FDA and FSIS have worked to standardize the nutritional labels under their respective jurisdictions, it remains in the interest of consumers that FSIS and FDA be consistent.

After extensive discussions over format, the Administration decided that the DRV's should be shown for both a 2,000 calorie diet and a 2,500 calorie diet. For the 2,000 caloric level the DRV's are: 65 g fat, 20 g saturated fat, 300 mg cholesterol, 2,400 mg sodium, 300 g total carbohydrate and 25 g fiber. For a 2,500 caloric level the DRV's are: 80 g fat, 25 g saturated fat, 300 mg cholesterol, 2,400 mg sodium, 375 g total carbohydrate and 30 g fiber.

VI. Serving Sizes

To make nutrition information on food labels meaningful, the NLEA requires FDA to establish standards to ensure that nutrition labeling provides the serving size which is an amount customarily consumed and is expressed in a common household measure appropriate to the food. NAS recommended that FDA and FSIS jointly establish sizes for limited, broad categories of foods to help consumers

make product comparisons. NAS suggested basing them on standard serving sizes as specified by dietary guidance recommendations to make their use in educational programs less difficult and to permit consistency among serving sizes shown in dietary guidance material and on the food label. NAS also advocated a petition process for desired deviations from the serving size set by FDA and FSIS or for creation of different food subcategories with new serving sizes.

In its November 1991 proposal, FSIS proposed the following regulations specific to serving sizes:

(1) Creating Reference Amounts for serving sizes for 23 food Product Categories;

(2) Establishing guidelines for converting Reference Amounts to serving sizes;

(3) Defining serving sizes for meal-type products and food products in pieces or units;

(4) Requiring presentation of nutrition information based on serving size "as packaged" for the mandatory labeling program and allow nutrition information for single-ingredient, raw meat and poultry products to be declared "as packaged" or "as consumed" under a voluntary nutrition labeling program;

(5) Requiring the use of both common household and metric measures to declare serving size;

(6) Defining serving size and single-serving container;

(7) Establishing guidelines for declaring the number of servings per container;

(8) Requiring the use of serving size and Reference Amounts to evaluate nutrition claims; and

(9) Allowing for labeling applications for changes in Product Categories and Reference Amounts.

1. *Reference Amounts for serving sizes for 23 food Product Categories.* a. Product Category. Through the work of the Interagency Committee on Serving Sizes, FSIS proposed to establish 23 food Product Categories for meat products, and 22 food Product Categories for poultry products regulated by FSIS. These Product Categories would provide consumers with a uniform food labeling system that categorizes similar foods by the same reference standard. Each Product Category has an accompanying Reference Amount which is based on food consumption data. These Reference Amounts are to be used by food companies as the basis for determining the serving sizes for nutrition labeling of their products.

Opposition to this approach came from manufacturers who contend that all products should have a 1-ounce or 100-gram standard Reference Amount. Although FSIS discussed this option in the proposed rule, it was not the option proposed because:

(a) The NLEA requires that the serving size be based on the "customarily consumed amount";

(b) Consumers may not realize that multiplication is necessary to arrive at the consumed amounts; and

(c) FSIS seeks harmonization with FDA to allow ready product comparisons.

There was strong support from a variety of industry representatives, industry associations, cattle associations, consumer advocacy groups, and individuals in favor of retaining the proposed approach to serving sizes. These commenters believe that a single, uniform set of nutrition labeling regulations for all foods will be in the consumers' best interest, easiest to understand, and prevent consumer confusion.

b. Three-ounce serving size. Several consumer advocacy groups contended that a 3-ounce serving size for single-ingredient, raw meat and poultry products is too small and the data used to determine the serving size were seriously flawed. They believed that the serving size should be determined using only 1977–78 Nationwide Food Consumption Survey (NFCS) data.

FSIS has decided to retain the 3-ounce serving size for single-ingredient, raw meat and poultry products. This is supported by many commenters who believe it is appropriate from an educational standpoint, and it is based on realistic data on food consumption. Food consumption survey data, such as NFCS, provide objective estimates of amounts of food customarily consumed. The NFCS is nationally representative of the most comprehensive data on food consumption practices of the U.S. population that are available to the Agency. Additionally, the 3-ounce serving size for fresh meat and poultry products is supported by dietary recommendations and the work of the Interagency Committee on Serving Sizes.

c. Weight-loss products. Many producers of weight-loss products, which are part of a weight loss program, have asked to be allowed to develop their own serving sizes based on their program. FSIS believes that the serving sizes for all foods available to the retail consumer should be based on the Reference Amount, including those intended for weight-control or weight-reduction. However, the Agency believes that it is in the best interest of participants of a weight-control program, which provides product only through the program, to have labeling which is consistent with the program meal plan. Therefore, the Agency will allow these programs to have serving sizes based on their meal plan. To avoid any confusion with retail products, manufacturers of product that will be used only through weight-control programs will be required to label their products "for sale only through the _____ program." The blank will be filled in with the appropriate weight control program (e. g., Smith's Weight Control).

d. Specific changes to Reference Amounts and Product Categories. Many manufacturers and industry representatives expressed confusion concerning which Reference Amount would apply to their product. Also, commenters had questions about the examples used for specific product categories. Manufacturers will decide the intended use of their product(s), which in turn will determine the appropriate Product Category and Reference Amount (e. g., ham that is intended for use in sandwiches would fit under the Product Category "Luncheon Meats" with a Reference Amount of 55 grams). Examples listed under Product Category are not all inclusive or exclusive, and are provided to assist manufacturers in identifying the appropriate Product Category for their products. FSIS believes this clarification will alleviate most concerns along with a few changes made to Product Category examples in this final rule.

Other comments focused on the lack of a specific Product Category and Reference Amount or a change in the proposed Reference Amount. Comments were received requesting a change in the Reference Amount but were not accompanied by food consumption data. Therefore, no change is being made to the Reference Amount. Comments asking for Product Category changes for specific markets or foods for specific eating occasions will not be granted at this time (e.g., toddler finger foods and breakfast burritos). Labeling applications requesting Product Category or Reference Amount changes will be accepted after the final regulation is published.

Several comments requested a range rather than a fixed Reference Amount. FSIS encourages manufacturers to use the optional second column of nutrition values based on either 100 grams, 100 milliliters, or 1 ounce.

Comments requested different Reference Amounts for products which

are sold at retail and food service products which are served at restaurants, schools, and other such facilities. FSIS believes consumers would be confused by two different Reference Amounts for the same product regardless of where it is sold.

Some comments requested Reference Amount changes based on the mode of the NFCS data. These requests are being denied because all Reference Amounts were calculated based on the mean and the median "consumed serving size" (CSS). The mode of the CSS was determined not to be useful as the sole criterion for determining the Reference Amount because most food groups had two or more modes, and there usually was no obvious or rational basis to choose one over the other. However, the mode did provide additional guidance in determining the Reference Amount. Therefore, FSIS used all three values (i.e., the mean, median, and the mode) in determining the amount customarily consumed.

e. Volume vs. weight. Some commenters stated that all Reference Amounts should be expressed in grams. Some of the specific Product Categories originally expressed in volume-based Reference Amounts have been changed to weight-based Reference Amounts. However, the Agency does not agree that it is appropriate or desirable to do so for all Product Categories, including some of those specifically mentioned in comments. As explained above, when products within a Product Category differ widely in density, the use of a fixed gram Reference Amount would result in a serving size that is too large for some products in the category and too small for others, even though the volume amounts consumed are similar for all products within the category. For example, although the Reference Amount for "mixed dishes measurable with a cup" is 1 cup, the gram-weights of different types of products within the category differ widely (e.g., about 180 grams for chili with beans and about 225 grams for beef stew). Thus, in this final rule, FSIS uses weight-based Reference Amounts in most cases but is retaining volume-based Reference Amounts for a limited number of categories with products that vary greatly in density (e. g., mixed dishes measurable with a cup).

f. Foods that are Packed or Canned in Liquid. Foods such as canned meats may be packed in water, brine, or oil, but food consumption data have shown that the liquid is not customarily consumed. FDA received comments requesting that foods packed or canned in liquid bear nutrition labeling based on the drained solids. FSIS agrees with the commenters that the label serving size most meaningful for these products would be the serving size based on drained solids. Therefore, FSIS will require that the declaration of nutrient and food components for foods that are packed or canned in water, brine, or oil be based on the drained solids.

g. Labeling applications. FSIS shall allow labeling applications to be submitted to amend the Reference Amount and/or Product Category through the rulemaking process. Any such labeling applications for changes to the Reference Amount and/or Product Category for meat and poultry products would be submitted to the Director, Food Labeling Division, FSIS, with specific information supporting such use. The supporting information includes statements that (1) identify the Reference Amount and/or Product Category; (2) explain why the Reference Amount and/or Product Category is not false or misleading; and (3) describe the product and the form the product will be used in. Such labeling application is required to be signed by the applicant or by the applicant's responsible officer or agent.

Upon receipt and review of the labeling application and supporting documentation, FSIS will notify the applicant, in writing, that the labeling application is either being considered for further review or that the labeling application has been denied by the Administrator. If the Administrator summarily denies the labeling application, he or she would notify the applicant, in writing, as to the reason(s) for the denial, including why the proposed Reference Amount and/or Product Category was determined by FSIS to be false or misleading, and would afford the applicant an opportunity to submit a written statement by way of answer to the notification, and a right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category. If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator would file with the Hearing Clerk of the Department the notification, answer, and the request for hearing, which would constitute the complaint and answer in the proceeding, which would thereafter be conducted in accordance with the Department's Uniform Rules of Practice. The hearing would be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who is delegated the authority to make the final determination for the Secretary. Any such determination by the Secretary will be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

If the Administrator does not summarily deny the labeling application, he or she would publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal would also summarize the labeling application, including where the supporting documentation could be reviewed. The Administrator's proposed rule would seek comments from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator will make a determination on whether the proposed Reference Amount and/or Product Category will be approved for use on the labeling. If the Reference Amount and/or Product Category is denied, the Agency would notify the applicant by letter of the basis for the denial, including the reason why the Reference Amount and/or Product Category was determined by the Administrator to be false or misleading. The applicant would have an opportunity to appeal this decision by instituting a proceeding which would be conducted under the same procedures specified above if a labeling application were summarily denied by the Administrator during the initial review. If the Reference Amount and/or Product Category is approved by the Administrator, the Agency would notify the applicant by letter and would also publish in the **Federal Register** a final rule regarding the approval of the Reference Amount and/or Product Category. The final rule would amend the regulations to authorize the use of the Reference Amount and/or Product Category in the labeling of meat and poultry products.

2. *Procedures for converting Reference Amounts to serving sizes.* As part of the Interagency Committee on Serving Sizes, FSIS fully participated in establishing the criteria for converting the Reference Amounts to serving sizes in common household measures. These procedures will help to assure

uniformity in the declared serving size within a Product Category and allow flexibility in the serving size to account for differing characteristics of diverse food products. The following are guidelines for converting Reference Amounts to Serving Sizes for: (a) Products in discrete individual units, (b) products in large discrete units that are usually divided for consumption, and (c) non-discrete bulk products.

a. Products in discrete individual units. FSIS proposed that serving sizes for products in discrete units be the number of units that most closely approximates the Reference Amount applicable to the product. Under this provision, if a unit weighs 67 percent or more, but less than 200 percent of the Reference Amount, serving size shall be one unit. If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion.

Several commenters opposed the lower limit of the proposal because a single-serve unit of many products in discrete units fall in the 50–67 percent range and one unit is customarily consumed. FSIS has decided to change the lower limit to >50 percent of the Recommended Amount Customarily Consumed (RACC). Products which are exactly 50 percent of the RACC will not be included because 50 percent is exactly half of the RACC. Therefore, two units of a product weighing 50 percent of the RACC per unit is exactly one serving.

Commenters also recommended that FSIS allow voluntary listing of nutrient contents per unit for products that come in discrete units (e.g., chicken nugget, chicken wing, cocktail frank), when the declared serving size of a multi-serving package is more than one unit. FSIS believes this would be beneficial for consumers, because many products in discrete units come in small units and consumers who consume one single unit would benefit from per-unit labeling.

b. Products in large discrete units that are usually divided for consumption. The proposal would require that the serving size for products in large discrete units (e.g., pizza) be the fractional slice of the food that most closely approximates the RACC. Commenters pointed out that the serving size may be ⅐ of the product. However, the product cannot be easily cut into 7 even slices; it can only be cut into fractions of multiples of 2 or 3. Therefore, FSIS will allow manufacturers to use ½, ⅓, ¼, ⅛, ⅙, or higher fractions of multiples of 2 or 3. This does not include ½₈ because it involves a division by 7.

3. *Serving sizes for meal-type products.* In the proposed rule, FSIS defined meal-type products as any product that is intended for consumption by one person. There was strong support from commenters for nutrition labeling of meal-type products in their entirety. Because meal-type products are typically consumed by one person and make up the major portion of a meal, it is more meaningful to provide consumers with nutrition information on these products in terms of the entire product. A consumer will have nutrition information on exactly what he or she purchases and typically consumes. Therefore, the consumer will be able to evaluate how the product fits into his or her total diet.

FSIS will require nutrition labeling for meal-type products, based on the contents of the entire package. Meal-type products must also meet the definition of a single serving container. FSIS addresses the definitions of meal-type products elsewhere in this final rule with a provision for the use of nutrient content claims with meal-type products.

4. *Nutrition information based on serving size "as packaged" vs. "as consumed".* To maintain consistency with FDA's mandatory and voluntary nutrition labeling scheme, FSIS proposed to require nutrient values "as packaged" for products under the mandatory program with an option of also presenting "as consumed" values. Products under the voluntary program may list nutrient values on an "as consumed" or an "as packaged" basis. The preparation method used for the "as consumed" values must be clearly indicated on the package.

The Agency proposed that the RACC for products which require further preparation before consumption be the amount required to make one RACC of the prepared form. Commenters stated that they are unable to identify raw product serving sizes to produce the cooked RACC.

Therefore, FSIS has developed yields for Product Categories which contain products that require further preparation (e.g., bacon, raw meat and poultry cuts). These yields are based on yields used in the Nationwide Food Consumption Surveys (NFCS) and USDA Handbook #8. These yields will appear as an additional column in the RACC tables found in §§ 317.312(b) and 381.412(b). These yields will only be used for the determination of Reference Amounts.

Some commenters opposed the labeling of fresh or raw, ready-to-cook food products on an "as packaged" basis. They believe the labeling on an "as consumed" basis would allow consumers to directly compare ready-to-cook and ready-to-serve or heat-and-serve products. However, this would only be the case if the consumer prepared the fresh or raw, ready-to-cook product exactly as the manufacturer stated on the label. There are varieties of cooking methods that affect the nutrient values of food products differently. Therefore, there is no method to assure the accuracy or measure compliance of the nutrient values of a food labeled on an "as consumed" basis.

Several commenters stated that special case products (e.g., bacon, breakfast sausage, and raw marinated meat or poultry products) undergo extreme composition changes prior to consumption. If labeled "as packaged", these products would provide the consumer with essentially useless information. FSIS strongly encourages manufacturers who believe the consumer would benefit from "as consumed" nutrition values to voluntarily provide this information. Manufacturers of special case products who believe their products should be labeled on an "as consumed" basis and not "as packaged" should submit a labeling application to the Agency.

FSIS believes that the addition of another column to the Reference Amount table based on NFCS yields and USDA Handbook #8 will provide the additional information needed by manufacturers to determine Reference Amounts for their products. Also, FSIS believes that "as consumed" nutrient values must be accompanied by preparation and cooking instructions. To retain harmonization of labeling between the FSIS and FDA, FSIS will require "as packaged" nutrient values for products covered under the mandatory program. "As consumed" nutrient values may voluntarily be added, provided that preparation and cooking instructions are clearly stated. Products covered by the voluntary program may list nutrient values either on an "as packaged" or "as consumed" basis.

5. *Units of measure for declaring the serving size.* FSIS proposed to require the use of common household and metric measures to declare serving sizes. In addition, FSIS proposed that serving sizes may be declared in ounces and fluid ounces (U.S. measure), in parenthesis, following the metric measure where other common household measures are used as the primary unit for serving size (e.g., 1 cup (28 g) (1 oz)). FSIS also proposed rules

for expressing serving size in common household measures. These rules are intended to ensure as much uniformity as possible in label serving sizes within a Product Category. The rules are as follows:

a. Whenever possible, cups, tablespoons or teaspoons should be used. Cups should be expressed in ¼ cup increments; tablespoons in whole numbers for quantities less than ¼ cup but equal to or greater than 1 tablespoon; teaspoons in whole numbers for quantities less than 1 tablespoon but equal to or greater than 1 teaspoon; and in ¼ teaspoon increments for quantities less than 1 teaspoon.

b. If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction of the whole piece or package should be used. These units are the common household measures that are most appropriate for food products not measurable by a cup, tablespoon, or teaspoon.

c. If neither of the above is applicable, ounces may be used. Ounce measurements should be expressed in 0.5 ounce increments most closely approximating the Reference Amount.

Several commenters stated that they believe that some foods would be more precisely measured in ⅓ cup increments and would like this option added to the final rule. FSIS believes this is an acceptable change.

Parenthetical metric measure is required and has been standardized; therefore, uniformity in the common household measure is not as critical. In addition, allowing ⅓ cup increments is likely to reduce potential manipulation of the label serving size for measurements that fall between ¼ and ½ cup (e.g., ¼, ⅓, ½, ⅔, ¾, and 1).

Several commenters stated that when declaring serving size, the U.S. measure should be mandatory, in addition to, or instead of the metric measure. Other commenters objected to voluntary declaration of the U.S. measure in addition to the common household measure, arguing that it was unnecessary, would crowd the label, and would be confusing to consumers. Because the comments indicated such varied views on the listing of the U.S. measure, FSIS has decided to make the listing of the equivalent U.S. measure after the metric measure voluntary.

Several comments opposed requiring the rounding of the ounce unit of measure to the nearest 0.5 ounce. They expressed that the ounce measurement should be rounded to the nearest 0.1 ounce increment. Listing ounce measure in 0.5 ounce increment would result in a large discrepancy between metric measure. Since listing gram quantities will be mandatory, commenters believe that more exact declaration of ounce measures should be used.

FSIS will require 0.5 ounce increments to be used when the primary serving size (household measure) is expressed in ounces [e.g., beef fillet 3 oz. (85 g)], to be meaningful to consumers. This does not apply to the voluntary ounce serving size (U.S. measure) declarations [e.g., chicken wing, 2 wings (80 g) (about 2.8 ounces)]. The ounce measure in this case can be a decimal quantity rounded to 0.1 increments. FSIS believes that the more exact ounce measures are justified because they will reduce the error in gram-to-ounce conversions and reduce consumer confusion.

Commenters opposed the requirement that products whose common household measure is an ounce must also bear an appropriate visual representation of the serving size. They contended that the ounce is a unit of measure that is well understood by the public and that the visual representation requirement will only serve to confuse the consumer; therefore, no artificial comparisons need be made. FSIS believes that a visual representation requirement is unnecessary and may be confusing to consumers. Therefore, FSIS will no longer require a visual representation of serving size for products whose common household measurement is in ounces.

Commenters expressed concern that the use of several parentheses within the serving size statement (e.g., 2 slices (28 g) (1 oz)) would make the statement more difficult to understand. The commenters recommended that FSIS allow flexibility to use commas and slashes. FSIS believes that allowing such flexibility would result in non-uniformity in the declaration of label serving sizes. For example, the serving size for sliced luncheon meat could be expressed five different ways: 2 slices (28 g) (1 oz) by brand A; 2 slices (28 g, 1 oz) by brand B; 2 slices (28 g / 1 oz) by brand C; 2 slices, 28 g, 1 oz by brand D; and 2 slices 28 g / 1 oz by brand F. The use of various formats for this declaration would be confusing.

After examining all possible combinations of the formats for the declaration of label serving size, FSIS finds that the most desirable format is to require the presentation of all serving size information other than the mandatory common household measure, in one set of parenthesis with the different serving size statements separated by a slash (i.e., 2 slices (28 g / 1 oz)).

FSIS also proposed to allow an additional column of figures to be declared on the nutrition label based on 100 grams, 100 milliliters, or 1 ounce of the food as packaged or purchased. Commenters were opposed to limiting the optional second column to 100 grams or 100 milliliters. Manufacturers believe they should be able to determine the unit of measure used in the optional second column. They believe that they are in the best position to determine which unit will best serve their consumers.

The purpose of the optional second column is to provide consumers with another means of comparing products. The advantage would be lost if each manufacturer listed its own unit of measure on the label. Therefore, FSIS will limit the optional second column to 100 grams, 100 milliliters, or 1 ounce.

6. *Definition of serving size and single-serving container.* The FSIS proposed definition for a serving or serving size was "an amount of food customarily consumed per eating occasion by persons 4 years of age or older, which is expressed in a common household measure that is appropriate to the food." If the article were represented to be for infants or for toddlers, the proposed definition of a serving or serving size was "an amount of food customarily consumed per eating occasion by infants through 12 months of age or by children 1 through 3 years of age."

FSIS proposed to define a single-serving container as a container or package containing less than 200 percent of the Reference Amount. The nutrition profile on the single-serving container will be declared on the total content of the container. Some comments stated that the upper limit on single-serving containers should be rolled back to 150 percent of the RACC because the 200 percent cut off level is too high for some products (e.g., entrees, mixed dishes not measurable with a cup, salads, soups). Other comments suggested allowing the manufacturer to decide the single-serving status of a package that contains between 150 percent and 200 percent of the RACC.

FSIS has found that products whose Reference Amounts are 100 grams or larger are less likely to be consumed at a level twice that of the Reference Amount. Therefore, FSIS will allow manufacturers to determine whether there are 1 or 2 servings in packages that contain more than 150 percent, but less than 200 percent of the Reference Amount, if the food in the package has a Reference Amount of 100 grams (or milliliters) or larger, and if the entire content of the package can reasonably

be consumed at a single-eating occasion. The determination should be based on food consumption data under actual conditions of use. Manufacturers should be prepared to provide FSIS with the data that supports the single-serving claim upon request. The Agency is aware that this allowance has a potential for misuse and products that are obviously intended to be consumed in one serving must be labeled as such or they would be considered misleading. The Agency intends to consider regulatory action for misuse of this allowance on single-serving containers.

An industry comment stated that the parenthetical listing of the equivalent metric weight of the serving size is unnecessary on single-serving containers when the net quantity of contents includes the metric weight and is provided on the principal display panel.

FSIS agrees with this comment. However, for some products the metric quantity for serving size and the metric quantity for net weight may differ. For example, the serving size for products packed or canned in liquid that is customarily consumed (e.g., canned meat or poultry), where the serving size is expressed on the drained weight. Therefore, FSIS believes it is reasonable to exempt single-serving containers from the parenthetical metric measure requirement, if the metric quantity for net weight and serving size are the same.

7. Declaration of number of servings her container. FSIS proposed that the number of servings per package or container be declared to the nearest whole or approximate whole number. Several comments opposed requiring a whole number and requested that the number of servings per container be rounded to the nearest 0.5 servings.

Commenters stated that rounding to the nearest whole serving would significantly distort a container's contents, especially for packages containing between 1.5 and 4.5 servings. Industry commenters agree that many consumers do not like to see a fractional number of servings in the nutrition information. However, they believe, and the Agency agrees, that the basis for this dislike is from the use of decimal fractions (e.g., 2.7 servings) and a decimal fraction number of servings on containers that are obviously single-serving containers. Commenters believe that rounding to the nearest 0.5 servings will be understood by all consumers.

FSIS believes that this is an acceptable change. FSIS does not believe that a half serving is necessary or meaningful for large containers (e.g., 8.5 servings) or is desirable on small packages containing less than 200 percent of the Reference Amount. Therefore, manufacturers will be allowed to round to the nearest 0.5 serving for packages containing between 2 and 5 servings. Products containing less than 200 percent of the Reference Amount must follow the rules for single-serving containers. Products containing 5 servings or more per container will be rounded to the nearest whole serving.

Additionally, the proposed rule provided two options for declaring number of servings per container: (a) Declare serving size as the approximate whole household measure that results in a whole number of servings in the container (e.g., serving size: approximately ½ cup; number of servings per container: (10) or (b) declare serving size in exact household measure and approximate the number of servings per container (e.g., serving size: ½ cup; number of servings per container: approximately 10) (see 21 CFR 101.9(b) (8) (i) and (ii)).

Several comments opposed the two options in the proposal. They recommended that manufacturers list the exact serving size and approximate number of servings per container. They believe it is more important for the consumer to know the exact serving size, which is the basis for the nutrition information.

FSIS recognizes that allowing the two options as proposed would result in nonuniformity, and would make nutrition comparisons of different brands of the same food difficult. Therefore, FSIS will require the exact serving size and the approximate number of servings.

The proposed rule made an exception for random weight products from the requirement for number of servings per container. For random weight products such as kielbasa, manufacturers would have problems in declaring the number of servings per package. FSIS proposed to accommodate random weight packages by allowing manufacturers to declare the number of servings per container as "varied", provided the nutrition information was based on the Reference Amount expressed in ounces.

The comments supported the option of listing the servings per container of random weight packages as "varied," but also suggested allowing an optional statement describing the typical number of servings per base weight unit when "varied" is used to declare the number of servings per container (e.g., varied (approximately 8 servings per pound)). FSIS believes this is a reasonable option that will provide further clarification for consumers.

VII. Nutrient Content Claims

To alleviate widespread public confusion associated with descriptors, the NLEA contains requirements regarding nutrient content claims. It precludes, except for specified limited exceptions, the use of any nutrient content term that characterizes the level of any nutrient that has not been defined by FDA by regulation, and requires FDA to define "free," "low," "light" or "lite," "reduced," "less," and "high." The NLEA places limitations on cholesterol, saturated fat, and dietary fiber claims for a food by requiring these claims to be accompanied by prominent disclosure of the food's level of fat or saturated fat, cholesterol, and total fat, respectively, on the label. The NLEA does not address the use of cholesterol claims based on threshold criteria for fat or saturated fat content.

The Food Labeling Division of FSIS has issued several policy memoranda in connection with its label approval system, outlining quantitative criteria for permitting the use of selected descriptors such as "low calorie," "low sodium," "low fat," and "lean." (Copies of these policy memoranda are available for public review in the FSIS Hearing Clerk's office.) For many years, the Agency's definition for "lean", except as applied to ground beef, hamburger, and products containing added substances, such as water or extenders, has been no more than 10 percent fat content. The memoranda currently require at least a 25 percent reduction from specific reference points for comparative expressions such as "lower." FSIS also uses informal working policies for nutrient content claims for some food constituents, such as cholesterol in meals and fiber. FSIS has no current regulatory definitions for any nutrient content claims.

FSIS proposed the adoption of most of FDA's proposals, published in the Federal Register simultaneously with FSIS's proposed rule, for 21 CFR 101.13, Nutrient Content Claims—General Principles; 21 CFR 101.54, Nutrient Content Claims for "Source" and "High"; 21 CFR 101.56, Nutrient Content Claims for "Light" or "Lite"; 21 CFR 101.60, Nutrient Content Claims for the Calorie Content; 21 CFR 101.62, Nutrient Content Claims for the Fat, Fatty Acids, and Cholesterol Content of Foods; and 21 CFR 101.69, Petitions for Nutrient Content Claims. In addition, FSIS proposed definitions for the terms "lean" and "extra lean" as unique descriptors for meat and poultry products. In the above documents, FDA

set forth proposals required by the NLEA. The FSIS proposals were an effort to harmonize food labeling regulations with FDA's and were in response to the comments received from FSIS's ANPR on nutrition labeling.

FSIS's proposal specifically included a discussion on the use of descriptive terms in brand names, since many products regulated by FSIS contain descriptive terms in the brand name ("brand name" is a generic term used to define a fanciful name, trademark, etc.). The proposal provided for the use of a descriptive term in a brand name, provided the product met the prescribed definition for the term. The proposal stated that nutrient content claims not defined by regulation that appeared as part of a brand name, could be used if they were not false or misleading, and only if the brand name was in use prior to November 27, 1991, the date of the proposal. A list of brand names that included descriptive terms was compiled from labels on file with the Food Labeling Division, and included to provide specific examples of some of the products that may be affected by the proposals.

FSIS proposed definitions for "lean" and "extra lean" based on fat, saturated fatty acids, and cholesterol thresholds suggested by the American Heart Association (AHA) in response to the ANPR. FSIS found merit in AHA's suggested values, and proposed the quantitative values per 100 grams of product by extrapolating the 1 ounce values AHA suggested, yielding the following values:

TABLE 4

	Fat	Saturated fatty acids	Cholesterol
Lean	<10.5 g	<3.5 g	<94.5 mg
Extra Lean	<4.9 g	<1.8 g	<94.5 mg

These values for the fat content of 10.5 and 4.9 grams approximated the Agency's current definitions for the terms "lean" and "extra lean."

FSIS proposed the values for "lean" and "extra lean" as descriptors for use in all meat and poultry products. Accordingly, the terms could be used on multi-ingredient, meal-type products as well as muscle cuts of meat, ground beef, and hamburger. Currently, FSIS extends special exception to ground beef and hamburger for the purposes of "lean" and "extra lean" labeling. "Lean" and "extra lean" ground beef and hamburger can contain up to 22.5 percent fat, a 25 percent reduction from the regulatory standard of 30 percent fat for these products.

Specifically mentioned in the proposal were the "_____ percent fat free" claims. FDA proposed to prohibit the claim in those circumstances in which it would be misleading. The FDA criteria was for the product to meet the definition for "low fat" and for the label or labeling to disclose the amount of total fat per serving of the product. The Agency reviewed FDA's proposal on this issue and fully agreed with FDA, and therefore proposed the same criteria for meat and poultry products.

There was overwhelming support in response to the proposal for FSIS to proceed with the adoption of FDA defined nutrient content claims (the term "nutrient content claim" is replacing "descriptor" for consistency with FDA). The majority of parties commenting on the FSIS proposal have primary interest in the products regulated by the Agency. Therefore, the majority of comments relating to nutrient content claims focused directly on the areas of the proposal that were unique to FSIS, namely the terms "lean" and "extra lean."

Trade associations, industry, and consumer groups supported the Agency's proposal to provide the unique descriptors "lean" and "extra lean." Several trade associations and manufacturers disputed the total fat and saturated fatty acids numbers as extrapolated to 100 grams, arguing that inherent to ruminant muscle, the saturated fatty acids to fat ratio is 40 percent.

Trade associations and manufacturers believe that the AHA values presented per 3 ounces cooked represented attainable values for meat. Many commenters suggested that including a saturated fatty acid criterion in the definition of "lean" and "extra lean" was too restrictive.

Trade associations believe that AHA, in its original presentation of "lean" and "extra lean" to the industries it represents, did not intend to discriminate against the inherent saturated fatty acid content of ruminant muscle.

TABLE 5 is a review of AHA's quantitative values, showing the saturated fatty acids to fat ratio:

TABLE 5

	Fat	Saturated fatty acids	Ratio (%)
Lean:			
1 oz. cooked.	<3 g	<1 g	33.3
3 oz. cooked.	<8 g	<3 g	37.5
Extra Lean:			
1 oz. cooked.	<1.4 g	<0.5 g	35.7
3 oz. cooked.	<4.3 g	<1.4 g	32.5

In response to the ANPR, AHA provided tables of meat and poultry that would be included in its proposed definitions of "lean" and "extra lean." As a parameter for determining the meat and poultry products that would meet the definitions, AHA factored a rounding margin of 0.4 grams for the 3 ounce cooked values (i.e., 8.4 could be rounded to 8.0 grams). Table 6 represents the ratios of the saturated fatty acids to fat for the 3 ounce values factoring in the rounding margins used by AHA:

TABLE 6

	Fat	Saturated fatty acids	Ratio (%)
Lean:			
3 oz. cooked.	<8.4 g	<3.4 g	40.5
Extra Lean:			
3 oz. cooked.	<4.4 g	<1.4 g	31.8

Many trade associations and industry comments suggested that the 3 ounce cooked numbers, when rounded to the according values in TABLE 5, would further provide an appropriate ratio of saturated fatty acids to total fat that meat could achieve. FSIS's proposal did not specify the rounding for the fat, saturated fat, and cholesterol values. Numerous commenters requested that FSIS clarify the rounding that would apply to the proposed values, and asked that the values be rounded to the whole gram.

The Agency's intention was to provide the unique nutrient content claims "lean" and "extra lean" specifically for use on meat and poultry products. As a result of the Agency's use of the 1 ounce cooked numbers to extrapolate to 100 grams, the "lean" and "extra lean" definition contained a saturated fatty acids to total fat ratio of 33.3 percent and 36.7 percent, respectively. As discussed earlier, some meat and poultry products will not utilize many of the descriptive terms included in FDA's nutrient content claims regulations. The Agency's resolve is to furnish meat and poultry products with equitable descriptive terms through the use of the terms "lean" and "extra lean." In light of the overwhelming comments indicating that adherence to the saturated fat to total fat

ratios are impossible for meat, FSIS is withdrawing the qualitative values proposed.

FSIS believes, and is supported by commenters, that the AHA 3 ounce cooked values have merit. The Agency also believes that "lean" and "extra lean" definitions that recognize and allow for the inherent saturated fatty acid content of meat can easily include a saturated fatty acid criterion in the definition.

The Agency further believes that defining the terms "lean" and "extra lean" with fat, saturated fatty acids, and cholesterol values per 3 ounces is difficult to apply to any definition. FSIS proposed the "lean" and "extra lean" values solely per 100 grams. It was the Agency's intent to propose a dual criteria, per 100 grams and per labeled serving.

To maintain as much consistency with the criteria for nutrient content claims as possible, the Agency is modifying in the definitions of "lean" and "extra lean," the dual criteria of per RACC and 100 grams for individual foods and per 100 grams and per labeled serving size for meal-type products. The Agency is retaining the 100 gram requirement for individual foods because the RACC for the same food may vary depending on the use of the food (e.g., ham used as a luncheon meat RACC is 55 grams, ham used as an entree RACC is 85 grams).

The effect this would have on nutrient content claims is the luncheon meat could have approximately ⅓ more of a nutrient (such as fat, saturated fatty acids, cholesterol, or sodium) to qualify for a claim such as "low". The Agency believes this would be false and misleading for consumers.

To facilitate the use of the 3 ounce values for the terms "lean" and "extra lean", the values were converted to a percentage (100 gram) basis. The following values are a result of extrapolating AHA's proposed 3 ounce cooked values to 100 grams (conversion factor 1 ounce=28 grams):

	Fat	Saturated fatty acids	Cholesterol
Lean	9.5 g	3.6 g	95.2 mg
Extra Lean	5.1 g	1.6 g	95.2 mg

The Agency took these numbers and rounded them to the nearest whole number:

	Fat	Saturated fatty acids	Cholesterol
Lean	10 g	4 g	95 mg
Extra Lean	5 g	2 g	95 mg

The ratio of saturated fatty acids to fat is 40 percent for both "lean" and "extra lean". The numerical rounding for these numbers will be the rounding proposed for the fat, saturated fatty acids, and cholesterol on the nutrition label after compliance considerations are taken into account. Fat and saturated fat will be rounded to the nearest 0.5 gram (i.e., 10.24 grams is rounded to 10 grams) and cholesterol to the nearest 5 milligrams.

The Agency's proposal to apply the "lean" and "extra lean" definitions to all meat and poultry products, including ground beef and hamburger, received divided comments. Many commenters supported the use of the terms to describe processed meat and poultry products while some commenters did not. Many ground beef and hamburger manufacturers urged the Agency to reconsider the exemption for ground beef and hamburger.

The criterion for some of the nutrient content claims defined by FDA will not allow many meat and poultry products to qualify for their use. The Agency is offering "lean" and "extra lean" as alternatives for meat and poultry products, including meal-type products, injected products, pumped products, and breaded and battered products. Offering these terms to muscle products exclusively would bring disparity to meat and poultry products. FSIS believes that a meat and poultry product meeting the definition for "lean" or "extra lean" should be permitted to label that product as such, regardless of whether the product has added ingredients or is a muscle meat. Carrying that belief further, the Agency believes that applying these definitions across all product categories would best benefit the consumer and aid in nutrition education. By granting ground beef and hamburger an exemption, there would be a dual criteria pertaining to these definitions. The Agency believes it cannot permit this confusion in the marketplace nor in the education of consumers. Therefore, the definitions of "lean" and "extra lean" will be applied categorically across all meat and poultry products.

Commenters also recommended the term "_____ percent lean" to be allowed on the labeling of muscle meats which contain 20 percent or less fat, especially as an alternative for ground beef and hamburger. The agency has given this recommendation careful consideration and believes that, in light of the "_____ percent fat free" regulation discussed below, "_____ percent lean" would be a viable alternative for meat and poultry. The Agency received comments in support of unified nutrient content claims, and, therefore, will adopt the definition for "_____ percent fat free" claims. The "_____ percent fat free" and "_____ percent lean" claims must meet the definition for "low fat."

Inadvertently omitted in the proposed codified language for "lean" and "extra lean" were the general requirements that accompany all the nutrient content claims. The general requirements provide that the product be labeled in compliance with § 317.309 or § 381.409, and the nutrient content claims comply with the requirement of § 317.313 or § 381.413. The Agency has corrected that oversight in this final rule.

The comments received by FDA, in response to its nutrient content claims proposals, specifically addresses the definitions of terms. Responses to the FSIS proposals that commented on nutrient content claims would, in some instances, include responses written to FDA, along with a brief comment expressing support for harmonization between FSIS and FDA.

In response to the comments it received, FDA has made modifications to its proposals. Since FSIS is adopting most of the FDA nutrient content claims proposals, the two Agencies have been working closely on the resolution of key issues raised by comments, and the modifications to the proposals. A brief discussion of six key issues related to nutrient content claims follows:

1. *Nutrient density.* FDA proposed for nutrient content claims the criteria of per RACC, per labeled serving size, and per 100 grams of food for individual foods. Commenters expressed concerns that the 100 gram criterion would inappropriately prohibit "low" claims on many foods, and that the 100 gram criterion, in addition with the RACC criterion, was excessive.

Weight based criterion was proposed to prevent "low" claims on certain foods that are dense in a nutrient on a weight basis yet still qualify for a low claim because of their small serving size.

This final regulation will be modified by applying a weight-based criterion for "low" claims and "very low sodium" claims only to foods with small serving sizes (i.e., 30 grams or less or 2 tablespoons or less). These foods will be evaluated on a per RACC and 50 gram requirement. All other individual foods will be evaluated on a per RACC basis only.

2. *Comparative claims.* Comments received in response to FDA's proposals suggest that consumers do not differentiate between the terms "less" ("fewer") and "reduced," and, therefore, the terms should be considered synonymous. Commenters also opposed

the minimum (quantitative) reduction requirement, stating that this criterion is overly restrictive, would prevent claims on small serving sizes, and would penalize foods that have already been nutritionally improved.

This final rule has been modified to permit the use of "reduced" and "less" ("fewer") as synonymous terms referring to a reduction of at least 25 percent in a nutrient. In order that reductions not be trivial, claims will be prohibited if the reference food already meets the criteria for "low." Disclosure of the percent reduction and the reference food will be required with a claim.

3. *"Light" or "lite".* Many comments to FDA's proposals contended that certain products would not be able to make a "light" claim under the proposed definition. Comments questioned the feasibility of creating an acceptable product reduced both in calories and fat (fat substitutes often contain a significant number of calories) or, in the case of products with small serving sizes, unable to make sufficient reductions due to the small amount of nutrients in the regular product. The proposed definition was based on the belief that consumers equated the use of the term "light" with calories. To support this belief, FDA cited data contained in (1) FDA's 1982 Health and Diet Survey and (2) Calorie Control Council's January 9, 1990, New Release, "Americans Finding 'light' to Their Liking." The Calorie Council's survey showed that consumers associate the term "light" with calories, as well as with fat. A National Consumers Survey by the Gallop Organization showed that 8 out of 10 consumers of "light" products use these products to reduce fat. Therefore, the "light" definition has been modified to include a fat and calorie reduction requirement. To satisfy the "light" definition, foods with greater than 50 percent calories from fat must reduce fat by 50 percent. Foods with less than 50 percent calories from fat must reduce the fat by 50 percent and the calories by one-third. FSIS and FDA believe that "light" for sodium can be nutrient specific, and has modified this final rule to provide for the use of the term "light in sodium." "Light in sodium" will mean 50 percent reduction in sodium.

4. *Implied claims.* FDA proposed that an "implied" claim was a statement that would lead a consumer to assume: (a) That a nutrient is absent or present in a certain amount, and (b) that a food, because of its nutrient content, is useful in achieving a total daily diet conforming to dietary guidelines (e. g., "healthy"). Healthy was not defined. Therefore, under the proposal, healthy could not be used, except in "grandfathered" brand names.

Health professionals, consumer organizations, States, and a segment of industry suggested that such claims should either be prohibited entirely or be defined. Many industry comments stated that terms such as "healthy," "nutritious," and "wholesome" are not implied claims under the NLEA.

Many comments proposed definitions for the term "healthy", ranging from "low in fat, saturated fat, cholesterol and sodium plus high in at least two key micronutrients," to "not exceeding the levels of fat, saturated fat, cholesterol and sodium that would be inconsistent with dietary guidelines"; e.g., the disclosure/disqualifier levels.

Before the term "healthy" can be defined, FSIS will seek public comment on this issue by publishing a proposed rule with request for comments.

5. *Meal-type products.* FDA's proposal included the definition of meal-type product as a food that: (a) Makes a significant contribution to the diet either by providing at least 200 calories per serving or by weighing at least 6 ounces per serving; (b) contains ingredients from two or more of the four food groups; and (c) is represented as a meal, main dish, entree or pizza. Claims for these meal-type products generally would be based on nutrient levels per 100 grams.

Industry comments generally supported the proposed definition of meal-type products whereas health professional and consumer advocacy groups found it too broad, and the 200 calorie requirement much too low. Some of these groups also found the requirement for a minimum of two ingredients (as opposed to two servings) too liberal, and would not meaningfully distinguish meal-type products from individual foods.

The responses FSIS received to the definition of meal-type products overwhelmingly supported, rather than opposed, the Agency's proposed definition. FSIS believes the majority of meal-type products fall under the Agency's purview, and does not believe the comments received warrant major changes in the definition proposed. Comments received suggest that a 200 calorie level is an insufficient amount of food for a meal-type product, even for those on a reducing diet and that a number of individual foods would meet this minimum caloric level. Increasing the caloric level substantially might exclude a number of meal products appropriate for weight maintenance or weight reduction.

Comments support the weight requirement of 6 ounces. Nielson Scantrack 1990 through 1991 Data, provided to the Agency, show that 78.7 percent of the frozen dinners (6.0 ounces—24.0 ounces) surveyed fall between 6 ounces and 12 ounces.

The Agency is convinced by comments that the 200 calorie requirement is insufficient. The Agency believes a weight requirement is necessary to ensure that products represented as meals contain adequate amounts because of their contribution to the overall diet. Therefore, the Agency is modifying the meals definition to exclude a minimum calorie requirement, but include a minimum and maximum weight requirement of 6 ounces and 12 ounces respectively.

The definition proposed will remain, with criterion (a) modified to: "Makes a significant contribution to the diet by weighing at least 6 ounces, but not more than 12 ounces." Meal-type products weighing more than 12 ounces will be evaluated on a case-by-case basis.

The term "source" for meal-type products was proposed to be used when a product contained 10–19 percent of the RDI or DRV for the nutrient per 100 grams of product. The term "high" was proposed for use on meal-type products that contained equal to or greater than 20 percent of a nutrient per 100 grams. Comments stated that the per 100 gram basis would result in inappropriately high nutrient levels to make products eligible for "high" or "good source" claims. For example, to make a "high in Vitamin C" claim, a 10-ounce dinner would be required to contain over one half of the DRV. Comments also stated that products that contain a smaller percent of the DRV still may be considered excellent nutrient sources. Therefore, the final regulation has been modified to provide for the use of the terms "source" and "high" on meal-type products that contain an individual food that meets the definitions of "source" and "high." For example, the label or labeling claim for a meal-type that contained carrots could state "Carrots are a source of Vitamin A."

6. *Brand to brand comparisons.* As a basis for comparative terms, the FSIS proposal provided as reference foods:

(1) An industrywide norm, i.e., a composite value weighted according to a national market share on a unit or tonnage basis for all the foods of the same type as the food for which the claim is made;

(2) A manufacturer's regular product that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business

entity or by one entitled to use its trade name; or

(3) A food or class of food whose composition is reported in a current valid data base.

Many industry comments objected to only a manufacturer's own brand for use as a reference food. The Agency believes that use of a competitor's products has the potential for unwarranted inferences. Therefore, this final rule does not permit competitors' products as reference foods.

For easy reference, the following two tables contain the nutrient content claims definitions which have been modified from the proposed definitions.

TABLE 7.—NUTRIENT CONTENT CLAIMS FOR FOODS

Nutrient	Free	Low	Reduced/less/fewer	Other
	Synonyms for "Free": "Free of", "No", "Zero", "Without", "Trivial source of", "Negligible source of", "Dietarily insignificant source of".	Synonyms for "Low": "Contains a small amount of", "Low source of", "Low in".	Synonyms for "Reduced/Less/Fewer": "Reduced in", "Lower", "Lower in".	
	Exception: "Sugarless", "Nonfat" .	Exception: "Little sodium", "Few" for calories, "Little fat", "A little saturated fat", "Little cholesterol".	.....	
Calories	<5/RACC	Reference Amount: >30g or >2T: <=40 cal/RACC.	>=25% fewer	
		Reference Amount: <=30g or <=2T: <=40 cal/RACC & /50 grams.	.....	
Sodium	<5mg/RACC	Reference Amount: >30g or >2T: <=140 mg/RACC.	>=25% fewer	"Very Low Sodium", "Very Low in Sodium".
	"Salt Free" may be used if food is "Sodium Free".	Reference Amount: <=30g or <=2T: <=140 mg/RACC & 50 g.	.....	Reference Amount >30g or >2T: <=35 mg/RACC, <=30 g or <=2T: <=35 mg/RACC & 50 g.
Total Fat	<0.5g/RACC	Reference Amount: >30g or >2T: <=3 g/RACC <=30% calories from fat.	>=25% fewer	"____% Fat Free" must meet "low fat" criteria.
				"____% Lean" must meet "low fat" criteria.
Saturated Fat	<0.5 g/RACC & Level of trans fatty acids.	Reference Amount: >30g or >2T: <=1 g/RACC <=15% calories SFA.	>=25% fewer	
	<1% of total fat	Reference Amount: <=30g or <=2T: <=1 g/RACC & /50 g <=15% calories SFA.	.....	
Cholesterol	<2mg/RACC <=2 g SFA/RACC	Reference Amount: >30g or >2T: <= 20 mg/RACC <= 2 g SFA/RACC.	>=25% fewer and <=2 g SFA/RACC.	
		Reference Amount: <=30g or <=2T: <=20 mg/RACC & 50 g <=2 g SFA/RACC.	.....	
Sugar	<0.5 g sugar/RACC	.....	>=25% fewer/RACC	"No added sugar", "Without added sugar", "No sugar added" if no amount of sugar, or ingredient that functionally substitutes for added sugars is added, the product does not contain ingredients containing added sugars, and the food declares (unless it meets definition that) it is not "low calorie" or "reduced calorie"

*RACC=Reference Amount Customarily Consumed.

TABLE 8—NUTRIENT CLAIMS FOR MEALS

Nutrient	Free	Low	Reduced/less/fewer	Other
	Synonyms for "Free": "Free of", "No", "Zero", "Without", "Trivial source of", "Negligible source of", "Dietarily insignificant source of".	Synonyms for "Low": "Contains a small amount of", "Low source of", "Low in".	Synonyms for "Reduced/Less/Fewer":.	
	Exception: "Sugarless", "Nonfat" .	Exception: "Little sodium", "Few" for calories, "Little fat", "A little saturated fat", "Little cholesterol".		
Calories	Not defined	<=120/100g	>=25% fewer/100 grams.	
Sodium	<5mg/Labeled Serving	<=140mg/100g	>=25% fewer/100 grams	"Very Low Sodium" "Very Low in Sodium" <=35 mg/100 gram
	"Salt Free" may be used if food is "Sodium Free".	.....	.....	
Total Fat	<0.5g/Labeled Serving	<=3 g/100g and <30% cal from fat	>=25% fewer/100 grams	"____% Fat free" must meet "low fat" criteria.

TABLE 8—NUTRIENT CLAIMS FOR MEALS—Continued

Nutrient	Free	Low	Reduced/less/fewer	Other
Saturated Fat	<0.5g/Labeled Serving and Level of trans fatty acids. <1% Total Fat	<=1 g/100g <10% calories SFA	>=25% fewer/100 grams.	"____ % Lean" must meet "low fat" criteria.
Cholesterol	<2 mg/Labeled Serving	<20 mg/100 grams	>=25% fewer	
Sugar	<=2g SFA/Labeled Serving ..... <0.5g/Labeled Serving	<=2 g SFA/100g	<=2 g SFA/100g. >=25% fewer/100 grams	"No added sugar", "Without added sugar", "No sugar added" if no amount of sugar, or ingredient that functionally substitutes for added sugars is added, the product does not contain ingredients containing added sugars, and the food declares (unless it meets definition that) it is not "low calorie" or "reduced".

7. *Petitions.* FSIS proposed to provide a petition process, consistent with FDA, to permit the use of nutrient content claims not included in the proposal, synonymous terms that are consistent with a regulatory term, and implied claims made as part of the brand name. The proposed rule would have required the petitions to be supported by detailed information, including:

(1) A description of the term and the nutrient that the term is intended to characterize;

(2) A detailed explanation of why use of the food component characterized by the claim is important to human nutrition;

(3) Analytical data that demonstrate the amount of the nutrient that is the subject of the claim; and

(4) A detailed analysis of the potential effect of the use of the proposed claim on food consumption.

The proposed rule would have required petitions for new nutrient content claims to be processed through rulemaking proceedings. Upon receipt and review of such petitions, FSIS would notify the applicant, in writing, that the petition was either being considered for further review or that the petition had been denied by the Administrator. If the Administrator denied the petition, he or she would notify the applicant, in writing, as to the reason(s) for the denial. If the claim were approved by the Administrator, the Agency would notify the applicant by letter and would also publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the claim in the labeling of meat and poultry products.

FSIS also proposed petition processes for synonymous terms and implied claims that would not require processing through rulemaking proceedings. The petition process proposed for synonymous terms generally followed the same process as the process for new nutrient content claims, except, instead of publishing a proposed rule and seeking comment, the Agency would publish a notice in the **Federal Register** informing the public of the Administrator's decision to grant the approval of the synonymous term.

The petition process proposed for implied claims would have required FSIS, upon receipt and review of such petition, to notify the applicant, in writing, that the petition was either being considered for further review or that the petition had been denied. The Administrator would publish in the **Federal Register** a notice of the petition, announcing its availability to the public and seeking comment on the petition. If the Administrator denied the petition, he or she would notify the applicant, in writing, as to the reason(s) for the denial. If the claim were approved by the Administrator, the Agency would notify the applicant by letter and would also publish a notice in the **Federal Register** informing the public of such fact.

As discussed in FSIS's proposed rule on nutrition labeling, many comments responding to the ANPR on nutrition labeling recommended that FSIS not approve the use of claims on a case-by-case basis under the prior label approval process. Such commenters suggested that such uses be permitted through a petition and rulemaking process that would provide full opportunity for public comment. In response to those comments, FSIS proposed to establish such a petition process.

FSIS received a comment urging FSIS to simplify its request for information in the petitioning process. The commenter contended that such elaborate information would be unduly burdensome to industry and would serve as a disincentive for the development of healthful products.

In reevaluating this proposed process, FSIS determined that a process for approving new claims would best be conducted under the prior label approval system. The requesting establishment will be required to submit only one request to FSIS for approval on the use of a new claim. Rather than petitioning for the use of a certain claim and, after FSIS approval, submitting a labeling application for the use of that same claim, the requesting establishment would be, in effect, "petitioning" the Agency for use of a certain claim through its submittal of a labeling application. Thereafter, other manufacturers desiring to use such claims would simply submit their standard labeling applications to FSIS for approval. Under such a process, label approval for the use of such claims will be provided in a more timely fashion, and preparation and submittal of certain duplicative information would be eliminated. FSIS's petition process is still consistent with FDA's except for the mechanism used by manufacturers to request use of a new claim. FDA requires a "petition" whereas FSIS requires a "labeling application." All other aspects of the process are generally the same. The opportunity for public comment will still be available through the publication in the **Federal Register** of proposed rules or notices on the proposed claims, except synonymous claims, which will satisfy concerns discussed above regarding the need for public participation in the approval of new claims. (Labeling applications for the use of synonymous claims will not be issued for public comment prior to the Administrator's final determination, which is consistent with FDA).

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In responding to the commenter of the proposed rule that the proposed information supporting a claim would be burdensome and discouraging to the industry, FSIS believes that determinations on the use of new nutrient content claims, synonymous claims, or implied claims must be validated by sound, reliable data. To assure the validity of any such claims, they must be supported by sound evidence on the potential effect of the proposed claim on food consumption and any corresponding changes in nutrient intake. The use of any such claims must also be proven to provide nutritional benefits to the public that are not already available through use of existing terms. Even more importantly, it must be demonstrated why the use of the proposed term would not be false or misleading.

FSIS maintains that responsibility for validating the use of a new claim rests with the manufacturer who desires to use the claim. Therefore, this final rule requires a manufacturer to request the use of a new claim by submitting a labeling application and the detailed proposed information which supports such use. Through review of the complete supporting information, FSIS can effectively determine the validity of such a proposed claim and, in the case of new nutrient claims and implied claims, provide the public with sufficient information upon which to base meaningful comment.

VIII. Compliance and Analytical Methods

As part of its prior label approval process, FSIS requires manufacturers to submit analytical data to support nutrient values and content claims on food labels. The Agency processed approximately 180,000 requests for label approvals in 1990, of which many contained nutrition information. FSIS conducts a nutrition labeling verification program to ensure the continued accuracy of label information after initial approval. Under the program, manufacturers periodically submit analytical data on their products for Agency review. FSIS nutrition labeling guidelines for meat and poultry products, which address requirements for initial label approval and continuing accuracy of labels, are contained in Policy Memoranda 85B and 86.

In the preamble to the proposed rule published in November 1991, FSIS maintained that each manufacturer is responsible for insuring the validity of nutrient declarations contained on product labels, and concluded that requirements for submission of laboratory data with requests for initial label approvals and nutrition labeling verification procedures are unnecessary. FSIS would require plant management to maintain records that support nutritional values and establish a partial quality control (PQC) program for nutrients that are subject of nutrient content claims. The Agency proposed to allow the most current representative data base values contained in USDA's National Nutrient Data Bank (NNDB) or its published form, the Agriculture Handbook No. 8 (AH–8) series, to be used for voluntary nutrition labeling of single-ingredient, raw meat and poultry products, without subjecting such labels or labeling to compliance review unless a nutrition claim was made.

On March 25, 1992, FSIS published a supplemental proposed rule in the **Federal Register** (57 FR 10298) to, in part, permit companies to base nutrient information on processed meat and poultry product labels on data bases, and on recipe analysis using data bases, as well as on laboratory analyses. The Agency proposed to adopt 80/120 tolerance levels in determining nutrition labeling compliance for naturally occurring nutrients and use samples consisting of a minimum of six units selected from within or across lots.

Commenters sought clarification about certain aspects of the compliance and analytical methods issues and suggested modification and revision of various provisions. A summary of these comments and the Agency's responses follow.

1. *Label approval and nutrition labeling verification.* All commenters addressing the current label approval requirements supported the termination of requirements relating to the submission of analytical data with initial requests for label approval, submission of periodic data to support the continuing accuracy of the label, and maintenance of FSIS-approved nutrition labeling verification procedures. Major reasons cited were associated burden, cost, and time consumption. Commenters supported Agency testing as the primary enforcement vehicle for the regulations. Trade associations and companies requested that current requirements be eliminated as soon as possible. Questions were raised as to whether a food may be labeled in compliance with the new nutrition labeling regulations, rather than existing policy memoranda, pending the implementation date of the nutrition labeling regulations.

FSIS believes that, in the best public interest, transition to nutrition labeling under the new regulations should begin immediately and that current testing requirements, as described in policy memoranda 85B and 86, be terminated upon publication of this final rule. This approach affords industry time to develop reliable data to meet the new labeling requirements and opportunity to develop or reformulate products to meet newly-defined nutrient content claims. During the 18-month interim period prior to implementation of these regulations, new labels bearing nutrition information that are not yet in compliance with these regulations will be accepted for initial prior label approval without previously required supporting laboratory data. Nutrition label panels will be validated as to conformance either with existing policy or the new regulations during initial approvals.

A number of commenters stated that firms with limited experience in nutrition and health-related labeling might need assistance in preparation and review of labels submitted for initial approval under the new regulations to ensure compliance and that manufacturers should be allowed to request such service. The Agency will provide such guidance in the form of instruction sheets for preparation of the nutrition panel and an FSIS manual on use of data bases. Copies of these materials may be obtained, without charge, from the Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Copies are also available for public review in the FSIS Hearing Clerk's office.

Many industry groups, including large trade associations and small packers, requested FSIS to develop the nutrient data for food products via Agency analysis and to format the nutrition panel at no charge, and/or to pay for the compliance samples taken from within the establishment to alleviate financial impacts on small businesses.

FSIS recognizes the potential economic impact of the regulations on small businesses and industry at large. Accordingly, this final rule provides a small business exemption and permits the use of data bases and recipe analysis using data bases to alleviate costs. In its proposal, the Agency stated it would monitor a minimum of six units for compliance and, in most cases, the number of samples taken would be 12 whenever feasible and not too costly. It further stated that for various products, such as large samples of ham, a composite of six units will be taken for cost and logistical efficiency. FSIS concludes that these multiple cost-saving measures negate commenters' concerns.

Numerous commenters requested clarification as to the content of records supporting the validity of label declarations. FSIS believes that adequate records may consist of results of direct product analyses, data base values and/or recipe calculations, or a combination of direct analyses, data base values, and recipe calculations.

Regarding direct analyses, the Agency will not dictate the number of tests to be performed because the frequency needed for accuracy of label values will vary according to the nature of the product, the nutrient, the sample size, and a host of other product-specific variables. Many different sampling plans can produce equal assurance that label declarations reflect nutrient content. FSIS believes the manufacturer is in the best position to determine the most appropriate plan for its own products. FDA has prepared a comprehensive guide for developing data bases based on direct analyses for food labeling purposes. The guide covers sampling objectives, the target population, and the sampling frame. While a person may follow the manual or choose to use alternate procedures, FSIS believes the manual will be useful to manufacturers in developing nutrition labeling. Copies of the manual entitled "FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases," 1992 edition, may be obtained from the Division of Nutrition, Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, Food and Drug Administration, Washington, DC 20240. Use of data base values and/or recipe calculations to satisfy recordkeeping requirements is discussed under part 2b of this section.

Commenters asked if the Agency planned to require companies to use FSIS-accredited laboratories to generate their nutrient data, which might preclude use of company-generated data. Historically, the Agency has conducted accreditation of laboratories for its own use, as opposed to use by companies. FSIS does not plan to accredit laboratories or conduct an accredited laboratory program for nutrient analysis for food labeling. Companies may use any laboratory of their choice and are responsible for the accuracy of the analytical information.

Trade associations and large companies requested that the regulations make clear that supporting records for multi-plant firms can be maintained at corporate headquarters or a central location, as opposed to individual manufacturing establishments, because manufacturers with multiple production facilities typically generate all labels at a central location. The provisions of 9 CFR 320.2 and 381.176 indicate that, if a person conducts business at multiple locations, records may be maintained at the headquarters' office.

Almost without exception, commenters voiced strong opposition to the requirement that establishments must, as a prerequisite to the use of labels or labeling containing nutrient content claims, seek FSIS approval of a PQC program. While not objecting to the concept or value of such programs to assure product quality, industry representatives argued that PQC requirements: (a) Are redundant under these regulations because FSIS monitoring would be the primary compliance and enforcement vehicle, (b) are unnecessary since well-defined compliance criteria are contained in the rules, (c) imply the Agency places lower enforcement priority on other mandated information, (d) would delay the introduction of new and reformulated products, and (e) might undo the economic benefits gained by eliminating the current nutrition labeling verification procedures. Some suggested that PQC requirements not be mandated for claims but, instead, PQC programs be allowed on a voluntary basis for all nutrition label compliance measures on the condition that Agency compliance monitoring results not be given enforcement precedence over PQC records.

The Agency has carefully considered these comments and concludes that the PQC requirements are contradictory to its regulatory objectives to place responsibility for label accuracy on manufacturers and implement nutrition labeling in the most cost-effective manner possible. FSIS encourages the timely marketing of new and reformulated products of benefit to public health and use of nutrient content claims that will help consumers to select among foods to achieve a healthy diet The Agency is convinced that the compliance criteria contained in the rules, coupled with its approach to inspection, including the presence of inspectors to oversee processing controls and ensure good manufacturing practice in every federally inspected establishment, will provide a high degree of assurance that products meet compliance provisions for nutrient content claims. Accordingly, the proposed provisions requiring approved PQC programs for use of nutrient content claims (9 CFR 317.309(g)(8) and 381.409(g)(8)) have been removed in this final rule.

2. *Use of data bases.* FSIS's proposal to permit the use of data bases and recipe analysis using data bases was supported by most commenters. FSIS continues to believe that the use of data bases, alone or in conjunction with analytical testing, can facilitate cost effective development of accurate nutrient declarations for meat and poultry products, which meet the requirements of these regulations and provide highly useful information to consumers. FSIS concludes that data bases, especially computerized systems, when effectively used, are powerful tools for developing nutrient declarations. Consequently, the final rule will allow nutrient declarations based on data base values, direct analysis, and/or combination approaches. The Agency encourages firms to fully exercise their prerogative to use data bases to construct labels reflecting the average nutrient levels in their products over time.

As previously discussed, the Agency has prepared a manual to provide guidance and practical information to meat and poultry product manufacturers who choose to use data base values or recipe analyses using such values to develop nutrition label declarations for all or selected nutrients in their products. The document will help establishments, especially those with limited experience in nutrition labeling or data base use, evaluate and use systems to insure compliance with USDA's nutrition labeling regulations. FSIS wants to stress that it is not its intent to proceed in a punitive manner against companies when problems surface during compliance monitoring. FSIS will expect the company to locate the source of the discrepancy and rectify any problem by such means as changing the label values and correcting the cause of the problem. If problems surface during Agency compliance sampling FSIS will review company records and work with the company to assure that label values reflect average nutrient levels in the food product. FSIS expects the focus of any compliance inquiry about labels based on data base values to be somewhat different from those based on direct analysis because variation can be introduced from multiple sources.

a. *Single-ingredient products.* Commenters generally supported the Agency's proposal to allow use of representative data base values from USDA's NNDB or the AH–8 series, without being subject to the compliance provisions of the regulations in the absence of claims, on point-of-purchase information and on labels for generic labeling of fresh meat and poultry products according to the guidelines for the voluntary program. Representatives

of the poultry industry requested FSIS to allow alternatively for the use of industry-prepared, separate data bases and other recognized data bases, such as "Nutri-Facts," to provide the information because AH–8 may not be representative of current poultry.

In its proposal, the Agency stated that it accepted the results of the research efforts to develop the nutrient profiles for meat and poultry as contained in the NNDB or AH–8 as adequately characterizing beef, pork, lamb, veal, chicken, and turkey. These data have been screened and accepted by USDA's Human Nutrition Information Service and, therefore, FSIS believes it is appropriate to exclude products using these data for labeling purposes from compliance review in the absence of claims. FSIS also stated that it did not discourage the use of private data base values but that products so labeled would be subject to compliance review. Products labeled with both USDA's public data base values and with private data base values will be included in measuring substantial participation in the voluntary program. FSIS will not approve, certify, or otherwise accept private data bases for single-ingredient, raw products for the purpose of exempting products labeled with such information from the compliance provisions of these regulations. FSIS holds that the accuracy of the data in these private systems is the responsibility of the developer.

Several commenters from foreign countries requested either to use their own national data or that FSIS allow use of U.S. data to label imported, single-ingredient, raw products without such labeling being subject to compliance review. FSIS considers foreign, nationally representative data bases to be private data bases that it will not accept for the purpose of exemption from the compliance provisions of these regulations. As with domestic private data bases, the accuracy of the data in these systems is the responsibility of the developer. FSIS cannot know in advance the scope of the research behind data in private systems as is possible with USDA's NNDB. The Agency notes that nutrient profiles for raw cuts of New Zealand lamb as contained in AH–8–17 are given the same status as NNDB or AH–8 data with regard to the labeling of imported product. Imported products bearing other U.S. data for labeling will be subject to compliance review because the Agency has no way to assess the applicability of data developed specifically for the U.S. food supply to foreign food sources.

A number of trade associations and companies contended the voluntary system should apply to all single-ingredient products whether or not they have been thermally processed. They argued that there is little difference between thermally processed and non-thermally processed single-ingredient products, particularly when the labeling options of "as packaged" and "as consumed" for voluntary goods is taken into account.

The Agency understands the argument about thermally processed products considering that information on single-ingredient, raw products may be presented on a cooked basis. In its discussion of alternatives considered in development of its proposed regulations, FSIS stated its belief that consumers should be provided with nutrition labeled products to the extent possible for all foods. Because nutrient values for single-ingredient, raw meat and poultry products are not modified through various stages of preparation, consumers have reasonable expectation as to their nutritional values such that a voluntary program for these products is suitable. The Agency cited referenced USDA sources which contain both raw and cooked nutritional data appropriate for these products. The cooked values in these sources were developed using protocols that reflected home preparation to every extent possible. The Agency has no information that industrial thermal processing procedures do not introduce different variables than considered in developing the USDA data. For these reasons, FSIS concludes that inclusion of thermally processed single-ingredient products in the voluntary program is not warranted.

Many trade associations and companies held the opinion that the voluntary program should include single-ingredient, raw products subjected to such mechanical activities as grinding, cubing, cutting, and pressing, and that there should be no distinction between fresh products packed in official establishments and at the retail level. FSIS notes that it has made no distinction between fresh products packaged in official establishments and those packaged at the retail level. The Agency does not believe that the site where a product is packaged has any relevance for its nutritional profile. The voluntary program includes retail cuts of meat and poultry (and ground beef), including those that have been previously frozen, because the nutrient values for these products are not modified through various stages of preparation, such as cooking and heat processing. Single-ingredient, raw products which are subjected to mechanical treatments, such as slicing, chopping, and shaping, would likewise meet the definition describing products considered to be suitable for inclusion under the voluntary nutrition labeling program. The nutrient contents of final products from mechanical treatments would be identical to those of their starting cuts and such products could be labeled appropriately using pertinent USDA data base information.

Commenters suggested that the definition of fresh product as "single-ingredient" was too strict and could greatly deter the introduction of new, minimally processed products such as low fat products containing binders. The Agency does not believe that multi-ingredient products are appropriate for the voluntary program because their nutrient content can vary significantly from single-ingredient, raw products, due to addition of ingredients and other steps during the manufacturing process.

FSIS proposed that appropriate nutritional values for labeling of single-ingredient, raw products are values for meat cuts with external cover fat at trim levels reflecting current market practices, and values for poultry cuts with skin on. The Agency also proposed to permit the additional listing of nutrients for the separable lean of meat cuts and skinless poultry cuts as an option. Consumer groups supported the Agency's position, but many commenters representing the red meat and food marketing industries objected to it. The industries cited several surveys of consumer trimming behavior suggesting many people trim fat from meat and, to a lesser extent, remove skin from poultry prior to cooking or eating.

The Agency recently received the preliminary results of a September 1992 study, sponsored by the National Live Stock and Meat Board, on consumer fat trimming behavior with regard to beef and pork cuts. A copy of the preliminary results of the work entitled "Determination of Consumer Behavior Regarding the Trimming of Fat from Selected Beef and Pork Cuts," October 1992, is available for public review in the FSIS Hearing Clerk's office. Actual trimming habits were measured through laboratory examination of meal preparation wastes and individual family member plate wastes.

The preliminary results show that 68 of 71 households participating in the study trimmed fat from beef ribeye steaks and 53 of 59 households trimmed fat from pork loin chops, either before or after cooking and before eating. Considering the margin of error in the study and sources of bias, the Agency accepts the results as conclusive of

consumer trimming behavior for beef and pork, and interprets them to show that many consumers do trim some fat from meat prior to eating. Preliminary calculations indicated that the amount of fat actually consumed equaled about 25 percent of the difference between the percent fat in the cooked total edible tissues (separable lean plus separable fat) and the percent fat in the cooked separable lean for the beef cut. Calculations also indicated that the amount of fat actually consumed equaled about 50 percent of the difference between the percent fat in the cooked total edible tissues and the percent fat in the cooked separable lean for the pork cut.

The Agency believes that these 25 and 50 percent differences can not be ignored, therefore, separable lean values would not be appropriate for beef and pork cuts. FSIS will not change its proposed position. The study indicated that not all consumers trim all fat and that there are some consumers who trim no fat from meat. Therefore, FSIS has not changed its proposed position on appropriate nutrient values for labeling of single-ingredient, raw meat products. Appropriate values for cuts of red meat are edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices. Additional nutritional data may be presented on an optional basis for the edible portions of the separable lean of meat cuts.

The broiler industry sought more flexible use of data base information because non-standardized multiple packs currently sold will create a great deal of variation in the nutrition profiles of raw poultry products. Other commenters questioned which specific cuts of meat and poultry from the NNDB or AH–8 referenced sources could be used for labeling. FSIS does not intend to limit the cuts to the 35 meat cuts listed in proposed 9 CFR 317.344 and 10 poultry cuts listed in proposed 9 CFR 381.444. The 45 cuts were identified only as major cuts for purposes of measuring significant participation in the voluntary program. FSIS believes data for any cut of beef, pork, lamb, veal, chicken, and turkey contained in the referenced USDA sources are appropriate for use for labeling purposes. The data for cuts may be used singly or in combination to accommodate multiple packs. Different tissues for cuts may be combined allowing for their proportions by weight, when such information is available, following calculation procedures described in the AH–8 publications. When data base values are not used directly and computations are applied, the Agency encourages manufacturers to keep track of the proportions of each AH–8 item combined so that the Agency can be satisfied that the values are actually derived from AH–8 data. Data for organ meats and data for species other than the six identified may also be used at the manufacturer's discretion although such data may not have as solid a research basis as noted for retail cuts of the major species.

Comments were received about the list of 45 major cuts of meat and poultry and the presentation of data on either a raw or cooked basis. These comments and the Agency's response are discussed under Part II, Mandatory Nutrition Labeling and Part VI, Serving Sizes, respectively.

b. *All other products.* Numerous trade associations and manufacturers requested explicit sanction of data base use to develop nutrition labels for processed or multi-component products to alleviate the cost of chemical analyses. Some firms supplied information and/or data attesting to the accuracy of the data base approach.

In response, FSIS proposed specifically to allow use of data base values and recipe analysis, and requested input on criteria for effective use of data bases, guidelines to provide producers who choose to use this approach, availability of data bases, and any changes that might be warranted in the compliance criteria if data bases are used. Many commenters provided such input to assist FSIS in development of a final rule which permits use of data base values and recipe analysis for nutrition labeling. Two consumer groups and one major company expressed concern that the data base approach would lead to less accurate nutrition information on labels and that the nutritional verification of such information would most likely cancel any savings. The Agency believes that effective use of data bases can reduce dramatically the overall cost for supporting nutrition labels and can provide consumers with high quality, useful nutrient information. Accordingly, FSIS will permit the use of data base values and recipe analysis using data bases to support nutrition labeling of processed and multi-component products. FSIS places responsibility for label accuracy on manufacturers. They may derive the nutritional values for product labels by any means to result in compliance with the provisions of these regulations. FSIS will accept introduction of the existence of a data base and supporting data, such as company ingredient analysis, USDA or supplier data for ingredients, formulas, and calculations applied, as appropriate records supporting nutrition label declarations.

FSIS believes the use of nutrient data bases, especially computerized systems, offers a very powerful tool for the development of nutrition labels. However, their effective use is a complex issue involving considerations about completeness, accuracy, precision, and support. Many commenters asked the Agency to provide guidelines for data base use that are simple and concise. As previously discussed, FSIS has compiled relevant suggestions by experienced data base users into a manual to assist those meat and poultry processors who elect to employ this approach, copies of which are available from the Product Assessment Division.

Many small companies requested FSIS to provide the data base values or systems for computerized calculation and not hold users liable for any faulty data in such systems. FSIS does not believe that it is practical for it to provide data bases or computer systems to industry for use in calculating nutrient values. FSIS will provide guidance for effective use of data bases and computer systems in the manual, as well as information about appropriate composite species data and computations it believes applicable to products that are not highly formulated, and references to commercial sources of computer data base systems. However, use of the guidelines in the manual does not negate a manufacturer's responsibility for the accuracy of the nutrient information on its labels.

A number of commenters asked FSIS to evaluate and certify data bases and/or computerized recipe systems for acceptability either as a prerequisite to use or on a voluntary basis. The Agency does not believe it is either practical or warranted that it perform such a function. Available data bases and/or systems include publicly available material, such as USDA's Nutrient Data Base for Standard Reference, commercial systems, and companies' proprietary data bases. FSIS believes manufacturers should evaluate and select a system best suited to meet their own needs, taking into account their type of product, its ingredient formulation, and the processing procedures employed. General factors to consider in a data base selection process are provided in the FSIS manual to help guide potential users.

Most commenters responding to the question in the supplementary proposed rule about compliance parameters (57 FR 10298, March 25, 1992) expressed the opinion that compliance criteria in

nutrition labeling should be the same for all processed and multi-component products regardless of the data source. One trade association stated that products which are supported by data base values should be in a fundamentally different compliance category, whereby reference to the data base would essentially curtail a compliance inquiry in most cases. The suggestion was also made that USDA adopt compliance parameters that reflect product characteristics so that commodity-type products, when labeled according to an accepted national data base, should not be subject to compliance checks.

The Agency believes that compliance criteria that allow variation based on data sources, i.e., direct analysis, data base values, recipe calculations using data base values, and combinations of these approaches, would be inconsistent with the intent of nutrition labeling. It will hold manufacturers of all products not exempted from compliance review under provisions of these regulations to identical compliance parameters. FSIS expects the focus of any compliance inquiry about labels of products based on data base values and/or recipe analysis to be somewhat different from products based on direct analysis because variation can be introduced from multiple sources. Nonetheless, the Agency expects companies to locate the source of a discrepancy and take appropriate steps to correct errors.

A number of commenters said FSIS should not allow manufacturers of products bearing nutrient content claims to base the claims on data base values or recipe analysis and that FSIS should require chemical analysis to justify the validity of claims. The Agency maintains that the manufacturer is responsible for the accuracy of the claims and will not dictate that direct analysis must be conducted on nutrients which are the subject of claims. Because of the high visibility of claims and their use as marketing tools, manufacturers would place themselves at risk if claims cannot be adequately substantiated.

3. *Compliance parameters.* Many commenters addressed the 80/120 tolerance levels, commonly referred to as the 80/120 rule, for naturally occurring nutrients and the Agency's proposed sampling scheme. Approximately half were supportive of the proposed requirements as written. A number of large trade associations and companies offered alternative enforcement schemes or sought modifications of the tolerance levels to accommodate specific nutrients or single versus multi-lot sampling. Many requested FSIS to discuss the considerations it would make during a compliance inquiry and before it would deem a product to be misbranded because nutrients did not meet compliance provisions. Commenters cited situations where variations in processed products might cause compliance parameters to be exceeded unavoidably as follows: (a) Wide natural variation of nutrients in an ingredient; (b) decreases in nutrients during shelf life of a product; (c) variability of methods at low levels of nutrients; (d) adjustments for container fill; and (e) processing methods, such as retorting, which degrade certain nutrients. A few commenters held misconceptions that the 80 and 120 percent values represented the upper and lower bounds of an acceptable range for every nutrient and/or that products must be labeled at lot averages without allowance for safety factors.

The Agency shares the concerns that wide variation can be introduced due to natural variability of nutrients in foods and that some nutrients do change over the course of product shelf life. Examples of such cases are variable contents of fat in hams and sides of bacon from relatively uniform groups of market hogs and decreases over time in sodium ascorbate (vitamin C sodium) levels in fermented sausage, respectively. Therefore, the Agency is outlining its interpretation of the 80/120 rule, which it will adopt, and how it intends to determine a misbranding status. It is the Agency's position that declared nutrient values on food labels preferably should reflect average nutrient levels in the product produced or manufactured by a company or establishment within the company. The provisions of these regulations and other policies in regard to implementing these regulations are consistent with this position. The allowance in the 80/120 rule for nutrition labeling, developed by FDA and first implemented by that agency in 1974, is meant to take into account inherent manufacturing and product variation. The FDA approach was concentrated on single lot sampling. Under this scheme of sampling, lot-to-lot variation is not taken into account. However, compliance sampling of 12 subsamples within a lot does not imply that such a sample is adequate to develop the nutrition label.

FSIS compliance procedures will involve collecting samples from within a lot and use of results on samples that are collected from different lots, either at the establishment or at the wholesale/retail level. The sampling of product from different lots has the effect of decreasing the producer's risk that test results will not be in compliance compared to sampling of product from a single lot, provided that the product is produced under similar conditions. This type of sampling is consistent with the Agency's position that the nutrition label reflect the average level of nutrients in the product over time. FSIS has also adopted a strategy for some products of collecting six units instead of 12. The primary reason for this change is that the size of some products makes it difficult to mail, store, cook in some instances, and prepare homogeneous composites within the laboratory. Use of six units, instead of 12, will also reduce cost to the establishment when the samples are drawn at that site. The Agency believes that results based on six samples will provide reasonable assurance of accuracy, while offering considerable benefits. The Agency does not believe that this decrease in sample size warrants a statistical adjustment to the rule as it is being applied.

The Agency's experience with the 80/120 rule shows that it works well to ensure reliable label values for the majority of processed products, and is not overly burdensome. FSIS believes that the labeling strategy suggested by FDA in development of the 80/120 rule was based on using statistical procedures for guiding a producer in selecting a label value in order to be highly confident that sample results would satisfy the rule. FDA outlined a procedure which suggested that the nutrients in a food in a package must be within the 80/120 percent tolerances with high probability (95 percent) regardless of the average amounts of the food's nutrients in packages over time. If, in fact, nutrient variability were high, the manufacturer would be forced, under this procedure, to label above or below the average, depending on the nutrient, in order to satisfy the procedure. Also, in the case where variability was small, the label value could be below the average for so-called negative nutrients like calories, sodium, and fat and above the average for so-called positive nutrients like vitamins, minerals and protein. In either case, the average nutrient level in a food in a package would not agree with the label value.

FSIS, as mentioned previously, has adopted the policy that values on food labels preferably should reflect average nutrient levels in the food product. If this is achieved, it would enable consumers to have more accurate information over time than is possible with the FDA approach described above. The Agency recognizes that, for some nutrients in foods, natural

variability will be large, thereby increasing the probability of noncompliance under the 80/120 rule when the label value reflects average nutrient content. Consequently, the Agency will provide exemptions if it can be demonstrated that variability is unavoidably high due to inherent nutrient variation in a product or product ingredient, which cannot be controlled under normal processing. This type of variation is shown with carrots, an ingredient in some meat and poultry products. The vitamin A activity of carrots varies extensively and increases with maturity at harvest. However, variation caused by changes in proportions of ingredients, such as beef and pork in a frankfurter, would not qualify a product for an exemption.

The Agency will use the FDA procedure as a guideline to determine high variability. If a manufacturer labels at the average, and if the standard deviation of values within a lot is 42 percent of the mean, i.e., the coefficient of variation (CV) equals 42 percent, then there is a 95 percent probability that analytical results on 12 samples will satisfy the 80 or 120 percent criteria when analytical variability is ignored. This 42 percent value can be used as a guideline for exemptions based on inherent nutrient variability. When six samples are taken, 95 percent probability of satisfying the criteria is achieved when the CV equals 30 percent. This 30 percent value will be used as a guideline for providing exemptions for those products on which only six samples will be drawn.

When Agency test sample results are not in compliance with the 80/120 rule, FSIS will expect the company to indicate how it will rectify the problem. Actions may include changing the label values or identifying and correcting the cause of the problem. Alternatively, the company could notify the Agency that it is going to present data or information to support the label. The company could either present data that shows to the Agency's satisfaction that the sample result found not in compliance is not representative or likely to reoccur under the establishment's normal processing. Alternatively, the company could present evidence to relax the 80/120 tolerance because of unavoidable variability, either because of large within lot variability as described above, or because of large processing variability caused by product variation over the year.

In order for the Agency to accept the label value as stated, information presented during a compliance inquiry should demonstrate that the company satisfies the Agency's goal to have the label value reflect the average. Such effort could be demonstrated by data showing, with 80 percent statistical confidence, that the label value is equal to or less than the process mean value for nutrients where the 80 percent tolerance applies. In addition, the company must show consistent processing to ensure that only low percentages of future samples would not be in compliance. Such consistency could be shown by data demonstrating process control to the extent that there is expected to be less than a 10 percent probability that the mean result from a composite of six or 12 units within a lot, as appropriate, would not be in compliance. Similarly, for nutrients where the 120 percent tolerance applies, the Agency would be satisfied and accept the label value if the company can show that there is 80 percent statistical confidence that the process mean value for the product is equal to or less than the label value, and also that there is expected to be less than a 10 percent probability that the mean result from a composite of six or 12 units within a lot, as appropriate, would not be in compliance. The results used in these statistical computations should be rounded to one additional significant digit beyond the prescribed label increment for the nutrient. This rounding requirement will increase the accuracy of the evaluation.

If the company wishes to relax the 80/120 rule, then it should provide FSIS records of data collected under good manufacturing practice that would provide evidence to relax the 80/120 rule based on unavoidable variability with the intent of judging a product on its time weighted average nutritional profile over a year. The company has to present information which will explain and document the unavoidable variability. This would include amounts of raw materials that are generally used in processing, together with nutrient information on these materials, as well as data showing process variability under good manufacturing practices. For example, variation in fat content of bacon might be due to variation in fat content of the pork source material from different suppliers producing carcasses of different yield grades. Relaxation of the 80/120 rule will be made when it can be shown that nutrient levels in raw products are of high variability over time, or that there is a high amount of within lot variability as described above.

The Agency concludes that it is not necessary to alter the provisions of proposed 9 CFR 317.309(g)(4)(ii) and (5) or 381.409(g) (4)(ii) and (5) to incorporate the above stated policies to implementing the compliance provisions of these regulations. However, FSIS has modified proposed 9 CFR 317.309(g)(2) and 381.409(g)(2) to allow individual samples to be analyzed and the results averaged by adding a third sentence to read "In each case, the units may be individually analyzed and the results of these analyses averaged." The Agency has also corrected errors at proposed 9 CFR 317.309(g)(6) and 318.409(g)(6), the meaning of which was questioned by two trade associations. These provisions are changed to read "The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over the labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under the labeled amounts within good manufacturing practice." The purpose of these provisions is to prevent large understatements of vitamins, etc., and overstatements of calories, etc., on labels as compared to amounts actually present in analyzed composites. For example, if a product is labeled at 100 calories, an analyzed composite's caloric value may be no higher than 120 calories for the sample to be found in compliance. However, if the analyzed sample is found to contain only 20 calories, the product may be misbranded, because the Agency would consider the value to be outside the levels generally expected during good manufacturing practices. The Agency could ascertain this either by data collected from the manufacturers or data collected through its own monitoring program. While the Agency does not preclude adjustments in label declarations to minimize risk of noncompliance, it encourages manufacturers to label close to average values and, as discussed above, will take into consideration inherent nutrient variability and shelf stability factors when nutrients in products fall outside the 80/120 tolerance levels.

Some commenters contended that nutrients present at low concentrations are particularly susceptible to compliance problems due to method variability and rounding procedures. They argued that if a process mean value of 1.3 units were rounded for label declarations to one unit, then the acceptable range would be 0.8 to 1.2 units when applying the 80/120 rule. The range would be below the true mean value which could result in many products being found not in compliance. Furthermore, these small differences of 0.2 units may not be

within the accuracy of many methods so that the analytical variance could be greater than the allowed regulatory variance.

FSIS points out that the 20-percent tolerance does not represent a range but rather a discrepancy of an analytical result on a sample from a label value. FSIS believes that the point that the commenters wish to make is that, for class II nutrients such as fat and sugars, the upper bound for a label claim of 1 would be 1.2, which, in the example presented, is below the mean. In response, FSIS believes it is the manufacturer's responsibility to target values to correspond to an appropriate label declaration so products will meet compliance requirements. This includes taking into consideration the effects of rounding. In this example, FSIS would expect the label to indicate 1.5 units for fat and 2 units for sugars.

The Agency also recognizes that analytical variability may be larger at low nutrient levels. For this reason, FSIS proposed at 9 CFR 317.309(g)(4)(ii) and 381.409(g)(4)(ii) for vitamins, minerals, protein, total carbohydrate, dietary fiber, etc., that no regulatory action will be taken unless the nutrient level found in the product exceeds both the 20-percent tolerance and whatever variability is recognized for the particular method being used at the nutrient level involved. FSIS believes this same provision should apply to all nutrients. The Agency has added the provision for allowance for method variability at proposed 9 CFR 317.309(g)(5) and 381.409(g)(5) to cover calories, sugars, total fat, saturated fat, cholesterol, and sodium. FSIS does not believe that incorporation into the regulations of any other explicit provision or compliance position for low level nutrients or small labeling increments, such as 2 percent, would provide added protection for manufacturers.

Several commenters stated that container fill, specifically over fill to assure compliance with declared quantity of contents, will contribute errors under the proposed definition for single-serving containers, which will use the entire contents of the container in determining compliance. FSIS does not consider this issue to be a valid concern. While the entire contents of a container will be used to prepare the sample for analysis, the Agency will not use the actual weight of the contents in determining compliance. FSIS will use the precise metric weight equivalent of the serving or portion size, fluids in milliliters and all other foods in grams, which is required to be included on the label, for compliance purposes. For purposes of clarity, the Agency is adding a provision at proposed 9 CFR 317.309(g) and 381.409(g) to state specifically that this metric measure will be used for compliance purposes.

While discussing nutrient variability, some trade associations and companies said manufacturing processes, such as heat treatments, alter nutrients. The Agency holds that such losses must be accounted for either by finished product testing or by use of yield and retention factors, as appropriate, during recipe analysis. The latter considerations are discussed in the FSIS manual on use of data bases.

Industry groups said decision criteria for compliance should be based on actual, unrounded values used in compiling the label information. If FSIS unrounded compliance sample data were compared to rounded label declarations, whether the industry source data came from direct analyses or data bases, errors in data interpretation might result. Because the Agency has dropped the requirement for submission of company data with initial label approvals, FSIS must make initial comparisons with label declarations. However, in the event of a compliance inquiry, FSIS will examine the company's records and make decisions using the company's original, unrounded values.

A few large companies sought clarification as to why FSIS defined and established tolerances for class I nutrients; i.e., those added in fortified and fabricated foods, noting that FSIS has not allowed fortification of meat and poultry products. In the preamble to the proposed rule, FSIS stated that it had little experience with added nutrients unless specific regulations permit their addition, e.g., vitamin A to margarine (9 CFR 319.700). The Agency proposed to define class I nutrients in these regulations to cover this situation. The use of nutrients solely for technological purposes, e.g., in curing meats to use L-ascorbic acid (vitamin C) or its sodium salt (sodium ascorbate) to accelerate color fixing or preserve color during storage, would not subject the added nutrient in the product to the class I compliance criteria shown at proposed 9 CFR 317.309(g)(4)(i) and 381.409(g)(4)(i). Similarly, the use of ingredients such as "textured vegetable protein" or enriched flour in a product would not subject the product to any class I criteria simply because the word "protein" is in an ingredient name or nutrients had been added to an ingredient of the product. The Agency also notes that if voluntary vitamins and minerals are required to be added or permitted in a standardized food (e.g., thiamin in enriched flour), which is used as an ingredient in a meat or poultry product, or if they are included solely for technological purposes and declared only in the ingredient statement, they need not be declared on the label if not otherwise referred to on the label or in labeling or advertising. The Agency believes that further discussion of its fortification policy is beyond the scope of this rulemaking.

A number of commenters expressed concerns about the need to analyze for nutrients which are not indigenous to meat or poultry products, e.g., dietary fiber in muscle meat tissue, stating that to analyze for "zero" level nutrients would be costly and a waste of time. FSIS does not expect manufacturers to conduct analyses for nutrients that are not present in a food or even to run tests to establish that fact unless there is reasonable doubt about the nutrient's presence or as to whether the level would round to "zero" for the label declaration. Knowledge of the food and information on its ingredient formulation and processing, review of food composition tables, consultation with nutritionists, food scientists, and others can all show that only certain nutrients should be targeted for analysis in specific foods or products. To undertake analyses for all mandatory nutrients in such situations would be a waste of resources.

Regarding analytical methodology, commenters stressed the importance that methods used for regulatory compliance by FSIS and FDA be the same except to the extent where the unique characteristics of meat and poultry products dictate a different method. Both the FSIS "Chemistry Laboratory Guidebook" and the "Official Methods of Analysis" of the AOAC International, formerly Association of Official Analytical Chemists, were recognized as appropriate sources of chemical methodology. Commenters said the "Guidebook" must be updated and include references for all required nutrients and that specific reference to the 15th edition, 1990, of the AOAC should not be made because, when subsequent editions are printed, the regulations will reference obsolete material. It was also noted that some AOAC methods are not current with contemporary analytical procedures and that there is a need to develop better, more reliable analytical methods subject to collaborative studies. The AOAC International Board of Directors established a Task Force on Nutrient Labeling Methods charged with identifying deficiencies in current methods and expediting key

collaborative studies. Many commenters also requested specific guidance as to the analytical procedures the Agency will use to enforce these regulations at the time the final rule is published.

The Agency agrees with the majority of these comments concerning analytical methodology and the goals of the AOAC Task Force on Nutrient Labeling Methods. USDA's Agricultural Research Service, FSIS and FDA are actively participating in the AOAC deliberations, as well as in development of appropriate standard reference materials for chemical analyses. FSIS recognizes that some of the methods now in use may be changed in the next several years in order to better meet nutrition labeling needs. Such changes, when accepted by the Agency, will be incorporated into the "Chemistry Laboratory Guidebook," which will be updated on an ongoing basis. In regard to the suggestion to delete the reference to the 15th edition of the AOAC, FSIS does not have the authority to delete such reference. The Office of the Federal Register requires that each statement of incorporation by reference into the Code of Federal Regulations contain specific information, including the date and edition of the publication. This is required because all incorporated material, like any other properly issued regulation, has the force and effect of law.

Accordingly, FSIS has modified the proposed 9 CFR 317.309(g)(2) and 381.409(g)(2) to change the cross reference to 21 CFR 101.9(c) to 9 CFR 317.309(b) for meat and 9 CFR 381.409(b) for poultry. The Agency also notes that the provisions at 317.309(h)(2) and 381.409(h)(2) state that, if no USDA, AOAC, or specified method is available or appropriate, that other reliable and appropriate analytical procedures should be used. Other reliable and appropriate procedures may not have been collaboratively tested, but rather include validated methods, published peer-reviewed methods and correlated methods. Because they are not necessarily fully characterized, like official methods, they are not specified. In the preamble to the proposed rule, FSIS said that if use of a method will result in a significant (10 percent or greater) under-representation of a caloric value or misrepresentation of an available nutrient such that the nutrients whose intakes should be limited appear to be present at lower levels than is actually the case, then a more appropriate method of analysis should be used. These provisions have relevance, for example, to products containing a large proportion of fat as phospholipid, which is not quantitatively extracted with ether.

The "Chemistry Laboratory Guidebook" is now in the process of being updated but is not yet available. For this reason and to provide commenters with specific guidance as to the methods for required nutrients, moisture, and ash that it will use for compliance purposes, FSIS has listed below the method citations with brief clarifying descriptions and/or additional considerations. A full description of the procedures, including measures of analytical variability, as well as any changes made for considerations outlined below or in response to Federal or AOAC deliberations prior to publication of the updated guidebook, will appear in the revised version. Further information about analytical methods may be obtained from the Chemistry Division, Science and Technology, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

FSIS Methods for Nutritional Analysis

- Calories—At 317.309(b) and 381.409(b). Calculated using specific Atwater factors; general factors of 4, 4, 9; general factors of 4, 4, 9 after subtracting insoluble dietary fiber from total carbohydrate, if desired; or, specific food factors approved by FDA.
- Moisture—AOAC, 15th ed., 1990, 950.46B. Air Drying; or AOAC, 15th ed., 1990, 950.46. Vacuum Oven.
- Total Fat—FSIS has tested several procedures to measure fat on various meat and poultry products, including AOAC, 15th ed., 1990, 960.39 using petroleum ether as solvent. The Agency is currently testing methods to measure only the total lipid fatty acids to be expressed as triglycerides, which constitute total dietary fat as defined in this final rule. More information will be provided as soon as it is available.
- Saturated Fat—Lipid Manual, "Methodology Appropriate for Fatty Acid-Cholesterol Analysis," 1992. U.S. Food and Drug Administration. Wm. C. Brown Publishers, Dubuque, IA, 109 pp. FSIS will use capillary columns, and the shortest chain fatty acid to be measured will be butyric acid.
- Cholesterol—Lipid Manual, "Methodology Appropriate for Fatty Acid-Cholesterol Analysis," 1992. U.S. Food and Drug Administration. Wm. C. Brown Publishers, Dubuque, IA, 109 pp. FSIS will use capillary columns.
- Total Carbohydrate—At § 317.309(b) and § 381.409(b). Determined by difference.
- Sugars—Chemistry Laboratory Guidebook, Revised Basic, 1987, 3.022. Dextrose, Sucrose, Maltose, and Lactose by HPLC.
- Dietary Fiber—AOAC, 15th ed., 1990, 985.29. Enzymatic Gravimetric Method; or AOAC, 15th ed., 1990: 3rd Supplement, 1992, 991.43. Enzymatic Gravimetric Method, MES-TRIS Buffer. Special precautions are needed to ensure that meat and poultry product samples are thoroughly defatted prior to analysis.
- Other Carbohydrate—At § 317.309(b) and § 381.409(b). Determined by difference.
- Protein—Chemistry Laboratory Guidebook, Revised Basic, 1987, 3.002. Kjeldahl.
- Ash—AOAC, 15th ed., 1990, 920.153.
- Vitamin A—High Pressure Liquid Chromatography. In-house FDA procedure. FSIS will measure preformed retinol and beta-carotene separated from other vitamin A precursors. The Agency will not make a noncompliance finding for this nutrient when a company includes other vitamin A active carotenoids in compiling the label declaration where data for such carotenoids have been determined using appropriate methods and the activity has been calculated using the factor of one retinol equivalent equal to 12 micrograms of these other carotenoids.
- Vitamin C—FSIS is studying the procedure of Vanderslice, J.T. and Higgs, D.J. 1990. "Separation of ascorbic acid, isoascorbic acid, dehydroascorbic acid and dehydroisoascorbic acid in food and animal tissue". J. Micronutrient Anal. 7, 67–70. This HPLC procedure can distinguish between L-ascorbic acid (and sodium ascorbate) and isoascorbic; i.e., erythorbic acid (and its sodium salt, sodium erythorbate), which is commonly used in meat and poultry products but has little or no vitamin C activity. FSIS has not yet determined whether this method is reliable. The Agency will use this procedure if reliability is established. FSIS is also studying the procedure of the International Organization of Standardization (ISO), 1990–09. "Meat and Meat Products—determination of L(+)—ascorbic acid—HPLC method", Document 34–SC6N337.
- Sodium—Chemistry Laboratory Guidebook, Revised Basic, 1987, 4.010. Using Inductively Coupled Plasma Optical Emission Spectrometry.
- Iron and Calcium—Analytical Chemistry Laboratory Guidebook, Residue Chemistry, Winter 1991. MTL. Inductively Coupled Plasma Optical Emission Spectrometry.

FSIS is extending this procedure to include calcium. FSIS notes that it does

not prescribe methods which must be used by manufacturers to support label values. The methods listed above are those the Agency will use to analyze samples for enforcement purposes. The Chemistry Division will make copies of single nutrient analyses available at interim periods between publications of the Chemistry Laboratory Guidebook.

IX. Health Claims

FSIS does not currently permit health claims explicitly linking food attributes to diet-related disease or health-related conditions. FSIS does permit statements informing consumers that a food can be part of a specific dietary pattern to meet an organization's dietary guidelines or that a food was developed to help follow a specific dietary pattern.

The rationale adopted by FSIS for approving health claims on labeling is to encourage labeling which supplements the information contained in the nutrition label with information that provides truthful data about a product's nutritional characteristics, and provides generally accepted information about how a product satisfies consumers' total dietary requirements. By contrast, labeling is not approved by FSIS under the FMIA or PPIA if the Secretary of Agriculture has reason to believe that the claim is false or misleading in any particular.

To implement the use of health claims on labeling, FSIS provides general guidelines and objectives which permit claims if they are based on a consensus of medical and scientific information, emphasize that good nutrition is a function of the total diet, and are reasonably uniform from product to product.

The following is an example of a health-related claim that would currently be permitted: "This food was specifically developed to help you follow the current U.S. Dietary Guidelines for sodium, fat and cholesterol. For further information on the U.S. Dietary Guidelines call * * *"

In its proposed rule on nutrition labeling, FSIS stated its intent to publish a proposed rule on health claims in line with FDA's proposal. At the time the FSIS proposal was published, the health claims issue was still under study by FDA and FSIS. FSIS is continuing its study of this issue and plans to publish a proposed rule in the near future.

X. Food Ingredients and Standards of Identity

FSIS requires full ingredient labeling on all meat and poultry products, including standardized products.

The Agency believes that concerns about disjunctive labeling of fats and oils can be resolved by proper labeling of saturated fat. Because USDA standards of identity and composition do not require minimum fat contents, development of products with desirable characteristics is not hampered by minimum fat criteria. However, levels for minimum amounts of meat and poultry are a part of most standards. These criteria protect consumers against economic fraud and dilution of beneficial micronutrients and protein expected in certain products. Due to the shift of concern from problems connected to underconsumption to those associated with overconsumption of certain food components such as fat, FSIS plans to reassess this matter after completing its rulemaking on nutrition labeling.

XI. Prior Label Approval

FSIS is considering changes to its current label approval process for labeling of meat and poultry products. At this time, two options are being considered: (1) Revising the current system by significantly reducing the scope of review, through expanding the categories of labeling that would be generically approved, and replacing the current general requirement of FSIS approval of final labeling with one for sketch labeling only; and (2) replacing the current system with a system in which all labeling would be generically approved and used without prior submission to FSIS. FSIS published an ANPR in the **Federal Register** on March 25, 1992 (57 FR 10300), requesting comments from interested parties on these two options. FSIS plans to issue a proposed rule based on comments received on the ANPR.

List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Incorporation by reference, Meat inspection.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 381

Food labeling, Incorporation by reference, Poultry and poultry products, Reporting and recordkeeping requirements.

Final Rule

For the reasons discussed in the preamble, FSIS is amending 9 CFR parts 317, 320, and 381 of the Federal meat and poultry products inspection regulations as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Part 317 is amended by designating the current sections 317.1 through 317.24 as subpart A—General, and by adding a new subpart B—Nutrition Labeling to read as follows:

Subpart B—Nutrition Labeling

Sec.

317.300 Nutrition labeling of meat products.
317.301 [Reserved]
317.302 Location of nutrition information.
317.303–317.307 [Reserved]
317.308 Labeling of meat products with number of servings.
317.309 Nutrition label content.
317.310 [Reserved]
317.311 [Reserved]
317.312 Reference amounts customarily consumed per eating occasion.
317.313 Nutrient content claims; general principles.
317.314–317.342 [Reserved]
317.343 Significant participation for voluntary nutrition labeling.
317.344 Identification of major cuts of meat products.
317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
317.346–317.353 [Reserved]
317.354 Nutrient content claims for "good source" and "high".
317.355 [Reserved]
317.356 Nutrient content claims for "light" or "lite".
317.357–317.359 [Reserved]
317.360 Nutrient content claims for calorie content.
317.361 Nutrient content claims for sodium content.
317.362 Nutrient content claims for fat, fatty acids, and cholesterol content of meat products.
317.363–317.368 [Reserved]
317.369 Labeling applications for nutrient content claims.
317.370–317.379 [Reserved]
317.380 Label statements relating to usefulness in reducing or maintaining body weight.
317.381–317.399 [Reserved]
317.400 Exemption from nutrition labeling.

Subpart B—Nutrition Labeling

§ 317.300 Nutrition labeling of meat products.

(a) Nutrition labeling shall be provided for all meat products, except single-ingredient, raw products, in accordance with the requirements of § 317.309; except as exempted under § 317.400 of this Subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw meat products in accordance with the

requirements of §§ 317.309 and 317.345. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 317.343 and 317.344 of this Subpart.

§ 317.301 [Reserved]

§ 317.302 Location of nutrition information.

(a) Nutrition information on a label of packaged meat products shall appear on the label's principal display panel or on the information panel, except as provided in paragraph (b) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

§§ 317.303–317.307 [Reserved]

§ 317.308 Labeling of meat products with number of servings.

The label of any package of a meat product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 317.2(h)(10).

§ 317.309 Nutrition label content.

(a)(1) All nutrient and product component quantities shall be declared in relation to a serving or to a portion, as defined in 21 CFR 101.9(b) (1) and (2) except (b)(2)(i), and 21 CFR 101.9(b) (5) through (9) except (b)(5)(iii).

(2) The declaration of nutrient and product component content shall be on the basis of the product "as packaged" for all products, except that single-ingredient, raw products may be declared on the basis of the product "as consumed" as set forth in § 317.345(a)(1). In addition to the required declaration on the basis of "as packaged" for products other than single-ingredient, raw products, the declaration may also be made on the basis of "as consumed," provided that preparation and cooking instructions are clearly stated.

(3) For products in discrete units (e.g., hotdogs, and individually packaged products within a multi-serving package), serving size shall be the number of whole units that most closely approximates the Reference Amount for the Product Category. If a unit weighs 67 percent or more, but less than 200 percent of the Reference Amount, serving size shall be one unit. If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may decide whether one unit is one serving. If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion.

(4) Serving size for meal-type products as defined in § 317.313(l) shall be the entire content (edible portion only) of the package.

(5) Another column of figures may be used to declare the nutrient and food component information in the same format as required by § 317.309(e),

(i) Per 100 grams, 100 milliliters, or 1 ounce of the food as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(6) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5-ounce increments most closely approximating the Reference Amount, with rounding indicated by use of the term "about" (e.g., about 2.5 ounces).

(b) The declaration of nutrition information on the label shall contain the following information, except for that which is identified as "VOLUNTARY" or for those meat products where a simplified format may be used as provided for in paragraph (g) of this section or as in § 317.400(b). No nutrients or food components, other than those listed in 21 CFR 101.9(c) as either voluntary or mandatory, except for stearic acid, may be included within the nutrition label. Information shall be presented using the nutrient names specified and in the formats specified in paragraph (e) of this section. Definitions, units of measure, increments for declaring values, and methods of calculation shall be in accordance with 21 CFR 101.9 (c)(1) through (c)(9), except 21 CFR 101.9(c)(1)(i)(E), bomb calorimetry, and in 21 CFR 101.9(c)(7)(ii), use of nitrogen conversion factors, other than 6.25.

(c)(1) If a product consists of assortments of meat products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(2) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided*, That the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(d) "Stearic acid" may be declared "VOLUNTARY." If stearic acid is declared "VOLUNTARY" a statement of the number of grams of stearic acid shall be included under saturated fat content and expressed to the nearest 0.5 (1/2) gram increment below 3 grams and to the nearest gram increment above 3 grams.

(e) Formats for nutrition labeling shall be in accordance with 21 CFR 101.9 (d) and (e) except for references to (f), (j)(5), and (j)(13), or in accordance with paragraph (g)(1) of this section.

(f) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (b), (e), and (g) of this section and § 317.302(a) by one or more of the following means:

(1) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns, if the package shape or size cannot accommodate a column display on any label panel. Nutrition information may be given in a linear fashion only if the label will not accommodate a tabular display and, in that case, subcomponents (e.g., saturated fat shall be declared in parentheses after total fat).

(2) Using any of the following abbreviations:

Serving size—Serv. size
Servings per container—Servings
Calories from fat—Fat cal
Saturated fat—Sat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber

(3) Omitting the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of 21 CFR 101.9 and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value," and

(4) Presenting the required nutrition information on any other label panel.

(g)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients,

are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include: Serving size, number of servings per container, calories, total fat (grams), total carbohydrate (grams), protein (grams), and sodium (milligrams).

(3) Any nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included within the nutrition label, "Not a significant source of _____." The blank shall be filled in with the appropriate nutrient or food component.

(4) The omission of the listing of daily values and the caloric conversion information, and the expression of the percent of daily value in the simplified format shall be in accordance with 21 CFR 101.9(f)(5) except for references to (j)(5) and (j)(13).

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the "Chemistry Laboratory Guidebook," or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the "Official Methods of Analysis" of the AOAC International, formerly Association of Official Analytical Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 317.309(b), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The "Official Methods of Analysis" is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., suite 400, Arlington, VA 22201. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 1(n) of the Federal Meat Inspection Act (21 U.S.C. 601(n)(1)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided,* That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h) (1) through (8) of this section shall not apply to single-ingredient, raw meat (including ground beef) products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series available from the Government Printing Office.

§ 317.310 [Reserved]

§ 317.311 [Reserved]

§ 317.312 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the Reference Amounts for serving (portion) sizes set forth in paragraph (b) of this section are found in 21 CFR 101.12(a), (c), (d) and (g).

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1,2,3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	80 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference amount Ready-to-serve	Reference amount Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young	110 g	n/a.
Lard, margarine, shortening	1 tbsp	n/a.
Salad and potato toppers; e.g., bacon bits	7 g	n/a.
Bacon (bacon, beef breakfast strips, pork breakfast strips, pork rinds)	15 g	54 g=bacon. 30 g = breakfast strips.
Dried; e.g., jerky, dried beef, Parma ham sausage products with a moisture/protein ratio of less than 2:1; e.g., pepperoni	30 g	n/a.
Snacks; e.g., meat snack food sticks	30 g	n/a.
Luncheon meat, bologna, Canadian style bacon, pork patties crumbles, beef patties crumbles, blood pudding, luncheon loaf, old fashioned loaf, berlinger, bengers, minced luncheon roll, thuringer, liver sausage, mortadella, uncured sausage (franks), ham and cheese loaf, P&P loaf, scrapple souse, head cheese, pizza loaf, olive loaf, pate, deviled ham, sandwich spread, teawurst, cervelat, Lebenon bologna, potted meat food product, taco fillings, meat pie fillings.	55 g	n/a.
Linked meat sausage products, Vienna sausage, frankfurters, pork sausage, imitation frankfurters, bratwurst, kielbasa, Polish sausage, summer sausage, mettwurst, smoked country sausage, smoked sausage, smoked or pickled meat, pickled pigs feet.	55 g	n/a. 75 g=uncooked sausage.
Entrees without sauce, cuts of meat including marinated, tenderized, injected cuts of meat, beef patty, corn dog, bagel dog, croquettes, fritters, cured ham, dry cured ham, dry cured cappicola, corned beef, pastrami, country ham, pork shoulder picnic, meatballs, pureed adult foods.	85 g	106 g.
Canned meats, canned beef, canned pork. [6]	55 g	n/a.
Entrees with sauce, barbecued meats in sauce	140 g	n/a.
Mixed dishes NOT measurable with a cup; [6] e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches, cracker and meat lunch type packages, gyro, stromboli, burger on a bun, frank on a bun, calzone, taco, pockets stuffed with meat, foldovers, meat lasagna, stuffed vegetables with meat, shish kabobs, empanada.	140 g (plus 55 g for products with sauce toppings)	n/a.
Mixed dishes measurable with a cup; e.g., meat casserole, macaroni and cheese with meat, pot pie, spaghetti with sauce, meat chili, chili with beans, meat hash, creamed chipped beef, beef ravioli in sauce, beef stroganoff, Brunswick stew, goulash, meat stew, ragout.	1 cup	n/a.
Salads—pasta or potato, potato salad with bacon, macaroni and meat salad	140 g	n/a.
Salads—all other meat, salads, ham salad	100 g	n/a.
Soups—all varieties	245 g	n/a.
Major main entree type sauce; e.g., spaghetti sauce with meat, spaghetti sauce with meatballs	125 g	n/a.
Minor main entree sauce; e.g., pizza sauce with meat, gravy	¼ cup	n/a.
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with meat.		
As reconstituted:		
Amount to make one Reference Amount of the final dish; e.g.,		
Gravy	¼ cup	n/a.
Major main entree type sauce	125 g	n/a.
Soup	245 g	n/a.
Entree measurable with a cup	1 cup	n/a.

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.

[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.

[4] If packed or canned in liquid, the Reference Amount is for the drained solids.

[5] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) The Reference Amount for products that represent two or more foods packaged and presented to be consumed together (e.g., lunch meat, cheese, and crackers) shall be the sum of the Reference Amounts for individual foods in the package if the Reference Amount is not listed in paragraph (b) of this section and the product is not a meal-type product.

(d) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

_____
(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.312 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., ham as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,
Applicant _____
By _____
(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading.

The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of meat food products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of an answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

§ 317.313 Nutrient content claims; general principles.

(a) This section applies to meat products that are intended for human consumption and that are offered for sale, except that nutrient content claims may not be made on products intended specifically for use by infants and toddlers less than 2 years of age.

(b) A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 317.309, may not be made on a label or in labeling of that product unless the claim is made in accordance with 21 CFR 101.13 (b) through (f).

(c) through (h) [Reserved]

(i) The labeling of a product may contain a statement about the amount or percentage of a nutrient in accordance with 21 CFR 101.13(i) (1) through (3).

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference food in accordance with 21 CFR 101.13(j), except comparison to product of another manufacturer at 21 CFR 101.13(j)(1)(ii)(B).

(k) The term "modified" may be used in the statement of identity of a product in accordance with 21 CFR 101.13(k).

(l) For purposes of making a claim, a "meal-type product" shall be defined as a product that:

(1) Makes a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group, and

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Nutrition labeling in accordance with § 317.309, shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 317.309(h).

(p) The Reference Amount shall be used to determine whether a product meets the criteria for a nutrient content claim as discussed in 21 CFR 101.13(p)(1).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 1(n) of the Act (21 U.S.C. 601(n)(1)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in 21 CFR 101.9(c) may be made on the label.

(4) The requirements of this section do not apply to products for special dietary use as described in § 317.2(j)(2).

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to

the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 317.369.

§§ 317.314–317.342 [Reserved]

§ 317.343 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw meat products, as identified in § 317.344, including those that have been previously frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw meat products, listed in § 317.344, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an approriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 317.344 Identification of major cuts of meat products.

The major cuts of single-ingredient, raw meat products are: Beef chuck blade roast, beef loin top loin steak, beef rib roast large end, beef round eye round steak, beef round top round steak, beef round tip roast, beef chuck arm pot roast, beef loin sirloin steak, beef round bottom round steak, beef brisket (whole, flat half, or point half), beef rib steak small end, beef loin tenderloin steak, ground beef regular without added seasonings, ground beef extra lean without added seasoning, pork loin chop, pork loin country style ribs, pork loin top loin chop boneless, pork loin rib chop, pork spareribs, pork loin tenderloin, pork loin sirloin roast, pork shoulder blade steak, pork loin top roast boneless, ground pork, lamb shank, lamb shoulder arm chop, lamb shoulder blade chop, lamb rib roast, lamb loin chop, lamb leg (whole, sirloin half, or shank half), veal shoulder arm steak, veal shoulder blade steak, veal rib roast, veal loin chop, and veal cutlets.

§ 317.345 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw meat products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either "as consumed" or "as packaged." In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen.

(2) If a retailer chooses to provide nutrition information at the point-of-purchase, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. If a nutrition claim is made on point-of-purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) The requirements of the mandatory nutrition labeling program apply, but the nutrition information may be supplied on an "as packaged" or "as consumed," basis;

(ii) The listing of DRV's may be voluntary; and

(iii) The point-of-purchase materials are not subject to any of the format requirements. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) [Reserved]

(c) The declaration of nutrition information may be presented in a simplified format as specified in § 317.309(g) for the mandatory nutrition labeling program.

(d) The nutrition label data should be based on either the raw or cooked edible portions of meat cuts with external cover fat at trim levels reflecting current marketing practices. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the separable lean of meat cuts.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen. These data may be composite data that reflect different quality grades of beef or other variables affecting nutrient content. Alternatively, data that reflect specific grades or other variables may be used, except that if data are used on labels attached to a product which is labeled as to grade of meat or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible meat tissues present in the package.

(f) If the nutrition information is in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 317.309(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw meat products (including ground beef), including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this subpart for the mandatory nutrition labeling program.

§ 317.346–317.353 [Reserved]

§ 317.354 Nutrient content claims for "good source" and "high".

Nutrient content claims about a nutrient in a product in relation to the Reference Daily Intake (RDI) established for that nutrient in 21 CFR 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in 21 CFR 101.9(c)(12)(i), excluding total carbohydrate and unsaturated fatty acids, may be used on the label or in

labeling, in accordance with 21 CFR 101.54 (a) through (d).

§ 317.355 [Reserved]

§ 317.356 Nutrient content claims for "light" or "lite".

(a) *General requirements.* The following nutrient content claims using the term "light" or "lite" to describe a product may be used on the label and in labeling, provided that the product is labeled in compliance with 21 CFR 101.56.

(b) The terms "light" or "lite" may be used in the brand name of foods to describe the sodium content, provided that:

(1) The product meets the sodium criteria provided in paragraph (a) of this section, and

(2) A statement specifically stating that the product is "light in sodium" or "lite in sodium" appears:

(i) Contiguous to the brand name;

(ii) In uniform type size, style, color, and prominence as the product name; and

(iii) The "light in sodium" or "lite in sodium" statement complies with paragraph (a) of this section.

§§ 317.357–317.359 [Reserved]

§ 317.360 Nutrient content claims for calorie content.

Nutrient content claims about the calorie content of a product may be used on the label or in labeling in accordance with 21 CFR 101.60(a) through (c).

§ 317.361 Nutrient content claims for sodium content.

Nutrient content claims about the sodium content of a product may be used on the label and in labeling in accordance with 21 CFR 101.61 (a) and (b).

§ 317.362 Nutrient content claims for fat, fatty acids, and cholesterol content of meat products.

(a) A claim about the level of fat, fatty acid, and cholesterol in a meat product may only be made on the label and in the labeling of the product in accordance with 21 CFR 101.62 (a) through (d), except, 21 CFR 101.62(c), (d)(1)(i), (d)(1)(ii) (A) through (D), (d)(2)(i), (d)(2)(ii) (A) through (D), (d)(4)(i), (d)(4)(ii) (A) through (D), (d)(5)(i), and (d)(5)(ii) (A) through (D).

(b) The terms "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a meal-type product as defined in § 317.313, provided that the product meets the requirements of 21 CFR 101.62(d)(2), except that requirements of 21 CFR 101.62(d)(2) (i)(A) and (ii)(A) shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirements of 21 CFR 101.62(d)(2) (i)(B) and (ii)(B) shall be modified to require that the product contain 2 grams or less of saturated fat per 100 grams.

(c) *"Lean" and "Extra Lean" Claims.* The following nutrient content claims may be used on the label or in labeling, provided that the product is labeled in accordance with § 317.309, and the nutrient content claim complies with § 317.313:

(1) The term "lean" may be used on the label or in labeling of a meat product, provided that the product contains less than 10 grams fat, less than 4 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and labeled serving size for meal-type products.

(2) The term "extra lean" may be used on the label or in labeling of a meat product, provided that the product contains less than 5 grams fat, less than 2 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and per labeled serving size for meal-type products.

§§ 317.363–317.368 [Reserved]

§ 317.369 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of chapter 1, title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in part 56 of chapter 1, title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in part 50 of chapter 1, title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or

her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250.

(Date)

The undersigned, _____, submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 317.309(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of meat and food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the preceding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the application appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States

Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the claim.

(l) (1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart B of part 317).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the **Federal Register** a notice informing the public that the synonymous term has been approved for use.

(m) (1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 317.369 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,

Applicant _____

By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the

reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the **Federal Register** seeking comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of meat food products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a notice informing the public that the implied nutrient content claim has been approved for use.

§§ 317.370–317.379 [Reserved]

§ 317.380 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 317.309 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 317.360(b) (2) and (3).

(d) *"Reduced calorie" foods and other comparative claims.* A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 317.360(b) (4) and (5).

§§ 317.381–317.399 [Reserved]

§ 317.400 Exemption from nutrition labeling.

(a) The following meat food products are exempt from nutrition labeling:

(1) Food products produced by small businesses provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for the purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claim or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g., sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol. Foods represented to be specifically for infants and children less than 4 years of age shall bear nutrition labeling, except that such labeling shall not include listings of percent of daily value and the daily value list. Nutrient names and quantitative amounts by weight shall be presented in two separate columns.

PART 320—RECORDS, REGISTRATION, AND REPORTS

3. The authority citation for part 320 continues to read follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

4. Section 320.1 is amended by adding a new paragraph (b)(8) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(8) Records of nutrition labeling as required by subpart B, part 317, of this subchapter.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

5. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451–470, 7 CFR 2.17, 2.55.

6. Section 381.175 is amended by adding a new paragraph (b)(5) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(5) Records of nutrition labeling as required by subpart Y of this part.

7. Part 381 is amended by adding a new subpart Y to read as follows:

Subpart Y—Nutrition Labeling

Sec.

381.400 Nutrition labeling of poultry products.
381.401 [Reserved]
381.402 Location of nutrition information.
381.403–381.407 [Reserved]
381.408 Labeling of poultry products with number of servings.
381.409 Nutrition label content.
381.410 [Reserved]
381.411 [Reserved]
381.412 Reference amounts customarily consumed per eating occasion.
381.413 Nutrient content claims; general principles.
381.414–381.442 [Reserved]
381.443 Significant participation for voluntary nutrition labeling.
381.444 Identification of major cuts of poultry products.
381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.
381.446–381.453 [Reserved]
381.454 Nutrient content claims for "good source" and "high".
381.455 [Reserved]
381.456 Nutrient content claims for "light" or "lite".
381.457–381.459 [Reserved]
381.460 Nutrient content claims for calorie content.
381.461 Nutrient content claims for sodium content.
381.462 Nutrient content claims for fat, fatty acids, and cholesterol content of poultry products.
381.463–381.468 [Reserved]
381.469 Labeling applications for nutrient content claims.
381.470–381.479 [Reserved]
381.480 Label statements relating to usefulness in reducing or maintaining body weight.
381.481–381.499 [Reserved]
381.500 Exemption from nutrition labeling.

Subpart Y—Nutrition Labeling

§ 381.400 Nutrition labeling of poultry products.

(a) Nutrition labeling shall be provided for all poultry products, except single-ingredient, raw products, in accordance with the requirements of § 381.409, except as exempted under § 381.500 of this subpart.

(b) Nutrition labeling may be provided for single-ingredient, raw poultry products in accordance with the requirements of §§ 381.409 and 381.445. Significant participation in voluntary nutrition labeling shall be measured by the Agency in accordance with §§ 381.443 and 381.444 of this subpart.

§ 381.401 [Reserved]

§ 381.402 Location of nutrition information.

(a) Nutrition information on a label of packaged poultry products shall appear on the label's principal display panel or on the information panel, except as provided in paragraph (b) of this section.

(b) Nutrition information for gift packs may be shown at a location other than on the product label, provided that the labels for these products bear no nutrition claim. In lieu of on the product label, nutrition information may be provided by alternate means such as product label inserts.

§§ 381.403–381.407 [Reserved]

§ 381.408 Labeling of poultry products with number of servings.

The label of any package of a poultry product that bears a representation as to the number of servings contained in such package shall meet the requirements of § 381.121(c)(7).

§ 381.409 Nutrition label content.

(a)(1) All nutrient and product component quantities shall be declared in relation to a serving or to a portion, as defined in 21 CFR 101.9(b) (1) and (2) except (b)(2)(i), and 21 CFR 101.9(b) (5) through (9) except (b)(5)(iii).

(2) The declaration of nutrient and product component content shall be on the basis of the product "as packaged" for all products, except that single-ingredient, raw products may be declared on the basis of the product "as consumed" as set forth in § 381.445(a)(1). In addition to the required declaration on the basis of "as packaged" for products other than single-ingredient, raw products, the declaration may also be made on the basis of "as consumed," provided that preparation and cooking instructions are clearly stated.

(3) For products in discrete units (e.g., chicken wings, chicken breasts, and individually packaged products within a multi-serving package), serving size shall be the number of whole units that most closely approximates the Reference Amount for the Product Category. If a unit weighs 67 percent or more, but less than 200 percent of the Reference Amount, serving size shall be one unit. If a unit weighs more than 50 percent but less than 67 percent of the Reference Amount, the manufacturer may decide whether one unit is one

serving. If a unit weighs 200 percent or more of the Reference Amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion.

(4) Serving size for meal-type products as defined in § 381.413(l) shall be the entire content (edible portion only) of the package.

(5) Another column of figures may be used to declare the nutrient and food component information, in the same format as required by § 381.408(e).

(i) Per 100 grams, 100 milliliters, or 1 ounce of the food as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multi-serving container is more than one unit.

(6) If cups, tablespoons and teaspoons, or units such as piece, slice, tray, jar, or fraction are not applicable, ounces may be used. Ounce measurements shall be expressed in 0.5 ounce increments most closely approximating the Reference Amount, with rounding indicated by use of the term "about" (e.g., about 2.5 ounces).

(b) The declaration of nutrition information on the label shall contain the following information, except for that which is identified as "VOLUNTARY" or for those poultry products where a simplified format may be used as provided for in paragraph (g) of this section or as in § 381.500(b). No nutrients or food components, other than those listed in 21 CFR 101.9(c) as either voluntary or mandatory, except for stearic acid, may be included within the nutrition label. Information shall be presented using the nutrient names specified and in the formats specified in paragraph (e) of this section. Definitions, units of measure, increments for declaring values, and methods of calculation shall be in accordance with 21 CFR 101.9 (c)(1) through (c)(9), except 21 CFR 101.9(c)(1)(i)(E), bomb calorimetry, and 21 CFR 101.9(c)(7)(ii) use of nitrogen conversion factors, other than 6.25.

(c)(1) If a product consists of assortments of poultry products (e.g., variety packs) in the same package, nutrient content shall be expressed on the entire package contents or on each individual product.

(2) If a product is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare the nutrient contents on the basis of the product as consumed for the product alone (e.g., a cream soup mix may be labeled with one set of Daily Values for the dry mix (per serving), and another set for the serving of the final soup when prepared (e.g., per serving of cream soup mix and 1 cup of vitamin D fortified whole milk)): *Provided,* that the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(d) "Stearic acid" may be declared "VOLUNTARY." If stearic acid is declared "VOLUNTARY" a statement of the number of grams of stearic acid shall be included under saturated fat content and expressed to the nearest 0.5 (½) gram incremented below 3 grams and to the nearest gram increment above 3 grams.

(e) Formats for nutrition labeling shall be in accordance with 21 CFR 101.9 (d) and (e) except for references to (f), (j)(5), and (j)(13), or in accordance with paragraph (g)(1) of this section.

(f) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (b), (e), and (g) of this section and 381.402(a) by one or more of the following means:

(1) Presenting the required nutrition information in a tabular or linear (i.e., string) fashion, rather than in vertical columns, if the package shape or size cannot accommodate a column display on any label panel. Nutrition information may be given in a linear fashion only if the label will not accommodate a *tabular display and, in that case, subcomponents (e.g., saturated fat shall be declared in parentheses after total fat).*

(2) Using any of the following abbreviations:

Serving size—Serv. size
Servings per container—Servings
Calories from fat—Fat cal
Saturated fat—Sat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber

(3) Omitting the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of 21 CFR 101.9 and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value," and

(4) Presenting the required nutrition information on any other label panel.

(g)(1) Nutrition information may be presented in a simplified format as set forth herein when any required nutrients, other than the core nutrients, are present in insignificant amounts. An insignificant amount shall be defined as that amount that may be rounded to zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount less than 1 gram.

(2) The simplified format shall include: Serving size, number of servings per container, calories, total fat (grams), total carbohydrate (grams), protein (grams), and sodium (milligrams).

(3) Any nutrient, other than a core nutrient, that is present in an insignificant amount may be omitted from the tabular listing, provided that the following statement is included within the nutrition label, "Not a significant source of _____." The blank shall be filled in with the appropriate nutrient or food component.

(4) The omission of the listing of daily values and the caloric conversion information, and the expression of the percent of daily value in the simplified format shall be in accordance with 21 CFR 101.9(f)(5), except for references to (j)(5) and (j)(13).

(h) Compliance with this section shall be determined as follows:

(1) A production lot is a set of food production consumer units that are from one production shift. Alternatively, a collection of consumer units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, constitutes a production lot.

(2) The sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each from a production lot. Alternatively, the sample for nutrient analysis shall consist of a composite of a minimum of six consumer units, each randomly chosen to be representative of a production lot. In each case, the units may be individually analyzed and the results of the analyses averaged, or the units would be composited and the composite analyzed. In both cases, the results, whether an average or a single result from a composite, will be considered by the Agency to be the nutrient content of a composite. All analyses shall be performed by appropriate methods and procedures used by the Department for each nutrient in accordance with the "Chemistry Laboratory Guidebook," or, if no USDA method is available and appropriate for the nutrient, by appropriate methods for the nutrient in accordance with the 1990 edition of the "Official Methods of Analysis" of the AOAC International, formerly Association of Official Analytical

Chemists, 15th ed., which is incorporated by reference, unless a particular method of analysis is specified in § 381.409(b), or, if no USDA, AOAC, or specified method is available and appropriate, by other reliable and appropriate analytical procedures as so determined by the Agency. The "Official Methods of Analysis" is incorporated as it exists on the date of approval. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be purchased from the AOAC International, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201. It is also available for inspection at the Office of the Federal Register Information Center, suite 700, 800 North Capitol Street, NW., Washington, DC.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) Class I. Added nutrients in fortified or fabricated foods; and

(ii) Class II. Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to Class II requirements unless the same nutrient is also added, which would make the total amount of such nutrient subject to Class I requirements.

(4) A product with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) unless it meets the following requirements:

(i) Class I vitamin, mineral, protein, dietary fiber, or potassium. The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium. The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(5) A product with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 4(h) of the Poultry Products Inspection Act (21 U.S.C. 453(h)(4)) if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label; *Provided*, That no regulatory action will be based on a determination of a nutrient value which falls below this level by an amount less than the variability generally recognized for the analytical method used in that product at the level involved, and inherent nutrient variation in a product.

(6) The amount of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium may vary over labeled amounts within good manufacturing practice. The amount of calories, sugars, total fat, saturated fat, cholesterol, or sodium may vary under labeled amounts within good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) The management of the establishment must maintain records to support the validity of nutrient declarations contained on product labels. Such records shall be made available to the inspector or any duly authorized representative of the Agency upon request.

(9) The compliance provisions set forth in paragraph (h)(1) through (8) of this section shall not apply to single-ingredient, raw poultry products, including those that have been previously frozen, when nutrition labeling is based on the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series.

§ 381.410 [Reserved]

§ 381.411 [Reserved]

§ 381.412 Reference amounts customarily consumed per eating occasion.

(a) The general principles followed in arriving at the Reference Amounts for serving (portion) sizes set forth in paragraph (b) of this section are found in 21 CFR 101.12(a), (c), (d) and (g).

(b) The following Product Categories and Reference Amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—INFANT AND TODDLER FOODS [1,2,3]

Product category	Reference amount
Infant & Toddler Foods:	
Dinner Dry Mix	15 g
Dinner, ready-to-serve, strained type	60 g
Dinner, soups, ready-to-serve junior type	110 g
Dinner, stew or soup ready-to-serve toddlers	170 g

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the Reference Amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve). If not listed separately, the Reference Amount for the unprepared form (e.g., dehydrated cereal) is the amount required to make one Reference Amount of the prepared form.

[3] Manufacturers are required to convert the Reference Amount to the label serving size in a household measure most appropriate to their specific product using the procedures established by the regulation.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]

Product category	Reference	Reference
	Ready-to-serve	Ready-to-cook
Egg mixtures, (western style omelet, souffle, egg foo young with poultry)	110 g	n/a
Salad and potato toppers; e.g., poultry bacon bits	7 g	n/a
Bacon; e.g., poultry breakfast strips	15 g	26 g = bacon. 18 g = breakfast strips
Dried; e.g., poultry jerky, dried poultry, poultry sausage products with a moisture/protein ratio of less than 2:1	30 g	n/a
Snacks; e.g., poultry snack food sticks	30 g	n/a
Luncheon products, poultry bologna, poultry Canadian style bacon, poultry crumbles, poultry luncheon loaf, potted poultry products, poultry taco fillings.	55 g	n/a
Linked poultry sausage products, poultry franks, poultry Polish sausage, smoked or pickled poultry meat, poultry smoked sausage.	55 g	n/a 69 g = uncooked sausage.

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION—GENERAL FOOD SUPPLY [1,2,3,4,5]—Continued

Product category	Reference Ready-to-serve	Reference Ready-to-cook
Entrees without sauce, poultry cuts, ready to cook poultry cuts, including marinated, tenderized, injected cuts of poultry, poultry corn dogs, poultry bagel dogs, poultry croquettes, poultry fritters, cured poultry ham products, adult pureed poultry.	85 g	106 g
Canned poultry, canned chicken, canned [4] turkey	55 g	n/a
Entrees with sauce, turkey and gravy	140 g	n/a
Mixed dishes NOT measurable with a cup; [5] e.g., poultry burrito, poultry enchiladas, poultry pizza, poultry quiche, all types of poultry sandwiches, cracker and poultry lunch-type packages, poultry gyro, poultry stromboli, poultry frank on a bun, poultry burger on a bun, poultry taco, chicken cordon bleu, poultry calzone, poultry lasagna, stuffed vegetables with poultry, poultry kabobs.	140 g (plus 55 g for products toppings)	n/a
Mixed dishes, measurables with a cup; e.g., poultry casserole, macaroni and cheese with poultry, poultry pot pie, poultry spaghetti with sauce, poultry chili, poultry chili with beans, poultry hash, creamed dried poultry, poultry ravioli in sauce, poultry a la king, poultry stew, poultry goulash.	1 cup	n/a
Salads—pasta or potato, potato salad with poultry, macaroni and poultry salad	140 g	n/a
Salads—all other, poultry salads, chicken salad, turkey salad	100 g	n/a
Soups—all varieties	245 g	n/a
Major main entree type sauce; e.g., spaghetti sauce with poultry	125 g	n/a
Minor main entree sauce; e.g., pizza sauce with poultry, gravy	¼ cup	n/a
Seasoning mixes dry, freeze dry, dehydrated, concentrated soup mixes, bases, extracts, dried broths and stock/juice, freeze dry trail mix products with poultry.		
As reconstituted: Amount to make one Reference Amount of the final dish; e.g.—		
Gravy	¼ cup	n/a
Major main entree type sauce	125 g	n/a
Soup	245 g	n/a
Entree measurable with a cup	1 cup	n/a

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–78 and the 1987–88 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Manufacturers are required to convert the Reference Amounts to the label serving size in a household measure most appropriate to their specific product using the procedures established by regulation.
[3] Examples listed under Product Category are not all inclusive or exclusive. Examples are provided to assist manufacturers in identifying appropriate product Reference Amount.
[4] If packed or canned in liquid, the Reference Amount is for the drained solids.
[5] Pizza sauce is part of the pizza and is not considered to be a sauce topping.

(c) The Reference Amount for products that represent two or more foods packaged and presented to be consumed together (e.g., lunch meat, cheese, and crackers) shall be the sum of the Reference Amounts for individual foods in the package if the Reference Amount is not listed in section (b) of this section and the product is not a meal-type product.

(d) The Administrator, on his or her own initiative or on behalf of any interested person who has submitted a labeling application, may issue a proposal to establish or amend a Product Category or Reference Amount identified in paragraph (b) of this section.

(1) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(2) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(3) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in subchapter D, title 9.

(4) Data accompanying the labeling application, such as food consumption data, shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(5) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(6) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(7) Labeling applications for a new Reference Amount and/or Product Category shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.412 with respect to Reference Amount and/or Product Category.

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement of the objective of the labeling application;

(ii) A description of the product;

(iii) A complete sample product label including nutrition label, using the format established by regulation;

(iv) A description of the form in which the product will be marketed;

(v) The intended dietary uses of the product with the major use identified (e.g., turkey as a luncheon meat);

(vi) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(vii) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(viii) The names of the most closely-related products (or in the case of foods for special

dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(ix) The suggested Reference Amount (the amount of edible portion of food as consumed, excluding bone, skin or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested Reference Amount. In determining the Reference Amount, general principles and factors in paragraph (a) of this section should be followed.

(x) The suggested Reference Amount shall be expressed in metric units. Reference Amounts for foods shall be expressed in grams except when common household units such as cups, tablespoons, and teaspoons are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as mixed dishes measurable with a cup.

(A) In expressing the Reference Amount in grams, the following general rules shall be followed:

(*1*) For quantities greater than 10 grams, the quantity shall be expressed in nearest 5 grams increment.

(*2*) For quantities less than 10 grams, exact gram weights shall be used.

(B) [Reserved]

(xi) A labeling application for a new subcategory of food with its own Reference Amount shall include the following additional information:

(A) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the Reference Amount for the parent category to warrant a separate Reference Amount. Data must include sample size, and the mean, standard deviation, median, and modal consumed amount per eating occasion for the product identified in the labeling application and for other products in the category. All data must be derived from the same survey data.

(B) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the product identified in the labeling application from the rest of the products in the category.

(xii) In conducting research to collect or process food consumption data in support of the labeling application, the following general guidelines should be followed.

(A) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(B) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(C) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(D) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(xiii) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(8) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(9) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(10) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed Reference Amount and/or Product Category is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(11) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the Reference Amount and/or Product Category. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed Reference Amount and/or Product Category. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed Reference Amount and/or Product Category shall be approved for use on the labeling of poultry products.

(i) If the Reference Amount and/or Product Category is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the Reference Amount and/or Product Category on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed Reference Amount and/or Product Category.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with

the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia.

(ii) If the Reference Amount and/or Product Category is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the Reference Amount and/or Product Category.

§ 381.413 Nutrient content claims; general principles.

(a) This section applies to poultry products that are intended for human consumption and that are offered for sale, except that nutrient content claims may not be made on products intended specifically for use by infants and toddlers less than 2 years of age.

(b) A claim, which expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling pursuant to § 381.409, may not be made on a label or in labeling of that product unless the claim is made in accordance with 21 CFR 101.13(b) through (f).

(c) through (h) [Reserved]

(i) The labeling of a product may contain a statement about the amount or percentage of a nutrient in accordance with 21 CFR 101.13(i) (1) through (3).

(j) Products may bear a statement that compares the level of a nutrient in the product with the level of a nutrient in a reference food in accordance with 21 CFR 101.13(j), except comparison to another manufacturer at 21 CFR 101.13(j)(1)(ii)(B).

(k) The term "modified" may be used in the statement of identity of a product in accordance with 21 CFR 101.13(k).

(l) For purposes of making a claim, a "meal-type product" shall be defined as a product that:

(1) Makes a significant contribution to the diet by weighing at least 6 ounces, but no more than 12 ounces per serving (container), and

(2) Contains ingredients from two or more of the following four food groups:

(i) Bread, cereal, rice and pasta group,

(ii) Fruits and vegetables group,

(iii) Milk, yogurt, and cheese group, and

(iv) Meat, poultry, fish, dry beans, eggs, and nuts group, and

(3) Is represented as, or is in a form commonly understood to be a breakfast, lunch, dinner, meal, main dish, entree, or pizza. Such representations may be made either by statements, photographs, or vignettes.

(m) [Reserved]

(n) Nutrition labeling in accordance with § 381.409 shall be provided for any food for which a nutrient content claim is made.

(o) Compliance with requirements for nutrient content claims shall be in accordance with § 381.409(h).

(p) The Reference Amount shall be used to determine whether a product meets the criteria for a nutrient content claim as discussed in 21 CFR 101.13(p)(1).

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that appear as part of a brand name that was in use prior to November 27, 1991, may continue to be used as part of that brand name, provided they are not false or misleading under section 4(h) of the Act (21 U.S.C. 453(h)(4)).

(2) [Reserved]

(3) A statement that describes the percentage of a vitamin or mineral in the food in relation to a reference daily intake (RDI) as defined in 21 CFR 101.9(c) may be made on the label.

(4) The requirements of this section do not apply to products for special dietary use as described in § 381.124.

(5) [Reserved]

(6) Nutrient content claims that were part of the name of a product that was subject to a standard of identity as of November 27, 1991, are not subject to the requirements of paragraph (b) of this section whether or not they meet the definition of the descriptive term.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by FSIS. Labeling applications requesting approval of such a claim may be submitted pursuant to § 381.469.

§ 381.414–381.442 [Reserved]

§ 381.443 Significant participation for voluntary nutrition labeling.

(a) In evaluating significant participation for voluntary nutrition labeling, FSIS will consider only the major cuts of single-ingredient, raw poultry products, as identified in § 381.444, including those that have been previously frozen.

(b) FSIS will judge a food retailer to be participating at a significant level if the retailer provides nutrition labeling information for at least 90 percent of the major cuts of single-ingredient, raw poultry products, listed in § 381.444, that it sells, and if the nutrition label is consistent in content and format with the mandatory program, or nutrition information is displayed at point-of-purchase in an appropriate manner.

(c) To determine whether there is significant participation by retailers under the voluntary nutrition labeling guidelines, FSIS will select a representative sample of companies allocated by type and size.

(d) FSIS will find that significant participation by food retailers exists if at least 60 percent of all companies that are evaluated are participating in accordance with the guidelines.

(e) FSIS will evaluate significant participation of the voluntary program every 2 years beginning in May 1995.

(1) If significant participation is found, the voluntary nutrition labeling guidelines shall remain in effect.

(2) If significant participation is not found, FSIS shall initiate rulemaking to require nutrition labeling on those products under the voluntary program.

§ 381.444 Identification of major cuts of poultry products.

The major cuts of single-ingredient, raw poultry products are: Whole chicken (without neck and giblets), chicken breast, chicken wing, chicken drumstick, chicken thigh, whole turkey (without necks and giblets; separate nutrient panels for white and dark meat permitted as an option), turkey breast, turkey wing, turkey drumstick, and turkey thigh.

§ 381.445 Guidelines for voluntary nutrition labeling of single-ingredient, raw products.

(a) Nutrition information on the cuts of single-ingredient, raw poultry products, including those that have been previously frozen, shall be provided in the following manner:

(1) If a retailer chooses to provide nutrition information on the label of these products, these products shall be subject to all requirements of the mandatory nutrition labeling program, except that nutrition labeling may be declared on the basis of either "as consumed" or "as packaged." In addition, the declaration of the number of servings per container need not be included in nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen.

(2) If a retailer chooses to provide nutrition information at the point-of-purchase by an appropriate means, such as by posting a sign, or by making the information readily available in brochures, notebooks, or leaflet form in close proximity to the food. If a nutrition claim is made on point-of-

purchase materials all of the requirements of the mandatory nutrition labeling program apply. However, if only nutrition information—and not a nutrition claim—is supplied on point-of-purchase materials:

(i) The requirements of the mandatory nutrition labeling program apply, but the nutrition information may be supplied on an "as packaged" or "as consumed," basis;

(ii) The listing of DRV's may be voluntary; and

(iii) The point-of-purchase materials are not subject to any of the format requirements. The nutrition labeling information may also be supplemented by a video, live demonstration, or other media.

(b) [Reserved]

(c) The declaration of nutrition information may be presented in a simplified format as specified in § 381.409(g) for the mandatory nutrition labeling program.

(d) The nutrition label data should be based on either raw or cooked edible portions of poultry cuts with skin. If data are based on cooked portions, the methods used to cook the products must be specified and should be those which do not add nutrients from other ingredients such as flour, breading, and salt. Additional nutritional data may be presented on an optional basis for the raw or cooked edible portions of the skinless poultry meat.

(e) Nutrient data that are the most current representative data base values contained in USDA's National Nutrient Data Bank or its published form, the Agriculture Handbook No. 8 series, may be used for nutrition labeling of single-ingredient, raw poultry products, including those that have been previously frozen. These data may be composite data that reflect different classes of turkey or other variables affecting nutrient content. Alternatively, data that reflect specific classes or other variables may be used, except that if data are used on labels attached to a product which is labeled as to class of poultry or other variables, the data must represent the product in the package when such data are contained in the representative data base. When data are used on labels attached to a product, the data must represent the edible poultry tissues present in the package.

(f) If the nutrition information is in accordance with paragraph (e) of this section, a nutrition label or labeling will not be subject to the Agency compliance review under § 381.409(h), unless a nutrition claim is made on the basis of the representative data base values.

(g) Retailers may use data bases that they believe reflect the nutrient content of single-ingredient, raw poultry products, including those that have been previously frozen; however, such labeling shall be subject to the compliance procedures of paragraph (e) of this section and the requirements specified in this Subpart for the mandatory nutrition labeling program.

§§ 381.446–381.453 [Reserved]

§ 381.454 Nutrient content claims for "good source" and "high".

Nutrient content claims about a nutrient in a product in relation to the Reference Daily Intake (RDI) established for that nutrient in 21 CFR 101.9(c)(11)(iv) or Daily Reference Value (DRV) established for that nutrient in 21 CFR 101.9(c)(12)(i), excluding total carbohydrate and unsaturated fatty acids, may be used on the label or in labeling, in accordance with 21 CFR 101.54(a) through (d).

§ 381.455 [Reserved]

§ 381.456 Nutrient content claims for "light" or "lite".

(a) *General requirements.* The following nutrient content claims using the term "light" or "lite" to describe a product may be used on the label and in labeling, provided that the product is labeled in compliance with 21 CFR 101.56.

(b) The term "light" or "lite" may be used in the brand name of foods to describe the sodium content, provided that:

(1) The product meets the sodium criteria provided in paragraph (a) of this section, and

(2) A statement specifically stating that the product is "light in sodium" or "lite in sodium" appears:

(i) Contiguous to the brand name;

(ii) In uniform type size, style, color, and prominence as the product name; and

(iii) The "light in sodium" or "lite in sodium" statement complies with paragraph (a) of this section.

§§ 381.457–381.459 [Reserved]

§ 381.460 Nutrient content claims for calorie content.

Nutrient content claims about the calorie content of a product may be used on the label or in labeling in accordance with 21 CFR 101.60 (a) through (c).

§ 381.461 Nutrient content claims for sodium content.

Nutrient content claims about the sodium content of a product may be used on the label and in labeling in accordance with 21 CFR 101.61 (a) and (b).

§ 381.462 Nutrient content claims for fat, fatty acids, and cholesterol content of poultry products.

(a) A claim about the level of fat, fatty acid, and cholesterol in a poultry product may only be made on the label and in the labeling of the product in accordance with 21 CFR 101.62 (a) through (d), except 21 CFR 101.62 (c), (d)(1)(i), (d)(1)(ii) (A) through (D), (d)(2)(i), (d)(2)(ii) (A) through (D), (d)(4)(i), (d)(4)(ii) (A) through (D), (d)(5)(i), and (d)(5)(ii) (A) through (D).

(b) The term "low in cholesterol" or "low cholesterol" may be used on the label or in labeling of a meal-type product as defined in § 381.413, provided that the product meets the requirements of 21 CFR 101.62(d)(2), except that requirements of 21 CFR 101.62 (d)(2) (i)(A) and (ii)(A) shall be limited to 20 milligrams of cholesterol per 100 grams, and the requirements of 21 CFR 101.62(d)(2) (i)(B) and (ii)(B) shall be modified to require that the product contain 2 grams or less of saturated fat per 100 grams.

(c) "Lean" and "Extra Lean" Claims. The following nutrient content claims may be used on the label or in labeling, provided that the product is labeled in accordance with § 381.409, and the nutrient content claim complies with § 381.413:

(1) The term "lean" may be used on the label or in labeling of a poultry product, provided that the product contains less than 10 grams fat, less than 4 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and labeled serving size for meal-type products.

(2) The term "extra lean" may be used on the label or in labeling of a poultry product, provided that the product contains less than 5 grams fat, less than 2 grams saturated fat, and less than 95 milligrams cholesterol per 100 grams and Reference Amount Customarily Consumed (RACC) for individual foods, and per 100 grams and per labeled serving size for meal-type products.

§§ 381.463–381.468 [Reserved]

§ 381.469 Labeling applications for nutrient content claims.

(a) This section pertains to labeling applications for claims, express or implied, that characterize the level of any nutrient required to be on the label or in labeling of product by this subpart.

(b) Labeling applications included in this section are:

(1) Labeling applications for a new (heretofore unauthorized) nutrient content claim,

(2) Labeling applications for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient, and

(3) Labeling applications for the use of an implied claim in a brand name.

(c) Labeling applications and supporting documentation to be filed under this section shall be submitted in quadruplicate, except that the supporting documentation may be submitted on a computer disc copy. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The labeling application shall state the applicant's post office address.

(d) Pertinent information will be considered as part of an application on the basis of specific reference to such information submitted to and retained in the files of the Food Safety and Inspection Service. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies accompany a labeling application, the applicant shall include, with respect to each nonclinical study included with the application, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of Chapter 1, Title 21, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations accompany a labeling application, the applicant shall include, with respect to each clinical investigation included with the application, either a statement that the investigation was conducted in compliance with the requirements for institutional review set forth in Part 56 of Chapter 1, Title 21, or was not subject to such requirements in accordance with § 56.194 or § 56.105, and that it was conducted in compliance with the requirements for informed consents set forth in Part 50 of Chapter 1, Title 21.

(g) The availability for public disclosure of labeling applications, along with supporting documentation, submitted to the Agency under this section will be governed by the rules specified in Subchapter D, Title 9.

(h) The data specified under this section to accompany a labeling application shall be submitted on separate sheets, suitably identified. If such data has already been submitted with an earlier labeling application from the applicant, the present labeling application must provide the data.

(i) The labeling application must be signed by the applicant or by his or her attorney or agent, or (if a corporation) by an authorized official.

(j) The labeling application shall include a statement signed by the person responsible for the labeling application, that to the best of his or her knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him or her pertinent to the evaluation of the labeling application.

(k)(1) Labeling applications for a new nutrient content claim shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the nutrient content claim and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement shall address why the use of the term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify the level at which the nutrient must be present or what other conditions concerning the product must be met for the appropriate use of the term in labels or labeling, as well as any factors that would make the use of the term inappropriate.

(ii) A detailed explanation supported by any necessary data of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed and why such benefit is not available through the use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, and scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

(iii) Analytical data that demonstrates the amount of the nutrient that is present in the products for which the claim is intended. The assays should be performed on representative samples in accordance with 381.409(h). If no USDA or AOAC methods are available, the applicant shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data shall include a statistical analysis of the analytical and product variability.

(iv) A detailed analysis of the potential effect of the use of the proposed claim on food consumption, and any corresponding changes in nutrient intake. The analysis shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and

files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish in the **Federal Register** a proposed rule to amend the regulations to authorize the use of the nutrient content claim. The proposal shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's proposed rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the proposed nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the proposed nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a final rule amending the regulations to authorize the use of the claim.

(l)(1) Labeling applications for a synonymous term shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under subpart Y of part 381).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the synonymous term, the existing term defined by a regulation with which the synonymous term is claimed to be consistent, and the nutrient that the term is intended to characterize the level of. The statement shall address why the use of the synonymous term as proposed will not be misleading. The statement shall provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of products on which the claim will be used. The statement shall also specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

(ii) A detailed explanation supported by any necessary data of why use of the proposed term is requested, including whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through use of existing terms defined by regulation. If the claim is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group, scientific data sufficient for such purpose, and data and information to the extent necessary to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use.

Yours very truly,

Applicant _____

By _____

(Indicate authority)

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed synonymous term is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed synonymous term.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the

Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the claim is approved, the Agency shall notify the applicant, in writing, and shall publish in the **Federal Register** a notice informing the public that the synonymous term has been approved for use.

(m)(1) Labeling applications for the use of an implied nutrient content claim in a brand name shall be accompanied by the following data which shall be submitted in the following form to the Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, Washington, DC 20250:

(Date)

The undersigned, _____ submits this labeling application pursuant to 9 CFR 381.469 with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, or on a computer disc copy, and constituting a part of this labeling application, are the following:

(i) A statement identifying the implied nutrient content claim, the nutrient the claim is intended to characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation, and the brand name of which the implied claim is intended to be a part. The statement shall address why the use of the brand-name as proposed will not be misleading. The statement shall provide examples of the types of products on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food would qualify the label of the product to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient shall meet the requirements stated under labeling application format in paragraph (k)(1)(iii) of this section.

(ii) A detailed explanation supported by any necessary data of why use of the proposed brand name is requested. This explanation shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis shall specifically address nutritional needs of such group and scientific data sufficient for such purpose.

Yours very truly,
Applicant _____
By _____

(2) Upon receipt of the labeling application and supporting documentation, the applicant shall be notified, in writing, of the date on which the labeling application was received. Such notice shall inform the applicant that the labeling application is undergoing Agency review and that the applicant shall subsequently be notified of the Agency's decision to consider for further review or deny the labeling application.

(3) Upon review of the labeling application and supporting documentation, the Agency shall notify the applicant, in writing, that the labeling application is either being considered for further review or that it has been summarily denied by the Administrator.

(4) If the labeling application is summarily denied by the Administrator, the written notification shall state the reasons therefor, including why the Agency has determined that the proposed implied nutrient content claim is false or misleading. The notification letter shall inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(i) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(ii) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(5) If the labeling application is not summarily denied by the Administrator, the Administrator shall publish a notice of the labeling application in the **Federal Register** seeking a comment on the use of the implied nutrient content claim. The notice shall also summarize the labeling application, including where the supporting documentation can be reviewed. The Administrator's notice rule shall seek comment from consumers, the industry, consumer and industry groups, and other interested persons on the labeling application and the use of the implied nutrient content claim. After public comment has been received and reviewed by the Agency, the Administrator shall make a determination on whether the implied nutrient content claim shall be approved for use on the labeling of poultry products.

(i) If the claim is denied by the Administrator, the Agency shall notify the applicant, in writing, of the basis for the denial, including the reason why the claim on the labeling was determined by the Agency to be false or misleading. The notification letter shall also inform the applicant that the applicant may submit a written statement by way of answer to the notification, and that the applicant shall have the right to request a hearing with respect to the merits or validity of the Administrator's decision to deny the use of the proposed implied nutrient content claim.

(A) If the applicant fails to accept the determination of the Administrator and files an answer and requests a hearing, and the Administrator, after review of the answer, determines the initial determination to be correct, the Administrator shall file with the Hearing Clerk of the Department the notification, answer, and the request for a hearing, which shall constitute the complaint and answer in the proceeding, which shall thereafter be conducted in accordance with the Department's Uniform Rules of Practice.

(B) The hearing shall be conducted before an administrative law judge with the opportunity for appeal to the Department's Judicial Officer, who shall make the final determination for the Secretary. Any such determination by the Secretary shall be conclusive unless, within 30 days after receipt of the notice of such final determination, the applicant appeals to the United States Court of Appeals for the circuit in which the applicant has its principal place of business or to the United States Court of Appeals for the District of Columbia Circuit.

(ii) If the claim is approved, the Agency shall notify the applicant, in writing, and shall also publish in the **Federal Register** a notice informing the public that the implied nutrient content claim has been approved for use.

§ 381.470–381.479 [Reserved]

§ 381.480 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any product that purports to be or is represented for special dietary use because of usefulness in reducing body weight shall bear:

(1) Nutrition labeling in conformity with § 381.409 of this subpart, unless exempt under that section, and

(2) A conspicuous statement of the basis upon which the product claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any product subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary product may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the product under the applicable law and regulations of this chapter. Any product that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener; e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A product purporting to be "low calorie" must comply with the criteria set forth for such foods in § 381.460(b) (2) and (3).

(d) *"Reduced calorie" foods and other comparative claims.* A product purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such foods in § 387.460(b) (4) and (5).

§§ 381.481–381.499 [Reserved]

§ 381.500 Exemption from nutrition labeling.

(a) The following poultry food products are exempt from nutrition labeling:

(1) Products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information,

(i) A food product, for purposes of the small business exemption, is defined as a formulation, not including distinct flavors which do not significantly alter the nutritional profile, sold in any size package in commerce.

(ii) For purposes of this paragraph, a small business is any single-plant facility or multi-plant company/firm that employs 500 or fewer people and produces no more than the following amounts of pounds of the product qualifying the firm for exemption from this subpart:

(A) During the first year of implementation of nutrition labeling, from July 1994 to July 1995, 250,000 pounds or less,

(B) During the second year of implementation of nutrition labeling, from July 1995 to July 1996, 175,000 pounds or less, and

(C) During the third year of implementation and subsequent years thereafter, 100,000 pounds or less.

(2) Products intended for further processing, provided that the labels for these products bear no nutrition claims or nutrition information,

(3) Products that are not for sale to consumers, provided that the labels for these products bear no nutrition claims or nutrition information,

(4) Products in small packages that are individually wrapped packages of less than ½ ounce net weight, provided that the labels for these products bear no nutrition claims or nutrition information,

(5) Products custom slaughtered or prepared,

(6) Products intended for export, and

(7) The following products prepared and served or sold at retail provided that the labels or the labeling of these products bear no nutrition claims or nutrition information:

(i) Ready-to-eat products that are packaged or portioned at a retail store or similar retail-type establishment; and

(ii) Multi-ingredient products (e.g. sausage) processed at a retail store or similar retail-type establishment.

(b) Restaurant menus generally do not constitute labeling or fall within the scope of these regulations.

(c) Foods represented to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except such labeling shall not include calories from fat, calories from saturated fat, saturated fat, polyunsaturated fat, monounsaturated fat, and cholesterol. Foods represented to be specifically for infants and children less than 4 years of age shall bear nutrition labeling, except that such labeling shall not include listings of percent of daily value and the daily value list. Nutrient names and quantitative amounts by weight shall be presented in two separate columns.

Done at Washington, DC, on: December 24, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 93–29 Filed 1–5–93; 8:45 am]

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Part III

Department of Agriculture

Food Safety and Inspection Service

9 CFR Parts 317 and 381

Nutrition Labeling: Use of "Healthy" and Similar Terms on Meat and Poultry Product Labeling; Proposed Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317 and 381

[Docket No. 91-006P-HLTH]

RIN 0583-AB34

Nutrition Labeling: Use of "Healthy" and Similar Terms on Meat and Poultry Product Labeling

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service is proposing to amend the Federal meat and poultry products inspection regulations to permit the use of the term "healthy" or any other derivative of the term "healthy," such as "healthful" or "healthier," on the labeling of meat and poultry products. FSIS is engaging in rulemaking proceedings to establish nutrition labeling regulations for meat and poultry products. This action is intended to provide consumers with accurate, informative labeling on meat and poultry products.

DATES: Comments must be received on or before February 5, 1993.

ADDRESSES: Written comments to: Policy Office, ATTN: Linda Carey, FSIS Hearing Clerk, Room 3171, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments as provided by the Poultry Products Inspection Act should be directed to: Mr. Charles R. Edwards at (202) 205-0080. (See also "Comments" under "SUPPLEMENTARY INFORMATION.")

FOR FURTHER INFORMATION CONTACT: Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 205-0080.

SUPPLEMENTARY INFORMATION: The Agency advises that it intends to make any final rule that derives from this rulemaking effective the same effective date as the final rule titled, "Nutrition Labeling of Meat and Poultry Products" (published elsewhere in this issue of the Federal Register). If, for some reason, a final rule on "healthy" and similar terms is not issued in time to meet the same effective date as FSIS's final rule on nutrition labeling, the use of "healthy" and similar terms would be subject to the nutrient content claim provisions set forth in the final rule on nutrition labeling.

Executive Order 12291 and Effect on Small Entities

FSIS is publishing elsewhere in this issue of the Federal Register a final rule on nutrition labeling of meat and poultry products. The rule was reviewed under USDA procedures established to implement Executive Order 12291 and was classified as a major rule pursuant to section 1(b)(1) of that order because it is likely to result in an annual effect on the economy of $100 million or more. The review is reported in a Final Regulatory Impact Analysis (FRIA) which is available for review in the FSIS Hearing Clerk's office. The FRIA also satisfies the analysis requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601 *et seq.*) which deals with the effect on small entities.

This proposed rule is one element of the overall nutrition labeling rulemaking which was considered in the FRIA. A summary of the FRIA can be found in the Agency's final rule on nutrition labeling published elsewhere in this issue of the Federal Register.

Executive Order 12778

This proposed rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. This proposed rule seeks comments on provisions for permitting the use of the term "healthy" or any other derivative of the term "health" on the labeling of meat and poultry products.

This proposed rule concerns labeling of meat and poultry products. States and local jurisdictions are preempted under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat or poultry products that are in addition to, or different than, those imposed under the FMIA or the PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and the PPIA, States that maintain meat and poultry inspection programs must impose requirements on State inspected products and establishments that are at least equal to those imposed on federally inspected products and establishments under the FMIA or PPIA. These States may, however, impose more stringent requirements on such State inspected products and establishments.

If adopted, no retroactive effect would be given to this proposed rule, and applicable administrative procedures must be exhausted before any judicial challenge to its provisions or their application. Those administrative procedures are set forth in the rules of practice governing proceedings for labeling determinations at 9 CFR parts 335 and 381, subpart W.

Paperwork Requirements

This proposed rule specifies the regulations permitting the use of the term "healthy," or any other derivative of the term "health" on the labeling of meat and poultry products.

The paperwork requirements contained in this proposed rule were incorporated into the Information Collection Request on Nutrition Labeling of Meat and Poultry Products which has been submitted to the Office of Management and Budget.

Regulatory Reform

Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President's Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the fullest extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Such comments should be addressed to

the Agency as provided in the "Comments" section below.

Comments

Interested persons are invited to submit comments concerning this proposed rule. Written comments should be sent to the Policy Office and refer to Docket No. 91–006P–HLTH. Any person desiring an opportunity for an oral presentation of views as provided by the Poultry Products Inspection Act should make such request to Charles R. Edwards so that arrangements can be made for such views to be presented. A record will be made of all views orally presented. All comments submitted in response to this proposed rule will be available for public inspection in the Policy Office from 9 a.m. to 12:30 p.m. and from 1:30 p.m. to 4 p.m., Monday through Friday.

Background

On November 27, 1991, FSIS published in the **Federal Register** a proposed rule entitled "Nutrition Labeling of Meat and Poultry Products" (56 FR 60302). In addition to proposing specific regulations for nutrition labeling, the Agency solicited comments on the appropriateness and usefulness of the term "healthy" on the labeling of meal-type products, and requested specific information on the criteria for the use of such term. The proposed rule would permit voluntary nutrition labeling on single-ingredient, raw meat and poultry products, and would establish mandatory nutrition labeling for most processed meat and poultry products.

Published elsewhere in this issue of the **Federal Register** is FSIS's final rule on nutrition labeling, which does not contain regulatory provisions covering the use of the term "healthy." Because the public has not been afforded the opportunity to comment on the regulatory provisions proposed herein, FSIS is issuing this proposed rule to allow public comment prior to issuing a final rule. The following discussion addresses the use of the term "healthy" on meat and poultry products, the comments received in response to the proposal relevant to this issue, and the regulatory provisions established to respond to the concerns of the issue.

As previously mentioned, FSIS solicited comments, in its November 1991 proposal, on the use of the term "healthy" on labeling of meal-type products. FSIS stated in the proposal that nutrient content claims not defined by regulation that appear as part of the brand name may be used on the label or in labeling if they are not false or misleading and only if the brand name was in use prior to November 27, 1991 (publication date of the proposal). The term "healthy" was not defined. The Agency specifically solicited comments on how best to determine when a term incorporated into a brand name should be regulated as a nutrient content claim.

FSIS included, in the proposal, examples of products with brand names, trade names, and product lines, that contain nutrient content claims, which may be affected by the proposed rule. The list of examples, which was not all inconclusive, contained 19 such products that include the term "healthy" or a derivative of the term "health," including "Light & Healthy," "Healthy Choice," "LeMenu Healthy," "HealthCheck," "Healthy Deli," and "Lean & Healthy."

The majority of the responses received from FSIS's solicitation for comments on the criteria for the term "healthy" suggested that the term be defined by meeting several criteria. Some comments suggested that the products should qualify if they meet several of the "low" criteria for certain nutrients. Others recommended that the term be equated with controlled amounts of fat, saturated fatty acids, cholesterol, and sodium. A few comments stated that, not only should the term equate controlled amounts of fat, saturated fatty acids, cholesterol, and sodium, use of the term should meet the "high" definition for a certain number of micronutrients.

In its final rule on nutrition labeling, FSIS discusses the rationale and basis for defining the terms "lean" and "extra lean." The primary focus of the Agency's decision to define these terms was to provide meat and poultry products with nutrient content claims that could be used to distinguish between products in that category that contained less fat, saturated fatty acids, and cholesterol. "Lean" is defined for a product that contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, and less than 95 milligrams of cholesterol. The Agency believes that these levels are appropriate "disqualifying" levels (i.e., levels above which would disqualify the food from making a health claim) to apply to the term "healthy" because they are based on dietary recommendations for Americans. Therefore, this proposed rule would permit the term "healthy" to be used on the label of meat and poultry products, provided the product contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, less than 95 milligrams of cholesterol, and less than 480 milligrams of sodium per 100 grams and Reference Amount Customarily Consumed for individual foods, and per 100 grams and labeled serving for meal-type products. In addition, products bearing the term "healthy" must comply with the nutrition label contents prescribed in 9 CFR 317.309 and 381.409, and the labeling of such products must comply with nutrient content claims provisions, prescribed in 9 CFR 317.313 and 381.413 (see FSIS's final rule on nutrition labeling).

On November 27, 1991, the Food and Drug Administration (FDA) also proposed regulations to require nutrition labeling on most foods that are meaningful sources of nutrients, to revise the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, and to establish up-to-date reference standards for those nutrients and food components.

In response to comments received on its general principles proposal, FDA is proposing a definition of the term "healthy," published elsewhere in this issue of the **Federal Register.** As proposed by FDA, uses of the term "healthy" that refer only to general dietary guidance, such as "eat lots of fruits and vegetables for a healthy diet," would not be implied nutrient content claims and would not be subject to any requirements. FDA believes that the term "healthy" constitutes an implied nutrient content claim only when it appears in a nutritional context, such as when the term is associated with an explicit or implicit claim or statement about a nutrient. An example of "healthy" used as an implied claim would be "Healthy, contains 5 grams of fat." The term "healthy," when used in this context, would be subject to a definition under FDA's proposal.

Both FSIS and FDA received comments suggesting that the definition for "healthy" should focus on restrictions for fat, saturated fat, sodium, and cholesterol, because these nutrients are of particular significance to public health. The agencies are tentatively in agreement with these comments and, accordingly, both FSIS and FDA have incorporated these four nutrients into their proposed definitions of "healthy."

Many recommendations for healthy diets from professional health organizations and the U.S. Dietary Guidelines for Americans advise choosing lean meat and poultry as a means of achieving a healthy diet. Food consumption data indicates that 89 percent of Americans eat meat and poultry on a daily basis. In its final rule on nutrition labeling, FSIS provides guidelines for the term "lean" that include restricted levels of fat, saturated fat, and cholesterol. FSIS believes it is

important to convey to consumers consistent dietary messages. Likewise, from a consumer education standpoint, it is essential to communicate analogous messages concerning healthy diets and the role meat and poultry products can play in achieving balanced, healthy diets.

FDA's definition for "healthy" applies to products that do not exceed the disqualifying level for sodium or cholesterol and are low in fat and saturated fat. Many cuts of meat and poultry would not meet such a definition. In order to maintain a consistent dietary message, FSIS believes that linking the definition of "lean" to the definition of "healthy" is an appropriate connection. Therefore, the Agency is proposing to define the term "healthy" with parallel levels for fat, saturated fat, and cholesterol as "lean," above which products would not be eligible for use of the term. In addition, the Agency believes a sodium requirement should be a criterion for eligibility because FSIS agrees with comments received suggesting that sodium be considered in defining "healthy." For the sodium requirement, FSIS is proposing that 480 milligrams would be the limit, parallelling FDA's sodium requirement for individual foods. The levels for the term "healthy" would be applied to both individual foods and meal-type products, with the criterion for individual foods per 100 grams and Reference Amount Customarily Consumed, and per 100 grams and labeled serving for meal-type products. The Agency also believes that any use of the term "healthy," whether in a brand name or used in conjunction with a nutrient, must meet this requirement. The Agency will refer to these levels as "disqualifying" levels.

In comparing the FSIS and FDA disqualifying levels for cholesterol and sodium for individual foods, the sodium levels are the same (480 milligrams); however, the FSIS cholesterol level of 95 milligrams is slightly higher than that of FDA's level of 60 milligrams. The higher cholesterol level is expected for meat and poultry products since these products contain inherent cholesterol, while products regulated by FDA typically contain no cholesterol.

In comparing the FSIS and FDA disqualifying levels for cholesterol and sodium for main dishes, FDA's proposed sodium level of 720 milligrams is one and a half times higher than the level proposed by FSIS, and FDA's cholesterol level (90 milligrams) is similar. FDA's proposed sodium level of 960 milligrams and cholesterol level of 120 milligrams are higher than FSIS's proposed levels for meal-type products. FSIS specifically requests comments on its proposed sodium and cholesterol levels.

Americans are interested in lowering their sodium intake because they are increasingly aware of the role sodium plays in hypertension. Two major public health reports, the Surgeon General's report on "Nutrition and Health" and the National Research Council report "Diet and Health: Implications for Reducing Chronic Disease Risk" identify high blood pressure as one of America's ten major chronic diseases that are affected by daily dietary patterns.

Hypertension is a major risk factor for heart disease, which is the leading cause of death in the U.S., and for stroke, the third most frequent cause of death. In addition, hypertension is also a problem in renal failure. Prevalence of hypertension increases with age in the U.S. population and is higher for black Americans (38 percent) than for white Americans.

Although the link between sodium intake and high blood pressure is not completely understood, a committee of the National Institute of Health's National Heart, Lung and Blood Institute recently issued new recommendations to lower Americans' blood pressure, including drastically reducing daily intake of salt.

The food industry has responded to this consumer interest by the development of a variety of products with lower sodium levels. Since as much as 80 percent of the salt consumed each day by the average American comes from processed foods, it is important to continue to provide incentives to the food industry to develop and market reduced sodium foods.

Although FDA and FSIS define "healthy" differently, FSIS believes this is one area where it is appropriate. Meat and poultry products are different from other foods in that all meat and poultry products contain fat, saturated fat, and cholesterol. In addition, cholesterol is not ubiquitous in the food supply but only found in foods of animal origin.

This proposed rule would apply the criteria for "healthy" to any term used anywhere on the label that includes the term "health." This includes, but is not limited to, the following terms:

Health
Healthy
Healthful
Healthfully
Healthfulness
Healthier
Healthiest
Healthily

Healthiness

Thus, this proposed rule would permit the use of the term "healthy" or any other derivative of the term "health" under the conditions described above.

List of Subjects

9 CFR Part 317

Food labeling, Meat inspection.

9 CFR Part 381

Food labeling, Poultry and poultry products.

The Proposed Rule

For the reasons discussed in the preamble, FSIS is proposing to amend 9 CFR parts 317 and 381 of the Federal meat and poultry products inspection regulations to read as follows:

Note: The following proposed amendments are based on the final rule published elsewhere in this issue which becomes effective July 6, 1994.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

1. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 317.309 would be amended by adding a new paragraph (j) to read as follows:

§ 317.309 Nutrition label content.

* * * * *

(j) The term "healthy" or any other derivative of the term "health" may be used on the label or in labeling of a meat product, provided that:

(1) The product contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, less than 95 milligrams of cholesterol, and less than 480 milligrams of sodium per 100 grams and Reference Amount Customarily Consumed for individual foods, and per 100 grams and labeled serving for meal-type products, as defined in § 317.313(l),

(2) The product is labeled in compliance with this section, and

(3) The term complies with the requirements of § 317.313.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 450, 21 U.S.C. 451–470, 7 CFR 2.17, 2.55.

4. Section 381.409 would be amended by adding a new paragraph (j) to read as follows:

§ 381.409 Nutrition label content.

* * * * *

(j) The term "healthy" or any other derivative of the term "health" may be used on the label or in labeling of a poultry product, provided that:

(1) The product contains less than 10 grams of fat, less than 4 grams of saturated fatty acids, less than 95 milligrams of cholesterol, and less than 480 milligrams of sodium per 100 grams and Reference Amount Customarily Consumed for individual foods, and per 100 grams and labeled serving for meal-type products, as defined in § 381.413(l),

(2) The product is labeled in compliance with this section, and

(3) The term complies with the requirement of § 381.413.

Done at Washington, DC, on: December 24, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 93–28 Filed 1–5–93; 8:45 am]

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Federal Register

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Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1, et al.
Food Labeling; General Provisions; Nutrition Labeling; Label Format; Nutrient content Claims; Health Claims; Ingredient Labeling; State and Local Requirements; and Exemptions; Final Rules

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 20, 100, 101, 105, and 130

[Docket No. 92N-0440]

Food Labeling Regulations Implementing the Nutrition Labeling and Education Act of 1990; Opportunity for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; opportunity for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is revoking the regulations implementing section 403(q) and (r) of the Federal Food, Drug, and Cosmetic Act (the act), and the lists implementing section 6 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), that were considered final by operation of law as of November 8, 1992 (hereinafter referred to as the November 8 regulations). Elsewhere in this issue of the **Federal Register**, FDA is adopting final rules based on public comment to replace the November 8 regulations. FDA is taking this action to ensure that the final regulations that implement the 1990 amendments are those based on full public comment, and that those regulations are put in place without delay.

DATES: Effective January 6, 1993. Comments by February 5, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Frank E. Scarbrough, Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, President Bush signed the 1990 amendments into law. Sections 2, 3, and 6 of the 1990 amendments gave FDA 24 months from the date of their enactment to promulgate final rules implementing those sections. In response, FDA published proposals on November 27, 1991 (56 FR 60366 through 60878) and July 28, 1992 (57 FR 33283).

Sections 2(b)(2) and 3(b)(2) of the 1990 amendments provided that, if final rules to implement section 403(q) and (r) of the act, respectively, were not promulgated by November 8, 1992, then the regulations proposed to implement these sections of the act were to be considered as final regulations. There are similar provisions in section 6(b)(3)(D) of the 1990 amendments.

The 24-month period established by the 1990 amendments expired on Sunday, November 8, 1992, without the issuance of final rules implementing section 403(q) and (r) of the act or section 6 of the 1990 amendments. Thus, on November 8, 1992, the proposed regulations implementing those sections of the act and section 6 of the 1990 amendments were considered final regulations by operation of law. Under sections 2(b)(2) and 3(b)(2) of the 1990 amendments, FDA was directed to promptly publish in the **Federal Register** notice of the new status of the proposed regulations. FDA published that notice on November 27, 1992 (57 FR 56347).

II. The Revocation

The triggering of the mechanism established in sections 2(b)(2), 3(b)(2), and 6(b)(3) of the 1990 amendments did not toll the rulemakings instituted on November 27, 1991, and July 28, 1992, in response to sections 2, 3, and 6 of the 1990 amendments. Elsewhere in this issue of the **Federal Register**, FDA is publishing the final rules that are the culmination of those rulemakings. FDA has concluded that the final rules based on public comment should replace the November 8 regulations.

Because the agency is completing the rulemaking process begun in 1991, it is necessary to revoke the November 8 regulations so that only the rules that have had the benefit of full notice-and-comment procedures are in effect and provide a basis on which industry can begin to conform its food labels to the new requirements. This revocation does not constitute a reversal of the agency's former views as expressed in the November 27, 1991, and July 28, 1992, proposals and in the November 8 regulations, except to the extent that any changes, in accordance with the Administrative Procedure Act (5 U.S.C. 553(b)), are a logical outgrowth of the proposals. To the extent that differences exist between the November 8 regulations and the new final rules, a reasoned analysis for the changes is supplied in the preambles to the final rules published elsewhere in this issue of the **Federal Register**.

The legislative history of the 1990 amendments states that, if the deadline for publishing final rules based on public comment was not met, there would be good cause to consider the proposed regulations as final regulations because of the importance of mandatory nutrition labeling, rules on claims, and a unified system of regulations on misbranding. The legislative history also pointed to the fact that Congress expected the agency to have received public input prior to issuing the proposed regulations (H. Rept. 101-538, 101st Cong., 2d sess. 18-19 (1990)). The November 8 regulations were to be considered final rules to ensure that some rules would be in place without undue delay to implement the statutory requirements of the 1990 amendments.

Congress contemplated that, if the agency did not issue final rules based on public comment by the specified date (H. Rept. 101-538, supra, 18), and the provisions of sections 2(b)(2), 3(b)(2), and 6(b)(3)(D) of the 1990 amendments were triggered, then the consideration of the proposed rules as final rules without notice and comment should occur and would be justified. This so-called "hammer" provision had an overriding purpose: to motivate FDA and all parties involved in these rules to resolve expeditiously the many issues raised in them, rather than become mired indefinitely in their complexity. FDA believes the hammer has fully achieved its important purpose. It has encouraged prompt resolution of outstanding issues and led to agreement on final rules that represent substantial improvement over the proposed rules and that will be in place sufficiently before the date the statute must be applied to allow full industry compliance.

There is no indication in the legislative history of the 1990 amendments that Congress intended FDA to disregard the comments that it had received on the November 27, 1991, and July 28, 1992, proposals once the "hammer" had fallen and the November 8 regulations were considered final, or that Congress intended the triggering of the mechanism in sections 2(b)(2), 3(b)(2), and 6(b)(3)(D) of the 1990 amendments to prevent FDA from putting in place final regulations based on public comments as quickly as possible. While the proposals to implement the 1990 amendments may have had the benefit of general public comment on food labeling issues, they are no substitute for final rules based on the extensive rulemaking record developed in response to those proposals. In response to the public comments on the proposals, FDA has improved the regulations in numerous respects, better achieving the goals of the 1990 amendments, to the benefit of both industry and consumers.

Revocation of the November 8 regulations will eliminate any ambiguity as to which final regulations are controlling. Thus, for the reasons set forth above, FDA believes that this revocation is fully consistent with the 1990 amendments.

This revocation is also fully consistent with the requirements of the Administrative Procedure Act. The Administrative Procedure Act provides that the agency may revoke a regulation without notice-and-comment procedures "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." FDA finds that there is good cause for dispensing with notice-and-comment procedures in revoking the November 8 regulations.

First, notice-and-comment rulemaking on the revocation of the November 8 regulations is impracticable. Very little time remains before the provisions added by the 1990 amendments and implemented by the November 8 regulations go into effect. The new provisions of the act on health claims are effective on May 8, 1993, without any possibility of extension. Under those provisions, foods are automatically misbranded if health claims are made on their labels that do not meet the requirements of FDA's regulations.

In the final rules published elsewhere in this issue of the **Federal Register**, FDA is exercising the statutory flexibility granted in section 10(a)(3)(B) of the 1990 amendments to extend the date on which it will apply the new provisions on nutrition labeling and nutrient content claims to May 8, 1994. Comments have shown that this additional time for compliance with the final regulations is necessary to prevent undue economic hardship to industry. Even a minimal prior notice-and-comment period on this revocation would be likely to delay issuance of any final rules for at least several months. This delay would reduce significantly the amount of time industry is permitted under the statute to come into compliance with the nutrition labeling and nutrient content claims rules. That compliance cannot begin until the final rules on which the agency intends to rely in enforcing the amendments are in place. Use of notice-and-comment procedures to revoke the November 8 regulations and to replace them with new final rules would thus risk causing the very harm Congress attempted to prevent in permitting this extension.

Secondly, engaging in notice-and-comment rulemaking on the revocation of the November 8 regulations would be contrary to the public interest. The delay caused by receiving and responding to comments on the revocation would increase confusion and could lead to substantial hardship and expense to industry, which would face the possibility of having to label its products to comply with the November 8 regulations and then having to relabel them to comply with any new final rules that the agency eventually issued after the comment period. Revoking the November 8 regulations without notice and comment allows the agency to replace them immediately with final rules based on extensive public comment and thus to provide certainty to industry as to the regulatory requirements with which it must comply.

There is a strong interest in ensuring continuity of regulation, particularly where the purpose of the regulations is to provide information to consumers that they can understand and on which they can rely. A situation in which labels appear that comply with the November 8 regulations, only to be replaced by labels that comply with any final rules that the agency might ultimately issue, would be inconsistent with this goal. Rather, it would contribute to consumer confusion, which is precisely what Congress was trying to prevent in enacting the 1990 amendments to reform the food label.

The agency's final rules implementing the 1990 amendments need to be the gold standard for the food marketplace. Based as they are on public comment, scientific evidence, and sound public policy, the final rules issued today are the culmination of the Department of Health and Human Services' efforts, begun in August 1989, and reinforced in 1990 by the Administration and Congress, to reform the food label.

Finally, it is in the public interest and consistent with the purposes of the Administrative Procedure Act to have in place as quickly as possible final rules that are the product of a full rulemaking procedure. As stated above, Congress included sections 2(b)(2), 3(b)(2), and 6(b)(3) in the 1990 amendments because of the importance of having final regulations in place implementing the 1990 amendments without undue delay. H. Rept. 101–538, supra, 18. Today's action is consistent with that goal, because final rules implementing section 403(q) and (r) will be in place. By revoking the November 8 regulations in a manner consistent with the Administrative Procedure Act, FDA is giving full recognition to the effect of sections 2(b)(2), 3(b)(2), and 6(b)(3) of the 1990 amendments. The rules that will be in place as a result of today's action have had the benefit of full public comment. Those comments established the existence of problems with the proposals, and FDA has fully addressed those problems in the final rules. (See the final rules published elsewhere in this issue of the **Federal Register**.)

Considering the factual situation as a whole, there is good cause for waiving notice and comment. FDA has been diligent in arriving at final rules. In the past year, FDA has reviewed over 40,000 comments, held three public hearings, and produced final rules in more than 20 separate proceedings. There has been full notice-and-comment rulemaking on the final rules that FDA is issuing today, and interested persons have had ample opportunity to comment on all substantive issues addressed in those rules. However, circumstances outside FDA's control prevented it from issuing those final rules by the statutory deadline. In light of this, the agency is acting responsibly and reasonably in dealing with the unique situation it faces. The agency's prompt action to withdraw the November 8 regulations is necessary to facilitate the enormous transformation of the food label that will occur over the coming months. Moreover, no hardship will result from replacing the November 8 regulations now, because not enough time has passed since November 8 to permit significant action in reliance on the November 8 regulations.

Therefore, FDA concludes that there is good cause for withdrawing the November 8 regulations without notice and comment.

Consistent with its own procedural regulations, however, FDA is providing an opportunity for comment on its decision to revoke the November 8 regulations. Under § 10.40(e)(1) (21 CFR 10.40(e)(1)), FDA may issue a regulation without notice and public procedures when the agency determines for good cause that they are impracticable, unnecessary, or contrary to the public interest. In such a situation, the FDA procedural regulations require that the notice promulgating the regulation state the reasons for the determination, and provide an opportunity for comment to determine whether the regulation should subsequently be modified or revoked. This notice complies with these procedural requirements. Given the present unique circumstances, however, FDA finds under § 10.40(b)(2) that there is good cause to limit the comment period to 30 days.

FDA also finds, based on the reasons discussed above, that there is good cause to issue this revocation effective immediately (5 U.S.C. 553(d)(3)). A delayed effective date would be contrary to the public interest in minimizing regulatory uncertainty: it would create unnecessary confusion if these rules remained in effect for 30 days after the issuance of the final rules based on notice and comment. Moreover, this revocation of regulations that are not yet effective will not impose any behavioral changes on regulated industry, unlike the promulgation of a normative rule. Thus, a delayed effective date for this final rule would be unnecessary, impracticable, and contrary to the public interest.

After carefully considering the provisions of the 1990 amendments and their legislative history, FDA believes that, in this final rule and in the other final rules published today, it has taken the appropriate steps to resolve any questions created by the hammer. FDA is taking a course that recognizes Congress' desire to have final regulations in place by November 8, 1992, but that also recognizes, as discussed above, that Congress ultimately would not want to undercut the benefits of notice-and-comment rulemaking. The agency considered various alternate courses of action but rejected them because they were inconsistent with the 1990 amendments, the amendments' legislative history, the relevant facts, or the urgency of the current situation.

One alternative would have been to propose to revoke the November 8 regulations and to propose rules to replace them. This course was rejected because it would create too much uncertainty for industry, which would then have been compelled to begin complying with section 403(r)(1)(B) of the act on May 8, 1993, and with requirements on nutrition labeling and nutrient content claims by May 8, 1994, and because this course of action gives no effect to the extensive rulemaking that FDA has conducted for the last 12 months.

A second course would have been to term the final rules published today "interim rules," with additional opportunity for comment and a commitment to publish "true" final rules based on further comment. The agency has concluded that there would be little gain from such a course. Calling the rules "interim rules" would only create confusion and could induce industry to postpone action to comply with the new regulations. Also, although the comment period on the November 27, 1991, proposals closed on February 25, 1992, FDA continued to receive and consider comments well into the early fall. FDA believes that, since that time, no new information has become available that would change the agency's regulatory approach. If such information exists, FDA's procedural regulations provide ways for bringing it to the agency's attention, e.g., a petition under 21 CFR 10.30.

A third course would be simply to leave the November 8 regulations in place. FDA has concluded that this course of action would make little sense. It would be unfair to both industry and consumers to forego promulgating the best regulations possible. The agency thus believes that, in publishing the new final rules today, it is acting in the best interests of industry and consumers.

The agency therefore urges all affected manufacturers, packers, and distributors to begin to act in accordance with the final rules published today. The agency has received numerous comments about how much work will be necessary to comply with the new regulations, and, in response, FDA is announcing elsewhere in this issue of the **Federal Register** that it is delaying until May 8, 1994, the application of section 403(q) and (r)(2) of the act. However, if there is to be compliance by the application date, work must begin now. The final rules published today establish the requirements that must be met.

III. Additional Comments

The final rules that FDA is issuing today are the product of notice-and-comment procedures, and no further such procedures are required. The Administrative Procedure Act provides for notice and opportunity for public comment on proposed agency rules to ensure meaningful public input into agency rules that affect the public. Public comment is not an end in itself. FDA believes that it has fulfilled any possible purpose of this requirement. The agency has provided three prior opportunities for public comment on food labeling reform: the 1989 advance notice of proposed rulemaking, proposed rules in 1990, and proposed rules implementing the 1990 amendments in 1991 and 1992. While additional comments are always possible, the agency believes the Administrative Procedure Act in no way requires an additional opportunity for them. Now, the public interest requires finality and expeditious actual reform of the label—to the benefit of both industry and consumers. Recognizing, however, that some people may argue that there is a technical requirement for further rulemaking procedures, FDA finds that there is also good cause to proceed without them. For the reasons discussed elsewhere in this document, and in light of the extensive rulemaking procedures that have already been followed, further notice and comment would be unnecessary, impracticable, and contrary to the public interest.

The agency firmly believes that all the final rules it is publishing today, including those superseding the November 8 regulations, are the logical outgrowth of the November 27, 1991, and July 28, 1992, proposals and are fully supported by the administrative record that has been developed. Although the agency does not believe that any public purpose would be served by reopening for further comment at this time the issues addressed in that rulemaking, FDA recognizes that in any rulemaking of this size there will be technical issues in specific provisions. Therefore, the agency is providing 30 days for comment on these final rules on such issues. FDA is not interested in receiving comments that it has already received and considered. Interested persons are urged to limit their comments to technical matters or technical unintended consequences in specific provisions if not raised in earlier comments. In order to assure consideration of any comments, interested persons must certify that their comments are so limited. Comments should be submitted to the specific docket of the final rule being commented on. If the comments identify any technical provision of the final rules that FDA agrees should be changed, FDA will take action to modify that provision. This approach will enable FDA to quickly address any unintended effects of the final rules, yet not delay the finality that FDA believes is imperative for both industry and consumers.

IV. Opportunity for Comments

Under § 10.40(e), an opportunity for comment on this final rule is being provided. Interested persons may, on or before February 5, 1993, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, the regulations that were considered final by operation of law on November 8, 1992, as announced in the

Federal Register of November 27, 1992 (57 FR 56347), are hereby revoked.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31499 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 101, 105, and 130

[Docket Nos. 90N-0134 et al.]

RIN 0905-AD08 and 0905-AB68

Food Labeling: Establishment of Date of Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing this final rule to establish May 8, 1994, as the date on which it will apply the mandatory nutrition labeling and nutrient content claims provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This action is in accordance with section 10(a)(3)(B) of the 1990 amendments which allows the Secretary (and, by delegation, FDA) to delay, for up to 1 year, the date on which FDA will apply those provisions to foods if the agency finds that compliance with the new provisions would cause "undue economic hardship."

DATES: The statutory effective date of sections 403(q) and 403(r)(2) of the Federal Food, Drug, and Cosmetic Act (the act) is May 8, 1993, except that section 403(q)(4) (raw agricultural commodities and raw fish) became effective November 8, 1991. However, FDA is delaying the date that it will apply sections 403(q) of the act (21 CFR 101.9) and 403(r)(2) of the act (21 CFR 101.13, all of the regulations in subpart D of 21 CFR part 101, and 21 CFR 130.10), except section 403(q)(4) of the act (21 CFR 101.42 through 101.45), until May 8, 1994. The effective date of the regulations published elsewhere in this issue of the **Federal Register** implementing sections 403(q) and 403(r)(2) of the act, except section 403(q)(4) of the act, is May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFF-302), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5267.

SUPPLEMENTARY INFORMATION:

I. Background

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). This statute adds section 403(q) (21 U.S.C. 343(q)), which makes nutrition labeling mandatory for all food, and section 403(r)(2) (21 U.S.C. 343(r)(2)), which gives FDA authority to define nutrient content claims, among other sections, to the act.

In accordance with the 1990 amendments, FDA published proposed rules on November 27, 1991, to implement these sections of the act. Under section 2(b)(1) of the 1990 amendments (21 U.S.C. 343 note), FDA is to adopt final regulations by November 8, 1992. If the agency fails to do so, under section 2(b)(2) of the 1990 amendments, the proposed rules are to be considered final rules. Under section 10(a)(1)(A) and (B) of the 1990 amendments (21 U.S.C. 343 note), sections 403(q) and 403(r)(2) of the act are effective 6 months after the promulgation of the final regulations or after the proposed regulations are considered to be final regulations. Thus, by statute, sections 403(q) and 403(r)(2) of the act will become effective no later than May 8, 1993.

However, section 10(a) of the 1990 amendments provides that if the Secretary of Health and Human Services and, by delegation, FDA "* * * find that compliance with sections 403(q) and 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year." In its regulatory impact analysis (RIA) published in the **Federal Register** of November 27, 1991 (56 FR 60856), FDA tentatively found that compliance with the 1990 amendments by May 8, 1993, will cost $1.5 billion, and that 6-month and 1-year extensions of the compliance date would result in significant reductions in those costs. Therefore, given the extent of these costs, FDA felt that the possibility of "undue economic hardship" was raised. The agency consequently requested comments on the meaning of "undue economic hardship," and on whether a delay in the application of sections 403(q) and 403(r)(2) of the act was appropriate. The agency also requested comments on whether a determination of "undue economic hardship" should be based on aggregate costs to industry generally, on industry-by-industry costs, or on firm-by-firm costs.

Interested persons were given until February 25, 1992, to comment. FDA received comments from government organizations, retailers, consumer groups, State groups, and private organizations. A discussion of the agency's decision, and a summary of the comments and the agency responses, follow.

II. Undue Economic Hardship

The 1990 amendments provide that the Secretary may delay the application of sections 403(q) and 403(r)(2) of the act for up to 1 year if he "* * * finds that compliance with [either section] would cause an undue economic hardship." There is no relevant legislative history on this provision. Clearly, however, Congress foresaw that there would be a significant cost to complying with these sections of the act. Its use of the phrase "undue economic hardship" implies that Congress recognized that some economic hardship may result from efforts to comply with the 1990 amendments. The question is whether that cost is so great as to constitute "undue" economic hardship.

"Undue" is defined as "exceeding what is appropriate or normal," "excessive," or "not just [or] proper." Synonyms include inequitable, inappropriate, extreme, and immoderate. As yet, no court has construed the meaning of the 1990 amendments; however, parallels may be drawn with cases discussing similar language. Cases involving an employer's accommodation of an employee's religious practices have looked for a simple increase in costs in assessing whether the accommodation created an "undue hardship" for the employer. See *Transworld Airlines* v. *Hardison*, 432 U.S. 63, 84 (1977) (more than a de minimis cost to employer is an undue hardship); *State Division of Human Rights* v. *Carnation Co.*, 366 N.E.2d 869, 870 (N.Y. Ct. App. 1977) (a palpable or significant increase in costs is enough to establish undue hardship; threat to economic stability of enterprise is not required). In determining whether a punitive damage award was "excessive," a court looked at whether it was "out of all proportion to the defendant's financial position." *T.D.S., Inc.* v. *Shelby Mutual Insurance Co.*, 760 F.2d 1520 (11th Cir. 1985). Where a company was ordered to reopen a plant after closing it discriminatorily, the remedy was to be upheld unless the company could show an undue economic burden, which was interpreted as a "substantial outlay of new capital or [other] undue financial hardship." *Teamsters Local Union N. 171* v. *NLRB*, 863 F.2d 946 (D.C. Cir. 1988), cert. denied, 490 U.S. 1065 (1989). In a case involving the Pension Benefit Guaranty Corporation's (PBGC's) authority to grant waivers under the Employee Retirement Income Security Act (ERISA) when an employer faced "unreasonable hardship," a court upheld the PBGC's denial of a waiver where the PBGC had considered only unusual, substantial economic hardship. *A-T-O, Inc.* v. *Pension Benefit Guaranty*

Corporation, 634 F.2d 1013 (6th Cir. 1980). According to the court, the waiver provision was Congress' way of dealing with unforeseeable, unexpected situations of serious employer hardship. Id., 1023.

It appears from these cases that an undue economic hardship must entail at least an increase in costs and at most an unusual and substantial economic burden. Given Congress' implicit assumption that compliance with the 1990 amendments would involve an economic burden, the agency believes that the best interpretation of Congress' intent would require that an undue economic hardship be a substantial economic burden, in excess of what Congress would have envisioned, although not necessarily threatening the viability of a company, attributable to the 6-month compliance date established by the 1990 amendments.

1. The comments that the agency received were generally consistent with this view of what constitutes undue economic hardship. A comment from a trade group stated that "undue economic hardship" should be defined by the lost product lines and businesses that will occur as a result of a short compliance time. Another comment defined "undue economic hardship" as any increase in costs of goods to consumers in the current economic climate. A large company stated that undue economic hardship was shown where there were large costs "without appreciable benefit."

The agency agrees with the comments that a large increase in industry's costs attributable to the application of sections 403(q) and 403(r)(2) of the act 6 months from November 8, 1992, would provide evidence of undue economic hardship if that increase is more than what was likely to have been envisioned by Congress. However, a simple increase in costs alone is insufficient to demonstrate such hardship because Congress envisioned that there would be some economic burden to industry when it passed the 1990 amendments.

2. One comment from a consumer group argued that industry will not experience undue economic hardship. The comment stated that: (1) There is no undue burden on industry because consumers would bear the costs, not industry; and (2) since the public at large would be the recipients of the benefits of labeling, and the benefits outweigh the costs, the public should be willing to bear the costs.

The agency disagrees with the first point. It is likely that much of the costs of nutrition labeling will not be passed on to consumers, although the agency is not in a position to estimate exactly how much of the amount will be passed on to consumers. Because the costs per product are primarily fixed costs, it is likely that manufacturers with low volume products, which constitute 80 percent of all products, with higher per product costs will not be able to pass these costs on if they are in competition with high volume products.

The agency agrees that the public at large will be the recipient of the benefits of nutrition labeling. However, because it is likely that many manufacturers will not be able to pass the costs on, and because the agency received no information with which to estimate the amount that can be passed on, the agency is not persuaded by this argument.

3. Several comments suggested that "undue economic hardship" should be based on a cost-benefit analysis. Both industry and consumer groups provided their views that benefits should be balanced against the costs of implementing the labeling provisions. Industry groups generally found the costs to be disproportionate to the benefits, while consumer groups commented that the potential health benefits far exceeded the cost to industry.

The agency finds that there is no basis in the statute, the legislative history, or the case law to find that the assessment of undue economic hardship entails a balancing of the costs and benefits of a delayed application date. In fact, it can reasonably be inferred from the 1990 amendments that Congress balanced the competing interests in framing the statute and provided in section 10(a)(3)(B) of the 1990 amendments that should the economic burden imposed by meeting the statutory compliance date be greater than reasonable, FDA is authorized to grant relief to affected industry. The court held in *A–T–O, Inc.* v. *PBGC*, that Congress, before enacting the ERISA statute, engaged in just such a "finely tuned balance between protecting pension benefits for employees while limiting the cost to employers." *A–T–O*, 634 F.2d at 1021. In enacting ERISA, as in the passage of the 1990 amendments, Congress could not foresee all possible situations of undue economic hardship, so it granted discretion to the administrative agencies to determine the circumstances in which undue economic hardship exists. Id., 1023.

III. How to Assess Whether There is Undue Economic Hardship

In its November 1991 RIA, the agency requested comments on whether it should assess undue economic hardship on a firm-by-firm, industry-by-industry, or on an aggregate basis.

4. Several comments argued that because FDA can expect requests for extension from most of the industry regulated by FDA as well as from many foreign firms, it would be difficult, if not impossible, for FDA to grant extensions on a firm-by-firm basis. Some comments stated that company-specific extensions would give some firms an unfair competitive advantage based solely on production and inventory schedules and would create consumer confusion. One comment stated that a firm-by-firm approach would not adequately judge economic hardship since many firms manufacture products that overlap different industries and, therefore, have different costs. Another comment appeared to advocate use of the firm-by-firm basis because it was seeking relief for itself.

In addition, one consumer advocate organization preferred that FDA assess undue economic hardship on a case-by-case basis. However, if this would be too burdensome, the comment suggested that FDA consider granting extensions by categories of firms, based on size or labeling capacity. Several other comments voiced similar requests by suggesting that if FDA does not determine the aggregate economic impact to be undue, then it should consider whether the impact is particularly burdensome to specific industries. Several comments, including two from governmental units, suggested that if FDA does not delay the application of sections 403(q) and 403(r)(2) of the act for all manufacturers subject to the 1990 amendments, FDA should consider applying a later date for small business. Other comments suggested that the industry-by-industry approach would create competitiveness problems and would be extremely difficult to apply fairly. The majority of comments expressed the opinion that undue economic hardship should be determined on an aggregate basis because it would be the only equitable and practical approach. The one consumer group that argued against an extension agreed that FDA should consider undue economic hardship on an aggregate basis.

FDA believes that it should determine whether there is undue economic hardship for the food industry as a whole. Because there are approximately 17,000 U.S. food companies in the portion of the food industry regulated by FDA, as well as a large number of foreign food manufacturers, it would be administratively infeasible for FDA to grant extensions on a firm-by-firm basis because the agency does not have the

resources to process and act on petitions. Similarly, the agency also is persuaded by the evidence provided by the comments that granting extensions on an industry-by-industry basis would be perceived as arbitrary because it would be extremely difficult to distinguish among industries on the basis of the costs that would have to be borne if there is early application of sections 403(q) and 403(r)(2) of the act. The overwhelming majority of comments provided evidence that such costs will have to be borne by most companies.

Moreover, from a compliance standpoint, FDA's job would be made more difficult if a delay was granted on other than an industry-wide basis. In such a situation, compliance checks would require not merely looking at the label but at whether the labeling requirement applied to the particular firm or segment of the industry. Therefore, FDA has decided to define "undue economic hardship" on an aggregate basis.

IV. Evidence of Hardship

A. General

In conformity with the case law cited above, the agency has interpreted the undue economic hardship standard to require a determination as to whether the costs of complying with sections 403(q) and 403(r)(2) of the act by May 8, 1993, impose an unexpected and excessive burden on industry. It is the costs that exceed the costs of implementing sections 403(q) and 403(r)(2) of the act that can reasonably be said to have been foreseeable that FDA has looked to in deciding whether there is undue economic hardship.

FDA has sought to determine the amount of those foreseeable costs even though the legislative history does not provide any explicit estimates of what Congress expected the costs of implementing sections 403(q) and 403(r)(2) of the act to be. However, the agency notes that Congress acted after FDA proposed to require nutrition labeling on food products in the **Federal Register** of July 19, 1990 (55 FR 29487). FDA's proposal contained a preliminary cost assessment of $315 million for implementation of the nutrition labeling proposals. Although this estimate was very rough and based on preliminary figures, and although there are differences between the agency's July 19, 1990, proposal and the 1990 amendments, Congress apparently was aware of, and may well have considered, FDA's estimate in considering the 1990 amendments (see H. Rept. 101–538, 101st Cong., 2d sess. 9 (1990)).

The agency now estimates the cost of implementation of all label changes required by the 1990 amendments to be $1.5 billion if the date of application of the nutrition labeling and nutrient content claims provisions is not delayed beyond May 8, 1993. Therefore, if $315 million is used as a baseline, the current estimated cost to industry of implementing sections 403(q) and 403(r)(2) of the act approximately quadruples it. In the RIA in which the 1990 estimate was calculated, for those costs that FDA did not have information to calculate, FDA stated that it was plausible that they would be considerable, but the agency was not specific as to exactly how large they could be. Therefore, the 1991 estimate, published in the **Federal Register** of November 27, 1991, as part of the RIA (56 FR 60856), can be considered unexpected and greatly increased because the available public data in July 1990, 4 months before the passage of the 1990 amendments, did not predict costs in that range. The 1991 estimate was based in large measure on data developed by FDA in interviews with food manufacturers and in a mailed survey that were conducted after July 1990.

Consequently, the agency concludes that the food industry will have significantly higher costs than could have been anticipated from the estimates and data at the time of passage of the 1990 amendments. The majority of comments that the agency received in response to its November 1991 RIA support the agency's cost estimates and demonstrate that there are substantial additional costs that result from a 6-month (November 1992 to May 1993), rather than a 1-year, 15-month, or 18-month, compliance date. These comments and the agency's responses are discussed in the section that follows.

B. Costs of Compliance with Section 403(q) of the Act

Having defined the term "undue economic hardship," the agency has considered whether compliance with section 403(q) of the act would cause an undue economic hardship for the affected industry. The comments received from industry overwhelmingly expressed concern regarding, and provided evidence of, such hardship.

5. Many comments stated that the cost of analytical testing for nutritional composition of products will be burdensome to meet within the proposed timeframe of May 8, 1993, especially for small companies that cannot afford the testing and that do not have their own laboratories to perform the nutritional analysis. Many of these comments stated that the increased demand for testing services would lead to increased costs for testing, which would burden all firms but especially smaller firms. The comments stated that as firms compete for laboratory services, preferred treatment will be given to the larger firms that can better afford these additional costs, thus exacerbating the competitive advantage of larger firms. One trade association estimated the average cost per product for nutrition testing to be $1,433 for small firms and between $627 and $864 for larger companies. Other comments provided estimates for the costs that ranged from $400 to $2,600 per product.

Based on the data developed by the agency in producing its November 1991 RIA, the agency believes that the estimates provided by these comments are accurate and thus finds that a short compliance period will increase the cost to firms of analytical testing. Food manufacturers will have to compete for position in the queue and to pay queuing costs to improve their position in line. In that RIA, FDA determined that 40 percent of the packaged food products covered by the labeling amendments are currently labeled and have undergone some analytical testing. The agency estimated the average cost per product to bring the product into compliance for products already nutritionally labeled to be $750, and for those not already so labeled, the agency estimated a cost of $1,785 per product (56 FR 50856 at 50864). Because less than half of all products have been tested, and because once the regulations become final, all firms will require at least some testing, the demand for laboratory services will more than double as a result of labeling regulations. The prices of these services will consequently increase substantially in the shortrun. However, because laboratory capacity is expected to increase based on an increase in long-term demand, FDA cannot predict the final price for these services. It is clear, however, that the increase in costs will be greatly mitigated by a delay in the date of compliance. Such a delay will reduce the pressure on the supply of these services because not all firms will test products at the same time, and therefore, a delay will mitigate the increase in prices for laboratory services.

6. Comments from small companies stated that the cost of laboratory testing could be reduced greatly by the use of nutrition data bases instead of requiring laboratory analyses of their products. One comment from a data base supplier

stated that a small data base product that could cover several products would sell for $1,000 to $2,000 and would last for several years—significantly cheaper than analytical tests, estimated in the November 1991 RIA at $723 to $1,785 per product.

The agency agrees with the comments. Nutrition data bases are currently under development throughout the food industry, particularly by large companies. There is no discussion of use of analytical data bases in the legislative history of the 1990 amendments, however, so Congress must have been unaware of the significant cost savings that these data bases would guarantee. The lack of data bases contributes to the costs of compliance, and a short compliance period limits the possibility of using data bases to mitigate costs. The agency has been informed that these data bases will not be operational in time to meet the May 8, 1993, deadline. To date, FDA has not approved any nutritional data bases for use in nutrition labeling. Many of those commenting, particularly small companies, requested at least a year beyond May 8, 1993, to develop and use these data bases. Assuming FDA will approve nutritional data bases, an extension will thus help in getting more data bases developed, approved by FDA, and in use by the food industry.

7. Some firms expressed concern that the capacity of analytical laboratories will be insufficient to provide all of the food testing needed by the 17,000 U.S. companies in the food industry by the 6-month effective date.

FDA does not have any data, nor was any submitted, on the number of laboratories equipped to perform nutrition analyses. FDA also does not know how many companies have inhouse facilities. However, a comment from an independent laboratory stated that it is increasing its capacity to meet "the huge surge of work brought about by the FDA mandatory labeling." Firms will continue to need to have their products tested as they reformulate their products or develop new ones. Also, firms will periodically retest their products to verify the information. The agency, therefore, anticipates that laboratory capacity will expand to meet this sustained demand. Thus, FDA does not believe that there will be undue economic costs associated with laboratory capacity.

8. Many firms expressed concern that labels could not be redesigned and printed on time to meet the statutory deadline of May 8, 1993, across the food industry because label designers and suppliers have stated that they do not have the capacity to handle the volume of business that will be generated as a result of the regulations. The comments stated that there is little incentive for printing and packaging firms to make capital improvements to meet the excess demand. The cost of capital improvements is high, and unlike the demand for analytic testing which will continue in the future, the demand for label printing is essentially a one-time label change for the entire industry. One firm estimated the cost to label printers for relabeling equipment to be $11,000 if compliance is required by May 8, 1993, with that cost dropping to $8,000 if compliance is delayed for 1 year. The comments suggested that the same scenario applies to printing capacity, whether inhouse printing or by contract. In some cases, if demand is high enough for a short compliance period, new equipment could be used which would result in excess printing capacity in the future. The comments pointed out that an additional problem with the earlier compliance date is the inability of some label suppliers to purchase and install new equipment and to find new personnel to operate such equipment within the established timeframe.

Packaging suppliers and label printers estimated that it would take between 2 to 5 months per label for redesign and printing. The comment said that time needed for other tasks, such as analytical testing, label approval, and distribution, would add considerable time to this estimate. Several comments stated that between one-third and one-half of all relabeling could be completed by May 1993, and that approximately two-thirds could be completed by November 1993. The agency also received a comment from a label printer who services 14,000 labels that stated that the company anticipates that the time that it will take it to do a job will double. Based on its present resources, the comment stated that even with a doubling of its capacity achieved by hiring new personnel, they will be almost 54 percent short of the estimated label changes needed by its customers.

FDA believes that redesign and printing of the food label to accommodate the new requirements of the 1990 amendments are compliance costs. FDA agrees that many firms may have difficulty relabeling their products in the 6-month compliance period in the statute. Because there is little incentive to increase printing capacity given the one-time nature of much of what needs to be done to print new labels, the agency does not anticipate additional printers entering the market to relieve the shortage. Because Congress did not have available to it printing cost differentials associated with different compliance periods, these costs may be construed as unexpected and undue.

9. Some firms commented that the costs of label inventory disposal would be great. According to the comments, small companies in particular carry large inventories of labels and will have a disproportionately large cost if forced to dispose of those inventories. One small firm stated that it would have to destroy 2 years worth of label inventory. In addition, specialty firms (e.g., manufacturers of gourmet products) noted that they have a large number of individual labels and a low volume of individual unit sales, which results in a large inventory of labels. Firms reported a cost of inventory disposal ranging from $79,000 to $3,603,000 for a May 1993 effective date and $0 to $227,000 for an extension to May 1994. Only one large food manufacturer provided an estimate of the cost of inventory disposal (i.e., approximately $800,000) for a compliance period ending in November 1993. One industry association representing supplement manufacturers estimated the cost of disposal for a November 1993 compliance date at $15 million. Another industry association, after conducting a survey of its members, stated that 37 member companies reported a total inventory disposal cost of $26 million and 1.5 billion labels for a compliance date of May 8, 1993. According to the comment, the cost to these 37 firms would decline to $2 million and 150 million labels with a 1-year extension.

In addition, several comments stated that another label disposal problem involves production of private labels for retail grocery and other companies. Typically, the manufacturer provides the art work and printing plates for private label customers. When orders for products are below normal, the manufacturer stores the packaging material at his cost. The comments stated that the new labeling changes will necessitate modification of all customer labels at the manufacturer's expense, and the manufacturer may have to write off as a loss considerable quantities of label and packaging material.

These figures do not conflict with those estimated by FDA in its November 1991 RIA. Based on a contractor's study of the food processing industry, FDA estimated the cost of disposal of remaining inventory to be $306 million. Although conducted before passage of the 1990 amendments, the information generated from this study was not available to Congress or to the public.

In the 1990 estimate, FDA assumed that 1 year was sufficient to dispose of all labels and thus did not estimate cost

of label disposal. Because the 1990 estimate was apparently the only information Congress had available to it, it may be presumed that these costs were unforeseen and, hence, are in excess of those anticipated by Congress.

10. Some small firms stated that the implementation of the nutrition labeling provisions would drive them out of business because the cost of compliance would eliminate their already low profit margins. These small firms claim that they cannot absorb costs, and relabeling will prevent their prices from being competitive.

FDA is aware that firms with low profit margins may be significantly affected by their effort to come into compliance with section 403(q) of the act. Although section 403(q) of the act includes a small business exemption, many small firms do not meet the requisite levels. Extending the date of application will help alleviate the impact on small businesses by mitigating increases in the cost of analytical, redesign, and printing services, and by reducing the amount of label inventory destroyed. Also, an extension will assist those firms forced to scale back or halt operations because they are unable to produce complying labels in a timely manner.

11. Comments from specialty food distributors noted that the cost of relabeling to be in compliance with section 403(q) of the act could result in the elimination of profitable product lines when the manufacturer decides that the unit cost of the labeling does not justify compliance or may trigger a price increase.

FDA agrees that some profitable product lines have such small profit margins that it is not unreasonable to expect that the cost associated with a short compliance period might increase the cost of manufacturing such that the product line is no longer profitable. The agency is currently exploring the possibility of legislation to relieve this undue hardship on small firms.

12. A European Community (EC) Commission expressed concern that overseas suppliers will be unable to meet the 6-month, May 8, 1993, deadline because of differences in definitions and analytical procedures between EC and the United States. The comment noted that the 6-month effective date would be impossible for EC producers to meet because there is a delay of several months between the labeling of products in Europe and their arrival in the United States because of travel time and customs formalities, giving overseas suppliers effectively only 3 months to analyze and relabel their products. Additionally, a trade association for herbal products confirmed that printing and analysis of the product for overseas suppliers would have to be accomplished in 3 months.

FDA agrees that foreign food manufacturers might need a longer compliance period than domestic manufacturers because of the differences in language, analytical methodology, and length of time it takes to transport the product. FDA believes the longer compliance period specified in this final rule will alleviate the concerns expressed by the comment. The agency notes that all products introduced into interstate commerce on or after May 8, 1994, must comply with sections 403(q) (except section 403(q)(4)) and 403(r)(2) and any final regulations promulgated to implement those sections.

13. A comment from a trade group for the sugar manufacturers pointed out that because in their industry the label is the package, the product cannot be packaged until it can be labeled. These manufacturers expressed concern that a substantial amount of sugar inventory will be misbranded and unmarketable, thus causing sugar to be destroyed or returned, opened, poured out, and reprocessed to be finally placed in packages conforming to label requirements. One sugar company estimated its cost of process and inherent losses to be $3.6 million.

As previously stated, FDA believes the longer compliance period specified in this final rule will alleviate the concerns expressed by the comment. Again, the agency notes that these manufacturers will have until May 8, 1994, to use up their inventory. They will also have ample time to develop their new packaging.

14. One trade association commented that their business was, in large part, seasonally based because of the holiday trade, such as Halloween, and that other businesses had special holiday or seasonal considerations. The comments noted that seasonal products need unusually long advance planning. Graphics and packaging must be finalized and ordered 9 months to 1 year in advance. The comment argued that label changes would occur in the middle of the packaging and shipping season for products that represent 20 percent of some of their members' product lines.

The agency agrees that the 6-month effective date might be impossible for some seasonal products and could result in some product lines being dropped. The agency believes that the loss of product lines would be an undue economic cost. The agency notes that a delay of applicability of section 403(q) of the act of approximately 15 total months will, according to the comments, be sufficient lead time for these products.

15. Some comments requested an extension of the date of application of the labeling provisions because initial analytical results might induce companies to reformulate their products in order to improve the nutritional composition of those products to appeal to the public. An industry association stated that the costs of reformulating products would be substantial--$20,000 per product. Another firm estimated the cost of reformulation to be $60,000 per item plus $400,000 to convert processing time to include controls.

The agency notes that one of the purposes of the 1990 amendments was precisely to encourage manufacturers to produce healthier products as a result of mandatory disclosure of food content. Reformulation, however, does not constitute undue economic hardship in itself because the industry is not required by statute to reformulate its products.

16. Several comments stated that the reduction in total costs that would result from a delay in the application of section 403(q) of the act would justify an extension. One comment from a major industry association stated that the total cost of food labeling would be reduced from $3.36 billion for the May 8, 1993, compliance date to $1.69 billion for a November 8, 1993, compliance date, and ultimately to $971 million for a May 8, 1994, compliance date. Another industry association stated that the total costs to its members would be reduced from $4.3 million to $900,000 if the compliance period were extended an additional year to May 1994. One large firm stated that total costs would be $251,146,000 for a May 1993, compliance date. Additionally, an industry association estimated that an extension from May 1993 to May 1994 would reduce total costs for its members from $160 million to one-tenth of that amount. Other firms stated their total costs would be reduced by 30 to 90 percent with a 1-year extension.

FDA finds that these comments are generally consistent with its own estimates. The agency estimates that the benefits of nutrition labeling and nutrient content revision will remain nearly the same ($3.6 to $3.4 billion) over the 1-year period from May 8, 1993 to May 8, 1994, while costs will decrease dramatically. In the November 1991 RIA, the agency estimated that a 6-month delay of the date of applicability would result in a savings of $600 million, a 9-month delay, $700 million

savings, and a 1-year delay, $835 million. As discussed in the final RIA published elsewhere in this issue of the Federal Register, FDA has found it appropriate to adjust these cost estimates upward somewhat.

C. Whether a Delay in Application of 403(q) of the Act is Appropriate

17. One comment from a consumer group favored no delay in applying section 403(q) of the act primarily because it wanted consumers to obtain health benefits as soon as possible from the mandatory disclosure of nutrients on food labels. A few comments tentatively favored an extension, but only if the food industry makes a strong case for undue economic hardship and provides substantial evidence of such hardship.

FDA has reviewed these comments and rejects the position that no extension of the May 8, 1993, deadline should be granted. FDA realizes that providing for early compliance with the 1990 amendments is desirable and follows the intent of Congress to implement promptly the provisions of section 403(q) of the act. However, the agency cannot ignore the evidence of undue economic hardship presented by industry comments and supported by FDA's own cost estimate. This hardship is particularly acute for small and medium-sized firms which will not be able to afford the analytical testing, printing, and inventory disposal costs if section 403(q) of the act is applied on May 8, 1993. Congress specifically provided that the Secretary may grant a delay of section 403(q) of the act of up to 1 year if such undue economic hardship is found.

Given the fact that a delay of the date of applicability for section 403(q) of the act will result in substantial cost reductions, and the evidence presented above that the costs of analytical testing, label printing, and inventory disposal far exceed the apparent expectations of Congress, a May 8, 1993, compliance date will generate a substantial economic burden. Therefore, the agency has decided that undue economic hardship will result from implementation of section 403(q) of the act on May 8, 1993, and has decided to delay the date of application of section 403(q), except for section 403(q)(4) (raw agricultural commodities and raw fish) which became effective November 8, 1991, as provided in section 403(q)(4)(B)(i).

D. Undue Economic Hardship from Application of Section 403(r)(2) of the Act

The agency also is authorized by the 1990 amendments to consider whether compliance with section 403(r)(2) of the act on May 8, 1993, will cause an undue economic hardship. Very few comments directly addressed the issue of undue economic hardship resulting from compliance with this section. Most comments did not distinguish between the two sections.

18. One comment from a consumer advocacy group stated that, because FDA's original estimates of the costs to restaurants represent roughly one percent of that industry's output, the economic burden to the food service industry cannot be deemed undue.

The agency disagrees with the comment. In its original assessment of the costs of food labeling (July 1990), FDA did not consider the costs to restaurants. Therefore, Congress had no information regarding the expense that would be incurred by restaurants as a result of the 1990 amendments. While no restaurant associations requested a delay of application of section 403(r)(2) of the act, according to a study conducted by the National Restaurant Association in a special analysis of their 1991 menu collection submitted in response to the November 1991 RIA, 89 percent of all menus would need to be changed to comply with the requirements of section 403(r)(2). While FDA is not including menus in the regulatory purview of this action, it is including restaurant signs and placards. Because this material is clearly reflective of the menu, much of it will have to be modified in response to the new law at significant cost. Thus, by any reasonable estimate, this figure is more than Congress could have envisioned and provides evidence of undue economic hardship.

The agency has decided not to undercut the relief that it is granting in delaying the application of section 403(q) of the act by forcing industry to comply with section 403(r)(2) of the act on May 8, 1993. The agency has considered that if a delay were granted in the application of section 403(q) of the act, but not in the application of section 403(r)(2) of the act, a substantial number of firms would still have to relabel their products to at least remove claims that are not in compliance with, or are not defined in, the regulations that FDA is issuing under section 403(r)(2).

The agency also notes that in section 10(a)(1)(B)(ii) of the 1990 amendments, Congress provided that persons who use a brand name that includes a term that is defined in section 403(r)(2)(A)(i) of the act have an additional 6 months, until November 8, 1993, to comply. FDA believes that the terms defined under section 403(r)(2)(A)(i) of the act will be most useful to consumers if they come onto the market at the same time. Therefore, FDA believes that an across the board delay in the application of section 403(r)(2) of the act for at least 6 months is appropriate.

E. Agency Finding of Undue Economic Hardship

The agency has considered the comments, relevant case law, and its November 1991 RIA, to determine whether undue economic hardship exists in implementing sections 403(q) and 403(r)(2) of the act by May 8, 1993. Having defined "undue economic hardship" above as a substantial economic burden in excess of what Congress would have envisioned attributable to the 6-month compliance date established by the 1990 amendments, the agency has examined the evidence presented and concludes the following:

The evidence from the comments demonstrates that undue economic hardship will occur in the aggregate because of increased analytical testing costs and pressures on printer capacity. Congress presumably was not aware that printing costs varied with different compliance periods. Therefore, a significant percentage of printing costs are unexpected costs. An estimate of label inventory disposal costs of $306 million was also not available to Congress. These costs have the greatest effect on small firms, which have low profit margins and which normally retain higher inventories of labels.

Consistent with agency figures, the comments demonstrate that the magnitude of the nutrition labeling costs are 4 times that which was reasonably expected by Congress. Additionally, these costs decrease dramatically with a 6-month, 9-month, or 12-month delay of the nutrition labeling and nutrient content provisions. Thus, the costs of applying sections 403(q) and 403(r)(2) of the act on May 8, 1993, are unnecessary and unexpected and constitute undue economic hardship for affected industry. Therefore, the agency concludes that there is an appropriate basis to delay the application of these sections.

V. How Long Should Application of Sections 403(q) and 403(r)(2) of the Act be Delayed?

Having concluded that there will be undue economic hardship to the food

industry if it is forced to comply with sections 403(q) and 403(r)(2) of the act on May 8, 1993, and that some delay is appropriate, the agency has considered how long to delay the application of these sections. Section 10(b)(3)(A) of the 1990 amendments permits the agency to delay the application of these sections for up to 1 year.

In deciding on the length of the delay, the agency notes that several factors are relevant. First, Congress has passed a second law that will require a change in food labels. The American Technology Preeminence Act of 1991 (Pub. L. 102–245) (amended in Pub. L. 102–329 (hereinafter referred to as "the metric amendments") which amended the Fair Packaging and Labeling Act (the FPLA), requires that manufacturers revise their labels and labeling by February 14, 1994, to declare net weight declarations in both the customary unit/pound system of measure and the International System of Units metric system on food labels. Second, as a result of circumstances beyond FDA's control, the issuance of the final regulations with which industry will have to comply was delayed by slightly more than a month. Both of these factors must be considered in deciding on an appropriate applicability date.

19. The agency received several comments related to the metric amendments, requesting that the agency apply sections 403(q) and 403(r)(2) of the act on the same date as the metric amendments in order to avoid a costly relabeling. One comment argued that the date of application of the nutrition labeling and nutrient content revisions and the effective date of the metric amendments should be May 8, 1994, while another comment requested simultaneous implementation on November 8, 1994, or May 8, 1995.

FDA agrees with the comments that it would be desirable if the date of application of sections 403(q) and 403(r)(2) of the act and the effective date of the metric amendments were the same. Section 107(b) of the metric amendments requires that the metric provisions take effect 2 years after the date of enactment of the act which will occur on February 14, 1994. While section 10(a)(3)(B) of the 1990 amendments provides for a delay of the date of application of sections 403(q) and 403(r)(2) of the act, the metric amendments contain no such provision.

Initially, FDA intended to make the regulations issued under section 403(q) and (r)(2) of the act effective on February 14, 1994, providing a 9-month extension and enabling manufacturers to coordinate their compliance with both laws. However, as stated above, events beyond the agency's control have led to a delay in the publication of these final regulations. Therefore, requiring compliance with the regulations implementing section 403(q) and (r)(2) of the act by February 14, 1994, would not provide industry with sufficient relief from undue economic hardship. The agency has thus decided that it is appropriate for those regulations to go into effect May 8, 1994. The resulting period provided to industry to comply with the regulations is in the range of the 15-month compliance period that the agency had earlier contemplated providing.

FDA recognizes that the metric amendments will take effect February 14, 1994. FDA encourages those firms that are able to consolidate their relabeling efforts and comply with both the metric amendments and the 1990 amendments by February 14, 1994, to do so. Moreover, FDA notes that under the metric amendments, firms are free to use up their existing label stocks before they are required to comply with the new provision. Thus, FDA is unlikely to bring an action against a product because it fails to comply with the metric amendments until after May 8, 1994.

20. Several comments favored the 6-month delay option because most of the cost burden will be alleviated by a delay of that length. The comments argued that a 6-month delay will have the effect of reducing the demand for printers, thereby causing a substantial decrease in printing costs. They also pointed out that inventory disposal costs will be significantly reduced because firms would be given additional time to use up old labels.

While the 6-month option relieves much of the economic hardship on industry by reducing the cost of labeling from $1.5 billion dollars to $800 million, the agency has rejected this option because it would leave firms in the position of having to make a second relabeling within 3 months to comply with the metric amendments. The agency has always sought to minimize the cost of relabeling. Furthermore, both seasonal products and products from other countries would have particular problems with only a 1-year compliance period which includes a 6-month delay in application of sections 403(q) and 403(r)(2) of the act.

21. Some comments suggested a phasein date of applicability over a longer period such as 18 to 24 months. One comment requested a period of trial application of the proposed regulations followed by a 90-day period for comment.

The agency rejects these comments because the 1990 amendments make no provision for such a trial period or for a longer than 1-year delay in application. Additionally, such a phasein period would be extremely difficult for FDA to administer because it does not have the personnel to ensure compliance with an application date that, as it is phased in, affects only some firms or products. Thus, the agency finds no basis to adopt the approach suggested by this comment.

22. One comment from a consumer favored a 2-year delay because the consumer believed that the costs of compliance by the May 8, 1993, deadline would be excessive ($10 billion), and that most of this added cost would be passed on to consumers. Several industry comments also requested a 2-year delay because of the cost of making label changes to meet the May 8, 1994, date.

The agency estimated in the November 1991 RIA that the cost of compliance with the 1990 amendments would be $1.5 billion. While some industry comments assert that the cost would be as high as $3 to $4 billion, there simply is no basis to find, as the comment suggests, that the cost of relabeling would be $10 billion. More importantly, a 2-year delay in the application of sections 403(q) and 403(r)(2) of the act cannot be granted because section 10(a)(3)(b) of the 1990 amendments authorizes a delay of no more than 1 year.

23. An ice cream manufacturer requested that FDA defer the date of applicability of the 1990 amendments to ice cream products until 12 months after the agency takes final action on the International Ice Cream Association's petition to establish specific standards for modified ice cream.

The agency disagrees with this comment. First, the agency does not have legal authority to grant the relief requested. As discussed above, the act grants the agency authority to delay application of sections 403(q) and 403(r)(2) of the act for 1 year from their effective date, not for a 1-year period from any particular date in the future. Secondly, the agency cannot presume that it will grant the petition in question. Even if it does, however, the modified ice cream products in question will be new foods. Thus, the costs involved in labeling these products will be the costs attributable to starting a new product line, and not costs attributable to the changes imposed by the act. Therafore, FDA finds no basis to grant the requested delay.

24. Two comments from food manufacturers stated that if the date of

applicability is delayed, two relabelings will occur because the ingredient labeling rules are statutorily mandated to take effect on May 8, 1993.

FDA finds no merit to these comments. By delaying the application of sections 403(q) and 403(r)(2) of the act until February 1994, FDA is not requiring firms to delay relabeling until that date. Quite the contrary, FDA urges firms to relabel their products as quickly as possible. However, FDA has no authority to delay the effect of the ingredient labeling provisions. Thus, whether a firm that must make labeling changes to comply with the ingredient labeling provisions makes all its changes at that time, or decides to take advantage in the delay of applicability and thus has two relabelings, is up to the firm.

25. The overwhelming majority of comments supported a delay of the date of applicability for the full 1 year for sections 403(q) and 403(r)(2) of the act. The primary reasons for these requests were that a 1-year delay is necessary to give printers time to meet the excess demand for labels imposed by the nutrition labeling provisions, and that printing and analytical testing costs, prohibitive in a short compliance period, would be reduced to more reasonable levels.

The agency agrees with these comments that a delay of the date of application of sections 403(q) and 403(r)(2) of the act will alleviate the undue economic hardship for the industry. As discussed above, FDA had intended to provide a 9-month extension to February 14, 1994, but considers that an extension to May 8, 1994, is now appropriate because of the delay in publication of these rules.

The agency is thus providing the most time for compliance permissible under the 1990 amendments, as requested by these comments, although the total compliance time provided will be closer to 15 than 18 months.

The agency fully expects that many firms will begin to comply well in advance of the May 8, 1994, date of application of the nutrition labeling and nutrient content claim provisions. For firms that have their own inhouse analytical testing or printing capability, the transition will be easier than for those who do not. Some firms are already conducting nutritional analysis of their products and may be able to comply before the required date. Some firms may receive favorable positions in the queue of label printers and may complete labeling well in advance of the May 8, 1994, date. As these firms complete nutritional analysis and labeling, they will begin to use the revised labels. Therefore, consumers will receive some of the expected health benefits of the label changes during the period between May 8, 1993, and May 8, 1994.

VI. Effective Date of Regulations Implementing Sections 403(q) and 403(r)(2) of the Act

The agency is announcing that the regulations implementing sections 403(q) and 403(r)(2) of the act will be effective May 8, 1994, the date that the agency will begin to apply these provisions. Under section 10(b)(1)(D) and (E) of the 1990 amendments, the effective date of the regulations implementing sections 403(q) and 403(r)(2) of the act need not be the same as the effective date of those provisions. There is nothing in the 1990 amendments nor in the legislative history that states when FDA's regulations are to be effective. FDA is, therefore, free to make them effective on whatever date it considers appropriate.

The agency has chosen May 8, 1994. As a result, the current regulations on nutrition labeling and nutrient content claims will remain in effect until the agency begins to enforce the new statutory provisions on these matters. The agency finds that it would be most appropriate to have the new regulations that implement those provisions take effect at that time. Thus, on the effective date of the final rule on nutrition labeling, current § 101.9 (21 CFR 101.9) will disappear and be replaced by the new provision.

Therefore, under the act and under authority delegated to the Commissioner of Food and Drugs, FDA is establishing May 8, 1994, as the effective date of the regulations implementing sections 403(q) and 403(r)(2) of the act (except section 403(q)(4)), with a date of applicability of May 8, 1994.

Accordingly, compliance with the implementing final regulations on mandatory nutrition labeling and nutrient content claims published elsewhere in this issue of the **Federal Register** in response to the following November 27, 1991, proposals: (1) Food Labeling: Reference Daily Intakes and Daily Reference Values and Nutrition Labeling, Mandatory Status and Content Revision (Docket Nos. 90N–0134 and 90N–0135) (56 FR 60366); (2) Serving Sizes (Docket No. 90N–0165) (56 FR 60394); (3) Nutrient Content Claims, General Principles, Petitions, and Definition of Terms (Docket No. 91N–0384) (56 FR 60421); (4) Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content (Docket No. 84N–0153) (56 FR 60478); (5) Use of Nutrient Content Claims for Butter (Docket No. 91N–0344) (56 FR 60523); (6) Food Standards: Requirements for Substitute Foods Named by Use of a Nutrient Content Claim and a Standardized Term (Docket No. 91N–0317 et al.) (56 FR 60512); and (7) Format for Nutrition Label (Docket No. 91N–0162) (57 FR 32058, July 20, 1992) may begin immediately. All products initially introduced into interstate commerce on or after May 8, 1994, shall comply.

VII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive RIA that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA, published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

Comments to the November 1991 RIA indicated that costs of complying with the proposed May 8, 1993, effective date would exceed FDA's estimate in the RIA. These costs would include queuing costs to food manufacturers trying to comply with the short deadline to relabel food products. The final RIA contains revised cost estimates for the societal costs involved, which, for the most part, do not include queuing costs. Such costs, which have been analyzed in this document, are largely transfers between food manufacturers and labeling firms.

FDA concludes, based on its review of available data and comments, that the costs of the overall food labeling reform initiative will be reduced by nearly one-

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half (a cost savings of approximately $700 million) by extending the date for compliance with the food labeling requirements to May 8, 1994. Further, the agency concludes that this action will significantly alleviate the economic hardship that would otherwise result if sections 403(q) and 403(r)(2) of the act were made applicable, as proposed, on May 8, 1993.

VIII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to not make these rules effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services

[FR Doc. 92–31500 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 101

[Docket Nos. 90N-0135, 91N-0162, 78P-0091, 87P-0194/CP, AND 90P-0052]

RIN 0905-AD08

Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to: (1) Require nutrition labeling on most foods that are regulated by FDA, (2) revise the list of required nutrients and food components and the conditions for declaring them in nutrition labeling, (3) specify a new format for declaring nutrition information, (4) allow specified products to be exempt from nutrition labeling, and (5) prescribe a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling may be used. This final rule also responds to citizen petitions on the declaration of dietary fiber in nutrition labeling and on methodologies for determining protein content.

DATES: Effective February 14, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in 21 CFR 101.9(c)(1)(i)(A), (c)(1)(i)(B), (c)(1)(i)(C), (c)(1)(i)(E), (c)(5), (c)(7)(ii), (c)(7)(ii)(B), and (g)(2), effective (February 14, 1994).

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFF-200), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-205-4561.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 19, 1990 (55 FR 29847), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter identified as "the mandatory nutrition labeling proposal") to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. FDA also proposed to revise the list of nutrients and food components that must be included in nutrition labeling by adding calories from fat, saturated fatty acids, cholesterol, and dietary fiber to that list. It proposed to make the listing of thiamin, riboflavin, and niacin optional rather than mandatory. In addition, FDA addressed the conditions under which other nutrients could be, or are required to be, included in nutrition labeling and proposed to allow manufacturers to voluntarily include a nutrition profile of selected food components in nutrition labeling.

During the comment period for these proposed regulations, Congress passed, and the President signed into law, the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535, November 8, 1990). The 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(q) (21 U.S.C. 343(q)) which specifies, in part that: (1) With certain exceptions, a food is to be considered misbranded unless its label or labeling bears nutrition labeling, (2) certain nutrients and food components are to be included in nutrition labeling, although the Secretary of Health and Human Services (the Secretary) can add or delete nutrients by regulation if he finds such action necessary to assist consumers in maintaining healthy dietary practices, (3) nutrition labeling is to be provided for the most frequently consumed varieties of raw produce (fruits and vegetables) and raw fish according to voluntary guidelines or, if necessary, regulations, (4) a simplified nutrition label is to be used when the food contains insignificant amounts of most nutrients, and (5) FDA is to develop regulations governing labeling of foods to which section 411 of the act (21 U.S.C. 350) applies.

In response to these requirements of the 1990 amendments, FDA published in the Federal Register of November 27, 1991 (56 FR 60366; as amended (57 FR 8178, March 6, 1992)) a proposal (hereinafter identified as the supplementary proposal) to modify its July 19, 1990, proposal by: (1) Adding sugars and complex carbohydrates to the list of required nutrients in nutrition labeling, (2) prescribing a simplified form of nutrition labeling and the circumstances in which such simplified nutrition labeling must be used, (3) allowing specified products to be exempt from nutrition labeling, and (4) establishing regulations for the nutrition labeling of vitamin and mineral supplements. The agency also responded to a citizen petition regarding methodologies for determining protein quality. Interested persons were given until February 25, 1992, to comment.

Subsequently, FDA published in the Federal Register of July 20, 1992 (57 FR 32058; amended at 57 FR 37190, August 18, 1992), a proposal (hereinafter identified as the format proposal) to adopt a new format, specifically the PERCENT DV (Daily Value) with DRV (Daily Reference Value) format, for use in presenting nutrition information on the food label. Interested persons were given until August 19, 1992, to comment. In addition, on July 23, 1992, a notice was published in the Federal Register (57 FR 32750) of a public meeting to be held on the format proposal in Bethesda, MD, on August 17, 1992.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (H.R. 6181) (hereinafter referred to as the "DS Act") that, in section 202(a)(1), establishes a 1 year moratorium on the implementation of the 1990 amendments with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. Section 202(a)(2) requires the Secretary, and by delegation FDA, to issue new proposed regulations that are applicable to dietary supplements no later than June 15, 1993, and final regulations by December 31, 1993. In addition, section 203 instructs FDA to not promulgate regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993 (other than regulations establishing the United States Recommended Daily Allowance (U.S. RDA) specified in 21 CFR 101.9(c)(7)(iv) as in effect on October 6, 1992).

FDA received approximately 1,500 responses to its July 19, 1990, mandatory nutrition labeling proposal, approximately 3,000 responses to the November 27, 1991, supplementary proposal, and approximately 1,000 responses to the July 20, 1992, format proposal, each of which contained one or more comments. Responses were received from consumers, health professionals, health promotion organizations, trade and retail associations, State and local governments, foreign governments, professional societies, consumer advocacy organizations, industry, and universities. The comments generally supported the proposals. Several comments addressed issues covered by other proposals that are a part of this overall food labeling initiative, and they will be addressed in those final documents, while other comments were outside the scope of these proposals and will not be discussed here. Many

comments dealt with issues pertaining to meat and poultry products whose labeling is regulated by the U.S. Department of Agriculture (USDA). Of those comments, comments pertaining to the content or format of the nutrition label are included in the following discussions. However, comments pertaining to issues covered exclusively by USDA, such as specific exemptions applicable to meat and poultry products, were considered to be outside the scope of this document.

A number of comments to both the July 19, 1990, and November 27, 1991, proposals suggested modifications in, or were opposed to, various provisions of the proposals. A summary of the suggested changes, the opposing comments, and the agency's responses follow.

II. Mandatory Nutrition Labeling—Legal Authority

1. Most comments agreed that the 1990 amendments clearly established FDA's authority to mandate nutrition labeling on most foods. One comment, however, argued that a requirement that labels say or not say certain things curtails freedom of the press.

The agency disagrees. FDA's authority to regulate the content of food labels has been broadly upheld against First Amendment challenges. This issue is discussed at length in both the final rule on nutrient content claims entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" and the final rule on health claims entitled "Food Labeling; General Requirements for Health Claims for Food," both of which are published elsewhere in this issue of the **Federal Register**. Those discussions are incorporated in this document by reference. As those discussions make clear, there is no merit to this comment. Therefore, FDA is taking no action on the basis of this comment.

2. One comment objected to FDA being given authority to mandate nutrition labeling on most foods on the basis that current nutrition labeling rules were legally questionable.

The question of FDA's authority to require nutrition labeling was a fundamental issue that led Congress to pass the 1990 amendments. As discussed in the legislative history, Congress concluded that legislation was needed to strengthen FDA's authority to require nutrition labeling on foods and to avoid the possibility of protracted litigation over the comprehensive nutrition labeling regulations that the agency adopts (Ref. 16). Therefore, there can be no question about FDA's authority to require nutrition labeling on most food products.

III. Content of the Nutrition Label

A. General Issues

1. Voluntary Declaration of Additional Information

3. A number of comments objected to the voluntary declaration of nutrients beyond those required in nutrition labeling. Numerous comments stated that the declaration of additional information on the food label would be confusing, or that it might mislead the consumer into believing that a product with additional nutrients listed is more nutritious or has greater public health significance than is the case. Some comments objected on the basis that the additional information would clutter the label and diminish the consumer's focus on mandatory nutrients. A few comments expressed concern that voluntary declaration of additional nutrients on the label will require smaller print on the food label to accommodate the inclusion of all the mandatory and voluntary information, and that the smaller type size would compromise the usefulness of the label information to the elderly or visually impaired.

A number of comments supported the voluntary listing of additional nutrients, pointing out that the 1990 amendments require that the regulations permit the label or labeling of food to include nutrition information, which is in addition to the information required by section 403(q) of the act and which is of the type described in subparagraph (1) or (2) of that section. A few comments supported the view that voluntary listing of additional nutrients may provide valuable information to an individual or aid the consumer in making an informed choice in food selection. Other comments supported voluntary listing of additional nutrients stating that some nutrients may satisfy nutrient needs of some individuals or pose a health risk to others. One comment pointed out that the Institute of Medicine (IOM) report (Ref. 1) recommends that regulations allow the declaration of all micronutrients for which Recommended Dietary Allowances have been established by the National Academy of Sciences.

Numerous comments that basically supported listing of additional information also supported limiting the information allowed. Some comments supported allowing voluntary information, but they suggested that FDA standardize the manner in which it is included on the label to the extent of requiring that it be separate from the nutrition label or in different type size. Five comments requested voluntary listing of specific nutrients including: Potassium; vitamins E, K, and B6; copper; manganese; iodine; maltodextrin; and L-glutamate, L-cysteine, and L-tryptophan. Two comments supported the listing of additional nutrients but recommended restricting the allowed nutrients to those for which Recommended Dietary Allowances have been set by the National Academy of Sciences (Ref. 23) or for which Reference Daily Intakes (RDI's) have been determined by FDA. One of these comments further suggested restricting the allowed nutrients to exclude nutrients that do not have Recommended Dietary Allowances but only have Estimated Safe and Adequate Daily Dietary Intakes (ESADDI's), which are also set by the National Academy of Sciences (Ref. 23). One comment suggested that additional information on the food label be restricted to information permitted by the Council of the European Communities (EC).

FDA, in its mandatory nutrition labeling proposal of July 19, 1990, proposed to allow the voluntary declaration of several nutrients (e.g., potassium and soluble fiber) and any naturally occurring vitamins and minerals for which RDI's had been proposed in § 101.9(c)(10)(iv) (21 CFR 101.9(c)(10)(iv)), which was redesignated as § 101.9(c)(11)(iv) in the November 27, 1991, proposal. Additionally, section 2(b)(1)(C) of the 1990 amendments states that regulations shall permit the label or labeling of food to include nutrition information that is in addition to the information required by section 403(q) of the act and that is of the type described in subparagraph (1) or (2) of that section. Section 403(q)(2) of the act refers to information that will assist consumers in maintaining healthy dietary practices.

FDA believes that it is required by statute to allow additional information on the food label insofar as it assists consumers in maintaining healthy dietary practices. However, the agency raised questions in the supplementary proposal about how the presence of these additional nutrients on the label would be interpreted by consumers, and whether the listing of some voluntary nutrients would actually be misleading (56 FR 60366 at 60372). The comments confirmed that unlimited additional information on the nutrition label would have the potential of being confusing or misleading.

FDA requested comments on whether it is necessary to include limits on the voluntary information that may be

provided on the nutrition label. The comments that FDA received on this issue have lead the agency to conclude that it has a responsibility to limit the number of nutrients permitted to be voluntarily listed on the food label. Such a limitation reflects the statement in the House report (Ref. 16, p. 18) that the regulations that FDA adopts should assure that the information that is included voluntarily does not interfere with the consumer's understanding of the information that is required to be included on the nutrition label. The agency finds that limits are necessary so that the emphasis is on the required information, and that the additional information does not clutter the food label or mislead or confuse the consumer.

Therefore, to limit the information that may be provided on the nutrition label, FDA is amending the proposed regulations to delete "calories from unsaturated fat," "calories from carbohydrates," "calories from protein," and quantitative declarations of "unsaturated fat" from the list of nutrients that are allowed to be declared voluntarily on the nutrition label. Each of these deletions is detailed below. FDA has decided to permit the voluntary declaration on the nutrition label of "calories from saturated fat," "polyunsaturated fat," "monounsaturated fat," "soluble fiber," "insoluble fiber," "sugar alcohol," "other carbohydrate," "potassium" and those vitamins and minerals for which RDI's have been established.

With respect to other nutrients suggested by individual comments for consideration for voluntary listing on the food label, the agency has not been persuaded that there are large numbers of consumers who desire a voluntary listing of the food components in question (e.g., maltodextrin or single amino acids. Therefore, FDA will not allow voluntary listing of these other substances or food components on the nutrition label. To implement this section, FDA has added a sentence to § 101.9(c) that states that no nutrients or food components other than those set forth in that section as either mandatory or voluntary may be included in the nutrition label. The inclusion of any other nutrient or food component would violate section 403(q) of the act and misbrand the food.

Also, while FDA supports efforts toward international harmonization of food labeling where possible, the 1990 amendments direct FDA to permit that a broad spectrum of nutrients be on the food label unless the agency finds that the information is not necessary to assist consumers in maintaining healthy dietary practices, a finding that FDA has generally not made. As a result, the spectrum of required and permitted nutrients exceeds those permitted by the EC.

FDA is not requiring that additional nutrients declared voluntarily be put in separate boxes or a different type size because it believes these actions would confuse consumers and would complicate and clutter the label needlessly. In some instances additional nutrients, whose declaration is usually voluntary, will be required to be declared. For example, in the case of fortified foods, enriched pasta must declare amounts of thiamin, riboflavin, and niacin, and margarine must declare vitamin D when it is added. In other cases, if certain claims are made, additional nutrients will be required to be declared. For example, when nutrient content claims are made about cholesterol, declaration of poly- and monounsaturated fats are required (see § 101.9(c)(2) (i) and (ii). Placing these nutrients in the principal box for nutrition labeling when required, and in a separate box (or different type size) when voluntarily added to the nutrition label would easily confuse consumers. Also, separating subcomponents that can voluntarily be declared, such as soluble and insoluble fiber, from the primary component, dietary fiber, for which declaration is mandatory, would unduly complicate the label.

However, in response to comments concerned that information on additional nutrients would clutter the label and to comments on the format proposal, FDA is providing in new § 101.9(d)(8) for a linear array of vitamins and minerals. This form of presentation, which is discussed in more detail in section V. of this document, is similar to that recommended in the IOM report (Ref. 1) which places more emphasis on the macronutrients.

2. Order of Nutrients

4. Several comments from industry, health promotional organizations, and academia supported the order of nutrients proposed by FDA in § 101.9(c) (56 FR 60366 at 60386 through 60390). One industry comment stated that the proposed sequence fairly prioritized the Dietary Guidelines for Americans (Ref. 4) and placed the proper emphasis on those dietary factors that affect the health of consumers. This comment, along with one from a health promotion organization, also endorsed the separation of vitamins and minerals from other nutrients seen in proposed formats (57 FR 32058), stating that this feature represented a logical break in the list of nutrition information and would both improve label readability and facilitate consumers' search for specific nutrient data. Another comment supporting the proposed order endorsed the listing of nutrients from those most important to consumers to those least important to consumers but questioned whether protein should be included.

On the other hand, several comments argued that the proposed order of nutrients has features that would mislead consumers. One comment characterized the proposed order as "an unwarranted effort to overemphasize some nutrients, such as fat, at the expense of the other important label components" and suggested that the decision on whether to emphasize one nutrient over another should be left to nutrition education programs that consider the total diet over a long period of time. Other industry comments criticized the proposed order of nutrients, stating that it would be consistent with the "good food/bad food" concept and would convey a negative impression to consumers. One industry comment supporting the current order of nutrients argued that protein should not be listed near the end, stating that beneficial nutrients should be listed at the beginning of the nutrient list. The comment suggested that from an educational standpoint, it is more positive to educate on the good points of nutrition labeling than to focus on negative aspects.

A number of comments advocated that the current order of nutrients be maintained, or that any modified order resemble the current order as closely as possible. Several comments supporting the current order of nutrients stated that consumers are already accustomed to the current order, and that changing the order would lead to unnecessary confusion and diminish consumers' understanding of the nutrition label.

A few comments suggested alternative nutrient orders. A comment from a professional organization stated that those nutrients whose overconsumption is related to increased risk of disease should be placed at the top of the list of required nutrients. One industry comment recommended that nutrients be regrouped to first list those nutrients whose Daily Value is dependent on calorie intake (i.e., total fat, saturated fat, carbohydrate, dietary fiber, and protein), followed by those whose Daily Value remains the same for varying calorie intakes (i.e., cholesterol and sodium). Another comment requested that sodium be listed with the vitamins and minerals rather than among the organic macronutrients.

A comment from a manufacturer addressed the issue of where to place the voluntary nutrients on the label. The comment suggested that voluntary nutrients should be sequenced in a logical manner with respect to the nutrients whose declaration is mandatory. The following examples were cited: Unsaturated fat should follow saturated fat (both should be indented), potassium should follow sodium, soluble and insoluble fiber should follow dietary fiber, and vitamins and minerals should follow those that are mandatory.

The agency is not persuaded by arguments stating that listing nutrients in order of public health importance will cast foods as either "good foods" or "bad foods." Listing nutrients in this manner will instead facilitate selection of an overall diet that is consistent with dietary guidelines based on what nutrients are present in a particular food and in what amounts. No data were presented to show that use of this nutrient order on the nutrition label is likely to be confusing to consumers.

The agency also does not agree with the request that sodium be placed with vitamins and minerals rather than with the organic macronutrients. Sodium is an electrolyte that is distinct from both organic nutrients and vitamins and minerals. However, excessive intake is associated with a potential increase in the risk of chronic diseases, as are excessive intakes of the other mandatory organic nutrients (i.e., macronutrients such as fat) in the nutrition label. Vitamins and minerals generally are associated with deficiency diseases. The agency believes this categorization supports the continued placement of sodium with the organic nutrients.

FDA agrees that the placement of voluntary nutrients should be sequenced in a logical manner with respect to the mandatory nutrients. FDA has provided in new § 101.9(c) that voluntary nutrients that are subcomponents are to be declared immediately beneath the primary components, and that potassium (the second electrolyte) is to be declared adjacent to sodium.

The agency believes that a revised order according to the public health significance of a nutrient will adequately convey nutrient information with no appreciable increase in consumer effort. This action is based on the order provided in section 403(q)(1) of the act (see Ref. 16, p. 13) and the comment recommending that nutrients whose overconsumption is related to increased risk of disease should be placed at the top of the list of required nutrients.

Accordingly, new § 101.9(c) is modified to require mandatory and voluntary nutrients to be arranged in the following order: Calories, calories from fat, calories from saturated fat, total fat, saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, sodium, potassium, total carbohydrate, dietary fiber, soluble fiber, insoluble fiber, sugars, sugar alcohol, other carbohydrate, protein, vitamin A, vitamin C, calcium, iron, and other vitamins or minerals in the order listed in proposed § 101.9(c)(11)(iv), redesignated as § 101.9(c)(8)(iv). This order deviates from that provided in section 403(q)(1) of the act only by reversing dietary fiber (and its subcomponents) and sugars. The reason for this reversal is discussed in comment 58 of this document.

Consequently, the paragraphs in § 101.9(c) are renumbered as discussed below for each nutrient. Redesignations also occur as a result of moving paragraphs (c)(1) and (c)(2) pertaining to serving size and servings per container, respectively, to new paragraph (d).

The agency believes that this amended order of nutrients, which lists them in order of public health significance, will benefit consumers. The agency's decision is a reasonable outgrowth of its commitment to present nutrition information in the context of a total daily diet, and it reflects the agency's commitment to link nutrient information with the dietary guidance considered important to public health (Ref. 4).

B. Calories

1. Total Calories

5. The majority of comments supported the proposal for mandatory declaration of calories with voluntary use of metric terminology (i.e., declaration of the number of kilojoules in addition to calories in proposed § 101.9(c)(3), redesignated as § 101.9(c)(1), and voluntary use of the term "energy" parenthetically as a synonym for calories, as provided in § 101.9(c)(11)(v), redesignated as § 101.9(c)(8)(v)).

Other comments expressed a preference for metric labeling. The comments argued that American consumers should become accustomed to the metric system of measurement and recommended the exclusive use of metrics to ensure compatibility with European markets. The comments suggested that the avoirdupois system of measurement used in the United States is outmoded and impedes international commerce and the exchange of scientific information. Several comments suggested that "energy" should be used in lieu of calories and requested that the conversion factor for calories to kilojoules be stated on each label.

Still other comments, taking the opposite position, suggested that metric units be disallowed to avoid consumer confusion and for the sake of simplicity.

Although FDA agrees that efforts should be made to familiarize consumers with metric units, the agency disagrees with the comments that urged the exclusive, mandatory conversion to metrics at this time. The technical amendments (August 3, 1992) to the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq., Pub. L. 102–329) require the use of the most appropriate units of both the customary inch/pound system of measure and the metric system on food labels for measuring quantity. These amendments do not require that kilojoules be declared in lieu of calories. Upon implementation, this act should further an awareness of metric measurement among American consumers and permit a greater concordance in units of measurement with the international market and scientific community. Until that time, the agency is not persuaded that the mandatory use of metric terminology, or the declaration of factors to convert calories to kilojoules, is justified. Accordingly, the agency is not making the requested changes.

2. Calories From Fat

6. Many comments were received from consumers, state and local governments, universities, professional associations, consumer groups, manufacturers, and health associations on the issue of calories from fat. The majority agreed with the proposal that the declaration of calories from fat should be mandatory on the nutrition label.

Several other comments suggested that calories from fat be voluntarily listed or disallowed because this information might be confusing or misleading to consumers and might establish artificial "good food" and "bad food" categories. These comments stated that consumers may tend to exclude foods with a significant amount of calories from fat, possibly creating nutritional deficiencies. Further, these comments stated that it is important that consumers view fat as part of a day's diet rather than in the context of individual foods. A few comments suggested that declaring the calories from fat is unnecessary because calories from fat can be easily calculated by multiplying the number of grams (g) of fat by nine, the number of calories per g of fat. A few comments suggested that

there be further study of the effectiveness of the declaration of calories from fat in nutrition labeling as a nutrition education tool. One comment suggested that low fat foods, such as fruits and vegetables that contain less than 2 g of fat, be exempted from the requirement to list calories from fat.

FDA is not persuaded by the arguments that the declaration of calories from fat should be voluntary or disallowed. The declaration of calories from fat is required by section 403(q)(1)(C)(ii) of the act. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, no data were presented that would support making such a finding with respect to the declaration of calories from fat.

It is well established that diets that are high in fat pose significant health risks. Dietary fat contributes more than twice the calories per g than does protein or carbohydrate. Overconsumption of fat is associated with higher rates of obesity (Refs. 2 and 3), and there is evidence from epidemiological and animal studies that high fat intakes are associated with some types of cancer (Refs. 2 and 3). The most common and consistent dietary recommendation for the general population is for calories from total fat to be reduced to less than or equal to 30 percent of total calories (Refs. 3 and 4).

Currently, the consumption of total fat in the general population is approximately 37 percent of total calories, an amount well above the recommended level (Ref. 2). Further, consumption of total fat in the United States is significantly higher than that consumed in countries with much lower rates of coronary heart disease, such as Japan, China, and the Mediterranean countries (Ref. 2).

Based upon this body of evidence, FDA believes that reducing total fat intake is an important public health priority. The agency is not persuaded that the declaration of calories from fat will automatically lead to consumers viewing foods in strict "good food," "bad food" categories, or that consumers cannot make appropriate decisions regarding the consumption of foods that may have a significant number of calories from fat in their diets. No evidence was presented demonstrating a relationship between the declaration of calories from fat in nutrition labeling and nutritional deficiencies.

Although calories from fat can, in fact, be readily calculated (FDA is requiring that information on the number of calories per g of fat, carbohydrate, and protein, be included as part of the nutrition label (see § 101.9(d)(10)), the declaration of calories from fat will be beneficial in assisting consumers to moderate their fat intake by providing an additional method, other than g of fat, for monitoring their fat intake.

However, the agency concurs that fat should be viewed as a part of the complete daily diet. Foods that may have a significant number of calories from fat may readily be included in the daily diet when the overall fat intake for the day is moderate. The agency intends to build this concept into its consumer education program, discussed later in this document. Further, FDA welcomes further study on the health implications of overconsumption of calories from fat and the effectiveness of this method of depicting fat content.

7. Many comments advocated the mandatory declaration of the percent of calories from fat. Other comments suggested that calories from total fat should be replaced by the percent of calories from fat. The comments stated that the process of determining the percent of fat is time consuming and unfamiliar to many consumers. Further, the comments argued that it is unlikely that substantial numbers of consumers would or could keep running totals of their fat intake in order to calculate the percent of daily fat consumed. The comments argued that the best way to determine whether a food is high or low in fat is to have fat content declared by percent of total calories.

A few comments suggested that percent of calories from fat for individual foods is incomplete information, while the percent of calories from fat for a complete meal or the daily diet is useful information. These comments suggested that the percent of calories from fat be voluntary and limited to meal-type products, such as frozen dinners, and disallowed for other foods.

The agency is not persuaded by the comments that the declaration of percent calories from fat is warranted. As discussed in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29494), information on the percent of calories from fat is only valuable in the context of a total daily diet. Recommendations from various health organizations to limit dietary fat intake to 30 percent or less of calories pertain not to individual foods but to the entire day's intake.

In addition, the percent of calories from fat in low calorie foods can be quite misleading. For instance, in radishes, over 25 percent of calories are from fat. Despite this relatively high percentage, radishes contain very low amounts of fat and readily fit within a daily diet that meets current dietary recommendations.

The agency agrees that calculating the percent of calories from fat consumed in a day may be difficult for many consumers. The agency notes that the PERCENT DV format (see section V.G.2) facilitates monitoring of dietary fat because the Daily Value for fat is set at 30 percent of calories from fat. Consumers need only add the percent DV for total fat with a target of no more than 100 percent or a target percentage adjusted for their individual caloric intake. Alternatively, consumers can determine the maximum number of g of fat recommended per day at their calorie level and track the number of g of fat. There are several publications listing recommended daily maximum amounts of fat according to caloric intake or that have simple arithmetical methods for deriving this information (Refs. 26 through 29). In a similar fashion, the DRV for fat, which is established in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter identified as the "RDI/DRV proposal") published elsewhere in this issue of the **Federal Register**, can be used as a guide, with levels being adjusted upward or downward depending on caloric intake. The agency encourages other organizations to develop and publish similar approaches.

8. One comment objected to that section of § 101.9(c)(3)(i) in the July 19, 1990, mandatory nutrition labeling proposal that allowed "calories from fat" to be omitted and replaced with the statement "Not a significant source of calories from total fat" if the product contains less than 1 g of fat per serving. The comment objected to similar provisions for saturated fat, cholesterol, and dietary fiber on the basis that it made the regulations complex and confusing. These provisions were carried forward in the November 27, 1991, supplementary proposal with the 1-g criterion being changed to ½ g, and similar provisions being added for complex carbohydrates and sugars.

These provisions were included in the July 19, 1990, mandatory nutrition labeling proposal (55 FR 29487 at 29502), which was published before the adoption of the requirement in section 403(q)(5)(C) of the act for a simplified format, to minimize the space required for nutrition labeling. This provision is similar to that allowed in current § 101.9(c)(7)(i) for vitamins and minerals that are present in amounts less than 2 percent of the U.S.

Recommended Daily Allowance (U.S. RDA). FDA did not delete these provisions in the November 27, 1991, supplementary proposal because the agency believed they might be helpful in minimizing space requirements on foods that do not qualify for the simplified format under proposed § 101.9(f).

FDA finds that the added flexibility that these provisions provide outweighs any added complexity they may create. USDA's final nutrition labeling regulations, which are being published simultaneously with these final rules, include similar provisions. Under FDA's regulations, with the exception of the core nutrients (i.e., calories, total fat, total carbohydrate, protein, and sodium), nutrients that are present in insignificant amounts may be omitted from the list of nutrients and grouped in a summary statement (e.g., "Not a significant amount of calories from fat, saturated fat, and cholesterol"). Therefore, the agency is retaining in § 101.9(c)(3)(i), redesignated as § 101.9(c)(1)(ii), for calories from total fat; in § 101.9(c)(4)(i), redesignated as § 101.9(c)(2)(i), for saturated fat; in § 101.9(c)(5), redesignated as § 101.9(c)(3), for cholesterol; in § 101.9(c)(6)(ii)(A), redesignated as § 101.9(c)(6)(ii), for sugars; in § 101.9(c)(7), redesignated as § 101.9(c)(6)(i), for dietary fiber; and in § 101.9(c)(11)(iii), redesignated as § 101.9(c)(8)(iii), for vitamins and minerals a provision that allows the nutrients to be omitted and replaced with a statement "Not a significant source of _____" when present in insignificant amounts. An example of this shortened format is given in appendix A of this document.

3. Calories From Saturated Fat

9. Several comments agreed with the proposal that declaration of calories from saturated fat should be voluntary. A few comments suggested that this information should be mandatory and referred to national dietary guidelines recommending that saturated fat be limited to less than 10 percent of total daily calories. A few comments requested that declaration of percent of calories from saturated fat be made mandatory.

Several comments believed that the declaration of calories from saturated fat should be disallowed. The comments argued that this information is redundant, confusing, and misleading.

FDA acknowledges that research has established the role of saturated fats in the etiology of atherosclerotic vascular disease and recognizes that there are national consensus recommendations regarding the levels of intake for saturated fat. However, section 403(q)(2)(A) of the act permits the Secretary to require the inclusion of information on additional nutrients in nutrition labeling if he determines that such information "will assist consumers in maintaining healthy dietary practices." The agency is not persuaded that the mandatory declaration of calories from saturated fat or the percentage of calories from saturated fat meet this criterion.

First, this information may be obtained by simple calculation if needed (i.e., calories from saturated fat can be calculated by multiplying the g of saturated fat by nine, the number of calories per g of fat; the percentage of calories from saturated fat can then be determined by dividing the number of calories from saturated fat by the total calories). Secondly, concerns have been expressed in comments that consumers will be faced with so much information that they will avoid using any of it. To minimize the possibility of this happening, FDA believes that it is preferable to have consumers concentrate on the number of calories from total fat. By controlling dietary intake of calories from fat, intake of calories from saturated fat will also be controlled.

However, in recognition of dietary recommendations that Americans should consume less than 10 percent of calories from saturated fat (Refs. 3, 4, and 30) FDA is continuing to allow voluntary declaration of calories from saturated fat in § 101.9(c)(3)(ii)(A), redesignated as § 101.9(c)(1)(iii).

4. Calories From Unsaturated Fat

10. Several comments agreed with proposed § 101.9(c)(3)(ii)(B) that the declaration of calories from unsaturated fat should be voluntary. A few comments suggested that the declaration of calories from unsaturated fat should be mandatory. These comments stated that caloric information on unsaturated fat would be helpful in monitoring unsaturated fat intake to maintain consumption of unsaturated fat at not more than the 20 percent of total calories.

Several other comments suggested that this information be disallowed because it will not be useful to the consumer in evaluating a total day's food intake, and because the information is potentially confusing.

A few comments requested that declaration of calories from monounsaturated and polyunsaturated fats be mandatory. One comment requested that declaration of the percent of calories from monounsaturated and polyunsaturated fats be mandatory. These comments stated that caloric or percentage information on monounsaturated and polyunsaturated fats would be helpful in limiting consumption of each of these two classifications of fatty acids to not more than 10 percent of total calories each.

The agency has decided not to permit declarations regarding calories from unsaturated fats because there is considerable uncertainty and controversy about the term "unsaturated fat" and its definition, specifically whether the "*trans*" isomers of monounsaturated fat should be included in this category of fats. These isomers have been implicated in the development of coronary heart disease and cancer (Ref. 31) and are discussed in the subject health claims rules published elsewhere in this issue of the **Federal Register.**

Further, the agency is not persuaded that it should allow the voluntary declaration of calories from monounsaturated and polyunsaturated fats. Definitions of monounsaturated and polyunsaturated fats include *cis* isomers only. *Trans* isomers are excluded. The declaration of calories from monounsaturated and polyunsaturated fats would therefore underrepresent the total caloric value of these fats because of the exclusion of the *trans* isomers. Such an underrepresentation would be misleading to consumers. Therefore, the agency is not allowing the declaration of calories from polyunsaturated and monounsaturated fats in the nutrition label.

11. One comment suggested that § 101.9(c)(3)(ii)(A) and (c)(3)(ii)(B) be modified to clarify that when the declaration of calories from saturated fat is declared adjacent to the declaration of g of saturated or unsaturated fat, that it be in a column headed "calories" as was stated in § 101.9(c)(3)(i) for calories from total fat.

The agency has reconsidered the proposed format in the supplementary proposal that would have allowed a separate column for listing calories. As discussed in section V. of this document, FDA is incorporating additional columns into the nutrition label to declare the percent of daily value and the daily value list. For this reason, the agency believes a column headed "calories" would add to label clutter and, therefore, has not made the suggested change. FDA has modified § 101.9(c)(1)(ii) to delete the option that calories from total fat be declared in a column headed "calories."

5. Calories From Carbohydrate

12. Several comments requested that the declaration of calories from carbohydrates be made mandatory so that consumers can monitor and adjust their intake of calories from carbohydrate to approach the recommended 50 to 60 percent of total calories. A few comments requested that the declaration of percent of calories from carbohydrate be made mandatory. Several comments agreed with the proposal to allow the voluntary listing of calories from carbohydrate. Several other comments requested that FDA not permit the declaration of calories from carbohydrate because this information is potentially confusing to consumers. These comments suggested that this information would not be helpful in evaluating a total day's food intake. A few comments argued that too much information is burdensome to the consumer, and that if it results in the manufacturer using smaller type size, it could make the information more difficult for the elderly to read. Further, the comments suggested that there was a danger of "information overload" and "label clutter."

Based on the comments to the July 19, 1990 and November 27, 1991, proposals, the agency has reconsidered its proposal to permit the voluntary declaration of calories from carbohydrate and has decided not to permit this declaration. As discussed in the mandatory nutrition labeling proposal of July 19, 1990 (55 FR at 29493), FDA's intent is to require the listing of only those nutrients that present public health concerns and for which quantitative intake recommendations have been made. FDA proposed to permit the voluntary declaration of calories from carbohydrate because of general recommendations that suggested that intake of carbohydrate should be increased to 50 to 60 percent of total calories but recognized that carbohydrate is not of pressing public health significance.

Based on its evaluation of the comments, FDA has become concerned that it will overemphasize the public health significance of carbohydrate if it allows the declaration of calories from this nutrient. Additionally, the legislative history of section (2)(b)(1)(C) of the 1990 amendments (Ref. 16) makes clear that while FDA must allow the declaration of additional nutrients in nutrition labeling, it must ensure that such information does not interfere with the consumer's understanding of the information required by the act. Thus, FDA considers it important to ensure the comprehensibility of the nutrition label.

The 1990 IOM report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1) emphasizes the importance of considering information quantity and complexity when determining the components of the food label (Ref. 1). The report suggests that too much information compromises the ability of many consumers to understand the label.

The agency is persuaded that because the amount of calories from carbohydrate is not of pressing public health significance, it should not provide for inclusion of this information in nutrition labeling. Accordingly, FDA has deleted proposed § 101.9(c)(3)(ii)(C) from the final regulation.

Consumers interested in determining the calories from carbohydrate for the vast majority of individual foods may simply multiply the number of g of carbohydrate by four, the number of calories per g of carbohydrate. Consumers attempting to compare their intake of carbohydrates to the recommended amounts of 50 to 60 percent of total caloric intake can use the Percent Daily Value format in the same way described for monitoring fat intake. Because the Daily Value for carbohydrate is set at 60 percent of calories, consumers need only add the percent DV for total carbohydrate with a target of 100 percent or a target of a percentage adjusted for their individual caloric intake. Alternatively, consumers can sum the g of carbohydrate consumed for the day, multiply the total by four, divide the result by the total calories consumed in that day, and multiply by 100 to obtain percent.

13. Although FDA chose not to propose the declaration of calories from sugars and complex carbohydrates, a few comments addressed this topic. Some of these comments stated that the declaration of calories from sugars and complex carbohydrates should be voluntary, and that this information, especially for sugars, was of interest to consumers. Other comments felt that the declaration of calories from sugars and complex carbohydrates should be mandatory. Both sets of comments felt that this information is potentially valuable to diabetics and parents of young children who are concerned about dental caries and excessive sugar intake. A few additional comments argued that the declaration of calories from sugars and complex carbohydrates is unnecessary and should not be permitted.

Interest in having calories from sugars and complex carbohydrates declared in the nutrition label was slight, and no data were presented to support the requests for such information. Further, dietary guidelines have not recommended specific quantitative amounts for caloric intake from sugars or complex carbohydrates. Therefore, the final rules do not permit the inclusion of such information in the nutrition label. FDA advises that the calculation of calories from sugars, which was of the most interest to the comments, can be easily calculated by multiplying the number of g of sugars present by four, the number of calories per g of sugars.

6. Calories From Protein

14. A few comments requested that the declaration of calories from protein as well as the percent of calories from protein be made mandatory to permit consumers to evaluate the quality of the food. Other comments agreed with the proposal for the voluntary declaration of calories from protein. On the other hand, additional comments suggested that this information would be confusing and misleading. These comments pointed out that concerns about protein intake are of limited public health significance in the United States and suggested that the declaration of calories would not be helpful in evaluating a total day's diet. The comments urged, therefore, that this declaration should not be permitted. One comment suggested that consumers would be tempted to overconsume protein if calories from protein were listed.

Upon consideration of the comments, FDA has reassessed its position. The agency agrees that the declaration of calories from protein and the percent of calories from protein are of limited usefulness to the consumer because the diets of the majority of Americans exceed the Recommended Dietary Allowances (Ref. 23) for protein. This lack of usefulness appears to outweigh any of the potential benefits of allowing the declaration of calories from protein. For this reason, and in an effort to reduce unnecessary information that might interfere with the consumer's understanding of required information, FDA is amending the final regulations by deleting proposed § 101.9(c)(3)(ii)(D) which allowed for the voluntary declaration of calories from protein.

Consumers interested in determining the calories from protein for an individual food may simply multiply the number of g of protein by four, the number of calories per g of protein. Consumers interested in determining the percent of calories from protein consumed in one day may add the g of protein consumed for the day, multiply

the total by four, divide the result by total calories consumed that day, and multiply by 100 to obtain percent.

7. Increments for Calories

15. The agency received only a few comments concerning the proposed change in § 101.9(c)(3) to delete the use of 2-calorie increments for expressing caloric content up to and including 20 calories per serving. Most of the comments agreed with the proposal which would express caloric content to the nearest 5-calorie increment up to and including 50 calories and to the nearest 10-calorie increment above 50 calories. While one comment disagreed with the proposed change to delete the 2-calorie increments on the basis that it would permit less accurate information for very low calorie foods, another comment considered 2-calorie differences as inconsequential to the consumer. Another suggestion was made to round all calorie levels to the nearest 5-calorie increment.

FDA is not persuaded by the comments that there is sufficient reason to maintain the use of 2-calorie increments for foods containing 20 or fewer calories or to use only 5-calorie increments. FDA acknowledges the concern expressed about very low calorie products. However, only a relatively small number of products will be affected by the change. In fact, the agency traditionally has been tolerant of slight differences in the declared and actual amounts of calories. Current § 101.9(e)(6), redesignated as § 101.9(g)(6), states that "Reasonable deficiencies of calories * * * under labeled amounts are acceptable within current good manufacturing practice." Thus, FDA is adopting this aspect of § 101.9(c)(3), redesignated as § 101.9(c)(1), as proposed.

C. Total Fat, Fatty Acids, and Cholesterol

1. Total Fat

In the mandatory nutrition labeling proposal, FDA proposed to require the declaration of fat, saturated fat, and cholesterol. In addition, FDA proposed definitions for saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat. The agency did not define "fat" (i.e., total fat) for nutrition labeling purposes. For compliance purposes, FDA has used as its definition the sum of compounds with lipid characteristics that are extracted by the Association of Official Analytical Chemists International (hereinafter referred to as AOAC) methods or by other reliable and appropriate analytical procedures (current § 101.9(e)(2)).

16. The agency received a number of comments concerning the agency's standards for assessing total fat. A few comments from food manufacturers and trade associations agreed with the customary method of estimating dietary fat. Comments from other food manufacturers, trade associations, college and university nutrition professionals, consumer advocate groups, other Government agencies, and foreign governments, disagreed with the agency's position regarding the determination of fat content. Some of these comments expressed uncertainty about what current declarations of fat represent. It became evident that some persons considered that the agency had implied a definition of total fat as the sum of all triglycerides by stating in current § 101.25(c)(2)(ii) that the amount of fatty acids was to be calculated as triglycerides. This statement led some comments to assume that mono- and diglycerides did not need to be included in the declaration of total fat.

Several comments suggested that the definition of fat should include all dietary lipids, especially mono-, di-, and triglycerides, phospholipids, and free fatty acids. These comments pointed out that advances in food technology have led to the development of fats and oils that reduce the triglyceride content found in foods by replacing triglycerides with mono- and diglycerides and phospholipids. These new forms of fats provide calories and should be included in total fat values declared in nutrition labeling.

One comment suggested changing the definition of fat to "substances possessing the physiological properties of fat." This comment stated that this definition would encompass all types of dietary fats. Another comment suggested that the definition be the "sum of fatty acids from a total lipid extraction." These comments pointed out that dietary lipids not only contribute to the total dietary caloric intake but have other physiologic functions attributable to fats. These functions include transporting of lipids and fat soluble vitamins in the body and structural functions in cell membranes, as well as serving as essential fatty acids and as precursors of certain hormones and eicosanoids.

Several comments suggested that FDA's position on total fat is not consistent with the definition found in Codex Alimentarius or with that used by the Canadian government and the EC. According to the comments, the international definition of fat is not restricted to triglyceride-releasable fatty acids but includes total free fatty acids and other lipids, including phospholipids.

A couple of comments suggested that the definition of fat should exclude some types of lipids (i.e., phospholipids, plant sterols, and novel lipids) because these lipids constitute only a small portion of total fat consumed, and, according to the comments, these types of lipids have not been reported as having a causal role in disease.

The agency is concerned about the obvious confusion caused by the lack of a precise definition for total fat. Because of the importance given to dietary recommendations to reduce the intake of total dietary fat, it is critical that all parties (i.e., Government agencies, food manufacturers, health professionals, nutrition scientists, and consumers) clearly understand what the values declared on the nutrition label represent.

Concerns that the total fat value not be underrepresented have persuaded the agency that it is not adequate to continue only using a reference to AOAC methods or "other reliable, appropriate analytical procedures." Such an approach allows for the use of many methods that measure different analytes. For example, according to AOAC procedures, "fat" content can be determined by ether or chloroform-methanol extraction. In the case of an ether extraction, results yield a value for neutral lipids which are primarily triglycerides (a complex lipid composed of glycerol and three fatty acids) and some mono- and diglycerides. In contrast, the chloroform-methanol extraction method extracts all classes of lipids. The two methods, which are both acceptable according to current regulations, may result in different values for total fat being obtained for the same product and different values being declared on the nutrition label.

The agency believes that the use of the implied definition of total fat as the sum of triglyceride fatty acids from saturated, polyunsaturated, and monounsaturated fatty acids, would in some cases underestimate both total g of fat and the caloric intake from fat. The agency agrees that all forms of fatty acids that contribute to energy intake of foods should be included in the calculation of total fat, particularly in view of dietary recommendations that target total fat intakes at 30 percent or less of calories.

For these same reasons, the agency disagrees with the suggestion that some lipids (e.g., mono- and diglycerides and phospholipids) be excluded from the definition of fat.

Therefore, the agency has decided to define total fat as total lipid fatty acids, that is, the sum of fatty acids from mono-, di-, and triglycerides, free fatty acids, phospholipid fatty acids, and sterol fatty acids. This definition includes all sources of fatty acids that provide energy, preventing underestimates of energy from total fat. It also acknowledges that certain lipid components, such as cholesterol and other sterols, do not contribute metabolizable calories and constitute only a very small amount of the total weight of lipids.

This definition represents all fatty acids obtainable from a total lipid extraction. The definition does not require that a single extraction method be used. The extraction method will depend upon the type of lipid being sought in the food and the type of food (i.e., the food matrix). Analytical procedures are discussed further in section IV. of this document.

The agency finds that this definition is more consistent with, although not identical to, international definitions for dietary fat. The Codex Alimentarius considers any source of dietary energy to be a nutrient (that would include nontriglyceride sources of fatty acids), and declaration of dietary fat would reasonably include all sources of fatty acids. The EC definition of fat is total lipids, including mono- and diglycerides and phospholipids. The difference between the EC definition and the agency's definition is that the agency excludes the sterol fraction, not a large difference in quantitative terms. Furthermore, the agency's definition reflects dietary goals for consumption of only 30 percent of calories from fat, because the sterols are not absorbed and therefore do not contribute calories.

However, the agency also recognizes that the definition of total fat as total lipid fatty acids does not account for the weight of glycerol to which the fatty acid chains are linked in the formation of mono-, di-, and triglycerides. Unless the glycerol is included in the weight of the total fat, it will be reported as carbohydrate. In this case, foods in which the fat is mostly triglyceride, e.g., corn oil and lard, will appear to have 95 percent total fat and 5 percent carbohydrate, while other products such as muscle meats which have never been reported to contain carbohydrate may now contain measurable amounts. These values would conflict with common perceptions of food composition because nutrient data bases and food composition tables routinely include the weight of glycerol in the declaration of total fat.

Therefore, the agency has decided to require that the declaration of total fat be expressed as the amount of triglyceride that would provide the analytically measured amount of total lipid fatty acids in the food. This position is supported by a recent report in The Referee, a publication of the AOAC International (Ref. 32). Likewise, because food composition data bases do not include glycerol in the declaration of fatty acids (i.e., values represent free fatty acid), the agency is not requiring that the amount of saturated fatty acids or other classes of fatty acids be expressed as triglycerides (see comment 30 of this document).

While the inclusive term "total lipid fatty acids expressed as triglycerides" would be the more accurate term to use in the nutrition label, the agency will continue to require use of the term "total fat" to be consistent with the terminology used in dietary recommendations and to avoid consumer confusion.

17. Several comments from manufacturers, trade associations, a consumer advocacy group, and a research firm addressed the issue raised in the preamble to the supplementary proposal (56 FR 60366 at 60371) of the increased use of fats containing very long (longer than 18 carbons) chain fatty acids in the food supply. These compounds provide the potential for marketing novel compounds in which fatty acids are linked to carbon structures in a manner that reduces their digestibility. As a result, these compounds have the technical effect of fat with less calories than traditional fats.

Comments requested that fat be defined to exclude various types of very long chain fatty acids because of their poor absorbability and reduced digestibility. A recent article was cited as evidence of the poor absorption of the very long chain fatty acids (Ref. 33). One comment stated that the definition of fat should exclude extractable compounds that do not have the physiological effects of fatty acid compounds. Two comments suggested the omission of these fatty acids from fat and calorie declarations similar to the omission of insoluble dietary fiber from calorie declarations. According to these comments "total fat" should be defined as "total 'digestible' fat" to allow for the use of fat-type ingredients that have reduced digestibility and therefore fewer calories than the fats they replace. The declared amount of fat would then be the total analytically determined fat times the fat digestibility coefficient.

FDA acknowledges the effect that the use of certain very long (longer than 18 carbons) chain saturated fatty acids with reduced digestibility have on the fat and calorie content of foods. In an effort to encourage innovation in the creation of products that provide lower fat and lower calorie contents to enable the consuming public to have a healthier diet and thus to meet one of the primary objectives of the Surgeon General's report on Nutrition and Health (Ref. 2), the agency is willing to consider the digestibility of novel fat compounds. However, the agency has concluded that because of the diversity of possible products, it is not appropriate to modify the definition of total fat in § 101.9(c)(2) to allow for alternate values because of reduced digestibility of very long chain fatty acids. Rather, the agency will address the digestibility of new ingredients containing these fatty acids on a case-by-case basis.

Because the digestibility of a substance is one of the identifying characteristics of the substance, the agency requests that manufacturers who wish to declare adjusted values of total fat based on reduced digestibility include information on the digestibility of the compound, analytical assay procedures for the compound, and data on interference with required methods of analysis in food additive petitions (21 CFR part 171) or in petitions for affirmation that the use of the substance is GRAS (21 CFR 170.35). The agency will include the specific digestibility coefficients that can be used in determining the quantitative declaration of fats and the caloric contribution from fats as part of the statement of identity for the substance in the listing regulation in part 172 for food additives and in part 184 for substances whose use is affirmed as GRAS. However, FDA recognizes that mechanisms other than food additive or GRAS petitions may be appropriate to bring issues involving the digestibility of a substance to the attention of the agency. Interested persons may wish to use the mechanism in § 101.9(g) to request to use specific digestibility coefficients.

18. Several comments said that there is a need for adequate analytical methods for assaying novel forms of fat in new low-fat foods. They noted the difficulty of isolating new ingredients by the traditional or AOAC determinations for fat. As one comment stated, the current acid hydrolysis analysis may not be appropriate for these type of substances.

FDA agrees with the concern about analytical methodology and is aware that different methods might be needed for each product or type of product. Because of this concern, and as noted in the preceding comment, the agency

finds that it is necessary that manufacturers delineate, in the documentation submitted to FDA in support of the lower fat content declarations, the methodology needed to assay for the novel fat compound. Use of the method by the manufacturer and the agency in lieu of conventional methods found in the AOAC or other recognized sources should alleviate labeling compliance concerns.

19. One comment urged the agency to allow manufacturers to use calculations from product formulas to arrive at the calorie or fat content of products containing these alternate ingredients.

As discussed in previous comments, the supporting documentation submitted to the agency to substantiate different caloric levels for novel fats should contain adequate information regarding the digestibility coefficient, analytical methodology, and other factors to ascertain an accurate label value for the fat and calorie declarations. FDA will use the information and analytical methodology for each such fat to determine whether the values for fat and calories stated on the label are correct. Manufacturers may use other methods, such as calculations from product formulas, to determine fat and calorie values if they have a reasonable basis on which to believe that the values so obtained will be consistent with values determined analytically. However, they do so at the risk that FDA will disagree.

2. Saturated Fat

a. *Definition.* FDA proposed (55 FR 29487 at 29495) to make the amount of fat, saturated fatty acids, and cholesterol mandatory elements of nutrition labeling. At the same time, FDA proposed in § 101.9(c)(4)(i) to continue to define saturated fatty acids as the sum of lauric (C12:0), myristic (C14:0), palmitic (C16:0), and stearic (C18:0) acids, the major saturated fatty acids in the U.S. food supply. FDA requested comments on the questions of what fatty acids should be considered as saturated fatty acids, and on what basis these decisions should be made (55 FR 29487 at 29495).

20. Many comments, including comments from food manufacturers and distributors, trade associations, professional organizations, nutritionists, and state health departments agreed with FDA's proposal to include only the four saturated fatty acids with 12 to 18 carbons (lauric, myristic, palmitic, and stearic acids) in the definition of saturated fat for labeling purposes. The reasons given included: (1) Lauric, myristic, palmitic, and stearic acids comprise the vast majority of saturated fatty acids in the American diet; (2) C12:0–C16:0 fatty acids raise total and low density lipoprotein (LDL)-cholesterol; (3) although some clinical and metabolic evidence suggests that C18:0 fatty acid (stearic acid) does not have the same blood total and LDL-cholesterol-raising effect as C12:0–C16:0 saturated fatty acids, the effect of C18:0 on blood total and LDL-cholesterol is not conclusive enough to warrant deletion of C18:0 from the definition; (4) stearic acid may be associated with other risk factors of cardiovascular disease such as thrombosis and platelet aggregation; and (5) a separate analysis for stearic acid would be costly.

Many other comments, including comments from other food manufacturers, trade associations, and health professionals, suggested that FDA include only lauric acid (C12:0), myristic acid (C14:0), and palmitic acid (C16:0) in the definition of saturated fat for labeling purposes. These comments stated that there is no evidence that stearic acid has a cholesterol-raising effect, and that the postulated role of stearic acid in thrombosis is open to dispute. With regard to the latter point, the comments cited the conclusion of a workshop on Dietary Fatty Acids and Thrombosis that there is no direct evidence of a prothrombotic effect of long chain fatty acids (e.g., C18) in humans (Ref. 34).

One comment from a trade association suggested that FDA not include palmitic acid in the definition of saturated fat because palmitic acid does not raise blood total and LDL-cholesterol. The comment cited recent research articles (Refs. 35 and 36) as the evidence.

A comment from a major food manufacturer suggested that FDA not include saturated fatty acids with less than 10 carbons in the saturated fat category. Other comments suggested FDA exclude lauric acid or myristic acid from the saturated fat category for labeling purposes. The reasons given were: (1) That the medium chain fatty acids (C6:0–C10:0), lauric acid (C12:0), and myristic acid (C14:0) are readily absorbed and oxidized and may not raise blood total and LDL-cholesterol, and (2) that medium chain fatty acids are minor sources of saturated fat in the American diet. In contrast, a consumer and a state agency suggested that FDA include saturated fatty acids with carbon numbers less than 12 in the saturated fat category because they may elevate blood cholesterol.

Some comments from a major food manufacturer and a state public health department stated that saturated fatty acids with carbon chains longer than 18 (i.e., C20–C24) should not be categorized as saturated fatty acids. The reasons given included: (1) These fatty acids compose a small part of saturated fat content in the U.S. diet, and (2) these fatty acids are poorly absorbed, have no or little physiological effects, and therefore do not contribute to heart disease.

Several comments, from a food manufacturer, a consumer, and foreign governments, suggested that FDA use a chemical definition of saturated fatty acids for labeling purposes. Two other comments from the meat industry suggested that FDA use a chemical definition if it is not possible to set a definition on the basis of the relationship of saturated fatty acids to the risk of cardiovascular disease. The reasons included in these comments were:

(1) Underrepresentation of the content of saturated fat. Several comments stated that the proposed definition, limiting saturated fat to only the four saturated fatty acids with 12 to 18 carbons, would result in underrepresentation of the saturated fatty acid content of foods, particularly of those foods that contain significant amounts of saturated fatty acids with less than 12 carbons or more than 18 carbons. They further stated that this underestimation of saturated fat contradicts the current dietary recommendation that Americans consume less than 10 percent of calories as saturated fats. The examples that they presented of foods in which the definition of saturated fat as C12–C18 would underrepresent saturated fat were milk, underrepresented by 8 percent; coconut oil, by 14 percent; and palm kernel oil, by 7.2 percent.

(2) Oversimplification. A consumer stated that FDA's proposal is an oversimplification and suggested that all saturated fatty acids be included.

(3) International harmonization. The Canadian Government and the EC stated that FDA's proposal to restrict the definition of saturated fat to only lauric, myristic, palmitic, and stearic acids is at variance with the Codex Alimentarius Commission, EC, and Canadian definitions. They stated that the proposed deviations from international definitions present serious problems for food companies in the EC and would be confusing for consumers. They suggested that FDA include all saturated fatty acids without double bonds in the saturated fat definition. A major food manufacturer also stated that it already had encountered minor problems with different definitions in labels for Canada and the United Kingdom and suggested that FDA consider international

harmonization in its decision on the definition of saturated fat.

FDA is persuaded by the comments that there is substantial controversy regarding the inclusion or exclusion of specific fatty acids in a definition of saturated fat that is based on effects on blood total and LDL-cholesterol.

Therefore, the agency has reconsidered its position of linking the definition of saturated fatty acids to effects of particular fatty acids on blood total and LDL-cholesterol levels and has determined that a chemical definition is appropriate for the following reasons.

First, a chemical definition avoids much of the controversy regarding the blood cholesterol effects of palmitic acid, very long (longer than 18 carbons) chain fatty acids, and short and medium chain fatty acids, because the definition is not subject to changes in knowledge about the physiologic effects of particular fatty acids. The chemical definition also avoids uncertainties about physiologic effects other than those regarding blood total and LDL-cholesterol, such as effects on thrombosis, and other possible health effects of very long chain, medium chain, and short chain saturated fatty acids.

Secondly, FDA agrees that the amount of saturated fat in some foods could be underrepresented when the definition of saturated fat is confined to the sum of four fatty acids. This underreporting of saturated fat may be increased as new foods containing saturated fatty acids less than C12 and more than C18 appear in the marketplace.

Thirdly, the agency also notes that the chemical definition is in line with EC and Canadian definitions of saturated fat and, hence, will promote international harmonization.

Finally, the agency notes that the chemical definition of saturated fat is more consistent with dietary recommendations to reduce fat consumption to 30 percent of calories and saturated fat consumption to less than 10 percent of calories. Food composition data tables have generally been used in epidemiologic investigations that relate diet to risk of chronic diseases, and these tables group all the chemically defined saturated fatty acids together as a class. Thus, the term "saturated fat" used in these dietary recommendations pertains to the chemical classification of fatty acids, not FDA's current, more restricted definition.

Accordingly, FDA has amended § 101.9(c)(4)(i), redesignated as § 101.9(c)(2)(i), to define saturated fat as the sum of all fatty acids containing no double bonds.

b. *Voluntary declaration of specific saturated fatty acids.* 21. Some comments specifically requested that the agency provide for labeling that distinguishes those fatty acids associated with increased blood total and LDL-cholesterol levels from those not associated with increased cholesterol. One approach that was identified in the comments and in a published commentary (Ref. 13) would allow a declaration of "cholesterol-raising fatty acids," so that a manufacturer could show that a particular food contained little or none of these fatty acids.

The agency recognizes that there is substantial uncertainty as to which saturated fatty acids are cholesterolemic and which are not. Conclusions of authoritative documents and review papers are not consistent on this issue (Refs. 2, 3, 37 through 41). The effects of most individual saturated fatty acids on blood total and LDL-cholesterol are not fully understood. The agency finds that the only saturated fatty acid that has been consistently reported as cholesterol-raising is myristic acid. The effects of palmitic acid and lauric acid are not as clearly associated with increased blood cholesterol, although the prominence of palmitic acid in the diet makes any contribution of this fatty acid important in the control of blood cholesterol. On the other hand, it has consistently been reported that stearic acid, when substituted for other saturated fatty acids in the diet, has a neutral effect on blood total and LDL-cholesterol concentration (Refs. 37 through 40). As a result, the agency is concerned that there is not an adequate basis for deciding which fatty acids should be included in the term "cholesterol-raising fatty acids."

In addition, the agency is concerned that the term "cholesterol-raising fatty acids" will be confusing to consumers. Since consumers are unfamiliar with the term "cholesterol-raising fatty acids," there is a possibility that they would misinterpret it and would avoid foods with such a declaration on the nutrition label, even if the intent of the labeling was to indicate the absence of these fatty acids. Also, given that the only fatty acid declaration the agency is requiring is saturated fat (defined as the sum of all saturated fatty acids), any added declaration of "cholesterol-raising fatty acids" would be on a voluntary basis. Under these circumstances, manufacturers could be expected to only include this declaration when the level of such fatty acids is low to emphasize the absence of such components from the product.

A variation of this term that avoids the negative connotation and applies positively to the composition of the product is the term "noncholesterol-raising fatty acids." However, this term suffers from the other problems with respect to cholesterol-raising fatty acids (i.e., the scientific uncertainty concerning what fatty acids to include and the likelihood of increased consumer confusion).

FDA is also concerned that either of the terms "cholesterol-raising fatty acids" or "noncholesterol-raising saturated fatty acids" could be seen as a health claim. Section 403(r)(1) of the act states that information that is required or permitted under 403(q) of the act to be included in the nutrition label is not a nutrient content or health claim. Because of the relationship between fatty acids and increased blood cholesterol and, thereby, heart disease, however, the agency is concerned that the use of either of the subject terms goes beyond the factual reporting of nutrients that is characteristic of the nutrition label.

For the reasons enumerated above, FDA has concluded that it is not appropriate to distinguish among fatty acids by the terms "cholesterol-raising fatty acids" or "noncholesterol-raising saturated fatty acids."

Another approach to distinguishing among fatty acids is to declare specific saturated fatty acids without any reference to effects on blood total and LDL-cholesterol. This approach is consistent with the agency's intention of providing factual information on the nutrition label. Because some comments strongly opposed the inclusion of stearic acid in the declaration of saturated fat because of the consumer's association of saturated fat with increased blood cholesterol levels, it is reasonable to indicate the extent of the saturated fat content of the food that is stearic acid and, thus, not associated with increased blood cholesterol. As noted above, a consensus that seems to be emerging is that stearic acid, when substituted for other saturated fatty acids, does not raise or lower blood total and LDL-cholesterol level. Consumer education programs could advise consumers that when a large portion of the saturated fat in a product consists of stearic acid, the fat content of the food is not likely to increase blood total and LDL-cholesterol levels.

The agency, however, has some reservations about allowing for the voluntary labeling of stearic acid in that: (1) Other saturated fatty acids that may raise blood total and LDL-cholesterol are not addressed; (2) only one risk factor of cardiovascular disease, blood

cholesterol level, is addressed; (3) it may complicate and overcrowd the label; and (4) it would require a consumer information program to have any meaning to consumers.

In addition, recognizing particular saturated fatty acid effects on blood cholesterol may require that the agency redefine the saturated fat threshold criterion for cholesterol claims in § 101.62(d) (cholesterol claims are not allowed on foods containing more than 2 g saturated fat, defined as the sum of all fatty acids containing no double bonds, per serving), as described in a companion document on nutrient content claims published in this issue of the **Federal Register**. Because of the agency's reservations about the meaningfulness of labeling of individual fatty acids and the need to reconsider criteria for cholesterol claims if such action was to be taken, the agency concludes that more information, including public comment, is necessary before taking further action on this approach. The agency intends to further address this issue at a later date, and would welcome submission of information and views on this question.

3. Polyunsaturated and Monounsaturated Fat

a. *Use of the term "unsaturated fat".* FDA proposed in both the July 19, 1990, and November 27, 1991, documents in § 101.9(c)(4)(ii) to permit the voluntary declaration of the quantitative amount of unsaturated fat in nutrition labeling. The agency proposed to make the declaration of unsaturated fat mandatory if claims were made about fatty acid or cholesterol content or if the manufacturer voluntarily declared the number of calories from unsaturated fat. Alternatively, the agency proposed to allow separate declarations of polyunsaturated and monounsaturated fats.

22. The agency received comments that either agreed or disagreed with the proposed definition and voluntary use of the term "unsaturated fat". Comments that supported the use of the inclusive term did so because neither monounsaturated nor polyunsaturated fats have been shown to increase the risk of coronary heart disease, and because both types of unsaturated fats decrease the risk of coronary heart disease relative to saturated fat.

Comments objecting to the term "unsaturated fat" argued that the term is not useful, that it offers no additional information that could not be obtained by subtracting the saturated fat content from total fat, and that it obscures the presence of essential fatty acids. Other comments were concerned that the term was misleading in that it suggests that all unsaturated fats are synonymous by including both *cis* and *trans* isomers and both poly- and mono-unsaturated fats together. These comments argued that in light of the current uncertainty and controversy surrounding the physiological effects of *trans* fatty acids (which are a particular type of unsaturated fatty acid having some physical properties of saturated fatty acids), use of the term "unsaturated fat" would not only be misleading to the consumer but possibly could have an adverse effect on the health of some individuals. This opposition to the inclusion of *trans* isomers in the definition of "unsaturated fat" was the most frequently repeated concern.

Comments suggesting that it would be misleading to group poly- and mono-unsaturates together argued that this action would imply that the two types of fatty acids are the same and have similar effects on blood total and LDL-cholesterol when, in fact, they do not. It has been reported that monounsaturates do not effect blood total and LDL-cholesterol levels and do not reduce high density lipoprotein-cholesterol when substituted for saturated fats. On the other hand, polyunsaturates have often been reported to reduce blood total and LDL-cholesterol levels and to decrease blood pressure.

A few comments suggested that if the term "unsaturated fat" is permitted, the declaration of the *cis* forms of polyunsaturates and monounsaturates should either be permitted or required at the same time. Comments also argued that there is no scientific consensus supporting the use of the inclusive term, and that it was not a term used in international trade.

FDA is persuaded by these comments that the use of the term "unsaturated fat" is potentially confusing to consumers, does not provide useful information, and could result in consumer deception. Accordingly, the agency is revising the regulation by not providing for the voluntary declaration of unsaturated fat in nutrition labeling. As a result, the proposed listings of polyunsaturated fat and monounsaturated fat in § 101.9(c)(4)(ii)(A) and (c)(4)(ii)(B), respectively, are redesignated as § 101.9(c)(2)(ii) and (c)(2)(iii). In addition, each paragraph has been modified to incorporate provisions that had been included in proposed § 101.9(c)(4)(ii). The revised listings provide that the disclosure of the level of polyunsaturated fat and monounsaturated fat is voluntary unless claims are made on the label about fatty acid or cholesterol content, and that, if either polyunsaturated or monounsaturated fat is declared, the other must also be declared.

b. *Trans Fatty Acids.* In its July 19, 1990 proposal on mandatory nutrition labeling (55 FR 29487 at 29496), the agency tentatively concluded that there is no basis for declaring *trans* isomers of fatty acids on the nutrition label. This conclusion was based on a consensus report that noted that current evidence does not support a blood cholesterol-raising effect for *trans* isomers when they are substituted for saturated fatty acids in the diet. The agency requested comments on this issue. Later that year new research and commentary was published (Refs. 12 and 13) which led FDA to request in the supplementary proposal (56 FR 60366 at 60371) comments on the significance of the new findings and a reevaluation of any comments submitted on *trans* fatty acids in response to the July 19, 1990 proposal.

23. Several comments, from a major food manufacturer, health professionals, a professional health organization, a state agency, a trade association, and a consumer, suggested that FDA include *trans* fatty acids in the saturated fat category because research suggests that *trans* fatty acids raise blood total and LDL-cholesterol. On the other hand, several comments were against the inclusion of *trans* fatty acids in the saturated fat category because the evidence of a cholesterol-raising effect of *trans* fatty acids is not conclusive. Several comments suggested that *trans* fatty acids should be declared separately because it may increase blood cholesterol.

FDA disagrees that there is sufficient evidence that indicates that *trans* fatty acids raise blood total and LDL-cholesterol. In 1985, a report of the Federation of American Societies for Experimental Biology on "Health Aspects of Dietary *trans* Fatty Acids"(Ref. 42) concluded that human studies indicate that *trans* isomers are little, if any, more cholesterolemic than *cis* isomers. In animals (rabbits, swine, and monkeys), *trans* fatty acids are cholesterolemic but not atherogenic. Since the publication of the Federation of American Societies for Experimental Biology report, a scientific review article, (Ref. 40) concluded that reports are inconsistent regarding the effects of *trans* unsaturates on blood total and LDL-cholesterol levels in humans.

Recently, two studies in The Netherlands (Refs. 12 and 43) have shown that a high intake of *trans* fatty acids may elevate blood total and LDL-cholesterol concentration. Concerns

have been raised about the applicability of these studies to U.S. diets because of certain methodologic limitations, because the level of *trans* fatty acid tested was 2–3 times higher than the current average consumption of the U.S. population, and because the methods for generating *trans* fatty acids might have been different from those used in the United States.

In contrast, another study (Ref. 44) seems to indicate that *trans* fatty acids do not raise blood total and LDL-cholesterol in mildly hypercholesterolemic, normotensive men, although diet differences other than *trans* fatty acids may have been responsible for the effects.

Finally, the agency is aware of preliminary results from a very recent unpublished study designed to address the criticisms of the studies from The Netherlands (Ref. 45) that suggests that *trans* fatty acids raise LDL-cholesterol.

In the absence of the fully analyzed data from this study, the agency considers it premature to require the labeling of *trans* fatty acids because of their effects on total or LDL-cholesterol. However, even if there was a need for labeling of *trans* fatty acids, the agency does not agree that *trans* fatty acids should be included in the category of saturated fats. The agency has argued against inclusion or exclusion of particular saturated fatty acids in the definition of saturated fat solely on the basis of their effect on blood total and LDL-cholesterol. In addition, the agency recognizes that inclusion of *trans* fatty acids in the definition of saturated fat is not consistent with the EC, Codex, or Canadian definitions of saturated fat.

Because of the current uncertainties, the agency does not agree that a separate declaration of *trans* fatty acids is appropriate at this time. Because new data are rapidly emerging (Ref. 45) that imply that *trans* fatty acids raise LDL-cholesterol, however, the agency recognizes that it may be necessary to readdress the labeling of *trans* fatty acids in the near future.

24. One comment suggested that not all foods voluntarily declaring levels of monounsaturates and polyunsaturates need to be analyzed to differentiate *cis* and *trans* fatty acids because only those containing hydrogenated fats would contain *trans* isomers.

The agency agrees with this comment in the case of vegetable oils and other plant lipids. However, naturally occurring *trans* fatty acids are found in some animal lipids (e.g., dairy products). If there is adequate and reliable reason to believe that a nutrient is not present in a food, there is no need to analyze for that nutrient. However, a manufacturer is responsible for ensuring that its labeling is truthful and not misleading.

c. *Definition of polyunsaturated fatty acids.* FDA proposed in §§ 101.9(c)(4)(ii)(A) and (c)(4)(ii)(B) in July 19, 1990 and November 27, 1991 to define polyunsaturated and monounsaturated fats as *cis, cis*-methylene interrupted polyunsaturated fatty acids and cis-monounsaturated fatty acids, respectively. These definitions exclude *trans* isomers. The definition of polyunsaturated fat is consistent with current § 101.25(c)(2)(ii)(*a*). FDA has not previously defined monounsaturated fat for labeling purposes.

25. Comments from food manufacturers, trade associations, health promotion organizations, consumer groups, and international agencies supported the agency's definition for polyunsaturated fat. However, some comments urged FDA to change the definition to reflect the various physiological roles of specific types of polyunsaturated fats, in particular to allow for the identification of omega-3 (n–3) and omega-6 (n–6) fatty acids, indicating that these are essential in the diet and that the ratio of consumption of these fatty acids can be important.

FDA is not persuaded that there is a need to require further breakdown of polyunsaturated fats in the nutrition label. As discussed above, FDA is concerned that additional information on the nutrition panel may confuse consumers and interfere with their understanding of other required information.

However, the agency agrees that there are valid reasons to consider the voluntary labeling of omega-3 and omega-6 fatty acids. These chemical distinctions are important nutritionally, because the omega-3 fatty acids (with the first double bond at the third carbon from the methyl end of the fatty acid) and omega-6 fatty acids (with the first double bond at the 6th carbon from the methyl end) are not interchangeable during metabolism in the body; rather each must be supplied by diet. Each subcategory has members that are considered essential nutrients (α-linolenic acid and linoleic acid, for the omega-3 and omega-6 classes, respectively) (Ref. 23). Dietary omega-3 and omega-6 fatty acids are precursors for biologically active compounds, e.g., prostaglandins, eicosanoids, and the nutritional balance of omega-3 and omega-6 fatty acids modulates the production of many of these biologically important substances. Furthermore, omega-3 and omega-6 fatty acids are important components of cell membranes.

Although the National Research Council has not yet established a Recommended Dietary Allowance for omega-3 and omega-6 fatty acids, they recognized in 1989 that "[T]he possibility of establishing Recommended Dietary Allowance's for these fatty acids should be considered in the near future." (Ref. 23)

FDA agrees that information on the amount of omega-3 and omega-6 fatty acids may be useful to allow interested consumers to select foods that provide these fatty acids. It is not difficult to consume a diet rich in omega-6 fatty acids because vegetable oils are rich in these fatty acids. However, vegetable oils vary widely in their content of omega-3 fatty acids, and labeling may be useful to identify those foods that contain substantial amounts of omega-3 fatty acids to encourage a balanced intake of these two classes of fatty acids.

However, FDA is not fully persuaded about the usefulness of additional label information on omega-3 and omega-6 fatty acids, and whether there are many consumers who desire this information. As discussed above, the agency is concerned that additional information on the nutrition panel may confuse consumers and interfere with their understanding of other required information. Because of these concerns, FDA concludes that it is not appropriate to allow for the voluntary declaration of these subcomponents of polyunsaturated fats at this time. The agency intends to address this issue at a later date and would welcome submission of information and views on this issue.

26. The majority of comments supported the voluntary declaration of polyunsaturated fats. However, a few comments suggested that their declaration be mandatory rather than voluntary. One of these comments was concerned with possible safety issues associated with increased consumption of polyunsaturated fats. The comment alleged that polyunsaturated fats convey a potential source of free-radical peroxidation products, and that consumers should be informed of the amounts of polyunsaturated fat present in a food. Other comments merely stated that mandatory declaration of polyunsaturated fat would provide consumers with valuable and more complete nutritional information.

FDA is not persuaded that there is a need to require the inclusion of polyunsaturated fats on the nutrition label. These fatty acids do not meet the criteria for mandatory declaration set forth in the mandatory nutrition

labeling proposal (55 FR 29487 at 29493) that the nutrient or food component be of particular public health significance, and that quantitative intake recommendations for the nutrient be given in major scientific consensus reports. The comments largely support this view, and the agency therefore rejects the suggestion that the declaration of polyunsaturated fats be mandatory.

The agency disagrees with the contention that commonly consumed amounts of polyunsaturated fats would pose any safety concerns. While the potential exists for formation of oxidative products as a result of the increased number of double bonds—present in polyunsaturated fats, any risk would only occur at very exaggerated levels of consumption.

d. *Monounsaturated fats.*

27. Comments both agreed and disagreed with the proposed definition of "monounsaturated fat." Those opposed generally requested that the definition not exclude *trans* fatty acids on the basis that they have not been proven to have an adverse effect on health or disease in humans, or that *cis* and *trans* isomers have similar metabolic and physiologic properties. One comment asked the agency to include *trans* fatty acids in the definition of monounsaturated fats until an expert panel can determine if *trans* or unusual *cis* isomers formed as components of commercial hydrogenation increase the risk for coronary heart disease or other health related conditions.

Comments from medical associations, trade associations, a consumer advocacy group, the Canadian government, and the EC supported the proposed definition, focusing particularly on two considerations. First, *trans* fatty acids or unusual *cis* isomers formed during commercial hydrogenation of unsaturated fats may increase the risk of coronary heart disease, and, second, monounsaturated fats, as defined in the proposal, may reduce blood total and LDL-cholesterol and reduce the risk of coronary heart disease. Comments also suggested that the inclusion of *trans* fatty acids may mislead consumers, who perceive monounsaturates as healthful or at least as not harmful.

FDA concludes that there is no need to amend the proposed definition of "monounsaturated fat." The comments received, the scientific reports they discuss (Refs. 12 and 43), and the concerns addressed in the preceding discussion of *trans* fatty acids establish that to include *trans* isomers in the definition of "monounsaturated fat" would be misleading and will not assist consumers in maintaining healthy dietary practices. The agency is not willing to include *trans* isomers in the label definition of "monounsaturated fat" until there is further consensus based on publicly available, well-designed, and well-conducted studies. However, as more data concerning the action and safety of *trans* fatty acids become available, the agency may reconsider its decisions to define monounsaturates as the usual *cis*-monounsaturated fatty acids.

28. One comment also objected to the proposed definition of "monounsaturated fat" because it would require manufacturers to conduct a further analysis of lipids to differentiate between *cis* and *trans* isomers. The comment argued that this extra analysis was not justified by available scientific data and would cause a financial burden.

The agency disagrees with the comment. The declaration of poly- and mono-unsaturates is voluntary. Therefore, an analysis of unsaturated isomeric forms is only required if the manufacturer chooses to declare poly- or mono-unsaturates or to make fatty acid or cholesterol claims. In such cases, given the controversy on the effect of *trans* fatty acids, the additional analysis is necessary to ensure that the declaration or claims are not misleading.

29. One comment suggested that the agency should include stearic acid in the definition of monounsaturated fat by virtue of its effects on blood total and LDL-cholesterol. The comment stated that scientific data suggests that stearic acid does not increase blood LDL-cholesterol, and that it is rapidly converted to oleic acid, an unsaturated fat that does not raise blood total and LDL-cholesterol levels.

FDA does not agree that stearic acid should be included in the definition of monounsaturated fat. Chemically, stearic acid is a saturated fat, and the agency, therefore, finds that it would be inappropriate to include it with monounsaturated fats. The agency has acknowledged above that some studies and some consensus statements suggest that stearic acid does not increase LDL-cholesterol relative to other saturated fats. However, stearic acid does increase LDL-cholesterol relative to monounsaturates and polyunsaturates (Refs. 12 and 43). Accordingly, the agency is not including stearic acid in the definition of monounsaturated fat.

4. General Issues Related to Declaration of Fats and Fatty Acids

a. Calculation of fatty acids as triglycerides.

30. A comment was received that disagreed with proposed § 101.9 (c)(4)(i) and (c)(4)(ii), which would require saturated fat and unsaturated fat content to be calculated as triglycerides. The comment noted that values in current data bases are reported as the free fatty acids.

Current § 101.25(c)(2)(ii) requires that fatty acids be calculated as triglycerides. This requirement dates back to the initial nutrition labeling regulation promulgated in 1974. This requirement was a result of comments from industry at that time.

To provide consumers with nutrition information that can readily be used for comparison to available nutrient data bases, FDA agrees that saturated and poly- and mono-unsaturated fat should be declared as free fatty acids instead of as triglycerides. As a consequence of the change in method of reporting, slightly lower values for the various fatty acid declarations will appear on the label because the weight of the glycerol molecule in triglycerides is not included when free fatty acids are declared. Also, fatty acids from mono- and di-glycerides used as a source of fat in many products will be included using this revised means of reporting fatty acids. Accordingly, FDA is amending § 101.9(c)(2)(i) for saturated fat and § 101.9(c)(2) (ii) and (iii) for polyunsaturated and monounsaturated fat, respectively, to remove the requirement that the fatty acids be "calculated as triglycerides."

b. Increments for declaring fats and fatty acids. The mandatory nutrition labeling proposal retained the current requirement for the declaration of fat in g and added, as a requirement, the amount of saturated fatty acids in g (55 FR 29487 at 29495). In the supplementary proposal, FDA proposed to change the increments for declaring fats and fatty acids (56 FR 60366 at 60380). The agency proposed to require the declaration of total fat, saturated fat, unsaturated fat, polyunsaturated fat, and monounsaturated fat in 0.5 (½)-g increments. The agency made this change in the proposed provisions to make the increments in which these nutrients are declared more consistent with the levels at which these substances will have nutritional significance. FDA believed the proposed change would consequently provide consumers with more precise information and a greater ability to discriminate among products. In this context, a level of less than 0.25 g per serving was established as the level at which saturated and unsaturated fat content would be expressed as zero.

31. Over 25 responses concerning fat increments were received in response to the request for comments. Almost twice the number of comments disagreed with the proposal to declare total fat and fatty acids in 0.5-g increments as those who agreed with the proposal to do so. The rationale given by essentially all who disagreed with the proposed change was the lack of analytical methods that are adequate and sensitive enough to provide data to that degree of precision. Several comments recommended that the fat content of foods containing 3 or less g fat be declared in 0.5 (½)-g increments, and the fat content of foods containing more than 3 g be declared in whole g increments. These comments suggested that the precision of 0.5 g increments for fat declarations is less important for higher fat foods. Additionally, these comments stated that the variability of some fat assays warrants whole-g increments, especially for moderate and high levels of fat. It should be noted, however, that several comments stated that methodology does exist to support the 0.5-g increment declaration. One comment noted the desirability of keeping all macronutrients, including fat, in whole-g increments. Several comments cited the cost of assaying to the 0.5 (½)-g level of precision as a reason for retaining the whole-g increment declarations for these nutrients.

FDA has given careful consideration to the comments. The agency recognizes that labeling requirements must not only convey desired nutrition information for the consumer but must also be enforceable. Because of concerns about analytical precision, variability, and the effect of product matrices on the methods necessary to quantify total fat, saturated fat, and poly- and mono-unsaturated fat declarations in 0.5-g increments, FDA has concluded that such precision is not necessary for amounts of fat above 3 g per serving of food. Consequently, the agency is modifying § 101.9(c)(2) and (c)(2)(i) through (c)(2)(iii) to require that levels below 3.0 g per serving be declared in 0.5 (½)-g increments and levels above 3.0 g be declared in g increments.

The agency disagrees that cost, although a factor, is a sufficient reason in and of itself to retain the current whole-g increments for total fat, saturated fat, and poly- and mono-unsaturated fats. The public health benefits attributed to decreasing dietary intakes of fat (Refs. 2, 3, 4, and 47) justify the use of 0.5-g increments to allow consumers to differentiate between products containing low levels of fats.

32. A few comments urged that fats not be declared in 0.5 (½)-g increments to improve the legibility of the label.

The agency is concerned about the legibility of the label. However, because of the public health significance of dietary intake of fats, FDA believes it is important to provide the increased precision at low levels of fat. Inasmuch as legibility is more dependent upon factors such as type size and color contrast than the addition of a decimal point and digit, FDA urges manufacturers to consider the readability factor and use great care to ensure that the information is legible.

33. Two comments requested that the agency permit the declaration of total fat and saturated fat in tenths of a g.

FDA does not agree. It is not possible to require the declaration of total fat and saturated fat in tenths of g increments because this degree of precision cannot be reliably obtained in all foods with available methodology.

34. Comments stated that the change from whole-g increments would be confusing and cumbersome to consumers. One comment requested that the agency adopt a consistent rule for all macronutrients by rounding values to the nearest g.

FDA does not agree that the use of different increments for different nutrients will be confusing and cumbersome. These final rules allow for calories to be declared to the nearest 5 or 10 calorie increment depending on amount, for fats to the nearest 0.5 (½) or whole g, for cholesterol to the nearest 5 milligram (mg) amount, for carbohydrates and protein to the nearest g and for sodium to the nearest 5 or 10 mg increment. The rationale for each of these increments was explained when the increments were proposed.

c. *Amounts of fatty acids to be rounded to zero.*

35. A few comments disagreed with 0.25 g as the cut-off level at which fatty acids could be declared at zero. The primary reason given for disagreeing with the 0.25 g cut-off was that the analytical methods are not sensitive and precise enough to detect that level with any degree of reliability. One of the comments noted that FDA had, in its proposal on serving sizes, referenced consumer complaints about fractional numbers. The comment felt it was contradictory to introduce a potentially confusing requirement for the proposed 0.25 g cut-off. Other comments stated it would be confusing to consumers if, because of the rounding requirements, a product containing either 0.4 g or 0.45 g total fat and 0.3 g saturated fat is declared as "0" g total fat and 0.5 g saturated fat.

The agency is persuaded that the level of 0.25 g as the cutoff for a zero declaration for saturated, polyunsaturated, and monounsaturated fat content implies unwarranted precision. The ability to distinguish 0.24 g as zero and 0.26 g as a 0.5 g increment is presently unsubstantiated. Therefore, FDA is amending § 101.9(c)(2)(i) through (c)(2)(iii), to require that when a serving contains less than 0.5 g of saturated fats, polyunsaturated fats, or monounsaturated fat, the content of the fatty acids will be expressed as zero.

5. Cholesterol

36. The majority of comments agreed with the proposal for the mandatory declaration of cholesterol content. A few comments disagreed stating that dietary cholesterol does not play a significant role in the etiology of atherosclerotic vascular disease. Some comments stated that the declaration of cholesterol would mislead consumers into believing that a food free of, or low in, cholesterol would be effective in lowering serum cholesterol levels no matter how much saturated fat or total fat it contained. These comments suggested that declarations of cholesterol content should be either voluntary or not permitted.

FDA disagrees that the declaration of cholesterol should be voluntary or not permitted. The declaration of cholesterol content is required by section 403(q)(1)(D) of the act. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, FDA does not believe that this is the case for cholesterol. There is a strong scientific consensus that high dietary intakes of total fat, saturated fatty acids, and cholesterol are associated with an increased risk of atherosclerotic cardiovascular disease, most notably with elevations in blood LDL-cholesterol and increased risk of coronary heart disease (Refs. 2, 3, 4, and 30).

Further, numerous controlled experiments, in both animals and humans, verify that dietary saturated fats and cholesterol elevate blood LDL-cholesterol. For this reason, current recommendations suggest limiting cholesterol to 300 mg per day as a means of lowering blood LDL-cholesterol and thereby reducing the risk of atherosclerotic vascular disease (Refs. 2, 3, 30, and 48). Accordingly, the agency concludes that the declaration of cholesterol is warranted and will be beneficial to many individuals in the general population in the monitoring of their cholesterol intake. Therefore, no

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changes have been made in § 101.9(c)(5), redesignated as § 101.9(c)(3).

37. A few comments requested the mandatory declaration of a cholesterol-saturated fat index. This index provides a single number for individual foods that describes their cholesterol and saturated fat content. The index indicates the potential of a given food, diet, or menu to raise blood cholesterol levels.

The agency is not persuaded that the declaration of a cholesterol-saturated fat index on the nutrition label is warranted. There currently exists no consensus on the efficacy of this index. Therefore, FDA believes that the declarations of cholesterol and saturated fat, as required by the 1990 amendments, are sufficient for those who wish to moderate their intake of these nutrients.

38. Several comments disagreed with the proposal to declare "not a significant source of cholesterol" if cholesterol is present at less than 2 mg per serving. One comment suggested that the label declare zero cholesterol only if the product is virtually devoid of cholesterol. The comments stated that it is misleading to have even minute quantities of a food component in a product when the label declares that the product is free of that component.

The agency is not persuaded by these arguments. As discussed in the July 19, 1990, tentative final rule on cholesterol (55 FR 29460 at 29461), FDA purposely selected a value, less than 2 mg of cholesterol per serving, that is dietarily insignificant yet that can be detected with reasonable analytical reliability. A quantitative declaration other than zero would not necessarily be more correct because methodological limitations do not generally permit precise quantification of cholesterol content within the 95 percent confidence level below 2 mg amounts. It is also extremely unlikely that sufficient quantities of foods containing less than 2 mg of cholesterol per serving would be consumed on a daily basis to represent a significant level of cholesterol intake.

39. A few comments requested that foods having less than 5 mg of cholesterol per serving be permitted to indicate "not a significant source of cholesterol" so that skim milk, at 4 mg cholesterol per cup, and similar foods could use the statement. Proposed § 101.9(c)(5) only allows its use on labels of foods containing less than 2 mg of cholesterol per serving.

FDA disagrees. The agency believes that the statement "not a significant source of cholesterol" is only appropriate on foods that contribute truly insignificant amounts of cholesterol to the diet. In the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, the agency has determined that foods that contain less than 2 mg of cholesterol per serving are dietarily insignificant sources, and that foods that contain larger amounts, both individually and collectively, contribute significantly to a person's daily cholesterol intake. Therefore, FDA is taking no action on the basis of these comments.

D. Sodium

40. The majority of comments supported the proposal for the mandatory declaration of sodium. A few comments requested alternate methods of declaring sodium, such as a sodium to potassium ratio and a sodium balance system.

The agency has no data, nor were any submitted, that demonstrate that these alternative methods would more effectively present sodium content. Accordingly, FDA has not revised the provision for the declaration of sodium content.

41. A few comments questioned potential beneficial effects of sodium restriction in nonhypertensive populations. The comments suggested that there is still debate within the scientific community as to whether it is appropriate for the general population to reduce its overall sodium consumption. Further, these comments stated that control of sodium intake is only relevant for those segments of the population that are sodium sensitive. These comments requested that the agency not permit the declaration of sodium, or that it make the declaration of sodium voluntary.

The agency disagrees. Section 403(q)(1)(D) of the act requires the declaration of sodium. While section 403(q)(2)(B) of the act allows the Secretary to delete nutrient information that is not necessary to assist consumers in maintaining healthy dietary practices, the bulk of the accumulated evidence strongly supports the prevailing consensus that it would be prudent for the general population to reduce sodium consumption, even though not all people display increased blood pressure in response to high sodium intakes.

The Surgeon General's report (Ref. 2) asserts the need for moderation in sodium consumption, not only because there is a benefit to persons whose blood pressures do rise with sodium intake, but also because there is no biological marker for individual sodium sensitivity. Additionally, the report notes that there is no apparent harm from moderate sodium restrictions (Ref. 2). Accordingly, § 101.9(c)(9), redesignated as § 101.9(c)(4), will continue to require sodium declaration.

42. One comment from a national manufacturer of carbonated soft drink syrups explained that these syrups must be mixed with local water supplies, and that, therefore, the final products vary in sodium content. The comment suggested that the sodium in these products be declared as an average value, such as "less than 35 mg," even though the product contains slightly more, or slightly less, than that amount. Further, the comment suggested that the manufacturer be allowed to make a claim, such as "very low sodium," based on that range.

Data on the sodium content of the United States water supplies were previously submitted, reviewed, and discussed in the April 18, 1984, final rule on the declaration of sodium content (49 FR 15524). FDA's evaluation of these data revealed that a single label would accurately reflect the sodium content of all but 10 percent of soft drink products bottled in the United States, and that a second label could apply to the remainder without severely overstating the sodium content.

Further, the agency stated that the manufacturer had the option of using a single nationwide label with the highest possible sodium level declared. This approach would result in the sodium content being overstated by about 50 mg for a majority of products. While 50 mg is not an insignificant amount of sodium, it represents a relatively small portion of the daily sodium intake for all but those persons on extremely restricted sodium diets. Even if sodium were declared based on the highest level of sodium found in any source of water, all regular and diet soft drinks would fall into the "low sodium" category.

FDA is not persuaded by the comment to the July 19, 1990 or November 27, 1991, proposals that an average value representing a range of sodium levels, such as "less than 35 mg," is appropriate for these products. Sodium content may be underrepresented by this method.

Inasmuch as the declaration of sodium is required by section 403(q)(1)(D) of the act, and no new data were presented with the comment, the agency is denying the request that a range of sodium content be declared on the nutrition label or be allowed as a basis to support a nutritional claim.

E. Potassium

43. Several comments supported the proposal for the voluntary declaration of potassium. One comment, however,

requested that the agency not allow any declaration of potassium content. The comment suggested that the general population is unaware of the dietary role of potassium, and any declaration of potassium content would only serve to confuse the consumer. No data were provided to support this argument.

FDA is not persuaded that it should not permit the voluntary declaration of potassium content. As discussed in the mandatory nutrition labeling proposal (55 FR 29500 at 29501), beneficial effects of potassium intake relative to reducing mortality from stroke have been reported. Data from animal studies suggest that dietary potassium may lower blood pressure and the risk for heart disease and may also protect against vascular damage and stroke (Ref. 3).

In addition, epidemiological evidence for humans suggests that diets with high levels of potassium—but also low levels of sodium—may be beneficial in lowering blood pressure (Ref. 3). Moreover, the IOM report concluded that even though deficits or excesses of potassium intake do not pose public health concerns, the voluntary declaration of potassium would be beneficial to consumers (Ref. 1). Based on the foregoing evidence, FDA concludes that the declaration of potassium in nutrition labeling may assist in maintaining healthy dietary practices. Accordingly, in § 101.9(c)(10), redesignated as § 101.9(c)(5), FDA will allow potassium to be declared in nutrition labeling on a voluntary basis.

44. Comments from several health and professional associations, consumers, consumer groups, and universities supported mandatory declaration of potassium content. The comments stated that this information is potentially helpful to persons with kidney disease. Others referred to epidemiological evidence of a positive association among high potassium intake, low sodium intake, and lower blood pressure.

Although potassium has been acknowledged as a potential public health issue (Refs. 1 and 49), no specific, quantitative recommendations have been made by national consensus reports. Accordingly, potassium does not meet FDA's criteria for inclusion as a mandatory element of nutrition labeling, as discussed in FDA's mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29500).

Until such time as quantitative recommendations are made, the agency does not believe there are sufficient grounds to require labeling of potassium content. Therefore, FDA is continuing to permit potassium content labeling in nutrition labeling on a voluntary basis in § 101.9(c)(5).

45. One comment suggested that the declaration of potassium content should be mandatory only if magnesium is not required as a reference nutrient. The comment stated that potassium and magnesium are abundant in whole grain cereals, legumes, nuts, and other unprocessed foods. Further, the comment suggested that if magnesium is required, potassium should be voluntary.

The agency is not persuaded that the mandatory declaration of magnesium is warranted, or that the declaration of potassium should be mandatory because the declaration of magnesium is not required. Magnesium is not a nutrient for which there are significant public health concerns (Ref. 23).

Further, while magnesium and potassium are found together in many foods, using magnesium as a reference nutrient for potassium in food labeling is questionable because there are many fruits and some vegetables that are excellent sources of potassium but poor to moderate sources of magnesium (Ref. 23). The agency does not believe that a mandatory declaration of magnesium content is warranted at this time.

46. One comment suggested that information on potassium should be available from manufacturers' toll-free telephone numbers. The comment explained that consumers who must monitor their potassium intake, such as renal dialysis patients, often have difficulty determining how much potassium is in a product. The comment suggested that manufacturer's toll-free numbers would provide easy access to more detailed nutrient content information.

While FDA encourages manufacturers to make additional information available to consumers, this request is beyond the authority of the agency. Toll-free telephone numbers for product information may or may not be supplied according to the preference of the manufacturer.

F. Total Carbohydrate, Dietary Fiber, Sugars, Sugar Alcohol, and Other Carbohydrate

1. Total Carbohydrate

47. Comments from trade associations, manufacturers, professional societies, and another federal agency recommended that FDA reconsider proposed § 101.9(c)(6) which excludes dietary fiber from total carbohydrate. As noted in several comments, dietary fiber traditionally has been included as part of the carbohydrate content of food, is considered part of carbohydrate in current nutrition labeling regulations, is included within total carbohydrate for nutritional labeling by Canada, and is included in the Atwater method of determining "carbohydrate by difference." Other comments pointed out that excluding dietary fiber from total carbohydrate is consistent with definitions for labeling used by Codex Alimentarius Commission and the European Community (EC), which include only metabolized carbohydrate. A comment remarked that to exclude dietary fiber from total carbohydrate is inconsistent with all major data bases and U.S. publications on food composition and is different from the way carbohydrate has been presented to the consumer in nutrition labeling for the past two decades. This comment suggested that inconsistency in definitions will contribute to consumer confusion.

In the 1990 mandatory nutrition labeling proposal, FDA proposed mandatory declaration of total digestible carbohydrate, which excluded dietary fiber, the nondigestible portion of carbohydrate. Several comments noted that while the intent of this definition for total carbohydrate was to include only energy yielding components, in fact there is evidence that fermentation of dietary fiber yields available energy. Comments noted that dietary fiber content was accounted for in deriving both the general energy factor of 4 calories per g of carbohydrate and the specific Atwater factors for calculation of energy value of carbohydrate in foods. The comments stated that total carbohydrate (excluding dietary fiber) content as defined in proposed § 101.9(c)(6) is not appropriate for calculating calories from carbohydrate as proposed in § 101.9(c)(3). As a result, two different values for "total carbohydrate" would be required to comply with nutritional labeling: (1) Total carbohydrate (excluding dietary fiber) for the content declaration, and (2) total carbohydrate (including dietary fiber) for calorie calculation.

In the mandatory nutritional labeling proposal, FDA stated that the reason for declaration of carbohydrate content was, in part, to allow consumers to determine the percentage of calories from carbohydrate (55 FR 29487 at 29497). Several comments argued that departing from the established use of the term "carbohydrate" (i.e., including dietary fiber) used in determining carbohydrate calories by the Atwater method, will be confusing and thereby detract from the value to consumers of the caloric information. Several comments suggested that in separating dietary fiber

from "energy yielding" components of carbohydrate, FDA's logic was faulty for two reasons. First, carbohydrate fractions are not clearly delineated as digestible or nondigestible fractions. Rather, there exists a continuum of digestibility among carbohydrate substances. Second, dietary fiber is appropriately included in total carbohydrate for calculation of energy content with use of Atwater factors.

Many comments noted that, except for lignin, substances comprising dietary fiber are carbohydrates. Comments pointed out that dietary guidelines (Ref. 4) urge increased consumption of types of foods rich in both dietary fiber and complex carbohydrate and stated that separating these carbohydrate components in nutrition labeling will mislead consumers as to the nature of dietary fiber.

FDA is persuaded by the comments that the separation of dietary fiber from carbohydrate is inconsistent with established methods of reporting food composition and confuses the issue of calculating energy content. Further, the agency agrees that the separation of dietary fiber from carbohydrate will decrease consumer understanding of label information and its application to dietary recommendations that link dietary fiber and complex carbohydrate together in advising increased consumption of foods high in both. Accordingly, FDA is modifying § 101.9(c)(6) to include dietary fiber in the declaration of total carbohydrates. This action results in the inclusion of both digestible and nondigestible carbohydrates under total carbohydrates.

Section 101.9(c)(6) is also modified to state that total carbohydrate content is to be calculated by subtracting the sum of crude protein, total fat, moisture, and ash from the total weight of food. Additionally, since total carbohydrate now includes dietary fiber, the paragraphs relating to dietary fiber are redesignated under § 101.9(c)(6)(i) rather than under § 101.9(c)(7). Consequently, the remaining paragraphs within § 101.9(c) are renumbered.

2. Dietary Fiber

48. Comments from consumers, health professionals, health promotional organizations, and manufacturers agreed that declaration of dietary fiber should be mandatory. Other manufacturers, trade associations, and a university food science department disagreed and urged voluntary, rather than mandatory, declaration of dietary fiber. The arguments against required listing of dietary fiber included: (1) Analytical methods for dietary fiber in foods are not yet routine, are expensive, and lack precision in some types of foods; (2) mandatory declaration imposes an unnecessary analytical burden on producers of foods that are not significant sources of fiber; and (3) mandatory declaration will likely encourage fiber supplementation of foods.

The agency does not agree that the specified methods for fiber analysis are difficult and expensive. The operations involved and equipment required for the methods are standard in analytical laboratories. The agency recognizes that the official AOAC method for dietary fiber analysis is relatively recent. However, as a validated method, it should be included in current nutrition labeling regulations.

In regard to the analytical burden on producers of foods with insignificant amounts of fiber, the agency advises that if there is adequate and reliable reason to believe that fiber is not present, there is no need to analyze for it; it can be declared as "0". Additionally, § 101.9(c)(6)(i) provides for expression of dietary fiber in 1 g increments in recognition of the precision of analytical methods. For foods that contain less than 1 g of dietary fiber per serving, manufacturers may choose to state "contains less than 1 g" or to omit dietary fiber from the list of nutrients and to state at the bottom of the nutrition label "Not a significant source of dietary fiber."

There have always been concerns that nutrition labeling will encourage the supplementation (i.e., fortification) of foods. In part for this reason, FDA published a policy statement on the addition of nutrients to food on January 25, 1980 (45 FR 6314). The statement was issued to promote the rational addition of nutrients to foods to preserve a balance of nutrients in the diet of American consumers. In the statement, FDA established guidelines in § 104.20, which the agency urges manufacturers to follow if they elect to add nutrients to a food.

FDA intends to continue to monitor the marketplace through the Food Labeling and Packaging Survey, consumer and industry complaints, and other means to determine if inappropriate fortification is occurring. If the agency finds that there is a problem with inappropriate fortification of foods with dietary fiber or any other nutrients, it will take steps to ensure that overfortification does not result in the imbalance of essential nutrients in the diet of American consumers or the presence of excessive amounts of particular nutrients that have the potential for toxicity.

Thus the agency is not persuaded that there is a compelling cause not to require declaration of dietary fiber in nutrition labeling. Section 403(q)(1)(D) of the act requires dietary fiber to be included in nutrition labeling. Section 403(q)(2)(B) of the act allows a required nutrient to be deleted if the Secretary determines that the nutrient is not necessary to assist consumers in maintaining healthy dietary practices, but no information contained in the comments would lead to such a conclusion. In fact, most comments supported the usefulness of mandatory declaration of dietary fiber. Accordingly, § 101.9(c)(6)(i) will require the declaration of dietary fiber in nutrition labeling.

This action represents the final disposition of two petitions regarding label declaration of carbohydrates, including dietary fiber. One petition from the Kellogg Co. dated May 14, 1978 (Docket No. 78P-0091), requested, in part, permission to list under "carbohydrate" the amounts of "starches and related carbohydrates" and "sucrose and other sugars." The other petition from the Center for Science in the Public Interest dated June 1, 1987 (Docket No. 87P-0194/CP) requested that dietary fiber be a mandatory component of nutrition labeling, and that regulatory letters be sent to all manufacturers making misleading claims about fiber content.

49. Comments from nutritionists representing state cooperative extension services and from one manufacturer cautioned that declaration of soluble and insoluble subcomponents of dietary fiber should be prohibited because the methodology for separating soluble from insoluble fiber is inadequate, and because there is no scientific agreement as to the health effects of the subgroups of dietary fiber.

The agency advises that analytical methods for the measurement of soluble and insoluble dietary fiber are now part of an official AOAC method for dietary fiber (Ref. 50). While experience with these methods is limited, they will allow for accurate separation of these subcomponents.

In regard to scientific agreement as to the health effects of soluble or insoluble fiber, FDA has evaluated the health effects of the dietary fiber subgroups and has concluded that there is sufficient scientific agreement to issue a final rule permitting health claims relating to the effects of intake of soluble dietary fiber on heart disease. This decision is discussed in a companion document entitled "Food Labeling; Health Claims; Dietary Fiber and Cardiovascular Disease" published

elsewhere in this issue of the **Federal Register.**

Accordingly, § 101.9(c)(7)(i), redesignated as § 101.9(c)(6)(i)(A) and (c)(6)(i)(B), will continue to allow the voluntary declaration of soluble and insoluble dietary fiber in nutrition labeling, except that when a claim is made about either type of fiber, label declaration of that type of fiber will be required. To clarify that soluble and insoluble fiber are to be indented under dietary fiber rather than under total carbohydrate, FDA has modified § 101.9(c)(6)(i)(A) and (c)(6)(i)(B) to state "indented under dietary fiber." FDA has also modified these two sections to remove the requirement that whenever one type of fiber is declared, the other type must also be declared. Because total dietary fiber is a mandatory component of nutrition labeling, the amount of an undeclared subcomponent (i.e., soluble or unsoluble fiber) can be calculated simply by subtracting the amount of the declared subcomponent from the amount of dietary fiber. This change will minimize space requirements caused by the voluntary declaration of additional nutrients.

3. Sugars

a. Definition of sugars.

50. Comments from consumers, consumer interest groups, state governments, trade associations, food retailers, and a manufacturer concurred with the agency's proposed definition for sugars as the sum of all free mono- and oligo-saccharides through four saccharide units and their derivatives having similar sweetening, nutritional, and metabolic effects. Consumer interest in the sugars content of food, and concern that "sugars" should include all forms of carbohydrate sweeteners added to foods, were cited as reasons for support for the proposed definition. Comments from many consumers, state governments, and a health promotion association stated that information on content of both sugars and of sugar derivatives is important to assist consumers to moderate intake of sugars and to assist diabetics in maintaining healthy dietary practices. Consumer interest groups argued that underreporting of the sugars content in products rich in corn syrups is an appropriate justification for an expanded definition for sugars. A comment noted that the agency has a precedent for considering sugar alcohols as sugars in § 100.130(d)(4), which states that "sugar-free" type statements cannot be made on labels of diet beverages containing "sorbitol, mannitol, or other hexitols."

Other comments from a wide variety of manufacturers, trade associations, foreign and state governments, professional associations, and a Federal agency objected to the proposed sugars definition. Most of these comments recommended that the sugars definition be limited to monosaccharides and disaccharides. One argument for limiting the sugars definition to mono- and di-saccharides is that this is the traditional and widely accepted use of the term "sugars." They pointed out that it is also the definition of the term in the IOM report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1). Many comments noted that for conformity with international regulatory definitions for nutrition labeling (EC, Codex Alimentarius Commission, and Canada) sugars should be defined as mono- and di-saccharides.

Another argument, brought forth in comments, for limiting the sugars definition to mono- and di-saccharides is that there are no compelling health or nutritional reasons for including tri- and tetra-saccharides as "sugars." The comments pointed out that the 1986 "Report From FDA's Sugars Task Force" (Ref. 51) concluded that the only public health concern from sugars consumption in the United States is the promotion of dental caries. The IOM report (Ref. 1) concurred with this conclusion. The comments argued that, in the absence of a clear relationship between number of saccharide units and carcinogenicity, the proposal to include tri- and tetra-saccharides within sugars is not relevant to the public health concern of dental caries.

Several comments questioned the agency's logic in including tri- and tetra-saccharides with sugars. FDA had stated in the 1990 mandatory nutrition labeling proposal (55 FR 29487 at 29497) that the intent of including tri- and tetra-saccharides as sugars was to preclude potential underdeclaration of the sugars content of foods containing corn syrups. Several comments noted that mono- and di-saccharides are logically grouped in that they are sweet, naturally occurring, and rapidly absorbed, but that these characteristics are, for the most part, not in common with tri- and tetra-saccharides. Comments also noted that most corn syrup used in sweetening is in the form of high fructose corn syrup, which is composed of 95 percent monosaccharides, and that high fructose corn syrup accounts for two thirds of total U.S. corn syrup consumption. Comments noted that corn syrups with greater proportions of higher saccharides are used for technical purposes other than sweetness. Thus, the comments argued that underestimation of simple sugars from corn syrups is not of sufficient importance to warrant imposing a unique sugars definition for labeling purposes that would differ from common usage of the term.

Many comments objected to the proposed sugars definition on methodological grounds, in that they claimed that the proposed definition is not compatible with standardized analytical methods for measuring sugars. The comments acknowledged that validated methods for measuring mono- and di-saccharides in foods exist but argued that there are not collaboratively validated methods for the measurement of tri- and tetra-saccharides. The comments noted that measurement in foods of oligosaccharides larger than disaccharides is difficult, costly, and inaccurate. The comments asserted that the lack of validated analytical methodology appropriate for the definition would result in compliance difficulties and inaccurate information on the label.

FDA has evaluated all comments in favor of the proposed expanded sugars definition and those opposed to this definition. FDA is persuaded that compliance with nutrition labeling will be impeded by adopting a definition for sugars that is not supported by validated analytical methods. FDA is also persuaded that the usefulness of nutrition labeling will be hindered by adopting a definition that is inconsistent with commonly accepted use, and with the international use of the term.

FDA finds that these factors outweigh any public health benefit from including tri- and tetra-saccharides in the definition of "sugars" for nutrition labeling purposes. The public health concern associated with sugars consumption is the promotion of dental caries. While simple sugars are the most cariogenic carbohydrates, all fermentable carbohydrates, including starches, are capable of promoting dental caries. Factors such as the characteristics of the food that contains the sugar (e.g., stickiness), the frequency of consumption, and the sequence in a meal, appear to be as important in the etiology of dental caries as the sugars themselves (Refs. 2 and 3). As such, the inclusion of tri- and tetra-saccharides with sugars would not improve the ability of the label to assist consumers in maintaining healthy dietary practices with respect to dental health.

Therefore, the agency is modifying the definition of "sugars" in § 101.9(c)(6)(ii)(A), redesignated as

§ 101.9(c)(6)(ii), to include only free monosaccharides and disaccharides.

51. Several comments recommended that lactose be specifically excluded from the sugars definition for nutrition labeling. These comments asserted that the listing of lactose with sugars in nutrition labeling may mislead some consumers who may equate the lactose sugar content of dairy products with "empty calories" of products high in added sugar. The comments expressed a fear that dietary guidelines to moderate sugars consumption may lead some consumers to forego the important nutritional benefit of dairy products if lactose is included in sugars content. Comments also noted that intestinal digestion of lactose is inefficient. As such, the digestion and absorption of lactose more closely resembles complex carbohydrate than simple sugars. Furthermore, comments argued that lactose is not sweet nor used as a sweetener and could logically be separate from sugars used as sweeteners.

FDA disagrees with the comments. As discussed in the preceding comment, the agency has been persuaded of the need to define "sugars" for nutrition labeling purposes to be consistent with standard analytical methodologies and in conformity with the traditional usage of the term. Lactose, a di-saccharide, is clearly a sugar by conventional standards and is identified with all other mono- and di-saccharides in routine analytical procedures. The nutritional significance of the sugars content of certain types of foods, such as lactose in dairy products and natural sugars in fruit, and the importance of such foods as sources for other important nutrients, needs to be addressed through the consumer education program discussed below.

Accordingly, the agency is not making the recommended change to exclude lactose in the definition of sugars.

52. Several comments suggested alternative definitions for "sugars" based upon physiological characteristics rather than the number of saccharide units. Among these alternatives were suggestions for definitions based on digestibility, caloric value, glycemic index, and serum insulin response.

FDA finds that such alternative approaches are not feasible from a compliance standpoint because validated analytical methods to quantitate sugars defined in these ways do not exist. In addition, use of any of these definitions for sugars would be unique to U.S. nutrition labeling and would thus likely impede foreign trade. Moreover, because these definitions do not correspond to the commonly recognized meaning of the term, the resulting labeling information would be of limited usefulness.

53. FDA received comments that suggested alternative terminology for the "sugars" component of carbohydrate. The agency's longstanding use of "sugar" as synonymous with sucrose in ingredient labeling was cited as evidence of the need for an alternative term. Several comments felt that FDA's distinction between "sugar" and "sugars" would not be clearly understood by consumers. Alternative terms suggested included "sweeteners" and "simple carbohydrates."

FDA considered these comments but has concluded that it is best to maintain the proposed terminology. The agency advises that the term "sweeteners" would logically include the noncarbohydrate intense sweeteners, which would not be appropriately declared as a part of carbohydrate content. In addition, the term appears to apply more to added sugars than to total sugars and, therefore, would cause compliance problems because it is not possible, in most foods, to differentiate between added and naturally present sugars.

"Simple carbohydrates" may have been a good term for the originally proposed definition (i.e., mono-, di-, tri-, and tetra-saccharides). However, the agency finds it is too broad a term to encompass only the traditional sugars (i.e., mono- and di-saccharides).

b. *Total sugars versus added sugars.*

54. Some comments recommended mandating declaration of added sugars only rather than total sugars. The comments noted that consumers need to be made aware of added sugars because dietary recommendations urge use of sugars in moderation, while at the same time recommending increased consumption of fruits which are sources of naturally occurring sugars. Other comments recommended either mandatory or voluntary declaration of both added and naturally occurring sugars. One comment suggested that added sugars be required in addition to total sugars in foods containing more than 2 g of added sugar.

The agency is not persuaded that there is a need for mandatory disclosure of added sugars in place of, or in addition to, total sugars. There is no scientific evidence that the body makes any physiological distinction between added sugar molecules and those naturally occurring in a food. In addition, the agency believes that it should not promulgate regulations that it cannot enforce. When a product is sampled for compliance, laboratory analysis yields a value for total sugars. For most foods, as stated above, it is not possible to differentiate between added and naturally occurring sugars. Accordingly, the agency would not be able to determine the accuracy of a label declaration of added sugars.

Furthermore, declaration of only added sugars may significantly underrepresent the sugars content of many foods that are high in naturally occurring sugars. For example, in some fruits canned in heavy syrup, added sugars may represent only about 50 percent of total sugars. Disclosure of only the added sugars could be misleading to consumers who are concerned with total sugar intake. Therefore, the agency is retaining the provision of § 101.9(c)(ii)(A), redesignated as § 101.9(c)(ii), to declare total sugar content, e.g., that added as well as that naturally present.

While FDA is not distinguishing, on the nutrition label, between added and naturally present sugars, the agency does intend to include information about this distinction in the consumer education program that it is preparing. This information will help consumers: (1) Use the information on the nutrition label to differentiate between sugar-containing foods with high versus low levels of other important nutrients, (2) use the ingredient statement to distinguish foods with naturally occurring versus added sugars, and (3) appreciate the important role in the total daily diet of foods, such as fruits and dairy products, with naturally occurring sugars.

c. *Mandatory declaration of sugars.*

55. In the 1991 supplementary proposal, FDA requested specific comments as to the utility, appropriateness, and feasibility of requiring declaration of sugars content, particularly as such declaration relates to, and is supported by, public health goals (56 FR 60366 at 60369). Comments received were relatively evenly divided on the issue of whether the declaration of sugars should be mandatory in nutrition labeling. In general, consumers and health professionals and their associations supported mandatory declaration of sugars. Several state attorneys general and a few industry groups also agreed that consumers have a right to know the amount of sugars present. Comments argued that section 403(q)(2)(B) of the act only allows FDA to delete sugars as a mandatory component of nutrition labeling if such information "is not necessary to assist consumers in maintaining healthy dietary practices," and that such information is vital to this end. Comments from many consumers, state governments, and a health promotion

association stated that information on sugars content is important to diabetics in assisting them to maintain healthy dietary practices and to consumers in general in selecting diets that will moderate the intake of sugars. One comment urged mandatory declaration of sugars as a way to inform consumers of the content of new foods that are being marketed as "low fat" and "fat free" in which fats are being replaced by sugars.

Most industry groups as well as a few health professional associations and the IOM report (Ref. 1) recommended allowing sugars declaration to be voluntary. They argued that dietary guidance recommendations have not specified quantitative goals for sugar consumption, and that sugar declaration should not be required until a definition has been recognized by scientific communities that reflects physiological effects. They also pointed out that data bases do not generally contain information on sugars composition, so a substantial investment of time and money is needed for analysis and data base update. The comments argued that such an expenditure would be inappropriate for a nutrient of little public health concern. There was also a concern expressed that because total sugars would be declared rather than only added sugars, consumers would be confused by the amount of sugars in fruits and reduce their consumption of these foods. Despite these concerns, industry generally conceded that if sugars information is needed, requiring sugars declaration in the nutrition label is a better approach than mandating grouping of sweeteners in the ingredient statement, as the agency proposed in a document on ingredient labeling (56 FR 28593, June 21, 1991). Final action on the issue of grouping sweeteners in the ingredient statement is addressed in the final rule on declaration of ingredients published elsewhere in this issue of the **Federal Register.**

FDA is persuaded that mandatory declaration of sugars is of great interest to consumers, and that it will assist consumers in planning diets that conform to current dietary guidelines for Americans to avoid too much sugars (Ref. 4). As discussed above, FDA is modifying its proposed definition of "sugars" to be in conformity with general usage and international definitions for this term. The use of this definition will minimize the costs associated with necessary laboratory analyses and update of data bases.

Therefore, FDA is requiring in § 101.9(c)(6)(ii) that declaration of sugars be included in nutrition labeling.

4. Sugar Alcohol

56. Comments from a wide variety of manufacturers, trade associations, foreign and State governments, professional associations, and a Federal agency were opposed to inclusion of saccharide derivatives, specifically sugar alcohols, within the proposed "sugars" definition. The agency's proposed definition included in its coverage saccharide derivatives that have sweetening, nutritional, and metabolic effects similar to simple sugars. The comments stated that sugar alcohols are inappropriately included with sugars because sugar alcohols have many different chemical and physiological properties than sugars. Comments noted that it is these differences that motivated the development of uses for these substances and makes them useful as sugar substitutes. Comments pointed out that a salient distinction between sugar alcohols and sugars lies in their digestion and absorption, which is slower for sugar alcohols. Also, intestinal absorption of monosaccharide sugar alcohols occurs only by passive diffusion, not by active or facilitated monosaccharide absorptive mechanisms. As a result, significant portions of ingested sugar alcohols remain unabsorbed and pass into the colon, where they are fermented, similar to fiber and complex carbohydrate. Thus, the caloric value, insulin response, and glycemic index for some sugar alcohols are less than for sugars.

Several comments also claimed that sugar alcohols have reduced cariogenic potential compared to sucrose or other sugars. The comments noted that FDA proposed in § 101.13(o)(8) in the document on the general principles for nutrient content claims to permit chewing gums sweetened with sugar alcohols to be labeled as "sugar free" or "sugarless" as a means of indicating that these products do not promote tooth decay. The comments argued that declaring sugar alcohols as sugars would deny manufacturers the means to promote the reduced cariogenic potential of other sugar alcohol sweetened products relative to sugar containing products.

Comments also noted that international regulatory definitions for nutrition labeling (EC, Codex Alimentarius Commission, and Canada) exclude sugar alcohols and provide for a separate declaration of sugar alcohols under carbohydrates. As a result, the comments stated that a definition for sugars that includes sugar alcohols for U.S. nutrition labeling could be seen as an obstruction to international trade. The IOM report (Ref. 1) recommended that sugar alcohols not be grouped with sugars in ingredient labeling. Some comments argued that in the absence of any quantitative dietary guidelines concerning sugar alcohols, it is inappropriate to require any declaration of sugar alcohols in nutrition labeling.

FDA is persuaded that sugar alcohols have metabolic effects different than sugars, have a history of being considered to be sugar substitutes rather than as sugars, and have a role in contributing to dental health. FDA also acknowledges that the proposal to define sugar alcohols as sugars for nutrition labeling purposes is inconsistent with the nutrition labeling practices of other countries. Thus, FDA is modifying § 101.9(c)(6)(ii) to remove sugar alcohols from the definition of "sugars" for nutrition labeling. The agency is doing so in recognition of their usefulness as sugar substitutes in reducing the cariogenic potential of foods.

However, FDA continues to believe that the content of nutritive carbohydrate sweeteners used as sugar substitutes is of interest and importance to consumers. Therefore, FDA is retaining § 101.9(c)(6)(ii)(B), which provides for the voluntary declaration of sugar alcohols except when a claim is made on the label or in the labeling about sugar alcohol or sugars (e.g., "sugar free") and sugar alcohols are present in the food, in which case their declaration is mandatory. Because sugar alcohols will no longer be a subcomponent of sugars, FDA is redesignating § 101.9(c)(6)(ii)(B) as § 101.9(c)(6)(iii).

Removing sugar alcohol from the definition of sugars necessitates a change in the definition of sugar alcohol. The proposed definition included a criterion that sugar alcohols "meet the definition of sugars as described in paragraph (c)(6)(ii)(A)." Accordingly, FDA has revised the definition for sugar alcohol in § 101.9(c)(6)(iii) to use a chemical definition, namely that sugar alcohols be defined as "saccharide derivatives in which a ketone or aldehyde group is replaced by a hydroxyl group, and whose use in food is listed by FDA (e.g., mannitol) or is GRAS (e.g., xylitol, sorbitol)."

57. Comments from trade associations and manufacturers stated that the term "sugar alcohol" is potentially confusing in that consumers may assume such components contain a sugar and ethyl alcohol. The comments requested that the term "polyol," which has been recognized by the EC, be used in lieu of "sugar alcohol." Another comment from

the Canadian government included a copy of their nutrition labeling regulations which allow for declaration of the specific sugar alcohols by name (i.e., sorbitol, mannitol, and xylitol).

FDA advises that the term "polyol," a contraction of "polyalcohol" or of "polyhydric alcohol," is neither uniquely descriptive of the alcohol derivatives of saccharides used as sugar substitutes, nor is it a term that FDA expects consumers to recognize or understand. While the agency recognizes that it is a term that may be used voluntarily on labeling in the EC, it is unlikely that American consumers will have any concept of what it represents. As such, the agency considers the term "polyol" to be potentially more confusing to consumers than would be "sugar alcohol."

Despite this fact, FDA acknowledges that many consumers also may not be familiar with the term "sugar alcohol." Thus, FDA has decided to adopt the approach used by the Canadian Government, which allows manufacturers to use the specific name of the sugar alcohol in the nutrition label. The names of sugar alcohols that are listed or GRAS for use in food, (e.g., sorbitol § 184.1835, mannitol § 180.25, and xylitol § 172.395) are currently used in ingredient statements on labels of food packages and, hence, should be recognized by many consumers.

The primary disadvantage to this option is the introduction of the name of an ingredient into the nutrition label. While FDA is generally opposed to such a result, the agency concludes that the arguments opposed to the term "sugar alcohol" and the desire to harmonize with Canadian labeling regulations are more compelling in this instance than the need to maintain a clear separation between the nutrition label and ingredient list. However, to avoid cluttering the nutrition label and confusing consumers, if more than one sugar alcohol is used in a food, § 101.9(c)(6)(iii) provides that the term "sugar alcohol," and not the names of the ingredients, must be used in the nutrition label.

Accordingly, FDA is modifying § 101.9(c)(6)(iii) to specify the continued use of the term "sugar alcohol" or, alternatively, if only one sugar alcohol is present in the food, the name of the specific sugar alcohol present in the food may be used.

5. Other Carbohydrate

a. *Definition.*

58. In the supplementary proposal, FDA noted that the term "complex carbohydrate" has not been clearly or consistently defined, and that consensus reports that have associated increased consumption of dietary complex carbohydrate with health benefits have not attempted to define this food component. The agency solicited suggestions on appropriate chemical definitions and analytical methodology for complex carbohydrate (56 FR 60366 at 60369). Many comments from trade associations, food manufacturers, professional societies, and state and foreign governments expressed opposition to the agency's proposed definition for the term complex carbohydrate as the sum of dextrins and starches that contain ten or more saccharide units (56 FR 60366 at 60388). A majority of these comments also recommended as an alternative that "complex carbohydrate" be defined as the difference between total carbohydrate and sugars. Comments that argued for changing the definition pointed to the lack of existing analytical methodology to support the proposed definition. Thus, these comments raised concerns about the feasibility of compliance and the economic burden of developing methods and data bases. These comments also pointed out that complex carbohydrate content defined as the difference between total carbohydrate and sugars could readily be calculated.

Another criticism of the proposed complex carbohydrate definition was that the cutoff at 10 saccharide units is arbitrary. These comments noted that there are no known nutritional or physiological differences, nor a methodological justification, to make a distinction between polysaccharides smaller than 10 saccharide units and those with 10 or more saccharide units. Several comments were concerned that there is the potential for consumer confusion regarding total carbohydrate because neither of the subcomponents for total carbohydrate included the 5 to 9 saccharide unit polysaccharides.

Several comments suggested that the commonly accepted usage of "complex carbohydrate" includes all carbohydrates larger than disaccharides. Other comments suggested that complex carbohydrate should be defined as all digestible polysaccharides (e.g., dextrins, starch, and glycogen) rather than on the basis of the number of saccharide units. Comments emphasized that while there is not a consensus on a precise definition for "complex carbohydrate," the agency's proposed definition is not commonly recognized, nor is it consistent with the use of the term in the IOM report (Ref. 1).

One comment from a State government recommended that to avert undue emphasis on complex carbohydrate substances added to foods and to avoid the potential for misleading claims about complex carbohydrates, the term "other carbohydrate" should be used rather than "complex carbohydrate."

The agency noted in the supplementary proposal (56 FR 60366 at 60368) that identification of a specific benefit for complex carbohydrate is confounded by the fact that diets high in complex carbohydrate are usually mixed diets that contain significant amounts of cereal grains, fruits, and vegetables which are high in fiber, vitamins, and minerals and low in fats (Ref. 2). Thus the extent to which complex carbohydrate provides health benefits separate from those provided by fiber, vitamins, minerals, and reduced fat is unclear. FDA has evaluated comments concerning the complex carbohydrate definition and concludes that there is not sufficient consensus on the meaning of the term to justify adopting a specific definition for "complex carbohydrate."

In response to the comments that suggested defining this term as "digestible polysaccharides," FDA advises that carbohydrate digestibility is not clear cut. Some soluble dietary fiber is relatively digestible, whereas some oligosaccharides are relatively nondigestible. At this time there is not a consensus regarding the most reliable methods for determining carbohydrate digestibility nor for distinguishing energy derived from intestinal digestion from that derived from colonic fermentation. As a result, the agency feels that it is inappropriate to base a regulatory definition upon digestibility.

FDA, therefore, is modifying the definition it proposed for "complex carbohydrates"(§ 101.9(c)(6)(i), redesignated as § 101.9(c)(6)(iv)) to provide that it is the difference between total carbohydrate and the sum of dietary fiber and sugars or, if sugar alcohol is declared, the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol. This modified definition accommodates quantification of the remaining carbohydrates by calculation rather than by requiring additional laboratory analysis, and it resolves concerns that the defined components of total carbohydrate were not inclusive of all carbohydrates.

In addition, because there is no consensus on a clear definition for the term "complex carbohydrate" as it relates to physiological effects, health benefits, or dietary guidelines, the

agency concurs with the recommendation from a state government that the term "other carbohydrate" be used rather than "complex carbohydrate." The agency recognizes that the new definition will include many substances added to processed foods for technical purposes, such as for texture modification or as bulking agents. To declare these substances as complex carbohydrates would be misleading. The intent of dietary recommendations to increase the consumption of complex carbohydrates and dietary fiber is to select diets with plenty of fruits, vegetables, and grain products, not foods that have complex carbohydrates as added texturizers or bulking agents. Accordingly, FDA is modifying § 101.9(c)(6)(iv) to change the terminology from "complex carbohydrate" to "other carbohydrate." In addition, FDA is modifying § 101.9(g)(4) and (g)(6) to reflect this change in terminology.

Finally, because "other carbohydrate" will be calculated as that amount of carbohydrate remaining after subtraction of the amount of dietary fiber, sugars, and sugar alcohols (when declared) from total carbohydrate, it is logical to rearrange the subcomponents of total carbohydrate to place "other carbohydrate" at the bottom of the list. This reordering should help to reduce any potential confusion over the meaning of the term "other carbohydrate." Accordingly, dietary fiber is designated as § 101.9(c)(6)(i), sugars as § 101.9(c)(6)(ii), sugar alcohol as § 101.9(c)(6)(iii), and other carbohydrates as § 101.9(c)(6)(iv).

b. *Voluntary declaration of "other carbohydrate".*

59. In the supplementary proposal, FDA requested specific comment on the utility, appropriateness, and feasibility of mandatory declaration of complex carbohydrate content, particularly as it relates to, and is supported by, public health goals (56 FR 60366 at 60369). Based on the comments and information that it received in response to the supplementary proposal, the agency said it would decide, under section 403(q)(2) of the act, whether to include complex carbohydrate in the required list of nutrients in nutrition labeling. Several comments from consumers, health professionals, a manufacturer, and state governments supported mandatory listing of complex carbohydrates on the grounds that this information will be helpful to persons attempting to follow dietary recommendations. However, a much larger number of comments from health professional associations, academia, manufacturers, trade associations, and foreign governments supported voluntary listing of complex carbohydrates. The overriding factors cited in these comments were the lack of an accepted definition for "complex carbohydrates" and the lack of reliable analytical methods for determining amounts present. Comments also stated that dietary recommendations do not specify amounts of complex carbohydrates to be consumed; therefore quantitative information in nutrition labeling is not necessary to assist consumers in maintaining healthy dietary practices. Additionally, comments noted that the IOM report (Ref. 1) recommended voluntary listing of complex carbohydrate. Comments also pointed out that currently available data bases do not contain information on complex carbohydrates, and that there would be an inherent variability in amounts present in minimally processed foods.

In light of these comments, the agency's decision to drop the term "complex carbohydrate" because of the lack of a consensus on the meaning of the term, and the lack of methods for reliably determining the amounts present, FDA has reassessed the requirement in section 403(q)(1)(D) of the act to declare complex carbohydrates. Section 403(q)(2)(B) of the act allows the Secretary to determine whether information relating to nutrients specified in section 403(q)(1)(C), (q)(1)(D), (q)(1)(E), or (q)(2)(A) of the act is necessary to assist consumers in maintaining healthy dietary practices. If not, the Secretary may delete such nutrients from the list of those required to be included in nutrition labeling. FDA concludes that, without a specific definition for "complex carbohydrates," it is not possible to include quantitative information in the nutrition label that would assist consumers in maintaining healthy dietary practices. Therefore, under the provisions of section 403(q)(2)(B) of the act, FDA is deleting the requirement for the listing "complex carbohydrate" in the nutrition label and is allowing for declaration of "other carbohydrate" on a voluntary basis.

When "other carbohydrate" is omitted from the label, the declared subcomponents of total carbohydrate (i.e., dietary fiber and sugars) will not add up to the value for total carbohydrate in most foods. Consumer education programs should inform interested persons that other forms of carbohydrate beyond those declared on the label are in the food product. This situation is analogous to the fat category where the sum of saturated, polyunsaturated, and monounsaturated fatty acids often do not add up to 100 percent of the value for total fat because *trans* fatty acids are not included in the definition of the fatty acids but are included in the value for total fat.

G. Protein

1. Quantitative Protein Content

60. Several food manufacturers agreed with the proposed provision requiring that if the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein digestibility-corrected amino acid score (PDCAAS) of less than 20 percent, and if foods represented or purported for children below 4 years have a protein quality value less than 40 percent of casein, the protein content statement must be modified by an adjacent statement, "not a significant source of protein," regardless of the actual amount of protein present. However, other food manufacturers objected to this provision of the proposal. These comments argued that the statement has little value in terms of the total dietary protein intake, and that there is no evidence of protein malnutrition in this country. These comments argued that, therefore, the statement is unnecessary. One food manufacturer stated that the statement should only be required if a claim is made. Another comment stated that the declaration of the percent of the RDI for protein should be required instead of the statement.

FDA disagrees with the comments that state the statement is unnecessary. Information on protein quantity alone can be misleading on foods that are of low protein quality. As stated in the supplementary proposal, dietary protein serves as a source of essential and nonessential amino acids, the building blocks of body protein. Because excess amino acids are not stored in the body, humans need a constant supply of good quality dietary protein to support growth and development. The determination of the quality of a protein is dependent upon the proportion and availability of essential amino acids (i.e., those amino acids that the human body cannot manufacture but must obtain through the diet) as well as the quantity of protein present. Foods that contain proteins that are low in one or more of the essential amino acids are known as incomplete proteins and are lower quality proteins than those that contain all the essential amino acids in sufficient quantities to support growth and development.

The agency believes that nutrition labeling must inform consumers when the quality of the protein is below

minimum specified levels. The majority of comments supported this position. Although the agency agrees that protein deficiency is not common in the United States, protein quality is still of concern for certain segments of the population, such as the very young and the elderly. Accordingly, the agency concludes that nutrition labeling must allow consumers to readily identify foods with particularly low quality protein to prevent them from being misled by information on only the amount of protein present.

Nonetheless, in the case of foods for adults and children over 1 year of age, the agency agrees with the comment that the percent of the reference value for protein (discussed below) is a satisfactory alternative to the statement, "not a significant source of protein," to allow consumers to readily identify foods of low protein quality. However, as discussed in the final rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" published elsewhere in this issue of the **Federal Register**, the label reference value for protein for adults and children 4 or more years of age has been established as a DRV rather than an RDI. As discussed in that document, this change to a DRV is necessary because the agency is no longer basing the label reference value for protein for this group on the Recommended Dietary Allowances for protein. Rather, they are now being based on percent of calories. However, because FDA did not propose DRV's for infants, children less than 4 years of age, pregnant women, and lactating women, the protein label reference values for these groups remain as RDI's.

Accordingly, the agency is amending § 101.9(c)(8), redesignated as § 101.9(c)(7), to permit the optional declaration of percent of the DRV or RDI for protein, as appropriate, expressed as "Percent Daily Value," in lieu of the statement "not a significant source of protein" when the food is represented or purported to be for use by adults and children 4 or more years of age and the protein quality value is a PDCAAS of less than 20 expressed as a percent, or when the food is represented or purported to be for use by children under 4 years of age and the protein quality value is a PDCAAS of less than 40 expressed as a percent.

FDA is not requiring declaration of percent DRV or RDI for protein instead of the subject statement, as requested in the comment, because of cost considerations. If a manufacturer is aware that the protein in a particular food product represented or purported to be for adults and children 4 or more years of age has a PDCAAS of less than 20 percent, or that the protein in a food represented or purported for children below 4 years has a protein quality value less than 40 percent of casein, and the manufacturer does not want to go to the expense of determining the precise percent of the label reference value present in the food, the agency has no objection to the use of the statement "not a significant source of protein."

In conjunction with this change, FDA is making a parallel modification in proposed § 101.9(c)(8)(i), redesignated as § 101.9(c)(7)(i), by deleting the prohibition on the declaration of percent of the RDI for protein on foods represented or purported to be for use by adults and children 4 or more years of age with a PDCAAS of less than 20 percent, or on foods represented or purported to be for use by children under 4 years of age with a protein quality value of less than 40 percent of the reference standard. That prohibition is no longer necessary because the PDCAAS method for assessing protein quality is more exact in measuring the protein quality for humans one year of age and above than the protein efficiency ratio (PER) which was previously used for all age groups. Because the PER is being retained to measure protein quality for infant foods, FDA has retained this prohibition for declarations on foods represented or purported to be for use by infants with a protein quality value of less than 40 percent of the reference standard of casein.

61. One comment requested that the food-specific conversion factors used by AOAC, and permitted in proposed § 101.9(c)(8), to convert amounts of nitrogen to protein content should be allowed in calculating the PDCAAS whenever such factors are available. The comment stated that in some cases (e.g., peanut butter) the amino acid score used in calculating the PDCAAS is artificially reduced when a conversion factor of 6.25 must to be used to calculate protein content rather than a food-specific conversion factor.

FDA agrees that there is an inconsistency in proposed § 101.9(c)(8) pertaining to the factors for converting g of nitrogen to g of protein when calculating protein content and when calculating the PDCAAS. While the method for calculating the PDCAAS described in the Report of the Joint Federation of Agriculture Organization and the World Health Organization (FAO/WHO) Consultation (Ref. 8) specifies a conversion factor of 6.25 (i.e., g of nitrogen x 6.25 = g of protein), the agency finds it appropriate to use more specific conversion factors for those foods where the official AOAC procedures require them. Therefore, to allow for consistent methods of calculating g of protein, the agency is modifying § 101.9(c)(7)(ii) to state that food-specific conversion factors required by the AOAC are to be used when calculating the PDCAAS.

2. Protein Content as a Percentage of the RDI/DRV

62. Several comments opposed the voluntary (in the absence of a claim) declaration of protein as percent of the RDI on the labels of foods intended for adults and children 4 or more years of age. The comments contended that mandatory declaration of protein as percent RDI for all groups would provide the consumer with information on how amino acid and protein needs are met and would assist consumers in appreciating that protein is an important part of the diet.

FDA disagrees with these comments. In the preamble of the mandatory nutrition labeling proposal, FDA stated that current evidence suggests that the diet typically consumed in the United States provides for an adequate protein intake of sufficiently high biological quality to meet the nutritional needs of adults and children 4 or more years of age (55 FR 29487 at 29499). Because protein intakes generally are adequate and not a public health concern for this population group, FDA finds that the additional costs associated with determination of the PDCAAS, which are necessary to calculate the percent of the DRV for protein, are not warranted on foods for this group unless protein claims are made. Therefore, while declaration of the quantitative amount of protein will continue to be required on all foods, § 101.9(c)(7)(i) allows voluntary declaration of the percent of the DRV for protein, expressed as "Percent Daily Value," for foods intended for adults and children 4 or more years of age unless a protein claim is made for the product.

63. Two baby food manufacturers suggested that the protein content expressed as percent of the RDI for protein should be voluntary for all foods, including those for infants and children less than four years of age, unless the food is infant formula or a protein claim is made. The comments stated that data show that breast or cow milk and formula are the main contributors of protein during the first 18 months, and that other foods are not sole sources of protein for infants above 4 months. One manufacturer provided survey data on the protein intake of children 2 to 18 months of age. The comments also stated that recent

evidence shows that the protein intake of children 1 to 4 years of age is 100 percent of the RDI, that nutrition information expressed as percent of the RDI would not be helpful to the parents, and that the requirement is burdensome. Other comments supported mandatory declaration of protein content expressed as percent of the RDI for children less than 4 years of age.

FDA rejects the suggestion that protein content expressed as the percent of the RDI should be voluntary for foods specifically intended for infants and children under 4 years of age. As noted in the preamble of the mandatory nutrition labeling proposal, mandatory declaration of the percent RDI is warranted for this age group because of the importance of protein quality in diets derived from a limited number of foods (55 FR 29487 at 29499). FDA acknowledges that breast or cow milk and formula are the major sources of protein during the first 18 months. However, as seen in the data provided in the comment, foods specifically intended for infants and young children, other than infant formula, do make a significant contribution to total protein intake. For example, at 6 to 7 months of age, infants are receiving approximately one-third of the total protein intake from baby foods (Ref. 52).

The agency recognizes that required declaration of the percent of the RDI for protein for foods for infants and children less than 4 years of age presents a burden to manufacturers. However, protein nutriture is critical during this period of life which is marked by rapid growth and development. Both protein quantity and quality are major factors in the utilization of protein. Because of the importance of adequate high quality protein in the diets of infants and young children, FDA considers the declaration of percent of the RDI for protein necessary. Moreover, with the information on digestibility the agency is providing in appendix B (see comment 66 in this document), declaring the percent of the RDI for protein should not be overly costly or difficult.

64. Several comments suggested the use of a system similar to the current approach of expressing the percent of the U.S. RDA for protein. Recommendations were made for the use of a single RDI or two RDI's (i.e., an RDI for proteins of high quality and another RDI for those of low quality) to calculate the percent RDI as long as the food is not intended for infants and toddlers. Three baby food manufacturers favored establishment of specific low and high protein quality-based RDI's to calculate the percent RDI for foods intended for infants.

FDA disagrees with the use of a system similar to the current approach of expressing protein as percent U.S. RDA. The use of breakpoints, as found in the existing regulation, creates artificial differences in apparent protein nutritive values of some foods when significant differences do not exist.

3. Protein Quality

65. One comment questioned FDA's authority to change the proposed protein quality methodology. The comment contended that the 1990 amendments did not require a change in methodology, and that the proposal must be reevaluated pursuant to President Bush's directive in his State of the Union address on January 28, 1992, and set forth in his memorandum on Reducing the Burden of Government Regulations (Ref. 53).

FDA stated in the supplementary proposal that while not directed to do so by the 1990 amendments, it was proposing to modify the approach for determination of protein quality in the mandatory nutrition labeling proposal. The agency did so in response to a citizen's petition submitted by Protein Technologies International Inc. (Docket No. 90P–0052), requesting that the agency accept an amino acid method that is corrected for digestibility as an alternative method for evaluating protein quality. FDA tentatively decided that the petition had merit, and that some of the concepts in the petition should be integrated into the rulemaking since protein quality is an important part of nutrition labeling. The agency has the authority under sections 201(n) of the act (21 U.S.C. 321(n), 403 (a) and (q) of the act, and 701(a) of the act (21 U.S.C. 371(a)) to modify the original proposed protein quality methodology to reflect expanding scientific knowledge. This final rule represents the final disposition of the subject petition.

66. Several comments commended the agency for acceptance of the PDCAAS method for assessing the protein quality of foods for regulatory purposes. Comments stated that the PDCAAS method was entirely appropriate and consistent with the FAO/WHO Consultation on protein quality evaluation (Ref. 8). Other comments from food manufacturers and a trade association conditionally supported the PDCAAS method. Several comments recommended that PDCAAS not be used as the sole method for measuring protein quality of foods intended for adults and children 4 or more years of age until more technical knowledge on the amino acid reference pattern and methodology is gained, and until manufacturers gain more practical experience in its application across a broad spectrum of foods. Two comments stated that compliance problems necessitate a transition period of 2 to 5 years to ease the logistical and economic burdens. Several comments supported the method but recommended that the current PER method also be permitted.

One manufacturer recommended: (1) Manufacturers be permitted to use calculated PDCAAS values for common foods and food ingredients; (2) that FDA issue a list of estimated digestibility values and PDCAAS values for major foodstuffs and ingredients before issuing the final regulation; and (3) that FDA convene an expert group to produce a data base on digestibilities and PDCAAS values and to make provision to update such a list.

Another manufacturer requested that FDA allow any valid methodology for determining protein quality for adults and children more than 1 year of age.

FDA disagrees with the recommendations that the PDCAAS method not be used as the sole method until more technical and practical knowledge is gained on its application to a broad spectrum of foods and disagrees that a transition period is needed. FDA advises that since most food products in the market place are intended for adults and children above 4 years of age, on which the declaration of percent DRV of protein is voluntary, a delay in the implementation of the PDCAAS as the sole method is not necessary.

The agency also rejects the recommendation that the PER method continue to be permitted for foods for adults and children 1 or more years of age as an option to the PDCAAS method for the following reasons: (1) The PDCAAS is based on human amino acid requirements and, therefore, is inherently more appropriate for evaluating the protein content of foods intended for human consumption than the PER which is based on the amino acid requirements of the rat (Ref. 8), (2) the PDCAAS method is recommended for regulatory purposes by a recognized international organization experienced in establishing such standards (Ref. 8), and (3) values obtained by the two methods differ so that their simultaneous use on different foods would not allow for comparison of food products.

FDA considered the recommendation that manufacturers be permitted to calculate PDCAAS values. The two pieces of information that are needed for

this calculation are the amino acid content and the digestibility of the food. FDA has concluded that current representative amino acid data bases on raw and processed food products are not sufficiently reliable to allow for calculated PDCAAS values. Current data bases often lack information on key essential amino acids, and the information that is there was often obtained using methodology that is now outdated. In addition, food processing, i.e., the chemical, biological, or physical treatment of foods, can reduce the amino acid content of the food, so that only data from a food that underwent similar processing or treatment should be utilized in calculating the PDCAAS. In time, the agency believes it will be possible to calculate PDCAAS values using representative amino acid data backed by periodic analytical spot checks, but, at the current time, more and better data are needed.

FDA does agree, however, that a data base on digestibility values could be of assistance in implementing the PDCAAS method and in reducing the expense of implementing this new methodology by eliminating the need for a bioassay. Therefore, FDA is providing a limited data base on published true digestibility values (determined using humans and rats) of commonly used foods and food ingredients, which manufacturers may use to calculate the PDCAAS for food products. The agency has decided not to publish the digestibility values in the Code of Federal Regulation at this time because the values are interim and subject to change on a frequent basis. The data base is being published in Appendix B to this document and is also available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF–260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

Appendix B lists foods from nine major food groups. In the development of this data base, the agency examined scientific data that included reports by national and international organizations, review articles and other scientific articles. In examining the data, FDA first considered true digestibility values of protein foods obtained using adult subjects, followed by data using the rat as an animal model. The agency did not consider digestibility data obtained using *in vitro* methods or other animal species. Comparative reviews of digestibility of some protein using humans and the rat model suggest that the true digestibility of a variety of foods is similar in humans and rats.

There are gaps in knowledge of the digestibility of protein in common food sources. Therefore, the data in Appendix B of this document are tentative. FDA believes that with the implementation of this regulation, better data will be forthcoming, and that, in due course, it will be able to revise the data base. The agency encourages industry to submit additional data to enable FDA to expand the assortment of foods included in the data base and to update current data.

FDA concludes that it would be premature to convene an expert group to develop a data base on digestibilities and PDCAAS values. There is a need to allow time for the compilation of reliable data based on digestibility and amino acid analyses obtained by the methods specified in this regulation. FDA will reconsider the idea of convening of an expert group on protein quality as such data become available.

The agency advises that manufacturers are not precluded from using other analytical methods for their own quality control purposes as long as they assure themselves that such unofficial methods compare adequately with the official methods. For compliance purposes the methods specified in the regulation will be used by FDA.

67. Several comments recommended that the proposed new method (PDCAAS) for the evaluation of protein quality be eliminated from the regulation. Some comments stated that the PDCAAS method will not provide flexibility and will be unnecessarily burdensome and expensive, because it requires that digestibility and amino acid analysis be performed on every product for which a declaration of the percent of the RDI for protein is made. One comment stated that foods are often reformulated, creating an ongoing cost. Several comments expressed concern that, because of the costs, the PDCAAS could have unintended negative effects on the competitive position of smaller companies and on the willingness of manufacturers to provide complete nutrition information to the consumer.

A few comments argued that for some foods, the PDCAAS will result in lower values being declared for the percent of the RDI than current methodologies using the PER, and that this will effect the ability of the foods to make claims about protein content. Another manufacturer opposed the change to new methodology and commented that the PDCAAS methodology should be reviewed and scrutinized by the AOAC before application.

FDA does not agree that the PDCAAS should be eliminated. FDA wishes to clarify that declaration of the percent DRV for protein (which uses the PDCAAS method) is voluntary for foods intended for adults and children 4 or more years of age unless a protein claim is made for the product. Therefore, for this age group, the burden and expense of the PDCAAS method are voluntarily assumed by the manufacturer.

FDA acknowledged in the preceding comment that values obtained for percent of label reference value differ when calculated using the PDCAAS rather than the PER. However, the PDCAAS, based on human requirements, is inherently more appropriate for assessing protein quality of foods intended for human consumption than the PER which is based on the amino acid requirements of the rat (Ref. 8). Accordingly, label claims based on these values will more accurately describe the role of the protein product in meeting human nutrition requirements.

FDA advises that the analytical methodologies for amino acid analyses involved in the calculation of the PDCAAS method have undergone collaborative studies and have been published in the Journal of the Association of Official Analytical Chemists.

68. One comment expressed uncertainty about the proposed amino acid scoring pattern used in calculating the PDCAAS and stated that the WHO/FAO recommended further research to confirm the currently accepted values of preschool children.

FDA acknowledges that the WHO/FAO Consultation (Ref. 8) recommended further research on the proposed scoring pattern to confirm and reinforce the existing information. The Consultation concluded, however, that the proposed scoring pattern is robust and represents the best available estimate of indispensable amino acids for this age group. Because of the high protein requirements of the preschool age group for adequate growth and development, protein foods and diets with an amino acid pattern that effectively meets the needs of the preschool child will adequately meet the needs of older children and adults, whereas the reverse may not be true (Ref. 10). Therefore, FDA concludes that the proposed amino acid scoring pattern for preschool age children is at present the most suitable pattern for use in the evaluation of dietary protein quality for all age groups, except infants.

69. Comments agreed that the amino acid pattern for 1 to 4 year old children should be the same as the amino acid reference pattern for 2 to 5 year old children when calculating the PDCAAS. According to the data presented in the comments: (1) There is little difference

in the portion of protein and amino acids needed for maintenance and growth between the two age groups; (2) there is no sound nutrition rationale for using 70 percent of casein as the reference standard for 1 to 3 year old children as recommended by the Codex Committee on Nutrition and Foods for Special Dietary Uses (Ref. 10a); and (3) there is no evidence that the pattern of intake of amino acids for 1 to 3 year old children differs from, or that the pattern is inadequate compared to, the pattern for 2 to 5 year old children. The comments also confirmed that there is sufficient overlap between the age groups to render one standard adequate.

In the preamble to the supplementary proposal, FDA specifically requested comments on the inconsistency between the FAO/WHO and the Codex Committee on Nutrition and Foods for Special Dietary Uses standards for the protein quality of foods intended for children 1 to 3 years old. The data presented in the comments (Refs. 54 and 55) supported the agency's tentative conclusion to use the amino acid scoring pattern for preschool 2 to 5 year old children for determining the PDCAAS of foods intended for children over 1 year of age. Therefore, the agency is maintaining the requirement in § 101.9(c)(7) that the PDCAAS be used to measure protein quality in foods for children above 1 year of age.

However, the agency inappropriately left a parenthetical notation in proposed § 101.9(c)(8) that indicated that casein was to be used as the reference standard for determining the PDCAAS for children greater than 1 but less than 4 years of age. Because by definition the PDCAAS uses an amino acid scoring pattern based on human requirements as the standard, the agency has modified proposed § 101.9(c)(8), redesignated as § 101.9(c)(7), to remove the reference to casein for that age group.

70. Two comments disagreed with retaining the PER method and the casein standard for assessing protein quality for infants. The comments asserted that the requirement was not consistent with the FAO/WHO Consultation recommendation for the use of the amino acid pattern of breast milk for this age group.

FDA acknowledges that the FAO/WHO Consultation (Ref. 8) recommended that the amino acid composition of human breast milk should be the basis of the scoring pattern to evaluate protein quality in foods for infants under the age of one. However, in the same document, the Consultation stated that further data on the amino acid profile of human breast milk using standardized methods of analysis are required to confirm the pattern for calculating the chemical score of infant formulas (Ref. 8).

Because of the uncertainties expressed in the FAO/WHO report (Ref. 8) and the inconsistencies in reported amino acid patterns of human breast milk (Ref. 56), the agency finds that it is premature to use the FAO/WHO reference pattern for infants, especially since this population group relies on relatively few foods for nutrients. Until further data become available, the safer course is to continue to use the current PER method using casein as a standard. When more data become available, FDA would be willing to reconsider this position in response to a petition.

71. A few comments stated that the use of the PDCAAS will understate the biological quality of vegetable proteins consumed in a mixed diet. Another comment requested that FDA provide manufacturers with ways to communicate the complementary nature of different proteins from different sources.

FDA agrees that use of the PDCAAS does not indicate the value of individual proteins consumed as part of a mixed diet. However, this is true with any method used to measure quality of proteins in individual foods. The calculation of the corrected amount of protein of a food does not take into account the complementary potential of the food in a mixed diet, i.e., how a food rich in a particular essential amino acid can "complement" a food low in that amino acid to result in a total diet that provides sufficient amounts of the amino acid. What the method does is allow for a greater awareness of the value of protein sources when consumed alone.

While FDA acknowledges that more consumer education would be helpful on the complementary effects of individual foods in mixed diets, providing such information is beyond the scope of nutrition labeling. Space limitations within the nutrition label generally prevent the addition of information to communicate the complementary nature of different proteins. However, FDA advises that the regulation does provide in § 101.9(e) for the voluntary inclusion of a second column to declare the nutrient content of common combinations of foods (e.g., milk and cereal, peanut butter and bread). It would be possible to declare in this column the percent of the DRV or RDI for protein, as appropriate, for the combination of foods. Also, the manufacturer may include nonmisleading statements about the complementary nature of protein sources in materials outside the nutrition label.

72. Several comments expressed concern over the amino acid analytical methodology and urged that high performance liquid chromatography (HPLC) technology be incorporated into the methodology, and that hydrolysis time be tailored for specific foods. One comment suggested that FDA appraise the use of plasma aminograms as indicators of protein quality.

FDA agrees that the HPLC technology should be incorporated into the suitable methodology for amino acid analyses. In the preamble of the supplementary proposal, the agency stated that the analytical methodology for PDCAAS is described in the Report of the Joint FAO/WHO Consultation, section 5.4.1 (Ref. 8). The analytical methodology includes HPLC and provides flexibility in the hydrolysis of specific foods.

The agency has evaluated the merits of using plasma aminograms for protein quality evaluation. FDA believes that the method is not appropriate for this purpose. Current methodologies using plasma amino acids for predicting the protein quality of foods are highly variable, nonstandardized, and expensive. Consequently, it is not practical on a routine basis to conduct tests using plasma amino acid changes in humans as a basis for estimating protein quality.

73. One comment requested information on how to implement the PDCAAS method and on whether commercial testing laboratories have the necessary capabilities to determine the PDCAAS value.

FDA advises that the methods for determining a food product's PDCAAS is found in "Protein Quality Evaluation, Report of a Joint FAO/WHO Expert Consultation" which is being incorporated by reference into the final rule. As stated in § 101.9(c)(7)(ii), this report is available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF–260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or is available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. To assist persons in using this report, FDA has modified § 101.9(c)(7)(ii) to add the specific sections of the FAO/WHO report in which the methodology is found. These sections are 5.4.1, 7.2.1, and 8.00.

For those foods for which the digestibility factors are known and found in FDA's interim data base, commercial testing laboratories will be able to calculate the PDCAAS after running an amino acid analysis as

described in the FAO/WHO report, section 8.00 (Ref. 8). The equipment necessary for amino acid analyses is commonly used by commercial laboratories and should be widely available.

For those foods for which the digestibility factor is not known, digestibility values must be determined in laboratories according to methods in the FAO/WHO Report, sections 7.2.1 and 8.00 (Ref. 8).

74. A comment noted that the agency had not specified increments for reporting the "Percent Daily Value" for protein as had been done in proposed § 101.9(c)(11)(iii) for reporting the "Percent Daily Value" for vitamins and minerals.

FDA acknowledges the oversight and is modifying § 101.9(c)(7)(i) by specifying that the "Percent Daily Value" for protein is to be declared to the nearest whole percent as it is for fat and carbohydrate in § 101.9(d)(7)(ii).

4. Conclusion

In all other respects, § 101.9(c)(8), redesignated as § 101.9(c)(7), remains unchanged except that § 101.9(c)(7)(iii) has been reserved in this document. That paragraph is included in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" published elsewhere in this issue of the **Federal Register** in which the DRV for protein for adults and children over 4 years of age and the RDI for protein for infants, children less than 4 years of age, pregnant women, and lactating women are established.

H. Vitamins and Minerals

75. Retaining the requirement for mandatory listing of vitamin A, vitamin C, calcium, and iron on the food label was supported by a large number of comments representing a broad spectrum of consumers and consumer organizations, public health organizations, health care professionals, industry representatives, and trade associations. These comments agreed with the rationale stated in the proposal for continuing the mandatory declaration of these nutrients in nutrition labeling.

There were, however, some comments that did not support the mandatory listing of these nutrients. Some comments suggested that vitamin A and vitamin C should not be mandatory but should be allowed on the food label on a voluntary basis. One comment questioned whether inadequate intake of these vitamins is a public health issue, noting that some milk is fortified with vitamin A and stating the belief that consumers are aware that citrus fruits are sources of vitamin C. One comment noted that the IOM report (Ref. 1) recommends that vitamin A and vitamin C should be allowed on the food label rather than required. Additionally, a few comments recommended voluntary rather than mandatory declaration of calcium and iron.

In view of the strong support for the mandatory listing of vitamin A, vitamin C, calcium, and iron on the food label, and in the absence of strong opposition to the agency's proposal to require the listing of these nutrients on the label, FDA is not persuaded that voluntary listing of these nutrients is desirable and in the interest of the public health. While the IOM report does suggest that vitamin A and vitamin C could be allowed, rather than required, on the food label, it identifies vitamin A and vitamin C as potential public health issues and states that certain subpopulations are still at risk for deficiencies of these vitamins (Ref. 1). The report states that inadequate dietary intake of vitamin A is found in children under 5 years of age, and that two segments of the population are at risk for vitamin C deficiency (infants fed cow's milk exclusively and elderly individuals on inadequate diets).

FDA continues to believe that public health concerns exist for vitamin A in these at-risk groups and for the general public. While fortification of certain foods, such as low fat and skim milk, has helped to improve intakes of this vitamin among healthy persons consuming a balanced diet, the inclusion of adequate vitamin A in the diet still requires care and effort on the part of a consumer in selecting good food sources of this vitamin. Vitamin A is found in a relatively limited number of foods within the food supply, and these foods must be selectively chosen by consumers on a regular basis to ensure adequate intake.

FDA also continues to believe, as supported by numerous comments, that vitamin C is a nutrient with public health significance, in that, even with fortification efforts and greater year-round availability of citrus fruits and dark green vegetables, certain subpopulations are considered at risk (see 55 FR 29487 at 29501).

In the case of calcium and iron, these minerals are identified as public health issues in the IOM report (Ref. 1) and by numerous other sources, including the Surgeon General's report (Ref. 2), Diet and Health (Ref. 3), and the report on "Nutrition Monitoring in the United States" (Ref. 49).

Therefore, § 101.9(c)(11)(ii), redesignated as § 101.9(c)(8)(ii), requires vitamin A, vitamin C, calcium, and iron as mandatory elements of nutrition labeling.

76. Many comments were received from persons at risk of iron overload, particularly hemochromatotics, supporting mandatory labeling of iron and requesting that the food label declare both added and naturally occurring iron.

FDA has carefully considered these comments. The agency recognizes that a segment of the population is at risk of iron overload. In deciding whether the declaration of a nutrient or component on the food label should be mandatory, however, the agency must consider the broad public health significance of its action. Inadequate intakes of dietary iron are responsible for the most prevalent form of iron deficiency in the United States. Iron deficiency remains a risk for certain segments of the U.S. population, notably young children, adolescents, women of childbearing age, and pregnant women, especially those with low incomes (Refs. 2, 3, 23, and 49). Thus, public health concerns relative to iron, as stated in the National Nutrition Goals for the Year 2000 (Ref. 47), center on the prevention of iron deficiency and support increased dietary intake of iron among children 1 to 2 years of age, women 20 to 44 years of age, and low-income pregnant women. The agency believes that the listing of iron on the food label aids the consumer in making individual food selections in structuring the total diet, and that this total diet has significant effects on health.

However, as discussed in comment 54 of this document concerning added sugars, the agency has taken the position that it should not attempt to regulate actions that it cannot enforce. Because available laboratory analytical methods do not differentiate between added and naturally occurring iron, the agency would not be able to determine compliance with declared amounts of added iron.

Therefore, the agency is denying the request that manufacturers declare on their labels separate quantitative amounts of added and naturally occurring iron.

For the segment of the U.S. population at risk of iron overload, the agency notes that the food label will provide quantitative declaration of iron and vitamin C content of a food, as well as a listing of ingredients (including iron compounds if iron is added to the food). As absorption of nonheme iron may be enhanced by consumption of vitamin C containing foods, those at risk

of iron overload can decrease their simultaneous consumption of foods containing iron and vitamin C by using the information on the iron and vitamin C content of foods found on the food label.

77. The majority of comments that the agency received from consumers, health care professionals, public health agencies, universities, industry, and trade associations agreed with FDA's proposal to allow thiamin, riboflavin, and niacin to be listed voluntarily unless a claim is made, or unless these nutrients are added to a food. Most comments based their position on the decline of public health concern for deficiencies of these vitamins over the past 20 years.

On the other hand, there were some comments that advocated continued mandatory listing of these vitamins on the food label. Several comments expressed the opinion that mandatory inclusion of thiamin, riboflavin, and niacin within nutrition labeling contributed to the reduction of the incidence of deficiencies of these vitamins in the United States. One comment stated that these vitamins continue to be important to a significant portion of the U.S. population, that listing these vitamins on the label provides information on the nutritional properties of a food, and that the 1990 amendments direct FDA to mandate declaration of any vitamin that the agency deems to be important for the maintenance of healthy dietary practices.

FDA does not agree that the listing of thiamin, riboflavin, and niacin on the food label has been the major cause of the declining incidence of deficiencies of these vitamins. Rather, the agency believes that the variety and abundance of the food supply and the enrichment of many standardized foods with these vitamins are the primary factors responsible for reducing the occurrence of deficiencies of these vitamins (Ref. 57).

FDA acknowledges that these vitamins continue to be important nutrients, and that listing these vitamins on the label provides information on the nutritional properties of a food. However, the agency notes that while the 1990 amendments direct the agency to include in the nutrition label information that will assist consumers in maintaining healthy dietary practices, not all information related to maintaining healthy dietary practices can be included on the food label. If all such information were included, all essential nutrients would be declared on the nutrition label. Not only would space constraints not allow for this, but the large amount of information would interfere with consumers' abilities to use the information of the greatest public health significance (see discussion in response to comment 3 of this document). Such a result would be contrary to the intent of Congress (Ref. 16).

For this reason, FDA developed criteria in its mandatory nutrition labeling proposal to assist it in determining which nutrients to require in nutrition labeling (55 FR 29487 at 29493). These criteria specify that nutrients should be required when quantitative intake recommendations have been made in scientific consensus documents, and when the nutrient is of particular public health significance. Based on the preponderance of comments that agreed with FDA's assessment that thiamin, riboflavin, and niacin are no longer of particular public health significance, FDA has decided to provide in § 101.9(c)(11)(ii), redesignated as § 101.9(c)(8)(ii), for the voluntary declaration of thiamin, riboflavin, and niacin.

78. Several comments requested that FDA clarify whether thiamin, riboflavin, and niacin are required to be listed on the nutrition label of a product made with enriched flour, a standardized food, if no claim is made about these enrichment nutrients other than their listing in the ingredient statement as part of enriched flour. Similarly, another comment suggested that FDA explicitly state, as in current § 101.9(h)(7), that labeling of voluntary nutrients will not become mandatory if present in a food product as part of an enriched ingredient that has a standard of identity. The comment also requested that nutrients added strictly for a technological effect not be required to be declared in nutrition labeling, in a similar fashion to current § 101.9(h)(6).

Proposed § 101.9(c)(11)(ii) stated that vitamins and minerals (other than vitamin A, vitamin C, calcium, and iron which must be declared) need only be declared in the nutrition label when they are added as a nutrient supplement, or when a claim is made about them. FDA's intent in this section, which is redesignated as § 101.9(c)(8)(ii), was that when a food product is made with enriched flour as an ingredient, but the label does not make an "enriched" claim or use "enriched" in the name of the food, the nutrition label need not declare the enrichment nutrients. If, however, the product is made with unenriched flour and supplemented with nutrients as ingredients to achieve the equivalent of a product made with enriched flour, the product's label must list the enrichment nutrients in the nutrition label. Information on the amount of the enrichment nutrients is also required if an "enriched" claim is made on the label, or if "enriched" is used in the name of the food. Section 101.9(c)(8)(ii) is modified to clarify this requirement.

FDA agrees with the comment that nutrients that are not required to be declared in the nutrition label and are added to a food strictly for a technological effect need not be declared if the nutrient is declared solely in the ingredient statement and is otherwise not referred to on the label or in labeling or advertising. This provision, similar to current § 101.9(h)(6), is added to § 101.9(c)(8)(ii).

79. Several comments stated that listing of other vitamins and minerals should be required, even without a claim, such as vitamin D, magnesium, and phosphorus. One comment supported the listing of all vitamins (even those absent from the food or food product).

FDA notes from these comments consumer interest in a variety of nutrients but points out that not all nutrient information related to maintaining healthy dietary practices can be included on the food label. As discussed in comment 3 of this document, the agency must be selective with regard to the information that it requires to be listed on the label. Thus, it emphasizes nutrients or components of particular public health significance. FDA does not believe that all vitamins and minerals are of equal public health significance, a view that is supported by the IOM and Nutrition Monitoring reports (Refs. 1 and 49). The agency is also aware that space limitations on the food label require that it use discretion in deciding which nutrients it requires to be listed there.

FDA does not agree that vitamin D, magnesium, or phosphorus are of particular public health significance in the United States. Because the human requirement for vitamin D can be met with sufficient exposure to sunlight, and because milk and other foods are fortified with vitamin D, deficiencies in this vitamin are very rare (Ref. 23). Magnesium and phosphorus are cited in both the Nutrition Monitoring and IOM reports as food components that are not currently public health issues (Refs. 1 and 49). FDA, therefore, is not requiring mandatory listing of vitamin D, magnesium, or phosphorus in the nutrition label.

80. Some comments suggested not requiring any vitamins or minerals on the food label unless claims are made, or the nutrient is added to the food, in

order to minimize the space requirements of nutrition labeling.

As discussed in the supplementary proposal (56 FR 60366 at 60368), FDA interprets section 403(q)(1)(E) of the act to require the inclusion of vitamins and minerals currently required in § 101.9(c)(7)(iii) if the Secretary (or FDA, by delegation) determines that such information will assist consumers in maintaining healthy dietary practices. For the reasons discussed above, FDA, has determined that vitamin A, vitamin C, calcium, and iron meet the criterion in section 403(q)(1)(E) of the act and, therefore, must continue to be required elements of nutrition labels. The 1990 amendments did not provide for nutrients to be omitted to save space. Therefore, § 101.9(c)(8)(ii) continues to require declaration of vitamin A, vitamin C, calcium, and iron.

81. One comment requested that the final regulations allow for the voluntary identification of foods that are important sources of beta-carotene, either as a subset of vitamin A or through an independent designation. The comment stated that beta-carotene may reduce the risk of chronic diseases and appears to have its own independent biological functions in addition to serving as a source of vitamin A. The comment also noted that "Recommended Dietary Allowances" (10th ed.) states that "For food products containing large quantities of carotenoids, it would be advisable in nutrition labeling to distinguish between retinol, which in large amounts is toxic, and carotenoids, which are not" (Ref. 23).

The agency has carefully reviewed the relationship of beta-carotene to cancer in the companion document entitled "Food Labeling; Health Claims and Label Statements; Antioxidant Vitamins and Cancer," published elsewhere in this issue of the **Federal Register**. Based on that review and the stated recommendations in "Recommended Dietary Allowances," FDA has concluded that there should be a method within nutrition labeling to voluntarily distinguish the amount of beta-carotene present in food products. Accordingly, FDA is adding § 101.9(c)(8)(vi), which states that the percent of vitamin A that is present as beta-carotene may be declared to the nearest 10-percent increment immediately adjacent to or beneath the nutrient name (e.g., "Vitamin A (90 percent as beta-carotene)," see example in appendix C).

82. A few comments objected to FDA's proposed deletion of the synonyms vitamin B1 and B2 for thiamin and riboflavin, respectively. The comments argued that many consumers continue to use these terms and understand them better than the "scary-sounding chemical" names. Similar comments were received in response to proposed § 101.36 *Nutrition labeling of dietary supplements of vitamins and minerals.*

Based on the comments, the agency has reassessed its position on this issue. FDA believes that for consistency the chemical name of the nutrient (i.e., thiamin and riboflavin) must always be given when the nutrient is declared in nutrition labeling, or when claims are made (e.g., "high in thiamin"). However, the agency will not object to the voluntary parenthetical listing of "vitamin B1" or "B1" following "thiamin" and "vitamin B2" or "B2" following "riboflavin." Accordingly, FDA has modified § 101.9(c)(11)(v), redesignated as § 101.9(c)(8)(v), by adding vitamin B1 and vitamin B2 as synonyms for thiamin and riboflavin, respectively. While FDA believes a similar change is appropriate in proposed § 101.36, given the requirements of the DS Act, FDA is taking no action with respect to dietary supplements, and thus is not acting on proposed § 101.36, at this time.

83. One comment suggested that other synonyms be allowed, namely "pyridoxine" as a synonym for vitamin B6 and beta-carotene for vitamin A when the vitamin A is solely beta-carotene.

FDA rejects this comment. Pyridoxine is only one of three different forms of vitamin B6 (Ref. 23). In addition, the agency believes that it would be a more difficult term for consumers to use and understand. In regard to vitamin A, FDA believes new § 101.9(c)(8)(vi) (see comment 81 of this document) is a preferable course because in most foods, beta-carotene is only a fraction of the total vitamin A content.

84. FDA received a few comments that addressed increments for those nutrients that are expressed as a percent of a reference standard. One comment proposed a more complex incremental scheme than that in the proposed rules, suggesting 1-percent increments up to and including the 5-percent level, 2-percent increments from 6 percent up to and including the 12-percent level, 5-percent increments from 15 percent up to and including 50 percent, and 10-percent increments above the 50 percent level. Another comment suggested increments of 5 percent up to the 50-percent level and 10-percent increments thereafter. This comment suggested that FDA not permit the use of 2-percent increments because the necessary measurements are not accurate enough to allow for such small increments.

FDA proposed to maintain the current increments for vitamins and minerals, i.e., percentages are expressed in 2-percent increments up to and including the 10-percent level, 5-percent increments above 10 percent and up to and including the 50-percent level, and 10-percent increments above the 50-percent level. FDA considered both the comment suggesting a more complex incremental system and the comment suggesting omission of the 2-percent increments. Neither suggestion provided sufficient justification for the change. One appears to believe that an accuracy of 1 percent of the RDI is necessary, the other that an accuracy at 5 percent of the RDI is sufficient. Inasmuch as the agency has experienced no problems with the increments that have been in use since the early 1970's, and given that so few comments addressed this issue, the agency sees no need to modify the incremental scheme in proposed § 101.9(c)(11)(iii), redesignated as § 101.9(c)(8)(iii).

85. One comment noted that regulations specified that all nutrients except vitamins and minerals were to be expressed to the "nearest" unit or increment (e.g., total carbohydrates are to be expressed to the nearest g, and sodium to the nearest 5-mg increment between 5 and 140 mg of sodium and to the nearest 10-mg increment above 140 mg of sodium). The comment asked for direction on reporting amounts of vitamins and minerals.

To clarify the regulations and promote consistency, FDA is modifying § 101.9(c)(8)(iii) to specify that vitamins and minerals are to be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level.

86. A comment objected to the provision in proposed § 101.9(c)(11)(iii) that allows vitamins and minerals that are not present to be represented by an asterisk that refers to a statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." The comment stated that consumers might be misled into thinking that small amounts of the vitamin or mineral are present when they are not.

FDA considered this comment and has concluded that the flexibility the use of the asterisk provides in allowing manufacturers to reduce the space needed for nutrition labeling outweighs any slight misunderstanding about the amount of a vitamin or mineral present

in a food that might result. Amounts of either zero or less than 2 percent of the RDI (declared as Percent Daily Value) for these nutrients are physiologically insignificant.

The RDI's are provided in § 101.9(c)(8)(iv) which has been reserved in this document. That paragraph is included in the companion document entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (hereinafter referred to as the RDI/DRV final rule) published elsewhere in this issue of the **Federal Register**. In accordance with section 203 of the DS Act that prohibits FDA from promulgating regulations based upon recommended daily allowances of vitamins and minerals other than the U.S. RDA's currently specified in § 101.9(c)(7)(iv) until November 8, 1993, § 101.9(c)(8)(iv) includes values for only one age group (i.e., adults and children 4 or more years of age) rather than the 5 proposed groups (i.e., adults and children 4 or more years of age, children less than 4 years of age, infants, pregnant women, and lactating women). FDA intends to adopt in accordance with section 203 of the DS Act, appropriate RDI's for all groups. Therefore, FDA has adopted the references to such groups in §§ 101.9 (a)(4), (c)(8)(i), (e), and (1) of this final rule, even though such values do not exist at this time. In the meantime, suggested RDI values for other age groups, which, to be consistent with the DS Act, are based on the 1968 RDA's are presented as guidance in the preamble of the RDI/DRV final rule.

IV. Analytical Procedures

A. General Issues

87. Several comments asserted that FDA should explicitly state the methods to be used for the analysis of various nutrients. Some comments expressed the opinion that the agency should not mandate listing of any nutrient when there are serious issues with the reliability of the analytical method. Dietary fiber was specifically cited as one example. One comment added that FDA must specify the method of analysis for analytes not available in the AOAC.

The agency acknowledges the concern expressed in the comments. In the mandatory nutrition labeling proposal (55 FR 29487 at 29498), FDA discussed the analytical methodologies for sugars and dietary fiber. The agency noted that in the 17 years since the promulgation of § 101.9, it had acquired substantial experience under the regulation, and techniques for analyzing foods for their nutrient content have greatly improved. The agency considers it is inadvisable to explicitly state a method for a particular nutrient. The applicability of a specific method to products of different matrices varies. As noted in several comments, values for some nutrients, such as fat, are dependent upon the procedure used. If a specific method is cited, it may give the erroneous impression that other methods that are more appropriate to the matrix or that utilize newer techniques could not, or would not, be acceptable. It is FDA's policy and practice that any method used to support a nutrient declaration value requires appropriate validation if it has not been collaborated for that nutrient in a specific matrix. Validation procedures are a necessary component of sound analytical technique and are frequently used even with official, collaborated methods.

The agency agrees that no nutrient should be a required component in nutrition labeling if there is no satisfactory analytical method for determining its level in a food. In fact, this view was a major factor in the agency's decision not to require declaration of complex carbohydrates. FDA believes that there is adequate methodology to assay for the nutrients that it has made mandatory elements of the nutrition label, even, as explained below, for dietary fiber.

Analysis is not needed for nutrients, however, where reliable databases or scientific knowledge establish that a nutrient is not present in the product. For example, there is no need to analyze for cholesterol in fruits and vegetables or for dietary fiber in seafood. Costs associated with nutrition labeling will be contained by not analyzing for a nutrient where there is no reasonable expectation that the nutrient occurs in the food.

88. Some comments noted that analytical variability—which ranges from 1 percent to as high as 20 percent according to one comment—may be a function of the method selected and its inherent variability, the laboratory performing the analysis, the level of nutrient in the food, and the ability to obtain a homogeneous sample composite. A few comments specifically cited the difficulty in measuring levels of complex carbohydrates or vitamin C in potatoes. These comments observed that the nutrient levels may differ between the time of harvesting and processing, as well as after a period of storage. One comment recommended that FDA allow flexibility in selecting analytical methodology such that there would be a broadened range of methods used to generate nutritional information.

FDA advises that manufacturers are free to use methods of their choice for ascertaining the quantity to declare on the label as well as for screening purposes as part of their quality control procedures. However, when questions arise as to the validity of the data, the agency will utilize the methods of the AOAC or other validated procedures.

Given the analytical problems in determining values for complex carbohydrates, the agency has deleted the requirement for declaring complex carbohydrates and is eliminating the term "complex carbohydrate" from the nutrition label. As discussed above, it is using instead the term "other carbohydrate." The term "other carbohydrate" is defined as the difference between total carbohydrates and the sum of dietary fiber, sugars, and sugar alcohols (when declared). Because a specific method of analysis is no longer required for complex carbohydrates, the concern about measuring this food component in potatoes has been addressed. In regard to the concern about the analysis for vitamin C in potatoes, FDA advises that in this situation vitamin C is a naturally occurring, or Class II, nutrient. Thus, the declaration is in compliance if the nutrient is present at a level of 80 percent or more of the declared label value. It should be noted that current regulations and § 101.9(g)(6) permit reasonable excesses within current good manufacturing practice for both vitamin C and other carbohydrate.

As more nutritional analyses are performed in support of label values, more methodologies will be validated. As a result, the number of methods that manufacturers may use in determining the amount of a nutrient will increase. Moreover, products that heretofore had not been labeled with nutrition information will now be subjected to testing. These new matrices will create new challenges for both the food industry and the agency. However, these challenges should not impede the development of full, accurate nutrition information on food labels. The agency is committed to working with industry to provide valid nutrition label information that will promote selection of healthier diets by U.S. consumers.

89. Some comments suggested that FDA work with trade associations and industry on the analytical techniques required to prepare nutrition labels. One comment recommended that designations be made as to which food matrices are appropriate for existing methods and which ones are not.

FDA agrees it should be actively involved in the review of suitable methods to be used in the

implementation of mandatory nutrition labeling. The AOAC Task Force on Nutrient Labeling Methods was established early in 1992 by AOAC for the purpose of assisting its membership in meeting the requirements of the agency's regulations. The agency worked closely with the Task Force, participating in meetings as well as in evaluating appropriate methods for various matrices. The Nutrient Labeling Task Force Report on Analytes for Nutritional Labeling is available from the agency or AOAC. The report lists the methods that are adequate for various nutrients and various matrices. As pointed out in the official AOAC publication, The Referee (Ref. 58), not all analyte/matrix combinations in the report have been fully collaboratively studied, however.

In this context, it should also be noted that § 101.9(g)(2) of these final rules allows for the use of other reliable and appropriate analytical procedures if no AOAC method is available or appropriate. Sources of such methods include FDA's "Lipid Manual" (Ref. 59) and FDA's Food Additive Analytical Manual, vol. I and vol. II (Ref. 60). Additional methods may be found in "Approved Methods of the American Association of Cereal Chemists" and "Official Methods and Recommended Practices of the American Oil Chemists Society."

The method of analysis used must be suitable to achieve the purpose for which it is used. For example, the method used to quantify vitamin C for nutrition labeling must be able to determine whether ascorbic acid or isoascorbic acid is present in the food. Isoascorbic acid and sometimes ascorbic acid are used as antioxidants in food processing. Only ascorbic acid, however, is an active form of vitamin C and considered in the determination of vitamin C content of the food. Thus, the method must be able to distinguish ascorbic acid from isoascorbic acid.

90. FDA received several comments regarding the use of the Official Methods of Analysis of the AOAC. One comment stated that the latest edition of this reference should be cited to avoid obsolescence when new editions are issued.

FDA does not have authority to not reference a particular edition of the Official Methods. The Office of the Federal Register requires that each statement of incorporation by reference into the Code of Federal Regulations contain specific information, including the date and edition of the publication. Accordingly, FDA has not modified § 101.9(g)(2).

91. A comment supported a policy whereby FDA would verify laboratory analysis results on file at a firm to substantiate the nutrition label information in lieu of doing nutrient analysis from a limited sample of products. The comment expressed the opinion that FDA should be required to perform additional sampling and testing and to consider the statistical variation inherent in test procedures before initiating a legal action, such as a seizure.

The agency disagrees with the comment. FDA is a law enforcement agency, and its mission is consumer protection. To support a misbranding charge for inaccurate nutrient content information, FDA must have accurate, reliable, and objective data to present in a court of law. To obtain that information, FDA relies upon the work performed by its trained employees because it does not have legal authority in most instances to inspect a food manufacturing firm's records.

The practice of performing nutrient analysis from a composite of 12 subsamples is well established. Compositing the contents of the twelve containers yields a numerical result essentially equivalent to what would be obtained if each container were analyzed, and the results averaged. Thus, the composite value is considered to be the same as the average of a sample of twelve containers. As noted in § 101.9(g)(4) and (g)(5), FDA will not take regulatory action based on a determination of a nutrient value that fails to meet appropriate levels by a factor inherent in the variability generally recognized for the analytical method used on that food at the level involved.

B. Calories

92. Comments stated that the regulations should clarify how calories are to be calculated. Several comments recommended adding "caloric content may be determined by the Atwater method" to proposed § 101.9(c)(3). Some comments objected to the use of the specific Atwater food factors published in "USDA Handbook 74" which have not been updated since 1955. Another comment noted that if a food item is a commodity-type product for which a specific Atwater factor is available, the caloric content for these products should be required to be calculated using the specific Atwater factors.

Several comments disagreed with the proposal to subtract dietary fiber from the amount of carbohydrate before applying the general factor of 4 (i.e., 4 calories per g of carbohydrate). These comments contended that the general factor is intended to apply to total carbohydrate including fiber. Because the gastrointestinal effects of dietary fiber were taken into account in the derivation of the general factors, these comments did not consider it to be legitimate to exclude fiber from carbohydrate content when calculating caloric content.

One comment suggested that calories be calculated from carbohydrate-plus-dietary fiber if the general factor of 4 calories per g of carbohydrate is used. Alternatively, the comment suggested that calories be calculated from available carbohydrate if the general factor of 3.75 calories per g of carbohydrate is used. The factor of 3.75 calories per g for carbohydrate is used by the United Kingdom for calculation of available carbohydrate energy (Ref. 61).

One comment suggested that both total dietary fiber and other nondigestible carbohydrate should be subtracted from the total carbohydrate content before calculating calories contributed by carbohydrates. As noted in the comments, many new food ingredients such as reduced-calorie fats, fat substitutes, and modified carbohydrates have been developed in recent years. Some of these ingredients have caloric values substantially less than the general factors of 4, 4, and 9 for protein, carbohydrate, and fat, respectively. Comments requested specific allowances for ingredients used as reduced calorie replacements for conventional ingredients to permit methods for calculating the available calories other than use of the general factors.

The agency recognizes that confusion may exist about methods for calculating caloric content because of the proposed changes in how total carbohydrate content has been defined in § 101.9(c)(6) and because of the changes in the treatment of dietary fiber. Therefore, the agency is modifying § 101.9(c)(1) to clarify how caloric content is calculated by providing five options for calculating the energy value of foods in § 101.9(c)(1)(i).

The first option, which is set forth in § 101.9(c)(1)(i)(A), is the use of specific Atwater factors that are found in Table 13 in "Energy Value of Foods—Basis and Derivation" by A. L. Merrill and B. K. Watt, USDA Handbook No. 74 (1955). FDA disagrees with the comment that suggested requiring the use of specific Atwater food factors for those foods for which such factors exist. The agency does not believe that there is any need to limit a manufacturer's flexibility in selecting a method for determining

caloric content. Current regulations do not require the use of specific Atwater food factors, and no data were presented to support a change in current practices.

The second and third options utilize the general factors of 4, 4, and 9 calories per g for protein, carbohydrate, and fat, respectively. In § 101.9(c)(1)(i)(B), which provides for calculating calories by general factors, dietary fiber is included in total carbohydrate. FDA also recognizes, however, that doing so can result in significant error for the caloric value of some foods because of the relatively low energy value of dietary fiber. Adjustments for dietary fiber content are therefore appropriate for nutrition labeling of some foods.

However, because some soluble dietary fiber can make a significant contribution to a food's energy value (Ref. 61), FDA does not consider it appropriate to allow an absolute exclusion of all dietary fiber from caloric calculation. Recognizing that there can be significant levels of available energy in some soluble fiber, and that official AOAC methods for dietary fiber now provide for separation of soluble and insoluble fiber, the agency considers it appropriate to permit exclusion of the insoluble component of dietary fiber alone from calculation of carbohydrate calories. Accordingly, FDA has added § 101.9(c)(1)(i)(C) in the final rule to permit calculation of caloric contribution from the carbohydrate portion of food by multiplying carbohydrate content minus insoluble dietary fiber content by the general factor of 4 calories per g.

In addition, § 101.9(c)(1)(i)(D) permits manufacturers or users of soluble dietary fiber additives or other food additive substances with reduced available energy to petition for use of alternative energy factors in nutrition labeling through established procedures for food additive or GRAS petitions. Soluble dietary fiber substances are frequently added to foods to replace fully caloric nutrients in formulating reduced calorie foods. In such cases, the burden for establishing the actual energy value of the food is appropriately with the manufacturer.

The calculation of the caloric contribution of novel fats and carbohydrates has been discussed in section III. of this document. The agency has stated that it will consider digestibility of new products on a case-by-case basis as requested. In support of this action, the agency requests that manufacturers who wish to declare adjusted values for the energy contribution of a substance, based on reduced digestibility, submit information on digestibility of the substance, analytical assay procedures for the substance, and data on interference with required methods of analysis. As stated in section III. of this document, this information should be included in a food additive petition or a petition for affirmation that the use of a substance is GRAS. The agency will then publish the specific digestibility coefficients in 21 CFR part 172 for food additives and in 21 CFR part 184 for GRAS substances. These coefficients can be utilized in determining the caloric value of specific food ingredients.

Other procedures may be required for particular foods and will be addressed by other appropriate means. FDA is allowing for this contingency in § 101.9(c)(1)(i)(D) by adding "or other means, as appropriate." For example, in the voluntary nutrition labeling program for raw fish, data were presented to FDA supporting a value of fat and calories for the fish "orange roughy" that omits a portion of the total fat since more than 90 percent of the fat in the product is in a wax ester that is not metabolized (Ref. 62). FDA published these corrected values for available fat and calories in Appendix B "Nutrition Labeling Provided by FDA for the 20 Most Frequently Consumed Fish" (57 FR 8175; March 6, 1992).

To afford even more flexibility in determining caloric content, FDA is including § 101.9(c)(1)(i)(E), to provide for the use of bomb calorimetry. The agency notes that the caloric value so obtained must be corrected for nonmetabolizable protein by subtracting 1.25 calories per g of protein to correct for incomplete digestibility, as discussed in Energy Value of Foods, Basis and Derivation, "USDA Handbook No. 74" (Ref. 63). The caloric value determined by bomb calorimetry may give a higher value than the other allowed methods. However, because it would produce an over-estimation of the caloric content of the food, FDA would not consider it to be disadvantageous to the consumer. A primary consideration in selecting which method to use must be the accuracy of the declaration of the caloric content in light of the agency's compliance criteria in § 101.9(g).

The agency is aware that some manufacturers have developed their own specific factors for conventional food ingredients that they use in calculating the caloric content of their products. FDA views this practice as analogous to using data bases to determine nutrient label values, in that the manufacturer assumes the responsibility for ensuring that the values obtained are consistent with those obtained analytically by FDA. As such, the agency does not believe it needs to provide for this option in § 101.9(c)(1)(i).

In summary, the agency is amending § 101.9(c)(1) to permit five optional methods for calculation of caloric content of foods: (1) Specific Atwater food factors (i.e., the Atwater method) given in Table 13, "Energy Value of Foods—Basis and Derivation," A.L. Merrill and B.K. Watt, USDA Handbook No. 74 (1955), (2) general factors of 4, 4, and 9 calories per g of protein, total carbohydrate including dietary fiber, and total fat, respectively, as described in USDA Handbook No. 74, (3) general factors of 4, 4, and 9 calories per g for protein, total carbohydrate, and total fat, respectively, as discussed in USDA Handbook No. 74, except that insoluble dietary fiber content may be subtracted from total carbohydrate content before calculating the caloric contribution of the carbohydrate portion of the food; (4) specific factors for particular food ingredients approved by FDA through incorporation in 21 CFR parts 172 or 184 or other means, as appropriate, or (5) bomb calorimetry data after subtraction of 1.25 calories per g protein to correct for incomplete digestibility, as described in USDA Handbook No. 74, p. 10.

By providing for these varied means of calculating caloric content, FDA is giving manufacturers flexibility in how they determine calorie content in a variety of foods, both conventional foods and new foods developed to meet changing marketing strategies.

93. A recommendation was made in one comment that products with a negligible amount of dietary fiber (suggested as less than 2.5 percent) should not be required to have dietary fiber analysis for determination of caloric content.

The agency advises that because revised § 101.9(c)(6) now includes dietary fiber in total carbohydrate content, separate analysis for dietary fiber is no longer required for calculation of either carbohydrate content or calories from carbohydrate. Therefore, the concern expressed in this comment has been addressed.

94. Several comments asked for clarification on the discussion in the mandatory nutrition labeling proposal (55 FR 29487 at 29493 and 29503) of the possible caloric contribution of macronutrient substitutes or other ingredients such as certain types of soluble fibers or gums. While one comment agreed with the agency's position that manufacturers of these ingredients should be asked to provide

evidence that these substances do not contribute to the energy value of food, another comment found the concern unwarranted and opposed the use of any correction factors for calories from soluble fibers (e.g., gums). One comment noted that more research is needed in this area.

In the mandatory nutrition labeling proposal, the agency expressed concern that available energy of soluble dietary fiber food additives (e.g., gums) would not be included under the agency's proposed method for caloric calculation, which excluded energy contribution of all dietary fiber. Innovations in food technology have resulted in reduced calorie foods that utilize various soluble dietary fibers and other modified carbohydrates, proteins, and fats for technical effects that allow reduction of total fat content. The agency considered it inappropriate to automatically assign a zero energy value to all soluble dietary fiber additives when some of these substances may have available energy. Likewise, some modified carbohydrate additives may have less available energy than the 4 calorie per g assigned by the general energy factor for carbohydrate but still have available energy. The agency has determined that petitions regarding specific caloric values for these types of food ingredients are appropriate. FDA's new policy is discussed in comment 92 of this document.

C. Fats, Fatty Acids, and Cholesterol

95. As discussed in section III. C. of this document, comments raised many questions about analytical procedures to be used to measure fat and their reliability. In addition, several comments expressed concern regarding the adequacy of methods for measuring cholesterol. One comment cited a published article on a method for measuring cholesterol that is undergoing collaborative study under the auspices of the AOAC.

The agency believes that its new definition for total fat in § 101.9(c)(2) (i.e., total lipid fatty acids expressed as triglycerides) will help to clarify what analytical procedures are to be used by clarifying what compounds are to be included in the declaration of total fat. As with all nutrient analyses, consideration must be given to the analyte and matrix when selecting a method to determine total fat content. To that end, the AOAC has established methods for analyzing for total lipid fatty acids in a variety of product matrices. A recent publication of the AOAC, The Referee (Ref. 32), contains a compilation of these methods. Other reliable and appropriate methods are also cited in comment 89 of this document.

FDA notes that issues exist about the reliability of methods for measuring low levels of fat. As discussed in a recent article, fat determinations are reliable down to concentrations of 1 to 5 g per 100 g, provided a large enough test portion is taken to obtain at least 50 mg of weighable residue (Ref. 64). The premise is that accuracy generally increases when larger amounts are used for analysis so that there is always a minimum quantity of extracted fat available for weighing.

Although official analytical methodologies for determining cholesterol content are somewhat limited at the present time, the agency is pleased to note that comments indicate that this is an area of active research. FDA, as a member of the AOAC Task Force on Nutrient Labeling Methods, looks forward to the development of additional collaborated methods for a range of matrices.

D. Dietary Fiber

In proposed § 101.9(c)(3) of the mandatory nutrition labeling proposal and proposed § 101.9(c)(7)(ii) of the supplementary nutrition labeling proposal, FDA specified that total, soluble, and insoluble dietary fiber content are to be determined by the method "Total Dietary Fiber in Foods, Enzymatic Gravimetric Method."

96. One comment noted that satisfactory analytical procedures for measuring dietary fiber are available and cited the American Association of Cereal Chemists Method No. 32–21 and the proposed AOAC method. This comment stated these methodologies were at least as accurate as certain other sanctioned procedures. It acknowledged that research should continue, however, to improve the utility and standardization of analytical methods for fiber. Another comment noted that the precision of the proposed method may cause difficulties at low levels, typical of that found in some fruits and vegetables (more than 1 percent to 5 percent) and especially when fat is present in the sample. The comment stated that because of questions concerning the accuracy of methods for measuring dietary fiber, companies may elect not to declare low levels of fiber in their products. The comment stated that there is a more accurate method for use in these situations.

Two comments from the meat industry expressed concern that the proposed method for fiber had only been evaluated on cereals, grains, and breads. They questioned the applicability of the method to other types of products. According to another industry comment, currently approved methods for analyzing dietary fiber seriously underestimate dietary fiber content of high moisture foods, which leads to inaccurate and misleading label information. This comment said that a current analytical method for high moisture products is unavailable. A comment expressed the hope that the tests adopted to measure dietary fiber would not falsely exclude low molecular weight bulking agents, such as polydextrose.

The few comments that addressed analytical methods for soluble and insoluble fibers were split on whether available methods are adequate or inadequate. One comment to the supplementary proposal noted that the agency's cited method does not measure soluble fiber directly. The comment said that the method measures total dietary fiber and insoluble dietary fiber, then calculates soluble dietary fiber as the difference between the two.

With the currently available AOAC methods for dietary fiber and its components, FDA believes that suitable methodology exists for the analysis of dietary fiber for nutrition labeling purposes. Since the issuance of the supplementary proposal, two additional methods for dietary fiber have been accepted by the AOAC, based upon the collaborative data. One new method (AOAC 15, 991.43) permits the discrete analysis of total dietary fiber and of each subcomponent, i.e., soluble and insoluble dietary fiber. The concern expressed by the comments as to the availability of validated methods for measuring dietary fiber is therefore alleviated. Because methods for measuring dietary fiber are now included in the Official Methods of Analysis of the AOAC, § 101.9(c)(7)(ii) of the supplementary proposal, which described dietary fiber methodology, and § 101.9(g)(2), which directs compliance by official AOAC methods, are redundant. As such, § 101.9(c)(7)(ii) has not been included in the final rule.

The enzymatic-gravimetric method (AOAC 15, 985.29) cited in proposed § 101.9(c)(7)(ii), is valid for high-moisture foods and those with fat present in the product. The method specifies drying conditions, as well as defatting procedures, that are to be performed before analysis for total dietary fiber. If drying conditions are a part of the analysis, analytical results must incorporate the loss on drying to obtain the total dietary fiber content of the "as received" product. Likewise, any loss of weight from fat or sugar removal must also be compensated for in the calculations.

Regarding the comment on the appropriateness of including low molecular weight bulking agents in dietary fiber, in the absence of a consensus on a chemical definition for dietary fiber, the available analytical methods dictate classification of such ingredients. Some manufactured low molecular weight, carbohydrate based, bulking agents, such as polydextrose, do not analyze as dietary fiber in the official AOAC methods for measuring dietary fiber. Such food ingredients, while not reported as dietary fiber in nutrition labeling, would be included in total carbohydrate and reported as "other carbohydrate."

97. A few comments recommended that dietary fiber be listed in 0.5-g increments, believing it to be a meaningful quantity to declare. Other comments concurred with the agency's proposal of whole-g declaration for dietary fiber on the basis that 0.5 g requires greater analytical precision than is possible for measuring dietary fiber.

The agency disagrees with the first comment. No data were presented to support a change to 0.5-g increments. Therefore, FDA continues to believe that the precision of the analytical methodology for determining quantitative amounts of dietary fiber does not allow for accuracy to the 0.5 g level. Accordingly, § 101.9(c)(6)(i) will require that dietary fiber be expressed to the nearest g.

98. One comment recommended use of the word "fiber" in lieu of "dietary fiber." The comment stated that consistency with the 1990 amendments was not needed and was far less important than using terms that consumers understood. The comment also contended that insertion of the word "dietary" into each term of fiber content would clutter the label.

The agency disagrees with the comment. No data were presented to support the contention that the term "dietary fiber" would confuse consumers. FDA believes that it is important to distinguish between dietary fiber and crude fiber to ensure that there is no question as to what fiber components are declared.

99. One comment took exception to the agency's citation of USDA Handbook 74 (1955) as the reference for the subtraction of dietary fiber in the calculation of total carbohydrate at § 101.9(c)(6) of the supplementary nutrition labeling proposal. In the cited reference, dietary fiber is not a part of the calculation. The comment noted that, as a defined, analyzable entity, dietary fiber was unknown in 1955.

FDA acknowledges the accuracy of the comment in regard to the concept of what dietary fiber was in 1955. As noted previously, the agency has modified § 101.9(c)(6) so that dietary fiber is no longer subtracted from the weight of the total food in the calculation of total carbohydrate content for nutrition labeling purposes. Therefore, the concern expressed by this comment has been addressed.

E. Sugars and Other Carbohydrate

In the mandatory nutrition labeling proposal, FDA discussed the analytical methodologies for sugars and dietary fiber (55 FR 29487 at 29498). The agency acknowledged in the supplementary proposal (56 FR 60366 at 60369) that analytical problems were a concern for the mandatory declaration of sugars and complex carbohydrate.

100. Essentially all of the comments stated that current methodology is inadequate to determine the levels of sugars and complex carbohydrate, as defined. Other comments described the methodology as unavailable, costly, difficult, and imprecise. One comment noted that there are no current analytical standards for measuring complex carbohydrates as defined in FDA's proposed rule. There were no comments that provided references for available, validated analytical methodology for these food components. Another comment noted that assay techniques for the quantitative determination of polysaccharides of 10 and higher saccharide units are beyond the reasonable capabilities of many in the food industry.

One comment included an evaluation of two liquid chromatographic procedures for monosaccharides through pentasaccharides and delineated disadvantages of each. The technique of high performance ion chromatography was identified by the comment as the technique that could provide the most accurate values for sugars. This technique has not however, been studied collaboratively by the AOAC.

Concerns expressed in regard to the analytical determination of sugars and complex carbohydrates have been alleviated by the revision of the definition of "sugars" to include only the sum of mono- and disaccharides and of "other carbohydrate" as the difference between total carbohydrates and the sum of dietary fiber, sugars, and sugar alcohols (when declared). There is established methodology in the Official Methods of Analysis of the AOAC for the determination of mono- and disaccharides in several food groups with a high degree of confidence. Continued analytical work will be necessary to validate methodology for a wider, more diverse food supply.

The agency will use the technique of HPLC in monitoring compliance with label statements concerning sugars content. The agency's use of this technique will not preclude the use of emerging technologies such as high performance ion chromatography or supercritical fluid chromatography as they are developed and validated.

F. Vitamins

101. A comment stated that the agency should list those carotene fractions that can be included in the declaration of vitamin A for labeling purposes. It noted that a variety of HPLC methods for vitamin A and carotene are available and currently in use by industry and FDA. The comment also stated that analytical reagents required for AOAC official methods for determining vitamin A content are no longer available.

In its RDI/DRV proposal, the agency proposed that vitamin A content is to be expressed in retinol equivalents (55 FR 29476 at 29485). One retinol equivalent was established to be equivalent to 1 microgram (µg) retinol or 6 µg beta-carotene. The nomenclature for vitamin A as retinol equivalents was carried forward in the supplementary proposal at § 101.9(c)(11)(iv). FDA is aware of literature data where alpha-carotene is present in some carrots in significant amounts. To account for this and other carotene fractions, the agency also recognizes the National Academy of Sciences' definition of retinol equivalents as 12 µg of provitamin A carotenoids other than beta-carotene (Ref. 23).

As noted above, the agency worked closely and actively with the AOAC Task Force on Nutrient Labeling Methods to judge the adequacy of AOAC methods to meet nutrition labeling needs. The decreased availability of the analytical reagents for some methods for determining vitamin A content has caused both industry and the agency to rely more on HPLC procedures. For example, the yellow OB dye (formerly FD&C Yellow No. 4) used for standardizing the alumina column in the AOAC method for determining the vitamin A content in margarine is no longer readily available. However, FDA advises that the Nutrient Surveillance Branch (HFF–266), Center for Food Safety and Applied Nutrition, FDA, can provide limited quantities of the dye upon request to the address listed at the beginning of this document.

V. Format

A. Legal Authority for an Improved Nutrition Label Format

Congress clearly intended that nutrition information be presented to the public in a manner that facilitates understanding of the information and that assists consumers in maintaining healthy dietary practices. This fact is evidenced by at least two provisions of the 1990 amendments. Section 403(q)(1) of the act, which was added by the 1990 amendments, states:

> The Secretary may by regulation require any information required to be placed on the label or labeling by this subparagraph or subparagraph (2)(A) (section 403(q)(1) or (2)(A)) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

In addition, section 2(b)(1)(A) of the 1990 amendments states that the implementing regulations shall:

> * * * require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.

Consistent with the authority vested in the Secretary (and FDA, by delegation) to determine if specific label information will assist consumers in maintaining healthy dietary practices, the House report accompanying the 1990 amendments directs FDA to consider a variety of format options, including: "information about the recommended daily intake, the use of descriptive terms such as 'high,' 'medium,' and 'low' or use of universal symbols to indicate desirable or undesirable levels of particular nutrients." The report goes on to state: "While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information" (Ref. 16).

B. The Role of the Nutrition Label

The 1990 amendments provide several descriptions of the role of the nutrition label. Section 403(q)(1) of the act, which was added by the 1990 amendments, uses the language "assist consumers in maintaining healthy dietary practices." Section 2(b)(1)(A) of the 1990 amendments uses the language "enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet." In the format proposal, FDA requested comment about how the nutrition label can best assume the information role mandated by the 1990 amendments.

102. A number of comments from food manufacturers, trade associations, health promotion organizations, and consumer groups identified more than one role for the nutrition label in assisting consumers in maintaining healthy dietary practices. One illustrative comment from a health professional organization described two different roles of the food label as: (1) Helping consumers choose appropriate foods and (2) helping consumers to understand the "importance of diet and proper dietary behaviors to a healthy life." Similarly, a comment from a trade association made the distinction between the food label "contributing to the consumer's understanding of the relative significance of the food in the context of a total daily diet" and providing "guidance on how to use information in the food label to make appropriate food choices." Many comments made similar distinctions between the food label helping to place the particular product in the context of a daily diet and the food label providing guidance on how to maintain healthy dietary practices. A number of comments from industry questioned whether the act mandated an explicit educational role for the nutrition label to provide guidance to consumers on how to maintain healthy dietary practices.

Many comments argued that the nutrition label cannot by itself provide all the information important to maintaining healthy dietary practices but reached different conclusions about the relevance of this limitation for the nutrition label format. A number of comments, particularly from industry, pointed out that because of the limited space available on the food label, the nutrition label cannot be expected to adequately convey all the information consumers need to understand the importance of nutrition information in maintaining healthy dietary practices. These comments concluded that the role of the nutrition label should be limited to providing factual, product-specific information, and that the broader dietary guidance role should be reserved to off-label activities of public and private nutrition education programs. These comments asserted that these programs will have sufficient time and space to inform consumers about the concepts of flexibility and personal choice necessary to maintain healthy dietary practices.

Other comments, primarily from consumer organizations and health professional groups, acknowledged the necessity of off-label consumer education to help consumers understand how to use the nutrition information to maintain healthy dietary practices but saw the nutrition label as a useful food selection tool that needs to be integrated with off-label educational programs.

FDA agrees that the nutrition label can and should help consumers make informed food choices, and that it can also contribute to helping consumers maintain healthy dietary practices. The two roles are by no means inconsistent. To help consumers make appropriate food choices contributes undoubtedly to maintaining healthy dietary practices. Among those choices are choices that will assist the consumer in maintaining healthy dietary practices. Maintaining healthy dietary practices, however, is a larger and more complex goal than informing food choices, and one that requires motivation and knowledge of how to combine and balance the many different kinds of foods and eating occasions that constitute a total diet. The 1990 amendments require the agency to take both senses of the possible role of the nutrition label into account in evaluating alternative formats for the nutrition label. However, the agency also agrees that the mandated role of the nutrition label to assist consumers in maintaining healthy dietary practices does not encompass an explicit educational role for the nutrition label to provide dietary guidance to consumers.

The agency believes that the nutrition label format needs to give first consideration to helping consumers make informed food choices by enabling them to both comprehend the nutritional value of the food and to understand its relative significance in the context of the total daily diet as called for in section 2(b)(1)(A) of the 1990 amendments.

The agency's view is that the basic format elements that best serve the mandated role of the nutrition label must be identified and justified on the basis of consumer research. Therefore, the implications of format elements for the use of the nutrition label in assisting consumers to understand the nutritional value of the food and to understand the food in the context of the total daily diet were extensively examined in the agency's format research.

C. Need for Consumer Research

Section 2(b)(1)(A) of the 1990 amendments specifies criteria for an acceptable format for nutrition label information. The operative terms in this section, "readily observe and

comprehend" and "understand its relative significance in the context of a total daily diet," are goals stated in terms of consumer perception and understanding. The consequences of various formats and format elements on consumer perception and understanding can only be measured objectively in terms of behavior (i.e., in terms of how well consumers use a format for a specific task). Formats and format elements can be assessed subjectively by asking consumers or experts to judge the usefulness of various formats. Behavior-based performance measures, however, rather than subjective judgment, are generally accepted as the more reliable and valid way to evaluate the consequences of information displays on consumer perception and understanding.

Major scientific groups (Refs. 1, 65, and 66) urged FDA to subject possible nutrition label formats to consumer testing to objectively determine which formats can be used most effectively by consumers. FDA has placed considerable emphasis on the importance of consumer research in developing a new format for the nutrition label because of this advice and because the techniques of consumer research (surveys, focus groups, experiments, and preference polls) provide the best and perhaps the only possible bases for evaluating alternative nutrition label formats against the consumer perception and understanding criteria specified in the 1990 amendments.

103. A number of comments argued that virtually any nutrition label format, even the current format, can serve to help consumers put foods in the context of a total daily diet depending on the knowledge and understanding of the person reading the label. To the same point, many comments recommended nutrition education activities to supplement the public's understanding of label information. Some comments suggested that nutrition education activities can be an alternative to including one or more information elements, such as a listing of DRV's for certain macronutrients, on the nutrition label.

FDA agrees that each person's knowledge is the necessary context for understanding label information, and that nutrition education activities can be an important complement to the public's understanding of label information. FDA disagrees with the implication sometimes drawn from these facts that FDA is thereby relieved from the burden of adopting a format based in part on the available evidence about what kind of format does the best job at achieving the objectives of the 1990 amendments. Although various considerations bear on the selection of a final nutrition label format, FDA believes that an essential criterion is how well a format conveys information that Congress expected would be provided by the nutrition label. Congress expected that such information would allow people to decide whether, based on the nutrition content of the food, they would want to buy the food (Refs. 67 and 68) and to understand the relative significance of the food in the context of the daily diet (section 2(b)(1)(A) of the 1990 amendments). FDA has sought to measure, and has sought other information that measures, the ability of various formats to achieve these objectives.

D. Consumer Research Submitted as Comments or Referenced in Comments to the Format Proposal

1. Background

The agency reviewed a number of qualitative studies (i.e., five focus groups, seven preference polls) and quantitative studies (i.e., five surveys, seven experiments,) that were submitted as comments or referenced in comments to the format proposal. Consumer research studies about format issues were conducted by FDA, food industry groups, individual food companies, consumer groups, public health organizations, health professionals, and academic researchers.

Much of this work was done in response to FDA requests for additional information, and became available only in comments submitted in response to such requests. For example, FDA published an advance notice of proposed rulemaking in the **Federal Register** of August 8, 1989 (54 FR 32610), soliciting public comment on a wide range of food labeling issues, including: (1) Whether to revise requirements for nutrition labeling and (2) whether to change the nutrition label format. FDA subsequently held four public hearings on food labeling, the last of which was held in Atlanta, Georgia on December 13, 1989. This last public hearing focused on the nutrition label format.

Additionally, in the **Federal Register** of May 20, 1991 (56 FR 23072), FDA published a notice announcing the availability of a report on research on alternative nutrition label formats that had been conducted by the agency and inviting comments on the report. The comments on this notice were used in the design and execution of subsequent consumer research conducted by the agency. In the **Federal Register** of July 1, 1991 (56 FR 29963), FDA announced a plan for a cooperative pilot program with industry to test alternative nutrition label formats that led to several industry sponsored nutrition label format studies. In the **Federal Register** of April 2, 1992 (57 FR 11277), FDA gave notice of a meeting for industry, including small businesses, at which the agency presented the results of its research studies related to the format and design of the nutrition label, so that comments to the proposed format rule (57 FR 32058) could be as informed as possible.

In a number of instances, FDA staff provided materials, information, support, and consultation on technical aspects of study design and label format to researchers. In addition, FDA received many comments from the general public in response to articles in newspapers and newsletters that solicited consumer opinions in the form of informal polls based on examples of possible nutrition label formats provided by FDA. Table 1 presents a summary of the various research studies received in response to the format proposal and the format research conducted by FDA.

Table 1.—Research Studies Submitted as Comments or Referenced in Comments to Docket Number 91N-0162: Food Labeling: Format of Nutrition Label; Proposal

A. Experimental Studies Submitted

1. Frito-Lay Study (Ref. 74)

a. Design: Between subjects; five format cells.

b. Subjects: Central location test; adults, age 18+ who purchased and/or ate salty snacks in the past 4 weeks, one site, N=750.

c. Formats tested: Same as FDA Study 1 on actual product.

d. Key dependent measures: (1) Scale based on seven questions, three number-of-serving type and four dietary-judgment type; (2) rating of single format based on helpfulness, ease of use and adequacy of information.

e. Assessment/comments: All subjects saw same product. Well controlled study.

2. GMA/NFPA Industry Study (Ref. 71)

a. Design: Between subjects; seven format cells.

b. Subjects: Shopping mall intercept/central location test; adults 18+ who did at least half of household food shopping, quota controls on age, income, education and race; 36 sites, N=5,600.

c. Formats tested: Same as FDA Study 2 on realistic product mockups.

d. Key dependent measures: (1) Product comparison task identical to FDA task; (2) four-product comparison task with specific nutrient probes, (3) dietary judgment task with specific nutrient probes, "if you were trying to get more/limit (NUTRIENT) in your diet, how would you feel about eating this

(FOOD)?"; (4) rating of single format based on adequacy of information and ease of use, (5) self-report of whether subjects knew how to use the DRV information.

e. Assessment/comments: Each subject worked with only one format executed in a variety of ways. Products are confounded with tasks. Format executions are inconsistent across products. Percent DRV formats are sometimes executed with 1, 3, or 4 column displays depending on product, while other formats have either one- or two-column displays. This complex execution for Percent DRV formats may explain why they show poor product comparison performance and are rated more negatively than other formats. Exposure to formats on early tasks may affect responses on later tasks.

3. FDA Format Study 1 (Ref. 69)

a. Design: Repeated measures within subjects; subjects assigned to one row of a 5(formats) X 5(products) Greco-Latin Square.

b. Subjects: Shopping mall intercept/central location test, adults 18+ who did at least half of household food shopping, quota controls on age, income, education and race; eight sites in seven states, N=1,560.

c. Formats tested: Five formats (see format proposal (57 FR 32058)).

d. Key dependent measures: (1) Product comparison task, measured both accuracy and time; (2) preference rating for most liked/least liked format among the five seen in the study, and reasons for choices.

e. Assessment/comments: Formats presented as two dimensional nutrition labels of realistic size but not on packages.

4. FDA Format Study 2 (Ref. 70)

a. Design: Repeated measures within subjects; subjects assigned to one row of one of three 4(formats) X 4(products) Greco-Latin Squares.

b. Subjects: Shopping mall intercept/central location test, adults 18 + who did at least half of household food shopping, no quota controls; 8 sites, N=1,232.

c. Formats tested: seven formats (see format proposal (57 FR 32058)).

d. Key dependent measures: (1) Product comparison task, measured both accuracy and time; (2) judgments of front panel nutrition claims; (3) judgments of nutrients that need to be balanced in the diet after eating product; (4) product healthfulness ratings before and after seeing nutrition label; (5) estimate of how many servings of product needed to meet daily requirement; (6) preference for most liked/least liked format out of the four seen, with stated reasons for choices.

e. Assessment/comments: Formats presented as two dimensional nutrition labels of realistic size but not on packages. All formats not tested on product comparison task. FDA Study 1 data used to impute product comparison performance for Control and Adjective formats. Percent DV/With DRV used as proxy for Percent DV/Without DRV on product comparison task.

5. Geiger Study (Ref. 72)

a. Design: Repeated measures within subject; subjects assigned to one of two format sets of either five or six formats.

b. Subjects: Shopping mall intercept/central location test, one site, eligibility requirements not specified, N=243.

c. Formats Tested: 11 formats including versions of Control, Control/DRV, Percent DV/With DRV, Percent DV/Without DRV and versions with adjectives, bar graphs and various combinations of these design features.

d. Dependent measures: (1) Reading accuracy; (2) number-of-serving type questions; (3) perceived usefulness of various formats based on a conjoint measurement procedure-equivalent to preference for large choice set.

e. Assessment/comments: All formats executed on same product. Learning effects across repeated measures may confound format effects on performance measures—the same information is available on all formats. Correct answers to number-of-serving type questions are not clearly defined.

6. Byrd-Bredbenner (Ref. 73)

a. Design: Repeated measures within subject; seven format cells.

b. Subjects: Supermarket intercept, 15 sites in same geographic area, food shoppers 18+, age and education quota controls, health and nutrition-related workers excluded, N=309.

c. Formats tested: seven formats including versions of Percent DV, Adjective, DRV Listing and Control in various combinations.

d. Key dependent measures: (1) Hybrid scale consisting of number-of-serving type questions and product comparison questions; (2) scale consisting of product comparison questions; (3) preference ratings of most helpful/least helpful with stated reasons.

e. Assessment/comments: Products confounded with formats. Order of format presentation partially confounded with amount of information in format.

7. Burton (Ref. 75)

a. Design: Between subjects, 4(formats) X 3(reference values: none/daily/meal) X 2(high/low nutrient values).

b. Subjects: Recruited for a university sponsored project by letter, cross-section of adults, n=500.

c. Formats tested: Versions of Control, Adjective and Percent DV with and without different versions of a DRV listing.

d. Key dependent measures: (1) Product ratings: bad-good, not nutritious/very nutritious, purchase intentions; (2) number-or-serving type measure; (3) rank ordering of formats on quantity and quality of information.

e. Assessment/comments: Well controlled study.

B. Survey Studies Submitted

1. AHA Quantitative Study (Ref. 87)

a. Design: Central location test, details unspecified.

b. Subjects: N=405.

c. Relevant format topics: Frequency of reading back of food labels, magnitude estimation of amount of fat in product, awareness of calorie base for fat, knowledge of how to adjust Fat DRV if person eats less than 2,350, likelihood of using information on food label to help reduce fat intake.

d. Assessment/comments: Most of the survey is devoted to issues related to use of the word "healthy" on food labels.

2. CSPI Study (Ref. 95)

a. Design: National probability sample of telephone households.

b. Subjects: N=2,008 adults, assigned to one of eight versions of magnitude estimation question.

c. Relevant format topics: Magnitude estimation of fat amounts in product.

d. Assessment/comments: Fat is the only nutrient considered.

3. American Meat Institute/Roper Study (Ref. 96)

a. Design: Multistage, stratified national probability sample of households, in home interviews.

b. Subjects: N=2,000, males who shared food shopping responsibility equally with other people in the household were selected when possible, otherwise any food shopper available from household was selected.

c. Relevant format topics: Attitudes and behavior regarding food labels, understanding of "RDA" and "DRV."

d. Assessment/comments: A comprehensive survey on food labeling issues.

4. Kellogg Study (Ref. 97)

a. Design: Not a probability sample, subjects call toll-free number for some product-specific reason.

b. Subjects: N=272, unknown characteristics.

c. Relevant format topics: Understanding of DRV, knowledge of how to adjust DRV for varying calorie needs, rated helpfulness of DRV information.

d. Assessment/comments: Sample characteristics are unknown.

5. GMA/NFPA Industry Study (Ref. 71)

a. Design: Central location test (see description above). Questions that were asked before subjects saw any food label formats or questions that did not involve use of formats are considered survey questions.

b. Subjects: See description above.

c. Relevant format topics: Frequency of reading food labels, frequency of various uses of food label information, understanding of DRV concept.

d. Assessment/comments: Large sample, detailed questions about possible label uses, DRV questions are asked after respondents have been exposed to particular food label formats, subjects exposed to Control format are not asked DRV questions, only 4,790 respondents are asked the DRV questions.

6. National Consumers League (Ref. 98)

a. Design: National probability sample of telephone households.

b. Subjects: N=1,139, 1,007 who read nutrition labels at least sometimes completed full questionnaire.

c. Relevant format topics: Frequency of reading food labels, reasons for reading food labels.

d. Assessment/comments: Most of the survey is devoted to issues related to use of the word "healthy" on food labels.

C. Focus Group Studies Submitted

1. FDA Study 1 (Ref. 85).
2. FDA Study 2 (Ref. 86)
3. Geiger (Ref. 72).

4. AHA Study 1 (Ref. 87).
5. AHA Study 2 (Ref. 87).

D. Informal Preference Polls

1. COSTCO Newsletter (Ref. 88).
2. Washington Post (Ref. 89).
3. Nutrition Action Newsletter (Ref. 90).
4. USA Today (Ref. 91).
5. Daily Herald (Ref. 92).
6. Atlanta Constitution (Ref. 92).
7. New York Times (Ref. 94).

The studies vary greatly in the issues addressed, methodology, sampling, types of nutrition formats studied, types of evaluation measures used to assess formats, and degree of control used in the research. Many of the consumer studies submitted or referenced in comments about nutrition label formats were based on recently conducted research studies and on interpretations that had not yet appeared in the scientific literature.

FDA considers the findings of research studies submitted in comments to constitute an important separate class of comments for purposes of evaluating various nutrition label formats. Research findings based on specific measures need to be considered as distinct from conclusions based on combining findings across several different measures. Research findings also need to be considered in the context of a body of similar research to evaluate consistency in the pattern of effects across studies (e.g., reliability) and consistency in the identification of important controlling factors (e.g., validity). Comments offering conclusions based on research findings are discussed below in the relevant sections. In this section, the research findings themselves are discussed in terms of methodologies used, types of evaluation measures, consistency of effects across studies, the strength of effects, and implications for the design of the nutrition label format. The agency believes that to clarify its reasons for decisions about the nutrition label format that rely on research findings, it is necessary to articulate its understanding of the relevance, reliability, and relative significance of the various research findings.

To facilitate discussion of research findings, FDA considers it useful to distinguish among three primary types of evaluation measures used to assess nutrition label formats: Performance measures based on label use tasks, consumer preference judgments of various formats, and questions about consumer understanding of selected elements of possible nutrition labels, such as Daily Values (DV's) (called in the format proposal DRV's). Each type of evaluation measure has a different relevance to the selection of an improved format for the nutrition label.

2. Performance Measures Based on Specific Label Use Tasks

As a rule, different tasks and performance measures have been used to evaluate how well a format meets the different primary performance objectives specified in the 1990 amendments. These objectives as discussed in section V.B. of this document are: (1) To enable consumers to readily observe the nutrition information, (2) to enable consumers to comprehend the nutrition content of the particular product, and (3) to enable consumers to understand the relative significance of product nutrition information in the context of a total daily diet. (Objectives (1) and (2) are closely linked for testing purposes and will be frequently discussed together in this document). In the research reviewed by FDA, measures to evaluate formats in relation to these objectives have appeared only in experimental studies, probably because this type of measure requires a substantial degree of control over the conditions under which such measurements are taken.

For performance measures based on specific label use tasks, respondents are asked to perform a task using the information from a nutrition label. The task is constructed so that a performance measure can be defined (e.g., speed, accuracy, likelihood of giving appropriate response), indicating the degree to which the respondent can readily observe and comprehend product label nutrition information or "understand its relative significance in the context of a total daily diet."

a. *Product comparison tasks.* The type of tasks most commonly used to evaluate formats with respect to the objective of enabling consumers to readily observe and comprehend product nutrition information were product comparison tasks. These tasks presented respondents with two or more product labels simultaneously and asked them to engage in a relatively simple information search (e.g., find differences between the products, identify which product is higher or lower in a certain nutrient) where answers were scored correct/ incorrect and timed.

104. The product comparison type of task was employed by the two FDA format studies (Refs. 69 and 70) and by three other studies submitted in comments to the format proposal (Refs. 71, 72, and 73). One study (Ref. 72) simply asked respondents to read certain information from a product label and scored whether they gave the correct answer.

Performance levels on product comparison tasks were high, with most of these studies finding accuracy levels of 70–90 percent correct.

The product comparison type of task tended to produce consistent format effects. The most consistent finding, replicated in all studies, was that simple formats that have clean, nonredundant displays of nutrient information per serving worked best in this kind of task. Because it has the least amount of information, the current format performed well on product comparison tasks. But several studies (Refs. 70, 72, and 73) found that other ways to display nutrient information per serving, using either g/mg amounts or percent DV declarations, were equally effective when the format was executed with a clean and uncluttered appearance.

Multiple column nutrient information per serving displays were much more difficult than single column displays for consumers to use for product comparisons. Several studies (Refs. 69, 70, and 71) found that product comparison performance dropped sharply for labels using the "as packaged/as prepared" dual declaration format. Both the major industry format study and FDA's first experimental format study found that declaring nutrient amounts per serving in adjacent columns of g/mg amounts and percent DV led consumers to make more mistakes and to take longer on the product comparison type of task. FDA's second experimental study, however, showed that when g/mg nutrient amount information was placed immediately next to the nutrient name in an unordered array, and percents were placed in a column array, the adverse effects on product comparison performance disappeared.

Most studies found that the addition to the label of a listing of the DV's for some or all nutrients did not greatly affect the ability of consumers to use the nutrition label for product comparison purposes. Similarly, the use of a highlighting or grouping scheme on the nutrition label neither impaired or improved respondents' performance of product comparison tasks.

The use of adjectives on the nutrition label did appear to cause respondents to miss nutrient differences between products when the adjectives used to describe the nutrient for each product were the same. Several studies (Refs. 69, 71, and 73) found that formats using adjectives did not perform as well as formats without adjectives on product comparison tasks.

FDA considers this product comparison type of performance measure to be a valid and reliable indicator of how well a given format's information can be readily observed and comprehended. The major conclusions that FDA drew from this research are that: (1) Clean, uncluttered nutrition label formats work best, (2) dual column declarations of nutrition information per serving make it harder for consumers to readily observe and comprehend nutrition information, and (3) adjective formats lead consumers to miss quantitative differences between products when different nutrient levels are characterized by the same adjective. The formats that FDA tested (Refs. 69 and 70) that were effective on product comparison tasks included the CONTROL, CONTROL/DRV, PERCENT, PERCENT/DRV, GROUPING, and HIGHLIGHTING.

b. *Dietary judgment tasks.* A different type of task was used to evaluate formats with respect to the second performance criterion, enabling consumers to understand the relative significance of product nutrition information in the context of a total daily diet. Most of the dietary judgment tasks presented respondents with one product label at a time and asked them to make a dietary judgment about the product (e.g., how likely they would be to eat the product if they were trying to limit/increase a specific nutrient in their diet; what nutrients they should try to cut back on/get more of in other foods they eat that day after eating three servings of the product; whether they consider a high/low nutrient claim for the product to be correct/incorrect). Respondent dietary judgments were then scored as correct/incorrect or appropriate/ inappropriate.

105. This type of dietary judgment task was used in the second FDA format study (Ref. 70) and two industry studies (Refs. 71 and 74). Measures based on dietary judgment tasks produced consistent format effects. The most consistent finding, replicated by all these studies, was that providing adjectives to describe nutrient levels per serving or declaring nutrient levels per serving as percentages of the nutrient DV helped respondents to make correct and appropriate dietary judgments relative to formats where nutrient levels were declared in g/mg amounts. These studies found that other nutrition label format design elements, such as inclusion of a listing of DV's, highlighting, or grouping nutrients on the label, did not improve performance on these types of dietary judgment tasks.

A consistent finding across two studies (Refs. 70 and 71) was that percent DV declaration had a moderating effect on dietary judgments relative to formats without percent DV declaration. Respondents were less likely to consider a given nutrient level unacceptably high or to say that they would avoid the food entirely because of its nutrient levels when the amount per serving information was presented as percent DV.

Performance levels on this type of dietary judgment task ranged from 45 to 80 percent correct across studies.

FDA considers that how well consumers are able to judge the magnitude of specific nutrient levels as measured by this type of dietary judgment task is a valid and reliable indicator of how effectively a given format helps consumers to understand the significance of product nutrition information in the context of a total daily diet. The major conclusions that FDA drew from this research are that: (1) The declaration of nutrient amount information as percentages of DV or the placement of adjectival descriptors next to the nutrient amount information are both effective ways to help consumers understand the significance of product nutrition information in the context of a total daily diet, (2) percent DV declarations moderate dietary judgments about a food, and (3) other format elements, such as a list of DRV's for important macronutrients, highlighting, or grouping nutrients according to dietary guidelines, do not help consumers make better dietary judgments. The formats that FDA tested that were effective on this kind of task were the PERCENT DV, PERCENT DV/ DRV, and ADJECTIVE.

106. Several comments on the format proposal recognized that the ADJECTIVE and PERCENT DV formats have benefits to consumers for dietary judgment types of tasks. They argued that both of these format design elements correct a common tendency to misjudge the magnitude of specific nutrient levels when they are given in g/mg amounts. The comments asserted that consumers make such errors because they tend to use a single numeric standard to estimate magnitude.

The comments stated that when nutrient amounts per serving are declared in g/mg amounts, the numbers appearing on the label cannot be used as guides to estimate the relative magnitude of nutrient levels in the product. These comments continued: A reasonable reference standard for one nutrient is quite different from the reasonable reference standard for another nutrient. For example, 5 g is a high level for saturated fat, but 100 mg is a low level for sodium. Because the nutrients on the label vary greatly in terms of reference standards, the common tendency of consumers to use a single numeric standard when nutrient amounts are declared in g/mg units leads to flawed dietary judgments.

Percent DV declarations, by contrast, display nutrient amounts per serving in comparable units, and this type of display facilitates the appropriate use of a common numeric reference standard for all nutrients. Adjectival descriptors also serve to translate nutrient levels into comparable units by describing disparate nutrient amounts per serving in easily understood ordinary language terms.

FDA agrees that this reasoning provides a plausible explanation of the research finding that percent DV declarations and adjectives help consumers make more appropriate magnitude estimates of nutrient levels in a product.

c. *Number-of-servings calculation tasks.* Some studies employed a one-product task where respondents were asked to estimate how many servings of the product were needed to meet a daily requirement for a certain nutrient. FDA considers this number-of-servings type task to be relevant to consumers' abilities to use product information for meal planning and quantitative dietary management purposes that are properly considered part of placing the product in the context of a total daily diet.

107. This type of performance measure was used in the second FDA format study (Ref. 70) and in four other studies submitted in comments to the format proposal (Refs. 71, 72, 73, and 75). The number-of-servings type of performance measure did not show consistent format effects across studies, possibly because of variations in stimuli and procedures between studies.

One well controlled study (Ref. 70) found that the current nutrition label format was the worst format on this type of performance task, but a less well-controlled study (Ref. 72) found that the current nutrition label was among the best formats on the number-of-servings type of task. One study (Ref. 70) that asked for a numerical answer found that PERCENT DV formats performed almost as well as the best formats on this measure, but another study (Ref. 71) that asked the respondent to articulate the computation process found that PERCENT DV formats were much worse than the best performing formats.

In all studies, performance levels on the number-of-servings calculation task were noticeably lower than for the kinds of tasks discussed above. Performance levels ranged from 10 to 50 percent

correct across studies. All studies found that this type of task was highly sensitive to respondents' education levels and arithmetic sophistication.

FDA considers this type of performance measure to be relevant to how well a given format serves to place product information into the context of the total daily diet, particularly with respect to the role played by including a listing of the DV's on the label. However, a lack of consistent results across studies and low levels of consumer competence to perform the required computations suggests that this measure be considered of secondary importance for evaluating nutrition label formats.

d. *Single product rating tasks.* Some studies showed respondents a product label in a given format and asked them to rate the product on healthfulness or to rate purchase intentions toward the product. The measure compared ratings made after seeing front panel information consisting of nutrient or health claims and ratings made after being exposed to product information on the nutrition label.

108. This type of measure was used in the second FDA format study (Ref. 70) and in one other study submitted as a comment (Ref. 75). Both studies showed a consistent effect: Consumers relied more heavily on back panel than front panel nutrition information when making general judgments about a product. They become more negative toward the product after seeing the back panel nutrition information relative to an initial impression based on front panel information alone. Neither study found that the format of the nutrition label had much effect on this type of measure.

Because it appeared insensitive to format effects, FDA does not consider this type of single product rating comparison to be an important consideration for evaluating how well a format meets the criteria specified by the 1990 amendments.

e. *Measures based on two or more types of tasks.* Some studies defined scales that combined more than one type of performance measure, such as product comparison questions and number-of-servings questions. Where possible, FDA considered these scales to represent only one of the composite measures, the one they most resembled, so that they could be discussed in the appropriate sections above. Such measures were evaluated by comparing results with other measures from the same study and with measures from other studies which utilized similar elements.

109. One study (Ref. 73) submitted as a comment to the format proposal reported results for a scale based on product comparison questions and number-of-servings questions (discussed in section V.D.2.a. and V.D.2.c. of this document). In this instance, the results showed that format effects on the scale were quite different from format effects on a different scale in the same study which was clearly made up of product comparison questions. Therefore, FDA considered this scale to be an example of the number-of-servings type of performance measure.

110. Another study (Ref. 74) reported results for a scale based both on number-of-servings type questions and dietary judgment type questions. Examination of the results for this scale showed that the performance findings most resembled findings from other studies based on dietary judgment questions. Therefore, FDA considered this scale to be an example of a dietary judgment performance measure.

3. Preference Judgment Measures

In the research reviewed by FDA, consumer preference judgments of various formats were primarily choice measures based on a direct or implied question to respondents about which of some given set of possible examples of nutrition label formats would be most helpful, most useful, or would work best for consumers. Measures of this type occurred in all research modalities and were often the principal measures in focus group and informal preference poll research. Because respondents were typically asked to express a relative preference, the set of choices presented to respondents influenced the selection process and thereby constitutes an important limitation on the validity of this type of measure.

Preference measures are not of the same order as behavioral measures, which address how well a given format performs in a given label use situation. Stated preferences for formats reflect a respondent's implicit theory about what kind of format generally works best. Judgment in these instances is abstracted from any particular product or any particular label use situation.

An extensive scientific literature review suggests that untested theories about the amount and type of information that are most useful to consumers are sometimes wrong (Refs. 76, 77, 78, 79, and 80). In particular, studies of preference for nutrition information have generally shown that consumers prefer the largest amount of information offered (Refs. 81, 82, and 83) but perform best with limited amounts of information specifically related to the task (Ref. 84).

a. *Experimental studies.* 111. Both FDA format studies and three other studies submitted as comments on the format proposal employed relative choice measures of format preference based on choosing a most preferred or least preferred format from the set of formats being evaluated in the study (Refs. 69, 70, 72, 73, and 75). Direct comparisons between studies are difficult because no two studies used exactly the same choice set of formats.

Despite differences between studies, there were basic consistencies in the pattern of preference results across studies. In every case, respondents tended to prefer the format with the most information in the choice set and tended to dislike formats with the least information in the choice set. The addition of a listing of DV's to the nutrition label for some or all of the nutrients was seen as more informative, and was always highly preferred, over alternatives lacking a listing of DV's. All of the studies that asked respondents to give reasons for their selection of a certain format (Refs. 69, 70, and 73) found that providing more information was one of the most common reasons given.

Other format features in addition to a DV list that were viewed positively relative to formats without such features were adjectives, bar graphs, highlighting, and, to a lesser extent, grouping and declaring nutrient amount per serving as percent of a DV.

All studies that included both performance and relative preference measures (Refs. 69, 70, 72, 73, and 75) found little or no consistency in the pattern of format results across performance and preference measures. For studies that included performance measures of the product comparison type (Refs. 69, 70, 72, and 73), the common finding was an inverse ordering between formats that were preferred and formats that performed well on this type of task.

Two experimental studies (Refs. 71 and 74) varied formats between subjects such that each subject saw a single format and rated only that format. One study (Ref. 74) asked respondents to rate the helpfulness, ease of use, and adequacy of information of the single format. The other study (Ref. 71) asked respondents to rate ease of use and adequacy of information. Neither study found that respondents gave the highest ratings to the format with the most information. A format similar to the current format that did not include a listing of DV's for some nutrients was

among the highest rated formats in both studies.

In one study, respondents expressed suspicion toward formats using adjectives (which provided relatively more information), apparently because they felt the company was deciding how and when the adjectives were used. In the other study, respondents were more negative toward formats using percent DV declarations. However, in the latter study, the PERCENT DV formats were executed with extra columns of information, so that a single nutrition label had as many as four numeric columns. Respondents in this study considered the PERCENT DV with DV list format to provide more information than was desirable.

FDA is convinced by these results that consumer preferences for various nutrition label formats were very sensitive both to the set of formats the respondent was asked to compare and to the particular methodology used to measure preference. Moreover, preferences did not correspond to objective measures of format performance. This lack of correspondence raises serious questions about the underlying validity of such measures, even though respondents were asked to base preferences on which formats they thought would work best. Given these methodological problems and the apparent lack of validity, FDA considers preference measures to be of secondary importance for decisions about the nutrition label format.

b. *Focus group studies.* Research using focus group discussions about nutrition label issues elicited preferences for various kinds of format design elements by showing the group examples of different formats and asking them to discuss their reactions.

112. The two FDA focus group studies and three other focus group studies submitted as comments on the format proposal discussed the groups' reactions to various format elements (Refs. 72, 85, 86, and 87). In every study, respondents indicated strongly that they would like more information on the nutrition label, particularly with respect to helping them understand whether given nutrient levels could be considered high or low. A listing of DV's for some or all nutrients was always among the most preferred additions to the nutrition label. Other format design features favorably mentioned in some or all of the focus group studies were bar graphs, percent DV declarations, and percent of calorie declaration for macronutrients. Other features, such as adjectives or pie charts, received some favorable mentions, but fewer than the above features.

Respondents in focus group discussions often stated they would like to see a simpler and easier to use label than the current nutrition label. One focus group study (Ref. 85) asked respondents to consider in detail how they might use certain format features and found that pie charts and bar graphs were seen to be hard to use. Formats using adjectives were sometimes criticized because of suspicion about who decided how and when the adjectives were to be used.

FDA considers the focus group preference results to be consistent with the preference results of experimental studies.

c. *Informal preference polls.* Many comments from the general public were generated by articles in newspapers and newsletters that solicited consumer opinions in the form of informal polls based on examples of possible nutrition label formats. FDA considers such articles to be informal preference polls and therefore a form of research. FDA recognizes limitations on the validity of such research: respondents are highly self selected, no background information about respondents is available, responses are influenced by the accompanying news article, and responses depend on the choice set of formats given in the article. FDA has tried to identify the actual articles and the choice sets of formats presented to readers in interpreting these comments.

113. FDA identified seven informal preference polls that generated comments on the format proposal (Refs. 88, 89, 90, 91, 92, 93, and 94). One informal preference poll conducted by a consumer buying club in its newsletter (Ref. 88) asked consumers to rate their preferences toward three formats taken from FDA's research formats: ADJECTIVE, HIGHLIGHTING, and GROUPING. Over 400 responses were received. Seventy percent of the responses favored the ADJECTIVE format.

A midwest newspaper (Ref. 92) published examples of all seven formats used in FDA's format study 2 and asked readers to indicate which one they preferred. Approximately 100 responses were received. Sixty-five percent of the responses favored the ADJECTIVE format.

A consumer group newsletter (Ref. 90) published an example of a recommended format that included adjectives and a listing of DV's for macronutrients and asked readers to respond to FDA in support of the recommended format. Approximately 130 responses were received in support of such a format.

A nationally distributed newspaper and a regional newspaper (Refs. 91 and 93) published an example of a graphically enhanced PERCENT DV with DRV format (Appendix C from the format proposal). Approximately 40 responses were received. Sixty-five percent of the responses disapproved of the published format.

A major eastern newspaper (Ref. 89) published examples of four formats taken from the format proposal; PERCENT DV with DRV (Appendix C), CONTROL with DRV Ranges (Appendix E), CONTROL with Sex-Specific DRV (Appendix E), and CONTROL with Dietary Guidance (Appendix F). It asked readers to respond to FDA with their preferences, and approximately 450 responses were received. Two formats (CONTROL with DRV ranges and CONTROL with Sex-Specific DRV) were most preferred overall, each by approximately 35 percent of respondents.

FDA considers the results of informal opinion polls to be consistent with the preference results observed in experimental studies and focus groups. Most consumers say they prefer the format with the most information out of the set of formats they are asked to evaluate. However, FDA is not convinced that formats that have more information are necessarily the formats that best meet the criteria specified in section 2(b)(1)(A) of the 1990 amendments.

4. *Measures of consumer understanding.* Some of the research submitted or referenced in comments to the nutrition label format proposal consisted of survey questions about consumer understanding of various elements of proposed nutrition labels (Refs. 71, 87, 95, 96, 97, and 98). Some of these questions addressed topics such as whether consumers use nutrition labels and, if so, for what purposes. Other questions addressed the concept of a DV: how consumers understand it, whether they can use it, how they might use it, or whether they are aware of it. A third type of question about consumer use of format elements was how consumers assign magnitude estimates to nutrient levels.

FDA considers this kind of research about format elements to provide an important context for the decision about an improved nutrition label format. Although it does not directly address the format objectives specified by the 1990 amendments, this research does provide some insight on how consumers understand and use the nutrition label.

a. *Survey questions about consumer use of nutrition labels.* 114. Four surveys submitted as comments on the format proposal (Refs. 71, 87, 96, and 98) asked questions about how often respondents read nutrition labels and ingredient information on food packages. These studies consistently found that approximately 70 to 80 percent of consumers report that they read this information almost always, often, or sometimes. These figures are consistent with a number of other surveys (Refs. 99 and 100) that asked similar questions.

In several studies submitted as comments, consumers were asked about specific purposes for reading nutrition labels. One study (Ref. 71), which asked 5,600 respondents detailed questions about possible label uses, found that the most common purposes for reading nutrition labels were: To calculate how high or low the product is in certain nutrients, to get a general idea of nutritional content, to compare different types of food products, and to help determine brand choices. The least common purposes for reading nutrition labels were to help in meal planning or to figure out how much of the product you should eat.

Other submitted studies reported results consistent with these findings. Specifically, one study (Ref. 96) found that only 7 percent of those who read nutrition labels did so "to help in planning a specific meal." Another study (Ref. 87) found that 83 percent of respondents would be very or somewhat likely to use information on the food label to help reduce fat intake.

FDA considers the results of these questions about consumer uses of nutrition labels to show that consumers are already using nutrition labels for purposes that are consistent with the format objectives of the 1990 amendments. Indeed, the two most common types of reported uses: (1) To evaluate nutrition characteristics of single products and (2) to assist in making choices between products, correspond well to the two primary criteria specified for formats in the 1990 amendments. The agency believes that the introduction of a revised nutrition label and accompanying educational activities will have a significant impact on use of the nutrition label for these purposes in the future.

b. *Questions about Daily Values.* 115. FDA received a number of studies as comments on the format proposal that asked questions related to consumer understanding of the concept of DV's. One study (Ref. 96) reported that 22 percent of respondents said that they were familiar with the term "Daily Reference Value" or "DRV" compared with 65 percent who said they were familiar with the term "Recommended Daily Allowance" or "RDA". Two studies (Refs. 87 and 97) found that only about half of respondents could correctly identify (i.e., read from the label) the DRV for a specific nutrient.

One study (Ref. 71) found that approximately two-thirds of all respondents considered the DRV to be appropriate for "everyone" or "most people." The same study found that 71 percent of respondents considered the DRV to apply to them personally. However, two other studies (Refs. 87 and 97) found that approximately two-thirds of all respondents stated that they understood that a DRV based on 2,350 calories would be high for a person who ate less than a 2,350 calorie diet.

One study (Ref. 87) showed respondents a label with a listing of DRV information and a footnote stating that DRV's were based on a 2,350 calorie diet. It found that more than half of all respondents could not correctly answer a question about the number of calories on which the DRV was based.

FDA considers results of questions about consumer use and understanding of DRV's to be tentative and likely to change because the public's exposure to the concept has been very limited, and educational activities to explain the concept have not been undertaken. The experimental format research (see section V.D.2. of this document) did not find that listing the DRV's on the nutrition label had much effect in a positive or negative direction on label uses that required evaluation or comparison of specific products, although it did improve calculation of number of servings needed to meet a daily requirement. None of this research, however, evaluated the impact of listing the DRV's on the food label on consumers' overall dietary management behavior, either alone or in conjunction with possible education initiatives.

FDA concludes that in the absence of reliable guidance from research findings, it has to rely on other comments to evaluate the potential value of listing the DRV's on the food label as a guide to better overall dietary management behavior.

c. *Magnitude estimation of specific nutrient amounts.* 116. Two studies submitted as comments addressed the issue of consumers' ability to make correct magnitude judgments about the level of a nutrient when told the amount. One study (Ref. 87) found that over one-half of all respondents considered 13 g of fat to be a large amount of fat.

A more detailed study (Ref. 95) asked respondents to estimate whether a given amount of fat in a product would be considered a low, medium, or high amount of fat. The amount of fat was systematically manipulated to determine how respondents assigned magnitudes across a range of values (7, 13, 20, and 33 g of fat). At the lowest level (7 g of fat per serving), approximately 20 percent of respondents considered the product to be high in fat. At the highest level (33 g of fat per serving), approximately 50 percent of respondents considered the product to be high in fat. The same magnitude estimation results were found when the amount of fat was expressed as a percentage of the DRV for fat. When amount of fat was expressed as a percentage of the DRV for fat, however, respondents were slightly less likely to give a "don't know/can't tell" answer than they were when fat amounts were expressed in g. Also, respondents were more likely to give a "medium" answer when the level of fat was expressed as 50 percent of the DRV instead of 33 g.

FDA considers these findings to show that consumers estimate nutrient level magnitudes of fat in a reasonable manner. However, the agency also concludes that a tendency exists for some consumers to see low fat levels as too high and other consumers to see high fat levels as less than high. More research is necessary to determine whether these results might be due to response biases inherent in the particular kinds of questions being used, or whether they reflect the different attitudes toward fat in the general population. FDA considers these findings to be consistent with the results of magnitude estimation measures used in experimental studies (see section V.D.2. of this document). FDA is convinced that an important consideration for decisions about the nutrition label format is whether the format helps consumers make appropriate magnitude estimations of nutrient levels in the product.

E. Criteria to Use in Judging Nutrition Labeling Format

Section 2(b)(1)(A) of the 1990 amendments specifies the requirements that an appropriate nutrition label format must meet (see Section V.C. of this document), but it does not specify how to weight these requirements with respect to various possible label uses or how to weight the various measures intended to evaluate alternate formats against the requirements. The 1990 amendments also do not specify how to balance the benefits of a revised

nutrition label against the practical limitations of small package sizes and the interests of many consumers, particularly older and less educated consumers, to have a highly legible label. In the format proposal, FDA requested comment on the criteria to use in judging nutrition label formats.

117. Most comments strongly supported the view expressed in the format proposal that a simple, uncluttered nutrition label is highly desirable. Comments from consumer groups and health professional organizations emphasized the benefits of a simple and uncluttered label for older and less educated consumers. Comments from food manufacturers and industry associations emphasized in addition that a simple, uncluttered format would allow greater flexibility to accommodate packaging constraints. Consumer research conducted by industry and by FDA demonstrated that simpler, less cluttered label formats help consumers to make comparisons between products.

FDA is convinced by the research results and these comments that a simple and uncluttered format is the best way for information on the nutrition label to be "readily observed and comprehended," as called for by the 1990 amendments. Accordingly, FDA is taking the steps discussed below to minimize the amount of information and the number of columns used on the nutrition label.

118. A number of comments from food manufacturers, consumer groups and health professional groups called for consistent label formats for both FDA and USDA regulated food products. The comments identified many benefits of having a uniform format for all food products including: (1) Making it easier for consumers to compare different kinds of products, (2) making it easier for consumers to become familiar with, and to learn how to use, the new labels, and (3) reducing the likelihood of consumer confusion because of apparent inconsistencies between different food labels.

FDA agrees that consistency between FDA and USDA regulated food labels should be an important consideration in decisions about the nutrition label format.

119. A number of comments from food manufacturers, consumer groups, and health professional groups argued that decisions about the nutrition label format should be informed by consumer testing, and that the agency should not propose formats that have not been tested. For the most part, these comments were directed at three label formats included in the format proposal that presented more elaborate listings of DRV's and more extensive educational footnotes than any of the formats included in FDA's previous nutrition label format research.

The agency agrees with the comments that emphasized the importance of consumer research in informing decisions about the nutrition label format. However, the agency is satisfied that most of the format elements that have been suggested for a revised nutrition label format have been sufficiently tested to permit research-based conclusions about their effects on consumer comprehension and label use behavior. The agency's view is that format elements that were less well tested, such as those suggested by the three formats described above, do not introduce sufficiently novel elements to the nutrition label to require independent testing. Information about the performance characteristics of more cluttered labels, listings of DV's, and elaborate footnotes is already available from extant research and can be extrapolated to estimate the performance characteristics of these particular formats as well.

120. The agency received a number of comments about the relative importance that should be assigned to product comparison versus dietary judgment measures of format performance in making decisions about nutrition label format. Many comments, primarily from food manufacturers and trade associations, argued that enabling consumers to compare the nutritional characteristics of food products is the fundamental use for the nutrition label and concluded that label formats should be evaluated mainly on this basis. Other comments, primarily from consumer groups and health professional organizations, gave more emphasis to the importance of the food label for helping consumers to make dietary judgments about the nutritional value of the food product that involve placing the product in the context of a total daily diet. These comments concluded that decisions about a nutrition label format need to take account of both product comparison measures and dietary judgment measures. The research on the reported frequency of different kinds of nutrition label uses showed that comparing products and assessing nutritional value are the two most important consumer uses of the nutrition label and are considered about equally important by consumers.

FDA is convinced by the research and by these comments that decisions about a nutrition label format should consider both types of label uses and evaluation measures rather than only one. Use of the nutrition label to compare products is dependent on the consumer's ability to comprehend the nutrition information, and use of the nutrition label to assess nutritional value is dependent on the consumer's ability both to comprehend the information and to understand its significance in the context of the total daily diet. Accordingly, FDA has considered these primary nutrition label uses in making decisions about the nutrition label format.

121. One comment from a health professional argued that consumer preferences for nutrition label formats should be considered as important as the ability of a format to achieve the format objectives specified in the 1990 amendments because a format that is more preferred will be more likely to be used by consumers.

FDA is not aware of any data that support the assertion that a more preferred label format will be more likely to be read. The agency's view is that people read the nutrition label because they are interested in what it says, not because they have an impulse to read the label based on its appearance. Actual ease of use, that is, the ease with which a consumer can extract needed information from the nutrition label, rather than preference for a format, is likely to influence the probability of reading a nutrition label. The consumer research shows that consumer preference for different label formats is, if anything, negatively related to actual ease of use (see sections V.D.2. and V.D.3. of this document). Therefore, FDA does not agree that preference should be considered as important as performance criteria for decisions about nutrition label formats.

122. One comment from a consumer organization argued that label uses should be weighted according to the likelihood that consumers engage in such uses. The comment recommended that less importance be given to label uses that assume that consumers will add up their daily totals of fat, saturated fat, or other nutrients because relatively few consumers are likely to engage in such difficult and burdensome monitoring. The comment suggested that many more people are interested in making qualitative judgments about individual foods, such as "is this food high or low in fat?" and recommended that dietary judgment measures assessing this aspect of label use be given the most weight in decisions about the nutrition label format.

Consistent with the comment, the consumer research did not show quantitative monitoring of dietary intake to be a common label use behavior.

However, it also did not show that making qualitative judgments about a food is the only important use of the nutrition label (see comment 114 of this document). FDA is convinced by the research that helping consumers to make qualitative judgments should be an important, but not overriding, consideration in making a decision about the nutrition label format. Other evidence shows that consumers use the nutrition label to compare products and to assess a product's nutritional value. Accordingly, FDA has considered facilitating qualitative judgments as one of the dietary judgment factors important for evaluating the various proposed formats.

F. FDA's Tentative View

In the format proposal, FDA presented its tentative conclusions about the elements that it will include in the final nutrition format and requested comments about them. The agency listed the following four elements as those that were likely to be included in the final nutrition format:

(1) The information must be presented in a manner that is simple and minimizes clutter.

(2) The information must be presented in tabular fashion, although perhaps enhanced by other graphic devices to provide rapid access to, and greater visibility of, key nutrition information.

(3) The nutrition information display must include either a listing of the quantitative amount of each nutrient, in absolute terms (e.g., g), or a listing of the amount as a percent of the proposed RDI or DRV, or both.

(4) Nutrient information must be linked to the dietary guidance that is considered important to public health.

123. Comments mentioning the first three elements were unanimously supportive. Comments mentioning the fourth element were generally supportive, although a number of comments argued either that the nutrition label cannot or should not be the primary vehicle for providing general dietary recommendations, or that educational materials should not appear on the food label at all.

The agency disagrees with statements that the nutrition label should not play a role in educating consumers. FDA is convinced that the nutrition label is an important source of basic information for consumers, and that the 1990 amendments require that the label facilitate consumer education. The agency's view of the educational role of the nutrition label is elaborated in section V.B. of this document.

However, the agency does agree that the nutrition label cannot be the primary vehicle for providing general dietary recommendations. Accordingly, as discussed later in this document, FDA, USDA, health professional organizations, and the food industry are developing a comprehensive consumer education program that will ease the transition to the revised nutrition label and help consumers to use the label to make well-informed dietary choices.

FDA points out that under the act, the requirement that nutrition information be linked to dietary recommendations need not require presentation of dietary guidance on the label. The House report that accompanied the 1990 amendments states, "While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information" (Ref. 16). The declaration of nutrient amounts as percent DV provides such information. For the nutrient in the food for which a DV has been established, the percent DV advises the consumer how much of the recommended intake of that nutrient is provided by the food. Seen in this way, a requirement that nutrition information be linked to dietary guidance plays a greater role in describing the food than in presenting educational material.

G. The Format and Format Elements

FDA received approximately 1,000 responses to the format proposal and to a public meeting, notice of which was given in the *Federal Register* of July 23, 1992. Responses were received from consumers, health professionals, trade and retail associations, State and local governments, foreign governments, professional societies, consumer advocacy organizations, industry, and universities. Many of the comments selectively responded to issues of particular concern to the individual or organization commenting, but a large number included a reference to the specific formats favored or opposed.

1. Titles and Terminology

a. *Title for the nutrition label.* 124. A number of comments addressed the issue of the title for the nutrition label. The majority of comments supported retaining the current label heading "Nutrition Information per Serving." Comments suggested that consumers are familiar with this heading, and that the title is descriptive of the information that follows. One comment opposed the introduction of any new title because new terms are confusing. Another comment expressed concern that new titles have not been proposed or tested. Other comments suggested such terms as "Nutrition Information," "Nutrient Information," and "Nutrient Facts."

FDA acknowledges that the current title is descriptive and familiar to consumers. However, the agency also notes that the current title requires more space than several alternatives that are equally descriptive. The agency has concluded that modifying one of the suggested alternatives to "Nutrition Facts" yields a term that will clearly describe the information declared on the nutrition label. This more succinct term also allows the title of the nutrition label to use a larger typeface in the same space so that the nutrition label will be more readily noticed, and thus, more readily observed by consumers. Accordingly, in § 101.9(d), the agency is requiring that the term "Nutrition Facts" instead of "Nutrition Information per Serving," be presented as the heading of the nutrition information.

b. *Terminology for subcomponents of nutrients.* In its format proposal (57 FR 32070 at 32071), FDA solicited comment on certain format elements not addressed by research studies. The agency requested comment on what terminology and graphic elements would most effectively distinguish subcomponents of nutrients from the declaration of the total amount of the nutrient and improve their visibility in the nutrition label display.

i. Subcomponents of fat and of carbohydrate. 125. The majority of comments supported the use of the terms "total fat" and "total carbohydrate." Many comments suggested using indentation of subcomponents as a graphic means to further distinguish subcomponents because it is a commonly used technique that would be easily understood by most consumers. A few comments suggested bolding and highlighting of the broader classification to further distinguish subcomponents of fat and carbohydrate. Other comments suggested using such terms as "includes," "including," "of which," and "which includes" before the subcomponent to further establish that the subcomponent is a part of a broader classification.

Section 403(q)(1) of the act specifies that nutrition labeling shall include information on several nutrients, including total fat and total carbohydrates. In order to be consistent with the terminology used in the 1990 amendments, the supplementary proposal (56 FR 60366 at 60387 and 60388) included provision for listing "total fat" and "total carbohydrate" as mandatory elements of the nutrition label. Given the statutory derivation of

this terminology, the support for its use in the comments, the fact that the terminology reflects the broad category of nutrient, and the lack of opposition to the use of this terminology, the agency is retaining the provisions for the declaration of total fat and total carbohydrate based in § 101.9(c)(2) and (c)(6) and, by reference, in § 101.9(d)(7).

The agency agrees that indentation of subcomponents along with the use of the term "total" before the major classification provides effective means of establishing separate and recognizable subcomponent status. The agency is not providing for the use of terms such as "including" and "of which." While these terms may add clarity, they will also introduce additional words to the label, contributing to label clutter. The agency is persuaded by the comments that the use of indentation of subcomponents is sufficient to clearly distinguish the subcomponents of total fat and total carbohydrate because it is a commonly used and well understood graphic device. Therefore, the agency is requiring the indentation of saturated, polyunsaturated, and monounsaturated fatty acids in § 101.9(c)(2)(i) through (c)(2)(iii), respectively, and the indentation of dietary fiber, sugars, sugar alcohol, and other carbohydrates in § 101.9(c)(6)(i) through (c)(6)(iv), respectively, when such nutrients are declared. In addition, as explained in section V.H.1. of this preamble, the broader classifications must be highlighted by boldface print as provided in § 101.9(d)(1)(iv).

ii. Calories and calories from fat. 126. The plurality of comments supported using the term "total" preceding or following "calories" to denote that it includes the calories from fat (i.e., "total calories" or "calories, total"). Some comments suggested that a potential for confusion exists because "calories from fat" must be declared on the nutrition label, and consumers may be unaware that they are included in the larger category "calories." These comments expressed concern that consumers would mistakenly add calories from fat to the larger classification declared simply as "calories." Additionally, several comments suggested indenting "calories from fat" to further distinguish it from "total calories."

The agency is persuaded by the comments that the term "total" preceding or following "calories" will better enable consumers to understand that it is the larger classification of which the subcategory "calories from fat" is a part. The agency notes that it is requiring the term "total" for the other larger classifications, total fat and total carbohydrate. A label that has the term "total" preceding two of the three larger classifications may have the potential to confuse consumers with regard to the third. However, the agency also notes that the term "calories" has fewer words, and therefore requires less space and minimizes clutter. Furthermore, consumers have been seeing the term "calories" on labels to designate total calories, and, unlike the other nutrient subcomponents, the subcomponent "calories from fat" designates subcomponent status by its structure. Therefore, in § 101.9(c)(1), FDA is providing for the use of the terms "total calories;" "calories, total;" or "calories." In addition, in § 101.9(c)(1)(ii), the agency is requiring that the subcategory "calories from fat" be indented for consistency with other nutrient subcomponents when it is listed in a column under the total calorie information.

c. *Terminology for Daily Reference Value.* In its mandatory nutrition labeling proposal (55 FR 29487) FDA asked for comments concerning an appropriate single new term to be used to refer to all the reference values in the nutrition label. On its own, FDA arrived at "Daily Value (DV)" as a possibility for use as this single term. FDA used this term in the research that it conducted on formats. Most consumers correctly interpreted the general meaning of the term. However, during probing in focus group discussions conducted by the agency, several consumers commented that the word "value" may connote something of worth and suggested that another term might be appropriate for food labeling purposes. In its supplementary proposal published November 27, 1991 (56 FR 60366 at 60371), the agency reiterated its request for comment on, and suggestions for, appropriate terminology to be used to refer to the entire set of reference values.

127. A number of comments responded to the issue of terminology for a single term to denote all label reference values. Two comments stated that the word "value" may give the impression that these levels are goals to be achieved rather than points of reference. A wide range of alternative terms were offered, including "Human Daily Need," "Recommended Daily Standard," "Reference Value," "Daily Amount," "Reference Daily Intake," and "Recommended Daily Intake." However, no general agreement emerged from the comments, and no research data were submitted in support of suggested alternatives for the term "Daily Value."

One comment stated that the term "reference" has little meaning for most consumers, while a few others said that the use of the term precludes persons assuming that the value is a goal. Another comment stated that the term "standard" avoids the confusion of having to differentiate between minimum and maximum intakes. One comment suggested that the term "U.S. RDA" be retained to denote all label reference values. Many other comments requested retention of the U.S. RDA's; however, those comments appeared to be referring to retention of the current numerical values for the U.S. RDA, not the terminology to be used on the label.

FDA disagrees that the term "U.S. RDA" should be retained. The term was developed in 1972 when label reference values for all nutrients listed on the label were derived from the Recommended Dietary Allowances (Ref. 23). The term was developed to suggest the link between the Recommended Dietary Allowance and the label reference values developed by the agency. However, the reference values for a number of the nutrients that are to be included in the nutrition label, under the final rule on DRV's and RDI's, published elsewhere in this issue of the Federal Register, are not based on a Recommended Dietary Allowance value because the National Academy of Sciences has not established Recommended Dietary Allowances for these nutrients. It therefore would be inaccurate and misleading to retain the term "U.S. RDA."

Further, the agency believes that terms that use the words "recommended," "requirement," or "need" would be misleading to consumers and would complicate nutrition education efforts. Some of the reference values that FDA is adopting are intended to guide consumers relative to maximum intakes (for example, saturated fat), while others are intended to serve as a basis for planning general diets to meet nutrient requirements (for example, vitamin C) or as minimum intakes (for example, potassium). It would be incorrect to imply that FDA "recommends" that consumers consume the maximum intake level for total fats, or that such levels are "required" or "needed." Also, FDA cannot agree that the term "standard" is appropriate. While the comment argued that this term does not suggest a minimum or a maximum, the agency believes that it commonly implies a level to be achieved or surpassed, and for which it is undesirable to fall below. Thus, it may connote a minimum level for many consumers.

Moreover, the term "daily intake" suggests a requirement or prescriptive

need for individuals, rather than a general reference point. Furthermore, the agency is concerned that if the term were used, it could become a source of confusion in information and educational materials on nutrition because "daily intake" for nutrients is used to mean current consumption levels, rather than reference intakes based on dietary recommendations. For example, the current daily intake of fat is estimated to be 95 g per day based on food consumption surveys. However, the agency's DRV for fat is 65 g for a 2,000 calorie diet and is based on dietary guidance.

After reviewing the comments carefully, the agency concludes that it is appropriate to retain the proposed term "Daily Value." FDA research has shown that the term is generally understood by consumers as a point of reference, and no appropriate or well-supported alternatives have been suggested to the agency. FDA acknowledges that two comments suggested that the word "value" may be indicative of a goal. However, no data were submitted to support this suggestion, and no other comments objected to the term on these grounds. Therefore, FDA will use "Daily Value" as the single term to refer to all reference values on the nutrition label and is providing for its inclusion in § 101.9(d)(6).

To preclude any confusion, the agency points out that the Daily Values are a specific, regulatorily established set of reference values that have been derived based on dietary guidance and, for certain nutrients, on the assumption of a 2,000 calorie per day diet (see the document on RDI's and DRV's published elsewhere in this issue of the **Federal Register**). FDA recognizes that alternate daily caloric requirements (e.g., 2,500 calories) produce alternate recommended values for those nutrients with dietary recommendations that are based on calorie requirements, and that these alternate values can be considered "daily values" for people consuming the given calorie level. However, the recommended values for various calorie intake levels other than 2,000 calories per day should not be confused with the Daily Values, specifically the DRV's that FDA is establishing by regulation (see § 101.9(c)(7)(iii)) and that are referenced in several of the regulations that FDA is adopting today (see, e.g., § 101.13).

2. PERCENT DV Format

The majority of comments that supported the PERCENT DV or PERCENT DV with DRV format were from consumer groups and health promotion organizations, although several industry and other types of organizations also supported the proposed format. The majority of comments that opposed the PERCENT DV format were from industry.

128. The major argument given in support of the PERCENT DV format was that the percent formats are easy to use and provide clear information about how a food fits into a total daily diet. FDA's research showing that the percent formats have superior performance characteristics, particularly with regard to label tasks related to dietary judgments, was sometimes cited. Some comments argued that consumers are mainly interested in using the nutrition label to make qualitative judgments about specific foods, such as whether the food is low or high in a nutrient of interest. Many fewer people, it was argued, keep running lists of nutrient amounts throughout the day. The comments argued that the percent format facilitates this type of qualitative judgment.

Many of the comments opposed to the PERCENT DV format also addressed the issue of consumers' ability to use the PERCENT DV information, arguing that consumers would not be able to use percent displays effectively. Specific arguments included that the percent formats did not perform well in the Grocery Manufacturers of America and the National Food Processors Association (GMA/NFPA) industry study (Ref. 71), and that consumers do not understand percents.

FDA has carefully considered the arguments regarding percent displays but finds no basis not to conclude that consumers will be able to use PERCENT DV declarations more effectively than they would any other format tested. The consumer research (see section V.D.2. of this document) supports the assertion that the PERCENT DV format, with or without a listing of the seven macronutrient reference DV's, improves consumers' abilities to make correct dietary judgments about a food in the context of a total daily diet. This result was replicated in three separate studies (Refs. 70, 71, and 74), two of them industry-sponsored, and on three different dietary judgment tasks: judging the correctness of nutrient claims about the product, identifying the nutrients in the product that needed to be counterbalanced by changes in the daily diet, and judging how much to eat of the given food if you want to reduce intake of certain nutrients. In one industry-sponsored study (Ref. 71), the PERCENT DV format helped consumers judge how much to eat of a given food despite the fact that PERCENT DV formats were executed with extra columns of nutrient information per serving.

As noted in section V.D.2. of this document, the percent DV format element is one of only two format elements that have been shown to improve consumer performance on dietary judgment tasks (the other format element is the use of adjectives). In addition, the PERCENT DV format, when executed without additional columns, scored as well or better than any other format on all of the other tasks measured in FDA's study. No evidence was submitted to FDA showing that consumers cannot effectively use a PERCENT DV format when it is appropriately executed.

FDA studies (Refs. 69 and 70) found that for label use tasks involving simple comparisons between products, PERCENT DV declaration formats were best executed as single column displays with g/mg amounts next to the nutrient name and not in a column. Executed in this manner, no difference was found between PERCENT DV formats and the CONTROL format on product comparison tasks.

The GMA/NFPA industry study (Ref. 71) found that when the format was executed as two adjacent columns of numbers with different units (g/mg amounts and percent DV declarations), performance on simple comparison tasks was adversely affected. This result is likely attributable to the additional columns added to the format, particularly since the units differed, and is not an inherent weakness of the PERCENT DV declaration formats (see section V.D.2. of this document). FDA considers the placement of g/mg amounts in an unordered array next to nutrient names to be a necessary feature of the PERCENT DV format because it improves consumers' abilities to readily observe and comprehend the percent information on the nutrition label as demonstrated by FDA format studies. Thus, use of this format is consistent with section 2(b)(1)(A) of the 1990 amendments.

The argument that people have difficulty in understanding percents is not borne out by the consumer research. In the nutrition label situation, a consistent system of percents is used such that virtually all the nutrients on the label can be declared in equivalent units, in this instance percent DV. A list of nutrients declared in equivalent units has the unique property that the list of values is self-anchoring, that is, values in the list can serve as references for each other. A low value on the list is likely to be a "true" low value, a high value on the list is likely to be a "true" high value. This consistency is not possible when the list contains nutrients declared in very different units. Five g

of saturated fat may be a "true" high value and 115 mg of sodium may be a "true" low value, but few consumers see the number 5 as high and the number 115 as low according to FDA research. Percent DV declarations help consumers because they overcome the problems associated with declaring nutrients in nonequivalent units (see comment 106 of this document).

Gram/milligram formats with a list of DV's give consumers the numbers they would need to calculate percentages and thus to transform the amounts to equivalent numbers. However, research, including FDA's format research, has consistently shown that most consumers are unwilling or unable to transform data provided on labels (Refs. 70 and 101). Available evidence shows that providing consumers with raw data is not effective. Providing them with data in the form needed to make judgments, e.g., in consistent percentages, is effective.

Consumers have been seeing vitamin and mineral levels expressed as percent of U.S. RDA on food products for about 20 years. Few know what the U.S. RDA's are for specific nutrients or even know what units the U.S. RDA's are in. No arguments have been raised that percents in this context are difficult to use or hard to understand. The presentation of macronutrient data in percents is a logical extension of the system that consumers have been using with apparent success for years.

Therefore, FDA is requiring in § 101.9(d)(7)(ii) that nutrition information per serving be declared as percent of the DV in the primary columnar display on the nutrition label.

129. Many of the industry supporters of the PERCENT DV format cited the relatively small space requirements for the format, particularly if the DV listing is not required.

FDA agrees that the PERCENT DV format without a DV listing requires little additional space relative to the CONTROL format. A strength of the PERCENT DV format not shared by any other format except ADJECTIVE is that consumers can use it equally well for most label use tasks with or without the reference DV listing. For this reason, the agency is not requiring that the reference DV list be displayed as such. Rather, it is displayed as part of an example of recommended nutrient amounts for different calorie intake levels, and the normal placement is not beside the Percent DV information but beneath it.

In addition, the calorie-specific daily value list may be omitted in simplified formats and on small and intermediate sized packages (§ 101.9(f)(5) and (j)(13), respectively). In contrast, labels declaring amounts of nutrients only in g/mg units require consumers to compare the reference DV list with the amount declarations in order to make dietary judgments. Thus, for such labels, the presentation of the reference DV list adjacent to the declaration of amounts is necessary for most label use tasks.

Accordingly, § 101.9(d)(9) provides that daily values for 2,000 and 2,500 calorie diets be placed in columns beneath the vitamin and mineral information. However, if space is not adequate beneath the vitamin and mineral information, § 101.9(d)(11) provides that the calorie-specific daily value information may be placed to the right of the Percent DV information. In addition, § 101.9(f)(5) allows the calorie specific daily value information to be omitted from labels of products that qualify for the simplified format, and § 101.9(j)(13)(ii)(C) allows it to be omitted from packages with 40 or less square inches of label surface available to bear labeling.

130. A number of comments argued against the PERCENT DV format because of poor legibility of the basic format. They argued that legibility will be lower because the absolute amount declarations are hidden and are likely to be hard for consumers to find and because two numbers are required for each nutrient.

FDA disagrees that the basic format has poor legibility. The agency's research showed that consumers are easily able to use the PERCENT DV format displayed with amounts by weight in parentheses next to the nutrient name (see section V.D.2. of this document). Most consumers will not need to use the amounts by weight. The format prominently and clearly displays the one piece of nutrient information that will be most easily used and understood by the general population. The amounts by weight are provided for consumers who find it easier to use them, such as individuals who manage their diets using g/mg amounts.

131. Other comments argued that consumers will be confused because they will have to learn a new type of declaration, and those consumers used to the amount by weight declarations may mistakenly use the percentages as absolute amounts.

FDA disagrees with this argument. Evidence from consumer research shows that consumers generally are not able to effectively use the current format for some important label uses, such as placing a food in the context of their total daily diet (see section V.D.2.b. of this document). In contrast, research shows that consumers are able to use percent displays for all of the label uses tested, including those tasks related to dietary judgments, such as placing the food in the context of the total daily diet. As consumer education reaches more people, and as consumers become more familiar with the percent display format, its effective use will increase. In addition, under § 101.9(d)(7)(ii), as explained in section V.H.1. of this document, the symbol for percent (i.e., "%") must be used after each number. Therefore, consumers are not likely to use the percentages as absolute weight amounts.

Many of the comments opposed to the use of the PERCENT DV formats did not acknowledge that these formats provide g/mg amount information on the nutrition label. FDA included amounts by weight to meet the needs of consumers who had come to rely on such information. An appropriate balance must be achieved between how much and how prominently information can be presented on the label. The relative numbers of people likely to use different information is an important consideration in achieving this balance. Few people currently engage in the kind of dietary management that requires keeping daily running sums of particular nutrients, such as assumed by some of the comments opposed to PERCENT DV formats.

132. Several comments stated that PERCENT DV formats are misleading because they provide inappropriate dietary guidance or offer no guidance to those consumers whose daily requirements differ from the DV. Concern was expressed that consumers will believe the numbers apply to them personally.

The agency disagrees that PERCENT DV declarations are misleading because they provide inappropriate dietary guidance. A major advantage of a percent unit is that it communicates the relative magnitude of the nutrient level in a food without the consumer having to be concerned about the absolute level or units of the underlying scale being used. Knowledge of quantitative dietary goals for specific nutrients is not inherent in, or necessary for, accurate magnitude assessments of the nutrient levels in the food. The DV base of the percent does not have to exactly fit each individual's needs in order for the percent to accurately reflect the relative magnitude of the nutrient level in the product.

FDA considers estimation of the relative magnitude of nutrient levels in the food to be central to the placement of a food in the context of the total daily diet. FDA's research and other research submitted as comments to the format

proposal showed that consumers were able to use PERCENT DV formats to assess high/low levels of nutrients more effectively than any other format (see section V.D.2.b. of this document).Therefore, for purposes of placing the food in the context of a total daily diet, a label use for which consumers have no need to adjust the scale for individual variations, the declaration of nutrient amounts as percent DV cannot be considered misleading or inappropriate dietary guidance.

Although, for the reasons described above, detailed knowledge of the DV's and their relation to an individual's diet is not necessary for using a PERCENT DV format to make product comparisons or dietary judgments about the product, it is useful for other dietary management purposes. Information about how daily values vary by calorie needs will help those people who so desire to estimate their own personal daily values and will help them to differentiate the concept of a reference Daily Value used for labeling and regulatory purposed from personally appropriate dietary guidance.

Therefore, to decrease the likelihood of consumer misunderstanding, the agency is requiring in § 101.9(d)(9)(i) that a footnote accompany the percent DV declarations stating that these declarations are based on a 2,000 calorie diet, and that personal needs vary depending on an individual's calorie intake. In addition, to assist consumers in estimating their own quantitative dietary needs relative to the reference DV's, the footnote will display daily values of total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 calories and 2,500 calories. By providing a concrete example of how individual dietary needs may vary depending on calorie intake level, the footnote will help people to place their personal dietary needs with respect to the reference Daily Values and to avoid any misunderstanding as to whether the reference DV's are dietary guidance meant for them.

133. Several comments argued that PERCENT DV formats are mathematically misleading because they are calculated against an implied range if the terms "or less" and "or more" are used, or because consumers will not be able to reconstruct the percents from the absolute amounts and the DV numbers because of the rounding rules for percents of macronutrients.

FDA disagrees that consumers will see qualifying terms such as "or less" and "or more" as constituting a range from which a percent cannot be calculated. These terms were included on the PERCENT DV/DRV format in the second FDA label format study, and no subject expressed confusion resulting from their presence (Ref. 70).

FDA agrees that the rounding rules for percents for macronutrients and sodium in proposed § 101.9(c)(12) (56 FR 60366 at 60390) have the potential to cause consumer confusion when used with the PERCENT DV format. The agency notes that the amount by weight declarations for these nutrients have already been rounded, and that additional rounding of the percents may lead to an undesirable degree of inaccuracy, depending on the specific percent.

Therefore, the agency is requiring in § 101.9(d)(7)(ii) that percent declarations for macronutrients, sodium, and potassium in the PERCENT DV/DV format be calculated by using as the numerator the actual amount of the specified nutrient before rounding for label declaration. The resulting proportion will be transformed to a percentage and rounded to the nearest whole percent.

134. Some comments argued that the PERCENT DV format should not be selected because the lack of DRV's for some nutrients will result in blanks in the principal numeric column. The comments argued that such blanks will leave consumers with no information about the level of some nutrients and will be confusing to them. However, none of the comments that supported the PERCENT DV format suggested that the lack of DV values for some nutrients was a disadvantage of the format.

Several of the comments that discussed the lack of reference values in the context of whether the DV list should be required on the label provided arguments that apply to all uses of the DV information and thus also apply to the PERCENT DV format. These comments argued that it is more beneficial for consumers to have the values for some nutrients than to have the values for no nutrients.

The agency disagrees that blanks in the principal numeric column resulting from the lack of DV's for some nutrients is sufficient reason to reject the PERCENT DV format. The g/mg amounts will be listed for nutrients that have no DV, so that some information will be presented for these nutrients. Since a reference value has not been set for these nutrients, none of the alternative formats would give additional information to help the consumer evaluate the food with respect to nutrients that lack a DV. For example, no value will appear in the DV listing for the nutrients, so comparison of the amount in the product with the DV, as might be done with the CONTROL/DV format, would not be possible. No scheme for assigning adjectives or for highlighting would be able to include nutrients without a DV, so that formats using these elements would not present more information about such nutrients than the PERCENT DV format. Since no other format overcomes the gap in information that results from lack of DV's for some nutrients, the lack of DV's for specific nutrients cannot be seen a reason to reject the PERCENT DV format. The agency agrees with the comments that argued that presenting DV related information for some nutrients is more beneficial to consumers than withholding such information about all nutrients.

135. Some comments argued that PERCENT DV formats are calculated against a base that will change as scientific knowledge about nutrition changes, just as dietary guidance changes as knowledge increases, and that, therefore, a PERCENT DV declaration should not be required.

These comments address the issue of putting on the label dietary information that will change over time with increasing knowledge. The underlying assumption of these comments is that percent DV declarations will communicate quantitative dietary goals for specific nutrients, but, as discussed above (see comment 132 of this document), FDA's view is that percent DV's are not likely to be used for this purpose. U.S. RDA's have been subject to change in the same sense, but this fact has not prevented their successful use on nutrition labels as a basis for declaring nutrient amounts as percentages. Therefore, the agency disagrees that the possibility of change is a substantial reason to avoid percent declarations on the nutrition label.

136. A number of comments argued that PERCENT DV formats encourage good/bad food judgments.

The agency does not agree with this argument. Both FDA and industry research found that PERCENT DV declarations tend to produce the most accurate judgments about whether products are high or low in various nutrients. The g/mg formats were more likely to lead to extreme and inappropriate dietary judgments than PERCENT DV declarations (section V.D.2.b. of this document and Ref. 102).

137. One comment expressed the view that FDA does not have the legal authority to require percentages, since the 1990 amendments only require the declaration of amounts. Others argued that the 1990 amendments do not mandate that FDA change the current format.

FDA disagrees with these comments. As discussed above, section 2(b)(1)(A) of the 1990 amendments requires that the nutrition information be conveyed in a manner that enables the public to understand the relative significance of the nutrition information in the context of the total daily diet. Moreover, the legislative history states that this provision requires the Secretary to specify requirements that permit the consumer to understand the nutrition information about a particular food in relation to recommended dietary information (Ref. 16, p. 18). Expressing the level of a nutrient in the food as a percent of a reference amount (the DV) is the simplest and most straightforward way of permitting the consumer to understand the amount of a nutrient in the context of the total daily diet. Thus, the 1990 amendments provide clear authority to require percentages. Moreover, given the requirements of the 1990 amendments, and particularly the requirement in section 2(b)(1)(A) of the 1990 amendments, revision of the current format is unavoidable and necessary.

138. A comment from a foreign government stated that PERCENT DV information is country-specific because the DRV information on which it is based varies by country, and mandatory inclusion of percent DV information on a label would make it difficult to achieve equivalence in nutrition labeling requirements between the United States and other countries. The comment noted that their free trade agreement with the United States requires that the two countries work toward equivalent requirements on nutrition labeling. The comment pointed out that Codex guidelines provide for supplementary nutrition information only on a voluntary basis.

The agency supports efforts toward international harmonization of food labeling. However, the 1990 amendments direct FDA to require a number of format elements that are not in harmony with international food labeling. The agency believes that it has been directed to require a format that will enable consumers to choose appropriate foods and to place the food within the context of their total daily diet, without the constraints of meeting international guidelines.

3. The DV List on the Label

a. *Including the DV list on the label.* A number of comments from industry, consumer groups, and health promotion organizations addressed the issue of whether the DV list should be required, optional, or not permitted on the nutrition label.

139. The major arguments supporting mandatory inclusion of the DV list on the label, made primarily by consumer groups and health professional organizations, were: (1) That the DV's must be listed for people to estimate how their needs may vary from those represented on the label, particularly if the individual is on a more restrictive diet than represented in the DV's, (2) that consumers need the DV information on the label because they have to become comfortable and familiar with the DV concept in order for them to use the new nutrition label to place the food in the context of their daily diet, to put nutrient content information in perspective, or to provide a frame of reference for decision making, and (3) that consumers need the information because quantitative dietary goals are necessary in order to encourage and help consumers understand proper dietary practices.

The major argument against inclusion of the DV list on the label, made primarily by food manufacturers and food industry associations, was that consumers will misinterpret the DV's as dietary recommendations for their personal dietary needs, which will lead to the DV's providing inappropriate dietary guidance. Comments argued that DV's are unacceptable for dietary guidance because they are population based reference values for an "average" consumer that do not take account of individual differences such as sex, weight, activity level, and other factors influencing personal dietary needs.

Many comments opposed to requiring DV's argued that a listing of DV's on the nutrition label provides no product-specific information to consumers, and that mandating the listing on all labels requires repeating the same information on millions of food labels. One comment likened the requirement of placing the list of DV's on food labels to a requirement that banks provide addition and subtraction tables to their customers in each and every monthly statement. Many of these comments argued that inclusion of a list of DV's on the nutrition label will significantly increase the space requirements of the nutrition label, and that the increased space needs will make it extremely difficult for small packages to comply with nutrition labeling requirements.

Many comments opposed the mandatory inclusion of the DV's on the nutrition label because it will clutter the label and thereby decrease consumers' ability to readily observe and comprehend the nutrition information on the label. A number of comments, particularly from industry, supported optional inclusion of the DV list. The arguments for making the listing of DV's optional were similar to those for opposing it.

The agency finds merit in the argument that presenting the DV list on the label may potentially mislead consumers by giving undue prominence to values intended as references only and not as dietary guidance for individuals. The consumer research (see section V.D.4.b. of this document) showed that consumers were likely to interpret a single list of values labeled as "Daily Values" as personally applicable. At the same time, the agency agrees with the comments that argued that consumers should be able to assess how their personal dietary needs, which vary by factors such as age, sex, and activity level, may differ from the reference DV's used on the label. After extensive consideration, the agency is convinced that the best solution to these conflicting requirements is not to list the reference DV's identified as such as part of the primary information, but to provide a footnote as specified in § 101.9(d)(9)(i) that gives individualized daily values of total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber based on 2,000 calories and 2,500 calories.

Without a prominent display of the list of reference DV's for macronutrients on the label, the likelihood that consumers will misunderstand the reference DV's as personally relevant dietary guidance is greatly reduced. At the same time, a concrete example of how recommended nutrient amounts vary depending on an individual's needs will help consumers to understand how their own dietary needs stand with respect to the reference Daily Values.

The agency believes that the information in the footnote will accomplish virtually all the benefits that comments identified would follow from including the list of reference DV's on the label. By enabling consumers to evaluate the appropriateness of the percent DV's for their personal needs, the information in the footnote will serve to increase consumer confidence in the nutrition label and lead to more effective use. For consumers who want to practice quantitative dietary regulation that involves setting intake targets for certain nutrients and keeping a running tally of intake of these nutrients, the information in the footnote will provide maximum flexibility in the use of the nutrition label. The percent DV's on the label can be adjusted for different personal needs or an individual's caloric intake either by working with the percentages (such as having a target value of 120 percent

for 2,400 calorie diet and a target of 90 percent for an 1,800 calorie diet) or by working from absolute values derived from the calorie-based daily values in the footnote. The footnote will yield these benefits without implying that a specific reference DV is the appropriate target for every consumer.

However, FDA also agrees with comments that point out that inclusion of DV-related information on the nutrition label, such as that in the required footnote, imposes significant costs in terms of label space without providing product-specific information. Considering the appropriate balance, FDA is convinced that the agency should be flexible in requiring the footnote on product labels, particularly since the benefits of having such a listing are not relative to the specific food that carries the information, and that the information will be available to consumers if it appears on a significant percentage of food labels.

Therefore, the information specified in § 101.9 (d)(9) and (d)(10) may be omitted from small and intermediate sized packages as provided for by § 101.9(j)(13), and from products that qualify for a simplified format as provided for in § 101.9(f)(5).

140. Comments also addressed the placement on the label of information intended as context to help people more effectively use the nutrition information of the label. In the proposal, this information was a listing of the reference DV's. The agency has considered these comments in deciding the issue of the placement of the information in the footnote that FDA is requiring instead of a listing of the reference DV's. Several comments suggested that the daily value information should be required to be listed in a column beside the percent DV information, not in a footnote. Some comments agreed that placement in a footnote is sometimes necessary and suggested that FDA require a listing on separate lines rather than in a string. Others also recommended that placement in tabular form be required. Many of the industry comments stated that, in order to accommodate daily value information on many packages, flexibility in placement is essential.

Because the PERCENT DV formats do not require consumers to use information about the reference DV values to perform product-related dietary management tasks, the agency believes that allowing some flexibility in placement of the calorie-specific daily value information and excluding small and intermediate sized packages and products with simplified labels from the requirement to provide the footnote information will not compromise the effectiveness of the format (see comment 128 of this document). As long as the information appears on a substantial percentage of food packages, it will be readily available to consumers. FDA recognizes that the added information requires increased label space and agrees that manufacturers should have flexibility to place it so that they can use available label space efficiently. Thus, in § 101.9(d)(11), FDA is providing that the footnote information may be placed to the right of the percent DV information when there is not adequate space to place it beneath that information.

b. *Lack of reference values.* In its final rule on RDI's and DRV's published elsewhere in this issue of the **Federal Register**, FDA has established DRV's for total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, potassium, and protein. However, the agency has not established DRV's for polyunsaturated fat, monounsaturated fat, other carbohydrates, sugars, sugar alcohol, soluble fiber, and insoluble fiber. Formats that include these nutrients will show missing values under the percent DV and the DV columns. In the format proposal (57 FR 32059 at 32070), FDA requested comment as to whether the missing values will cause consumer confusion and, if so, whether it would be helpful to place an entry in the column stating that a reference value is not available.

141. The comments were divided on whether the lack of reference values for some nutrients would be confusing to consumers. Several comments stated that appropriate educational efforts would reduce consumer confusion, and that the potential confusion possibly caused by missing values does not outweigh the usefulness of providing the percent DV and DV information for nutrients for which such values exist. Several comments suggested that it was most appropriate to merely leave the entry blank, citing concerns about label clutter and the need to keep the label simple. Other comments suggested that the format include an entry of some type to indicate that a reference value has not been established. One comment pointed out that it is current practice for some food and supplement labels to state that a U.S. RDA has not been established for some nutrients.

As noted in comment 134, the agency agrees that presenting DV information for some nutrients is more beneficial to consumers than withholding such information about all nutrients. The agency is concerned about space limitations on food labels and label clutter. The label format presented in this final rule contains considerably more information than is required by the existing label, and comparisons to the current practice of stating that U.S. RDA's have not been established for some nutrients may overlook the increased information required on the nutrition label. Given the fact that nutrition labeling has been extended to virtually all foods regulated by the agency and the concern that too much information on the nutrition label may overwhelm consumers, FDA finds no basis to conclude that statements that a reference value is not available for the particular component will add clarity to the label. Therefore, FDA is not providing for the use of statements regarding the lack of established reference values.

c. *Use of qualifying terms in presentation of calorie-specific recommended nutrient amounts.* The agency proposed (57 FR 32058 at 32070) to require the use of the qualifying terms "or less" and "or more" in conjunction with the proposed DRV list. Comments about qualifying terms are relevant to the presentation of calorie-specific daily values, as provided for by § 101.9(d)(8). While the agency did not specifically discuss the nutrients for which each of these qualifying terms were appropriate in the proposal, the examples presented in the appendices made it clear that the agency's intent was to use these terms in conjunction with those nutrients for which current dietary guidance specifies an "open-ended" decrease or increase in consumption. Therefore, because recommendations for total fat, saturated fat, cholesterol, and sodium intake are stated in specific amounts or less (Refs. 2, 3, and 4), the agency used the qualifying term "or less" with these nutrients. On the other hand, the recommendation for carbohydrate is stated as 55 percent or more (Ref. 3). Thus the agency used the qualifier "or more" with this nutrient. FDA included such qualifiers in its research.

142. A few comments opposed the use of the qualifying terms because of the interest in reducing label clutter or because their use conveys a message that a food should be avoided if it contains high amounts of a nutrient qualified by "or less." Several comments opposed the use of the qualifying terms if a range of values was used rather than a single value. One comment considered the qualifying terms unnecessary if FDA adopts a 2,000 calorie base.

The majority of comments supported the use of qualifying terms and suggested that such terms convey to consumers the notion of a variable target intake rather than a prescriptive intake.

Some comments supported "or less" and "or more." Others stated that "less than" was preferable to "or less," and one stated that "no more than" and "no less than" were preferable to "or less" and "or more." These comments argued that the recommendation for saturated fat intake was less than 10 percent of calories from saturated fat, and therefore the use of "less than"as a qualifier in general was more appropriate. No comment presented data concerning consumer use and interpretation of qualifier terms. A comment suggested dropping "or more" for carbohydrate, regardless of calorie base, as it is in conflict with the Dietary Guidelines for Americans (Ref. 4), which recommend the use of sugars only in moderation.

FDA agrees that the use of qualifying terms assists consumers in appropriate interpretation of the daily value information and may help to preclude too literal an interpretation of the values. Moreover, since no single caloric level can be specific for all individuals, the agency concludes that qualifying terms are appropriate regardless of the caloric level used. Furthermore, the agency is convinced that regardless of which term is selected, the qualifiers should be used consistently to avoid consumer confusion.

FDA acknowledges that, while Diet and Health (Ref. 3) recommends that 55 percent or more of calories be consumed as carbohydrate, the Dietary Guidelines (Ref. 4) recommend the use of sugars only in moderation. The label format will list sugars as a subset of carbohydrate. The agency is persuaded that the use of the qualifying term "or more" or "more than" with carbohydrate has the potential to be misleading to consumers given that carbohydrate includes sugars. The use of this term may be particularly confusing to consumers when the source of carbohydrate in a food is primarily sugars. Therefore, FDA will not provide for the use on the label of the qualifier "more than" or "or more" with carbohydrate.

FDA finds merit in the term "or less" because this term is presented after the quantitative value and thus does not interfere with the consumer's ability to locate the quantitative values (especially when the daily values are presented in a column). However, the agency believes that the term "less than" conveys a less specific target and thus meets the concerns of many comments that asserted that consumers need to be alerted to the fact that recommended amounts vary greatly from individual to individual. The agency also acknowledges that the qualifying term "less than" is more consistent with the recommendation for saturated fat.

Therefore, FDA is persuaded that qualifying terms should be included when daily values are presented, and that the qualifying term should be "less than." The agency has included this requirement in § 101.9(d)(9)(i). For consistency and to avoid consumer confusion, FDA will not provide for the use of the term "or less."

143. One comment stated that the agency should allow the use of the term "or more" with dietary fiber because such a qualifier is consistent with current dietary guidance.

FDA disagrees that it is appropriate to use the qualifying term "or more" with dietary fiber. While there is relatively little evidence that high fiber intake impedes mineral absorption and bioavailability (Ref. 3), concerns about excessive fiber consumption have led to specific recommended ranges for dietary fiber intake rather than open-ended recommendations. The report from the Life Sciences Research Organization (Ref. 103), which provides the basis for the DV for dietary fiber, specifically provides a range for recommended dietary fiber intake (10 to 13 g per 1,000 calories, or approximately 20 to 35 g per day) and is not stated as 25 g or more. Therefore, the use of "or more" with fiber is not consistent with dietary recommendations, and FDA will not provide for its use on the label to qualify dietary fiber.

d. *Clarifying footnote for daily value caloric intake level.* In the format proposal (57 FR 32058 at 32071), FDA asked for comment on the effectiveness of a footnote to convey to consumers the need to modify the DV amounts to meet their nutritional needs and for suggestions for alternative footnote statements. The proposal included the following explanatory footnote in the PERCENT DV with DRV graphic format: "For a 2,350 calorie diet. Your Daily Value may be higher or lower depending on your calorie intake."

Comment was requested on the following three alternative footnotes listed in the proposal (57 FR 32058 at 32071):

(1) Based on a 2,300 calorie diet. Fewer calories are recommended for women and young children.

(2) As part of a 2,400 calorie diet. Many young children and women over 50 need 2,000 calories or less. For a 2,000 calorie diet the Daily Value would be less than 65 g Fat, less than 20 g Saturated Fat, less than 275 g Carbohydrate, and 25 g Fiber (Sodium and Cholesterol do not change).

(3) A 2,000 calorie diet is for women over 50 and young children. Most teenagers, sedentary men, active and very active persons, and pregnant and breastfeeding women need more calories.

144. Comments were received from manufacturers, health promotion organizations, State governments, trade associations, universities, and consumer advocate organizations. The majority of comments supported the requirement of a footnote to clarify the calorie base for the daily value listing.

The explanatory footnote in the PERCENT DV with DRV graphic format was specifically supported by five of the comments. This footnote stated "For a 2,350 calorie diet. Your Daily Value may be higher or lower, depending on your calorie intake." However, one manufacturer objected to this footnote on the basis that it was ambiguous and ineffective and did not provide the necessary information.

Most comments stated that it is important for the consumer to understand that the DV may need to be adjusted because it is based on the number of calories consumed, and recommended calorie consumption depends on various factors, such as physical activity level, age, sex, weight, height, and metabolism. Two comments, although opposing inclusion of the DV, argued that an explanatory footnote should be included if the DV is included.

Two comments objected to all of the alternatives. One comment, from a consumer advocacy organization, asserted that the third alternative listed above would create more confusion by attempting to identify every segment of the population.

Two comments, one from a health professional organization and the other from a food manufacturer, stated a preference for using the footnote in the format shown in appendix F (57 FR 32058 at 32089) as the footnote clarifying the DV list. This footnote summarizes the Dietary Guidelines and includes statements such as "Eat a wide variety of foods." However, it does not include a reference to the DV's or the caloric level on which they are based because the format that the footnote appears on does not list DV's. (The format in appendix F of the format proposal is discussed in section V.G.11 of this document). One of the comments recommending this footnote stated that the footnote should be prefaced with a statement about DV's varying with calorie needs. The following was suggested: "Your calorie, fat, carbohydrate, fiber, and protein intake will vary based on age, height, weight, metabolism and activity level."

A trade association opposed the footnote included in appendix F of the format proposal as the clarifying footnote for the DV list, stating that it added to the clutter, and that it did not provide any relevant information to the consumer because too many calculations would be required to use the information in the footnote. Two comments suggested that the statement in the footnote of appendix F, "choose a diet low in fat (30% or less)," be clarified to reference the total caloric intake for the day. One comment requested that footnote information be consistent with dietary guidance and the nutrition label by changing "Use sugar * * * in moderation" to "Use sugars * * * in moderation."

Various other suggestions were made for the appropriate wording of a footnote. Some comments were concerned with brevity in the interest of space. Other comments emphasized clarity, offering longer footnotes. Several comments were concerned with conciseness. Some variations arose from the preference for a range rather than a single number for the DV.

The various footnotes offered in the comments stated that an individual's DV depends on calorie needs, listed individual characteristics that affect calorie needs, or simply provided the calorie base of the DV on the label.

Three comments from manufacturers suggested that footnotes should be optional. Another comment suggested a voluntary program of explanatory information provided in footnotes, with a stipulation that the footnote become mandatory if 70 percent of packages were not including it by 1996. Two comments objected to inclusion of a footnote on the basis that the label cannot be a source of dietary guidance. Others were concerned about the space used by the footnote.

Two comments addressed other possible footnotes to the nutrition information. Inclusion of dietary guidance for special dietary needs was suggested by a manufacturer. A consumer advocacy organization suggested the use of footnotes to explain the use of adjectives such as "high" on the basis that FDA is wrong in assuming that people will relate "high" to the idea of limiting consumption elsewhere. The following statement was suggested: "People eating this food may need to limit the fat (or other nutrient) that they consume from other foods."

The agency notes that the consumer research suggests that many consumers do not notice footnotes. One survey asked respondents how many calories the DRV's were based on, while the respondents viewed a label with a footnote providing the information. Over half of the respondents could not give the answer (Ref. 87). Another study provided subjects with a nutrition label that had a footnote stating the caloric level base (2,350 calories) of the DRV list. Over 70 percent of the subjects stated that the DRV's applied to them (Ref. 71), even though, according to this report, this caloric base should apply to only 10 percent of the population. However, in other surveys, when respondents were asked directly whether DRV's based on a specific calorie level applied to them, most recognized that adjustment would be needed and were able to give the correct direction of adjustment (Refs. 87 and 97). These results show that although most consumers do not notice footnotes, those who are given the information (and by inference, those who do read the footnote) are able to interpret it appropriately.

FDA, in section V.B. of this document, has addressed comments regarding whether the nutrition label is subject to a requirement to provide general dietary guidance to consumers. The agency concluded that the first consideration for the nutrition label must be to help consumers make informed food choices by enabling them to both comprehend the nutritional value of the food and to understand its relative significance in the context of the total daily diet. Thus, general dietary guidance is not to be provided as part of the nutrition label. If a particular label has space, however, general dietary guidance may be included outside of the nutrition label, as discussed further below.

The agency does not agree that a footnote should be placed on the label urging people, after eating the food, to limit nutrients in which the food is high. Such information depends on the use of adjectives with the PERCENT DV format, which the agency is not allowing, as discussed in section H.4. of this document.

FDA agrees with the majority of comments that a footnote is necessary to help consumers determine how their individual dietary needs compare with the reference DV's used on the label and to prevent the possible misunderstanding of the applicability of the reference DV's (see comment 132 of this document). At a minimum, an acceptable footnote must specify the calorie level used for the reference DV's so that consumers have some basis to evaluate possible differences between their dietary needs and the reference DV's used on the label. Also, a statement that an individual's daily values vary according to calorie needs is essential when calorie-specific daily values are presented. FDA has provided for a footnote that includes this information in § 101.9(d)(9)(i).

The agency believes that many other pieces of information mentioned in comments, such as the information presented in Appendices E and F ... the format proposal, may be appropriately included on the food label to give useful context to the nutrition information. However, this information may not be included within the nutrition label itself because such additional information would require significant additional space to present and therefore would detract from the readily identifiable image of the nutrition label. Specifically, it would be appropriate to list typical calorie intakes for men, women, and children and to summarize dietary guidance on the food label. Furthermore, if the manufacturer is willing to supply copies of the Dietary Guidelines for Americans upon request, a statement of the availability of such information would be appropriate. Examples include the following:

(1) Typical intakes for women are 1,600 to 2,200 calories, for men 2,000 to 3,000 calories, and for children (ages 4 to 14) 1,800 to 2,500 calories.

(2) Use this nutrition information to help you plan your total daily diet. The Dietary Guidelines recommend that Americans:

- Eat a wide variety of foods
- Choose a diet with plenty of vegetables, fruits, and grain products
- Choose a diet low in fat (30 percent of calories or less), saturated fat (less than 10 percent of calories), and cholesterol
- Use sugars, salt, and sodium in moderation

(3) For more complete information, a copy of the "Dietary Guidelines for Americans" may be obtained from (manufacturer's name and address).

e. *Footnote listing the caloric conversion factors.* 145. A number of comments addressed the inclusion of caloric conversion factors for fat, carbohydrate, and protein on the label to help consumers use the nutrition information to apply the recommended Dietary Guidelines for Americans. Several comments agreed that stating the caloric value per gram of fat, carbohydrate, and protein would help consumers better understand and use the nutrition information on the label. Many other comments objected to the inclusion of caloric conversion factors because of space considerations and because of reservations about how many people would be able and likely to use such information.

The agency is persuaded by comments from nutrition education experts that the public will benefit from having the caloric conversion factors on the label. FDA recognizes, as discussed above, that 9, 4, and 4 calories per gram for fat, carbohydrate, and protein, respectively, are general factors that may not apply to all foods. However, they are applicable to the majority of foods, and therefore, inclusion of these factors will be useful as a general guide. Moreover, FDA finds that any concerns about space are eliminated by its providing for intermediate size labels in § 101.9(j)(13). Accordingly, § 101.9(d)(9) requires that this information be included on the label.

4. CONTROL Format; Expression of Absolute Amounts in Grams/Milligrams

The majority of comments that opposed the PERCENT DV formats supported the CONTROL format. A few comments supported the current format, rejecting the revised list of nutrients, the new order in which nutrients are declared, and the PERCENT DV display. FDA has responded to the comments opposing the revision in the required list of nutrients and the order of nutrients earlier in this document (section III.A.2. of this document). A majority of the industry comments supported the CONTROL format without the DRV list. Some consumer groups and health organizations also supported the CONTROL format; however, they recommended that the DRV list be included.

146. Most comments in favor of the CONTROL format stated that research has not consistently shown that any other format has better performance characteristics on label use tasks than the CONTROL format.

The agency disagrees with this argument. Both FDA's and industry's research found that the simplest label formats with the smallest amount of information and the least number of columns had the best performance for label use tasks that require only simple comparisons or identifying differences between products. Because it has the least amount of information, the CONTROL format performs well on this kind of task. FDA's research suggests that with certain placement of the information, some other formats, including the percent formats, that provide more information can perform as well as the CONTROL format on these tasks. The industry study demonstrates that these other formats can also be designed in ways that lead to poorer performance on simple comparison tasks (e.g., by adding more columns to the display).

Both FDA's and industry's research also shows that for label use tasks that require consumers to make dietary judgments about the product, such as whether the food is high or low in certain nutrients or how the food fits into a daily diet, the best performing formats are those that include either the PERCENT DV declaration or adjectives. Other design elements such as listing reference DV's, grouping nutrients, or highlighting nutrients do not appear to improve performance on these types of dietary judgment tasks. The CONTROL format is among the poorest performers on tasks that require dietary judgment.

Being able to comprehend the nutrition information and to understand its relative significance in the context of a total daily diet means, at least in part, that consumers must be able to make accurate high/low judgments about the food. PERCENT DV and ADJECTIVE displays present high/low information directly. The g/mg formats (such as the CONTROL format) require that the consumer calculate percentages to get the information. The CONTROL format requires, in addition, that the consumer know the recommended amount for each nutrient. Research results show that consumers do not know the recommended amounts for nutrients, that many are not able to make such calculations, and that many are not willing to make the large number of calculations that would be required to include all of the listed nutrients in the judgment (see comments 105, 106, and 107 of this document).

147. Other comments supported the CONTROL format because it is uncluttered, because consumers are used to it, and because it is more consistent with dietary guidance, which is given in terms of g/mg amounts, than is the PERCENT DV format.

The agency agrees that simplicity and lack of clutter are important criteria in selecting a format. However, enough effective information must be presented to make the nutrition label useful. Therefore, the selection of a required nutrition label cannot be based simply on which one has the least amount of information.

Some of the arguments about consumer familiarity with a format were addressed in section V.G. 2 above. The agency noted that evidence from consumer research shows that consumers are not able to effectively use the current format for some important label uses. Therefore, consumers' greater familiarity with it does not have important benefits. In contrast, research shows that consumers are able to effectively use the PERCENT DV format, even though the format is new to them. The agency also noted above that g/mg amounts will continue to appear on the nutrition label for use by consumers who have come to rely on nutrition information presented this way

148. A large number of comments were opposed to the CONTROL format because it does not meet the criterion in the 1990 amendments of enabling consumers to understand the significance of the nutrition information in the context of a total daily diet. This argument was sometimes stated in conjunction with FDA's research finding that the CONTROL format had poor performance characteristics, particularly with regard to the dietary judgment tasks.

FDA agrees with this argument. A summary of research findings related to the CONTROL format appears in section V.D.2. of this document. For all the reasons discussed in this section, FDA concludes that the CONTROL format is not adequate to meet the criteria of the 1990 amendments.

5. HIGHLIGHTING Format

Highlighting was discussed in the format proposal both as a separate format and as a format enhancement. Most comments regarding the use of HIGHLIGHTING dealt with it as a format enhancement, and these comments are discussed in a later section.

149. The comments that discussed HIGHLIGHTING as a format were from industry health professional organizations, and consumer advocacy organizations. Most comments were opposed to the format. Many of these comments discussed the HIGHLIGHTING, ADJECTIVE, and GROUPING formats together. The comments argued that the HIGHLIGHTING format is inadequate and misleading because it gives undue emphasis to desirable components, thus tending to obscure the levels of undesirable components. In addition the comments stated that the HIGHLIGHTING, ADJECTIVE, and GROUPING formats have no satisfactory means of communicating the level of components that do not have a DV, such as complex carbohydrates and sugars. Some comments argued that a modified HIGHLIGHTING format that flagged both desirable and undesirable components of a product should not be selected because extensive consumer testing would have to be conducted to determine whether people are able to distinguish between the two types of flags. Other comments argued that the HIGHLIGHTING, ADJECTIVE, and GROUPING formats foster good-bad food messages.

Several comments from professional organizations argued that the HIGHLIGHTING format is redundant because nutrient content claims can be made on the front of the package. These comments stated that if anything is highlighted, it should be undesirable components to balance the front panel. Other comments argued that this format did not score well in consumer research and did not improve consumer comprehension of the label. One comment noted that international harmonization is problematic with HIGHLIGHTING, ADJECTIVE, and GROUPING formats because in Canada, such information is generally required to be grouped together and given equal prominence, whereas these formats include some form of emphasis in one or more parts of the nutrition label.

A supporting comment argued that the HIGHLIGHTING format is best because it is straightforward, easy to understand, and information can be quickly gleaned from it. The agency is persuaded by the comments and the research that the HIGHLIGHTING format should not be selected. FDA notes that this format has most of the disadvantages of the CONTROL/DV format (of which it is a variant), and it has several additional limitations. The format did not score well in consumer research on measures that involved putting the food into the context of a total daily diet. In addition, it emphasizes desirable features of products, which may already be emphasized by front panel statements and which may tend to obscure the levels of less desirable components. Therefore, FDA is not requiring the use of the HIGHLIGHTING format.

6. ADJECTIVE Format

Issues regarding the use of adjectives to describe nutrient levels arose in three contexts: support or opposition to the ADJECTIVE format itself; mandatory use of adjectives with another format, particularly the PERCENT DV with DRV format; and voluntary use of adjectives as a format enhancement. Adjectives as a format enhancement are discussed in section V.H.2. of this document.

150. Some comments argued that adjectives are inherently value-laden and would communicate a good-bad food perception.

The agency does not agree with this argument. As noted above in the discussion of this argument for the PERCENT DV format (section V.G.2. of this document), both FDA and industry research found that the ADJECTIVE and the PERCENT DV declarations tended to produce the most accurate judgments about whether products are high or low in various nutrients (Refs. 70 and 71). The g/mg formats were more likely than ADJECTIVE formats to lead to extreme and inappropriate dietary judgments, such as responses that a food was high in a nutrient in which it was actually low, or that a food should be avoided altogether because of a particular nutrient level. The agency is not requiring the ADJECTIVE format for other reasons.

151. Several comments argued that a complete scheme for assigning adjectives to all nutrients required to be listed on the label does not exist. They argued that because DRV's have not been established for all nutrients, including sugars and polyunsaturated fats, an acceptable scheme would be time consuming to develop.

The agency agrees that a complete scheme for assigning adjectives to all nutrients does not currently exist, and that the lack of DV's for some nutrients would complicate the development of such a scheme. However, as explained in Comment 134, all of the alternative formats except the CONTROL format share the limitation that DV's have not been set for some nutrients. Because the limitation is constant for almost all formats, it cannot be seen as a disadvantage unique to one format. The agency believes that providing DV information for the nutrients that have DV's is more beneficial than withholding it for all nutrients because it is unavailable for some. Nonetheless, the agency is not requiring the ADJECTIVE format for reasons stated in comment 152 of this document. Therefore, the issue raised by these comments need not be addressed further.

152. Several comments opposed the ADJECTIVE format because it would be confusing to consumers. One comment argued that the format provides information on whether a nutrient is high, medium, or low, but not whether it is a desirable or undesirable nutrient. Some comments argued that the format is too cluttered and directive. Some comments noted that the ADJECTIVE format showed a number of weaknesses in the consumer research, particularly a tendency for consumers to fail to differentiate between products when different nutrient levels were described by the same adjective. The comments noted that wide ranges, as proposed for the category "medium," would be misleading to consumers who did not attend to the nutrient values.

Several comments supported the ADJECTIVE format, arguing that the format is easy to read and does not require math calculations or working with numbers at all. One stated that it would be easier for the elderly and visually impaired to use. Other comments supported it because it was preferred by consumers in the research.

FDA is not requiring the ADJECTIVE format for the following reasons. The agency agrees that the ADJECTIVE format showed weakness on an important label use task, the product comparison task that required detecting differences between nutrients. The agency also agrees with the comments that argued that the wide range for some of the adjective categories may be misleading to consumers who use the label in certain ways. The agency acknowledges that the ADJECTIVE format was the most preferred in some studies but notes that preference measures must be interpreted cautiously and cannot be used as a definitive criterion, for the reasons discussed in section V.D.3. of this document. The agency further notes that none of the studies provided evidence that the ADJECTIVE format is easier for elderly consumers to use.

7. GROUPING Format

Grouping by whether dietary guidelines recommend choosing a diet high or low in specific nutrients was tested in FDA's Study 2 (Ref. 70). This format element did not generate many comments, and the comments about it were frequently included in statements about the HIGHLIGHTING or ADJECTIVE format. Most of the comments were opposed to GROUPING.

153. One argument against the GROUPING format was that it is too value-laden, lending itself to a good–bad food message. Another comment argued that the GROUPING format does not provide meaningful information related to the particular product. Other related comments argued that the GROUPING format did not have good performance characteristics in research, and that subjects reported that they found it too prescriptive. Some comments argued that it would be confusing to consumers in general, and one comment argued that it would be especially confusing to consumers with diabetes.

The agency agrees with these comments. FDA's research showed that the GROUPING format did not perform well on the dietary management tasks and did not offer any significant advantages over other formats (Ref. 70). In addition, although the format was not strongly disliked, many subjects who disliked it reported that they found it too prescriptive. This complaint is consistent with the complaints of many of the comments.

The agency has decided not to require that nutrients be listed under the

GROUPING format headings for the reasons discussed in the paragraphs above and below.

154. A few comments argued that the GROUPING format would be a challenge to implement because adequate consensus does not exist on where to place some subcomponents, such as polyunsaturated fats. In addition, comments challenged the format because its recommendations are not entirely consistent with those of the dietary guidelines. For example, the dietary guidelines recommend moderate intake of some nutrients, such as sodium, but the GROUPING format recommends low intake.

The agency agrees that the placement of some nutrients and nutrient subcomponents is problematic under the GROUPING format. This problem in placing all nutrients is one of the reasons the agency has decided against the GROUPING format.

155. Several comments in support of the GROUPING format argued that it provides nutrition education by stating which nutrients should be eaten in greater and lesser amounts. A few comments argued that the proposed order of nutrients on the label tends to group them into those targeted for lower and higher intakes, so that the GROUPING format is unnecessary with the new nutrient order.

FDA agrees that the intent of the grouping format is to provide general dietary guidance. However, the fact that the format did not offer significant advantages over other formats on any performance measure considered in the consumer research shows that dietary guidance as offered in this format did not benefit consumers. The proposed new order of nutrients uses the widely accepted design of placing first the elements of greatest importance and is intended to accomplish some of the goals of the GROUPING format. The GROUPING format's failure to convey the intended dietary guidance, as measured in the consumer research (Ref. 70), is one of the reasons the agency has decided against this format.

8. Modified Grouping Format

A few comments mentioned the Modified Grouping format in which the order of the nutrients changed according to the amount in the product.

156. Almost all comments were opposed to the Modified Grouping format. The major argument against it was that it would reduce consistency and increase confusion among consumers. Comments stated that using this type of format is especially difficult for older people, who have a particular need for nutrition information. As the population ages, larger numbers of consumers will have difficulty with such a format.

The agency agrees with this argument and notes further that available research shows that with advancing age, consumers have increasing difficulty extracting relevant information from displays in which the order of nutrients vary (Ref. 104).

The agency is not requiring the Modified Grouping format because it has no reason to believe that this format would meet the requirements of the 1990 amendments for the reasons stated above. The agency further notes that consistency of placement of nutrition information is a principle that has guided the development of the new format because such consistency has been shown to help consumers, as noted above.

9. CONTROL Format With DV Ranges

In its format proposal (57 FR 32058 at 32072), the agency discussed several alternative formats to those tested by the agency. For those reference values based on caloric intake, one alternative was the use of a range of DV's based on a caloric intake range instead of a single caloric intake value (Appendix E in the format proposal). The agency requested comment on this alternative.

157. Comments were evenly divided concerning the use of ranges for DV's. A number of comments, primarily from food industry representatives, supported the use of a range for the DV's because a range could assist consumers in realizing that nutritional needs vary with individuals, and ranges are easier for consumers to work with than single DV values. Others supported the use of a range because the use of a specific reference value would cause consumers to conclude that the values applied directly to them as individuals. Several comments suggested specific caloric ranges to be used (including 1600 to 2800, 1600 to 2400, and 1500 to 2800).

A number of comments from a variety of groups, including consumer advocates and the food industry, argued against the use of ranges. Reasons for opposing the use of ranges included concerns that ranges would be confusing to consumers, that they would overwhelm consumers, that they are too broad to be meaningful, that they use more label space than single values, that consumers would not be able to calculate their reference value from a range, and that they have not been evaluated in appropriately designed studies to determine if they would be more effective and less misleading than a single value. One comment cited research conducted for the purposes of developing a dietary guidance graphic (Ref. 105) that showed that consumers experienced difficulties using a range of values relative to dietary guidance.

FDA has carefully considered these comments and concludes that there is not sufficient support, nor a substantial rationale, for providing reference values as a range. The agency notes that no comment contained research or other data to substantiate the utility or appropriateness of ranges. No evidence shows that consumers do in fact find ranges easier to work with, and no data suggest that ranges are less likely than single values to confuse or mislead consumers. In fact, the agency has reviewed the literature on how people assign magnitude to numbers (e.g., Ref. 120). This literature concludes that in order to estimate magnitude, people generally have to answer the question, "compared with what?" usually invoking a norm or reference standard as a context for comparison. The DV is intended to be such a reference standard. When expressed as a range, the value of the DV as a norm against which the level of the nutrient can be understood is compromised because the norm cannot be easily identified without additional assumptions and computations. Thus, the use of ranges is inconsistent with the 1990 amendments, which require that nutrition information be conveyed in a manner that allows consumers to comprehend the nutrition information (section 2(b)(1)(A) of the 1990 amendments). Ranges apparently have the opposite effect.

The agency is also concerned that the use of ranges would mislead some consumers to believe that the consumption of a nutrient at any level within the declared range is appropriate for them. For consumers whose calorie intake is at the middle or low end of the range, however, the label could induce consumption of nutrients such as fat or saturated fat in excess of the dietary guidelines, which would adversely affect public health.

For these reasons, FDA has rejected the presentation of reference values as ranges. The argument that consumers need assistance to realize that nutritional needs vary with individuals has been addressed by requiring daily value information for 2,000 and 2,500 calorie diets.

10. CONTROL Format With Sex-specific Daily Values

158. A few comments supported reference values based on gender (Appendix E in the format proposal). One comment suggested that gender specific reference values were appropriate because women have

different nutritional requirements than men. Other comments opposed the use of separate reference values for men and women. The primary concerns were the issues of space, readability, and clutter on the label. One comment suggested that the format presented too much information for the consumer to process. The same comment opposed gender-based reference values because their use did not recognize that some active women are more like men in terms of their calorie need, while some older men have calorie needs more like those suggested for women. Several comments argued that gender is only one factor to consider in determining an individuals's dietary intake, and therefore its presentation on the label has the potential of inappropriately emphasizing one factor.

While the agency acknowledges that women in general have different nutritional needs than men, FDA notes that such comparisons can be made for a variety of groups comprised of persons 4 or more years of age. Thus, the agency agrees that the use of gender specific reference values may inappropriately emphasize only one factor in evaluating dietary intake. However, the agency agrees that examples of recommended nutrient amounts for different calorie level intakes may help consumers to estimate their personal daily recommendations. Therefore, as discussed in comment 139 of this document, FDA is requiring the inclusion of recommended nutrient amount information for 2,000 calorie and for 2,500 calorie diets in the nutrition information.

11. CONTROL Format With dietary guidance

159. A number of comments, primarily from industry, supported the CONTROL Format with Dietary Guidance (Appendix F in the format proposal). Several comments supported this format on the basis that it was most like the current format and therefore familiar to consumers. Two comments argued that FDA should select the CONTROL Format with Dietary Guidance because USDA prefers it, and harmonization between the two agencies is important. Supporting comments argued that this format helps consumers to put the food in the context of a total daily diet, reinforces the dietary guidelines, and is simple and uncluttered. One comment suggested that the caloric equivalents of the macronutrients may enable consumers to better utilize the information provided.

The major arguments against CONTROL with Dietary Guidance were that the information is too vague to be effective and adds clutter to the label. Some of these comments noted that the footnote discusses foods when the information on the label is about nutrients, so that, except for vague information about fat, no relevant information about recommended nutrient amounts is available on this label. Several comments argued that it would not be clear to consumers that the dietary guidance information applied to total diet and not to individual foods. Other comments noted that because this format has not been tested, the agency has no basis to assume that consumers will be able to relate the dietary guidance to the nutrition information. Comments also pointed out that many calculation steps and further instruction would be required to apply the dietary guidance to the consumer's daily diet.

Some comments noted that the dietary guidance footnote would be problematic for meat products because it recommends a diet high in vegetables, fruits, and grain products, which might imply to consumers that they should not eat meat.

The agency does not agree that CONTROL with Dietary Guidance format as shown in the format proposal is consistent with the requirements, or effective for meeting the objectives, of the 1990 amendments. The addition of the dietary guideline and calorie conversion information does not serve to put the levels of nutrients in the food into the context of a daily diet. However, the format includes information that helps consumers to understand the significance of the nutrient levels in the food.

Therefore, the agency is incorporating one of the elements from this proposed format as a mandatory requirement of the nutrition label format. Specifically, FDA recognizes that it will be useful to some consumers to have the caloric conversion factors on the label. The placement beside the nutrient names as shown in Appendix F of the format proposal is not acceptable, however, because the g/mg amounts will be placed beside the nutrient names in the required format. Both pieces of information on the same line would decrease or eliminate the spacing that helps to make the format comprehensible. Therefore, the agency is requiring that the caloric conversion factors be included on the nutrition label as a footnote, as described in § 101.9(d)(10).

12. New Formats Submitted as Comments

160. One comment suggested a format for the nutrition label quite different from any other format suggested and quite different from any format that had been previously tested. Called a graphical profile, the format expressed quantitative nutrition information in terms of distance along a spoke radiating from a central point, where each spoke represented a mandatory nutrient component. The points on each spoke were connected with each other to form a pattern that distinctively identified the nutrient profile for the product. The comment claimed that the format has a number of advantages, including: (1) Providing consumers with easily remembered mental "shapes" of the products that they wish to consume or avoid and (2) helping consumers to place the food in the context of a total daily diet by allowing for easy comparison between the shape of the nutrient profile for the product and an ideal shape based on dietary recommendations.

FDA is impressed by the ingenuity of this format but is convinced that such an innovative format for the nutrition label cannot be required without extensive consumer testing. No consumer research to support use of this format to accomplish the requirements specified in the 1990 amendments was submitted. Furthermore, FDA notes that the format encourages a comparison between the specific food and the dietary guidelines, whereas the recommended comparison is between the total daily diet and the dietary guidelines. Therefore, FDA is not adopting the graphical profile format. The agency is prepared to work with interested persons to develop consumer research that would show the usefulness and validity of this format.

H. Graphic Enhancements and Format Elements

The agency received numerous comments concerning the various format elements and graphic enhancements discussed and illustrated in the format proposal.

1. Format Legibility

161. Many comments, particularly from older and vision-impaired consumers and from organizations and health care professionals serving their needs, suggested that the legibility of nutrition information should be improved through regulations specifying larger sized or boldface type, easier to read type styles, use of upper and lower case letters, minimum type

spacing, and greater color contrast between print material and background, such as black lettering on white background. An alternative suggestion was for FDA to specify minimum print size and color contrast.

A number of comments from package designers and from individual food companies pointed to the problems in requiring graphic elements that add to the space requirements for the nutrition label, given the limited size of many packages and the competition for label space from other required or desirable information (e.g., UPC information, storage and preparation instructions, recipes). Other comments urged the agency to set minimal and flexible standards for graphic requirements related to readability that would allow manufacturers to accommodate the wide variation in package sizes, package shapes, and current graphic elements on packages.

The agency recognizes that mandating graphic elements to assure a desirable level of readability for the required nutrition information has both advantages and disadvantages, particularly when these elements may require more space. The agency agrees that some flexibility in the mandated graphical elements is necessary in order to accommodate the wide range of packages on which the information will appear. However, FDA also agrees with the comments that stated that the readability of the nutrition label needs to be improved to help older and vision-impaired consumers who otherwise would be effectively denied access to nutrition information of food packages. The agency points out that, as stated in the format proposal (section V.B.), certain graphic techniques go directly to the requirements in the 1990 amendments (section 2(b)(1)(A)) that the information be presented in a way that enables consumers to readily observe the information.

With the aim of achieving minimal readability standards for the required nutrition information, FDA has developed for use in this document, and in the presentation of the new label, a format design that incorporates many of the graphic elements suggested by the comments to produce a more readable label. FDA agrees with comments that argue that a consistent "look" to the required nutrition information on food packages will help consumers to find the information on the package and to recognize the information for what it is—a profile of the nutrient content of the food. Although FDA is providing for some flexibility in label execution, companies are encouraged to use this label as a model for designing labels for their packages (see section 101.9(d)). The specifications for this presentation of the graphical elements are included in the Code of Federal Regulations as appendix B to part 101.

FDA understands that some flexibility in execution of the nutrition label is necessary to accommodate various package sizes and shapes and current graphic features that serve as brand identifiers. For these reasons, a number of graphic alternatives to the model label are permitted. For example, § 101.9(d)(11) allows the footnote to be moved to the right of the percent DV information if space is not adequate beneath the vitamin and mineral information, and § 101.9(d)(8) allows for a vertical display of vitamin and mineral information when more than four vitamins and minerals are declared.

In addition, although the model label calls for dark or one color type on a white or neutral color background, flexibility in background and type color is allowed § 101.9(d)(1)(i). FDA is aware that some products traditionally use color as a brand identifier and print nutrition information in white or neutral color type on a darker color background. This type of graphic technique, called "reverse type," is known to have poorer readability characteristics than regular type. FDA is not prohibiting the use of reverse type. However, FDA expects that unless impractical, the nutrition information will be presented in dark type on a light color background. Impracticability is presented by situations like those described above, in those situations in which reverse type will be significantly less expensive than the FDA preferred alternative, or in other similar appropriate circumstances. If reverse type is used, FDA expects that the impairment in readability resulting from such a technique will be compensated for by the use of other graphic techniques to improve readability, such as increased type size. It will not be acceptable to reduce the contrast between print and background, whether by light letters on a light background or dark letters on a dark background, to the point where readability of the label is significantly degraded.

Although the agency is committed to the flexible application of graphic techniques to achieve an acceptable level of readability for the required nutrition information, FDA considers it necessary in order to ensure that the nutrition information is conveyed in a manner that enables the public to readily observe and comprehend such information to set minimal standards and requirements for certain key graphic elements of the nutrition label. Such requirements will prevent confusion about the minimal level of readability that is necessary for the nutrition information. The key graphic elements that are specifically required on all packages are set forth in §§ 101.9(d)(1)(ii), 101.9(d)(1)(iii), and 101.9(d)(1)(iv). They consist principally of type size and type style requirements, namely that a consistent upper and lower case type style be used, that a single, easy-to-read type style be used, that product information be in at least 8 point type (the lower case "o" no smaller than 1/16th inch) with at least 2 points leading (i.e., space above and below letters) and kerned (space between letters) no tighter than −4 setting, and that headings, certain nutrient names, and percentage amounts be highlighted by bolding or other form of highlighting.

In addition, to preserve a readily identifiable image or "look" for the label, a number of other graphic elements are required, as discussed in § 101.9(d)(1)(i), (d)(1)(v), (d)(2), and (d)(7)(ii). These sections require a hairline box to set off the nutrition information, hairline rules in certain places within the nutrition label, larger print size for the title, "Nutrition Facts," and display of the percent sign (%) after the numerical value of the percent DV for each nutrient.

FDA has been persuaded by comments and careful consideration of alternatives that these requirements will benefit a substantial number of consumers who currently have difficulty reading nutrition information on food packages. FDA considers this benefit to be worth the cost of the small increase in space allotted to nutrition information that may be required for some food packages. The agency notes that the previous regulations on type size also mandated a minimum type size for the lower case "o" of 1/16th inch but applied the same minimum type size requirement to the upper case "o" as well, which resulted in most manufacturers using all upper case type styles. The practical effect of requiring upper and lower case type styles and keeping the same minimum type size requirement will be to increase the minimum size of upper case letters by approximately 30 percent. To further compensate for the increased demands on label space, FDA will allow the information in the footnote, which unlike the product specific information is the same for all products, to meet or exceed a 6 point type minimum type size requirement. FDA considers that the requirements for upper and lower case type styles, leading, and kerning will enhance the readability of 6 point

type enough that it will not present problems for most consumers.

2. Other Graphic Enhancements

162. Several comments from retailers, manufacturers, graphics designers, universities, and a nutrition professional group were directed specifically at reverse printing as used in the graphic adaptations of appendix C of the proposal. Two comments stated that reverse printing would be helpful to consumers and should be permitted on a voluntary basis. However, the remaining comments addressed technical or legibility problems. Several comments stated that the format examples were not readable, that the reverse printing overwhelmed the smaller type, and that "stacked" titles (i.e., with components arranged vertically, e.g., placing "servings" on one line and "per container" on the next line) were confusing. The principal technical problem mentioned was that reverse printing tends to fill in and become unreadable, depending on the printing process used and available label area.

One manufacturer of many products stated that only two out of four printing processes used by the firm would be able to implement the graphic adaptations of appendix C. Another manufacturer stated that it would be able to print reverse graphics only for large containers. A graphics design firm stated that reverse printing adds significant costs. Another design firm cited two technical barriers to reverse printing: Multi-screen labels are difficult to hold in alignment and retain clarity, and reverse printing cannot be applied to packages with light backgrounds because the background must be dark for light, reverse print, to show through. The comments stated that many brand identification colors are light, and manufacturers object to having to change them, arguing that brand identification would be lost.

FDA agrees that reverse printing should not be required, given the difficulties mentioned in the comments. The agency finds convincing the arguments against the legibility of reverse print discussed in the professional literature (Ref. 107).

Because of the need for flexibility to place the nutrition panel in variously sized panels, the agency does not object to stacked titles.

163. The majority of comments stated that other kinds of graphic enhancement of nutrition information, such as underlining, bolding, and using larger type size or contrasting color, would encourage and assist consumers in using the information. However, opinions were divided as to whether the combination of enhancements illustrated in appendix C of the proposal would be helpful. A number of comments criticized the graphic adaptations as cluttered, jumbled, obtrusive, or distracting from or overwhelming the smaller type. However, except for a few suggestions that graphic enhancements be entirely at the discretion of the manufacturer, the comments favored some degree of standardization through FDA regulations. Comments frequently stressed the need for uniformity of appearance of labels across the food supply to facilitate education efforts and consumer access to and use of the nutrition information.

Several comments from consumers, a graphics designer, and a nutrition professional group stated that the number of different font sizes on a label should be minimized to ensure legibility. One comment cited a book in support of this view (Ref. 108). Several comments urged FDA to keep the label uncluttered. Other comments provided specific guidelines for maximizing the label's usefulness. These guidelines generally involved removing as much print as possible, keeping titles linear rather than stacking them, and including only essential information.

Several comments from industry and health education organizations endorsed voluntary, judicious use of other graphic enhancements such as spacing, indentation, use of upper and lower case letters, and selection of type face and size. These comments generally opposed making such enhancements mandatory until consumer research is conducted to ensure that they effectively aid consumer comprehension. Other comments from groups representing older readers and the vision impaired provided research demonstrating the importance of type size, type style, type spacing, the use of upper and lower case letters, and contrast between type and background to these readers. A consumer organization suggested that FDA establish an advisory committee of experts to provide guidance for the selection of graphic devices for further consideration. Two manufacturers opposed graphic enhancements altogether as contrary to the requirements of 1990 amendments for consistency in presentation of information. One comment characterized the combination of extreme bolding and close proximity of columns in the graphic adaptation of the PERCENT DV with DRV format as diverting attention from the quantitative values and stated that, with respect to the objectives of the 1990 amendments, the format constitutes near misbranding.

Based on the research submitted in comments, the agency is convinced that it can proceed to require certain graphic enhancements. While some comments questioned the appropriateness of requiring such enhancements at this time, other comments submitted research that demonstrated that these enhancements are effective and appropriate for creating a nutrition label that is readily observable and comprehensible, as required by the 1990 amendments. The agency agrees that keeping the format uncluttered is important and therefore has minimized clutter in the model format. The agency has carefully considered which format enhancements to combine, based on the comments and the research presented.

FDA is convinced that the specific elements mandated provide a visually integrated image that will give the nutrition label a uniformity of appearance across the various types of packages in the market and will enhance consumer use of the information. For example, an important element in the appearance of the nutrition label is its pattern of bolding. In § 101.9(d)(1)(iv), the agency is requiring bolding of the heading "Nutrition Facts" which is being employed as an identifying title, like a logo or trademark, to distinguish the nutrition label from other information on the package, as well as bolding of headings of certain nutrient names and percentage amounts. The agency is convinced that this and the other measures that it is requiring will serve to establish the readily identifiable "look" that it is seeking and finds to be necessary to achieve the relevant goals of the 1990 amendments.

164. Comments were received from a consumer, a health care provider, a State government agency, and two manufacturers suggesting that industry be permitted to use graphical devices, such as pie charts, to illustrate nutrient content claims. Comments suggested that uniformity of labeling could be maintained by requiring that any supplementary graphics be placed outside the nutrition label area. Other suggestions were that FDA permit the voluntary inclusion on the label of information from authoritative sources, such as the Dietary Guidelines for Americans (Ref. 4) or Diet and Health (Ref. 3), to aid consumer understanding of nutrition information in the broader context of current dietary advice to the public.

FDA has no objections to the use of graphic devices to amplify or explain nutrition information, provided that the

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illustrations are presented in a manner that is truthful and not misleading, and that the devices are not placed within the label area in which the nutrition information appears. The agency also agrees that supplementary information outside the nutrition label can help consumers better understand the characteristics of individual foods in relation to the total diet. However, such supplementary information must be consistent with the requirements for nutrient content or health claims that are established in companion documents published elsewhere in this issue of the **Federal Register**. Manufacturers are also encouraged to utilize other means to disseminate dietary guidance information, such as incorporation of such materials in promotional and print advertising materials or by means of shelf talkers and placards at point-of-sale.

165. Several industry comments requested that manufacturers be given flexibility, either in the case of small packages or in general, to declare vitamins and minerals and DRV's in either tabular or linear arrangement for both full and simplified formats. A manufacturer suggested permitting a linear array for micronutrients present at levels of at least 2 percent of the DV.

The agency agrees that manufacturers need flexibility in accommodating the required nutrition information, particularly for small packages and printable surface areas that are oddly shaped or narrow. Consequently, FDA is providing options in the display of a number of the types of information required. For example, in § 101.9(d)(ii), the agency is providing that the information about calorie-specific daily values and caloric conversion information may be placed beneath the vitamin and mineral declarations or to right of the Percent DV column. In § 101.9(d)(8), the agency is providing that the vitamin and mineral declarations may be presented vertically in the Percent DV column when more than four vitamins and minerals are declared or horizontally beneath the macronutrients. In § 101.9(f), the agency is providing for optional use of a simplified format under certain circumstances. In § 101.9(j)(13)(i), the agency is providing exemptions to the requirement to bear nutrition labeling for small packages, and in § 101.9(j)(13)(ii), the agency is providing options for intermediate sized packages to minimize the amount of label space that must be used for nutrition labeling. For small or intermediate sized packages, manufacturers may list nutrition information in a linear fashion, use certain abbreviations, omit the calorie-specific recommended nutrient amounts, or present the nutrition information on other label panels (see sections V.G.3., V.H.1., and V.J. of this document).

3. Highlighting

In the format proposal, the agency requested comments on the feasibility of allowing highlighting as a voluntary graphic enhancement of the principal format. Specifically, the agency requested comments related to whether the use of voluntary highlighting would confuse or assist consumers to observe and comprehend label information. Many different possible schemes for highlighting could be applied to the nutrition label. Many comments addressed noncontingent highlighting, in which certain material is highlighted regardless of any product characteristics, such as highlighting certain nutrient names (e.g., fat, sodium, cholesterol) or titles (e.g., Percent DV, Amount per serving) on the nutrition panel. Other comments addressed contingent highlighting, in which certain material is highlighted only if the product has certain characteristics, such as highlighting the nutrition information for fat on the label of a product that meets FDA's criterion for low fat. In it's research, the agency tested a contingent highlighting scheme that highlighted nutrients whose levels in the food qualified for adjectival descriptors (high or low depending on the nutrient) that were consistent with dietary guidelines.

Many different possible techniques of highlighting exist, including boldface print, all capital letters, italic print, larger print, reverse print, different colored print, and color banding. In the format examples published in the format proposal, only boldface print was used for highlighting.

166. Many of the comments that discussed noncontingent highlighting suggested that highlighting should be considered as a format enhancement and should be used for column headings and names of nutrients. Other comments argued that the agency should require the highlighting of certain nutrients because of their health significance regardless of the level in the product. The nutrients most frequently mentioned in the comments in this regard were those associated with chronic disease, such as sodium, fat, and cholesterol. Most of these comments suggested that boldface type and all capital letters are adequate to achieve such highlighting.

Several comments addressed the issue of whether noncontingent nutrition label highlighting should be mandatory or voluntary. Some manufacturers objected to any required highlighting because of the increased cost and increased label space required. Other comments argued that if highlighting is allowed at all, it should be mandatory so that the benefits of highlighting would be universally available to consumers, and so that labels would be uniform. Some of these comments argued that uniformity of labels is important to reduce consumer confusion.

The agency agrees than mandatory highlighting imposes some burden on manufacturers and needs to be justified on the basis of obvious benefits to consumers. The agency also agrees that the use of highlighting to enhance column headings and nutrient names can increase the visual interest of the label and make it more legible for some consumers.

However, the agency is concerned that allowing too many optional highlighting schemes will lead to less consistency between labels, and that highlighting has the potential to increase label clutter and consumer confusion. Therefore, in § 101.9(d)(i)(iv) the agency is requiring mandatory highlighting of the title of the nutrition panel, "Nutrition Facts", headings ("Amount per serving" and "% Daily Value"), nutrient names ("Calories", "Total Fat" "Cholesterol," "sodium," "total Carbohydrate," and "Protein") and percentage amounts for certain nutrients. The agency concludes that these requirements, by establishing a specific "look," strike an appropriate balance between establishing a nutrition label that is readily observable and one that only increases clutter and confusion.

The agency does not agree that nutrients associated with chronic disease should be highlighted. The agency notes that the revised order of the nutrients already calls attention to the nutrients of major public health significance.

167. Several comments supported or opposed the voluntary highlighting of certain nutrients based on their level in the product (contingent highlighting). Supporting comments, primarily from food manufacturers or trade associations, argued that allowing such highlighting would provide useful information to consumers. Opposing comments, primarily from health professionals, professional associations, and consumer advocate or health promotion organizations, argued that allowing contingent highlighting on a voluntary basis would likely lead to inconsistent and possibly self-serving

highlighting that would be more likely to misinform than inform consumers.

Several comments supported contingent highlighting but recommended that it be subject to the definitions used in FDA's research studies or to the requirements for nutrient content claims, because highlighting is a nutrient content claim. Related comments supported a link between a nutrient content claim on the front panel and highlighting the relevant information on the nutrition panel. For example, if a low fat claim is made on the front panel, the nutrition information for fat would be highlighted.

Some comments recommended that highlighting of undesirable rather than desirable aspects of foods be required because manufacturers will emphasize the good qualities, and such highlighting will provide a balance. In contrast, a trade association commented that the highlighting of "bad" nutrients should not be required because it would be misleading. Another comment suggested that highlighting be allowed only on a case-by-case basis so that both FDA and food manufacturers have maximum flexibility.

Some comments opposed highlighting and argued that attention should be drawn to specific nutrient levels by nutrient content claims rather than by highlighting. Other comments argued that the highlighting of positive information only will accentuate benefits without including information about risks and will lead consumers to ignore vital information on negative aspects of certain products. Several comments from industry were opposed to contingent highlighting because it would communicate a good food/bad food message. Several comments stated that highlighting will imply an educational message which is more appropriately addressed in educational materials.

Other comments opposed highlighting because, they claimed, FDA will not have adequate enforcement resources. Permitting voluntary highlighting will open the door for inappropriate use of highlighting, which will then require additional regulatory intervention. Another comment, consistent with comments about other forms of dietary guidance on the label, argued that selective highlighting based on current dietary recommendations will change over time, and that it is unwise to include shifting format elements on the label.

FDA is not persuaded by the comments that contingent highlighting on the nutrition label will benefit consumers. Consumer research did not find that contingent highlighting increases effective use of the nutrition label for product comparison or dietary judgment uses (see section V.D.2.a. and V.D.2.b. of this document). There is no consensus among the comments, and the consumer research does not support that requiring a particular contingent highlighting scheme is appropriate. FDA is persuaded by comments that voluntary contingent highlighting can be applied inconsistently in a way that would be potentially misleading to consumers. Among products with similar nutrition profiles, some would highlight certain nutrients and others would not. Consumers who read nutrition labels could not depend on the fact that all labels of similar products would look the same, and the differences could undermine the credibility of the information on the nutrition label and lead to consumer confusion.

The inconsistency of labels that would result also leads the agency to disagree that highlighting should be allowed on a case-by-case basis. Consistent treatment of similar information is important for effective use of the nutrition label by consumers. FDA agrees that attention can be drawn to the levels of specific nutrients in a food by nutrient content claims rather than by highlighting information on the nutrition label. Because of problems of inconsistent treatment of similar information and the lack of demonstrated benefits in the research, FDA is not allowing the use of contingent highlighting on the nutrition label.

4. Adjectives

168. A majority of the comments that addressed the issue of adjectives were in favor of their use in some context. Several consumer groups recommended that the PERCENT DV with DRV format be enhanced by a footnote providing FDA's definition of high and low for nutrients. The comments argued that adjectives help consumers to make qualitative judgments about the food without having to make calculations or evaluate percentages. Some comments noted that the ADJECTIVE format was the most preferred in FDA's research.

In contrast, comments opposed to adjectives in the nutrition label argued that they clutter the format and would be redundant with PERCENT DV formats. Comments also expressed the concern that the wide range of values that will fall in the medium category may mislead consumers.

The agency does not agree that there is a need to include adjectives on the PERCENT DV with DRV format. The agency's research showed that consumers are able to make accurate high/low judgments using percents alone, and that when consumers relied on adjectives (see section V.D.2.a. above), they tended to overlook nutrient differences if the nutrients were described by the same adjective. The additional words would add clutter to the label without benefit to consumers. Therefore, FDA is not providing for the addition of adjectives to the PERCENT DV with DV format.

I. Dual Declarations

A few comments raised format issues with respect to foods that use dual declaration displays on the nutrition label (i.e., nutrition information declared both on as packaged/as prepared or per serving/per 100 g bases) A number of issues related to the topic of dual declarations are discussed in detail in the companion document on serving sizes published elsewhere in this issue of the **Federal Register**. FDA recognizes that such displays raise special format issues, and these are discussed here.

169. One trade association comment urged that FDA consider the label space requirements of dual declaration formats before deciding to require a change in the current nutrition label format. Several comments stated that the PERCENT DV with DRV format would not leave room enough for both "as packaged" and "as prepared" columns on nutrition labels. One industry comment stated that industry sponsored research has shown that the PERCENT DV with DRV format becomes particularly complex and cumbersome when used on food labels using dual declaration displays.

FDA agrees that dual declaration displays have much greater space requirements than the single base display required for most food products. FDA notes, however, that dual declaration displays are voluntary, not mandatory. For this reason, FDA does not agree that the requirements of dual declaration displays should be a determining factor in the decision about the nutrition label format. However, FDA does agree that the unique requirements of dual declaration displays should be accommodated as much as possible within the constraints of the format that is required for all nutrition labels, and the agency therefore has created a new section, § 101.9(e), to specifically address the format of the nutrition label when dual columns are utilized.

FDA notes that several studies submitted as comments or listed in the format proposal found that dual

declaration displays of any kind made the product nutrition label significantly harder for consumers to use and understand (see section V.D.2. of this document). The execution of dual declaration displays for the PERCENT DV with DV format in the GMA/NFPA industry study (Ref. 71) demonstrated the problem with multiple column displays on the nutrition label. In that study, a number of the dual declaration displays placed both g/mg and PERCENT DV declarations in separate columns on the nutrition label, resulting in as many as five columns of information when DV's were listed. The display was complex and cumbersome, but it is not the only, and certainly not the best, way to execute the PERCENT DV format with dual declarations.

FDA's execution of the PERCENT DV format in Study 2 (Ref. 70) purposely arranged the percent declarations in two columns and presented a single g/mg declaration per nutrient in a noncolumn array next to the nutrient name so as not to intrude visually on the columns of percents. With this execution, the PERCENT DV with DRV format performed as well as other formats on labels using dual declaration displays. The agency is convinced that dual declaration executions of the PERCENT DV with DV format should follow the pattern of minimizing the number of columns displaying nutrient amount per serving information. Accordingly, in § 101.9(e) the declaration of the required g/mg nutrient amounts on dual declaration nutrition labels is required to follow the same requirements as for single declaration nutrition labels, which is to be in an unordered array next to the nutrient name. Placement of optional g/mg amounts is discussed in comment 170 of this document.

170. A comment argued that declaring two g/mg amounts in parentheses next to the nutrient name as proposed in the dual declaration format example included in the format proposal looks like "matrix coordinates" and is likely to be confusing to many consumers. One comment suggested an alternative for presenting dual declaration g amounts. The comment suggested that only the g/mg amounts of the product as packaged be in the table, and that a footnote provide the additional amounts in the second declaration for the food.

FDA agrees that even when presented in a noncolumn array, the declaration of two g/mg amounts for each nutrient on the nutrition label (e.g., one each for as packaged/as prepared or per serving/per 100 g) in addition to two columns of percent DV amounts for nutrients having DV's is likely to be cumbersome and confusing to some consumers. Based on the research findings (see section V.D.2. of this document), FDA is confident that a single g/mg amount declared in a noncolumn array does not have a detrimental effect on consumers' abilities to understand and use the nutrition information on the label, but FDA did not test a format with two g/mg amounts for each nutrient. FDA is convinced by this comment that only a single g/mg amount (as packaged and according to the label serving size based on reference amounts in § 101.12(b)) for each nutrient should be required in dual declaration labels. The second set of g/mg amounts may be presented optionally next to the required g/mg values, differentiated from them by a comma or other means. Alternatively, the second set of g/mg amounts may be presented in a footnote. When the second set of g/mg amounts is presented in a footnote, either the total amounts or the additional amounts may be declared. When the additional amounts are declared, only those nutrients that are present in different amounts than the amounts declared in the required g/mg information may be listed. The footnote must clearly state which amount is declared. The agency has included this provision in § 101.9(e)(3)(i).

Examples of nutrition label formats for products using a dual declaration display that conforms to the new regulations are presented in appendix E.

J. Simplified Format

Most comments from consumers, industry, and professional organizations supported the concept of using a simplified format stating that it is easier for consumers to understand, cuts down on label clutter, and gives manufacturers flexibility in preparation of labels. The comments and FDA's response to concerns raised by the comments are summarized below.

1. Terminology

171. A few comments commended FDA and USDA for attempting to bring consistency to nutrition labeling regulations by allowing for similar types of simplified formats but requested that the two agencies use the same term rather than "simplified" format in FDA regulations and "abbreviated" format in USDA regulations.

Both FDA and USDA are in agreement with these comments. In accordance with the language in the 1990 amendments, they will use the term "simplified" format. However, because the foods regulated by each agency are different, the specific regulations pertaining to the simplified format will differ somewhat by agency.

2. Required Use and Criteria

172. Several comments disagreed with FDA's interpretation of that part of section 403(q)(5)(C) of the act which states "the Secretary *shall require* the amounts of such nutrients to be stated in a simplified form * * *" (emphasis added) to mean that foods that qualify for the simplified format must use that format, i.e., they may not choose to use the full nutrition labeling format. These comments urged that use of the simplified format be optional as, in some instances, consumers may be better served by one uniform nutrition label, and manufacturers should be given the flexibility to meet consumer preferences. In support of such labeling being voluntary, the comment cited the following legislative history:

> However, the bill provides that the Secretary *may permit* the information to be included on the label or labeling in a simplified form if a food contains insignificant amounts of more than one-half of the nutrients required to be on the label. (emphasis added)

(Ref. 16)

FDA advises that the draft legislation was revised by the Senate subsequent to the above House report to replace the word "may" with "shall" and to add that the form of the simplified format was to be "prescribed by the Secretary" (136 Congressional Record, S. 16607 (Oct. 24, 1990)). The changes were not explained in legislative history, so that the intent of Congress is not clear. The agency acknowledges that it is possible that Congress was merely trying to require that the final regulations provide for a simplified format rather than requiring that the format be used whenever a food met the qualifying criteria. In fact, inasmuch as the intent of the 1990 amendments was to increase the amount of nutrient information provided to consumers, it is not entirely consistent that the act would require less information on certain foods.

Based on reassessment of the statute and its legislative history in response to the comments, FDA concludes that use of the simplified format should be at the manufacturer's discretion, whenever a food product meets the criteria of containing insignificant amounts of half of the required nutrients. Accordingly, FDA has modified § 101.9(f)(1) by changing the word "shall" to "may."

173. A comment from a consumer group suggested that FDA require a different base than one-half of all 15 required nutrients for determining if a product qualifies for the simplified format because using all 15 nutrients results in "double-dipping." The comment suggested that calories from

fat should not be included because total fat represents the same nutrient, and that total carbohydrate should also not be included because complex carbohydrate and sugars comprise total carbohydrate. The comment stated that this procedure would result in a base of 13 different nutrients, of which seven must be present in insignificant amounts to qualify to use the simplified format.

FDA agrees that counting both "total fat" and "calories from fat" for the purpose of determining whether a food qualifies for use of the simplified format results in a double count being given to the fat content of a product. The agency, therefore, has deleted calories from fat from the qualifying criteria. However, in the case of "total carbohydrate," the agency notes that § 101.9(c)(6) is revised to delete "complex carbohydrate" as an element of nutrition labeling. Although "other carbohydrate" replaced "complex carbohydrate," the declaration of "other carbohydrate" is not mandatory. Therefore, the required subcomponents in § 101.9(f) no longer comprise the total amount of the component "total carbohydrate." Accordingly, "total carbohydrate" must continue to be included among the nutrients used as a base for determining whether a food qualifies for use of the simplified format.

The deletion of "calories from fat" and "complex carbohydrate" results in a base of only 13 nutrients. According to section 403(q)(5)(C) of the act, the simplified format is to be allowed if a food contains insignificant amounts of "more than one-half the nutrients required * * *." Therefore, it follows that the simplified format may be used when a food contains insignificant amounts of seven or more of the base nutrients.

As a result, and in accordance with the reordering of nutrients in § 101.9(c), FDA has modified § 101.9(f) to state that the nutrition information may be presented in a simplified format "when a food product contains insignificant amounts of seven or more of the following: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron."

Although FDA has deleted "calories from fat" from the list of nutrients in § 101.9(f) used to determine when a product may use the simplified format, "calories from fat" continues to be a nutrient that must be declared under section 403(a) of the act in nutrition labeling when present in more than insignificant amounts. Therefore, FDA has modified § 101.9(f)(3)(ii), redesignated as § 101.9(f)(2)(ii), to require declaration of calories from fat in addition to any other nutrients identified in § 101.9(f) that are present in more than insignificant amounts. For the same reason, the agency has modified § 101.9(f)(4) to require calories from fat to be included in the statement "not a significant source of _____" if it is present in insignificant amounts.

174. One comment requested that FDA confirm that eligibility for use of the simplified format is not limited to those foods listed in the supplementary proposal as examples of foods that would use the simplified format (56 FR 60421 at 60474), but that the use of a simplified format is determined on a product-by-product basis.

FDA advises that the interpretation in the comment is correct. The determination that a food qualifies for the simplified format is dependent on the amount of nutrients in that food.

175. Some industry comments requested that FDA provide guidance on how the simplified format applies to foods for children under two years of age as these products are exempted by proposed § 101.9(j)(4) from labeling of calories from fat, saturated fat, and cholesterol, all of which are included in the list in proposed § 101.9(f)(1) of the 15 "required nutrients." Comments questioned whether the stipulation of insignificant amounts of eight or more required nutrients for the simplified format applies to such foods and if it does apply, whether calories from fat, saturated fat, and cholesterol are included in the eight insignificant nutrients, even though they are not required to be labeled.

In developing the proposed rules, FDA did not consider the application of regulations governing the use of the simplified format to foods for children less than 2 years of age. Since these foods have a required base of only 11 nutrients (i.e., calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron), it is appropriate that they be allowed to use a simplified format when more than one-half (i.e., 6) of these 11 nutrients are present in insignificant amounts. Section 101.9(f) has been modified to include this provision for foods for children less than 2 years of age.

3. Definition of "insignificant amount"

176. A few comments recommended changes in FDA's proposed definition of "insignificant amount" of a nutrient as that amount that allows a declaration of zero in nutrition labeling. The term "insignificant amount" was used in section 403(q)(5)(C) of the act in reference to when a food would be exempt from nutrition labeling (proposed § 101.9(a)) and to when a food would qualify for the simplified format (proposed § 101.9(f)(1)). Comments on both uses of the term are discussed in this section to ensure consistent use of the term.

A few comments stated that the use of a mathematical base for determining "insignificant amounts" does not consider the actual need for the nutrients in the maintenance of good health, and that because FDA proposed to define "source" as from 10 to 19 percent of the RDI or DRV, anything less than 10 percent should be "insignificant." Other comments recommended the level of insignificance be changed to 0.5, 2, 5, or 8 percent of the RDI or DRV for particular nutrients. Another comment noted that defining "insignificant amount" as an amount less than 0.5 g of carbohydrate and protein is in conflict with the definition of "insignificant amount" for calories as less than 5 calories, given that 1 g of carbohydrate and protein furnishes only 4 calories. A comment also stated that, as a practical matter, consumers cannot reasonably be expected to differentiate between 0.5 g amounts.

FDA did take maintenance of health into consideration when it based its proposed definition of "insignificant amount" for calories (including calories from fat), total fat, cholesterol, sugars, and sodium on the amount defined as "free" under the proposed nutrient content claims rule (see final rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" published elsewhere in this issue of the **Federal Register**). (In addition, in the final rule on nutrient content claims, FDA defined "saturated fat free" as less than 0.5 g of saturated fat per serving.) For most nutrients, FDA has determined the level that is dietetically trivial or physiologically inconsequential (56 FR 60421 at 60433) and has established those levels as the "free" levels. Therefore, for those nutrients for which a level of "free" has been defined, FDA is denying the request to change the definition of "insignificant amount."

For those macronutrients that are required to be included in nutrition labeling but that do not have definitions of "free" levels (i.e., total carbohydrate, dietary fiber, and protein), FDA has reconsidered the proposed amounts and, in accordance with the comments, it is specifying in § 101.9 (f)(1) and (j)(4) that an insignificant amount of these nutrients is "an amount that allows a declaration of less than 1 g." Because 1 g of each of these food components

yields 4 calories, this amount is closer to the amount that will yield an "insignificant" amount of calories. By doing this, differentiation of amounts of 0.5 g will no longer be necessary.

In the case of vitamins and minerals, which also do not have definitions of "free" levels, FDA is not persuaded that amounts less than the amount defined as a source of a nutrient (i.e., less than 10 percent of the RDI) in § 101.54(c)(1) in the document on nutrient content claims published elsewhere in this issue of the **Federal Register** can be considered "insignificant." In fact, assuming that as many as 20 foods are consumed in a day (Ref. 109), levels of 5 percent or more of the RDI per food would be sufficient to assure that a person's daily requirements were met. Therefore, FDA rejects the suggestions that amounts greater than 2 percent but less than 10 percent of the RDI be considered insignificant.

177. One comment expressed concern about a potential compliance problem with § 101.9(f)(1) for firms who elect to "round down" Class II nutrients under § 101.9(g)(4)(ii) and to "round up" calories, sugars, total fat, saturated fat, cholesterol, or sodium under § 101.9(g)(5). The comment stated that by defining "insignificant" based on analytical capabilities while at the same time requiring that the simplified format be used, a firm could find itself in violation of § 101.9(f)(1) by either claiming that it is required to use the simplified format, or by asserting that it must use the complete nutrition format.

FDA does not believe its proposed definition of "insignificant" has any bearing on this concern because the concern could exist at any defined level. However, the amendment of § 101.9(f)(1) discussed above, whereby the simplified format is allowed, not required, on foods that meet the qualifying criteria, resolves the comment's concerns for Class II nutrients. For other nutrients, FDA advises that firms should determine label values to be in compliance with § 101.9(g) and then determine, based on those values, whether or not a food qualifies to use the simplified format.

4. Nutrients To Be Declared

178. While most comments supported the required declaration of "core" nutrients (i.e., calories, total fat, total carbohydrate, protein, and sodium) in the simplified format, a few comments requested that the proposed mandatory declaration of the "core" nutrients be deleted. Comments from firms manufacturing honey, chewing gum, and spices requested that FDA adopt a more simplified format for foods that have very limited nutritional value. These comments requested that only those nutrients that are present at more than insignificant levels be required to be declared. For example, chewing gum would declare only calories and carbohydrates, and seasoned salt only sodium.

FDA is not persuaded that it should drop the requirement for declaration of the core nutrients. This core information is essential to aid consumers in learning about the relative nutritional qualities of all foods, and it allows them to judge the consequences of the food selections they make. Most comments supported this position. Also, as discussed above in this section on format, consistency in presentation is a principle that has guided the agency in developing the new format because such consistency has been shown to help consumers. Therefore, FDA is not making the requested change.

179. A few comments from the soft drink industry expressed opposition to mandatory listing of sugars in the simplified format stating that it is not consistent with the intent of the law which is to enhance consumers' understanding of sound dietary practices. The comments contended that mandatory declaration of sugars places undue emphasis on a nutrient that does not warrant such emphasis in light of its physiological impact. One comment explained that the greatest concern posed by sugars is their potential carcinogenicity which, considering the rapid passage of soft drinks through the mouth, is significantly lower than other sugar-containing foods.

A comment from the honey industry also objected to required declaration of sugars on honey products on the basis that it "could mislead consumers into thinking that the honey had been manufactured from what consumers most likely regard as 'sugar'—table sugar."

As discussed in section III.F.3. of this document, the agency has concluded that the mandatory declaration of sugars content in nutrition labeling is consistent with the law. In regard to the simplified format, the 1990 amendments and its legislative history give no direction on the content of the simplified label, only that it be "in a simplified form prescribed by the Secretary." Based on the criteria Congress put on the use of the simplified format, it is possible to infer that its purpose is not to save space on the label nor to allow the declaration of otherwise mandatory nutrients to be omitted, but rather to modify the label by allowing nutrients not present in significant amounts to be omitted. FDA does not believe that the legislation allows it, or that there is any reason, to permit a nutrient that is required to be declared in complete nutrition labeling to be omitted from the simplified format when that nutrient is present in more than insignificant amounts.

In response to the comments from the honey industry, FDA acknowledges that consumers must be made aware of the different purposes of the ingredient statement and the nutrition label and be taught how to use the information in each. Developing this awareness will be a component of the consumer education program discussed in section IX. of this document.

The comment presented no data to show that consumers will be misled by a declaration of sugars in the nutrition label. As discussed in section III.F.3. of this document, FDA believes that sugars should be a mandatory component of nutrition labeling because it will assist consumers in planning diets that conform to current dietary guidelines and is of great interest to consumers. Therefore, FDA finds no basis not to require that sugars be treated in the nutrition label of honey as they would be in the nutrition label of any other product that is a natural source of sugars, such as fruits.

5. Use of statement "Not a Significant Source of"

A number of comments were received that addressed the requirement in § 101.9(f)(4) that the simplified format include the statement "Not a significant source of _____," with the blank filled in with the name of the missing nutrient, when additional nutrients are voluntarily added to the food or declared in the simplified format.

180. Many comments on this subject supported the proposal. However, a few comments from consumers, health professional associations, and industry suggested that all simplified labels should include a statement identifying those nutrients present in insignificant amounts, such as "Not a significant source of _____." One comment stated that consumers may be misled by the missing information unless the nutrients that are not present are identified. Two other statements that were suggested were: "This product does not provide you with any _____" where the blank is filled in with the names of nutrients present in insignificant amounts, or a statement that informs consumers that "This food contains less than ½ of the nutrients required for full nutrition labeling."

FDA is not persuaded that consumers will be confused by the absence of certain nutrients on simplified labels.

Most of the foods that will be able to use this format are basic commodities or simple foods (e.g., oil, butter, sugar, syrups, juices, drinks) for which it is reasonable to expect that consumers will know that the missing nutrients are not present in the food. Therefore, in response to the Congressional intent that the label be "simplified," the agency is not making the suggested change.

181. Other industry comments generally opposed requiring such a statement when additional nutrients are voluntarily added to the food or declared in the simplified format on the grounds that it clutters the label with a long list of nutrients that are not present. One comment stated such a requirement is discriminatory, especially if the additional nutrient is declared because of a nutrient content claim. Another comment suggested that simplified labels that declare naturally occurring nutrients be treated differently from those that declare added nutrients. Several comments suggested that the statement "Not a significant source of other nutrients" be used in lieu of the proposed statement as this would provide consumers information without cluttering the label.

FDA disagrees with the comments. When nutrients are voluntarily added to a food or voluntarily declared in the nutrition label, or when a nutrient content claim is made on the label, the food is being marketed as a significant source of nutrients. In such cases, the food label would be in violation of section 201(n) of the act unless consumers are advised about the full nutritional profile of the food.

FDA shares the concern about the space required by the list of nutrients not present. However, the statement "Not a significant source of other nutrients" is too broad and therefore could be misleading on a large proportion of foods. Even though the food may not contain significant amounts of the nutrients required in § 101.9(c), it may contain significant amounts of other essential nutrients that are not required to be declared in nutrition labeling. The language suggested by the comment, however, asserts that the food is not a source of any other nutrients. Thus, to determine whether such a statement is true, it would be necessary to analyze for all known essential nutrients. The agency believes that such a situation makes no sense and therefore is not making the suggested change.

182. One industry comment opposed the exemption of standardized enriched foods from the required statement "Not a significant source of _____," stating that there is no basis for treating different food products (i.e., nonstandardized enriched foods) discriminatorily. Another comment wanted FDA to state that the addition of a nutrient such as vitamin C to a food, if required by a standard of identity or another government standard (i.e., a purchase specification to qualify for use in the Special Supplemental Food Program for Women, Infants, and Children (WIC)) would not require the statement "Not a significant source of _____."

FDA is persuaded that foods containing added vitamins and minerals, whether under a food standard or not and whether required by purchase specifications or not, should be treated similarly. Therefore, FDA has modified proposed § 101.9(f)(4) to require that if any vitamins or minerals are declared as part of the simplified format for any reason, the statement "not a significant source of _____" shall be included at the bottom of the nutrition label. This statement is also required if any additional naturally occurring nutrients are voluntarily declared in the simplified format. To clarify the regulation, the requirement that any added vitamins and minerals must be declared as part of the simplified format is removed from proposed § 101.9(f)(4) to become new § 101.9(f)(2)(iv). Additionally, § 101.9(f)(4) is subdivided into § 101.9 (f)(3) and (f)(4).

6. Format for the Simplified Label

183. Many comments from industry responding to the supplementary proposal were opposed to requiring the DRV list in the simplified format, arguing that such a required list would considerably expand the simplified format and therefore defeat its purpose.

A few comments responding to the format proposal argued that examples of simplified formats illustrated at appendix D of the proposed rule were merely abbreviated versions of the nutrition label format and not simplified formats as called for by the 1990 amendments. These comments were particularly critical of the inclusion of the listing of DRV's in the simplified format because they argued that an abbreviated list of DRV's would communicate incomplete, and therefore misleading, information about a total daily diet. Other comments supported the examples of simplified formats in the proposed rule on the grounds that they eliminated unnecessary information but retained a consistent appearance with the regular format.

FDA agrees that an important consideration for the simplified format is that it retain common elements with the regular format to facilitate consumer understanding and use of the nutrition information. FDA does not agree that section 403(q)(5)(C) of the act requires a simplified format that is simpler in other respects than being an abbreviated version of the regular format. As discussed in comment 179 of this document, the 1990 amendments and their legislative history give no direction on the content of the simplified format. However, FDA agrees with the concern expressed about the value of an abbreviated list of DRV's. After careful consideration of the comments, the agency is convinced that by declaring quantitative amounts as percent of Daily Values, the simplified format will retain sufficient common elements with the regular format to facilitate consumer use and comprehension. The agency is also convinced that not requiring the full footnote and calorie conversion information required in § 101.9 (d)(8) and (d)(9) on the simplified format will not sacrifice important objectives of the legislation because the information is not specific to the particular food and is available on a significant portion of the food supply. Therefore, FDA is requiring in § 101.9(f)(5) that a simplified format contain only quantitative and Percent of Daily Value information in the same format as required for full or dual nutrition labeling in § 101.9 (d) and (e), respectively.

184. Comments to the format proposal addressing the use of the simplified PERCENT DV formats generally preferred the use of columns rather than the in-line presentation. Comments stated that the in-line presentations appear significantly more difficult to use and make it difficult to distinguish the actual quantitative amounts from the DRV's. One comment was received from a consumer interest group opposing the line concept on the grounds that it is difficult to read, confusing, and will allow a company to hide the content of fat, sodium, or other undesirable nutrients in the product. The comment maintained that if a line format is allowed, it should only be permitted when no additional voluntary disclosures are made. The comment stated that such additions would make the nutrition information comparable in length to the required format, and FDA has already determined that the required format would not be legible in a line format. However, several industry comments were received in support of allowing the abbreviated nutrition information to be presented in either vertical columns or lines because of the

flexibility and saving in space provided in this option.

FDA agrees that, where label space is adequate, the simplified label is best understood when the information is presented in columns, particularly when additional nutrients are voluntarily disclosed. However, as discussed in section VI.K. of this document, the agency is aware that special allowances are necessary on labels of small or intermediate sized packages. Therefore, in § 101.9(f)(5) the agency is requiring that nutrition labels on products qualifying for the simplified format present the required information in the same format as is required in § 101.9 (d) and (e) for other packaged foods, except that foods in small and intermediate sized packages that come under § 101.9(j)(13) are allowed by that section to present the information in a linear fashion. Examples of simplified formats are seen in appendix F.

185. One industry comment said that while it supported the simplified nutrition label format for sugar, this format, as depicted in the proposal, may be confusing on labels of soft drinks because consumers may conclude that the soft drink has 36 g carbohydrate and 36 g sugars. If sugars are required to be listed, the format should provide for indentation that would clarify that sugars are a subcategory of total carbohydrates.

FDA agrees that the format must allow for subcomponents to be indented under the primary component. Accordingly, § 101.9(c)(6)(ii) specifies that sugars are to be indented under total carbohydrate. A similar requirement is specified for each subcomponent. In addition, § 101.9(d)(1)(iv) requires the primary component to be highlighted to further differentiate it from its subcomponents.

VI. Exemptions and Special Conditions

A. Small Business

The 1990 amendments granted an exemption from mandatory nutrition labeling for small businesses. Under section 403(q)(5)(D) of the act, a small business is defined as a business with less than $500,000 annual gross sales of food or any commodity, or a business with annual gross sales of more than $500,000 but less than $50,000 in food sales. The exemption does not apply to those products that make nutrition claims or provide nutrition information.

186. Many comments from industry, trade associations, and international organizations have stressed that the dollar exemption limits in proposed § 101.9(j)(1) that implement the 1990 amendments are too low. The comments note that the sum of analytical, printing, and other costs of nutrition labeling are prohibitively expensive for low volume products. Many small food producers that exceed the $500,000/$50,000 sales limit report that they will suffer a severe economic hardship if forced to comply with the nutrition labeling rules. One comment stated that without an increased exemption, 25 percent of food businesses in Kansas would close. Retail bakery and confectionery trade groups stated that the nature of their business dictates that they offer hundreds of different products throughout the year, and that limiting and standardizing product lines would cause a retail operation to lose its character and appeal. Yet, the need to nutrition label products would force such standardization. Other consequences for small businesses that would not qualify for the exemption that were identified in the comments included the loss of a substantial portion of annual profits, loss of low volume product lines, and small business failure.

FDA has considered these comments and believes that there is merit in many of the contentions they raise. To gain adequate information on what to recommend as a reasonable and appropriate adjustment to the 1990 amendments' standard, FDA participated in a series of public forums that had been scheduled by USDA to discuss the small business issue. These forums were held in May, 1992, in Kansas City, MO; Atlanta, GA; and San Francisco, CA. In a notice of the public forums (57 FR 19410, May 6, 1992), FDA announced its participation in the forums and requested comment on a number of issues, such as which option should be used to amend the current statutory exemption—increasing the gross annual sales exemption, providing an exemption based on the number of units sold of a particular product line, basing the exemption on the number of employees, or any combination of such options. Comments were also requested on the feasibility of compliance with various limits and the effect on the percent of the diet bearing nutrition labeling.

The agency has compiled the information it received. However, at the current time the agency is constrained by the requirements of section 403(q)(5)(D) of the act. Therefore, § 101.9(j)(1)(i) has not been changed. If Congress amends the statute, FDA will implement the change as soon as possible thereafter.

187. Comments have questioned FDA's interpretation of that part of section 403(q)(5)(D) of the act that states "If a person offers food for sale * * * or has business done in sales to consumers" to mean that foods produced by small businesses that are exempt would have to bear nutrition labeling if they were sold by a larger retailer who was not exempt. The comments stated that this interpretation would have a devastating impact on many small entrepreneurs who primarily sell their products through larger retailers or department stores.

In § 101.9(j)(1)(ii), FDA proposed that this exemption applied to any "person who manufactures, packs, or distributes food for ultimate sale to consumers at the retail level as well as any person directly involved in the retail sale of foods to consumers." The legislative history was not specific as to whether the term "retailer" applied only to the small business retailer/producer or to a larger retailer acting as a middle-man in handling the sale of the items to the ultimate consumer (Ref. 16). The agency is convinced by the comments that its interpretation would have unintended consequences on small businesses and, therefore, is removing "as well as any person directly involved in the retail sale of foods to consumers" from § 101.9(j)(1)(ii). To further clarify which foods are covered by the small business exemption and to streamline the regulations, FDA is also deleting the remaining portion of § 101.9(j)(1)(ii) and revising § 101.9(j)(1)(i) to state that "Food offered for sale by a manufacturer, packer, or distributor who has annual gross sales made or business done in sales to consumers that is not more than * * *." The agency's intent with this change is that the exemption will apply to persons whose name appears on the label as the manufacturer, packer, or distributor of the product, regardless of who ultimately sells the product to the consumer. As a consequence, § 101.9(j)(1)(iii) is redesignated as § 101.9(j)(1)(ii).

B. Ready-to-Eat Foods

188. Comments stated that proposed § 101.9 (j)(2) and (j)(3) did not adequately track section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act, which both pertain to foods ready for consumption but differ in that section 403(q)(5)(A)(i) of the act addresses foods served for immediate human consumption and section 403(q)(5)(A)(ii) addresses similar types of foods that are sold ready for human consumption but not for immediate human consumption and that are processed and prepared primarily on the premises.

The agency is persuaded that proposed § 101.9 (j)(2) and (j)(3) in its supplementary mandatory nutrition

labeling proposal (56 FR 60366) (which were based on proposed § 101.9 (h)(2) and (h)(3) in FDA's July 19, 1990, mandatory nutrition labeling proposal) did not adequately implement the 1990 amendments. FDA is therefore revising these two sections as discussed below in accordance with the 1990 amendments and in response to comments.

1. Foods for Immediate Human Consumption

In proposed § 101.9(j)(2) of its supplementary proposal (56 FR 60366), FDA proposed to exempt "food products provided by restaurants or other food service facilities offering restaurant-type services (e.g., delicatessens, bakeries, feeding facilities in organizations such as schools, colleges, hospitals, and transportation carriers (such as trains and airplanes))." While this list was not all-inclusive, it was intended to respond to section 403(q)(5)(A)(i) of the act which directed the agency to exempt food "which is served in restaurants or other establishments in which food is served for immediate human consumption * * *." Examples of congressional intent concerning the types of facilities covered by section 403(q)(5)(A)(i) of the act are limited in the legislative history to cafeterias and hospitals (Ref. 16).

189. While many comments supported the exemption in § 101.9(j)(2) for restaurants, several comments requested clarification about the coverage of the proposed section. For example, comments asked whether it covers retail confectioners, ready-to-eat food carryouts, vending machines, and food delivery systems such as meals-on-wheels programs or establishments such as pizza-delivery companies. Comments also pointed out the great diversity in the types of establishments in which food is served for immediate human consumption in the United States. For instance, comments stated that in addition to full-service restaurants, many establishments such as delicatessens, bakeries, candy stores, and convenience stores provide customers with tables and chairs to sit and immediately consume foods purchased. Others, whether for lack of space or for other reasons, do not provide such facilities. For example, frequently food franchises in shopping malls sell cookies or other snack foods expecting customers to eat the foods while walking in the mall or while sitting on benches located throughout the mall.

Comments from a company producing sandwich and salad items in a commissary for sale in vending machines requested to be included under this exemption because the subject foods are sold for immediate consumption, not for "take-home" use, and because the foods are prepared in a commissary kitchen similar to a restaurant/cafeteria kitchen, where foods are assembled by hand and subject to individual product variations. The comment argued that mandatory nutrition labeling would require standardization of menu items, thereby prohibiting common day-to-day variations in the food items produced, and would require larger labels or smaller type-size, both of which would be difficult or impossible to read through the small glass door of a refrigerated vending machine.

Similarly, one comment pointed out that some foods sold in convenience stores are intended for immediate human consumption and compete directly with foods served by restaurants and delicatessens. It stated that many stores have seating areas for customers to use while eating foods purchased on-site, and that in some states, such convenience stores must have restaurant licenses. Foods sold range from self-service beverages to prewrapped sandwiches, prepared off-site by vendors and offered for sale in store display cases.

FDA notes that section 403(q)(5)(A)(i) of the act addresses restaurants and "other establishments in which food is served for immediate human consumption." To respond to the comments stating the proposed rules did not adequately track the 1990 amendments, the agency is revising proposed § 101.9(j)(2) to include a new paragraph (ii) that states that the exemption is to include food products served in "other establishments in which food is served for immediate human consumption." In addition, in response to comments seeking clarification of the coverage of such "other establishments," and in recognition of the diversity of food service operations in the United States, the agency advises that while some enforcement decisions will need to be made on a case-by-case basis, for efficient enforcement of the act, it is providing in § 101.9(j)(2)(ii) that, in addition to food service in hospitals and cafeterias, the agency considers that this exemption applies to establishments such as bakeries, delicatessens, and retail confectionery stores where there are facilities for "immediate consumption" on the premises (i.e., tables or counters with chairs); to food service vendors such as lunch wagons, mall cookie counters, vending machines, and sidewalk carts where foods are generally consumed immediately where purchased or while walking away (including similar foods sold from convenience stores); and to food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices for immediate consumption.

FDA recognizes that some persons might consider that it is inconsistent for the agency to exempt packaged foods sold in vending machines from nutrition labeling but not from ingredient labeling. However, the agency is convinced that such foods are exempted from nutrition labeling by section 403(q)(5)(A)(i) of the act because vending machines serve food for immediate consumption, and there is no similar statutory exemption from ingredient labeling.

Regarding convenience stores, FDA agrees that some foods sold in such stores bear many similarities to foods sold at restaurants and delicatessens and should qualify for similar exemptions. Because circumstances will vary greatly according to the services a particular convenience store offers, it is not possible to state precisely which foods do or do not have to provide nutrition labeling. Rather, determinations will have to be made on a case-by-case basis. However, § 101.9(j)(2) generally provides an exemption for foods of the type served in restaurants or other establishments in which food is served for immediate human consumption. Such foods might include beverages (both self-service and those served by store personnel), frankfurters in a roll, cold sandwiches, pizzas, and hand-packed ice cream cones.

190. Many comments requested that proposed § 101.9(j)(2) be amended to clearly exempt foods "sold for sale or use" in restaurants or other establishments in which food is served for immediate human consumption as specified in section 403(q)(5)(A)(i) of the act. They argued that the statutory language indicates that food intended for use in restaurants is exempt from mandatory nutrition labeling in the absence of nutrient content or health claims. The comments pointed out that proposed § 101.9(j)(2) merely provided an exemption for foods provided by restaurants and did not cover foods intended for sale or use in restaurants.

The agency agrees that the proposed regulations did not fully implement section 403(q)(5)(A)(i) of the act that covers foods sold for sale or use in restaurants or other such establishments. As directed in the statute, this exemption applies to all foods sold in restaurants, including packaged products such as a specialty

house dressings made by the restaurant, or used in restaurants, such as portion controlled packages (e.g., individual catsup or coffee whitener packages) for use only in restaurants. If a manufacturer makes a product for sale only in restaurants (e.g., a package of candy), that product need not be nutrition labeled. However, if there is a reasonable possibility that the product will be purchased directly by consumers in a setting other than a restaurant or other establishment in which it is served for immediate consumption, it must be nutrition labeled (see Ref. 25). Accordingly, FDA has modified proposed § 101.9(j)(2) to add a new paragraph (iii) that exempts foods sold for sale or use only in restaurants or other establishments in which food is served for immediate human consumption.

191. A few comments requested that the second sentence of proposed § 101.9(j)(2) be revised to adequately implement section 403(q)(5)(F) of the act that exempts food "which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells." The comments pointed out that the second sentence in proposed § 101.9(j)(2) would only exempt "foods sold to restaurants by distributors * * *" which is duplicative of that part of 403(q)(5)(A)(i) of the act that stipulates an exemption for foods sold for sale or use in restaurants and fails to include the broader exemption in 403(q)(5)(F) of the act for all foods sold by distributors who principally sell food to restaurants or other establishments in which food is served for immediate human consumption and who do not manufacture, process, or repackage the food they sell.

The agency is persuaded that there is a need to revise the second sentence of proposed § 101.9(j)(2). As discussed in the legislative history (Ref. 25), the food distributor that sells principally to restaurants and other food service establishments is exempted from mandatory nutrition labeling requirements as long as the food distributor does not manufacture the product sold to the consumer. However, the legislative history states:

> The manufacturer of such products would be responsible for providing the nutrition information on the products if there is a reasonable possibility that the product will be purchased directly by consumers, even if the principal customers are restaurants and other wholesale purchasers. * * * [T]he distributor is not liable as long as the distributor does not manufacture the product sold to the consumer.
> (Ref. 25)

In essence, this legislative history makes clear that section 403(q)(5)(F) of the act is intended to direct the agency to do for foods sold to restaurants what it does for foods sold to consumers; that is, to hold the manufacturer, not the seller, responsible for nutrition labeling of foods. (The only exception to this approach is the voluntary nutrition labeling program for raw fruits, vegetables, and fish in which the retailer is to provide the nutrition information.) This exemption would apply to an independent distributor who principally distributes institutional foods directly to restaurants and similar establishments and does not manufacture, process, or repackage the food it sells.

Thus, under this exemption, such a distributor is not responsible for nutrition labeling a product, even if it sells the product in a so-called "cash and carry" store, unless it manufactures, processes, or repackages the food for sale to consumers. On the other hand, a manufacturer of institutional size food products is responsible for nutritionally labeling those products if there is a reasonable possibility that they will be sold to consumers, for example, through such a mechanism as a cash and carry store.

Therefore, proposed § 101.9(j)(2) is modified by adding § 101.9(j)(2)(iv) to fully implement this exemption.

192. One comment recommended that statements such as "for food service use" or "not labeled for retail sale" be used as one means of qualifying for the exemption or that such foods be identified by the size of the package. The comment suggested that such a rule would be of particular help for foods imported for the food service trade.

The legislative history quoted in the preceding comment makes clear that nutrition labeling is required "if there is a reasonable possibility that the product will be purchased directly by consumers * * *." Therefore, the agency does not believe that a label statement can be used as the basis for this exemption. The agency is concerned that, if permitted, a label statement such as "for food-service use" would be used to claim exemption for products that Congress intended to be nutrition labeled. Therefore, rather than create the possibility for potentially misleading labeling, FDA is denying this request.

Imported foods that are in large packages that are obviously not intended or packaged for sale to consumers would be considered exempt under § 101.9(j)(9) which deals with foods shipped in bulk form that are to be processed, labeled, or repacked at a subsequent site.

193. Several comments opposed proposed § 101.9(j)(2) because it would exempt restaurants from mandatory nutrition labeling. These comments urged that restaurants, particularly the regional and national chain restaurants, be required to have nutrition information available to consumers. Some comments suggested that the required information could be: (1) limited to calories, fat, saturated fat, cholesterol, and sodium; (2) based on computer analysis of nutrient databases; and (3) presented in alternative ways such as brochures, menu boards, posters, or tray liners. A few large fast food restaurant chains requested guidelines for voluntary nutrition labeling with flexibility in format and content. They requested that restaurants be allowed to use their own serving sizes, present information on an as-served basis, and update information annually.

In response to comments requesting that restaurants be required to provide nutrition information, the agency points out that section 403(q)(5)(A)(i) of the act specifically exempts restaurants and other establishments in which food is served for immediate human consumption from mandatory nutrition labeling, unless a nutrient content claim or a health claim is made. The requirements that pertain when claims are made are discussed extensively in the final rules on the general requirements for nutrient content claims and health claims that are published elsewhere in this issue of the **Federal Register**.

FDA is aware, however, of the consumer interest in knowing the nutrient content of foods eaten away from home. In response to that interest and to the comments from fast food chains, the agency intends to work closely with all interested parties, particularly those in the food-service sector, to develop guidelines for presenting nutrition content information in a restaurant setting in such a way that it will not inhibit the flow of useful nutrition information (e.g., claims) to the consumer, while at the same time providing assurance of the reasonable accuracy of the information, thus furthering the goal of the 1990 amendments to aid consumers in maintaining healthy dietary practices.

194. One comment agreed that the 1990 amendments exempt restaurants from mandatory nutrition labeling but requested that they be regulated under sections 201 and 403(a) of the act. The comment also requested that FDA clarify that the 1990 amendments have

no preemptive effect on state or local regulation of the nutritional disclosures by restaurants.

FDA advises that the exemptions in § 101.9(j) in no way exempt any foods from regulations promulgated under sections 201 and 403(a) of the act. In regard to State and local preemption, the legislative history states that "Because food sold in restaurants is exempt from the nutrition labeling requirements of section 403(q)(1) through (q)(4) of the act, the bill does not preempt any State nutrition labeling requirements for restaurants. If States do require such labeling in restaurants, it is important that they make every effort to make those requirements consistent with the requirements of the bill." (Ref. 110).

2. *Foods Not for Immediate Consumption.* 195. Many comments objected to proposed § 101.9(j)(3) that allowed an exemption for in-store delicatessen and bakery foods only when they were sold from behind service counters. Comments pointed out that the 1990 amendments made no distinction for such foods when sold from behind the counter rather than from a self-service display. They stated that such a rule would be totally unworkable and would adversely affect the bakery and deli departments. Such a rule, according to the comments, would make it impossible to sell foods that are sold from behind the service counter during the day, at night, when no service clerks are available, or to assemble sandwiches and salads for fast pickup during the lunch hour from self-service counters, without nutrition labeling those foods. A trade association reported that 21 percent of in-store bakeries' sales come from bulk self-service units and 42 percent from prepackaged self-service cases, and that, if compelled to standardize and label their products, such bakeries would be unable to continue in competition with wholesale bakery items.

The comments argued that in-store delicatessens and bakeries should be able to adhere to the same regulations as their independent counterparts, with whom they compete for business. They stated that in-store delicatessens and bakeries operate as independent bakeries in that their accountability is separate from the rest of the store.

Other comments stated that the intent of Congress was that foods similar to restaurant foods that are ready for immediate consumption, and that are produced by retailers that offer variable and nonstandardized products, should be exempt from nutrition labeling to eliminate the substantial burdens that would otherwise be imposed if such labeling were mandatory. Many comments have pointed out that the average baker or confectioner produces hundreds of different products each year, and that the average sales per product are relatively low. Comments stated that the precise selection of foods produced is frequently modified according to changing preferences of customers, seasons, holidays, ingredient availability, and the individuality of the baker/confectioner. Comments argued that it is this ability of the retailer to vary and customize food products that gives the establishment its character and appeal, and that forced standardization to allow for nutrition labeling would eliminate product competitiveness by disallowing innovation and creativity. This loss of competitiveness, in turn, would create a major economic burden and thereby lessen consumer choice.

The agency is persuaded that proposed § 101.9(j)(3) did not adequately implement section 403(q)(5)(A)(ii) of the act, could result in economic harm to in-store delicatessens and bakeries, and created an artificial demarcation between foods sold from service versus self-service areas of the delicatessen or bakery. Therefore, FDA believes that it is necessary to revise § 101.9(j)(3) to more closely reflect the language of the act.

As stated above, section 403(q)(5)(A)(ii) of the act applies to foods that are: (1) Similar to the type addressed in section 403(q)(5)(A)(i) of the act, (2) ready for human consumption, and (3) offered for sale to consumers but not for immediate human consumption. Accordingly, FDA is modifying § 101.9(j)(3) by adding paragraphs (i) through (iii) to reflect these three statutory requirements. There were no specific concerns presented in comments that suggest any problems with these requirements.

Section 403(q)(5)(A)(ii) of the act also requires that the foods to which it applies be processed and prepared primarily in the retail establishment. The agency is codifying this requirement in § 101.9(j)(3)(iv). Comments were very divided on this issue, particularly for bakery items. Some comments argued that breads shipped to a retail store in a semi-finished condition and baked-off just before retail sale would not meet the criteria of "prepared and processed primarily" at the retail store and should not be exempt. However, other comments disagreed with this position, stating that frozen dough products are further processed at the bakery by being proofed, shaped, molded, filled, decorated, cut, assembled, customized, or otherwise completed or further processed and should be exempt.

The legislative history discusses this situation stating that for bakeries "simply thawing frozen bread would not be sufficient; the bread would have to be baked on the premise" (Ref. 16). While this statement appears to indicate that baking (i.e., cooking at a high temperature in an oven) is sufficient to qualify a food for this exemption, comments have argued that "baking" is not equivalent to heating but includes a number of steps, such as "selecting, weighing, and mixing ingredients, fermentation, and shaping and forming the dough prior to actual heating the product."

This example with bread illustrates the difficulty in applying the criterion of "processed and prepared primarily in a retail establishment." Because of the wide variety of foods sold in delicatessens, bakeries, retail confectionery stores, and other stores of this type that may not qualify for exemption under § 101.9(j)(2), it becomes administratively impossible to identify for each type of food sold the exact amount of processing or preparation that would be needed to say that that food was "processed and prepared primarily" on-site.

In many establishments, foods such as bakery items or salads, may be prepared entirely on-site; however, in other similar establishments, much less of the processing and preparation of these foods is actually done on the premises. Similar variations are encountered with other foods, such as cheeses, which may only need to be sliced and portioned, or puddings, which may be purchased in cans and only need to be put in trays in the display case for portioning. The characteristics that all of these foods have in common is that they are ready-to-eat, they are the same type of foods sold in restaurants, and they are portioned and packaged on-site.

Legislative guidance to assist the agency in defining what is meant by "processed and prepared primarily in a retail establishment" in addition to that cited above is scant. However during Senate debate, one of the sponsors of the bill that became the 1990 amendments stated that:

> This exemption recognizes that when food is processed and prepared primarily on the premises and sold there, as in the prepared food sections of supermarkets; nutrition labeling is not appropriate. On the other hand, if the preparation or processing of food is standardized and is accomplished primarily at another establishment and the same food is then shipped to a retail food store in a form that requires minimal or no further processing, nutrition labeling can be easily accomplished and is required.

(Ref. 110).

The agency interprets this legislative history to mean that if the food arrives at a store in a form to be sold directly to the consumer (i.e., it is "standardized"), then nutrition labeling must be required. However, if the food is not standardized, i.e., it has to undergo processing or preparation, including portioning, before being sold to the consumer, then nutrition labeling is inappropriate and should not be required. In the case of the examples cited above, FDA finds that nutrition labeling would therefore not be required on bread that is shaped; filled, decorated, assembled, or customized and baked (i.e., cooked at a high temperature) in the retail establishment. Cheese that is sliced and portioned according to directions given by the consumer, and pudding that is portioned according to directions given by the consumer, also need not be nutrition labeled. In these examples, the food is not "standardized" in the form that it is to be sold to consumers when it arrives at the store. Similarly, candies sold in retail confectionery stores that are selected by consumers to be part of a packaged assortment are not "standardized."

However, because of the great diversity of situations in which foods are sold, it must be recognized that a decision regarding exactly what foods do or do not require nutrition labeling cannot be fully resolved by regulation. Circumstances at the retail location must be the deciding factor.

196. A few comments from the retail baking and confectionery industries and from grocery stores requested that the exemption for single-unit bakeries, delicatessens, and confectioneries apply equally to multi-unit establishments that do most or all of their preparation at a central facility or shop. Each type of respondent attempted to limit such an exemption by describing what it would encompass. For example, a comment from the retail baking industry described multi-unit bakeries as being owned, controlled, and operated by the same entity and stated that finished products would be delivered unwrapped or in bulk delivery boxes to each store or outlet. The confectionery industry requested that the exemption cover satellite operations operated by the same businesses, selling the same products, and using the same packaging. A small retail grocery chain suggested limiting the exemption to foods prepared in central kitchens for use in the retailer's own stores. Reasons given for using central facilities included ensuring quality control through a controlled environment that promotes food safety and integrity and allowing for economies of scale. Comments stated that the average number of bakeries operated by a multi-unit retail bakery was 2.4 in 1988, and that many small independent confectioneries only operate one additional outlet.

FDA does not believe that the 1990 amendments allow for exemptions beyond those discussed in the preceding comments. This position is based on the final criterion given in section 403(q)(5)(A)(ii) of the act, which states that foods to which the section applies shall not be offered for sale outside the retail establishment in which they are primarily processed and prepared. The agency is codifying this requirement in § 101.9(j)(3)(v). While foods that are fully prepared and portioned (i.e., "standardized") at the central facility are required to bear nutrition labeling, there may be some types of food products or circumstances in which the portioning or packaging is not standardized, and in which nutrition labeling would consequently not be required (e.g., salads that are portioned and packaged according to directions given by the consumer).

FDA notes that the problems presented in most of the comments on this aspect of this exemption have more to do with the size of the businesses than whether there are good reasons not to require nutrition labeling. FDA believes that the best way to deal with most of these comments is through a change in the small business exemption.

C. Foods of No Nutritional Significance

To reflect the first sentence in section 403(q)(5)(C) of the act, FDA proposed an exemption for foods of no nutritional significance in § 101.9(a). It proposed to include the other exemptions in § 101.9(j). To minimize any confusion that these differences in placement may cause, the agency has decided to group all exemptions in one place in this final rule. Accordingly, that part of proposed § 101.9(a) that exempted foods of no nutritional significance is redesignated as § 101.9(j)(4).

197. Comments from the coffee industry noted that, unlike FDA's mandatory nutrition labeling proposal, the supplementary proposal did not explicitly identify coffee as being nutritionally insignificant. Thus, the comment requested clarification in the final rule. The comments pointed out that coffee is always consumed as a brew. An analogy was drawn to § 101.45(b)(4) in the guidelines for voluntary nutrition labeling of raw fruit, vegetables, and fish, which states that nutrition information is to be based on the edible portion of the food. Comments stated that the available nutrients in brewed or plain instant coffee would meet the criteria for being nutritionally insignificant.

The agency agrees that only the edible portion of coffee should be considered in determining the nutritional significance of the product. Therefore, based on a review of available nutritional data on a serving of coffee and on the revisions in the levels that are significant, discussed in comment 176 of this document, FDA has concluded that coffee beans, roasted ground coffee, or dry plain (i.e., unsweetened) instant coffees contain no nutrients at other than nutritionally insignificant levels. As a result, these foods are exempt from mandatory nutrition labeling. Unsweetened plain tea powders or tea leaves likewise would be exempt.

In response to comments requesting clarification of the exempt status of coffee and tea, FDA has included in § 101.9(j)(4) a listing of coffee beans (whole or ground), tea leaves, and unsweetened plain instant coffee and tea as examples of foods that are exempt from nutrition labeling because of their lack of nutrients. The agency reiterates, however, that this exemption is available only when there are no nutrient content or health claims on the label or in labeling or in advertising of the coffee or tea.

198. The spice industry commented that FDA did not establish a reference amount for spices, thereby implying that spices are exempt from mandatory nutrition labeling. Comments requested that the agency provide an explicit statement in the final rule regarding the exemption of spices, spice blends (e.g., curry powder), and condiment-type dehydrated vegetables (e.g., dried garlic) as well as flavor extracts and food colors, from the nutrition labeling requirements.

As discussed in the final rule on serving size published elsewhere in this issue of the Federal Register, FDA has set a reference amount of ¼ teaspoon for most spices and condiment-type dehydrated vegetables. In reviewing the nutritional data in Agriculture Handbook No. 8–2 and 8–11 (Refs. 111 and 112), the agency has found that, under FDA's criteria for determining nutritional insignificance, the vast majority of spices, spice blends, and condiment-type vegetables are exempt from mandatory nutrition labeling. FDA found, however, that one spice (paprika) and one spice blend (chili powder), exceed the cutoff levels for one or two nutrients. Using the appropriate rounding procedures, paprika is over

the cutoff for vitamin A (6 percent of the RDI), and chili powder is over the cutoff for both vitamin A (4 percent of the RDI) and sodium (5 mg) per ¼ teaspoon serving. The levels at which these nutrients are nutritionally insignificant (i.e., the amounts that can be rounded to zero) are less than 2 percent of the RDI for vitamin A and less than 5 mg for sodium. Therefore, under the act, paprika and chili powder will have to be nutrition labeled (see Ref. 16, p. 16: "Foods such as certain spices, which have insignificant amounts of most but not all nutrients, are covered by the nutrition labeling requirements."). Because not all spices and spice blends are nutritionally insignificant, they are not included as a category under § 101.9(j)(4).

Condiment-type dehydrated vegetables, flavor extracts, and food colors do meet the criteria for foods of no nutritional significance and, therefore, are exempt from mandatory nutrition labeling. As with unsweetened coffee and tea, § 101.9(j)(4) will include these examples of nutritionally insignificant foods.

199. One comment suggested that "fun foods" defined as foods with empty calories (i.e., those with no nutrients other than calories), such as plain sugar candies, gum, and carbonated beverages, should be exempt from mandatory nutrition labeling except for a declaration of calories and the statement "no other significant sources of nutrients." The comment argued that the statement "Contains less than 2 percent of the RDI" for such foods is deceptive and miseducates consumers.

FDA advises that these types of foods would qualify under § 101.9(f) for the simplified label and would only be required to list the core nutrients, not the statement "Contains less than 2 percent of * * *." Moreover, Congress did not provide for an exemption of such a category of foods in the statute. Therefore, the agency is taking no action on this comment.

200. The pickle industry commented that, as a cost-saving measure, only sodium content (as is permitted under current regulations) should be required to be labeled on dill pickle products, rather than the full simplified format. The comment argued that, even though a serving of dill pickles also contains 1 g of carbohydrate, sodium is the only nutrient of any concern to consumers.

FDA rejects this comment. Section 403(q)(5)(C) of the act exempts from nutrition labeling foods that contain insignificant amounts of all of the nutrients required within nutrition labeling. The same section also provides for a simplified form of nutrition labeling if a food contains insignificant amounts of more than one-half the mandatory nutrients. No provisions of the 1990 amendments would allow for declaration of only a single nutrient in nutrition labeling. Accordingly, FDA is not making the suggested changes in the regulations.

201. One trade association commented that bottled water products have little or no nutritional value, and that such products should be exempt from mandatory nutrition labeling. The comment asserted that the following industry practices should be permitted without triggering nutrition labeling obligations: (1) Bottlers should be allowed to add back minerals as flavor enhancers that are removed during purification and declare "minerals added" on the principal display panel; (2) bottlers should be allowed to describe bottled water with natural or added fluoride as "fluoridated water;" (3) bottlers should be allowed to add sodium fluoride or add back trace minerals that may contain sodium as an incidental additive and still be permitted to claim "sodium free" on the label; (4) "essence" bottled water products (i.e., those containing 1 percent or less of juice or flavors) should be considered nutritionally insignificant; and (5) bottled mineral water products should be permitted to have a listing on the label of certain minerals, e.g., sodium, bicarbonate, calcium, magnesium, and other trace minerals in mg per liter in addition to a declaration of total dissolved solids content (which some state laws currently require). The comment argued that the EC Directive on Nutrition Labeling expressly exempts mineral water and other waters from nutrition labeling, and, for the sake of harmonization, FDA should do likewise.

FDA points out that, separate from this rulemaking on nutrition labeling to implement the 1990 amendments, the agency is in the process of amending its regulations on bottled water, partly in response to a petition from the trade association that submitted the comment. The bottled water regulations will address certain aspects of labeling apart from nutrition labeling, e.g., definitions, information about mineral content, and required label statements. Under the 1990 amendments, Federal regulations will preempt any State standards of identity that are not identical to it (section 403(a)(1) of the act).

A recent IOM report, "Food Labeling: Toward National Uniformity" (Ref. 113), noted that many States have expressed concern about the heightened potential for consumer confusion because of the increased number of bottled water products on the market and the aggressive marketing and advertising claims of superiority made for them. Thus, FDA maintains its position that nutrition information relating to food must be provided for all products, including bottled and mineral water, that contain more than insignificant amounts of any of the nutrients or food components that are required to be listed, or whose label, labeling, or advertising contains a nutrient content claim or any other nutrition information in any context. For products that qualify for the simplified format, if manufacturers voluntarily declare nutrients allowable under § 101.9(c) that are not among the 14 required nutrients (e.g., potassium), the required statement "Not a significant source of _____." must be used, with the blank filled in with the name of any of the 14 required nutrients or food components that are not present or are present in insignificant amounts. Moreover, if a product is voluntarily enriched or fortified with added vitamins or minerals, any such nutrients must be declared using the simplified format and followed by the above statement. Thus, a product labeled as "bottled water, minerals added" will have to bear nutrition labeling.

The agency considers the identity statement "fluoridated water" misleading if the product is derived from a source naturally containing fluoride. Use of the term "fluoridated" represents that fluoride has been added in the processing. Thus, the term "fluoridated water" should be used to describe only products to which fluoride has been added in the manufacturing process, and such products would be required to bear nutrition labeling that complies with the simplified format.

Bottled water products containing juice or other flavors are subject to the same nutrition labeling requirements as any other food. If a product meets the criteria for no nutritional significance, and no claims are made, then nutrition labeling is not required. A "sodium free" declaration on bottled water or on any other food label will trigger nutrition labeling, because such a claim promotes the nutritional properties of the product.

202. One comment stated that, to avoid varying interpretation, FDA should clarify what it means by the term "implicit" as it applies to nutrient content claims or information that will bar a food from an exemption from nutrition labeling under the "no nutritional significance" provisions.

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A thorough discussion of implicit claims may be found in the companion documents on nutrient content claims and health claims, found elsewhere in this issue of the **Federal Register**.

D. Foods for Infants and Children Less Than 2 Years of Age

In the mandatory nutrition labeling proposal (§ 101.9(h)(4)) and in the supplementary proposal (§ 101.9(j)(4)), the agency proposed to require that foods, other than infant formula, that are represented or that purport to be specifically for infants and toddlers less than 2 years of age bear nutrition labeling, except that such labeling shall not include information on the number of calories from fat or the amount of saturated fat and cholesterol present in the food.

203. The comments supported this proposal. One comment, noting that proposed § 101.9(j)(4) refers to "toddlers less than 2 years of age" and other references in § 101.9 refer to toddlers as children less than 4 years of age, recommended that "children less than 4 years of age" be used, or that the term "toddler" be clarified. Another comment pointed out the practical fact that some foods used in the 1 to 2 year age bracket are also used by some children up to 4 years of age as well as by adults who have problems chewing food.

FDA does not agree that these special labeling requirements proposed for foods for infants (other than infant formula) and toddlers less than 2 years of age should be extended to children less than 4 years of age despite the fact that no other nutrition labeling requirements use 2 years of age as a cutoff. The agency does not believe there is scientific support to change the cutoff to 4 years because dietary recommendations for very young children are specific in citing 2 years of age as the age under which dietary modifications are not appropriate. For instance, the "Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents" of the National Cholesterol Education Program (NCEP) states:

> The fast growth of infants requires an energy-dense diet with a higher percentage of calories from fat than is needed by older children. Based on current knowledge, it is inappropriate to apply nutrient guidelines for fats, cholesterol, and calories to children under 2 years of age.

(Ref. 114.)

and:

> As toddlers over 2 years of age begin to eat with the family, they may safely make the transition to this [recommended] eating pattern.

(Ref. 114.)

However, FDA believes that some clarification is needed as to the types of foods addressed in § 101.9(j)(4) (which is redesignated as § 101.9(j)(5)(i)). The agency advises that the infant and toddler foods to which the special labeling requirements are intended to apply are the types of foods represented in § 101.12(b), Table 1 entitled "Reference Amounts Customarily Consumed: Infant and Toddler Foods" in the rule entitled "Food Labeling; Serving Sizes" published elsewhere in this issue of the **Federal Register**. FDA notes, however, that in its serving size reproposal (November 27, 1991, 56 FR 60394 at 60397), "toddlers" was interpreted to mean children 1 through 3 years of age. Therefore, the agency advises that no special significance should be given to the word "toddler;" rather it is the age category that is important. To reduce the possibility of confusion, FDA is replacing the word "toddler" with "children." The distinguishing characteristic of foods to which the special labeling requirements in § 101.9(j)(5)(i) apply is that they are specifically represented or purported to be "for use by infants and children less than 2 years of age." Foods represented or purported to be for use by "children less than 4 years of age" or by "children 3 or more years of age" are not subject to the special labeling requirements of § 101.9(j)(5)(i) but should fully declare required information on fats and cholesterol.

With regard to the comment that these foods are sometimes used by older children or adults, FDA acknowledges that this occurs. The agency believes, however, that the represented use of the product must be the deciding factor. Inasmuch as the foods to which § 101.9(j)(5)(i) applies are represented to be for use by infants and children less than 2 years of age, the agency considers the use of these types of foods by children over 2 years of age or by older persons to be not particularly relevant in determining how these foods should be labeled. Accordingly, FDA has not made any change to § 101.9(j)(5)(i) in response to this comment.

204. One comment stated that the word "or" was used ambiguously in the proposed version of § 101.9(j)(5)(i) so that it was not clear whether "calories from saturated fat" or "saturated fat content" was prohibited. The comment also suggested that information on calories from saturated and unsaturated fat and the amount of unsaturated fat also should be prohibited, and that § 101.9(j)(5)(i) should be clarified by enumerating those parts of § 101.9(c) that are affected.

FDA agrees that all information relating to fatty acids should be prohibited on foods represented or purported to be for use by infants and toddlers (i.e., children) less than 2 years of age. In the proposed version of § 101.9(j)(5)(i), FDA only specified the fatty acid component that is required in nutrition labeling.

Therefore, to make the suggested change and to clear up any confusion, § 101.9(j)(5)(i) is modified to state: "* * * such labeling shall not include calories from fat ((c)(1)(ii) of this section), calories from saturated fat ((c)(1)(iii)), saturated fat ((c)(2)(i)), polyunsaturated fat (c)(2)(ii)), monounsaturated fat ((c)(2)(iii)), and cholesterol ((c)(3))."

205. One comment suggested the additional exclusion of fiber on labels of foods for infants, citing a statement made by the American Academy of Pediatrics that fiber probably is not needed in infants less that 1 year old.

FDA, in reviewing the reference cited by the comment (Ref. 115), noted that on the same page as this cited statement is the additional statement that more work needs to be done before any firm recommendations can be made on dietary fiber in pediatric nutrition.

FDA is thus not convinced that dietary fiber should be excluded from nutrition labels for foods intended for infants and children less than 2 years of age. Most foods included in Table 1 of § 101.12(b) in the final rule entitled "Food Labeling; Serving Sizes," published elsewhere in this issue of the **Federal Register**, contain less than 1 g of fiber per 100 g of edible portion (Ref. 116). Under usual circumstances, these levels would seem to preclude the consumption of high-fiber, low-calorie diets by infants or children under 2 years of age who consume such foods. Also, because dietary fiber has a natural laxative effect, the label declaration of fiber content may be useful information to the purchasers of these foods.

206. A comment to the format proposal objected to the inclusion of DRV's on foods for infants and toddlers because DRV's were not proposed for infants or children less than 4 years of age, and labels on jars of baby food are too small to allow for the additional information. The comment argued that DRV's for adults and children 4 or more years of age are not appropriate for infants and toddlers, and that there could be serious health consequences if a parent tried to adapt an infant's diet to the proposed DRV's.

FDA agrees with the comment for the reasons presented therein. In addition,

the agency believes that it is inappropriate and unnecessary to include the caloric conversion information required by § 101.9(d)(10) on foods intended for children less than 4 years of age because DRV's for this group have not been established and calculation related to such values may be misleading. Accordingly, for foods for infants and children less than 4 years of age, the agency is adding an exemption in § 101.9(j)(5)(ii) that excludes the declaration of Percent Daily Values for nutrients other than vitamins and minerals for which there are RDI's specifically established for infants and children less than 4 years of age. The exemption also applies to the footnote and caloric conversion information. Except for the omission of this information, which is otherwise required in § 101.9(d)(2)(ii), and the footnote and caloric conversion information required in (d)(9) and (d)(10), the format of the nutrition labels on such products should comply with the requirements of § 101.9 (d), (e), or (f), as appropriate. Examples of labels for foods for children less than 4 years of age and less than 2 years of age are given in appendix G.

E. Medical Foods

207. All comments received supported this exemption. In addition, several comments expressed support for the agency's intention, stated in the supplementary proposal (56 FR 60366 at 60377), to develop specific regulations for medical foods in the near future. Some comments suggested that nutrition labeling, intended for use by the general population, does not provide the kind of information needed by health care professionals or patients selecting or using medical foods. The comments noted that, in light of this exemption, there is little guidance for labeling of medical foods, other than general food labeling regulations, citing the need for labeling of nutrient content and purported uses and adequate and appropriate directions for use. In addition to the need for specific labeling requirements, some comments identified the need for quality control and good manufacturing practices specific for medical foods.

Section 403(q)(5)(iv) of the act exempts medical foods from nutrition labeling requirements. The agency agrees with the comments that the exemption for medical foods from nutrition labeling is appropriate considering that these products are not intended for use by the general population but rather are intended for use under the supervision of a physician for specific dietary management of a disease or condition. However, the agency also recognizes that the exemption creates a void in terms of specific labeling regulations suitable for these products. FDA believes, as noted in some comments, that the proper labeling of the nutrient content and purported uses of medical foods, perhaps in a different manner or in more detail than is required for other, more traditional foods, and adequate and appropriate directions for use, as well as assurances of the quality of medical food products, are all of vital public health interest. While these issues are beyond the scope of this rulemaking, the agency intends to develop regulations covering these aspects of medical foods in a future **Federal Register** document.

208. The comments support incorporation into the nutrition labeling regulations the definition of medical foods from section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). Section 403(q)(5)(iv) of the act incorporated this definition by reference into the statute, and FDA in proposed § 101.9(j)(7) to incorporate the statutory definition of "medical food" into the nutrition labeling regulations. Some clarification of this definition was included in the preamble and codified sections of the proposal, providing some guidance in regard to the intended use of a medical food. However, several comments cited particular products and asked whether the products would be regulated as medical foods.

FDA considers the statutory definition of medical foods, from section 5(b) of the Orphan Drug Act, to delineate the principal characteristics of medical foods. Additional clarification of this definition, contained in the preamble of the proposal, gives guidance on some of the types of products that the term "medical foods" pertains to by identifying a variety of foods that the agency regards as medical foods and some that are not presently regarded as medical foods. Criteria that product must meet to be considered a medical food are stated in the preamble of the proposal, as well as in proposed § 101.9(j)(7), redesignated as § 101.9(j)(8) in the final rule. FDA believes that this definition and the information clarifying the definition in the proposal are reasonable guides for use by industry in determining the characteristics of a medical food at present.

However, following review of the comments generated by this proposal, FDA acknowledges that further clarification of the types of products that are considered to be medical foods by the agency would be helpful to manufacturers. While these comments go beyond the scope of this rulemaking, the agency intends to address this issue in a future **Federal Register** document.

209. One comment suggested that in proposed § 101.9(j)(7)(v), the words "* * * provided only to a patient receiving active and ongoing medical supervision * * *" be changed to read "* * * intended only for a patient receiving active and ongoing medical supervision * * *." The comment stated that manufacturers can label products in a manner that gives a clear indication of the intended level of supervision, but that the word "provided" in this section might require a distribution system beyond the control of the manufacturer, restricting availability of medical foods to prescription status or distribution through an institution.

The agency agrees with this recommended change for the reasons stated in the comment and has modified new § 101.9(j)(8)(v) accordingly.

210. One comment suggested that the word "seeks" in proposed § 101.9(j)(7)(v) be changed to "require." The comment noted that while some patients receiving a medical food under the supervision of a physician are capable of seeking "medical care on a recurring basis," others receiving a medical food under the supervision of a physician are not able to actually "seek medical care" on their own (e.g., a comatose patient).

FDA agrees with the suggested change. The agency acknowledges that a medical food, under the supervision of a physician, may be consumed by, or be administered enterally to, some patients capable of seeking medical care and may be administered enterally to other patients who may be too ill to actively seek medical care. In both instances, the patient may require a medical food for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. FDA has modified § 101.9(j)(8)(v) accordingly.

F. Foods Shipped in Bulk Form

211. FDA received many comments that supported proposed § 101.9(j)(8) that exempts foods shipped in bulk form. A few comments sought clarification of this exemption, requesting that new § 101.9(j)(8) include a statement that flavors and other food ingredients (as opposed to processed foods) shipped in bulk form from one manufacturer to another for use in the manufacture of other foods are exempt.

FDA intended the term "processed" in § 101.9(j)(8) (redesignated as

§ 101.9(j)(9)) to indicate that food ingredients used in the manufacture of other foods were exempt, maintaining the scope of current § 101.9(h)(8). However, for further clarification, FDA is modifying § 101.9(j)(9) as requested to state:

> Food products shipped in bulk form that are not for distribution to consumers in such form and that are *for use solely in the manufacture of other foods or that are* to be processed, labeled, or repacked at a site other than where originally processed or packed. (Emphasis added).

G. Foods for Institutional Food Service Use

212. Several comments objected to proposed § 101.9(j)(9) that would require manufacturers or distributors of foods for institutional food service use (i.e., for use by hospitals, schools, prisons) to provide nutrition information required by this section directly to the institutions on a current basis. The comments stated that this requirement was in conflict with section 403(q)(5)(A)(i) of the act, which exempts food that is sold for sale or use in restaurants or other establishments in which food is served for immediate human consumption. The act does not differentiate between food served in institutional and noninstitutional settings. In fact, the comments pointed out that the legislative history specifies that similar food service establishments include cafeterias and hospitals.

FDA agrees with the comments and has deleted proposed § 101.9(j)(9) to bring the final rule into compliance with the 1990 amendments. To clarify that institutional food service establishments are included under the exemption for restaurants and other establishments, FDA has added them as examples in § 101.9(j)(2)(ii).

However, the agency finds merit in other comments that supported nutrition labeling of foods sold to restaurants and other food service establishments in order to enable food service operators to become more aware of the nutritional content of foods they serve, to offer more healthful menu options, and to use more accurate descriptors on their menus. The agency, therefore, encourages manufacturers, packers, and distributors to make nutrition information available to food service operators whenever possible.

H. Single-Ingredient Packaged Fish Products

213. Comments received from the fish industry objected to the inconsistencies between the voluntary nutrition labeling program for raw fish and the mandatory nutrition labeling program. They pointed to the potential for confusion when raw fish under the voluntary program are labeled on an "as consumed" (i.e., "as proposed") basis, and the same fish, when frozen and packaged by a manufacturer, are labeled on an "as packaged" basis. They also pointed to the inconsistency with the USDA proposal that allows single-ingredient raw meat and poultry items, whether frozen or unfrozen, to be under a voluntary program with nutrition information reported on either an "as packaged" or "as consumed" basis.

FDA agrees that consumers may be confused to find inconsistent nutrition labeling on two packages of the identical fish (e.g., fillet of flounder) when one is under the voluntary program for raw fish, and the other is under the mandatory program for frozen packaged fish. According to the final rule for the voluntary program (November 27, 1991 56 FR 60880; corrected at, March 6, 1992, 57 FR 8174), nutrition information for raw fish is to be reported for a 3 ounce, cooked edible portion (see appendix B, 57 FR 8174 at 8175). The final rule on serving size, published elsewhere in this issue of the **Federal Register**, provides that under the mandatory nutrition labeling program, nutrition information for frozen packaged fish is to be reported for that amount required to prepare 85 g (approximately 3 ounces) of cooked fish (§ 101.12 (b) and (c)) but is to be based on the product "as packaged" (§ 101.9(b)(9)).

To reduce the inconsistencies in nutrition labeling between raw versus frozen packaged single-ingredient fish, and between single-ingredient fish versus single-ingredient meat and poultry, FDA is adding a special labeling provision for fish in § 101.9(j)(11) that allows single-ingredient fish to be labeled on a cooked (i.e., "as prepared") basis consistent with the voluntary program for fish and with USDA's rules for single-ingredient meat and poultry products. Packaged fish that contain added ingredients such as water, salt, or additives such as sodium tripolyphosphate are considered multi-ingredient processed packaged fish products and must continue to be labeled on an "as packaged" basis.

However, in the companion document on nutrient content claims published elsewhere in this issue of the **Federal Register**, claims such as "lean," "extra lean," and "low fat" are based on as packaged values. Therefore, single ingredient packaged fish products that make such claims must provide nutrition information on an "as packaged" basis.

I. Raw Fish in Voluntary Nutrition Labeling Program

214. One comment objected to the manner in which FDA defined "raw" for the purpose of determining what fish products are covered by the exemption in proposed § 101.9(j)(10) that subjects the food to the voluntary nutrition labeling program. The comment stated that "absent a definition in the NLEA, the term "raw" means "uncooked" regardless of whether or not the product is frozen and, therefore, packaged frozen raw fish should not be subject to mandatory nutrition labeling.

FDA discussed its interpretation of the word "raw" as it pertains to fish in its proposed rule (July 2, 1991, 56 FR 30468 at 30470) and final rule (56 FR 60880 at 60886) implementing the voluntary nutrition labeling program for raw fruit, vegetables, and fish. Lacking legislative guidance, the agency chose to draw a practical line in terms of retail selling practices and program implementation rather than one based on a strict definition of the term "raw." While the agency included in the voluntary program those fish that are generally sold raw (i.e., not heat treated), it also included thermally processed shelled or unshelled lobster, crab, and shrimp. The intent was to allow for voluntary nutrition labeling of fish that are generally sold refrigerated, or on ice, or are alive at purchase in fish stores or in the fresh fish section of grocery stores and that are not packaged or are packaged by the retailer or by a packer. These are the types of products for which mandatory nutrition labeling is most impractical. In contrast, providing nutrition labeling for raw, frozen fish that are packaged by a manufacturer (usually in a box with a printed label and brand name) and sold in the frozen food case of a grocery store is no more difficult for a manufacturer than providing nutrition labeling of other packaged foods. Thus, these products appropriately come under the mandatory nutrition labeling program.

The agency has made a similar distinction with frozen packaged raw fruit and vegetables and has received no comment on it. It is likely that the greater concern on the part of the fish industry was a result of the inconsistency between nutrient values to be declared in the voluntary versus mandatory programs (i.e., nutrient values based on "as prepared" versus "as packaged" levels, respectively). The agency believes the exemption in new § 101.9(j)(11) should eliminate this concern. Accordingly, FDA sees no need to amend its interpretation of the term "raw."

The agency would like to clarify, however, a misinterpretation of the above definition of raw fish that appeared in comments. FDA considers raw shellfish in or out of the shell to be under the voluntary program, whether they are sold bagged in plastic containers or displayed loosely in trays or bowls. In addition, pasteurized crab meat that is not shelf-stable and is sold on ice or refrigerated would be included under the voluntary program, whereas canned pasteurized crab meat that is shelf-stable would be subject to mandatory nutrition labeling regulations. As discussed above, the agency considers nutrition labeling of the refrigerated product that may not have gone through a manufacturing plant impractical. However, the processing of the canned product is standardized, and nutrition labeling can be easily accomplished and is required.

J. Meat Products Regulated by FDA

215. Several comments recommended that nutrition labeling of game meat should be on a voluntary rather than mandatory basis. One game meat association stated that because buffalo is a red meat, it should be exempt from FDA regulations and should be allowed the option of voluntary labeling under USDA guidelines. The comment also requested that any required nutrition information should be allowed to be displayed at the point of purchase to reduce costs associated with nutrition labeling.

A number of comments expressed concern that the cost of analytical testing and nutrition labeling would be prohibitive for the small game meat producer. A request was made that an economic impact study be conducted of the effect of the proposed regulations on the buffalo industry before any final rule is issued. Comments suggested small business exemptions for producers marketing less than from 100,000 to 150,000 pounds per year per each product label. A few comments also requested that introductory test market, seasonal, short run, and experimental products should be exempt from nutrition labeling.

FDA is responsible for the regulation of all meats not covered by USDA under the Federal Meat Inspection Act and the Poultry Products Inspection Act (e.g., deer, bison, rabbit, wild turkey, or ostrich, hereinafter identified as "game meats"). Therefore, the law does not provide an option for such products to be covered by USDA guidelines. However, FDA appreciates the fact that game meat producers have had little, if any, experience with nutrition labeling, and that analytical data base information is scarce. Accordingly, the agency will give game meats as much latitude as possible under the 1990 amendments.

Because many game meat producers are small enterprises, it is possible that some will fall under the current small business exemption. Many of those that do not may do so in the future if a legislative amendment is passed to increase the exemption. However, if an amendment is not forthcoming, all nonexempt producers must provide the required nutrition information when the regulations become effective.

While the statute does not allow FDA to include raw game meats under the voluntary nutrition labeling program for raw fruit, vegetables, or fish, for consistency among all animal flesh products, single-ingredient game meat products (frozen or unfrozen, packaged or unpackaged) will also be included in § 101.9(j)(11) that permits the information to be declared on either an "as purchased" or "as prepared" basis (see comment 213 of this document).

Also, in response to a comment, FDA is adding § 101.9(j)(12) to the final regulations to allow nutrition information to be provided in accordance with paragraph (a)(2) of this section which allows the required information to be placed on labeling, that is on signs, posters, tags, or in binders or booklets displayed at the point-of-purchase. FDA believes that this action will allow game meat producers to give first priority to nutrient analyses and data collection and to update nutrient declarations more frequently than would be possible if the information were printed on food labels.

216. One comment requested the use of a data base to reduce the cost of nutrition labeling for game meat. It was noted that the nutrient composition of buffalo meat varies widely according to whether the animal was grain fed or range fed and according to age at slaughter. Another comment recommended that nutrient information for buffalo meat come from actual sample testing and not computer composites. The comment requested that FDA/USDA "do the same complete nutritional study for the buffalo industry as it does for other industries enveloped by the proposal."

FDA acknowledges that there is limited nutrient data available on game meats. The agency advises that it does not conduct nutrient analyses for any commodities; however, it is willing to work cooperatively with game meat producers to produce a valid nutrient data base. To this end, the Agriculture Research Service of USDA has experience in working collaboratively with industry in developing food composition data (Ref. 117).

217. Many game meat processors requested exemption from nutrition labeling for custom services. Custom processed meat includes wild game or domestic stock that is butchered to the specifications of the customer. The meat may have been sold to the customer or brought in by the customer for butchering. Comments stated that because the customer owns the animal at the time of butchering, the nutritional aspect of the meat product is the responsibility of the customer.

Consistent with similar regulations being issued simultaneously by USDA for nutrition labeling of meat and poultry products, FDA is exempting custom processed fish and game meats from mandatory nutrition labeling. This exemption is found in new § 101.9(j)(11)(ii). Legal authority for this is that what is being sold is not the food but the processing. Thus, the food is not subject to section 403(q) of the act.

K. Small Packages

218. A number of comments supported the small package exemption proposed in § 101.9(j)(11). While a few comments supported the provision that nutrition labeling be provided for foods in small packages at the point of purchase in accordance with paragraph § 101.9(a)(2), many other comments objected to this requirement. Several of these comments objected on the grounds that the 1990 amendments did not include a requirement for point of purchase disclosure for small packages, or that point of purchase displays of nutrition information would create "unnecessary clutter" and "place an undue burden on retailers" to find space for the information. One comment stressed the economic impact the proposal would have on supermarkets, especially those with front-end operations and checkout lanes where a wide variety of small package items are offered for sale. The comment stated that such areas would have to be reconfigured with fewer items available because of space lost to signage and fewer inventory changes made throughout the year. A comment raised a question about who would be held responsible if the information was not available at the point of purchase. Comments recommended that manufacturers, not retailers, should be responsible for nutrition information on all packaged foods. A suggestion was also made that interested consumers could refer to larger retail packages of the same product or could write or call the manufacturer for the nutrition

information by using an address or telephone number given on the package label.

FDA is persuaded by the comments that it is impracticable to require point of purchase display of nutrition information for small packages. However, because section 403 (q)(5)(B) of the act states only that the nutrition labeling requirements shall not apply to the label of the food, not the labeling as is included in section 403(q)(5)(C) and (q)(5)(D), the agency concludes that nutrition information about food in small packages must be provided to consumers through alternative means. The agency agrees with the comments that manufacturers should bear the responsibility for nutrition labeling of packaged foods and finds merit in the suggestion that manufacturers provide an address or telephone number on the package for consumers to write or call for nutrition information. FDA believes that almost all small packages should be able to add a short phrase, such as "For nutrition information, call 1-800-123-4567" to the label. In fact, many packages currently give an address or telephone number for consumer use in obtaining additional information about the product.

Therefore, FDA has modified § 101.9(j)(11), redesignated as § 101.9(j)(13)(i), to delete the requirement that foods in small packages that bear no nutrition claims or other nutrition information provide the required nutrition labeling in accordance with § 101.9(a)(2). The agency replaced it with a requirement that the manufacturer clearly state on the package label where a consumer may write or call to obtain the required nutrition information. If a manufacturer finds that it is impracticable to comply with even this requirement on a particular product, the manufacturer should write to the agency in accordance with § 101.9(g)(9) (see section VI.P.3. of this document).

219. A few comments from health professional organizations expressed the belief that the 12 square inch standard for "small packages" was too large, and that consumers should have as much information as possible about what they purchase and consume. One comment stated that "with the increase in fabricated foods and single serving size packaging, [they were] convinced that nutrition information can and should go on less space," adding that by using an abbreviated format, nutrition labeling is possible on smaller packages, down to 8 square inches.

However, several other comments objected to the 12 square inch definition for small packages, stating that it would not allow enough space for all the required information on the label, especially on a product with a lengthy ingredient list. The comments stated that the 12 square inch standard for exempting small packages was established years ago when much less information was required on food labels (i.e., before mandatory nutrition labeling). The comments also expressed concern that attempting to include all of the required information in 12 square inches would result in a label that would not be legible, making it difficult for sight-impaired or elderly persons to read. Comments also said that such a presentation would discourage use of the nutrition information, thereby undermining the purposes of the 1990 amendments.

Two manufacturers commented on the unique space problems arising when more than one language is used on small packages inasmuch as § 101.15(c)(2) requires that if a language other than English is used, all information on the label must be printed in both English and the other language. One comment pointed to the fact that the United States has become an increasingly bilingual nation, making Spanish-language labeling a "necessity in many parts of the country."

Several comments requested a more flexible rule based on "practically available space" or "usable surface space" on labels. One comment stated that the term "surface area available to bear labeling" is newly coined and unfamiliar and likely to be confusing. The comment recommended that the exemption be couched in terms of "total square inches on the information and alternate panels," which are familiar terms to manufacturers.

Other suggestions included: (1) Using a 20 square inch surface area, (2) excluding the principal display panel from the 12 square inch requirement, (3) excluding odd shaped parts of packages from the total surface area available for nutritional labeling, (4) allowing a linear (i.e., string) format for the nutrition information, (5) making the nutrition profile optional, (6) allowing for abbreviations of nutrients, (7) deleting the requirement for declaration of "Servings per container" on single-serving containers, and (8) allowing required nutrition information to appear anywhere on the package expected to be read by consumers rather than just on the information panel as required by § 101.2. In regard to the latter comment, one comment suggested that § 101.2 be modified to allow required information to be placed on other label panels adjoining the principal display panel or the information panel when there was insufficient space on a single panel.

A few comments stated that no manufacturer should be required to change its existing label style or container size to accommodate nutrition labeling. The comments urged that areas of a package not traditionally used for labeling should be excluded from the total surface area (e.g., many companies do not use lids of jars, necks of bottles, or bottoms of cans for labels). One comment recommended that current company practices be grandfathered until the company changes its packaging or container.

The agency received additional comments regarding small package limitations in response to the format proposal. Several comments from manufacturers of smaller size products such as candy rolls and bars, chewing gum, canned fish, and cookies stated that such labels could accommodate only the CONTROL format. Two comments suggested raising the minimum 12 square inch requirement for "small packages" to 13 square inches.

A number of comments addressed the inclusion of the DRV's on the labels of small packages. These comments apply to inclusion of the footnote providing calorie-specific recommended nutrient amount information specified in § 101.9(d)(8)(i).

The majority of comments asserted that it would be difficult to accommodate the DRV's without a relaxation of the minimum requirement of 12 square inches of printable label space. Most of those seeking relief suggested the option of listing DRV's in linear rather than column array over an intermediate range of printable package area. Alternate upper limits suggested were 20 and 26 square inches or no more than 30 percent of printable package area devoted to the nutrition label. One manufacturer provided support for 20 square inches as a minimum area below which DRV's could not be accommodated without violating minimum type size or principal display panel size requirements. It submitted executions of the proposed and alternate formats for several existing products. One comment suggested several principles to be followed by FDA in establishing a range within which the DRV listing could be modified or deleted while preserving legibility and remaining in conformance with existing labeling requirements concerning type size and area devoted to the principal display panel.

FDA acknowledges the need to give consumers as much information as possible. The agency is persuaded,

however, that with requirements for more nutrition-related information, it may be difficult to get all of the required information on packages that just meet or slightly exceed 12 square inches of surface area available to bear labeling, particularly for products that do not qualify for the simplified format. However, in light of the exemption from nutrition labeling on the package label for products with less than this amount of usable surface space, provided that no nutrition claim is made (see preceding comment), the agency believes that exempting a larger number of foods by increasing the definition of "small package" size would undermine the intent of the 1990 amendments.

However, based on the comments, FDA has concluded that justification exists for developing a graduated system that would allow added flexibility for foods in an intermediate package size group. To select the dimensions of such an intermediate sized package, FDA reviewed comment suggestions, examined the space requirements of the required label with the calorie-specific daily values, and reviewed data on available label area for a sample of packaged foods (Ref. 117a). The agency is rejecting suggestions such as the use of only "practically available space" or "usable surface space" or the exclusion of "oddly shaped parts of packages" because there is a significant potential for differences of opinion about what is "practically available," "usable," or "oddly shaped." The remaining suggestions are to exclude the principal display panel, to use an upper limit of 20 or 26 square inches of surface area available to bear labeling, or to require that no more than 30 percent of the surface area available to bear labeling be devoted to the information panel.

The agency believes that the suggestion to apply the 30 percent criterion to space requirements necessary to comply with FDA regulations has merit. Based on current requirements (see § 101.1(b) and (c)), the principal display panel can be considered to cover 40 percent of the total surface area available to bear labeling. On the assumption that no more than half of the remaining 60 percent of the label should be required to be devoted to FDA-required information (i.e., the nutrition label and ingredient list), 30 percent of the total surface area would be used for such information. This is consistent with the comment.

Based on the data examined, FDA believes an upper limit of 40 square inches of surface available to bear labeling is appropriate to define an intermediate sized package. The smallest legal sized execution of the format required under § 101.9(d) is approximately 7 square inches. For many processed foods, the addition of the ingredient list could bring the space needed for presenting this FDA-required information to 11 square inches. Using the 30 percent factor, this information could be accommodated on packages with 37 square inches available to bear labeling. In order to provide incentive to allow sufficient space to make the label readily observable and easily comprehensible, the agency has decided to round this number up to 40 square inches. The agency is providing for this upper limit in § 101.9(j)(13)(ii).

The agency does not agree with the comment that the term "surface area available to bear labeling" is newly coined and unfamiliar, inasmuch as it has been used in § 101.2(c)(3)(i) for 17 years.

FDA looked to the comments for suggestions of added flexibility for the labeling of foods in intermediate sized packages available to bear labeling. Suggestions in the comments included: Allowing a linear (i.e., string) format for nutrition information (including the DRV listing), making DRV's optional, allowing for abbreviations, deleting the requirement for declaration of "Servings per container" on single-serving containers, and allowing required nutrition information to appear in other places than those required by § 101.2 (i.e., the information panel). Dependent upon the circumstances of a particular package size and shape, the agency is not opposed to the use of any of these suggested methods. In addition, as provided for in § 101.9(g)(9), manufacturers may request special allowances for provision of the required information on tags affixed to the product according to § 101.9(a)(2) as discussed in section VI.P.3. of this document, Foods For Which Labeling Is Impracticable.

In regard to the request to delete the requirement for declaration of "Servings per container" on single serving containers, FDA finds that inasmuch as the declaration of "Serving size" on such products will specify that the serving is the entire unit (e.g., 1 can or 1 bar), it would be needlessly repetitive to state that there is one serving per container. Therefore, FDA has modified § 101.9(d)(3)(ii) that pertains to all container sizes to state that "Servings per container" is not required on single serving containers as defined in § 101.9(b)(6).

While the provisions being made to increase flexibility are for the purpose of making it easier for manufacturers to place mandatory nutrition labeling on packages of an intermediate size, they may also be used on "small packages" (i.e., packages with less than 12 square inches of surface area available to bear labeling) whose labels are exempt under § 101.9(j)(13)(i) when manufacturers elect to provide a nutrition label on those foods.

FDA is providing in § 101.9(j)(13)(ii)(A) that the required nutrition information may be presented in a tabular fashion when the package shape or size cannot accommodate a column display on any label panel. This form of presentation is currently used on many foods in long rectangular or round packages, such as candy bars and is shown in Appendix H. In addition, to facilitate the provision of information on small packages, § 101.9(j)(13)(ii)(A) provides for the use of a tabular presentation on all products with less than 12 square inches of surface area available to bear labeling, regardless of the package shape. Further, if the label will not accommodate a tabular display, § 101.9(j)(13)(ii)(A) also provides that the required nutrition information may be presented in a linear (i.e., string) fashion.

In regard to abbreviations, one comment stated that the design limits of their company's printers for labels to be affixed to foods packaged in retail stores limited the description of nutrients to 10 characters. While the agency is concerned about the use of abbreviations and any possible consumer confusion they may cause, FDA believes their use under limited and controlled conditions may be preferable to overcrowding within the nutrition label. Therefore, based on this comment, the agency is providing the following abbreviations in § 101.9(j)(13)(ii)(B) for those mandatory nutrients whose names exceed 10 characters.

Serving size: Serv. size
Servings per container: Servings
Calories from fat: Fat cal
Saturated fat: Sat fat
Cholesterol: Cholest
Total carbohydrate: Total carb
Dietary fiber: Fiber

Section 101.9(d)(9)(iv) allows these abbreviations to also be used in a footnote within the nutrition label.

As discussed above in section V. of this document on the format of the nutrition label, FDA is providing in § 101.9(j)(13)(ii)(C) that the footnote and caloric conversion information required in § 101.9(d)(9) and (d)(10) may be omitted on intermediate sized packages. When the footnote required by § 101.9(d)(8) is omitted, an alternate footnote must be used that states:

"Percent Daily Values are based on a 2,000 calorie diet."

The agency believes that concerns expressed in comments requesting that the nutrition information be allowed to appear elsewhere on the package rather than just on the information panel as required by § 101.2 (see § 101.9(i)) are generally addressed by § 101.2(a)(1). This section states that if the information panel is too small to accommodate the necessary information or is otherwise unusable label space, e.g., folded flaps or can ends, the panel adjoining to the right may be used. However, in recognition of the increased need for this flexibility in packages with less than 40 square inches available to bear labeling, FDA is providing in § 101.9(j)(13)(ii)(D) that nutrition labeling on intermediate sized packages may appear on any label panel.

As a conforming change, § 101.9(c), (d), and (i) have been modified to reflect the provisions of § 101.9(j)(13).

In regard to the comments requesting an exemption or postponement based on current company labeling practices, FDA advises that Congress did not provide in the 1990 amendments for any such actions. The agency recognizes the possible economic burdens associated with changing labeling practices and has tried to incorporate sufficient flexibility to minimize the need for such changes but has no authority to prevent them. FDA advises that in § 101.1 the agency stated that, in determining the area of the principal display panel, tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles and jars were to be excluded. Therefore, it is reasonable to conclude that the agency will not include these areas in determining the "surface area available to bear labeling."

220. A comment requested clarification as to whether manufacturers of products that are sold in small packages that qualify for the small package exemption are required to omit nutrition information from the label and then present it through other means as required in proposed § 101.9(a)(2), or whether they may attempt to provide the nutrition labeling.

While comment 218 of this document addressed the underlying concern in this comment about the mandatory inclusion of required nutrition information in labeling at the point of purchase, FDA does not view this or any other exemption under § 101.9(j) (except for infant formula which is subject to other labeling requirements) as prohibiting a manufacturer from including nutrition labeling on the label of a food product. The agency encourages the inclusion of nutrition information on the label of exempted products whenever possible. To clarify the situation, § 101.9(j)(13)(i) has been modified to state that the new requirement for an address or telephone number for consumer use in obtaining nutrition information is to apply to products that qualify and use this exemption.

L. Shell Eggs

221. One manufacturer commented on the labeling of egg cartons, stating that proposed § 101.9(j)(12) allowing for the presentation of the required nutrition information immediately beneath the carton lid is as impractical for many egg cartons as requiring its display on the upper surface of the lid because both surfaces conform to the shape of the eggs. The comment suggested that packaging of this kind may not be readily imprinted at all. The comment further stated that eggs are a largely homogeneous agricultural commodity, and eggs sold at retail in their shells should all be treated alike with respect to nutrition labeling, whether the eggs are in bulk, on trays without cartons, or in cartons. The comment requested that eggs be exempt under 21 U.S.C. 343(q)(3) that allows the Secretary to provide that nutrition labeling be displayed at the point of purchase for foods received in bulk containers.

FDA is persuaded by the comment that it may be impractical for egg cartons that conform to the shape of the eggs to bear nutrition labeling. Accordingly, FDA is modifying § 101.9(j)(12) (redesignated as § 101.9(j)(14)) to allow the required nutrition information to appear on the inside or the outside of the carton, or on an insert that can be clearly seen when the carton is opened. By doing this, FDA is greatly expanding the total surface area available to bear labeling.

FDA rejects the suggestion that, because some eggs are sold in bulk, all eggs should be allowed to be labeled at the point of purchase according to the exemption for bulk foods (§ 101.9(j)(9)). As discussed above, nutrition labeling for eggs may appear on the egg carton or on a package insert. FDA concludes that there is no need to modify § 101.9(j)(14) to allow for further special conditions for shell eggs packed in cartons. If, in fact, a manufacturer finds it impossible to label a particular egg carton or to include a package insert, it may request a special allowance from the agency, as discussed in comment 223 of this document.

M. Multi Unit Packages

222. A few comments disagreed with the requirement in proposed § 101.9(j)(13)(iii) that each unit within a multipack state "this unit not labeled for retail sale." Comments stated that this requirement is redundant because § 101.9(j)(13)(i) and (j)(13)(ii) adequately prevent the product from being sold without nutrition labeling.

The agency does not agree that the requirement is redundant. Although multiunit containers may be enclosed and are not intended to be separated from the retail package under normal conditions of sale, occasionally the individual units are separated from the multiunit container and purchased separately. Proposed §§ 101.9(j)(13)(i) and (j)(13)(ii), redesignated as §§ 101.9(j)(15)(i) and (j)(15)(ii), state: "The multiunit retail food package labeling contains all nutrition information in accordance with this section;" and "The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale." These sections cannot guarantee that the units in a multiunit package will not be separated; e.g., frozen juice bars, soft drink bottles, and sticks of butter are sometimes separated from an enclosed multiunit package by consumers prior to purchase at the retail level. Therefore, FDA is not modifying the regulation.

223. A soft drink trade association requested a provision in the final rule to exempt from nutrition labeling glass bottles with lithographed labeling that are marketed in multi-unit packages. These bottles, the comment pointed out, are often loosely packed rather than securely enclosed. The comment made reference to the technical limitations of labeling glass by the lithograph method, and the impracticality of placing nutrition labeling on the individual bottles or "unit containers." The comment requested that the agency clarify the proposal to ensure the continued availability of lithographed bottle multiunit packages and suggested that the nutrition labeling information appear on the information panels of the multiunit retail package.

The agency acknowledges that there will be some circumstances in which strict adherence to the regulations (in this case the requirement that units be securely enclosed in the retail package) is not technologically feasible, or some other circumstance makes it impracticable. Proposed § 101.9(g)(8) would have allowed for alternative means of compliance or additional exemptions to deal with the situation when firms were unable to develop

adequate nutrient profiles. The agency concludes based on this comment that this latitude should be available for additional circumstances. Accordingly, FDA is modifying § 101.9(g)(8), redesignated as § 101.9(g)(9), to broaden its scope by stating "When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section (e.g., to develop adequate nutrient profiles to comply with paragraph (c)), * * *."

Additionally, FDA believes that actions taken to address technological or other problems on a case-by-case basis do not need to be established by regulation in response to a petition to initiate rulemaking. Therefore, the agency is replacing "establish by regulation" with "permit" in § 101.9(g)(9) and is deleting the reference to a petition, stating instead that firms in need of such special allowances shall make their request in writing to the Food and Drug Administration, Office of Nutrition and Food Sciences (HFF-200), 200 C St., SW., Washington, DC 20204. However, FDA concludes that no change is necessary in § 101.9(j)(15) in response to this comment.

N. Foods Sold from Bulk Containers

224. A food retailer wrote in support of the requirement in proposed § 101.9(j)(14) that nutrition labeling information for bulk foods be provided at the point of purchase. However, the comment took exception to the agency's intention to include within the requirement individually wrapped bulk food items such as candies, arguing that the exemption for small packages should apply to small individually wrapped food items that are sold in bulk.

FDA disagrees with this comment. The labels of individually wrapped small food items, such as bite size pieces of candy, are exempt from nutrition labeling under the small package exemption (§ 101.9(j)(13)) because of the lack of space needed to print the required information. However, under section 403(q) of the act, foods sold from bulk containers must be nutrition labeled whether or not they are individually wrapped. Nutrition labeling can, and should, be presented on the labeling of the bulk container or on a counter card, sign, or other appropriate device as identified in § 101.100(a)(2). Moreover, as discussed above, the exemption for small packages only applies to the label and not to a product's labeling. The agency reiterates its position as stated in the **Federal Register** of July 19, 1990 55 FR 29487 at 29505, and 56 FR 60366 at 60379:

> * * * Many foods, such as candies, cookies, and pasta, are offered for sale from large containers such as barrels or bins. FDA has traditionally required that these foods be labeled in accordance with section 403(i)(2) of the act through the use of a counter sign or card on the labeling of the bulk container [21 CFR 101.100(a)(2)]. The agency believes that nutrition labeling can be provided in a similar manner. Therefore, the agency will require nutrition information for such foods.

Accordingly, no changes are being made to § 101.9(j)(14), redesignated as § 101.9(j)(16).

225. Several other comments were received in support of the requirement in the proposed version of § 101.9(j)(16) that nutrition labeling information for bulk foods be provided at the point of purchase. Two comments recommended that nutrition information be provided in the form of brochures or "tear-off" sheets at the point of purchase, so that consumers can have the information available at home.

FDA agrees that tear-off sheets or brochures with the required nutrition information would be useful to consumers and encourages manufacturers to provide retailers with the required nutrition information in such form. Section 403(q)(3) of the act states: "For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required * * * be displayed at the point of sale." Thus, the statute does not specify the form in which this information is to be provided. Accordingly, FDA has not made the recommended change.

226. A retail ice cream manufacturer requested that the proposed version of § 101.9(j)(16) be clarified so that scoops of ice cream that are dispensed by store employees from bulk ice cream containers are clearly not subject to the "sold from bulk containers" requirement.

FDA advises that it is not necessary to exempt ice cream from the requirements of § 101.9(j)(16). Ice cream that is dispensed by store employees from bulk ice cream containers at an ice cream store is for immediate human consumption and would therefore be exempt from mandatory nutrition labeling under revised § 101.9(j)(2)(ii).

227. A retail grocery chain stated that popular bulk food items sold from bins and barrels but packaged by clerks for customer convenience should not be required to have nutrition labeling on each package.

FDA advises that § 101.9(j)(16) allows food products sold from bulk food containers to display the required nutrition information "either on the labeling of the bulk container plainly in view or in accordance with provisions of paragraph (a)(2) of this section." Section 101.9(a)(2) allows use of counter cards, signs, tags affixed to the product, or other appropriate devices. Accordingly, the containers such foods are put into when sold to the consumer need not bear nutrition labeling as long as the required nutrition information is plainly in view, regardless of whether it is the consumer or a store employee that packages the product. However, if the foods are packaged in an area that is off-limits to customers, and the information is not plainly in view, the required nutrition information must be available on the package label or in labeling adjacent to the packages accordingly to the provisions of § 101.9(a)(2).

O. Foods Used as the Sole Item of the Diet

228. One professional organization and one consumer interest group wrote in support of FDA's tentative decision to delete the exemption in current § 101.9(h)(3) for foods promoted as the sole item in a diet (such as formulated weight-loss products) and to have the same labeling requirements for those products as all other foods. The consumer interest group stated that "considering the minimal long-term benefit from these products and the potential for harm from the unsupervised use of these products, FDA should consider greater labeling requirements for these products."

FDA intends to monitor the use and labeling of foods used as the sole item of the diet and, as discussed in the supplementary proposal (56 FR 60366 at 60378), will consider at a later date whether there should be additional or different requirements for the nutrition labeling of these products.

P. Other Requests for Exemption

1. Donated Foods

229. Two comments from food banks requested an exemption from mandatory nutrition labeling, citing that food banks are nonprofit charitable organizations, and as such, it would be "unreasonably costly and unduly burdensome for (food banks) to be required to apply complete nutrition labeling to repacked food products." The comments stated that the exemption is necessary to ensure that mandatory nutrition labeling rules do not hamper the ability of charitable organizations to receive and distribute foods to needy individuals.

Section 403(q)(1) of the act requires nutrition labeling on food that "is intended for human consumption and is

offered for sale." Accordingly, donated foods that are given without charge to the ultimate consumer are not subject to mandatory nutrition labeling. This provision of the 1990 amendments was not included in the proposed implementing regulations. To correct this omission, the agency is modifying § 101.9(a) to state that "Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale * * *."

230. A second request from these foods banks was that food companies having inventories of foods not in compliance with new labeling rules after the effective date of section 403(q) of the act be permitted to donate those products to charitable organizations.

Section 10(a)(2) of the 1990 amendments states that the new nutrition labeling requirements shall not apply to foods labeled before the effective date. Therefore, companies will be able to continue to sell all foods that are labeled in compliance with current regulations before the effective date of section 403(q) of the act, May 8, 1993. As a result, there should be no inventories of labeled food that cannot be sold to consumers. The agency wishes to state, however, that it has long been the agency's policy that misbranded foods, such as those that have been the subject of a seizure or recall, can be donated to charitable organizations rather than being destroyed if they do not present a safety concern, and the recipient is fully informed as to the problem with the food (e.g., short weight).

231. Two comments expressed concern that if donated foods are exempted from nutrition labeling, the goals of nutrition labeling will not be met for individuals who rely on such foods.

In passing the 1990 amendments, Congress intended to require that consumers have the necessary information at their disposal to select diets that are consistent with dietary recommendations aimed at improving the health status of Americans. However, by requiring nutrition labeling only on foods offered for sale, Congress limited the coverage of the nutrition labeling requirements. Therefore, while the agency would encourage nutrition labeling on any foods repackaged or relabeled by charitable organizations, the statute does not require such labeling.

The agency is pleased to note, however, that in conversations with the Food and Nutrition Service, USDA, which administers the Food Distribution Program, the Food and Nutrition Service has stated that it plans to incorporate nutrition labeling on all foods that it distributes to individuals. The Food Distribution Program purchases surplus foods from American markets and distributes them to State agencies for further distribution to individuals and eligible local outlets.

2. Exported Foods

232. Comments from a trade association and a manufacturer requested that products intended for export be exempt from U.S. nutrition labeling regulations because they will necessarily be required to comply with the importing country's labeling criteria.

FDA advises that under section 801(e) of the act, foods intended for export will not be deemed misbranded under section 403 of the act under certain circumstances. Section 801(e) states that:

> A food, drug, device or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it:
>
> (A) Accords to the specifications of the foreign purchaser,
>
> (B) Is not in conflict with the laws of the country to which it is intended for export,
>
> (C) Is labeled on the outside of the shipping package that it is intended for export, and
>
> (D) Is not sold or offered for sale in domestic commerce.

Thus, if a company complies with the requirements of section 801(e) of the act, it need not be concerned about misbranding the food by failing to comply with section 403(q) of the act.

3. Foods for Which Labeling Is Impracticable

233. Two dairy companies requested that returnable glass milk bottles be exempt from nutrition labeling because the total surface area available for labeling is much less than 12 square inches. The labeling surface is the closure on the top of the bottle. If the label were placed on the side of the bottle it would be impossible to recycle the bottle for milk use because of problems with washing and disinfecting the bottle after each use. The comments stated that the returnable glass bottle is important for the environment, and that many of their customers purchase it for that reason. They suggested the nutrition labeling for milk in returnable glass bottles be placed on placards at the point of purchase.

Other comments requested special allowances for uniquely shaped package containers (such as containers of honey in the shape of a bear, individual juice containers in the shape of a hand grenade, or cheese balls) or packaging materials that do not allow for fine printing (e.g., styrofoam ice cream cups).

FDA is willing to consider allowing the required nutrition information for returnable glass milk bottles to be available in labeling, as provided for in § 101.9(a)(2). As discussed in comment 223 of this document, § 101.9(g)(9) of this final rule allows that when it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of nutrition labeling, FDA may permit alternative means of compliance or additional exemptions to deal with the situation.

4. Foods Purchased Under Government Contract

234. One trade association and one manufacturer requested exemptions for products produced for Government contracts (e.g., the National School Lunch Program, military feeding operations), using the reasoning that any products sold would be offered to the final consumer as part of a total meal/diet, and nutrition information on the meal must be supplied by the facility offering the meal.

FDA advises that products of the type discussed in the comment that are sold for use in restaurants and institutional food service operations are exempt under § 101.9(j)(2)(iii). As long as it is not reasonably possible that they will be sold directly to consumers, they need not be nutrition labeled. Therefore, no further exemption is necessary.

VII. Other Issues

A. Assortments of Food

235. A few comments requested clarification on whether assortments of foods, such as a box of assorted chocolates or nuts, would have to bear nutrient information on each type of chocolate (or nuts), or whether an average nutrient value would suffice.

The agency advises that in the preamble to the mandatory nutrition labeling proposal (55 FR 29487 at 29505), it stated that "where assortments of food are packaged, firms will be required to express nutrient content based on the package as a whole (e.g., the entire product contents may be combined for a nutrient analysis)." FDA recognizes that the terms "will be required" and "may be combined" appear inconsistent. Therefore, to clarify the regulation and in accordance with the agency's intent to offer flexibility in the labeling of assortments of foods, FDA has modified § 101.9(e)(1), recodified as § 101.9(h)(1), by deleting "of the total product" and adding a new sentence that states that when

separately packaged ingredients or assortments of the same type of foods are intended to be eaten at the same time, the nutrition information may be specified for each component or as a composite value. In developing a composite nutrient value, the entire product contents would be combined for a nutrient analysis.

In addition, to clarify the term "assortments of food" FDA has modified § 101.9(h)(1) by adding "assortments of the same type of food" and including the example of assorted nuts.

236. A few comments addressed the labeling of variety packs containing an assortment of individually packaged products (e.g., assorted ready-to-eat breakfast cereals or snack foods such as corn chips, cheese puffs, and potato chips). A food manufacturer marketing variety packages stated that they currently label each of the single-serving packages placed in a multi-serving container separately. The comment stated that the outer wrapping is generally transparent, making extensive labeling on the outer wrapping infeasible. Another comment suggested that the outer label contain the statement "Individual inner units carry nutrition information" where each of the single-serving packages in the variety pack bears nutrition labeling. The comment also stated that larger sizes of the individual packages of foods in the variety pack are invariably available to consumers at the same location, and the nutrition labels on those larger packages may be reviewed if desired.

FDA points out that a primary purpose of the 1990 amendments is to allow consumers to maintain healthy dietary practices. To do this, consumers must have access to nutrition information at the point of purchase. In many situations, consumers can look at the nutrition labels of larger packages of the individual foods for nutrition information. However, the agency does not agree that it is always possible to do so.

With respect to the transparent nature of the outer wrapping, FDA does not believe this makes labeling on that wrapping infeasible. Many bakery products are packaged in transparent wrappers and these products provide nutrition and other label information.

Inasmuch as many variety packs are currently printing the required nutrition information for each of the products contained in the variety pack in a table on the outer package, and because the outer packages are generally large, the agency concludes that a special allowance is not required for variety packs. Accordingly, FDA rejects the suggestion that the outer label merely state that the individual units within the package provide nutrition information.

However, the agency has no objection to manufacturers labeling only the individual inner packages if the information is provided in such a way that consumers can clearly see it at the time of purchase. Examples of this type of packaging can be found currently in the marketplace where nutrition labeling is provided on the tops of single-serving packages of breakfast cereals. Accordingly, FDA is adding a new paragraph § 101.9(h)(2) to specify that nutrition labeling of single-serving packages within variety packs must be clearly visible at the point of purchase. Proposed § 101.9(e)(2) is redesignated as § 101.9(h)(4).

237. FDA received comments from companies that sell food products by mail order, particularly varieties of foods and food assortments that are marketed as gifts. The comments requested special provisions in the regulations to provide some flexibility for packaged gift assortments because these packages are assembled from several thousand separately labeled food items, many of which are similar, differing only in size or flavor, and which are used in many different assortments. Because of the unique characteristics of the mail order gift food industry, caused, in part, by rapidly changing selections of gift packages offered, the comments contended that nutrition labeling would have a devastating effect on the industry, unless alternative means of compliance are allowed.

The comments requested that a new paragraph be added under proposed § 101.9(e) for assortments of foods intended to be used as gifts, allowing for nutrition information on such foods to: (1) Be included on labeling, (2) be based on uniform serving sizes, (3) omit reference to "servings per container," (4) be calculated as averages for categories of foods having similar dietary uses or similar significant nutritional characteristics for characterizing nutrients, (5) be based on calculations from nutrient data bases, and (6) omit foods meeting the definition of "small package" in § 101.9(j)(13) from determinations of nutrient content. A subsequent comment on behalf of the mail order gift food companies modified the last provision to state that foods in small packages only be omitted if they are not listed in promotional catalogues and are "optical garnishes" used to enhance the appearance of the gift package, or bonus items included as a free gift or promotional item.

FDA is persuaded that special allowances are justified for gift packages containing a variety of foods (e.g., cheese, jams, and crackers packed together in one gift box) or of food assortments (e.g., several different types of jam in one box). Accordingly, the agency is adding a new paragraph § 101.9(h)(3) to address gift packages.

New § 101.9(h)(3)(i) allows the required nutrition information to appear on the label or in labeling that is within or attached to the outer gift package. This provision allows the information to be consolidated in a single document that could accompany several different gift food packages that contain the same assortment of foods, although not necessarily in consistent size packages, as are identified in the document. This action is in recognition of the fact that the person who buys the gift package is generally not the person who will use the information. According to the comments, on average, 65 percent of company sales are shipped to recipients other than the purchaser. Moreover, many packages shipped to purchasers are subsequently offered as gifts to other persons.

The "outer package" is intended to mean the container directly within which component items are packed. It does not mean the shipping carton, unless component items are packed directly within the shipping carton instead of being packed in a separate inner container.

Comments also have persuaded the agency that standardizing the serving sizes for foods included in gift packages will simplify the simultaneous presentation of information on a variety of different types of foods by putting the information for all products on a comparable weight basis and, thereby, increase the likelihood that consumers will use and understand the information. The comments requested that, where there is no uniform household measure that is either a common multiple or fraction of the quantity of an individual food in an assortment, one ounce (fluid or solid as appropriate) be used as the standard serving size. Rather than leaving open the possibility of the use of any "uniform household measure," however, FDA believes that an allowable exemption from the serving size requirements would be permissible only when all of the foods in a particular gift package are not subject to the same reference amount customarily consumed, as specified in § 101.12(b).

FDA has no objection to the suggestion of a one ounce serving size

for solid foods in such circumstances. The selection of one ounce is acceptable based on the fact that it is the simplest value for use in calculations, many of the foods are packaged in multiples of one ounce, and it is the same as the reference amounts customarily consumed for many of the types of foods used in gift packages (e.g., many cheeses, crackers, and nuts) specified in § 101.12 in the companion document on serving sizes published elsewhere in this issue of the **Federal Register**.

In the case of liquids, the agency believes a larger serving size is needed because of the extra weight of water, and because there are no reference amounts specified in § 101.12 for liquids at only one fluid ounce. Based on the reference amounts in § 101.12, FDA believes a serving size of 2 fluid ounces is more appropriate for nonbeverage liquids such as syrups, and 8 fluid ounces is appropriate for beverages. These are the reference amounts in § 101.12(b) for maple syrup and for all beverages, respectively. The agency does not believe that it is reasonable to collapse the number of categories of foods any further than these three groups for the purpose of nutrition labeling of gift packages. Therefore, in response to the comments and in an effort to minimize the number of different serving sizes required in the nutrition labeling of gift packages, § 101.9(h)(3)(ii) allows for a serving size of 1 ounce for all solid foods, 2 fluid ounces for nonbeverage liquids, and 8 fluid ounces for beverages where there is no uniform reference amount customarily consumed for each individual food used in an assortment or variety of foods within a gift package.

However, the agency believes it would be misleading to allow nutrient content or health claims based on these serving sizes for foods packaged in gift packs where they differ from reference amounts specified in § 101.12(b) that are used as criteria for the claims. Therefore, § 101.9(h)(3)(ii) states that the reference amounts customarily consumed that are listed in § 101.12 must continue to be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

Inasmuch as section 403(q)(1)(B) of the act requires that the number of servings per container be included on the nutrition label, FDA does not believe that it has the authority to permit this information to be deleted. However in § 101.9(h)(3)(iii), FDA is allowing for the number of servings per container to be stated in the nutrition label as "varied" in recognition of the fact that each type of gift package will furnish a different number of servings. This action is consistent with § 101.9(b)(8) in the companion document on serving size published elsewhere in this issue of the **Federal Register**, which allows a manufacturer to declare "varied" for the number of servings per container for random weight products. The assembling of gift packs has a random quality. FDA is persuaded that requiring more specific information on labeling would necessitate a unique label or labeling for each package, negating the usefulness of these special provisions.

Section 101.9(h)(3)(iv) provides that average, composite nutrient values may be declared in nutrition labeling for reasonable categories of foods having similar dietary uses and similar significant nutritional characteristics. While the comments requested that composite values be allowed for reasonable categories of foods having similar dietary uses or similar significant nutritional characteristics, FDA believes that both criteria are necessary. Many forms of cheese and peanut butter have similar dietary uses in that they are used to make sandwiches or are eaten on crackers, yet they have far different nutritional characteristics and should not be composited.

The comments suggested, and FDA concurs, that companies should submit to FDA their determinations of "reasonable categories" for review and acceptance. FDA's decision on the companies' determinations will be based, in large part, on whether the values of the characterizing nutrients for foods in the category meet the compliance criteria set forth in § 101.9(g)(3) through (g)(6). To that end, companies should also submit a list of proposed characterizing nutrients for each "reasonable category" of foods.

For example, assuming total calories, total fat, saturated fat, and cholesterol are the categorizing nutrients for a group of cheeses, each cheese's content of these 4 nutrients would have to be no greater than 20 percent in excess of the declared values in the nutrition label, in accordance with § 101.9(g)(5), or reasonably less than the declared values, in accordance with § 101.9(g)(6). Nutrients other than the characterizing nutrients could be stated as an average, or composite, for the category, without having to meet the standards of § 101.9(g)(3) through (g)(6).

While the comments requested that FDA specifically permit the use of data bases for calculating the nutrition information for foods in gift packages, the agency does not believe a separate policy from that which the agency is establishing for other packaged foods (see section VII.B.2. of this document) is necessary or appropriate.

Section 101.9(h)(3)(v) allows foods that meet the definition for small packages under § 101.9(j)(13)(i) that are included in a gift package to be omitted in determining the nutrition information if they are not specifically listed in a promotional catalogue, and they are used in small quantities as "optical garnishes" to enhance the appearance of the gift package or are included as a free gift or promotional item. According to the comment, these items are used in very small quantities and may vary greatly from package to package. On the understanding that the "optical garnishes" are generally small plain candies wrapped in bright colored paper, the agency believes that the small amount used will make an insignificant nutrient contribution to the total package. Free gifts or promotional items, by definition, are not "offered for sale" and are therefore exempt under § 101.9(a).

B. Compliance (§ 101.9(g))

1. Compliance Procedures

In discussing the agency's rationale for requiring a single nutrient value on the label in lieu of permitting ranges of values, FDA tentatively concluded that its current compliance policy with respect to nutrient variability satisfied the requirements of the 1990 amendments (56 FR 60366 at 60373).

The compliance policy in current § 101.9(e) (proposed § 101.9(g)) requires that the nutrient content of the composite of 12 subsamples be at least equal to the labeled value for Class I nutrients (i.e., added nutrients in fortified and fabricated foods) and at least 80 percent of the labeled value for Class II nutrients (naturally occurring or indigenous nutrients). Proposed § 101.9(g)(4) specified that these requirements are applicable for vitamins, minerals, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, and potassium content. Likewise, in proposed § 101.9(g)(5), the nutrient content of the composite is required to be no more than 20 percent above the labeled value for calories, sugars, total fat, saturated fat, cholesterol, and sodium.

238. The agency received a number of comments regarding its compliance policy as stated in proposed in § 101.9(g) (56 FR 60366 at 60391). A few comments agreed with allowing an 80 to 120 percent leeway in the compliance of foods. One comment noted that while the nutrient values may not be absolute,

they are more consistent for the consumer. Also, the present system makes it easier for manufacturers to obtain compliance. However, the majority of comments disagreed with FDA's compliance policy, requesting that either a tighter or looser standard be used.

Consumers were strongly opposed to the so-called "80-120 rule." They felt the range was too lenient and stated that they would like to see a tighter standard adopted, especially for calories. Fat, carbohydrate, and cholesterol were also identified as nutrients that should have very accurate or exact label declarations. Some suggested other limits of acceptance, such as a plus or minus 5 to 10 percent range. Several comments supported a more accurate declaration of nutrients in consideration of the needs of persons with medical conditions requiring adherence to specialized or restricted diets. Other consumers considered the 20 percent margin of error as being inaccurate and misleading. Some comments considered that with today's available technology, food manufacturers could and should more accurately declare nutrients, notably calories, on the labels and meet more stringent standards.

Several comments included suggestions as how to better declare nutrient content on the label. Suggestions included the declaration of a tolerance standard on all product labels and an example of what the tolerance could mean. For example, the label of a product having a 10 percent tolerance for calories would state the declaration as "100 calories--could be 90 or 110 calories." One comment suggested that a statement be required adjacent to the calorie value declaring that it is "only an approximate figure." Another suggested that all food labels carry a warning of the 20 percent margin of error permitted for calories.

Comments from industry and trade associations considered the 80/120 percent range unduly restrictive. They supported more flexible compliance standards that would provide "representative values" of a product's nutrient content. Representative data in one comment was defined as the mean or the mean plus or minus one standard deviation. Their contention was that, because of the natural variation of foods, application of FDA's compliance procedures result in gross under-representation of some nutrients, such as vitamin A in carrots, and gross over-representation of other nutrients, such as sodium in soft drinks (because of variability in water sources). The comments took exception to FDA's assertion in the discussion on fresh produce and seafood, in the mandatory nutrition labeling proposal (55 FR 29487 at 29506) that nutrient content can largely be controlled in most manufactured foods. In fact, they stated there is greater variability in processed foods because of the complexity of prepared foods, the further processing that is required, the need to total the variability for each ingredient for prepared foods, the flexibility needed for obtaining ingredients from various sources or suppliers, and the analytical variability for required nutrients. One comment recommended that an 80 to 120 percent compliance range be used for nutrients with a low degree of natural or analytical variability. For nutrients with a high degree of natural or analytical variability, a less stringent 65 to 135 percent compliance range was suggested.

Another comment endorsed a more flexible compliance standard whereby micronutrient levels need only be present at a minimum level of 80 percent of declared levels. They recommended that no maximum compliance level be set. This comment was particularly in reference to the difficulty of achieving compliance for a product that has a standard of identity, such as pasta, where maximum and minimum levels of enrichment are specified by the standard. The comment stated that levels of added nutrients may vary depending upon the method of enrichment, indigenous nutrient levels in the wheat, analytical error, rounding of values declared on the label, and loss of nutrients during the drying process.

The agency disagrees with establishing more stringent requirements for label values. FDA shares concerns about individuals with very specific health problems where diets must be closely monitored and controlled. However, no data have been presented, and FDA is not aware of any such data, to suggest that health problems have been created because of the allowable variances. Therefore, the agency considers health management under professional guidance satisfactory using the nutrient values on the labels based on current regulations. In addition, it should be noted that the natural variability of foods may lead to both under- and over-reporting within the allowable variances for individual foods. These variances will tend to balance out over the entire day's diet.

While it is highly desirable to have a precise nutrient value on the label, it is impractical. The natural variability of a food is dependent upon a number of factors. Among them are the season of the year, soil type, variety (cultivar), and weather conditions. The processing that a food undergoes also alters its nutrient content. In addition to these variables, the agency places restrictions on the label declarations in regard to the rounding of nutrient values. These rounding rules are to avoid the impression of unwarranted accuracy as well as to make a label easier for a consumer to review and understand. To declare nutrient values more accurately or precisely than is presently required would place an onerous burden on the manufacturer. The costs associated with the excessive controls to provide more exact label declarations are unreasonable and would not be commensurate with any possible additional health benefit.

The agency rejects the suggestions that declared values be qualified by statements that they reflect tolerance levels or margins of error. Such statements on the label informing consumers of the possible variation between labeled and analytical values would cause great confusion with no real benefit.

Similarly, FDA disagrees with the comments that suggested establishing less stringent requirements for determining compliance with declared label values. As seen in comments, consumers rely on the declared values, and the accuracy of those values is important. FDA does not believe larger suggested ranges, such as 65 to 135, would give consumers the information that they need to adequately evaluate their nutrition intake. Therefore, the agency is not making requested changes in § 101.9(g).

FDA advises that it has not set maximum compliance levels in § 101.9(g) for Class I and Class II nutrients, nor has it set minimum compliance levels for nutrients specified in § 101.9(g)(5) (i.e., calories, sugars, total fat, saturated fat, cholesterol, and sodium). The 20 percent variability permitted is not a range but rather a lower or upper limit, depending on the nutrient. The only regulatory limit on overages of Class I and II nutrients is given in § 101.9(g)(6), which states that "reasonable excesses" are acceptable within current good manufacturing practice. Likewise, § 101.9(g)(6) also states that "reasonable deficiencies" of calories, sugars, total fat, saturated fat, cholesterol, and sodium under labeled amounts are acceptable within current good manufacturing practice. FDA anticipates that manufacturers will be diligent in their own behalf in not underdeclaring Class I and II nutrients, such as vitamins and minerals, and in not overdeclaring nutrients such as calories and fat.

Regarding maximum levels of micronutrients in standardized enriched pasta products, regulatory relief cannot be achieved through modifications of § 101.9 but require changes in the standards of identity of such products.

239. Several comments suggested that the 80 and 120 percent criteria should only be a guideline or screening tool. A few comments expressed the position that FDA should not declare a product misbranded until the manufacturer has had an opportunity to establish that the variations are reasonable under the circumstances.

Other comments suggested that the 80 and 120 percent criteria be waived when there are small quantities. (The quantity limits suggested were 10 and 20 or fewer "units." "Units" were interpreted to be units of measurements, such as 10 or 20 calories or 10 or 20 mg of sodium.) The comments noted that small numbers combined with rounding rules and analytical variability result in inequities for label compliance (i.e., the analytical variance for some low levels of nutrients is greater than the allowed regulatory variance). For example, the comment stated that if a mean value of 1.3 units was rounded for label declaration to the nearest whole unit (i.e., 1 unit), then the acceptable range would be 0.8 to 1.2 units when applying the 80 and 120 percent criteria. The range would be below the true mean value which could result in many products being found out of compliance. Furthermore, these small differences of 0.2 units may not be within the accuracy of many methods, so that the analytical variance could be greater than the allowed regulatory variance. For these small quantities of 20 or fewer units, the comments recommended that a 50 to 150 percent rule be applied. One comment recommended that FDA clarify in the final rule that the rounding of nutrient values, as required by the proposal, would not disadvantage a manufacturer when making nutrient content claims to meet compliance criteria as well as standards of identity.

An alternative suggestion in another comment to avoid an extreme over- or under-declaration when the value is small is to declare the nutrient content to the nearest whole unit with compliance based on a fixed percentage (e.g., within 80 percent) or a fixed unit amount (e.g., one unit or 2 percent U.S. RDA, the basic increment of rounding). The regulation would then require that declared amounts be within 80 percent or one unit (such as a g) for Class II nutrients or within 120 percent or one unit for nutrients such as calories, fat, or sodium.

The agency is not persuaded that the current or proposed acceptance criteria for compliance evaluation should be changed. The compliance criteria permit reasonable excesses over labeled amounts or deficiencies under labeled amounts, dependent upon the nutrient being evaluated, (current § 101.9(e)(6), redesignated as § 101.9(g)(6)) within current good manufacturing practices. As discussed in section IV.A. of this document, the level of "reasonable" is not specified.

It is the manufacturer's responsibility to target labeled values to correspond to actual nutrient levels so that products will meet compliance requirements. This responsibility includes taking into consideration the effects of rounding. Any effect caused by the rounding of labeled values to meet the agency's requirements in § 101.9(c) should be accounted for by the manufacturer in developing a label value and would be included in the evaluation of a "reasonable" level by the agency. Analytical variance is also one of the factors in determining compliance acceptance. This fact is stated in § 101.9(g) (4) and (5) in this final rule.

Manufacturers should perform shelf-life stability studies to substantiate the declared nutrient levels of the product and to demonstrate that a product can meet label claims over the shelf life of the product. FDA does not believe that incorporation into the regulations of any additional explicit provision or compliance position for low level nutrients or small labeling increments would provide added protection for manufacturers.

240. One comment strongly recommended that FDA address sampling issues. It suggested that the current procedure in § 101.9(e)(2) (and in proposed § 101.9(g)(2)) of preparing a composite of 12 subsamples taken from a single lot be changed. Instead, it was suggested that a sample composite for analysis represent 12 different lots.

The agency disagrees with the suggested change in sampling procedures. The comment's suggestion reflects a sampling objective that appears to focus on estimating the nutrient content of product for a specified quantity (e.g., a company's production). FDA's sampling objective is to determine whether the average, within a given lot (a quantity that is defined in current § 101.9(e)(1)), meets label claims. From a compliance evaluation standpoint, the suggested sampling scheme is not a feasible alternative because the results obtained would not be traceable to a specific lot should an overage or deficiency be encountered. Instead of a compliance action against a smaller quantity (a single lot), it might be necessary to take a compliance action against a larger quantity (e.g., a company's production for a larger specified point in time). Therefore, FDA is making no change in § 101.9(g)(2) in response to this comment.

241. Several comments that disagreed with the agency's compliance policy provided suggestions to clarify the codified language. One comment recommended the elimination of total carbohydrate, complex carbohydrate, and unsaturated fat from the Class I category of nutrients at § 101.9(g)(4)(i). It maintained that these three nutrients are unlikely to be "added" but are the result of having used ingredients that inherently have these nutrients.

FDA agrees with the recommendation Therefore, the agency is amending § 101.9(g)(4)(i) to delete total carbohydrate, complex carbohydrate, and unsaturated fat from the Class I category. This deletion should allay the concerns of having the cited nutrients meet Class I nutrition labeling requirements. These nutrients remain in the Class II category (§ 101.9(g)(4)(ii)), although in accordance with the changes made in section III. of this document, complex carbohydrate is changed to other carbohydrate and unsaturated fat to poly- and monounsaturated fat.

To clarify the compliance policy concerning variability because of analytical methodology for Class I and Class II nutrients, FDA is modifying § 101.9(g)(4) by making a new paragraph out of the last sentence which begins with the word "Provided." This change should make clear that the proviso information regarding consideration of regulatory action is applicable to both Class I and Class II nutrients. This qualifying information was inadvertently moved under the paragraph on Class II nutrients in the July 19, 1990 mandatory nutrition labeling proposal, and the error was carried forward in the supplementary proposal.

242. One comment stated that manufacturers should be able to use mean values in all cases, except that statistical outliers should be ignored. The comment also urged the agency to codify its compliance policy to the extent that if a nutrient is found out of the 80 to 120 range of the labeled amount, the product would not be deemed out of compliance as long as the manufacturer can demonstrate that the label declarations represent mean values based on reasonable and adequate sampling and analyses.

FDA disagrees with the comment. The agency's position on the use of mean values is summarized in the preamble of the supplementary proposal (56 FR 60366 at 60373). This position is discussed in more detail in the "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases" and in section VII.B. of this document. In short, FDA will allow the use of mean values derived from satisfactory data bases if the coefficient of variation is equal to or less than the maximum coefficient of variation specified in the above manual. The coefficient of variation is the standard of deviation (a measure of variability) expressed as a percentage of the mean.

243. A recommendation was made in one comment to amend § 101.9(g)(5) by adding: "Provided, that no regulatory action will be based on a determination of a nutrient value which falls above this level by a factor less than the variability generally recognized for the analytical method used in that product at the level involved." The comment noted this addition would extend the allowance for analytical variability permitted for vitamins, minerals, protein, total carbohydrate, complex carbohydrate, dietary fiber, unsaturated fat, and potassium, as given in proposed § 101.9(g)(4) to the nutrient declarations for calories, sugars, total fat, saturated fat, cholesterol, and sodium.

The agency agrees that analytical variance is a valid consideration when contemplating regulatory action for all nutrients. Accordingly, the proviso stated in § 101.9(g)(4), which is applicable for Class I and Class II nutrients, is added to § 101.9(g)(5).

244. One comment recommended a two-stage enforcement procedure. The first stage would involve analysis of a single 12-sample composite to determine whether the product passes the compliance standard of 80 to 120. If it passed, the agency would have no enforcement issue. If it did not pass, the agency would collect and measure the nutrient content in three other lots. The average of all four lots tested would be evaluated for compliance purposes.

The agency is not making the change in its procedures that was suggested by this comment. As recognized in several comments from manufacturers, it is the manufacturer's responsibility to accurately declare the nutrient content of a product. As discussed above, the interpretation of results obtained from more than one lot (same ingredients, same processing conditions) cannot be translated to other lots. Factors that could have altered the nutrient content of one lot may not be present for subsequent lots. Through quality control programs and careful consideration of declared nutrient amounts according to the guidelines in "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases," manufacturers can help to ensure that each lot meets compliance standards. The suggestion made in this comment or in comment 240 of this document in regard to evaluating results representing the analysis of a composite from 12 different lots or an average of results from four composites could be implemented in a manufacturer's quality control procedures to assure compliance with § 101.9(g).

It should be noted that the analyzed nutrient content is not the sole factor in determining whether the agency will bring a particular enforcement action. Other factors that it considers include the effect of matrix upon the analyte, the level of the analyte in the food, information obtained during an establishment inspection of a firm, consumer complaints, past compliance history of the firm, and the firm's demonstrated ability to adequately perform the analysis for a nutrient.

245. A comment recommended that a new section be added to the codified language to the effect that "The metric declaration of the serving size shall be used to determine compliance under this section." The comment said that this change would eliminate any confusion about which of the dual declarations required for serving size would be the determining factor for nutrient declaration.

FDA agrees with the comment. In its serving size proposal (56 FR 60394 at 60410), the agency stated that in addition to the more approximate household measure, it needed a precise weight statement for serving size for compliance purposes. Accordingly, the agency proposed in § 101.9(b)(7) that the serving size in common household measures must be followed by the equivalent metric quantity. However, FDA did not specifically state that this metric measure would be used for compliance purposes. Therefore, for purposes of clarity, the agency is adding a new section, § 101.9(g)(7), to correct this oversight. Consequently, the remaining paragraphs in § 101.9(g) are redesignated.

246. One comment expressed concern that net weight regulations must be considered when evaluating a product against the 80 to 120 rule for compliance. The comment stated that manufacturers are required to sell products at levels above the declared label weight. The comment concluded that this resulted in a discrepancy between labeled nutrition information and actual nutrition values.

The agency does not consider this issue to be a valid concern. Because of the economic considerations of manufacturing, most products are close to label claims for net weight. Additionally, while an overage or underage of the net weight may slightly alter the nutrient content of the container (and particularly if the container is a single serving size), the serving size is the factor by which the nutrients are evaluated. As discussed in the preceding comment, FDA will composite samples and then use the metric weight declared as the label serving size to evaluate the accuracy of declared nutrient values.

2. Data Bases

247. FDA received a large number of comments regarding the use of data bases as sources of nutrient information for nutrition labeling. Most comments supported the use of data bases, giving as reasons that the use of data bases would reduce costs to industry (especially to small businesses), moderate food cost increases to be passed on to consumers, promote fair competition, save time, reduce the use of laboratory chemicals, provide sufficient accuracy, and ease compliance verification procedures. Comments requested the opportunity to use nutrient composition data in commercially available or published data bases directly or through calculation of ingredient values to yield the final composition of formulated products.

FDA appreciates the important role data bases can play in nutrition labeling. Industry-wide data bases were first suggested in 1979 as a possible means of reducing the cost of developing nutrition labeling for individual companies. FDA, USDA, and the Federal Trade Commission encouraged this concept in a notice of proposed rulemaking published in the **Federal Register** of December 21, 1979 (44 FR 75990) describing the agencies' policies and intentions with respect to numerous food labeling issues. In that notice, FDA, while not agreeing to approve data bases, stated that it would work with industry to resolve any compliance problems that might arise for food labeled on the basis of a data base that the agency had accepted.

FDA is concerned about the reliability of data bases to meet compliance requirements for nutrition labeling. Nutrient data may be valid for some purposes and not for others. For example, data bases that were developed largely for determining

average daily dietary intakes generally serve that purpose well. However, such data bases are usually not adequate to determine natural variability of a particular food or to develop labeling values that are in compliance with FDA nutrition labeling regulations.

Despite these concerns, FDA continues to acknowledge the potential usefulness of data bases to reduce costs associated with nutrition labeling. The agency set out its general policy on the use of data bases most recently in the proposed and final rules on the voluntary nutrition labeling program for raw produce and fish (58 FR 30468 at 30474, July 2, 1991 and 56 FR 60880 at 60884, November 27, 1991, respectively) and the supplementary nutrition labeling proposal (56 FR 60366 at 60373). In addition, the agency announced in the **Federal Register** of July 23, 1992 (57 FR 32796) the availability of a draft manual entitled "FDA Nutrition Labeling Manual: A Guide for Developing and Using Databases." The manual, which replaces the former guide "Compliance Procedures for Nutrition Labeling," is intended to aid companies and trade organizations in developing and using a data base for nutrition labeling that would meet the regulations proposed as a result of the 1990 amendments. It also discusses the conditions under which the mean value derived from a satisfactory data base may be used for nutrition labeling. Comments were requested on the draft manual. These comments have been considered, and the agency is hereby announcing the availability of the final manual. The manual may be obtained from the Division of Nutrition (HFF–260), Office of Nutrition and Food Sciences, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

FDA anticipates that this manual will be of assistance in identifying a data base that is of a quality to provide an adequate basis for nutrition labeling. The use of such a data base to calculate the final composition of a product formulated from several ingredients presents additional problems, however, in that there are no allowances or determinations of the loss of nutrients that may occur during further processing. Depending on the type and amount of processing, significant amounts of nutrients may be lost. The agency is willing to work with manufacturers and trade associations to determine if successful models can be developed showing the relationship between ingredient composition and final product composition that account for losses during processing. While extensive analyses of ingredients and final products would be required to develop and validate a successful model, such action could lead to an acceptable data base.

If a manufacturer wishes to use a data base for nutrition labeling, it is advantageous to follow the statistical procedures outlined in the manual and have the data base accepted by FDA. If the agency finds that the nutrition label of a product which is based on a data base that has been accepted by FDA is not in compliance with § 101.9, FDA will not take immediate action against the product, provided that the company has followed good manufacturing practices in producing the food. Instead, the agency would work with the manufacturer to resolve the compliance issue. Action would be taken only if noncompliance was the result of failure to follow good manufacturing practices.

It must be noted that submission of a data base to FDA for review and acceptance is voluntary. The agency has not prescribed how an individual company is to determine nutrient content for labeling purposes. The choice of a data source is the prerogative of the manufacturer. The manufacturer needs to be judicious in this selection, however, to ensure that the product labeling is in compliance with the regulations. The compliance policy of the agency remains unchanged from current § 101.9(e). An FDA investigator/inspector will collect random units of food (e.g., consumer packages, items of product) from each of 12 different randomly chosen shipping cases of the same code/lot, and an FDA laboratory will prepare a single composite from the 12 units of food. Analysis of the composite will be performed using methods of the AOAC or other reliable and appropriate methods. FDA will then compare the values declared in the nutrition label and labeling with the results from the laboratory analyses. Section 101.9(g)(8) provides for the use of an approved data base.

248. Many comments were received expressing support for use of data bases because they can be used by a company one time, and there would be only a one time cost to determine the nutritional values for the label without regard to future changes in the product.

The agency is concerned that there is a misunderstanding regarding the use of data bases. Data bases are not static but dynamic because of changes in products. Those data bases submitted to the agency or used by companies are expected to reflect the nutritional content of products being offered for sale. Changes in variety, supplier, recipe, or manner of processing could lead to very different nutritional values for the product than those in the original data base. The agency, in monitoring products for compliance, will also review the maintenance of these data bases to ensure that the information in the data bases reflects the nutritional content of the products being offered for sale. Maintenance of a data base means that laboratory analyses of the product are done on a periodic basis to ensure that the nutritional values of the product are within the limits of the data base values. Proper maintenance of the data base is left to the originators of the data base. Frequency and type of maintenance are determined by the data base holders based on their knowledge of the changes in the products. Satisfactory data bases could be useful for periods of up to 10 years based on the size of the data base, plan for maintenance, and the complexity of the product. FDA reviews will be based on the amount of supplementation of the data bases with additional laboratory data (maintenance) during the period of use and the changes in the products covered by the data base.

3. "Nutrition Labeling Manual: A Guide for Developing and Using Data Bases"

FDA announced in the **Federal Register** (57 FR 32796) on July 23, 1992, the availability of a draft manual entitled "Nutrition Labeling Manual: A Guide for Developing and Using Data Bases" (the manual). This manual is intended to aid companies and trade organizations in developing and using a data base for nutrition labeling that meets the regulations resulting from the 1990 amendments. Comments on the manual were accepted until September 8, 1992. This manual provides generic instructions on how to develop and use a data base in preparing nutrition labeling for a food product. Eighteen comments were received from companies or trade associations. The following summarizes the comments and provides the agency response to those comments.

249. Almost all of the comments were opposed to the limit of 80 percent of the label claim for Class II (indigenous) nutrients and 120 percent for calories, sugars, total fat, saturated fat, cholesterol or sodium. The comments argued that these limits were overly restrictive and should be widened or average values should be used with no consideration of limits.

The use of 80 percent or 120 percent as limits for regulatory purposes is established in § 101.9(g) and has been addressed above in section VI. of this document. The manual was developed to aid in the calculation and

construction of data or data bases to meet the regulatory requirements of the agency. Should the agency change its regulations, it will reflect those changes in the manual. Until such changes are made, however, the manual must reflect the applicable regulatory limits.

250. All but one of the comments addressed the use of recipe data bases to calculate final composition of mixed products. The comments cited the savings in money to small businesses, the constant changes in recipes that make it too costly to do analytical testing of products, and the cost of analyzing a large number of products for which the volume is low. The expressed belief was that calculated values better represent the nutrient content over time. Several comments suggested criteria for a good recipe data base. One comment offered the following four proposed principles of good ingredient composition data bases:

(1) Confidence in the quality of data, supported by documentation of data sources. Companies maintaining or using ingredient composition data bases must be able to demonstrate the data source used for each type of product and each nutrient for which ingredient composition data bases are utilized.

(2) Proper maintenance of the data base. Companies developing or using ingredient composition data bases must have procedures in place to ensure that the values in the ingredient composition data bases are reviewed and updated as needed and on a regular basis.

(3) Specificity with respect to ingredients, product formulations, and processes. Companies using ingredient composition data bases must have procedures in place to ensure that the nutrient values are used only for specific applications. For example, a company should have a procedure to ensure that nutrient data specific for one product formulation or process are not used to prepare nutrient declarations for similar product formulations or processes, without assurance that the data are applicable to those products or processes.

(4) Validation of the data base. Companies developing or using ingredient composition databases must have procedures in place to ensure that nutrient values receive reviews, audits, and confirmation through nutrient analyses as often as necessary.

Other comments suggested that manufacturers should be required to substantiate any nutrient content or health claims with analytical data.

The agency agrees that the principles suggested by the comment are worthwhile and necessary for construction of a proper ingredient composition data base. This was the intent of the statement in the manual that calculation of the final composition of a mixed product using data bases of the nutrient composition of ingredients might be acceptable if properly modelled. The agency wanted to assure itself that the ingredient composition information was adequate, and that the calculation of the final nutrient value of the finished product reflected any possible loss of nutrients during processing. In addition, a successful mathematical model used for this purpose should be augmented over time with a review of its applicability by laboratory analysis of the nutrient content of both ingredients and final products. Models constructed with the features described above, and applied to a limited range of appropriate products, would receive serious consideration from the agency. The above features of an appropriate data base will be included in the manual.

The agency believes that in time the calculation of the final composition of mixed products from ingredient data bases may be acceptable for a range of food products. At this time, however, the agency believes that the data that make up ingredient data bases are of mixed quality and, therefore, of limited value. Companies that wish to use ingredient data bases must look at the individual analytical values of each ingredient to evaluate the data to assure themselves that the data are sufficient, meet the requirements expressed in the manual for representativeness, are valid from an analytical standard, and are sufficient to account for any variation in the ingredient.

The agency has stated that the company bears the final responsibility for the accuracy of the label. This principle has not changed and was repeated and supported by several of the comments.

251. Comments were received on changing various aspects of the agency's regulatory policy such as larger number of lots sampled and the average taken, composite samples consisting of several lots, exemption from compliance procedures when data bases are used regardless of whether the agency has accepted them or not, exemption from compliance procedures for nutrients that have a low concentration, and exemption from compliance procedures for companies/associations that have submitted basic data and a plan for data base development over time.

The manual is intended to aid manufacturers/associations in meeting the compliance regulations of the agency. The manual does not set compliance policy but rather offers some explanation for the compliance policy and provide different means of complying with the nutrition labeling regulations. Should the compliance policy of the agency change, the manual will also be changed to reflect those changes.

252. Many comments were received regarding the confidentiality of the submitted data bases. Developers of data bases did not want to see the information gained through analyses of products and ingredients released through freedom of information requests or used in unacceptable ways or for inappropriate products. In addition, development of data bases is a program with costs shared among the participating companies. The comments sought assurance that the data would not be available at no cost to companies that did not participate in its development. Formulations that are used to produce mixed products are also regarded as confidential company information, and the comments sought assurance that they would not be available to anyone who requests the information.

The agency is aware that the development of a data base is costly, and that it may contain information that is of a confidential nature. The agency agrees that release of a data base could vitiate substantial proprietary interests in valuable documents submitted to the agency. Furthermore, it has never been the agency's intent, nor does it have the resources, to maintain and manage data bases that are developed by manufacturers or associations. The agency believes that the availability of a data base is therefore the primary responsibility of the developer. The agency will continue with the policy of assisting the developers of data bases, providing guidance to those who ask for it, and accepting adequate data bases for the products submitted for review. Only those data sufficient to support the agency's decision to accept or not accept a data base will be retained. Confidentiality of such data will be determined and maintained in accord with regulations in part 20 (21 CFR part 20).

Those data base developers who choose to do so are encouraged to make their information available through such compilations as the USDA Handbook No. 8 so that all may benefit from the additional analytical information.

C. Proposed § 101.9(h)

253. A few comments objected to the requirement in proposed § 101.9(h) that nutrition information provided by manufacturers or distributors directly to professionals (e.g., physicians,

dietitians, educators) must contain or have attached to it the nutrition information exactly as required by § 101.9. The comments stated that it was inappropriate for a Federal agency to regulate the transfer of information in this manner.

FDA notes that this section of the regulation has been carried unchanged since 1973 (49 FR 6961, March 14, 1973). At that time, the agency stated that it did not want to restrict the flow of information from food manufacturers to professionals (such as more precise amounts rather than the increments used in nutrition labeling) but rather wanted nutrition information included or attached to it in the form it would be provided to consumers. Inasmuch as nutrition labeling is now mandatory, so that consumers will have the required information available to them on food product labels, FDA has decided to delete this requirement and is doing so in this final rule.

D. Section 101.9(k)

254. Many comments objected to proposed 21 CFR 101.9(k) which details types of nutrition-related claims that cause a food to be misbranded. Most of these comments asserted that the provisions of § 101.9(k) are contrary to the intent of the 1990 amendments and contrary to the will of Congress.

Many comments offered specific objection to proposed § 101.9(k) (3) and (4) and asserted that manufacturers should be allowed to provide information about the effects of soil, storage, transportation, or cooking on the nutrient content of foods. Some comments maintained that the restriction of such information is unconstitutional. A number of comments felt that labels should be required to provide information as to the exact identity of the contents (including substances of no nutritional value), the source of the contents, the amounts of all ingredients, and the techniques and dates of processing. One comment proposed that manufacturers should be required to put toll-free telephone numbers on all of their products so that consumers could call for information about those products.

Many comments asserted that proposed § 101.9(k)(5) is arbitrary and restrictive and expressed a belief that certain naturally-occurring food constituents will be rendered unavailable by this provision. A number of comments maintained that there is no legitimate reason for prohibiting substances found in nature from being incorporated into nutritional products and listed on the label. Some comments suggested amending proposed § 101.9(k) to allow the use of naturally-occurring constituents of foods and herbs, unless there is sufficient evidence that any specific such substance is harmful to human health.

Some comments also objected to proposed § 101.9(k)(6), maintaining that vitamins that are naturally present are better than added synthetic vitamins. These comments expressed a strong desire to know whether vitamins contained in any specific product are naturally-occurring or synthetic.

FDA regrets that its publication of § 101.9(k)(2) through (6) in the November 27, 1991 (56 FR 60393) proposal has created confusion. The publication of § 101.9(k)(2) through (k)(6) did not constitute a proposal of new regulations. It merely represented a proposed redesignation and republication of existing regulations for clarity and completeness.

The provisions embodied in current § 101.9(i)(2) through (i)(6), redesignated in the November 27, 1991, supplementary proposal as § 101.9(k)(2) through (k)(6), to which the comments directed their objections, were first proposed in the **Federal Register** of March 30, 1972 (37 FR 6493), and were promulgated and published in the **Federal Register** of January 19, 1973 (38 FR 2125), as § 1.17(i)(2) through (i)(6). Following an appropriate comment period, these regulations were modified and published as final regulations in the **Federal Register** of March 14, 1973 (38 FR 6961). The regulations were subsequently applied, with certain exemptions, to all food labeling ordered after December 31, 1973, and all labeling used for food products shipped in interstate commerce after June 30, 1975. In the reorganization and republication of section 21 of the Code of Federal Regulations that appeared in the **Federal Register** of March 15, 1977 (42 FR 14308), § 1.17(i) was renumbered as § 101.9(i). No changes were made to the original codified language of the subject paragraphs during any of these renumberings, and those regulations remain as adopted in 1973.

The only change in § 101.9(k) in the supplementary proposal was in the document entitled "Labeling; General Requirements for Health Claims for Food" (56 FR 60537, November 27, 1991). This document proposed to amend current § 101.9(i)(1), redesignated as § 101.9(k)(1), by adding a second sentence that reads "Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and subpart E of part 101." No comments voiced specific objection to this proposed change.

FDA notes that the provisions of current § 101.9(i) had long been in effect at the time Congress drafted the 1990 amendments. While Congress did enact provisions under the 1990 amendments that allow for health claims on foods, nothing in the act or in the legislative history of the act suggests that Congress intended that current § 101.9(i) should be changed. The agency therefore finds no basis for the assertion that the provisions of current § 101.9(i), redesignated as § 101.9(k), are now contrary to the intent of the 1990 amendments.

FDA has reconsidered the requirements of § 101.9(k)(5), however, in light of the comments. The agency concludes that there is no reason to prohibit safe substances from being incorporated into conventional foods or dietary supplements of vitamins and minerals as long as their presence is noted in the ingredient list, and the product's label or labeling does not state or imply that the food has special dietary properties because of the presence of the substance when, in fact, its usefulness has not been established. Section 411(b)(2) of the act provides that vitamin and mineral products may contain substances that are not vitamins or minerals as long as the substances are only identified as a part of the ingredient list. Therefore, proposed § 101.9(k)(5) is amended by deleting the second and third sentences.

Questions have been raised as to whether the amounts of these substances that are not vitamins or minerals can be included on the food label. Such information can be included in the ingredient list if, in addition to listing the ingredients in order of predominance by weight, quantitative information on each of the ingredients in the food is presented. However, information about the ingredients that are not vitamins and minerals may not be presented in a way that suggests that the dietary usefulness of these substances has been established.

While the comments raised objections to the other provisions of proposed § 101.9(k) (i.e., (k)(3), (k)(4) and (k)(6)), none provided arguments that convinced the agency that deletion or revision of those provisions was either appropriate or necessary in fulfilling the mandates of the 1990 amendments. The objections that were raised, however, suggest that a clarification of the intent of those provisions would prove helpful to those who voiced the objections. Such a clarification was provided in the **Federal Register** of March 14, 1973 (38 FR 6961). In that document, the agency

noted that § 1.17 (i)(3) and (i)(4) (redesignated as § 101.9(k)(3) and (k)(4)) are aimed at prohibiting unsubstantiated generalizations about nutrient losses because of soil, transportation, or processing and do not preclude a producer, manufacturer, or vendor from indicating a higher nutrient retention in a particular product as compared to other similar products. Nor do they preclude an indication that such retention results from special handling of the product, provided that such indications are factual. Further, these provisions do not preclude a manufacturer from suggesting cooking or handling methods that would result in optimum nutrient retention. While the agency recognizes that such information may be useful to consumers, it does not believe that it would be appropriate to require manufacturers to provide such information, either on the labeling or through other media.

Current § 101.9(i)(6), redesignated in the supplementary proposal as § 101.9(k)(6), prohibits any suggestion that a naturally-occurring vitamin is superior to an added vitamin. The agency finds no basis for such an assertion, and the comment offered no data in support of such an assertion. As the agency clarified in the repromulgation of March 14, 1973 (38 FR 6950 at 6958), this section (then § 1.17(i)(6)) "forbids any suggestion that a natural vitamin is superior to an added vitamin, but permits any truthful designation of any nutrient as natural in origin."

FDA acknowledges its inadvertent oversight in not including a reference to proposed § 101.36, Nutrition Labeling of Dietary Supplements of Vitamins and Minerals, in proposed § 101.9(k). The inclusion of this reference is a logical outgrowth of the agency's stated intention that "nutrition labeling of vitamin and mineral supplements appear as similar as possible to the nutrition labeling of other foods" (56 FR 60366 at 60382). Section 101.9(k) applies to all foods, including dietary supplements of vitamins and minerals, and the agency did not intend to narrow its scope. Therefore, FDA tentatively concluded that it should correct this oversight by including an appropriate cross reference to § 101.36 in the final rule. However, the agency will propose its position on this issue following the DS Act. For completeness, FDA is inserting the word "label" in the first paragraph of § 101.9(k) to clarify that this section pertains to food labels as well as labeling.

255. One comment asserted that the phrase "represents, suggests, or implies" in the opening sentence of § 101.9(k) is unconstitutionally vague.

FDA disagrees with the comment's assertion that the phrase "represents, suggests, or implies" is unconstitutionally vague. The agency notes that the vagueness doctrine is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. See, e.g., *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498-99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). The provisions of § 101.9(k) are narrowly tailored and clearly delineate the types of statements about nutrients that will render a food misbranded. Thus, § 101.9(k) provides clear and precise guidance on the type of speech that is prohibited.

E. Conforming Amendments

256. A trade association wrote in support of the multiunit retail exemption in § 101.9(j)(15) and requested that § 1.24(a)(14) be amended to reflect the change by including a reference to section 403(q) and (r) of the act. The comment stated "we submit that this amendment is fully consistent with the requirements of the 1990 amendments and the provisions of the proposed § 101.9(j)(13) in that nutrition labeling will be provided on the outer carton together with the other information required under the referenced sections."

The agency agrees that § 1.24(a)(14) of the General Enforcement Regulations should be amended to reference 403(q) of the act, as amended by the 1990 amendments. This change merely conforms § 1.24(a)(14) to the rule that FDA is adopting in § 101.9(j)(15). Accordingly, the agency is amending § 1.24(a)(14) to read as follows: "The unit containers in a multiunit or multicomponent retail food package shall be exempt from regulations of section 403(e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when * * *."

However, FDA cannot grant the comment's request with respect to section 403(r) of the act. Any container that bears a nutrient content claim or a health claim must comply fully with the requirements of that section of the act and of the regulations that implement it.

257. A food trade association requested that FDA amend § 101.100(d) to include section 403(q) and (r) of the act to provide that products shipped in bulk for further processing, labeling, or repacking in substantial quantities at an establishment other than where originally processed or packed, are exempt during the time of introduction into, and movement in, interstate commerce and during the time of holding in such establishment.

FDA agrees that § 101.100(d), Exemptions From Food Labeling Requirements, should be amended to include 403(q) of the act. Again, this modification merely reflects the rule that FDA is adopting in § 101.9(j)(9). However, for the reason explained in response to the previous comment, FDA is not granting the request with respect to section 403(r) of the act. Accordingly, FDA is amending 21 CFR § 101.100(d) to read as follows:

> Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of food which is, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if: * * *."

Nutrition Labeling of Dietary Supplements of Vitamins and Minerals

258. Most comments, including those from supplement manufacturers and trade associations, supported the general concept of nutrition labeling for dietary supplements of vitamins and minerals. One comment, however, suggested that any decisions on nutrition labeling of vitamin and mineral supplements be deferred until the agency decides how it intends to regulate dietary supplements, in general. This comment is referring to FDA's Task Force on Dietary Supplements. The comment argued that the proposed labeling requirement would create a label with large amounts of information that is of little value to the consumer, particularly for single vitamin and mineral supplements.

As pointed out in the supplementary proposal (56 FR 60366 at 60381), section 403(q)(5)(E) of the act states that if a food to which section 411 of the act applies (i.e., dietary supplements of vitamins and minerals) contains one or more of the nutrients required to be listed in nutrition labeling, "the label or labeling of such food shall comply with the requirements of paragraphs (1) and (2) [of section 403(q) of the act] in a manner which is appropriate for such food and which is specified in regulations of the Secretary." In the supplementary proposal (56 FR 60366 at

60381 through 60382), the agency also stated that vitamin and mineral supplements are required to bear nutrition labeling under section 403(q)(5)(C) of the act even if they do not contain any of the nutrients required to be in nutrition labeling. Section 403(q)(5)(C) of the act provides that nutrition labeling is not required in such circumstances unless a claim is made about the nutritional value of the food. The statement of identity for supplements of vitamins or minerals, including single vitamins or minerals, may be a claim about the nutritional value of the supplement. However, because the DS Act imposes a moratorium on the implementation of the 1990 amendments, FDA is not taking any action to implement section 403(q)(5)(c) of the act at this time.

FDA's Task Force on Dietary Supplements is consequently irrelevant to this issue. Nothing in the Task Force's report would relieve the agency of the obligation to adopt regulations to implement the explicit requirements of the law.

Furthermore, the agency does not agree that nutrition information for vitamin and mineral supplements is of little value to the consumer. These products are represented and sold for their vitamin and mineral content. Thus, nutrition information about them will assist consumers in determining the role that the products can play in maintaining healthy dietary practices. Moreover, the agency notes that most vitamin and mineral supplements already bear nutrition information on their labels.

For the reasons stated, the agency tentatively concluded that it is not necessary to modify its requirement for mandatory nutrition labeling on labels of dietary supplements of vitamins and minerals. However, the agency will propose its position on this issue based on the provisions of the DS Act.

259. In testimony at one of the public meetings held by FDA, there was a comment suggesting that small packages of dietary supplements of vitamins and minerals be exempt from mandatory nutrition labeling.

Section 403(q)(5)(B) of the act provides for an exemption for foods in small packages "if the label of such foods does not contain any nutrition information." This provision is implemented in § 101.9(j)(13)(i). Thus, the question is raised as to whether the statement of identity for supplements of vitamins and minerals is a claim. FDA will address this question and the implementation of section 403(q)(5)(B) with respect to dietary supplements in accordance with the terms of the DS Act.

260. One comment recommended deleting proposed § 101.36(b)(1) that required the number of units recommended per day to be declared in the nutrition label on the basis that it is repetitious of information that is on the label in other places.

Likewise, a few comments were opposed to proposed § 101.36(b)(2) that required declaration of "Units per container" in the nutrition label. These comments asserted that such a requirement is redundant and unnecessary because the number of units per container is already listed on the principal display panel of dietary supplements as part of the net contents declaration.

FDA considered these comments and agrees that, for supplements in which the unit is a discretely defined unit (e.g., tablets or capsules), "Units per day" could be confusing. The agency is concerned that consumers could be confused by a statement that indicates that several units are to be taken per day (e.g., 3 tablets per day) when the nutrient information is given for one unit. If consumers do not look at the column legend that states that the nutrient information is "per unit," they might assume that the nutrient information is for the amount specified for consumption per day. To avoid the possibility for confusion, FDA tentatively concludes that the subheading "Each unit contains:" should be allowed for supplements in which the unit is a discretely defined unit (e.g., tablets or capsules). Directions concerning the number of units to be consumed per day should be given outside of the nutrition label.

The agency also agrees that, since § 101.105(a) requires the net quantity of content declaration to include a numerical count when appropriate, there is little benefit to be derived from information on the number of units per container appearing in two different places on the label. However, when the supplement is in a liquid or powdered form, FDA believes additional information similar to that on conventional foods best informs the consumer about the dosage unit. Therefore, FDA tentatively concludes that for dietary supplements of vitamins and minerals in liquid or powdered form, "Serving size" and "Servings per container" should be stated consistent with § 101.9(d). The agency will propose its position on these issues in the rulemaking required by the DS Act.

261. Several comments, mostly from the dietary supplement industry, opposed the dual labeling of nutrient content "per unit" and "per day" if more than one unit is specified for consumption per day. Comments argued that dual declaration is impractical and will result in overcrowding of already small labels, creating consumer confusion and obfuscating the label's message. Other arguments against dual declaration were that such a requirement may discriminate against supplements that are not in the one-per-day format, and that it would force the industry to reformulate products so that labels can accommodate all of the information. One comment pointed out that the proposed regulation does not address how required information should be presented when the recommended daily dose is a range, e.g., 1 to 3 tablets per day.

Among the comments opposing dual declaration, however, there was disagreement as to which declaration is preferable, "per unit" or "per day." Some comments stated that it was the total amount of nutrients that is important, and therefore, declaration should be on a "per day" basis. These comments pointed out that FDA regulations (§ 105.77) promulgated in 1973 specified that dietary supplements be labeled according to the quantity specified for consumption during one day. The comment stated that although these regulations were withdrawn in 1979, most companies still comply with them.

Other comments stated that consumers may deviate from the recommended dose and should be given credit for being able to multiply quantities of nutrients by the number of units consumed. Therefore, these comments stated that declaration should be on a "per unit" basis. Comments pointed out that the U.S. Pharmacopeia is developing quality standards for dietary supplements in which they propose that nutrient information be presented "per dosage unit."

Other comments suggested that as an alternative to just one form of declaration on the label, the label could reference other labeling such as package inserts that contain all of the required information, or could permit either "per unit" or "per day" listing as long as the label clearly states which type of information is provided. A few comments favored dual declaration. One comment stated that omitting either declaration might confuse people who think that the nutrition information for one unit applies to a day or vice versa.

The agency is persuaded that dual declaration of nutrition information "per unit" and "per day," when a daily dose of more than one unit is recommended, may create a readability

problem for consumers, given the limited label space available on most dietary supplement products. FDA also agrees that recommended daily consumption of other than well defined dosages (e.g., "consume 1 to 3 tablets per day") would pose a problem in terms of labeling on a "per day" basis.

FDA is concerned that consumers have nutrition information available at the point of purchase upon which to base purchase decisions. Therefore, the agency is not considering package inserts which could be viewed only after purchase of the product. Additionally, rather than allowing manufacturers to label on a "per day" or "per unit" basis, the agency favors one consistent method of labeling. A consistent method will allow consumer education programs to explain how nutrition labeling is to always appear and to teach consumers how to calculate their individual consumption levels if their intake differs from the amount specified within the nutrition label. The agency believes labeling "per unit" is more useful in that the product will always be consumed "per unit," however, consumers may not always follow a manufacturer's recommendation to consume a certain number of units per day and therefore may not actually consume the amount indicated "per day."

For these reasons, and to harmonize with the U.S. Pharmacopeia, the agency tentatively concludes that nutrition information should be declared on a "per unit" basis. FDA intends to propose its position in the rulemaking that is required under the DS Act.

262. In the supplementary proposal, FDA proposed that nutrition labels for dietary supplements of vitamins and minerals include a column of quantitative amounts by weight and a second column of percent of RDI's, expressed as "Percent Daily Value." Comments were requested on the usefulness of a list of DRV's and the percent of the DRV for fat, saturated fat, cholesterol, carbohydrate, dietary fiber, and sodium provided by the supplement when they are declared (i.e., when they are present in the supplement in more than insignificant amounts) (56 FR 60366 at 60383). In the format proposal, FDA stated that it anticipated modifying § 101.36, Nutrition Labeling of Dietary Supplements, to be as consistent as possible with the nutrition labeling of other foods and requested comment (57 FR 32058 at 32072).

Several comments to both the supplementary proposal and the format proposal addressed the format for declaring amounts of nutrients present. About half of the comments supported FDA's position. However, one comment argued that the unique characteristics of dietary supplements demand a different approach to their nutrition labeling. Characteristics identified included: (1) The vast majority of supplements are marketed in relatively small packages, (2) the nutrition profiles for these products typically reflect high levels of micronutrients and relatively insignificant amounts of macronutrients, (3) consumers look for and expect nutrition information on supplements that is different from that on conventional foods, and (4) consumers of supplements will already be asked to search through an array of nutrient names and units of measure to find the information they look for most: The percentage of their daily nutritional requirements that the supplement provides.

One comment from a manufacturer stated that there was no need to make significant changes in dietary supplement labels because current labels that have been used for many years are widely accepted and present the necessary data on vitamins and minerals in a logical and readily understandable form. A comment from another manufacturer opposed the required declaration in separate columns of quantitative amounts by weight of nutrients and by the percent RDI or percent DRV (expressed as "Percent of Daily Value"). The comment argued that only percent of daily value should be mandatory, and that listing of quantitative amounts by weight should be voluntary, because there is no congressional mandate to list quantitative amounts on two bases, no agency justification that two bases are useful to consumers, and a potential to confuse consumers with little understood terms, e.g., mg alpha-tocopherol. The comment also asserted that a requirement for too much information is discriminatory against products with larger numbers of nutrients and might discourage use of smaller packages that are less expensive to consumers. The comment also stated that a requirement for declaration of only percent of daily value would be consistent with the requirement for vitamins and minerals on conventional food labels.

A few comments objected to the required inclusion of a list of daily values in addition to the quantitative amounts by weight and the percent of daily value on the label. The comments stated that this additional information will produce an even more cluttered appearance and further contribute to the proliferation of numerical values on dietary supplement labels. One comment argued that "The goal of meeting the supplement consumer's need for relevant, comprehensible nutrition information should not be sacrificed out of a blind concern for consistency." The comment concluded that consumers of supplements are already familiar and comfortable with the concept of percent of daily value and their focus on this information should not be diverted by additional unnecessary and potentially confusing information.

While FDA continues to believe it is helpful to consumers to minimize inconsistencies in the label format between types of foods, the agency is persuaded that the unique characteristics of dietary supplements require a reevaluation of whether the format requirements for conventional foods should be carried over to dietary supplements. For example, the agency believes that the declaration of quantitative amounts on two bases (i.e., both by weight and by percent of daily value) needs to be considered for dietary supplements in terms of its usefulness to consumers. In that regard, the agency considers dietary supplement consumers to have special needs for quantitative nutrition information about the products they use by virtue of the way such products are formulated, marketed, and used. Dietary supplements are often formulated and marketed on the basis of offering specific amounts of certain nutrients to consumers. Dietary supplement product users are often trying to maintain a certain quantitative intake of specific nutrients in their diets and use the product to obtain this quantitative goal. Some of the nutrients contained in dietary supplements and declared on the nutrition label are not well known to many consumers. The quantitative goals that are importantly relevant to consumption of dietary supplement products may be stated in various units including units of weight or of percent of RDI's or DRV's. FDA intends to address this issue in the rulemaking that it will undertake in response to the DS Act.

In its reevaluation of format requirements for dietary supplements, the agency also looked at the requirement in nutrition labeling of conventional foods for a list of daily values for all nutrients declared on the label. After careful consideration of the comments, the agency tentatively concludes that it is not necessary or appropriate to require the inclusion of the DV list on dietary supplements. Because of the small size of most supplement packages and the

duplication of the more complex nomenclature of units for vitamins (e.g., mg alpha-tocopherol) that would be required in a DV list, the agency believes that the added complexity and proliferation of numerical values would interfere with consumers use of the quantitative information by weight and by percent of daily value. FDA will propose its position regarding the format of the nutrition label for dietary supplements based on the provisions of the DS Act.

263. A few comments opposed the requirement for declaration of the quantitative amount and the percent of the DRV of fat, saturated fat, cholesterol, carbohydrate, dietary fiber, sodium, and potassium when these nutrients are present in a supplement in more than insignificant amounts. One comment suggested that the declaration either be optional or be required only when these nutrients are present at levels greater than 10 percent of their respective DRV's. The comment stated that: (1) Excessive and useless information would detract from the importance of a product's vitamin and mineral content; (2) even though the vast majority of supplements lack these substances, all products would have to undergo extensive and expensive testing to determine whether listing of these components is necessary, thus burdening small companies with diverse supplement product lines; and (3) these requirements would hinder product development and increase the cost of bringing innovative products to market. Another comment stated that declaration of fat should be required only for fatty acid supplements of 1 g or more per unit since declaration of smaller amounts would clutter the label and be difficult to read.

As discussed in the preceding comment, FDA agrees that the declaration of the amount of the DRV's (i.e., the DV list) is not necessary on labels of dietary supplements of vitamins and minerals. However, FDA continues to believe that the quantitative amount and the percent of the DRV should be declared for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, sodium, and potassium when these nutrients are present in a supplement in more than insignificant amounts. Information about these food components, which are important to the maintenance of good health, is useful for consumers. This view was supported by comments from health professionals, consumer organizations, and the general public. Moreover, supplements are formulated products, and manufacturers should know from the ingredients that they use to make these products whether a supplement contains more than insignificant amounts of any of the nutrients for which DRV's have been established. When such ingredients are not used, laboratory analyses for such nutrients would be unnecessary. As discussed in comment 176 of this document, the definition of insignificant has been modified so that an "insignificant amount" of total carbohydrate, dietary fiber, and protein is an amount that allows a declaration of "less than 1 g" in the nutrition label. The agency will propose its position on this issue in the rulemaking that it does in response to the DS Act.

264. Several comments, predominantly from manufacturers and trade associations, disagreed with FDA's statement in the supplementary proposal that dietary supplements of selenium and chromium are not permitted because there are no regulations declaring these nutrients as approved food additives, GRAS, or prior-sanctioned ingredients. A trade association stated that nutrition labeling regulations are not the appropriate place to announce decisions about the GRAS status of nutrients. Comments argued that selenium and chromium are recognized as essential nutrients for humans. They pointed out that the National Research Council's Food and Nutrition Board has established a Recommended Dietary Allowance for selenium and an ESADDI for chromium (Ref. 23), and that FDA proposed RDI's for these nutrients. Moreover, comments stated that FDA has advised for many years that these trace minerals are "safe and suitable" for use in supplements. The comments argued that, therefore, FDA should adopt a general policy that trace minerals for which a Recommended Dietary Allowance or ESADDI has been established are GRAS, at least at levels not to exceed their respective Recommended Dietary Allowance/ESADDI.

The agency agrees that this rulemaking is not the appropriate place to announce decisions about the GRAS status of nutrients. Therefore, FDA reiterates that there are currently no sources of selenium or chromium that are either affirmed as GRAS or approved food additives for addition to human food. Any direct addition of these trace minerals to a food is based solely on the manufacturer's judgment that the nutrient sources are GRAS and is not sanctioned by the agency.

265. One comment advocated the parenthetical listing of the source of each vitamin or mineral immediately following its declaration on the nutrition information panel in lieu of a separate ingredient list. The comme argued that this listing would avoid confusion by enabling consumers to readily identify the nutrient source and would save limited label space. Furthermore, the comment stated that it is already common practice in the supplement industry. The comment suggested that information about the source of the nutrient would allow the consumer to identify whether the source is the most physiologically desirable, e.g., beta-carotene versus vitamin A palmitate.

FDA advises that dietary supplements, like any food, are required to bear a complete list of ingredients under section 403(l)(2) of the act, and such list should not be confused with the nutrition label. Ingredient listing, moreover, is needed for substances other than vitamins or minerals, e.g., lactose, other fillers, artificial colors, flavors, binders, and excipients. Consumers desiring to know the source of a nutrient can merely look at the list of ingredients just as they would for a conventional food product. Therefore, in accordance with ingredient labeling regulations, the specific source of vitamin A must be shown in the ingredient list.

However, in response to this and another similar comment (see comment 81 of this document), the agency is allowing for the declaration of the percent of vitamin A present as beta-carotene in § 101.9(c)(8)(vi). The agency will propose its position regarding a similar provision in nutrition labeling regulations pertaining to dietary supplements of vitamins and minerals following provisions of the DS Act.

266. One comment objected to the listing of the quantitative amounts of vitamins and minerals to the nearest unit of the same level of significance at which the RDI's are specified in § 101.9(c)(8)(iv). The comment stated that it would be potentially confusing to consumers for thiamin, for example, to be declared to the first decimal place, e.g., 100.0 mg, and niacin to be declared to the nearest whole number, e.g., 100 mg. The comment suggested that decimal places be dropped, and that all nutrients be listed to the nearest whole number when nutrient levels are ten or more times the RDI.

While FDA intends to deal with this issue in its rulemaking that responds to the DS Act, the agency offers the following comments. FDA is not persuaded that consumers would be confused by decimals for some nutrients and not others. In addition, requiring only whole numbers would introduce a large amount of imprecision in the declarations of some nutrients. For

example, it would cause 1.5 mg of thiamin (i.e., 100 percent of the RDI) to be rounded up to 2 mg—a 33 percent increase.

However, when the decimal is followed by a zero, the agency generally has no objection to the zero being dropped. In fact, in the supplementary proposal, this was done in the declaration of the amount of vitamin B12 in the hypothetical sample label for "Daily Vitamins Plus Iron" (56 FR 60366 at 60383). Since RDI's in § 101.9(c)(8)(iv) are established only in whole numbers or in tenths of a unit, allowing zeros following decimals to be dropped, in effect, allows all nutrients to be declared to the nearest whole number when nutrient levels are ten times the RDI.

267. A couple of comments objected to FDA's proposal that compliance with the requirements for labeling of dietary supplements be determined in accordance with § 101.9(g), i.e., 100 percent of label claim for Class I nutrients. Comments argued that the 100 percent requirement is unreasonable in that it is more stringent than United States Pharmacopeia (USP) requirements for certain vitamin and mineral products, which generally allow lower limits of 90 percent to 95 percent of label claim.

FDA intends to deal with this issue in the rulemaking that responds to the DS Act. However, the agency notes that dietary supplements are fabricated products. Therefore, the question is raised why they should not be held to the same Class I nutrient standards as conventional foods that are fortified or enriched. Based on the agency's current compliance policy it has informed USP that anything less than 100 percent of the label claim for vitamin and mineral products is not acceptable to FDA, and that the only permissible deviation from this requirement would be the variability of the analytical method (Ref. 118).

The agency notes that, contrary to the statement in the comments, the General Notices of the USP state that a dosage should be formulated to provide 100 percent of the labeled amount (Ref. 119). The limits in the monographs allow for overages of ingredients known to decrease with time, for analytical error, for manufacturing and compounding variations, and for deterioration to an extent considered insignificant under practical conditions (Ref. 119).

268. One comment asserted that manufacturers should be prohibited from labeling a supplement in such a way as to confuse the weight of a unit of supplement with its nutrient content. For example, a calcium supplement that contains 250 mg of elemental calcium as calcium chloride should not be labeled as "calcium—625 mg" anywhere on the label.

FDA concurs that such labeling is potentially misleading to consumers. Section 403(a) of the act provides that a food will be deemed to be misbranded if its labeling is false or misleading in any particular. FDA concludes that existing statutory authority is sufficient for taking regulatory action if the weight of a product is specified on the label in a manner that is likely to mislead consumers into thinking that that is the weight of the nutrient contained in the product if those amounts are different.

IX. Consumer Education Program

Section 2(c) of the 1990 amendments directs the Secretary (and FDA, by delegation) to carry out activities that educate consumers about nutrition information on the food label and the importance of that information in maintaining healthy dietary practices. To achieve this purpose, FDA and USDA have jointly initiated a multi-year food labeling education campaign. The major goals of this campaign are to increase consumers' knowledge and effective use of the new food label to make accurate and sound dietary choices; to integrate food labeling education into existing and new nutrition and health education programs; and to build extensive partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low literacy consumers, minorities, older Americans, children, and people with dietary restrictions.

As part of this effort, the agencies have established the National Exchange on Food Labeling Education which includes an information center housed in the Food and Nutrition Information Center at the National Agricultural Library. The National Exchange on Food Labeling Education provides the general public and professionals with access to information about food labeling research and educational activities (projects, programs, and materials) from both the public and private sector.

FDA and USDA have also worked to establish cooperative projects with diverse organizations and to facilitate the communication of information that targets various subpopulations as well as the general public. The agencies have thus developed extensive food label education networks that include consumers, health professionals and organizations, educators, trade associations, Federal and local government, and many others to assist in the dissemination and development of information and activities.

To ensure that consumers have accurate and adequate resource materials and information, the agencies have begun, and will continue, to conduct and report on existing and planned food labeling research; to develop education initiatives at the national and local level; to hold regularly-scheduled meetings to build labeling education exchanges; to produce videos; and to produce an array of public education materials, including a special edition of FDA Consumer magazine that summarizes the final food labeling regulations, and brochures (in English and other languages) on the new label and how to use it to meet the Dietary Guidelines for Americans (Ref. 4). These materials will be targeted to the general public, nutritionists, such special groups as ethnic minorities, and others. Organizations will also be able to use these resource materials to develop educational materials of their own.

X. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96-354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule

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as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the Federal Register of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

In its November 1991 nutrition labeling proposed rules, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the Federal Register. Several comments on the nutrition labeling proposed rules suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste.

Based on its review of available data and comments received, the agency has decided to allow additional time for companies to use up their old labels. Thus, the nutrition labeling final rules will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 101 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 403, 502, 512, 602, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 352, 355, 360, 362, 371); sec. 215 of the Public Health Service Act (42 U.S.C. 216).

2. Section 1.24 is amended by revising paragraph (a)(14) to read as follows:

§ 1.24 Exemptions from required label statements.

* * * * *

(a) * * *

(14) The unit containers in a multiunit or multicomponent retail food package shall be exempt from regulations of section 403 (e)(1), (g)(2), (i)(2), (k), and (q) of the act with respect to the requirements for label declaration

of the name and place of business of the manufacturer, packer, or distributor; label declaration of ingredients; and nutrition information when:

(i) The multiunit or multicomponent retail food package labeling meets all the requirements of this part;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than one-sixteenth of an inch in height. The word "Individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

* * * * *

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.9 is revised to read as follows:

§ 101.9 Nutrition labeling of food.

(a) Nutrition information relating to food shall be provided for all products intended for human consumption and offered for sale unless an exemption is provided for the product in paragraph (j) of this section. A nutrition claim or any other nutrition information on the label or in labeling or advertising in any context, and in any form of expression, implicit, as well as explicit, shall negate any exemption and subject a food to the provisions of this section.

(1) When food is in package form, the required nutrition labeling information shall appear on the label in the format specified in this section.

(2) When food is not in package form, the required nutrition labeling information shall be displayed clearly at the point of purchase (e.g., on a counter card, sign, tag affixed to the product, or some other appropriate device). Alternatively, the required information may be placed in a booklet, looseleaf binder, or other appropriate format that is available at the point of purchase.

(3) Solicitation of requests for nutrition information by a statement "For nutrition information write to _____" on the label or in the labeling or advertising for a food, or providing such information in a direct written reply to a solicited or unsolicited request, does not subject the label or the labeling of a food exempted under paragraph (j) of this section to the requirements of this section if the reply to the request conforms to the requirements of this section.

(4) If any vitamin or mineral is added to a food so that a single serving provides 50 percent or more of the Reference Daily Intake (RDI) for the age group for which the product is intended, as specified in paragraph (c)(8)(iv) of this section, of any one of the added vitamins or minerals, unless such addition is permitted or required in other regulations, e.g., a standard of identity or nutritional quality guideline, or is otherwise exempted by the Commissioner, the food shall be considered a food for special dietary use within the meaning of § 105.3(a)(1)(iii) of this chapter.

(b) [Reserved]

(c) The declaration of nutrition information on the label and in labeling of a food shall contain information about the level of the following nutrients, except for those nutrients whose inclusion, and the declaration of amounts, is voluntary as set forth in this paragraph. No nutrients or food components other than those listed in this paragraph as either mandatory or voluntary may be included within the nutrition label. Except as provided for in paragraphs (f) or (j) of this section, nutrient information shall be presented using the nutrient names specified and in the following order in the formats specified in paragraphs (d) or (e) of this section.

(1) "Calories, total," "Total calories," or "Calories": A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. Energy content per serving may also be expressed in kilojoule units, added in parentheses immediately following the statement of the caloric content.

(i) Caloric content may be calculated by:

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, "Energy Value of Foods—Basis and Derivation," by A. L. Merrill and B. K. Watt, United States Department of Agriculture (USDA) Handbook No. 74 (slightly revised, 1973), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF–260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.;

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9–11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of this chapter, or by other means, as appropriate; or

(E) Using bomb calorimetry data and subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised 1973) p. 10, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section).

(ii) "Calories from fat": A statement of the caloric content derived from total fat as defined in paragraph (c)(2) of this section in a serving, expressed to the nearest 5-calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that label declaration of "calories from fat" is not required on products that contain less than 0.5 gram of fat in a serving and amounts less than 5 calories may be expressed as zero. This statement shall be declared as provided in paragraph (d)(5) of this section. Except as provided for in paragraph (f) of this section, if "Calories from fat" is not required and, as a result, not declared, the statement "Not a significant source of calories from fat" shall be placed at the bottom of the table of nutrient values in the same type size.

(iii) "Calories from saturated fat" or "Calories from saturated" (VOLUNTARY): A statement of the caloric content derived from saturated fat as defined in paragraph (c)(2)(i) of this section in a serving may be declared voluntarily, expressed to the nearest 5-

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calorie increment, up to and including 50 calories, and the nearest 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero. This statement shall be indented under the statement of calories from fat as provided in paragraph (d)(5) of this section.

(2) "Fat, total" or "Total fat": A statement of the number of grams of total fat in a serving defined as total lipid fatty acids and expressed as triglycerides. Amounts shall be expressed to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(i) "Saturated fat," or "Saturated": A statement of the number of grams of saturated fat in a serving defined as the sum of all fatty acids containing no double bonds, except that label declaration of saturated fat content information is not required for products that contain less than 0.5 gram of total fat in a serving if no claims are made about fat or cholesterol content, and if "calories from saturated fat" is not declared. Except as provided for in paragraph (f) of this section, if a statement of the saturated fat content is not required and, as a result, not declared, the statement "Not a significant source of saturated fat" shall be placed at the bottom of the table of nutrient values in the same type size. Saturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(ii) "Polyunsaturated fat" or "Polyunsaturated" (VOLUNTARY): A statement of the number of grams of polyunsaturated fat in a serving defined as *cis,cis*-methylene-interrupted polyunsaturated fatty acids may be declared voluntarily, except that when monounsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of polyunsaturated fat is required. Polyunsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(iii) "Monounsaturated fat" or "Monounsaturated" (VOLUNTARY): A statement of the number of grams of monounsaturated fat in a serving defined as *cis*-monounsaturated fatty acids may be declared voluntarily except that when polyunsaturated fat is declared or when a claim is made on the label or in labeling about fatty acids or cholesterol, label declaration of monounsaturated fat is required. Monounsaturated fat content shall be indented and expressed as grams per serving to the nearest 0.5 (½) gram increment below 3 grams and to the nearest gram increment above 3 grams. If the serving contains less than 0.5 gram, the content shall be expressed as zero.

(3) "Cholesterol": A statement of the cholesterol content in a serving expressed in milligrams to the nearest 5-milligram increment, except that label declaration of cholesterol information is not required for products that contain less than 2 milligrams cholesterol in a serving and make no claim about fat, fatty acids, or cholesterol content, or such products may state the cholesterol content as zero. Except as provided for in paragraph (f) of this section, if cholesterol content is not required and, as a result, not declared, the statement "Not a significant source of cholesterol" shall be placed at the bottom of the table of nutrient values in the same type size. If the food contains 2 to 5 milligrams of cholesterol per serving, the content may be stated as "less than 5 milligrams."

(4) "Sodium": A statement of the number of milligrams of sodium in a specified serving of food expressed as zero when the serving contains less than 5 milligrams of sodium, to the nearest 5-milligram increment when the serving contains 5 to 140 milligrams of sodium, and to the nearest 10-milligram increment when the serving contains greater than 140 milligrams.

(5) "Potassium" (VOLUNTARY): A statement of the number of milligrams of potassium in a specified serving of food may be declared voluntarily, except that when a claim is made about potassium content, label declaration shall be required. Potassium content shall be expressed as zero when the serving contains less than 5 milligrams of potassium, to the nearest 5-milligram increment when the serving contains less than or equal to 140 milligrams of potassium, and to the nearest 10-milligram increment when the serving contains more than 140 milligrams.

(6) "Carbohydrate, total" or "Total carbohydrate": A statement of the number of grams of total carbohydrate in a serving expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, or if the serving contains less than 0.5 gram, the content may be expressed as zero. Total carbohydrate content shall be calculated by subtraction of the sum of the crude protein, total fat, moisture, and ash from the total weight of the food. This calculation method is described in A. L. Merrill and B. K. Watt, "Energy Value of Foods—Basis and Derivation," USDA Handbook 74 (slightly revised 1973) pp. 2 and 3, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section).

(i) "Dietary fiber": A statement of the number of grams of total dietary fiber in a serving, indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, declaration of dietary fiber is not required or, alternatively, the statement "Contains less than 1 gram" or "less than 1 gram" may be used, and if the serving contains less than 0.5 gram, the content may be expressed as zero. Except as provided for in paragraph (f) of this section, if dietary fiber content is not required and as a result, not declared, the statement "Not a significant source of dietary fiber" shall be placed at the bottom of the table of nutrient values in the same type size.

(A) "Soluble fiber" (VOLUNTARY): A statement of the number of grams of soluble dietary fiber in a serving may be declared voluntarily except when a claim is made on the label or in labeling about soluble fiber, label declaration shall be required. Soluble fiber content shall be indented under dietary fiber and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(B) "Insoluble fiber" (VOLUNTARY): A statement of the number of grams of insoluble dietary fiber in a serving may be declared voluntarily except that when a claim is made on the label or in labeling about insoluble fiber, label declaration shall be required. Insoluble fiber content shall be indented under dietary fiber and expressed to the nearest gram except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(ii) "Sugars": A statement of the number of grams of sugars in a serving, except that label declaration of sugars content is not required for products that contain less than 1 gram of sugars in a

serving if no claims are made about sweeteners, sugars, or sugar alcohol content. Except as provided for in paragraph (f) of this section, if a statement of the sugars content is not required and, as a result, not declared, the statement "Not a significant source of sugars" shall be placed at the bottom of the table of nutrient values in the same type size. Sugars shall be defined as the sum of all free mono- and disaccharides (such as glucose, fructose, lactose, and sucrose). Sugars content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iii) "Sugar alcohol" (VOLUNTARY): A statement of the number of grams of sugar alcohols in a serving may be declared voluntarily on the label, except that when a claim is made on the label or in labeling about sugar alcohol or sugars when sugar alcohols are present in the food, sugar alcohol content shall be declared. For nutrition labeling purposes, sugar alcohols are defined as the sum of saccharide derivatives in which a hydroxyl group replaces a ketone or aldehyde group and whose use in the food is listed by FDA (e.g., mannitol) or is generally recognized as safe (e.g., xylitol, sorbitol). In lieu of the term "sugar alcohol," the name of the specific sugar alcohol (e.g., "xylitol") present in the food may be used in the nutrition label provided that only one sugar alcohol is present in the food. Sugar alcohol content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less then 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(iv) "Other carbohydrate" (VOLUNTARY): A statement of the number of grams of other carbohydrates may be declared voluntarily. Other carbohydrates shall be defined as the difference between total carbohydrate and the sum of dietary fiber, sugars, and sugar alcohol, except that if sugar alcohol is not declared (even if present), it shall be defined as the difference between total carbohydrate and the sum of dietary fiber and sugars. Other carbohydrate content shall be indented and expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero.

(7) "Protein": A statement of the number of grams of protein in a serving, expressed to the nearest gram, except that if a serving contains less than 1 gram, the statement "Contains less than 1 gram" or "less than 1 gram" may be used as an alternative, and if the serving contains less than 0.5 gram, the content may be expressed as zero. When the protein in foods represented or purported to be for adults and children 4 or more years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 20 expressed as a percent, or when the protein in a food represented or purported to be for children greater than 1 but less than 4 years of age has a protein quality value that is a protein digestibility-corrected amino acid score of less than 40 expressed as a percent, either of the following shall be placed adjacent to the declaration of protein content by weight: The statement "not a significant source of protein," or a listing aligned under the column headed "Percent Daily Value" of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the Daily Reference Value (DRV) or Reference Daily Intake (RDI), as appropriate, for protein and expressed as Percent of Daily Value. When the protein quality in a food as measured by the Protein Efficiency Ratio (PER) is less than 40 percent of the reference standard (casein) for a food represented or purported to be for infants, the statement "not a significant source of protein" shall be placed adjacent to the declaration of protein content. Protein content may be calculated on the basis of the factor of 6.25 times the nitrogen content of the food as determined by the appropriate method of analysis as given in the "Official Methods of Analysis of the AOAC International" (formerly the Association of Official Analytical Chemists), 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, except when the official procedure for a specific food requires another factor. Copies may be obtained from AOAC, 2200 Wilson Blvd., suite 400, Arlington, VA 22201-3301, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(i) A statement of the corrected amount of protein per serving, as determined in paragraph (c)(7)(ii) of this section, calculated as a percentage of the RDI or DRV for protein, as appropriate, and expressed as Percent of Daily Value, may be placed on the label, except that such a statement shall be given if a protein claim is made for the product, or if the product is represented or purported to be for use by infants or children under 4 years of age. When such a declaration is provided, it shall be placed on the label adjacent to the statement of grams of protein and aligned under the column headed "Percent Daily Value," and expressed to the nearest whole percent. However, the percentage of the RDI for protein shall not be declared if the food is represented or purported to be for use by infants and the protein quality value is less than 40 percent of the reference standard.

(ii) The "corrected amount of protein (gram) per serving" for foods represented or purported for adults and children 1 or more years of age is equal to the actual amount of protein (gram) per serving multiplied by the amino acid score corrected for protein digestibility. If the corrected score is above 1.00, then it shall be set at 1.00. The protein digestibility-corrected amino acid score shall be determined by methods given in sections 5.4.1, 7.2.1, and 8.00 in "Protein Quality Evaluation, Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation," Rome, 1990, except that when official AOAC procedures described in section (c)(7) of this paragraph require a specific food factor other than 6.25, that specific factor shall be used. The "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation" as published by the Food and Agriculture Organization of the United Nations/World Health Organization is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Division of Nutrition, Center for Food Safety and Applied Nutrition (HFF–260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC. For foods represented or purported for infants, the corrected amount of protein (grams) per serving is equal to the actual amount of protein (grams) per serving multiplied by the relative protein quality value The relative protein quality value shall be determined by dividing the subject food protein PER value by the PER value for casein. If the relative protein value is above 1.00, it shall be set at 1.00.

(iii) [Reserved]

(8) Vitamins and minerals: A statement of the amount per serving of the vitamins and minerals as described in this paragraph, calculated as a

percent of the RDI and expressed as percent of Daily Value.

(i) For purposes of declaration of percent of Daily Value as provided for in paragraphs (d), (e), and (f) of this section, foods represented or purported to be for use by infants, children less than 4 years of age, pregnant women, or lactating women shall use the RDI's in paragraph (c)(8)(iv) of this section that are specified for the intended group. For foods represented or purported to be for use by both infants and children under 4 years of age, the percent of Daily Value shall be presented by separate declarations according to paragraph (e) of this section based on the RDI values for infants from birth to 12 months of age and for children under 4 years of age. Similarly, the percent of Daily Value based on both the RDI values for pregnant women and for lactating women shall be declared separately on foods represented or purported to be for use by both pregnant and lactating women. When such dual declaration is used on any label, it shall be included in all labeling, and equal prominence shall be given to both values in all such labeling. All other foods shall use the RDI for adults and children 4 or more years of age.

(ii) The declaration of vitamins and minerals as a percent of the RDI shall include vitamin A, vitamin C, calcium, and iron, in that order, and shall include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are added as a nutrient supplement, or when a claim is made about them. Other vitamins and minerals that are:

(A) Required or permitted in a standardized food (e.g., thiamin, riboflavin, and niacin in enriched flour) and that standardized food is included as an ingredient (i.e., component) in another food; or

(B) Included in a food solely for technological purposes and declared only in the ingredient statement need not be declared if neither the nutrient nor the component is otherwise referred to on the label or in labeling or advertising. The declaration may also include any of the other vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are naturally occurring in the food. The additional vitamins and minerals shall be listed in the order established in paragraph (c)(8)(iv) of this section.

(iii) The percentages for vitamins and minerals shall be expressed to the nearest 2-percent increment up to and including the 10-percent level, the nearest 5-percent increment above 10 percent and up to and including the 50-percent level, and the nearest 10-percent increment above the 50-percent level. Amounts of vitamins and minerals present at less than 2 percent of the RDI are not required to be declared in nutrition labeling but may be declared by a zero or by the use of an asterisk (or other symbol) that refers to another asterisk (or symbol) that is placed at the bottom of the table and that is followed by the statement "Contains less than 2 percent of the Daily Value of this (these) nutrient (nutrients)." Alternatively, except as provided for in paragraph (f) of this section, if vitamin A, vitamin C, calcium, or iron is present in amounts less than 2 percent of the RDI, label declaration of the nutrient(s) is not required if the statement "Not a significant source of _____ (listing the vitamins or minerals omitted)" is placed at the bottom of the table of nutrient values. Either statement shall be in the same type size as nutrients that are indented.

(iv) [Reserved]

(v) The following synonyms may be added in parentheses immediately following the name of the nutrient or dietary component:

Vitamin C—Ascorbic acid
Thiamin—Vitamin B_1
Riboflavin—Vitamin B_2
Folate—Folacin
Calories—Energy

(vi) The percent of vitamin A that is present as beta-carotene may be declared to the nearest 10-percent increment immediately adjacent to or beneath the nutrient name (e.g., "Vitamin A (90 percent as beta-carotene)").

(9) [Reserved]

(d)(1) Nutrient information specified in paragraph (c) of this section shall be presented on foods in the following format, as shown in paragraph (d)(12) of this section, except on foods on which dual columns of nutrition information are declared as provided for in paragraph (e) of this section, on those food products on which the simplified format is required to be used as provided for in paragraph (f) of this section, on foods for infants and children less than 4 years of age as provided for in paragraph (j)(5) of this section, and on foods in small or intermediate-sized packages as provided for in paragraph (j)(13) of this section. In the interest of uniformity of presentation, FDA urges that the nutrition information be presented using the graphic specifications set forth in Appendix B to Part 101.

(i) The nutrition information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the nutrition label shall utilize:

(A) A single easy-to-read type style,

(B) Upper and lower case letters,

(C) At least one point leading (i.e., space between two lines of text) except that at least four points leading shall be utilized for the information required by paragraphs (d)(7) and (d)(8) of this section as shown in paragraph (d)(12), and

(D) Type that is kerned (i.e., has proximity of placement) no tighter than −4 setting.

(iii) All information except for the information required in paragraphs (d)(4), (d)(6), (d)(9), and (d)(10) of this section shall be in type size no smaller than 8 point. The information required in paragraphs (d)(4), (d)(6), (d)(9), and (d)(10) of this section shall be in type size no smaller than 6 point.

(iv) The headings required by paragraphs (d)(2), (d)(4), and (d)(6) of this section (i.e., "Nutrition Facts," "Amount per Serving," and "% Daily Value*"), the names of all nutrients that are not indented according to requirements of paragraph (c) of this section (i.e., "Calories," "Total Fat," "Cholesterol," "Sodium," "Total Carbohydrate," and "Protein"), and the percentage amounts required by paragraph (d)(7)(ii) of this section shall be highlighted by bold or extra bold type or other highlighting (reverse printing is not permitted as a form of highlighting) that prominently distinguishes it from other information. No other information shall be highlighted.

(v) A hairline rule that is centered between the lines of text shall separate "Amount Per Serving" from the calorie statements required in paragraph (d)(5) of this section and shall separate each nutrient and its corresponding percent Daily Value required in paragraphs (d)(7)(i) and (d)(7)(ii) of this section from the nutrient and percent Daily Value above and below it, as shown in paragraph (d)(12) of this section.

(2) The information shall be presented under the identifying heading of "Nutrition Facts" which shall be set in a type size larger than all other print size in the nutrition label and, except for labels presented according to the format provided for in paragraph (d)(11) of this section, unless impractical, shall be set the full width of the information provided under paragraph (d)(7) of this section, as shown in paragraph (d)(12) of this section.

(3) Information on serving size shall immediately follow the heading as

shown in paragraph (d)(12) of this section. Such information shall include:

(i) "Serving Size": A statement of the serving size as specified in paragraph (b)(7) of this section.

(ii) "Servings Per Container": The number of servings per container, except that this statement is not required on single serving containers as defined in paragraph (b)(6) of this section.

(4) A subheading "Amount Per Serving" shall be separated from serving size information by a bar as shown in paragraph (d)(12) of this section.

(5) Information on calories shall immediately follow the heading "Amount Per Serving" and shall be declared in one line, leaving sufficient space between the declaration of "Calories" and "Calories from fat" to allow clear differentiation, or, if "Calories from saturated fat" is declared, in a column with total "Calories" at the top, followed by "Calories from fat" (indented), and "Calories from saturated fat" (indented).

(6) The column heading "% Daily Value," followed by an asterisk (e.g., "% Daily Value*"), shall be separated from information on calories by a bar as shown in paragraph (d)(12) of this section. The position of this column heading shall allow for a list of nutrient names and amounts as described in paragraph (d)(7) of this section to be to the left of, and below, this column heading. The column headings "Percent Daily Value," "Percent DV," or "% DV" may be substituted for "% Daily Value."

(7) Except as provided for in paragraph (j)(13) of this section, nutrient information for all nutrients required by paragraph (c) of this section, except vitamins and minerals, shall be declared as follows:

(i) The name of each nutrient specified in paragraph (c) of this section shall be given in a column and followed immediately by the quantitative amount by weight for that nutrient appended with a "g" for grams or "mg" for milligrams as shown in paragraph (d)(12) of this section.

(ii) A listing of the percent of the DRV as established in paragraphs (c)(7)(iii) and (c)(9) of this section shall be given in a column aligned under the heading "% Daily Value" established in paragraph (d)(6) of this section with the percent expressed to the nearest whole percent for each nutrient declared in the column described in paragraph (d)(7)(i) of this section for which a DRV has been established, except that the percent for protein may be omitted as provided in paragraph (c)(7) of this section. The percent shall be calculated by dividing the actual amount (i.e., before rounding) for each nutrient by the DRV for the nutrient, except that the percent for protein shall be calculated as specified in paragraph (c)(7)(ii) of this section. The numerical value shall be followed by the symbol for percent (i.e., %).

(8) Nutrient information for vitamins and minerals shall be separated from information on other nutrients by a bar and shall be arrayed horizontally (e.g., Vitamin A 4%, Vitamin C 2%, Calcium 15%, Iron 4%) as shown in paragraph (d)(12) of this section, except that when more than four vitamins and minerals are declared, they may be declared vertically with percentages listed under the column headed "% Daily Value."

(9) A footnote, preceded by an asterisk, shall be placed beneath the list of vitamins and minerals and shall be separated from that list by a hairline.

(i) The footnote shall state:

Percent Daily Values are based on a 2,000 calorie diet.

Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total fat	Less than	65 g	80 g
Saturated fat.	Less than	20 g	25 g
Cholesterol	Less than	300 mg	300 mg
Sodium	Less than	2,400 mg	2,400 mg
Total carbohydrate.		300 g	375 g
Dietary fiber		25 g	30 g

(ii) If the percent of Daily Value is given for protein in the Percent of Daily Value column as provided in paragraph (d)(5)(ii) of this section, protein shall be listed under dietary fiber, and the DRV established in paragraph (c)(7)(iii) of this section shall be inserted on the same line in the numeric columns.

(iii) If potassium is declared in the column described in paragraph (d)(5)(i) of this section, potassium shall be listed under sodium and the DRV established in paragraph (c)(9) of this section shall be inserted on the same line in the numeric columns.

(iv) The abbreviations established in paragraph (j)(13)(ii)(B) of this section may be used within the footnote.

(10) Caloric conversion information on a per gram basis for fat, carbohydrate, and protein shall be presented beneath the information required in paragraph (d)(9) and shall be separated from that information by a hairline. This information may be presented horizontally as shown in paragraph (d)(12) of this section (i.e., "Calories per gram: fat 9, carbohydrate 4, protein 4") or vertically in columns.

(11) If the space beneath the information on vitamins and minerals is not adequate to accommodate the information required in paragraphs (d)(9) and (d)(10) of this section, the information required in paragraph (d)(9) may be moved to the right of the column required in paragraph (d)(7)(ii) and set off by a line that distinguishes it and sets it apart from the percent daily value information The caloric conversion information required in paragraph (d)(10) of this section may be presented beneath either side or along the full length of the nutrition label.

(12) The following sample label illustrates the provisions of paragraph (d) of this section.

BILLING CODE 4160-01-m

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Nutrition Facts

Serving Size 1/12 cup (45g)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	135
	% Daily Value**	
Total Fat 5g*	**13%**	**36%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**8%**	**9%**
Total Carbohydrate 34g	**9%**	**9%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

*Amount in Mix

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(e) Nutrition information may be presented for two or more forms of the same food (e.g., both "as purchased" and "as prepared") or for common combinations of food as provided for in paragraph (h)(4) of this section, for different units (e.g., slices of bread or per 100 grams) as provided for in paragraph (b) of this section, or for two or more groups for which RDI's are established in paragraph (c)(8)(iv) of this section (e.g., both infants and children less than 4 years of age) as shown in paragraph (e)(5) of this section. When such dual labeling is provided, equal prominence shall be given to both sets of values. Information shall be presented in a format consistent with paragraph (d) of this section, except that:

(1) Following the subheading of "Amount Per Serving," there shall be two or more column headings accurately describing the forms of the same food (e.g., "Mix" and "Baked"), the combinations of food, the units, or the RDI groups that are being declared. The column representing the product as packaged and according to the label serving size based on the reference amount in § 101.12(b) shall be to the left of the numeric columns.

(2) When the dual labeling is presented for two or more forms of the same food, for combinations of food, or for different units, total calories and calories from fat (and calories from saturated fat, when declared) shall be listed in a column and indented as specified in paragraph (d)(5) of this section with quantitative amounts declared in columns aligned under the column headings set forth in paragraph (e)(1) of this section.

(3) Quantitative information by weight required in paragraph (d)(7)(i) of this section shall be specified for the form of the product as packaged and according to the label serving size based on the reference amount in § 101.12(b).

(i) Quantitative information by weight may be included for other forms of the product represented by the additional column(s) either immediately adjacent to the required quantitative information by weight for the product as packaged and according to the label serving size* based on the reference amount in § 101.12(b) or as a footnote.

(A) If such additional quantitative information is given immediately adjacent to the required quantitative information, it shall be declared for all nutrients listed and placed immediately following and differentiated from the required quantitative information (e.g., separated by a comma). Such information shall not be put in a separate column.

(B) If such additional quantitative information is given in a footnote, it shall be declared in the same order as the nutrients are listed in the nutrition label. The additional quantitative information may state the total nutrient content of the product identified in the second column or the nutrient amounts added to the product as packaged for only those nutrients that are present in different amounts than the amounts declared in the required quantitative information. The footnote shall clearly identify which amounts are declared. Any subcomponents declared shall be listed parenthetically after principal components (e.g., 1/2 cup skim milk contributes an additional 40 calories, 65 mg sodium, 6 g total carbohydrate (6 g sugars), and 4 g protein).

(ii) Total fat and its quantitative amount by weight shall be followed by an asterisk (or other symbol) (e.g., "Total fat (2 g)*") referring to another asterisk (or symbol) at the bottom of the nutrition label identifying the form(s) of the product for which quantitative information is presented.

(4) Information required in paragraphs (d)(7)(ii) and (d)(8) of this section shall be presented under the subheading "% DAILY VALUE" and in columns directly under the column headings set forth in paragraph (e)(1) of this section.

(5) The following sample label illustrates the provisions of paragraph (e) of this section:

BILLING CODE 4160-01-M

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Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

(f) The declaration of nutrition information may be presented in the simplified format set forth herein when a food product contains insignificant amounts of seven or more of the following: Calories, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron; except that for foods intended for children less than 2 years of age to which § 101.9(j)(5)(i) applies, nutrition information may be presented in the simplified format when a food product contains insignificant amounts of six or more of the following: Calories, total fat, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron.

(1) An "insignificant amount" shall be defined as that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram."

(2) The simplified format shall include information on the following nutrients:

(i) Total calories, total fat, total carbohydrate, protein, and sodium;

(ii) Calories from fat and any other nutrients identified in paragraph (f)(1) of this section that are present in the food in more than insignificant amounts; and

(iii) Any vitamins and minerals listed in paragraph (c)(8)(iv) of this section when they are required to be added as a nutrient supplement to foods for which a standard of identity exists.

(iv) Any vitamins or minerals that are voluntarily added to the food as nutrient supplements.

(3) Other nutrients that are naturally present in the food in more than insignificant amounts may be voluntarily declared as part of the simplified format.

(4) If any nutrients are declared as provided in paragraphs (f)(2)(iii), (f)(2)(iv), or (f)(3) of this section as part of the simplified format, the statement "Not a significant source of _____" (with the blank filled in with the name(s) of any nutrient(s) identified in § 101.9(f) and calories from fat that are present in insignificant amounts) shall be included at the bottom of the nutrition label.

(5) Except as provided for in paragraphs (j)(5) and (j)(13) of this section, nutrient information declared in the simplified format shall be presented in the same manner as specified in paragraphs (d) or (e) of this section, except that the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of this section are not required. When the footnote and caloric conversion information are omitted, an asterisk shall be placed at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(g) Compliance with this section shall be determined as follows:

(1) A collection of primary containers or units of the same size, type, and style produced under conditions as nearly uniform as possible, designated by a common container code or marking, or in the absence of any common container code or marking, a day's production, constitutes a "lot."

(2) The sample for nutrient analysis shall consist of a composite of 12 subsamples (consumer units), taken 1 from each of 12 different randomly chosen shipping cases, to be representative of a lot. Unless a particular method of analysis is specified in paragraph (c) of this section, composites shall be analyzed by appropriate methods as given in the "Official Methods of Analysis of the AOAC International," 15th Ed. (1990), which is incorporated by reference in accordance with 5 U.S.C. 552(a) or 1 CFR part 51 or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. The availability of this incorporation by reference is given in paragraph (c)(7) of this section.

(3) Two classes of nutrients are defined for purposes of compliance:

(i) *Class I.* Added nutrients in fortified or fabricated foods; and

(ii) *Class II.* Naturally occurring (indigenous) nutrients. If any ingredient which contains a naturally occurring (indigenous) nutrient is added to a food, the total amount of such nutrient in the final food product is subject to class II requirements unless the same nutrient is also added.

(4) A food with a label declaration of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium shall be deemed to be misbranded under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act) unless it meets the following requirements:

(i) *Class I vitamin, mineral, protein, dietary fiber, or potassium.* The nutrient content of the composite is at least equal to the value for that nutrient declared on the label.

(ii) *Class II vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium.* The nutrient content of the composite is at least equal to 80 percent of the value for that nutrient declared on the label.

Provided, That no regulatory action will be based on a determination of a nutrient value that falls below this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(5) A food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium shall be deemed to be misbranded under section 403(a) of the act if the nutrient content of the composite is greater than 20 percent in excess of the value for that nutrient declared on the label. *Provided,* That no regulatory action will be based on a determination of a nutrient value that falls above this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved.

(6) Reasonable excesses of a vitamin, mineral, protein, total carbohydrate, dietary fiber, other carbohydrate, polyunsaturated or monounsaturated fat, or potassium over labeled amounts are acceptable within current good manufacturing practice. Reasonable deficiencies of calories, sugars, total fat, saturated fat, cholesterol, or sodium under labeled amounts are acceptable within current good manufacturing practice.

(7) Compliance will be based on the metric measure specified in the label statement of serving size.

(8) Compliance with the provisions set forth in paragraphs (g)(1) through (g)(6) of this section may be provided by use of an FDA approved data base that has been computed following FDA guideline procedures and where food samples have been handled in accordance with current good manufacturing practice to prevent nutrition loss. FDA approval of a data base shall not be considered granted until the Center for Food Safety and Applied Nutrition has agreed to all aspects of the data base in writing. The approval will be granted where a clear need is presented (e.g., raw produce and seafood). Approvals will be in effect for a limited time, e.g., 10 years, and will be eligible for renewal in the absence of significant changes in agricultural or industry practices. Approval requests shall be submitted in accordance with the provisions of § 10.30 of this chapter. Guidance in the use of data bases may be found in the "FDA Nutrition Labeling Manual—A Guide for Developing and Using Data Bases," available from the Division of Nutrition, Center for Food Safety and Applied

Nutrition (HFF–260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(9) When it is not technologically feasible, or some other circumstance makes it impracticable, for firms to comply with the requirements of this section (e.g., to develop adequate nutrient profiles to comply with the requirements of paragraph (c) of this section), FDA may permit alternative means of compliance or additional exemptions to deal with the situation. Firms in need of such special allowances shall make their request in writing to the Office of Nutrition and Food Sciences (HFF–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(h) Products with separately packaged ingredients or foods, with assortments of food, or to which other ingredients are added by the user may be labeled as follows:

(1) If a product consists of two or more separately packaged ingredients enclosed in an outer container or of assortments of the same type of food (e.g., assorted nuts or candy mixtures) in the same retail package, nutrition labeling shall be located on the outer container or retail package (as the case may be) to provide information for the consumer at the point of purchase. However, when two or more food products are simply combined together in such a manner that no outer container is used, or no outer label is available, each product shall have its own nutrition information, e.g., two boxes taped together or two cans combined in a clear plastic overwrap. When separately packaged ingredients or assortments of the same type of food are intended to be eaten at the same time, the nutrition information may be specified per serving for each component or as a composite value.

(2) If a product consists of two or more separately packaged foods that are intended to be eaten individually and that are enclosed in an outer container (e.g., variety packs of cereals or snack foods), the nutrition information shall be specified per serving for each food in a location that is clearly visible to the consumer at the point of purchase.

(3) If a package contains a variety of foods, or an assortment of foods, and is in a form intended to be used as a gift, the nutrition labeling shall be in the form required by paragraphs (a) through (f) of this section, but it may be modified as follows:

(i) Nutrition information may be presented on the label of the outer package or in labeling within or attached to the outer package.

(ii) In the absence of a reference amount customarily consumed in § 101.12(b) that is appropriate for the variety or assortment of foods in a gift package, 1 ounce for solid foods, 2 fluid ounces for nonbeverage liquids (e.g., syrups), and 8 fluid ounces for beverages may be used as the standard serving size for purposes of nutrition labeling of foods subject to this paragraph. However, the reference amounts customarily consumed in § 101.12(b) shall be used for purposes of evaluating whether individual foods in a gift package qualify for nutrient content claims or health claims.

(iii) The number of servings per container may be stated as "varied."

(iv) Nutrition information may be provided per serving for individual foods in the package, or, alternatively, as a composite per serving for reasonable categories of foods in the package having similar dietary uses and similar significant nutritional characteristics. Reasonable categories of foods may be used only if accepted by FDA. In determining whether a proposed category is reasonable, FDA will consider whether the values of the characterizing nutrients in the foods proposed to be in the category meet the compliance criteria set forth in paragraphs (g)(3) through (g)(6) of this section. Proposals for such categories may be submitted in writing to the Office of Nutrition and Food Sciences (HFF–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(v) If a food subject to paragraph (j)(13) of this section because of its small size is contained in a gift package, the food need not be included in the determination of nutrition information under paragraph (h) of this section if it is not specifically listed in a promotional catalogue as being present in the gift package, and:

(A) It is used in small quantities primarily to enhance the appearance of the gift package; or

(B) It is included in the gift package as a free gift or promotional item.

(4) If a food is commonly combined with other ingredients or is cooked or otherwise prepared before eating, and directions for such combination or preparations are provided, another column of figures may be used to declare nutrition information on the basis of the food as consumed in the format required in paragraph (e) of this section (e.g., a dry ready-to-eat cereal may be described with one set of Percent Daily Values for the cereal as sold (e.g., per ounce), and another set for the cereal and milk as suggested in the label (e.g., per ounce of cereal and 1/2 cup of vitamin D fortified skim milk) and a cake mix may be labeled with one set of Percent Daily Values for the dry mix (per serving) and another set for the serving of the final cake when prepared): *Provided*, That, the type and quantity of the other ingredients to be added to the product by the user and the specific method of cooking and other preparation shall be specified prominently on the label.

(i) Except as provided in paragraph (j)(13) of this section, the location of nutrition information on a label shall be in compliance with § 101.2.

(j) The following foods are exempt from this section or are subject to special labeling requirements:

(1)(i) Food offered for sale by a manufacturer, packer, or distributor who has annual gross sales made or business done in sales to consumers that is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers of not more than $50,000, *Provided*, That the food bears no nutrition claims or information on a label or labeling or in advertising.

(ii) For purposes of this paragraph, calculation of the amount of sales shall be based on the most recent 2-year average of business activity. Where firms have been in business less than 2 years, reasonable estimates must indicate that annual sales will not exceed the amounts specified. For foreign firms that ship foods into the United States, the business activities to be included shall be the total amount of food sales, as well as other sales to consumers, by the firm in the United States.

(2) Food products which are:

(i) Served in restaurants;

(ii) Served in other establishments in which food is served for immediate human consumption (e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; bakeries, delicatessens, and retail confectionery stores where there are facilities for immediate consumption on the premises; food service vendors, such as lunch wagons, ice cream shops, mall cookie counters, vending machines, and side-walk carts where foods are generally consumed immediately where purchased or while the consumer is walking away, including similar foods sold from convenience stores; and food delivery systems or establishments where ready-to-eat foods are delivered to homes or offices);

(iii) Sold for sale or use only in such facilities; or

(iv) Sold by a distributor who principally sells food to such facilities: *Provided*, That:

(A) This exemption shall not be available for those foods that are manufactured, processed, or repackaged by that distributor for sale to any persons other than restaurants or other establishments that serve food for immediate human consumption, and

(B) The manufacturer of such products is responsible for providing the nutrition information on the products if there is a reasonable possibility that the product will be purchased directly by consumers.

(3) Food products that are:

(i) Of the type of food described in paragraphs (j)(2)(i) and (j)(2)(ii) of this section,

(ii) Ready for human consumption,

(iii) Offered for sale to consumers but not for immediate human consumption,

(iv) Processed and prepared primarily in a retail establishment, and

(v) Not offered for sale outside of that establishment (e.g., ready-to-eat foods that are portioned and packaged on-site and sold by independent delicatessens, bakeries, and retail confectionery stores where there are no facilities for immediate human consumption, by in-store delicatessen, bakery, or candy departments, or at self-service food bars such as salad bars).

(4) Foods that contain insignificant amounts of all of the nutrients and food components required to be included in the declaration of nutrition information under paragraph (c) of this section. An insignificant amount of a nutrient or food component shall be that amount that allows a declaration of zero in nutrition labeling, except that for total carbohydrate, dietary fiber, and protein, it shall be an amount that allows a declaration of "less than 1 gram." Foods that are exempt under this paragraph include coffee beans (whole or ground), tea leaves, plain unsweetened instant coffee and tea, condiment-type dehydrated vegetables, flavor extracts, and food colors.

(5)(i) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 2 years of age shall bear nutrition labeling, except as provided in paragraph (j)(5)(ii) and except that such labeling shall not include calories from fat (paragraph (c)(1)(ii) of this section), calories from saturated fat ((c)(1)(iii)), saturated fat ((c)(2)(i)), polyunsaturated fat ((c)(2)(ii)), monounsaturated fat ((c)(2)(iii)), and cholesterol ((c)(3)).

(ii) Foods, other than infant formula, represented or purported to be specifically for infants and children less than 4 years or age shall bear nutrition labeling, except that such labeling shall not include listings of percent of Daily Value and the footnote required in paragraphs (d)(7), (d)(9), and (d)(10) of this section. Nutrient names and quantitative amounts by weight shall be presented in two separate columns.

(6) Dietary supplements of vitamins and minerals except that the labeling of a dietary supplement of vitamins and minerals in conventional food form, e.g., a breakfast cereal, shall conform to the labeling established in this section.

(7) Infant formula subject to section 412 of the act, as amended, except that such foods shall be labeled in compliance with part 107 of this chapter.

(8) Medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)). A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. A food is subject to this exemption only if:

(i) It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube;

(ii) It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone;

(iii) It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation;

(iv) It is intended to be used under medical supervision; and

(v) It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

(9) Food products shipped in bulk form that are not for distribution to consumers in such form and that are for use solely in the manufacture of other foods or that are to be processed, labeled, or repacked at a site other than where originally processed or packed.

(10) Raw fruits, vegetables, and fish subject to section 403(q)(4) of the act, except that the labeling of such foods should adhere to guidelines in § 101.45. The term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish, amphibians, and other forms of aquatic animal life.

(11) Packaged single-ingredient products that consist of fish or game meat (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) subject to this section may provide required nutrition information for a 3-ounce cooked edible portion (i.e., on an "as prepared" basis), except that:

(i) Such products that make claims that are based on values as packaged must provide nutrition information on an as packaged basis, and

(ii) Nutrition information is not required for custom processed fish or game meats.

(12) Game meats (i.e., animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, or ostrich) may provide required nutrition information on labeling in accordance with the provisions of paragraph (a)(2) of this section.

(13)(i) Foods in small packages that have a total surface area available to bear labeling of less than 12 square inches, *Provided*, That the labels for these foods bear no nutrition claims or other nutrition information. The manufacturer, packer, or distributor shall provide on the label of packages that qualify for and use this exemption an address or telephone number that a consumer can use to obtain the required nutrition information (e.g., "For nutrition information, call 1–800–123–4567").

(ii) Foods in packages that have a total surface area available to bear labeling of 40 or less square inches may modify the requirements of paragraphs (c) through (f) and (i) of this section by one or more of the following means:

(A) Presenting the required nutrition information in a tabular or, as provided below, linear (i.e., string) fashion rather than in vertical columns if the product has a total surface area available to bear labeling of less than 12 square inches or if the package shape or size cannot accommodate a column display on any label panel. Nutrition information may be given in a linear fashion, only if the label will not accommodate a tabular display, and, in that case, any subcomponents declared shall be listed

parenthetically after principal components (e.g., saturated fat shall be declared in parentheses after total fat).

The following sample label illustrates a tabular display.

BILLING CODE 4160-01-M

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Nutrition Facts

Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10
*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	**2%**	**Total Carb.** 0g	**0%**
Sat.Fat 0g	**0%**	Fiber 0g	**0%**
Cholest. 10mg	**3%**	Sugars 0g	
Sodium 200mg	**8%**	**Protein** 17g	

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

BILLING CODE 4160-01-C

(B) Using any of the following abbreviations:
Serving size—Serv. size
Servings per container—Servings
Calories from fat—Fat cal
Saturated fat—Sat fat
Cholesterol—Cholest
Total carbohydrate—Total carb
Dietary fiber—Fiber

(C) Omitting the footnote and caloric conversion information required in paragraphs (d)(9) and (d)(10) of this section and placing another asterisk at the bottom of the label followed by the statement "Percent Daily Values are based on a 2,000 calorie diet" and, if the term "Daily Value" is not spelled out in the heading, a statement that "DV" represents "Daily Value."

(D) Presenting the required nutrition information on any label panel.

(14) Shell eggs packaged in a carton that has a top lid designed to conform to the shape of the eggs are exempt from outer carton label requirements where the required nutrition information is clearly presented in no less than 1/16-inch type size immediately beneath the carton lid or in an insert that can be clearly seen when the carton is opened.

(15) The unit containers in a multiunit retail food package where:

(i) The multiunit retail food package labeling contains all nutrition information in accordance with the requirements of this section;

(ii) The unit containers are securely enclosed within and not intended to be separated from the retail package under conditions of retail sale; and

(iii) Each unit container is labeled with the statement "This Unit Not Labeled For Retail Sale" in type size not less than 1/16-inch in height. The word "individual" may be used in lieu of or immediately preceding the word "Retail" in the statement.

(16) Food products sold from bulk containers: *Provided*, That nutrition information required by this section be displayed to consumers either on the labeling of the bulk container plainly in view or in accordance with the provisions of paragraph (a)(2) of this section.

(k) A food labeled under the provisions of this section shall be deemed to be misbranded under sections 201(n) and 403(a) of the act if its label or labeling represents, suggests, or implies:

(1) [Reserved]

(2) That a balanced diet of ordinary foods cannot supply adequate amounts of nutrients.

(3) That the lack of optimum nutritive quality of a food, by reason of the soil on which that food was grown, is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(4) That the storage, transportation, processing, or cooking of a food is or may be responsible for an inadequacy or deficiency in the quality of the daily diet.

(5) That the food has dietary properties when such properties are of no significant value or need in human nutrition.

(6) That a natural vitamin in a food is superior to an added or synthetic vitamin or to differentiate in any way between vitamins naturally present from those added.

5. Section 101.100 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 101.100 Food; exemptions from labeling.

* * * * *

(d) Except as provided by paragraphs (e) and (f) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (k), and (q) of the act if:

* * * * *

6. Appendix B to Part 101 is added to read as follows:

BILLING CODE 4160-01-M

Appendix B to Part 101

Graphic Enhancements used by the FDA

A. Overall

1. Nutrition Facts Label is boxed with all black or one color type printed on a white or neutral ground.

B. Typeface and size

1. The "Nutrition Facts" label uses 6 point or larger Helvetica Black and/or Helvetica Regular type. In order to fit some formats the typography may be kerned as much as -4, (tighter kerning reduces legibility).
2. Key nutrients & their % Daily Value are set in 8 point Helvetica Black (but "%" should be set in Helvetica Regular).
3. "Nutrition Facts" is set in either Franklin Gothic Heavy or Helvetica Black to fit the width of the label flush left and flush right.
4. "Serving Size" and "Servings per container" are set in 8 point Helvetica Regular with 1 point of leading.
5. The table labels (for example; "Amount per Serving") are set 6 point Helvetica Black.
6. Absolute measures of nutrient content (for example; "1g") and nutrient subgroups are set in 8 point Helvetica Regular with 4 points of leading.
7. Vitamins and minerals are set in 8 point Helvetica Regular, with 4 points of leading, separated by 10 point bullets.
8. All type that appears under vitamins and minerals is set in 6 point Helvetica regular with 1 point of leading.

C. Rules

1. A 7 point rule separates large groupings as shown in example. A 3 point rule separates calorie information from the nutrient information.
2. A hairline rule or 1/4 point rule separates individual nutrients, as shown in the example. Descenders should not touch rule. The top half of the label (nutrient information) has 2 points of leading between the type and the rules, the bottom half of the label (footnotes) has 1 point of leading between the type and the rules.

D. Box

1. All labels are enclosed by 1/2 point box rule within 3 points of text measure.

Appendix B to Part 101

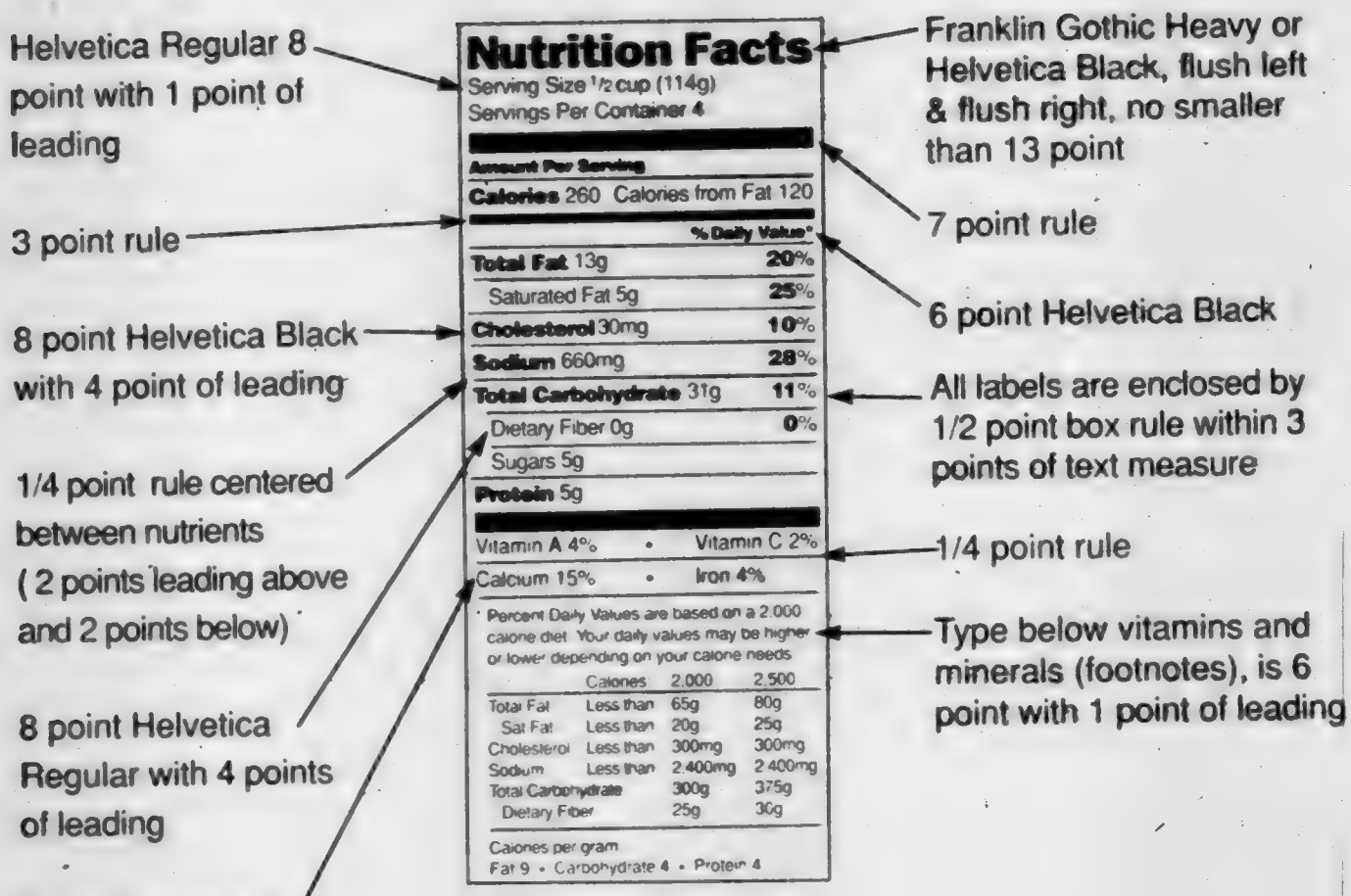

BILLING CODE 4160-01-C

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Editorial Note: The following appendixes will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-M

Appendix A:
Shortened Format (See comment 8)—Vegetable Soup

Nutrition Facts

Serving Size 1cup (245g)
Servings Per Container 2

Amount Per Serving

Calories 55 Calories from Fat 20

	% Daily Value*
Total Fat 1g	**2%**
Sodium 800mg	**33%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 4g	**16%**
Sugars 0g	
Protein 2g	

Vitamin A 20% • Vitamin C 4% • Iron 2%

Not a significant source of saturated fat, cholesterol, and calcium.

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

BILLING CODE 4160-01-C

APPENDIX B.—TRUE PROTEIN DIGESTIBILITY VALUE OF COMMON FOODS

Major product group	Subgroup	Product	True digestibility	References
Cereals and grains	Barley	Barley	90	1
	Corn and Corn Products	Corn, Extruded Cereal	82	2
		Corn, Corn Flake	70	2
		Corn, Degerminated Opaque 2	94	2
		Corn, Puffed Cereal	76	2
		Corn, Whole	89	2
		Corn, Whole Opaque 2	92	2
		Corn meal	84	2
	Millet	Millet	79	2
	Oats and Oat products	Oat, Sugared Flakes	67	2
		Oat Flakes	70	2
		Oat, Extruded Oat/Wheat	76	2
		Cereal	89	2
		Oat, Quick Oatmeal	82	2
		Oat, Oatmeal	90	3
		Oats, Rolled	.....	.....
	Rice and Rice Products	Rice	91	2
		Rice, Germ	87	4
		Rice, Brown, Cooked	72	5
		Rice, High Protein	85	2
		Rice, Milled, Cooked	86	6
		Rice, Polished	87	2, 5
		Rice, Crisped Rice Cereal	77	2
		Rice, Flakes	83	2
	Sorghum	Sorghum, Cooked	73	6
	Triticale	Triticale	90	2
	Wheat and Wheat Products	Bread	96	2
		Bread, Coarse, Brown	91	2
		Bread, White	89	2
		Bread, Whole Wheat	92	2
		Wheat, Bran	75	15
		Wheat, Brown, Cooked	93	6
		Wheat Endosperm (Farina)	98	2
		Wheat, Flour, 90% extracted	89	2
		White, Flour, 80% extracted	92	2
		Wheat Germ	91	2
	Wheat and Wheat Products	Wheat Gluten	99	2
		Wheat, Hard Spring	86	2
		Wheat, Meat Analogue	95	2
		Wheat, Puffed Wheat	84	2
		Wheat, Shredded	73	2
		Wheat, Wheaties	80	2
		Wheat, White Flour	97	2
		Wheat, Whole	87	2
		Wheat, Whole, Hot Cereal	85	2
		Wheat, 40% Bran Flakes	69	2
Dairy Products	Casein	Acid-Casein	95	7
		Casein	96	8, 4
		Caseinate	95	7
		Rennet-Casein	94	7
	Cheese	Cheese, Cheddar	99	4
		Cottage, Cheese	99	2
	Lactalbumin	Lactalbumin	94	2
	Milk	Milk Retentate	97	7
		Milk, Skim	94	8
		Milk, Whole	94	2
		Milk, Whole, Powdered	95	2
	Whey	Whey Protein	95	4
Egg and Egg Products		Egg albumen	97	2
		Egg, Flakes	82	2
		Egg, Powdered, Dried	93	4
		Egg, Dried	98	2
		Egg, Powdered Defatted	100	2
		Egg, Scrambled	96	2
		Egg, Spray Dried	92	2
		Egg, Whole, Unprocessed	97	2, 9
Legumes and Oilseed Products	Beans (Mucunoa Spp.)	Beans, Velvet	68	4
	Beans (Phaseolus lunatus)	Beans, Butter	57	4
		Beans, Lima	78	4
	Beans (Phaseolus vulgaris)	Beans, Black	69	4, 10
		Beans, Brown, Cooked	79	11
		Beans, Common	82	4
		Beans, Harticot	71	4
		Beans, Kidney	81	8
		Beans, Natal round Yellow	80	4
		Beans, Pinto, Canned	73	8
		Beans, Red	78	4
		Beans, Seafarer	84	4
		Beans, Snap, Frozen	82	11
		Beans, Spotted Sugar	81	4

APPENDIX B.—TRUE PROTEIN DIGESTIBILITY VALUE OF COMMON FOODS—Continued

Major product group	Subgroup	Product	True digestibility	References
		Beans, Sugar	69	4
		Beans, Sugar, Speckled	78	4
		Beans, White Kidney	76	4
	Beans (Vicia Faba)	Beans, Broad	87	4
		Beans, Faba	86	10
	Cottonseed	Cottonseed	78	2
		Cottonseed Meal	80	4
		Cottonseed, Glandless flour	98	2
	Flaxseed	Flaxseed	85	4
	Lentils (Len culinaris)	Lentils	85	4, 8
	Lupins (Lupinus albus)	Lupine	76	4
	Peanut Products	Peanut Butter	95	2
		Peanut Flour	93	2
		Peanuts	87	4
		Peanut Meal	91	12
	Peas (Cajanus cajan)	Pigeon Peas	76	13
		Pigeon Peas, Raw	41	13
	Peas (Cicer Arietinum)	Chick peas, Canned	86	8
	Peas (Pisum sativum)	Pea Concentrate	94	3
		Peas	88	14
		Peas, Century, Autoclaved	83	10
		Peas, Green, Frozen	94	11
		Peas, Trapper, Autoclaved	84	10
		Peas, Yellow, Cooked	86	11
		Pea Flour	88	10
		Peas, Alaskan Field	86	2
	Peas (Vigna unguiculata)	Cowpeas	79	4
	Sesame	Sesame Seed, Dehulled	82	4
	Soy Products	Soybean	91	4
		Soy Concentrate	95	4
		Soy Flour	84	2
		Soy Flour, Defatted	87	2
		Soy Isolate	96	2
		Soy protein, spun	100	2
	Sunflower	Sunflower Seed	82	2
		Sunflower Seed-Flour	90	2
Meats and Meat Products	Beef	Beef	95	2
		Beef, Low Fat, Ground	91	2
		Beef, Powdered, Defatted	97	2
		Beef, Salami	98	8
		Beef, Stew	89	8
		Beefsteak	97	2
		Beef Tenderloin, Roasted	91	2
	Fish and Seafood	Haddock	100	4
		Sardine	95	4
		Shark	72	4
		Tuna, Canned	90	2
	Luncheon Meats	Canned Frankfurters	97	4
		Chicken, Frankfurters	97	8
		Sausage	94	8
	Pork	Pork Loin and Tenderloin	98	2
	Poultry	Chicken	100	4
		Chicken, Dark Meat	92	4
		Chicken, Light Meat	93	4
		Turkey Breast, Roasted	91	2
Miscellaneous Foods		Macaroni/Cheese, Canned	94	3
Nuts and Nut Products		Cashew	85	4
		Coconut, meal (defatted)	80	4
		Pecan	71	4
Starchy Roots, Tubes		Potato	89	4
Vegetables		Cabbage	88	4
		Kale	85	4
		Rape	85	4
		Mustard	82	4
		Turnip Leaves	86	4
		Mushrooms	90	4

Notes

True digestibility values obtained using adult subjects were considered first followed by data using the rat as the animal model. When more than one value was considered the values were averaged. Data sources:

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BILLING CODE 4160-01-M

Appendix C:
Sweet potatoes. Canned

Nutrition Facts

Serving Size 1/2 cup (95g)
Servings Per Container 4

Amount Per Serving	
Calories 90	Calories from Fat 0
	% Daily Value*
Total Fat 0g	**0%**
Saturated Fat 0g	**5%**
Cholesterol 0mg	**0%**
Sodium 55mg	**2%**
Total Carbohydrate 21g	**7%**
Dietary Fiber 2g	**8%**
Sugars 5g	
Protein 2g	

Vitamin A 160% (100% as Beta Carotene)

Vitamin C 40% • Calcium 2% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix D

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	• Vitamin C 2%
Calcium 15%	• Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg.
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix D:
Footnote to side

Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving

Calories 260 Calories from Fat 120

	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**11%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4% • Vitamin C 2%
Calcium 15% • Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix E:
Sample labels with dual declaration

Nutrition Facts

Serving Size 1/12 cup (45g)
Servings Per Container 12

Amount Per Serving	Mix	Baked
Calories	190	280
Calories from Fat	45	135
	% Daily Value**	
Total Fat 5g*	**13%**	**36%**
Saturated Fat 2g	**10%**	**13%**
Cholesterol 0mg	**0%**	**23%**
Sodium 300mg	**8%**	**9%**
Total Carbohydrate 34g	**9%**	**9%**
Dietary Fiber 0g	**0%**	**0%**
Sugars 18g		
Protein 2g		
Vitamin A	0%	0%
Vitamin C	0%	0%
Calcium	6%	8%
Iron	2%	4%

* Amount in Mix

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

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Appendix E:
Dual declaration with footnote of nutrients added by combination of foods

Nutrition Facts

Serving Size 1 cup (35g)
Servings Per Container 10

Amount Per Serving	Cereal	Cereal with 1/2 cup Skim Milk
Calories	130	170
Calories from Fat	0	0
	% Daily Value**	
Total Fat 0g*	**0%**	**0%**
Saturated Fat 0g	**0%**	**0%**
Cholesterol 0mg	**0%**	**0%**
Sodium 200mg	**8%**	**11%**
Total Carbohydrate 30g	**10%**	**12%**
Dietary Fiber 4g	**16%**	**16%**
Sugars 18g		
Protein 3g		
Vitamin A	25%	25%
Vitamin C	25%	25%
Calcium	0%	15%
Iron	10%	10%

*Amount in Cereal. One half cup skim milk contributes an additional 40 calories, 65 mg sodium, 6g total carbohydrate (6 g sugars), and 4g protein.

**Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

Appendix F:
Simplified format (Vegetable oil)

Nutrition Facts

Serving Size 1 Tbsp (14g)
Servings Per Container 64

Amount Per Serving	
Calories 130 Calories from Fat 130	
	% Daily Value*
Total Fat 14g	**22%**
Saturated Fat 2g	**10%**
Polyunsaturated Fat 4g	
Monounsaturated Fat 8g	
Sodium 0mg	**0%**
Total Carbohydrate 0g	**0%**
Protein 0g	

Not a significant source of cholesterol, dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron.

* Percent Daily Values are based on a 2,000 calorie diet.

Appendix F:
Simplified format (Soft Drink)

Nutrition Facts

Serving Size 1 can (240 ml)

Amount Per Serving	
Calories 145	
	% Daily Value*
Total Fat 0g	**0%**
Sodium 20mg	**1%**
Total Carbohydrate 36g	**12%**
Sugars 36 g	
Protein 0g	**0%**

* Percent Daily Values are based on a 2,000 calorie diet.

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Appendix G:
Format for same food represented to be specifically for children less than 2 years of age (Fruit Dessert)

Nutrition Facts

Serving Size 1 jar (140g)
Servings Per Container 1

Amount Per Serving	
Calories 110	
	Amount
Total Fat	**0g**
Sodium	**10mg**
Total Carbohydrate	**27g**
Dietary Fiber	**4g**
Sugars	**18g**
Protein	**0g**

Vitamin A 6%	•	Vitamin C 45%
Calcium 2%	•	Iron 2%

Appendix G:
Format for foods for children less than 4 years of age (Fruit Dessert)

Nutrition Facts

Serving Size 1 jar (140g)
Servings Per Container 1

Amount Per Serving	
Calories 110	Calories from Fat 0
	Amount
Total Fat	**0g**
Saturated Fat	**0g**
Cholesterol	**0mg**
Sodium	**10mg**
Total Carbohydrate	**27g**
Dietary Fiber	**4g**
Sugars	**18g**
Protein	**0g**
Vitamin A 6% •	Vitamin C 45%
Calcium 2% •	Iron 2%

Appendix H:
Tabular Display

Nutrition Facts
Serv. Size 1/3 cup (56g)
Servings about 3
Calories 80
Fat Cal. 10
*Percent Daily Values (DV) are based on a 2,000 calorie diet.

Amount/serving	% DV*	Amount/serving	% DV*
Total Fat 1g	2%	**Total Carb.** 0g	0%
Sat.Fat 0g	0%	Fiber 0g	0%
Cholest. 10mg	3%	Sugars 0g	
Sodium 200mg	8%	**Protein** 17g	

Vitamin A 0% • Vitamin C 0% • Calcium 0% • Iron 6%

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 104

[Docket No. 90N-0134]

RIN 0905-AD08

Food Labeling; Reference Daily Intakes and Daily Reference Values

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to establish two sets of label reference values, Reference Daily Intakes (RDI's) and Daily Reference Values (DRV's), for use in declaring the nutrient content of a food on its label or labeling. FDA intends to use these two sets of values as a single set of label reference values known as the Daily Value, which will assist consumers in understanding the relative significance of the information about the amount of certain nutrients in a food in the context of a total daily diet. It will also assist consumers in comparing the nutritional values of food products.

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Christine Lewis, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5588.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 19, 1990 (55 FR 29476), FDA published a proposed rule entitled "Food Labeling; Reference Daily Intakes and Daily Reference Values" (the July 1990 proposal) to amend its food labeling regulations by revising and expanding label reference values for nutrients in foods. In the **Federal Register** of November 27, 1991 (56 FR 60366, and corrected at 57 FR 8178, March 6, 1992), FDA issued a document entitled: "Food Labeling: Reference Daily Intakes and Daily Reference Values; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter referred to as the "supplementary proposal") to supplement and to republish, in modified form, the July 1990 proposal. The agency proposed to: (1) Replace the current label reference values known as "U.S. Recommended Daily Allowances" (U.S. RDA's) with RDI's; (2) provide RDI's for five groups: adults and children 4 or more years of age, children less than 4 years of age, infants, pregnant women, and lactating women; (3) establish RDI's for protein and 26 vitamins and minerals for all five groups; and (4) establish DRV's for adults and children 4 or more years of age for eight nutrients and food components considered important to the maintenance of good health. FDA requested comments on the proposed regulation. Interested persons were given until February 25, 1992, to comment.

FDA received approximately 800 responses to the July 1990 proposal and approximately 700 responses to the supplementary proposal, each of which contained one or more comments, from trade and retail associations, government organizations, retailers, consumer groups, State groups, private organizations, professional societies, and universities. Many comments suggested modification and revision of various provisions of the proposal. A summary of the suggested changes and the agency's responses follows.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (hereinafter referred to as the "DS Act" that, in section 203, instructed FDA to not promulgate regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals before November 8, 1993, (other than regulations establishing the United States recommended daily allowances specified in 21 CFR 101.9(c)(7)(iv) as in effect on October 6, 1992).

II. Authority for New Label Reference Values

A. RDI's: Revision of U.S. RDA's

1. Several comments suggested that the change from the current label reference values, the U.S. RDA's, to the proposed new label reference values, the RDI's, was not mandated by the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments), and that retaining the U.S. RDA's is not inconsistent with the amendments.

FDA agrees that the 1990 amendments do not require that the U.S. RDA's be changed. The agency points out, however, that section (2)(b)(1)(A) of the 1990 amendments (21 U.S.C. 343 note) does require that the required nutrition label information be conveyed in a manner that enables the public to readily observe and comprehend the information and to understand its relative significance in the context of a total daily diet. Such information should be consistent with current scientific knowledge about nutrients and health.

Over the last 20 years, there have been significant advances in scientific knowledge with respect to essential nutrient requirements. In 1989, the National Academy of Sciences (NAS) updated the Recommended Dietary Allowances (RDA's)—the basis for label reference values derived by the agency—to include for the first time RDA values for vitamin K and selenium and to make significant revisions in the allowances for several nutrients, including vitamin B_6, folate (folic acid), vitamin B_{12}, magnesium, iron, and zinc. In addition, scientific advances permitted NAS to substantively revise values for the listing known as "Estimated Safe and Adequate Daily Dietary Intakes" (ESADDI's). The ESADDI's published in 1989 include revised values for three nutrients (biotin, pantothenic acid, and copper) for which FDA established U.S. RDA's in 1973 as well as new values for manganese, fluoride, chromium, and molybdenum.

Based on these considerable changes in scientific knowledge, FDA tentatively determined that it was appropriate to revise the current U.S. RDA's to be more consistent with newer data on nutrient allowances. FDA attempted in this food labeling initiative to base its actions on the most current scientific and public health knowledge. Continuing to base label reference values on a 1968 standard would be inconsistent with such an approach and would not appropriately assist consumers in understanding the nutrition label information relative to a total daily diet. However, based on the provisions of the DS Act, the agency is, in this rulemaking, retaining the current label reference values, the U.S. RDA's as established in 21 CFR 101.9(c)(7)(iv). As discussed in section III below, the terminology used to designate label reference values for vitamins and minerals is being changed however.

The label reference values in current § 101.9(c)(7)(iv) will be referred to, in this document and in companion documents published elsewhere in this issue of the **Federal Register**, as "Reference Daily Intakes" (RDI's). As specified by the DS Act, the agency will promulgate final regulations on label reference values for vitamins and minerals after November 8, 1993. The agency will consider any further information submitted or obtained in the interim in reaching a decision on the form and substance of such final regulations.

B. DRV's: New Label Reference Values for Nutrientsof Public Health Concern

2. A few comments suggested that establishing DRV's was beyond the authority granted by the 1990 amendments.

The majority of comments supported the concept of establishing a DRV. These comments were provided by consumers, health professionals, and trade representatives. Several comments specifically highlighted the DRV's as an invaluable addition to nutrition labeling, as a labeling component that is important to the idea of the relative contribution of a food to the total day's recommended amount of a nutrient, and as a way to decrease confusion among consumers.

FDA disagrees that the establishment of DRV's is inconsistent with the 1990 amendments. The agency proposed this new set of label reference values in 1990 in an attempt to address current concerns about information on food components that have an important bearing on diet and health. With the passage of the 1990 amendments, the agency also recognized that these values respond to the directive in the legislation that the information required in the nutrition label be conveyed to the public in a manner that enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet (section 2(b)(1)(A) of the 1990 amendments).

FDA does not believe that merely listing the quantitative amount of nutrients such as fat and fiber on the nutrition label will adequately allow consumers to understand the significance of the amount of the nutrient in the food in the context of the total daily diet or to understand the nutrition information pertaining to that food in relation to recommended daily intakes of the food component. FDA found in focus group discussions that it conducted as part of its research on label format that many persons could not specify the recommended intakes for nutrients such as sodium, even when they indicated that the nutrient was important to their health and were concerned about their intake of the nutrient (Ref. 29).

Moreover, contrary to the assertion in some of the comments, the use of DRV's was clearly contemplated by Congress. In discussing section 2(b)(1)(A) of the 1990 amendments, the House report states:

> In order to present nutrition information in a manner that facilitates the public's understanding, the Secretary may choose among a variety of options. For example, one way that this could be accomplished would be to include information about the recommended daily intake on the label.

(Ref. 19, p. 18)

Therefore, for the foregoing reasons and consistent with the majority of the comments, FDA concludes that DRV's provide an appropriate approach to accomplishing the statutory mandate and are fully consistent with the authority extended to the agency by the 1990 amendments. Significantly, consumers are becoming more aware of diet/health interrelationships and have expressed growing interest in the inclusion of information about food components on labels to help them determine how individual foods fit within general recommendations for a total daily diet. Additionally, "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" (Ref. 30) proposes that there be an increase in nutrition labeling that provides information to facilitate choosing foods consistent with the Dietary Guidelines for Americans published jointly by the U.S. Department of Agriculture (USDA) and the U.S. Department of Health and Human Services (DHHS). The DRV's will be an important tool for this purpose.

III. RDI'S: Label Reference Values for Vitamins and Minerals

A. Terminology

3. Several comments expressed concerns about consumer confusion if the more familiar U.S. RDA term was replaced with a new term. These comments generally suggested that the term "U.S. RDA" be retained and used on the label in order to reduce consumer confusion. One comment argued that while the agency asserts that the term "U.S. RDA" is too confusing, FDA cited no evidence of this confusion.

A number of other comments supported eliminating the term "U.S. RDA." One health professional stated that even professionals fail to make the distinction between the RDA established by NAS and the U.S. RDA. A food company stated that it frequently encountered expressions of confusion from consumers and professionals alike over the difference between the U.S. RDA and the NAS RDA. An association of nutrition educators agreed that a change in terminology is needed in order to reduce consumer confusion surrounding the distinction between RDA's and U.S. RDA's. Several comments specifically supported the term "RDI." One comment stated that the use of terminology that differentiates between reference standards used for nutrition labeling and the RDA established by NAS should be beneficial to the consumer.

In 1973, FDA created label reference values known as "U.S. RDA's" and based them on the "Recommended Dietary Allowances," 7th ed., 1968 (the NAS RDA publication) (Ref. 27). As stated in the proposal for this final rule, FDA believes that the term "U.S. RDA" can easily be confused with "RDA," and that this confusion presents difficulties both in consumer education and professional communication (55 FR 29476 at 29478). The comments received have supported the need for a change in terminology, and FDA agrees that because of the potential for confusion a change in terminology is appropriate. FDA notes that in the comments submitted in response to this proposal, the agency found numerous examples of confusion and inappropriate interchange concerning the two terms.

Additionally, the agency advises that consumers will not be confused by the change from U.S. RDA to RDI because the term will not appear on the food label. The RDI's, which refer to label reference values for vitamins and minerals only, will not be used on the food label because a new more comprehensive term will be used, a term that includes label reference values for DRV's as well as RDI's. The provision for a single term ("Daily Value") is discussed in more detail in a companion document entitled "Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision" (hereinafter referred to as "Mandatory Nutrition Labeling final rule"), published elsewhere in this issue of the **Federal Register**.

As discussed in this companion document, the decision to use a single term is based on the fact that the nutrition label will contain label reference values for nutrients other than those with NAS RDA's (e.g., total fat). Clearly, the term "RDI" cannot be used to generally refer to all the new label reference values because it implies that all values are based on the NAS RDA. In fact, less than half of the mandatory components of the nutrition label will be nutrients with a NAS RDA. The agency also believes that it would be needlessly confusing to consumers if the two terms were used on the food label. Consumers are expected to perceive the label reference values as a single overall set of values. Therefore, to reduce consumer confusion, FDA has decided to choose a new term to denote the combined set of label reference values, a term that refers to both RDI's and DRV's.

The distinction between RDI and DRV nutrients remains necessary for regulatory purposes because the values were derived from separate sources and because these nutrients play different roles under the imitation and substitute food regulations. However, there is no need to make consumers aware of the regulatory distinction between RDI and DRV. Rather, educational efforts will focus on the overall set of label reference values.

4. Several comments suggested that FDA delay selecting terminology for the food label until consumer research can be completed.

While FDA supports and recognizes the value of consumer research, the time constraints placed on the agency by the 1990 amendments and the clear need to provide for the label terminology at the time of final rules, preclude the possibility of extensive consumer research. The terminology specified in these final rules derives from available information.

During the Fall of 1990, FDA conducted focus group research that included some discussions of terminology (Ref. 29). The sessions suggested that the term for the overall label reference value (proposed as "Daily Value") could be problematic, yet better terms for this or any other label reference values did not emerge during these sessions. The agency requested in the supplementary proposal (56 FR 60366) that persons submit available research, information, or suggestions concerning terminology. FDA has reviewed the relevant comments and they are discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. Based on these comments, as explained in the Mandatory Nutrition Labeling document, FDA has decided to use the term "Daily Value" to refer to the combined set of label reference values.

5. Two comments suggested that the proposed term "RDI" created consumer confusion by continuing to use the letters R and D in some combination, and that "RDI" was too similar to "U.S. RDA" and "RDA." Another comment suggested that to avoid confusion with the previous U.S. RDA terminology, the term "recommended" be retained and used instead of the term "reference."

FDA acknowledges that the inclusion of the letters R and D in RDI may have the potential to cause consumer confusion relative to U.S. RDA. However, because the term will not be used either on the food label or in most consumer education programs, the agency rejects this argument as a basis to abandon a term that accurately reflects the fact that the value it denotes represents a point of reference rather than a specific recommended intake level for individuals. Therefore, FDA has retained the term "RDI" to denote those nutrients whose label reference values have been derived from the NAS RDA's and ESADDI's.

6. One comment requested that FDA work with the European Economic Community and Codex Alimentarius to establish compatible nomenclature whenever possible.

FDA agrees with this suggestion and will, in its ongoing labeling activities, attempt to harmonize with international terminology as much as possible. However, within the time constraints of the 1990 amendments, the agency finds that it must make a unilateral decision concerning terminology.

B. Use of the 1989 NAS RDA's as the Basis for Label Reference Values

In 1973, FDA created label reference values known as U.S. RDA's and based them on the 7th edition of the NAS RDA publication (Ref. 27). At that time, comments supported the use of a single set of values derived from the NAS RDA's. In the July 1990 proposal (55 FR 29476) and again in the supplementary proposal (56 FR 60366), FDA proposed to revise the U.S. RDA's using the 1989 NAS RDA's (Ref. 26). This section responds to the comments that addressed the continued use of the NAS RDA's as the basis for developing label reference values for vitamins and minerals, as well as the appropriateness of using the most current NAS RDA's (i.e., the 10th edition of the NAS RDA publication (1989)), for this purpose.

7. The majority of comments on this topic, primarily from health professionals and the food industry, supported the continued use of the NAS RDA's as the basis for developing label reference values for vitamins and minerals. These comments also supported the desirability of updating the current label reference values (U.S. RDA's) to be consistent with the most recent edition (i.e., 1989) of the NAS RDA's. Numerous comments stated that revisions to the values were long overdue given the fact that changes had not been made by FDA since it developed the label reference values in 1973 based on the 1968 NAS RDA's. Comments urged FDA to continue to review and update label reference values as advances in scientific data lead to significant changes in the NAS RDA's. One comment requested that FDA establish an official mechanism in the final rule to provide for regular updates of label reference values.

FDA tentatively agrees with the appropriateness of continuing to rely on the NAS RDA's as the basis for label reference values. Strong and uniform support was provided for the use of NAS RDA's during the initial development of label reference values in 1972. As evidenced by the comments to the current proposal, this support remains. The agency believes that these established nutrient allowances remain the most widely accepted and respected source of information on human nutrient requirements and recommended intakes. FDA also notes that the preface to the 1989 edition of the NAS RDA's (Ref. 26) states that the RDA's reflect a concurrence of scientific opinion and will be appropriate for use by governmental and private agencies as a basis for developing nutrition programs and policies pertaining to public health. In general, the comments submitted in this rulemaking agreed with this statement. FDA therefore, has tentatively concluded that the label reference values (formerly known as U.S. RDA's, now RDI's) should be based on the 1989 NAS RDA's. However, based on the provisions of the DS Act and as discussed above, the agency is, for the time being retaining the current label reference values as established in § 101.9(c)(7)(iv) and will reach a final decision on the issue of the appropriate reference values for vitamins and minerals following the provisions of the DS Act.

8. One comment suggested that the agency's reliance on the NAS RDA values raises questions under the Administrative Procedure Act. According to this comment, the NAS RDA report has been developed under closed processes and thus the use of such reports may not be appropriate for rulemaking. Another comment submitted by a health professional on behalf of 40 other health professionals suggested that any future replacement of the labeling standard should be developed by the nutrition and public health community, through an open and scientifically sound process conducted by FDA, USDA, and other relevant Federal agencies.

FDA does not agree with the comment that use of the NAS RDA's as the basis for the RDI's is inconsistent with the requirements of the Administrative Procedure Act. The NAS RDA's were developed under a National Institutes of Health (NIH) contract and are based on nutrient intake measurements, nutrient balance studies, experimental intake studies, biochemical measurements, epidemiological observations of nutrient status, and extrapolation of data from animal experiments. Furthermore, as

part of the contract, public meetings were held which afforded opportunity for public input into the development of the NAS RDA's. Additionally, the NAS subjected the draft of the RDA publication to outside review by qualified experts.

More importantly, while the NAS RDA's served as the starting point for the RDI's, FDA developed its proposal based on its review of the NAS RDA's, its views on the relevant science, and its tentative conclusions about how to turn the NAS RDA's into RDI's. Moreover, the agency subjected its proposed approach to public comment (55 FR 29476 and 56 FR 60366). In reviewing the comments that it received, FDA was open to any evidence that values other than those derived from the NAS RDA's would provide a more appropriate starting point in developing values that will place the information required to appear on the nutrition label into the context of a total daily diet. No such evidence was submitted. Thus, FDA tentatively finds that the NAS RDA's provide a scientifically valid starting point from which to develop the RDI's. As stated above, FDA will reach a final decision on the appropriate reference values for vitamins and minerals in accordance with the DS Act.

9. One comment suggested that the NAS RDA's are of questionable value for developing RDI's because NAS RDA's are reflective of diets that people actually eat without showing signs of deficiency, rather than being based on the recommended diets that people should eat according to government authorities. Several comments suggested that the NAS RDA's are designed to avoid deficiency diseases and are not the optimal levels to prevent chronic diseases. A few comments suggested that the NAS RDA's (and resulting label reference values) are inconsistent with current dietary guidance.

As stated in the "Summary" section of the 10th edition of the NAS RDA publication (Ref. 26), the NAS RDA's are based not only on data from nutrient intake measurements but also on information from nutrient balance studies, experimental intake studies, biochemical measurements, epidemiological observations of nutrient status, and extrapolation of data from animal experiments. The NAS RDA's reflect scientific judgment on nutrient allowances for the maintenance of good health. Their purpose is not just to prevent nutrient deficiency but also to meet nutrient needs for good health (Ref. 26).

Available government reports have stressed the importance of healthy dietary patterns and increased consumption of certain food categories and food components rather than quantitative recommendations for intake, especially for vitamins and minerals (Refs. 2, 3, and 5). FDA is not aware of any Federal government-issued quantitative recommendations for the general public for a vitamin or mineral that surpasses the levels specified by the NAS RDA's with the exception of 1,500 milligrams (mg) calcium for postmenopausal women suggested as a result of a 1984 consensus conference sponsored by NIH (Ref. 31) and, very recently, a PHS recommendation that women of childbearing age consume 400 µg/day of folate (Ref. 40). NIH republished the report of this conference in 1986 with the following caveat: "It has not yet been proven by convincing scientific evidence that a high calcium intake will prevent osteoporosis" (Ref. 31). This qualification reflected the results of studies that failed to show that calcium intakes above the NAS RDA slowed bone loss in postmenopausal women (Refs. 31 through 34).

Furthermore, the major consensus report Diet and Health (Ref. 3), which is an important summary of the current science on the relationship between diet and chronic disease, does not offer quantitative intakes for vitamins and minerals for the purpose of reducing the risk of chronic disease. Instead, it states that it is advisable to use the NAS RDA's in combination with the dietary recommendations in planning optimal diets to attain maximal benefit. This view is echoed in the 10th edition of the NAS RDA publication (Ref. 26), which states that the RDA's and the recommendations specified in Diet and Health should be considered together in planning appropriate diets.

Therefore, FDA concludes that the NAS RDA's are consistent with, as well as necessary for, implementation of current dietary recommendations. As such, NAS RDA's can be considered to be an appropriate basis for developing label reference values (i.e., RDI's) for nutrition labeling of foods.

10. Two comments stated that while it is reasonable for FDA to begin to develop new label reference values based on the most current NAS RDA's, FDA should not necessarily limit label reference values to only those values derived from the NAS RDA's because the most current NAS RDA's are derived from data available 3 or more years ago. Therefore, these comments suggested that rather than adopting the 1989 NAS RDA's as the sole basis for setting label reference values for vitamins and minerals, FDA should consider the totality of evidence for each nutrient. Another comment suggested that FDA, as a well-qualified, scientifically-based agency, should conduct its own reviews, if for no other reason than to be sure that the latest data are encompassed in its rulemaking.

FDA is aware that it is desirable to base label reference values on the most current scientific data. However, the existence of data from recently completed or ongoing studies does not necessarily mean that there is scientific agreement or consensus that these data require changes in the NAS RDA, or that these data render the NAS RDA invalid. FDA believes that, should scientific consensus shift or compelling evidence of a need for change in the RDI's be presented to the agency, its rulemaking procedures are sufficiently flexible to allow for timely and appropriate changes to label reference values.

In this rulemaking, FDA tentatively concludes that the NAS RDA's provide an appropriate starting point for the values that it is adopting. FDA will reach a final decision in this matter in accordance with the provisions of the DS Act.

11. One comment from a consumer organization suggested that 1989 NAS RDA values for certain nutrients (vitamin D, vitamin B_{12}, and vitamin B_6) are too low for older persons, and that this, in turn, results in label reference values that are too low. The comment urged FDA to consider basing the reference values for certain nutrients on the NAS RDA's in the 1980 edition which are higher than the 1989 NAS RDA's, and thus, according to the comment, provide greater protection to older citizens. Furthermore, two comments specifically expressed concern for the nutriture of the elderly relative to the 1989 NAS RDA's for vitamin B_{12} because these values are lower than the 1980 NAS RDA's. The comments suggested that FDA retain the current U.S. RDA value of 6 micrograms (µg) rather than adopting the 1989 NAS RDA's as the basis for the RDI's.

FDA does not agree that it is necessary to use the 1980 rather than the 1989 NAS RDA's for certain nutrients because of nutritional risk relative to older persons. The comment provided no specific evidence to support the statement that the 1989 values are too low for this segment of the population. FDA notes that the discussion provided in the 1989 NAS RDA publication clearly reveals that the development of the NAS RDA's took into consideration available evidence on nutrient levels needed by the elderly.

FDA further notes that the 1980 NAS RDA for vitamin D for persons 51 or more years of age is the same as the

1989 NAS RDA for vitamin D. While the 1989 NAS RDA's for vitamins B_1 and B_6 are lower, they are the result of a systematic lowering for all persons, not just those over 51 years of age. The 1989 NAS RDA publication cites decisions on the desirability of maintaining a substantial body pool of the vitamin as the reason for the change for vitamin B_{12} relative to 1980 levels, and the need to correct the figure for mg per gram (g) of protein as the basis for the change in vitamin B_6. Thus, FDA finds that this comment does not provide any basis for changing the agency's approach in calculating the RDI's.

Finally, FDA does not agree that concerns for vitamin B_{12} nutriture among the elderly require that the agency retain the U.S. RDA value for vitamin B_{12} (which is based on the 1968 NAS RDA's). FDA notes that the discussion in the 1989 NAS RDA publication (Ref. 26) clearly states that the NAS RDA's are based on consideration of the available evidence on the nutrient needs of older persons. In fact, an allowance is specified for persons 51 or more years of age.

Furthermore, the discussion on vitamin B_{12} in the NAS RDA publication (Ref. 26) specifically addresses the issue of vitamin B_{12} nutriture and the elderly. The text states that the results of various surveys have shown that although serum vitamin B_{12} levels decline in the elderly, they tend to remain in the normal range. The evidence suggests that the decline in the serum level is the result of the gradual appearance among the elderly of vitamin B_{12} malabsorption. As stated in the NAS RDA report (Ref. 26), such malabsorption would require injection of vitamin B_{12}, rather than an increase in the allowance or, by implication, the label reference value. Therefore, the agency's tentative view is that the need for an increased RDI relative to the issues of malabsorption cannot be supported.

However, based on the provisions of the DS Act, the agency is, for the time being, retaining the current label reference values as established in current § 101.9(c)(7)(iv) and will reach a final decision on this issue following the provisions of the DS Act.

C. Use of a Population-Adjusted Mean of the NAS RDA's to Derive RDI's for Vitamins and Minerals

The NAS RDA for a vitamin or mineral is established for each of approximately 18 age and sex categories. When FDA created the label reference values known as U.S. RDA's in 1973, it concluded that it was most practical to develop a single label reference value for each nutrient for the purposes of food labeling. Generally, the agency selected the highest NAS RDA value (for persons 4 or more years of age excluding pregnant and lactating women) to serve as the U.S. RDA. In July of 1990 and again in November of 1991, FDA proposed to replace the approach of generally selecting the highest NAS RDA value with an approach that averages the NAS RDA values for the various age/sex categories and adjusts the average for differences in population size of the age/sex groups. This section deals with the comments that addressed the proposed change in approach used to calculate label reference values for those vitamins and minerals based on NAS RDA's.

The use of a population-adjusted average (or mean) of NAS RDA's was the major issue addressed by many commenting on the proposal. Several health professional groups and food industry representatives supported the use of an averaged value as the label reference values for vitamins and minerals. However, the majority of comments urged FDA to abandon the averaging approach and to continue to use the approach of selecting the highest NAS RDA value as the label reference value. A wide range of persons submitted comments supporting this view, including health professionals, industry representatives, and consumers. Many of the comments from consumers were variations of a form letter that opposed the change but did not provide a substantive rationale for the position expressed.

12. A few comments opposing use of averaged values raised the concern that lower label reference values would downgrade the nutritional quality of fortified and substitute foods. Some comments asserted that a change in label reference values would affect FDA food fortification practices or the nutrient content of food assistance programs. Other comments expressed concern that the approach changed the label reference values by as much as 80 percent.

The agency notes that many comments concluded that the difference (i.e., lower values) between the current label reference values (U.S. RDA's) and the proposed label reference values (RDI's) could be attributed solely to the change in the approach used to calculate the values. The comments were incorrect. The proposed approach lowered the label reference values for vitamins and minerals by an average of about 14 percent compared to values that would have been derived if the agency had used the approach of selecting the highest 1989 NAS RDA value, i.e., the traditional approach with the most recent NAS RDA values. The remaining differences are the result of changes in the NAS RDA values from 1968 to 1989. In the 10th edition of the NAS RDA publication, NAS lowered several of its RDA values compared to the 1980 or earlier NAS RDA values to reflect new evidence in nutrition science and advances in analytical methodology. Thus, regardless of which approach had been used with the 1989 NAS RDA's—either the population adjusted mean approach or the approach of selecting the highest NAS RDA value—the resulting revised label reference values would be lower when compared to the existing U.S. RDA's.

FDA further advises that label reference values are not used in the agency's policies on nutrient fortification. Some foods must be fortified to meet standards of identity, nutrition quality guidelines, substitute food regulations, or infant formula regulations. Moreover, FDA's guidelines on food fortification (§ 104.20 (21 CFR 104.20)) recommend that nutrients be added on the basis of specific quantities for a given amount of food. The levels are based on the needs of those segments of the population that are at risk of deficiency of those nutrients and not on the U.S. RDA's.

FDA's fortification policy states that traditional foods will be fortified if there is a public health need, or if nutrients need to be restored to a particular food, for example, if they are depleted during processing. Fortification of foods not covered by this policy is at the discretion of the manufacturer. The agency acknowledges that it is common practice for some manufacturers to fortify to a specific percentage of the label reference value (e.g., 25 percent). To the extent that this practice is continued, nutrient levels in some foods could be affected by changes in label reference values. However, this practice does not derive in any way from FDA regulations.

FDA also advises that the current label reference values (U.S. RDA's) have never served as standards for food packages or meal patterns for government feeding programs such as the Food Stamp Program, the Special Supplemental Food Program for Women, Infants and Children (WIC), or the National School Lunch Program and other child-feeding programs. There is one reference to U.S. RDA's in the regulations governing the National School Lunch Program, but it is merely used to determine whether certain foods—such as some snack food items that do not contain meaningful levels of nutrients—can be sold near or in school

cafeterias in competition with the school lunch program (7 CFR 210.11). The food packages and meal patterns used by these programs are based on the specific NAS RDA for each program's targeted group or include foods that contain required amounts of nutrients per unit. Thus, much of the comment that opposed the use of the averaging approach was significantly misinformed in several important respects.

13. The most frequent concern expressed in the comments that opposed the averaging approach was that the approach resulted in a value that was too low for at least half of the population, and that these lower values will result in suboptimal nutrient intakes. Many commented that consumers should be assured that if they meet 100 percent of the label reference value, they are meeting or exceeding their own individual allowances. Some were concerned that for certain nutrients, such as calcium, for which health authorities are emphasizing maximum intakes within a target population group, a label reference value based on an average undermines these dietary guidance efforts. Several comments argued that health educators have invested years in teaching consumers about the use and interpretation of the current label reference value (U.S. RDA), and that the proposed change would consequently cause consumer confusion as well as erase educational inroads. One professional commented that the label reference value should not provide guidance about what amount a person should consume; rather, its purpose is to provide values that allow comparative shopping. However, according to the comment, if a single value is to be used as a guide for nutritional adequacy, the first principle of public health should be followed, which is to aim at the most vulnerable group. Several comments provided data or reviews of studies linking nutritional deficiencies or suboptimal intakes with a range of adverse effects from learning disabilities to cataracts.

FDA is persuaded by the comments that the proposed averaging approach should be modified. To understand the modified approach some background discussion is necessary.

The agency has always viewed the food label as an important tool for informing consumers about the nutritional content of the foods that they buy—one that shoppers can use to compare the vitamins, minerals, and protein in one food with another. This view is reinforced by the 1990 amendments. Additionally, the agency has been concerned that label reference values be set at levels consistent with levels of nutrients found naturally in foods so that regular, unfortified foods do not appear to be less than nutritious. If regular, unfortified foods were to appear less than nutritious, this could encourage needless fortification of foods.

Furthermore, FDA has also been concerned that the label reference values that appear on food labels not be interpreted as recommended intakes for individuals. Given the limited nutrition information that can be presented within the small space of most food labels, the agency sought in the proposal to establish values that represented a population-based average that consumers could use as a reference, adjusting it upward or downward based on how they compared to the average.

Most comments agreed that nutrition information on food labels must by necessity be limited and generalized, but suggested that public health concerns as well as consumer confidence and educational goals are best served by selecting label reference values that target "vulnerable groups" or at least that provide coverage for most of the population (i.e., the highest level recommended). Comments urged FDA to select protective levels of intake for vitamins and minerals that would be compatible with health promotion and disease prevention.

One comment suggested that consumers will not necessarily distinguish between a reference intake and a recommended intake, and that FDA should assume that consumers will see label reference values as recommended intakes. This comment offered a modification of the general approach of selecting the highest NAS RDA values. According to the comment, for each nutrient FDA should choose the most vulnerable segments of the population as the basis for the RDI. This segment should be established, the comment said, by identifying the group that has the highest NAS RDA and assessing its risk of a health problem caused by inadequate intakes of the nutrient. If the group with the highest NAS RDA is not at risk, FDA should move to the group with the second highest NAS RDA and assess its risk, and so on until the agency identifies a group that is at risk, or until it reaches a group that constitutes a major portion of the population.

FDA has considered all of these comments in determining the most appropriate alternative approach. FDA finds that there is considerable and uniform support for continuing to establish a label reference value for vitamins and minerals with NAS RDA's by selecting the highest NAS RDA value from among those persons 4 or more years of age (excluding pregnant and lactating females). The comments clearly demonstrated that vulnerable or at-risk groups would be sufficiently covered by selecting the highest value. While FDA understands the intent of the comment suggesting that the agency conduct an iterative process to determine at-risk groups or vulnerable segments of the population, the broad support in the comments for the view that the highest value is sufficient to protect vulnerable groups must be taken into account. Moreover, the iterative approach could complicate the selection of label reference values, especially in situations where data are limited or subject to varying interpretations. Thus, FDA has concluded that the iterative process offers no public health advantages as compared to the approach of selecting the highest NAS RDA.

Furthermore, it is likely that the overall concern of the comment that suggested the iterative process is reasonably met by selecting the highest NAS RDA, in that the comment suggested an approach that was intended to provide coverage for a larger proportion of the population than did the proposed averaging approach. Therefore, FDA has tentatively determined that label reference values (i.e., RDI's) should be based on an approach that selects the highest NAS RDA values from among those for adults and children 4 or more years of age but excludes values for pregnant females and lactating females. FDA refers to this approach as the "population coverage approach." The label reference values that result from application of this approach to the 1989 NAS RDA's are set out in the following table:

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Children less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Vitamin A	retinol equivalents[3]	1,000	400	375	800	1,300
Vitamin C	mg	60	40	35	70	95
Calcium	do	1,200	800	600	1,200	1,200

[4]

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Children less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Iron	do	15	10	10	30	15
Vitamin D	µg[4]	10	10	10	10	10
Vitamin E	alpha-tocopherol equivalents[3].	10	6.0	4	10	12
Vitamin K	µg	80	15	10	65	65
Thiamin	mg	1.5	0.7	0.4	1.5	1.6
Riboflavin	do	1.8	0.8	0.5	1.6	1.8
Niacin	niacin equivalents[3]	20	9.0	6	17	20
Vitamin B_6	mg	2.0	1.0	0.6	2.2	F2.1
Folate[5]	µg	400	50	35	400	400
Vitamin B_{12}	do	2	0.7	0.5	2.2	2.6
Phosphorus	mg	1,200	800	500	1,200	1,200
Magnesium	do	400	80	60	320	355
Zinc	do	15	10	5	15	19
Iodine	µg	150	70	50	175	200
Selenium	do	70	20	15	65	75
Chloride	mg	3,400	1,000	800	3,400	3,400[6]

[1] The term "children less than 4 years of age" means persons 13 through 47 months of age.
[2] The term "infants" means persons not more than 12 months of age.
[3] 1 retinol equivalent = 1 µg retinol or 6 µg beta-carotene; 1 alpha-tocopherol equivalent = 1 mg d-alpha-tocopherol (RRR-alpha-tocopherol); 1 niacin equivalent = 1 mg niacin or 60 mg of dietary tryptophan.
[4] As cholecalciferol.
[5] Discussion of folate RDI in section III. G. (comment 21) of this document.

However, based on the provisions of the DS Act, the agency is retaining the current label reference values established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv) and redesignated as "Reference Daily Intakes"). It should be noted, however, that there are, in current § 101.9(c)(7)(iv), no label reference values for vitamin K, selenium, or chloride. Therefore, for the time being, the agency is not establishing label reference values for these three nutrients. FDA will reach a final decision on these issues, following the provisions of the DS Act.

D. Use of the NAS ESADDI as a Basis for Establishing an RDI

14. One comment was received that suggested that the RDI's based on ESADDI's may be a risk to health because in establishing the ESADDI's, NAS has stated that the upper limits of the ranges of intake should not be habitually exceeded. The comment asserted that some of the proposed RDI's based on ESADDI's exceed the upper limits of intake for children, specifically biotin, pantothenic acid, copper, manganese, and molybdenum.

FDA disagrees that the proposed label reference values based on the ESADDI's represent a risk to children. The agency is unaware of any evidence that would suggest that consumption at the proposed levels constitutes a health risk for children. The 10th edition of the NAS RDA publication (Ref. 26) states that:

(1) There have been no reports of toxicity associated with biotin intakes as high as 10 mg/day;

(2) Evidence suggests that pantothenic acid is relatively nontoxic;

(3) Usual intakes of copper in the U.S. are between 2 and 5 mg/day which is considered safe, and occasional intakes of up to 10 mg/day are probably safe for human adults;

(4) Manganese toxicity is rare, and nearly all cases are associated with environmental exposure. While there have been reports that learning disabilities in children might be associated with increased manganese levels in hair, more evidence is required before this association can be substantiated; and

(5) While the level of dietary intake of molybdenum that is known to be associated with increased loss of copper in the urine is approximately 2-fold that of the highest ESADDI, relatively large doses are necessary to overcome homeostatic mechanisms (Ref. 35).

Chloride tolerance is very high and likely many times the proposed RDI. The 9th edition of the NAS RDA publication (Ref. 36), which provides the basis for the RDI for chloride, does not even discuss the possibility of chloride toxicity.

As for chromium, although the agency is unaware of any safety issues at levels of current consumption, FDA recognizes that the safe range of intake of this mineral is fairly narrow. Thus, until sources of chromium have been affirmed, FDA advises that the RDI for chromium should not be interpreted as a recommendation for use for either direct supplementation or adding nutrients to foods.

Finally, a label reference value for fluoride does not present issues of risk for children because it is to be used only in conjunction with a declaration of the level of this nutrient that is naturally present in a food.

Thus, the agency concludes that children eating from the general food supply are extremely unlikely to be at risk for toxic intakes of these micronutrients. To be consistent with the population coverage approach being used for other vitamins and minerals with NAS RDA's, FDA has selected the highest ESADDI within the specified age group to serve as the label reference value. If an ESADDI value is presented as a range, FDA has used the midpoint of the range as the RDI. No comments were received that objected to this approach.

FDA's approach would provide RDI's for three age groups for nutrients with ESADDI's: adults and children 4 or more years of age, children less than 4 years of age, and infants. The NAS does not provide ESADDI's for pregnant or lactating females, but, as proposed, FDA used the midpoint of the ESADDI range for adults as the basis for the RDI for pregnant and lactating women in order to provide a reasonably appropriate reference value for this population. No comments objected to this approach. The RDI's determined by the agency based on the ESADDI's are set out in the following table:

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Biotin	µg	65	20	15	65	65

Nutrient	Unit of measurement	Adults and children 4 or more years of age	Less than 4 years of age[1]	Infants[2]	Pregnant women	Lactating women
Pantothenic acid	mg	5.5	3.0	3.0	5.5	5.5
Copper	do	2.5	0.9	0.7	2.5	2.5
Manganese	do	3.5	1.3	0.8	3.5	3.5
Fluoride	do	3.0	1.0	0.6	3.0	3.0
Chromium	µg	130	50	40	130	130
Molybdenum	do	160	38	30	160	160

[1] The term "children less than 4 years of age" means persons 13 through 47 months of age.
[2] The term "infants" means persons not more than 12 months of age.

However, based on the provisions of the DS Act, the agency is retaining the current label reference values as established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv) and redesignated as "Reference Daily Intakes"). FDA notes that, in current § 101.9(c)(7)(iv), there are no label reference values for manganese, fluoride, chromium, and molybdenum. Therefore, for the interim, the agency is not establishing label reference values for these four nutrients. FDA will reach a final decision on these issues following the provisions of the DS Act.

E. Five Sets of RDI's for Different Developmental Groups

15. One comment supported the development of RDI's for different age groups and recognition of the special needs of pregnant or lactating women. However, the comment suggested that the grouping of adults and children more than 4 years of age into a single group is not appropriate and is contrary to well established evidence that nutritional requirements vary throughout the lifecycle. On the other hand, many comments supported the agency's proposed approach.

FDA faced considerable difficulties in developing the RDI's for use on foods given that nutritional needs vary considerably among persons who will consume the foods. This issue was also a consideration in the early 1970's when FDA was promulgating its first set of label reference values known as U.S. RDA's.

Because of space constraints on the food label—a problem that is becoming ever more compelling given the mandatory requirement for nutrition labeling on most foods—FDA does not believe that a viable option exists other than to develop a single set of label reference values for most consumers of the general food supply. Clearly, children over the age of 4 years consume the same foods that the rest of the population consumes.

Further, label reference values are intended to help persons to understand the nutrient levels in the context of a total daily diet, to compare foods, and to plan general diets. They are not intended to be used to decide whether a particular individual's consumption of nutrients is appropriate. Therefore, FDA believes that no harm can be done by using a single set of label reference values for nutrition labeling, especially if appropriate nutrition education is conducted.

The agency notes that, in following the provisions of the DS Act and retaining the label reference values in current § 101.9(c)(7)(iv), there will be no label reference values codified specifically for use on foods purported to be or represented for use by infants, children under 4 years of age, or pregnant or lactating women. FDA had proposed such label reference values and had intended to include RDI's for different development groups in these final regulations.

The agency further notes that label reference values for these groups had been established in 1976, based on the 1968 NAS RDA's (41 FR 46156, October 19, 1976). These values were codified in § 125.1(b) (21 CFR 125.1(b)), later redesignated as § 105.3(b) (21 CFR 105.3(b)). In 1979, FDA in response to a decision by the Court of Appeals of the Second Circuit, revised § 105.3 by, among other things, deleting paragraph (b) (44 FR 16005, March 16, 1979). Therefore, since 1979 there have been no codified label reference values for these specific groups. However, some manufacturers have continued to use the values that were contained in § 105.3(b) for labeling products, without objections from FDA.

Thus, following the spirit of the DS Act that implies that 1968 NAS RDA's should be used for labeling purposes and to provide guidance to manufacturers, the agency is republishing, in this document, the values formerly contained in § 105.3(b). The label reference values are as follows:

Vitamins and Minerals	Units of measurement	Infants	Children under 4 years of age	Pregnant or lactating women
Vitamin A	International Units	1,500	2,500	8,000
Vitamin D	do	400	400	400
Vitamin E	do	5	10	30
Vitamin C	Milligrams	35	40	60
Folic acid	do.	1	.2	.8
Thiamine	do	.5	.7	1.7
Riboflavin	do	.6	.8	2.0
Niacin	do	8	9	20
Vitamin B_6	do	.4	.7	2.5
Vitamin B_{12}	Micrograms	2	3	8
Biotin	Milligrams	.05	15	.30
Pantothenic acid	do	3	5	10
Calcium	Grams	.6	.8	1.3
Phosphorus	do	.5	.8	1.3
Iodine	Micrograms	45	70	150
Iron	Milligrams	15	10	18
Magnesium	do	70	200	450
Copper	do	.6	1.0	2.0
Zinc	do	5	8	15

These values are to be used as guidance in the interim for labeling products purported to be or represented for use by infants, children under 4 years of age, or pregnant or lactating women. FDA will make a final decision on these issues, following the provisions of the DS act.

F. Units of Measurement

16. A dietary supplement trade association requested that the agency continue to use the International Units nomenclature for vitamins A, D, and E. The comment stated that the new equivalents nomenclature (e.g., retinol equivalents) would be confusing and is not well understood by either professionals or consumers.

FDA advises that units of measurement based on units of equivalents have been in wide use for over 15 years, and, in fact, the NAS RDA has been listed in such units since the 1980 edition. The comment cites no evidence to support the contention that professionals are confused by the nomenclature, or that consumers will necessarily be mislead. FDA believes that it is more likely that consumers will use label information to compare products, and that the agency's provision for uniform units of measurement that are consistent with current measurement practices will be most beneficial. Additionally, for many foods, specific units of measurements will not be expressed. Rather, the levels of the nutrient present will appear as a percentage of the label reference value.

However, based on the provisions of the DS Act, the agency is, for the time being, retaining the current label reference values as established in § 101.9(c)(7)(iv) (recodified as § 101.9(c)(8)(iv)), including the units of measurement contained therein. Therefore, in the interim the agency will continue to use the International Units nomenclature for vitamins A, D, and E. FDA will reach a final decision on these issues, following the provisions of the dietary supplement act.

G. RDI's for Specific Nutrients

17. Several comments stated that the proposed RDI's for particular nutrients were too low. Several of the comments recommended higher levels for these nutrients. Specifically, the comments said that vitamin A should be 1,000 retinol equivalents; calcium, 1,200 mg; iron, 15 mg; vitamin D, 400 IU; vitamin E, 10 alpha-tocopherol equivalents; thiamin, 1.5 mg; riboflavin, 1.7 mg; niacin, 19 niacin equivalents; vitamin B_6, 2 mg; and zinc, 15 mg.

If FDA decided to use the population coverage approach in establishing the RDI for vitamins and minerals, the RDI values for the nutrients listed above would be consistent with the comments. However, based on the provisions of the DS Act, the agency is retaining the label reference values as established in current § 101.9(c)(7)(iv). Therefore, FDA notes that the RDI for vitamin A is 5000 International Units; for calcium, 1.0 g; iron, 18 mg; vitamin E, 30 International Units; and niacin 20 mg. FDA will reach a final decision on these issues, following the provisions of the DS Act.

18. Several comments asserted that there is a need to distinguish between retinol and beta-carotene as a source of vitamin A activity, and one requested that FDA establish a label reference value for beta-carotene. The general rationale provided was that beta-carotene is more strongly associated with reducing the risk of chronic disease than is retinol.

The issue of providing for separate beta-carotene declarations in the nutrition label is discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. FDA does not agree that it is appropriate to establish a label reference value for beta-carotene separate from the value for overall vitamin A activity. As set forth in the preamble to the proposal for this final rule (55 FR 29476 at 29479), FDA intended to establish label reference values for those nutrients for which quantitative values were provided by the widely recognized and accepted consensus reports, specifically the 10th edition of the NAS RDA publication (Ref. 26), Diet and Health (Ref. 3), and the Surgeon General's Report on Nutrition and Health (Ref. 2). While these reports have discussed evidence to link lower beta-carotene consumption with increased risk for certain cancers, notably lung cancer, the reports noted the evolving nature of the issue and failed to make specific dietary recommendations concerning this food component. The reports, therefore, did not specify quantitative recommendations for intake, and the comments received relative to this proposal have not suggested or justified an appropriate intake level.

Without guidance from established scientific bodies and in the absence of scientific consensus both on the role of beta-carotene in the risk of onset of certain chronic diseases and on the quantitative level that could be appropriate for a population-based recommended intake of beta-carotene, FDA concludes that establishing such a label reference value cannot be supported. However, FDA will continue to monitor scientific advances as well as ongoing recommendations relative to beta-carotene nutriture. The agency will consider modifying or expanding label reference values as evidence warrants.

19. A few comments specifically expressed concern that the RDI for vitamin C was too low for persons in the U.S. population who smoke. This concern stems from evidence that persons who smoke cigarettes may require more vitamin C than persons who do not.

FDA is aware that the 10th edition of the NAS RDA publication includes a statement in the text that recommends that regular cigarette smokers ingest at least 100 mg of vitamin C daily. However, FDA advises that the NAS RDA for vitamin C for the general population is set no higher than 60 mg. FDA has established label reference values that, of necessity, must be targeted to the entire population, rather than special population subgroups. In the absence of information to suggest that the 1989 NAS RDA's are an inappropriate basis for label reference values, FDA does not agree that the RDI for vitamin C should be a value other than the highest value set for persons 4 or more years of age. FDA supports nutrition education efforts that will inform those individuals whose requirements may be altered by lifestyle choices about their special nutrient needs.

20. One comment from a research foundation expressed concern about the high levels of iron available in the diet and thus supported the proposed RDI for iron of 12 mg as compared to the current U.S. RDA of 18 mg. The comment was made within the context of a discussion of hemochromatosis, a genetic disorder resulting in iron overload. A number of comments from consumers also expressed concern about excess levels of iron in the diet and supported lower label reference values for iron.

FDA advises that with the advent of mandatory nutrition labeling, virtually all foods will bear information on iron content. Thus, those persons diagnosed with, or at risk for, hemochromatosis will be able to select or reject a food based on their special dietary needs. Additionally, the agency will continue to make use of the active nutrition monitoring system to evaluate clinical measures and dietary intakes concerning the incidence of hemochromatosis. The agency notes that data from the Third National Health and Nutrition Examination Survey conducted by the National Center for Health Statistics can be used as a basis for reconsidering of the values for iron if concerns regarding hemochromatosis are demonstrated.

21. A number of comments addressed the issue of the RDI for folate. The majority opposed the proposed RDI value of 180 µg, which is lower than the current U.S. RDA of 400 µg. Several of the comments suggested that the 1989 NAS RDA for folate was an

inappropriate basis for establishing a RDI for folate, and a number of comments requested that the agency retain the U.S. RDA level of 400 µg (800 µg for pregnant women). One comment, in referring to the conclusion in the 1989 NAS RDA publication (Ref. 26) that diets containing about half as much folate as the previous NAS RDA maintain adequate folate status, asserts that the folate content of foods in nutrient data bases is recognized as inaccurate and incomplete. According to the comment, basing recommended intakes on intake data derived from these data bases is unsound. Several comments stated that there is evidence that folic acid supplements play a role in reduction in neural tube defects.

To a certain extent, some of these comments would be addressed by use of the population coverage approach to deriving RDI's. As a result of this approach, the RDI for folate would be 200 µg, i.e., based on the highest RDA value for persons 4 or more years of age (excluding pregnant or lactating women). However, FDA is aware of concerns regarding the adequacy of the data base for folate content of foods, which in part served as the basis for establishing the RDA for folate. Recent analytical work (Ref. 37) has shown that folate content of some foods may be underestimated because of methodological problems in current food folate assay procedures. FDA therefore agrees that additional work is needed to evaluate the adequacy of current intakes of folate.

Moreover, several studies have become publicly available since the publication of the 1989 RDA's, and these studies have shown that periconceptional intake of folate may reduce the risk of some neural tube defects. A randomized clinical intervention trial conducted in Great Britain by the Medical Research Council (Ref. 38) showed significant protective effects against recurrence of neural tube defects when women at high risk of recurrence were treated periconceptionally with daily doses of 4,000 µg of folic acid. Additionally, data available from a recently terminated Hungarian trial showed reductions in occurrence of neural tube defects with periconceptional use of a multivitamin/multimineral supplements containing 800 µg/day of folic acid (Ref. 39).

The results of these trials have led to reassessment of several earlier observational studies. Protective effects of the vitamin at levels of 100 to 1,000 µg/day (obtained from foods and supplements) against occurrence of neural tube defects have been found in several but not all such observational studies.

FDA concludes that the available data demonstrate that there is a folate-related subset of neural tube defects in populations with high prevalence rates for these defects, and that folate intakes of about 400 µg/day may reduce the risk of some, but not all, neural tube defects in such populations. Furthermore, the agency notes that the United States Public Health Service (U.S. PHS) recently recommended that women of childbearing age in the United States who are capable of becoming pregnant should consume 400 µg of folate/day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 40).

FDA has seriously considered these findings relative to the appropriateness of retaining the approach of selecting the highest 1989 NAS RDA value (excluding pregnant or lactating women) when determining the RDI for folate. The agency has weighed the established and well-recognized scientific consensus inherent in the NAS RDA along with newer evidence of a possible at-risk population that constitutes a considerable segment of the U.S. population. Taken together, the agency concludes that these findings—specifically, the evidence of problematic data on folate intakes, the possibility that intakes of 400 µg/day may reduce the risk of some neural tube defects, and the recommendation of the U.S. PHS that women of childbearing age consume 400 µg/day of folate—are sufficiently compelling to justify at this time a RDI value of 400 µg for persons 4 or more years of age and, for consistency, a RDI of 400 µg for lactating women. Given that the current U.S. RDA is 400 µg, and that the DS Act compels retaining the U.S. RDA's at this time, no action is necessary. However, the issue of folate allowances for women is a significant one. Specifically, as discussed in a companion document entitled "Final Rule; Health Claims: Folic Acid and Neural Tube Defects" published elsewhere in this issue of the **Federal Register**, FDA is concerned about the uncertainties regarding the folate requirement of women of childbearing age and is planning to implement a peer review of several scientific issues relating to folate and its benefits for U.S. women. In this review, the agency will include an evaluation of the appropriate intake level for folate for women of childbearing age.

22. Two comments suggested that an intake based on a range of 6 to 10 mg/kilogram (kg) body weight would be appropriate for maintenance of healthy magnesium status. Another comment suggested that the RDI be increased to at least 350 mg as compared to the proposed value of 300 mg.

The 10th edition of the NAS RDA publication (Ref. 26) states that 4.5 mg/kg is the upper range of requirements determined in modern balance studies for adults of both sexes. Therefore, FDA cannot agree that a range of 6 to 10 mg/kg is supported. The level of 4.5 mg/kg provides the basis for the NAS RDA's for magnesium which range from 120 to 400 mg for persons 4 or more years of age. Given that dietary magnesium deficiency has not been reported in people consuming foods commonly available and has been induced experimentally only once (Ref. 26), the agency believes that this level is more than adequate to cover the needs of virtually all population groups.

Moreover, FDA use of the population coverage approach in establishing the RDI for vitamins and minerals, would result in an RDI for magnesium of 400 mg, and thus would respond to concerns that the proposed RDI of 300 mg was too low. However, in accordance with the DS Act, FDA is not acting on this issue at this time.

23. FDA received several comments expressing concern about the generally recognized as safe (GRAS) status of selenium, fluoride, and chromium. These comments centered primarily around issues of their use in supplements.

The use of selenium, fluoride, and chromium compounds in dietary supplements is discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**. In that final rule, the agency states that FDA is deferring resolution of the status of selenium and chromium. However, FDA would like to reiterate (as stated in the July 1990 proposal, 55 FR 29476) that until the GRAS status of sources of these nutrients is resolved, the RDI's for selenium, fluoride, and chromium, if established, would be intended to be used only in conjunction with a declaration of the levels of these nutrients that are naturally present in the food or, in the case of fluoride, that are present as a result of the use of a fluoridated water supply in the processing operation (in accordance with 21 CFR 250.203). Any direct addition of these trace minerals to a food is based solely on the manufacturer's judgment that the nutrient sources are GRAS and is not sanctioned by the agency.

However, because FDA is, for the time being, retaining the label reference values in current § 101.9(c)(7)(iv), there

are no label reference values for selenium, fluoride, or chromium. FDA will reach a final decision on these issues based on the provisions of the DS . ct.

IV. Label Reference Value for Protein

24. Two comments were received concerning the inconsistency between the label reference value for protein (RDI) and the label reference values for fat and carbohydrate (DRV's) in that the total caloric contribution of the three nutrients does not sum to 100 percent. One comment stated that the proposed value of 50 g for protein is too low because, based on a 2,350 calorie diet (i.e., the level proposed to serve as the basis for certain label reference values), the proposed 50-g level of protein would provide only 8.5 percent of the calories in a daily diet. The comment suggested that a level of protein that is consistent with 10 to 11 percent of calories from protein is appropriate, along with levels of 35 percent of calories from fat and 55 percent of calories from carbohydrate. The second comment suggested that FDA should resolve the discrepancy between the proposed protein RDI (50 g) and the value for protein that would be established if the value were based on the percentage of calories derived from protein. The comment stated that 10 percent of calories from protein is appropriate, and that the remaining 5 percent of calories that results after 30 percent of calories is attributed to fat, 10 percent to protein, and 55 percent to carbohydrate should be added to the carbohydrate caloric contribution (specifically, to the contribution from complex carbohydrates).

FDA has not traditionally specified label reference values for calorie-providing nutrients other than protein (i.e., no label reference values existed for fat or carbohydrate). Thus, the agency has not needed to consider issues related to the sum of caloric contributions from protein, carbohydrate, and fat, specifically that these values sum to 100 percent. Furthermore, recognized authorities on protein allowances provide for the allowance based on the amount of protein needed per kg of body weight rather than on the basis of percent of calories (Refs. 2, 3, and 26).

However, the agency agrees that with the advent of label reference values for fat and carbohydrate, it is appropriate to reconsider the approach used to derive the label reference value for protein. In addition to providing for a consistent and interrelated set of label reference values for calorie-providing nutrients, the change in approach will facilitate consumer education efforts.

Furthermore, the decision to use the population coverage approach (i.e., selecting the highest NAS RDA value for persons 4 or more years of age excluding pregnant or lactating females) for establishing label reference values for essential vitamins and minerals (i.e., nutrients with NAS RDA's) must also be evaluated relative to its appropriateness for protein, a nutrient for which an NAS RDA is also established. This is especially important given the caution expressed in Diet and Health (Ref. 3) concerning excessive protein intake, particularly from animal sources.

While FDA received many comments that suggested that FDA return to the approach of selecting the highest NAS RDA value to serve as the label reference value, no specific comments were received suggesting that the proposed label reference value for protein (50 g, based on an adjusted average of the RDA's for protein) was too low because of public health concerns, or that the label reference value placed certain population groups at-risk for low protein intakes. Therefore, the appropriateness of using the population coverage approach for protein was not specifically supported by the comments.

FDA therefore concludes that there is sufficient support to establish a DRV for protein rather than a RDI. This change to a DRV is necessary because the agency is no longer basing the label reference value for protein on the RDA's for protein. RDI's are based on RDA's. Rather, like the label reference values (i.e., DRV's) for fat and carbohydrate, the label reference value for protein is based on percent of calories.

Neither the NAS RDA publication (Ref. 26), the Surgeon General's Report (Ref. 2), nor Diet and Health (Ref. 3) suggests a specific level of total daily calories from protein. However, current intake of total dietary protein among Americans is estimated to be about 11 percent of calories (Ref. 3) and generally exceeds the NAS RDA for all age groups. Furthermore, some international guidelines for nutrient intake recommend that protein constitute 10 to 12 percent of calories (Ref. 3).

Based on the comments that suggested that approximately 10 percent of calories from protein should provide the basis for establishing a label reference value for this nutrient, FDA concludes that basing the DRV for protein on 10 percent of calories is reasonable. The level of 10 percent of calories is consistent with the NAS RDA in that the percent of calories from protein that results when the NAS RDA for each age/sex group is compared with the caloric allowance established for that group ranges from 5 to 11 percent and could be rounded to 10 percent.

Thus, FDA advises that the label reference value for protein for adults and children 4 or more years of age (excluding pregnant or lactating females) will be a DRV rather than a RDI (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)), and will be the value that constitutes 10 percent of the calorie level to be used as the caloric basis for the DRV's. As discussed below, this calorie level is 2,000 calories. Therefore, the label reference value (DRV) for protein will be 50 g (i.e., 10 percent of 2,000 calories = 200 calories from protein; because 1 g of protein furnishes 4 calories (Ref. 26), the result is 50 g of protein).

FDA did not propose DRV's for infants, children less than 4 years of age, pregnant women, and lactating women. Therefore, for these groups the protein label references remain as RDI's (proposed as § 101.9(c)(11)(iv) and redesignated below as § 101.9(c)(8)(iv)). To be consistent with the population coverage approach, FDA has selected the highest NAS RDA for protein for infants and the highest NAS RDA for protein for lactating females. Only one NAS RDA value is provided for pregnant women and for children less than 4 years of age, thus no selection need be made. However, despite the change in approach, the RDI's for protein are the same as those proposed for these four groups. Therefore, the label reference value for protein will be: (1) A DRV of 50 g for adults and children 4 or more years of age and (2) RDI's of 14 g for infants, 16 g for children less than 4 years of age, 60 g for pregnant women, and 65 g for lactating women.

The decision to establish a DRV for protein based on 10 percent of calorie intake (so that DRV's for calorie-providing nutrients sum to 100 percent of calories) requires an adjustment in the proposed label reference value for total carbohydrate, i.e., 55 percent calories from carbohydrate. The necessary adjustment is discussed below.

Also, consistent with these changes, additional changes are necessary in proposed conforming amendments. FDA is amending § 101.3(e)(4)(ii) (21 CFR 101.3(e)(4)(ii)) by not only removing the term "U.S. RDA" and adding in its place the term "RDI," but also by adding the term "DRV of protein." FDA is also amending § 104.20(c)(1) and (d)(3) to list the DRV for protein.

V. DRV'S: Label Reference Values for Eight Nutrients without NAS RDA'S

A. Terminology

25. Two comments were received that expressed concern about the use of the word "value" in the term DRV. These comments stated that the word "value" may imply a goal rather than a reference level, and that the word generally connotes desirability.

No data were submitted to support the suggestion that word "value" may mislead consumers. Furthermore, FDA research has indicated that the term is generally understood by consumers as a point of reference. No other comments objected to the term on these grounds. FDA finds there is no compelling reason to abandon the proposed DRV terminology.

B. Scientific Basis for DRV's

26. Several comments expressed concern that the DRV's were based on insufficient or conflicting data, or that they lack sufficient scientific justification.

FDA acknowledges that the role of nutrients and food components in reducing the risk of disease is in an evolving state. However, numerous dietary reports and reviews relating to diet and health—particularly on the effect of diet on the risk of developing certain chronic diseases—have been published within the last decade. These reports, including Diet and Health (Ref. 3), the Surgeon General's Report on Nutrition and Health (Ref. 2), and Dietary Guidelines for Americans (Ref. 5), represent a sufficient scientific consensus that justifies the agency's proceeding with the establishment of DRV's. This conclusion is supported by the Institute of Medicine report entitled "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 1), which states that health professionals have achieved a consensus on the characteristics of foods Americans should choose to have both a healthier diet and to reduce the risk factors for chronic diseases and conditions.

Concerns pertaining to the possibility that scientific consensus may change are not unique to the DRV's. The NAS RDA's, and thus the RDI's, are also subject to change and can be affected by shifts in scientific consensus. While it can be argued that the NAS RDA's are less likely to change because they have evolved over a longer period of time than the DRV's, any force from this argument is not sufficient to preclude using widely recognized and accepted recommendations to establish DRV's. This action is important given current public health goals and the clear role that the food label can play in achieving these goals. FDA acknowledges that the scientific knowledge that underlies the DRV's may change over time, and so the agency intends to monitor and evaluate scientific consensus relative to existing DRV's as well as other nutrients known to bear on to the diet/health relationship. Furthermore, the petition process provided by agency regulations enhances and encourages this review. Accordingly, FDA is adopting the DRV's as proposed, with some modifications.

C. Caloric Basis for DRV's

27. While several comments supported FDA's proposal to use 2,350 calories as the basis for establishing certain DRV's that are based on daily caloric intake, most comments were opposed to the proposed value because they believed that it is too high. Many expressed concern that the resulting DRV's for total fat and saturated fat would overstate acceptable intakes for population groups that habitually consume less than 2,350 calories. Others were concerned that the calorie level would appear too high and, thus, would be irrelevant to many consumers. A few comments suggested that the level of 2,350 may encourage overconsumption of calories, especially among women.

Many comments suggested that FDA use 2,000 calories as the basis for the DRV's. The rationale for selecting 2,000 calories as opposed to other lower values varied, but reasons given included the fact that it is consistent with widely used food plans, it approximates the caloric requirements for postmenopausal women who are at-risk for excessive intake of calories and fat, and it is a "rounded down" value for 2,350 calories. These comments also pointed out that 2,000 calories is easier to use in quick, mental calculations compared to other calorie levels such as 1,900 or 2,350. Therefore, it is an easier tool for education purposes and is "consumer friendly." A few comments suggested 1,900 calories be used as the basis because it reflects the caloric allowance set by the NAS for women 51 or more years of age, a group believed to be at-risk for excessive calorie and fat intake.

FDA agrees with the comments that there is a need to select a lower calorie level for the DRV's. First, FDA agrees that a rounded value will be easier for consumers to use and is less likely to suggest such a level of precision that consumers lose sight of the concept of tailoring recommendations and reference values to their own diets. Secondly, the use of a lower caloric value is consistent with the population coverage approach to be used for vitamins and minerals. The group "at risk," in this case the group most often targeted for weight control (i.e., older women), is covered by selecting a lower caloric basis for the DRV's, one that approximates the caloric requirements of such women. Given the support expressed for the 2,000 calorie level and how well it fits the reasons that support making this change, FDA will use 2,000 calories as the basis for DRV's (proposed as § 101.9(c)(12)(i), redesignated below as § 101.9(c)(9)).

Based on a 2,000 calorie level, the resulting DRV's being incorporated into § 101.9(c)(9) are listed in the following table:

Food component	Unit of measurement	DRV
Total fat	g	65
Saturated fat	do	20
Cholesterol	mg	300
Total carbohydrate.	g	300
Dietary fiber	do	25
Sodium	mg	2,400
Potassium	do	3,500
Protein	g	50

As stated in the July 1990 proposal (55 FR 29476 at 29484), revisions of the nutrition labeling regulations in § 101.9 to update the U.S. RDA values necessitate that, for consistency, FDA revise several other regulations. FDA proposed to revise § 104.20(d)(3) to include the statement "The food contains all of the following nutrients per 100 calories based on 2,350-calorie total intake as a daily standard" and by providing a proposed table that listed the amounts of nutrients (per 100 calories) based on a 2,350 calorie diet and based on the proposed RDI levels. FDA has recalculated the nutrient levels in § 104.20(d)(3) to reflect the RDI values presented in this final rule based on a 2,000 calorie diet and included a statement indicating that the amounts of nutrients per 100 calories are based on a 2,000 calorie total intake.

28. Several comments stated that DRV's should be established in a fashion that provides for a different set of DRV's for different caloric intakes or, alternatively, that provides for a range of values such as a minimum/maximum range. These comments argued that the proposed DRV's are too simplistic and would encourage overconsumption of calories and fat, especially among women. One of these comments provided an extensive rationale for developing three sets of DRV's based on three levels ("benchmarks") of calorie intake.

FDA is aware of the problems associated with providing a single label reference value when in fact

recommended intakes or nutrient allowances for individuals vary considerably. The concern expressed is somewhat analogous to the difficulties in deriving a single set of RDI's based on the NAS RDA's, which are established for different sex/age groups.

In the case of DRV's, FDA believes that the purposes of nutrition labeling are better served by implementing a single value to serve as the DRV for each nutrient because the percent DRV (expressed as Daily Value) will be a component of mandatory nutrition labeling. This labeling will be required on virtually all foods and, therefore, space considerations are significant. At the same time, if consumers are to use the important and necessary information provided by DRV's (expressed as Daily Value), the information must be presented in a readable format and in a manner that does not overburden or overwhelm consumers. The agency finds that a single value DRV will best accommodate these considerations of space and readability. In the companion document that specifies the final rule for Mandatory Nutrition Labeling, FDA is providing for a statement that is to be added to the label advising that the particular amount of certain nutrients a person may consume will vary depending upon calorie requirements. This information, coupled with education, should adequately address the concerns raised by the comments by ensuring that consumers will understand that diets of individuals will not necessarily match label reference values.

The concerns that the proposed DRV's will encourage overconsumption among women is addressed by FDA's decision to base the DRV's on a caloric consumption of 2,000 calories rather than 2,350 calories. The 2,000 calorie level is very close to the 1,900 calories recommended for women 51 or more years of age.

However, the requirement that a single DRV be used in the nutrition label does not preclude the option of manufacturers voluntarily adding a listing of DRV's for other calorie intakes if label space allows. The comments have persuaded FDA that this voluntary declaration could be useful to consumers. Therefore, while the DRV's based on a 2,000 calorie diet constitute the mandatory component of the listing (space permitting), producers and retailers may voluntarily add a listing of DRV's for a different specified calorie level or levels than those provided by § 101.9(c)(9). Manufacturers who wish to take advantage of this option should calculate, with appropriate rounding, (1) fat based on 30 percent of calories, (2) saturated fat based on 10 percent of calories, (3) carbohydrate based on 60 percent of calories, (4) protein based on 10 percent of calories, and (5) fiber based on 11.5 g of fiber per 1,000 calories. These calculations reflect those used to derive the DRV's based on a 2,000 calorie diet. As an example, a manufacturer could voluntarily list DRV's for a 1,500 calorie diet as follows: 50 g fat, 15 g saturated fat, 225 g carbohydrate, 40 g protein and 20 g fiber; or for a 2,500 calorie diet: 80 g fat, 25 g saturated fat, 375 g carbohydrate, 60 g protein, and 30 g fiber.

D. Units of Measurement and Rounding Procedures for DRV's

29. One comment disagreed with FDA's rounding procedure for the DRV's for fat, unsaturated fat, polyunsaturated fat, and carbohydrate. The comment suggested that the whole numbers derived before rounding should be used as the DRV. For instance, 30 percent of calories from fat (based on a 2,350 calorie diet) results in 78.3 g of fat. The comment argued that the DRV should be a value rounded to 78 g instead of the proposed 75 g.

FDA's rounding procedures for DRV's were intended to provide values that are "consumer friendly" numbers easily incorporated into educational programs as well as values that are generally consistent with the dietary recommendations. The possibility that DRV's could be listed on food labels as quantitative amounts instead of as percentage values led the agency to conclude that rounding to numbers such as 25 or 325 facilitated consumer education and did not imply more scientific precision than is justified given the evolving state of dietary recommendations. Furthermore, several comments urged FDA to select values that are easy for consumers to use and that do not suggest precision in determining the values. Therefore, the agency believes that there is support for the rounding approach that it used and agrees that consumers will find numbers such as 75 and 25 as more "friendly" and easily remembered than numbers such as 78 and 26. No other comments were received concerning this issue, and therefore FDA finds no compelling reason to provide alternative rounding procedures.

E. DRV for Total Fat

30. Several comments suggested that the use of 30 percent of calories from fat is inappropriate as the basis for developing a DRV for total fat. Some comments suggested that the level used should be 25 percent of calories from fat; one stated that 20 percent of calories from fat should be used. These comments argued that the established recommendation is a maximum level because it is stated as 30 percent or less of calories from fat. Therefore, some level below this maximum should be used. On the other hand, one comment recommended that FDA use 35 percent of calories from fat. The concern expressed in this comment was that levels below 35 percent of calories from fat will bias diets toward vegetarianism.

FDA rejects the arguments that the DRV should be based on a criterion other than 30 percent of calories from fat. As described in the preamble to the proposal, the major available consensus documents, which were used by FDA in developing the DRV, consistently recommend 30 percent of calories or less from fat as an appropriate intake, given that current intake approaches 40 percent of calories from fat. Thus, a level higher than 30 percent of calories cannot be supported because the widely supported recommended intake is no more than 30 percent of calories from fat. The comment stating that intake levels below 35 percent of calories from fat will bias diets toward vegetarianism did not provide evidence to support this statement. FDA is not aware of any data that suggests that diets at or below 30 percent of calories from fat preclude the inclusion of animal products.

On the other hand, while current consensus reports suggest that less than 30 percent of calories from fat is achievable and may be desirable, they fail to provide specific quantitative recommendations as to how far below 30 percent is advisable. In fact, no consensus exists on the appropriateness of specific intakes of less than 30 percent of calories from fat.

However, the agency is aware of the desirability of alerting consumers to the direction of the DRV for total fat in that it is helpful for consumers to know that intakes of 30 percent of calories or less is the goal. Thus, FDA is providing that the listing of the DRV for total fat on the nutrition label include the words "less than," as described in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**.

31. Many comments suggested that the DRV for total fat should be lower than the proposed value of 75 g.

FDA agrees with these comments. With the change to a 2,000 calorie basis for DRV's, the DRV for total fat will be 65 g. The level was derived by calculating 30 percent of 2,000 calories and dividing by 9 which is the number of calories per g of fat. The calculated value is 66.7 g of fat. FDA rounded this

amount down to 65 g because, given that the current recommendation for total fat intake is 30 percent of calories or less, it is more appropriate to round down than to round up. Furthermore, as explained above, many comments have encouraged the agency to select label reference values that are easier for consumers to work with and recall, for instance 65 g of fat rather than 66 g.

F: DRV for Saturated Fat

32. Several comments suggested that because the proposed calorie basis (2,350 calories) is greater than the allowance for many persons, the proposed DRV for saturated fat (25 g) is too high.

FDA agrees with these comments. With the change in the basis for DRV's to 2,000 calories, and using the recommended intake of less than 10 percent of calories from saturated fat, the DRV for saturated fat is 20 g. The actual amount calculated using 10 percent of 2,000 calories is 22.2 g. However, because the current dietary recommendation specifies less than 10 percent of calories from saturated fat and for other reasons discussed above, FDA rounded this value down to 20 g.

33. One comment referenced Diet and Health (Ref. 3) which states that a saturated fat intake that is 7 to 8 percent of calories or lower would confer greater health benefits than the recommendation for less than 10 percent of calories. The comment suggested that FDA use 7 percent of calories from saturated fat as the basis for the DRV.

While the report cited does include an advisory statement as to the possibility of increased benefits with lower intakes, the committee responsible for Diet and Health specifically recommended less than 10 percent of calories from saturated fat. This recommendation was based not only on issues of health benefits but also on considerations of realistic diet modifications among American consumers. FDA believes that this approach is both prudent and practical. No other comment suggested the level of 7 percent of calories from saturated fat as the basis for the DRV. The agency, therefore, used 10 percent of calories from saturated fat with a rounding down procedure as described above in deriving the DRV for saturated fat.

G. DRV for Unsaturated Fat

FDA's intent in developing a DRV for unsaturated fat was to complete the set of label reference values for fat. The DRV's for fat and saturated fat reflect current recommendations to limit total fat intake to 30 percent of calories and saturated fat intake to less than 10 percent of calories. To account for the component of total fat that remains, FDA derived the DRV for unsaturated fat by calculating 20 percent of calories and dividing by 9. The agency arrived at the factor of 20 percent by subtracting the 10 percent of calories from saturated fats from the 30 percent of calories for total fat.

However, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, comments have convinced the agency that the listing of unsaturated fat on the food label is potentially confusing to consumers and could result in consumer deception. As discussed in that companion document, comments stated that the listing was not useful, that it offered no additional information that could not be obtained by subtracting the saturated fat content from total fat, and that it obscures the presence of essential fatty acids.

Moreover, other comments persuasively argued that the term "unsaturated fat" is misleading because it suggests that all unsaturated fats are synonymous by including both cis and trans isomers and poly- and monounsaturated fats together. Based on these comments, FDA decided not to include a listing of unsaturated fat in nutrition labeling. Therefore, FDA finds that there is no need for a label reference value for unsaturated fat and, accordingly, has deleted the proposed DRV for it in this final rule.

34. One comment requested that FDA eliminate the proposed DRV for unsaturated fat and replace it with a DRV for polyunsaturated fat with a value of 25 g. The comment argued that this approach was supported by evidence that: (1) Polyunsaturated fats lower serum cholesterol, (2) current dietary recommendations are to maintain or modestly increase polyunsaturated fat intake, (3) low polyunsaturated fat intake is linked to increased risk of coronary heart disease, (4) consumers are familiar with polyunsaturated fat declarations on labels, and (5) declarations of unsaturated fat will clutter a nutrition label and do not provide useful information.

While FDA has been persuaded to eliminate the DRV for unsaturated fat, FDA does not agree that the establishment of a DRV for polyunsaturated fat of 25 g is appropriate. As stated in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, FDA is not persuaded that there is a need to require the inclusion of polyunsaturated fats on the nutrition label. As discussed, these fatty acids do not meet the agency's criteria set forth in the proposal to the final rule (55 FR 29487 at 29493) that the nutrient be of particular public health significance and that quantitative intake recommendations be given in major scientific consensus reports.

Nonetheless, given consumer interest in polyunsaturated fats, FDA is allowing manufacturers to voluntarily list the amounts of polyunsaturated fats on the nutrition label. This provision is discussed in detail in the Mandatory Nutrition Labeling final rule, published elsewhere in this issue of the **Federal Register**. Also, the agency acknowledges that Diet and Health (Ref. 3) has recommended that total polyunsaturated fat intake be maintained at 7 percent of calories and not exceed 10 percent of calories. This guideline translates into a recommended level of intake of approximately 16 g of total polyunsaturated fat, which should not exceed 22 g, based on the criterion of a 2,000 calorie diet.

However, FDA's definition for polyunsaturated fat includes only the cis isomers of the polyunsaturated fatty acids, as described in the Mandatory Nutrition Labeling final rule. Thus, voluntary label declarations for polyunsaturated fat exclude trans isomers. As discussed in the Mandatory Nutrition Labeling proposed rule (55 FR 29487 at 29496), FDA believes that the limited definition is appropriate because declarations concerning polyunsaturated fats are at a level of specificity associated with targeted diet and health relationships.

Therefore, while label declarations include only the cis isomers, the available recommendation for polyunsaturated fat intake is based on total polyunsaturated fat intake. There are no quantitative recommendations for polyunsaturated fat intake that distinguish between the recommended intake of cis isomers and trans isomers of polyunsaturated fat. FDA concludes that a DRV based on recommendations pertaining to total polyunsaturated fat would be inappropriate when label declarations are to be based on only a component of the total polyunsaturated fat. Declarations when compared to the DRV would be misleading. Thus, the agency has not established a DRV for polyunsaturated fat.

35. One comment stated that the proposed DRV for unsaturated fat (50 g) was too high because current guidelines suggest that saturated and polyunsaturated fat should be up to 10 percent of calories, and that the rest of

the caloric contribution should come from monounsaturated fats.

The comment does not reference the source for the guideline that it discusses, and FDA is unaware of such a guideline. FDA does not agree that the current consensus reports suggest that 20 percent of calories should come from monounsaturated fats, and that the remaining caloric contribution of 10 percent of calories should be attributed to all other fats. Rather, as discussed in Diet and Health (Ref. 3), the current general recommendations are that polyunsaturated fat not exceed 10 percent of total calories, and that saturated fat be less than 10 percent of total calories. No specific recommendations for monounsaturated fat are provided in the major consensus reports currently available to the agency.

36. One comment stated that it is not appropriate to recommend 20 percent of calories from unsaturated fat without also stating that linoleate is an essential fatty acid and as such should comprise at least 3 percent, and perhaps as much as 7 percent, of calories in line with the current average intake in the United States.

The agency's decision to eliminate the DRV for unsaturated fat responds to the essential concern of this comment, that declarations concerning levels of unsaturated fat could be misleading without further information. As stated earlier, no DRV for unsaturated fat will be established, and thus the issue concerning the linoleate component of the DRV need not be addressed.

H. DRV for Cholesterol

37. One comment suggested that many experts agree that a single number for recommended cholesterol intake cannot be supported and requested that FDA eliminate this DRV. The comment also suggested that if the DRV is to be retained, the DRV for cholesterol should be expressed as a range. However, the comment did not specify an appropriate range. One comment stated that the DRV for cholesterol was inappropriate because Canadian nutrition recommendations do not provide quantitative advice on cholesterol intake.

FDA cannot agree that a DRV for cholesterol is unnecessary, or that many experts do not support a single overall recommended intake for cholesterol. Major public health initiatives in the United States have cited the need to limit cholesterol intake, and quantitative recommendations for cholesterol intake have evolved over a long period of time. Recently, the report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction, National Cholesterol Education Program (Ref. 41) stated that it is important for Americans to change their eating patterns to reduce the average intakes of dietary cholesterol.

As documented in Diet and Health (Ref. 3), there are a number of sources of recommendations concerning cholesterol intake, and the most widely used recommendation is to limit intake to 300 mg or less/day. The American Heart Association has recently re-reviewed this issue and recommended that cholesterol intake should be less than 300 mg/day (Ref. 42). Furthermore, a review of a summary table in Diet and Health (Ref. 3) reveals only one U.S. recommendation that provides a range for cholesterol. The range is 250 to 300 mg/day prescribed for a high-risk population rather than for the general public. Therefore, FDA does not agree that the DRV for cholesterol is unnecessary or inappropriate, nor that it should be expressed as a range. The agency is retaining the DRV for cholesterol at 300 mg (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)).

38. One comment recommended that the DRV for cholesterol be eliminated because the 300 mg level may encourage women and children, whose mean intakes as indicated by national surveys are below 300 mg, to increase their intakes.

FDA cannot agree that the DRV of 300 mg for cholesterol will encourage women and children to increase consumption of cholesterol. The major consensus reports, upon which the DRV is based, have considered the intake of cholesterol relative to women and children and have found no evidence that establishing a recommendation at approximately 300 mg/day will cause risk for these groups, which constitute a large percentage of the target population (Refs. 2 and 3).

More importantly, the lower calorie intakes among these population groups will likely result in lower intakes of cholesterol by these persons. Given current widespread and highly visible education programs, it is very unlikely that individuals will attempt to increase cholesterol intake to match a label reference value for a nutrient that is so generally known as one to be limited in the diet. Furthermore, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, the DRV for cholesterol will be stated as less than 300 mg, thus providing nutrition information in a way that will further discourage any increase intake.

39. One comment referenced a statement in Diet and Health (Ref. 3) that reductions beyond 300 mg/day of cholesterol intake, for example to levels of 250 or 200 mg/day, may also confer health benefits. The comment suggested that the 300 mg level was based not only on issues of public health but on the feasibility of achieving lower intakes given current consumption patterns, which, in turn, was based largely on anecdotal evidence and personal opinion.

While the report cited does include a statement as to the possibility of increased benefits with lower intakes of cholesterol, the committee responsible for the report specifically recommended a level of 300 mg/day. This recommendation was based not only on issues of health benefits but also on considerations of realistic diet modifications among American consumers. The comment does not cite specifically in what way this recommendation is based on anecdotal evidence or personal opinion, and the agency is unaware of any evidence to support this claim. FDA believes that the DRV of 300 mg for cholesterol is both prudent and practical, and is consistent with current dietary recommendations. No other comment suggested a lower level of cholesterol for the DRV. The agency will therefore retain the DRV of 300 mg. However, as with other nutrients, FDA will continue to monitor consensus reports and scientific evidence concerning the appropriateness of this DRV.

I. DRV's for Total Carbohydrate, Complex Carbohydrates, and Sugars

In the July 1990 proposal (55 FR 29476) and again in the supplementary proposal (56 FR 60366), FDA proposed a level of 325 g to serve as the DRV for total carbohydrate. This quantity was based on recommendations provided by major consensus reports, and specifically on the quantitative recommendation from Diet and Health (Ref. 3) that carbohydrate intake be 55 percent or more of calories. The amount, 325 g, reflects 55 percent of 2,350 calories, the caloric level proposed to serve as the basis for the DRV's.

40. One comment expressed concern that the proposed DRV for carbohydrate exceeds levels that should be consumed by many in the population and is not based on a scientific consensus. The comment suggested that the DRV for carbohydrate be eliminated.

FDA disagrees with this comment. The vast majority of comments that FDA received support the appropriateness of establishing DRV's as well as the validity of the scientific documents

upon which they (including the DRV for carbohydrate) are based. A DRV for total carbohydrate is necessary to assist consumers in understanding the significance of the level of that nutrient in a food within the context of an overall total daily diet. Thus, establishing a DRV for total carbohydrate is consistent with section 2(b)(1)(A) of the 1990 amendments. Additionally, several comments stated that it would be desirable to account for 100 percent of caloric intake in the DRV's for fat, protein, and carbohydrate (i.e., the energy-providing nutrients). Therefore, FDA concludes that a DRV for carbohydrate is appropriate.

41. A few comments requested that FDA establish a DRV for complex carbohydrate. One comment suggested that FDA establish such a DRV because it could be used in nutrition education efforts to help consumers put the dietary recommendations regarding increased carbohydrate intake into perspective. This comment provided a rationale based on the assumption that the current dietary recommendation to increase consumption of complex carbohydrates is meant to provide a caloric source to replace the decrease in caloric intake that will result from following the recommendation to decrease fat in the diet. On this basis, a DRV for complex carbohydrate derived from 35 percent of calories was suggested. Another comment suggested that a DRV based on 40 percent of calories is appropriate (assuming that 10 percent of calories is attributed to naturally-occurring sugars and 10 percent to added sugars, for a total carbohydrate DRV of 60 percent of calories). The third comment suggested that a DRV for total carbohydrate in the absence of DRV's for complex carbohydrates and simple sugars is inappropriate. One comment suggested eliminating the DRV for total carbohydrate and replacing it with a DRV for complex carbohydrate.

FDA agrees that recent dietary recommendations have included suggestions that persons increase their intake of complex carbohydrates. However, FDA does not agree that there is scientific agreement on a specific recommended intake of complex carbohydrates, particularly a level of agreement that will support establishing a DRV. To date, major consensus reports and dietary recommendations have provided only qualitative recommendations for intake of complex carbohydrates. No quantitative recommendations exist. While the calculations that accompany the suggestion of 35 percent of calories from complex carbohydrate are well thought out, they are not at this time supported by other sources. The alternative suggestion of 40 percent of calories from complex carbohydrate is based on a calculation by difference that assumes that 20 percent of calories from naturally occurring and added sugars is justified. Again, FDA finds no basis in the consensus reports upon which to agree.

Moreover, as discussed in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, the chemical definition for complex carbohydrate remains problematic. A DRV for complex carbohydrate would be inappropriate in the absence of an acceptable chemical definition for complex carbohydrate because the agency does know which chemical entities should be reflected in the complex carbohydrate DRV, and because the agency would be unable to measure complex carbohydrate to determine whether a level listed as present in a food is correct. FDA acknowledges that recommendations concerning complex carbohydrate intake as well as the analytical methodologies for this food component are in an evolving state. Therefore, the agency will continue to monitor scientific evidence relative to the appropriateness of establishing a DRV for this food component.

42. One comment from a consumer advocacy group suggested that a DRV for added sugars and a DRV for naturally-occurring sugars be developed. The comment stated that DRV's in general do not describe ideal diets and do not reflect absolute scientific knowledge but are instead estimates based on the best knowledge available. The comment suggested that because sugars intake is a major public health concern, it is appropriate for FDA to establish a DRV for sugars despite the fact that neither the Surgeon General's Report (Ref. 2) nor Diet and Health (Ref. 3) present quantitative recommendations on sugars intake. The comment suggested that a DRV of approximately 50 g be established for added sugars. The comment said that this level was derived from a FDA report (Ref. 43) that estimated that, on average, 53 g of added sugars are consumed per person per day. The comment asserted that FDA underestimated added sugars intake by one half (although it did not provide evidence to support this claim) and thus said that 50 g would be an appropriate level. The comment also suggested that the DRV for naturally-occurring sugars should be 50 g, also based on the FDA report concerning average consumption/day. The comment again suggested that this estimate is too low by half.

Another comment concerning complex carbohydrates stated that a DRV for complex carbohydrate should be based on 35 percent of calories from carbohydrate, and implied that 20 percent of calories should be attributed to sugars.

In reviewing these comments, FDA considered the report from the World Health Organization (WHO) entitled "Diet, Nutrition and the Prevention of Chronic Diseases" (Ref. 44). The agency recognizes that the recommendation in the WHO report that consumption of refined sugars be limited to 10 percent of calories is not inconsistent with the comment that recommended that a DRV for added sugars be established at 50 g, because, with the agency's use of 2,000 calories as the basis for the DRV's, 50 g of sugars would constitute 10 percent of calories. Furthermore, the agency stated in its proposals (47 FR 53917, November 30, 1982 and 47 FR 53923, November 30, 1982) to affirm that sucrose, corn sugar, corn syrup, and invert sugar are GRAS, that it would monitor average dietary consumption of these ingredients and would reevaluate the safety of their use if total dietary consumption were to increase significantly. The agency concluded in those documents that there could be safety concerns if intake of these ingredients increased significantly over the current levels (approximately 50 g).

FDA acknowledges that there is some support for limiting the intake of added sugars to current intakes of about 50 g or 10 percent of calories. However, the agency has concluded that this support does not furnish a sufficient basis for establishing a DRV for added sugars. First, DRV's are established for nutrients of public health concern. As such, a rational basis for a DRV must in some way link particular, if not specific, levels of intake with adverse or positive health outcomes. Other than dental caries—the incidence of which has been declining considerably among the American population (Ref. 43)—no public health concerns are articulated by the comment or in the relevant reports. Further, in a special review conducted by the agency in the mid-1980's, FDA concluded that other than the contribution to dental caries, there is no conclusive evidence that demonstrates that sugars intake from any source is associated with chronic disease conditions (Ref. 43). The report also states that the development of dental caries occurs whether a sugar is added or naturally occurring, and that caries development is associated with the nature and texture of the food

consumed, not just the total amount of sugars present in the food. Therefore, a specific level of intake that causes risk cannot be identified.

Secondly, as discussed in more detail in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the **Federal Register**, there is currently no analytical methodology that would allow the agency to distinguish between sugars that are added to a food and those that are naturally occurring. Therefore, FDA would be unable to evaluate the accuracy of claims about the levels of added sugars in foods. FDA discussed this consideration earlier in its final rule on the GRAS status of certain sugars (53 FR 44863, November 7, 1988). The agency concluded that it would be impractical to enforce limitations on the use of these ingredients in foods.

Moreover, in the absence of analytical capabilities to distinguish between added sugars and naturally-occurring sugars, FDA does not believe that it would be appropriate to establish a DRV for total sugars. There is no consensus concerning the specific proportions of total carbohydrate that should be attributed to total sugars and to complex carbohydrate. Moreover, a DRV for total sugars could be inconsistent with dietary guidelines that encourage the consumption of certain foods, such as fruits and dairy products, that contain naturally-occurring sugars, sometimes at high levels. FDA, therefore, concludes that DRV's for added sugars, naturally-occurring sugars, and total sugars cannot be supported.

This conclusion, however, does not mean that FDA supports unlimited intake of sugars or sugar-rich foods that contain few nutrients except calories. Rather, FDA analyses of food consumption data (Ref. 45) suggest that certain groups in the population would benefit from educational efforts to help them assess the amount of sugars present in foods in relation to the amounts of other nutrients contained in the food. Given this need, as well as consumer interest in levels of sugars in food, FDA has made provision in the Mandatory Nutrition Labeling final rule, published elsewhere in this issue of the **Federal Register**, for declarations in the nutrition label concerning the amount of total sugars present in the food. With educational efforts, consumers will be able to use the nutrition label to differentiate between sugars-containing foods with high versus low nutrient values.

J. Adjustment in DRV for Carbohydrate Resulting from Change in Label Reference Value for Protein

As discussed earlier, the agency has decided to use a caloric basis for the DRV's of 2,000 calories instead of 2,350 calories and to establish a DRV for protein based on 10 percent of calories. These changes from the proposed approach have necessitated an adjustment in the DRV for total carbohydrate.

Based on comments, particularly as discussed above in comment 24, FDA is establishing a DRV for protein rather than an RDI. The DRV value reflects 10 percent of calories from protein, based on a 2,000 calorie diet. FDA proposed to base the DRV's for fat and carbohydrate on their percent contribution to total calories, 30 percent and 55 percent, respectively. If protein is to contribute 10 percent of calories, then it is necessary to account for the remaining 5 percent of calories using the contribution from fat or from carbohydrate. Given the current established recommendation that persons consume 30 percent or less of calories from fat (Refs. 2 and 3), FDA does not believe it would be appropriate to add the remaining 5 percent of calories to the contribution from fat.

Guided by a comment submitted to this docket, discussed above in comment 41, as well as by the fact that Diet and Health recommends that 55 percent or more of calories be derived from carbohydrate (Ref. 3), FDA believes that it is appropriate to increase the DRV for carbohydrate. While the comment suggested the change from 55 to 60 percent of calories from total carbohydrate within the context of providing a DRV for complex carbohydrates (which was not proposed by the agency), the approach can still be applied to total carbohydrate in the absence of a DRV for complex carbohydrate.

This change from 55 percent to 60 percent of calories from carbohydrate is consistent with the recommendation that persons consume 55 percent or more of their calories from carbohydrate, and it allows the energy-yielding nutrients to sum to 100 percent of calories as suggested by the comments to this docket. Therefore, FDA is adopting a DRV for carbohydrate of 300 g, which is 60 percent of 2,000 calories (i.e., 60 percent of 2,000 calories = 1,200 calories; carbohydrate provides 4 calories per g (Ref. 26), thus 1,200 calories divided by 4 calories per g results in 300 g). This change is incorporated into § 101.9(c)(9)).

K. DRV for Dietary Fiber

43. Two comments suggested that the DRV for dietary fiber should not be associated with a specific caloric intake, and that, as in the case of cholesterol, this DRV should be independent of the number of calories consumed. One comment stated that nutritionists recommend similar levels of fiber intake at different levels of caloric intake. However, the comment did not specify a level that would be appropriate for all persons.

As acknowledged in the proposal for this regulation, there is a relative lack of consensus concerning recommended quantitative values for fiber intake. However, several scientific bodies have recommended increased intake of fiber, and comments from consumers and health professionals have strongly suggested the desirability of providing quantitative fiber content labeling on foods. Available recommendations tend to be expressed as a range or as a level that should not be exceeded, rather than as a single number applicable to all persons.

FDA considers the current most authoritative source on recommended fiber intake to be the report issued by the Life Sciences Research Organization (LSRO) of the Federation of American Societies for Experimental Biology (Ref. 46). This report based recommended fiber intakes on an amount (10 to 13 g) per 1,000 calories which, when based on the 2,000 calorie level used for the DRV's, results in a level of intake (20 to 26 g) that is in general agreement with the recommendation of the National Cancer Institute, i.e., 20 to 30 g per day (Ref. 47).

FDA finds no reason to change the basis for deriving the DRV for dietary fiber that it used in the proposal which involved calculating 11.5 g, the midpoint of the 10 to 13 g range, of fiber per 1,000 calories. The change to a 2,000 calorie basis from a 2,350 calorie basis will not change the DRV for fiber (proposed as § 101.9(c)(12)(i) and redesignated below as 101.9(c)(9)), which FDA proposed as 25 g based on a 2,350 caloric intake. The 2,000 calorie calculation (i.e., 11.5 g times 2) results in a value of 23 g, which rounds up to 25 g to provide a number that is easily incorporated into educational programs and is generally consistent with the dietary recommendations.

44. One comment recommended that the DRV for fiber be established as 20 g rather than 25 g. The comment noted that the National Cancer Institute (Ref. 47) and the report from LSRO (Ref. 46) both specify a range of about 20 to 35 g per day. The comment suggested that

the low end of the range is a more realistic goal for the U.S. population considering that current intakes are half of that amount.

FDA does not find the argument for dietary feasibility sufficiently compelling to abandon a level that is clearly within the range recommended by major scientific bodies. FDA is unaware of any evidence to suggest that 25 g per day cannot be met by consumers who select foods from the available food supply, or that it is not achievable through realistic diet modifications. FDA believes that the recommended intake is readily achievable with enhanced educational efforts. FDA is planning for and supporting such efforts.

45. One comment expressed concern that the proposed DRV for fiber exceeds levels consumed by many in the population and is not based on sufficient scientific data. The comment did not further specify the nature of the insufficient data.

As stated in the proposal to this document (55 FR 29476 at 29483), comments received by FDA show that many consumers and health professionals desire quantitative fiber content labeling. Yet, as the agency acknowledged, there is a lack of consensus concerning quantitative values for recommended fiber intake. However, several scientific bodies (Refs. 2, 3, 47, and 48) have recommended increased intake levels for fiber on the basis that fiber may have important health benefits, particularly relative to intestinal function. Furthermore, LSRO has issued a report that provides a quantitative recommended intake for dietary fiber (Ref. 46). Its recommendation of 10 to 13 g fiber per 1,000 calories in the diet is consistent with that of the National Cancer Institute (Ref. 47). The report developed for LSRO by a panel of qualified scientists contains numerous references to scientific research articles and reports in professional journals and publications. FDA is not aware of any concerns about the soundness of the LSRO review. Therefore, FDA is not persuaded that the scientific rationale for the fiber DRV is based on insufficient data.

Secondly, the fact that the DRV exceeds levels currently consumed by many in population is not significant in setting this DRV. As discussed in the preceding comment, FDA is unaware of any evidence to suggest that 25 g per day cannot be met by consumers who select foods from the available food supply. Therefore, FDA concludes that the 25 g level for the DRV for fiber is appropriate.

L. DRV for Sodium

46. A few comments specifically supported creating a DRV for sodium by pointing out that the scientific evidence demonstrates that sodium reduction is beneficial for hypertensive and normotensives alike, and that high salt intake coupled with low potassium and calcium intake is a major cause of high blood pressure and risk of stroke. A few were opposed and argued that the data are scientifically insufficient or questionable.

FDA disagrees that the data are insufficient or questionable. The basis for the agency's position is discussed in detail in the proposal pertaining to a sodium/hypertension health claim (56 FR 60825, November 27, 1991) and in the final rule for this health claim published elsewhere in this issue of the **Federal Register**. As discussed in these documents, it is the agency's opinion that based on the totality of publicly available scientific evidence, there is significant scientific agreement that there is a relationship between sodium and hypertension. There is also agreement that reductions in dietary sodium intake will provide a substantial public health benefit. Given the need to reduce sodium intake and the directive in the legislation that the information required in the nutrition label be conveyed to the public in a manner that enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet (section 2(b)(1)(A) of the 1990 amendments), FDA believes that a DRV for sodium is supported.

47. Some comments argued that there is no consensus regarding sodium recommendations, and that a DRV is therefore inappropriate. One comment stated that Canada provides no quantitative advice regarding sodium, and another noted that public health agencies do not agree among themselves about an appropriate recommendation. It was pointed out that the Joint National Committee (Ref. 49) described "moderate sodium intake" as 1,500 to 2,500 mg, while the Surgeon General's Report (Ref. 2) discussed a desirable range of 1,100 to 3,300 mg in noting that dietary intakes exceed this range, which was established as "safe and adequate" in the 9th edition of the NAS RDA publication (Ref. 36). The Dietary Guidelines for Americans (Ref. 5) recommend "moderation" but provide no quantitative values, while the 10th edition of the NAS RDA publication (Ref. 26) specifies a minimum intake of 500 mg but no maximum bound. The comment pointed out that the participants at the National Heart, Lung, and Blood Institute (NHLBI) Workshop held in 1989 (Ref. 50) expressed disparate views.

FDA is aware of these differences but believes that they are attributable to differences in the intended purposes of the recommendations and not necessarily to a lack of underlying agreement. In fact, these recommendations are usually expressed as a range that includes the 2,400 mg level proposed as the DRV.

The Surgeon General's Report (Ref. 2) cited the 9th edition of the NAS RDA publication (Ref. 36) that has been superseded by the more recent 10th edition (Ref. 26). The 10th edition of the NAS RDA publication identifies a minimum safe adult intake of 500 mg but also supports the level of 2,400 mg recommended in Diet and Health (Ref. 3). Diet and Health served as the basis for establishing the DRV for sodium.

The Joint National Committee (Ref. 49), in the context of hypertension detection and treatment, reported no serious adverse effects with moderate sodium restriction of 1,500 to 2,500 mg, which includes the 2,400 mg level used for the DRV. Finally, the NHLBI workshop (Ref. 50) was designed to explore current research topics and was not convened as a Federal government consensus panel, nor did it have the objective to identify a recommended intake.

Therefore, FDA believes that the level of 2,400 mg that is proposed as the DRV for sodium, and that is recommended in the major consensus report Diet and Health, is consistent with other recommendations and government reports and, thus, provides an appropriate basis for a DRV. The level of 2,400 mg is also well above the recommended minimum safe intake levels of 500 mg.

48. A few comments supported a DRV for sodium that is lower than the proposed 2,400 mg. One comment from a consumer stated that 2,400 mg seems too high. Two comments that preferred 1,800 mg argued that Diet and Health (Ref. 3) had recommended 2,400 mg as an "initial goal" and had stated that a level of 1,800 mg would probably confer greater health benefit. One of these comments supported the lower value as a way to better protect millions of Americans, especially older citizens, with hypertension.

FDA proposed a DRV for sodium of 2,400 mg based on the recommendation in Diet and Health. While this report does note that a lower value of 1,800 mg may confer greater benefit, the committee specifically recommended 2,400 mg sodium. This recommendation

was based not only on issues of health benefits but also took into consideration realistic diet modifications among American consumers. FDA, therefore, concludes that a DRV of 2,400 mg is consistent with the recommendation provided by Diet and Health. However, to guide consumers to the benefits of even lower levels, the agency is providing for the use of the phrase "less than" in the presentation of the DRV standard on the label. This label format provision is discussed in more detail in the Mandatory Nutrition Labeling final rule published elsewhere in this issue of the Federal Register.

49. Several comments favored a higher DRV for sodium. One comment supported 2,900 to 3,000 mg, suggesting that a reasonable interpretation of the guideline provided in the 10th edition of the NAS RDA publication (Ref. 26) was to add the recommended intake to the 500 mg minimum naturally occurring (2,400 mg + 500 mg). This approach would produce a DRV of 2,900 mg (rounded to 3,000 mg). The comment stated that this level would be more realistic than 2,400 mg. Two other comments favored the 3,000 mg level. One expressed support for the American Heart Association position which is that sodium intake should not exceed 3 g per day (Ref. 42), and another stated that 3,000 mg has been recommended by most reputable health and nutrition organizations. One comment supported 3,300 mg, and another suggested a DRV of no less than 3,500 mg for a 2,350 calorie diet. According to the comment, the latter value represented a one-quarter decrease in what the comment identified as the usual American dietary intake of 4 to 6 g of salt. The one-quarter reduction was identified as the moderate intake recommended by Dietary Guidelines (Ref. 5). Another comment supported 4,000 mg, noting that the DRV is considered by dietitians to be in the range of "low sodium" diets (less than 2,000 mg), and that the general public should not use a "low sodium" diet as a reference because consumers would wrongly believe that sodium intakes in excess of safe and adequate levels would be harmful. One comment suggested that a range from 500 to 4,600 mg would be preferable to a single value.

First, FDA does not agree that the committee responsible for the 1989 NAS RDA's intended that 2,400 mg sodium should be consumed in addition to the 500 mg identified as safe and adequate in the 10th edition of the NAS RDA publication (Ref. 26). The publication specifically states that "there is no known advantage in consuming large amounts of sodium" and references the recent NAS Diet and Health report (Ref. 3) which recommends that daily intakes of sodium chloride be limited to 2,400 mg of sodium or less. Further, FDA believes that a sodium DRV of 2,400 mg is not inconsistent with the current American Heart Association position that sodium intake should not exceed 3 g per day (Ref. 38). The agency notes that the written comments to this docket submitted by the American Heart Association did not object to the DRV of 2,400 mg for sodium (Ref. 51).

FDA remains unconvinced that there is any reason to establish a value that is higher than the 2,400 mg specified in Diet and Health. The suggested higher values are not consistently supported, whereas 2,400 mg is consistent with other Federal agency recommendations and with current public health agency policies to moderate or reduce sodium intake. Furthermore, the 2,400 mg level is a feasible goal because sodium in food is primarily present as added salt, and current dietary recommendations specify a moderate reduction that is large enough to produce significant decreases in intake while remaining well in excess of the minimum safe intake level of 500 mg specified in the 10th edition of the NAS RDA publication (Ref. 26).

50. The feasibility of achieving an intake approximating the proposed DRV of 2,400 mg of sodium was questioned by a few comments. These comments stated that the proposed DRV is not reasonable or practical, will be difficult to achieve, and will cause unnecessary frustration to consumers trying to meet the goal. One comment suggested that the proposed DRV is too restrictive for restaurant nutrition programs, which must be concerned with taste, affordability, and availability. To emphasize the difficulty of achieving daily sodium intakes of 2,400 mg, the comment referred to a recent review article on sodium intervention trials (Ref. 52) that found that daily intakes of 3,000 mg were only achievable with intensive, multifaceted interventions and highly motivated individuals. The article concluded that general population goals must be modest, or the food supply must change significantly.

FDA recognizes that the current sodium intake of many people exceeds the DRV level of 2,400 mg (56 FR 60825 at 60825), and that sodium is very prevalent in the food supply. However, the agency disagrees that intakes of 2,400 mg sodium are not feasible. Sodium is largely a discretionary addition to foods, usually as sodium chloride or table salt. In fact, estimates suggest that 90 percent of the sodium in foods is from added salt (Refs. 53 and 54) and thus can more easily be controlled by food processors and consumers than can substances in food that are naturally-occurring. Additionally, because reduced sodium intake is a recognized public health priority (Refs. 2, 3, and 5), the agency believes that it is appropriate to set the DRV at a level that is consistent with that goal and that will stimulate changes in the marketplace that are technologically feasible. Therefore, FDA is retaining the DRV of 2,400 mg for sodium (proposed as § 101.9(c)(12)(i) and redesignated below as § 101.9(c)(9)).

51. One comment suggested that the statement in FDA's proposal that the "majority of the current dietary intake of sodium results from ingestion of sodium chloride" contradicts a previous FDA statement that a substantial amount of sodium comes from nonsalt sources. The comment did not identify the FDA statements to which it was referring.

This comment infers that "substantial" and "majority" are synonymous. FDA disagrees with this comment. A dictionary definition (Ref. 55) for the word "substantial" characterizes the word as meaning of ample or considerable amount, quantity, size, etc., or of real worth, value, or effect. It does not define "substantial" as "majority." In its proposal on RDI's and DRV's, the agency referenced a statement from Diet and Health (Ref. 3) that the majority of sodium intake is from sodium chloride. This statement is not inconsistent with the agency's 1982 findings (47 FR 26590) that nonsalt sources can also provide meaningful, important, or "substantial" contributions to the diet.

M. DRV for Potassium

52. One comment suggested that the DRV's should be limited to those dietary components that are the subject of dietary guidelines. It highlighted the establishment of a DRV for potassium as scientifically unjustifiable.

As described in the proposal to this final rule, FDA has used major consensus reports in developing the DRV's. Among these is the well recognized and accepted Diet and Health (Ref. 3), published by NAS. This report specifically recommends a quantitative intake of potassium to assist in reducing the risk of stroke. FDA does not find compelling the comment's argument that, because potassium is not specifically listed in Dietary Guidelines for Americans (Ref. 5), a DRV is not justified. The Dietary Guidelines are intended to provide general food guidance and do not necessarily specify recommended intakes for individual nutrients. The agency notes that no

other comments were received expressing concern about this DRV. The agency is, therefore, retaining the DRV for potassium (3,500 mg).

Additionally, for completeness, FDA is including the listing of potassium based on its DRV value in §§ 101.3(e)(4)(ii) and 104.20(c)(1) and (d)(3).

VI. Conforming Amendments

53. One comment expressed concern that the proposed RDI's will have implications for all alternative products (e.g., reduced fat) formulated to achieve nutritional equivalency to their traditional counterparts. According to the comment, a traditional product containing nutrient levels at less than the 2 percent U.S. RDA criterion, and thus not requiring fortification of the analog, could now meet a 2 percent RDI criterion and thus fortification of the analog would be required. For example, a typical dressing contains 1.88 percent of the U.S. RDA for vitamin E. Because this amount is less than the 2 percent U.S. RDA criterion, fortification of an analog product is not required. However, under the proposed RDI's, the traditional product would contain 4.58 percent of the RDI for vitamin E, requiring fortification in an analog product if the analog did not contain this level of the nutrient. The comment questioned whether the agency intended expanded fortification of analog products with introduction of new RDI's, because the agency had failed to address identity labeling of food in packaged form (§ 101.3(e)), particularly where the definition of "nutritional inferiority" is concerned.

The agency acknowledges that the levels of nutrients chosen as the RDI's will have an effect on achieving nutritional equivalency for all alternative products formulated to be substitutes for traditional products. However, FDA believes that the levels of the RDI should not be established or influenced by the effect that they will have on how nutritional equivalency is achieved in the formulation of alternative products. Rather, they should be based on sound public health principles. FDA established the 2 percent threshold for achieving nutritional equivalency (§ 101.3(e)) because that level is a measurable amount of most nutrients in a food. The adjustment of the RDI's upward, consistent with the population coverage approach, would however limit the number of situations in which nutrient levels in traditional products were below the threshold for some U.S. RDA's but are above that threshold with respect to the RDI's.

54. One comment suggested that vitamin K, molybdenum, and chloride be removed from the list of nutrients required to meet nutritional equivalency (proposed § 101.9(c)(11)(iv) and redesignated as § 101.9(c)(8)(iv)), and that FDA should include a clear statement in § 101.3(e) that selenium, fluoride, and chromium are not to be considered for nutritional equivalency purposes. According to the comment, these nutrients are of little health significance for the general healthy population.

The agency acknowledges that an increase in the number of nutrients for which label reference values (RDI's) are established would mean that efforts to obtain nutritional equivalency may require the addition of additional nutrients to substitute foods. Furthermore, the agency agrees that some of these nutrients are not considered to be of public health interest. However, any change in what constitutes nutritional equivalency would require a reevaluation of § 101.3(e), which is beyond the scope of the 1990 amendments.

However, the agency recognizes that at this time there are no listed sources (i.e., GRAS or approved food additive) for selenium, molybdenum, fluoride, and chromium. In its proposal to this final rule, the agency failed to identify molybdenum as a nutrient without a listed source. However, despite no known issues of safety, the agency believes that it would be inappropriate to include molybdenum on a list of nutrients to be added to a food for nutritional equivalency when there are no listed sources for molybdenum. Therefore, FDA would have amended § 101.3(e)(4)(ii) to state that these elements are not required for nutritional equivalency.

However, based on the provisions of the DS Act, FDA is retaining, for the time being, the label reference values as established in current § 101.9(c)(7)(iv). Because there are no label reference values for the nutrients mentioned in the comments (i.e., vitamin K, molybdenum, chloride, selenium, fluoride, and chromium), there is no need to revise § 101.3(e)(4)(ii) to specifically exclude these nutrients. Therefore, § 101.3(e)(4)(ii) is amended to be consistent with these final regulations by referring to the Daily Reference Values (DRV's) of protein in § 101.9(c)(7)(iii) and of potassium in § 101.9(c)(9) and to the Reference Daily Intakes (RDI's) of vitamins and minerals in § 101.9(c)(8)(iv). FDA will reach a final decision on the other issues discussed in this comment following the provisions of the DS Act.

VII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the proposed rule on reference daily intakes and daily reference values and mandatory nutrition labeling (56 FR 60366, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, nutrition labeling proposed rule, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided not to make the final rule effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human

environment is expected and that an environmental impact statement is not required.

VIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 104

Food grades and standards, Frozen foods, Nutrition.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101 and 104 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.3 is amended by revising paragraph (e)(4)(ii) to read as follows:

§ 101.3 Identity labeling of food in packaged form.

* * * * *

(e) * * *

(4) * * *

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the Daily Reference Value (DRV) of protein listed under § 101.9(c)(7)(iii) and of potassium listed under § 101.9(c)(9) and the Reference Daily Intake (RDI) of any vitamin or mineral listed under § 101.9(c)(8)(iv).

* * * * *

3. Section 101.9 is amended by adding paragraphs (c)(7)(iii), (c)(8)(iv), and (c)(9) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(7) * * *

(iii) For the purpose of labeling with a percent of the Daily Reference Value (DRV) or RDI, a value of 50 grams of protein shall be the DRV for adults and children 4 or more years of age, and the RDI for protein for children less than 4 years of age, infants, pregnant women, and lactating women shall be 16 grams, 14 grams, 60 grams, and 65 grams, respectively.

* * * * *

(8) * * *

(iv) The following RDI's and nomenclature are established for the following vitamins and minerals which are essential in human nutrition:

Vitamin A, 5,000 International Units.
Vitamin C, 60 milligrams.
Thiamin, 1.5 milligrams.
Riboflavin, 1.7 milligrams.
Niacin, 20 milligrams.
Calcium, 1.0 gram.
Iron, 18 milligrams.
Vitamin D, 400 International Units.
Vitamin E, 30 International Units.
Vitamin B_6, 2.0 milligrams.
Folic acid, 0.4 milligrams.
Vitamin B_{12}, 6 micrograms.
Phosphorus, 1.0 gram.
Iodine, 150 micrograms.
Magnesium, 400 milligrams.
Zinc, 15 milligrams.
Copper, 2 milligrams.
Biotin, 0.3 milligram.
Pantothenic acid, 10 milligrams.

(9) For the purpose of labeling with a percent of the DRV, the following DRV's are established for the following food components based on the reference caloric intake of 2,000 calories:

Food component	Unit of measurement	DRV
Fat	gram (g)	65
Saturated fatty acids	do	20
Cholesterol	milligrams (mg)	300
Total carbohydrate	grams (g)	300
Fiber	do	25
Sodium	milligrams (mg)	2,400
Potassium	do	3,500
Protein	grams (g)	50

* * * * *

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

4. The authority citation for 21 CFR part 104 continues to read as follows:

Authority: Secs. 201, 403, 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371(a)).

5. Section 104.20 is amended in paragraph (a) by removing "U.S. RDA's" the two times it appears and replacing it with "Reference Daily Intakes (RDI's)" and "RDI's", respectively, and by revising paragraphs (c)(1) and (d)(3) to read as follows:

§ 104.20 Statement of purpose.

* * * * *

(c) * * *

(1) The nutrient is shown by adequate scientific documentation to have been lost in storage, handling, or processing in a measurable amount equal to at least 2 percent of the Daily Reference Value (DRV) of protein and of potassium and 2 percent of the Reference Daily Intake (RDI) in a normal serving of the food.

* * * * *

(d) * * *

(3) The food contains all of the following nutrients per 100 calories based on 2,000 calorie total intake as a daily standard:

Nutrient	Unit of measurement	DRV or RDI[1]	Amount per 100 calories
Protein	grams (g)	50	2.5
Vitamin A	International Unit (IU)	5,000	250
Vitamin C	milligrams (mg)	60	3
Calcium	g	1	0.05
Iron	mg	18	0.9
Vitamin D	IU	400	20
Vitamin E	do	30	1.5
Thiamin	mg	1.5	0.06
Riboflavin	do	1.7	0.09
Niacin	do	20	1
Vitamin B_6	do	2.0	0.1
Folate	micrograms (μg)	400	20
Vitamin B_{12}	do	6.0	0.3
Biotin	mg	0.3	0.015
Pantothenic acid	do	10	0.5
Phosphorus	g	1.0	0.05
Magnesium	mg	400	20
Zinc	do	15	0.8
Iodine	μg	150	7.5
Copper	mg	2.0	0.1
Potassium	do	3,500	175

[1] RDI's for adults and children 4 or more years of age.

Dated: October 29, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31502 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 90N-0165]

RIN 0905-AD08

Food Labeling; Serving Sizes

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its nutrition labeling regulations to: (1) Define serving size on the basis of the amount of food customarily consumed per eating occasion; (2) establish reference amounts customarily consumed per eating occasion (reference amounts) for 139 food product categories; (3) provide criteria for determining label serving sizes from the reference amounts; (4) require the use of both common household and metric measures to declare serving sizes; (5) define a "single-serving container;" (6) require that the use of claims such as "low sodium" be based on the reference amount; (7) permit the declaration of serving size in U.S. measures (ounces (oz), fluid ounces (fl oz)); and (8) permit the optional declaration of nutrient content per 100 grams (g) or 100 milliliters (mL). This action is in response to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Youngmee K. Park, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5489.

SUPPLEMENTARY INFORMATION:

I. Background

A. Proposed Regulation, Nutrition Labeling and Education Act of 1990, and Institute of Medicine's Report on Nutrition Labeling

In the **Federal Register** of July 19, 1990 (55 FR 29487), FDA published a proposed rule entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" to amend its food labeling regulations to require nutrition labeling on most food products that are meaningful sources of nutrients. In the same issue of the **Federal Register** (55 FR 29517), FDA published a technical supporting proposal entitled "Food Labeling; Serving Sizes" (hereinafter referred to as the 1990 proposal).

The 1990 proposal on serving sizes stated that in view of the many comments that the agency had received stating the need for more realistic and consistent serving sizes, FDA had concluded that reasonable and standardized serving sizes should be established. The agency proposed to amend the nutrition labeling regulations to: (1) Define serving and portion size on the basis of the amount of food commonly consumed per eating occasion by persons 4 years of age or older, by infants, or by children under 4 years of age (toddlers); (2) require the use of both U.S. and metric measures to declare serving size; (3) permit the declaration of serving (portion) size in familiar household measures; (4) permit the optional declaration of nutrient content per 100 g or 100 mL; (5) define "single-serving containers" as those that contain 150 percent or less of the standard serving size for the food product; and (6) establish standard serving sizes for 159 food product categories to ensure reasonable and uniform serving sizes upon which consumers can make nutrition comparisons among food products. Interested persons were given until November 16, 1990, to submit comments to the agency on the 1990 proposal.

On September 26, 1990, the National Academy of Sciences' Institute of Medicine (IOM) issued a report entitled "Nutrition Labeling, Issues and Directions for the 1990s" (hereinafter referred to as the IOM Report) (Ref. 1). The IOM report was written under contract to the Public Health Service, U.S. Department of Health and Human Services (DHHS) and the Food Safety and Inspection Service, U.S. Department of Agriculture (USDA). On October 5, 1990, FDA published a notice in the **Federal Register** (55 FR 40944) announcing the availability of the IOM report and requesting that interested persons comment on the implications of the report for the agency's July 19, 1990, proposals on food labeling. The report made several recommendations related to serving sizes.

On November 8, 1990, the President signed into law the 1990 amendments (Pub. L. 101-535). The 1990 amendments added section 403(q) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)). Section 403(q) of the act specifies, in part, that:

> * * * the serving size * * * is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or * * * if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food.

The 1990 amendments also require, in section 2(b)(1)(B), that FDA adopt regulations that: "* * * establish standards * * * to define serving size or other unit of measure for food, * * *."

While the requirements of the 1990 amendments that pertain to serving size are similar in many respects to FDA's 1990 proposal, differences exist, and questions about the exact meaning and the implementation of those provisions have been raised.

On February 26, 1991 (56 FR 8084), FDA announced a public meeting to discuss several issues arising from the comments on the serving size proposal, the 1990 amendments, and the IOM report. The meeting was held on April 4, 1991 (hereinafter referred to as the 1991 public meeting), and provided an opportunity for the public to submit oral and written comments on the issues identified in the notice.

B. The 1991 Serving Size Regulation

FDA carefully considered the serving size provisions of the 1990 amendments, the comments that it received in response to the **Federal Register** documents on serving size and at the 1991 public meeting, and the recommendations related to serving size contained in the IOM report. As a result, the agency decided to repropose the serving size regulation for two major reasons. First, FDA wished to take advantage of the explicit legal authority provided by the 1990 amendments to regulate the serving sizes used on the nutrition label. Secondly, the agency decided to make a number of changes in response to the comments received on the **Federal Register** documents and at the public meeting on serving sizes and to explain its reasons for agreeing or not agreeing with the comments.

To implement the 1990 amendments, FDA issued a proposed rule in the **Federal Register** of November 27, 1991 (56 FR 60394; corrected at 57 FR 8179, March 6, 1992) (hereinafter referred to as the 1991 serving size proposal). In that document, FDA proposed to: (1) Modify the definition of serving size in the 1990 proposal to be consistent with that in the 1990 amendments; (2) adopt regulations that provide standards for defining serving sizes; and (3) require the use of both common household and metric measures to declare serving sizes. The proposed standards had two basic elements: (1) Reference amounts of food that are customarily consumed per eating occasion for 131 product categories; and (2) procedures for determining serving sizes for use on

product labels from the reference amounts. The second element was necessary because while the reference amounts are defined primarily in metric units, under the act the serving sizes must be expressed in common household measures that are appropriate to the particular food.

In addition, in response to the many requests for changes in other aspects of the 1990 proposal and on its own initiative, the agency proposed to: (1) Revise the definition for single-serving containers to increase the upper limit from "150 percent or less" to "less than 200 percent;" (2) revise the basis for evaluating label claims such as "low sodium" to include both the declared serving size and the reference amount; (3) permit the optional declaration of serving size in U.S. measures; and (4) permit the optional declaration of nutrient content per 100 g, 100 mL, 1 oz, or 1 fl oz. Interested persons were given until February 25, 1992, to submit comments to the agency on the 1991 serving size proposal.

On January 3, 1992 (57 FR 239), FDA announced a public hearing to discuss all of the agency's proposed food labeling regulations that implement the 1990 amendments. The hearing was held on January 30 and 31, 1992 (hereinafter referred to as the 1992 public hearing). Some of the presentations and written comments submitted in response to this hearing discussed issues related to serving sizes.

This final rule responds to the written comments received on the 1991 serving size proposal and the written comments and presentations given at the 1992 public hearing on issues related to serving sizes.

II. Review of Comments

FDA received about 700 comments on the 1991 serving size proposal. Approximately 50 percent were from domestic food industries and trade organizations; about 35 percent were from consumers and consumer organizations; about 10 percent were from health professionals, health and other professional organizations, and academia; about 5 percent were from Federal, State, and local government; and less than 1 percent was from foreign industries and governments.

About 20 oral presentations at the 1992 public hearing discussed issues related to serving sizes. A written transcript of the meeting is on file with Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. FDA also received written comments that discussed issues related to serving sizes in response to the notice of the public hearing. Issues discussed at the hearing mostly reiterated the issues discussed in written comments on the 1991 serving size proposal. Therefore, a separate evaluation has not been done for the comments received in response to the 1992 public hearing. FDA will respond to these comments together with all comments received in response to the 1991 serving size proposal.

Consumers overwhelmingly supported the provisions in the 1991 serving size proposal and again emphasized the need for realistic and standardized serving sizes. Health professionals and nutritional or health professional organizations generally supported the provisions in the 1991 serving size proposal. Many industry and trade associations supported the general approach that FDA took in the 1991 serving size proposal. However, they often disagreed with specific aspects of the procedures used to determine reference amounts, specific reference amounts, or some other specific aspects of the 1991 serving size proposal. International comments again emphasized the need for international harmonization of food labeling (e.g., these comments usually recommended the use of 100 g (or mL) as the basis for the nutrition information).

The agency will describe the comments on serving sizes in more detail and respond to them by topic in the discussion of the final regulation that follows.

III. The Final Regulation

A. Legal Authority

1. A manufacturer contended that the 1990 amendments did not mandate that FDA establish, by regulation, specific serving sizes for each food. The comment objected to FDA taking away its right to set serving sizes within the broad parameters of being reasonable, fair, and consistent. The comment stated that the 1990 amendments authorized FDA to establish standards or guides that the manufacturer must follow when the manufacturer sets the specific serving size. A trade association stated that FDA's proposed "device" of reference amounts does not qualify as standards because when reference amounts are applied using the proposed procedures, they amount to specific serving sizes. Another industry comment stated that some reference amounts were expressed in common household measures (e.g., cups, tablespoon (tbsp.)), and therefore, label serving sizes in common household measures will be the same as the reference amount. This, the comment argued, disqualifies these reference amounts from being standards.

FDA disagrees with the comments. First, FDA did not establish "specific serving sizes" for each food. The agency established a system that consists of the two basic elements described above. A manufacturer uses these elements to determine the serving size most appropriate for specific products. The fact that a manufacturer has relatively limited discretion within that system does not represent an infirmity in the system. Section 403(q)(1)(A)(i) of the act establishes the fundamental principle for determining serving size. This principle is much more specific than as one comment suggested, that the amount be reasonable, fair, and consistent. The act requires that the serving size be an amount of the food that is customarily consumed.

The legislative history in section 2(b)(1)(B) of the 1990 amendments is silent as to what type of standards that Congress contemplated in that section. It merely directs the agency to establish them (H. Rept. 101–538, 101st Congress, 2d sess. 18 (1990)). (See also the House report at page 7: "In order to make this information meaningful, the bill requires the FDA to issue standards providing that uniform serving size information and information concerning the number of servings be furnished on the food label." Thus, the question as to whether the standards that FDA proposed are adequate and consistent with the act really becomes a question of whether the serving size that results from applying that standard represents an amount customarily consumed. Significantly, none of these comments claimed that it does not. Consequently FDA concludes that the two element system that it proposed in the 1991 serving size proposal constitutes a standard for determining serving sizes that is consistent with the act.

2. An industry comment stated that the 1990 amendments give FDA the legal authority to use any unit of measure (not necessarily a serving based on customarily consumed amounts) that it deems most appropriate for expressing the nutrient content of foods. The comment stated that food consumption surveys, such as the Nationwide Food Consumption Survey (NFCS) conducted by USDA, do not provide "real" consumption values, because there are too many varieties of different foods, different uses of the same foods, different foods for the same use, and other variables, and because there is too much diversity in individual consumption to establish any sort of meaningful or representative consumption standard. The comment

asserted that as long as competitive products are given the same serving size value, it is not that important whether there is valid supporting data. The comment recommended the use of "reference nutrition units" that would eliminate the idea that the serving size represents what people really eat. Under the system suggested by this comment, all foods would be given a reference point that represents a reasonable quantity of food for a given category, and all competitive foods would be given the same reference point.

FDA disagrees with the comment that the 1990 amendments allow the agency to use any unit of measure that it deems most appropriate for expressing the nutrient content of foods. Section 403(q)(1)(A)(i) of the act clearly defines serving size as an amount of food customarily consumed. As discussed in the 1991 serving size proposal (56 FR 60394 at 60400), FDA is well aware of the high variability in the amounts customarily consumed by individuals, as well as other factors such as many different uses of the same food and many different foods for the same use. These issues complicate the process for determining reference amounts. However, FDA continues to believe that by using data from national food consumption surveys, such as the NFCS, and by following the principles and procedures that it described in the 1991 serving size proposal, a reasonable reference amount that represents the amount of food customarily consumed within each product category can be determined for the major usage of the food.

FDA also disagrees with the comment that stated that as long as competitive products are given the same serving size value, valid supporting data are not important. FDA does not believe that the only intent of the 1990 amendments is to establish the same serving size for competitive products. FDA believes that the intent is also to ensure that nutrition information will be based on a meaningful quantity of food, the amount customarily consumed. Competitive foods often differ in characteristics (e.g., density) that affect the amount customarily consumed. For example, ready-to-eat breakfast cereals compete with one another, but their densities (g per cup) differ widely, from less than 20 g per cup to over 120 g per cup. Food consumption data show that the amount customarily consumed depends on the density of the cereal. Therefore, the same serving size should not be used for all ready-to-eat breakfast cereals. In this case using the same serving sizes for competitive products could be misleading to consumers.

B. Definition of Serving Size

In accordance with the 1990 amendments, FDA proposed in § 101.9(b)(1) to define "serving" or "serving size" to mean:

> an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

In the same section, FDA proposed to define "portion" to mean "an amount of a food that is not typically expressed in a serving size, i.e., a food customarily used only as an ingredient in the preparation of other foods, (e.g., 1/4 cup flour or 1/4 cup tomato sauce)."

Over 75 percent of the approximately 80 comments that addressed the definition of serving size agreed with FDA's proposal for the definition of serving size. These comments pointed out that the act explicitly states that the serving size shall be an amount customarily consumed in terms of a common household measure appropriate to the food, and that thus FDA's proposed definition is consistent with the requirements of the act. Approximately 25 percent of the comments received on this issue disagreed with FDA's proposal. The reasons for the disagreement, and the definitions suggested in these comments, are discussed below.

3. Several comments stated that FDA should use the serving sizes in the diabetic exchange list as the serving sizes for nutrition labeling of food because they are already in use, and because people are familiar with the serving size contained in the exchange list.

FDA disagrees with these comments. Section 403(q)(1)(A)(i) of the act defines serving size as "an amount customarily consumed." Thus, the act links serving size to the amount consumed. Serving sizes contained in the diabetic exchange list are not based on amounts customarily consumed by the American public. They are tailored to meet a special dietary need of a subpopulation that has a unique health problem. They are inappropriate to use as serving sizes for the nutrition labeling of products for the general population because the serving sizes for a population with a medical problem do not necessarily reflect the consumption practices of the general healthy population. For example, to facilitate achievement of medical goals of this subpopulation, the serving sizes in the exchange lists are based on the calorie content and the energy-producing macronutrient content of specific foods and may not, as required by the act, reflect amounts of food customarily consumed by average consumers. The 1991 serving size proposal discussed in detail the reasons why FDA cannot use the serving sizes contained in the diabetic exchange list for the nutrition labeling of food (56 FR 60394 at 60399). None of the comments provided any basis for finding that that discussion was wrong. Therefore, FDA has not modified the definition of "serving size" in response to these comments.

4. International comments and several U.S. manufacturers opposed nutrition information based on serving sizes. Some pointed out that the European Community directive requires that all nutrition information be on a 100 g or 100 mL basis. The comments argued that requiring nutrition information on a per serving basis offers little consistency with nutrition labeling in other countries and creates a significant trade barrier.

FDA recognizes that many foreign countries use 100 g or 100 mL as the basis for nutrition labeling. However, the act requires that the nutrition information be provided on a per serving basis. The act also defines serving size as an amount customarily consumed which is expressed in a common household measure that is appropriate to the food. The 100 g or 100 mL does not represent an amount customarily consumed for many foods. In addition, g and mL are not common household measures in the United States. Therefore, FDA cannot use 100 g or 100 mL as the basis for the primary serving size. However, partly to facilitate the utility of the serving size in the international community, FDA is requiring in new § 101.9(b)(7) that the equivalent metric quantity be declared on the label in addition to the serving size in a common household measure and is permitting, in new § 101.9(b)(10)(i), a voluntary listing of a second column of values on a per 100 g or 100 mL basis.

5. Several industry and consumer comments suggested using 1 oz for the serving size rather than customarily consumed amounts. The comments contended that: (1) A uniform 1-oz serving size allows nutrition comparisons of all foods; (2) nutrition information per oz allows calculation of the nutrient content of food per serving of an individual's choice; and (3) the word "serving" is confusing and should be eliminated. Another consumer comment argued that few people

measure out a serving of a product as noted on packages. Most people just pour an amount that they feel is reasonable or desirable. Therefore, it is not necessary to have standard serving sizes. Rather, FDA should use 1 oz as the basis for nutrition information.

As discussed above, section 403(q)(1)(A)(i) of the act requires that serving sizes be in amounts customarily consumed. Because 1 oz is not an amount customarily consumed for many products, FDA cannot use 1 oz as the basis for nutrition information for all products.

6. Some consumer comments suggested defining serving size as the amount consumed by adult females. The comments stated that females need smaller amounts of food to maintain good nutrition and health. The comments were concerned that if serving sizes are based on the amount consumed by adult males, the quantity will be too large for females. Another consumer comment suggested that FDA define serving size as the amount consumed by a "middle consumption group between youth and men." The comment contended that if the serving size is set at a middle consumption level, it would be "easier to decrease for youth and increase for men."

FDA believes that these comments misunderstand the purpose of a serving size on product labels. The serving size declared on the product label is not an amount recommended for consumption. It is, by statute, the amount customarily consumed. FDA believes that promoting recommended servings can best be addressed through public education. The agency's promulgation of nutrition labeling regulations will be followed by a consumer education program to assist consumers in using the nutrition information on the label, including how nutrition information based on labeled serving size should be adjusted on the basis of an individual's actual or recommended serving size. FDA is currently planning for these activities.

The general food supply is consumed by the general population which is defined, for regulatory purposes, as all persons 4 years of age or older. Therefore, serving sizes should reflect the amounts customarily consumed by the general population and not by any selected age or sex group (e.g., adult male or female) within the general population.

7. An industry comment stated that the phrase "per eating occasion" should be deleted from the definition of serving size because small amounts of food consumed, such as for tasting during food preparation, could be counted as an eating occasion.

FDA does not believe that the issue raised by this comment presents a problem. The term "eating occasion" in food consumption surveys usually refers to meals and snacks. Even if the small amounts of food consumed during tasting are included in determining the amount of food customarily consumed per eating occasion, the general principles and factors (e.g., use of the mean, median, and modal consumed amount per eating occasion) considered by FDA in arriving at the reference amounts ensure that such infrequently reported small amounts would not affect the determination of the amount customarily consumed per eating occasion. Furthermore, deletion of the term "per eating occasion" would leave the definition of serving size open-ended, which would likely result in more inconsistencies among serving sizes. Therefore, FDA is retaining the term "per eating occasion" as part of the definition for serving size.

8. A consumer comment stated that because different units are used for serving size (e.g., oz, tbsp.) and nutrition information (e.g., g), the current nutrition information is not useful to estimate the percent of a nutrient (e.g., fat) in the product. The comment stated that expressing both serving size and nutrition information in g would facilitate computation of the percentage of a nutrient in the product. The comment, therefore, suggested that FDA mandate that the nutrition information of all products be provided on a per 100-g basis, instead of common household measures.

FDA understands the consumers' desire for information on the percentage of fat in the product. However, the act mandates that the primary unit for the serving size should be a common household measure that is most appropriate to the specific product. Therefore, serving sizes will continue to be expressed in common household measures (e.g., cups, tbsp., oz). However, FDA notes that it is also requiring metric equivalents of the household measures (e.g., 1 cup (55 g)). Therefore, nutrition information on a per 100-g basis is not necessary to facilitate such computation. Consumers who desire information on the percentage of a nutrient in the product should be able to calculate this number from the metric equivalent of the serving size and the amount of the nutrient, expressed in g.

9. A trade association stated that industry makes no distinction between the terms "serving" and "portion." The comment contended that FDA's definition is not consistent with the industry's usage of "portion." Limiting the term "portion" for use with products that are used primarily as ingredients (e.g., flour, tomato sauce) creates more confusion in terminology and contributes nothing to nutrition labeling.

FDA agrees with this comment. Because foods such as flour and tomato sauce are not served by themselves but as part of other foods, conceptually the term "serving" may not be as appropriate as the term "portion" as defined in the 1991 serving size proposal. However, FDA acknowledges that many manufacturers use "serving" and "portion" interchangeably. These terms are also used interchangeably in the literature (Ref. 37). FDA also recognizes that consumers are not likely to distinguish between the two terms, and that the use of two different terms on the label could be confusing. For these reasons, FDA is deleting the definition of "portion" from new § 101.9(b)(1).

C. Definition of Single-Serving Container

FDA proposed in § 101.9(b)(6) to define a single-serving container as a product that is packaged and sold individually containing less than 200 percent of the applicable reference amount. (Section 101.9(b)(6) of the 1991 serving size proposal had a typographical error and stated "packaged or sold individually" instead of "packaged and sold individually.") The agency proposed to require that the entire content of such products be labeled as one serving. In addition, the agency proposed that packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single eating occasion.

FDA received many comments on issues related to the definition of a single-serving container. About half of the comments agreed with the proposed definition. The other half, mostly industry comments, opposed or had reservations on some aspects of the proposed definition.

10. The majority of the comments disagreeing with the proposal objected to the proposed upper limit of "less than 200 percent." These comments argued that FDA provided insufficient reasons for increasing the upper limit from 150 percent to 200 percent of the reference amount, placing considerable importance on a few new single-serving products, such as buffet cans of canned fruit with pop-tops and king-sized candy bars. The comments stated that FDA ignored many other products on

the market for which the 200 percent cutoff level would be unreasonably high. Examples given included 6 oz cans of tuna, 10 oz cans of canned fruits, 9 oz cans of canned vegetables, and 15 to 16 oz cans of ready-to-serve soup or entrees (e.g., chili with beans, spaghetti). These comments recommended that the upper limit be lowered to 150 percent of the reference amount. Several other comments recommended that FDA allow manufacturers to decide whether a package containing 150 to 200 percent of the reference amount is a single serving.

FDA originally proposed 150 percent of the standard serving size (equivalent to the reference amount in the 1991 serving size proposal) for the upper limit (55 FR 29487, July 19, 1990). Several comments and presentations at the 1991 public meeting on serving sizes argued that single-serving packages that are larger than 150 percent of the "standard serving sizes" are not uncommon in the market and may be increasing in number. The agency had also learned, from its own observations in the marketplace, of a trend towards larger "single-serving" packages (e.g., snacks). Therefore, in the 1991 serving size proposal, FDA proposed to change the upper limit for the single-serving container from "less than or equal to 150 percent" to "less than 200 percent."

After careful examination of all comments for and against the 200 percent upper limit, the agency concludes that 200 percent of the reference amount is a more reasonable cutoff level for most products than 150 percent. If FDA lowered the upper limit for single-serving containers to 150 percent of the reference amount as the comments suggested, many foods that are clearly intended for one serving (e.g., 1.8 oz snacks, 1.7 oz candy bars) could be labeled as 2 servings. The agency does not believe that such a result would represent the amount that people customarily consume; therefore, representing such foods as two servings would be confusing and misleading to consumers.

However, FDA agrees with the comments that the 200 percent cutoff level may be too high for some products (e.g., canned fruits and vegetables, soups, and entrees). The reference amounts of these products are very large compared to many other products, and examination of food consumption data showed that the average variability (defined as the standard deviation as a percent of the mean) in the amount customarily consumed for foods having a reference amount of 100 g (or mL) or larger is about two-thirds of the variability for foods having a reference amount less than 100 g (Ref. 38). In other words, it is much less likely that a person will consume approximately twice the reference amount of a food with a reference amount of 100 g or more than it is that he or she would consume twice the reference amount of a food with a smaller reference amount. The agency has therefore concluded that for those products that have reference amounts of 100 g (or mL) or larger, 150 percent is a more reasonable cutoff for a single-serving container. Therefore, FDA is revising § 101.9(b)(6) to allow manufacturers to determine whether there are 1 or 2 servings in packages that contain more than 150 percent but less than 200 percent of the reference amount if the food in the package has a reference amount of 100 g (or mL) or larger.

The agency, however, also concludes that regardless of the package size, a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as "singles" or "the perfect size for one") must be labeled as one serving. Otherwise, the labeling will be misleading under section 403(a) of the act.

11. An organization of nutrition professionals recommended changing the upper limit for single-serving containers to include 200 percent of the reference amount, so that 16 fl oz soft drinks would be required to be labeled as one serving. An organization of health professionals urged FDA to require that snack foods provide nutrition information for the entire contents of the package, regardless of the declared serving size. The organization stated that such a requirement would reflect "more accurately consumption patterns for these products."

FDA does not believe that it is appropriate to change the definition of a single-serving container so that certain sizes of a selected class of products can be labeled as a single serving or to set a different requirement for a selected class of products without food consumption data or a scientifically sound basis that supports such a different requirement. The comments did not present any food consumption data or other scientific basis that would justify the suggested changes in the definition of single-serving containers. Therefore, FDA has not adopted these recommendations.

12. Several industry comments requested that the definition of a single-serving container be eliminated, and that nutrition information on all containers be based on the reference amount. The comments requested that the agency, if it chooses to retain the single-serving container definition, allow dual labeling of nutritional values for single-serving containers (i.e., per reference amount and per entire contents of the container). The comments expressed concern that the single-serving container definition would result in different nutrition information on the labels of the same food product found in different sized containers. The comments argued that: (1) Consumers would be confused by such information, and (2) consumers would not be able to compare nutritional values of different brands of the same food because they come in different single-serving sizes. Therefore, these comments contended that FDA should allow manufacturers to voluntarily provide a second column of values based on the reference amount. A few of the comments that supported dual labeling also preferred that the required nutrition information be based on the reference amount, not on the entire contents of the container. However, a large number of consumers requested that FDA require that nutrition information on single-serving products be provided for the entire contents of the container.

FDA recognizes that the proposed rule could result in different nutritional values appearing on the labels of the same food product contained in different container sizes. Whether this would be confusing to consumers was discussed at the 1991 public meeting. In the notice of public meeting, the agency specifically requested views and data on whether differences in the listing of the nutritioal content of the same food in different container sizes would be confusing to consumers. No data on this issue were presented at the meeting or in written comments. Comments on the 1991 serving size proposal again claimed that different nutrition information on the same food found in different-sized containers would be confusing to consumers. However, the comments did not submit any data to support their claim. Considering the strong consumer support for the nutrition information based on the entire contents of the container, and in the absence of any data showing that the nutrition information based on the entire contents of the container would be confusing to consumers, the agency has concluded that the definition of single-serving container should be retained, and that nutrition information

of the single-serving containers should be based on the entire contents of the container.

With regard to the requests for dual labeling of single-serving containers, the agency does not believe that it is appropriate under the act. Because, by definition, a single-serving container has a number of servings of 1, nutrition information based on the reference amount would have a fractional number of servings (e.g., 1.4 servings). Consumers repeatedly complained about fractional number of servings on a single-serving container and asked that FDA require manufacturers to provide nutrition information based on the entire contents of the single-serving containers. Thus, there is strong evidence in the record to conclude that presenting a second column of nutrition information based on the reference amount on the single-serving containers will be confusing to consumers. The agency also notes that such information will clutter the label on the already limited space devoted to nutrition labeling. In considering whether to grant this request, FDA considered permitting dual labeling with the number of servings left blank. However, such labeling would fail to include a material fact—how many servings are being provided. Thus, such an approach is not acceptable under the act. Therefore, for these reasons, FDA is rejecting this request.

13. A manufacturer expressed confusion about the definition of single-serving containers. While the preamble of the 1991 serving size proposal specifically stated that no lower limit for the definition of a single-serving container is being established, proposed § 101.9(b)(2)(i) stated, "If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, serving size shall be one unit." The comment interpreted this provision to mean that the lower limit for single-serving containers is 67 percent of the reference amount. The comment also requested clarification on how to label single-serving containers that contain less than 100 percent of the reference amount.

The comment confused a single-serving unit of products in discrete units (e.g., muffin, sliced bread, apple) in a multiunit, and thus multiserving, container with a single-serving container. For products in discrete units that come in multiserving containers, new § 101.9(b)(2)(i) describes the procedure to convert the reference amounts in new § 101.12(b) to label serving sizes in common household measures. Products in discrete units come in many different sizes. To promote uniformity in the serving sizes of similar products, FDA proposed in the 1991 serving size proposal that a unit that weighs at least 67 percent or more, but less than 200 percent, of the reference amount be called a single-serving unit. (The lower limit of the single-serving unit in the final regulation has been changed from 67 percent or more to more than 50 percent (see section III.E.1. of this document).) This provision (new § 101.9(b)(2)(i)) applies to products in discrete units that come in multiserving packages (e.g., sliced products, small candy bars), but it does not apply to single-serving containers.

A single-serving container is a product that is packaged and sold individually and that contains less than 200 percent of the reference amount. As discussed in the 1991 serving size proposal (56 FR 60394 at 60398), FDA did not consider that a lower limit for the single-serving containers was necessary because the agency proposed to base the qualification for claims on the reference amount and the label serving size. The use of the reference amount for the claim evaluation would prevent a single-serving container from qualifying for a descriptor based on the package size alone. Therefore, concern about the potential manipulation of single-serving container sizes to qualify for a "low" claim (e.g., a 1/2 oz. bag of potato chips making a "low sodium" claim) was eliminated. Because there is no lower limit for a single-serving container, a product that is packaged and sold individually and that contains less than the upper limit of the single-serving container must be labeled with the entire contents of the package being one serving. For example, if a muffin that weighs 45 percent of the reference amount is packaged and sold individually, it is a single-serving container product, and the nutrition information is to be provided per the entire content of the container, i.e., one muffin. The agency notes, however, that if a number of these muffins are packaged in a multiserving container, the label serving size for this multiserving container would be the number of muffins that most closely approximates the reference amount, i.e., in this case two muffins.

To avoid any potential confusion, FDA has modified new § 101.9(b)(2) to clearly state that single-serving containers are exempted from the general rule set forth in that section. The modified provision reads: "Except as provided in paragraphs (b)(3), (b)(4), and (b)(6) of this section, * * * serving size declared on a product label shall be determined from the 'Reference Amounts Customarily Consumed Per Eating Occasion' * * *." Single-serving containers are discussed in § 101.9(b)(6).

14. An industry comment did not object to a manufacturer voluntarily listing a product as a single serving if it is slightly greater than 200 percent of the reference amount, provided that this claim was preapproved by FDA. A nutrition professional organization also recommended preapproval of the single-serving status of a package that contains 200 percent or more of the reference amount.

FDA finds no basis to conclude that preapproval is necessary. Because the regulation requires that the serving size for single-serving containers or units (single-serving products) be the entire contents of the container or unit, FDA expects that the manufacturer's decision to declare products that contain 200 percent or more of the reference amount as a single serving will be self-limiting. As the size of the single-serving product increases, the nutrition information will show proportionately larger amounts of nutrients. Although a larger size of single-serving product will show larger amounts of nutrients having positive connotations (e.g., calcium, fiber), most foods also contain nutrients having negative connotations (e.g., calories, fat, sodium). Therefore, single-serving products that are good sources of nutrients with positive connotations will also show larger amounts of nutrients with negative connotations. FDA thus does not anticipate that there will be abuse of this option. In addition, the agency can control obvious abuses of this option under section 403(a) of the act.

15. A consumer organization expressed concern that the proposed upper limit restriction may lead to the declaration of two servings for obviously single-serving products (e.g., a large candy bar, ice cream bar, frozen dinner) that contain slightly more than 200 percent of the reference amount. The comment contended that consumers would be misled by a label that gives nutrition information for half of the obviously single-serving products. The comment requested that FDA require manufacturers to disclose how many servings the package contains on the front panel of packages that contain between 200 and 300 percent of the reference amount.

FDA does not believe that it should require the number of servings on the front panel of products that contain more than the upper limit for the single-serving container. The agency is concerned that such a requirement would result in an information overload, contribute to the space problem for single-serving containers,

and clutter the label. Moreover, to have a clear, readily understandable, and usable definition for "single-serving container," FDA finds that it is appropriate to adopt less than 200 percent of the applicable reference amount as the defining level. However, the agency recognizes the comment's concern. FDA's position, as stated earlier in this section, is that regardless of the package size, a product that is obviously intended to be consumed in one serving (e.g., one unit products in discrete units such as muffins, ice cream bars, and sandwiches; products bearing label descriptions that suggest a single serving such as "singles" and "the perfect size for one") must be labeled as one serving. If it is not, the labeling of the product will be misleading under section 403(a) of the act. Therefore, FDA concludes that no action in response to the comment is necessary.

16. An industry comment stated that, in determining whether a product meets the definition of a single-serving container, it is not clear whether the exact weight of an oz (i.e., 28.35 g) or a rounded value of 30 g or 28 g should be used to calculate the percent of the reference amount from the net oz weight of the package.

The Compliance Policy Guides (7150.17) define 1 oz as 28.34952 g for metric declarations of quantity of contents on product labels (Ref. 39). Therefore, manufacturers should use 28.35 g to convert the oz weight of the package to the g weight.

To calculate the percentage of the reference amount from the net weight of the package, because it is a determination made on a weight/weight basis, manufacturers should divide the net weight of the package in g by the reference amount of the product and multiply by 100. For example, the percent of a reference amount of a product having a net weight of 1.3 oz and a reference amount of 30 g would be [(1.3 x 28.35)/30] x 100, i.e., 123 percent.

For the purpose of expressing the serving size for nutrition labeling, new § 101.9(b)(5)(iv) defines 1 oz as 28 g. Therefore, to express the serving size, manufacturers should use 28 g to convert the serving size in oz to the g-weight equivalent.

D. Reference Amounts for Serving Sizes

To comply with the act with respect to serving sizes, FDA proposed, in § 101.12(b), reference amounts customarily consumed for 131 product categories, covering almost all food products that are regulated by FDA. FDA proposed that these reference amounts be used as the basis for determining serving sizes for specific products. FDA set forth the methodology (general principles and procedures) by which it arrived at the 131 reference amounts. FDA also proposed general rules for determining reference amounts for several product classes, including: (1) Products that require further preparation before consumption; (2) imitation or substitute foods, altered foods, and foods for special dietary use; and (3) products consisting of 2 or more foods having individual reference amounts. This section discusses the comments received on the methodology that FDA used to determine the reference amounts, the number and names of product categories, the reference amounts for specific product categories, the reference amounts for special product classes mentioned above, and how to express or present the reference amounts.

1. Methodology for determining reference amounts

This section discusses comments that addressed the general principles and procedures for determining the reference amounts. Comments that discussed the methodologies for determining the reference amounts for specific product categories are included in section III.D.5. of this document, which discusses issues related to the reference amounts for specific categories.

17. Some comments objected to using food consumption data as the primary source in determining the reference amounts. The reasons for this objection varied. Some comments reasoned that food consumption data have many limitations, and therefore it is not possible to derive accurate estimates of the customarily consumed amounts from such data. Other objections included that: (1) Food consumption data, such as the NFCS used by FDA, contain only a limited number of days of information (e.g., 3 days) and are not appropriate to use to determine "long-term" intake, and (2) reference amounts should be based on what people should eat rather than what they usually eat. The comments recommended using other sources of information such as industry's "longstanding" serving sizes, the serving sizes currently used by industry, or the serving sizes in dietary guidance documents. Some industry comments also stated that changing the currently used serving sizes would be confusing to consumers. Other comments, however, opposed the use of industry's "longstanding serving sizes or opposed the use of any data other than food consumption data, arguing that they do not fulfill the act's requirement that the serving sizes reflect amounts customarily consumed.

Section 403(q)(1)(A)(i) of the act, which states that a serving size is the amount customarily consumed, effectively requires the use of food consumption data as the primary basis for determining serving sizes. Without such data, it is impossible to determine the amount of food that is customarily consumed. FDA is well aware of the limitations of the available food consumption data bases. However, these data bases are still the best sources of food consumption data collected under actual conditions of use available to the agency. Thus, FDA concludes that its use of food consumption data as the primary source for the customarily consumed amounts of food for nutrition labeling purposes is appropriate.

FDA agrees with the comments that stated that sources other than food consumption data are sometimes appropriate. Thus, when food consumption data were inadequate, the agency used the other sources of information listed in § 101.12(a)(5) to determine the reference amounts.

As for the use of the "longstanding" serving sizes, in the notice for the 1991 public meeting (56 FR 8084), FDA requested comments and supporting data on the definition of a "longstanding" serving size. In response to this notice, the agency received only one comment that stated that "longstanding" serving size should include serving sizes used before 1973, as a minimum, and presented three examples of serving size used before that date. Since it had no established definition or sufficient data to define "longstanding" serving sizes, the agency took into consideration all serving sizes suggested in comments regardless of their history of use in determining the reference amounts proposed in the 1991 serving size proposal. In comments to the 1991 serving size proposal, the agency has not received any additional information or data on how to define a "longstanding" serving size. Therefore, it is unable to define "longstanding" serving sizes.

FDA does not agree with the industry comment that changing the currently used serving sizes would be confusing to consumers, and the agency has not received any data to support these arguments. On the contrary, consumer comments overwhelmingly attest to the fact that the current system that allows a proliferation of serving sizes has been very confusing. Congress also recognized this fact. The House Report specifically states: "The Committee believes that the current information

about serving size on many foods is extremely misleading" (H. Rept. 101–538, supra, 18). Establishing standard serving sizes will reduce this confusion and provide a consistent basis for serving sizes and for claims based on them. Moreover, some of the serving sizes currently in use (e.g., 2 servings on a 12-fl oz can of soft drink) are not consistent with the act because they do not reflect the amount customarily consumed.

With regard to the use of other dietary guidance materials and the claim that reference amounts should be based on what people should eat rather than what they usually eat, FDA acknowledges that it would be desirable to have serving sizes on product labels that are consistent with the serving sizes in the dietary guidance documents published by Federal agencies. However, FDA advises that the act defines serving size as an "amount customarily consumed," not an amount people should eat. The agency has made some modifications in reference amounts where the changes are consistent with the customarily consumed amounts of the products under consideration, such as those described for bread in section III.D.5. of this document. Although these changes have not deviated from the definition of serving size, they have resulted in serving sizes more in agreement with dietary guidance documents.

However, because dietary guidance documents were developed for purposes other than regulatory uses, these documents have several problems that prevent their use as the primary source in determining reference amounts. Of greatest significance is the fact that many serving sizes in the dietary guidance documents are not based on the amounts customarily consumed and, therefore, are not consistent with the definition of serving size in the act. Dietary guidance documents published by Government agencies usually list approximate amounts of food for the purpose of providing "general" guidance as to what quantity of each food group a person should consume to maintain good health. Therefore, the amount that represents a serving is often not well defined (e.g., 1 slice for bread when the weight of a slice of bread varies among different brands).

The documents also provide a measure that is not applicable for all products within a product category. For example, these documents recommend the serving size for vegetables, other than raw leafy vegetables, as 1/2 cup. Vegetables in small pieces (e.g., green peas, cut corn) can be measured with a cup. However, many other vegetables come in a form that cannot be measured with a cup (e.g., broccoli spears; although broccoli can be measured if it is cut in small pieces, the weight per cup would vary widely depending on the shape and size of the cut piece).

In addition, dietary guidance documents give one serving size for a broad food group. Customarily consumed amounts, however, vary for different types of food within the food group. Therefore, for nutrition labeling purposes, FDA cannot use one reference amount for the broad groups defined in these documents.

In summary, dietary guidance documents are written for purposes other than implementing the serving size requirements of the act, and thus the serving sizes in these documents do not provide the accuracy and specificity that are needed for the reference amounts that are used for nutrition labeling under section 403(q) of the act.

With regard to the comment that a food consumption data base such as the NFCS is inappropriate to determine long-term intake because the survey covered only a limited number of days, FDA notes that the comment has confused the procedures used to estimate the reference amounts with the procedures used to estimate the average daily intake of food. FDA advises that the number of days of data collection is not critical for the estimation of reference amounts, particularly if the survey included a large number of people as was done in the NFCS.

The number of days of data collection is an important issue when an estimate of the long-term intake (chronic intake) is needed, e.g., for the safety evaluation of a food or a component of food. A survey that contains a limited number of days of data may overestimate the chronic intake, by eaters, of a food that is consumed infrequently (e.g., a specific fish) but that was consumed during the survey. For example, estimates of the average daily intakes of swordfish derived from the NFCS are likely to overestimate the chronic intake of swordfish because this fish is not consumed frequently in the United States. If an uncommon food is consumed during the survey and the amount consumed is divided by the number of survey days, 3 in this example, the average daily intake estimate for long-term intake will be greatly exaggerated because even people who like swordfish are not likely to consume it once every 3 days.

However, in determining reference amounts, FDA used the amount consumed per eating occasion, which is a short-term not a long-term intake. Thus, it was not necessary to average the amount of food consumed by the number of survey days. For the determination of reference amounts, the amount of food consumed for each eating occasion reported was counted as a separate entry. Consequently, surveys that contain 3-day data for a large number of people, like the NFCS, are appropriate for use in determining the amount of food customarily consumed per eating occasion.

18. Several comments discussed the selection of the food consumption data base used in determining the reference amounts. Most of the comments objected to using the 1987–1988 NFCS either by itself or with the 1977–1978 NFCS. The comments were concerned that, because of the low response rate, the data from this survey may not represent the amount customarily consumed as directed by the act. Some comments stated that FDA should use only the 1977–1978 NFCS. Some comments opposed using the 1985 and 1986 Continuing Surveys of Food Intakes by Individuals (CSFII) because these data bases included only selected age/sex groups (women 19 through 50 and children 1 through 5 years of age). These comments asserted that the use of the CSFII data bases resulted in an underestimation of the amount customarily consumed because men and older children, who as a group usually consume larger quantities of food than women and younger children, were not included.

A comment from a consumer organization strongly objected to FDA's use of the 1987–1988 NFCS with validation by the CSFII if data from the 1987–1988 NFCS suggested a change in consumption practices since 1977–1978 NFCS. The comment asserted that the CSFII is an inappropriate data base for validating serving sizes because the CSFII included only women ages 19 through 50 and their young children ages 1 through 5. Therefore, the comment asserted, the data base did not reflect the food consumption practices of the entire population, and the validation cannot be used for the entire population. The comment also contended that in validating the trend change in consumption, FDA did not compare the data from the CSFII to what women and young children were eating in the 1977–1978 NFCS.

A manufacturer stated that FDA should solicit consumption data from manufacturers because "the industry may well be the most efficient, accessible and accurate source of information" because "an ongoing knowledge of current consumption data * * * is vital and basic to [the] production and marketing of a product."

Because the final results of the 1987–1988 NFCS were not available in time for the 1990 proposal, FDA relied primarily on the 1977–1978 NFCS to determine the "standard serving sizes." Numerous comments on the 1990 proposal opposed FDA's use of a data base that is more than 10 years old. The comments argued that the food consumption practices have changed since the 1977–1978 NFCS, and that, therefore, estimates derived from the 1977–1978 NFCS may not reflect current food consumption practices.

Since the publication of the 1990 proposal, USDA released the final data tape for the 1987–1988 NFCS. However, FDA could not use the 1987–1988 NFCS alone because this survey had an unusually low response rate. Therefore, FDA used both the 1977–1978 and the 1987–1988 survey data in developing the reference amounts in the 1991 serving size proposal. If the 1987–1988 NFCS had a higher response rate, the new survey data would have been preferable to the 1977–1978 NFCS data for determining the reference amounts of food because of its recency. The use solely of the 1977–1978 NFCS is also not desirable because the data are almost 15 years old, and many new products have been introduced into the marketplace for which the 1977–1978 NFCS had no data. Also, changes in the customarily consumed amounts that might have occurred since the 1977–1978 NFCS could not be determined from the use of that survey alone. Therefore, FDA tentatively concluded that using both survey data bases is the most desirable approach because such an approach compensates for limitations in each of the two surveys; increases the number of available data points; provides two sets of mean, median, and modal amount consumed rather than one; and therefore strengthens the reliability of the reference amounts determined. Comments that objected to the use of the 1987–1988 NFCS did not provide any solution on how to determine the current customarily consumed amount of food that reflect changes in the food consumption practices of the U.S. population since the 1977–1978 NFCS. In addition, the comments did not provide any suggestions on how to estimate the consumption of new products introduced into the marketplace since the 1977–1978 NFCS. Thus, in order to determine the customarily consumed amount of food that is representative of U.S. food consumption, that reflects current consumption practices, and that includes new products introduced into the marketplace since the 1977–1978 NFCS, the agency concludes that the use of both the 1977–1978 NFCS and the 1987–1988 NFCS is necessary to compensate for limitations in each of the two surveys.

The comments that objected to the use of the CSFII data bases because these data may have lowered the reference amounts, misunderstood the way FDA used these data bases in determining reference amounts. When the results of the 1987–1988 NFCS suggested a change in food consumption practices since the 1977–1978 NFCS (e.g., customarily consumed amounts increased or decreased substantially), FDA used the CSFII data bases, which had a high response rate, only to confirm the validity of the trends observed, i.e., to show that the apparent trends were not an artifact of the low response rate in the 1987–1988 NFCS. As mentioned in the 1991 serving size proposal (56 FR 60394 at 60403), such a validity check to confirm the trend observed in the 1987–1988 NFCS was recommended by an expert ad hoc committee that evaluated the impact of nonresponse in the 1987–1988 NFCS (Ref. 26). Only when the same trends were observed in the CSFII did FDA rely solely on the 1987–1988 NFCS, so that the reference amount would reflect the current consumption practices more accurately. The estimates of intakes derived from the CSFII were not used in arriving at the reference amounts proposed in the 1991 serving size proposal. Therefore, potentially lower estimates derived from the CSFII data bases had no effect on lowering reference amounts.

With regard to the objection to FDA's use of the 1987–1988 NFCS if it suggested a change in consumption since the 1977–1978 NFCS and the use of CSFII to validate that change, the agency recognizes that the CSFII included only limited age and sex groups. Although the CSFII data bases used to confirm the trends included only women 19 through 50 and children 1 through 5 years of age, these data bases were the only other recent data bases that: (1) Were produced in a study conducted about the same time period as the 1987–1988 NFCS using the same survey methodology, (2) reflected food consumption practices representative of the U.S. population groups that were studied under the actual conditions of use, and (3) had a high response rate. Therefore, the CSFII data bases were the only data bases available to the agency for the purpose of confirming the apparent trend observed in the 1987–1988 NFCS, and, as mentioned above, their use in this manner was recommended by an expert ad hoc committee that evaluated the impact of nonresponse in the 1987–1988 NFCS (Ref. 26).

As for the assertion that FDA should have compared the data from the CSFII to what women and young children were eating in the 1977–1978 NFCS, the agency has done data analysis for women and young children in the 1977–1978 NFCS for those product categories that relied on the 1987–1988 NFCS because of consumption changes since the 1977–1978 NFCS. The results showed that the same consumption changes were observed for women and young children as for the total population since the 1977–1978 NFCS (Ref. 40). Thus, FDA concludes that it used the 1987–1988 NFCS and the CSFII data appropriately, and that it made the best use of the available food consumption data bases.

With regard to the request that FDA solicit consumption data from manufacturers, in the preamble to the 1991 serving size proposal (56 FR 60394 at 60401), FDA requested such data by stating that "[T]he agency is willing to consider any data that may give a better estimate of an amount customarily consumed of a specific product category." Many comments submitted food consumption and other data in support of the requests for changes of the reference amounts. FDA has considered all data that were submitted. It will discuss and respond to these data in section III.D.5. of this document, which discusses requests for changes in reference amounts for specific product categories. However, while some of these data have led the agency to modify the specific reference amounts in Table 2 in new § 101.12(b), the fact that they have caused the agency to make only a relatively small number of changes supports the basic validity of FDA's reliance on the 1977–1978 and 1987–1988 NFCS data.

19. A few comments stated that reference amounts should be based solely on the modal amount consumed, which represents the most frequently consumed amount, not the mean or median amount consumed.

FDA received the same suggestions in the comments on the 1990 proposal. As explained in the 1991 serving size proposal (56 FR 60394 at 60400), the mode was not useful as the sole criterion for determining the reference amount because most food groups had two or more modes, and there usually was no obvious or rational basis to choose one over the other. Therefore, FDA used all three (or more, if there was more than one mode) values that could represent an amount customarily (commonly) consumed, i.e., the mean, the median, and the mode. Following

the procedures detailed in the 1991 serving size proposal (56 FR 60394 at 60404), FDA determined the reference amount that was most likely to represent the amount customarily consumed for each product category. The new comments offered no additional data or arguments to support that using only the modal value is better than using all three values suggestive of the amount customarily consumed and no suggestions for how to select one modal value over another when there were multiple modes that were similar in frequency. Thus, FDA concludes that it is appropriate to consider all three values that provide data on which to derive the customarily consumed amount (i.e., mean, median, and mode).

2. Expression of reference amounts

In the 1991 serving size proposal (56 FR 60394 at 60406), FDA described the general principles that it followed in expressing the reference amounts in proposed § 101.12(b). FDA expressed reference amounts for fluids in mL. It expressed reference amounts for other foods, to the extent possible, in g. For a limited number of product categories, FDA expressed the reference amounts in common household measures. For example, when foods within a product category varied considerably in density, and the customarily consumed amounts for different products were more uniform when expressed in volume than in weight, FDA expressed the reference amounts in cups, tbsp., and teaspoons (tsp.). In these limited cases, FDA selected volumes that could easily be expressed in fractions or multiples of common household measures as described in proposed § 101.9(b)(5). Several comments requested changes in some of these principles.

20. One manufacturer stated that all reference amounts should be expressed in g, and another suggested that reference amounts for specific product categories (e.g., soups, sauces, gravies, beans, and mixed dishes) should be in g instead of cups.

FDA agrees that when possible, reference amounts should be expressed in g. As discussed more fully in section III.D.5. of this document, some of the specific product categories originally expressed in volume-based reference amounts have been changed to weight-based reference amounts. However, the agency does not agree that it is appropriate or desirable to do so for all product categories, including some of those specifically mentioned in comments. As explained above, when products within a product category differ widely in density, the use of a fixed g reference amount would result in a serving size that is too large for some products in the category and too small for others, even though the volume amounts consumed are similar for all products within the category. For example, although the reference amount for "mixed dishes measurable with cup" is 1 cup, the g-weights of different types of products within the category differ widely, e.g., about 160 g for seafood with vegetables without sauce and about 250 g for seafood stew. Also, fluids (e.g., beverages) have been customarily expressed in volume (mL or fl oz) not in weight, and they can easily and accurately be measured in volumetric units. Thus, FDA has used weight-based reference amounts in most cases but has retained volume-based reference amounts for fluids and for a limited number of categories with products that vary greatly in density (e.g., mixed dishes measurable with a cup, product category having aerated products) or for which information on the g-weight of the household measure is scarce, and comments have provided no appropriate weight-based reference amounts that are accurate and nonmisleading for all products within the category (e.g., condiments).

21. A manufacturer stated that reference amounts should not be adjusted to reflect "nonmetric" household measures. The comment suggested that such adjustments would be confusing and of no assistance to the consumer. A consumer recommended expressing reference amounts in rounded metric units, e.g., 250 mL for juice (8.45 fl oz), not 240 mL (8 fl oz).

FDA disagrees with the comment. The act requires that serving sizes be declared in common household measures, and therefore, those measures must drive the reference amounts. The common household measures are the declaration that appears first on the nutrition label, followed in parentheses by the equivalent metric measure which may or may not be the same as the reference amount. Many consumers complained about odd fractions (e.g., 1.4, 2.3). Therefore, a fractional serving size such as 8.45 fl oz, which was suggested in the comment, is not desirable. Thus, it is important to adjust the reference amounts to be in metric amounts that convert to useful, whole number household measures rather than rounded metric units.

22. A manufacturer requested that FDA express the reference amounts in either U.S. measures or in metric equivalents that reflect the more precise factors of 28.35 g per oz instead of 28 g per oz and 29.57 mL per fl oz instead of 30 mL per fl oz.

FDA notes that the reference amounts are amounts customarily consumed that will guide manufacturers to determine the label serving sizes of their specific products in common household measures. The serving sizes in common household measures will be in units such as pieces, cups, tbsp., and tsp. These household measures are primarily for consumer use, and it is unlikely that they will measure a cup with the 4-digit accuracy suggested in the comment. Accordingly, the reference amount that will be used as a guide for determining the serving size in household measure does not need the 4-digit accuracy of the g and mL equivalency suggested in the comment. Also, both 28.35 g and 28 g will be translated to 1 oz for the label serving size when oz is used as the serving size. Both 29.57 mL and 30 mL will be translated to 1 fl oz for the label serving size. In addition, in the case of fl oz, the 30 mL equivalency of 1 fl oz allows for the exact conversion of 1 cup to 8 fl oz. Therefore, the agency has concluded that for nutrition labeling purposes, 28 g for 1 oz and 30 mL for 1 fl oz are sufficiently accurate and appropriate because they provide the accuracy needed for nutrition labeling purposes without implying unrealistic accuracy, and because whole numbers are easier to use than decimal fractions.

3. Presentation of reference amounts

23. In footnote 2 under Tables 1 and 2 in proposed § 101.12(b) in the 1991 serving size proposal (56 FR 60394 at 60418 and 60419), FDA stated that, unless otherwise noted in the reference amount column, the reference amounts in the tables are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve), and that if the reference amount is not listed separately, the reference amount for the unprepared form (e.g., dry mix, concentrate) of the product is the amount required to make one reference amount of the prepared form.

A trade association requested that FDA delete footnote 2 from Tables 1 and 2 because it "implies that most of the major reference amounts used to determine number of servings will be based on a cooked (consumed) basis." The comment further requested that if FDA did not mean that the number of servings should be based on the cooked basis, the agency should provide a complete explanation in the preamble of this document or in another official, readily accessible reference. The comment contended that it would be difficult to determine the number of servings for the unprepared form of the product.

FDA believes that the comment has misinterpreted the footnote. Many foods are available in the marketplace in several different forms: Ready-to-serve, almost ready-to-serve, dry mixes, batters, or concentrates. For example, pancakes come in three different forms: Dry mix, batter, and the frozen almost ready-to-serve form, which requires only heating before consumption. If FDA were to list reference amounts for all of the different forms of these foods, the tables would be needlessly lengthy. In addition, the list would not include forms of the food requiring further preparation that may be introduced in the future. Because the amounts of food consumed are similar for the ready-to-serve and the unprepared forms on an as consumed basis, as explained in the preamble of the 1991 serving size proposal (56 FR 60394 at 60407), FDA listed all forms of the same food together and provided one reference amount listed on an as consumed basis. Footnote 2 merely explains that the reference amounts in the table are expressed in the quantity of the food that is in the ready-to-eat or the almost ready-to-eat form of the food. Since nutrition labeling is required to be on an "as packaged" basis, the footnote further informs the manufacturer that, for the unprepared form of a product that requires further preparation before consumption (e.g., dry mix, batter, uncooked food), the manufacturer must determine the quantity of the unprepared product that is required to make one reference amount of the prepared product as specified in new § 101.12(b). Using the reference amount for the unprepared product, the manufacturer must then determine what the serving size of the unprepared product "as packaged" should be in common household measure.

For the pancake example, this requires that the manufacturer determine the weight of dry mix or batter required to make one reference amount (110 g) of the prepared pancake according to the label directions for the preparation. If 40 g of a pancake mix is needed to make 110 g of pancakes, 40 g of dry mix is the reference amount of this pancake mix. The serving size for this pancake mix will be about 1/3 cup (40 g). The number of servings per container will then be estimated from the net quantity of contents of the container and the reference amount for the unprepared form of the product. For the pancake example above, if the net quantity of the package is 12 oz, the number of servings per container can be determined by dividing the net quantity in g by the reference amount for the dry mix (40 g), e.g., (12 oz) x (28.35 g/oz)/ 40 g = 8.5, i.e., about 9 servings according to the provision for declaring the number of servings per container in new § 101.9(b)(8).

As requested in the comment, FDA has provided a complete explanation of the footnote and how to determine the number of servings per container for unprepared products that require further preparation. Therefore, the agency is retaining Footnote 2 for Tables 1 and 2 in the final regulation to inform manufacturers that the reference amounts in Tables 1 and 2 are the amount of the final product on a ready-to-serve or almost ready-to-serve basis. In addition, for clarity, the agency has added, at the end of footnote 2 to Tables 1 and 2, the following statement: "Prepared means prepared for consumption (e.g., cooked)."

24. A trade association suggested that FDA express the reference amounts in Tables 1 and 2 in proposed § 101.12(b), where possible, in common household measures with the equivalent metric quantity in parenthesis. The comment stated that consumers, FDA, and the food industry will be best served if the reference amounts in the regulation tables are stated as they should appear on the label.

FDA understands the concern expressed by the comment. However, different characteristics (e.g., shape, size, density) of different products preclude the presentation of most reference amounts as they would appear on the product label. For example, the reference amount for bread is 50 g. The serving sizes for most sliced bread will be 1 slice. However, the parenthetical metric measure will differ depending on the thickness of the slice. In addition, if a slice weighs 50 percent or less of the reference amount, the serving size will be the number of slices that most closely approximates the reference amount. Thus, both the household measure and the metric measure may vary for brands that come in different thicknesses as shown in the examples below.

BRAND A: 1 slice (35 g)
BRAND B: 1 slice (28 g)
BRAND C: 2 slices (45 g)

Therefore, for most products, FDA cannot express the reference amounts as they should appear on the label. However, in response to the comment, FDA is adding a label statement column to Tables 1 and 2 in new § 101.12(b). This column provides guidance on how the serving sizes of specific products in each product category will appear on the product labels and should help reduce confusion and promote uniformity in label serving size units. For example, the label statement for bread and rolls states "——— piece(s) (———g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g) for unsliced bread." For sliced bread or rolls, manufacturers will then fill in the number of slices or rolls that most closely approximates the 50 g reference amount and the g-weight equivalent of that number of slices or rolls. For unsliced bread, oz is the household measure most appropriate for the food and 2 oz most closely approximates the 50 g reference amount for bread. The metric measure equivalent to 2 oz is 56 g because 1 oz in weight is defined as 28 g for nutrition labeling purposes in § 101.9(b)(5)(iv). Therefore, the label statement for unsliced bread states "2 oz (56 g 1-inch slice)."

Where possible, FDA has also provided the exact household measure and the equivalent metric measure for serving sizes in volumetric measures other than oz (e.g., cups, tbsp.), using the g weight of the household measure reported by the USDA. For example, for the product category of "Confectioner's sugar," the reference amount is 30 g which is equivalent to 1/4 cup. Therefore, the label statement column states "1/4 cup (30 g)," which is how the information will appear on the product label.

25. An industry comment urged FDA not to include the reference amount table (proposed § 101.12(b)) in the regulation itself. Instead, the comment asked that FDA generally establish its intention to use such a table, then reference and formalize the table through policy memoranda. The comment stated that if the reference amount table is in the regulation, the petition process for modifying the reference amounts would require a notice and comment rulemaking which would necessitate publication in the Federal Register before a change could be made.

The reference amount table appropriately is included in the regulation because these amounts have the force and effect of law. While it is true that any changes in the reference amounts will require a notice and comment rulemaking, FDA concludes that giving the reference amounts legal effect is required to implement section 403(q)(1)(A)(i) of the act. The legislative history of section 2(b)(1)(B) of the 1990 amendments directs FDA to establish meaningful serving size *requirements* (H. Rept. 101–538, supra, 18). Such requirements are necessary to ensure that the serving size that appears on the label reflects the amount customarily consumed.

4. Product categories

a. Number of product categories

FDA proposed 131 product categories: 9 for foods specially formulated or processed for consumption by infants or toddlers and 122 for the general food supply. The agency asked for comments on whether these categories adequately cover the food supply (56 FR 60394, 60407).

Many comments addressed whether the 131 product categories are adequate. Some comments expressed their support for the 131 product categories proposed in the 1991 serving size proposal. These comments stated that the proposed product categories are reasonable and recognizable. Several comments suggested that some of the product categories should be combined. The vast majority of the comments, however, stated that the 131 categories were too restrictive and recommended expanding some of the categories.

Because the comments about the number of product categories are closely related to the comments on the reference amount, those comments that requested merging or expanding specific categories will be discussed in the next section of this document on requests for changes in reference amounts for specific product categories. This section includes only those comments that requested recategorization of entire product categories or addition of a product category.

26. A State government comment recommended that FDA regroup all products into six categories and establish one standard measure for each category that is easily understood and multipliable. For example, the comment suggested grouping dry cereal, rice, beans, raisins, nuts, bread, tortilla, crackers, cooked fish, and hard cheese into one category with a standard serving size of 1 oz.

Section 403(q)(1)(A)(i) of the act defines serving size as an amount of food customarily consumed. Therefore, FDA has not grouped products together unless their customarily consumed amounts are similar. Grouping of foods into such broad categories as those suggested by the comment is not possible because the amounts customarily consumed vary widely. For example, 1 oz may be an appropriate reference amount for some foods in the grouping suggested by the comment (e.g., cheese, some ready-to-eat cereals), but it is too small for other foods in that grouping (e.g., bread, fish). Food consumption data show that the amount customarily consumed for fish without sauce is 3 oz cooked, and that for fish with sauce (e.g., fish with cream sauce), it is 5 oz cooked.

27. A manufacturer requested that FDA add a product category for snack sandwiches, which have recently been introduced into the market, with a reference amount of 70 g.

The 1991 serving size proposal has a product category that includes products such as snack sandwiches. These sandwiches belong to the category of "mixed dishes not measurable with cup." The proposed reference amount for this category, that is retained in the final regulation, is 140 g. Because snack sandwiches are discrete unit products, the label serving size will be one sandwich if it weighs more than 70 g. If the sandwich weighs 70 g or less each, the serving size will be the number of sandwiches that most closely approximates the 140 g reference amount. However, the agency notes that, as discussed in section III.F.1. of this document, new § 101.9(b)(10)(ii) allows manufacturers to voluntarily provide a second column of values per unit on multiserving containers.

Regardless of the size of the individual unit, the 140 g reference amount will be used to evaluate the product's qualification for claims unless the sandwich meets the definition of a meal product or main dish product in new § 101.13(l) and (m). If the sandwich meets the definition of meal product or main dish product, the product's qualification for a claim will be evaluated by the rules described in the nutrient content claim regulation published elsewhere in this issue of the **Federal Register**.

28. A comment from a Federal agency stated that there should be a product category for gelatin salad.

In the 1991 serving size proposal, all gelatin products were included in the "Custards, gelatin, or pudding" category under Desserts. Because some gelatin products are served as salads rather than desserts, FDA agrees with the comment that it would be desirable to have a separate category for gelatin salads. Accordingly, a new category "Gelatin Salad" has been added to Table 2 in new § 101.12(b). Following the general principles and the procedures described in the 1991 serving size proposal (56 FR 60394 at 60402), FDA has determined the reference amount for the category to be 120 g, which is equivalent to 1/2 cup (Ref. 41).

29. A manufacturer of "herring salad" and smoked salmon spread stated that their products were not included in the 131 product categories proposed in the 1991 serving size proposal. The manufacturer stated that "herring salad" is a "fanciful name" and is not a fish salad. "Herring salad" and smoked salmon spread are ground pastes of herring or salmon and other ingredients such as celery, pickle relish, mayonnaise, and spices. They are neither used nor marketed for use as sandwich spreads like tuna salad. They are promoted for use as an appetizer to be spread on crackers, in the same manner consumers would use pickled herring. The manufacturer stated that "herring salad" and smoked salmon spread should be added to the 'Smoked or pickled fish or shellfish" category.

FDA agrees that the characteristics and the usage of "herring salad" and smoked salmon spread suggested in the comment most closely resemble those products used as appetizers in the "Smoked or pickled fish or shellfish" category. In addition, "herring salad" and smoked salmon are canned fish products. Both of these categories have a reference amount of 55 g. Therefore, it is a matter of choice in which category these products are placed. FDA has concluded that "herring salad" and smoked salmon are types of fish products used in the same manner of those products in the "Smoked or pickled fish or shellfish" category and thus, fit better in the "Smoked or pickled fish or shellfish" category than in the canned fish category. Therefore, FDA has modified the name for the "Smoked or pickled fish or shellfish" category in Table 2 in § 101.12(b) to include fish or shellfish spread.

30. A consumer comment stated that a category is needed for products such as tempeh. The comment suggested 1 oz as the reference amount for these products.

FDA acknowledges that tempeh should be included in § 101.12(b). However, the agency disagrees with the comment that it should have a separate category with a reference amount of 1 oz. The comment did not provide any data on the amount customarily consumed to support the recommendation of a 1 oz reference amount. Because tempeh is a type of soy product that is used interchangeably with tofu (Ref. 42), the agency concludes that tempeh belongs in the "Bean cake (tofu)" category with a reference amount of 85 g. Accordingly, FDA has revised the "Bean cake (tofu)" category to include tempeh.

In addition, the agency is aware that there are an increasing number of ethnic foods entering the general food supply. However, available food consumption data do not usually provide information on these ethnic foods. Therefore, FDA requests that manufacturers or other interested persons submit a petition as described in § 101.12(h), if any

additions or amendments to § 101.12(b) are necessary to encompass the ethnic foods sold to the general public.

31. The spice industry requested exemption from nutrition labeling on the basis that spices in general contain insignificant amounts of nutrients on a 1/4 tsp. basis. The comments requested that FDA establish 1/4 tsp. as the reference amount and "acknowledge that when used at that level, the industry is not covered by the mandatory nutrition labeling requirements of the proposals."

Exemptions from mandatory nutrition labeling are discussed in the final regulation entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" published elsewhere in this issue of the Federal Register. The agency agrees with the comment that there is a need for a reference amount for spices and herbs and, accordingly, has added a category for these products. Spices and herbs are used to flavor foods. Cookbooks (Refs. 43 and 44) usually recommend using 1 to 2 tsps. of these products in recipes that make several servings. Therefore, one serving of food contains only a fraction of a tsp. of spices or herbs (e.g., 1/4 tsp. or less). One-fourth tsp. is also the smallest household measure allowed to be declared as a serving size for nutrition labeling purposes. Therefore, FDA has concluded that 1/4 tsp. is the most reasonable reference amount for this product category. For spices and herbs that cannot be measured with a tsp. (e.g., whole clove, whole bayleaf), the agency has determined the reference amount of 0.5 g which represents the average g weight of 1/4 tsp. of spices and herbs. Consequently, FDA has added a new product category under the miscellaneous category for spices and herbs with a reference amount of 1/4 tsp. or 0.5 g if not measurable by a tsp.

32. An industry comment stated that it is confused about which products go into the breads category. Another industry comment requested clarification as to which category canned hot dog chili sauce belongs.

First, the agency notes that as discussed in section III.D.5. of this document, FDA has divided the "Bakery Products: Breads (excluding sweet quick type), biscuits, rolls, * * *" category (the original bread category) into two categories: One for breads and rolls, and the other for the remaining products included in this category in the 1991 serving size proposal. This was done in response to many requests for dividing the original bread category into several subcategories. The breads and rolls category in the final regulation includes all breads (e.g., white, wheat, rye, multigrain, raisin, and soda bread) and all rolls (e.g., dinner rolls, hamburger rolls, hot dog rolls).

With regard to the hot dog chili sauce, FDA advises that it belongs to the "Major condiments, e.g., catsup * * *" category under "Sauces, Dips, Gravies and Condiments" because it is used as a substitute for catsup on hot dogs.

To help manufacturers and others to identify the category in which their specific products fit, in the 1991 serving size proposal, FDA provided an extensive list of products for each product category (Ref. 20). The agency has updated this list to incorporate changes made in product categories and in the products included in each product category in response to the comments on the 1991 serving size proposal (Ref. 45). FDA will continue to update the list as necessary. Copies of the list are available from the Division of Nutrition (HFF–260), Food and Drug Administration, 200 C St. SW., Washington, DC 20204. FDA advises that those who are not sure about which product category their specific products belong should refer to this list or consult with the agency.

33. A manufacturer contended that "not having a provision for new or undefined food products is of concern" to those developing new products.

FDA agrees that new products should be provided for in this regulation. It was for this reason that FDA proposed to establish a petition process in § 101.12(h) by which a reference amount could be amended or added. New § 101.12(h) describes the information needed in the petition in order for FDA to evaluate the request for a change or addition of a product category or a reference amount of a food in Tables 1 and 2, as well as the information needed to determine a suitable reference amount for the petitioned food, if the agency concludes that the change or addition is appropriate.

From the comments on the 1991 serving size proposal and through its own observation of products in the marketplace, the agency has identified three additional product classes (dessert shells, pastry shells, and dehydrated vegetables) that were not covered in the 1991 serving size proposal. The agency intends to publish a proposal for reference amounts for these product classes in the near future.

b. Product category names

Because each product category encompasses many different types and brands of products, it is impossible to fully describe all products within each product category. Therefore, in the 1990 proposal, FDA provided a generic description of each product category. A generic description is also desirable to accommodate the brands and types of products that may be introduced in the future. Some comments on the 1990 proposal stated that because some product categories were not sufficiently descriptive, they experienced difficulty in identifying the product category in which their products fit. Thus, in the 1991 serving size proposal, FDA modified the names of some product categories to be more descriptive and also provided a few recognizable examples where it felt that it was necessary to do so. In addition, the agency provided a separate extensive list of products for each product category (Ref. 20). Several comments on the 1991 serving size proposal again requested clarifications or changes in product category names as described below.

34. An industry comment requested that FDA add "crumbcakes and similar products" to the "Coffee cakes * * *" category under Bakery Products.

FDA advises that because crumbcakes are similar to coffee cakes in their nutrient content and use in the diet, coffee cakes and crumbcakes are included in the same food code in the NFCS. Consequently, crumbcakes were included in the coffee cake group in determining the customarily consumed amount of coffee cakes. Therefore, the agency agrees with the comment that it is appropriate to include crumbcakes in the name of the coffee cake category. However, the agency finds that it would not be appropriate or desirable to add a term such as "similar products" to the product category name because such a term could be interpreted differently by different companies and may result in an inappropriate classification of a product. For example, because apple crisp has a crumb topping, like crumbcakes, it could be misclassified as belonging to the "Coffee cakes * * *" category. However, apple crisp belongs in the "Pies, cobblers * * *" category, not the "Coffee cakes * * *" category because apple crisp resembles products in the "Pies, cobblers * * *" category in nutrient content and in use in the diet as indicated by being listed in the same food group as cobblers in the NFCS. Therefore, FDA has modified the name for the "Coffee cakes * * *" category to read: "Coffee cakes, crumbcakes * * *" For clarity, FDA has also modified the name for the "Pies, cobblers * * *" category to read: "Pies, cobblers, fruit crisp * * *"

35. Another comment pointed out that game meats are missing from FDA's product category list.

Game meats belong to the major product category of "Fish, Shellfish, and Meat or Poultry Substitutes," because this category includes all meat or poultry substitutes and is the product category comparable to the meat and poultry categories in the USDA regulation. Because meat and poultry substitutes replace meat and poultry in the diet, FDA used the amount customarily consumed for meat and poultry as a surrogate for the amount customarily consumed for meat and poultry substitute products. Therefore, because game meat is a type of meat and is used interchangeably with other meat, fish, or poultry in the diet, similar to those products in the "Fish, Shellfish, and Meat or Poultry Substitutes" category, FDA has included game meat in that category. Accordingly, FDA has modified the name of this major product category, and the names of its two subcategories, to include game meats as shown below:

"Fish, Shellfish, Game Meats, and Meat or Poultry Substitutes:"
"Fish, shellfish, and game meat, canned"
"Smoked or pickled fish, shellfish, or game meat; or fish or shellfish spread"

36. A nut industry comment stated that it is not clear in which category sliced nuts fit, "Nuts, seeds, and mixtures;" or "Nuts and Seeds: Used primarily as ingredients, e.g., coconut, nut, and seed flour, etc."

The agency advises that sliced nuts belong in the "Nuts, seeds, and mixtures" category because they were included in the analysis for the amount customarily consumed for the "Nuts, seeds, and mixtures" category. For clarity, FDA has modified the name for the "Nuts, seeds, and mixtures" category to "Nuts, seeds and mixtures, all types, sliced, chopped, slivered, and whole."

37. A manufacturer requested that FDA not use "popsicle" as part of the product category name because it is a trademark owned by a particular company.

FDA has deleted "popsicle" from the product category name. The new name for the product category is "Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups)." As discussed in section III.D.5. of this document, this category has been moved from the category for Sugars and Sweets and placed under the category for Desserts.

38. A pickle trade association stated that the product category name for relish ("Pickles, relish") suggests that the category excludes relishes that contain nonpickle ingredients. The comment argued that the category should include all relishes and requested that FDA change the category name from "Pickles, relish" to "Pickle relishes."

FDA agrees with the comment that "Pickle relishes" is a more appropriate name for the category that includes all vegetable relishes, including relishes containing nonpickle ingredients. The agency notes, however, that fruit relishes (e.g., cranberry relish) are a different type of product and are listed under "Fruits and Fruit Juice" with the reference amount of 70 g.

In addition, for clarity or for a better categorization of products, FDA on its own initiative has modified the names of the following product categories:

(1) Hushpuppies and cornbread have been deleted from the "Coffee cakes * * *" category under Bakery Products and placed in the "Biscuits * * *" category under Bakery Products.

(2) To prevent a misclassification of tortillas as taco shells because they are often used as a wrapper for tacos, the name for the taco shell category has been modified to read: "Taco shells, hard."

(3) To incorporate "frozen flavored and sweetened ice" and to reflect better the products included in the category, the name for the "Ice cream, ice milk, frozen yogurt, sherbet: All types, bulk and novelties * * *" category under Desserts has been changed to "Ice cream, ice milk, frozen yogurt, sherbet, frozen flavored and sweetened ice, frozen fruit juices: All types, bulk and novelties * * *"

(4) To reduce the number of product categories, FDA has deleted water as a separate category. For a better categorization of products, fruit-flavored drinks have been deleted from the "Juices, nectars, fruit drinks, or fruit-flavored drinks" category under Fruits and Fruit Juices. Water and fruit-flavored drinks have been combined with the category for "Carbonated beverages * * *" under Beverages. The revised name for the "Carbonated beverages * * *" category is "Carbonated and noncarbonated beverages, wine coolers, water."

These changes are intended only to clarify Table 2 and to make it more usable. They do not result in any substantive changes in the reference amounts of the products affected.

As mentioned in the previous section, to help manufacturers identify the product category in which their specific products fit, FDA has updated the list of products for each product category (Ref. 45). The agency will keep updating this list as new products are identified. Copies of the list are available from the Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

5. Reference amounts for specific product categories

FDA proposed, in § 101.12(b), the reference amounts for 131 product categories that it developed through the use of the general principles and procedures described in the 1991 serving size proposal. These reference amounts were presented in two tables. Table 1 contained the reference amounts for the 9 product categories that are specially formulated or processed for consumption by infants or toddlers. Table 2 contained the reference amounts for the 122 product categories in the general food supply.

FDA received more comments on the proposed reference amounts for specific product categories than on any other serving size issue. Many comments supported the proposed reference amounts. However, the majority of the comments that discussed specific reference amounts opposed one or more specific proposed reference amounts. The agency received requests for changes of the reference amounts for about 80 specific product categories. About half of the requests merely voiced their opinion on the proposed reference amounts for certain product categories (e.g., too large or too small) or provided generic types of bases for wanting the changes. The other half of the requests presented more specific reasons for each product or product category or presented data supporting their requests. FDA will first respond to the requests that provided generic types of bases and then will respond to the requests that provided more specific bases by product category.

a. Generic requests

Because many comments provided similar bases for wanting changes in the reference amounts, responding separately to them would be repetitive and would make the document needlessly lengthy. Therefore, FDA has grouped these bases and is responding to each type of basis for a change.

39. Many comments merely stated that they believed that the proposed reference amounts for specific product categories were too large or too small, but they did not present any specific arguments or data supporting their beliefs.

Section 403(q)(1)(A)(i) of the act defines serving size as "an amount customarily consumed." To determine this amount of food, FDA performed extensive analyses and evaluations of

data from four large national food consumption survey data bases, namely the 1977–1978 NFCS, 1985 CSFII, 1986 CSFII, and the 1987–1988 NFCS conducted by the USDA (56 FR 60394 at 60403). To respond to the recommendations in the IOM report and to comments requesting the use of other relevant information in addition to food consumption data, and to promote international harmonization, in addition to the food consumption data, FDA used several other sources of information listed in the proposed § 101.12(a)(5) in developing the proposed reference amounts. The agency carefully considered the food consumption data and the other information to determine the reference amounts proposed in the 1991 serving size proposal. Food consumption data and the other information used, along with the detailed description of the procedure and the basis used to determine the proposed reference amounts, were made available to the public (Ref. 2).

The law establishes an objective standard against which serving sizes are to be established. FDA cannot change the proposed reference amounts that were determined after careful and extensive consideration of food consumption data and other relevant information simply because some comments stated that the reference amounts are too large or too small without providing any data to support their assertions. Accordingly, FDA has not adopted recommendations based merely on belief or opinion.

40. A consumer organization and a few fast food companies recommended that FDA change some reference amounts to make them consistent with the average serving sizes of restaurant foods.

First, FDA advises that in determining the customarily consumed amount for each product category, it used both foods consumed at home and away from home (e.g., restaurant foods). Therefore, the serving sizes of restaurant foods were reflected in the reference amounts determined for each product category. In addition, the act mandates the nutrition labeling of retail products, not restaurant foods. Accordingly, new § 101.9(j)(2) exempts restaurant foods from the nutrition labeling regulation unless a claim is made. Therefore, it is more important for the reference amounts to be appropriate and applicable to retail products than to restaurant foods. Reference amounts that are solely based on the serving sizes of restaurant foods may not be appropriate for retail products. Furthermore, most restaurant foods are single-serving products. Based on the reference amounts in new § 101.12(b) and the definition for single-serving products, the serving sizes for restaurant foods will be one unit. Therefore, FDA has not changed the reference amounts to make them consistent with the average serving sizes of restaurant foods.

41. A manufacturer requested that FDA establish two different reference amounts, one for retail products and one for food-service products, for some product categories (e.g., 1 cup for retail soups and 3/4 cup for food service soups). The comment argued that the proposed reference amounts represent the amount customarily consumed in the home. The serving sizes used for food service products are smaller. Because these products are sold in some retail "club" stores, they will be required to bear nutrition labeling. The comment contended that if these products are required to use the same serving size as for the regular retail products, it would cause problems in providing preparation instructions and yield information directed to the food service operator because the serving size recommended for food service would differ from the serving size shown on the nutrition panel. The comment claimed that such labeling would be very confusing to the food service buyers and operators. The comment requested that food service products be allowed to use serving sizes that correspond to their traditional label instructions as long as the simplified-format of nutrition information is provided per serving based on the reference amount.

The same food cannot have different reference amounts (or label serving sizes) simply because it is intended to be sold or served for different purposes. Reference amounts of the same food sold at retail stores must be the same to facilitate nutrition comparisons of different brands regardless of where they are purchased. The reference amount for the food service products that are sold at retail stores must be based on the same reference amount as for the regular retail products.

42. Some comments recommended using a range of values rather than a fixed reference amount.

The reference amounts in § 101.12(b) will serve two purposes: (1) They will be used by manufacturers to determine serving sizes for their specific products, and (2) they will be used to determine whether food products meet the definitions for nutrient content and health claims. As explained in the 1991 serving size proposal (56 FR 60394 at 60414), both of these purposes require specific reference amounts, not a range of values. None of the comments provided any evidence that a range of values would be better than a fixed value to meet the two objectives of the reference amounts. Therefore, FDA has not adopted the recommendations for using a range of values.

43. A comment from a foreign government recommended changing the reference amounts because they differ from the amounts in its own guidelines or differ from the food consumption data developed in its country.

Although the act did not explicitly define the serving size as an amount customarily consumed by the U.S. population, it is implicit that the food consumption data used to determine this amount of food should be based on the food consumption practices by the U.S. population, not food consumption data from surveys conducted in other countries. The nutrition information on products sold in the United States is for the U.S. consumer. Moreover, the legislative history of the 1990 amendment talks about helping Americans to maintain a balanced and healthful diet and to follow the Surgeon General's guidelines (H. Rept. 101–538, supra 9–10). Moreover, one of the main sponsors of the legislation said in thanking the other main sponsor in the House that: "He has insisted that the bill be as effective as possible so that all Americans can be fully and fairly informed about the nutritional characteristics of the food that they eat" (136 Congressional Record H5841 (July 30, 1990)). Therefore, the reference amounts should be appropriate to U.S. consumers. FDA cannot change the reference amounts that reflect the food consumption practices of the U.S. population to make them consistent with the guidelines that are targeted for non-U.S. population groups or to make them agree with the data from food consumption surveys conducted in foreign countries. Accordingly, FDA has not adopted these recommendations.

b. Specific requests

In addition, FDA received many comments requesting changes in specific reference amounts. Some comments addressed meat and poultry products which are regulated by USDA. Unless such comments contained specific issues that were directed to FDA or that significantly bear on the labeling of products regulated by FDA (e.g., how to determine reference amounts for the unprepared form of the product), FDA is not responding to those comments pertaining to meat and poultry. FDA has forwarded these comments to USDA for consideration. Comments about game meats are included in this document.

Although the names and the order of the product categories in the final regulation have been changed somewhat, for the purpose of discussing the comments on specific reference amounts, the names and the order of the product categories presented in the 1991 serving size proposal are used below for ease of identifying the product category to which the comments were directed.

(1) Infant and toddler foods: other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts

FDA proposed 7 g as the reference amount for this product category.

44. A manufacturer of infant and toddler foods stated that 7 g is appropriate for infants but not for toddlers. Based on the published value for the median amount of ready-to-eat breakfast cereals consumed by toddlers 1 and 2 years of age as reported in the 1977–1978 NFCS, the manufacturer recommended 21 g, or 3/4 oz, as the reference amount for ready-to-eat cereals for toddlers.

FDA derived the proposed 7 g reference amount from the amount consumed by infants. Some of the products in this product category (e.g., teething biscuits, teething cookies) are primarily consumed by infants. However, FDA acknowledges that other products in the product category (e.g., cereals) may be consumed by both infants and toddlers. Therefore, the agency agrees that it is appropriate to have a separate reference amount for toddlers. However, the agency could not adopt the reference amount suggested in the comment because it was based solely on the 1977–1978 NFCS and included only toddlers 1 and 2 years of age. As discussed in section III.D.1. of this document, FDA is not using a reference amount that is solely based on the 1977–1978 NFCS. Also, new § 101.9(b)(1) defines toddlers as children 1 through 3 years of age. Therefore, the reference amount for toddlers should reflect the amount customarily consumed by toddlers 1 through 3 years of age. Following the procedures for determining the reference amount described in the 1991 serving size proposal (56 FR 60394 at 60403), FDA has determined the reference amount of cereals for toddlers 1 through 3 years of age to be 20 g (Ref. 41).

(2) Dinner, fruit, vegetable, stew or soup for toddlers, ready-to-serve

FDA proposed 170 g as the reference amount for this product category.

45. A manufacturer of infant and toddler foods stated that 170 g is too large for fruits and vegetables specially formulated or processed for consumption by toddlers. The comment recommended a separate reference amount of 100 g or 3 to 4 oz for fruits and vegetables based on the published data for the amount of fruits and vegetables consumed by toddlers 1 and 2 years of age as reported in the 1977–1978 NFCS.

FDA agrees with the comment that a separate reference amount is needed for fruits and vegetables. Detailed information on the characteristics of fruits and vegetables specially formulated or processed for consumption by toddlers was not available to FDA during the formulation of the 1991 serving size proposal. The information provided in the comment showed that fruits and vegetables specially processed for consumption by toddlers differ from fruits and vegetables specially formulated or processed for consumption by infants. Toddlers' products more closely resemble the canned fruits and vegetables in the general food supply than do fruits and vegetables for infants. The toddler products differ from the products in the general food supply primarily in the piece size, which makes them easier for toddlers to pick up with their fingers. Therefore, the agency believes that it is appropriate to use the amount of fruits and vegetables consumed by toddlers reported in the NFCS to derive the reference amount for the fruits and vegetables specially processed for consumption by toddlers.

Consistent with the discussion in section III.D.1. of this document, FDA is not using a reference amount that was suggested in the comment because it was solely based on the 1977–1978 NFCS and included only toddlers 1 and 2 years of age. Following the procedures for determining the reference amount that it described in the 1991 serving size proposal (56 FR 60394 at 60403), FDA has determined the reference amount for ready-to-eat fruits and vegetables specially formulated or processed for consumption by toddlers 1 through 3 years of age to be 125 g and 70 g, respectively (Ref. 41). Therefore, FDA has added 2 categories, "Fruits for toddlers, ready-to-serve" with a reference amount of 125 g and "Vegetables for toddlers, ready-to-serve" with a reference amount of 70 g.

(3) Infant and toddlers foods: egg/egg yolk, ready-to-serve

FDA proposed 55 g as the reference amount for this product category.

46. One comment recommended that FDA change the reference amount to 50 g because 50 g corresponds more closely to one-half of the net contents of a jar.

As discussed in the 1991 serving size proposal (56 FR 60394 at 60401), the act requires that the serving size be the amount customarily consumed. Therefore, jar size cannot be used as the basis for determining reference amounts. Furthermore, there is nothing that ties jar size to the amount customarily consumed. One may change, while the other does not. Therefore, FDA has not adopted this recommendation.

(4) Infant and toddler foods: juice, all varieties

FDA proposed 120 mL as the reference amount for juices specially formulated or processed for consumption by infants.

47. A consumer recommended that FDA change the reference amount to 125 mL because 125 mL is a rational metric size.

For the reason explained in section III.D.1. of this document, concerning the presentation of reference amounts in rational metric size, FDA has not adopted this recommendation. Accordingly, FDA has retained the reference amount as proposed.

(5) Bakery products: breads (excluding sweet quick type), biscuits, rolls, croissants, bagels, tortillas, soft bread sticks, soft pretzels (hereinafter referred to as "the original bread category" for simplicity).

FDA proposed 55 g as the reference amount for this product category.

48. Many industry comments requested that FDA divide this category into several subcategories with separate reference amounts for each subcategory. Two bakery trade associations recommended dividing the category into 4 subcategories with the following reference amounts: 45 g for bread, 50 g for rolls, 60 g for biscuits and English muffins, and 70 g for tortillas. The comments submitted published data from the 1977–1978 NFCS to support their position. In addition to these four subcategories, another industry comment suggested separate reference amounts for sliced and unsliced bread (e.g., 45 g for sliced bread and 55 g for unsliced bread). Several additional comments recommended a 45 g reference amount for bread but did not specify what the reference amount should be for other products in the bread category. The major reason stated by the industry in comments was to have a separate, lower reference amount for sliced bread so that the label serving size for sliced bread will be 1 slice, which is consistent with the serving size

in the dietary guidance documents published by Federal agencies. A nutrition professional organization also stated that the 2-slice serving size conflicts with the serving sizes in dietary guidance documents. This comment contended that consumers who hear that dietary guidance documents recommend 6 to 11 servings daily from the bread/cereal group, and then see that a label serving size is 2 slices, may be confused and think that the recommendation means 12 to 22 slices of bread a day. A few other comments suggested a 25 to 30 g reference amount for bread which is equivalent to the g weight of 1 slice of most breads. An international comment suggested changing the reference amount for bread to 45 g but keeping the 55 g reference amount for rolls because rolls are heavier than breads. One comment stated that the amount of bread customarily consumed was overestimated because FDA did not include the bread that was consumed as toast. The comment asserted that many people consume only one piece of bread as toast, and thus the amount customarily consumed would have been lower if FDA had included the bread consumed as toast in the data analysis.

FDA agrees that the 55 g reference amount could result in 2-slice serving sizes for some brands of sliced bread, and that it would be desirable to have serving sizes of sliced bread consistent with that in the dietary guidance documents published by Federal agencies. However, the agency does not agree that it should divide the original bread category into four subcategories with their own individual reference amounts. The data submitted in support of the four subcategories came from a USDA publication from the 1977–1978 NFCS (Ref. 46). These data are inappropriate for use in determining the reference amounts for several reasons.

First, the data represent the mean consumed amount per eating occasion by the total population including infants and children less than 4 years of age. New § 101.9(b)(1) defines the term "serving" or "serving size" for the general food supply as an amount of food customarily consumed by persons 4 years of age or older. Therefore, the reference amounts for the general food supply should reflect the customarily consumed amounts by individuals 4 years of age or older, not by the total population which includes infants and children less than 4 years of age.

Secondly, as discussed in the 1991 serving size proposal (56 FR 60394 at 60400), the mean is often influenced by "outliers" (i.e., extremely small or extremely large amounts). Therefore, the mean alone is not sufficient to determine the customarily consumed amount. As explained above, FDA has concluded that to determine a reliable estimate of the amount customarily consumed, all three statistical estimates that represent an amount customarily consumed (the mean, the median, and the mode) must be considered.

Thirdly, the data submitted in the comments represent estimates from the 1977–1978 NFCS. The sole use of the 1977–1978 NFCS is not appropriate for the reason stated in section III.D.1. of this document.

FDA, therefore, has reanalyzed the 1977–1978 NFCS and the 1987–1988 NFCS to determine the mean, median, and modal consumed amounts of bread per eating occasion including the bread that was eaten as toast for persons 4 years of age or older. The amounts consumed as toast were adjusted to account for the moisture loss during toasting in order to more closely determine the weight of the bread, i.e., the form sold.

The reanalysis of the food consumption data showed that both the 1977–1978 NFCS and the 1987–1988 NFCS showed somewhat lower customarily consumed amounts for breads and rolls than for other products included in the original bread category (Ref. 47). Therefore, the agency concludes that it is appropriate to divide the original bread category into two categories, one for breads and rolls and one for all other products (e.g., bagel, English muffins, tortillas). Based on the results of the reanalysis, FDA finds that 50 g is the amount customarily consumed of breads and rolls, and 55 g is the amount customarily consumed for all other products. Accordingly, FDA has divided the bread category into 2 categories with separate reference amounts.

FDA notes that the new 50 g reference amount together with the new lower limit for a single-serving unit (more than 50 percent of the reference amount) in § 101.9(b)(2)(i) would make 1 slice as the serving size for most sliced breads on the market. The agency also notes that it has added a provision in new § 101.9(b)(10)(ii) that allows voluntary labeling of a second column of values per unit (per slice in the case of sliced bread) if the serving size of a product in discrete units is more than one unit. Both of these changes should help alleviate any potential for consumer confusion, as discussed in the comments.

As for the other comments, FDA does not agree with having separate reference amounts for sliced and unsliced bread. The same food cannot have different reference amounts simply because it comes in different forms or shapes. The act directs the agency to establish uniform serving size. Therefore, the same food should have the same reference amount regardless of its form or shape. The agency also disagrees with the comments that recommended reference amounts based on the weight of 1 slice of bread because food consumption data did not support such reference amounts. The agency also does not agree with the international comment that suggested keeping the 55 g reference amount for rolls because rolls are heavier than bread. The agency notes that the act defines the serving size as an amount customarily consumed. Food consumption data of the U.S. population showed that the amount customarily consumed is not higher for rolls than for bread (Ref. 47). Therefore, FDA has not adopted these recommendations.

49. A manufacturer of "lite bread" suggested a separate category for "lite" breads with a reference amount of 40 g. The comment stated that if "lite" breads are grouped with regular breads, the serving size for "lite" breads will be 3 slices, not 2 slices.

FDA advises that § 101.12(e) of the 1991 serving size proposal, which has been combined with new § 101.12(d) (see section III.D.6. of this document), requires that the reference amount for an altered version of a food be the same as for the food for which it is offered as a substitute. Therefore, it is inappropriate to have a lower reference amount for "lite" breads. However, if the product has been modified to be an aerated product as described in new § 101.12(e), manufacturers may determine the density-adjusted reference amount for the "aerated" bread by adjusting for the difference in density of the "aerated" bread relative to the density of the appropriate reference bread. (See section III.D.6. of this document for further discussion).

50. Comments from the tortilla industry unanimously requested a separate category for tortillas because: (1) Tortillas are not used interchangeably with other products in the bread category; (2) the tortilla industry continues to grow and deserves a separate category; and (3) a separate category would "help focus guidelines more specific to tortillas rather than baked goods in general." The comments did not suggest what the reference amount for this separate category should be. A comment from a foreign government contended that tortillas should be included in the "Taco shell" category.

FDA does not agree with the comments. To minimize the number of product categories, FDA proposed to include tortillas in the bread category because the amounts customarily consumed of tortillas and other products in the bread category (e.g., bagel, English muffin) are similar. The comments did not provide data to the contrary. FDA recognizes that tortillas have uses somewhat different from other products in the bread category, and that the tortilla industry is growing. However, balancing the interest in minimizing product categories against the significance of these facts, FDA concludes that it is appropriate to list tortillas with other bakery products that have the same reference amount. Therefore, FDA is not creating a separate category for tortillas.

Also, tortillas cannot be grouped with taco shells because the reference amounts for the two foods differ by two-fold. Although they both are foods that originated in Mexico, tortillas are much higher in moisture content and thus are much heavier than hard taco shells. This difference in the moisture content is reflected in the g weight of the reference amount.

(6) Bakery products: breakfast bars and toaster pastries

FDA proposed 55 g as the reference amount for this product category.

51. Manufacturers of breakfast bars and toaster pastries commented that it is more appropriate to separate these products into two categories with separate reference amounts because they are not consumed in similar amounts or in similar manners. The comments submitted market research data that showed that less than 20 percent of the bars are actually consumed at breakfast, and almost 80 percent are consumed at lunch or as a snack. In contrast, approximately 80 percent of the toaster pastries are eaten at breakfast. The comments suggested 40 g or 41 g as the reference amount for grain-based bars including breakfast bars and granola bars. Another comment suggested a 35 g reference amount for granola bars. The comments agreed on the 55 g reference amount proposed for toaster pastries, but they contended that these products are used interchangeably with the products in the coffee cake category. The comments said that, therefore, they should be included in the coffee cake category.

FDA agrees that grain-based bars should have a separate category with their own reference amount. The agency finds that 40 g is appropriate because it is consistent with the amount of these bars customarily consumed (Ref. 2). FDA also agrees with including toaster pastries in the Coffee cake category with a reference amount of 55 g. The comments support that doing so reflects how these products are customarily consumed. Therefore, in Table 2 of new § 101.12(b), FDA has deleted the category for breakfast bars and toaster pastries and has added a new category for "Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars" with a reference amount of 40 g, after the category for French toast and pancakes under the major category for Bakery Products. The agency has also revised the name of the coffee cake category to include toaster pastries.

(7) Bakery products: brownies

FDA proposed 40 g as the reference amount for this product category.

52. Two industry comments agreed with the 40 g reference amount. One comment, however, contended that brownies should have the same reference amount as cake because brownies do not differ from cake nutritionally, technologically, or in ingredients. Another comment asserted that an 80 g reference amount for brownies is consistent with consumption data and industry practice. Another comment recommended that FDA change the reference amount for brownies to make it uniform with the reference amount for snacks.

FDA disagrees with all of the comments that requested a change in the reference amount for brownies. Products that are similar nutritionally, technologically, and in ingredients often differ in amounts customarily consumed because they differ in other characteristics that affect the amount consumed (e.g., density). For example, the customarily consumed amount of dense ready-to-eat breakfast cereals (e.g., sweetened granola cereals) is about twice that of light weight cereals (e.g., flake-type cereals). Therefore, foods do not have the same reference amount simply because they are similar nutritionally, technologically, and in ingredients. They have the same reference amount if consumption data show that they do.

Data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that 40 g, not 80 g, is consistent with consumption data for brownies (Ref. 2). FDA cannot change a reference amount simply to make it consistent with industry practice. The reference amount must reflect the amount customarily consumed. Also, the agency is not adopting the recommendation for a uniform reference amount for brownies and snacks because these foods are not necessarily used interchangeably, and such a uniform reference amount is not supported by food consumption data (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(8) Bakery products: cake

FDA proposed 4 categories with separate reference amounts based on the density of the cakes: Heavy weight, medium weight, light weight, and very light weight. The heavy weight category included cakes weighing more than or equal to 10 g per cubic inch (e.g., cheese cake, fruit cake, and pineapple-upside down cake). The medium weight category included all cakes weighing more than or equal to 6 g but less than 10 g per cubic inch (e.g., most cakes with icing or filling, carrot cake, pound cake). The light weight category included all cakes weighing more than or equal to 4 g but less than 6 g per cubic inch (e.g., most cakes without icing or filling, very light cakes with icing or filling, eclairs). The very light weight category included all cakes weighing less than 4 g per cubic inch (e.g., angel food, chiffon, or sponge cake without icing or filling).

53. All comments that addressed the reference amounts for cakes opposed the density-based categories. The comments recommended eliminating the density specifications from the product category because: (1) Density has never been used by industry, the Government, or the trade to classify cakes; (2) it is difficult to determine the density because it varies with shelf life, temperature, and atmospheric pressure; (3) the density of a commercially prepared cake and the same cake baked from a mix may be slightly different and may result in the same type of cake falling into two different categories; and (4) there is potential for the manipulation of the densities of cakes that fall near category boundaries to fit in a favorable category.

Most comments recommended that FDA regroup cakes into 3 categories based on cake types: Heavy weight, medium weight, and light weight. The comments essentially requested retaining the proposed heavy and the very light weight categories with some modifications and combining the two proposed middle categories with a reference amount of 80 g. The comments also suggested including only those fruit cakes that contain 35 percent or more of the finished weight as fruit or nuts, as opposed to all fruit cakes, in the heavy weight category. The combined medium weight category would contain all chemically leavened cakes with or without icing or filling and other cakes (e.g., Boston cream pie, eclair) that do

not belong to the heavy or light weight category. A comment submitted a detailed description and results of analysis of data from the 1987–1988 NFCS in support of the 80 g reference amount recommended for the medium weight category.

FDA recognizes that it is difficult to determine the density of cake because it varies with shelf life, temperature, and atmospheric pressure. The agency also recognizes that other problems may arise from using the density-based categories such as that the density of a commercially prepared cake and the same cake baked from a mix may have slightly different densities that could result in the same type of cake falling into two different categories, and that the product categories based on density may encourage the manipulation of the density of cakes that fall around the borderline of a category to fit in a favorable category. The agency thus agrees with the comments that it is better to group cakes by type and to combine the proposed two middle categories into one medium weight category. The agency has reanalyzed the NFCS to confirm the 80 g reference amount suggested in the comment for the medium weight category (Ref. 41). Accordingly, the product category names for cakes have been renamed by type of cakes as suggested in the comments and the proposed middle two categories have been combined into one medium weight category with a reference amount of 80 g. The revised product category names and reference amounts are as follows:

Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables)—125 g

Cakes, medium weight (chemically 80 g leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables; light weight cake with icing; Boston cream pie; cupcake; eclair; cream puff)—80 g

Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling)—55 g.

The agency notes that although the cake categories are named by the type of cakes, not by the density, density was used as a guideline to group the cakes into the three categories. The heavy weight category includes cakes that weigh 10 g or more per cubic inch, the medium weight category includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch, and the light weight category includes cakes that weigh less than 4 g per cubic inch. The density information described here provides guidance for cakes that may enter into the future market and do not fit in the cake types described in the product category names. The agency also notes that angel food, chiffon, and sponge cake without icing or filling that are prepared by traditional recipes and preparation methods are light and usually weigh less than 4 g per cubic inch. Therefore, they are included in the light weight category. However, if angel food, chiffon, or sponge cake contains heavy ingredients (e.g., fruits, chocolate chips, and nuts) that are usually not called for in the traditional recipes of these cakes, or if these cakes are processed in such a way as to increase the density, they will not be qualified to be called light weight cakes.

54. Two comments recommended a three-category system similar to the one discussed above but suggested that the medium weight category include only cakes without icing. The comments contended that the reference amount for the medium weight cakes with icing is not necessary because icing has a separate reference amount.

The system suggested by this comment will work for cakes with icing only. Many cakes have fillings. There is no reference amount for cake fillings. The agency is unable to determine a reference amount for cake fillings because there is no information from food consumption surveys or other sources to determine the customarily consumed amount of the fillings. Accordingly, FDA has not adopted this recommendation.

55. Some comments recommended that FDA include all cheese cakes other than New York style cheese cake in the medium weight category, rather than the heavy weight category. The comments contended that the 125 g reference amount is too large for non-New York-style (aerated) cheese cakes. One comment recommended that if FDA decides not to include cheese cake in the medium weight category, cheese cake should have a separate category with its own reference amount because cheese cakes differ from other cakes in many characteristics that affect the consumption size. The comment recommended 85 g as the reference amount for cheese cakes and submitted data collected by a "mail panel" survey that supported the 85 g reference amount.

FDA acknowledges that some commercially-prepared cheese cakes have air incorporated (aerated cheese cakes) and therefore, weigh much less than the unaerated (New York style) cheese cakes. The agency agrees with the comments that these aerated cheese cakes need a separate approach.

As discussed in section III.D.6. of this document, the agency has provided guidelines for determining the reference amount for products that are modified by incorporating air. If the aerated cheese cakes mentioned in the comment meet the 25 percent minimum reduction in density relative to the density of the appropriate unaerated cheese cake, manufacturers may use the "density-adjusted" reference amount for the aerated cheese cake following the guidelines described in section III.D.6. of this document, provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated cheese cake (see section III.D.6. for further discussion). Therefore, it is not necessary to create a separate category for aerated cheese cake or to establish a separate reference amount for aerated cheese cakes. Accordingly, FDA has retained the proposed 125-g reference amount for cheese cakes.

56. Some comments recommended that FDA include pound cake without icing in the light weight category with angel food, sponge, and chiffon cake without icing. The comments argued that USDA's density data used to convert a piece of pound cake to the g weight (conversion factor) were based on home recipes. The comments contended that commercially-prepared pound cakes are much less dense than the home-prepared versions. Thus, the conversion factor used in the NFCS was too high. Consequently, the amount customarily consumed for pound cake was overestimated. One comment recommended that if FDA decides not to include pound cake in the light weight category, pound cake should have a separate category with its own reference amount because pound cake differs from other cakes in many characteristics that affect the consumption amount. The comment recommended 45 g as the reference amount for pound cakes as a separate category and submitted data collected by a "mail panel" survey in support of the 45 g reference amount.

FDA disagrees with the comments. The cakes included in the light weight category (e.g., angel food, sponge, and chiffon cake) weighs less than 4 g per cubic inch (density). Commercial pound cakes without icing are much higher in density (about 6.1 g per cubic inch) than the cakes included in the light weight category (Ref. 48). The comment did not present density data to prove that commercial pound cakes weigh less than 4 g per cubic inch. All cakes that weigh more than 4 g per cubic inch, with the exception of those included in the heavy weight cake category, are

included in the medium weight cake category.

With regard to the survey data submitted in support of a separate reference amount of 45 g, FDA notes that in this survey, respondents were asked to record the total number of servings (slices) they usually get from a specific size of pound cake but were not asked how many slices each person in the household ate at a particular eating occasion. People often consume multiple slices at a single eating occasion. In addition, the survey included only frozen pound cake manufactured by the company that submitted the comment. The survey did not include the unfrozen, ready-to-eat forms of pound cake or competitors' products. Therefore, the data submitted in the comment do not represent all forms of pound cake in the marketplace. Therefore, the agency questions the representativeness and appropriateness of the data submitted in the comment and finds that they do not support a change in the reference amount.

FDA has thus concluded that the comments did not submit adequate data to justify the inclusion of pound cake without icing in the light weight category or to establish a separate category for pound cake with a reference amount of 45 g. Accordingly, the agency has retained pound cake without icing in the medium weight cake category.

57. One comment suggested a 90 g reference amount for all cakes.

Considering the large variability in the density of cakes, a uniform reference amount, regardless of the value, would result in a serving size too large for some cakes and too small for other cakes. The 90 g reference amount suggested would make the serving size for a light cake (e.g., angel food cake) a huge piece (e.g., about 1/3 of a 10 oz (about 8 inch diameter) angel food cake), whereas the serving size for a heavy fruit cake would be a small, thin slice.

58. One comment suggested separate reference amounts for cupcakes, 55 g for iced cupcakes and 35 g for un-iced cupcakes. The comment contended that the NFCS data suggest 55 g as the reference amount for frosted cupcakes and that the 55 g reference amount agrees with the reference amount for other products that are used interchangeably with cupcakes (e.g., muffins, Danish, doughnuts, coffee cakes). One comment requested that FDA establish a reference amount for assorted cupcakes.

FDA advises that the smallest reference amount for cake is 55 g for the light weight cake category. The cakes included in the light weight category (e.g., angel food, sponge, and chiffon cake) weigh less than 4 g per cubic inch. The comment did not present density data to prove that cupcakes weigh less than 4 g per cubic inch. All cakes that weigh more than 4 g per cubic inch, with the exception of those included in the heavy weight cake category, are included in the medium weight cake category. The labels of cake mixes that belong to the medium weight cake category (e.g., chocolate, yellow, or white cake) frequently provide preparation directions for a 2-layer cake, a sheet cake, and cupcakes. These label directions suggest that cupcakes are the same cake as a 2-layer or a sheet cake included in the medium weight category but differ only in shape, i.e., cupcakes are an individually shaped form of cake. The act directs the agency to establish uniform serving sizes. Therefore, the same food should have the same reference amount regardless of its shape. Thus, the agency included all cupcakes both with and without icing (including assorted cupcakes) in the medium weight category in this final regulation with the reference amount of 80 g. Accordingly, FDA has not established a separate reference amount for cupcakes.

59. One comment requested that FDA change the reference amount for muffins prepared at home, either from scratch or from a mix, to 45 g. The comment contended that a 45 g reference amount more closely approximates the weight of the muffin made with consumer baking pans.

FDA disagrees with the comment. First, food prepared at home from scratch is not subject to nutrition labeling. Secondly, the agency cannot establish a separate reference amount for the same food depending on the equipment used for preparation (e.g., commercial equipment versus equipment used at home). The reference amount for muffins is based on what consumption data show as the amount customarily consumed. Thus, it complies with the statute. Accordingly, FDA has not adopted this recommendation.

60. One comment suggested that FDA add microwave cakes to the coffee cake category. The comment stated that because of the characteristics of microwave cooking, microwave cakes have an unusually high density (7 to 7.5 g per cubic inch) and are very rich. According to the density classification, microwave cakes belong to the proposed medium weight category with the reference amount of 110 g. The comment contended that 110 g is too large for the microwave cakes. The comment, therefore, suggested including microwave cakes in the coffee cake category.

FDA does not agree that microwave cakes should be grouped with the products in the coffee cake category because microwave cakes are not used interchangeably with the products in the coffee cake category. Microwave cakes are a kind of cake that differs from other cakes only in that they are prepared in the microwave oven rather than in the conventional-type oven. Therefore, microwave cakes belong to a cake category. The agency points out that all cakes other than those classified as heavy weight and light weight are included in the medium weight category in the final regulation. The 7 to 7.5 g per cubic inch density for microwave cakes that the comment reported is within the range of the density of cakes in the medium weight cake category (4 g or more per cubic inch but less than 10 g per cubic inch). The agency notes that the reference amount for this new medium weight category is 80 g, not 110 g. Therefore, the agency has provided the relief that the comment sought, although for different reasons.

(9) Bakery products: crackers, all varieties excluding sweet and sandwich type—includes hard bread sticks and ice cream cones

FDA proposed 15 g as the reference amount for this product category.

61. Several comments argued that it is unfair to have two different reference amounts for competing products (i.e., crackers and snacks) that are used interchangeably. The comments requested that FDA establish a uniform reference amount for snacks and "snack crackers." If not, the comments asserted that a false impression will be created that snack crackers are lower in fat than the competing snack products. Some of these comments pointed out that some products that are more appropriately classified as snacks bear the name cracker (e.g., Cracker Crisps). A manufacturer suggested defining snacker crackers as crackers to which oil has been applied after baking (postbaking oil application).

FDA agrees with the comment that many crackers are used interchangeably with products in the snacks category. The agency acknowledges that it is very difficult to draw a line between cracker and snack products. Therefore, FDA has reexamined the products included in the cracker category and has concluded that it is more reasonable to divide it into two categories: Crackers that are usually not used as snacks and crackers that are usually used as snacks, based on their customary usage, how they are positioned in the marketplace, and the

amount of the cracker that is customarily consumed.

The former category includes saltines, soda crackers, and oyster crackers. These crackers are usually used as part of the meal (e.g., with soup) rather than as snacks. Reanalysis of the data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that the proposed 15-g reference amount is reasonable for crackers that are usually not used as snacks. However, the customarily consumed amount of other crackers is closer to 1 oz than to 0.5 oz. Therefore, the agency has concluded that the cracker category should be divided into two categories with separate reference amounts. Accordingly, FDA has revised the cracker category as follows:

Crackers that are usually used as snacks—30 g

Crackers that are usually not used as snacks—15 g

The agency could not use the postbaking oil application suggested in the comment to divide the cracker category into "snack crackers" and "nonsnack crackers" because manufacturers can change the practice of the postbaking oil application, and therefore, a classification system based on this application could easily become irrelevant.

(10) Bakery products: French toast, pancakes

FDA proposed 110 g as the reference amount for this product category.

62. One comment recommended that FDA combine French toast and pancakes with waffles, with a reference amount of 85 g. The comment contended that these products "make similar contributions to the diet and are customarily consumed in the same way."

FDA agrees that French toast, pancakes, and waffles are used interchangeably in the diet. However, because French toast and pancakes are denser than waffles, the amount customarily consumed in g is much larger for French toast and pancakes than for waffles. Food consumption data do not support the 85 g reference amount for French toast and pancakes suggested in the comment (Ref. 2). Therefore, these foods cannot be grouped into one category. Accordingly, FDA has retained reference amounts for French toast and pancakes as proposed.

63. One comment recommended that FDA add a new category for dry pancake mix and variety mixes with a reference amount of 55 g. The comment contended that 55 g is equivalent to the amount of mix required to make three 4-inch pancakes, which is equivalent to the reference amount proposed by FDA.

New § 101.12(c) provides that the reference amount of a product that requires cooking or the addition of water or other ingredients be the amount required to prepare one reference amount of the final product as established in new § 101.12(b). Therefore, the reference amount for dry pancake mix will be the amount of the mix required to make one reference amount of the prepared product, so there is not need to establish a reference amount for dry pancake mix. Moreover, this approach is more reasonable than that suggested by the comment because pancake mixes come both in complete and incomplete forms, and the amount to make one reference amount may differ for the different forms.

Because variety mixes are used for many different purposes, the agency agrees with the comment that a reference amount for the dry form would be desirable so that all variety mixes will have a uniform label serving size to facilitate nutrition comparisons of different brands. Otherwise, different brands may choose different uses as the basis to determine the amount of the dry mix to make one reference amount of the prepared food.

According to the product label, a major use of variety mixes is to make pancakes. Using the recipe file for the 1987–1988 NFCS (Ref. 49), the agency has estimated that about 40 g of dry mix is needed to make one reference amount of the prepared pancakes. Therefore, FDA has established the reference amount for the variety mixes to be 40 g of dry mix. Accordingly, the agency has revised the product category to read: "French toast, pancakes, variety mixes." The reference amount has been revised to read: "110 g prepared for French toast and pancakes; 40 g of dry mix for variety mixes."

(11) Bakery products: pies, cobblers, turnovers, other pastries

FDA proposed 125 g as the reference amount for this product category.

64. A comment from a trade association for bakery products supported the proposed reference amount. A few other comments opposed the 125-g reference amount. One comment requested that FDA change the reference amount to 4 oz (110 g) based on the size of 1/6 and 1/8 of pies tested. Another comment argued that the proposed reference amount would result in an extremely large serving size for some pies (e.g., 1/3 of an 8-inch frozen cream pie) and a small serving size for other pies (e.g., 1/10 of a 10-inch fruit pie). The comment recommended that FDA establish three separate reference amounts: 1/6 of a pie for 8 inch pies, 1/8 of a pie for 9-inch or larger pies, and 125 g for individual pies and pastries. The comment submitted estimates of amounts consumed per serving for various pies that it manufactures which were derived from a "Mall Intercept Method" survey conducted in 15 cities in the United States. The survey was designed to recruit people who are representative of the demographic and socioeconomic characteristics of the people who buy the test products based on the sales data for frozen pies.

FDA carefully examined all data submitted in the comments. FDA disagrees with the request to change the reference amount to 4 oz. The data submitted in support of the 4-oz reference amount do not represent food consumption data collected under actual conditions of use or an estimate representative of all types and varieties of products included in the product category.

FDA also disagrees with the comment that contended that reference amounts should be expressed in fractions of pies. The agency used fractions as the reference amount for pie crust because in this particular case, fractions are the most meaningful measure, and there is not much concern about the manipulation of the serving size for the pie crust. Because pies come in different diameters and heights, reference amounts based on fractions of pies would result in different reference amounts for different size pies of the same brand as well as for different brands of the same kind of pie. Therefore, there would be no uniform basis to evaluate the qualification for claims on pies. For example, data submitted in the comment showed that the reference amount based on fractions of pies for one brand alone could vary from 64 to 163 g. Furthermore, reference amounts based on fractions of pies may encourage the manipulation of the reference amount to produce a more favorable presentation of the nutrition information or to qualify for a claim by changing the diameter or height.

The agency, however, agrees that the 125-g reference amount would result in an unreasonably large serving size for frozen cream pies. These commercially prepared frozen cream pies differ from homemade cream pies. Commercial cream pies are aerated and thus weigh much less than homemade cream pies. Therefore, FDA believes that these pies need a separate approach that is more reasonable for aerated cream pies.

As discussed in section III.D.6. of this document, the agency has provided guidelines for determining the reference amount for products that are modified by incorporating air. If the aerated

cream pies mentioned in the comment meet the 25 percent minimum reduction in density relative to the density of the appropriate unaerated cream pie, manufacturers may use the "density-adjusted" reference amount for the aerated cream pie following the guidelines described in section III.D.6. of this document, provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated cream pie (see section III.D.6. for further discussion). Therefore, it is not necessary to establish a separate reference amount for aerated cream pies. Accordingly, FDA has retained the proposed 125-g reference amount for cream pies.

(12) Bakery products: taco shell

FDA proposed 30 g as the reference amount for this product category.

65. A comment from a trade association for bakery products supported the proposed reference amount. Another comment recommended that FDA change the reference amount to 15 g which is equivalent to 1 taco shell. The comment contended that one filled taco shell equals the reference amount for the mixed dishes not measurable with cup category (140 g).

FDA disagrees with the latter comment. The agency points out that according to the USDA manual (Ref. 31), one filled taco weighs about 70 to 80 g. Therefore, two filled tacos would approximate one reference amount for filled tacos. Accordingly, FDA has retained the reference amount as proposed.

(13) Bakery products: waffles

FDA proposed 85 g as this reference amount for the product category.

66. Two comments from a trade association for bakery products and a manufacturer supported the proposed reference amount. One comment from another manufacturer opposed the 85-g reference amount. The comment contended that the 85-g reference amount would make the serving size for some of their waffles three waffles instead of two. The comment recommended that FDA revise the reference amount for waffles to state "85 g, and not to exceed 2 waffles or 2 sets of connected waffles, if their total weight is 67 percent of the reference amount or more." The comment submitted data from a "Mall Intercept Method" survey conducted in 15 cities in the United States to support that people customarily consume 2 waffles or 2 sets of connected waffles. The comment also requested that FDA allow manufacturers to provide nutrition information per waffle or per 1 set of waffles.

FDA advises that it is inappropriate to call 2 pieces of a product that weigh 67 percent of the reference amount one serving when 3 pieces are equal to one reference amount. In addition, FDA notes that the 85-g reference amount was derived using data from large national food consumption surveys that were collected under actual conditions of use and included all types of waffle products (dry mixes and frozen) and many different brands available in the marketplace. The agency finds that it would be inappropriate to modify the reference amount to make it consistent with questionable data submitted in the comment.

The data submitted in the comment have several problems. First, they are not food consumption data that were collected under actual conditions of use. People were asked to show the number of waffles that the participants and other members of their families normally eat. People did not answer or record the number of waffles that they actually ate during the survey days. In addition, the survey tested only frozen waffles manufactured by the company that submitted the comment. Waffles come in dry mixes and frozen prepared forms. There are many different brands of waffle products in the marketplace. Therefore, it is questionable if the data submitted in the comment are representative of all waffle products in the marketplace.

Accordingly, FDA has retained the reference amount as proposed. The agency notes that new § 101.9(10)(ii) allows voluntary labeling of a second column of values per unit for products in discrete units.

(14) Beverages: all categories

Because FDA proposed a uniform 240-mL (8-fl oz) reference amount for all beverages, comments on all the categories under Beverages are considered together.

67. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. There were no objections to the 8-fl oz reference amount for carbonated beverages, wine coolers, or water. However, two comments from the carbonated beverage industry stated that if FDA abandons the uniform 8-fl oz reference amount, they want a 6-fl oz reference amount for carbonated beverages. Comments from coffee and tea manufacturers and their trade associations opposed the 8-fl oz uniform reference amount. These comments contended that the reference amount for coffee and tea should be 180 mL (6 fl oz). Among other things, these comments argued that: (1) 6 fl oz is the serving size currently used by the industry, in recipe books and other literature, (2) hot beverages are generally not used interchangeably with cold beverages, and (3) standard coffee cups as well as the graduation on coffee makers and pots are designed for 5 1/2- to 6-fl oz serving sizes. The comments contended that changing the serving size for coffee to 8 fl oz would cause unnecessary costs to manufacturers to change the graduation on the coffee making apparatuses. Such cost increases would be passed on to consumers.

First, FDA advises that new § 101.9(j)(4) exempts plain coffee and tea from all requirements of the nutrition labeling regulation. Accordingly, the reference amount for plain coffee and tea has been deleted from Table 2 in new § 101.12(b). As for the reference amount for flavored and sweetened coffee and tea, the agency points out that food consumption data support the 8-fl oz reference amount for these coffees and teas (Ref. 2). The agency notes that unlike plain coffee, flavored and sweetened coffee are not made in coffee makers, and thus there is no concern about changing the graduation on the coffee making apparatuses which would increase the cost of coffee. Flavored and sweetened tea (e.g., iced tea mixes) is also used interchangeably with other cold beverages. Considering the weight of support for the uniform 8-fl oz reference amount for all beverages and the reasons stated here, the agency has concluded that the uniform 8-fl oz reference amount for all beverages including flavored and sweetened tea is appropriate under section 403(q)(1)(A)(i) of the act. Accordingly, FDA has retained the reference amount as proposed for all beverages under the beverages category except for plain coffee and tea. The uniform reference amount for all beverages facilitates nutrition comparisons among different beverages.

(15) Cereals and other grain products: breakfast cereals (hot cereal type), hominy grits

FDA proposed 1 cup prepared or 40-g plain dry cereal or 55-g flavored, sweetened dry cereal as the reference amounts for this category.

68. Several comments opposed the proposed reference amounts for the dry cereal form. One comment recommended that FDA change the

reference amount to 1-oz dry because this amount is more consistent with current labeling practices by manufacturers. Another comment recommended a 35-g uniform reference amount for all cereals, including hot and ready-to-eat cereals (and a 50-g reference amount for a second category if a second category is necessary). The comment did not submit any supporting data for the recommended reference amounts. A manufacturer of hot cereals recommended that FDA use a uniform reference amount of 40 g for both regular, and flavored and sweetened cereals. To support the uniform 40-g reference amount, the comment submitted estimates of the dry weight of cereals derived from the mean consumed amounts from the 1987–1988 NFCS for the two types of cereals (regular and quick hot cereals and instant hot cereals) and the conversion factors it used to determine the dry weight from the prepared weight.

Under the act, the serving size must reflect an amount customarily consumed, not the current labeling practices by manufacturers. Therefore, the agency cannot change the reference amount derived from the food consumption data, which represents the customarily consumed amount, to make it consistent with the current labeling practices.

With regard to the comment that recommended a uniform reference amount of 40 g for all hot cereals, FDA carefully examined the data submitted in support of the uniform 40-g reference amount. The data showed that the mean intake for the instant cereal was lower than the mean intake for the regular and quick cereal because many instant cereals come in single-serving packages, and the single-serving packages currently on the market generally contain less than the amount of dry cereal required to make one reference amount (1 cup) of the prepared cereal. Therefore, the mean consumed amount of flavored and sweetened cereals was lower than that of regular and of quick hot cereals.

Basing the reference amount on the data in the comment would result in using two different bases for determining the reference amount for hot cereals: (1) Regular and quick hot cereals would reflect the amount customarily consumed from multiserving containers, and (2) flavored and sweetened hot cereals would reflect the amount customarily consumed from current single-serving containers. As the comment pointed out, the flavored and sweetened hot cereals currently come in single-serving containers only. However, although the amount of hot dry cereal customarily consumed may remain the same, the single-serving container size may change, or these products may be available in multiserving containers in the future. Therefore, the agency has concluded that the reference amounts for both varieties of hot dry cereal must reflect the multiserving containers.

FDA's independent analysis, using both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed for the plain dry hot cereals is 40 g (Ref. 41). The flavored and sweetened hot cereals, however, contain additional ingredients (e.g., sugar, dried fruit) and, therefore, weigh more than plain dry hot cereals on an "as packaged" basis. Based on the difference in weight of plain dry hot cereal and flavored and sweetened cereal, FDA estimated the difference in weight to be, on the average, about 15 g (Ref. 2). Therefore, the reference amount for flavored and sweetened hot cereals must include the 15-g extra weight to account for the additional ingredients. Accordingly, FDA has retained the reference amount as proposed (55 g). The agency points out, however, that according to new§ 101.9(b)(2)(i) and (b)(6), the serving sizes of all single-serving packages of hot cereals will be one package.

(16) Cereals and other grain products: breakfast cereals, ready-to-eat, all categories

FDA proposed three reference amounts for ready-to-eat cereals depending on the density or shape of the cereal: 1 cup for cereals weighing less than 3 oz per cup; 1/2 cup for cereals weighing more than or equal to 3 oz per cup; and 50 g for cereals not measurable with a cup (e.g., biscuit type).

69. Most comments objected to the reference amount in a volumetric (cup) measure because of the lack of precision in the measurement of the g weight of the cup measure. The comments preferred weight-based reference amounts. One comment stated that the volumes of small pieces of dry solids can be accidentally altered or even intentionally manipulated to reach different volumetric measurements. Cereals' shapes, sizes, ingredients, and textures, as well as handling practices, settling characteristics, measurement methods, and timing can affect the accuracy of measurements. The comment contended that measured g weights of the servings by two persons trained to follow identical procedures varied not only for servings from the top to the bottom of the boxes but at identical levels of different boxes. Overall, the g weights of the individual cup measurements differed by more than two-fold (29 to 68 g). The comment contended that because there are large variabilities in the estimates for g-weight-per-cup measure, the specific g-weight measure a manufacturer chooses to declare on the label may be arbitrary and, worse, may be manipulated in order to permit nutrient content claims.

As a solution to the problems discussed above, some comments recommended a uniform weight-based reference amount for all ready-to-eat cereals. Others recommended that the cereals be divided into two categories based on density with separate weight-based reference amounts. For a uniform reference amount, a health professional organization recommended 1 oz, and a cereal manufacturer recommended 35 g. Comments that recommended the two-category system differed in both how the two categories should be split and the reference amounts for the two categories. One comment suggested a 35-g reference amount for all cereals and, if a second category is necessary, 55 g for the second category. The comment did not provide details about what products the second category should include. Another comment recommended a 15-g reference amount for plain puffed cereal grains and a 35 to 40 g reference amount for all other cereals. Two other comments recommended a 30-g reference amount for cereals weighing less than 43-g per cup and for cereals that contain at least 8 g of fiber per oz, and a 55-g reference amount for cereals weighing 43 g or more per cup.

The comments provided a good description of the difficulties in accurately determining the g weight equivalents of the cup measures of ready-to-eat cereals. FDA acknowledges the characteristics of ready-to-eat cereals that present particular problems in determining the g-weight equivalents of household measures. The agency agrees with the comments that volume-based reference amounts present compliance problems and may result in manipulation of the serving size. Therefore, FDA has concluded that the reference amounts for ready-to-eat cereals should be in g quantities.

FDA carefully examined the weight-based reference amounts suggested in the comments. FDA does not believe that a uniform reference amount for all ready-to-eat cereals is appropriate. Regardless of the value, a uniform reference amount would result in serving sizes that are too large for some cereals and too small for others. For example, the 35-g reference amount

suggested in the comment would result in serving sizes that range from about 1/4 cup for heavy cereals (e.g., sweetened granola-type cereals) to about 3 cups for light cereals (plain puffed rice or wheat). These serving sizes are not consistent with the amounts of these types of cereals customarily consumed. Food consumption data showed that customarily consumed amounts for the heavy cereals are about 1/2 cup and for the light cereals about 1 cup (Ref. 41).

FDA also carefully examined all reference amounts for the two-category system suggested in the comments. One of the comments submitted a detailed description and results of an analysis of data from the 1987–1988 NFCS to support the 43-g per cup dividing line, with 30- and 55-g reference amounts. FDA has done an independent data analysis of ready-to-eat cereals and confirmed the validity and reasonableness of the reference amounts recommended in the comment for most cereals (Ref. 41).

However, the agency does not believe that the 30-g reference amount is reasonable for light cereals that weigh less than 20-g per cup (e.g., plain puffed rice or wheat). The 30-g reference amount would result in a serving size that is about 2 to 2 1/2 times the customarily consumed amounts of these cereals. Therefore, FDA has divided the category for cereals weighing less than 43 g per cup into 2 categories: Cereals weighing less than 20 g per cup, which primarily consist of plain puffed cereal grains, and cereals weighing 20 g or more but less than 43 g per cup. Following the principles and procedures described in the 1991 serving size proposal, FDA has determined the reference amount for light cereals to be 15 g (Ref. 41).

Accordingly, FDA has revised the product categories, and the reference amounts, for ready-to-eat cereals as follows:

Breakfast cereals, ready-to-eat weighing less than 20 g per cup, (e.g., plain puffed cereal grains)—15 g

Breakfast cereals, ready-to-eat weighing more than 20 g but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g—30 g

Breakfast cereals, ready-to-eat weighing 43 g or more per cup; biscuit types—55 g

70. Other comments on the reference amounts for ready-to-eat cereals included objections to some specific aspects of the methodology used to determine the reference amounts. One comment objected to the first step used in determining the product categories (56 FR 60394 at 60403) for cereals. This step divided the cereals into subcategories according to "other characteristics" that are likely to affect the levels of consumption of foods within the product class, i.e., in this case, the density of the cereals. Other comments objected to relying solely on the 1987–1988 NFCS in determining the reference amount for cereals measurable with a cup. Another comment stated that USDA's density information that FDA used to categorize ready-to-eat cereals differed from the manufacturers' data for at least 11 cereals.

As mentioned above, the amounts customarily consumed for ready-to-eat cereals vary by the density of the cereal. Therefore, the step that divided the cereals into subcategories by density was necessary in order to determine the appropriate amounts customarily consumed for specific types of cereals. As explained in the technical report (Ref. 2), FDA relied solely on the 1987–1988 NFCS because many new cereals have been introduced since the 1977–1978 NFCS, and the 1977–1978 NFCS did not contain food consumption data or density information for the new varieties. Also, density information in the 1977–1978 NFCS was not as useful as that in the 1987–1988 NFCS even for cereals that existed at the time of, or prior to, the 1977–1978 NFCS. Also cereals that differed in density had often been combined into one food code in the 1977–1978 NFCS. In the 1987–1988 NFCS, however, USDA greatly expanded the list of ready-to-eat cereals and their density information. FDA continues to believe that ready-to-eat cereals need to be divided into subcategories, and that it is necessary to rely solely on the 1987–1988 NFCS to estimate the amounts customarily consumed for the cereals currently on the market and to reflect the more recent data on density.

With regard to the discrepancy in measurements of densities of ready-to-eat cereals between USDA and manufacturers' data, the comment did not specify the cereals for which there was a discrepancy, or how large the discrepancies were. USDA's density information is the most current and the best data available to FDA. These density measurements were done without any knowledge about a possible use in nutrition labeling. Therefore, there was no manipulation of the measurements to provide a favorable nutrition profile or to be able to make a claim. In light of the extreme difficulties in measuring the g weights of cup measures and the lack of well-established standard procedures for measuring the g weights of cup measures for ready-to-eat cereals, FDA will use USDA's measurements for compliance purposes to check for proper categorization of ready-to-eat cereals. USDA's density data can be found in Reference 45.

If a manufacturer does not agree with USDA's density data, the manufacturer can petition FDA for a reevaluation of the density of a particular cereal. The manufacturer should submit density data that includes a detailed description of the methodology used (e.g., materials and equipment used, procedures followed), name and qualification of the operator, records of all individual measurements, the mean and the standard deviation of the measurements, and any other information that may help FDA to evaluate the density of the product in question. Density measurements should be repeated a sufficient number of times to produce a reliable estimate. In determining the density, manufacturers should also follow FDA's general Guidelines for Determining the Gram Weight of the Household Measure mentioned in new § 101.9(b)(7).

(17) Cereals and other grain products: flours or cornmeal

FDA proposed 30 g as the reference amount for this product category.

71. One comment opposed the 30 g reference amount for bread. The comment contended that their research showed that 55 g (2 oz) of flour is needed to make 2 slices of homemade bread. The comment stated that they used 2 slices as the amount customarily consumed because the 1977–1978 NFCS showed that consumers typically consume 2 slices of bread per eating occasion regardless of the density. Because the primary use of flour is homemade bread, and homemade bread is typically more dense than commercially-made bread, the comment argued that more flour is needed to make 2 slices of homemade bread than 2 slices of commercial bread. The comment did not submit the protocol for the research upon which it relied or data in support of the suggested change in the reference amount.

FDA disagrees with the comment. The agency notes that the comment's assumption that the amount customarily consumed in g is larger for homemade bread than for commercial bread is wrong. Data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed of homemade bread is not greater than 55 g (Ref. 41). The 30-g reference amount is the amount of flour required to make 55 g of bread. Accordingly, FDA retained the reference amount as proposed.

(18) Cereals and other grain products: grains, e.g., rice, barley, plain

FDA proposed 140 g prepared or 45 g dry as the reference amount for this product category. The agency notes that the product category name in the 1991 serving size proposal (56 FR 60394 at 60418) had a typographical error and included seasoned rice. A correction notice was published on March 6, 1992 (57 FR 8179).

72. Several comments from the rice industry stated that the proposed reference amount was based on the 1977–1978 NFCS data which are outdated. The comments argued that rice consumption patterns have changed since the 1977–1978 NFCS, and that the proposed 140-g reference amount does not reflect the amount of rice customarily consumed today. The comments contended that rice products introduced since the 1977–1978 NFCS (e.g., rice mixes) are customarily consumed in 1/2-cup servings. None of the comments submitted food consumption data to support this claim. One comment pointed out that the 140-g prepared reference amount yields different cup measures for different types of rice, and therefore, the label serving size will differ for different types of rice. The comment contended that rice is easily and conveniently measured with a cup, and that a reference amount that is expressed in a volume measure would yield more consistent label serving sizes for different types of rice. The comment recommended 3/4 cup prepared as the reference amount and submitted the g weights per cup measures of different types of rice in support of the 3/4-cup reference amount. A few comments requested that FDA delete the reference amount for the dry form because the customarily consumed amounts are more consistent on a prepared basis among different types and forms of rice.

FDA advises that it used both the 1977–1978 NFCS and the 1987–1988 NFCS to determine the reference amount for plain rice (Ref. 2). In the 1991 serving size proposal, seasoned rice mixes were included in the Mixed dishes measurable with cup category (see further discussion on seasoned rice mixes under the Mixed dishes measurable with cup category).

FDA disagrees that the reference amount for cooked rice should be expressed in cups. Although cup is the household measure most appropriate for expressing the label serving size for rice, its use in defining the reference amount for rice is not desirable for several reasons. First, cooked rice has several unique characteristics that make it difficult to accurately determine the g weight of the cup measure. For example, cooked rice is not free-flowing, and when cooked, some rice becomes sticky. Secondly, there is no well-established procedure for determining the g weight of the household measure. Therefore, if the reference amount is expressed in cups, the parenthetical metric measure that is used for compliance monitoring would be inaccurate. Thus, the agency has concluded that it is more important to have the reference amount in the most accurate measure possible, i.e., in g. In addition, comments on the 1990 proposal wanted a uniform "standard" serving size (equivalent to the reference amount in the 1991 serving size proposal) for pastas and rice. Changing the reference amount for rice to 3/4 cup would make the reference amounts for these two foods nonuniform. Accordingly, FDA has retained the reference amount of cooked rice as proposed (140 g).

FDA also disagrees that the reference amount for the dry form should be deleted. Because the weight of the cooked rice depends on the amount of water used in the preparation, the amount required to make one reference amount in cooked form can vary widely. The reference amount on a cooked basis also opens a door to a manipulation of the reference amount for dry rice. Therefore, if the reference amount for rice is expressed only on a cooked basis, FDA cannot effectively monitor the compliance. Consequently, the agency rejects this recommendation and has decided to retain the reference amount for the dry form as proposed.

(19) Cereals and other grain products: pastas, without sauce

FDA proposed 140 g prepared or 55 g dry as the reference amount for the product category.

73. A comment from a trade association for pasta products supported the proposed reference amount. One comment contended that because FDA relied on the 1977–1978 NFCS and the 1987–1988 NFCS, refrigerated filled pastas were not adequately represented. The comment argued that the refrigerated filled pastas (e.g., tortelloni, tortellini, and ravioli) were introduced to the market in 1987, and the comment further argued that a study of consumer "habits and attitudes" done by a company showed that people eat smaller portions of meat and cheese filled pastas compared to "cut pasta." Therefore, the comment recommended a 100 g reference amount for filled pasta and claimed that 100 g most closely agrees with the amount customarily consumed of filled pasta. The comment did not submit the results of the consumer "habits and attitudes" study or data supporting the claim that 100 g represents the amount customarily consumed for filled pasta.

FDA advises that this category includes only plain pastas. Filled pastas contain components from two or more food groups, pasta and filling from another food group (e.g., cheese, meat). Filled pastas are included in the Mixed dishes measurable with cup category (Refs. 2 and 20). Because the refrigerated filled pastas were introduced into the market in 1987, there were more reportings of these products in the 1987–1988 NFCS than in the 1977–1978 NFCS. The 1987–1988 NFCS had a total of 67 individual eating occasions of ravioli and tortellini. The customarily consumed amount was 1 cup or about 200 g without sauce (Ref. 41), not 100 g. Accordingly, FDA has retained filled pasta under the Mixed dishes measurable with cup category, with a reference amount of 1 cup. For clarity, the agency has revised the product category name to read: "Pastas, plain."

74. A few comments stated that the proposed 140 g reference amount is too large for lasagna noodles because lasagna noodles are used only as an ingredient of lasagna. One comment recommended 2 oz prepared as the reference amount for lasagna noodles. The comment contended that 2-oz prepared would be consistent with the amount of lasagna noodles required to make one reference amount of lasagna, but the comment did not explain how it arrived at this amount. Another comment recommended 1-oz dry as the reference amount for lasagna noodles. The comment contended that this amount is reasonable because it is half of the reference amount for the dry form of other pastas in the category.

FDA acknowledges that lasagna noodles have a specific usage, i.e., they are customarily consumed as an ingredient of lasagna. However, other pastas in this category are also used primarily as an ingredient of other foods (e.g., spaghetti noodles in spaghetti, macaroni noodles in macaroni and cheese or macaroni salad). Because neither comment explained or submitted data in support of the recommended reference amount for lasagna noodles, FDA has independently estimated the amount of lasagna noodles that are required to make one reference amount (1 cup) of lasagna. Using the recipe file for the 1987–1988 NFCS (Ref. 49) and the percent yield information reported by USDA (Ref. 18), the agency has estimated that about 3.5-oz prepared or about 1.5-oz dry lasagna noodles are

needed to make 1 cup of lasagna (Ref. 50). These values are considerably larger than the 2 oz prepared and 1 oz dry that were suggested in the comments. The data from the 1977–1978 NFCS and the 1987–1988 NFCS showed that customarily consumed amounts of products in this category vary widely, and the 3.5-oz cooked lasagna is well within one standard deviation of the mean customarily consumed amount (Ref. 41). Considering the large variability in customarily consumed amounts of pastas, the relatively small difference between the amount of lasagna required to make one reference amount of lasagna and the reference amount for the pasta category, and that lasagna is not the only pasta used as an ingredient, the agency has concluded that a separate reference amount specific for lasagna noodles is not warranted. Accordingly, FDA had retained the reference amount as proposed.

(20) Dairy products and substitutes: cheese, grated hard, e.g., Parmesan and Romano

FDA proposed 5 g as the reference amount for this product category.

75. One comment contended that the 5-g reference amount is too small and requested that FDA change it to 1 tbsp. FDA advises that 5 g is equivalent to 1 tbsp. in terms of volume. Accordingly, FDA has retained the reference amount as proposed.

(21) Dairy products and substitutes: eggnog

FDA proposed 120 mL as the reference amount for this product category.

76. One comment requested that FDA change the reference amount to 8 fl oz to make it consistent with the reference amounts for other beverages.

FDA does not believe that a uniform 8-fl oz reference amount is necessary for eggnog. Eggnog differs from other beverages. It usually is not used interchangeably with other beverages. Eggnog is a special type of beverage that is customarily served at special occasions (e.g., holidays and parties) and is customarily consumed in amounts smaller than other beverages, such as soft drinks. Comments on the 1990 proposal supported the 120 mL (4 fl oz) reference amount. Food consumption data did not provide a reasonable basis to increase the reference amount to 8 fl oz. Therefore, FDA has retained the reference amount as proposed.

(22) Dairy products and substitutes: milk, evaporated, undiluted

FDA proposed 15 mL as the reference amount for this product category.

77. Several comments from the dairy industry opposed the proposed reference amount. The comments contended that: (1) Evaporated milk is used interchangeably with condensed milk in recipes, (2) the proposed reference amount reflected the use of evaporated milk in coffee, and (3) evaporated milk is used more often as an ingredient of other foods, and 30 mL is closer than 15 mL to the amount used as an ingredient. The comments requested that FDA change the reference amount to 30 mL. One comment submitted data from a recent survey on the use of evaporated milk involving 2,000 households that showed that about 70 percent of the households surveyed used evaporated milk as an ingredient in recipes as opposed to about 35 percent of the households that used it in coffee. The comment also submitted results from a study done by a manufacturer that showed the amounts of evaporated milk consumed per serving of the recipes most frequently used by consumers.

FDA carefully examined the arguments and data submitted in the comments. The agency agrees that evaporated milk is used primarily as an ingredient of other foods, and that the amount customarily consumed as an ingredient is generally larger than the proposed reference amount. The data submitted in the comment showed that the amount of evaporated milk, as an ingredient, consumed per serving ranged mostly from 20 to 50 mL. The mid-range of these values is 35 mL (about 1 fl oz). Because the major use of evaporated milk is as an ingredient, the agency has concluded that the reference amount for evaporated milk should reflect the amount used as an ingredient. Following the principles in expressing the reference amounts for fluids described in the 1991 serving size proposal (56 FR 60394 at 60406), the agency has determined the reference amount for evaporated milk to be 30 mL. Accordingly, FDA has revised the reference amount to 30 mL.

(23) Dairy products and substitutes: milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa

FDA proposed a uniform 240 mL (8 fl oz) as the reference amount for all beverages.

78. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. A few comments requested that FDA create a separate category for hot cocoa or hot cocoa and cocoa beverages with a reference amount of 6 fl oz. The comments contended that 70 percent of the servings of hot cocoa mix sold are in single-serving envelopes that yield a 6-fl oz serving, and that hot cocoa sold from vending machines also has a 6-fl oz serving.

Cocoa beverages are a type of flavored and sweetened milk beverages. FDA does not believe that it is appropriate to have two different reference amounts for flavored and sweetened milk beverages, one for cocoa beverages and one for other flavored and sweetened milk (e.g., chocolate milk, malted milk). Cocoa beverage mixes are available both in single-serving and multiserving containers. These beverage mixes are consumed both hot or cold and interchangeably with other hot or cold beverages. Food consumption data showed that the amount customarily consumed for cocoa beverages is 8 fl oz (Ref. 41). FDA also notes that the 6-fl oz single-serving envelopes in a multiserving container are single-serving units according to new § 101.9(b)(2)(i), and therefore, the serving size will be one envelope. Considering the weight of the support for the uniform 8-fl oz reference amount for all beverages, food consumption data, and the other reasons stated here, the agency concludes that 8 fl oz is the appropriate reference amount for cocoa beverages under the act. Accordingly, FDA has retained the reference amount as proposed.

(24) Dairy products and substitutes: yogurt

FDA proposed 225 g as the reference amount for this product category.

79. Two comments requested that FDA change the reference amount to 170 g (6 oz). One comment argued that the mean consumed serving from the 1987–1988 NFCS was 6.9 oz, and this value rounded to the nearest container size would be 6 oz. Another comment contended that recent data from a marketing survey on yogurt sales showed that 6 oz rather than 8 oz would be a more appropriate reference amount. The comment stated that on a pound-volume basis, the survey showed that 40 percent of all yogurt was packaged in 6-oz containers or smaller, and approximately 60 percent was packed in 8-oz containers. The comment claimed that when these data were converted to a per serving basis, they showed that 52 percent of yogurt was eaten from 6-oz containers or smaller. The comment did

not submit actual survey data or explain how the 5?-percent estimate on a per serving basis was derived.

FDA disagrees with all requests for a change in the reference amount for this category. As for the comment that requested a change based on the mean intake of yogurt from the 1987–1988 NFCS, FDA advises that it is not using the mean alone or a reference amount that is solely based on the 1987–1988 NFCS for the reasons explained in section III.D.1. of this document, unless there is a valid reason for doing so (e.g., trends that are confirmed by another survey that had a high response rate, or information was not available in the 1977–1978 NFCS).

As for the comment that requested a change based on the sales volume of single-serving yogurt containers, FDA notes that sales data are not consumption data and do not necessarily equate to consumption data. For example, some people could have consumed two 4-oz containers of yogurt which makes the consumed amount 8 oz, while the sales data would have counted two 4-oz containers. It is not clear how the comment derived the percent estimates on a serving basis from the sales data. FDA's independent analysis of the sales data from the same source as the comment showed that both on a pound basis and on a serving basis, 8-oz containers were clearly the major container size (Ref. 51). On a pound basis; containers that were 6 oz or smaller accounted for about 21 percent of the total weight, whereas 8-oz containers accounted for about 59 percent. On a serving basis, the respective values were about 27 and 54 percent (Ref. 51). Therefore, the sales data also supported the 8-oz reference amount derived from food consumption data.

Accordingly, FDA has retained the reference amount as proposed.

(25) Desserts: ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones)

FDA proposed 1/2 cup (4 fl oz) as the reference amount for the product category. The reference amount included the volume of coatings and wafers for the novelty type varieties.

80. Several comments recommended that FDA divide this category into two categories, one for bulk products and one for novelties. Some comments agreed with the 1/2-cup (4-fl oz) reference amount for bulk products. A few other comments asserted that the reference amount for bulk products should be larger. One comment suggested 6 oz, and another comment suggested 1 cup. Most comments recommended a 2.5-fl oz (an average size of 1 novelty) as the reference amount for novelties. The comments contended that novelty type products are consumed by piece, and the serving size should be 1 piece. The comments argued that the proposed reference amount of 4 fl oz would make the serving size 2 bars for some novelties packaged in multiserving containers.

First, FDA notes that food consumption data showed that the customarily consumed amount for novelty-type products was 2.5 oz. When converted to volume, 2.5 oz is equivalent to about 4 fl oz (Ref. 2). Bulk products and novelty-type products are the same type of products in different shapes. Some novelty-type products come without coating or wafers, and thus the bulk-type and the novelty-type differ only in shape. It is inappropriate to have two reference amounts for two forms of the same food that are used interchangeably. If FDA did have two separate reference amounts as suggested in the comments, one for bulk products (e.g., 4 fl oz) and one for novelty-type products (e.g., 2.5 fl oz), nutrition information and the evaluation for the qualification for claims for these two types of products would be based on different amounts. Consequently, although a bulk product might not be able to qualify for a claim, a similar novelty-type product might be able to do so because of the smaller reference amount. This result would be misleading.

Therefore, based on available consumption data, the agency has concluded that a uniform 1/2-cup reference amount is appropriate for both the bulk and the novelty-type products (Ref. 2). The 1/2-cup reference amount is also consistent with the reference amount for other desserts (e.g., custard, pudding, and gelatin desserts), which are often used interchangeably with products in this category as a dessert. The 1/2 cup reference amount is desirable for several other reasons: (1) It is in agreement with most serving sizes in dietary guidance documents, (2) it is consistent with the Canadian serving size guidelines, (3) it is the serving size currently used by many manufacturers, and (4) it was supported by many comments on the 1990 proposal.

The agency notes that new § 101.9(b)(2)(i) allows optional declaration of nutrition information on a single unit basis for products in discrete units that are more than 50 percent but less than 67 percent of the reference amount. Therefore, the serving size for most novelty-type products will be one unit.

For all the above reasons, FDA has retained the reference amount as proposed.

(26) Desserts: custard, gelatin or pudding

FDA proposed 1/2 cup as the reference amount for this product category.

81. Two comments opposed the proposed 1/2-cup reference amount. The comments argued that the powdered mix type of puddings comprised only about 52 percent of the retail food store sales of puddings in 1990. More recently, ready-to-eat puddings have taken the lead in terms of market share and are growing at a faster rate as compared to dry-mix type puddings. The comment stated that the reference amount should reflect the recent sales trend in puddings, or that FDA should establish a separate reference amount of 4 oz for ready-to-eat puddings. The comments contended that ready-to-eat puddings either come in 4 oz single-serving containers or in bulk containers that are multiples of 4 oz. Therefore, the customarily consumed amount of the ready-to-eat puddings is 4 oz. The comments argued that a volumetric measure is appropriate for dry pudding mixes but is inappropriate for ready-to-eat puddings.

FDA recognizes the recent trend in the availability of ready-to-eat puddings. However, the agency is not establishing separate reference amounts for different forms of the same food because the act directs the agency to establish uniform serving sizes. Therefore, it would be inconsistent with the act to have different reference amounts for different forms of the same food that are used interchangeably. The act also relates serving size to the amount of the food customarily consumed, not the form in which the food is sold. The comments did not present any food consumption data to prove that the amount of all forms of puddings customarily consumed is 4 oz, not 1/2 cup. The agency notes that sales data are not consumption data and do not necessarily equate to consumption data.

In addition, the agency points out that direct interpretation of the sales data often result in the wrong conclusion. For example, the comments compared sales data for ready-to-eat puddings and dry-mix type puddings on an as packaged basis. These two types of puddings cannot be compared directly on an as packaged basis because ready-to-eat puddings are in a prepared form whereas dry-mix type puddings are not. Before these two types of products can be compared, they should be on an equal basis in weight, i.e., both types

should be on a prepared basis. FDA's independent analysis of the recent sales data showed that when the two types of products were compared on a prepared basis, dry-mix type puddings are still the major type of puddings in the marketplace, accounting for about 88 percent of the total prepared weight of all types of puddings sold (Ref. 51), as they were when the NFCS's were conducted. The results of this analysis reconfirmed that the 1/2 cup reference amount, which reflects the customarily consumed amount of the dry-mix type puddings, is still valid because the dry-mix type is still the major type of puddings used in the United States. Finally, the agency notes that according to new § 101.9(b)(2)(i), 4-oz containers of ready-to-eat puddings in the multiserving package are single-serving units, and under that section of the regulations, the serving size for the 4-oz container will be one container, i.e., 4 oz. Accordingly, FDA has retained the reference amount for puddings as proposed (1/2 cup).

(27) Egg and egg substitutes: egg mixture, e.g., egg foo young, scrambled egg, omelet

FDA proposed 110 g as the reference amount for this product category.

82. One comment contended that the reference amount for this category should be 100 g. The comment argued that it is inappropriate to add the weight of 2 eggs (100 g) and then an arbitrary amount of 10 g for the reference amount of egg mixtures. Another comment stated that the reference amount for an omelette should be related to the number of eggs used per omelette. For example, a "one egg omelette" should have a smaller reference amount than a "two egg omelette."

First, FDA points out that it did not arrive at the proposed reference amount by adding the weight of 2 eggs and then arbitrarily adding 10 g. According to the act, the serving size is an amount customarily consumed. The proposed reference amount represents the customarily consumed amount of the foods belonging to this category determined from food consumption data, following the procedures described in the 1991 serving size proposal (56 60394 at 60403) (Ref. 2). Secondly, the same food cannot have two different reference amounts, one for the egg mixture containing one egg and one for the egg mixture containing two eggs because, under the act, the reference amount is the amount of the food customarily consumed. These mixtures are used interchangeably. Therefore, FDA is establishing the same reference amount for both. Accordingly, FDA has not adopted these requests.

(28) Fats and oils: butter, margarine, oil, shortening

FDA proposed a uniform 1 tbsp. reference amount for this product category.

83. Comments on this reference amount were split fairly evenly for and against the proposed 1 tbsp. reference amount. Comments from the margarine and oil industry and a few others, including a consumer, supported the 1-tbsp. reference amount. Comments from the dairy industry and others, including a nutrition professional organization, opposed the proposed reference amount. Two comments recommended that FDA change the reference amount to 1 tsp. to be consistent with the serving size in the diabetic exchange list or to be consistent with dietary guidance recommendations which recommend lowering the total fat in the diet.

FDA has examined all arguments for and against the proposed uniform 1-tbsp. reference amount. FDA advises that it cannot change the reference amount to make it consistent with the serving size in the diabetic exchange list because, as explained in the 1991 serving size proposal (56 FR 60394 at 60407) and in section III.B. of this document, the serving size for the diabetic exchange list is designed to meet the needs of a special subgroup of the population having medical problems. It is not intended for the general public. As for the recommendation to change the reference amount to 1 tsp. to be consistent with the dietary guidance recommendations, FDA points out that the serving size on the product label is not the amount recommended for consumption. In section III.D.1. of this document, the agency has explained in detail why the serving sizes in the dietary guidance documents are not appropriate for nutrition labeling purposes. The agency also points out that food consumption data showed that 1 tsp. is not the customarily consumed amount of foods in this category. The amount customarily consumed for most products in this category is 1 tbsp. (Ref. 2). The comments to the 1991 serving size proposal merely reiterated the reasons stated in the comments on the 1990 proposal. No new arguments or data have been presented to persuade the agency to change the proposed uniform 1 tbsp. reference amount. Therefore, FDA finds no basis to change the reference amount, and it has retained the reference amount as proposed.

(29) Fats and oils: dressings for salad

FDA proposed 30 g as the reference amount for this product category.

84. Two comments suggested that FDA change the reference amount to 15 g (equivalent to 1 tbsp.). One comment argued that 30 g is too large and precludes dressings for salads "from claims where they would be considered as good sources of oils that would reduce serum cholesterol."

FDA advises that the serving size declared on the product label is by statute an amount customarily consumed. The amount customarily consumed for dressings for salad is 2 tbsp., not 1 tbsp. (Ref. 2). The agency cannot change a reference amount so that certain products can make a claim. Accordingly, FDA has retained the reference amount as proposed.

(30) Fish, shellfish, and meat or poultry substitutes: entrees (cooked) with sauce, e.g., fish with cream sauce, shrimp with lobster sauce

FDA proposed 140 g as the reference amount for this product category.

85. Two comments requested that FDA establish a uniform 85-g reference amount for all fish products with or without sauce. One comment contended that the proposed reference amount of 140 g is too high. The comment did not submit data to support this claim. The other comment contended that it will be difficult to categorize products into two categories, with and without sauce.

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. The amount customarily consumed for the products in this category (that is, with sauce) is 140 g, not 85 g (Ref. 2). No consumption data that would support a different reference amount were presented. The agency notes that it has provided an extensive list of products for each product category to assist manufacturers to locate the product category in which their specific products fit (Ref. 44). Accordingly, FDA has retained the reference amount as proposed.

(31) Fish, shellfish, and meat or poultry substitutes: entrees (cooked) without sauce, plain or fried fish and shellfish, fish and shellfish cake

FDA proposed 85 g as the reference amount for this product category. Many comments on the reference amount for this category specifically addressed the reference amount for meat and poultry products. FDA has forwarded these comments to USDA for consideration in the development of the final regulation for nutrition labeling of meat and

poultry products. The agency is responding to comments that included discussions on the reference amounts of FDA regulated products.

86. Comments from a nutrition professional organization and a nutrition professional supported the proposed 3-oz reference amount. However, FDA received a large number of comments from consumers stating that the 3-oz "serving size" is too small for "meat, poultry, and fish." These consumer comments did not state what the serving size for "meat, poultry, and fish" should be. (Although FDA does not regulate meat and poultry, the comments were responding to a prestructured questionnaire distributed by a consumer organization that discussed the serving sizes of meat, poultry, and fish together. Many other consumer comments that were not recorded on the prestructured questionnaire also stated that the 3-oz serving size is too small for meat and poultry, but they did not mention fish. Thus, the agency is not sure that the comments recorded on the questionnaire apply to the reference amount for fish. Therefore, the agency has presented the food names as they appeared in the questionnaire.) Two comments from consumer organizations requested that FDA establish two separate reference amounts for fish and shellfish. They suggested 1.4 or 1.5 oz for "shrimp" and 4 oz for fish based on the published data for the median consumed amount per eating occasion from the 1977–1978 NFCS. One industry comment requested that FDA create a new category for fish sticks with a reference amount of 70 g. The comment submitted data on the mean, percentiles, and modal consumed amounts from the 1987–1988 NFCS in support of the 70-g reference amount.

FDA has carefully examined all arguments against the 3-oz reference amount and the data submitted in support of the requested changes of the reference amount. FDA believes that comments from consumers indicated a misunderstanding of the meaning and purpose of the serving size on the product label. The serving size on the product label is not the amount recommended as the serving size for any individual. It represents an amount customarily consumed by the U.S. population that manufacturers are to use to present the nutrition information on their products. Therefore, the serving size on the product label may be too small or too large for some individuals. FDA plans to followup the publication of the nutrition labeling regulations with consumer education to assist consumers in using nutrition information on the label. Consumer education will include information on how nutrition information based on labeled serving size should be adjusted for the individual's own serving size.

As for the request for two separate categories for fish and shellfish, FDA finds that separate categories are inappropriate. As explained in the 1991 serving size proposal (56 FR 60394 at 60403), the agency grouped similar foods to determine reference amounts for product categories, not for specific foods. This grouping allows for product comparisons among similar foods that are likely to be used interchangeably. In determining the reference amount for this product category, fish and shellfish were grouped together because they are used interchangeably as entrees. Two separate reference amounts for fish and shellfish would undermine nutrition comparisons of these products that are used interchangeably in the diet. Although, if determined separately, the amount customarily consumed would be lower for shellfish than for fish (Ref. 41), it is also the case that the 1977–1978 NFCS and the 1987–1988 NFCS showed that about 40 to 50 percent of people consumed 3 oz or more shellfish per eating occasion, the amount of fish consumed per eating occasion by most people (Ref. 47). The two separate reference amounts suggested in the comment (1.5 oz for shellfish and 4 oz for fish) could also give a false message about the nutrient contents of fish and shrimp to the people who consume fish and shellfish in similar amounts. For example, shrimp is known to be high in cholesterol. On the same serving basis, shrimp is about three times as high in cholesterol as most finfish (Ref. 52). However, if shellfish has a serving size that is about one-third of the serving size for finfish as suggested in the comment, there will be little difference in the cholesterol content per serving. This information would be a disservice to the public, particularly to those consumers who have been told by their physician to limit their cholesterol intake. In addition, the agency points out that it is not using a reference amount that is derived solely from the 1977–1978 NFCS for the reasons stated in section III.D.1. of this document.

Therefore, to reduce consumer confusion and to promote uniform serving sizes for nutrition comparisons of products that are used interchangeably, the agency has concluded that fish and shellfish should have the same reference amount.

As for the request for a separate category for fish sticks, FDA advises that a separate category for fish sticks is not justified. FDA's independent data analysis for fish sticks from the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed is 85 g, not 70 g (Ref. 41). Also, as discussed in section III.D.1. of this document, unless there is a good reason for relying solely on the 1987–1988 NFCS, FDA has used both the 1977–1988 NFCS and the 1987–1988 NFCS. Data submitted in the comment were based solely on the 1987–1988 NFCS without any explanation.

Having carefully examined all arguments and data submitted in the comments, FDA has concluded that the proposed 85-g reference amount is the amount of fish customarily consumed. Accordingly, the agency has retained the reference amount as proposed.

87. Proposed § 101.12(c) requires that the reference amount of uncooked seafood be the amount required to prepare 85 g of cooked seafood. A seafood trade association stated that they are very concerned that their members will be unable to determine the serving sizes for uncooked seafood needed to produce the reference amount. The comment contended that the amount of uncooked seafood required to make one reference amount is affected by many uncontrollable variables such as methods of cooking (e.g., frying in oil or conventional and microwave cooking) and cooking time. The comment asserted that given these uncertainties, the serving size should be based on an "as packaged" basis for processed foods that require no further preparation other than cooking.

FDA recognizes the variability in cooking methods and time used to prepare seafoods. The agency agrees that this variability makes it difficult to determine the serving size of the uncooked seafood. Therefore, the agency has concluded that it should establish a reference amount for uncooked seafoods except for those fish and shellfish that are allowed to provide nutrition information on a cooked basis in new § 101.9(j)(11) and § 101.45. Using USDA's cooking yield information (Ref. 18), FDA has estimated the reference amount for uncooked fish and shellfish as 110 g (Ref. 53). Accordingly, the description "(cooked)" has been deleted from the product category name and the reference amount has been changed to read: "85 g cooked; 110 g uncooked." A footnote has been added to inform manufacturers that the 110 g uncooked reference amount does not apply to the raw fish and shellfish subject to § 101.45 and packaged single-ingredient fish and shellfish in new § 101.9(j)(11).

(32) Fish, shellfish, and meat or poultry substitutes: fish and shellfish, canned

FDA proposed 85 g as the reference amount for this product category.

88. Two comments opposed the proposed reference amount. One comment from a trade association contended that the category should be divided into subgroups with separate reference amounts: 56 g for canned tuna and bonito and 100 g for canned salmon. The comment contended that these reference amounts are more consistent with the current industry practices and equal to the contents of single-serving containers on the market. A comment from a seafood trade association requested that FDA change the reference amount to 55 g to make it consistent with the reference amount for luncheon meats. The comment submitted data showing that the largest use of tuna is as an ingredient in sandwiches.

FDA advises that it cannot change the reference amount simply to make it consistent with current industry practices or to make it equal to the contents of single-serving containers on the market. The agency's review of the data submitted in the comment showed that the major usage of tuna is as an ingredient in sandwiches. One of the general principles in determining the reference amount in new § 101.12(e)(7) states that the reference amount should reflect the major usage of the food. In the United States, more tuna is consumed than other canned fish (Ref. 47), and its major use is as an ingredient in sandwiches. The amount of the sandwich cutomarily consumed is one sandwich, and about 2 oz tuna (on a drained weight basis) is used to make one sandwich (Ref. 47). Thus, the agency has concluded that the reference amount for canned fish should be changed to 55 g to reflect the use as an ingredient in sandwiches. The 85-g reference amount proposed in the 1991 serving size proposal was based on all uses of tuna and other canned fish, including their use as an entree and for fish salad.

Accordingly, FDA has revised the reference amount to 55 g.

(33) Fish, shellfish, and meat or poultry substitutes: smoked or pickled fish or shellfish

FDA proposed 55 g as the reference amount for this product category.

89. A comment from a seafood trade association stated that smoked/pickled fish are specialty foods consumed as appetizers, not as a "center-of-the-plate item." Therefore, the comment said, the reference amount should be closer to the reference amount for snacks (30 g). The comment did not submit any data to support the 30 g reference amount that it recommended.

FDA advises that food consumption data did not support a 30-g reference amount. The 55-g proposed reference amount reflects the amount customarily consumed for smoked or pickled fish or shellfish (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(34) Fruits and fruit juice: dried

FDA proposed 40 g as the reference amount for this product category.

90. A comment from a Federal agency recommended that FDA change the reference amount to 30 g. The comment contended that the proposed reference amount is too large for some dried fruit (e.g., dried apple rings, dried apricots).

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the amount customarily consumed for the products in this category is 40 g, not 30 g (Ref. 2). The comment did not present any data to support that 30 g better reflects the customarily consumed amounts of products in this category. Accordingly, FDA has retained the reference amount as proposed.

(35) Fruits and fruit juice: fruits used primarily as ingredients, e.g., avocado, cranberries, lemon, lime

FDA proposed 55 g as the reference amount for the product category.

91. One comment from a Federal Government agency opposed the 55 g reference amount. The comment stated that the proposed reference amount is too large, but the comment did not suggest what the reference amount should be. A comment from a trade association for avocadoes requested that FDA change the reference amount of avocados to 1 oz. The comment contended that USDA's g weight conversions (conversion factors) of small, medium, and large avocados were too high and did not reflect the California avocados which account for over 90 percent of the total U.S. avocado crop. In addition, the percent yield values used to determine the edible portion of avocados in the NFCS were too high. The comment submitted corrected conversion factors from a "National Retail Weight Study" sponsored by a trade association, an extensive list of the updated percent yield values, and results of a reanalysis of the NFCS data using the corrected conversion factors and the updated percent yield values. The data supported a 1-oz reference amount rather than 2 oz.

FDA carefully examined all of the data submitted in the comment. The results of the "National Retail Weight Study" showed that the conversion factors for small, medium, and large avocados were considerably lower than the values used in the NFCS. The updated percent yield values for 200 avocados of three California avocado varieties were significantly lower than the yield values used in the NFCS. The results of the comment's reanalysis of the 1987–1988 NFCS data using corrected conversion factors, and the updated percent yield values showed that the mean was about 2 oz, the median was about 1 oz, and the primary mode, that which accounted for over 50 percent of the total number of eatings, was 1 oz. The data submitted in the comment clearly showed that the customarily consumed amount is closer to 1 oz than to 2 oz. Because data from the 1987–1988 NFCS showed a decreasing trend in the amount of avocado consumed since the 1977–1978 NFCS, and the trend was confirmed by the CSFII (Ref. 40), the agency is relying on the data from the 1987–1988 NFCS submitted in the comment. Therefore, the agency has concluded that avocados should have a separate category with a reference amount of 30 g. Accordingly, FDA has divided the "Fruits used primarily as ingredients * * *" category into two categories: "Fruits used primarily as ingredients, avocado" with a reference amount of 30 g and "Fruits used primarily as ingredients, others (cranberries, lemon, and lime)" with a reference amount of 55 g as proposed.

(36) Fruits and fruit juice: all other fruits (except those listed as separate categories), fresh, canned or frozen

FDA proposed 140 g as the reference amount for this product category.

92. Several comments from the industry stated that the 140-g reference amount (equivalent to 5 oz) is too large. The comments requested that FDA change the reference amount to the g-equivalent of 1/2 cup.

FDA advises that it cannot use the g-equivalent of the 1/2 cup measure as the reference amount for two reasons: (1) For fruits that can be measured with a cup (e.g., canned or frozen fruits), food consumption data showed that the amount customarily consumed is about 5 oz, not 1/2 cup (Ref. 2), and (2) for the fruits that cannot be measured with a cup (e.g., most fresh fruits), the g-equivalent for the 1/2 cup measure cannot be determined. Food consumption data showed that the amount of fresh fruits is also about 5 oz

(Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(37) Fruits and fruit juice: juice, nectar, fruit drinks, or fruit-flavored drinks

FDA proposed 240 mL (8 fl oz) as the reference amount for the product category.

93. Comments from several manufacturers and trade associations (including a juice manufacturer and trade associations for juices) and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. Comments from two other trade associations requested that FDA change the reference amount for juices to 6 fl oz. One comment stated that 6 fl oz is the amount that represents long established industry practice, and that 6 fl oz is a more appropriate reference amount when extended to multiserving containers. The comment submitted no data to support its claims, however. A manufacturer contended that FDA has no authority to manipulate the customarily consumed amount of food in order to standardize the reference amount. The comment argued that FDA's own data from the 1977–1978 NFCS (Ref. 2) indicated that 4 fl oz is the amount customarily consumed, and therefore, FDA must change the reference amount to 4 fl oz. A consumer asserted that 250 mL (8.45 fl oz) is a more appropriate reference amount because most small size juices are sold in 250 mL packs.

The agency notes that data from the 1977–1978 NFCS suggested 6 fl oz (not 4 fl oz as claimed by one comment) to be the customarily consumed amount. The agency notes that the comment that asserted that 4 fl oz is the amount customarily consumed misread the data. Data from the 1977–1978 NFCS had a mean of 6.3 fl oz, the median of 6 fl oz and 3 modes (4 fl oz, 6 fl oz, 8 fl oz). However, data from the 1987–1988 NFCS suggested that 8 fl oz is the customarily consumed amount for juices. Also, both the 1977–1978 NFCS and the 1987–1988 NFCS showed that 8 fl oz is the customarily consumed amount for fruit juice drinks and fruit-flavored drinks that are used interchangeably with fruit juices. Therefore, the agency has concluded that 8 fl oz is the most reasonable reference amount for all fruit juices and drinks.

As for the consumer comment, the agency advises that food consumption data did not support a 250-mL reference amount. The agency notes that the 250 mL packs of juice are single-serving containers and, therefore, will be labeled as 1 serving

Considering the weight of support for the uniform 8 fl oz reference amount for all beverages and for the other reasons stated above, the agency has concluded that 8 fl oz is the appropriate reference amount under section 403(q)(1)(A)(i) of the act for all beverages including fruit juices and fruit drinks. The uniform reference amount for all beverages facilitates nutrition comparisons of different beverages. Accordingly, FDA has retained the reference amount as proposed.

(38) Legumes: bean cake (tofu)

FDA proposed 85 g as the reference amount for the product category.

94. A comment from a consumer organization stated that, because the sample size for tofu in the 1977–1978 NFCS was so small (n=12), an accurate estimate of the amount customarily consumed could not be derived from this survey. The comment contended that because tofu is used as a substitute for meat and poultry, the reference amount should be equivalent to the reference amount for meat and poultry.

FDA agrees that the sample size for tofu in the 1977–1978 NFCS was too small to give a reliable estimate of the amount customarily consumed. However, for other reasons explained in section III.D.1. of this document, the agency is not using a reference amount that is based solely on the 1977–1978 NFCS. The 1987–1988 NFCS had a larger sample size for tofu (n=31), and all three statistical values from the 1987–1988 NFCS data that FDA uses in determining the amount customarily consumed (the mean, the median, and the mode) showed that 3 oz is the amount of tofu customarily consumed (Ref. 2). Therefore, the agency has concluded that 3 oz is a reasonable reference amount for tofu. The 3 oz reference amount is the same as the reference amount for fish, shellfish, game meats, and meat or poultry substitutes without sauce regulated by FDA and the reference amount for meat and poultry regulated by USDA. Accordingly, FDA has retained the reference amount as proposed.

(39) Legumes: beans, plain or in sauce

FDA proposed 1/2 cup as the reference amount for the product category.

95. Two comments, from a trade association and a manufacturer, supported the proposed 1/2-cup reference amount. However, the comments requested that FDA change the 1/2 cup reference amount to a g weight. One comment opposed the use of drained weight for plain canned beans. The comment contended that nutrition information on the canned beans should be based on an as packaged basis, including the liquid.

In light of the difficulty in determining the g weight of the household measure, FDA has concluded in section III.D.2. of this document that volume-based reference amounts should be converted to weight-based reference amounts where a weight-based reference amount is feasible. The agency has reexamined foods in this product category and has concluded that the weight-based reference amount can be determined for this category. By taking the average of the g weights per 1/2 cup of cooked plain beans reported by USDA (Ref. 54), the agency has determined that the reference amount for beans that are not canned in liquid or in sauce to be 90 g (Ref. 55).

Regarding the comment that requested nutrition information of canned beans on an as packaged basis, including the liquid, the agency, as discussed in section III.H.2. of this document, has concluded that the nutrition information of canned beans will be based on an as packaged basis including the liquid because a large percentage of people do use the liquid in the canned food. By taking the average of the g weights per 1/2 cup of canned beans including the liquid reported by USDA (Ref. 54), the agency has determined that the reference amount for canned beans, including the liquid, is 130 g (Ref. 55). Also, by taking the average of the g weights per 1/2 cup of beans with sauce (e.g., pork and beans, baked beans) reported by USDA (Ref. 54), the agency has determined that the reference amount for beans in sauce is 130 g (Ref. 55).

Accordingly, FDA has revised the reference amount to read: "130 g for beans in sauce or canned in liquid; 90 g for others."

(40) Miscellaneous category: batter mixes, bread crumbs, meat, poultry, and fish coating mixes, dry

FDA proposed 30 g as the reference amount for this product category.

96. An industry comment opposed the 30 g reference amount for coating mixes. The comment stated that because of the varying densities of the products and the varying surface areas of the products they coat (e.g., meat and fish), 30 g of coating mix will coat between 3 and 8 oz of meat. The industry suggested including coating mixes with seasoning mixes with a reference amount equal to the amount of the product required to prepare one portion of the end product (e.g., the amount necessary to coat 3 oz of meat or fish).

FDA recognizes that coating mixes vary in density, and that the amount needed to coat the surface areas depends on the type of the mixes and the products they coat. These products are made for use in a specific end dish (e.g., coating mix for fish). Thus, a reference amount that is the amount required to prepare one reference amount of the end product would be more consistent with the amount customarily consumed of coating mixes.

Therefore, the agency has concluded that the reference amount for coating mixes should be changed to the amount to make one reference amount of the final dish as listed in new § 101.12(b). In the case of multiple uses, manufacturers should determine the major use of the coating mix based on food consumption data, marketing survey data on the consumer usage of the product, or in the case of a new product, promoted use, and use that major use to determine the reference amount. The agency agrees that coating mixes should be grouped with seasoning mixes because they are a type of seasoning mixes. Accordingly, FDA has revised the seasoning mixes category to read: "Meat, poultry and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes."

(41) Miscellaneous category: chewing gum

FDA proposed 3 g as the reference amount for the product category.

97. Two comments from the chewing gum industry stated that the reference amount for chewing gum should be one piece because, according to a recent marketing research study, people consume chewing gum piece by piece, not by weight. The comment contended that because chewing gum products vary so widely in the piece size, it is not possible to fix a standard weight that adequately encompasses the serving size. The comment also argued that much of the chewing gum consumed weighs less than 2 g per piece. Another comment argued that a 3 g reference amount is too small because it corresponds to 3/4 stick or 1 7/8 chiclets. The comment requested that FDA change the reference amount to 4 g.

FDA agrees that chewing gums vary widely in the piece size, and that chewing gums are usually consumed by piece. However, the agency cannot use one piece as the reference amount. Some chewing gums come in very small pieces (mini-size chewing gums weighing about 1 g per 10 to 12 pieces), and people usually chew several pieces at a time. Therefore, it is not appropriate to call one piece of these mini-size chewing gums a serving. The reference amount is needed to determine the serving size of these mini-size chewing gums.

As explained in section III.D.5.a. of this document, for compliance monitoring, the agency also needs a fixed value as the reference amount, not a measure that varies from brand to brand (e.g., piece). The wide variability in the piece size makes the determination of the reference amount difficult. Based on the piece size of the chewing gums commonly available in the Washington, DC metropolitan area, the agency has determined 3 g to be a reasonable reference amount (Ref. 2). The agency acknowledges that there are some chewing gums that weigh less than 2 g per piece. The new lower limit for the single-serving unit in new § 101.9(b)(2)(i), however, will make all chewing gums that weigh more than 1.5 g per piece one serving.

The agency also recognizes that there are many chewing gums that weigh more than 200 percent of the reference amount. Although they weigh more than the upper limit of the single-serving unit, marketing data submitted in the comment show that gums are intended to be single-serving products. Therefore, footnote 9 of Table 2 informs the manufacturer that the serving sizes of all chewing gums that weigh more than 3 g, that can reasonably be consumed at a single-eating occasion, is 1 piece.

As for the comment that recommended the 4-g reference amount, a 4-g reference amount would make the serving sizes of all chewing gums weighing 2 g or less, 2 or more pieces. Chewing gums, with the exception of the mini-size chewing gums, are customarily consumed one piece per eating occasion. In light of the many chewing gums weighing less than 2 g per piece mentioned in the comment, the agency has concluded that a 4 g reference amount is too large. The agency also notes that FDA's measurements showed that commonly available chewing gums weigh about 3 g per stick (Ref. 2).

Accordingly, FDA has retained the 3-g reference amount as proposed.

(42) Miscellaneous category: salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits

FDA proposed 7 g as the reference amount for the product category.

98. One comment opposed the proposed reference amount. The comment recommended that FDA change the reference amount to 5 g (approximately 2 tsp.). The comment contended that a 5-g reference amount is supported by "consumer-based consumption data" collected by the comment. The comment submitted no data, however, to support this claim.

FDA advises that food consumption data showed that the customarily consumed amount for products in this category is 7 g (Ref. 2). The 7 g reference amount also approximates 1 tbsp., a convenient household measure, and is consistent with the reference amount for croutons that are used as a salad topper. The comment did not submit any data. Thus, there is no basis for the agency to change the reference amount to 5 g. Accordingly, FDA has retained the reference amount for this category as proposed.

(43) Miscellaneous category: salt, salt substitute, seasoning salt (e.g., garlic salt)

FDA proposed 1 g as the reference amount for this product category.

99. One comment agreed with the proposed reference amount because it is in the best interest of the consumers. A comment from a trade association for spice products agreed with the proposed reference amount of 1 g for seasoning salts. However, the comment requested that FDA allow manufacturers to voluntarily declare the sodium content per 1/4 tsp. Another comment objected to the weight-based reference amount. The comment contended that it had developed a low-density salt product that provides a salt taste similar to that of regular salt in a smaller g amount, because the low-density salt is processed to dissolve faster and more completely than the regular salt. Because the low-density salt weighs significantly less than salt, a weight-based reference amount (e.g., 1 g) would result in a serving size of the low-density salt 2 1/2 to 3 times larger than that of salt. Therefore, the comment requested that FDA change the reference amount to a volume-based reference amount (e.g., 1/4 tsp.). The comment did not submit any data to support that regular salt and the low-density salt are consumed equally on a volume basis.

FDA advises that the reference amount for sugar substitutes is "an amount equivalent to one reference amount for sugar in sweetness." Both sugar and salt are used as flavoring agents. People use them to attain the level of sweetness or saltiness that they desire. Therefore, like sugar the reference amount for a salt substitute (e.g., low-density salt) should be the amount necessary to provide a salty taste equivalent to one reference amount of salt. Salt is used both in cooking and at the table. Although regular salt may not completely dissolve when added at

the table, it will dissolve completely when used in cooking. Because, as the name indicates, the low-density salt is lighter than the regular salt, 1/4 tsp. of the low-density salt will contain less salt than 1/4 tsp. of the regular salt. Therefore, when used in cooking, a larger volume of the low-density salt than the regular salt will be required to achieve the same salty taste. Thus, low-density salt and regular salt may not be used on an equal volume basis at least in cooking. Accordingly, the agency rejects the request for a volume-based reference amount.

100. A comment from a consumer organization stated that the reference amount should be expressed as 1,000 milligrams (mg), instead of 1 g, to be consistent with the sodium content listed in the nutrition information panel. The comment contended that most Americans are unfamiliar with the metric system, so they will not understand that 1 g is equal to 1,000 mg.

FDA does not agree with the comment. Whether the reference amount is expressed 1 g or 1,000 mg, the serving size on the product label by statute has to be in a common household measure (e.g., 1/4 tsp.). The nutrition information on the label tells consumers how much sodium is in one serving (1/4 tsp.) of salt. It is not necessary for consumers to know that 1 g equals 1,000 mg to use the nutrition information on the product label. Therefore, the agency has concluded that it is not necessary to change the reference amount to 1,000 mg.

(44) Mixed dishes: measurable with cup, e.g., casserole, hash, macaroni and cheese, pot pie, spaghetti with sauce, stew, etc.

FDA proposed 1 cup as the reference amount for the product category.

101. Many comments agreed with the proposed reference amount. One manufacturer agreed with the 1-cup reference amount for mixed dishes that are served as main dishes. However, the comment contended that 1/2 cup is a more appropriate reference amount for mixed dishes that are served as side dishes (e.g., potato dishes, pasta salad, potato salad). The comment contended that the 1987–1988 NFCS supported the 1/2-cup reference amount for these products. The comment did not submit data to support this claim.

FDA advises that pasta salad and potato salad have a separate category under Salads with a reference amount of 140 g which is equivalent to about 3/4 cup. Because the comment did not submit data to support the 1/2-cup recommendation, the agency is unable to verify the 1/2-cup reference amount claimed by the comment for the mixed dishes that belong to this product category. However, the agency notes that both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the customarily consumed amount for products that belong to the "Mixed dishes measurable with cup" category is 1 cup, not 1/2 cup (Ref. 2). The agency recognizes that mixed dishes are used for both a main dish and a side dish. However, FDA rejects the suggestion to establish two different reference amounts for the same type of food for three reasons. First, one of the uses of the reference amount is to determine the appropriateness of nutrient content and health claims made on food products. Such a determination cannot be made for the same food on two or more different bases (i.e., reference amounts), e.g., a smaller reference amount (1/2 cup) to evaluate a claim for a side dish and a larger reference amount (1 cup) to evaluate a similar claim on a similar product labeled as a main dish.

Secondly, there is no assurance that a product labeled as a side dish will not be consumed as a main dish, and vice versa. Thirdly, this suggestion is not in the best interest of the consumers. Two reference amounts for the same type of products will interfere with the goal that there be uniformity among serving sizes declared on similar products by different manufacturers.

In the 1991 serving size proposal (56 FR 60394 at 60402), the agency stated that it would not object to manufacturers providing a second column of nutrition information as a side dish or as a main dish. The agency advises that the second column of information is allowed only if the serving size as a side dish or as a main dish meets the requirement for the second column in new § 101.9(b)(11), i.e., if the serving size for the second column differs from the serving size for the required column by at least two fold. However, the agency wants to make it clear that it will use the appropriate reference amount in new § 101.12(b) to evaluate whether a mixed dish that does not qualify as a meal product or a main dish product as defined in new § 101.13(l) and (m) meets FDA standards for any claim made for the product.

102. Several comments requested that FDA use a weight-based reference amount or include g weight equivalent of 1 cup in the reference amount (e.g., 1 cup (235 g)). One manufacturer suggested a 7.5 oz reference amount. Another manufacturer requested that the same reference amount be used for canned mixed dishes and frozen mixed dishes and suggested a 7.5-oz reference amount.

Although mixed dishes measurable with a cup are consumed in similar quantities by volume (e.g., 1 cup), it is not possible to have one uniform g-weight equivalent reference amount (e.g., 235 g) or weight-based reference amount (e.g., 7.5 oz) because mixed dishes come in many different forms and combinations of ingredients. Therefore, the g-weight-per-cup measure will vary greatly for different dishes. Accordingly FDA has retained the volume-based reference amount.

With regard to the comment that recommended that the same reference amount be used for both canned and frozen mixed dishes, FDA advises that although the reference amounts in new § 101.12(b) are expressed in the prepared ready-to-eat weight, they apply to all forms of the products in the product category: Dry, canned, frozen, refrigerated, and ready-to-eat. Therefore, both canned and frozen (fully-cooked "heat and serve") mixed dishes have the same reference amount. The reference amount for uncooked frozen mixed dishes would be the amount of such a product necessary to prepare one reference amount established in new § 101.12(b).

103. A manufacturer requested that FDA use a uniform 6-oz (170 g) reference amount for both mixed dishes measurable with a cup and mixed dishes not measurable with a cup to provide more continuity and consistency in reference amounts for products that qualify as "meal-type" products.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. Both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amounts customarily consumed for the mixed dishes measurable with a cup and the mixed dishes not measurable with a cup differ considerably (Ref. 2). Therefore, it is not possible to have a uniform reference amount that reflects the amount customarily consumed for the two categories. Accordingly, the agency rejects this request.

104. One comment recommended that FDA delete seasoned flavored rice mixes from this category and include it in the rice category. The comment contended that flavored rice mixes differ from all other products in the mixed dishes category, which all contain two or more components from at least two different food groups. Rice mixes contain only rice and seasoning.

FDA agrees with the comment that many flavored rice mixes are mixtures of rice and seasoning. However, some varieties do contain two or more components from two or more food

groups. For example, dry spanish rice mix contains rice and tomato. Also, seasoned flavored rice comes both canned and in dry mixes. The canned flavored rice (e.g., canned spanish rice) contains a large amount of tomato.

The agency included seasoned flavored rice mixes in the Mixed dishes measurable with cup category instead of the plain rice category for the following reasons: First, the amount of seasoned flavored rice customarily consumed was generally higher in g than that of plain rice (Ref. 2), and therefore, the 140 g reference amount for the plain rice was not appropriate for seasoned flavored rice.

Secondly, "seasoned flavored rice" includes a diverse variety of rice products. Some are clearly mixed dishes and others are not. Because the customarily consumed amount in volume of seasoned flavored rice (1 cup) was similar to that of other products in the "Mixed dishes measurable with cup" category (1 cup), the agency included all seasoned flavored rice in the "Mixed dishes measurable with cup" category in the proposal.

FDA concludes that seasoned flavored rice fits best in the "Mixed dishes measurable with cup" category because the amount customarily consumed is the same for both of these products. Accordingly, the agency rejects the request.

(45) Mixed dishes: not measurable with cup, e.g., burrito, egg roll, enchilada, pizza, pizza roll, quiche, all types of sandwiches

FDA proposed 140 g for pizza and products without sauce and 195 g for products topped with sauce as the reference amounts for the product category.

105. Some manufacturers contended that unlike other products included in this category that are consumed as a main dish (e.g., burritos, enchiladas, sandwiches, and pizza), pizza rolls and egg rolls are not customarily consumed as the main part of a meal, and thus pizza rolls and egg rolls should not be classified as a mixed dish not measurable with a cup. The comments asserted that these products are designed and promoted as snacks. The comments recommended that FDA either include pizza rolls and egg rolls in the category "Entrees without sauce" or create a separate category for appetizers with a reference amount of 85 g. Another manufacturer agreed with the 5-oz reference amount for pizza as a meal, and they also agreed that the claim evaluation should be based on the 5-oz reference amount. However, the comment requested that FDA establish a separate reference amount (e.g., 70 g) for presenting the nutrition information when pizza is used as a snack. The comment stated that the manufacturer should have the right to decide if the product is a meal or a snack.

FDA advises that the "Entrees without sauce" category under the major category for Fish, Shellfish, Game Meat, or Meat or Poultry Substitutes includes products whose major ingredients are fish, shellfish, game meat, or meat or poultry substitutes such as plain or fried fish and shellfish, fish and shellfish cake, and meatless hamburger. Pizza rolls and egg rolls do not belong to the "Entrees without sauce" category because the major ingredients of these rolls are not fish, shellfish, game meat, or meat or poultry substitutes. The NFCS included pizza rolls and egg rolls in the same group as pizza which is classified as mixed dishes not measurable with cup in § 101.12(b). Therefore, the agency has concluded that pizza rolls and egg rolls belong to the category of mixed dishes not measurable with cup.

With regard to a separate category for pizza rolls and egg rolls as appetizers, FDA finds no basis to justify a separate category. As explained in the 1991 serving size proposal (56 FR 60394 at 60403), the agency grouped similar foods to determine reference amounts for product categories, not specific foods. This grouping allows for product comparisons among similar foods that are likely to be used interchangeably. The agency included pizza rolls and egg rolls in the category for mixed dishes not measurable with cup because they are frequently used interchangeably with other products in this category as entrees. Although pizza rolls and egg rolls may be promoted as a snack or appetizer, and the amount of these rolls customarily consumed may be smaller than the amount customarily consumed for other products in the mixed dishes not measurable with cup category (e.g., pizza) that are used primarily as an entree, food consumption data show that a large percentage of people consumed 4.5 to 9 oz (Ref. 47) of pizza rolls or egg rolls per eating occasion, which are amounts that are appropriate for use as an entree, not an appetizer. To promote uniform serving sizes for nutrition comparisons of products that are used interchangeably, FDA has concluded that pizza rolls and egg rolls should have the same reference amount as other products in the mixed dishes not measurable with cup category. Accordingly, FDA rejects this request.

106. A consumer organization contended that the reference amount for pizza should be 7 oz. The comment stated that the 5-oz reference amount is too small because: (1) The average weight of single-serving pizzas in supermarkets is 6.6 oz, (2) two slices of pizza at a popular pizza restaurant averages 7.3 to 7.4 oz, and (3) a personal pan pizza served at a popular pizza restaurant is 9 oz. The comment also argued that the reference amount for vegetable burgers should be 7 oz because the average weight of hamburgers in fast-food restaurants is 7 oz. The comment contended that the "serving size" should reflect what is commonly consumed at fast food restaurants as well as at home.

FDA advises that all sizes of pizzas mentioned in the comment will be one serving based on the 5-oz reference amount and the single-serving container definition in § 101.9(b)(6). There is no need to change the reference amount which is based on consumption data, not the weight of products on the market (Ref. 2).

As explained in section III.D.5.a. of this document, FDA included the pizza and hamburger consumed at the fast food restaurants in arriving at the 5-oz reference amount. Therefore, there is no need to change the reference amount to reflect the amount consumed at fast food restaurants.

Accordingly, FDA has retained the reference amount as proposed.

(46) Nuts and seeds: nuts, seeds and mixtures

FDA proposed 40 g as the reference amount for the product category.

107. Many comments were received from the nut industry requesting that FDA change the proposed reference amount to 1 oz or 28 g or 30 g. The comments contended that nuts are used interchangeably with snacks and thus should have the same reference amount as snacks to facilitate nutrition comparisons of different types of snacks. The comments argued that 1 oz is the historical serving size and airline single-serving packets are less than 1.5 oz. Many of these comments stated that a research study conducted by a consulting firm on the comments' behalf uncovered a series of potential biases built into the protocol for using consumption data for the purposes of determining a reference amount. The comments claimed that many of the g-weight equivalents of cup measures in the NFCS data base used to convert the cup measures of nuts to the g weights were too high. Consequently, the g amounts reported in the NFCS that FDA used to estimate the reference amount for the nut category were overestimated. The comments contended that reanalysis of the NFCS data, using their

own "correct" g-weight equivalents per cup measures, showed that 1 oz is closer to the customarily consumed amount than 1.5 oz. Some comments submitted the g-weight equivalents of cup measures used in the reanalysis and detailed descriptions and data from the reanalysis. Other biases in determining the reference amounts for nuts described in the comments included: (1) FDA's analysis did not include all food codes in the nuts and seeds category, and (2) FDA used mean weights that were between two modal values when one modal value was twice as large as the other.

One comment contended that estimates of nut consumption from the NFCS are not accurate because the amounts consumed were reported in an approximate measure (e.g., cups). To obtain more accurate estimates of the consumption, the comment conducted an independent "in-home usage" survey in 20 cities across the United States, using a diary method in which the respondents recorded the number of nuts that they consumed at each eating occasion. The survey tested four different nuts commonly consumed in the United States and included 568 households. The survey was designed to parallel, as closely as possible, the demographic and socioeconomic characteristics of the nut users in the United States. The comments contended that the results of this survey showed that the amount of nuts customarily consumed is 1 oz, not 1.5 oz. The comment submitted detailed descriptions of the survey methodology and the methodology for the sample selection and the determination of the number of nuts per oz, and detailed data.

FDA carefully examined all arguments and data submitted in the comments. In the absence of well-established procedures, the agency acknowledges that NFCS data may have inaccuracies, as data from food consumption surveys usually do. The agency also recognizes the difficulties in determining the g-weight equivalents of cup measures of solid foods such as nuts. However, the agency advises that the comments' own reanalysis of the NFCS data using the comments' own estimates of the g-weight equivalents of cup measures did not give any better estimates of the nut consumption. The comments' reanalysis of the NFCS underestimated the nut consumption reported in the NFCS because the technique used to determine the g-weight equivalent of cup measures did not measure a volume of nuts equivalent to 1 cup as defined in new § 101.9(b)(5)(iv), i.e., 240 mL (Ref. 47). Therefore, FDA cannot use the results of the reanalysis of the 1987–1988 NFCS submitted by the many comments.

However, the agency agrees that the methodology used in the independent "in-home usage" survey (counting the number of nuts) estimated the nut consumption more accurately than the NFCS. The survey also had a much larger sample size (number of individual eating occasions) than the NFCS. The survey's sample size was 8 times as large as that in the 1987–1988 NFCS. The methodology used to determine the number of nuts per oz that was then used to convert the number of nuts consumed to g weight was sound. Data from this survey showed that the amount of nuts customarily consumed is closer to 1 oz than 1.5 oz. Accordingly, FDA has revised the reference amount to 1 oz.

FDA does not agree that FDA's estimate of the customarily consumed amount for nuts was biased because the analysis did not include all food codes in the nuts and seeds category. To facilitate data analysis given severe time constraints, FDA, in some cases, selected foods having a high frequency of consumption to represent the category instead of using all foods appropriate for the category. In response to a similar comment on the 1990 proposal, the agency presented evidence that inclusion or exclusion of infrequently consumed food did not affect the determination of the amount customarily consumed (Ref. 19). In response to the above comment on the 1991 serving size proposal, FDA reanalyzed the data analysis including all food codes for nuts, seeds and mixtures (excluding boiled peanuts which the comment said was inappropriate), and the results showed that the inclusion of all food codes did not make a significant difference (Ref. 41).

With regard to the comment that stated that FDA's estimate of the customarily consumed amount for nuts is inappropriate because it used mean weights that were between two modal values, the agency advises that the comment misinterpreted the way FDA derived the reference amount from the survey data. When the sample sizes were adequate, but the three statistical estimates that represent an amount customarily consumed (mean, median, and mode) did not agree, the agency considered all three values in deciding the reference amount (56 FR 60394 at 60405). Nuts had adequate sample size, but the three values differed. Therefore, the agency considered all three values to determine the reference amount for nuts. When all three values were considered together, 1.5 oz was determined to be the customarily consumed amount which happened to be closer to the mean value than to either of the two modes. The agency did not arbitrarily take the mean weights that were between two modal values.

After a careful examination of all arguments and data submitted in the comments and for the reasons explained above, FDA has concluded that the amount of nuts customarily consumed is 1 oz. Therefore, the agency has revised the reference amount for nuts to 30 g (equivalent to 1 oz).

(47) Nuts and seeds: nut and seed butter, paste, or cream

FDA proposed 30 g as the reference amount for this product category.

108. A manufacturer pointed out that several new product developments within the peanut butter market, of which FDA was not likely aware during the development of the 1991 serving size proposal, have resulted in a range of product densities among existing products. The comment stated that consumers eat peanut butter according to volume. The comment contended that the weight-based reference amount makes the serving size for whipped butter 3 tbsp., instead of 2 tbsp. Therefore, the proposed weight-based reference amount would severely undermine manufacturers' incentive to produce a peanut butter lower in fat. The comment pointed out that when products within the product category differ widely in density, FDA expressed the reference amount in volume, not in weight. The comment contended that because the densities of different brands of peanut butter differ widely, FDA should express the reference amount for peanut butter in volume, not in weight. The comment, therefore, requested that FDA change the reference amount to a volume-based reference amount (e.g., 2 tbsp.). The comment submitted data showing the differences in the densities of the regular and whipped peanut butter.

FDA acknowledges that it was not aware of the new line of whipped peanut butter during the deliberation of the 1991 serving size proposal. The agency also agrees that it has expressed the reference amount in volume, not in weight, when the density of the products within the product category vary widely and the amount customarily consumed is more uniform in volume. The agency also acknowledges that commonly used cookbooks show that peanut butter is used by volume (e.g., tbsp. and cups), not by weight (Refs. 43 and 44). Therefore, the agency has concluded that the reference amount for

peanut butter should be changed to a volume-based reference amount to encompass the differing densities of the different brands of peanut butter. Accordingly, FDA has changed the reference amount for the "Nut and seed butter * * *" category from 30 g to 2 tbsp. (volume equivalent to 30 g). However, manufacturers that make whipped peanut butter must comply with other labeling requirements for aerated food in new § 101.12(e).

(48) Potatoes and sweet potatoes/yams: French fries, hash browns, skins, or pancake

FDA proposed 70 g as the reference amount for this product category.

109. Two comments stated that French fries come in many different sizes and styles (e.g., shoestrings, thin crinkles, regular crinkles, dinner fries), and that they are prepared in many different ways (e.g., deep fat frying, microwave cooking, skillet frying, conduction oven hearing). The variation in the size and style of the cut and in the preparation method makes it difficult to determine the serving size of frozen French fries because the yield differs for different sizes, styles, and preparation methods. The comment requested that FDA establish a reference amount of 85 g for the uncooked form of the products. The comment submitted data on the cooking loss for different types of french fries that showed that the weight loss varied from about 15 to 40 percent for different sizes, styles, and quantities cooked.

FDA recognizes that there are many differing sizes, styles, and preparation methods for French fries and agrees that a reference amount for the uncooked frozen product would promote uniformity in the serving sizes of frozen french fries. Based on the average percent cooking yield of 78 percent reported by USDA (Ref. 18), FDA estimated that 89-g frozen French fries would be needed to make the 70 g of prepared French fries that are customarily consumed. The 89-g reference amount approximates 3 oz in a household measure. Therefore, the 85-g reference amount (equivalent to 3 oz) suggested in the comment is reasonable for the uncooked frozen French fries. Accordingly, FDA has revised the reference amount to read: "70 g prepared; 85 g for frozen unprepared French fries."

(49) Potatoes and sweet potatoes/yams: plain, fresh, canned, or frozen

FDA proposed 110 g as the reference amount for this product category.

110. A trade association requested that FDA change the reference amount to the g weight of 1/2 cup because it is the amount currently used by the industry on canned potato products. The comment also opposed the requirement that the nutrient content be based on the drained weight of the product. The comment contended that nutrition labeling for this product has been traditionally labeled on the contents of the entire container.

FDA advises that the serving size declared on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the amount customarily consumed for plain potatoes is 110 g, not the g equivalent of 1/2 cup (90 g drained solids) as recommended in the comment (Ref. 2). Therefore, FDA rejects this request.

Consistent with the agency decision on the nutrition information on an "as packaged" basis for canned beans, potatoes, and vegetables discussed in section III.H.2. of this document, FDA has revised the reference amount for canned potatoes to include the liquid. Using the average yield of 68 percent reported by USDA (Ref. 18), the agency has determined the reference amount for canned potatoes including the liquid, to be 160 g. Accordingly, FDA has revised the reference amount to read: "110 g for fresh or frozen; 160 g for canned in liquid."

(50) Salads: pasta or potato salad

FDA proposed 140 g as the reference amount for the product category.

111. One comment recommended that FDA change the reference amount to a volume-based reference amount. The comment contended that consumers measure these products on a volume basis, and therefore, a volume measure is more consumer friendly than a weight measure. The comment recommended 1/2 cup for the reference amount.

FDA advises that it is not necessary to change the reference amount to a volume-based reference amount to make it consumer friendly. Reference amounts appear only in the Code of Federal Regulations, and consumers usually do not see them. Although the reference amount is in g, the label serving sizes of products in this category will be expressed in cup measures because cup is the common household measure most appropriate for products in this category. Manufacturers should determine the cup measure that most closely approximates 140 g of their product.

112. A few comments claimed that the proposed reference amount is too large. The comments contended that most single-serving containers of these products hold 3.5 oz, and that manufacturers do not make single-serving containers that hold 5 oz (140 g). One comment claimed that serving scoops measure 3.5 oz. The comments recommended that FDA change the reference amount to 100 g.

The serving size on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the customarily consumed amount of products in this category is 140 g, not 100 g (Ref. 2). Therefore, the agency cannot change the reference amount to make it consistent with the single-serving container size or the serving scoop size. The agency notes that the serving size of a 3.5 oz single-serving container will be the content of the container, not 140 g. However, the 140 g reference amount, not 3.5 oz, will be used to evaluate the qualification of this single-serving container for claims.

(51) Salads: all other salad, e.g., egg, fish, shellfish, bean, fruit, or vegetable salad

FDA proposed 100 g as the reference amount for this product category.

113. One comment requested that FDA expand the salads category to have a separate reference amount for "entree" type salads (e.g., pasta and seafood salad, tuna salad) and to reflect changes in the past decade in the availability and variety of salads in the supermarkets and restaurants. The comment contended that these major changes in salad consumption have occurred since the 1977–1978 NFCS, and therefore, the changes were not reflected in that survey.

FDA advises that it used both the 1977–1978 NFCS and the 1987–1988 NFCS in determining the reference amount for salad proposed in the 1991 serving size proposal. Therefore, by using data from the 1987–1988 NFCS, the changes in the salad consumption practices since the 1977–1978 NFCS were factored into the determination of the reference amounts for salads. The agency also points out that § 101.9(j)(2) and (j)(3) exempt deli foods and restaurant foods (e.g., salad bars). Accordingly, FDA has retained the reference amount as proposed.

(52) Sauces, dips, gravies, and condiments: all categories

FDA grouped these products into five categories with separate reference amounts.

114. One comment stated that some sauces might be more appropriately grouped in different categories. The comment contended that because barbecue sauce and marinade are more similar to catsup than to dips in their usage, they "might" be included in the

major condiments instead of with the hollandaise and tartar sauce. The comment continued that cocktail sauce is used in the same manner as tartar sauce and would more appropriately be grouped with tartar sauce. Worcestershire sauce might be more appropriately included with major condiments because it is used in a similar manner to steak sauce and soy sauce. The comment did not submit any data to substantiate the suggested regrouping of sauces.

FDA advises that it has classified products in this category according to the similarity in the customarily consumed amounts as reported in the 1977–1978 NFCS and the 1987–1988 NFCS. As explained in section III.D.5.a. of this document, the agency cannot recategorize products merely because someone believes that the products need to be regrouped. Accordingly, FDA rejects this suggestion.

(53) Sauces, dips, gravies, and condiments: barbecue sauce, Hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa), marinade

FDA proposed 2 tbsp. as the reference amount for this product category.

115. Several comments stated that the 2-tbsp. reference amount is too large for marinades. The comments contended that most of the marinade is discarded after use, so the amount consumed is only about 1 tbsp. or less. The comments recommended that FDA include marinade in the "Major condiments" category because the amount of marinade consumed is closer to the reference amount for this category than that of the proposed category.

FDA acknowledges that much of the marinade is discarded after use. There is no good estimate about what percentage of the marinades used is actually consumed, but the amount consumed is certainly less than the amount used. The smaller reference amount for related products is 1 tbsp. Therefore, the agency has concluded that 1 tbsp. is more reasonable for marinades than 2 tbsp. Accordingly, FDA has moved marinades to the "Major condiments" category.

(54) Sauces, dips, gravies, and condiments: major main entree sauces, e.g., spaghetti sauce

FDA proposed 1/2 cup as the reference amount for this product category.

There was no request for a change in the reference amount for this product category. However, to follow the decision made in section III.D.2. of this document for converting the volume-based reference amount to the weight-based reference amount, the agency has changed the reference amount from 1/2 cup to 125 g (Ref. 55) using the g-weight-per-cup measure for spaghetti and marinara sauce reported by USDA (Ref. 56).

(55) Sauces, dips, gravies, and condiments: minor main entree sauce (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce

FDA proposed 1/4 cup as the reference amount for this product category.

116. One comment stated that the 1/4-cup reference amount seems large, and that a 2-tbsp. reference amount may be more appropriate. The comment also suggested that cocktail sauce is used in the same manner as tartar sauce, so it would be more appropriate to include it in the Barbecue sauce category.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. Food consumption data showed that the customarily consumed amount of cocktail sauce is 1/4 cup (Ref. 2). Accordingly, FDA has retained the reference amount as proposed.

(56) Sauces, dips, gravies, and condiments: major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, etc.

FDA proposed 1 tbsp. as the reference amount for this product category.

117. One comment requested that FDA change the reference amount to 2 tbsp. because it believed that 2 tbsp. is more consistent with the usage of these condiments. The comment submitted no data to support this change in the reference amount.

FDA advises that the 1 tbsp. reference amount was based on the amount customarily consumed of these condiments (Ref. 2). As explained in section III.D.5.a. of this document, the agency cannot change the reference amount because someone believes it is too small. Accordingly, FDA has retained the reference amount as proposed.

(57) Sauces, dips, gravies, and condiments: minor condiments, e.g., horseradish, hot sauce, mustard, worcestershire sauce, etc.

FDA proposed 1 tsp. as the reference amount for this product category.

118. One comment argued that 1 tsp. of hot sauce is too large. The comment contended that the average amount consumed is 1/2 tsp. for the regular hot sauce and 1/4 tsp. for extra hot sauce. The comment did not submit any data to support the suggested reference amounts.

FDA advises that the 1977–1978 NFCS and the 1987–1988 NFCS showed that the amount customarily consumed of hot sauce is about 1 tsp. (Ref. 2). The comment did not submit food consumption data to support that the amounts customarily consumed are 1/2 tsp. for the regular hot sauce and 1/4 tsp. for the extra hot sauce. Accordingly, FDA has retained the reference amount as proposed.

(58) Snacks: all varieties, chips, pretzels, popcorns, extruded snacks, fruit-based snacks (e.g., fruit chips), grain-based snack mixes

FDA proposed 30 g as the reference amount for the product category.

119. Many comments from the popcorn industry opposed the weight-based reference amount. The comments stated that popcorn kernels differ in their expansiveness. More expansive hybrid kernels produce a larger volume than less expansive kernels. Therefore, the comments said, the proposed 30-g reference amount would result in different serving sizes in volume (cups) for different brands of popcorns on a popped basis. The comments contended that popcorn typically is consumed by volume rather than weight and requested that FDA establish a separate volume-based reference amount for popcorn. The comments recommended 3 cups popped as the reference amount.

One comment contended that when products within the product category differ widely in density, FDA expressed the reference amount in volume, not in weight. As an example, the comment argued that FDA proposed the reference amount for ready-to-eat breakfast cereals in cups, instead of g. The comment contended that because the densities of different brands of popcorns differ widely, FDA should also express the reference amount for popcorn in volume, not in weight. Some comments claimed that consumers will be confused when they see different volume serving sizes on different brands that represent the same serving size because they weigh the same. The comments did not submit any food consumption data to support their contention that more expansive popcorns and less expansive popcorns are consumed in equal volume on a popped basis, or data to substantiate the claim that the different volume serving sizes on different brands of popcorn would be confusing to consumers.

FDA recognizes that popcorns differ in their expansiveness, and that the

weight-based reference amount would result in different volume serving sizes for different brands of popcorn because the expansiveness of popcorn kernels depends on the variety of corn and its moisture content (Ref. 57). However, the agency advises that it cannot have a volume-based reference amount (cups) for popcorn because the g weight of the cup measure of popcorn cannot be determined accurately. Expansiveness of unpopped corn depends on the popping method (Ref. 57). Many factors such as handling and shipping practices, measurement methods, and timing of measurement can affect the accuracy of the g weight of the cup measure of popped corn. As discussed in sections III.D.5. and III.F.1. of this document, there is no well-established standard procedures for determining the g-weight equivalents of the household measures. This inaccuracy in volume-based reference amount makes compliance monitoring impossible. The agency notes that in light of the difficulty in accurately measuring the g-weight equivalents of the household measures, it has decided to convert volume-based reference amounts to the weight-based reference amount where feasible (see section III.D.2. of this document). As a result, the reference amount for ready-to-eat breakfast cereals in the final regulation is in g, not in cups.

Because none of the comments submitted food consumption data to support their contention that more expansive and less expansive popcorns are consumed in equal volume, the agency is not sure that popcorns having different expansion ratios are consumed in equal volume. Furthermore, the agency points out that popcorns come in many different varieties: Plain, flavored, and carameled with or without nuts. The uniform 3 cup reference amount suggested in the comments may not be applicable to all popcorns. Food consumption data showed that the customarily consumed amount of carameled popcorn is 1 cup (Ref. 41).

As for the comments that claimed that consumers will be confused to see serving sizes that differ in the number of cups on different brands of popcorn, the comments did not submit any data to substantiate this claim. Therefore, the agency is not sure of its validity. However, the agency recognizes that many consumers may consume popcorn by volume rather than weight. For the benefit of consumers who consume popcorn on a volume basis and would like to know the nutrient contents of different brands of popcorn on an equal volume basis, the agency would not object to manufacturers providing voluntary labeling of a second column of values on a per cup popped basis (see § 101.9(b)(10)(iii)). This voluntary second column per cup applies only to popcorn and not to other snacks.

For the reasons explained above, the agency has concluded that the weight-based reference amount for popcorn should be retained. Accordingly, FDA has retained the 30-g reference amount as proposed in new § 101.12(b), Table 2.

120. Some comments stated that it is not clear whether the reference amount for popcorn refers to the weight of the kernels before popping or to the weight of the finished product because popcorn is sold both in popped and unpopped form. The comments contended that the reference amount for popcorn should be on a popped basis.

As explained in the preamble (56 FR 60394 at 60407) and in footnote 2 to Tables 1 and 2 in the 1991 serving size proposal, the reference amounts in § 101.12(b) are for the ready-to-serve or almost ready-to-serve (e.g., heat and serve, brown and serve) form of the product. Therefore, the 30 g reference amount is for the popped popcorn. New § 101.12(c) provides that the reference amount of a product that requires cooking or the addition of water or other ingredients is the amount required to prepare one reference amount of the final product as established in new § 101.12(b). Therefore, the reference amount for the unpopped popcorn would be the amount of unpopped corn that is required to make 30 g popped corn.

121. One comment recommended that FDA change the reference amount for all "bulk snacks measurable by a cup" other than popcorn to 1 cup. The comment claimed that NFCS data showed that the mean consumption of snacks is "38.1 g" which reasonably supports the 1 cup reference amount that it recommended.

As stated above, the serving size on the product label is, by statute, an amount customarily consumed. Food consumption data show that the customarily consumed amount for snacks is 30 g (Ref. 2). The g-weight-per-cup measure reported by USDA (Ref. 31) showed that the g weight of 1 cup of snacks, other than popcorn, that are measurable by a cup vary widely. For example, one cup of cheese balls weighs 35 g, whereas one cup of corn nuts weighs 91 g. Therefore, the 1 cup reference amount suggested in the comment does not reflect the amount customarily consumed of snacks, and FDA rejects this recommendation.

122. A manufacturer of "dried fruit snacks" (pressed dried fruit) stated that each individual piece of the dried fruit snack comes in 0.5 to 1 oz pieces. The 30-g reference amount would make the serving size of many of these products two pieces. The comment requested that FDA change the reference amount for the "dried fruit snacks" to 0.5 or 0.75 oz. The comment did not submit any food consumption data to support the suggested reference amounts.

The serving size on the product label is, by statute, an amount customarily consumed. Because the 1977–1978 NFCS did not have dried fruit snacks listed, the agency used the 1987–1988 NFCS to determine the amount customarily consumed for all types of pressed dried fruit. The analysis showed that the customarily consumed amount for pressed dried fruit is about 1 oz, not 0.5 or 0.75 oz (Ref. 41). Therefore, FDA rejects the request.

(59) Soups: all varieties

FDA proposed 1 cup as the reference amount for the product categories.

123. A manufacturer requested that FDA define the reference amount for soups in g. The manufacturer contended that a volume-based reference amount will cause an enormous additional laboratory and administrative burden for the manufacturer.

In light of the difficulty in determining the g weight of the household measure, FDA has concluded in section III.D.2. of this document that the volume-based reference amount should be converted to the weight-based reference amount where the weight-based reference amount is feasible. Because the g-weight-per-cup information is available, and products in this category are relatively uniform in density, the agency has concluded that a weight-based reference amount can be determined for this category. Using the g-weight-per-cup measure reported by USDA (Ref. 58), the agency has determined the average weight per cup for soups to be 245 g (Ref. 55). Accordingly, FDA has revised the reference amount to 245 g.

(60) Sugars and sweets: baking candies (e.g., chips) and hard candies

FDA proposed 15 g as the reference amount for the product category.

124. Several comments from the hard candy industry opposed the uniform 15 g reference amount for all hard candies. The comments stated that the entire package of breath mints or the entire roll of roll candies would be one serving with a 15 g reference amount. The comments contended that some hard candies (e.g., breath mints, hard roll candies) are consumed in much smaller quantities than other hard candies and

should have separate smaller reference amounts.

The comments differed with respect to specific recommendations for the reference amounts. Comments from the breath mint industry stated that breath mints are consumed for the purpose of "freshening" one's breath, not as a candy. Most of these comments recommended one piece as the reference amount for breath mints because breath mints are customarily consumed one piece at a time. One comment stated that a recent consumer survey showed that 60 percent of those surveyed customarily consumed one piece of the breath mint per eating occasion. The comment did not submit any data to support the statement. Another comment recommended that the reference amount should be one piece for hard roll candies and three pieces for "bite-size" hard candies, including breath mints. The comment submitted data from a marketing research survey to support the recommended reference amounts. This survey showed the number of candies that people put in their mouth at a time.

One comment argued that although breath mints and hard candies are often consumed one piece at a time, several pieces are consumed together during what should be considered one eating occasion. Therefore, the reference amount for these candies should not be one piece. The comment did not submit any supporting data.

One comment recommended that FDA divide hard candies into three categories by the piece size and establish a separate reference amount for each size category. Another comment from a manufacturer of hard candies recommended a 4-g reference amount for hard candies that weigh 4 g or less, based on the candy consumption data that it collected through an independent "home use test" mail survey. The comment also suggested placing these candies under the Miscellaneous category with baking decorations. The manufacturer submitted detailed descriptions of the survey methodology and demographic and socioeconomic distributions of the survey respondents, the methodology used to determine a piece weight, and detailed piece weight and consumption data. The survey tested four different "mini candies and mints" that weigh 2.4 g or less per piece. The survey included 1,333 households, covering all 9 U.S. census divisions, that have used the "test candies" or similar candies. The survey was designed to parallel, as closely as possible, the demographic and socioeconomic characteristics of the U.S. population ages 4 and older.

A comment from a Federal agency suggested a 10-g reference amount because it believed that the 15-g reference amount was too large. No data were submitted to support the suggested 10-g reference amount. A comment from a foreign government recommended that FDA change the reference amount to 30 g. The comment stated that, in the case of baking chocolate, 30 g closely approximates 1-oz squares of baking chocolate and is equivalent to the weight of chocolate chips in 3 to 5 cookies.

FDA recognizes that the hard candy category encompasses a wide variety of hard candies which may differ in amounts customarily consumed. Because the NFCS grouped all hard candies in one food code, the agency was unable to establish separate reference amounts for different types of hard candies. The NFCS showed that the amount customarily consumed for all hard candies was 1/2 oz. Consequently, the agency proposed a 15-g reference amount for the hard candy category.

FDA carefully examined all arguments and data submitted in the comment. With regard to the comments that requested a 1-piece reference amount for breath mints, the comments did not submit any food consumption data to support that 1 piece is the customarily consumed amount. Therefore, FDA has not adopted this request.

With regard to the comment that requested a 1-piece reference amount for hard roll candies and a 3-piece reference amount for "bite-size" hard candies, the data from the marketing research survey that were submitted in support of these reference amounts do not represent the customarily consumed amount. The survey asked how many pieces of the test candies people put in their mouth at a time. The survey, however, did not ask how many candies the people wound up eating per eating occasion. To determine the amount consumed per eating occasion, information on the number of candies people put in their mouth at a time and the number of times this process was repeated. Consequently, the data submitted are inappropriate. Therefore, FDA rejects this request.

With regard to the comment that requested dividing hard candies into three categories by the size of the candy and establishing a separate reference amount for each size, the comment did not submit food consumption data to show that the customarily consumed amounts of hard candies by size. In addition, dividing hard candies into three categories by the size of candy can encourage manipulation of the candy size to fit in a more favorable category. Therefore, FDA rejects this request.

FDA examined carefully the data from the "home use test" mail survey. The data were collected under the actual conditions of use and represented the consumption by the U.S. population 4 years of age or older. The survey had a sample size over 10 times that of the 1977–1978 NFCS and over 40 times that of the 1987–1988 NFCS for the hard candy consumption. The results of this survey supported that the customarily consumed amount is 2 g for breath mints and 5 g for roll-type hard candies. The survey also showed that the customarily consumed amount of mini-size candies in dispenser-type packages is less than 5 g. Although the survey only tested the comment's own brand, this study is the only food consumption data available to the agency for specific types of hard candies that were collected under actual conditions of use, and the manufacturer is a major producer of the types of candies tested.

Therefore, the agency has concluded that breath mints, roll-type candies, and mini-size candies in dispenser-type packages should have separate reference amounts. Accordingly, FDA has divided hard candies, based on the type of candy, into three categories each with their own reference amount as shown below:

Hard candies, breath mints—2 g
Hard candies, roll-type and mini-size in dispenser-type packages—5 g
Hard candies, others—15 g

With regard to the comment from the Federal agency, the comment did not submit any food consumption data to support the 10-g reference amount. With regard to the comment from the foreign government, the agency also notes that because the reference amount for cookies is 30 g, the reference amount for baking candies (e.g., chocolate chips), which are only part of the cookie, cannot be 30 g. Therefore, FDA rejects these requests.

(61) Sugars and sweets: all other candies

FDA proposed 40 g as the reference amount for this product category.

125. A few comments recommended a 1-oz reference amount. The comments contended that a uniform 1-oz reference amount would allow for fast and accurate nutrition comparisons of different candies.

Food consumption data showed that 40 g (not 1 oz) is the amount customarily consumed of candies (Ref. 2). The agency notes that regardless of what the reference amount is, most candies come in discrete units, and

therefore, the serving size for most candies will be in the number of pieces according to new § 101.9(b)(2)(i). Because the piece size varies for different candies, the serving sizes for candies will differ. Therefore, a uniform 1-oz reference amount is not going to facilitate nutrition comparisons of different candies any better than the 40-g reference amount. Accordingly, based on these factors and the fact that the comment did not present any data to show that the amount customarily consumed is any different than the amount that the agency proposed, FDA has retained the reference amount as proposed.

126. One comment from a manufacturer requested that FDA create a separate category for specialty fine chocolates/pralines with a reference amount of one piece. The comment contended that these specialty fine chocolates/pralines are unique and deserve a separate category because: (1) The proposed reference amount would make the serving size of these candies three to four pieces, yet these candies are individually wrapped and intended and promoted to be consumed one piece at a time, (2) purchasers of these candies do not "customarily consume" three to four pieces at a time, and (3) unlike other candies that come in several sizes, the manufacturer's chocolates/pralines come only in one size. A comment from another manufacturer stated that the 40-g reference amount is too large for "after dinner mints," and that FDA should establish a separate reference amount for "after dinner mints." Two comments from a foreign country stated that the proposed reference amount is too large for fine bonbons. The comments did not suggest what the reference amount for bonbons should be or submit any data to support their claim.

FDA advises that the serving size on the product label is, by statute, an amount customarily consumed. None of the comments submitted food consumption data that show that the customarily consumed amounts of these candies differ from the proposed reference amount. Therefore, FDA has rejected this request.

(62) Sugars and sweets: confectioner's sugar

FDA proposed 1/4 cup as the reference amount for this product category. The agency notes that the reference amount in the 1991 serving size proposal (56 FR 60394 at 60419) had a typographical error and stated that the reference amount is 2 tbsp. A correction notice was published on March 6, 1992 (57 FR 8179).

No objections have been raised on the proposed reference amount. As discussed in section III.D.2. of this document, the agency has decided to change the volume-based reference amount to the weight-based reference amount where feasible. Accordingly, FDA has changed the 1/4-cup reference amount to the g-weight equivalent to 1/4 cup, i.e., 30 g, using the g-weight-per-cup measure in the USDA Agriculture Handbook (Ref. 57).

(63) Sugars and sweets: honey, jams, jellies, fruit butter, molasses

FDA proposed 1 tbsp. as the reference amount for this product category.

127. A comment from a trade association for jelly and preserves supported the proposed reference amount. Comments from a trade association and a consumer organization requested that FDA change the reference amount to 2 tsp. for honey. One comment contended that the reference amount for honey should be the same as the reference amount for sugar because these products are used interchangeably. In addition, the comment asserted that data from the 1977–1978 NFCS supported the 2-tsp. reference amount for honey because the median consumption was 2 tsp., and the mode was 1 tsp.

FDA acknowledges that honey is used interchangeably with sugar in some foods (e.g., tea). However, honey has many uses. It is also used interchangeably with jam and jelly on toasts and in sandwiches, as shown by the manufacturers' suggested uses on the label. The agency notes that the 1977–1978 NFCS and the 1987–1988 NFCS together reveal that the customarily consumed amount of honey is 1 tbsp., not 2 tsp. (Ref. 2). As explained in section III.D.1. of this document, the agency is not using a reference amount that is based solely on the 1977–1978 NFCS. The agency also notes that the 1977–1978 NFCS showed the mean consumed amount was 3.3 tsp. with two modes (not one as claimed in the comment), one at 1 tsp. and one at 3 tsp. (equivalent to 1 tbsp.). The comments thus have not shown that a separate 2 tsp. reference amount for honey is appropriate. Accordingly, FDA has retained the reference amount as proposed.

128. A manufacturer requested adding "Nutella" to this category. "Nutella," ifnported from Europe, is a chocolatey spread made from sugar, milk powder, cocoa, pulverized toasted hazelnuts, cocoa butter, and vegetable oil. The company promotes it for use with fruit, crackers, breads, or desserts and asserted that it is used like jams and jellies and, therefore, should be included in this category with a reference amount of 1 tbsp. The company submitted a home use survey conducted by an independent research group to support its assertion.

Because this product is not a commonly consumed food in the United States, it was not listed in the USDA NFCS, which FDA relied on as the source for information on food consumption practices of the U.S. population. As a result, "Nutella" was not included in the "List of products for each product category" that FDA referenced in the 1991 serving size proposal (Ref. 20). According to the description provided in the comment, the product resembles chocolate syrups used as a dessert topping, except that "Nutella's" consistency is thicker than chocolate syrup. The survey data submitted by the manufacturer showed that the major use of 'Nutella" is as a dessert topping with ice cream as opposed to a substitute for jam and jelly with bread. Twenty-seven percent of the 157 respondents surveyed stated that their favorite way of using "Nutella" is with ice cream, whereas only 8 percent named bread. FDA concludes, based on the product characteristics and the usage data provided in the comment, that "Nutella" belongs to the "Other dessert toppings * * *" category under Dessert Toppings and Fillings, not the "Honey, jams, jellies, * * *" category under Sugars and Sweets with a reference amount of 2 tbsp. FDA has revised the product category name for dessert toppings to include the dessert spread. The modified name reads: "Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow * * *" If the company believes that FDA misclassified its product, it can petition FDA to reclassify the product category, but the petition must be accompanied with information specified in § 101.12(h), including food consumption data (the amount customarily consumed) under actual conditions of use.

(64) Sugars and sweets: popsicles, snow cones

FDA proposed 85 g as the reference amount for this product category.

129. Two comments recommended moving popsicles to the frozen dessert category because they are frozen desserts, and they are used interchangeably with products in that category (e.g., ice cream, frozen yogurt, sherbet). The comments differed, however, in the recommended reference amount. One comment recommended a 1/4-cup or 2.5-fl oz reference amount for popsicles because the nutrition

information for these products has been traditionally declared on a volume basis. The other comment recommended a 1/2-cup reference amount, the same as for other frozen desserts in the "Ice cream, ice milk * * *" category (the ice cream category).

First, FDA notes that the product category name has been changed to read: "Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups)" (referred to as frozen pops for simplicity) (see section III.D.4.b. of this document).

With regard to the placement of these products, in the 1991 serving size proposal, the agency listed the frozen pops under Sugars and Sweets following the categorization system for the NFCS. The agency agrees with the comments that frozen pops are used as a substitute for other frozen desserts, as shown by how they are positioned in the marketplace, and by how they are grouped in common food composition books (Refs. 37 and 59). Therefore, the agency has concluded that frozen pops should be moved to the Desserts category.

With regard to the request for changing to a volume-based reference amount because the nutrition information on these products has been traditionally declared on a volume basis, the agency advises that according to the act, the serving size should be in a common household measure that is appropriate to the product (section 403(q)(1)(A)(i) of the act). Products in the frozen pops category, with the exception of frozen ice, come in discrete units (e.g., bars), and therefore, the serving size will be the number of pieces, not the volume (e.g., fl oz or 1/2 cup) that is customarily consumed. Consequently, under the act, the nutrition information on frozen pops (excluding frozen ice) will be provided on a piece, and not a per fl oz or per cup, basis. Therefore, the comments' arguments do not justify changing the weight-based reference amount to a volume-based reference amount. Unlike the products in the ice cream category, which are difficult to express in weight because they tend to be highly aerated and differ in density, frozen pops are usually not aerated, are high in moisture, and are relatively uniform in density. Thus, the reference amount can be expressed in g. For compliance monitoring purposes, the weight-based reference amount is more effective than the volume-based reference amount. Therefore, the agency has decided to retain the weight-based reference amount for frozen pops.

With regard to the request to change the reference amount to 4 fl oz to make it the same as the reference amount for other frozen desserts, the agency advises that the customarily consumed amount in volume is not the same for the frozen pops and the products in the ice cream category. The 3-oz customarily consumed amount for frozen pops is equivalent to about 2.6 to 2.8 fl oz because of their high density. Consequently, the agency cannot change the reference amount of frozen pops to 4 fl oz to make it the same in volume as the reference amount for the ice cream category.

Accordingly, FDA has retained the reference amount as proposed.

(65) Sugars and sweets: sugar

FDA proposed 8 g as the reference amount for this product category.

130. Two industry comments requested that FDA change the reference amount to 1 tsp. One comment contended that the available food consumption data do not provide a good estimate of the amount of sugar customarily consumed. The comment stated that the concept of an eating occasion is not suited to a serving size determination for sugar because of the multiple uses of sugar that result in its being consumed in several foods at one eating occasion and in multiple servings of food with added sugar (e.g., coffee) as part of that eating occasion. For example, sugar may be added to coffee, cereal, and grapefruit at breakfast. The amount of sugar consumed per eating occasion in this case would be the total amount of sugar added to all three foods. In addition, many people consume multiple servings of coffee per eating occasion, and the sugar consumed in the multiple servings must be summed to arrive at the amount consumed per eating occasion. The comment also pointed out that the 1977–1978 NFCS and the 1987–1988 NFCS assumed a 2-tsp. serving size when the quantity consumed was not provided by the respondent. The comment contended that this assumption contributed to the conclusion that 2 tsp. is the amount customarily consumed. The comment submitted results of its analysis of data from the 1987–1988 NFCS to show the impact that the use of the default serving size and the consumption of multiple servings had on the determination of the customarily consumed amount of sugar. The comment urged FDA to utilize other relevant information in determining the reference amount, such as the 1-tsp. serving size currently used by the industry and in single-serving packets currently available in grocery stores and restaurants. The comment also contended that: (1) The 1 tsp. serving size has been used by industry for over 12 years, (2) the 1 tsp. serving size is well understood and accepted by consumers, and (3) 1 tsp. is the most convenient and practical measure of sugar.

FDA carefully examined all arguments and data submitted in the comment in support of the 1-tsp. reference amount. FDA acknowledges that because the determination of the serving sizes of foods was not one of the major objectives of the NFCS, data were not collected in a manner to accurately determine all serving sizes, and the NFCS does not accurately reflect the amount of sugar customarily consumed per eating occasion. The agency acknowledges that the amount customarily consumed per eating occasion derived from the NFCS may have been overestimated because the amount of sugar consumed per eating occasion may have included the sugar used in several foods rather than in separate eating occasions. The agency also acknowledges that a major home use of sugar in the United States is to sweeten coffee and tea. The data submitted in the comment showed that a large percentage of people consumed multiple servings of coffee (i.e., 2 or more times the reference amount). The amount of sugar consumed in these multiple servings of coffee would be more than what is used in one reference amount of coffee. Consequently, the amount of sugar customarily consumed in coffee would have been overestimated each time more than 1 cup was consumed.

For the reasons explained above, the agency has concluded that the 2-tsp. customarily consumed amount, derived from the NFCS, is an overestimate of the true customarily consumed amount for sugar. The true customarily consumed amount for sugar is less than 2 tsp. Therefore, the agency has concluded that NFCS data are insufficient to determine the amount customarily consumed for sugar.

As stated in § 101.12(a)(5), when food consumption survey data are insufficient, the agency considered other sources of information including serving sizes recommended in comments and serving sizes used by manufacturers. Because: (1) The next smallest reference amount less than 2 tsp. that corresponds to a common household measure is 1 tsp., (2) 1 tsp. serving size has been used for over 12 years and thus consumers are likely to be familiar with the 1 tsp. serving size, (3) several comments both on the 1990

and the 1991 serving size proposals supported 1 tsp. serving size, and (4) food consumption data did not provide a reasonable basis to change the current industry practice, the agency has concluded that 1 tsp. is the most reasonable reference amount for sugar. Accordingly, FDA has revised the reference amount to 4 g (equivalent to 1 tsp.).

(66) Sugars and sweets: syrups

FDA proposed 60 mL as the reference amount for this product category.

131. An industry comment requested that FDA change the reference amount for light and dark corn syrups to 30 mL. The comment contended that these syrups are used for different purposes than the syrups used on pancakes and waffles. The comment submitted data from a "strategic study" showing that these syrups are used as cooking ingredients rather than poured on pancakes or waffles.

FDA has examined the data submitted in the comment. The agency agrees that the data submitted in the comment show that light and dark corn syrups are used as cooking ingredients rather than poured on pancakes or waffles. Because these syrups are consumed as an ingredient of other foods, NFCS did not have food consumption information for these syrups per se. Using the recipe file for the 1987–1988 NFCS (Ref. 49), the agency has estimated the average amount of these syrups consumed in one reference amount of the final dishes that contain these syrups is about 30 mL. Therefore, the agency has concluded that 30 mL (equivalent to 30 g) is a more reasonable reference amount for light and dark corn syrups than 60 mL (Ref. 50). Accordingly, FDA has revised the reference amount to read: "30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others."

(67) Vegetables primarily used for garnish or flavor, e.g., pimento, chili pepper, green onion, parsley: fresh or canned

FDA proposed 30 g as the reference amount for this product category.

132. One comment contended that pimiento/pimento is a specialty canned food item and is an ingredient that is used only in small quantities to enhance the flavor and color of various dishes. The comment argued that because pimento is never used by itself as a vegetable, the 30-g reference amount is too large for pimentos. A nutrition professional organization stated that the proposed reference amount reflects use as a vegetable, not a garnish or flavor.

FDA has reexamined the reference amount for this category. In the interest of minimizing product categories, in the 1991 serving size proposal, the agency included pimento, chili pepper, green onion, and parsley in one group. Because pimento is used primarily as an ingredient of other foods, and the analysis to determine the amount of pimento customarily consumed is time consuming, the agency did not determine the customarily consumed amount for pimento per se due to time constraints. In response to the comment, FDA has determined the amounts of pimento and parsley customarily consumed. The results of the data analysis supported a smaller reference amount (4 g) for pimento and parsley than for chili pepper or green onion (Ref. 41). Therefore, the agency has concluded that this product category should be divided into two categories: Vegetables primarily used for garnish or flavor, e.g., pimento, parsley with a reference amount of 4 g, and chili pepper, green onion with a reference amount of 30 g. FDA has revised § 101.12(b) accordingly.

(68) Vegetables: all other vegetables without sauce: fresh, canned, or frozen

FDA proposed 85 g as the reference amount for this product category.

133. Comments from two trade associations supported the reference amount. One comment opposed the use of the nutrition information on a drained weight basis. The comment presented data showing that a large percentage of consumers consume the liquid in canned vegetables.

As discussed in section III.H.2. of this document, the agency has decided that nutrition information on canned vegetables should be on an "as packaged" basis including the liquid. The 85-g proposed reference amount represents the amount customarily consumed for the solids only, and therefore, it is still applicable to fresh and frozen vegetables without sauce. To reflect the decision in section III.H.2. of this document, the reference amount for canned vegetables has to be reestimated to include the liquid. Using the information on the percent yield of the drained solids for canned vegetables reported by USDA (Ref. 18), the agency has determined that the amount customarily consumed for canned vegetables including the liquid is as follows: 95 g for vacuum packed vegetables and 130 g for vegetables canned in liquid (Ref. 55).

In the 1991 serving size proposal, pumpkin and winter squash were included in the vegetables with sauce category because although pumpkin and winter squash do not contain sauce, the customarily consumed amount was closer to the 110 g than the 85-g reference amount. In the final regulation, the agency has grouped pumpkin and winter squash with vegetables canned in liquid under the category of vegetables without sauce because the customarily consumed amounts of these vegetables are similar. In addition, FDA has moved cream-style corn and canned or stewed tomatoes from footnote 5 of Table 2 in the 1991 serving size proposal to the reference amount column in the final regulation because the reference amount for these two vegetables is the same as that for the vegetables canned in liquid, and therefore, the footnote is no longer necessary. The revised reference amount reads: "85 g for fresh or frozen; 95 g for vacuum packed; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash."

134. One comment recommended that vegetables with pasta and vegetables with rice be included in the vegetable category, not in the Mixed dishes category. The comment contended that the dietary guidance documents recommend 1/2 cup for vegetables, rice, and pasta, so there may be consumer confusion if 1/2 cup is not used for these foods when combined.

Vegetables with pasta and vegetables with rice are neither rice nor pasta nor vegetables. They are clearly mixed dishes because they contain two foods from two different food groups (the grain product group and the vegetable group). The comment did not submit any data to show that, for these products, a serving size other than 1/2 cup would cause consumer confusion.

Accordingly, FDA has rejected this comment.

(69) Vegetables: all other vegetables with sauce: fresh, canned, or frozen

FDA proposed 110 g as the reference amount for this product category.

135. A comment from a consumer recommended that FDA change the reference amount to 100 g because 100 g is a more rational metric size than 110 g.

FDA advises that for reasons explained in section III.D.1. of this document, it is not changing the reference amount to make it more rational in metric quantity. Accordingly, FDA has retained the reference amount as proposed.

(70) Vegetables: vegetable juice

FDA proposed a uniform 240-mL (8 fl oz) reference amount for this product category.

136. Comments from several manufacturers and trade associations and a comment from a nutrition professional organization supported the proposed uniform 8-fl oz reference amount for all beverages. One comment from a manufacturer requested that FDA establish a separate category for vegetable juice with a reference amount of 6 fl oz.

Considering the weight of support for the uniform 8-fl oz reference amount for all beverages and the benefit of the uniform reference amount that facilitates nutrition comparisons of different beverages, the agency has decided to retain the uniform 8-fl oz reference amount for all beverages, including vegetable juice. Vegetable juice is frequently used interchangeably with fruit juice and other beverages. Food consumption data also did not show that the customarily consumed amount for vegetable juice differs from that of fruit juice or of many other beverages (Ref. 2). The comment did not submit data that would support a different result. Accordingly, FDA has retained the reference amount as proposed.

(71) Vegetables: olives

FDA proposed 15 g as the reference amount for this product category.

137. One comment requested that FDA change the reference amount to 30 g. The comment contended that 30 g is the serving size that is currently used on packaging, and because pickles and olives have similar consumer usage patterns, the reference amount for olives should be the same as the reference amount for pickles.

FDA disagrees with the comment. The agency advises that the serving size on the product label is, by statute, an amount customarily consumed. Both the 1977–1978 NFCS and the 1987–1988 NFCS showed that the customarily consumed amount of olives is closer to 0.5 oz, not 1 oz. The comment did not present any data to show that 0.5 oz is not the customarily consumed amount. Accordingly, FDA has retained the reference amount as proposed.

6. Reference amounts for imitation or substitute food, altered food, and foods for special dietary use

To prevent the manipulation of serving sizes for nutrient content claims, FDA proposed in § 101.12(d) that the reference amount for an imitation or substitute food be the same as that of the food for which it is offered as a substitute. In addition, the agency proposed in § 101.12(e) that the reference amount for an altered version of a food, such as a "low calorie" version, be the same as for the food for which it is offered as a substitute.

FDA received about a dozen comments on this proposal from manufacturers, trade associations, and professional organizations. About one-third of the comments supported the proposal. The rest of the comments opposed it.

138. Comments opposing the proposal stated that one way that industry is reducing the fat and calorie content of foods is through a new technology that incorporates air into the product (referred to as "aerated food" for simplicity). Many aerated foods weigh significantly less than their regular counterparts. Comments stated that there is no concern when the reference amount is established in volume, but that there is a concern when a weight-based reference amount is used. For example, using a reference amount of 85 g for waffles, 3 aerated waffles would be compared to 2 regular waffles of the same size and shape. Therefore, the calorie and fat content of the aerated food would not be lower than that of the regular food when compared on an equal weight basis. Manufacturers would thus be unable to use a nutrient content claim for the aerated foods.

These comments argued that the proposal would diminish manufacturers' incentive to develop "nutritionally improved" foods and prevent consumers from benefitting from low fat, low calorie alternatives. The comments suggested that when the reference amount is determined by weight, FDA should allow the manufacturers to use "the volume measure (e.g., common household volumetric or dimensional measure or number of discrete units) equivalent to the volume measure of the manufacturer's regular product pursuant to the reference amount," e.g., 2 waffles for both the aerated and the regular food.

FDA has given careful consideration to all arguments and suggestions presented in these comments. Although the comments claimed that the amount customarily consumed for the regular and the aerated food is the same in volume, not in weight, no food consumption data were presented with the comments or are available from other sources to verify the claim. It is possible that people eat three aerated waffles, instead of two, to attain satiety. Therefore, FDA is not certain that the amount customarily consumed for the aerated foods and their regular counterpart is the same in volume.

At the same time, in light of the current dietary guidelines for reducing fat and calorie intakes (Refs. 60 through 62), FDA acknowledges that it is desirable to have a wide selection of low fat and low calorie foods available to consumers. Some consumers may benefit from having such aerated foods if they consume an equivalent volume of aerated food as they would have the regular food, e.g., two instead of three aerated waffles. However, FDA does not believe that the solution suggested in the comments is appropriate or desirable considering the wide variability in the unit size and shape of the regular products in discrete units. This variability would make it difficult to determine a reference point, i.e., volume equivalent to the reference amount of the regular counterpart.

FDA finds that the most reasonable solution to this problem is to allow the manufacturers to determine the reference amount in g for the aerated food by adjusting for the difference in density of the aerated food relative to the density of the regular counterpart (density-adjusted reference amount). For example, if the density of the aerated food is 30 percent lower than the density of the regular counterpart, the reference amount for the aerated food would be 30 percent less than the reference amount of the regular counterpart. For example, the reference amount for regular waffles is 85 g, so the reference amount for aerated waffles, which are 30 percent lower in density, would be 60 g. A manufacturer may use the density-adjusted reference amount to determine the label serving size and the qualification of the aerated food for nutrient content and health claims, provided that, upon request, the manufacturer will show FDA the detailed protocol and records of data described below. FDA will consider regulatory action under sections 402(b) and 403 of the act on any misuse of this allowance.

Such density-adjusted reference amounts may not be done for cakes. Although the product categories for cakes in the final regulation are identified by types of cakes, not by density, the three cake categories in Table 2 in new § 101.12(b) were determined according to the density of various cakes. FDA took the differences in the densities of different types of cakes having different degrees of air incorporation into consideration in determining the reference amounts for cakes. Therefore, further adjustment of the reference amounts for aeration is not permissible for cakes.

For the aerated food to qualify to use the density-adjusted reference amount, the product must be sufficiently lower in density than the regular counterpart. The agency finds that a 25-percent

reduction in density is a reasonable cutoff level for this purpose. The 25-percent minimum reduction is consistent with the minimum percent reduction requirement to qualify for a "less" or "reduced" claim in the regulation entitled "Food Labeling; Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (hereinafter referred to as the nutrient content claims regulation), published elsewhere in this issue of the **Federal Register**. In estimating the difference in density, manufacturers must use an appropriate reference food as described in new § 101.13(j)(ii)(A) of the nutrient content claims regulation, published elsewhere in this issue of the **Federal Register**, for the regular counterpart.

In expressing the weight-based reference amounts for the regular foods in new § 101.12(b), FDA rounded the values to the nearest 5-g increment to avoid the appearance of an overly exact g-weight. Under § 101.12(e), this procedure must also be followed in determining the reference amount for the aerated food. Manufacturers must use the rounded density-adjusted reference amount to determine the serving size and whether the aerated food qualifies for a claim. The table below shows an example of the calculated density-adjusted reference amount and the corresponding rounded reference amount to be used for aerated waffles that have been reduced in density by 25 to 35 percent. As the table shows, aerated waffles with density reductions of 27 to 32 percent must use 60 g, not 58 to 62 g, as the reference amount.

Reference Amount for the Regular Waffle: 85 g

Percent reduction in density	Calculated Density-adjusted reference amount	Reference amount for "aerated" food
(%)	(g)	(g)
25	64	65
26	63	65
27	62	60
28	61	60
29	60	60
30	60	60
31	59	60
32	58	60
33	57	55
34	56	55
35	55	55

To use a density-adjusted reference amount, manufacturers must have the following available for inspection by FDA upon request: (1) A detailed protocol and records of all raw data and calculations used to determine densities of both the regular and the aerated products; (2) records of the sample size, the mean, and the standard deviation for the density measurements of the regular and the aerated products; and (3) records of all data, calculations, and procedures used to arrive at the "density-adjusted" reference amount for the aerated product. The protocol must contain identification and descriptions of all materials used (e.g., equipment) to determine the density. In determining the differences in the densities of the regular and the aerated products, manufacturers must also observe the following: (1) The regular and the aerated product must be the same in size, shape, and volume. To compare the densities of products having nonsmooth surfaces (e.g., waffles), manufacturers must use a device or method that ensures that the volumes of the regular and the aerated products are the same. One way to ensure the same volume is to use the same equipment to make the regular and the aerated products; (2) sample selections for the density measurements must be done in accordance with the provisions in § 101.9(g); (3) density measurements of the regular and the aerated products must be conducted by the same trained operator using the same methodology (e.g., the same equipment, procedures, and techniques) under the same conditions; and (4) density measurements must be replicated a sufficient number of times to ensure that the average of the measurements is representative of the true differences in the densities of the regular and the aerated products.

Manufacturers must use a descriptive term such as "whipped" or "aerated" as part of the product name (e.g., whipped peanut butter, aerated waffle) so that consumers are properly informed that extra air has been incorporated into the product. The use of this term is necessary, under section 201(n) and 403(a) of the act, to disclose a material fact.

To incorporate the labeling requirements for aerated foods, FDA has combined § 101.12(d) and (e), redesignated as § 101.12(d), and added the requirements for aerated products in § 101.12(e).

139. A manufacturer of medical foods stated that several aspects of the serving size regulation (e.g., expressing the serving size in the common household measure) are not accurate enough for medical foods.

FDA advises that the serving size regulations do not apply to medical foods because section 403(q)(5)(A)(iv) of the act exempts medical foods from all requirements of nutrition labeling. The agency intends to develop regulations for proper labeling and uses of medical foods in a future **Federal Register** document.

7. Reference amounts for products consisting of 2 or more foods having individual reference amounts

FDA proposed in § 101.12(f) that the reference amount for products packaged and presented to be consumed together (e.g., peanut butter and jelly combination, cracker and cheese pack, pancakes and syrup pack) be the sum of the reference amounts for the individual foods in the package.

140. FDA received only a few comments on this aspect of the proposal. Comments from nutrition professional organizations agreed with the proposal. A consumer organization disagreed with the proposal and stated that the proposal is reasonable only for foods that are not packaged in single-serve containers such as peanut butter and jelly. The comment contended that for foods in single-serve containers (e.g., cheese-and-cracker snack trays, yogurt and granola, pancakes and sausage, waffles and fruit sauce, spaghetti and tomato sauce,, macaroni and cheese, or rice with vegetables), the reference amount should be based on the weight of the entire package.

First of all, FDA wishes to clarify that the proposal applies to the products that contain two or more foods having individual reference amounts that are not listed in proposed § 101.12(b). Although this fact was mentioned in the preamble (56 FR 60394 at 60407), FDA did not state it in the codified language in proposed § 101.12(f). To clarify its intent, FDA has revised § 101.12(f) to read:

> The reference amount for products that represent two or more foods packaged and presented to be consumed together * * * shall be the sum of the reference amounts for individual foods in the package if the reference amount for the product is not listed in paragraph (b) of this section.

Some of the examples mentioned in the comment (spaghetti and tomato sauce, macaroni and cheese, rice with vegetables) are mixed dishes measurable with a cup that have reference amounts in new § 101.12(b). As explained previously, FDA does not believe that it is consistent with the act to have different reference amounts for the same product in different package sizes, one for single-serving packages and one for multiserving packages. The reference amount for the same product must be the same regardless of the package size.

In addition, the agency points out that the package of yogurt and granola is one food. It simply is another variety of flavored yogurt. Like frozen entrees in pouches, yogurt and granola are

packaged in separate containers for technical reasons (e.g., better preservation of the texture), but they are combined before consumption and eaten as one food. The reference amount for yogurt and granola is 225 g, the same as for any other yogurts.

141. An industry comment stated that the reference amount is not necessary for "meal-type" products because claims on these products will be evaluated on a per 100 g basis.

The agency disagrees with the comment. Reference amounts are also used to determine the label serving sizes of specific products for presenting nutrition information. Many "meal-type" products (reclassified and redefined as "meal product" and "main dish product" in the final nutrient content claims regulation published elsewhere in this issue of the **Federal Register**) (e.g., lasagna, pizza) are available both in single-serving and multiserving containers. Reference amounts provide a basis on which to determine the label serving sizes of these products in multiserving containers and whether these products are qualified to be called single-serving.

142. A consumer organization requested that FDA establish reference amounts for "frozen meals" (e.g., breakfast, lunch, or dinner trays) based on the average weight of the products in the marketplace or on the "industry-wide average."

The agency notes that the "frozen meals" mentioned in the comment currently come only in containers clearly intended for a single serving, and therefore, the nutrition information for these products will be based on the entire content of the package. The agency also notes that the reference amount is not needed to evaluate whether these products are qualified for claims because the qualification for claims on these products will be based on 100 g of the product and not on the reference amount as discussed in the final nutrient content claims regulation published elsewhere in this issue of the **Federal Register**. If a reference amount is needed for "frozen meals," new § 101.12(f) can be used to determine the reference amount for specific frozen meals. Breakfast, lunch, or dinner trays contain two or more distinct products which have reference amounts in new § 101.12(b). According to new § 101.12(f), the reference amounts of these products are the sum of the reference amounts of the individual foods in the tray. For example, the reference amount of a dinner tray containing fish, french fries, and mixed vegetables will be the sum of the reference amounts of fish (85 g), french fries (70 g if cooked), and mixed vegetables (85 g), i.e., 240 g. Therefore, there is no need to establish separate reference amounts for these "frozen meals."

8. Miscellaneous issues related to reference amounts

143. Some industry comments stated that restaurants should be permitted to declare nutrition information according to their own specifications for serving size.

Restaurant foods are not required to bear nutrition labeling. However, when nutrient content or health claims are made for restaurant foods, the restaurateur must provide nutrition information in compliance with the nutrient content or health claims regulations published elsewhere in this issue of the **Federal Register**. Meals, entrees, or other menu items served in restaurants are analogous to single-serving products. Therefore, in most cases, the restaurateur must have a reasonable basis for believing, based on the amount served, that the food qualifies for the claim. However, if nutrient content claims are made relative to a competitor's product, it is important that like amounts be compared.

144. A trade association recommended that FDA allow manufacturers to deviate from the reference amounts if such deviation is supported by food consumption data.

The act requires that FDA establish standards providing that uniform serving sizes information will be furnished on the food label (H. Rept. 101–538, supra, 7). The reference amounts are part of the standards. Manufacturers cannot deviate from the reference amount simply because they believe that such deviation is supported by food consumption data. If the uniformity expected by Congress is to be maintained, the information on the need for revised or separate reference amounts must be evaluated by FDA through the petition process that it has established in new § 101.12(h) before changes in, or deviations from, the reference amounts can occur.

E. Procedures for Converting the Reference Amount to Serving Size

For the purpose of converting the reference amounts for multiserving products into label serving sizes, FDA grouped these products into three categories according to the shape and characteristics of products and the way products are usually served. The three categories were: (1) Products in discrete individual units (e.g., muffin, sliced bread, apple), (2) products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), and (3) nondiscrete bulk products (e.g., breakfast cereals, flour, sugar). The agency proposed separate procedures for each category to ensure that the serving size declared on the label is most appropriate for the specific type of product.

FDA received about 20 comments on issues related to these procedures. About one-third of the comments agreed with the proposed procedures. The remaining two-thirds suggested other ways of determining label serving sizes for specific products or requested modification or clarification of certain specific aspects of the procedures. FDA will first respond to the "general" types of comments and then discuss the comments on procedures for each specific category.

145. A foreign manufacturer stated that the reference amounts should be used only to ascertain that the serving size chosen by the manufacturer is reasonable, and that they should not be used to determine the label serving size. The comment argued that products packed in foreign countries are packaged according to "whole number" metric amounts and do not translate easily into U.S. household units. The comment requested that FDA show a certain amount of flexibility. A domestic comment stated that several of the reference amounts are "atypical in retail practice" in the United States even though they may represent consumers' consumption practice. The comment, therefore, suggested that FDA permit industry to use the reference amount as a guideline and require them to justify, with marketing data, those serving sizes that substantially deviate from the reference amount. A few consumer comments, on the other hand, requested that FDA not allow the manufacturers to deviate from the "standard serving size."

The 1990 amendments direct FDA to establish standards, not guidelines, to define serving sizes. As alluded to above, the House report on the 1990 amendments, in explaining section 2(b)(1)(B) states: "It is critical to the successful implementation of this legislation that the FDA develop meaningful serving size requirements * * *." (H. Rept. 101–538, supra, 18). Accordingly, FDA established the standards described above to define how to determine the label serving size that is most appropriate for a specific product. FDA believes that the standards provide enough flexibility to both domestic and foreign manufacturers to permit them to determine the serving sizes most

appropriate for their products from the reference amounts in new§ 101.12(b).

FDA does not agree with the comment that products packaged in foreign countries according to "whole number" metric amounts cannot easily be translated into common U.S. household measures. Some domestic products are also packaged according to "whole number" metric amounts (e.g., 1- or 2-liter (L) bottles of soft drinks). FDA allows the number of servings per container to be expressed in an approximate number. Therefore, it should not be difficult to translate the products packaged according to "whole number" metric amounts into common U.S. household measures. For example, the serving size and the number of servings for a 1–L container of soft drink can easily be translated to the common U.S. household measure by dividing the 1-L (1,000 mL) net quantity of the product by the 240-mL reference amount for soft drinks and expressing an approximate number of servings, e.g., serving size: 1 cup (240 mL); number of servings per container: about 4.

FDA notes that the act links serving size to food consumption practices, not to the "typical retail practice" or marketing data. Therefore, FDA cannot use information (e.g., "typical retail practice" or marketing data) other than food consumption data as the primary basis for reference amounts when appropriate food consumption data are available. The agency has considered serving sizes used by the industry (i.e., retail practice) in developing the reference amounts in this final rule. When appropriate food consumption data were not available, the agency gave more weight to other information listed in new § 101.12(a)(5), including serving sizes currently used by the industry, in arriving at the reference amount.

146. An industry comment asked that FDA clarify how to determine the label serving size if there are more than one use of a product.

The reference amounts in new § 101.12(b) reflect the major usage of the products in each product category. If there is more than one use for a product, manufacturers should use the major usage of the product to determine the label serving size. For example, the label serving size for a cake mix which has directions for a 2-layer cake and cupcakes should be based on the 2-layer cake. Manufacturers should determine the major usage of the product based on food consumption data, marketing survey data on the consumer usage of the product, or, in the case of a new product, promoted use.

147. An industry comment requested that FDA clarify how to determine the label serving size if the label serving size determined according to the procedures in proposed § 101.9(b)(2) and the incremental rules in proposed § 101.9(b)(5) falls exactly half way between two sizes, e.g., exactly 2.5 tbsp.

FDA notes that the common standard procedure for rounding is to round up values 0.5 or larger. FDA is not aware of any reason not to follow this procedure. Therefore, for clarity, FDA has added a new § 101.9(b)(5)(v), on rounding rules as follows:

> When a serving size, determined from the reference amount in § 101.12(b) and the procedures described in this section, falls exactly half way between two serving sizes, e.g., 2.5 tbsp, manufacturers shall round the serving size up to the next incremental size.

148. Several comments suggested different serving sizes for celery or for other of the 20 most frequently consumed raw fruits and vegetables identified in § 101.44.

FDA advises that serving sizes for the 20 most frequently consumed raw fruits and vegetables, including celery, are provided in Appendix A to the regulation entitled "Food Labeling; Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Definition of Substantial Compliance" (56 FR 60880 as amended at 57 FR 8174, March 6, 1992). Retailers who wish to use different serving sizes for these fruits and vegetables may do so subject to the provisions of § 101.45. FDA urges such retailers, and retailers who wish to provide the nutrition information of raw fruits and vegetables not included in § 101.44, to use the reference amount specified in new § 101.12(b) for the fruit or vegetable category appropriate for the specific fruits or vegetables and to follow the procedures described in this section to determine the label serving size.

1. Products in discrete individual units

FDA proposed in § 101.9(b)(2)(i) that "for products in discrete units (e.g., muffin, sliced bread, apple), the serving size shall be the number of units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent, of the reference amount, the serving size shall be one unit. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion."

149. Several industry comments opposed the lower limit of the single-serving unit because single units of many products in discrete units weigh less than 67 percent of the reference amount. One comment requested changing the lower limit from 67 percent to 50 percent because food consumption data (e.g., 1977–1978 NFCS) show that a significant proportion of "eatings" (e.g., up to 25th percentile) were about one-half or less of the average quantity consumed. Therefore, the comment contended, a unit that weighs 50 percent of the reference amount should be able to declare one serving per unit. Another comment requested changing the lower limit from 67 percent to 50 percent and allowing single-serving declaration on a single unit that weighs less than 50 percent of the reference amount if a single unit can reasonably be consumed at a single-eating occasion. The latter comment stated that this approach is analogous to the optional declaration as a single serving of a single unit that weighs 200 percent or more of the reference amount if the whole unit can reasonably be consumed at a single-eating occasion. Some comments recommended that FDA let the manufacturers determine whether a unit that weighs less than 67 percent is a single serving.

FDA carefully examined all requested changes for the lower limit of a single-serving unit. The agency has examined the amount of food consumed per eating occasion for several products that come in discrete units and find that a significant number of people consume between 50 and 67 percent of the reference amount per eating occasion (Ref. 63). Considering that: (1) Many single units fall between 50 and 67 percent of the reference amount, (2) a significant number of people consume between 50 and 67 percent of the reference amount per eating occasion, and (3) serving sizes in dietary guidance documents are often based on a single unit, FDA believes that it is reasonable to let manufacturers have the flexibility to determine whether a unit that weighs more than 50 percent but less than 67 percent is a single serving. However, a unit that weighs 50 percent of the reference amount is, by definition, one-half of a serving, not one serving. Therefore, products that weigh 50 percent or less cannot be called one serving. Accordingly, FDA has revised § 101.9(b)(2)(i) to allow optional declaration of a serving based on a single unit of a product if the unit weighs more than 50 percent but less than 67 percent of the reference amount.

150. Several industry comments requested that FDA permit the use of an oz measure for the serving size for products that naturally vary in piece

size (e.g., shrimp, pickles) instead of the number of discrete units. A seafood trade association stated that great difficulty and financial burden would be placed on the industry if serving sizes of seafoods have to be expressed in the number of discrete units. The comment pointed out that seafoods such as shrimp, scallops, oysters, clams, lobster, and fillet of fish vary naturally and substantially in size. For example, processed breaded shrimp products are made in as many as 12 to 15 sizes because of the natural variation in shrimp size. The comment stated that if a manufacturer packed these products in three different sized packages, up to 45 different labels would be necessary to accurately designate serving sizes based on discrete units, and the cost of printing different labels would be prohibitive.

A pickle trade association also stated that the size and shape of cucumbers naturally vary widely because of numerous factors, including the variety, weather conditions, and maturation when harvested. Therefore, according to the comment, pickles, even in the same grade established by the USDA, vary considerably in size and weight. The comment contended that the serving size cannot be declared by the number of pickles because of the inherent variability in pickle sizes. If the serving size of pickles were required to be declared in the number or fraction of pickles, the comment continued, pickle manufacturers would have to have a different label for each pickle size. The comment contended that such a result would represent an unnecessary burden and cost. Therefore, the comment recommended that the serving size for pickles should be declared in terms of oz.

FDA recognizes the wide variability in the unit size of seafoods and agricultural commodities such as pickles where the size is determined by nature, not the manufacturer. The costs incurred in ensuring that the number of discrete units in the serving size declaration for these naturally-variable products is appropriate would be unreasonable because of the numerous labels for each product size, and the costs would likely be passed on to the consumer. The agency, therefore, believes that the most reasonable solution to this problem is to express the serving size in an oz measure most closely approximating the reference amount, followed by the g equivalent weight and the approximate number of pieces for small pieces (e.g., shrimp) or the dimension for a large piece (e.g., fillet of fish) in parenthesis. For example, serving sizes may be declared as 3 oz (84 g/about 5 shrimp) for cooked shrimp, 3 oz (84 g/about one fillet) for cooked fish fillet, 1 oz (28 g/about 1 pickle) for small pickles, and 1 oz (28 g/about 1/2 pickle) for large pickles. This approach will satisfy the act by providing the declaration in household measures in terms of oz. It also provides a uniform g weight within and across brands. This approach also facilitates nutrition comparisons among brands. Because many consumers stated that they do not understand oz measure, the approximate number of pieces or the dimension allows consumers to visualize the serving size in more easily identifiable units. Therefore, FDA has revised § 101.9(b)(2)(i) to exempt products that vary naturally in the unit size such as pickles, shellfish, whole fish, and fillet of fish. In addition, the agency has added a statement that serving sizes for these products shall be expressed in the amount in oz that most closely approximates the reference amount for the product category, and a second statement that refers manufacturers to § 101.9(b)(5) for instructions on how to express the serving size in oz. The agency notes that this exemption does not apply to processed products, such as fish sticks and fish squares, where manufacturers can control the piece size.

FDA recognizes that unit sizes of products in individual discrete units (e.g., fish sticks, muffins, sliced products) for which the size of the product is controlled by the manufacturer, not by nature, also vary somewhat from unit to unit within the package as well as from batch to batch for the same container size. This variation is also true for products in large discrete units (e.g., cake, pizza). Therefore, the g weight of a unit or a fraction will vary from unit to unit as well as from batch to batch. It is thus impossible to label accurately the g weight that is equivalent to the household measure in each package. FDA concludes that the most reasonable solution for this problem is to state the average g-weight equivalent of the unit or the fraction that represents the serving size. To determine the average g-weight equivalent of the household measure, manufacturers must follow the sampling procedures in § 101.9(g)(2) for nutrient analysis. The g-weight equivalent of a unit or a fraction for each package can be determined by dividing the net weight of the package in g by the number of units or fractions in the package or by actually weighing the units or the fractions. In determining the average g-weight equivalent, the measurements should be replicated a sufficient number of times to ensure that the average of the measurements is truly representative of the g-weight equivalent of the serving size in household measure. FDA urges manufacturers to maintain records of all data and calculations used to determine the average g-weight equivalent to substantiate the parenthetical metric quantity declared on the label.

151. A comment from a maraschino cherry trade association stated that according to the 1991 serving size proposal, the serving size for maraschino cherries would be 1 cherry. However, maraschino cherries naturally vary in size ranging from 4 g for a small cherry to 7 g for a large cherry depending of the locality of growth and the crop year. The comment contended that because of this natural variation in the size of cherries, the maraschino cherry packers would have to keep changing the labels to have the accurate serving size information. In addition, the comment stated that the number of servings per container vary because of the variation in the cherry size. The comment requested that FDA allow the maraschino cherry packers to use a range of values (e.g., 4 to 7 g) for the parenthetical metric measure for the serving size and exempt the maraschino cherries from the declaration for the number of servings per container.

As for pickles, FDA recognizes the wide variability in the unit size of agricultural commodities where the size is determined by nature, not the manufacturer. As stated above, the costs incurred in ensuring that the number of discrete units in the serving size declaration would be unreasonable because of the numerous labels necessary for each product size. Unlike pickles, however, cherries cannot have a serving size expressed in oz because the reference amount for cherries (4 g) is too small to express in oz. Therefore, the agency finds that the most reasonable solution to this problem is to declare the serving size as one cherry and the parenthetical metric measure as the g-weight equivalent of one medium cherry (e.g., 1 cherry (5 g)). The number of servings per container would then be declared as the usual number of servings per size of container (e.g., usually 20 servings), and the nutrition information would thus be provided for one medium cherry. The agency recognizes that different size containers hold different numbers of cherries. Therefore, this approach will require the manufacturer to have one set of labels for each size of container. Accordingly, new § 101.9(b)(2)(i) has been further revised to include the special serving

size requirement for maraschino cherries.

152. Several industry and professional comments stated that the serving size for products in discrete units (e.g., sliced bread, frozen novelties) should be one unit.

FDA disagrees with the comments. Products in discrete units vary widely in unit size. For example, the unit size for sliced bread varies from about 0.3 oz to 1.2 oz and from 0.4 oz to 6 oz for muffins. If one unit were defined as the serving size, there would be no uniformity in the serving sizes for products in discrete units. Furthermore, single units of some of these products are too small to be reasonably considered a serving.

The act defines serving size as an amount customarily consumed. Reference amounts established by this regulation represent FDA's best estimate of the amounts customarily consumed for the 139 product categories. To provide flexibility and to ensure that the serving size in common household measures is meaningful for specific types of products, FDA has provided procedures in new § 101.9(b)(2) to convert the reference amounts to the label serving size. Therefore, unless one unit represents the serving size for the product as determined from the reference amount in new § 101.12(b) using the procedures in new § 101.9(b)(2), one unit cannot be used on the labels as the serving size.

153. Some comments requested that FDA clarify serving sizes of packages within packages.

FDA advises that packages within a package (i.e., individually wrapped products in a multiserving container) are considered to be products in discrete units. Each individually wrapped package (e.g., fun size candy bars, roll candies, tiny box of raisins) is one unit. The serving size of these products is the number of individual units whose total net content most closely approximates the reference amount. FDA has revised § 101.9(b)(2)(i) to clarify this point by adding individually packaged products within a multiserving package to the list of examples of products in discrete units.

154. A manufacturer suggested that FDA change the single-serving unit criteria from "67 percent or more, but less than 200 percent" of the reference amount to "2/3 or more, but less than twice" the reference amount. The comment asserted that this modification would avoid a difference of opinion as to whether 66.67 percent should be rounded to 67 or should be considered less than 67 percent for a single-serving determination.

As discussed earlier, the common standard procedure for rounding is to round up values 0.5 or larger. Thus, 66.67 percent is considered to be 67 percent. Therefore, defining the lower cutoff point as 67 percent is as clear as defining it as 2/3, and defining the upper limit as less than 200 percent is as clear as defining it as less than twice. Since the proposed language and the suggested change are equally clear, the agency has concluded that it is not necessary to modify the proposed regulatory language. Accordingly, FDA has retained the language for the single-serving unit criteria as proposed.

155. A consumer organization requested that FDA clarify whether, for products in discrete units, manufacturers must list the nutrition information on the basis of units that constitute the label serving size (e.g., 2 slices) or for the underlying reference amount (e.g., 2 1/2 slices). The comment contended that FDA should require nutrition information for products in discrete units to be listed based on the former approach.

FDA agrees that clarification is needed. Accordingly, the agency is revising § 101.9(b)(2)(i) to state that, except for products that naturally vary in size, the serving size of discrete-unit products is the number of whole units that most closely approximates the reference amount for the product category. This revision makes it clear that the serving size is to be expressed in whole number of units which was the original intent in the proposal.

156. A manufacturer requested that FDA clearly state in the preamble to the final regulation that a slice of cheese, whether or not wrapped individually, like sliced bread, constitutes a discrete unit for purposes of determining serving size. The manufacturer stated that this fact was evident, but ambiguous, in light of specific examples of discrete units cited in the 1991 serving size proposal.

Because it is impossible to provide the entire list of the products that are sold in discrete units, FDA provided a few examples of products that are sold in discrete units in § 101.9(b)(2)(i) of the 1991 serving size proposal. They included muffins, sliced bread, and apples. The specific examples given in the 1991 serving size proposal were to provide some idea of what is meant by products in discrete units. The agency included "sliced bread" as an example to convey the message that a slice of sliced products is a discrete unit product. A slice of sliced cheese is thus a discrete unit product. For clarity, FDA has modified the "sliced bread" example to read "sliced products such as sliced bread."

2. Products in large discrete units that are usually divided for consumption

FDA proposed in § 101.9(b)(2)(ii) that for products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving size is the fractional slice of the food (e.g., 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the reference amount for the product category.

157. A manufacturer recommended that the fractional slice should be "geometrically friendly" to consumers. The comment stated that some fractional slices may not be easy for the consumers to cut or visualize. For example, a cake cannot be easily cut into seven even slices. The comment provided two separate lists of "geometrically friendly" fractions in support of their position, one "for products that are not cut in two directions" (e.g., round cakes) and one for "products that must be cut in two directions" (e.g., sheet cakes). A few other comments also expressed a concern about odd fractional serving sizes.

FDA recognizes that the proposal could result in an odd fractional slice such as 1/7 of a cake or pie. The agency agrees with the comment that the serving size for products in large discrete units should be expressed in fractions friendly to consumers. Although manufacturers may have a means to cut these products in odd fractions, consumers generally would have difficulty in cutting them into certain odd fractions such as 1/7.

To rectify this problem, the agency carefully examined all possible fractional slices including those suggested in the comment. FDA could not directly adopt the two sets of fractional schemes suggested in the comment because the agency cannot require that some products be cut in one direction and others in two directions. Contrary to the assumption in the comment, some large, round cakes are often cut in two directions. The fractional list provided by the manufacturer was also inconsistent in that it suggested that a square cake could not be divided into five pieces but listed 1/20, which is a multiple of 5, as "geometrically friendly" for a square or rectangular product.

For the reasons outlined above, FDA cannot directly adopt the list of fractions suggested by the comment. However, the agency agrees with the concept of friendly fractions and is responding to the spirit of the comment by adopting a two-part scheme for identifying them. The scheme involves

establishing a base set of fractions and describing a process for generating a continuing set of smaller divisions of the base set. For the base set, FDA has selected integer increases of fractions up to and including 6 (1/2, 1/3, 1/4, 1/5, and 1/6). The agency has not included 1/7, which both FDA and the comment recognize would be difficult to cut and which the comment did not include in either of it's suggested lists. This base set is consistent with the comment's list of fractions for round products but not for square and rectangular products, which excluded 1/5 as geometrically unfriendly. The agency acknowledges that dividing a product into five pieces is more difficult than other fractions in the base set. However, the difference between a serving size of 1/4 and 1/6 of a product is substantial and therefore could result in a serving size that is too large or too small. The comment also included 1/5 as a friendly fraction for round products. Thus, the agency has included a 1/5 fraction to provide a more reasonable serving size for products that contain between 450 and 550 percent of the reference amount.

The process for generating a continuous set of friendly fractions is based on creating further divisions of the base set. FDA and the comment both agree that it is easy to divide objects into two or three pieces. Therefore, the process selected for generating additional fractions involves dividing any of the base set or any newly created fractions by 2 or 3. Thus under this scheme, the set of friendly fractions includes 1/2, 1/3, 1/4, 1/5, 1/6, 1/8, 1/9, 1/10, 1/12, 1/16, 1/18, 1/20, 1/24, 1/32, 1/36, etc. The only fraction included in the comment list and not included here is 1/28 because it involves a division by 7 and that was not acceptable to the comment or FDA. Therefore, the agency excluded 1/28 from the friendly fractions.

To incorporate the friendly fractions in the regulations, FDA has revised § 101.9(b)(2)(ii) to read: "For products in large discrete units that are usually divided for consumption * * * the serving size shall be the fractional slice of the food * * * that most closely approximates the reference amount for the product category. In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3."

F. Declaration of Serving Size on the Product Label

1. Label statement of serving size

FDA proposed in § 101.9(b)(7) that a label statement regarding a serving shall be the serving size expressed in common household measures followed by the equivalent metric quantity in parenthesis. In addition, FDA proposed that serving sizes may be declared in oz and fl oz (U.S. measure), in parenthesis, following the metric measure where other common household measures are used as the primary unit for serving size, e.g., 1 cup (28 g)(1 oz).

158. Over 100 comments addressed this issue. The majority supported the use of common household measures as the primary unit for the serving size. About one-third of the comments agreed that the equivalent metric quantity should be required, and that manufacturers should be allowed to voluntarily list the equivalent U.S. measure. Comments disagreeing with the proposal varied widely as to how serving sizes should be stated.

Several comments stated that the U.S. measure should be mandatory in addition to or instead of the metric measure. Others objected to voluntary declaration of the U.S. measure in addition to the common household measure, arguing that it was unnecessary, would crowd the label, and would be confusing to consumers. However, none of the comments presented any supporting data or evidence.

Several comments opposed the use of the metric measure arguing that U.S. consumers are not familiar with metric measurements, that a g is not commonly used in food preparation, and that declaration of the exact metric weight might mislead consumers by implying an accuracy that is often unachievable for food products. Some suggested making the metric measure optional. Other comments favored allowing only one of the three measures; some of these expressed no preference and others specifically supported one of the three. However, many comments from professional organizations and consumers supported listing the metric measure parenthetically. These comments noted that the world is progressively moving toward the metric system, and it is important for Americans to become familiar and feel comfortable with metric measurements. They stated that using metric measurements to declare serving sizes would educate consumers about the metric system.

The 1990 amendments require that serving size be expressed in a common household measure that is appropriate to the specific food. The Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418) declares that the metric system is the preferred measurement system for U.S. trade and commerce. Federal agencies are required to use the metric system in procurement, grants, and other business-related activities to the extent economically feasible by the end of fiscal year 1992. As discussed in the 1991 serving size proposal, FDA needs a precise quantity statement (e.g., metric measure), in addition to the common household measure, for compliance purposes because of the variability in the quantity of different brands in common household units. After carefully considering the statutory requirement, the Omnibus Trade and Competitiveness Act of 1988, the need for a compliance measure, and the arguments presented in the comments, FDA concludes that the most straightforward way to comply with the law, to fulfill the agency's regulatory needs, and to make the label most useful to consumers is to require the serving size to be declared in common household units followed by the equivalent metric quantity in parenthesis as proposed in the 1991 serving size proposal.

Given the conflicting views in comments on the use of the U.S. measure, the agency has decided to make the listing of the equivalent U.S. measure after the metric measure voluntary. Because of consumers' familiarity with U.S. measures, this declaration is likely to help consumers understand the serving size. However, because its use is voluntary, there is no reason to believe that it will create a crowding problem. Manufacturers will only include this information if they have ample label space. Accordingly, FDA is retaining in new § 101.9(b)(7) the requirement that the label serving size be expressed in common household measures, followed by the metric quantity in parentheses.

159. An industry comment stated that the parenthetical listing of the equivalent metric weight of the serving size is unnecessary on those single-serving containers for which the metric weight of the net quantity of contents is provided on the principal display panel. The comment requested that single-serving containers be exempted from this requirement. The comment contended that the parenthetical metric statement unnecessarily uses valuable label space for small single-serving containers.

FDA agrees that the parenthetical listing of the equivalent metric quantity is not necessary on the single-serving containers when the metric quantity of the net quantity of contents is provided on the principal display panel. However, for some products the metric quantity for the serving size and the metric quantity for the net quantity of

contents may differ. For example, the serving size for products packed or canned in liquid that is not customarily consumed (e.g., canned fish, pickles) must be expressed on a drained weight basis. In this case, the metric quantity on the principal display panel, which includes both the solids and the liquid, may differ from the parenthetical metric quantity for the serving size, which is based on the drained solids only. Thus, FDA has concluded that it is reasonable to exempt single-serving containers from the requirement for listing the parenthetical metric measure but only if the metric quantity for the net quantity of contents is the same as the metric quantity for the serving size. Accordingly, FDA has revised § 101.9(b)(7) to reflect this conclusion.

160. An industry comment stated that because individual products that belong to the same category, and thus have the same reference amount, vary in size and shape, the parenthetical metric measure equivalent to the serving size in household measure can vary from brand to brand. For example, g equivalents of 1/4 cup of nuts may vary from 30 g to 40 g. Thus, different metric equivalents can be declared by different brands for the same product. One brand may declare 30 g as the metric equivalent and present the nutrition information based on the 30 g serving, and another brand may declare 40 g as the metric equivalent and present the nutrition information based on the 40 g serving. The comment stated that this result is confusing and invites manipulation of the metric equivalent of the household measure. The comment recommended that FDA standardize the metric quantity of the reference amount for bulk products and have manufacturers declare an approximate household measure that is closest to that reference amount (e.g., about 1/4 cup (30 g)). Several other industry comments stated that there is no standard procedure for determining g equivalents of household measure, and that it is difficult to measure the g weight of a household measure accurately.

FDA recognizes that the parenthetical metric equivalents of the household measure of the same food may differ for different brands due to the differences in the products' size and shape. However, the agency notes that the 1990 amendments provided FDA with the authority to establish the standards to define serving sizes, not specific label serving sizes. Standardizing the parenthetical metric quantity on the reference amount is like using the reference amount (standard) as the label serving size. Therefore, FDA rejects this request.

However, the agency recognizes that the procedure for determining metric equivalents of household measures needs to be standardized, and that there is no well-established standard procedure used by industry or any other organization for doing so. To promote uniformity in label serving sizes in household measures of the same food declared by different manufacturers, the agency is providing Guidelines for Determining the Gram Weight of the Household Measure. The guidelines can be obtained from Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

161. An industry comment requested that FDA allow voluntary labeling of the number of pieces in addition to the serving size in oz for products such as chips and nuts.

FDA agrees that oz is an appropriate household measure for chips. The agency points out that new § 101.9(b)(5)(iii) requires an appropriate visual unit of measure when oz is used as the serving size. Therefore, manufacturers must provide a visual unit of measure, such as the number of chips or a fraction of the package (e.g., 1/4 package), that is equivalent to the oz amount declared.

FDA does not agree that oz is the common household measure most appropriate for nuts. The agency believes that cups is the appropriate household measure for most nuts because most nuts are small in size and can be measured with a cup. When cups are used to express the serving size for nuts, the parenthetical statement for the number of nuts is not required. However, the agency does not object to a manufacturer voluntarily providing an additional visual measure such as the number of nuts, which may help consumers better visualize the serving size. For some exceptionally large nuts that are hard to measure with a cup (e.g., unshelled walnuts), the agency believes the number of nuts would be the most appropriate household measure.

162. A trade association expressed concern that the use of several parentheses (e.g., 1 slice (28 g) (1 oz)) would make the serving size statement more difficult to understand. The comment recommended that FDA allow the flexibility to use commas and slashes.

FDA disagrees with the comment. Allowing such flexibility would result in nonuniformity in the declaration of label serving sizes by different manufacturers. For example, the serving size for sliced breads could be expressed in five different ways: 1 slice (28 g) (1 oz) by brand A; 1 slice (28 g, 1 oz) by brand B; 1 slice (28 g/1 oz) by brand C; 1 slice, 28 g, 1 oz by brand D; and 1 slice/28 g/1 oz by Brand E. The use of these various formats for this declaration would be confusing.

After examining all possible combinations of the formats, FDA finds that the most desirable format is to require the presentation of all serving size information other than the mandatory common household measure, in one set of parenthesis with the different serving size statements separated by slashes, i.e., 1 slice (28 g/1 oz). This format requires less space than most of the other formats and separates the household measure from the rest of the information. Therefore, FDA has modified § 101.9(b)(7) to require that all serving size information, other than the mandatory common household measure, be presented in one set of parenthesis with the different serving size information separated by slashes.

163. An industry comment stated that the label statement example given in proposed § 101.9(b)(7) is confusing because there is no indication of the product for which the example applies.

FDA has revised § 101.9(b)(7) to correct this oversight by adding a phrase indicating what product was used for the example.

164. Several comments recommended that FDA allow voluntary listing of nutrient contents per unit for products that come in discrete units (e.g., 1 slice of bread, 1 doughnut, 1 ice cream bar), when the declared serving size of a multiserving package is more than one unit. These comments stated that: (1) Per-unit nutrition information would aid nutrition professionals in providing dietary guidance to their clients, and (2) although two or more units are determined to be the label serving size according to the FDA regulation, these foods are clearly meant to be consumed one unit at a time. The comments said that per-unit nutrition information will thus help consumers to better understand the nutrient content of the food as consumed.

Because many products in discrete units come in small units, and people customarily consume more than one unit per eating occasion, reference amounts of these products are in multiunits (e.g., 2 small doughnuts). However, FDA recognizes that some individuals may consume only one unit at a time. In addition, the serving sizes contained in some dietary guidance or nutrition education documents (e.g., diabetic exchange list) are often expressed in terms of a single unit. In

an attempt to make the nutrition information on these products more useful to those consumers who consume only one unit at a time and to nutrition professionals who provide dietary guidance to their clients, the agency has revised § 101.9(b)(10) to allow voluntary labeling of a second column of nutrition information on a per unit basis. Finally, for individuals who consume multiple units that differ from the label serving size, the per-unit labeling would facilitate calculating the nutrient content for any multiple of a single unit.

However, products in discrete units vary greatly in size. Also, "mini" or "bite" size versions (e.g., "mini" cookies) are gaining popularity in the marketplace. FDA believes that per unit nutrition information on some of these products would be misleading. For example, a "bite" size version of a product could be labeled as containing zero fat or calories because of FDA's round-off rules for nutrient declaration, when in fact, enough units to constitute a serving contain significant amounts of fat and calories. The agency, therefore, considers that per unit labeling of "mini" or "bite" size products is misleading. FDA will consider regulatory action under section 403(a) of the act for any misuse of this allowance.

165. An industry comment recommended that the serving size declaration should conform to the rules for the net quantity of contents in § 101.105.

Most rules in § 101.105 do not apply to the serving size regulation. The applicable portion of the net quantity rule has been incorporated in the Guidelines for Determining the Gram Weight of the Household Measure mentioned in new § 101.9(b)(7).

2. Definition of household measures

FDA proposed in § 101.9(b)(5) to define "common household measure" or "common household unit" to mean cup, tbsp., tsp., piece, slice, fraction (e.g., 1/4 pizza), oz, or other common household equipment used to package food products (e.g., jar, tray).

166. One comment recommended that units other than those listed in proposed § 101.9(b)(5) be allowed to be used for a common household measure, e.g., 1 cake for single-serving cakes, 1 bar for frozen novelties, and 1 sandwich for sandwiches.

FDA advises that new § 101.9(b)(5)(ii) allows the use of 1 cake, 1 bar, 1 sandwich, and similar units for label serving sizes. These units are examples of "piece" measurements for specific products. FDA listed them as a generic term "piece" because it is not possible to name all common household measures appropriate for specific products in discrete units.

167. Because all beverages can be measured with a cup, the proposed definition for the household measure did not include fl oz. Some comments stated that it would be helpful to have fl oz measures for liquids. Although many consumer comments stated that they do not understand oz measures, they stated that fl oz is known and understood. The comments suggested that parts of the public want fl oz as a measure for expressing serving sizes.

FDA notes that fl oz is a common measure used to express the serving sizes of beverages. Therefore, on the basis of the comments, the agency concludes that it is appropriate to include fl oz in the definition of common household measures. Accordingly, FDA has revised § 101.9(b)(5) to include fl oz as a household measure. In addition, § 101.9(b)(5)(i) has been modified to allow beverages to express the primary household measure in fl oz.

3. Rules for declaring household measures

168. FDA proposed in § 101.9(b)(5)(i) through (b)(5)(iv) a set of rules that manufacturers should follow in expressing serving sizes in household measures. Most comments agreed with the proposed rules. One comment, however, stated that some foods would be more precisely measured in 1/3 cup increments rather than 1/4 cup increments and requested that this option be added to the final rule.

FDA proposed to require that cup measurements be declared in 1/4 cup increments to assure as much uniformity as possible in label serving sizes within a product category. Without such a rule, one manufacturer may choose to use 1/3 cup as the serving and another manufacturer may choose to use 1/4 cup for similar quantities of products. To prevent such inconsistencies in serving sizes, the agency proposed to require that cup measures be expressed in 1/4 cup increments. FDA has reexamined this aspect of the proposal. The agency agrees with the comment that some foods can be measured more precisely in 1/3 cup increments. In addition, FDA recognizes that contrary to the agency's intention, 1/4 cup increments may result in a larger discrepancy in label serving sizes of different brands or contribute to the manipulation of serving sizes when the label serving size is on the borderline between two sizes. One manufacturer may declare 1/4 cup and another manufacturer may declare 1/2 cup for similar quantities of a product. Therefore, FDA has concluded that adding 1/3 cup increments to the final rule is desirable. Accordingly, FDA has revised § 101.9(b)(5)(i) to read: "Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. * * * Cups shall be expressed in 1/4 or 1/3 cup increments, * * *."

169. Because common household measures such as cups, tbsp., and pieces may not be appropriate for some foods, FDA proposed in § 101.9(b)(5)(iii) the use of oz as the common household unit for such foods. When oz is used as the common household measure for serving size, FDA proposed that the oz statement should be accompanied by an appropriate visual unit of measure such as a dimension of a piece (e.g., "about 1 inch slice" for unsliced bread). An industry comment objected to the proposed requirement for an appropriate visual unit of measure. The comment stated that oz is a unit of measure that is understood by the public, and that the parenthetical dimensional measurement will only confuse the consumers. The comment did not submit any data to support its claim.

FDA disagrees that oz is a unit of measure well understood by the public. Consumer comments on the 1990 proposal overwhelmingly opposed the oz measure for serving sizes. They stated that they did not understand the oz measurement very well, and that they did not have a scale to measure food. They preferred common household measures such as cups, tbsp., and pieces. Several consumer comments on the 1991 serving size proposal again stated that they did not understand oz measurement. Therefore, FDA rejects the industry comment. Based on the comments, the agency concludes that when the oz measurement is used as the primary unit for serving size, an appropriate visual unit of measure is needed to help consumers visualize the serving size. Accordingly, FDA has retained the requirement for an appropriate visual unit of measure. However, FDA has revised § 101.9(b)(5)(iii) to permit the use of a fraction as a visual unit if it is the appropriate unit.

170. FDA stated in § 101.9(b)(5)(iii) that when oz is used as the common household measure for serving size, the oz measurements must be expressed in 0.5-oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz).

A manufacturer recommended that oz measures should be rounded to the nearest 0.1-oz increment. The

manufacturer stated that since an appropriate visual unit of measure is required, there is no need to round the oz measure to the nearest 0.5 oz. The comment contended that when consumers complained about fractional numbers, it is because they have no means of visualizing what quantity the weight represents. Therefore, as long as they have a visual description, consumers would not object to fractions. The comment further stated that under the proposal, products weighing from 22 to 35 g would all be listed as "about 1 oz." In addition, a product with an exact serving size of 64 g would declare "about 2.5 oz" whereas a product with an exact serving size of 63 g would declare "about 2 oz." The manufacturer stated that it would be a disservice to metric education in this country if people thought that a 1 g difference was a 1/2 oz difference. Because listing g quantities will be mandatory, the manufacturer felt that more exact oz measures need to be used, e.g., in increments of 0.1 oz.

FDA advises that the proposed § 101.9(b)(5)(iii) applies to the oz measure when it is used as the primary serving size. It does not apply to the parenthetical oz measure equivalent to the metric measure that is provided voluntarily by the manufacturer (see § 101.9(b)(7)). The nonuniformity in the oz measure described in the comment (i.e., about 2 oz for 63 g and about 2.5 oz for 64 g) would not occur when oz is used as the primary serving size because in determining the reference amounts, FDA made sure that the values would be in 0.5-oz increments. However, in expressing the reference amounts in g, FDA rounded the g quantity to the nearest 5 g for quantities. Therefore, some reference amounts will not convert to exactly 0.5-oz increments. For example, 30 g reference amount would be translated to about 1.1 oz. To prevent the use of odd decimals and unusually accurate fractional numbers for the primary serving size, the agency proposed to require in § 101.9(b)(5)(iii) that oz measures be expressed in 0.5-oz increments. When oz is used as the primary serving size, the main purpose is to be a reference for consumers. Comments from consumers have strongly objected to odd decimals and fractions (55 FR 29517 at 29524, July 19, 1990) (56 FR 60394 at 60411, November 27, 1991). Therefore, the agency concludes that the primary serving size should be expressed in 0.5-oz increments to be meaningful to consumers. Accordingly, FDA has retained the 0.5-oz incremental rule in § 101.9(b)(5)(iii) when oz is used as the primary serving size.

In the 1991 serving size proposal, FDA did not specifically address how to express voluntary parenthetical labeling of the oz measure that is equivalent to the primary household measure. The oz measure in this case can be any decimal quantity (e.g., 1.4 oz, 2.2 oz, 5.1 oz). These oz measures are not the primary serving size required. They represent the equivalent oz quantity that corresponds to the metric quantity declared. For example, the primary measure would be the household measure followed in parentheses by the g equivalent weight. At the manufacturer's discretion, the equivalent oz quantity could also be included. The primary measure is presented in household units or common fractions of household units (1/4 cup) that are familiar and meaningful to consumers. For secondary measures, it is important that the equivalent oz quantity be an accurate reflection of the primary household measure, and it is less important to round to even divisions since the primary measure is "consumer friendly." Therefore, FDA concludes that it is desirable to have a more accurate oz quantity and has modified § 101.9(b)(7) to provide that the oz quantity equivalent to the metric quantity should be expressed in 0.1 oz increments.

For the same reason, it is important that the g-weight equivalent be an accurate reflection of the primary household measure. In the 1991 serving size proposal, the agency did not provide specific guidelines for expressing the parenthetical g-weight equivalent of the household measure. Because the product categories in new § 101.12(b) have been expanded to include spices and herbs that have very small serving sizes (usually less than 1 g), the agency has concluded that it is particularly important to provide guidelines for expressing the g-weight equivalent of the household measure, so that the parenthetical g-weight equivalent would accurately reflect the primary household measure. The agency is providing the following guidelines for expressing the parenthetical g-weight equivalent: For a parenthetical g-weight of 5 g or more, the values should be expressed in the nearest whole number of g. For a parenthetical g-weight of 2 g or more but less than 5 g, the values should be expressed in 0.5-g increments. This incremental rule is consistent with the incremental rule in § 101.9(b)(8) for the number of servings per container for products that contain 2 or more servings but less than 5 servings per container. For a parenthetical g-weight of less than 2 g, the values should be expressed in 0.1-g increments. Accordingly, FDA ha revised § 101.9(b)(7) to read:

> A label statement regarding a serving shall be the serving size expressed in common household measure * * * followed by the equivalent metric quantity in parenthesis * * * The g quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g. The g quantity between 2 and 5 g should be rounded to the nearest 0.5 g and the g quantity less than 2 g should be expressed in 0.1 g increments. In addition, serving size may be declared in oz and fl oz * * *.

171. A consumer organization recommended that FDA require manufacturers to round up the label serving size when the reference amount is 0.5 oz. For example, 0.5 oz should be rounded up to 1 oz, 1.5 oz up to 2 oz, and so forth.

FDA disagrees with the comment. Such rounding would introduce large errors in the label serving size, and the label serving sizes would not reflect the amount customarily consumed. For example, rounding 0.5 oz to 1 oz would introduce 100 percent error and rounding 1.5 oz to 2 oz would introduce 33 percent error. Accordingly, FDA has not adopted this recommendation.

172. A manufacturer recommended that the serving size for a single-serving container should be the net weight of the container, and that it should not be rounded to the nearest 0.5 oz. The comment pointed out that if this were not the case, the serving size of a single-serving container having a net weight of 7.2 oz will state 7 oz. The comment said that such a discrepancy would be confusing.

FDA points out that new § 101.9(b)(5) allows manufacturers to use oz as the serving size only if cups, tbsp., tsp., or units such as piece, slice, tray, jar, and fraction cannot be used. The household unit most appropriate for a single-serving container is the description of the container itself (e.g., tray, package, carton, or box), not oz. Therefore, the serving sizes of single-serving containers must be stated in tray, package, carton, or a similar unit appropriate for the specific container. Accordingly, the rounding rule in new § 101.9(b)(5)(iii) does not apply to the single-serving containers.

173. Some consumers requested that FDA standardize abbreviations used on the label.

FDA advises that new § 101.9(b)(7) standardizes abbreviations for units (e.g., g, mL) if a manufacturer elects to use abbreviations.

4. Labeling of "meal-type" products

FDA proposed in § 101.9(b)(3) that the serving size for "meal-type" products, as defined in § 101.13(l) of the nutrient content claims proposal, be the entire content of the package.

174. Several comments requested that the entire content of "meal-type" products that come in multiserving containers (e.g., lasagna, pizza) not be required to be labeled as one serving.

FDA agrees with the comment. Accordingly, the agency is revising § 101.9(b)(3) to exclude multiserving containers. The agency also notes that it has revised § 101.13(l) of the nutrient content claims regulation, published elsewhere in this issue of the **Federal Register**, by dividing these products into two categories, meal products and main dish products, and adopting new definitions for these products. For clarification, FDA advises that the serving size for a multiserving product that has a reference amount in new § 101.12(b) must be determined according to provisions in § 101.9(b), even if these products are classified as a "meal product" or a "main dish product" in new § 101.13(l) and (m). FDA also notes that for products that do not meet the definition of "meal product" or a "main dish product," claims will be evaluated according to the reference amount in new § 101.12(b) applicable to the product.

To reflect the reclassification and new definitions of "meal product" and "main dish product" in new § 101.13(l) and (m), and for clarity, FDA has revised § 101.9(b)(3) to read: "Serving size for meal products and main dish products as defined in § 101.13(l) and (m) of this chapter that come in single-serving containers as defined in paragraph (b)(6) of this section shall be the entire content (edible portion only) of the package. Serving size for meal products and main dish products in multiserving containers shall be based on the reference amount applicable to the product in § 101.12(b) if the product is listed in § 101.12(b). Serving size for meal products and main dish products in multiserving containers that are not listed in § 101.12(b) shall be based on the reference amount according to § 101.12(f)."

175. One comment requested that FDA require dual declaration, per serving and per 100 g, on "meal-type" products to facilitate nutrition comparisons of these products on an equal basis and to ensure "a level playing field."

FDA disagrees with the comment. The agency recognizes, that because many of these products are used interchangeably in the diet, consumers may want to compare nutritional values of these products. "Meal-type" products (reclassified and redefined as "meal product" and "main dish product" in new § 101.13(l) and (m)) encompass a wide variety of products which vary in product characteristics. Therefore, these products differ greatly in amounts customarily consumed. The agency believes that nutrition information per serving derived from the reference amount applicable to each type of these products facilitates nutrition comparisons of these products on an equal basis in terms of the amount used in the diet. In addition, the 1990 amendments do not provide the authority to require nutrition information per 100 g or 100 mL basis. Accordingly, FDA has not adopted the recommended modification. (However, the agency notes that under new § 101.13(l) and (m), the eligibility of such products to bear nutrient claims will be determined on a per 100 g basis.)

176. Several industry comments suggested that frozen entrees packaged in separate pouches that contain more than one distinct food per package (e.g., rice or pasta with sauce or toppings) should be classified as "meal-type" products rather than mixed dishes.

For the purpose of determining the label serving size, the agency considers these "pouch-type" frozen entrees to be "mixed dishes" rather than "meal-type" products. The components of these frozen entrees are packaged separately for technical reasons, such as differences in required cooking times for the different components and better preservation of the texture and flavor during storage. However, the components from all pouches in a package are consumed as one product like other products in the mixed dishes categories. The only difference between the "pouch-type" products and other mixed dishes is that different components of the "pouch-type" products are packaged in separate pouches within the container, while all components of the other type of mixed dishes are packaged in one container. There is no difference in the characteristics, usage, or the manner of consumption between these two types of products.

However, if a "pouch-type" product meets the definition of "meal product" or "main dish product" in new § 101.13(l) and (m) of the final regulation on nutrient content claims, it will be classified as such for the evaluation of whether the product qualifies to bear a nutrient content claim. If a "pouch-type" product does not meet the definition of "meal product" or "main dish product," its qualification for claims will be based on the reference amount of the specific product.

5. Labeling of variety packs

FDA proposed to require in § 101.9(b)(4) that a variety pack, such as a package containing several varieties of single-serving packages or a product having two or more compartments with each compartment containing a different food, provide nutrition information for each variety or food per serving size that is derived from the reference amount applicable to each variety or food.

177. One comment requested that FDA revise the proposed rule on the labeling of variety packs to state that nutrition labeling should be based on the individual serving actually in each inner container rather than serving size derived from the reference amount.

FDA advises that as long as each inner package meets the requirements for the single-serving unit as defined in § 101.9(b)(2)(i), the content of each inner package is one serving. Thus, the nutrition information would be based on the content in each inner package. Many variety packs contain different products that differ in reference amounts. Therefore, to determine whether each inner package qualifies for the single-serving unit, manufacturers must use the reference amount applicable to each product. Accordingly, FDA has not adopted the comment's request. However, for clarity, FDA has revised § 101.9(b)(4) to read: "A variety pack such as a package containing several varieties of single-serving units as defined in paragraph (b)(2)(i) of this section * * * shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in § 101.12(b) applicable for each variety or food and the procedures to convert the reference amount to serving size in paragraph (b)(2) of this section."

6. Labeling of foods for special dietary use

In the preamble to the 1991 serving size proposal (56 FR 60394 at 60408), FDA tentatively concluded that the serving size requirements that applied to foods intended for weight control or weight reduction, available in the marketplace, should also apply to the products sold only to enrollees of a weight control program. The agency also stated that it would not object if products available only as part of a weight-control program provided dual columns of nutrition information based on the reference amount and the serving size prescribed by the program.

178. A consumer organization supported the proposal but recommended that FDA require both the nutrition information and the product's qualification for claims to be based on the reference amount. Industry comments objected to the proposed requirement. A manufacturer of weight-control products requested that FDA allow manufacturers of portion controlled or other products that are part of a weight-control or weight-maintenance plan to base serving sizes on amounts specified under such plans and not necessarily on serving sizes derived from reference amounts in new § 101.12(b). Comments from the providers of weight-control programs requested that FDA allow them to determine serving sizes that are consistent with the meal plans for products that are available only through the weight-control program. The comments asserted that if portion controlled products are required to use the same serving size as for the regular counterpart, it could lead to overconsumption of these foods and defeat the purpose of the program. The comments claimed that the dual labeling proposed by FDA could be confusing. A nutrition professional organization also stated that dual columns of nutrition information on these products may be confusing.

FDA has given careful consideration to all arguments presented in the comments on this issue. To ensure that the labeling is not misleading, the serving sizes for all foods available in the marketplace to the general public, including those intended for weight-control or weight-reductions, must be based on the reference amount in new § 101.12(b). However, the agency also finds that for weight-control products that are available only as part of a weight-control program, the use of a serving size that differs from the serving size for the meal plan may be confusing to the enrollees and may undermine the purpose of the program. Therefore, the agency concludes that, for products that are available only through the weight-control program and are not available at a general retail store, it is in the best interest of the enrollees of the weight-control program to have labeling that is consistent with the meal plan of the program in order to avoid any potential confusion about the serving size. FDA has revised § 101.9(b)(2) to exempt products that are both intended for weight-control and available only through weight-control or weight-maintenance programs. To avoid any confusion with the general retail products, manufacturers are required to label their products as "for sale only through the ———— program" (fill in the blank with the name of the appropriate weight-control program, e.g., Smith's Weight Control), on the principal display panel. If these products are also available at the retail market, the serving size derived from the reference amount must be used. FDA advises that qualification of these products for nutrient content or health claims will be based on the reference amount, not the serving size determined by the provider of the weight-control program.

In addition, FDA advises that the label statements regarding the usefulness of these products in reducing or maintaining body weight are subject to the provisions in new § 105.66 of the nutrient content claims regulation published elsewhere is this issue of the **Federal Register**.

G. Declaration of Number of Servings Per Container

FDA proposed in § 101.9(b)(8) that a manufacturer, in declaring the number of servings per container, may use either of the two options listed in that section, choosing the one most meaningful for a specific product. The options proposed were: (1) Declare serving size as the approximate whole household measure that results in a whole number of servings in the container (e.g., serving size: approximately 1/2 cup; number of servings per container: 10) or (2) declare the serving size in the exact household measure and the approximate number of servings per container (e.g., serving size: 1/2 cup; number of servings per container: approximately 10). In either case, FDA proposed to require that whole numbers of servings be used with the exception of random weight products. For random weight products, FDA proposed to use "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in oz.

179. Most comments supported the proposed requirements for the declaration of the number of servings per container. However, several comments objected to rounding the number of servings to the nearest whole number. The comments argued that rounding to the nearest whole number does not accurately account for the actual number of servings in a container and in many cases would significantly distort a container's contents, especially for packages containing between 1.5 to 4.5 servings. Some of the comments acknowledged that many consumers do not like fractional numbers of servings on the label but argued that this dislike results primarily from the use of odd decimal fractions (e.g., 2.7 servings) and from fractional numbers of servings on packages typically consumed in their entirety (e.g., 1.5 servings on a 12 fl oz can of soda). The comments stated that rounding to the nearest 0.5 servings would be understood by virtually all consumers. A few comments suggested that at the very best, FDA should permit rounding to the nearest half-serving for packages containing 4.5 servings or fewer.

FDA acknowledges that consumer objections to the fractional number of servings may be the result of the use of odd fractional numbers of servings and of their use on products typically consumed in their entirety. The agency agrees that, for packages containing 4.5 servings or less, the number of servings in 0.5-increments would reflect more closely the number of servings in the container. For larger containers, the 0.5 serving difference between the next lower or next higher whole number is a smaller relative percentage of the total number of servings in the package and, therefore, reflects an unrealistic and meaningless precision (e.g., 8.5 servings or 28.5 servings) because the number of servings are approximations. For this reason, FDA has revised § 101.9(b)(8) to allow fractional servings on packages containing between 2 and 5 servings. This procedure would reduce the errors in the number of servings per container to a maximum of about 12 percent (2.24 servings rounded to 2 servings) or less.

179a. Several comments addressed the two options proposed in § 101.9(b)(8) for declaring the number of servings per container. A comment from a trade association stated that the two options would provide manufacturers flexibility in deciding the number of servings per container appropriate to their food products and providing the consumer with the most useful serving size information. Other comments from industry, consumers, and consumer organizations expressed concern about providing an option. They stated that allowing the two options would result in different serving sizes (and thus different nutrition information) for different brands of the same food, making nutrition comparisons of different brands difficult. One consumer organization contended that it is more important for consumers, especially those on medically-prescribed diets, to know the exact serving size that is the basis for the nutrition information than the exact number of servings. These latter comments recommended that FDA require manufacturers to list the exact serving size and an approximate number of servings per container.

Although the two options would provide flexibility to manufacturers, FDA recognizes that it would result in nonuniformity in serving sizes of different brands of the same food. The agency also agrees with the latter comments that it is more important to have the exact serving size than the exact number of servings. Many comments on the 1991 serving size proposal stated that the serving size regulation should facilitate nutrition comparisons of different brands. Therefore, FDA has revised § 101.9(b)(8) to require the exact serving size and the approximate number of servings.

180. Most comments approved of permitting the "varied" declaration for the number of servings on random weight products. However, one comment from a consumer organization expressed concern. The comment argued that the "varied" declaration is unnecessary because random weight products, such as cheese, are usually priced per pound, and the retailer or manufacturer must weigh a package of cheese to determine the price. The comment contended that once the weight has been measured, the servings per container can be easily calculated.

FDA agrees that random weight products are usually priced by weight, and that the retailer or manufacturer must weigh the product first to price it. However, because these products vary widely in weight, it would be difficult for retailers and manufacturers to have labels printed with the number of servings per container unless they have automated label machines that print the number of servings as they print the weight. Therefore, it would be unreasonable to require all retailers and manufacturers to include the number of servings on random weight products. Accordingly, FDA is retaining the "varied" declaration for the number of servings on random weight products. However, the agency encourages the retailers and manufacturers to label the number of servings per container if they have automated machines or some means to provide the information.

181. A few comments suggested that FDA permit an optional declaration of "typical number of servings" with the term "varied" on random weight packages. The comments contended that an approximate number of servings per container could help consumers determine the approximate number of servings contained in the package.

FDA agrees with the comment. Accordingly, FDA has revised § 101.9(b)(8) to allow voluntary labeling of the "typical number of servings" when "varied" is used to declare the number of servings per container, e.g., "varied (usually 5 servings)" or "varied (usually 4 to 6 servings)." The agency encourages manufacturers to provide the typical number of servings whenever feasible.

182. Several comments from the pickle industry stated that the size and shape of the vegetables used to make pickles vary widely as a result of numerous factors, including the variety, weather conditions, and maturation when harvested. The comment contended that pickles are random weight products and should be allowed to use "varied" for the number of servings per container.

FDA disagrees with the comments. Products that contain individual units in the container that vary in size, such as pickles, are not random weight products because the net quantity of the container size remains constant. Random weight products are those products that are sold in units whose net quantity of contents is random, e.g., cheese. In the case of random weight cheese, the number of servings is difficult to estimate because the net quantity of content vary widely from package to package of the same product. Because the container size of pickles (and thus the net quantity of contents) is constant, pickle manufacturers, unlike cheese manufacturers, can have a label printed for each size of the container. Therefore, FDA is not allowing a "varied" declaration on pickles.

However, because the serving size for pickles will be based on the drained solids, the net quantity of the drained solids in the same size container may vary somewhat because of the variation in the size and shape of pickles. Consequently, the number of servings per container may vary somewhat for different containers of the same size. Therefore, FDA has revised § 101.9(b)(8) to allow declaration of the typical number of servings per container (e.g., usually 5 servings) for canned products that naturally vary in unit size, and the serving size is required to be expressed on the drained solids basis (e.g., pickles).

183. A few comments from the produce industry requested that FDA clarify in the serving size regulation that raw fruits and vegetables are exempt from declaring the number of servings per container.

FDA advises that raw fruit, vegetables, and fish are exempt from mandatory nutrition labeling requirements under new § 101.9(j)(10) (see document entitled "Food Labeling; Mandatory Status of Nutrition Labeling and Nutrient Content Revision" published elsewhere in this issue of the Federal Register). These foods are subject to the guidelines of the voluntary nutrition labeling program in § 101.45. Section 101.45(b)(3) states that the number of servings per container need not be included in nutrition labeling of raw fruit, vegetables, and fish. Accordingly, there is no need to cover this exemption in new § 101.9(b).

184. A manufacturer requested that FDA confirm in a preamble statement to the final rule that the product of the number of servings multiplied by the parenthetical metric equivalent of the serving size is not expected to precisely equal the net quantity of the product declared on the principal display panel.

FDA concurs with the comment's statement. It is true for two reasons: (1) An oz is defined differently for the net quantity of content regulation than for the serving size regulation, and (2) the number of servings are usually an approximate number. One oz is defined as 28.3452 g for the determination of the net quantity of contents (Ref. 39) and 28 g for the purpose of labeling serving size.

H. Other Related Issues

1. "As packaged" versus "as consumed" as the basis for the nutrition information

In § 101.9(b)(9) of the 1991 serving size proposal, FDA proposed that the declaration of nutrient content information shall be on the basis of food as packaged or purchased with the exception of those products that were specifically excluded. Additionally, FDA encouraged manufacturers to voluntarily provide the nutrient content of their products on an as consumed basis using package directions for preparation (56 FR 60394 at 60413).

185. Several comments supported the proposed rule. A health professional organization strongly opposed nutrition labeling on an as prepared (i.e., as consumed) basis because nutrition information should reflect the content of food in the package that consumers are selecting and purchasing. A consumer comment stated that all nutrition information should be based on food as packaged. Anything beyond that becomes the consumer's responsibility.

Many other comments objected to the proposal for basing the nutrition information of the products that require further preparation before consumption (e.g., dry mixes) on an as packaged basis. The comments requested that FDA require that nutrition information on these products be provided on an as consumed basis. The comments contended that because these products cannot be eaten in the form packaged and often require adding additional

ingredients, nutrition information on an as packaged basis is not meaningful to consumers. Some comments argued that nutrition information on an as packaged basis does not allow consumers to make informed comparisons between similar products in different forms (prepared and dry) and provides no incentive for manufacturers to develop preparation directions in support of current dietary recommendations. A manufacturer argued that the nutrition information on an as packaged basis for products that require the addition of other ingredients often underestimates the nutritional contribution of the product in the total daily diet because it does not include the nutrient contribution of other ingredients added in the preparation for consumption. The comment contended that in these cases, as packaged information violates the 1990 amendments that require the nutrition information to be conveyed in a manner which enables the public to understand its relative significance in the context of a total daily diet.

Some comments from the popcorn industry objected to nutrition labeling on an as packaged basis because: (1) Popcorn is inedible as packaged, and (2) some of the fat that is added to microwave popcorn to facilitate popping sticks to the bag after popping and is therefore not consumed. Nutrition labeling on an "as packaged" basis would, therefore, overstate the fat content as consumed.

Several comments also asserted that the qualification of a product for nutrient content claims should be based on the product "as prepared." Comments stated that nutrient content claims based on the product as packaged could be misleading on those products that, when prepared according to package directions, would not meet the criteria for the claim on an "as prepared" basis.

Other comments suggested that products that require the addition of ingredients, such as dry cake mixes, should list nutrition information on both an "as packaged" and an "as prepared" basis. The comments contended that if they did not, labels that list the fat and sodium contents as "0" (zero) would lead consumers to believe that these products are fat free or sodium free when eaten, even though fat and salt must be added according to the preparation directions.

FDA does not agree with the comments that suggested that FDA should require nutrition information on an "as prepared" basis. The agency has found that it cannot regulate products as effectively on an "as prepared" basis. For example, many products that require further preparation before consumption require the addition of ingredients. The nutrient content of a particular ingredient may vary from brand to brand (e.g., different brands of butter may vary in sodium content; different brands of fats and oils may vary in saturated fatty acid content). In addition, manufacturers often provide multiple directions for preparation (e.g., using different types of fats, several directions for preparing different foods such as pancakes, waffles, and biscuits). There may be no obvious or rational basis for the agency to determine which set of directions should be used to check the accuracy of the nutrition information. Furthermore, a product may be used by consumers in many different ways, and the agency has no control over how a product is used after purchase.

However, FDA recognizes that it would be helpful to make comparisons of foods in their prepared state (e.g., prepared package salad dressing and bottled salad dressing). Therefore, for the benefit of the consumers who follow the package directions in preparing these products, the agency continues to encourage manufacturers to voluntarily provide nutrient information on their products on an as prepared basis, using the package directions in preparing the food, and, in the case of multiple directions, using the directions that represent the major usage of the product. The agency agrees that such voluntary information may provide an incentive for manufacturers to develop methods of preparation that support dietary recommendations.

The agency disagrees with the comment that "as packaged" nutrition information violates the 1990 amendments because the "as packaged" information underestimates the nutritional contribution of the product to the total daily diet. Section 403(q)(1) of the act states that nutrition information is to be provided on "a food intended for human consumption and is offered *for sale* * * *" (emphasis added). Thus, the manufacturer has the responsibility to provide nutrition information on the product as offered for sale. Once the product is purchased and other ingredients are added, the packaged product becomes a different product. Therefore, the contribution of a product to a total daily diet must be evaluated in terms of the nutrient content of the product in the package as sold.

With regard to the comments about the nutrition labeling of unpopped popcorn, the agency notes that popcorn is no different than other foods that require further preparation before consumption (e.g., cake mixes, pancake mixes) and that are required to provide nutrition information on an as packaged basis. Therefore, no special provision is needed for unpopped popcorn. The agency notes, however, that § 101.9(b)(10)(iii) permits a second column on nutrition information on popcorn products in multiserving containers on a per cup popped basis.

As for the fat in microwave popcorn, the agency notes that the amount of fat that is retained with the popcorn may vary depending on the popping conditions and equipment used. Therefore, the agency cannot monitor compliance on an as consumed basis.

In regard to comments that nutrient content claims should be based on the product "as prepared," FDA notes that it did not address this issue in either the 1991 serving size proposal or the proposal entitled "Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (56 FR 60421, November 27, 1991). The agency does not believe that the 1990 amendments contemplated regulation of claims on products as prepared by the consumer. Section 403(r) of the act focuses on claims for nutrients in the food that is offered for sale. Moreover, regulation on an "as prepared" basis would raise significant compliance problems. However, the agency does agree that a nutrient content claim could be misleading if directions for use of the packaged product specify the addition of ingredients that would result in the finished edible product no longer meeting the criteria for the claim. If FDA finds that a problem exists in the marketplace after implementation of these final rules, the agency will consider further rulemaking under section 403(a) of the act.

Likewise, FDA did not propose to require that a product that requires the addition of ingredients declare nutrition information on both an as purchased and an as prepared basis, and, as discussed previously, the agency does not believe that it is appropriate to do so.

186. Some comments stated that for products where water must be added before the product can be consumed (e.g., dry soup or noodle mixes), the nutrition information should be based on the rehydrated product.

FDA advises that water contains some minerals. In its final rule on the declaration of sodium content in nutrition labeling, the agency reviewed and discussed data on the sodium content of the U.S. water supplies (49 FR 15510 at 15524). The data showed that sodium ranged from less than 3 mg to approximately 52 mg per 6 fl oz.

However, to prevent the introduction of error in the analysis of a product for compliance purposes, the agency is denying this request.

187. A health professional organization recommended that for products where choice in the preparation method can markedly alter its nutritional content, nutrition information on the product as prepared should be provided through educational point of purchase materials or in places on the package other than the nutrition label.

FDA has no objections to the placement of nutrition information other than that required in the nutrition label on other places on the label or in labeling (such as point of purchase materials). However, the agency has no authority to require such information. Accordingly, no action is being taken on this comment.

2. Nutrition information on a drained solids basis

Food consumption data showed that the liquid in foods such as canned fish, canned maraschino cherries, pickled fruits, olives, and canned or pickled vegetables is not customarily consumed. Therefore, FDA proposed in § 101.9(b)(9) to require that the declaration of nutrient and food component content of such foods be based on the drained solids.

188. Comments from a food manufacturer and a trade association opposed the proposal for basing nutrition information on a drained solids basis for beans, potatoes, and vegetables canned in liquid. The comments contended that upon cooking starch and other nutrients are released into the packing medium. The comments argued that because the entire contents of the container is frequently consumed, information on a drained weight basis would be misleading. One comment submitted data from a marketing survey showing that a large percentage of people use the liquid.

FDA agrees with the comment that the marketing survey showed that a large percentage of people use the liquid and that the liquid also contains nutrients (Ref. 64). Accordingly, the agency has deleted canned beans, potatoes, and vegetables from the list of foods in new § 101.9(b)(9) that are exempted from the requirement for nutrition information on an "as packaged" basis and has modified footnote 6 for Table 2 in new § 101.12(b) to reflect this change. Canned beans, potatoes, and vegetables will, therefore, be required to provide nutrition information on an "as packaged" basis.

189. An industry comment stated that the liquid that is present in "Alaska" canned salmon is the natural juice that has cooked out of the fish during thermal processing, and no additional liquid is added to "Alaska" canned salmon. The comment, therefore, asserted that nutrition information for canned salmon should be on an "as packaged" basis.

FDA agrees with the comment that nutrition information on canned salmon to which liquid has not been added for canning should be based on an as packaged basis. Accordingly, the agency has revised the footnote to Table 2 in new § 101.12(b) so that canned salmon that is not in a liquid packing medium is required to be labeled on an "as packaged" basis. Canned salmon that is in a liquid packing medium is subject to being labeled on a drained weight basis. The revised footnote reads: "If packed or canned in liquid * * *."

3. Miscellaneous issues

190. A manufacturer requested that FDA install a toll-free telephone number regarding questions on the reference amounts.

FDA advises that budgetary constraints do not allow for the installation of a toll-free telephone number to assist manufacturers in any aspect of the implementation of these final rules. However, agency personnel will respond to the maximum extent possible to all written or telephone requests for assistance. In addition, the agency intends to prepare materials to assist manufacturers in implementing these regulations as well as the educational materials to assist consumers in understanding and using the new nutrition labels.

I. Listing of a Second Column of Values

1. Listing nutrient contents based on 100 g, 100 mL, 1 oz, or 1 fl oz

FDA proposed in § 101.9(b)(10) that another column of figures may be used to declare the nutrient and food component information on the basis of 100 g or 100 mL or of 1 oz or 1 fl oz of the food as packaged or purchased.

191. Most comments on this issue supported voluntary labeling of a second column of values on a uniform basis. These comments reasoned that the second column of values provides nutrition information on a uniform basis, which aids consumers in making nutrition comparisons of different products. Some comments that supported voluntary labeling of a second column of values stated that FDA should not provide two choices for the basis of the second column. Comments that addressed the choice for the basis of the second column preferred 100 g or 100 mL over 1 oz or 1 fl oz. These comments stated that nutrition information per 100 g (or mL): (1) May be useful for persons on a special diet for medical reasons, (2) may assist consumers in understanding the metric system, or (3) is the only presentation of nutrition information internationally understood. One international comment stated that nutrition information per 100 g should be mandatory, and the information per serving should be voluntary. Another international comment stated that nutrition information per 100 g or 100 mL should be allowed on European products. A domestic comment stated that the second column of values per 100 g or 100 mL should be mandatory.

Comments objecting to the use of a second column stated that: (1) The second column of values would be confusing to consumers or is too much information, thus contributing to label clutter, (2) consumers may not understand why this information is on the label or understand how this quantity differs from a typical serving size, (3) consumers may have little need to compare 100 g of mustard with 100 g of a 12 oz frozen dinner, or (4) it is not necessary to add a second column on a per 100 g or 100 mL basis for the reason of international harmonization because every country has its own unique label requirements. Comments argued that because of these vastly different requirements, it is virtually impossible to use U.S. labels internationally.

FDA has given careful consideration to all arguments for and against the second column of values presented in the comments. To facilitate comparison of the nutritional composition of different products, the agency agrees that it would be desirable to have a uniform basis for the second column. However, for consistency with USDA's regulation, the agency has decided to retain the two choices for the basis of the second column as proposed.

FDA disagrees with the comment that stated that the second column of values per 100 g or 100 mL should be mandatory. The 1990 amendments do not mandate such a requirement. Further, nutrition information per 100 g or 100 mL is not meaningful for many foods that are customarily consumed in small quantities (e.g., croutons, crackers, cream and cream substitutes, sugar, butter, margarine, oil, and condiments) and dry mixes (e.g., dry beverage mixes). Therefore, the agency has not adopted this recommendation.

FDA is not persuaded that the declaration of nutrition information in a second column on a per 100 g or 100 mL basis should be prohibited. The provision is voluntary; therefore, manufacturers who do not wish to present the second column of values are not required to provide it. However, the presence of the information could help to facilitate comparisons between types of foods. While one comment stated that there is little need to compare 100 g of foods which would not be used interchangeably (e.g., mustard and frozen dinner), FDA notes that facilitation of nutrition comparisons is intended for different products which are used interchangeably in the diet.

Considering the weight of the comments supporting the second column of values on a uniform basis, FDA believes that voluntary labeling of a second column of values is desirable. This information will enable those who desire the information to benefit from it. Additionally, in response to comments that said a second column would be confusing, FDA intends to follow publication of these final rules with consumer education activities about the new food labeling requirements. This education initiative will assist consumers in understanding the utility of a second column of values based on 100 g, 100 mL, 1 oz, or 1 fl oz and should minimize consumer confusion.

Therefore, FDA has retained § 101.9(b)(10) as proposed and redesignated as § 101.9(b)(10)(i).

2. Mandatory listing of nutrient contents for a use that differs in quantity by two-fold or greater from the use upon which the reference amount was based

FDA proposed in § 101.9(b)(11) that if a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer must provide a second column of nutrition information based on the amount customarily consumed for the promoted use in addition to the nutrition information per serving derived from the reference amount in § 101.12(b).

192. Two comments from consumer and nutrition professional organizations supported the proposal. One of the comments recommended that FDA also require dual columns of values on foods "that are consumed in two quantities that differ by two-fold or greater, as long as the alternative use occurs at least 25 percent of the time." To illustrate the point, the comment cited the use of liquid cream substitutes in coffee versus on cereal or fruit. On the other hand, a comment from a trade association argued that this approach is not required under the act and could severely hamper traditional marketing techniques and reduce the flow of helpful information to consumers. They further stated that such a requirement is simply unworkable, particularly for nondiscrete bulk products packaged in multiserving containers (e.g., flour, sugar, multipurpose baking mixes). Many manufacturers make recipes available to the consumer through labeling (e.g., recipe booklets) and advertising. Many of these recipes are for the use of modified substitutes in regular recipes, such as lower fat alternatives. Manufacturers may also promote multiple uses of their products, some of which may suggest the use of the quantity of the product by twofold or greater than the reference amount. In such circumstances, the manufacturer could not possibly label the amount customarily consumed for every promoted use. Under such a rule, manufacturers will be less likely to promote several types of legitimate uses for their products. The comment stated that FDA should not discourage the dissemination of information that consumers find useful and informative.

FDA disagrees that in addition to requiring dual columns for promoted uses, FDA should also require dual columns for alternative uses that occur at least 25 percent of the time. Many foods are used for more than one purpose, and it is not always possible for manufacturers to determine which uses constitute 25 percent or more of the total usage of the food and to continually monitor trends in usage with this kind of precision. Consequently, FDA is not requiring dual columns based on percentage of use of the food.

However, FDA does find that this situation must be addressed. Section 403(q) of the act defines a serving size to be an amount customarily consumed. In some cases, such as the example given in proposed § 101.9(b)(11) of cream substitutes, the reference amount for the product category in § 101.12(b) clearly does not represent the customarily consumed amount for the product's promoted use on breakfast cereal. Thus, a separate customarily consumed amount is needed for the promoted use according to the definition of the serving size under the act. In addition, the agency notes that under 403(a) of the act, the nutrition information based on the reference amount (1 tbsp.) for the liquid cream substitute example is misleading for its promoted use with breakfast cereals (1/2 cup). Therefore, FDA believes that it has legal authority under section 403(a) and (q) of the act to require dual columns of values based on the customarily consumed amount for each use.

Finally, FDA agrees with the comment that stated that it is unreasonable to require multiple columns of values for some nondiscrete bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes (e.g., mixes with multiple recipes) because the products are promoted generically and are listed in hundreds of recipes and requiring hundreds of columns would be impractical and impossible.

Accordingly, in regard to dual columns, in new § 101.9(b)(11), FDA has retained the requirement for dual labeling for products that are promoted for a use that differs by twofold or greater from the use upon which the reference amount is based. However, the agency has added a statement that specifically exempts certain foods from this requirement for dual labeling: nondiscrete bulk products used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils) or traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes.

193. A trade association objected to the use of advertising to determine whether a second column of nutrition information is required under § 101.9(b)(11).

The agency advises that it views advertising as evidence of how the manufacturer intends the product to be used. If, as discussed in the preceding comment, this use is significantly different than the use on which the reference amount is based, the provisions of new § 101.9(b)(11) are triggered. Accordingly, FDA is not making the suggested change.

J. Use of Serving Size to Evaluate Nutrient Content and Health Claims

FDA proposed in § 101.12(g) to require that the reference amount be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. However, the agency noted that label serving sizes often differ from the reference amounts. Thus, products that meet the criteria for a claim on a reference amount basis may not qualify on a serving size basis. For example, a soft drink that contains 30 mg of sodium per reference amount (240

mL) meets the criteria for a "very low sodium" claim (less than or equal to 35 mg per 8 fl oz (240 mL)). A 12-fl oz single-serving container of this soft drink, however, contains 50 mg of sodium and, therefore, would not qualify for the "very low sodium" claim. For these products, FDA proposed that both the reference amount and the label serving size be used to determine whether the product meets FDA criteria for a claim. The agency also discussed another option based solely on the reference amount plus a disclaimer and solicited comments on both options.

194. Many comments supported the proposal to base claims on both the reference amount and the label serving size. However, numerous comments from the food industry, nutrition professionals, Government, and consumers contended that claim evaluations for all products should be based solely on the reference amount. The comments argued that claims should reflect the true characteristics of the product, and that a product that qualifies for a claim should be able to bear the claim on all container sizes. According to these comments, using both the reference amount and the label serving size as criteria will result in a product that would be able to bear a claim for one container size but would not be able to bear the same claim for another. The comment stated that such inconsistency in the use of claims for the same product in different-sized containers would be confusing to consumers and should not be permitted. Some of these comments suggested that FDA's concern about the misleading claims could be alleviated by requiring a statement of the basis for the claim along with the claim on a product that meets the criteria only on the basis of the reference amount, e.g., "very low sodium, 35 mg or less per 8 fl oz."

As discussed in the 1991 serving size proposal (56 FR 60394 at 60412), there are advantages and disadvantages to both options. After careful consideration of the comments received and of the advantages and disadvantages of both options, FDA concludes that the most reasonable solution for this issue is to base claim evaluations on the reference amount and to require a disclaimer with the claim. FDA agrees with the comments that claims should reflect the true characteristics of a product, and those characteristics do not change if the product is packaged in a different size container. Thus, it is appropriate to use the standard established by FDA, the reference amount, as the basis for evaluating claims. However, FDA also recognizes that products packaged in containers that differ from the reference amount may contain an amount of the nutrient significantly different from the amount on which the claim is based (e.g., 50 mg of sodium in a 12-fl oz container that can claim "very low sodium" since it contains only 35 mg sodium per 8 fl oz). In order to not be misleading, FDA agrees with the comments suggesting that a disclaimer that includes a statement of the basis for the claim is appropriate on such products. The agency recognizes that consumers may not readily understand the significance of the disclaimer (i.e., that it is alerting them to the fact that the product does not meet the criteria for the claim on the basis of the label serving size). The agency intends to inform consumers about the meaning of various claims on product labels through nutrition education activities that will follow the publication of the final regulations for food labeling. Accordingly, FDA has revised § 101.12(g) to base the qualification for a claim on the reference amount and to require a disclaimer if the label serving size of a product differs from the reference amount, and the product does not qualify for the claim on the basis of the label serving size.

In presenting the disclaimer, manufacturers must state the reference amount as it appears in new § 101.12(b). The reference amount in metric measure should be followed, in parenthesis, by the equivalent household measure appropriate for the food. Many consumers have complained that they do not understand metric measures. The parenthetical household measure should help consumers to visualize the quantity on which the claim is based. For example, a 12-fl oz soft drink that meets the criteria for "very low sodium" per reference amount, but not per 12 fl oz, would state "very low sodium, 35 mg or less per 240 mL (8 fl oz)." A slice of bread that meets the criteria for "high in fiber" per reference amount, but not per slice, would state "high in fiber, 20 percent or more of the Recommended Daily Intake per 50 g (about 1 1/2 slices)."

Revised § 101.12(g) reads:

The reference amount set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b) followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl oz).

195. A few comments recommended that the determination as to whether a food qualifies to bear a nutrient content or health claim should be based only on the label serving size.

FDA disagrees with the comment. Basing claim evaluations only on the label serving size could encourage manipulation of serving sizes to qualify for claims. Therefore, FDA is not adopting this recommendation.

196. Other comments recommended using 1 oz as the basis for the claim evaluation. The comments contended that 1 oz is a simple criterion and provides a "level playing field" for all products making claims.

FDA believes that 1 oz is inappropriate to use for declaring nutrient content or for evaluating claims because it has no relation to the amount of food customarily consumed or a food's contribution to the total daily diet as required by the 1990 amendments and thus will result in misleading or meaningless claims. For example, on a 1 oz basis, foods that may qualify for a "high" claim on a per serving basis (e.g., "high calcium" on yogurt) may not be able to bear the claim, whereas foods that may not qualify for a "low" claim on a per serving basis (e.g., "low calorie" cake) may be able to bear the claim. Therefore, FDA is not adopting this recommendation.

K. Petition Process

FDA proposed in § 101.12(h) a set of requirements for filing a petition to establish or amend a reference amount.

Several comments from nutrition professional organizations and the industry supported the petition process. A major trade association stated that the system is necessary because of the changing consumption patterns of Americans and the everchanging nature of food products. The association further stated that it agrees with the type and amount of information proposed by FDA to be included in the petition. A few comments opposed or expressed a reservation on certain specific aspects of the petition process as described below.

197. FDA proposed in § 101.12(h)(11)(i) to provide that a petition to create a new subcategory of food with its own reference amount must include data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size

and the mean, median, and modal amounts consumed per eating occasion for the petitioned product and for the products in the parent category, excluding the petitioned product.

An industry comment objected to the requirement in proposed § 101.12(h)(11)(i) for data on other products in the category. The comment stated that this information is not necessary, and that the data requirement is so burdensome that a petition for a new subcategory is almost impossible.

FDA disagrees with the comment that the data requirement for other products in the parent category is not necessary. The consumption data for other products in the category are needed to compare with the consumption data for the petitioned product to ensure that the customarily consumed amounts of the two product groups differ enough to warrant a separate reference amount for the petitioned product. The consumption data for other products in the parent category serve as the reference standard against which the consumption data for the petitioned product can be compared. Without a reference standard, it can not be known whether the difference in the customarily consumed amount of the petitioned product and the reference amount for the parent category is real or the result of the methodological or procedural differences in the surveys used. Use of the data on the other products is analogous to using a control or a reference standard in a laboratory experiment to validate the value of a test article.

FDA also disagrees that the data requirement is so burdensome that a petition for a new subcategory is almost impossible. Available national food consumption data bases provide information needed to meet the data requirement in new § 101.12(h)(11)(i). Some comments on the 1991 serving size proposal presented evidence that a relatively inexpensive survey can be conducted to collect food consumption data under actual conditions of use when information is not available from data bases.

However, to avoid an overly stringent data requirement, paragraph (h)(11)(i) has been modified to reduce the amount of information that must be submitted. While the proposed provision required information "* * * for the petitioned product and for all products in the category, excluding the petitioned product * * *," the modified provision seeks only data "* * * for the petitioned product and for other products in the category, excluding the petitioned product * * *." Also, to correct an oversight, the agency has added standard deviation to the data requirement to read "* * * Data must include sample size; and the mean, standard deviation, median, and modal consumed amount * * *."

198. FDA proposed in § 101.12(h)(14) that as part of the petition submission, a statement must be included concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648). A consumer organization opposed the negotiated rulemaking in establishing a reference amount through a petition. The comment contended that the process is resource-intensive and will favor those organizations and companies that have the time and money to devote to such negotiations.

FDA believes that in certain circumstances, negotiated rulemaking may be a useful tool in developing new or amended reference amounts. The feasibility of convening an appropriate group of interested parties would be discussed by the petitioner; however, the decision on whether to convene a discussion session would be at FDA's discretion with full awareness of agency resources. FDA is convinced that it is frequently useful to provide a forum for open discussion of particularly contentious issues. All interested parties, including consumer organizations, would be invited to participate in any such negotiated rulemaking. Therefore, FDA has retained § 101.12(h)(14) as proposed.

199. One industry comment requested that a procedural method be established to modify, add, or expand a category or reference amount. Because of the length of time necessary for issuing and finalizing a proposal as a result of a petition, the comment stated that the proposed petition method is not optimal. The comment recommended that USDA and FDA investigate alternatives to the proposed petition process.

FDA believes that the petition process referred to in § 101.12(h) is the appropriate process to establish or amend a reference amount. Such a process is necessary because the reference amounts adopted by the agency have the force and effect of laws. However, new § 101.12(h) merely incorporates the citizen petition process in § 10.30. This petition process will ensure full participation of all interested parties. FDA recognizes that issuing and finalizing a proposal does take time. Therefore, the agency will do its best to expedite the petition for establishing or amending a reference amount so that the petitioner can properly label and market its product at the earliest date possible.

200. A trade association contended that manufacturers of the products with reference amounts in § 101.12(b) are at a competitive advantage over those manufacturers whose products are not included in § 101.12(b) because they do not have the burden or expense of petitioning for a reference amount. The comment argued that the petition process is unfair, and that it is the government's responsibility to provide a rational basis for determining serving sizes on all products. The comment further contended that in the absence of a meaningful reference amount for a product, a "small" business should be permitted to determine an appropriate reference amount or to delay nutrition labeling until FDA has completed its task.

FDA disagrees with the comment. To comply with the act, the agency has established reference amounts for virtually all foods in the current food supply that are regulated by FDA. The agency notes that the list of reference amounts in new § 101.12(b) is extensive and applicable to all products that belong to the generic description of the product category. Therefore, manufacturers should be able to find reference amounts for practically all products currently in the food supply.

The agency is aware that new products are continuously being introduced into the market. Because the product category description is generic, manufacturers should also be able to find the reference amounts in § 101.12(b) that are applicable to most of these new products. However, some new products may not fit in the product categories in § 101.12(b). Therefore, the agency has installed a petition process to establish or amend reference amounts to encompass new products that do not fit in any of the product categories in § 101.12(b) and any products in the current food supply that were not brought to FDA's attention in this rulemaking process. Although FDA recognizes that there is both time and money involved in the petition process, this process is necessary to keep the reference amounts in § 101.12(b) current.

The agency agrees that it has the authority to establish the reference amount. However, it is not FDA's responsibility to know every new food product that is introduced in the market. The agency points out that it is the manufacturer's responsibility to inform FDA if any products have not been covered by § 101.12(b) and to provide appropriate information to

establish or amend the reference amounts in § 101.12(b).

Lastly, the agency points out that "small" businesses as defined in § 101.9(j)(1) are exempt from nutrition labeling and thus, there is no need for concern about the petition process.

V. Other Affected Rules

The agency proposed to revise 21 CFR 101.8(a) to state that where nutrition information is required, and firms elect to place statements on product labels concerning the number of servings in a package in other locations in addition to the location where nutrition information is placed, such statements must be in the same terms as that used for nutrition information. FDA proposed this revision to prevent consumer confusion over serving size.

FDA received no comments on this provision. However, to correct a typographical error in the 1991 serving size proposal, the agency has modified § 101.8(a) to read: "* * * Such statement shall not be misleading in any particular * * *."

V. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the **Federal Register** of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

In its November 1991 nutrition labeling proposed rules, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**. Several comments on the nutrition labeling proposed rules suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste.

Based on its consideration of comments received, the agency has decided to allow additional time for companies to use up their old labels. Thus, the nutrition labeling final rules will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. Paperwork Reduction Act

In the **Federal Register** of February 14, 1992 (57 FR 5398), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60394) that provided, in part, for petitions regarding serving sizes. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

Based on its consideration of the written comments received in response to the aforementioned **Federal Register** documents and the oral presentations made at the public hearing on food labeling, FDA modified the serving size petition requirements from those that were proposed. Those modifications were discussed in detail earlier in this final rule. Accordingly, FDA has also revised its estimated annual collection of information burden.

This final rule contains collection of information requirements that are subject to review by OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). Therefore, in accordance with 5 CFR 1320, the title, description, and respondent descriptions of the collection of information requirements are shown below with an estimate of the annual collection of information burden. Included in the estimate is the amount of time for reviewing instructions, searching existing data sources, gathering necessary information, and completion and submission of petitions.

Title: 21 CFR 101.12—Food Labeling: Serving Sizes.

Description: This final rule provides the procedures and format for the submission of petitions to the agency. Section 101.12(h) describes the information needed by FDA to evaluate the need for the change or addition requested in the petition and to

determine the appropriate reference amount for the petitioned food if the change or addition is judged as needed. The information included in these petitions will be reviewed by the agency, and a decision will be made in accordance with the criteria specified in this final rule.

Description of Respondents: Persons and businesses, including small businesses.

Estimated Annual Reporting and Recordkeeping Burden:

Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Annual Burden Hours
101.12(h)	10	1	10	60	600
Total					600

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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2. Park, Youngmee K., memo to file, October 30, 1991.

3. USDA, "Developing the Food Guidance System for 'Better Eating for Better Health,' a Nutrition Course for Adults," Administrative Report No. 377, USDA, Hyattsville, MD, 1985 (A condensed version published by Cronin, F. J., A. M., Shaw, S. M., Krebs-Smith, P. M., Marsland, and L., Light, "Developing a Food Guidance System to Implement the Dietary Guidelines," *Journal of Nutrition Education*, 19:281–302, 1987).

4. USDA, "Good Sources of Nutrients," Administrative Report No. 371, USDA, Hyattsville, MD, 1989.

5. American Diabetes Association, Inc. and American Dietetic Association, "Exchange Lists for Meal Planning," American Diabetes Association, Alexandria, VA, 1989.

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8. USDA and DHHS, "Nutrition and Your Health: Dietary Guidelines for Americans," 3 ed., U.S. Government Printing Office, Washington, DC, 1990.

9. Dennis, D. Adele, memorandum of meeting, October 5, 1990.

10. Thompson, Susan, memorandum of meeting, October 15, 1990.

11. Stephenson, Marilyn G., memorandum of meeting, October 23, 1990.

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14. Johnson, Carl B., memorandum of meeting, March 13, 1991.

15. Stephenson, Marilyn G., memorandum of meeting, April 12, 1991.

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22. USDA, Nationwide Food Consumption Survey/Individual—Summer Quarter 1977–1978, accession no. PB80–197429/HAE, National Technical Information Service, Springfield, VA, 1980.

23. USDA, Nationwide Food Consumption Survey/Individual—Fall Quarter 1977–1978, accession no. PB80–200223/HAE, National Technical Information Service, Springfield, VA, 1980.

24. USDA, Nationwide Food Consumption Survey/Individual—Winter Quarter 1977–1978, accession no. PB81–118853/HAE, National Technical Information Service, Springfield, VA, 1981.

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26. Life Sciences Research Office, "Impact of Nonresponse on Dietary Data from the 1987–1988 Nationwide Food Consumption Survey," Federation of American Societies for Experimental Biology, Bethesda, MD, 1991.

27. United States General Accounting Office, "Nutrition Monitoring, Mismanagement of Nutrition Survey Has Resulted in Questionable Data," GAO/RCED–91–117, Washington, DC, 1991.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.8 is amended by revising paragraph (a) to read as follows:

§ 101.8 Labeling of food with number of servings.

(a) The label of any package of a food that bears a representation as to the number of servings contained in such package shall bear in immediate conjunction with such statement, and in the same size type as is used for such statement, a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving; however, such statement may be expressed in terms that differ from the terms used in the required statement of net quantity of contents (for example cups, tablespoons) when such differing term is common to cookery and describes a constant quantity. Such statement shall not be misleading in any particular. Where nutrition labeling information is required in accordance with the provisions of § 101.9, however, the statement of the net quantity of each serving shall be consistent with the requirements for serving size expression set forth in that section (e.g., 10 1-cup (240 milliliters) servings). A statement of the number of units in a package is not in itself a statement of the number of servings.

* * * * *

3. Section 101.9 is amended by revising paragraph (b) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(b) Except as provided in § 101.9(h)(3), all nutrient and food component quantities shall be declared in relation to a serving as defined in this section.

(1) The term "serving" or "serving size" means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food. When the food is specially formulated or processed for use by infants or by toddlers, a serving or serving size means an amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively.

(2) Except as provided in paragraphs (b)(3), (b)(4), and (b)(6) of this section and for products that are intended for weight control and are available only through a weight-control or weight-maintenance program, serving size declared on a product label shall be determined from the "Reference Amounts Customarily Consumed Per Eating Occasion" (reference amounts) that appear in § 101.12(b) using the procedures described below. For products that are both intended for weight control and available only through a weight-control program, a manufacturer may determine the serving size that is consistent with the meal plan of the program. Such products must bear a statement, "for sale only through the ———— program" (fill in the blank with the name of the appropriate weight control program, e.g., Smith's Weight Control), on the principal display panel. However, the reference amounts in § 101.12(b) shall be used for purposes of evaluating whether weight-control products that are available only through a weight-control program qualify for nutrient content claims or health claims.

(i) For products in discrete units (e.g., muffins, sliced products such as sliced bread, apples, or individually packaged products within a multiserving package), except for products that naturally vary in size such as maraschino cherries, pickles, shellfish, whole fish, and fillet of fish, serving size shall be the number of whole units that most closely approximates the reference amount for the product category. If a unit weighs 67 percent or more, but less than 200 percent of the reference amount, the serving size shall be one unit. If a unit weighs more than 50 percent but less than 67 percent of the reference amount, the manufacturer may declare one unit as one serving. If a unit weighs 200 percent or more of the reference amount, the manufacturer may declare the whole unit as one serving if the whole unit can reasonably be consumed at a single-eating occasion. Serving size for maraschino cherries shall be expressed as 1 cherry with the parenthetical metric measure equal to the average weight of a medium size cherry. Serving size for other products that naturally vary in size shall be expressed in the amount in oz that most closely approximates the reference amount for the product category. Manufacturers shall adhere to the requirements in paragraph (b)(5) of this section for expressing the serving size in oz.

(ii) For products in large discrete units that are usually divided for consumption (e.g., cake, pie, pizza, melon, cabbage), the serving size shall be the fractional slice of the food (e.g., 1/12 cake, 1/8 pie, 1/4 pizza, 1/4 melon, 1/6 cabbage) that most closely approximates the reference amount for the product category. In expressing the fractional slice, manufacturers shall use 1/2, 1/3, 1/4, 1/5, 1/6, or smaller fractions that can be generated by further division by 2 or 3.

(iii) For nondiscrete bulk products (e.g., breakfast cereal, flour, sugar, dry mixes, concentrates), serving size shall be the amount in household measure that most closely approximates the reference amount for the product category.

(3) The serving size for meal products and main dish products as defined in § 101.13(l) and (m) of this chapter that come in single-serving containers as defined in paragraph (b)(6) of this section shall be the entire content (edible portion only) of the package. Serving size for meal products and main dish products in multiserving containers shall be based on the reference amount applicable to the product in § 101.12(b) if the product is listed in § 101.12(b). Serving size for meal products and main dish products in multiserving containers that are not listed in § 101.12(b) shall be based on the reference amount according to § 101.12(f).

(4) A variety pack such as a package containing several varieties of single-serving units as defined in paragraph (b)(2)(i) of this section, and a product having two or more compartments with each compartment containing a different food, shall provide nutrition information for each variety or food per serving size that is derived from the reference amount in § 101.12(b) applicable for each variety or food and the procedures to convert the reference amount to serving size in paragraph (b)(2) of this section.

(5) For labeling purposes, the term "common household measure" or "common household unit" means cup, tablespoon, teaspoon, piece, slice, fraction (e.g., 1/4 pizza), ounce (oz), fluid ounce (fl oz), or other common household equipment used to package food products (e.g., jar, tray). In expressing serving size in household measures, the following rules shall be used:

(i) Cups, tablespoons, or teaspoons shall be used wherever possible and appropriate except for beverages. For beverages, a manufacturer may use fl oz. Cups shall be expressed in 1/4 or 1/3 cup increments, tablespoons in whole number of tablespoons for quantities less than 1/4 cup but greater than or equal to 1 tablespoon, and teaspoons in whole number of teaspoons for quantities less than 1 tablespoon but greater than or equal to 1 teaspoon and in 1/4 teaspoon increments for quantities less than 1 teaspoon.

(ii) If cups, tablespoons or teaspoons are not applicable, units such as piece, slice, tray, jar, and fraction shall be used.

(iii) If paragraphs (b)(5)(i) and (b)(5)(ii) of this section are not applicable, oz may be used with an appropriate visual unit of measure such as a dimension of a piece, e.g., 1 oz (28 g/about 1/2 pickle). Ounce measurements shall be expressed in 0.5 oz increments most closely approximating the reference amount, with rounding indicated by use of the term "about" (e.g., about 2.5 oz).

(iv) For nutrition labeling purposes, a teaspoon means 5 milliliters (mL); a tablespoon means 15 mL; a cup means 240 mL; 1 fluid ounce (fl oz) means 30 mL; and 1 oz in weight means 28 g.

(v) When a serving size, determined from the reference amount in § 101.12(b) and the procedures described in this section, falls exactly half way between two serving sizes, e.g., 2.5 tbsp, manufacturers shall round the serving size up to the next incremental size.

(6) A product that is packaged and sold individually and that contains less than 200 percent of the applicable reference amount shall be considered to be a single-serving container, and the entire content of the product shall be labeled as one serving except for products that have reference amounts of 100 g (or mL) or larger, manufacturers may decide whether a package that contains more than 150 percent but less than 200 percent of the reference amount is 1 or 2 servings. Packages sold individually that contain 200 percent or more of the applicable reference amount may be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.

(7) A label statement regarding a serving shall be the serving size expressed in common household measures as set forth in paragraphs (b)(2) through (b)(6) of this section and shall be followed by the equivalent metric quantity in parenthesis (fluids in mL and all other foods in g) except for single-serving containers. For a single-serving container, the parenthetical metric quantity, which will be presented as part of the net weight statement on the principal display panel, is not required except where nutrition information is required on a drained weight basis according to § 101.9(b)(9). The g quantity equivalent to the household measure should be rounded to the nearest whole number except for quantities that are less than 5 g. The g quantity between 2 and 5 g should be rounded to the nearest 0.5 g and the g quantity less than 2 g should be expressed in 0.1-g increments. In addition, serving size may be declared in oz and fl oz, in parenthesis, following the metric measure separated by a slash where other common household measures are used as the primary unit for serving size, e.g., 1 slice (28 g/1 oz) for sliced bread. The oz quantity equivalent to the metric quantity should be expressed in 0.1 oz increments. If a manufacturer elects to use abbreviations for units, the following abbreviations shall be used: tbsp for tablespoon, tsp for teaspoon, g for gram, mL for milliliter, oz for ounce, and fl oz for fluid ounce. To promote uniformity in label serving sizes in household measures declared by different manufacturers, FDA has provided Guidelines for Determining the Gram Weight of the Household Measure. The guidelines can be obtained from Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

(8) Determination of the number of servings per container shall be based on the serving size of the product determined by following the procedures described in this section. The number of servings shall be rounded to the nearest whole number except for the number of servings between 2 and 5 servings and random weight products. The number of servings between 2 and 5 servings shall be rounded to the nearest 0.5 serving. Rounding should be indicated by the use of the term "about" (e.g., about 2 servings, about 3.5 servings). When the serving size is required to be expressed on a drained solids basis and the number of servings vary because of a natural variation in unit size (e.g., maraschino cherries, pickles), the manufacturer may state the typical number of servings per container (e.g., usually 5 servings). For random weight products, a manufacturer may declare "varied" for the number of servings per container provided the nutrition information is based on the reference amount expressed in oz. The manufacturer may provide the typical number of servings in parenthesis following the "varied" statement.

(9) The declaration of nutrient and food component content shall be on the basis of food as packaged or purchased with the exception of raw fish covered under § 101.42 (see § 101.44), packaged

single-ingredient products that consist of fish or game meat as provided for in paragraph (j)(11) of this section, and of foods that are packed or canned in water, brine, or oil but whose liquid packing medium is not customarily consumed (e.g., canned fish, maraschino cherries, pickled fruits, and pickled vegetables). Declaration of nutrient and food component content of raw fish shall follow the provisions in § 101.45. Declaration of nutrient and food component content of foods that are packed in liquid but the liquid packing medium is not customarily consumed, shall be based on the drained solids.

(10) Another column of figures may be used to declare the nutrient and food component information,

(i) Per 100 g or 100 mL or per 1 oz or 1 fl oz of the food as packaged or purchased.

(ii) Per one unit if the serving size of a product in discrete units in a multiserving container is more than one unit.

(iii) Per cup popped for popcorn in a multiserving container.

(11) If a product is promoted on the label, labeling, or advertising for a use that differs in quantity by twofold or greater from the use upon which the reference amount in § 101.12(b) was based (e.g., liquid cream substitutes promoted for use with breakfast cereals), the manufacturer shall provide a second column of nutrition information based on the amount customarily consumed in the promoted use, in addition to the nutrition information per serving derived from the reference amount in § 101.12(b), except that nondiscrete bulk products that are used primarily as ingredients (e.g., flour, sweeteners, shortenings, oils), or traditionally used for multipurposes (e.g., eggs, butter, margarine), and multipurpose baking mixes are exempt from this requirement.

* * * * *

4. Section 101.12 is added to subpart A to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

(a) The general principles and factors that the Food and Drug Administration (FDA) considered in arriving at the reference amounts customarily consumed per eating occasion (reference amounts) which are set forth in paragraph (b) of this section, are that:

(1) FDA calculated the reference amounts for persons 4 years of age or older to reflect the amount of food customarily consumed per eating occasion by persons in this population group. These reference amounts are based on data set forth in appropriate national food consumption surveys.

(2) FDA calculated the reference amounts for an infant or child under 4 years of age to reflect the amount of food customarily consumed per eating occasion by infants up to 12 months of age or by children 1 through 3 years of age, respectively. These reference amounts are based on data set forth in appropriate national food consumption surveys. Such reference amounts are to be used only when the food is specially formulated or processed for use by an infant or by a child under 4 years of age.

(3) An appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use.

(4) To determine the amount of food customarily consumed per eating occasion, FDA considered the mean, median, and mode of the consumed amount per eating occasion.

(5) When survey data were insufficient, FDA took various other sources of information on serving sizes of food into consideration. These other sources of information included:

(i) Serving sizes used in dietary guidance recommendations or recommended by other authoritative systems or organizations;

(ii) Serving sizes recommended in comments;

(iii) Serving sizes used by manufacturers and grocers; and

(iv) Serving sizes used by other countries.

(6) Because they reflect the amount customarily consumed, the reference amount and, in turn, the serving size declared on the product label are based on only the edible portion of food, and not bone, seed, shell, or other inedible components.

(7) The reference amount is based on the major intended use of the food (e.g., milk as a beverage and not as an addition to cereal).

(8) The reference amounts for products that are consumed as an ingredient of other foods, but that may also be consumed in the form in which they are purchased (e.g., butter), are based on use in the form purchased.

(9) FDA sought to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount.

(b) The following reference amounts shall be used as the basis for determining serving sizes for specific products:

TABLE 1

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: INFANT AND TODDLER FOODS[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Cereals, dry instant	15 g	1/3 cup (13 g)
Cereals, prepared, ready-to-serve	110 g	——— cup(s) (——— g)
Other cereal and grain products, dry ready-to-eat, e.g., ready-to-eat cereals, cookies, teething biscuits, and toasts.	7 g for infants and 20 g for toddlers for ready-to-eat cereals; 7 g for all others.	——— cup(s) (——— g) for ready-to-eat cereals; ——— piece(s) (——— g) for others
Dinners, desserts, fruits, vegetables or soups, dry mix	15 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, junior type.	110 g	——— cup(s) (——— g)
Dinners, desserts, fruits, vegetables or soups, ready-to-serve, strained type.	60 g	——— cup(s) (——— g)
Dinners, stews or soups for toddlers, ready-to-serve	170 g	——— cup(s) (——— g)
Fruits for toddlers, ready-to-serve	125 g	——— cup(s) (——— g)
Vegetables for toddlers, ready-to- serve	70 g	——— cup(s) (——— g)
Eggs/egg yolks, ready-to-serve	55 g	——— cup(s) (——— g)
Juices, all varieties	120 mL	4 fl oz (120 mL)

[1] These values represent the amount of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.
[2] Unless otherwise noted in the Reference amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry cereal) is the amount required to make one reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).
[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).
[4] Copies of the list of products for each product category are available from the Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.
[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

TABLE 2

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Bakery Products:		
Biscuits, croissants, bagels, tortillas, soft bread sticks, soft pretzels, corn bread, hush puppies.	55 g	——— piece(s) (——— g)
Breads (excluding sweet quick type), rolls	50 g	——— piece(s) (——— g) for sliced bread and distinct pieces (e.g., rolls); 2 oz (56 g/——— inch slice) for unsliced bread
Bread sticks—see crackers		
Toaster pastries—see coffee cakes		
Brownies	40 g	——— piece(s) (——— g) for distinct pieces; fractional slice (——— g) for bulk
Cakes, heavy weight (cheese cake; pineapple upside-down cake; fruit, nut, and vegetable cakes with more than or equal to 35 percent of the finished weight as fruit, nuts, or vegetables)[6].	125 g	——— piece(s) (——— g) for distinct pieces (e.g., sliced or individually packaged products); ——— fractional slice (——— g) for large discrete units
Cakes, medium weight (chemically leavened cake with or without icing or filling except those classified as light weight cake; fruit, nut, and vegetable cake with less than 35 percent of the finished weight as fruit, nuts, or vegetables; light weight cake with icing; Boston cream pie; cupcake; eclair; cream puff)[7].	80 g	——— piece(s) (——— g) for distinct pieces (e.g., cupcake); ——— fractional slice (——— g) for large discrete units
Cakes, light weight (angel food, chiffon, or sponge cake without icing or filling)[8].	55 g	——— piece(s) (——— g) for distinct pieces (e.g., sliced or individually packaged products); ——— fractional slice (——— g) for large discrete units
Coffee cakes, crumb cakes, doughnuts, Danish, sweet rolls, sweet quick type breads, muffins, toaster pastries.	55 g	——— piece(s) (——— g) for sliced bread and distinct pieces (e.g., doughnut); 2 oz (56 g/visual unit of measure) for bulk products (e.g., unsliced bread)
Cookies	30 g	——— piece(s) (——— g)
Crackers that are usually not used as snack, melba toast, hard bread sticks, ice cream cones[9].	15 g	——— piece(s) (——— g)
Crackers that are usually used as snacks	30 g	——— piece(s) (——— g)
Croutons	7 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g); ——— piece(s) (——— g) for large pieces
French toast, pancakes, variety mixes	110 g prepared for french toast and pancakes; 40 g dry mix for variety mixes.	——— piece(s) (——— g); ——— cup(s) (——— g) for dry mix
Grain-based bars with or without filling or coating, e.g., breakfast bars, granola bars, rice cereal bars.	40 g	——— piece(s) (——— g)

Ice cream cones—see crackers		
Pies, cobblers, fruit crisps, turnovers, other pastries	125 g	——— piece(s) (———g) for distinct pieces; ——— fractional slice (——— g) for large discrete units
Pie crust	1/6 of 8 inch crust; 1/8 of 9 inch crust	1/6 of 8 inch crust (——— g); 1/8 of 9 inch crust (——— g)
Pizza crust	55 g	——— fractional slice (——— g)
Taco shells, hard	30 g	——— shell(s) (——— g)
Waffles	85 g	——— piece(s) (——— g)
Beverages:		
Carbonated and noncarbonated beverages, wine coolers, water	240 mL	8 fl oz (240 mL)
Coffee or tea, flavored and sweetened	240 mL prepared	8 fl oz (240 mL)
Cereals and Other Grain Products:		
Breakfast cereals (hot cereal type), hominy grits	1 cup prepared; 40 g plain dry cereal; 55 g flavored, sweetened cereal	——— cup(s) (——— g)
Breakfast cereals, ready-to-eat, weighing less than 20 g per cup, e.g., plain puffed cereal grains.	15 g	——— cup(s) (——— g)
Breakfast cereals, ready-to-eat weighing 20 g or more but less than 43 g per cup; high fiber cereals containing 28 g or more of fiber per 100 g.	30 g	——— cup(s) (——— g)
Breakfast cereals, ready-to-eat, weighing 43 g or more per cup; biscuit types.	55 g	——— piece(s) (——— g) for large distinct pieces (e.g., biscuit type);——— cup(s) (——— g) for all others
Bran or wheat germ	15 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g)
Flours or cornmeal	30 g	——— tbsp(s) (——— g) or ——— cup(s) (——— g)
Grains, e.g., rice, barley, plain	140 g prepared; 45 g dry	——— cup(s) (——— g)
Pastas, plain	140 g prepared; 55 g dry	——— cup(s) (——— g); ——— piece(s) (——— g) for large pieces (e.g., large shell) or 2 oz (56 g/visual unit of measure) for dry bulk products (e.g., lasagna or spaghetti noodles)
Pastas, dry, ready-to-eat, e.g., fried canned chow mein noodles	25 g	——— cup(s) (——— g)
Starches, e.g., cornstarch, potato starch, tapioca, etc.	10 g	1 tbsp (8 g) for cornstarch; 1 tbsp (10 g) for tapioca; 1 tbsp (——— g) for others
Stuffing	100 g	——— cup(s) (——— g)
Dairy Products and Substitutes:		
Cheese, cottage	110 g	1/2 cup (105 g) for small curd; 1/2 cup (113 g) for large curd, low fat, or with fruit added; 1/2 cup (——— g) for others
Cheese used primarily as ingredients, e.g., dry cottage cheese, ricotta cheese.	55 g	1/3 cup (48 g) for dry curd cottage cheese; 1/4 cup (62 g) for ricotta cheese
Cheese, grated hard, e.g., Parmesan, Romano	5 g	1 tbsp(s) (5 g)
Cheese, all others except those listed as separate categories—includes cream cheese and cheese spread.	30 g	——— piece(s) (——— g) for distinct pieces;——— tbsp(s) (——— g) for cream cheese and cheese spread; 1 oz (28 g/visual unit of measure) for bulk
Cheese sauce—see sauce category		
Cream or cream substitutes, fluid	15 mL	1 tbsp (15 mL)
Cream or cream substitutes, powder	2 g	1 tsp (2 g)
Cream, half & half	30 mL	2 tbsp (30 mL)
Eggnog	120 mL	1/2 cup (120 mL) or 4 fl oz (120 mL)
Milk, condensed, undiluted	30 mL	2 tbsp (30 mL)
Milk, evaporated, undiluted	30 mL	2 tbsp (30 mL)
Milk, milk-based drinks, e.g., instant breakfast, meal replacement, cocoa.	240 mL	1 cup (240 mL) or 8 fl oz (240 mL)
Shakes or shake substitutes, e.g., dairy shake mixes, fruit frost mixes	240 mL	1 cup (240 mL) or 8 fl oz (240 mL)
Sour cream	30 g	2 tbsp (30 g)
Yogurt	225 g	1 cup (——— g)
Desserts:		
Ice cream, ice milk, frozen yogurt, sherbet: all types, bulk and novelties (e.g., bars, sandwiches, cones).	1/2 cup-includes the volume for coatings and wafers for the novelty type varieties.	——— piece(s) (——— g) for individually wrapped or packaged products; 1/2 cup (——— g) for others
Frozen flavored and sweetened ice and pops, frozen fruit juices: all types, bulk and novelties (e.g., bars, cups).	85 g	——— piece(s) (——— g) for individually wrapped or packaged products; ——— cup(s) (——— g) for others
Sundae	1 cup	1 cup (——— g)
Custards, gelatin or pudding	1/2 cup	——— piece(s) (——— g) for distinct unit (e.g., individually packaged products); 1/2 cup (——— g) for bulk
Dessert Toppings and Fillings:		
Cake frostings or icings	35 g	——— tbsp(s) (——— g)
Other dessert toppings, e.g., fruits, syrups, spreads, marshmallow cream, nuts, dairy and nondairy whipped toppings.	2 tbsp	2 tbsp (——— g)
Pie fillings	85 g	——— cup(s) (——— g)
Egg and Egg Substitutes:		
Egg mixtures, e.g., egg foo young, scrambled eggs, omelets	110 g	——— piece(s) (——— g) for discrete pieces;——— cup(s) (——— g)

TABLE 2—Continued

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Eggs (all sizes)[9]	50 g	1 large, medium, etc. (——— g)
Egg substitutes	An amount to make 1 large (50 g) egg	——— cup(s) (——— g)
Fats and Oils:		
Butter, margarine, oil, shortening	1 tbsp	1 tbsp (14 g) for butter, margarine, or oil; 1 tbsp (9 g) for whipped butter or margarine; 1 tbsp (13 g) for shortening
Butter replacement, powder	2 g	——— tsp(s) (——— g)
Dressings for salads	30 g	2 tbsp (——— g)
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g	1 tbsp (14 g) for mayonnaise; 1 tbsp (15 g) for imitation mayonnaise, mayonnaise-type dressings or sandwich spread
Spray types	0.25 g	About ——— seconds spray (——— g)
Fish, Shellfish, Game Meats[10], and Meat or Poultry Substitutes:		
Bacon substitutes, canned anchovies,[11] anchovy pastes, caviar	15 g	——— piece(s) (——— g) for discrete pieces; ——— tbsp(s) (——— g) for others
Dried, e.g., jerky	30 g	——— piece(s) (——— g)
Entrees with sauce, e.g., fish with cream sauce, shrimp with lobster sauce.	140 g cooked	——— cup(s) (——— g); 5 oz (140 g/visual unit of measure) if not measurable by cup
Entrees without sauce, e.g., plain or fried fish and shellfish, fish and shellfish cake.	85 g cooked; 110 g uncooked[12]	——— piece(s) (——— g) for discrete pieces; ——— cup(s) (——— g); ——— oz (——— g/visual unit of measure) if not measurable by cup[13]
Fish, shellfish or game meat[10], canned[11]	55 g	——— piece(s) (——— g) for discrete pieces; ——— cup(s) (——— g)
Substitute for luncheon meat, meat spreads, Canadian bacon, sausages and frankfurters.	55 g	——— piece(s) (——— g) for distinct pieces (e.g., slices, links); ——— cup(s) (——— g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Smoked or pickled[11] fish, shellfish, or game meat[10]; fish or shellfish spread.	55 g	——— piece(s) (——— g) for distinct pieces (e.g., slices, links) or ——— cup(s) (——— g); 2 oz (56 g/visual unit of measure) for nondiscrete bulk product
Substitutes for bacon bits—see miscellaneous category		
Fruits and Fruit Juices:		
Candied or pickled[11]	30 g	——— piece(s) (——— g)
Dehydrated fruits—see snacks category		
Dried	40 g	——— piece(s) (——— g) for large pieces (e.g., dates, figs, prunes); ——— cup(s) (——— g) for small pieces (e.g., raisins)
Fruits for garnish or flavor, e.g., maraschino cherries[11]	4 g	1 cherry (——— g)
Fruit relishes, e.g., cranberry sauce, cranberry relish	70 g	——— cup(s) (——— g)
Fruits used primarily as ingredients, avocado	30 g	See footnote 13
Fruits used primarily as ingredients, others (cranberries, lemon, lime)	55 g	——— piece(s) (——— g) for large fruits; ——— cup(s) (——— g) for small fruits measurable by cup[13]
Watermelon	280 g	See footnote 13
All other fruits (except those listed as separate categories), fresh, canned, or frozen.	140 g	——— piece(s) (——— g) for large pieces (e.g., strawberries, prunes, apricots, etc.); ——— cup(s) (——— g) for small pieces (e.g., blueberries, raspberries, etc.)[13]
Juices, nectars, fruit drinks	240 mL	8 fl oz (240 mL)
Juices used as ingredients, e.g., lemon juice, lime juice	5 mL	1 tsp (5 mL)
Legumes:		
Bean cake (tofu)[11], tempeh	85 g	——— piece(s) (——— g) for discrete pieces; 3 oz (84 g/visual unit of measure) for bulk products
Beans, plain or in sauce	130 g for beans in sauce or canned in liquid; 90 g for others	1/2 cup (——— g)
Miscellaneous category:		
Baking powder, baking soda, pectin	1 g	1/4 tsp (——— g)
Baking decorations, e.g., colored sugars and sprinkles for cookies, cake decorations.	1/4 tsp or 4 g if not measurable by teaspoon	——— piece(s) (——— g) for discrete pieces;1/4 tsp (——— g)
Batter mixes, bread crumbs	30 g	——— tbsp(s) (——— g) or——— cup(s) (——— g)
Cooking wine	30 mL	2 tbsp (30 mL)
Drink mixers (without alcohol)	Amount to make 240 mL drink (without ice)	——— fl oz (——— mL)
Chewing gum[9]	3 g	——— piece(s) (——— g)
Meat, poultry and fish coating mixes, dry; seasoning mixes, dry, e.g., chili seasoning mixes, pasta salad seasoning mixes.	Amount to make one reference amount of final dish	——— tsp(s) (——— g) or ——— tbsp(s) (——— g)
Salad and potato toppers, e.g., salad crunchies, salad crispins, substitutes for bacon bits.	7 g	——— tbsp(s) (——— g)

Salt, salt substitutes, seasoning salts (e.g., garlic salt)	1 g	——— tsp(s) (——— g);——— piece(s) (——— g) for discrete pieces (e.g., individually packaged products)
Spices, herbs (other than dietary supplements)	1/4 tsp or 0.5 g if not measurable by teaspoon	1/4 tsp (——— g); ——— piece(s) (——— g) if not measurable by teaspoons (e.g., bay leaf)
Mixed Dishes:		
Measurable with cup, e.g., casseroles, hash, macaroni and cheese, pot pies, spaghetti with sauce, stews, etc..	1 cup.	1 cup (——— g)
Not measurable with cup, e.g., burritos, egg rolls, enchiladas, pizza, pizza rolls, quiche, all types of sandwiches.	140 g, add 55 g for products with gravy or sauce topping, e.g., enchilada with cheese sauce, crepe with white sauce[14].	——— piece(s) (——— g) for discrete pieces; ——— fractional slice (——— g) for large discrete units
Nuts and Seeds:		
Nuts, seeds, and mixtures, all types: sliced, chopped, slivered, and whole.	30 g	——— piece(s) (——— g) for large pieces (e.g., unshelled nuts);——— tbsp(s) (——— g) or——— cup(s) (——— g) for small pieces (e.g., peanuts, sunflower seeds)
Nut and seed butters, pastes, or creams	2 tbsp	2 tbsp (——— g)
Coconut, nut and seed flours	15 g	——— tbsp(s) (——— g)
Potatoes and Sweet Potatoes/Yams:		
French fries, hash browns, skins, or pancakes	70 g prepared; 85 g for frozen unprepared french fries	——— piece(s) (——— g) for large distinct pieces (e.g., patties, skins); 2.5 oz (70 g/——— pieces) for prepared fries; 3 oz (84 g/——— pieces) for unprepared fries
Mashed, candied, stuffed, or with sauce	140 g	——— piece(s) (——— g) for discrete pieces (e.g., stuffed potato); ——— cup(s) (——— g)
Plain, fresh, canned, or frozen	110 g for fresh or frozen; 160 g for canned in liquid	——— piece(s) (——— g) for discrete pieces;——— cup(s) (——— g) for sliced or chopped products
Salads:		
Gelatin Salad	120 g	1/2 cup (120 g)
Pasta or potato salad	140 g	——— cup(s) (——— g)
All other salads, e.g., egg, fish, shellfish, bean, fruit, or vegetable salads.	100 g	——— cup(s) (——— g)
Sauces, Dips, Gravies and Condiments:		
Barbecue sauce, hollandaise sauce, tartar sauce, other sauces for dipping (e.g., mustard sauce, sweet and sour sauce), all dips (e.g., bean dips, dairy-based dips, salsa).	2 tbsp	2 tbsp (——— g)
Major main entree sauces, e.g., spaghetti sauce	125 g	1/2 cup (——— g)
Minor main entree sauces (e.g., pizza sauce, pesto sauce), other sauces used as toppings (e.g., gravy, white sauce, cheese sauce), cocktail sauce.	1/4 cup	1/4 cup (——— g)
Major condiments, e.g., catsup, steak sauce, soy sauce, vinegar, teriyaki sauce, marinades.	1 tbsp	1 tbsp (——— g)
Minor condiments, e.g., horseradish, hot sauces, mustards, worcestershire sauce.	1 tsp	1 tsp (——— g)
Snacks:		
All varieties, chips, pretzels, popcorns, extruded snacks, fruit- based snacks (e.g., fruit chips,) grain-based snack mixes.	30 g	——— cup(s) (——— g) for small pieces (e.g., popcorn) ——— piece(s) (——— g) for large pieces (e.g., large pretzels; pressed dried fruit sheet); 1 oz (28 g/visual unit of measure) for bulk products (e.g., potato chips)
Soups:		
All varieties	245 g	1 cup (——— g)
Sugars and Sweets:		
Baking candies (e.g., chips)	15 g	——— piece(s) (——— g) for large pieces; ——— tbsp(s) (——— g) for small pieces; 1/2 oz (14 g/visual unit of measure) for bulk products
Hard candies, breath mints	2 g	——— piece(s) (——— g)
Hard candies, roll-type, mini-size in dispenser packages	5 g	——— piece(s) (——— g)
Hard candies, others	15 g	——— piece(s) (——— g) for large pieces;——— tbsp(s) (——— g) for "mini-size" candies measurable by tablespoon; 1/2 oz (14 g/visual unit of measure) for bulk products
All other candies	40 g	——— piece(s) (——— g); 1 1/2 oz (42 g/visual unit of measure) for bulk products
Confectioner's sugar	30 g	1/4 cup (30 g)
Honey, jams, jellies, fruit butter, molasses	1 tbsp	1 tbsp (——— g)
Marshmallows	30 g	——— cup(s) (——— g) for small pieces or ——— piece(s) (——— g) for large pieces
Sugar	4 g	1 tsp (——— g); ——— piece(s) (——— g) for discrete pieces (e.g., sugar cubes, individually packaged product)

TABLE 2—Continued

REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
Sugar substitutes	An amount equivalent to one reference amount for sugar in sweetness	——— tsp(s) (——— g) for solids; ——— drop(s) (——— g) for liquid; ——— piece(s) (——— g) (e.g., individually packaged products)
Syrups	30 mL for syrups used primarily as an ingredient (e.g., light or dark corn syrup); 60 mL for all others.	2 tbsp (30 mL) for syrups used primarily as an ingredient; 1/4 cup (60 mL) for all others
Vegetables:		
Vegetables primarily used for garnish or flavor, e.g., pimento, parsley	15 g	——— piece(s) (——— g); ——— tbsp(s) (——— g) for chopped products
Chili pepper, green onion	30 g	——— piece(s) (——— g)[13]; ——— tbsp(s) (——— g) or ——— cup(s) (——— g) for sliced or chopped products
All other vegetables without sauce: fresh, canned, or frozen	85 g for fresh or frozen; 95 g for vacuum canned; 130 g for canned in liquid, cream-style corn, canned or stewed tomatoes, pumpkin, or winter squash.	——— piece(s) (——— g) for large pieces (e.g., brussel sprouts); ——— cup(s) (——— g) for small pieces (e.g., cut corn, green peas); 3 oz (84 g/visual unit of measure) if not measurable by cup[13]
All other vegetables with sauce: fresh, canned, or frozen	110 g	——— piece(s) (——— g) for large pieces (e.g., brussel sprouts); ——— cup(s) (——— g) for small pieces (e.g., cut corn, green peas); 4 oz (112 g/visual unit of measure) if not measurable by cup
Vegetable juice	240 mL	8 fl oz (240 mL)
Olives[11]	15 g	——— piece(s) (——— g); ——— tbsp(s) (——— g) for sliced products
Pickles, all types[11]	30 g	1 oz (28 g/visual unit of measure)
Pickle relishes	15 g	1 tbsp (15 g)
Vegetable pastes, e.g., tomato paste	30 g	2 tbsp (33 g) for tomato paste; 2 tbsp (——— g) for all others
Vegetable sauces or purees, e.g, tomato sauce, tomato puree	60 g	1/4 cup (61 g) for tomato sauce; 1/4 cup (63 g) for tomato puree; 1/4 cup (——— g) for all others

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the USDA.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e., heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; dry, fresh, and frozen pasta) is the amount required to make one reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Division of Nutrition (HFF–260), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term "piece" is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for frozen novelties).

[6] Includes cakes that weigh 10 g or more per cubic inch.

[7] Includes cakes that weigh 4 g or more per cubic inch but less than 10 g per cubic inch.

[8] Includes cakes that weigh less than 4 g per cubic inch.

[9] Label serving size for ice cream cones and eggs of all sizes will be one unit. Label serving size of all chewing gums that weigh more than the reference amount that can reasonably be consumed at a single-eating occasion will be one unit.

[10] Animal products not covered under the Federal Meat Inspection Act or the Poultry Products Inspection Act, such as flesh products from deer, bison, rabbit, quail, wild turkey, geese, ostrich, etc.

[11] If packed or canned in liquid, the reference amount is for the drained solids, except for products in which both the solids and liquids are customarily consumed (e.g., canned chopped clam in juice).

[12] The reference amount for the uncooked form does not apply to raw fish in § 101.45 or to single-ingredient products that consist of fish or game meat as provided for in § 101.9(b)(j)(11).

[13] For raw fruit, vegetables, and fish, manufacturers should follow the label statement for the serving size specified in Appendices A and B to the regulation entitled "Food Labeling; Guidelines for Voluntary Nutrition Labeling; and Identification of the 20 Most Frequently Consumed Raw Fruits, Vegetables, and Fish; Definition of Substantial Compliance; Correction" (56 FR 60880 as amended 57 FR 8174, March 6, 1992).

[14] Pizza sauce is part of the pizza and is not considered to be sauce topping.

(c) The reference amount of a product that requires cooking or the addition of water or other ingredients shall be the amount required to prepare one reference amount of the final product as established in paragraph (b) of this section.

(d) The reference amount for an imitation or substitute food or altered food such, as a "low calorie" version, shall be the same as for the food for which it is offered as a substitute.

(e) If a food is modified by incorporating air (aerated), and thereby the density of the food is lowered by 25 percent or more in weight than that of an appropriate reference regular food as described in § 101.13(j)(1)(ii)(A), and the reference amount of the regular food is in g, the manufacturer may determine the reference amount of the aerated food by adjusting for the difference in density of the aerated food relative to the density of the appropriate reference food provided that the manufacturer will show FDA detailed protocol and records of all data that were used to determine the density-adjusted reference amount for the aerated food. The reference amount for the aerated food shall be rounded to the nearest 5 g increment. Such products shall bear a descriptive term indicating that extra air has been incorporated (e.g., whipped, aerated). The density-adjusted reference amounts described above may not be used for cakes except for cheese cake. The differences in the densities of different types of cakes having different degrees of air incorporation have already been taken into consideration in determining the reference amounts for cakes in § 101.12(b). In determining the difference in density of the aerated and the regular food, the manufacturer shall adhere to the following:

(1) The regular and the aerated product must be the same in size, shape, and volume. To compare the densities of products having nonsmooth surfaces (e.g., waffles), manufacturers shall use a device or method that ensures that the volumes of the regular and the aerated products are the same.

(2) Sample selections for the density measurements shall be done in accordance with the provisions in § 101.9(e).

(3) Density measurements of the regular and the aerated products shall be conducted by the same trained operator using the same methodology (e.g., the same equipment, procedures, and techniques) under the same conditions.

(4) Density measurements shall be replicated a sufficient number of times to ensure that the average of the measurements is representative of the true differences in the densities of the regular and the "aerated" products.

(f) The reference amount for products that represent two or more foods packaged and presented to be consumed together (e.g., peanut butter and jelly, cracker and cheese pack, pancakes and syrup) shall be the sum of the reference amounts for individual foods in the package if the reference amount for the product is not listed in paragraph (b) of this section.

(g) The reference amount set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b) followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl oz)").

(h) The Commissioner of Food and Drugs, either on his or her own initiative or in response to a petition submitted pursuant to part 10 of this chapter, may issue a proposal to establish or amend a reference amount in § 101.12(b). A petition to establish or amend a reference amount shall include:

(1) Objective of the petition;

(2) A description of the product;

(3) A complete sample product label including nutrition label, using the format established by regulation;

(4) A description of the form (e.g., dry mix, frozen dough) in which the product will be marketed;

(5) The intended dietary uses of the product with the major use identified (e.g., milk as a beverage and chips as a snack);

(6) If the intended use is primarily as an ingredient in other foods, list of foods or food categories in which the product will be used as an ingredient with information on the prioritization of the use;

(7) The population group for which the product will be offered for use (e.g., infants, children under 4 years of age);

(8) The names of the most closely-related products (or in the case of foods for special dietary use and imitation or substitute foods, the names of the products for which they are offered as substitutes);

(9) The suggested reference amount (the amount of edible portion of food as consumed, excluding bone, seed, shell, or other inedible components) for the population group for which the product is intended with full description of the methodology and procedures that were used to determine the suggested reference amount. In determining the reference amount, general principles and factors in paragraph (a) of this section should be followed.

(10) The suggested reference amount shall be expressed in metric units. Reference amounts for fluids shall be expressed in milliliters (mL). Reference amounts for other foods shall be expressed in grams (g) except when common household units such as cups, tablespoons, and teaspoons, are more appropriate or are more likely to promote uniformity in serving sizes declared on product labels. For example, common household measures would be more appropriate if products within the same category differ substantially in density such as frozen desserts.

(i) In expressing the reference amounts in mL, the following rules shall be followed:

(A) For volumes greater than 30 mL, the volume shall be expressed in multiples of 30 mL.

(B) For volumes less than 30 mL, the volume shall be expressed in mL equivalent to a whole number of teaspoons or one tablespoon, i.e., 5, 10, or 15 mL.

(ii) In expressing the reference amounts in g, the following general rules shall be followed:

(A) For quantities greater than 10 g, the quantity shall be expressed in nearest 5 g increment.

(B) For quantities less than 10 g, exact g weights shall be used.

(11) A petition to create a new subcategory of food with its own reference amount shall include the following additional information:

(i) Data that demonstrate that the new subcategory of food will be consumed in amounts that differ enough from the reference amount for the parent category to warrant a separate reference amount. Data must include sample size; and the mean, standard deviation, median, and modal consumed amount per eating occasion for the petitioned product and for other products in the category, excluding the petitioned product. All data must be derived from the same survey data.

(ii) Documentation supporting the difference in dietary usage and product characteristics that affect the consumption size that distinguishes the

petitioned product from the rest of the products in the category.

(12) A claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter; and

(13) In conducting research to collect or process food consumption data in support of the petition, the following general guidelines should be followed.

(i) Sampled population selected should be representative of the demographic and socioeconomic characteristics of the target population group for which the food is intended.

(ii) Sample size (i.e., number of eaters) should be large enough to give reliable estimates for customarily consumed amounts.

(iii) The study protocol should identify potential biases and describe how potential biases are controlled for or, if not possible to control, how they affect interpretation of results.

(iv) The methodology used to collect or process data including study design, sampling procedures, materials used (e.g., questionnaire, interviewer's manual), procedures used to collect or process data, methods or procedures used to control for unbiased estimates, and procedures used to correct for nonresponse, should be fully documented.

(14) A statement concerning the feasibility of convening associations, corporations, consumers, and other interested parties to engage in negotiated rulemaking to develop a proposed rule consistent with the Negotiated Rulemaking Act (Pub. L. 101–648).

Dated: October 27, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31503 Filed 12–28–92; 8:45 am]

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Part IV—Continued

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 1, et al.

Food Labeling; General Provisions; Nutrition Labeling; Label Format; Nutrient content Claims; Health Claims; Ingredient Labeling; State and Local Requirements; and Exemptions; Final Rules

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5 and 101

[Docket Nos. 91N-0384 and 84N-0153]

RIN 0905-AD08 and 0905-AB68

Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to: (1) Provide definitions for specific nutrient content claims using the terms "free," "low," "lean," "extra lean," "good source," "high," "reduced," "light" or "lite," "less," "fewer," and "more" and provide for their use on the food label; (2) provide for the use of implied nutrient content claims; (3) define and provide for the use of the term "fresh;" and (4) address the use of the terms "natural" and "organic." This action is part of the food labeling initiative of the Secretary of Health and Human Services (the Secretary) and in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: February 14, 1994, except §§ 101.10 and 101.13(q)(5) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on February 14, 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In the **Federal Register** of November 27, 1991 (56 FR 60421), FDA published a proposed rule (entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" hereinafter referred to as the general principles proposal) to: (1) Define nutrient content claims (also known as descriptors) and to provide for their use on foods labels; (2) define specific nutrient content claims that include the terms "free," "low," "source," "reduced," "light" or "lite," and "high"; (3) provide for comparative claims using the terms "less," "fewer," and "more"; (4) set forth specific requirements for sodium and calorie claims; (5) establish procedures for the submission and review of petitions regarding the use of nutrient content claims; (6) revise § 105.66 (21 CFR 105.66), to solely cover foods for special dietary use in reducing or maintaining body weight; (7) establish criteria for the appropriate use of the term "fresh;" and (8) address the use of the term "natural." A document correcting various editorial errors in that proposed rule was published in the **Federal Register** of March 6, 1992 (57 FR 8189).

In the same issue of the **Federal Register** (56 FR 60478), FDA also published a proposed rule (entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" hereinafter referred to as the fat/cholesterol proposal) to define and provide for the proper use of the nutrient content claims "fat free," "low fat," "reduced fat," "low in saturated fat," "reduced saturated fat," "cholesterol free," "low cholesterol," and "reduced cholesterol." A document correcting various editorial errors in the fat/cholesterol proposal was also published in the **Federal Register** of March 6, 1992 (57 FR 8177). The agency published the fat/cholesterol proposal as a separate document from the general principles proposal, even though it had based the two documents on the same statutory provisions, because it had published a tentative final rule on cholesterol content claims in the **Federal Register** of July 19, 1990 (55 FR 29456). FDA included proposed definitions for fat and fatty acid content claims in the fat/cholesterol proposal because of the interrelationship among these nutrients and cholesterol in the etiology of cardiovascular disease.

Also in the same issue of the **Federal Register** (56 FR 60507), FDA published a proposed rule (entitled "Food Labeling: 'Cholesterol Free,' 'Low Cholesterol,' and '——— Percent Fat Free' Claims") to define "cholesterol free" and "low cholesterol" and to provide for the proper use of these terms and the term "——— percent fat free." The proposed rule was intended to ensure on an interim basis that these terms are not used in a manner that is misleading to consumers.

The general principles proposal (56 FR 60421) and the fat/cholesterol proposal (56 FR 60478) were issued as part of the agency's food label reform initiative and in response to the 1990 amendments (Pub. L. 101-535). The food label reform began in 1989 when FDA published an advance notice of proposed rulemaking (ANPRM) that announced a major initiative concerning the use of food labeling as a means for promoting sound nutrition. The following year (November 8, 1990), the President signed the 1990 amendments into law. This legislation clarified and strengthened FDA's legal authority to require nutrition labeling on foods and to establish those circumstances whereby claims can be made about nutrients in foods. Now as FDA prepares to implement the new regulations, the agency reiterates that the 1990 amendments have three basic objectives. They are: (1) To make available nutrition information that can assist consumers in selecting foods that can lead to healthier diets, (2) to eliminate consumer confusion by establishing definitions for nutrient content claims that are consistent with the terms defined by the Secretary, and (3) to encourage product innovation through the development and marketing of nutritionally improved foods. With these goals in mind, the agency believes that the new regulations will reestablish the credibility of the food label.

With respect to nutrient content claims, the 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(r)(1)(A) of the act (21 U.S.C. 343(r)(1)(A)) which states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling, unless such claim is made in accordance with section 403(r)(2).

The agency received over 1,800 comments in response to the general principles proposal, and 500 comments in response to the fat/cholesterol proposal. Each comment addressed one or more of the provisions in these proposals. The comments were from a variety of sources including consumers, health care professionals, trade organizations, manufacturers, consumer advocacy organizations, foreign governments, and State and local governments. Many of the comments generally agreed with one or more provisions of the proposal, without providing other grounds for support other than those provided by FDA in the preamble to the proposal. Several comments addressed issues covered by other proposals that are a part of this overall food labeling initiative and will be addressed in those final documents, while other comments addressed issues

outside the scope of the proposal and will not be discussed here.

A number of comments to the general principles and fat/cholesterol proposals suggested modifications in, or were opposed to, various provisions of the proposals. Because the general principles governing both documents are identical, and because the issues raised in comments responding to the two proposals are similar, FDA has chosen to address the comments on, and to establish regulations based on, both proposals in this single document. The agency will summarize the issues raised in the comments and address them in this document.

The agency also notes that it received about 125 comments on the tentative final rule on cholesterol content claims after the closing date for comments of August 20, 1990. These comments were not addressed in the fat/cholesterol proposal. However, the agency has reviewed these comments and is also responding to them in this final rule.

As for the third proposal on cholesterol claims and "——— percent fat free," FDA has concluded that this final rule will provide adequate assurance to consumers that these terms are not used in a misleading manner. Therefore, the agency is announcing that it is withdrawing this proposal. Comments that were submitted on this proposal (Docket No. 84N–153A) have been considered in the development of this final rule. They will be addressed with the other comments on the general principles proposal and the fat/cholesterol proposal in this final rule.

B. Foods for Special Dietary Use

In 1978, FDA promulgated regulations in § 105.66 pertaining to the use of the terms "low calorie" and "reduced calorie" on foods represented as or purporting to be for special dietary use in the maintenance or reduction of caloric intake or body weight. Under the 1990 amendments, FDA is defining the terms "low" and "reduced" as nutrient content claims that identify the level of a nutrient in a food intended for consumption by the general population and is adopting specific definitions for the terms "low calorie" and "reduced calorie." To reflect these actions, the agency is revising § 105.66 to delete the provisions that define "low calorie" and "reduced calorie." Because § 105.66 was adopted under the authority of section 403(j) of the act, these revisions must be made in accordance with the formal rulemaking procedures in section 701(e) of the act (21 U.S.C. 371(e)). Under these procedures, there is an opportunity to object to a final rule and to request a public hearing based upon such objection. Such an opportunity is not provided as part of the notice-and-comment rulemaking procedures that are appropriate for most of the rest of the rulemaking that FDA is doing in response to the 1990 amendments. Therefore, for administrative convenience, FDA is publishing the final rule amending § 105.66 elsewhere in this issue of the **Federal Register**.

II. General Principles for Nutrient Content Claims

A. Legal Basis

FDA has the authority to issue this final rule regarding nutrient content claims under sections 201(n) (21 U.S.C. 321(n)), 403(a), 403(r), and 701(a) of the act. These sections authorize the agency to adopt regulations that prohibit labeling that: (1) Is false or misleading in that it fails to reveal facts that are material in light of the representations that are made with respect to consequences that may result from use of the food, or (2) uses terms to characterize the level of any nutrient in a food that has not been defined by regulation by FDA.

B. Scope

Section 403(r)(1)(A) of the act provides that claims, either expressed or implied, that characterize the level of a nutrient which is of a type required to be declared in nutrition labeling may not be made on the label or in labeling of any food intended for human consumption that is offered for sale unless the claim is made in accordance with section 403(r)(2). In the general principles proposal, the agency proposed to incorporate this general statutory requirement into proposed § 101.13(a) and (b) and to establish a new § 101.13 and the applicable regulations in part 101, subpart D (21 CFR part 101) as the provisions governing nutrient content claims.

1. One comment stated that the claims that are subject to the proposed regulations, which implement section 403(r)(1)(A) of the act, are appropriately called "nutrient descriptors," not "nutrient content" claims as proposed by FDA. The comment pointed out that the statutory language of the 1990 amendments does not include the phrase "nutrient content" claim. It stated that the words in section 403(r)(1)(A) of the act refer to a covered claim as a claim that "characterizes the level of any nutrient * * *." The comment's purpose in contrasting the wording of the proposal and that of the statute is to limit the applicability of the regulation to claims about the level of a nutrient and to exclude statements about amounts of nutrients. The comment stated that simple factual information about the nutrient content of a food, for which no characterizing claims are made, is explicitly excluded from regulation under section 403(r)(1)(A) of the act. It said that the last sentence in section 403(r)(1) of the act provides that a statement of the type contained in nutrition labeling—for example, that a food contains 25 calories per serving, or 10 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for vitamin C, or 50 milligrams (mg) of sodium—is not a claim characterizing the level of the nutrient. The comment requested that to assure that the regulations for section 403(r)(1)(A) of the act claims are not misunderstood to extend to nutrient statements that do not "characterize the level of a nutrient," all references to "nutrient content" claims be redesignated to "nutrient descriptors" or "nutrient descriptor claims."

The agency advises that while it can agree that the terms "nutrient descriptor" and "nutrient descriptor claims" may be used to describe the claims subject to section 403(r)(1)(A) of the act and these regulations, it does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food. The distribution the comment draws between "nutrient descriptors" and "nutrient content" claims is unpersuasive. In fact, one of the sponsors of the 1990 amendments in the Senate specifically used the term "nutrition content claim" to refer to claims covered under section 403(r)(1)(A) (136 Cong. Rec. S16608 (October 24, 1990)). Moreover, the statement in section 403(r)(1) of the act referred to by the comment as excluding from coverage statements of the type contained in nutrition labeling, in fact excludes "a statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph * * *." FDA stated in the general principles proposal (56 FR 60421 at 60424), that the legislative history of this provision specifically states that the identical information will be subject to the descriptor requirements if it is included in a statement in another portion of the label (136 Congressional Record H5841 (July 30, 1990)). In addition, section 403(r)(2)(E) of the act specifically exempts from the limitations on claims established in section 403(r)(2)(A)(i) through (r)(2)(A)(v), "a statement in the label or labeling of food which describes the percentage of vitamins and minerals in

the food which describes the percentage of such vitamins and minerals recommended for daily consumption by the Secretary." If such declarations as "10 percent of the U.S. RDA for vitamin C" were not within the scope of section 403(r)(1)(A) of the act, there would have been no need for Congress to provide a specific exemption for such claims. Furthermore, section 3(b)(1)(A)(iv) of the 1990 amendments provides that the mandated regulations "shall permit statements describing the amount and percentage of nutrients in food which * * * are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act." Again, if statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food. Thus, FDA's use of the term "nutrient content claims" is fully consistent with the act.

2. In proposed § 101.13(b)(3), FDA stated that no nutrient content claims could be made on foods specifically intended for infants and children less than 2 years of age.[1] A few comments stated that the prohibition was inconsistent with the overall intent of the 1990 amendments, which is to avoid consumer confusion by providing relevant and useful information to consumers by which they can make informed food choices. The comments said that such a prohibition would unfairly restrict nutrient content claims on foods primarily intended for infants and children less than two years of age while allowing such claims on products that, though aimed primarily at adults and older children, are actively promoted either on the label or in the advertising as being for use by infants or children less than 2 years of age. Although the comments recognized the validity of this prohibition with respect to certain nutrients, they requested that the agency provide an exception from this general prohibition for claims about other nutrients. Specifically, the comments requested changes that would, among other things, allow "no salt added" and "no sugar added" claims, permit "high protein cereal" to be so labeled, allow the percentage of the Reference Daily Intake (RDI) of a vitamin or mineral to be stated on the principle display panel (PDP), allow claims about fortification of the product with vitamins and minerals, and allow products to be labeled with a statement of identity that includes an ingredient that is a standardized food whose name includes a claim (e.g., "juice with low fat yogurt") without the normal referral statements required for nutrient content claims. The comments maintained that these exceptions would place infant foods on a par with foods intended for the general population that are promoted for infants and children less than 2 years of age and would allow continuation of the long standing practice of providing information relevant to the perceived special nutritional needs of this group.

The comments added that permitting "no sugar added" and "no salt added" claims on these foods is consistent with recent research that shows that sugar and salt are not necessary for a baby's palate, and that feeding sweetened or salted foods to infants can enhance their preference for such foods which is carried into adult eating patterns. Such "no salt added" and "no sugar added" claims, the comments said, would also allow manufacturers to highlight products that are consistent with dietary recommendations for infants and children less than 2 years of age provided over the past 11 years by health authorities, including the American Academy of Pediatrics, the U.S. Surgeon General, and U.S. Department of Agriculture (USDA)/FDA Dietary Guidelines.

In response to the comments, FDA has reconsidered the propriety of nutrient content claims on foods specifically intended for infants and children less than 2 years of age. The agency now believes that the complete prohibition of nutrient content claims on foods for infants and children less than 2 years of age may have been overly broad. Although current dietary recommendations for Americans do not include infants and children less than 2 years of age, there is no basis in the 1990 amendments to limit nutrient content claims to only foods intended for the population over the age of 2. In addition, the agency cannot discount the possibility that information may be developed that will allow the agency to define specific claims on the level of a nutrient in the food that are appropriate for foods for infants and children less than 2 years of age. Such claims are subject to the requirements of section 403(r) of the act.

Accordingly, the agency has revised new § 101.13(b)(3) to state that no nutrient content claims may be made on foods for infants and children less than 2 years of age unless a regulation specifically authorizing such a claim has been established in part 101, subpart D, among certain other parts of the regulations. Interested persons may submit a petition under new § 101.69 with appropriate information that would provide a basis on which the agency could determine that a specific nutrient content claim would be appropriate for foods for infants and children less than 2 years of age.

The agency also notes that it can permit, by regulation under section 403(j) of the act, claims that are made because of the special dietary usefulness of the food. The agency intends to use its authority under section 403(j) and (r) of the act to regulate foods for infants and children less than 2 years of age. In evaluating a petition for the use of a claim, it will determine under which authority of the act the claim is appropriately regulated. Accordingly, the agency is including in new § 101.13(b)(3) a reference to regulations in part 105 among those regulations that permit claims on foods for infants and children less than 2 years of age. In addition, in the general principles proposal, FDA stated that the regulations in part 107, issued under the authority of section 412 of the act (21 U.S.C. 350), permit certain nutrient content claims on infant formulas. For clarity, FDA has also included part 107 among the regulations permitting claims in new § 101.13(b)(3).

The comments that requested permission to make certain claims did not provide, nor has the agency developed, a sufficient basis on which to conclude that any of the nutrient content claims that FDA is defining, or any other claims, are appropriate for food specifically intended for infants and children less than 2 years of age. Although the agency is not prohibiting the statement of identity, "juice with low fat yogurt" because low fat yogurt is a standardized food and the statement of identity accurately characterizes the product, the agency notes that the other statements about the fat content of a product would be inappropriate on a food intended for infants and children less than 2 years of age. Such a food would be inconsistent with the guidance provided by various health authorities, which was noted in the general principles proposal and

[1] The agency notes that in the comments on the mandatory nutrition labeling proposal, one comment stated that the term "toddler" was improperly used. In the final rule for mandatory nutrition labeling, the agency agrees with this comment and is replacing the term "toddler" with the phrase "children less than 2 years of age". The term "toddler" was also used throughout the nutrient content claims proposal. Therefore, for clarity and consistency, the agency is using the phrase "children less than two years of age" in lieu of the term "toddler" in this final rule.

published in a report by the National Heart, Lung, and Blood Institute, National Cholesterol Education Program (NCEP) (Ref. 1), that fat and cholesterol should not be restricted in the diets of infants.

The agency has also considered the request to authorize the use of "no sugar added" and "no salt added" claims on foods specifically intended for infants and children less than 2 years of age. The terms "no sugar added" and "no salt added" have been defined as nutrient content claims for adult foods in §§ 101.60(c)(2) and 101.61(c)(2) and imply that the food is either "low" or "reduced" in calories or sodium, respectively. However, because dietary guidelines urging Americans to moderate their intake of sodium and salt are specifically for adults and children over 2 years of age, claims on foods intended specifically for infants and children less than 2 years of age are not appropriate. Therefore, the agency is not granting this request.

However, terms "unsweetened" and "unsalted" can be viewed differently. In the general principles proposal (56 FR 60421 at 60437), the agency cited the September 22, 1978, final rule on label statements for special dietary foods (43 FR 43238). In that final rule, FDA concluded that the term "unsweetened" was a factual statement about an organoleptic property of a food. The general principles proposal stated that the agency was not aware of any reason to change this view. Although the agency did not propose in the general principles proposal to define the terms "unsweetened" for foods intended specifically for infants and children less than 2 years of age the agency considers that this statement on baby food, as on adult food, is not intended as a nutrient content claim but as a taste claim. As such it is consistent with the recommendations of the American Academy of Pediatrics (Ref. 33) and the Surgeon General's report (Ref. 4) that sugar should be added sparingly, if at all, to foods prepared for normal infants. Consequently, the agency believes that highlighting that a food is unsweetened may provide useful information about the organoleptic properties of the food. Accordingly, the agency is adding foods intended specifically for infants and children less than 2 years of age to the exceptions provided in § 101.60(c)(3) for the term "unsweetened" as a factual statement.

Similarly, the agency believes that a statement that the food is "unsalted" on foods for infants and children less than 2 years of age can also be viewed as a statement about the organoleptic properties of the food. This term is also consistent with the recommendation from the same health authorities, noted in the comments, that, similar to sweetness, a salty taste is not necessary for an infant's palate. The agency recognizes that although the word "sweet" is used exclusively to identify a taste, the word "salt" may be associated with the level of a nutrient or with the taste of a food. However, consistent with the use of the word "unsweetened" as a statement of taste, the agency is permitting the term "unsalted" to be used on foods intended exclusively for infants and children less than 2 years of age. The agency is providing in § 101.61(c)(3) that "unsalted" may be used on these foods provided that it refers only to the taste of the food and is not otherwise false and misleading.

Finally, in keeping with section 403(r)(2)(E) of the act as amended, which permits, without further definition, label statements that describe the percentage of vitamins and minerals in the food relative to the RDI, the agency concludes that it is appropriate to permit statements of this type on foods intended specifically for infants and children less than 2 years of age. Elsewhere in this issue of the **Federal Register**, FDA is listing values that may be used as RDI's specifically for infants and for children under 4 years of age. These reference amounts provide an appropriate basis for label statements on foods intended specifically for infants and children less than 2 years of age that describe the percentage of vitamins and minerals relative to the RDI. Accordingly, the agency is clarifying its intentions by amending new § 101.13(q)(3) to specifically include foods for infants and children less than 2 years of age among those that may bear a percent RDI statement.

The agency has not prohibited claims on foods that are promoted for infants and children under the age of 2 but that are intended primarily for adults and older children. However, the agency cautions that any nutrient content claims made on such products in association with a statement about use of the food for infants and children under the age of 2 would be misleading under section 403(r) of the act unless such claim has specifically been permitted for such a population by regulation.

C. Labeling Mechanics

The 1990 amendments do not include specific limits on the prominence of nutrient content claims. However, FDA did propose certain requirements on how claims are to be presented. In the general principles proposal (56 FR 60421 at 60424), FDA proposed to require in § 101.13(f) that a nutrient content claim be, in type size and style, no larger than the statement of identity. The agency stated that this proposed requirement would ensure that descriptors are not given undue prominence. The agency proposed this requirement under section 403(f) of the act and under its general authority under section 403(r). Section 403(f) of the act states that a food is misbranded if any statement required by or under the authority of the act is not placed on the label with such conspicuousness, as compared to other words, statements, designs, or devices, as to render it likely to be understood by the ordinary consumer.

Section 403(r)(2)(B) of the act states that if a nutrient content claim is made, the label or labeling of the food shall contain, prominently and in immediate proximity to such claim, a statement referring the consumer to the nutrition label (i.e., "See ———— for nutrition information"). FDA proposed to incorporate this requirement in § 101.13(g).

Section 403(r)(2)(B) of the act requires that the referral statement appear prominently, but it does not contain specific requirements such as to type size or style. However, section 403(r)(2)(A)(iii) through (r)(2)(A)(v) of the act require that statements that disclose the level of fat, saturated fat, or cholesterol, which must be presented in conjunction with certain nutrient content claims, "have appropriate prominence which shall be no less than one-half the size of the claim." For consistency and because the referral statement and the statement disclosing the level of another nutrient must both be in immediate proximity to the claim, and therefore adjacent to one another, the agency tentatively concluded that these statements should be of the same type size. Therefore, the agency proposed in § 101.13(g)(1) that the referral statement be in type one-half that of the claim, but in no case less than one-sixteenth of an inch, consistent with other minimum type size requirements for mandatory label information.

3. Many comments stated that no type size requirements for either nutrient content claims or referral statements (other than those specifically included in section 403(r)(2)(A)(iii) through (r)(2)(A)(iv)) are mandated by the 1990 amendments, and that the agency should not impose requirements beyond those included in these amendments.

While the 1990 amendments do not specify type size requirements for nutrient content claims or for the

referral statement, the act must be read as a whole. Section 403(f) of the act requires that information required under the act be placed on the label with such conspicuousness as to render it likely to be read. FDA has, therefore, included those prominence requirements in these regulations that it finds necessary to ensure that this requirement is satisfied with respect to the information required under the 1990 amendments.

1. Relationship of size of nutrient content claim to statement of identity

4. Some comments suggested that the type size for claims be limited to a size no larger than the most prominent type size on the PDP. Some comments suggested that the type size should not exceed either the size of, or one-half the size of, the largest type or brand name. Some of these comments stated that these alternatives will allow manufacturers more flexibility and be more in line with the Executive Order 12291. Several comments stated that there is no reason to connect type size of the nutrient content claim to that of the statement of identity because if the nutrient content claim is disproportionately large, the statement of identity as well as other mandatory information on the PDP, such as net quantity of contents, will be so obscured or small as to violate existing section 403(f) of the act.

The agency rejects these comments. The nutrient content claim and the statement of identity are two of the most important pieces of information on the PDP. Given the limited amount of space on the PDP, the agency finds that it is necessary to link the size of the two pieces of information, so that manufacturers, can, and will, give appropriate prominence to each of them in planning their labels. The options suggested by the comments to unlink the size of the nutrient content claim from the statement of identity could result in a claim being unduly prominent. It would not be consistent with the goal of adopting regulations for the efficient enforcement of the act if the agency's regulations created a situation in which violations of the act were likely to develop. Thus, the agency rejects those options. However, the agency does agree that more flexibility with respect to the size of the nutrient content claim is appropriate.

5. Several comments stated that claims should have maximum prominence and be permitted to be of a type size greater than the statement of identity, especially when the claim is included in a brand name, since claims both provide important information to the consumer and serve to draw consumer attention to a specific product among other similar products. Several comments stated that the claim should not be more than twice the size of the statement of identity to provide for flexibility in communicating the claim effectively. Some comments stated that this alternative will allow manufacturers more flexibility and be more in line with the Executive Order 12291.

FDA recognizes the concerns expressed in these comments. FDA has reconsidered the proposed limit on type size for nutrient content claims and concludes that the proposed limit may unduly restrict the effectiveness of claims. FDA is concerned that, as a result, the incentives for manufacturers to innovate and improve their food products may be reduced. As some comments pointed out, style and format play important roles in effective marketing which is important not only in selling the product but in bringing the healthful attributes of the product to consumers' attention. The alternative presented in the comments of limiting the claim to not more than twice the size of the statement of identity provides for the flexibility requested to further the effectiveness of claims, while ensuring a certain proportionality of these two important pieces of information on the PDP. Therefore, the agency is revising new § 101.13(f) to require that the claim be no larger than two times the statement of identity.

2. Referral statements

6. Several comments stated that referral statements are redundant if the claim appears on the information panel with complete nutrition information. Other comments stated that these statements contribute to label clutter and cause the PDP to look like an information panel.

In response to the first group of comments, the agency points out that under proposed § 101.13(g)(2), a referral statement is not required when a claim appears on the information panel. More importantly, the requirement for a referral statement when a claim is made is statutory. Section 403(r)(2)(B) of the act specifically provides that the label contain this statement prominently and in immediate proximity to the nutrient content claim. Although the referral statement does add to the information in the PDP, this statement is necessary to ensure that consumers fully understand the nutrient content claim that is being made.

7. Several comments stated that referral statements, if required at all, should be one-half the size of the claim. Other comments stated that if a minimum type size requirement is necessary for the referral statement, FDA should specify only a minimum type size of one-sixteenth of an inch, which is the minimum type size prescribed for most mandatory information on a food label. Other comments suggested that referral statements if required at all, should be a minimum of one-sixteenth of an inch, or be of a minimum type size consistent with that required for the net quantity of contents statement in § 101.105(i) (which varies from one-sixteenth of an inch to one-quarter of an inch depending upon the area of the PDP), because this standard would assure a proportionality to the other printed material on the label.

The agency has considered these comments on the minimum type size of the referral statement. FDA agrees that it is not necessary to link the type size of the referral statement to that of the claim (as the proposal does). Such a requirement could contribute to label clutter. However, FDA does not agree that specifying only a minimum type size of one-sixteenth of an inch for the referral statement will assure adequate prominence for that statement, particularly on packages where the area of the PDP is large, and the claim is in large letters. Rather, FDA agrees that the requirements of section 403(f) and (r)(2)(b) of the act will be satisfied if the referral statement is presented in a type size consistent with the minimum type size requirements for the net quantity of contents declaration, which are linked to the area of the PDP. The proportionality between the size of the referral statement and the size of the label will ensure that the referral statement is presented with appropriate prominence.

However, FDA does not wish to inadvertently establish minimum type sizes for nutrient content claims. When the claim is less than twice what the minimum size of the referral statement would be given the size of the label and § 101.105(i), FDA believes that the type size of the referral statement may be less than that required under § 101.105 for net quantity of contents. In such circumstances, the referral statement is of appropriate prominence if it is at least one-half the size of the claim and not less than one-sixteenth of an inch. The agency believes that this approach to the type size requirement for the referral statement provides additional flexibility to firms in utilizing label space but still ensures adequate prominence for this statement.

Therefore, FDA is revising the referral statement requirement in new § 101.13(g)(1) to provide that the type

size of the referral statement be no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

8. Several comments requested that FDA provide that the referral statement on labels bearing a nutrient content claim become optional after 2 years. The comments argued that after 2 years, consumers will have learned that information supporting the claim is elsewhere on the label.

Section 403(r)(2)(B) of the act does not provide any authority for the agency to make such a modification to the requirement for the referral statement. Therefore, the agency rejects this request.

D. Disclosure Statements

Section 403(r)(2)(B)(ii) of the act states that if a food that bears a nutrient content claim "contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the required referral statement shall also identify such nutrient," i.e., a disclosure referral statement. FDA referred to this level as the "disclosure level" in the general principles proposal (56 FR 60425). In proposed § 101.13(h), FDA defined such levels for fat, saturated fat, cholesterol, and sodium, based upon an approach that considered dietary recommendations for these nutrients, the number of servings of food in a day, and available information on food composition. The proposed provision set out the required contents of the referral statement that would result (56 FR 60421 at 60425).

9. Several comments supported the disclosure level concept. However, others expressed the view that the concept places emphasis upon a single food rather than on the total diet, with the result that a food is perceived by consumers as being "good food" or "bad food," based upon the presence or absence of a disclosure referral statement.

The disclosure statement is required under section 403(r)(2)(B)(ii) of the act, and the disclosure provision in this final rule is consistent with that requirement. However, FDA disagrees with the assertion that the presence of a disclosure statement on a food label will lead consumers to perceive that the labeled food is "bad," or that the absence of a disclosure statement on a food label will be perceived as "good." The disclosure statement specifically directs the consumer to the information panel for information about other nutrients in the food in addition to the nutrient for which disclosure is triggered, e.g., "See side panel for information about fats and other nutrients." Thus, consumers' attention will be directed to the nutrition label, and they will be able to utilize the information therein, not just the disclosure statement, as a basis for making a purchase decision about the food. The disclosure statement is not intended to serve as a primary basis for making a purchase decision. However, if a nutrient content claim is made, the label must provide the consumer with the facts that bear on the advantages asserted by the claim and with sufficient information to understand how the product fits into a total dietary regime.

10. Several comments noted that in the preamble of the general principles proposal (56 FR 60421 at 60425), the agency stated that "there are no generally recognized levels at which food components such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease," and that a similar statement appears in the preamble of the November 27, 1991, proposed rule entitled "Labeling; General Requirements for Health Claims for Food" (56 FR 60537 at 60543). Based on these statements, the comments reasoned, the agency would not be able to make the analysis required in section 403(r)(2)(B)(ii) of the act for including a disclosure statement in the referral statement.

The agency disagrees with the comments. Although the agency stated in the proposal that "there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease," and thus "if FDA were to attempt to set these (disclosure) levels on an individual food basis, it would not be possible to do so," the agency also specifically noted that the act directs the agency to take into account the significance of the food in the total daily diet when making its analysis for when a disclosure statement is required.

The analysis that the agency performed in arriving at the circumstances where a disclosure statement is required was based upon dietary guidelines, taking into account the significance of the food in the total daily diet. The analysis utilized the agency's proposed Daily Reference Value's (DRV's) for total fat, saturated fat, cholesterol, and sodium and estimates of the amounts of these nutrients in foods and the number of servings of food consumed in a day. Therefore, although the disclosure levels are applied to individual foods, the basis of their derivation is the total dietary intake of nutrients that may pose an increased risk of diet-related disease, and the difficulty in maintaining healthy dietary practice that is created if these nutrients are consumed in particular foods at levels that exceed those established as disclosure levels. Thus, the agency concludes that its statements in the proposal did not preclude it from performing this analysis, and that it performed its analysis in a manner consistent with the statute's guidance.

11. Some comments asserted that consumers should be warned if the level of certain nutrients poses an increased risk of disease, irrespective of whether a nutrient content claim is made.

The agency disagrees with these comments. Although section 403(r)(2)(B)(ii) of the act mandates that the agency require that referral statements identify particular nutrients in certain circumstances where health or nutrient claims are made, the act does not direct the agency to require the identification of such nutrients in instances where a claim is not made.

Under sections 201(n), 403(a), and 701(a) of the act, the agency could require the identification of nutrients that are present at levels that increase the risk of a disease or health-related condition in the absence of a claim. However, in the absence of a nutrient content claim, there would be no basis to conclude that consumption of the food would receive any particular emphasis as part of the total daily diet, and thus there would be no particular basis for concern, and hence for a warning, about the levels of fat, saturated fat, cholesterol, or sodium in the food. Only when the significance of the food in the total daily diet is highlighted, as it is when a nutrient content claim is made, does the level of these other nutrients become material not only for purposes of section 403(r)(2)(B)(ii) of the act but also for sections 201(n) and 403(a) of the act.

12. One comment expressed concern that the agency's establishment of disclosure levels will be an open invitation for product liability suits for all products exceeding the threshold amounts.

As stated above, the agency believes that "there are no generally recognized levels at which nutrients such as fat, saturated fat, cholesterol, or sodium in an individual food will pose an increased risk of disease." The

disclosure levels are not tied to concerns about consuming the individual food but to concerns that claims can mislead consumers about the significance of the food in the total daily diet, and that rather than facilitating compliance with dietary guidelines (see H. Rept. 101–538, 101st Cong., 2d sess. (October 1990)), such claims could make compliance with such guidelines more difficult if certain relevant information is not brought to the consumer's attention. The disclosure levels should be understood in this way. The agency wishes to make clear, however, as stated in the final rule on health claims, published elsewhere in this issue of the **Federal Register**, that foods that contain nutrients at levels that exceed the disclosure level are not unsafe, will not cause a diet related disease, and are not dangerous or "bad" foods.

13. Several comments suggested that levels other than 15 percent of the DRV should be used as the threshold level for disclosure statements. Some comments stated that a 20 percent level should be used because it is consistent with the definitions of "more" and "high" and supportable on the basis of estimates of food consumption. Another comment suggested a 7 1/2 percent level specifically for fat and saturated fat, believing that 15 percent is too high for these nutrients. Similar comments pertaining to a disqualifying level for a nutrient for a health claim in response to the November 27, 1991, proposal on "Labeling; General Requirements for Health Claims for Food," were received by the agency.

The statutory language defining a disclosure level for a nutrient in conjunction with a nutrient content claim is the same as that for a disqualifying level for the nutrient for a health claim. The agency is, therefore, adopting the same levels for the individual nutrients for both types of claims. The agency is modifying the disclosure levels in new § 101.13(h)(1) and the disqualifying levels in new § 101.14(a)(5) to 20 percent of the DRV. The rationale for increasing these levels to 20 percent of the DRV is given in the final rule on general requirements for health claims for food, which is published elsewhere in this issue of the **Federal Register**, and is incorporated herein. Therefore, the disclosure levels in new § 101.13(h) are being revised to 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 mg of cholesterol and 480 mg of sodium per reference amount customarily consumed (hereinafter referred to as "reference amount"), per labeled serving size or for foods with reference amounts of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must have water added to them prior to typical consumption, the 50 g criterion applies to the "as prepared" form) (see also discussion in section III.A.1.b. of this document).

14. Several comments opposed the proposed requirement of § 101.13(h) that if a food contains more than the specified amounts of fat, saturated fat, cholesterol, or sodium per reference amount, per labeled serving size, or per 100 g, then the referral statement must include a disclosure statement. The comments stated that "per 100 g" unfairly discriminates against foods with standard serving sizes of less than 100 g, e.g., cheese, crackers, cookies, margarine, and butter. The comments further stated that the 100-g criterion makes little sense and should be eliminated.

The agency considered these comments and continues to believe that a weight-based criterion, in addition to the per reference amount and per labeled serving size criteria, is needed as a criterion for disclosure levels to ensure that if a claim is made for a food that is dense in fat, saturated fat, cholesterol, or sodium, the claim will not be misleading in light of the levels of fat, saturated fat, cholesterol, or sodium in the food. Therefore, the agency is retaining a weight-based criterion for disclosure levels in the final rule.

However, the agency agrees that the 100-g criterion is too restrictive and is modifying the criterion applied to disclosure levels in new § 101.13(h) and disqualifying levels in new § 101.14 to a weight-based criterion of 50 g that is applicable only to foods with reference amounts of 30 g or less or 2 tablespoons or less (see also discussion in section III.A.1. of this document). The rationale for this modification is fully set forth in the final rule on general requirements for health claims for food, published elsewhere in this issue of the **Federal Register** and is incorporated herein.

15. One comment contended that there is not an appropriate scientific basis for establishing a disclosure level for sodium.

The agency rejects the comment's assertion that the scientific evidence is not sufficient to support the establishment of a disclosure level for sodium. In the general requirements for health claims for food document and in the sodium/hypertension health claims document published elsewhere in this issue of the **Federal Register**, FDA responds to comments that assert that identifying sodium as a disqualifying nutrient for health claims is inappropriate and to comments that the scientific evidence relating sodium to hypertension is insufficient. Those responses are incorporated herein. The agency notes that the evidence from clinical trials supports that high sodium intake is related to high blood pressure, that the evidence from human observational studies is generally consistent and supportive, that the long-term prospective study data are sometimes inconclusive and sometimes supportive, and that there is significant scientific agreement among experts that this relationship exists. The agency concludes that the scientific basis is sufficient, and that sodium reduction is likely to benefit a significant portion of the general population.

However, as explained in the general requirements for health claims in food document published elsewhere in this issue of the **Federal Register**, in response to comments FDA is increasing the disqualifying/disclosure level to 20 percent of the DRV, as compared to 15 percent as proposed, and thus the level will be 480 mg per serving as compared with the proposed level of 360 mg.

E. Amount and Percentage of Nutrient Content Claims

In the general principles proposal (56 FR 60421 at 60426), FDA proposed to regulate the use of statements of amount (e.g., contains 2 g of fat) or that use a percentage (e.g., less than 1 percent fat) to describe the level of a nutrient in a food. The agency proposed in § 101.13(i) that foods bearing statements about the amount or percentage of a nutrient in food must meet the definition for "low" in the case of fat, saturated fat, sodium, and calories and "high" for fiber, vitamins, minerals, and other nutrients for which the term is defined.

16. Some comments expressed the view that statements regarding the amount and percentage of nutrients in food are confusing, deceptive, and misleading to most consumers and should not be permitted. One comment suggested that studies are needed to ascertain consumer perceptions in this area, and that amount or percentage labeling statements are not necessary on foods.

The agency is not persuaded that studies are needed to ascertain how these statements are understood by the consumer, or that it is necessary to ban these statements. The agency believes that statements concerning the amount and percentage of nutrients in food can provide useful information to consumers and flexibility to the food manufacturer in stating the nutritional attributes of a food. However, FDA recognizes that these statements can be

misleading. Therefore, FDA has carefully prescribed the circumstances in which such statements may be used in new § 101.13(i).

17. One comment stated that the 1990 amendments do not require FDA to limit amount or percentage statements about nutrient claims in the manner that the agency has proposed.

The 1990 amendments provide, in section 3(b)(1)(A)(iv), that FDA shall permit statements describing the amount and percentage of nutrients in food if they are not misleading, and if they are consistent with the terms defined by the agency. As discussed in the general principles proposal (56 FR 60421 at 60426), the legislative history of the 1990 amendments contemplates that the agency would define the circumstances by regulation "under which statements disclosing the amount and percentage of nutrients in food will be permitted" (136 Congressional Record, H5841–2 (July 30, 1990)). This portion of the legislative history states that "amount and percentage statements must be consistent with the terms that the Secretary has defined under section 403(r)(2)(A)(i) of the act [definition of descriptive terms] and they may not be misleading under section 403(a) in the current law." Thus, the agency believes that regulations to ensure that these statements will not be used in a misleading manner are consistent with the 1990 amendments. Therefore, the agency concludes that, consistent with the intent of the 1990 amendments, regulations controlling the use of label statements that state the amount or percentage of a nutrient in a food are appropriate.

18. Several comments suggested that amount and percentage disclosure statements should be permitted without restriction if the statement is accompanied by appropriate explanatory information, and as long as the statements are not misleading. Additionally, the comments implied that the agency should not prohibit or restrict the use of claims that convey the amount and percentage of nutrients in food because this information can direct consumers to the favorable characteristics of a food and allow consumers to compare food products within the same product line.

Other comments stated that foods should not be required to comply with such strict requirements before they can use amount and percentage statements. These comments contended that the agency has ample authority to regulate amount and percentage statements under section 403(a) of the act.

FDA finds that some restrictions on amount and percent claims are necessary. FDA advises that numerous consumer complaints, comments on a 1989 ANPRM on food labeling (54 FR 32610, August 8, 1989), and comments on the general principles and fat/cholesterol proposals about misuse of label statements such as "—— percent fat free" have persuaded the agency that, in many cases, statements regarding the amount and percentage of nutrients in food have been misleading. Moreover, section 3(b)(1)(A)(iv) of the 1990 amendments prescribes specific conditions in which such claims may be made. Therefore, FDA believes that it is necessary to limit the use of such statements in a manner that ensures that they will not mislead consumers, and that, if they implicitly characterize the level of a nutrient, they are consistent with the terms defined under section 403(r)(2)(A)(i) of the act. If amount and percentage statements are to be limited in this manner, the circumstances in which they can be used must be specifically presented. Thus, the agency concludes that, consistent with the 1990 amendments, it is necessary to limit by regulation the use of label statements that state the amount or percentage of a nutrient in a food. Therefore, as discussed in response to the next comment, the final regulation will include a provision in new § 101.13(i) limiting the use of such statements.

19. Many comments requested that FDA consider revisions in the provisions for amount and percent statements in the final rule. Some comments stated that the agency should not prohibit the use of amount and percentage statements on foods that do not meet the definition for "low" or "high" for a particular nutrient. One comment argued that, as proposed, this regulation would deprive consumers of useful information, hinder consumers from making informed food choices, and prohibit consumers from quickly differentiating between similar foods within the same product category. A similar comment suggested that FDA should permit the use of amount and percentage statements on foods where the value in the factual statement does not exceed the proposed nutrient claim disclosure level for single foods.

A few comments asserted that amount and percentage labeling statements should be permitted on foods that qualify for a "source" claim. Another comment suggested that FDA should permit the use of amount and percentage statements on foods that qualify for a "reduced" claim.

Some comments suggested that FDA should permit the use of amount and percentage statements to convey information regarding the calorie content per serving of food, consistent with the number of calories that appear on the nutrition panel. Other comments suggested that it is customary for consumers to refer to calorie information when selecting foods, and, therefore, the use of amount and percentage statements to describe this information should be permitted in the final regulation.

A few comments suggested that amount and percentage statements about the sodium content of a food provides factual information to consumers and should be permitted. Another comment stated that very few foods could convey amount and percentage statements for sodium under the proposed provisions.

These comments have convinced the agency to reconsider the proposed provisions for statements concerning the amount and percentage of nutrients in foods. The agency believes that statements relating the amount and percentage of nutrients in foods are generally useful to consumers for such purposes as pointing out the level of a nutrient in the food and facilitating comparisons between foods. The proposed provisions for amount and percentage statements would have limited the use of these statements to only foods that are "low" or "high" in the particular nutrient. FDA believes that the provisions in the proposal were too restrictive because they would deny consumers the use of such statements to evaluate many foods. FDA has considered how to permit statements of amount and percent that implicitly characterize the level of a nutrient (e.g., "less than 10 grams of fat") in a manner that benefits consumers and also satisfies the requirements of the statute. FDA believes that these conditions are met when such amount and percentage statements about a nutrient are made on foods that meet the criteria for any nutrient content claim, including relative claims, for the nutrient. Such amount and percentage statements are useful in helping consumers identify foods that facilitate conformance to current dietary guidelines. This includes foods that are a "good source of" or foods "low" or "high" in a nutrient as well as, foods that are alternatives to other reference foods (e.g., foods that are "reduced" in a nutrient.

Thus the final rule has been revised in new § 101.13(i)(1) to provide that a statement of percent and amount may be contained on the label or in the labeling of a food that meets the definition for a claim (as defined in part 101, subpart D) for the nutrient that the label addresses.

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The agency also believes that a statement about the amount and percentage of nutrients that implicitly characterize the level of the nutrient can provide useful information to consumers even if the food does not meet the criteria for a claim, provided the statement does not misleadingly imply that a food contains a small or large amount of a nutrient and makes clear whether the food meets one of the nutrient content claims that the agency is defining. In circumstances in which a food does not meet the criteria for a claim, an amount or percentage statement that implicitly characterizes the level of a nutrient, appearing by itself might be misinterpreted. Thus, the statement must be accompanied by a disclaimer such as "less than 10 grams of fat, not a low fat food" or "only 200 mg of sodium per serving, not a low sodium food." The disclaimer will not only make the claim not misleading, as required by section 3(b)(1)(A)(iv) of the 1990 amendments, it will also provide the means by which the amount or percentage can be declared consistently with section 403(r)(2)(A)(i) of the act by affirmatively stating that the amount does not meet the relevant definition.

To provide for statements about the amount or percentage of a nutrient in a food that implicitly characterize the level of the nutrient under these circumstances, FDA is adding new § 101.13(i)(2) to allow for the use of amount and percentage statements when the level of the nutrient does not meet the definition for a claim if a disclaimer accompanies the claim.

This revision also includes provisions for the location and type size of the disclaimer statement that require that the disclaimer be in easily legible print or type and in a size no less than required by § 101.105(i) for net quantity of contents except where the size of the claim is less than two times the size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth inch. This approach has been fully discussed in response to comment 7 of this document.

Because these revisions permit the use of amount and percentage statements where a food qualifies for all relative claims, and not just "high" or "low," the agency is deleting from new § 101.13(i) the phrase that refers to these statements as implying that a food is "high or low" in a nutrient and is inserting language that states that these statements imply that the food "contains a large or small amount" of that nutrient.

In addition, based on the comments and its review of the 1990 amendments, FDA finds that there are some circumstances in which an amount claim cannot be considered to characterize in any way the level of a nutrient in a food. For example, the statement "100 calories" or "5 grams of fat" on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient. As long as such a statement is not false or misleading, it can appropriately be included in food labeling. Therefore, FDA is providing in new § 101.13(i)(3) that an absolute statement of amount may be made without a disclaimer if "[t]he statement does not in any way implicitly characterize the level of the nutrient in the food, and it is not false, or misleading in any respect."

Finally, the agency is advising in new § 101.13(i)(4), for clarification, that amount and percentage statements made on labels or in labeling as "—— percent fat free" are not subject to the provisions of that paragraph. These statements are regulated separately under new § 101.62(b)(6). The agency believes this clarification is necessary because the preamble discussion in the general principles proposal supporting § 101.13(i) cited "—— percent fat free" as an example of a claim subject to section 3(b)(1)(A)(iv) of the 1990 amendments. While this example is appropriate, the agency is making it clear that the actual regulations governing "—— percent fat free" statements are provided in new § 101.62(b)(6) because those provisions differ from those of new § 101.13(i). The provisions for "—— percent fat free" statements are discussed below in the preamble section III.B.c.vi. [on Percent Fat Free] of this document.

F. Nutrition Labeling Required When a Nutrient Content Claim is Made

In the general principles proposal, the agency proposed (56 FR 60421 at 60426) in § 101.13(m) (redesignated as § 101.13(n) in this final rule) that a nutrient content claim may be used on the label or in labeling of a food, provided that the food bears nutrition labeling that complies with the requirements in proposed § 101.9 or, if applicable, proposed § 101.36.

20. The majority of comments addressing this issue favored the proposed requirement. One comment was concerned that requiring nutrition labeling on all foods bearing a claim will confuse consumers rather than empower them to make informed dietary selections.

The agency disagrees with the latter comment. Nutrition labeling is necessary when a claim is made to ensure that other important nutritional aspects of the food are presented along with that aspect highlighted by the claim. This fact is recognized in section 403(r)(2)(B) of the act, which requires that any nutrient content claim be accompanied by a statement referring the consumer to the nutrition label. Thus, nutrition labeling in the labeling of a food that bears a claim will assist consumers in making informed dietary selections because it provides them with additional important information about a food.

However, the Dietary Supplement Act of 1992 imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Therefore, FDA is not adopting § 101.36 and has modified § 101.13(n) to reflect this fact. The agency has also added a reference to § 101.10 to cover the situation in which a nutrient content claim is made for restaurant food (see section IV. of this document).

G. Analytical Methodology

In the general principles proposal (56 FR 60421 at 60428), the agency proposed in § 101.13(n) (redesignated as new § 101.13(o) in this final rule) to determine compliance with the requirements for nutrient content claims using the analytical methodology prescribed for determining compliance with nutrition labeling in proposed § 101.9.

21. A comment expressed the view that specifying methods such as official Association of Official Analytical Chemists (AOAC International) methods for the verification of nutrient claims is a barrier to innovation. The comment suggested that FDA should specify that appropriate valid methods may be used for determining nutrient content. The comment noted that if the manufacturer uses a nonofficial method, the manufacturer should have the burden of substantiating the validity of the method that is used.

FDA notes that new § 101.9(g), as amended by the mandatory nutrition labeling document published elsewhere in this issue of the **Federal Register**, states that, unless otherwise specified, compliance with nutrition labeling will be determined using methods validated by AOAC International. That regulation also states that if no "official" analytical method is available or appropriate, other reliable and appropriate analytical procedures may be used.

An AOAC International Task Force on Nutrient Labeling Methods has

considered the adequacy of AOAC International methods to meet nutritional labeling needs. The task force judged adequacy on the basis of a survey of nutrient method users and on the basis of the collaboratively validated and officially approved status of methods in the AOAC International Official Methods of Analysis. The methods judged to be adequate relative to the regulations and to reflect current analytical definitions are listed in *The Referee* 16:7–12 (1992) (Ref. 2).

Section 101.9(g) sets out the methods that the agency will use for compliance determinations. Manufacturers may use nonofficial methods of analysis to establish nutrient content label values, but in doing so, they should ensure the validity of their methods with respect to applicability, specificity, sensitivity, accuracy, precision, and detectability. If they fail to do so, and their methods produce significantly different results than the official method, their label may subject them to regulatory action. Reliable and appropriate alternative analytical methods may be submitted to FDA for a review of their acceptability.

Thus, by referencing new § 101.9, new § 101.13(o) does not preclude a manufacturer from using alternative analytical methods for determining nutrient content label values. No amendment of the regulation is necessary to comply with the comment's suggestion.

Analytical methodology is more extensively discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**.

H. Exemptions

This section addresses provisions in the general principles proposal for certain exemptions from the requirements for nutrient content claims: (1) Claims in a brand name; (2) "diet" soft drinks; (3) certain infant formulas; and (4) standards of identity. Other exemption provisions are addressed in the sections of this document pertaining to scope, restaurant foods, sugar free, and petitions. FDA advises that the exemption provisions proposed as § 101.13(o) have been redesignated as new§ 101.13(q) in this final rule.

1. Claims in a brand name

Under section 403(r)(2)(C) of the act, manufacturers may continue to use brand names that include nutrient content claims that have not been defined by regulation, as long as those claims appeared as part of a brand name before October 25, 1989, and are not false or misleading under section 403(a). Section 403(r)(2)(B) of the act, which requires the nutrition information referral statement, does apply to foods whose brand name includes such claims. Consequently, the labeling of products whose brand name includes such terms will have to bear an appropriate referral statement.

To implement this provision of the act, the agency proposed § 101.13(o)(1) (redesignated as § 101.13(q)(1)), which states that nutrient content claims not defined by regulation, appearing as part of a brand name that was in use prior to October 25, 1989, may be used on the label or in labeling of a food, provided that they are not false or misleading under section 403(a) of the act.

22. Several comments stated that allowing some products to continue to use a nutrient content claim in a brand name while precluding others on the basis of a date (October 25, 1989) is not justified, even if it is legally sustainable. Further, some comments contended that some nonexempt products could have an equivalent or superior nutritional profile. Other comments stated that the agency should broaden the exemption to include some claims in brand names appearing after October 25, 1989, without requiring a petition or other administrative process.

The agency advises that section 403(r)(2)(C) of the act grants the agency authority to exempt only those claims in the brand names of products bearing such claims before October 25, 1989, unless the brand name contains a term defined by the Secretary under section 403(r)(2)(A)(i) or is false or misleading. While some nonexempt foods may have an equivalent or superior nutrition profile, such foods are not recognized by the statute as exempt from the section 403(r)(2)(A) of the act. Thus, the agency is obligated by the statute's language to subject nonexempt foods to the general requirements of section 403(r)(2)(A) of the act that claims contained in a brand name be defined by regulation or by an approved brand name petition submission.

23. Several comments stated that claims in brand names should be restricted to terms that have been defined by FDA, so that claims appearing before October 25, 1989, will be consistent with claims in brand names appearing after that date. The comments stated that requiring claims to be consistent will facilitate the education of the public, while allowing some claims to be exempt will create multiple meanings for the same term depending on whether it appeared on a label before or after October 25, 1989. The comments stated further that such an exemption would likely lead to nonuniformity in the marketplace and consequent consumer confusion. One of these comments stated that FDA lacked the resources necessary to provide exemptions for some products while enforcing regulations on others.

A clarification of the 1990 amendments' provisions concerning exemptions is necessary. For a claim in a brand name to remain exempt from the act's requirements, that claim would have to be, of necessity, one that has not been defined by the agency by regulation. Thus, after the effective date of section 403(r)(1)(A) of the act, that claim could not be used on food products that were not on the market before October 25, 1989. Therefore, while an undefined term may have inconsistent meanings in brand names of food products that were on the market before October 25, 1989, it will not have multiple meanings depending on whether it appeared on a food label before or after October 25, 1989, as the comment stated. Until the claim is defined, it can not be used at all on post-October 25, 1989, products or anywhere but in the brand name of pre-October 25, 1989, products. Once it is defined, it can only be used in accordance with that definition.

The agency agrees that the establishment of definitions that state clear and consistent meanings for nutrient content claims will facilitate consumer understanding of those claims. Toward this end, the agency has endeavored in this final rule to establish definitions for both expressed and implied claims that will govern as many of the types of claims that frequently appear in brand names as is possible.

However, the agency notes that because numerous types of claims appear as part of brand names, this final rule will not likely define all of the claims that may be expressed or implied as part of a brand name. The agency expects that some of these claims will continue to be used under the exemption granted in section 403(r)(2)(C) of the act. In this regard, after these regulations become effective, FDA will monitor claims used in brand names that remain exempt, and if there is evidence that use of undefined claims could result in consumer confusion or misleading labeling, the agency will consider defining terms for such claims on its own initiative.

FDA believes that defining such claims will further the statute's goal of providing consistent nutrition information on food labels and will encourage competition in the marketplace by making the terms available for products not eligible for the exemption. The agency does not

agree with the comment that stated that FDA lacks the resources necessary to enforce a regime in which some products are subject to exemptions while others are not. The agency does not expect a significant added burden to be placed upon its resources if some claims in a brand name remain exempt, since exempt status does not flow from agency action or approval but is granted by the statute if the claim appeared in a brand name of a food product before October 25, 1989.

24. Some of the comments requested that FDA either define terms that are implied nutrient content claims used in brand names by regulation, to provide for their use under section 403(r)(2)(A) of the act, or regulate their use on a case by case basis under the general misbranding provisions of the act.

The agency agrees in principle with this comment's suggestion that it should define terms used as part of a brand name that may express or imply a nutrient content claim. As noted in the response to the previous comment, the agency has endeavored in this final rule to establish definitions for both expressed and implied claims that will permit, to the extent feasible at this time, as many as possible of the types of claims that frequently appear in brand names.

However, as also noted above, the provisions in this final rule will not likely define all claims made as part of a brand name. With regard to any claim not defined by the agency, the alternatives provided by the statute are that either the claim is exempt, or it must be the subject of a brand name petition that is granted by the agency. There is no provision in the statute for nondefined terms used in claims to be evaluated under the broad misbranding provisions of the act, other than that which states that exempt claims in brand names (i.e., claims that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989; see discussion in comment 25 of this document) must not be misleading under section 403(a) of the act. Therefore the agency rejects the suggestion that it either define all the terms or regulate their use on a case by case basis under the provisions of the act that prohibit false or misleading labeling.

25. Several comments stated that proposed § 101.13(o)(1) should be revised to clearly state that the exemption applies only to terms used in brand names used on specific and discrete food products before October 25, 1989, and not to products introduced after that date. These comments stated that the statutory exemption in section 403(r)(2)(C) of the act is triggered on a product-by-product basis, i.e., "such brand name" must have been in use on "such food" before October 25, 1989, for the exemption to apply. Some of these comments stated that an across-the-board exemption to a particular brand name would give an unfair competitive advantage to manufacturers who happened, before October 25, 1989, to have used an expressed or implied nutrient content claim in a brand name.

Other comments disagreed, arguing that product line extensions of qualifying brand names should also be exempted from the requirements for nutrient content claims because it would be unfair to exclude new products from bearing the same claim in the brand name until a petition for the use of the claim in the brand name is approved. Some comments stated that the 1990 amendments are ambiguous regarding whether the exemption provision for brand names applies to specific products bearing the brand name or to the brand name itself. These comments stated that this provision should be interpreted broadly because: (1) Laws afford special protection from government interference to trademark brand names; (2) a broad interpretation would be in accordance with Executive Order 12630, which directs that agency actions for the protection of public health and safety should be designed to advance significantly the health and safety purpose and be no greater in scope than is necessary to achieve that purpose and (3) a broad interpretation would be consistent with the President's "Memorandum For Certain Department and Agency Heads" on reducing the burden of government regulation (Ref. 3).

The agency does not believe the 1990 amendments are ambiguous on this issue because the statutory language, specifically the requirement that "* * * such brand name was in use on such food," limits the scope of the exemption to specific foods bearing the claim in the brand name. Thus, the agency does not agree with the comments that asserted that the agency should apply the exemption to line extension products.

The agency agrees with the comment that the final rule should be revised to clarify the scope of the exemption for brand names, and therefore it is revising the first sentence of new § 101.13(q)(1) to read:

> Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989, may continue to be used as part of that brand name for such product, provided that they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

26. One comment requested clarification as to whether the exemption for claims in brand names in use before October 25, 1989, applies to the type size of the claim on the label as well as to the claim itself. Several comments stated that referral statements should not be required for claims that are made as part of a brand name. Several comments stated that brand name claims should be required to bear referral statements, particularly if accompanied by a claim that uses a defined term.

Section 403(r)(2)(C) of the act exempts certain claims contained in a brand name from the requirements of section 403(r)(2)(A). This exemption covers all the requirements in section 403(r)(2)(A) of the act , including the disclosure requirements in section 403(r)(2)(A)(iii) through (r)(2)(A)(iv) as well as the accompanying type size requirements. Claims in brand names are not exempted however from section 403(r)(2)(B) or (f). Therefore, such claims are not exempt from the type size requirement in new § 101.13(f) or from the referral statement requirements in new § 101.13(g) and (h). FDA is adding a sentence to new § 101.13(q)(1) to make this clear.

27. Several comments requested that FDA adopt a policy whereby enforcement action will not be taken against products bearing an expressed or implied claim in a brand name that is the subject of a petition until the agency has ruled on the use of the claim.

The agency disagrees with these comments. The statute establishes a petition process for new nutrient content claims, including use of an implied claim in a brand name. See section 403(r)(4)(A) of the act. The latter type of petition is deemed to be granted if the agency does not act on it in 100 days (section 403(r)(4)(A)(iii) of the act). It would make little sense for Congress to have included a petition process with such tight timeframes if it intended that a claim could appear while the petition for such claim is under agency review. Therefore, the agency denies this request.

28. Several comments stated that no nutrient content claim used before October 25, 1989, in a brand name should be permitted regardless of whether or not it has been defined, but provided no supporting rationale for this position.

Because these comments are inconsistent with section 403(r)(2)(C) of

the act, and in the absence of any information to support the position they advance, FDA is rejecting them.

29. Several comments stated that the agency should allow the use of undefined claims in a brand name that were not in use before October 25, 1989 if the claim is accompanied by clarifying information.

The agency disagrees with these comments. The course of action advocated by these comments would nullify the explicit provisions of the statute that require that any claim in a brand name that is not exempt under section 403(r)(2)(C) of the act be used only in accordance with a definition established by the agency, or after the agency has granted a petition for the claim (section 403(r)(1)(A) and (r)(2)(A)). While such information may cure a misbranding under section 403(a) of the act, it would not be consistent with section 403(r). Therefore the agency denies the comment's request that it allow the use of undefined nonexempt claims in a brand name if accompanied by qualifying information.

2. "Diet" soft drinks

Section 403(r)(2)(D) of the act exempts use of the term "diet" on soft drinks from the requirement that a term may be used only in accordance with the definitions established by FDA, provided that its use meets certain conditions: (1) The claim must be contained in the brand name of such soft drink; (2) the brand name must have been in use on the soft drink before October 25, 1989; and (3) the use of the term "diet" must have been in conformity with § 105.66. In accordance with these conditions, the agency proposed in § 101.13(o)(2) that if the claim of "diet" was used in the brand name of a soft drink before October 25, 1989, in compliance with the existing § 105.66, the claim may continue to be used. Any other uses of the term "diet" must be in compliance with amended § 105.66.

30. Several comments requested clarification that the exemption for a claim that uses the term "diet" in the brand name of a soft drink does not preclude line extensions, e.g., new flavors for the brand after October 25, 1989.

For the reason discussed in comment 25 of this document, the statutory exemption for claims using the term "diet" in the brand name of a soft drink does not extend beyond discrete products that were available before October 25, 1989. However, the agency is continuing to define the term "diet" in its regulations, specifically in § 105.66, as discussed in the general principles proposal (56 FR 60421 at 60457). Thus, if the use of the term "diet" in the brand name of a soft drink is in conformity with § 105.66, it may be used on a soft drink product whether or not that product was available before October 25, 1989. The agency is unaware of any instances whereby line extensions for "diet" soft drinks would not be in conformity with § 105.66, and no such instances were presented in the comments. For clarity, the agency is specifying in new § 101.13(q)(2) that soft drinks marked after October 25, 1989, may use the word "diet" provided they are in compliance with current § 105.66.

31. Several comments requested clarification that claims that use the term "diet" in the brand name of a soft drink are exempt from the requirement in section 403(r)(2)(B) of the act that nutrient content claims be accompanied by the referral statement. These comments further stated that the exemption applies to all of the requirements imposed by section 403(r)(2) of the act.

The agency agrees with the comments that section 403(r)(2)(D) of the act exempts a soft drink bearing the term "diet" as part of the brand name from all provisions of section 403(r)(2), including the requirement that a referral statement accompany the claim.

3. Infant formulas and medical foods

Section 403(r)(5)(A) of the act states that section 403(r) does not apply to infant formulas subject to section 412(h) of the act or to medical foods as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)). Section 412(h) of the act applies to any infant formula that is represented and labeled for use by an infant who has an inborn error of metabolism or a low birth weight or who otherwise has an unusual medical or dietary problem. Section 5(b)(3) of the Orphan Drug Act defines the term "medical food" as a food that is formulated to be consumed or administered enterally under the supervision of a physician and that is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. FDA presented its views on what constitutes a medical food in its supplementary proposal on mandatory nutrition labeling (56 FR 60366 at 60377). Accordingly, the agency proposed in § 101.13(o)(4) to reflect these provisions of the act.

32. Several comments pointed to the fact that the agency already permits, under § 107.10(b)(4) (21 CFR 107.10(b)(4)) which was issued under authority of sections 412 and 403 of the act, the labels of certain infant formula products to bear statements such as "with added iron" (see 56 FR 60366 at 60378). These comments requested that the agency revise proposed § 101.13(o)(4) to state explicitly that claims permitted by part 107 (21 CFR part 107) can continue to be made without respect to the requirements of part 101 for infant formulas for normal full term infants, as long as the claims comply with the requirements of part 107. One comment stated that the infant formula regulations ensure FDA oversight for these foods, making additional restrictions unnecessary. These comments stated that such a revision would make it clear that claims permitted under part 107 are not subject to the regulations established under the 1990 amendments.

Under section 403(r)(5)(A) of the act, section 403(r) applies to all infant formulas except infant formula that are exempt under section 412(h) of the act. Under section 403(r)(2)(A)(i) of the act, a claim that characterizes the level of a nutrient in a food may be made only if it uses terms that are defined by regulation by the Secretary (and FDA, by delegation). Thus, while the terms used on infant formula are subject to a nutrient content claims regime, claims made on infant formula in accordance with part 107 are in compliance with that regime because they use terms defined in the regulations of the agency. To reflect this fact, FDA has added references to part 107 in new § 101.13(b) and (b)(3).

33. One comment requested that nutrition information in the form of publications and promotional materials provided to pediatricians concerning infant formula products for normal full-term infants be exempt from the labeling requirements of this final rule.

The agency advises that to the extent that nutrition information in any form, including publications and promotional materials of the type described, is labeling, it must comply with all applicable requirements of the act and their implementing regulations in this final rule. Further, FDA does not have authority to exempt any food labels or labeling from the requirements of the act. Labeling on infant formula products for normal full-term infants is not exempted by the 1990 amendments from the act's requirements for nutrient content claims. Therefore, the labeling for these foods must comply with the requirements in this final rule.

4. Standards of identity

Section 403(r)(5)(C) of the act states that nutrient content claims that are

made with respect to a food because the claim is required by a standard of identity issued under section 401 of the act (21 U.S.C. 341) shall not be subject to section 403(r)(2)(A)(i) or (r)(2)(B). Thus, a nutrient content claim that is part of the common or usual name of a standardized food may continue to be used even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts, or if FDA has not defined the term. Moreover, the label of the standardized food would not need to bear a statement referring consumers to the nutrition label. However, in the general principles proposal (56 FR 60421 at 60429), FDA reviewed the legislative history of this provision, which makes clear that Congress did not intend section 403(r)(5)(C) of the act to imply, in any way, that new standards issued under the act would be exempt from the provisions for nutrient content claims in part 101. Rather, Congress intended that this exemption would apply only to nutrient content claims made in the names of existing standards of identity (see H. Rept. 101–538, 101st Cong., 2d sess. 22 (1990)).

Accordingly, the agency proposed in § 101.13(o)(6) that nutrient content claims that are part of the name of a food that was subject to a standard of identity on November 8, 1990, the date of enactment of the 1990 amendments, are not subject to the requirements of proposed § 101.13(b),(g), and (h) or to the definitions of part 101, subpart D.

34. Several comments disagreed that nutrient content claims that are part of the common or usual name of a food that was subject to a standard of identity on November 8, 1990, should be exempt from having to comply with the definitions for such claims established by the agency. These comments stated that consumers may be confused by inconsistent meanings of the same term in standardized versus nonstandardized foods because many consumers do not know the difference between standardized and nonstandardized foods. Additionally, these comments stated that it was unfair to exempt standardized foods from the general requirements for nutrient content claims.

Section 403(r)(5)(C) of the act specifically exempts nutrient content claims that were part of the common or usual name of a food subject to a standard of identity on November 8, 1990, from the requirement that terms used to make claims comply with definitions established by regulation. Because this exemption is statutory, the agency must make it available to foods that meet the criteria for the exemption. Therefore FDA is retaining new § 101.13(q)(6) as proposed. The agency more fully discusses this exemption in the document addressing labeling requirements for foods named by use of a nutrient content claim and a standardized term published elsewhere in this issue of the **Federal Register**.

5. Other

35. The agency determined in the final regulation on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, that bottled water is not exempt from nutrition labeling unless it contains insignificant amounts of nutrients. Similarly, label statements on bottled water that make claims about nutrients of the type required to be declared in nutrition labeling are nutrient content claims requiring definition under section 403(r) of the act. In this regard, the proposal asked for comment as to how to decide what constitutes a nutrient content claim (56 FR 60421 at 60424). Comments on this issue have led FDA to conclude that fluoride is a special nutrient that warrants different labeling requirements than other nutrients.

Many public drinking water systems add fluoride to drinking water to help reduce dental caries. In addition, the Surgeon General has supported this practice (Ref. 4). However, there are concerns that fluoride levels in drinking water not be too high. The Environmental Protection Agency has established primary and secondary drinking water standards for fluoride (51 FR 11396, April 2, 1986) and FDA has proposed to revise its quality standard for fluoride in bottled water accordingly (53 FR 36036, September 16, 1988). Therefore, FDA believes that while the presence of fluoride in bottled water is of interest to consumers and its declaration should not be prohibited, the agency does not wish to encourage unnecessary addition of fluoride to bottled water. The agency is concerned that if terms like "good source of fluoride" or "high in fluoride" were permitted, they might encourage such additions.

Consequently, the agency has not defined a nutrient content claim for fluoride. Instead, it has provided that a statement indicating the presence of added fluoride may be used, but the claim may not include a description of the level of fluoride present. FDA has provided in new § 101.13(q)(8) that bottled water containing added fluoride may state that fact on the label or in labeling using the term "fluoridated," "fluoride added," or "with added fluoride."

III. Definition of Terms

A. General Approach

1. Criteria for definitions of terms

a. Serving size to evaluate nutrient content claims

In a proposal addressing food labeling and serving sizes that was published in the **Federal Register** on November 27, 1991 (56 FR 60394), FDA proposed among other things to: (1) Define serving and portion size on the basis of the amount of food customarily consumed per eating occasion, (2) establish reference amounts (reference amounts customarily consumed) per eating occasion for 131 food product categories, and (3) provide criteria for determining labeled serving sizes from reference amounts. In § 101.12(g), FDA proposed that if the serving size declared on the product label differs from the reference amount listed in proposed § 101.12(b), then both the reference amount and the serving size declared on the product label are to be used in determining whether the product meets the criteria for a nutrient content claim.

The agency also discussed this requirement in the general principles proposal (56 FR 60421 at 60430), stating that it believed it would be misleading to make a claim on a product that met the criteria for a claim on a reference amount basis but that did not qualify for the claim on the basis of the labeled serving size, i.e., the entire container. The agency noted, however, that this approach created situations in which a product in one size container would be eligible to bear a claim, while the same product in a different size container would not be eligible. In the serving size proposal (56 FR 60394 at 60413), FDA discussed another approach to eligibility for a claim based solely on the reference amount plus a disclaimer on the label and solicited comments on both options.

36. Most comments addressing this issue, including several industry comments, supported FDA's proposal for basing claims on both the reference amount and the labeled serving size. However, several comments from industry, trade associations, and a few professionals objected to requiring both the reference amount and the labeled serving size. These comments stated that claim evaluations should be based solely on the reference amount. The comments argued that claims should reflect true characteristics of the product, and that a product that qualifies for the claim should be able to bear the claim on all container sizes. They argued that inconsistency from

container to container in the use of claims on the same product in different sized containers would be confusing to consumers.

These comments and FDA's responses are fully discussed in the final rule on serving sizes, elsewhere in this issue of the Federal Register. As explained in that document, the agency has been persuaded to reconsider its proposal and has concluded in that final rule to base eligibility for a claim solely on the reference amount and to require a disclaimer when the amount of the nutrient contained in the labeled serving size does not meet the maximum or minimum amount criterion in the definition for the nutrient content claim for that nutrient. The disclaimer that follows the claim will inform consumers of the basis on which the product qualifies for the claim. Therefore, the possibility of misleading the consumer is reduced. The agency believes that this approach resolves the objections raised in the comments. Further, under this approach the claim would reflect true characteristics of the product, not the container size, and may be less confusing to consumers.

Accordingly, in the final rule FDA is revising all of the provisions for specific nutrient content claims that, as proposed, would have required foods bearing claims to meet both a per reference amount criterion and a per labeled serving size criterion. These sections, as revised, now require that the food only meet a per reference amount criterion.

FDA is also codifying the requirements for the disclaimer in the final rule in new § 101.13(p). New § 101.13(p)(1) states:

> The reference amount set forth in § 101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount, and the amount of the nutrient contained in the label serving size does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 101.12(g) (e.g., "very low sodium, 35 mg or less per 240 mL (8 fl oz)").

Further, new § 101.13(p)(2) provides that the criteria for the claim must appear immediately adjacent to the most prominent claim in easily legible print or type and in a size no less than that required by § 101.15(i) for net quantity of contents except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement should be no less than one-half the size of the claim but not smaller than one-sixteenth inch. This provision ensures that the disclaimer will have appropriate placement on the label and that its prominence will be consistent with other required supporting statements (e.g., referral statements).

b. Criterion based on a designated weight

In the general principles and fat/cholesterol proposals, FDA proposed in §§ 101.60, 101.61, and 101.62 that the definition of certain terms (e.g., "low" for calories, fat, sodium, and cholesterol and "very low" for sodium) be based on the following criteria: (1) The amount of nutrient per reference amount (reference amount), (2) the amount of nutrient per labeled serving size, and (3) the amount of nutrient per 100 g of food. The weight-based criterion (i.e., per 100 g of food) required that the maximum amount of the nutrient allowed per serving also be the maximum amount of the nutrient contained in 100 g of the food (e.g., for "low fat," 3 g or less of fat per serving and 3 g or less of fat per 100 g).

In the general principles proposal (56 FR 60421 at 60430), FDA stated that without the weight-based criterion, "low" claims would be allowed on certain foods that are dense in a nutrient on a weight basis yet still qualify for a "low" claim because of their small serving size. For example, without the weight-based criterion, butter and some margarines could make "low sodium" claims, although they contain as much as 900 mg sodium per 100 g of food. In addition to stating the misleading nature of such claims, FDA expressed concern that nutrient dense foods with small serving sizes may be consumed frequently throughout the day and ultimately make substantial contributions to the diet despite their "low" claims. Thus, FDA proposed the weight-based criterion to prevent misleading "low" claims on certain nutrient dense foods. FDA further stated that such claims may be counterproductive relative to educating consumers about the nutrient quality of foods.

37. Many comments requested that the agency delete the weight-based criterion from the final rule. The comments cited various reasons for this request. One of these comments stated that the weight-based criterion would eliminate important foods from the diet of persons advised by medical personnel to "watch" a particular nutrient and suggested that such persons might not eat particular foods if such foods were not labeled as "low" in that nutrient. The comment maintained that foods that do not meet the agency's proposed criteria for "low" can still be included in a healthy diet.

The agency realizes that some foods that do not meet its criteria for "low" can be included in a diet that meets current guidelines. The agency notes that the proposed definition of "low" is designed to allow a consumer to meet current dietary recommendations while selecting a variety of foods, including some that are "low" in a nutrient such as fat, and some that are not "low." Thus, FDA disagrees with the essential point of this comment, that it should not include a weight-based criterion for "low" claims because some foods that do not meet the criteria for "low" can be included in a diet that meets current guidelines. The agency believes that a weight-based criterion is a necessary criterion for the definition of "low" to prevent misleading claims on certain nutrient dense foods.

38. Some comments argued that the need for the criterion was eliminated or diminished by FDA regulations that would require serving sizes to reflect amounts customarily consumed and would require the listing of both serving size and nutrient content on the nutrition label. One of these comments further stated that if there were still problems with certain nutrient dense foods qualifying for "low" claims, then the reference amount might be adjusted to solve these problems.

FDA considered the comments suggesting that the weight-based criterion could be deleted because serving sizes will be based on amounts customarily consumed. However, the agency rejects this suggestion because basing eligibility for a claim on serving size alone would mean that certain foods with small serving sizes that have a substantial amount of a particular nutrient on a per weight basis could make "low" claims. For example, the agency conducted an analysis to assess the effect of deleting the weight-based criterion using food composition data of USDA (Ref. 5) in conjunction with the reference amounts in FDA's final rule on serving sizes. The analysis showed that without a weight-based criterion, products such as sugar, grated parmesan cheese, and 25 percent fat cream could be labeled as "low calorie;" evaporated whole milk, nondairy creamer, green and ripe olives, and whipped dessert toppings as "low fat;" salted peanuts, butter, margarine, mayonnaise, ripe olives and mustard as "low sodium;" and grated parmesan cheese and regular mayonnaise as "low cholesterol" (Ref. 6). "Low" claims on these foods are contrary to recommendations made in the "Nutrition and Your Health: Dietary

Guidelines for Americans," issued jointly by the U.S. Department of Health and Human Services and USDA (Ref. 7) and would mislead and confuse the consumer.

Furthermore, "low" claims may promote increased consumption of such foods and thus, result in dietary practices even more inconsistent with dietary guidelines. For example, "low calorie" claims could appear on the labels of granulated sugar and brown sugar, although the guidelines state that sugars and the many foods that contain them in large amounts should be used in moderation by most healthy people and used sparingly by people with low calorie needs. A "low fat" claim could be made on evaporated whole milk, although the guidelines promote the consumption of skim or low fat milk to help obtain a diet low in fat. In addition, "low sodium" claims could be made on ripe olives, mayonnaise, and mustard, although the guidelines identify olives, salad dressing, and condiments such as mustard as foods that contain considerable amount of sodium. Further, "low sodium" claims could be made on some salted snacks, although the guidelines recommend that salted snacks be consumed sparingly. Consumer confidence in the validity of nutrient content claims would likely be undermined by "low" claims on foods that are clearly not "low" in certain nutrients but could make a claim because the established serving size is so small. For these reasons, FDA has concluded that the weight-based criterion should not be eliminated.

Furthermore, the agency rejects the suggestion made in one comment to adjust reference amounts (serving size) to prevent claims on nutrient dense foods. The agency does not have the authority to do so. Section 403(q)(1)(A)(i) of the act states that the serving size is an amount that is customarily consumed. Therefore, FDA concludes that a weight-based criterion is the best way to address the problem that it has identified.

39. Several comments stated that the weight-based criterion should be deleted because: (1) The 100 g amount is not based on amounts of foods customarily consumed; (2) consumers do not make food choices based on 100 g of food; (3) some foods now labeled as "low sodium" may no longer be permitted to use that term; and (4) not all food products with similar amounts of a nutrient per serving would be permitted to bear "low" claims.

As discussed in the general principles proposal (56 FR 60421), the 100-g criterion is a criterion that reflects nutrient density. As such, it is not intended to reflect an amount of food customarily consumed. FDA finds no reason to conclude that this criterion will confuse consumers because it is not disclosed to the consumer. Additionally, the agency is not persuaded that consumers will be confused if some products currently using terms such as "low sodium" no longer qualify because of the additional criterion. Rather, the agency believes that consumers expect changes in claims on products to result from the implementation of the 1990 amendments.

Further, FDA does not believe that consumers will be confused if all food products with similar amounts of nutrients per serving did not bear "low" claims because consumers will likely recognize certain foods as being nutrient dense and others as not being nutrient dense. On the contrary, consumer confusion is likely to result if "low" claims appear on foods that are generally known to contain considerable amounts of the subject nutrient on a weight basis.

40. Several comments opposed to the weight-based criterion also disagreed with the statement in the general principles proposal (56 FR 60421 at 60431) that some nutrient dense foods with small serving sizes may be consumed frequently throughout the day. These comments said there was no evidence that these foods are overconsumed, nor was there evidence that they are consumed more than food products with larger serving sizes. A few of these comments stated that consumer education efforts could address any problems with these foods including their possible overconsumption.

FDA has reconsidered whether nutrient dense foods with small serving sizes will be frequently consumed, and the importance of this issue in justifying a weight-based criterion. The agency acknowledges the difficulty in providing persuasive evidence that many nutrient dense products may be frequently consumed, in part because of certain limitations in the available food consumption estimates. However, the agency believes that "low" claims on certain nutrient dense foods with small serving sizes, such as those cited in comment 38 of this document, may promote increased consumption of these foods, and when considered in the context of the total diet, such consumption would be inconsistent with current dietary recommendations. Therefore, the agency believes that "low" claims on these foods will be misleading to consumers.

Further, it would be inappropriate for the agency to use consumer education to promote the acceptance of labeling claims that it regards as misleading because such an approach would undermine the provision of the act that directs the agency to establish regulations to prevent false and misleading label declarations. Therefore, the agency rejects the suggestion that it abandon the weight-based criterion in favor of efforts to educate consumers about "low" claims for nutrient dense foods.

41. Other comments opposed to the proposed weight-based criterion asserted that it will act as a disincentive to manufacturers to produce healthier food products if they could not use claims such as "low" on the label. One of these comments said that manufacturers will have difficulty reformulating some products to meet the weight-based criterion, while another said that the inability to advertise a healthier product could lead to a manufacturer's shifting the emphasis from reducing fat or salt to adding fat or salt for better taste.

FDA examined the extent to which a weight-based criterion would be a disincentive to manufacturers to produce healthier products. The agency acknowledges that an overly restrictive weight-based criterion would limit the number of products that could be reformulated to qualify for "low" claims. However, the agency disagrees that manufacturers are likely to resort to adding fat or salt if they are unable to make "low" claims, because the manufacturer would still have available comparative claims such as "less" to publicize nutritional improvements in products. Therefore, FDA rejects these comments.

42. Several comments were opposed to the weight-based criterion because of the number and type of food products that would be precluded from bearing claims by this criterion. Some of the food products cited by the comments included certain dry food products (e.g., dry hot cereals and dehydrated soups); some types of bread, pasta, crackers, and other cereal grain products; snack products and cookies; lower fat cheeses and other dairy products; lower fat salad dressings; spice blends and seasoning blends; and sauces, margarine, butter, and oils. One comment said that it would make it almost impossible for products whose reference amount was less than 100 g to qualify for certain nutrient content claims, while other comments said that the criterion discriminates against food with small serving sizes and nutrient-dense foods. Other comments said that this criterion

diminished the distinction between the terms "low" and "free" and was unfair to low moisture foods.

FDA considered the comments that said that the weight-based criterion should be deleted because of the number and types of food products that would be precluded from bearing claims. The agency disagrees with the comment that the proposed criterion would make it almost impossible for products with a reference amount of less than 100 g to qualify for certain content claims. Many products with reference amounts under 100 g would qualify for "low" claims under FDA's proposed criterion (e.g., many vegetable products, dried fruit, legumes, some gravies and sauces, some fish products, several cereal grain and pasta products, and a number of breakfast cereals could make "low fat" claims) (Ref. 8).

FDA also considered the comments that said that the proposed weight-based criterion discriminates against foods with small serving sizes and nutrient dense foods, but concluded that a weight-based criterion is needed to prevent nutrient dense foods with small serving sizes from making misleading claims. Further, the agency disagrees that the revised weight-based criterion would diminish the distinction between "low" and "free" claims. The agency has provided clearly distinctive definitions for these two nutrient content claims.

43. At least two comments suggested alternative criteria that would incorporate the frequency of consumption of a food. One comment suggested that nutrient dense foods with small serving sizes should be prevented from making "low" claims only if they are consumed many times during the day. Another comment proposed that foods be required to meet the criteria for "low" claims based both on levels per reference amount and per total daily intake (i.e., reference amount times average number of servings per consumer per day). The daily number of servings would be derived from national food consumption surveys. This comment acknowledged that a major disadvantage to this approach would be the complexity of determining the figures.

The agency agrees that an approach that considers frequency of consumption would be complex. FDA rejects this approach principally because it does not adequately address the agency's concerns with regard to nutrient dense foods with small serving sizes. The agency believes that the suggested approach would not effectively control misleading claims on nutrient dense foods with small serving sizes because it does not provide any means of dealing with the likely effect of the appearance of the claim on the food. In other words, it would make little sense for the agency to allow a claim based on current consumption levels, but then to move to withdraw the authorization for the claim as soon as new consumption information appears showing that there is increased consumption of the food in response to the claim, and that consumption is inconsistent with dietary guidelines. A weight-based criterion will ensure that increased consumption of the food will still be consistent with dietary guidelines.

44. One comment suggested, as an alternative to the weight-based criterion, that food products that may have significantly different serving sizes because of different uses be required to meet the "low" level based on all of the respective reference amounts. The comment stated that one-third of all nondairy creamers are consumed with cereal in place of milk, and thus the reference amount used as a basis for claims should reflect this use. This comment also suggested as an alternative to the weight-based criterion that food products that have small serving sizes be required to meet a lower nutrient level per serving to make a claim. For example, for foods with a one ounce reference amount or less, fat content could not exceed 2 g per reference amount.

The agency rejects these suggestions because the first has only limited application, and the second is not an effective alternative in preventing misleading claims. With regard to the first suggestion, most nutrient dense foods with small serving sizes (e.g., butter) would be subject to only one reference amount. The second suggested alternative would not prevent "low fat" claims on foods such as grated parmesan cheese and whipped dessert toppings (Ref. 9), and, as discussed in comment 38 of this document, such claims would be misleading.

45. Some comments suggested applying a weight-based criterion only to foods with small serving sizes. One comment suggested that the agency develop a provision to cover foods that weigh 40 g or less per serving and contain more than 5 calories per g. Another comment suggested that the proposed weight-based criterion only be applied to foods with reference amounts 15 g or less or 2 tablespoons or less and that are consumed frequently throughout the day. Other comments suggested that certain nutrient content claims be prohibited on specific categories of foods with very small serving sizes or prohibited on foods with less than a minimum serving size that contained more than a certain amount of fat on a dry weight basis. One comment suggested that a minimal serving size for specific nutrient content claims be established such as one tablespoon.

The agency has carefully considered the suggestions raised in the comments that a weight-based criterion apply only to foods with small serving sizes. Because the intent of the agency is to prevent misleading claims on nutrient dense foods that have small serving sizes, the agency has concluded that narrowing the scope of the provision such that it only applies to foods with small serving sizes adequately addresses its concern of misleading claims on nutrient dense foods with small servings. Moreover, the agency has concluded that with appropriate provisions applicable only to foods with small serving sizes, misleading claims on nutrient dense foods can be prevented. However, the alternatives suggested in the comments were not the most effective options in preventing such claims. For example, with the first alternative suggested by the comments, green olives with about 13 g of fat per 100 g could qualify as "low fat" and 25 percent fat cream with about 240 calories per 100 g as "low calorie" (Ref. 10). With the second suggested alternative, salted peanuts with about 430 mg sodium per 100 g could qualify as "low sodium" (Ref. 10).

The agency considered, however, that if the second suggested alternative was modified to apply to foods with reference amounts of 30 g or less or 2 tablespoon or less, and the concept of frequency of consumption was deleted, then the proposed weight-based criterion applied to such foods would prevent inappropriate claims (Ref. 6). In addition, this criterion would permit more foods that are promoted in dietary guidelines to make "low" claims than FDA's proposed criterion. For example, breads and pastas that qualified on a per serving basis could make "low" claims. Accordingly, in the final rule, the agency is including a weight-based criterion for "low" claims only for those foods that have reference amounts of 30 g or less or 2 tablespoons or less. As discussed below, in comment 48 of this document, the agency is also persuaded to adopt a less restrictive weight-based criterion.

46. At least two comments suggested as an alternative that foods with small serving sizes be required to have a qualifying statement such as "low fat per one tablespoon" or "low fat when consumed in a 1-ounce serving." One

comment suggested that this qualifying statement only be required for foods that exceeded FDA's proposed per 100-g criterion. These comments said that the disclosure would alert people to the possibility that the product would no longer be "low fat" if a larger serving were consumed and would educate consumers who did not know that nutrient content claims are dependent on serving sizes.

This alternative would permit claims on all foods meeting the per serving criterion and would provide additional clarification of the claim to the consumer. However, the agency is not persuaded to adopt this alternative because the agency believes that even with the additional disclosure, such claims may confuse the consumer if the food product contains considerable amounts of the nutrient on a weight basis.

47. A few comments suggested as an alternative that all food products that meet the per serving criterion for a claim also be required to meet a caloric density criterion. Reasons cited in support of a caloric density criterion were that it would prevent nutrient dense foods with small serving sizes from making misleading claims, would allow products of widely differing serving sizes and calorie levels to be assessed fairly, and would eliminate inequities of the proposed 100-g criterion that favored hydrated products. One comment recommended that "low fat" foods not contain more than 15 g of fat per 100 g on a dry weight basis, which is equivalent to about 30 percent of calories from fat. Another comment recommended that instead of a weight-based criterion, a criterion of less than 45 percent of calories from fat should be applied to the "low fat" definition.

Disadvantages to a caloric density approach were also cited in comments. They included the potential for: (1) Manufacturer misuse such as increasing the fat/calorie content of a product to obtain a lower level of a particular nutrient (e.g., a lower sodium or cholesterol level) on a per calorie basis, and (2) manufacturer disincentive to produce "lower calorie" foods because, with the caloric density approach, the levels of problem nutrients would be higher compared to the higher calorie version of the product.

Other comments suggested that a weight-based criterion be based on nutrient levels per 100 calories or nutrient levels per 117.5 calories. The latter caloric level was derived by dividing the agency's proposed reference daily caloric intake of 2,350 calories by the agency's estimate of 20 servings of food being consumed in a day. The comment stated that this caloric level would be tied to average daily consumption, whereas 100 g has no relation to daily food consumption.

The agency has considered the appropriateness of applying a caloric density criterion for "low" claims for fat, cholesterol, and sodium. The agency acknowledges that it proposed this type of approach for a weight-based criterion for saturated fat in order to provide "low" claims for saturated fat on certain fats and oils (e.g., canola oil) because all fats and oils would exceed a weight-based criterion based on 100 g.

The agency is concerned, however, that the caloric density approach would permit misleading "low" claims for cholesterol and sodium. For example, if the criterion was that a food could have no more than proposed nutrient levels per 117.5 calories, then butter with about 800 mg of sodium per 100 g could qualify for a "low sodium" claim and grated parmesan cheese with about 80 mg of cholesterol per 100 g for a "low cholesterol" claim (Ref. 11). The agency also agrees with comments that the caloric density approach could encourage the development of higher fat, higher calorie products in order to make "low sodium" and "low cholesterol" claims. Thus, this approach would be inconsistent with national dietary goals of lowering fat intake (Refs. 4, 7, and 12).

The agency also considered whether this type of criterion might be applied to fat but not to sodium and cholesterol. However, if a criterion such as less than 30 percent calories from fat were used, then low calorie, high moisture products such as ready-to-serve gazpacho soup may not qualify for a "low fat" claim (Ref. 11), even though a serving of a cup might contain only 2 g of fat and be consistent with foods promoted in dietary guidelines. In addition, the agency does not believe that there is a sufficient basis to justify a higher level such as no more than 45 percent calories from fat, as suggested by one of the comments. Furthermore, national goals that target nutrient intake as a percentage of calories focus on the total diet, not on the percentage of calories in individual foods (Refs. 4, 7, and 12). Accordingly, the agency rejects a criterion based on caloric density for claims for nutrients other than saturated fat.

48. Several comments suggested as an alternative that FDA use a less restrictive weight-based criterion. Variants of this alternative were to use: (1) The disclosure/disqualifying levels per 100 g, (2) proposed levels per 30 g (one ounce), or (3) proposed levels per 50 g. One of these comments further stated that the use of the proposed levels per 30 g would be more closely tied to reference amounts and would allow truthful nutrient claims on the majority of foods, while preventing claims on nutrient dense foods with small serving sizes. This comment cited as a disadvantage, however, that this approach would still be arbitrary and not related to how consumers actually eat foods.

Another comment supported the use of proposed levels per 50 g because it would allow more grain products to qualify as "low fat." In addition, the comment stated that a per 50-g criterion would prevent higher fat crackers and cookies and other high fat foods with small serving sizes from making "low fat" claims. This comment further stated that the per 50-g criterion would allow more products to qualify for "low sodium" and "low cholesterol" claims and would result in more flexibility for manufacturers and more choices for consumers.

FDA considered the options presented in the comments for a less restrictive weight-based criterion. Upon reconsideration, the agency acknowledges that the level it proposed, per 100 g, is too restrictive. While the proposed criterion would have prevented "low" claims on certain nutrient dense foods, it also would have prevented some breads and other cereal grain products for which increased consumption is recommended in national dietary guidance from qualifying for "low" claims (Ref. 7). FDA has thus rejected maintaining the weight-based criterion as proposed.

The agency disagrees that a main reason for selecting a weight-based criterion should be the relationship of per 100 g, per 50 g, or per 30 g to the amounts of foods consumers actually eat. The criterion serves only as a measure of nutrient density. The reference amount reflects what consumers actually eat. However, FDA notes that a criterion based on proposed levels per 50 g or per 30 g would be more compatible with consumption amounts than per 100 g for individual foods, although 50 g or 30 g amounts would still be substantially greater than the reference amounts for some food products such as minor condiments.

While the agency acknowledges that the proposed criterion of 100 g is too restrictive, FDA is concerned that the alternative suggestions of applying the proposed disqualifying levels per 100 g (e.g., 11.5 g per 100 g for fat) or proposed levels per 30 g (e.g., 3 g per 30 g for fat, which is about 10 g per 100 g) could still result in misleading claims

even if the weight-based criterion is applied only to foods that have reference amounts of 30 g or less or 2 tablespoons or less. For example, with either of these criteria, evaporated whole milk and liquid nondairy creamers could still make "low fat" claims, and regular cream cheese could still make a "low sodium" claim (Ref. 6). In addition, the use of the per 30-g criterion when applied to foods with these reference amounts (i.e., 30 g or less or 2 tablespoons or less) could result in misleading "low calorie" claims on products such as half-and-half, olives, and maraschino cherries. Accordingly, FDA has not adopted these alternatives.

The agency also considered the alternative suggested in the comment of using proposed levels per 50 g. If a 50-g criterion was applied only to foods that have reference amounts of 30 g or less or 2 tablespoons or less, then all of the products cited above as inappropriate for "low" claims would be prevented from making misleading "low" claims (Ref. 6). In addition, compared with FDA's proposed per 100-g criterion, the per 50-g criterion would permit more foods for which increased consumption is recommended in current dietary guidelines to make "low" claims. For example, more breakfast cereals and snacks such as pretzels and air popped popcorn could make "low fat" claims.

The agency concludes that the use of a per 50-g criterion when applied to foods with reference amounts of 30 g or less or 2 tablespoons or less minimizes confusing or misleading claims while maximizing appropriate "low" claims consistent with dietary guidance. Accordingly, the agency is revising relevant paragraphs of new §§ 101.60, 101.61, and 101.62 to provide for a weight-based criterion for these foods be based on nutrient levels per 50 g of food for "low" claims. The agency is also revising new § 101.61(b)(2) to require that the per 50-g criterion apply to "very low sodium" claims.

49. One comment stated that a weight-based density criterion would be unduly restrictive to dry products such as dehydrated soups and dry hot cereals that require water to be added and that would qualify based on an "as prepared" form but not on the "as purchased" form. This comment suggested that a criterion based on the hydrated product would be more equitable for foods that must have water added to them before typical consumption.

The agency points out that the weight-based criterion in the final rule does not apply to dehydrated soups or dry hot cereals because their reference amounts exceed the specified reference amounts to which the weight-based criterion applies. However, the agency agrees with the comment that the weight-based criterion should be applicable to the "as prepared" form when the product purchased is dehydrated, because the reference amount of the product, as well as any accompanying nutritional information, is based on the hydrated form of the food. Thus, the agency concludes that it would be inconsistent to require that a weight-based criterion be based on the dehydrated form when all other accompanying information is based on the "as prepared" or hydrated form. Thus, the agency supports this recommendation for its limited application to dehydrated products with reference amounts of 30 g or less or 2 tablespoons or less. Accordingly, FDA is also revising the above cited sections by inserting "For dehydrated foods that are typically consumed when rehydrated with only water, the per 50-g criterion refers to the as prepared form," to allow products that must have water added to them before typical consumption to make a claim if the "as prepared" hydrated form meets the per 50-g criterion.

2. Need for consistency of terms and limited number of terms

As discussed in the general principles proposal (56 FR 60431), the agency's approach to developing a system of nutrient content claims emphasizes three objectives: (1) Consistency among definitions, (2) claims that are in keeping with public health goals, and (3) claims that can be used by consumers to maintain healthy dietary practices.

The agency also noted that it has followed an approach that will limit the number of defined terms. This approach is consistent with that advocated in the Report of the "Fourth Workshop on Nutritional Quality and Labeling in Food Standards and Guidelines," Committee on the Nutritional Aspects of Food Standards, International Union of Nutritional Sciences (IUNS) (Ref. 13), which states that caution should be exercised to constrain the number of descriptors that are considered desirable. The IUNS Committee questioned the wisdom of more detailed descriptors because of the difficulties of consumer understanding of a plethora of such terms.

Alternatively, the agency noted that some have argued that establishing flexible provisions for the use of terms will facilitate consumer understanding by better attracting attention to the message being delivered about the food. In addition, the agency noted that some have suggested that defining more terms or providing greater flexibility for the use of various terms to convey nutritional information encourages competition among products and fosters nutritional improvement in products. The agency specifically requested comments on how it can balance the goals of consumer understanding and competition (56 FR 60421 at 60431).

50. Some comments did not agree with the objective of maintaining consistency among the definitions. One comment stated that consumers will not be confused by the use of nonconsistent terms. One comment stated that because the proposed definitions for absolute nutrient content claims such as "low" and "high" are based on uniform standards that apply across all food groups, many foods that can help consumers improve their diets will not meet the standards in these definitions.

It is important for effective consumer education to establish consistent definitions for descriptive terms whenever possible to limit the possibility of consumer confusion. Thus, FDA has not made changes in its regulations in response to these comments. However, should a situation arise in which a flexible approach to defining a term would promote public health goals or assist consumers in maintaining healthy dietary practices, the agency will consider adopting such an approach. In implementing the provisions of the act on nutrient content claims (e.g., through the petition process), the agency intends not to inhibit useful and informative competition in the marketplace, so long as it is still consistent with the three objectives stated above.

3. Synonyms

Section 3(b)(1)(A)(ix) of the 1990 amendments provides that regulations for nutrient content claims may also include similar terms that are commonly understood to have the same meaning.

To implement these provisions, the agency requested in the general principles proposal (56 FR 60421 at 60431) comments on a list of synonyms suggested by the Grocery Manufacturers of America (GMA), for the terms "no," "very low," "low," "significant," "high," and "very high." The agency also requested comments on a report by the Institute of Medicine (IOM) of the National Academy of Sciences (NAS'), entitled, "Nutrition Labeling Issues and Directions for the 1990's" (the IOM report) (Ref. 14) addressing concerns that a proliferation of synonyms on food labels will be confusing to consumers

who may believe that there are differences among the terms. Further, the agency requested comments on the use of synonyms for the nutrient content claims "free," "low," "high," and "source."

Section 403(r)(4)(A)(ii) of the act grants to any person the right to petition the Secretary (and FDA, by delegation) for permission to use terms in a nutrient content claim that are consistent (i.e., synonymous) with terms defined in regulations issued under section 403(r)(2)(A)(i).

51. Several comments stated that it is important to limit the number of synonyms, while some comments advocated that FDA ban the use of all synonyms. The comments argued that the 1990 amendments do not require synonyms, that the use of synonyms does not contribute to improved public health, and that synonyms are used by companies only to gain a competitive edge.

Some comments suggested that all synonyms put forward by GMA should be accepted. The comments generally contended that synonyms are necessary to allow manufacturers greater flexibility; that there are many truthful and informative synonyms for the basic descriptors FDA is defining; that all terms will carry some defined meaning; that use of multiple synonyms will encourage competition among products; and that as long as there is a single definition for a term and its synonyms, consumers will not be confused.

A few comments stated that FDA should permit undefined synonyms to be used in conjunction with either a consistent defined claim or a disclosure statement explaining the intended meaning. The comments argued that this approach would increase consumer understanding and confidence, without discouraging manufacturers' flexibility.

Another comment stated that qualitative research is needed to assess consumer understanding of descriptors before the publication of final regulations, and if such testing is not possible, definitions and synonyms should be tentative for 2 years and then reassessed.

FDA notes that many comments advocated either an extremely open or extremely restrictive approach to synonyms. However, FDA has not taken either of these positions. Because a goal of the 1990 amendments is to make nutrition information on the label or labeling of foods available in a form that consumers can use to follow dietary guidelines (H. Rept. 101–538, supra, 10), and the act envisions that synonyms for defined terms can be an appropriate means to communicate such information, the agency will evaluate synonyms according to the standard in the 1990 amendments, i.e., that the term is commonly understood to have the same meaning as a defined term. In doing so, FDA intends to be open to considering terms that meet this standard. However, FDA does not intend to permit any synonym that it believes would be unclear in meaning to consumers with respect to characterizing the level of a nutrient in a food. For instance, FDA does not consider the term "smidgen" to be commonly understood to mean "very low" in describing the level of a nutrient. Similarly, FDA does not consider the term "loaded" to be commonly understood to mean "high."

FDA disagrees with the comments that suggested that the terms and synonyms being established in this final rule should be permitted on a tentative basis for 2 years. FDA has sought to select terms and synonyms that are familiar to consumers. The standardization of these terms by regulation and the availability of nutrition labeling in conjunction with the claims, coupled with consumer education, will promote consumer understanding of their meaning. Thus, FDA believes that consumers will be able to use the terms and synonyms that it is defining to make informed dietary choices. Further, through petitions and rulemaking, FDA can change, add, or delete synonyms as new terms come to have established meanings or problems with defined terms become apparent.

FDA also disagrees with the suggestion that it permit undefined synonyms to be used in conjunction with either a consistent defined claim or a disclosure statement explaining its intended meaning, because the act requires that terms (including synonyms) used to characterize the level of a nutrient in a food be either defined by the agency or approved by the agency in response to a petition. There is no provision in the act that allows for the use of undefined synonyms in the absence of action by the agency.

In this document, FDA has considered various synonyms that have been suggested in the comments. The issues considered by the agency and its conclusions regarding specific synonymous terms are discussed in detail in the relevant sections of this document.

B. Terms Describing the Level of a Nutrient

1. Free

In the general principles and the fat/cholesterol proposals (56 FR 60421 and 60478), FDA proposed to define the term "free" for total fat, cholesterol, sodium, sugars, and calories. FDA also proposed to define the terms "no," "zero," "trivial source of," "negligible source of," and "dietarily insignificant source of" as synonyms for the term "free." The agency specifically requested comments on whether consumers commonly understand the meaning of all these terms to be, and whether the terms are in fact, synonymous.

In arriving at the proposed definition for "free" for each nutrient, the agency chose the level of the nutrient that is at or near the reliable limit of detection for the nutrient in food and that is dietetically trivial or physiologically inconsequential. The agency noted, however, that some manufacturers may add very small amounts of certain nutrients to aid in the manufacturing process for some products. FDA proposed not to allow use of the term "free" on such products, even if the products met the quantitative criteria for use of the term. However, the agency requested comments on whether "free" claims should be allowed on these products if they provide an appropriate disclosure statement and also on what such a disclosure statement should be.

FDA also proposed that "free" claims used on foods that are inherently free of a nutrient must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency requested comments on this provision.

a. Synonyms. A number of comments addressed synonyms proposed by FDA for "free" in the general principles and the fat/cholesterol proposals (56 FR 60421 and 60478). Many of these comments supported the use of synonyms for "free." Several comments agreed specifically with one or more of FDA's proposed synonyms for "free" such as "no" or "zero." One comment provided data showing that "free" and "no" are synonymous terms. Another comment provided data that "free" and "without" are synonymous terms.

52. At least one comment (a Ph.D. thesis) requested that the term "without" be a synonym for "free." The comment presented data in support of its request. This investigation (Ref. 15) was conducted at the University of South Dakota using 192 undergraduate students. The students' perceived notions of the amount of calories, fat, and cholesterol relative to 12 nutrient content claims terms were examined. The results demonstrated statistically that the participants perceived that "without" and "free" have the same meaning.

FDA agrees with this comment. The data presented, along with FDA's previous approval of the claim "without added salt," persuade the agency that "'without' should be a synonym for 'free'." Accordingly, the agency is revising new § 101.60(b)(1) on calories, new § 101.60(c)(1) on sugar, new § 101.61(b)(1) on sodium, new § 101.62(b)(1) on fat, new § 101.62(c)(1) on saturated fat, and new § 101.62(d)(1) on cholesterol, to allow "without" to be a synonym for "free."

53. One comment maintained that manufacturers are likely to abuse the terms "free" and "no."

FDA believes that most manufacturers will comply with the requirements of these regulations. However, manufacturers who violate the requirements for these definitions will be dealt with by appropriate regulatory action.

54. One comment suggested that "free" be used where there is an absence of a nutrient, and that a phrase such as "very small amount of" be used where the food contains very small amounts of a nutrient, even if the amount of the nutrient present is physiologically insignificant.

FDA rejects this suggestion. As discussed in the general principles proposal (56 FR 60421 at 60432), FDA believes that it is appropriate to apply the term "free" to a nutrient when a food contains that nutrient in a dietetically trivial or physiologically inconsequential amount, even though the nutrient is present at a level at or near its reliable limit of quantitation. With modern analytical methods, the level at which the presence of a nutrient may be quantified is becoming increasingly smaller. For example, there are almost no foods that can be said to be truly sodium free, yet the level of sodium present in some foods has no impact on the diet. Furthermore, the additional term would likely cause consumer confusion because it is ambiguous and would not be clearly distinguishable from "free" in a meaningful way.

55. One comment stated its support for the use of the word "none." Another comment suggested that "none" be used instead of "free" but gave no reason for this suggestion.

The comment did not provide sufficient supporting information to persuade the agency that consumers commonly understand "none" to have the same meaning as "free." Therefore, FDA is not providing for the use of "none" as a synonym for "free" at this time. However the agency advises that interested persons may submit a synonym petition for the use of this term as prescribed in new § 101.69.

56. Several comments supported the synonyms for "free" that contain "source of" language (i.e., "trivial source of," "negligible source of," "dietarily insignificant source of"). One comment stated that the de minimis nutrient threshold levels encompassed by such phrases are of no public health concern. Several comments disliked these proposed synonyms. Some of these comments asserted that these phrases could be confusing or misleading to consumers. One comment pointed out that the inclusion of the word "source" in some of the synonyms for "free" could confuse consumers because the agency had given another meaning to this word in the general principles proposal.

In this final rule, as explained later in this document, FDA is changing the descriptive term "source" to "good source" to clarify its meaning and relative position in the hierarchy of descriptive terms. As a result, FDA does not believe that the use of the words "_____ source of" in some synonyms for "free" will be confusing to consumers. Therefore, FDA is maintaining the position that it took in the general principles proposal (56 FR 60421 at 60434) that the terms "trivial source of," "negligible source of," and "dietarily insignificant source of" are suitable synonyms for "free," provided that they are used on the labels or in labeling of foods in accordance with the agency's definition.

57. Another comment stated that, unlike "no" and "zero," which are absolute terms, the terms containing the language "_____ source of" could be misinterpreted.

FDA acknowledges that "free," "no," and "zero" are absolute terms that are synonymous to one another in their meaning. However, FDA also believes that the "_____ source of" terms that it has listed as synonyms of "free" are appropriate for use on the food label and consistent with the agency's definition for "free" because they express that the nutrient is present at or near the reliable limit of detection and thus at a dietetically trivial or physiologically inconsequential level. Therefore, FDA concludes that no change is warranted in response to this comment.

58. One comment objected to the use of the phrases "trivial source of," "negligible source of," and "dietarily insignificant source of" as synonyms for "free" because such phrases equate the presence of trivial amounts of a nutrient with the absence of a nutrient. The comment asserted that people can experience life-threatening reactions to "trivial" amounts of substances.

FDA does not agree that these phrases are inappropriate as synonyms for the "free" nutrient content claims that are being defined in this final rule. As explained above, FDA defined the term "free" based on a dietarily insignificant amount of the nutrient in question, and these terms are consistent with that definition.

Further, FDA advises that the nutrient content claims that it is defining in this final rule provide consumers with information about nutrients in a food, and not about substances in foods that consumers may need to avoid because of allergies or intolerances. A consumer should read the ingredient list on the food label to determine whether a food contains a substance he or she needs to avoid.

59. Several comments suggested that FDA include the terms "not any," "not a bit," "not a trace," "never a bit," "never a trace," "negligible," "dietary isignificance," "trivial amount of," and "meaningless" as synonyms for "free."

These comments did not provide sufficient supporting information to persuade the agency that consumers commonly understand the terms "not any," "not a bit," "not a trace," "never a bit," "never a trace," "negligible," "dietary insignificance," "trivial amount of," and "meaningless" to have the same meaning as "free." Therefore, FDA is not providing for the use of any of these terms as synonyms for "free" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in new § 101.69 of this final rule.

60. Some comments suggested that variations in spelling be allowed for descriptors and their synonyms.

Although FDA has not specifically provided for variations in the spelling of various descriptive terms or their synonyms, except for "light" ("lite"), the agency believes that reasonable variations in the spelling of these terms would be acceptable, provided that these variations are not misleading to consumers. However, should the agency encounter terms that use questionable variations in spelling, it will evaluate these variations on a case-by-case basis to determine whether they comply with section 403(a) and (r) of the act.

b. Statutory limitations on circumstances in which an absence ("free") claim may be made. The 1990 amendments describe the circumstances in which claims that state the absence of a nutrient may be made on a food. Section 403(r)(2)(A)(ii)(I) and (r)(2)(A)(ii)(II) of the act, respectively,

provide that a claim may not state the absence of a nutrient unless: (1) The nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary (and FDA, by delegation), or (2) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices, and the statement discloses that the nutrient is not usually present in food.

i. Substitute foods. In the general principles proposal (56 FR 60421 at 60432), FDA proposed to define when one food may be considered to substitute for another to eliminate any confusion that may arise over this issue. In § 101.13(d), FDA proposed that a substitute food is one that is used interchangeably with another food that it resembles in its physical, organoleptic, and functional characteristics, and that it is not nutritionally inferior to that food unless it is labeled as an "imitation." The agency also proposed in § 101.13(d)(1) that a food that does not possess the same characteristics as the food for which it substitutes must declare the difference on its label or in its labeling, adjacent to the most prominent claim. FDA also proposed in § 101.13(d)(2) that any declaration (i.e., disclaimer) made regarding the different characteristics of the substitute food should be in easily legible print or type, no less than one-half the size of the descriptive term.

The agency also stated in the proposal that it believes that identifying imitation foods that meet nutrient content claim definitions may provide a benefit to the consumer, even though they are nutritionally inferior. Therefore, FDA tentatively concluded that such foods should be allowed to bear nutrient content claims, as long as they are appropriately labeled.

61. A few comments agreed with FDA's proposed definition for substitute foods. Some of the supporting comments stated that regulations governing the use of substitute foods are necessary to avoid misleading consumers who are not aware of the dissimilarities between an original food and a food that serves as a substitute food. However, one comment stated that the agency lacks the legal basis to prescribe the use of disclosure statements on substitute foods as extensive as that proposed by the agency. This comment suggested that a disclaimer statement should not be required on substitute foods, and that the required statement is excessive and will result in a label that is confusing to consumers.

The agency disagrees with the comment that FDA has no legal basis to require disclaimer statements on substitute foods. As the agency stated in the proposal (56 FR 60421 at 60432), section 201(n) of the act provides that food labeling is misleading, and thus the food is misbranded under section 403(a) of the act, if it fails to disclose facts material to the consequences of the use of the food. For example, if a food has different performance characteristics than the food for which it substitutes, this fact must be disclosed in conjunction with the claim that draws a connection between the two foods. Under sections 201(n), 403(a), and 701(a) of the act, the agency has the authority to require disclaimer statements when these statements are necessary to disclose material facts.

The agency also disagrees with the contention that disclaimer statements will confuse consumers. The agency believes that this information is of value to consumers because it informs them about important aspects of the food that otherwise would not be evident.

62. Some comments addressed specific aspects of disclaimer statements. One comment that opposed the agency's proposed definition for a substitute food stated that the proposal is overly broad, and that FDA should limit the disclosure requirements to differences that materially limit the uses of a substitute food when compared to the food it resembles.

The agency has reconsidered its proposed requirements for disclaimer statements. FDA believes that "differences in performance characteristics" between a substitute food and an original food may include minor differences that consumers would consider relatively unimportant for that food (e.g., a different freezing point for a nonfat thousand island dressing substitute). The agency believes that such differences are significant only when they materially limit the use of the food compared to the use of the original food (e.g., "not recommended for frying"). FDA concludes that when the differences between the substitute food and the original food do not limit the use of the substitute, they need not be disclosed because they would not be considered to be material facts that relate to the consequences of the use of the food. Therefore, the agency is revising new § 101.13(d)(1) to state, that:

> If there is a difference in performance characteristics that materially limits the use of the food, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

Furthermore, to ensure that the disclaimer is presented with appropriate prominence, consistent with the requirements for other required supplementary information (e.g., referral statements), the agency is revising new § 101.13(d)(2) to read:

> This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth inch.

63. A few comments stated that "shelf life" should be deleted from the definition because future developments may result in superior substitute foods with a longer shelf life.

The agency rejects this comment. The agency believes that, for two foods to be considered to be used interchangeably, they should generally resemble each other with respect to shelf life. However, the agency points out that the definition does not require that the substitute possess the same shelf life characteristics as the original food. As revised, the regulation would only require disclosure of the shelf life of the substitute food if that information is a material fact, as discussed in the previous comment.

64. One comment requested that FDA provide clarification in the final rule that differences in shelf life can be disclosed through code dates or freshness guarantee statements.

When shelf life information is required under the revised provisions, it would be appropriate to disclose the information through code dates or freshness guarantee statements if this information is presented in a readily understandable manner, in accord with the other requirements for disclaimers.

65. One comment suggested that any differences in performance characteristics associated with substitute foods should be located in the bottom 30 percent of the PDP as provided for in proposed § 101.67(b). This comment argued that proposed § 101.13(d)(1) should be revised to conform to that provision.

FDA rejects this comment. The agency believes that the disclaimer should be adjacent to the most prominent claim as it proposed because of the importance of the information. Further, the agency also notes that in the final rule on the use of nutrient content claims for butter, which appears elsewhere in this issue of the **Federal Register**, it is revising new

§ 101.67 to be consistent with new § 101.13(d)(1).

66. One comment argued that the dietary, health, and economic consequences regarding the use of substitute foods have not been addressed. This comment stated that the nutritional science associated with substitute foods is insufficient to fully determine whether they should be considered equivalent to traditional foods.

FDA is not authorized under the act to judge the dietary, health, or economic consequences of the use of substitute foods. Under section 403(r)(2)(A) of the act, foods that substitute for other foods must satisfy certain requirements if they are to bear nutrient content claims that highlight differences between them and the foods for which they substitute (see, e.g., section 403(r)(2)(A)(ii)(I) of the act). By issuing these labeling provisions for substitute foods, FDA has not judged that substitute foods are equivalent to traditional foods. These provisions are intended to ensure that material differences between the use of the substitute food and the use of the original food are conspicuously stated on the label or labeling of the food, so that consumers can make fully informed judgments about their value and their usefulness in maintaining healthy dietary practices.

67. A few comments expressed the view that consumers may not understand the difference between substitute foods and imitation foods. One of these comments suggested that data should be used to evaluate consumer perception on the differences between these terms.

FDA is not aware of any consumer confusion from the use of the terms "substitute" and "imitation" on food labels, nor did these comments provide any information to show that such confusion exists. Imitation foods are a subgroup of substitute foods. Under § 101.13(e), imitation foods are defined as being nutritionally inferior to the foods for which they substitute and that they resemble. FDA believes that the labeling requirements for substitute, and imitation foods will enable consumers to understand the nature of each of these types of foods. Therefore, FDA is making no change in response to these comments.

ii. Foods inherently free of a nutrient. In the general principles proposal (56 FR 60421 at 60433), the agency proposed for calories in § 101.60(b)(1)(ii) and sodium in § 101.61(b)(1)(iii) that if a food is inherently free of the nutrient, without the benefit of special processing, alteration, formulation, or reformulation to lower the content of that nutrient, a "free" claim on such food must refer to all foods of that type and not to a particular brand. In the fat/cholesterol proposal, the agency proposed a similar requirement for foods inherently cholesterol free (proposed § 101.62(d)(1)(i)(D) and (d)(1)(ii)(E)) or fat free (proposed § 101.62(b)(1)(iii)).

FDA proposed to establish this approach as a general requirement for nutrient content claims for "free" and claims for "low" in § 101.13(e)(2). Conversely, the agency provided in proposed § 101.13(e)(1) that, if a food has been processed, altered, formulated, or reformulated to remove the nutrient from the food, it may appropriately bear the terms "free" or "low" before the name of the food. FDA specifically requested comments on the proposed provision allowing "free" or "low" claims on foods that do not usually contain, or are usually low in, a nutrient.

68. A few comments stated that the agency should not allow use of the statement "————, a (nutrient) free food," on processed foods that do not normally contain the nutrient. These comments contended that this approach would eliminate the use of claims where the only benefit is to the manufacturer.

The agency rejects this comment. The agency believes, as stated in the proposal (56 FR 60421 at 60433), that highlighting that a food is free of a nutrient can help consumers to maintain healthy dietary practices whether the food is inherently free of that nutrient or is processed to be that way. Further, FDA believes that when a food is inherently free of a nutrient as a result of how it has been formulated, the disclosure "————, a (nutrient) free food" is necessary to prevent "(nutrient) free" claims from being misleading.

69. One comment argued that FDA should consider use of the term "naturally low in fat" instead of "————, a fat free food." Another comment preferred more flexibility in the wording of nutrient qualifiers (e.g., "as always, sodium free" or "naturally sodium free").

FDA points out that new § 101.13(e)(2) does not dictate the precise wording that manufacturers are to use to advise consumers that the food inherently meets the criteria and to clearly refer to all foods of that type. Therefore, the agency believes that the regulation contains sufficient flexibility with respect to the wording of the required qualifier. FDA will assess qualifying statements used on labels to determine whether the wording used meets the requirements of the regulations and take action on those that do not. Clearly, all such possible qualifiers do not meet the regulatory criteria. For example, FDA believes that the term "always" as used in the disclosure statement suggested by the comment does not clearly indicate that all foods of that type are also free of the nutrient. Thus, it may be interpreted to mean that only that brand of the food is free of the nutrient, and, as such, the claim is misleading.

70. Some comments opposed use of the statement "a fat free food" on foods that are inherently fat free. These comments stated that foods naturally "fat free" are placed at a disadvantage as compared to foods that have been modified to lower their fat level. One comment suggested that use of the term "fat free" instead of "————, a fat free food" should be appropriate on foods that are inherently fat free.

The agency disagrees with these comments. FDA continues to believe that when a "fat free" claim is made on foods that are inherently free of that nutrient, the claim is misleading unless it is accompanied by a statement that all foods of that type are inherently fat free. Thus, the agency is not providing for the use of "fat free" without the disclaimer on foods that are inherently fat free.

71. One comment requested clarification of proposed § 101.13(e)(1). The comment noted that the language of that section allows only those foods that are formulated, reformulated, specially processed, or altered to remove a nutrient from the product to bear the claim "free" or "low" before the name of the food, without the generic statement that all foods of that type are "free" of, or "low" in, that nutrient. The comment asserted that it is not clear whether a food that has been formulated to not include a nutrient that could be present in the food would be allowed to bear a claim addressed by proposed § 101.13(e)(1). For example, potato chips, fried in vegetable oil are free of cholesterol because the oil is cholesterol free, while potato chips fried in lard are not cholesterol free because of the cholesterol introduced by the lard. The comment emphasized that such foods are not "inherently free" of a nutrient but have instead been formulated so that the nutrient is not added. The comment recommended that the agency allow the terms "free" and "low" to be used on such products.

FDA agrees that there is a need for clarification in proposed § 101.13(e)(1) to allow for the use of "free" and "low" claims on foods that are formulated in such a way that certain nutrients that may be present in the food are not added to the product. The agency

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believes that formulating a food in a way that precludes certain nutrients from being added to the food is equivalent to processing a food such that the nutrient is removed from the product. Thus FDA has modified new § 101.13(e)(1) to state:

> Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food may bear such a claim (e.g., "low sodium potato chips").

FDA believes that this amendment will alleviate any confusion concerning the appropriate use of "free" and "low" claims.

72. A few comments suggested that FDA should expand its criteria for claims regarding the absence of a nutrient to encompass foods produced by modern advances in technology, e.g., biotechnology, horticulture, or crop selection.

FDA's criteria for nutrient content claims apply to all foods. The agency is not aware of special needs with respect to foods of the types mentioned in the comment and cannot conclude at this time that special provisions in the regulations are needed for these foods.

c. Specific definitions

i. Sodium free and terms related to salt

73. Several comments objected to the provision in proposed § 101.61(b)(1)(ii) that a food containing added salt (sodium chloride) or any ingredient that contains sodium cannot be labeled "sodium free," even though it still contains 5 mg or less of sodium per serving. One of these comments stated that "free" terms should be based solely on the analytical definition, and that consumer education programs should be set up to explain the definitions. Other comments agreed that the food should not contain any added sodium chloride but believed that disallowing ingredients containing sodium was unnecessary and overly restrictive. A trade association for the cracker industry said that for years "sodium free" crackers have been used at hospitals for patients on sodium-restricted diets. Because these crackers are made with enriched wheat flour that naturally contains trivial amounts of sodium, they could not continue to be marketed as "sodium free" under the proposed rule. This comment requested that proposed § 101.61(b)(1)(ii) be entirely eliminated or modified to allow a "sodium free" claim when a food has ingredients that contain naturally occurring sodium.

Alternatively, some comments totally supported the proposed rule. They agreed that the listing of salt as an ingredient of a product bearing a "sodium free" claim is confusing, and, therefore, its addition should be disallowed. Other comments suggested that the confusion could be eliminated if the label of such a product explained that the product contains a trivial amount of sodium. Most of these comments preferred that such a disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of sodium chloride or ingredients that contain sodium to foods that bear a "sodium free" claim and is persuaded that it is unduly restrictive. The agency accepts the recommendation that the proposed provision be eliminated, and that a disclosure statement be required to avoid consumer confusion about the quantity of sodium in the food. The agency is persuaded that it is the listing of salt (sodium chloride) or related substances that are generally understood by consumers to contain sodium (e.g., baking soda or ingredients with sodium as part of their common or usual name such as sodium ascorbate) that creates the confusion. Accordingly, the agency is revising new § 101.61(b)(1)(ii) to require that the listing of these ingredients in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement is to read: "adds a trivial amount of sodium," "adds a negligible amount of sodium," or "adds a dietarily insignificant amount of sodium." The agency concludes that ingredients that may contain trivial amounts of sodium, such as enriched flour used in making crackers, do not contribute to consumer confusion and, thus, do not need a disclosure statement.

74. One comment requested that any label on which the term "sodium free" appears be required to include the disclosure, "contains less than 5 mg of sodium per serving." This comment stated this disclosure would alert consumers to the possible presence of a dietarily insignificant amount of sodium, and, thus, an ingredient list that includes a sodium-containing compound would no longer be a potential source of confusion.

The agency disagrees with this recommendation because it believes that requiring a disclosure with all "sodium free" claims is not necessary and would add to label clutter. In the document on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, FDA is concluding that less than 5 mg of sodium is a dietarily insignificant amount and may be declared as "0" in the nutrition label. The agency sees no reason to take a different position with respect to the nutrient content claim. Disclosing the quantitative amount of sodium on a label that bears a "sodium free" claim and declares "0" sodium in the nutrition label would only create consumer confusion. Accordingly, the agency is not revising new § 101.61(b)(1) to require the requested disclosure.

75. A few comments requested that products not meeting the "sodium free" definition because they contain 5 mg or more of naturally occurring sodium should be allowed to use the claim "unsalted" ("without added salt," "no salt added") without having to disclose "not a sodium free food." One comment stated that there is virtually no risk that a consumer would associate "unsalted" as being synonymous with "sodium free." Another comment requested that the term "unsalted" be a synonym for "salt free" foods. Other comments disagreed and supported the requirement for a disclosure.

The term "unsalted" ("without added salt" or "no salt added") on a food that is not sodium free and that does not disclose that it is "not a sodium free food" could mislead consumers, as explained in the proposed rule (56 FR 60435). The comments presented no evidence that consumers would not be confused by this claim without the disclosure. Therefore, the agency is not persuaded to change its position on the need for the disclosure. However, to reduce the amount of information required on the principal display panel, the agency will allow this disclaimer to be placed in the information panel. The referral statement required by section 403(r)(2)(5) of the act will refer the consumer's attention to the information panel. This statement will ensure that this material fact is brought to the consumer's attention through a statement made in conjunction with the claim. Accordingly, the agency is changing the required location of this disclosure in § 101.61(c)(2)(iii).

Furthermore, the agency does not agree that the term "unsalted" should be used as a synonym for the term "salt free." To confine "unsalted" claims only to foods that meet the "sodium free" definition, including foods bearing a "salt free" claim, would be overly restrictive. The agency is denying this request.

76. One comment stated that for over 25 years, cracker manufacturers have been making crackers with no surface

salt that are described on their labels as "Unsalted Tops * * * Crackers." These crackers are made with sodium chloride and baking soda and have never claimed to be low or reduced in sodium. The comment says that these products meet the desire of some consumers for crackers that taste less salty. The comment asked whether this name can continue to be used in light of proposed § 101.61(c)(2)(i), which specifies that the term "unsalted" may only be used on a food label if no salt is added to the food during processing. It requested that the rule be modified to allow for the use of the name "Unsalted Tops * * * Crackers" as well as other names in which the term "unsalted" is qualified and does not refer to the entire food.

The use of the term "unsalted," as it appears in the name "Unsalted Tops * * * Crackers," modifies the word "tops." When used in this context, "unsalted" does not refer to the salt content of the entire food. For this reason, the agency does not consider this use of the term "unsalted" to be subject to the requirements of new § 101.61 and does not believe that this rule needs to be modified to allow for the use of this name or other names in which the term "unsalted" is qualified in this manner. Accordingly, the agency has not revised the definition of "unsalted."

77. One comment stated that it is misleading for plain corn to claim "no added salt" when frozen corn does not have added salt.

In the absence of details in the comment, the agency presumes that this comment is referring to canned corn by the term "plain corn." The agency has a food standard (§ 155.130) for canned corn that permits salt as an optional ingredient and understands that salt is usually added to this product. The agency believes that if no salt is added to canned corn, the food that it resembles and for which it substitutes is canned corn, not frozen corn. Therefore, the agency concludes that it is not misleading for the product to bear the claim "no added salt."

ii. Sugar free. 78. At least one comment recommended that FDA define the term "sucrose free" instead of "sugars free."

The agency disagrees. Sucrose is only one of the sugars found in foods. For this reason, the agency believes that the term "sucrose free" would mislead consumers into believing that the food is free of all sugars. Accordingly, the agency is not defining "sucrose free."

79. At least one comment recommended that FDA define the term "no refined sugar."

The agency is not accepting these comments. The agency is concerned that consumers would be misled into believing that a food containing no refined sugar is better than a food containing refined sugar. The dietary guidelines (Ref. 7) advise Americans to consume sugars in moderation. Consumers need to understand that it is the amount of dietary sugar, not whether or not it is refined, that is important in following the guidelines. Accordingly, the agency is not defining the term "no refined sugar."

80. A couple of comments requested that the term "sugar free" be used instead of the term "sugars free." One comment said that the term "sugar free" would be in harmony with the term permitted in Canada and other countries. Another comment stated that although the term "sugars free" is technically correct, it is unfamiliar and will confuse the majority of consumers. The comment expressed doubt that consumers understand or care about FDA's reasons for proposing "sugars free" and believed that only a few consumers would notice that the listing in the nutrition label is for "sugars," not "sugar."

The agency is persuaded, based on the arguments made by the comments, that the term "sugars free" may be confusing to consumers. Accordingly, the agency is defining the term as "sugar free" in § 101.60(c)(1). The agency points out that this section provides that a food label may bear this claim if the food contains less than 0.5 g of sugars, as defined in new § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register** (redesignated from § 101.9(c)(6)(ii)(A) in the proposal). FDA proposed to define "sugars" as the sum of all free mono- and oligosaccharides through four saccharide units and their derivatives (such as sugar alcohols). However, as discussed in the final rule on nutrition labeling, in response to comments, the agency is changing the definition to include only mono- and disaccharides. Thus, the term "sugar free" refers to less than 0.5 g of mono- and disaccharides.

81. At least one comment requested that FDA define "sugar free" as free of all simple sugars.

FDA disagrees with this comment. As explained in the above section, the agency is defining "sugar free" as less than 0.5 g of sugars, that is mono- and disaccharides. FDA believes that this terminology is more precise than the term "simple sugars."

82. Numerous comments requested that the term "sugar free" be allowed to describe foods containing sugar alcohols (polyols). These comments suggested that FDA either should exclude sugar alcohols from the definition of "sugars" or should broaden the exemption in proposed § 101.13(o)(8) that allows the term "sugar free" on the label of chewing gums that contain sugar alcohols. The comments requested that foods containing sugar alcohols, such as soft candies, hard candies, breath mints, lozenges, and sodas, be included in the exemption. Alternatively, a few comments stated that allowing the claim "sugar free" on chewing gums would be confusing to consumers if sugar alcohols are included in the definition of sugars. One of these comments proposed that the claim on chewing gums should be "contains sugar alcohols" rather that "sugar free." Other comments suggested that the claim on chewing gums as well as other foods containing sugar alcohols should be "sugarless" to avoid confusion with foods meeting the definition of "sugar free." They believed that this term should be allowed only for foods that typically contain sugar, are modified to contain only sugar alcohols, and do not contain other carbohydrates.

The agency has reconsidered this issue and is persuaded that the term "sugar free" should be allowed to describe foods containing sugar alcohols. As described above, the agency is changing the definition of sugars to include only mono- and disaccharides. Thus, sugar alcohols are no longer included in this definition. A food containing sugar alcohols may bear a "sugar free" claim as long as it meets the requirements in new § 101.60(c)(1) for "sugar free" and in new § 101.9(c)(6)(iii) that polyol content be disclosed, as discussed in the final rule on nutrition labeling published elsewhere in this issue of the **Federal Register**. Accordingly, the agency is deleting proposed § 101.13(o)(8) because the exemption that is provided is no longer needed.

83. Numerous comments supported the statement "useful only in not promoting tooth decay" in proposed § 101.13(o)(8), to continue to allow on the label of chewing gums that claim to be "sugar free." Many of the comments requested that the statement be allowed on the labels of other foods containing sugar alcohols that claim to be "sugar free." One comment suggested that FDA should revise the definition of "sugars" to exclude sugar alcohols and revise proposed § 101.60(c)(1)(iii)(B) to allow the requested statement to accompany "sugar free" claims. This provision, as proposed, would require either the statement "not a reduced calorie food," "not a low calorie food," or "not for

weight control." Other comments suggested that FDA should broaden the exemption in proposed § 101.13(o)(8) to allow the requested statement to appear on other foods. Alternatively, at least one comment suggested only the statements "not a reduced calorie food" and "not a low (free) calorie food" are appropriate. The comment specifically suggested that FDA should disallow the statement "useful only in prevention of tooth decay" with "sugar free" claims. This comment also implied that FDA should disallow the statement "not for weight control" with "sugar free."

The agency has reviewed these comments and has determined that there is no compelling reason to disallow the statement "not for weight control." However, the agency has concluded that the statement "useful only in not promoting tooth decay" should not be allowed because it is an unauthorized health claim. In the general principles proposal (56 FR 60437), the agency stated that it intended to reevaluate the usefulness of chewing gums sweetened with sugar alcohols in not promoting tooth decay. The agency acknowledged that the data supporting the claim were over 20 years old and requested new data. The agency received data in response to the request and will make a determination on the validity of this claim in accordance with the final rule on health messages published elsewhere in this issue of the **Federal Register**. Accordingly, the agency is not revising § 101.60(c)(1)(iii)(B) to allow the statement "useful only in not promoting tooth decay" to appear with "sugar free" claims.

The agency is deleting the exemption in proposed § 101.13(o)(8) that would have allowed a "sugar free" claim on chewing gums containing sugar alcohols and the statement about not promoting tooth decay. As explained above, this exemption is no longer needed because the agency has decided not to define sugar alcohols as "sugars."

84. Many comments requested that FDA revise proposed § 101.13(o)(8) to allow the statement "Toothfriendly" to accompany "sugar free" claims on the label of chewing gums in place of the statement "useful only in not promoting tooth decay." In addition, these comments requested that such statements may be accompanied by a pictogram of a smiling tooth. These comments stated that the term "Toothfriendly" is more readily understood by consumers with limited reading and vocabulary skills. One comment said the "Toothfriendly" dental education programs have been successfully promoted in several European countries by "Toothfriendly Sweets International," a nonprofit organization dedicated to promoting dental health. The agency received at least one comment opposing the term "Toothfriendly." The comment contended that the "Toothfriendly" program is just another third party endorsement program similar to those the agency has considered in the past. It stated that the claim is unsupported by any evidence and would promote the consumption of foods that are completely without nutritive benefit.

The agency is denying this request because it believes that the statement "Toothfriendly" accompanied by a pictogram of a smiling tooth is an implied health claim that, unless a regulation is established, is unauthorized (see section 403(r)(1)(B) of the act). As discussed in the previous comment, the agency has not made a determination that chewing gums sweetened with sugar alcohols are useful in not promoting tooth decay.

85. A few comments stated that the definition of "sugar free" should be less than 4 g per serving. They said that they selected this value because it is the dietary requirement for diabetics. Another comment requested that the term "sugar free" be accompanied by the statement: "For use in diabetic meal plans. Not a reduced calorie food (if appropriate)."

The agency does not agree that "sugar free" should be less than 4 g of sugars per serving as explained in the general principles proposal (56 FR 60421 at 60436). The agency emphasized there that the definitions of nutrient content claims do not specifically address issues related to diabetes management practices, and that diabetes management should not be based solely on the consumption of "sugar free" foods. Rather, diet planning for diabetics should encompass the entire diet and be supervised by a trained professional. The agency notes that the American Diabetes Association (ADA) submitted a comment that expressed strong support for defining "sugar free" at less than 0.5 g per serving. It stated that the amount of sucrose or other sweeteners in their recipes should not be used in the context of support for defining this claim. Accordingly, the agency is not defining "sugar free" as less than 4 g per serving. Consistent with this policy on "sugar free," the agency also denies the request that "sugar free" claims be accompanied by the statement, "For use in diabetic meal plans. Not a reduced calorie food."

86. A couple of comments objected to the provision in proposed § 101.60(c)(1)(ii) that a food containing added ingredients that are sugars cannot be labeled "sugar free," even though it still contains less than 0.5 g of sugars. One comment stated that FDA should not distinguish between trivial amounts present naturally, and those present because they were added. Other comments supported the proposal. They agreed that the listing of a sugar, for example, as an ingredient of a product bearing a "sugar free" claim is confusing and misleading. One comment expressed concern that the agency is allowing ingredients containing sugars, such as fruit juices, to sweeten foods that bear a "sugar free" claim. Other comments suggested that the confusion could be eliminated if the label of a "sugar free" food that has ingredients containing sugars disclose that the amount of sugar is trivial. Most of these comments preferred that the disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of ingredients that are sugars to foods that bear a "sugar free" claim and is persuaded that it is unduly restrictive. The agency accepts the recommendation that the proposed provision be revised and that a disclosure statement be required to avoid consumer confusion about the quantity of sugar in the food. The agency believes that it is the listing of sugar or ingredients that are generally known to contain sugars that creates the confusion. Accordingly, the agency is revising new § 101.60(c)(1)(ii) to require that the food contain no ingredient that is a sugar, or that is generally understood by consumers to be a sugar, unless the listing of the ingredient in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of sugar," "adds a negligible amount of sugar," or "adds a dietarily insignificant amount of sugar."

iii. "No added sugar," and "unsweetened"/"no added sweeteners". In the general principles proposal (56 FR 60421 at 60437), FDA proposed in § 101.60(c)(2) to permit the use of the terms "no added sugars," "without added sugars," or "no sugars added" (revised in this final rule to state "no added sugar," "without added sugar," or "no sugar added" as discussed in the section on "Sugar Free"). The agency said, however, that to use the claim five conditions must be met: (1) No amount of sugars, as defined in proposed § 101.9(c)(6)(ii)(A) (redesignated as § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**), is added during processing or

packaging; (2) the product does not contain ingredients that contain added sugars; (3) the sugars content has not been increased above the amount naturally present in the ingredients by some means such as the use of enzymes; (4) the food that it resembles and for which it substitutes normally contains added sugars; and (5) the product bears a statement that the food is not low calorie or calorie reduced (unless the food meets the requirements for a low or reduced calorie food) and directing consumers' attention to the nutrition panel for further information on sugars and calorie content.

The intent of the agency in defining these terms was to aid consumers in implementing dietary guidelines that stipulate that Americans should "consume sugars only in moderation," consistent with the definition for "sugars" that FDA is adopting in new § 101.9(c)(6)(ii) in the final rule on mandatory nutrition labeling. In implementing the guidelines, the purpose of the "no added sugar" claim is to present consumers with information that allows them to differentiate between similar foods that would normally be expected to contain added sugars, with respect to the presence or absence of added sugars. Therefore, the "no added sugar" claim is not appropriate to describe foods that do not normally contain added sugars. In such cases, proposed § 101.60(c)(3) would provide for the use of a factual statement that the food is unsweetened, or that it contains no added sweeteners in the case of a food that contains apparent substantial inherent sugar content, e.g., fruit juices, without requiring that the food meet the definition for "sugar free."

87. Some comments addressed use of the "no added sugar" terms on foods containing fruit juice as an ingredient. One comment interpreted the proposal as providing that modified juice products and juice products that function as sweeteners are not to be considered as added sugars. The comment specifically requested that FDA clarify its position on this matter. Another comment stated that the use of fruit juices as sweetening agents caused problems for diabetics and suggested that the five requirements listed in new § 101.60(c)(2) for a "no added sugar" claim should be supplemented by a sixth criterion: That a food does not contain sugars in the form of fruit juice, fruit concentrate, applesauce, or dried fruit.

The agency advises that the purpose of a "no added sugar" claim is to identify a food that differs from a similar food because it does not contain the added sugars that would normally be present in the other food. For this provision to be of practical benefit to consumers, it must preclude use of the claim on a food where the sugars that are normally added are replaced with an ingredient that contains sugars that functionally substitute for the added sugars. Thus, the agency concludes that the use of any ingredient that contains sugars, including fruit juice and modified or concentrated fruit juice, for the purpose of substituting for sugars that would normally be added to a food precludes the use of the "no added sugar" nutrient content claim. To avoid misinterpretation of the regulation on this matter, FDA is revising new § 101.60(c)(2)(i) to state: "No amount of sugars, as defined in § 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging."

88. One comment interpreted proposed § 101.60(c)(2) to mean that a "no added sugar" claim would not be precluded on a product such as an all-fruit spread if that product does not contain sugar-sweetened ingredients.

FDA advises that to qualify for a "no added sugar" claim, the ingredients in the all-fruit spread could not include any ingredient that meets the agency's definition of "sugars" (new § 101.9(c)(6)(ii)), or any ingredient that contains sugars that functionally substitute for added sugars (e.g., fruit juice) (new § 101.60(c)(2)(i)), nor any ingredient that contains added sugars (e.g., concentrated fruit juice) (new § 101.60(c)(2)(ii)).

89. A comment recommended that foods that contain only indigenous sugars, but not including sugars present in concentrated or otherwise altered ingredients or products, be exempt from the requirement for disclaimer and referral statements. This comment stated that a statement such as "no added sugar" is less a nutrient content claim than an assurance that the sweetness characteristics of a product are not derived from added processed sugars, such as sucrose or high fructose corn syrup, and that this information is essential to diabetics that have been instructed by a physician to seek out foods that do not have added processed sugar but instead are fruit juice based.

The comment suggested that the required disclaimer indicating that a food is not "low" or "reduced" in calories may be misleading to consumers, causing unjust alarm that a juice product is high in calories and unhealthy. As an alternative to the disclaimer, the comment favored a qualifying statement for foods sweetened with concentrated juices, such as "sweetened with concentrated grape juice."

A similar comment requested that FDA exempt pure fruit juices from the provisions of proposed § 101.60(c)(2) or revise this section by deleting proposed § 101.60(c)(2)(iv) and (c)(2)(v) (i.e., the requirements that the food that the product resembles and for which it substitutes normally contains added sugars, and that the product bear a disclaimer statement that it is not low calorie or calorie reduced and that directs the consumer's attention to the nutrition panel). The comment stated that a "no added sugar" claim on fruit juices had been used for many years without consumer confusion, that it helped to increase consumer awareness of the added sugars in flavored drinks, and that products that are pure juices do not contain added sugars. The comment also stated that consumers regard the terms "no added sweeteners" and "no added sugar" as synonymous, and that they do not regard juices as low or reduced calorie products.

The agency disagrees with the fundamental position of these comments that a special allowance for the "no added sugar" claim should be made when the sugars added to a food are inherent to the ingredient through which they are added. As discussed in comment 79 in section III.B.c.ii. of this document, the agency believes that it is misleading to imply that a food that contains inherent sugars is nutritionally superior to a food that contains refined sugars. Thus, the labeling of a product sweetened with juice concentrate, though it bears a factual statement identifying the source of the sweetener, would be misleading if it included the statement "no added sugar." The agency concludes that granting the allowances that these comments seek would permit the use of "no added sugar" in a manner that is inconsistent with the purpose of this claim, i.e., to aid consumers in implementing dietary guidelines that stipulate that Americans should "consume sugars only in moderation." Thus, FDA is not making any changes in response to these comments.

90. One comment expressed concern that the addition of concentrated juice to unconcentrated apple juice for the purpose of achieving uniformity in the finished juice may preclude the use of the term "no sugar added."

The agency advises that the addition of a concentrate of the same juice to achieve uniformity would not, in itself, preclude the use of a "no sugar added" claim, provided, the other conditions for the claim are met. (See also the document on ingredient labeling

published elsewhere in this issue of the **Federal Register**.) If a concentrate of another juice were added for the purpose of increasing the sugar content of the finished juice, the product could not bear a "no sugar added" claim.

91. One comment sought assurance that fruit juice from concentrate that has been reconstituted to normal strength would be able to make a "no sugar added" claim.

The agency advises that the addition of water to a juice concentrate to produce a single strength juice would not preclude the use of a "no added sugar" claim; however, the other conditions for the claim must still be met.

92. Several comments requested confirmation that fruits packed in fruit juice would be able to make a "no sugar added" claim under the provisions of proposed § 101.60(c)(2). One of the comments stated that the Brix of the juice would not be above that of the fruit itself, and another noted that no refined sugars would be used in the product but only fruit juices or concentrated fruit juice.

The agency concludes that juice-packed fruits that contain juice with the same sugars content as the single strength juice of the fruit would qualify for a "no sugar added" claim, provided that the other conditions for the claim are met. This food meets the criteria for the claim in § 101.60(c)(2). If these same fruits were packed in syrup or in juice concentrate, they would not qualify for this claim under § 101.60(c)(2)(ii) because syrup and juice concentrate are ingredients that contain added sugars.

93. One comment stated that if enzymes are used primarily for flavor or texture development, or for reasons other than to intentionally alter the sugars content of a product, then the food should be permitted to bear a "no sugar added" claim. The comment maintained that although such enzymatic processes may result in a slight increase in the sugar content of the product, the increase would not necessarily alter the sweetness profile of the product. The comment expressed the view that the agency's limitation in proposed § 101.60(c)(2)(iii) for "no sugar added" for such foods is overly restrictive and not in the best interest of consumers.

The agency agrees that proposed § 101.60(c)(2)(iii) should not preclude the use of enzymes or other processes where the intended functional effect of the process is not to increase the sugars content of a food, even though an increase in sugars that is functionally insignificant does occur. FDA concludes that such a prohibition would be overly restrictive and without benefit to consumers seeking to moderate their sugars intake because any increase in the sugars content of a food from such processes would be of little, if any, consequence in the total diet. Accordingly, FDA has revised new § 101.60(c)(2)(iii) in the final rule to state:

> The sugars content has not been increased above the amount naturally present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results.

iv. Calorie free. 94. The agency received a few comments on the term "calorie free." These comments supported the proposed definition of less than 5 calories per serving. One comment preferred that the definition be less than 2.5 calories but did not object to the proposed definition.

Based on these comments, the agency concludes that no change in the definition of "calorie free" is necessary.

95. One comment requested that soda water not be used as an example of a "calorie free" food because some consumers may conclude that all diet soft drinks are "calorie free" foods.

To avoid confusion, the agency is revising new § 101.60(b)(1)(ii) to read: (e.g., "cider vinegar, a calorie free food").

v. Fat free. 96. Most of the comments on the definition of the term "fat free" supported the proposed definition of less than 0.5 g of fat per serving. A few comments disagreed with less than 0.5 g. Some of these comments stated that "fat free" should be zero fat, while at least one comment suggested that the definition should be 0.5 g or less of fat.

The agency points out that zero fat is not an option as a limit because it is analytically impossible to measure. The proposed definition of less than 0.5 g of fat is appropriate because it is the reliable limit of detection of fat in all types of foods, and thus analytically it equates to zero. Furthermore, 0.5 g of fat is low enough compared to the DRV for fat, which the agency is establishing at 65 g (§ 101.9(c)(9)), to be considered dietarily and physiologically insignificant. For example, a person consuming 10 servings per day of "fat free" foods would consume less than 5 g of fat from these sources.

The agency is not including 0.5 g in the definition because the comment that suggested this change provided no compelling reason for it. Less than 0.5 g of fat is consistent with the way "free" terms have been defined by FDA in the past and with the way the agency is defining other "free" terms in this final regulation. Accordingly, the agency has not revised this definition.

97. At least one comment suggested that "fat free" be defined in terms of the fat content per serving and per 100 g of the food. The comment noted that the density criterion would prevent foods with small serving sizes, such as crackers, from making a "fat free" claim.

The agency is not persuaded that a second criterion based on the amount of fat per 100 g is necessary for the definition of "fat free." The first criterion of less than 0.5 g of fat requires that the food contain such a trivial level of fat that even frequent consumption of foods that bear a "fat free" claim would not affect in any meaningful way the overall fat level in the diet. Accordingly, the agency has not revised the definition of "fat free." This conclusion applies equally to all of the "free" claims that are being defined.

98. A few comments recommended that "fat free" be defined solely on the basis of less than 0.5 g per 100 g.

FDA considered this approach of defining nutrient content claims solely on the amount of a nutrient in a specified weight of food. This approach has the advantage of presenting a nutrient content claim for a food in a way that is more consistent with labeling used internationally. In addition, it allows consumers a means to more readily compare very dissimilar foods. However, FDA does not believe that this approach alone is appropriate for defining nutrient content claims. Foods are consumed in various amounts depending upon their nature and use in the diet. The agency believes that nutrient content claims could be misleading and not useful to consumers when expressed solely in terms of 100 g of food because this approach does not reflect amounts customarily consumed for all foods. For this reason, FDA did not take this approach in defining the term "fat free." Accordingly, the agency is not revising the definition of "fat free" in this manner.

99. Several comments objected to the provision in proposed § 101.62(b)(1)(ii) that a food containing added fat cannot be called "fat free," even though it still contains less than 0.5 g of fat per serving. One comment stated that "the agency should not speak of good faith or bad; it is simply a matter of definition and materiality." It contended that whether the fat is inherent or added should not be relevant as long as the amount present is less than 0.5 g. Comments stated that this provision would deprive consumers of the benefit of many innovative, nutritious products and argued that it would discriminate

against foods in certain categories based on dietarily insignificant amounts of fat. For example, less than 0.5 g of fat is added to some salad dressings that would otherwise meet the definition of "fat free." Furthermore, one comment noted that the proposed rule may be difficult to enforce since fat that is inherent cannot be distinguished from added fat.

Alternatively, many comments supported the proposal. They agreed that the listing of soybean oil, for example, as an ingredient of products bearing "fat free" claims is confusing and misleading. One comment said that "fat free" is a misnomer if fat has been added to the food. A few of these comments believed that even the addition of ingredients containing fat, such as nuts, should be disallowed. Other comments suggested that the confusion could be eliminated if the label of products containing any ingredient that contains fat were required to bear a disclosure statement, such as, "soybean oil (trivial source of fat)." Most of these comments preferred that the disclosure appear in the ingredient statement.

The agency has reconsidered the provision that disallows the addition of fat to foods that bear the claim "fat free" and is persuaded that it is unduly restrictive. The agency has decided to revise new § 101.62(b)(1)(ii) in the same way that is has revised § 101.60(c)(1)(ii) on "sugar free" claims and § 101.61(b)(1)(ii) on "sodium free" claims because the same considerations apply with respect to each of these claims. The agency believes that it is the listing of fats or ingredients that are generally understood by consumers to contain fat (i.e., nuts) in the ingredient statement that creates the confusion, and that a disclosure statement about the amount of fat in the food will eliminate that confusion. Accordingly, the agency is revising new § 101.62(b)(1)(ii) in the final rule to require that the listing of fats or ingredients that are understood to contain fat in the ingredient statement be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of fat," "adds a negligible amount of fat," or "adds a dietarily insignificant amount of fat."

vi. "Percent fat free" claims. FDA proposed several provisions in the fat/cholesterol proposal (56 FR 60478) regulating the use of "percent fat free" claims to ensure that the consumer is not misled by these claims, and that, as the claim implies, the food does in fact contain only a small amount of fat. Specifically, FDA proposed in § 101.62(b)(6)(i) to require that "percent fat free" claims can only be made: (1) For "low fat" foods (i.e., foods containing 3 g or less of fat per serving and per 100 g of food) or (2) for "low fat" meal-type products (i.e., meal-type products containing 3 g or less of fat per 100 g of product).

The agency also proposed in § 101.62(b)(6)(ii) to require that a disclosure statement of the amount of total fat in a serving of food appear in immediate proximity to the most prominent "percent fat free" claim, and that such disclosure statement be in type no less than one-half the size of the type of the "percent fat free" claim. In § 101.62(b)(6)(iii), FDA proposed that the type size of all the components of the "percent fat free" claim must be uniform.

Finally, FDA proposed in § 101.62(b)(iv) that a "100 percent fat free" claim must meet all of the criteria for "fat free" claims (i.e., foods containing less than 0.5 g of fat per serving and not containing any added ingredient that is a fat or oil). Furthermore, the agency advised that if the food is inherently free of fat, the label will disclose that fat is not usually present in the food (e.g., "a 100 percent fat free food").

The agency specifically requested comments as to whether the proposed requirements were sufficient to prevent "percent fat free" claims from being misleading, or whether such claims should be prohibited entirely.

100. Although the majority of comments supported the proposal to permit "percent fat free" claims on low fat foods, several comments opposed permitting the use of this claim. The primary reason cited in these comments was that this claim is misleading and confusing to consumers. One comment further stated that if FDA allowed "percent fat free" claims, it should only allow them on foods that meet the definition of "fat free." Another comment suggested that such claims be restricted to meat and poultry products, because they help to identify leanness.

The agency acknowledges that under current regulations, the use of a "percent fat free" claim has the potential to be misleading and confusing to consumers, especially when this claim appears on foods that derive a high percentage of their calories from fat. However, the agency concludes that with implementation of the provisions of this final rule regulating the appropriate use of a "percent fat free" claim (i.e., being restricted to use on products that meet "low fat" definitions), the claim will not be misleading or confusing. Furthermore, the comments that requested that the use of this term be prohibited did not provide evidence to persuade the agency that the requirements, as proposed, were insufficient to prevent misleading claims on food labels. In addition, FDA advises that the purpose of a "percent fat free" claim on nonmeat products does not relate to leanness but to information regarding the total amount of fat present in a serving of the food.

Further, the agency believes that to allow "percent fat free" claims only on "fat free" foods would be unduly restrictive. Such claims on foods that are "low" in fat, can, if properly made, be useful in assisting consumers to maintain healthy dietary practices. Consequently, the agency is denying these requests to prohibit or restrict the "percent fat free" claim.

101. One comment stated that "percent fat free" claims on bakery products may encourage consumers to purchase such products because they are low in fat, but the comment noted with concern that bakery products are high in calories, sugar, or sodium.

The agency recognizes that certain low fat foods may contain varying amounts of calories, sugar, or sodium. However, the agency does not expect a single claim (e.g., "97 percent fat free") to provide information regarding all of the nutrients contained in a product. Information on calories, sugar, and sodium will be provided in nutrition labeling, and therefore, available to the consumer at the time he or she makes a purchase decision. Moreover, if the nutrient levels in the food exceed levels at which a disclosure statement is required, a disclosure statement must appear in close proximity to the claim.

102. A comment from a foreign government opposed permitting "percent fat free" claims. The comment stated that its laws did not permit such terms to be used because they are potentially misleading. The comment suggested that FDA should not allow such claims on products.

As discussed in the previous comment, the agency recognizes that a "percent fat free" claim under regulations currently in effect can be misleading and confusing to the consumer. However, the provisions that the agency is establishing in new § 101.62(b)(6) regulating the use of a "percent fat free" claim address the aspects of such claims currently in use that have the potential to make them confusing or misleading. Thus, the agency concludes that in light of the action that it is taking, it is not necessary to ban these claims.

103. Other comments suggested that the "percent fat free" claim should be based on the amount of total calories contributed by the fat and not on the weight of the product, because basing the claim on the weight of the product has the potential to be misleading.

The agency disagrees with the comment. FDA believes that consumers are most familiar with claims expressed in terms of g per serving, and not claims based on the percentage of calories contributed by fat. FDA further believes, as stated in the fat/cholesterol proposal, that "percent fat free" claims imply that the food contains very small amounts of fat (i.e., "low" fat), and that the food is useful in structuring a diet that is low in fat. Basing the "percent fat free" claim on a designated percentage of total calories from fat would not limit the total amount of fat present in the food. Thus, a food high in calories may be able to make a "percent fat free" claim under a calorie criterion, because the percentage of total calories contributed by the fat falls within an established guideline. Yet, the amount of fat in such foods could exceed the amount that is defined as "low" fat. On such a food, the "percent fat free" claim would be misleading. Accordingly, the agency is not permitting "percent fat free" claims to be based on the percentage of calories contributed by fat.

104. Some comments requested that the agency require disclosure of the percent of calories from fat and the amount of available calories (i.e., total calories minus calories attributed to dietary fiber).

The comments requesting disclosure statements of percent calories from fat and available calories did not provide evidence on which the agency could make a finding that such disclosures were necessary to prevent a "percent fat free" claim from being misleading. Therefore, the agency finds no basis for requiring those disclosure statements. Furthermore, the agency believes that disclosure statements based on percent of calories would confuse consumers when all other disclosure statements are based on amount of g per serving. Therefore, the agency is denying the request for these disclosure statements.

105. The comments on the proposed requirement of a disclosure statement in immediate proximity to the "percent fat free" claim which specified the amount of fat in the product were equally divided in support of and against the provision. Some comments opposing the disclosure statement argued that the disclosure statement was unnecessary because the food must meet the definition of "low fat" before a "percent fat free" claim can be made. The comments also pointed out that a referral statement will direct the consumer to the nutrition label where fat is declared.

The agency recognizes that the "percent fat free" claim may not be made on the label or labeling of a product unless the food bearing the claim is "low in fat." This fact ensures that foods bearing a "percent fat free" claim will not contribute excessive amount of fat to the total diet. Thus, upon reconsideration, FDA does not find it necessary to require that foods bearing a "percent fat free" claim also disclose the amount of total fat per serving adjacent to the claim. Further, as one comment pointed out, the "percent fat free" claim will have to be accompanied by a statement referring consumers to the nutrition label, and that the total amount of fat in the product will be provided there. In addition, as discussed in response comment 214, FDA has concluded that it is not necessary to include absolute amounts in the principal display panel. Therefore, the agency is persuaded by the comments that these requirements obviate the need for a statement, adjacent to the claim, which discloses the amount of fat per serving in the product bearing such a "percent fat free" claim, and the agency is deleting this requirement in the final rule.

106. Two comments that supported the "no percent fat free" claim stated that the 3 g limitation was too restrictive and should be raised to 4 g. A third comment supporting the "percent fat free" claim stated that the only criterion should be 3 g or less per serving and that there should not be a second criterion of 3 g or less per 100 g.

As discussed in the fat/cholesterol proposal (56 FR 60478 at 60491), a "percent fat free" claim emphasizes how close the food is to being free of fat. The agency believes that this claim implies, and consumers expect, that products bearing "percent fat free" claims contain relatively small amounts of fat and consequently are useful in maintaining a diet low in fat. Thus, the agency finds that the appropriate approach to defining a "percent fat free" claim is that it be based on the definition of "low fat." Having said this, the agency points out that these comments raise objections to the definition for "low fat." The agency's decision on the final definition of "low fat" is discussed elsewhere in this document.

107. A few of the comments supporting the provision that "100 percent fat free" claims appear only on "fat free" foods, requested that "100 percent fat free" claims should also be allowed on foods to which fat has been added, as long as the food still complies with the "fat free" definition.

Although the agency has reconsidered its definition of "fat free" to allow foods with added fat that meet the definition of "fat free" to make a "fat free" claim, the agency has not been persuaded that a "100 percent fat free" claim should appear on foods with added fat. The agency believes that a "100 percent fat free" claim places more emphasis on the complete absence of fat in the food, and therefore the food should not have added fat. Thus, the agency is not permitting a food with added fat to make a "100 percent fat free" claim.

108. One comment objected to all "percent fat free" claims under the proposal. This comment stated that a "100 percent fat free" claim can be made on a food that contains 0.4 g of fat per serving and 3 g of fat per 100 g if the fat is not added, e.g., crackers with no added fat that contain 0.4 g per serving. However, if the crackers had the same amount of fat but as added fat, the claim would have to say "97 percent fat free." The comment asserted that such inconsistencies would be misleading and confusing to the consumer. Further, another comment objected to the provision that allows some foods to claim "100 percent fat free" when in fact they contain more than 0.5 g of fat per 100 g of the food and are, therefore, not 100 percent fat free. This comment stated that proposed § 101.62(b)(6)(iv) only requires that a food bearing this claim contain less than 0.5 g of fat per serving. Thus, a food with a serving size of 20 g, for example, could contain 2.45 g of fat per 100 g of the food.

The agency agrees with the latter comment. The agency did not intend to allow foods containing 0.5 g or more of fat per 100 g to bear the claim "100 percent fat free." Accordingly, the agency is revising the final rule in new § 101.62(b)(6)(iii) to require that a "100 percent fat free" claim can be made only on foods that meet the criteria for "fat free," that contain less than 0.5 g of fat per 100 g, and that contain no added fat. This revision also addresses the problem raised in the first comment. Furthermore, the agency advises that in declaring other "percent fat free" claims, the claim must accurately reflect the amount of fat present in 100 g of the food. For example, if a food contains 2.5 g of fat per 50 g then the claim should be "95 percent fat free."

109. A few comments suggested that the "percent fat free" claim be defined separately from, and not include, the "low fat" criteria because the "low fat" definition is unduly restrictive and does

not adequately differentiate the two claims. The comments further suggested that "percent fat free" claims for foods that are between 90 and 100 percent fat free be allowed. They contended that setting a threshold level of 97 percent fat free (3 g or less per 100 g) discourages consumers from eating products that are fairly low in fat but do not conform to the proposed definition for "low" and therefore gives the impression that FDA is making good food/bad food distinctions.

As stated in response to comment 106 of this document, a "percent fat free" claim is properly viewed as a "low fat" claim because it emphasizes how close the food is to being free of fat. Furthermore, basing the "percent fat free" claim on the criteria required for "low fat" products provides the consumer with a consistent method of comparison with respect to "low fat," "fat free," and "percent fat free" claims such that accurate comparisons can be made among different products. To establish separate criteria for a "percent fat free" claim could cause confusing and misleading information to be disseminated to the consumer and, thus, be contrary to the purpose of the nutrient content claims provisions of the act.

The agency also rejects the comments proposing that claims of up to "90 percent fat free" be allowed. The agency believes that such a definition would not be consistent with consumers' expectations of the fat content of foods bearing this claim because it would allow "percent fat free" claims on foods with significantly greater amounts of fat than "low fat" foods.

Furthermore, the agency is not convinced by the comments or other available information that if FDA does not permit a "90 percent fat free" claim, consumers would be discouraged from purchasing products that are "fairly" low in fat (less than 10 g per 100 g) but that do not meet the definition for "low fat." In the absence of a "percent fat free" claim, consumers will still be able to consult the nutrition label to determine the total amount of fat contained in a product and to make purchase decisions based on this information according to their individual dietary preferences.

Although the agency does not agree that a "percent fat free" claim should be allowed for foods containing up to 10 percent fat by weight, the agency has reconsidered the basis and application of the weight-based criterion for "low fat" and "percent fat free" claims such that the weight-based criterion only applies to foods with reference amounts 30 g or less or 2 tablespoons or less (see comment 45). Further, foods with reference amounts of 30 g or less or 2 tablespoons or less may bear such claims provided that they contain 3 g or less fat per reference amount and per 50 g. Therefore, foods with small reference amounts containing 6 g or less fat per 100 g will be able to bear a "percent fat free" claim. Consequently, claims of up to "94 percent fat free" will be allowed on these products that also meet the criteria for "low fat." In addition, foods with reference amounts greater than 30 g or greater than 2 tablespoons that meet the "low fat" definition may bear "percent fat free" claims. The agency believes that permitting such claims is consistent with dietary guidelines for reducing fat intake, because it would allow such claims on a wider variety of foods for which increased consumption is recommended in national dietary guidance. This issue is fully discussed in section III.A.1.b. of this document.

110. One comment suggested that the "percent fat free" claim be allowed on products containing 5 g or less fat per 100 g. Another comment suggested that the "percent fat free" claim be allowed on products containing 5 g or less fat per serving and per 100 g; no more than 30 percent of calories from fat; and no more that 10 percent of calories from saturated fat. The comment asserted that these three criteria would ensure that a "percent fat free" claim is not misleading, yet be less restrictive than the provisions proposed in the fat/cholesterol proposal.

Another comment proposed that the definition for "percent fat free" claims be based on either: (1) The food being "low fat," where low fat is 4 g or less per serving and being at least 90 percent fat free, or (2) the product being 90 percent fat free but providing no more than 4 g of fat per serving; the label disclose the number of g of fat per serving in conjunction with the "percent fat free" claim; and the product be at least 2 g of fat per serving less than the weighted average fat level of other similar products. The comment asserted that these criteria would provide an effective and less restrictive means of drawing consumers' attention to a reduced-fat content food, while allowing the consumer more reduced-fat products from which to choose.

The agency considered the alternative criteria for "percent fat free" claims as suggested in these comments. The suggested approaches establish differences between the "low fat" and "percent fat free" claims that the agency believes are inappropriate. As explained in comment 106 of this document, consumers expect a product with a "percent fat free" claim to be low in fat, and the comments did not present evidence to FDA to demonstrate to the contrary. Consequently, the most logical approach for defining a "percent fat free" claim is to choose criteria that make the claim consistent with the definition of "low fat" or "fat free." Thus, the agency rejects the alternative approaches recommended in the comments. Furthermore, the comments suggested alternatives that require comparison of amounts of fat among different products. This approach is more consistent with the criteria used for comparative claims such as "reduced" or "less" and is not appropriate for nutrient content claims such as "percent fat free." Further, in addition to not being consistent with the definitions for "low fat" or "fat free," the suggested alternatives are based on extremely complex definitions that could result in consumer confusion concerning the meanings of the terms "low fat," "fat free," and "percent fat free."

vii. Saturated fat free. 111. A number of comments strongly recommended that FDA define the term "saturated fat free" and terms that would be synonyms for "saturated fat free." These comments argued that a "free" claim is one of the most powerful claims, and that saturated fat is one of the more important nutrients from a public health perspective. They stated that this claim would be extremely useful because the foods that would qualify are the foods that consumers are being encouraged to eat more frequently. Furthermore, the availability of this claim would provide an incentive for the development of new foods that are "saturated fat free."

Some of the comments responded to FDA's reason for not defining this term. The agency argued that since less than 0.5 g per serving is "fat free," one-third of this amount, or 0.17 g per serving, would be the appropriate definition for "saturated fat free." The agency did not propose a definition because it concluded that saturated fat could not be accurately measured at this level. The comments did not dispute this point, but they argued it is appropriate to define "saturated fat free" as less than 0.5 g of saturated fat per serving based on the same criteria used for "fat free" claims, i.e., dietary insignificance and reliable detection.

One of these comments contended that a food that is "fat free" logically must be free of saturated fat because saturated fat is included in the definition of total fat. Other comments suggested that the definition be less than 0.25 g per serving on the basis of dietary insignificance. These comments did not discuss problems with

detection, except for one comment that stated that it should not be difficult to reliably detect saturated fat at 0.25 g per serving. This comment pointed out that in the proposed rule on mandatory nutrition labeling (56 FR 60366) less than 0.25 g of saturated fat per serving is the level that can be declared as "0." Another comment noted that consumers would likely be confused if foods declaring "0" g of saturated fat in the nutrition label bear the claim "low in saturated fat" instead of "saturated fat free."

The agency is persuaded by the comments that the term "saturated fat free" would be useful to individuals trying to reduce their intake of saturated fat. It is defining this term as less than 0.5 g of saturated fat per serving because the majority of the comments on this proposed rule and on the proposed rule on mandatory nutrition labeling (56 FR 60366) that addressed this issue stated that a lower value cannot be reliably detected. FDA has been convinced by these comments, which showed that less than 0.5 g of saturated fat is the reliable limit of detection of saturated fat in all types of foods, and thus analytically it equates to zero.

The agency notes that it is aware of the concerns that trans fatty acids, which are unsaturated fatty acids, may raise serum cholesterol and has requested data on this issue. A review of the information submitted and of the published literature shows that the evidence that suggests that trans fatty acids raise serum cholesterol remains inconclusive, as fully discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. However, because of the uncertainty regarding this issue, the fact that consumers would expect a food bearing a "saturated fat free" claim to be free of saturated fat and other components that significantly raise serum cholesterol, and the potential importance of a saturated fat free claim, the agency believes that it would be misleading for products that contain measurable amounts of trans fatty acids to bear a "saturated fat free" claim. Thus, the agency is including a limit on trans fatty acids of 1 percent of the total fat in the definition of "saturated fat free" because the analytical techniques for measuring trans fatty acids below that level are not reliable. Accordingly, the agency is providing in new § 101.62(c)(1)(i) that the term "saturated fat free" ("free of saturated fat," "no saturated fat," "without saturated fat," "zero saturated fat," "trivial source of saturated fat," "negligible source of saturated fat" or "dietarily insignificant source of saturated fat") may be used on the label of a food if the food contains less than 0.5 g of saturated fat per serving and 1 percent or less of total fat as trans fatty acids.

Consistent with the requirements for other "free" claims, the agency is requiring in new § 101.62(c)(1)(ii) that the listing of ingredients generally understood by consumers to contain saturated fat must be accompanied by a statement such as "adds a trivial amount of saturated fat." Also, the agency is requiring in new § 101.62(c)(1)(iii) that foods meeting the definition without special processing must be labeled in a manner that makes this clear.

To accommodate this insertion, proposed § 101.62(c)(1) through (c)(3) is being redesignated as § 101.62(c)(2) through (c)(4), respectively. It should be noted that proposed § 101.62(c) required that all foods bearing claims about saturated fat should disclose the amount of total fat and cholesterol in the food in immediate proximity to such claims. As discussed in response to comment 138 of this document, the provision on the disclosure of cholesterol with these claims is required by section 403(r)(2)(A)(iv) of the act. Because FDA is now defining the term "saturated fat free," the provision on the disclosure of total fat is revised to require the disclosure of total fat with a "saturated fat free" claim unless the food contains less than 0.5 g of total fat per reference amount (i.e., unless the food meets the definition of "fat free"), in which case the amount of total fat need not be disclosed. The agency concludes that disclosure of the amount of total fat is necessary when a "saturated fat free" claim is made for a food that is not "fat free" to prevent consumers who do not differentiate between a "saturated fat free" and "fat free" claim from being misled by a "saturated fat free" claim (see comment 139 of this document for related discussion).

112. One comment requested that FDA define the term "very low saturated fat" as less than 0.5 g per serving. This comment stated that "saturated fat free" should be defined as less than 0.25 g per serving. Other comments requested that FDA define "very low" claims for other nutrients.

The agency rejects this request because it concludes that "saturated fat free" should be defined as less than 0.5 g per serving, as explained in the previous comment. Defining the term "very low saturated fat" is unnecessary because the proposed value for "low saturated fat" is only double the value for "saturated fat free." Furthermore, the agency is not defining any new "very low" terms because it believes that consumers would be confused by these terms in addition to the "free" terms. The term "very low sodium" is being retained because it has been in use for a number of years and is defined as 35 mg or less of sodium per serving, which is 7 times the cutoff level for "sodium free" and one-quarter of the cutoff level for "low sodium." Accordingly, the agency is not defining "very low saturated fat."

viii. Cholesterol free. 113. Most of the comments on the definition of the term "cholesterol free" supported the definition in proposed § 101.62(d)(1) of less than 2 mg of cholesterol per serving. A few comments disagreed. Some of the latter comments stated that a "cholesterol free" claim is misleading if the food contains any cholesterol. One of these comments suggested that a "cholesterol free" claim be accompanied by the statement, "this product may contain up to 2 mg of cholesterol." Other comments stated that "cholesterol free" should be less than 5 mg per serving, so that nonfat dairy products can make this claim. One of these comments said that changing the requirement to 5 mg or less would be an incentive to food manufacturers to reformulate products so as to make this claim. Another comment said that FDA has failed to establish that 5 mg of cholesterol would not also be dietarily insignificant.

The agency is not persuaded that the proposed value of less than 2 mg of cholesterol per serving should be changed or needs to be defined on the label. The agency selected this value because it represents the typical limit of reliable detection for existing analytical methods. A value of zero is not an option because it is analytically impossible to measure. Furthermore, 2 mg per serving is low enough compared to the DRV for cholesterol, which is 300 mg, to be considered dietarily and physiologically insignificant. As discussed in the tentative final rule on cholesterol terms of July 19, 1990 (55 FR 29456 at 29460), FDA believes that a limitation of 5 mg for the term "cholesterol free" is misleading. A person who consumes foods labeled as "cholesterol free" would expect that they would not contribute significantly to the cholesterol levels of his or her diet. Yet the consumption of 5 to 10 foods per day containing up to 5 mg of cholesterol per serving could furnish 25 to 50 mg of dietary cholesterol. This amount of cholesterol cannot be considered to be insubstantial. Moreover, the analytical limits on detecting cholesterol support a lower limit than 5 mg. Accordingly, the

agency has not revised the definition of "cholesterol free."

114. A couple of comments said that consumers are confused when they see ingredients containing cholesterol in the ingredient statement of foods bearing "cholesterol free" claims.

The agency agrees that consumers may be confused by reading that eggs, for example, are listed as an ingredient of a food bearing a "no cholesterol" claim. The agency has reviewed these comments with the many comments on fat being added to foods labeled as "fat free." The agency has been persuaded by these comments that a clarification of this issue is needed to avoid consumer confusion. The agency believes that it is the listing of ingredients, such as eggs, that creates the confusion. Accordingly, the agency is revising § 101.62(d)(1)(i)(B) and (ii)(B) in the final rule to require that the listing of ingredients that are generally understood by consumers to contain cholesterol be followed by an asterisk that refers to a disclosure statement appearing below the list of ingredients. The statement shall read: "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol." The agency points out that because of these inserted sections, proposed § 101.62(d)(1)(i)(B) and (d)(1)(i)(C) are redesignated as § 101.62(d)(1)(i)(C) and (d)(1)(i)(D), and proposed § 101.62(d)(1)(ii)(B) through (d)(1)(ii)(E) are redesignated as § 101.62(d)(1)(ii)(C) through (d)(1)(ii)(F).

115. A few comments requested that FDA ban all cholesterol content claims. The comments argued that dietary cholesterol has an insignificant impact on blood cholesterol levels compared to saturated fat, and that the response to dietary cholesterol varies from individual to individual.

The agency is denying this request. The Surgeon General's report (Ref. 4) and the NAS report "Diet and Health, Implications for Reducing Chronic Disease Risk" (Ref. 12) considered the evidence on the effect of diet on an individual's health. One of the main conclusions from these reports is that consumption of diets high in fat, saturated fat, and cholesterol is associated with increased risk of developing certain chronic diseases. These reports recommended that Americans reduce their consumption of these substances in their diets. To help Americans achieve this goal, the 1990 amendments authorize FDA to define nutrient content claims, including those relating to cholesterol content. Accordingly, the agency is not revising the final rule to ban cholesterol claims.

116. The agency received a number of comments on the proposed saturated fat threshold (i.e., limit) that allows foods bearing "no cholesterol" claims as well as other cholesterol claims to contain only 2 g or less of saturated fat per serving. About 20 comments opposed this threshold. About half as many comments supported the proposed rule and stated that a threshold of 2 g or less of saturated fat per serving is appropriate. One comment stated that this threshold should have a second criterion of 15 percent or less of energy (calories) from saturated fat. Similarly, another comment favored a second criterion of 6 percent or less of saturated fat on a dry weight basis. The comments recommending a different threshold were almost evenly divided between a higher value and a lower value. One comment requested that the threshold apply only to "cholesterol free" and "low cholesterol" claims, not to comparative claims. Other comments stated that foods bearing cholesterol claims should contain no saturated fat.

Many of the comments opposing the threshold on saturated fat with cholesterol claims were from manufacturers of dairy products that have up to 95 percent of their cholesterol removed. These products contain more than 2 g of saturated fat per serving. The comments stated that cholesterol claims should be allowed on these products regardless of their saturated fat content. They contended that the proposed saturated fat threshold is inappropriate and unduly restrictive because the relationship of cholesterol and saturated fat has not been satisfactorily defined. A few comments against the threshold favored disclosure of saturated fat. One comment said that disclosure of saturated fat, rather than a threshold, would be more consistent with the 1990 amendments (section 403(r)(2)(A)(iii)(II) of the act). They stated that a saturated fat threshold based on section 403(r)(2)(A)(vi) of the act fails to take into account the fact that certain foods containing more than 2 g of saturated fat may contain "substantially less" cholesterol than foods for which they might substitute.

Some of the comments for a higher threshold recommended a value of 3 g or less of saturated fat per serving. The comments said that this threshold would allow nuts and peanut butter to make a "no cholesterol" claim. A few comments stated that the threshold should be 4 g or less to be consistent with the level of saturated fat above which risk is likely to increase and disclosure is required. One comment stated that consumers believe that cholesterol is found in all fats and oils. They argued that claims are needed to help consumers select foods that do not contain cholesterol, rather than foods that do contain cholesterol (e.g., margarine for butter).

Most of the comments for a lower threshold recommended 1 g or less of saturated fat per serving and 15 percent or less of calories from saturated fat, to be consistent with the definition of "low in saturated fat." One comment suggested that the first criterion be 1.5 g or less of saturated fat per serving, and another comment suggested that the second should be no more that 7 calories from saturated fat per 100 calories.

These comments were concerned that the threshold proposed would encourage a proliferation of inappropriate cholesterol claims. Also, they were concerned that consumer education efforts would be hampered by a saturated fat limit of 1 g for "low in saturated fat" claims, of 2 g for cholesterol claims, and of 4 g for disclosure of saturated fat (e.g., a product bearing a sodium claim that contains more than 4 g of saturated fat per serving must disclose: "See [appropriate panel] for information on saturated fat and other nutrients"). The comments encouraged FDA to strive for consistency along with strictness and simplicity.

The agency is not persuaded that the saturated fat threshold should be eliminated or changed. FDA finds that there is general scientific agreement on the relationship between saturated fat and cholesterol and serum cholesterol levels. In the general principles proposal (56 FR 60421 at 60426), the agency noted that under section 403(r)(2)(A)(vi) of the act, it can by regulation prohibit a nutrient content claim if the claim is misleading in light of the level of another nutrient in the food. Further, FDA stated that it has tentatively made such a finding with regard to cholesterol claims and the presence of saturated fat, as fully discussed in the fat/cholesterol proposal (56 FR 60478 at 60495). FDA pointed out that NAS's "Diet and Health" report (Ref. 12) stated that "saturated fatty acid intake is the major dietary determinant of the serum total cholesterol and low-density lipoprotein (LDL) cholesterol levels in populations and thereby of coronary heart disease risk in populations" (56 FR 60482). Furthermore, an FDA survey has found that consumers are interested in cholesterol content claims because they believe that eating foods with no or low cholesterol will have a significant effect on their blood cholesterol levels and on their chances of developing heart

disease (Ref. 16). Consequently, FDA continues to believe that to ensure that cholesterol claims do not mislead consumers it is necessary to permit their use only when the foods also contain levels of saturated fat that are below a specified threshold level. Accordingly, the agency is denying the requests to eliminate the threshold. This decision applies to "cholesterol free," "low cholesterol," and comparative cholesterol claims.

The agency does not agree that disclosure of the amount of saturated fat in proximity to a cholesterol claim is sufficient to prevent consumers from being misled. As stated above, consumers expect foods with cholesterol claims to affect blood cholesterol levels, and saturated fat is the major dietary determinant of blood cholesterol levels. These expectations are not met if disclosure of saturated fat is permitted because the saturated fat is still present. Therefore, the agency is also denying the request to allow disclosure of saturated fat instead of a threshold.

Additionally, the agency does not agree that the saturated fat threshold should be a higher value or a lower value. The rationale for the threshold level of 2 g or less of saturated fat per serving is explained in the July 19, 1990, tentative final rule (55 FR 29456 at 29458). In summary, the value is consistent with the recommendations of recent dietary guidelines (Refs. 7, 12, and 17) that saturated fat intake should be less than 10 percent of calories. The agency believes that a saturated fat level that exceeds 2 g would make a cholesterol claim misleading because consumer expectations would not be met if such a food is not consistent with the recommendations of the guidelines with respect to saturated fat. For this reason, the agency concludes that levels of 2 g or less are not misleading and finds no basis for lowering the threshold below 2 g.

A review of the composition of food shows that a reasonable number of foods qualify for cholesterol claims under the criteria that FDA is establishing. For example, a number of oils including soybean, corn, safflower, and olive oil, qualify for a "no cholesterol" claim (Ref. 6). Accordingly, the agency is denying the requests to change the threshold.

Finally, the agency is not persuaded that it is necessary for the threshold to have a second criterion. The agency proposed a second criterion of 6 percent or less saturated fat on a dry weight basis in the July 19, 1990, tentative final rule (55 FR 29456). In response to comments stating that the second criterion was unnecessary and would unfairly penalize foods that have a high moisture content, the agency proposed to eliminate this provision. The agency still agrees that this provision is unnecessary and is not persuaded by the comments herein to reverse this action.

117. At least one comment suggested that a food bearing a "cholesterol free" claim should have a 3 g limit on fat content. Another comment believed that such a food should be "fat free."

The agency disagrees with these comments because it has concluded that disclosure of fat on a food bearing a "cholesterol free" claim is preferable to a fat limit as fully discussed in response to comment 143 of this document. The agency does not find that a cholesterol claim on the label of a food containing high levels of fat is misleading when the fat amount is disclosed in proximity to the claim because total fat per se does not affect blood cholesterol levels.

118. A few comments stated that a "cholesterol free" claim is misleading on a product that contains trans fatty acids. These comments stated that consumers select foods that contain no cholesterol to lower their blood cholesterol levels and argued that trans fatty acids increase these levels.

The agency understands the concerns about trans fatty acids expressed in these comments and has requested data on this issue. However, as discussed in comment 111 of this document, a review of the information submitted and of the published literature shows that the evidence that suggests that trans fatty acids raise serum cholesterol remains inconclusive, as fully discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. For this reason the agency believes that a "no cholesterol" claim on a food containing trans fatty acids is not misleading. Accordingly, the agency is making no change in the final rule in response to these comments. However, as explained in comment 111 of this document, the agency has included a limit for trans fatty acids as a criterion for a "saturated fat free claim," because of the implications of that claim and the particular importance of that claim.

2. Low

In the general principles and fat/cholesterol proposals (56 FR 60421 and 60478), FDA proposed to define the term "low" for total fat, saturated fat, cholesterol, sodium, and calories. The agency stated that it did not believe that the term "low" should necessarily mean that a nutrient is present in a food in an inconsequential amount, as with "free," but rather that the selection of a food bearing the term should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit the intake of certain nutrients.

FDA proposed the terms "little" or "few," "small amounts of," and "low source of" as synonyms for the term "low" and specifically requested comments on how consumers commonly understand the meaning of all these terms. The agency also asked whether the terms are in fact synonymous.

FDA also proposed that "low" claims used on foods that inherently contain low levels of a nutrient must refer to all foods of that type and not merely to the particular brand to which the labeling is attached. The agency requested comments on this provision.

a. General comments. 119. A few comments addressed the concept of using 2 percent of the DRV per serving as the starting point in defining "low" claims. These comments questioned FDA's statement that 2 percent or more of the DRV is a "measurable amount." They said that amounts under this level could be measured accurately as evidenced by the fact that less than 0.5 g of fat per serving, or less than 1 percent of the proposed DRV, is the cutoff proposed for the "fat free" claim.

The agency agrees with this comment that amounts of fat less than 2 percent of the DRV for this nutrient can be measured accurately. The agency believes that, in general, less than 0.5 g of fat per serving represents the cutoff below which fat cannot be measured accurately in all food matrices and thus was the level chosen to define "fat free" (56 FR 60484, November 27, 1991). The agency acknowledges that its discussion of a "measurable amount" being 2 percent or more of the DRV of a nutrient in a serving of a food is not clear (56 FR 60439). This terminology was taken from § 101.3(e), issued in 1977, which describes how foods are to be named, and under what circumstances the word "imitation" must precede the name of a food that has a decreased level of an essential nutrient. FDA determined that nutrients present at a level of 2 percent or more of the U.S. RDA were present in a "measurable amount" and thus were of sufficient importance to be considered in deciding whether a substitute product should be labeled as an "imitation."

In the proposed rule, the agency selected less than 2 percent as the starting point in defining "low" claims based on the precedent established in § 101.3(e) that a decrease of a nutrient in a food by this amount was not sufficiently important to the diet to justify concern. Thus, the agency

tentatively concluded that this level was appropriate to use in defining "low." In this context, the agency did not mean to imply by the words "measurable amount" that lower amounts could not be measured. Given this explanation, the agency concludes that no changes are necessary in response to these comments.

120. At least one comment requested that the definitions for the nutrient content claims "free" and "low" not overlap. For example, "low cholesterol" should be defined as 2 to 20 mg of cholesterol rather than less than 20 mg of cholesterol per serving.

The agency agrees that a "low" claim on a product that could make a "free" claim could be confusing. However, FDA concludes that it is not necessary to make these definitions mutually exclusive because it is unlikely that a "low" claim would be used on a food that is eligible to bear a "free" claim. Accordingly, the agency is denying this request. However, the agency advises manufacturers to use the most appropriate claim to avoid confusion.

121. A few comments requested that FDA define "low sugar." One comment requested that FDA define this term as 3 g or less of sugar per serving or less than or equal to 10 percent sugar for the cereal category. This comment stated that because there is such a large number of products from which to select, it is important that cereals that are low in sugar be able to communicate this fact to consumers. Of the 180 products that label sugar content, about 20 percent contain 3 g or less of sugar per serving. Also the comment stated that 3 g of sugar provide 12 calories, which is 10 percent of the calories contributed by a typical 1-ounce serving of cereal. This comment also requested that "very low sugar" be defined as one-half of the quantity for "low sugar" or 1 g or less of sugar per serving. Another comment recommended a definition of 5 g or less of sugar per serving. This comment stated that presently 20 percent of adult caloric intake is attributed to sugar. Using an arbitrary 25 percent decrease in this level, a reference diet of 2000 calories, and 20 servings per day, the comment computed a value of 5 g for the cutoff. Using the same rationale, this comment requested that "very low sugar" be defined as 3 g or less of sugar per serving.

The agency does not believe that these comments provide an acceptable basis for defining "low sugar." The fact that 20 percent of cereals may contain 3 g or less of sugar per serving is not a sufficient reason to define "low sugar" in this manner, even for cereal. Likewise, a value based on a 25 percent decrease from current intake is not a sufficient basis to define this term. To be consistent with the approach the agency has taken for other "low" definitions, a definition for a "low" level of sugar would have to relate to the total amount of the nutrient recommended for daily consumption, as discussed in the general principles proposal (56 FR 60439). However, because the available consensus documents do not provide quantitative recommendations for daily intake of sugars, FDA is not proposing a reference value for this nutrient. The agency concludes that without a reference value for sugar intake, the term "low sugar" cannot be defined. For the same reason, the agency is also not defining the term "very low sugar." Accordingly, the agency is not accepting the recommendations of this comment. The agency points out, however, that much of the information that these comments seek to convey can be communicated by use of a "reduced sugar" or "less sugar" claim made in accordance with new § 101.62(c)(4).

b. Synonyms for low. Several comments discussed synonyms for the descriptive terms "low" and "very low" that FDA defined in the general principles and fat/cholesterol proposals. The agency notes that it defined "very low" only in the context of sodium claims (i.e., "very low sodium").

122. One comment offered the term "lowest" as a synonym for "low" and suggested that it be applicable to all nutrients for which FDA is defining "low" nutrient content claims.

FDA disagrees with this comment because "lowest" is a comparative term that describes the position of a product with regard to one or more of its attributes relative to that of other products within a particular category. Therefore, FDA believes that "lowest" is not an appropriate synonym for "low," and the agency is not adopting this suggested term.

123. Two comments suggested that terms like "short" or "small" be permitted as synonyms for "low."

These comments did not provide supporting information to persuade the agency that consumers commonly understand the terms "short" or "small" to have the same meaning as "low." Therefore, FDA is not providing for the use of any of these terms as synonyms for "low" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in § 101.69 of this final rule. The agency has, however, provided for the use of "a small amount of" as a synonym for "low."

124. One comment offered the terms "dab," "dash," "hardly," "insignificant," "minimum," "negligible," "next to nothing," "pinch," "slight," "smidgeon," "tinge," "trivial," "tiny," "touch," or "very little" as synonyms for "very low."

The agency notes that it has defined the term "very low" only for of sodium content claims and has not provided for any synonyms for this term. The comment did not provide supporting information to persuade the agency that consumers commonly understand the terms "dab," "dash," "hardly," "insignificant," "minimum," "negligible," "next to nothing," "pinch," "slight," "smidgeon," "tinge," "trivial," "tiny," "touch," or "very little" to have the same meaning as "very low." Therefore, FDA is not providing for the use of any of these terms as synonyms for "very low" at this time. However the agency advises that interested persons may submit a synonym petition for the use of any of these terms as prescribed in § 101.69 of this final rule.

c. Specific definitions. i. Low and very low sodium.

125. Some comments disagreed with the agency's proposal to retain 140 mg as the level for "low sodium, contending that the basis of the definition for this term should be consistent with that for other nutrients, which would result in "low sodium" being defined as 96 mg or less per serving, i.e., 4 percent of the DRV. One comment specifically opposed lowering the criterion to 96 mg per serving, noting that it is important to retain consistency with existing definitions. Others argued that the sodium/salt sensitive portion of the population is small in number, so that there would be little public health benefit in reducing the "low sodium" definition. Other comments generally contended that consumers are familiar with 140 mg through its widespread use in describing "low sodium" foods over the last 8 years, and that there have been no apparent problems. One comment proposed that "low sodium" claims should be allowed on foods containing 10 percent of the DRV, per serving or per 100 g. It provided no basis for this suggestion which would result in increasing the cutoff level for "low sodium" foods from 140 mg to 240 mg.

The agency has reviewed the comments and is not persuaded to change the proposed definition for "low sodium." As discussed in the general principles proposal (56 FR 60421 at 60441) and noted by some of the

comments, the descriptive terms for sodium have been in use for approximately 8 years, and the agency believes that consumers are familiar with them. In general, comments received in response to the 1989 ANPRM and at the public hearings that followed, did not indicate a need for change, and most of the comments to this rulemaking supported the existing criteria, even though it was not derived in the same manner (i.e., which would have yielded a value of 96 mg per serving) as other "low" claims.

The agency also disagrees with comments suggesting a definition for "low sodium" of 240 mg per serving. If the definition were established at this level, a person could easily exceed the DRV for sodium (e.g., if more than 10 foods are consumed per day which are "low sodium"). This result would be inconsistent with dietary recommendations and with the approach that FDA is taking in defining other terms. As discussed in the general principles proposal (56 FR 60421 at 60439), the agency believes that the selection of a food bearing the term "low" should assist consumers in assembling a prudent daily diet and in meeting overall dietary recommendations to limit certain nutrients. Therefore, the agency is retaining its criteria for "low sodium" claims.

126. Many comments agreed with the proposed definition for "very low sodium," stating that it is useful and has come to be understood by consumers. However, one comment stated that the term is not necessary.

The agency has reviewed the comments and is not persuaded to change the proposed definition for "very low sodium." "Very low sodium foods" will be useful to individuals in the population wishing to reduce their total sodium intake to a more moderate level and will be especially useful to individuals on medically restricted diets (see 56 FR 60441). In general, comments received in response to the 1989 ANPRM and at the public hearings did not indicate a need for change, and most of the comments to this rulemaking supported keeping the existing criteria. Therefore, the agency is retaining 35 mg as the eligibility level for "very low sodium" claims.

ii. Low calorie. 127. Many comments agreed with the agency's definition of "low calorie." Some comments, however, disagreed. One comment suggested that "low calorie" be defined at 4 percent of the DRV or RDI, rather than the 2 percent. One comment suggested that the maximum calorie level was too low, and that only a few products would qualify to make a "low calorie" claim.

The agency agrees with the majority of the comments that 40 calories or less is the appropriate per serving criterion for the "low calorie" definition. FDA is not persuaded by the comments or by its own review of the calorie content of foods (Ref. 18) that increasing the per serving allowance in the definition of "low calorie" is prudent if the term is to be useful to consumers attempting to control their intake of calories.

As explained in the general principles proposed rule (56 FR 60439), FDA is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. While a DRV for calories has not been established, FDA used a reference caloric intake of 2,350 calories for reviewing the definition of "low calorie" and for establishing DRV's for other nutrients. As discussed in the RDI/DRV final rule published elsewhere is this issue of the **Federal Register**, FDA has changed the reference caloric intake to 2,000 calories. Using the general approach described above, 2 percent of 2,000 calories computes to 40 calories. Accordingly, the agency is not changing the per reference amount criterion for the definition of "low calorie."

128. One comment suggested that the definition of "low calorie" should be based on foods that can be eaten freely without adding significantly to the caloric content of the total diet.

FDA disagrees with this comment. The term "calorie free" already describes foods that can be eaten freely without adding significantly to the caloric content of the total diet. Accordingly, the agency is not defining "low calorie" in this manner.

iii. Low fat. 129. Only a few comments supported proposed § 101.62(b)(2) that defines "low fat" as 3 g or less per serving and per 100 g of the food. Most of the comments on this issue objected to the second criterion of 3 g or less per 100 g. Some of these comments suggested alternatives to the second criterion.

The second criterion for the term "low fat," as well as the second criterion for the other "low" terms, has been discussed in section III.A.1.b. of this document on the general approach to nutrient content claims. In this section, the agency is addressing the comments on the first criterion of 3 g or less per serving.

The majority of the comments recommended that "low fat" remain at 3 g or less per serving. About 20 comments requested that the cutoff be 4 g or less per serving. These comments argued that defining "low fat" in this manner could still lead to a significant reduction of fat in the total diet as well as allow more flexibility for product development. A few comments requested that the cutoff be at more than 4 g per serving.

Some of the comments that requested that the cutoff be 4 g or less presented the following rationale: A diet of 2,350 calories per day with 30 percent of calories from fat allows a maximum of 78 g of fat per day. The typical adult consumes 20 servings of food per day. These comments estimated that 13 of these servings contain fat. Dividing 78 g by 13 gives an average of 6 g of fat. Based on this reasoning, 4 g of fat would be below the average of 6 g (a 1/3 reduction) and could be considered to be "low fat."

These comments pointed out that if each of 13 servings of foods contained 4 g of fat, the total amount of fat would be only 52 g, well short of 78 g. Another comment based its calculations on 10 servings of food containing fat. It observed that if 5 of 10 fat-containing foods had 4 g, they would provide 20 g of fat in the diet. Thus, the other 5 servings could contain 11 g of fat each for a total of 75 g, which was the proposed DRV for fat. Other comments stated that 4 g or less of fat per serving is appropriate because even if all 20 servings of food a day contained 4 g of fat (i.e., less than 5 percent of the DRV), the daily total would slightly exceed the DRV.

The agency agrees with the majority of the comments that 3 g or less of fat is the appropriate per serving criterion for the "low fat" definition. FDA is not persuaded by the comments or by its own review of the fat content of foods (Ref. 19) that increasing the per serving allowance in the definition of "low fat" is necessary or prudent if the term is to be useful to consumers attempting to control their intake of fat.

As explained in the fat and cholesterol proposed rule (56 FR 60486), FDA is defining a "low" claim for a nutrient that is ubiquitous in the food supply as an amount equal to 2 percent of the DRV for the nutrient. To arrive at a definition when a nutrient is not ubiquitous, the agency proposed to increase the 2 percent amount to adjust for such a nutrient's uneven distribution in the food supply. This adjustment recognizes the practice of dietary planning in which a person consumes, in a day, a reasonable number of servings of foods labeled as "low," balanced with a number of servings of foods that do not contain the nutrient in question and a number of servings of foods that contain the nutrient at levels

above the "low" level and is still able to stay comfortably within the guidelines of the various dietary recommendations (Refs. 7, 12, and 17).

With respect to fat, current dietary guidelines recommend that a person consume a maximum of 30 percent of calories from fat, which in a diet of 2,000 calories per day would allow for consumption of a maximum of 67 g of fat per day. FDA is adopting this value rounded to 65 g as the DRV for fat. Two percent of the DRV is 1.3 g, which rounded to the nearest one-half g would be 1.5 g.

The agency is not using 1.5 g as the cutoff of a "low fat" claim, however, because fat is not ubiquitous in the food supply. Because fat is not ubiquitous but is found in more than a few food categories, FDA concludes that an appropriate upper limit for a "low fat" claim should be set at two times 3 percent of the DRV or 3 g per serving. The agency remains convinced that this amount is a reasonable definition for "low fat" because an average level of 3 g in 16 to 20 servings of food per day (balancing the number of foods that do not contain fat with those that contain higher levels of fat to yield an average of 3 g of fat per serving) would supply 48 to 60 g of fat daily, within the DRV of 65 g of total fat. An average level of 4 g in 16 to 20 servings would supply 64 to 80 g of total fat, exceeding the DRV Similarly, an average of 5 g would supply 80 to 100 g of fat. For this reason the agency concludes that 4 g or more of fat per serving is not an appropriate definition for "low fat." Accordingly, the agency is not making the suggested change.

130. Some of the comments that requested that FDA change the definition of "low fat" (proposed § 101.62(b)(2)) to 4 g or less of fat per serving also requested that FDA define "very low fat." They stated that 2 g or less of fat per serving could be considered "very low fat" if 4 g or less of fat were the definition of "low fat." One comment offered the rationale that on a per serving basis, "very low fat" should be 0.5 g to 2 percent or less of the DRV (based on 75 g of fat) for fat, and "low fat" should be 5 percent or less of the DRV.

The agency is rejecting this recommendation because it is based upon an increase in the proposed definition of "low fat," which the agency is not making as explained in the previous comment. Also, as discussed in response to comment 124 of this document, additional "very low" terms will be confusing to consumers. Accordingly, the agency is not defining "very low fat."

131. At least one comment recommended that "low fat" foods be defined only as those foods containing no more than 3 g of fat per 100 g. The reason given for this recommendation is that it would simplify the comparison of foods.

As explained in response to a similar suggestion for "fat free" claims (see comment 98 of this document), FDA does not believe that this approach alone is appropriate for the definition of nutrient content claims because it does not adequately account for the way foods are consumed.

132. A few comments objected to the agency's approach of defining "low fat" in terms of g of fat per serving (proposed § 101.62(b)(2)(i)). One comment recommended that a "low fat" food be defined as a food having no more than 30 percent of calories derived from fat. Other comments recommended limits of 25 percent and 20 percent of calories derived from fat. Similarly, another comment stated that a "very low fat" food should have no more than 10 percent of calories derived from fat.

The agency disagrees with this suggestion for several reasons. Dietary recommendations to obtain no more than 30 percent of calories from fat are aimed at the total diet, not at individual foods. The agency believes that expressing claims in terms of g per serving as the basis for all "low" nutrient content claims is preferable because this amount is absolute. The percent of calories from fat varies disproportionately with the total number of calories in a food. If the number of calories is low, the percent of calories from fat can be relatively high. For example, the percent of calories from fat for radishes is over 25 percent. Thus, they would not be considered a "low fat" food using one of the approaches suggested. In fact, radishes contain only about 0.3 g of fat per serving and qualify as a "fat free" food using FDA's approach. Consequently, FDA concludes that the requested approach can be extremely misleading, especially when applied to certain categories of foods that are consistent with recommended diets (e.g., fresh fruits and vegetables).

Furthermore, FDA recognizes that consumers are most familiar with nutrient content claims being expressed in terms of g per serving. Comments that the agency has received in response to the 1989 ANPRM and in the public hearings that followed also supported continued use of serving sizes in the definition of nutrient content claims, as did the IOM report (Ref. 14). Finally, one of the goals of nutrient content claims is to help consumers construct a diet that is consistent with dietary guidelines. Claims based on absolute per serving amounts are much easier to use in this way than claims based on percentages computed for the individual food. Accordingly, the agency is not defining "low fat" in terms of percent of calories from fat.

133. A number of comments suggested that FDA should vary the quantitative definition of "low fat" according to food category and designate as "low" those foods that are relatively low compared to other foods in the same food category. In support of this approach, the comments argued that a single criterion may cause consumers to avoid food categories in which no foods qualify for a claim, making the task of educating consumers about appropriate choices within those categories more difficult.

The agency considered this approach and is rejecting it for the reasons discussed in the general principles proposal (56 FR 60421 at 60439). In summary, the agency believes that relative claims can be used to highlight certain foods in the same food category. The use of different criteria for "low fat" foods in different food categories would make it difficult for consumers to compare products across food categories and to substitute one food for another in their diets. Furthermore, this approach would make it possible for some foods that did not qualify to use the nutrient content claim to contain less fat than foods in other categories that did qualify. FDA has received many comments asking for consistency among nutrient content claims to aid consumers in recalling and using the defined terms. In addition, the IOM report (Ref. 14) recommended such consistency. None of the comments provided any basis for why these factors should not be controlling. Accordingly, the agency will not vary the quantitative definition of "low fat" from food category to food category.

134. At least one comment suggested that foods be described as "low fat" if they contain one-third less fat than the "regular" food.

FDA disagrees with this terminology because it believes it is not appropriate. However, FDA agrees that foods with a one-third reduction in fat content compared to an appropriate reference food should be able to make a claim and is providing in new § 101.62(b)(4) that such foods may be described as "reduced fat" or "less fat." Consequently, the agency concludes that no change is warranted in response to this comment.

135. One comment suggested that a food that is "low fat" should also be

"low cholesterol," and that the descriptor should be "low fat/low cholesterol." Using the same rationale, the comment suggested that the claim "fat free/cholesterol free" be used in place of "fat free" and "cholesterol free." Another comment expressed concern about "fat free" being used to describe foods that contain high levels of cholesterol.

The agency believes that this approach is overly restrictive and is not in accord with section 403(r)(2)(B)(ii) of the act, which provides that cholesterol should be identified on the PDP (i.e., "See ———— panel for information on cholesterol and other nutrients") only at levels associated with increased risk taking into account the significance of the food in the total diet. The agency has determined that these levels for cholesterol are those exceeding 20 percent of the DRV or 60 mg of cholesterol per reference amount, per labeled serving size, or, for foods with reference amounts of 30 g or less or 2 tablespoons or less, per 50 g of food. Section 403(r)(2)(A) of the act, which makes special provisions for cholesterol, saturated fat, and fiber claims, makes no such provision for fat claims. Accordingly, the agency is making no change in response to these comments. The agency notes that it is unaware of any "fat free" foods that contain 60 mg cholesterol.

iv Low saturated fat. 136. The agency received several comments on proposed § 101.62(c)(1) which defines "low in saturated fat" as 1 g or less per serving and no more than 15 percent of calories from saturated fatty acids. Most of the comments supported the criterion of 1 g or less per serving. Other comments requested that the cutoff be a higher value. One comment stated that this claim should be defined only in terms of percent of calories from saturated fat but did not suggest a percentage. Another comment stated that it would be more appropriate to permit this claim on foods that are high in total fat and relatively low in saturated fat but did not make a specific recommendation.

The second criterion for the term "low in saturated fat" is discussed in comment 137 of this document. In this section, the agency is addressing the comments on the first criterion of 1 g or less of saturated fat per serving.

The comments recommending a cutoff of 2 g per serving stated that this value would be consistent with Canada's definition of "low in saturated fat" and with the proposed saturated fat threshold on cholesterol claims. They pointed out that FDA's rationale for the 2 g threshold is that it is consistent with current dietary recommendations that 10 percent of calories come from saturated fat. One comment complained that a cutoff of 1 g would result in canola oil being the only oil able to bear this claim. The comment said that this oil is very minor in both production and consumption in the United States. It alleged that FDA has failed to recognize the strong body of scientific evidence that consumption of polyunsaturated fat lowers blood cholesterol. The comment contended that in terms of its effect on blood cholesterol, the effect of the low saturated fat content of canola oil is negated by its polyunsaturated fat content. The comment said that it has been shown conclusively in humans that both corn oil and soybean oil are better than canola oil in lowering serum cholesterol. The comment argued that the proposed definition "is clearly discriminatory, arbitrary, and ill-serves the U.S. industry and the consumer."

Another comment, which supported a definition of 2 g or less of saturated fat per serving and no more than 15 percent of calories from saturated fat, presented data that it claimed showed that saturated fat intake both for the total population and the 90th percentile is basically identical whether the first criterion is 1 or 2 g per serving. It concluded that a cutoff of 1 g would unreasonably restrict consumer choices of foods with no dietary impact on saturated fat.

The agency has reconsidered this issue and agrees with the majority of the comments that 1 g or less is the appropriate per serving criterion for the "low in saturated fat" claim, which is the proposed value. FDA is not persuaded by the arguments or by its own review of the saturated fat content of foods (Ref. 20) that increasing the per serving allowance in the definition is necessary or prudent if the term is to be useful to consumers attempting to control their intake of saturated fat. FDA acknowledges that only a limited number of fats and oils will be able to make this claim but points out that in addition to canola oil, high oleic safflower oil, almond oil, apricot kernel oil, and hazelnut oil qualify. Also, mayonnaise type salad dressing and various types of low calorie salad dressings can make this claim. With respect to the statement that corn oil and soybean oil are better than canola oil in lowering serum cholesterol, the agency notes that this statement was not supported by data in the comment.

As explained in the fat/cholesterol proposed rule (56 FR 60486) and in the section on "low fat" in this final rule, FDA is defining "low fat" as 2 percent of the DRV for fat times two to adjust for the fat distribution in the food supply, or 3 g of fat per serving. Using the same approach for saturated fat and the recommendation of current dietary guidelines (Refs. 7, 12, and 17) that the consumption of saturated fat be less than 10 percent of calories, the agency concludes that "low in saturated fat" should be defined as 1 g or less per serving.

This conclusion reflects the fact that total fat and saturated fat have similar distributions in the food supply. An FDA analysis has determined that both total fat and saturated fat are present in over half of 18 USDA-defined food categories (Ref. 21). For the purpose of that analysis, a nutrient was considered to be "present" in a food category if over one-half of the foods in the category contained 2 percent or more of the proposed DRV. Further, the agency remains convinced that this amount is a reasonable definition for "low in saturated fat" because an average level of 1 g in 16 to 20 servings of food per day would supply 16 to 20 g of saturated fat daily, within the DRV for saturated fat of 20 g (§ 101.9(c)(9)(i)). An average level of 1.5 g in 16 to 20 servings per day would supply 24 to 30 g of saturated fat, exceeding the DRV. Similarly, an average level of 2 g would supply 32 to 40 g of saturated fat. For this reason, the agency concludes that 1.5 g or more of saturated fat per serving is not an appropriate definition for "low in saturated fat." Accordingly, the agency is denying the requests that the cutoff for the per serving criterion be increased or eliminated.

137. Some comments recommended that the second criterion in proposed § 101.62(c)(1), which defines "low in saturated fat" as 1 g or less per serving and no more than 15 percent of calories from saturated fatty acids, be eliminated, and a few comments suggested that it be changed to a lower value.

The comments that recommended that the second criterion should be eliminated said that this criterion prevents claims on some of the foods recommended by NCEP for lowering saturated fat intake. Also, one comment pointed out that when fat is reduced in a food that is relatively low in saturated fat, the percent of calories from saturated fat is increased (i.e., a food able to make this claim could be disqualified by fat removal). Other comments stated that the second criterion is not needed because manufacturers will no longer be able to manipulate serving size. Furthermore, one comment contended that there is no evidence that foods that are nutrient dense are consumed in excess. A few comments said that "percent of calories

from saturated fat" should apply to the total diet, not to individual foods, and that 15 percent is inconsistent with the guidelines. Values of 10 percent and 7 percent were recommended.

The agency is not persuaded by the comments that it should eliminate the second criterion or lower this value. The agency continues to believe that a second criterion is needed to prevent misleading "low" claims on nutrient-dense foods with small serving sizes. The second criterion in the agency's definition for "low in saturated fat" is for this purpose. A general discussion of second criteria for "low" claims may be found in section III.A.1.b. of this document.

The agency agrees with the comment that "percent of calories from saturated fat" generally should apply to the total diet, not to individual foods. For this reason, the agency did not accept the recommendation that a "low fat" food should be defined as having no more than 30 percent of calories derived from fat as discussed in response to comment 132 of this document. The agency also pointed out in comment 132 of this document that for a given level of fat, the "percent of calories from fat" varies with the total number of calories in a food, that is, this approach focuses on the relative amount of the nutrient present in the food rather than the absolute amount. If the number of calories is low, the percent of calories from fat is relatively high. The percent of calories from saturated fat can increase either by increasing the amount of saturated fat or by decreasing the amount of total calories. As one comment observed, removal of fat could make the percent of calories from saturated fat increase, conceivably disqualifying a food from making a "low in saturated fat" claim. However, as stated above, this second criterion is necessary to prevent misleading "low in saturated fat" claims. As explained in the fat and cholesterol proposed rule (56 FR 60478 at 60492), the agency selected a second criterion of no more than 15 percent of calories from saturated fat because it tentatively determined that the approach used in selecting the second criterion for the other "low" claims yielded a criterion that was too restrictive (i.e., less than 1 g of saturated fat per 100 g of food). Consequently, FDA sought a different approach and considered the criteria of other nations. FDA found merit in Canada's approach of no more that 15 percent of calories coming from saturated fat, although the agency does not agree with Canada's first criterion of 2 g or less of saturated fat per serving. While dietary recommendations are for less than 10 percent of calories in the diet being provided by saturated fat, the fact that saturated fat is not ubiquitous in the food supply would allow higher amounts in those foods that contain saturated fats to balance off those that are lower, resulting in a total daily diet that meets dietary recommendations.

An examination of food composition data (Ref. 20) reveals that a regulation that allows foods containing 1 g or less of saturated fat per serving and no more than 15 percent of calories from saturated fat to make a "low in saturated fat" claim results in a reasonable number of foods being able to make this claim. These foods include most fruit, vegetables, and grains; skim milk and other dairy foods made from skim milk; a few nondairy cream substitutes and dessert toppings; egg substitutes; mayonnaise type salad dressing, low calorie salad dressings, canola oil, and high oleic safflower oil; fish and shellfish; many cereals, breads, and soups; and some cookies and candies. However, evaporated milk, non-dairy desert toppings, and margarine spreads will not be able to make a "low in saturated fat" claim because the percent of calories from saturated fat in these foods exceeds 15 percent. "Low in saturated fat" claims on these foods would be misleading because they do not contain especially low levels of saturated fat.

The agency acknowledges that this definition prevents this claim from appearing on some of the foods that NCEP recommends be used as substitutes for other foods in achieving a lower intake of saturated fat. For example, the NCEP recommends using skim or 1 percent fat milk as a substitute for whole milk, and 1 percent fat milk will not be able to make a "low in saturated fat" claim. The agency agrees with NCEP's recommendations but does not believe that all such substitute foods, including 1 percent fat milk, are necessarily "low in saturated fat." The NCEP, in many cases, recommends selections that are "lower" in fat than the foods for which they substitue in the diet. The agency continues to believe that this claim should enable consumers to easily identify the foods that contain especially low levels of saturated fat, and that the proposed definition achieves this purpose. Accordingly, the agency is denying the request that the second criterion of no more than 15 percent of calories from saturated fat be eliminated or changed in value.

138. At least one comment requested that FDA eliminate the requirement in proposed § 101.62(c) that the amount of cholesterol be disclosed in proximity to the claim "low in saturated fat." The comment stated that disclosure of cholesterol is unwarranted because dietary cholesterol has no effect on serum cholesterol levels. Other comments supported the proposed rule with respect to disclosure of cholesterol. At least one comment stated that the cholesterol disclosure is too lenient. This comment stated that a "low in saturated fat" claim should only be allowed on foods that never contain cholesterol.

The agency points out that the provision on the disclosure of cholesterol with a "low in saturated fat" claim, as well as the other saturated fatty acid claims, is required by section 403(r)(2)(A)(iv) of the act. Accordingly, the agency is making no change in response to these comments. The effect of dietary cholesterol on serum cholesterol levels is discussed in response to comment 115 of this document requesting that all cholesterol claims be banned.

139. A few comments objected to the requirement in proposed § 101.62(c) that the amount of fat in a food be disclosed in proximity to the claim "low in saturated fat." One comment said that this provision goes beyond the demands of the 1990 amendments and is unwarranted. Another comment requested an exemption from fat disclosure for margarine. The comment said that it is unfair because disclosure is not required for butter. One comment stated that fat disclosure is only necessary for products that contain excessive fat. The comment recommended that fat disclosure be required only if the fat level exceeds 11.5 g per serving and noted that such a requirement would be consistent with the level at which fat is disclosed with cholesterol claims. Comments said that at the very least, fat disclosure should not be required at levels of 3 g or less per serving (i.e., a "low fat" food would not have to have a fat disclosure). Another comment recommended that if the fat level of a food exceeds 11.5 g per serving, the label should state, "high in fat." It said that stating the amount of fat is not meaningful to most consumers. Other comments supported the proposed rule with respect to disclosure of fat.

The agency agrees that this provision is not required in the 1990 amendments and is persuaded that fat disclosure should not be required at levels of 3 g or less per serving. The agency concludes that such disclosure is unnecessary because 3 g or less is the per serving criterion for the term "low fat." A consumer who does not differentiate between a "low in saturated fat" and "low fat" claim

would not be misled by a "low in saturated fat" claim as long as the fat level of the food is 3 g or less per serving. For uses of "low in saturated fat" on foods with more than 3 g of fat, disclosure of fat content is required to avoid misleading the consumer. For this reason, the agency is denying the requests that disclosure of fat content be required only when the fat content exceeds 11.5 g per serving. The fat content is a material fact at levels above 3g when a "low in saturated fat" claim is made.

Also, the agency is denying the request that margarine be exempt from fat disclosure. The disclosure of total fat on foods (except foods that are "low fat") that bear a "low in saturated fat" claim is necessary to ensure that consumers who do not differentiate between a "low fat" and a "low in saturated fat" claim are not misled by the latter claim. The agency notes that butter is not required to disclose fat because it does not bear a "low in saturated fat" claim.

Finally, the agency is not requiring that the label of a food with a "low in saturated fat" claim state that it is "high in fat" if it contains more than 11.5 g per serving. FDA has not defined "high in fat." In addition, 11.5 g was the proposed disclosure level. As explained in comment 13, FDA has raised the disclosure level to 13.0 g of fat. However, to require a "high in fat" statement on foods that bear a claim and contain more than that level of fat would be inconsistent with the disclosure concept in section 403(r)(2)(B) of the act.

140. At least one comment stated that the "low in saturated fat" claim is misleading on a food that contains hydrogenated oil (i.e., contains trans fatty acids).

As discussed in comment 111 and 118 of this document, the evidence suggesting that trans fatty acids raise serum cholesterol remains inconclusive. For this reason, the agency finds that it cannot conclude that a "low in saturated fat" claim on a food containing trans fatty acids is misleading. Accordingly, the agency is making no change in the final rule in response to this comment. However, as explained in comment 111 of this document, the agency has included a limit for trans fatty acids as a criterion for a "saturated fat free claim," because of the implications of that claim and the particular importance of that claim.

141. A few comments requested that "——— percent unsaturated fat" be allowed as a synonym for a claim about saturated fat. One of the comments stated that without the ability to make this claim, there is an economic incentive for manufacturers to substitute soybean oil for canola and safflower oil. They said the data do not support FDA's concern that positive claims about high fat will increase consumption.

The agency is not allowing the term "unsaturated fatty acids" to appear in the nutrition label because of uncertainty about its definition, specifically, the inclusion of trans isomers of monounsaturated fat, as discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. Therefore, the agency concludes that it would be inappropriate to define the term "——— percent unsaturated fat," and the agency is denying this request.

v. Low cholesterol. 142. Only a few comments supported proposed § 101.62(d)(2) that defines "low cholesterol" as less than 20 mg per serving and per 100 g of the food. Most of the comments on this issue objected to the criterion based on weight, and some of these comments suggested alternatives to this criterion.

The weight-based criterion for the term "low cholesterol," as well as for the other "low" terms, has been discussed in section III.A.1.b. of this document on the general approach to nutrient content claims. In this section, the agency is addressing the comments on the criterion of less than 20 mg of cholesterol per serving.

The majority of the comments recommended that "low cholesterol" remain at 20 mg or less per serving. A few comments requested that the cutoff be a lower value, and a few other comments wanted a higher value. The comments favoring a cutoff of 15 mg pointed out that many foods consumed throughout the day have ingredients that contain cholesterol (e.g., bread). They stated that the recommended intake of less than 300 mg of cholesterol per day could easily be exceeded if these foods are eaten in sufficient quantity. One of the comments favoring a cutoff of 30 mg also believed that "cholesterol free" should be less than 5 mg per serving. The comment contended that the cutoff for "low cholesterol" should be six times the cutoff for "cholesterol free" because the cutoff for "low fat" is six times the cutoff for "fat free."

The agency agrees with the majority of the comments that 20 mg or less cholesterol is the appropriate per serving criterion for the "low cholesterol" definition. As explained in the fat/cholesterol proposed rule (56 FR 60478 at 60486), FDA considered that a "low" claim for a nutrient that is ubiquitous in the food supply should be an amount equal to 2 percent of the DRV for the nutrient. To arrive at a definition when a nutrient is not ubiquitous, the agency proposed to increase the 2 percent amount to adjust for the nutrient's uneven distribution in the food supply. If the nutrient is found at measurable levels in foods from only a few food categories, the agency proposed to define "low" as three times 2 percent of the DRV. Cholesterol, which is found only in foods of animal origin, is in this group of foods. The DRV for cholesterol is 300 mg, 2 percent of which is 6 mg. Therefore, the value for "low cholesterol" computes to 18 mg, which rounded to the nearest 5 mg increment, is 20 mg per serving.

Consequently, the agency is denying the request that the cutoff for "low cholesterol" be less than 30 mg because it concludes that this value is too high to be useful to consumers attempting to control their intake of cholesterol. Moreover, the agency disagrees with the rationale presented for 30 g that the cutoff for "low cholesterol" should be six times the cutoff for "cholesterol free" based on a value of 5 mg, because the cutoff for "low fat" is six times the cutoff for "fat free." The agency emphasizes that the "low" values are derived from the DRV's, not from the limit of detection. Also, the agency is denying the request that the cutoff for "low cholesterol" should be less than 15 mg on the basis that is too restrictive. Cholesterol is not so widespread in the food supply that such low levels are necessary to help consumers to structure their diets to be consistent with dietary guidelines for cholesterol. A "low cholesterol" claim based on 20 mg will be useful to consumers in structuring a total diet that is consistent with dietary guidelines.

Accordingly, the agency is not revising the final rule to change the amount allowed per serving for a "low cholesterol" claim.

143. The agency received relatively few comments on the requirement for disclosure of total fat with cholesterol claims. Some of the comments supported the provision of the proposed rule that the amount of fat must be declared next to a cholesterol claim if the fat content exceeds 11.5 g per serving or per 100 g of food. Other comments favored disclosure at other levels of fat, including all levels of fat, while some comments opposed disclosure of any amount of fat. One comment said that disclosure of the amount of fat would not be useful to the average consumer and suggested the statement, "this product is not low in total fat."

A few comments stated that the term "low cholesterol" on the label of a food containing high levels of fat is misleading, even if the amount of fat is disclosed. These comments recommended that cholesterol claims have a fat threshold above which claims are disallowed. One comment requested that a "low cholesterol" claim, as well as a "cholesterol free" claim, not be allowed on foods containing more than 3 g of fat and 0.15 g of fat per g of dry matter. This comment argued that a limit on total fat is needed to prevent manufacturers from meeting the saturated fat threshold by replacing saturated fat with trans fatty acids. As discussed in response to comment 117 of this document, another comment proposed a 3 g limit on fat specifically for "cholesterol free" claims but did not refer to "low cholesterol" claims. One other comment requested that a "low cholesterol" claim not be allowed on food containing more than 5 g of fat and more than 20 percent total fat on a dry weight basis.

The agency has reviewed this issue and continues to believe that fat disclosure is preferable to a fat limit above which the claim "low cholesterol," as well as other cholesterol claims, cannot be made. The agency has the authority under the act to establish a fat limit with cholesterol claims. Section 403(r)(2)(A)(vi) of the act states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food." The agency has used this authority to prohibit cholesterol claims on foods containing more than 2 g of saturated fat per serving, which is discussed in response to comment 116 of this document. However, the agency does not find that a cholesterol claim on the label of a food containing high levels of fat is misleading when the fat amount is disclosed in proximity to the claim because total fat per se does not affect blood cholesterol levels. Thus, consumer expectations regarding blood cholesterol levels are met as long as the food contains the requisite amount of cholesterol and 2 g or less of saturated fat per serving.

The agency proposed that amounts of fat exceeding 11.5 g per serving or per 100 g of food have to be disclosed. The 11.5 g amount represents 15 percent of the DRV for fat. Disclosure of the amount of fat, rather than the statement, "this product is not low in total fat," is in accordance with section 403(r)(2)(A)(iii) of the act. This section states that the amount of total fat shall be disclosed in immediate proximity to a cholesterol claim if a food, taking into account its significance in the total diet, contains fat in an amount that increases the risk for persons in the general population of developing a diet-related disease or health condition.

In response to comments requesting that FDA modify the disclosure level in § 101.13(h) to 20 percent of the DRV, the agency is changing the final rule to provide that disclosure levels for fat are those exceeding 13 g of fat per reference amount, per labeled serving size, or, for foods with a reference amount of 30 g or less or 2 tablespoons or less, per 50 g of food. The rationale for this change is presented in the final rule on health claims, published elsewhere in this issue of the **Federal Register**.

144. About 15 comments opposed the provision in proposed § 101.62(d)(1)(ii)(E) and (d)(2)(ii)(E) that the amount of cholesterol in certain foods bearing "cholesterol free" or "low cholesterol" claims must be "substantially less" than the food for which it substitutes (i.e., it must meet the requirements for a comparative claim using the term "less" in proposed § 101.62(d)(5)(i)(A)). The foods included were those that contain more than 11.5 g of fat per serving or per 100 g of food and that contain, only as a result of special processing, an amount of cholesterol per serving that meets the relevant criterion for a "free" or "low" claim. The proposed requirements for comparative claims that apply are that the food contain at least 25 percent less cholesterol, with a minimum reduction of more than 20 mg cholesterol per serving, than the reference food.

The majority of the comments opposed the minimum reduction of cholesterol of more than 20 mg. One comment contended that the requirement for a minimum reduction goes beyond the requirements of section 403(r)(2)(A)(iii)(I) of the act that the level of cholesterol should be substantially less than the level usually found in the food or in a food that substitutes for the food. Many of these comments opposed this minimum because it would disallow a cholesterol claim on products such as 2 percent milk that has up to 95 percent of its cholesterol removed. These comments also opposed the proposed saturated fat threshold because the dairy products that have undergone cholesterol removal contain more than 2 g of saturated fat per serving. These comments requested that a cholesterol claim be allowed on the label of a food, regardless of the food's fat or saturated fat content, provided that the food has at least 33 percent of the indigenous cholesterol removed, and that the content of total fat is disclosed.

At least two comments supported the proposed minimum but opposed the disclosure statement (i.e., disclosure of the percent that the cholesterol was reduced, the identity of the reference food, and quantitative information comparing the level of cholesterol in the product per serving with that of the reference food). At least one comment opposed the required minimum, the 25 percent reduction, and the disclosure statement. This comment stated that the claims "cholesterol free" and "low cholesterol" should refer to an absolute level of cholesterol rather than to a relative level.

The agency is persuaded by these comments that the minimum reduction of cholesterol of more than 20 mg is unduly restrictive because it discriminates against products containing relatively small amounts of cholesterol. Accordingly, the agency is eliminating this requirement in the final rule for the "cholesterol free" and "low cholesterol" claims as well as for comparative claims (as discussed in response to comment 158 of this document). However, the agency continues to believe that "substantially less" cholesterol should be interpreted as 25 percent less cholesterol than the reference food. Twenty-five percent represents the extent of reduction necessary to make a "less" or "reduced" claim. Consequently, the agency is denying the request that the labeled food contain 33 percent less cholesterol, or that no reduction in cholesterol be required.

Furthermore, under section 403(r)(2)(A)(iii)(II) of the act, the disclosure statement must appear in immediate proximity to the claim, as proposed. FDA is providing, however, in § 101.62(d)(1)(ii)(F)(2) and (d)(2)(iii)(E)(2) in this final rule that the quantitative information comparing the level of cholesterol in the product with that of the reference food may appear on the information panel in conjunction with nutrition labeling. The agency is making this change in § 101.13(j)(2)(iv) to prevent label clutter on the PDP, as discussed in response to comment 214 of this document. The request that a cholesterol claim be allowed regardless of saturated fat content is addressed elsewhere in this document (see comment 116 of this document), as is the need for fat disclosure with cholesterol claims (see comment 143 of this document).

vi. Lean. 145. FDA received several comments that supported use of the terms "lean" and "extra lean" with FDA-regulated meat products or meal-

type products in accordance with definitions of these terms as proposed by the Food Safety and Inspection Service (FSIS). Meal-type and main dish products are defined and fully discussed elsewhere in this final rule.

One comment requested that FDA allow use of the terms "lean" and "extra lean" on the labels of fishery products in a manner similar to that proposed by FSIS. The comment noted that the composition of some fishery products would prevent them from bearing the nutrient content claim "low fat" on their labels in accordance with the definition of this term in FDA's fat/cholesterol proposal. The comment also pointed out that FDA's general principles and fat/cholesterol proposals did not provide for use of the term "lean" or "extra lean" on the labels of fish products. However, if these foods were considered under FSIS' proposed regulation, a substantial number of them would qualify for use of the term "lean" or "extra lean" on their labels.

Another comment stated that FDA should permit product lines that contain both USDA- and FDA-regulated meal-type products to bear descriptive terms such as "lean" and "extra lean" that can be applied to the entire product line for labeling and advertising purposes. The comment further stated that, if FDA does not allow the terms "lean" and "extra lean" on food products regulated by the agency, then these terms will most likely not be used on any meal-type products. The comment also stated that the USDA proposed criterion for saturated fat should be eliminated because it is too restrictive.

These comments raise an issue that FDA finds has merit. By way of background, on November 27, 1991, FSIS published a proposed rule (56 FR 60302) on nutrition labeling of meat and poultry products. In that proposal, FSIS presented definitions of the descriptive terms "lean" and "extra lean" that would only be applicable to the meat and poultry products that FSIS regulates under the authority of the Federal Meat Inspection Act (21 U.S.C. 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq.). FSIS proposed that the term "lean" could be used to describe a meat or poultry product that contained less than 10.5 g fat, less than 3.5 g saturated fat, and less than 94.5 mg cholesterol per 100 g. The term "extra lean" could be used to describe a meat or poultry product that contained less than 4.9 g fat, less than 1.8 g saturated fat, and less than 94.5 mg cholesterol per 100 g. FSIS also proposed to permit these terms to be used to describe multi-ingredient meal-type products.

Data supplied by the American Heart Association (AHA), in response to the April 2, 1991, FSIS ANPRM (56 FR 13564) on nutrition labeling of meat and poultry products, provided the basis for the criteria that FSIS used in its proposed definitions of these terms. These data consisted of levels for total fat, saturated fat, and cholesterol of selected fresh and processed "meat" items (various types of beef, veal, pork, lamb, poultry, and fish) on a "cooked weight" basis. Using recommended food consumption patterns and dietary guidance recommendations as bases, AHA selected threshold values for fat, saturated fat, and cholesterol levels of these muscle foods on a 1 oz and 3 oz "cooked weight" basis. Threshold values for "lean" represent approximately 7 percent fat in raw meat and 10 percent fat by weight in cooked meat. Threshold values for "extra lean" represent approximately 5 percent fat by weight.

The levels in FSIS' proposed definitions were derived by converting AHA's threshold values from a 1 oz to 100 g basis. Upon making this calculation, FSIS found that the values obtained approximated the agency's criterion for use of the terms "lean" and "extra lean" on the labels of meat and poultry products as discussed in a November 18, 1987, FSIS policy memorandum 7OB(Ref. 22).

Based on comments received in response to its nutrition labeling proposal (56 FR 60302), FSIS, in a final rule published elsewhere in this issue of the **Federal Register**, has changed the rounding rule that it originally used. In addition, FSIS has developed modified criteria for levels of total fat, saturated fat, and cholesterol such that the ratio of saturated fat to total fat would be 40 percent for both nutrient content claims. FSIS considers the ratio of 40 percent to be reasonable because it is representative of the ratio of saturated fat to total fat inherent in ruminant muscle. Although AHA's suggested criteria were based upon fresh and processed cooked meat (cut or ground), in its final rule, FSIS is adopting criteria on an "as packaged" basis to achieve consistency with that agency's past labeling policy.

Under the FSIS final rule, to bear the term "lean," a meat or poultry product must contain less than 10 g fat, less than 4 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g. To bear the term "extra lean," the product must contain less than 5 g fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount and per 100 g for individual foods. The criteria in the definitions of these terms for meal-type products under the FSIS final rule are presented elsewhere in this final rule.

The comments supporting use of the terms "lean" and "extra lean" on the labels of meat products and meal-type products have persuaded FDA to include provisions in this final rule consistent with those of FSIS to provide for use of the terms "lean" and "extra lean" to describe certain comparable foods regulated by FDA under the act. In the proposal, FDA solicited comments on whether additional defined terms were needed (56 FR 60421, 60431), and these comments demonstrated that the agency needed to add terms useful for these types of foods. FDA has statutory authority to enforce the act's provisions that prohibit misbranding of all foods except for those products exempted under the act (section 902 of the act (21 U.S.C. 392)). Thus, FDA is responsible for regulation of the labeling of certain types of meat products (e.g., seafood, bison, rabbit, game meats) not regulated by USDA under the Federal Meat Inspection Act (21 U.S.C. 601–623 et seq.) or the Poultry Products Inspection Act (21 U.S.C. 451–469) or in situations in which these products are not subject to USDA regulation. In addition, FDA is responsible for regulation of meal-type products not regulated by USDA under either of the aforementioned acts.

The agency recognizes that seafood and seafood products play a comparable role in the diet to that of meat and poultry products and, like meat and poultry products, contribute to the total dietary intake of fat, saturated fat, and cholesterol. In addition, FDA-regulated meal-type products are consumed in the same manner as USDA-regulated meal-type products covered by the FSIS rule. FDA concludes that providing for use of the descriptive terms "lean" and "extra lean" as nutrient content claims on the labels of seafood (including finfish and shellfish) and meal-type products that it regulates would be of value to consumers in maintaining healthy dietary practices. The terms "lean" and "extra lean" will describe foods of these types with relatively lower levels of fat, saturated fat, and cholesterol. In addition, the agency recognizes that the same conclusion applies to other meat products regulated by FDA (e.g., bison, rabbit, game meats).

Analyses of FDA's Food Composition Data Base (Ref. 23), which is based on USDA's Agriculture Handbook Number 8 on food composition, show that many fish/shellfish products (on a raw basis with a reference amount of 110 g) would qualify to bear "lean" or "extra lean" claims under FSIS' definitions of these

terms that FDA is adopting. Haddock, swordfish, and clams, for example, could be appropriately labeled as "extra lean," while Spanish mackerel and Bluefin tuna would be eligible for use of the term "lean" on their labels. On the other hand, neither term could be used on such seafood items as shrimp, Chinook salmon, or any other seafood item with a composition that exceeds the limits on the levels of total fat, saturated fat, or cholesterol established for use of the term "lean." Similarly, for game meats and related FDA-regulated meat products (on a raw basis with a reference amount of 110 g), based on data from USDA's Agriculture Handbook Number 8 on food composition (Ref. 24), domesticated rabbit could be differentiated from deer (venison) because domesticated rabbit would qualify for "lean" and deer for "extra lean."

FDA's action in promulgating equivalent definitions of these terms will enable consumers to compare the nutritional values of meat products and meal-type products that may serve as substitutes for one another in a balanced diet. Therefore, FDA is including in this final rule § 101.62(e) that permits use of the terms "lean" and "extra lean" on individual foods and on meal and main dish products. Use of these descriptive terms for FDA-regulated meal and main dish products is addressed elsewhere in this final rule. Because the agency is including this definition in the final rule, it is redesignating proposed § 101.62(e), a provision that addresses misbranding, as § 101.62(f) in the final rule.

FDA recognizes that the definitions of "lean" and "extra lean" for meat items allow this claim to be used when cholesterol levels exceed FDA's disclosure levels for this nutrient in the food (i.e., 60 mg). The agency considered whether to prohibit these claims on FDA-regulated meat products that contain greater than 60 mg cholesterol. However, the agency concluded that it would be of benefit to consumers to permit the claim on meat products that have a cholesterol content exceeding the disclosure level because the claims identify foods relative to other foods in this broad food class that contain lower amounts of fat and saturated fat. Thus, use of these claims would assist consumers in selecting such foods in constructing a total diet. Furthermore, when the cholesterol level in the food exceeds FDA's disclosure level, § 101.13(h) requires a disclosure statement referring the consumer to the nutrition information panel for additional information about cholesterol content.

3. "High" and "source"

Section 3(b)(1)(A)(iii)(VI) of the 1990 amendments requires that the agency define the term "high." Section 403(r)(2)(A)(v) of the act states that foods bearing a "high" claim for fiber either must be "low" in fat, or their labeling must disclose the level of total fat in the food in immediate proximity to the claim with appropriate prominence. In the general principles proposal (56 FR 60443), the agency proposed definitions for "high" and for "source," terms that may be used to emphasize the presence of a nutrient.

The agency proposed in § 101.54(a) to exclude total carbohydrate and unsaturated fatty acids from coverage under the proposed definition for "high" and "source." The agency explained that a nutrient content claim for these nutrients would be misleading.

The agency proposed in § 101.54(b)(1) that the terms "high," "rich in," or "major source of" may be used to describe the level of a nutrient in a food (except meal-type products) when a serving of the food contains 20 percent or more of the proposed RDI or the proposed DRV for that nutrient. The agency also proposed in § 101.54(c)(1) that the terms "source," "good source of," or "important source of" may be used to describe a food when a serving of the food contains 10 to 19 percent of the proposed RDI or the proposed DRV.

The agency also proposed in § 101.54(d) that if a nutrient content claim is made with respect to the level of dietary fiber, that is, that the product is "high" in fiber, a "source" of fiber, or that the food contains "more" fiber, and the food is not low in total fat as defined in proposed § 101.62(b)(2), then the label must disclose the level of total fat per labeled serving in immediate proximity to the claim and preceding the referral statement required in § 101.13.

The agency requested comments concerning its approach of limiting the number of descriptors that emphasize the presence of a nutrient to two levels. The agency explained that it took this approach to assist consumer understanding of, and confidence in, nutrient content claims. The agency also requested comments on whether an additional term describing an upper level amount of a nutrient (such as "very high") is necessary and appropriate. The agency also requested comments on the use of synonyms for terms like "high" and "source" and on consumer understanding of the terms proposed as synonyms for "high" and "source."

a. Synonyms

146. A few comments agreed that "rich in" and "major source of" are appropriate synonyms for "high." However, many comments disagreed with the proposed synonyms. Many of the latter comments stated that the agency should not allow use of any synonyms because the use of synonyms will be very confusing to consumers and could easily mislead them. A few comments requested the additional synonym "excellent source of" for "high."

Other comments agreed that "good source of" and "important source of" are appropriate synonyms for "source." However, many comments disagreed with the proposed synonyms. A few comments requested the use of additional synonyms for "source" such as: "meaningful source," "significant source," "provides," and "fortified with." Some stated that the term "provides" informs consumers that the food supplies the nutrient in question and has been in common use on food labels for years further assuring consumer familiarity with it. Some stated that the term "fortified with" has also been used on food labels for years, and is easily understood by consumers.

The agency notes that section 3(b)(1)(A)(ix) of the 1990 amendments provides that, in defining terms used for nutrient content claims, the agency may include similar terms that are commonly understood to have the same meaning as defined terms. Thus, the 1990 amendments clearly give the agency the authority to allow for synonyms. Moreover, section 403(r)(4)(A)(ii) of the act authorizes any person to petition the Secretary (and FDA, by delegation) for permission to use terms consistent with those defined by the agency under section 403(r)(2)(A)(i). Therefore, it is clear that the act contemplates that synonyms can be used. Further, the agency still believes, as stated in the general principles proposal (56 FR 60421 at 60444), that certain synonyms should be allowed in order to provide some flexibility in the use of defined terms.

The agency has, however, reconsidered the proposed synonyms for "high" and has revised some of them in this final rule to include terms that it believes would be more readily understood by consumers, and that convey the qualitative aspects of "good source" and "high." FDA recognizes that the synonyms it is providing for involve judgment on its part, and that individuals may have different views on appropriate synonyms. Nonetheless, FDA believes that a limited number of

synonyms will provide flexibility for food manufacturers in making claims and has endeavored to exercise reasonable judgment in providing for some synonyms while avoiding granting so many synonyms as to promote consumer confusion about their meaning.

Thus, in § 101.54(b), FDA is retaining "rich in" and adding "excellent source" as synonyms for "high." The agency is also providing for the use of "contains" and "provides" as synonyms for "good source" in § 101.54(c). FDA has deleted the proposed synonyms "major source of" for "high," and "important source of," for "good source." FDA notes that the terms it has added to the final rule, "excellent source," "contains," and "provides" are terms that have been used in the past and thus consumers will be familiar with them.

b. Definitions

147. Several comments agreed with the agency's proposed definition of "high" and the rationale upon which it was based, while other comments disagreed with the proposed definition. A few of the comments argued that 20 percent of the RDI or DRV is too high and would lead to little consumer benefit because few foods would be eligible to bear a "high" claim. One comment suggested lowering the eligibility level to 15 percent of the RDI or DRV so that more products would meet the definition without unnecessary supplementation.

The agency recognizes that many foods will not be able to meet the definition for "high." However, the agency is not persuaded by comments suggesting that it lower the eligibility level in the definition of "high" for this reason. The agency tentatively concluded in the proposal, and continues to believe, that a criterion of 20 percent or more of the RDI or DRV provides an appropriate basis for upper-level nutrient content claims.

Furthermore, the agency does not agree with comments that few foods would be eligible to bear "high" claims. In arriving at a definition for "high," FDA used its food composition data base to examine the types of foods that contain nutrients at levels that meet or surpass 20 percent of the proposed reference value per serving (Ref. 35). For the majority of the 17 nutrients considered, at least 10 percent of the foods in the data base contained 20 percent or more of the proposed RDI or DRV. For these nutrients there was at least one and often more than one food category that contained a substantial number of foods containing 20 percent or more of the RDI or DRV. Those nutrients for which fewer than 10 percent of the foods in the data base contain 20 percent or more of the RDI or DRV were calcium, magnesium, copper, manganese, potassium, pantothenic acid, and vitamin A. However, even with these nutrients (with the exception of potassium), there were a substantial number of foods in at least one food category that would qualify for "high" claims if the proposed definition were used.

Thus, the agency concludes that the 20 percent eligibility level will permit a sufficient number of food items to bear a "high" claim to allow consumers to use the claim in selecting a varied diet, and that this level provides an appropriate basis for upper-level nutrient content claims and can readily be used by consumers to implement current dietary guidelines. Therefore, FDA is retaining the 20 percent eligibility level in the definition of "high."

148. Several comments suggested lowering the eligibility level of "high" and "source" for dietary fiber claims. They argued that the proposed levels are too restrictive given that fiber is not ubiquitous in foods, and that it would preclude some good sources of dietary fiber, such as fruits, vegetables and whole grain breads, from bearing a "high fiber" claim. Suggested levels were as follows: "high" as 3 g and "source" as 1 g per serving; "high" as more than 4 g and "source" as 2 to 4 g per serving; and "high" as 4 to 8 g and "very high" as greater than 8 g per serving.

The agency has reviewed the comments and is not persuaded to lower the eligibility levels for "high" or "source" claims for dietary fiber. The agency agrees that fiber is not ubiquitous in foods. However, FDA notes that there are some fruits and vegetables that do qualify for "high," and considerably more that qualify for "source," claims for fiber under the proposed definitions. Based upon nutrient values for the 20 most commonly consumed raw fruits and raw vegetables (56 FR 60880, November 27, 1991, and corrected at 57 FR 8174, March 6, 1992), at least 25 percent of the products listed would be able to meet the proposed definition for "source." Furthermore, the agency believes that it is important to maintain consistency in defining terms for all nutrients and food components. Therefore, FDA is making no change in response to these comments.

149. A few comments requested that FDA define "high" and "source" for soluble and insoluble fiber. The comments stated that the Expert Panel on Dietary Fiber for the Federation of American Societies of Experimental Biology (FASEB) estimates that the dietary fiber in the current diet is comprised of approximately 70 to 75 percent insoluble fiber and 25 to 30 percent soluble fiber, and that some individuals are seeking products with higher levels of the specific fiber components.

The agency has established a DRV for dietary fiber but not one for insoluble or soluble fiber because no quantitative guidelines for daily intakes of soluble and insoluble fiber components have been established. Therefore, the agency has no basis on which to define "high" for insoluble and soluble fiber and has not made the suggested change.

150. One comment suggested that "high" and "source" claims for protein should be based on protein quality as well as level because such claims may be misleading if a food contains a lower quality protein. The comment suggested as a second criterion that a "high" in protein claim be allowed only for foods with a protein digestibility-corrected amino acid score (PDCAAS) greater than or equal to 40, and that for a "source" of protein claim, the food must have a PDCAAS of greater than or equal to 20.

The agency notes that § 101.9(c)(7)(i), proposed as § 101.9(c)(8)(i), provides that the percent DRV for protein must represent the corrected amount of protein based on its PDCAAS. Thus, the agency has already factored in the PDCAAS (see the discussion of protein quality in the Mandatory Nutrition Labeling proposal). Therefore, the agency believes that adding a second criterion based on the PDCAAS for "high" and "good source" in protein claims is not necessary. To determine whether a product qualifies for a claim as "high" in, or as "good source" of, protein, manufacturers must use the percent DRV for protein in a food that represents the corrected amount of protein based on its PDCAAS.

151. Some of the comments recommended defining the term "very high" to provide for use of this claim when a food contains 30 percent or more of the RDI or DRV per serving, so that consumers can distinguish between foods with "high" levels of nutrients and those with significantly more. Some comments recommended that the agency permit the term "principal source" as a synonym for "very high." However, a few comments agreed with the agency's position that the term "very high" should not be defined because allowing such a term could discourage consumption of a wide variety of foods in favor of fewer highly fortified foods and supplements. Other comments

proposed a three- or four- level system for claims that emphasize the presence of a nutrient. One suggested a three level system is as follows: "source of" as 10 to 19 percent; "good source of" as 20 to 49 percent; and "excellent source of" as 50 percent or more. A suggested four-level system is as follows: "source of" as 10 to 19 percent; "good source of" as 20 to 34 percent; "very good source of" as 35 to 49 percent; and "excellent source of" as 50 percent or more.

The agency has reviewed these comments and is not persuaded that it should define terms that correspond to levels of a nutrient that normally do not occur naturally in foods, e.g., "very high." In the general principles proposal (56 FR 60421 at 60443), the agency stated that defining a term such as "very high" could discourage adherence to current dietary guidelines such as those stated in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7), which emphasize the need to select a diet from a wide variety of foods and to obtain specific nutrients from a variety of foods rather than from a few highly fortified foods or supplements. The comments provided no information to cause the agency to change its position.

152. A majority of comments agreed with the agency's proposed definition for "source," while a few comments disagreed. Generally, the latter comments contended that the agency should not define "source" because consumers cannot reasonably be expected to distinguish between foods that are "high" in a nutrient as opposed to foods that are simply a "source" of a nutrient.

The agency agrees that consumers may not be able to understand the distinction between the meanings of "high" and "source." For example, the term "high" has a quantitative connotation, while the term "source" merely connotes that a nutrient is present but does not signify the quantity present. Therefore, the term "source" alone does not enable the consumer to conclude that the level of nutrient present is less than "high." However, the agency believes that the term "good source" conveys the appropriate information for a midlevel content claim, i.e., that a dietarily significant level of the nutrient is present, but that the level present is not exceptional with respect to levels naturally found in foods. Therefore, the agency is revising in § 101.54 the primary term for midrange nutrient content claims from "source" to "good source."

Thus, FDA concludes that adopting a two-level approach to claims that emphasize the presence of a nutrient based upon "good source" (as a replacement for "source") and "high" as the representative terms will provide meaningful information to consumers consistent with the intent of these proposed definitions.

FDA is, however, making a change in § 101.54. In proposed § 101.54(a)(3), FDA referred to § 101.36, in which the agency proposed to set forth the requirements for nutrition labeling of dietary supplements. In October of 1992, the Dietary Supplement Act of 1992 was enacted, which imposes a moratorium on implementation of the 1990 amendments. In response to this moratorium, FDA is not adopting § 101.36 at this time. Therefore, FDA has deleted the reference to § 101.36 from § 101.54(a)(3). FDA intends to revisit this issue in accordance with the provisions of the Dietary Supplement Act of 1992.

153. One comment stated that for fresh fruits and vegetables, the eligibility level for "source" should be 5 percent of the RDI for a nutrient because several nutrients occur naturally in fruits and vegetables at levels below 10 percent of the RDI.

The agency is not persuaded that the criteria for a mid-range nutrient content claim should include a lower eligibility level for fresh fruits and vegetables. As stated in the general principles proposal (56 FR 60421 at 60444), the agency has long held that a food is not a significant source of a nutrient unless that nutrient is present in the food at a level equal to or in excess of 10 percent of the U.S. RDA in a serving. The agency is unaware of any evidence suggesting that this policy should be changed, and none was presented in any comments to the proposal. Therefore, the agency is not including a lower eligibility level in the definition of "source" for fresh fruits and vegetables.

154. Some comments disagreed with the agency's exclusion of total carbohydrates from coverage under the proposed definitions for "high" and "source." The comments stated that "high" and "source" should be defined for complex carbohydrates because health authorities recommend that consumers increase the amount of complex carbohydrates in their diets.

The agency does not agree that it should define "high" and "good source" for complex carbohydrates. The agency has concluded that it is unable to define "complex carbohydrates," as discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. Therefore, there is no basis for nutrient content claims about this nutrient.

155. One comment suggested establishing definitions for "source" for polyunsaturated fatty acids and monounsaturated fatty acids because health authorities recommend increasing the intake of unsaturated fat while decreasing the intake of saturated fat.

Because the agency has determined that a DRV for unsaturated fat (including polyunsaturated and monounsaturated fatty acids) is potentially misleading, as explained in the RDI's and DRV's final rule, published elsewhere in this issue of the **Federal Register**, the agency concludes that there is no basis for defining "high" and "good source" for unsaturated fat.

156. A few comments opposed proposed § 101.54(d) that requires that unless a food meets the definition for "low fat" (3 g or less fat per serving and per 100 g), a "high fiber," "source of fiber," or "more fiber" claim must be accompanied by a declaration of the amount of total fat per serving in immediate proximity to the claim and preceding the referral statement. These comments stated that this provision targets only fat as an unhealthy nutrient, and therefore it is discriminatory and anti-competitive.

The focus on fat in conjunction with fiber claims derives from the statute itself. As stated above, section 403(r)(2)(A)(v) of the act provides that a claim may not state that a food is high in fiber unless the food is low in total fat, or the label discloses the level of total fat in the food. Thus, § 101.54(d) is required by the statute, and the agency is retaining this requirement in the final rule. Moreover, it is consistent with the statute's focus on fat in conjunction with fiber claims to require a similar fat disclosure when a "good source" or "more" claim for fiber is made.

c. relative claims

Sections 3(b)(1)(A)(iii)(III), (b)(1)(A)(iii)(IV), and (b)(1)(A)(iii)(V) of the 1990 amendments require that the agency define the terms "light" or "lite" (referred to collectively in this document as "light"), "reduced," and "less," unless the agency finds that the use of any of these terms would be misleading under section 403(a) of the act. These terms are used for comparing the amount of nutrient in one food with the amount of the same nutrient in another food or class of foods. The comparisons are called "relative claims." In the general principles proposal, the agency proposed definitions for "light," "reduced," and "less," as well as the terms "fewer" and "more." In addition, the agency proposed in § 101.13(j), requirements

specifying: (1) The reference foods that may be used as a basis for comparing the level of nutrients in one food with the level of those nutrients in another food for the various types of relative claims; (2) the information about the foods being compared that must accompany the claim; and (3) the minimum absolute amount of a nutrient by which the food must differ from the reference food in order to make a relative claim.

The definitions for relative claims proposed in the general principles proposal placed "less" (or "fewer"), "reduced," and "light" on a continuum using two criteria, both of which a food would have to meet to bear a specific relative claim. First, the proposal would have required that a food be reduced in the particular nutrient by a specific minimum percentage, depending on the claim. Secondly, it would have required that the level of a nutrient in the food be reduced by a minimum absolute amount (e.g., 3 g fat). The agency believed that such a regulatory scheme would limit consumer confusion with respect to the meaning of these terms.

To provide a basis by which comparisons between two foods could be made using relative terms, the agency proposed three types of reference foods (56 FR 60421 at 60445). These reference foods were: (1) A composite value of all foods of the same type, referred to as an industry-wide norm (proposed § 101 13(j)(1)(i)), which could be used as a basis of comparison for all relative claims; (2) a manufacturer's regular product (§ 101 13(j)(1)(ii)) which could be used for "reduced," "less," and "more" claims; and (3) a food or class of foods whose composition is reported in a current valid data base (proposed § 101.13(j)(1)(iii)) for use with "less" and "more" claims.

However, the agency acknowledged that it is possible that because of the natural vagaries of the language (56 FR 60421 at 60458), the terms "reduced" and "less" (or "fewer") may have no innately understood differences. Consequently, the agency acknowledged that any proposed regulatory distinction between the two terms may still be misleading. Therefore, the agency discussed the possibility, as an alternative approach, of providing the same definition for "reduced" and "less" and requiring information describing exactly how the foods differ to accompany the claim. Under this scheme, the percent that the nutrient in the labeled food differed from the reference food, a comparison of the actual amounts of nutrient in the labeled food and the reference food, and the identity of the reference food would have been conspicuously disclosed on the PDP of the label. The agency did not, however, discuss what reference foods would be appropriate as the basis for these claims if they were given the same definition. In the proposal, FDA discussed the possibility of publishing a supplemental notice on this alternative. Although a document was drafted and made available at a hearing that the agency held in January of 1992, it was never published in the **Federal Register** and thus must be considered a draft. However, the agency has fully considered comments it received on the alternative approach in arriving at this final rule.

1 "Reduced" and "less" (or "fewer")

a General provisions

Relative claims have traditionally been defined by the agency using a minimum percentage reduction. Under existing regulations, to make a "reduced sodium" claim or a "reduced calorie" claim, for example, the food must be reduced by 75 percent in sodium (§ 101.13(a)(4)) or 33 1/3 percent in calories (§ 105.66(d)). Moreover, in earlier documents on cholesterol claims, the agency proposed to require that cholesterol be decreased by 75 percent for a food to make a reduced claim (51 FR 42584, November 25, 1986; 55 FR 29456, July 19, 1990). The minimum percentage reduction has been used by the agency to ensure that the level of the nutrient that is the subject of a claim in a food that bears a claim has been decreased by a significant amount compared to the reference food.

In the general principles proposal FDA proposed that for a food to bear the term "reduced," it must contain at least one-third fewer calories or 50 percent less fat, saturated fat, cholesterol, or sodium than the reference food. To bear the term "less" (or "fewer") the agency proposed that a food must contain at least 25 percent less of the nutrient than the reference food.

However, the agency was concerned about misleading relative claims that highlight a decrease in the amount of a nutrient on products that normally contain only a small amount of that nutrient. For example, if such claims were allowed on the basis of a percentage reduction only, a food containing 50 calories per serving could be reformulated to contain 33 calories (a one-third reduction) and thereby qualify to make a "fewer" claim. The agency was concerned that such claims would be misleading because the difference in the amount of the nutrient would be insignificant with respect to the total daily diet.

To ensure that claims for products having relatively small amounts of nutrient not bear a claim unless the difference in the amount of nutrient was significant relative to the total daily diet, the agency proposed that a product also be reduced by an absolute minimum amount in order to bear a claim. The agency proposed to require that the minimum reduction necessary for the food to bear a relative claim be equal to the value of "low" for that nutrient, i.e., a reduction of at least 40 calories, 140 mg of sodium, 3 g fat, 1 g saturated fat, or 20 mg cholesterol. Consequently, the agency proposed that the definitions for "reduced" and "less" claims be based on both a minimum percentage difference and a minimum absolute difference in the amount of the nutrient.

In the general principles proposal (56 FR 60421 at 60458), as discussed above, FDA also requested comment on an alternative approach under which "reduced" and "less" (or "fewer") would have the same definition, and there would be a numeric disclosure of the actual amount and the percentage that nutrient in the labeled food differed from the reference food Under this approach, there would not be a single, across-the-board minimum percent reduction required to support the claim, but any claimed reduction or difference in the level of a nutrient would have to be large enough to be nutritionally significant.

157. Many comments said that there was an insufficient distinction between the terms "less" and "reduced" to warrant separate definitions for these terms, and that use of the two terms was confusing. They suggested that "reduced" not be defined. Other comments suggested that "less" (or "fewer") was the redundant term and should not be defined. However, many more comments stated that "reduced" and "less" should have the same definition. These comments said that the distinction made by FDA is artificial and confusing, and that consumers do not understand there to be any real distinction between the two terms. Many comments said that declaration of the extent of the reduction is more meaningful than the descriptive term used because it provides more information about the nutrient content of the product. Some stated that separate definitions would make it more difficult for manufacturers to meet consumer demand for modified products that comply with defined terms.

The agency has reviewed these comments and is persuaded that the terms "less" and "reduced" may not

have two distinct nutrition meanings to the ordinary consumer, and that, therefore, it could be confusing if the terms were to have two distinct nutrition definitions. The agency considered eliminating one or the other of these terms but chose not to do so. Both of these terms are listed in section 3(b)(1)(A)(iii) of the 1990 amendments. While FDA could have decided not to define one of the terms listed in that section if it found that the use of the term would be misleading, the agency has no information on which to base such a conclusion for either "less" or "reduced."

The current use of both "reduced" and "less" suggests that both terms have a place in the market. The terms are commonly understood to have different meanings. "Reduced" applies to a characteristic of an entity that has been altered with the resulting entity differing from the original by only that alteration, while "less" encompasses "reduced" and can also apply to a difference in a characteristic between two distinct entities (Ref. 25). Accordingly, as discussed in detail below, the agency is revising new §§ 101.60(b)(4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4), by providing the same definition for the terms "less" (or "fewer" in the case of calories) and "reduced," (See comments 158 through 160 of this document). It is also deleting the separate definition for "less" (or "fewer") proposed in §§ 101.60(b)(5), 101.61(b)(7), 101.62(b)(5), (c)(4), and (d)(5). Instead of distinct definitions for each of the two terms, the agency will rely on the information that accompanies the claim to inform consumers of the levels of reduction of a nutrient achieved by the labeled food. However, as is discussed in greater detail in comment 204 of this document, the agency believes that because of their different commonly understood meanings, the two terms may not always be used interchangeably.

158. There was only limited support for the definitions proposed for "reduced" and "less," which would have required a minimum percentage reduction and a minimum absolute reduction for a product to bear such a claim.

Generally, the comments expressed concern that the two part definition, particularly because of the minimum absolute reduction, was too strict. Many comments opposing the minimum absolute reduction requirement requested that it be deleted in the final rule. These comments said that such a requirement discriminated against products with small serving sizes. They cited situations in which the modified product might contain substantially less of a nutrient, on a percentage basis, compared to the reference food, but where the labeled food did not contain an amount of the nutrient sufficient for the food to be reduced by the minimum absolute amount. (One comment gave as an example, a serving of sour cream that contains 60 calories. A one-third reduction is 20 calories, which is only one-half of the 40 calories proposed as the minimum calorie reduction necessary in order to make a claim.) The comments stated that although differences in the absolute amount of a nutrient in such products might be small, the nutritional benefits derived from several servings of similarly modified foods over a day could have a significant impact on the level of the particular nutrient in the total diet.

Comments suggested a wide variety of alternative definitions, including various minimum percentage reductions, some with minimum absolute reductions and others without. Several comments that supported a definition based solely on a minimum percentage reduction stated that such a criterion is necessary to ensure that claims are made only for nutrient reductions that are nutritionally significant, especially for those foods containing large amounts of a nutrient. They gave as examples salty soups having 1,000 mg of sodium and candy bars with 300 calories.

Only a few comments preferred a minimum absolute reduction over a percentage reduction as a sole criterion. However, most of those comments voiced little reason for their preference. Of those commenting, a very few stated that without the proposed minimum reduction requirements, claims might be permitted on products where only very small reductions were made. They said that if the products were already very low in, or free of, the nutrient, such claims would be misleading.

A few comments suggested that a minimum absolute reduction other than the proposed values based on the definition for "low" should be used to control claims made for very small nutrient reductions, e.g., 20 or 30 calories, instead of the proposed 40 calories; 1.5 or 2 g fat instead of 3 g fat; 0.5 g saturated fat instead of 1 g; 35 or 100 mg sodium instead of 140 mg; and 10 or 15 mg cholesterol instead of 20 mg.

Some comments suggested that there should be no single, across-the-board minimum percentage difference or minimum absolute reduction, but that there should be a general requirement that the nutrient reduction be large enough to be nutritionally significant. Others suggested that "reduced" or "less" claims be permitted for any decrease in the level of a nutrient in a food so long as small improvements in a product were not exaggerated, and the absolute difference was disclosed. One comment suggested that any definition would serve as a floor representing the minimum amount of reductions that manufacturers would make, and that because of competitive forces, actual reductions would increase.

The agency proposed that both a minimum percentage reduction of a nutrient in a food and a minimum absolute reduction were necessary in order to ensure that meaningful reductions in the amount of nutrient in a food would occur, and thereby increase the likelihood that selection of nutritionally reduced foods would have a positive effect on an individual's overall dietary intake of the nutrient. The agency believed that a minimum absolute reduction was necessary to ensure that relative claims were significant and would not be made on products that, although they had a large percentage reduction, had only insignificant changes in the amount of nutrient. Such reductions could occur if relative claims were based only on a minimum percentage reduction in products that normally contain only a small amount of the nutrient. On the other hand, the agency was also concerned that products containing large amounts of a nutrient not have insignificant reductions compared to the amount of nutrient in the food and its overall contribution of the nutrient to the total diet.

The comments have convinced the agency that a definition using both criteria is too restrictive and will prohibit claims on a number of products that are useful in constructing diets consistent with dietary guidelines. However, the agency is not convinced, nor have the comments supported with data or other information, that having no minimum criteria will provide sufficient assurance that reductions in the level of a nutrient will be sufficient to prohibit misleading claims by assuring that only foods with nutritionally significant reductions may bear a "reduced" or "less" claim. Without such criteria, it would be difficult to ensure that nutrient reductions in a product were large enough to be significant in the case of products with a small amount of a nutrient or sufficient relative to the food's contribution of the nutrient to the total diet for products with a large amount of a nutrient.

In addition, the agency does not agree with the suggestion that additional labeling can be used to counteract a misleading claim that is used to represent a truly insignificant reduction in the level of a nutrient. Stating the absolute amount of difference, as recommended by the comment, would suggest that the product had undergone nutritionally significant reductions when it had not.

Therefore, FDA concludes that it is necessary to establish specific requirements to define when the difference in the level of a nutrient is large enough that claims about the difference are not misleading, and the terms "less" and "reduced" may be used.

The agency believes that of the options suggested in the comments, either a percentage reduction or a minimum absolute reduction offers the greatest assurance that the reductions achieved will be nutritionally significant.

The agency has evaluated both types of criteria. If an absolute minimum reduction were used as the sole criterion, there would always be a nutritionally significant change in the amount of the nutrient for all foods bearing the terms "reduced" or "less." However, the agency also considered the argument that was strongly made in the comments that a minimum absolute reduction for relative claims may unfairly discriminate against products with small serving sizes. Furthermore, the agency is persuaded by the comments that smaller reductions, in nutrient-dense foods traditionally used in small amounts for example, 20 calories in sour cream rather than 40 calories, may be beneficial to consumers and will not be misleading if changes in absolute amounts are declared. Although the agency remains convinced that only claims about significant changes in a product should be authorized, it acknowledges that for products with small servings, nutrient reductions that do not meet the proposed absolute minimum reduction requirements can be significant in the context of a daily diet.

Many foods with small serving sizes, crackers for example, may be consumed several times throughout the day. Thus, the agency agrees that the small absolute reductions that occur with consumption of each serving of such foods may have a significant cumulative effect on the amount of a nutrient consumed over the course of a day. The agency understands that label claims that highlight such changes could assist consumers in making useful changes in their diet.

However, if only a minimum absolute reduction is required in order for a product to bear a "reduced" or "less" claim, products with larger serving sizes that contain large amounts of a nutrient could still contain a large amount of the nutrient after reduction.

On the other hand, with a minimum percentage reduction requirement, more products containing small amounts of a nutrient would qualify to make "reduced" or "less" claims based on smaller absolute reductions in the amount of a nutrient than would be permitted under the requirements of the proposal. Such a criterion would also require larger, more nutritionally significant changes on products containing large amounts of the nutrient.

The agency has carefully weighed the concerns expressed by the comments. The agency believes that the terms "less" and "reduced" should be used only when a nutritionally significant reduction in the level of the nutrient has been reached so as not to mislead consumers into believing that a product would provide nutritionally significant reduction in the level of a nutrient when it would not.

The agency has determined that it is most appropriate to require a minimum percentage reduction rather than a minimum absolute reduction in order for a product to bear a "reduced" or "less" claim for the following reasons. First, the use of a minimum percentage reduction instead of a minimum absolute reduction is compellingly supported by comments and generally consistent with the agency's proposed approach. Secondly, it will allow more foods with smaller reductions in a nutrient to make a "reduced" or "less" claim. By eliminating the minimum absolute amount that a nutrient must be reduced for a product to bear a claim, the agency believes that manufacturers may have an additional incentive to produce modified products that are helpful in maintaining healthy dietary practices. Although these changes are smaller per product, they will cumulatively contribute overall to reduction in the amount of certain nutrients in the diet. Thirdly, this approach will assure nutritionally significant changes in products containing large amounts of a nutrient.

Therefore, FDA concludes that it is appropriate to require a minimum percentage reduction in the level of a nutrient in order for a food to bear a relative claim. Accordingly, the agency is deleting from new § 101.13(j)(3) and from the regulations on claims for specific nutrients (§§ 101.60(b)(4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4)), the requirement for an absolute reduction in the level of a nutrient in order for the food to bear a claim.

159. Several comments suggested that to prevent relatively small quantitative reductions from being touted as large percentage reductions, as an alternative to a minimum absolute reduction, "reduced" and "less" claims not be permitted on products if the reference food qualifies for a "low" claim.

The agency is concerned that for products in which the level of a particular nutrient is very low, requiring only minimum percentage reductions would mean that very small, nutritionally insignificant changes could be made in the amount of the nutrient, and the product would still qualify to make a "reduced" or "less" claim. It agrees that the suggested approach would provide assurance that the changes made to qualify for a "reduced" or "less" claim are not so small as to not be nutritionally significant. The agency notes that the value for "low" is the level at or above which the amount of a nutrient becomes significant relative to the total diet. A difference between two foods in a nutrient that is present in both foods at a level that is less than that of nutritional significance is not a significant difference. Such differences cannot be considered meaningful relative to the overall diet because even the level of the nutrient in the reference food is so low that the impact of its consumption on total dietary intake of the nutrient is minimal.

Thus, the agency agrees with the comments that contended that it would be misleading for products to make a relative claim if the nutrient is present at a "low" level in the reference food. Consequently, the agency is prohibiting "reduced" and "less" claims that are based on a difference from a reference food that meets the requirement for a "low" claim with respect to the nutrient in question. The agency is revising new § 101.13(j)(3) to include this requirement.

The agency believes that the overall approach described above will provide the best balance between encouraging manufacturers to produce foods with significant nutrient reductions by authorizing them to tell the public about the products' attributes and protecting consumers from being misled by claims directing them to foods that are not meaningfully improved in nutrient content.

160. Many comments discussed the percentage that a food should be reduced to bear a "reduced" or "less" claim. They suggested a wide range of percentage reductions, from a 50

percent reduction for "reduced" or "less" for all nutrients (including calories) to a 10 percent reduction for all nutrients. Some comments stated that FDA has historically used a 10 percent reduction as the minimum amount required for nutritional significance, and, therefore, it was an appropriate basis for a "reduced" claim. Other comments said that small incremental nutrient changes such as 10 percent are beneficial to consumers and represent modifications that are achievable. The comments argued that banning label information about incremental changes is likely to hurt consumers and discourage innovation.

Many other comments stated that a 25 percent reduction was an appropriate minimum reduction requirement. These comments said that using this level would allow "reduced" and "less" to have the same definition as originally proposed for "less." In addition, they said that a 25 percent reduction is a nutritionally significant reduction.

One such comment said that there is a sound scientific foundation upon which to require a minimum percentage reduction of 25 percent. The comment included comparisons of target daily intakes to current intakes and concluded that a 25 percent reduction is fully consistent with the reduction in intake needed to achieve current national dietary goals for fat, saturated fat, and cholesterol. The comment also concluded that although these calculations suggested that a 40 percent overall reduction in sodium was necessary to reach dietary goals, a 25 percent reduction was more practicable. This comment said that its conclusion was based on experience in marketing foods with reductions in sodium. It said that it had found that smaller incremental reductions were necessary to avoid consumer rejection of altered foods. The comment said that taste preferences will change as consumers adapt to lower salt levels, and that a 25 percent incremental reduction at this time would be a practical approach to the 40 percent reduction that is ultimately desired.

Another comment stated that a 25 percent threshold for claims was appropriate because it is supported by a variety of international governments and organizations, including Codex Alimentarius.

A few comments said that a one-third minimum reduction in the level of a nutrient was an appropriate criterion for a food to bear a "reduced" or "less" claim. They stated that a one-third reduction was a significant reduction, and that it is consistent with the percentage reduction required for "reduced calorie" claims (§ 105.66). Other comments suggested that foods should be permitted to bear a "reduced" or "less" claim only if there was a 50 percent or greater reduction in a nutrient (including calories) than the reference food. They said that requiring this percentage reduction was important for consistency across the nutrients. Other comments said that a minimum percentage reduction of 50 percent was necessary to ensure that the reduction is truly nutritionally significant compared to the original food and is useful to consumers in following dietary guidelines. A very few comments suggested that the definition for "reduced sodium" and "reduced cholesterol" should be returned to the 75 percent reductions previously established or proposed.

The agency does not agree that it has established a precedent for using 10 percent as a criterion for a minimum percent reduction in the level of a nutrient. Current agency regulations (§ 101.9(c)(7)(v)) provide that a food is not a significant source of a nutrient unless the nutrient is present at a level that is 10 percent of the U.S. RDA, and that no claim may be made that a food is nutritionally superior to another unless it contains at least 10 percent more of the U.S. RDA of the claimed nutrient per serving than the other food. For "reduced" and "less" claims, on the other hand, the percentage is used as the basis for a direct comparison between the amount of the nutrient in each of the foods. Therefore, the agency concludes that this comment did not provide sufficient justification to permit "reduced" or "less" claims on products having only a 10 percent reduction.

In addition, in the final rule on sodium labeling (49 FR 15510 at 15521, April 18 1984), the agency stated that a 10 percent reduction criterion for comparative claims was too low because of product variability. The agency said that because of expected statistical distribution of a nutrient (in that case sodium) in the food, there is a measurable probability that the sodium content of a sample of a product for which a lowered sodium content claim was made would actually exceed the sodium content of a sample of the unaltered product. Because it had been suggested that such product variations may not be as common now as they were in 1984 because of manufacturers' ability to more precisely control the amount of nutrient in a product, the agency solicited comments on this suggestion. However, comments provided no data to substantiate that improvements in food technology or other factors make it practicable for manufacturers to reliably achieve a 10 percent reduction. Thus, in the absence of data to support a different finding, the agency concludes that, because of product variability, a 25 percent reduction is the lowest level of reduction that can be supported.

The agency's decision to require a 25 percent reduction as the basis for a "reduced" or "less" claim is also based on the recognition, as outlined in the general principles proposal (56 FR 60421 at 60451), that this level will provide an incentive for manufacturers to reduce the level of the relevant nutrients in their food and at the same time has the potential to produce meaningful changes in overall nutrient intake for consumers. The comments provided significant support of these conclusions.

While the agency agrees that large reductions (such as 33, 50 or 75 percent) in the levels of certain nutrients present in a food may increase the likelihood that these foods will decrease the nutrient intakes of individuals who select these foods, FDA cannot agree that these percentage reductions are the most appropriate criteria on which to base "reduced" and "less." The comments supporting levels higher than a 25 percent reduction did not provide evidence that a 25 percent reduction would not be adequate, nor did they specifically demonstrate why a higher level than 25 percent is needed.

FDA recognizes that it has previously provided guidelines and definitions for nutrient reductions in foods, and that these specified reductions were greater than 25 percent. However, the agency now believes that with the advent of mandatory nutrition labeling and an ever increasing interest in healthy eating, more manufacturers will attempt reductions in the levels of nutrients like fat, saturated fat, cholesterol, and sodium in their foods. With the definition set at the reasonably achievable level of a 25 percent reduction, more foods are likely to be available, and consumers will be able to select from more and different foods in order to meet dietary guidelines. Furthermore, as suggested by one comment, market competition will undoubtedly spur some manufacturers to exceed this minimal reduction, thereby resulting in foods with even greater levels of reduction.

Therefore, the agency has concluded that an appropriate minimum percentage reduction for the terms "reduced" and "less" is 25 percent. Accordingly, the agency has revised new §§ 101.60(b)(4)(i), 101.61(b)(6)(i), 101.62(b)(4)(i), (c)(4)(i), (d)(4)(i)(A), and (d)(4)(ii)(A) to reflect this change.

161. One comment stated that the percentage reductions expressed on the label should not exceed the actual amount of the reduction of the nutrient in the product. Thus, the comment argued that manufacturers should be prohibited from "rounding up" the amount of the reduction to make it appear greater than it actually is.

The agency advises that for a product to bear a claim, the level of the nutrient must be reduced by at least a certain value. Thus, the amount of the reduction must be equal to or greater than the specified amount. There is no provision for rounding up the difference in nutrient content.

It is not clear to FDA whether the "rounding up" referred to in this comment is the rounding off provided in the regulation on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**. If the comment was concerned about such rounding, the agency advises that declaration of nutrients in, for example, 5 calorie increments or 0.5 g fat increments, which is permitted in nutrition labeling under § 101.9(c), is not permitted in determining the difference in nutrient levels between two foods. However, as discussed in the preamble of the proposal on mandatory nutrition labeling (55 FR 29487, July 19, 1990), the rounded differences are nutritionally insignificant. The agency would not consider a claim to be misleading if the declaration of the difference in absolute amount of nutrient between the foods were rounded off in conformance with rounding provisions for nutrition labeling in § 101.9.

162. A few comments requested that the regulation provide for use of "modified" as a synonym for "reduced" or "less."

The agency does not consider the word "modified" by itself to be a nutrient content claim. While it implies the product has been changed, "modified" does not necessarily imply that the change is in the content of a nutrient. As discussed elsewhere in this document, the word "modified" is permitted for use as part of the statement of identity on foods that qualify for "reduced" or "less" claims. However, "modified" is intended to be used in the presence of these claims, not in lieu of them. The term advises consumers that the product has been changed, and the nutrient content claim describes the change. Accordingly, FDA is not amending the regulation as requested.

163. One comment requested that the agency provide for the term "lower" as a synonym for "less." The comment stated that the term was currently in use on a comparative basis.

The agency agrees that "lower" should be permitted as a synonym for "less." Although the comment provided no further verification of the meaning of the term, the "American Heritage Dictionary," 1976 edition, (Ref. 25) defines the term to mean "below a similar or comparable thing." Such a definition is consistent with the principles for "less" claims which are used to compare two similar or comparable foods. Accordingly, the agency is including in §§ 101.60(b)(4) and (c) (4), 101.61(b)(6), 101.62(b)(4), (c)(4), and (d)(4)"lower" as a synonym for "less" (or "fewer").

164. One comment suggested that "less" rather than only the term "fewer" should be allowed for calorie claims.

As was stated in the general principles proposal (56 FR 60451), the agency defined "fewer calories" instead of "less calories" because the term "fewer" is grammatically correct. The agency does not believe that it is appropriate to amend the regulation to specify use of an improper term. However, FDA does not ordinarily consider a product to be misbranded because it bears a label statement that is grammatically incorrect. Accordingly, because the criteria for "less" and "fewer" claims are the same, the agency will not consider "less calories" to be misleading.

b. "Reduced" and "less" claims for sugar

In the general principles proposal, FDA proposed a definition for "less sugars" that included a minimum percentage difference of 25 percent but did not include a minimum absolute amount criterion. The agency did so because the minimum absolute amount criterion for other nutrients was the amount proposed to be defined as "low." The proposed criteria for "low" claims were based on DRV's for the nutrients, and because there was no DRV for sugars, there was no "low sugars" definition. The agency solicited comments for an appropriate requirement that could be used as the second criterion for this claim and signaled its intentions to establish a second criterion if one were not forthcoming.

165. Only a few comments addressed the term. Some supported defining the claim "less sugars," while a few others suggested that the term "less sugars" is not useful to consumers, is misleading, and should not be used. However, those objecting did not provide information as to why this was so.

As discussed in comment 80 of this document, the agency has determined that the term "sugars free" may be confusing to consumers and therefore is providing for use of the term "sugar free." The agency believes that "less sugars" would also be confusing. Therefore, for consistency the agency has determined that "less sugar" is the more appropriate term to describe reductions in the sugars content. Further, because the comments provided no arguments why the term should be eliminated, and because the term would provide certain useful information to consumers in comparing the sugars content of one food to another, the agency is not persuaded that the definition for "less sugar" should be eliminated. Accordingly, the agency has retained this definition.

In addition, FDA has included use of the term "reduced" in the provision for "less sugar" (§ 101.60(c)(4)). Although the agency had not proposed criteria for "reduced sugar" claims, now that the term "reduced" and "less" have the same criteria, it would be inconsistent not to also permit use of "reduced sugar" claims.

166. Only one comment suggested a second criterion for the definition of "less sugar." It recommended that the claim be permitted only if the labeled food contained at least 2 g less sugar than the reference food.

The comment did not provide rationale or other information to substantiate the recommendation. Consequently, FDA still does not have a basis for a minimum absolute reduction to be used in lieu of a definition for "low sugar." However, as discussed above in response to comment 158 of this document, FDA is no longer using the minimum absolute reduction as a criterion for "reduced" and "less" claims.

In view of this fact, the agency is persuaded that the need for a second criterion for sugar is similarly diminished. The agency has established in new § 101.13(j)(3) (see comment 159 of this document) a requirement that a relative claim may not be made if the amount of nutrient in the reference food is less than the value for "low." Although for consistency, a similar requirement for sugars might be useful, the agency does not believe that there is a compelling reason to definitively establish the criterion, especially given the fact that the basis for such a criterion, a DRV for sugar, does not exist. The agency will evaluate on a case-by-case basis whether claims on food that emphasize a very small reduction in the amount of sugar are misleading.

2. "Light"

a. General

In the general principles proposal (56 FR 60421 at 60449), FDA said that although the term "light" or "lite" is primarily a relative claim that compares one food to another food, it is often used to directly describe the food itself in the way that an absolute claim such as "low calorie" is used. The agency proposed several circumstances in which the term "light" could be used.

167. Several comments were concerned about the way that the term "light" is used in the marketplace. A few comments asserted that the term "light" is purely marketing puffery. Other comments said that "light" has no scientifically acceptable meaning but instead has a multitude of meanings and as such will do more to mislead consumers than assist them in making better food choices. Another comment said that because of the various consumer interpretations of the meaning of the term "light," there needs to be further research on its meaning before the term can be defined. A few comments stated that because "light" has no meaning, it should not be defined.

Section 3(b)(1)(A)(iii)(III) of the 1990 amendments requires FDA to define "light" or "lite" unless it finds that the term is misleading. While the agency agrees that some current uses of the term are misleading, it has not made a finding that the term is inherently misleading, or that it cannot be used in a nonmisleading manner. The agency concludes that it has sufficient information, including consumer surveys cited in the general principles proposal (Refs. 26 and 27) and other information submitted in comments with which to establish an appropriate definition for the term. By defining "light" and the conditions for its use in a meaningful way, the agency intends to help alleviate the confusion caused by the many uses of the term and to ensure that products that bear the term are useful in maintaining healthy dietary practices.

168. A few comments stated that "light" is not an expressed claim, but rather that it is an implied claim. The comments pointed to the House report on the 1990 amendments (H. Rept. 101–538, 101st Cong., 2d sess. 19 (June 13, 1990)) which said that an implied claim is a statement that "implies that the product is low in some nutrient (typically calories or fat) but does not say so expressly" and cited "lite" as an example of such a claim. One comment went on to say that as an implied claim, "light" should be permitted with any nutrient content claim, provided that the food qualifies for the claim.

The agency acknowledges that the House report stated that "lite" was an example of an implied claim. However, the agency believes that this term is used as an expressed claim because, as discussed in the general principles proposal (56 FR 60421 at 60449), it has a history of use both as a relative claim and as an absolute claim. "Light" has been used as a direct statement of the level of both calories and fat in food (see § 101.13(b)(1)). In the proposal, FDA stated that in spite of the reference to "light" in the legislative history, it intended to treat this term as an expressed claim (56 FR 60421 at 60449 through 60450). The comments that addressed this issue did not provide any justification for not following the course that the agency proposed. Therefore, FDA is defining "light" as an expressed claim in this final rule.

b. Definition of "light" based on fat and calories

In the general principles proposal (56 FR 60421 at 60449) the agency acknowledged that "light" has been used for a number of years to connote a wide variety of meanings such as low or reduced calories; reduced fat, sugar, or sodium; light in weight, texture, or color; and thin or less viscous. The agency cited studies that showed a stable perception by the majority of consumers that "light" means that the caloric level has been altered. However, it noted that "light" has also been used to directly describe the food itself in much the same way as the term "low" has been used. Because the agency believed that the definition of the term "light" should be based primarily on consumers' perception that "light" means "reduced in calories," the agency proposed that a food be permitted to bear the term "light" without further qualification if the food had been specifically formulated or processed to reduce its calories by at least one-third compared to a reference food specified in § 101.13(j)(1)(i), with a minimum reduction of more than 40 calories per reference amount and per labeled serving size.

The agency also noted that it had recently allowed the term "light" to be included as part of the name of dairy products that are altered to have, in addition to one-third fewer calories, at least 50 percent less fat. The agency also noted that other normally high-fat products are using "light" to describe fat and calorie reductions. In view of these facts, and because the agency believed that products with large amounts of fat should not be labeled as "light" unless a substantial amount of the fat in the food was also reduced, the agency proposed that if the food derives 50 percent or more of its calories from fat, its fat content must also be reduced by 50 percent or more compared to the reference food that it resembles or for which it substitutes. The proposal also would have required a minimum reduction of more than 3 g of fat per reference amount and per labeled serving size in order to bear the term "light."

169. A number of comments supported the agency's view that the percentage of a food's calories that are derived from fat should be considered in determining whether the food contains a substantial amount of fat and should, therefore, be required to be reduced in fat for the product to bear the term "light." Several comments supported the agency's proposal that 50 percent or more of a food's calories from fat was an appropriate level at which fat reduction should be required. Another comment suggested that if 40 percent or more of a food's calories are normally derived from fat, a fat reduction should be required, but it offered no substantiation for the suggestion. One comment suggested that a food contains relatively high levels of fat if 30 percent or more of the food's calories are derived from fat. It noted that the 30 percent threshold relates to the dietary guideline that no more than 30 percent of the calories in the total diet should be derived from fat. The comment suggested that a food that normally contains more than 30 percent of calories from fat would be inconsistent with this guideline and therefore should be required to be reduced in fat in order to bear the term "light."

The agency has considered these comments and is not persuaded by the comments that it is necessary to change its determination that foods that normally derive more than 50 percent of their calories from fat should be reduced in fat to make a "light" claim. The agency acknowledges that the dietary guidelines recommend that Americans eat a diet that consists of 30 percent or fewer calories from fat. However, because fat is found in only about one-half of the food supply, it is not necessary that each food contain only 30 percent of its calories from fat for the total diet to meet this goal. Rather, because a diet would normally consist of a combination of foods containing various levels of fat, those foods that derive somewhat more than 30 percent of their calories from fat would be balanced by foods that contain less than 30 percent of their calories from fat. A diet consisting of both types of foods

would be consistent with dietary guidelines. Consequently, it would not be necessary for all foods that derive over 30 percent of their calories from fat to be reduced in fat to meet dietary guidelines. There were no comments that suggested the percentage of calories from fat should be raised to a higher percentage. Therefore, the agency is retaining the provision as proposed, that products that normally contain over 50 percent of their calories from fat contain a substantial amount of fat and should, therefore, have the amount of fat they contain reduced to qualify for a "light" claim.

170. While a number of comments agreed with the agency's assessment that "light" is primarily associated with reduced calorie content, a greater number of comments maintained that consumers primarily perceive "light" to mean lower in fat. One comment cited a 1989 Gallup Organization consumer poll stating that 8 out of 10 consumers select "light" products in order to reduce fat consumption. Others cited a survey reported in an article entitled "Americans to Make LIGHTER Choices in the 90's" that appeared in "Calorie Control Commentary," vol. 12, No. 1 (Spring 1990), stating that 83 percent of consumers select products labeled as "light" in the belief that such products are low in fat. One comment included a study that found that 46 percent of consumers think that products labeled as "light" should have "almost no fat" or "no fat at all." Another comment stated that "light" has been used for decades to refer to fat reductions without evidence of consumer misunderstanding. The comment included a survey of 1,000 trademarks using the word "light" and noted that 35 percent of those trademarks were associated exclusively or primarily with reduced fat content in products. Many comments favored allowing "light" claims for foods on the basis of fat reduction alone.

The agency has carefully reviewed these comments and, on the basis of the evidence presented in them, has been convinced that in addition to "reduced in calories," the term "light" is also commonly understood to mean "reduced in fat." Consumers apparently view reductions in fat as a major reason for purchasing "light" products. Therefore, FDA does not consider that the term "light" is appropriately used only on products in which there has been a reduction in calories. The term also is appropriate on products in which there has been a reduction in fat.

171. Many comments contended that the proposed definition for "light" is too restrictive, especially for foods that normally contain large amounts of fat. The comments maintained that certain products, such as butters, ice creams, chocolate-coated ice cream novelties, cheeses, cakes, brownies, muffins, frostings, peanut spreads, savory snacks (pretzels and chips), popcorn, and coffee creamers could not be altered to qualify for a "light" claim under the proposed definition. A number of these comments pointed out that many fat substitutes contain a substantial amount of calories, and that even though it is often possible to reduce the fat content in products by 50 percent, it is not always possible to also reduce the calorie content by one-third unless all or most of the fat is removed.

The comments stated that in the case of ice cream novelties, for example, because some of the preferred fat replacers, such as carbohydrate or protein solids, contain a substantial amount of calories, it is difficult to remove enough of the calories normally contained in the product to achieve a one-third calorie reduction solely by replacing the fat. To accomplish this calorie reduction, the comment said, would require that virtually all of the fat be removed and replaced with an ingredient such as polydextrose which has a lower calorie content than other fat replacers. However, in achieving this caloric reduction, the comments maintained, consumer acceptance is "lost along the way."

The comments asserted that similar problems occur with cheeses and other products. The comments contended that manufacturers' present inability to make products that can substitute for products normally high in fat, that are acceptable to most consumers, and that can meet the "light" definition will significantly reduce labeling and marketing incentives for such products. Several comments maintained that, as a result, many reduced fat alternatives will be removed from the market, and that development of more "light" products will be retarded. Several comments asserted that having fewer options will cause difficulty for consumers who wish to reduce their fat intake to 30 percent or less of their calories from fat, as recommended by dietary guidelines. They stated that, consequently, the criteria for use of the term "light" should not incorporate both a 50 percent fat reduction and a one-third calorie reduction for products with a substantial amount of calories from fat.

The agency has reviewed these comments and is persuaded that because of the difficulty in achieving "light" products that are reduced both in calories and in fat, the agency will not require that both nutrients be reduced for a food to bear the term. FDA believes that while the criteria for making a "light" claim must result in labeling that consumers can understand and rely on, the criteria should also be reasonably achievable to encourage manufacturers to produce altered products that will assist consumers in maintaining healthy dietary practices. The agency recognizes that it is difficult to achieve reductions of both calories and fat in a number of products containing more than 50 percent of calories from fat, particularly dairy products such as cheeses, ice creams, and frozen confections. In addition, consumers will not purchase, and therefore will not benefit from, altered products that do not meet their acceptance requirements.

In the general principles proposal, FDA stated that a majority of consumers associate "light" with a reduction in calories, even though there are other meanings for the term. However, as discussed in comment 170 of this document, the comments provided information that establishes that consumers strongly associate the term "light" with reduced fat levels. Thus, as discussed in more detail below, FDA no longer believes that a reduction in calories in the food is essential or is always expected by consumers who choose a food because it bears the term "light." Accordingly, the agency has deleted from § 101.56(b) the requirement that products that contain more than 50 percent of calories from fat be reduced both in calories and in fat to bear the term "light."

172. In the general principles proposal, FDA requested comment on whether it was necessary to prohibit a "light" claim on a product containing more than half its calories from fat that is reduced by one-third in calories but that has not also been reduced in fat by the required minimum. The agency asked for comment on whether the claim was misleading and should be prohibited, or whether a statement informing the consumer that the product was not reduced in fat would make the label not misleading. In response, the comments did not support the use of a label statement in alerting consumers that a particular product that was labeled as "light" was high in fat. In addition, although comments did not directly suggest that "light" be permitted on foods that derive one-half of their calories from fat that had been reduced by one-third in calories but not by one-half in fat, many comments did suggest that in such foods, fat reduction is necessary.

The Surgeon General's report (Ref. 4) and the NAS's report "Diet and Health:

Implications for Reducing Chronic Disease Risk" (Ref. 12), in considering the effect of diet on an individual's health, concluded that consumption of a diet high in fat, saturated fat, and cholesterol is associated with increased risk of development of certain chronic diseases. These reports and "Nutrition and Your Health: Dietary Guidelines for Americans" (Dietary Guidelines) (Ref. 7) recommend that Americans reduce their consumption of these substances in their diets. Given the significance of dietary intake of fat and saturated fatty acids, FDA believes that it is important to assist consumers in modifying their diets to reduce their intake of these food components and thereby to maintain healthy dietary practices. By ensuring that foods that normally contain large amounts of fat are substantially reduced in fat in order to bear the term "light," FDA believes that it will assist consumers in constructing diets that are consistent with dietary guidelines by providing substitute foods in which there is a large reduction in fats that will assist them in reducing the fat content of their diets. Therefore, FDA concludes that it would not be appropriate to permit the term "light" to appear on a food that normally derives one-half of its calories from fat that has not been reduced in fat content by the required minimum amount. Accordingly, because the term "light" implies that the food is useful in achieving a diet that conforms to dietary guidelines, foods with relatively high levels of fat (i.e., more than 50 percent of calories form fat) must be substantially reduced in fat if they would be useful in such diets. If the fat level in such foods is not reduced, the use of the term "light" in their labeling would be misleading.

To summarize, FDA concludes that consumers understand the term "light" to connote a reduction in fat as well as a reduction in calories, depending on the food involved. Accordingly, the agency has determined that it is appropriate for a food to bear the term when it has been sufficiently reduced in fat or, where appropriate, calories. (The amount of fat or calories necessary to constitute such a reduction is discussed below.) The agency is therefore providing in § 101.56 that the term "light" may be used when the labeled food differs from the reference food by a minimum percentage reduction in either fat or calories (comments 170 and 171 of this document). However, FDA also concludes that for foods that derive more than 50 percent of their calories from fat, the minimum percentage reduction in fat is necessary for the term "light" to not be misleading (comment 172 of this document). The agency, therefore, is providing in § 101.56(b)(1) a requirement for a minimum percentage fat reduction for such foods.

173. Of those commenting on the subject, a large number of comments stated that because it is a relative claim, "light" should be defined in the same manner as the other relative claims, "reduced" and "less." Many comments said that if "reduced," "less," and "light" all had the same definition, consumer confusion about the meaning of these relative terms would be diminished, especially if the exact nature of the modification was specified adjacent to the claim, as would be required by the accompanying information provisions. One comment said that allowing this more liberal definition for "light," but providing information on the exact nature of the reduction, was consistent with the policy of allowing other "light" claims provided the subject physical or organoleptic properties were specified. A few comments said that if FDA set reasonable parameters for use of the terms "light," "reduced," and "less," consumers would receive truthful, easy to understand information, and food manufacturers would be encouraged to produce foods with significant nutritional reductions because they would be able to tell consumers about their product's attributes.

Another comment said that defining "reduced," "less," and "light" at a lower standard than originally proposed for "light" would minimize the number of brand names prohibited on the grounds that the food did not meet the definitional requirements. One comment said that the same definitions for the term "reduced," "less," and "light" would significantly lower the cost to the manufacturer, and eventually to the consumer, by significantly reducing the costs associated with compliance. Other comments said that any definition would serve as a floor, and that competition and innovations in the market place would push actual reductions higher.

The agency has considered the arguments that because "light" is a relative claim, it should be defined in the same manner that the other relative claims "reduced" and "less" are defined. However, the agency is not persuaded by the comments that such a definition is appropriate. "Light" is a term that has special usefulness as a marketing tool for manufacturers to quickly and easily convey to consumers that the product to which the term is attached has been significantly reduced in the level of fat or calories. Although the agency recognizes that specifying the exact nature of the modification would help mitigate confusion caused by similar definitions for all relative claims, the agency is not convinced that defining "light" in the same manner that other relative claims are defined would be consistent with the special position of the term "light" in the marketplace and with the strong impression that products labeled as "light" are particularly useful in achieving a diet that is consistent with dietary guidelines as the available data and comments show.

The agency remains concerned about striking the proper balance between allowing manufacturers flexibility in the use of the term "light" and providing a definition that will ensure that products are improved significantly in the nutritional attributes addressed by the term. Striking the proper balance will provide consumers with meaningful product information and meaningful product choices. To define the term "light" with the same definition as for the terms "reduced" and "less" would sufficiently dilute the term so as to diminish its usefulness. Moreover, the agency is convinced that reserving the term "light" for those products that are more significantly improved will provide a greater incentive for manufacturers to continue to improve their products by providing a unique marketing vehicle by which such nutritionally significant changes can be highlighted for the consumer (See comment 174 of this document).

The agency recognizes the effect that any definition may have on brand names. However, FDA does not believe that it should permit or encourage "light" claims without further qualification on products that do not represent a major modification in fat or calorie consumption, as appropriate. Furthermore, the agency does not believe that the costs associated with compliance relative to distinctions between the two definitions for "light" and "reduced" and "less" are sufficient to warrant modification of this decision, and the comment did not provide cost information to substantiate its assertion. Accordingly, the agency is not providing the same definitions for "reduced," "less," and "light."

174. Comments expressed a variety of opinions as to the minimum percentage of fat by which a food should be reduced to qualify to bear the term "light." A number of comments objected to the 50 percent fat reduction requirement. They asserted that in certain product categories, it is not technically feasible to develop products that are reduced in fat by 50 percent or more and that are acceptable to the

consumer. The comments stated that consumers want products lower in fat but with organoleptic properties similar to the reference foods. Other comments noted a variety of manufacturing problems, such as undesirable changes in the texture, flavor, cooking applications, and storage requirements of a food, that are encountered with a 50 percent reduction in fat in a product. In addition, the comments maintained that replacement of the sensory properties of fat is difficult in low moisture content bakery products. The comments also asserted that a 50 percent or greater fat reduction in cheeses results in products with low consumer acceptance, higher moisture content, increased potential for bitter flavor development, poorer physical properties, such as rubbery texture, and microbial instability during curing and storage.

The comments also stated that a 50 percent or greater fat reduction in savory snacks, such as pretzels and chips, will have significant concomitant reductions in flavor and texture acceptability. Some comments contended that because of these problems, there is a greater likelihood that industry will develop and market fat modified foods with a one-third fat reduction than foods with a 50 percent reduction. The comments maintained that without these reduced fat products, consumers will be less able to achieve a diet composed of a variety of different foods (including products normally high in fat such as many dairy products) that is consistent with dietary guidelines.

Some comments suggested that the fat content need only be reduced by 25 percent in order to bear the term "light." The comments maintained that such a reduction would ensure truthful and nonmisleading "light" claims. One comment maintained that a 25 percent reduction was appropriate especially since the product was also required to have a minimum absolute reduction in fat of 3 g, which is significant.

A number of comments favored using "light" claims on foods whose fat content is reduced by one-third or more. Some comments suggested that a one-third reduction in fat was significant and would be desirable because it is consistent with a one-third reduction in calories. They maintained that it was easy for consumers to understand the meaning of the term "light" if a food must be reduced by a single percentage of either fat or calories in order to bear the term. One comment suggested that a one third or greater fat reduction would make a valuable contribution towards helping consumers to reduce fat intake.

Other comments stated that products should be reduced in fat by a minimum of 50 percent in order to bear a "light" claim. One comment, which acknowledged that the term "reduced" may have insufficient marketing appeal to encourage industry to create new, healthier products, proposed that "light" replace "reduced" altogether and suggested that the nutrient that is the subject of the "light" claim, for example fat, be reduced by 50 percent or more. Some comments stated that such a revised definition of "light" is desirable because the term "light" is a powerful marketing tool, and by reserving the use of "light" for truly significant reductions, FDA will create an incentive for food companies to develop new products that are nutritionally superior. One comment maintained that a 50 percent reduction in fat is sufficiently substantial to benefit consumers and feasible for industry to achieve. One of these comments suggested that 50 percent or "half as much" is an easy level for consumers to remember. Finally, one comment stated that a consumer study, conducted under their sponsorship by the University of Michigan, suggested that 78 percent of the respondents viewed "light" products to have at least a 50 percent reduction in fat.

The agency has carefully considered all of the comments. Although the agency recognizes the difficulties involved in reducing fat by 50 percent, it is not convinced that they are so great as to prevent manufacturers from producing and marketing a significant number of products with a large enough fat reduction to bear the term "light." The agency notes that the technology problems associated with fat reductions in baked goods would not be pertinent to such products' ability to bear a "light" claim because these products generally do not contain 50 percent of their calories from fat, and the 50 percent fat reduction is, therefore, not required. The same is true for certain savory snacks such as pretzels. A fat reduction is required only for products that derive more than 50 percent of their calories from fat.

The agency is not persuaded by the comments that a 25 or 33 1/3 percent reduction in the amount of fat is sufficient for a food to bear a "light" claim. The comments establish that "light" is a special term with particular marketing appeal, and as such it should have a higher standard than that used for "reduced" and "less" claims which may be used on the label of foods having a 25 percent reduction in fat. The agency believes that the definition for light should take into account consumers' perception of the term as it relates to reductions in fat. One example provided in the comments demonstrates that 78 percent of those surveyed believe that when "light" is associated with fat reduction, it means at least a 50 percent reduction in fat.

As discussed above, the agency believes that a standard for "light" should be higher than that for "reduced" and "less" claims because it would encourage innovation, leading to a greater variety of products with substantial reductions in fat, and thereby help consumers to make significant reductions in the amount of fat in the total diet. Although the agency recognizes that some products would achieve reductions greater than 25 percent if that level were the minimum fat reduction required for products to bear the term "light," additional product innovation will be encouraged because of the desirability of the term, and a wider variety of products with greater fat reductions will, in time, be developed in response to the definition that FDA is adopting. Encouraging the development and marketing of innovative fat reduced foods will provide consumers with a greater variety of foods from which to choose in building a total diet.

In addition, the agency is aware of a variety of currently marketed products, such as cheeses and cheese products, that do have reductions in fat in excess of 33 1/3 and 50 percent, including products that are fat free. With the variety of such products currently on the market, the agency is not persuaded that it is not possible to make and market consumer-acceptable products that are reduced in fat by more than 33 1/3 percent. Furthermore, manufacturers wishing to make and market similar products with fat reductions between 25 and 50 percent will still be able to inform to consumers, through use of the terms "reduced" and "less," that the product did contain a certain percentage less fat than their regular product or other similar products. Although the agency is aware from comments that such terms are less marketable than the term "light," these terms are a method of effectively communicating product changes to consumers.

In summary, FDA concludes that the 50 percent minimum fat reduction is an appropriate criterion for use of the term "light." Accordingly, the agency is retaining this provision in the final regulation.

175. One comment suggested that the term "light" should be permitted on foods whose fat content is 10 percent or less. It noted that this would conform to

the policy of FSIS for the term "light" and would be consistent with FSIS' definition for "lean."

The agency does not agree. Both agencies are developing regulations on use of "light" and "lean." In its Nutrition Labeling of Meat and Poultry Products proposal (56 FR 60302), FSIS adopted FDA's proposed criteria for "light" in place of the 10 percent or less fat content criterion used previously. Because FSIS is no longer using this criterion, the comment that FDA could harmonize the two agencies' policies by adopting the 10 percent or less criterion is not correct. Furthermore, FDA is adopting in this final regulation, FSIS' definition for "lean." Thus, these regulations will provide distinct definitions for both terms. The comment did not present any other rationale to justify its request.

176. Several comments recommended that a food be required to meet the definition of "low fat" to qualify for use of the term "light." One comment referred to a consumer survey that, it claimed, found that many consumers expect "light" foods to have "almost no fat" or "no fat at all." The comment also stated that if foods cannot meet these strict criteria now, "light" should be used only on the few foods that do qualify until food technology developments can achieve the appropriate changes. The comment argued that such an approach would encourage development of products with greater nutrient reductions.

The agency does not agree that a food should have to be "low fat" to bear the term "light." The agency acknowledges that many consumers expect "light" foods to not contribute significant amounts of fat. However, FDA does not agree that the submitted survey substantiates that consumers generally expect "light" foods to have "almost no fat" or "no fat at all." FDA's interpretation of the survey is that some consumers expect a "light" product to have "somewhat less fat" or "one-half the fat." The agency believes that requiring a 50-percent minimum reduction for foods that derive more than 50 percent of calories from fat will ensure that foods bearing "light" claims will not mislead consumers. In addition, FDA is requiring declaration of the percentage of fat reduction on all foods that bear "light" claims, not just those for which the reference foods derive 50 percent of calories from fat (§ 101.56(b)). This declaration will inform the consumer of the meaning of the term for each food that bears it.

The agency also does not agree that overly strict definitions for claims will encourage manufacturers to produce foods with greater improvements in nutrient content. As stated in the general principles proposal with respect to "reduced sodium" claims (56 FR 60421 at 60448), the current requirement for 75 percent sodium reduction is too strict. Consequently, very few foods bear the claim. The agency believes that consumers are more likely to make better food choices if a greater variety of improved foods is available, and if information on the improvement is available. Consequently, FDA is not adopting the suggestion in the comments to require that foods meet the definition of "low fat" to qualify to bear the term "light."

177. A few comments stated that the term "light" should be permitted to be used on products that are "low" in a nutrient. They stated that in the legislative history of the 1990 amendments, Congress said that it considered the term "light" to imply that a product is "low" or "reduced" in fat or calories. Another comment suggested that there are a large number of product labels that have enjoyed longstanding marketing under an interpretation of § 105.66 that "light" means either "low calories" or "reduced in calories," and that the agency should continue to allow the descriptor "light" to mean "low" or "reduced" in any nutrient.

The agency has reviewed these comments and is not convinced that the term "light" should be permitted to be used on products that are "low" in a nutrient. In proposing definitions for terms, FDA tentatively determined that it should provide unique definitions for each of the individual terms that the statute required FDA to define. However, the definitions, while distinct, provide for a range of terms to describe significant levels or differences in levels of nutrients. FDA has been persuaded by the comments that it is appropriate that the terms "reduced" and "less" have the same quantitative definition. However, the agency is not convinced by the comments that it would be appropriate for a product that is "low" in a nutrient to bear a "light" claim based only on the "low" level of that nutrient in the product. On the contrary, as discussed below in comment 179 of this document, a "light" claim is prohibited on foods for which the reference food is "low" in the nutrient. The agency has concluded that "light" implies a difference in nutrient content between two foods. Thus, in general, a reduction in a nutrient that is already "low" is insignificant, and a claim about that difference is misleading. The agency believes that the term "low" should be used to describe the level of the nutrient in such a food.

178. Most comments addressing the issue agreed with FDA's inclusion of calorie reduction as a component of the definition of "light." Most also agreed with the proposed requirement that a food's caloric content be reduced by one-third or more to qualify for use of the term. The comments said that such a reduction was significant and sufficient to justify a "light" claim. However, some comments proposed that the caloric content of a food be reduced by 50 percent or more in order for the food to be labeled as "light." One comment suggested that a 50 percent reduction in calories would be consistent with the level of fat reduction required for "light" claims and would reduce the number of insignificant claims.

The agency is not persuaded by the comments that a calorie reduction criterion for "light" claims other than the proposed one-third reduction is appropriate. The comments did not provide information to substantiate why a 50 percent calorie reduction was more appropriate. The agency discussed the one-third reduction requirement in the general principles proposal in reference to "reduced calories." It noted that because of the ubiquity of calories across all food categories, the reduction in calories in each food necessary to achieve an overall reduction of public health significance could be less than the 50 percent reduction necessary for other nutrients, including fat. Thus, given the difference in the occurrence of the nutrients in the food supply, a 50 percent reduction in fat and a one-third reduction in calories do perform a consistent function in the total diet. Moreover, permitting calorie claims at one-third reduction will allow a greater variety of nutritious foods to bear claims useful in reducing or maintaining calorie intake or body weight.

In addition, FDA has used the one-third reduction in calories as the basis for "reduced calorie" claims in § 105.66 since 1980. In that time, the agency has not found a problem with insignificant reduction in calories in foods bearing such claims. Accordingly, the agency is not revising in § 101.56(b) the percentage of calories that a food must be reduced in order to bear a "light" claim.

179. Many comments disagreed with the proposed requirement for a minimum absolute reduction of 3 g of fat or 40 calories for a food to bear a "light" claim. One comment asserted that the proposed minimum 40 calorie and 3 g criteria would eliminate "light" claims on sour cream, because those

criteria cannot be met while still retaining organoleptically acceptable products. Some comments proposed a minimum absolute reduction of 2 g of fat per serving.

FDA proposed the minimum absolute reduction requirement for "light" claims for the same reason that it proposed a minimum absolute reduction for "reduced" and "less" claims: to prevent claims for trivial reductions in nutrient content. In addition, the objections raised in comments about required minimum absolute reductions for "light" claims have the same basis as those for "reduced" and "less" claims. As was discussed in comment 158 of this document, the agency has become convinced that such a requirement discriminates against those products with small serving sizes, which could not bear "reduced" or "less" claims because they contain an insufficient amount of the nutrient to make the reduction necessary to justify a claim. The agency also was persuaded by the comments that the consumption of several servings of such products (bread for example) over the course of a day would result in significant reductions in the amount of a nutrient when considered cumulatively. Consistent with its position on "reduced" and "less" claims, FDA is persuaded that the minimum absolute reduction in the amount of a nutrient that a product must be reduced in order to bear a "light" claim, namely 40 calories or 3 g of fat, should be deleted. Accordingly, the agency is deleting this requirement from new § 101.56(b).

In addition, consistent with the requirements for "reduced" and "less" claims, the agency considers "light" claims to be misleading on products that base their reduction on reference foods that are already "low" in the target nutrient. As discussed in comment 159 of this document, the agency considers such a reduction to be trivial. Accordingly, the agency has prohibited such a reference food for products bearing a "light" claim in new § 101.56(b)(4).

180. The general principles proposal (56 FR 60421 at 60446) provided that like "reduced" and "less" claims, a "light" claim must be accompanied by a declaration of the percent of nutrient reduction, the identity of the reference food, and the absolute amount of calories and, where appropriate, fat in both the labeled food and the reference food. However, a number of comments suggested that for a "light" claim meaning "reduced calorie" or "reduced fat," a disclosure statement, qualifying statement, or other similar statement, such as the definition of the term, should appear on the label in close proximity to the "light" claim. One comment suggested that such a disclosure statement should incorporate the words "low" or "free" when they are appropriate, and that the disclosure should include a prominent comparison of both calories and fat in the food bearing the "light" claim and in the reference food. Some comments proposed that where a "light" claim is made based on fat content alone, a defining statement such as "light in fat" or "light in fat only," should appear on the label, and where a "light" claim is based on calories, a statement such as "light in calories" or "light in calories only" should appear. Several comments suggested that if a "light" product is not designated as "light" on the basis of reduced fat, it should bear a qualifying statement such as "This product is not lower in fat," and that if the product is not designated as "light" on the basis of reduced calorie content, it should bear a qualifying statement such as "This product is not lower in calories." The comments suggested that this clarification is necessary because many people are uncertain as to whether the "light" claim refers to reductions in fat or calories. Another comment proposed that where a "light" claim is made on the basis of fat content, there should be a prominent calorie disclosure which would list the percent reduction of calories compared to the reference food.

The agency advises that although the general principles proposal required accompanying information for the nutrient that has been reduced (i.e., the percent and the amount, compared to the reference food that the calories and, where appropriate, fat have been reduced), the agency did not propose to require this information for the nutrient that had not been reduced. While FDA has determined that declarations of absolute amounts of fat and calories may appropriately be made on the information panel instead of the PDP (see comment 214 of this document), the agency agrees with the comments that the term "light" may be misunderstood unless it is properly clarified. The agency concludes that because it is permitting the unqualified use of "light" when either a minimum percentage reduction in fat or a minimum percentage reduction in calories is met, but not necessarily both, the specific nature of the reduction for each nutrient must be declared. This declaration is necessary to prevent the term "light" from misleading the consumer into believing that the food has been significantly reduced in both calories and fat when it has not. This modification is in accord with suggestions in comments and is consistent with provisions of sections 403(a) and 201(n) of the act (a label is misleading if it fails to bear a material fact). Accordingly, the agency is modifying new § 101.56(b)(3) to require that the percentage that the fat is reduced, and the percentage that calories are reduced, be declared in immediate proximity to a "light" claim in conformance with the requirements of new § 101.13(j)(2), regardless of which nutrient is reduced by at least the minimum amount required in the definition.

However, the agency has determined that if a labeled product has a sufficiently small amount of fat or calories, so that it complies with the definition of "low" for the nutrient (whether normally or by modification), it would not be misleading if the percentage that the nutrient has been reduced is not specified on the label (see § 101.56(b)(3)(iii)). The absence of such information would not be misleading because the product is "low" in the nutrient and thus would be consistent with any expectations that the consumer might have that the product will be useful in achieving a diet consistent with dietary guidelines.

i. Other nutrients

The agency did not propose a definition for "light sodium" (56 FR 60421 at 60451). It stated that use of the term "light" to reflect a sodium reduction in a food would be misleading on products that were not also reduced in calories and, where appropriate, fat because consumers expected these nutrient reductions in association with the term "light." However, the agency tentatively concluded that the term "light" when used on a salt substitute would not be misleading in view of the long marketing history of these products, and because a salt substitute has virtually no calories and would, therefore, not be expected to be reduced in calories or fat. The agency, therefore, proposed that the term "light" could be used on a salt substitute if the product contained 50 percent less sodium than ordinary table salt.

181. Many comments agreed with the proposal that "light" should be defined for use on salt substitutes. They stated that "light" was an appropriate term on such products because they had essentially no calories. However, some comments stated that "light" would be confusing on a salt substitute because consumers associated the term "light" with reduced calories. Others said th "light" should not be permitted on a salt substitute as an unqualified term if the

product cannot meet the definition for "low sodium." A few comments stated that if "light" is defined for salt substitutes, the amount of sodium in the product should be declared. They said that information on the amount of sodium in a salt substitute is very important for persons who must restrict their salt intake.

The agency concludes that, as proposed, "light" is appropriate for use on salt substitutes. Salt substitutes bearing the term have had a long history of use without apparent consumer confusion. As one comment pointed out, the possibility of confusion is minimized because these products have no calories as well as no fat. Also, the agency is not persuaded that such products should be prohibited to bear a "light" claim if they are not "low sodium," i.e., 140 mg per serving, because such a rule would prohibit "light" claims on most, if not all, sodium reduced salt substitutes. Such a product would have to be reduced in sodium by approximately 85 percent to qualify for the claim.

Further, the agency advises that it recognizes that salt substitutes bearing the term "light" are used primarily by persons who are trying to limit their sodium intake, and that the amount of sodium in such a product is important information. The amount of the nutrient, in this case sodium, that is in the labeled product compared to the reference product (table salt) is required to be stated on the information panel. This statement should provide adequate information for consumers about the amount of sodium in the product. Accordingly, FDA is not changing the proposed provisions for "light" claims on salt substitutes.

182. Several comments suggested that the term "light" without qualification should be permitted for use on foods reduced in sodium. The comments suggested definitions of "nutritionally significant reduction in the amount of sodium" and minimum percentage reductions of 25, 33 1/3, or 50 percent. The comments cited a report of a study by the Calorie Control Council, "Americans Find 'Light' to Their Liking" (Ref. 27), in support of their suggestion that the term "light" should be authorized for use on products that are reduced in sodium. According to the comments, the study demonstrates that 71 percent of those surveyed knew that "light" is used to refer to a variety of product qualities such as lower in calories, fat, cholesterol, or sodium or lighter in texture, color, taste, or weight. The comments stated that their experience suggested that consumers perceive "light" to mean reduced in "more than one macronutrient," and that the term was widely used in the market place. One comment said that "light" should be defined for sodium, so that if a company could not comply with the "light" fat or "light" calories requirements, they would not be prohibited from using the term "light."

Other comments disagreed, saying that "light" claims for sodium should not be defined because consumers associate "light" with calorie content. They suggested that any product bearing the term "light" will be perceived as containing fewer calories and not less sodium. One comment cited a recent Canadian study (Tandemar Research, Inc., Consumer Use and Understanding of Nutrition Information of Food Package Labels (Jan. 1992)), in which only 3 percent of those surveyed volunteered that "light" meant "less salt," as support for its claim that "light" should not be defined to describe a reduction in sodium. Another comment related experience in marketing a product that was reduced in sodium as part of a line of "light" products, saying that there had been a number of complaints from consumers who were confused because they expected the product to be reduced in fat, not in sodium, and consequently the company had dropped the product from the "light" product line.

Another group of comments suggested that "light" should be defined for soy sauce and other low calorie foods that are used primarily as salt substitutes. They said that like salt substitutes, these products also contained virtually no calories. They added that even if a "light" claim on one of these products was misinterpreted to mean "reduced in calories or fat," no harm would come to the consumer because these products had an insignificant amount of fat and calories. Therefore, such a product would not be misleading. Yet another comment suggested that foods that are used in place of salt, but that are not calorie free, should be required to meet a calorie/fat based definition for "light."

The agency has carefully considered all of these comments concerning use of the term "light" without qualification to reflect reductions in sodium. As discussed above, the agency remains concerned that the use of the term "light" without qualification on products that are reduced in sodium but not reduced in fat or calories would be misleading to consumers because of consumers' expectations that a product labeled as "light" has been reduced in fat or calories. The agency has already considered the study by the Calorie Control Council (Ref. 27) and acknowledges that "light" has been used to connote a wide variety of meanings, such as reduced sodium and lighter in texture, color, or weight. However, the same study suggests that controlling calories (85 percent of respondents) and fat (83 percent) were two of the major reasons for use of "light" products. In addition, the report of the Calorie Control Council summary used by FDA stated that 69 percent of those surveyed cited "lower in calories" as the first response when asked the meaning of the term "light." Clearly, although consumers do consider that "light" can mean "light" in sodium, they are primarily concerned with fat and calorie reductions in "light" products. Therefore, the agency remains convinced that "light" claims without qualification on products would be misleading if the product did not have significant reductions in fat or calories. Accordingly, the agency is not providing a definitions for "light" for use on all products having only reductions in sodium.

However, on careful consideration of the comments, the agency is persuaded that, like "light" claims on salt substitutes, "light" claims without qualification on sodium reduced products containing only a few calories and little fat (i.e., a "low calorie," "low fat" food) are not misleading to consumers and can assist consumers in maintaining healthy dietary practices. The food meets the expectations of the consumer that the product is useful in achieving a diet consistent with dietary guidelines for calories and fat, albeit because the food was normally low in fat and calories rather than low in fat and calories by modification. Consequently, the agency has determined that if the sodium content of a "low calorie," "low fat" food has been reduced by 50 percent, it may appropriately bear an unqualified "light" claim. This determination is consistent with the suggestions in the comments and the definition proposed for "light" on a salt substitute. Further while other percentage reductions were suggested, no justification for any of those other reductions was provided in the comments. Accordingly, the agency is providing for this use of "light" as a 50 percent reduced sodium claim in § 101.56(c).

183. A few comments suggested that "light" sodium claims would not be misleading if a disclosure statement such as "this product is not lower in fat or calories" or other qualifying information about the nature of the modification was specified adjacent to the term. One comment cited the findings from the Calorie Control Council's study that 67 percent of those

responding believe that "light" is appropriate to differentiate product qualities so long as the term is clearly explained.

The agency has carefully considered these comments. Given the significant traditional association between the term "light" and sodium content, and the dietary guidelines that suggest a reduction in sodium intake (Ref. 7), FDA has concluded that while an unqualified "light" claim for sodium would generally be misleading, it is appropriate to provide for such a claim with respect to sodium content for use on foods that contain more than 40 calories and 3 g of fat per reference amount if the claim is appropriately qualified. The agency has determined that such a claim can be used to highlight a large, that is, a 50 percent or more, reduction in the sodium content of such food. Such a requisite reduction is consistent with the definition of "light" for fat and for sodium on foods that contain less than 40 calories and 3 g of fat per reference amount.

Therefore, to ensure that this additional "light" claim for sodium does not mislead or confuse consumers, FDA has concluded that it is necessary to tightly limit the circumstances in which it may be used. Thus, FDA is requiring in § 101.56(c)(2)(i) that this use of the term "light" must be qualified to distinguish it from the unqualified use of the term that describes reductions in fat or calories. The qualified term that FDA is defining is "light in sodium." Second, to convey to consumers that "light in sodium" is a single term, and to ensure that a misleading impression is not created by manipulations in type size, FDA is requiring in § 101.56(c)(2)(i) that the entire term be presented in uniform type size, style, color, and prominence. Consequently, if a manufacturer wishes to use the term "light" in a brand name to describe a reduction in sodium, the qualifying phrase "in sodium" or the statement "light in sodium" must appear in immediate proximity to the term "light," in uniform type size, style, color, and prominence.

Therefore, in § 101.56(c)(2), FDA is providing for a qualified "light in sodium" claim when there has been at least a 50-percent reduction in sodium content of a food as compared to an appropriate reference food (see § 101.13(j)(1)). In addition, for reasons that are similar to the discussion in comment 179 with respect to light claims for foods that are low in fat or calories, the agency believes that a "light in sodium" claim on a food whose reference food is already "low in sodium" would be misleading. Therefore, in § 101.56(c)(2)(iii) the agency is prohibiting such a claim except for meals and meal-type products (see comment 272).

184. A few comments suggested that "lightly salted" should be permitted, particularly for use on nuts. The comments suggested that the definition should be either one-third less added sodium or 140 mg of sodium per serving ("low sodium"). The comments said that because of a long history of use, consumers were familiar with the term "lightly salted." The comments also stated that "lightly salted" was an easy way for consumers to identify products with less added salt. One comment requested an exemption for "lightly salted nuts," saying that it would be similar to the "sugar free" exemption proposed for chewing gum.

The agency agrees with the comments that "lightly salted" is a claim long used, for example, on nuts, to mean that less salt has been added to the labeled product than to the regular product. In this sense, it is used as a relative claim. As such, "lightly salted" may be an appropriate term to reflect such a salt reduction. However, to be consistent with the other uses of the term "light," the agency has determined that the product must have at least 50 percent less added sodium than the regular brand. In addition, as discussed in comment 75 of this document, the agency has determined that a claim of "no added salt" would be misleading on products that are not sodium free, unless the label has a statement "Not a sodium free food" or "Not for control of sodium in the diet." Consistent with that determination, a comparable disclaimer, i.e., "Not a low sodium food," must be placed on the information panel of "lightly salted" products that are not "low" in sodium. This disclaimer will assist the consumer who may wish to control his or her sodium intake by consuming the labeled product rather than the regular version of the product from being misled into thinking that the labeled product is "low" in sodium when it is not. In addition, because this is a relative claim, the appropriate accompanying information, as specified in § 101.13(j)(2) is required. Accordingly, the agency has provided for "lightly salted" in § 101.56(g).

185. A few comments suggested that "light cholesterol" should be defined. The comments suggested definitions ranging from the criteria for "low cholesterol" to 50 percent less cholesterol. They said that to ensure such a claim was not misleading, the statement, "this product is not lower in fat or calories" could be added to the claim. However, the comments provided no justification as to why the agency should promulgate such a definition other than the finding from the Calorie Control Council Study cited previously that "light" has been used to refer to products lower in cholesterol.

The agency is not convinced by the comments that a "light" claim is appropriate on products that are reduced only in cholesterol. As discussed above in comments 170 and 182 of this document, consumers most associate "light" with reductions in fat, calories, and in certain respects, sodium. There is not the same strong association between "light"and cholesterol content. Although the report on the Calorie Control Council study mentions cholesterol as one of many qualities with which the term "light" has been associated, the report does not provide a basis to distinguish cholesterol from these other qualities as it does with fat, calories, and sodium. Thus, the agency does not consider the mention of cholesterol in the Calorie Control Council report to provide adequate justification for a "light cholesterol" claim. It does not establish a particular association between "light" and cholesterol reduction. Consequently, the agency is not providing a definition for "light" for use on products that are reduced only in cholesterol.

186. A few comments also suggested that "light saturated fat" should be defined. The definitions suggested for this term ranged from "a nutritionally significant reduction in the amount of saturated fat" to 50 percent less saturated fat. There was no justification other than the report of the Calorie Control Council's study.

As with cholesterol, the agency is not convinced that a "light" claim is appropriate on products that are reduced only in saturated fat. In the report of the Calorie Control Council Study used by FDA (Ref. 27), saturated fat is not specifically mentioned as a quality associated with use of the term "light." Consequently, the agency has no basis to determine that consumers perceive "light" to mean reduced in saturated fat. Lacking any other justification, the agency is not persuaded that use of "light" is appropriate on products that are reduced in saturated fat.

187. A few comments suggested that "light sugar" claims should be permitted. One comment stated that a "light sugar" claim should be defined to mean that the food had 25 percent less sugar and at least 5 g less sugar than the appropriate reference food. Other comments stated that "light sugar"

should be defined to mean 50 percent less added sugar. However, none of the comments provided a rationale for why "light sugar" should be defined.

The agency has reviewed these comments and is not convinced that there is sufficient reason to provide a definition for this term. The agency has determined that definitions of "light" for nutrients other than calories, fat, and, on certain products, sodium would be misleading. In addition, although the agency has not defined "less added sugar," the term "less sugar" could be used to communicate changes in the amount of sugar in the food of the sort that could be communicated if the agency adopted the suggested definition for "light sugar." However, lacking an adequate justification for the term "light sugar," the agency is not convinced that such a definition should be established. Accordingly, the agency is not providing for a definition for this term.

ii. Other uses of the term "light"

In the general principles proposal (56 FR 60421 at 60451) the agency proposed that the unqualified use of the term "light" not be permitted on the label or in labeling of a food unless the term was used to describe a reduction in calories and, where appropriate, a reduction in fat (discussed above) or on a salt substitute that contained at least 50 percent less sodium than salt. However, the agency proposed that the term "light" could also be used to describe physical or organoleptic characteristics of a food so long as that attribute adequately qualified the term "light," e.g., "light in color" or "light and fluffy," and was in the same type size, style, color, and prominence as the word "light" and in immediate proximity thereto. The agency also proposed that if the term "light" had been associated through common use with a particular food, such as "light brown sugar," to the extent that the term "light" had become part of the statement of identity, such use of the term would not be considered a nutrient content claim.

188. A majority of those commenting on the subject had no objections to products bearing the term "light" to refer to other physical or organoleptic properties of a product, so long as that property was specified. They said that in these circumstances, consumers are aware of the meaning of the term "light." However, a few comments objected to allowing such "light" claims. One stated that use of the word "light" to describe color, texture, or taste may mislead some consumers and undermine credibility of the term.

The agency acknowledges that the term "light" has at times been used in describing the physical characteristics about a product without appropriate qualifying information. An example of such a claim is "light" used to describe an oil that is "light" in color but is not altered in nutrient quality. This use is clearly misleading. However, the agency is not convinced by the comments that a claim using the word "light" to describe a physical or organoleptic property, if it adequately characterized the nature of the claim, such as "light in color" or "light and fluffy," would be misleading because the word "light" would be defined as part of the claim. In new § 101.56(e)(2), FDA is requiring that product attribute in question (e.g., the color or the fluffiness of the product) be placed in immediate proximity with the term "light." Accordingly, the agency concludes that its regulations provide adequate assurance that this type of claim will not be abused, and therefore, it is adopting the provisions (new § 101.56(e)) that provide for such claims as proposed.

189. Several comments agreed with the proposal that the physical or organoleptic properties of the food that are described in such claims should be identified immediately adjacent to, and in the same type size, style, and color as, the word "light." One comment said that without this requirement, the claim would be misleading, and the same uses of "light" that exist in today's marketplace will be perpetuated, undermining the basic purpose of the 1990 amendments. However, other comments objected to this type size requirement, saying that the attribute information should not be required to be the size of the claim. Suggestions were that the attribute should be in type one-half the size of the word "light," one-half the size of the brand name, one-half the size of the name of the food, or as prominent as the statement of identity. Another comment said that there should be no type size or placement requirements for the defining attribute. Another comment said that the graphics requirement for this information was so unreasonable and burdensome as to constitute a virtual prohibition for use of the term.

The agency has considered these comments and is persuaded that the type size requirements proposed for the information that defines a "light" claim about a physical or organoleptic property of a product would be burdensome, and that this information need not be as large as the claim to effectively clarify the physical or organoleptic properties of the labeled product. However, because of the special nature of the term "light," and the great potential for its misuse, the agency believes that it is essential that this defining information be declared adjacent to the term, and that the word "light" not have undue prominence relative to this information. The agency believes that to severely diminish the size of the defining information, or to remove it spatially from the claim, would affect the ability of the information to clarify what might otherwise be a misleading claim. FDA concludes that by permitting such information to be as small as half the size of the term "light," it will eliminate the burdensomeness of the proposal and yet still insure that the information was sufficiently prominent so as to mitigate any misimpressions caused by the use of this term. Accordingly, the agency is revising § 101.56(e)(2) to permit the defining information to be one-half the type size of the word "light."

190. Of those commenting, a majority agreed that if the term "light" had, through common use, come to be part of the statement of identity (e.g., "light brown sugar"), the term "light" need not be further defined or qualified. However, a few comments disagreed. They said that all such physical or organoleptic uses of the term should be specifically clarified no matter what the history of use of the term was. Another comment stated that this provision should be narrowed in scope so that this unqualified usage of the word "light" would be limited to situations in which the term reflected physical or organoleptic properties of the food, such as color or weight and not nutritional qualities.

The agency advises that the provision in proposed § 101.56(f) was intended to apply only to use of "light" to describe physical and organoleptic properties of the food. It was not intended to permit uses of "light" that are contrary to other parts of the regulation. Accordingly, FDA has modified new § 101.56(f) to clarify the permitted use of the term. Where the word "light" has come to be part of the statement of identity through longstanding use of the term, it is generally used to characterize a product not in comparison to a regular product, but to a contrasting version of the product e.g., "light brown sugar" versus "dark brown sugar." Without use of the term "light" to distinguish the food from its counterpart, there would be confusion as to the specific identity of the product. Therefore, the agency concludes that for such products, the word "light" is fundamental to an understanding of the product's identity. Consequently, in such circumstances, FDA is allowing, under § 101.56(f), the

use of the term "light" without qualification other than the other components of the identity statement.

191. Another comment suggested that because of a 60-year history of use, the term "light," without qualification, should be allowed on a particular brand of fruit cake to differentiate it from the "dark" version of the same brand of fruit cake.

The agency agrees that it would be appropriate in this long standing situation, for the manufacturer to use the word "light" without qualification to differentiate a version of a particular brand of fruit cake that is "light" in color from a version of the same brand of fruit cake that is "dark" in color. However, FDA advises that for this use the term "light" must appear in the statement of identity, e.g., "light fruit cake." In addition, FDA would expect the dark version of the product to be labeled "dark fruit cake," so that the terms "light" and "dark" have the same conspicuousness on the label. The agency believes that such a use is not misleading to consumers because it is clear from the relative use of the terms "light" and "dark" that the word "light" in this instance refers to the color and not to any other properties of the fruit cake.

192. One comment requested that the agency clarify and codify the method for a manufacturer to demonstrate that its use of the term "light" on a product is permissible because the term has come, through long use, to be part of the statement of identity.

The agency believes that the situations in which such a demonstration would be appropriate are sufficiently few that specific provisions are not necessary to implement this procedure. When the use of the term is broadly applicable to a class of products, a petition would be appropriate. There is provision in part 10 (21 CFR part 10) for this type of request. However, the agency does not believe that it is generally necessary to submit a formal petition to address this matter. Except for those regarding brand names, petitions are broadly applicable to a class of products and do not address a single manufacturer's product. If a manufacturer wishes to have advice on whether a product's use of the term "light" in its statement of identity is appropriate, the manufacturer may submit to the agency evidence to substantiate the longstanding, nonmisleading use of the term for this purpose. The agency will review each situation on a case-by-case basis and notify the manufacturer whether the label declaration is appropriate.

193. Another comment asked for advice on whether its brand name "Sunny Delight" was subject to the requirements for "light" nutrient content claims.

The agency advises that the term "Sunny Delight" would not, by itself, constitute a nutrient content claim. The ordinary meaning of the word "delight," as long as it is presented as a single word without any use of printing, hyphenation, or spelling that unduly emphasizes "light," does not state or imply the level of a nutrient. However, FDA also advises that it will evaluate label statements using forms of the word "light" to determine if they are used in a context in which they make claims that a nutrient has been reduced in the food.

iii. Additional terms

194. One comment stated that additional terms such as "extra light" or "ultra light" should be defined. They said that the state of California allows these definitions to describe reductions in milk fat and urged the agency to define "light" with enough flexibility to allow this labeling to continue. The comment said that "extra light" should be defined as a two-thirds fat reduction, and that "ultra light" should have no fat (a 100 percent fat reduction) compared to whole milk.

The comments have not provided sufficient justification for the terms "extra light" or "ultra light." Therefore, the agency is not providing definitions for those terms at this time. The agency is not persuaded that the consumer would understand the differences among "light," "extra light," and "ultra light," especially since definitions for such terms would be available for use on a wide variety of food. In addition, the comment did not present justification for establishing an additional definition for use on foods that appear to qualify for "low fat" and "fat free." The agency advises that, under new § 101.69, the person who submitted the comment, or any other interested party, may submit a petition to the agency, with substantiating information, requesting definition for these terms.

195. A few comments disagreed with the idea of defining "light" and "lite" as synonyms. One comment suggested that sound alike spellings for "light" (e.g., "lite") should be prohibited. Another comment suggested that the term spelled "l-i-t-e" should be used to refer to calorie reductions and the spelling "l-i-g-h-t" should refer to other product qualities.

The agency does not agree that the terms "lite" and "light" should not be synonymous. The agency points out that the statute required that the agency define "'light' or 'lite'" (section 3(b)(2)(A)(iii)(III) of the 1990 amendments). From this instruction, the agency can reasonably conclude that Congress intended that the two spellings of the term be synonymous. Further, under the statute, to not define both of these terms, the agency would need to find that one of them was misleading under section 403(a) of the act. The comment gives the agency no basis to make this finding, nor is one apparent to the agency. In addition, the agency believes that because of similarity of the terms "lite" and "light," the suggested distinct definitions for the two spellings of the term would cause confusion to consumers and would indeed be misleading. Accordingly, the agency is not changing the status of the terms "light" and "lite" as synonyms.

iv. Dietary Supplement Act

FDA proposed to require in § 101.56(a)(3) that if a food bears a "light" claim, it must be nutrition labeled in accordance with §§ 101.9, 101.10, or 101.36, as appropriate. However, as stated above, the Dietary Supplement Act of 1992 established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. As a result, FDA is not adopting § 101.36 at this time. To reflect this fact, FDA has deleted the reference to § 101.36 from § 101.56(a)(3). FDA has also deleted references to § 101.36 from §§ 101.60(a)(3), 101.61(a)(3), and 101.62(a)(3).

3. "More" claims

Although the 1990 amendments do not require that FDA define the term "more," the agency proposed a definition and requirements (proposed § 101.54(e)) for use of "more" to describe a food in the general principles proposal (56 FR 60421 at 60453).FDA proposed that a comparative claim using the term "more" may be used to describe a food, including a meal-type product, that contains at least 10 percent or more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium than the reference food that it resembles and for which it substitutes (proposed § 101.54(e)(1)(i)).

Further, the agency proposed that when the claim is based on a nutrient that has been added to the food, fortification be in accordance with the policy on fortification of foods in § 104.20 (21 CFR 104.20) (new § 101.54(e)(1)(ii)). Also, the agency proposed to require that the identity of the reference food, the percentage (or

fraction) that the nutrient was increased relative to the RDI or DRV, and quantitative information comparing the level of the nutrient in the product per labeled serving size with that of the reference food that it replaces be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(1)(iii)).

Further, the agency proposed to permit a comparative claim using the term "more" on a food to describe the level of complex carbohydrates in a food, including a meal-type product as defined in proposed § 101.13(l), provided that the food contains at least 4 percent or more of the DRV for carbohydrates than the reference food, and that the difference between the two foods is only complex carbohydrates as defined in proposed § 101.9(c)(6)(i). The identity of the reference food and quantitative information comparing the level of complex carbohydrates with the level in the reference food that it replaces would have had to be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(2)).

Finally, FDA proposed to permit a comparative claim using the term "more" to describe the level of unsaturated fat in a food, including meal products as defined in proposed § 101.13(l), provided that the food contains at least 4 percent more of the DRV for unsaturated fat than the reference food, the level of total fat is not increased, and the level of trans fatty acids does not exceed 1 percent of the total fat. Under the proposal, the identity of the reference food and quantitative information comparing the level of unsaturated fat with that of the reference food that it replaces would have had to be declared in immediate proximity to the most prominent such claim (proposed § 101.54(e)(3)).

The agency specifically requested comments on certain specific aspects of the proposed definitions of "more" for describing levels of complex carbohydrates and unsaturated fatty acids (56 FR 60421 at 60453 through 60454). First, both of the proposed definitions deviated from FDA's past requirements for superiority claims which, as stated above, have been based on a food having 10 percent more of the U.S. RDA of a nutrient per serving than the food to which it is being compared. Secondly, the provision in the "more" definition for unsaturated fatty acids limiting the level of trans fatty acids to 1 percent of the total fat was included because the agency believed that it would be misleading for products containing significant levels of trans fatty acids to bear claims of more unsaturated fatty acids in light of recent data suggesting that trans fatty acids act like saturated fat in raising serum cholesterol.

196. A few comments were opposed to the proposed definition of "more." The comments argued that claims for "more" should not be permitted because the 10 percent eligibility criterion is too small to be of significance to consumers. One comment suggested that claims of "more" be expressed in 5 percent increments to prohibit food companies from rounding up to make the increased nutrient level appear greater than it actually is. A few comments stated that the definition for "more" should be similar to the definition for "less," and that the food should contain 25 percent "more" of the nutrient than the reference food to be eligible to bear the term "more." A few comments were concerned that a 25 percent eligibility criterion may lead to over fortification of foods in order to be eligible to bear this term.

The agency has not been persuaded to change the definition for "more." As discussed in the general principles proposal (56 FR 60421 at 60453), the agency believes that a 10 percent greater level of a nutrient relative to the RDI or DRV in a serving of a food is nutritionally significant and is also necessary to ensure that there is truly a difference in the foods being compared. This level is the minimum level of a nutrient that must be provided by a food for the food to meet the definition of "good source" in this final rule. Consistent with this requirement, a food must provide at least an additional 10 percent of the DRV or RDI compared to the reference food before it can be designated as a better source, i.e., having "more" of the nutrient.

The nutrition labeling regulations allow for the standard practice of rounding values to the nearest percent when determining levels of nutrients (new § 101.9(c)(8)(iii)). However there is no provision in the final rule that allows for inappropriate rounding up of values when making claims.

Additionally, the values represented by a "more" claim must be truthful and not misleading. The agency considered requiring at least a 25 percent increase relative to the RDI or DRV as compared to the reference food in arriving at the proposed definition for the term "more." As discussed in the general principles proposal (56 FR 60421 at 60453), FDA rejected this approach because of the agency's concern that a level higher than 10 percent of the DRV or RDI would result in inappropriate fortification of foods in an attempt to make superiority claims. Therefore, the agency is retaining the proposed definition of "more" in the final rule.

197. A few comments disagreed with the proposed requirements for use of the term "more" for complex carbohydrates. The comments generally argued that defining "more" for complex carbohydrates but not defining "high" in this regard is inconsistent, and that further scientific evidence about the benefits of consuming complex carbohydrates is needed.

As discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, the agency has determined that it cannot presently define, and, therefore is not defining, "complex carbohydrates." FDA has concluded that there is not sufficient consensus about the meaning of the term or appropriate analytical methodology for a specific definition for "complex carbohydrates." Therefore, the agency is not providing for the term "more" for complex carbohydrates in the final rule.

198. Most of the comments disagreed with the proposed definition for "more" for use with unsaturated fat. Most comments expressed the view that "more unsaturated fat" should not be defined until there is more scientific evidence to support the benefits of the claim. The comments were concerned that allowing the claim at this time will confuse consumers about the benefits of increased consumption of unsaturated fat. One comment suggested eliminating the additional criterion for trans fatty acid in the proposed definition because no conclusive evidence exists that trans fatty acids function like saturated fatty acids. One comment requested that the agency define "more" for monounsaturated fat.

The agency agrees that a definition for "more unsaturated fat" is unnecessary. As discussed in the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, the agency has decided not to establish a DRV for "unsaturated fat." FDA has been persuaded by comments that the use of the term "unsaturated fat" is potentially confusing, does not provide useful information, and could result in consumer deception. Therefore, the agency is not defining "more unsaturated fat" or "more monounsaturated fat" in this final rule.

199. A few comments disagreed with the proposed requirement that a food containing added nutrients must be in compliance with the agency's fortification policy to be eligible to bear the term "more" on its label. The comments noted that this policy is only a guideline.

The agency concludes that this requirement is appropriate. As discussed in the general principles proposal (56 FR 60421 at 60453), the fundamental objective of the agency's policy on appropriate fortification of foods is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. While it is true that the fortification policy is only a guideline, in the context of new § 101.54(e)(1)(ii), FDA has subjected the use of § 104.20 (21 CFR 104.20) to notice and comment rulemaking. Interested persons were given notice that FDA intends to use that provision as more than a guideline. Such persons had an opportunity to object to provisions of that regulation and explain why such provisions did not provide an appropriate basis on which to limit the use of "more" on food labels. No comments did. Therefore, the fact that part 104 (21 CFR part 104) is generally intended to be used as a guideline has no significance here.

In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. In authorizing a claim for "more," the agency is making a finding that the claim will assist consumers in maintaining healthy dietary practices (see section 403(r)(2)(A) of the act). The agency cannot make such a finding for nutrient additions that are not consistent with the fortification policy. Therefore, FDA is retaining the requirement that foods bearing the term "more" comply with the agency's fortification policy.

200. A few comments expressed interest in use of the terms "fortified" and "enriched" as synonyms for "source." The comments were of the view that these terms should be permitted because they are easily understood by consumers as a result of their use in food labeling for many years.

The agency believes that the terms "fortified" and "enriched" are not synonymous with the term "source" but more appropriately may be defined in the same manner as the term "more." "Fortified" and "enriched" convey the meaning that there is "more" or a nutrient in a food compared to another food. This approach is consistent with the agency's fortification policy § 104.20(h)(3), which states that when labeling claims are permitted, the term "enriched," "fortified," "added," or similar terms may be used interchangeably to indicate the addition of one or more vitamins or minerals or protein to a food, unless an applicable Federal regulation requires the use of specific words or statements. Section 403(r)(2)(A)(i) of the act limits the terms that can be used to those provided for by § 101.54(e).

Therefore, the agency is providing, in this final rule, for the use of the terms "fortified," "enriched," and "added" with the same quantitative definition as the term "more" when these terms are used to describe the level of a nutrient that has been added to a food. However, as discussed in greater detail in the section of this document on reference foods, there are circumstances in which the term "more" is appropriately used but "fortified," "enriched," and "added" are not. These circumstances, which are delineated in new § 101.13(j)(1)(i), turn on whether the comparisons are being made to similar (bread to bread) or dissimilar (bread to rolls) foods.

4. Reference foods

a. Reference foods for "reduced" and "less"

201. Many comments suggested that if "reduced" and "less" were defined in the same manner, they should both be permitted to use the same types of reference foods, i.e., a manufacturer's regular brand or a food in a valid data base in addition to an industry-wide norm.

Because the agency has determined that "reduced" and "less" should have the same quantitative definition, the agency believes that it is appropriate for these two terms to be permitted to have many of the same types of reference foods (see new § 101.13(j)(1)(ii)(B)). In many circumstances, these terms can be used interchangeably.

Consequently, the agency has concluded that the manufacturer's regular brand, another manufacturer's regular brand, and a representative value for a broad base of foods of the particular type, are appropriate reference foods for both "reduced" and "less" claims. Accordingly, the agency is providing in new § 101.13(j)(1)(ii)(B) that "reduced" and "less" claims may use as a reference a food or class of foods whose composition is reported in a representative valid data base.

However, as discussed in greater detail in comment 204 of this document, not all reference foods that are appropriate for "less" claims are appropriate for "reduced" claims. Even though these terms are based on the same percent reduction, reductions from a certain class of reference foods, those foods that are different than the labeled food but that would fall in the same product category (e.g., potato chips as a reference food for pretzels) are not appropriately described, simply as a matter of English, by use of the term "reduced." Claims that are designed to draw consumers' attention to such reductions are more appropriately phrased using the term "less." FDA has reflected this fact in new § 101.13(j)(1)(i) and has modified §§ 101.60(b)(4), 101.61(b)(6) and 101.62(b)(4), (c)(4), and (d)(4) accordingly.

In this context, the agency notes that because it has determined that "light" claims should be subject to a more rigorous standard than the other relative claims, it is limiting the reference foods that are appropriate for use with "light" claims. Under new § 101.13(j)(1)(ii)(A), FDA is requiring that the reference for a "light" claim be limited to a representative value for the type of food that bears the claim. This value may be drawn from such sources as a valid data base, an average of the three top national or regional brands, or a market basket norm.

These determinations are explained in more detail in response to the comments that follow.

202. Several comments stated that use of nutrient values from data bases as references for claims should not be limited to the kinds of data bases cited as examples in proposed § 101.13(j)(1)(iii). They suggested that other published or unpublished data bases should be available for use as a basis for claims because established data bases like USDA's Handbook 8 (Ref. 24) are not updated frequently enough to keep up with product innovation. The comments contended that more flexible data bases should be used. In addition, one comment stated that the established data bases are not truly average values because they do not account for variations in preparation of foods. For example, the comment stated, they do not provide the fat content of potato chips cooked in a variety of oils. Some comments requested clarification, including examples of what constitutes a valid data base. One suggested that there is inadequate control over the quality of the data going into a data base.

The agency recognizes the limitations of data bases. Data bases, as they apply to relative claims, are intended to be used to determine representative values for nutrients in a particular type of food for the purpose of determining nutrient differences on which to base a claim. They are not intended to provide all-inclusive nutrient values, such as nutrient values for potato chips cooked in a variety of oils. The agency recognizes that while published data bases, by their nature, are often not up-

to-date, they do provide a reference that is readily available. Further, the agency advises that while USDA's Handbook 8 (Ref. 24) was cited in the proposal as an example of an acceptable data base, it is not the only data base available for use as a reference for relative claims.

On July 23, 1992, the agency published (57 FR 32796) a notice of availability of a draft document entitled "Nutrition Labeling Manual, A Guide for Developing and Using Data Bases." This draft manual has now been subject to review and comment and is being made available in final form with the publication of the regulations. This manual details the parameters that the agency believes to be appropriate for data bases used for nutrition labeling. Because the use of descriptive terms is directly related to these same nutrient values, data derived from data bases, as described in this manual, would be appropriate for use as a basis for relative claims.

203. Some comments said that products that have been improved in order to bear nutrient content claims, especially those meeting the definition of "light," should not be included in data for reference values to be used as the basis for claims. They stated that if nutrient values of improved products were included, some improved products would eventually be disqualified from bearing claims because the data base would change as additional modified products become available.

The agency believes that all improved foods, including those that bear "light" claims, should be considered when deriving appropriate reference foods on which to base claims. To the extent that the claim is based on a reference food that is representative of a particular type of food, for the claim to not be false or misleading, the reference food should fairly reflect the market. Thus, the effect of improved foods on the market must be reflected in the reference food. The agency agrees that this position may well result in a progression of the overall nutrient values of marketed foods in a direction that is consistent with dietary guidelines, but this result is consistent with the 1990 amendments.

204. Some comments specifically supported basing claims on a comparison of dissimilar products within a product category, e.g., potato chips to pretzels. They said that without the ability to make such claims, there would be no incentive for the industry to develop reformulated products. Several other comments suggested that "reduced" claims should not be based on the difference in amount of a nutrient in dissimilar products, such as a potato chip compared to a pretzel, but that such claims should be limited to comparisons between similar products (potato chips to potato chips).

One comment stated that comparisons between dissimilar products could result in consumer confusion and would increase the possibility of misleading claims. The comment said that consumers view a "25 percent less fat" claim as a comparison to another version of the same type of food as the food that bears the claim. It went on to say that unless all products of a particular type (e.g., pretzels) make the same claim, consumers could be misled into thinking that products making the claim are nutritionally superior to those that do not, despite the fact that such claims refer to a different type of food. The comment suggested that if cross-food comparisons are permitted, additional restraints on their use are needed. As an example, the comment asked whether a "reduced sodium" claim could be made for pretzels simply because they contained 25 percent less sodium than potato chips. The comment stated that using the term "reduced" to represent such a comparison could mislead consumers.

The agency has evaluated these comments and is convinced that comparisons using the terms "light" and "reduced" are only appropriate for use in comparing similar foods, e.g., a reformulated version of a manufacturer's product to the original product (potato chips to potato chips). These terms say that there has been a change in the level of a nutrient in a given food and, therefore, are only appropriate to reflect actual changes in the level of a nutrient. Thus, they are not appropriate for use to reflect differences between two dissimilar foods (pretzels to potato chips).

The term "less," on the other hand, can have the same connotation as "reduced" and "light," or it can denote the existence of a difference between two products without implying that there has been a change in nutrient level in the product that bears the term. For example, a "reduced" claim would clearly be misleading under section 403(a) of the act if it were used on the label of a pretzel to describe that the pretzel had 25 percent less fat than potato chips if there had been no change to the pretzel to achieve the difference in the level of the nutrient, and the pretzel bearing the claim was no different than other pretzels. On the other hand, the agency is also convinced that comparisons between products that are dissimilar but within the same product category, and that can generally be substituted for one another in the diet, are useful to point out alternative food choices. This type of comparison can provide the consumer with valuable information useful in making food selections to achieve a diet consistent with dietary guidelines.

The agency does not believe that the consumer will be led to believe that claims comparing dissimilar products are applicable only to the brand bearing the claim because the use of the claim with the reference food, e.g., "25 percent less fat than potato chips," will adequately characterize the claim. Accordingly, the agency in new § 101.13(j)(1)(i)(A) is providing that the term "less" may be used to compare dissimilar foods within a product category, and in new § 101.13(j)(1)(i)(B) is limiting the reference foods for "light" and "reduced" claims to products similar to the product bearing the claim (e.g., potato chips to potato chips).

In addition, the agency points out that the 1990 amendments repeatedly state that claims provided for in this regulation and other regulations promulgated under this statute must not be misleading (e.g., section 403(r)(2)(A)(vi) of the act and section 3(b)(1)(A)(iii) of the 1990 amendments). In these regulations, FDA has attempted to provide clear guidance to manufacturers on how to state claims and on what foods are appropriate as reference foods. However, these provisions do not mandate precise phrasing for each permissible claim. Particularly for use of dissimilar foods as reference foods, the regulation does not specify what "product category" means. The agency has intentionally used a flexible standard. This flexibility is intended to facilitate useful comparisons on foods that are generally interchangeable in the diet (for example, "apples have less fat than potato chips") while prohibiting meaningless or misleading claims. As a consequence, manufacturers will have to use judgment in developing claims to ensure that the claims comply with the regulations and are not misleading under section 403(a) of the act. The agency advises that it will determine on a case-by-case basis whether a claim is misleading because its overall context or presentation is misleading.

205. Several comments stated that in addition to using the nutrient values of a manufacturer's own brand of food as a basis for a "reduced" or "less" claim, similar claims should also be permitted based on comparisons of the product to another manufacturer's brand of the same food. In addition, comments stated that a recognized regional or national brand, with a significant market share,

that is competitive to the product making the claim should also be an appropriate reference food for "reduced" or "less" claims. They said that allowing for brand-to-brand comparisons would provide incentives for development of new products consistent with dietary guidelines.

The agency has evaluated these comments and has determined that use of a competitor's product as a reference food for "reduced" and "less" claims could be appropriate if done in a nonmisleading manner. A competitor's product used for comparison should be an accurate reflection of the products competing with the labeled product. Using a brand of product that is markedly different from the typical foods of the type that includes the labeled food has a great potential to result in a misleading claim. The agency would not, however, consider comparisons between the labeled product and competing products of the type with which the consumer is familiar (e.g., a market leader) to be misleading under section 403(a) of the act unless the competing product is significantly dissimilar in its nutritional attributes.

Accordingly, the agency is providing in new § 101.13(j)(1)(ii)(A) that for relative claims other than "light," another manufacturer's product may be used as a reference food.

206. A few comments suggested that products that had previously been offered for sale but are not currently being sold should be considered appropriate reference foods for products bearing "reduced" and "less" claims. Comments suggested that such a product should be useable as a reference food for up to 6 months or 1 year after being taken off the market.

The agency agrees that it would not be misleading to highlight changes in the formulation of the labeled food, even though the old version of the product is not being marketed. Such claims could be used to point out changes in the level of a nutrient in the new product that would assist consumers in maintaining healthy dietary practices. However, FDA believes that such comparisons to discontinued products should be limited. The agency advises that it would not consider comparisons to such products misleading, provided the labeling for FDA regulated products is attached to that product no more than 6 months after the product has been discontinued from the product line. Any such comparisons after that time would be misleading because of the absence of the old "regular product" for which the new product is a substitute. As the new product replaces the old product, the new product becomes the manufacturer's regular product, thus eliminating the old product as an alternative food choice. Without this alternative choice, the comparison becomes meaningless. In addition, the agency points out that similar time restrictions are appropriate when comparing a labeled product with a competitor's product. In the event that a competitor discontinued a product, the agency believes that claims using that food as a reference would also only be appropriate for 6 months after discontinuation of the product. After that time such claims would no longer be valid because the old product would have become unavailable for consumers either to purchase or to compare.

b. Reference foods for "added," "enriched," and "fortified"

As discussed in comment 200 of this document, the agency is providing for the additional terms "added," "enriched," and "fortified" (referred to collectively for purposes of this discussion as "added"), which will have the same quantitative definition as the term "more."

The agency believes that the difference in meaning between "reduced" and "less," discussed above, also exists between "added" and "more." Comparison of the level of a nutrient between two dissimilar foods using the word "added" is misleading because the term "added" implies that the labeled food is the same as the reference food except for the addition of the nutrient. On the other hand, like "less," the term "more" would not necessarily be misleading in a comparison of two dissimilar foods within a product category that can generally be substituted for one another in the diet. The term "more" states that there is a difference between the two foods but does not imply that difference is a result of modification of the food bearing the term. Accordingly, the agency is reflecting this distinction in new § 101.13(j)(1)(i).

c. Reference foods for "light" products

In the general principles proposal (56 FR 60421 at 60445 through 60446), FDA proposed that an "industry-wide norm" be the only reference for "light" claims. The agency said that because of the special nature of this term, the reference should take into account all foods of a particular product class so as to provide the broadest base and the least opportunity for abuse of the term. The general principles proposal defined an industry-wide norm as "a composite value weighted according to a national market share on a unit or tonnage basis of all the foods of the same type as the food for which the claim is made."

207. A few comments agreed with the concept of an industry-wide norm, saying that maintaining a high standard for the reference for "light" claims would ensure the term's utility, and that such claims would not be misleading. However, an overwhelming majority of the comments that addressed the issue forcefully disagreed with this concept, especially since the industry-wide norm was the only basis proposed for "light" claims. The comments said that the standard of an industry-wide norm was ambiguous and could lead to erroneous comparisons between foods because of the difficulty in deriving such values. Some comments asked who was going to derive the industry-wide norm, while others, recognizing that manufacturers were responsible for label information, said that because of the difficulty in deriving the industry-wide norm, different manufacturers were likely to reach different nutrient values for similar foods. The comments said that the industry-wide norm was: (1) Too complicated to derive because it encompassed 100 percent of the foods of a particular type; (2) excessively restrictive; and (3) prohibitively expensive because of the cost involved in obtaining all the necessary marketing and nutrition information. The comments went on to say that an industry-wide norm is impractical because of frequently changing formulations, variations in products from region to region, and wide variations within certain food types even within a region.

The agency has reviewed the comments and has concluded that requiring use of an industry-wide norm as proposed would be impracticable because of the amount of data needed to include 100 percent of the foods of a particular type, because such data are not always available and because of frequently changing formulations and product variation. In addition, the agency acknowledges that the cost of acquiring such data would be very high. Accordingly, the agency finds that using the proposed industry-wide norm as a reference is unworkable and is deleting the requirement from new § 101.13(j)(1)(i).

However, because an industry-wide norm was proposed as the sole reference for products making "light" claims, as explained in response to the comments that follow, the agency has developed alternative references for "light" foods.

208. Several comments suggested that a manufacturer's own brand or another version of the food from a different manufacturer or competitor should be

an acceptable reference food for a "light" claim. They said that this reference food is appropriate especially when the labeled food was a "light" version of an existing product.

The agency disagrees. As stated in the proposal, FDA believes that for "light" claims, comparisons to a single food in a product class may be misleading, particularly when the reference food differs significantly from the norm for the product class and contains the nutrient at a level that is at the extreme end of the range for the product, e.g., deluxe chocolate chip cookies. Using such a single product as a reference for a "light" claim would result in skewed comparisons in which a product that would normally be considered average for the product type could qualify to make a "light" claim. Clearly such a claim would be misleading to a consumer who, based on it, concludes that the labeled product has 50 percent less fat or one-third fewer calories, than similar foods of the same type.

Because the comments did not provide information to persuade the agency that a provision permitting use of single foods as references for "light" claims will not result in misleading claims, the agency does not consider a manufacturer's own product to be an appropriate reference food for a "light" claim.

209. A few comments stated that the reference for "light" should be based on a market basket norm or a less comprehensive version of the industry-wide norm, e.g., 70 percent of market volume instead of 100 percent of the product.

Although these alternatives are less comprehensive than the 100 percent of the market share based industry-wide norm, they still present problems in their derivation, either because the marketing data collection and nutrient analyses are expensive, especially for small manufacturers, or because they are almost as difficult to derive as the industry-wide norm. Therefore, the agency concludes that such a comprehensive standard is too burdensome to be required as a reference food for products bearing the term "light" and will, therefore, not compel manufacturers to use such a high standard for a reference. However, the agency believes that these composite values would in all likelihood be representative of the market and thus would be an appropriate representative reference for a product bearing the term "light." While the agency is not requiring these specific references, it encourages manufacturers to use them where feasible.

210. Other comments stated that values from a valid data base would be appropriate references for "light" claims.

It is possible that nutrient levels from a data base can provide the appropriate reference against which "light" comparisons could be made. A data base is an appropriate reference if it is representative of the nutrient values for foods that are similar to the food for which the claim is being made and that are currently on the market (see Nutrition Labeling Manual, A Guide for Developing and Using Data Bases). However, the agency cautions that broader, general data bases such as USDA Handbook 8 (Ref. 24) may not be representative of a single food because they may not represent the current market, especially when such data are for a rapidly changing food category such as bakery products or snack foods. Therefore, such data bases should be used with caution.

211. Several comments suggested other types of references for use with "light" claims, such as a leading national brand (e.g., one of the top three brands or a brand with 5 percent or more of the market share), or a top regional brand (for that region only). Comments noted that there needs to be a reference for manufacturers to use who only sell "light" products.

As discussed in comments 209 and 210 of this document, FDA is concerned that when a "light" claim is made, it be based on a reduction in the amount of the nutrient in the product compared to the level of that nutrient in a reference food that is accurately reflective of the foods of that specific type of food on the market. For example, if a "light" claim were made on chocolate ice cream, the agency would expect that reference the nutrient levels would not be derived exclusively or disproportionately from nutrient values from high fat or premium chocolate ice creams. Such a claim would clearly be misleading.

To the extent that values such as those suggested in the comments are representative of the market place, they would be appropriate references for "light" products. The leading national or regional brand also might be an appropriate reference food if the food is firmly and convincingly established as the market leader. However, if there were two market leaders with widely different nutrient profiles, selecting the one with the slightly higher market share for comparison could be misleading.

In summary, the agency has determined that any food or group of foods would be appropriate as a reference for a "light" product if their nutrient levels are convincingly reflective of a broad base of foods of the type that includes the product bearing the claim. Accordingly, the agency is revising new § 101.13(j)(1)(ii)(A) to provide that the reference for a "light" claim must be nutrient values for a food or group of foods whose nutrient values are accurately representative of a broad base of individual foods of the same type as that bearing the claim, e.g., an average value determined from the top three national (or regional) brands of the food, a market basket norm, or from a representative valid data base.

However, when claims are based on reference nutrient values derived from one of a variety of sources, most of which may be unknown or generally unavailable to the average consumer, the agency is concerned that in order for consumers to fully understand such claims, the basis upon which the reference nutrient values are derived be available to consumers on request. Individual reference foods are identified with the claim and thus the reference nutrient value derived from that food would be available by checking its nutrition labeling. In contrast, broad based reference nutrient values derived form average values, market basket norms, data bases, and similar sources are not ordinarily readily available to the public. Therefore, to fully inform consumers, firms that use a broad based reference nutrient value as a basis for a claim must be prepared to make information on how they derived the reference nutrient value available to consumers on request. In addition, the information must also be made available to appropriate regulatory officials on request. This additional requirement will assist regulatory officials in determining compliance with the requirements for appropriate reference nutrient values for products bearing a claim to ensure the claim is not false or misleading. Accordingly, the agency is providing for this requirement in new § 101.13(j)(1)(ii)(A).

5. Accompanying information

In the general principles proposal (56 FR 60421 at 60446), the agency stated that relative claims would be misleading unless they are accompanied by certain material facts that are necessary for consumers to understand the comparisons that are being made. The agency tentatively concluded that the percent and amount of difference of a nutrient in the labeled product compared to the reference food are material facts under sections 403(a) and 201(n) of the act. The agency proposed that this information accompany the relative claim that is in the most

prominent location. The agency also proposed that this information be in type size no less than one-half the size of the claim but no less than one-sixteenth of an inch.

212. A number of comments agreed with the proposed requirement that for a food to bear a relative claim, the product to which the food is being compared must be identified on the label. They said that naming the reference food provides information about the basis on which the claim is made and makes the other required information relevant. In addition, a majority of the comments agreed that the percentage (or fraction) that a nutrient in a product is changed should also be stated. However, a few comments stated that none of this type of information was necessary.

Because the latter comments did not present information to support their assertion, the agency concludes, that consistent with the proposal, the percentage difference of the nutrient compared to a reference food and the identity of the reference food are facts material to the claim under section 201(n) of the act. Without this information the consumer cannot fully evaluate the claim or understand the utility of the food that bears the claim in maintaining healthy dietary practices. Therefore, a claim without declaration of the percentage difference and the identity of the reference food would be misleading under section 403(a) of the act. Accordingly, the agency is retaining this requirement.

213. The comments were less in agreement regarding the necessity of retaining information about the amount of the nutrient in the product compared to the amount in the reference food. Although many comments agreed that this information was useful in assisting a consumer to evaluate the claim and to understand the role of the food in maintaining healthy dietary practices, many felt that the information was not necessary because it could be ascertained from other information on the label, such as the percentage that the nutrient in the labeled food was different from that in the reference food. Others stated that the amount of the nutrient in the labeled food compared to the amount in the reference food was redundant of the information indirectly provided by the minimum difference in the amount of the nutrient that must be achieved for the food to qualify to bear the claim.

The agency has reviewed these comments. FDA finds that a quantitative comparison between the labeled food and the reference food is not a redundant requirement. First, as explained in comments 158 and 179 of this document, the agency is not retaining the requirement of a minimum absolute reduction from the reference food because the agency has concluded that such a requirement is not necessary to ensure the validity of the claim and would only serve to deprive consumers of useful information. Consequently, the amount that the nutrient has been reduced will not be redundant of the definition of the claim. In addition, the amount of the nutrient in a food compared to the reference food is not readily discernable from the other information on the label but would be attainable only by a mathematical calculation using the percentage reduction and the nutrition information. Consequently, the agency concludes that the stated amount of the nutrient in the labeled product compared to the amount in the reference food is necessary for consumers to fully and easily evaluate and understand these claims and for it to be useful to them in maintaining healthy dietary practices. Therefore, the agency is retaining this requirement.

214. Several comments agreed with the proposed requirement that the accompanying information be adjacent to the most prominent claim. However, others disagreed. Some stated that the accompanying information should appear wherever the claim is made. A few comments suggested that it should be permitted to be located next to any claim. Others objected to any specific provisions and recommended that there be a general requirement that accompanying information appear prominently and conspicuously. Still others stated that the information could be placed on the information panel with a notation, for example an asterisk, on the PDP to encourage consumers to turn the package to the information panel for the accompanying information.

A larger number of comments took a different approach and suggested that requiring declaration of the absolute amounts of the nutrient in addition to the identity of the reference food and the percentage difference in the nutrient between the two foods resulted in too much information being required to directly accompany the claim. They stated that this information adds to label clutter on the PDP. Comments said that this provision would make it difficult, if not impossible, to provide information necessary to market the product, especially for multi-language labels. They suggested that all or part of this information, particularly the absolute amount of the nutrient in the product compared to the reference food, should be placed on the information panel. On the other hand, other comments suggested that the amount of the nutrient in the labeled food compared to the reference food was more important than the other accompanying information, and it should be retained on the PDP.

The agency has reviewed these comments and has reconsidered the proposed requirement that all the accompanying information be next to the most prominent claim. FDA evaluated the need for each of the three components of the explanatory information for the consumer to understand the claim at the point of purchase and has concluded that because the relative claim describes a difference in nutrient content between two foods, the identity of each food is essential for the consumer to understand the claim. In addition, a description of the difference in nutrient content between the two foods is needed with the claim because such a description actually defines the relative claim. The agency concludes that the most readily understood description of the difference between two foods is the percentage difference. Therefore, the percentage difference in content of the nutrient appropriately appears with the claim. Accordingly, new § 101.13(j)(2)(i) of the final regulation requires declaration of the identity of the reference food and the percentage difference in content of the nutrient to accompany the most prominent relative claim on the PDP.

However, FDA concludes that the declaration of the absolute amount of the nutrient in each of the two foods provides the type of quantitative information that generally appears on the information panel, and that, therefore, the absolute amount declaration need not directly accompany the claim. In fact, while the absolute amount declaration is a material fact under section 201(n) of the act, FDA finds that it is consistent with the scheme in section 403(r)(2) of the act to place this information on the information panel in conjunction with nutrition labeling. Specifically, if a food that bears a nutrient content claim contains another nutrient in an amount that exceeds the applicable disclosure level, section 403(r)(2)(B)(ii) of the act requires that that nutrient be highlighted in conjunction with the claim, and that the consumer be referred to the information panel for quantitative information about that nutrient. Here, analogously, the comparative percentage differences are to be set forth with the relative claim, and the referral statement will guide the consumer to the information panel for the relevant

quantitative comparison. Accordingly, FDA has revised new § 101.13(j)(2)(iv) to permit declaration of the absolute amount of the nutrient in each food on the information panel. Of course, a manufacturer is free to place this information in direct proximity with the claim.

FDA disagrees with comments that requested that all accompanying information be declared with the claim each time it is stated on the label. In the general principles proposal, the agency tentatively concluded that the consumer will likely read the most prominent claim at the point of purchase, and that if the essential information is declared near that claim, the consumer will receive adequate explanation of the meaning of the claim.

The comments did not explain why this presentation is inadequate. In addition, requiring that accompanying information appear with every claim would add considerably to label clutter. FDA agrees with the many comments that stressed that label clutter should be minimized to the extent possible. The agency concludes that requiring that the information accompany the claim each time it appears would reduce the readability of the label while providing no additional information. Therefore, the agency is not adopting such a requirement.

Finally, FDA concludes that requiring an asterisk on the PDP to guide the consumer to the amount of nutrient information on the information panel is not necessary. The referral statement required to accompany all nutrient content claims (new § 101.13(g)) will be on the label and will direct the consumer to the information panel. Additional referrals to the information panel would be redundant.

215. One comment stated that while the percentage the nutrient differs compared to the reference food and the referral statements were appropriate for single nutrient claims, this same information for multiple claims would clutter the PDP.

The agency recognizes that multiple claims would require more information on the PDP. However, because the absolute amount of the nutrient compared to the reference food will no longer be required to be on the PDP, and because § 101.13(g) requires that there be only a single referral statement when multiple claims are made on the same panel, the label information required to be on that panel is considerably lessened. In addition, although not required, a single reference food will likely be used when multiple claims are made on a particular product. Use of the same reference food will considerably reduce the amount of information on the label. In addition, in light of the changes that the agency is making in this final rule, the percentage that the nutrient has been changed will often be part of the claim, e.g., "25 percent reduced fat cheese cake." Therefore, the agency concludes that no additional changes in declaration requirements are necessary for multiple nutrient claims.

216. Several comments suggested that the percentage declaration that accompanies the claim be in the same type size, style, and color as the rest of the claim. However, many other comments suggested that the proposed type size requirement would make the declaration too large and would leave insufficient label space to effectively convey information about the product. To substantiate this contention, the comments provided mock ups of labels showing how the type size requirements would lead to label clutter. They requested that the type size be reduced.

The agency considered these comments and examined the label examples that were submitted. As a result, the agency has become convinced that the type size requirements for accompanying information may so crowd the PDP that manufacturers may not be able to effectively communicate needed information to the consumer. Therefore, the agency has determined that a different type size requirement is appropriate for this information. Because the accompanying information is adjacent to (although preceding) the referral statement and, like the referral statement, is used to clarify the claim, the agency concludes that the accompanying information should be subject to the same type size and style requirements that it has prescribed for the referral statement. Therefore, the agency in new § 101.13(j)(2)(ii) is cross-referencing the type size requirements in new § 101.13(g)(1) for referral statements. Thus, the accompanying information will be in the type size required by § 101.105(i) for net contents declaration or one-half the size of the claim, as appropriate, but in no case less than one-sixteenth inch.

217. A few comments suggested that the labeling disclaimers for substitute foods that do not have the same performance characteristics as the original food, e.g., "Not for use in cooking," be required on foods that bear "light" claims as well those that bear "reduced" claims.

The agency advises that the requirement for performance characteristic labeling for substitute foods applies to all foods that bear claims that they may be used interchangeably with another food. Therefore, the disclaimer requirement in § 101.13(d) will apply equally to any food in which a nutrient level has been changed and that bears a nutrient content claim including "free," "low," "reduced," "less" (or "fewer"), "light," "more," and "added."

6. Modified

218. Of those commenting on the term "modified," most agreed with the proposed use of the term. However, one comment stated that the term "modified" does not explain whether the nutrient has been reduced or augmented. Another comment suggested that the word "modified" used to compare dissimilar products would be misleading and recommended that foods bearing the term "modified" as part of the statement of identity not be allowed to use a dissimilar food as reference food. It said that a food labeled "modified" should be required to be actually changed as compared to other foods of its type. A few comments said that "modified" should be used only to distinguish chemical changes in a food or to refer to the nutrient character of the food (e.g., "modified fat" or "modified food starch"), not to a change in the amount of a nutrient. A comment suggested that "adjusted" should be used instead of "modified." Another comment suggested that the term "modified" was unattractive for marketing purposes.

The agency points out that the term "modified" is not meant to be used alone, nor was the term meant to be used to describe products that had not been altered. Therefore, as discussed in comment 204 of this document, the term will not be permitted based on a comparison to a dissimilar product.

Additionally, because the word "modified" reflects a change in the food, the reference food used for the "modified" would be one that was appropriate for a "reduced" or "added" claims. For example, a modified fat cheddar cheese would have as its reference a full fat version of cheddar cheese, not some other cheese.

The comment suggesting "adjusted" did not provide any basis to believe that this term is more useful as part of the statement of identity to reflect a change in a food than is the term "modified." In addition, the agency is not persuaded that the term "modified" is an inappropriate term to reflect nutrient changes in a food, or that it should be limited only to uses describing changes in the chemical nature of a food or in the character of the food, such as "modified food starch." Accordingly, the agency is not amending its provision

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for the term "modified" and is retaining the criteria as proposed in § 101.13(k).

D. Implied Claims

In the general principles proposal (56 FR 60421 at 60423), FDA proposed to define an implied nutrient content claim as any claim that describes the food or an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that the food because of its nutrient content, may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy"). The agency stated that, under the provisions of the statute, such implied claims are prohibited until they are defined by FDA by regulation.

However, the agency recognized that an argument could be made that statements such as "contains oat bran" are not intended to be nutrient content claims but are intended to advise consumers about the nature of certain ingredients. Likewise, the agency said that statements that a particular ingredient constitutes 100 percent of the food, e.g., "100 percent corn oil," should not be considered implied nutrient content claims when such statements are the statement of identity for the food. Moreover, the agency reasoned that claims such as "contains no preservatives" could not be characterized as nutrient content claims because they do not relate to nutrients of the type addressed in nutrition labeling.

The agency requested comments on how to draw an appropriate line between implied nutrient content claims and ingredient and other label claims. The agency did not propose regulations that authorized specific implied claims. However, it solicited comments concerning criteria for evaluating whether implied claims are appropriate and not misleading, as well as information on specific implied claims. The agency said that if it received sufficient information in comments, it would consider providing for specific implied claims in the final regulation. The agency said that, alternatively, it would defer action on implied claims until after the rulemaking required by the 1990 amendments is complete and would then consider individual implied claims through the petition process on a case-by-case basis.

1. General

219. The agency received a wide variety of comments on what should constitute an implied nutrient content claim, and on what steps the agency should take to regulate such claims. Some comments stated that FDA must maintain strict control of claims made on food labels in order to prevent misleading nutrient content claims and subsequent consumer confusion. Another comment stated that the agency should develop a list of acceptable implied nutrient content claims and accept others on a petition basis. Several comments asserted that the proposed regulations are too vague and will not allow manufacturers to determine whether or not an ingredient claim will be considered an implied nutrient content claim by the agency. Some of these comments stated that because of the vagueness of provisions that rely on interpreting consumer perception and the criminal nature of violations of the act, it is incumbent on the agency to define with specificity, and through rulemaking, the standards by which implied claims will be judged. Other comments provided a wide variety of suggestions, discussed in detail below, as to what should constitute an implied nutrient content claim, what should not constitute such a claim, and what, if any, implied nutrient content claims should be provided for in regulations.

Other comments suggested that factual statements, particularly ingredient statements, that constitute implied claims and that are found to be misleading should be regulated under the general misbranding provision of section 403(a) of the act. One of these comments asserted that whether a label statement is an implied nutrient content claim can only be determined on a case-by-case basis in which the context of the entire label is considered. The comment stated that it is highly implausible to identify specific words that will always constitute implied claims. Some comments supported such a case-by-case approach on the grounds that a blanket prohibition of ingredient claims that constitute implied nutrient content claims would prohibit the presentation of truthful labeling statements concerning the content of a food product. Another comment stated that affording manufacturers wide latitude in language would better serve to educate consumers about nutrition and the nutrient content of food, because they would not become bored with and disregard a limited number of repetitive descriptors.

The agency disagrees with those comments that said that implied claims should be prohibited and also with those that suggested that all implied claims should be regulated under section 403(a) instead of 403(r) of the act. The language of the statute and the legislative history make clear that implied nutrient content claims are subject to the nutrient content claims regime. Section 403(r)(1)(A) of the act provides that a food is misbranded if it bears a claim that "expressly or by implication characterizes the level" of a nutrient unless the claim is made in accordance with regulations established by FDA. Section 3(b)(1)(A)(i) of the 1990 amendments instructs the agency to establish regulations that identify claims described in section 403(r)(1)(A) of the act that comply with section 403(r)(2). The legislative history (H. Rept. 101–538, supra 19) includes reference to "high in oat bran" as an example of an implied nutrient content claim. This reference to an ingredient claim as an implied claim subject to section 403(r)(1)(A) of the act clearly demonstrates that Congress intended that at least some statements about ingredients be subject to regulation under section 403(r)(1)(A). Accordingly, FDA concludes that it must attempt to define implied nutrient content claims.

The agency examined the comments carefully in attempting to devise a scheme for determining when a label statement is an implied nutrient content claim. The agency agrees with the comment that stated that in many cases whether a label statement is an implied nutrient content claim can only be evaluated on a case-by-case basis, considering the entire label and the context within which the claim is made. However, FDA also agrees with the comments that the definition in proposed § 101.13(b)(2) is too vague. Accordingly, as discussed below, FDA has modified that definition. Moreover, FDA has identified groups of claims that it concludes can be defined and would not be misleading. The agency is providing in new § 101.65(c) definitions for these claims.

However, because of the large variety of statements that can be considered to be implied claims, because of resource constraints, and because of the strict timeframes under which this rulemaking has been accomplished, FDA is unable to adopt a comprehensive set of implied nutrient content claims. Interested persons may provide information to the agency with which it can develop additional definitions, or they may submit petitions requesting approval of specific definitions or brand names.

2. Statements that are not implied claims

The agency has attempted to define as many groups of implied claims as possible so as to permit as many appropriate, nonmisleading implied nutrient content claims as possible in

this final rule. In addition, FDA examined the comments carefully to identify groups of label statements about ingredients and other attributes of foods that are not implied nutrient content claims. The agency finds that it can distinguish several types of statements that can be excluded from the requirements for nutrient content claims. The agency is describing these claims in new § 101.65(b).

a. Statements that facilitate avoidance

220. Several comments stated that some statements of the absence of a substance or an ingredient provide valuable information to consumers who seek to avoid certain substances. The comments noted that statements such as "100 percent milk free" or "contains no milk or milk fat" serve primarily to assist those buyers who adhere to Kosher dietary laws, or those who suffer from lactose intolerance, and wish to avoid dairy products. Other comments noted that statements such as "contains no MSG" or "contains no wheat flour" provide useful, indeed, sometimes vital, information to consumers who are sensitive to these substances. The comment stated that it was not clear from the proposal whether these ingredient statements would be permitted.

The agency has considered these comments and agrees that such statements are not nutrient content claims. Statements of the absence of an allergen are regulated under § 105.62 (21 CFR 105.62), which provides for labeling of foods for special dietary use by reason of the absence of an allergenic property. Statements that declare the absence of other food components or ingredients that are not nutrients of the type required to be declared in nutrition labeling and that are intended to facilitate avoidance of the substance for such reasons as food intolerance, religious beliefs, or dietary practices (such as vegetarianism), e.g., "100 percent milk free," are also not nutrient content claims. FDA has included new § 101.65(b)(1) in its regulations to recognize this fact. However, the agency cautions that such a statement could be made in such a way as to connote a nutrient content claim. For example, a statement such as "contains no milkfat" made in context with other label information about the benefits of reducing fat intake, implies that the product is "fat free." In such a context, the statement would be a nutrient content claim subject to section 403(r)(1)(A) of the act. Also, for example, claims such as "no tropical oils" or "contains no animal fat" are usually made in a context that implies that the product has little or no saturated fat. Therefore, such claims would not be avoidance claims under the provisions of § 101.65(b)(1) but implied "saturated fat free" claims. Thus, they would have to meet the requirements for such claims.

b. Ingredients that do not serve nutritive purposes

221. Several comments stated that factual statements about ingredients, by their very nature, are not nutrient content claims and should be allowed on food labels (e.g., "no artificial colors" and "contains no preservatives"). One comment suggested that this criterion should also apply to nonnutritive or nutritionally insignificant sweeteners such as saccharin, aspartame, and acesulfame-K and to the brand name Nutra-Sweet. Such claims, the comment said, should be accompanied by "not a reduced calorie food" if appropriate, and the label should provide a statement referring specifically to the caloric and sugar declarations in nutrition labeling.

The agency continues to believe, as it stated in the proposal, that claims about the absence of certain substances that do not function as nutrients, such as preservatives and artificial colors, provide information important to certain consumers but are not nutrient content claims because they are not claims about the level of a nutrient. Consequently, such claims are subject to regulation under section 403(a) of the act, to ensure that they are truthful and not misleading, but not section 403(r). Accordingly, the agency is listing in new § 101.65(b)(2) as a second class of claims that are not nutrient content claims, those that are about substances that do not have a nutritive function and do not substitute for nutritive substances, e.g., "contains no preservatives" or "no artificial colors."

However, FDA does not agree with the comment's suggestion that this policy should also apply to label statements referring to the presence of nonnutritive or nutritionally insignificant sweeteners. In the past the agency has regulated statements like "artificially sweetened" and "sweetened with nonnutritive sweetener" as claims of special dietary usefulness (§ 105.66), which in some contexts imply that the food is "low calorie" or "reduced calorie." Elsewhere in this issue of the **Federal Register**, in a companion final rule on revisions to § 105.66 related to the nutrient content claims regulations in this final rule, FDA has discussed its policy on label statements that refer to the presence of a nutritionally insignificant sweetener in a food. In that document the agency reiterated its position that such claims are subject to either new § 105.66(a) and (b), or (e).

c. Ingredients that provide added value

222. A few comments stated that claims about ingredients that provide added value to products convey important information about the quality of the products and should not be considered implied nutrient content claims. The comments suggested that claims such as "made with butter," "contains buttermilk," "made with whole wheat flour," "contains real fruit," or "made with natural, not processed, cheese" would be examples of added value claims.

The agency agrees that some of these claims would be useful as tools for the manufacturer to communicate to the consumer that the product is of high quality because premium or otherwise preferred ingredients have been used. In most instances, statements such as "made with butter," "made with whole fruit," or "contains honey" would not be considered to be a statement about the product's nutrient content. Accordingly, in new § 101.65(b)(3) the agency is listing claims about the presence of an ingredient that is perceived to add value to the product, such as "made with butter," "made with whole fruit," or "contains honey," as statements that are not nutrient content claims. However, there would be cases, such as "made with whole wheat flour," where the added value statement is made in such a context that it could imply not only that a preferred ingredient was used, but also that the product contained a certain level of a nutrient (e.g., fiber). Such statements would be subject to section 403(r) of the act.

d. Statements of identity

223. Some comments agreed with FDA's discussion in the proposal that factual statements that a particular ingredient constitutes 100 percent of the food (e.g., 100 percent corn oil or 100 percent Columbian coffee) are statements of identity and not implied nutrient content claims. In addition, one comment specifically requested that FDA clarify that the names of dietary supplements (e.g., Vitamin C supplements) will not be considered implied nutrient content claims.

The agency concludes that when an ingredient constitutes essentially 100 percent of the food, so that the name of the ingredient is the statement of identity, the name of the ingredient does not constitute an implied nutrient content claim. In such circumstances, the name of the ingredient constitutes

the common or usual name of the product as described in § 101.5 or the identity of the commodity as described in § 101.3. As such it must provide an adequate description of the food.

When the ingredient is not associated with a nutritional benefit (e.g., Colombian coffee), it is clear that the statement of identity does not imply that a nutrient is present or absent in a certain amount. When the ingredient is associated with a particular nutritional benefit (e.g., corn oil), declaring its presence could imply the presence or absence of a nutrient. However, when used as the statement of identity, the name of the ingredient does not imply that the nutrient is present in a certain amount. Rather, it describes the nature of the product and does not specifically characterize the level of the nutrient. Hence, it would not be considered a nutrient content claim. As for the comment that the names of dietary supplements (e.g., vitamin C supplements) are usually not nutrient content claims, FDA intends to deal with this issue in the rulemaking that it will conduct under the Dietary Supplement Act of 1992.

Accordingly, FDA is providing in new § 101.65(b)(4) that the name of an ingredient is not a nutrient content claim when the ingredient constitutes essentially 100 percent of a food, so that the name of the ingredient is the statement of identity of the food. The agency notes, however, that a statement of identity may include an express nutrient content claim (see e.g., the final rule on requirements for foods named by use of a nutrient content claim and a standardized term, published elsewhere in this issue of the **Federal Register**). Such nutrient content claims are fully subject to new § 101.13 and the regulations in part 101, subpart D.

224. Several comments suggested that common names or statements of identity of foods that include terms that relate directly or indirectly to the nutrient content of a food (e.g., "oat bran muffins") should be considered implied nutrient content claims. Other comments suggested that such statements are merely statements of the characterizing ingredient and should not be considered implied nutrient content claims. They suggested that "oat bran muffin" is not different from "carrot spice muffin." One comment stated that truthful statements such as these should be assumed to be nonmisleading unless there is evidence to the contrary and should be permitted as part of the statement of identity.

While FDA agrees that most statements of identity are statements about the character of a food, there are a limited number of statements of identity that contain the name of an ingredient that is associated with a nutrient or a nutritional benefit and that therefore may also be implied nutrient content claims, depending on what other statements are made on the label or in labeling. Examples of such statements of identity would be "corn oil margarine," "oat bran muffins," and "whole grain bread." The agency will evaluate such claims on a case-by-case basis in the context of the entire label and the labeling to determine whether they are nutrient content claims. For example, if the labeling of oat bran muffins includes a discussion of the importance of fiber in the diet, FDA believes that the "oat bran muffins" name is an implied claim that the muffins are high in fiber. If the labeling is devoid of such information, FDA is not likely to consider the name to be an implied nutrient content claim. Accordingly the agency is providing in new § 101.65(b)(5) that a statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient (e.g., "corn oil margarine," "oat bran muffins," or "whole wheat bagels") is not an implied nutrient content claim unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount.

Statements of identity that are provided by a standard of identity subject to section 403(r)(5)(c) of the act are not subject to definition under section 403(r) of the act and are therefore not considered nutrient content claims.

e. Statements of special dietary usefulness

225. One comment requested that the agency clarify that FDA will not deem a statement of special dietary usefulness made on the label or in labeling of a food in accordance with part 105 of FDA's regulations to be an implied nutrient content claim solely because it represents the food to be for special dietary use.

The agency has considered this comment. As stated in the general principles proposal (56 FR 60421 at 60457), FDA views claims on a food relative to special dietary needs to be different from claims made on a food relative to the nutrient content of the food. The agency would not consider claims made solely to portray the usefulness of the food for supplying a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition as described in part 105 to be a nutrient content claims subject to new § 101.13. A claim such as "use as part of a weight reduction program" in and of itself, would not be considered to be a nutrient content claim.

However, there are circumstances in which a claim that a food is useful in a special diet may be made in a context that portrays a nutritional aspect of the food relative to the general population. If, for example, in addition to including a claim that the food was part of a weight reduction program, the label said that the food was "low calorie," or the label contained other statements of specific nutritional information, then such statement would be subject to the requirements for nutrient content claims because the label contained information directed toward the general population. Accordingly, the agency is providing in new § 101.65(b)(6) that label statements made in compliance with part 105 solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition where the claim identifies the special diet of which the food is intended to be a part, is generally not a nutrient content claim.

3. Single nutrient implied claims

a. Ingredient statements

226. Many comments addressed how requirements for implied claims should be applied to ingredient statements like "contains oat bran" and "corn oil margarine." Some stated that ingredient statements should not be considered implied nutrient content claims. Other comments stated that even though there are good reasons for having ingredient statements on labels, the fact that a declaration is an ingredient statement does not preclude the possibility that it is also an implied claim. Some said that claims such as "contains no tropical oils" and "made with 100 percent vegetable oil" would be misleading to consumers who would be led to assume that such a product is low in or free from saturated fat, when that is often not the case. A few comments stated that to prevent ingredient claims from being misleading nutrient content claims, all ingredient statements should be subject to the provisions of section 403(r) of the act.

The agency disagrees both with the comments stating that no ingredient claims should be considered to be implied nutrient content claims, and with those that want all ingredient claims to be regulated under section 403(r) of the act. As discussed above, some ingredient statements clearly are not implied nutrient content claims, and

some clearly are, while other ingredient statements will have to be evaluated on a case-by-case basis to determine whether they are implied claims. The agency will evaluate ingredient statements in the context of the total label to determine whether they are implied claims and therefore subject to section 403(r)(1)(A) of the act. The agency's focus will be on whether the ingredient statement identifies a nutrient explicitly or by implication, and whether it states or implies that the nutrient is absent, or that it is present in a certain amount.

227. One comment disagreed with FDA's definition for single nutrient implied claims in proposed § 101.13(b)(2), stating that the phrase "leads a consumer to assume" should be changed to "consumers acting reasonably under the circumstances." This phrase is preferable, the comment said, because it requires that the label be interpreted reasonably, rather than in an arbitrary, unusual, or unreasonable fashion. The comment asserted that a standard that is based on the interpretations of a few credulous people is not legally sustainable. The comment stated that the phrase "consumers acting reasonably under the circumstances" correctly takes into account the context in which the statement is made.

The agency has considered the comment and disagrees that "consumers acting reasonably under the circumstances" is a more valid standard for implied nutrient content claims than the one proposed by the agency. The focus of FDA's definition of implied claims is on what the claim suggests. The definition is not intended to be a quantitative standard to determine the number of consumers who have a particular conception about an individual claim but is intended to focus on what the claim is saying. To clarify the intent of the definition, FDA is striking the phrase in question and replacing it with the word "suggests."

228. A few comments said that FDA should evaluate, on a case-by case basis, whether a manufacturer intends a particular label statement to make an implied nutrient content claim, and whether consumers perceive the statement to be that claim. The comments asserted that a similar approach has been supported by the courts in determining whether a product is sold as a food or a drug.

In making an evaluation of a label statement within the context of the labeling as a whole, FDA agrees that it should consider both the manufacturer's intent and consumer perception. However, it notes that intent means more than the manufacturer's subjective intent. See *National Nutritional Foods Association* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). An article's intended use is established by its label, labeling, promotional materials, advertising, and "any other relevant source." Id.

FDA advises that it will evaluate ingredient label statements on a case-by-case basis using the definition of implied claims in new § 101.13(b)(2) and the other provisions of the regulations to determine whether a label statement is an implied nutrient content claim. As stated above, the agency's primary focus will be whether the statement identifies the nutrient explicitly or by implication, and whether it states or implies absence of that nutrient or its presence in a certain amount.

229. Several comments suggested that the agency should consult popular media, scientific articles, and consumer surveys to determine when an ingredient claim constitutes an implied nutrient content claim. Several of these comments suggested that implied claims should not be allowed on food labels unless there is scientific consensus as to what these terms mean. On the other hand, a few comments suggested that a statement about an ingredient is not an implied nutrient content claim, unless there is direct consumer survey evidence that a substantial number of consumers understand the statement to imply a specific nutrient claim. The comment contended that any other position would create chaos because manufacturers would continually be in doubt as to whether an ingredient claim would be interpreted by the agency to be an implied nutrient content claim.

Another comment asserted that claims must be interpreted in their historical context. The comment stated that "high in oat bran," implying "high in fiber," for example, is taken out of context. The comment stated that at the time the claim became widely used, consumers believed that they needed to eat oat bran, not soluble fiber, to lower cholesterol. The comment further stated that consumers wanted to know the amount of oat bran in a product in order to follow a diet high in oat bran. However, current scientific evidence may not substantiate this early finding, and the necessity for consuming large amounts of oat bran may not currently be supported by scientific data. Therefore, for an implied claim to be considered valid, the comments said, current scientific data must be considered.

The agency agrees that nutrient content claims should be defined so as to be meaningful to consumers. It has attempted to ensure through the definitions established in these regulations that permitted claims will assist consumers in maintaining healthy dietary practices. In addition, where possible, FDA has used information on consumer understanding of terms. However, the agency is not persuaded that direct consumer survey information is always needed for it to provide clear guidance to manufacturers on whether an ingredient statement is an implied nutrient content claim. As discussed above, FDA is describing in this document some label statements that clearly are nutrient content claims, and others that clearly are not. For those label statements not addressed in this document, manufacturers who wish guidance can submit a petition requesting approval of a claim. The minimum requirements for information needed to support such a request are described in new § 101.69. Petitioners are welcome to provide consumer survey information as well as other types of information in support of a petition.

230. Some comments asserted that FDA's definition of implied nutrient content claims should be limited to those statements that either expressly or by implication describe the level of a nutrient present in a food, as opposed to simply describing the food's composition. One comment stated that such an approach is consistent with Congressional intent as recorded in the House Report, which states:

> An example of an implied claim covered by this section would be the statement "lite", which implies that the product is low in some nutrient (typically calories or fat), but does not say so expressly, or "high oat bran" which conveys an implied high fiber message.

(H. Rept. 101–538, 101st Cong. 2d sess. (June 13, 1990).)

Another comment asserted that it would be inconsistent with the language of the 1990 amendments to regulate claims about an ingredient that do not characterize the level of that ingredient as implied nutrient content claims. The comment requested that FDA specifically exempt ingredient claims that do not directly or indirectly refer to the level of a nutrient (e.g., "contains oat bran" and "made with vegetable oil").

As already discussed, FDA agrees that statements that describe (expressly or by implication) the level of a nutrient present in a food are nutrient content claims. In addition, for ingredients with nutrient implications (e.g., "bran" implies fiber and "tropical oils" implies saturated fat), a claim that describes the

level as "high," "low," or "free" clearly constitutes a nutrient content claim.

The agency does not agree, however, that claims such as "made with oat bran" and "contains vegetable oil" should be exempt from the regulations. It is not clear to FDA that such claims describe the nature of the food and not the level of a nutrient. The agency notes that it is providing in new § 101.54 that a claim that a food is a "good source" of a nutrient can only be made if the nutrient is present at 10 percent or more of the RDI or the DRV per serving of the food. The agency is also providing for use of the terms "contains" and "provides" as synonyms for "good source." As a result, "contains fiber" is a defined expressed claim that must meet the 10 percent of the DRV criterion.

The question then becomes whether "contains oat bran" and "contains whole wheat" imply that the food is a "good source of fiber." Some comments state that such claims are implied nutrient content claims, while others argue that they are statements about an ingredient and not the level of a nutrient. The agency concludes that, in certain contexts, these statements would be nutrient content claims because they call attention to the fact that the product has been made with an ingredient that contains a valuable nutrient. For example, if a label declared "Joe's Oat Bran Muffins" or "Joe's Muffins, made with oat bran" the prominence of "oat bran" may not call attention to it is a way that proclaims its nutritional value. However, if "Joe's Muffins" bore a bright banner with "oat bran" in large, bright letters, the emphasis on "oat bran" would likely place it in the overall context of a nutrient content claim. However, FDA will evaluate these claims on a case-by-case basis, taking into account the entire label and the labeling, including the placement and prominence of the claim as well as the text of label statements.

231. Some comments asserted that FDA should narrow the definition of nutrient content claims to include only those claims specifically mentioning a nutrient of the type addressed in section 403(q) of the act and of the type appearing as part of the nutrition panel (e.g., fat or cholesterol). Similar comments asserted that any statement regarding an ingredient, as opposed to a nutrient, should not be considered an implied claim. One comment asserted that even those ingredient claims that imply that a nutrient is absent or present in a certain amount are not implied claims. Rather, according to these comments they are more appropriately considered statements of identity or parts of ingredient claims. Some comments specifically disagreed with the House report and FDA that the phrase "high in oat bran" should automatically constitute an implied fiber claim. These comments argued that this claim, as well as others that simply describe the ingredients present in a product in a truthful and nonmisleading manner, should be considered ingredient statements. One comment supported this position by stating that these claims do not automatically lead a consumer to assume that fiber is absent or present in any amount. The comment asserted that such a statement simply advises consumers that oat bran is used as a significant ingredient in the product. The comment went on to say that while oat bran does have some relationship to fiber, consumers will not automatically associate the two. A similar comment requested that FDA alter proposed § 101.13(b)(2) to read, "e.g., high in oat bran, which may imply that a food is also high in fiber."

The agency does not agree that nutrient content claims under section 403(r)(1)(A) of the act are limited to label statements that specifically identify a nutrient, e.g., fat or cholesterol. The legislative history identifies the term "high in oat bran" as an example of an implied nutrient content claim (H. Rept 101–538, 101st Cong. 2d sess. 19 (June 13, 1990)). This statement provides strong evidence that when Congress said that "a claim * * * which expressly or by implication—characterizes the level of a nutrient * * * must be made in accordance with section 403(r)(2)," it intended to include ingredient claims that imply that a nutrient is present at a particular level in, or is absent from, the food. Accordingly, FDA rejects the comment that objected to this interpretation.

The agency advises that there are long established relationships between ingredients and nutrients that are covered under the definition of implied nutrient content claims. Some of these ingredient-nutrient relationships have been regulated as claims for special dietary use. For example, terms like "sugar free" have been regulated by FDA as implying that the product is low or significantly reduced in calories (§ 105.66). In addition, FDA has issued warning letters regarding foods that contain tropical oils (which contain significant levels of saturated fat) when they bear label statements, like "100 percent vegetable oil," that imply that these ingredients have low levels of saturated fat.

Consequently, FDA is not granting the request to exempt from the nutrient content claim requirements ingredient claims that do not explicitly identify a nutrient. However, as discussed in the previous comment, the agency acknowledges that some statements that name ingredients that have nutritional relevance are not nutrient content claims. The agency will evaluate such claims on a case-by-case basis. In addition, where appropriate, manufacturers may submit petitions under new § 101.69 requesting approval of specific claims.

232. A few comments suggested that only those ingredient statements that meet the definition for a defined nutrient content claim should be considered implied nutrient content claims, and that all other ingredient claims should not be considered nutrient content claims. However, several other comments suggested that all ingredient claims that imply that a nutrient is either absent or present at a particular level, whether or not they met the definition of the expressed term, should be considered implied nutrient content claims.

Some of the latter comments said that only those implied claims that meet the requirement for an analogous expressed claim should be permitted on the label or in labeling. For example, several comments said that a statement that a product "contains oat bran" implies that the product is a good source of fiber and should, therefore, only be permitted on foods that meet the definition for "good source of fiber." The comments said that requiring that the expressed claim be met in order to make an implied claim would be effective in preventing manufacturers from using claims on food that may not meet appropriate nutritional standards. Another group of comments stated that any "no [ingredient]" claims (e.g., "contains no tropical oils") that imply that the product is free of a nutrient, but that disparage the absent ingredient, could be misleading if there is inadequate scientific support for health concerns about the ingredient and therefore should be prohibited. The comments presented various other examples to either support or oppose a requirement that an implied ingredient claim that meets the requirements for an explicit nutrient content claim should be permitted.

The agency agrees that ingredient claims that make implied representations about the level of a nutrient in a food, whether or not they meet the definition of the expressed claim, should be considered implied nutrient content claims. This conclusion is consistent with section 403(r)(1)(A) of the act, which states that a food can be misbranded by a statement that

expressly or by implication characterizes the level of a nutrient in a food. An ingredient claim that implies that a nutrient is present in the food at a particular level, but that fails to meet the requirements for the equivalent express claim, will misbrand the food under section 403(r)(1)(A) of the act.

The question of whether claims like "contains no tropical oil" should be prohibited as misleading because they disparage the ingredient will turn on what the scientific evidence shows about the ingredient. If it is commonly known that the ingredient for which absence is claimed is a source of a nutrient for which the current dietary guidelines recommend decreased or moderated intake, then there is no reason for the agency to refuse to permit the claim. The fact that FDA would permit such a claim, however, would in no way represent a disparagement of the ingredient. The claim provides a means by which a manufacturer could highlight the saturated fat content of its food. It does not imply that the ingredient in question is a "bad" food.

233. One comment suggested that FDA allow companies to use expressed or implied nutrient content claims (in brand names or otherwise) that have not been defined or specifically approved by the agency if the claim is not false and misleading and is consistent with, and explained by, an immediately adjacent term that is defined in the agency's regulations. Alternatively, the comment requested that FDA permit ingredient claims that did not meet the expressed nutrient content claims definition but require them to be followed by a factual statement clarifying the nutrient content implication (e.g., "no tropical oils—this product contains 2 g of saturated fat" or "contains oat bran—not a significant source of fiber"). The comment stated that, in effect, companies would be allowed to define certain ingredient claims as implied nutrient content claims. Such a process would be in addition to the petition process established by FDA, thus allowing a company to choose whether to determine its own definition of an expressed or implied nutrient content claim or to petition the agency for a codified definition. The inclusion of a self-definition procedure would, the comment contended, be more in keeping with Executive Order 12630. Also, according to the comment, under such a policy, companies would not be forced to abandon nonmisleading implied claims and brand names, as they would under FDA's proposed rule. Companies would also not be made to change labels repeatedly, or ce by the effective date of the regulations and again after each new implied nutrient content claim is approved. Finally, the comment stated that the rule proposed by FDA would lead to a proliferation of unexplained terms that have been defined by FDA in the regulations but which have little or no meaning to consumers, whereas the procedure suggested in the comment would require the use of a defined term on the label to explain the intended meaning of the implied claim, adding significantly to consumer understanding. The comment asserted that the alternative method is fully consistent with the language and the intent of the 1990 amendments.

The agency does not agree that allowing manufacturers to use undefined claims that do not meet the definition for an expressed claim to be accompanied by a defining statement is consistent with either the intent or the letter of the 1990 amendments. The act provides that claims that characterize the level of a nutrient either expressly or by implication "may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary" (section 403(r)(2)(A)(i) of the act). Thus, Executive Order 12630 is not relevant to the approach that FDA is required by statute to take on this matter. To do as the comment requests and allow manufacturers to continue using any label statements they choose (provided they add a defining statement as explanation) would be inconsistent with the letter and spirit of the act. The agency points out that under section 403(r)(4)(A) of the act, any person may petition the agency for permission to use terms that are subject to section 403(r)(2)(A)(i). This section also provides timeframes in which the agency must act on these petitions. Thus, there should not be any undue delay in obtaining a determination as to whether the claims can be used. Because the act specifically provides a mechanism by which use of claims can be authorized, the agency concludes that it would be inappropriate for FDA to establish an alternate mechanism by which such claims can be used.

The agency disagrees that companies would be required to make frequent label changes because of the approval of each new term. The company could decide what term it wants to use, determine whether the use of the term has been authorized, and if it has not been, petition for such authorization. Once the use of a term is authorized, the firm would be free to use it. Any change in the company's labeling made after that point because FDA approved a new term would occur because the company wanted to take advantage of the term, not because FDA compelled a change.

The agency also disagrees that there would be a proliferation of unexplained terms defined by FDA that would have little meaning to consumers. The agency is establishing only a distinct group of terms and synonyms with well defined meanings that may be used as nutrient content claims. Any additional terms that are included in response to a request of a petitioner will have been shown to be as well supported as those terms originally defined.

The agency concludes that the approach to regulating implied nutrient content claims suggested by the comment is not consistent with the structure established by 1990 amendments and will not promote better consumer understanding of label claims. Accordingly, FDA is not permitting use of undefined nutrient content claims accompanied by an explanation.

234. Many comments asserted that factual declarations of the amount of an ingredient (e.g., "160 mg of sodium," or "contains less than 300 calories") do not constitute implied nutrient content claims. Other comments maintained that statements concerning the percent of a nutrient (e.g., "9 percent fat") should also not be considered implied nutrient content claim.

The agency advises that declarations of the amount of a nutrient or the percent of a nutrient are provided for in new § 101.13(i). That provision, pursuant to section 3(b)(1)(A)(iv) of the 1990 amendments, states that such statements must meet the definition for a defined term or must be accompanied by a statement that the food does not meet the appropriate definition. Comments 16 through 19 of this document contain a full discussion of such claims.

235. One comment suggested that "equivalent" be defined as a nutrient content claim so that comparisons could be made to indicate that a food had the amount of a nutrient equivalent to a reference food, e.g., "contains as much fiber as an apple." The comment stated that this type of claim was particularly appropriate for dietary supplements.

The agency advises that it considers the example given in the comment to be an implied claim about the fiber content of the food. "Contains as much dietary fiber as an apple" implies that one apple is a good source of fiber, and that by being equivalent in fiber to an apple, the labeled food is also a good source of fiber. Such a claim can be used to provide valid, valuable information to the consumer about the nature of a

product in terms of another product that the consumer already understands. However, the agency believes that such a statement would be misleading if the labeled food was compared to the level of nutrient in a food that was not consistent with dietary guidelines, namely the amount of nutrient in a food which is "free," "low," a "good source," or "high." Likewise such a claim would be misleading if comparisons between the foods were not made on a common basis. Because a serving of the product is the amount customarily consumed in one eating occasion (a value which is applicable to all foods), the agency concludes that comparisons using this type of claim should be made on a per serving basis.

Accordingly, the agency is providing in new § 101.65(c)(2) for the use of equivalence claims using the phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" to imply that the reference food is a good source of specified nutrient, and that on a per serving basis, the labeled food is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "contains the same amount of Vitamin C as a glass of orange juice").

236. Several comments requested that the agency define specific implied claims so that their use would be permitted in labeling. Claims that were suggested included "high in oat bran," "contains no oil," "no tropical oils," and "contains canola oil." While the comments suggested definitions for the claims, they were not always in agreement on what the definitions should be.

The agency has carefully considered these terms and is providing its interpretation of the nutrient content implied by the label statement. Label statements about oils like corn, sunflower, safflower, and canola generally refer to the oils' fatty acid content. Accordingly, FDA considers a statement about a type of oil as an ingredient, such as "made with canola oil" or "contains corn oil," to generally imply that the oil in the product was low in saturated fatty acids. The statement "made only with vegetable oil" implies that because vegetable oil was used instead of animal fat, the oil component was low in saturated fat.

A claim that a product contains "no tropical oils," including a statement about the absence of a specific tropical oil, assumes that the consumer understands that tropical oils have a large amount of saturated fats. Such a claim would imply that another oil had been used that did not have a large amount of saturated fat. Consequently, a claim that a product "contains no tropical oils" would imply that the product is "low in saturated fat."

The agency considers that a statement that a product "contains no oil" implies that the product is not made with lipids (fat). Accordingly, such a claim would imply that the product was "fat free." Such a claim on a product that contained another source of lipids (e.g., animal fat) would be misleading.

Further, the agency considers that a claim that a product is made with or otherwise contains a whole grain, a bran, or any type of dietary fiber (such as soluble fiber), implies that the product is a good source of total dietary fiber. Such a claim would therefore be misleading if the product did not contain sufficient fiber derived largely from the sources of fiber mentioned such that the product met the definition for "good source of dietary fiber." However, a claim naming these ingredients that also used the term "high" or a synonym thereof would be misleading if the product was not "high in dietary fiber."

The agency would generally not consider ingredient claims that are consistent with the meanings that it has outlined above to be misleading under section 403(a) of the act. However, as with any implied claim, the agency will consider the appropriateness of the use of the claim in the context in which it is made.

The agency advises that it does not consider that the terms that it has mentioned provide an all-inclusive list of those ingredients that imply the level of a nutrient. Claims for other nutrients will be considered on a case-by-case basis.

In conclusion, a claim that states or implies a characteristic that distinguishes a particular nutritional attribute of an ingredient will generally be considered an implied nutrient content claim. Whether or not it is a nutrient content claim will depend on the context in which it is presented, taking the entire label into consideration. The level of the ingredient may be implicit or explicit. The agency has described generically in new § 101.65(c)(3) circumstances under which such implied claims can be made. The regulation states that claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either low in or a good source of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., "high in ————"), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

The agency believes that the approach that it is taking in § 101.65(c)(3) strikes an appropriate balance between the interest of industry in making claims and the consumers' interest that claims that appear on the label accurately and fairly characterize the level in the food of the nutrient that, either explicitly or implicitly, is the subject of the claim.

b. Accompanying information

237. One comment suggested that implied nutrient content claims should be accompanied by appropriate referral statements that are consistent with the requirement for such statements to accompany nutrient content claims.

The agency advises that implied nutrient content claims that are defined in new § 101.65 (a)(2), must comply with all of the requirements for nutrient content claims described in new § 101.13. Among the requirements is the requirement for referral statements. In addition, FDA advises that as with other nutrient content claims, labels bearing such implied claims must also bear nutrition labeling in accordance with the requirements of new § 101.9 or, where applicable, new § 101.10. For clarity, the agency is listing the latter requirement in new § 101.65(a)(3).

4. General nutrition claims

In the general principles proposal (56 FR 60421 at 60423) FDA proposed to include in § 101.13(b)(2) a provision that label statements that imply that a product would be useful to consumers in selecting foods that are helpful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy") are implied nutrient content claims.

a. General comments

238. Many comments asserted that FDA's definition of implied nutrient content claims should not include claims that imply that a "food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., healthy)."Some of these comments stated that Congress showed no interest in regulating such claims but instead was concerned only with regulating those statements that characterize the level of a nutrient present in a food. One such comment noted that neither the act nor the legislative history contains any

language addressing general nutrition claims.

The agency does not agree with these comments. First, the reading of section 403(r)(1)(A) of the act suggested by these comments is clearly too narrow. A claim that a food, because of its nutrient content, may by useful in maintaining healthy dietary practices is clearly a claim that characterizes the level of nutrient in that food. The claim is essentially saying that the level of nutrients in the food is such that the food will contribute to good health.

Moreover, Congress was clearly concerned with such claims. The October 24, 1990, proceedings in the Senate show that one purpose of the 1990 amendments was to regulate the use of nutrient content claims that appear on food labels and labeling in order to help consumers make appropriate dietary choices (136 Congressional Record S16610 (October 24, 1990)). In addition, section 403(r) of the act itself, repeatedly uses the phrase "* * * will assist consumers in maintaining healthy dietary practices" to describe the information for which provision is being made (see e.g., section 403(r)(2)(A)(ii)(II) and (r)(2)(A)(iii)(I) of the act).

The agency is therefore not persuaded that this aspect of the proposed definition of implied nutrient content claims is inconsistent with the language of the act, the intent of Congress, or the goals of the 1990 amendments. However, FDA is modifying § 101.12(b)(2)(ii) to replace the phrase "* * * achieving a total diet that conforms to current dietary recommendations" with the statutory phrase "* * * maintaining healthy dietary practices."

239. Some comments objected to regulating terms such as "nutritious," "healthy," and "wholesome" under section 403(r) of the act because they have different meanings depending on their contextual use and would be difficult to define. These comments asserted that the agency should instead regulate the use of such terms on a case-by-case basis under section 403(a) of the act. The comments asked for assurance that these terms would not be regulated under section 403(r) of the act.

Other comments asserted that terms such as "wholesome," "nutritious," "eating right," "basic 4," "smart," and "good for you" are implied nutrient content claims and should be banned from food labels. A few of these comments suggested that such terms are more appropriately used to describe an overall diet and should not be used on the labels of individual foods. One of these comments cited a poll that was conducted for them in February 1992, in which 1,007 individuals were interviewed concerning their interpretations of the terms "wholesome" and "nutritious." The comment reported that, other than the 55 percent who responded that the term "wholesome" on a food label meant that the product was "good for you," none of the possible responses for the meaning of either term garnered more than 23 percent of the respondents. Some comments, however, suggested that terms such as "wholesome," "nutritious," "eating right," "basic 4," "smart," and "good for you" could be defined as synonyms for "healthy." Some of these comments supported such a definition only as a secondary option to banning the terms, while other comments stated that the terms should be allowed but controlled. One comment stated that if terms such as "healthy" are held to be implied nutrient content claims, then other suggestive words having to do with a product's quality, such as "beneficial" and "hearty," must similarly be defined or banned.

Some comments expressed concern about continued use of such terms in brand names grandfathered under section 403(r)(2)(C) of the act. One of these comments stated that leaving the terms undefined allows companies that used the claims before October 25, 1989, to continue to use them on foods that may not meet appropriate standards. The comment stated that if FDA chooses to define such terms, then the definition must include strict and comprehensive criteria.

One comment stated that the proposed definition for general nutrition claims could have an impact on many proprietary trademarks or slogans such as "Keeping Fit!", "Stay 'n Shape," "Product 19," "Breakfast of Champions," "Eat Right and Look It," and "Right Choice." Although the comment maintained that Congress did not intend these terms to be regulated, it acknowledged that these brand names serve as a beacon to consumers to indicate that there is something nutritionally desirable about the product.

FDA disagrees that terms such as those cited in the comments should be automatically excluded from regulation under section 403(r) of the act. The agency believes that these terms can be implied nutrient content claims when they appear in a nutritional context on a label or in labeling. FDA advises that it will consider these terms to be in a nutritional context when they appear in association with an explicit or implicit claim or statement about a nutrient. For example, in the statement "nutritious, contains 3 g of fiber," "nutritious" is an implied nutrient content claim because it suggests that the food may be useful in maintaining healthy dietary practices. Accordingly, the agency is providing in new § 101.65(d)(1) that such statements are implied nutrient content claims and are subject to the requirements of section 403(r) of the act.

However, the agency also believes that when a term such as "healthy," "wholesome," and "nutritious" appears on a food label in a context that does not render it an implied nutrient content claim, it is not subject to the requirements of section 403(r) of the act. Under such conditions, the use of the term is subject to section 403(a) of the act, and FDA will determine whether it is misleading on a case-by-case basis.

The agency further advises that, except for "healthy," it does not have enough information to decide if definitions for the terms mentioned in these comments are needed, and if so, what those definitions should be. In a tentative final rule published elsewhere in this issue of the **Federal Register**, the agency is providing its tentative position on an appropriate definition for "healthy" based on information received in the comments. In addition, because of the time constraints of this rulemaking, FDA has been unable to develop information with which to make such a decision. The agency solicits information on whether such definitions are appropriate, and if definitions are appropriate, what they should be. Interested persons may submit appropriate petitions under new § 101.69 with accompanying substantiating information to initiate this process.

E. Use of Nutrient Content Claims with Meal-type Products

1. Definition of meal-type products

In the general principles proposal (56 FR 60421 at 60455), FDA proposed a definition for a "meal-type product" for the purpose of regulating nutrient content claims for these products on a different basis than for individual foods. The proposal cited the many comments that the agency received in response to the ANPRM (54 FR 32610), and during the public hearings that followed, that requested that FDA define and allow for the use of nutrient content claims for meal-type products. FDA proposed in § 101.13(l), to define a "meal-type product" as a food that: (1) Makes a significant contribution to the diet either by providing at least 200 calories per serving (container) or by weighing at least 6 ounces per serving (container);

(2) contains ingredients from 2 or more of 4 food groups; and (3) is represented, or is in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. The four food groups in § 101.13(l) were: (1) Bread, cereal, rice and pasta group; (2) fruits and vegetables group, (3) milk, yogurt, and cheese group; and (4) meat, poultry, fish, dry beans, eggs, and nuts group. The agency recognized that current guidelines for daily food intake specify five food groups, distinguishing between fruits and vegetables. However, FDA proposed to combine the fruits and vegetables groups for regulatory purposes.

FDA requested comments on the appropriateness of this definition of a "meal-type product" as well as on the appropriateness of specific amounts (e.g., 200 calories and 6 ounces) and specific product types (e.g., "main dish") used as a basis for this definition.

The agency received many comments on the need for separate criteria for meal-type products and the definition of meal-type products. After reviewing these comments, the agency continues to believe that separate criteria for meal-type products are needed but is revising the definition of a "meal-type product" to establish separate definitions for meal products and main dish products for the purpose of regulating claims (these products will still be referred to collectively as "meal-type products" in this preamble).

246. The majority of comments supported separate criteria for meal-type products as compared to individual foods. Two comments, however, stated that FDA should not create separate nutrient content claim definitions for these foods because meal-type products contain no more food or calories than ordinary foods. One of these comments also stated that FDA's proposal arbitrarily sets up a double standard for nutrient content claims in the marketplace. Alternatively, these comments recommended that the criteria for claims such as "low," "source," and "high" on all food products be based on specified nutrient levels per serving and per reference amount, or specified nutrient levels per 100 calories (or per 100 nonfat calories in the case of sodium and cholesterol). For example, for "low fat," one comment suggested that the criteria be no more than 3 g of fat per serving and per reference amount, or no more than 20 percent of calories from fat. For "low cholesterol," the comment suggested that the criteria be no more than 20 mg of cholesterol per serving and per reference amount, or no more than 15 mg per 100 nonfat calories. The comments stated that the alternative criteria would allow foods that are high in calories to make "low" claims for certain nutrients.

The agency acknowledges the complexity in defining a meal-type product for the purpose of regulating claims and agrees that, with any such definition, there is the potential for certain requirements that may result in similar food products having different bases for claims. The agency carefully considered the suggestion that it establish a single set of criteria for all types of food products but concluded that it was not appropriate to do so. This approach would generally result in the application of the per 100 calorie criterion rather than the per serving and per reference amount criterion to meal-type products, because the former would permit products to contain greater amounts of nutrients per serving. For example, a 400 calorie product could have as much as 9 g of fat if "low fat" was defined as not more than 20 percent of calories from fat. However, the agency concludes that the primary criterion for all "low" definitions for nutrients should be based on nutrient levels per 100 g as proposed, rather than on specified nutrient levels per 100 calories (or per 100 nonfat calories). The agency concludes that it is inappropriate to have as a primary basis for "low" claim a criterion that considers total fat levels in a food in addition to the levels of another nutrient that is the subject of the claim. For example, given the suggested criterion of no more than 15 mg of cholesterol per 100 nonfat calories, a 400 calorie dinner with 40 percent of the calories contributed by total fat could have only 36 mg of cholesterol, whereas another dinner with the same number of calories but only 20 percent of the calories contributed by total fat could have as much as 48 mg of cholesterol. The agency further believes that it would confuse consumers to have a criterion that links the amount of total fat in a product to the product's ability to make a "low" claim about another nutrient such as cholesterol or sodium. Accordingly, the agency is not persuaded to adopt this alternative set of criteria for meal-type products and individual foods.

However as discussed in comment 52 of this document, the agency has concluded that it is appropriate to have for "low" claims for fat and saturated fat, a second criterion that considers their caloric contribution to a meal-type product.

247. Some industry comments supported the proposed definition of a meal-type product, whereas others stated that the definition was too broad with respect to the minimum requirement of either 200 calories or 6 ounces and with respect to the inclusion of main dishes, entrees, and pizzas in this category.

One comment said that the 200 calorie level is an insufficient amount of food for a "meal-type product," even as part of a reducing diet, and that those who purchase such food could easily be misled that such foods will provide them with a filling, balanced meal. Other comments maintained that 200 calorie food items are meal segments, not meal replacers, for the vast majority of consumers and should not be included in a definition for a "meal-type product." Some comments recommended that a minimum of 500 calories be used. These comments maintained that a 500 calorie minimum would be a more accurate reflection of the calorie content of an individual's meal. They stated that foods that contain this higher calorie level still comprise less than one-third of the calories consumed by the segment of the population that consumes the fewest calories, and that this level would comprise about one-fourth of the typical consumer's daily caloric intake. One comment suggested that 350 calories be the minimum level, while another comment suggested that 300 calories be the minimum requirement.

These comments acknowledged, however, that a minimum calorie requirement, whether at 200 calories or 500 calories, could result in similar products slightly below or above these levels having very different outcomes with respect to claims. For example, it was stated that with FDA's proposal, a 200 calorie serving of soup could qualify for a "low fat" claim with 6 g of fat, whereas a 190 calorie soup that contained only 4 to 5 g of fat could not.

The agency acknowledges that the 200 calorie level is about equal to or less than one-tenth of the National Research Council's recommended energy allowances for adults (Ref. 28). The agency further agrees with the comments that a number of individual foods would meet this minimum caloric level. In addition, the agency has noted that, with this proposed minimum caloric level, it would be possible for meal-type products below the 300 calorie range that met the 3 g per 100-g criterion for "low fat" to contain more than 30 percent of calories from fat. This result would not occur if the agency adopted a higher minimum caloric level, such as 500 calories. However, this higher minimum caloric level would exclude a number of meal products that for some consumers are

appropriate for weight maintenance and for other consumers are appropriate for intended weight reduction.

The agency also considered whether to adopt the suggested levels of 350 or 500 calories. However, as pointed out in the comments, using a 350 or 500 calorie minimum requirement would not eliminate the problem of similar products having different outcomes for claims.

For these reasons, the agency is persuaded that a minimum calorie requirement is not an appropriate basis on which to define meal-type products, and that another product type category that would make the meal-type product category less broad is necessary. Accordingly, the agency has dropped a minimum calorie requirement from the definition of a "meal product" in § 101.13(l) and is not including one in the definition of a "main dish product" in § 101.13(m) (discussed below).

248. A few comments addressed the proposed requirement in the definition of a meal-type product that the food be represented as, or in a form commonly understood to be, a breakfast, lunch, dinner, meal, main dish, entree, or pizza. These comments stated that there needed to be a clear distinction in the regulations of the types of foods that are eligible to bear claims as "meal products." One comment raised the question of whether foods such as a danish, fruit sweetened yogurt, or a bowl of cereal could be a breakfast entree, or whether pasta, beans in tomato sauce, soup, or a baked potato with topping could be a lunch or dinner entree. Another comment suggested that entrees including pizza have a different basis for claims than meal products, and that this basis should be the reference amounts for mixed dishes.

These comments further demonstrate that the proposed category of a meal-type product is too broad for the purpose of regulating claims, and that an additional category needs to be established. The types of products that the agency intended to include in meal-type products, besides meal products, included foods that are often represented as main dish products and, thus, represent only a portion of the complete meal. Based on the comments, however, the agency is persuaded that it would be inappropriate to apply the same criteria to a product that represents a meal and to a product that represents a significant portion of a meal. Thus, the agency is persuaded that separate criteria for claims should be established for meal products and for main dish products. Accordingly, FDA is revising proposed § 101.13(l) to define a "meal product" and is defining a "main dish product" in § 101.13(m). The requirements in these definitions are discussed in comments 249, 251, and 252 of this document.

249. Some comments agreed with the 6-ounce minimum requirement, while other comments stated that this minimum requirement was too low. One of the latter comments stated that this minimum would be met by such products as canned soups, pastas, beverages, and most containers of yogurt, and that even the skimpiest meals or entrees weigh closer to 10 ounces. Another comment suggested that the minimum weight requirement should be at least 7 ounces per serving.

The agency acknowledges that the minimum 6-ounce weight is low for many meal products, even though it is within the range of main dish products that are now marketed. USDA has required that frozen products labeled as "dinner" or "supper" weigh at least 10 ounces (Ref. 29). Thus, FDA concludes that it is appropriate to require that products represented as meals weigh, at a minimum, 10 ounces to be consistent with USDA. Further, FDA believes that products weighing between 6 and 10 ounces which were defined as meal-type products in the proposal, generally are marketed as entrees and side dishes. Thus, the agency finds that because of their contribution to the overall diet and because of consumer expectations, it is appropriate to require that main dishes weigh at least 6 ounces.

Accordingly, for the purpose of making a claim, FDA is defining a "meal product" in § 101.13(l)(1) as a food that makes a major contribution to the total diet by weighing at least 10 ounces per labeled serving. Likewise, for the purpose of making a claim, FDA is defining a "main dish" in § 101.13(m)(1) as a food that makes a major contribution to a complete meal by weighing at least 6 ounces per labeled serving.

Consistent with these provisions, the agency is also revising proposed § 101.13(l)(3) (redesignated as new § 101.13(l)(2)) to provide that to qualify as a "meal product" the food be represented as or be in a form commonly understood to be, a breakfast, lunch, dinner, or meal. The agency is retaining the provision that such representations may be made either by statements, photographs, or vignettes. The agency is aware that some products currently available in the marketplace are represented as meals but weigh somewhat less that 10 ounces. Should these products make nutrient content claims, the agency advises that such claims should comply with the provisions established for main dish products in § 101.13(m)(2). This will ensure the application of appropriate disclosure levels for such products (see comment 273 of this document).

The agency is requiring in new § 101.13(m)(2) that to qualify as a "main dish" the food be represented as, or be in a form commonly understood to be, a main dish (e.g., not a beverage or a dessert). The agency has cited beverages and desserts in this provision because they are not commonly understood to be a main dish and thus are appropriately excluded. However, foods that may be marketed as main dishes in the future are not categorically excluded from being main dishes but will be considered by the agency on a case-by-case basis. 250. A few comments objected to use of the term "container" in the agency's proposed requirement that a meal-type product weigh at least 6 ounces per serving (container). The comments maintained that the term "container" effectively equates meal-type products with single-serving containers, whereas meal-type products are packaged in both single-serve and multiple-serve containers. One comment stated that it makes no sense to have a provision that would allow a product in a single-serve container to make a claim but not an identical product packaged differently.

The agency agrees with the comments that the term "container" may inappropriately equate meal-type products with single-serving containers. This was not the intent of the proposal. Therefore, the agency is deleting the term "container" from new § 101.13(l)(1)(i) and (m)(1)(i).

251. Some comments suggested revisions to FDA's proposed requirement that a meal-type product contain ingredients from two or more of four food groups. Several comments supported a requirement that the product contain at least 3 different foods. A few comments suggested that a specified number of food servings be required rather than ingredients, because, according to one comment, the requirement for two "ingredients," irrespective of their amount, was meaningless. Another comment suggested that a serving be at least one-half the reference amount.

Given the decision to provide separate criteria for meals and main dishes, the agency is persuaded that a meal product should contain at least three different foods from at least two of four food groups and is revising new § 101.13(l)(1)(ii) accordingly. Dietary guidance recommends that Americans assemble daily diets by selecting a variety of foods from the various food groups. Because meals are large

segments of the diet, it is appropriate to expect that meals would include at least three different foods from at least two food groups. Main dishes, on the other hand, are combined with other foods to create a meal and thus may contain as few as two foods from two food groups. Therefore, the agency is requiring in § 101.13(m)(1)(ii) that a main dish product contain at least two different foods from two of four food groups.

The agency also agrees that the requirement for a specified number of foods may be problematic without a minimum weight requirement. FDA considered whether there should be a requirement based on a minimum percentage of a reference amount such as 50 percent. The agency has concluded, however, that such a requirement would be difficult to implement and may not in the end be meaningful. Different reference amounts could be applied to a food in a meal-type product depending on how the food was prepared (e.g., with or without sauce), how it was used in a product (e.g., as a major component or a garnish), or whether the food is subject to a mixed dish reference amount.

Therefore, the agency has developed an alternative approach that derives from the comment that suggested that a serving be at least one-half of the reference amount, the aim of which would be to prevent an ingredient that is present in small amounts from counting toward the requirement that a meal product and a main dish product contain a minimum number of foods from at least two food groups. Thus, FDA has revised new § 101.13(l)(1)(ii) and (m)(1)(ii) to require that a meal product contain not less than 40 g each of the minimum number of different foods.

The 40 g minimum requirement is about one-half of the reference amount for fish, shellfish, or meat/poultry substitutes without sauce (reference amount is 85 g) and is about one-half of the reference amount for drained vegetables (reference amount is 85 g). The 40 g amount is also within the middle range when comparing one-half the reference amount of foods with large reference amounts (e.g., 140 g is the reference amount for pasta) to products with small reference amounts (e.g., 30 g is the reference amount for cheese); that is, 40 g is about midway between 15 g and 70 g. The 40 g amount should not be confused with the reference amounts for individual foods.

252. One comment stated that FDA's proposed requirement that a meal-type product contain ingredients from at least two food groups sets up an artificial distinction between foods. The comment asked, for example, would breaded fish, but not unbreaded fish, be considered as consisting of two food groups?

The agency finds that it is inappropriate to include certain types of foods when determining the number of foods from the four food groups because such foods cannot be considered to contribute a recommended serving of food. These type of foods are gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, and garnishes. The agency also believes that it is inappropriate to count sauces toward this requirement because of their high water content. However, a food that is in a sauce and that belongs to one of the four food groups can be counted toward the requirement for the particular food group if the food weighs a minimum of 40 g (e.g., 40 g of tomatoes in tomato sauce). The agency believes that a requirement for a minimum amount of a food in a meal or main dish product should be determined by the weight of the food and not by the way in which the food is presented in the product (i.e., an ingredient in a sauce).

Accordingly, the agency is providing for a meal product in § 101.13(l)(1)(ii)(E) and main dish product in § 101.13(m)(1)(ii)(E) that gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, and garnishes can not be counted as foods to meet the requirement for a specified number of foods from at least two food groups. This provision also excludes sauces except for foods in the four food groups that are in the sauces.

253. One comment suggested that there be separate food groups for fruits and for vegetables. It pointed out that such a separation would be consistent with the food groups recommended in current dietary guidelines.

FDA endorses the five food groups recommended in current dietary guidelines. For this particular regulatory application, however, the agency believes fruits and vegetables should not be treated as separate groups. While the agency acknowledges the important and distinct contributions each makes to the diet, FDA is concerned that a combination of a fruit and a vegetable could be classified as a main dish. The nutritional contribution of each, while not the same, is more similar than any other two food groups. These products would contribute only a limited number of calories and would fail to contribute as diverse a range of nutrients and food components as a combination of two other food groups.

2. Definition of "free" for meal-type products

In the general principles proposal (56 FR 60421 at 60473), FDA proposed definitions of the term "free" to describe the content of sugar and sodium in a food. The agency also proposed in the fat/cholesterol proposal (56 FR 60478) definitions of the term "free" to describe the content of fat and cholesterol in a food. These proposed definitions applied both to individual foods and to meal-type products, and for meal-type products, were based on specified nutrient levels per reference amount and per labeled serving. The rationale proposed for the definition of "free" was based on the finding that this nutrient content claim is an absolute term implying absence of a nutrient. The agency further stated that the definition considered the level of a nutrient that is at the reliable limit of detection and that is dietetically trivial or physiologically inconsequential.

254. One comment supported the use of the same criteria for "free" claims for individual foods and for meal-type products. Another comment suggested that all nutrient content claims for meal-type products should be based on nutrient levels per 100 g of food.

The agency continues to believe, as it stated in the general principles proposal (56 FR 60421 at 60433), that the term "free" is an absolute term implying absence of a nutrient in a serving of a food, whether it is an individual food or a meal-type product, not absence of a nutrient in a specified weight of food such as per 100 g. Therefore, the agency rejects the suggestion that it base "free" claims for meal-type products on nutrient levels per 100 g.

255. One comment stated that the proposed requirement of less than 2 mg per serving in the definition of "cholesterol free" for meal-type products is unreasonable. This comment stated that 2 mg of cholesterol in a 9-ounce serving is less than 0.008 percent, whereas in a small serving product such as crackers, the same amount of cholesterol represents 0.015 percent. This comment suggested raising the cholesterol free level for meal-type products to 5 mg per serving. The comment stated that at the 5 mg level, 60 servings of a meal-type product would be required to be consumed to meet the DRV and thus would result in ample protection for the consumer.

This comment has not convinced the agency to raise the level for "cholesterol free" for meals and main dishes. The agency acknowledges that 2 mg of cholesterol in a meal/main dish product will be a much smaller percentage by

weight than a small serving size product but points out that these percentage differences also occur with individual foods that vary considerably in serving size weight. The agency continues to believe that the same cholesterol level for the definition of "free" should be used for meal-type products as for individual foods, because it is defining "free" as an absolute term implying absence of a nutrient in a serving of food, irrespective of the serving size of the food in question. Accordingly, the agency has retained the proposed cholesterol levels in the final rule, including the disclosure statement allowed for ingredients commonly understood to contain the nutrient in question.

3. Definition of "low" and "very low" for meal-type products

a. Basis for claims

In the general principles proposal, FDA proposed that the definition of "low" and "very low," when describing the content of single nutrients in meal-type products, be based on nutrient levels per 100 g. The proposal stated that this approach would alleviate the need to accommodate the variations in serving size for the various types of meals. The agency proposed that the nutrient levels per 100 g, except for calories, be the same levels for meal-type products as for individual foods. As part of the rationale for proposing specific levels of nutrients for the "low" definition of individual foods (56 FR 60421 at 60440), the agency considered that the "low" definition should be sufficiently restrictive to allow consumers to select a variety of foods, including some that are "low" in a nutrient and some that are not "low," and still meet current dietary recommendations.

256. Many comments supported using amounts of nutrients per 100 g as the basis for regulating "low" and "very low" claims on meal-type products. One of these comments stated that this is the only workable approach because of the wide variety of products and the range in net weights encompassed within meal-type products. However, another comment stated that meal-type foods should have to meet the same criteria (i.e., a per serving rather than per 100 g basis for claims) as single item foods to qualify for nutrient content claim. An additional comment expressed the view that an approach based only on nutrient amounts per 100 g would allow many claims on meal-type products that would be prohibited on individual foods. This comment and two other comments suggested, for example, that FDA consider requiring that a meal-type product obtain no more than a certain percentage of its calories from fat (e.g., 20 percent) in order to qualify for a "low fat" claim. Two other comments supported upper limits for "low calorie" claims, with one comment recommending an upper limit of 300 calories and another recommending an upper limit of 350 calories.

FDA agrees with the majority of comments that support the use of per 100 g as the basis for regulating "low" and "very low" claims on meal-type products. FDA does not agree with the comment that meal-type products should have to meet the same criteria as single foods because meal/main dish products are generally a larger part of the total diet than single foods.

The agency has not been persuaded by these comments that there is a need or an appropriate basis for establishing upper limits for absolute amounts of calories or nutrients per serving when a claim for "low" is made. Rather, the agency believes that providing for the level of the nutrient per 100 g of food is generally sufficient to prevent misleading claims on meal-type products. While FDA has usually assumed that food consumption patterns generally reflect 3 meals per day and a snack (with about 25 percent of daily intake for each), the agency notes that even if a meal-type products weighs as much as 400 g, the absolute amount of a nutrient or calories consumed would be relatively low and thus consistent with the claim. For example, a 400 g meal could contain no more than 12 g of fat, which is only about one-fifth of the DRV.

Moreover, meal size will increase and decrease as a function of the number of servings of individual foods in the meal-type product. Larger persons in need of more calories and greater amounts of nutrients are expected to select a meal comprised of more servings of an individual food or of more servings of different foods (hence a larger meal) than would be expected to be selected by a smaller person. Thus, a basis for determining an absolute amount of a nutrient that would preclude the product from being considered "low" in a particular nutrient is problematic.

However, FDA is persuaded by comments that it is appropriate to require that meal-type products contain no more than a certain percentage of calories from fat. The agency recognizes that it is possible for certain meal-type products to contain no more than 3 g of fat per 100 g of product and still derive more than 30 percent of their calories from fat. FDA is concerned that claims be consistent with dietary guidance. Current recommendations are that 30 percent or less of calories from fat and less than 10 percent of calories from saturated fat. These recommendations are targeted toward the total diet, and the agency has stated in this document several times that they should not be applied to individual foods. However, the agency believes that a meal-type product makes a significant contribution to the diet and, thus, finds that it is appropriate to apply these total diet-oriented recommendations to meal-type products. By their nature, meal-type products are not single foods but combinations of foods intended to contribute a larger amount to the diet than a single food.

FDA has therefore concluded that "low fat" or "low saturated fat" claims on meal-type products that have more than 30 percent of calories from fat or 10 percent or more of calories from saturated fat are misleading to consumers and inconsistent with dietary guidance. Accordingly, the agency is providing in new § 101.62(b)(3)(i) that meal-type products that contain 3 g or less of fat per 100 g and derive 30 percent or fewer of their calories from fat may bear a "low fat" claim. Likewise, the agency is providing in new § 101.62(c)(3)(i) that meal-type products that contain 1 g or less of saturated fat per 100 g and derive less than 10 percent of their calories from saturated fat may bear a "low saturated fat" claim.

b. "Low calorie"

257. In the general principles proposal, FDA requested comments on whether the criterion of 105 calories per 100 g of product for "low calorie" meal-type products was too low. A few comments from industry recommended that the level be raised from 105 calories per 100 g to 120 calories per 100 g. One of these comments was submitted by the organization that had previously suggested the 105 calories that became the level in FDA's proposal. At least one comment suggested that FDA not establish an upper limit for calories in a serving. However, a foreign government suggested an upper limit of 300 calories, and a well-known health organization suggested 350 calories as the upper limit. Another comment maintained that the proposed criterion of 105 calories per 100 g was arbitrary and did not bear any relation to the definition of "low calorie" for individual foods. This comment further maintained that a weight-based criterion was not necessarily relevant, that a "low calorie meal" was a contradiction in terms, and that consumers did not need this provision because of the availability

of comparative claims. An additional comment recommended that the number of calories be disclosed next to the nutrient content claim for meal-type products.

First, FDA disagrees with the comment that the agency should not provide a separate definition for "low calorie" for meal-type products because of the availability of comparative claims. Obesity is a major public health concern and the agency has long acknowledged that the availability and marketing of low calorie food products helps to promote weight control among American consumers. The agency has made provisions for absolute claims (such as "low") as well as comparative claims (such as "reduced") on individual foods, and, given that meal-type products are combinations of individual foods, finds no reason why such claims on meal-type products would not be helpful to consumers.

Secondly, as discussed in response to the previous comment, the agency has established no upper limit for nutrient or calorie levels in meal-type products making nutrient content claims, but instead believes that the amount per 100 g of food provides sufficient control so that claims are not misleading to consumers and are consistent with current dietary recommendations.

The agency acknowledged in its general principles proposal (56 FR 60421 at 60455) that establishing a definition for "low calorie" meal-type products was problematic but accepted the suggestion put forth in a comment that 105 calories per 100 g of food was reasonable and consistent with market practices. FDA specifically asked for comments on this issue. Little support was expressed for this level, while several comments suggested that the level be raised from 105 calories to 120 calories per 100 g.

FDA finds that it is appropriate to increase the definition to this level. The agency notes that 120 calories per 100 g of food is low enough to allow consumers to select different types of meal-type products during the day, including some that are "low" in calories and some that are not "low," and still consume calories at a level consistent with weight control goals. For example, even if a meal product weighs 400 g it would be limited to no more than 480 calories. This calorie amount is less than one-fourth of the average recommended energy allowance for most adult age/sex groups (Ref. 28). Accordingly, FDA is revising new § 101.60(b)(3)(i) to provide that to qualify for a "low calorie" claim, a main dish or a meal product contain 120 calories or less per 100 g.

c. "Low sodium"

258. Several industry comments supported raising the level of sodium that would justify a "low sodium" claim on meal-type products to 200 mg per 100 g. One comment stated that the 140 mg per 100 g level is more appropriate for medically supervised therapeutic diets to manage serious health conditions than for the general population or for many individuals on restricted diets. The comment further stated that the 140 mg per 100 g level would inhibit, if not effectively preclude, the marketing of meal-type products to persons interested in restricting sodium intake. Another comment stated that they knew of no products that would qualify for "low sodium" at the 140 mg per 100 g level, while other comments maintained that products below the 140 mg per 100 g level would have an unacceptable flavor profile. Still another comment stated that for a 10 ounce product, the 200 mg per 100 g level would represent one-fourth of the sodium DRV. The comment further stated that this definition for "low sodium" is reasonable because it provides sufficient room for consumption of other sodium-containing foods during the day while remaining within the DRV. Additional comments stated that current USDA guidelines for low sodium meals require that sodium content be no more than 560 mg for a four component dinner (minimum weight 10 ounces), which is a level to which consumers have grown accustomed.

The agency is not persuaded that the 140 mg of sodium per 100 g level for meal-type products should be raised, or that the level is too restrictive for products marketed to the general population. This level is consistent with the level for individual foods. Further, FDA believes that meal products labeled "low" should be low enough in a nutrient to allow a consumer to eat several such products and still have a significant reduction in total daily intake in the particular nutrient when compared to the DRV for that particular nutrient. The agency notes that with the 140 mg/100 g level, a meal product that weighs as much as 400 g could have no more than 560 mg of sodium. However, with the higher suggested level of 200 mg/100 g, a meal product at this weight could have as much as 800 mg of sodium, which is one-third of the sodium DRV (i.e., 2,400 mg). This level would be too high for a low sodium claim on a meal product, given the assumption of a daily food consumption pattern that includes three meals and a snack (with about 25 percent of daily intake contributed by each).

The agency acknowledges that many products now on the market would not qualify for "low sodium" with the criterion of 140 mg per 100 g but does not believe that currently marketed foods should be the driving force for a "low" definition. Accordingly, FDA has retained the 140 mg per 100 g level in new § 101.61(b)(5)(i).

d. Other sodium claims

259. One comment recommended that in addition to "low sodium," "moderate sodium" be defined as a nutrient content claim on meal-type products for levels of sodium higher than "low." This term was recommended to allow consumers interested in modifying sodium intake a wider choice of products.

The agency believes that the existing nutrient content claims "low sodium" and "very low sodium" are adequate to provide information about sodium content to consumers wishing to limit their sodium intake. The comments did not provide any support for an additional term. The agency believes, for reasons discussed above, that the number of nutrient content claims should be limited. The additional term suggested in the comment is likely to confuse the consumer and possibly reduce the effectiveness of the other nutrient content claims for sodium. Furthermore, consumers interested in modifying their sodium intake will be able to refer to the nutrition label to determine if the product meets their personal dietary needs. Accordingly, the agency is not defining "moderate sodium" for meal-type products.

e. "Low fat"

260. Two industry comments supported defining "low fat" for meal-type products as no more than 3.5 g per 100 g instead of no more than 3 g per 100 g as FDA proposed. One of these comments stated that most meal-type products contain meat or poultry, and in order to use these ingredients, even lean cuts, the fat content will often be greater than 3 g per 100 g because of the meat requirements. The 3.5 g level, it was argued, would provide consumers with a greater number and variety of products available to them.

As it stated in the general principles proposal (56 FR 60421 at 60455), the agency believes that the fat level for meal products and main dish products should be consistent with the level for individual foods. Such consistency will minimize consumer confusion and assist consumers and health professionals in recalling and using

these definitions. The agency acknowledges that a number of meal-type products may not be able to make "low fat" claims. However, the term "lean" will be available to these products. FDA has retained the proposed level of 3 g or less per 100 g for a "low fat" claim in new § 101.62(b)(3)(i).

f. "Low saturated fat"

261. A few comments supported the proposed "low saturated fat" definition of no more than 1 g of saturated fat per 100 g for a meal-type product. Two comments, however, recommended that "low saturated fat" for all food products be defined as no more than 1 g of saturated fat per serving or no more than 7 percent calories from saturated fat.

As discussed in comment 256 of this document, the agency believes that nutrient amounts per 100 g should be the basis for regulating "low" claims on meal-type products. However, as discussed in comment 256 of this document, the agency is establishing an additional criterion in new § 101.62(c)(3)(i) that a meal-type product derive less than 10 percent of its calories from saturated fat in order to bear a "low saturated fat" claim.

g. "Low cholesterol"

262. Two comments recommended that FDA define "low cholesterol" for all meal-type products as no more than 20 mg of cholesterol per serving or no more than 15 mg cholesterol per 100 nonfat calories.

The agency is not persuaded to adopt this alternative criterion because, as previously stated, it believes that it is inappropriate and would confuse consumers to have a primary criterion for a "low" claim that links the amount of total fat in a food to the food's ability to make a "low" claim for another nutrient. However, the agency is including in the "low cholesterol" definition of meal-type products in new § 101.62(d)(3) a criterion that requires that a meal product contain no more than 2 g of saturated fat per 100 g. The agency has established this additional criterion under the authority in the 1990 amendments to establish a saturated fat limit with cholesterol claims. Section 403(r)(2)(A)(vi) of the act states that a nutrient content claim "may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food." As discussed above in response to comment 116 of this document, the agency believes that a saturated fat level that exceeds 2 g would make a cholesterol claim misleading because consumer expectations would not be met if such a food is not consistent with the recommendations of the health and dietary guidelines to lower blood cholesterol levels by limiting cholesterol and saturated fat intake. Thus, with respect to "low cholesterol" claims on meal-type products, the agency concludes that consumer expectations regarding blood cholesterol levels are met as long as the food contains 20 mg or less of cholesterol and 2 g or less of saturated fat per 100 g.

4. Definition of "percent fat free" for meal-type products

263. A few comments supported the proposed requirement that a meal-type product meet the "low fat" definition to make a "percent fat free" claim, whereas another comment stated that "percent fat free" claims can be particularly deceptive on meal-type products because many of these products, such as frozen dinners, have a high moisture content. The latter comment further stated that because moisture contributes significantly to a product's weight, foods with a high moisture content can make higher (more impressive) "percent fat free" claims than foods with lower moisture levels. The comment pointed out that a label on an 18 ounce frozen dinner containing 15 g of fat could make a "97 percent fat free" claim.

The agency is not persuaded by the latter comment that a "percent fat free" claim on an 18-ounce dinner that meets the "low fat" definition would be deceptive. Regardless of the total weight of the dinner, it still contains 3 g or less fat per 100 g, is a "low fat" meal-type product, and would assist consumers in limiting their fat intake. Thus, the agency finds that a percent fat free claim on meal-type products that meet the "low fat" definition, regardless of the serving size of the product, is not deceptive and can be useful in assisting consumers in meeting their dietary goals.

5. Definition of "high" and "good source"

In the general principles proposal (56 FR 60421 at 60457), FDA proposed that for meal-type products, the nutrient levels for "high" and "good source" be the same percentages of the DRV or RDI as for individual foods, but that the basis for these nutrient levels be per 100 g, not per serving. The agency proposed in § 101.54(b)(2) that "high" be defined as 20 percent or more of the DRV or RDI per 100 g of product, and in § 101.54(c)(2) that "good source" be defined as 10 to 19 percent of the RDI or DRV per 100 g of product.

While one comment supported the use of a per 100 g basis for the definitions of "high" and "good source," a few comments opposed this basis. For the reasons cited below, the latter comments have persuaded the agency to reconsider the basis for "high" and "good source" claims for meal products and for main dish products.

264. One comment recommended that FDA base its definition of "high" and "good source" for all foods including meal-type products on a criterion that considers the nutrient/caloric contribution of a food. This comment proposed that "good source" be defined as at least 10 percent of the DRV or RDI per serving and at least 10 percent of the DRV per 200 calories. Similarly, "high" would be defined as at least 20 percent of the DRV or RDI per serving and at least 20 percent of the DRV or RDI per 200 calories.

The agency rejects this alternative because it could result in plain vegetable products being able to make a claim for "high in vitamin C," but a similar product with these vegetables in a sauce not being able to make this claim. The additional calories contributed by the sauce would cause the product not to meet the minimum DRV level per 200 calories. Such an approach to defining these claims would create inconsistencies in the use of the claims and could cause consumer confusion.

265. Several comments stated that the per 100 g basis would result in inappropriately high nutrient levels for meal-type products eligible to make "high" or "good source" claims. For example, it was stated that to make a "high in fiber" or "high in vitamin C" claim, a 10-ounce frozen dinner would be required to contain over one-half of the DRV or RDI. The comments stated that products that contain a smaller percent of the DRV or RDI still may be considered excellent nutrient sources. Alternatively, one comment recommended that the basis for the definitions of "high" and "good source" for meal-type products be per labeled serving rather than per 100 g of food.

FDA is persuaded, for the reasons given in the comments, that the per 100 g basis would result in inappropriately high nutrient levels for meal-type products. The per 100 g basis would require that a 10-ounce meal-type product have at least 30 percent of the DRV to be labeled a "good source" of a nutrient, or at least 60 percent of the DRV or RDI to be labeled "high" in a nutrient. The agency acknowledges that some meal-type products on the market meet these definitions, but it is

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concerned that the proposed levels may encourage increased fortification of these products, with little benefit to the consumer.

Furthermore, the agency is not persuaded to adopt the suggested alternative to define "good source" and "high" using the same percentage levels as individual foods per labeled serving because it would be misleading to state on a label that a three component meal is "high" in a nutrient, when each of the three components may only have 6 percent of the DRV or RDI.

Having considered the alternatives for defining "high" and "good source" claims for meal-type products and finding inadequacies in each, FDA now concludes that such claims should not be defined for meal-type products. FDA is, therefore, not providing definitions for "high" and "good source" claims for meal products and main dish products. The agency concludes that it would not be misleading, however, to state on a label that a specific individual food in a meal-type product is a "good source" of a nutrient or is "high" in a nutrient if that food meets the individual food criteria for these claims.

Accordingly, FDA is revising new § 101.54(b)(2) and (c)(2) to allow "high" and "good source" claims for a food contained in the meal product or main dish product provided that the food meets the individual food criteria for these claims and provided that this food is identified with the use of the nutrient content claim (e.g., "The serving of broccoli in this product is high in vitamin C;" "The serving of sweet potatoes in this product is a good source of dietary fiber").

6. Relative claims for meal-type products

FDA also proposed definitions for "less" and "fewer," "more," "reduced," and "light" for individual foods in the general principles proposal (56 FR 60421 at 60456). With the exception of the terms "reduced" and "light," FDA proposed that the provisions for individual foods apply to meal-type-products.

Some of the comments, as discussed below, have persuaded the agency to change the basis for "less," "fewer," and "more" claims and to provide for "reduced" and "light" claims on meal products and main dish products.

a. "Less," "fewer," and "more"

FDA proposed requirements for "less" and "fewer" claims on meal-type products that were consistent with the requirements for these claims on individual foods. The proposed provisions included a requirement that the product have a minimum percentage and absolute reduction of a nutrient per labeled serving size compared with the reference food that it resembles and for which it substitutes. For "more" claims, the proposed requirements included a provision that the product contain at least 10 percent more of the DRV or RDI for a nutrient per labeled serving than the reference food that it resembles and for which it substitutes.

However, information provided in comments has persuaded the agency to revise the proposed requirements for the percent nutrient reduction and absolute nutrient reduction for the use of the comparative claims "less" and "fewer" on meal-type products. The agency has also revised new § 101.13(j)(1) with regard to reference foods, as previously discussed in this document. This revision applies to meal products and main dish products as well as to individual foods.

266. One comment suggested that the criteria for comparative claims on meal-type products should be based on a percentage difference in a nutrient per 100 g of food compared with per 100 g of the reference food. This comment pointed out that meal-type products include a wide variety of types of foods and a range of serving sizes. It further stated that claims that compare dissimilar products, such as a two component product to a three component product or spaghetti and tomato sauce to macaroni and cheese, would only lead to consumer confusion and misinterpretation of the claim.

The agency agrees that both the meal and main dish categories include products that vary substantially in the number of foods, type of foods, and size of the labeled serving, and that claims that compare dissimilar products on a per labeled serving basis have the potential to confuse consumers. For example, the only difference between two products that may bear a comparative claim under the proposed criteria may be the amount of the food components. The agency has also considered that comparative claims based on FDA's proposed labeled serving size may encourage manufacturer manipulation of serving size to make these comparative claims, given the fact that the labeled serving size for many of these products is the single serve container rather that the reference amount.

Thus, the agency finds merit in the comment's suggestion to base a comparative claim for meal-type products on a per 100-g criterion rather than per labeled serving size. A per 100 g basis reflects the composition of the product based on an absolute amount and not a serving size that can vary from one product to another. Moreover, a per 100-g criterion is likely to not encourage manipulation of serving size because the serving size will have no bearing on whether the food qualifies to bear the claim. Thus, a claim will result in more meaningful comparisons of dissimilar products.

Accordingly, the agency is establishing a per 100 g basis for the use of these comparative terms on meal/main dish products in new §§ 101.54(e)(2)(i), 101.60(b)(5) and (c)(5), 101.61(b)(7), 101.62(b)(5), (c)(5), and (d)(5). Like other relative claims, a statement that identifies the reference food and the percentage change in the nutrient must be declared in immediate proximity to the most prominent claim (e.g., Contains 33 percent less fat per ounce than Brand Y meal product.). Moreover, quantitative information comparing the level of the nutrient that is the subject of the claim in the labeled food to the level of that nutrient in the reference food must be declared either adjacent to the most prominent claim or on the information panel (e.g., Fat content has been reduced from 2.5 g per ounce to 1.7 g per ounce.). In addition, consistent with the use of relative claims on individual foods, meal or main dish products may not bear comparative claims if the level of the nutrient that is the subject of the claim in the reference foods meets the definition for a "low" claim for such nutrient.

267. One comment contended that the agency's published correction (57 FR 8189, March 6, 1992) of the minimum absolute reduction criterion in the definition of "fewer calories" from "more than 40 calories" to "more than 105 calories" must be withdrawn from this rulemaking because it changes the substance of the proposal, and the agency is not permitted to make a substantive proposal in a notice of correction.

The agency disagrees with the comment. In proposing the absolute minimum reduction criterion for making comparative claims, the agency concluded that the amount of nutrient in the food bearing the claim should reflect a nutritionally significant reduction in the amount of that nutrient when compared to the reference food. The agency recognized, however, that no guidelines or definitions were available to determine the amount of reduction in a nutrient that would be nutritionally significant. Thus, the agency tentatively concluded that such a criterion should be based on the amount specified in the definition of "low" for the nutrient in question. The

agency applied this rationale to individual foods as well as to meal type products. The amount specified in the proposed definition of "low calorie" for meal-type products was 105 calories per serving. Thus, it was clear that the intent of the agency was to propose an absolute minimum reduction criterion for comparative claims for decreased levels of calories for meal-type products as "more than 105 calories." Therefore, the notice of correction did not make a substantive change in the proposal but only an editorial change.

b. "Reduced"

FDA proposed not to provide for the use of "reduced" claims on meal-type products because it was of the opinion that there was an insufficient basis on which to establish a reference criterion. In the general principles proposal (56 FR 60421 at 60456), the agency stated that meal-type products may have the same basic ingredient, e.g., fish, but may differ in their preparation and in added ingredients. Consequently, the agency expressed concern that such a provision could result in inappropriate comparisons of dissimilar products.

268. One comment agreed that FDA should not allow "reduced" as a nutrient content claim for meal-type products, whereas a few comments recommended that the term be permitted. One of the latter comments recommended that a single set of criteria for all comparative terms be applied to meal-type products. Thus, the same definitions would be used for "reduced," "less," "fewer," and "light." Another comment was specifically concerned that there was no definition for "reduced fat" and "reduced cholesterol" meal-type products. An additional comment stated that manufacturers should be permitted to make a "reduced" claim for a meal-type product if the recipe has been changed to effect a meaningful reduction in a nutrient from the previous recipe, and that to disallow "reduced" on these products would be a serious disincentive for manufacturers to improve their products' nutritional profiles and a disservice to consumers.

In response to these comments, the agency has reconsidered its proposal to disallow "reduced" claims on meal-type products. In another section of this document, the agency has concluded that comparisons using the term "reduced" are only appropriate for use in comparing similar foods, i.e., a reformulated version of a manufacturer's product to the original product (e.g., a lasagna meal-type product that uses low fat ricotta cheese and lean meat may bear the claim "reduced" when the original product uses regular ricotta cheese and meat, whereas a lasagna with low fat ricotta cheese that substitutes spinach for the meat portion could not bear a "reduced" claim but may bear a "less" claim with respect to the original product). This revised position of the agency is consistent with the comment that recommended that "reduced" be allowed on meal-type products that have been reformulated and addresses the agency's earlier concerns, as stated in the general principles proposal (56 FR 60421 at 60456), that "reduced" not be used to compare dissimilar products. Accordingly, the agency is establishing similar provisions for use of the term "reduced" on meal-type products in new §§ 101.60(b)(5) and (c)(5), 101.61(b)(7), 101.62(b)(5), (c)(5), and (d)(5). In addition, the agency advises that if the manufacturer should discontinue the original product used as the basis for the "reduced" claim, the use of the "reduced" claim is limited to a maximum of 6 months after the original product has been removed from the market. As with other comparative claims such as "less," these provisions will require that the comparisons be based on per 100 g of the product, so that "reduced" claims will not be subject to manipulation by reducing the label serving size (e.g., reduced fat—33 percent less fat than our former recipe. Fat content has been lowered from 1.7 to 1.1 g per ounce).

c. "Light"

FDA did not propose a definition for "light" for meal-type products in its general principles proposal because, similar to "reduced" claims, the agency could not identify appropriate reference foods to permit this use of the claim (56 FR 60421 at 60456). However, the agency tentatively concluded that the term "light" could be useful to consumers in selecting products that contain fewer calories than would be expected in a normal meal and asked for comments on the need for, and definition of, this term on meal-type products. The agency stated that it was considering allowing the term "light" to be used if a meal-type product met the criteria for a "low calorie" claim, provided that the product did not contain more than one-fourth of the DRV for fat, saturated fat, sodium, or cholesterol. The agency noted that the proposed "low calorie" level for a 10-ounce meal product (i.e., 105 calories per 100 g or 300 calories per 10 ounces) was nearly one fourth of the calorie intake in a calorie-restricted diet of 1,200 calories a day. FDA further stated that the requirement that these four nutrients not exceed one-fourth of the DRV would ensure that "light" meal-type products would not contribute amounts of these nutrients that would cause total daily intake to exceed recommended values.

269. One comment agreed with FDA's suggested definition of "light" for meal-type products (i.e., a "low calorie" meal-type product that contained no more than 25 percent of the DRV for fat, saturated fat, cholesterol, and sodium). Several comments, however, offered alternative definitions for the use of the term on meal-type products. A few comments suggested that comparative criteria be used to define "light" for meal-type products. One comment recommended that the definition for "light" for meal-type products be consistent with the definition of "light" for other foods. In addition, this comment stated that meal-type products should meet the per 100-g criterion. Other comments recommended that a "light" claim be permitted on meal-type products if a food product meets the definition for a "low nutrient" product, or if the product achieved a reduction of at least 25 percent of calories. One of these comments stated that there may be some instances when there will be an appropriate reference food to which a comparison could be made.

The agency's general approach in defining nutrient content claims is to try to define terms as consistently as possible for all types of food. Thus, if the agency were to adopt comparative criteria for "light" claims for meal-type products, it would be consistent with the criteria that it has established for use of this term on individual foods. However, the agency believes that in the case of meal-type products, there is only a limited group of appropriate reference foods for use with comparative claims. Meal-type products vary greatly in the number and type of ingredients as well as in labeled serving size, and as one comment stated, meal-type products, other than reformulated meal-type products do not truly "substitute" for a definable reference food as do individual foods. The agency is providing for the use of "reduced" on those meal-type products that are reformulated, and it considered whether the term "light" might also be appropriately used on these products. Limiting the use of "light" on meal-type products to only reformulated products would, however, greatly limit the number of such products that could bear this term. The agency has concluded that because of its widespread appeal and its potential usefulness in denoting foods that can assist consumers in maintaining healthy dietary practices,

the use of this term should not be so limited. Accordingly, the agency has rejected the suggestions to use criteria that compare a product with a reference food in defining "light" for meal-type products.

270. A few comments recommended that the term "light" not be permitted on meal-type products. Two of these comments stated that products meeting the criteria for a low calorie meal would already meet consumer expectations, and therefore a "light" claim is unnecessary. Comments further noted that eliminating unnecessary terms and different criteria for the same term would help reduce consumer confusion.

The agency does not agree with the comments that contended that the use of the term "light" is without value on meal-type products. As explained above in the section on "light" claims for individuals foods, the terms "light" and "light in sodium" in comment 185 are terms that have special usefulness as marketing tools for manufacturers to quickly and easily convey to consumers that the product to which the term is attached has been significantly reduced in fat, calories, or sodium. Furthermore, available data and comments show that products labeled as "light" are particularly useful in achieving a diet that is consistent with dietary guidelines.

Thus, the agency has concluded that provisions for the use of the terms "light" and "light in sodium" on meal products and main dish products that require (as discussed below in comment 272 of this document) that meal-type products bearing such claims meet the definition of "low calorie," "low fat," or "low sodium" will assist consumers in implementing dietary recommendations with respect to limiting caloric, fat, and sodium intake. Further, as reflected in the legislative history (136 Congressional Record 16609 (October 24, 1990)), Congress' intent was to permit the use of the comparative claim "light" for entrees, meals, dinners (i.e., meal-type products). Accordingly, the agency rejects the suggestion to not allow this term on meal-type products.

271. One comment contended that FDA's calorie criterion for "light" (i.e., no more than 105 calories per 100 g) was too restrictive. This comment recommended that "light" be allowed on products that contain no more than 450 to 550 calories (or about one-fifth to one-fourth of a 2,350 calorie diet).

FDA has made a number of changes that have had the effect of making this criterion not as restrictive as this comment contended. The agency has modified the criterion, as discussed above, to 120 calories per 100 g and is basing its dietary calculations on a 2,000 calorie diet, as discussed in the document on RDI's and DRV's, published elsewhere in this issue of the Federal Register. Thus, a "light" claim will be allowed on a 300 g (approximately 10 oz) meal if it contains no more that 360 calories.

272. Some of the comments also addressed what nutrients in addition to calories should be limited for a meal-type product to qualify for a "light" claim. One comment suggested that the term "light" as applied to meal-type products should focus on healthfulness rather than low calorie, while another comment stated that the conceptual basis of "light" should be different from "healthy." The latter comment stated that "light" claims should be allowed on meal-type products that are "low calorie," "low fat," or both, with the relevant expressed claim (e.g., "low in calories) appearing in close proximity to the "light" claim. This comment stated that the term has been widely used to enable consumers to select products that contain less fat or fewer calories than would be expected in a normal meal. However, this comment specifically objected to the proposal's suggestion of not allowing more than 25 percent of the DRV for fat, saturated fat, cholesterol, and sodium for a "light" claim to be made. Other comments agreed that there should be no restrictions on these four nutrients, whereas another comment stated that the restrictions should correspond to one-eighth of the DRV, rather than one-fourth, because the maximum permitted level of about 300 calories for a 10 ounce product would correspond to one-eighth of the reference caloric intake of 2,350 calories.

FDA has reconsidered what nutrients should be limited in a meal-type product for it to be permitted to bear a "light" claim. FDA is persuaded by the comment that an unqualified "light" claim on meal/main dish products may appropriately refer to fat, calories, or both. However, as discussed in comment 269, the agency has determined that for meal-type products, "light" should not be limited to reductions in the level of nutrients in existing foods. Rather, the agency is persuaded by the comments that the term should denote those meal-type products in which the level of the nutrients are particularly useful in constructing a diet that is consistent with dietary guidelines, that is, the term should be permitted on foods that are "low in calories," "low in fat," or both. The agency notes that a provision for "light" to refer either to calories or to fat is consistent with the definition of "light" for individual foods that have less than 50 percent of calories from fat. It is also consistent with consumer understanding of this term. FDA is also persuaded, however, that a statement that explains whether "light" is used to mean "low in fat," "low in calories," or both should appear on the principal display panel to clarify the nature of the claim for consumers who may be interested in limiting only calories, only fat, or both (§ 101.56(d)(2)(i)). Furthermore, to ensure that this explanatory statement is sufficiently prominent relative to the "light" claim, FDA concludes that it should be in no less than one-half the type size of the "light" claim (new § 101.56(d)(2)(ii)). This requirement is also consistent with the final rule on "light" claims on individual foods that requires that qualifying statements of sufficient type size must accompany the claim.

Accordingly, FDA is defining "light" for meal products and main dish products in new § 101.56(d). To meet this definition, a meal product or main dish product must meet the definition of "low" for calories, fat, or both (new § 101.56(d)(1)). Further, the agency believes that for consistency with individual foods, it should provide for use of the additional claim "light in sodium" on meal-type products. As with individual foods, the agency has determined that the words "light in sodium" or "lite in sodium" is a single descriptive term, presented in the manner described above, that should all be presented in the same type size, style, color, and prominence. Further, the agency believes that such a "light in sodium" claim for meal-type products should be based on the same criteria as the "light" claim for other nutrients for meal-type products, i.e., it should be based on the "low" definition for the specified nutrient. Accordingly, the agency is defining "light in sodium" for meal-type products in new § 10.56(d)(2). To qualify to make this claim, a meal product or a main dish product must meet the definition of "low" for sodium (new § 101.61(b)(5)(i)). However, because the nutrient that is the subject of the claim is identified as part of the claim i.e., the defined term is "light in sodium," the agency believes that the additional defining label statement (i.e., "low in sodium") that is required with other "light" claims on meal-type products would be redundant. Therefore, the agency is not requiring this additional information to be stated adjacent to the claim.

FDA has also reconsidered whether the definition of "light" should require that fat, saturated fat, cholesterol, and sodium not exceed specified levels in a

product. The agency has no evidence that would suggest that consumers who use "light"roducts expect these products to have restricted levels for all of these nutrients, especially if the "light" claim is clarified by a statement that identifies the nutrients that are the subject of the claim. Further, if the levels of any of these nutrients were sufficiently high in a product, the product will have to bear a disclosure statement referring the consumer to the nutrition information panel that discloses the amount of the nutrient (new § 101.13(h)(2) and (h)(3)). Accordingly, the agency is not including in the definition of "light" restrictions on the amount of saturated fat, cholesterol, or sodium.

7. Definition of "lean" and "extra lean" for meal-type products

As discussed elsewhere in this document, although FDA did not propose to define "lean" or "extra lean" in the general principles proposal, the comments have persuaded the agency to adopt the provisions that the FSIS is establishing for "lean" and "extra lean" for meat and poultry products, including meal-type products, regulated by USDA. FDA is providing for the use of the term "lean" and "extra lean" to describe FDA regulated products comparable to those covered by the FSIS regulation. The criteria that FDA is adopting for "lean" as used to describe meal and main dish products are provided in new § 101.62(e)(2) and "extra lean" as used to describe meal and main dish products are provided in new § 101.62(e)(4).

Accordingly, the provisions in new § 101.62(e)(2) require that for the term "lean"o be used on the label or in labeling of a meal product or main dish product that product must contain less than 10 g of fat, less than 4 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving. The provisions in new § 101.62(e)(4) require that for the term "extra lean" to be used on the label or in labeling of a meal product or a main dish product that product must contain less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

The agency recognizes that the definitions for "lean" and "extra lean" for main dish products allow for use of the claim when levels of cholesterol exceed FDA's disclosure levels for this nutrient in a main dish product (i.e., 90 mg). It considered whether to prohibit the claim on products that contained greater than 90 mg of cholesterol. However, the agency has concluded that it would be more beneficial to consumers to allow the claim on meal-type products whose cholesterol content exceeds the disclosure level because the claims identify foods relative to other foods in this broad category of foods that contain lower amounts of fat and saturated fat. Consequently, these changes will assist consumers in selecting such foods. Furthermore, when the level of cholesterol exceeds FDA's disclosure level, the food will be required to bear a disclosure statement that refers the consumer to the nutrition information panel for additional information about cholesterol content.

8. Disclosure statement

In the general principles proposal (56 FR 60421 at 60457), the agency applied the concept of disclosure levels for individual foods to meal-type products. However, the agency did not propose specific disclosure levels for meal-type products and solicited comment on whether the disclosure levels should be different for meal-type products than for individual foods, and if so, what the levels should be and why.

273. FDA received comments recommending that it provide separate disclosure criteria for meal-type products. Several comments argued that the single food disclosure levels were too stringent to be applied to large quantities of food such as meal-type products. Two comments suggested that a specified amount of the designated nutrient per 100 g of product was the most appropriate basis for a criterion.

The agency considered whether to retain the disclosure levels for individual foods as the disclosure levels for meal-type products but on a per 100 g basis rather than per serving (i.e, 13 g of total fat, 4 g of saturated fat, 60 mg cholesterol and 480 mg sodium). On this basis, a meal weighing 10 ounces (280 g) would be subject to the disclosure requirements if it contained approximately 36 g of fat or 55 percent of the DRV. A single meal product weighing 12 ounces (336 g) would be subject to the disclosure requirement if it contained about 44 g of fat or about 67 percent of the DRV for total fat. If it is assumed that a "meal constitutes one-fourth of a total day's nutrient/calorie intake, this criterion appears to be too high in that such a meal could contribute more than half of the total amount of the nutrient (i.e., fat, saturated fat, cholesterol, or sodium) generally recommended as a total daily intake, not be required to bear a disclosure, yet still be able to bear a health claim.

The comments received offered no alternatives to the per 100 g basis for disclosure levels for main dishes and meal products. FDA, therefore, has developed an approach that extends the rationale used for individual foods to main dishes and meal products. This approach allows a greater percentage of the DRV for main dish products and meal products than for individual foods.

In arriving at specific percentage levels for disclosure nutrients, FDA considered that the amount of a nutrient in the total daily diet that may increase the risk of a disease may be between 100 percent and 200 percent of the DRV for that nutrient. The agency then considered that if three meals and a snack were consumed during the day, and each contained 40 percent of the DRV for a particular disclosure nutrient, and if foods that sometimes accompany meals such as beverages, breads, and desserts were also consumed and contributed an additional 40 percent of the DRV for that nutrient, then the total daily intake of the nutrient would not exceed 200 percent of the DRV, the level the agency used to establish disclosure levels for individual foods (see the final rule on health claims that appears elsewhere in this issue of the Federal Register). Thus, the agency is adopting 40 percent of the DRV as the disclosure level for meal products in this final rule.

The agency further considered that the contribution of main dish products is generally between meal products and individual foods (for which a disclosure level of 20 percent of the DRV is established in this final rule). Thus, the agency chose 30 percent of the DRV, the mid-point between meals and individual foods, as the disclosure level for main dish products.

Based on the comments received, the agency has established separate disclosure criteria for meal/main dish products. For meal products, new § 101.13(h)(2) requires that a disclosure statement be made on a product that makes a nutrient content claim if the food contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving. These levels correspond to no more than 40 percent of the DRV per labeled serving. For main dish products, new § 101.13(h)(3) requires that a disclosure statement be made on a product that makes a nutrient content claim if the food contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg cholesterol, or 720 mg of sodium per labeled serving. These levels correspond to no more than 30 percent of the DRV per labeled serving.

9. Other

275. The agency received a comment that recommended that the term "controlled" be defined as an implied

nutrient content claim for meal-type products. This comment asserted that this term would be very useful in describing carefully established levels of nutrients and has historically referred to established levels in a line of products designed to be used regularly within the context of a total diet that met dietary guidelines. The recommended criteria for the term "controlled" recommended by the comment were: (1) Less than 300 calories, (2) less than 30 percent of calories from fat, (3) no more than 65 mg cholesterol, and (4) less than 600 mg of sodium.

The term "controlled" has traditionally been used in the marketplace (especially on products marketed for special dietary use) to refer to designated size portions of foods and not to levels of nutrients. Thus, the agency has not defined the term "controlled" as suggested in the comment. However, the agency advises that individuals who believe that there is a need for additional terms for the use of implied claims on meal-type products may petition the agency under the provisions of § 101.69.

IV. Restaurant Foods

A. Nutrient Content Claims for Restaurant Foods

FDA received many comments regarding the proposed nutrient content claims criteria as they would apply to restaurant foods and to foods sold in other establishments in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering). In this discussion, such foods will be referred to as "restaurant foods," firms selling such foods will be referred to as "restaurants," and responsible individuals in these firms will be referred to as "restaurateurs." However, the concepts and policies discussed are intended to apply broadly to the foods covered by section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act. Issues with respect to menus are discussed separately below.

276. Several comments stated that because the 1990 amendments are silent with respect to requiring restaurant foods to comply with the requirements for nutrient content claims, FDA is not legally required to regulate such claims for restaurant foods in a manner identical to that proposed for packaged foods.

FDA disagrees with the comments that the 1990 amendments do not apply to nutrient content claims made for restaurant foods. As explained in the general principles proposal (56 FR 60421 at 60428), the 1990 amendments, fully support the agency's proposal in § 101.13(o)(5) (redesignated as new § 101.13(q)(5)) that a nutrient content claim may not be used for food that is served in restaurants or other establishments in which food is served for immediate human consumption, or for food that is sold for sale or use in such establishments, unless the claim is used in a manner that is authorized by a definition that FDA has adopted. However, FDA agrees that under section 403(r)(2) of the act, it is not required to regulate claims on restaurant foods in a manner identical to that for packaged foods. In fact, restaurants are exempt from the referral and disclosure requirements in section 402(r)(2)(B) of the act and certain of the requirements in section 402(r)(2)(A). FDA's regulations incorporate these exemptions. While the regulatory criteria governing claims for restaurant-type foods need not be identical to those governing other foods, if claims on foods are to be useful for consumers, the criteria for those claims must be consistent.

277. Several comments stated that restaurant foods should be required to comply with the proposed requirements for nutrient content claims. Some comments stated that many restaurant foods are centrally manufactured and conform to system-wide composition and quality standards. Therefore, many restaurants and restaurant chains, especially the larger ones, already have access to the nutrition information necessary to verify claims about their products. Finally, these comments stated that portion control of foods is practiced by many restaurants to control their food costs, and that this control will facilitate compliance by the industry.

Some comments stated that the proposed regulations governing nutrient content claims would be impracticable for the restaurant industry because packaged foods and restaurant foods differ markedly in the way they are prepared and sold. For example, variability in the nutrient level of individual foods sold in restaurants occurs as a result of: (1) Seasonal, regional, and market variations in ingredients; (2) differences in preparation methods of similar foods; and (3) consumer preferences in terms of how food is prepared. The comments pointed out that these variabilities would require repeated costly analyses to determine if each food meets the criteria for the content claim. The comment cited additional, complicating factors such as: performance of 100-g calculations for meal-type products; inadequacy of current data bases on nutrient levels in many foods for validating nutrient-content claims; and variations in recipes for restaurant foods. One comment estimated the cost of compliance in terms of redoing printed materials in the commercial sector of the food-service industry to be more than $500 million. Additionally, the comments assert that costs associated with product development, testing, preparation, marketing, and staff training will be required. For these reasons, these comments requested that FDA exempt restaurant foods from the requirements for nutrient claims it is establishing in this final rule.

Several comments stated that the proposed regulation for nutrient content claims for restaurants is not the least restrictive alternative available to FDA, in accordance with Executive Order 12291, because it would essentially eliminate a foodservice operator's ability to communicate meaningful nutrition information to consumers and create a disincentive for foodservice operators to develop healthful foods. These comments said that substantial costs of compliance with the new regulations would be passed on to consumers, and the small business segment of the industry would be especially adversely affected. The alternatives suggested by the comments are: (1) Develop definitions for foodservice oriented nutrient content claims; (2) develop voluntary guidelines for foodservice that specify how foodservice operators should provide nutrition information, or (3) establish a standard set of criteria concerning a recommended daily diet so that foodservice operators could flexibly and reliably design meals that may be promoted as healthful.

Several comments specifically addressed the use of the term "light" on restaurant foods. One of these comments said that "light" used on a restaurant food or meal should have the same meaning as when placed on a packaged food. Another comment said that "light" should mean only a reduction in calories, and that it should be restricted to use on meal-type products, on salt substitutes, and for describing physical or organoleptic attributes. One comment said that "light" as used in a restaurant can mean a wide variety of things from lighter texture, color, or consistency to overall healthiness, and that the proposed definition was too restrictive. A comment from a restaurant chain recommended that the term "light" should be used to refer to total meal packages that have at least 25 percent less fat, cholesterol, sodium, or calories than the traditional menu selections. This comment contended that a

restaurant meal will take the place of at least three servings, and that a 25 percent reduction would be significant in terms of total diet.

Other comments were less specific in addressing the issue of restaurant foods or meals bearing relative claims. One of these comments said that relative claims should be permitted for total meal packages at restaurants. Another of these comments said that for relative claims, a restaurant should compare a product to the restaurant's own product.

Given that almost half of the American food dollar is spent on food consumed away from home, and that perhaps as much as 30 percent of the American diet is composed of foods prepared in food service operations, FDA believes that, from an overall public health perspective, this important segment of the diet cannot be ignored. Further, FDA believes that dietary information provided to consumers at point of purchase in restaurants and other food service operations can be useful in helping Americans in maintaining healthy dietary practices. FDA wants to encourage the provision of such dietary information. However, FDA firmly believes that consumers expect, and deserve, that the claims made at point of purchase are truthful and not misleading.

FDA advises that not all claims made for restaurant foods are necessarily the type of claims that are covered by the 1990 amendments. For the sake of clarification, the agency offers the following observations. Statements such as "lightly breaded," "light crust," or "in a light sauce" on a sign or placard are not nutrient content claims covered by the 1990 amendments. Moreover, because of the importance of context, statements such as "Light Fare," "Lite Bites," or "Light Entrees" will not be considered nutrient content claims if the sign or placard on which the statement appears offers an explanation of the basis for the terms that makes clear that they are not intended to characterize the level of a nutrient. For example, a term such as "Lite Fare," on a sign or placard followed by an asterisk referring to a note that makes clear that in this restaurant the term means dishes with smaller portion sizes than normal would not be considered a nutrient content claim under section 403(r) of the act. In most cases, a prominently displayed disclaimer or information that clearly explains the basis for the use of the term, and that does not characterize the level of a nutrient in the explanation, will be sufficient to remove that use of the term from the coverage of the 1990 amendments.

Similarly, a restaurant may be able to use symbols next to the listing of an item on a sign or placard where the symbols are clearly explained in terms that would not subject the claim implied by the symbol to the 1990 amendments. For example, the use of a star symbol next to the name of an entree, where the symbol is explained in a footnote stating that the item is broiled instead of fried, would not be subject to the 1990 amendments.

Also, a restaurant may use symbols or make reference on a sign or placard to the criteria of a health professional organization or accrediting group and explain that the entree or meal is consistent with the general dietary guidelines of that group and not be subject to the 1990 amendments. For example, use of a heart symbol with reference to a note that explains that this entree is consistent with the general dietary guidelines of the AHA will be considered dietary guidance and not a nutrient content or health claim subject to section 403(r) of the act, provided the explanation does not characterize the level of a nutrient.

Finally, a restaurant also may be able to devise foods or complete meals that are formulated in complete accordance with the Dietary Guidelines for Americans (e.g., moderate calories, less than 30 percent calories from fat, less than 10 percent calories from saturated fat, emphasis on vegetables, fruits, and grain products, moderate use of sugars and sodium). FDA encourages such actions because a meal, especially a restaurant meal, represents a significant portion of the day's consumption, as compared to an individual food product. A restaurateur may signal to customers by the use of a term or symbol on a sign or placard that the meal is formulated in accordance with dietary guidelines, and FDA will consider such indications to be dietary guidance and not nutrient content claims under the 1990 amendments.

FDA is including a provision in new § 101.13(q)(5)(iii) that describes when such indications will be considered to constitute dietary guidance and not nutrient content claims. The agency will evaluate the validity of such guidance on the basis of its being truthful and not misleading under section 403(a) of the act. However, if the restaurateur goes on to characterize the level of nutrients in the food, it would subject the food and the claims for the food to the nutrient content claim regime. When a restaurant uses a defined term such as "low calorie," uses the term "light" without further explanation, or uses a term or symbol that is explained in such a way that states or implies levels of nutrients in the food, it must comply with FDA's definitions of those terms.

How the restaurant demonstrates compliance with those definitions is a difficult matter. FDA recognizes that, as detailed in the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants. Manufacturers of packaged foods also have to deal with differences in nutrient levels as a result of seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (e.g., methods of preparation). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making claims or to prevent the agency from being able to assure consumers that the nutrient content claims that appear on restaurant foods reasonably reflect the nutrient content of the food. Thus, FDA is providing in new § 101.13(q)(5)(ii) that, except if a claim is made on a menu, a restaurant food may bear a nutrient content claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the definition for the claim that FDA has established under section 403(r)(2)(A)(i) of the act. Thus, if a restaurateur labels a fish dish as "low fat," on a sign or a placard he or she must have a reasonable basis for believing that the dish complies with FDA's definition for "low fat," that is it contains less than 3 g of fat per 100 g. The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA's guideline on nutrient levels in seafood (56 FR 60880, Appendix B, November 27, 1991) shows that the fish contains less than 3 g of fat per 100 g, and that the method of cooking and other foods used in the dish would not add fat. In addition, the restaurateur could show that he or she relied on a reliable cookbook that gave values for fat in the finished food that were less than 3 g per 100 g. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients or inappropriate substitutions of ingredients), FDA will

find that there is a reasonable basis for believing that the food meets the criteria for a defined nutrient content claim.

Upon request, the restaurateur will be expected to present the basis on which he or she believes that the pertinent nutrient levels are present in the foods. In addition, the firm must be prepared to demonstrate that it adhered to the information that provides the basis for its belief, i.e., to the recipe, use of certain types and amounts of ingredients, or preparation methods in preparing the food. The agency will then determine whether the basis cited by the restaurant reasonably supports its use of a nutrient content claim such as "low calorie" or "low fat."

This reasonable basis for belief standard for restaurant nutrient content claims will provide regulatory officials, especially State and local authorities, with an effective standard for verifying that such claims are truthful and not misleading and in accordance with FDA regulations. FDA does not have resources to adequately enforce its regulations in restaurants. State and local authorities have traditionally carried out this responsibility. In addition, section 4 of the 1990 amendments provides that State and local authorities may enforce section 403(r) of the act in Federal court.

The agency notes, however, that while restaurants, and particularly small restaurants, have nominally been subject to FDA's existing nutrition labeling regulation (see § 101.10), they have, as a practical matter, not been required to comply with these regulations or with State or local regulations that focused on the nutrient content of the food. Thus, the efforts that will be necessary on the part of restaurants to show that they have a reasonable basis to believe that their food complies with the nutrient content claims requirements will be significant. These efforts will place particularly great demands on the resources of the small business segment of the industry, that is, restaurant firms that have ten or less individual restaurant establishments (Ref. 34). FDA will refer to this segment of the industry as "small restaurants."

Small restaurants generally do not have the established nutrition support component that larger restaurant chains have. Thus, it will be more difficult for small restaurants to determine how to adapt nutrient content information to their individual food selection and preparation methods. In addition, it is likely that they will not be as aware of available information sources, like nutrient content data bases, as large chains. Moreover, because of resource limitations, a small restaurant is not as likely as a large restaurant chain to be familiar with Federal requirements. Thus, small restaurants will have to become familiar with not only FDA's requirements, but with available FDA information, like the nutrient content information that FDA published in conjunction with its regulation on the voluntary labeling of raw fruits and vegetables (56 FR 60880, November 27, 1991).

Because of the great initial demands that small restaurants will find if they wish to make claims, FDA has decided that they should be given additional time to come into compliance with these regulations. Without additional time, for the reasons discussed above, small restaurants will be placed at a disadvantage with respect to their ability to make claims. As a result, they may decide not to even attempt to provide useful nutrition information to consumers about their foods. To provide for equitable implementation of these requirements for small restaurants, FDA has decided to not make § 101.13(q)(5) effective with respect to such establishments until February 14, 1995.

While the statute will be in effect during that period, FDA will not enforce the statute's nutrient content claim requirements in small restaurants until the regulations are effective. Although state action is not preempted under section 403A(a)(5) of the act until Federal regulations are effective, the agency expects that States will refrain from enforcing any nutrient content claim requirements in small restaurants until the Federal regulations are effective for those restaurants.

FDA believes that this action is fully consistent with the 1990 amendments and with the act. The 1990 amendments impose no date by which the agency's regulations must be effective, only when they must be promulgated (see sections 3 and 10 of the 1990 amendments). Moreover, FDA believes that this action will facilitate effective enforcement of the act. FDA believes that the agency's and State's resources can best be used during this initial period in educating small restaurants about the requirements of the law and by developing a better understanding of the unique practical circumstances of small restaurants in complying with nutrient content labeling requirements. Moreover, during this period, there will be an opportunity for interested persons to develop new data bases that will help facilitate the provision of nutrition information on foods sold in restaurants and particularly in small restaurants.

As an additional measure of flexibility, which will especially benefit small restaurants, it was decided not to include claims on menus within the coverage of these regulations. FDA has considerable discretion in regulating nutrient content claims in restaurants. As the comments have indicated, there are unique problems and concerns associated with regulating such claims. The 1990 amendments do not specify precisely how such claims are to be regulated. These regulations will apply to nutrient content claims made in restaurants except on menus. The agency's efforts will focus on signs, placards, and posters, which are increasingly used in fast food and other restaurants to bring nutrition information and claims about food to consumer's particular attention. The comments pointed out that menus are subject to frequent, even daily, change. This additional measure of flexibility for menus will help assure that restaurants, especially small restaurants, will not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. State's remain free, however, to ensure under their own consumer protection laws that menus do not provide false or misleading information.

Although it has arrived at an approach that will provide for nutrient content claims on restaurant foods, other than the exclusion of menus, FDA does not consider the problem of assuring the useful and reliable provision of nutrient related information in restaurants to be solved. It is possible that there are other definitional criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, terms used for restaurant foods as compared to the same terms used on packaged foods. If this is the case, a different glossary of terms for use in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how terms are used on restaurant foods and whether such terms are appropriate. For example, with FDA's cooperation, the National Restaurant Association is planning to undertake a survey of industry use of nutrition information and of consumer knowledge, practices, expectations, and understanding of various terms and symbols in restaurants. FDA is open to petitions for different criteria for nutrient content

claims for restaurant foods, and if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

FDA also recognizes that there are a number of significant issues concerning the adequacy of existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases and to encourage the development of additional or newer data where those data bases are found to be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods. FDA regulations state that for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared, and that for calories, carbohydrate, fat, and sodium, the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities, and that a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims based on nutrient levels drawn from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

278. One comment stated that the use of the terms "healthy" or "healthful" on meal-type products is necessary for restaurants to assist the consumer in identifying the choices that fit an eating pattern consistent with reducing the risk of certain chronic diseases. This comment further stated that disqualifying levels for fat, saturated fat, sodium, and cholesterol should be set in order to prevent inappropriate foods from bearing this claim.

The agency is publishing a proposed rule concerning use of the term "healthy" as an implied nutrient content claim elsewhere in this issue of the Federal Register. Any comments and information with respect to whether the agency's tentative definition of "healthy" is appropriate for restaurant meals and main dishes will be considered in that rulemaking.

B. Nutrition Labeling of Restaurant Foods

279. Several comments agreed that FDA has authority to require nutrition labeling when nutrient content claims are made on restaurant foods and stated that nutrition labeling should be required on restaurant foods bearing claims. These comments generally contended that restaurants should be required to follow the same nutrition labeling requirements as food manufacturers when nutrient content claims are made.

Many comments expressed the opinion that FDA does not have authority to require nutrition labeling when nutrient content claims are made on restaurant foods and stated that nutrition labeling should not be required on restaurant foods bearing nutrient content claims. These comments generally contended that since the act exempts restaurant foods from nutrition labeling, FDA should allow for the nutrition labeling of restaurant foods on a voluntary basis.

FDA finds nothing in the comments to persuade the agency to adopt a position different from that stated in the general principles proposal (56 FR 60421 at 60427). The agency continues to believe that it has the authority to issue regulations requiring restaurants that make nutrient content claims to adhere to the requirements for such claims, including nutrition labeling.

280. A few comments stated that if nutrition labeling were required for restaurant foods bearing nutrient content claims, restaurants would not make such claims because restaurant foods are not standardized, and it would be too costly to provide accurate nutrition information for these foods. The comments also stated that mandatory nutrition labeling (when a claim is made) would inhibit restaurants from making frequent and more healthful changes in food.

Full nutrition labeling provides the consumer with a way of evaluating a claim within the nutrient context of the food or meal and, therefore, is advantageous in allowing more informed comparisons. However, in the general principles proposal (56 FR 60421 at 60427), the agency recognized the difficulty of providing nutrition labeling for restaurant foods and asked for comment. The comments have persuaded the agency that, at this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable nutritional characteristics of restaurant foods. Therefore, FDA is not requiring that full nutrition labeling be provided when a nutrient content claim is made for restaurant foods. It is adopting a somewhat different approach to the provision of nutrient information to the consumer, as explained in the response to the next comment. The agency does, however, encourage the voluntary provision of full nutrient information for restaurant foods, even when claims are not made.

281. Some comments stated that if nutrition labeling were required for restaurant foods bearing a claim, restaurants could utilize available nutrition software programs and recognized databases to provide the necessary information for the nutrition label. One comment stated that FDA should develop educational materials for restaurants that explain their obligation not to make nutrient or health claims without providing nutrition labeling. A few comments stated that before requiring mandatory nutrition labeling of restaurant foods bearing nutrient content claims, a pilot study should be done to determine the cost and feasibility of such labeling, and that more study is needed before the agency requires labeling on restaurant foods.

FDA believes that consumers should have access to information about the nutrient content of restaurant foods for which nutrient content claims or health claims are made. The agency is requiring in new § 101.10 that such information be available upon request by a consumer. However, because FDA recognizes the difficulty of providing nutrition labeling for restaurant foods, at this time it will allow such information to be conveyed either by nutrition labeling as described in new § 101.9 or by the provision of information to the consumer about the level of the nutrient for which the claim is made in a serving of the food upon request by the consumer. Under the latter alternative, for example, if a 333 g meal is characterized as being "low fat," the consumer could be informed that the meal contains less than 10 g of fat. Therefore, under this alternative the restaurateur need not state the actual amount of the nutrient present in a serving of the food but may simply state that the nutrient is present at "less than" or "greater than" the amount that would enable the serving of the food to make the claim. Thus, the agency is not requiring that the firm conduct an analysis of the food in order to provide this information. On the contrary, this information should be readily available to the firm from its determination that the food conforms to the criteria for the

claim. For the interim, the agency will consider that the provision of this limited amount of information to consumers will serve as the functional equivalent of nutrition labeling.

Further, the considerations discussed in the previous section concerning the effective date for small restaurants that make nutrient content claims also apply with respect to nutrition labeling when a nutrient content claim is made in those restaurants. Therefore, FDA is also deferring the effective date of § 101.10 for 1 year for small restaurants.

FDA agrees with the comments that educational programs and further study will be helpful. However, the statutory timeframes imposed on the agency by the 1990 amendments do not afford FDA the luxury of deferring until some future time all rulemaking on restaurant foods. The agency recognizes the limitations in the approach that it is taking and encourages the restaurant industry to continue to work with FDA to devise a program that will provide consumers with truthful and accurate nutrition information, without at the same time inhibiting the flow of such information or the development of healthier foods. The agency points out that the conduct of feasibility and consumer studies is more properly the responsibility of the regulated industry, and that FDA is currently working with the industry to do such studies.

282. One comment stated that § 101.10 should be deleted because it would be outdated if nutrition labeling requirements are imposed for restaurant foods bearing claims.

For the reasons discussed above, FDA is deleting current § 101.10. However, FDA is replacing it with a new provision that sets forth how nutrient information is to be provided when a claim that is subject to section 403(r) of the act is made for restaurant foods. The agency believes that information in § 101.10 was useful in advising firms about alternatives for declaring nutrition information when a claim is made, and as revised, § 101.10 will continue to serve this purpose.

283. Other comments addressed specific issues of nutrition labeling for restaurant foods, such as whether the requirement for nutrition labeling of restaurant foods should apply only to large restaurants with fixed items, and whether the content or format of nutrition labeling should be different for the foodservice industry than for packaged foods.

FDA will address these issues in its further deliberations and in its continued interactions with the regulated industries. The agency is likely to seek comment on a number of these issues in the future.

V. Petitions

In the general principles proposal (56 FR 60421 at 60458), FDA proposed to establish procedural regulations to govern the submission, content, and agency review of the three types of petitions authorized by section 403(r)(4) of the act (i.e., petitions for nutrient content claims, for synonymous terms, and for the use of an implied claim in a brand name). The agency also proposed to redelegate to the Director and Deputy Director of the Center for Food Safety and Applied Nutrition (CFSAN) all of the functions of the Commissioner of Food and Drugs relating to petitions for label claims under section 403(r) of the act involving noncontroversial issues. Further, the agency reiterated its interim policy on petitions submitted pursuant to the 1990 amendments that it announced in a notice published in the Federal Register of March 14, 1991 (56 FR 10906), i.e., that the agency intends to defer or deny action on all such petitions until it establishes the final procedural regulations for the submission, content, and review of these petitions.

284. One comment stated that the 1990 amendments do not require FDA to establish procedural regulations for petitions, and that the agency does not have the authority to defer or deny any petition submitted to the agency on the basis that the agency has not established regulations.

Although the 1990 amendments do not require FDA to establish procedural regulations for the petitions prescribed therein, FDA stated in a notice in the Federal Register of March 14, 1991, (56 FR 10906) that the most efficient way to manage a large influx of petitions likely under the 1990 amendments and to utilize agency resources is for FDA first to establish procedural regulations for handling petitions, and secondly to make them final at the same time as the other substantive regulations implementing the 1990 amendments. The agency continues to believe in the wisdom of this approach. Obviously, it will be more efficient for the agency to be able to simply review petitions to determine whether the petitioner has provided an appropriate basis to justify a claim, than to have to first determine whether a petition has provided the appropriate information and then to review it substantively. FDA believes that adopting new § 101.69 will greatly increase the likelihood that the petitions it receives are adequate.

Also, as explained in the general principles proposal (56 FR 60421 at 60458), the need to promulgate procedural regulations necessitates that the agency defer or deny petitions submitted before such regulations are finalized. Therefore, the agency concludes that the promulgation of procedural regulations for petitions submitted pursuant to the 1990 amendments, and its procedure for handling petitions before the final regulations are established, is appropriate.

285. Another comment urged that FDA not redelegate to the Director and Deputy Director of CFSAN all the functions of the Commissioner of Food and Drugs concerning petitions for label claims under section 403(r) of the act that do not involve controversial issues. The comment stated that all petitions that will be submitted to the agency concerning nutrient content claims and health claims will involve controversial issues that will require a response from the Commissioner of Food and Drugs.

FDA does not agree with this comment. Based on its experience with other types of petitions that have been submitted to FDA for consideration, it is not uncommon for a petition to contain major deficiencies that necessitate the denial of the petition or that result in the petition being put in a "not-filed" status until all deficiencies have been resolved. The agency believes that redelegating such functions to the Director and Deputy Director of CFSAN will permit the agency to take the required actions (e.g., denial of such a petition) in the most resource efficient manner.

Although the agency agrees that many petitions concerning label claims will indeed involve controversial issues, no basis was provided by the comment to support the contention that all such petitions will be controversial, and the agency does not believe that it should make this assumption. If a petition does not involve a controversial issue, the redelegation of the functions provision will enable the agency to take action in the most resource efficient manner. Therefore, the agency is retaining the redelegation provision in this final rule.

286. One comment stated that FDA should include a list of terms and synonyms in the final regulation so that the petition process would not be necessary.

This final rule is not intended to define by regulation all conceivable terms that may be used now or in the future to make nutrient content claims. The 1990 amendments included the petition process to enable FDA to amend the regulations to provide for

new terms and synonyms that may be presented to the agency with appropriate justification. Thus, this final rule does not render the petition process unnecessary.

287. Several comments were concerned that the requirements established for the petition process are ambiguous and should be streamlined. A few other comments suggested that the petition process would impose a significant burden on manufacturers.

The agency has reviewed these comments and has concluded that, in some cases, changes should be made to the requirements to clarify and simplify the petition process and eliminate unnecessary elements. The specific revisions in the final rule are discussed below.

288. One comment suggested that FDA should use the criteria established in section 403(a) and (r) of the act for determining when to deny or grant a petition. This comment also implied that no other requirements are necessary for the agency to use as a basis to determine whether to deny or grant a petition.

The agency does not agree with this comment. While it is true that section 403(a) and (r) of the act are the statutory provisions upon which the proposed procedural regulations are based, these statutory provisions do not provide petitioners with a clear description of the types of information and scientific data that would be necessary for a petition to be acceptable.

Given the large influx of petitions that the agency anticipates receiving, and the statutory time constraints placed on the agency regarding the review of these petitions, it is in the best interest of petitioners and of the agency for FDA to establish procedural regulations that clearly delineate the requirements that petitioners must satisfy when submitting a petition to FDA for consideration. This course will lead to the most efficient use of the petitioner's and the agency's resources because the data requirements for petitions will be clearly stated, and, as stated above, less agency resources will be expended in reviewing deficient petitions.

289. A number of comments expressed concern that the petition process will prevent manufacturers from developing innovative ways to convey nutrient levels in foods, retard product development, and serve as a disincentive for the development of new healthful foods. One comment suggested that the petition process will stifle product innovation because new marketing claims will need agency approval. This same comment also stated that one way to somewhat alleviate this problem would be for the petition that is under review to remain confidential until it is approved by the agency.

As stated above, FDA has in some cases made changes in the final rule to clarify, simplify, and eliminate unnecessary petition requirements. However, the agency's procedures must be consistent with the statutory requirement that all nutrient content claims used on food labels use terms that are defined in the regulations of the Secretary as provided in section 403(r)(2)(A)(i) of the act. Thus, the requirement of agency approval of a claim, and the petition process by which that approval is obtained, derive directly from the act itself.

Furthermore, section 403(r)(4)(A) of the act requires that nutrient content claim petitions that are filed for further action after 100 days and brand name petitions be made available to the public. Because of this requirement in the statute, FDA is retaining the provisions concerning the public availability of these petitions. However, the availability of information in these petitions will be determined in accordance with § 20.61 (21 CFR 20.61). This regulation provides that trade secrets and commercial or financial information that is confidential or privileged are not to be made available for public review.

290. A small number of comments stated that some specific requirements that the agency proposed for nutrient content claim petitions and synonym petitions (e.g., submission of consumer survey data and submission of data to demonstrate that consumers will understand the meaning of the proposed term) should not be included in the petition requirements. Most of these comments regarded the proposed petition requirements as unduly burdensome. Some of the comments stated that the proposed petition requirements command more information than FDA cited in issuing the proposed regulations for nutrient content claims.

FDA has reviewed the proposed requirements and has concluded that it is not necessary (as was proposed under format item B) for descriptor petitions and synonym petitions (proposed § 101.69(m)(1) and (n)(1)) to include data and information to demonstrate that consumers can be expected to understand the meaning of the proposed term under the proposed conditions of use. The agency believes that it can make a rational determination concerning the ability of consumers to understand a term without requiring such data and information, and, therefore, this requirement would impose an unnecessary burden on the petitioner. However, the inclusion of such information in a petition would, if it shows that consumers do correctly understand the term, enhance the persuasiveness of the petition.

The petitioner will still be required to address why the proposed use of the term will not be misleading (format item A). In this regard, if any concerns arise during the agency's review concerning the ability of consumers to understand the meaning of the proposed term, the agency is likely to deny the petition. Therefore, the agency is removing from new § 101.69(m)(1) and (n)(1) the provision stating "The petition shall include data and information, e.g., surveys to the extent necessary, to demonstrate that consumers can be expected to understand the meaning of the term under the proposed conditions of use."

291. Some comments that addressed synonym and brand name petition requirements stated that the agency should delete the requirements in proposed format item C (proposed § 101.69(n)(1) and (o)(1)) that the petitioner provide a detailed analysis of the potential effects of the use of a proposed claim on food consumption and any corresponding changes in nutrient intake when requesting approval for a synonym or for a brand name containing an implied nutrient content claim. These comments stated that the burden imposed by this requirement guarantees that no petition will be successfully submitted. They also argued that such requirements treat synonyms as nutrient content claims rather than as alternative terms for claims that have already been approved by the agency.

The agency has considered this comment and agrees that synonym and brand name petitions need not include detailed analyses of food consumption and nutrient intake effects associated with use of the petitioned term. These matters will have been considered by the agency in approving the primary term with which the petitioned term is claimed to be consistent.

The agency is, therefore, deleting proposed format item C from the requirements for synonym and brand name petitions (new § 101.69(n)(1) and (o)(1)) in the final rule.

292. A comment stated that it is not necessary for FDA to publish a Federal Register notice informing the public of the agency's decision on whether to deny or to grant a synonym petition because it is not required by the statute.

FDA continues to believe that publishing a notice announcing the

agency's decision to either grant or deny a synonym petition will provide useful information to the public. Such decisions have relevance to persons interested in the outcome of the agency's review of the petition, because a synonym, if approved, may be used by any firm and, if denied, may not be used on labels or in labeling. Further, such action is appropriate because the granting of a synonym petition is an agency decision that has the force and effect of law. Public notice of the agency's action will notify all potentially affected parties of the legal status of the synonym. FDA is therefore retaining this provision in the final rule.

However, FDA is correcting an error in the proposed codified language. Proposed § 101.69(n)(4) should have stated that FDA will publish a notice in the Federal Register "As soon as practicable following the agency's decision to grant or deny the petition, * * *" as indicated by the preamble discussion. However, the proposed codified text only referred to the "granting" of the petition. FDA is making the appropriate revision in the final rule.

293. One comment stated that the petition process is unnecessary for the use of a nutrient content claim in a brand name if the term has been defined by the agency.

FDA agrees with this comment. In cases where a nutrient content claim has been defined by regulation or provided for under the regulations for implied nutrient content claims in new § 101.65, the term may be used in a brand name in accordance with the provisions of the applicable regulation. However, a brand name petition would be required for the use of a proposed term in a brand name that has not been defined by the agency by regulation or provided for under new § 101.65, but where the petition could establish that the proposed term is consistent with a defined term.

VI. Constitutional Issues

A. The First Amendment

294. A number of comments from trade associations and individual companies argued that truthful nutrient content claims are protected speech under the first amendment. Many comments contended that food labeling, including nutrient content claims, is commercial speech and argued that FDA's proposed regulations do not pass the Supreme Court's test for regulation of commercial speech. Comments asserted that any suggestion that consumers should be screened from truthful information for their own good is the kind of paternalism rejected by the Supreme Court in *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 770 (1976), and that the idea that the public cannot be trusted to make judgments based on truthful information contravenes the basic principles of the first amendment. Comments maintained that the public has an interest in obtaining useful information, and that the Government's interest is best served by allowing the free flow of truthful information. FDA also received a comment expressing the opinion that the proposed rule does not violate the first amendment and urging the agency not to change its position on first amendment grounds.

FDA believes that its nutrient content claim regulations are consistent with the first amendment, and that the act, as amended by the 1990 amendments, does not violate the first amendment. The act has withstood numerous first amendment challenges. See, e.g., *United State* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975); *United States v. 8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951).

Parts of the 1990 amendments and these regulations have an incidental effect on speech in a narrowly defined area, food labeling. See *NAACP* v. *Claiborne Hardware* Co., 458 U.S. 886, 912 (1982). The Supreme Court, however, "has recognized the strong governmental interest in certain forms of economic regulation, even though such regulation may have an incidental effect on rights of speech and association." Id. The Government may regulate in areas of economic activity such as securities, antitrust, and labor in ways that affect speech. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d 365, 372-73 (D.C. Cir. 1988), cert. denied, 489 U.S. 1066 (1989); see also *SEC* v. *Suter*, 732 F.2d 1294, 1299 (7th Cir. 1984) (the first amendment does not remove a business engaged in the communication of information from general laws regulating business practices). The Government "does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of the activity." *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978); see also *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 46 (D.C. Cir.) ("[R]ules restricting speech do not necessarily abridge freedom of speech."), cert. denied, 434 U.S. 829 (1977).

As with securities, labor, and antitrust regulation, the Government exerts extensive regulatory authority over the economic activity surrounding food and its labeling. Yet the regulation of food and food labeling clearly encompasses more than mere economic activity: It protects consumer health and safety in an area where harm to the public can be direct and immediate. See *Ohrali*, 436 U.S. at 456. FDA's crucial role in ensuring that food labels are informative, are not misleading, and do not otherwise misbrand products under the act has long been recognized. See 79 Congressional Record 4734 (1935), reprinted in Dunn, Federal Food, Drug, and Cosmetic Act 280 (1938) (statement of Sen. Copeland) ("No one disputes that the [FDA] should determine the quality of the product; no one disputes that it should determine what is on the label."). In such an area of extensive Federal regulation, the Government may place restrictions on speech by a regulated party where the speech relates directly to the Government's objectives. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372. Indeed, regulation of food labeling would be impossible if the Government could not restrict speech. See id. at 373.

Thus, when FDA seeks to ensure that food is not misbranded, it may place restrictions on label contents. "Freedom of [s]peech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act." *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975). "[C]ertain speech in a certain limited context" becomes part of the labeling of a product and may serve as evidence of a violation of the act. *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986). Thus, the seizure and condemnation of a book that misbrands a product is not a violation of the first amendment, even though in another context the book might be protected. See *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Articles of Drug*, 32 F.R.D. 32, 35 (S.D. Ill. 1963). "It is the product and the manner in which the product is marketed which is said to be illegal," rather than the speech itself. *General Nutrition*, 638 F. Supp. at 562. A prohibition on selling a misbranded product restrains the violative act of selling, not speech itself. *Kellogg Co.* v. *Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex. 1991) (construing Texas food and drug law), aff'd without opinion, 940

F.2d 1530 (5th Cir. 1991). "The substantial government interest in the goals of the Act justifi[ies] this extremely narrow encroachment" on speech. *General Nutrition*, 638 F. Supp. at 562. Indeed, where certain claims misbrand a product, "[a] requirement that the claims be removed, in order to sell the product, is certainly less restrictive than a flat prohibition of the sale of the product." *Kellogg*, 763 F. Supp. at 1381.

With the provisions of the 1990 amendments that govern nutrient content claims, Congress sought to put an end to the proliferation of confusing and contradictory nutrient content claims. 136 Congressional Record S16610 (Oct. 24, 1990) (statement of Sen. Hatch); 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman). In order to assist consumers in improving their eating habits, Congress devised a scheme to ensure that nutrient content claims in food labeling will help consumers to make good nutrition choices, not mislead them. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); 136 Congressional Record S16609 (Oct. 24, 1990) (statement of Sen. Mitchell). Under this scheme, only those claims that FDA has defined by regulation, see section 343(r)(2)(A)(i) of the act, or approved pursuant to a petition, see section 343(r)(4)(A), are permitted, and a food that bears an unapproved nutrient content claim is misbranded. Since FDA case law makes clear that a label statement that misbrands a food product is not subject to first amendment protection, an unapproved nutrient content claim on a food label would not be protected speech. See *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975); *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Articles of Drug*, 32 F.R.D. 32, 35 (S.D. Ill. 1963).

Congress considered existing labeling practices to be harmful to the public because of the "confusing" and "misleading" nutrient content claims made by many manufacturers. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); see also 136 Congressional Record H5843 (July 30, 1990) (statement of Rep. Madigan); cf. *Ohralik*, 436 U.S. at 456 ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity."). Congress dealt with this problem by crafting a system to permit certain useful information to appear on the food label, while ensuring that the information is not misleading. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley); 136 Congressional Record S16609 (Oct. 24, 1990) (statement of Sen. Mitchell). Congress considered these restrictions on speech necessary to further the government's interest in ensuring that nutrient content claims on food labeling would not mislead consumers. The government's action in regulating the food label does not offend the first amendment simply because speech is involved. *Ohralik*, 436 U.S. at 456. The case law establishes that FDA's power to regulate the food label derives from its broad regulatory powers over food, and these regulations are valid under the limited scrutiny that has been afforded restrictions on speech under extensive regulatory schemes involving areas of economic activity. See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372–73; see also *Dun & Bradstreet, Inc.* v. *Greenmoss Builders*, 472 U.S. 749, 758 n.5 (1985); *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978).

295. Many comments argued that labeling is commercial speech, and that restrictions placed on it must pass the tests enunciated by the Supreme Court in cases involving commercial speech. Unlike "advertising pure and simple," *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985), labeling does not fall clearly within the bounds of commercial speech. The agency does not consider it necessary for first amendment analysis, however, to determine whether or not food labeling fits the definition of commercial speech. See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372. Rather, the agency considers labeling on foods to form "a distinct category of communications in which the Government's power to regulate is at least as broad as with respect to the general rubric of commercial speech." *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 373. Nonetheless, recognizing that at least one court has categorized labeling as commercial speech, General Nutrition, 638 F. Supp. at 562, FDA agrees that labeling should certainly be considered closer to commercial speech than to "pure" speech.

Even if labeling is analyzed as commercial speech, these regulations do not violate the first amendment. First, speech that is misleading is not protected and may be prohibited. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 563–564 (1980). Secondly, speech that is only potentially misleading may be restricted, so long as the restrictions directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest. *Central Hudson*, 447 U.S. at 566. These regulations govern a kind of speech that is inherently misleading and that, in Congress' judgment, has been used to mislead the American public for years: Unregulated, nonstandardized nutrient content claims on the food label. However, even if such claims are considered only potentially misleading, the regulations pass the test enunciated in *Central Hudson*.

Commercial speech receives only limited protection under the first amendment. See, e.g., *Bolger* v. *Youngs Drug Products Corp.*, 463 U.S. 60, 64–65 (1983). For commercial speech to be protected, it must concern lawful activity and not be misleading. *Central Hudson*, 447 U.S. at 563–64. The Supreme Court has recognized that restrictions on commercial speech may be appropriate to prevent deception. *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748, 771 n.24 (1976). These regulations will have the effect of ensuring that the nutrition claims that appear in food labeling are not misleading. See *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977) (because FDA regulation was based on the agency's conclusion that "labeling which fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act," the regulation did not violate the first amendment).

The Supreme Court has labeled as misleading—and thus not protected—both speech that is inherently likely to deceive and that which "experience has proved * * * is subject to abuse." In re *R.M.J.*, 455 U.S. 191, 203 (1982). For example, in *Friedman* v. *Rogers*, 440 U.S. 1, 14–15 (1979), the Court held that Texas could prohibit the use of trade names by optometrists where there was a history of deception and abuse of the public. See also *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 468 (1978) (upholding State bar's rules against in-person solicitation where there was an inherent potential for abuse and prophylactic regulation was needed).

By enacting the 1990 amendments, Congress sought to ensure that food labeling, including express and implied nutrient content claims, would be accurate, uniform, and "based on science." 136 Congressional Record S16610 (Oct. 24, 1990) (statement of

Sen. Hatch). With respect to nutrient content claims, the principal problem that Congress sought to correct was the use of ambiguous, undefined claims like "light" and "low." See, e.g., 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman). Experience had shown that consumers were being misled because these terms were being used differently by different manufacturers. Id.; 136 Congressional Record H12, 953–954 (Oct. 26, 1990) (statement of Rep. Madigan). Congress recognized that consumers were being hampered in their attempts to achieve a healthy diet by confusing implied nutrient content claims like "light." 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley).

Because of the misleading character of unregulated, nonstandardized nutrient content claims, Congress legislated that any claim that is not consistent with FDA regulations misbrands a food. Section 403(r)(2)(A)(i) of the act states that a food is misbranded if its label or labeling contains a claim that "expressly or by implication * * * characterizes the level of any nutrient * * * of the food *unless* the claim" complies with regulations promulgated by FDA (emphasis added). Section 403(r)(1)(A) of the act. By taking this approach, Congress chose to permit only those nutrient content claims that FDA defines or approves, effectively recognizing that unregulated claims mislead the public.

Particular attributes of unregulated nutrition claims on the food label make them inherently misleading. Because nutrition claims are of great importance to the public, they have a greater potential to be deceptive: Representations relating a product to an issue of public concern as a means to induce purchases may take on exaggerated importance in the public mind and thus be more likely to mislead. *FTC* v. *Pharmtech Research, Inc.*, 576 F. Supp. 294, 301 (D.D.C. 1983) (advertisements for food supplement were misleading where they "played on the average consumer's well-founded fear of cancer"). In addition, nutrient content claims on food labeling are difficult for consumers to verify independently. *See American Home Products* v. *FTC*, 695 F.2d 681, 698 (3d Cir. 1982); cf. *Peel* v. *Attorney Reg. & Disciplinary Commission*, 496 U.S. 91, 110 S. Ct. 2281, 2288 (1990) (a lawyer's certification is a "verifiable fact"). Finally, consumers place great reliance on the portions of the food label that they believe to be regulated by the Government. FDA's 1990 Health and Diet Survey, Division of Consumer Studies, CFSAN. Unapproved nutrient content claims that consumers assume to be consistent with government regulations are therefore more likely to be misleading. "Pervasive Government regulation * * * and consumer expectations about such regulation, create a climate in which questionable claims * * * have all the more power to mislead." *American Home Products v. FTC*, 695 F.2d at 697.

296. Many comments argued that nutrient content claims are only potentially misleading, pointing out that the Government may not absolutely prohibit potentially misleading speech if it can also be presented in a nondeceptive way. *Peel* v. *Attorney Registration & Disciplinary Comm'n*, 110 S. Ct. 2281, 2287 (1990); In re R.M.J., 455 U.S. 191, 203 (1982). The preferred remedy for potentially misleading speech, these comments stress, is not a prohibition but a requirement of disclaimers or explanation. In re *R.M.J.*, 455 U.S. at 203 (citing *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 375 (1977)); see also *Peel*, 110 S. Ct. at 2292 (referring to "[t]he presumption favoring disclosure over concealment"). Comments argued that given the constitutionally based preference for more speech, rather than less, FDA should require disclaimers or explanations rather than prohibiting unapproved claims.

Even if unregulated nutrition claims are considered only potentially misleading, rather than actually or inherently misleading, these regulations are constitutional. The government may place restrictions on commercial speech that is merely potentially misleading. Such restrictions must directly advance a substantial governmental interest and be no more extensive than necessary to serve that interest. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). These regulations pass that test.

First, the government's interest is clearly substantial. The 1990 amendments and these regulations seek to ensure that consumers have access to nutrition information that is truthful, reliable, understandable, scientifically valid, and not misleading. This information will enable consumers to make more healthful food choices. The Supreme Court has recognized "the health, safety, and welfare of * * * citizens" as a substantial government interest. *Posadas de Puerto Rico Associates* v. *Tourism Co.*, 478 U.S. 328, 341 (1986). Moreover, consumers have a first amendment interest in obtaining information on which to base a decision whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157, 162 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978) "The fact that health is involved enhances the interests of both consumers and the public in being assured 'that the stream of commercial information flow[s] cleanly as well as freely.'" Id. (quoting *Virginia State Board of Pharmacy*, 425 U.S. at 772); *American Home Products*, 695 F.2d 681, 714. Moreover, FDA is implementing legislation whose purpose is "essential if the consumer is to obtain reasonable information regarding * * * the foods he buys.". *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 553 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977).

Secondly, the regulations directly advance the government interest. Under the 1990 amendments and these regulations, FDA will define a nutrient content claim by regulation or make an administrative determination that a suggested claim is synonymous with a previously defined claim before permitting the claim to be used. In this way, the regulations will ensure that such claims are consistent, understandable, and do not confuse or mislead consumers. The regulatory scheme will also encourage companies to provide consumers with information that will enable them to improve their diets. There is an "immediate connection," *Central Hudson*, 447 U.S. at 569, between nutrient content claims on food labels and consumers' food choices.

Finally, these regulations are no more extensive than necessary to serve the Government's interest. Under *Board of Trustees* v. *Fox*, regulations that are narrowly tailored to serve the Government's interest will meet this prong of the *Central Hudson* test. 109 S. Ct. 3028, 3032–35 (1989). Narrow tailoring requires a reasonable fit between regulatory ends and means: "Not necessarily the single best disposition but one whose scope is 'in proportion to the interest served.'" Id. at 3035; see also *Ward* v. *Rock Against Racism*, 109 S. Ct. 2746, 2758 (1989) (a regulation is narrowly tailored if Government interest would be achieved less effectively without the regulation). These regulations reasonably and effectively ensure that nutrient content claims on food labels will be informative, consistent, and not misleading. Thus, they meet the third prong of the *Central Hudson* test and do not violate the first amendment.

FDA recognizes that the Government may not absolutely prohibit potentially misleading information if the information can also be presented in a

nondeceptive way. See In re *R.M.J.*, 455 U.S. 191, 203 (1982). The agency further acknowledges that the preferred remedy for potentially misleading speech is a disclaimer or explanation rather than a prohibition. Consequently, these regulations impose only those restrictions that are necessary to ensure that nutrient content claims are presented in a nondeceptive way. Conceding for the sake of argument that some unapproved claims are only potentially misleading, FDA has not outlawed the information conveyed by such claims; instead, the agency has prescribed that the information be presented in standardized form, using uniform, terms defined by the agency, so that consumers will not be misled.

297. Some comments argued that nutrient content claims, which help consumers to achieve healthy eating habits, convey information of general interest about nutrition and health. Thus, the comments argued, nutrient content claims are "pure" speech, not commercial speech, and as such are entitled to full first amendment protection.

FDA disagrees with these comments. As discussed above, FDA believes nutrient content claims belong to a distinct category of communications in which the government's power to regulate is broad. Under the comprehensive Federal scheme for the regulation of food and drugs, the Government has authority to impose incidental restrictions on food labeling, including nutrient content claims. As between commercial speech and "pure" speech, however, FDA believes nutrient content claims should be categorized as commercial speech. Labeling statements on food products intended for sale would clearly appear in the context of a commercial transaction and would "propose" such a transaction. See *Bolger* v. *Youngs Drug Products*, 463 U.S. 60, 66, 103 S. Ct. 2875, 2880 (1983); *Central Hudson Gas* v. *Public Service Commission*, 447 U.S. 557, 562 n.5, 100 S. Ct. 2343, 2349 n.5 (1980). A label is not entitled to the protection due noncommercial speech simply because it relates to an issue of broad public interest. See *Board of Trustees* v. *Fox*, 109 S. Ct. 3028, 3032 (1989); *Bolger*, 463 U.S. at 68, 103 S. Ct. at 2881; *Central Hudson*, 447 U.S. at 562 n.5, 100 S. Ct. at 2349 n.5. In determining whether the statements on a label are pure speech, it is irrelevant that they might be considered protected in other contexts. See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 n.7, 105 S. Ct. 2265, 2274 n.7 (1985). Just as informational pamphlets were considered commercial speech in *Bolger*, so too nutrient content claims on food labels, as between pure speech and commercial speech, should be considered commercial speech. See *Bolger*, 463 U.S. at 66–68, 103 S. Ct. at 288–81.

298. Several comments argued that the requirement that nutrient content claims be approved by FDA before they may be used places an unconstitutional prior restraint on expression. The agency, the comments reasoned, would be banning speech not previously determined to be false or misleading. The speech would remain banned until the agency defined the term at issue. Some comments further complained that the petition process is too burdensome. Citing *Space Age Products* v. *Gilliam*, 488 F. Supp. 775 (D. Del. 1980), one comment argued that "the public has an interest in minimizing the frequency and duration of erroneously imposed prior restraints on commercial speech." Id. at 784. This interest, according to *Gilliam*, mandates narrow tailoring of prior restraints on commercial speech and "such traditional safeguards with respect to these restraints as are not inconsistent with its ability to achieve its important and legitimate objectives." Id.

The Supreme Court has said that because commercial speech is not easily chilled, the heavy presumption against prior restraints may not apply to commercial speech. *Virginia State Board of Pharmacy*, 425 U.S. at 772 n.24. The Court has repeated its position on this subject since *Space Age Products* was decided. In Central Hudson, the Court remarked that the State could have required that ads for electricity be approved by the state before being used and reiterated that traditional prior restraint doctrine may not apply to commercial speech. *Central Hudson*, 447 U.S. at 571 n. 13.

Even assuming for the sake of argument that the presumption against prior restraints does apply to commercial expression, the agency believes that its regulations are constitutional because, as discussed more fully above, they limit only speech Congress has already determined to be misleading. This speech is therefore unprotected. See *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977) (FDA regulation based on agency's conclusion that labeling that fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act was not unconstitutional prior restraint). In addition, the regulatory scheme incorporates procedural safeguards that provide for a prompt determination of whether a particular claim is permissible. The agency is required to act on nutrient content claim petitions expeditiously. See section 403(r)(4)(A) of the act.

299. Some comments argued that the requirement that the proponent of an undefined claim submit a petition for its approval unconstitutionally shifts the burden of distinguishing misleading and nonmisleading speech from the Government to the speaker. See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 646 (1985). Even a showing that the speech has the potential to mislead does not allow the Government to shift that burden, one comment contended, citing *Peel* v. *Attorney Registration & Disciplinary Comm'n*, 110 S. Ct. 2281, 2292 (1990).

As discussed above, the Government has met its burden of showing that the speech being restricted is misleading. Congress made specific findings that both nutrient content claims in general and particular terms, such as "light," have misled the public. See, e.g., 136 Congressional Record H5840 (July 30, 1990) (statement of Rep. Waxman); id. at H5843 (statement of Rep. Cooper); 136 Cong. Rec. S16609 (Oct. 24, 1990) (statement of Sen. DeConcini). In addition, the comment misconstrues *Peel*. In that case, the Supreme Court said that a mere potential to mislead did not justify prohibition of the speech at issue. The Court did not say that the Government could not, based on a showing that a particular kind of speech had the potential to mislead the public, require preapproval of the speech.

300. Some comments suggested that the nutrient content claims regulations are unconstitutionally overbroad because, according to the comments, they reach a substantial amount of protected speech.

FDA disagrees. As discussed in detail elsewhere in this document, these regulations are narrowly tailored to meet a substantial government interest and do not "sweep[] within [their] prohibitions what may not be punished under the First * * * Amendment[]." *Grayned* v. *City of Rockford*, 408 U.S. 104, 115 (1972). In any event, it is doubtful that the overbreadth doctrine would apply to these regulations, particularly if they were considered to regulate commercial speech, because the overbreadth doctrine does not apply to commercial speech. *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982); *Central Hudson*, 447 U.S. at 565 n.8.

301. One comment cited several lower court decisions involving food labeling and the first amendment to support its argument that these regulations are

unconstitutional. *Lever Bros.* v. *Maurer*, 712 F. Supp. 645 (S.D. Ohio 1989); *Taylor Wine Co.* v. *Department of the Treasury*, 509 F. Supp. 792 (D.D.C. 1981); *American Meat Inst.* v. *Ball*, 424 F. Supp. 758 (W.D. Mich. 1976); *Anderson, Clayton & Co.* v. *Washington State Dep't of Agric.*, 402 F. Supp. 1253 (W.D. Wash. 1975).

FDA disagrees with the comment's interpretation of these cases. *Anderson*, which predated *Virginia Pharmacy* and the Supreme Court's other commercial speech cases, struck down a State law prohibiting use of dairy terms in the advertising of margarine. The court mistakenly applied strict scrutiny to the statute, holding that the State must show a *compelling* government interest to justify restrictions on speech. 402 F. Supp. at 1257 (emphasis added). As discussed above, under current Supreme Court jurisprudence the Government need only demonstrate a substantial interest in regulating potentially misleading speech. *Central Hudson*, 447 U.S. at 564. If the speech is actually or inherently misleading, it may be prohibited or restricted on that basis alone. See *Peel*, 110 S. Ct. at 2292–93; In re *R.M.J.*, 455 U.S. at 203.

In *Lever Bros.* v. *Maurer*, which involved a similar statute prohibiting the use of "butter" in advertising for products intended as imitations of or substitutes for butter, the court held that prohibition of the term "butter" without regard for whether the term was used in a misleading way violated the first amendment. 712 F. Supp. at 652–653. Here, Congress has already found the labeling practices at issue to be misleading. In addition, here the Government's interest is not merely in accuracy, but also in uniformity. Standardizing the nutrition information that appears in food labeling, including nutrient content claims, will make it easier for consumers to find, understand, and compare the information they need to make healthy eating choices. No such government interest was present in *Lever Bros.*

Taylor Wine is also inapposite. That case involved a regulatory scheme that required preapproval of wine labeling. The challenge was not to the preapproval requirement itself, as here, but to the agency's refusal to approve a claim that it had conceded would not confuse or mislead consumers of the plaintiffs' wines. 509 F. Supp. at 795. In addition, the agency had conceded that the claim, which used the term "light," met the requirements established by the agency for use of that term. Id. at 793. Under the regulatory scheme at issue here, FDA will allow use of terms defined by FDA in nutrient content claims without preapproval.

Finally, in *American Meat Institute*, there was no first amendment challenge to the legislation at issue; rather, the first amendment was used to uphold the legislation against a preemption argument. The challenged legislation required meat producers whose products did not meet Michigan standards to notify Michigan consumers of that fact. The court upheld the law in part on the basis of the consumers' first amendment right to receive information. 424 F. Supp. at 769. The court further found that the State had a strong interest in consumer education and protection and suggested that striking down the statute might limit the State's communications with its citizens in violation of the first amendment. Id. at 767. The court said that the first amendment question that would arise if the Michigan law were preempted provided additional support for its holding that the notices required by the State were not "labeling" as defined in the Federal Wholesome Meat Act (21 U.S.C. 678). Id. at 769. Thus, far from serving to undermine the nutrient content claim regulations, *American Meat Institute*, if anything, supports them, since it recognizes consumers' strong interest in receiving accurate, useful information about food and the government's strong interest in ensuring that such information will be provided.

302. A number of comments argued that the rule prohibits certain nonmisleading uses of particular terms ("fresh" or "light") and types of claims (comparative statements or amount statements), and that such nonmisleading uses cannot constitutionally be prohibited.

FDA disagrees with the premise of these comments. As explained more fully above, Congress found that the unregulated use of undefined nutrient content claims is inherently and actually misleading. This final rule allows use of the referenced terms and types of claims, but only in ways that will inform the public rather than mislead it. The agency's response to the comments' suggestions concerning particular terms and types of claims can be found elsewhere in this document.

303. Two comments contended that with respect to certain types of nutrient content claims, FDA should use its authority under section 403(a)(1) of the act to regulate false and misleading claims on a case-by-case basis, rather than issuing regulations under the 1990 amendments. Specifically, the comments argued that statements of the amount or percentage of nutrients in foods (e.g., "contains 160 mg sodium") and certain ingredient claims that FDA has classified as implied nutrient content claims (e.g., "high in oat bran") should be regulated under section 403(a)(1) of the act rather than under the 1990 amendments.

FDA disagrees. Congress enacted the 1990 amendments because it found that existing law was insufficient to protect consumers from misleading food labeling practices. While FDA could have regulated deceptive nutrient content claims, including ingredient and amount claims, under section 403(a)(1) of the act, Congress considered FDA's authority to do so unclear and in need of strengthening. H. Rept. 101–538, 101st Cong., 2d sess. 7 (1990). Consequently, Congress passed new legislation directing FDA to issue new regulations that would curb deceptive food labeling. Congress specifically authorized FDA to issue regulations governing amount claims, see section 3(b)(1)(A)(iv) of the 1990 amendments, and also provided more generally for the issuance of regulations limiting the use of claims that expressly or by implication characterize the level of a nutrient required to be on the food label. See section 403(r)(1)(A) of the act. A claim that a food contains an ingredient associated with a particular nutrient by implication characterizes the level of that nutrient.

It is entirely appropriate for FDA to regulate ingredient and amount claims under the new regulations, which specifically target these claims, rather than under section 403(a)(1) of the act; indeed, FDA had no choice but to do so, given the congressional mandate. Moreover, the regulations themselves are narrowly tailored and do not prohibit nondeceptive speech.

304. Some comments asserted that FDA should not prohibit the use of undefined terms and should allow synonyms of FDA-defined terms as long as the synonyms meet the standard for the defined term.

Section 403(r)(2)(A)(i) of the act states that nutrient content claims may be made only if the characterization of the level made in the claim uses terms which are defined in regulations by the Secretary (and FDA, by delegation). This rule also applies to synonyms. See section 3(b)(1)(A) of the 1990 amendments. As discussed above, Congress was concerned about the proliferation of confusing and conflicting nutrient content claims; hence, it sought uniformity on the food label. Allowing unapproved terms and synonyms would undermine that goal. The petition process provided for in new § 101.69 allows anyone who wishes to suggest both new terms and

synonyms of already-defined terms. In light of Congress' findings and the availability of the petition process to expand the vocabulary of nutrient content claims, FDA does not believe its regulations unduly burden expression.

305. One comment proposed that FDA permit the use of unapproved nutrient content claims if they are consistent with and explained by an immediately adjacent term that is defined by regulation. The comment argued that this solution would cure the first amendment infirmity caused by the prohibition of unapproved claims yet would fulfill the goals of the 1990 amendments.

The agency rejects this suggestion because it would lead to the same kind of inconsistent use of terms that Congress wanted to eradicate. For example, one company might use "lean" as a synonym for "light," while another might use it as a synonym for "low fat." Thus, "lean" would be used in contradictory ways on different products. Such a result is not permissible under the act. As discussed above, the agency does not believe that its approach is constitutionally infirm.

306. In response to FDA's request for comments as to whether it should define "natural" or ban such claims entirely on the ground that they are false or misleading, one company argued that prohibition of "natural" would be an unconstitutional restriction on free speech. FDA has decided not to define the term "natural" or to prohibit its use. Therefore, this comment is moot.

307. One comment asserted that because those who violate the act are subject to criminal prosecution, FDA must define clearly which nutrient content claims are allowable. The comment further argued that a manufacturer who uses a term not intended as a nutrient content claim may learn, too late, that FDA so interprets it as such.

The comment seems to be invoking the vagueness doctrine, which, in the first amendment context, is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. See, e.g., *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498—99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972). That is not the case here. Only approved nutrient content claims will be permitted on the food label, and all other nutrient content claims will misbrand a food. It should thus be clear which type of speech is prohibited and which permitted. Manufacturers will be on notice that the use of an unapproved nutrient content claim is prohibited conduct.

As to the comment's second point, FDA agrees that it is important to consider intent when determining whether an implied nutrient content claim has been made. However, the agency notes that intent means more than the manufacturer's subjective intent. "FDA is not bound by the manufacturer's subjective claims of intent * * *." *National Nutritional Foods Ass'n* v. *Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). An article's intended use is established by its labeling, promotional material, advertising, and "any other relevant source." Id.; *United States* v. *An Article * * * Consisting of 216 Individually Cartoned Bottles * * * "Sudden Change,"* 409 F.2d 734, 739 (2d Cir. 1969). If a phrase on a food label meets the definition of an implied nutrient content claim, it is such a claim regardless of the manufacturer's subjective intent. The definition of an implied nutrient content claim is clear from the statute as interpreted by the regulations. See section 403(r)(1)(A) of the act; new § 101.13(b). Manufacturers are required to keep abreast of changes in the law and are responsible for scrutinizing their labeling to determine whether it makes nutrient content claims.

B. The Fifth Amendment

These regulations will affect some companies' use of brand names, including names subject to trademarks. A brand name that includes an FDA-defined nutrient content claim, such as "light," will be permitted to appear only on products that meet the regulations' definition of "light." Brand names that include nutrient content claims that FDA has not defined will not be permitted unless they were in use before October 25, 1989, the date the 1990 amendments were reported out of committee, or unless a petition for their use is submitted and approved.

308. Some comments contended that outlawing a brand name could violate the fifth amendment. Because brand names are property, banning their use could constitute a taking without just compensation, these comments argued. The comments suggested that in keeping with Executive Order No. 12630, FDA should conduct a takings analysis to assess whether compensation to owners of affected brand names would be appropriate.

In its November 27, 1991, regulatory impact analysis (RIA), 56 FR 60856 at 60865, FDA stated that any alteration of trade names required by the new regulations would not constitute a taking, and that, as a result, no takings analysis was necessary. In view of the comments and concerns raised about the takings issue, however, the agency reconsidered and decided that it was appropriate to conduct a formal takings analysis pursuant to Executive Order No. 12630. The agency has completed the takings analysis and still believes that there is no regulatory taking under the fifth amendment if a manufacturer is required to alter its brand name when that brand name asserts, expressly or by implication, a nutrient content claim that has not been approved by FDA. The basis for this conclusion is set forth in response to the comment that follows.

309. Comments from industry argued that the regulations' effect on companies' ability to use brand names constitutes a taking without compensation in violation of the fifth amendment of the U.S. Constitution. They point foremost to the financial consequences of losing the use of a valuable brand name. Standing alone, however, diminution in property value does not establish a taking. *Penn Central Transp. Co.* v. *City of New York*, 438 U.S. 104, 131 (1978). Indeed, "[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law." *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 413 (1922).

The Supreme Court has identified three factors for courts to consider in assessing whether a regulatory taking has occurred: (1) The character of the governmental action; (2) the extent to which a regulation interferes with reasonable investment-backed expectations; and (3) the regulation's economic impact. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 1005 (1984); *Penn Central*, 438 U.S. at 124. When examined in light of these three factors, it is clear that FDA's regulations do not effect a taking in violation of the Constitution.

With respect to the first factor, courts are more likely to find a taking when the interference with property can be characterized as a physical invasion by the Government than when the interference is caused by a regulatory program that "adjust[s] the benefits and burdens of economic life to promote the common good." *Penn Central*, 438 U.S. at 124. Courts have accorded particular deference to governmental action taken in order to protect the public interest in health, safety, and welfare. See *Keystone Bituminous Coal Ass'n* v. *DeBenedictis*, 480 U.S. 470, 488 (1987); *Penn Central*, 438 U.S. at 125; *Atlas Corp.* v. *United States*, 895 F.2d 745, 757 (Fed. Cir.), cert. denied, 111 S. Ct. 46 (1990);

Calvert Invs. v. *Metro. Sewer Dist.*, 847 F.2d 304, 309 (6th Cir. 1988).

With the 1990 amendments and these regulations, Congress and FDA seek to protect the public interest in health by ensuring that consumers who wish to maintain healthy dietary practices may be assisted in doing so by the information on food labels. This action constitutes a reasonable effort by the Government to promote the common good. By defining nutrient content claims, the regulations will "bring a sense of order to the understanding of terms used when describing characterizations of food products." 136 Congressional Record S16610 (Oct. 24, 1990) (statement of Sen. Hatch). By permitting approved nutrient content claims, the regulations seek to provide useful information to consumers while ensuring that the information is not confusing or misleading. 136 Congressional Record H12954 (Oct. 26, 1990) (statement of Rep. Moakley). These regulations substantially advance and are rationally related to FDA's legitimate interest in promoting the public health through the food label. See *Keystone*, 480 U.S. at 485; *Monsanto*, 467 U.S. at 1007; see also *Pace Resources, Inc.* v. *Shrewsbury Township*, 808 F.2d 1023, 1030 (3d Cir.) ("[T]he governmental action is entitled to a presumption that it does advance the public interest."), cert. denied, 482 U.S. 906 (1987).

Although these regulations will restrict the use of certain defined terms, including terms that appear in some trade names, this restriction does not rise to the level of a taking. Governmental restrictions on the uses individuals can make of their property are "properly treated as part of the burden of common citizenship." *Keystone*, 480 U.S. at 491 (citation omitted). These burdens are "borne to secure 'the advantage of living and doing business in a civilized community.'" *Andrus* v. *Allard*, 444 U.S. 51, 67 (1979) (quoting *Pennsylvania Coal Co.* v. *Mahon*, 260 U.S. 393, 422 (1922) (Brandeis, J., dissenting)). Moreover, these regulations are not without benefit to manufacturers. See *Keystone*, 480 U.S. at 49[illegible] While each of us is burdened somewhat by such restrictions, we, in turn, benefit greatly from the restrictions that are placed on others."); see also *Penn Central*, 438 U.S. at 134 ("preservation of landmarks benefits all * * * citizens and all structures"). By defining certain terms, the regulations will increase the reliability of the food label and thus will bolster consumer confidence in label statements. They will also level the commercial playing field: No manufacturer will be able to use a defined term unless its use is consistent with the definition.

The second factor that courts consider is whether a company has a reasonable investment-backed expectation in continuing to use its brand name. To be reasonable, expectations must take into account the power of the State to regulate in the public interest. *Pace Resources*, 808 F.2d at 1033. Reasonable expectations must also take into account the regulatory environment, including the foreseeability of changes in the regulatory scheme. "In an industry that long has been the focus of great public concern and significant government regulation," *Monsanto*, 467 U.S. at 1008, the possibility is substantial that there will be modifications of the regulatory requirements. "Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end." *Connolly* v. *Pension Benefit Guar. Corp.*, 475 U.S. 211, 227 (1986) (citation omitted); cf. *Lucas v. South Carolina Coastal Council*, 112 S. Ct. 2886, 2899 (1992) ("[I]n the case of personal property, by reason of the State's traditionally high degree of control over commercial dealings, [the property owner] ought to be aware of the possibility that new regulation might even render his property economically worthless * * * ."). Participants in a highly regulated industry are "on notice that [they] might be subjected to different regulatory burdens over time." *California Housing Secs., Inc.* v. *United States*, 959 F.2d 955, 959 (Fed. Cir. 1992), petition for cert. filed, 61 U.S.L.W. 3083 (U.S. July 22, 1992). In contrast, a regulatory scheme that appears suddenly may interfere with a company's reasonable expectations. Id.

It is not reasonable for a company to expect to be able to continue indefinitely to use a brand name that contains a defined nutrient content claim. Such an expectation would ignore FDA's power to regulate the food label, the regulatory environment of the food industry, and the foreseeability that FDA would regulate health and content claims on the food label.

FDA's authority to regulate the food label is broad and longstanding. Governmental authority to regulate the food label has long been recognized. For example, the Supreme Court stated in 1919 that "it is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold." *Corn Products Refining Co.* v. *Eddy*, 249 U.S. 427, 431 (1919). With the 1990 amendments, Congress did not suddenly grant the agency new authority of the sort that interfered with a company's reasonable expectations about the way the food label would be regulated, see *California Housing Secs.*, 959 F.2d at 959, but rather clarified FDA's authority to define nutrient content claims. The authority granted by the 1990 amendments was consistent with FDA's existing power over the food label. For example, FDA already had authority to define common or usual names for food and to set standards of identity. See, e.g., *American Frozen Food Inst.* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977). Moreover, under preexisting authority—e.g., sections 201(f) and (n) and 403(a) and (j)—the agency had regulated or taken steps to regulate nutrient content claims on the food label. Although FDA had earlier regulated the use of certain nutrient content claims, the 1990 amendments gave the agency specific authority to define terms such as "light" and "low" consistently across product categories. See, e.g., 136 Congressional Record H12953–54 (Oct. 26, 1990) (statement of Rep. Madigan).

Moreover, the food industry is highly regulated. Companies are well aware that they operate subject to the restrictions of the act. Like other regulatory schemes, the act has not been static, see *California Housing Secs.*, 959 F.2d at 959, and companies that are subject to the act should understand the possibility that its requirements will evolve over time. The food industry has long been "the focus of great public concern and significant government regulation," and "the possibility was substantial" that the government would, "upon focusing on the issue," decide that the actions now being undertaken are in the public interest. *Monsanto*, 467 U.S. at 1009.

Not only was the industry on notice that the regulatory scheme under which it operated might be amended, but it also had specific notice of the type of action FDA might take with respect to the food label. FDA promulgated regulations on the use of certain nutrient content claims years before the 1990 amendments were passed. The terms "sodium free," "very low sodium," "low sodium," and "reduced sodium" are defined in current § 101.13. Current § 101.25 governs information that may appear on food labels regarding fat, fatty acid, and cholesterol content. Current § 105.66 controls the use of the claims "low calorie," "reduced calorie," and "sugarfree." It would be unreasonable for a company to expect that the agency would forever

refrain from further regulation of nutrient content claims.

Thus, companies that use brand names that contain express or implied nutrient content claims lack a reasonable investment-backed expectation that they will be able to continue to use those names. Only with the passage of the 1990 amendments and the publication of these final rules does the possibility arise that a company might have a reasonable investment-backed expectation in continuing to use an approved claim. See *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. at 1010–1013.

The final factor that courts consider is the economic impact of the governmental action. "There is no fixed formula to determine how much diminution in market value is allowable without the Fifth amendment coming into play." *Florida Rock Industries, Inc.* v. *United States*, 791 F.2d 893, 901 (Fed. Cir. 1986), cert. denied, 479 U.S. 1053 (1987). It is clear, however, that a regulation's economic impact may be great without rising to the level of a taking. See *Pace Resources*, 808 F.2d at 1031 (citing *Hadacheck* v. *Sebastian*, 239 U.S. 394 (1915) (reduction in value from $800,000 to $60,000); *Euclid* v. *Ambler Realty Co.*, 272 U.S. 365 (1926) (75 percent diminution in value)). Mere denial of the most profitable or beneficial use of a property does not require a finding that a taking has occurred. *Tirolerland, Inc.* v. *Lake Placid 1980 Olympic Games, Inc.*, 592 F. Supp. 304, 313 (N.D.N.Y. 1984); see also *Andrus* v. *Allard*, 444 U.S. 51, 66 (1979); *Florida Rock*, 791 F.2d at 901. Rather, courts look for extensive or drastic interference with a property's possible uses. See *Pace Resources*, 808 F.2d at 1031.

In assessing whether a regulation effects a taking, the Supreme Court has considered whether the regulation denies an owner the "economically viable" use of its property. See, e.g., *Keystone*, 480 U.S. at 499. This analysis involves looking not just at what has been lost, but at the whole "bundle" of property rights. *Andrus* v. *Allard*, 444 U.S. at 65–66. Courts focus on the remaining uses permitted and the residual value of the property. *Pace Resources*, 808 F.2d at 1031. Although it is undeniable that compliance with these regulations will cost money and may mean that certain product names must be altered, companies will not be denied the economically viable use of their property.

Many firms will be able to minimize the regulations' impact by reformulating those products that do not meet the regulations' definitions. These reformulated products could continue to bear the original brand name. Reformulation may be costly, but it is not the kind of economic impact that leads to a taking. "Requiring money to be spent is not a taking of property." *Atlas Corp.*, 895 F.2d at 756. Nor may companies argue, as one comment did, that their legal and other costs of seeking compensation for losses from these regulations should be included in the assessment of economic impact. These costs are not included in calculating just compensation under the fifth amendment. *United States* v. *Bodcaw Co.*, 440 U.S. 202, 203 (1979); *United States* v. *101.80 Acres*, 716 F.2d 714, 717 n.5 (9th Cir. 1983).

Other companies may be able to continue using their brand names with some, but not all, of their products. These companies will retain a residual economically viable use of their brand names. These companies will retain the ability to use their brand names on some of their products. Those with trademarks will also retain the important right to prevent other companies from marketing under the protected name. See *PruneYard Shopping Center* v. *Robins*, 447 U.S. 74, 82 (1980) ("[O]ne of the essential sticks in the bundle of property rights is the right to exclude others."). They would, moreover, be able to market new products that meet the applicable definition under the brand name. And finally, those foods that could not be marketed under the original brand name may continue to be sold under another name that does not violate the regulations.

It is unlikely that these regulations will force any company to stop using a brand name entirely. However, even if these regulations do have such an effect, the economic impact of this loss, without more, would not establish a taking: It is also critical to consider the character of the Government's action and its interference with reasonable investment-backed expectations. In addition, a company in this position lacks a property right to continue marketing a product under a defined term that its food does not meet. See 56 FR 60856 at 60865, November 27, 1991. For example, a food that bears a "light" claim but does not meet the definition of "light" and cannot be reformulated as a "light" product is not light and should not be called "light." Such a product is misbranded not only under section 403(r) of the act but also under section 403(a)—that is, even before the passage of the 1990 amendments, its labeling was false or misleading and in violation of the act. See *Lucas* v. *South Carolina Coastal Council*, 112 S. Ct. 2886, 2901 (1992) ("The use of these properties for what are now expressly prohibited purposes was always unlawful * * *.").

310. One comment inquired why, if so many misbranded products were on the market before the 1990 amendments, FDA did not take action to stop the misbranding.

In fact, FDA did send warning letters to a number of manufacturers who were making misleading claims. In virtually all of these cases, the manufacturer removed the misleading claim from the product. The agency would have done more but for lack of resources. In addition, consumer confusion resulted as much from the lack of any defined standards for claims as from individual claims that were objectionable. To solve the problem, it was necessary to address it globally by developing a regulatory scheme designed specifically for nutrient content claims.

311. One comment argued that to avoid an unnecessary taking, the agency should interpret section 403(r)(2)(C) of the act (the grandfather clause) to apply to product line extensions. The comment asserts that section 403(r)(2)(C) of the act is ambiguous and reads FDA's proposed implementing regulation (proposed § 101.13(o)(1)) to extend grandfathering to new products introduced under an existing brand name.

FDA does not believe the grandfather clause is ambiguous but has revised its regulation (new § 101.13(p)(1)) to clarify that the grandfather clause does not apply to product line extensions. The grandfather clause provides that unapproved nutrient content claims that are part of the brand name of a food are permitted if the brand name was in use *on the food* before October 25, 1989—not if the brand name was being used on some other food before that date (emphasis added). Therefore, new products introduced under the same brand name are not covered. Any company that started using a preexisting brand name on a new product after the grandfather date did not have a reasonable expectation of being able to use the name on that product. Therefore, the regulation does not effect a taking.

312. Another comment contended that the wording of the grandfather clause demonstrates that a product whose brand name includes an undefined nutrient content claim is not necessarily misbranded under section 403(a) of the act, which proscribes false and misleading labeling. The comment reasoned that, where there are two brand names that contain the same undefined claim—one grandfathered, one not—it would be absurd to say that

the nongrandfathered brand name is misleading, but that the grandfathered brand name is not.

The agency agrees that a grandfathered brand name is not necessarily false or misleading under section 403(a) of the act, nor is a nongrandfathered brand name that makes the same claim. A product with a nongrandfathered brand name that makes an unapproved nutrient content claim is misbranded under the 1990 amendments, however, because they prohibit the use of undefined claims. See section 403(r)(1)(A) of the act. Moreover, after the claim has been defined, both the grandfathered and nongrandfathered product will be misbranded under both section 403(a) of the act and the 1990 amendments if they do not conform to the definition. (See section 403(r)(2)(C).)

It should be noted that Congress did not make a judgment as to whether grandfathered brand names are misleading or nonmisleading; rather, it decided not to disrupt the market until FDA had a chance to define the terms used in grandfathered brand names. There is no taking of an undefined, nongrandfathered brand name because companies had no reasonable investment-backed expectation of being able to use undefined claims after the 1990 amendments were reported out of committee.

It should be pointed out that it is the statute, not FDA's regulations, that forbids the use of undefined terms in nutrient content claims.

313. The same comment argued that because the Patent Office considers the comment's trademark nondeceptive, the company has a reasonable, investment-backed expectation of being able to use the trademark.

The agency disagrees. FDA, not the Patent Office, has primary expertise in food labeling, and FDA does not consider itself bound by the Patent Office's decision as to whether a trademark is misleading.

314. Two comments argued, citing FTC case law, that the policy of the law to preserve trade names protects them from destruction if less drastic means would prevent deception. See *Jacob Siegel Co.* v. *FTC*, 327 U.S. 608, 612 (1946); *FTC* v. *Royal Milling Co.*, 288 U.S. 212, 217 (1933). The comments argued that prohibiting certain brand names is inappropriate because deception can be prevented by adding disclaimers or explanations to the brand names. One comment said the cited cases are rooted in takings doctrine. The other asserted that these cases are based on first amendment principles. See *Beneficial Corp.* v. *FTC*, 542 F.2d 611, 620 (3d Cir. 1976), cert. denied, 430 U.S. 983 (1977).

FDA disagrees with these comments. According to *Jacob Siegel Co.*, whether prohibition of a trade name is necessary "is a question initially and primarily for the [agency] * * * [which] is the expert body to determine what remedy is necessary to eliminate the unfair or deceptive trade practices which have been disclosed." 327 U.S. at 612. In another case, the Supreme Court upheld the prohibition of a trade name when, in the agency's judgment, the prohibition was necessary to prevent deception. *FTC* v. *Algoma Lumber Co.*, 291 U.S. 67, 81–82 (1934). With respect to food labeling, no disclaimer or explanation could eliminate the deceptive effect of a brand name that incorporates an FDA-defined term if the food on which the brand name appears does not meet the definition of that term.

The Supreme Court recently acknowledged the protection given to trade names in *Jacob Siegel* and *Royal Milling*, which were decided under section 5 of the Federal Trade Commission Act (15 U.S.C. 45) (the FTC act), but also recognized that those decisions rested on statutory—not constitutional—grounds. The court made clear that the holdings of those decisions do not carry over to cases decided on first amendment principles alone:

> [T]here is no First Amendment rule, comparable to the limitation on § 5, requiring a State to allow deceptive or misleading commercial speech whenever the publication of additional information can clarify or offset the effects of the spurious communication. *Friedman* v. *Rogers*, 440 U.S. 1, 12 n.11 (1979). Like the first amendment, the act contains no limitation comparable to section 5 of the FTC act.

Finally, FDA is not bound to follow FTC case law. Although cases involving FTC may sometimes be relevant, it is important to note that fundamental differences exist between the regulatory schemes administered by the two agencies. See *Bristol-Myers Co.* v. *FTC*, 738 F.2d 554, 559 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985). Congress has long recognized the division of roles between the two agencies. See 79 Congressional Record 4749 (1935), reprinted in "Federal Food, Drug, and Cosmetic Act: A Statement of its Legislative Record" 280–81 (Charles W. Dunn ed., 1938) (statements of Senators Copeland and Austin) (FTC concentrates on the interests of commerce and economic needs, whereas the objective of FDA is "the health of the people"). The FTC regulates unfair competition and trade practices, including food advertising. See, e.g., 15 U.S.C. 45 and 52. In contrast, FDA is a scientific agency empowered to regulate the food label, among other things. Thus, FTC case law does not govern FDA regulation.

VII. Other Issues

315. One comment stated that because of the range of meanings already attached to terms such as "light," "low," "free," "source of," and "reduced," FDA's attempt to define such terms will not be completely successful at eliminating confusion. The comment suggested that a better approach would have been for FDA to create a set of terms, either chosen from words not currently used in relationship to food or completely made up, to attach to their definitions instead of attempting to define terms already in vogue.

In response to this comment addressing the agency's basic approach to defining terms used to make nutrient content claims, the agency advises that many of the terms that it is defining are those that the 1990 amendments require the agency to define. Section 3(b)(1)(A)(iii) of the 1990 amendments directs the agency to define the terms "free," "low," "light" or "lite," "reduced," "less," and "high" when these terms are used to characterize the level of any nutrient in food, unless it finds that the use of such terms would be misleading. The agency has not found that any of these terms are misleading per se, although some consumer confusion as to their meanings may exist as a result of the variety of ways in which they have been used in the marketplace. Providing regulatory definitions for these terms that must be used by any manufacturers that use these terms in their labeling should alleviate or eliminate confusion. Therefore, the agency does not have the prerogative of creating a set of terms for nutrient content claims that have not previously been associated with claims for food as the comment suggested.

316. One comment stated that nutrient content claims such as "free," "low," and "reduced" should be defined for modified lactose levels in foods.

The agency does not agree with this comment. These regulations are intended to define nutrient content claims for categories of nutrients or individual nutrients that are required for maintaining a diet that meets current dietary guidelines (e.g., fiber, cholesterol, and fat). Lactose, a sugar that occurs in milk, is not a nutrient addressed in current dietary guidelines. However, labeling in regard to the lactose content of a food does have

significance for individuals who cannot tolerate this nutrient. FDA advises that provisions for the labeling of hypoallergenic foods are in § 105.62.

317. A comment stated that someone will still have to "educate" consumers about the meaning of the terms that FDA is defining. Another comment recommended that since terms are meaningless without the definitions to help distinguish among them, glossaries of allowed nutrient content claims should be available at points of purchase in the form of posters and free pamphlets. An alternative suggested in the comments was to abandon the effort to simplify nutrition information for consumers, to disallow claims on labels, and to educate consumers to interpret nutrition labels.

FDA does not agree that it should disallow claims on labels and instead only educate consumers to interpret nutrition labels. FDA believes that claims serve to highlight important nutritional aspects of foods, and as a result, they assist consumers in the identification and selection of foods that are useful for meeting dietary goals.

FDA agrees that educational programs will be necessary to develop consumer and industry understanding of the regulatory definitions. Section 2(c) of the 1990 amendments calls for activities that educate consumers about nutrition information on the food label and the importance of that information in maintaining healthy dietary practices. To achieve this purpose, FDA and USDA have jointly initiated a multi-year food labeling education campaign. The major goals of this campaign are to: (1) Increase consumers' knowledge and effective use of the new food label and to assist them in making accurate and sound dietary choices; (2) to integrate food labeling education into existing and new nutrition and health education programs; and (3) to build extensive partnerships capable of developing and evaluating labeling education targeted to the dietary needs of diverse populations, such as low literacy consumers, minorities, older Americans, children, and people with dietary restrictions.

As part of this effort, the agencies have established the National Exchange on Food Labeling Education which includes an information center housed in the Food and Nutrition Information Center at the National Agricultural Library. It provides the general public and professionals with access to information about food labeling research and educational activities (projects, programs, and materials) from both the public and private sector. Together, the agencies will facilitate cooperative projects with diverse organizations and the communication of information that targets various subpopulations as well as the general public. Thus, the agencies are developing an extensive food label education network that includes consumers; health professionals and organizations; educators; trade associations; Federal, State, and local governments and many others, to assist in the dissemination and development of information and activities.

To ensure that consumers have accurate and adequate resource materials and information, the agencies have begun, and will continue to: (1) Conduct and report on existing and planned food labeling research; (2) develop education initiatives at the national and local levels; (3) hold regularly-scheduled meetings to build labeling education exchanges; (4) produce video news releases and longer videos; and (5) produce an array of public education materials, including a special edition of *FDA Consumer* magazine that summarizes the final food labeling regulations, and brochures (in English and other languages) on the new label and how to use it to meet the Dietary Guidelines for Americans. These materials will be targeted to the general public, nutritionists, such special groups as ethnic minorities, and others. Organizations will also be able to use these resource materials to develop educational materials of their own.

318. Several comments stated that the proposed rules define claims so narrowly and require such burdensome disclosure requirements that manufacturers would have little or no incentive to develop new nutritionally improved products to qualify for nutrient content claims, to make substantial investments in research and development, or to develop the supporting manufacturing marketing capabilities.

The agency agrees that new products that are truly nutritionally improved can make positive contributions to public health. Thus, FDA is sensitive to the concerns raised by the comments that the proposed definitions could inhibit innovation. In response, FDA has attempted in the final regulations to make the definitions more flexible, while at the same time ensuring that the terms will be useful in maintaining healthy dietary practices and will be used in a manner that is truthful and not misleading. FDA believes that the final regulations, as revised, will stimulate innovation in food product research and the development of new versions of foods and food formulations that will meet the definitions, because nutrient content claims are an important aspect of a product's marketability.

319. Several industry comments stated that because these regulations depart significantly from the European Community (EC) nutrition labeling directive and from the Food Agricultural Organization/World Health Organization (FAO/WHO) Codex International recommendations, they will impede the resolution of differences under the General Agreement on Tariff and Trade.

The agency recognizes that the 1990 amendments and substantive provisions of these regulations are not in complete accord with the FAO/WHO Codex food labeling regulations or with regulations or directives of the EC or other countries. The agency also recognizes that this is an area that the FAO/WHO Codex has not yet addressed. Therefore, the regulations may have an impact on the resolution of issues related to international trade. However, these regulations are fully responsive to the 1990 amendments. The agency believes that these regulations will provide U.S. consumers with accurate and reliable information, information that consumers in other countries could use and may demand of their food regulators. The agency believes that the principles of these regulations may be adopted by other countries and serve as a basis for harmonization. This agency is committed to working with representatives of other nations and international organizations to achieve the greatest degree of harmonization possible.

VIII. Terms that Describe Other Aspects of Food

A. "Fresh" and Related Terms

The 1990 amendments do not require that FDA define labeling terms such as "fresh" that do not make nutrient content claims. However, the continued misuse of "fresh" and related terms in the marketplace, and the consumer confusion that has resulted, led the agency to propose definitions in the general principles proposal that establish labeling regulations to govern the use of "fresh," "freshly——" (e.g., "freshly baked"), and "fresh frozen" as they appear on the label or in the labeling of foods, including the use of these terms in brand names and as sensory modifiers (fresh tasting) (56 FR 60421 at 60462).

FDA also identified several questions in the general principles proposal regarding the use of the term "fresh" and solicited comments on whether these should be addressed in the final rule. The agency asked whether: (1) It

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should allow the use of the term "fresh" to describe certain raw foods that have been treated with ionizing radiation in accordance with § 179.26 (21 CFR 179.26), specifically, those foods where irradiation at a maximum dose of 1 kiloGray (100 kilorads) is permitted; (2) it is appropriate to limit use of the term "freshly —— " to foods that are available for sale within 24 hours of preparation as the agency proposed, or whether other approaches to defining this term should be considered and incorporated into the final rule; (3) it would be misleading to allow the use of the term "freshly prepared" to describe recently prepared foods that contain processed ingredients; (4) it is important to the consumer to be able to distinguish between processed products made with fresh, as opposed to processed ingredients, and whether FDA should permit the use of a factual statement such as "spaghetti sauce—made with fresh mushrooms" on processed foods made from fresh as opposed to processed fruits and vegetables. Related to this issue, FDA requested comments on whether the inclusion of blanching as part of a continuous process at a facility should preclude labeling the ingredient as fresh; (5) the use of remanufactured ingredients affects the attributes of a finished product, such as a tomato product, to such a degree that the consumer is misled about the product if its labeling does not specifically declare the remanufactured nature of the ingredient. The agency asked whether it should require the use of a term such as "reconstituted," "remanufactured," or "made from concentrate" on the PDP of processed products made from remanufactured ingredients; and (6) extended shelf life foods merit the use of the term "freshly prepared," and if so, what factors should be considered to ensure that the term is not used in a misleading manner.

320. Several comments objected to the agency issuing a regulation that would define "fresh" and related terms while it is implementing the mandatory requirements of the 1990 amendments. These comments argued that a regulation governing the use of the term "fresh" is not mandated by the 1990 amendments and does not meet the President's reform directive of January 28, 1992. Some of these comments urged FDA to defer rulemaking on use of the term "fresh" until after it completes the mandatory rulemaking required by the 1990 amendments.

The agency does not agree that it should defer rulemaking to define "fresh." Although the 1990 amendments do not require the agency to define the term "fresh," FDA believes that a definition for certain uses of the term "fresh" is necessary because the term has been continuously misused in certain contexts. FDA concludes that a regulatory definition will discourage such misuse and will allow the agency to efficiently enforce the misbranding provisions of the act, particularly section 403(a) of the act, when the term is misused.

In issuing regulations concerning use of the term "fresh," the agency has also taken into account the requirements outlined in the President's reform directive regarding burdensome government regulations. Having concluded that it is necessary to promulgate regulations concerning use of the term "fresh," the agency considers that taking such action at this time is the most cost effective option because any required labeling changes that result from this action can be accomplished simultaneously with the label changes required by the 1990 amendments.

321. Comments addressing the proposed definition for the term "fresh" expressed widely diverse views on this subject. The agency received comments that supported the proposed definition, suggested alternatives to it, opposed the provision as proposed, or opposed FDA defining the term altogether.

Comments suggested that "fresh" should be defined as recently made, produced, or harvested foods that are not stale, spoiled, or withered. Numerous comments suggested that in addition to defining "fresh" as meaning raw and unprocessed, the term can also be associated with product quality, and therefore, a case-by-case determination may have to be made to determine where misleading uses of "fresh" have occurred rather than establishing one definition for the term. Some other comments contended that "fresh" has various meanings, and that the context in which it is used should ultimately dictate its meaning. One comment argued that the term "fresh" should be defined in such a way to distinguish between "garden fresh" and "market fresh."

Some comments that favored a regulation to govern the use of "fresh" suggested that the term should not refer to products prepared from concentrates, to commercially packed pasteurized products, or to products that are stored in cold storage warehouses until they are marketed. Some of these comments also stated that raw produce that has been trimmed or cut into smaller pieces should not be precluded from being described as fresh.

Some comments suggested that the proposed definition was too restrictive and did not consider the many ways consumers use and understand "fresh" because, as defined in the proposal, the term could only be used to describe raw, unprocessed foods. For example, these comments pointed out that, as proposed, the term "fresh" could not be used to describe some foods that are generally accepted by consumers as "fresh," such as fresh bread and pasteurized milk.

Some comments argued that there are numerous consumer perceptions associated with the term, and therefore, it is impossible to derive one definition that is universally acceptable. Another comment suggested that FDA should not permit the use of the term "fresh" on food labels because it is too difficult to define the term in a manner that would encompass all of the ways consumers use and understand it.

The volume of comments that expressed significantly different conceptions about the term "fresh," and that expressed reservations about the proposed definition of "fresh," has led FDA to reconsider this provision. FDA has been persuaded that the proposal was too restrictive, because it did not allow for various contexts in which "fresh" is appropriately used and would have disallowed uses of this term that are not misleading and are widely accepted by consumers ("fresh bread"). After considering all of the comments, FDA concludes that it is not necessary to establish a definition for "fresh" that would address all uses of this term as the proposal would have done.

However, FDA concludes that a definition for "fresh" is necessary to preclude the types of misuses of the term that the agency most frequently encounters, i.e., use of the term to imply that a product is unprocessed, when in fact it has been processed. The definition has particular applicability where there are processed and unprocessed forms of the food available. The use of the term "fresh" would imply that the food is the unprocessed form. If this is not the case, the food is misbranded. Therefore, FDA has revised the definition of "fresh" in § 101.95(a) so that it retains the same criteria that were in the proposal, but it only applies the criteria when the term "fresh" is used in a manner that suggests or implies that the food is unprocessed.

FDA is providing some examples of how certain foods relate to the definition of "fresh." These examples are intended to be illustrative. Except in a few cases where FDA believes clarification is necessary, FDA is not providing specific guidance in this final

rule on the many types of foods for which comments stated an opinion concerning the appropriateness of the use of the descriptive term "fresh." Under the definition of "fresh" that the agency is establishing, foods such as cut raw vegetables and expressed juices from raw produce could bear the term "fresh" on the label because these foods meet the requirements of the definition. However, if the term "fresh" were used to describe a pasteurized orange juice, that term would misbrand the product because when used in this context, the term implies that the food is unprocessed (e.g., fresh squeezed orange juice), when in fact it is a pasteurized food.

By contrast, in the case of pasteurized milk that is labeled as "fresh," such a food would not be subject to new § 101.95(a) because this term does not imply that milk is unprocessed inasmuch as consumers recognize that milk is nearly always pasteurized, and that unpasteurized milk (in states where it is permitted to be sold) would be labeled as "raw" milk. Also, the term "fresh" as used on bread would not be subject to new § 101.95(a) because bread is not a food that exists in a raw state, and the term "fresh bread" does not imply that the food is unprocessed and in its raw state. For clarity, FDA is including milk in § 101.95 as an example of a use of the term "fresh" that is not subject to this regulation, and pasta sauce as an example of a food that is subject to this regulation.

The agency advises that uses of the term "fresh" to describe foods that do not suggest or imply that a food is unprocessed will not be subject to the definition established for "fresh." However, all uses of this term in food labeling are subject to the requirements of 403(a) of the act, the act's prohibition of false or misleading labeling. Therefore, the agency has the authority to take action on a case-by-case basis against foods that use the term "fresh" on the label in a manner that is false or misleading, even though the food may not be subject to new § 101.95(a).

322. One comment stated that the agency should adopt FSIS' policy memo 022C that outlines conditions in which the term "fresh" can be used on approved labeling of meat and poultry products. FSIS' policy memo 022C states that the term "fresh" may not be used as part of a name on any product that is canned, cured, dried, chemically preserved, or hermetically sealed. In addition, FSIS' policy memo 022C states that "fresh" may not be used on any poultry or poultry part that has been frozen or previously frozen at or below zero degrees Fahrenheit.

FDA does not find it appropriate to adopt FSIS' policy memo O22C that addresses use of the term "fresh" on the labeling of meat and poultry products. Although the memo has provided FDA with useful information in formulating its "fresh" policy, the reference of the policy memo is limited in that it specifically addresses meat and poultry products and the conditions under which they are sold. Therefore, the agency does not find merit in the suggestion that it adopt the provisions set forth in that policy memo.

323. Several comments addressed the use of "fresh" as it relates to crabmeat. Comments on this issue urged FDA to reconsider its definition for "fresh" because as proposed, it would prohibit the use of this descriptor to describe crabmeat. These comments argued that it is not feasible for consumers to purchase raw crabmeat, and, furthermore, use of the term "fresh" has been traditionally associated with crabmeat that has been cooked and picked but not subjected to any other processing procedures. Other comments stated that some consumers look for the term "fresh crabmeat" as a way of distinguishing it from pasteurized crabmeat that is a lower price and that requires special handling.

FDA finds that the terms "fresh" or "fresh picked" as used to distinguish picked crabmeat from pasteurized crabmeat is not a use of the term "fresh" that implies that the food is unprocessed (as it is understood to mean that the food has been cooked and is not raw), nor is it misleading to consumers who are accustomed to this usage. Therefore, such use of the term is not subject to new § 101.95(a), and FDA will not object to such usage of the term.

324. One comment disagreed with some of the proposed exemptions that allowed for use of the term "fresh," i.e., (1) If an approved wax or coating has been applied to raw produce, (2) if a mild chlorine or mild acid wash has been applied to raw produce, or (3) if raw produce has been treated with approved pesticides after harvest. The comment stated that it is misleading to use the term "fresh" to describe raw produce that has been washed with a chlorine or mild acid wash, waxed, or treated with an approved pesticide. However, another comment suggested that the agency should permit use of the term "fresh" on foods whose surface is treated with ascorbic acid, calcium chloride, citric acid, potassium chloride, or sodium bisulfite, provided that these treatments are used at levels allowed by FDA regulations. The comment argued that these treatments affect a food's surface, and that they do not appreciably affect the body or alter the state of the food.

The agency does not agree that surface treatments such as waxing, washing with a mild chlorine or a mild acid wash, or the use of an approved pesticide should preclude describing the food as "fresh." As stated in the proposal, these applications are recognized as routine practices in the distribution and handling of raw produce. However, the agency does not agree that the use of the term "fresh" is appropriate if a food has been subjected to chemical treatments, including but not limited to antioxidants, antimicrobial agents, or preservatives, that introduce chemically active substances that remain in or on the food to preserve or otherwise affect the food. Thus, FDA is not providing for the use of the term "fresh" on foods that have been treated with the substances listed in the second comment. FDA is, however, retaining the exempting provisions in the final rule and is redesignating them as § 101.95(c)(1).

325. A number of the comments stated that use of low dose ionizing radiation has little effect on the attributes of a food in its raw state, and that "fresh" labeling should be permitted for foods that have been treated with low dose ionizing radiation. Other comments that supported the use of the term "fresh" on some irradiated foods suggested that irradiation enables a product to remain wholesome.

A small number of comments argued that use of the term "fresh" to describe certain irradiated raw foods would be misleading because irradiation is considered to be a form of processing that results in a loss of vitamins in foods. The comments also stated that safety procedures have not been established for irradiated foods, and that irradiation may affect the food in some unhealthful way. None of the comments that opposed the use of ionizing radiation on raw unprocessed foods provided the agency with supporting data to substantiate these claims. A few comments suggested that the labeling information associated with irradiated foods should state whether the food has been exposed to gamma or ionizing radiation from man-made sources. The majority of the comments agreed that the agency should require comprehensive and informative labeling on any raw unprocessed food that has been irradiated.

After reviewing the comments pertaining to the use of "fresh" to describe foods that have been exposed to ionizing radiation, the agency notes

that the concerns expressed relate primarily to safety and to the use of appropriate labeling to identify foods that have been irradiated. These comments appear to confuse safety and proper identification of foods that have been irradiated with perceptions related to the state of freshness of these foods. None of the comments, however, provided information to support the contention that use of currently approved low doses of irradiation on raw foods (not exceeding 1 kiloGray (100 kilorads)) would degrade the characteristics of a food associated with a food's raw state.

Under the provisions of § 179.26(b), irradiation of fresh foods is limited to the use of low dose irradiation (not to exceed 1 kiloGray) for the purpose of disinfestation of arthropod pests in food, for growth and maturation inhibition of some fresh foods, and for control of Trichina spiralis in pork carcasses. In approving these uses of irradiation, the agency concluded that foods treated with the approved levels of ionizing irradiation are safe. FDA requires that retail packages and bulk containers of such food bear a unique logo that distinguishes irradiated from nonirradiated foods and the statement "treated with radiation" or "treated by irradiation" (§ 179.26(c)). Therefore, FDA concludes that the safety and proper identification of any food that has been treated with low dose ionizing irradiation is not relevant in determining whether food that is "fresh" under § 101.95 before irradiation can continue to be described as "fresh" after such treatment.

The test for determining the appropriateness of applying the term "fresh" to foods treated with post harvest applications, including treatment with low dose irradiation, is the effect that the process has on a food. The low doses of irradiation approved for fresh foods (less than 1 kiloGray) are used to prevent maturation (sprouting) and to kill insects (§ 179.26(b)). Exposure of raw food to low dose irradiation typically causes insignificant changes in their appearance and nutrient content. While it is true that certain vitamins are sensitive to irradiation, the available literature indicates that foods irradiated at levels below 1 kiloGray are not nutritionally inferior to unirradiated foods (51 FR 13376, 13381, April 18, 1986).

The agency is not aware of any information that suggests that low dose (up to 1 kiloGray) irradiation of raw foods causes adverse changes in their physical or sensory qualities that would affect consumer's perceptions as to whether they are raw. Therefore, in the absence of meaningful differences in the appearance and quality between pre- and post- irradiated foods, and in light of the requirement that irradiated foods must be clearly labeled as such, the agency believes that it is appropriate to provide that the term "fresh" may be used to describe foods that have been treated with ionizing radiation at a maximum dose of 1 kiloGray (100 kilorads) in accordance with § 179.26(b) and that otherwise meet the requirements of new § 101.95(a). Accordingly the agency is adding an exemption for treatment with irradiation to new § 101.95(c)(iv).

326. None of the comments objected to the agency's position that use of the term "fresh" is appropriate to describe raw, unprocessed foods that are refrigerated and that otherwise meet the definition of "fresh."

Although refrigeration is a means of preserving food, consumers apparently generally regard raw unprocessed foods that are refrigerated as "fresh" (e.g., "fresh" produce). The agency also believes that consumers are not misled when the term "fresh" is used to describe raw unprocessed foods that are refrigerated. Accordingly, the agency is retaining in new § 101.95(c)(2) the provision that states that a food that meets the definition for "fresh," and that is refrigerated, is not precluded from the use of the term "fresh" under this regulation.

327. Many comments objected to the agency's proposed definition for the term "freshly prepared." Some of these comments pointed out that one of the major limitations associated with the proposed definition of "freshly prepared" is that bakery products (including bread) would not merit use of the term "fresh baked" because, in most cases, it is a common practice for the baking industry to utilize mold inhibitors. Other comments stated that consumers recognize baked bread containing mold inhibitors as "fresh baked" and are not misled by the use of this terminology. Numerous related comments suggested that bread and other bakery products (regardless of whether they contain mold inhibitors), should be permitted to use the term "freshly prepared."

Several comments objected to the provision in the proposal limiting the use of "freshly prepared" to foods available for sale within 24 hours after their preparation or production. Comments stated that the agency has no factual or scientific basis on which to impose a 24-hour restriction for prepared foods to qualify to be labeled "freshly prepared." Comments also stated that the 24-hour timeframe is applied inconsistently across the food industry, is unrealistic, and is impossible for most foods to achieve.

A few comments recommended that as an alternative to the 24-hour timeframe associated with "freshly prepared," the agency should consider timeframes such as 12 hours, 72 hours, 10 days from preparation, or 3 to 7 days, with "freshly baked" meaning those products that are baked within a 24-hour timeframe. A small percentage of comments suggested that any time restriction associated with "freshly prepared" should be based on a product's normal shelf life.

A review of the comments has persuaded the agency to reconsider its proposed definition of "freshly prepared." FDA now recognizes several problems with this proposed definition. First, the comments have persuaded the agency that the 24-hour timeframe proposed for the term "freshly prepared" is impractical and impossible to apply to foods across the board because of the diversity of foods in the marketplace that could be described as "freshly prepared." Additionally, no practical alternatives for defining "freshly prepared" were presented to the agency. To the contrary, because of the wide variety of contexts in which the term could be used to describe foods, FDA doubts that a practical definition for "freshly prepared" that would address all uses of the term is achievable.

FDA has thus reconsidered whether a need exists for a regulatory definition for the term "freshly prepared." First, FDA believes that systematic misuse of terms such as "freshly prepared" is not a significant problem in the marketplace. FDA is not aware of widespread misuse of this term. Further, as stated above, any use of terms such as "freshly prepared" are subject to the requirements of section 403(a) of the act, which prohibits false or misleading labeling. Therefore, the agency has the authority to take action on a case-by-case basis against foods that use the term "freshly prepared" on the label in a manner that is false or misleading. Given these factors, FDA believes that a definition of this term is not necessary to enable the agency to effectively enforce the provisions of the act that forbid false or misleading labeling on foods, and accordingly, FDA is withdrawing the proposed definition for "freshly prepared."

328. Several comments agreed with the agency's longstanding policy that use of the term "fresh frozen" is appropriate to describe a food that is quickly frozen while still "fresh." One comment requested that FDA extend the

proposed definition for "fresh frozen" to include foods such as "fresh" vegetables that are blanched before blast-freezing.

The agency agrees with the comment that foods blanched before blast-freezing merit use of the term "fresh frozen." Upon review of the literature, FDA finds that the blanching of vegetables before freezing is essential to prohibit the development of off-colors, off-flavors, and other kinds of enzymatic spoilage that are known to develop over a period of time in the frozen product (Ref. 30). Therefore, FDA is including a provision in new § 101.95(b) that provides for use of the term "fresh frozen" on raw foods that are blanched before blast-freezing.

329. Several comments requested that FDA reconsider the provision in the proposal that a food must comply with the definition of "fresh" for the term to be used in its labeling as part of a brand name. Some of these comments expressed the concern that prohibiting the use of "fresh" in brand names would mean banning the use of many brand names and trade names (some that are registered trademarks) that have been used for years in a nonmisleading manner.

The agency has reviewed the comments regarding the use of "fresh" in brand names. FDA is aware that situations exist where "fresh" is employed as an integral part of some brand names. In addition, the agency recognizes that some brand names are registered trademarks, and it is not uncommon for these brand names to be used as part of a company logo or on company promotional material.

The use of the term "fresh" on a food label in any manner, including its use in a brand name, is misleading if the use implies that the food is unprocessed when in fact it has been processed. Further, some of the instances where the term "fresh" has been misused in this regard have involved the use of this term as part of a brand name. For these reasons, FDA concludes that the use of "fresh" as part of a brand name should be subject to the definition it is establishing and is thus retaining reference to the use of "fresh" in a brand name in the introductory paragraph of new § 101.95. If, however, a use of the term "fresh" as part of a brand name does not imply or suggest that the food is unprocessed, and the use is not otherwise false and misleading, there is nothing in this final rule that would prevent this use of the term.

330. A few comments on the use of "fresh" in brand names suggested that FDA should continue to permit the term "fresh pack" on the label of pickles to refer to uncured, unfermented cucumbers packed in a vinegar solution and preserved by either pasteurization or refrigeration. These comments contended that consumers and USDA officials use the term "fresh pack" to distinguish these pickles from brine-cured pickles.

FDA has reviewed these comments. FDA is aware that the term "Fresh Pack" is recognized by USDA to distinguish a certain type of pickles. USDA regulations in 7 CFR 52.1684 specifically state that pickles of fresh-pack type are prepared from uncured, unfermented cucumbers that are packed in a vinegar solution with other ingredients to give the characteristics of the particular type of pickle. They are sufficiently processed by heat for preservation of the product in hermetically-sealed containers. That regulation also identifies characteristics for fresh-pack dill pickles, fresh-pack sweetened dill pickles, fresh-pack sweetened dill relish, fresh-pack sweet pickles, fresh-pack mild sweet pickles, fresh-pack sweet relish, and fresh-pack mild sweet relish, respectively. In recognition of USDA's standards, FDA will not take action against the term "Fresh Pack" when it refers to pickles that are graded according to those standards.

331. Some comments requested that FDA reconsider the provision in the proposal that a food must comply with the definition of "fresh" for the term to be used on its labeling as part of a sensory modifier. Other comments argued that as long as the term "fresh" is not misleading, the agency should permit its use as a sensory modifier, especially in those cases where the term refers to the sensory attributes of a food (i.e., "fresh flavor," "fresh-tasting," "tastes-fresh," "taste as good as fresh,"). However, a small percentage of comments asserted that the use of "fresh" as a sensory modifier is misleading to consumers and should not be allowed in any product.

FDA has considered these comments concerning the use of "fresh" as a sensory modifier. The use of "fresh" on the label of a food, including its use as a sensory modifier, is misleading if it implies that the food is unprocessed when in fact it has been processed. For this reason, FDA concludes that the use of "fresh" as a sensory modifier should be subject to the definition that it is establishing, and therefore the agency is retaining reference to the use of the term "fresh" as sensory modifier in the introductory paragraph of new § 101.95.

332. Several comments stated that a factual statement such as "spaghetti sauce-made with fresh mushrooms" provides useful information about a food product and should be permitted on the label of a processed food made with a fresh ingredient. One comment suggested that such factual statements should be allowed on frozen foods as well. A few comments contended that an ingredient that has undergone processing is no longer "fresh," and that, therefore, the use of such a statement on a processed food made with a fresh ingredient should be prohibited. The comment said that such a statement would be confusing, meaningless, and misleading to consumers. One comment stated that if "fresh" were defined to mean unprocessed as the agency proposed, it would be inconsistent to allow the term to be used to define an ingredient that had been added to the food before processing.

In the general principles proposal, FDA asked for comments regarding the use of these statements on a processed food because it intended to comprehensively regulate the use of the term "fresh" on food labels. Because the agency is taking a more limited approach in this final rule, it does not believe that it is necessary to specifically address the use of the term "fresh" to describe ingredients used in a processed food in its regulation. The agency concludes that this use of the term can be effectively regulated on a case-by-case basis.

FDA believes, however, that consumers generally are not misled when such statements are made about ingredients used in processed foods, provided that the statements clearly refer to the ingredient and do not imply that the food itself is unprocessed. The agency has not received complaints from consumers about this practice, and most of the comments that mentioned this use of the term said that such statements provide useful information. FDA advises that should specific situations arise where such statements are used in a manner that is misleading, the agency will take regulatory action under section 403(a) of the act.

333. Numerous comments expressed the opinion that the inclusion of blanching as part of a continuous process should not preclude labeling an ingredient as "fresh." These comments stated that blanching does not significantly damage the cellular structure of an ingredient and does not affect the taste of a product. A small number of comments argued that blanched ingredients should not be labeled as "fresh," especially if the entire product is heat-treated after the blanched ingredients have been added to the product.

FDA notes that blanching, as addressed here, is a common and sometimes required process that is accomplished by subjecting a food to a set temperature for a specific period of time. This practice is used in many food industries to arrest changes in the flavor profile of the food, to expel air and gases to inactivate food enzymes, and to destroy some microorganisms before the food is processed (Ref. 31). FDA believes that when the blanching operation is part of a continuous process, it is not misleading if the label of the processed product contains a statement such as "made from fresh ——" because the statement functions to inform the consumer of a noteworthy characteristic of the ingredient (i.e., that the ingredient was fresh, not canned, frozen, or dried at the time the food was processed).

334. Many comments both from industry and from consumers, stated that processed products (particularly tomato products) that are made from remanufactured ingredients should include a statement such as "remanufactured," "reconstituted," or "made from concentrate" on the product's PDP to avoid consumer deception and economic fraud in the marketplace. Other comments expressed the view that organoleptic, quality, and structural differences exist between remanufactured ingredients and fresh ingredients, resulting in significant differences in products made from them. Some comments provided data on these differences.

However, numerous comments opposed requiring a declaration on the PDP that a processed product is made from remanufactured ingredients. Some of these comments stated that FDA lacked legal authority and sufficient analytical and scientific data to promulgate a regulation requiring PDP declaration of the use of remanufactured ingredients, and that before the agency suggests that there is a quality difference between remanufactured tomatoes and raw unprocessed tomatoes, this issue would require further investigation. Some of these comments stated that some existing food standards allow for the use of processed ingredients in processed foods without requiring a declaration about the processed ingredient on the PDP. Therefore, these comments asserted, FDA could not require a declaration on the PDP for remanufactured ingredients without proposing to revise some existing food standards. Some of these comments argued that there was no indication in the rulemaking proceedings for the above food standards that consumers are misled by the lack of PDP labeling.

Some comments urged FDA to separate this issue from this rulemaking and to address the labeling of remanufactured ingredients in a separate proceeding after the agency completes implementing the mandatory requirements of the 1990 amendments.

Other comments on this issue argued that, if the agency were to mandate this requirement, it would impose substantial costs on industry. Another comment implied that use of remanufactured ingredients is necessary because it is impossible for manufacturers to meet the demand of tomato-based products using only fresh tomatoes.

The agency has reviewed these comments and concludes that the issue of labeling for remanufactured ingredients involves matters that go well beyond those that the agency raised in the proposal. There is a large amount of information to be evaluated, and any decision on the issue will have a far reaching impact. Because this rulemaking has been conducted under the very tight time constraints of the 1990 amendments, the agency has not been able to fully evaluate all the information that it has received in comments or to develop appropriate provisions for a regulation. In addition, before FDA published the general principles proposal, the California Tomato Packers had submitted a petition (Docket No. 90P–0430) concerning, among other things, declaration of remanufactured ingredients in finished tomato products. This petition includes data and other information and is undergoing agency review.

However, the 1990 amendments do not require that FDA address this issue, and the time constraints in those provisions therefore are not applicable. The agency is persuaded that some of the issues discussed in the proposal concerning remanufactured ingredients warrant further consideration to determine whether labels should be required to inform consumers that processed products have been made with remanufactured ingredients. Accordingly, FDA has not established provisions in this final rule to address these products. The agency will complete its evaluation of all available information and will take appropriate action separately from this rulemaking. The agency solicits information on differences in finished products made with remanufactured ingredients from those made with unprocessed ingredients. In particular, FDA requests information on whether such differences occur in finished products other than tomato products, and, if so, whether the differences are significant. Information should be identified with Docket No. 90P–0430 and sent to the Dockets Management Branch (address above). If the agency determines that differences in finished products because of the use of processed ingredients are significant, such differences would form the basis for subsequent rulemaking.

In the interim, FDA advises that it has already established labeling provisions that apply to some foods made from processed ingredients. This final rule, in § 101.95, precludes processed products such as tomato products made using remanufactured ingredients from being described as "fresh." In addition, as discussed in comment 334 of this document, processed products made with fresh ingredients may bear label statements stating that fact. The agency will evaluate labels that are not subject to these provisions on a case-by-case basis to determine if they are false or misleading under section 403(a) of the act because they misrepresent a finished product made with a processed ingredient.

335. Several comments stated that extended shelf life foods do not merit use of the terms "fresh" or "freshly prepared." The comments suggested that extended shelf life foods are preserved using modern preservation techniques and should not be given special consideration over other methods of preservation. A small number of comments expressed the view that pasta products that are packaged in modified atmosphere packaging should be able to utilize the term "fresh" as a way to distinguish these pasta products from dried pasta.

FDA notes that "extended shelf life" is a term used to describe a potentially broad class of products in the marketplace. These products include many types of foods, e.g., vegetables, pasta, complete meals; employ many types of preparation and packaging technologies; and are subject to varying degrees of processing. The use of the term "fresh" on extended shelf life foods is subject to new § 101.95 when such use suggests or implies that the product is unprocessed. However, because of the diversity of products in the extended shelf life category, the question of what constitutes processing for such products is not being addressed in this rule and is subject to a case-by-case review by the agency.

336. Some comments suggested that terms that refer to packaging technology (e.g., "freshness seal," "Stay Fresh seal") would be prohibited under the agency's proposed definition for "fresh." These comments suggested that FDA does not have the authority to

prohibit the use of such terminology as it relates to packaging, specifically in cases where use of these terms are properly qualified. The comments said that such a prohibition would hamper the development of improved packaging technology. Comments also stated that the agency does not have sufficient evidence to suggest that consumers are misled when code dates and freshness guarantees (e.g., guaranteed fresh until) are used on foods. Some comments argued that phrases such as "vacuum packed," "vacuum sealed to lock in freshness," and "for maximum freshness use before a specific date," serve as tools for consumers to distinguish "fresh" product from "stale" product. One comment stressed that vacuum packaging is analogous to blast freezing in that both techniques allow foods to maintain their fresh state.

A small number of comments opposed permitting this use of the term "fresh." Another comment stated that the use of "fresh" in a guarantee statement (e.g., guaranteed fresh) should be restricted and should only be allowed if a food in question meets the definition for "fresh."

The agency has reviewed these comments and has concluded that the use of terms such as "freshness seal," "guaranteed fresh until," "and vacuum packed to preserve freshness," when they relate only to the function of the package and do not imply or suggest that the food itself is unprocessed, is outside the scope of this rulemaking. FDA acknowledges that these terms are used on numerous food products in the marketplace. To the extent that these terms might be used in any manner that is misleading, the agency will review specific situations on a case-by-case basis under the general misbranding provisions of section 403(a) of the act.

B. Natural

Although the use of the term "natural" on the food label is of considerable interest to consumers and industry, FDA's intent was not to establish a definition for "natural" in this rulemaking. However, the agency did note in the general principles proposal (56 FR 60421 at 60466) that, because of the widespread use of this term, and the evidence that consumers regard many uses of this term as noninformative, the agency would consider establishing a definition. Further, the agency stated that it believed that if the term "natural" is adequately defined, the ambiguity in the use of this term, which has resulted in misleading claims, could be abated. Therefore, the agency solicited comments on several issues that the agency must consider in deciding how to address the use of this term on foods, including: (1) Should the agency establish a definition for "natural" so that the term would have a common understanding among consumers, or should "natural" claims be prohibited altogether on the basis that they are false and misleading? (2) If a definition should be established, how should the agency define "natural?" (3) How should the agency proceed in developing a definition for "natural?" (4) Should a food that is represented as "natural" be considered to be misbranded if it has undergone more than minimal processing (and what constitutes minimal processing?), or if it contains any artificial or synthetic ingredients? In addition, FDA asked that identification of "natural" foods accompany the comments. FDA also solicited comments on how the agency distinguishes between artificial and natural flavors in § 101.22, and on how the agency should provide for a clearer, more appropriate distinction between natural and artificial flavors.

337. The comments provided a wide range of ideas for the agency to consider on the issue of developing a definition for "natural." Some comments stated that the term "natural" should be prohibited entirely on the basis that it generates confusion when used on the label or in the labeling of foods, and that the term is also false and misleading. Some comments stated that the agency should eliminate statements such as: "all natural," "100 percent natural," and made from "100 percent natural ingredients." Some comments suggested that the agency should not consider defining "natural" while it is implementing the mandatory requirements of the 1990 amendments.

Other comments suggested that the agency should address the use of the term "natural" in a separate rulemaking.

Some comments suggested that if FDA does establish a definition for the term "natural," it should encompass those foods that do not contain artificial or synthetic ingredients. A few comments stated that processing should not necessarily preclude a product from being deemed "natural." Other comments stated that the term "natural" and claims for natural ingredients should be permitted, provided that the manufacturer uses the term in a truthful, nonmisleading manner. Comments recommended that the use of natural color ingredients should not be precluded in foods that are represented as "natural." One comment suggested that manufacturers should be allowed to make claims for natural ingredients, regardless of any policy established for labeling finished foods as "natural." One comment stated that foods containing refined sugars should be allowed to be represented as "natural," whereas foods containing artificial sweeteners should not be represented as "natural."

None of the comments provided FDA with a specific direction to follow for developing a definition regarding the use of the term "natural." However, it was suggested that FDA should work with USDA to harmonize its definition for "natural."

A small percentage of comments addressed "minimal processing." Some of these comments proposed somewhat similar definitions under which "minimal processing" would refer to those processes that are familiar to consumers and that can be performed in the home (e.g., milling, grinding, baking). One comment suggested that "minimal processing" should include fermentation. Another comment implied that "minimal processing" should include traditional processes such as smoking, roasting, freeze drying, fermenting, and the separation of a product into component parts. The remaining comments defined "minimal processing" as those processes that do not fundamentally alter a raw food or any material derived from the raw food. Finally, some comments stated that FDA's current regulations for labeling natural flavors should not be changed.

After reviewing and considering the comments, the agency continues to believe that if the term "natural" is adequately defined, the ambiguity surrounding use of this term that results in misleading claims could be abated. However, as the comments reflect, there are many facets of this issue that the agency will have to carefully consider if it undertakes a rulemaking to define the term "natural." Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for "natural" at this time. The agency will maintain its current policy (as discussed in the general principles proposal (56 FR 60421 at 60466)) not to restrict the use of the term "natural" except for added color, synthetic substances, and flavors as provided in § 101.22. Additionally, the agency will maintain its policy (Ref. 32) regarding the use of "natural," as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food. Further, at this time the agency will continue to distinguish between natural and artificial flavors as outlined in § 101.22.

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C. Organic

In the general principles proposal (56 FR 60421 at 60467), FDA noted that responsibility for regulating use of the term "organic" was assigned by Congress to USDA in Title XXI—Organic Certification, also known as the "Organic Foods Production Act of 1990." The agency stated that it would defer issuing regulations governing the term "organic" until USDA had adopted appropriate regulations.

338. The majority of the comments addressing the use of "organic" as a food label term agreed with the agency's proposal to defer action until USDA has adopted appropriate regulations governing the term "organic." A small number of comments argued that defining the term "organic" was outside the scope of the 1990 amendments and, therefore, should not be part of this regulation.

However, other comments suggested that FDA should initiate rulemaking on the use of the term "organic" on food labels. Some of these comments suggested that the term "organic" should be applied to foods free of any artificial or synthetic ingredients, pesticides, growth enhancers, harmful fertilizers, or fungicides, and that it should not be applied to foods exposed to ionizing radiation. One comment stated that "organic" should not be allowed as a labeling term because there is no "scientifically acceptable" meaning for this term. Many of the consumer comments proposed that FDA adopt USDA's future definition for "organic" and consider adopting criteria established by the Organic Foods Production Act of 1990.

Most of the comments generally supported the agency's position as expressed in the proposal. Comments that opposed FDA's decision to defer rulemaking did not provide the agency with any justification why it should proceed with rulemaking before USDA has established regulations. Therefore, the agency continues to believe that it is best to defer rulemaking regarding the use of the term "organic" until USDA has adopted appropriate regulations. At that time, FDA will determine whether any regulations governing the term "organic" are necessary.

IX. Conclusions

After review and consideration of the comments received in response to the general principles and fat/cholesterol proposals, FDA concludes that it should amend parts 5 and 101 as set forth in those proposals and in the specific revisions to those proposed regulations discussed in this document. For the purposes of this final rule, certain changes, in addition to those discussed in this document, were made for editorial purposes, clarity, and consistency only. These changes do not amend any matter of substance.

X. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive RIA that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

One particular comment to the RIA stated that the shelf flag highlighting a particular nutrient content of a food in the Giant Foods, Inc./FDA Special Dietary Alert study (SDA) that was used to estimate benefits of the 1990 amendments overestimated the benefits. The comment also noted that shelf flag highlighting may have been used in addition to highlighting the product characteristics on the label such that no similar results could be obtained unless other retailers also used shelf flags. In addition, the comment contended that it is unlikely that retailers will use shelf flags because their use may trigger additional labeling requirements.

The agency notes that these final rules will not prohibit shelf flags from being displayed by manufacturers exactly as they were displayed by Giant Foods, Inc., during the SDA study. The agency is announcing here that it is encouraging retailers to use such devices consistent with the definitions for nutrient content claims provided in this document and the definitions for health claims in the final rule published elsewhere in this issue of the **Federal Register**.

XI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the general principles proposal (56 FR 60521) and the fat/cholesterol proposal (56 FR 60478), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for

nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided that this final rule will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

XII. Paperwork Reduction Act

In the **Federal Register** of February 14, 1992 (57 FR 5395), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60421) that provided, in part, for petitions regarding nutrient content claims, synonyms for those claims, and implied nutrient content claims in brand names. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

Based on its consideration of the written comments received in response to the aforementioned **Federal Register** documents and the oral presentations made at the public hearing on food labeling, FDA modified the nutrient content claim petition requirements from those that were proposed. Those modifications were discussed in detail earlier in this final rule. Accordingly, FDA has also revised its estimated annual collection of information burden.

This final rule contains collection of information requirements that are subject to review by OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). Therefore, in accordance with 5 CFR part 1320, the title, description, and respondent descriptions of the collection of information requirements are shown below with an estimate of the annual collection of information burden. Included in the estimate is the amount of time for reviewing instructions, searching existing data sources, gathering necessary information, and completion and submission of petitions.

-Title: 21 CFR 101.69—Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms.

Description: This final rule provides the procedures for the submission of petitions to the agency. The information included in these petitions will be reviewed by the agency, and a decision will be made in accordance with the criteria specified in this final rule.

The 1990 amendments added section 403(r)(4) to the act. This section provides that any person may petition the Secretary to make nutrient content claims that are not specifically provided for in FDA's regulations. It describes the procedures for petitions that seek to define additional nutrient content claims, to establish synonyms, and to use an implied nutrient content claim in a brand name.

Nutrient Content Claim petitions—Section 403(r)(4)(A)(i) of the act grants to any person the right to petition FDA to issue a regulation to define a nutrient content claim that has not been defined in the regulations under section 403(r)(2)(A)(i) of the act. The statute requires that such a petition include an explanation of the reasons why the claim that is the subject of the petition meets the requirements of section 403(r) of the act and a summary of the scientific data that support those reasons. Section 101.69(m) sets forth the data requirements specific to descriptor petitions.

Synonym petitions—Section 403(r)(4)(A)(ii) of the act grants the right to petition the FDA for permission to use terms in a nutrient content claim that are consistent (i.e., synonymous) with terms defined in regulations issued under section 403(r)(2)(A)(i) of the act. The petition requirements in § 101.69(n) are those that FDA believes are necessary to demonstrate that use of the proposed synonym is not misleading and is consistent with the purpose of the 1990 amendments.

Brand-name petitions—Section 403(r)(4)(A)(iii) of the act grants the right to petition FDA for permission to use an implied claim in a brand name that is consistent with terms defined by the Secretary under section 403(r)(2)(A)(i) of the act. Section 101.69(o) sets forth the data requirements specific to brand-name petitions. These requirements are, in FDA's opinion, those necessary for the petition to demonstrate that use of the proposed implied claim is not misleading and is consistent with the purpose of the 1990 amendments.

Description of Respondents: Persons and businesses, including small businesses.

Estimated Annual Reporting and Recordkeeping Burden;

Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Annual Burden Hours
101.69(m)	5	1	5	240	1,200
101.69(n)	10	1	10	80	800
101.69(o)	7	1	7	107	749
Total	22		22		2,749

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. National Heart, Lung, and Blood Institute, NCEP, "Report of the Expert Panel on Blood Cholesterol Levels in Children and Adolescents," DHHS, Public Health Service, National Institutes of Health, April 7, 1991.

2. AOAC International, "Nutrient Labeling Task Force Report," *The Referee*, 16:7–12, July, 1992.

3. President's "Memorandum for Certain Department and Agency Heads on Regulatory Coordination," January 28, 1992.

4. "The Surgeon General's Report on Nutrition and Health," DHHS, Public Health Service Publication No. 88–50210 (Government Printing Office Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington DC, 1988.

5. Crane, N. T., memorandum to file, Modification of USDA's Nutrient Data Base

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for Standard Reference Release 9, October 15, 1992.

6. Crane, N. T., memorandum to file, Data Analysis CC1, Effect of a less Restrictive or No Weight-Based Criterion, October 15, 1992.

7. DHHS and USDA, "Nutrition and Your Health, Dietary Guidelines for Americans," 1990.

8. Crane, N. T., memorandum to file, Data Analysis CC2, Products with Reference Amounts under 100 Grams that met Proposed Criteria, October 15, 1992.

9. Crane, N. T., memorandum to file, Data Analysis CC3, Effect of Lowering Nutrient Levels per Serving, October 15, 1992.

10. Crane, N. T., memorandum to file, Data Analysis CC4, Effect of Weight-Based Criteria Applied Only to Small Serving Size Foods, October 15, 1992.

11. Crane, N. T., memorandum to file, Data Analysis CC5, Effect of Caloric Density Criteria, October 15, 1992.

12. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, NAS, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington DC, 1989.

13. Report of the 4th Workshop on Nutritional Quality and Labeling in Food Standards and Guidelines, Committee on the Nutritional Aspects of Foods Standards, International Union of Nutritional Sciences, 1989.

14. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, IOM, NAS, "Nutrition Labeling, Issues and Directions for the 1990's," Washington, DC, National Academy Press, 1990.

15. Meier, C., "Calories, Fat, and Cholesterol: A Comparison of Modifier Words on Food Labels," doctoral dissertation, University of South Dakota, Vermillion, South Dakota, 1992.

16. Levy, A. S. et al., "Recent Trends in Beliefs about Diet/Disease Relationships: Results of the 1979–1988 FDA Health and Diet Surveys," presented at FDA/USDA Food Editor's Conference, December 1 to 2, 1988.

17. National Heart, Lung, and Blood Institute, "National Cholesterol Education Program Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Population Panel)," NIH Publication No. 90–3046, 1990.

18. Crane, N. T., memorandum to file, Data Analysis CC8, Caloric Content of Selected Foods, October 15, 1992.

19. Crane, N. T., memorandum to file: Data Analysis CC9, Fat Content of Selected Foods, October 15, 1992.

20. Crane, N. T., memorandum to file: Data Analysis CC6, Foods that Meet FDA's Definition for Low Saturated Fat, October 15, 1992.

21. Crane, N. T., memorandum to file, Data Analysis for Proposal, Distribution of Nutrients Across Food Categories, October 16, 1991.

22. USDA, FSIS, Policy Memo 070B, November 18, 1987.

23. Crane, N. T., memorandum to file: Data Analysis CC7, Fish and Shellfish that May Qualify for "Lean," October 15, 1992.

24. USDA, "Composition of Foods, Raw, Processed, Prepared," Agriculture Handbook No. 8–1 to 8–17, Human Nutrition Information Service, Washington, DC, 1976–1987.

25. Morris, W., "The American Heritage Dictionary of the English Language," Houghton Mifflin Co., Boston, 1976.

26. FDA's Health and Diet Survey, 1982.

27. Calorie Control Council News Release "Americans Finding 'Light' to their Liking," January 9, 1990.

28. Subcommittee on the 10th Edition of the Recommended Dietary Allowances, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Recommended Dietary Allowances, 10th ed.," Washington, DC, National Academy Press, 1989.

29. Standards and Labeling Policy Book, USDA, FSIS, p. 47, June 1991.

30. Potter, Norman N., "Heat Preservation and Processing," in *Food Science*, Ch. 8, pp. 149–150, AVI Publishing Co., Inc., Westport, Connecticut, 1968.

31. Luh, B. S. and J. G. Woodroof, "Canning of Vegetables," in *Commercial Vegetable Processing*, Ch. 6, pp. 198–199, AVI Publishing Co., Inc., Westport, Connecticut, 1975.

32. Raymond E. Newberry, letter to Clinton K. Davies, PhD, September 29, 1988.

33. Committee on Nutrition, American Academy of Pediatrics; Gilbert B. Forbes, ed., Calvin W. Woodruff, associate ed., 2d ed., Elk Grove Village, Ill.: The Academy, 1985.

34. Food Retailing Review—1992 Edition, The Food Institute Information and Research Center, Fair Lawn, NJ, February 1992, p. 254.

35. Crane, N. T., Memorandum of File, Data Analysis No. 4, Foods With 20 Percent or More of Reference Value Per Service, October 16, 1991.

List of Subjects

21 CFR Part 5

Authority delegations (Government agencies), Imports, Organization and functions (Government agencies).

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 5 and 101 are amended as follows:

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

1. The authority citation for 21 CFR part 5 continues to read as follows:

Authority: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309, secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

2. Section 5.61 is amended by revising the section heading and by adding a new paragraph (g) to read as follows:

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

* * * * *

(g) The Director and Deputy Director, CFSAN are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuing of decisions to grant or deny, letters of filing, and notices of proposed rulemaking in response to petitions for nutrient content claims and health claims that do not involve controversial issues.

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.10 is revised to read as follows:

§ 101.10 Nutrition labeling of restaurant foods.

Nutrition labeling in accordance with § 101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in § 101.13 or in subpart D of this part) or a health claim (as defined in § 101.14 and permitted by a regulation in subpart E of this part) is made (except on menus). Except: That information on the nutrient amounts that are the basis for the claim (e.g., "low fat," this meal provides less than 10 grams of fat) may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 and other reasonable means.

5. Section 101.13 is revised to read as follows:

§ 101.13 Nutrient content claims—general principles.

(a) This section and the regulations in subpart D of this part apply to foods that

are intended for human consumption and that are offered for sale.

(b) A claim that expressly or implicitly characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling under § 101.9, with the exception of such claims on restaurant menus, may not be made on the label or in labeling of foods unless the claim is made in accordance with this regulation and with the applicable regulations in subpart D of this part or in part 105 or part 107 of this chapter.

(1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium" or "contains 100 calories."

(2) An implied nutrient content claim is any claim that:

(i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"); or

(ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams (g) of fat").

(3) Except for claims regarding vitamins and minerals described in paragraph (q)(3) of this section, no nutrient content claims may be made on food intended specifically for use by infants and children less than 2 years of age unless the claim is specifically provided for in parts 101, 105, or 107 of this chapter.

(c) Information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. If such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

(d) A "substitute" food is one that may be used interchangeably with another food that it resembles, i.e., that it is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an "imitation."

(1) If there is a difference in performance characteristics that materially limits the use of the food, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim as defined in paragraph (j)(2)(iii) of this section, informing the consumer of such difference (e.g., "not recommended for frying").

(2) This disclaimer shall be in easily legible print or type and in a size no less than that required by § 101.105(i) for the net quantity of contents statement except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(e)(1) Because the use of a "free" or "low" claim before the name of a food implies that the food differs from other foods of the same type by virtue of its having a lower amount of the nutrient, only foods that have been specially processed, altered, formulated, or reformulated so as to lower the amount of the nutrient in the food, remove the nutrient from the food, or not include the nutrient in the food, may bear such a claim (e.g., "low sodium potato chips").

(2) Any claim for the absence of a nutrient in a food, or that a food is low in a nutrient when the food has not been specially processed, altered, formulated, or reformulated to qualify for that claim shall indicate that the food inherently meets the criteria and shall clearly refer to all foods of that type and not merely to the particular brand to which the labeling attaches (e.g., "corn oil, a sodium-free food").

(f) A nutrient content claim shall be in type size and style no larger than two times that of the statement of identity.

(g) The label or labeling of a food for which a nutrient content claim is made shall contain prominently and in immediate proximity to such claim the following referral statement: "See _____ for nutrition information" with the blank filled in with the identity of the panel on which nutrition labeling is located.

(1) The referral statement "See [*appropriate panel*] for nutrition information" shall be in easily legible boldface print or type, in distinct contrast to other printed or graphic matter, that is no less than that required by § 101.105(i) for net quantity of contents, except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the referral statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch.

(2) The referral statement shall be immediately adjacent to the nutrient content claim and may have no intervening material other than, if applicable, other information in the statement of identity or any other information that is required to be presented with the claim under this section (e.g., see paragraph (j)(2) of this section) or under a regulation in subpart D of this part (e.g., see §§ 101.54 and 101.62). If the nutrient content claim appears on more than one panel of the label, the referral statement shall be adjacent to the claim on each panel except for the panel that bears the nutrition information where it may be omitted.

(3) If a single panel of a food label or labeling contains multiple nutrient content claims or a single claim repeated several times, a single referral statement may be made. The statement shall be adjacent to the claim that is printed in the largest type on that panel.

(h) In place of the referral statement described in paragraph (g) of this section,

(1) If a food, except a meal product as defined in § 101.13(l), a main dish product as defined in § 101.13(m), or food intended specifically for use by infants and children less than 2 years of age, contains more than 13.0 g of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium per reference amount customarily consumed, per labeled serving, or, for a food with a reference amount customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g (for dehydrated foods that must have water added to them before typical consumption, the per 50 g criterion refers to the "as prepared" form), then that food must disclose, as part of the referral statement, that the nutrient exceeding the specified level is present in the food as follows: "See [*appropriate panel*] for information about [*nutrient requiring disclosure*] and other nutrients," e.g., "See side panel for information about total fat and other nutrients."

(2) If a food is a meal product as defined in § 101.13(l), and contains more than 26 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(3) If a food is a main dish product as defined in § 101.13(m), and contains more than 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per labeled serving, then that food must disclose, in accordance with the requirements as provided in paragraph (h)(1) of this section, that the nutrient exceeding the specified level is present in the food.

(i) Except as provided in § 101.9 or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is consistent with a definition for a claim, as provided in subpart D of this part, for the nutrient that the label addresses. Such a claim might be, "less than 10 g of fat per serving;"

(2) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not low in or a good source of the nutrient, such as "only 200 mg sodium per serving, not a low sodium food." The disclaimer must be in easily legible print or type and in a size no less than required by § 101.105(i) for net quantity of contents except where the size of the claim is less than two times the required size of the net quantity of contents statement, in which case the disclaimer statement shall be no less than one-half the size of the claim but no smaller than one-sixteenth of an inch;

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., "100 calories" or "5 grams of fat"), in which case no disclaimer is required; or

(4) "Percent fat free" claims are not authorized by this paragraph. Such claims shall comply with § 101.62(b)(6).

(j) A food may bear a statement that compares the level of a nutrient in the food with the level of a nutrient in a reference food. These statements shall be known as "relative claims" and include "light," "reduced," "less" (or "fewer"), and "more" claims.

(1) To bear a relative claim about the level of a nutrient, the amount of that nutrient in the food must be compared to an amount of nutrient in an appropriate reference food as specified below.

(i)(A) For "less" (or "fewer") and "more" claims, the reference food may be a dissimilar food within a product category that can generally be substituted for one another in the diet (e.g., potato chips as reference for pretzels) or a similar food (e.g., potato chips as reference for potato chips).

(B) For "light," "reduced," "added," "fortified," and "enriched" claims, the reference food shall be a similar food (potato chip reference for potato chip), and

(ii)(A) For "light" claims, the reference food shall be representative of the type of food that includes the product that bears the claim. The nutrient value for the reference food shall be representative of a broad base of foods of that type; e.g., a value in a representative, valid data base; an average value determined from the top three national (or regional) brands, a market basket norm; or, where its nutrient value is representative of the food type, a market leader. Firms using such a reference nutrient value as a basis for a claim, are required to provide specific information upon which the nutrient value was derived, on request, to consumers and appropriate regulatory officials.

(B) For relative claims other than "light," including "less" and "more" claims, the reference food may be the same as that provided for "light" in paragraph (j)(1)(ii)(A) of this section or it may be the manufacturer's regular product, or that of another manufacturer, that has been offered for sale to the public on a regular basis for a substantial period of time in the same geographic area by the same business entity or by one entitled to use its trade name. The nutrient value(s) for a single manufacturer's product shall be the value declared in nutrition labeling on the product.

(2) For foods bearing relative claims:

(i) The label or labeling must state the identity of the reference food and the percentage (or fraction) of the amount of the nutrient in the reference food by which the nutrient has been modified, (e.g., "50 percent less fat than (reference food)" or "1/3 fewer calories than (reference food)"),

(ii) This information shall be immediately adjacent to the most prominent claim. The type size shall be in accordance with paragraph (g)(1) of this section.

(iii) The determination of which use of the claim is in the most prominent location on the label or labeling will be made based on the following factors, considered in order:

(A) A claim on the principal display panel adjacent to the statement of identity;

(B) A claim elsewhere on the principal display panel;

(C) A claim on the information panel; or

(D) A claim elsewhere on the label or labeling.

(iv) The label or labeling must also bear:

(A) Clear and concise quantitative information comparing the amount of the subject nutrient in the product per labeled serving with that in the reference food; and

(B) This statement shall appear adjacent to the most prominent claim or on the information panel.

(3) A relative claim for decreased levels of a nutrient may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the requirement for a "low" claim for that nutrient (e.g., 3 g fat or less).

(k) The term "modified" may be used in the statement of identity of a food that bears a relative claim that complies with the requirements of this part, followed immediately by the name of the nutrient whose content has been altered (e.g., "Modified fat cheesecake"). This statement of identity must be immediately followed by the comparative statement such as "Contains 35 percent less fat than _____." The label or labeling must also bear the information required by paragraph (j)(2) of this section in the manner prescribed.

(l) For purposes of making a claim, a "meal product shall be defined as a food that:

(1) Makes a major contribution to the total diet by:

(i) Weighing at least 10 ounces (oz) per labeled serving; and

(ii) Containing not less than 40 g for each of at least 3 different foods from 2 or more of the following 4 food groups except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts group; except that;

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces), gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a breakfast, lunch, dinner, or meal. Such representations may be made either by statements, photographs, or vignettes.

(m) For purposes of making a claim, a "main dish product" shall be defined as a food that:

(1) Makes a major contribution to a meal by

(i) Weighing at least 6 oz per labeled serving; and

(ii) Containing not less than 40 g for each of at least two different foods from two of the following four food groups except as noted in paragraph (l)(1)(ii)(E) of this section:

(A) Bread, cereal, rice, and pasta group;

(B) Fruits and vegetables group;

(C) Milk, yogurt, and cheese group;

(D) Meat, poultry, fish, dry beans, eggs, and nuts groups; except that:

(E) These foods shall not be sauces (except for foods in the above four food groups that are in the sauces) gravies, condiments, relishes, pickles, olives, jams, jellies, syrups, breadings, or garnishes; and

(2) Is represented as, or is in a form commonly understood to be, a main dish (e.g., not a beverage or a dessert). Such representations may be made either by statements, photographs, or vignettes.

(n) Nutrition labeling in accordance with § 101.9 or § 101.10, as applicable shall be provided for any food for which a nutrient content claim is made.

(o) Except as provided in § 101.10, compliance with requirements for nutrient content claims in this section and in the regulations in subpart D of this part, will be determined using the analytical methodology prescribed for determining compliance with nutrition labeling in § 101.9.

(p)(1) Unless otherwise specified the reference amount customarily consumed set forth in § 101.12(b) through (f) shall be used in determining whether a product meets the criteria for a nutrient content claim. If the serving size declared on the product label differs from the reference amount customarily consumed, and the amount of the nutrient contained in the labeled serving does not meet the maximum or minimum amount criterion in the definition for the descriptor for that nutrient, the claim shall be followed by the criteria for the claim as required by § 101.12(g) (e.g., "very low sodium, 35 mg or less per 240 milliliters (8 fl oz.)").

(2) The criteria for the claim shall be immediately adjacent to the most prominent claim in easily legible print or type and in a size in accordance with paragraph (g)(1) of this section.

(q) The following exemptions apply:

(1) Nutrient content claims that have not been defined by regulation and that are contained in the brand name of a specific food product that was the brand name in use on such food before October 25, 1989, may continue to be used as part of that brand name for such product, provided that they are not false or misleading under section 403(a) of the Federal Food, Drug, and Cosmetic Act (the act). However, foods bearing such claims must comply with section 403(f), (g), and (h) of the act;

(2) A soft drink that used the term "diet" as part of its brand name before October 25, 1989, and whose use of that term was in compliance with § 105.66 of this chapter as that regulation appeared in the Code of Federal Regulations on that date, may continue to use that term as part of its brand name, provided that its use of the term is not false or misleading under section 403(a) of the act. Soft drinks marketed after October 25, 1989, may use the term "diet" provided they are in compliance with the current § 105.66 of this chapter;

(3) A statement that describes the percentage of a vitamin or mineral in the food, including foods intended specifically for use by infants and children less than 2 years of age, in relation to a Reference Daily Intake (RDI) as defined in § 101.9 may be made on the label or in labeling of a food without a regulation authorizing such a claim for a specific vitamin or mineral unless such claim is expressly prohibited by regulation under section 403(r)(2)(A)(vi) of the act.

(4) The requirements of this section do not apply to:

(i) Infant formulas subject to section 412(h) of the act; and

(ii) Medical foods defined by section 5(b) of the Orphan Drug Act.

(5) A nutrient content claim used on food that is served in restaurants (except on menus) or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments shall comply with the requirements of this section and the appropriate definition in subpart D of this part, except that:

(i) Such claim is exempt from the requirements for disclosure statements in paragraphs (g) and (h) of this section and §§ 101.54(d), 101.62(c), (d)(1)(ii)(C), (d)(2)(ii)(C), (d)(3), (d)(4)(ii)(C), and (d)(5)(ii)(C); and

(ii) In lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. This reasonable basis may derive from recognized data bases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (e.g., types and amounts of ingredients, cooking temperatures, etc.). Firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim; and

(iii) A term or symbol that may in some contexts constitute a claim under this section may be used, provided that the use of the term or symbol does not characterize the level of a nutrient, and a statement that clearly explains the basis for the use of the term or symbol is prominently displayed and does not characterize the level of a nutrient. For example, a term such as "lite fare" followed by an asterisk referring to a note that makes clear that in this restaurant "lite fare" means smaller portion sizes than normal; or an item bearing a symbol referring to a note that makes clear that this item meets the criteria for the dietary guidance established by a recognized dietary authority would not be considered a nutrient content claim under § 101.13.

(6) Nutrient content claims that were part of the common or usual names of foods that were subject to a standard of identity on November 8, 1990, are not subject to the requirements of paragraphs (b), (g), and (h) of this section or to definitions in subpart D of this part.

(7) Implied nutrient content claims may be used as part of a brand name, provided that the use of the claim has been authorized by the Food and Drug Administration. Petitions requesting approval of such a claim may be submitted under § 101.69(o).

(8) The term "fluoridated," "fluoride added" or "with added fluoride" may be used on the label or in labeling of bottled water that contains added fluoride.

§ 101.25 [Removed]

6. Section 101.25 *Labeling of foods in relation to fat and fatty acid and cholesterol content* is removed from subpart B.

7. New subpart D, consisting of §§ 101.54 through 101.69, is added to read as follows:

Subpart D—Specific Requirements for Nutrient Content Claims

Sec.

101.54 Nutrient content claims for "good source," "high," and "more."
101.56 Nutrient content claims for "light" or "lite."
101.60 Nutrient content claims for the calorie content of foods.
101.61 Nutrient content claims for the sodium content of foods.
101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.
101.65 Implied nutrient content claims and related label statements.
101.69 Petitions for nutrient content claims.

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Subpart D—Specific Requirements for Nutrient Content Claims

§ 101.54 Nutrient content claims for "good source," "high," and "more."

(a) *General requirements.* Except as provided in paragraph (e) of this section, a claim about the level of a nutrient in a food in relation to the Reference Daily Intake (RDI) established for that nutrient in § 101.9(c)(8)(iv) or Daily Reference Value (DRV) established for that nutrient in § 101.9(c)(9), (excluding total carbohydrates) may only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"High" claims.* (1) The terms "high," "rich in," or "excellent source of" may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that the food contains 20 percent or more of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (b)(1) of this section may be used on the label and in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains a food that meets the definition of "high" in paragraph (b)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., the serving of broccoli in this product is high in vitamin C).

(c) *"Good Source" claims.* (1) The terms "good source," "contains," or "provides" may be used on the label or in the labeling of foods, except meal products as described in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that the food contains 10 to 19 percent of the RDI or the DRV per reference amount customarily consumed.

(2) The terms defined in paragraph (c)(1) of this section may be used on the label and in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in 101.13(m), provided that:

(i) The product contains a food that meets the definition of "good source" in paragraph (c)(1) of this section; and

(ii) The label or labeling clearly identifies the food that is the subject of the claim (e.g., the serving of sweet potatoes in this product is a "good source" of fiber).

(d) *"Fiber" claims.* (1) If a nutrient content claim is made with respect to the level of dietary fiber, that is, that the product is high in fiber, a good source of fiber, or that the food contains "more" fiber, and the food is not "low" in total fat as defined in § 101.62(b)(2) or, in the case of a meal product, as defined in § 101.13(l), or main dish product, as defined in § 101.13(m), is not "low" in total fat as defined in § 101.62(b)(3), then the label shall disclose the level of total fat per labeled serving.

(2) The disclosure shall appear in immediate proximity to such claim, be in a type size no less than one-half the size of the claim and precede the referral statement required in § 101.13(g) (e.g., "contains [*x amount*] of total fat per serving. See [*appropriate panel*] for nutrition information").

(e) *"More claims."* (1) A relative claim using the terms "more," "fortified," "enriched," and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber, or potassium in a food, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium (expressed as a percent of the Daily Value) per reference amount customarily consumed than an appropriate reference food; and

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in § 104.20 of this chapter; and

(iii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber than white bread"); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving, with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "Fiber content of white bread is 1 gram (g) per serving; (this product) 3.5 g per serving").

(2) A relative claim using the terms "more," "fortified," "enriched," and "added" may be used on the label or in labeling to describe the level of protein, vitamins, minerals, dietary fiber or potassium, except as limited in § 101.13(j)(1)(i), in meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 10 percent more of the RDI for protein, vitamins, or minerals or of the DRV for dietary fiber or potassium (expressed as a percent of the Daily Value) per 100 g of food than an appropriate reference food.

(ii) Where the claim is based on a nutrient that has been added to the food, that fortification is in accordance with the policy on fortification of foods in § 104.20 of this chapter; and

(iii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percentage (or fraction) that the nutrient was increased relative to the RDI or DRV are declared in immediate proximity to the most prominent such claim (e.g., "contains 10 percent more of the Daily Value for fiber per 3 oz than does 'X brand of product'"), and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight, with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "the fiber content of 'X brand of product' is 2 g per 3 oz. This product contains 4.5 g per 3 oz").

§ 101.56 Nutrient content claims for "light" or "lite."

(a) *General requirements.* A claim using the term "light" or "lite" to describe a food may only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food is labeled in accordance with § 101.9, § 101.10, or § 101.36, where applicable.

(b) *"Light" claims.* The terms "light" or "lite" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), without further qualification, provided that:

(1) If the food derives 50 percent or more of its calories from fat, its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to an appropriate reference food as specified in § 101.13(j)(1); or

(2) If the food derives less than 50 percent of its calories from fat:

(i) The number of calories is reduced by at least one-third (33 1/3 percent) per reference amount customarily consumed compared to an appropriate reference food; or

(ii) Its fat content is reduced by 50 percent or more per reference amount customarily consumed compared to the reference food that it resembles or for which it substitutes as specified in § 101.13(j)(1); and

(3) As required in § 101.13(j)(2) for relative claims:

(i) The identity of the reference food and the percent (or fraction) that the calories and the fat were reduced are declared in immediate proximity to the most prominent such claim, (e.g., "1/3 fewer calories and 50 percent less fat than our regular cheese cake");

(ii) Quantitative information comparing the level of calories and fat content in the product per labeled serving size, with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., lite cheese cake—200 calories, 4 grams (g) fat; regular cheese cake—300 calories, 8 g fat per serving); and

(iii) If the labeled food contains less than 40 calories or less than 3 g fat per reference amount customarily consumed, the percentage reduction for that nutrient need not be declared.

(4) A "light" claim may not be made on a food for which the reference food meets the definition of "low fat" and "low calorie."

(c)(1)(i) A product for which the reference food contains 40 calories or less and 3 g fat or less per reference amount customarily consumed may use the term "light" or "lite" without further qualification if it is reduced by 50 percent or more in sodium content compared to the reference food; and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium was reduced shall be declared in immediate proximity to the most prominent such claim (e.g., 50 percent less sodium than our regular soy sauce); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "lite soy sauce 500 milligrams (mg) sodium per serving, regular soy sauce 1,000 mg per serving").

(2)(i) A product for which the reference food contains more than 40 calories or more than 3 g fat per reference amount customarily consumed may use the term "light in sodium" or "lite in sodium" if it is reduced by 50 percent or more in sodium content compared to the reference food, provided that "light" or "lite" is presented in immediate proximity with "in sodium" and the entire term is presented in uniform type size, style, color, and prominence; and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium was reduced shall be declared in immediate proximity to the most prominent such claim (e.g., 50 percent less sodium than our regular canned peas); and

(B) Quantitative information comparing the level of sodium per labeled serving size with that of the reference food it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "light canned peas, 175 milligrams (mg) sodium per serving, regular canned peas 350 mg per serving.")

(iii) Except for meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), a "light in sodium" claim may not be made on a food for which the reference food meets the definition of "low in sodium".

(d)(1) The terms "light" or "lite" may be used on the label or in the labeling of a meal product as defined in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that:

(i) The food meets the definition of:

(A) "Low in calories" as defined in § 101.60(b)(3); or

(B) "Low in fat" as defined in § 101.62(b)(3); and

(ii)(A) A statement appears on the principal display panel that explains whether "light" is used to mean "low fat," "low calories," or both (e.g., "Light Delight, a low fat meal"); and

(B) The accompanying statement is no less than one-half the type size of the "light" or "lite" claim.

(d)(2)(i) The term "light in sodium" or "lite in sodium" may be used on the label or in the labeling of a meal product as defined in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that the food meets the definition of "low in sodium" as defined in § 101.61(b)(5)(i); and

(ii) "Light" or "lite" and "in sodium" are presented in uniform type size, style, color, and prominence.

(e) Except as provided in paragraphs (b) through (d) of this section, the term "light" or "lite" may not be used to refer to a food that is not reduced in fat by 50 percent, or, if applicable, in calories by 1/3 or, when properly qualified, in sodium by 50 percent unless:

(1) It describes some physical or organoleptic attribute of the food such as texture or color and the information (e.g., "light in color" or "light in texture") so stated, clearly conveys the nature of the product; and

(2) The attribute (e.g., "color" or "texture") is in the same style, color, and at least one-half the type size as the word "light" and in immediate proximity thereto.

(f) If a manufacturer can demonstrate that the word "light" has been associated, through common use, with a particular food to reflect a physical or organoleptic attribute (e.g., light brown sugar, light corn syrup, or light molasses) to the point where it has become part of the statement of identity, such use of the term "light" shall not be considered a nutrient content claim subject to the requirements in this part.

(g) The term "lightly salted" may be used on a product to which has been added 50 percent less sodium than is normally added to the reference food as described in § 101.13(j)(1)(i)(B) and (j)(1)(ii)(B), provided that if the product is not "low in sodium" as defined in § 101.61(b)(4), the statement "not a low sodium food," shall appear on the information panel and the information on the label or labeling as specified in § 101.13(j)(2).

§ 101.60 Nutrient content claims for the calorie content of foods.

(a) *General requirements.* A claim about the calorie content of a food may only be made on the label or in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"Calorie content claims."* (1) The terms "calorie free," "free of calories," "no calories," "zero calories," "without calories," "trivial source of calories," "negligible source of calories," or "dietarily insignificant source of calories" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 5 calories per reference amount customarily consumed; and

(ii) As required in § 101.13(e)(2), if the food meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the caloric content, it is labeled to

disclose that calories are not usually present in the food (e.g., "cider vinegar, a calorie free food").

(2) The terms "low calorie," "few calories," "contains a small amount of calories," "low source of calories," or "low in calories" may be used on the label and in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and does not provide more than 40 calories per reference amount customarily consumed; or

(ii) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and does not provide more than 40 calories per reference amount customarily consumed and, except for sugar substitutes, per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g criterion refers to the "as prepared" form); and

(iii) If a food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the caloric content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "celery, a low calorie food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The product contains 120 calories or less per 100 g; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the calorie content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which it attaches.

(4) The terms "reduced calorie," "reduced in calories," "calorie reduced," "fewer calories," "lower calorie," or "lower in calories" may be used on the label or in the labeling of foods, except as limited by § 101.13(j)(1)(i) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories have been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced calorie cupcakes "33 1/3 percent fewer calories than regular cupcakes"); and

(B) Quantitative information comparing the level of the nutrient in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "calorie content has been reduced from 150 to 100 calories per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or labeling of foods if the reference food meets the definition for "low calorie."

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent fewer calories per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the calories have been reduced are declared in immediate proximity to the most prominent such claim (e.g., Larry's Reduced Calorie Lasagna, "25 percent fewer calories per oz (or 3 oz) than our regular Lasagna"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., calorie content has been reduced from 108 calories per 3 oz to 83 calories per 3 oz).

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or labeling of food if the reference food meets the definition for "low calorie."

(c) *Sugar content claims*—(1) *Use of terms such as "sugar free," "free of sugar," "no sugar," "zero sugar," "without sugar," "sugarless," "trivial source of sugar," "negligible source of sugar," or "dietarily insignificant source of sugar."* Consumers may reasonably be expected to regard terms that represent that the food contains no sugars or sweeteners e.g., "sugar free," or "no sugar," as indicating a product which is low in calories or significantly reduced in calories. Consequently, except as provided in paragraph (c)(2) of this section, a food may not be labeled with such terms unless:

(i) The food contains less than 0.5 g of sugars, as defined in § 101.9(c)(6)(ii), per reference amount customarily consumed or in the case of a meal product or main dish product less than 0.5 g of sugars per labeled serving; and

(ii) The food contains no ingredient that is a sugar or that is generally understood by consumers to contain sugars unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of sugar," "adds a negligible amount of sugar," or "adds a dietarily insignificant amount of sugar;" and

(iii)(A) It is labeled "low calorie" or "reduced calorie" or bears a relative claim of special dietary usefulness labeled in compliance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of this section; or

(B) Such term is immediately accompanied, each time it is used, by either the statement "not a reduced calorie food," "not a low calorie food," or "not for weight control."

(2) The terms "no added sugar," "without added sugar," or "no sugar added" may be used only if:

(i) No amount of sugars, as defined in § 101.9(c)(6)(ii), or any other ingredient that contains sugars that functionally substitute for added sugars is added during processing or packaging; and

(ii) The product does not contain an ingredient containing added sugars such as jam, jelly, or concentrated fruit juice; and

(iii) The sugars content has not been increased above the amount present in the ingredients by some means such as the use of enzymes, except where the intended functional effect of the process is not to increase the sugars content of a food, and a functionally insignificant increase in sugars results; and

(iv) The food that it resembles and for which it substitutes normally contains added sugars; and

(v) The product bears a statement that the food is not "low calorie" or "calorie reduced" (unless the food meets the requirements for a "low" or "reduced calorie" food) and that directs consumers' attention to the nutrition panel for further information on sugar and calorie content.

(3) Paragraph (c)(1) of this section shall not apply to a factual statement that a food, including foods intended specifically for infants and children less than 2 years of age, is unsweetened or contains no added sweeteners in the

case of a food that contains apparent substantial inherent sugar content, e.g., juices.

(4) The terms "reduced sugar," "reduced in sugar," "sugar reduced," "less sugar," "lower sugar" or "lower in sugar" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sugar per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sugar has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "these corn flakes contain 25 percent less sugar than our sugar coated corn flakes"); and

(B) Quantitative information comparing the level of the sugar in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "Sugar content has been lowered from 8 g to 6 g per serving").

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in the labeling of a meal product as defined in § 101.13(l) and a main dish product as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sugars per 100 g of food than an appropriate reference food as described in § 101.13(j)(1), and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sugars have been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced sweet and sour shrimp dinner, "25 percent less sugar per 3 oz than our regular sweet and sour shrimp dinner"); and

(B) Quantitative information comparing the level of the nutrient in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., sugar content has been reduced from 17 g per 3 oz to 13 g per 3 oz).

§ 101.61 Nutrient content claims for the sodium content of foods.

(a) *General requirements.* A claim about the level of sodium in a food may only be made on the label and in the labeling of the food if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"Sodium content claims."* (1) The terms "sodium free," "free of sodium," "no sodium," "zero sodium," "without sodium," "trivial source of sodium," "negligible source of sodium," or "dietary insignificant source of sodium" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 5 milligrams (mg) of sodium per reference amount customarily consumed or in the case of a meal product or a main dish product less than 5 mg of sodium per labeled serving; and

(ii) The food contains no ingredient that is sodium chloride or is generally understood by consumers to contain sodium, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states: "Adds a trivial amount of sodium," "adds a negligible amount of sodium" or "adds a dietarily insignificant amount of sodium;" and

(iii) As required in § 101.13(e)(2) if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to disclose that sodium is not usually present in the food (e.g., "leaf lettuce, a sodium free food").

(2) The terms "very low sodium," or "very low in sodium," may be used on the label and in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 grams (g) or greater than 2 tablespoons and contains 35 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 35 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form);

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "potatoes, a very low-sodium food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains 35 mg or less of sodium per 100 g of product; and

(ii) If the product meets this condition without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "low sodium," or "low in sodium," "little sodium," "contains a small amount of sodium," or "low source of sodium" may be used on the label and in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 140 mg or less sodium per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 140 mg or less sodium per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g criterion refers to the "as prepared" form); and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to vary the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "fresh spinach, a low sodium food"); and

(5) The terms defined in paragraph (b)(4) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains 140 mg or less sodium per 100 g; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower the sodium content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(6) The terms "reduced sodium," "reduced in sodium," "sodium reduced," "less sodium," "lower sodium," or "lower in sodium" may be used on the label or in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sodium per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1).

(ii) As required for § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "reduced sodium ————, 50 percent less sodium than regular ————"); and

(B) Quantitative information comparing the level of the sodium in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "sodium content has been lowered from 300 to 150 mg per serving").

(iii) Claims described in paragraph (b)(6) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low sodium."

(7) The terms defined in paragraph (b)(6) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less sodium per 100 g of food than an appropriate reference food as described in § 101.13(j)(1), and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the sodium has been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced sodium eggplant parmigiana dinner "30 percent less sodium per oz (or 3 oz) than our regular eggplant parmigiana dinner").

(B) Quantitative information comparing the level of sodium in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., sodium content has been reduced from 217 mg per 3 oz to 150 mg per 3 oz).

(iii) Claims described in paragraph (b)(7) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low sodium."

(c) The term "salt" is not synonymous with "sodium." Salt refers to sodium chloride. However, references to salt content such as "unsalted," "no salt," "no salt added" are potentially misleading.

(1) The term "salt free" may be used on the label or in labeling of foods only if the food is "sodium free" as defined in paragraph (b)(1) of this section.

(2) The terms "unsalted," "without added salt," and "no salt added" may be used on the label or in labeling of foods only if:

(i) No salt is added during processing;

(ii) The food that it resembles and for which it substitutes is normally processed with salt; and

(iii) If the food is not sodium free, the statement, "not a sodium free food" or "not for control of sodium in the diet" appears on the information panel of the food bearing the claim.

(3) Paragraph (c)(2) of this section shall not apply to a factual statement that a food intended specifically for infants and children less than 2 years of age is unsalted, provided such statement refers to the taste of the food and is not otherwise false and misleading.

§ 101.62 Nutrient content claims for fat, fatty acid, and cholesterol content of foods.

(a) *General requirements.* A claim about the level of fat, fatty acid, and cholesterol in a food may only be made on the label or in the labeling of foods if:

(1) The claim uses one of the terms defined in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food for which the claim is made is labeled in accordance with § 101.9 or § 101.10, where applicable.

(b) *"Fat content claims."* (1) The terms "fat free," "free of fat," "no fat," "zero fat," "without fat," "nonfat," "trivial source of fat," "negligible source of fat," or "dietarily insignificant source of fat" may be used on the label or in labeling of foods, provided that:

(i) The food contains less than 0.5 gram (g) of fat per reference amount customarily consumed or in the case of a meal product or main dish product less than 0.5 g of fat per labeled serving;

(ii) The food contains no added ingredient that is a fat or is generally understood by consumers to contain fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of fat," "adds a negligible amount of fat," or "adds a dietarily insignificant amount of fat;" and

(iii) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to disclose that fat is not usually present in the food (e.g., "broccoli, a fat free food").

(2) The terms "low fat," "low in fat," "contains a small amount of fat," "low source of fat," or "little fat" may be used on the label and in labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i)(A) The food has a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contains 3 g or less of fat per reference amount customarily consumed; or

(B) The food has a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contains 3 g or less of fat per reference amount customarily consumed and per 50 g of food (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g criterion refers to the "as prepared" form); and

(ii) If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "frozen perch, a low fat food").

(3) The terms defined in paragraph (b)(2) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m), provided that:

(i) The product contains 3 g or less of total fat per 100 g and not more than 30 percent of calories from fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced fat," "reduced in fat," "fat reduced," "less fat," "lower fat," or "lower in fat" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less fat per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the fat has been reduced and are declared in immediate proximity to the most prominent such claim (e.g., "reduced fat—50 percent less fat than our regular brownies"); and

(B) Quantitative information comparing the level of fat in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "fat content has been reduced from 8 g to 4 g per serving").

(iii) Claims described in paragraph (b)(4) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low fat."

(5) The terms defined in paragraph (b)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less fat per 100 g of food than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the fat has been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced fat spinach souffle, "33 percent less fat per 3 oz than our regular spinach souffle"); and

(B) Quantitative information comparing the level of fat in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent such claim or on the information panel (e.g., fat content has been reduced from 7.5 g per 3 oz to 5 g per 3 oz).

(iii) Claims described in paragraph (b)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low fat."

(6) The term "——— percent fat free" may be used on the label or in the labeling of foods, provided that:

(i) The food meets the criteria for "low fat" in paragraph (b)(2) or (b)(3) of this section;

(ii) The percent of reduction and the words "fat free" are in uniform type size; and

(iii) A "100 percent fat free" claim may be made only on foods that meet the criteria for "fat free" in paragraph (b)(1) of this section, that contain less than 0.5 g of fat per 100 g, and that contain no added fat.

(c) *"Fatty acid content claims."* The label or labeling of foods that bear claims with respect to the level of saturated fat shall disclose the level of total fat and cholesterol in the food in immediate proximity to such claim each time the claim is made and in type that shall be no less than one-half the size of the type used for the claim with respect to the level of saturated fat. Declaration of cholesterol content may be omitted when the food contains less than 2 milligrams (mg) of cholesterol per reference amount customarily consumed or in the case of a meal or main dish product less than 2 mg of cholesterol per labeled serving. Declaration of total fat may be omitted with the term defined in paragraph (c)(1) of this section when the food contains 0.5 g or less of total fat per reference amount customarily consumed or, in the case of a meal product or a main dish product, when the product contains less than 0.5 g of total fat per labeled serving. The declaration of total fat may be omitted with the terms defined in paragraphs (c)(2) through (c)(5) of this section when the food contains 3 g or less of total fat per reference amount customarily consumed or in the case of a meal product or a main dish product, when the product contains 3 g or less of total fat per 100 g and not more than 30 percent calories from fat.

(1) The terms "saturated fat free," "free of saturated fat," "no saturated fat," "zero saturated fat," "without saturated fat," "trivial source of saturated fat," "negligible source of saturated fat," or "dietarily insignificant source of saturated fat" may be used on the label or in the labeling of foods, provided that:

(i) The food contains less than 0.5 g of saturated fat per reference amount customarily consumed and the level of trans fatty acids does not exceed 1 percent of the total fat, or in the case of a meal product or main dish product, less than 0.5 g of saturated fat per labeled serving and the level of trans fatty acids does not exceed 1 percent of the total fat; and

(ii) The food contains no ingredient that is generally understood by consumers to contain saturated fat unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients which states, "adds a trivial amount of saturated fat," "adds a negligible amount of saturated fat," or "adds a dietarily insignificant amount of saturated fat;" and

(iii) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to disclose that saturated fat is not usually present in the food.

(2) The terms "low in saturated fat," "low saturated fat," "contains a small amount of saturated fat," "low source of saturated fat," or "a little saturated fat" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains 1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids; and

(ii) If a food meets these conditions without benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches (e.g., "raspberries, a low saturated fat food").

(3) The terms defined in paragraph (c)(2) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The product contains 1 g or less of saturated fatty acids per 100 g and less than 10 percent calories from saturated fat; and

(ii) If the product meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower saturated fat content, it is labeled to clearly refer to all foods of its type and not merely to the particular brand to which the label attaches.

(4) The terms "reduced saturated fat," "reduced in saturated fat," "saturated fat reduced," "less saturated fat," "lower saturated fat," or "lower in saturated fat" may be used on the label or in the labeling of foods, except as limited by § 101.13(j)(1)(i)(A) and except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less saturated fat per reference amount customarily consumed than an appropriate reference food as described in § 101.13(j)(1); and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food and the percent (or fraction) that the saturated fat was reduced are declared in immediate proximity to the most prominent such claim (e.g., "reduced

saturated fat. Contains 50 percent less saturated fat than the national average for nondairy creamers"); and

(B) Quantitative information comparing the level of saturated fat in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "saturated fat reduced from 3 g to 1.5 g per serving").

(iii) Claims described in paragraph (c)(4) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low saturated fat."

(5) The terms defined in paragraph (c)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) The food contains at least 25 percent less saturated fat per 100 g of food than an appropriate reference food as described in § 101.13(j)(1), and

(ii) As required in § 101.13(j)(2) for relative claims:

(A) The identity of the reference food, and the percent (or fraction) that the fat has been reduced are declared in immediate proximity to the most prominent such claim (e.g., reduced saturated fat Macaroni and Cheese, "33 percent less saturated fat per 3 oz than our regular Macaroni and Cheese").

(B) Quantitative information comparing the level of saturated fat in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., saturated fat content has been reduced from 2.5 g per 3 oz to 1.7 g per 3 oz).

(iii) Claims described in paragraph (c)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low saturated fat."

(d) *"Cholesterol content claims."* (1) The terms "cholesterol free," "free of cholesterol," "zero cholesterol," "without cholesterol," "no cholesterol," "trivial source of cholesterol," "negligible source of cholesterol," or "dietarily insignificant source of cholesterol" may be used on the label or in the labeling of foods, provided that:

(i) For foods that contain 13 g or less of total fat per reference amount cutomarily consumed, per labeled serving, and per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared form"), or, in the case of meal products, 26.0 g or less total fat per labeled serving, or, in the case of main dish products, 19.5 g or less total fat per labeled serving:

(A) The food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving; and

(B) The food contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol;" and

(C) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed or, in the case of a meal product or main dish product, 2 g or less of saturated fatty acids per labeled serving; and

(D) As required in § 101.13(e)(2), if the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "applesauce, a cholesterol-free food").

(ii) For food that contain more than 13 g of total fat per reference amount customarily consumed, per labeling serving, per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" form), or in the case of a meal product, more than 26 g of total fat per labeled serving, or, in the case of a main dish product more than 19.5 g of total fat per labeled serving:

(A) The food contains less than 2 mg of cholesterol per reference amount cutomarily consumed or, in the case of a meal product or main dish product, less than 2 mg of cholesterol per labeled serving; and

(B) The food contains no ingredient that is generally understood by consumers to contain cholesterol, unless the listing of the ingredient in the ingredient statement is followed by an asterisk that refers to the statement below the list of ingredients, which states "adds a trivial amount of cholesterol," "adds a negligible amount of cholesterol," or "adds a dietarily insignificant amount of cholesterol;" and

(C) The food contains 2 g or less of saturated fatty acids per reference amount cutomarily consumed or, in the case of a meal product or main dish product less than 2 g of saturated fatty acids per labeled serving; and

(D) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim appears more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(E) As required in § 101.13(e)(2), if the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to disclose that cholesterol is not usually present in the food (e.g., "canola oil, a cholesterol-free food, contains 14 g of fat per serving"); or

(F) If the food contains less than 2 mg of cholesterol per reference amount customarily consumed or in the case of a meal product or main dish product less than 2 mg of cholesterol per labeled serving only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol was reduced are declared in immediate proximity to the most prominent such claim (e.g., "cholesterol-free margarine, contains 100 percent less cholesterol than butter"); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of

the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "contains no cholesterol compared with 30 mg in one serving of butter. Contains 11 g of fat per serving.").

(2) The terms "low in cholesterol," "low cholesterol," "contains a small amount of cholesterol," "low source of cholesterol," or "little cholesterol" may be used on the label or in the labeling of foods, except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) For foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain 13 g or less of total fat per reference amount customarily consumed and per labeled serving:

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed; and

(C) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "low fat cottage cheese, a low cholesterol food.").

(ii) For foods that have a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contain 13 g or less of total fat per reference amount customarily consumed, per labeled serving, and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form);

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form);

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches (e.g., "low fat cottage cheese, a low cholesterol food").

(iii) For foods that have a reference amount customarily consumed greater than 30 g or greater than 2 tablespoons and contain more than 13 g of total fat per reference amount customarily consumed or per labeled serving,

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or

(E) If the food contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share. As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "low-cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers"); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "cholesterol lowered from 30 mg to 5 mg per serving, contains 13 g of fat per serving").

(iv) For foods that have a reference amount customarily consumed of 30 g or less or 2 tablespoons or less and contain more than 13 g of total fat per reference amount customarily consumed, per labeled serving, or per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form),

(A) The food contains 20 mg or less of cholesterol per reference amount customarily consumed and per 50 g (for dehydrated foods that are typically consumed when rehydrated with only water, the per 50 g refers to the "as prepared" form),

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(e)(2), if the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower cholesterol content, it is labeled to clearly refer to all foods of that type and not merely to the particular brand to which the label attaches; or

(E) If the food contains 20 mg or less of cholesterol only as a result of special processing, alteration, formulation, or reformulation, the amount of cholesterol is substantially less (i.e., meets requirements of paragraph (d)(4)(ii)(A) of this section) than the food for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more of a national or regional market) market share. As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "low-cholesterol peanut butter sandwich crackers, contains 83 percent less cholesterol than our regular peanut butter sandwich crackers"); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., "cholesterol lowered from 30 mg to 5 mg per serving, contains 13 g of fat per serving").

(3) The terms defined in paragraph (d)(2) of this section may be used on the label and in labeling of meal products as defined in § 101.13(l) or a main dish product as defined in § 101.13(m) provided that the product meets the requirements of paragraph (d)(2) of this section except that the determination as to whether paragraph (d)(2)(i) or (d)(2)(iii) of this section applies to the product will be made only on the basis of whether the meal product contains 26 g or less of total fat per labeled serving or the main dish product contain 19.5 g or less of total fat per labeled serving, the requirement in paragraphs (d)(2)(i)(A) and (d)(2)(iii)(A) of this section shall be limited to 20 mg of cholesterol per 100 g, and the requirement in paragraphs (d)(2)(i)(B) and (d)(2)(iii)(B) of this section shall be modified to require that the food contain 2 g or less of saturated fat per 100 g rather than per reference amount customarily consumed.

(4) The terms "reduced cholesterol," "reduced in cholesterol," "cholesterol reduced," "less cholesterol," "lower cholesterol," or "lower in cholesterol" except as limited by § 101.13(j)(1)(i)(A) may be used on the label or in labeling of foods or foods that substitute for those foods as specified in § 101.13(d), excluding meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) For foods that contain 13 g or less of total fat per reference amount customarily consumed, per labeled serving, and per 50 g if the reference amount customarily consumed is 300 g or less or 2 tablespoons or less (for dehydrated food that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" form):

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more) market share; and

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed; and

(C) As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim; and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel.

(ii) For foods that contain more than 13 g of total fat per reference amount customarily consumed, per labeled serving, or per 50 g if the reference amount customarily consumed is 30 g or less or 2 tablespoons or less (for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" form):

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (i.e., 5 percent or more of a national or regional market) market share;

(B) The food contains 2 g or less of saturated fatty acids per reference amount customarily consumed;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel, the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., 25 percent less cholesterol than ————————); and

(*2*) Quantitative information comparing the level of cholesterol in the product per labeled serving with that of the reference food that it replaces is declared adjacent to the most prominent claim on the information panel (e.g., "Cholesterol lowered from 55 mg to 30 mg per serving. Contains 13 g of fat per serving").

(iii) Claims described in paragraph (d)(4) of this section may not be made on the label or in labeling of a food if the nutrient content of the reference food meets the definition for "low cholesterol."

(5) The terms defined in paragraph (d)(4) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m), provided that:

(i) For meal products that contain 26.0 g or less of total fat per labeled serving or for main dish products that contain 19.5 g or less of total fat per labeled serving;

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share;

(B) The food contains 2 g or less of saturated fatty acids per 100 g; and

(C) As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food, and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., "25% less cholesterol per 3 oz than ————————."); and

(*2*) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim or on the information panel (e.g., Cholesterol content has been reduced from 35 mg per 3 oz to 25 mg per 3 oz).

(ii) For meal products that contain more than 26.0 g of total fat per labeled serving or for main dish products that contain more than 19.5 g of total fat per labeled serving:

(A) The food has been specifically formulated, altered, or processed to reduce its cholesterol by 25 percent or more from the reference food it resembles as defined in § 101.13(j)(1) and for which it substitutes as specified in § 101.13(d) that has a significant (e.g., 5 percent or more of a national or regional market) market share.

(B) The food contains 2 g or less of saturated fatty acids per 100 g;

(C) The label or labeling discloses the level of total fat in a serving (as declared on the label) of the food. Such disclosure shall appear in immediate proximity to such claim preceding the referral statement required in § 101.13(g) in type that shall be no less than one-half the size of the type used for such claim. If the claim appears on more than one panel the disclosure shall be made on each panel except for the panel that bears nutrition labeling. If the claim is made more than once on a panel, the disclosure shall be made in immediate proximity to the claim that is printed in the largest type; and

(D) As required in § 101.13(j)(2) for relative claims:

(*1*) The identity of the reference food and the percent (or fraction) that the cholesterol has been reduced are declared in immediate proximity to the most prominent such claim (e.g., 25 percent less cholesterol than ————————); and

(*2*) Quantitative information comparing the level of cholesterol in the product per specified weight with that of the reference food that it replaces is declared adjacent to the most prominent claim on the information panel (e.g., "cholesterol lowered from 30 mg to 22 mg per 3 oz of product.")

(iii) Claims described in paragraph (d)(5) of this section may not be made on the label or in the labeling of a food if the nutrient content of the reference food meets the definition for "low cholesterol."

(e) *"Lean" and "extra lean" claims.* (1) The term "lean" may be used on the label or in labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a seafood or game meat product and as packaged contains less than 10 g total fat, less than 4 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g;

(2) The term defined in paragraph (e)(1) of this section may be used on the label or in the labeling of meal products as defined in § 101.13(l) or main dish products as defined in § 101.13(m) provided that the food contains less than 10 g total fat, less than 4 g saturated fat, and less than 95 mg cholesterol per 100 g and per labeled serving;

(3) The term "extra lean" may be used on the label or in the labeling of foods except meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food is a discrete seafood or game meat product and as packaged contains less than 5 g total fat, less than 2 g saturated fat, and less than 95 mg cholesterol per reference amount customarily consumed and per 100 g; and

(4) The term defined in paragraph (e)(3) of this section may be used on the label or in labeling of meal products as defined in § 101.13(l) and main dish products as defined in § 101.13(m) provided that the food contains less than 5 g of fat, less than 2 g of saturated fat, and less than 95 mg of cholesterol per 100 g and per labeled serving.

(f) *Misbranding.* Any label or labeling containing any statement concerning fat, fatty acids, or cholesterol that is not in conformity with this section shall be deemed to be misbranded under sections 201(n), 403(a), and 403(r) of the Federal Food, Drug, and Cosmetic Act.

§ 101.65 Implied nutrient content claims and related label statements.

(a) *General requirements.* An implied nutrient content claim can only be made on the label and in labeling of the food if:

(1) The claim uses one of the terms described in this section in accordance with the definition for that term;

(2) The claim is made in accordance with the general requirements for nutrient content claims in § 101.13; and

(3) The food is labeled in accordance with § 101.9 or 101.10, where applicable.

(b) *Label statements that are not implied claims.* Certain label statements about the nature of a product are not nutrient content claims unless such statements are made in a context that would make them an implied claim under § 101.13(b)(2). The following types of label statements are generally not implied nutrient content claims and are not subject to the requirements of § 101.13 and this section:

(1) A claim that a specific ingredient or food component is absent from a product, provided that the purpose of such claim is to facilitate avoidance of the substances because of food allergies (see § 105.62 of this chapter), food intolerance, religious beliefs, or dietary practices such as vegetarianism or other nonnutrition related reason, e.g., "100 percent milk free;"

(2) A claim about a substance that is nonnutritive or that does not have a nutritive function, e.g., "contains no preservatives," "no artificial colors;"

(3) A claim about the presence of an ingredient that is perceived to add value to the product e.g., "made with real butter," "made with whole fruit," "contains honey;"

(4) A statement of identity for a food in which an ingredient constitutes essentially 100 percent of a food, (e.g. "corn oil," "oat bran.");

(5) A statement of identity that names as a characterizing ingredient, an ingredient associated with a nutrient benefit (e.g., "corn oil margarine," "oat bran muffins," or "whole wheat bagels"), unless such claim is made in a context in which label or labeling statements, symbols, vignettes, or other forms of communication suggest that a nutrient is absent or present in a certain amount; and

(6) A label statement made in compliance with a specific provision of part 105 of this chapter, solely to note that a food has special dietary usefulness relative to a physical, physiological, pathological, or other condition, where the claim identifies the special diet of which the food is intended to be a part.

(c) *Particular implied nutrient content claims.* (1) Claims about the food or an ingredient therein that suggest that a nutrient or an ingredient is absent or present in a certain amount (e.g., "high in oat bran") are implied nutrient content claims and must comply with paragraph (a) of this section.

(2) The phrases "contains the same amount of [nutrient] as a [food]" and "as much [nutrient] as a [food]" may be used on the label or in the labeling of foods, provided that the amount of the nutrient in the reference food is enough to qualify that food as a "good source" of that nutrient, and the labeled food, on a per serving basis, is an equivalent, good source of that nutrient (e.g., "as much fiber as an apple," "Contains the same amount of Vitamin C as an 8 oz glass of orange juice.").

(3) Claims may be made that a food contains or is made with an ingredient that is known to contain a particular nutrient, or is prepared in a way that affects the content of a particular nutrient in the food, if the finished food is either "low" in or a good source of the nutrient that is associated with the ingredient or type of preparation. If a more specific level is claimed (e.g., "high in ————————"), that level of the nutrient must be present in the food. For example, a claim that a food contains oat bran is a claim that it is a good source of dietary fiber; that a food is made only with vegetable oil is a claim that it is low in saturated fat; and that a food contains no oil is a claim that it is fat free.

(d) *General nutritional claims.* (1) Claims about a food that suggest that the food because of its nutrient content may be useful in maintaining healthy dietary practices and that are made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 grams of fat") are implied nutrient content claims covered by this paragraph.

(2) [Reserved]

§ 101.69 Petitions for nutrient content claims.

(a) This section pertains to petitions for claims, expressed or implied, that:

(1) Characterize the level of any nutrient which is of the type required to be in the label or labeling of food by section 403(q)(1) or (q)(2) of the Federal Food, Drug, and Cosmetic Act (the act); and

(2) That are not exempted under section 403(r)(5)(A) through (r)(5)(C) of the act from the requirements for such claims in section 403(r)(2).

(b) Petitions included in this section are:

(1) Petitions for a new (heretofore unauthorized) nutrient content claim;

(2) Petitions for a synonymous term (i.e., one that is consistent with a term defined by regulation) for characterizing the level of a nutrient; and

(3) Petitions for the use of an implied claim in a brand name.

(c) An original and one copy of the petition to be filed under the provisions of section 403(r)(4) of the act shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. Petitioners interested in submitting a disk should contact FDA's Center for Food Safety and Applied Nutrition for details. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which published notices as required by section 403 of the act may be sent.

(d) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized (with the understanding that such information may in whole or part be subject to release to the public) in a written statement signed by the person who submitted it. Any reference to published information should be accompanied by reprints or photostatic copies of such references.

(e) If nonclinical laboratory studies are included in a petition submitted under section 403(r)(4) of the act, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(f) If clinical investigations are included in a petition submitted under section 403(r)(4) of the act, the petition shall include a statement regarding each such clinical investigation relied upon in the petition that the study either was conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or was not subject to such requirements in accordance with § 56.104 or § 56.105 of this chapter, and that it was conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(g) The availability for public disclosure of petitions submitted to the agency under this section will be governed by the rules specified in § 10.20(j) of this chapter.

(h) All petitions submitted under this section shall include either a claim for a categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

(i) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application from the petitioner, the present petition may incorporate it by specific reference to the earlier petition.

(j) The petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

(k) The petition shall include a statement signed by the person responsible for the petition, that to the best of his knowledge, it is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him pertinent to the evaluation of the petition.

(l) All applicable provisions of Part 10—Administrative Practices and Procedures, may be used by the Commissioner of Food and Drugs, the petitioner or any outside party with respect to any agency action on the petition.

(m)(1) Petitions for a new nutrient content claim shall include the following data and be submitted in the following form.

———

(Date)

Name of petitioner ————

Post office address ————

Subject of the petition ————

Regulations and Industry Activities Branch (HFF–312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.

To Whom It May Concern:

The undersigned, — submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the claim and its proposed use).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the descriptive term and the nutrient that the term is intended to characterize with respect to the level of such nutrient. The statement should address why the use of the term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify the level at which the nutrient must be present or what other conditions concerning the food must be met for the use of the term in labels or labeling to be appropriate, as well as any factors that would make the use of the term inappropriate.

B. A detailed explanation, supported by any necessary data, of why use of the food component characterized by the claim is of importance in human nutrition by virtue of its presence or absence at the levels that such claim would describe. This explanation shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing terms defined by regulation under section 403(r)(2)(A)(i) of the act. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.

C. Analytical data that shows the amount of the nutrient that is the subject of the claim and that is present in the types of foods for which the claim is intended. The assays should be performed on representative samples using the Association of Official Analytical Chemists International (AOAC International) methods where available. If no AOAC International method is available, the petitioner shall submit the assay method used, and data establishing the validity of the method for assaying the nutrient in the particular food. The validation data should include a statistical analysis of the analytical and product variability.

D. A detailed analysis of the potential effect of the use of the proposed claim on food consumption and of any corresponding changes in nutrient intake. The latter item shall specifically address the intake of nutrients that have beneficial and negative consequences in the total diet. If the claim is intended for a specific group within the population, the above analysis shall specifically address the dietary practices of such

group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group.

Yours very truly,
Petitioner ————
By ————
(Indicate authority)

(2) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received by the agency. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition), and the petitioner will subsequently be notified of the agency's decision to file or deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 100 days of the date of receipt of the petition, the Commissioner of Food and Drugs will notify the petitioner by letter that the petition has either been filed or denied. If denied, the notification shall state the reasons therefor. If filed, the date of the notification letter becomes the date of filing for the purposes of section 403(r)(4)(A)(i) of the act. A petition that has been denied shall not be made available to the public. A filed petition shall be available to the public as provided under paragraph (g) of this section.

(4) Within 90 days of the date of filing the Commissioner of Food and Drugs will by letter of notification to the petitioner:

(i) Deny the petition; or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the new term will be published in the **Federal Register**. The Commissioner of Food and Drugs will publish the proposal to amend the regulations to provide for the requested use of the nutrient content claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public disclosure.

(n)(1) Petitions for a synonymous term shall include the following data and be submitted in the following form.

————

(Date)
Name of petitioner ————
Post office address ————
Subject of the petition ————
Regulations and Industry Activities Branch (HFF–312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
To Whom It May Concern:

The undersigned, ————
submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the synonymous term and its proposed use in a nutrient content claim that is consistent with an existing term that has been defined under section 403(r)(2) of the act).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the synonymous descriptive term, the existing term defined by a regulation under section 403(r)(2)(A)(i) of the act with which the synonymous term is claimed to be consistent. The statement should address why the proposed synonymous term is consistent with the term already defined by the agency, and why the use of the synonymous term as proposed will not be misleading. The statement should provide examples of the nutrient content claim as it will be used on labels or labeling, as well as the types of foods on which the claim will be used. The statement shall specify whether any limitations not applicable to the use of the defined term are intended to apply to the use of the synonymous term.

B. A detailed explanation, supported by any necessary data, of why use of the proposed term is requested, including an explanation of whether the existing defined term is inadequate for the purpose of effectively characterizing the level of a nutrient. This item shall also state what nutritional benefit to the public will derive from use of the claim as proposed, and why such benefit is not available through the use of existing term defined by regulation. If the claim is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group, and should include scientific data sufficient for such purpose.

Yours very truly,
Petitioner ————
By ————
(Indicate authority)

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition) and the petitioner will subsequently be notified of the agency's decision to grant the petitioner permission to use the proposed term or to deny the petition; or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) Within 90 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and consequently denied, the Commissioner of Food and Drugs will notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed term, with any conditions or limitations on such use specified, or to deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition.

(4) As soon as practicable following the agency's decision to either grant or deny the petition, the Commissioner of Food and Drugs will publish a notice in the **Federal Register** informing the public of his decision. If the petition is granted the Food and Drug Administration will list, the approved synonymous term in the regulations listing terms permitted for use in nutrient content claims.

(o)(1) Petitions for the use of an implied nutrient content claim in a brand name shall include the following data and be submitted in the following form:

————

(Date)
Name of petitioner ————
Post office address ————
Subject of the petition ————
Regulations and Industry Activities Branch (HFF–312),
Food and Drug Administration,
Department of Health and Human Services,
Washington, DC 20204.
To Whom It May Concern:

The undersigned,

————

submits this petition under section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) with respect to (statement of the implied nutrient content claim and its proposed use in a brand name).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. A statement identifying the implied nutrient content claim, the nutrient the claim is intended to

characterize, the corresponding term for characterizing the level of such nutrient as defined by a regulation under section 403(r)(2)(A)(i) of the act, and the brand name of which the implied claim is intended to be a part. The statement should address why the use of the brandname as proposed will not be misleading. It should address in particular what information is required to accompany the claim or other ways in which the claim meets the requirements of sections 201(n) and 403(a) of the act. The statement should provide examples of the types of foods on which the brand name will appear. It shall also include data showing that the actual level of the nutrient in the food qualifies the food to bear the corresponding term defined by regulation. Assay methods used to determine the level of a nutrient should meet the requirements stated under petition format item C in paragraph (k)(1) of this section.

B. A detailed explanation, supported by any necessary data, of why use of the proposed brand name is requested. This item shall also state what nutritional benefit to the public will derive from use of the brand name as proposed. If the branded product is intended for a specific group within the population, the analysis should specifically address nutritional needs of such group and should include scientific data sufficient for such purpose.

Yours very truly,
Petitioner ————————
By ————————

(2) Within 15 days of receipt of the petition the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner:

(i) That the petition is undergoing agency review (in which case a docket number will be assigned to the petition); or

(ii) That the petition is incomplete, e.g., it lacks any of the data required by this part, it presents such data in a manner that is not readily understood, or it has not been submitted in quadruplicate, in which case the petition will be denied, and the petitioner will be notified as to what respect the petition is incomplete.

(3) The Commissioner of Food and Drugs will publish a notice of the petition in the **Federal Register** announcing its availability to the public and seeking comment on the petition. The petition shall be available to the public to the extent provided under paragraph (g) of this section. The notice shall allow 30 days for comments.

(4) Within 100 days of the date of receipt of the petition that is accepted for review (i.e., that has not been found to be incomplete and subsequently returned to the petitioner), the Commissioner of Food and Drugs will:

(i) Notify the petitioner by letter of the agency's decision to grant the petitioner permission to use the proposed brand name if such use is not misleading, with any conditions or limitations on such use specified; or

(ii) Deny the petition, in which case the letter shall state the reasons therefor. Failure of the petition to fully address the requirements of this section shall be grounds for denial of the petition. Should the Commissioner of Food and Drugs not notify the petitioner of his decision on the petition within 100 days, the petition shall be considered to be granted.

(5) As soon as practicable following the granting of a petition, the Commissioner of Food and Drugs will publish a notice in the **Federal Register** informing the public of such fact.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number ————————)

8. Subpart F is redesignated as subpart G and new subpart F, consisting of § 101.95, is added to read as follows:

Subpart F—Specific Requirements for Descriptive Claims that are Neither Nutrient Content Claims nor Health Claims

§ 101.95 "Fresh," "freshly frozen," "fresh frozen," "frozen fresh."

The terms defined in this section may be used on the label or in labeling of a food in conformity with the provisions of this section. The requirements of the section pertain to any use of the subject terms as described in paragraphs (a) and (b) of this section that expressly or implicitly refers to the food on labels or labeling, including use in a brand name and use as a sensory modifier. However, the use of the term "fresh" on labels or labeling is not subject to the requirements of paragraph (a) of this section if the term does not suggest or imply that a food is unprocessed or unpreserved. For example, the term "fresh" used to describe pasteurized whole milk is not subject to paragraph (a) of this section because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized). However, the term "fresh" to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients would be subject to paragraph (a) of this section because the term implies that the food is not processed or preserved. Uses of fresh not subject to this regulation will be governed by the provisions of 403(a) of the Federal Food, Drug, and Cosmetic Act (the act).

(a) The term "fresh," when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation, except as provided in paragraph (c) of this section.

(b) The terms "fresh frozen" and "frozen fresh," when used on the label or in labeling of a food, mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). Blanching of the food before freezing will not preclude use of the term "fresh frozen" to describe the food. "Quickly frozen" means frozen by a freezing system such as blast-freezing (sub-zero Fahrenheit temperature with fast moving air directed at the food) that ensures the food is frozen, even to the center of the food, quickly and that virtually no deterioration has taken place.

(c) *Provisions and restrictions*—(1) The following do not preclude the food from use of the term "fresh:"

(i) The addition of approved waxes or coatings;

(ii) The post-harvest use of approved pesticides;

(iii) The application of a mild chlorine wash or mild acid wash on produce; or

(iv) The treatment of raw foods with ionizing radiation not to exceed the maximum dose of 1 kiloGray in accordance with § 179.26 of this chapter.

(2) A food meeting the definition in paragraph (a) of this section that is refrigerated is not precluded from use of "fresh" as provided by this section.

Dated: December 17, 1992.

David A. Kessler,
Commissioner of Food and Drugs.
Louis W. Sullivan,
Secretary of Health and Human Services.

[FR Doc. 92–31504 Filed 12–28–92; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 105

[Docket No. 91N-384L]

RIN 0905-AD06

Food Labeling: Label Statements on Foods for Special Dietary Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food labeling regulations to conform them to the requirements of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). With the passage of the 1990 amendments to the Federal Food, Drug, and Cosmetic Act (the act), certain provisions concerning label statements on foods for special dietary use in reducing or maintaining caloric intake or body weight are no longer appropriately included in that regulation but are now more appropriately defined as nutrient content claims applicable to the general population and regulated under 21 CFR part 101. FDA is making changes in 21 CFR 105.66 to reflect this fact. FDA is also announcing its intention to reexamine 21 CFR part 105 and revise that part as necessary to ensure that it provides appropriate coverage for foods for special dietary use.

DATES: Effective May 8, 1994, except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by February 5, 1993.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFS–155), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS–155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60421), FDA published a proposed rule entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" (the general principles proposal) that would, among other things, establish general principles for the use of claims describing the nutrient content of a food and define certain specific nutrient content claims that can be used to describe the levels of certain nutrients in a food.

The general principles proposal was issued in response to the 1990 amendments (Pub. L. 101–535) to the act. With respect to nutrient content claims, the 1990 amendments amended the act by adding section 403(r)(1)(A) (21 U.S.C. 343(r)(1)(A)) which states that a food is misbranded if it bears a claim in its label or labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling, unless such claim is made using terms which are defined in regulations adopted by the agency under section 403(r)(2).

The proposed regulations on nutrient content claims included provisions similar or identical to some provisions in § 105.66, which addresses foods for special dietary use in reducing or maintaining caloric intake or body weight. Therefore, the general principles proposal included several changes in § 105.66 to eliminate redundancy in the regulations and to conform § 105.66 to the 1990 amendments. Specifically, FDA proposed to redesignate requirements for terms such as "low calorie" and "reduced calorie," for other comparative calorie claims, and for sugar claims from § 105.66 to new § 101.60, which defines terms used to make nutrient content claims for the calorie content of foods. This redesignation is necessary because terms such as "low calorie" and "reduced calorie" are no longer appropriately regulated under the regulations for foods for special dietary use but are now more appropriately defined under the 1990 amendments as nutrient content claims for foods intended for use by the general population. FDA also proposed to delete from § 105.66 any inappropriate reference to specific nutrient content claims or similar terms and any statement that is inconsistent with the 1990 amendments.

FDA also proposed to delete the exemption (§ 105.66(e)(3)) for formulated meal replacements and other foods that are represented for special dietary use as a whole meal from the requirements in § 105.66(e)(1). These requirements bear on the use of label terms that suggest usefulness as low calorie or reduced calorie foods, such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener." FDA proposed to remove this exemption so that such claims could be expressly permitted under § 105.66, and thus not be prohibited as implied nutrient content claims under the 1990 amendments, until more appropriate regulations can be issued. The agency stated its view that claims that are permitted under § 105.66 meet the requirements of section 403(r) of the act (56 FR 60421 at 60458).

FDA noted in the proposal that a significant portion of § 105.66 remains appropriate for regulating foods that are for special dietary use (56 FR 60421 at 60457). Such foods are those that are specifically represented as, or that purport to be, useful as part of a weight control plan, as opposed to those that are simply represented as being low or reduced in calories (although products low or reduced in calories can be useful in reducing or maintaining body weight). The agency did not propose to remove the remaining portion of § 105.66, which includes requirements for label statements about nonnutritive sweeteners and for the use of the term "diet" and related terms. FDA noted, however, that it plans to reexamine the provisions remaining in § 105.66 and initiate additional rulemaking as appropriate (56 FR 60421 at 60457).

FDA is publishing a final rule based on the general principles proposal and on a related proposal (56 FR 60421 at 60478, November 27, 1991) concerning nutrient content claims related to the fat, fatty acid, and cholesterol content of food elsewhere in this issue of the **Federal Register**. This final rule effecting revisions in § 105.66 is being published as a separate document because § 105.66 was issued under the authority of section 403(j) of the act. Thus, revisions to § 105.66 must be made in accordance with the formal rulemaking procedures in section 701(e) of the act (21 U.S.C. 371(e)). Under these procedures, there is an opportunity to object to the provisions of a final rule and to request a public hearing on that objection. Such an opportunity is not provided as part of the notice and comment procedures apply to that most of the rest of the rulemaking that FDA is doing in response to the 1990 amendments.

The agency received only a few comments in response to the proposed revisions in § 105.66. Some of the comments received by the agency addressed matters concerning other regulations in 21 CFR part 105 (i.e., §§ 105.62 and 105.67) which are outside the scope of this rulemaking and are not being addressed here. However, after review of these comments, FDA believes that other regulations in part 105 may need to be reexamined, and that additional rulemaking may need to be initiated to ensure that these regulations

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fully address their subject matter. In its reexamination of § 105.66, FDA will consider among other things, whether that regulation adequately describes foods for use in reducing or maintaining body weight, such as formulated meal replacements, whether it appropriately provides for use of terms such as "diet" on such foods, and whether "artificially sweetened" or "sweetened with a nonnutritive sweetener" should be included as label terms suggesting usefulness as low calorie or reduced calorie foods. These actions will be undertaken at some time in the future and FDA will solicit comments on the relevant issues at that time.

All of the relevant comments on proposed revisions in § 105.66 supported FDA's intent to revise this regulation to conform it to the provisions of the 1990 amendments. However, some of the comments raised concerns about some of the specific actions that FDA proposed. These comments are addressed below.

II. Comments and Agency Response

1. One comment asserted that requiring formulated meal replacements that bear terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" to meet the requirements for low or reduced calorie foods, or to make another comparative calorie claim, would effectively ban the sale of these foods. The comment stated that formulated meal replacements do not meet the definition of "low calorie" or "reduced calorie," and that a "reference" food would have to be identified to make a "reduced calorie" or other comparative calorie claim. The comment pointed out that FDA did not address what the reference food should be for formulated meal replacements. The comment requested that FDA provide in the regulations that a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, and that bears terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," not be required to be a "low calorie" or "reduced calorie" food, or to bear another comparative calorie claim, if its labeling is not false or misleading, and the product is useful as part of a weight loss or weight control program.

As noted above, FDA had proposed to delete the exemption in § 105.66(e)(3) for formulated meal replacements and other foods that are represented to be of special dietary use as a whole meal, from the requirements in § 105.66(e)(1) so that such foods would be expressly authorized to make "diet," "dietetic," or "artificially sweetened" claims under § 105.66. Thus, these claims on these foods would not be prohibited as unauthorized implied nutrient content claims under the 1990 amendments. However, FDA has reconsidered the circumstances under which claims should be regarded as implied nutrient content claims and as claims for special dietary use. As stated in the final rule on nutrient content claims, published elsewhere in this issue of the **Federal Register**, the agency does not consider claims made solely to portray the usefulness of a food for supplying a particular dietary need that exists by reason of a physical, physiological, pathological, or other condition, as described in part 105, to be a nutrient content claim subject to § 101.13. On the other hand, a claim of dietary usefulness made in a context that is relevant to the general population (e.g., where the label states that the food is "low calorie") would be subject to the requirements for nutrient content claims. FDA views a claim such as "use as part of a weight reduction program," made in conjunction with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener," on a formulated meal replacement to be a claim that solely portrays the usefulness of the food for a special dietary need, as described in part 105. Thus, such a claim by itself, without any other reference to nutrient aspects of the food relative to the general population, is not a nutrient content claim. Therefore, FDA concludes that there is no need to subject formulated meal replacements to the requirements of § 105.66(e)(1) to preclude claims such as "diet" on such products from being prohibited as implied nutrient content claims.

FDA, thus, has decided not to delete § 105.66(e)(3) and thus will continue to permit formulated meal replacements and other foods that are represented to be of special dietary use as whole meals to use terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on their labels and labeling without having to comply with the requirements of § 105.66(e)(1). Therefore, the concern raised that formulated meal replacements are unable to comply with the requirements of § 105.66(e)(1) is moot.

However, FDA advises that the use of terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on the label or in the labeling of any food, including a food for special dietary use, is subject to the act's general prohibition against false or misleading labeling in section 403(a) of the act. Thus, FDA can take action against any false or misleading use of a term such as "diet." For example, if a food that is not a formulated meal replacement purported on its label to be a formulated meal replacement to avoid the requirement that foods using the label term "diet" either be low in calories, reduced in calories or bear another comparative calorie claim, FDA would consider the food to be misbranded because it is falsely represented as a formulated meal replacement. Such a food would also be in violation of § 105.66(e)(1) because it is not a formulated meal replacement. FDA is likely to take action against any food that uses terms such as "diet," "dietetic," "artificially sweetened," and "sweetened with nonnutritive sweetener" on its label or in its labeling in this manner.

2. A comment stated that FDA should amend § 105.66(e)(1) in the final rule to clarify that this regulation applies only when the specific terms "diet," "dietetic," "artificially sweetened," and "artificially sweetened with nonnutritive sweetener" appear on the label as self-contained terms, but not when a term such as "diet" is used in a statement that represents the product to be useful as part of a weight loss "diet." The comment stated that the proposal could be misunderstood to mean that FDA is prohibiting the use of all other claims suggesting that a product is useful in a weight loss "diet" if that product does not meet the definition for "low calorie" or "reduced calorie." The comment stated that such an interpretation would be inconsistent with FDA's express intention of permitting such claims as stated in the final rule establishing § 105.66 (43 FR 43248 at 43253, September 22, 1978), wherein the agency stated:

> * * * any food may make a claim of special dietary usefulness for weight control on some basis other than its being "low calorie," "reduced calorie," or comparatively useful * * *. The claim must not be misleading and the basis for the claim must be conspicuously and clearly stated in conjunction with the claim. These foods may make appropriate claims, e.g., "for calorie restricted diets" or "useful for weight control."

The agency advises that it continues to hold the position that it stated in the final order establishing § 105.66. In that rulemaking, FDA stated that a food that purports to be useful for weight control on some other basis than its being "low calorie," "reduced calorie," or comparatively useful in controlling calorie intake is subject to the provisions of § 105.66(a) and (b) but not § 105.66(e). The agency stated that to

comply with § 105.66(a) and (b), such foods must bear nutrition labeling, labeling about the presence of nonnutritive ingredients, and a conspicuous and nonmisleading statement about the basis of the claim (43 FR 43248 at 43253, September 22, 1978).

Concerning the matter raised by the comment, i.e., the use of statements incorporating the term "diet" on foods for special dietary use intended for weight reduction, the agency concludes that such statements do not invoke the requirements of § 105.66(e), except when made on meal replacements or other foods represented to be of special dietary use as a whole meal, which are subject to § 105.66(e)(3), when they are used in a manner that does not suggest that the food is a "low calorie" or "reduced calorie" food. Such foods are subject to the requirements of § 105.66(a) and (b). However, the revision of the regulation sought by this comment, i.e., a provision in the regulation clarifying the circumstances where § 105.66(e) applies, is beyond the scope of this rulemaking. FDA stated in the general principles proposal that it only intended to make changes in § 105.66 at this time that are necessary to conform this section to the 1990 amendments. FDA will fully consider any necessary clarification of § 105.66(e)(1) in this regard when it initiates additional rulemaking on this section as stated above.

3. One comment suggested that the "Weight Watchers" line of foods falls within the provisions of § 105.66 because it provides information on the product label that suggests that these products can be useful in an overall weight-control diet plan. In addition, this same comment expressed concern that use of the brand name "Weight Watchers" would be prohibited on those products introduced into the marketplace after October 25, 1989, i.e., the date after which products introduced into the marketplace that make nutrient content claims in their brand names must use terms in the claims that are defined by the agency in a regulation, or that have been approved by the agency in response to a petition (section 403(r)(2)(A)(i), (r)(2)(C), and (r)(4)(A)(iii) of the act).

FDA advises that, in general, it would regard a brand name such as "Weight Watchers," when accompanied by information on the product label that suggests that the product can be useful in an overall weight-control diet plan, without any other reference to nutrient aspects of the food relative to the general population, to be a claim that solely portrays the usefulness of the food for a special dietary need as described in part 105 (see comment 1 of this document). Under these circumstances, such a claim is subject to the provisions of § 105.66 and is not a nutrient content claim. Accordingly, such a claim in a brand name may continue to be used on such products irrespective of whether a specific product under that brand name was introduced into the marketplace before October 25, 1989.

III. Conclusions

After review and consideration of the comments received in response to the November 27, 1991, proposal, FDA concludes that no evidence or information has been presented that would alter the agency's tentative determination that it should amend § 105.66 to conform that regulation to the provisions of the 1990 amendments. Therefore, FDA is amending § 105.66 as proposed with the exception of the revision in the final rule discussed in comment 1 of this document. FDA has also corrected two inadvertent errors that appeared in the proposal in the codified text of paragraph (e)(1). First, the proposed text omitted the words "such as" that had immediately preceded "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" in the existing regulation. It was not the agency's intent to delete these words from the revised text, and thus, they are being restored in the final rule. Secondly, FDA has conformed paragraph (e)(1) with respect to comparative calorie claims to paragraph (d). FDA has also made other minor editorial revisions in the text of the final rule for internal consistency.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the general principles proposal (56 FR 60467). At that time, FDA determined under § 25.24(a)(11) that the actions proposed therein (which include this action) are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

4. Several comments on the general principles proposal suggested that there would be significant adverse environmental effects from the actions proposed therein because they would cause large stocks of labels and labeled packaging materials to be discarded and require a great number of trees to be harvested to provide new labeling material. One comment estimated the number of label units from the dairy industry that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, this comment did not: (1) Show how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to this action, or (3) describe what impact the discarded labeling and packaging would have on the disposal of solid waste.

Neither the 1990 amendments nor FDA's proposed regulations require a food company to make nutrient content claims on its product labels. Food companies have known since November 8, 1990, the date of enactment of the 1990 amendments, that possibly by May 8, 1993, their labels would not be able to include nutrient content claims unless the claims conformed to FDA's regulations. In the general principles proposal (56 FR 60421) the agency proposed that this final rule would become effective 6 months after its date of publication in the **Federal Register**. However, the agency has determined that this final rule will become effective May 8, 1994. FDA believes that this effective date will allow ample time for food companies to use up most of the label and packaging stocks that existed on November 8, 1990, and that contained nutrient content claims. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected, and that an environmental impact statement is not required.

V. Economic Impact

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has reviewed the final rule to redesignate certain requirements in § 105.66 to § 101.60 to determine its impact on small entities, including small businesses. Although the food labeling reform initiative taken as a whole, would result in a major rule, FDA has determined that redesignating certain requirements in § 105.66 to § 101.60 for conformance to the 1990 amendments, will not result in a significant impact on a substantial number of small entities. FDA has not received any new information or comments that would alter this determination. Therefore, FDA certifies in accordance with the Regulatory Flexibility Act, that no significant impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this final rule, and the agency has determined that the rule, if promulgated, will not be a major rule as defined by that order.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before December 10, 1992, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects in 21 CFR Part 105

Dietary foods, Food grades and standards, Food labeling, Infants and children.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 105 is amended as follows:

PART 105—FOODS FOR SPECIAL DIETARY USE

1. The authority citation for 21 CFR part 105 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 411, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 350, 371, 376).

2. Section 105.66 is revised to read as follows:

§ 105.66 Label statements relating to usefulness in reducing or maintaining body weight.

(a) *General requirements.* Any food that purports to be or is represented for special dietary use because of usefulness in reducing or maintaining body weight shall bear:

(1) Nutrition labeling in conformity with § 101.9, or, where applicable, § 101.36 of this chapter, unless exempt under that section; and

(2) A conspicuous statement of the basis upon which the food claims to be of special dietary usefulness.

(b) *Nonnutritive ingredients.* (1) Any food subject to paragraph (a) of this section that achieves its special dietary usefulness by use of a nonnutritive ingredient (i.e., one not utilized in normal metabolism) shall bear on its label a statement that it contains a nonnutritive ingredient and the percentage by weight of the nonnutritive ingredient.

(2) A special dietary food may contain a nonnutritive sweetener or other ingredient only if the ingredient is safe for use in the food under the applicable law and regulations of this chapter. Any food that achieves its special dietary usefulness in reducing or maintaining body weight through the use of a nonnutritive sweetener shall bear on its label the statement required by paragraph (b)(1) of this section, but need not state the percentage by weight of the nonnutritive sweetener. If a nutritive sweetener(s) as well as nonnutritive sweetener(s) is added, the statement shall indicate the presence of both types of sweetener, e.g., "Sweetened with nutritive sweetener(s) and nonnutritive sweetener(s)."

(c) *"Low calorie" foods.* A food purporting to be "low calorie" must comply with the criteria set forth for such foods in § 101.60(b)(2) and (b)(3) of this chapter.

(d) *"Reduced calorie" foods and other comparative calorie claims.* A food purporting to be "reduced calorie" or otherwise containing fewer calories than a reference food must comply with the criteria set forth for such food in § 101.60(b)(4) and (b)(5) of this chapter.

(e) *Label terms suggesting usefulness as low calorie or reduced calorie foods.* (1) Except as provided in paragraphs (e)(2) and (e)(3) of this section, and in § 101.13(q)(2) of this chapter for soft drinks, a food may be labeled with terms such as "diet," "dietetic," "artificially sweetened," or "sweetened with nonnutritive sweetener" only if the claim is not false and misleading, and the food is labeled "low calorie" or "reduced calorie" or bears another comparative calorie claim in compliance with part 101 of this chapter and this section.

(2) Paragraph (e)(1) of this section shall not apply to any use of such terms that is specifically authorized by regulation governing a particular food, or, unless otherwise restricted by regulation, to any use of the term "diet" that clearly shows that the food is offered solely for a dietary use other than regulating body weight, e.g., "for low-sodium diets."

(3) Paragraph (e)(1) of this section shall not apply to any use of such terms on a formulated meal replacement or other food that is represented to be of special dietary use as a whole meal, pending the issuance of a regulation governing the use of such terms on foods.

(f) *"Sugar free," and "no added sugar."* Criteria for the use of the terms "sugar free" and "no added sugar" are provided for in § 101.60(c) of this chapter.

Dated: October 22, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 130

[Docket No. 91N–0317 et al.]

RIN 0905–AD08

Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the General Provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (21 CFR part 101) (such as "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (for example "reduced fat sour cream"). FDA is taking this action to assist consumers in maintaining healthy dietary practices by providing for modified versions of certain standardized foods that bear descriptive names that are meaningful to consumers. FDA believes that this action will promote honesty and fair dealing in the interest of consumers. This rule applies only to standards of identity and not to standards of quality or fill.

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5112.

SUPPLEMENTARY INFORMATION:

I. Background

One of the main purposes of the Nutrition Labeling and Education Act of 1990 (Pub. L. 101–535) (the 1990 amendments) was to establish the circumstances in which claims could be made that describe the nutrient content of food. In response to the requirements of the 1990 amendments, elsewhere in this issue of the **Federal Register**, in a document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule), FDA is establishing in part 101 definitions for such nutrient content claims together with general principles and procedures governing their use.

In the **Federal Register** of November 27, 1991 (56 FR 60512), FDA published a proposal to amend the General Provisions for food standards to prescribe a general definition and standard of identity for foods named by use of a nutrient content claim defined in part 101 (e.g., "fat free," "low calorie," and "light") in conjunction with a traditional standardized name (e.g., "reduced fat sour cream"). Interested persons were given until February 25, 1992, to comment on the proposed regulation.

FDA received approximately 200 responses, each of which contained one or more comments, from trade and retail associations, government organizations, manufacturers, consumers, retailers, consumer groups, State groups, private organizations, professional societies, and universities. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., serving size and nutrition labeling) that will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follow.

II. Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term Under the 1990 Amendments

A. General Comments

1. Appropriateness and Need for Regulation

In the proposal, FDA invited comments with respect to the appropriateness and need for a general standard in proposed § 130.10 to establish the requirements for modified foods named by use of a nutrient content claim and a standardized term (56 FR 60512 at 60517).

1. Several comments stated that it is important to keep the present standards of identity as they are. One comment stated that, while allowing for the establishment of standards of identity for products like "light sour cream" and "lowfat ice cream," FDA must ensure that the existing standards for "milk," "sour cream," "ice cream," or "butter" are not diluted or debased. These comments stated that under no circumstances should a product that has undergone any form or degree of defatting be allowed to be called simply "milk," "sour cream," or "ice cream."

The agency agrees with these comments. FDA is not amending any of the existing standards of identity with this regulation. Under section 403(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(g)), a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been 0prescribed by regulation, unless it conforms to such definition and standards.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule entitled "Food Labeling: Use of Nutrient Content Claims for Butter Products," which adds new § 101.67. Except as provided in new § 101.67 for "butter," any food whose name includes a standardized term must conform to the standard of identity for that food found in parts 131 through 169 (21 CFR parts 131 through 169) or in new § 130.10. For example, a food labeled as "ice cream" must conform to the standard for ice cream in § 135.110, or it is misbranded. Similarly, a food labeled as "lowfat ice cream" must comply with new § 130.10. New § 130.10(a) states that the nutrient content claim must comply with the requirements of § 101.13 and with the requirements of the regulations in part 101 that define the particular nutrient content claim that is used. Thus, use of the term "lowfat" on a label for "lowfat ice cream" must comply with § 101.13 and § 101.62(b)(2) (i.e., the food must contain 3 grams (g) or less of fat per serving and per 50 g of food). New § 130.10(a) also provides that the "lowfat ice cream" must comply with the relevant standard in all other respects (e.g., major ingredients and the freezing process) except as provided in new § 130.10(b), (c), and (d).

2. One comment expressed concern that each modified food permitted to use a standardized food name meet consumer expectations. The comment suggested that if consumers no longer want or expect standardized products to have certain characteristics, the standards should be changed.

FDA appreciates the concern expressed by the comment. Section 401 of the act (21 U.S.C. 341) gives the agency authority to establish definitions and standards of identity for foods whenever such action will promote honesty and fair dealing in the interest of consumers. FDA has traditionally established individual standards to provide consumers with foods that include a modifier, such as a nutrient content claim or some other descriptive term, and a standardized term in their name. For example, the agency has established a standard of identity for milk in § 131.110 (21 CFR 131.110), but there are 17 other standards in part 131 (21 CFR part 131) that use the term "milk" in the name of the food (e.g., "cultured milk" (§ 131.112), "evaporated milk" (§ 131.130), and "skim milk" (§ 131.143)). FDA does not believe that use of these modifiers with

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the term "milk" is confusing to consumers because these terms are defined by the standards.

FDA believes that establishing a general definition and standard of identity for modified versions of standardized foods that qualify for use of a nutrient content claim is a more efficient way to provide consumers with these foods than having to issue temporary marketing permits to each manufacturer desiring to market test a new modified food and, ultimately, establishing individual new food standards for each new modified version. New § 130.10 provides that the nutrient content claims that are used with standardized terms must be defined by FDA regulation. The food must comply with the nutrient content claim definition and with the requirements in new § 130.10 concerning performance characteristics, addition of nutrients and other ingredients, and labeling. Such requirements will ensure not only that a "lowfat" version of a standardized food is low in fat, but also that the food appropriately bears the standardized name. Therefore, FDA concludes that use of nutrient content claims with a standardized name will promote honesty and fair dealing in the interest of consumers.

2. Scope of Regulation

3. One comment stated that it presumed that the agency did not intend that proposed § 130.10 be mandatory.

FDA advises that the comment's presumption is incorrect, at least to the extent that a firm wants to make a food under the provisions of new § 130.10. The agency is establishing a general definition and standard of identity for such foods. Section 403(g) of the act states that a food is misbranded if it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 of the act, unless it conforms to such definition and standard, and its label bears the name of the food specified in the definition and standard. Therefore, modified foods that conform to the definition and standard established in new § 130.10 must be labeled with the name provided under new § 130.10 or be misbranded under section 403(g) of the act. For example, sour cream must contain not less than 18 percent milkfat (§ 131.160). A sour cream product containing 12 percent milkfat and conforming to the standard of identity for sour half-and-half (§ 131.185) must be labeled in compliance with § 131.185(d) as either "sour half-and-half" or "cultured sour half-and-half." A sour cream product containing 9 percent milkfat that conforms to new § 130.10 and to the definition of "light" in § 101.56 must be labeled as "light sour cream."

4. One comment stated that proposed § 130.10(a) should be revised to make the intended scope of the regulation explicit. It stated that, as written, proposed § 130.10(a) creates an undesirable ambiguity with respect to foods that substitute for standardized foods that are themselves substitutes for one another (e.g., butter and margarine or cream cheese and neufchatel cheese). The comment suggested that FDA revise the language of proposed § 130.10(a) to limit the scope of proposed § 130.10 to "foods that substitute for a standardized food * * * and that use the name of that standardized food in their statement of identity but that do not comply * * *." The comment noted that a statement in the preamble limited the intended scope of proposed § 130.10 to substitute foods whose statement of identity includes the name of a standardized food. The comment added that an alternative way to solve the problem would be to provide in proposed § 130.10(a) that, in the case of a food that substitutes for more than one standardized food, the modified food needs to comply with proposed § 130.10 only with respect to one standardized food.

The agency agrees with the comment. Foods that comply with any standard of identity established in parts 131 through 169, are not subject to new § 130.10, even if they would qualify for a nutrient content claim as a modified version of a standardized food (e.g., sour half-and-half (§ 131.185) cannot be labeled as reduced fat sour cream under new § 130.10). However, foods that do not comply with a standard, that are modified versions of standardized foods, that qualify for use of a nutrient content claim, and that use the traditional standardized name in their statement of identity are the standardized foods that are defined by new § 130.10. This is consistent with the approach that FDA took in the proposal (56 FR 60512).

The agency has been persuaded by the comment that new § 130.10(a) should be revised to limit the scope of the regulation. Therefore, FDA is revising new § 130.10(a), as requested by the comment, to state: "* * * foods that substitute for a standardized food * * * and that use the name of that standardized food in their statement of identity but that do not comply * * *." In addition, FDA is revising the title of the regulation to delete the term "substitute" because new § 130.10 applies only to a certain category of substitute foods and not to all types of substitute foods as defined under §§ 101.3(e)(4) and 101.13(d). FDA believes that these revisions will more clearly establish the scope of the regulation and eliminate confusion as to foods that may substitute for other foods in a more general sense. Therefore, FDA concludes that these revisions will promote honesty and fair dealing in the interest of consumers.

FDA also agrees with the comment that in the case of a food that qualifies as a modified version of more than one standardized food, the food must be named under new § 130.10 only with reference to one standardized food. The § 130.10 product is a substitute for the standardized food that is named in its statement of identity. For example, cream cheese is defined in § 133.133 (21 CFR 133.133) as a product containing at least 33 percent milkfat by weight of the cream cheese. Neufchatel cheese (§ 133.162 (21 CFR 133.162)) is a product similar to cream cheese except that the milkfat content is not less than 20 percent but less than 33 percent by weight of the finished food. A reduced fat cream cheese-type product containing 15 percent milkfat may be considered a modified version of either cream cheese or neufchatel cheese because it contains at least 25 percent less fat than either food. Under new § 130.10, if the product is called "reduced fat cream cheese," it is a modified version of "cream cheese" because "cream cheese" is the standardized term used in conjunction with the nutrient content claim. If the product is called "reduced fat neufchatel cheese," it is a modified version of "neufchatel cheese."

5. One comment asked how this regulation would affect the nonstandard substitute cheese category (e.g., cheese containing vegetable oil in place of milkfat). It also asked if the regulations regarding "imitation" and "substitute" foods cited in § 101.3(e) would remain intact, or if this regulation would trigger the development of new requirements.

This final rule only sets forth the requirements for certain modified versions of standardized foods that qualify for the use of a nutrient content claim. Foods that do not use a traditional standardized term but use a nutrient content claim must comply with the general requirements of § 101.13 and the specific requirements for the particular nutrient content claim as well as the other provisions on common or usual names (§ 102.5 (21 CFR 102.5)). A modified food that does use a traditional standardized term but that does not comply with the traditional standard of identity or with

new § 130.10 must be labeled either as an "imitation," if it is nutritionally inferior, or as a "substitute," "alternative," or other appropriate term, if it is not nutritionally inferior, as specified in § 101.3(e) which will remain in effect. For example, a mozzarella cheese product made with skim milk and vegetable oil does not comply with the standard for mozzarella cheese (§ 133.155) or with new § 130.10(d)(2) and, therefore, must be labeled as "imitation mozzarella cheese" if nutritionally inferior to mozzarella cheese or as "mozzarella cheese alternative" or "mozzarella cheese substitute" if it is not nutritionally inferior. For this reason, FDA concludes that there is no need to amend the definitions for "imitation" or "substitute" foods in § 101.3(e) at this time.

6. One comment stated that there should be some listing of the standards as to which proposed § 130.10 is intended to apply. It stated that there was uncertainty as to when a particular food is subject to the general rule or requires individual agency action. Another comment stated that there is no reason to exclude any category of standardized foods from this proposal and urged FDA to retain the general applicability of the generic standard to all standardized foods in the final rule.

The agency disagrees that it needs to establish a specific list of standards to which new § 130.10 is to apply. New § 130.10(a) states that the foods prescribed by this general definition and standard of identity are those foods that substitute for a standardized food defined in parts 131 through 169. Thus, a modified version of any food defined by a standard of identity would be subject to new § 130.10, and no more specificity in new § 130.10 is necessary. This generic standard will minimize the need to establish individual new standards or to amend existing standards. FDA will establish new standards or amend existing ones if it determines that such action is necessary to promote honesty and fair dealing in the interest of consumers.

However, FDA notes that at the present time some standardized foods that are merely processed (e.g., canned green beans and canned wax beans (§ 155.120 (21 CFR 155.120)), tomato juice (§ 156.145 (21 CFR 156.145)), canned oysters (§ 161.145 (21 CFR 161.145))) cannot be modified so that the food does not comply with the traditional standard of identity, although they may still qualify to bear a defined nutrient content claim. For example, salt is an optional ingredient in the standard of identity for canned green beans and canned wax beans (§ 155.120). Therefore, if the product contains no added salt, the product remains the standardized food under § 155.120 and outside the scope of new § 130.10, although it may still qualify to bear a "no added salt" claim.

B. Product Deviations

In the proposal, FDA requested comments concerning how far a product may deviate from a standard and still qualify for use of the standardized name (56 FR 60512 at 60518).

7. Several comments stated that it is unnecessary for FDA to try to establish specific, quantitative limits. One comment stated that the agency should apply the general criteria for determining whether a food is a "substitute" for a standardized food. It stated that those criteria, which have been developed primarily through case law over the years, are based on everyday characteristics of the food that would be significant to the consumer, such as taste, texture, and appearance. Importantly, such an approach would conform to the President's directive, which requires regulations to use performance standards, not command-and-control techniques.

Several comments urged the agency to establish guidelines as to how much a modified food can deviate from the standardized product and still comply with proposed § 130.10.

The agency agrees that general requirements as to how far a modified food may deviate from the standard of identity and still use the standardized name are necessary. FDA also acknowledges that general criteria concerning significant characteristics of foods that are important to consumers have been developed primarily through case law, and the agency will use these criteria as needed for enforcement purposes. Some general requirements were included in the proposal and are now mandated by new § 130.10. A § 130.10 food must not be nutritionally inferior to the standardized food (new § 130.10(b)) and must have similar performance characteristics as the standardized food, including physical properties, flavor characteristics, functional properties, and shelf life (new § 130.10(c)).

In addition, under new § 130.10(d)(1), ingredients mandated to be present in a food by a standard of identity must also be present in the § 130.10 food. FDA believes that consumers expect certain ingredients to be present in specific foods. For example, the agency believes that consumers expect that a product such as "light mayonnaise" contains a significant amount of vegetable oil and egg yolk because these ingredients are required to be present in regular mayonnaise (§ 169.140). Thus, FDA has added new § 130.10(d)(4) to require that mandated ingredients must be present in a significant amount if the food is to be considered a modified version of the traditional standardized food. A significant amount is defined in that paragraph as at least that amount of the ingredient that is necessary to achieve the technical effect that the ingredient provides to the traditional standardized food. FDA concludes that this requirement in new § 130.10(d)(4) will promote honesty and fair dealing in the interest of consumers because it will ensure that a § 130.10 food will bear an appropriate relationship to the traditional standardized food.

8. One comment requested that FDA recognize that the removal of sugar and calories from a juice would result in a product that is still juice (e.g., "reduced calorie orange juice" or "light orange juice"). It added that the principles for naming products that are nutritionally modified versions of standardized products should be no different for standardized juices than for other standardized products. The comment requested that FDA ensure that this regulation is consistent with the regulation on percent juice labeling.

FDA agrees that the principles for naming products that are modified versions of standardized juice products should be no different than for other modified products. The agency recognizes that the reduction of sugars from a juice, and the subsequent sweetening of the product with a safe and suitable sweetener that provides an insignificant amount of calories, results in a modified juice product. Use of a sweetener with the same caloric density as the sugar naturally present in the juice is prohibited under new § 130.10(d)(2) because it would be replacing the sugar component of the juice with a similar ingredient from another source. For example, sucrose and glucose that have been removed from orange juice (§ 146.135 (21 CFR 146.135)) could not be replaced with fructose even though fructose is sweeter than the sucrose and glucose that are naturally present in orange juice. If, on the other hand, the product has been reduced in sugars so that it qualifies for use of a nutrient content claim and complies in all other aspects to new § 130.10, then the product is a food defined by new § 130.10 and must be labeled accordingly.

FDA notes that juices are defined in part by their Brix level or soluble solids content. The soluble solids of juices consist primarily of sugars. If any of the

sugars have been removed from a juice, the resulting product is a modified juice. As discussed in the final rule on percent juice labeling published elsewhere in this issue of the **Federal Register**, modified juices cannot use the percent juice labeling values in § 101.30 because of the reduced soluble solids content. The manufacturer would have to develop an alternate means of determining the percent juice in modified juice products.

9. Several comments stated that they considered the allowance of additional moisture in a modified cheese product to be necessary. One comment added that maximum moisture content requirements are as much barriers to lower fat versions of standardized products as minimum fat requirements.

Another comment added that other deviations from the standard, such as different levels of total solids or the use of modified processing conditions, are frequently required to meet the performance characteristics of the traditional standardized food and should be explicitly permitted in this regulation. It recommended that the last sentence of proposed § 130.10(a) be changed to read, "The food shall comply with paragraphs (b), (c), and (d) of this section." It further recommended that the following sentence be added at the beginning of proposed § 130.10(c):

Deviations from noningredient provisions of the standard of identity (such as moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possess performance characteristics similar to those of the standardized food.

FDA agrees that there are noningredient requirements mandated by some standards in parts 131 through 169 that could restrict manufacturers' ability to produce modified foods under new § 130.10. The agency recognizes that in some standardized foods, such as cheeses, the standard mandates a maximum moisture content, and that modified foods may not conform to this requirement and still retain the necessary performance characteristics to use the standardized name.

New § 130.10(a) states that the foods prescribed by this general definition and standard of identity are those foods that substitute for a standardized food but that do not comply with the standard because of a deviation that is described by a nutrient content claim. FDA noted in the proposal that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard with only those deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used (56 FR 60512 at 60519). Thus, under new § 130.10(d)(1) the agency is providing for the addition of safe and suitable ingredients not normally found in the standardized food so that § 130.10 foods are not inferior in performance characteristics to the traditional standardized food. In like manner, FDA believes that the modified version of the standardized food should comply with the noningredient provisions of the traditional standard with only those noningredient deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used.

For the above reasons, FDA has been persuaded by the comments that modifications to the regulation are needed to allow for deviations from the noningredient requirements of the standards. Therefore, the agency is adding a new sentence at the beginning of new § 130.10(c) which states:

Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food.

In addition, the agency is amending the last sentence of new § 130.10(a) to read: "The food shall comply with the relevant standard in all other respects, except as provided in paragraphs (b), (c), and (d) of this section." The agency believes that this action will: (1) Increase the manufacturers' ability to produce modified foods under new § 130.10, (2) provide consumers with a greater variety of such foods, and (3) assist consumers in maintaining healthy dietary practices. The agency notes, however, that this exception does not apply to processes that are important to public safety such as pasteurization. FDA concludes that this action will promote honesty and fair dealing in the interest of consumers.

10. One comment stated that the requirement of nutritional equivalency (new § 130.10(b)) for lower fat ice creams mitigates the need for lower fat ice creams to meet the 4.5 pounds per gallon requirement in the standard of identity for ice cream in § 135.110.

FDA agrees with the comment. FDA published an advance notice of proposed rulemaking (ANPRM) (Docket No. 88P–0251) in the **Federal Register** of January 22, 1991 (56 FR 2149) concerning the filing of several petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, lowfat, and nonfat ice creams. The petitions requested that FDA establish a minimum weight of 4.0 pounds per gallon for the lower fat products.

A comment received in response to the ANPRM that opposed the reduction in weight stated that the change could be construed as intentionally deceiving the consumer. The comment stated that while there are economic and competitive advantages, there appears to be no other serious justification for such cheapening of the product.

However, most of the comments received in response to the ANPRM that addressed the minimum weight issue supported the proposed minimum requirement of 4.0 pounds per gallon. They stated that the processing and formulation changes that accompany the removal of fat in the manufacture of fat reduced ice cream products result in a less dense product. According to these comments, creaminess and product stability, which are lessened by fat removal, can be improved by increasing the amount of air incorporated into the product or by utilizing more precise control of the freezing process.

FDA concludes that it is reasonable to exempt modified ice cream products from the minimum weight requirement of 4.5 pounds per gallon, so that these products can achieve the performance characteristics (e.g., creaminess) of ice cream, as long as the product is not nutritionally inferior to ice cream. The agency concludes that this exemption will assist consumers in maintaining healthy dietary practices by providing for modified ice cream products that have performance characteristics that are similar to ice cream. This exemption is provided by the new sentence that is being added to the beginning of new § 130.10(c). However, FDA does not believe that fat reduced ice cream products should contain less than 4.0 pounds per gallon, as recommended by the petitioners of these ice cream products, because the desired effects can be achieved within this allowance, and the modified foods should resemble the traditional standardized foods as closely as possible.

The inclusion of air in § 130.10 foods (e.g., nonfat ice cream, light margarine, and reduced fat peanut butter) in excess of that which is reasonably required to achieve the performance characteristics of the standardized food for which it substitutes constitutes deception and will be deemed to adulterate the food under section 402(b) of the act in that excess air is substituting for a valuable constituent. Therefore, FDA is including in new § 130.10(c) a requirement that deviations from provisions of the standard must be the minimum necessary to achieve this effect, or the

food will be deemed to be adulterated under section 402(b) of the act. FDA believes that this requirement will promote honesty and fair dealing in the interest of consumers.

Serving size issues relating to "aerated" products (i.e., products that include added air) that are sold by weight are addressed elsewhere in this issue of the **Federal Register** in a document entitled "Food Labeling: Serving Sizes."

C. Nutrient Content Claims

11. Several comments stated that the use of nutrient content claims such as "lowfat," "lite," and "reduced" should not be allowed on the label of standardized foods because they are confusing, even if they are defined.

Other comments expressed concerns about the required labeling, arguing that it is excessive. One comment urged FDA not to include too many restrictions on the wording or use of nutrient content claims because such restrictions would only befuddle the consumer and defeat the purpose of the claims.

FDA is establishing definitions for a number of nutrient content claims in the nutrient content claims final rule. In defining these terms, FDA has carefully considered each nutrient content claim to ensure that it will be meaningful to consumers. The definitions for the claims and § 101.13 prescribe the specific labeling that must accompany the claim. As consumers learn what a claim means, they will be able to understand that a product such as "light margarine" has been modified in a way that has reduced its fat content. Thus consumers will be able to easily identify the food and will be able to find out more about the food through information on the label. Therefore, FDA concludes that no action is necessary in response to these comments.

12. One comment stated that only expressed nutrient content claims should be used with the names of standardized foods. It stated that implied nutrient content claims such as "light" or "healthy" should not be used in this manner (e.g., "healthy ice cream").

The agency agrees with the comment. However, the term "light" is not an implied claim and is being defined as an expressed nutrient content claim as discussed in the nutrient content claims final rule. In § 101.13(b)(1), FDA defines an "expressed nutrient content claim" as any direct statement about the level (or range) of a nutrient in the food, e.g., "low sodium." An "implied nutrient content claim" is defined in § 101.13(b)(2) as any claim that describes the food or an ingredient therein in such a manner that suggests that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., "healthy, contains 3 g of fat").

Because the name of a new modified food distinguishes it from the standardized food, the claim must be expressed for consumers to understand how the new modified food differs from the traditional food. Therefore, FDA concludes that only expressed nutrient content claims may be used in the name of the food under new § 130.10. Implied claims may be used as provided in § 101.13(b)(2) but not in conjunction with the name of the § 130.10 food. Therefore, the agency is modifying new § 130.10(a) and (e) to state that the nutrient content claim must be an expressed claim. FDA believes that this revision will promote honesty and fair dealing in the interest of consumers.

D. Nutritional Inferiority

13. One comment stated that in determining nutritional inferiority, there is no clear indication of the nutrients and levels thereof that a § 130.10 food is expected to match. It stated that some specifications should be made, or provisions should be included, for developing nutrient data bases for those standardized foods that § 130.10 foods with nutrient content claims must match to avoid "nutritional inferiority."

FDA disagrees with the comment. New § 130.10 sets forth general requirements for foods named by use of an expressed nutrient content claim and a standardized term. Under new § 130.10(b), the modified product must not be nutritionally inferior, as defined in § 101.3(e)(4), to the standardized food. FDA believes that this general requirement is adequate because § 101.3(e)(4) sets very specific requirements defining nutritional inferiority. The agency concludes that new § 130.10 should not specify required amounts of essential nutrients that must be added to a modified food, and that no change is necessary in new § 130.10.

The agency adds that nutrient values for the traditional standardized product can be found in a current valid composite data base.

14. One comment agreed that § 130.10 foods should not be nutritionally inferior to the traditional standardized food. However, it stated that inferiority in any single nutrient should be defined as a "significant" reduction, that is, a reduction of 10 percent or more of the Reference Daily Intake/Daily Reference Value (RDI/DRV) of a nutrient that is present in a "measurable amount." In addition, the comment stated that nutritional inferiority of the product itself should not be based on inferiority in a single nutrient. It stated that in such cases, the unavoidable reduction of one nutrient could be compensated by meaningful additions or improvements in one or more other nutrients. For example, the comment stated, there are some foods for which it is difficult or impossible to reduce the amount of a component such as fat without also reducing the amount of a nutrient such as protein. It stated that the reduction in protein could be balanced by additions of vitamin A and riboflavin.

FDA disagrees with this comment. According to § 101.3(e), a food that is nutritionally inferior to another food is an imitation of that food and must be labeled as such. Section 101.3(e)(4)(i) defines nutritional inferiority as any reduction in the content of an essential nutrient that is present in a measurable amount (excluding fat or calories). Section 101.3(e)(4)(ii) defines a measurable amount of an essential nutrient in a food as 2 percent or more of the DRV of protein or the RDI of any vitamin or mineral listed under § 101.9(c)(7)(iv). The agency considers a measurable amount to be a significant amount for this purpose. All nutrients that are considered in determining the status of a food under § 101.3(e)(4) are important, and the agency does not believe that the addition of one nutrient could compensate for another. Therefore, FDA concludes that foods that have significantly less protein or other essential nutrients than a standardized food are not modified versions of the standardized food, do not comply with the requirements of this regulation, and must be labeled as "imitation."

15. One comment stated that the agency should reconsider the requirement that any modified food, identified as a "light," "reduced," or "lowfat" version of a standardized food, in which there is a nutrient reduction be fortified in order not to be called "imitation." The comment stated that such nutrient addition was not necessary because the comparative nutrition label will clearly identify the nutritional differences between these two different foods.

The agency disagrees with the comment. Although FDA agrees that the nutritional differences between these products would be apparent from the nutrition information, foods that are

nutritionally inferior to the standardized food must be labeled as "imitation" under section 403(c) of the act. New § 130.10 does not include imitation foods.

16. One comment requested that the agency clarify that when the modified food substitutes for more than one standardized food, the modified food should be deemed in compliance with proposed § 130.10 if it is nutritionally equivalent to any of the several standardized foods. The comment stated that cottage cheese (21 CFR 133.128) and lowfat cottage cheese (21 CFR 133.131) may vary in vitamin A content based on their different fat levels. Thus, the comment stated, a nonfat cottage cheese should be considered nutritionally equivalent under new § 130.10 if its vitamin A content is equivalent to that required by either food standard because it clearly is a modified version of either food.

FDA disagrees with this comment. The agency recognizes that a nonfat cottage cheese product could be compared to cottage cheese (§ 133.128), dry curd cottage cheese (§ 133.129) or one of the lowfat cottage cheese products (§ 133.131). The agency acknowledges that target levels for nutrients necessary to determine nutritional equivalency of a food will depend on whether the food is compared to one food or another. However, the § 130.10 food must not be nutritionally inferior to the standardized food whose name is used in the name of the food. FDA concludes that because the reference food in the name "nonfat cottage cheese" is "cottage cheese," it would be misleading to consumers to make the comparison of nutritional equivalency to any other cottage cheese product.

E. Performance Characteristics

In the proposal for this final rule, FDA requested comments concerning: (1) The requirement that the performance characteristics of the new product be similar to those of the standardized food, (2) the performance properties that are of greatest importance to consumers, and (3) what differences in performance characteristics a modified standardized product should be able to have and still be considered to resemble the standardized food closely enough to be included in that product category (56 FR 60512 at 60519 and 60521).

17. Several comments stated that it would be acceptable to a consumer that wants lower fat foods to have products with fat replacers resemble the original products as closely as possible, especially with respect to texture, taste, and nutrition. One comment urged FDA to set high standards for performance requirements for § 130.10 foods. It stated that without appropriately high standards, consumers may be misled by the use of familiar names, and that, ultimately, the value of the standards themselves will be diluted.

Two comments suggested that, in order to use the name of the standardized product with a nutrient content claim, the product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product. Consumers can then choose to purchase the modified product instead of the standardized product for use in that function. One comment added that a reduced fat cheese must at a minimum be suitable for eating directly from the package or for melting and cooking. It stated that the product need not serve both purposes, so long as the performance deficiencies are clearly and prominently labeled on the front of the package.

The agency agrees that the § 130.10 food should resemble the standardized food in as many ways as possible. FDA also agrees that at a minimum, a modified food must perform at least one of the principal functions of the standardized product as well as the standardized food. FDA believes that consumers should be able to count on using a modified food in the same manner that they use the traditional standardized food in, at the very least, one of the principal functions as the standardized food. To achieve this objective, FDA is requiring in new § 130.10(c) that modified standardized foods must resemble the standardized foods, and that differences in the performance characteristics must be clearly stated on the principal display panel of the label. In addition, the agency is adding a statement to new § 130.10(c) to require that "the modified product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product." FDA believes that this action is necessary to ensure the minimum necessary similarity between the modified and traditional products and, thus, will promote honesty and fair dealing in the interest of consumers.

18. One comment questioned what methods the agency would use to measure significant differences in product quality and to monitor critical performance characteristics.

FDA expects that modified versions of standardized foods will perform in a manner that is generally acceptable to the public. New § 130.10 requires that the performance characteristics of the food be similar to those characteristics of its standardized counterpart unless the differences between the two foods are explicitly stated on the label. In addition, the § 130.10 food must perform at least one of the principal functions of the standardized food substantially as well as the standardized product. Although it was not the agency's intent to develop specific performance standards for each product, FDA plans to examine the performance characteristics and product quality of these modified versions of standardized foods, as it would for other types of food products, through scientific reviews or experimental investigations. In addition, FDA will use all avenues available to the agency (e.g., sample analysis, inspections, surveys, and followup investigations of consumer and trade complaints) to identify products that do not comply with the new regulation and will enforce this regulation as the need arises.

F. Labeling of Performance Characteristics

19. Several comments objected to the requirement in proposed § 130.10(c) that if there is a significant difference in performance characteristics between the food under proposed § 130.10 and the standardized food, the label must include a statement informing the consumer of such difference. One comment stated that some performance characteristics (e.g., flavor or texture) tend to be more subjective, and that if a flavor comparison is not favorable, manufacturers would not be inclined to call attention to such a difference. It stated that it would be a disincentive to food manufacturers to reduce the fat content in food. Another comment stated that a regulation to require a label statement pointing out differences in performance is not necessary unless health or safety is involved. One comment stated that the most specificity FDA should include in this regulation regarding performance characteristics is a reference to substantial equivalence in organoleptic and nutritional qualities.

One comment stated that manufacturers would find it advisable, for marketing reasons, to inform the consumer how a modified version of a standardized food performs differently than the standardized product. One comment supporting the label statements noted that bread spreads currently on the market are erratic about stating whether they can be used for cooking, and that consumers are confused as a result. Other comments expressed concern about diluting the value of the standards if consumers are

misled by the use of familiar names on modified products.

Under sections 201(n) (21 U.S.C. 321(n)) and 403(a) of the act, the label or labeling of the food must disclose to consumers what they are buying when they purchase these modified foods. Information disclosing differences in performance characteristics (e.g., physical properties, flavor characteristics, functional properties, and shelf life) is a material fact under section 201(n) of the act because it bears on the consequence of the use of the article. Accordingly, this information must be communicated to the consumer on the product label, or the labeling would be misleading, and the product would be misbranded under section 403(a) of the act.

Therefore, a provision in new § 130.10(c) that requires disclosure of differences in performance characteristics between the modified food and the traditional standardized food is fully consistent with the act.

FDA is providing for noningredient deviations in new § 130.10(c) (e.g., moisture content) and for the use of safe and suitable ingredients for certain specified purposes in new § 130.10(d)(1) (e.g., to add flavor) in order that the modified food may possess similar performance characteristics as the traditional standardized food. FDA believes that these provisions in new § 130.10 provide manufacturers ample latitude in producing modified products.

20. Two comments recommended that the label statement be mandatory only for differences in performance characteristics that materially limit the uses of the modified food compared to the traditional standardized food that it resembles. One comment stated that market forces will encourage manufacturers to inform consumers about positive differences, and that consumers who select a product for its reformulated nutrient content will not be misled if they are not told about a positive change that the manufacturer believes is not sufficiently important to highlight on the product label. The comment noted that FDA would not object if the label did not alert consumers to a minor improvement in a performance characteristic that consumers consider to be relatively unimportant for that food, such as the freezing point of eggnog. In addition, the comment stated, a product may have several differences in performance characteristics, and several label statements could be confusing to consumers. The comment recommended that FDA modify new § 130.10(c) by limiting the labeling requirement to adverse changes that materially affect the use of the product.

The agency has been persuaded by these comments. FDA agrees that there are differences in performance characteristics that consumers may not deem to be important, such as the freezing point of eggnog. Consumers commonly store eggnog at refrigerator temperatures, and, therefore, the freezing point of this product is not of material interest to consumers. In addition, FDA believes that unnecessary label statements may be confusing to consumers and may detract from other important information on the label.

Therefore, the agency is revising new § 130.10(c) to state that:

> * * * if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for cooking").

21. Comments also suggested that FDA affirm in the final rule that statements of differences in performance characteristics can be presented as recommendations for use.

FDA agrees with the comments suggesting that differences in performance characteristics may be presented as recommendations for use. For example, a reduced fat margarine may not perform the same as margarine for use in frying. A statement such as "not recommended for frying purposes" or as "recommended for use only as a spread" would be acceptable to advise consumers of the difference in performance characteristics.

22. Comments also asked whether shelf life could be presented as a date by which the product should be used.

The agency agrees that a date by which a product should be used is an appropriate manner to express differences in shelf life.

23. Several comments objected to the requirement in proposed § 130.10(c) that label statements concerning differences in performance characteristics must appear on the principal display panel within the bottom 30 percent of the area of the label panel with appropriate prominence, in type that shall be no less than one-half the size of the type used in such claim but no smaller than one-sixteenth of an inch. One comment noted a conflict with proposed § 101.13(d)(1) with regard to location of this information on the label. Some comments addressed concerns about label clutter on the principal display panel and stated that these concerns are enhanced by the proposed requirement that the bottom 30 percent of the principal display panel contain a statement of any differences in performance characteristics between the § 130.10 food and the standardized food. Comments urged FDA to allow the statements to appear on any panel of the food product. One comment added that a simple requirement of proximity and appropriate prominence should be more than adequate to prevent consumer confusion. One comment stated that the proposed requirements are excessive and fail to meet the requirements of the President's directive that regulation should rely on market mechanisms to the maximum extent possible. It stated that consumers who buy nutritionally modified versions of familiar foods and are disappointed with their performance, because they did not know in advance what to expect, simply will not buy again, and the products will quickly fail. It added that FDA does not need to regulate this guaranteed result. Some comments stated that they did not believe it necessary to prescribe a minimum type size for this disclosure statement, but that the statement should appear on the principal display panel in a clear and conspicuous fashion.

The agency disagrees with these comments. Different brands of a particular modified food may have different performance characteristics depending on the manufacturing technology used in making the § 130.10 food. For example, reduced fat cheddar cheese made by one manufacturer may be suitable only for melting and cooking, while another brand may be suitable only for eating directly from the package as a snack. Therefore, consumers must be informed about the characteristics of a food to make judgments concerning the use of a product before purchase. The necessary information must appear on the same part of the label as the name of the § 130.10 food (i.e., the principal display panel) so that consumers can make informed choices. Moreover, this regulation is consistent with the President's directive because it is providing increased flexibility to the market in that it provides that qualifying versions of standardized foods may be sold under names that consumers recognize.

Under section 403(f) of the act, FDA believes that the statement informing consumers of differences in performance characteristics must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. The agency concludes that the statement must appear in the same area of the label as the statement of identity for the

modified product so that consumers will know where to find such information. Moreover, because the statement is a material fact that helps to describe the differences between the modified food and the traditional food, it must appear in close proximity to the statement of identity. See, e.g., *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. Supp. 746, 749 (E.D. N.Y. 1974).

FDA recognizes that it inadvertently proposed in § 130.10 to require statements informing consumers of differences in performance characteristics to appear in possibly two separate locations on the label. The agency acknowledges that one statement is sufficient to inform consumers. To be consistent with the labeling of other foods, the agency concludes that the statement concerning differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d)(1). Thus, the agency has modified new § 130.10(c) to state that the statement explaining differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d).

G. Ingredients

1. Ingredients Provided for By the Regulation

24. Two comments objected to FDA restricting the major ingredients used in § 130.10 foods to those specified in the standard. One comment stated that this provision would not empower consumers to select a healthy diet but would restrict the number of apparent "healthy" choices available by requiring products made with alternate ingredients to bear unappealing names. It also stated that this provision would not provide an incentive to manufacturers to develop nutritionally improved foods but would restrict their ability to develop such products by unnecessarily limiting the technology available.

The agency disagrees with these comments. The agency believes that foods named by use of a nutrient content claim and a standardized term must resemble the standardized food in as many ways as possible, or the use of the standardized term would be misleading to consumers. Therefore, FDA concludes that the ingredients used in the modified version of the standardized food should be those ingredients provided for by the traditional standard, with only those deviations necessary to attain an acceptable finished product that meets the requirements of the nutrient content claim that is used and new § 130.10.

2. Safe and Suitable Ingredients

25. Several comments stated that proposed § 130.10(d) should provide for the use of safe and suitable ingredients generally in accordance with current good manufacturing practices rather than limiting them to specific functions. One comment stated that the language in proposed § 130.10(d) concerning ingredient substitutions should be broadened to encompass all of the product characteristics embraced by proposed § 130.10(c) and by the definition of "substitute" in § 101.13(d). Another comment added that safe and suitable ingredients should be allowed for purposes of improving appearance as well as the other characteristics mentioned in the proposal.

FDA disagrees that the use of safe and suitable ingredients should be extended for all purposes. The agency believes that § 130.10 foods should deviate from the standard of identity only when necessary to achieve the functions of ingredients or components of ingredients that are no longer present in the mandated quantities. As required in new § 130.10(c), the performance characteristics (e.g., physical properties, flavor characteristics, functional properties, and shelf life) of the modified food must be similar to those of the traditional standardized food. FDA believes that the use of safe and suitable ingredients added as necessary to improve texture, add flavor, prevent syneresis, and extend shelf life adequately compensates for any deficiencies in performance characteristics. As discussed previously, § 130.10 foods do not include all substitute foods. Therefore, FDA does not believe that new § 130.10(d) should be broadened to encompass all types of substitute foods.

However, FDA concedes that the use of safe and suitable ingredients to improve the appearance of a product has merit. For example, modified foods with significantly less fat may appear more translucent than the standardized food. Thus, such ingredients are necessary to ensure that the product is not inferior in performance characteristics. Therefore, FDA is amending new § 130.10(d)(1) to provide that safe and suitable ingredients may be added to improve the appearance of a modified food named by use of a nutrient content claim and a standardized term.

26. One comment stated that it believes that to "add flavor" includes sweetness and requested that FDA confirm this interpretation by including a parenthetical "(including sweetness)" following "add flavor" in proposed § 130.10(d)(1).

FDA disagrees with the premise of this comment. In § 170.3(o)(12), FDA defines "flavoring agents and adjuvants" as substances added to impart or help impart a taste or aroma in food. FDA defines nonnutritive and nutritive sweeteners separately from flavoring agents in § 170.3(o)(19) and (o)(21). In addition, labeling requirements for flavors differ significantly from those for sweeteners.

However, FDA does agree that the use of safe and suitable sweeteners to add sweetness should be provided for in new § 130.10 for modified foods. Many standards of identity provide only for the use of safe and suitable nutritive sweeteners or nutritive carbohydrate sweeteners (e.g., sour cream (§ 131.160), eggnog (§ 131.170), and margarine (§ 166.110)). Nonnutritive sweeteners could be effectively used to add the sweetness, but not the calories, that would otherwise be contributed by nutritive sweeteners in the traditional standardized food. Therefore, FDA believes that the use of safe and suitable sweeteners to add sweetness would assist consumers in maintaining healthy dietary practices. Thus, the agency is revising new § 130.10(d)(1) to provide that safe and suitable ingredients may be added to add sweetness to a modified food named by use of a nutrient content claim and a standardized term. When a sweetener that meets the "safe and suitable" definition in new § 130.3(d) is used in the formulation of a modified food for the purpose of adding sweetness to that food, the sweetener must be declared on the food label in accordance with all applicable regulations. FDA believes that this action will promote honesty and fair dealing in the interest of consumers.

27. One comment questioned whether the provision for the use of "safe and suitable" ingredients in § 130.10 foods would promote long-term product development, even though short-term product innovation may benefit from this policy. This comment further contended that allowing these foods into the marketplace would: (1) Erode the market share of traditional standardized foods, (2) harm the integrity of traditional standardized foods, and (3) lead to consumer confusion by blurring the differences between these standardized foods and their modified counterparts.

FDA disagrees with this comment. The agency believes that providing for the use of "safe and suitable" ingredients to improve texture, add flavor, prevent syneresis, extend shelf

life, improve appearance, or add sweetness in modified versions of standardized foods should not stifle long-term product development, nor should the introduction of these foods into the marketplace be damaging to the food industry on the whole.

On the contrary, standards of identity have been criticized as being too strict and confining, and because they limit food companies from achieving true product innovations. For instance, the dairy industry purportedly has been harmed because many of the products that dairy processing companies manufacture are subject to rigid standards of identity that require specific fat content. As a result, these firms have not been able to create new dairy food products that respond to consumer needs and demands for products that are reduced in fat and in calories.

FDA anticipates that there will be shifts in dietary consumption patterns from traditional foods that are higher in calories or in fat to modified forms of these foods that are reformulated to be lower in calories or in fat. However, this pattern of increased consumption of modified forms of traditional foods should help consumers to achieve recommended nutritional goals and should have a beneficial impact on the public health. In addition, FDA believes that the development, production, sale, and consumption of these reformulated foods will contribute to overall industry growth. Although the agency acknowledges that there is the potential that sales of certain standardized foods may remain stagnant or may even decline, these changing patterns in consumers' food purchasing habits in relation to recommended nutritional goals should create new opportunities for innovative food processors to develop a virtually limitless array of new products that will ultimately lead to an overall increase in sales and an expansion into new markets.

Regarding consumer confusion about the differences between a traditional standardized food and a modified form of such food bearing one or more nutrient content claims on its label, the agency believes that the use of carefully defined nutrient content claims as a part of the statement of identity on the label will enable purchasers of the modified versions of standardized foods to distinguish these foods from their standardized counterparts. New § 130.10 provides for proper labeling of these foods and the listing of all ingredients in the ingredient statement. Adequate product labeling, including defined nutrient content claims, accompanying label statements, and nutrition labeling, will enable consumers to distinguish traditional foods from modified versions of these foods, thereby contributing to improved consumer understanding of the characteristics of the products that they are purchasing.

28. One comment inquired whether specific caseinates would meet the "safe and suitable" definition and be permissible for use in § 130.10 foods.

FDA advises that the "safe and suitable" definition in new § 130.3(d) would permit the use of caseinates in foods subject to new § 130.10 provided that the standard of identity for the traditional food in question provides for such use. For example, the standard of identity for ice cream in § 135.110 permits the optional addition of one or more of the caseinates listed in § 135.110(c) in an ice cream mix containing not less than 20 percent total milk solids. Caseinates may be added to ice milk (§ 135.120) when the content of total milk solids is not less than 11 percent. FDA believes that it is reasonable to permit the use of such caseinates in modified versions of ice cream, provided that the product contains equivalent levels of nonfat milk solids to those contained in a 10 percent milkfat ice cream. That is, the modified product must contain at least 10 percent nonfat milk solids, and caseinates could be added after this minimum nonfat milk solids requirement has been met. FDA believes that modified ice cream, regardless of the milkfat content, should contain at least 10 percent of nonfat milk solids to ensure that the § 130.10 ice cream is not nutritionally inferior to ice cream with respect to calcium and protein. The addition of caseinates to replace the milk solids content constitutes deception and will be deemed to adulterate the food under section 402(b) of the act (21 U.S.C. 342(b)) in that caseinates are substituting for a valuable constituent.

On the other hand, the standards of identity for cheeses and related cheese products in part 133 (21 CFR part 133) do not provide for the use of caseinates. Therefore, under new § 130.10(d)(1) manufacturers may not use this class of ingredients in modified versions of cheese products as replacements for the optional dairy ingredients listed in the standards of identity in part 133. However, use of small amounts of safe and suitable caseinates may be used for the reasons listed in new § 130.10(d)(1) (e.g., to improve texture) in modified versions of standardized foods as appropriate.

Any caseinates used in a § 130.10 food must be declared in the ingredient statement according to new § 130.10(f), including identification with an asterisk if the use of caseinates is not provided for by the traditional standard.

3. Addition of Water and High Moisture Ingredients

In the proposal, FDA requested comment from interested persons concerning the appropriateness of the addition of high moisture ingredients and water to foods as ingredients to replace fat and calories in modified products (56 FR 60512 at 60520).

29. A number of comments requested that FDA provide for the addition of water. Two comments stated that the addition of water is critical to the manufacture of modified standardized products such as modified salad dressing and mayonnaise. One comment added that the emulsifying properties of certain gums are activated only by the addition of water. Several comments stated that it is appropriate to allow for the addition of water as long as it is appropriately labeled. Conversely, two comments requested that FDA not permit the addition of water to a food subject to proposed § 130.10.

A number of comments stated that the addition of high moisture ingredients to foods subject to proposed § 130.10 is appropriate. One comment noted that moisture content variability may occur because of water contributed by safe and suitable ingredients that are components of such foods. It added that provision should be made to require that such moisture differentials are accurately and adequately reflected on the label of foods subject to new § 130.10. Another comment stated that where, with current technology, the production of reduced fat products is not possible without the addition of high moisture ingredients, their addition should be permitted.

One comment stated that most current fat reduction technologies require the addition of high moisture ingredients and water. It recommended that FDA allow high moisture ingredients and water to replace fat in § 130.10 products, and that FDA use performance standards rather than deviations from a "recipe" to protect consumers. Another comment recommended that FDA allow the use of high moisture ingredients and water to the level necessary to replace fat and calories, as long as the modified food is not nutritionally inferior to the traditional food.

FDA agrees that the addition of water may be necessary for the hydration of some ingredients that would be permitted under the safe and suitable ingredient provision. In addition, FDA notes that there is consumer demand to

purchase products that have a significant reduction in fat and calories. Water is an ingredient that could effectively accomplish this purpose when used to replace fat and calories in modified products. Therefore, the agency is adding new § 130.10(d)(5) to provide for the addition of water as an ingredient to replace fat and calories in modified products. FDA believes that such addition of water will assist consumers in maintaining healthy dietary practices by providing for an ingredient that will allow manufacturers to produce a greater variety of modified versions of traditional standardized foods. Moreover, the consumer is protected against the possibility of excess water being added by new § 130.10(c), which states that deviations from the ingredient and noningredient provisions of the traditional standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be adulterated under section 402(b) of the act.

FDA also agrees that the use of high moisture ingredients is necessary to reduce calories and fat in some foods. Comments did not mention any specific high moisture ingredients that the regulation should include. Therefore, all high moisture ingredients used in a § 130.10 food must either be ingredients that are provided for by the respective standard of identity or provided for by the safe and suitable ingredient provision of new § 130.10(d)(1).

The agency notes that some foods subject to new § 130.10 may need to exceed the moisture requirements of the respective standards of identity to make a nutrient content claim. For example, the standard of identity for cheddar cheese (§ 133.113) stipulates a maximum moisture content of 39 percent by weight and a minimum milkfat content of 50 percent by weight of the solids. Under new § 130.10(c), a reduced fat cheddar cheese may exceed the maximum moisture level stipulated by § 133.113 concurrent with the 50-percent reduction in the fat content, but it still must not be nutritionally inferior. The increase in moisture content occurs because less whey is drained from the product during processing. The high moisture ingredients would, therefore, be the same dairy ingredients (i.e., milk, nonfat milk, or cream) provided for by the traditional standard.

The addition of water and high moisture ingredients must be declared in the ingredient statement as required in new § 130.10(f). Because new § 130.10(b) requires that the modified food must not be nutritionally inferior to the standardized food, a modified food that contains significantly less calcium or any other nutrient than the standardized food because of the use of water or a high moisture ingredient must be labeled as an imitation. FDA believes that moisture differentials will be adequately reflected on the label through order of predominance ingredient labeling and labeling of any differences in performance characteristics (e.g., shorter shelf life because of increased moisture content).

4. Flavors

30. Two comments urged FDA to exempt from the labeling requirement of § 101.22(i) those flavors added solely at the level necessary to replace flavors lost by reformulation of the food. The comments also said that there was no reason to exempt any flavor added in amounts greater than necessary to maintain the flavor of the traditional food.

FDA disagrees that there is a need to exempt flavors added to replace flavors lost by reformulation of the food from the requirements of § 101.22(i). Section 101.22(i) only refers to the labeling of characterizing flavors. Natural and artificial flavors that do not characterize a food need only be declared in the ingredient statement. However, FDA believes that consumers should be informed from information on the principal display panel when artificial characterizing flavors have been added to a food.

In the **Federal Register** of January 19, 1973 (38 FR 2139), FDA proposed a uniform labeling policy for flavor designation that was patterned, with appropriate modification, after the ice cream standard of identity in § 20.1 (21 CFR 20.1) (current § 135.110 (21 CFR 135.110)). According to the standard, ice cream may or may not be characterized by the addition of flavoring ingredients. The existing standard in 1973 listed the optional characterizing ingredients (§ 20.1(b)) that could be used in ice cream. These characterizing ingredients, not the individual flavors contributed by the milk, cream, and other optional ingredients, were the flavors subject to the labeling provisions.

Therefore, the flavors that are lost by reformulation are likely not to be those that characterize the food but those that are an inherent part of the basic required ingredients that are no longer present in the reformulated food. Thus, they need only be declared in the ingredient statement as natural or artificial flavors, as appropriate. For example, natural and artificial eggnog flavor components may be added to light eggnog to add flavor. These flavor components must be included in the declaration of ingredients but need not appear anywhere else on the label. However, if a natural and artificial eggnog flavor that comprises the total eggnog flavor profile is added to a light eggnog, it is a characterizing flavor and must be labeled according to § 101.22(i). If any portion of the characterizing flavor is artificial, it must be labeled as artificial flavor under § 101.22(i).

31. A comment objected to FDA's choice of "light margarine" as an example of a § 130.10 food using a standardized name. According to the comment, this example implied that the label of a food with the name "light margarine" would have to comply with the flavor labeling regulations of § 101.22 if artificial butter flavor were used in the food for flavoring purposes.

According to § 166.110(b)(7) (21 CFR 166.110(b)(7)) on flavoring substances in margarine, "if the flavoring ingredients impart to the food a flavor *other* than in semblance of butter, the characterizing flavor shall be declared as part of the name of the food in accordance with § 101.22 of this chapter" (emphasis added). Flavoring ingredients that impart the flavor of butter to margarine thus may be added to the food without declaring such flavor as part of the name of the food.

Because the intent in producing "light margarine" is to modify the fat and calorie content and not the flavor, the agency believes that it is reasonable to treat the declaration of flavoring ingredients on the label of "light margarine" in a like manner to their declaration on the label of margarine that complies with the standard of identity in § 166.110. The use of an artificial butter flavor in the formulation of a "light margarine" would not, therefore, necessitate the naming of this food as "light margarine, artificially flavored" as the preamble to the November 27, 1991, proposal (56 FR 60512 at 60519) stated. The agency reiterates, however, that natural and artificial flavors other than those in semblance of butter in "light margarine" must be declared in the ingredient statement in accordance with the applicable sections of part 101.

5. Fat Analogs

In the proposal, FDA stated that it is aware of the recent development of fat analogs and requested comments from interested persons concerning the appropriateness of the use of approved fat analogs to replace the fat in foods subject to proposed § 130.10 (56 FR 60512 at 60520).

32. A number of comments stated that it would be appropriate to allow for the

addition of fat analogs in modified versions of standardized foods that are subject to proposed § 130.10. One comment recommended that FDA not impose any unique requirements on the use of fat analogs as replacements for fat and calories. Several comments stated that the addition of fat analogs would be appropriate as long as the food is properly labeled. One comment urged the use of a prominent disclosure statement of ingredients such as fat analogs on the principal display panel.

One comment stated that the use of approved fat analogs should be permitted in proposed § 130.10 foods only: (1) Where a particular analog is appropriate for the type of food in view of the composition of the standardized food (e.g., dairy fat analogs for dairy products), and (2) use of an analog is necessary to achieve a substantial reduction in fat. The comment stated that limiting the uses of analogs to those appropriate for a particular product category would serve the consumer interest in limiting deviations from standardized products to those really necessary to achieve reductions of fat.

Another comment stated that without the ability to use fat analogs, food manufacturers may find it difficult or impossible to accomplish the desired reductions in fat while maintaining product performance. It urged FDA to provide for the use of these ingredients in proposed § 130.10, rather than requiring a much more cumbersome regulatory process in the future. It stated that a statement should be added to proposed § 130.10(d) to the effect that fat substitutes that are approved for use in the food may replace the milkfat or other fat required by the standard.

Several comments stated that no addition of fat analogs should be allowed for a food subject to proposed § 130.10. One comment was concerned that the use of fat analogs would significantly alter the identity of the food and, therefore, the food would no longer resemble the traditional food. Other comments stated that fat analogs should not replace ingredients that would provide more healthful nutrients in modified foods.

FDA believes that there may be some instances where the use of fat analogs is appropriate and may be necessary to reduce the fat and calories while maintaining the performance characteristics of a food. The use of fat analogs will allow manufacturers to produce a variety of modified foods with greater reductions in fat and with the same performance characteristics as the traditional food. Thus, consumers will benefit by having a greater variety of modified foods available.

However, under § 130.10(d)(1), the fat analog used in § 130.10 foods must be safe and suitable as defined in new § 130.3(d). Moreover, under § 130.10(c), the amount used must be the minimum necessary to achieve similar performance characteristics as with the fat they replace, and under § 130.10(c). In addition, FDA agrees with the comment that stated that the fat analog must be appropriate for use in the particular type of food. New § 130.10(d)(2) states that an ingredient or component of an ingredient that is specifically required by the standard must not be replaced or exchanged with a similar ingredient from another source unless the traditional standard provides for the addition of such ingredient. The § 130.10 food must resemble the traditional standardized food. Thus, the major ingredients of a category of products should be from that variety of food (e.g., the major ingredients in dairy products should be dairy ingredients), and some ingredients are not appropriate to add to some modified foods that use the traditional standardized name. For example, under new § 130.10(d)(2), vegetable oil is not an appropriate ingredient to replace the milkfat in dairy products, or the fat in egg products, if the food is to use the standardized name as provided for in new § 130.10. Similarly, a fat analog from a vegetable or egg source is not an appropriate ingredient to replace the milkfat in dairy products using the standardized terms unless the dairy product provides for the use of egg or vegetable ingredients.

Therefore, FDA is adding a provision to new § 130.10(d)(5) to permit the use of safe and suitable fat analogs in accordance with new § 130.10(c), (d)(1), and (d)(2) in modified versions of the standardized food. The addition of fat analogs must be declared in the ingredient statement as required in new § 130.10(f). Because new § 130.10(b) requires that the modified food must not be nutritionally inferior to the standardized food, a modified food that contains significantly less of any nutrient than the standardized food because of the use of fat analogs must be labeled as an imitation. FDA believes that any use of fat analogs would be adequately reflected on the label through order of predominance ingredient labeling.

6. Use of Similar Ingredients

33. One comment suggested that the requirement that ingredients "specifically required" in new § 130.10(d)(2) either needs to be defined or its relationship to "mandatory" and "characterizing" ingredients needs to be explained by FDA. The comment said it assumed that it was FDA's intent in the proposed rule to not allow substitution for ingredients with similar ingredients that are deemed to be mandatory by the standard. FDA agrees with this comment. Ingredients that are specifically required by the standard are mandatory ingredients in standardized foods. Characterizing ingredients may be as optional ingredients under some standards (e.g., ice cream (§ 135.110)) and in those cases are not mandatory. The provision in new § 130.10(d)(2) prohibits the replacement or exchange of ingredients specifically required or mandated by the traditional standard with functionally similar ingredients from other sources that are not provided for by the traditional standard.

34. One comment stated that only dairy products should be used to replace milkfat in dairy products.

FDA agrees that dairy ingredients should be used to replace milkfat in dairy products. However, FDA acknowledges that other ingredients may be needed in small amounts to replace all of the functions of the milkfat that has been removed. A safe and suitable ingredient may be added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness under new § 130.10(d)(1), so long as it meets the requirements of the other parts of new § 130.10(d) and the label of the food complies with new § 130.10(f)(2). FDA adds that as stated previously, any fat analog used in dairy products must be from a dairy source.

35. One comment stated that proposed § 130.10(d)(2) is unnecessary and has the potential to be misinterpreted as, for example, prohibiting the use of a synthetic fat replacer to replace milkfat.

FDA disagrees that proposed § 130.10(d)(2) is unnecessary. Some ingredients are not appropriate to add to some modified foods that use the standardized name. In new § 130.10(d)(5), FDA is specifically providing for the use of safe and suitable fat analogs in new § 130.10 foods to replace fat and calories. However, some fat analogs are not appropriate for a particular type of food and are prohibited from use in a modified food by new § 130.10(d)(2). For example, the standard for sour cream (§ 131.160) states that sour cream contains not less than 18 percent milkfat. FDA believes that replacing the milkfat in sour cream with vegetable oil would be misleading because consumers expect sour cream to be a dairy product. Similarly, consumers would be misled if a fat analog from a

vegetable source replaced the milkfat in sour cream.

7. Ingredients Prohibited By the Reference Standard

36. Several comments opposed proposed § 130.10(d)(3), which states that an ingredient or component of an ingredient that is specifically prohibited by the standard cannot be added to a substitute food under this section.

Two comments requested that proposed § 130.10(d)(3) be made more flexible. One comment stated that the use of nutritionally insignificant amounts of ingredients, such as colorings and flavorings, could be permitted in § 130.10 foods, even if they are specifically forbidden by a standard of identity, to enhance the consumer acceptance of the substitute food. Another comment requested that FDA permit the use of flavorings simulating the flavor of a cheese of any age or variety in reduced fat versions of pasteurized process cheese to achieve a similar product to the traditional full fat counterpart.

FDA disagrees that safe and suitable ingredients specifically prohibited by a standard should be provided for in a substitute food under new § 130.10. There are valid reasons why these ingredients were specifically excluded in the traditional standard (e.g., economic deception or inappropriateness for the type of food). However, in some cases there are other quality ingredients that may be added for the same purposes.

For example, the agency finds that simulated cheese flavors are unsuitable for use in cheese and related cheese products. Although new § 130.10(d)(1) would permit ingredients to add flavor in substitute foods, flavoring ingredients that are specifically prohibited by standards of identity from inclusion in such foods are specifically prohibited in the modified form of such food (new § 130.10(d)(3)). The standard of identity for pasteurized process cheese in § 133.169(d)(6) specifically excludes any flavorings that, singly or in combination with other ingredients, simulate the flavor of a cheese of any age or variety from use in such food. However, "safe and suitable enzyme modified cheese" may provide a source of flavor in pasteurized process cheese, and this source of flavor is one of the optional ingredients that the agency now permits in this food, as specified in § 133.169(d)(9).

37. One comment asked that the use of "skim milk cheese for manufacturing" in § 133.189 be permitted in the formulation of fat-modified pasteurized process cheese, even though the standard of identity in § 133.169 does not now provide for this lower fat, "traditional" dairy ingredient.

FDA disagrees with this comment. Although skim milk cheese for manufacturing is an ingredient in the same class as other cheese ingredients used in the manufacture of the pasteurized process cheese products, because the standard for pasteurized process cheese (§ 133.169) specifically prohibits the use of this ingredient, this lower fat cheese ingredient may not be used in modified versions of this food. Manufacturers wanting to utilize this ingredient in pasteurized process cheese products must label the product as a nonstandardized food or, if appropriate, as pasteurized process cheese food (§ 133.173) or a modified version of pasteurized process cheese food.

Persons interested in providing for the use of skim milk cheese for manufacturing in modified versions of pasteurized process cheese (§ 133.169) may petition the agency to amend the standard.

H. Nomenclature

38. Several comments stated that they believed that allowing the use of the name of a standardized food on foods to which additional safe and suitable ingredients are added is deceiving to consumers, in direct conflict with the standards of identity concept/procedure, and should not be permitted. Comments stated that if FDA is going to permit optional ingredients to be added to standardized foods to accomplish the performance criteria cited in proposed § 130.10(d)(1), it should require that terms such as "substitute" or "modified" be used in the name of the food.

FDA disagrees with these comments. The major ingredients in a substitute food under new § 130.10 must be ingredients mandated by the relevant standard of identity. The only deviations from the standard that are authorized are those that are necessary to make the nutrient content claim, to ensure that the food meets the performance characteristics of the traditional standardized food, and to ensure the food is not nutritionally inferior to the traditional standardized food. FDA believes that the use of the nutrient content claim in the name of the food and the use of asterisks in the ingredient statement will alert consumers to the fact that the food contains ingredients that differ from those found in the standardized food. Therefore, FDA concludes that consumers will be adequately informed of differences between the § 130.10 food and the traditional standardized food. Because the § 130.10 food is itself a standardized food, it does not need to be labeled as a substitute.

39. One comment requested that the agency clarify that use of "substitute," "alternate," and a distinctive common or usual name remain viable for naming nonstandardized foods. Another comment stated that FDA should require the use of the term "substitute" in conjunction with a standardized name of a food when one or more of the basic characterizing ingredients of a standardized dairy food has been replaced with nondairy ingredients (e.g., vegetable oil in place of milkfat).

FDA notes that § 101.3(e)(4) requires that a food that resembles a standardized food but does not comply with the standard of identity must be labeled as imitation if it is nutritionally inferior to the food, or as a substitute or alternative if it is not nutritionally inferior. As stated above, foods that comply with new § 130.10 comply with a standard of identity.

New § 130.10(d)(2) prohibits the use of functionally similar ingredients to replace an ingredient that is specifically required by the standard. Therefore, a lowfat substitute for mozzarella cheese that is made with vegetable oil would have to be labeled as "imitation mozzarella cheese" if it is nutritionally inferior to mozzarella cheese, or "mozzarella cheese substitute" or "mozzarella cheese alternative" if it is not nutritionally inferior to mozzarella cheese because it does not comply with the standard of identity for mozzarella cheese (§ 133.155) or with new § 130.10.

40. One comment stated that FDA should clearly indicate that any applicable modifier may be used if more than one is applicable.

FDA agrees that any applicable nutrient content claim, if defined by FDA, may be used if more than one is applicable.

41. Two comments stated that if the name of a standardized food, coupled with the nutrient content claim, presents a contradiction in terms (e.g., nonfat ice cream), then the use of such nutrient content claim should be restricted. One comment added that standardized dairy products (e.g., ice cream) should not be reformulated to the extent that they lose their "dairy product" identity (e.g., nonfat ice cream). They would become "nondairy" products and should be named accordingly.

FDA disagrees with these comments. In the January 22, 1991, ANPRM (56 FR 2149) concerning the filing of several petitions to amend the standards for ice cream and ice milk and to establish standards for reduced fat, low fat, and

nonfat ice creams. FDA received comments in response to the ANPRM concerning whether the use of the terms "reduced fat ice cream," "low fat ice cream," and "nonfat ice cream" is misleading to consumers.

Several comments received in response to the ANPRM maintained that consumers will recognize "reduced fat ice cream," "low fat ice cream," and "nonfat ice cream" as products that, while containing less fat than ice cream, will deliver what they have come to expect from that food, i.e., similar taste, appearance, mouthfeel, and nutrition as ice cream products. The comments also noted that the nutrition labeling on the reduced fat products will provide additional information on the fat content of the products for comparison purposes.

As noted in these comments on the ANPRM, consumers have had experience for many years with the term "nonfat" on other dairy products (e.g., nonfat milk and nonfat yogurt). In addition, FDA has issued a number of temporary marketing permits and an extension of a temporary marketing permit for "nonfat cottage cheese," a mixture of dry curd cottage cheese with a dressing that contains less than 0.5 percent of milkfat, and has granted temporary marketing permits for "no fat sour cream." FDA believes that these products are dairy products even though milkfat has been reduced or removed because the milkfat is replaced with skim milk or other dairy ingredients. Nutrition labeling will also assist consumers in making value comparisons relative to the fat reduction as well as calorie reductions in these foods. Therefore, FDA concludes that consumers will not be confused or misled by the use of the nutrient content claim "nonfat" in conjunction with a standardized term such as "ice cream."

42. One comment disagreed with the prohibition on the use of a name permitted on a food under the new generic standard of identity if that food complies with another standard. It stated that this prohibition is a barrier to directing consumers to lower fat versions of products with which they are familiar. It stated that if a modified product meets a traditional standard and the general standard, food producers should be given the option of naming the food using any of the terms allowed under those standards.

FDA disagrees that the name of a modified food that meets the requirements of another standard in parts 131 through 169 should be either name. The common or usual name of a food that has been defined by a standard of identity under section 401 of the act is the name prescribed by the standard. Foods that comply with any standard in parts 131 through 169 must use that standardized name, and this rulemaking is not intended to amend existing standards nor create duplicative standards.

As FDA stated in the proposal (56 FR 60512 at 60520), comparative labeling in accordance with regulations in part 101 may be used to provide consumers with useful information in the selection of a variety of foods.

I. Ingredient Labeling

In the proposal, FDA requested comments on the proposed approach to ingredient labeling in proposed § 130.10(f) and on other methods of identifying ingredients not provided for by the traditional standard of identity (56 FR 60512 at 60520).

43. A number of comments objected to the proposed labeling requirements that ingredients not in the standardized food be highlighted with an asterisk, with a statement following the ingredient statement. One comment urged FDA not to establish the specific words that processors must use to convey information about the amount of ingredients not in the standardized food. Several comments stated that consumers generally are not concerned about, or even interested in, how these formulations are achieved, and that the use of asterisks and label statements may be potentially confusing. Several comments stated that the proposed ingredient disclosures would be burdensome to manufacturers and would result in label clutter.

The agency also received comments strongly supporting the use of the disclosures as meaningful steps in the goal of consumer information and understanding. One comment stated that food companies need to inform the consumer as to whether adjustments have been made to their products, and that the item is no longer the same as the standardized food. It stated that the simple labeling of a product as "low fat" is not sufficient because this claim may give the consumer the impression that the product is the same as always, but contains less fat, which may or may not be true.

FDA disagrees with the comments that opposed the use of asterisks. Standards of identity regulations are established when such action will promote honesty and fair dealing in the interest of consumers. The highlighting of ingredients that are not part of the traditional standard of identity, or that are added in excess of what is permitted by that standard, is appropriate to ensure continued consumer confidence in standardized foods. FDA believes that under sections 201(n) and 403(d) of the act, consumers are entitled to know how the new standardized food differs from the traditional standardized food. In some cases, consumers may have allergies to certain ingredients that may not be normally encountered in the standardized food. Therefore, FDA finds that these ingredients must be highlighted.

44. Many comments stated that it is important for persons with hemochromatosis to know when iron is added to a food. They stated that added iron is often more biologically available than other forms of iron. Several of the comments opposed the language of proposed § 130.10(f)(2) that exempts added iron from being identified with an asterisk in the ingredient statement.

Any added iron must be listed as an ingredient in the ingredient statement. As stated in the proposal (56 FR 60512 at 60520), the consumer may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. Iron is added to a number of foods, not just standardized foods including foods under new § 130.10. Most § 130.10 foods to which iron will need to be added to ensure that the product is not nutritionally inferior are foods that must contain added iron under the traditional standard of identity (e.g., enriched bread, rolls, and buns (§ 136.115)). The agency notes that nutrition labeling will inform consumers of any iron present in significant amounts in the food. Thus, FDA concludes that persons with hemochromatosis will be adequately informed of added iron in any food, and that the use of an asterisk in the ingredient statement is not necessary for nutrients added to a § 130.10 food.

45. Two comments stated that FDA should require that the principal display panel of the label contain a referral statement directing consumers to the ingredient statement to be informed of any nonstandard ingredients. One comment recommended that this statement should be tailored to different types of foods, based on the ingredients that characterize the foods to consumers. For example, the comment noted, dairy products could be labeled with the term "made with nonstandard nondairy ingredients." In addition, the comment stated that products that meet the nutrient content claim requirements, but are made only from standard ingredients, could be permitted to use the term "pure" as part of the common

or usual name ("pure reduced fat sour cream").

The agency disagrees with these comments. FDA believes that this additional labeling is not necessary because the ingredients that are not in the traditional standardized food are already identified with an asterisk in the ingredient statement. FDA also disagrees with this use of the term "pure." The agency has not defined the term "pure" and believes that the use of the term in the requested manner could cause consumer confusion because of its ambiguity.

46. One comment stated that if these products contain saccharin, aspartame, or acesulfame potassium, they should clearly state this fact on the front label.

FDA notes that a product is misbranded under section 403(o)(1) of the act if it contains saccharin, unless, its label and labeling bear the following statement: "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS." This statement must be located in a conspicuous place on the label and labeling, as proximate as possible to the name of such food, and must appear in conspicuous and legible type in contrast by typography, layout, and color with other printed matter on such label and labeling.

FDA also notes that § 172.804 (21 CFR 172.804) requires that the label of any food containing aspartame bear, either on the principal display panel or on the information panel, the following statement: "PHENYLKETONURICS: CONTAINS PHENYLALANINE." The statement must appear in the labeling prominently and conspicuously as compared to other words, statements, designs or devices and in bold type and on clear contrasting background in order to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

The regulation in § 172.800 (21 CFR 172.800) concerning acesulfame potassium requires no special label statements. However, whenever acesulfame potassium, aspartame, or saccharin are ingredients in a food, the name of the ingredient must appear in the ingredient declaration according to part 101.

The comment did not provide any basis for requiring special label statements concerning the addition of these sweeteners for foods subject to new § 130.10. FDA believes that the above requirements provide adequate notice of the presence of these ingredients when they are used. Therefore, FDA concludes that no additional statements need be required other than those that are required by the act and current FDA regulations, including the use of asterisks and label statements required in new § 130.10(f)(2).

J. Label Format

47. Two comments suggested that FDA should develop more simplified principal display panel labeling requirements and consider a mandatory format for comparative labeling of § 130.10 foods. The comment gave the following example: Reduced Fat "Modified" Cheddar Cheese; 25 percent Less Fat than Cheddar Cheese; Side panel provides nutrition information, per serving size comparisons, and nonstandardized (*) ingredients.

FDA disagrees with this comment. The principal display panel labeling requirements for use of nutrient content claims are mandated by the 1990 amendments and regulations in part 101 concerning the claim. New § 130.10(c) requires additional labeling on the principal display panel only when there are differences in performance characteristics. FDA concludes that the requirements that it is adopting are the minimum necessary to ensure that the labeling of § 130.10 foods is informative, adequate, and not misleading. In addition, FDA believes that except as provided in new § 130.10(c), it is not necessary to mandate a particular format for the principal display panel.

K. Existing Standards Using Nutrient Content Claims

48. One comment expressed concern about FDA's tentative decision to exclude from this rule standards of identity that already incorporate nutrient content claims (e.g., lowfat milk). Another comment stated that FDA should give serious consideration to eliminating the existing standards of identity for those foods that have a nutrient content claim as part of their standardized names, in cases where the remainder of the name is also a standardized term.

The agency appreciates the concerns expressed in these comments. FDA did not include existing standards in the proposal to this final rule because Congress exempted nutrient content claims that are part of the name of a food defined by an existing standard of identity even if the use of the term in the standardized name is not consistent with the definition for the term that FDA adopts (section 403(r)(5)(C) of the act). However, the legislative history makes clear that this exemption was included in the law because of the preexisting standards of identity and the possibility that these standards would conflict with the definitions adopted under the new law. The legislative history goes on to state that to the extent that those standards do provide definitions that are different from the definitions in the regulations issued by FDA under the 1990 amendments, one basic purpose of the 1990 amendments will be partially undermined. Therefore, the legislative history points out that the Secretary (and, by delegation, FDA) has the authority to correct this problem by amending the standards of identity to conform with the regulations issued under section 403(r) of the act (H. Rept. 101–538, 101st Cong., 2d sess. 22 (June 13, 1990)).

FDA will consider amending the existing standards of identity that use nutrient content claims in a food name to make them consistent with the definitions that the agency is adopting. The agency's options include amending standards of identity to comply with the nutrient content claim or deleting some standards and allowing the use of these claims with standardized terms in accordance with new § 130.10. Thus, FDA does intend to consider taking the actions suggested by these comments, although it is unable to do so at this time.

L. Legal and Policy Analysis

49. One comment stated that the same legal and policy analysis applies to foods that substitute for foods standardized by statute as to foods that substitute for foods standardized by regulation. It suggested that the preamble to the final rule adding new § 130.10 state that the same legal and policy analysis applies to foods subject to new § 130.10 as to foods subject to § 101.67.

FDA disagrees with this comment. Butter, nonfat dry milk, milk, and oleomargarine or margarine are foods that have been defined by statute. Under section 401 of the act, FDA has modified the definitions and has established standards of identity for nonfat dry milk, milk, and oleomargarine or margarine. However, under section 401 of the act, FDA is prohibited from establishing standards for butter. Therefore, the legal and policy analysis of butter is different from foods standardized by regulation. Proposed § 101.67 deals only with the use of nutrient content claims for butter. FDA can establish standards for other foods under section 401 of the act, and terms that are standardized by regulation are those that may be used under new § 130.10.

III. Pending Petitions

As stated in the proposal (56 FR 60513 at 60516), FDA has received petitions from: (1) The Milk Industry Foundation (MIF) (Docket No. 88P–0329), H. P. Hood, Inc. (Docket No. 89P–0105), and Crowley Foods, Inc. (Docket No. 89P–0403) to establish a standard for "light sour cream;" (2) MIF (Docket No. 88P–0334) and H. P. Hood, Inc. (Docket No. 89P–0329) to establish a standard for "light eggnog;" and (3) the International Ice Cream Association (IICA), the Public Voice for Food and Health Policy, Kraft General Foods, and the Calorie Control Council to amend the standards for "ice cream" and "ice milk" and to establish standards for "reduced fat ice cream," "lowfat ice cream," and "nonfat ice cream" (Docket No. 88P–0251).

FDA has received a number of applications from companies desiring to market test "nonfat cottage cheese." The agency has issued approximately 22 temporary marketing permits for the product. MIF filed a petition, dated November 2, 1991 (Docket No. 91P–0448), to establish a standard of identity for "nonfat cottage cheese." MIF stated in its petition that establishing a standard of identity for "nonfat cottage cheese" would enhance public health, satisfy consumer demand, and promote honesty and fair dealing in the interest of consumers.

All of the petitions are requesting that the agency establish standards for modified versions of traditional standardized foods. Nutrient content claims for the fat content of foods are defined in § 101.62 and include "nonfat" (§ 101.62(b)(1)), "low fat" (§ 101.62(b)(2)), and "reduced fat" (§ 101.62(b)(4)). The term "light" or "lite" is defined in § 101.56. New § 130.10 establishes the requirements for use of these defined nutrient content claims with a standardized term. Therefore, the agency is responding to the above petitions by adopting this final rule. However, new § 130.10 does not encompass some portions of the petitions to amend the standards for ice cream and ice milk. Therefore, FDA is responding to those portions of the petitions to amend the standards for ice cream and ice milk in a separate proposal published elsewhere in this issue of the **Federal Register**.

50. One comment requested that to ensure that there is consistency in nomenclature regarding nutrient modified ice creams, FDA should take final action on the petition from the IICA to establish specific standards for modified ice creams and defer the applicability of the provisions of the 1990 amendments to the products within the scope of the IICA petition until 12 months after: (1) The effective date of regulations that FDA adopts in response to the IICA petition, or (2) FDA takes final action to reject the petition, whichever is applicable.

The agency disagrees with the comment. The standard of identity for ice milk (§ 135.120) states that its milkfat content is more than 2 percent but not more than 7 percent. The agency realizes that some reduced fat ice cream products may comply with the standard of identity for ice milk and must be labeled as "ice milk." As stated above, elsewhere in this issue of the **Federal Register**, FDA is proposing changes in the standards of identity for ice cream and ice milk. The agency is proposing to repeal the standard of identity for ice milk. If FDA repeals the standard for ice milk, manufacturers would be able to label ice cream products containing more than 2 percent but not more than 7 percent milkfat according to new § 130.10.

Because FDA is taking action on the IICA petition at this time, it does not believe that deferring the applicability of the provisions of new § 130.10 for ice cream products is necessary.

IV. Noncharacterizing Changes in Standardized Foods

51. One comment stated that because the use of nutrient content claims is voluntary, and because the standardized name alone is a proper statement of identity for a standardized food, the suggested use and placement of any nutrient content claim in conjunction with the name of a standardized food that meets the requirements of the standard of identity would, of course, be optional.

FDA agrees with this comment. The labeling for foods meeting a standard of identity and qualifying for the use of a nutrient content claim must comply with the respective standard of identity in parts 131 through 169 and the requirements of § 101.13 concerning nutrient content claims. Because these foods are not modified foods, they do not fall within the scope of new § 130.10. Therefore, FDA concludes that the use of a nutrient content claim in the name of a food complying with a standard of identity is not mandatory. For example, reduced cholesterol liquid eggs may still comply with the standard for liquid eggs (§ 160.115) although part or all of the cholesterol has been removed. The nutrient content claim "reduced cholesterol" may appear as part of the statement of identity in conjunction with the standardized name, or it may appear elsewhere on the label, according to applicable sections of part 101, with the statement of identity consisting of the standardized name.

V. Conclusion

In response to comments submitted regarding the proposal for requirements for foods named by use of a nutrient content claim and a standardized term (56 FR 60512), FDA has revised new § 130.10. The following summarizes the changes being made to new § 130.10 by this final rule:

FDA has revised the title of the regulation to delete the term "substitute" because new § 130.10 applies only to a certain category of substitute foods and not all types of substitute foods as defined under § 101.3(e)(4) and § 101.13(d).

FDA has revised new § 130.10(a) to more clearly establish the scope of the regulation by adding that § 130.10 foods use the name of the traditional standardized food in their statement of identity but do not comply with the traditional standard.

The agency has revised new § 130.10(a) to state that the deviation from the standard of identity "is described by an expressed nutrient content claim that has been defined by FDA regulation."

FDA has revised the last sentence of new § 130.10(a) to read: "The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section."

FDA has added a new sentence to new § 130.10(c) at the beginning of the paragraph to state: "Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food." In addition, FDA has included in new § 130.10(c) a requirement that deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to achieve this effect or the food will be deemed to be adulterated under section 402(b) of the act.

The agency has added a statement to new § 130.10(c) to require that the modified product must perform at least one of the principal functions of the standardized product substantially as well as the standardized product.

The agency has also revised new § 130.10(c) by limiting the labeling requirement to changes that materially affect the use of the product.

Finally, FDA has revised new § 130.10(c) to require that the mandated

label statement concerning any differences in performance characteristics be in accordance with the requirements of § 101.13(d).

The agency has revised new § 130.10(d)(1) to include the use of safe and suitable ingredients to improve appearance and to add sweetness.

FDA has added new § 130.10(d)(4) to state that an ingredient specifically required by the standard as defined in parts 131 through 169 must be present in a significant amount. A significant amount of an ingredient is at least that amount that is required to achieve the technical effect provided by that ingredient in the modified food.

The agency has added new § 130.10(d)(5) to provide for the use of water and safe and suitable fat analogs in accordance with new § 130.10(c), (d)(1), and (d)(2) in modified foods to replace fat and calories.

FDA has revised new § 130.10(e) to state that the name of the substitute food "is the appropriate expressed nutrient content claim and the applicable standardized term."

VI. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to allow additional time for companies to use up their old labels. Thus, the final rule will not be effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

VII. Economic Impact

In its November 27, 1991, food labeling proposals (56 FR 60366), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

List of Subjects in 21 CFR Part 130

Food additives, Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 130 is amended as follows:

PART 130—FOOD STANDARDS: GENERAL

1. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

2. Section 130.10 is added to subpart A to read as follows:

§ 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.

(a) *Description.* The foods prescribed by this general definition and standard of identity are those foods that substitute (see § 101.13(d) of this chapter) for a standardized food defined in parts 131 through 169 of this chapter and that use the name of that standardized food in their statement of identity but that do not comply with the standard of identity because of a deviation that is described by an expressed nutrient content claim that has been defined by FDA regulation. The nutrient content claim shall comply with the requirements of § 101.13 of this chapter and with the requirements of the regulations in part 101 of this chapter that define the particular nutrient content claim that is used. The food shall comply with the relevant standard in all other respects except as provided in paragraphs (b), (c), and (d) of this section.

(b) *Nutrient addition.* Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in

§ 101.3(e)(4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(c) *Performance characteristics.* Deviations from noningredient provisions of the standard of identity (e.g., moisture content, food solids content requirements, or processing conditions) are permitted in order that the substitute food possesses performance characteristics similar to those of the standardized food. Deviations from ingredient and noningredient provisions of the standard must be the minimum necessary to qualify for the nutrient content claim while maintaining similar performance characteristics as the standardized food, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, flavor characteristics, functional properties, shelf life) of the food shall be similar to those of the standardized food as produced under parts 131 through 169 of this chapter, except that if there is a significant difference in performance characteristics that materially limits the uses of the food compared to the uses of the standardized food, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for cooking"). Such statement shall comply with the requirements of § 101.13(d) of this chapter. The modified product shall perform at least one of the principal functions of the standardized product substantially as well as the standardized product.

(d) *Other ingredients.* (1) Ingredients used in the product shall be those ingredients provided for by the standard as defined in parts 131 through 169 of this chapter and in paragraph (b) of this section, except that safe and suitable ingredients may be used to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the standardized food defined in parts 131 through 169 of this chapter.

(2) An ingredient or component of an ingredient that is specifically required by the standard (i.e., a mandatory ingredient) as defined in parts 131 through 169 of this chapter, shall not be replaced or exchanged with a similar ingredient from another source unless the standard, as defined in parts 131 through 169 of this chapter, provides for the addition of such ingredient (e.g., vegetable oil shall not replace milkfat in light sour cream).

(3) An ingredient or component of an ingredient that is specifically prohibited by the standard as defined in parts 131 through 169 of this chapter, shall not be added to a substitute food under this section.

(4) An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount. A significant amount of an ingredient or component of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

(5) Water and fat analogs may be added to replace fat and calories in accordance with § 130.10(c), (d)(1), and (d)(2).

(e) *Nomenclature.* The name of a substitute food that complies with all parts of this regulation is the appropriate expressed nutrient content claim and the applicable standardized term.

(f) *Label declaration.* (1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of part 101 of this chapter and part 130.

(2) Ingredients not provided for, and ingredients used in excess of those levels provided for, by the standard as defined in parts 131 through 169 of this chapter, shall be identified as such with an asterisk in the ingredient statement, except that ingredients added to restore nutrients to the product as required in paragraph (b) of this section shall not be identified with an asterisk. The statement "*Ingredient(s) not in regular _____" (fill in name of the traditional standardized food) or "*Ingredient(s) in excess of amount permitted in regular _____" (fill in name of the traditional standardized food) or both as appropriate shall immediately follow the ingredient statement in the same type size.

Dated: October 27, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0344]

RIN 0905-AD06

Food Labeling: Use of Nutrient Content Claims for Butter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting a regulation that will permit nutrient content claims that are defined by regulation in 21 CFR part 101 to be made for butter. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5112.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the 1990 amendments (Pub. L. 101-535) and to a citizen petition submitted by Johanna Farms, Inc., Flemington, NJ 08822, (Docket No. 90P-0141), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60523), a proposal to adopt § 101.67, which would permit nutrient content claims that are defined by regulation in part 101 (21 CFR part 101) to be made for butter. Interested persons were given until February 25, 1992, to comment on this proposed regulation.

FDA received approximately 70 responses on the proposal, each of which contained one or more comments, from trade and retail associations, government organizations, manufacturers, consumers, retailers, consumer groups, State groups, private organizations, professional societies, and universities. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., serving size and nutrient content claims definitions) and will not be discussed here. A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follow.

II. Use of Nutrient Content Claims for Butter Under the 1990 Amendments

A. The Proposed Approach

FDA requested comments on its proposed approach to permit nutrient content claims to be made for butter (56 FR 60523 at 60525).

1. Two comments stated that FDA had the authority to promulgate § 101.67 independent of the 1990 amendments. One of the comments said that a better approach would have been under the general provisions of proposed § 130.10 or through a standard of identity. It stated that a food that does not meet the statutory standard for butter is not butter, and that accordingly, a product with less milkfat simulating butter would need to be labeled "imitation" in the absence of some other governing agency mechanism, such as a standard of identity for "light butter." The comment maintained that since "light" would be part of the name, the product would not be butter because the definition would be different. The product would not be nutritionally inferior, the comment continued, because it would be required to provide the same nutrients as butter (except for less fat), and it would not be deceptive because properly informative labeling would be required and monitored by the agency.

The agency disagrees with the comments. As explained in the proposal (56 FR 60523 at 60524), the agency does not have the authority to establish a definition and standard of identity for "light butter." Section 401 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 341) states that no definition and standard of identity can be established for butter. Moreover, FDA has historically taken the position that a product using the term "butter" must comply with the statutory definition of butter, or its labeling would be false, and it would be misbranded under section 403(a)(1) of the act (21 U.S.C. 343(a)(1)) (see 56 FR 60523 at 60524). In addition, a food sold under the name "butter" that does not comply with the statutory standard for butter also is in violation of section 403(b) of the act in that it is sold under the name of another food.

As discussed in the proposed rule, FDA sought an interpretation that gave effect both to section 3(b)(1)(A)(viii) of the 1990 amendments (21 U.S.C. 343 note), which stated that FDA could establish a regulation that would permit a nutrient content claim, such as "light," to be made for butter, and to section 401 of the act. FDA believes that it achieved this goal in proposed § 101.67. These comments, since they rely on section 401 of the act, have not provided any basis to conclude to the contrary.

2. A number of comments opposed providing for the use of nutrient content claims for butter. Several comments recommended that the term "butter" be used only if the product complies with the statutory standard for butter, and that other names such as "dairy spread" be used for other butter products. Some comments stated that if a product is good it will develop its own distinctive name.

The agency understands the concerns expressed by these comments. However, the 1990 amendments and their legislative history make clear that Congress fully intended that a claim described in section 403(r)(1)(A) of the act (such as "light") be permitted to be made for butter (H. Rept. 101-538, 101st Cong., 2d sess. 22-23 (June 13, 1990)). Given this fact, there is no basis to require the use of terms such as "dairy spread" in the common or usual names of these products. Accordingly, FDA is allowing, as proposed, nutrient content claims to be made for butter.

B. The Nutrient Content Claim

3. Several comments expressed concern about consumers being able to identify butter products on the store shelf. The comments were concerned that nutrient content claims could mislead and confuse consumers even if they are defined.

The agency appreciates the concerns expressed by the comments. In response to the requirements of the 1990 amendments, published elsewhere in this issue of the **Federal Register**, in a document entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms" (hereinafter referred to as the nutrient content claims final rule), FDA is establishing in part 101 definitions for nutrient content claims together with general principles governing their use. FDA has carefully considered each nutrient content claim to ensure that these definitions will be meaningful to consumers. Each of the definitions for the nutrient content claims also prescribes specific labeling that must accompany the claim. The agency believes that as consumers learn what a claim means, they will be able to understand that a product such as "light butter" is reduced a certain amount in fat. Thus, the use of nutrient content claims for butter products in accordance with new § 101.67 will not mislead or confuse consumers but will assist them in maintaining healthy dietary practices.

New § 101.67 only provides for the use for butter of nutrient content claims

that have been defined by FDA. Any product labeled as "butter" that does not come within the provisions of new § 101.67 will need to comply with the statutory standard for butter, or its labeling will be false, and it will be misbranded under the act.

FDA notes, however, that there are two potential problems that proposed § 101.67 failed to address that could cause confusion among consumers. In the proposal, FDA did not require that the nutrient content claim be included as part of the statement of identity of the butter product. Consequently, a claim could be made for the butter product in an inconspicuous location on the label, and consumers could be misled about the identity of the product that does not comply with the statutory standard for butter (section 201a of the act (21 U.S.C. 321a)).

In addition, FDA did not distinguish between express and implied claims in the proposal. Yet section 403(r)(1)(A) of the act applies to both types of nutrient content claims.

Therefore, to rectify this potential confusion, FDA is adding § 101.67(a)(4) to make clear that while nutrient content claims may be made anywhere on the label, if the product would violate section 201a of the act but for the nutrient content claim that characterizes the level of nutrients, that claim must be included as part of the common or usual name of the product. This provision will ensure that consumers are not misled about the identity of the product.

New § 101.67(a)(4) also provides that if the name of the butter product is necessary to distinguish it from butter, the claim must be an express claim as defined in new § 101.13(b)(1). If the claim is not express, consumers will not understand how the new modified food differs from the traditional food. Thus, only expressed nutrient content claims may be used in the name of the food under new § 101.67. While implied claims may be used as provided in new § 101.13(b)(2), they may not be used in conjunction with the name of the butter product because they would not be adequately informative to consumers.

4. One comment stated that FDA should decide on a more appropriate name than "light butter," such as "light butter product."

The agency does not believe the suggested additional term (i.e., "product") is necessary. If a butter product does not comply with the statutory standard for butter or the requirements of new § 101.67 set forth below, FDA requires that it be labeled either as an imitation food if it is nutritionally inferior to butter (§ 101.3(e)(1)), or as a substitute or alternative food if it is not nutritionally inferior to the food for which it substitutes, with an appropriately descriptive common or usual name that is not false and misleading, as provided for in § 102.5 (21 CFR 102.5), or, in the absence of an existing common or usual name, an appropriately descriptive term that is not false and misleading (§ 101.3(e)(2) (21 CFR 101.3(e)(2))). As explained above in comment 2 of this document, the legislative history of the 1990 amendments makes clear that Congress fully intended that a claim described in section 403(r)(1)(A) of the act (such as "light") be permitted to be made for butter (H. Rept. 101–538, supra, 22–23). Given this fact, there is no basis to require the use of additional terms such as "product" in the common or usual names of these foods. The use of a nutrient content claim that is permitted by regulation with the term "butter" in the statement of identity will provide a clear indication to consumers that the food is different from traditional butter and will describe the nature of the modification. In addition, the label must comply with all the requirements for the use of the nutrient content claim. Accordingly, the agency is not making the suggested modification to new § 101.67.

5. A number of comments suggested that FDA should develop unique nutrient content claims for butter because the proposed nutrient content claim requirements for fat in proposed § 101.62 are not appropriate or realistic for butter products. Two comments added that the use of unique nutrient claims for butter is consistent with the directive in the President's Executive Order 12630 that regulations harness the mechanisms of the market (e.g., competition in percentage reductions) to accomplish the agency's goal. One comment stated that it had test marketed a 50-percent reduced fat butter for over a year, but that the product failed to meet consumers' expectations, principally in physical performance characteristics. Another comment suggested that a reduced fat butter containing one-third less fat than butter is a product that will significantly reduce fat consumption while having all the characteristics of full-fat butter. The comments urged FDA to adopt simple definitions for nutrient content claims that will allow the industry to make dairy products with less fat and cholesterol available to consumers. One comment noted that a number of states have established regulations for light butter that differ from FDA's proposal. The comment urged FDA to use the knowledge and information obtained by these states in their respective hearing processes to modify FDA's proposed regulations to redefine the term "light" as used with butter products.

FDA notes that because no uniform set of definitions has existed for many nutrient content claims, these claims have been used in an inconsistent manner, which has resulted in consumers being confused and misled. The legislative history of the 1990 amendments makes clear that Congress was aware that many food labels bear terms such as "light" when a product may not be as "light" as the label indicated, or the product was "light" in different ways (e.g., calories or sodium). The purpose of the 1990 amendments was to correct this deceptive and misleading state of affairs by requiring that terms such as "light" have a single meaning (136 Congressional Record H5844, July 30, 1990).

The agency recognizes that because butter is at least 80 percent milkfat, a significant reduction in milkfat produces a significant change in the product. In the nutrient content claims final rule, FDA is redefining "reduced" and "less" to be a reduction of 25 percent or more. Thus, many butter products will be able to meet these requirements and make a nutrient content claim. Also, there is evidence that some manufacturers will be able to meet the 50-percent reduction to qualify for use of the term "light." Thus, FDA sees no reason to create a special set of definitions for butter products under new § 101.67.

FDA recognizes that some states and foreign governments have developed their own definitions for nutrient content claims for butter. However, FDA concludes that use of nutrient content claims in an inconsistent manner would be confusing to consumers, and, thus, the agency is not considering the use of any unique nutrient content claims for butter.

C. Minimum Milkfat Level

In the House report on the 1990 amendments, FDA is directed to consider arguments concerning the appropriate characteristics of butter. In a footnote, the report states:

> The Committee is aware that the dairy industry takes the position that products containing less than approximately 50 percent milkfat lose some of the characteristics of butter. In connection with the promulgation of the regulations, representatives of dairy interests and health experts will have the opportunity to present their views on the issue to the Secretary. (H. Rept. 101–538, supra, 23, n.3.)

In the proposal, FDA requested comments on whether its tentative

decision not to include a minimum milkfat level in proposed § 101.67 was appropriate (56 FR 60523 at 60526).

6. A number of comments concurred with the agency's tentative decision. Comments stated that there is no need to stipulate minimum levels. The comments also stated that not requiring a minimum milkfat level for butter products would leave room for advances in food processing technology that could lead to products with lower levels of milkfat and greater health benefits while still maintaining the characteristics of standardized butter. Another comment concurred as long as the product bearing the term "butter" is describable as a form of butter, because of the fact that its similarities to butter nutritionally, organoleptically, functionally, and in other ways would clearly outweigh its dissimilarities to butter.

One comment stated that FDA should set a minimum butterfat level, below which the product is no longer a butter product. However, the comment did not recommend a minimum level.

FDA agrees with the comments suggesting that a minimum milkfat level is not necessary. A product remains a butter product as long as the major ingredients used in manufacturing it are cream, milk, or constituents of milk and cream and as long as it can be used like butter. In addition, the butter product must comply with all the requirements of new § 101.67 for the use of nutrient content claims for butter products. For example, the milkfat content of butter contributes some of the basic characteristics of the food. New § 101.67(b) provides that the performance characteristics must be similar to those of butter, or the differences must be stated on the principal display panel.

The agency notes that Canadian regulations do not stipulate a minimum milkfat level for "calorie reduced butter."

Therefore, for the above reasons, the agency concludes that there is no need to specify a minimum milkfat level for butter products. The absence of a minimum level will permit technological advances that will provide consumers with butter products that have even greater reductions in fat and calories.

D. Ingredients

FDA requested comments on the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend shelf life. FDA also requested comments concerning the addition of water as well as skim milk, whey, or milk to replace milkfat as an ingredient in substitute butter products. FDA stated in the proposal that if the comments supported the use of safe and suitable nondairy ingredients and provided a substantial basis for their use, FDA might provide for the use of these ingredients in the final rule (56 FR 60523 at 60526).

(1) Safe and Suitable Nondairy Ingredients

7. A number of comments stated that the use of nondairy ingredients should not be permitted. Several comments argued that if manufacturers are adding anything that makes the food something other than butter, it should be labeled as "margarine," "spread," or "margarine." One comment stated that use of nondairy ingredients in a butter product would mislead consumers because consumers expect "butter" to be a dairy product. It added that use of such ingredients would erode the goodwill associated with the term "butter." The comment stated that the fact that current reduced fat butter products made without nondairy ingredients are not satisfactory for some cooking applications is not a reason to permit the use of such ingredients in products whose statement of identity includes the term "butter." It stated that consumers who want reduced fat, reduced calorie products for use in cooking can turn to products properly labeled as margarines and spreads.

Another comment stated that consumers purchasing and using a butter product expect it to be a 100 percent dairy product and thus made from the ingredients and constituents of the ingredients listed in section 201a of the act for standardized butter. It added that use of additional safe and suitable ingredients is not necessary for butter products. It stated that the only exception should be the permitted addition of nutrients to prevent nutritional inferiority and the permitted use of safe and suitable bacterial cultures as proposed in the regulation.

A number of other comments urged FDA to allow the use of safe and suitable nondairy ingredients to improve texture, prevent syneresis, add flavor, or extend the shelf life of the product. One comment stated that FDA should permit the addition of safe and suitable nondairy ingredients that are not fat ingredients for such purposes. Another comment urged FDA to allow the use of safe and suitable ingredients without the restriction that they must be used to maintain the traditional food's performance characteristics as long as the use is in keeping with current good manufacturing practices. The comment stated that the potential need to use safe and suitable ingredients for processing, as well as performance, purposes is most apparent for reformulated butter products because butter is a high fat food, and fat affects processing characteristics as well as final performance characteristics. Several comments argued that providing for the use of safe and suitable ingredients would allow the development of additional products with lower saturated fat, total fat, and cholesterol.

One comment stated that using current technology, "reduced fat" butter made strictly from dairy ingredients is not suitable for frying or baking. It stated that in the event that a "reduced fat" butter made primarily from dairy ingredients cannot be developed with good baking characteristics, then the field needs to remain open to "reduced fat" butter that is made with some nondairy ingredients and that has good baking properties. It added that without these additional ingredients, consumers will have trouble finding "reduced fat" butter that meets their needs and will be discouraged from shifting from full fat to reduced fat butter.

One comment argued that FDA's authority to allow the use of nutrient content claims for butter also gives the agency the authority to allow safe and suitable ingredients, including nondairy ingredients, in a product that is named by using a nutrient content claim with the term "butter." The comment added that FDA has already recognized this authority by providing for two types of ingredients (nutrients and bacterial cultures) in the proposed rule that are not permitted in standardized butter. It urged FDA to modify the regulation consistent with the regulation for substitute foods.

One comment stated that a reduction in milkfat of 50 percent in a butter product made without the use of safe and suitable nondairy ingredients results in a product that fails to meet consumers' expectations for many of the principal uses of a butter product (e.g., baking, frying, melting, sauteing). The comment stated that a light butter product that meets the proposed requirements in proposed § 101.67 (i.e., 50 percent less milkfat than butter and no ingredients other than those allowed in proposed § 101.67) is currently being marketed in Canada. The comment stated that Professor David Bandler of Cornell University testified before the New York Department of Agriculture and Markets regarding a hearing to establish a standard of identity in New York for light butter. The comment stated that Professor Bandler testified that the Canadian light butter product that he evaluated was really a

combination of butter and cream mixed together, and one could easily determine that the product may not be butter for many of the principal uses a consumer would have for butter. (Hearing Transcript, December 4, 1990. State of New York Department of Agriculture and Markets, p. 66.) The comment stated that New York and five other states have established standards for light butter and have provided for the use of safe and suitable nondairy ingredients. The comment urged FDA to allow safe and suitable nondairy ingredients in butter products for which nutrient content claims are made.

Other comments added that use of other safe and suitable ingredients was acceptable as long as the addition of these ingredients is clearly stated on the label and explained in the labeling.

The legislative history of the 1990 amendments makes clear that Congress intended that consumers should be able to use nutrient content claims made for butter to assist them in following dietary guidelines (see H. Rept. 101–538, 101st Cong., 2d sess. 10, 23 (1990)). This intent has two necessary implications. First, Congress obviously intended that FDA adopt provisions that authorize that butter products that bear nutrient content claims be marketed. This intent is reflected in section 3(b)(1)(A)(viii) of the 1990 amendments.

Secondly, it is not enough to merely allow such products on the market. If these products are to be used to accomplish the purpose envisioned by Congress, they must have consumer acceptance, and they must be available for the full range of uses for which people use butter. If not, the products will quickly disappear from the market, or the uses of these products will be so limited as to have little dietary significance.

In light of these factors and of the comments that the agency received, FDA has reconsidered the proposal and concludes that it took too narrow an approach to defining the products that can appropriately include the term "butter" in their names. The comments have demonstrated that there are instances in which the minor addition of safe and suitable nondairy ingredients is necessary to reduce the fat and calories in butter products while maintaining the characteristics of butter, thereby increasing the products' consumer acceptability.

The agency notes that the use of nondairy ingredients in a dairy product like butter is not unprecedented, does not change its character, and, thus, would not mislead consumers. FDA has reviewed the dairy standards of identity in parts 131, 133, and 135 (21 CFR parts 131, 133, and 135) to determine what nondairy ingredients may be optionally added to dairy products. A number of the dairy standards provide for the use of ingredients such as flavors, emulsifiers, and stabilizers (e.g., lowfat dry milk (§ 131.123), evaporated milk (§ 131.130), skim milk (§ 131.143), and heavy cream (§ 131.150)). The standard of identity for sour cream (§ 131.160) provides for the optional use of safe and suitable ingredients that improve texture, prevent syneresis, or extend the shelf life of the product. The standard for sour cream also provides for the optional use of fruit and fruit juice and safe and suitable natural and artificial food flavoring as flavoring ingredients. Therefore, safe and suitable nondairy ingredients are already added to many types of dairy products to improve texture, add flavor, prevent syneresis, and extend shelf life, and these products remain dairy products. If these nondairy ingredients are useful in dairy products standardized in parts 131, 133, and 135, FDA believes that they may be useful in butter products.

FDA disagrees with the comment that urged FDA to allow the use of safe and suitable ingredients without restriction. The agency concludes that butter products should contain minor amounts of safe and suitable nondairy ingredients only when necessary to achieve the functions of ingredients or components of ingredients that are no longer present in the mandated quantities. As required in new § 101.67(b), the performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, and shelf life) of the butter product must be similar to those of butter. Safe and suitable ingredients added only as necessary to butter products to improve texture, add flavor, prevent syneresis, and extend shelf life will compensate for many deficiencies in performance characteristics.

The agency disagrees that it should permit safe and suitable ingredients in butter products to be consistent with the general standard in all cases. As explained in the proposal (56 FR 60523 at 60524 and 60525) and in a document entitled "Foods Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term" (hereinafter referred to as the general standard final rule) published elsewhere in this issue of the **Federal Register**, the legal and policy analysis of butter is different from foods standardized by regulation. Therefore, butter products are not included in § 130.10 foods but are regulated separately.

However, in § 130.10(d)(1), FDA provides for the use of safe and suitable ingredients in modified standardized foods to improve texture, add flavor, prevent syneresis, extend shelf life, improve appearance, or add sweetness so that the product is not inferior in performance characteristics to the traditional standardized food. FDA believes that the additional purposes (i.e., to improve appearance and add sweetness) for adding safe and suitable ingredients to modified foods also has application to butter products. Butter products with significantly less fat may appear more translucent than butter. Thus, ingredients to improve appearance are necessary to ensure that the product is not inferior in performance characteristics. Additionally, butter products may lack the sweetness of unsalted, sweet cream butter. Thus, ingredients to add sweetness may also be necessary to ensure that the product is not inferior in organoleptic characteristics.

Thus, FDA concludes that it is reasonable to provide for the use of safe and suitable ingredients because such use would enhance manufacturers' ability to produce butter products that perform as consumers expect. However, butter products must be made from cream or milk, or their constituents, with only those safe and suitable ingredients added as necessary to improve texture, add flavor, prevent syneresis, improve shelf life, improve appearance, and add sweetness. FDA emphasizes that butter products in compliance with new § 101.67 are dairy products, and that any addition of safe and suitable nondairy ingredients must be only in minor amounts. The addition of safe and suitable nondairy ingredients to butter products labeled under § 101.67 in excess of that which is reasonably required to achieve the performance characteristics of butter produced under 21 U.S.C. 321a constitutes deception and will be deemed to adulterate the food under section 402(b) of the act in that these ingredients are substituting for a valuable constituent. Therefore, FDA is including in new § 101.67(b) a requirement that deviations from ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve this effect, or the food will be deemed to be adulterated under section 402(b) of the act. The agency advises that products with nondairy ingredients in excess of these amounts fall outside of new § 101.67 and must be labeled as imitation butter if nutritionally inferior to regular butter, as butter alternatives or substitutes if not nutritionally

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inferior to butter, or, if appropriate, as margarine, a margarine product, or a spread.

The agency also concludes that butter products labeled according to applicable regulations will not decrease the significance associated with the term "butter." The addition of safe and suitable ingredients must be declared in the ingredient statement as required in § 101.67(c).

FDA advises that if flavors are added to a butter product, the label must comply with § 101.22. According to § 101.22(i), if the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor, by word, vignette, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor is considered to be the characterizing flavor. If the food contains any artificial flavor that simulates, resembles, or reinforces the characterizing flavor, under § 101.22(i), the name of the food on the principal display panel or panels of the label must be accompanied by the common or usual name of the characterizing flavor, in letters not less than one-half the height of the letters used in the name of the food. In addition, the name of the characterizing flavor must be accompanied by the word or words "artificial" or "artificially flavored," in letters not less than one-half the height of the letters in the name of the characterizing flavor.

(2) Water

8. A few comments opposed the addition of water to butter products. One comment maintained that water is not an ingredient traditionally added to butter. It stated that with current technology, the addition of water is not needed to produce a reduced fat butter, and, therefore, the addition of water to butter products should not be permitted. Another comment stated that added water would constitute a deviation from the butter standard and is not required to make an acceptable reduced fat butter product.

A number of comments stated that FDA should allow food manufacturers to add water to replace milkfat and reduce the caloric content of the product. Comments stated that water should be allowed if needed to yield an acceptable "butter" product. They stated that this might allow the development of additional products with lower saturated fat, total fat, and cholesterol. Two comments stated that the addition of water would be appropriate as long as it is clearly stated on the food label.

FDA acknowledges that the addition of water is not provided for in the statutory standard for butter, but the agency has decided to permit butter products to include ingredients that are not included in the statutory standard so that consumers may purchase such products with the characteristics of butter. There is consumer demand for products that have a significant reduction in fat and calories. Water is an ingredient that can be used to produce such a reduction as a replacement for milkfat in butter products. Although FDA agrees that with current technology, the addition of water may not always be needed to produce a reduced fat butter, the consumer may benefit from the increased reduction in saturated fat, total fat, cholesterol, and calories that can be accomplished through the addition of water. Thus, the addition of water will provide more flexibility in the formulation of butter products that may have an improved nutrition profile and may perform better than butter products formulated without any water. Therefore, FDA concludes that water may be added to butter products to replace milkfat.

Water can be added to replace milkfat in butter products in potentially very large amounts. In fact, none of the comments supporting the use of water to replace milkfat suggested any maximum level. However, to preserve the food's identity as a dairy product, the amount of water added may not exceed the amount of milk or cream ingredients. Therefore, FDA is providing in new § 101.67(a)(2) that the product may contain water to replace milkfat, although the amount of water added must be less than the amount of cream, milk, or milk constituents in the product.

The addition of water must be declared in the ingredient statement as required in § 101.67(c).

E. Minimum Dairy Ingredient Requirement

9. One comment recommended that a minimum percentage by weight of dairy ingredients (milk and its natural constituent components) be required in order to use the name "butter." The comment stated that without a minimum dairy ingredient requirement, the distinction between butter and margarine essentially vanishes. However, the comment did not recommend a specific level.

The agency disagrees with the comment. As discussed above, new § 101.67(a)(2) requires that the major ingredients in butter products be milk, cream, and derivatives of milk and cream. Because these ingredients are not generally used, or are used only in small amounts, in margarine, the distinction between the two products will be maintained. Therefore, FDA concludes that the requirement in new § 101.67(a)(2) is adequate, and that there is no need to specifically establish a minimum dairy ingredient level for butter products.

F. Nutritional Inferiority

10. One comment stated that the proposed regulation lacked specificity as to what is necessary to satisfy the requirement that the product not be nutritionally inferior. It stated that the standard for margarine (§ 166.110 (21 CFR 166.110)) specifies the required amount of vitamin A (15,000 International Units (IU) per pound) and an optional level of vitamin D (1,500 IU per pound).

The agency acknowledges that the standard for margarine designates the amount of vitamin A that must be added to margarine (§ 166.110(a)(3)) and the amount of vitamin D that may optionally be added to margarine (§ 166.100(b)). However, FDA disagrees that proposed § 101.67 lacks specificity concerning nutritional inferiority. Under proposed § 101.67(a)(3), the butter product must not be nutritionally inferior, as defined in § 101.3(e)(4), to standardized butter. This general requirement is adequate because § 101.3(e)(4) sets very specific requirements defining nutritional inferiority. The agency concludes that new § 101.67 need not specify required amounts of essential nutrients that must be added to butter products, and that no change is necessary in new § 101.67. The agency notes that general points for comparison of the nutrient values of the traditional standardized product can be found in a current valid composite data base.

G. Labeling Concerning Performance Characteristics

11. One comment recommended that the label statement be mandatory only for differences in performance characteristics that materially limit the uses of the butter product compared to the traditional standardized food that it resembles. It stated that market forces will encourage manufacturers to inform consumers about positive differences, and that consumers who select a product for its reformulated nutrient content will not be misled if they are not told about a positive change that the manufacturer believes is not sufficiently important to highlight on the product label. The comment noted that FDA

would not object if the label did not alert consumers to a minor improvement in a performance characteristic that consumers consider to be relatively unimportant for that food. In addition, the comment stated, a product may have several differences in performance characteristics, and several label statements could be confusing to consumers. The comment recommended that FDA modify proposed § 101.67(b) by limiting the labeling requirement to adverse changes that materially affect the use of the product.

The agency has been persuaded by these comments. FDA agrees that there are differences in performance characteristics that consumers may not consider important. In addition, unnecessary label statements may be confusing to consumers and may detract from other important information on the label.

Therefore, the agency is modifying new § 101.67(b) to state that:

"* * * if there is a significant difference in performance characteristics that materially limits the uses of the product compared to butter, the label shall include a statement informing the consumer of such difference (e.g., if appropriate, "not recommended for baking purposes").

12. One comment noted that there is an apparent conflict in the agency's proposed requirements for the location of the disclosure of differences in performance characteristics. It stated that proposed § 101.67(b) provides that such statement must appear on the principal display panel within the bottom 30 percent of the area of the label panel; proposed § 101.67(a)(1) requires that a nutrient content claim for a butter product comply with proposed § 101.13; and proposed § 101.13(d)(1) states that if there is a difference in performance characteristics, the food may still be considered a substitute if the label includes a disclaimer adjacent to the most prominent claim. The comment requested that the final versions of proposed §§ 101.67(b) and 101.13(d)(1) be consistent. It stated that a disclosure in the bottom 30 percent of the principal display panel could easily be as prominent as, or more prominent than, a disclosure that immediately follows disclosures about the nature of the product and the reference statement. The comment stated that it is in the interest of consumers that the required disclosure of differences in performance characteristics be located in the bottom 30 percent of the principal display panel, as provided in proposed § 101.67(b). Another comment requested that FDA allow any statements concerning differences in performance characteristics to appear on any panel of the label of the product.

Under section 403(f) of the act, FDA believes that the statement informing consumers of differences in performance characteristics must appear on the label with such conspicuousness and in such terms as to render it likely to be read and understood by the consumer under customary conditions of purchase and use. The agency concludes that the statement must appear in the same area of the label as the statement of identity for the butter product so that consumers will know where to find such information. Moreover, because the statement is a material fact that helps to describe the differences between the modified food and the traditional food, it must appear in close proximity to the statement of identity. See, e.g., *United States* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. supp. 746, 749 (E.D. N.Y. 1974).

FDA recognizes that it inadvertently proposed in § 101.67 to require statements informing consumers of differences in performance characteristics to appear in possibly two separate locations on the label. The agency acknowledges that one statement is sufficient to inform consumers. To be consistent with the labeling of other foods, the agency concludes that the statement concerning differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d)(1). Thus, the agency has modified new § 101.67(b) to state that the statement explaining differences in performance characteristics must appear on the label in compliance with the requirements of § 101.13(d).

13. Some comments suggested that, in order to use nutrient content claims for butter, the product must perform at least one of the principal functions of regular butter substantially as well as butter produced under section 201a of the act. Consumers can then choose to purchase the product instead of regular butter for use in that function.

FDA agrees that at a minimum, a butter product must perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a. Consumers should be able to count on using a butter product in the same manner in which they use regular butter for, at the very least, one of its principal functions. To achieve this objective, FDA is requiring in § 101.67(b) that butter products must resemble butter as produced under section 201a of the act, and that differences in the performance characteristics must be clearly stated on the principal display panel of the label. In addition, the agency is adding a statement to new § 101.67(b) to require that "the modified product must perform as least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a." FDA believes that this action is necessary to ensure the minimum necessary similarity between the modified and traditional products.

H. Other Labeling

14. One comment stated that products made with nondairy ingredients should be labeled, with appropriate prominence on the principal display panel of the label, "contains nondairy ingredients."

FDA does not agree that it should require this statement on the principal display panel of the label. The agency is requiring that the major ingredients in butter products be cream, milk, or derivatives of cream or milk and is only providing for minor additions of safe and suitable ingredients (e.g., nondairy ingredients) as necessary, so that the butter product has the same characteristics as butter. Although the agency is providing for the addition of water to replace milkfat, it must not be the predominant ingredient in the product. In addition, FDA points out that new § 101.67(c)(1) requires that each of the ingredients added to the product be listed in the ingredient statement, as required by the applicable sections of part 101.

However, to further assist the consumer in differentiating between regular butter and butter products with nontraditional ingredients added, FDA is establishing a requirement in new § 101.67(c)(2) that all safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness and water added to replace milkfat must be appropriately identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" must immediately follow the ingredient statement in the same type size. FDA is requiring similar labeling for modified standardized foods in new § 130.10, as explained in the general standard final rule.

FDA believes, however, that consumers may be misled to believe that ingredients added to restore nutrients are present in greater amounts than needed to obtain nutritional equivalency if these nutrients are identified with an asterisk in the ingredient statement. In addition, because butter has historically been a cultured product, the addition of safe and suitable bacterial cultures does not

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require identification with an asterisk. Therefore, the agency is not requiring that nutrients added to restore nutrients or added safe and suitable bacterial cultures be identified by an asterisk in the ingredient statement.

15. One comment stated that the percentage of water in light butter products should be declared on the label.

FDA disagrees with the comment. As discussed above in comment 8, cream, milk, and milk constituents will be the predominant ingredients in butter products. Any water added to butter products may not be present in an amount greater than the amount of the dairy ingredients. According to § 101.4(a), all ingredients, including water, must be listed by common or usual name in descending order of predominance by weight on the label. In addition, new § 101.67(c)(2) requires that water that is added to replace milkfat must be identified with an asterisk in the ingredient statement, followed by a statement explaining that the ingredient is not in regular butter. Therefore, FDA concludes that listing water as an ingredient in this manner is adequate, and percentage labeling is not necessary.

16. One comment stated that in addition to the comparative statements allowed to appear on the label of a butter product, the label for such a product should also include a clear statement of the identity and percentage of characterizing fat or oil, for example: "Reduced Fat Butter—40% Milkfat." It stated that such a prominent statement will allow consumers to easily and readily discern the nature of the food and, thus, facilitate comparisons with other table spreads, both dairy based and vegetable based.

The agency disagrees that the additional labeling is necessary. The provisions in § 101.56(b)(3) and § 101.62(b)(4)(ii) for use of the terms "light" and "reduced fat" require that the percent reduction in fat and the identity of the reference food be declared in immediate proximity to the most prominent claim and that quantitative information comparing the fat content in the product per serving size with that of the reference food be declared adjacent to the most prominent claim or on the information panel. Under § 101.9(a), nutrition information must be provided for all butter, margarine, and substitute products. The serving size for butter, margarine, and their substitutes is one tablespoon (§ 101.12(b)). The nutrition labeling must provide information on a food product's nutrition profile, including total fat, saturated fat, and cholesterol (§ 101.9(c)(12)). In addition, information on unsaturated fat may be included in the nutrition information. The only fat ingredient permitted in butter products is milkfat, and the ingredient statement will reflect this requirement. Consumers may use this information to compare the amount of fat in butter products and margarine products. Therefore, FDA concludes that there is adequate information to inform consumers concerning the fat content of a product already required to be present on the label without requiring the additional labeling requested by the comment. However, the agency will not object if manufacturers include additional labeling to state the percentage and type of fat in the product, provided that the information is not false or misleading.

17. One comment opposed the proposed rule on the grounds that people with food sensitivities will be placed at greater risk because of difficulties of knowing what is in a product.

Section 403(i) of the act requires that all ingredients used in a food be included in the ingredient statement. Consistent with the provisions of section 403(i) of the act, FDA is including a provision in § 101.67(c)(1) that each of the ingredients used in the food must be declared on the label, as required by part 101. This requirement will ensure that consumers that have food sensitivities are informed of the presence of ingredients to which they may have allergies.

III. Conclusion

In response to comments submitted regarding the proposal for use of nutrient content claims for butter (56 FR 60523), FDA has modified proposed § 101.67. The following summarizes the changes being made to proposed § 101.67 by this final rule:

FDA has modified § 101.67(a)(2) to provide for the use of safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness. FDA also has modified this paragraph to provide for the addition of water to replace milkfat, although the amount of water in the product must be less than the amount of cream, milk, or milk constituents.

FDA has added new § 101.67(a)(4) to require that if the product would violate section 201a of the act but for the nutrient content claim that characterizes the level of nutrients, that claim must be included as part of the common or usual name of the product.

FDA has added a statement to new § 101.67(b) to require that deviations from ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act.

The agency has modified § 101.67(b) by limiting the labeling requirement to changes that materially affect the use of the product.

FDA has revised § 101.67(b) to require that the mandated label statement concerning any differences in performance characteristics be in accordance with the requirements of § 101.13(d).

The agency has added a statement to new § 101.67(b) to require that the product must perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

In new § 101.67, paragraph (c) has been redesignated as paragraph (c)(1) and new paragraph (c)(2) has been added to require that water and safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness shall be identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" shall immediately follow the ingredient statement in the same type size.

IV. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the reproposed rule for mandatory nutrition labeling (56 FR 60366, November 27, 1991) and the proposed rule for nutrient claims (56 FR 60421, November 27, 1991), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rule suggested that there would be significant adverse environmental effects from the final rules unless the agency allowed more time between the publication of the final rules and their effective dates. The concern in these comments was that, if the agency did not allow firms more time between the publication of the final rules and their effective dates to use up existing label inventories, large stocks of labels and labeled packaging would have to be discarded. These comments questioned whether the agency had sufficiently examined the impact of disposing of

obsolete labels and labeled packaging on this country's solid waste disposal capabilities. Two comments estimated the amounts of labeling from their respective industries, i.e., dairy and confectionery, that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, these comments did not: (1) Provide details on how these estimates were derived, (2) identify what portion of the estimated amounts are attributable to these two actions, or (3) describe what impact the discarded labels and packaging would have on the disposal of solid waste. In its November 27, 1991, reproposed rule for mandatory nutrition labeling and proposed rule for nutrient content claims, the agency proposed that the final rules for these actions would become effective 6 months following their publication in the **Federal Register**.

However, the agency has decided to not make this rule effective until May 8, 1994. FDA believes there will thus be ample time for food companies to use up most of the existing labeling and packaging stocks and to incorporate labeling language that complies with FDA's regulations into their food labels. Consequently, the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.67 is added to subpart D to read as follows:

§ 101.67 Use of nutrient content claims for butter.

(a) Claims may be made to characterize the level of nutrients, including fat, in butter if:

(1) The claim complies with the requirements of § 101.13 and with the requirements of the regulations in this subpart that define the particular nutrient content claim that is used and how it is to be presented. In determining whether a claim is appropriate, the calculation of the percent fat reduction in milkfat shall be based on the 80 percent milkfat requirement provided by the statutory standard for butter (21 U.S.C. 321a);

(2) The product contains cream or milk, including milk constituents (including, but not limited to, whey, casein, modified whey, and salts of casein), or both, with or without added salt, with or without safe and suitable colorings, with or without nutrients added to comply with paragraph (a)(3) of this section, and with or without safe and suitable bacterial cultures. The product may contain safe and suitable ingredients to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, and add sweetness. The product may contain water to replace milkfat although the amount of water in the product shall be less than the amount of cream, milk, or milk constituents;

(3) The product is not nutritionally inferior, as defined in § 101.3(e)(4), to butter as produced under 21 U.S.C. 321a; and

(4) If the product would violate 21 U.S.C. 321a but for the nutrient content claim that characterizes the level of nutrients, that claim shall be an explicit claim that is included as part of the common or usual name of the product.

(b) Deviations from the ingredient provisions of 21 U.S.C. 321a must be the minimum necessary to achieve similar performance characteristics as butter as produced under 21 U.S.C. 321a, or the food will be deemed to be adulterated under section 402(b) of the act. The performance characteristics (e.g., physical properties, organoleptic characteristics, functional properties, shelf life) of the product shall be similar to butter as produced under 21 U.S.C. 321a. If there is a significant difference in performance characteristics (that materially limits the uses of the product compared to butter,) the label shall include a statement informing the consumer of such difference.(e.g., if appropriate, "not recommended for baking purposes"). Such statement shall comply with the requirements of § 101.13(d). The modified product shall perform at least one of the principal functions of butter substantially as well as butter as produced under 21 U.S.C. 321a.

(c)(1) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of this part.

(2) Safe and suitable ingredients added to improve texture, prevent syneresis, add flavor, extend shelf life, improve appearance, or add sweetness and water added to replace milkfat shall be identified with an asterisk in the ingredient statement. The statement "*Ingredients not in regular butter" shall immediately follow the ingredient statement in the same type size.

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Dated: October 20, 1992.
David A. Kessler,
Commissioner of Food and Drugs.
Louis W. Sullivan,
Secretary of Health and Human Services.
[FR Doc. 92-31507 Filed 12-28-92; 8:45 am]
BILLING CODE 4160-01-F

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[Docket No

RIN 0905-

State Enf
Nutrition
of 1990

AGENCY: F
HHS.

ACTION: Fi

SUMMARY:
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 100

[Docket No. 91N–0343]

RIN 0905–AD08

State Enforcement Provisions of The Nutrition Labeling and Education Act of 1990

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to implement section 4 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). This section provides for State enforcement of certain requirements of the Federal Food, Drug, and Cosmetic Act (the act), so long as the State gives FDA 30 days notice of its intent to act, and certain other conditions apply. The agency is adopting regulations that will provide the States with instructions on how to give the requisite 30-day notice. FDA has framed these instructions to ensure that this notification system functions efficiently. The final rule also describes relevant State and Federal obligations.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Janice F. Oliver, Center for Food Safety and Applied Nutrition (HFS–600), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4187.

SUPPLEMENTARY INFORMATION:

I. Background

In response to the requirements of the 1990 amendments (Pub. L. 101–535), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60534), a proposal to implement section 4 of those amendments. Section 4 amended section 307 of the act (21 U.S.C. 337) to provide for State enforcement of certain requirements of the act, so long as the State provides 30 days notice of its intent to act, and certain other conditions apply. The agency proposed to adopt regulations that would provide the States with instructions on how to give the requisite 30-day notice and to describe relevant State and Federal obligations. Interested persons were given until February 25, 1992, to comment.

FDA received approximately 24 responses to this proposal, each containing one or more comments, from trade associations, government organizations, individual States, food manufacturers, consumers, and consumer groups. The comments generally supported the proposal. Several comments addressed issues outside the scope of the proposal (e.g., delaying implementation of the regulations and delaying enforcement of the regulations) that will not be discussed here. A number of comments disagreed with various aspects of the proposal. These comments suggested modification and revision of various provisions of the proposal. A summary of these comments and the comments' suggested changes, along with the agency's responses, follows.

II. State Enforcement Provisions of the 1990 Amendments

A. Informal Enforcement Actions

In proposed § 100.2(j), FDA defined "informal enforcement actions," a term that is used in section 307(b)(2)(B) and (C) of the act, and defined in the agency's proposed implementing regulations, to include warning letters, recalls, and detentions as well as other administrative actions.

1. One comment suggested that FDA remove detentions as a type of informal enforcement action because FDA has no detention authority for foods.

The use of the word "detentions" in the proposal refers to detentions of imports under the provisions of section 801 of the act (21 U.S.C. 381) and detentions authorized under the provisions of the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA). The agency is authorized to detain imported food products if it appears that the products have been manufactured, processed, or packaged under insanitary conditions, or that the products are adulterated or misbranded, under the act. The agency also is authorized to detain meat, poultry, and egg products if they are found outside a plant inspected by the U.S. Department of Agriculture, and the agency has reason to believe that the products are adulterated or misbranded, under 21 U.S.C. 467f(b), 679(b), and 1052(d). Import detentions and detentions under the FMIA, PPIA, and EPIA are all administrative enforcement actions, and, therefore, informal actions under proposed § 100.2(i)(1). Consequently, the agency concludes that no change in the regulation in response to this comment is necessary.

2. Another comment suggested that FDA remove warning letters as a type of informal enforcement action. This comment stated that the agency often issues warning letters when no further action is planned by FDA, and that no response stating that corrections have been made is required from the recipient.

FDA disagrees with this comment. Warning letters are used by the agency to notify a firm that it is not in compliance with the act or with agency regulations, that failure to correct these violations may result in formal enforcement actions by FDA, and that a reply with a full statement of all corrections that have been or will be made is required within 10 days. A study of warning letters by FDA revealed that approximately 93 percent of the warning letters issued by FDA elicit a response from the recipient. Because of these facts, FDA continues to believe that it is appropriate to include warning letters as a type of informal enforcement action in the final rule. If the firm does not respond to the warning letter within the time provided in the warning letter, and the agency does not take any further action, the State will be free to act after 90 days under section 307(b)(2)(B) of the act.

3. Two comments suggested that adverse publicity be included as a type of informal enforcement action because FDA has the authority to issue publicity under section 705 of the act (21 U.S.C. 375). The agency acknowledges that it has the authority to issue publicity under section 705 of the act. The authority is conferred to the agency in situations involving imminent danger to health or gross deception of the consumer. However, the agency does not believe that it is necessary to specifically list publicity as a type of informal enforcement action in the final rule below. This type of action is included among the "other administrative enforcement actions" that are listed in proposed § 100.2(j)(1).

4. Several comments expressed concern that informal enforcement actions taken by FDA will preclude formal enforcement actions that could be taken by the State. One of these comments said there was no indication in the 1990 amendments that Congress intended the States to be preempted by anything other than formal action by FDA. Several comments wanted FDA to clarify that State and local enforcement mechanisms remain unaffected by the 1990 amendments.

Section 307(b)(2)(C) of the act states that no proceedings for the civil enforcement, or to restrain violations, of certain enumerated sections of the act may be commenced by a State if FDA has settled an informal or formal enforcement action against that food. Thus, contrary to what at least one

comment asserted, State action can be precluded by informal FDA action. Section 307 of the act, however, only applies to actions by a State to enforce certain sections of the act. Nothing in this section would preclude a State from taking action against a particular food under its own State law, even if FDA has commenced or settled an enforcement action against that food.

B. State Intervention in Criminal Proceedings

5. Several comments expressed concern that proposed § 100.2 would permit States to intervene as a matter of right in Federal criminal proceedings. The comments stated that no criminal authority was conferred upon the States by section 307(b)(1) of the act.

In response to these comments, FDA reconsidered whether to include criminal proceedings among the formal enforcement actions listed in proposed § 100.2(j)(2). While section 307(b) of the act is not clear on its face as to whether a pending criminal proceeding would, under section 307(b)(2)(B) or (C) of the act, preclude State action, there is nothing in the act to require the agency to hold that it would.

Therefore, FDA has decided to reverse the position that it tentatively took in the proposal. FDA is striking criminal actions from the list of formal enforcement actions in proposed § 100.2(j). FDA is revising this section to include only civil judicial enforcement action. As a result, § 100.2(j)(2) is coextensive with section 307(b)(1) of the act. A second result of this change will be that a pending Federal criminal action that arises out of a misbranding under the sections listed in section 307(b)(1) of the act will not serve to preclude a State from bringing a civil action under the act in Federal court against the underlying misbranding.

C. Agency Action Barring State Action Against Food in Federal Court

6. Several comments discussed the agency's statement that an agency action anywhere in the United States against the food in question would, under section 307(b)(2) of the act, bar a State action against the same food in Federal court. The majority of the comments agreed with this statement. One of the comments said that this preclusive effect should not be limited to FDA actions. This comment said that an action by a State to enforce the Federal law against a food within its jurisdiction precludes a second enforcement proceeding by another State or by FDA against the same food. The comment also said that if the States can enforce identical State regulations in the State courts, such actions should preclude an FDA action in the same State. Another comment, objecting to the agency's interpretation of the preemptive provisions of the 1990 amendments, argued that a State's action should be preempted only in cases where the FDA action will result in the discontinuation of the illegal practice in that State and in the nation. Finally, one comment requested that FDA revise proposed § 100.2 to provide that if the agency, upon notification by the State under section 307(b)(2) of the act, advises a State not to proceed, that State may not thereafter independently initiate enforcement proceedings based upon the same violations in State court under an identical State law.

The agency agrees in part with these comments. The enforcement actions available to the States under the provisions of section 307 of the act are seizure and injunction. The agency agrees that if FDA or a State brought a seizure action against a particular misbranding violation, the action would have a preclusive effect on another State or FDA. Section 304 of the act prohibits multiple seizures based on the same alleged misbranding of food. In light of the changes in section 307 of the act, who brings the first action, whether it is FDA or a State, would not be significant for the purposes of section 304 of the act. The first action filed would preclude any others.

In the case of an injunction, however, there is nothing in the act that limits the number of such actions that can be brought. Therefore, while an FDA injunction action would preclude State enforcement actions under the act for at least 90 days under section 307(b)(2), such action by a State would have no effect on FDA's or another State's ability to bring an action. However, the agency also notes that particularly in this time of limited government resources, it is highly unlikely that any jurisdiction would bring a duplicative injunction action.

The agency does not agree that a State action to enforce a State law that is identical to the act against food in its own jurisdiction precludes an FDA action based on the same violation. Section 307 of the act applies only to proceedings to enforce the act. State law cannot act to preempt Federal law or to preclude Federal action. Conversely, the act does not give FDA the authority to preclude a State from enforcing an identical State law. If FDA advises a State that the agency is commencing or has settled an enforcement action or proceeding, then the State is precluded from bringing an action under the act in Federal court. The act does not prohibit a State from enforcing an identical State law. Nonetheless, FDA intends to work with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with FDA's interpretation of the Federal provisions.

D. State Notification Letter

7. Several comments wanted States to provide FDA with evidence supporting the proposed action. The comments said that FDA should require the same evidence from a State that it requires from one of its district offices when reviewing proposed enforcement actions. These comments also wanted a State to inform FDA of the type of enforcement action that it expects to bring. On the other hand, one comment said that FDA was requiring too much information from States, and that the information that FDA is seeking may not be available at the beginning of an investigation. The comment stated that the 1990 amendments only require that a State give notice to FDA that it intends to bring an action, and that the detailed information being asked for by FDA would needlessly delay State enforcement action where an FDA action may not even be contemplated.

FDA stated in the preamble to the proposed regulation that it wanted the States to inform it of the type of action that they planned to take (56 FR 60534 at 60535). FDA included this provision as part of a parenthetical statement in the proposed format in § 100.2(d) (i.e., "name of products covered by the notification and the enforcement action that is to be initiated"). In view of the comments, and to eliminate any possible confusion, the agency is revising proposed § 100.2(d) to include in the format for the State's notification specific provision under item I., "Type of Enforcement Action," for the State to inform FDA of the type of action it is planning to take.

The agency disagrees with the suggestion that it require more specific information as part of the State notification, including a description of the evidence that the State is relying on to support its action. The agency considered the need for States to submit evidence to support the proposed action. However, the factors that FDA will consider in reviewing State notices of their intent to enforce certain sections of the act bear on different concerns than those that the agency considers in reviewing a recommendation from a district office.

When a district recommendation for an enforcement action is reviewed within the agency, there is a great deal

of concern about the merits of the case. A decision must be made as to whether to commit the agency's resources to prosecuting it. In reviewing a State notice of intent, FDA is not responding to the merits or strengths of the State's proposed action. The agency is only trying to determine whether FDA has taken, is taking, or, in the near future, is likely to take action. The States may proceed if FDA has not commenced or settled an action. It is up to the courts to decide the merits of the State's case. The information that the agency is asking a State to submit as part of its notification is the information that is necessary to ensure that the State and FDA are not duplicating efforts. Thus, FDA rejects the suggestion that it require the same information from a State as from its district offices.

The agency also disagrees with the request that the agency limit the information necessary in a notice. The comment suggested that the notice should be limited to only the names of the State and of the official giving notice, the name of the product involved, a copy of the label involved, when appropriate, and the alleged violation of the act. Although the 1990 amendments only require that the State give notice to the agency that it intends to bring an action, the information that the agency is asking the State to include in the notification letter is the information that is necessary if the agency is to provide a timely response to the State's notice.

The purpose of section 4 of the 1990 amendments is to provide a role for State enforcement of Federal statutory provisions that have preemptive effect. (See 136 Congressional Record H5840 (July 30, 1990)). However, such a role requires close coordination between State and Federal officials. The agency believes that it is requesting the minimum amount of information that is necessary to ensure that such close coordination exists. As mentioned above, the types of action that are available to the States for the enforcement of the act under the provisions of section 307 of the act are seizure and injunction. The agency would expect that a State would normally have the information requested in proposed § 100.2(d) before it could initiate these types of actions. Thus, the agency does not believe that compiling the information that it is requesting in proposed § 100.2 will delay State action.

However, the agency has reconsidered the provisions for the State notice in light of this comment and has determined that format items E and F are redundant. Moreover, the agency recognizes that there may be situations, such as in the case of a seizure of misbranded food, where the identity of the responsible firm cannot be readily determined. Thus, the agency is modifying the format for the notice by deleting item F and revising item E to read "Name and Address of firm believed to be responsible for violations."

E. Response to State Notification Letter

8. Several comments disagreed with proposed § 100.2(h) that provided that the Director of the Division of Regulatory Guidance in the Office of Compliance at the Center for Food Safety and Applied Nutrition, FDA, will respond to the State notification letter. The comments suggested that the agency follow its existing procedures for formal enforcement actions under which such actions are taken with the concurrence of the Director of the Office of Compliance and the Chief Counsel along with review by the Office of Enforcement.

The agency disagrees with these comments. These comments do not correctly characterize the action that occurs as a result of the submission of a State notification. FDA's response to such a letter simply informs the State of action that FDA has taken or is taking, and it is not an evaluation of the merits of the State's case. The Division of Regulatory Guidance is the central focus within FDA for all enforcement actions regarding food. Thus, the agency concludes that it is appropriate that this division be given authority to inform a State whether Federal action is being taken concerning a particular product or firm.

9. Several comments stated that the relationship between the State and FDA once the State notification letter is submitted is not well understood.

Once a State has notified the agency of its intent to bring an action, FDA believes that it is incumbent on the agency to inform the State whether it (FDA) has commenced an informal or formal action pertaining to the food in question within 30 days of the State notification. FDA has reflected this obligation in proposed § 100.2(h). If FDA advises a State that the agency has commenced an informal or formal action, under section 307(b)(2)(B) of the act, the State must wait a total of 90 days before it can commence an action. FDA will also advise the State if the agency has not commenced an informal or formal action, in which case the State may proceed with its proposed action. FDA must either have an informal or formal action pending or begin such an action within 30 days of the State's initial notice, for the State to be precluded from taking the enforcement action. FDA will maintain communication with the State regarding the resolution of enforcement actions.

10. One comment requested that FDA clarify that once a State has begun an enforcement action against a particular product, "no new notice is required to add defendants to the State action where these defendants are involved in the same scheme or where these defendants are acting or participating with other defendants to sell the same product."

The question raised by the comment is too general for the agency to provide specific clarification. The agency notes that it would generally agree that the simple addition of a corporate officer as a defendant or of an additional lot of a product in an action addressing a specific violation of the act would not require a new notice. However, the extension of an action to include new corporate entities or differing products would likely require a new notice. The agency believes that proposed § 100.2(a) is sufficiently clear on this point that there is no need to revise the regulations.

F. Public Disclosure

11. One comment requested that FDA publicly disclose information contained in State notification letters, excluding trade secrets and confidential information. Several comments wanted public disclosure of information contained in FDA's response to State notification letters.

The agency believes that proposed § 100.2(i), regarding exemption from public disclosure of information in State notification letters, is appropriate. Section 20.61 of FDA's regulations (21 CFR 20.61) provides that trade secret and confidential commercial information is not available for public disclosure. Section 20.64 of FDA's regulations (21 CFR 20.64) provides that an investigatory record for law enforcement purposes may be withheld by the agency from public disclosure if disclosure of the record would interfere with enforcement proceedings and disclose investigative techniques and procedures. The State notification letter is an investigatory record in that it relates to a potential regulatory enforcement action. Such an investigatory record is available for public disclosure as provided in § 20.64(c) and (d).

Section 20.88 (21 CFR 20.88) provides that investigatory records compiled for law enforcement officials who perform counterpart functions to FDA at the State and local level are exempt from

public disclosure pursuant to § 20.64. The agency's response to a State notification letter is not available for public disclosure as provided by §§ 20.64 and 20.88.

G. Preemption and Enforcement

12. Several comments expressed concern that a State could enforce a State law that is identical to a section of the act but have an interpretation of the law that is different from FDA's interpretation of the act.

FDA realizes that it is possible for State laws that are identical to Federal laws to be interpreted differently by the different States. As discussed above, the agency believes that close cooperation between FDA and the States will ensure that goals of uniformity are met while still addressing the concerns of the citizens of a State.

H. FDA's Authority to Interpret the Act

In the preamble to the proposed regulations the agency stated that to avoid any suggestion of an unconstitutional delegation to States to enforce the act, FDA retains full authority to advise States of what FDA believes is the proper interpretation of any of the sections of the act that they may seek to enforce. The agency stated that if FDA advises a State that its proposed action is inconsistent with FDA's interpretation, section 307 of the act requires that the State conform its interpretation to FDA's (56 FR 60534 at 60535 to 60536).

13. Several comments agreed, and one comment disagreed, with this agency statement. One comment wanted the final rule to add a new § 100.2(h)(3) that would require the agency to advise the States that the interpretation of the act that they seek to enforce is inconsistent with FDA's interpretation, that the labeling in question does not violate the act, and that they may not bring an enforcement proceeding. The comment that disagreed said that it is up to the courts to decide the ultimate meaning of the provisions of the act in disagreements between the States and FDA.

As stated above, FDA generally will not be issuing an interpretation to the State of the Federal requirements when it responds to a State notification letter. It will merely inform the State that the agency has commenced or settled an informal or formal enforcement action or is prosecuting or has settled a court proceeding, or has done none of these things. Therefore, the final rule does not need to include a section to require the agency to advise a State that its interpretation is inconsistent with FDA's. However, after consideration of the comments, the agency continues to believe that the position that it enunciated in the proposal is correct for the reasons that it presented (see 56 FR 60534 at 60535 to 60536). Therefore, FDA reserves the right to advise a State that its proposed action is inconsistent with FDA's interpretation of the act and will do so as circumstances warrant.

14. Several comments wanted the agency to ensure that a mechanism was available to provide the States with agency interpretations. These comments wanted FDA to impose time limits upon itself to issue interpretations.

Whenever a State would like an interpretation of the act, it may seek an advisory opinion under § 10.85 (21 CFR 10.85). FDA will respond to the request in a timely manner. The agency's Division of Federal-State Relations also will work closely with the States to ensure that FDA's interpretations of the act and the agency's regulations on food labeling are made available to the States. The State Training Branch of FDA's Office of Regulatory Affairs will conduct training classes for the States after implementation of the final regulations.

15. One comment recommended that the agency consider establishing an advisory panel of State and local officials to assist FDA in the development of interpretations.

FDA is charged by Congress to enforce requirements of the act. Therefore, FDA believes that as a general matter, it is its responsibility to interpret the act. However, the agency also recognizes the value of receiving input from State and local officials as well as others in the development of its interpretations. To this end the agency is establishing a Food Advisory Committee that will consider a broad range of questions concerning food (57 FR 8128, March 6, 1992). FDA will be including representatives from State and local governments on this committee. The agency notes that it utilizes a number of other approaches to ensure that it is aware of State and local government concerns, including participation in activities of the Association of Food and Drug Officials and regular contacts with the State through FDA's Division of Federal-State Relations. Thus, FDA does not believe that it is necessary to establish a separate standing advisory panel of State and local officials as a regular part of FDA's process of interpreting the act.

III. Conclusion

FDA is revising proposed § 100.2(d) in response to comments submitted regarding the proposal on the State enforcement provisions of the 1990 amendments (56 FR 60534). FDA has revised proposed § 100.2(d), regarding the State notification letter format, by modifying the format item E to read "E. Name and address of firm believed to be responsible for violations," deleting item F, renumbering items G, H, and I as F, G, and H, and including a new format item I to read "I. Type of enforcement action." FDA has also modified proposed § 100.2(j)(2) to read: "formal enforcement actions" include seizures, injunctions, or other civil judicial enforcement actions that pertain to the food in question." The agency has adopted the remainder of the provisions of § 100.2 as proposed with only minor editorial revisions because the agency did not receive any comments concerning them, or because, as discussed above, the comments that it did receive did not justify a change.

IV. Economic Impact

In its November 1991 proposal, FDA concluded that the proposed requirements did not constitute a major rule and that no significant impact on a substantial number of small entities, including small business, would derive from this action. FDA has not received any new information or comments on the proposal that would alter its previous determination.

V. Paperwork Reduction

Section 100.2 of this final rule contains notification requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0275.

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 100 is amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. Section 100.2 is added to subpart A to read as follows:

§ 100.2 State enforcement of Federal regulations.

(a) Under section 307 of the Federal Food, Drug, and Cosmetic Act (the act),

a State may bring, in its own name and within its own jurisdiction, proceedings for the civil enforcement, or to restrain violations, of sections 401, 403(b), 403(c), 403(d), 403(e), 403(f), 403(g), 403(h), 403(i), 403(k), 403(q), or 403(r) of the act if the food that is the subject of the proceedings is located in the State.

(b) No proceeding may be commenced by a State under paragraph (a) of this section:

(1) Before 30 days after the State has given notice to the Food and Drug Administration (FDA) that the State intends to bring such proceeding.

(2) Before 90 days after the State has given notice to FDA of such intent if FDA has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding.

(3) If FDA is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

(c) A State may intervene as a matter of right, in any court proceeding described in paragraph (b)(3) of this section.

(d) The notification that a State submits in accordance with paragraph (b) of this section should include the following information and be submitted in the following recommended format:

———————

(Date)
Name of State agency ————————
Post office address ————————
Street address ————————
City, State, and ZIP code ————————
Name of product(s) covered by the notification ————————
Reporting official, title, and telephone no. ————————
FAX No. ————————
Agency contact (if different from reporting official), title, and telephone no. ————————

Director,
Division of Regulatory Guidance (HFF–310),
Center for Food Safety and Applied Nutrition,
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204.

To Whom It May Concern:

The undersigned, ———, submits this letter of notification pursuant to section 307(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 337(b)(1)) with respect to ————. (name of products covered by the notification and the enforcement action that is to be initiated)

Attached hereto, and constituting a part of this letter of notification are the following:

A. The name of the product.

B. The type and size of each product container.

C. Copy of the label and labeling of the product.

D. Manufacturing code (if applicable).

E. Name and address of firm believed to be responsible for violations.

F. Name and address of parent firm (if known).

G. Reason for the anticipated State enforcement action (list specific violations, including sections of the law violated).

H. Name of firm against which action is anticipated (if applicable).

I. Type of enforcement action.

Yours very truly,
Reporting Agency
By ————————
(Indicate authority)

(e) The letter of notification should be signed by a State official authorized by the State to institute the contemplated enforcement actions.

(f) The letter of notification should be sent to the Division of Regulatory Guidance (HFF–310), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, FAX number 202–205–4642.

(g) FDA will notify the State of the date in which its letter of notification was received by FDA, Center for Food Safety and Applied Nutrition, Division of Regulatory Guidance (HFF–310) (within 2 working days after date of receipt). This date will be the date of notification for the purposes of paragraph (b) of this section.

(h) The Director, Division of Regulatory Guidance, Office of Compliance, Center for Food Safety and Applied Nutrition, FDA, will respond to the State's notification within 30 days of the date of notification by advising:

(1) Whether FDA has commenced an informal or formal enforcement action pertaining to the food that is the subject of the notification; or

(2) Whether FDA is prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled informal or formal enforcement action pertaining to such food.

(i) Information contained in State notification letters shall be exempt from public disclosure to the same extent to which such information would be so exempt pursuant to §§ 20.61, 20.64, and 20.88 of this chapter.

(j) *Definitions.* (1) "Informal enforcement actions" include warning letters, recalls, detentions, or other administrative enforcement actions that pertain to the food in question.

(2) "Formal enforcement actions" include seizures, injunctions, or other civil judicial enforcement actions that pertain to the food in question.

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB control number 0910–0275.)

Dated: October 20, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31508 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 100

[Docket No. 91N-0038]

RIN 0905-AD08

State Petitions Requesting Exemption from Federal Preemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to provide for petitions requesting exemption from preemption for State or local food standards and for certain other State or local labeling requirements that are preempted under the provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments). The regulations set out the procedures for the submission, and for agency review, of these petitions and the information that the petitioner should supply. Petitions by State and local governments seeking exemption from specified preemptive Federal requirements are specifically authorized by the 1990 amendments.

EFFECTIVE DATE: February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In response to requirements of the 1990 amendments (Pub. L. 101-535), FDA published in the **Federal Register** of November 27, 1991 (56 FR 60528), a proposal to provide for petitions requesting exemption from preemption for State or local food standards and for certain other State or local labeling requirements that are preempted under the provisions of the 1990 amendments. The proposed regulations set out the procedures for the submission, and for agency review, of these petitions and the information that the petitioner should supply. Interested persons were given until February 25, 1992, to comment.

FDA received over 50 letters, each containing one or more comments, from industry, trade associations, States, government organizations, consumer organizations, a Congressman, and a consumer. The comments generally supported the proposal. Several letters submitted in response to the proposal addressed issues outside the scope of the proposal and will not be discussed here. A number of comments disagreed with, and requested clarification of, various aspects of the 1990 amendments or the proposal. Some of these comments suggested modification and revision in various provisions of the proposal. A summary of the comments and the agency's responses follow.

II. General Comments

1. One comment asserted that individuals should have the right to petition for exemption. The comment stated that this would allow for a more universally equitable resolution of preemption issues.

Only States and political subdivisions of States have legal standing to petition for exemption. Section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343-1(b)) provides only that upon the petition of a State or a political subdivision of a State, the Secretary may exempt a State or local requirement from the effect of section 403A(a) of the act. Thus, Congress did not provide for petitions from other parties, and the agency has no authority to grant the comment's request.

2. Some comments wanted to know if State requirements were preempted when the products in question were strictly intrastate products.

The agency advises that under section 403A(a) of the act, State requirements are not subject to preemption to the extent that they apply to intrastate products.

III. What State Laws Are Covered

A. "Not Identical To"

3. One comment suggested that whether a State or political subdivision of a State needs to seek exemption from preemption for a law or regulation should be based on whether there are substantive differences between the State and the Federal requirements.

The agency does not accept the comment. While the results under the comment's suggested test might be the same as under the agency's proposal, FDA believes its proposal is more consistent with the statutory test. Under § 100.1(c)(4), if the State requirement is identical to the Federal law, it is not subject to preemption under section 403A(a) of the act. In addition, if the State requirement does the same thing that the Federal law does, even if the words are not the same, then it is effectively the same requirement as the Federal requirement. FDA's view, as embodied in § 100.1(c)(4), is that such a State or local requirement need not be preempted, and that there is consequently no need to exempt it from preemption. Therefore, the only State requirements that are subject to preemption are those that are affirmatively different on matters that are covered by section 403A(a) of the act.

A State will only petition for exemption of a requirement from preemption if the requirement is, or the State has a good reason to believe that it is, subject to preemption. The agency believes that the petition process that it is establishing provides States with an appropriate mechanism for requesting such an exemption from preemption. If a State can adequately demonstrate the need for the labeling requirement, that such requirement will not cause a food to be in violation of Federal law, and that it will not unduly burden interstate commerce, then FDA will propose to grant the exemption.

B. More Stringent State Requirements

4. Several comments expressed concern that stringent State laws may be preempted by less restrictive Federal regulations. These comments said that States should retain the authority to enforce strict State laws that serve the needs of its citizens. One of the comments was concerned that its regulation pertaining to open dating for perishable and semiperishable food products would be preempted, and it would be precluded from enforcing these open-dating provisions. Another comment said that producers who are able to successfully differentiate their products based on superior quality should not be prevented by Federal law from marketing that product under a State standard that rewards that quality.

FDA acknowledges that some stringent State laws will be preempted by less restrictive Federal regulations. However, one of the goals of the 1990 amendments is national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 States in a cost-effective manner (Statement of Rep. Madigan, 136 Congressional Record H12954, October 26, 1990). Thus, in enacting the 1990 amendments, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result. In regard to open dating, the agency notes that State laws and regulations will not be preempted because FDA does not have authority to establish such requirements under the

sections of the act that have been given preemptive effect. Therefore, a State will not be precluded from enforcing its open-dating provisions. With respect to the latter comment, the agency advises that producers who choose to market a superior quality product are not precluded by Federal preemption from doing so.

In response to inquiries from State officials and food producers concerned about the consequences of the preemption provisions, FDA has informed them that while the agency may act in the future to remove from its regulations any provisions that permit more stringent State requirements, those provisions remain in place for the moment and presumably have the force and effect of law. FDA does not intend to interfere with actions by States to enforce their standards based on existing regulations.

C. State Common or Usual Name Regulations

5. Several comments questioned whether a State common or usual name regulation was preempted if the regulation was promulgated in conformance with § 102.5 *General principles* (21 CFR 102.5), and it is a food for which FDA has not adopted a common or usual name as a standard.

Section 403(i)(1) of the act, which requires that the label of a food bear its common or usual name, if any, is one of six misbranding sections of the act identified in section 403A(a)(3) of the act that were the subject of a study mandated by section 6(b) of the 1990 amendments. The purpose of the study was to determine which of the six sections are adequately being implemented by FDA regulations and which are not. The agency contracted with the National Academy of Sciences, Institute of Medicine (IOM) to conduct the study.

On July 28, 1992 (57 FR 33283), as required by the 1990 amendments, the agency published its proposed lists of those sections that are adequately being implemented and those sections that are not. Based on the IOM's recommendations, the agency tentatively concluded that FDA regulations in part 102 (21 CFR part 102) adequately establish procedures for the development and application of common or usual names under section 403(i)(1) of the act.

The agency is publishing elsewhere in this issue of the **Federal Register** a final rule entitled, "Certain Misbranding Sections of the Federal Food, Drug, and Cosmetic Act That Are, and That Are Not, Adequately Being Implemented by Regulation Notice of Final Lists." Based upon FDA's evaluation of the recommendations of the IOM, its consideration of the comments on the proposed lists, and other available information, the agency provides in that final rule its finding that section 403(i)(1) of the act is being adequately implemented.

Section 6(b)(3)(B) of the 1990 amendments provides that "With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to such section." Thus, a State common or usual name regulation promulgated in conformance with § 102.5 for a food for which there is no specific Federal common or usual name regulation is preempted. However, the agency would consider an exemption for preemption based on the conditions that led the State to believe that there was a need for the State common or usual name regulation.

D. State Standards of Identity, Quality, or Fill Regulations

6. Several comments asked whether a State standard of identity, quality, or fill is preempted if it is for a food for which there are no Federal standards.

Under section 403A(a)(1) of the act, a State may not establish or continue in effect a standard of identity, quality, or fill for a food that is the subject of a standard of identity under section 401 of the act (21 U.S.C. 341) that is not identical to the Federal standard. If there is no Federal standard of identity, quality, or fill for a particular food, then there is no basis, under the terms of section 403A(a)(1) of the act, for finding that there is Federal preemption. By contrast, under section 403A(a)(2) through (a)(5) a State may not establish or continue in effect any requirement "of the type" set forth in the sections of the act specified in section 403A(a)(2) through (a)(5). Thus, State or local requirements can be preempted under section 403A(a)(2) through (a)(5) even if no analogous Federal regulation had been promulgated.

7. A comment noted that there was a typographical error in proposed § 100.1(c)(4) in that the word "quantity" should be "quality" instead.

The agency acknowledges the typographical error, and it has replaced the word "quantity" with the word "quality" in § 100.1(c)(4) set forth below.

E. State Laws Adopted from the U.S. Department of Commerce Handbook

8. Two comments asked if the weights and measures standards for food products adopted by States from U.S. Department of Commerce publications, contained in the National Institute of Standards and Technology (NIST) Handbook 130 1992 (Uniform Packaging and Labeling Regulation and the Uniform Regulation for the Method of Sale of Commodities) and the NIST Handbook 133 (Checking the Net Contents of Packaged Goods), would be preempted under the 1990 amendments. The comments said that the requirements of these publications do not appear to be different than those in § 101.105 *Declaration of net quantity of contents when exempt* (21 CFR 101.105) but do go into more detail. The comments asked if FDA would adopt these U.S. Department of Commerce publications as part of its regulations.

The agency advises that State requirements adopting U.S. Department of Commerce publications would not be subject to preemption if the State requirements can be considered to be identical to § 101.105. FDA's view, as reflected in § 100.1(c)(4), is that the fact that the State requirements contain more detail than found in the Federal regulation does not necessarily mean that the State requirements would be subject to preemption. Preemption would occur only if the detailed information included in the State requirements imposes different or stricter requirements than provided for in § 101.105.

To resolve any concerns that a State may have about a potential conflict between its requirement and a Federal requirement, a State may petition the agency for exemption from preemption for its requirement. If FDA concludes that the State requirement is identical to the Federal requirement, the agency will advise the State of that fact and deny the State's petition without prejudice. While the agency's opinion is not binding, it will, if a question of preemption with regard to that State requirement is raised in court, provide evidence that the State requirement, in FDA's view, is not preempted. If the court later decides otherwise, the State still has the option of petitioning FDA for an exemption from preemption.

FDA is not adopting the U.S. Department of Commerce publications as part of its regulations at this time. However, because the issues surrounding the harmonization of FDA's regulations and the U.S. Department of Commerce publications that have been adopted and enforced by States are both

important and complex, the agency would welcome a meeting with the National Conference on Weights and Measures, State officials, and other interested Federal agencies to decide what steps are necessary and appropriate to ensure that FDA's regulations and the relevant Department of Commerce publications are harmonized.

9. A comment asked whether all the States that had adopted regulations identical to those the Department of Commerce publications had to petition for exemption, or whether FDA could issue a blanket exemption for all of those States.

The agency advises that it will accept blanket exemption petitions that cover circumstances such as those represented by the example of the State regulations adopted in response to the U.S. Department of Commerce's publications. If, because of the detailed information from such publications that is included in the States' requirements, the States consider their regulations to be subject to preemption, one or more States should submit an exemption petition that meets the requirements set forth below in § 100.1. Among other things, the exemption petition would need to show the authority for the petitioner to act on behalf of the other States or political subdivisions of the States, identify the State requirements and the dates that they were enacted, and include a statement of the grounds upon which the petition is based. Depending upon the circumstances, the agency will consider granting an exemption from preemption for the requirements of each of the States or political subdivisions covered by the petition.

IV. State Petitions

A. General

10. Several comments objected to the statutory provision that allows a State to petition for an exemption from preemption by Federal food labeling regulations. These comments were of the view that all State laws regarding food labeling should be preempted by Federal food labeling regulations, and that States should not be allowed to petition for an exemption. On the other hand, another comment said that State laws regarding food labeling should not be preempted by Federal regulation, and thus there is no need for a process to petition for an exemption.

Section 403A(b) of the act specifically allows a State, or a political subdivision of a State, to petition the Secretary for an exemption from preemption. It states that the Secretary may, upon being petitioned by a State, or political subdivision of a State, exempt any State or local requirement that: (1) Would not cause any food to be in violation of any applicable requirement under Federal law, (2) would not unduly burden interstate commerce, and (3) is designed to address a need for information that is not met by the misbranding sections of the act referred to in section 403A(a) of the act. Given this provision, the agency has concluded that the procedures that it is establishing for the submission and consideration of petitions for exemption from preemption are necessary to effectuate the law. Therefore, the agency rejects the comments on this point.

B. Use of Medical Device Amendments as a Model

11. One comment suggested that FDA model its regulations on State petitions for exemption from preemption under the 1990 amendments after FDA's medical device regulations for such exemptions (21 CFR 808.20, 808.25, and 808.35) rather than after the Consumer Product Safety Commission (CPSC) regulations. The comment asserted that the medical device regulations are better suited as a model because they are more comprehensive than the CPSC regulations. The comment noted that the medical device regulations require States to provide more information in the petition than they would be required to provide under proposed § 100.1 and provide interested persons with an opportunity to have an oral hearing on whether a petition should be granted.

The agency does not believe that the medical device regulations on exemption petitions are an appropriate model for implementing the 1990 amendments. The statutory provisions under which the medical device regulations were promulgated are different from the 1990 amendments in a fundamental respect. The medical device statutory provisions require a hearing. The 1990 amendments do not. Consequently, the agency chose to model its regulations after the CPSC regulations rather than the medical device regulations because the CPSC regulations provided a mechanism in which no hearing is required.

Moreover, the agency believes that the information proposed by FDA for submission by a State in its exemption petition is appropriate because it responds directly to the criteria established by section 403A(b) of the act. Accordingly, FDA is not making the suggested changes.

12. Several comments requested that FDA provide for the periodic review of granted exemptions and for the revocation of an exemption if the conditions that were present when the exemption was granted no longer exist. One comment noted that the medical device procedures provide for such revocation of previously granted exemption petitions.

The agency understands the concerns expressed by these comments and is open to citizen petitions to revoke an exemption if such revocation is warranted. However, the agency does not have the resources to commit itself to periodic reviews of exemptions granted to States. If an interested person becomes aware of a change in the conditions that led FDA to grant an exemption, that person can submit a citizen petition under § 10.30 *Citizen petition* (21 CFR 10.30) requesting revocation of that exemption. The agency will review any such petition that is submitted. If the petition shows that the conditions that justified an exemption no longer exist, the agency will consider revoking that exemption.

C. What the Petition Must Show About Effect on Interstate Commerce

13. Several comments suggested that FDA should balance a State or locality's particular need against the burden on interstate commerce in determining whether an exemption petition should be granted.

The agency does not believe that the test for whether a State requirement does, in fact, "unduly burden" interstate commerce is one of balancing burden versus need. The statute anticipates that a State or locality's need for a particular labeling requirement will be assessed separately under section 403A(b)(3). In case law interpreting "undue burden," the court equated the term with unfairness. (See *Mid-South Bottling Co. v. NLRB*, 876 F.2d 458, 461 (5th Cir. 1989)). Applying this unfairness standard, one could argue, for example, that if a State requirement can be readily accommodated (e.g., a stick-on label) or is not applied to out-of-state firms, it does not unduly burden interstate commerce. On the other hand, if the State requirement required a completely different label than would be appropriate everywhere else in the country, a strong argument could be made that it does unduly burden interstate commerce. Accordingly, the agency is not including the suggested balancing test as a criterion for determining whether a State's petition for exemption from preemption should be granted.

14. Several comments objected to the amount of information required in a State petition on the effect that granting it will have on interstate commerce. These comments were particularly

opposed to the agency's position that States should obtain information in the form of statements from producers of food products indicating that it is practical and feasible for them to comply with the State requirement.

The congressional intent in enacting the 1990 amendments was to provide national uniformity and to allow industry to conduct business in an efficient and cost-effective manner (136 Congressional Record H12954, October 26, 1990). Accordingly, the State has the burden to show why an exemption is appropriate, and why such an exemption, if granted, would not unduly burden interstate commerce.

To meet this burden, a State will need to contact industry to determine the effect of its regulations upon interstate commerce. Although a company may say that the burden is significant, the State would have the opportunity to show as part of its petition that the company's view is overstated and, therefore, does not provide a basis for denying the petition. Accordingly, the agency is retaining this requirement in the final rule.

15. Some comments requested that FDA require States to include more information in their petitions to show not only the costs of distributing products labeled differently for different States but also the cost of changing labels if an exemption petition is granted.

The agency proposed in § 100.1(d)(2) (Part C, Statement of Grounds) to only provide States with guidance as to what a petition for exemption from preemption should contain. The agency continues to believe, and it was not persuaded by the comments to conclude otherwise, that it is not appropriate to establish requirements on the contents of a State petition for an exemption from preemption. Therefore, FDA rejects the comments on this point. However, the agency does agree that the costs of changing labels and of using different labels in different localities bear on the issue of burden on interstate commerce and, therefore, should be included in the State's petition as part of the cost of compliance.

16. Some comments suggested that, with respect to possible burdens on interstate commerce, FDA should give more specific guidance about what it intends to consider in deciding whether to grant an exemption from preemption for a State or local requirement. One comment stated that the factors depicted in proposed § 100.1(d)(2) (i.e., economic feasibility, comparison of costs of compliance, effects on the availability of a food to consumers, and the practicality of industry compliance) do not accurately or fully summarize the constitutional considerations employed by Federal courts. The latter comment suggested that a State must be able to show: (1) The important public interests its regulation supposedly furthers, (2) that the regulation treats in-state and out-of-state manufacturers or advertisers evenhandedly, (3) the degree of burden imposed by the regulation, (4) that the burden is not clearly excessive in relation to any putative local benefits, (5) that the regulation does not project the State's standards into other States, and (6) that the regulation does not unduly impede the free flow of interstate commerce.

The agency believes that the guidance that it has provided in § 100.1(d)(2) (Part C, Statement of Grounds) as to the information necessary to support an exemption petition fully reflects the considerations that the Federal courts have applied in determining whether there is an undue burden on interstate commerce. The agency, however, with the exception of item (2) above, does not object to a State addressing the listed items in an exemption petition. With respect to item (2), the agency notes that it does not have jurisdiction over products manufactured and distributed in intrastate commerce, nor does it have jurisdiction over advertising, which is regulated by the Federal Trade Commission. Therefore, FDA considers this item to be of marginal relevance to the determination that the agency must make.

D. Particular Need for Information

17. Several comments argued that FDA has misinterpreted the portion of the 1990 amendments requiring a State to show a "particular need for information" to mean that a State or locality must show that a labeling requirement fulfills a unique local need in order to exempt a requirement from preemption. The comments stated that a petition for exemption from preemption should not be denied simply because the need for information is also national in scope.

While the agency agrees with the comments' interpretation of the statute, an agency decision to grant an exemption from preemption is likely to be based largely on the agency's evaluation of the situation within the requesting State. If the need for an exemption is not only local, the agency is likely to consider whether it would not in fact be more appropriate to amend the relevant Federal regulation rather than grant an exemption. Therefore, while the agency is open and willing to consider any need for exemption asserted in a State petition, it seems prudent for such a petition to address the question of why the agency should limit its consideration to the exemption and not address the broader concern.

18. One comment suggested that FDA include a provision in the final rule that requires that petitions for exemption that are based on a claim that a particular Federal requirement fails to meet the petitioning State's particular local need be accompanied by a citizen's petition under § 10.30 to amend the Federal requirement. The comment said that the agency should defer consideration of the exemption petition until it has ruled on the citizen's petition.

The agency does not believe that such a requirement is appropriate or necessary. It would be an unnecessary burden on States to require that they submit all the information necessary for a citizen petition to amend FDA's regulations. The agency, however, has no objection to other interested persons submitting a citizen petition under § 10.30 for an amendment to a Federal regulation. Although the agency cannot commit itself to acting on such citizen petition first, it will review it as appropriate and in an expeditious manner.

19. Several comments suggested that States should be required to identify alternatives that might be used to meet the need for information without negating Federal preemption and to explain why those alternatives could not be reasonably implemented within the State. These comments argued that this requirement would satisfy the State's burden to prove that uniformity should be compromised. Not every perceived shortcoming in Federal requirements, the comment stated, must be remedied by different labeling requirements.

The 1990 amendments provide only that a State show that its requirement would not cause any food to be in violation of Federal law, would not unduly burden interstate commerce, and is designed to meet a particular need for information that is not met by the Federal requirements. There is no provision in the 1990 amendments that requires that the States identify and consider a number of alternatives beyond that for which it is seeking exemption from preemption. Accordingly, FDA is not including the suggested provision in the final rule.

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V. Procedural Provisions

A. When to File—Submission of Petition Before a State Rule is Finalized

20. Several comments disagreed with the proposed requirement in § 100.1(c)(1) that States submit an exemption petition only after the State requirement has been enacted or issued as a final rule by an authorized State official and is in effect or would be in effect but for the provisions of section 403A of the act. The comments suggested that States be allowed to petition for exemption at any time once a State rulemaking proceeding starts, or when the State believes that the rule will become final. The comments said that it would be too burdensome to promulgate a State regulation only to have it preempted by the Federal regulation. The comments also requested guidance from FDA about preemption and its effects on current and possible future State laws.

Acceptance of a State petition for exemption from preemption for a State law or regulation that has not been enacted or promulgated could result in a waste of FDA resources if the State subsequently decides not to enact the law or not to adopt the regulation. FDA is willing to communicate and work with States when questions about preemption arise. However, the agency does not believe that it is prudent to accept exemption petitions for laws or regulations that are not yet enacted. Because preemption can only occur if there is a State law or regulation in effect, the agency will not grant an exemption to a proposed State law or regulation.

The agency, however, advises that a State should be aware of the possible preemption problems at the time it considers whether to adopt the law or regulation. Realizing that the primary purpose of preemption is uniformity of State laws, the State will need to find that there are particular needs that compel it to adopt the law or regulation if it is to do so in the face of the likelihood of preemption. Those are exactly the needs that ought to be brought to the agency's attention as part of the exemption from preemption process.

B. Filing State Exemption Petitions

21. Several comments recommended that proposed § 100.1(c) be revised in the final rule to set "threshold requirements for the acceptance of petitions for suitability for filing of State petitions." The comments noted that the proposed prerequisites would establish only that there is a State requirement, that the State and Federal requirements are not identical, and that the petitioner is an appropriate State official. These comments suggested that FDA not accept for filing in the first instance any exemption petition unless it contains a prima facie showing that the statutory prerequisites are met; i.e., that the proposed exemption will not result in a violation of any Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement (section 403A(b) of the act). One comment viewed a demonstration of threshold compliance with the statutory prerequisites as critical in light of the fact that under section 10(b)(2) of the 1990 amendments, a petition submitted by May 8, 1992, has the effect of staying Federal preemption until FDA takes action on the petition. The comment was concerned that because the State petitioning regulation itself is not proposed to become effective until November 8, 1992, FDA action on State petitions submitted before May 8, 1992, will be deferred for a very long time. Consequently, the comment argued that without a meaningful petition threshold regulation, even a State petition unapprovable on its face would stay Federal preemption for that time.

The agency believes that the threshold requirements it proposed in § 100.1(c) are more than adequate for determining whether a petition for exemption from preemption should be accepted for filing. The requested prima facie showing that the exemption petition has met the statutory prerequisites goes to the merits of the petition, and whether it should be granted or denied, not to whether it is suitable for filing. Given this fact, along with the complexities of the factors to be considered in determining whether the statutory prerequisites have been met by the petitioner, and the amount of time (90 days) in which the agency is expected to make a final decision on the merits of each exemption petition, FDA is not amending § 100.1(c) to grant the comments' request.

The agency notes that the suggested inclusion of additional threshold requirements for the acceptance of exemption petitions will not address the concerns expressed by the comments. The comments address the provision of section 10(b)(2) of the 1990 amendments that exempts a State requirement described in section 403A(a)(3) through (a)(5) of the act from preemption for a limited period of time if the State submits a petition under section 403A(b) of the act by May 8, 1992. Because the time limit of May 8, 1992, for submitting exemption petitions that would temporarily except State requirements from preemption has passed, any value in establishing threshold requirements for petitions submitted by that date is moot. Moreover, the agency does not believe that it can retroactively establish threshold requirements that would exclude certain or all State petitions from the exemption provisions of section 10(b)(2) of the 1990 amendments.

22. Several comments recommended that § 100.1(f)(4) and (f)(5) be revised to provide for public notification in the **Federal Register** of the filing of State exemption petitions. One comment suggested that a notice of filing of an exemption petition be sent to the petitioner. Some comments also recommended that FDA provide for a comment period between the filing of an exemption petition and the agency's response. Other comments wanted the submission of an exemption petition and the agency's responses to be made public. These comments expressed concern that without public notification, an interested person may not know that his or her interests require the filing of comments. Some comments suggested that FDA also should establish a specific time between the receipt and the filing of an exemption petition so that interested persons may provide meaningful comment.

The agency does not believe public notification in the **Federal Register** of the submission or filing of exemption petitions is necessary. Nor does the agency find it necessary to establish a comment period for either submitted or filed petitions. The procedures for the handling of petitions for exemption from preemption are generally consistent with those in § 10.30 for citizen petitions. Section 100.1(e) provides that once an exemption petition is accepted for filing, it will be made available for public examination and copying at the Dockets Management Branch under the rules provided for in § 10.20(j) (21 CFR 10.20(j)). In addition, § 100.1(f)(3) provides that the petitioner will be notified in writing of the filing and docket number of the petition. Section 100.1(f)(4) allows any interested person to submit written comments to the Dockets Management Branch on a filed petition, as provided in § 10.30(d). If the agency tentatively decides that an exemption petition has merit, it will publish in the **Federal Register** a proposal to grant the exemption, and interested persons will have an opportunity to comment on the proposal at that time.

The agency recognizes that not providing for a public notice of the filing or submission of an exemption petition in the procedures that it is establishing may limit the ability of a person who might consider the petition significant to comment on the petition before the agency makes a decision to propose to grant the exemption or to deny the petition. The agency has concluded, however, that there is no prejudice from this fact because the petition will be available at the Dockets Management Branch, comments can be submitted on the petition, and the agency will not grant the petition until after there has been rulemaking on whether such action is appropriate. Interested persons will thus have ample opportunity to comment on the petition.

23. One comment requested that FDA establish a comment period for accepting comments to a proposal to grant an exemption.

The agency points out that all FDA published proposals are subject to the requirements of § 10.40 *Promulgation of regulations for efficient enforcement of the law* (21 CFR 10.40). Section 10.40(b)(2) provides that the proposal will provide 60 days for comment, although the Commissioner of Food and Drugs may shorten the comment period (to not less than 10 days) or lengthen this time period for good cause.

24. One comment said that FDA should make a decision on the exemption petition in 90 days and not just issue a response that it has not made a decision.

The agency advises that it intends to make every effort to make its decisions on exemption petitions within the 90-day period. However, there are circumstances that arise, such as other agency priorities and a need for additional information, that may not permit the agency to respond within 90 days. Accordingly, the agency has concluded that a provision for a tentative response, similar to that which is permitted in § 10.30(e)(2)(iii), is both appropriate and warranted.

25. Some comments wanted FDA to publish a list of all petitions filed before May 8, 1992, and to act promptly on these petitions.

Five petitions from States requesting exemption from preemption were submitted to the agency by May 8, 1992. As announced in the **Federal Register** of March 14, 1991 (56 FR 10906), the agency has deferred action on these petitions and has not reviewed them to any extent at this time. These petitions are: State of California petitions on milk, dated January 7, 1991 (Docket No. 91P–0009); slack fill, dated May 6, 1992 (Docket No. 92P–0361); bottled water, dated May 8, 1992 (Docket No. 92P–0216); State of Michigan petition on nonalcoholic beverages, dated March 15, 1991 (Docket No. 92P–0360); State of Vermont petition on maple syrup, dated July 30, 1991 (Docket No. 92P–0359); and a joint petition by 44 states, territories or jurisdictions on net content, dated November 9, 1992 (Docket No. 92P–0441). The agency fully intends to respond to these petitions in the very near future.

26. One comment from a foreign country requested that FDA notify it of any State exemption petitions that could affect trade. The comment expressed concern that any exemptions not violate the General Agreement on Tariffs and Trade or the Free Trade Agreement with Canada.

The agency advises that if it should tentatively decide that an exemption petition has merit, it will publish a proposal in the **Federal Register** to grant the exemption through rulemaking. Any foreign government concerned about trade implications would have an opportunity to comment on such a proposal at that time. The agency believes that publication of proposals to grant an exemption in the **Federal Register** will provide adequate notice to foreign governments of State petitions for exemption from preemption.

C. Exemption Granted through Notice and Comment Rulemaking

27. Several comments were opposed to granting exemptions through rulemaking. The comments said there is nothing in the language of the 1990 amendments indicating the necessity for issuing exemptions in the form of regulations.

The agency considered these comments but finds no basis to change its tentative conclusion that granting of exemptions through notice and comment rulemaking is the best procedure to follow. The agency believes that rulemaking is appropriate because section 403A(b) provides that FDA is to grant the exemption by regulation, and because the granting of an exemption from preemption will have the force and effect of law. In addition, rulemaking will ensure that all interested persons have an opportunity to comment, and that all opinions are expressed. Accordingly, FDA is retaining § 100.1(f)(5)(i), as proposed, but is adding the phrase "under such conditions as it [FDA] may prescribe by regulation" to the last sentence of § 100.1(a)(2) to reflect the language of section 403A(b).

After considering the comments that FDA received on the proposal, FDA is adding a new subpart A, consisting of § 100.1.

VI. Paperwork Reduction Act

Section 100.1(d) of this final rule contains information collection requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3504(h) of the Paperwork Reduction Act of 1980. The requirements were approved and assigned OMB control number 0910–0277.

VII. Economic Impact

In its November 1991 proposal, FDA concluded that the proposed requirements did not constitute a major rule and that no significant impact on a substantial number of small entities, including small businesses, would derive from this action. FDA has not received any new information or comments on the proposal that would alter its previous determination.

VIII. Environmental Impact

The agency previously determined under 21 CFR 25.24(a)(8), as announced in the proposed rule and published in the **Federal Register** of November 27, 1991 (56 FR 60528), that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental assessment or an environmental impact statement is not required.

List of Subjects in 21 CFR Part 100

Administrative practice and procedure, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 100 is amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 is revised to read as follows:

Authority: Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. A new subpart A consisting of § 100.1 is added to read as follows:

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Subpart A—State and Local Requirements

§ 100.1 Petitions requesting exemption from preemption for State or local requirements.

(a) *Scope and purpose.* (1) This subpart applies to the submission and consideration of petitions under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the act), by a State or a political subdivision of a State, requesting exemption of a State requirement from preemption under section 403A(a) of the act.

(2) Section 403A(b) of the act provides that where a State requirement has been preempted under section 403A(a) of the act, the State may petition the agency for an exemption. The agency may grant the exemption, under such conditions as it may prescribe by regulation, if the agency finds that the State requirement will not cause any food to be in violation of any applicable requirement under Federal law, will not unduly burden interstate commerce, and is designed to address a particular need for information that is not met by the preemptive Federal requirement.

(b) *Definitions.* (1) *Act* means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

(2) *Agency* means the Food and Drug Administration.

(3) *Commissioner* means the Commissioner of Food and Drugs.

(4) *State* means a State as defined in section 201(a)(1) of the act (which includes a territory of the United States, the District of Columbia, and Puerto Rico) or any political subdivision of a State having authority to issue food standards and food labeling regulations having force of law.

(5) *State requirement* means any statute, standard, regulation, or other requirement that is issued by a State.

(c) *Prerequisites for petitions for exemption from preemption.* The Food and Drug Administration will consider a petition for exemption from preemption on its merits only if the petition demonstrates that:

(1) The State requirement was enacted or was issued as a final rule by an authorized official of the State and is in effect or would be in effect but for the provisions of section 403A of the act.

(2) The State requirement is subject to preemption under section 403A(a) of the act because of a statutory provision listed in that section or because of a Federal standard or other Federal regulation that is in effect, or that has been published as a final rule with a designated effective date, and that was issued under the authority of a statutory provision listed in that section. For the purposes of this subpart, all petitions seeking exemption from preemption under section 403A(a)(3) through (a)(5) of the act submitted before May 8, 1992, will be considered timely even though the applicable statutory provisions or regulations are not yet in effect.

(3) The petitioner is an official of a State having authority to act for, or on behalf of, the Government in applying for an exemption of State requirements from preemption.

(4) The State requirement is subject to preemption under section 403A(a) of the act because it is not identical to the requirement of the preemptive Federal statutory provision or regulation including a standard of identity, quality, and fill. "Not identical to" does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that:

(i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act; or

(ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act.

(d) *Form of petition.* (1) All information included in the petition should meet the general requirements of § 10.20(c) of this chapter.

(2) An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.)

(3) Petitions for exemption from preemption for a State requirement shall be submitted to the Dockets Management Branch in the following form:

(Date) _____

Dockets Management Branch,
Food and Drug Administration,
Department of Health and Human Services,
rm. 1–23, 12420 Parklawn Dr.,
Rockville, MD 20857.

Petition Requesting Exemption from Preemption for State Requirement

The undersigned submits this petition under section 403A(b)of the Federal Food, Drug, and Cosmetic Act to request that the Food and Drug Administration exempt a State requirement from preemption.

The undersigned has authority to act for, or on behalf of, the (*identify State or political subdivision of the State*) because (*document petitioner's authority to submit petition on behalf of the State*).

A. Action Requested

1. Identify and give the exact wording of the State requirement and give date it was enacted or issued in final form.

2. Identify the specific standard or regulation that is believed to preempt the State requirement and the section and paragraph of the act that the standard or regulation implements.

B. Documentation of State Requirement

Provide a copy of the State requirement that is the subject of the application. Where available, the application should also include copies of any legislative history or background materials used in issuing the requirement, including hearing reports or studies concerning the development or consideration of the requirement.

C. Statement of Grounds

A petition for an exemption from preemption should contain the following:

1. An explanation of the State requirement and its rationale, and a comparison of State and Federal requirements to show differences.

2. An explanation of why compliance with the State requirement would not cause a food to be in violation of any applicable requirement under Federal law.

3. Information on the effect that granting the State petition will have on interstate commerce. The petition should contain information on economic feasibility, i.e., whether the State and Federal requirements have significantly different effects on the production and distribution of the food product; comparison of the costs of compliance as shown by data or information on the actual or anticipated effect of the State and Federal requirements on the sale and price of the food product in interstate commerce; and the effect of the State requirement on the availability of the food product to consumers. To the extent possible, the petition should include information showing that it is practical and feasible for producers of food products to comply with the State requirement. Such information may be submitted in the form of statements from affected persons indicating their ability to comply.

4. Identification of a particular need for information that the State requirement is designed to meet, which need is not met by Federal law. The petition should describe the conditions that require the State to petition for an exemption, the information need that the State requirement fulfills, the inadequacy of the Federal requirement in addressing this need, and the geographical area or political subdivision in which such need exists.

D. Environmental Impact

The petition shall contain a claim for categorical exclusion under 21 CFR 25.24 or an environmental assessment under 21 CFR 25.31.

E. Notification

Provide name and address of person, branch, department, or other instrumentality of the State government that should be notified of the Commissioner's action concerning the petition.

F. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies.

(Signature) _____

(Name of petitioner) _____

(Mailing address) _____

(Telephone number) _____

(Information collection requirements in this section were approved by the Office of Management and Budget (OMB) and assigned OMB number 0910–0277)

(e) *Submission of petition for exemption; public disclosure.* The availability for public disclosure of a petition for exemption will be governed by the rules specified in § 10.20(j) of this chapter.

(f) *Agency consideration of petitions.* (1) Unless otherwise specified in this section, all relevant provisions and requirements of subpart B of part 10 of this chapter, are applicable to State petitions requesting exemption from Federal preemption under section 403A(b) of the act.

(2) If a petition does not meet the prerequisite requirements of paragraph (c) of this section, the agency will issue a letter to the petitioner denying the petition and stating in what respect the petition does not meet these requirements.

(3) If a petition appears to meet the prerequisite requirements in paragraph (c) of this section, it will be filed by the Dockets Management Branch, stamped with the date of filing, and assigned a docket number. The docket number identifies the file established by the Dockets Management Branch for all submissions relating to the petition, as provided in this part. Subsequent submissions relating to the matter must refer to the docket number and will be filed in the docket file. The Dockets Management Branch will promptly notify the petitioner in writing of the filing and docket number of a petition.

(4) Any interested person may submit written comments to the Dockets Management Branch on a filed petition as provided in § 10.30(d) of this chapter.

(5) Within 90 days of the date of filing the agency will furnish a response to the petitioner. The response will either:

(i) State that the agency has tentatively determined that the petition merits the granting of an exemption, and that it intends to publish in the **Federal Register** a proposal to grant the exemption through rulemaking;

(ii) Deny the petition and state the reasons for such denial; or

(iii) Provide a tentative response indicating why the agency has been unable to reach a decision on the petition, e.g., because of other agency priorities or a need for additional information.

(g) If a State submitted a petition for exemption of a State requirement from preemption under section 403A(a)(3) through (a)(5) of the act before May 8, 1992, that State requirement will not be subject to preemption until:

(1) November 8, 1992; or

(2) Action on the petition, whichever occurs later.

Dated: October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31509 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 91N-0134]

Certain Misbranding Sections of the Federal Food, Drug, and Cosmetic Act That Are, and That Are Not, Adequately Being Implemented by Regulation; Notice of Final Lists

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing, in accordance with the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), final lists delineating which of six sections of the Federal Food, Drug, and Cosmetic Act (the act) that define circumstances in which a food is misbranded are adequately being implemented by FDA regulations and which are not. These six sections are: Sections 403(b) (offered for sale under the name of another food), 403(d) (misleading container), 403(f) (information of appropriate prominence), 403(h) (compliance with standard of quality and fill), 403(i)(1) (common or usual name), and 403(k) of the act (declaration that the product contains artificial flavoring, coloring, or preservatives) (21 U.S.C. 343(b), 343(d), 343(f), 343(h), 343(i)(1), and 343(k)).

Based upon its evaluation of the recommendations of the National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (hereinafter referred to as IOM), its consideration of the comments on the proposed lists, and other available information, the agency finds that all but section 403(d) of the act are adequately being implemented.

EFFECTIVE DATE: The final lists of sections of the act that are, and that are not, being adequately implemented become effective on February 5, 1993.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Center for Food Safety and Applied Nutrition (HFS-151), Food and Drug Administration, 200 C. St. SW., Washington, DC 20204, 202-205-5162.

SUPPLEMENTARY INFORMATION:

I. Background

In response to section 6(b) of the 1990 amendments (Pub. L. 101-535), FDA published in the **Federal Register** of July 28, 1992 (57 FR 33283), proposed lists that identified which of six sections of the act (sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k)) that define circumstances in which a food is misbranded are adequately being implemented by FDA regulations and which are not adequately being implemented. The agency tentatively concluded that sections 403(b), 403(f), 403(h), 403(i)(1), and 403(k) of the act are adequately being implemented, and that section 403(d) is not adequately being implemented. FDA's tentative conclusions were based on the recommendations of IOM, with whom FDA had contracted, in accordance with section 6(b) of the 1990 amendments, to study:

(A) State and local laws that require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act, and

(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

Interested persons were given until September 28, 1992, to comment. FDA received six letters, each containing one or more comments, from two trade organizations, a food manufacturer, a professional organization, and a consumer organization. A summary of the issues raised by the comments and the agency's responses follow.

II. Response to Comments

A. Adequate Implementation

1. One comment objected to the criteria used by IOM to determine whether a particular section is adequately being implemented. Specifically, the comment interpreted the legislative history to provide that "adequate implementation" means full implementation of the six misbranding sections and thus requires Federal adoption of the strongest legal standards that effectively accomplish the goals of the provisions under study. The comment stated that:

> IOM's conclusions are contrary to the NLEA because the legislative history indicates that Congress intended to avoid preempting state and local governments unless the FDCA has been fully implemented, and no additional federal regulation is necessary.

The agency disagrees with this comment. The agency can find no support in the legislative history or in the 1990 amendments for a conclusion that the intent of the procedures established by section 6(b) was to identify the strongest regulations relevant to each of the six sections listed in section 403A(a)(3) of the act and to have FDA adopt those regulations.

In discussing the preemption provisions of the 1990 amendments, Congressman Waxman identified two principles that should be considered in preempting State laws. First, State laws should not be preempted unless the nature of the laws at issue makes it difficult and even impossible for companies to operate in interstate commerce. Secondly, the States should never be preempted unless a strong Federal regulatory system is in place (136 Congressional Record H5840 (July 30, 1990)). Mr. Waxman noted that the requirements for nutrition labeling and for health claims that were in the bill that had been reported out of the House Committee on Energy and Commerce (and that became the 1990 amendments) created such a strong regulatory system (id.). Implicitly, Congress also recognized the strength and adequacy of FDA's implementation of sections 401 of the act (standards of identity) and 403(g) of the act (standards of identity labeling) to which it gave preemptive effect on the date of enactment and of sections 403(c) (imitation foods), 403(e) (name and address of responsible firm and net contents declaration), and 403(i)(2) of the act (ingredient labeling) which Congress made preemptive 1 year after enactment.

However, Mr. Waxman stated that Congress was unable to determine whether the Federal standard is strong in the areas covered by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the act (136 Congressional Record H5840). Thus, he said, the bill provides for a study of Federal and State standards to determine whether additional Federal regulations on each of the sections is needed.

Further information on the nature of the study is provided by the House Manager's report:

> The purpose of this study is to provide the Secretary information upon which to determine whether federal laws are adequate once the state laws are preempted. It is anticipated that the study will identify all federal regulations that are applicable as well as State laws that will be preempted. The study should also survey local laws, but it is not anticipated that every local law will need to be identified.

(136 Congressional Record H5842 (July 30, 1990)).

It is clear from this legislative history that what Congress intended was for FDA, through a contractor, to compare its regulations implementing the sections of the act in question with those of the States. To the extent that

that study identified major matters covered by those sections that the States were addressing but FDA was not, FDA would have to address those matters before the sections in question would be preemptive.

However, there is nothing in the statute or the legislative history that suggests that the purpose of the study was to identify the strongest State standard on each of the matters covered by those sections of the act and for FDA to implement that provision. Therefore, FDA rejects this comment.

2. One comment stated that the IOM had erred in failing to consider the level of FDA enforcement in determining whether a particular section has been adequately implemented.

The agency disagrees that its enforcement record is appropriately a factor in determining adequacy of implementation. There is nothing in the act or the legislative history that would indicate that it should be. Nor does it make any sense in light of the legislative history that level of enforcement is a relevant factor. Congress cited nutrition labeling and health claims as topics on which a strong Federal regulatory system is in place, even though the statutory provisions on these topics had never been enforced (136 Congressional Record H5840 (July 30, 1990)). Apparently, Congress did so because it anticipated that adoption of the regulations necessary in response to the 1990 amendments would establish such a strong regulatory system. Thus, it is appropriate to look to the regulatory systems in place for each of the sections in question—that is, to the regulations that effect those sections—to determine whether they are adequately being implemented.

3. One comment stated that IOM cannot legally determine whether a particular section is adequately being implemented without considering the level of industry compliance.

FDA disagrees. Because IOM received no information from FDA or the States concerning industry compliance, and because only anecdotal information exists, IOM concluded that there was no objectively verifiable data regarding compliance that could be used to evaluate adequacy of implementation of the misbranding sections. Therefore, IOM decided that to evaluate compliance on the basis of such limited data would be contrary to the intent of the 1990 amendments.

Again, there is nothing in the legislative history that would suggest that industry compliance was a factor that either IOM or FDA should consider in deciding whether the Federal regulations implementing the sections in question are adequate. If compliance is a problem, what the statute seems to contemplate is that FDA would establish a strong national standard that the States and the agency would then work together to enforce. As Congressman Waxman said: "Third, any preemption provision must recognize the important contribution that the State can make in regulation, and it must leave a role for the states." (136 Congressional Record H5840 (July 30, 1990)). Thus, FDA rejects this comment.

B. Preemption

4. One comment argued that IOM misinterpreted the 1990 amendments as to the extent of preemption by concluding that all State and local requirements, not just those that conflict with Federal law, should be preempted if FDA determines that the section under study has, as a whole, adequately been implemented. The comment argued that the national uniformity portion of the 1990 amendments was intended to ease the burden to industry by preempting inconsistent labeling requirements. The comment stated that, therefore, State and local requirements that serve consumer protection purposes should only be preempted if they conflict with FDA regulations.

The comment noted as an example that under IOM interpretation, a State requirement for a common or usual name for a particular product would be preempted even if there is no Federal requirement for a common or usual name for that product. The comment summarized its position by concluding that the IOM had incorrectly interpreted which State and local requirements were "of the type" or "related to" the six areas under study. As support for its position, the comment cited the FDA November 27, 1991, proposal entitled "State Petitions Requesting Exemption From Federal Preemption" (hereinafter referred to as the State petitions proposal) (56 FR 60528).

The agency disagrees with this comment. The comment misinterprets the extent of preemption that occurs under section 403A of the act.

FDA sought to address this issue in its proposal on State petitions for exemption from preemption. In that proposal the agency stated:

> Section 403A is only operative in matters where there is a Federal requirement applicable to the labeling addressed in the State requirement. If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under the 1990 amendments for Federal preemption or grounds to justify the submission of a State petition for exemption. (56 FR 60528 at 60530)

In discussing examples of State laws that would not be preempted, FDA listed the following:

> The examples included State laws pertaining to issues for which there is no national framework, such as open date labeling, unit price labeling, container deposit labeling, religious dietary labeling, and previously frozen labeling.

These examples do not include situations that are covered by the sections of the act that are given preemptive effect by section 6(b) of the 1990 amendments or regulations issued under those sections. With respect to those sections, however, the preemptive effect is quite broad. Section 403A(a)(3) of the act, for example, states that no State or political subdivision of a State may directly or indirectly establish or continue in effect as to any food in interstate commerce "* * * any requirement of the type required by section 403(b), 403(d), 403(f), 403(h), 403(403(i)(1), or 403(k) that is not identical to the requirement of such section." Thus, under this provision, as is discussed below in this document and as explained more fully in the final rule entitled "State Petitions Requesting Exemption from Federal Preemption," published elsewhere in this issue of the **Federal Register**, a State common or usual name regulation promulgated in conformance with the requirements of § 102.5 (21 CFR 102.5) for a food for which there is no specific Federal common or usual name would apparently be preempted. It would be a requirement of the type required by section 403(i)(1) of the act, but it would not be identical to the provisions that FDA has adopted under that section.

C. The Six Misbranding Sections Under Review

1. Section 403(b)—Offered for Sale Under the Name of Another Food

5. Four comments supported FDA's tentative determination that section 403(b) of the act is adequately being implemented. However, one comment argued that section 403(b) of the act is not adequately being implemented because FDA has issued no regulations under this section nor has it prosecuted many cases under this section. The comment also noted that IOM, while finding section 403(b) of the act adequately implemented, suggested that FDA should promote the development and introduction of new foods by pursuing more aggressively the regulatory options that will allow the formal naming of new nonstandardized foods.

Having considered the comments to the proposal, the IOM report, and other available information, the agency concludes that IOM was correct in its recommendation, and is finding that section 403(b) of the act is adequately being implemented. The agency notes, as did IOM, that it does have a regulation that implements section 403(b) of the act, § 101.18 *Misbranding of food* (21 CFR 101.18). Moreover, none of the comments pointed to State regulations that implement provisions that are similar to section 403(b) of the act that address matters not covered by FDA's regulations.

As to the enforcement, or lack thereof, of section 403(b) of the act, FDA agrees that there are not many actions brought against manufacturers solely under this general misbranding provision. Any such action taken by FDA against a manufacturer under section 403(b) of the act would almost always be brought in conjunction with counts that charge a violation of the more specific misbranding provisions of section 403, namely section 403(g) (standards of identity) and section 403(i)(1) (common or usual name). However, as discussed above, the level of enforcement is not relevant to the inquiry mandated by Congress.

The agency believes that IOM's suggestion that FDA actively pursue its regulatory options to allow the formal naming of nonstandardized foods was misinterpreted by the comment. IOM was simply offering a suggestion. There is no indication in IOM's report that IOM believed that there was a problem with the implementation of section 403(b) of the act, as evidenced by its recommended finding that this section is being adequately implemented. For these reasons, FDA rejects this comment.

2. Section 403(d)—Misleading Container

6. Two comments cited FDA's current requirements for net weight declaration and standards of fill regulations as evidence that section 403(d) of the act is adequately being implemented. One of the comments added that IOM's determination that section 403(h) of the act (fill of container) is adequately being implemented precluded the IOM from finding that section 403(d) is not adequately being implemented.

The agency disagrees with the comments. The suggestion that the provisions for net weight declaration (as provided by section 403(e) of the act) and standards of fill (as provided by section 403(h)(2) of the act) serve to implement section 403(d) of the act would basically serve to render section 403(d) of the act a nullity. Although there is clearly an interrelationship among the three sections, the agency believes that the presence of an accurate net weight statement or compliance with a standard of fill does not eliminate the misbranding that occurs when a container is made, formed, or filled so as to be misleading.

7. One comment argued that it would not be cost effective for FDA to implement section 403(d) of the act by promulgating detailed specific commodity and container regulations, such as those the agency has adopted in the past under section 401 of the act and enforced under section 403(h)(2) for all food products or specific food product classes. The comment also argued that further regulatory activity would be inappropriate in light of the IOM's failure to identify any State commodity and package regulations that should be adopted and of FDA's previous determination that the expenditures of agency resources that would be needed to implement such regulations would exceed potential benefits.

FDA disagrees. The fact that IOM was unable to identify any specific state law that FDA should adopt was not a basis for ending their consideration of whether a particular section is being adequately implemented. As noted above, the task was to determine the adequacy of Federal implementation by considering: (1) The extent of State regulation for each topic and the corresponding Federal regulation and (2) whether the States were doing anything that FDA should be doing. FDA notes that IOM did mention California's experience in this area suggested using the provisions of the Fair Packaging and Labeling Act (FPLA) as a guide for Federal regulations to implement section 403(d) of the act.

The agency's earlier decisions not to implement general or individual regulations concerning slack-fill or deceptive packaging were in relation to the efficient utilization of the agency's resources, not the adequate implementation of the intent of section 403(d) of the act. The provisions of the 1990 amendments require that the agency examine its implementation of section 403(d) of the act from a different perspective, i.e., not in terms of efficient use of resources but instead whether its regulations adequately implement the intent of section 403(d) of the act. Based upon the findings of IOM and its own review of the record, FDA concludes that section 403(d) of the act is not adequately being implemented.

8. One comment, without addressing whether the IOM recommendation concerning 403(d) of the act is correct, urged the agency to take whatever action is necessary to implement section 403(d) of the act adequately. The comment suggested that the agency consider using the definition for slack-fill that appears in section 5 of the FPLA. Another comment opposed the proposed determination that section 403(d) of the act is not being adequately implemented by FDA on the basis that the IOM report, in supporting its determination of inadequacy, does no more than suggest that FDA adopt some general regulations merely parroting the language of section 5(c)(4) of the FPLA which: (1) Authorizes FDA to adopt product-by-product regulations to prevent the nonfunctional slack-fill of packages when it finds such regulations are necessary to prevent the deception of consumers or to facilitate value comparisons, and (2) provides that a package shall be deemed to include nonfunctional slack-fill if it is filled to substantially less than capacity for reasons other than: (a) Protection of the contents of such package or (b) the requirements of machines used for enclosing the contents in such package. The comment argued that the adoption of a general regulation to implement statutory language of the FPLA would provide no further guidance to the agency, the public, or the industry than is now provided in the relevant case law under section 403(d) of the act and in the legal literature discussing nonfunctional slack-fill. Moreover, the comment argued, any attempt to write more specific requirements in a general slack-fill regulation would certainly founder on the widely different considerations that apply to different foods and different packages—as is graphically illustrated in the differing fill of container standards adopted by FDA.

The issue here is not how to adequately implement section 403(d) of the act, but whether it is being adequately implemented. Based on the evidence cited by IOM, FDA finds that the States have addressed fill of container matters that are not addressed by FDA's regulations. Therefore, FDA concludes that section 403(d) of the act is not adequately being implemented. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal entitled "Misleading Containers; Nonfunctional Slack-fill" which is based on the FPLA definition for nonfunctional slack-fill but goes beyond it in ways that the agency has tentatively found to be appropriate to address the types of concerns that were raised by the latter comment. FDA urges that interested persons comment on that proposal.

3. Section 403(f)—Information of Appropriate Prominence

9. One comment stated that IOM was incorrect in recommending that FDA find that section 403(f) of the act is adequately being implemented. The comment stated that, although numerous regulations have been promulgated under this section, several important problems have not been addressed. For example, the comment cited the IOM report's concern that FDA's current regulations "do not provide as precise a definition of 'conspicuous' and 'prominent' as do some States." The IOM report had expressed concern that this lack of definition may place a greater enforcement burden on FDA. The comment submitted excerpts from "Guidelines for Document Designers," a product of the Document Design Project funded by the National Institute of Education as support for its concern on the readability of labels. The comment noted that there is no Federal regulation against obstructing important label information with, for example, price tags.

The agency disagrees with the comment. While FDA has not adopted as precise a definition for "conspicuous" and "prominent" as some States, the regulations adopted by FDA have specific requirements for placement of mandatory information such as product name, net weight, ingredients, and name and address of manufacturer with specifications for type size. FDA finds that these requirements adequately implement section 403(f) of the act. Although FDA has not explicitly enunciated definitions of "conspicuous" or "prominent", its regulations reflect the standard of prominence and readability in *United States* v. *46 Cases, More or Less, "Welch's Nut Caramels,"* 204 F. Supp. 321, 323 (D.R.I. 1962):

> * * * The Act prescribes no minimum specific standard as to how prominent such statements should be. It would seem that the requirements of said section 403(f) are met in a particular case if such statements are prominent enough to be seen and understood by the ordinary individual who is interested in discovering and learning the information disclosed thereby, and who makes the minimum examination of the package to determine its net weight and the ingredients of the candy contained in said package.

While studies on readability may suggest methods of highlighting label information, the question is whether or not the product meets the legal standard of being seen and understood by the ordinary individual. Section 101.1 requires that the principal display panel "shall be large enough to accommodate all the mandatory label information required * * * with clarity and conspicuousness and without obscuring design, vignettes, or crowding." Section 101.2 requires that all information that must appear either on the principal display panel or the information panel must be prominent and conspicuous, but in no case may the letters or numbers be less than one-sixteenth inch in height unless otherwise exempted. These requirements meet the legal standard by ensuring that the information can be seen and understood by the ordinary individual. Thus, while FDA has not chosen to implement section 403(f) of the act in the same way as some of the States, it has adequately implemented that section and established a strong standard.

As to the issue of obscuring label information, § 101.1 prohibits "obscuring design, vignettes, or crowding." The agency has not adopted more specific regulations regarding obscuring by price tags or other means because these tags are placed on the product at the retail level for the most part, and FDA does not have the resources to police individual food outlets across the nation. While the States do regulate at that level, FDA finds that the language of § 101.1 will give them an appropriate and adequate tool to address this problem.

4. Section 403(h)—Compliance With Standards of Quality and Fill

10. One comment set forth what it considered to be four major problems with IOM's conclusion that section 403(h) of the act is adequately being implemented. First, the comment argued that the statements that a product is substandard provided in § 130.14(a) and (b) (21 CFR 130.14(a) and (b)) do not adequately inform consumers of the reason the product is below standard. The comment suggested that FDA require an additional line in both statements to explain briefly the defect in quality or fill (e.g., similar to that which is provided in § 103.5(b) for bottled water, "contains excessive bacteria"). Secondly, the comment argued that the IOM's conclusion that section 403(h) is adequately being implemented should not be based on the fact that companies rarely use the statement "Below Standards in Quality," because it is equally plausible that companies are simply not complying with the requirement, or that there are insufficient substantive standards of quality, fill, and identity to make this determination. Thirdly, the comment stated that IOM's reliance on the lack of court cases involving section 403(h) of the act is not a valid criterion for determining whether the section is adequately being implemented because it is possible that FDA simply does not enforce this section. Finally, the comment argued that IOM did not consider the adequacy of the substantive standards themselves (i.e., the standards of identity, quality and fill) in determining whether section 403(h) of the act is adequately implemented.

Under section 403(h) of the act, a food is considered misbranded if it purports to be or is represented to be a food for which either a standard of quality or fill of container has been prescribed by regulations under section 401 of the act, and its quality or fill falls below such standards. The purpose of the disclosure requirements in § 130.14 (21 CFR 130.14) is simply to permit manufacturers, if they so choose, to sell a product that is not in compliance with section 403(h) of the act because of inadvertent manufacturing error.

The agency points out that the lack of an additional line in the disclosure statement explaining the defect in quality and fill is not germane to determining whether section 403(h) of the act is adequately being implemented for purposes of section 6(b) of the 1990 amendments. Under section 6(b) of the 1990 amendments, the standard that FDA is to use in determining the adequacy of its implementation of section 403(h) of the act is whether States or localities have adopted laws or regulations to implement requirements of this type that address matters not covered by FDA's regulations. Neither the comment nor the IOM report have shown that there are matters with respect to standards of quality or fill covered by States laws that FDA is not addressing.

With respect to the fact that companies rarely use the disclosure statements (e.g., "Below standard in fill"), the comment offered no evidence, nor is FDA aware of any such evidence, to substantiate that its claim that companies are not complying with section 403(h) of the act is in fact true. FDA's compliance efforts have not produced any evidence to this effect. Therefore, FDA can give no credence to this argument.

The agency notes that the lack of court cases involving section 403(h) of the act is not germane to determining whether this section is adequately being implemented. As noted elsewhere in this document, enforcement is not a criterion for making a determination of adequate implementation.

The last argument put forth by the comment is also not germane because the sufficiency of individual standards is not at issue in determining whether

the agency is adequately implementing section 403(h) of the act.

Therefore, FDA rejects the comment and concludes that section 403(h) of the act is adequately being implemented by its regulations.

5 Section 403(i)(1)—Common or Usual Name

11. One comment stated that the language of the IOM report contradicts IOM's conclusion that section 403(i)(1) of the act is adequately being implemented. The comment stated that the fact that the food industry continues to develop new foods for which no regulated common or usual name exists is evidence that section 403(i)(1) of the act is not adequately being implemented. The comment noted that the areas examined by IOM, i.e., bottled water, honey, fish, oriental noodles, Vidalia onions, and wild rice, are indicative of the fact that State standards offer more consumer protection than Federal standards.

The agency disagrees with the comment. The general regulation for common or usual names (§ 102.5 (21 CFR 102.5)) provides general principles that direct how to name any new food for which an individualized common or usual name regulation or standard of identity does not exist. Section 102.5 provides that:

> The common or usual name of any new nonstandardized food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name.

In addition, § 102.5 requires that "each class or subclass of food shall be given its own common or usual name that states in clear terms, what it is in a way that distinguishes it from different foods." Section 102.5 also includes percentage labeling requirements for characterizing ingredients in certain foods. It provides that a common or usual name of a food may be established by regulation in 21 CFR part 102, Subpart B (Requirements for Specific Nonstandardized Foods), in 21 CFR part 104 (Nutritional Quality Guidelines for Foods), in a standard of identity regulation (21 CFR part 131 through 169), or in other regulations in Chapter I of Title 21 of the Code of Federal Regulations. It also states that a common or usual name of a food may be established by common usage.

The agency disagrees with the comment's statement that the specific common or usual name examples cited in the comment are indicative that State standards are stronger than Federal standards. The IOM report identifies several foods, including the six mentioned in the comment, for which States had common or usual name requirements but for which there were no Federal requirements. FDA finds, as did IOM, that each of IOM's examples represents a situation that either is not subject to section 403A of the act or calls for a state petition for exemption from preemption under section 403A(b), and that these examples do not demonstrate that the requirements of FDA's regulations do not adequately implement section 403(i)(1) of the act.

The agency notes that of the products cited by the comment, only three would be candidates for a common or usual name regulation. Wild rice, Vidalia onions, and fish. With respect to wild rice, IOM did state in its report that there was a potential for consumer fraud through substitution and blending of the more expensive wild rice with other cheaper rice products. However, the agency has no data, nor was any submitted, to confirm that this in fact is the situation in the marketplace. Moreover, the agency does not believe establishing a specific common or usual name regulation for wild rice would necessarily give the consumer any more protection than is currently provided by § 102.5. While the agency is not persuaded that there is a consumer fraud problem with wild rice, it would certainly entertain a citizen petition to establish a specific common or usual name regulation if a proper case is presented that demonstrates that there is a problem and a regulation is needed.

IOM also concluded that the Georgia State requirement for Vidalia onions appears to be predominantly protectionist in that no specific justification is provided for limiting the source to the defined producing locality. The agency concurs with IOM's assessment and, therefore, concludes that a specialized Federal common or usual name regulation for this product is not necessary. Again, while FDA believes that § 102.5 adequately provides for the naming of this product, it would have no objection to the State of Georgia or any other group or industry submitting a citizen petition to FDA to establish a specific common or usual name regulation for Vidalia onion based on measurable geographical, botanical, or quality criteria that differentiates it from other varieties or species of onion.

With respect to fish, FDA has issued "The Fish List FDA Guide to Acceptable Market Names for Food Fish Sold in Interstate Commerce 1988" to provide acceptable market, scientific, and common names for a wide range of common species. The agency believes, as did IOM, that The Fish List provides order to the marketplace. FDA also has Compliance Policy Guides (CPG's) for "red snapper" and for surimi-based (minced fish) imitation crab and other fish substitutes (CPG 7108.04 and 7108.16, respectively). The agency believes that The Fish List and the various CPG's more than adequately protect the consumer from fraud, while establishing specific common or usual name regulations for the many species of fish would be beyond the agency's resources and would not result in an appreciable reduction in consumer fraud. Anyone who believes a specific common or usual name regulation is needed for a particular species of fish may, of course, submit a citizen petition with appropriate justification as to why such action is warranted.

Bottled water, honey, and oriental noodles were also cited by the comment as products examined by IOM. Oriental noodles have compositional requirements, and, therefore, any regulations promulgated by FDA for this product would be in the form of a standard of identity regulation. Food standards are promulgated under the authority of section 401 and 403(g) of the act, not section 403(i)(1). The agency further notes that it has issued a compliance policy guide for oriental noodles (CPG 7102.02: Chow Mein Noodles, Chinese noodles, and other Oriental Noodles; Labeling). The agency believes that the CPG for oriental noodles more than adequately protects the public from consumer fraud. Again, the agency would not object to any interested persons submitting a citizen petition to establish a standard of identity for oriental noodles. The agency notes that it is currently considering a citizen petition from the International Bottled Water Association requesting that FDA regulate bottled water. The agency hopes to take action on this petition by the end of this year.

Thus, FDA concludes that it does have a strong and adequate regulatory system in place to implement section 403(i)(1) of the act. Therefore, the agency accepts IOM's recommendation and rejects the comment on this point.

6. Section 403(k)—Declaration That the Product Contains Artificial Flavoring, Coloring, or Preservatives

12. One comment argued that section 403(k) of the act is not adequately being implemented because there are several areas where FDA's current regulations fall short. As examples the comment

noted that current regulations: (1) Do not require all artificial flavorings in foods to be specifically identified on the label by their common or usual name (the comment stated that artificial flavorings can be listed as "flavorings"), (2) do not give consumers that are sensitive to monosodium glutamate (MSG) or sulfites sufficient label information to be able to avoid these substances, and (3) do not require labeling to reflect the percentage of each type of ingredient (e.g., the term "natural and artificial flavoring" can be used for a product which has 5 percent artificial and 95 percent natural flavoring and vice versa) when both natural and artificial coloring and flavoring are used in a food.

The agency disagrees with the comment. The premise of the comment is based upon a faulty interpretation of the requirements of section 403(k) of the act, of the agency's implementation of those requirements, and of IOM's report. The issues being raised by this comment would require fundamental statutory changes.

With regard to the first point, although they are separate requirements, section 403(i)(2) and (k) of the act must be read together. Section 403(i)(2) of the act requires the listing of the ingredients of a food by their common or usual names except that spices, flavorings, and color additives not required to be certified under section 706(c) of the act may be designated as spices, flavorings, and colorings without naming each (see also section 403(g)). Section 403(k) of the act provides that a food shall be deemed to be misbranded if it bears or contains any artificial flavorings unless it bears labeling stating that fact. FDA has implemented and amplified the requirements of section 403(k) of the act in § 101.22(h), which provides that the label of a food to which a flavor is added shall declare the flavor in the statement of ingredients as "artificial flavor" or "natural flavor" or any combination thereof, as the case may be.

Thus, contrary to the comment's assertion, FDA does not have the legal authority to require that artificial flavorings be listed by their common or usual name. However, again contrary to what the comment asserted, FDA has required that artificial flavorings be designated by the term "artificial flavoring."

The agency notes that the comment's concerns about the need for sensitive individuals to have sufficient label information to be able to avoid substances such as MSG and sulfites and the lack of percentage labeling of artificial and natural flavorings when both are used in food are not germane to whether section 403(k) of the act is adequately being implemented. To the extent that MSG, sulfites, or other substances that cause food sensitivities are flavorings, section 403(k) of the act would not require that they be declared in a way that would permit consumers to avoid them. FDA regulations do require that sulfites that are present in detectable amounts are declared on the food label (see § 100.100(a)(4) and the document on ingredient labeling published elsewhere in this issue of the **Federal Register**), however, FDA adopted this requirement under other provisions of the act. Similarly, percentage labeling requirements are outside the scope of section 403(k) of the act, which requires only that the presence of artificial flavorings (or artificial colors or chemical preservatives) be declared on the label. Section 101.22(h)(1) of FDA's regulations set forth how the addition of both artificial and natural flavorings to a food is to be declared. Therefore, the agency rejects the comment on this point.

Having considered the comments, the IOM report and other available information, FDA finds that section 403(k) of the act is being adequately implemented.

D. Procedural Issues

13. One comment argued that the agency's failure to present more than a conclusionary acceptance of IOM's recommendations did not provide the agency's views on the decision as to which sections were adequately being implemented.

The agency disagrees. The agency explicitly stated its tentative conclusions as to those sections that were adequately being implemented, and those that were not, were based on the recommendations of IOM and all of the information that IOM supplied to the agency as a result of the contract between FDA and IOM (57 FR 33283 at 33285). The July 28, 1992, proposal announcing the proposed lists discussed in detail the approach taken by IOM and the criteria that it used to determine adequate implementation. The notice summarized the basis for IOM's recommendations with respect to each section of the act (57 FR 33283 at 33284 through 33285). All the comments and other information considered by IOM, along with its draft final manuscript and final report, were placed on public display for all interested persons to review.

FDA's presumptive tentative acceptance of IOM's recommendations was fully consistent with the 1990 amendments and with the Administrative Procedure Act. Section 6(b)(3)(A) of the 1990 amendments directs the agency to publish the proposed lists as determined under the contract with a public or nonprofit private entity, which turned out to be IOM. This is eactly what the agency did. Moreover, § 10.40(b) (21 CFR 10.40(b)), FDA's regulation that implements the Administrative Procedure Act on informal rulemaking, states that the proposal shall act out the terms or substance of the proposed action and summarize the facts and policy that underlie it. Again, the July 28, 1992, proposal fully complies.

Thus, the agency finds that it provided adequate notice for all persons interested in this rulemaking as to the basis for its tentative determinations of adequacy of implementatien.

III. Economic Impact

FDA has examined the economic implications of the final lists as required by Executive Orders 12291 and 12612 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis when making decisions, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this final rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, because these lists implement a statute that provides for preemption of State and local laws in specified circumstances, FDA finds that there is no substantial federalism issue that would require an analysis under Executive Order 12612.

A. Alternatives

The primary alternatives available to FDA were as follows:

1 Accept recommendation of IOM report

2. Reject recommendation of IOM report

B Costs

1 Accept Recommendation of IOM Report

By accepting the recommendation of the IOM report, FDA is legally required to publish regulations that ensure that section 403(d) of the act is adequately implemented. The compliance costs imposed by FDA's acceptance of this

legal obligation depend on the regulations that FDA promulgates to fulfill this obligation. One possible regulation that FDA might promulgate simply repeats the language of section 403(d) of the act. The compliance cost of this regulation would be zero because section 403(d) is already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then compliance costs may occur. Potential compliance costs to industry include designing and manufacturing new packages. FDA has estimated the cost of implementing the regulations in the proposal on misleading containers that is published elsewhere in this issue of the **Federal Register**.

2. Reject Recommendation of IOM Report

If FDA had rejected the recommendation of the IOM report, then FDA could have made one of the following decisions: (1) Find that all sections of the act defining circumstances in which a food is misbranded are adequately implemented, or (2) find that one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) are not adequately being implemented.

If all relevant sections of the act had been found to be adequately implemented, then compliance costs would have been zero. If one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) had been found to be not adequately implemented, then compliance costs may have occurred. One possible regulation that FDA might have promulgated in the latter case would have simply repeated the language of the relevant sections of the act. The compliance cost of this regulation would have been zero because these sections of the act are already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then some compliance costs may be incurred.

C. Benefits

1. Accept Recommendation of IOM Report

By accepting the recommendation of the IOM report, FDA is legally required to publish regulations that ensure that section 403(d) of the act is adequately implemented. One possible regulation that FDA might promulgate simply repeats the language of section 403(d) of the act. The benefit of this regulation would be zero because section 403(d) of the act is already legally binding on food package manufacturers. If more restrictive regulations are promulgated, then there may be positive benefits. The potential benefit of more restrictive regulations would be a reduction in consumer dissatisfaction with the fill of food containers. FDA has estimated the benefits of implementing regulations in the proposal on misleading containers that is published elsewhere in this issue of the **Federal Register**.

2. Reject Recommendation of IOM Report

If FDA had rejected the recommendation of the IOM report, then FDA could have made one of the following decisions: (1) Find that all sections of the act defining circumstances in which a food is misbranded are adequately implemented, or (2) find that one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) of the act are not adequately being implemented.

If all relevant sections of the act had been found to be adequately implemented, then benefits would have been zero. If one or more sections of the act defining circumstances in which a food is misbranded other than section 403(d) had been found to be not adequately implemented, then there may have been positive benefits. One possible type of regulation that FDA might have promulgated in this case would have simply repeated the language of the relevant section of the act. The benefit of this type of regulation would have been zero because these sections of the act are already legally binding on food package manufacturers. Thus the benefits of this alternative would have been estimated to be zero. If more restrictive regulations had been promulgated, then there may have been positive benefits.

D. Conclusion

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this proposed rule and has determined that this rule, if promulgated, will not be a major rule as defined by that order.

In accordance with the Regulatory Flexibility Act, the agency has considered the effect that this regulation would have on small entities including small businesses and has determined that this final rule will not have a significant economic impact on a substantial number of small entities.

The costs and benefits of this final rule depend on the regulations that FDA produces in response to the requirement that it promulgate regulations ensuring the adequate implementation of sections of the act that it finds are not adequately being implemented. The costs and benefits of those regulations will be zero if those regulations simply repeat the language of the relevant sections of the act. As noted above, the costs and benefits of implementing regulations are considered in the proposal on misleading containers.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Final Lists

Based on its review of the IOM report, the comments to the July 28, 1992 proposal, and other available information, the agency is announcing its conclusions related to the adequacy of Federal implementation of sections 403(b), 403(d), 403(f), 403(h) 403(i)(1), and 403(k) of the act. FDA finds that the following sections are adequately implemented by FDA regulations: sections 403(b), 403(f), 403(h), 403(i)(1), and 403(k) of the act. Based upon the same considerations, FDA finds that section 403(d) of the act on misleading containers is not adequately being implemented by FDA regulations.

Having made these findings, FDA advises that section 403A(a)(3) of the act and section 6(b)(3)(B) of the 1990 amendments provide that no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement for the labeling of food of the type required by sections 403(b), 403(f), 403(h), 403(i)(1), or 403(k) of the act that is not identical to the requirement of such section, effective February 5, 1993.

Published elsewhere in this issue of the **Federal Register** is a proposal entitled "Misleading Containers; Nonfunctional Slack-Fill," in which FDA is proposing revisions of its regulations to ensure adequate implementation of section 403(d) of the act. Upon the effective date of the final regulations based upon that proposal, no State or local subdivision of a State may establish or continue in effect any requirement that is not identical to the requirements of section 403(d) of the act and regulations issued thereunder. If the agency does not issue final regulations in response to the proposal by May 8, 1993, the proposed regulations will be

considered the final regulations under the 1990 amendments, and preemption will become effective on the effective date of the rules that, on May 8, 1993, are considered final rules.

Dated: November 5, 1992.

David A. Kessler,

Commissioner of Food and Drugs

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20 and 101

[Docket No. 85N-0061]

RIN 0905-AB67

Food Labeling; General Requirements for Health Claims for Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of foods in conventional food form (conventional foods), and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in such food. This action is being taken in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims for conventional foods. However, in the Dietary Supplement Act of 1992 (the DS Act), Congress imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements with only very limited exceptions. Therefore, these final rules do not apply to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. Elsewhere in this issue of the **Federal Register**, FDA is issuing final rules that respond, at least with respect to conventional foods and, to the extent that they would permit claims, with respect to dietary supplements, to the 1990 amendments' directive that the agency consider 10 topics associating substances with diseases or health-related conditions. Those final rules have been developed in accordance with the general principles of the requirements in this document.

EFFECTIVE DATE: May 8, 1993, except § 101 9(k)(1) which will become effective February 14, 1994, and §§ 101.14(d)(2)(vii)(B) and 101.14(d)(3) concerning restaurant firms consisting of 10 or less individual restaurant establishments for whom these sections will become effective on May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Victor P Frattali, Center for Food Safety and Applied Nutrition (HFF-261), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-4064.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60537), FDA published a proposed rule to establish general requirements pertaining to: (1) The use of health claims that characterize the relationship of a substance to a disease or health-related condition on the labels and in labeling of both conventional foods and dietary supplements, and (2) the content of petitions regarding the use of such health claims pertaining to specific substances in food. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims. With respect to health claims, the 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) by adding a provision (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B))) that provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain healthy dietary practices and to protect these consumers from unfounded health claims. The House Report of June 13, 1990, states, "Health claims supported by a significant scientific agreement can reinforce the Surgeon General's recommendations and help Americans to maintain a balanced and healthful diet" (Ref. 1). Senator Orrin Hatch, one of the primary authors of the 1990 amendments, noted that diet has been implicated as a factor in the three leading causes of death (heart disease, cancer, and stroke) (Ref. 2). In addition, the statement of the House Floor Managers noted that "There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims" (Ref. 3). The House Report characterized the need for regulation as "compelling" (Ref. 1).

FDA's first step in support of the congressional goals of the 1990 amendments appeared in the form of the proposed health claims regulation. The proposed regulation contained: (1) Definitions to clarify the meaning of specific terms used in the regulation; (2) preliminary requirements that a component of food must meet to be eligible to be the subject of a health claim; (3) a scientific standard for assessing the validity of claims both for dietary supplements and for conventional food, general labeling requirements for health claims that are permitted by regulation, and prohibitions on certain types of health claims; and (4) the required content of petitions for health claims.

In response to the proposed rule, FDA received over 6,000 letters, each containing one or more comments, from consumers, health care professionals, universities, State and local governments, foreign governments, trade organizations, consumer advocacy organizations, research institutes, industry, and professional organizations. In addition to receiving these written comments, the agency held a public hearing on January 30 and 31, 1992 (57 FR 239, January 3, 1992), on a number of food labeling issues, including the requirements for health claims. Some of the comments agreed with one or more provisions of the proposed rule without providing further grounds for support other than those presented by FDA in the preamble to the proposal. Other comments disagreed with one or more provisions of the proposed rule without providing specific grounds for the disagreement. A few comments addressed issues outside of the scope of the regulations and will not be addressed in this document. Most of the comments provided specific grounds in support of their positions concerning provisions of the proposed regulations. The agency has summarized and addressed the issues raised in the sections of this document that follow.

In October 1992, the DS Act was enacted. This statute states that, with certain limited exceptions, the Secretary (and FDA, by delegation) may not implement the 1990 amendments with respect to dietary supplements earlier than December 15, 1993. As a result, this final rule applies only to conventional food (Ref. 34). The DS Act establishes a timetable for the adoption of final rules implementing the 1990 amendments with respect to dietary supplements by December 31, 1993. One exception to the moratorium on the implementation of the 1990 amendments is a provision (section 202(b)) that states that FDA may, earlier than December 15, 1993, approve claims with respect to dietary supplements that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the 1990 amendments. FDA is responding to this provision in the documents on the 10 specific substance-disease topics that accompany this final rule.

II. Definitions

FDA proposed definitions for "health claim," "substance," "nutritive value," and "dietary supplement" to serve as tools for clearly establishing the scope of the types of claims that would be

subject to the regulations promulgated under section 403(r)(1)(B) of the act. In addition, the agency proposed a definition for "disqualifying nutrient levels" to establish limits on the amounts of certain nutrients that are known to increase the risk of disease that can be in a food if that food is to bear a health claim in its labeling.

A. Definition of a Health Claim

As proposed, § 101.14(a)(1) stated:

Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" endorsements, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include only those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a health or disease-related condition.

(56 FR 60537 at 60563)

As was explained in the preamble of the proposal (56 FR 60542), FDA derived this definition almost directly from the provisions of section 403(r)(1)(B) of the act. The proposed definition establishes that a claim must have at least two basic elements for it to be regulated as a "health claim." First, the claim must be about a "substance" as that term is defined in proposed § 101.14(a)(2). Secondly, the claim must characterize the relationship of the substance to a "disease or health-related condition." If a claim has one of these elements without the other, it would not be a "health claim," although it may still be subject to regulation under other provisions of the act (e.g., the requirement of section 403(a)(1) of the act that a label statement be truthful and not misleading).

Although FDA attempted in the proposed definition of a "health claim" to draw clear lines between health claims and other types of claims about diet and health, comments raised significant questions about the applicability of one or both of the elements highlighted in the definition. Many of these questions resulted because, at the time that it issued the proposal, FDA had not itself decided on the precise coverage of the definition. For example, in the proposal (56 FR 60537 at 60542), FDA stated:

While the act focuses on the substance-disease relationship, it is clear that the Congress was concerned about any disease claims that are made on food (Ref. 1). In reviewing the evidence on the 10 topic areas, however, FDA has become aware that there may be certain relationships between foods and diseases that are supported by the available evidence but that cannot be attributed to a particular nutrient. For example, the scientific evidence shows that diets high in whole grains, fruits, and vegetables, which are low in fat and rich sources of fiber and certain other nutrients, are associated with a reduced risk of some types of cancer. The available evidence does not, however, demonstrate that it is total fiber, or a specific fiber component, that is related to the reduction of risk of cancer. The question is thus whether, to fulfill Congress's intent in the 1990 amendments, FDA should regulate claims about apparent food-disease relationships and, if so, how it should do so.

In response to comments questioning the meaning of the proposed definition of a "health claim," the agency has sought to clarify this definition as well as the meaning of the terms "substance" and "disease or health-related condition."

B. Substance—The First Basic Element

As proposed, § 101.14(a)(2) stated:

Substance means a component of a conventional food or of a dietary supplement of vitamins, minerals, herbs, or other nutritional substances.

1. Some comments maintained that because section 403(r)(1)(B) of the act specifically addresses only a claim that characterizes the relationship of any nutrient required to be on the label of a food to a disease or health-related condition, claims about other types of nutrients or about foods are not subject to the provisions of section 403(r). Many of these comments contended that claims about foods and other types of claims must be controlled under the general regulatory regime that requires that a label be truthful and not misleading, and they maintained that FDA could not therefore require preapproval of such claims.

However, other comments stated that Congress intended to control claims about foods as well as nutrients. One comment pointed out that people do not eat nutrients as such; they eat foods that contain (or do not contain) those nutrients. Another comment advised that consumers would more readily understand claims about foods than about nutrients, and that where food claims were appropriate, consumers might be more likely to improve their diets. One comment stressed that FDA has historically defined "substance" expansively, asserted that this policy should not be changed, and suggested that the definition of "substance" should be consistent with the wording of § 170.3(g) (21 CFR 170.3(g)), which defines "substance" as including "a food or food component consisting of one or more ingredients." A few comments pointed out that an understanding of Congress' intent can be obtained by considering the legislative history of the 1990 amendments. One comment advised that, before the enactment of these amendments, Congress considered a great deal of testimony about how health claims should be related to an overall diet of various foods. For example, a representative from one professional organization told the House of Representatives in a hearing on the bill that ultimately became the 1990 amendments (Ref. 24) that health claims should be compatible with the dietary recommendations of the National Research Council's (NRC's) report "Diet and Health: Implications for Reducing Chronic Disease Risk" (the Diet and Health report) (Ref. 6). That NRC report recommends that people eat five or more servings per day of vegetables or fruits and increase their intake of starches and complex carbohydrates. This recommendation is tied to the conclusion that "Diets high in plant foods—i.e., fruits, vegetables, legumes, and whole-grain cereals—are associated with a lower occurrence of coronary heart disease and cancers of the lung, colon, esophagus, and stomach."

In addition, the comment stated that this theme was echoed by the American College of Physicians, which told the House in a prepared statement that the NRC, the Surgeon General, and other organizations "recommend a reduction in fat and an increase in complex carbohydrates and fruits and vegetables in order to reduce the risk of these cancers." Further, the comment advised that the Senate hearing held on November 13, 1989, before the Committee on Labor and Human Resources (Ref. 25), also included significant testimony about the overall health benefits of foods. For example, an official with the American Dietetic Association told the Senate that that organization supported the dietary recommendations of NRC and the Surgeon General, and that health claims should reflect those recommendations and "should assist the public to integrate specific food products into a well-balanced diet." Thus, the comment maintained that both the House and the Senate had before them a record in which various private and public health organizations endorsed the linking of health claims to foods consumed as part of an overall diet, an endorsement validated by repeated references to the dietary recommendations of the NRC and the Surgeon General, sources that FDA has considered authoritative.

Another comment stated that the congressional debates reveal an equal, if not a greater, concern for the health benefits of foods, as opposed to nutrients, and that this concern makes sense when one considers that many public and private health organizations recommend obtaining an adequate nutrient intake through the consumption of a variety of foods. The comment pointed out that it is clear that during the debates over the 1990 amendments, Congress drew no distinction between foods and nutrients. The comment cited a variety of statements from the Congressional Record to substantiate its contention. For example, the comment pointed out that Senator John Chafee of Rhode Island, cosponsor of S. 1425 (the Senate's version of the bill that became the 1990 amendments), said that the proposed legislation would provide definite guidelines governing "the claims and statements that can be made about food" (Ref. 26). Similarly, Senator Orrin Hatch of Utah, cosponsor of the Senate amendments to the House's version of the 1990 amendments, viewed the bill as covering health and diet-related claims about food products (Ref. 2).

FDA does not agree that section 403(r)(1)(B) of the act addresses health claims for only those nutrients required to be on the label of a food and does not include claims about other types of nutrients. The language of section 403(r)(1)(B) of the act is clear in that it pertains to a claim that "* * * characterizes the relationship of any nutrient which is *of the type* required by paragraph (q)(1) or (q)(2) to be in the label or labeling of a food * * *" (emphasis added). Section 403(q)(1) of the act lists specific nutrients that are required for food labeling as part of nutrition labeling. Section 403(q)(2) of the act permits the Secretary of Health and Human Services (the Secretary) to include by regulation any other nutrient not required to be listed by section 403(q)(1) if information about the nutrient will assist consumers in maintaining healthy dietary practices. Moreover, section 403(r)(5)(D) of the act relates to vitamins, minerals, herbs, or other similar substances. Thus, claims relating to a broad range of substances are potentially subject to regulation under section 403(r)(1)(B) of the act, and claims about a nutrient-disease relationship are not outside the coverage of section 403(r) simply because the nutrient in question is not required to be listed in the nutrition label. For these reasons, FDA is retaining the broader term "substance" in the regulations and will use it in this preamble.

In fact, FDA agrees with the comments that contended that the proposed rule interpreted the 1990 amendments too narrowly with respect to the regulation of claims about foods. The agency has reviewed the legislative history of the 1990 amendments and concluded that this history does indeed contain evidence to support the conclusion that Congress intended that foods could be the subject of claims that are regulated under section 403(r) of the act. However, this legislative history also makes clear that, to be subject to section 403(r) of the act, a claim about a food must be, at least by implication, a claim about a substance in the food. The House Report (Ref. 1) states:

> The requirement applies to any disease claim that is made with respect to required nutrients and other nutrients in food. However, a statement about the importance of good nutrition which does not make a direct or implied connection between any nutrient in the food and a particular disease is not necessarily a disease claim that will be covered by this section.

Thus when a consumer could reasonably interpret a claim about the relationship of a food to a disease or health-related condition to be an implied claim about a substance in that food, that claim would satisfy the first element of a health claim.

However, a claim about the benefits of a broad class of foods that does not make an express or implied connection to any of the substances that are found in foods that comprise that class would not constitute an implied claim. Such claims about classes of foods (e.g., fruits and vegetables) are not health claims because they are not about a substance.

Accordingly, FDA has revised the definition of "substance" in new § 101.14(a)(2) to include a specific food as well as a component of food. Although, the agency's tentative view is that the term "substance" has the same meaning regardless of whether the food is a conventional food or a dietary supplement that includes vitamins, minerals, herbs, or other nutritional substances, in response to the DS Act, FDA is not reflecting this view in the final regulation. FDA will decide whether to do so in the rulemaking it will undertake in response to the DS Act. For consistency with the revised definition of "substance," new § 101.14(d)(2)(vii) has also been revised, as explained in section V.E. of this preamble, to provide guidance for identifying the appropriate dietary intake of a specific food necessary to achieve the claimed effect.

FDA has not modified new § 101.14(a)(2) to be identical to § 170.3(g). However, new § 101 14(a)(2) and § 170.3(g) are fully consistent, and any differences in their wording reflect the different contexts to which they apply. The definition of "substance" in § 170.3(g) is specific to the definition of the term "food additive," and in that context it is appropriate because of the statutory definition of "food additive" as "any substance the intended use of which results or may reasonably be expected to result * * * in its becoming a component or otherwise affecting the characteristics of any food." (See section 201(s) of the act (21 U.S.C. 321(s))). Proposed § 101.14(a)(2) was drafted to reflect the broad coverage of section 403(r)(1)(B) of the act. Importantly, a substance under § 170.3(g) would also be a substance under new § 101.14(a)(2) and vice versa.

Under the revised definition of a substance that FDA has included in new § 101.14(a)(2), phrases on labeling such as "eat apples to ———," "eat low sodium foods to ———," "eat fruits high in fiber to ———," or "cook with garlic to———" would constitute references to a substance and would thereby satisfy one of the two essential elements of a health claim. However, phrases on labeling such as "eat a variety of foods to ———," "eat a variety of fresh fruits and vegetables to ———," or "follow the food pyramid to ———," without any reference, either express or implied, to a substance that might be in the foods, would not satisfy this element. The latter types of claims would not be subject to regulation as health claims. Of course, such claims would still be subject to the requirement in section 403(a) of the act that they be truthful and not misleading.

C. Disease or Health-Related Condition—Second Basic Element

As mentioned previously in this preamble, the proposed definition of "health claim" contains two basic elements, "substance" and "disease or health-related condition," that must be present for a claim to be a "health claim." FDA did not define the phrase "disease or health-related condition" in the proposal. This omission raised many questions and concerns in the comments.

2. Many comments objected that FDA's interpretation of the phrase "health-related" could be too broad. One comment was concerned that FDA might interpret the phrase to apply to statements pertaining to general good health. The comment noted that food itself sustains life, so the mere

identification of a product as a food is to that extent a "health-related" claim.

Another comment argued that such phrases as "invigorating," "relaxing," "stimulating," "feel better," "enjoy a good night's sleep," and "perform at your best" should be exempt from regulation because they do not refer to a disease. A few comments contended that claims about relationships between nutrients and the structure or function of the body (e.g., "this calcium fortified product helps build strong bones") should not be considered health claims.

Some of the comments suggested that the definition of a "health claim" should refer only to "disease" or "disease-related" claims because such a characterization more accurately reflects the nature of claims regulated by section 403(r)(1)(B) of the act. One comment asserted that the statutory phrase "a disease or health-related condition" does not set up two categories and maintained that the phrase "health-related" as used in the law appears to be nothing more than an expansion of the word "disease." The comment submitted a definition of the word "disease" from "Stedman's Medical Dictionary," (25th ed., p. 444, 1990), which states that a disease is "a morbid entity characterized by at least two of the following criteria: (1) Recognized etiologic agent(s), (2) identifiable group of symptoms, or (3) consistent anatomical alterations."

Although the legislative history of the 1990 amendments gives clear direction that Congress intended that health claims do include disease-specific claims, this history is not as explicit concerning what kind of claims are claims about a "health-related condition." As FDA pointed out in its response to the previous comment, Congress did, however, give clear direction that a statement about the importance of good nutrition that does not make a direct or implied connection between any substance in the food and a particular disease is not necessarily a disease claim that will be regulated as a health claim (Ref. 1). Thus, it is clear that Congress did not intend that all claims pertaining to general good health be considered health claims.

However, the inclusion of the phrase "health-related condition" in section 403(r)(1)(B) of the act in addition to the term "disease" leaves no question that Congress intended that claims about conditions other than diseases be regulated under this provision. Further, the legislative history of the 1990 amendments confirms this fact. In hearings before the Senate and the House of Representatives preceding the passage of the 1990 amendments, many references were made to two texts, the Diet and Health report by the NRC (Ref. 6) and "The Surgeon General's Report on Nutrition and Health" (the Surgeon General's report) (Ref. 5). In the former text (Ref. 6), a section entitled "Hypertension and Hypertension-Related Diseases" states the following:

> Deaths related to hypertension have been variously classified over recent years. They have either been considered as a separate entity or combined with such classes of atherosclerotic cardiovascular diseases as CHD and stroke. Thus, it is not useful to consider vital statistics alone in discussing the epidemiology of hypertension. Hypertension is treated here primarily as a risk characteristic of atherosclerotic cardiovascular diseases rather than a disease entity in itself.

Elsewhere in the Diet and Health report (Ref. 6), hypertension is defined as sustained, elevated arterial blood pressure measured by an inflatable cuff and pressure manometer. The text goes on to say:

> It [hypertension] has been clearly shown to increase the risk of developing stroke, coronary heart disease, congestive heart failure, peripheral vascular disease, and nephrosclerosis.

Further, the Surgeon General's report identifies high blood pressure as a common, chronic medical problem in the United States responsible for a major portion of cardiovascular disease. It then states that public health efforts have increased public awareness and knowledge of the risks and treatment of this condition (Ref. 5).

The repeated references in the legislative history to texts that place significant importance on the control of risk factors as a means of reducing the risk of disease persuades FDA that the agency should include such factors in any definition of a "health-related condition." In view of the explicitly stated intention of Congress to help Americans maintain a healthful diet (Ref. 1), Congress intended that the 1990 amendments facilitate communication to consumers of information about risk factors such as hypertension, which is a risk characteristic or factor for several diseases, including coronary heart disease and stroke. Accordingly, the agency concludes that the inclusion of "a health-related condition" in the coverage of section 403(r)(1)(B) of the act means that claims about risk factors related to disease, as well as claims about a disease, can be health claims.

Having reached this conclusion, FDA finds that one limitation on the coverage of the phrase "disease or health-related condition" is appropriate. The limitation is for claims about nutrient deficiency diseases. In the legislative history, Congress focused only on those health claims that related to chronic diseases affected by diet, such as cancer, heart disease, and osteoporosis. There is no indication that it intended to cover classical deficiency diseases (diseases resulting directly from a deficiency of a vitamin, essential mineral, or other essential nutrient). The relationships between nutrients and classical deficiency diseases are well-established. Moreover, such diseases are of little public health significance in this country. Under such circumstances, FDA believes that it would not be appropriate to subject such relationships to the health claims regime. Claims about such classical nutrient deficiency diseases are adequately regulated under the provisions of section 403(a) of the act and thus must be truthful and not misleading. However, as discussed in more detail further in this document, a claim about the benefits of vitamin D in preventing vitamin D deficiency, for example, would be misleading where the claim does not explain that few individuals in the United States are at risk of such a deficiency. Of course, some claims about such diseases may result in a product being regulated as a drug. Thus, claims about the administration of a nutrient either intravenously or nasally will be regulated as drug claims. This position is consistent with the position that the agency took in the February 13, 1990, proposal (55 FR 5176) with respect to nutrient deficiency diseases.

Therefore, to assist affected parties in clearly understanding what the second element of a health claim encompasses, FDA is adopting the following definition of "disease or health-related condition" in new § 101.14(a)(6):

> *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to §§ 101.14 or 101.70).

This definition does not differentiate between a "disease" and a "health-related condition." The two states are often so closely related that no bright-line distinction is practicable. Further, both states are regulated under section 403(r) of the act. Thus, there is no reason to separate one state from the other as long as both are covered.

FDA structured this definition primarily after the common sense definition of "disease" that appears in

the second edition of "Random House Dictionary of the English Language" (Random House, Inc., New York, NY, copyright 1987) without referring to examples of the causes of the dysfunctioning that were cited in that definition. For purposes of this rule, the agency did not pattern the definition after the one suggested in the comment because the clinical nature of the suggested definition would not be readily understandable. Thus, it is not suitable for use in a regulation.

The definition of "disease or health-related condition" would not generally encompass terms or phrases such as "invigorating," "relaxing," "stimulating," "feel better," and "perform at your best." Such terms would be covered under the regulatory regime of a label needing to be truthful and not misleading. Moreover, they may also subject the product to regulation under the structure or function of the body aspect of the "drug" definition (section 201(g)(1)(C) of the act). However, the definition would clearly encompass terms such as "osteoporosis," "heart disease," "cancer," and "high blood pressure."

For further clarification, the definition of "disease or health-related condition" is not considered by FDA to include a change in a biological parameter, such as a decrease in platelet (a type of blood cell that promotes blood coagulation) aggregation time or an increase in serum cholesterol, unless the parameter is associated with a disease or health-related condition, and there is evidence that altering the parameter can improve the condition. Of the two examples cited, high serum cholesterol is generally accepted as a predictor of risk for coronary heart disease, and there is evidence that decreasing high serum cholesterol can decrease that risk. For the health claim in new § 101.73, published elsewhere in this issue of the **Federal Register**, which associates dietary lipid intake with an increased risk of coronary heart disease, it may be appropriate, then, to permit as optional information a discussion of how dietary saturated fat, cholesterol, or both, affect blood cholesterol levels and, thereby, the disease that is the subject of the claim. Nevertheless, the agency considers it is inherently misleading for the claim to be articulated as an association between dietary lipids and serum cholesterol because of the potential to confuse consumers about the relevant disease for which the claim is authorized. It is not the biological indicator that is the disease or health-related condition for which the claim is authorized. Where there is no well-documented association or specificity between a biological parameter and a disease or health-related condition and some evidence that improving the parameter improves the condition, the agency will be disinclined to consider a petition for a health claim for that parameter because it fails to meet the definition of a disease or health-related condition.

3. Some comments asked if FDA intended to regard any statements that describe the "special dietary uses" of foods (e.g., hypoallergenic, lactose-free, wheat gluten-free, and dietetic foods) as health claims. The comments were concerned that health claim disqualifying levels would bar many such foods from disclosing dietary information. One of the comments requested that FDA revise the definition of a "health claim" to include advice that a statement in the labeling of a food subject to part 105 (21 CFR part 105) shall not be deemed to be a health claim solely because it represents the food to be for special dietary use.

FDA advises that any statement that appears on the label or in the labeling of a food intended for "special dietary use" that is consistent with provisions of the regulations promulgated under section 403(j) of the act will not be regulated as a health claim by the agency. Thus, such foods will not be subject to health claim disqualifying levels. However, FDA cautions firms that information not specifically provided for by specific regulations for foods for special dietary use may create an express or implied health claim and thereby subject such a food to the provisions of new § 101.14, including the disqualifying levels.

FDA has not revised the final rule to address foods subject to part 105 in the definition of "health claim." The requested revision is unnecessary in view of the agency advice in the previous paragraph. Further, the agency believes the requested revision might mislead some firms to assume that such foods would be exempt from the health claim provisions regardless of the nature of claims appearing in labeling where the claims are not specifically authorized in part 105. In addition, if FDA were to revise the final rule with respect to part 105, the rule should also be revised with respect to other provisions in the act and the regulations promulgated thereunder (e.g., infant formula subject to section 412 of the act (21 U.S.C. 350a)), and the agency does not believe that it would be appropriate to have the rule reference every other similar situation in the regulations in Title 21, Code of Federal Regulations.

D. Implied Health Claims

The agency proposed to define "implied health claim" as:

> • • • those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or would be likely to be understood, to assert a direct beneficial relationship between the presence or level of any substance in the food and a disease or health-related condition.

The agency then provided some examples of such claims—"third party" endorsements, written statements such as a brand name including a term such as "heart," and symbols such as a heart symbol.

1. General

4. Comments varied widely on whether FDA should regulate implied health claims. Some comments, noting the difficulty in specifically defining an implied health claim, suggested that implied health claims should not be regulated under the proposed regulations. One of these comments asserted that FDA could regulate implied health claims only under the general requirement that a label must be truthful and not misleading. However, other comments urged FDA to strictly regulate implied health claims because they have the potential to undermine the sound regulatory approach for explicit health claims.

FDA advises that there is no basis under the act for it not to regulate implied health claims. Regulation of such claims is specifically mandated. Under section 403(r)(1)(B) of the act, a food is misbranded if "• • • a claim is made in the label or labeling of the food which expressly *or by implication* • • •" (emphasis added) characterizes the relationship of any substance to a disease or health-related condition unless the claim is made in accordance with the health claims provisions of the act. Thus, FDA must reject the comments that suggested that it not regulate implied health claims.

5. While a number of comments encouraged FDA to take a broad view of what constitutes an implied claim, other comments argued that any "bright-line" definition of an implied health claim would be too inflexible to enforce fairly because labeling displays can have different meanings in different contexts. Some comments urged that both manufacturers' intent and consumer perception be considered in determining whether an implied claim has been made. One comment proposed that if vendor intent is not considered, then the test should be whether consumers acting reasonably under the circumstances would interpret language on labels or labeling in a particular

fashion and noted that such a test has been applied by the Federal Trade Commission (FTC) in the context of misleading advertising claims. The comment contended that the fact that a few credulous people may perceive a claim in a particular manner should not suffice if the vast majority perceive it otherwise.

FDA agrees that no "bright-line" definition can be established for implied health claims. Labeling claims need to be considered in their entirety and in context to determine if the elements of a health claim are present. FDA has therefore revised the definition of an implied health claim in new § 101.14(a)(1) to clarify that the claim will be evaluated within the context of the total labeling to determine if an implied health claim has been made.

FDA has also revised the list of the types of claims that may be implied claims. The agency has substituted the term "'third party' references" in place of the term "'third party' endorsements" because it has become clear that a third party endorsement is only one type of reference to a third party that may constitute a health claim in the context of the entire labeling. Further, FDA has corrected the phrase "health or disease-related condition" in the definition of an implied health claim in the last sentence in new § 101.14(a)(1) to "disease or health-related condition." FDA had intended to consistently use this latter phrase throughout proposed § 101.14(a)(1), but the terms "disease" and "health" inadvertently were interchanged in the proposal.

In the case of implied claims, FDA will evaluate all of the labeling to determine whether, within the context in which a claim is presented, both basic elements of a health claim are present. Where both elements are present in a product's labeling, the product bears a health claim, regardless of whether one or both of the basic elements are explicit or implied.

In making an evaluation of a claim within the context of the labeling, FDA agrees that it should consider both manufacturer's intent and consumer perception. However, the agency notes that intent means more than the manufacturer's subjective intent. Therefore, the agency concludes that the focus of its determination as to whether a claim is an implied claim should be on what the claim is saying. To be consistent with the definition of "implied nutrient content claim" in new § 101.13(b)(2) in the nutrient content claims document published elsewhere in this issue of the **Federal Register**, the agency is striking the phrase "* * * a manufacturer intends, or would be likely to be understood, to assert * * *" and is replacing it with the word "suggest" in the definition of a health claim in new § 101.14(a)(1). Section 101.14(a)(1) now reads:

Health claim means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

The agency believes that this will clarify what the agency's inquiry will be when it determines whether a claim is an implied claim.

FDA has not used the comment's proposed "reasonable person" test for deciding when a claim is impled. The regulation reflects the fact that courts have construed the act as protecting not just the reasonable person but also the "ignorant, the unthinking and the credulous." (See *United States* v. *an article * * * consisting of 216 cartoned bottles * * * "Sudden Change,"* 409 F.2d 734, 741 (2d Cir. 1969).) Given relevant case law construing the act, it is unnecessary to look to the standard applied by FTC for guidance.

2. Brand names

6. A number of comments asserted that all brand names containing words such as "heart" are inherently misleading and therefore should be banned. Other comments urged FDA to permit the use of words such as "heart" in the brand names of foods only when the food qualifies for an approved heart-related health claim. Other comments maintained that some brands that incorporate the word "heart" (e.g., Sweetheart) have been used for decades in a nonmisleading manner to convey an old-time, homey feeling and therefore should not be banned or construed to be an implied health claim.

FDA does not agree that all brand names containing words such as "heart" are inherently misleading. Certainly where this term is placed on a product that qualifies for an express health claim on cardiovascular disease that is provided for in part 101, subpart E, and where such a claim is appropriately included elsewhere in the labeling, consumers would not be misled by the term "heart." In addition, there may be situations in which, when considered within the context of the full labeling, the term cannot be reasonably understood to be a health claim (e.g., "sweetheart" or "from the heartland of America," where no claims about the fat, cholesterol, or sodium content of the food are made).

However, comments from several consumer, health professional, and regulatory organizations demonstrate that the use of the word "heart" in the brand name of a food may lead consumers to believe that the specific food bearing that brand name has properties deriving from a substance that it contains that are beneficial for reducing the risk of developing a disease or health-related condition, specifically cardiovascular disease. Both basic elements of a health claim may be implied in a brand name containing the term "heart." Therefore, any product bearing such a brand name is subject, depending of course on the full content of the labeling, to be viewed by FDA as bearing an implied health claim. Thus, FDA has retained the term "heart" as an example of what may be an implied claim in the definition of "health claim" in new § 101.14(a)(1) to alert firms to the agency's position on this matter. However, FDA will review the context in which this term is presented and consider how the term would be understood in deciding whether a particular use of the term "heart" or a use of a heart symbol on a particular label is a health claim.

3. Other written statements

7. A number of comments suggested that any statement on a label, including nutrient content claims such as the word "healthy" or other terms that may lead consumers to believe that a food has health benefits, should be regarded as implied health claims. Comments suggested that FDA use broad latitude in considering such words as health claims.

As FDA advised earlier in this preamble, the agency will evaluate all of the labeling to determine whether, within the context in which a claim is presented, both basic elements of a health claim are present. Thus, FDA will take a flexible case-by-case approach to assessing whether labeling contains a health claim.

In the case of the word "healthy," the agency does not believe that the use of this word would normally be a health claim. "'Healthy" has a wide variety of meanings in addition to ones that would satisfy the second basic element of a health claim. For example, "healthy" can certainly imply general nutritional well-being. Thus, while a claim such as "Eat a diet low in fat for a healthy heart" may be a health claim, "Eating

five fruits or vegetables a day is a good way to a healthy lifestyle" is not. Moreover, as explained in the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**, FDA may also regulate the term "healthy" in certain circumstances as an implied nutrient content claim. A proposal on how to define the term in such circumstances appears elsewhere in this issue of the **Federal Register**. The varied uses of the term "healthy" demonstrate the need for FDA to take a flexible case-by-case approach in deciding whether a claim is an implied health claim.

4. Third party references

8. Some comments requested that FDA explain its interpretation of the term "third party endorsement" and clarify when such an endorsement constitutes a health claim. One comment observed that the courts have been careful not to define the concept of "endorsement" too broadly and noted that disclaimers can be used where the perception of endorsement may be construed. Other comments asserted that the mere presence of endorsements should not automatically constitute health claims. One suggested that regulatory limits concerning such endorsements should be set.

FDA agrees that third party endorsements do not automatically constitute health claims. "Funk & Wagnall's Standard Dictionary," Harper Paperbacks, New York, 1980, defines the term "endorse" as "to state one's personal support of (a product) to promote its sale." FDA views third party endorsements as references, made through a name or logo, to a person or organization such as a professional society or association that is independent of the product's manufacturer or distributor, on product labeling or advertising, to promote that organization's approval of a product.

In response to the comments addressing the term "third party endorsements," as explained in the agency's response to comment 5 of this document, the codified language of new § 101.14(a)(1) has been revised to refer to "'third party' references." This term, which includes third party endorsements, better describes the type of information from an organization or individual not directly associated with the manufacturer that may be included in a label and that could constitute an implied or express health claim.

Third party references on food labels include a wide variety of information about diet and general health that is disseminated by reputable public or private organizations. Such information will be regulated as a health claim if, within the context of the total labeling, the third party reference can be reasonably understood to characterize the relationship between a substance and a disease or health-related condition. Thus, an endorsement by the American College of Nutrition or the National Nutritional Foods Association would not, of itself, cause a product to be considered to bear a health claim, even if these organizations were promoting the consumption of a specific food or nutrient, if the resultant claim did not include reference to a disease or health-related condition.

However, a third party endorsement would constitute an implied health claim if the endorsement references a particular food or substance, and the name of the endorsing organization references a particular disease (e.g., American Heart Association). In such an endorsement, both basic elements would be present. As a result, a link would be created between the food/substance and the specific disease that could be reasonably understood by consumers as asserting that the product is useful in reducing the risk of developing that disease.

The following illustration using the National Cancer Institute's (NCI's) Five-a-Day Program (Ref. 27) exemplifies how the context of the label will determine whether a statement is a health claim or dietary guidance. A cereal label that says "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables" is not a health claim because the information cannot be reasonably understood to be about a substance. There is neither a nutrient nor a product-specific element in the claim, and there is therefore no characterization between a substance and the disease included in the name or the organization. However, if the statement said "The National Cancer Institute recommends that you eat five servings daily of fruits and vegetables to increase your intake of fiber," it would be a health claim because of the reference to a specific nutrient, fiber, and to a disease, cancer.

9. Several comments questioned the status of the American Diabetes Association's "Exchange Lists for Meal Planning." One comment questioned the status of the American Diabetes Association's "Self-Test" public awareness program printed on the back of certain cereal boxes, which is designed to enable consumers to recognize diabetes based on warning signs and symptoms of the disease. The comments expressed the belief that these situations should not be interpreted as either an endorsement or a health claim because no claim is made about a specific nutrient in the foods, and no link is created between the products and diabetes. Comments also requested clarification of FDA's position on fund raising activities conducted with the cooperation of manufacturers using organizational logos and messages such as: "A proud sponsor of the American Diabetes Association" or "A contribution from the sale of this product has been made to the American Diabetes Association." The consensus of these comments was that these situations should not be interpreted as endorsements because no claim is made about the nutrient content of the foods, and there is no association between the products and the disease, diabetes mellitus.

FDA recognizes the value that providing exchange lists on food labeling has for certain consumers and advises that the mere inclusion of that information on a food will not, of itself, subject the labeling to the health claim regime. Reference to the exchange lists lacks the substance element of the "health claim" definition because it relates to many foods rather than to a specific food or a nutrient. Such information is instead subject to section 403(j) of the act and, more specifically, to § 105.67 relating to foods for use in the diets of diabetics. Of course, the labeling would be subject to regulation under section 403(r) of the act if the labeling bears any implication that a substance in the food is helpful in reducing the risk of diabetes or any other disease.

In the absence of an explicit or implied reference to a substance in food labeling, the "Self-Test" program and sponsorship/fund raising information also are outside the coverage of section 403(r)(1)(B) of the act. However, labeling for both of these programs would be subject to section 403(a) of the act, which requires that a label be truthful and not misleading, and section 201(n) of the act which describes the circumstances in which labeling is misleading.

10. Some comments requested that paid third party endorsements be prohibited. These comments stated that such references often give the public the impression that endorsed products are superior in terms of health, safety, or nutrition to other foods not bearing the same endorsement, when, in fact, they are not.

FDA has no authority under the act to prohibit either paid or unpaid third party endorsements or references, provided that, when such statements ar- included on food labeling, the

statements are made in a manner that is in compliance with all applicable provisions of the act. However, the agency recognizes that endorsements made for compensation by private organizations or individuals may be misleading to consumers. The agency is advising that when such endorsements are made, a statement should be included in close proximity to the claim, informing consumers that the organization or individual was compensated for the endorsement. Failure to divulge this information on a label that bears a paid endorsement would cause the product to be misbranded under sections 403(a) and 201(n) of the act for failure to reveal a fact that is material.

11. A number of comments suggested that all unpaid endorsements be regarded as explicit health claims.

FDA disagrees, because the issue of whether an endorsement is made in exchange for monetary compensation is not germane to the issue of whether the endorsement or other third party reference constitutes a health claim. As discussed in the response to comment 8 of this document, for a third party reference to be a health claim, two criteria must be met. There must be an implied or explicit reference to both a substance and to a disease or health-related condition. In the absence of these elements, a third party reference is not a health claim, regardless of any financial arrangement that may have been entered into before making the endorsement.

12. Other comments urged FDA to allow the use of third party endorsements of specific products. Many of these comments asserted that references from credible health organizations reduce or eliminate consumer confusion about specific products, provide useful and relevant information about products, and assist consumers in making healthy food choices. The comments also argued that the use of third party endorsements and references should also encourage the development of new products that attract such endorsements.

FDA has no basis in principle for objecting to the use of third party endorsements and other third party references for specific products, provided that such references are made in compliance with all applicable provisions of the act, including the nutrient content claims and health claims requirements of the 1990 amendments and sections 403(a) and 201(n) of the act. The agency is aware of the potential impact of the 1990 amendments on the development of more healthful products that will appeal to consumers and encourage people to improve their eating habits. In the Congressional Record of October 24, 1990, Senator Hatch (Ref. 2) stated:

> * * * manufacturers should have the economic incentives they need to be creative and innovative so that more and more low-fat, reduced sodium, and high-fiber foods come into the market. We should not deter such benefits for the consumer.

FDA is very much in favor of product innovation as a means of bringing more healthful products to the American public and recognizes that appropriate and lawful third party endorsements may have some potential to stimulate innovation and play a useful role in educating consumers about the importance of developing diets that will improve their health.

13. A number of comments recommended that FDA selectively designate which governmental and nongovernmental organizations are allowed to make third party endorsements. One comment suggested that FDA require organizations that grant endorsements to have the expertise in the area in question as well as a formal product approval process. The organization should actively disseminate additional explanatory information concerning the meaning of the endorsement and manner of its use. Other comments recommended that third party endorsements be considered to be misleading unless the reason for the presence of the endorsement is clearly explained (including but not limited to disclosure of financial arrangements).

With the exception of disclosing the fact that an endorsement has been paid for, as discussed in comment 10 of this document, FDA believes that it lacks the factual and legal basis at this time for imposing such requirements on third party endorsements. FDA recognizes, however, that third party references have significant potential to be abused or to be misleading if, for example, they come from organizations or programs that exist primarily for commerical or marketing purposes, they are not based on sound nutritional criteria, or they appear on products that are not appropriate in light of the actual or implied nutritional purpose underlying the endorsement. Therefore, the agency will closely monitor the use of endorsements on food labels. Interested persons should submit their views on the need for additional regulatory controls to the Center for Food Safety and Applied Nutrition. FDA intends to consider in a future rulemaking proceeding whether additional criteria or controls are necessary.

In the meantime, any labeling generated with a third party endorsement or reference would be subject to regulation under sections 201(n) and 403(a) of the act and must, therefore, be truthful and not misleading. Further, if the reference meets the definition of a nutrient content claim or a health claim, such a claim must be consistent with FDA's regulations.

14. A number of comments suggested that all written health claims be banned in favor of third party endorsements. One of the comments favored allowing third parties, such as the American Heart Association and the American Dental Association, to independently review products and to place their logos on the labeling if they determine that use of the product would be helpful in reducing the risk of their specialty disease.

FDA has an obligation under the act to ensure that health claims comply with section 403(r) of the act, and that they are truthful and not misleading under section 403(a). Delegation of this responsibility to private organizations associated with specific diseases would not be consistent with the act. Such organizations are free to submit well-supported petitions pertaining to the health benefits of any substance to FDA, as provided for in new § 101.70. However, FDA will always have the obligation of ensuring compliance with the act.

5. Symbols

In the preamble to the proposed rule (56 FR 60537 at 60542), FDA recognized that there is often ambiguity in the message conveyed by a symbol or logo and solicited comments on the appropriate meaning to be attributed to a heart symbol and other currently used logos and symbols. The agency also invited comments on the issue of how logos should be regarded: as nutrient content claims, health claims, or both? The comments, which are summarized below, ranged from those that wanted strict regulation of symbols to those that felt symbols should not be regulated as health claims. Many comments took an intermediate position, arguing that symbols should be evaluated within the context of total labeling.

15. Many comments supported FDA's proposal to regulate symbols as health claims. These comments stated that the uncontrolled use of medical symbols (e.g., a heart or an electrocardiogram (EKG)) should not be permitted. Some comments suggested that symbols be allowed only when the food qualifies for the health claim implied by the symbol, and then only if they are not misleading

and increase consumers' comprehension of the claim.

Many industry comments argued that symbols cannot practicably be included in the definition of a health claim. One comment pointed out that candy packages bearing a heart symbol near Valentine's Day should not be regulated as an implied health claim. Another comment cited examples where the heart symbol may do nothing more than operate as a design motif with no implicit health claim (e.g., the combination of a heart symbol plus the statement "Hey Fudge Lovers! More Fudge Filling!"). The comments maintained that any analysis of how the symbol is construed must focus on the entire label, not on an isolated aspect of it.

FDA agrees that a determination as to whether a symbol constitutes a health claim must be made based on the entire food label. As explained in the response to comment 5 of this document, FDA has provided for such flexibility by revising new § 101.14(a)(1) to state:

> Implied health claims include those statements, symbols, vignettes, or other forms of communication that a manufacturer intends, or that would be reasonably understood in the context in which they are presented, to assert a relationship between the presence or level of a substance in the food and a disease or health-related condition.

"Funk & Wagnall's Standard Dictionary" defines the term "symbol" as "something chosen to represent something else; esp., an object used to typify a quality, abstract idea, etc." Determining whether a symbol on a label represents an implied health claim requires an evaluation of all of the labeling to ascertain whether, within the context of that labeling, the presence of that symbol results in both basic elements of a health claim being present in the labeling.

Because of the abstract nature of symbols, they have considerable potential for conveying a wide variety of meanings on labeling. As the comments pointed out, the same symbol on a food label may have a multitude of meanings for the same food as the context of the labeling is changed from one label to another. Certainly, the combination of a heart symbol and the statement "Hey Fudge Lovers!" on a food containing fudge adequately explains the meaning of the heart symbol and prevents consumers from being misled about its meaning. Under such circumstances, the heart symbol would not convey either of the basic elements of a health claim. The statement "Hey Fudge Lovers!" clarifies that the symbol does not refer to a substance in the specific food bearing the symbol or to any health benefits from consuming that food.

However, if the statement "Hey Fudge Lovers!" does not appear on the product, and no other explanation of the heart symbol appears on the labeling, the context of the labeling no longer explains the meaning of the symbol. Under such circumstances, the symbol may well be perceived by consumers in a wide variety of ways, many of which would not be true. FDA believes that most of the perceptions about heart symbols fall under the regulatory regime of a health claim. For example, consumers may logically assume that the symbol is equivalent to the term "heart." Under such circumstances, these consumers may conclude that the symbol means that the food has properties that are beneficial for reducing the risk of developing a disease or health-related condition, specifically cardiovascular disease. Thus, the second basic element (i.e., disease or health-related condition) would be conveyed by the symbol. Further, the first basic element (i.e., substance) would also be present. In the absence of an explanation for the symbol, consumers would likely infer that the symbol pertains to the specific food bearing the symbol and to the substances that it contains. Thus, both basic elements of a health claim can be implied through the unexplained presence of a heart symbol on a label.

Even if the heart symbol is not perceived by some as a health claim, the symbol would still be misleading within the meaning of section 403(a)(1) of the act because the context of the labeling would not explain what the symbol means and thus would fail to disclose a material fact. Accordingly, FDA advises that the use of health-related symbols in food labeling without some clarification of their meaning in context is likely to cause the food to be misbranded.

Similarly, an EKG (a record of the electrical current produced by the action of the heart muscle) also constitutes a health claim where the context of the labeling does not explain the meaning of the EKG. Although it is unlikely that most consumers would be able to interpret an EKG reading as representing a healthy or unhealthy heart, most consumers would probably make a connection between an EKG graph and heart function. Under such circumstances, the symbol alone could lead consumers to believe that a substance in the product is related to the risk of cardiovascular disease and thereby constitute a health claim.

Of course, symbols with specific reference to nutrients may also constitute health claims. For example, a heart on a label that also makes a claim that the product is low in fat would be an implied health claim. The explicit nutrient content claim would satisfy the substance basic element, and the disease or health-related basic element would be provided by the symbol because it implies that the low level of fat has a beneficial effect relative to a disease of the heart. (This decision assumes the label does not contain sufficiently clarifying information to change the meaning of the heart symbol, so that the symbol would not constitute a basic element.)

However, in some circumstances, the context of the labeling may make it obvious that there is no connection between the symbol and a substance in the food or between the symbol and a disease or health-related condition. In such a situation, the symbol would not constitute an implied claim. For example, a heart shaped box of candy or a heart shaped candy, whose label does not include an explicit or implied reference to a disease or health-related condition, would not be an implied claim.

In addition, some symbols, such as the U.S. Department of Agriculture/Department of Health and Human Services (USDA/DHHS) Health Pyramid, a symbol for the American Heart Association, or a symbol for the American Cancer Society, may not constitute health claims when the labeling contains no other references to a substance or a disease or health-related condition. In all of these situations, the organizations provide general dietary guidance for good health. Thus, consumers should not assume from the name of the organization that the symbol implies an association with the disease or health-related condition basic element.

When symbols constitute a health claim, they should only be used on foods that qualify for the express claim they represent. Since it is unlikely that a symbol alone can convey all the information necessary as part of a health claim, health claims implied by symbols must be accompanied by a written message that includes the essential elements of the claim authorized by FDA's regulations in part 101, subpart E. To prevent misinterpretation of the claim by consumers, this message should be located in close proximity to the symbol but could be located in other labeling provided that a reference statement appears next to the symbol. The appropriate content of health claims reference statements is discussed subsequently in section V.C. of this preamble. FDA has revised the

provision of the final rule addressing reference statements in new § 101.14(d)(2)(iv) to provide that such statements shall appear in immediate proximity to the graphic material (e.g., symbol). Anyone wishing to use a symbol alone to deliver a health claim may submit a petition with supporting data that demonstrate that the essential elements of the health claim are conveyed to consumers by the proposed symbol.

FDA recognizes that symbols are an important means of conveying information to consumers, and that they are useful when used in a truthful and nonmisleading manner. The agency will continue to protect the interests of the public by monitoring the use of symbols and will take appropriate action under either section 403(a) or (r) of the act when symbols are used to mislead consumers.

16. Some comments proposed that, if symbols such as a heart are to be regulated as implied health claims, products that bore such symbols before the implementation of the regulation should be exempted from the health claims regime.

Although the statute provides very explicit guidance regarding grandfathering of nutrient content claims in sections 403(r)(2)(C) and (r)(2)(D) of the act, it is silent with respect to any such provision regarding health claims. In light of this omission, it is clear that Congress did not intend to provide such relief for labeling making either implied or explicit health claims (see *Andrus* v. *Glover*, 446 U.S. 608 (1980)). Further, grandfathering of labels that do not qualify to bear an implied health claim would result in confusion on the part of consumers and reduce the credibility of symbols on food labels that are eligible to bear such claims. Therefore, FDA is rejecting this proposal.

17. Several comments suggested that the final rules should make some provision for the use of FDA standardized symbols and logos on products that would qualify for health claims. The comments stated that such logos and symbols would help individuals with poor reading skills plan a more healthful diet, although they did not make clear whether the use of symbols and logos should be optional or mandatory.

As stated above, FDA recognizes the value that symbols and emblems have in promoting good health and dietary guidelines to consumers. However, at this time the agency feels that it is inappropriate to permit an emblem alone to deliver the substance of a health claim, and it would be difficult for FDA to design standardized symbols or logos in a manner that would be in compliance with the statute. Section 403(r)(3)(B)(iii) of the act requires that a health claim be accurate and comprehensible within the context of the daily diet. New § 101.14(d)(2)(iii) requires the inclusion of factors other than consumption of the substance when such factors affect the substance-disease relationship (e.g., exercise).

Further, under section 201(n) of the act, labeling can be misleading based on what is omitted as well as on what appears on the label. Designing an emblem that would deliver the message required by the act while also meeting the criterion of being truthful and not misleading, as mandated by section 403(a)(1) of the act, would be extremely difficult.

However, the agency will consider petitions for use of a symbol or emblem for approved claims or as part of a new health claim petition, provided that appropriate data are submitted that provide the agency with some assurance that consumers accurately interpret the claim. Such data should include the results of tests using the suggested symbol.

6. Dietary guidance

As FDA explained earlier in this preamble, when the proposal was issued, FDA had not yet decided how certain types of claims should be regulated when they pertain to truthful information about health and diet and are not in the form of an explicit health claim. FDA referred to "dietary guidance" as a class of claims that might not be regulated under section 403(r) of the act. The agency cited the NCI "Five-A-Day" program as an example of dietary guidance that is not a health claim. Unfortunately, use of that program as an example created confusion because, even though most of the messages in the program only encouraged consumers to eat fruits and vegetables, a small number of the messages refer to nutrients (e.g., fiber) and disease (cancer).

Further, use of the term "dietary guidance" to describe claims that do not constitute "health claims" is also confusing because "health claims" themselves provide a form of dietary guidance. In addition to "health claims" and "dietary guidance," there is a broader class of claims that encompasses all other truthful information about diet and health as well as drug claims. In view of the overlapping nature of these categories of claims, it is understandable that there was considerable confusion among the comments about "dietary guidance."

For the sake of clarity in this preamble, FDA will use the term "dietary guidance" to refer to claims that do not contain both basic elements of a health claim and are therefore not "health claims." However, use of this term in the comments may, or may not, have encompassed a "health claim." FDA will attempt to clarify the use of the term by the comments in the summaries to the comments.

18. Some comments asserted that dietary recommendations that relate to a specific disease but provide guidance concerning general food choices without unduly emphasizing a particular substance, or recommendations that emphasize a particular substance but are related to a variety of diseases or to a healthy lifestyle in general, should not constitute implied health claims.

As discussed in the response to comment 1 of this document, claims that do not satisfy either the substance element or the disease or health-related condition element of the "health claim" definition are not health claims. Accordingly, claims that provide guidance about a general food choice or about how to achieve a healthy lifestyle would not be health claims. Claims that are related to a variety of diseases are likely to be health claims, although a specific determination will be made based on the context in which a claim is made and on its specific content.

19. A number of comments contended that the agency unjustly regulated accessibility to recommendations from authorities, such as the National Institutes of Health and USDA. Most comments felt that such dietary guidance should not be regulated as health claims on food labeling because such regulation would discourage education of the public on sound nutrition practices. One comment suggested that the furtherance of consumer information was mandated under the 1990 amendments and asserted that industry and FDA need to focus more attention on the education authority provided therein. This comment and others stated that public health organizations, such as NCI, can more effectively reach consumers with valuable advice if products that fit into their recommendations are free to display this information on their labels, and that consumers are more likely to notice and appreciate recommendations from a respected source. Other comments felt that nongovernmental sources (e.g., the American Dietetic Association and the American Heart Association) also provide credible dietary guidance.

FDA has reconsidered the tentative position that it took in the proposal (56

FR 60537 at 60555) that references to programs sponsored by such organization as the American College of Nutrition, the American Heart Association, the American Medical Association ("Campaign Against Cholesterol"), and the American Medical Women's Association would always be regulated as implied health claims. The comments have convinced the agency that it would not be appropriate to establish by regulation the specific types of statements that may be used on food labeling concerning either Federal programs or private sector programs because the guidance offered by such organizations may not include a reference to a substance or to a disease or health-related condition. The agency has therefore concluded that publicly available dietary information provided to consumers by Federal or private programs and used in food labeling by manufacturers may be either dietary guidance or a health claim depending upon the content of the information and the context in which it is presented in the labeling.

In taking this position, FDA hopes to encourage the dissemination of information to consumers regarding nutrition and health that has been provided by such sources as the U.S. Surgeon General, the National Academy of Sciences, USDA/DHHS Dietary Guidelines, NRC, and the National Cholesterol Education Program. However, information from such programs presented in labeling in a context that includes explicit or implicit references to both elements of a health claim is subject to the health claims provisions of the act.

20. Many consumers asserted that dietary supplements, including supplements containing herbs, should be permitted to include all types of nutritional and dietary guidance in their labeling, including information based on folklore and historical use, provided that the claims are made truthfully. These comments maintained that such information is essential to making informed choices of such alternatives to conventional drug therapies.

Manufacturers of dietary supplements are free to provide dietary guidance within the regulatory framework discussed above. However, if a product's labeling characterizes the relationship between a disease or health-related condition and a substance, the product will be subject to the provisions of section 403(r) of the act, although in the case of dietary supplements they will not be subject to section 403(r) of the act until the expiration of the moratorium established by the DS Act. If the claim reveals that the product is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of a disease, the product, like any other product that does so, is a drug under section 201(g)(1)(B) of the act. When the moratorium expires, and subject to the regulations in place at that time, supplement and herb manufacturers, like all other food manufacturers, will be welcome to submit health claim petitions that establish the validity of claims that characterize the relationship of a substance to a disease or a health-related condition.

E. Definition of Nutritive Value

21. A number of comments asserted that FDA's definition of "nutritive value" in proposed § 101.14(a)(3) is unduly restrictive and does not fully recognize the important role that nutrients play in helping to reduce the risk of chronic disease. Other comments requested that FDA state in the definition that the list of processes cited is not all-inclusive. Another comment asked that the proposed rule be modified to specifically recognize the nutritive value of fat substitutes (triglycerides and other substances that contain fatty acids but are modified in ways that limit the bioavailability of those acids).

FDA recognizes that certain substances can play a major role in reducing the risk of certain chronic diseases and may confer their benefits through a number of processes. Accordingly, the agency has worded the definition of "nutritive value" in new § 101.14(a)(3) to provide significant flexibility in determining whether a substance possesses such value. FDA used the phrase "such * * * as" in the definition to insure that the three referenced processes will be understood to be general examples of the ways in which a substance may legitimately confer nutritive value, rather than as an all-inclusive list.

The agency believes that it is inappropriate to codify findings of nutritive value for specific substances. Such findings would only serve to undermine the intended flexibility of the definition because an extended listing of those substances that possess nutritive value could be interpreted as an exclusive list.

FDA considers it more appropriate for the agency to evaluate the nutritive value of substances that are the subjects of health claim petitions on a case-by-case basis. This approach will best ensure that the definition retains its intended flexibility and does not become an unintentional barrier to the approval of legitimate health claims.

F. Definition of Dietary Supplement

22. A number of comments suggested that the proposed definition of "dietary supplement" in proposed § 101.14(a)(4) should be revised to include foods as well as components in foods (e.g., herbs as well as components in herbs).

FDA advises that the proposed definition of "dietary supplement" already covers foods. Reference to a "component" with nutritive value encompasses the specific portion of the food, that is, of the dietary supplement, responsible for this value. Under section 201(f)(3) of the act, a component of a food is itself a food. However, because of the provisions of the DS Act, FDA is not adopting § 101.14(a)(4) at this time. FDA will reach a final decision on the appropriate definition of this term following in accordance with the provisions of the DS Act.

G. Definition of Disqualifying Nutrient Levels

As proposed, "disqualifying nutrient levels" was defined in proposed § 101.14(a)(5) as:

> *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 11.5 grams (g) of fat, 4.0 g of saturated fat, 45 milligrams (mg) of cholesterol, or 360 mg of sodium, per reference amount commonly consumed, per label serving size, and per 100 g. Any one of the levels, on a per reference amount commonly consumed, a per label serving size or a per 100 g basis, will disqualify a food from making a health claim.

For consistency with the final rule on serving sizes published elsewhere in this issue of the **Federal Register**, the word "commonly" in the term "reference amount commonly consumed" in the definition above is corrected to read "customarily."

1. Consistency with statute

23. Most industry comments contended that the proposed definition of "disqualifying nutrient levels" in proposed § 101.14(a)(5) is either overly restrictive or inconsistent with the statutory provision of section 403(r)(3)(A)(ii) of the act. The comments based their arguments on the language of the provision that provides that a health claim cannot be made by a food that contains "any nutrient in an amount which increases * * * the risk of a disease or a health related condition." Several comments stated that the agency correctly acknowledged that there are no generally recognized levels at which nutrients in an individual food pose an increased risk of disease, although there are

recommended levels associated with decreased risk of disease for dietary intake of total fat, saturated fat, cholesterol, and sodium. A number of these comments argued that the acknowledgment by FDA of a lack of recognized risk levels in an individual food should prevent the agency from establishing any disqualifying nutrient levels because the 1990 amendments require FDA to consider whether the individual food for which the claim is made contains a nutrient at a level that increases to persons in the general population the risk of a diet-related disease, taking into account the significance of the food in the total daily diet.

The comments argued that single foods, even when their significance in the total daily diet is considered, do not increase disease risk because only total diets consisting of many foods consumed over time have that potential. Thus, these comments argued that FDA cannot reasonably take the position that the analysis upon which the proposed disqualifying levels are based constitutes a credible scientific determination that the specific levels are the levels that, if exceeded in an individual food, increase the risk of disease in the general population. Other comments stated that if the agency believes that it has in fact determined levels that will increase the risk of diet related disease when present in individual foods, then either the marketing of such foods should be disallowed under the act by virtue of their being injurious to health under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)), or warning labeling should be required on all foods containing such levels regardless of whether they contain health claims.

Some comments asserted that Congress intended for FDA to disallow a health claim on the basis of disqualifying nutrient content only if there exists an actual risk as determined by the analysis of actual consumption data for the specific food, and not as determined from models based on theoretical diets and extrapolation. Therefore, these comments argued that disallowing health claims on the basis of theoretically-derived nutrient disqualifying levels is contrary to the legislative intent of section 403(r)(3)(A)(ii) of the act, which reads, "If the Secretary determines * * *" and not "The Secretary shall determine * * *." These comments maintained that FDA had failed to show that a person exposed to foods with levels of fat, saturated fat, cholesterol, and sodium above the disqualifying levels were actually at an increased risk for various diseases and maintained that such an actual risk must be shown for FDA to legally establish disqualifying levels for these nutrients.

One comment noted that FDA's proposed model health claims emphasize the role of the total diet in reducing the risk of various diseases and do not allow manufacturers to claim that an individual food will reduce the risk. The comment stated that it was ironic and inappropriate, then, that FDA would single out individual foods as increasing the risk of those same diseases, and set disqualifier levels for those foods. Other comments agreed, saying that an individual food could no more cause a disease than prevent one.

FDA disagrees that the 1990 amendments require that FDA consider whether the individual food for which the claim is made contains a nutrient at a level that increases to persons in the general population the risk of a diet-related disease. There is nothing in the legislative history of the 1990 amendments that would support such a contention. To the contrary, the legislative history and the language of the statutory provision that ultimately resulted suggest that Congress intended that the risk of diet-related disease be considered in a far broader context than that of an individual food. Section 403(r)(3)(A)(ii) of the act states that the risk of a disease or health-related condition be considered "* * * taking into account the significance of the food in the total daily diet * * *." Thus, FDA must consider the role that a particular food plays in the total diet, and the effect that its nutrient levels will have on a person's ability to structure a healthy diet in making a determination under section 403(r)(3)(A)(ii) of the act. That provision contains no language implying that risk should be considered in terms of the immediate impact of consuming the particular food at issue.

Further, if Congress had been concerned about the impact of consuming a nutrient in a particular food, it would not have provided an exemption to disqualification in section 403(r)(3)(A)(ii) of the act when FDA finds that a claim will assist consumers in maintaining healthy dietary practices. Under the comment's view of this provision, no such circumstances could exist. Similarly, Congress would not have elected to provide for nutrient content claims with only disclosure requirements for such nutrients in section 403(r)(2)(B) of the act if the risk from a particular food was the concern that it was addressing. Further, if risk from a particular food was its concern, Congress would not have exempted nutrient content claims on restaurant foods from these disclosure requirements (see section 403(r)(5)(B) of the act).

Congress intended that health claims would not merely provide information on particular substance-disease relationships, but that they would help individuals to maintain healthy dietary practices. The House Report (Ref. 1) states:

> * * * Health claims supported by significant scientific agreement can reinforce the Surgeon General recommendations and help Americans to maintain a balanced and healthful diet * * *.

Health claims on foods with levels of fat, saturated fat, cholesterol, or sodium that exceed the disqualifying levels will make it much more difficult for consumers to follow the Surgeon General's recommendations and to construct a healthy diet. An increase in risk in a diet-related disease follows as a result. All references in the legislative history concerning the meaning of section 403(r)(3)(A)(ii) of the act show that Congress was concerned with general levels of nutrients in broad food classes that could increase risk rather than levels of nutrients that could increase risk from individual foods. For example, the House Report (Ref. 1), in addressing the meaning of this provision, states:

> By requiring the Secretary to decide this issue in the total daily diet, the bill permits the Secretary to differentiate between different foods which have the same level of a nutrient. For example, a particular level of fat in a frozen dinner might not trigger the provision [disqualification], whereas the same amount of fat in a snack food product might trigger it.

Further, in testimony presented before the House of Representatives on a predecessor bill to the 1990 amendments (Ref. 24), a consumer organization identified ways by which health claims on products in the U.S. marketplace can deceive consumers. One such way was for a product to highlight a characteristic that may help reduce the risk of a disease but remain silent about another characteristic that may affect the risk of the same, or another, disease. An example cited in the testimony was a breakfast cereal bearing a health claim approved by NCI on the association between dietary fiber and cancer while containing 4 g of fat per serving—an amount characterized as quite high for a breakfast cereal. In testimony presented before the Senate on a predecessor Senate bill to the 1990 amendments (Ref. 25), another consumer organization stated that a health claim on a product must provide consumers with the assurance that the

product does not also contain properties that are potentially harmful to health. The testimony continued:

> But a health claim on whole milk, promoting its calcium content [relative to osteoporosis], could encourage consumption of a product high in saturated fat. Low-fat milk has all the benefits of whole milk, without the accompanying risks, and would be a more appropriate vehicle for health claim labeling.

Congress obviously recognized the fact that, as pointed out in some of the comments, single foods, when their significance in the total daily diet is considered, do not generally increase disease risk. It is the total diet, consisting of a number of foods consumed over time, that has the potential to increase disease risk. Thus, FDA believes that the purpose of section 403(r)(3)(A)(ii) of the act is to ensure that FDA establishes appropriate disqualifying levels for those nutrients that have the potential, at high levels of consumption, to increase disease risk so that consumers who rely on health claims will be consuming foods that will assist them in meeting dietary guidelines in constructing their total daily diet, and not foods that make it more difficult to do so.

FDA also does not agree that Congress intended that section 403(r)(3)(A)(ii) of the act only prohibit health claims where the level of risk from a nutrient is sufficient to invoke the adulteration provisions of the act. Disqualifying levels in no way should be construed as nutrient levels that FDA believes are harmful in an individual food. The House Report (Ref. 1) explains that this provision pertains to nutrients required to appear on the label and specifically points out that certain levels of fat in foods may trigger this provision. Foods that are 100 percent fat are still safe and lawful under the act. FDA believes that fat was cited to make it obvious that the provision is intended to provide a measure of control for diet-related diseases that are influenced by excessive consumption of safe and lawful nutrients.

In appropriate amounts, such nutrients have a necessary or useful place in the total daily diet. In fact, where the only safety issue is an increased risk of a chronic disease from excessive consumption, the safety provisions of the act would not provide regulatory sanctions against such components of foods, at least if they have not been added to foods. For such components, FDA must show that the component is a poisonous or deleterious substance that would ordinarily render the food injurious to health. If Congress had intended that section 403(r)(3)(A)(ii) of the act to prohibit health claims only where the level of risk from a nutrient is sufficient to invoke regulatory sanctions, the provision would have been unnecessary. Clearly, Congress had something else in mind.

The agency also disagrees with the comments that argue that FDA developed disqualifying nutrient levels based on a misconstruction of the statutory language and intent of section 403(r)(3)(A)(ii) of the act. That section does not read, as one comment stated, that disqualifying nutrient levels may be established * * * "if the Secretary determines * * *." Instead, it states that a health claim may only be made "* * * if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount that increases to persons in the general population the risk of a disease or health-related condition which is diet related * * *." FDA believes that the most straightforward reading of this provision is as an instruction to the agency to establish a list of levels of nutrients in food that, taking into account the makeup of the total daily diet, increase to persons in the general population the risk of diet-related diseases or health-related conditions.

In addition, the agency disagrees with the contention that the definition of "disqualifying nutrient levels" is either overly restrictive or based on an inappropriate scientific basis. The agency stated in the November 1991 proposal that although there are well-established recommendations for dietary intake for fat, saturated fat, cholesterol, and sodium that are consistent with maintaining good health, there are no levels for these nutrients in an individual food generally recognized by the health community to pose an increased risk of disease. However, this statement was intended to point out that scientists have not developed a scheme for transposing quantitative information on the nutrient content of a diet to comparable quantitative information for the broad array of individual foods as they may fit within the context of a healthful diet. Because of this fact, the agency stated in the November 1991 proposal that it did not know of an established or accepted approach for identifying levels for fat, saturated fat, cholesterol, and sodium in an individual food that would increase the risk of a diet-related disease and that would, therefore, disqualify that food from bearing a health claim. In the absence of an established approach, FDA arrived at an approach in which the amounts of fat, saturated fat, cholesterol, and sodium that the agency proposed as disqualifying nutrient levels were the amounts that, in a single food, would make it difficult to construct a diet that meets dietary guidelines, particularly if consumption of the food is encouraged and emphasized by a health claim. Because the guidelines identify dietary levels for specific nutrients (e.g., saturated fat) for which higher levels of intake are linked to an increased risk for a diet-related disease (e.g., heart disease), failure to meet them can reasonably be expected to increase the risk of a disease. Indepth discussions of the agency's conclusions about risk inherently associated with each of the disqualifying nutrients appear elsewhere in this issue of the **Federal Register** in the preambles of the final rules for health claims for dietary lipids and cardiovascular disease, dietary lipids and cancer, and sodium and hypertension.

Accordingly, the definition for disqualifying nutrient levels is fully consistent with the information contained in the legislative history of the 1990 amendments.

2. Disclose rather than disqualify

24. Several comments suggested that Congress sought through the exception process permitted by section 403(r)(3)(A)(ii) of the act to limit the disqualifying effect of nutrient levels to only those nutrients that have a direct effect on the disease that is the subject of the health claim. Some comments suggested that the agency should have utilized the flexibility accorded by Congress to opt for disclosure of nutrients that are not directly related to the disease mentioned in a claim, rather than disqualification of the product from bearing any health claim. In support of their position, the comments cited the discussion on section 403(r)(3)(A)(ii) of the act contained in the House Report on the 1990 amendments (Ref. 1). Comments argued that even though sodium is linked to hypertension, which is a risk factor for heart disease, a product with high sodium content should not be disqualified from bearing a claim about dietary lipids and heart disease because of the lack of major linkage between sodium as a causative factor for heart disease. Another comment, which asserted that prohibiting an osteoporosis claim for whole milk would be misleading because none of the disqualifying levels have any relevance to osteoporosis, also maintained that FDA had made no room for the disclosure permitted by section 403(r)(3)(A)(ii) of the act for a food

containing a nutrient exceeding the disqualifying level.

The agency disagrees with these comments. Section 403(r)(3)(A)(ii) of the act states that a health claim "may only be made if the food for which the claim is made does not contain * * * *any* nutrient in an amount which increases to persons in the general population the risk of *a* disease or health-related condition which is diet related * * *" (emphasis added). That language is clear in that it does not permit a claim for a product containing a nutrient that increases the risk of any diet-related disease or condition and is not limited to a substance that is associated only with the subject disease. The provision then goes on to state that exceptions to this requirement may be made by regulation in the interest of providing consumers with information in maintaining healthy dietary practices. Contrary to the assertion by one comment, FDA provided for the disclosure permitted by section 403(r)(3)(A)(ii) of the act for a food containing a nutrient exceeding the disqualifying level in proposed § 101.14(e)(3).

Because of the time constraints for issuing regulations on health claims, the agency did not exercise the option to develop exceptions to disqualifying nutrient levels. Nevertheless, the changes made in the disqualifying levels that are explained in response to comments 29 and 32 of this document will reduce, but may not eliminate, any need to develop exceptions to disqualifying levels. With those changes, the number of foods that would be disqualified from making a claim will decrease significantly.

Even though § 101.14(e)(3) provides for exceptions from disqualifying levels and the use of an appropriate referral statement, FDA believes that the use of disqualifying levels will be clearer if § 101.14(a)(5) also reflects the fact that exceptions are possible. Thus, FDA has revised this section to state that exceptions to the disqualifying levels may be provided in the specific health claim regulations in part 101, subpart E. The agency will be receptive to petitions that present the reasons that, and the circumstances in which, an exception to disqualification would assist consumers in maintaining a healthy diet.

3. Additional disqualifiers

25. Several comments recommended that health claims be prohibited in labeling for candies, soft drinks, and other sugars-containing foods on the basis of added sugars content. Some comments stated that a Daily Reference Value (DRV) of 50 g for added sugars should be established, and they recommended a disqualifying nutrient level of 8 g of added sugars. This disqualifying level would represent 15 percent of the DRV recommended by the comments. The comments noted that sugars have been associated with the development of plaque, dental caries, and periodontal disease and further noted that the Dietary Guidelines for Americans (Ref. 7) urges the public to consume sugars only in moderation. Another comment asserted that health claims should not be allowed on the label or labeling of a food when more than 15 percent of the food's total calories is contributed by added sugars.

The agency finds that it would not be appropriate to limit health claims on foods on the basis of added sugars either in terms of an absolute amount per serving or as a function of percent of calories per serving. In determining the disqualifying nutrient levels for fat, saturated fat, cholesterol, and sodium, the agency used an approach based on the DRV's for these nutrients. As explained in the proposal to establish DRV's (55 FR 29476), the values for fat, saturated fat, cholesterol, and sodium were based on recommendations that American consumers limit or reduce dietary intake of these nutrients in order to lower their risk of a number of diet-related diseases whose incidence in the general population is considered by the vast majority of public health experts to be unacceptably high. Such recommendations were derived from two publications: The Surgeon General's report (Ref. 5) and the Diet and Health report (Ref. 6) and are reflected in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7). One of these recommendations, for example, is for Americans to reduce dietary fat intake from about 37 percent of total energy intake to 30 percent or less. Accordingly, the DRV for total fat is derived from the recommendation that daily total fat intake not to exceed 30 percent of calories. This and other recommendations are believed to have the potential for a substantial reduction in the risk of diet-related chronic diseases in the general population.

Of the comments recommending a DRV of 50 g of added sugars as the basis for a disqualifying level of 8 g, only one provided a rationale for the suggestion. The comment arrived at its recommendation by first estimating in a nonrigorous fashion that the current consumption level is about 100 g per day. The comment then offered that, because FDA concluded in a 1986 report (Ref. 28) that the average American consumes 53 g of added sugars per day, one-half of their 100 g estimate is close to 53 g which should be rounded to 50 g to become the DRV. It offered that, if the agency sets the DRV for added sugars at what the agency considers to be a current consumption level, it would be difficult to argue that the agency has restricted sugars intake too severely.

FDA does not believe that a disqualifying level for sugars can presently be established because of the lack of suitable criteria in the aforementioned comment on which to base a DRV. Even if the comment's estimate of current consumption is scientifically sound, it is significant that no other DRV has been established with average daily consumption as the criterion. Moreover, the public health community has not identified a dietary level above which consumption of sugars has been demonstrated to increase the risk of a disease. Thus, the agency finds that there is no sound basis on which to establish the requested DRV for sugars. Accordingly, the agency is declining to set a disqualifying level for added sugars at this time. Nevertheless, the agency points out that the criteria established in response to comment 87 of this document for limiting health claims based on the nutritional value of a food will provide at least some of the relief requested in that a food fabricated with sugars and few other nutrients will not qualify for a claim.

26. A few comments recommended that FDA prohibit health claims on foods containing any "unnecessary substances," food or color additives or flavor enhancers. One of these comments justified the recommendation by stating that saccharin is associated with a major disease.

FDA does not believe it is appropriate for it to judge whether use of an ingredient is necessary, or to make the mere presence of a food additive disqualify foods from bearing health claims unless the use of the food additive has not been listed by FDA for use in food under section 409 of the act (21 U.S.C. 348). When it passed the Food Additives Amendment in 1958, Congress concluded that use of food additives is in the public interest, provided that their use is safe and not deceptive. For those comments concerned about the safety of food and color additives, the agency advises that the act requires that the use of these additives be shown to be safe before they are listed for use in food. Other ingredients that may be added to food are limited to those that are generally recognized as safe (GRAS) by the scientific community by virtue of their history of use or other scientific knowledge (i.e., GRAS), or whose use

was sanctioned by FDA or USDA before the enactment of the Food Additives Amendment (i.e., prior sanctioned ingredients).

With respect to the comments that specifically mentioned saccharin, FDA did propose on April 15, 1977 (42 FR 19996), to ban its use, based on its interpretation of evidence available from animal studies at that time. However, Congress decided that the additive should be permitted in food and blocked the proposed ban through enactment of the Saccharin Study and Labeling Act. Therefore, unless there is a change in its legal status, the use of saccharin in compliance with § 101.11 (21 CFR 101.11) and § 180.37 (21 CFR 180.37) must be treated the same as any other legally authorized use of an ingredient.

4. Fifteen Percent of the DRV

a. *Criticism of approach.*

27. A number of comments stated that, despite FDA's assertions to the contrary, a total ban on health claims for foods exceeding a disqualifying level would create a good food/bad food image in the minds of consumers. The comments claimed that consumers may turn away from foods that provide significant amounts of essential nutrients simply because the foods do not carry a health claim. One comment noted that whole milk would be prohibited from making a claim about calcium and osteoporosis in spite of the fact that it is recommended as a source of calcium for children 1 to 2 years of age. The comment cautioned that parents may inappropriately substitute skim and low fat milk because of an assumption that whole milk is inferior.

Other comments proposed that if FDA decides to establish disclosure/disqualifying levels for nutrients, the agency should employ extreme care in informing consumers that individual foods do not increase the risk of disease, because it is the total daily diet that must be taken into account.

FDA disagrees with the contention that if foods that exceed a disqualifying level are ineligible to bear a health claim, consumers will perceive those foods as bad. A food without a claim, even if it does not exceed a disqualifying level, may not have the appropriate level of a nutrient to qualify for a claim. For various reasons, a food manufacturer may decide not to label a product with a claim even if the product qualifies. On the other hand, a product bearing a claim is required to provide the consumer with sufficient information to understand how the product may be useful to achieve the claimed effect within the context of the total daily diet. The agency believes that there are sufficient safeguards within section 403(r) of the act that are fully implemented in the final rules on health claims to prevent consumers from being misled about the value of any food based on whether it does or does not bear a health claim.

The agency acknowledges, however, that the full array of all of the new labeling regulations effected by the 1990 amendments may not be immediately understood by consumers. To deal with this, FDA will conduct an education program to effectively communicate how this new food labeling can assist consumers to maintain a healthy diet through informed food selection.

In response to the last group of comments, the agency reiterates that the disqualifying levels represent the amount of these nutrients in a single food that would make difficult the construction of a diet that meets dietary guidelines. They in no way represent a finding by the agency that these levels will cause diet-related disease or that foods that contain nutrients at these levels are unsafe, dangerous, or bad.

28. Other comments contended that an across-the-board disqualifying level based on a set percentage of the DRV for a nutrient could not be justified. One comment stated that it could not support the food composition analysis the agency used in developing the proposed disclosure/disqualifying levels because that approach does not fully meet the requirements of section 403(r)(3)(A)(ii) of the act. Specifically, the comment asserted that FDA's approach to disclosure/disqualifying levels ignores the legal requirement of accounting for the "significance of the food in the total daily diet." The comment claimed that this requirement implies a food consumption analysis that considers how a food is customarily used in the context of a daily diet. Further, the comment said that only a careful examination of food consumption data, in which foods are inherently related to their use in daily diets, can properly address the requirements of the law. The comment offered that the agency's proposed disclosure/disqualifying levels have some basis in daily consumption because of the use of DRV's. However, it said that the evaluation of individual foods in the agency's model is based on food composition values compared to food consumption values derived from DRV's. The comment argued that the composition of a food has no meaning in the context of the daily diet until its customary use is considered. The comment concluded that FDA did not do this, and that this error invalidates the agency's analysis.

The food composition methodology used by the agency in arriving at the proposed disclosure/disqualifier nutrient levels is fully consistent with section 403(r)(3)(A)(ii) of the act. As FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish these levels by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. The focus of this provision was clearly not on consumption of the individual food. Thus, references to "the significance of the food in the total diet" in that section does not imply that a food consumption analysis of how individual foods are used in a daily diet should be made. Instead, that section requires that FDA consider consumption in a far broader context. As explained in the subsequent paragraphs of this response, FDA's approach considers daily food consumption through use of the DRV's.

The DRV's were developed from recommendations in, for example, the Surgeon General's report (Ref. 5) and Dietary Guidelines for Americans (Ref. 7). They reflect current and established scientific evidence related to overall nutrient intake and risk of diet-related diseases. They also reflect total dietary intake from foods in general, but not intake from individual foods. Thus the disclosure/disqualifying nutrient levels are also based on food consumption in general, not just food composition.

Further, in arriving at the numerical value for the disclosure/disqualifying levels, the agency looked at the daily diet as being composed of approximately 20 servings of food and the likely distribution of the subject nutrients in the diet. The agency concluded that such nutrients were likely to be found at significant levels in as many as 10 of those 20 foods. Thus, while the agency did not consider the role of specific individual foods in the diet in arriving at the disclosure/disqualifying levels, the significance of particular types of food, such as those that contain a significant amount of fat, were considered. In sum, FDA's approach considers consumption in a broad manner that enhances the chances of consumers constructing total daily diets that meet dietary guidelines. Accordingly, contrary to the point made in the comment, the agency concludes that it did effectively consider food consumption data in which foods were related to their use in the diet in establishing the disclosure/disqualifying nutrient levels.

b. *Fifteen percent should increase to 20 percent.*

29. A number of comments, mostly from consumer organizations, agreed with the agency's rationale for selecting 15 percent of the DRV as the disclosure/disqualifying level for a specific nutrient; however, many comments from industry objected. In lieu of the 15 percent level chosen by FDA, the latter comments recommended 20 percent of the DRV because that is the amount the agency proposed as a "high" or "major source" nutrient content claim. Other comments strongly urged FDA to raise the disqualifying level to 20 percent of the DRV for cholesterol and sodium.

In addition, comments from industry and a Federal agency expressed concern that the disqualifying levels for fat, saturated fat, cholesterol, and sodium would prevent manufacturers from making potentially beneficial health claims on food that could assist consumers in making dietary changes. Some of the comments claimed that 99 percent of the food items in the categories of poultry, meat, and fish are disqualified from mentioning the health reasons for changes in consumption, despite recommendations from dietary authorities to substitute lean chicken and fish for meat. Similarly, the comments argued that the disqualifying levels would prevent nearly 90 percent of the items in mixed foods (grain), ready-to-eat cereal, and cheese categories and over 80 percent of the items in bread and crackers/salty snacks categories from making health claims. One comment concluded that the disqualifying levels would preclude many foods that could contribute to a better diet from mentioning truthful health reasons for making desirable substitutions, even where there is general scientific agreement on the desirability of these changes.

The agency agrees that the disqualifying levels for fat, saturated fat, cholesterol, and sodium should not serve as impediments to providing consumers with important information on diet and health by precluding health claims for major food groups, such as fish and whole grain cereals, that can be significant foods in a balanced and healthy diet. As FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish disqualifying levels by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. Thus it would not be appropriate for FDA to establish disqualifying nutrient levels that would be so stringent that major food groups that have an appropriate place in a healthful diet would not qualify for health claims.

In concert with the Surgeon General's recommendations, USDA and DHHS provided the American consumer with food guide information on food selection to achieve a healthy diet in the current edition of "Nutrition and Your Health, Dietary Guidelines for Americans" (Ref. 7). Most recently, USDA published "USDA's Food Guide Pyramid" (Ref. 29), which is intended to assist consumers in putting these dietary guidelines into action. The pyramid booklet provides information on dietary moderation, proportionality, and variety to ensure that consumers get the nutrients they need without too many calories or too much fat, saturated fat, cholesterol, sodium, sugar, or alcohol. The pyramid booklet suggests a range of daily servings from five major food groups, one of which includes meat, poultry, fish, dry beans, eggs, and nuts. As the comments indicate, a very large proportion of the items in this food group would exceed one or more of the disqualifying nutrient levels. Consequently, products in this group would not be permitted to bear health claims despite recommendations from dietary authorities to choose, for example, fish, lean meat, and poultry without skin as a way to reduce dietary fat intake. Accordingly, the agency has decided to revise the disqualifying nutrient levels to make it possible for a greater variety of foods in all food groups that are consistent with dietary guidelines to bear health claims.

FDA developed the disclosure/disqualifying levels for fat, saturated fat, cholesterol, and sodium to ensure that health claims are not made for foods that contain a nutrient in an amount that makes it difficult for consumers to comply with dietary guidelines. In developing these levels, FDA found no ready guidance on how to calculate them. The legislative history of section 403(r)(3)(A)(ii) of the act does not suggest what amount of a nutrient in a food should be considered as the limit to ensure compliance with dietary guidelines. Furthermore, current dietary guidance is presented in terms of daily nutrient intake rather than intake from individual foods.

Thus, in the absence of an accepted means for deriving the levels of nutrients in food that could be considered to increase the risk of disease, FDA, after considering the language of the act and its legislative history and based on the agency's scientific expertise, arrived at a tentative approach that was based on the proposed DRV's and available information on food composition and dietary intake patterns. The agency considered that a consumption pattern of individual foods that allowed for the intake of 100 percent of the DRV's would not increase the risk of diet-related disease, but that intakes resulting in the consumption of 200 percent of the DRV would do so. Therefore, an amount of a nutrient that would not increase the risk of disease would fall somewhere between 100 percent and 200 percent of the DRV. Based on the assumptions that diets generally include approximately 20 food/beverage items per day (Refs. 8 through 10), and that, given the uneven distribution of nutrients among the food categories, only about half of the foods consumed during a day will contain the nutrients of concern, the agency tentatively concluded that an increase in risk from an individual food was likely to result if it contained between 10 and 20 percent of the DRV per serving of fat, saturated fat, cholesterol, or sodium.

Based on food composition data available to the agency, FDA evaluated the kinds and types of foods that would be disqualified from bearing a health claim on the 10, 15, and 20 percent levels. Based on this evaluation, FDA tentatively concluded that 15 percent of the DRV represented the amount of the nutrients in question that increases to persons in the general population the risk of a diet-related disease or health-related condition.

After reviewing additional information on food composition (Ref. 30) and the comments recommending that the disclosure/disqualifying levels be raised from 15 to 20 percent of the DRV's, FDA is persuaded that its approach to calculating this level should be modified. FDA acknowledges that its primary concern in its initial development of these criteria was that foods that contain levels of nutrients that are not consistent with dietary recommendations be precluded from making a health claim. However, comments on this approach strongly urged that FDA also ensure that types of foods that are consistent with dietary recommendations—or, more specifically, types of foods whose increased consumption has been promoted in dietary recommendations—be able to bear claims if they meet the specified definition for the claim. In other words, comments argued that the disclosure/disqualifying levels should be sufficiently liberal so as to maximize the number of foods that bear claims and to allow claims on foods that are generally regarded as desirable components of an overall healthy diet.

assuming that the food meets the basic definition for the claim.

Based on consideration of foods highlighted by the comments as well as on a review of the food composition data available to the agency, FDA agrees that the use of a 20 percent DRV criterion will permit foods that are appropriately included in an overall healthy diet, for example a greater variety of bran and oat breakfast cereals or legume and vegetable products, to bear a health claim, even though they would not have been permitted to do so under the 15 percent DRV criterion. Furthermore, FDA finds compelling the argument made in comments that the criterion for "high" levels of a nutrient in a food can be applied not only as proposed (i.e., to emphasize the presence of a nutrient when it is considered desirable) but also can provide a consistent and appropriate basis for defining the levels at which the presence of a nutrient may be undesirable.

FDA acknowledges the debate on the issue that an exact level is not readily identifiable for a nutrient in a food that increases the risk of a disease or health-related condition to persons in the general population. With levels set at 20 percent of the DRV's for fat, saturated fat, cholesterol, and sodium, the question arises as to whether there are foods included among those containing 20 percent or less of a DRV that may lead to a diet inconsistent with dietary guidelines for maintaining good health. On reconsideration, the agency believes that the answer is no. Since the primary consideration from dietary guidance for avoidance of disease risk focuses on nutrient composition of the diet, and since there is no generally accepted way to extend that risk to the multiplicity of foods that may be selected in a daily diet while remaining consistent with dietary guidance, the agency finds that, taking into account the significance of the foods in question (that is, foods with 20 percent or less of the DRV for fat, saturated fat, cholesterol, or sodium) in the total daily diet, it is appropriate to adjust the disqualifying levels to the higher value of 20 percent of a DRV. In doing so, the agency is balancing the availability of valid information against the probability that food with that information will result in diets that increase the risk of a disease or health-related condition. FDA believes that, in the 15 to 20 percent range for establishing disqualifying levels, the importance of providing health claim information is greater than the possibility that risk of disease will be increased. Above 20 percent, however, the agency believes that that risk will increase and thus section 403(r)(A)(ii) of the act should be brought to bear. Therefore, FDA finds that, if a food contains more than 20 percent of the DRV for fat, saturated fat, cholesterol, or sodium (i.e., more than 13 g of fat, 4 g of saturated fat, 60 mg of cholesterol, or 480 mg of sodium) per reference amount customarily consumed or per label serving size it may not bear a health claim because these levels in an individual food can lead to a diet inconsistent with dietary guidelines for maintaining good health. Moreover, as explained in the response to comment 32 of this document, if a food that has a reference amount of 30 g or less or of 2 tablespoons or less contains more than 20 percent of the DRV for any of these nutrients per 50 g of food, it may not bear a health claim because claims on such nutrient-dense foods would be inconsistent with dietary guidelines.

c. *Increase for meals and meal replacements.*

30. Some comments suggested that FDA establish separate disqualifying levels for meal-type products at 25 percent of the DRV. They contended that products ordinarily consumed as meals contribute much more to the total diet than do individual foods. The comments argued that the single-food disqualifying levels for these meal-type items is too strict. A disqualifying level of 25 percent DRV for saturated fat, total fat, sodium, and cholesterol would ensure that persons eating three meals a day plus a snack would not exceed 100 percent DRV of any nutrients of concern.

The agency agrees that single food disqualifying levels are too strict when applied to meal-type products, which contain multiple servings of food. Because disqualifying levels for health claims are the same as disclosure levels for nutrient content claims, and because both are derived from the same statutory standard regarding nutrient levels in amounts that increase the risk of a diet-related disease in the general population, the definition for disqualifying levels in new § 101.14(a)(5) has been revised to be consistent with comparable requirements in new § 101.13 on disclosure levels for nutrient content claims for meal-type products published elsewhere in this issue of the **Federal Register**.

FDA is now providing for the definition of "meal product" in new § 101.13(l) and "main dish product" in new § 101.13(m) within the context of providing for nutrient content claims. As described in the nutrient content claims final rule, the agency is adopting different criteria for nutrient content claims for these products as compared with individual foods. The definition for a "meal product," which is described in more detail in the nutrient content claims final rule, is that: (1) It is represented as, or commonly understood to be, a dinner, lunch, breakfast, or other meal; and (2) it makes a major contribution to the diet by weighing at least 10 ounces (per labeled serving), containing at least 3 different foods from at least 2 of 4 food groups, and containing not less than 40 g of each of the 3 different foods. The definition for a "main dish product" is that: (1) It is represented as or is in a form commonly understood to be a main dish, and (2) it weighs at least 6 ounces per labeled serving, contains at least 2 different foods from 2 of 4 food groups, and contains not less than 40 g of a food from each of 2 food groups.

FDA has considered the appropriate disclosure/disqualifying level for main dish and meal products. As mentioned above, comments have suggested that the criterion be based on the amount per 100 g of product. Using this approach, the amounts used for individual foods (i.e., 13 g of total fat, 4 g of saturated fat, 60 mg cholesterol, and 480 mg sodium) would be the amount per 100 g of a meal or a main dish. FDA however notes that, on this basis, a meal weighing 10 ounces (280 g) would be subject to disclosure/disqualification if it contained approximately 36 g of fat or 55 percent of the DRV. A single meal product weighing 12 ounces (336 g)—not an uncommon weight for a meal—would be subject to disclosure/disqualification if it contained approximately 44 g of fat or about 67 percent of the DRV for total fat. If it is assumed that a "meal" constitutes one-fourth of a total day's nutrient/calorie intake, which, if anything understates the contribution of a meal, this criterion is seen to be too high because a meal could contribute more than half of the total amount of one of the nutrients in question (i.e., fat, saturated fat, cholesterol, or sodium) generally recommended as a total daily intake and yet still bear a health claim.

The comments received offered no approaches other than use of the "per 100 g" basis relative to disclosure/disqualifying levels for main dishes and meals. FDA, therefore, has developed an approach that extends the rationale used for individual foods to main dishes and meals. Specifically, given that main dishes and meals constitute a larger portion of the diet than individual foods, the criterion for disclosure/disqualification for main dishes and meals should be a greater percentage of the DRV than for individual foods.

FDA has determined that criteria of 30 percent of the DRV as a disclosure/disqualifying level for main dishes and of 40 percent of the DRV as that level for meals are appropriate. Assuming a typical consumption of three meals and a snack, each of which contain 40 percent of the DRV for a particular disclosure/disqualifying nutrient, and foods that sometimes accompany meals such as beverages, bread, and desserts that contribute an additional 40 percent of the DRV for the nutrient, 200 percent of the DRV would be consumed during the day. As discussed in the response to comment 29 of this document, FDA has concluded that on balance, given the benefits and the probabilities that risk of disease will be increased, a disqualifying level based on a total dietary intake of 200 percent of the DRV is appropriate.

Disclosure/disqualifying levels for main dishes are appropriately placed at 30 percent because it is likely that consumption levels of these products is between the level for individual foods and the level for meals. Therefore, FDA has set the criterion at 30 percent which is between the 20 percent criterion for individual foods and the 40 percent criterion for meals. Finally, FDA's review of available data suggests that these criteria have practical application in that the criteria of 30 and of 40 percent of the DRV would not be overly restrictive (Ref. 35). Accordingly, the definition of disqualifying nutrient levels in new § 101.14(a)(5) has been revised to incorporate these changes for meals and main dish products.

31. One comment from a manufacturer of foods for special dietary uses suggested that the proposed disqualifying provisions of proposed § 101.14(a)(5) should not apply to a formulated product presented as a meal replacement where a serving provides one-fourth to one-third of the daily nutrient intake based on calories. Rather, the comment suggested that the disqualifying levels should be based on the amount of total fat, saturated fat, cholesterol, or sodium when the amount of any of these substances exceeds the equivalent portion of the DRV on a caloric basis. For example, according to the comment, a meal replacement that provides 25 percent of the daily caloric intake in a single serving should have the disqualifying levels set at or above 25 percent of the DRV's. The comment said that such a provision would provide a standard for these products consistent with the regulation. Each "serving" of the formulated product would represent an entire meal and would replace several servings of conventional food. Establishing disqualifying levels on this basis, the comment said, would allow consumers access to important health information. The comment suggested that the proposed regulation be modified to read as follows:

> Formulated meal replacement products that provide 25% to 33–1/3% of the daily caloric intake shall be disqualified when the level of fat, saturated fat, cholesterol, or sodium exceeds, on a caloric basis, the equivalent portion of the Daily Reference Value [21 CFR 101.9(c)(12)(i)].

The agency acknowledges the point made by this comment that a meal replacement product, particularly one that is a food for special dietary use, may be sufficiently different from a serving or amount of a conventional food to warrant a different criterion for disqualifying nutrient levels. Nevertheless, the agency does not believe that it is appropriate to modify the codifiéd language as recommended because of a lack of essential information needed to implement the change. Specifically, where the proposed codified language applies to "formulated meal replacement products," there is no definition or other characterizing information that identifies this class of products.

The agency published proposed regulations on June 14, 1974, to establish a nutritional quality guideline and a common or usual name for formulated meal replacements (39 FR 20905). Subsequently, however, those proposals were withdrawn. Although they may serve as a basis to reconsider what had been proposed, a significant number of changes have occurred in the intervening 18 years with regard to the regulations and policy on the nutrient content of foods.

For example, the proposed nutrition quality guideline regulation defined a formulated meal replacement, in part, as a product that supplies a minimum of 700 kilocalories per serving (the term "calorie" has the same meaning as "kilocalorie" in the text that follows), unless the product is represented for use in a reduced calorie diet (39 FR 20905, June 14, 1974). On the presumption that a meal should provide at least 25 percent of daily caloric intake, the value of 700 calories per serving was derived from a proposed intake standard of 2,800 calories per day. Subsequently, as reflected in the current fortification policy (21 CFR 104.20), the energy intake standard has been lowered to 2,000 calories per day. This value is the same as the reference caloric intake that FDA used in determining the DRV's, published elsewhere in this issue of the **Federal Register**. Accordingly, the agency advises that with the necessary steps to establish a definition and nutrient composition and nutrition quality requirements for the class of "meal replacement products," particularly those that are foods for special dietary use, consideration may be given to providing an exception to disqualifying levels for that class of products.

The agency has examined several products currently in the marketplace promoted for use, among other things, as either a "meal replacement" or as a "balanced meal" that included a formulated ready-to-consume fluid product and dry mixes for addition to fluid milk to produce an "instant breakfast drink." The former, but not the latter, type product bore other labeling for use of the product to either lose or gain weight, thus classifying the product as a food for special dietary use. A single serving of the ready-to-consume product provides 360 calories, whereas the dry mixes provide 220 calories when combined with 8 fluid ounces of skim milk. From nutrition labeling information, neither type of product exceeds the disqualifying levels for fat and sodium defined in new § 101.14(a)(5) for an individual food. From the list of ingredients and nutrient content information from standard data bases, it is also unlikely that either product would exceed the disqualifying levels for saturated fat or cholesterol. Further, it appears that if a serving of the ready-to-consume meal replacement were adjusted to increase the caloric yield from 360 to 470 calories per serving, the disqualifying levels for fat, saturated fat, cholesterol, and sodium would still most likely not be exceeded. Although this assessment, admittedly, is extremely limited in scope, the agency concludes that the disqualifying levels in new § 101.14(a)(5) for an individual food will apply to a product promoted as a meal replacement until a more appropriate requirement is established by regulation.

d. *Per 100 grams.*

32. A number of comments from industry and from other Government agencies objected to the part of the proposed definition for "disqualifying nutrient levels" in proposed § 101.14(a)(5) that tied such levels to the amount of fat, saturated fat, cholesterol, or sodium "per 100 g." One comment asserted that 100 g means nothing to the public and suggested that standardized serving sizes should be the basis of labeling. Others agreed that the "per 100 g" criterion is unnecessary with the adoption of standardized serving sizes, which, the comments asserted, effectively eliminate the agency's concern that manufacturers may

manipulate serving sizes to make their products appear more attractive. One comment cautioned that using both the 100 g and serving size requirements risks substantial confusion.

FDA does not agree that a weight-based criterion is unnecessary. The agency notes that section 403(r)(3)(B)(iii) of the act states that a claim should enable the public to comprehend the information in a claim and understand the relative significance of that information in the context of a total daily diet. Because certain foods are consumed in small amounts and thus have small serving sizes, it is possible that a food dense in a nutrient such as fat or sodium could qualify for a health claim because the serving size of the food is so small that there is not a sufficient amount of the nutrient present to disqualify the food. Accordingly, the nutrient density, or weight-based, criterion was developed to deal with foods with small serving sizes that may be consumed more frequently than once a day.

However, the food itself could be inconsistent with dietary guidelines in that it has been identified as a food to be limited in the diet. "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7) states that certain types of foods high in fat, for instance, should be limited in the diet without regard to the amounts typically consumed in a single serving. Furthermore, the recommendations provided in "USDA's Food Guide Pyramid" (Ref. 29) are consistent with the guidance to limit the intake of certain types of foods regardless of serving size. Claims on such foods would promote their consumption and, thus, fail to set the food in its proper dietary context.

Therefore, FDA has concluded that criteria for health claims based solely on serving size would be inconsistent with dietary guidance and would fail to respond to section 403(r)(3)(B)(iii) of the act, which requires that the claim set the food properly in the context of the diet. This conclusion is supported by the comments to the docket discussed in the response to comment 87 of this document, which stated that health claims should be prohibited on foods that are inconsistent with a sound dietary pattern. Moreover, claims intended to promote the consumption of a food that appear on a food that is inconsistent with dietary guidelines could be misleading to consumers under section 403(a) of the act and, thus, such claims are inappropriate.

However, the agency has concluded that the weight-based criterion is only needed for foods with small serving sizes that include those foods with reference amounts of 30 g or less or 2 tablespoons or less. For foods with reference amounts above 30 g or 2 tablespoons, the per label serving size or per reference amount customarily consumed criteria are sufficient to prevent nutrient-dense foods from bearing health claims.

Accordingly, FDA has provided for a weight-based criterion in addition to the criterion that specifies the amount of nutrient present per reference amount customarily consumed and per label serving. The weight-based criterion precludes claims on nutrient-dense foods and would qualify for a health claim solely because they have very small serving sizes.

A weight-based criterion for foods with small serving sizes is also used with nutrient content claims, which are discussed in a final rule published elsewhere in this issue of the **Federal Register**. As discussed in that document, comments to the nutrient content claims proposal stated that basing the criterion on per 100 g may be overly restrictive. These comments pointed out that the per 100-g criterion precludes claims on foods that are consistent with dietary guidelines, such as whole grains and cereals. Alternative and less restrictive criteria were suggested including a criterion based on 50 g rather than 100 g. As discussed in the nutrient content claims final rule, FDA has been persuaded that it is appropriate to use 50 g rather than 100 g as the weight-based criterion.

To ensure that its treatment of disqualifier and disclosure levels is consistent, FDA has reexamined the 100-g criterion for use with health claims. Data analyses (Ref. 31) demonstrate that changing from 100 g to 50 g and applying the criterion only to foods with small serving sizes allows a number of foods that would otherwise have been precluded from bearing a claim and that are consistent with dietary recommendations, such as certain cereals and whole grains as well as fish and milk products, to qualify for health claims. Moreover, such a change would allow only a few foods that are inconsistent with dietary guidelines to bear claims. Therefore, to provide for claims that are consistent with dietary guidance, FDA is providing for a weight-based criterion for foods with small serving sizes based on per 50 g rather than per 100 g. In addition, for dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the "as prepared" (that is, hydrated) form.

The agency also disagrees that using three criteria, nutrient density, reference amount customarily consumed, and label serving size, to determine disqualifying levels runs the risk of confusing consumers. The determination as to whether a food contains a disqualifying level of a nutrient is not discussed on the label or in labeling. Thus, there is no basis on which a consumer could be confused.

e. *Relevant nutrients.*

i. *Fat and saturated fat.*

33. One comment recommended that in conjunction with the health claim on skim milk and 1 percent lowfat milk, the agency requires that the products display a statement that "whole milk is more appropriate for the growth and development of children under two years who are drinking milk." The comment noted that children in this age group require an adequate amount of fat in their diet for proper growth and development.

FDA does not believe that skim and lowfat milk should be required to bear the suggested statement. The health claim about calcium and osteoporosis is directed primarily to those individuals with known family histories of osteoporosis and to adolescent and young adult Caucasian and Asian American women. Such claims are not directed to children. In fact, health claims are prohibited, except in very limited circumstances, wherever a food is represented or purports to be for infants and toddlers less than 2 years of age. Therefore, FDA rejects the request in this comment.

34. Some comments asserted that the disqualifying levels for fat and saturated fat were too high and should be lowered.

The agency disagrees with this contention. Absent a showing to the contrary, and the comments did not contain such a showing, the agency has no basis to find that levels in a food of fat and saturated fat of less than 15 percent of the respective DRV's increase the risk of a diet-related disease. Further, as explained above, FDA has reassessed the issue and concluded that the disqualifying levels for fat and saturated fat should be raised to 20 percent of their DRV's. The agency finds that this decision is consistent with dietary recommendations to limit energy intake from fat and saturated fat to 30 and 10 percent of calories, respectively. Accordingly, the agency rejects the comment's recommendation.

35. One comment stated that the disqualifying regulations for fats and saturated fats should be adjusted to reflect the use of reduced calorie novel fats and fat replacers. The comment

explained that products employing novel fats should be eligible to display a lipid and cardiovascular health claim consistent with other requirements for this claim. The comment asserted that the identity of fat should be limited to those materials that do in fact provide measurable bioavailable fatty acids and calories. The comment asserted that fatty acid containing fat substitutes that are essentially nondigestible do not qualify as fats and should be treated separately. The comment stated that the quantity of fat should be determined by the amount of bioavailable fatty acids that such a fat substitute contains. This approach, the comment said, would provide a common basis for quantifying the fat equivalence of novel fats as well as mono- and diglycerides, phospholipids, and "natural" fats of limited digestibility. Under it, total fat could be quantified, and fatty acid type could be expressed as the triglyceride equivalent of the bioavailable fatty acid fraction. For the novel fats, the average characterizing bioavailability could be established by the manufacturer and submitted to FDA as part of a petition for regulatory food-use approval. Application of a "bioavailability" index for fats would be similar to the use of the Protein Digestibility Corrected Amino Acid Score or Protein Efficiency Ratio used to characterize proteins and of the bioequivalence values assigned to vitamin products.

The agency does not disagree with the comment's main point that the quantity of fat in a product, which determines whether a claim can be made, should be determined by the amount of bioavailable fatty acids that the product contains. Total fat content is a part of nutrition information mandated by section 403(q)(1)(D) of the act. Thus, any claim (i.e., a health claim or nutrient content claim) based on fat content must be based on the amount of fat declared in the nutrition label. How total fat content is determined is addressed in the regulation on mandatory nutrition labeling, new § 101.9, published elsewhere in this issue of the **Federal Register**. Thus, the agency sees no need to provide for a separate method in the health claims regulation for purposes of declaring whether a food contains a disqualifying, or a qualifying, level of fat.

The agency advises that any proposal to modify the methods for determining the total fat and fatty acid content of a food may be submitted as a petition to amend new § 101.9. Moreover, as explained in the final rule on mandatory nutrition labeling, when seeking approval from the agency for use of a fat replacer or novel fat in food, the petitioner should include information on the caloric value and macronutrient content of the ingredient. Nutrient content requirements for health claims will be subject to the appropriate requirements for nutrition labeling and any other related regulation.

ii. *Cholesterol.*

36. Many comments expressed support for the proposed cholesterol disqualifying levels. One Federal agency objected to the proposed cholesterol disqualifying level which, it contended, appears to be based on behavioral assumptions about consumption patterns that are not borne out by USDA data. Another comment urged that FDA raise the disqualifying level for cholesterol to one-third of the DRV.

As discussed in detail above, FDA has reassessed the disqualifying levels for cholesterol, fat, saturated fat, and sodium. The agency has concluded that the levels for all 4 can be set at 20 percent of the DRV's. Accordingly, having concluded, for the reasons set out previously, that a nutrient level in excess of 20 percent of the DRV for each of the 4 disqualifying nutrients is associated with an increased risk of a diet-related disease or health-related condition, the agency rejects the recommendation that the disqualifying level for cholesterol be raised to one-third of the DRV.

iii. *Sodium.*

37. Some comments challenged FDA's decision to set a disqualifying level for sodium. One of these comments noted that it was FDA and not Congress that identified sodium as a nutrient of concern because sodium, like fat, saturated fat, and cholesterol, has been "associated with increased risk of disease." Several comments asserted that there is a lack of significant scientific agreement on a link between dietary sodium and hypertension.

One comment cited reports by the Surgeon General and others as proof of the divided and inconclusive opinions of experts in the field. Furthermore, the comment charged that FDA had failed to independently analyze the results of the INTERSALT study, which, the comment alleged, refutes the traditional sodium-hypertension hypothesis.

Another comment submitted published studies that it claimed supported the comment's position that there is no rational basis for concluding that any single food contains sodium "in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related," and that "FDA has absolutely no statutory or scientific basis by which to establish any disqualifying level for sodium." One comment warned that a final decision by FDA to set such a level without proper regard to conflicting scientific data would not meet the statutory requirements of sections 403(r)(3)(A)(ii) or 403(r)(2)(B)(ii) of the act governing the establishment of disqualifying and disclosure nutrient levels and would clearly constitute arbitrary and capricious rulemaking.

The agency disagrees with the contention that sodium has not been associated with increased risk of disease. As explained in detail in the specific health claim document on this subject that is published elsewhere in this issue of the **Federal Register**, the available data, including the INTERSALT study, establish that dietary sodium intake is associated with hypertension. This discussion is referenced. For example, "Dietary Guidelines for Americans" (Ref. 7) states:

> Many American diets have too many calories and too much fat (especially saturated fat), cholesterol, and sodium. * * * Such diets are one cause of America's high rates of obesity and certain diseases—heart disease, high blood pressure, stroke, diabetes, and some forms of cancer.

FDA is convinced not only of the scientific soundness of the sodium/hypertension health claim but also of the appropriateness of a disqualifying level for sodium.

38. One comment suggested that it would be appropriate to include on the label of a food, in immediate proximity to any health claim, information on the sodium content (such as that required by new § 101.13(h) published elsewhere in this issue of the **Federal Register**), thus benefitting the small segment of the population for which sodium may be of concern, while providing a health message that could potentially benefit a much larger population.

FDA recognizes that there may be a number of different ways to display selected information, like sodium content, to meet various consumer needs or preferences. Although a display of sodium content information like that recommended by the comment may benefit a certain segment of the population, the 1990 amendments do not provide the agency with authority to require for health claims the type of nutrient disclosure required for nutrient content claims by new § 101.13(h). That regulation derives from section 403(r)(2)(B)(ii) of the act which states that if a food that bears a nutrient content claim that increases to persons in the general population the risk of a disease or health-related condition, the claim shall also identify such nutrient. Under those same circumstances,

however, the 1990 amendments do not permit a health claim to be made. The regime by which nutrient content claims are made is different than that for health claims.

The agency points out, nevertheless, that any food with a health claim will also bear nutrition information listing sodium and other nutrient content. Although the information on sodium content may not be displayed as conveniently or prominently as that recommended by the comment, it will, nevertheless, be readily accessible on a product's label.

39. Other comments called for a higher disqualifying level for sodium. One comment argued that the decision to set the sodium disqualifying level at 15 percent of the DRV is not as solidly based as the disqualifying levels for fat, saturated fat, and cholesterol. The comment further concluded that because much of the sodium in the American diet is concentrated in a few products, a product containing 20 percent of the DRV for sodium (480 mg) could easily be incorporated into a diet without increasing the risk of hypertension. Another comment agreed that the proposed sodium disqualification levels are too strict and noted that many breads would be restricted from making any health claims if the proposed level is adopted.

Another comment urged that FDA raise the disqualifying level for sodium to one-third of the DRV. The comment warned that setting such a low disqualifying level as 15 percent of the DRV for sodium would discourage manufacturers from producing lowfat products, because salt is required to improve the taste, and thus the marketability, of many such lowfat products.

As discussed previously in this section, FDA has reassessed its analysis for defining disqualifying levels and determined that the levels can be set for sodium and the 3 dietary lipids at 20 percent of the DRV's. Having concluded that nutrient levels greater than 20 percent of the DRV's, including that for sodium, increase the risk of diseases or health-related conditions that are diet related, FDA rejects the recommendation that the disqualifying level for sodium be set at one-third of that nutrient's DRV.

f. *Exception from disqualification.*

40. Some comments stated that exceptions to the disqualifying levels should not be granted. Other comments urged FDA to consider requests for exemptions from the disqualifying levels only on a case-by-case basis, and only when virtually all foods containing significant levels of the nutrient would otherwise be disqualified. One of these comments asserted that none of the currently proposed health claims would warrant an exception. Furthermore, many of the comments suggested that if FDA did grant an exception, a statement disclosing the level of the disqualifying nutrient should appear prominently next to the health claim.

The agency disagrees with those comments recommending that exceptions to the disqualifying levels should not be granted. Similarly, it is not convinced that the only basis to permit exceptions is when virtually all foods containing significant levels of the health claim nutrient would be disqualified. Section 403(r)(3)(A)(ii) of the act provides the Secretary (and FDA, by delegation) discretionary authority to permit a claim for a food that would otherwise be disqualified if the Secretary determines that the claim would assist consumers in maintaining healthy dietary practices. The agency is prepared to consider whatever arguments may be brought to bear with respect to a particular claim or with respect to a particular nutrient as to why an exception to a disqualifying level should be granted. Thus, the agency is not prepared to limit its discretion in the manner suggested by several of the comments.

If an exception to the disqualifying levels is authorized, section 403(r)(3)(A)(ii) of the act specifies that the label of the product contain a disclosure of the type required by section 403(r)(2)(B)(ii) of the act. Thus, the disclosure will have to be made prominently and in immediate proximity to the claim. It will have to identify the nutrient, and it will have to refer the consumer to the labeling panel where nutrition information may be found.

41. Other comments urged the use of discretion in permitting health claims for foods in cases where such claims would assist consumers in maintaining healthy dietary practices. Oils and margarine were cited as examples of foods for which exceptions should be made to provide consumers with information on the health reasons for choosing oils that are lower in saturated fat, because all oils exceed the disqualifying level of 11.5 g of fat. One comment emphasized the importance of focusing on the type of fat in the fats that are consumed and concluded its comment by suggesting that FDA could address its concern about total fat by requiring a clear message on such products that consumers should consume less fat.

The agency intends to use discretion in permitting health claims that encourage certain dietary practices generally recognized by the public health community as being consistent with guidelines for maintaining and promoting good health. FDA acknowledges that "Dietary Guidelines for Americans" (Ref. 7), while recommending that diets low in fat be chosen, also provides advice on how certain fats and oils used sparingly can assist the consumer in maintaining a relatively low saturated fat intake. Although fats and oils obviously exceed the disqualifying level for fat, section 403(r)(3)(A)(ii) of the act does permit exceptions, as discussed previously. Accordingly, FDA is willing to consider a petition that provides a basis for excepting certain fats and oils based on compositional or other characteristics from being disqualified from bearing a particular health claim.

42. A number of comments asked that FDA exempt milk and other dairy products from the disqualifying levels for fat and saturated fat. One comment noted that dairy products contribute 76.8 percent of the dietary calcium in the food supply, yet contribute only 20 percent of the saturated fats and 12 percent of the total fat. The comment contended that allowing only fat-reduced dairy products to make a calcium/osteoporosis claim would be misleading to those individuals who prefer whole milk to reduced-fat milk.

While milk and other dairy products do in fact contribute a large percentage of the daily supply of calcium, the agency noted in the preamble to the proposed regulations that lowfat and skim milk will be able to bear a health claim under proposed § 101.14(a)(5), as will many products made from these reduced-fat milks. FDA, therefore, cannot conclude that an exception for whole milk and other dairy products that exceed the fat disqualifying level would assist consumers in maintaining healthy dietary practices.

III. Preliminary Requirements for a Claim

FDA proposed several criteria in proposed § 101.14(b) that would have to be met before a substance would qualify to be the subject of a health claim. These criteria reflect not only the requirements of section 403(r) of the act but also the fact that FDA is charged with ensuring that the food supply is safe, and that the food label is not misleading. Given that agency evaluations of the validity of a health claim will be resource intensive, FDA proposed not to make such an evaluation unless a petition for a health claim demonstrates that the preliminary requirements are met.

A. Effect on General Population

As proposed, § 101.14(b)(1) stated:

The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health related-condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

43. Several comments endorsed, or advised that there was no objection to, the agency's preliminary requirement in proposed § 101.14(b)(1). Some of these comments stressed that the agency should always interpret this provision with flexibility. One comment asked for clarification as to whether a proven substance-disease claim would be allowed if the affected population was few in number or not readily identifiable as a subpopulation (e.g., vitamin D insufficiency in an undefined population group).

FDA intends to apply a flexible approach in interpreting this provision. The proposed alternative aspect of the provision, which would permit petitioners to explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet, evidences a determination by FDA to disqualify as few proposed claims as possible under this provision. However, if a proposed claim is ultimately authorized by FDA that involves an affected population that is few in number, that fact will have to be declared in the labeling in conjunction with the claim. Where the affected population is not readily identifiable, information about the prevalence of the disease or health-related condition in the U.S. population will be a material fact and thus will have to be provided in conjunction with the claim if the claim is not to misbrand the product.

As explained previously in this preamble (see comment 2 of this document), FDA does not believe that the 1990 amendments pertain to claims about diseases resulting solely from classical deficiencies of vitamins and essential minerals. Thus, for example, a claim about the benefits of vitamin D in reducing the risk of rickets, if not representing the product as a drug, needs no preclearance under the provisions of new § 101.14. However, such claims must be truthful and not misleading. In view of the fact that very few people are at risk of vitamin D deficiency disorders, a claim about the benefits of vitamin D in preventing vitamin D insufficiency would be misleading where the claim does not explain that few individuals in the United States are at risk of such insufficiency. Further, the claim would need to be more specific about the affected population to be adequately informative. For example, the claim might advise that although the vast majority of the U.S. population is not at risk for vitamin D deficiency disorders, the vitamin may be effective in reducing the risk of vitamin D deficiency problems in some segments of the elderly who are house-bound for prolonged periods and are not exposed to sunlight.

B. Components of Food within the Context of a Daily Diet

New § 101.14(b)(2) and (b)(3)(i) contain provisions requiring that the substance be a component of food. If the substance is present at decreased dietary levels, under new § 101.14(b)(2), it must be a nutrient that is required to be included in nutrition labeling (e.g., cholesterol, total fat). If the substance is present at other than decreased dietary levels, under new § 101.14(b)(3)(i), it must contribute taste, aroma, or nutritive value, or any technical effect listed in § 170.3(o) to the food, and must retain that attribute when consumed at levels that are necessary to justify a claim.

1. General

44. One comment suggested that FDA predetermine for each nutrient appearing in an approved health claim a level below which the nutrient is considered to be present in the context of the total daily diet and above which the nutrient is considered to be present at therapeutic levels.

FDA does not believe that it is practicable or appropriate for the agency to attempt to identify any single nutrient level as a boundary between those levels that are within the context of the daily diet and those which are therapeutic. The agency simply does not have sufficient resources to devote to the suggested determinations without unduely sacrificing resources from other high priority regulatory matters. Instead, FDA believes that it is more appropriate that the burden be upon the petitioner to demonstrate that the claimed effect actually can be achieved through consumption of dietary levels of the substance. At such levels, the presence of therapeutic effects should not be at issue.

2. Section 101.14(b)(3)(i)

45. Some comments stated that the eligibility restrictions on the term "substance" in proposed § 101.14(b)(3)(i) are too restrictive and asked that they be removed. One comment asserted that the agency is creating needless procedural confusion by having a broad definition of the term "substance" in proposed § 101.14(a)(2), which it then immediately narrows in proposed § 101.14(b)(3)(i). A few comments contended that, if FDA retains the food eligibility restrictions in the final rule, the agency should permit a broader interpretation of what constitutes food. Another comment stated that although the phrase "taste, aroma, or nutritive value" is borrowed from the Seventh Circuit's opinion in *Nutrilab Inc.* v. *Schweiker*, 713 F.2d 335, 338 (7th Cir. 1983), the court noted in that decision that these food characteristics were only the primary reasons why people consume food. The court, according to the comment, did not intend to give an all-inclusive list. One comment stated that not all of the other possible food characteristics are encompassed in the listing provided in § 170.3(o). Some comments asserted that food should include everything that can be consumed.

FDA does not believe that it is overly restrictive to require, as it does in proposed § 101.14(b)(3)(i), that a substance be a food or a component of food for it to be the subject of a health claim. Section 403(r) of the act describes the circumstances in which a food will, and will not be, misbranded if it bears a health claim. Thus, it is appropriate for the agency to make it incumbent upon the proponent of a health claim to demonstrate that the substance that is the subject of the claim is a food or component of food.

FDA believes that the framework that it has created in its regulations is appropriate and fully consistent with the act. Under it, manufacturers will be able to make claims that characterize the relationship between any substance and a disease or health-related condition so long as the substance achieves its effect through its use as a food, that is, through its nutritional value.

FDA disagrees with the comments' interpretation of the *Nutrilab* decision and believes that the agency's reliance on the case is justified. The *Nutrilab* court adopted a "common sense" definition under section 201(f)(1) of the act: "When the statute defines 'food' as 'articles used for food,' it means that the statutory definition of 'food' includes articles used by people in the ordinary way most people use food—primarily for taste, aroma, or nutritive value." *Nutrilab*, 713 F.2d at 338. Other courts have followed suit. (See *United States* v. *Undetermined Quantities of Cal-Ban*

3000, 776 F. Supp. 249, 254–55 (E.D.N.C. 1991); *American Health Products Co.* v. *Hayes*, 574 F. Supp. 1498, 1508–09 (S.D.N.Y. 1983), aff'd, 744 F.2d 912 (2d Cir. 1984).) By describing taste, aroma, and nutritive value as the "primary" reasons for consuming food, the *Nutrilab* court acknowledged that a food consumed for one of these reasons might sometimes also be consumed for an additional purpose. 713 F.2d at 338 (giving prune juice and coffee as examples of foods that "may be consumed on occasion for reasons other than taste, aroma, or nutritive value"). Under *Nutrilab*, a substance whose uses do not include taste, aroma, or nutritive value is not a food.

FDA does not believe that the word "food" should be defined any more broadly than it is in the proposed regulation, and the agency specifically rejects the proposal to define "food" as "any substance that is consumed by people for any purpose other than the treatment of disease." Under such an expanded definition, the parenthetical exception for food to the definition of drug in section 201(g)(1)(C) of the act would swallow the rule. Section 201(g)(1)(C) of the act states that "articles (other than food) intended to affect the structure or any function of the body of man or other animals" are drugs. Under the definition of food suggested in the comment, the only products consumed by people that would be considered drugs under section 201(g)(1)(C) of the act would be those intended both to affect the structure or function of the body and to treat a disease. Substances taken to treat a disease are already drugs under section 201(g)(1)(B) of the act, regardless of whether they are foods. The suggested definition of "food" would thus render section 201(g)(1)(C) of the act meaningless. It is a basic principle of statutory construction that a statute should not be construed in such a way as to render certain provisions superfluous or insignificant. *United States* v. *Leonard*, 868 F.2d 1393, 1395–96 (5th Cir. 1989), cert. denied, 496 U.S. 904 (1990).

46. Numerous comments from producers and consumers of dietary supplements expressed concern that the proposed provision represents an attack by the agency against dietary supplements. Some comments maintained that FDA lacks the legal authority to restrict approved health claims on nutritional supplements that are beyond daily diet limits. Other comments asserted that FDA intends to use regulations based on the proposal to ban health claims on dietary supplements wherever the supplements contain a substance above the context of an ordinary daily diet. Other comments stated that the agency would ban the supplements themselves by making them available only by prescription or by limiting the potency of the supplements. A few comments believed that FDA would also ban supplements where they lack a therapeutic effect at levels within the context of an ordinary daily diet. While most of the comments did not specify any particular proposed provisions that could lead to these actions, they strongly protested that any restriction on dietary supplements would infringe on consumers' freedom of choice and would be in conflict with the Proxmire Amendment (21 U.S.C 350) and the 1990 amendments.

As stated above, the DS Act imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Thus, nothing in these final rules will affect dietary supplements in any way. However, FDA disagrees with the comments' characterization of its proposal and disagrees with the statement that the proposed regulations were in conflict with section 411 of the act (21 U.S.C. 350) (the Proxmire Amendment). Nothing in the proposed regulations would have affected the availability of dietary supplements. Rather, these regulations were intended to regulate claims that may be made for all foods, including dietary supplements.

Nothing in the regulations would necessarily prevent a supplement from bearing a health claim when that supplement contains a level of a substance that exceeds the level achievable in the context of the daily diet. To the contrary, the final rule concerning calcium (where health benefits are provided within the context of the daily diet), for example, which is published elsewhere in this issue of the **Federal Register**, permits a calcium health claim for dietary supplements and requires only that the supplement labeling advise consumers that there is no known benefit from consuming more than 200 percent of the U.S. Recommended Dietary Allowance (U.S. RDA) for calcium.

Section 411 of the act does not authorize health claims for dietary supplements or in any way affect FDA's authority under section 403(r)(5)(D) of the act to regulate such claims. Under section 411(a)(1)(B) of the act, FDA may not classify a dietary supplement as a drug solely because it contains vitamins or minerals exceeding the level of potency that the agency determines is nutritionally rational or useful. Nothing in the proposed regulations would have done so. Absent a claim, FDA will not consider a dietary supplement to be a drug simply because it contains vitamins or minerals at levels above those normally found in food. However, a claim on a product may indicate the product's intended use. If a claim reveals that the product is intended to be used in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body (other than food), the product is a drug. (See 21 U.S.C. 321(g)(1)(B) and (g)(1)(C)).

47. Another comment asked for assurance that approved health claims appearing on dietary supplements will not automatically be considered drug claims. The comment noted that section 201(g)(1)(B) of the act exempts approved health claims on foods from consideration as drug claims and stated that dietary supplements should be afforded the same exemption under FDA regulations.

Section 202(b) of the DS Act does permit FDA to approve health claims with respect to dietary supplements. FDA advises that, as provided in section 201(g)(1)(B) of the act, any food, including dietary supplements, for which an authorized health claim is made in accordance with the requirements of section 403(r) of the act, and of the regulations that FDA has adopted to implement that section of the act, is not a drug under section 201(g)(1)(B) solely because its label or labeling contains such a claim. FDA considers this provision to provide the same type of assurance as that in sections 406, 408, and 409 of the act that foods containing substances used in accordance with regulations issued under those sections of the act are not subject to regulatory action under section 402(a)(1) of the act. This provision does not create an exception to the "drug" definition. Thus, a product whose intended use is as a drug will continue to be regulated as a drug.

3. Drugs

48. One comment contended that FDA should permit the use of health claims on over-the-counter (OTC) antacid products containing only calcium carbonate. The comment noted that the preamble to the proposed regulations cited the potential for confusion if health claims were allowed for bulk-fiber laxatives that have not been shown to be useful in lowering cholesterol and for which appropriate labeling for that claim does not exist. The comment asserted that while health claims may be inappropriate for laxatives, such claims would be appropriate for antacids. The comment stated that calcium has been

identified as an essential nutrient which, unlike psyllium, has a defined intake requirement as well as a claim that FDA has proposed to authorize relating to the role of calcium in helping to reduce the risk of developing osteoporosis. The comment asserted that FDA's objection to OTC drugs bearing health claims is not appropriate in the case of calcium-based antacids because antacids have been labeled for years with both food and drug labeling. The comment explained that many antacids bear calcium nutrient content claims with directions for using the products as calcium dietary supplements as well as antacids.

Further, the comment pointed out that, in addition to calcium carbonate, there are several multiple use products currently in the marketplace (e.g., sodium bicarbonate). The comment stated that sodium bicarbonate, marketed under the name "baking soda," is labeled as a baking ingredient, a deodorizer, and an antacid. The comment suggested that FDA approve health claims on drugs under the following conditions: (1) The drug is properly labeled; (2) a health claim has been approved by FDA for an ingredient in the drug; (3) the OTC product meets or exceeds the requirement for a minimum recommended intake of "the natural supplement" as established by regulation; and (4) all labeling is in compliance with the authorizing regulation.

Multiple use products that are both foods and drugs present a difficult set of competing concerns for the agency. Such products are likely to be, like the product that is the subject of the comment, both an OTC drug and a dietary supplement.

Most OTC drug products are developed to address some type of acute physical problem that is expected to be of short duration. If the problem persists, it is important that the person with the problem know that it may be more severe than he or she otherwise thought, and that he or she seek medical attention. Labeling on such products, therefore, includes instructions to use the product for a limited period of time and, if the problem persists, to seek medical intervention. Thus, the time limits on use of the product are important to the health of the users.

Dietary supplements, on the other hand, are developed for inclusion in a daily diet at levels that are consistent with dietary use and may often be consumed throughout most of a person's lifetime. Labeling on dietary supplements contains no instructions for seeking medical intervention or for limiting the duration of consumption of the supplement. Rather, under the 1990 amendments (subject to the DS Act), they will be able to bear nutrient content and health claims, which focus the consumer's attention on the advantages that consuming the product will have in helping the consumer to maintain a healthy diet. Moreover, where the supplement bears a health claim, the claim will contain information about how long-term ingestion of the supplement may promote health.

The comment's reference to baking soda (sodium bicarbonate) as an example of a dual labeled drug/food is not apposite. As a food, baking soda is consumed only as an ingredient in other foods, and it is unlikely that labeling would result in increased consumption of this product. Baking soda is not labeled with either a nutrient content claim or a health claim. Thus, there is little opportunity for consumer confusion presented by this product.

Where dietary levels and therapeutic levels differ (as is generally the case and is in fact the case with antacids and calcium supplements), an apparent conflict is created when both food and drug labeling appear on the same product. In the case of the drug labeling, consumers are given directions for use that involve high consumption during a limited time period. In the case of the food labeling, consumers are given directions for lower consumption with no time constraints. Even though label instructions may identify those directions for food and drug use in separate locations, FDA is concerned that consumers will incorrectly assume that the therapeutic dosage is appropriate for dietary use, and that the directions for food use will undercut the warning in the drug labeling to seek medical care if use persists. Where the labeling is not properly followed, significant adverse consequences may result.

The agency knows of no broad approach that it can use to harmonize a nutrient content claim or a health claim with drug labeling. A drug that is labeled with instructions for use that both limit and do not limit consumption would be misbranded under section 502(a) of the act (21 U.S.C. 352(a)) if it failed to contain a material fact—that is, how to reconcile these conflicting instructions. Therefore, FDA advises that it will tend to view dual claims as misbranding the product.

However, FDA does not believe that it would be appropriate to preclude such claims under all circumstances. Such claims may be permissible if a firm can demonstrate that dual claims can be made in a manner that will neither misbrand the product nor create a safety problem. The agency suggests that anyone desiring to make a health claim or a nutrient content claim that complies with section 403(r) of the act on a product that is both a food and a drug contact the Center for Drug Evaluation and Research, OTC Compliance Branch (HFD–312), FDA, 7500 Standish Pl., Rockville, MD 20855, to discuss whether it would be possible to put such a claim on the product and still comply with the drug provisions of the act.

49. Some comments asserted that FDA should permit the use of health claims on herbs whose only known use is for medicinal effects. A few of these comments objected that the herbs that FDA cited in the preamble of the proposal also have food uses.

As FDA explained fully in the preamble of the proposal (56 FR 60554), Congress clearly intended that the health claim provisions of the 1990 amendments apply only to foods. A product that is intended for medicinal effects, that is, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, is a drug and not a food. Thus, there is no basis under the act for FDA to permit health claims for herbs whose only known use is for medicinal effects. Health benefits of such herbs may appear in the labeling only in accordance with the drug provisions of the act. Where herbs have a history of use both as foods and drugs, the context of all of the available information on the intended use of the product will determine whether FDA will regulate the herbs as foods, as drugs, or as both foods and drugs.

In this regard, the agency points out that the relationship of a food or a food component to a disease is quite different from that of a drug. The Surgeon General's report (Ref. 5) points out that, apart from classic disorders resulting from dietary deficiencies of essential nutrients (e.g., pellagra and niacin), it has proved difficult to demonstrate causal associations between specific dietary factors and chronic or other diseases (e.g., dietary fiber and cancer). The report states:

> Development of the major chronic disease conditions—coronary heart disease, stroke, diabetes, or cancer—is affected by multiple genetic, environmental, and behavioral factors among which diet is only one—albeit an important—component. These other factors interact with diet in ways that are not completely understood. In addition, foods themselves are complex; they may contain some factors that promote disease as well as others that are protective. The relationship of dietary fat intake to causation of atherosclerotic heart disease is a prominent example. An excess intake of total fat, if

characterized by high saturated fat, is associated with high blood cholesterol levels and therefore an increased risk for coronary heart disease in many populations. A higher proportion of mono- and polyunsaturated fats in relation to saturated fats is associated with lower blood cholesterol levels and, therefore, with a reduced risk for coronary heart disease.

Because of these complexities, definitive scientific proof that specific dietary factors are responsible for specific chronic disease conditions is difficult—and may not be possible—to obtain, given available technology.

(Ref. 5). Thus a claim that a substance can be used in the prevention, diagnosis, cure, mitigation, or treatment of a disease or symptom is inappropriate on a food: (See § 101.9(k)(1).)

C. Safety

Proposed § 101.14(b)(3)(ii) would require that to justify a claim for a substance that is to be consumed at other than decreased levels, the use of the substance must be shown by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the act.

The preamble of the proposed rule stated further:

> * * * This showing can be based on: (1) A demonstration that the substance is generally recognized as safe (GRAS) within the meaning of 21 CFR 170.30; (2) a listing of the substance as GRAS in 21 CFR part 182 or as affirmed as GRAS in 21 CFR part 184; (3) a food additive regulation; or (4) a sanction or approval granted by FDA or the United States Department of Agriculture prior to September 6, 1958. If the safety and lawfulness of the substance is not expressly recognized in an FDA regulation, the burden will rest on the claim's proponent, as a prerequisite to FDA's evaluation of the health claim, to submit all the scientific data and other relevant information required to demonstrate safety and lawfulness in accordance with applicable petition requirements. FDA will withhold review of the health claim until it is satisfied on these points.

(56 FR 60537 at 60546 through 60547)

50. Many industry comments objected to the safety provisions as proposed. Some of these comments asserted that the 1990 amendments do not require a separate showing of safety for nutrients that are the subject of disease-related claim petitions, and that FDA should not add such a requirement to its regulation. Many comments particularly disagreed with the application of FDA's preliminary safety requirement to dietary supplements and herbs. The comments pointed out that many herbs and supplements have been used for thousands of years with no known ill effects. Requiring further evidence of safety for these products, the comments contended, would be superfluous and expensive. However, other comments agreed with FDA that it would be inappropriate to allow a health claim on a product that contains a substance that is not GRAS, is not the subject of a food additive regulation, or has not received a prior sanction of approval.

FDA believes that the preliminary requirement that substances must be components of food that are safe and lawful must be included in the health claims final rules. Sections of the act enacted by the 1990 amendments cannot be implemented independently of the remaining portions of the act. The act must be considered as a whole, and FDA's responsibility for ensuring the safety of foods is explicitly provided for in other sections of the act (see sections 201(s), 402(a)(1) and (a)(2), and 409 of the act).

This fact is particularly significant because the agency will be specifically providing for the health claims that will be made. In view of this affirmative action, FDA authorization of a health claim places the agency's imprimatur on the claim. It would be a violation of the agency's responsibility under the act to authorize a health claim about a substance without being satisfied that the use of the substance is safe. Furthermore, safety considerations are also of unique importance in the case of health claims because such claims will inevitably change consumption patterns of many Americans.

Even though there is no explicit provision in the 1990 amendments requiring a separate showing of safety, it must be kept in mind that the act "* * * is designed to ensure the safety of the food we eat * * *." Les v. Reilly, ——— F.2d ——— (9th Cir. 1992). This requirement is implicit in the 1990 amendments. Section 403(r)(3)(A)(ii) of the act states that a health claim may be made only for a food that does not contain any nutrient in an amount that increases the risk of a disease or health-related condition that is diet related to persons in the general population, taking into account the significance of the food in the total daily diet. FDA believes that, in addition to requiring establishment of disqualifying levels, this provision evidences a concern by Congress that a substance that is the subject of a health claim be used in a manner that is safe. This concern was reflected in the statements of the sponsors in both the House and the Senate (Refs. 2 and 3).

Further, section 9 of the 1990 amendments states that the amendments "shall not be construed to alter the authority of the Secretary of Health and Human Services * * * under the Federal Food, Drug, and Cosmetic Act * * *." Thus, FDA's responsibility for ensuring the safety of foods has in no way been diminished by the passage of the 1990 amendments.

As a result of the DS Act, herbs and other substances in dietary supplements are generally not subject to the provisions of this final rule. However, to the extent that these substances bear an approved health claim under section 202(b) of the DS Act, they will also bear the agency's imprimatur. To that extent, they will be treated in the same manner as other substances that bear such claims. Other issues with respect to the safety of substances in dietary supplements will be addressed in the rulemaking provided for in the DS Act.

51. Some comments argued that the agency should give full weight to manufacturers' private GRAS determinations in instances where food manufacturers seek to use substances that are not listed by FDA as safe. Some of these comments asserted that if FDA does not recognize private GRAS determinations for fulfilling the preliminary safety requirement, the agency will frustrate Congress' intent to permit health claims, because the GRAS petition procedure is usually quite lengthy, and many GRAS affirmation petitions are pending that are more than 10 years old. Some of the comments requested that if the agency does not recognize private GRAS determinations, FDA should shorten the timeframe for making its GRAS determination or establish an alternate procedure. One suggested that FDA relinquish responsibility for making GRAS determinations to USDA. Another comment suggested that FDA recognize the findings of an independent panel of experts, pending the results of the formal review process.

FDA acknowledges that the GRAS affirmation and food additive listing process can be lengthy. Thus, FDA designed new § 101.14(b)(3)(ii) to provide flexibility with respect to the type of showing of safety that is necessary to make a substance eligible to be the subject of a health claim. GRAS affirmation and food additive listing are but two of the procedures by which a substance may meet this preliminary requirement.

FDA intends to consider the basis of manufacturers' independent GRAS determinations where such determinations are submitted with petitions for health claims and may use its discretion to accept, without formal affirmation, the independent determination of GRAS where FDA believes that such action would be

appropriate. As FDA pointed out in the previous comment, however, the agency would not be fulfilling its responsibilities under the act if it were to permit a substance to be the subject of a health claim without satisfying itself that the use of that substance is safe.

Although FDA will consider all manufacturers' independent GRAS determinations where the bases for such determinations are submitted with petitions for health claims, the agency advises that it will generally not be possible for FDA to judge whether GRAS determinations based on complex scientific evidence are valid within the short timeframes mandated under the 1990 amendments for health claims petitions. Instead, agency agreement with an independent determination that a substance is GRAS will be most likely where the substance is an ingredient, or a component of a food ingredient, that was in common use in food prior to January 1, 1958, in a similar context. However, where such agreement occurs, the agreement does not constitute GRAS affirmation. Instead, the history of common use in food, coupled with the fact that FDA knows of no reason to question the safety of the food ingredient, means that the substance will be treated as if it is an unlisted GRAS substance (as provided for in §§ 170.30(d) and 182.1(a) (21 CFR 170.30(d) and 182.1(a))) in the manner provided for in the food ingredient list in 21 CFR part 182.

In response to comments requesting that FDA relinquish responsibility for making GRAS determinations to USDA, or that FDA recognize the findings of an independent panel of experts pending the results of the formal review process, the agency advises that neither course of action would be appropriate. FDA is charged under the act with the responsibility of protecting interstate commerce from adulterated foods. There is no basis under the act for delegation of this responsibility to other Federal agencies or to individuals outside of FDA.

IV. Validity Requirements for a Claim

A. The Scientific Standard

As proposed, the scientific standard in § 101.14(c) stated:

> * * * FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.
>
> (1) It must be supported by the totality of publicly available scientific evidence (including evidence from welldesigned studies conducted in a manner which is consistent with generally recognized scientific procedures and principles); and
>
> (2) There must be significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims that this support exists.

(56 FR 60537 at 60563)

In the preamble of the proposal (56 FR 60547), FDA advised that this standard embodies the language in the statutory requirements for conventional food in section 403(r)(3)(B)(i) of the act that there be significant scientific agreement about the support for the claim and the mandate provided in the legislative history of the 1990 amendments that FDA have "a high level of comfort that the claim is valid" (Ref. 1). Thus, the agency will authorize a claim when the evidentiary and review components of the scientific standard are met. However, FDA also stated in the proposal:

> It has been suggested that FDA should allow claims that reflect more preliminary * * * scientific findings so long as such claims are qualified in a way that appropriately reflects the state of the scientific evidence. For example, under this suggestion, FDA would allow a claim such as "Preliminary data show that diets rich in fiber reduce the risk of heart disease," so long as there is significant scientific agreement that this is in fact what the evidence shows. FDA has significant reservations about these types of claims, however, because of their potential to be misunderstood by consumers and therefore to be misleading. The agency is also concerned that such claims will undercut the credibility of the food label. This concern exists despite the fact that because such claims arguably do not assert a [causal] relation between diet and diseases they can never by disproved. FDA requests comments on whether it should authorize these types of claims in implementing the health claim provisions of the act.

(56 FR 60537 at 60552)

52. A number of comments objected that the wording of proposed § 101.14(c)(1) and (c)(2) changes the meaning of the scientific standard presented in section 403(r)(3)(B)(i) of the act. One comment asserted that the proposed provisions treat the totality of publicly available scientific evidence as a separate evidentiary element in showing that the claim is sound, thus distorting Congress' clearly-expressed intent. Similarly, the comment asserted that the language "supported by" in proposed § 101.14(c)(1) "eviscerates" the provisions of the statute because the level of support called for by this requirement is not consistent with the "significant scientific agreement" that the act prescribes. Some comments appeared to interpret the basis of the standard proposed in section 403(r)(3)(B)(i) of the act as being primarily or exclusively the review component, which incorporates the criterion of "significant scientific agreement."

FDA did not intend to change the meaning of the scientific standard presented in section 403(r)(3)(B)(i) of the act through the inclusion of paragraphs (c)(1) and (c)(2) in proposed § 101.14(c). The agency merely intended to clarify that, in accordance with the language of the 1990 amendments, the scientific standard does, in fact, include both a body of evidence component and a review component. However, the agency now recognizes that this attempt to provide greater clarity within the regulatory language itself was unnecessary and, to the extent that it has been interpreted as an attempt to change the meaning of the scientific standard, undesirable. The agency is therefore deleting proposed § 101.14(c)(1) and (c)(2). Without these paragraphs, the wording in new § 101.14(c) is virtually identical to that in section 403(r)(3)(B)(i) of the act.

The wording in section 403(r)(3)(B)(i) of the act and in new § 101.14(c), as amended, clearly establishes two components within the scientific standard. The evidentiary component arises from the inclusion of the phrase "evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles" in the statutory qualification of "the totality of publicly available scientific evidence." This aspect of the standard clearly mandates that the claim be based on a body of sound scientific evidence. The requirement that there be "significant agreement among experts qualified by scientific training and experience to evaluate such evidence * * * that the claim is supported by such evidence" constitutes the separate and distinct review component of the standard.

53. Some comments objected to the standard and suggested modifications. Several comments stated that Congress intended the scientific standard to be one of substantial evidence (i.e., "more than a scintilla and less than a preponderance"). The comments asserted that the 1990 amendments require that FDA adopt such a standard. The comments contended that a standard of substantial scientific evidence, even in the absence of significant scientific agreement, would be in accordance with sound scientific

principles and prevention of consumer fraud. They argued that such a standard would better serve public health through the prompt communication of the health and disease information. Further, other comments objected that the requirement of significant scientific agreement in the proposed standard expands FDA authority beyond legislative intent.

A number of comments maintained that, instead of "significant scientific agreement," FDA should use a scientific standard encompassing different degrees of certainty for different types of health claims. Most industry comments urged FDA to allow health claims based on preliminary evidence if the preliminary status of the claim is truthfully disclosed on the label (e.g., "preliminary data suggest"). Many of these comments contended that such claims would not be misleading and asserted that there was no evidence that the public might misunderstand such claims. Some of the comments asserted that such claims would be consistent with the statutory scientific standard because that standard requires only that there be agreement that the claim is supported by some of the available scientific evidence. Other comments argued that any preliminary study that is sufficiently well-designed and well-conducted should be sufficient to engender "significant scientific agreement" that it supports the health claim being made. Another comment stated that there was no evidence to warrant FDA concern that the public might misunderstand such claims, and that past regulatory policies and court cases involving both FDA and FTC clearly allowed such claims.

Some comments maintained that preliminary claims should be permitted because the benefit to a consumer if a preliminary claim is later proven to be true is significantly greater than the loss if it proves to be false. The comments cited various cases in which preliminary evidence has proven to be correct only after a period of several years. For example, one comment asserted that many lives would have been saved had FDA allowed preliminary health claims regarding cholesterol and heart disease. Other comments expressed concern that one effect of limiting health claims on food labels will be that manufacturers, not being able to assert the dietary characteristics of new foods which fail to meet the new standards, will lose a significant incentive to conduct nutrition research of new food formulations.

A few comments maintained that FDA should permit all preliminary claims, including claims about those nutrient-disease relationships that the agency proposed not to authorize, because those claims that FDA proposed to permit are actually preliminary claims. The comments explained that the claims that FDA proposed use qualifying words such as "may," as in the phrase "may help to reduce disease risk," rather than absolute claims.

However, other comments, primarily from the health care and regulatory sectors, favored the scientific standard as proposed and strongly opposed permitting preliminary health claims, stating that preliminary evidence does not meet the scientific standard of the 1990 amendments. The comments pointed out that one of the main purposes of this new standard is to prevent the type of questionable health claims that have grown all too common in recent years. They noted that if a health claim is still the subject of conflicting reports, it is entirely inappropriate for the food label. Many comments suggested that, even with a disclosure statement as to the preliminary nature of the claim, many consumers would be misled, as the word "preliminary" does little to lessen the impact of a claim, and many consumers would not understand that the findings could be disproved later. Other comments stated that allowing preliminary claims could open the floodgates to a large number of partially supported claims, thereby undercutting the credibility of the valid health claims on food labels.

FDA does not have authority to modify the scientific standard for health claims. Section 403(r)(3)(B)(i) of the act directs FDA to promulgate regulations authorizing health claims only if it determines:

> * * * based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

FDA has incorporated this standard into its regulations. Thus, the requirement objected to by several of the comments, that there be significant scientific agreement that the claim is supported by the publicly available evidence, derives directly from the act.

FDA does not agree that a "substantial evidence" standard, as described by one comment, was intended by Congress, or that the agency is under any obligation to adopt such a standard. Congress adopted the scientific standard for health claims in section 403(r)(3)(B)(i) of the act from FDA's February 13, 1990, reproposal (55 FR 5176). Congress had the opportunity to adopt a different standard, to modify FDA's proposed standard, or to equate the standard with the substantial evidence standard, but it did not. The standard adopted permits FDA to make case-by-case determinations on the scientific validity of a claim, giving greater weight to studies that it finds more persuasive (Ref. 1). Congress intended the scientific standard to be "strong" and for the agency to have a high level of confidence that a claim is valid. Id. Of course, in applying this standard, FDA will act in a manner that is fair and neither arbitrary nor capricious.

In determining whether preliminary evidence would provide the basis for a health claim under this standard, FDA looked carefully at the language of the act and its legislative history. The legislative history establishes that Congress' intent was to ensure the scientific validity of authorized health claims. (See statement of Rep. Waxman; Ref. 4, H5844: "What we have sought to do is to permit health claims but only health claims based on *scientifically valid* information * * *" (emphasis added).) If Congress' aim had been solely to prohibit false or misleading claims, it could have left FDA with its authority under sections 403(a) and 201(n) of the act. Instead it added section 403(r) of the act to ensure not only that claims are not false or misleading, but also that they are scientifically valid.

The fact that Congress adopted in section 403(r)(3)(B)(i) of the act the standard that FDA set out in its reproposed rule on health messages is significant in other respects. In the reproposal, the agency stated that it would not accept preliminary support for a label statement (55 FR at 5180). FDA proposed to permit only claims "supported by a sound body of scientific evidence" (55 FR at 5180). Congress adopted FDA's proposed standard without stating that it was expanding the standard to include preliminary claims; instead it stated that it was adopting the same standard (Ref. 1).

Allowing claims based only on preliminary data would thus not be consistent with the terms of the statute and indeed would undercut the statutory scheme. The standard for permitting a health claim requires that the claim be supported by the totality of publicly available scientific evidence, and that there be significant scientific agreement among qualified experts that this support exists. A claim based on

preliminary data would not reach the threshold of scientific validity required by this standard. It is not sufficient that there simply be agreement among scientists that a statement accurately characterizes the preliminary nature of the data, or that preliminary data could be interpreted in the way stated. Authorizing a claim in such circumstances would produce claims that are little more than hypotheses. While such claims might not be false or misleading, they would not be scientifically valid. Under the statutory scheme, a health claim is to describe the scientifically established relationship between a nutrient and a disease or health-related condition, not the state of the evidence that might support such a claim. FDA is to focus on the state of the evidence in determining whether the claim is valid. Thus, preliminary claims are not permissible under the act.

FDA does not agree that its past regulatory practices dictate that it permit preliminary or controversial health claims. The 41 year-old consent decree in *United States* v. *Mytinger & Casselberry*, referenced by one comment, is not relevant to the current situation and has been superseded by subsequent developments. With the 1990 amendments, Congress added the specific requirement to the act that any health claim on a food must not only not be misleading but also must be scientifically valid. The agency does not have the authority to permit preliminary or controversial health claims that are qualified by an explanation that a difference of scientific opinion exists. Moreover, the agency does not consider itself in any way obligated to follow the FTC consent decree referenced by a comment.

While FDA concludes that preliminary claims are not consistent with the act, that does not mean that the agency concludes that any qualification in a health claim would bar its use. Elsewhere in this issue of the **Federal Register**, FDA is authorizing health claims on food labels that are qualified claims. FDA is authorizing these claims because it finds that they meet the standard of scientific validity. For each of the claims that FDA is authorizing, there is significant scientific agreement that there is a high probability that a reduction in risk of disease will occur.

Further, absolute claims about diseases affected by diet are generally not possible because such diseases are almost always multifactorial. Diet is only one factor that influences whether a person will get such a disease. For example, in the case of calcium and osteoporosis, genetic predisposition (e.g., where there is a family history of fragile bones with aging) can play a major role in whether an individual will develop the disease. Because of factors other than diet, some individuals may develop the disease regardless of how they change their dietary patterns to avoid the disease. For those individuals, a claim that changes in dietary patterns will reduce the risk of disease would be false. Thus, health claims must be free to use the term "may" with respect to the potential to reduce the risk of disease. However, use of this term would not be appropriate for health claims on food labeling where significant scientific agreement does not exist that there is a high probability that a reduction in disease risk will occur.

Furthermore, Congress clearly concluded that there is a great deal of consumer confusion over health claims on food labeling (Ref. 1). FDA believes that much of the confusion results from claims based on preliminary data, and the agency believes that comments opposed to permitting preliminary claims are correct in their assessment that many consumers do not understand that preliminary claims are based on science considerably weaker than claims based on science about which there is a significant amount of scientific agreement. Also, FDA agrees with those comments maintaining that allowing preliminary claims would open the floodgates to a large number of partially supported claims, thereby undercutting the credibility of valid health claims on food labels and of the food label itself. FDA believes that health claims must be credible if they are to be useful to consumers.

If FDA were to focus only on the impact of a single preliminary claim, arguments that benefits to consumers from permitting that claim where it might be true would outweigh losses where the claim later proved to be false might have merit. However, FDA must focus on the ultimate impact that permitting a multitude of preliminary claims would have on public health and on public confidence in the food label. That ultimate impact could easily involve a perception among many consumers that health claims and food labels are not reliable. To the extent that consumers do not change their dietary patterns to reduce their risk of disease, they will be less healthy, and there will be needless deaths from disease as well as costs to the national economy. Thus, FDA disagrees with comments asserting that preliminary claims would be in the best interests of consumers.

Further, FDA doubts the accuracy of comments asserting that manufacturers will lose significant incentive to conduct research on new food formulations. The agency believes that the high credibility of FDA sanctioned claims and their impact on consumer purchasing decisions will prove to be sufficient incentive to continue such research. Further, if the agency were to permit almost all health claims of a preliminary nature, the value of such claims as marketing tools would surely be considerably weakened as consumers lose faith in all claims.

Of even more importance, however, is the fact that, even though FDA's approach to permitting health claims may not permit as many claims as some firms desire, FDA's approach will provide for scientifically valid health claims. Over time, FDA's approach is likely to prove to be of far greater value in promoting good public health than permitting almost all preliminary claims. Further, FDA's approach does not require absolute proof of the validity of a claim. Instead, this approach requires that there be sound science to support the claim.

54. A number of comments called for a consensus among scientists prior to the approval of a claim.

The legislative history of the 1990 amendments makes clear that Congress did not intend, in calling for significant scientific agreement about the support for a claim, to require that such agreement represent a full consensus among scientists. The House Report (Ref. 1) states: "* * * the standard does not require that there be a unanimous agreement among experts. Instead there must be a significant agreement among experts, but it does not require that every expert in the field approve or agree with the claim."

The agency believes that a consensus, if defined as unanimous agreement among scientists about the validity of a particular claim, would be difficult to achieve, and that a standard requiring consensus would therefore prove impracticable. The agency is concerned that the stringent requirement of consensus would cause many valid health claims not to be approved and, by restricting such claims, would counter Congress' intent that health claims supported by a significant scientific agreement be made available to consumers. In view of these concerns, and in conformity with the expressed intent of Congress and with the statutory language of the 1990 amendments, the agency will not require that claims be supported by a consensus among scientists.

55. Several comments objected that the scientific standard, particularly the phrase "significant scientific agreement," is vague and subjective. One comment asked for clarification as

to the degree to which this phrase is qualitative or quantitative in nature and noted that a standard of evidence must be specific and consistent. Several comments suggested that the manner in which FDA applied the scientific standard is overbroad.

The agency is sensitive to the comments' perception that the scientific standard, particularly the phrase "significant scientific agreement," is subjective. The agency believes, however, that any standard involving the evaluation of scientific evidence and the opinions derived from that evidence must be somewhat subjective. FDA, in choosing not to define "significant agreement" among experts in the November 27, 1991, proposal (56 FR 60548), noted that each situation may differ with the nature of the claimed substance/disease relationship. The agency believes that in deciding whether significant scientific agreement about the validity of a claim exists, it is necessary to consider both the extent of agreement and the nature of the disagreement on a case-by-case basis. The agency is concerned that if scientific agreement were to be assessed under any quantitative or rigidly defined criterion, the associated inflexibility of such a criterion might cause some valid claims to be disallowed where the disagreement, while present, is not persuasive.

The House Report (Ref. 1) affirms the intended flexibility of the "significant scientific agreement" standard by pointing out that, in reviewing scientific studies, FDA may give greater weight to the studies that it finds more persuasive. The House Report also clarifies that the overriding consideration in assessing whether to authorize a claim should be the Secretary's level of comfort about the validity of the claim. Id. The agency believes that this clarification provides clear guidance for the application of the standard.

56. Several comments suggested that FDA should look to the new drug provisions in section 505 of the act (21 U.S.C. 355) for direction in assessing significant agreement with the proposed validity requirement and suggested that the degree of scientific agreement needed for health claims approval should be significant but less than that necessary for approval of a new drug application.

FDA agrees that the scientific standard for health claims is less stringent than the requirements for approval of a new drug. In the case of a new drug, section 505(d)(5) of the act provides that the Secretary shall refuse to approve an application for approval of such a drug where there is a lack of substantial evidence that the drug will have the effect that it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. The term "substantial evidence" is not, in and of itself, a particularly stringent standard. Section 505(d) of the act provides, however, that the term "substantial evidence" means evidence consisting of adequate and well-controlled investigations, including clinical investigations (human studies conducted in a controlled clinical setting), by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. (In identifying the source of substantial evidence, the law limits the kinds of studies that can be used. Even this high standard, however, has a degree of flexibility.) Based on this statutory direction, the agency has identified a number of characteristics that are present in "adequate and well-controlled" studies in 21 CFR 314.126.

However, section 403(r) of the act does not mandate requirements as stringent as those for drugs in section 505(d)(5) of the act. Section 403(r) of the act does not reference substantial evidence, adequate and well-controlled investigations, or clinical investigations. To the contrary, section 403(r) of the act contains more flexibility than the drug provisions of the act by providing FDA with authority to authorize claims based on "scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence" (section 403(r)(3)(B)(i)).

The legislative history of this section of the act evidences a concern by Congress that health claims should not necessarily be restricted to the stringent evidence necessary to support a drug claim. H. Rept. 101–538 states: "Under this standard, the Secretary must review all the scientific evidence available that is pertinent to a claim." (Ref. 1).

In debate preceding passage of the 1990 amendments, the sponsors of the bill raised concerns as to whether food claims should not be subject to a more flexible standard than drug claims. For example, in the July 30, 1990, Congressional Record (H5844) (Ref. 3), Congressman Waxman stated:

> And then there is the issue of health claims. Prior to the mid-1980's, health claims were simply not permitted. A health claim on a food product turned that food product, in a legal sense, from a food to drug because if the health claim were made, then the product had to go through the approval process at FDA to show the efficacy of that claim was valid, the same as would be required by a pharmaceutical.
>
> That was an awfully stringent requirement.

Further, on October 26, 1990 (Ref. 3), Congressman Madigan, the other House sponsor of the 1990 amendments, stated:

> Neither Federal regulation nor industry efforts have kept pace with scientific knowledge about diet and nutrition. This bill is an effort to remedy this situation while allowing FDA sufficient flexibility to modify the rules when valid, new scientific information is presented. Given increased awareness and advances in our scientific knowledge on the relationship between diet and health, this legislation is very timely.

Consistent with this flexibility, FDA is not now prescribing a specific set, type, or number of studies as being necessary to support a health claim. The agency will consider all relevant data on a topic, including clinical studies, epidemiological data, and animal studies. Of course, the type, quality, and relevance of a study from which data are derived have an important bearing on how much weight is placed upon the data. For example, FDA will give the greatest weight in its evaluation to well-designed studies conducted with human subjects. Data from laboratory studies using animals, in vitro tests, and chemical analyses of the food substance may be useful, however, in providing an understanding of the nature of the relationship between the substance and the disease or health-related condition.

In the preamble to the proposal (56 FR 60537 at 60548 through 60549), FDA drew heavily on chapter two of the Diet and Health report (Ref. 6) for a discussion of how it will evaluate the studies that are submitted on the impact of intake of a substance on health. Interested persons are referred to that preamble discussion for further information about how the agency intends to apply the validity standard in new § 101.14(c).

In summary, FDA sees the standard for health claims as different from the standard for establishing the effectiveness of a new drug. The agency is not now establishing any minimum data requirements under this standard, although the agency might find it appropriate to do so in the future as it

gains more experience under the health claims regime. Rather, the agency will review all available scientific evidence that is pertinent to a claim and decide whether, on the basis of that evidence, the characterization of the relationship of a substance to a disease or health-related condition that is presented in the claim is scientifically valid.

B. Assessment of Conformity to Scientific Standard

1. General

57. A few comments expressed concern about specific types of studies that FDA advised that it would consider in evaluating health claims. One comment objected that human studies in general would not be very useful. Another comment objected that human studies based on non-U.S. populations that exhibit consistent results may not be useful. Another comment noted that case-control and cohort studies based on the U.S. population are often not powerful enough to detect diet-disease relationships because the range of nutrient intakes within the population is too narrow. However, most comments agreed with the agency's intention not to prescribe a specific set, type, or number of studies as being sufficient to support a disease-related claim, and with its statement that it will "seek to avoid the pitfalls of inflexible adherence to rigidly defined criteria" (56 FR 60548).

The statutory language of section 403(r)(3)(B)(i) of the act is specific in directing the Secretary to consider the totality of publicly available scientific evidence. FDA cannot, therefore, and would not be inclined to, exclude any scientific evidence from consideration in assessing the validity of a claim. The agency recognizes, however, that the evidence relating to a particular claim may vary in its usefulness, and that some types of studies may be more probative than others in establishing the validity of particular nutrient-disease relationships. The agency will consider, therefore, as it stated in the November 1991 proposal (56 FR 60537 at 60548), the type, quality, appropriateness of design and relevance of each of the studies and of the other information that together constitute the totality of scientific evidence when assessing the validity of a claim. The agency will evaluate the strengths and weaknesses of each individual study and weight it accordingly in reaching a decision about the validity of a particular claim.

58. Other comments urged FDA to consider with fairness any proposed health claim that relies on data derived from non-Western cultures. The agency advises that it will consider the evidence submitted in support of a claim on its scientific merits and in the context of the totality of available evidence. It will not underrate any study on the basis of its cultural or geographic origin. Evidence in support of a proposed health claim, however, will attain value in direct proportion to the significance in the U.S. population of the effects of the disease or health-related condition addressed by the claim.

2. Dietary supplements

59. Many comments asserted that FDA should establish a more lenient standard for substances in dietary supplements. Some of these comments argued that such a standard is mandated by Congress and cited the statement of Senator Hatch, one of the primary authors of the 1990 amendments, that "a more lenient standard for dietary supplement[s] is envisioned." (Ref. 2). Other comments argued that the standard should be sufficiently lenient to permit marketing of supplements without any labeling restrictions. Some of these comments argued that dietary supplements needed no stringent requirements because supplements could be adequately regulated under the regulatory regime of a label needing to be truthful and not misleading under section 403(a)(1) of the act. A number of comments asserted that the same standard effectively renders section 403(r)(5)(D) of the act superfluous. Some comments asserted that, by not adopting a more lenient standard, FDA would restrict the amount of health information available to consumers and stated that such information is important to consumers in deciding which products to buy. A number of comments asserted that the same standard for supplements is counter to the intent of the 1990 amendments because Congress intended to make more, rather than less, information about the health benefits of foods available to consumers.

However, other comments agreed with FDA's proposal to use the same scientific standard for dietary supplements that the act provides for conventional foods. One comment noted that it is especially important to place dietary supplements under the same standard because they are marketed mainly on the basis of their purported health benefits. Another pointed out that the proposed standard will facilitate purchasing decisions for consumers by reducing fraudulent labeling claims.

A few comments contended that FDA should establish a more stringent standard for substances in dietary supplements. One comment asserted that FDA has adequate authority to do so and asserted that the legislative history of the 1990 amendments supports a more stringent standard. The comment stated that FDA recognized, when it proposed not to authorize a health claim for omega-3 fatty acids in Docket No. 91N-0103 (56 FR 60663, November 27, 1991), that it does make a difference whether one receives nutriment from food or from pills. In that document, the comment maintained, FDA asserted that benefits have been shown for fish but not for omega-3 fatty acids.

Under the DS Act, there is a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. Therefore, FDA is not adopting a standard to implement section 403(r)(5)(D) of the act. The agency will adopt a standard in accordance with the procedures established in the DS Act. However, FDA has carefully considered these comments and, in response, would make the following observations.

Although Congress did convey flexibility in resolving this issue to FDA, and one sponsor did state that this flexibility should be used to establish a more lenient standard, as the agency explained in the preamble of the proposal (56 FR 60537 at 60539 through 60540), the legislative history concerning section 403(r)(5)(D) of the act makes clear that Congress did not intend to require that the agency adopt a different standard for these products (Refs. 2 and 3). Instead, the exemption on its face gives the agency the discretion to adopt a scientific standard respecting the validation of claims for supplements, regardless of whether the standard is more lenient or more stringent (Ref. 3). The exemption gives the agency the same discretion with respect to establishing a procedure under which claims may be made.

The statement of House Floor Managers (Ref. 3), addresses section 403(r)(5)(D) of the act by stating, in part:

> The Senate version of the bill, which we are voting on today, retains this standard for all foods except vitamins, minerals, herbs, and other similar nutritional substances (referred to below as "vitamins"). The bill requires that vitamins that include claims defined under section 403(r)(1)(B) shall be subject to a "procedure and standard" defined by the Secretary in regulations that require an evaluation of the validity of the claim. The FDA is given the discretion to define both the procedure and the standard because the principals in the Senate could not agree on the appropriate procedure or the appropriate standard.

It is obvious from the language that the agency could adopt the same procedure and standard that Congress has adopted for disease claims on food other than vitamins; it is also obvious that it could adopt a stronger standard for vitamins, minerals, herbs, and other similar nutritional substances.

In addition, the Metzenbaum-Hatch managers' statement in the Senate (Ref. 2) addresses section 403(r)(1)(B) of the act by stating, in part: "The purpose for the different handling of conventional food products and dietary supplements is to provide the Secretary flexibility in the development of the procedure and standard for health claims for dietary supplements."

Thus, both the Senate and the House of Representatives agreed that FDA has the flexibility to adopt the standard and procedure for dietary supplements that appears appropriate to the agency. As pointed out by the comments, Senator Hatch left no question about his position that FDA should use this flexibility to adopt a more lenient standard. However, other members of Congress were equally clear about their position that FDA should not adopt a more lenient standard. In the October 24, 1990, Congressional Record, (Ref. 2), Senator Metzenbaum, the other primary author of the Senate amendments, stated:

* * * It is my view that there is no reason to do anything other than utilize the same procedure and standard for dietary supplements.

Whatever approach the Secretary takes, he must establish a system that evaluates the validity of health claims for dietary supplements. The system must be based on the same considerations that guide other agency decisions: public health, sound scientific principles and consumer fraud.

Further, the House of Representatives clearly did not support a more lenient standard for dietary supplements. The statement of House Floor Managers that appears in the October, 26, 1990, Congressional Record (Ref. 3) states:

* * * Whatever approach the agency takes, it must adopt a system that evaluates the validity of any disease claims made with respect to these substances. Its system must be based on considerations of public health and consumer fraud. As in every similar decision made by the agency today, we fully expect that the agency's evaluation of disease claims made with respect to vitamins will be based on sound scientific principles.

There is a great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims. The potential is just as great for vitamins as it is for other products. In our view, vitamins and other substances covered by this provision should be subject to at least as strong a standard as is applicable to other foods that contain claims that the food will treat a disease or health condition.

Thus, some members of Congress opposed a more lenient standard for dietary supplements. However, it also seems that assertions that Congress supported a more stringent standard in the legislative history of the 1990 amendments are not well-founded. The above-mentioned statements on a more stringent standard were included in the legislative history to demonstrate that one could be established, if appropriate.

The agency will consider this legislative history together with the legislative history of the DS Act in proposing rules to implement the 1990 amendments, with respect to the DS Act. The agency notes that if it were to adopt a more lenient standard and procedure for supplements, there might be a significant potential for consumer confusion when confronted with a situation in which there would be health claims for substances when they are present in supplements but not when they are present in conventional foods. If there is reason to conclude that this would not in fact be the case, FDA urges interested persons to come forward with evidence to support such a conclusion during the rulemaking mandated by the DS Act.

The Managers Report on the DS Act (Ref. 34) states that among the policy goals of the DS Act is to assure the public that health or disease-related claims for dietary supplements are properly supported. In the rulemaking under the DS Act, FDA will try and determine what proper support should incude. In particular, the agency is interested in why the standard for the scientific validity of health claims in section 403(r)(3)(B)(i) which applies by law to claims for all substances for which claims are made except for those in dietary supplements, is not also appropriate for substances in dietary supplements.

The agency also points out that it did not tentatively conclude in the omega-3 fatty acids proposal that it makes a difference whether one receives nutriment from food or from pills, as the comment suggested. While FDA did state in the summary of that docket that there is inadequate evidence to support a beneficial relationship between reduced risk of coronary heart disease and increased consumption of omega-3 fatty acids, and that there is some evidence that benefit may be gained through the consumption of fish, the agency noted that benefits attributed to fish could not necessarily be ascribed to the presence of omega-3 fatty acids. The example, therefore, does not show that a substance is any more beneficial when it is in a conventional food than when it is not in a conventional food.

60. A number of comments suggested that the agency should adopt a separate mechanism for evaluating the validity of claims for herbs. Under the suggested mechanism, an oversight committee would appoint an expert panel that would consist of a director and at least four scientists with training and experience related to herbal and botanical products. (FDA would participate as a nonvoting member.) The panel could hire outside consultants. The committee, which would be charged with the responsibility of reviewing all health claims petitions pertaining to herb or botanical components, would relieve FDA of all responsibility for initial review of these petitions. Such petitions would not be permitted to be submitted directly to FDA. The expert panel that was selected by the committee would conduct an evaluation of scientific data pertaining to the requested claim, subject the evaluation to peer review, and prepare a final recommendation about the claim. The recommendation and all supporting documents would then be forwarded to FDA, and the agency would be permitted 120 days to approve, disapprove, or modify the report. Under draft regulations submitted by one of the comments, there would be a codified presumption in favor of the committee recommendation.

The comment asserted that this mechanism for evaluating petitions would not involve a transfer of the agency's authority and obligation to enforce the act because the final authority for decisions rests with FDA. Further, the comment asserted that there is precedent for the requested mechanism in FDA's past use of reviews of food and cosmetic ingredients that have been prepared by the Federation of American Societies for Experimental Biology (FASEB) and the Cosmetic Ingredient Review (CIR).

Although the DS Act establishes a moratorium on the implementation of the 1990 amendments with respect to dietary supplements of herbs, the agency considers it appropriate to respond to this comment. FDA believes that the mechanism suggested by the comment would involve a significant transfer of agency authority for the control of health claims on herbs, and there is no basis under the act for such a transfer. Although the comment asserts that such a transfer would not take place by maintaining that the final authority for decisions rests with FDA, the assertion is not correct. Because of the codified provision providing that there would be a presumption in favor of the committee recommendation, the agency would be obligated to prove that

the committee was wrong or else it would be required to follow the committee's recommendation. Under such circumstances, FDA could be forced to propose to authorize a health claim that the agency believed, but was unable to prove, was not valid. Thus, there would, in fact, be a significant transfer of authority under the requested mechanism.

Further, there is no precedent for the requested mechanism in FDA's use of FASEB and CIR reviews of food and cosmetic ingredients. Neither type of review created a presumption in favor of the review recommendation. Also, FDA has never required that petitions pertaining to food and cosmetic ingredients be submitted for such reviews. With respect to FASEB reviews, FDA contracted for these reviews as part of its GRAS review in the early 1970's and then once to update information on sulfiting agents. FASEB only submitted a recommendation as to whether, and what, uses of a substance were GRAS. FDA conducted its own review of the evidence and was free to elect to use the FASEB review as it saw fit.

With respect to CIR reviews, such reviews are used primarily by industry to make self-determinations of cosmetic ingredient safety. The agency may, or may not, comment on any CIR review. Even where FDA comments on a CIR review, there would be little likelihood that agency rulemaking would result. In situations where such a review does serve as a stimulus for a rulemaking proceeding, the review would not be the sole reason for the proceeding. The agency fully retains its enforcement authority in both situations.

Moreover, the committee suggested by the comment would be subject to the Federal Advisory Committee Act (5 U.S.C. App. 2). The burdens imposed on an agency by this statute are heavy. FDA has limited resources for advisory committees. While the agency may, on occassion, use advisory committees as part of the health claims process, it believes that it would be an inappropriate expenditure of those limited resources to commit them to the committee suggested by the comment.

Of course, both the conventional food and dietary supplement industries may, if desired, work through committees in preparing well-supported petitions for submission to FDA, and FDA will cooperate with such committees at a scientific level by explaining the agency's requirements to them and sharing publicly available information. However, the agency would not require firms to use such committees, and FDA would still have the ultimate obligation of determining whether the petitioned-for claim is scientifically valid. To clarify that the agency will consider all recommendations by such committees, FDA has revised provisions of new § 101.70(b) to provide that information that is submitted with petitions may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area at issue. While the agency will consider any findings of a panel included in a petition, the agency will not use that panel to make its decision.

61. Some comments asserted that in addition to the proposed regulatory framework for evaluating health claims, which involves permitting supplement claims on the same terms as for conventional foods, FDA should also subject dietary supplements to an alternative involving a different level of validity substantiation and a different procedure. Under the alternative procedure, claims for which there is substantial scientific evidence but not yet significant scientific agreement would have to undergo a certification and notification procedure rather than rulemaking proceedings. Under the alternative, claims could be made for supplements so long as: (1) The claim expressly discloses the absence of scientific agreement as to the relationship, (2) the manufacturer provides FDA with a fully documented certification by a panel of at least three qualified experts that there is substantial scientific evidence supporting the claim, and (3) FDA does not disapprove the claim within 90 days of receipt of the certification. (When additional information is needed, the 90 day period could be extended an additional 45 days.) Under the alternative, FDA would have an opportunity to participate in the selection of the expert panel.

Given the moratorium on the implementation of the 1990 amendments established by the DS Act, the agency is reserving making a detailed response to these comments at this time. The Managers Report on the DS Act (Ref. 34) states that FDA may wish to propose new rules or to repropose rules under section 403(r)(5)(D) of the act. FDA will consider these comments in deciding what action to take with respect to section 403(r)(5)(D) of the act in responding to the DS Act.

V. General Labeling Requirements

Proposed § 101.14(d)(1) provides that when FDA determines that a health claim is valid, the agency will propose a regulation in part 101, subpart E to authorize the use of the claim. Further, the provision states that if the claim pertains to a substance not provided for in § 101.9 or § 101.36, FDA will propose amending those regulations to include declaration of the substance. FDA points out that § 101.9(a) requires that where a claim about a nutrient is made, the nutrition labeling information shall include appropriate information about that nutrient. Proposed § 101.36(a) also would require nutrition information on dietary supplements. However, given the moratorium established by the DS Act, FDA is not adopting § 101.36 at this time. FDA has deleted the reference to that section from § 101.14(d)(1).

62. Several comments argued that FDA should not permit firms to place any health claims on the labels of conventional foods or of dietary supplements.

Through enactment of section 403(r) of the act, Congress has mandated that firms be permitted to place health claims on food labels when FDA finds that the claims are valid and establishes regulations authorizing their use. Although the comments cited a wide variety of reasons to support their objections, FDA is not addressing these reasons because the 1990 amendments settled this issue. The agency has, therefore, not made any changes in response to these comments.

A. Consistency with Summary of Scientific Information and Model Health Claim

Proposed § 101.14(d)(2)(i) stated that all label or labeling statements about the health benefit that is the subject of the health claim shall be based on, and consistent with, the conclusions set forth in the summary of scientific information and model health claims provided in regulations in part 101, subpart E.

63. Some comments urged FDA not to allow manufacturers to paraphrase an established model health claim. These comments stated that claims should be repeated in the same way on each qualifying food product to ensure that only one clear message is being given to consumers. One of these comments cautioned that consumers faced with health claims stated in a wide variety of ways will be confused about the possibility of differences among the claims. Another suggested that in light of the practical inability of FDA to police varying wordings for accuracy, the only way to ensure that claims are an accurate representation of the facts is to require that agency-drafted claims be used. The comment noted that although the 1990 amendments did not specifically contemplate mandatory FDA-created wording for the health

claims, section 403(r)(3)(B)(iii) of the act could be interpreted to allow such an approach on the basis that the agency wording is the only one that "enables the public to comprehend the information provided in the claim."

However, other comments maintained that manufacturers should not be held to the specific language in the model health claims and asked that the regulations be amended to specifically state that label claims need not be identical to the model claim language. The comments explained that the model claims are too complex to be meaningful to consumers and expressed concern that the proposed requirement for consistency might be interpreted in such a rigid manner that effectively only the model claim would be permitted.

FDA does not believe that the 1990 amendments allow the agency to prohibit manufacturers who wish to place a health claim on a product from paraphrasing language in the model claim. Section 3(b)(1)(A)(vii) of the 1990 amendments prohibits FDA from requiring persons to secure agency approval before placing a health claim on a product, provided that the claim is in compliance with the applicable regulation. The House Report (Ref. 1), states that this section "makes it clear that the regulations will not require premarket review of each claim; they will only require that the claim be consistent with the terms and requirements of the regulations." The agency believes that it is possible to paraphrase a model health claim while remaining consistent with the terms and requirements of the regulations permitting that claim. This position is similar to agency policy that permits the use of terminology other than that established in a final OTC drug monograph in labeling of an OTC drug product to describe indications for use (51 FR 16258, May 1, 1986). Consistent with that policy for OTC drug labeling, the agency believes that the goal of ensuring scientifically valid, truthful, and nonmisleading labeling without inhibiting effective consumer communication does not require exclusive use of language in a model health claim. The model language along with other requirements for that claim will, nevertheless, provide the standard for measuring the accuracy of alternative language developed by food manufacturers for their products because FDA has included all mandatory labeling elements of a health claim in the model claim. Of course, manufacturers should recognize that a paraphrased health claim that fails to convey all the mandatory elements of the claim will subject a product to regulatory action.

Section 403(r)(3)(B)(iii) of the act does not require the verbatim use of the agency's model health claims. The provision states that the agency must require in a regulation authorizing a health claim that the claim be stated in such a way as to allow the public to comprehend the presented information and to understand the relationship of the substance to the disease or health-related condition, the significance of the substance in affecting the disease or health- related condition, and the significance of the information in the context of the total daily diet. The agency's model wording of a health claim is likely not to be the only way in which one can convey all the required information.

Although FDA agrees that manufacturers should not be held to the specific language in the model health claims, the agency does not believe that it is necessary to state this fact in the regulations. Just as some could misinterpret the proposed codified requirement that claims be "consistent with" model claims, others could misinterpret a provision stating that claims "need not be identical to the model claim language." Thus, FDA has revised new § 101.14(d)(2)(i) to require that labeling statements conform to the conclusions set forth in the regulations in part 101, subpart E without any specific reference to provisions contained therein.

64. Some comments contended that FDA's proposed regulations would require too much information in health claims, and that the appearance of so much information in a health claim would confuse consumers. Some of these comments suggested that this confusion could thwart FDA's goal of educating the public. Others asserted that, rather than trying to clear up their confusion, many consumers would simply assume that the product is unhealthy for them and choose products that did not bear the lengthy claims. One of these comments stated that the calcium/osteoporosis claim was, according to computer analysis, so complex that a "fourteenth-grade" reading level was required to properly understand it.

Another comment objected that the proposed policy of codifying "all" effects of a nutrient on a condition or disease would lead to the inclusion of effects that were of tangential importance or that were not the subject of significant scientific agreement. Instead, the comment stated, FDA should limit its description to significant effects on which there was such scientific agreement.

However, other comments agreed with FDA's proposal that health claims should include information on factors that affect the nutrient-disease relationship (e.g., exercise). One consumer advocacy organization strongly asserted that it is important that nutrient intake not appear to be the sole factor in matters affecting the risk of disease when other factors are considered to be of similar importance. The comment stated that use of such language as "one of several factors" and "can help" in health claims will help the public to understand that the nutritional characteristics of the foods bearing claims are not "cure-alls" for the disease/health condition mentioned.

FDA agrees that consumers should be presented with health claim information in a clear, nonconfusing manner, and the agency realizes that there is a limit to the amount and complexity of information that can be presented in a health claim. However, the agency believes that it must require enough information in a health claim to ensure that consumers understand that factors other than dietary intake of the nutrient may bear on the substance-disease relationship. Given these imperatives, the agency is faced with the difficult task of determining what information is necessary in a claim, and what information is not.

FDA has reviewed the requirements for the health claims that it is authorizing elsewhere in this issue of the **Federal Register** to determine whether they call for the inclusion of information in the claim that is not absolutely necessary to allow the consumer to understand the claims in the context of a total daily diet. FDA has deleted information that is not necessary from the list of mandatory information and instead has listed this information as information that a manufacturer may opt to include in a health claim. FDA will take a similar approach in the future. FDA believes that its regulations in part 101, subpart E now represent an acceptable balance between the consumer's right to understand the full context of the claim and the manufacturer's concern over claim length. By delineating the information that is mandatory and optional in a claim, FDA is relieving manufacturers from having to include information that is of tangential importance but allowing those who wish to use the information to do so without violating the authorizing regulation.

As for the comments that asserted that the sentence structure and phrasing of

the model claims are too complex, the agency has sought to minimize complexity but has found that some unavoidably results from trying to provide the information necessary to ensure that consumers understand the claim in its proper context. FDA believes that the versions of the claims that it is adopting mandate less information, and are significantly less complex, than those proposed. However, manufacturers who are not satisfied with the model claims are free to develop their own versions of the claim, provided that those versions include all of the information required by the authorizing regulation.

65. One comment asserted that product-specific health claims, which emphasize the role of a specific product or brand of product in a diet-disease relationship already the subject of an agency regulation, should be allowed and even encouraged.

FDA disagrees with this comment. Section 403(r)(3)(B)(iii) of the act directs the agency to require that health claims enable the public to understand the information in the context of the total daily diet. FDA believes that a claim that refers specifically to the health benefits conferred by the consumption of a certain brand name of product would unduly emphasize the importance of that brand in the context of the daily diet. Also, such claims could imply that other brands of the same food, as well as other foods containing the substance, might not have the same effect on the disease or health-related condition and thus be misleading under section 403(a) of the act. Accordingly, the agency rejects this comment's recommendation.

66. A number of comments suggested that FDA should develop health claims about general food choices, rather than substances, and a disease or health-related condition. Other comments, however, cautioned that such an approach might create more consumer confusion than benefit.

As FDA pointed out in its response to comment 1 of this document, claims about the benefits of general classes of food such as fruits and vegetables that do not make an express or implied connection to any specific substances do not constitute health claims because the multiplicity of substances found in those foods renders the claim too general to satisfy the first basic element of a health claim (i.e., substance). However, where a claim about a general food choice is an implied claim for a substance or specific substances contained in the food and a disease or health-related condition, it would be subject to the health claims regime.

Development of information about general food choices and diseases or health-related conditions, to the extent it is not subject to section 403(r) of the act, is an activity authorized by the National Nutrition Monitoring and Related Research Act of 1990 (Ref. 32) which was enacted at about the same time as the 1990 amendments. In brief, the Nutrition Monitoring and Related Research Act authorizes the Secretary of the Department of Health and Human Services and the Secretary of the Department of Agriculture to establish dietary guidance by jointly publishing at least every 5 years a report entitled "Dietary Guidelines for Americans." Each such report is to contain nutritional and dietary information and guidelines for the general public which are based on the preponderance of the scientific and medical knowledge that is current at the time the report is prepared. The Secretaries are also authorized to review and approve any dietary guidance for the general population or identified population subgroup proposed to be issued by any Federal agency to assure that the guidance either is consistent with the "Dietary Guidelines for Americans," or that the guidance is based on medical or new scientific knowledge that is determined to be valid by the Secretaries.

The goals to be achieved by both the 1990 amendments and the Nutrition Monitoring and Related Research Act (7 U.S.C. 5341) are complementary in every respect. Where the 1990 amendments ensure the validity of health claims, the Nutrition Monitoring and Related Research Act ensures the validity of dietary guidance. In considering whether to authorize health claims, the agency will exercise great care to see that the claims that it authorizes are fully compatible with national dietary guidance.

B. Complete, Truthful, and Not Misleading

Proposed § 101.14(d)(2)(iii) stated that a health claim shall be complete, truthful, and not misleading. In keeping with these requirements, FDA asserted that where factors other than consumption of the substance bear on the claimed effect on a disease or health-related condition, such factors must be addressed in the claim.

67. One comment proposed that the word "complete" as used in proposed § 101.14(d)(2)(iii) is vague and would lead to confusion. It noted that each company in the food industry will be free to paraphrase FDA's model health claims and, since such paraphrasing necessarily implies different words and sentences, to the extent that a company's claim does not track the model exactly, such claims will not be "complete." The comment suggested that the word "complete" be deleted from the final regulation.

FDA disagrees that the word "complete" should be deleted from the regulation. The agency believes that it is imperative that consumers be informed of factors other than the consumption or nonconsumption of the substance that significantly bear on the claimed effect on a disease or a health-related condition. To this end, FDA will codify all such information in part 101, subpart E. FDA believes that the word "complete" is necessary in § 101.14(d)(2)(iii) to ensure that manufacturers understand that their health claims must include all such mandated information. This policy is consistent with section 201(n) of the act, which provides that an article's labeling may be misleading if it omits material facts.

68. One comment stated that dietary supplements should be required to balance their health claims by including warnings against any negative health effects that might result from their use. The comment also suggested that the labels of such products should declare the maximum amount of the dietary supplement that can be consumed without incurring risk of toxicity.

FDA disagrees. To be eligible for a health claim, a substance, if it is to be consumed at other than decreased dietary levels, is required to be a food or a food ingredient whose use at the levels necessary to justify the claim is safe and lawful under the applicable food safety provisions of the act. Thus, there is no reason to treat dietary supplements any differently than other food by requiring that they bear special warnings.

To avoid any misunderstanding as to the appropriate level of consumption in relation to the daily diet, the agency may require, in its authorizing regulation for a claim, that the claim state the level of consumption beyond which no additional benefit is likely to be gained. The agency notes as an example that the calcium/osteoporosis health claim includes the statement that "adequate calcium intake is important, but daily intakes above about 2,400 mg are not likely to provide any additional benefit."

If at some point in the future, the agency approves a health claim that has some safety concern to any subpopulation of consumers, the agency will, of course require that the claim include sufficient information to alert that subpopulation. For example, if FDA

ever approves a health claim for vitamin D, the claim would be required to inform consumers of the potential for an adverse effect from excess consumption.

C. Layout

Proposed § 101.14(d)(2)(iv) stated that all claims must appear in one place, in the same type size, without intervening material. FDA included in this provision an exception to allow a short reference statement to appear on the label, "See ———— for information about the relationship between ———— and ————," with the blanks filled in with references to the location of the labeling (other than the label) on which the full claim appears, the name of the substance, and the disease or health-related condition.

69. A number of comments suggested that proposed § 101.14(d)(2)(iv) be amended to allow the use of a front-panel reference to a full health claim appearing on the side or back panels. Many of these comments contended that a referral statement on the principal display panel would help make consumers aware of the full claim, which itself might be too long to appear on the principal panel. Some comments suggested that abbreviated forms of a health claim be allowed to serve as reference statements. One of these comments suggested that this approach would avoid overcrowding of the principal display panel, would place the health claims where they would be of greatest use to consumers, and would still provide conveniently located, detailed information to consumers.

FDA takes note of those comments on reference statements and abbreviated health claims. Some of the issues raised by these comments have been resolved with revisions made in all of the model health claims. For example, among the sample claims for sodium and hypertension in new § 101.74(e) is one that reads: "Diets low in sodium may reduce the risk of high blood pressure, a disease that is dependent upon many factors." Similarly short claims have been developed for other health claims. Since these abbreviated claims are not much different in length than a reference statement that would have been used on the principal display panel or elsewhere in labeling of a product, it is now possible to present the health claim in place of a reference statement. However, since the agency cannot provide assurance that future health claims will be crafted to be as short at the example given above, FDA has retained proposed § 101.14(d)(iv). The agency's responses to comments on reference statements and abbreviated claims follow.

FDA does not believe that it is appropriate to use abbreviated health claims as referral statements. Shortened health claims used as referral statements, even those as simple as "See side panel for information on how calcium may reduce the risk of osteoporosis," still constitute a health claim because they clearly characterize the relationship between a substance and a disease or health-related condition. Further, such a health claim is misleading because it does not include facts that are material in light of the representation that is made, and that are necessary to understand the claim in the context of the daily diet. For example, in the case of calcium and osteoporosis, the shortened claim does not reveal that regular exercise and a balanced diet are important to the maintenance of good bone health, and that a daily intake of calcium in excess of 2,400 mg is not likely to provide additional benefit for reducing the risk of osteoporosis.

Such situations are possible whenever the full health claim information appears in a location different from that of the reference statement and are especially likely to occur when a multiplicity of labeling is associated with a product. For example, a cereal manufacturer could place an abbreviated claim as a reference statement on the principal display panel of the cereal box and then bury the full claim on one of several paper inserts. In such a case, a consumer is unlikely to search through the inserts to find the full claim. A similar situation might arise were a grocer to display an abbreviated calcium-osteoporosis claim as a referral statement on a dairy case and then place the full claim on a billboard in a far corner of the store. A consumer is not likely to search through the store for the detailed health information.

In each of these examples, the consumer would be misled because he/she has received an incomplete health claim that does not disclose information on nondietary factors that may affect the nutrient-disease relationship and that does not allow the consumer to understand the claim in the context of the total daily diet. Case law clearly supports the agency's position that the mere presence of the full health claim elsewhere in the product labeling does not counteract the misleading nature of the abbreviated reference statements in such instances. See, e.g., *U.S.* v. *An Article of Food * * * "Manischewitz * * * Diet Thins,"* 377 F. Supp. 746, 749 (E.D.N.Y. 1974).

The referral statement provided in § 101.14(d)(2)(iv) does not constitute a health claim, as it does not characterize the relationship between a substance and a disease or health-related condition. The statement simply refers the consumer to a location where the complete health claim appears. A consumer who reads the referral statement without reading the full health claim may realize that there is some relationship between the nutrient and the disease. The nature of that relationship, however, is only presented in a context that is complete, truthful, and not misleading and that thus allows the consumer to fully understand and evaluate the claim. Thus, the consumer will not be misled by reading the provided referral statement. Accordingly, the referral statement provided in proposed § 101.14(d)(2)(iv) is the only one that should be used. As explained previously in this preamble (section I.D.5. of this document), the statement must appear in immediate proximity to any graphic material such as a symbol that constitutes an explicit or implied health claim.

70. A number of comments suggested that the complete health claim should be allowed only on the principal display panel unless the panel is too small to accommodate it.

FDA does not agree that health claims should be required to appear only on the principal display panel. The adoption of such a policy, for those labels that are physically large enough to contain the full health claim, could easily lead to overcrowding of some principal display panels and would eliminate their use on those that are not. Such a requirement would significantly undercut the congressional intent in providing for health claims in section 403(r) of the act. Therefore, FDA rejects this comment.

71. A number of comments asserted that the type size requirement proposed for health claims is not mandated by law. It was also argued that the requirement may make it impossible for manufacturers to include other truthful and nonmisleading information on the principal display panel.

FDA recognizes that the proposed type sizes are not mandated by law. The agency proposed this requirement because it was concerned that many consumers, when faced with a health claim printed in differing type sizes, might read only those portions of the claim that appear in larger type and thus would overlook the information printed in smaller type. However, FDA has reconsidered this issue and now believes that, as proposed, the provision is unnecessarily restrictive. Certainly consumers would not likely ignore portions of a health claim that are

printed in a reasonably related type size to the largest printed matter in the claim. FDA believes that any abusive use of type size could adequately be prevented under § 101.14(d)(2)(iii), which requires, in part, that a claim not be misleading. Accordingly, FDA has removed the requirement that a claim appear in the same type size. While the agency encourages manufacturers to observe the minimum type size required by § 101.2 for mandatory labeling information to ensure that the claims are easily legible, manufacturers who want to include a complete health claim on the principal display panel of a product may utilize whatever type size they feel is necessary to achieve this end.

72. One comment recommended that, in order to avoid the label space problems that would result from the appearance of lengthy bilingual claims, health claims on imported products should be allowed to appear in English without translations into the foreign languages that appear on the label. The comment asserted that competitive pressure will force U.S. importers to make label claims comparable to domestically produced products and cited the model health claim for calcium and osteoporosis in exemplifying the difficulty that would result from providing lengthy bilingual claims. Another comment from a foreign industry organization objected to permitting any health claims on food labels because multi-language labeling will be so burdensome that it will serve as a nontariff trade barrier.

FDA advises that the provisions of § 101.15(c)(2) require only that all mandatory labeling information be translated into any foreign languages that appear on any part of a product's labeling. Because the presence of a health claim on a food label is voluntary, manufacturers who place an English-language health claim on a multi-language label may choose whether to translate that claim into one, all, or none of the foreign languages appearing on the label.

D. Enables Public to Understand Significance of Claim in Context of Total Daily Diet

Proposed § 101.14(d)(2)(v) stated that a health claim must enable the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet.

73. Some comments asserted that the multiplicity of labeling requirements exceeds the statutory language of the 1990 amendments and stated there is no evidence in the legislative history to suggest that Congress intended label claims about nutrient/disease relationships to include the kinds of detailed information mentioned in the preamble. One of these comments stated that FDA is authorized under the amendments to require only that information that is necessary to prevent the health claim from being misleading.

Another comment disagreed with FDA's conclusion that section 403(r)(3)(B)(iii) of the act allowed "only those effects found to be substantiated" to be included in the health claim. The comment instead asserted that the requirements of the provision would be fulfilled if a health claim merely characterized the level of a nutrient vis-a-vis a disease, provided that there was significant scientific agreement that the intake of the nutrient at the level present in the food was beneficial in reducing the risk of the disease.

FDA disagrees with these comments. Section 403(r)(3)(B)(iii) of the act requires that a regulation that authorizes a claim require that the claim be stated in a manner that enables the public to comprehend the information in the claim and to understand the relationship of the substance to the disease, the significance of the substance in affecting the disease, and the significance of the information in the context of the total daily diet. Thus, a wide variety of factors may need to be addressed in the claim in order to fulfill these requirements, and the agency is not limited to requiring only that information that is necessary to prevent a claim from being misleading.

For example, the regulation authorizing a claim on the relationship between calcium and osteoporosis requires that the claim explain that adequate calcium intake during adolescence and early adulthood appears to have a positive effect on bone health, and that optimizing peak bone mass during that period may reduce the risk of osteoporotic fracture in old age (see new§ 101.72(d)(3)). Additionally, the regulation requires that claims point out that adequate calcium intake be accompanied with exercise and the maintenance of a balanced diet. The claim must also identify factors such as the age range within which women can expect to achieve the greatest effect for decreasing the risk of developing osteoporosis in later life (see new § 101.72(d)(2)). These are considered to be facts essential for consumers to understand the conditions and circumstances under which the claimed effect of calcium on the risk of osteoporosis is more likely to be obtained.

Accordingly, if FDA were to permit a health claim that simply characterized the level of a nutrient vis-a-vis a disease or health-related condition, the agency would not meet the statutory requirements of section 403(r)(3)(B)(iii) of the act. Therefore, FDA rejects the comments.

74. Some comments stated that the model health claims were themselves misleading in that the identification of certain high-risk groups in a claim might easily lead consumers in other groups to believe that the information presented in the claim does not apply to them, when in fact it may (for example, osteoporosis affects some men as well as women).

The model claims that are targeted to specific subpopulations have been carefully worded to encompass all of the affected subpopulations. The agency, therefore, sees no potential for a consumer who is in a group that is at increased risk of a disease that is discussed in a health claim to be misled by the claim into believing that he/she is not at an increased risk of the disease. The agency addresses concerns about specific model health claims in the preambles to the specific regulations authorizing those claims.

75. Other comments asserted that model health claims should emphasize the importance of good nutrition habits to all consumers. One also recommended that FDA require a statement about the need to seek medical advice for treating the related disease as part of the health claim.

FDA does not agree that it is appropriate to require that all health claims emphasize the importance of good nutrition to all consumers. In many cases, a health claim may be targeted toward a specific subpopulation. The inclusion of a statement directed at the general U.S. population could lead some consumers who are not targets of the claim to mistakenly believe that the entire health claim has relevance to them. For example, a calcium-osteoporosis claim targeted toward teenage women that bears a statement concerning the importance of good nutrition to the general population could mislead some middle-age men with no family history of osteoporosis to believe that the claim was also targeted toward them.

Also, FDA does not believe that it is appropriate for health claims to bear statements concerning the need to seek medical advice for treating the disease or health-related condition mentioned in a claim. The agency is concerned that the appearance of a statement concerning the treatment of a disease on the label of a food could mislead some consumers to believe that the food possesses therapeutic value for an

existing disease or health-related condition. Further, such an interpretation could encourage some consumers who suffer from the disease or condition to attempt "home remedies" by consuming more of the product and, ironically, temporarily or even permanently foregoing the medical attention that they need.

E. Presence of "Low" Level of Nutrient to be Consumed at Decreased Dietary Levels; Presence of "High" Level of Nutrient to be Consumed at Other Than Decreased Dietary Levels

Proposed § 101.14(d)(2)(vi) stated that to bear a claim about the benefits of consuming a substance at reduced dietary levels, a food must be sufficiently low in that substance to meet the definition of the term "low" if the term has been defined for that substance, or if the term has not been defined, to meet the level set in the regulation authorizing the claim. Proposed § 101.14(d)(2)(vii) stated that to bear a claim about consuming a substance at other than decreased dietary levels, a food must be sufficiently high in that substance to meet the definition of "high" if the term has been defined for that substance, or if the term has not been defined, to meet the level set in the regulation authorizing the claim.

With the decision in section II.B of this document to revise the definition of "substance" in proposed § 101.14(a)(2) to include a specific food as well as a component of food, the requirements of proposed § 101.14(d)(2)(vii) (i.e., the requirements for "high") must be revised as they apply to a health claim for a specific food. Where a health claim for a specific food (e.g., garlic, rice bran) is established by the agency, it is presumed that the claim will deal with either inclusion of the food in the diet or increased dietary intake to effect the benefit that is the object of the claim. The agency does not envision authorizing a health claim for a specific food based on decreased intake of that food because, where moderation in or a decrease in daily intake is at issue, that action is directed toward food components rather than whole foods (e.g., "choose a diet low in fat, saturated fat, and cholesterol;" "use sodium only in moderation").

Accordingly, FDA has revised proposed § 101.14(d)(2)(vii) to state that, where no definition for "high" has been established, that is where the claim pertains to a whole food or to the food's use as an ingredient in other foods, the claim must specify the daily dietary intake necessary to achieve the claimed effect as established in the regulation authorizing the claim.

76. Most comments concurred with the proposal to allow a health claim only when a food contains the claimed substance in an amount that meets the criterion for either a "high" or "low" level of that substance. However, some comments qualified their concurrence by saying that they did not agree with the definitions for "high" and "low." One comment stated that, absent a definitive showing that health claims would be misleading on foods that do not meet the "high" or "low" definitions, FDA's approach cannot be considered narrowly tailored to directly advance the government's interest in providing important diet and health information to consumers. Unless deception could be proved, the comment urged FDA to eliminate the requirements linking health claims to "high" and "low" definitions for nutrient content of foods.

The agency has considered these comments and concludes that it is appropriate to retain the requirements in proposed§§ 101.14(d)(2)(vi) and (d)(2)(vii) linking health claims to "high" and "low" definitions for nutrient content of foods. The definitions for "low" and "high" levels of a substance (nutrient) have been developed specifically to assist consumers in maintaining healthy dietary practices (see section 403(r)(2) of the act). The same basis underlies the purpose for health claims. This is evident from the House of Representatives report on the 1990 amendments (Ref. 1):

> The Surgeon General has advised Americans that diets low in fats, low in salt and high in fiber can reduce the risk of chronic diseases such as cancer and heart disease. Health claims supported by a significant scientific agreement can reinforce the Surgeon General'[s] recommendations and help Americans to maintain a balanced and healthful diet. Similarly, statements regarding the level of these nutrients in foods will assist Americans in following the Surgeon General's guidelines.

Accordingly, a requirement with respect to the level in a food of a substance that is the subject of a health claim is consistent with the intent of the 1990 amendments. The definitions of "high" and "low" are addressed by FDA in the rule on nutrient content claims published elsewhere in this issue of the **Federal Register**.

77. One comment urged FDA to modify the proposed requirement that would permit a health claim on a product for which a nutrient (specifically sodium) is assessed only on the basis of the reference amount customarily consumed (as defined in the final rule on serving size published elsewhere in this issue of the **Federal Register**). The comment suggested that the product should additionally comply on the basis of the total amount of the nutrient in the actual package if the package contains less than 200 percent of the reference amount customarily consumed.

This comment misinterpreted FDA's proposal. In the proposal on serving sizes (56 FR 60394), FDA proposed that both the reference amount customarily consumed (hereinafter referred to as the reference amount) and the label serving size be used to determine whether a product met the criteria for both nutrient content and health claims. The agency solicited comment on another approach that is based solely on the reference amount and that would require a disclaimer where, for example, a reference amount of a product would qualify for a sodium claim, but a single-serving container with 150 percent of the reference amount would not.

As discussed in detail in the preamble to the final rule on serving sizes published elsewhere in this issue of the **Federal Register**, the agency has considered the comments on this issue, along with the advantages and disadvantages of both options, and acknowledges that nutrient content claims should reflect, and health claims should be based on, the reference amount customarily consumed. The agency has concluded that problems created when the amount of the substance in the labeled serving size would not qualify for a claim are resolved by requiring a disclaimer that makes clear the basis for the claim. This disclosure is necessary to ensure that the consumer is not misled. On this basis, the agency is rejecting the recommendation made by this comment.

The agency has reflected this determination with respect to claims in new § 101.12(g) of the final rule on serving sizes, published elsewhere in this issue of the **Federal Register**, which has been revised in response to comments to that proposal to state, in part:

> The reference amount [i.e., the reference amount customarily consumed] set forth in paragraphs (b) through (f) of this section shall be used in determining whether a product meets the criteria for nutrient content claims, such as "low calorie," and for health claims. If the serving size declared on the product label differs from the reference amount, and the product meets the criteria for the claim only on the basis of the reference amount, the claim shall be followed by a statement that sets forth the basis on which the claim is made. That statement shall include the reference amount as it appears in § 101.12(b)

followed, in parenthesis, by the amount in common household measure if the reference amount is expressed in measures other than common household measures (e.g., for a beverage, "Very low sodium, 35 mg or less per 240 mL (8 fl. oz)").

That declaration is necessary because in containers of this type, consumers customarily consume more than the reference amount. The declaration is necessary to ensure that the claim is not misleading. The criteria for health claims referenced in proposed § 101.12(g) are the qualifying criteria contained in proposed §§ 101.14(d)(2)(vi) and (d)(2)(vii). Therefore, to reflect the modification that has been made in § 101.12(g) that a health claim can be made on a product when the product meets the criteria of proposed §§ 101.14(d)(2)(vi) or (d)(2)(vii) only on the basis of the reference amount customarily consumed, new § 101.14(d)(2)(vii)(A) has been added to state:

> Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed, and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in salt and sodium may help lower blood pressure in many people. A serving of ——— ounces of this product conforms to such diets.").

F. Requirements for Restaurants

1. Health claims on restaurant foods

FDA received many comments regarding the proposed health claims criteria as they would apply to restaurant foods and to foods sold in other establishements in which food that is ready for human consumption is sold (e.g., institutional food service, delicatessens, catering). In this discussion, such foods will be referred to as "restaurant foods," firms selling such foods will be referred to as "restaurants," and responsible individuals in these firms will be referred to as "restaurateurs." However, the concepts and policies discussed are intended to apply broadly to the foods covered by section 403(q)(5)(A)(i) and (q)(5)(A)(ii) of the act. Issues with respect to menus are dicussed separately below.

78. Many comments objected that the proposed health claim provisions should not apply to restaurant foods and foods sold in other establishments in which food that is ready for human consumption is sold. These comments asserted that Congress did not mandate the application of the proposed health claim regulations to restaurant foods. A number of comments observed that section 403(q)(5)(A)(i) of the act exempts restaurant foods from mandatory nutrition labeling requirements, and that sections 403(r)(2)(A)(iii) and (r)(2)(A)(iv) exempt them from the restrictions placed on claims related to cholesterol, fat, and fiber content. The comments further noted that the 1990 amendments are silent with respect to the regulation of health claims made in connection with restaurant foods, and that, at a minimum, FDA is not required to regulate restaurant foods. Other comments maintained that even if the agency does believe that restaurants must be subject to health claims regulations, FDA is not obligated to regulate these foods in an identical manner to that proposed for packaged foods.

However, many other comments disagreed. Some of these comments maintained that because the 1990 amendments contain no specific exemptions for health claims in restaurants, Congress intended for restaurants to be fully subject to the health claim regulations. Other comments argued that restaurant food plays too great a role in the American diet not to have been covered by the 1990 amendments. One comment pointed out that a large percentage of the money spent for food by Americans is spent away from home in restaurants. Several comments stated that requiring restaurants to comply with all of the health claims regulations where they choose to make health claims would best support the philosophy of an "even playing field" between restaurateurs and other food vendors. Others expressed concern that the preemption clause of the 1990 amendments could prohibit state and local authorities from enacting regulations concerning health claims made on restaurant foods if FDA fails to do so. One consumer comment proposed that FDA ban restaurants from making any health claims for any of their products, rather than exempting them from the health claim regulations.

FDA believes that the provisions of the 1990 amendments pertaining to health claims clearly encompass restaurant food wherever a health claim is made (except, for the reasons discussed below, when the claim is made on a menu). FDA disagrees with comments that asserted that the absence of specific exemptions for restaurant food from the health claims provisions in these amendments conveys flexibility to the agency to exempt such food from § 101.14. The House Report (Ref. 1) states that "under sections 403(r)(1)(B) and 403(r)(3) of the act, restaurants and similar food service establishments would have to comply with the bill in order to make a disease claim concerning a food sold in such establishment." In view of this explicit statement of congressional intent on this matter and the presence of specific exemptions for restaurant food pertaining to other provisions of the 1990 amendments where Congress wanted different regulatory treatment for restaurant food, the absence of a restaurant food exemption pertaining to health claims can only mean that Congress intended for restaurants to be subject to health claim regulations. Because of the congressional intent that restaurants be subject to the health claim regulations, FDA disagrees with assertions that the agency should not permit health claims on restaurant food.

However, FDA agrees that it is not legally required to regulate claims on restaurant foods in a manner identical to that for packaged foods. Nevertheless, it is only logical that if claims on food are to be useful for consumers, the criteria for those claims must be consistent. Therefore, the agency has determined that additional flexibility is needed to facilitate the helpful provision of health claims on restaurant foods, but that there must be assurance that the claims being made are indeed valid. The agency's responses to the following comments discuss how FDA intends to achieve this degree of flexibility with appropriate assurance of validity.

79. Many comments argued that all health claims provisions affecting packaged food should also apply to restaurant food. Several comments stated that the regulation of restaurant foods would be practical because many of the menu items are centrally manufactured and are required to conform to system-wide composition and quality standards. One comment asserted that many restaurant chains, especially the larger ones, already have access to nutrition information about their products. Another comment stated that private services that determine the level of various nutrients in foods are readily accessible to restaurants. A comment from an organization representing the nation's state, local, and Federal food regulatory officials asserted that the proposed regulations would not place an additional burden on restaurants seeking compliance with the health claim requirements, as most state laws already require that foods be labeled in compliance with all applicable laws and regulations and do not differentiate between labeling at the wholesale or manufacturing level and the retail level. The comment cited the model regulations developed jointly

between FDA and the Association of Food and Drug Officials (Rules of Food Service Sanitation and the Retail Food Store Sanitation Code) as an example. Other comments argued that health claims are misleading without nutrition labeling information. Some comments suggested that restaurants be required to at least provide an abbreviated nutrition statement, consisting of a disclosure of the amount of calories, fat, and sodium as well as of all nutrients relevant to the health claim.

However, many comments confirmed that restaurant food differs in a number of significant respects from other types of food that is mass-produced and packaged and maintained that the differences make it impracticable for restaurants to conform to some of the health claims provisions that were proposed. The comments advised that the provisions at issue are those pertaining to qualifying levels (e.g., the "low" or "high" levels of the substance, as appropriate) and the "disqualifying nutrient levels," as well as nutrition labeling. The comments asserted that the cost of providing nutrient content information would be unreasonable for each of these provisions. Some of these comments explained that restaurants experience significant variations in the foods they serve because of variations in the manner of preparation, varying ingredients, consumer preferences, varying serving sizes, and the lack of central control over food preparation in many restaurants. Because of this wide variation, frequent nutrient analyses would have to be performed to determine nutrient content, so that restaurants may conform to these provisions. The comments advised that these analyses could become very burdensome, and that the cumulative costs of these analyses could prevent establishments from making health claims, prevent them from making frequent changes in the dishes they offer, or force them to limit the options that consumers have in ordering a food. Further, the comments advised that small businesses would be especially burdened by such cumulative costs.

Even in "standard" items in multi-unit operations, the comments asserted, there is inherent variation. The comments advised that such variation is present in items such as daily specials, test products, local optional items, promotional items, and all items in restaurants offered for limited periods of time. A number of comments objected to the application of the proposed health claim regulations to traditional ethnic restaurants and similar small businesses on the grounds that it is extremely difficult to modify many of their foods to the degree necessary to meet the various provisions of the health claim proposals.

In addition, some comments pointed out that the proposal requires that qualifying and disqualifying levels be met per reference amount, per serving, and per 100 g. This aspect of the proposed definition, the comments maintained, wreaks havoc when applied to restaurant foods. Comments advised that restaurant foods that conform to the proposed qualifying and disqualifying levels in terms of reference amounts and 100 g are nonetheless ineligible to use health claims because their larger serving size results in the food failing to conform to the disqualifying nutrient levels. A number of comments suggested that restaurant food claims be judged on a per 100 g basis consistent with FDA's meal proposal, since most consumers view restaurant foods as a "meal."

Given that almost half of the American food dollar is spent on food consumed away from home, and that perhaps as much as 30 percent of the American diet is composed of foods prepared in food service operations, FDA believes that, from an overall public health perspective, this important segment of the diet can not be ignored. Further, FDA believes that dietary information, including health claims, provided to consumers at point of purchase in restaurants may be useful in helping Americans in maintaining healthy dietary practices. FDA wants to encourage the provision of such information. However, FDA firmly believes that consumers expect health claims made at point of purchase to be truthful and not misleading.

FDA advises that not all claims made for restaurant foods are necessarily the type of claims that are covered by the 1990 amendments. For the sake of clarification, the agency offers the following observations. Because of the importance of context, a restaurant may be able to use symbols next to the listing of an item where the symbols are clearly explained in terms that would not subject the claim to the 1990 amendments. Thus, restaurant labeling may use symbols or make reference to the criteria of a health professional organization and explain that the entree or meal is consistent with the general dietary guidelines of that group and not be subject to the 1990 amendments. For example, use of a heart symbol with reference to a note that explains that this entree is consistent with the dietary guidelines of the American Heart Association will be considered dietary guidance, and not a health claim subject to section 403(r) of the act. If the restaurateur went on to link the claim with levels of substances in the food, however, it would subject the food and the claims to the health claims regime (see discussion above about implied health claims).

When a restaurant makes explicit or implied reference to a substance and directly or indirectly links levels of that substance in the food to an effect on the risk of a disease or health-related condition (i.e., when both basic elements of a health claim are present) on a sign or placard, it must comply with the health claims regime.

How the restaurant demonstrates compliance with that regime is a difficult matter. FDA recognizes that, as detailed in the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants. Manufacturers of packaged foods also have to deal with differences in nutrient levels that result from seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (e.g., methods of preparation). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making health claims or to prevent the agency from being able to assure consumers that the health claims that are made for restaurant foods are valid. Because of the nature of the difficulties, however, FDA is providing in § 101.14(d)(2)(vii)(B) that a restaurant food may bear a health claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the regulations for the claim that FDA has established under section 403(r) of the act, and that basis is provided upon request. The difficulties and costs outlined in the comments would make it unfair to require that restaurateur determine whether their food qualifies for a claim in the same manner that a manufacturer of a packaged food makes this determination. By requiring that the restaurateur have a reasonable basis to believe that the food qualifies, the restaurateur, is provided with a readily achievable way to make claims for his or her food, and the consumer is provided with a reasonable assurance that the claim is valid. Thus, if a

restaurateur labels a vegetarian main dish or meal as "heart healthy," he must have a reasonable basis for believing that the product contains less than the disqualifying level for sodium and meets the "low" definitions for fat, saturated fat, and cholesterol.

The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA's guidelines on nutrition labeling of fruits and vegetables show that meal or main dish is "low fat," "low saturated fat," "low cholesterol," and does not contain a disqualifying level of sodium, and that the method of cooking the meal or main dish would not add fat or any disqualifying nutrient. In addition, the restaurateur could show that he or she used a reliable cookbook that gave values for fat, saturated fat, sodium, and cholesterol in the finished food that met FDA's requirements for making the health claim. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients, inappropriate substitutions of ingredients), FDA will consider this use to be a reasonable basis for believing that the food meets the qualifying and disqualifying levels. Upon demand, the restaurateur will be expected to present to appropriate regulatory officials information on the pertinent nutrient levels in the foods and the basis on which these levels were determined. A determination will then be made as to whether the basis of calculation reasonably supports the restaurateur's use of a permitted health claim. FDA believes that the reasonable basis approach will make it practicable for all restaurants, including those that are very small businesses, to provide consumers with better information on more healthful dietary choices for the foods that they offer for sale.

Further, this reasonable basis approach for making a health claim will provide regulatory officials, especially State and local authorities, with an effective standard for verifying that claims made for restaurant-type foods are truthful and not misleading and in accordance with FDA regulations. While health claims used in restaurants are under FDA's jurisdiction, the agency does not have resources to adequately enforce its regulations in restaurants. State and local authorities have traditionally carried out this responsibility. In addition, section 4 of the 1990 amendments provides that State and local authorities may enforce section 403(r) of the act in Federal court.

While restaurants, and particularly small restaurants, have nominally been subject to FDA's existing nutrition labeling regulation (see § 101.10), they have, as a practical matter, not been required to comply with these regulations or with State or local regulations that focused on the nutrient content of the food. Thus, the efforts that will be necessary on the part of restaurants to show that they have a reasonable basis to believe that their food complies with the health claims requirements will be significant. These efforts will place particularly great demands on the resources of the small business segment of the industry, that is, restaurant firms that have ten or less individual restaurant establishments (Ref. 37). FDA will refer to this segment of the industry as "small restaurants."

Small restaurants generally do not have the established nutrition support component that larger restaurant chains have. Thus, it will be more difficult for small restaurants to determine how to adapt health claims information to their food preparation methods. In addition, it is likely that they will not be as aware of available information sources, like nutrient content data bases, as large chains. Moreover, because of resource limitations, a small restaurant is not as likely as a large restaurant chain to be familiar with Federal requirements. Thus, small restaurants will have to become familiar with not only FDA's requirements, but with available FDA information, like the nutrient content information that FDA published in conjunction with its regulation on the voluntary labeling of raw fruits and vegetables (56 FR 60880, November 27, 1991).

Because of the great initial demands that small restaurants will find if they wish to make claims, FDA has decided that they should be given additional time to come into compliance with these regulations. Without additional time for the reasons discussed above, small restaurants will be place at a disadvantage with respect to their ability to make claims. As a result, they may decide not to even attempt to provide useful nutrition information to consumers about the foods they serve. To provide for equitable implementation of these requirements for small restaurants, FDA has decided to not make part 101 effective with respect to such establishments until May 1994.

While the statute will be in effect during that period, FDA will not enforce the statute's health claim requirements in small restaurants until the regulations are effective. Although state action is not preempted under section 403A(a)(5) of the act until Federal regulations are effective, the agency expects that states will refrain from enforcing any health claim requirements in small restaurants until the Federal regulations are effective for those restaurants.

FDA believes that this action is fully consistent with the 1990 amendments and with the act. The 1990 amendments impose no date by which the agency's regulations must be effective, only when they must be promulgated (see sections 3 and 10 of the 1990 amendments). Moreover, FDA believes that this action will facilitate effective enforcement of the act. FDA believes that the agency's and State resources can best be used during this initial period in educating small restaurants about the requirements of the law and by developing a better understanding of the unique practical circumstances of small restaurants in complying with health claims labeling requirements. Moreover, during this period, there will be an opportunity for interested persons to develop new data bases that will help facilitate the provision of nutrition information on foods sold in restaurants and particularly in small restaurants.

As an additional measure of flexibility, which will especially benefit small restaurants, it was decided not to include claims on menus within the coverage of these regulations. FDA has considerable discretion in regulating health claims in restaurants. As the comment's have indicated, there are unique problems and concerns associated with regulating such claims. The 1990 amendments do not specify precisely how such claims are to be regulated. These regulations will apply to health claims made in restaurants except on menus. The agency's efforts will focus on signs, placards, and posters, which are increasingly used in fast food and other restaurants to bring nutrition information and claims about food to consumer's particular attention. The comments pointed out that menus are subject to frequent, even daily, change. This additional measure of flexibility for menus will help assure that restaurants, especially small restaurants, will not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. State's remain free, however, to ensure under their own consumer protection laws that menus do not provide false or misleading information.

Although it has arrived at an approach that will provide for health claims on restaurant foods, FDA does not consider the problem of restaurant

food to be solved. It is possible that there are other health claim criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, restaurant foods as compared to packaged foods. If so, different criteria for use of health claims in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how health claims are used on restaurant foods, and whether such claims are appropriate. For example, with FDA's cooperation, the National Restaurant Association has undertaken a survey of industry use of nutrition information and of consumer knowledge, practices, expectations, and understanding of various terms and symbols in restaurants. FDA is open to petitions for different criteria for health claims for restaurant foods, and if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

FDA also recognizes that there are a number of significant issues concerning the adequacy of currently existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases and to encourage the development of additional or newer data where those data bases are found to be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods. FDA regulations state that, for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared and for calories, carbohydrate, fat, and sodium, the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities, and that a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims verification based on nutrient levels from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

80. Some comments cautioned that any adopted health claims provisions applied to restaurants must be flexible in format and content. These comments asserted that the distinct differences between the delivery systems of restaurant foods and packaged retail products must be factored into the regulations if they are to apply to restaurant foods, as most consumers select and purchase their food before ever seeing it or its container. Other comments asserted that the impracticality of compliance with the current inflexible health claims regulations would tempt restaurant operators to simply choose not to promote healthful menu alternatives.

FDA does not agree that firms should be given special flexibility concerning the content of health claims that appear on restaurant food. FDA believes that section 403(r)(1)(B) and (r)(3)(b)(iii) of the act require that a health claim be complete and consistent with the authorizing regulation. Specific health claims regulations in part 101, subpart E set forth certain mandatory aspects of permitted health claims. Where any mandatory aspect of a health claim is absent, the claim will be misleading, and the agency cannot sanction such a situation.

With respect to format, FDA believes that there is already ample flexibility in the rules that it is adopting. For example, new § 101.14(d)(2)(iv) permits full health claims to appear on any part of a food's labeling, including a sign or a placard. Accordingly, labeling listing 20 items, 3 of which qualify for the fat-cardiovascular disease claim, could carry the full health claim next to each of the 3 qualifying items. Alternately, it could list the names of the three items in a distinct area, such as a box or section, and print the full health claim once within that area.

New § 101.14(d)(2)(iv) also provides for the use of a short referral statement that directs the consumers' attention to another part of the food's label or labeling where the full health claim appears. Therefore, in the example above, the message "See ———— for details concerning the relationship between fat and cancer" could appear next to each of the items or in the box, with the full health claim printed only once in the label or in the labeling location identified in the blank. For example, the labeling could be in the form of placards placed in full view of the consumer, flyers made available to the public, and other such items. The agency cautions, however, that the referral statement must clearly be associated only with the item or items that qualify for the health claim, and that the location of the full health claim must not be such that it is likely to be associated with a product that does not qualify for the claim.

2. Nutrition labeling on restaurant foods making health claims

81. Many comments asserted that the cost of providing nutrient content information for restaurant foods making health claims would be unreasonable. Some comments that opposed any form of mandatory labeling requirements offered ways in which FDA could minimize the financial burden on restaurants, if any such regulations were in fact adopted. Many of these comments proposed that only fixed items should be required to bear nutrition labeling, thus exempting items such as daily specials, test products, local optional items, promotional items, and all items in restaurants for limited periods of time. Some comments asserted that FDA should permit the use of various data bases, including computer reference bases, for the determination of a food's nutrient content. Other comments suggested that only chains should be required to furnish nutrition labeling for their foods. Other comments suggested that any restaurant with profits of below $50,000 be exempted from any nutrition labeling requirements. However, comments from larger restaurant chains argued that any nutrition labeling requirements should be applied equitably to the restaurant industry as a whole, because a selective application of the regulations could place major chains at an economic disadvantage.

FDA finds nothing in the comments to persuade the agency to adopt a position different from that stated in the general requirements proposal (56 FR 60553). The agency continues to believe that it has the authority to issue regulations requiring restaurants that make health claims to adhere to the requirements for such claims including nutrition labeling. Full nutrition labeling provides the consumer with a way of evaluating a claim within the nutrient context of the food or meal and, therefore, is advantageous in allowing more informed comparisons. However, in the general principles proposal for nutrient content claims (56 FR 60427),

the agency recognized the difficulty of providing nutrition labeling for restaurant foods and asked for comment. The comments have persuaded the agency that, at this time, a requirement for full nutrition labeling could be a significant barrier to the transfer of information about favorable health-related characteristics of restaurant foods. Therefore, FDA is not requiring that full nutrition labeling be provided when a health claim is made for restaurant foods. The agency is adopting a somewhat different approach to the provision of nutrient information to the consumer, as explained below.

FDA believes that consumers should have information about the nutrient content of restaurant foods on which health claims are based. The agency has therefore established alternative nutrition labeling provisions for restaurant food in new § 101.14(d)(3) providing for such information in lieu of full nutrition labeling. For example, if a meal is characterized as being "heart healthy," the restaurateur should be able to provide consumers with information about the level of the nutrients that provide the basis for the claim. Therefore, the agency will require that if a restaurateur makes a health claim for a meal, he or she must be prepared to advise the consumer about the information that provides the reasonable basis for believing that the food complies with FDA's requirements for the claim (e.g., nutrient levels from data bases, cookbooks, or analyses). For the interim, the agency will consider that the provision of this limited amount of information to consumers will serve as the functional equivalent of nutrition labeling.

82. Many comments asserted that if restaurants are required to provide nutrition labeling, they should be afforded significant flexibility in determining where to present the required nutrient information. Some comments pointed out that restaurant food frequently is not packaged, and that, when it is packaged, the packaging is frequently too small to physically accommodate nutrition information. Other comments stated that much of the labeling used in restaurants is too small to physically accommodate nutrition information for all of the products which could potentially bear health claims. Some suggested that flyers, leaflets, and other printed handouts are acceptable places for such information to appear. Others suggested that all such information should be allowed to appear in a fixed location, such as in a wall display. Others suggested that tray liners be allowed to provide the nutrition information in fast food restaurants.

FDA agrees that restaurants do need significant flexibility in determining where to present the required nutrient information. Accordingly, the agency has revised the nutrition labeling provision in new § 101.14(d)(3) to provide that restaurants may provide nutrition labeling information through conformance with the provisions of § 101.9 or § 101.10, as appropriate. (In response to the DS Act, FDA has removed the reference to § 101.36 in this regulation.) As explained in the next comment, § 101.10 has been revised to convey considerable flexibility for nutrition labeling for restaurants.

83. Many comments contended that in view of the above mentioned problems outlined in the foregoing comments, any regulations regarding health claims on restaurant foods should be promulgated under a separate rulemaking more tailored to the unique nature of the restaurant industry's needs. A number of comments asserted that existing nutrition labeling provisions pertaining to restaurants in § 101.10 are outdated by the application of the proposed health claim regulations to restaurant foods and suggested that those provisions be revoked or modified accordingly.

FDA has determined that § 101.10 should not be deleted. Rather this section is being revised to reflect the agency's determinations with respect to the need for a reasonable basis for believing that the food complies with the qualifying and disqualifying levels and with respect to the provision of information to the consumer. The revision of new § 101.10 has been addressed in the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**.

3. Other restaurant issues

84. One comment suggested that FDA develop educational materials that explain the obligations of restaurateurs relevant to health claims, and that FDA offer alternative, nonmisleading ways in which restaurants might communicate health-related information. The comment noted that the 1990 amendments called for FDA to educate the public about the regulations adopted under them.

Section 2(c) of the 1990 amendments directs the Secretary to carry out activities to educate consumers about the availability of nutrition information in the label or labeling of food and the importance of that information in maintaining healthy dietary practices. While the language of the act does not specifically direct FDA to develop educational materials for industry segments, the agency intends to work with industry, particularly trade associations and small restaurants, so that all parties (e.g., consumers, industry, and State/local regulators) understand the regulations and their obligations and rights under them. Further, FDA believes that the preamble to this document clearly defines those obligations and rights and thus should give the restaurant industry much of the guidance it needs. Where an issue is not resolved in the preamble to the full understanding of a restaurateur, the agency invites correspondence on the specific matters that are unclear.

VI. Prohibited Health Claims

A. Claims not Authorized by FDA

The provisions of new § 101.14(e)(1) and (e)(2) prohibit on a food label or in labeling any claim that expressly or by implication characterizes the relationship of any substance to a disease or health-related condition unless: (1) The claim is a health claim specifically provided for in part 101, subpart E; and (2) the claim conforms to all general provisions of new § 101.14 as well as to all specific provisions in the appropriate section of part 101, subpart E. These provisions embody the statutory restriction in section 403(r)(1)(B) of the act that directs that a food shall be deemed misbranded if a health claim is made in its label or labeling unless the claim is made in accordance with section 403(r)(3), which make such claims subject to the requirements adopted by the Secretary (and FDA, by delegation) by regulation. (Section 403(r)(1)(B) of the act also references section 403(r)(5)(D). However, action on that section is deferred based on the moratorium established by the DS Act).

85. Numerous comments voiced support for or opposition to the proposal to prohibit unauthorized health claims.

FDA has adopted new § 101.14(e)(1) and (e)(2) as proposed because they are explicitly required under section 403(r)(1)(B) and (r)(3) of the act. Because these regulations respond directly to the language of the act, FDA is constrained to adopt them.

B. Disqualifying Levels Exceeded

New § 101.14(e)(3) requires that none of the disqualifying levels identified in new § 101.14(a)(5) be exceeded in a food that bears a health claim, unless specific alternative levels have been established for the substance in part 101, subpart E, or unless FDA has by regulation

permitted such a claim based on a finding that such a claim will assist consumers in maintaining healthy dietary practices. If FDA makes such an exception, the label of the food will have to bear a statement in immediate proximity to the claim that refers the consumer to the nutrition label for information about the nutrient that exceeds the disqualifying level. This statement must be made in a manner that complies with proposed § 101.13(h).

FDA received numerous comments on its proposed disqualifying levels. Some comments voiced unsubstantiated support or disapproval for the proposals, while others offered substantive arguments for their positions. These comments are discussed in section II.G. of this document (see comments 23 through 42 of this document).

C. Inappropriate Levels of Other Substances

New § 101.14(e)(4) will prohibit claims for any food where a substance, other than one for which a disqualifying nutrient level is established, is present at an inappropriate level as determined in the specific provision authorizing the claim in part 101, subpart E. In the preamble to the proposed regulations, the agency explained that this provision will prevent health claims from appearing on foods that contain substances other than the substance that is the subject of the claim if any of those other substances, although not harmful in their own right, could interfere with the claimed effect on the risk of disease. For example, foods containing phosphorus in equal or greater proportion to calcium would not be eligible to bear the calcium-osteoporosis health claim, because diets high in phosphorus and relatively low in calcium result in osteoporosis in experimental animals.

FDA did not receive any comments on this proposed regulation. However, the agency did receive several comments that suggested that disqualifying levels be set for minimum nutrient content, sugars, saccharin, food colors, and various other food additives. These comments are discussed in section II.G.3. of this document (see comments 25 and 26 of this document) and further in this section in response to comment 87 of this document.

D. Infant Foods

Proposed § 101.14(e)(5) provided that no food may bear a health claim if it is represented or purports to be for infants and toddlers less than 2 years of age.

86. One comment questioned the prohibition of health claims on foods promoted for use by infants and toddlers. The comment asserted that claims for all infant formulas, including those formulas that are not subject to the requirements of section 412(h) of the act (i.e., "nonexempt" infant formulas), were meant by Congress to be regulated solely under section 412. More specifically, the comment contended that the agency has already successfully used the premarket notification process of section 412(d) of the act to obtain substantiation of claims from manufacturers of both exempt and nonexempt infant formulas. Further, the comment asserted that the notification process provides the agency adequate oversight of claims for all infant formulas, in keeping with the intent of the requirements for health claims in the 1990 amendments, without impeding product innovation or denying access to product information. Accordingly, the comment recommended deleting proposed § 101.14(e)(5) and revising proposed § 101.14(f)(1) to exclude nonexempt infant formulas, in addition to exempt formulas, from the requirements in that section for health claims.

Another comment viewed a total ban on infant food health claims as an abridgement of commercial free speech protected by the First Amendment. The comment suggested that a more acceptable approach would be to require explanatory information to accompany such claims in order to eliminate any consumer misconceptions.

Although section 403(r)(5)(A) of the act excludes exempt infant formulas from the requirements in section 403(r) for health claims, the 1990 amendments are silent on the applicability of section 403(r) to health claims for nonexempt infant formulas. Thus, health claims on such products are subject to the requirements of section 403(r) of the act. However, in the proposal on general requirements for health claims, FDA pointed out that it had received a letter from the American Academy of Pediatrics that expressed concern that a health claim directed to adults may be inappropriate or harmful to infants and young children (56 FR 60537 at 60556). The letter pointed out that where health claims primarily embody dietary recommendations for the adult U.S. population to reduce the risk of chronic, degenerative diseases, such recommendations are not meant to apply to infants and young children. "Nutrition and Your Health—Dietary Guidelines for Americans" (Ref. 7) states, for example, that the guidelines are "advice for healthy Americans ages 2 years and over—not for younger children and infants, whose dietary needs differ." Accordingly, the agency proposed in § 101.14(e)(5) to prohibit a health claim in labeling of a food represented or purported to be for infants or children less than 2 years of age. The proposed prohibition would have applied to nonexempt infant formulas.

In view of the concerns expressed by the comments, FDA has reconsidered the propriety of health claims on infant food. The agency now believes that the proposed prohibition on infant and toddler foods may have been overbroad. Although health claims based on current dietary recommendations for Americans do not include infants and toddlers, FDA believes that Congress did not intend to limit health claims to only the adult population or to diseases affecting only that population. Thus, the agency cannot discount the possibility that, in the future, information may be developed to support a claim appropriate for infants and young children on the relationship between a substance and a disease or health-related condition. A claim that characterizes this substance-disease relationship would meet the definition for a health claim and thus be subject to the requirements of section 403(r) of the act. The agency has therefore revised new § 101.14(e)(5) to provide for exceptions from the prohibition of infant and toddler health claims when a regulation has been established in part 101, subpart E.

However, the agency has the option, and believes that it may be more prudent, to regulate claims for infant and toddler foods under sections 403(j) and 411(c) of the act, which deal with foods for special dietary use. Thus, should the agency receive a petition that appears to justify a health claim directed to infants and toddlers under section 403(r) of the act, it will decide how best to proceed to authorize the inclusion of the information in the food label.

The agency disagrees with the contention that health claims for nonexempt, as well as exempt, infant formulas should be exempt from section 403(r) of the act and be subject only to the requirements of section 412 of the act. Congress specifically chose to exclude only exempt infant formulas from section 403(r) of the act. Section 412 of the act, although specific to infant formulas, does not exclude such formulas from requirements that are based on other parts of the act. Hence, a labeling claim for an exempt or nonexempt infant formula may be found to misbrand the product under section

403(a) or (j) of the act. In addition, a claim for a nonexempt formula, but not an exempt formula, may also be subject to section 403(r) of the act.

Although the agency has reviewed manufacturers' claims to ensure their validity for both exempt and nonexempt infant formulas in premarket notifications submitted in compliance with section 412 of the act, the agency's conclusions were based on compliance with all applicable sections of the act, not just section 412. The agency is obliged to administer the act as a whole. Because section 412 of the act is not the only section governing labeling for infant formulas (see section 412(e)(1)(B)), the agency must reject the comment's recommendation that health claims requirements in proposed § 101.14 not apply to nonexempt infant formulas.

In light of the agency's conclusion that it will consider health claims for infant and toddler foods, where appropriate, and will establish specific regulations providing for their use, the constitutional issue of a ban on health claims for such foods is now moot. New § 101.14(e)(5) has been revised to prohibit only those claims on infant and toddler foods that are not specifically provided for in part 101, subpart E. Comments that have raised constitutional questions will be dealt with at length later in this document.

E. Additional Limits on Health Claims

87. Some comments urged the agency to allow health claims only on foods that are consistent with dietary guidelines. A number of these comments suggested that this could be done by prohibiting health claims on foods with insignificant amounts of all nutrients required on the label (e.g., coffee), as well as on candies, soft drinks, and other snack foods characterized as not being recognized as part of a sound dietary pattern. However, comments from the snack food industry protested such limitations on health claims and maintained that any food that provides a "high" (or "low") level of a nutrient without exceeding the disqualifying levels for fat, saturated fat, cholesterol, and sodium can be consumed within the framework of a healthy diet and should be allowed to bear health claims.

FDA is not persuaded that a prohibition from bearing a health claim based on a food's categorization or characteristic use—such as a snack food—is in keeping with the intent of the statute. The House Report (Ref. 1) contains an example intended to illustrate the Secretary option to decide whether to grant an exception from a disqualifying nutrient level in the context of the total daily diet. The example compares a frozen dinner with a snack food, both with a particular level of fat, and suggests that the frozen dinner may be considered sufficiently more significant in the total daily diet than the snack food. Implicit in this example, however, is a recognition by Congress that snack foods would be able to bear health claims if they did not contain a level of a nutrient that exceeds the disqualifying level. Thus, the agency concludes that Congress did not intend that snack foods or other foods that could be in general use in the diet should be subject to a per se prohibition on bearing a health claim.

However, as FDA explained earlier in this preamble in its response to comment 23 of this document, Congress intended that FDA establish provisions of health claims regulations by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines. Thus, FDA finds merit in the suggestion that foods bearing health claims should be those consistent with dietary guidelines, and that the value of health claims should not be trivialized or compromised by their use on foods of little or no nutritional value. The agency, therefore, agrees that the final rule should be modified in some way to more fully assure consistency with dietary guidelines.

Dietary guidelines do stress the importance of selecting foods so that dietary sources of calories are coupled with sources of nutrients. FDA specifically notes that "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 7) states that foods that supply calories but are limited in nutrients should be used in moderation. Furthermore, the recommendations provided in "USDA's Food Guide Pyramid" (Ref. 29) expand on this approach to food selection. Given the requirement in section 403(r)(3)(B)(iii) of the act that states that a claim should enable the public to comprehend the information in a claim and understand the relative significance of that information in the context of a total daily diet, FDA concludes that it is appropriate to provide a basis for health claims that takes into account the nutritional contribution of the food beyond its role as a source of calories. Without such a criterion, foods that are not compatible with dietary guidelines could bear health claims. The claim would promote the consumption of the food but would fail to set the food in its proper dietary context. In addition to being inconsistent with section 403(r) of the act, claims intended to promote the consumption of a food that is incompatible with dietary guidelines would be misleading to consumers and, thereby, be in violation of section 403(a). Such claims would be misleading because consumers would be purchasing the food, in part, to achieve a more healthful diet. However, foods inconsistent with dietary guidelines should not be associated with the more healthful diets recommended by Federal agencies that are mentioned above.

Therefore, in addition to the requirements in new § 101.14(d)(vi) and (d)(vii) for content in a food of a substance that is the subject of a health claim, the agency has developed an approach that would limit health claims to foods that contribute certain nutrients to the diet and, thus, are sources of more than calories. This approach incorporates established levels of significance for nutrients in food and is based on the amounts in foods of certain nutrients required to be listed on the label as part of mandatory nutrition labeling. As such, this approach applies to all foods in conventional food form.

Dietary supplements not in conventional food form are not subject to this requirement. Such supplements are not intended to provide more than nutritive value to the daily diet and make no pretense that they should serve as substitutes for conventional food. As a result it would not be logical to hold such products to criteria designed to assure consistency with dietary guidelines for conventional food. A dietary supplement that meets the qualifying criterion in proposed § 101.14(d)(2)(vii) and does not contain a nutrient at a disqualifying level specified in proposed § 101.14(a)(5) possesses nutritive value for a health claim irrespective of whether or not it may also provide calories. (FDA is including the exception for dietary supplements in § 101.14(e) because under section 202(b) of the DS Act, the agency can approve claims for such products).

The final rule for mandatory nutrition labeling published elsewhere in this issue of the **Federal Register** requires the listing of 12 nutrients apart from calories as follows: Total fat, saturated fat, cholesterol, total carbohydrates, sugars, fiber, protein, sodium, vitamin A, vitamin C, calcium, and iron. As described in that document, FDA concluded that these nutrients are of sufficient public health importance to warrant their inclusion in the nutrition label. Therefore, these same nutrients provide an appropriate basis for a criterion intended to preclude health

claims on foods that do not make a nutritional contribution to the diet and thus are inconsistent with dietary guidelines. This conclusion is supported by comments that suggested that FDA should establish such a criterion based on the nutrients required in the mandatory listing on the food label.

Of the 12 mandatory nutrients, vitamin A, vitamin C, iron, calcium, protein, and fiber constitute nutrients for which the levels in foods can serve as a basis for determining a food's nutritional contribution to the overall diet. Total fat, saturated fat, sodium, and sugars are nutrients for which the current recommendations are to limit intake. Therefore, the presence of the latter nutrients in a food would not provide an appropriate basis for measuring the positive contribution of a food to the diet. While total carbohydrates reflects the contribution to the diet of complex carbohydrates, a nutrient for which current recommendations are to increase intake, it also reflects the contribution of sugars for which current recommendations are to limit intake. Therefore, total carbohydrates is not an appropriate component of a nutritional contribution criterion.

The final rule on nutrient content claims published elsewhere in this issue of the **Federal Register** states that a food is a good source of a nutrient when the nutrient is present in the food at a level of 10 percent or more of the label reference value. The agency concludes, therefore, that this defined level is an appropriate basis for a criterion to measure the nutritional contribution of a food. Therefore, assuming that a food meets the definitions prescribed in this final rule for bearing a health claim, the food must also contain one or more of the six nutrients listed above (vitamin A, vitamin C, iron, calcium, protein, or fiber) in an amount at or above 10 percent of the Reference Daily Intake (RDI) or DRV per reference amount customarily consumed for that nutrient. Based on a review of the regulatory food composition data base (Ref. 33), the agency notes that most foods consistent with dietary guidelines meet this criterion.

Furthermore, in order to preclude the fortification of foods solely for the purpose of making a claim, the nutrient or nutrients must not be derived from fortification or other additions to the food. Fortification of a food of little or no nutritional value for the sole purpose of qualifying that food for a health claim is misleading for several reasons. There is great potential to confuse consumers if foods like sugars, soft drinks, and sweet desserts are fortified to qualify for a health claim when, at the same time, dietary guidance as contained in USDA's Food Guide Pyramid (Ref. 29), for example, states that "[T]hese foods provide calories and little else nutritionally. Most people should use them sparingly." Indiscriminate fortification of such foods with one nutrient would not make such foods consistent with dietary guidelines. Further, fortifying such foods is not consistent with FDA's fortification policy in § 104.20 that has been in effect for many years. The fundamental objective of FDA's policy on appropriate fortification of foods is to establish a uniform set of principles that serve as a model for the rational addition of nutrients to foods. In that policy, FDA clearly states its concern that random fortification of foods could result in deceptive or misleading claims for foods. In the document concerning nutrient content claims that appears elsewhere in this issue of the **Federal Register**, FDA is including a provision requiring that added nutrients must be in compliance with § 104.20 for a food to be eligible to bear the term "more" on its label.

FDA stresses that the exclusion of fortification pertains only to fortification to specifically meet the requirements of this provision and not to fortification of the food itself. Thus, a fortified food, including a dietary supplement in conventional food form, may still qualify for a health claim, provided the qualification is not on the basis of that fortification. Accordingly, FDA has added a new § 101.14(e)(6) to require that, except for dietary supplements not in conventional food form, the food shall contain 10 percent or more of the RDI or DRV for vitamin A, vitamin C, iron, calcium, protein, or fiber prior to any nutrient addition.

VII. Exemption of Medical Foods and Exempt Infant Formulas

FDA proposed in § 101.14(f) that medical foods, as defined in section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee(b)), and infant formulas subject to section 412(h) of the act are specifically exempted from requirements for health claims and nutrient content claims. This exemption reflects the exemption in section 403(r)(5)(A) of the act.

FDA received no comments on this aspect of the proposal. Therefore, the agency is adopting this section as proposed.

VIII. Applicability of Health Claims

FDA proposed in § 101.14(g) that the requirements for health claims in proposed § 101.14 only apply to foods intended for human consumption that are offered for sale.

FDA received no comments on this aspect of the proposal. Therefore, this section is being adopted by the agency as proposed.

IX. Petitions

A. Agency Review Period

88. One comment asserted that FDA should not establish any health claim petition provisions because citizen petition regulations in § 10.30 (21 CFR 10.30) are adequate to provide for petitions to FDA that request that the agency authorize a health claim.

FDA disagrees with this comment. Section 403(r)(4)(A)(i) of the act establishes unique statutory procedures for the handling of health claim petitions that are not applicable to the existing citizen petition regulation. The statute has specific timeframes for FDA to evaluate health claim petitions and, unlike the provisions of § 10.30, provides for not releasing the content of a petition if it is denied prior to acceptance for filing. If FDA were to accept health claims petitions in accordance with § 10.30, petitions that the agency denies after its initial 100-day review might be released. Further, FDA believes that a procedural regulation for health claims petitions is necessary so that petitioners will clearly understand what is required, that the agency's review will be conducted on a consistent and equitable basis, and that the grounds for agency action on the petition will be clearly understood.

89. Some comments objected that the timeframes in the petition provisions for FDA assessing the validity of the proposed claim and for issuing a proposed regulation are too rigid. One of these comments suggested that in cases where there is minimal or nonexistent controversy, FDA should streamline the petition approval process. The comment noted that while the statutory filing period gives the agency time to determine whether a proposed claim is valid, that filing period also serves to deprive the public of truthful claims until final approval is granted. The comment suggested that FDA adopt a mechanism to quickly determine whether there is a large consensus among scientists on the validity of a proposed claim and, if so, to shorten the timeframes. However, other comments suggested that longer timeframes are needed so that the agency can review the data and request additional information if needed, after which FDA should allow, modify, or reject the health claim application and notify the applicant.

FDA advises that the agency may not consider longer timeframes for the evaluation of petitions about health claims because the timeframes are specifically established in section 403(r)(4) of the act. These short timeframes do not provide an opportunity for continuing correspondence between the petitioner and FDA. With respect to suggestions for shorter timeframes, FDA advises that the agency's ability to meet timeframes is influenced by many factors such as work priorities and availability of personnel. FDA considers the statutory timeframes for assessing the validity of health claims and for issuing a proposed regulation to be extremely short, given the need to evaluate the totality of available scientific evidence on a substance and a disease. Given the agency's limited resources, it would not be practicable to shorten these timeframes further. However, FDA points out that although action on petitions for most claims will require virtually all of the time provided by the statutory timeframes, nothing would prohibit the agency from acting in less time than the timeframes provide if it is possible to do so. Thus, it is likely that a petition for a claim on a well-accepted substance/disease relationship would be reviewed more expeditiously than one for which scientific agreement is not as clear.

90. Some comments recommended that FDA allow new health claims to be used as soon as the proposal issues, instead of waiting until the final regulation becomes effective. One comment asserted that this approach would greatly benefit the public by quickly disseminating truthful health claim information, and that there would be little risk to consumers from consuming additional amounts of a food if the health claim is eventually denied.

The agency advises that there is no basis under the act to provide for the use of proposed health claims. Section 403(r)(1)(B) of the act deems a food misbranded when its label or labeling bears a health claim unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D). Section 403(r)(3) and (r)(5)(D) of the act requires that the health claim be made in accordance with regulations. Proposed rules are not "regulations."

Further, even if FDA had a basis under the act to permit the use of proposed health claims, the agency does not believe that it would be prudent to provide for such use. The comment period following the publication of proposed rules is a critical step in determining whether a proposed regulation is appropriate for adoption. In the instance of health claim regulations, significant information concerning validity of the substance-disease relationship underlying the proposed health claim may be submitted by interested parties during the comment period. In addition, the comment period may bring to light a previously unforeseen potential for the health claim to be misleading to consumers if adopted without modification.

B. Public Disclosure

91. Some comments expressed concern regarding public release of private or proprietary data submitted as part of a health claim petition. Other comments agreed with the proposal as written in § 101.70(j)(2) on the grounds that allowing the public to scrutinize information submitted in a petition will help ensure that the evidence is scientifically sound and unbiased.

Section 403(r)(3)(B)(i) of the act mandates that the Secretary (and FDA, by delegation) determination as to whether to authorize a health claim be based on the totality of "publicly available evidence." Moreover, section 403(r)(4)(A)(i) of the act provides for not making a petition available to the public only when FDA decides to deny it without filing it. Consequently, FDA does not have authority to withhold this information from public scrutiny and will make all information submitted in support of a health claim publicly available when the petition is filed.

C. Preparation of Model Health Claim

92. One comment objected to the petitioner having to propose model health claims, asserting that the format and wording of model health claims should be the responsibility of FDA. The comment stated that the 1990 amendments did not require the petitioner to prepare model health claims. Another comment, however, endorsed the proposal that a petitioner include a model health claim, because it will promote efficiency by giving FDA a starting point and ensure that the petitioner is planning to use the claim to promote the public's health.

FDA agrees with the latter comment. Because the petitioner should be one of the parties most knowledgeable about the relevant substance-disease relationship, the agency does not believe that requiring the inclusion of a model health claim will constitute a significant burden on the petitioner. Such a requirement will, however, provide significant benefit by ensuring that the agency can easily and correctly identify what the petitioner believes to be the full substance-disease relationship within the short review timeframes.

D. Summary of Scientific Data

93. Some comments argued that unpublished research findings, including proprietary data, should be considered in support of proposed health claims. However, a number of comments disagreed asserting that only data suitable for publication and data already accepted for presentation in a scientific community would be suitable for the substantiation of health claims.

FDA will consider all unpublished findings that are submitted in support of proposed health claims. Although the agency will consider such findings, FDA points out that, as suggested in the legislative history (Ref. 1), the agency may give greater weight to a research report published in a peer-reviewed journal because such reports have been subjected to scientific evaluation before publication. The agency is likely to give greatest weight, however, to research reports of well-conducted, relevant studies regardless of publication status.

E. Denial of Petitions

94. A number of comments stated that if the agency is to deny a petition without filing it, FDA should do so based on a review of the petition as a whole. One comment said that even if the "Preliminary Requirements" section of the petition is inadequate FDA should still examine the "Summary of Scientific Data." The comment stated that if the agency did so, and discussed that review in the denial notice, it would provide the petitioner with some indication as to whether a redrafted petition would be justified. The comment contended that such a procedure would be more efficient in the longrun and presumably would save FDA from having to review repeatedly submitted petitions.

FDA does not believe that it would be prudent to adopt a general policy of conducting exhaustive reviews of petitions that are to be denied because they fail to meet preliminary requirements. The denial of a petition on the grounds that the preliminary requirements are not met would reflect a fundamental problem with the petition. Such problems may take a fair amount of time to remedy. Therefore, to ensure that it uses its resources most effectively and efficiently, FDA will not undertake an evaluation of the scientific validity of a claim unless the preliminary requirements are satisfied.

95. Several comments dealt with the language of the regulation disapproving the health claim. They particularly disapproved of the language "FDA has

concluded that there is no basis for claims about the following * * *." The comments suggested alternate wordings for proposed § 101.71 that would recognize that "although there is considerable interest in these areas, and although new evidence is continually emerging, the data are not yet strong enough to permit approval of health claims for the reasons summarized below." The comments stated that this language should be followed by an enumeration of the disapproved claims together with a short paragraph describing both the strength and the perceived shortcomings of the evidence in each case. This approach would, according to comments, establish an appropriate record of FDA's determination, without unnecessarily damaging any of these active areas of scientific research.

FDA agrees with the comments that there should be some codified record of its consideration of the health claims on which it proposed action, either in response to the 1990 amendments or a petition, but ultimately decided not to authorize. That record is provided by the citation to the final rule denying the health claim that is included in the listing in new § 101.71. The discussion in the preamble to the final rule summarizes the agency's consideration of the claim. Thus, the agency does not believe that paragraphs describing the strengths and shortcomings of the evidence regarding specific health claims are needed in the codified language to "establish an appropriate record of FDA's determinations."

The agency disagrees that a negative decision regarding a particular health claim will be damaging to active areas of scientific research. It is obvious that the extensive literature regarding the complex relationships between substances and diseases and health-related conditions developed without consideration of whether specific health claims on particular foods might be allowed at some time in the future. FDA's denial is just as likely to highlight the matters on which further research is needed as it is to damage the prospects for further research. However, for greater clarity, the agency has revised the statement in new § 101.71 that there is "no basis for claims" to state that there is "not a sufficient basis for claims * * *."

F. Other Petition Issues

96. Another comment urged that FDA not redelegate to the Director and Deputy Director of CFSAN all the functions of the Commissioner concerning petitions for label claims under section 403(r) of the act that do not involve controversial issues. The comment stated that all petitions that will be submitted to the agency concerning health claims will involve controversial issues that will require a response from the Commissioner.

FDA does not agree. Based on the agency's experience with petitions that have been submitted to FDA for consideration, it is not uncommon for a petition to contain major deficiencies that necessitate denial of the petition. The agency believes that redelegating such functions to the Director and Deputy Director of CFSAN will permit the agency to take the required actions (e.g., denial of a petition) in the most resource efficient manner.

Further, the agency does not agree that it should assume that all petitions submitted under section 403(r) of the act will involve controversial issues. The agency should have the prerogative to take action on a petition in the most resource efficient manner. For example, in the future, it is certainly possible that some substance-disease relationships will become established, and that there will be no controversy about the scientific basis for a claim. If such a situation occurs, the agency should have the flexibility to authorize information about such relationships in food labeling in an efficient manner. Therefore, the agency is retaining the redelegation provision in the final rule.

X. Constitutional Issues

A. The First Amendment

97. Several comments from industry and nonprofit organizations asserted that truthful information about health and diet consists of speech protected under the First Amendment, and at the very least is protected commercial speech. According to the comments, such truthful information encompassed a wide variety of labeling information ranging from information that FDA classifies as a "health claim" to general information about what food categories should be included in a diet to affect disease that FDA classifies as "dietary guidance." (As explained previously in this preamble, for the sake of clarity in this preamble, references by FDA to "dietary guidance" will refer to claims that do not contain both basic elements of a health claim and are therefore not "health claims.") Comments stated that the commercial speech doctrine recognizes that such speech not only serves the economic interests of the speaker but assists consumers and furthers society's interest in "the fullest possible dissemination of information." Therefore, while such speech is entitled to less protection than other forms of expression, that protection is nonetheless substantial. Several comments cited case law that stated that if the commercial expression at issue is neither false nor misleading, then any regulation restricting it must directly advance the governmental interest asserted and must be no more extensive than necessary to serve that interest. Comments contended that any suggestion that consumers should be screened from truthful information "in their own best interest" is the type of paternalism rejected by the Supreme Court in *Virginia State Bd. of Pharmacy* v. *Virginia Citizens Consumer Council Inc.*, 425 U.S. 748 (1976), and the concept that the public cannot be trusted to make valid judgments based on truthful information contravenes the basic principles of the First Amendment. Comments asserted that the public interest and, indeed, the public right is in obtaining useful information, and the government's interest is best served by placing no barriers to its free circulation. Another comment specifically requested that FDA clarify how the health claims regulations comply with Supreme Court standards for constitutionally protected civil or commercial speech.

However, other comments stated that the health claim regulations do not violate manufacturers' First Amendment rights, because food labels that are not in compliance with the act are inherently misleading and therefore not entitled to constitutional protection. The comments argued further that, even if a court found that a nonconforming health claim was not misleading, it would uphold these regulations because they are tailored specifically to meet the substantial Government interest of protecting the public.

FDA advises that neither these regulations, nor the act as amended by the 1990 amendments, violate the First Amendment. The act has withstood numerous First Amendment challenges. (See, for example, *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986); *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419 (D. Idaho 1975); *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626 (W.D.N.Y. 1951).) The 1990 amendments amended the act to permit certain information about the relationship of nutrients in food and disease to appear on a food label without misbranding the food under section 403 of the act or transforming it into a drug under section

201(g)(1)(B) of the act. The regulations implementing these amendments thus permit more information on food labels than has previously been allowed under the act.

Nonetheless, parts of the act and these regulations may have an incidental effect on speech in a narrowly defined area, food labeling. (See *NAACP* v. *Claiborne Hardware Co.*, 458 U.S. 886, 912 (1982).) The Supreme Court, however, "has recognized the strong governmental interest in certain forms of economic regulation, even though such regulation may have an incidental effect on rights of speech and association." Id. The Government may regulate in areas of economic activity such as securities, antitrust, and labor in ways that affect speech. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d 365, 372–73 (D.C. Cir. 1988), cert. denied, 489 U.S. 1066 (1989); see also *SEC* v. *Suter*, 732 F.2d 1294, 1299 (7th Cir. 1984) (the First Amendment does not remove a business engaged in the communication of information from general laws regulating business practices). The Government "does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of the activity." *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978); see also *Home Box Office, Inc.* v. *FCC*, 567 F.2d 9, 46 (D.C. Cir. 1977), cert. denied, 434 U.S. 829 (1977) ("[R]ules restricting speech do not necessarily abridge freedom of speech.")

As with securities, labor, and antitrust regulation, the Government exerts extensive regulatory authority over the economic activity surrounding food and its labeling. Yet the regulation of food and food labeling clearly encompasses more than mere economic activity: It protects consumer health and safety in an area where harm to the public can be direct and immediate. (See *Ohralik*, 436 U.S. at 456.) FDA's crucial role in ensuring that food labels are informative, are not misleading, and do not otherwise misbrand products under the act has long been recognized. (See 79 Congressional Record 4734 (1935), reprinted in "Dunn, Federal Food, Drug, and Cosmetic Act," 280 (1938) (statement of Sen. Copeland) ("No one disputes that the [FDA] should determine the quality of the product; no one disputes that it should determine what is on the label.")) In such an area of extensive Federal regulation, the Government may place restrictions on speech that bears directly on the Government's objectives. *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 373. Indeed, regulation of food labeling would be impossible if the Government could not restrict speech. Id.

Thus, when FDA seeks to ensure that food is not misbranded, it may place restrictions on label contents. "Freedom of Speech does not include the freedom to violate the labeling provisions of the Federal Food, Drug, and Cosmetic Act." *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419, 424 (D. Idaho 1975). "[C]ertain speech in a certain limited context" becomes part of the labeling of a product and may serve as evidence of a violation of the act. *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556, 562 (W.D.N.Y. 1986). Thus, the seizure and condemnation of a book that misbrands a product is not a violation of the First Amendment, even though in another context the book might be protected. (See *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626, 628 (W.D.N.Y. 1951); *United States* v. *Article of Drug*, 32 F.R.D. 32 (S.D. Ill. 1963).) "It is the product and the manner in which the product is marketed which is said to be illegal," rather than the speech itself. *General Nutrition*, 638 F. Supp. at 562. A prohibition on selling a misbranded product restrains the violative act of selling, not speech itself. *Kellogg Co.* v. *Mattox*, 763 F. Supp. 1369, 1381 (N.D. Tex. 1991) (construing Texas food and drug law). "The substantial government interest in the goals of the Act justif[ies] this extremely narrow encroachment" on speech. *General Nutrition*, 638 F. Supp. at 562. Indeed, where certain claims misbrand a product, "[a] requirement that the claims be removed, in order to sell the product, is certainly less restrictive than a flat prohibition of the sale of the product." *Kellogg*, 763 F. Supp. at 1381.

With the provisions of the 1990 amendments that govern health claims, Congress sought to "permit health claims but only health claims based on scientifically valid information." (statement of Rep. Waxman; Ref. 4). In order to assist consumers improving their eating habits, Congress devised a scheme to permit certain claims not previously allowed under the act. Under this scheme, only those claims that FDA finds to be "supported by science" are permitted, (statement of Rep. Waxman; Ref. 3), and a food that bears an unapproved health claim is misbranded. Because FDA case law makes clear that a label statement that misbrands a food product is not subject to First Amendment protection, an unapproved health claim on a food label would not be protected speech. (See *United States* v. *General Nutrition, Inc.*, 638 F. Supp. 556 (W.D.N.Y. 1986); *United States* v. *Articles of Food * * * Clover Club Potato Chips*, 67 F.R.D. 419 (D. Idaho 1975); *United States* v. *8 Cartons, Containing Plantation The Original etc. Molasses*, 103 F. Supp. 626 (W.D.N.Y. 1951); *United States* v. *Article of Drug*, 32 F.R.D. 32 (S.D. Ill. 1963).)

Congress considered the use of "unfounded" health claims on the food label to be harmful to the public (statement of Rep. Waxman; Ref. 3); cf. *Ohralik*, 436 U.S. at 456 ("[T]he State does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity.") Congress dealt with this problem by crafting a system to permit certain useful information to appear on the food label, while ensuring that the information is scientifically valid and not misleading (statement of Rep. Waxman; Ref. 4). Congress considered these restrictions on speech necessary to further the Government's interest in ensuring the scientific validity of health claims on the food label. The Government's action in regulating the food label does not offend the First Amendment simply because speech is involved. *Ohralik*, 436 U.S. at 456. The case law establishes that FDA's power to regulate the food label derives from its broad regulatory powers over food, and these regulations are valid under the limited scrutiny that has been afforded restrictions on speech under extensive regulatory schemes involving areas of economic activity. (See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372–73; see also *Dun & Bradstreet, Inc.* v. *Greenmoss Builders*, 472 U.S. 749, 785 n.5 (1985); *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 456 (1978).)

Many comments argued that labeling is commercial speech, and that restrictions placed on it must pass the tests enunciated by the Supreme Court in cases involving commercial speech. Unlike "advertising pure and simple," labeling does not fall clearly within the bounds of commercial speech. *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 (1985). The agency does not consider it necessary for its First Amendment analysis to determine whether or not food labeling fits the definition of commercial speech. (See *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 372.) Rather, the agency considers labeling on foods to form "a distinct category of communications in which the government's power to regulate is at least as broad as with respect to the general rubric of commercial speech." *SEC* v. *Wall Street Publishing Institute*, 851 F.2d at 373.

Recognizing, however, that at least one court has categorized labeling as commercial speech, *General Nutrition*, 638 F. Supp. at 562, FDA agrees that labeling should certainly be considered closer to commercial speech than to "pure" speech.

Even if labeling is analyzed as commercial speech, however, these regulations do not violate the First Amendment. First, speech that is inherently misleading is not protected and may be prohibited. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 563–64 (1980). Secondly, speech that is only potentially misleading may be restricted, so long as the restrictions directly advance a substantial governmental interest and are no more extensive than necessary to serve that interest. Id. at 566. These regulations govern speech that is inherently misleading, health claims on the food label. However, even if such claims are considered to be only potentially misleading, the regulations pass the test enunciated in *Central Hudson*.

Commercial speech receives only limited protection under the First Amendment. (See, for example, *Bolger* v. *Youngs Drug Products Corp.*, 463 U.S. 60, 64–65 (1983).) For commercial speech to be protected, it must concern lawful activity and not be misleading. *Central Hudson*, 447 U.S. at 563 through 564. The Supreme Court has recognized that restrictions on commercial speech may be appropriate to prevent deception. *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. at 771 n.24. These regulations will have the effect of ensuring that the health claims that appear in food labeling are scientifically valid and not misleading. (See *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548, 555 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977)) (FDA regulation constituted the agency's conclusion "that labeling which fails to meet the requirements of the regulation is misleading or otherwise not in compliance with the act," and as such it did not violate the First Amendment).

The Supreme Court has labeled as misleading—and thus not protected—both speech that is inherently likely to deceive and that "experience has proved * * * is subject to abuse." In re *R.M.J.*, 455 U.S. 191, 203 (1982). For example, in *Friedman* v. *Rogers*, 440 U.S. 1, 14–15 (1979), the Court held that Texas could prohibit the use of trade names by optometrists where there was a history of deception and abuse of the public. See also *Ohralik* v. *Ohio State Bar Association*, 436 U.S. 447, 468 (1978) (upholding state bar's rules against in-person solicitation where there was an inherent potential for abuse and prophylactic regulation was needed).

By enacting the 1990 amendments, Congress sought to ensure that health claims would be scientifically valid and not misleading. (See, for example, statement of Rep. Madigan, and statement of Rep. Waxman, Ref. 4). Experience had shown that many "unfounded" health claims were being used on foods (statement of Rep. Waxman; Ref. 3). Congress recognized the "great potential for defrauding consumers if food is sold that contains inaccurate or unsupportable health claims." Id. (statement of House floor managers).

In response to the high potential for health claims to be misleading, Congress legislated that any claim that is not consistent with FDA regulations will misbrand a food. Section 403(r)(1)(B) of the act states that a food is misbranded if its label or labeling contains a claim that "expressly or by implication * * * characterizes the relationship of any nutrient * * * of the food to a disease or a health-related condition *unless* the claim complies with regulations promulgated by FDA. § 403(r)(1)(B)" (emphasis added). By taking this approach, Congress chose to permit only those health claims on food that FDA determines to be scientifically valid, effectively recognizing that health claims are so potentially misleading as to be inherently misleading.

Indeed, particular attributes of health claims on the food label make them inherently misleading. Because health claims are of great importance to the public, they have a great potential to be deceptive: Representations relating a product to an issue of public concern as a means to induce consumer purchases may take on increased importance in the mind of the public and thus be more likely to mislead. *FTC* v. *Pharmtech Research, Inc.*, 576 F. Supp. 294, 301 (D.D.C. 1983) (advertisements for food supplement were misleading where they "played on the average consumer's well-founded fear of cancer"). A health claim on a food label is the type of information that a consumer would have difficulty verifying independently. *American Home Products* v. *FTC*, 695 F.2d 681, 698 (3d Cir. 1982); cf. *Peel* v. *Attorney Reg. & Disciplinary Commission*, 496 U.S. 91, 110 S. Ct. 2281, 2288 (1990) (a lawyer's certification is a "verifiable fact"). Consumers place great reliance on the portions of the food label that they believe to be regulated by the Government (Ref. 36). Unapproved health claims that consumers assume to be consistent with government regulations are therefore more likely to be misleading. "Pervasive government regulation * * * and consumer expectations about such regulation, create a climate in which questionable claims * * * have all the more power to mislead." *American Home Products* v. *FTC*, 695 F.2d at 697.

Even if health claims are considered only potentially misleading, rather than actually or inherently misleading, these regulations are constitutional. The government may place restrictions on commercial speech that is merely potentially misleading. Such restrictions must directly advance a substantial governmental interest and be no more extensive than necessary to serve that interest. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). These regulations pass that test.

First, the government's interest is clearly substantial. The 1990 amendments and these regulations seek to ensure that consumers have access to information about food that is scientifically valid, truthful, reliable, understandable, and not misleading. This information will enable consumers to make more healthful food choices. The Supreme Court has recognized "the health, safety, and welfare of * * * citizens" as a substantial government interest. *Posadas de Puerto Rico Associates* v. *Tourism Co.*, 478 U.S. 328, 341 (1986). Moreover, consumers have a First Amendment interest in obtaining information on which to base a decision whether to buy a product, and this interest is "served by insuring that the information is not false or deceptive." *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157, 162 (7th Cir. 1977), cert. denied, 439 U.S. 821 (1978). "The fact that health is involved enhances the interests of both consumers and the public in being assured 'that the stream of commercial information flow clearly as well as freely.'" Id. (citing *Virginia State Board of Pharmacy*, 425 U.S. at 772); *American Home Products*, 695 F.2d 681, 714. Moreover, FDA is implementing legislation whose purpose is "essential if the consumer is to obtain reasonable information regarding * * * the foods he buys." *American Frozen Food Institute* v. *Mathews*, 413 F. Supp. 548 (D.D.C. 1976), aff'd, 555 F.2d 1059 (D.C. Cir. 1977).

Secondly, the regulations directly advance the government interest. Under the 1990 amendments and these regulations, FDA will assess the relevant scientific evidence on a proposed health claim before permitting that claim to

appear on the food label. In this way, the regulations ensure that health claims are scientifically valid, reliable, understandable, and do not mislead consumers. At the same time, the regulatory scheme encourages the provision of information to consumers that will enable them to improve their diets. There is an "immediate connection" between health claims on food labels and consumers' food choices. *Central Hudson*, 447 U.S. at 569.

Finally, these regulations are no more extensive than necessary to serve the government interest. Under *Board of Trustees* v. *Fox*, regulations that are narrowly tailored to serve the government interest will meet this prong of the *Central Hudson* test. 109 S. Ct. 3028, 3032–35 (1989). Narrow tailoring requires a reasonable fit between regulatory ends and means: "not necessarily the single best disposition but one whose scope is 'in proportion to the interest served.'" Id. at 3035. These regulations reasonably and effectively ensure that health claims on food labels will be scientifically valid, informative, and not misleading. (See *Ward* v. *Rock Against Racism*, 109 S. Ct. 2746, 2757–58 (1989).) Thus they meet the third prong of the *Central Hudson* test, and they do not violate the First Amendment.

98. Some comments maintained that dietary guidance may, in appropriate circumstances, be classified as pure speech entitled to constitutional protection, and that merely because speech is presented in a commercial context does not necessarily categorize it as "commercial speech." Thus, for example, "speech is not rendered commercial by the mere fact that it relates to an advertisement." *Pittsburgh Press Co.* v. *Pittsburgh Comm'n on Human Relations*, 413 U.S. 376, 384 (1973). Speech is also "not commercial merely because it proposes a transaction or because there is an economic motivation." *Asian American Business Group* v. *City of Pomona*, 716 F. Supp. 1328, 1330 (C.D.Cal. 1989) (citing *Bolger* v. *Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983)). The consensus of the comments was to conclude that where a manufacturer, either on a label or in package inserts or accompanying brochures, accurately summarizes dietary guidance promulgated by some public health body or medical institution, that message should be treated as noncommercial speech deserving full protection under the First Amendment, and that the such messages are not solely the product of economic motivation.

FDA believes that its approach to dietary guidance, as discussed above, does not raise First Amendment concerns. Dietary guidance on labeling will be considered to fall outside the coverage of section 403(r)(1)(B) of the act, although it would remain subject to other provisions of the act (e.g., sections 403(a) and 201(n) of the act).

FDA disagrees with the comments that argue that certain dietary guidance—e.g., label summaries of information promulgated by a public health body—should be considered pure, noncommercial speech. To the extent that it may be necessary to categorize these statements, FDA believes they should be considered commercial speech. Labeling statements on food products intended for sale would clearly appear in the context of a commercial transaction and would "propose" such a transaction. (See *Bolger* v. *Youngs Drug Products*, 463 U.S. 60, 66, 103 S. Ct. 2875, 2880 (1983); *Central Hudson Gas* v. *Public Service Commission*, 447 U.S. 557, 562 n.5, 100 S. Ct. 2343, 2349 n.5 (1980).) A label is not entitled to the protection due noncommercial speech simply because it contains a discussion of an issue of broad public interest. *Board of Trustees* v. *Fox*, 109 S. Ct. 3028, 3032 (1989); *Bolger*, 463 U.S. at 68, 103 S. Ct. at 2881; *Central Hudson*, 447 U.S. at 562 n.5, 100 S. Ct. at 2349 n.5. Nor is dietary guidance that discusses a product generically, rather than by specific name, exempt from categorization as commercial speech. *Bolger*, 463 U.S. at 66 n.13, 103 S. Ct. at 2880 n.13. And in determining whether the statements on a label are pure speech, it is irrelevant that they might be considered protected in other contexts. (See *Zauderer* v. *Office of Disciplinary Counsel*, 471 U.S. 626, 637 n.7, 105 S. Ct. 2265, 2274 n.7 (1985).) Just as informational pamphlets were considered commercial speech in *Bolger*, so too dietary guidance on food labels should be considered commercial speech. (See *Bolger*, 463 U.S. at 66–68, 103 S. Ct. at 2880–81.)

99. Some comments suggested that the proposed regulations were in conflict with the First Amendment because it protects manufacturers from burdensome and unnecessary labeling requirements.

FDA disagrees with the comments' assertion that the agency is imposing unduly burdensome and unnecessary labeling requirements. Nothing in the regulations goes beyond the statutory requirements imposed by the 1990 amendments. In formulating these regulations, the agency has attempted to reach a reasonable balance between the interest in making information available about the relationship between diet and disease and the interest in ensuring that this information is scientifically valid. The regulations are narrowly tailored to serve a significant governmental interest and do not violate the First Amendment.

100. A number of comments recommended that foods exceeding a disqualifying nutrient level be allowed to bear an approved health claim if they also bear a statement disclosing the level of the disqualifying nutrient. Comments contended that the legislative history of the 1990 amendments clearly establishes Congress' intent to require increased information and disclosure on food labels, and that section 403(r)(3)(A)(ii) of the act is consistent with this approach. Some comments argued that this procedure is consistent with the public's "right to know" and the manufacturers' First Amendment rights to present consumers with information that is truthful and not misleading. Most maintained that the First Amendment principles discussed under the Preliminary Health Claims and Dietary Guidance sections also prohibit FDA from using disqualifying levels to ban health claims on products.

FDA agrees that section 403(r)(3)(A)(ii) of the act gives it the ability to permit approved health claims on foods exceeding a disqualifying nutrient level if they bear a statement disclosing the level of the disqualifying nutrient. The agency "may by regulation permit * * * a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices" (section 403(r)(3)(A)(ii) of the act).

FDA disagrees, however, with the implication expressed by the comments that it should permit approved health claims for all foods exceeding a disqualifying nutrient level if their labels disclose the level of the disqualifying nutrient. The agency will permit such claims on a case-by-case basis, when it finds that a claim would assist consumers in maintaining healthy dietary practices. Reading the statute to mandate disclosure rather than disqualification would ignore the terms of the statute and would be inconsistent with Congress's intent. When the bill that became the 1990 amendments was reported out of committee in the House, the prohibition in section 403(r)(3)(A)(ii) of the act on health claims was on food containing "any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food

in the total daily diet." H. Rept. 538, 101st Cong., 2d sess. 5 (1990). Subsequently, while the bill was awaiting passage in the House, language was added to section 403(r)(3)(A)(ii) of the act permitting the agency to exempt certain foods from the prohibition (statement of Rep. Waxman; Ref. 4). Had Congress chosen to require disclosure rather than disqualification in all cases, it could have done so explicitly rather than providing for exceptions to the general rule.

In its proposal, the agency noted that "a health claim on a food label is a promise to consumers that including the food in a diet, along with other dietary modifications, will be helpful in attaining the claimed benefit and will not introduce a risk of another disease or health-related condition" (56 FR 60537 at 60544). Including a health claim on the label of a food that contains unhealthful levels of nutrients would be misleading, and the First Amendment permits the government to ban misleading speech. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). FDA recognizes that the Supreme Court has expressed a preference for disclaimers or explanations over prohibitions in the context of commercial speech that is merely potentially misleading. In re *R.M.J.*, 455 U.S. 191, 203 (1982). Nothing in these regulations is inconsistent with that approach. Section 403(r)(3)(A)(ii) of the act specifically permits the agency to allow disclosure instead of disqualification where a claim "would assist consumers in maintaining healthy dietary practices." In situations where the government's substantial interest in improving dietary practices would be promoted by permitting disclosure rather than disqualification, and where disclosure would ensure that the health claim was not misleading, FDA will permit disclosure instead of disqualification.

101. Several comments asserted that the First Amendment allows manufacturers to place preliminary health-related statements on labeling as long as those statements are properly qualified. In support of this position, comments cited a series of opinions in *FTC* v. *National Comm'n on Egg Nutrition*, 517 F.2d 485 (7th Cir. 1975), appeal after remand, 570 F.2d 157 (7th Cir. 1977), cert. denied, 483 U.S. 921 (1978). The comments noted that in affirming the grant of a preliminary injunction, the Seventh Circuit held that the Commission could not "prohibit NCEN from stating that there is scientific evidence supporting the theory that dietary cholesterol intake is not unhealthy, provided that it also states that there is substantial contrary evidence." 517 F.2d at 489–490. The comments also noted that the Seventh Circuit struck down an anti-egg warping statement that FTC had asked be mandated in all future advertising, saying that "the First Amendment does not permit a remedy broader than that which is necessary to prevent deception * * * or correct the effects of past deception * * *." The desired preventative effect can be achieved by requiring the disclosure that there is a controversy among the experts and NCEN is presenting its side of that controversy. The additional statement in the form now ordered by FTC should be required only when NCEN chooses to make a representation as to the state of the available evidence or information concerning the controversy." (570 F.2d at 164)

The comments also cited Court of Appeal decisions that followed the Seventh Circuit in requiring a manufacturer to qualify controversial or preliminary claims with statements that a substantial question exists regarding their scientific validity. Bristol-Myers Co., 102 F.T.C. 21, 294–295 (1983), enforced, 783 F.2d 554 (2d. Cir. 1894), cert. denied, 469 U.S. 1189 (1985); American Home Prods. Corp., 98 F.T.C. 136, 333 (1981), enforced as modified, 695 F.2d 681 (3d. Cir. 1982). The comments asserted that FDA policy must therefore allow the inclusion of properly disclosed health claims that are based on preliminary or controversial findings, as long as the studies that led to those findings are sufficiently well-designed and well-conducted to garner "significant scientific agreement" about how the findings should be interpreted.

FDA does not agree that there is a First Amendment right to make preliminary claims on the food label, regardless of the statutory constraints imposed by the 1990 amendments. As discussed in greater detail above, FDA does not have the authority to permit preliminary health claims under section 403(r)(1)(B) of the act. The statutory scheme and these regulations that produce this result do not violate the First Amendment.

As explained above, misleading commercial speech is not protected under the First Amendment. *Central Hudson Gas & Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 566 (1980). Health claims have such a high potential to be misleading as to be inherently misleading, as Congress recognized when it chose to permit only those health claims on food that FDA determines to be scientifically valid (section 403(r)(1)(B) of the act). In the context of inherently misleading claims, there is no requirement that explanatory information be permitted to eliminate consumers' misconceptions. (See In re *R.M.J.*, 455 U.S. 191, 203 (1982).)

FDA does not agree that it is bound to follow cases involving FTC's regulation of advertising and to permit labeling that presents one side of a scientific controversy, so long as there is a statement that a controversy exists. Although cases involving FTC may sometimes be relevant, it is important to note that fundamental differences exist between the regulatory schemes administered by the two agencies. (See *Bristol-Myers Co.* v. *FTC*, 738 F.2d 554, 559 (2d Cir. 1984), cert. denied, 469 U.S. 1189 (1985).) Congress has long recognized the division of roles between the two agencies. (See 79 Congressional Record 4734 (1935), reprinted in "Dunn, Federal Food, Drug, and Cosmetic Act," 280–281 (1938) (statements of Senators Copeland and Austin) (FTC concentrates on the interests of commerce and economic needs, whereas the objective of FDA is "the health of the people.")) FTC regulates unfair competition and trade practices, including food advertising. (See, for example, 15 U.S.C. sections 45 and 52.) In contrast, FDA is a scientific agency empowered to regulate the food label, among other things. Under section 403(r)(3)(B)(i) of the act, FDA may permit health claims on foods only if it has determined that those claims meet the statutory test for scientific validity. The laws under which FTC operates do not include a comparable statutory standard. Thus, it would not be appropriate for FDA to follow the case law involving FTC.

B. Other Amendments

102. Some comments alleged that outlawing brand names that include an unapproved health claim could violate the Fifth Amendment, as brand names reasonably constitute cognizable private party interests, and banning their use could amount to "taking" those interests without just compensation. Comments warned that the courts have frowned upon banning the use of trade names when less drastic measures would eliminate the possibility of deception. (See In re *R.M.J.*, supra.) (Also, see *Jacob Seigel Co.* v. *FTC*, 327 U.S. 608, 612 (1946) (the policy of the law to protect [brand names] indicates that their destruction should not be ordered if less drastic means will accomplish the same result'").) The comments further suggested that, in keeping with Executive Order 12630 (March 15, 1988), "Governmental Actions and

Interference with Constitutionally Protected Property Rights," FDA should complete a Takings Impact Analysis (TIA) in order to assess whether compensation to the brand name owners would be appropriate, and whether there were viable alternatives to banning the use of the brand names.

In the November 1991 Regulatory Impact Analysis (RIA) (56 FR 60856 at 60865), FDA considered the takings issue and concluded that a TIA was not necessary because the proposed regulations "serve to reemphasize existing regulations as to how products may be named." In view of the comments and concerns raised involving the takings issue, the agency has concluded that it was necessary to conduct the more formalized TIA as set forth in Executive Order 12630. The agency has completed the TIA and concludes that the regulations as set forth below do not present a potential takings. Under the provisions of the Executive Order, the TIA is an internal government decision making document to assist the responsible agency in reducing the likelihood that a "takings" will occur and to provide the decision maker for the agency with information as to any likely cost due to compensable takings. As such, the TIA is not released for public review.

In its November 1991 RIA statement (56 FR 60856 at 60865), FDA stated that the required alteration of trade names did not constitute a taking, and that, as a result, no takings analysis was necessary. FDA still believes that there is no regulatory taking under the Fifth Amendment if a manufacturer is required to alter its brand name when that brand name asserts by implication a relationship between the presence or level of a substance in the food and a disease or health-related condition, and that relationship is not the subject of an approved health claim. These final regulations on health claims constitute a reasonable exercise of the agency's authority to promote policies in the interest of public health. (See *Keystone Bituminous Coal Association* v. *DeBenedictis*, 480 U.S. 470, 488 (1987).) The 1990 amendments made explicit FDA's authority to permit certain health claims if it determines, based on the totality of publicly available scientific evidence, that the claims are scientifically valid. H. Rept. 538, 101st Cong., 2d sess. 9 (1990). The food industry "has long been the focus of great public concern and significant government regulation," and "the possibility was substantial" that the government would, "upon focusing on the issue," decide that the actions now being undertaken are in the public interest. *Ruckelshaus* v. *Monsanto Co.*, 467 U.S. 986, 1009 (1984); see also *Connolly* v. *Pension Benefit Guarantee Corp.*, 475 U.S. 211, 227 (1986) ("Those who do business in the regulated field cannot object if the legislative scheme is buttressed by subsequent amendments to achieve the legislative end.")

Companies that use brand names that contain implied health claims lack a reasonable investment-backed expectation that they will be able to continue to use those names. *Monsanto*, 467 U.S. at 1005. Under the act before the 1990 amendments, and under prior FDA policy, products whose labeling included implied health claims were subject to regulation as drugs without regard to the content of the claim. In 1987, FDA proposed to permit certain health claims on food, but this proposal was never made final and thus cannot be considered to provide the basis for reasonable expectations that specific claims would be allowed. The 1990 amendments for the first time provided companies with the basis for an expectation that certain implied claims, if approved, could be made. Only with the publication of these final rules does the possibility arise that a company might have a reasonable investment-backed expectation in continuing to use an approved claim.

103. One comment noted the possibility that the scientific standard for health claims has the potential to be unconstitutional, either facially or as applied, under the First (manner of application is overbroad and limits constitutionally protected free speech), the Fifth (the vagueness of the standard is such that due process will be violated when organizations are not given fair notice of what conduct is prohibited), the Ninth (without a clearer definition of the standard, oversight of agency actions that exceed its authority would be hindered), and the Fourteenth Amendments.

FDA disagrees with the comment's assertion that these regulations are unconstitutional. As discussed in greater detail at the beginning of this section of this preamble, these regulations do not violate the First Amendment.

FDA further disagrees that the scientific standard is unconstitutionally vague or overbroad, and it questions the applicability of the vagueness and overbreadth doctrines in the current context. The vagueness doctrine is generally applied to strike down prohibitions on speech that leave individuals without clear guidance on the type of speech that is prohibited. (See, for example, *Village of Hoffman Estates* v. *Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498–99 (1982); *Grayned* v. *City of Rockford*, 408 U.S. 104, 108 (1972).) This is not the case here. Only approved health claims will be permitted on the food label, and all other health claims will misbrand a food. It will thus be clear which type of speech is prohibited and which permitted. Further, these regulations are narrowly tailored to meet a substantial government interest and are not overbroad. They do not "sweep[] within [their] prohibition what may not be punished under the First * * * Amendment[]." *Grayned*, 408 U.S. at 115. In any event, it is doubtful that the overbreadth doctrine would apply to these regulations, particularly if they were considered to regulate commercial speech, because the overbreadth doctrine does not apply to commercial speech. *Village of Hoffman Estates*, 455 U.S. at 497.

The comment does not explain its reasons for arguing that the regulations violate the Ninth and Fourteenth Amendments, and the agency does not agree that they do so. These regulations do not deny any fundamental rights not enumerated in the Constitution and so do not violate the Ninth Amendment. Because these regulations involve Federal and not State action, the Fourteenth Amendment does not apply.

The agency also disagrees that the regulations violate the due process clause of the Fifth Amendment because organizations will not be on notice of what constitutes prohibited conduct. Under the statutory scheme, as implemented by these regulations, certain health claims will be permitted to appear on food labels without misbranding the food or making the food a drug. No other health claims will be permitted. Organizations will be on notice that the use of an unapproved health claim is prohibited conduct.

The agency also disagrees that Congress has unconstitutionally delegated legislative power to FDA. "Congress does not violate the Constitution merely because it legislates in broad terms, leaving a certain degree of discretion to executive or judicial actors. As long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power.'" *Touby* v. *United States*, 111 S. Ct. 1752, 1756 (1991) (citing *J.W. Hampton, Jr., & Co.* v. *United States*, 276 U.S. 394, 409 (1928)).

XI. Consumer Summaries

FDA's 1990 proposal (55 FR 5176), issued prior to the enactment of the

1990 amendments, would have required that a health claim reference a consumer summary that provided full information about the relationship between the food and the disease about which the claim pertained. The summary was intended to facilitate the consumer's assessment of whether the health claim applied to him or her, and, in certain instances, to what extent it applied. The summary was also intended to help alleviate the potential problem of information overload on the label.

In the 1991 proposal for health claims (56 FR 60537), issued in response to the 1990 amendments, FDA suggested that consumer summaries may no longer be necessary. Section 403(r)(3)(B)(iii) of the act provides that the regulation authorizing a claim shall require that the claim be stated in a manner that: (1) Accurately reflects the relationship between a substance and a disease or health-related condition, and the significance of the substance in affecting the disease or health-related condition; and (2) enables the public to comprehend the information provided in the claim and understand the relative significance of such information in the context of a total daily diet. This statutory provision requires that the claim present the most significant aspects of the information that the agency was intending to require in the consumer summaries.

104. Some comments contended that FDA should require or strongly encourage the use of consumer summaries. Several of these comments asserted that their use is necessary to put health claims into the perspective of the total daily diet and alluded to their use as being similar to the package inserts employed for certain drug products. Others stated that their use would be an excellent vehicle for consumer education, and they should be provided and widely disseminated.

However, other comments argued that consumer summaries will have limited benefit in the light of the provisions of the 1990 amendments. Some of these comments stated that any of the proposed health claims will succinctly express the same message originally intended by FDA to be contained in the corresponding summary.

FDA is not persuaded that the use of consumer summaries is necessary in light of the provisions of this final rule. The comments did not contain a basis for the agency to require the summaries. New § 101.14(d)(2) requires, in part, that a health claim that appears in labeling be based on, and consistent with, the authorizing regulation in part 101, subpart E, and that the claim allow the public to understand the information provided in the claim and to understand the significance of that information in the context of a total daily diet. The agency agrees that these requirements fulfill the objectives of the consumer summaries, and that requiring the use of consumer summaries would therefore not be of additional benefit to the consumer. Furthermore, FDA knows of no basis under the act nor any other reason to require more information in the health claim than that that is already required under these rules.

105. Other comments suggested that FDA prepare and distribute a consumer guide containing information on how to use the new nutrition labels and health claim messages to improve eating habits.

Section 2(c) of the 1990 amendments directs the Secretary to carry out activities to educate consumers about the availability of nutrition information in the label or labeling of food and about the importance of that information in maintaining healthy dietary practices. Although FDA has not yet determined all of the measures that it will undertake to fulfill this directive, the agency believes that the guide suggested by these comments would be extremely useful in assisting consumers to achieve healthier dietary habits. Thus, the agency advises that it will prepare such a guide in partial fulfillment of this provision of the law. These comments, as well as those received in response to the 1990 proposal (55 FR 5176), will be considered in developing this guide.

XII. Other Issues

106. One comment objected to allowing a health claim for a nutrient that has been added to a food, arguing not only that the food containing the added nutrient would be subject to undue emphasis in the diet, but that the added nutrient would have a "dilution effect" on the food's naturally-occurring nutrients. The comment made specific reference to added fiber.

FDA disagrees. FDA believes that it is almost always the nutrient content of the diet that is significant, not the source. The comment provided no data to justify a change in the agency's belief. However, wherever the agency becomes aware of a situation in which the relationship of a particular nutrient to a disease or health-related condition is dependent upon the source of the nutrient, FDA will make appropriate provisions in the specific regulation in part 101, subpart E to ensure that the health claim is valid with respect to the source of the nutrient.

107. One comment objected that foods should not be permitted to bear multiple health claims because they might be viewed as "wonder foods." The comment submitted no data to support this position.

The agency has no basis to conclude that multiple valid health claims will be misleading to consumers. To the contrary, FDA believes that if it were to limit the number of different health claims that could appear on the label of a single product, it would place the manufacturer in the position of having to choose which of several valid health claims should appear on the label. Such choices would inevitably lead to a situation where the same food would bear different health claims depending on the particular manufacturer's marketing preferences. Under such circumstances consumers may question which claim was valid, or whether there were differences in the beneficial nutrients in the same food packaged by different manufacturers. Further, if the agency were to restrict the number of health claims on food, such a restriction would be contrary to the Congressional intent of the 1990 amendments that consumers be helped by health claims to maintain a healthful diet (Ref. 1).

108. A comment stated that a manufacturer may occasionally run an offer inviting consumers to submit requests for brochures containing dietary guidance or specific recommendations of a private organization, such as NCI. The comment requested that FDA clarify whether such brochures should conform to the health claims regulations.

For many years, the agency has taken the position that brochures containing nutrition information about a food constitute labeling. For example, § 101.9(f) provides that a statement may be included on the label or in labeling offering additional nutrition information upon written request to a specified address. The provision states further that any additional labeling furnished to consumers or professionals shall comply with all applicable requirements of chapter 1. (The preamble discussion about this provision appears in the response to comment 37 in the **Federal Register** of March 14, 1973 (38 FR 6950 at 6957).) Accordingly, FDA advises that where a food label contains an offer inviting consumers to submit requests for a brochure, and the brochure explicitly or implicitly characterizes the relationship of a substance to a disease or a health-related condition, the brochure is labeling that contains a health claim and thus must conform to the health claims regulations.

109. Some comments contended that in-store educational programs should not be subject to the health claim regulations. One comment noted that

such programs provide beneficial health and dietary information to consumers and can assist the agency in educating the public about the new labeling initiative. Another comment advised that the guidance in these programs may, or may not, conform to health claims regulations.

FDA recognizes that a wide variety of in-store nutrition education programs incorporating written, printed, or graphic materials, videotapes, or other media, may serve a useful role in assisting consumers maintain a balanced and healthful diet and thereby make a positive contribution toward one of the major goals of the 1990 amendments. Accordingly, the agency wishes to encourage, rather than discourage, their use, provided that such programs conform to health claims regulations if they characterize the relationship of a substance to a disease or health-related condition.

However, the agency points out that such programs, by virtue of their association with the articles of food in the retail store, generally constitute food labeling under section 201(m)(2) of the act and, as such, would be subject to regulation under section 403(r) of the act if a health claim is made. FDA does not agree that such programs should be exempt from these regulations. Consumers could be confused by differing claims on food labels and in these programs. For example, if under an in-store program, informational placards with a calcium/osteoporosis health claim were placed on a dairy case containing a wide variety of dairy products, some of the products contained in the case would likely be misbranded, as a number of dairy products exceed the disqualifying nutrient levels for fat and saturated fat or fail to meet other provisions of new § 101.14. Even those products that would otherwise qualify for a health claim would likely be misbranded if the placard claim itself did not conform to the provisions of new § 101.14 and part 101, subpart E.

The agency's regulations are designed to enable consumers to understand the significance of the consumption of the substance on the risk of disease within the context of the daily diet. Relevant in-store programs should be carefully crafted to convey such an understanding.

110. A number of comments took a position that one or more of the proposed provisions should not be established because they are subjects for regulatory review under the January 28, 1992, Presidential memo, "Reducing the Burden of Government Regulation." The comments asserted that these requirements are exercises in discretion by the agency rather than requirements mandated by Congress.

FDA advises that after considering these comments, it has concluded that none of the preliminary requirements reaches beyond the act to impose an unnecessary burden on manufacturers. As explained in the preamble of the proposal (56 FR 60537 at 60545 through 60547), each of these requirements is directly derived from existing provisions of the act. Even though these provisions are derived from the act, FDA has carefully reviewed each provision in accordance with the direction provided by the January 28, 1992, Presidential memo. FDA has carefully considered the benefits to society of these rules and concluded that the benefits clearly outweigh the expected costs (see the final RIA, published elsewhere in this issue of the **Federal Register**). Each provision of the rules has been fashioned to maximize net benefits to society. Further, the provisions have been crafted to clearly convey to the regulated community what is required of firms choosing to make health claims.

XIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), along with the food labeling proposals, and the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XIV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (November 27, 1991 (56 FR 60537 at 60562)). At that time, FDA determined under 21 CFR 25.24(a)(8) and (a)(11) that this action was of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

Several comments on the proposed rules on health claims suggested that there would be significant adverse environmental effects from these rulemakings because it would cause large stocks of labels and labeled packaging materials to be discarded and require a great number of trees to be harvested to provide new labeling material. One comment estimated the number of label units from the dairy industry that would need to be discarded following publication of FDA's final rules on several food labeling actions, including this action. However, this comment did not: (1) Show how these estimates were derived, (2) identify what portion of the estimated amounts are attributable solely to this action, or (3) describe what impact the discarded labeling and packaging would have on the disposal of solid waste. Another comment questioned the appropriateness of requiring lengthy explanations on the labels of foods for which health claims are made because those requirements might result in extra packaging so that sufficient label space would be available for the required elements of the health claims. The comment said that this extra packaging might increase the burden on the environment but did not estimate the amount of extra packaging that might be needed or describe what impact this extra packaging would have on the environment.

According to section 10(a)(2) of the 1990 amendments, section 403(r) of the act does not apply to food labeled before May 8, 1993. Thus, all labels that are

applied to food prior to that date will not have to be destroyed. The comments contained no data with respect to labels that might remain that would fail to comply with the requirements of section 403(r)(1)(B) of the act. In the absence of such data, FDA has no basis on which to assess the validity of assertions that considerable label stocks will be destroyed and thereby determine the extent of any potential adverse environmental impact. Given the fact that section 10(a)(2) of the 1990 amendments provides an exemption for labeled products, and that FDA is authorizing various health claims elsewhere in this issue of the **Federal Register**, FDA believes that very little, if any, labeling will have to be discarded because of this final rule. Also, in its final rules, FDA has limited the required elements of many of the health claims compared to the elements that were proposed. Thus, FDA believes that the information required on a label when a health claim is made can be incorporated into the label without significantly increasing the amount of packaging required. Consequently, FDA concludes that the comments on the potential for adverse environmental effects do not affect the agency's previous determination that no significant impact on the human environment is expected and that an environmental impact statement is not required.

XV. Paperwork Reduction Act

In the **Federal Register** of February 14, 1992 (57 FR 5396), FDA announced that the agency had submitted to the Office of Management and Budget (OMB) for its review the collection of information requirements contained in the proposed rule (November 27, 1991, 56 FR 60537) that provided, in proposed § 100.70, for petitions regarding the use of health claims in conjunction with food labeling. Also in the February 1992 document, FDA published its estimated annual collection of information burden.

FDA considered over 6,000 written comments received in response to the aforementioned **Federal Register** documents and the oral presentations made at the public hearing on food labeling in developing this final rule. FDA has not been persuaded by the comments or any other relevant information to modify, in this final rule, the health claim petition requirements that it proposed last year. Thus, the agency's estimated annual reporting and recordkeeping burden from the health claim petition requirements contained in this final rule remains unchanged from that announced in February.

FDA has submitted copies of the final rule to OMB for its review of these reporting requirements.

XVI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. House of Representatives, House Report 101–538, "Nutrition Labeling and Education Act of 1990," June 13, 1990.

2. 136 Congressional Record—Senate, S16607–16612, October 24, 1990.

3. 136 Congressional Record—House, H12951–12955, October 26, 1990.

4. 136 Congressional Record—House, H5836–5845, July 30, 1990.

5. DHHS, Public Health Service, "The Surgeon General's Report on Nutrition and Health," DHHS (PHS) Publication No. 88–50210 (GPO Stock No. 017–001–00465–1), U.S. Government Printing Office, Washington, DC, 1988.

6. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, NRC, "Diet and Health: Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

7. USDA and DHHS, "Nutrition and Your Health: Dietary Guidelines for Americans," 3d ed., Home and Garden Bulletin No. 232, U.S. Government Printing Office, Washington, DC, 1990.

8. Dresser, C. M., National Center for Health Statistics, Interagency memorandum to Marilyn Stephenson, FDA, December 3, 1981.

9. USDA, Human Nutrition Information Service, "Nationwide Food Consumption Survey—1986," NFCS, Continuing Survey of Food Intakes by Individuals, Report No. 86–3, Hyattsville, MD, p. 168, September 1988.

10. Buzzard, I. M., Letter to Virginia Wilkening, FDA, February 12, 1991.

11. Clinical Nutrition Branch, memo to file: Data Analysis HM1, Percent Daily Reference Value Per Serving, October 16, 1991.

12. Clinical Nutrition Branch, memo to file: Data Analysis HM2, Presence of Nutrients in Food Categories, October 16, 1991.

13. Clinical Nutrition Branch, memo to file: Data Analysis HM3, Assessment of Disqualifying Levels of 10, 15, and 20 Percent of the DRV Per Serving, October 16, 1991.

14. Clinical Nutrition Branch, memo to file: Data Analysis HM4, Assessment of Need for Disqualifying Levels Based on 100 Grams, October 16, 1991.

15. Senate Report No. 493, 73d Cong., 2d sess., March 15, 1934. Cited in: Food and Drug Administration, "A Legislative History of the Federal Food, Drug, and Cosmetic Act," vol. 2, pp. 721–3, FDA, Rockville, MD, 1979.

16. Fosmire, G. J., "Zinc Toxicity," *The American Journal of Clinical Nutrition*, 51:225–227, 1990.

17. Fischer, P. W. F., A. Giroux, and M. R. L'Abbe, "Effect of Zinc Supplementation on Copper Status in Adult Man," *The American Journal of Clinical Nutrition*, 40:743–746, 1984.

18. FDA, "Compliance Program Guidance Manual," Chapter 21, Program No. 7321.002 (1988–1991), FDA, 1990.

19. Schoeller, D. E., "How Accurate is Self-Reported Dietary Energy Intake?", *Nutrition Reviews*, 48:373–379, 1990.

20. Food and Nutrition Board, NRC, "Recommended Dietary Allowances," 10th ed., Chapter 1, National Academy Press, Washington, DC, 1989.

21. Yetley, E. A. and Y. K. Park, "Obtaining Data on Intake of Supplements," in *Nutritional Status of the Individual*, G. E. Livingston, Ed., pp. 113–123, Food and Nutrition Press, Inc., Trumbull, CT, 1989.

22. Burke Marketing Research, "Analysis: Restaurant Users Focus Group Session," Study BMR No. 39–545 conducted for the American Heart Association, Dallas, TX, March 1989.

23. Burke Marketing Research, "Logo/Name Study for American Heart Association," Study BMR No. 39–651 conducted for the American Heart Association, Dallas, TX, June 1989.

24. U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Environment, Hearing on the Nutrition Labeling and Education Act of 1989, H.R. 3028, August 3, 1989, Serial No. 101–65, U.S. Government Printing Office, Washington, DC, 1989.

25. U.S. Senate, Committee on Labor and Human Resources, Hearing on the Nutrition Labeling and Education Act of 1989, S. 1425, November 13, 1989, U.S. Government Printing Office, Washington, DC, 1990.

26. Congressional Record—Senate, S8894–8895, July 27, 1989.

27. NCI, "Eat More Fruits and Vegetables—Five-a-Day For Better Health," NIH Publication No. 92–3248, October, 1991.

28. Glinsmann, W. H., H. Irausquin, and Y. K. Park, "Evaluation of Health Aspects of Sugars Contained in Carbohydrate Sweeteners," *The Journal of Nutrition*, 116:S1–S216, 1986.

29. USDA, Human Nutrition Information Services, "USDA's Food Guide Pyramid," Home and Garden Bulletin No. 249, April, 1992.

30. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC1, Disqualifying Levels at 20 Percent versus 15 Percent of the Daily Reference Value, October 15, 1992.

31. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC2, Disqualifying Levels per 50 Grams versus per 100 Grams, October 15, 1992.

32. The National Nutrition Monitoring and Related Research Act of 1990, Pub. L. 101–445, October 22, 1990.

33. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC3, Health Claim Requirement for Minimum Levels of Nutrients, October 15, 1992.

34. Managers Statement on the DS Act of 1992.

35. FDA, Clinical Nutrition Branch, memo to file: Data Analysis HC4, Disclosure/Disqualifying Levels for Meals and Main Dishes, October 15, 1992.

36. FDA's 1990 Health and Dietary Survey, Division of Consumer Studies, Center for Food Safety and Applied Nutrition, FDA.

37. Food Retailing Review—1992 Edition, The Food Institute Information and Research Center, Fairlawn, NJ, p. 245, February 1992.

List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 20 and 101 are amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 302, 303, 307, 310, 311, 351, 352, 354–360F, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1); 5 U.S.C. 552; 18 U.S.C. 1905.

2. Section 20.100 is amended by revising the section heading and by adding new paragraph (c)(34) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(34) Health claims petitions, in § 101.70 of this chapter.

PART 101—FOOD LABELING

3. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

4. Section 101.9 is amended by adding new paragraph (k)(1) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(k) * * *

(1) That the food, because of the presence or absence of certain dietary properties, is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom. Information about the relationship of a dietary property to a disease or health-related condition may only be provided in conformance with the requirements of § 101.14 and part 101, subpart E.

* * * * *

5. New § 101.14 is added to read as follows:

§ 101.14 Health claims: general requirements.

(a) *Definitions.* For purposes of this section, the following definitions apply:

(1) *Health claim* means any claim made on the label or in labeling of a food, including a dietary supplement, that expressly or by implication, including "third party" references, written statements (e.g., a brand name including a term such as "heart"), symbols (e.g., a heart symbol), or vignettes, characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements, symbols, vignettes, or other forms of communication that suggest, within the context in which they are presented, that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition.

(2) *Substance* means a specific food or component of food.

(3) *Nutritive value* means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.

(4) [Reserved]

(5) *Disqualifying nutrient levels* means the levels of total fat, saturated fat, cholesterol, or sodium in a food above which the food will be disqualified from making a health claim. These levels are 13.0 grams (g) of fat, 4.0 g of saturated fat, 60 milligrams (mg) of cholesterol, or 480 mg of sodium, per reference amount customarily consumed, per label serving size, and, only for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. For dehydrated foods that must have water added to them prior to typical consumption, the per 50-g criterion refers to the as prepared form. Any one of the levels, on a per reference amount customarily consumed, a per label serving size or, when applicable, a per 50 g basis, will disqualify a food from making a health claim unless an exception is provided in subpart E of this part, except that:

(i) The levels for a meal product as defined in § 101.13(l) are 26.0 g of fat, 8.0 g of saturated fat, 120 mg of cholesterol, or 960 mg of sodium per label serving size, and

(ii) The levels for a main dish product as defined in § 101.13(m) are 19.5 g of fat, 6.0 g of saturated fat, 90 mg of cholesterol, or 720 mg of sodium per label serving size.

(6) *Disease or health-related condition* means damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition (claims pertaining to such diseases are thereby not subject to § 101.14 or § 101.70).

(b) *Eligibility.* For a substance to be eligible for a health claim:

(1) The substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk, or, alternatively, the petition submitted by the proponent of the claim otherwise explains the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet and satisfies the other requirements of this section.

(2) If the substance is to be consumed as a component of a conventional food at decreased dietary levels, the substance must be a nutrient listed in 21 U.S.C. 343(q)(1)(C) or (q)(1)(D), or one that the Food and Drug Administration (FDA) has required to be included in the label or labeling under 21 U.S.C. 343(q)(2)(A); or

(3) If the substance is to be consumed at other than decreased dietary levels:

(i) The substance must contribute taste, aroma, or nutritive value, or any technical effect listed in § 170.3(o) of this chapter, to the food and must retain that attribute when consumed at levels that are necessary to justify a claim; and

(ii) The substance must be a food or a food ingredient or a component of a food ingredient whose use at the levels necessary to justify a claim has been demonstrated by the proponent of the claim, to FDA's satisfaction, to be safe and lawful under the applicable food safety provisions of the Federal Food, Drug, and Cosmetic Act.

(c) *Validity requirement.* FDA will promulgate regulations authorizing a health claim only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(d) *General health claim labeling requirements.* (1) When FDA determines that a health claim meets the validity requirements of paragraph (c) of this

section, FDA will propose a regulation in subpart E of this part to authorize the use of that claim. If the claim pertains to a substance not provided for in § 101.9, FDA will propose amending that regulation to include declaration of the substance.

(2) When FDA has adopted a regulation in subpart E of this part providing for a health claim, firms may make claims based on the regulation in subpart E of this part, provided that:

(i) All label or labeling statements about the substance-disease relationship that is the subject of the claim are based on, and consistent with, the conclusions set forth in the regulations in subpart E of this part;

(ii) The claim is limited to describing the value that ingestion (or reduced ingestion) of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition;

(iii) The claim is complete, truthful, and not misleading. Where factors other than dietary intake of the substance affect the relationship between the substance and the disease or health-related condition, such factors may be required to be addressed in the claim by a specific regulation in subpart E of this part;

(iv) All information required to be included in the claim appears in one place without other intervening material, except that the principal display panel of the label or labeling may bear the reference statement, "See ———— for information about the relationship between ———— and ————," with the blanks filled in with the location of the labeling containing the health claim, the name of the substance, and the disease or health-related condition (e.g., "See attached pamphlet for information about calcium and osteoporosis"), with the entire claim appearing elsewhere on the other labeling. Provided that, where any graphic material (e.g., a heart symbol) constituting an explicit or implied health claim appears on the label or labeling, the reference statement or the complete claim shall appear in immediate proximity to such graphic material;

(v) The claim enables the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet; and

(vi) If the claim is about the effects of consuming the substance at decreased dietary levels, the level of the substance in the food is sufficiently low to justify the claim. To meet this requirement, if a definition for use of the term "low" has been established for that substance under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "low" has been established, the level of the substance must meet the level established in the regulation authorizing the claim; or

(vii) If the claim is about the effects of consuming the substance at other than decreased dietary levels, the level of the substance is sufficiently high and in an appropriate form to justify the claim. To meet this requirement, if a definition for use of the term "high" for that substance has been established under this part, the substance must be present at a level that meets the requirements for use of that term, unless a specific alternative level has been established for the substance in subpart E of this part. If no definition for "high" has been established (e.g., where the claim pertains to a food either as a whole food or as an ingredient in another food), the claim must specify the daily dietary intake necessary to achieve the claimed effect, as established in the regulation authorizing the claim; *Provided* that:

(A) Where the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section based on its reference amount customarily consumed, and the labeled serving size differs from that amount, the claim shall be followed by a statement explaining that the claim is based on the reference amount rather than the labeled serving size (e.g., "Diets low in salt and sodium may help lower blood pressure in many people. A serving of ———— ounces of this product conforms to such a diet.").

(B) Where the food that bears the claim is sold in a restaurant (except if the claim is made on a menu) or in other establishments in which food that is ready for human consumption is sold, the food can meet the requirements of paragraphs (d)(2)(vi) or (d)(2)(vii) of this section if the firm that sells the food has a reasonable basis on which to believe that the food that bears the claim meets the requirements of paragraphs (d)(2)(vi) and (d)(2)(vii) of this section and providing that basis upon request.

(3) Nutrition labeling shall be provided in the label or labeling of any food for which a health claim is made in accordance with § 101.9 or, for restaurant foods, in accordance with § 101.10.

(e) *Prohibited health claims.* No expressed or implied health claim may be made on the label or in labeling for a food unless:

(1) The claim is specifically provided for in subpart E of this part; and

(2) The claim conforms to all general provisions of this section as well as to all specific provisions in the appropriate section of subpart E of this part;

(3) None of the disqualifying levels identified in paragraph (a)(5) of this section is exceeded in the food, unless specific alternative levels have been established for the substance in subpart E of this part; or unless FDA has permitted a claim despite the fact that a disqualifying level of a nutrient is present in the food based on a finding that such a claim will assist consumers in maintaining healthy dietary practices, and, in accordance with the regulation in subpart E of this part that makes such a finding, the label bears a referral statement that complies with § 101.13(h), highlighting the nutrient that exceeds the disqualifying level;

(4) Except as provided in paragraph (e)(3) of this section, no substance is present at an inappropriate level as determined in the specific provision authorizing the claim in subpart E of this part;

(5) The label does not represent or purport that the food is for infants and toddlers less than 2 years of age except if the claim is specifically provided for in subpart E of this part; and

(6) Except for dietary supplements not in conventional food form, the food contains 10 percent or more of the Reference Daily Intake or the Daily Reference Value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition.

(f) The requirements of this section do not apply to:

(1) Infant formulas subject to section 412(h) of the Federal Food, Drug, and Cosmetic Act, and

(2) Medical foods defined by section 5(b) of the Orphan Drug Act.

(g) *Applicability.* The requirements of this section apply to foods intended for human consumption that are offered for sale.

6. Subpart E, consisting of §§ 101.70 and 101.71, is added to read as follows:

Subpart E—Specific Requirements for Health Claims

Sec.
101.70 Petitions for health claims.
101.71 Health claims: claims not authorized.

Subpart E—Specific Requirements for Health Claims

§ 101.70 Petitions for health claims.

(a) Any interested person may petition the Food and Drug

Administration (FDA) to issue a regulation regarding a health claim. An original and one copy of the petition shall be submitted, or the petitioner may submit an original and a computer readable disk containing the petition. Contents of the disk should be in a standard format, such as ASCII format. (Petitioners interested in submitting a disk should contact the Center for Food Safety and Applied Nutrition for details.) If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall state the petitioner's post office address to which any correspondence required by section 403 of the Federal Food, Drug, and Cosmetic Act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints, or easily readable copies of such information.

(c) If nonclinical laboratory studies are included in a petition, the petition shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been conducted in compliance with the good laboratory practice regulations as set forth in part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(d) If clinical or other human investigations are included in a petition, the petition shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter, or were not subject to such requirements in accordance with § 56.104 or § 56.105, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter.

(e) All data and information in a health claim petition are available for public disclosure after the notice of filing of petition is issued to the petitioner, except that clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Petitions for a health claim shall include the following data and be submitted in the following form:

_____

(Date)

Name of petitioner _____

Post office address _____

Subject of the petition _____

Food and Drug Administration,
Regulatory Affairs Staff (HFF–204),
Office of Nutrition and Food Sciences,
200 C St. SW.,
Washington, DC 20204,

The undersigned, _____ submits this petition pursuant to section 403(r)(4) or (r)(5)(D) of the Federal Food, Drug, and Cosmetic Act with respect to (statement of the substance and its health claim).

Attached hereto, in quadruplicate, and constituting a part of this petition, are the following:

A. Preliminary requirements. A complete explanation of how the substance conforms to the requirements of § 101.14(b) (21 CFR 101.14(b)). For petitions where the subject substance is a food ingredient or a component of a food ingredient, the petitioner should compile a comprehensive list of the specific ingredients that will be added to the food to supply the substance in the food bearing the health claim. For each such ingredient listed, the petitioner should state how the ingredient complies with the requirements of § 101.14(b)(3)(ii), e.g., that its use is generally recognized as safe (GRAS), listed as a food additive, or authorized by a prior sanction issued by the agency, and what the basis is for the GRAS claim, the food additive status, or prior sanctioned status.

B. Summary of scientific data. The summary of scientific data provides the basis upon which authorizing a health claim can be justified as providing the health benefit. The summary must establish that, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

The summary shall state what public health benefit will derive from use of the claim as proposed. If the claim is intended for a specific group within the population, the summary shall specifically address nutritional needs of such group and shall include scientific data showing how the claim is likely to assist in meeting such needs.

The summary shall concentrate on the findings of appropriate review articles, National Institutes of Health consensus development conferences, and other appropriate resource materials. Issues addressed in the summary shall include answers to such questions as:

1. Is there an optimum level of the particular substance to be consumed beyond which no benefit would be expected?

2. Is there any level at which an adverse effect from the substance or from foods containing the substance occurs for any segment of the population?

3. Are there certain populations that must receive special consideration?

4. What other nutritional or health factors (both positive and negative) are important to consider when consuming the substance?

In addition, the summary of scientific data shall include a detailed analysis of the potential effect of the use of the proposed claim on food consumption, specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter item shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

If the claim is intended for a significant subpopulation within the general U.S. population, the analysis shall specifically address the dietary practices of such group, and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

If appropriate, the petition shall explain the prevalence of the disease or health-related condition in the U.S. population and the relevance of the claim in the context of the total daily diet.

Also, the summary shall demonstrate that the substance that is the subject of the proposed claim conforms to the definition of the term "substance" in § 101.14(a)(2).

C. Analytical data that show the amount of the substance that is present in representative foods that would be candidates to bear the claim should be obtained from representative samples using methods from the Association of Official Analytical Chemists (AOAC), where available. If no AOAC method is

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available, the petitioner shall submit the assay method used and data establishing the validity of the method for assaying the substance in food. The validation data should include a statistical analysis of the analytical and product variability.

D. Model health claim. One or more model health claims that represent label statements that may be used on a food label or in labeling for a food to characterize the relationship between the substance in a food to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the petition. The model health claim shall include:

1. A brief capsulized statement of the relevant conclusions of the summary, and

2. A statement of how this substance helps the consumer to attain a total dietary pattern or goal associated with the health benefit that is provided.

E. The petition shall include the following attachments:

1. Copies of any computer literature searches done by the petitioner (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for the support of the health claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the substance).

c. All information pertaining to the U.S. population.

F. The petitioner is required to submit either a claim for categorical exclusion under § 25.24 of this chapter or an environmental assessment under § 25.31 of this chapter.

Yours very truly,

Petitioner ————————

By ————————

(Indicate authority)

(g) The data specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such data have already been submitted with an earlier application from the petitioner or any other final petition, the present petition may incorporate it by specific reference to the earlier petition.

(h) The petition shall include a statement signed by the person responsible for the petition that, to the best of his/her knowledge, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to him/her to be pertinent to the evaluation of the proposed health claim.

(i) The petition shall be signed by the petitioner or by his/her attorney or agent, or (if a corporation) by an authorized official.

(j) *Agency action on the petition.* (1) Within 15 days of receipt of the petition, the petitioner will be notified by letter of the date on which the petition was received. Such notice will inform the petitioner that the petition is undergoing agency review and that the petitioner will subsequently be notified of the agency's decision to file for comprehensive review or deny the petition.

(2) Within 100 days of the date of receipt of the petition, FDA will notify the petitioner by letter that the petition has either been filed for comprehensive review or denied. The agency will deny a petition without reviewing the information contained in B. *Summary of Scientific Data* if the information in A. *Preliminary Requirements* is inadequate in explaining how the substance conforms to the requirements of § 101.14(b). If the petition is denied, the notification will state the reasons therefor, including justification of the rejection of any report from an authoritative scientific body of the U.S. Government. If filed, the date of the notification letter becomes the date of filing for the purposes of this regulation. A petition that has been denied without filing will not be made available to the public. A filed petition will be available to the public to the extent provided under paragraph (e) of this section.

(3) Within 90 days of the date of filing, FDA will by letter of notification to the petitioner:

(i) Deny the petition, or

(ii) Inform the petitioner that a proposed regulation to provide for the requested use of the health claim will be published in the **Federal Register**. If the petition is denied, the notification will state the reasons therefor, including justification for the rejection of any report from an authoritative scientific body of the U.S. Government. FDA will publish the proposal to amend the regulations to provide for the requested use of the health claim in the **Federal Register** within 90 days of the date of filing. The proposal will also announce the availability of the petition for public review.

§ 101.71 Health claims: claims not authorized.

In response to the Nutrition Labeling and Education Act of 1990, FDA has reviewed the evidence on the following topics that Congress specifically asked FDA to evaluate and has concluded that there is not a sufficient basis for claims about the following:

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31511 Filed 12-28-92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N–0096]

RIN 0905–AD06

Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between dietary fiber and cancer. However, FDA is authorizing a health claim relating diets low in fat and high in fiber-containing grain products, fruits, and vegetables to a reduced risk of cancer. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and was developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

Based on the totality of the publicly available scientific evidence, including recently available evidence, the agency has concluded that there is not significant scientific agreement among qualified experts that a claim relating dietary fiber to reduced risk of cancer is supported. The publicly available evidence does indicate, however, that diets low in fat and rich in fiber-containing grain products, fruits, and vegetables are associated with a decreased risk of several types of cancer, and there is significant scientific agreement that the evidence supports this association. The evidence is not sufficient to fully explain the role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods in reducing cancer risk.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60566), FDA proposed to deny the use of health claims relating dietary fiber to the risk of cancer on food labeling. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101–535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or 403(r)(5)(D) of the act (21 U.S.C. 343(r)(3) or 343(r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments (Pub. L. 101–535) to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The relationship between dietary fiber and cancer is one of the claims required to be evaluated. In carrying out this inquiry, FDA limited its scientific review to the area for which the strongest scientific evidence and agreement existed: Dietary fiber and cancers of the colon and rectum (colorectal cancers).

FDA published a notice in the **Federal Register** of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments, including dietary fiber and cancer. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on dietary fiber and cancer, and they were included in the proposed rule. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed below.

In the proposed rule (56 FR 60566), FDA requested written comments on its tentative determination not to authorize a health claim for dietary fiber and cancer. FDA also requested comments on the following issues: (1) Should the agency permit the label or labeling of certain foods to state, for example, that diets high in fruit, vegetables, and whole grains are associated with a reduced risk of certain forms of cancer and cardiovascular disease?; (2) If such a statement were permitted, what criteria should be used to identify eligible foods? For example, should such statements be limited to fresh fruit, vegetables, and milled whole grains; or should processed foods derived from these products also be included?; (3) What measures should the agency adopt to assure that consumers are not misled as to the benefit of consuming a specific product?; (4) Does FDA have the authority to allow health claims for foods as well as nutrients?; (5) What qualifying and disqualifying criteria should be used to determine eligibility for a claim, and what methods or criteria should be used for regulatory monitoring and compliance?; (6) What criteria could be used to develop a health claim for foods that would provide truthful and not misleading messages to consumers that changes in dietary patterns are related to reductions in cancer risk (56 FR at 60577)?

In addition, FDA held public hearings on January 30 and 31, 1992, on all aspects of the proposed rules published in response to the 1990 amendments.

II. Summary of Comments and the Agency's Responses

The agency received approximately 100 comments (including those from the March 28, 1991, request) in response to its proposed rule on health claims for dietary fiber and cancer. Comments were received from consumers, consumer advocacy groups, state health departments, organizations of health professionals, the food industry, and Government agencies.

The agency has summarized and addressed the issues raised in these comments below. Data submitted in scientific articles that were not reviewed in the proposed rule or in any of the Federal Government consensus documents or Life Sciences Research Office (LSRO) reports are discussed in the agency's review of recent scientific evidence in section III of this document. A number of the comments received were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

A. General Comments

1. Several comments stated that there is sufficient scientific evidence to support a health claim that diets high in dietary fiber can reduce the risk of colon cancer. These comments maintained that it is well known that population groups who consume high-fiber diets have a lower incidence of cancer, and these comments cited the strength of international correlational data on per capita availability of fiber and risk of colon cancer. Other comments stated that FDA should allow a health claim regarding dietary fiber and cancer

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because cancer is a major public health problem, and it is important for consumers to be well informed. Several comments stated that FDA failed to consider the rapid pace of scientific advances linking nutritional substances to the maintenance of long-term health and disease prevention.

FDA agrees that cancer is a significant public health problem and is a significant cause of death. Colorectal cancers are the second and third leading causes of cancer deaths in the United States for men and women, respectively (Ref. 46). As FDA described in its proposed rule (56 FR 60566), numerous human and animal studies have examined the possible role of dietary fiber intake in reducing the risk of developing colon cancer. Most correlational studies and many (but not all) case-control studies show that diets high in fiber-containing foods (whole grains, fruits, and vegetables) are associated with a reduced risk of colorectal cancer. Prospective epidemiologic studies are few in number and give mixed results. Animal studies indicate that certain types of dietary fiber, but not others, may be important in modulating the effects of chemical carcinogens.

FDA agrees that there is substantial evidence that diets high in fiber-rich foods, including whole grains, fruits, and vegetables, are associated with reduced risk of colorectal cancer. These diets differ, however, in levels of many nutrients and in types of dietary fiber, making it difficult to attribute the observed diet-disease relationship to a single nutrient. Overall, the available data are not sufficient to demonstrate that it is the total dietary fiber, or a specific fiber component, or specific vitamins and minerals (singly or interactively) that are related to reduction of cancer risk.

The agency disagrees with the comments that assert that international correlational data on fiber per capita availability and risk of colon cancer are sufficient to justify a health claim regarding dietary fiber and cancer. While the correlation coefficients of such studies are often large, these studies are very weak in controlling for confounding variables. Many of the countries with low incidences of colon cancer are undeveloped nations that differ in many ways from Western countries (for example, in prevalence of obesity, environmental pollution, genetic susceptibility, parasitic diseases, etc.). None of the international correlation studies reports actual food consumption; instead, each attributes consumption of fiber from averages of food disappearance. This approach does not account for food disappearance through loss or wastage (peeling, etc.) or for differing dietary habits among various socioeconomic groups within a single country. Thus, in its proposed rule, FDA tentatively found that a basis did not exist on which to authorize a health claim relating to an association between ingestion of dietary fiber and risk of cancer. In this final rule, FDA is not authorizing a dietary fiber and cancer health claim because, based on the agency's review of the scientific evidence, including scientific literature that became publicly available after the proposal's publication, and review of data in comments, the agency has concluded that the evidence is not sufficiently conclusive or specific for dietary fiber per se to justify such a health claim. The agency has concluded, however, that there is sufficient evidence to support a claim relating the ingestion of fruits, vegetables, and whole grain products to reduced risk of some cancers. These foods are also generally low in fat and are good sources of dietary fiber.

2. Several comments stated that FDA did not follow the congressional mandate to consider whether there is significant scientific agreement supporting specific health claims. The comments argued that the agency should have first identified the range of specific health claims that could be made about dietary fiber and cancer and then examined the scientific support for each claim. A related comment asserted that FDA's evaluation criteria for specific scientific studies were based on a fundamental misapprehension of its role under the 1990 amendments. The comments stated that FDA's proper role is to search the science for significant agreement, not decide the validity of studies.

FDA disagrees with these comments. The 1990 amendments did not instruct the agency to identify the wide range of health claims that might be made with respect to the 10 topics identified and then to evaluate all published literature relevant to the claims. Rather, the 1990 amendments instructed the agency to determine whether claims respecting the 10 areas, including "dietary fiber and cancer," meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The agency interpreted this directive in a straightforward and logical way. Indeed, FDA's chosen approach was necessary if the agency hoped to accomplish the congressional mandate within the prescribed timeframe and with its limited resources. Thus, FDA, in its proposed rule (56 FR 60566), focused its scientific review on those aspects of the dietary fiber and cancer relationship for which the strongest scientific evidence exists: dietary fiber and colorectal cancer.

The agency developed its proposed rule regarding dietary fiber and cancer in conformity with the standards mandated by the 1990 amendments. FDA's role is to evaluate the totality of the publicly available scientific evidence and to assess whether there is significant scientific agreement among qualified experts that the available evidence supports the proposed claim. This evaluation necessarily involves an assessment of the validity of studies rather than merely a search for scientific agreement.

3. Several comments stated that FDA rejected health claims for dietary fiber and cancer because of rigid application of a scientific standard higher than that mandated by the 1990 amendments and that this rejection will have unfortunate public health consequences because valuable health-related information will not be transmitted to the American population.

FDA does not agree that it has applied a scientific standard higher than the one set out in section 403(r)(3)(B)(i) of the act. As required by the statute, FDA evaluated possible health claims for dietary fiber and cancer by inquiring whether, based on the totality of publicly available scientific evidence (including evidence from well-designed studies), there is significant scientific agreement among qualified experts that the claim is supported. FDA is codifying the scientific standard of section 403(r)(3)(B)(i) of the act at 21 CFR 101.14(c) in the final rule on general requirements for health claims, which is published elsewhere in this **Federal Register**.

4. Several comments stated that FDA used different criteria to assess the relationship between dietary lipids and cancer and the relationship between dietary fiber and cancer.

FDA disagrees with this comment. In reviewing the scientific literature, FDA followed the standard mandated by the 1990 amendments. However, the strength and consistency of the data in these two areas led the agency to reach two different conclusions about permitting health claims.

Assessments of the relevant scientific data, in Federal Government reports and other authoritative documents, have consistently concluded that dietary fat contributes to the risk of cancer at certain sites. In developing its proposed rule on this relationship (56 FR 60764), the agency found that new evidence was consistent with these earlier conclusions. Based on the totality of the evidence, FDA concluded that diets low

in total fat are associated with a reduced risk of some types of cancer.

In contrast, authoritative scientific documents, including Federal Government reports, have concluded that a number of components of diets rich in fruits, vegetables, and grain products contribute to their beneficial effect on cancer. For example, in its summary on dietary fiber and cancer in the National Academy of Sciences' report "Diet and Health: Implications for Reducing Chronic Disease Risk"("Diet and Health") (Ref. 30), the Committee on Diet and Health stated that "[E]ven where the evidence is strongest, it is not possible to adequately separate the effects of fiber from those of other components of the diet (e.g., total calories, fats, vitamins, minerals, and nonnutritive constituents of fruits and vegetables) and nondietary factors (e.g., socioeconomic status)." Similarly, "Healthy People 2000: National Health Promotion and Disease Prevention Objectives" ("Healthy People 2000") (Ref. 46) notes that recommendations from the National Cancer Institute (Refs. 53 through 55), the Surgeon General's Report, the National Academy of Sciences' "Diet and Health," and "Nutrition and Your Health: Dietary Guidelines for Americans" support increased consumption of vegetables, fruits, and whole grains and cereals (Refs. 47, 30, and 45, respectively). In developing its proposed rule on dietary fiber and cancer, the agency found that new evidence did not alter these earlier conclusions. Rather, the agency found that the available scientific evidence was not sufficiently conclusive or specific for fiber per se to justify a health claim relating intake of dietary fiber alone to reduced risk of cancer.

5. Several comments stated that there were disparities in the agency's treatment of confounders, the weight given clinical studies, and emphasis on animal studies between the proposed rules on fat and cancer and on fiber and cancer. One comment stated that FDA criticized several of the fiber and cancer studies because it was not possible to separate the effects of dietary fiber from the effects of a reduced fat intake, but that the agency did not make this criticism of the fat and cancer studies.

FDA disagrees with these comments. In the fiber and cancer studies referred to in the comment, dietary fat was decreased and dietary fiber was increased; therefore, the effects could not be separated. In the majority of the fat and cancer studies, however, dietary fat was decreased and dietary fiber remained the same. Therefore, the reduction in risk of cancer observed in these studies could not have been due to an increased fiber intake.

FDA also disagrees that it relied excessively on animal studies in the fat and cancer proposal. As FDA noted in the proposed regulation on dietary fiber and colon cancer (56 FR 60566), in general, animal studies on fiber show no consistent protective effect. In contrast, animal studies on fat and cancer, taken as a whole, support a promoting effect of fat on carcinogenesis at several sites independent of the effect of energy intake. Human studies on fat are also generally supportive of a promoting effect of fat on carcinogenesis with respect to some types of cancer. The evidence on the relation between fat and cancer is further discussed in the document "Dietary Lipids and Cancer" published elsewhere in this issue of the **Federal Register**.

6. One comment stated that there are several clinical studies on fiber and few on fat and, therefore, the health claim on fiber and cancer should be approved.

FDA disagrees with this comment. The available clinical studies on fiber investigate its relationship to precursor lesions such as polyps, dysplasias, and abnormal cell morphology of the colonic epithelium, rather than to cancer itself. These studies are difficult to interpret, because at this time the actual risk factors for colorectal cancer are still incompletely understood. Moreover, it is not known how valid are markers such as secondary bile acid concentration, fecal mutagenicity, fecal weight, fecal deoxycholic acid, and activity of fecal bacterial enzymes as surrogates for the disease of colon cancer. Additional studies are needed to establish which, if any, of these factors affect the development of human colon cancer.

7. Some comments stated that FDA failed to justify its rejection of authoritative Federal Government reports (specifically, National Cancer Institute (NCI) recommendations containing the word "fiber").

FDA does not agree that, in developing its proposed rule regarding fiber and cancer, it rejected conclusions of Federal Government reports. Some comments, by citing only those portions of dietary recommendations that include the word "fiber," seek to attribute the protective effects of diets high in fruits, vegetables, and grain products to fiber per se. FDA believes that this emphasis distorts the meaning of sound dietary recommendations by failing to acknowledge the important contributions to reduced risk of disease of the wide variety of nutrients and non-nutritive substances present in diets high in fruits, vegetables, and grain products. Such an emphasis also focuses attention away from changes in overall dietary patterns and their potential contribution to reducing risk of chronic diseases.

To date, neither the Surgeon General's Report on "Nutrition and Health" (Ref. 47), the National Academy of Sciences' "Diet and Health" (Ref. 30), nor DHHS' "Healthy People 2000" (Ref. 46) has found the scientific evidence strong enough to attribute the protective effects against cancer of dietary patterns high in fruits, vegetables, and grain products solely to the fiber content of such diets. The recommendations in the Surgeon General's Report (the Report) include increased consumption of whole grain foods and cereal products, vegetables (including dried beans and peas) and fruits (Ref. 47). The Report states, "While inconclusive, some evidence also suggests that an overall increase in intake of foods high in fiber might decrease the risk for colon cancer. Among several unresolved issues is the role of various types of fiber, which differ in their effects on water-holding capacity, viscosity, bacterial fermentation, and intestinal transit time."

Similarly, the National Research Council's "Diet and Health" recommends, "Every day eat five or more servings of a combination of vegetables and fruits, especially green and yellow vegetables and citrus fruits. Also, increase intake of starches and other complex carbohydrates by eating six or more daily servings of a combination of breads, cereals, and legumes." (Ref. 30). The summary concludes:

> Studies in various parts of the world indicate that people who habitually consume a diet high in plant foods have low risks of atherosclerotic cardiovascular diseases, probably largely because such diets are usually low in animal fat and cholesterol. Some constituents of plant foods, e.g., soluble fiber and vegetable protein, may also contribute—to a lesser extent—to the lower risk of atherosclerotic cardiovascular diseases. The mechanism for the link between frequent consumption of vegetables and fruits, especially green and yellow vegetables and citrus fruits, and decreased susceptibility to cancers of the lung, stomach, and large intestine is not well understood because the responsible agents in these foods and the mechanisms for their protective effect have not been fully determined. However, there is strong evidence that a low intake of carotenoids, which are present in green and yellow vegetables, contributes to an increased risk of lung cancer. Fruits and vegetables also contain high levels of fiber, but there is no conclusive evidence that the dietary fiber itself, rather than other nutritive and non-nutritive components of these foods, exerts a protective effect against these

cancers. The Committee does not recommend the use of fiber supplements.

"Healthy People 2000" (Ref. 46) notes that recommendations from the National Cancer Institute, the Surgeon General's Report, the National Academy of Sciences' "Diet and Health," and "Dietary Guidelines for Americans" support increased consumption of vegetables, fruits, and whole grain breads and cereals (Refs. 47, 30, and 45, respectively).

The agency's decision to prohibit the use on the label or labeling of foods of health claims relating intake of dietary fiber to decreased risk of cancer is consistent with the conclusions of Federal Government and other authoritative reports. Moreover, the agency's determination in this final rule to authorize a health claim relating diets low in fat and high in fiber-containing grains, fruits, and vegetables to a reduced cancer risk is quite consistent with the conclusions of these reports.

8. Several comments criticized the agency for starting its review of the scientific literature with consensus documents and Government reports rather than conducting its own review of the older literature and, secondly, for focusing on the scientific evidence concerning the relationship between dietary fiber and colorectal cancer rather than on that between insoluble fiber and colorectal cancer.

FDA disagrees with these comments. In evaluating the publicly available evidence for each of the 10 health claim topics, FDA reviewed the evidence and conclusions reached in several Federal Government documents and in other reports from recognized scientific bodies (56 FR 60566). These authoritative documents represent comprehensive reviews and evaluations of the literature available at the time of their publication (generally from 1987 to 1989) and represent scientific consensus at that time. Although the reports may not have referenced a particular study described in the comment, it is improbable that the studies reviewed in the reports missed an important effect.

In preparing its proposed rule, FDA updated these reports by independently reviewing subsequently published studies. In addition, to ensure that its review of relevant evidence was complete, FDA requested in the **Federal Register** of March 28, 1991 (56 FR 12932), scientific data and information on the 10 specific topic areas. The agency also reviewed and considered comments received in response to that **Federal Register** notice in developing its proposed rules. In reviewing the totality of the publicly available evidence, FDA considered studies that addressed the relationship between dietary fiber and colorectal cancer and those that addressed the relationship between insoluble fiber and colorectal cancer.

9. One comment questioned the motivation behind the agency's tentative rejection of health claims for fiber and cancer. The comment stated that the National Cancer Institute did not endorse health claims on dietary supplements, and stated that health claims for fiber should not be prohibited based on a concern that dietary supplements will be able to bear claims. Comments from supplement manufacturers asserted that, if health claims are permitted on foods containing fiber, then fiber supplements should also be permitted to carry claims. The comment argued that there is no difference between fiber in foods and fiber in supplements and that all fiber supplements are safe, although data were not included to substantiate such a claim.

FDA does not agree that its motivation for rejecting health claims associating dietary fiber and reduced cancer risk was to prevent supplement manufacturers from making such claims. As the agency's proposal makes clear, FDA tentatively decided to deny health claims for dietary fiber and cancer because the currently available scientific evidence is not sufficiently conclusive or specific for fiber per se to justify such a claim, not because the agency wishes to preclude use of such a claim on dietary supplements.

B. Comments Regarding a Relationship Between Dietary Fiber and Cancer

10. Several comments stated that health claims for insoluble fiber, particularly grain fiber, should be allowed. Another comment stated that wheat bran and related products that affect gastrointestinal transit time and fecal weight may help prevent colon cancer when consumed with a diet low in saturated fat and high in plant foods. This comment argued that the fact that animal studies show a protective effect in the colon by fibers with bulking properties is more important than understanding the underlying mechanism. The comment stated further that only specific fibers shown in animal studies to be protective, such as whole grain wheat, should be permitted to carry label claims.

FDA disagrees with these comments. Animal data are not consistent in showing a protective effect for insoluble dietary fiber. Indeed, corn bran, a predominantly insoluble fiber source (78 percent neutral detergent fiber), has been shown in three animal studies to enhance chemical carcinogenesis in rodents (Refs. 59, 60, and 61). While it is true that animal feeding studies using wheat bran are the most consistent in showing protective effects, animal data cannot be applied directly to humans. Taken together, the evidence for a significant role of wheat fiber in humans is still controversial. The number of human studies breaking fiber down by type (soluble, insoluble, etc.) is too small to be considered more than preliminary. Only two studies published since 1987 consider fiber type, while seven consider total fiber by source (fruit, vegetable, or grain), and five consider total dietary fiber as a single entity. The authors of a recent study state in their conclusion, "The efficacy of grain fiber in reducing the risk of colon and rectal cancer remains in question. While our results indicate some protective effect for the colon for grain fiber, most other studies do not find a grain effect" (Ref. 9). For example, the 1988 study by Slattery et al. (Ref. 40) found no effect of grain fiber.

11. Another comment provided data from an animal study that showed that wheat bran is superior to cellulose in reducing the incidence of colonic tumors in rats treated with the colonic carcinogen 1,2 dimethylhydrazine (Ref. 67). The data show that, even among insoluble fibers, differences exist in their effects on tumorigenesis. The study also showed that cellulose was more effective in reducing fecal bile acid concentrations compared to wheat bran, although this difference was apparently not statistically significant. Elevated fecal bile acid concentrations are putative risk factors for colon cancer, although in this study the cellulose group, with its lower fecal bile acid concentration, actually had significantly more colon tumors than the wheat bran group. This may further call into question the importance of dilution of fecal bile acids by fiber, a potential mechanism of action cited in this and other comments.

FDA notes that such results support its tentative conclusion in the proposed rule that fibers (even insoluble fibers) have different effects. The importance of bile acid dilution as a mechanism for effects of fiber remains to be determined.

12. One comment provided that the 1989 study by West et al. (Ref. 48), reviewed in the proposal, did control for micronutrient intake.

FDA agrees that this was incorrectly reported in the proposed rule.

13. A comment stated that the 1989 intervention study by DeCosse et al (Ref.

7) is relevant to the fiber-cancer relationship.

FDA disagrees with this comment. The patients in this study had no colons and, therefore, metabolized fiber differently and developed lesions at a different site from colon cancer patients. For these reasons, FDA believes that this study does not contribute to understanding the fiber-cancer relationship.

14. A comment cited the study of Rosen et al. (Ref. 37) to support the role of grains in reducing the risk of colon cancer.

FDA disagrees with this comment. The comment did not mention that the referenced study examined mortality data from 1969 to 1978 and surveyed food expenditures for 1978 only. Thus, the individuals who died of colon cancer had been dead for up to 10 years when the food expenditure data was collected. It is a weakness of this study that only a single year's food survey (1978) data were used, while mortality figures from the previous 10 years are incorporated. It is possible that this type of food data collection would accurately reflect the diet of the group which died from colon cancer up to 10 years earlier.

15. Several comments stated that studies with statistically insignificant but generally favorable results should be regarded as supportive of the relationship between fiber and cancer risk reduction.

FDA disagrees with this comment. Lack of statistical significance indicates that such findings could have arisen by chance and thus cannot be used to support a causal relationship.

16. One comment stated that overestimation of fiber intake (by inaccurate dietary or analytical methods) will result in underestimation of risk reduction.

FDA disagrees with this comment. Fiber consumption may be overestimated by a consistent factor in both the control and cancer groups. Such overestimation would have the effect of multiplying the intake of both groups by a common factor; for example, it could increase the intake in both groups by 30 percent. The differences between groups would also be multiplied by this common factor, and should be no less readily apparent than without this factor of overestimation, provided fiber intake is overestimated in each group to the same extent. Only if fiber intake were consistently overestimated in the cancer group, but not in the control group, would there be an apparent reduction of a protective effect. Because the same survey and analytical methods were applied to both groups, this seems an unlikely occurrence.

FDA recognizes that imprecise measures of fiber intake will usually tend to reduce associations between fiber intake and risk. Imprecise measurements do not necessarily result in overestimation of fiber, but merely inaccuracy in reporting the fiber content of certain foods. Lack of accuracy will hinder demonstration of a true relationship if one indeed exists between fiber and colon cancer risk reduction.

17. One comment noted that lack of a known mechanism of action for the putative effects of fiber in colon cancer risk reduction should not prevent the acceptance of claims of fiber's usefulness for this purpose. The comment made an analogy to drugs, arguing that they are often approved simply on evidence of efficacy, without clear knowledge of their mechanism of action.

FDA does not believe that the comparison to drug approval is apt. Drugs are substances of known chemical composition. In contrast, it is not known what fiber component or components may be responsible for the effects observed in some epidemiological studies. Fiber is a complex mixture of cellulose, hemicellulose, pectic substances, or other polysaccharides. Some of these materials, when isolated, have been found to promote rather than inhibit chemical carcinogenesis in rodents. Certainly it has not been established which of the components (all of which are types of "fiber") may reduce the risk of colon cancer in humans. Thus, more is at issue here than the mechanism of action; the identity of the actual active agent, if any, is also obscure.

18. One comment noted that fat and fiber intake correlate inversely with one another in many studies, and that this correlation is often statistically significant.

FDA notes that correlations between two dietary variables within a study do not demonstrate that either is causally related to the study endpoint (cancer). Rather, the two measures are merely associated with one another, in such a way that when one increases, the other decreases, and vice versa. Therefore, such a finding does not imply that increased fiber intake is causally related to decreased cancer incidence.

19. A comment noted that increasing fiber intake may promote decreased energy intake and that adding fiber in purified form to foods is not known to be harmful. The comment cited a 13-week study of oat hull feeding in rats as support.

FDA disagrees with this comment and notes that decreased energy intake in response to high fiber intake has not been shown consistently in all animal studies in which fiber-fed groups generally had similar body weights compared to no-fiber groups. FDA also disagrees with the broad statement that adding purified fiber to foods is not known to be harmful. A 13-week study dealing with one specific type of fiber is not sufficiently long to address chronic safety issues about all types of fiber. Nor were the full battery of toxicological endpoints customarily examined in safety evaluations performed in this study.

C. Food Claims Versus Nutrient Claims

In its proposed rule, FDA specifically requested comments on how best to inform consumers of the general dietary guidance to increase consumption of fruits, vegetables, and whole grain products that are rich sources of dietary fiber and other nutrients. In response to this request, FDA received a wide range of comments expressing strong support for health claims for foods rather than only for specific nutrients. National cancer research and health organizations, consumers, and consumer advocacy groups recommended allowing claims for whole foods. Several comments from the food industry also supported health claims for whole foods. These comments are summarized below.

20. Many comments supporting health claims for foods recommended that only those foods high in fiber should be permitted to carry a claim and that claims should not be allowed if they give the impression that dietary fiber, as a single nutrient, is responsible for the reduction in cancer risk associated with diets high in fruits, vegetables, and grain products.

FDA agrees with this comment that a health claim should not give the impression that a single nutrient is responsible for the reduction in cancer risk. Where the evidence is strongest, it is not possible to separate the effects of fiber from those of other components of the diet, such as fat, total calories, and vitamins.

21. Another comment stated that because the public is advised to increase its daily intake of dietary fiber, FDA should "exert control where it is needed" to avoid abusive use of fiber in foods and supplements. The comment stated that specific foods (e.g., no-fiber foods to which fiber is added) and fiber supplements should not be allowed to bear health claims.

FDA has determined that a health claim relating dietary fiber to cancer is

not supported by the totality of the publicly available scientific evidence. The claim that the agency is authorizing deals instead with diets high in fruits, vegetables, and grain products and may be carried by fruits, vegetables, and grain products that, without fortification, qualify as "good sources" of dietary fiber. This claim respects the state of the scientific evidence; it does not represent a position that other foods, including supplements, may not be able to bear a fiber/cancer claim in the future, should appropriate evidence demonstrating the validity of such a claim be brought to the agency's attention.

22. Other comments supported narrowly worded statements concerning overall diets and their effect on risk of cancer.

FDA agrees with this comment that a health claim, as outlined in the final rule, "Labeling; General Requirements for Health Claims for Food," should be stated in context of the total diet. Certain statements about overall diets and their effects on disease or health-related conditions would be considered dietary guidance and not regulated as health claims. In this rule, FDA is authorizing a reference to certain substances (fat and fiber) as part of a statement relating diets high in fruits, vegetables, and grain products to cancer risk.

23. Some comments stated that, if claims are allowed for fiber-containing foods, the fat content should be disclosed on the label.

FDA shares the comments' concern about the fat content of foods bearing the authorized claim. For a food to qualify for a health claim under § 101.76, it must meet the requirements for a "low fat" food as defined under § 101.62.

24. Some comments provided recommendations for developing regulatory criteria. For example, several comments stated that all foods, whether fresh or processed, should meet the same standards. Other comments stated that fiber-only products should be carefully evaluated to ensure that they qualify as foods according to criteria defined in the proposed regulations.

FDA notes new § 101.76(c)(2)(ii) contains the criteria that food must meet to qualify for the authorized health claim. A food must be or contain a fruit, vegetable, or grain product; must be "low fat;" and must be a "good source" of fiber.

25. Several comments noted that FDA acknowledges that virtually all dietary guidelines for Americans have encouraged consumption of fiber-rich foods, including whole grain cereals, fruits, and vegetables, and that comprehensive government reviews and other reviews by recognized scientific bodies have concluded that dietary patterns that include fiber-rich foods are associated with reduced risk of colorectal cancer, coronary heart disease, and other chronic diseases. The comment asserted that FDA should authorize the use of health claims for the relationship between dietary fiber and cancer.

FDA disagrees that the evidence is sufficient to support a claim that dietary fiber, as a single nutrient, is responsible for the reduction in cancer risk. However, FDA is authorizing a claim relating diets high in fiber-containing grain products, fruits, and vegetables to reduced cancer risk.

26. The American Cancer Society commented that it is unclear what aspect of fiber-rich foods reduces the risk of colorectal cancer. According to the American Cancer Society, the evidence does show, however, that fiber-rich diets reduce the risk of cancer. In its nutrition guidelines, the Society recommends that people "eat more high fiber foods, such as whole grain cereals, legumes, vegetables, and fruits." This recommendation emphasizes the importance of the total diet rather than individual components of it. The American Cancer Society recommended the use of a general food claim at the point of purchase that does not mention fiber or specific cancer sites. The comment stated further that, although the American Cancer Society does refer to the cancer prevention possibilities of fiber-rich foods in its educational materials, the American Cancer Society does not think this reference should be stated on food labels, because it is still unclear which qualities of such foods actually reduce cancer risk. For example, many fiber-rich foods are also low in fat and high in antioxidant vitamins. The American Cancer Society believes that if a claim is allowed, it should not be used on food labels unless the food meets the requirements for a "high fiber" nutrient content claim.

The National Cancer Institute supports the use of health claims on whole foods and diets high in fiber-containing foods and low in fat. Their comment stated that there is substantial and sufficient evidence that consumption of diets high in fruits, vegetables, and cereal grains are associated with the reduced risk of some types of cancer, particularly colorectal cancer. The National Cancer Institute recommended that the statement "high fiber diets" or some similar term be included in the label claim. In contrast to the American Cancer Society, the National Cancer Institute also recommended that only foods that contain naturally occurring fiber be allowed to carry a claim relating consumption of vegetables, fruits, and grain products to reduced risk of cancer. The comment stated that there is no agreement among scientific experts that fiber from fortified foods and supplements has a similar protective effect. In addition, the National Cancer Institute expressed safety concerns relative to the consumption of large amounts of fiber from a single dietary source.

FDA agrees that dietary patterns with higher intakes of vegetables (including legumes), fruits, and whole grains are associated with a reduced risk of some types of cancer (see Refs. 15, and 21 through 23 in the proposed rule (56 FR 60566) and Ref. 56 in this document). Although the specific roles of the numerous potentially protective substances in plant foods are not yet understood, populations with diets rich in these foods experience many health advantages, including lower rates of some cancers. Currently, there is not scientific agreement about whether the observed protective effects against cancer are due to a combination of the nutrient components of the foods, including fiber, to other components of the diet (for example, minerals, vitamins, etc.), or to displacement of other foods in fiber-rich diets (for example, replacement of meats, fats). Rather, the evidence currently demonstrates that it is the dietary pattern, and not a single nutrient, that is important in the reduction in risk of diseases such as cancer. If the scientific evidence were sufficient to support a health claim regarding the relationship between dietary fiber and cancer, no distinction would be made between "naturally occurring" fiber and fiber supplements. The final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, treats dietary supplements and conventional foods consistently.

III. Review of the Recent Scientific Evidence

A. Human Studies

FDA has reviewed studies that became publicly available after the publication of its proposed rule and data submitted as comments. These studies are summarized in Table 1.

A case control study by Soltero et al. (Ref. 56) in Puerto Rico focused on prior cholecystectomy as a risk factor for right-sided colon cancer. A food frequency questionnaire was also

administered to the subjects (or next of kin, if subjects were deceased). Cholecystectomy was confirmed to be a significant risk factor for right-sided colon cancer. Subjects with cancer reported consumption of significantly more meat and poultry and less fiber (as crude fiber) and vegetables than controls. Differences in fat intake were not statistically significant. It was not clear from the report if fiber included all sources of fiber or only cereal fiber. A protective effect was also seen for vegetables; it cannot be determined whether the effect reported for fiber was due to fiber itself or to other nutrient constituents of fiber-containing foods.

Giovannucci et al. (Ref. 62) studied a cohort of 49,296 U.S. health professionals, 40 to 75 years of age, for 2 years. The authors recorded diet by questionnaire and assessed colonic adenoma incidence based on sigmoidoscopy biopsy reports. Intake of animal fat was found to be positively associated with polyp incidence. Fiber from either fruits, vegetables, or grains were all significantly protective, whether measured as crude fiber or dietary fiber. Vegetable-associated nutrients (potassium, β-carotene, vitamins C and E) were also protective, but in a combined statistical analysis they did not account for the independent effect of fiber. Three factors limit the applicability of these findings. (1) The total fat intake of most of the subjects was low by general population standards; (2) right-sided lesions in the colon were not considered, and therefore no conclusions can be drawn about right-sided colon cancer from these data; and (3) all of the study subjects were men. A large cohort study involving U.S. nurses, the majority of whom were female, published in 1990, showed no protective effect of fiber or its components on colon cancer (Ref. 49). Giovannucci et al. do not address the differences between these two studies.

Kune et al. (Ref. 63) studied dietary factors in a case-control study of colonic polyp patients. Forty-nine patients with histologically confirmed colonic polyps (greater than 1 centimeter in size) were interviewed about their dietary practices from the previous 20 years. Interview results were compared with those of 727 community controls. Consumption of fiber and vegetables was associated with a significantly reduced relative risk (in both sexes) of polyps, while consumption of milk, beef, and beer were all associated with significantly increased risk (in males only). The study combines fiber and vegetable consumption, making it difficult to assess any independent role of fiber. Micronutrient intake from vegetables (except vitamin C), exercise, and total energy intake are potential confounding variables that were not controlled.

Gregoire et al. (Ref. 64) examined rectal cell proliferation, fecal bile acid concentration, and fecal pH in a 5-day feeding study in normal, healthy volunteers. Groups of 10 or 11 subjects consumed either a low fat/low fiber, low fat/high fiber, high fat/low fiber, or high fat/high fiber diet. Fiber was derived from a bread containing 43 percent wheat bran, 45 percent wheat flour, and 2 percent gum tragacanth as fiber sources. Approximately 41 grams (g) per (/) day of fiber were consumed in the high-fiber groups, versus 6 to 7 g/day in low fiber groups. Statistical analysis for main effects of fiber on labeling index, fecal pH, and fecal bile acid concentration revealed no statistically significant effects.

Entry of fiber into the colon influences short-chain fatty acid production. Cell culture studies have suggested that altered concentrations of short-chain fatty acids within the colon may influence colonic carcinogenesis. Butyrate production may be especially protective. Clausen et al. (Ref. 65) studied fecal short-chain fatty acid composition in 16 controls, 17 patients with resected adenomatous polyps, and 17 patients with resected colonic cancer. An analysis of fresh feces from the three groups revealed no significant differences in types or relative amounts of fecal short-chain fatty acids. Feces were also incubated in vitro for 6 to 24 hours with added boluses of wheat bran or psyllium. Under these conditions, relatively less butyrate was produced by inocula from adenoma and carcinoma patients. The authors propose that reduced butyrate production in patients may be of significance in the etiology of the neoplasms, although the butyrate content of the feces from cases was similar to that of control subjects when not incubated in vitro. It cannot be determined whether the same effects in the in vitro incubations would occur in vivo if the subjects were fed wheat bran or psyllium. The role of butyrate and other short-chain fatty acids in human colon carcinogenesis has not been clearly established.

McGarrity et al. (Ref. 66) studied the effects of fat and cellulose fiber on the growth and biochemical characteristics of two human colon cancer cell lines implanted subcutaneously in nude mice. Mice received either a low fat/low fiber diet, a high fat/low fiber diet, or a high fat/high fiber diet. The added cellulose tended to eliminate the growth-enhancing properties of a high fat diet, but the effects were not statistically significant. Differences in weight gain among the different groups at least partially explained the differences in tumor growth observed. Results with implanted tumors at a noncolonic site cannot be directly generalized to spontaneous colon tumors, which are exposed to the colonic contents as well as to the systemic blood supply.

Reduced fecal bile acid content is thought to be a beneficial factor for colon cancer risk. One comment described preliminary results of a human dietary intervention study (Ref. 58) in this area that has not yet been published. In this study, female subjects consumed wheat, corn, or oat bran supplements in addition to their usual diets. Fecal bile acids, neutral sterols, and fecal enzymatic activities of enzymes that produce fecal mutagens or carcinogens were measured before and after the intervention. Wheat bran supplementation reduced the activity of all four "risk factor" enzymes studied, while oat bran produced significant reductions in three of four enzymes, and corn bran produced significant reductions in only two of four. Alterations in stool weight are probably responsible for some of these changes. Wheat bran supplementation significantly reduced total and secondary bile acid concentration in feces, while oat bran and corn bran did not.

B. Conclusions From New Studies

These additional studies provide further data on the possible link between consumption of dietary fiber consumption and reduced risk of colon cancer. With the exception of the study by Giovannucci et al. (Ref. 62), none of the studies provides evidence of an independent contribution of fiber itself (distinct from its presence in food) to risk reduction. Rather, the studies show a relationship between diets rich in fiber-containing foods and reduced risk of cancer. The Giovannucci et al. study is limited in its applicability, however, as only lesions of the descending colon were considered, and the subjects were men who already consumed a diet lower in fat and higher in vegetables than a typical U.S. diet.

The preliminary results of Reddy's study (Ref. 58) on the effects of amount and type of dietary fiber on colonic bacterial enzymes and bile acids in humans support FDA's observations that insoluble fiber has not consistently been shown to be the protective fiber fraction. Wheat bran and corn bran (both largely insoluble fibers) exerted opposite effects in this risk factor study, as they do in most published animal

carcinogenesis studies. It must also be noted that the risk factors measured in this study have only postulated significance in the etiology of human colon cancer at the present time.

Although the current scientific evidence does not support a specific health claim for dietary fiber and reduced risk of cancer, the data do support a relationship between diets high in fiber-rich foods and low in fat and a reduced risk of some forms of cancer. Therefore, as discussed below, FDA will allow a health claim on vegetables, fruits, and grain products relating diets high in these foods to a reduced risk of cancer, and specifying that these foods contain dietary fiber.

IV. Decision to Deny a Health Claim Relating Dietary Fiber to a Reduced Risk of Cancer

Overall, the currently available scientific evidence is not sufficiently conclusive or specific for fiber per se to justify use of a health claim relating the intake of dietary fiber to a reduced risk of cancer. A major limitation in designing and evaluating research studies has been the need for better defined measures of dietary fiber and standardized descriptions for source, type, and amount of dietary fiber. Commonly used analytical methodologies do not detect many of the characteristics that may vary among fibers and that may be related to biological function (e.g., particle size, chemical composition, water-holding capacity). The inability to detect many of the differences among fibers and the general lack of clear evidence as to the mechanisms of action of fibers raise questions about the ability of commonly used analytical measures of dietary fiber to adequately predict biological actions of specific fibers. Therefore, for these reasons, new § 101.71(a) is added to reflect FDA's decision not to authorize use of a health claim relating dietary fiber to a decreased risk of cancer.

FDA's decision is consistent with recent recommendations in the Institute of Medicine's report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 57). This report notes that there has been great interest in the specific effects of dietary fiber on several chronic diseases. According to the report, the strongest argument for an increased consumption of dietary fiber is the important contribution it makes to normal bowel function. Clear scientific associations of fiber intake with the incidence of cancer have not been made. The report indicates that one reason for this may be the difficulty in designing appropriate experiments to test specifically for the effect of dietary fiber. Foods high in dietary fiber are also generally low in calories and total and saturated fatty acids and devoid of cholesterol; thus, determination of a specific fiber effect in a feeding study is difficult. Moreover, according to the report, foods have a variety of fiber components and each may have different actions. Chemically and physiologically, cellulose, lignin, hemicellulose, pectin and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogenous mixtures of fibers) are not similar in composition. It is also very difficult to analyze dietary fiber chemically, and thus it is hard to correlate the role of specific fiber components to health effects (Refs. 30 and 57).

Therefore, FDA is not authorizing the use on the labels and labeling of foods of health claims relating to an association between the ingestion of dietary fiber and a reduction in the risk of cancer. In reaching this decision, the agency considered all comments received in response to its proposed rule (56 FR 60566), and reviewed the scientific literature that became publicly available after the proposal's publication and data submitted with comments.

V. Decision to Allow a Health Claim on Foods Relating Diets Low in Fat and High in Fiber-Containing Grain Products, Fruits, and Vegetables to a Reduced Risk of Cancer

FDA has reviewed numerous authoritative documents, including Federal Government reports, as well as recent research on dietary fiber and cancer risk. In addition, the agency considered all comments received in response to its proposed rule. The agency has concluded that the publicly available scientific evidence supports an association between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and reduced risk of cancer.

FDA agrees with the comments that argue that dietary patterns that are low in fat and high in fiber-containing grain products, fruits, and vegetables (including legumes), are associated with a decreased risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets high in fiber-containing foods are associated with reduced risk of some types of cancer.

Thus, the conclusion that diets low in fat and high in fiber-containing grain products, fruits, and vegetables, foods also generally low in fat, are associated with a reduced risk of cancer is consistent with the available scientific evidence. As discussed in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, statements about good nutrition that do not expressly or by implication refer to a substance are considered dietary guidance and not health claims. In this rule, FDA is authorizing the inclusion of a reference to dietary fiber in a statement about the value of grain products, fruits, and vegetables in reducing cancer risk. Thus, the health claim permitted under this regulation to be used on the label or labeling of certain foods associates diets low in fat and high in fiber-containing grain products, vegetables, and fruits with a reduced risk of some cancers.

VI. Description of and Rationale for Components of the Health Claim.

A. Relationship and Significance Statements

In new § 101.76(a), the summary of the relationship between diets high in fiber-containing grain products, fruits, and vegetables and reduced cancer risk is consistent with the conclusions reached in the review of the scientific evidence. It is not known whether it is fiber, per se, or some other substance in fruits, vegetables, and grain products that functions as the protective agent; or, if it is fiber, what types and characteristics of the heterogeneous family of fiber compounds are most beneficial. Yet, because of the usefulness of dietary fiber in identifying the types of foods most likely to correlate with reduced cancer risk, fiber is specifically identified as being characteristic of the protective dietary pattern. Thus fiber can serve as the identifying marker. Other components of the relationship statement, for example, risk factors, have been indicated, as in other authorized health claims.

New § 101.76(b), on the significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and reduced risk of cancer, includes the information that U.S. diets tend to be high in fat and low in grains, fruits, and vegetables. A discussion of current dietary guidelines on recommended servings of grain products, fruits, and vegetables is also provided.

B. Nature of the Claim

In new § 101.76(c)(2)(i), FDA is authorizing a health claim relating

substances in diets low in fat and high in fiber-containing grain products, fruits, and vegetables to reduced risk of cancer. In new § 101.76(c)(2)(i)(A), the agency is requiring, consistent with other authorized claims, that the relationship be qualified with the terms "may" or "might." These terms are used to indicate that not all persons can necessarily expect to benefit from these dietary changes.

In new § 101.76(c)(2)(i)(B), the agency, consistent with other authorized claims, is requiring that the claim not indicate that all cancers may be affected, but rather that the risk of "some types of cancer" or "some cancers" may be reduced. The relationship between dietary factors and various types of cancers is variable; in many cases, the available data are inadequate to specifically identify which cancers may be affected.

In new § 101.76(c)(2)(i)(C), the agency is requiring that the claim be limited to grain products, fruits, and vegetables that contain dietary fiber. As noted in the conclusions reached from the available scientific evidence, it is not known what fiber substance or other substances in grain products, fruits, and vegetables are responsible for their protective effect. A role for dietary fiber has been hypothesized and has biological plausibility. Intakes of fiber and other nutrients from grains, fruits, and vegetables are correlated with reduced cancer risk. By requiring that the characterizing nutrient be identified as characteristic of a dietary pattern rich in fiber-containing grains, fruits, and vegetables, without specifically attributing the cause to a nutrient, the claim is more consistent with the current scientific knowledge. The claim should also minimize consumer confusion, because its wording is similar to current dietary guidelines from the U.S. Government, including the National Cancer Institute.

New § 101.76(c)(2)(i)(D) requires that health claims indicate that development of cancer depends on many factors. This requirement is intended to prevent consumers from being misled that grain product, fruit, and vegetable intake is the only factor connected with cancer risk. In new § 101.76(c)(2)(i)(E), FDA, consistent with other authorized health claims, is prohibiting the attribution of a specific reduction in risk of cancer to diets low in fat and high in fiber-containing grain products, fruits, and vegetables. In new § 101.76(c)(2)(i)(F) and (c)(2)(i)(G), FDA is prohibiting, consistent with other authorized health claims, more specific use of dietary terms than is warranted by the current state of the scientific evidence. These requirements also standardize use of these terms, thus minimizing consumer confusion as they compare food labels across products, or as they compare a health claim to the nutrition information panel.

C. Nature of the Food

New § 101.76(c)(2)(ii)(A) requires that the food bearing the health claim be or contain a grain product, fruit, or vegetable. Because the claim relates to diets high in these foods, it would not make sense for it to appear on the labeling of another type of food. A health claim that appears on a food that meets all the requirements in § 101.76(c)(2)(ii), but contains only a trivial amount of grain product, fruit, or vegetable, could be considered misleading and might misbrand the food under section 403(a) of the act. FDA; consistent with the requirements for the health claim on dietary fat and cancer (published elsewhere in this issue of the **Federal Register**), is requiring in new § 101.76(c)(2)(ii)(B) that foods bearing the health claim be "low fat" foods, or alternatively, belong to a class of products that is "low in fat." Low fat diets are associated with reduced cancer risks. Low or negligible fat is also one of the characterizing features of diets rich in grain products, fruits, and vegetables. Because the effect of fat is not readily separated from the effect of other nutritive components of grain products, fruits, and vegetables, it is being made a qualifying nutrient.

In new § 101.76(c)(2)(ii)(C), FDA is requiring that grains, fruits, and vegetables, bearing the authorized health claim qualify as a "good source" (greater than or equal to 10 percent of the daily reference value (DRV)) for dietary fiber. The requirement that these foods contain 10 percent of the DRV for dietary fiber is being set as a specific alternate to the 20 percent (i.e., "high") requirement for qualifying nutrients in the final rule on general requirements for health claims, published elsewhere in this **Federal Register**. This alternate level was deemed useful to assure that most grain products, fruits, and vegetables, would be eligible for this health claim, because these foods in general have been correlated with reduced cancer risk, and because they are significant sources of dietary fiber in the U.S. dietary pattern. Without this alternate level, very few grain products, fruits, and vegetables, would qualify for the health claim, which would be contrary to the available scientific evidence and to the purpose of health claims.

This section also requires that foods qualify as a good source of fiber based on their natural level of fiber. This means that foods which require fortification with dietary fiber, in order to meet the qualifying criteria for the health claim, cannot bear the claim. This requirement is consistent with the scientific basis for the claim, that is, that grains, fruits, and vegetables, in their native form correlate with reduced cancer risk. Because there are not sufficient data that specifically identify dietary fiber, or particular components of fiber, as causal and because this nutrient is being used as a marker for the substance or substances in grain products, fruits, and vegetables, that provide the observed protective effect, it is the native composition of the foods that identifies their usefulness. At the same time, this requirement does not prohibit fortification of qualifying foods with dietary fiber, once the qualifying level has been met naturally.

D. Optional Information

Under new § 101.76(d), similarly to other authorized health claims, health claims may identify additional risk factors for cancer. The regulation specifies the factors that may be listed; all are risk factors about which there is general scientific agreement. This additional information can provide a context that is useful for an understanding of the relationship of the diet to the disease, but manufacturers are cautioned that it should not be presented in a way that is misleading to the consumer. A health claim may also indicate that reductions in fat intake and consumption of fruits, vegetables, and grain products are part of a total dietary pattern that is consistent with the latest "Nutrition and Your Health: Dietary Guidelines for Americans," published jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services (Ref. 45). Consistent with other health claim regulations, the claim may also include information on the prevalence of cancer in the United States. In order to ensure that this information is valid, the agency is requiring that it come from one of three specified authoritative sources.

E. Model Health Claims

In new § 101.76(e) FDA is providing several model health claims to illustrate the requirements of new § 101.76. FDA is not prescribing specific language for claims, but certain elements are required, and these models include the required elements.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a

type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

IX. References

The following references have been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (a) to read as follows:

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§ 101.71 Health claims: claims not authorized.

* * * * *

(a) Dietary fiber and cancer.

3. New § 101.76 is added to subpart E to read as follows:

§ 101.76 Health claims: fiber-containing grain products, fruits, and vegetables and cancer.

(a) *Relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include: A family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The scientific evidence establishes that diets low in fat and high in fiber-containing grain products, fruits, and vegetables are associated with a reduced risk of some types of cancer. Although the specific role of total dietary fiber, fiber components, and the multiple nutrients and other substances contained in these foods are not yet fully understood, many studies have shown that diets low in fat and high in fiber-containing foods are associated with reduced risk of some types of cancer.

(b) *Significance of the relationship between consumption of diets low in fat and high in fiber-containing grain products, fruits, and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in grain products, fruits, and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (five or more servings daily), and grain products (six or more servings daily).

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in fat and high in fiber-containing grain products, fruits, and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fiber-containing grain products, fruits, and vegetables "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer," or "some cancers";

(C) The claim is limited to grain products, fruits, and vegetables that contain dietary fiber;

(D) The claim indicates that development of cancer depends on many factors;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fiber-containing grain products, fruits, and vegetables;

(F) In specifying the dietary fiber component of the labeled food, the claim uses the term "fiber", "dietary fiber" or "total dietary fiber"; and

(G) The claim does not specify types of dietary fiber that may be related to risk of cancer.

(ii) *Nature of the food.* (A) The food shall be or shall contain a grain product, fruit, or vegetable.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low fat" food.

(C) The food shall meet, without fortification, the nutrient content requirements of § 101.54 for a "good source" of dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables, and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, overweight and obesity, alcohol consumption, ultraviolet or ionizing radiation, exposure to cancer causing chemicals, and dietary factors.

(3) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health; or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and cancer risk:

(1) Low fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in grain products, fruits, and vegetables that contain dietary fiber may reduce your risk of some cancers.

Dated: November 3, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

DIETARY FIBER AND CANCER

Study	Study Design	Subjects	Methods	Results	Comments
Kune et al, 1991 (Ref. 63).	Case-control	Cases: 49 patients who had one or more histologically confirmed adenomatous polyp larger than 1 cm in diameter previously removed by endoscopy. Controls: 727 community controls.	50 patients from Melbourne, Australia, who had histologically confirmed adenomatous polyps removed, were selected randomly from a pool of 223. Dietary assessment was done through dietary questionnaire and a quantitative diet history, relying upon subject recall for prior 20 years.	Those with adenomatous polyps were found to have a lower fiber/vegetable intake ($p = 0.04$). Increased consumption of milk, beef, and beer were all significant risk factors in males.	Study combines fiber and vegetable consumption. Confounders were not considered in the model, such as smoking, urban v. rural, exercise, total energy intake, micronutrients other than Vitamin C. Colorectal polyps are used as a proxy for colorectal cancer.
Clausen et al, 1991 (Ref. 65).	Correlational	16 healthy control subjects with no history of GI disease; 17 patients with resected colonic adenomas; 17 patients with resected colonic cancer.	Freshly passed feces was homogenized with isotonic NaKCl for study in an anaerobic fecal incubation system. No patient showed signs of recurrence at the time of fecal sampling, which was at least 3 months after surgery. Patients were excluded from the group with former adenomas if they had previously had abdominal surgery, and from the group with former colonic cancer if the cancer operation had resulted in colostomy. Furthermore, intake of antibiotics within the previous two weeks caused exclusion. Both normal subjects and patients were on a ordinary Danish diet. Fecal short chain fatty acids were measured in both freshly passed feces and following incubations in vitro for 6 to 24 hours. In vitro incubations included trials with added carbohydrate substrates.	Without in vitro incubation, the total concentrations and ratios of short chain fatty acids and the concentrations of individual acids including butyrate in fecal suspensions from 16 normal subjects, 17 patients with resected colonic adenomas, and 17 patients with resected colonic cancer were not significantly different. The ratio of butyrate production to total short chain fatty acid production from fiber sources added to the in vitro fecal inoculum was significantly reduced in patients with colonic cancer and adenomas compared with healthy controls after 6 hours incubation ($p<.05$) and more significantly reduced when the incubation time was extended to 24 hours ($p<.01$). The authors feel that subjects characterized by a colonic flora with a relatively low butyrate formation may have an increased risk of developing colonic adenomas and cancer.	Subjects are somewhat matched by age and sex, but not completely. Polyp and cancer patients were characterized by relatively less butyrate production from fiber substrates in vitro than healthy controls. In vivo, without incubations fecal short chin fatty acid concentrations were similar in both controls and cases. It cannot be assessed whether in vivo consumption of the fiber substrates would result in findings similar to those reported in vitro.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Gregoire et al, 1991 (Ref. 64).	Clinical trial.	43 healthy volunteers, ages and sex distribution not reported.	Volunteers were randomly allocated, after stratification by age and sex to one of 4 dietary groups: A. low fat, low fiber B. low fat, high fiber C. high fat, low fiber D. high fat, high fiber The source of fat is butter, mayonnaise, dressing, cream, Bernaise sauce, and ground beef. The source of fiber is Fibread (9.3 g wheat fiber per slice) Three day food records kept by subjects just prior to intervention period. Cell proliferation was assessed with tritiated thymidine labeling of 3 rectal biopsies. Fecal pH and fecal bile acid concentrations were measured as well.	A short-term increase in dietary fat and decrease in dietary fiber does not result in a large increase in cell proliferation rate. Changes in fecal pH and fecal bile acid concentrations were not significantly different.	During the intervention, dietary variables other than the added fat and fiber were not controlled. The rate of colonic proliferation is a possible intermediary towards colon cancer, not the end point.
Soltero et al., 1990 (Ref. 56).	Case control study in Puerto Rico.	200 patients treated for right-sided colon adeno-carcinoma. Neighborhood controls matched for age and sex.	Subjects (or next of kin, if dead) were interviewed with a quantitative food frequency questionnaire regarding the diet 1 year prior to diagnosis. Fiber was calculated from USDA Handbook #8 (crude fiber).	Cholecystectomy was a risk factor for right sided colon cancer. Meat and poultry intake were significantly greater in cancer cases than controls. Fiber and vegetable intakes were significantly greater in controls than in cancer cases. No significant association with fat intake and cancer.	Major focus of the study was on cholecystectomy and colon cancer. Both fiber and vegetables noted as protective, and the relative contribution of each to risk reduction cannot be determined. It is not clear if all sources of fiber were considered, or only cereal fiber (discrepancy between text and table 5).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Giovanucci et al., 1992 (Ref. 62).	Prospective study among U.S. health professionals.	45,296 health professionals, ages 40 to 75 years, in 1986. 170 documented cases of rectal or colonic adenomatous polyps. Controls--7,284 subjects who had colonoscopy 1986 to 1988.	Subjects received a food frequency dietary questionnaire by mail two years after enrollment. Analyzed for crude fiber, dietary fiber and fat. Fiber sources: vegetables, fruits, or grain.	Animal fat intake significantly associated with polyps. Red meat and dairy fat significantly associated with polyps. All sources of dietary fiber associated with ↓risk. Also, other plant nutrients (potassium, β-carotene, vitamin C, vitamin E) all inversely associated with polyp risk. These associated nutrients did not cancel out fiber's effect when entered in multiple logistic regression.	Intake of meat and fat relatively low compared to U.S. population. This may limit applicability of fiber findings. Right sided adenomas were excluded from analysis. Inference cannot be made about the impact of fiber on right sided colonic tumors. All subjects were men.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0099]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Dietary Fiber and Cardiovascular Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between dietary fiber and cardiovascular disease (CVD). However, FDA is authorizing a health claim relating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain dietary fiber (particularly soluble fiber), to a reduced risk of coronary heart disease (CHD). This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and was developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

On the basis of the totality of the publicly available scientific evidence, including recently available evidence, the agency has concluded that there is significant scientific agreement among qualified experts that a claim relating diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain soluble fiber, to reduced risk of CHD is supported. The evidence is not sufficient to attribute the reduction in risk to soluble fiber or to a specific type or characteristic of soluble fiber, or to other components of these diets.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5916.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60582), FDA proposed to deny the use on food labeling of health claims relating diets high in dietary fiber to reduced risk of CVD. The proposed rule was issued under provisions of the 1990 amendments (Pub. L. 101–535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with sections 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether health claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship between dietary fiber and CVD is one of the claims required to be evaluated. In the proposed rule published in the **Federal Register** of November 21, 1991 (56 FR 60582), FDA limited its review of the science to those aspects of the dietary fiber/CVD relationship for which the strongest scientific evidence and agreement already existed: dietary soluble fiber and CHD.

In the proposed rule, FDA requested written comments on its tentative determination not to authorize a health claim for dietary fiber and CVD. FDA also requested comments on the following issues: (1) Should the agency permit a claim on the label or in labeling of foods that states that diets high in fruit, vegetables, and whole grains are associated with a reduced risk of certain forms of cancer and CVD?; (2) If such statements should be permitted, what criteria should be used to identify foods that are eligible for such statements?; (3) What measures should the agency adopt to assure that consumers are not misled as to the benefit of consuming a specific product?; and (4) Does FDA have the authority to allow and should it allow health claims for foods as well as nutrients?

On January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for dietary fiber and CVD. In addition, because of new evidence identified from literature searches and new data submitted with comments to the proposed rule, FDA reopened the comment period on dietary fiber and CVD for 30 days (57 FR 32751, July 23, 1992).

In response to its proposed rule on dietary fiber and CVD, the agency received approximately 130 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately answered in other dockets, and these were forwarded to the appropriate docket for response.

Most of the comments specific to the proposal for a health claim for fiber and CVD provided explanations in support of or in opposition to provisions of the proposed regulation. Some of the comments contained relevant scientific studies not included in the agency's proposed rule. These additional studies and those identified through literature searches that had not been previously reviewed in the proposal (56 FR 60582) are included in the agency's review below. The agency has summarized and responded to issues raised in the comments in section III. of this document.

II. Updated Review of Scientific Evidence

FDA, to ensure that it had not overlooked new and significant scientific data, reviewed human studies published since the publication of the proposed rule that it had identified in a standard literature search. In addition, FDA carefully reviewed all relevant scientific data submitted as comments. The availability of the new data was announced in a notice of reopening of comment period (57 FR 32751).

A. Human Studies

Detailed summaries of studies discussed below are presented in Table 1. FDA's explanation for separately evaluating studies on mildly to moderately hypercholesterolemic individuals and normocholesterolemic individuals is found in its proposed rule (56 FR 60587). Multiple sources of soluble fiber, including oat bran and other cereal brans, legumes, pectin, psyllium, and guar gum, were used in these studies.

1. Hypercholesterolemics: "typical" or "usual" diets

Leadbetter et al. (Ref. 83) evaluated the hypocholesterolemic effects of increasing intakes of β-glucan, the major type of dietary soluble fiber in oat bran. A four-by-four Latin square design was used in this randomized intervention study with 40 hypercholesterolemic (total serum cholesterol 250 to 348 milligram/deciliter (mg/dL)) men and women, ages 25 to 64, in New Zealand. Subjects added 0, 30, 60, and 90 grams/day (g/day) oat bran to their usual diet

for 1-month intervals. There was no wash-out between periods. Oat bran was provided in weighed packages and detailed advice and recipes were provided on how to incorporate it into the diet. The total dietary fiber content of the regular diets, without oat bran, ranged from 23 to 27 g/day. Results showed no significant effect of oat bran on serum cholesterol at any dose. There was no dose-related trend and no correlation between bran dose and changes in serum cholesterol. The authors stated that the oat bran used in this study was lower in soluble fiber (3.7 to 4.2 percent β-glucan) than oat bran used in studies showing a significant lowering of serum cholesterol with oat bran supplementation.

Cara et al. (Ref. 84) evaluated the hypocholesterolemic properties of wheat germ in 10 hypercholesterolemic men and women (serum cholesterol 254 to 367 mg/dL), ages 35 to 68 years. Subjects consumed their regular diets for 1 week, then added 30 g/day wheat germ (2.9 g dietary fiber) for 4 weeks. At the end of the treatment period, subjects were monitored for an additional 4 weeks with no supplementation. Their base diet included 13.6 g/day dietary fiber and 6 g/day alcohol. Serum cholesterol decreased significantly (8.6 percent) after wheat germ intervention and returned to baseline during the 1 month followup period. Dietary soluble fiber and total saturated fat before and during the treatment period were not reported. The authors speculate that the high vegetable protein content of wheat germ could account for the observed results.

Karlander et al. (Ref. 85) evaluated the hypocholesterolemic properties of beet fiber in 13 hypercholesterolemic noninsulin-dependent diabetics mellitus (NIDDM) men and women (mean serum cholesterol of 275 mg/dL). Five subjects were on chronic beta blockers and diuretics and eight were on diet treatment with sulfonylurea (SU). This was a controlled, randomized intervention trial with cross-over design. The study was divided into three 6-week periods with a run-in period followed by either fiber intervention (20 g/day beet fiber) or the subject's regular diet for 6 weeks, then cross-over to the other diet. Obese subjects were given dietary advice to aid in weight control. Results showed no significant difference in total serum cholesterol between control and fiber periods for subjects advised to reduce energy intake. The SU group showed significantly decreased (10 percent) serum cholesterol during the fiber phase (total cholesterol decreased from 275 to 247 mg/dL). The SU group had a slight but significant loss of body mass during the run-in period only. There was no effect on serum triglycerides.

Spiller et al. (Ref. 87) evaluated the cholesterol-lowering properties of guar gum compared to oat bran in a 3-week, intervention trial with cross-over. Thirteen men and women, mean age 62 years, with mild to moderate hypercholesterolemia (serum cholesterol 204 to 276 mg/dL), were randomized to receive either 15 g (11 g dietary fiber, of which there was 10 g soluble fiber) of guar gum per day or 77 g/day (11 g dietary fiber, 5 g soluble fiber) oat fiber source, divided into three servings. The fibers were provided in weighed packets with instructions to mix the fiber with water or juice and consume before each main meal. After 21 days, subjects switched to the other fiber source. There was no wash-out between test periods. Blood samples were collected on days 14 and 21 during treatment periods. Results showed a significant reduction in serum cholesterol, compared to baseline, for both groups. Guar reduced serum cholesterol 11 percent and oat fiber 6 percent. Maximum cholesterol reduction was experienced after 14 days on the test fiber. No significant change occurred in serum cholesterol between days 14 and 21 on either test fiber, with serum cholesterol values increasing slightly but not significantly. Factors confounding these results include small sample size, the absence of a wash-out between test periods, and short treatment periods. Dietary intakes of soluble fiber were not reported.

Kawatra et al. (Ref. 88) reported significant reductions in total serum cholesterol and low density lipoprotein (LDL)-cholesterol in 20 overweight Indonesian men and women with mild to moderate hypercholesterolemia consuming guar gum. Subjects consumed 15 g/day guar gum with their normal diet for 6 weeks. The guar was consumed 15 minutes before the main meal in the form of biscuits (10 g guar) and mixed (5 g guar gum) with a flavored drink. Total serum cholesterol decreased 16.7 percent and LDL-cholesterol decreased 26.5 percent. Intake of total dietary fiber, dietary soluble fiber, and saturated fat were not reported.

Tinker et al. (Ref. 89) evaluated the cholesterol-lowering properties of prunes in a randomized, cross-over trial. Forty-one men, ages 29 to 79, with mild to moderate hypercholesterolemia (serum cholesterol 201 to 290 mg/dL) consumed either grape juice (360 milliliter (mL)/day) or 12 prunes (100 g/day) for 4 weeks followed by cross-over to other diet for an additional 4 weeks. Prunes provided 6 to 7 g of total dietary fiber and 3.6 to 4.2 g of soluble fiber as pectin. Base diets included 18 g of total dietary fiber during the grape juice period and 24 g of fiber during the prune period. Four to five percent of the energy was from alcohol. There was no significant difference between serum cholesterol on the prune diet and on the grape juice diet.

A final report by Earll et al., July 1986 (Ref. 90), was submitted with one of the comments. This was an intervention study with seven free living hyperlipidemic (serum cholesterol ranged from 261 to 346 mg/dL) male and female patients. Subjects were asked to consume 24 g/day of corn fiber (containing less than 2 g soluble fiber) for 6 weeks, then 48 g/day corn fiber for an additional 6 weeks with their regular diet. The test period was followed by an 8-week wash-out period. Actual consumption of corn fiber was slightly less according to records kept by the subjects. Total cholesterol was reduced, on average from 298 to 253 mg/dL (significant), although much smaller changes were seen in two subjects, and one subject had an increase in serum cholesterol during the study period. In all but one of the subjects, serum cholesterol remained above 200 mg/dL with fiber intervention, suggesting dietary therapy was not adequate. The dietary intakes of the subjects before and during the test period were not recorded.

Whyte et al. (Ref. 104) reported significant reductions in serum cholesterol in 23 men with mild hypercholesterolemia (total cholesterol ranged from 209 to 259 mg/dL) consuming oat bran. Subjects consumed 123 g/day oat bran or 54 g/day wheat bran cereal with their regular diets for 4 weeks followed by cross-over to the other fiber cereal. All subjects consumed wheat cereal during a 3-week baseline period prior to randomization to test groups. Total dietary fiber and fat intake were approximately the same between groups. Total serum cholesterol and LDL-cholesterol, when consuming oat bran, decreased 4 percent and 5.5 percent, respectively, compared to wheat bran. The authors note that one of their earlier studies with 12 g of oat bran showed significant decreases in serum cholesterol of 6 percent compared to 12 g of wheat bran. According to their analyses, both oat brans were similar in composition (Ref. 104). The smaller decrease in serum cholesterol reported in this study as compared to some other oat bran studies, not conducted by these authors, may be due to the difference in β-glucan

content of different strains of oats. This 4-week study does not address long-term effectiveness of oat bran intervention.

Uusitupa et al. (Ref. 100), in a randomly-allocated, double-blind parallel group trial, tested the effects of guar gum on 39 individuals with NIDDM (mean serum cholesterol of groups: 253 and 237 mg/dL). The test group received 5 g of guar gum three times per day (estimated total of 10 g soluble fiber) before meals for 3 months, while the control group received 5 g of wheat flour 3 times per day before meals. After 3 months, the control group was switched to guar and both groups were followed for an additional 10 months. At the end of 3 months, the guar group showed a significant lowering of serum total cholesterol. Over the remaining 10 months, the group which began as the test group had an increase in total cholesterol, although it remained significantly lower than prior to the trial. The group which began as the control group, but switched to guar, demonstrated the lowest serum cholesterol during month 5 (208 mg/dL). This was followed by increasing serum cholesterol to a maximum at month 11 (242 mg/dL). After 12 months, serum cholesterol for this group was 233 mg/dL. Significant weight loss occurred in both the control and treatment groups to a similar degree. The dietary intakes for both groups were not reported.

Spencer and Gee (Ref. 109) evaluated the cholesterol-lowering properties of apple juice supplemented with 10 g of dietary fiber (70 percent soluble fiber, predominantly from gum arabic) versus plain apple juice. Thirty-one mildly hypercholesterolemic men (serum cholesterol between 200 and 270 mg/dL) consumed their regular diets in this 6-week cross-over, blinded trial. With both ordered groups totalled, there was a significant decrease in serum total cholesterol and LDL-cholesterol during the period of consumption of fiber-enriched juice. When order of presentation is considered, there were inconsistencies in the changes. The group which began the trial with the placebo did not show any change from baseline in serum cholesterol during the placebo phase, whereas the group which received the placebo during the second half of the trial maintained the lower cholesterol level which occurred during the fiber supplementation period. Cholesterol intake was significantly higher in the juice-only group.

Niemi et al. (Ref. 99), in a double-blind, cross-over trial, reported significant lowering of serum cholesterol in a group that received 15 g/day guar gum (estimated total of 10 g soluble fiber) as a supplement for 12 weeks when compared to the group which received cellulose, the placebo. The 16 women and 6 men chosen as subjects were all (NIDDM) between the ages of 40 and 76. Nineteen of these subjects were on medication for their diabetes. Although the patients were advised to maintain their normal diets, no dietary measurements were reported to verify this.

Kirsten et al. (Ref. 97) evaluated the hypocholesterolemic properties of guar gum in 13 men and women with type IIa and IIb hyperlipidemia (serum cholesterol concentration >251 mg/dL). The study was divided into three phases: the 30-day pretreatment phase (baseline), the 60-day treatment, and the 60-day post-treatment period. During the treatment phase, subjects consumed 4 g of guar gum, mixed with water or juice before breakfast, lunch, and dinner (12 g guar/day, estimated—8 g soluble fiber). Subjects were only instructed to avoid cholesterol-rich foods during the study period. Both total serum cholesterol and LDL-cholesterol decreased significantly compared to pretreatment levels. During the post-treatment period, serum cholesterol returned to baseline and LDL-cholesterol increased above baseline. The dietary intakes of the subjects during each phase of the study were not reported.

Cerda et al. (Ref. 105) evaluated the hypocholesterolemic effects of grapefruit pectin in a double-blind, placebo-controlled, cross-over study. Twenty-seven hypercholesterolemic men and women (mean serum cholesterol of 275 mg/dL) consumed 15 g of grapefruit pectin (27 tablets, 9 per meal) or 15 g of flour (also in tablet form) per day for 4 weeks followed by a 4-week wash-out before cross-over. During the pectin period total cholesterol decreased by almost 8 percent and LDL-cholesterol by 11 percent (both significantly lower compared to baseline). There was no change in serum cholesterol during the placebo period. The dietary intake of the subjects during each period of the study was not reported. The short test periods do not address long-term usefulness of pectin.

Haskell et al. (Ref. 106) evaluated the hypocholesterolemic properties of four isolated, purified soluble fibers in four separate trials. All subjects had serum cholesterol levels between 200 and 280 mg/dL and were randomized to 1 of the four studies. Study one was a 12-week intervention trial using a powdered soluble fiber mixture providing 17.2 g/day of soluble fiber. The powder consisted of acacia gum (9.7 g), psyllium (4.9 g), and guar gum (2.6 g). The soluble fiber mixture was tested against a fructose placebo (15 g/day). Results showed no statistically significant changes from baseline to 6 or 12 weeks within or between groups. Study two was a 4-week intervention testing 15 g/day of acacia gum powder against 15 g/day fructose powder. There was no significant change from baseline or compared to the placebo. Study three was an 8-week cross-over trial using 10 g/day of guar (estimated 6.7 g soluble fiber) as a control and a 15 g/day fiber mixture of pectin (3.9 g), psyllium (6.3 g), guar (3.3 g), and locust bean gum (1.5 g). Each test period was 4 weeks. Results showed both the guar and the fiber mixture reduced serum cholesterol (approximately 10 percent and 8 percent, respectively), LDL-cholesterol (approximately 14 percent and 12 percent, respectively), and high density lipoprotein (HDL)-cholesterol (about 6 percent) significantly. Study four was a 4-week dose-response study with increasing amounts of soluble fiber from a mixture of pectin, psyllium, guar, and locust bean gum. Three groups received either 5 g, 10 g, or 15 g/day of the mixture. Results showed that the serum cholesterol and LDL-cholesterol of the group consuming 15 g/day was significantly lower than the placebo.

A 1984 study by Anderson et al. (Ref. 110) was submitted with comments in support of a long-term hypocholesterolemic effect of soluble fiber from oat bran and beans. Ten men, ages 46 to 66, with serum cholesterol above 260 mg/dL were randomly assigned to oat bran or bean-supplemented diets for 21 days following a 7-day baseline period on a metabolic ward. The base diet was a "typical" American diet with 38 percent of calories as fat and 450 mg cholesterol. To this diet, the subjects added either 100 g of oat bran or 100 g of dried beans per day. Both of these diets provided 18 g of total soluble fiber and 48 to 50 g of total plant fiber per day. Before discharge, the subjects were instructed on the use of a high fiber (50 g of total fiber per day) maintenance diet with oat or bean product supplements at home. The high fiber diet was also low in fat (30 percent of calories as fat), low in saturated fat (10 percent of calories), and low in cholesterol (150 mg/day). Ten men were followed on their home diets for 24 weeks and 4 for 99 weeks. Results of the metabolic ward phase of the study showed that the oat bran and bean diets lowered serum cholesterol significantly (23 percent) over the 3-week period compared to baseline. At 24 weeks (the followup phase), serum

cholesterol levels were significantly (26 percent) lower than baseline. Cholesterol levels in the four men followed for 99 weeks were 23 percent lower than baseline (significant at $p<0.0025$). Reductions in LDL-cholesterol were also significant during both phases of the study. HDL-cholesterol decreased significantly (20 percent) during the metabolic ward phase but increased during the long-term followup. All 10 subjects lost approximately 4 pounds (lb) (significant at $p<0.0025$) during the metabolic ward phase of the study. The investigators reported that changes in body weight were not significantly correlated with the changes in serum cholesterol. An additional 4 lb of weight was lost during the 24-week phase of followup.

An unpublished study (Ref. 119) evaluated the cholesterol lowering properties of oat gum in hypercholesterolemics (mean serum cholesterol of 255 mg/dL). Instant oat gum (3.6 g) or a placebo (maltodextrin) were mixed with a noncarbonated diet fruit drink (250 mL) and consumed twice a day at each main meal for 4 weeks. There was a 3-week wash-out between treatment periods and after the last oat gum period. Subjects were randomly assigned to start the treatment period with either the oat gum beverage or the placebo. Results showed significantly lower serum cholesterol after 4 weeks on oat gum compared to both the baseline ($p = 0.02$) and the placebo ($p = 0.001$). Although subjects were asked to maintain their weight, subjects' weights were not reported.

Bridges et al. (Ref. 120) evaluated the effect of oat bran on serum cholesterol and serum acetate in hypercholesterolemic men admitted to a metabolic ward. Animal studies have shown that both acetate and propionate inhibit cholesterol synthesis (Ref. 120). The 20 subjects were divided into two groups: Wheat bran group (mean serum cholesterol of 252 mg/dL) and oat bran group (mean serum cholesterol of 305 mg/dL). Following 1 week on a typical American diet, the diets were supplemented for 21 days with either 110 g of oat bran per day or 40 g of wheat bran. Results showed that the oat bran group experienced significantly lower ($p = 0.05$) serum cholesterol than the wheat bran group. However, in the wheat bran group, the baseline cholesterol level had been higher than in the oat bran group. There was a significant ($p = 0.001$) weight loss in both groups. The weight loss appeared to be greater in the oat bran group. LDL-cholesterol was significantly lower ($p = 0.005$) in the oat bran group as compared to the group's pretreatment values. There was no significant difference in LDL-cholesterol between groups. Serum acetate values were significantly higher in the oat bran group than in the pretreatment diets. Wheat bran did not change serum acetate significantly compared to the pretreatment diets.

Kashtan et al. (Ref. 121) evaluated the effects of wheat bran and oat bran supplements on blood lipids and lipoproteins in 84 subjects with mild hypercholesterolemia. This was a controlled, parallel, double-blind study in which subjects consumed either oat bran supplements (with 11 to 17 g dietary fiber and an estimated 5 to 8 g of soluble fiber) or a wheat bran cream of wheat mixture (11 to 17 g of dietary fiber) each day for 14 days. Defined diets were delivered to the subjects' homes. The diets provided one of four energy amounts: 1,600, 2,000, 2,400, and 2,800 calories, with 37 percent of energy as fat, 47 percent carbohydrate, and 16 percent protein. Results showed mean serum cholesterol decreased significantly (-10.8 percent, $p = 0.001$) in the oat group compared to the wheat group (-4.7 percent). However, the baseline cholesterol was higher among the oat bran group. The wheat bran group also experienced significantly decreased serum cholesterol compared to their baseline ($p < 0.001$). LDL-cholesterol decreased significantly compared to baseline for both groups ($p = 0.03$ for the wheat bran group and $p < 0.001$ for the oat group). The short test period of 2 weeks in this study makes interpretation of the results difficult.

Ranhotra and coworkers (Ref. 122) studied lipidemic responses in 17 hypercholesterolemic men consuming foods high in soluble fiber. This was a 6-week intervention study with a 6-week control period prior to the test period. Subjects consumed their usual diet during the control period and kept daily records of intake for 4 weeks. Subjects were then given a list of foods that were identified as good sources of soluble fiber and a diet supplement containing 30 g each of rice bran and oat bran, and were instructed to incorporate foods on the list into their usual diet. Each subject served as his own control. Results showed that only 6 (34 percent) of the 17 subjects were responders to the soluble fiber intervention. The authors reported that not all subjects consumed the supplement daily and that intakes of soluble fiber varied greatly among the participants. Serum cholesterol values decreased from 1 percent to 17 percent compared to individual control levels in those responding to soluble fiber. However, the authors did not perform a statistical analysis of the results, and the results in this study are too inconsistent in direction and magnitude to support an effect of soluble fiber on serum cholesterol.

Zhang et al. (Ref. 123) studied the mechanism of cholesterol lowering in nine subjects with ileostomies. This was a randomized, controlled, cross-over study design. Subjects were instructed to consume their own food, which was modified to be low fiber, and were assigned to either a low fiber diet (supplemented with wheat-flour bread) or a high fiber diet (supplemented with oatbran bread) for 3 weeks followed by cross-over to the other fiber bread for another 3 weeks. Ileostomy effluents were collected on sampling days in both dietary periods. Subjects were also divided into two subgroups according to the amount of bile acids excreted in the ileostomy effluents. Results showed subjects with low bile acid excretion had significantly increased daily excretion of total bile acids on the high fiber diet as compared to the low fiber diet. There were no significant differences in daily excretion of total bile acids between the high fiber period and the low fiber period in subjects with high daily bile acid excretion. There was no baseline serum cholesterol measurement. Compared to the low fiber period, serum cholesterol and LDL-cholesterol decreased significantly ($p = 0.01$ and $p = 0.05$, respectively) in all nine subjects on the high fiber diet. Subgroup analysis showed that subjects with low daily bile acid excretions had significantly reduced serum cholesterol on the high fiber diet than on the low fiber diet. Subjects with a high daily excretion of bile acids showed no significant difference in serum cholesterol between the test periods. Conclusions about fiber mechanisms in lowering serum lipids in subjects with ileostomies may not apply to the general population.

2. Hypercholesterolemics: Step 1 or 2 diets

A study by Israelsson et al. (Ref. 86) was submitted with a comment. This placebo-controlled, double-blind, cross-over intervention study used 30 g/day beet fiber or bread. Twenty-seven hypercholesterolemic (serum cholesterol 263 to 297 mg/dL) women, 55 to 56 years old, were chosen from a CVD screening program. Subjects consumed a moderate cholesterol, low fat diet with increased polyunsaturated fatty acids/saturated fatty acids (PUFA/SFA) for a 1-month run-in period and were then randomized to the fiber group or placebo for 1 month followed by cross-over to the other diet. The beet fiber provided 6 g soluble fiber, 16.5 g

insoluble fiber, and 22.5 g total dietary fiber. Subjects decreased alcohol intake after the run-in period. No data on saturated fat or soluble fiber intakes were provided. Results showed a significant reduction in serum cholesterol in the fiber group compared to the placebo after 2 weeks, but not after 4 weeks. LDL-cholesterol showed a modest but significant reduction after 4 weeks of fiber intervention. HDL remained constant or increased significantly after 1-month intervention. The ratio of LDL:HDL was significantly reduced at the end of the test period. The short test period of this study does not address long-term effectiveness of beet fiber.

Bremer et al. (Ref. 91) evaluated the cholesterol lowering effects of oat bran and wheat bran in a randomized, single-blind, cross-over, placebo-controlled intervention trial. The fibers were incorporated into breads. Twelve hyperlipidemic men and women (total serum cholesterol 220 to 348 mg/dL) were stabilized on a American Heart Association (AHA) phase II diet (total fat 25 to 30 percent of energy, saturated fat <8 percent of energy, polyunsaturated fat 5 to 10 percent of energy, cholesterol <250 mg/day) for 3 months prior to intervention. There was a 2-week run-in prior to test during which subjects added additional bread to their diets. Subjects were randomized to one of the two fiber groups for 4 weeks, followed by 2-week wash-out, then cross-over to other fiber group. The bread (10 to 12 slices/day) was added to the diet in place of other carbohydrate foods. Subjects had a mean intake of 44.6 g/day of oat bran (range of 34.2 to 68.4 g/day). Total dietary fiber intake during the oat period was 32.2 g, and 34.1 g during the wheat period. Results showed no significant differences in total serum cholesterol or LDL-cholesterol between the oat and wheat periods. Authors account for the lack of observed response on serum cholesterol from oat bran as due to the lower soluble fiber content of New Zealand oat bran compared to oat bran used in other studies.

Anderson et al. (Ref. 92) evaluated the hypocholesterolemic effects of two bulk laxatives, relative to psyllium and a placebo (cellulose), in mild to moderately high hypercholesterolemic (total serum cholesterol 200 to 300 mg/dL) men and women. The laxatives were evaluated at the manufacturer's recommended dosages. Of the 163 subjects screened, 105 completed the 16-week study. Subjects were instructed in and consumed the AHA Step 1 diet (total fat 30 to 33 percent of energy, saturated fat 10 percent of energy, carbohydrate 46 percent of energy, cholesterol <300 mg/day) for 8 weeks followed by an 8-week parallel treatment with diets supplemented with one of three fiber supplements or placebo. Fiber sources used were the following bulk laxatives: psyllium (10.2 g/day), methylcellulose (6 or 10.2 g/day), calcium polycarbophil (4 g/day), and cellulose placebo (4 g/day). The authors note that psyllium and methylcellulose were most effective in lowering serum cholesterol. There was no significant difference between psyllium and methylcellulose in lowering serum cholesterol. Soluble fiber was not controlled in this study. Subjects on psyllium had the highest soluble fiber intake. Side effects were reported for each laxative.

An unpublished manuscript entitled "High soluble fiber foods reduce serum lipids even when diets are already low in saturated fat and cholesterol" (Ref. 93) was received as part of a comment. This 4-week, cross-over, metabolic study in 12 hyperlipidemic (mean total cholesterol of 272 mg/dL) subjects compared a psyllium cereal/low fat diet (9.35 g psyllium/day = ≤3 oz of psyllium cereal) with a similar diet substituting wheat bran for the psyllium cereal. The low fat diets were the same in both phases of the study, low in saturated fat (<4 percent of energy) and cholesterol (<50 mg/day) and high in carbohydrate (>60 percent of energy). The psyllium cereal was significantly more effective in lowering total and LDL-cholesterol than the wheat bran cereal. Mean total cholesterol reduction was from 272 mg/dL to 249 mg/dL, and from 192 mg/dL 172 mg/dL for LDL cholesterol. Preliminary subgroup analysis by the authors of the study suggested that patients with both elevated cholesterol and triglycerides (Type IIb) showed no reduction in LDL cholesterol, while patients with only Type IIa (isolated elevation of cholesterol) benefited. Additional concerns are raised by this study regarding the usefulness of psyllium in Type IIb patients.

An unpublished manuscript entitled "High fiber foods reduce serum lipids even on diets low in saturated fat and cholesterol" (Ref. 94) was received as a comment. This was a cross-over study with 11 hyperlipidemic volunteers. Each 16-week test period was separated by a 2-month wash-out period during which subjects consumed only the Step 2 diet (total fat <20 of energy, saturated fat <7 percent of energy, cholesterol <100 mg/day, and carbohydrate >60 percent of energy). During one metabolic phase, subjects were fed foods considered good sources of soluble fiber (e.g., legumes and psyllium-containing cereals) as part of the Step 2 diet. During the second phase, wheat bran-containing foods were fed. Results showed that both the soluble- and insoluble-fiber groups lost weight during the 4-month test period. The insoluble-fiber group lost significantly more than the soluble-fiber group. Although, blood lipids fell on both diets, total cholesterol, LDL- and HDL-cholesterol values were significantly lower (6.3 percent, 8.6 percent, and 5.7 percent, respectively) in the soluble-fiber group than in the insoluble-fiber group. The soluble fiber diet emphasized foods shown in other studies to reduce serum cholesterol, i.e., dried beans, peas, other legumes, oat bran, and a psyllium-containing cereal. The actual difference in soluble fiber content between the soluble and insoluble fiber diets was only about 3.2 g/day, on average. The authors felt that the specific foods they fed contribute to lowering of serum cholesterol, but expressed concern that not all soluble fibers show this effect, and that no mechanism of action is apparent. They, therefore, expressed "concern over lipid lowering claims for direct dietary fibers."

An intervention study by Anderson et al. (Ref. 95) with 44 hyperlipidemic (serum cholesterol 200 to 300 mg/dL) men and women was conducted using a randomized, double-blind, and parallel design. Subjects consumed a Step 1 diet and 3.7 ounce (oz)/day (on average) of either a wheat bran cereal or a psyllium cereal for 6 weeks. The psyllium cereal provided 10.7 g/day of psyllium. The psyllium group had a lower total cholesterol by about 8 percent and LDL cholesterol by nearly 13 percent by the end of the study. Mean total cholesterol, however, was still higher than 200 mg/dL despite these reductions. Both groups had comparable weight loss of about 1 (lb) pound. Because this study had a short test period, it did not address the long-term usefulness of psyllium in reducing serum cholesterol. In a parallel design, nonblinded clinical trial with 59 men and women with total cholesterol between 215 and 396 mg/dL, Neal and Balm (Ref. 98) placed all subjects on Step 1 diets for 7 weeks. The control group continued on the Step 1 diet, and the test group received 20.4 g of psyllium per day in the form of Metamucil immediately after breakfast and the evening meal for 13 weeks. After the treatment period, the psyllium group had a decrease in total cholesterol of 7.1 percent, while the control group had a 1.6 percent decrease. The difference between the test and control

groups was 5.5 percent, a significant decrease. Although there was a 5.1 percent decrease in LDL in the psyllium group compared to the control, this decrease was not significant. The authors failed to report the amounts of total fat, saturated fat, and total soluble dietary fiber consumed during each period.

Two short-term studies by Wolever et al. (Refs. 101 and 102) evaluated the effectiveness of psyllium in lowering serum cholesterol (Ref. 101) and its effectiveness when psyllium was taken with meals or between meals (Ref. 102). These studies were done with men and women, some of whom were on lipid-lowering drugs, who were instructed on a Step 2 diet. The test periods were for 2 weeks. In both studies, serum cholesterol was lowered significantly at the end of the 2 weeks.

O'Connor et al. (Ref. 103) conducted a well-controlled multicenter, double-blind randomized, parallel group, placebo-controlled trial with men and women between the ages of 18 and 70 years with a diagnosis of mild to moderate primary hypercholesterolemia (see Table 1). A five fiber supplement, containing guar and pectin and providing 7.5 g of soluble fiber and 2.5 g of insoluble fiber, was administered either once or twice a day for 15 weeks with a Step 1 diet. The placebo group received 5.2 g of insoluble fiber with no soluble fiber before breakfast and dinner. All nutrients were kept constant except for fiber. Serum cholesterol and LDL-cholesterol were significantly reduced compared to placebo in all studies (see Table 1, studies B301 and B302 in). An extension of this study evaluated the long-term usefulness of the five fiber supplement for an additional 36 weeks (total of 51 weeks). Significantly reduced levels of total and LDL-cholesterol were maintained (5.3 percent and 8.4 percent, respectively) compared to baseline. This study shows both the ability of a particular soluble fiber product for reducing blood lipids and the long-term benefits of soluble fiber supplementation with a low fat diet.

An unpublished study (Ref. 108) evaluated the hypocholesterolemic effect of psyllium in 23 hypercholesterolemic men (mean total cholesterol greater than 240 mg/dL). Using a double-blind, double cross-over design, the subjects were randomly assigned to either the psyllium-wheat bran-psyllium group or to the wheat bran-psyllium-wheat bran group for 8, 5, and 5 weeks, respectively. Subjects consumed a total of 10 g of soluble fiber/day from psyllium and 2 g of soluble fiber per day from wheat bran. All subjects consumed a Step 1 low fat diet as the base diet. Results showed significant cholesterol and LDL-cholesterol lowering (4.3 percent) with psyllium compared to the wheat phase of the test. Initial cholesterol values for each group were not given.

A 1987 study by Turnbull and Leeds (Ref. 111) was submitted with comments from the food industry as further evidence for a hypocholesterolemic effect of soluble fiber from oat bran. In this study, 17 free living men and women aged 23 to 73 years (serum cholesterol levels above 232 mg/dL) were given varying degrees of instruction on a low fat diet (<35 percent calories from fat). All subjects followed this diet for a 1-month run-in period. Eight subjects were followed intensively during the run-in period and fiber periods through blood sampling and diet histories. Subjects were then randomly assigned to receive either 150 g/day oats (from cereal and muffins) or 100 g/day wheat flour biscuits for 1 month followed by cross-over to the other fiber diet for an additional month. The oat products provided 5.4 g of soluble fiber per day. The wheat products provided 3.1 g/day. Results during the run-in period showed a significant loss of weight and reduction in serum cholesterol in the group of eight subjects studied intensively during the first month. At the start of the first test period (whether oat or wheat) all subjects had a mean fat intake of 34 percent of calories. During the oat period, the subjects' energy intakes increased and fat intake increased to 35 percent. Mean body weight, however, remained constant. Combining all results from the oat-wheat and wheat-oat periods, serum- and LDL-cholesterol fell significantly ($p = 0.02$ and $p = 0.003$, respectively). During the wheat period, the subjects' caloric intake increased with a mean body weight increase of 0.3 kilogram (kg). Total fat consumption during the wheat period was 36 percent of calories. Mean serum cholesterol of the combined period showed a nonsignificant increase (1.6 percent) in serum cholesterol during the wheat period. LDL-cholesterol showed a nonsignificant increase. In the eight subjects followed intensively throughout the study, the results showed that most of them had further reductions in total and LDL-cholesterol on the oat diet beyond the low fat diet alone. In a later study (Ref. 126) of the same design and using the same levels of oats and wheat flour, the authors reported favorable changes in apolipoprotein A1 and no change in apolipoprotein B in subjects on the oat diet.

The purpose of the study by Fukagawa et al. (Ref. 114) was to evaluate the effects of a very high carbohydrate high fiber (HCF) diet on peripheral-tissue insulin responsiveness in a group of healthy young men (ages 18 to 24 years, Group A) and in a group of older men and women (ages 67 to 86 years, Group B). The young men had normal serum cholesterol (199 mg/dL) and the older adults were hypercholesterolemic (237 mg/dL). The subjects were studied while consuming their usual ad libitum diet and after consuming a HCF diet for 21 to 28 days. The older group was admitted to the metabolic ward for the duration of the study. The younger subjects only ate their meals on the metabolic ward. The study was not blinded or placebo controlled. Test diets provided the following: Group A— 23.6 g/day soluble fiber, 88.2 g of plant fiber/day, 134 mg dietary cholesterol, 14 percent energy as fat, 3 percent energy as saturated fat, 69 percent of energy as carbohydrates; Group B— 17 g of soluble fiber, 67.7 g of plant fiber/day, 90 g of dietary cholesterol, 15 percent energy as fat, 3 percent energy as saturated fat, and 70 percent energy as carbohydrates. Results showed a significant reduction in serum cholesterol in both groups after 4 weeks (Group A: 26 percent; Group B: 45 percent). The results of this study are inconclusive for an effect of fiber on serum cholesterol (which was not the objective of the study) because the subjects' ad libitum diets were significantly higher than the test diet in fat (37 to 42 percent of calories compared to approximately 14 percent on the test diet), saturated fat (15 to 17 percent of calories versus 3 percent of calories), and lower in carbohydrates (40 to 45 percent of calories versus 68 to 70 percent of calories). In addition, there was no control group.

Anderson et al. (Ref. 118) evaluated the cholesterol-lowering benefits of psyllium-enriched cereal in subjects with mild to moderate hypercholesterolemia (serum cholesterol range of 200 to 300 mg/dL). Subjects consumed their usual diets for 1 week before being randomly assigned to receive psyllium-flake or wheat bran flake cereal for 6 weeks. Subjects were also instructed on a Step 1 diet and asked to adhere to it for 6 weeks. Soluble fiber intake during the treatment period was 5.9 g per day for the wheat bran group and 15.1 g/day for the psyllium group. Results showed significantly reduced serum- and LDL-cholesterol in the psyllium group compared to the wheat group. Serum

cholesterol was reduced 8.36 percent ($p = 0.01$) and LDL-cholesterol 12.9 percent ($p = 0.01$) in the psyllium group. There was no significant change in serum- or LDL-cholesterol in the wheat group.

3. Normocholesterolemics: "typical" or "usual" diets

Resnicow et al., 1991 (Ref. 96), measured total serum lipids in a population of 31 Seventh Day Adventists, ages 5 to 46 years, who had consumed a pure vegetarian diet for at least 6 months prior to taking of blood samples. Diets of vegans were compared to those of omnivore controls. Blood samples were not taken from the controls and blood values for these subjects were derived from the Lipid Research Clinics Population Studies Data Book. Results showed that the adult vegans consumed significantly less energy and energy from fat (31 percent versus 38 percent of calories), total fat, saturated fat, monounsaturated fat, cholesterol, and protein. They also consumed significantly more fiber (45 g/day versus 20 g/day) than the omnivores. Total dietary soluble and insoluble fibers were not assessed. Foods consumed in greater frequency by vegans included almonds, cashews, and their nut butters, dried fruits, citrus fruits, soy milk, and greens. Total serum cholesterol for vegans was approximately 23 percent lower (139 mg/dL versus 182 mg/dL) than expected values for omnivores.

One study submitted with comments evaluated the effect of glucomannan, a pectin-like gel fiber derived from purified tubers of *Amorphophallus koniac* K. Koch, on serum cholesterol and weight reduction in obese patients consuming their normal diets (Ref. 117). Weight loss and serum cholesterol decreased significantly in the test group compared with the placebo group at the end of the 8-week trial. After 4 weeks on the test product, subjects had a mean weight loss of 4.9 lb and mean serum cholesterol reduction of 20.9 mg/dL. After another 4 weeks, weight loss was only 0.6 lb and serum cholesterol was reduced only 0.8 mg/dL. Because weight loss and serum cholesterol are closely correlated, the effect of glucomannan on serum cholesterol cannot be determined from this study.

An unpublished study studied the mechanism of serum cholesterol reduction by oat bran (Ref. 124). This was a 2-month metabolically-controlled intervention trial with nine normocholesterolemic men. A single isotope was used to determine bile acid kinetics during the oat bran period. During the first month, subjects consumed a constant diet provided in a metabolic unit. The fat content of the diet was 35 percent of the energy. The total soluble fiber content of the low fiber diet ranged from 3.0 to 4.9 g/day and for the high fiber period 9 to 12 g/day. During the second month, this same diet was supplemented with 100 g of oat bran per day. Results showed significantly lowered serum cholesterol during both periods. Serum cholesterol was 14 percent lower compared to the prestudy period during the low fiber period and 22 percent lower during the high fiber period. Serum cholesterol during the high fiber period was also significantly lower than that of the low fiber period (an additional decrease of 9 percent). Bile acid excretion approximately doubled during the high fiber period.

4. Normocholesterolemics: low fat diets

Nervi et al. (Ref. 107) reported than an intake of 120 g/day of legumes for 30 to 35 days significantly lowered serum cholesterol (from 162 to 143 mg/dL) in 20 Chilean young men compared to responses of men on a control diet. The men consumed beans, peas, or lentils each day as part of a diet that provided 33 percent of calories from fat and 12.5 g of total fiber. The study was designed to evaluate the hypothesis that legumes may be a risk factor for cholesterol gallstones in certain subpopulations. The authors reported significantly increased biliary cholesterol saturation and modification of bile acid composition during the legume diet period.

5. Other studies

Evidence for the cholesterol-lowering effect of soluble fiber from oats was evaluated using meta-analysis (Ref. 125). In this study, after pooling the raw data from 5 investigators who had looked at the effect of consumption of oat products on blood total cholesterol, a modest reduction (average decrease of 5 to 6 mg/dL) on blood total cholesterol levels was found. The decrease in blood total cholesterol was largest in those trials with initially higher blood total cholesterol levels, particularly where an intervention dose of 3 g or more of soluble fiber from oats was used. To assess whether other dietary factors, i.e., dilution of saturated fat and calorie intakes by the oatmeal or oat bran addition to diets, might have been responsible for the drop in blood total cholesterol levels, the authors used the experimentally derived, predictive equation of Keys to see if dietary changes in fat components of the test diets could account for the observed decreases in serum cholesterol. The fat and saturated fat changes did not appear to be responsible for the drop in serum cholesterol levels, thus suggesting that some other factor in the test diets (e.g., the soluble fiber fraction) was responsible for the observed effects. The authors concluded, therefore, that incorporation of oats (a rich source of soluble fiber, primarily as β-glucan) into diets causes a modest decrease in average blood cholesterol. The authors also suggested that there was a dose-response relationship between the amount of soluble fiber from oats and the reduction in blood cholesterol levels, with intakes of soluble fiber from oats above 3 g/day showing more effect than lower intakes. Additionally, the authors noted that other components in oats may play a role in the observed cholesterol reduction and suggested the need for long-term clinical trials (6 months or more) with multiple doses to verify their conclusions from the meta-analysis.

6. Summary of human studies

The human studies reviewed above suffered from many of the same design flaws noted in the proposed rule on health claims for dietary fiber and cardiovascular disease (56 FR 60582 at 60591). Some studies were conducted with very small sample sizes (Refs. 84, 85, 87, 90, 91, 93, 94, 97, 110, 111, 114, 122, 123, 124, and 126). Another limitation was short study times (Refs. 87, 101, 102, 110, 114, 120, 121, and 123). Inadequate control of confounding factors, such as concomitant weight losses and changes in other dietary components which may have affected results, plagued some studies (Refs. 86, 96, 107, 108, 110, 117, 119, and 120). The absence of adequate dietary intake data to assure that dietary changes other than differences in soluble fiber intakes had not occurred was a problem for a number of studies (Refs. 84, 86, 87, 88, 90, 91, 95, 97, 99, 105, 106, 119, and 123).

Several studies were suggestive of positive effects of soluble fiber intakes on blood cholesterol levels. One study provided evidence of a relationship between consumption of foods high in soluble fiber and reduced levels of blood total- and LDL-cholesterol levels (Ref. 118). In a comparison of a breakfast cereal fortified with psyllium, a rich source of soluble fiber (12 g of psyllium/day from 114 g/day of a psyllium-containing cereal) to a wheat bran cereal which contributed negligible amounts of soluble fiber, the psyllium-containing cereal was associated with lower blood total- and LDL-cholesterol levels after 6 weeks than were observed in subjects following a diet containing wheat bran

cereal. In another study (Ref. 104), consumption of 123 g of oat bran cereal (contributing 10.3 g soluble fiber daily) versus consumption of 54 g of wheat bran cereal per day (contributing 3.4 g of soluble fiber daily) was associated with lower blood total- and LDL-cholesterol levels after 4 weeks. Dietary intakes of fat and saturated fat were estimated to be similar across treatments. On the other hand, some studies found no relationship between intakes of high soluble fiber diets and blood total- or LDL-cholesterol levels (Refs. 83 and 91). Several explanations for the lack of a relationship in these studies were offered by the authors, including the possibility that the oat bran used was low in soluble fiber content (Refs. 83 and 91). The study by Neal and Balm (Ref. 98) showed significantly lower blood total-cholesterol levels with consumption of a psyllium-fortified cereal, but the decline in LDL-cholesterol levels compared to the control was not statistically significant. A small body weight loss in both groups may have confounded the relationships. However, since it is the LDL-cholesterol, rather than the total-cholesterol, that is the desired endpoint for evaluating beneficial changes, the lack of statistical significance for serum LDL-cholesterol levels limits this study's usefulness.

Finally, the meta-analysis on the cholesterol-lowering effect of oat products was useful and suggested a benefit from oat consumption. However, the authors noted that, while grams of soluble fiber were chosen to represent the dose of oat product, it is entirely possible that other components of oats, as well as the way in which the oat product is prepared, may also play a role in reduction of blood LDL-cholesterol levels. The authors recommended that, because there are several components of oats which could provide beneficial effects on blood cholesterol levels, future clinical studies should test multiple doses of oat products with the simultaneous measurement of other possible active components, including soluble fiber, β-glucan, and tocotrienols.

The most definitive results linking soluble fiber intakes to beneficial changes in blood cholesterol levels were for studies in which dietary supplements of guar (Refs. 99 and 100), gum arabic (Ref. 109), psyllium (Ref. 92), or a combination of soluble fiber sources (Ref. 103) were given. Some of these studies (Refs. 99, 100, and 109) also, however, failed to provide adequate information on dietary intakes, thus limiting the ability to rule out possible confounding effects from other dietary changes that may have occurred concomitantly with addition of these supplements. A series of well-conducted clinical trials were done to design and test the effectiveness of fiber mixtures (guar, pectin, psyllium, and locust bean) on blood cholesterol levels (Refs. 103 and 106). Early studies in one series (Ref. 106) showed no benefit from acacia gum alone or a mixture of acacia gum, psyllium and guar (Studies 1 and 2). Only when a mixture of pectin, psyllium, guar and locust bean was given were beneficial effects seen (Study 4). These results strongly suggest that benefits of fiber supplements are not readily predicted by an analytical definition of soluble fiber, but rather vary, in some unknown way, among different sources or combinations of sources, of soluble fiber. Thus, generalizing results from one fiber source to another must be done cautiously.

B. Animal studies submitted with comments

FDA received a number of animal studies submitted as comments. FDA has reviewed these studies as described below.

1. Relationship between specific soluble fibers and plasma cholesterol

Ney et al. (Ref. 127) evaluated the effect of soluble oat fiber on blood very low density lipoprotein (VLDL), low density lipoprotein (LDL), and high density lipoprotein (HDL) levels by feeding male rats cholesterol-raising diets (diets which contained 1 percent cholesterol and 0.2 percent cholic acid as the stimulus for increasing blood cholesterol levels) and 6 percent dietary fiber from cellulose (control) or from three oat products with increasing levels of soluble fiber: Oat bran, high fiber oat flour or a processed oat product. Compared to the cholesterol-fed cellulose control, all oat fibers lowered plasma total cholesterol by 25 to 45 percent, lowered VLDL + LDL cholesterol levels by 40 to 60 percent, and raised HDL-cholesterol by 25 to 40 percent (all significant at $p = 0.01$). This pattern of changes in blood lipid components is associated with decreased risk of heart disease. The processed oat product, which contained 40 percent more soluble fiber than oat bran or oat flour, resulted in a lipoprotein profile similar to that obtained without the cholesterol-raising stimulus of dietary cholesterol and cholic acid. The oat product with the highest soluble fiber content was, therefore, more effective with ingestion of the cholesterol-raising diet than was the oat bran or oat flour with lower amounts of soluble fiber. The authors suggested that these data, which show greater benefits as the soluble fiber content increases, support the suggestion that soluble fiber is the component of oat fiber responsible for the cholesterol-lowering effect of oat-containing diets.

Nishini et al. (Ref. 128) evaluated the effect of dietary fibers from oat bran, wheat bran, cellulose, and pectin on plasma lipoproteins, apolipoproteins and enzymes involved on cholesterol metabolism in non-fasted rats. The animals were fed experimental diets estimated to contain 8 percent dietary fiber by weight. Results showed that pectin-fed animals (i.e., animals receiving the highest soluble fiber) had significantly lower serum cholesterol, HDL-cholesterol, and apolipoprotein A-1 levels compared to the fiber-free control. Total cholesterol levels in the wheat-bran-fed (primarily insoluble fiber) or oat bran-fed (mixed soluble/insoluble fiber) animals were not significantly different from the fiber-free control. No data were given on the soluble fiber content of the diets, although the pectin diet would be expected to have the highest level of soluble fiber. Results showed that blood lipid distributions are affected differently by dietary fibers, and that changes among lipid components frequently occurred without a change in overall cholesterol concentrations.

Prentice et al. (Ref. 129) compared the effects of ground and rolled caryopses of barley and rolled oats to ground corn on hepatic cholesterol and fatty acid synthesis in chickens. Approximately 7 to 8 percent of the barley and oat cereals was β-glucan; corn had less than 1 percent β-glucan. Both barley and oats decreased plasma total cholesterol by 32 percent and 25 percent, respectively. The authors attributed the effect on serum cholesterol to the higher soluble fiber content of barley and oat diets.

Summaries of unpublished animal studies (Ref. 130) suggested that oats may be effective in lowering plasma cholesterol compared to controls fed white flour, wheat flour, or corn starch. However, the data were preliminary and, thus, had limited usefulness.

Other summaries of unpublished animal studies (Ref. 136) suggested that rolled oats (75 percent by weight in diet) significantly lowered serum cholesterol in chicks. Extruded oat bran, equivalent to 47 percent of oat bran by weight in the diet, significantly depressed ($p = 0.05$) serum cholesterol in chicks. Oat gum at 0.05 percent and 0.10 percent by weight in the diets of rats significantly lowered serum cholesterol. Data comparing several oat fractions fed to chicks suggested that oat gum may be

the active cholesterol depressant component, and that ground rolled oats and instant oatmeal are equal in effect to the defatted, defibered oat flour. The oat oil also had a depressive effect. Additionally, pectin (high soluble fiber) was found to significantly lower serum cholesterol in rats. These studies were done in the mid-1970's and did not have analyzed values for soluble fiber content of the respective diets. Methods and data were not well described, making results difficult to interpret.

Qureshi et al. (Ref. 131) reported the effects of diets supplemented with either corn (61.5 percent by weight of the base diet), wheat (75 percent of the diet), barley (73.5 percent), oats (74.5 percent), or rye (73.5 percent) on serum cholesterol in chickens. This was part of a study to investigate the effects of dietary cereals on the metabolic regulation of lipid metabolism in chicken livers. Compared to corn, barley and oats lowered serum cholesterol 45 percent and 32 percent, respectively. Presumably, barley and oats were higher in soluble fiber content than was corn. However, no fiber content data were presented. Additionally, body weights for animals consuming the barley and oats diets varied, making it difficult to ascribe the effects to fiber per se.

Ranhotra and co-workers (Ref. 132) evaluated the effect of oat bran and oat bran concentrate on serum lipids in rats. Animals were fed experimental diets containing oat bran (5.57 percent soluble fiber) or oat bran concentrate (13.75 percent soluble fiber). Results showed the high soluble fiber content of the oat bran concentrate was associated with a significantly lower serum cholesterol level, but that the oat bran diet (which contained lower amounts of soluble fiber) and the diet free of soluble fiber were not associated with lower serum cholesterol levels.

Shinnick et al. (Ref. 133) evaluated the ability of various sources and forms of oat fiber to lower plasma and liver cholesterol in male rats fed a diet with 6 percent dietary fiber as cellulose (0 percent soluble fiber), oat bran (7 percent soluble fiber), high fiber oat flour (8 to 10 percent soluble fiber), or one of four processed high fiber oat flours (8 to 12 percent soluble fiber). All diets were supplemented with 1 percent cholesterol and 0.2 percent cholic acid to stimulate increased levels of blood total cholesterol. Results showed that all oat products significantly lowered serum cholesterol compared to the control. In a second experiment, diets containing 4 percent dietary soluble fiber in a processed oat flour significantly lowered serum cholesterol. The processed oat flours had higher soluble fiber fractions than the less processed oat products.

In a study published in 1983, Rogel and Vohra (Ref. 135) reported no effect from five varieties of oats (oat bran or oat hulls) fed for 4 weeks on the serum cholesterol levels of quail. No data on soluble fiber were given.

Kritchevsky et al. (Ref. 138) evaluated the cholesterol-raising effects of oat and wheat bran on blood cholesterol levels in rats in a three-week feeding study in which semipurified diets containing 0.5 percent cholesterol and 10 percent oat bran, wheat bran or cellulose were fed to male rats. Weight gains varied among the diets. Results showed that, under these study conditions, there were no effects of diet on any of the serum lipids. No data on soluble fiber content of the diets were provided.

Kahlon et al. (Ref 140) evaluated the effects of rice brans (full-fat or defatted), oat bran, or rice-wheat bran combinations on cholesterol in hamsters. The control diet contained 10 percent cellulose and 0.5 percent cholesterol. Test diets were composed of the control diet plus one of the brans. The oat bran contained 8 percent dietary soluble fiber versus 2 to 3 percent soluble fiber in the other brans. Results showed that rice bran (with fat) and oat bran resulted in significantly lower plasma cholesterol than the control diet. Defatting rice bran resulted in loss of its cholesterol-lowering properties, suggesting that it is the lipid portion rather than the fiber portion of rice bran which is responsible for its cholesterol-lowering effects.

In another study, rats were fed a diet containing 1 percent cholesterol and 0.2 percent cholic acid with added cellulose, oat gum, chitosan, or cholestyramine (5 percent of the diet). Cholestyramine, oat gum, and chitosan all significantly lowered blood and liver cholesterol levels, with the greatest effect with cholestyramine, a commonly used cholesterol-lowering drug. Oat gum, at 5 percent of the diet, reduced serum cholesterol by 23 percent (Ref. 141).

Forsythe et al. (Ref 142), in a study published in 1978, evaluated the influence of source and particle size of dietary fibers on hypocholesterolemic effects in rats. The sources of fiber were cellulose, wheat bran, wheat midlings, oat bran, oat flour, sugar beet pulp, soybean hulls and psyllium seeds. There were significant differences in weight gain and food intake among dietary treatments. No fiber decreased serum cholesterol compared to the fiber-free group.

Significantly lower values of plasma total cholesterol and liver cholesterol in rats fed fiber sources known to contain soluble fibers (oat bran, oat gum, and pectin) compared to rats fed cellulose (insoluble fiber) were reported by Chen et al. (Ref. 143). Rats were fed a base diet containing 1 percent cholesterol and 10 percent by weight of one of the four fiber types. The greater effect of oat gum compared to oat bran was interpreted by the authors to suggest that the plasma and liver cholesterol-lowering effects of oat bran are due to its gum fraction.

Chen and Anderson (Ref. 144) examined the effects of fiber-supplemented diets on total and LDL-cholesterol in rats. Rats were fed one of five experimental diets containing sucrose and 10 percent plant fibers. The diets were as follows: sucrose and cellulose, sucrose-cholesterol with cellulose, sucrose-cholesterol-pectin, sucrose-cholesterol-guar gum, and sucrose-cholesterol-oat bran. Results showed that fiber-fed rats had significantly lowered plasma cholesterol than rats that received cellulose; the lowest concentrations were observed in the pectin-treated group. No data were given on the soluble fiber content of the test diets, although the pectin would presumably contain the highest concentration of soluble fiber.

Chen and Anderson (Ref. 146), in two experiments, examined the effects of guar gum or wheat gum on the plasma and liver lipid levels of rats. In the first experiment, animals were fed one of three diets for three weeks: diet plus sucrose and 10 percent cellulose; sucrose, 15 percent wheat bran, and 4 percent cellulose; and sucrose and 45 percent wheat bran. Each diet provided 10 g of plant fiber. In experiment two, animals were fed one of four diets: diet plus sucrose, sucrose plus cholesterol, sucrose plus cholesterol and wheat bran, or sucrose, cholesterol, and guar gum. The wheat and guar diets provided 7 g of plant fiber; the other two diets provided 4 g of plant fiber. Results from experiment 1 showed that the two wheat bran diets (high in insoluble fiber) significantly raised plasma cholesterol compared to the control. Results of experiment 2 showed the guar diet (high in soluble fiber) significantly lowered serum cholesterol compared to those fed the sucrose-cholesterol or sucrose-cholesterol-wheat bran diets. Plasma cholesterol was similar between the sucrose-cholesterol and wheat groups.

Wilson et al. (Ref. 148) examined the influence of different soluble fibers upon the metabolism of lipids in genetically hyperlipemic, obese Zucker rats. Four diets were tested: a non-fiber diet (no added fiber), a 0 percent soluble fiber diet (cellulose fiber), an oat bran

diet (33 percent soluble fiber), and a pectin-citrus fiber diet (100 percent soluble fiber). Except for the control, the fibers provided 10 percent of the total diet weight. Results showed non-significant decreases in total plasma cholesterol in the oat bran and pectin groups compared to the no-fiber and cellulose groups. However, the pectin group (the highest soluble fiber group) had changes in blood lipid components associated with reduced risk of heart disease: significantly lower LDL-cholesterol and significantly higher HDL-cholesterol.

Welch et al. (Ref. 149) evaluated the hypocholesterolemic effects of oat bran fractions. Oat bran was separated into five fractions: oil, insoluble fraction (rich in starch and insoluble fibre), protein-rich, oat gum, and soluble residue. These were fed to chicks. Results showed that, compared to the control, only the diets containing oat bran, oat gum, or the protein fractions significantly lowered plasma cholesterol. Oat gum was the only fraction which had the same effect in reducing plasma cholesterol levels as did the native oat bran. Thus, oat gum was concluded to be the main cholesterol-lowering component of oat bran. Beta-glucan was the main component of the gum fraction. However, the protein fraction also had a beneficial effect on plasma cholesterol levels, although of a lesser magnitude than the gum portion.

Five sources of dietary fiber were compared for their effect on blood and liver cholesterol in beef-fed C57BL/6 male mice (Ref. 150). Mice were fed one of the following fiber supplements (7 percent dietary fiber) with the experimental diet: soybean fiber, rice bran (full fat), oat bran, barley bran, and mixed bran (one-third each of rice, barley, and oat brans). Results showed significantly lower plasma total cholesterol compared to the control in the rice bran and soybean fiber groups.

Ginter et al. (Ref. 151) reported that addition of 5 percent citrus pectin (a high soluble fiber source) and 0.5 percent ascorbic acid to a high-fat diet fed to guinea pigs prevented cholesterol accumulation in blood serum and the liver.

Kakis et al. (Ref. 152) reported reduced serum cholesterol and HDL levels in all psyllium-fed (a soluble fiber) animals as compared to wheat bran-fed (a relatively high insoluble fiber source) animals after a three week experimental period. Relative to the appropriate wheat bran control, psyllium had a graded serum hypocholesterolemic effect that varied from a high of 41 percent at low dietary cholesterol concentrations to 26 percent at high dietary cholesterol concentrations. However, HDL cholesterol (in mg percent and as a percent of total cholesterol), the "beneficial blood cholesterol," was lower in the psyllium groups than in the respective wheat bran controls. Thus, the overall benefit of psyllium was not clear from this study.

Life Sciences Research Office's (LSRO) 1982 report to FDA on the health aspects of psyllium seed and other food ingredients (Ref. 153) was submitted with comments. Summaries of studies with beagles fed psyllium-supplemented diets consistently showed lowered serum cholesterol compared to controls.

2. Animal studies: dose-response relationship between soluble fiber and plasma cholesterol

Shinnick et al. (Ref. 134), following evaluation of several approaches to improve the cholesterol-fed rat model used to evaluate the hypocholesterolemic potential of foods, fed nine levels of a high fiber oat flour (HFOF) derived from oat bran to male Sprague-Dawley rats. Ingestion of increasing amounts of HFOF, containing 0 to 10 percent dietary fiber, by rats in which high blood cholesterol levels had been produced with 1 percent cholesterol and 0.1 percent cholic acid, resulted in a significant inverse relationship between serum cholesterol levels and HFOF intake for serum and liver cholesterol levels. Similar results were obtained for liver cholesterol levels. The authors suggested that, although this study does not distinguish among the components of HFOF that may contribute to the cholesterol-lowering effect, the observed dose-response relationship in the rat model is suggestive that larger intakes of soluble oat fiber sources may be accompanied by greater reductions in serum cholesterol levels in humans.

Turley and co-workers (Ref. 147) conducted a dose-response study to three levels of psyllium supplementation in the diets of hamsters. Results were compared to two other nonabsorbable polymers known to have cholesterol-lowering effects (i.e., cholestyramine and surfomer). Animals were fed diets containing 0 percent, 1 percent, 4 percent, or 7.5 percent psyllium. Results showed significantly lowered plasma cholesterol compared to the control group in animals consuming 4 percent and 7.5 percent psyllium. The group consuming 7.5 percent psyllium had the lowest plasma cholesterol, although the authors did not report any significant difference between the 4 percent and 7.5 percent psyllium groups. While all three polymers were effective in reducing plasma total and LDL-cholesterol levels, each exerted different quantitative and qualitative effects on bile acid and cholesterol metabolism, suggesting that mechanisms of action may vary by fiber type.

3. Animal studies: relationship between β-glucan and plasma cholesterol

Three cultivars of hull-less barley containing β-glucans were evaluated for their hypocholesterolemic responses in chickens (Ref. 137). The authors identified the Arizona cultivar of barley as a waxy-starch genotype of high molecular weight and with a high β-glucan content. The Washonupana cultivar was second highest in molecular weight and is also described as a waxy-starch type genotype. The third cultivar, Franubet, has the lowest molecular weight and is not waxy in texture. These latter two genotypes have normal β-glucan contents. Both the Arizona and Washonupana varieties produce highly viscous slurries in water, and this viscosity was greatly reduced by addition of the enzyme, endo-β-glucanase, which destroys the β-glucan. Results of feeding studies in rats showed that both the Arizona and Washonupana cultivars reduce serum cholesterol in chickens. The Franubet variety had no effect. The authors interpreted these results to mean that the cholesterol-lowering properties of the Arizona and Washonupana cultivars were probably a function of their viscous β-glucan content.

Klopfenstein and Hoseney (Ref. 139) evaluated the cholesterol-lowering effect of β-glucan-enriched bread. Oat, barley, wheat, and sorghum breads were made with and without β-glucan from each type of grain (e.g., oat β-glucan was processed into oat bread) and fed to rats for 35 days. Breads containing β-glucans from oats and barley adversely affected weight gains and feed efficiencies. Results showed lowered serum and liver cholesterol in rats fed the β-glucan-enriched bread than those fed the control breads. Given differences in weight gains, results are difficult to interpret.

Fadel et al. (Ref. 145) evaluated the hypocholesterolemic effects of β-glucans in different barley diets fed to chickens and the influence of β-glucanase on the hypocholesterolemic effects. The animals were divided into five groups and fed one of five diets: a corn-diet, Washonupana (WSNP) barley, WSNP with β-glucanase, Fraubet (FNBT) barley, FNBT with β-glucanase. Results showed significantly lowered serum

cholesterol only in chicks fed the WSNP diet. LDL-cholesterol levels for all barley fed chicks were significantly lower than that of the corn diet-fed chicks. Only the WSNP fed chicks had serum cholesterol significantly lower than WSNP fed chicks with supplemental β-glucanase. There was no significant difference in total cholesterol in FNBT and FNBT plus supplemental β-glucanase fed chicks. β-glucan in the Washonupana barley has hypocholesterolemic effects and addition of the β-glucanase to this diet reverses the hypocholesterolemic effects. However, the lack of similar finding with added β-glucanase to the Franubet variety suggests that β-glucans may differ among different varieties.

4. Summary of results from animal studies

The animal studies received as comments, and reviewed above, provide evidence to support the likely effectiveness of soluble fibers relative to the cholesterol-lowering characteristics of diets high in some cereals. However, the animal studies, like the human studies, fail to provide adequate specifications characterizing the test fiber sources. Indeed, similarly to many human studies, many animals studies did not analyze experimental diets for soluble fiber content, nor provide descriptions of the physical characteristics or commercial sources of the soluble fibers used as test substances.

Results from the animal studies showing effectiveness of increasing levels of oat products are suggestive, but not conclusive, evidence of a dose response for soluble fiber (Refs. 127, 132, 134). A specificity for the gum portion of oats, the major source of soluble fiber in oats—and specifically, of beta-glucan as the predominant soluble fiber source—is suggested by several studies (Refs. 127, 129, 132, 134, 137, 141, 143, 145, and 149). However, the solubility (and possibly, the effectiveness) of beta-glucan is apparently variable, and can be affected by such factors as plant variety (Refs. 137 and 145), or food processing such as baking of bread (Ref. 154). These results, therefore, suggest that analysis of the beta-glucan content per se may not be sufficient to characterize the active soluble fiber content of foods.

Other soluble fibers were also shown to have serum cholesterol-lowering effects in animals, including pectins (Ref. 128, 143, 144, 148, and 151), psyllium (Refs. 147 and 152), and guar gum (Ref. 146). However, in the psyllium study (Ref. 152), adverse effects on HDL-cholesterol levels were observed, raising the issue that individual fibers need to be evaluated as to their overall effect on all relevant blood lipid components, not simply limited to blood total or LDL-cholesterol levels. The various fiber sources also appear to have different mechanisms of action and different relative magnitudes of effect (Refs. 128 and 147), thus suggesting that caution is necessary before generalizing from one type of dietary fiber to another.

C. Conclusions from new studies

FDA reviewed over 40 human studies that became available since publication of its proposed rule, and a number of animal studies submitted as comments. The most commonly studied soluble fiber sources were oat bran, pectin, guar gum, and psyllium. Other fibers studied were wheat germ, beet fiber, and gum arabic. A few studies evaluated the effects of mixtures of soluble and insoluble fibers or food sources of soluble fibers.

FDA evaluated results from these studies in light of studies reviewed in the proposal and conclusions from Federal government and other authoritative reviews. In the proposal, FDA noted that, although most reviews by authoritative scientific bodies had concluded that diets rich in water-soluble fiber fractions were associated with cholesterol-lowering effects in humans, it was not possible to conclude that the observed effects were due to the soluble fiber or to other components associated with consumption of foods rich in soluble fiber. FDA also noted that there was some evidence that different types of soluble fiber have different effects, and that the analytical measure of soluble fiber may not be adequately predictive of its physiological effects. Thus, FDA concluded that:

> Overall, the available data are not sufficient to demonstrate that it is the total soluble dietary fiber, or a specific measurable and quantifiable subcomponent, that is related to lower blood cholesterol levels. (56 FR 60582 at 60592).

The newer evidence available since the proposed rule and reviewed above do not change the conclusions reached by the earlier review. If, however, additional information becomes available to demonstrate that a specific soluble fiber-containing product, a soluble fiber-containing ingredient, or a more highly specified form of foods soluble fiber is effective in lowering bloood LDL-cholesterol and does not adversely affect other risk factors for cardiovascular disease (e.g., blood HDL-cholesterol levels), then FDA encourages manufacturers to petition for a health claim for their particular product. The same science will be applicable, regardless of whether the petition is for a single supplement-type product, a clearly specific ingredient, or a specific type of soluble fiber contained in foods.

III. Comments

A. Food Claims Versus Nutrient Claims

1. In the proposal on general requirements for health claims (56 FR 60537), FDA specifically requested comments on issues relating to health claims on the label or labeling of foods which targeted foods rather than nutrients, criteria to identify foods eligible for such claims, and possible measures to assure that consumers are not misled as to the benefit of consuming specific products.

A variety of comments submitted in response to the proposed rule on dietary fiber/CVD supported claims on foods. Specifically, relative to a claim for dietary fiber and heart disease, a few comments stated that FDA does have the authority to regulate claims about foods as well as nutrients and that the agency should allow a generic health claim on fruits, vegetables, whole grain and similar types of foods, stating that generous intakes of such foods in diets may help lower the risk of heart disease and certain forms of cancer. Other comments stated that, at this time, a scientific basis does not exist on which to authorize a specific claim for dietary fiber and heart disease, and that a food claim was more appropriate. Other comments suggested that such claims be developed in concurrence with "The Surgeon General's Report on Nutrition and Health," (Surgeon General's Report) (Ref. 63) and objectives identified in "Healthy People 200: National Health Promotion and Disease Prevention Objectives," (Healthy People 2000) (Ref. 64), and should focus on the total diet.

A number of comments stated that the amount of fat in the American diet should be lowered and the amount of dietary fiber increased through a variety of food choices from among all the food groups. Several comments favored a limited claim at point of purchase for foods that would help increase dietary fiber intake and lower fat intake. A number of comments noted that an appropriate health statement on food labels should emphasize that eating a variety of food sources of dietary fiber daily (cereals, grains, fruits, and vegetables) can decrease the risk of certain forms of cancer and heart disease. A number of comments stated that food claims, if allowed, should not give the impression that a single

nutrient (for example, dietary fiber) is responsible for the reduction in risk of heart disease. Several comments suggested that a health claim regarding dietary fiber and heart disease be made only on fruits, vegetables (fresh or processed), or whole grains and not on products that combine these foods with other ingredients (such as bread products or sauce). Other comments favored use of claims on foods but not supplements.

One comment stated that FDA should allow a fiber health claim because virtually all dietary guidelines for Americans have encouraged consumption of fiber-rich foods, including whole grain cereals, fruits, and vegetables, and that comprehensive government and other reviews by recognized scientific bodies concluded that dietary patterns that include fiber-rich foods are associated with reduced risk of colorectal cancer, heart disease, and other chronic diseases.

As the agency has discussed, in the final rule on general requirements for health claims published elsewhere in this issue of the Federal Register, statements about good nutrition that do not, expressly or by implication, refer to a substance are considered dietary guidance and not health claims. In this rule, the agency has concluded that the scientific evidence is sufficient to support a health claim that refers to a substance contained in certain fruits, vegetables, and grain products and relates those foods to a reduced risk of heart disease. Specific reference to the fact that these foods contain soluble fiber is authorized, since this nutrient serves as a useful marker for the broad product categories of foods which correlate with reduction in blood LDL-cholesterol levels, and consequently, with reduced risk of heart disease. Thus, the agency has been persuaded by the comments that the totality of the evidence supports a health claim which identifies foods whose use is protective against heart disease and whose selection can be facilitated by reference to the marker nutrient, soluble fiber. Because soluble fiber is usually considered a useful adjunct to, but not a replacement for, a diet low in saturated fat and cholesterol (Ref. 66), the agency is also requiring this information in the label claim.

B. General Comments

2. Several comments supported a health claim for dietary fiber and heart disease, stating that there is sufficient scientific evidence to support such a claim or that a claim is warranted because heart disease and, hence, CVD are major public health problems. Other comments stated that because such a claim would help Americans become aware of the importance of fiber, and because it is well known that population groups who consume high fiber diets have a low incidence of heart disease, these claims should be allowed. Several comments stated that FDA should consider the rapid pace of advances in knowledge that link nutritional substances to good health and disease prevention. Other comments stated that a claim regarding dietary fiber and CVD should not be allowed because overall health depends on a number of factors, such as exercise and lifestyle characteristics.

FDA agrees that CVD and, consequently, CHD are significant public health problems. The agency, in the proposal, tentatively concluded that diets high in fiber-rich foods, including whole grains, fruits and vegetables, are associated with reduced risk of CHD, and thus CVD. In the proposal, the agency also noted that these diets differ in levels of many nutrients, such as saturated fat and vegetable protein, and in types of dietary fiber, making it difficult to ascribe, from observational studies on whole diets, the observed nutrient and disease relationship to a single dietary component (56 FR 60582 at 60592 and 60593).

Several new studies that became available after publication of the proposal were suggestive of positive effects of soluble fiber intakes on blood total- and LDL-cholesterol levels, risk factors for heart disease. However, FDA has also concluded, as noted in the proposal, that the effectiveness of these fibers may be affected by other dietary components (e.g., the level of saturated fat and cholesterol in the diets), as well as by physical characteristics (e.g., particle size or water-holding capacity), or by the fiber source itself. Thus, while the agency has concluded that not all soluble fibers, i.e., as identified by the AOAC method for soluble fiber determination, are effective in lowering cholesterol, and other components of fiber-rich foods, i.e., vegetable proteins or lipids, may contribute to the cholesterol-lowering effect observed. In addition, the hypocholesterolemic effectiveness of some soluble fibers has been reported in studies in which the source of soluble fiber was consumed as an adjunct to a low saturated fat, low cholesterol, and low total fat diet.

3. Several comments stated that FDA is not following the congressional mandate to consider whether there is significant scientific agreement supporting specific health claims. Specifically, the comments argued that the agency should have placed its inquiry in the proper context by first identifying the range of specific health claims that could be made about dietary fiber and CVD, and then examining the scientific support for each claim.

FDA disagrees with this comment. The 1990 amendments did not require the agency to identify the wide range of health claims that might be made with respect to the 10 topics identified in the act and then to evaluate all published studies relevant to the claims. Rather, the 1990 amendments instructed the agency to determine whether claims respecting the 10 areas, including "dietary fiber and cardiovascular disease" meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The agency interpreted this directive in a straightforward and logical way. Indeed, FDA's chosen approach was necessary if the agency hoped to accomplish the congressional mandate within the required timeframe. Thus, FDA, in its proposed rule (56 FR 60582), focused its review of the science on those aspects of the dietary fiber and CVD relationship for which the strongest scientific evidence exists: Soluble fiber and CHD.

4. Some comments stated that FDA's denial of a health claim for dietary fiber and CVD, because of rigid application of a scientific standard higher than that mandated by the 1990 amendments, would have unfortunate public health consequences.

FDA disagrees with the comment that the agency is applying a standard higher than that mandated by the 1990 amendments. To ensure the validity of health claims, Congress enacted a scientific standard in section 403(r)(3)(B)(i) of the act. FDA intends to authorize any claim shown to meet that standard; specifically, any claim for which, based on the totality of the publicly available scientific evidence, there is significant scientific agreement, among experts qualified by training and experience to evaluate such claims, that the claim is supported by the evidence. FDA also disagrees that applying the scientific standard mandated in section 403(r)(3)(B)(i) of the act will have unfortunate public health consequences. FDA believes that for health claims to be truly educational and provide public health benefits, they must be scientifically valid and not misleading. The issue of the scientific standard is discussed in more detail in the final rule on general requirements for health claims, published elsewhere in this issue of the Federal Register.

5. Some comments stated that FDA used disparate criteria in assessing the relationship between lipids and CVD

and dietary fiber and CVD, but did not elaborate on this issue.

FDA disagrees with these comments. In reviewing the scientific literature for the development of its proposed rules for health claims, FDA followed the standard mandated by the 1990 amendments.

Federal Government reports and other authoritative documents have consistently concluded that there is a strong relationship between the total amount and types of dietary fat and other lipids in the diet and the risk of heart disease. In developing the proposed rule on lipids and CVD, the agency found that new evidence supported these conclusions. The weight of the evidence showed that diets low in saturated fat and cholesterol are associated with reduced blood total- and LDL-cholesterol and a lower risk of CHD.

In contrast, Federal Government reports and other authoritative documents did not reach similar conclusions that the scientific evidence supported a claim that dietary fiber per se is associated with the reduced risks of CVD. The available evidence showed an association between consumption of diets high in fruits, vegetables, and grain products—diets which are generally high in fiber—and risk of heart disease. For example, in its recommendations in the NAS report "Diet and Health" (Ref. 48), the committee on Diet and Health "agree[d] with most other expert groups in proposing that the intake of vegetables, fruits, and other sources of complex carbohydrates should be increased and that the intake of sugars should be limited." The committee further noted that "the strength of the evidence does not justify making specific recommendations pertaining to dietary fiber at this time. The committee's recommendation to emphasize the consumption of vegetables, fruits, and other sources of complex carbohydrates would, however, indirectly result in increased consumption of dietary fiber."

In developing its proposed rule on dietary fiber and CVD, the agency found that the evidence available at the time the proposal was developed did not alter these conclusions. The agency found that the scientific evidence was not sufficiently conclusive or specific for dietary fiber per se versus other components in the diet to justify use of a health claim relating intake of dietary fiber to reduced risk of CVD.

6. One comment stated that FDA failed to comply with the 1990 amendments (section 403(r)(4)(C) of the act) in that it has rejected the conclusion of authoritative Federal Government reports without justifying its decision to do so as the act requires. The comment stated that the National Cholesterol Education Program (NCEP) has concluded that soluble fiber may help reduce blood cholesterol levels. The comment refers to the NCEP 1989 consumer pamphlet (Ref. 5), which recommends breads, pasta, rice, cereals, dried peas and beans, fruits, and vegetables as good sources of complex carbohydrates (starch and fiber). The comment quotes from the pamphlet that these foods are "excellent substitutes for foods that are high in saturated fat and cholesterol. The type of fiber found in foods such as oat and barley bran, some fruits like apples and oranges, and in some dried beans may even help reduce blood cholesterol levels" (Ref. 5). The comment also noted that the NCEP expert panel report, "Population Strategies for Blood Cholesterol Reduction" (Ref. 66), supports the recommendation to consume vegetables, fruits, breads, legumes, and whole grain cereals. The comment quotes the NCEP report that "Dietary fiber supplements are not a panacea for blood cholesterol problems. Foods rich in soluble dietary fiber are, however, a useful addition to a low saturated fatty acid, low fat, and low cholesterol eating patterns* * *" and:

"Oat bran exhibits hypocholesterolemic properties due to its appreciable content of oat gum. Soluble fibers such as pectin, guar gum, locust bean gum, or psyllium in large quantity supplementation have been shown to lower total and LDL-cholesterol levels. The absolute effect on LDL-cholesterol concentrations is modest even when the amount of soluble fiber such as oat bran is consumed in appreciable amounts (60 g). This effect, however, represents a useful adjunct to an eating pattern low in saturated fatty acids and cholesterol" (Ref. 65).

FDA disagrees that, in developing its proposed rule regarding fiber and CVD, it rejected conclusions of Federal Government reports. Comments, through repetition of those portions of the text that accompanies dietary recommendations and that includes the words "soluble fiber," are attributing greater significance to the statements relating soluble fiber to heart disease risk than was given to these results by the expert panels. This selected emphasis distorts the meaning of the authoritative reports in question by failing to acknowledge important contributions to reduced risk of disease by the wide variety of nutrients and nonnutritive substances present in diets high in fruits, vegetables, and grain products. Such an emphasis also focuses attention away from changes in overall dietary patterns and their potential contributions to reducing risk of chronic diseases.

In the NCEP report (Ref. 65) cited by the comment, the expert panel noted the hypocholesterolemic effects of some soluble fibers, but recommends "a habitual pattern of eating that is consistently low in saturated fatty acids, total fat, and cholesterol." NCEP further recommended that "all healthy Americans recognize that no single food or supplement is the answer to achieving a desirable blood cholesterol level" (Ref. 65). NCEP's recommendation to Americans is to "eat a greater quantity and variety of fruits, vegetables, breads, cereals, and legumes" (Ref. 65). These food choices "will help to meet nutritional needs for minerals, vitamins, dietary fiber (including soluble fiber), and complex carbohydrates, and to replace calories from fat." Thus, the NCEP acknowledges the importance of a dietary pattern that focuses on reducing fats in the diet in order to reduce serum cholesterol. It did not attribute a protective effect from CVD to dietary fiber alone.

Neither the Surgeon General's report on "Nutrition and Health" (Ref. 63), the National Academy of Sciences (NAS) "Diet and Health: Implications for Reducing Chrinic Disease Risk"(Diet and Health) (Ref. 48), nor (The Department of Health and Human Services (DHHS)) "Healthy People 2000" (Ref. 64) found the scientific evidence strong enough to attribute the protective effects against CVD of dietary patterns high in fruits, vegetables, and grain products exclusively to the soluble fiber content of such diets. Specifically, the Surgeon General's report on "Nutrition and Health" (Ref. 63) recommends increased consumption of whole grain foods and cereal products, vegetables (including dried beans and peas) and fruits. The report states that:

"the association shown in epidemiologic and animal studies between diets high in complex carbohydrates and reduced risk for CHD and diabetes mellitus is, however, difficult to interpret. The fact that such diets tend also to be lower in energy and fats, especially saturated fats and cholesterol, clearly contributes to this difficulty. Some evidence from clinical studies also suggest that water-soluble fibers from foods such as oat bran, beans, and certain fruits are associated with lower blood glucose and blood lipid levels" (Ref. 63).

The section concludes with the statement, "Current evidence suggests the prudence of increasing consumption of whole grain foods and cereals, vegetables (including dried beans and peas), and fruits" (Ref. 63).

Similarly, the Executive Summary of the National Research Council's "Diet

and Health" recommends, "Every day eat five or more servings of a combination of vegetables and fruits, especially green and yellow vegetables, and citrus fruits. Also, increase intake of starches and other complex carbohydrates by eating six or more daily servings of a combination of breads, cereals, and legumes" (Ref. 48). The summary continues "Studies in various parts of the world indicate that people who habitually consume a diet high in plant foods have low risks of atherosclerotic CVD's, probably largely because such diets are usually low in animal fat and cholesterol. Some constituents of plant foods, e.g., soluble fiber and vegetable protein, may also contribute—to a lesser extent—to the lower risk of atherosclerotic cardiovascular diseases." The Committee does not recommend the use of fiber supplements.

"Healthy People 2000" states that recommendations from the National Cancer Institute, the Surgeon General's report on "Nutrition and Health," NAS' "Diet and Health," and "Dietary Guidelines for Americans" support increased consumption of vegetables, fruits, and whole-grain breads and cereals (Ref. 64). "Healthy People 2000" also states that further research is needed to clarify whether the effect on blood lipids is an independent effect, and if so, to quantify the relationship (Ref. 64).

Therefore, in its proposed decision not to authorize the use on the label or labeling of foods of health claims relating intake of dietary fiber to decreased risk of CVD, the agency's tentative conclusion was consistent with those of Federal Government and other authoritative reports.

FDA's position was also consistent with recommendations in the Institute of Medicine's report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 81). In this report, the authors note that:

> "there has been a great deal of interest in the specific effects of dietary fiber on several chronic diseases. The strongest argument for an increase in consumption of dietary fiber is the important contribution it makes to normal bowel function. Clear scientific associations of fiber intake with the incidence of heart disease, certain types of cancer, and diabetes mellitus have not been made. One reason may be the difficulty in designing appropriate experiments to specifically test for the effect of dietary fiber. Foods high in dietary fiber are also generally low in calories and total and saturated fatty acids and devoid of cholesterol; thus, determination of a specific fiber effect in a feeding study is difficult. Moreover, foods have a variety of fiber components and each may have different actions. Chemically and physiologically, cellulose, lignin, hemicellulose, pectin and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogeneous mixtures of fibers) are not similar in composition. It is also very difficult to analyze dietary fiber chemically, and thus it is hard to correlate the role of specific fiber components to health effects * * *" (Ref. 81).

The Institute of Medicine's report (Ref. 81) also provided specific recommendations, including: (1) "FDA and USDA should require the disclosure of fiber content per serving in grams on the nutrition information panel under the term total dietary fiber"; and (2) "FDA and USDA should discourage labeling of soluble or insoluble fiber contents until methodologies approved by the agencies allow for the adequate and reproducible quantification of the soluble and insoluble fiber contents of a variety of foods" (Ref. 81).

Therefore, FDA is not rejecting the conclusions of these government reports. In its final rule, § 101.76, the agency is permitting a claim relating dietary consumption of fruits, vegetables, and grain products, i.e., good sources of fiber, with reduced risk of heart disease.

7. One comment criticized FDA for misinterpreting the conclusions of the Government of Canada's 1985 "Report of the Expert Advisory Committee on Dietary Fiber" to the Department of Health and Welfare (Ref. 46). The comment stated that the committee expressly advocated health claims for soluble fiber and CHD.

FDA agrees that the Canadian report in question noted hypocholesterolemic effects of some soluble fiber sources, but FDA disagrees that the Department of Health and Welfare supports health claims on soluble fiber in Canada. In its comments to FDA regarding the proposed rule, dietary fiber and CVD, the Canadian Department of Health and Welfare stated its opposition to health messages. Its comment stated that health messages and claims for heart disease and cancer, among other diseases, are not permitted under the Canadian Food and Drugs Act. These diseases are considered to require medical diagnosis and treatment under medical supervision, and thus products bearing messages about them are regulated as drugs. The 1985 report suggested that, if a company desired to use a health claim, then that company should present the evidence of the product's effectiveness based on acceptable test protocols (Ref. 46).

8. One comment stated that FDA failed to note, in the proposed rule, epidemiological studies cited in the NAS' "Diet and Health" that found an inverse association between dietary fiber and CHD, even after adjusting for the possible confounding effects of calories and fat (Ref. 48).

FDA disagrees with this comment. One study was cited in "Diet and Health" that showed a protective effect of dietary fiber from cereals on risk of CHD independent of caloric intake. Results of a study by Khaw and Barrett-Connor (Ref. 31) (reviewed by FDA in the proposal) found an inverse association between fiber intake and ischemic heart disease mortality independent of calories among other dietary components. However, "Diet and Health" also states that the authors used 24-hour dietary recall to assess intake, a method which has limited applicability in the assessment of the usual dietary intake of individuals in the United States (Ref. 48). Results from the 1982 epidemiological study by Burr (Ref. 82), also cited in "Diet and Health," showed a lower risk of CHD in 10,943 vegetarians than in nonvegetarians, but their decreased risk could not be accounted for by increased fiber consumption, because many other components of the diet also differed between these two groups. Therefore, FDA did not misinterpret the conclusions of "Diet and Health" that there is no conclusive evidence that it is dietary fiber, rather than other components of fiber-rich foods, that reduces risk of CVD.

9. One comment disagreed with the indication in the proposed rule that a "risk/benefit" argument was not a sufficient or appropriate basis on which to authorize a health claim for food labels. The comment stated that, although the data for dietary fiber do not support the hypothesis for reduced risk of CVD, the "potential benefits far outweigh the potential disadvantages."

FDA disagrees with this comment. Congress enacted a scientific standard for health claims in section 403(r)(3)(B)(i) of the act. Claims must meet the statutory requirements; that is, based on the totality of the scientific evidence, there must be significant scientific agreement, among experts qualified by training and experience to evaluate such claims, that the claim is supported by such evidence. The concept of "potential benefits outweighing potential disadvantages" is not an acceptable substitute for the scientific standard mandated by Congress.

C. Specificity of the Relationship Between Soluble Dietary Fiber and Heart Disease

10. Several comments stated that FDA's refusal to authorize a health claim on dietary fiber and CVD is based

on the agency's determination to treat all dietary fiber as a group, rather than considering each fiber source individually. The comment stated that dietary fiber is composed of a diverse group of materials, as the agency observed, and each has its own physiological effects. The comment noted that certain water soluble fibers have been documented to reduce serum cholesterol, thereby lowering the risk of CHD.

FDA disagrees with this comment. In the proposed rule (56 FR 60582), FDA limited its review of the science to those aspects of the dietary fiber and CVD relationship for which the strongest scientific evidence exists: soluble dietary fiber and CHD. FDA also noted, however, that soluble fiber was a heterogenous family of fibers which vary in both chemical and physical characteristics. After reviewing the totality of the evidence, the agency is persuaded that even if soluble fiber alone is effective in reducing risk of heart disease, greater specificity than that identified by existing analytical methods is needed in order to predict the effectiveness of soluble fiber in foods.

11. LSRO submitted its document, "Dietary Fiber and Cardiovascular Disease" (Ref. 40), as a comment. In this final report, LSRO stated that it remains to be determined whether the observed effects of dietary fiber on serum cholesterol reduction result strictly from the fiber or from other components of the fiber-rich food or from a combination of these factors. The report stated that studies suggest that soluble fiber, a specific type of dietary fiber, is hypocholesterolemic, while insoluble fiber is not. Further, when foods are used, foods rich in β-glucans seem to have a more hypocholesterolemic effect. The report states that there is no indication of optimum level or even a dose-related effect, and notes that there are suggestions as to optimum level of intake for "better health" (e.g., normal bowel function) but not for prevention of disease. In addition, there are no data relating to transience of fiber effects, although this is amenable to experimental testing. The LSRO report also noted that generalization to the U.S. population is difficult. Presumably, persons at high risk, such as those with a family history of hyperlipidemia or heart disease, would benefit most.

The LSRO report also states that it is unclear whether the lipid-lowering effects observed in some studies are the result of the fact that most high fiber diets are low in fat. According to the report, most of the available evidence suggests that isolated polysaccharides, such as pectin, guar gum, locust bean gum, oat gum, and psyllium mucilloid, have the ability to lower serum cholesterol levels; however, there are no data to indicate that a fiber present in a food is the same as when it has been extracted and purified. The data suggest that diets high in fiber-rich foods can influence lipidemia, but this effect is probably due to overall changes in the diet caused by the addition of fiber sources rather than simply to a direct effect of fiber.

One comment stated that FDA failed to cite LSRO's (Ref. 39) conclusions regarding hypocholesterolemic effects of some soluble fibers.

FDA agrees that the results of clinical studies suggest that soluble fiber is hypocholesterolemic, while insoluble fiber is not. FDA also agrees that the effect of fiber-rich foods on serum lipids is related to the total diet, i.e., one that is low in saturated fat and cholesterol and high in soluble fiber-rich foods, such as vegetables, fruits, and grain products.

FDA disagrees that the agency failed to consider the conclusions of this report. Both of LSRO's reports (Refs. 39 and 40) concluded that soluble fibers were related to reduced blood cholesterol levels, but the LSRO report (Ref. 40) also concluded, as noted above, that it remains to be determined whether the observed effects of dietary fiber on serum cholesterol reduction result strictly from the fiber or from other components of fiber-rich foods or from a combination of these factors. Data available since LSRO's report (Ref. 40) provided some additional information as to the effect of soluble fiber on blood cholesterol reduction.

12. One comment stated that FDA failed to note part of the World Health Organization's (WHO) report (Ref. 71) on the relationship between soluble fiber and blood cholesterol levels (and hence CHD). The comment quotes the report, "[o]ther dietary components, such as dietary fibre, have an effect on serum cholesterol in experimental studies and are correlated in intercountry comparisons. As with fatty acids, the different forms of dietary fibre may have different effects on serum cholesterol" (Ref. 71). The comment concludes that, although the WHO report did not analyze the relevant science, it acknowledges the evidence that soluble fibers have hypocholesterolemic effects.

FDA disagrees with the comment that it failed to note the WHO statements regarding soluble fiber. Although the WHO report states that "different forms of dietary fiber may have different effects on serum cholesterol," it does not identify which form of dietary fiber effects serum cholesterol; the term "soluble fiber" was not used in the report (Ref. 71).

13. Several national health organizations with expertise in heart disease agreed with FDA's proposed conclusion, that, at this time, there is insufficient evidence to link dietary fiber, per se, to CVD. The comments stated that the proposal is consistent with the conclusions of all previous expert groups. The comments stated that the association between fiber and blood lipids is specific to soluble fiber and that specificity to fiber class is unresolved. The amount of soluble fiber necessary to produce blood cholesterol lowering is unclear; nor is it known whether (and if so, how much) the response differs by type of soluble fiber (i.e., β-glucan versus pectin). Furthermore, the comments state that FDA's review of the scientific literature (56 FR 60574) mentions the tumor-enhancing effect of soluble fibers in animal studies. They recommended that FDA not allow health claims that link fiber to risk of CVD's. The comments stated that there are insufficient data to warrant such a claim and that it is misleading to permit a claim that singles out a particular food or foods in diets. The comments stated that if there were sufficient data to make a claim, it should be stated in the context of a low fat, low cholesterol diet. It would also be necessary to specify the type of fiber, e.g., soluble fiber, in the case of CVD.

FDA agrees that a health claim for a dietary component should be stated in the context of the total daily diet and, in this case, should be specific to the type of dietary fiber. The agency has been persuaded, based on its review of the comments and its review of the scientific literature, that questions remains as to whether the cholesterol-lowering effect observed with some soluble-fiber food sources (e.g., oats) is due to the soluble fiber component or to a combination of other components associated with these foods.

14. One comment questioned the motivation behind the agency's tentative rejection of health claims for fiber and CVD. The comment stated that FDA does not want any health claims on dietary supplements and that the agency should not preclude claims because of concern that dietary supplement manufacturers will then be able to make such claims. Comments from supplement manufacturers stated that, if health claims are permitted on fiber-containing foods, then fiber supplements should also be permitted to carry a claim because there is no difference between fiber in foods and

fiber in supplements and all fiber supplements are safe. Other comments stated that FDA should authorize health claims on supplements because supplements offer an alternative to consumers who might otherwise not eat sufficient amounts of fiber in their diets.

FDA disagrees with the comment that it does not want health claims on fiber supplements and with the suggestion that it rejected dietary fiber and CVD health claims because of concern that supplement manufacturers would then be allowed to make such claims. FDA has applied the law equally to supplements and conventional foods.

As the agency's proposed rule stated, FDA proposed to deny a health claim for dietary fiber and CVD because the agency tentatively concluded that the available scientific evidence was not sufficiently conclusive or specific for dietary fiber per se. FDA notes that the comment claimed that there is no difference between fiber in foods and fiber in supplements but submitted no data were submitted to support this statement. Indeed, several expert reports (Refs. 39, 40, and 46) concluded that there is no evidence that fiber, when isolated and/or processed in foods, has the same physiological effects on serum cholesterol as consumption of the native fiber from fiber-rich foods. These reports note that the predictive capability of analytically determined values for soluble fiber and physiologic activity has not been established, and effectiveness may vary by source of fiber or by physical characteristics not detected with chemical methods of analysis (e.g., particle size or water-holding capacity). They also note that safety may vary between native and isolated sources of fiber.

D. Comments Regarding a Relationship Between Specific Soluble Dietary Fibers and CVD

15. One comment submitted a review of available literature for particular fibers. The comment stated that several of these fibers are "effective as cholesterol lowering agents and in addition, they are safe to use provided a few reasonable precautions are taken." The comment identified fibers such as locust bean gum, guar gum, oats, pectin, and psyllium mucilage as materials with hypocholesterolemic effects. Less well-tested fibers that have some hypocholesterolemic effects (for example, barley, acacia gum, dried beans, and karaya gum) were also mentioned. The comment stated that wheat fiber requires more study to determine its effects. The comment notes that, since dietary fiber represents a diverse group of materials, FDA should consider allowing health claims and statements on individual dietary fiber materials. The comment also recommended separate health claims on fibers with "hypocholesterolemic" activity, because each of these fiber materials also has a different dose-response. The comment provided some criteria on which to base the individual fiber claims.

FDA agrees that the scientific literature shows that dietary fiber is a complex group of dietary substances with differing chemical, physical, and physiological properties, and that not all soluble fibers are alike in their hypocholesterolemic properties. FDA disagrees with the recommendation to allow individual health claims on various soluble fibers, but does concur that the effectiveness of individual fibers in foods may be documented for specific food products or for fibers whose physical and chemical characteristics are well specified (e.g., oat brans meeting specified parameters). Thus, if manufacturers can document, through appropriate studies, that the soluble fiber in their particular food is effective in lowering LDL-cholesterol, and has no adverse effects on other heart disease risk factors (e.g., HDL-cholesterol), then FDA encourages manufacturers to petition for a health claim for their particular product or ingredient. Additionally, if new evidence becomes available which more clearly identifies what type of soluble fiber is effective, this also would be appropriate for a petition.

16. Another comment stated that part of FDA's difficulty in interpreting data on dietary fiber and CVD results from the consideration of soluble fiber as a single nutrient instead of as a class of diverse substances. The comment stated that data exist to support at least one soluble fiber, β-glucan, as the substance responsible for the majority of the cholesterol-lowering effects observed with some fiber sources. Another comment stated that there is a preponderance of literature supporting oat bran and its hypocholesterolemic effects and that the active mechanism behind oat bran's effectiveness is the β-glucan component. The comment suggested that the agency allow foods to be identified that contribute to eating patterns that reduce the risk of disease.

FDA agrees, as discussed in the proposal, that dietary fiber is a diverse group of substances and not all soluble fibers are alike in their hypocholesterolemic properties. FDA also agrees, based on new data submitted as comments, that there is evidence to suggest that β-glucan has hypocholesterolemic properties. However, as noted in the meta-analysis (Ref. 125), other components of oats, such as tocotrienols and oat oil, may play a role in the reduction of blood LDL-cholesterol levels. However, FDA is authorizing a claim on fruits, vegetables, and grain products—foods that are good sources of soluble fiber and other substances that may have cholesterol-lowering properties.

17. Comments from a health professional organization stated that several studies have shown that soluble fibers, such as those in oat, beans, psyllium, and guar, appeared to lower serum cholesterol, at least when given in large amounts. The comment further stated that weight loss observed in some studies may possibly be far more important than fiber in contributing to cholesterol reduction.

FDA agrees that weight loss associated with test diets may affect the ability to differentiate between the effects of the test substance (i.e., soluble fiber) versus the well-documented effect of weight loss on blood total- and LDL-cholesterol. This was discussed in the meta-analysis submitted as a comment (Ref. 125). Several studies observed reductions in blood cholesterol levels in studies in which loss did not occur. For example, in a study by Marlett et al. (Ref. 124), submitted with another comment, there was no significant weight loss in either the control or soluble fiber (oat bran) groups during the fiber intervention period. Serum cholesterol was significantly lower in the oat bran group than in the control group. Spiller et al. (Ref. 87) reported no weight changes in two groups receiving either guar gum or oat fiber. Both groups experienced significantly lowered serum cholesterol. In two other studies (Refs. 118 and 120), there was no significant difference in the weight loss between subjects consuming oat bran (Ref. 120) or psyllium cereal (Ref. 118) and those consuming wheat bran. The oat bran group had significantly lower serum cholesterol than the wheat group and compared to the control period. Thus, while the agency agrees that weight loss may be a confounding factor, the new evidence is consistent with the concept that consumption of diets high in certain soluble fiber-rich foods, independent of body weight, has a beneficial effect on blood cholesterol levels.

E. Comments Regarding FDA's Interpretation of Specific Studies

Some comments cited references that were already reviewed by FDA or the consensus documents, or were studies of questionable relevance to human CVD (e.g., studies evaluating

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postprandial glucose response of fiber diets). Some abstracts were also cited that do not provide sufficient information for evaluation. Review articles that provided no new data were also included with some comments.

18. One comment stated that the study by Kahn et al. (Ref. 25) showed significant decreases in relevant parameters in the test groups versus baseline and that the authors concluded that soluble fiber "appears to be quite effective" in lowering those parameters. In the proposed rule, FDA reported that there was no significant difference in serum cholesterol between the test group and the control group.

FDA notes that it did report that a significant difference in serum cholesterol existed between baseline and intervention values if the results are examined without consideration of the immediate versus delay constraint of the design. The agency initially concluded that the study did not support an effect of oat bran on serum cholesterol lowering because of the lack of statistical significance when examining only the difference between the immediate intervention group and its control. FDA believes that the study design should have been modified to overcome this problem of the time delay in comparing the groups. However, after further review, FDA agrees with the authors (Ref. 25) that, after correcting for the time delay, the study does show that oat bran supplementation reduced serum cholesterol.

19. One comment criticized FDA for calling a "p value" of 0.052 in the paper by Anderson et al. (Ref. 5) "nearly significant." The comment suggested that a more precise term would be "borderline significant."

FDA acknowledges that the term "borderline significant" is more commonly used professionally, but considers that this does not negate the need for caution in reviewing the results of this paper.

20. One comment stated that FDA failed to report the modest effect, from a study by Bell et al. (Ref. 12), of a pectin-enriched cereal on serum cholesterol.

FDA disagrees with this comment. Of the two fiber-enriched cereals (one enriched with psyllium and the other with pectin) tested by Bell et al. (Ref. 12), FDA reported that only psyllium demonstrated a significant reduction in cholesterol. The agency correctly stated that the psyllium-enriched diet demonstrated significant lowering of total- and LDL-cholesterol, but that the pectin did not.

21. A comment disagreed with FDA's statement that the study by Davidson et al. (Ref. 15) did not demonstrate significant reductions from baseline levels in total cholesterol with daily intakes of up to 2 oz of oatmeal (1.2 to 2.4 g β-glucan/day) or 1 oz oat bran (2.0 g β-glucan/day) in persons on a Step 1 diet.

FDA correctly reported that only the higher fiber intake groups showed statistically significant effects. The small sample size may have prevented seeing an effect in the lower doses. FDA agrees that, based on the results of this study, an intake of soluble fiber (in this case, β-glucan from oats) of about 3 g per day or more was beneficial in that it resulted in a significant lowering of serum cholesterol in persons consuming a low-fat diet.

22. A comment asked FDA to consider a result from a study by Newman et al. (Ref. 50) which used β-glucan from barley and compared it to wheat fiber. The cholesterol levels of the high β-glucan group did not differ significantly from baseline after four weeks. The author explains this lack of significance by citing the small sample size and small amounts of β-glucan consumed.

FDA does not necessarily disagree with this comment, but considers that it was correct in not assessing the results as positive (i.e., a true difference exists) because a statistically significant effect was not demonstrated.

23. One comment stated that FDA failed to consider significant the results by Van Horn et al. (Ref. 68). In this study, the investigators tested the effects of oat-bran intervention on serum cholesterol levels in subjects with normal or mildly elevated serum cholesterol levels. The authors reported a difference ($p = 0.074$) in serum cholesterol between the oat group and the control after 8 weeks.

FDA did not consider this result significant because the small sample size was not a problem in this study and the p values reported are one-tailed. Such values allow leeway over the more conventional and conservative two-tailed tests.

24. One comment stated that FDA did not properly interpret the results of a study by McIntosh et al. (Ref. 44), which compared the cholesterol-lowering effect of β-glucan from barley to that of wheat fiber.

FDA disagrees with this comment. Although there was a significant difference between cholesterol levels of the two groups, this was largely due to a rise in total cholesterol that occurred in the wheat group compared to baseline. In this case, it is not possible to know whether wheat acted as a placebo, or whether wheat itself is cholesterol-raising. However, because the group fed barley did not show a significant lowering of cholesterol from their own baseline level, the agency does not find that a positive effect of barley was demonstrated.

25. Another comment addressed a study by Burr et al. (Ref. 13) that examined whether there was a change in mortality rates between men given dietary advice to increase fiber intake or to reduce fat intake. The comment was specifically concerned with FDA's conclusion that the study was not able to show a difference between mortality rates in the two groups. The comment stated that the results show that increasing fiber intake is no less effective than decreasing fat intake in the prevention of CHD.

FDA disagrees with this comment. Because there was no group in this study which acted as a control (no changes in diet), the study does not provide evidence that either diet in the studies is effective or that neither is effective. The agency finds that the study does not add to the evidence of the effects of fiber.

26. One comment stated that a study by Little et al. (Ref. 42) that shows that lowering fat is responsible for significant lowering of total cholesterol, while increasing fiber is not, did not specify the type of fiber (i.e., soluble versus insoluble) and should not be considered as part of the fiber-CHD evaluation.

FDA disagrees with this comment. The agency considered any fiber study which might be relevant to the health claim. However, the weight given to study results was influenced by several factors, including the quality and usefulness of the information on soluble fiber intakes.

27. One comment noted that the study by Demark-Wahnefried et al. (Ref. 16) showed a significant drop in total serum cholesterol in all three of the following dietary groups: A high fiber, low-fat diet; a low-fat diet alone; and a regular diet with fiber added. The comment contended that, because there was no significant difference between any of the groups, this study showed that increasing soluble fiber intake is as effective as reducing fat intake.

FDA disagrees with this comment. This study does not support a conclusion that soluble fiber is as effective as reducing fat intake. These results showed that the cholesterol-lowering effect of a low-fat diet was not further enhanced by the addition of fiber. Additionally, there was a significantly decreased consumption of fat and cholesterol in all groups; this is consistent with the hypothesis that fat displacement is one mechanism by

which high fiber diets lower total cholesterol.

28. Another comment also criticized FDA's review of the Demark-Wahnefried et al. study (Ref. 16). The comment stated that, according to the Keys equation for predicting changes in blood cholesterol levels from changes in intakes of fatty acids, only 40 percent of serum cholesterol's lowering is explained by changes in dietary fat.

FDA disagrees with this comment. The agency's evaluation of this study pointed out the lack of significant difference between cholesterol lowering on the regular diet plus oats or the low fat, low cholesterol diets. The study did not estimate how much, if any, of the remaining 60 percent is attributable to oat bran.

29. One comment stated that FDA misinterpreted the results of the study by Keenan et al. (Ref. 26) by failing to note that the control group decreased its soluble fiber intake over the study period, thus accounting for the return to baseline for serum cholesterol in this group by the end of the study.

FDA disagrees that it misinterpreted the results of this cross-over study, in which the authors compared the hypocholesterolemic effects of oat- or wheat-supplemented Step 1 diets with a control group on the Step 1 diet only. Although FDA recognizes the problem with the control group, the agency correctly reported that there was a lack of significance in the change in serum cholesterol in the oat-wheat group during the oat phase. Recognizing that the control group decreased its soluble fiber over the study period may suggest redoing the study with a better control of soluble fiber in this group.

30. Another comment also disagreed with FDA's criticism that the study by Keenan et al. (Ref. 26) did not have a placebo. The comment stated that the wheat group was considered a placebo because it has been well documented that wheat has virtually no cholesterol lowering properties. A similar comment was made regarding FDA's criticism of a study by Swain et al. (Ref. 57) in which wheat was also used as a placebo.

FDA has expressed concern about the use of wheat as a placebo due to its inconsistent effect on serum cholesterol in some reports. Although the study by Keenan demonstrated an increased total cholesterol in the "oat-wheat" group of 6 percent above baseline during the wheat period, in Swain's study the wheat group showed a 7 percent decrease in serum cholesterol. Based on these studies and other reviews, FDA now believes that these variations in serum cholesterol may be a function of the amount and method of administration of the wheat and must be reviewed with caution. Rather than discounting the use of wheat as a placebo, FDA believes that the placebo, whether it is wheat or another fiber, must be evaluated individually for each study.

31. One comment suggested that the FDA failed to note that the study by Davidson et al. (Ref. 15) was specifically designed to determine whether β-glucan has a dose-response effect on serum cholesterol after reducing and controlling for fat intake. Subjects in this study consumed a Step 1 diet with two levels of oat bran incorporated into the diet. FDA disagrees that it failed to note this point. The authors of the study stated that there is a "lack of continued dose response" (Ref. 15). In addition, the authors say that "the impact of fat substitution on serum cholesterol reduction with oat cereals cannot be completely excluded" due to the lack of isocaloric control for the higher-dose treatment groups (Ref. 15).

32. Another comment on the Davidson et al. study (Ref. 15) stated that FDA's criticism of the lack of a control group was not valid due to the 6-week wash-out period. The comment states that, during this wash-out period, the serum cholesterol values of all treatment groups returned to baseline levels, suggesting that the hypocholesterolemic effects observed were the result of oat β-glucan supplementation.

Although the wash-out period is not the equivalent to a true control, FDA agrees that, considered with the evidence from the intervention period, the decrease in serum cholesterol suggests an effect of β-glucan at the higher levels of intake.

33. One comment criticized FDA for failure to note regarding the study by Bell et al. (Ref. 11) that the psyllium group on the Step 1 diet had significant reductions in total cholesterol levels as compared to the placebo (wheat fiber) controls.

FDA disagrees with this comment. The problem with this study is that, during the second 8-week test period, the psyllium group's total cholesterol had risen to only 1.5 percent below the baseline level. The significant difference still exists between placebo and test group because the mean serum cholesterol level of the placebo group actually increased to a level higher than baseline. The agency believes that these results weaken the support for cholesterol-lowering effectiveness over time on this diet.

34. One comment stated that the study by McIvor et al. (Ref. 45), showing no effect of guar gum on serum cholesterol in a population of overweight noninsulin dependent diabetics, should not have been discussed in the proposed rule. The comment explained that this was not a typical population group (diabetics consume large amounts of fiber products to help with carbohydrate metabolism), and the objective of the study was to test the safety of guar. In addition, the comment states that the diets were uncontrolled so the results could be confounded by additional fat from the granola-type bars in which the guar gum was incorporated.

FDA disagrees with this comment. Although overweight diabetics may not be a typical group, FDA did not eliminate the noninsulin diabetics from the criteria for evaluating fiber studies; insulin-dependent diabetics are excluded, however. Although the objective of the study was not to evaluate cholesterol-lowering effects, this information was presented and FDA considered it to be relevant. In addition, adding fiber to a diet without changing the overall diet is probably a very typical form of consumer behavior. The agency also notes that it did not say that fiber intake had no effect in this study, but rather that the results are "inconclusive."

35. One comment addressed FDA's review of the study by Lo and Cole (Ref. 43), in which pooled periods only show a significant difference between the placebo and soy fiber groups. The comment stated that the placebo's effects on total cholesterol were insignificant, while soy's effects were significant.

FDA disagrees with this comment. As shown in table IV of the paper, the 2 percent decrease in serum cholesterol reported after soy fiber consumption in Group B is not significant. FDA questions the inconsistency of the results (i.e., after the placebo effect is gone, is Group B more representative of the effect?). The order of treatment effects on the results should have been considered in the conclusion.

36. One comment criticized FDA's review of the study by Superko et al. (Ref. 56), which FDA discounted as demonstrating significant differences between fiber groups. The comment stated that FDA has failed to consider the significant reductions in serum cholesterol levels between baseline and test group consuming guar gum.

FDA disagrees with this comment. While it is true that at 4 weeks there was a significant difference between total cholesterol levels from baseline, at 8 weeks the p value dropped to 0.15, which is not statistically significant. When FDA calculated the difference

between the placebo to guar supplementation at the 4 and 8 week intervals, neither was significant as defined by a p value of 0.05 or less.

37. One comment stated that FDA incorrectly reported results in the study by Beling et al. (Ref. 10). The comment stated that FDA reported nonsignificant reductions in serum cholesterol between the group using oat-enriched cereal and the control group.

FDA agrees with this comment. After reexamining the results, FDA notes that they show a significant difference between the two groups, thus adding support to a cholesterol-lowering effect of soluble fiber-rich foods in combination with consumption of a low-fat diet.

38. Another comment stated that the weight loss differences reported in the study by Beling et al. (Ref. 10) were not significant between groups, so effects of weight change should be similar. The comment also stated that it is not possible to completely "blind" a study that uses ready-to-eat cereal.

FDA agrees with the comment.

39. One comment stated that FDA criticized the lack of baseline fiber intake data in the study by Gold and Davidson (Ref. 19), but did not explain the significance of that assertion.

FDA considers baseline fiber intake data necessary to determine if the effect seen could have resulted from fat displacement in the diet.

40. One comment criticized FDA's evaluation of a study by Stewart et al. (Ref. 55) and stated that FDA failed to consider the effect after adjustment when reporting the study as nonconclusive of an effect. The study by Stewart and colleagues (Ref. 55) noted that the psyllium supplement administered had a nonsignificant effect on total serum cholesterol when dose was not considered, but a significant effect after adjusting for dose.

FDA disagrees with this comment. Referring to both Figure 1 and Table 4 in the study, the linear trend is driven by the higher dose values, which have very small numbers compared to the overall study population. In addition, the author has excluded the 739 control subjects in the dose-specific analysis for a dose of 0 (no psyllium intake), which, if included, would most likely eliminate any trend. The results of the study do not support any overall effect of psyllium on serum cholesterol.

41. One comment stated that FDA unnecessarily distinguishes studies using separate fiber supplements from those using fiber-enriched foods.

FDA disagrees with this comment. FDA is applying a consistent legal standard to its consideration of studies on fiber supplements and studies of fiber-rich foods. However, from a scientific standpoint there is reason to believe that the use of fiber at higher intakes and higher concentration (i.e., a fiber supplement taken as a single dose prior to meals) may well differ from the typical intake of fiber from foods (i.e., smaller amounts of fiber consumed throughout the day). If an effect is seen when fiber is consumed at higher intakes and higher concentrations, it cannot be assumed that there is a linear dose-response effect that will translate into significant effects at more usual levels of intake. Conversely, if an effect is seen when fiber is consumed with more typical intake from foods, it may not automatically translate into an effect from fiber supplements. Additionally, isolated fibers (as used in supplements) may vary in chemical and physical characteristics from native or less processed fibers. Since a mechanism of action for soluble fiber in reducing blood LDL-cholesterol levels has not been identified, it is possible that processing of soluble fibers may affect their ability to lower blood cholesterol levels.

F. Comments Regarding Applicability to the General Population/Public Health Aspects

42. One comment criticized FDA for including, in the dietary fiber-CVD proposal, the criterion that studies must be conducted in persons who generally represent the healthy U.S. population, i.e., adults with cholesterol readings below 300 mg/dL. The comment stated that this criterion eliminated many valid studies that demonstrate significant scientific agreement for a claim about the relationship between soluble fiber and CHD; and secondly, that these studies remain useful to demonstrate soluble fiber's hypocholesterolemic effects at lower doses, for longer durations, in conjunction with reduced-fat diets.

FDA agrees that populations at higher risk may provide a more sensitive group for identifying a nutrient/disease relationship. However, extrapolation of results from a high risk group to the general population must be done with caution and generally requires some confirmatory studies in the general population. FDA included, in its review, studies on persons considered to be at high risk, i.e., with levels of blood total cholesterol between 200 and 300 mg/dL. FDA, thus, included a large segment of the general population whose risk levels fall in this range, but excluded the much smaller segment of persons with blood total cholesterol levels above 300 mg/dL, because these people often have multiple and serious health problems, making it difficult to generalize results beyond the particular study populations. According to the National Center for Health Statistics (Ref. 79), only 5 percent of the U.S. adult population of men and women have serum cholesterol levels 300 mg/dL or higher. Results of two studies (Refs. 9 and 59) showed that subjects with a mean serum cholesterol level ≤300 mg/dL had significantly lowered serum cholesterol at the end of the test period compared to baseline. Final serum cholesterol levels, however, was still greater than 300 mg/dL. Thus these individuals remained severely hypercholesterolemic and at high risk for CVD.

It is also important to note that the hypocholesterolemic effect in these two studies (Refs. 9 and 59) and many of the other studies attenuated with time, and serum cholesterol levels increased toward baseline. Thus, the agency does not agree with the comment that such results are necessarily useful to demonstrate a long-term hypocholesterolemic effect of soluble fiber at lower doses. Interpretation of results depends on how well compliance with the test regimen was accomplished.

Of the other 33 studies reviewed in the proposed rule (56 FR at 60596 through 60609), the mean blood total cholesterol was in the mid- to upper-200's (mg/dL) because many of the subjects had individual serum cholesterol levels greater than 300 mg/dL. These studies were included in the evaluation of the relationship between dietary fiber and CVD if they met the other evaluation criteria.

43. Another comment criticized FDA for separately evaluating studies using "typical" or "usual" American diets (i.e., approximately 37 percent of calories from fat) and those using a reduced fat (Step 1) diet. The comment stated that the agency should have given equal weight to studies whether they involved a "typical" American diet or a reduced fat (Step 1) diet.

FDA disagrees with this comment. As stated in the proposed rule (56 FR 60582 at 60587), "Responses of blood cholesterol levels to dietary treatment are affected by many factors, including initial (baseline) blood cholesterol levels and dietary factors (i.e., the level of saturated fat and cholesterol in the diet)." Because serum cholesterol is responsive to dietary intakes of saturated fat and cholesterol, FDA separated the studies on the basis of whether fiber effects were being evaluated as part of a typical American diet or as part of a reduced fat diet.

Results of fiber studies become confounded when the test diet is not adequately controlled, or not assessed at all, and when subjects make their own changes to their diets by consuming less total and saturated fat. In such cases, the true effects of fiber, if any, cannot be adequately determined. Although the agency grouped studies based on type of diet, it did give them equal weight based on the evaluation criteria.

44. One comment stated that FDA failed to consider studies reporting only modest reductions in serum cholesterol as strong evidence of soluble fiber's effectiveness. The comment refers to the public health significance of even a small reduction in serum cholesterol; i.e., a 1 percent reduction in serum cholesterol levels predicts approximately a 2 percent reduction in CHD (Ref. 41).

FDA disagrees with this comment. FDA recognizes that changes in serum cholesterol in fiber-feeding studies are generally small. However, if, due to the sample size of the study, this change is not sufficient to demonstrate statistical significance beyond that which may occur by chance (generally accepted by epidemiologists and biostatisticians as $p<.05$), it cannot be concluded that a true effect has been observed.

45. Another comment stated that there is no scientifically valid basis for excluding studies involving subjects whose blood cholesterol levels exceed 300 mg/dL.

FDA disagrees with this comment. As stated above, 5 percent of the U.S. population have serum cholesterol levels greater than 300 mg/dL (Ref. 79). It is important to remember that "the magnitude of plasma lipid response is frequently related to the initial plasma lipid status of the experimental subjects. Persons with higher plasma lipids initially usually experience the greatest plasma lipid response to diet intervention" (Ref. 33). What may cause an effect to look significant may be driven largely by the magnitude of the change, which is more likely to be observed in those individuals with very high serum cholesterol levels. To base conclusions on one group that will respond to a much greater extent than another is misleading as to those persons with normal to moderately elevated serum cholesterol levels, who comprise 95 percent of the adult population.

46. One comment noted that population compliance was essential to the success of dietary intervention for improved public health and that adding fiber to the diet is more acceptable to consumers than removing fat.

FDA agrees that compliance is an important factor, but, with respect to fiber and CVD, it must first be established that addition of fiber alone to the diet is an effective means of reducing serum cholesterol.

G. Comments Regarding Issues of Study Design, Confounders, Fat, etc.

47. One comment stated that FDA criticized studies that do not control for the effects of low dietary fat when examining increased dietary fiber consumption and cholesterol reduction.

FDA disagrees with this comment. Although many studies provide compelling evidence of the effect of a combined low-fat, high fiber diet on lowering serum cholesterol, FDA examined the scientific evidence to determine whether a specific relationship existed between soluble dietary fiber and risk of heart disease, and whether sufficient scientific evidence was available to support a health claim for dietary fiber and heart disease.

48. Another comment criticized FDA's evaluation of a study by Van Horn et al. (Ref. 67) for inappropriately discounting the correlation of fiber intake with serum cholesterol by pointing out that many other nutrient intakes besides fiber showed correlations with cholesterol levels. The comment stated that dietary fiber had correlations with CHD that were as statistically significant as those for fat and CHD, and this argues for a finding that significant scientific agreement supports a claim about the relationship between fiber and CHD.

FDA disagrees with this comment. FDA again emphasizes that many other nutrient intakes in addition to dietary fiber show statistically significant correlations. In a cross-sectional survey analyzed in this manner, one of the first things that must be considered when many factors show significance is whether they are highly correlated with each other. If this is the case, displacement of fat in the diet by fiber is one explanation for the observed effect.

49. Another comment argued that, although FDA has stated there may be other micronutrients or components in vegetables, cereal, fruits and berries other than soluble fiber that may have contributed to the cholesterol-lowering effects of some soluble fiber-containing foods, the agency has failed to identify them.

FDA agrees that it did not identify other components in foods that may have serum cholesterol lowering effects. Its point in this statement was that attribution of effects to soluble fiber per se, when foods contain a wide range of vitamins, minerals, and other substances, is misleading. The authors of the meta-analysis (Ref. 125) also noted that other components of oats may play a role in the cholesterol-lowering properties observed in human studies.

50. Another comment criticized FDA's evaluation of a study by Van Horn et al. (Ref. 69).

FDA stands by its evaluation of the Van Horn study. FDA criticized the study because there are significant changes in diet between the control and test group in total fat intake, saturated fat intake, and monounsaturated fat intake, and the authors did not demonstrate that these changes did not contribute to the cholesterol-lowering effect observed.

51. Another comment suggested that weight loss is not a confounder, but rather a result of fiber's ability to effect weight reductions independently of changes in caloric or fat intake.

FDA disagrees with this comment. Although this may be a possible mechanism of action, no studies reviewed have provided clear evidence of this.

52. One comment stated that confounding variables and lack of a mechanism of action are not a valid basis for denying a link between ingestion of fiber and reduced risk of heart disease which experimental evidence shows in fact exists.

FDA disagrees with the comment's description of the basis for its proposed action. If factors such as weight loss, changes in diet, lifestyle changes, and/or exercise, which are known to influence serum cholesterol, are not controlled in a clinical study, or if analytical methods for determining the soluble fiber content in food sources are not clearly established, the specificity for an effect of soluble fiber on serum cholesterol cannot be determined. In its proposal, FDA made a tentative decision to deny a health claim regarding dietary fiber and CVD for a number of reasons, including confounding factors identified in many of the clinical studies reviewed, but not because there is no recognized mechanism(s) of action for hypolipidemic effects of different soluble fibers. For a more thorough discussion of FDA's proposal to deny a health claim on dietary fiber and CVD in the proposed rule, see 58 FR 60582 at 60591 through 60592. FDA believes that, for health claims to be educational and result in changed eating habits, the claims should be truthful and not misleading.

H. Conclusions From Comments

FDA agrees with many of the comments that a problem in determining the relationship between dietary fiber and heart disease is the fact that dietary fiber is a diverse group of chemical substances that may be associated with different physiological functions, and that the analytical methodology to identify the soluble fiber content of a food may not be predictive of the likely physiological effect.

IV. Decision to Deny a Health Claim Relating Dietary Fiber to Reduced Risk of CHD

Overall, the currently available scientific evidence is not sufficiently conclusive or specific for soluble fiber per se to justify use of a health claim relating the intake of dietary soluble fiber to a reduced risk of heart disease. A major limitation in designing and evaluating research studies has been the need for better defined measures of dietary soluble fiber and standardized descriptions for source, type, and amount of dietary soluble fiber. Commonly used analytical methodologies do not detect many of the characteristics that may vary among fibers and that may be related to biological function (e.g., particle size, chemical composition, water-holding capacity). Other components associated with soluble fiber in foods (e.g., tocotrienols) may also have some cholesterol-lowering capabilities. The inability to detect many of the differences among fibers, fiber components, and other substances in foods which contain soluble fiber, and the general lack of conclusions as to the mechanism(s) of action of soluble fibers raise questions about the ability of commonly used analytical measures of dietary fiber to adequately predict biological actions of specific fibers. For these reasons, FDA is not authorizing use of a health claim relating dietary fiber to a decreased risk of CHD.

FDA's decision is consistent with recent conclusions reached about the state of the scientific evidence by the National Heart, Lung, and Blood Institute of the National Institutes of Health (Ref. 155) and recommendations in the Institute of Medicine's report "Nutrition Labeling: Issues and Directions for the 1990s" (Ref. 81). This report notes that there has been great interest in the specific effects of dietary fiber on several chronic diseases. According to the report, the strongest argument for an increased consumption of dietary fiber is the important contribution it makes to normal bowel function. Clear scientific associations of fiber intake with the incidence of cancer, heart disease, and diabetes mellitus have not been made. The report indicates that one reason for this may be the difficulty in designing appropriate experiments to test specifically for the effect of dietary fiber. Foods high in dietary fiber are also generally low in calories and total and saturated fatty acids and devoid of cholesterol; thus, determination of a specific fiber effect in a feeding study is difficult. Moreover, according to the report, foods have a variety of fiber components and each may have different actions. Chemically and physiologically, cellulose, lignin, hemicellulose, pectin, and alginate (all relatively purified fiber types) behave differently. Wheat bran, oat bran, and rice bran (all heterogeneous mixtures of fibers) are not similar in composition. It is also very difficult to analyze dietary fiber chemically, and thus it is hard to correlate the role of specific fiber components to health effects (Refs. 48 and 81). Therefore, FDA is not authorizing the use on the labels and labeling of foods of health claims relating to an association between the ingestion of dietary fiber (particularly soluble fiber) and a reduction in the risk of heart disease. In reaching this decision, the agency considered all comments received in response to its proposed rule (56 FR 60582), and reviewed the scientific literature that became publicly available after the proposal's publication and data submitted with comments.

V. Decision to Allow a Health Claim on Foods Relating Diets Low in Saturated Fat and Cholesterol and High in Fruits, Vegetables, and Grain Products, Foods That Contain Fiber, Particularly Soluble Fiber, to a Reduced Risk of CHD

FDA has reviewed the numerous authoritative documents, including Federal government reports, as well as recent research on dietary fiber and CHD risk. In addition, the agency considered all comments received in response to its proposed rule. The agency has concluded that the publicly available scientific evidence supports an association between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products, foods that are low in saturated fat and cholesterol and are good sources of dietary fiber, to reduced risk of heart disease.

FDA agrees with the comments that show that dietary patterns that are low in saturated fat and cholesterol and high in fruits, vegetables (including legumes), and grain products are associated with a decreased risk of CHD. Although the specific roles of the numerous potentially protective substances in such plant foods are not yet understood, populations with diets rich in these foods experience many health advantages, including lower rates of heart disease. Currently, there is not scientific agreement as to whether the observed protective effects against heart disease are due to a combination of nutrient components of the foods, including soluble fiber, to other components of soluble fiber-rich diets (for example, potassium and magnesium), to displacement of saturated fat and cholesterol from the diet, or to non-nutritive substances in these foods.

Thus, the conclusion that diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products, foods low in saturated fat and cholesterol and containing soluble fiber, are associated with a reduced risk of heart disease is consistent with the available scientific evidence. The fact that these foods contain dietary fiber, particularly soluble fiber, can serve, therefore, as a useful marker for identifying those fruits, vegetables, and grain products which, when added to diets low in saturated fat and cholesterol, may help in reducing blood LDL-cholesterol levels. As discussed in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, statements about good nutrition that do not expressly or by implication refer to a substance are considered dietary guidance and not health claims. In this rule, FDA is authorizing the inclusion of a reference to dietary fiber (a substance) in a statement about the value of fruit, vegetables, and grain products in reducing the risk of heart disease. Thus, the health claim permitted under this regulation to be used on labels and labeling of certain foods associates diets low in saturated fat and cholesterol and high in vegetables, fruit, and grain products, that contain soluble fiber with a reduced risk of heart disease.

VI. Rationale and Description of the Final Regulation

A. Relationship and Significance Statements

In new § 101.77(a), the summary of the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber and reduced heart disease risk is consistent with the conclusions reached in the review of the scientific evidence. Although the specific roles of dietary soluble fiber, or

of specific soluble fibers and fiber components, and the multiple nutrients and other substances contained in these foods, are not yet fully understood, many studies have shown that diets high in soluble-fiber-containing foods are associated with lower blood LDL-cholesterol levels and with reduced risk of heart disease. These diets are generally low in saturated fat, cholesterol and total fat, nutrients known to have a detrimental effect on blood LDL-cholesterol levels, and therefore, on risk of heart disease. Dietary soluble fiber can be used as a marker to identify the types of foods which correlate with reduced heart disease risk, and whose addition to diets low in saturated fat and cholesterol is considered to be useful in lowering blood LDL-cholesterol (Ref. 66). The relationship statement in § 101.77(a) also includes other information about heart disease, such as risk factors, as in other authorized health claims.

New § 101.77(b), on the significance of the relationship between consumption of diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber and reduced risk of heart disease, includes the information that U.S. diets tend to be high in saturated fat and cholesterol and low in fiber-containing fruits, vegetables, and grain products. A discussion of current dietary guidelines on recommended servings of fruits, vegetables, and grain products is also provided.

B. Nature of the Claim

In new § 101.77(c)(2)(i), FDA is authorizing a health claim relating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber to reduced risk of heart disease. In new § 101.77(c)(2)(i)(A), the agency is requiring, consistent with other authorized claims, that the relationship be qualified with the terms "may" or "might." These terms are used to indicate that not all persons can necessarily expect to benefit from these dietary changes.

In new § 101.77(c)(2)(i)(B), the agency, consistent with other authorized claims, is requiring that the claim use the specific terms "heart disease" or "coronary heart disease" to define the type of disease dealt with by this claim. These disease terms reflect terms commonly used in dietary guidance materials, and are also reflective of the scientific evidence which links these dietary factors to heart disease risk via the intermediate mechanism of reducing blood LDL-cholesterol levels, rather than to the broader category of cardiovascular disease.

In new § 101.76(c)(2)(i)(C), the agency is requiring that the claim discuss only those fruits, vegetables, and grain products that contain dietary fiber, rather than all fruits, vegetables, and grain products. Diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, are correlated with reduced heart disease risk. Thus, a claim discussing those fruits, vegetables, and grain products that contain the marker nutrient, but does not attribute a protective effect to soluble fiber, is consistent with current scientific knowledge.

New § 101.77(c)(2)(i)(D) specifies the terms that can be used to describe the fiber component of the fruits, vegetables, and grain products that bear a health claim. Consistent with the state of the scientific evidence, this paragraph permits a choice among a number of terms, but does not allow terms for specific types of fiber to be used, e.g., those connoting the origin of the fiber. The term "soluble fiber" may be used in combination with a more general term for fiber. This permits reference to soluble fiber, which is a useful marker nutrient for foods associated with reduced risk of heart disease. However, the present scientific evidence does not permit a determination of whether it is the soluble fiber or other components in these foods or displacement of fat that provides the protective effect. Given these uncertainties about the specific role of soluble fiber, it would be misleading to place undue emphasis on soluble fiber standing alone.

New § 101.77(c)(2)(i)(F) requires that health claims specify that development of heart disease depends on many factors. This requirement is intended to prevent consumers from being misled that fruits, vegetables, and grain product intake is the only factor connected with heart disease risk.

In new § 101.77(c)(2)(i)(E), FDA is prohibiting, consistent with other authorized health claims, more specific use of dietary terms than is warranted by the current state of the scientific evidence. New § 101.77(c)(2)(i)(G) is also consistent with other authorized health claims, and prohibits any attribution of degree of risk for heart disease and fiber-containing fruits, vegetables, and grains. These requirements also standardize use of terms, thus minimizing consumer confusion as they compare food labels across products, or as they compare a health claim to the nutrition information panel.

C. Nature of the Food

New § 101.77(c)(2)(ii)(A) requires that the food bearing the health claim be or contain a fruit, vegetable, or grain product. Because the claim relates to diets high in these foods, it would not make sense for it to appear on the labeling of another type of food. A health claim that appears on a food that meets all the requirements in § 101.77(c)(2)(ii), but contains only a trivial amount of fruit, vegetable, or grain product, could be considered misleading and might misbrand the food under section 403(a) of the act.

FDA, consistent with the requirements for the health claim on dietary saturated fat and cholesterol and heart disease (published elsewhere in this issue of the **Federal Register**), is requiring in new § 101.77(c)(2)(ii)(B) that foods bearing the health claim meet requirements for "low saturated fat," "low cholesterol," and "low total" fat, or alternatively, belong to a class of products that is "low in saturated fat," "low in cholesterol," and "low in total fat." Low saturated fat and cholesterol diets are associated with reduced heart disease risk. Low or negligible total fat is also one of the characterizing features of diets rich in fiber-containing fruits, vegetables, and grain products. Because the effects of saturated fat and cholesterol are not readily separated from the effects of other nutritive components of fruits, vegetables, and grain products, and because the scientific evidence linking diets low in saturated fat and cholesterol to reduced risk of heart disease is strong, saturated fat and cholesterol are specified as qualifying nutrients. Total fat is also specified as a qualifying nutrient because a low content of total fat is characteristic of dietary patterns which relate to lower heart disease risk, and because it facilitates the ability of consumers to achieve diets low in saturated fat and cholesterol. (See final rule on "Dietary Saturated Fat and Cholesterol and Coronary Heart Disease," published elsewhere in this issue of the **Federal Register**).

In new § 101.77(c)(2)(ii)(C), FDA is requiring that fruits, vegetables, and grain products bearing the authorized health claim contain at least 0.6 g of dietary soluble fiber per reference amount commonly consumed. Because soluble fiber is a qualifying nutrient, FDA, in new § 101.77(c)(2)(ii)(D), is requiring declaration of soluble fiber content consistent with requirements in § 101.9(c)(6)(i)(A). The qualifying value of 0.6 g of soluble fiber is based on several considerations. First, an exper. panel convened by LSRO (Ref. 39)

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recommended total dietary fiber intakes of 20 to 30 g daily for adults (see final rule on daily reference values published elsewhere in this issue of the **Federal Register**). It further recommended that approximately 25 percent (or about 6 g) of this be soluble fiber. This level of soluble fiber represents the same ratio of soluble to insoluble fiber normally found in foods and for which there is a long history of use, and therefore was considered by the panel to be safe. Since current U.S. dietary fiber intakes, including soluble fiber intakes, are estimated to be approximately half of the recommended levels, Americans would need to double their intakes to meet the current dietary guidelines. A total daily intake of 6 g of soluble fiber from fruits, vegetables, and grains is consistent with current dietary guidelines for the general population.

The qualifying criterion of 0.6 g per reference amount customarily consumed is also consistent with the definition of a "good source" of a nutrient (i.e., 10 percent of the daily reference value (DRV)) in the final rule on general requirements for nutrient content claims published elsewhere in this issue of the **Federal Register**. Although there is no DRV for soluble fiber, the requirement that a nutrient be present at 10 percent of a reference standard has been set as a qualifying level in other regulations authorizing health claims. (See the final rules on antioxidant vitamins and cancer and on fiber cancer published elsewhere in this issue of the **Federal Register**.) The 10 percent level is deemed useful and appropriate, because very few foods could naturally meet the requirement for a "high" source of soluble fiber. The current dietary guidance recommendations of five or more servings of fruits and vegetables and six or more servings of grain products daily, if followed, would likely result in intakes of soluble fiber close to or exceeding the recommended daily intake of 6 g. Thus, use of a qualifying criterion consistent with that used to define a "good" source for nutrients which have DRV's provides for an amount that allows a number of fruits, vegetables, and grain products to qualify, and is consistent with current dietary guidelines for general dietary patterns. Without this alternate level, very few fruits, vegetables, and grain products would qualify for the health claim, which would be contrary to the available scientific evidence and to the purpose of health claims.

Section 101.77(c)(2)(ii)(C) also requires that foods qualify as a good source of soluble fiber based on their natural level of soluble fiber. This means that foods which require fortification with soluble fiber, in order to meet the qualifying criteria for the health claim, cannot bear the claim. This requirement is consistent with the scientific basis for the claim, that is, that intakes of fruits, vegetables, and grains in their native form correlate with reduced heart disease risk. Because there are not sufficient data that specifically identify dietary soluble fiber, or particular components of soluble fiber, as the cause of a reduction in heart disease risk, and because this nutrient is being used as a marker for the substance or substances in fruits, vegetables, and grain products that provide the observed protective effect, it is the native composition of the foods that identifies their usefulness.

D. Optional Information

Under new § 101.77(d), similarly to other authorized health claims, health claims may identify additional risk factors for heart disease. The regulation specifies the factors that may be listed; all are risk factors about which there is general scientific agreement. This additional information can provide a context that is useful for an understanding of the relationship of the diet to the disease, but manufacturers are cautioned that it should not be presented in a way that is misleading to the consumer. A health claim may also indicate that reductions in saturated fat and cholesterol intake and consumption of fruits, vegetables, and grain products are part of a total dietary pattern that is consistent with the latest "Nutrition and Your Health: Dietary Guidelines for Americans," published jointly by the U.S. Department of Agriculture and the U.S. Department of Health and Human Services. Consistent with other health claim regulations, the claim may also include information on the prevalence of heart disease in the United States. In order to ensure that this information is valid, the agency is requiring that it come from one of three specified authoritative sources. Finally, because consumers frequently know their cholesterol levels or can determine their levels through readily available facilities in shopping malls and health clinics, the agency, similarly to other authorized health claims, is requiring that when information in the claim allows consumers to "self-diagnose" their own risk level, that additionally, the claim indicate the need for medical guidance if a consumer falls within a risk category.

Similarly to the requirements in § 101.73 on "Dietary Saturated Fat and Cholesterol and Coronary Heart Disease," the claim may indicate that the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grains that contain fiber, particularly soluble fiber, is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol." Such information is useful to consumers, but could add unnecessarily to the length and complexity of the required health claim. For these reasons, this provision is optional rather than mandatory.

E. Model Health Claims

In new § 101.77(e), FDA is providing model health claims to illustrate the requirements of new § 101.77. FDA is not prescribing specific language for claims, but certain elements are required, and these models include the required elements.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–854), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's

discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

IX. References

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.71 is added to subpart E to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(b) Dietary fiber and cardiovascular disease.

3. New § 101.77 is added to subpart E to read as follows:

§ 101.77 Health claims: fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.

(a) *Relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams per deciliter (mg/dL) (6.21 (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(3) Populations with relatively low blood cholesterol levels tend to have dietary patterns that are not only low in total fat, especially saturated fat and cholesterol, but are also relatively high in fruits, vegetables, and grain products. Although the specific roles of these plant foods are not yet fully understood, many studies have shown that diets high in plant foods are associated with reduced risk of coronary heart disease. These studies correlate diets rich in fruits, vegetables, and grain products and nutrients from these diets, such as some types of fiber, with reduced coronary heart disease risk. Persons consuming these diets frequently have high intakes of dietary fiber, particularly soluble fibers. Currently, there is not scientific agreement as to whether a particular type of soluble fiber is beneficial, or whether the observed protective effects of fruits, vegetables, and grain products against heart disease are due to other components, or a combination of components, in these diets, including, but not necessarily limited to, some types of soluble fiber, other fiber components, other characteristics of the complex carbohydrate content of these foods, other nutrients in these foods, or displacement of saturated fat and cholesterol from the diet.

(b) *Significance of the relationship between diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events; such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals, including persons with blood cholesterol levels in the normal range. Additionally, consuming diets high in fruits, vegetables, and grain products, foods that contain soluble fiber, may be a useful adjunct to a low saturated fat and low cholesterol diet.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. Intakes of fiber-containing fruits, vegetables, and grain products are about half of recommended intake levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Recommended total dietary fiber intakes are about 25 grams (g) daily, of which about 25 percent (about 6 g) should be soluble fiber.

(4) Current dietary guidance recommendations encourage decreased consumption of dietary fat, especially saturated fat and cholesterol, and increased consumption of fiber-rich foods to help lower blood LDL-cholesterol levels. Results of numerous studies have shown that fiber-containing fruits, vegetables, and grain products can help lower blood LDL-cholesterol.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber, particularly soluble fiber, with reduced risk of heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the following terms: "heart disease" or "coronary heart disease;"

(C) The claim is limited to those fruits, vegetables, and grains that contain fiber;

(D) In specifying the dietary fiber, the claim uses the term "fiber," "dietary fiber," "some types of dietary fiber," "some dietary fibers," or "some fibers;" the term "soluble fiber" may be used in addition to these terms;

(E) In specifying the fat component, the claims uses the terms "saturated fat" and "cholesterol;" and

(F) The claim indicates that development of heart disease depends on many factors; and

(G) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit, vegetable, or grain product.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food.

(C) The food contains, without fortification, at least 0.6 g of soluble fiber per reference amount customarily consumed;

(D) The content of soluble fiber shall be declared in the nutrition information panel, consistent with § 101.9(c)(6)(i)(A).

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for heart disease about which there is general scientific agreement: A family history of coronary heart disease, elevated blood-, total- and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of diets low in saturated fat and cholesterol, and high in fruits, vegetables, and grain products that contain fiber to heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL-cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber and coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term "total fat" in addition to the terms "saturated fat" and "cholesterol."

(5) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated blood total- and LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or

normal blood total- and LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, GPO.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain soluble fiber:

(1) Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.

(2) Development of heart disease depends on many factors. Eating a diet low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that contain fiber may lower blood cholesterol levels and reduce your risk of heart disease.

Dated: November 6, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

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Dietary Fiber and Cardiovascular Disease

Study	Study Design	Subjects	Methods	Results	Comments
Anderson et al., 1991 (Ref. 92).	Intervention, parallel, placebo-controlled, randomly assigned to treatment groups after 8 weeks of diet therapy on American Heart Association (AHA) Step 1 diet and stratification by gender and cholesterol level. Purpose of study: to compare hypocholesterolemic effects of two bulk laxatives relative to psyllium and placebo.	163 mild to moderately hypercholesterolemic males and females enrolled in study, 117 completed 8-week diet therapy, and 105 completed the study protocol. Subjects, ages 30 to 70 years, were free living. (total serum cholesterol (TC) 200 to 300 mg/dL and body weight within 130% of ideal.	Subjects consumed AHA Step 1 diet for an 8-week adaptation period followed by an 8-week parallel treatment period. Four doses of test product were taken each day, including one before each meal. Diet monitored with 3-day food records at 4-week intervals. Step 1 diet: Energy from fat--30 to 33%; protein--17 to 18%; carbohydrate (CHO)--46 to 51%; Cholesterol--<300 mg/day. Bulk laxatives tested: g/day psyllium powder (PSY) 10.2 methylcellulose powder (MC) 6 or 10.2 calcium polycarbophil tablets (CP) 4 cellulose placebo (PLA) 4	Average Diet During Test Period PSY MC CP PLA Energy, Cal 1755 1742 1833 1760 Fat, % of Cal 30 33 32 31 Protein, % Cal 17.6 18 17.5 16.7 CHO, % 49.8 46.1 47.6 50.9 Fiber, g Total 14.5 14.2 13 15.1 Soluble 4.6 4.4 4 4.7 CHOL, mg 225 219 213 190 Baseline Diet phase: TC ↓4.5%; LDL ↓4.7%; HDL ↓2.9%; TG ↓5.8% The difference in TC between the PSY group and the placebo is not significant (↓4.3% difference). Lipids Values--Diet + Fiber Comparison to baseline PSY MC CP PLA TC, % ↓8.2* ↓5.3* ↑2 ↓3.9 LDL, % ↓13.4* ↓7.8* ↑4.1 ↓4.6 HDL, % ↓2.2 ↓4.8* ↑4.8 ↑0.1 LDL/HDL ↓10.8* ↓3.8 ↓1.2 ↓4 TG, % ↑12.4 ↑8.2 ↓10.9* ↓7.3 * Significant from baseline.	No weight change by more than 0.5% from baseline. Weights at baseline and final were not given. Compliance reported as good for all test groups.* Side effects reported were mostly gastrointestinal. Choice of cellulose as a placebo is questionable. Cellulose may actually have a cholesterol lowering effect. *No data on saturated fat

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Study	Study Design	Subjects	Methods	Results	Comments
Bremer, J. M. et al., 1991 (Ref. 91).	Intervention, randomized, single-blind, cross-over, placebo controlled.	12 hyperlipidemic men and women (TC 220 to 340 mg/dL), free living.	Subjects were stabilized on phase II AHA diet for 3 months prior to study. Base diet: fat 25 to 30% total energy; saturated fat <8%; polyunsaturated fatty acid (PUFA) 5 to 10%; monounsaturated fat >10%; cholesterol <250 mg/d; fiber >20 g/1,000 Calories. Two-week run-in with the addition of bread to the diet prior to test. Subjects randomized to oat or wheat group for 4 weeks, followed by 2-week washout, then cross-over to other diet. Bread added to diet in place of other CHO foods. Men consumed 10 to 12 slices bread/day; women consumed 6 slices. Dietary assessment by food records and bread charts. Oat bread: Total fiber, g% 5.2; Insoluble fiber, g% 4.0; Soluble fiber, g% 1.2 Wheat bread: Total fiber, g% 6.1; Insoluble fiber, g% 5.2; Soluble fiber, g% 0.9 Oat bran intake: 34.2 to 68.4 g/day Total dietary fiber intake: Oat period 32.2 g; Wheat period 34.1 g	At beginning of first study period, there was no significant difference between TC, LDL, and HDL between groups. At end of 4 weeks, no significant difference between lipid parameters. TC, mg/dL: Oat bran Week 0 286, Week 4 274, % change -4.1; Wheat bran Week 0 297, Week 4 286, % change -3.9 LDL % change from baseline: Oat bran -5.4; Wheat bran -6.8 HDL % change from baseline: Oat bran +10.3; Wheat bran +0.7 Mean body weights did not change during the oat period but decreased significantly during the wheat period.	There was no measure of dietary soluble fiber. Subjects increased consumption of PUFA and decreased intake of saturated fat (all NS) during test period. Investigators accounted for ↑ in fat consumption as due to use of PUFA margarine with bread. Oat bran bread was no better than wheat bran bread on lowering serum CHOL when subjects were on AHA diet. Small sample size.
Leadbetter J. et al., 1991 (Ref. 83).	Intervention, randomized, not blinded.	40 men and women, ages 25 to 64 (TC 250 to 348 mg/dL), free-living.	A four-by-four Latin square design; subjects added 0, 30, 60, and 90 g/day oat bran to their usual diet for 1 month intervals. No washout between periods. Oat bran provided in weighed sachets and detailed advice and recipes were provided. Five-day food records were kept prior to study and single-day records were kept during study periods. Beta-glucan content of oat bran was 3.7 to 4.2%.	Base diets (excluding oat bran): 0 g/d: Cal. 1854, % Fat 36.6, % CHO 45.3, % Sat Fat 13.5, Fiber, g 27, Starch, g 64 30 g/d: Cal. 1947, % Fat 34.7, % CHO 49.2, % Sat Fat 13.0, Fiber, g 23, Starch, g 86 60 g/d: Cal. 2017, % Fat 33.5, % CHO 50.2, % Sat Fat 13.4, Fiber, g 26, Starch, g 93 90 g/d: Cal. 2017, % Fat 34.0, % CHO 48.6, % Sat Fat 14.0, Fiber, g 24, Starch, g 99 Results: No S effect of OB at any dose on TC or LDL; no dose-related trend and no correlation between bran dose and change in CHOL conc. Oat Bran Intake, g/day: 0 / 30 / 60 / 90 TC, mg/dL: 278 / 284 / 279 / 273 LDL, mmol/L: 4.77 / 4.65 / 4.65 / 4.58 HDL, mmol/L: 1.56 / 1.49 / 1.49 / 1.42	Authors state that OB used in this study may be lower in SF content than the OB used in studies showing ↓ CH with OB supplementation. No dietary or body weight data.

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Study	Study Design	Subjects	Methods	Results	Comments
Resnicow, K. et al., 1991 (Ref. 86).	Health survey, not controlled.	31 Seventh Day Adventist, ages 5 to 46 years (8 children 5 to 17 yrs; 27 adults 19 to 46 yrs); mean serum CH 131.5 mg/dL; free living.	Subjects chosen had not consumed food of animal origin (including meat, poultry, fish, eggs, milk or other dairy products) for at least 6 mo prior to study. Lipid levels were reported separately for children. There were no blood lipid values for omnivore controls, so derived these values from Lipid Research Clinics Population Studies Data Book for basis of comparing vegans and omnivore controls. Current food intake measured using a quantitative food frequency questionnaire based on weekly consumption and typical portion sizes. Fiber intake for vegans: 45 g/day, controls: 20.	Results for adults only; vegans observed mean values, mg/dL; expected; % differ.: TC 139 182 -23 LDL 81 116 -30 HDL 54 50 +8 *Statistical significantly not reported. Vegans had 8 lower daily intake of energy; % energy from fat (11% versus 38%), total fat, saturated fat, monounsaturated fatty acid, and CHOL; and protein; also 8 higher intake of fiber.	There are multiple confounding factors not addressed in this survey. Exercise pattern, lifestyles, and body weight are just a few examples. Soluble and insoluble fiber were not assessed. Foods consumed in greater frequency by vegans: almonds, cashews, and their nut butters, dried fruits, citrus fruits, soy milk and greens. These foods contributed almost 40% of daily energy (only 7% for controls).

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Study	Study Design	Subjects	Methods	Results	Comments
Spiller, G. A. et al., 1991 (Ref. 87).	Intervention, randomized, cross-over.	13 male and females, 62 ± 3.0 years, TC 204 to 276 mg/dL, free living.	Three-day food record kept during baseline period and during 3rd week of treatment. Each treatment dose was preweighed in pouches; 3-week supply given to subjects at start of each test period. Both fiber were mixed with water or other fluid and consumed before each meal. Subjects remained on regular diets. Test periods: 21 days then cross-over to other fiber for 21 days. Blood lipid values made on days 14 and 21 during treatment period and on days 16 and 16 after treatment stopped. Fiber sources: guar gum: 15 g/day providing 11 g/d dietary fiber and 10 g/d SF; oat fiber source: 77 g/d providing 11 g/d dietary fiber and 5 g/d SF, 3.3 g β-glucan.	TC / LDL mg/dL / HDL Baseline 244 / 152 / 62 Guar at day 14 217 / 124 / 63 day 21 219* / 126* / 63 oat bran at day 14 235 / 142 / 62 day 21 236* / 143* / 62 * significant from baseline. Guar: 11% ↓ TC Oats: 6% ↓ TC	Study needs a control group. Changes in TC for both treatment groups took place within 14 days with no significant changes taking place between days 14 and 21. Limitations of study: Short test period. No washout between test periods. Baseline diets and dietary intake during treatment periods not reported; total dietary soluble fiber was not reported. Small sample size. No dietary data. No weight changes. Both guar and oat fibers consumed before meals--not typical dietary intake.
Cara, L. et. al., 1991 (Ref. 84).	Intervention.	10 men and women (8 women), 35 to 68 years, TC 254 to 367 mg/dL, 6 had mild to severe hypertriglyceridemia, free living.	Subjects consumed regular diet for one week as baseline period, followed by 4 weeks on 30 g wheat germ (2.9 g dietary fiber), then 4 weeks on regular diet with no supplementation. Base diet monitored by 7-day food recall; 3-day food recall during last week of test period. Base diet: pro. 14.4% energy; fat 35.9%, refined CHO 8.7%, complex CHO 41%, dietary fiber 13.6 g/d, alcohol 6 g/d.	Baseline / Wheat Germ / Follow up TC, mg/dL 302 / 276* / 284 LDL, mg/dL 191 / 189 / 195 HDL, mg/dL 41.5 / 47 / 50 * Significant from baseline TC after final 4 weeks with no wheat germ not significantly different from baseline.	No control. Small sample size, no reporting of dietary soluble fiber and saturated fat in diet during baseline and treatment periods. Authors speculate that the protein content of wheat germ (high in vegetable protein) could account for the results observed. No saturated fat data.

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Study	Study Design	Subjects	Methods	Results	Comments
Rawatra, A. et al., 1991 (Ref. 88).	Intervention.	20 overweight men and women (bodyweight 10% higher than Standard Weight for Height of Life Insurance Company India), TC 172.5 to 277.5 mg/dL, free living.	Subjects added 15 g guar gum to normal diet for 6 weeks. 10 g of guar was consumed in form of salted biscuits and 5 g was mixed with flavored drink 10 to 15 minutes before main meal. 1/5 of normal diet was collected for 3-days prior to start of test period and during the last week of the test period and analyzed for nutrient composition.	Baseline / Final / % change TC, mg/dL 212 / 176 / ↓16.7* LDL, mg/dL 144 / 105 / ↓26.5* MDL, mg/dL 54.8 / 55.4 / ↑1.5 TC/MDL 3.9 / 3.2 / ↓13.7%* * significant.	Total dietary fiber, dietary soluble fiber and saturated fat were not reported. No body weight data.
Tinker, L. F. et al., 1991 (Ref. 89).	Intervention, randomized, cross-over, Subjects acted as own controls.	41 men, ages 39 to 79, TC 201 to 290, free living. 6 had history of cardiovascular disease or CV surgery.	Dietary records made from self-reported food records collected every other day for 2 weeks prior to test. Food records kept during test periods. Subjects consumed either grape juice (GJ) (360 mL/day) or 12 prunes (PR) (100 g/d) for 4 weeks, followed by cross-over to other diet for additional 4 weeks. 100 g of prunes provides 6 to 7 g DF, of which approximately 60% is pectin.	Base diet / GJ diet / PR diet Energy 2522 / 2572 / 2579 Pro, % 16 / 15 / 14 Fat, % 33 / 30 / 30 CHO, % 47 / 51 / 51 alcohol, % 4 / 4 / 5 CHOL, mg 276 / 255 / 277 DF, g 21 / 18 / 26 TC, mg/dL 226 / 230 / 226 LDL, mmol 3.89 / 4.09 / 3.92 MDL, mmol 1.38 / 1.27 / 1.26 There was no difference in TC levels between baseline diet & prune diet. Percent of energy from CHO on GF and PR diets increased, % fat and Pro decreased. Fiber intake increased on PR diet, decreased on GJ diet.	Authors compared results of prune diet to grape juice noting that plasma cholesterol tended to be lower at the end of the prune period, although not statistically significant.

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Study	Study Design	Subjects	Methods	Results	Comments
Karlander, S. et al., 1991 (Ref 85).	Intervention, controlled, randomized, cross-over.	13 men and women with NIDDM, mean TC 275 mg/dL, free living. 5 were on chronic treatment with beta-blockers and diuretics because of hypertension; 8 were only on diet treatment with sulfonylurea (SU).	Study was divided into three 6-week periods: a run-in period and 2 study periods. Run in period: subjects given routine dietary counseling aimed at optimizing body weight and glucose control. Subjects then randomized to start fiber-rich diet or continue with regular diet (control). After first test period, subjects switched to other diet. Medications were left unchanged. Diet history and weights were taken every 3rd week. Dietary advice: energy reduction for obese patients--CHO 55% energy, fat 30%, Pro 15%. Fiber: beet fiber--30 g Fibrex/day (16 g DF) divided into thirds and taken with each meal. Diet history showed base diets: 44% energy as CHO, 40% fat, 16% Pro, mean DF in control diet and SU-tx patients was 18 g/day. TDF during test period was 34 g/day.	During run-in period SU tx group had 8 loss in body mass index; no other weight loss occurred with either group during the test periods. Diet group / SU group TC, mg/dL fiber 278 / 247* control 275 / 275 *Significant difference from SU control group.	Cholesterol lowering (10%) only in patients treated with SU. Authors state that hypocholesterolemic effect of this magnitude appears to be common during fiber treatment of NIDDM. Authors also note that another study noted a similar effect of guar in insulin-treated, but not SU-treated patients with NIDDM. They conclude that this suggests that a hypocholesterolemic effect of fiber in NIDDM patients is not linked to the type of treatment but may be explained by patient selection. Beet fiber had no effect on serum triglycerides or in glucose control in this study. No body weight data.

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Study	Study Design	Subjects	Methods	Results	Comments
Israelsson, B. et al., undated (Ref. 86).	Intervention, placebo controlled, double blind, cross-over.	27 women, 55 to 56 years, TC 263 to 297 mg/dL, free living, selected from health screening program concerned with cardiovascular disease risk factors and the effects of high alcohol consumption.	One month run-in period on a moderate cholesterol, low fat diet with increased ratio of PUFA/SFA; followed by randomized assignment to intervention or placebo group for 1 month, then cross-over. Placebo (bread crumbs or bread crumbs with bread) 30 g/day (3.5% fiber). Beet fiber (crumbs packed in 5 g portions or as bread with 3 g fiber/slice) 30 g/day. Beet fiber, Fibrex: SF 20%, IF 55%, TDF 75%. Diets provided between 1615 to 1696 Cal, 17 to 19.7% Pro, 27.6 to 26.9% fat. Total fiber 11.7 to 14.7 g/day (low fiber periods) and 33 to 34 g/day (high fiber periods).	Compared to placebo, beet fiber reduced serum cholesterol $ after 2 weeks. After 4 weeks, the difference was not significant. MEAN DIFFERENCE AFTER INTERVENTION (Fiber minus Placebo) mg/dL TC LDL HDL After 2 weeks -10.0* -0.5 -3.1 w/ fiber After 4 weeks -7.7 -11.6* +4.3 * Significant.	Subjects made changes to their diet after the run-in period by significantly decreasing their intake of alcohol. No report on the intake of dietary fat, especially the amounts of saturated and polyunsaturated fat consumed during test periods. Soluble fiber intake from diets not reported. Subjects on fiber consumed $ higher energy from fat; placebo subjects consumed $ more CHO. Limitations of study: short duration of study. No body weight data.
Kirstem, R. et al., 1989 (Ref. 97).	Intervention, controlled.	13 men and women (7 with type IIa and 6 with type IIb hyperlipidemia), mean age 57.2 yrs, mean TC 266 mg/dL, free living.	Study was divided into three phases: a 30-day pretreatment observation phase, 60 days of treatment, and 60 days of post-treatment observation. During test period subjects consumed 6 g of guar with water before each main meal (total of 12 g guar/day). Subjects instructed to avoid cholesterol-rich foods during the study.	PreTx Tx TC, mg/dL 266 251* LDL, mg/dL 213 186* HDL, mg/dL 46 44 *Significant compared to baseline Total cholesterol, LDL and HDL all returned to baseline 60 days after cessation of treatment.	Sample size was small. Dietary intakes were not reported. No control group.

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Study	Study Design	Subjects	Methods	Results	Comments
Jenkins, et al., unpublished (Ref. 94).	Intervention, randomized, cross-over controlled feeding.	11 normal subjects (6 men, 5 postmenopausal women) with mildly increased blood cholesterol. (mean = 243 mg/dL) (3 Type IIa, 7 Type IIb, 1 Type IV), free living.	After a 3-month treatment with the AHA Step 2 diet, Ss randomized to a high soluble fiber diet (SF) or a high insoluble fiber (IF) diet for first test period. Test period 1 to 16 weeks; 2-month washout on Step 2 diet only; cross-over to test period 2 to 16 weeks. Step 2 diet: <20% kilocalories total fat, 20% Pro, 60% CHO, <50 mg cholesterol. The SF diet provided fiber from beans, peas, lentils, barley, oat bran, and psyllium enriched cereal. Ss received foods from the clinic, but lived at home. SF diet provided 16 g SF/d and 37.5 g/d IF. IF diet provided 12.8 g SF/d and 42.1 g/d IF.	Both diets (SF and IF) reduced total and LDL cholesterol. SF diet reduced total cholesterol by 6.3% and LDL cholesterol by 8.6% compared to the IF diet. Insoluble Fiber Diet Baseline / After 16 Weeks TC, mg/dL 242 / 226 LDL,mg/dL 163 / 152 Soluble Fiber Diet TC, mg/dL 257 / 211* LDL, mg/dL 172 / 139* *Significantly lower compared to IF diet.	Well controlled study. The "soluble" and "insoluble" fiber diets differed by less than 4 g of SF, on average. The authors speculate that either current analytical methods may actually underestimate SF, or that IF may have some hypolipidemic effect from certain components such as lignin. They also note that some SF have no hypolipidemic effect (acacia, agar). Authors encourage consumption of fiber sources known to lower TC.

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Study	Study Design	Subjects	Methods	Results	Comments
Jenkins et al., unpublished (Ref. 93).	Intervention, controlled feeding study with randomized, cross-over design.	13 hyperlipidemic subjects (3 men, 9 postmenopausal women), ages 38 to 70, mean TC--272 mg/dL, mean LDL--192 mg/dL.	Subjects consumed a Step 2 basal diet (see study above) for 3 months then randomized to receive either psyllium or wheat bran cereal. Test period 1 to 4 weeks; 2-week washout on Step 2 diet; Test period 2 to 4 weeks. Patients received their food from the clinic, but lived at home during the study. The psyllium cereal diet provided 16.2 g/d of SF, while the wheat bran cereal diet provided 9.5 g/d SF. Subjects in the psyllium group ate 9.35 g of psyllium/day.	The psyllium cereal diet significantly reduced TC and LDL cholesterol, while the wheat bran diet did not. PSY diet: Week 0 4 mg/dL Total CHOL 275 269* LDL 199 173* Control diet: Total CH 260 257 LDL 186 182 *Significant $p < 0.05$. In individuals with increased cholesterol and triglycerides in this study (Type IIb), the psyllium cereal diet did not reduce serum LDL cholesterol, while it was effective in Type IIa (elevated cholesterol without elevated triglycerides).	Small sample size. Well controlled study. Psyllium containing cereal was shown to significantly reduce serum total and LDL cholesterol. The effect was independent of a low fat diet. No significant difference between groups for TC/HDL, LDL/HDL, apo B/A1. Preliminary results also suggest that psyllium cereals may not effectively lower LDL cholesterol in individuals with concomitantly elevated triglycerides (Type IIb). Subjects ate 9.35 g of psyllium per day (>2 ounces of cereal).

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Study	Study Design	Subjects	Methods	Results	Comments
Anderson, unpublished (Ref. 95).	Intervention, randomized, double blind, parallel.	44 men and women, mild to moderate hypercholesterolemic (TC 200 to 300 mg/dL), free living.	Subjects (Ss) were followed for 7 weeks. Week 1 was baseline period when subjects consumed their usual diets. Then Ss randomized to receive psyllium (PSY) cereal or wheat bran cereal and instructed on Step 1 diet and asked to adhere to it for 6 weeks. Step 1 diet: 55% total energy as CHO; 15% as protein; 30% as fat, less than 10% as saturated fat, and less than 300 mg cholesterol/day. Ss returned to clinic after 2, 4, 5, and 6 weeks on cereal. 3-day diet records were kept during week 3 of test period. Ss consumed 4 ounces of cereal (2 ounces in morning and 2 in evening). PSY cereal provided 11.6 g PSY, 24 g TDF, 12 g SF. Wheat cereal provided 28 g TDF and negligible SF.	PSY group TC significantly ↓ (8%) 251 to 230 mg/dL compared to baseline and significantly lower than wheat group. LDL ↓ significantly (13%) in PSY group compared to baseline. No significant changes in wheat group.	Average consumption of psyllium cereal was 3.7 ounces/day.
Baril et al. unpublished (Ref. 96).	Intervention.	7 men and women, hyperlipidemic (TC 261 to 346 mg/dL), free living, ages 32 to 71, treated by physician for (average) 2.4 years for hyperlipidemia.	Each subject served as own control. Ss were asked to take 24 g of fiber/day for 6 weeks and 40 g/day for 6 more weeks. At week 20 (0 weeks after test period ended), Ss had another blood lipid test. Ss instructed by dietitian on how to incorporate fiber into their diet and how to keep diet records. Diet records were kept for 3 days at the start, after 6 weeks, and again after 12 weeks. Corn fiber (milled and ground) provided 89% dietary fiber and less than 2% SF. Ss mixed the fiber with water. No indication when fiber was consumed during the day.	Mean fiber consumption for first 6 weeks was 22.7 g/day; for second 6 weeks--41 g/day. Two Ss stated that they could not consume 6 packets per day for 6 weeks so continued with 3 packets/day. Total cholesterol was significantly reduced on an average from 290 to 253 mg/dL, although much smaller changes were observed in two Ss and one subject had an increase in TC. TC returned to baseline after the 8-week followup period when there was no intervention. There was no significant effect on HDL. LDL was not reported.	Total dietary fiber, total SF, dietary saturated fat before, during, and after test period were not reported. Small number of subjects in this study. The serum cholesterol for all Ss except 1 remained above 200 mg with fiber intervention. No control group. No body weight data.

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Study	Study Design	Subjects	Methods	Results	Comments
Wolever et al., unpublished (Ref. 101).	Intervention, randomized, controlled, cross-over.	43 subjects (21 men, mean age 55 years; 21 women, mean age 58 years), 14 Ss were on lipid lowering drugs, 3 had type 2 diabetes.	Subjects were tested for two 2-week periods separated by a 2-week washout period. The base diet was an AHA Step 2 diet. During test period Ss asked to consume 2 servings of breakfast cereal daily: one in morning and one in evening. The test and control cereals were matched for energy and fed at a dose of 60 g/day. Psyllium (PSY) cereal provided 6.7 g/d of psyllium.	After 2 weeks on PSY: Baseline Test TC, mg/dL 261 248* LDL, mg/dL 183 168* HDL, mm/L 1.14 1.10* * Significantly different from baseline.	Subjects were consuming Step 2 diet which restricts fat to less than 30% of calories. Subjects consuming lipid lowering drugs had decreased TC of 6.1% and LDL of 6.7%, not statistically significant from diet alone group. The short test period of 2 weeks of this study limits the usefulness of the results.
Wolever et al., unpublished (Ref. 102).	Clinical trial to evaluate the effectiveness of psyllium taken in foods versus psyllium taken between meals.	18 subjects (9 men and 9 women), mean age 54 years; 3 Ss were on lipid lowering drugs.	Study design with three 2-week test period separated by 2-week washout periods. Ss all consumed AHA Step 2 diet prior to study. Three treatment periods: Ss provided with cereal were asked to consume one with breakfast and one with dinner; Ss asked to consume PSY cereal between meals; Ss asked to consume control breakfast cereal. PSY cereal provided 6.7 g TDF per day from psyllium and 23.1 g/d TDF from the cereal. The control cereal provided 23.2 g/d TDF.	PSY with meals: Control PSY TC, mg/dL 259 237* LDL, mg/dL 185 164* PSY between meals: Control PSY TC, mg/dL 259 251 LDL, mg/dL 185 174 * Significantly different from control.	The 2 week period of this study limits the usefulness of the results.

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Study	Study Design	Subjects	Methods	Results	Comments
Spencer and Coe, unpublished (Ref. 109).	Intervention, cross-over, blinded, placebo used.	31 male, serum chblesterol between 200 to 270 mg/dL.	A 6-week test period. Test subjects consumed 20 ounces of a fiber-supplemented juice per day to the regular diet, which supplied 10 g of DF (70% soluble fiber, predominantly from gum arabic) Placebo group received 20 ounces per day of nonsupplemented apple juice. Ss were asked to maintain normal eating and lifestyle habits.	With both ordered groups totaled, there is a significant decrease in serum total cholesterol and LDL-cholesterol during the period of consumption of fiber-enriched juice.	The cholesterol intake was significantly higher in the juice only group. In the group, ordered plain juice, then fiber-enriched juice, there is no change in total serum cholesterol followed by a significant decrease while on fiber-enriched juice. In the group which was given fiber-enriched juice first, there is a significant decrease while on the fiber-enriched juice, followed by no increase while on plain juice. The authors attribute this to a carryover effect of the fiber, but this is difficult to say.

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Study	Study Design	Subjects	Methods	Results	Comments
Heel and Balm, 1990 (Ref. 98).	Intervention, parallel, open-label, clinical trial.	59 subjects with total cholesterol between 215 and 396 mg/dL.	29 subjects were assigned to dietary intervention only; 30 subjects were assigned to dietary and psyllium intervention. During the first 7 weeks, all subjects were to adapt to the AHA phase I diet. The subjects who were in the diet plus psyllium group were instructed to take psyllium in the form of Metamucil immediately after breakfast, and immediately after the evening meal for a 13-week period.	Dietary response period: During the first 7 weeks, men had significant lowering in their total serum cholesterol; women experienced very little change. After the treatment period, the PSY group had 5.5% additional decrease (significant) in TC compared to diet only group after the treatment period. Although there was a 5.1% in LDL in PSY group compared to control, this decrease was not significant. Total Cholesterol (mg/dL): Control: After diet 263, Final 261, Avg Individual % Change -1.6 PSY: After diet 266, Final 247, Avg Individual % Change -7.1* LDL Cholesterol (mg/dL): Control 182 176 -3.5 PSY 190 172 -8.6* *Significant from post diet.	Although the compliance to the diet was checked, the breakdown of nutrients and amount of total soluble finer, total fat and saturated fat were not reported for each group. During the 7 weeks pretreatment period, results showed the women's TC did not respond to the AHA diet. Small weight loss in both groups.
Uusitupa et al., 1989 (Ref. 100).	Randomized, double-blind parallel group.	39 patients with NIDDM, mean age 50.6--men and 61.4 years--women, mean TC 253 mg/dL; all 39 subjects were on drug treatment for diabetes, 15 were on antihypertensives, 7 Ss were on drug treatment for coronary heart disease, and 6 Ss were on drug treatment for both hypertension and coronary heart disease, free-living.	Ss were randomly assigned to test or control groups. Group A: Received 5 g guar gum three times per day before meals. Group B: received 5 g wheat flour three times per day before meals. After 3 months, group B switched to guar gum for the remaining 10 months of the study, and group A continued on guar. Ss advised to lower fat calories to 35% and increase carbohydrates to 50% of calories.	Serum total cholesterol (mg/dL) run-in / 3 mo / 12 mo A: 253 / 220 / 237 B: 253 / 242 / 233 There is a significant difference between the guar gum group and the control at 3 months.	Significant weight loss occurred, but in both the control and treatment groups to a similar degree. Authors question compliance of Ss during months 4 to 12 because serum cholesterol increased in both groups. Group B showed highest serum cholesterol at month 11 (242 mg/dL). Diets during the test period were not reported. Total soluble fiber, total fat, and saturated fat were not reported.

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Study	Study Design	Subjects	Methods	Results	Comments
O'Connor et al., in press B302 (Ref. 103).	Multicenter (7), double-blind, randomized, parallel group, placebo controlled trial.	Males and females (169 randomized, 135 completed study), between the ages of 18 and 70 years with a diagnosis of mild to moderate primary hypercholesterolemia.	Step one diet for 9 weeks; 15-week test period. Five Fiber Supplement (FFS) packet consists of 7.5 g SF (guar and pectin) and 2.5 g of IF. Placebo packet consists to 5.2 g of IF, no soluble fiber. During Week 1 of supplementation, Ss took 1 packet FFS per day, before dinner. During Week 2, they alternated days between one packet per day before dinner, and two packets per day, one before breakfast and one before dinner. During weeks 3 to 15, Ss took two packets of FFS per day, one before breakfast and one before dinner. Ss assigned to the two packet (26.4 g) group received FFS for all doses during Week 1 through Week 15. Ss who were assigned to the placebo group received placebo treatment for all doses during weeks 1 to 15.	Percent change in fiber from baseline minus % change in placebo from baseline: Week TC LDL-C 3 -5.6 -11.7 6 -7.8 -10.3 9 -8.7 -11.8 12 -6.2 -10.3 15 -6.8 -10.2 All values are significant.	Tightly-controlled trial. Dietary factors well-controlled; all major nutrients kept constant except for fiber.

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Study	Study Design	Subjects	Methods	Results	Comments
O'Connor et al., in press B301 (Ref. 103).	Multicenter (4) double-blind, randomized, parallel group, placebo controlled trial.	Males and females (161 randomized, 127 completed study), between the ages of 18 and 70 years with a diagnosis of mild to moderate primary hypercholesterolemia.	Step 1 diet for 9 weeks; 15-week test period. Five Fiber Supplement consists of 7.5 g SF (guar and pectin) and 2.5 g of IF. Placebo consists to 5.1 g of IF, no soluble fiber. During Week 1 of supplementation, subjects took one packet of treatment per day, before dinner. During Week 2, they alternated days between one packet of treatment per day before dinner, and two packets of treatment per day, one before breakfast and one before dinner. During weeks 3 to 15, #s took two packets of treatment per day, one before breakfast and one before dinner. #s who were assigned to the one packet (13.2 g) of Five Fiber Supplement group received active treatment with the dose before dinner each day. The dose before breakfast during Week 2 (as required) and during Week 3 through Week 15 was placebo. #s who were assigned to the two packet (26.4 g) group received active treatment for all doses during Week 1 through Week 15. #s who were assigned to the placebo group received placebo treatment for all doses during weeks 1 to 15.	Percent change from baseline in "Relative Efficacy" over time (relative to placebo). 1 Packet Supplement LDL-C / 2 Packets Supplement LDL-C Week 3: -7.6 / -12.0 Week 6: -9.3 / -13.8 Week 9: -4.5 / -7.5 Week 12: -4.2 / -8.6 Week 15: -5.9 / -7.9 All values are significant for the two-packet group. Week / TC / TC 3: -5.2* / -6.5* 6: -5.0* / -8.8* 9: -2.4 / -4.3* 12: -2.2 / -4.7* 15: -3.6* / -5.3* * Significant difference.	Well-controlled, free-living, trial. Dietary factors well-controlled. All major nutrients kept constant except for fiber. A dose-response was not statistically demonstrated between placebo, one-packet dosage and two-packet dosage.
O'Connor et al., in press (Study B301 extension) (Ref. 103).	An open-label study of the safety and efficacy of Five Fiber Supplement administered twice a day in conjunction with a low fat diet for 36 weeks.	Patients who completed 15 weeks of treatment with either one packet of Five Fiber Supplement per day, two packets of Five Fiber Supplement per day or placebo were eligible to continue therapy with two packets of Five Fiber Supplement per day for an additional 36-week period. 103 entered and 59 completed the 36 additional weeks.	During this open-label extension, patients were continued on their Step 1 Diet. During the first week of the extension, patients took one packet of treatment per day (before dinner). Thereafter, during weeks 17 to 51, patients took two packets of treatment per day (one before breakfast and one before dinner).	During the 36-week extension of the trial, total Cholesterol was maintained at 5.3% (Significant) and LDL-cholesterol at 8.4% (Significant) lower than baseline.	This extension to the above study was not blinded by definition. The study was well-controlled for dietary factors and other major confounders.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Whyte et al., 1992 (Ref. 104).	Intervention, randomized with cross-over.	23 men, mean age 45 years, mild hypercholesterolemia (TC 209 to 259 mg/dL), free living.	Subjects were randomly assigned to either the wheat cereal group or the oat cereal group after a 3-week baseline diet. During baseline period, all Ss consumed wheat cereal. Preweighed packages of cereal were provided: 54 g of wheat bran per day; 123 g oat bran per day. Base diet was typical Australian diet with approximately 30 to 34% of calories as fat. Ss instructed on how to keep dietary records, measure and restrict fiber (so all Ss would have approximately same total fiber intake of less than 30 g/d. Each fiber cereal (2 servings/day) was consumed for 4 weeks followed by cross-over to other fiber cereal for an additional 4 weeks. Oat cereal: 10.3 g/d SF Wheat cereal: 3.4 g/d SF All diets: TDF approximately 27 g/d. Oat diets provided 71 g/d starch; wheat diets provided 42 g/d starch.	Data analysis showed no effect of treatment order. mg/dL: Baseline / Oat / Wheat TC: 228 / 218* / 226 LDL: 159 / 150* / 159 * Significantly compared to both baseline and wheat period.	Consumption of total fat and saturated fat during both test periods was about the same (35.5 g fat/1,000 kilocalories and 12.7 to 13 g saturated fat/1000 kilocalories). Short test period No dietary cholesterol intake data.
Nicoi et al., 1980 (Ref. 99).	Double-blind, cross-over trial with placebo.	22 subjects: 16 women, 6 men; with poorly controlled type 2 diabetes. Ages 40 to 76. Mean serum cholesterol 335 mg/dL and 255 mg/dL. 19 subjects on medication.	The study consisted of two 12-week treatment periods separated by 4-week washout period. Eleven patients, selected at random, started with microcrystalline cellulose during the first 12-week treatment phase followed by treatment with guar gum in the second 12-week period. In the other 11 subjects, the sequence was reversed. Both types of fiber were taken with meals three times daily. The initial dose was 5 g/day, which was increased up to 15 g/day during the 2-week period at the beginning of each treatment phase.	The pooled data show that serum cholesterol was significantly lower after 12 weeks on guar gum, but no significant change was found after cellulose. Serum cholesterol (mg/dL) Time: Cellulose / Guar Start: 235 / 255 12 weeks: 240 / 230* *significant from start.	Although patients were advised to keep to their normal diet, no measurements of diet (total soluble fiber, total fat and saturated fat, etc.) were discussed to verify this. Only the pooled data was reported. It would be helpful to examine the response of each group separately. Is cellulose an appropriate control?

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Cerda et al., 1988 (Ref. 105).	Intervention, double-blind, cross-over with placebo.	27 subjects: 9 men, 18 women, ages 27 to 69 years. Mean serum cholesterol 275 mg/dL (range of 208 to 420 mg/dL), free living.	A 16-week study: 4-week baseline, 4 weeks on placebo or pectin, 4-week washout, then cross-over to 4 week on placebo or pectin tablets. Ss consumed normal diets but consumed 27 tablets (9 at each main meal) daily during test periods. Dietary records were kept during weeks 1, 7, and 16. Each S served as own control. Grapefruit Pectin: 15 g/day Placebo (flour): 15 g/day.	Baseline / Pectin / Placebo (mg/dL) TC 275 / 254* / 275 LDL 195 / 174 / 191 HDL 41.6 / 41.1 / 41.5 *Significant from baseline and placebo.	Authors reported good compliance to tablet consumption. The subjects dietary intake of calories, total fat, saturated fat, cholesterol, and soluble fiber were not reported. Short test period. No body weight data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Haskell et al., 1992 (Ref. 106).	Intervention, randomized, double-blind, placebo-controlled trials.	Total cholesterol range for all studies: 200 to 280 mg/dL Study (S) 1: 58 men and women, mean age 57 yrs. S 2: 40 men and women, mean age 56.4 yrs S 3: 16 men and women, mean age 52.5 yrs S 4: 49 men and women, mean age 56.3 yrs. All free living subjects.	After baseline period Ss randomly assigned to one of 4 studies: S 1: 12-week test. Evaluated CH-lowering properties of mixed SF with 56% from acacia gum. Fiber product: powder mixture of acacia gum (9.7 g), psyllium (4.9 g) and guar gum (2.6 g) for a total of 17.2 g/day divided into 3 servings/day. All placebos consisted of 15 g of fructose. S 2: 4-week test. 15 g/day acacia gum powder divided into 3 servings/day. S 3: 6-week cross-over using guar as control. Test fiber mixture: pectin (3.9 g), psyllium (6.3 g), guar (3.3 g), and locust bean gum (1.5 g) for total of 15 g/day SF given in 3 servings per day; guar control: 10 g guar and 1 g pectin for total of 11 g/day given in 3 servings/day. S 4: 4 weeks. A dose-response study with SF test mixture used in S 3. Mixtures tested: 1 svg/d 2 svg/d 3 svg/d pectin, g 1.3 2.6 3.9 psyllium, g 2.1 4.2 6.3 guar, g 1.1 2.2 3.3 locust bean, g 0.5 1 1.5 Total g/day 5 10 15	S 1: There were no statistically significant changes from baseline to 6 or 12 weeks within or between groups. S 2: TC placebo 264 269 ↑1.9 acacia 266 265 ↓0.4 LDL placebo 200 206 ↑3.1 acacia 194 195 0.0 HDL placebo 55 52 ↓5.4 acacia 60 58 ↓3.9 * not statistically significant from baseline. S 3: TC guar 249 225* ↓9.7 fiber mix. 249 230* ↓8.3 LDL guar 186 163* ↓13.6 fiber mix. 186 166* ↓12.4 HDL guar 56 50** ↓6.5 fiber mix. 56 51** ↓5.9 * Significant from baseline p<0.01 ** Significant from baseline p<0.05. S 4: TC placebo 261 262 0.3 5 g/d 255 242 ↓5.2 10 g/d 259 247 ↓4.9 15 g/d 275 242* ↓12.2 LDL placebo 184 186 0.8 5 g/d 186 176 ↓5.6 10 g/d 187 174 ↓6.8 15 g/d 211 179* ↓14.9 HDL placebo 67 62 ↓6.4 5 g/d 57 54 ↓4.1 10 g/d 61 62 ↑1.9 15 g/d 53 49 ↓9.4 * significant from placebo.	Subjects' diets were not reported. Short test periods.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Mervi et al., 1989 (Ref. 107).	Purpose of study was to evaluate hypothesis that legumes may be a dietary risk factor for cholesterol gallstone formation in Chileans. Nonblinded cross-over intervention study.	20 young Chilean men, ages 18 to 22 years, mean TC 162 mg/dL.	Subjects received a control diet for 25 to 30 days. Food preparation and intakes were controlled by nutritionists. Diets eaten for 6 days a week; Ss were allowed free food intake on Sunday. Test period was 30 to 35 days on a legume diet: beans 4 days, peas 2 days, lentils 1 day. Ss received 120 g dry legumes each day. Control and test diets were matched for calories, protein, fat, fiber and cholesterol intakes. Energy, Cal: Control Diet 3219; Legume Diet 3319 % of Calories Protein: 14; 14 Carbohydrate: 54; 53 Fat: 32; 33 Cholesterol, mg: 388; 382 Total Fiber, g: 13.4; 12.5	Serum cholesterol (mg/dL) Control diet: 162 Legume diet: 143 Difference is significant (p<.001).	Short test period. Authors reference a study that indicates that epidemiological studies have demonstrated increased prevalence of gallstones in men ingesting a diet that lowers serum cholesterol. No saturated fat intake data. No body weight data, low baseline serum cholesterol.
Unpublished study submitted with comments (Ref. 108).	Double-blind double cross-over intervention.	23 healthy men, Age > 18 years, TC > 240 (exact ages and total cholesterol not reported), free living.	Baseline period: 4 weeks Step 1 diet. Subjects randomly assigned to either psyllium-wheat bran-psyllium (n=12) or wheat bran-psyllium-wheat bran (n=11) for 0, 5 and 5 weeks respectively on each regimen (10 weeks total). Subjects were provided with boxes of cereal and instructed to eat 2 ounces of the study cereal in the morning and one ounce in the evening. The psyllium cereal had a total of 5 g of soluble fiber and 7.4 g of total dietary fiber per ounce. The wheat bran cereal had 1 g of soluble fiber and 5 g of total dietary fiber per ounce. Relative percentages of protein, fat, sugar and starch in the two products were reported to be similar.	Effect of Psyllium versus Wheat Bran Cereal (in mg/dL) PSY: TC 225; LDL 140; HDL 46 WHEAT-BRAN: TC 235; LDL 157; HDL 45 Difference: TC 6.3% *; LDL 6.1% *; HDL - * Significantly different p<.0001.	It is difficult to evaluate the results of the study because the authors do not report the initial cholesterol values of either group, instead relying on differences between the groups' average cholesterol values. It is important to review the effect of the diet order, to observe any changes in going from one test product to the other, and note any temporal trends in rising or falling of cholesterol levels on each diet. No dietary data

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Anderson et al., 1984 (Ref. 116).	Metabolic ward, study for 21 days with random allocation to groups.	10 male subjects age 46 to 66 with initial serum cholesterol > 260 mg/dL.	All subjects received the control diet for 7 days, and then were placed on a test diet for 21 days. Control diets provided 19% of energy as protein, 43% as CHO, 38% as fat 20 g plant fiber, and 6 g soluble fiber per day. The oat-bran diet provided 100 g of oat bran per day served as a bowl of hot cereal and five oat bran muffins per day. This supplied approximately 48 g total plant fiber and 16 g soluble fiber per day. The bean diet containing 100 g of dried beans per day provided the same amount of total plant fiber and soluble fiber as did the oat-bran diet. After controlled trial ended, subjects were given high-fiber maintenance diets to follow for an additional 24 weeks; four of the subjects were followed for a total of 99 weeks.	Mean serum cholesterol values of oat and bean groups: (values in mg/dl). TC LDL HDL Week 1 296 216 37.2 4 226 167 29.8 7 233 169 31.4 10 214 164 33.9 16 232 164 33.9 24 210 164 35.2 *Note: All values are significantly lower when compared to week 1. After 99 weeks of followup (free-living on high-fiber maintenance diets), serum chol values were 26% (p<.001) below initial values at 24 week and 23% lower (p<.003) at 99 weeks.	Small sample size. Significant weight loss during test period; no significant weight loss during control period. Short period. No control.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Fukagawa et al., 1990 (Ref. 114).	Metabolic ward study; clinical trial, nonblinded, no placebo. Young men only ate their meals on the metabolic ward. The older group were admitted to the ward.	Six healthy male students, age 18 to 24 (TC 200 mg/dL) and six healthy older men and women, age 67 to 86 (TC 230 mg/dL).	The subjects were placed on a high fiber diet for a period of 21 to 28 days after consuming their usual ad libitum diet. High fiber diet: 68% of energy from CHOs, fat intake of 14%, protein of 18%; 33 g per 100 kilocalories of fiber. Plant fiber was provided by whole grain or grain cereals and breads(40%), vegetables such as beans, corn, or peas (20%), other vegetables (31%), and fruits (9%). Soluble fiber/day Reg. Diet / High Fiber younger group: 3.5 g / 23.6 g older group: 3.7 g / 17.1 g Ad libitum diet assessed by dietary recall.	Serum cholesterol in young and old subjects before and after 4 weeks of a high fiber diet: Before / After (mg/dL) Both (n=12): 219 / 170 / ↓22%* Young (n=6): 200 / 147 / ↓26%* Old (n=6): 238 / 193 / ↓45%* *All "after" values are significantly lower than corresponding "before" values.	Small sample size. There was no control group, fat was not controlled. The ad libitum diet was significantly higher in fat (37 to 42% versus 14% of calories), saturated fat (15 to 17% versus 3% of calories), and cholesterol (720 to 755 versus 90 to 136 mg/d) than the test diet. Ad libitum diet relied on dietary history alone. It should be noted that the objective of this study was to examine the effects of a high fiber diet on insulin sensitivity; the cholesterol findings were secondary. No body weight data.
Turnbull and Leeds, 1987 (Ref. 111).	Clinical study, randomly allocated, cross-over.	9 men, 8 women, age 23 to 59, initial serum cholesterol level of at least 232 mg/dL, free living.	Subjects were placed on a one-month run-in period when they followed a low-fat diet (< 35% of calories from fat). Subjects were then randomly allocated to 1 month of an oat diet (50 g oats each day at breakfast and 100 g oats as biscuits or a wheat diet (37 g wheat biscuits each day at breakfast and 100 g wheat as biscuits. At the end of the month, subjects switched diets. Oat products provided 5.4 g SF/day. Wheat products provided 1.1 g SF/day.	Values for cholesterol before and after intervention: Initial / Final / Sig Change? (mg/dL) Oat period Total chol: 232 / 220 / Y LDL-chol: 167 / 143 / Y HDL-chol: 46 / 54 / NS Wheat period Total chol: 220 / 232 / NS LDL-chol: 159 / 163 / NS HDL-chol: 50 / 50 / NS	Fat intake is higher during oat period (this does not invalidate cholesterol-lowering effect of oats). No saturated fat or cholesterol intake data.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Walsh et al., 1991 (Ref. 117).	Clinical trial, double-blind, randomly-assigned, with placebo.	30 women, (ages not given), obese (20% or more over ideal weight), mean serum cholesterol 199 mg/dL.	The trail was of 8-week duration. The glucomannan group (GM) took two capsules of a supplement containing 500 mg of purified glucomannan, three times per day, with 8 ounces of water, 1 hour before each meal. The placebo group (PG) took two capsules containing 500 mg starch under the same conditions. All patients were instructed not to deviate from their previously-established eating and exercise patterns.	Changes in weight and cholesterol Weight Change (lbs): Week 4: GM -4.9*, PG 0.4; Week 8: GM -5.6*, PG 1.8 Chol Change (mg/dl): Week 4: GM -20.9*, PG 5.9; Week 8: GM -21.7*, PG 4.7 Difference between groups. 7.0 lbs 26.2 * Significant difference between groups.	Because weight loss and cholesterol-lowering are closely correlated, it is not possible to conclude that the cholesterol-lowering effect is an independent result of glucomannan supplementation.
Anderson et al., 1992 (Ref. 118).	Intervention, randomized, double-blind, parallel design.	44 men and women, ages 25 to 70, total cholesterol 199 to 300 mg/dL, 80 to 130% of desirable body weight, free living.	One-week baseline period--Ss consumed usual diet then randomized to receive psyllium-flake or wheat-bran-flake cereal (control) for 6 weeks. Ss also instructed on step 1 diet and asked to adhere to this diet for 6 weeks. Wheat cereal: 28.4 g serving with 5 g total DF, negligible SF. PSY cereal: 28.4 g serving with 6 g total DF, 2.9 g PSY, 3 g SF. Ss were instructed to consume one serving of cereal the first day and add 28.4 g additional daily until a maximum of 114 g/day was reached. 114 g of PSY cereal would provide 24 g total DF, 11.6 g PSY, 12 g SF. Ss completed 3-day diet record during week 5 of treatment period.	Base Diets Wheat bran: Baseline / Final; PSY: Baseline / Final Energy (Cal): 1786 / 1899 / 1821 / 1725 Fat (% energy): 30.7 / 24.3 / 32.2 / 22.9 SF, g: 5.6 / 5.9 / 6.1 / 18.1* *Significant difference from wheat group. Serum cholesterol, mg/dL TC: 252 / 252 / 238 / 230* LDL: 176 / 174 / 170.5 / 149*	Authors reported slight but significant decreases in body weight in both groups across time. However, there was no significant difference in weight loss between groups.

*Significant difference from baseline. Change in PSY group significantly different from change in wheat group.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Braaten et al., unpublished (Ref. 119).	Intervention, randomized.	21 men and women, ages 43 to 64, hypercholesterolemic (mean serum cholesterol 255 mg/dL), free living.	Subjects consumed usual diets with the fat content adjusted to be at least 20% and preferably more than 25% of their daily caloric content. Three-day food dairy was used to record their diets before and during each treatment period. Instant soluble oat gum (3.6 g, 80% β-glucan) or placebo (maltodextrin) was mixed with noncarbonated diet fruit drink (250 mL) and consumed during each of the two main meals of the day for each 4-week period. There was a 2-week stabilization period prior to treatment, a 3-week washout period between treatments, and a 3-week washout period for the group on oat gum.	Dietary fat intake ranged from 30% to 31% of energy, total caloric intake was 2161 calories (stabilization period), 2069 calories (gum period), 1980 calories (washout), and 2077 calories (placebo period). Total Cholesterol Initial / Final mg/dL Placebo 255 / 255 Oat gum 262 / 230* *Significantly different from baseline and placebo. LDL-Cholesterol mg/dL Placebo 174 / 176 Oat gum 169 / 154 During washout following oat gum treatment serum cholesterol increased from 230 to 250 mg/dL.	Total dietary soluble fiber, saturated fat and cholesterol intakes was not reported. Body weights before and after treatment were not reported. During final washout following oat period, serum cholesterol returned toward pretreatment levels further supporting a true effect of oat gum. Short test period.
Bridges, S. et al., 1992 (Ref. 120).	Clinical study, metabolic ward.	20 men, ages 38 to 73, mean serum cholesterol range of 252 mg/dL (wheat group) to 305 mg/dL (oat group).	Subjects received a base diet for 7 days followed by 3 weeks of oat bran or wheat bran supplementation. The base diet was a typical American diet composed of 43% energy from carbohydrate, 16% protein, 41% fat, and 450 mg cholesterol. Treatment = Tx; Pretreatment = Pretx Total dietary fiber = TDF Fiber Intake on Diets Wheat Bran: Pretx / Tx; Oat Bran: Pretx / Tx TDF, g: 10 / 34 / 10 / 31 SF, g: 5.6 / 7.8 / 6.0 / 13.4 Oat bran and wheat bran were served as cereal or muffins.	Wheat Bran / Oat Bran mg/dL Total CHOL Pretx 252 / 305 Tx 242 / 267* LDL-CHOL Pretx 130 / 167 Tx 123 / 146* *Significantly different from pretx period.	Control period of 7 days is inadequate. Pretreatment serum cholesterol was calculated from data presented. Serum cholesterol and LDL-cholesterol between groups is not well matched; oat group had much higher serum- and LDL-cholesterol than wheat group. Both groups experienced slight but significant weight loss. Not randomized; short test period.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Rashtan et al., 1992 (Ref. 121).	Intervention, randomized, metabolically controlled, parallel, double-blind.	84 subjects in two groups: group 1 to 42 men and women, mean age 41.3, with history of previous polypectomy; and group 2 to 42 men and women, mean age 51.2, with normal colon and colonic examination. Mean serum cholesterol of group 1: 207 mg/dL; group 2: 227 mg/dL.	Subjects were randomly assigned to either the oat bran group or the wheat bran (control) group. Subjects consumed the bran products twice a day for 2 weeks. All food was prepared and delivered to the subjects. Energy content of diet was one of four amounts: 1,600, 2,000, 2,400, and 2,800 calories Ss were fed the amount closest to their requirements based on the Lipid Research Clinics tables. Base diet: 37% fat, 16% protein, 47% carbohydrate; total dietary fiber--24 to 25 g/day. Oat bran supplement: 99.4 g/day: 11 to 17 g fiber; estimated 5 to 8 g SF Wheat bran cream of wheat: 73 g/day: 11 to 17 g fiber/day.	<u>Before / After / Change</u> (mg/dL) Total CHOL Wheat bran 207 198** -0.25 Oat bran 227* 203** -0.63* LDL-CHOL Wheat bran 129 125** -0.11 Oat bran 150* 131** -0.48* *Significantly different from wheat bran. **Significantly different from baseline.	Soluble fiber consumption was not reported. Short term study--14 days.
Ranhotra et al., 1989 (Ref. 122).	Intervention, self-controlled.	17 men, ages 37 to 60 years, hypercholesterolemic (mean serum cholesterol 226 mg/dL), free living. One subject had a history of heart attack and one subject was a type II diabetic.	A 6-week control period followed by a 6-week test period. Ss consumed their usual diet during the control period but maintained daily records of intake for first 4 weeks. Ss were provided a list of cereal-based and other foods identified as sources of SF and asked to consume these with their daily diets. Additional SF supplement of processed rice bran (30 g) and oat bran (30 g) was provided.	Nutrient Intake: <u>Control / Test</u> Energy, Cal. 2370±431 2331±419 Fat, % energy 35.3±4.7 33.9±4.9 Saturated Fat, % 10±1.7 9±1.9 Total fiber, g 15.0±5.0 20.3±4.7 Soluble fiber, g 5.0±1.6 9.4±1.5 Ss individual data were reported. Six of the 17 Ss experienced lowered serum cholesterol of 1 to 17% compared to control values.	Statistical analysis not performed by authors. Results are too inconsistent in direction and magnitude to support an effect of SF on serum cholesterol. Some subjects failed to consume the supplement daily. Intake of both soluble and dietary fiber varied greatly among the participants.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zhang et al., 1992 (Ref. 133).	Intervention, randomized, controlled, cross-over.	9 men and women (2 women, 7 men), ages 46 to 67 years, with ileostomies. Mean serum cholesterol--231 mg/dL.	The goal of this study was to elucidate the cholesterol-lowering mechanisms of oat bran and to compare the sterol excretion pattern on a basic diet (wheat flour bread, low fiber diet (LFD)) to oat bran (oat bran bread, high fiber diet (HFD)). Subjects were randomly assigned to two groups (LFD or HFD) and each group followed for 3 weeks followed by cross-over to the other diet. Ss consumed the bread products with their own food which was modified to be low fiber. wheat flour bread: 4.8 g dietary fiber; oat bran bread: 19 g dietary fiber.	Serum Cholesterol mg/dL All Ss (n=9) LDF 216 HDF 196.8* Ss with low daily bile acid excretion (n=5) LDF 234 HDF 207* Ss with high daily bile acid excretion (n=4) LDF 189 HDF 179 *significantly different from LFD.	Total dietary soluble fiber intake and intake of fat, saturated fat, and cholesterol were not reported. All subjects had ileostomies. Conclusions about fiber mechanisms in lowering serum lipids may not apply to the general population. Short test period.
Marlett et al., 1992 (Ref. 134).	Intervention, metabolically controlled, single isotope used to determine bile acid kinetics.	9 men, ages 20 to 28 years, normocholesterolemic (estimated range of 131 to 244 mg/dL).	A 3-month study: period 1: low fiber control period and period 2: high fiber period with oat bran. Base diets: energy--2,700, 3,000, 3,300, and 3,600 Cal/day with 30% fat, 15% protein, and 50% carbohydrate. Foods were consumed in a metabolic unit except an evening snack which could be taken home. Oat bran--100 g, provided 16.1% dietary fiber, of which 30% was β-glucan, and 46% was soluble fiber. Wheat gluten--an amount comparable to protein provided by oat bran was included in foods in the low fiber diet.	Low Fiber Period / High Fiber Period Mean dietary fiber intake: D.F., g/day 16 / 33.9 S.F., g/day 4.8 / 10.3 Serum Cholesterol mg/dL Prestudy 177 / Low Fiber 153* / High Fiber 135** *significantly lower than prestudy value. **significantly lower than low fiber period. Total daily fecal bile acid excretion more than doubled when oat bran was incorporated into the metabolic diet: Total B.A., micromoles/day 476.4 / 1026.2	There were no changes in body weights. Small sample size.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0100]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Folic Acid and Neural Tube Defects

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize a health claim for folic acid and neural tube defects at this time. However, consistent with the recently announced recommendations of the U.S. Public Health Service (PHS) that all women of childbearing age in the United States consume 0.4 milligram (mg) (400 micrograms (μg)) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects, FDA plans to work expeditiously to authorize a claim, if appropriate. At that time the PHS identified several issues that remain outstanding, including the appropriate level of folic acid in food and safety concerns regarding increased intakes of folic acid. Given the significance of neural tube defects and the PHS recommendation, the agency is continuing to address the issues about folic acid. FDA recently convened an advisory committee to consider the outstanding concerns (57 FR 52781, November 5, 1992). The advisory committee provided recommendations to the agency on the following issues: (1) What is the target population for a folic acid neural tube defect health claim? (2) How does the information available on the effective level of intake affect options for implementation? (3) What safety concerns for the target population and for persons in the general population must be addressed? and (4) If a claim is authorized, what is the most appropriate method for presenting it to the target population? The advisory committee's recommendations are currently under FDA review.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFF-268), 8301 Muirkirk Rd., Laurel, MD 20708, 301-344-5832.

SUPPLEMENTARY INFORMATION:

I. Background

A. Procedural Status

In the **Federal Register** of November 27, 1991 (56 FR 60610), FDA proposed not to authorize the use on the label and labeling of foods, including dietary supplements, of health claims relating to an association between folic acid and the reduction in risk of neural tube birth defects. The agency issued this proposal in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). The agency tentatively found that the available scientific evidence showed that daily periconceptional use of 4 mg (4,000 μg) of folic acid, an amount that exceeds the level of 0.4 mg (400 μg) per (/) day permitted under the current food additive regulation (21 CFR 172.345), was needed for reduction in risk of neural tube birth defects in women at high risk of this complication because of a previously affected pregnancy. The agency also tentatively concluded at that time that there was not significant scientific agreement that periconceptional supplementation with doses of folic acid lower than 4 mg/day would significantly reduce the risk of neural tube defects in women of childbearing age in the general U.S. population, who are at much lower risk of an occurrence of this complication.

In September 1992, following an open meeting sponsored by the Centers for Disease Control (CDC) in Atlanta, GA (57 FR 29323) and based on additional reviews of existing data and on new scientific data, the PHS recommended that all women of childbearing age in the United States consume 0.4 mg (400 μg) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 1). In discussing this recommendation, the PHS raised several issues that directly bear on FDA's responsibilities under the Food, Drug, and Cosmetic Act (the act) and the agency's pending rulemaking on whether to authorize a health claim regarding folic acid and neural tube defects. These issues include: (1) Identifying the population at risk, (2) considerations of appropriate level of intake with respect to options for implementation, (3) magnitude of benefit, (4) safety considerations, and (5) identifying the best approach for implementing the recommendation.

The 1990 amendments, in section 3(b)(1)(A)(x), direct FDA to consider whether to grant a health claim for dietary supplements on the effects of folic acid on neural tube defects. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to make this judgment based on the standard that FDA is to establish for determining the reliability of health claims for dietary supplements of vitamins, minerals, herbs, and other nutritional substances under section 403(r)(5)(D) of the act (21 U.S.C. 343(r)(5)(D)). In its November 27, 1991 proposal, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that folic acid is found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on folic acid and neural tube defects on any foods.

On October 6, 1992, Congress passed the Dietary Supplement Act of 1992 (the DS Act) which prohibits implementation of the 1990 amendments with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional supplements before December 15, 1993. Under the DS Act, FDA may grant health claims for foods, including dietary supplements, using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act. Given this fact and given the breadth of FDA's November 27, 1991 proposal, which included conventional foods as well as dietary supplements, FDA has decided to move forward to determine whether it can authorize a health claim under section 403(r)(3)(B)(i) of the act for folic acid and neural tube defects by resolving the outstanding issues identified in the PHS recommendation (Ref. 1) and in comments to the November 1991 proposal.

With its recommendation, PHS made comments that identified several possible approaches for the delivery of folic acid in the dosage recommended to the general population: (a) Improvement of dietary habits, (b) fortification of the U.S. food supply; and (c) use of dietary supplements. PHS stated that FDA, in deciding whether to authorize a health claim, will have to determine which approaches will best achieve the goal of increasing folic acid intake, while ensuring that potential risks created by overfortification of food with folic acid, and overconsumption of this substance, do not occur.

FDA recognizes that fortification of a wide variety of foods could occur following authorization of a health claim, and that such fortification could lead to a significant increase in the

intake of folic acid by women in their childbearing years as well as by other portions of the general population. Such an increase would bring with it certain risks. The most widely recognized adverse effect of high intakes of folic acid is the potential for progressive neurologic damage resulting from undiagnosed or masked vitamin B_{12} deficiency. This potential risk was recognized by PHS, which stated that because the effects of higher intakes of folic acid are not well known but include complicating the diagnosis of vitamin B_{12} deficiency, care should be taken to keep total folate consumption at less than 1 mg (1,000 µg)/day, except under the supervision of a physician (Ref. 1).

FDA's current food additive regulation for folic acid (21 CFR 172.345) does not include limits on the fortification of specific commodities, and thus, a wide variety of foods could be fortified with folic acid to provide up to 400 µg/day from each source. Such fortification could lead to individual intakes in the range of 3 to 5 mg (3,000 to 5,000 µg) or more of folic acid per day. Thus, there is a significant question as to whether a health claim relating intake of folic acid and reduced risk of neural tube defects, if approved, could be implemented safely.

The requirement that substances eligible for health claims be safe and lawful is included in the final rule for health claims on foods (see General Requirements for Health Claims for Foods, published elsewhere in this **Federal Register**). Sections of the Federal Food, Drug, and Cosmetic Act (the act) enacted by the 1990 amendments cannot be implemented independently of the remaining portions of the act. The act must be considered as a whole, and FDA's responsibility for ensuring the safety of foods is explicitly provided for in other sections of the act (see sections 201(s), 402(a)(1) and (a)(2), and 409, as well as 403(r)(3)(A)(ii) of the act (21 U.S.C. 321, 342(a)(1) and (a)(2), 348, 343(r)(3)(A)(ii))).

The process by which FDA fulfills its responsibilities under the act will require rulemaking. While this process is underway, and before FDA can issue final regulations on fortification of food with folic acid and permissible health claims on foods that contain folic acid, further food fortification with folic acid would be inappropriate; and no health claims should be made (Ref. 1). FDA notes that the PHS recommendation clearly stated that there were risks attendant on overconsumption of folic acid.

B. Neural Tube Defects: Public Health Aspects

As discussed in the proposal (56 FR 60610), several specific malformations of the central nervous system are referred to as "neural tube defects" because the brain and spinal cord develop within the neural tube. The neural tube forms between the 18th and 20th days of pregnancy and closes between the 24th and 27th days. Anencephalus and spina bifida are serious birth defects and account for about 90 percent of neural tube defects. The majority of children with spina bifida survive and have substantial physical disabilities. Most anencephalic infants are stillborn or die shortly after birth. The minimum number of neural tube defect births in the United States is 2,500. This is an underestimate of neural tube defect pregnancies, however, because it does not include neural tube defect pregnancies identified by prenatal diagnosis and electively terminated. Recent data from state-based birth defects surveillance systems show decreasing trends for spina bifida from 1983 to 1990. The combined state rate is 4.6 cases of spina bifida per 10,000 live births (0.046 percent) (Ref. 2).

The multifactorial nature of neural tube birth defects is well recognized (56 FR 60610 at 60611). The single greatest risk factor currently recognized is having a previous neural tube defect-affected pregnancy. Prevalence rates of neural tube defects at birth have been reported to vary with a wide range of factors, including: Genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health including maternal age and reproductive history. Certain geographic areas may have, for unknown reasons, considerably higher rates than other areas. For example, a cluster of anencephalic deliveries occurred in the Brownsville, TX area between 1989 and 1991. Investigations of potential causes, including environmental contamination and other factors, are ongoing in this area (Ref. 3).

Maternal health (e.g., febrile illness) and maternal use of certain drugs (e.g., the anticonvulsant drug valproic acid) also contribute to risk of neural tube birth defects. There is an increased incidence of malformations, including neural tube defects, among infants of diabetic mothers. Carriership for an inborn error of homocysteine metabolism has been proposed as a risk factor for having an infant with a neural tube defect (Ref. 4). Poor maternal nutrition, which is among a number of factors associated with poverty, may increase the risk for neural tube defects. A recent case-control study of the cluster of anencephalic deliveries in the Brownsville, TX area found that women with less than a high school education were more than twice as likely to have an infant with a neural tube defect as were women who had finished high school (Ref. 3). This observation correlates with poverty as a known risk factor for neural tube birth defects (Ref. 3).

C. Folic Acid: Regulatory History

1. Drug regulation

The agency evaluated the use of folic acid as a drug in the **Federal Register** of April 9, 1971 (36 FR 6843) in response to reports received from the National Academy of Sciences on the therapeutic uses of folic acid. The agency concluded that folic acid administered orally or parenterally is effective for the treatment of megaloblastic anemias of tropical and nontropical sprue, those of nutritional origin, and those that may occur during pregnancy, infancy, and childhood. The agency found that administration of folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient because such treatment may mask the symptoms of vitamin B_{12} deficiency.

In the presence of excess folic acid and inadequate vitamin B_{12}, the anemia of vitamin B_{12} deficiency may not develop, but severe and irreversible nerve damage may continue. Because the anemia of vitamin B_{12} deficiency is frequently the earliest clinical symptom, failure of patients to present with this symptom may unduly delay the diagnosis of vitamin B_{12} deficiency and allow neurologic damage to progress without treatment. The interaction between the functions of folic acid and vitamin B_{12} has been recognized for many years and is the basis for the precautionary statement on preparations of folic acid for therapeutic use.

In the **Federal Register** of April 9, 1971 (36 FR 6843), the agency announced the conditions under which it would approve new drug applications for folic acid preparations. The labeling conditions included the following precaution: "Folic acid especially in doses above 1.0 mg daily may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive."

Based upon the available data and information, in the **Federal Register** of October 17, 1980 (45 FR 69043 at 69044), FDA amended the "Precautions" statement to be included

in the labeling of oral and parenteral preparations of folic acid for therapeutic use because the agency found that the revision more accurately stated the level at which folic acid may obscure pernicious anemia. The Federal Register notice stated that "While obscuration of pernicious anemia does not occur at levels of 0.1 mg for folate per day, hematologic remissions in pernicious anemia have been reported at levels as low as 0.25 mg of folate per day. The precautions section of the labeling conditions for folic acid preparations is amended to read as follows: 'Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive'."

2. Food additive regulation

Folic acid is an approved food additive subject to the limitations on use set forth in the food additive regulations (§ 172.345). The food additive regulation states that: "Folic acid (folacin) may be safely added to a food for its vitamin properties, provided the maximum intake of the food as may be consumed during a period of 1 day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive in excess of 0.4 mg for foods labeled without reference to age or physiologic state; and when age or the conditions of pregnancy or lactation are specified, in excess of 0.1 mg for infants, 0.3 mg for children under 4 years of age, 0.4 mg for adults and children 4 or more years of age, and 0.8 mg for pregnant or lactating women" (21 CFR 172.345). However, this regulation provides no limits, other than 0.4 mg, on the amounts that may be provided by specific foods.

In 1981, the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) reviewed evidence concerning effects of physiologic and pharmacologic doses of folic acid in patients with pernicious anemia (Ref. 5). LSRO noted that virtually all of the experimental work reviewed dealt with the administration of pteroylmonoglutamic acid (folic acid) in relatively pure forms. Responses to folic acid in food products are less well defined than responses to a pure preparation. LSRO concluded at that time that it was not possible to answer with certainty whether intakes of folic acid in foods approaching 400 µg (0.4 mg)/day could result in transient hematologic remission in patients with pernicious anemia (Ref. 5).

D. The Proposed Rule

The scientific data relating to an association between folic acid and neural tube defects that was publicly available at the time of publication of the agency's proposed rule (56 FR 60610) consisted of four clinical intervention trials in women at high risk of recurrence of these birth defects (Refs. 6 through 9), four observational studies (Refs. 10 through 13), a number of studies in which clinical parameters such as serum or red blood cell levels of folate and other vitamins were measured in women who gave birth to one or more infants with neural tube defects (Refs. 14 through 17), and studies that attempted to identify factors that may lead to neural tube defects in animal model systems (Refs. 18 through 26).

The agency developed its proposed rule on the basis of the publicly available scientific evidence. An ongoing randomized controlled trial in Hungary of multivitamin/multimineral supplementation of women at risk of an occurrence of a pregnancy complicated by a neural tube defect had been discussed at scientific meetings (Ref. 27), but the scientific data from this trial were not publicly available.

The agency proposed not to authorize the use on the labels and labeling of foods, including dietary supplements, of health claims relating to an association between ingestion of folic acid and reduction in risk of neural tube defects. The agency based its tentative decision on the available scientific evidence, which showed that daily periconceptional intake of 4 mg (4,000 µg) of folic acid was needed for reduction in risk of neural tube birth defects in women at high risk of this condition based on a previously-affected pregnancy. Among women with histories of neural tube defect-complicated pregnancies, rates for recurrence of such defects have been estimated to be as high as 2 to 10 percent compared to occurrence rates of less than 0.1 percent in the general population (Ref. 28). Thus, because of their significantly increased risk, such women have been the focus of several clinical intervention trials. The amount of folic acid found to be effective in reducing risk of recurrence was significantly in excess of usual daily intakes and exceeded the level of 0.4 mg (400 µg)/day permitted under the current food additive regulation. FDA also tentatively concluded that there was not significant scientific agreement that periconceptional supplementation with doses of folic acid lower than 4 mg (4,000µg)/day in women of childbearing age in the general U.S. population would significantly reduce the risk of occurrence of neural tube birth defects. For these reasons, FDA tentatively determined that claims on foods, including dietary supplements, relating to folic acid and reduction in risk of neural tube birth defects were not justified.

E. Recent Developments

1. New scientific data

Preliminary data from the Hungarian randomized, controlled trial of efficacy of multivitamin/multimineral supplements containing 0.8 mg (800 µg) of folic acid in preventing occurrence of neural tube defects were presented at a meeting held in May 1992 (Ref. 29). A report of preliminary results of this trial of the effects of multivitamin/multimineral supplementation in women at risk of a first occurrence of a neural tube birth defect pregnancy became publicly available in August, 1992 (Ref. 30). This trial was conducted under the auspices of the Hungarian Optimal Family Planning Program and was directed toward overall improvement in pregnancy outcomes among Hungarian women. Nonpregnant women 18 to 35 years of age without histories of infertility or previous fetal death volunteered for this program and, upon determination of eligibility, were randomized to treatment with a multivitamin/multimineral preparation containing 12 vitamins and 7 minerals or to a placebo containing 3 trace minerals only. The multivitamin/multimineral preparation contained 0.8 mg (800 µg) of folic acid. The women participated in a 3-month preparation for pregnancy and began taking their assigned treatments 1 month before a planned conception. Treatments continued through the third month of pregnancy. Six cases of neural tube defects occurred in the pregnancies of 2,052 women taking the placebo, and no cases occurred in the pregnancies of 2,104 women taking the multivitamin/mineral supplement with folic acid. Based upon the preliminary results of this study, periconceptional use of a multivitamin/multimineral supplement apparently significantly reduced the rate of occurrence of isolated neural tube defects in women in the Hungarian population. However, use of the supplement did not affect the incidences of a wide range of other birth defects that occurred in both treatment groups (Ref. 30).

Results of a case-control study of periconceptional use of folic acid-containing multivitamins and risk of occurrence of neural tube defects in

women in Boston, Philadelphia, and Toronto were also presented at the meeting held in May 1992 (Ref. 29).

In the **Federal Register** of July 1, 1992 (57 FR 29323), CDC announced an open meeting in Atlanta, GA on July 27, 1992, to discuss a recommendation that all women of child-bearing age in the United States consume 0.4 mg (400 µg) of folic acid daily to reduce their risk of having a neural tube defect-complicated pregnancy. The results of the case-control study of periconceptional use of folic acid-containing multivitamins and risk of occurrence of neural tube defects in women in Boston, Philadelphia, and Toronto were presented at this meeting, and the transcript of the meeting is publicy available (Ref. 31). In this study, 436 occurrent neural tube defect cases (live born and still born cases and therapeutic abortuses) were selected from metropolitan hospitals in Boston, Philadelphia, and Toronto (areas of moderate prevalence) from 1988 through 1991 and compared to 2,615 controls with other major malformations as to maternal periconceptional use of folic acid. Daily use of a folic acid-containing vitamin supplement in the periconceptional period was reported by mothers of 8 percent of cases and 13 percent of controls; the adjusted odds ratio was 0.6 (95 percent confidence interval (CI)= 0.4 to 0.8). This represented approximately a 40-percent reduction in prevalence. A dietary folate assessment was also conducted among the mothers who did not use folic acid-containing supplements. A significant decrease in risk was found for the group who consumed 0.311 to 0.391 mg of folate daily; the adjusted odds ratio was 0.6 (95 percent CI=0.3 to 0.9). The results of this study as presented at the CDC meeting support a relationship between decreased risk of occurrent neural tube defects and periconceptional intake of either folic acid-containing multivitamins or dietary intake of folate at levels of 0.3 to 0.4 mg/day.

2. Reopening of comment period

The period for submitting comments in response to the November 27, 1991, proposal closed on February 25, 1992. In the **Federal Register** of July 23, 1992 (57 FR 32751), however, FDA reopened the comment period to permit the submission of new scientific data and information that might become available as a result of the meeting held by the CDC on July 27, 1992, and to provide an opportunity for public comment on that scientific data and information. The agency took this action, in part, because it had been advised that the scientific evidence to be discussed at the CDC meeting was not publicly available. The 1990 amendments require that the evidence relied upon by the agency as the basis for allowing health claims relating to a nutrient-disease relationship be publicly available.

3. PHS recommendation

In *Mortality and Morbidity Weekly Reports* of September 14, 1992 (Ref. 1), the Public Health Service issued a recommendation that:

All women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg of folic acid per day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTDs. Because the effects of high intakes are not well known, but include complicating the diagnosis of vitamin B_{12} deficiency, care should be taken to keep total folate consumption at less than 1 mg per day, except under the supervision of a physician. Women who have had a prior NTD-affected pregnancy are at high risk of having a subsequent affected pregnancy. When these women are planning to become pregnant, they should consult their physicians for advice.
(Ref. 1)

PHS noted that the evidence that consumption of folic acid before conception and during early pregnancy (the periconceptional period) can reduce the number of neural tube defects has been accumulating for several years and includes published data from two randomized controlled intervention trials (Refs. 6, 7, and 18), two nonrandomized intervention trials (Refs. 8, 9, and 33), and four observational studies (Refs. 10 through 13). Based on a synthesis of information from these studies, including those which used multivitamins containing folic acid at a daily dose level greater than 0.4 mg, it was inferred that folic acid alone at levels of 0.4 mg per day will reduce the risk of neural tube defects (Ref. 1).

In the discussion accompanying its recommendation, the PHS (Ref. 1) identified several issues that require further attention:

(1) Effective intake: The PHS (Ref. 1) recommended that all women of childbearing age should consume 0.4 mg of folic acid daily to reduce their risk of neural tube defect pregnancies. The PHS (Ref. 1) noted that because supplements containing folic acid at the 0.4 mg (400 µg) level are widely available, this dosage has been the focus of the available observational research studies. PHS also noted that "it is possible that lower doses of folic acid may reduce the risk of neural tube defects, but further research would be needed to learn the minimum effective dose" (Ref. 1).

(2) Multivitamins: The PHS recommendation for the use of folic acid alone was, by necessity, derived by inference from results of the available studies. The Medical Research Council intervention trial included a group of women who used folic acid at a dose of 4 mg per day (plus calcium and iron) and who could be compared with a control group taking calcium and iron only (Ref. 6). Thus, the specificity of folic acid as an etiologic agent in reducing recurrences by 72 percent was established for the study population at this high dose. In contrast, all four observational studies and two of the other three intervention trials measured the use of folic acid-containing multivitamins. Folic acid content and content of other nutrients in these preparations varied, or in some cases, could not be identified (Ref. 1). The preparations used in studies that obtained this information contained (at least) vitamin A, vitamin D, thiamin, riboflavin, pyridoxine, vitamin C, and niacin in addition to folic acid.

Thus, the possibility that nutrients other than folic acid, particularly at intakes of folic acid less than 4 mg daily, could contribute to the protective effect warrants further discussion.

(3) "Folate-preventable" fraction of neural tube defects in the U.S. population: The PHS recommendation recognized that protective effects against occurrence of neural tube defects found in observational studies of multivitamins containing low doses of folic acid have ranged from none to substantial (Ref. 1). Based on the information available, the PHS suggested that a reasonable estimate of the expected reduction in neural tube defects in women in the general U.S. population was 50 percent (Ref. 1).

This issue warrants further discussion because estimates of the magnitude of the preventable fraction and the variation in risks among subgroups of women of child-bearing age may affect decisions as to the best method of implementation.

(4) Safety considerations: The PHS recommendation advised women that care should be taken that folate consumption not exceed 1 mg (1,000 µg)/day except under the supervision of a physician because the effects of higher intakes are not well known (Ref. 1). One of the adverse effects noted was the effect of high intakes on the making a diagnosis of vitamin B_{12} deficiency.

The agency recognizes the risk that increased intakes of folic acid will complicate the diagnosis of the anemia of vitamin B_{12} deficiency and thereby allow the neurological damage caused by this vitamin deficiency to progress

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untreated Several other safety considerations are identified below These issues also warrant further discussion as the questions of whether and how to provide for a health claim are evaluated.

II. Comments on the Proposed Rule

A Introduction

The agency received approximately 150 comments in response to its proposed decision on health claims for folic acid and neural tube defects. Comments were received from: Consumers, consumer advocacy groups, national professional organizations of nutrition educators, national professional organizations of dietitians, organizations of Federal, state, and local regulatory officials, state and territorial public health nutrition directors, manufacturers and suppliers of vitamins to the conventional food industry and dietary supplement industry, trade associations of nutritional supplement manufacturers, practicing physicians and dietitians, and a foreign government A number of comments were received that were more appropriately answered in other dockets, and these were forwarded to the appropriate docket for response.

FDA has considered all of the comments on folic acid and neural tube defects that it received The agency reviewed all of the documents, including letters, press releases, scientific articles and data supporting those articles, review articles, and recommendations that were included in the comments A summary of the comments that the agency received and the agency's responses follow:

B Comments

1 Several comments suggested that health claims should be allowed if potential benefits exceed risks, and that FDA should have used a risk/benefit analysis in determining the validity of health claims Other comments stated that supplementation with folic acid is essentially risk-free

FDA disagrees with this comment. Section 403(r)(3)(B)(i) of the act requires that a decision to authorize a health claim be based on the totality of the publicly available scientific evidence and on significant agreement among experts qualified by training and experience to evaluate such evidence that the evidence supports a claim The concept of "no risk" as a justification for a health claim is inconsistent with the requirements of the 1990 amendments. Moreover, there are safety concerns associated with increased intakes of folic acid. These concerns are discussed below.

2. Several comments asked whether studies must be carried out in the United States for health claims. These comments noted that for the calcium/osteoporosis claim, much of the data related to peak bone mass was derived from studies in rural Yugoslavia and found to be "generalizable" to the U.S. population, but for folic acid and neural tube defects, data from non-U.S. populations studies seemed not to be acceptable to FDA. The comment also stated that in rejecting the folic acid/neural tube defect claim, FDA relied heavily on the argument that much of the data was from non-U.S. studies.

In the proposed rule on general requirements for health claims (56 FR 60610 at 60549), FDA stated that consistent results from different types of well-conducted human studies, by different investigators, in different populations would contribute to the totality of scientific evidence from which a valid health claim may be developed. In its November 27, 1991, proposal on folic acid and neural tube defects (56 FR 60610), FDA stated that it was unable to directly apply results from some studies done outside of the United States because these studies were conducted on populations at significantly higher risk than the U.S. population, they lacked adequate control groups, or they were multiply confounded.

FDA participated in the development of the recently published PHS recommendation (Ref. 1). This recommendation relied heavily upon data from other countries and was developed by combining the results from several types of studies carried out in the United Kingdom, Hungary, Cuba, Western Australia, and the United States. Thus, the folic acid rulemaking does not evidence an unwillingness on the part of FDA to consider studies on non-U.S. populations. However, the characteristics of the population at issue may affect the relevance of the study to the FDA's rulemaking.

3. Comments received from state and national professional organizations, an organization of Federal, state, and local regulatory officials, and U.S. state attorneys general were supportive of FDA's proposed rule denying a health claim for folic acid and neural tube defects. One comment stated that the preponderance of scientific literature does not strongly support such a relationship. Another comment recommended that statements regarding the relationship between folic acid and neural tube defects be postponed until further studies have been completed. One comment stated that when the confounding variables relating to the causation of neural tube defects are also considered, the wholesale claim that folic acid supplementation will reduce neural tube defects becomes even more unfounded. Another comment cited the irreversible neurological damage that can result from excess intake of folic acid by persons with undiagnosed pernicious anemia and noted that maternal hyperthermia (for example, from use of hot tubs during the first month following conception) was a recognized risk factor for neural tube defects.

Several comments stated that FDA should allow a health claim that "Folic acid intakes, at about the U.S. RDA level of 400 µg/day, have been associated with significantly lowered risk of severe birth defects, including spina bifida." A consumer advocacy group recommended that a claim for folic acid and neural tube defects be permitted only on supplements containing free folic acid because there is evidence that neural tube defects will be reduced by such supplements. The comment noted further that there is additional evidence that the incidence of neural tube defects may be reduced by food sources of folate, although there is currently no consensus on this point.

These comments raise several important issues. The agency agrees that neural tube defects are multifactorial in nature. A history of neural tube defects is the single greatest risk factor currently recognized. However, the well-conducted Medical Research Council trial (Ref. 6) demonstrated a specific relationship between intake of high doses of folic acid and reduction in risk of recurrence of some neural tube defects in women at increased risk of this complication because of a prior affected pregnancy. The effect of lower doses of folic acid on neural tube defects is less clear. However, based upon a synthesis of information from several studies (including a major study that became available after FDA published its proposal in November, 1991) (Ref. 31), all of which recorded use of multivitamins containing varying levels of folic acid, PHS has recommended that all women of childbearing age consume 0.4 mg (400 µg) of folic acid per day for the purpose of reducing their risk of neural tube defect-complicated pregnancy (Ref. 1).

With regard to the issue of effectiveness of nonsupplement food sources of folate in reducing the incidence of neural tube defects, the agency notes that the vast majority of women do not experience an occurrence of a pregnancy complicated by a neural

tube defect, and the available evidence does not provide clear evidence of the optimum folate intake to prevent this complication. Although the lowest effective dose is not known, the PHS concluded that 0.4 mg (400 µg)/day is an effective dose Dietary folate insufficiency per se does not seem to be causative in neural tube defects. The vast majority of women appear not to be predisposed to have a folate-related neural tube defect pregnancy. Data from the observational study of Milunsky et al., 1989 (Ref. 13) suggested that women whose diets contained more than 100 µg of folic acid had a lower risk of a neural tube defect pregnancy than did women whose diets contained less than 100 µg folate per day. Laurence (1983) (Ref. 32) observed that when dietary counseling to improve overall diets was provided to women at risk of a recurrence of a neural tube defect, and when such improved diets were consumed, risk reduction approached 50 percent. Similarly, a case-control study conducted in Western Australia suggested that diets containing increased amounts of folic acid, vitamin C, beta-carotene, and fiber (nutrients associated with fruits and vegetables), were protective against occurrence of neural tube defects (Ref. 11). Therefore, the agency believes, that with respect to options for implementation, the scientific data provide a basis for further discussion of the appropriate intake and source.

4. Several comments stated that FDA, in developing its proposed rule regarding folic acid and neural tube defects, rejected conclusions of the LSRO report (Ref. 33). Several comments quoted from conclusions of the LSRO report to support a health claim and stated that the conclusions of the LSRO report contributed to the significant scientific agreement that existed regarding the validity of a health claim respecting folic acid and neural tube defects.

The agency contracted with the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (LSRO/FASEB; FDA Contract No. 223–88–2124, Task Order No. 9) to independently evaluate the scientific literature respecting folic acid and neural tube defects. At the time of publication of FDA's proposal in November, 1991, FDA had available a draft copy of the LSRO report "Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relationships: 1. Folic Acid and Neural Tube Defects" (Ref. 33). In its proposal (56 FR 60610), FDA noted several concerns with the LSRO report, including its failure to focus on the specific relationship of folic acid to neural tube defects in studies where multiple nutrients were given, or where specific nutrient effects could not be isolated; its failure to differentiate between risk of occurrence and risk of recurrence of neural tube defects; and its failure to differentiate between daily doses of 4 mg (4,000 µg) versus 400 µg in terms of effectiveness in reducing the risk of neural tube defects.

LSRO/FASEB submitted its final report as a comment in February 1992 (Ref. 34). The agency's concerns with the draft report were not addressed in the final LSRO report. Therefore, because the final LSRO/FASEB report did not differ from the draft report available to the agency before publication of its proposal, no change in FDA's tentative conclusion is warranted.

The agency notes, however, that there are significant areas in which the agency's proposed rule and the LSRO/FASEB report (Refs. 33 and 34) are in agreement. For example, the agency is in agreement with the report on the following topics: (1) That 4 mg of folic acid has been demonstrated to have a protective effect against development of neural tube defects, (2) that there is no evidence that the effect of folic acid is long-lasting as a protectant or potential protectant against neural tube defects, (3) that in addition to maternal and fetal nutrition, other individual, dietary, nutrition, and health factors also contribute to the risk of neural tube defects, (4) that there are significant gaps in our knowledge of the etiology of neural tube defects and of how folic acid either alone or in conjunction with other vitamins may protect against neural tube defects, and (5) that it is currently unknown whether neural tube defects are caused by a gene-dependent or drug-induced vitamin dependency requiring a higher than physiological intake of folic acid or other micronutrient.

5. Several comments stated that following publication of the results of the Medical Research Council's trial in July 1991 (Ref. 6), significant scientific agreement emerged concerning the importance of folic acid for the prevention of neural tube birth defects.

FDA agrees that the Medical Research Council's randomized double-blind multicenter trial (Ref. 6) clearly found a significant reduction in recurrence rate of neural tube defects in women supplemented periconceptionally with 4 mg folic acid/day. No protective effects of vitamins other than folic acid were observed. The Medical Research Council's study established a specific role for folic acid in reduction in risk of recurrence in a significant proportion of women at high risk of this complication because of a history of neural tube defect pregnancies. This study did not investigate the efficacy of doses of folic acid lower than 4 mg (4,000 µg) per day. Based on a synthesis of available studies, however, including preliminary results of the Hungarian intervention trial, the PHS has inferred that a lower intake of folic acid will reduce the risk of occurrence of neural tube defects. However, a number of concerns have arisen with respect to the effects of a folic acid health claim that must be resolved before such a claim can be authorized.

6. A number of comments identified options for implementing a health claim, suggested means by which the folate status of the population can be improved, recommended daily doses of folic acid lower than 400 µg, identified safety concerns, or expressed concerns about the current food additive regulation on folic acid. Because these comments largely address the issues raised as needing resolution in the discussion accompanying the PHS recommendation (Ref. 1), FDA believes that it is useful to summarize these comments. However, given the ongoing nature of this rulemaking process, responses to these comments are not possible now but are likely to emerge as the process proceeds.

1. Proposed criteria for health claims and use of the food additive regulation

Several comments stated that the agency should establish criteria for foods or supplements making folic acid claims and proposed such criteria. For example, a comment suggested that requiring foods and supplements to contain more than 20 percent of the reference daily intake would be inappropriate because the widespread fortification of foods might lead to excessive folacin intakes. The comment further suggested that the agency monitor folacin intakes closely after health claims for folic acid appear in the marketplace to determine whether the public is ingesting levels that greatly exceed or fall short of the recommended daily intake of 400 µg. The comment recommended that if the agency found that excess intakes of folic acid posed a risk, it could restrict either the number of foods or supplements to which the vitamin could be added or the maximum levels allowed in foods or supplements, according to the food additive regulation for folic acid. Alternatively, the comment suggested that FDA could lower the minimum folic acid content of foods or

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supplements that are allowed to make health claims

FDA intends to review the question of the appropriate level of folic acid in food However, the agency notes that the nature of the rulemaking process, particularly the formal rulemaking process applicable to food additives, does not provide the flexibility or responsiveness envisioned by the comment

Another comment stated that the agency should require full and nondeceptive health claims concerning neural tube defects and folic acid so that consumers are not misled into believing that folic acid might prevent all neural tube defects or reduce the risk of nonneural tube defect birth defects. The comment emphasized that the agency should ensure that claims on folic acid-containing supplements provide full and nondeceptive information. The comment stated that a nondeceptive claim would state that: (a) Folic acid reduces the risk of only neural tube birth defects; (b) scientists estimate that folic acid intakes may prevent only half of neural tube defects; (c) consuming more than 400 µg (0.4 mg) of folic acid daily will not necessarily provide additional protection against birth defects; and (d) scientists have not fully evaluated the safety of doses higher than 800 µg (0 8 mg).

The act requires that claims on foods must be truthful and not misleading. The failure to disclose material facts would render a claim misleading under section 403(a) of the act. The agency agrees that, based on the results of the Medical Research Council trial (Ref. 6), the association between folic acid intake and birth defects is specifically related to neural tube defects. This trial also found that folic acid, while significantly reducing the risk of neural tube defects in women at high risk of recurrence of this complication, did not significantly alter the incidences of a wide variety of other birth defects in the population studied. Therefore, in deciding whether to authorize a health claim, the agency will consider whether such a claim should specifically state that the only types of birth defects for which an association with folic acid has been identified are neural tube defects, such as anencephaly, spina bifida, and anencephalocoele.

2. Effective intake

One comment stated that better information on the lowest effective level of folic acid is desirable in order to provide as strong a basis as possible for a food fortification program. Another comment noted that the available data suggest that the recommended level of 400 µg of folic acid/day is probably considerably higher than is actually needed to achieve protection. Several comments suggested that a daily dose of 0.2 mg folate (200 µg) was probably adequate for reduction in risk of neural tube defects, and that data from older as well as more recent studies support such a conclusion. Several comments stated that the consideration of efficacy of lower doses is important because there are uncertainties as to whether daily supplements of folic acid plus iron can reduce zinc absorption and result in intrauterine growth retardation in pregnant women.

The question of effective intake was highlighted by PHS This issue was addressed by the advisory committee that FDA convened. Although PHS acknowledged that there may be a lower dose that is effective, it concluded that all women who could become pregnant should ingest 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with a neural tube defect (Ref. 1).

3. Specific safety issues

Another comment observed that widespread fortification of the food supply could result from authorization of a health claim as products added folate in order to claim that they were useful in reducing the risk of neural tube defects. The comment noted that following such fortification, the usual intake of folic acid by the U.S. population would rise from about 250 µg/day/person to about 3 to 4 mg (3,000 to 4,000 µg)/day/person, and that the safety of such an outcome is by no means clear. The comment identified large segments of the population with low vitamin B_{12} status and mentioned the potential for development of neurological deficits in such persons as a result of a food supply highly fortified with folic acid. The comment urged the agency to delay action until a full public airing permits a review of all of the implications of each approach to policy in this and related areas. One comment stated that the proposed intake of 0.4 mg (400 µg) should be evaluated in subjects with low zinc status because findings from the United States, Sweden, and Britain suggest that low zinc status is much more common in pregnancy than has been previously suspected, and that zinc deficiency is a known cause of neural tube defects in animal model systems. The comment cited several references that reported that folate can interfere with the utilization of dietary zinc.

These issues were considered by the advisory committee that FDA convened and by the agency in reaching a final decision in this matter

4. Options for implementation

One comment noted that while the quickest and easiest approach to increasing the folate intake of women of reproductive age is to encourage the consumption of folic acid supplements, compliance with such a program would be poor. The comment noted that many adolescent women refuse to use birth control even when provided free of charge and choose not to protect themselves against life-threatening diseases, such as acquired immunodeficiency syndrome (AIDS). Several comments observed that because of the higher rates of neural tube defects among women from lower socioeconomic status groups, alternatives to a "one-a-day" pill method of implementation should be considered. Several comments recommended that fortification of a staple food would likely reach greater numbers of women than would programs utilizing the pill approach. One comment stated that food fortification would require careful documentation of population distributions of consumption of the designated foodstuffs by age, gender, and socioeconomic status. Several comments also included references dealing with the folate status of specific subgroups of the U.S. population and suggested that fortification of staple foods in the food supply would be an appropriate method of improving folate status. The comment noted groups within the population identified in surveys or in clinical studies as at potential risk of folate deficiency include children, adolescents, adults (including pregnant women), and the elderly who could also benefit from folate fortification. Comments also identified other segments of the population at risk of low folate status as those who use alcohol, oral contraceptives, antifolates, and specific nonsteroidal anti-inflammatory drugs.

Again, the comments parallel concerns that were raised by PHS. They will be fully addressed by the agency in deciding, if a health claim is authorized, what is the most effective method of presenting the claim to the U.S. public.

III. Review of the Recent Scientific Literature

In addition to its evaluation of all comments received in response to its proposed rule regarding folic acid and neural tube defects, FDA, using the same criteria identified in the proposal (56 FR 60610 at 60614), also reviewed the scientific literature, including

human studies and studies in animal model systems, that has become publicly available since publication of its proposed rule relative to the relationship between folic acid and neural tube defects.

A. Human Studies

1. Laurence (1991) (Ref. 35) reported the results of an uncontrolled folic acid supplementation trial in women who had a previous pregnancy complicated by a neural tube defect. Women in Cardiff, United Kingdom, at recurrent risk of a neural tube defect pregnancy and who declined to participate in the Medical Research Council trial (Ref. 6) were advised to take a supplement containing 4 mg folic acid and minerals for not less than 1 month before conception and continuing until 12 weeks of gestation. Laurence (1991) (Ref. 35) reported that there were two (2) recurrences of neural tube defects among 234 pregnancies (recurrence risk of 8.5 per 1,000) in the supplemented women. The estimated risk for recurrence among untreated women (none were included in the trial) was about 30 per 1,000. Laurence (1991) (Ref. 35) estimated that the folic acid plus minerals supplementation reduced the risk of recurrence of neural tube defects by more than two-thirds. The author noted that although this was an uncontrolled trial, folic acid should be offered to all high risk women planning further pregnancies.

2. Measurement of maternal or fetal blood levels of specific vitamins is one method used to test the hypothesis that folic acid status is directly related to risk of neural tube defects. Several investigations have tested this hypothesis by determining whether occurrence of neural tube defects is associated with decreased maternal levels of vitamins (Refs. 14 through 17). A recently reported study, Holzgreve et al. (1991) (Ref. 36), found no differences in serum and erythrocyte folate in blood samples from fetuses with neural tube defects (n=17) or fetuses without such defects (n=45). Samples were obtained at 16 to 22 weeks of gestational age. The folate level of women pregnant with a neural tube defect-affected fetus was normal, and nutritional status did not differ between the two groups. The authors noted that their findings of no correlation between neural tube defects and fetal blood folate values do not necessarily contradict the Medical Research Council study (Ref. 6) but show that an easy explanation for the protective effect of folate observed in the British study cannot as yet be provided. The authors also stated that further research is needed to define the role of micronutrients in the development of neural tube defects.

3. The results of the Medical Research Council trial (Ref. 15) demonstrated that women at very high risk of having a recurrence of a neural tube defect-complicated pregnancy could significantly reduce their risk by taking a high level of folic acid periconceptionally. Other investigators have attempted to determine how these results might apply to a general population of women at much lower risk of occurrence of neural tube defects. Mills et al. (1992) (Ref. 37) measured levels of folate, vitamin B_{12}, and retinol in maternal serum samples drawn early in 89 pregnancies resulting in neural tube defect offspring and in 178 control pregnancies. Samples were obtained within 8 weeks of neural tube closure. The results of this population-based study in Finland, a low prevalence area for neural tube defects, demonstrated no relationship between maternal serum folate, vitamin B_{12}, and retinol during pregnancy and the risk of neural tube defects.

B. Animal Studies

Studies with animal model systems are one of several lines of evidence that are used to establish associations between various nutrients or toxicants and birth defects. The relationship between folate deficiency and the incidence of neural tube defects in experimental animal model systems is not clear. A variety of protocols have been used to study the relationship between nutritional status and risk of neural tube defects (56 FR 60610). The anticonvulsant drug valproic acid is suspected of causing neural tube defects in humans. The mechanism for such effects is unknown but has been postulated to involve induction of a deficiency of folic acid. Hansen and Grafton (1991) (Ref. 38) examined this possibility by culturing rat embryos concurrently in valproic acid and folinic acid, a folic acid derivative. The authors reported a dose-related increase in the number of open neural tubes in rat embryos cultured in valproic acid. When various concentrations of folinic acid were added in combination with a teratogenic dose of valproic acid, there was no decrease in the incidence of open neural tubes. The results of this study suggested that valproic acid-induced open neural tubes in this experimental animal model system are not the result of a deficiency of folic acid.

However, Wegner and Nau (1991) (Ref. 39) also studied the protective effects of folinic acid against valproic acid-induced neural tube defects in the mouse and reported a different result. These authors observed significant diurnal variations in folate metabolism in mouse embryos between days 8.5 and 9.5 of gestation. They measured significant time dependent protective effects against valproic acid-induced teratogenesis such that folinic acid reduced neural tube defects when provided at one time period but not when provided at another time period. Such findings indicate the extreme sensitivity of developing embryonic tissue to external factors and are of importance in considering interactions of drugs with folate metabolism as a possible mechanism of teratogenesis (Ref. 39).

Other investigations have sought to determine whether mice deficient only in folic acid produce embryos with neural tube defects. For example, Heid et al., 1992 (Ref. 40) used folate-free amino acid-based diets for producing well-defined dietary concentrations of folic acid for rats and mice. Heid et al (Ref. 40) reported that when Swiss-Webster mice were fed inadequate dietary folic acid, fewer and smaller embryos (that developed normally) were produced during pregnancy. Their studies indicated that folate deficiency alone is insufficient to produce neural tube defects in Swiss-Webster mice.

C. Authoritative Statements

1. Institute of Medicine, National Academy of Sciences

In 1990, the Institute of Medicine of the National Academy of Sciences published its report, "Nutrition During Pregnancy" (Ref. 28). The Institute of Medicine updated this report in 1992 (Refs. 41 and 42) to reflect new data (primarily the results of the Medical Research Council trial; Ref. 6) that had become available since the first publication of the report. Data from the Hungarian randomized intervention trial were not publicly available at the time the report was updated. The report noted that a previous history of a neural tube defect should alert health care providers to the need for preventive measures before a subsequent pregnancy. The report recommended that women with a history of neural tube defect-complicated pregnancy follow the CDC recommendations (Refs. 41 and 42) for high-dose folic acid supplementation (preconceptionally and throughout the first trimester, under a physician's supervision) to reduce their risk of recurrent neural tube defects (Refs. 41 and 42). The report noted that questions remain concerning the etiology of neural tube defects, the most appropriate dosage, and the

appropriate role of nutrition in preventing first occurrences.

2. World Health Organization

That there is still considerable uncertainty as to how best to reduce the risk of neural tube defects is shown by information in a recently published "World Health Organization (WHO) Drug Information Bulletin" (Ref. 43). The bulletin notes that an expert advisory committee has now been set up in the United Kingdom to consider how best to ensure that all women likely to become pregnant receive supplementary folic acid (Ref. 44). The WHO Bulletin states "Unfortunately the available data provide no indication of how long supplementation needs to be continued to obtain the maximum effect, or of whether the same protective effect can be obtained with lower doses. These are matters of some importance because it may be impracticable to supply a supplement of 4 mg daily from dietary sources alone. Some empiricism will be required to arrive at a recommendation. Short of conducting a further trial with different dosage regimens, formal demonstration of a dose-effect relationship will remain outstanding" (Ref. 43). FDA notes that data from the Hungarian intervention trial were not publicly available at the time this statement was prepared.

D. Conclusions from the Recent Scientific Literature

The recent scientific literature, including studies in humans and animals, is consistent with PHS recommendation and raises a number of issues that PHS noted as needing resolution.

IV. Actions on Folic Acid

A. Determination That No Claim Can be Authorized at This Time

Section 403(r)(3)(B)(i) of the act states that FDA is to grant a health claim when there is significant scientific agreement that the scientific data relating a nutrient to a disease or health condition supports such a claim. The recent PHS recommendation (Ref. 1) evidences that such agreement exists. However, the Food, Drug and Cosmetic Act must be read as a whole.

Sections 403(r)(3)(A)(ii), 402(a), and 409 of the act express the proposition that the use of a substance in food must be safe. As the PHS recommendation states (Ref. 1), there are significant questions that persist about the use of folic acid in food. Questions raised in the PHS recommendation (see section I.E.3. of this document) include the safety of high intakes by both the target population as well as by other segments of the population who may unintentionally be exposed to high intakes if overfortification of the food supply were to occur as a result of the PHS recommendation. There are, additionally, several other unresolved scientific questions that will require discussion before a claim is authorized.

Based on these concerns, FDA concludes that under section 403(r)(3) of the act, it cannot authorize a health claim on folic acid and neural tube defects. FDA is concerned that the possibility exists that folic acid itself could be a substance that increases the risk of a disease or a health-related condition in persons in the general population (see section 403(r)(3)(A)(ii) of the act). Therefore, FDA concludes that it cannot authorize a health claim on folic acid until the questions regarding the safety of the use of this nutrient as well as the other concerns raised by PHS are satisfactorily resolved. However, the agency is undertaking efforts to address and resolve these concerns. The remainder of this document outlines how the agency will do so.

B. Issues

1. Estimation of range of increased intakes

FDA expects that there would likely be a significant increase in consumption of folic acid by women in their childbearing years, and by the general population, if a health claim were to be authorized because manufacturers would add folic acid to their products in order to claim that these products are useful in reducing the risk of birth defects. Intakes of multiple doses of free folic acid in the form of supplements and from its increased presence in the food supply could rapidly result in intakes of more than 3 mg (3,000 µg)/day by persons in the target population as well as by persons in the general population (see Table, Estimate A). Considerably higher amounts of folic acid (approximately 7 mg (7,000 µg)/day) could be consumed by subgroups of the population (e.g., teen-age and young adult males, heavy users of supplements) (see Table, Estimate B).

a. *Differences in bioavailability between free folic acid and food folates.* It is well-recognized that the bioavailability of free folic acid (the form included in dietary supplements and in fortified foods) is several-fold greater than that of naturally occurring food folates. Estimates of the increased bioavailability ("potency") of free folic acid relative to food folates range from at least 2-fold to 4-fold or greater (Ref. 45). The pronounced differences in bioavailability between free folic acid and food folates must be factored into considerations of appropriate dose as well as considerations of potential safety issues.

b. *History of use.* Because the National Research Council recommended daily allowances have been set below 500 µg of food folates ("folacin") (except those for pregnant women) since 1968 (Refs. 46, 47, and 48), and because the food additive regulation has limited the amount of free folic acid added to fortified foods and supplements to 400 µg/day (except supplements for pregnant or lactating women), there is no history of long-term use by persons in the general U.S. population, including pregnant women, of daily intakes of free folic acid in excess of about 1 mg (1,000 µg). Therefore, potential safety concerns must be addressed.

2. Specific safety issues and estimates of magnitude

If a wide variety of food sources were fortified with 400 µg folic acid/serving, as would likely occur following authorization of a health claim, intakes of folic acid could easily reach 3 mg (3,000µg)/day or higher. FDA's concerns regarding large increases in folic acid fortification, and the large increases in intake that would result, are summarized below.

a. *Vitamin B_{12}-related issues.* (i) Issue: As mentioned above, in the presence of excess folic acid and inadequate vitamin B_{12}, the anemia of vitamin B_{12} deficiency may not develop but severe and irreversible nerve damage may continue. This interaction between the functions of folic acid and vitamin B_{12} has been recognized for many years and is the basis for the precautionary statement on oral and parenteral preparations of folic acid for therapeutic use in treating folate-deficiency anemias. The agency is reviewing the literature upon which this concern is based.

In 1945, folic acid was introduced as a possibly specific substance for the treatment of pernicious anemia. A large number of reports based on small numbers of cases studied for short periods of time followed the introduction of this new therapy (Ref. 49). It was soon recognized that the two manifestations of pernicious anemia (the hematologic disturbances and the neurologic disturbances) responded differently to therapy with folic acid. Reports began to appear in the literature calling attention to the deleterious and sometimes "explosively" harmful effects of folic acid on the neurologic

manifestations of the disease (Refs. 50 through 53).

There is ample evidence that most patients with pernicious anemia respond hematologically to folic acid (Refs. 54 through 59). Doses of 1 to 5 mg folic acid can reverse the hematologic abnormalities of the deficiency (Refs. 60 through 64). Hematologic improvement in pernicious anemia has also been noted at doses of folic acid lower than 1 mg (e.g., 200 to 500 µg) (Refs. 58, 59, 65 through 67, and 100), but the responses have been less predictable than those to doses of 1 to 5 mg. For example, Chosy et al. (1962) (Ref. 66) reported that daily injections of 400 µg of folic acid caused hematologic responses in some patients with pernicious anemia. Some investigators have not been convinced that amounts of folic acid within the range of 200 to 500 µg/day would mask pernicious anemia (Refs. 65, 68, and 101), while others have reported suboptimal responses to 500 µg of folic acid in patients with pernicious anemia (Refs. 58 and 59).

On the basis of the degree of reticulocyte response, 200 µg folic acid has been used to differentiate between the megaloblastic anemias caused by folate deficiency and vitamin B_{12} deficiency (Ref. 69). Chanarin (1969) (Ref. 69) cautioned that this use should not be interpreted to mean that long-term administration of 200 µg of folic acid could not mask pernicious anemia in some otherwise untreated patients. Herbert (1975) (Ref. 70) and Herbert et al. (1980) (Ref. 71) recommended that 100 µg folic acid be administered orally in therapeutic trials. This dosage has been shown to provide a maximal hematologic response in patients with folate deficiency but not in those with vitamin B_{12} deficiency (Ref. 72). This finding is in agreement with the statement of Chanarin (1969) (Ref. 69) that doses of folic acid greater than 200 µg/day might produce hematologic responses in some patients with pernicious anemia.

Pernicious anemia is not an insignificant or rare condition in the United States (see section IV.B.2.a.ii. of this document), nor is its diagnosis always straightforward. For example, Lindenbaum et al. (1990) (Ref. 73) has reported that while serum cobalamin levels have been generally considered to be essentially 100 percent sensitive in the detection of clinical disorders caused by cobalamin deficiency, there is a significant minority of patients with cobalamin deficiency whose serum cobalamin levels are normal. In such individuals, measurements of serum metabolite concentrations of methylmalonic acid and total homocysteine may be necessary to facilitate the diagnosis of vitamin B_{12} deficiency (Ref. 73).

In summary, the available evidence indicates that some patients with pernicious anemia will respond to folate therapy in doses less than 500 µg/day. Other individuals with pernicious anemia will not exhibit hematologic remission at such doses but will respond to doses of 1 mg of folic acid and higher. It is not possible to answer with certainty whether intakes of folic acid in foods approaching 400 µg/day could result in transient hematologic remission in patients with pernicious anemia. The agency believes that this issue warrants further discussion.

(ii) Estimates of magnitude: Vitamin B_{12} deficiency anemias are not uncommon in the U.S. population. Information from the National Center for Health Statistics indicates that there were 740,000 patient visits to physicians' offices with a diagnosis of pernicious anemia during the 2-year interval 1989 to 1990 (Ref. 74). Approximately 524,000 of these visits were by women (Ref. 74). An additional 16,000 patient visits during this interval involved a diagnosis of other vitamin B_{12} deficiencies (for example, those associated with consumption of vegetarian diets).

National Center for Health Statistics records from the National Hospital Discharge survey for 1990 identified 31,000 discharges that included a diagnosis of pernicious anemia and an additional 7,000 discharges that included a diagnosis of other vitamin B_{12} deficiency anemia (Ref. 75).

It is recognized that among African-Americans, particularly African-American women, pernicious anemia is not confined to the elderly, as it generally is among whites (Refs. 76 through 78). Thus, a large subgroup of young African-American women in the general population may be especially vulnerable to adverse effects of significantly increased intakes of folic acid.

Although the number of "visits" recorded in the ambulatory care surveys mentioned above include multiple visits by some patients, the data show that pernicious anemia is not an insignificant or rare condition in the U.S. population. There is currently no way to determine how many persons in the general U.S. population have undiagnosed vitamin B_{12} deficiency. A large number of people have subnormal levels of serum vitamin B_{12} without having any classical manifestations of vitamin B_{12} deficiency (Refs. 79 and 80). Ten to twenty percent of elderly persons, more than 25 percent of demented patients, 15 to 20 percent of AIDS patients, and 15 to 20 percent of patients with malignant diseases have low serum vitamin B_{12} levels. In addition, 5 to 10 percent of all patients, regardless of age or clinical status, are found to have low serum B_{12} levels. Metabolic and subtle neurologic dysfunction are demonstrable in a significant fraction of such cases (Ref. 79). Very little is known about whether folate supplementation has any effect on such persons, who are more numerous in the population than are patients with pernicious anemia (Ref. 79). This issue requires consideration in assessing the potential impact of increased intakes of folic acid.

b. *Risks to pregnant women.* In "Nutrition During Pregnancy," the Institute of Medicine (IOM) stated that the safety of large doses of folic acid during pregnancy has not been systematically determined (Ref. 28). The IOM noted that large doses of folic acid may inhibit the absorption of other nutrients by competitive interaction and can also obscure the diagnosis of onset or relapse of pernicious anemia which is extremely rare in women of childbearing age. The IOM recommended modest supplementation for some segments of the U.S. population at risk of folate inadequacy. Such subpopulations include some pregnant women who lack the knowledge or financial resources to purchase adequate food, abusers of alcohol, cigarettes, or drugs, those with malabsorption syndromes, pregnant adolescents, and women bearing more than one fetus. Based upon data available at the time, the IOM recommended 300 µg folate daily during pregnancy for such subpopulations (Ref. 28).

(i) Issue. A potential risk of increased folic acid supplementation involves effects of high blood levels of free folic acid on the embryo during early gestation. The Medical Research Council study that treated women at high risk of a recurrence of a neural tube defect pregnancy with 4 mg folic acid daily did not have the power to ascertain the safety of such high level supplementation in the population studied. This concern was stated by the study's author (Ref. 6). The agency noted above that there is no history of long-term use in the United States of folic acid at levels at or above about 1 mg/day.

(ii) Estimate of magnitude. About 4 million pregnancies occur in the United States each year. The concern regarding the lack of safety data for high doses of folic acid in pregnant women has been

discussed in the scientific literature since the report of the successful Medical Research Council trial (Ref. 6). For example, Leeming et al. (1991) (Ref. 81) stated that while 4 mg of folic acid until 12 weeks of pregnancy may reduce the incidence of neural tube defects in women at high risk of recurrence, there may also be damaging effects. These authors suggested that substantial amounts of unmetabolized folic acid appear in the plasma after a single high dose and suggested that high circulating levels of folic acid may damage developing neural tissue during early embryonic development. They further noted that high levels of folic acid are not normally found in the circulation. Scott et al. (1991) (Ref. 82) also suggested the seriousness of risk during early embryonic development. They stated that while the fully developed brain may be protected from neurotoxic effects of high circulating levels of folic acid, no information is available as to whether developing neural tissue is similarly protected.

c. *Persons with epilepsy* (i) Issue. The possibility has been raised that folic acid supplements in high doses may reverse the effectiveness of anticonvulsant medication (Ref. 83). Folic acid and certain anticonvulsants compete with each other for receptors on brain cells. A potential concern is whether high intakes of folic acid exacerbate seizures in persons with uncontrolled or with drug-controlled epilepsy.

(ii) Estimates of magnitude. There are an estimated 200,000 persons in the United States whose epilepsy is not controlled. Most studies on the effects of folic acid in persons with drug controlled epilepsy have involved institutionalized individuals and responses to increased intakes have been variable.

d. *Persons taking drugs that interfere with folate metabolism.* (i) Issue. Folate antagonists such as Methotrexate are used in the treatment of various cancers, including leukemias (Ref. 84). In addition, low doses of Methotrexate are currently used in the treatment of psoriasis, rheumatoid arthritis, and bronchial asthma. The antifolate Trimethoprim is used to treat bacterial infections. Other therapeutic drugs that interfere with folate metabolism include: Pyrimethamine, Triamterene, sulfasalazine, colchicine, phenytoin, and Trimetrexate (Ref. 84). Recognition of the therapeutic usefulness of these antifolate drugs for the conditions above has developed during the last 30 years.

(ii) Estimates of magnitude. The drugs mentioned above are used in the treatment of: Psoriasis, rheumatoid arthritis, bronchial asthma, malaria, hypertension, Crohn's disease, gout, epilepsy, and AIDS. Taken together, many of these conditions affect significant portions of the general U.S. population.

The safety of significantly increased folate intakes by persons with these disorders, whether or not they are receiving antifolate medications, remains an open question (Ref. 85). The safety or toxicity of oral folic acid supplements in persons who are being treated with drugs known to interfere with folate metabolism requires further discussion.

It is not known whether substantially increased intakes of folic acid would impair (or reverse) the therapeutic effectiveness of these medications. It is known, for example, that "rescue" by 5-formyl-tetrahydrofolate (a biologically active reduced folate derivative that can compete with antifolate compounds and does not require the activity of the enzyme dihydrofolate reductase for conversion to an active form) is used in patients undergoing chemotherapy with the antifolate Methotrexate. Treatment with 5-formyl-tetrahydrofolate is used to reduce the toxicity of Methotrexate and to protect nonmalignant cells (for example, those in the intestinal tract) from damage by the chemotherapeutic agent.

3. Identifying and targeting the population at risk

a. *The target population.* Given the absence of biological markers to identify women at greatest risk of a neural tube defect pregnancy, a very large population of women must be reached in attempts to reduce the risk of neural tube defects. There are about 70 million women of reproductive age in the United States, of whom about 2,500 annually will have a pregnancy complicated by a neural tube birth defect. As noted above, this number is an underestimate of the number of neural tube defect pregnancies that occur. The safety issues show the importance of the method of implementation chosen to reach the target population. Fortification of the food supply, for example, would expose more than 250 million people to increased folic acid intakes to reach the approximately 4 million women who become pregnant each year. Use of supplements, while potentially capable of targeting some of the population at risk, would not likely reach those of lower socioeconomic status or noncompliers who might also be at increased risk.

b. *Estimation of the "folic acid-preventable" fraction of neural tube defects.* The folic acid-protective effects against risk of neural tube defects found in studies of folic acid at levels lower than 1 mg/day have ranged from none to substantial (Ref. 1). In general, observational studies in areas of moderate prevalence (2–5 neural tube defects/1,000 births) have found protective effects, while a study in two areas of lower prevalence (less than 1 neural tube defect/1,000 births) found no protective effect. While such considerations should not negate an appropriate recommendation for women of child-bearing age, the magnitude of the preventable fraction may influence decisions on how best to implement the PHS recommendation and thus whether and how to provide for a health claim.

4. How does the available information on effective levels of intake affect options for implementation

The neural tube forms and closes during the first month after conception before most women are aware of their pregnancy. For this reason, and since more than half of the pregnancies in the United States are unplanned (Ref. 119), the PHS recommendation stated that it would be prudent for women to consume 0.4 mg of folic acid daily on a regular, continuous basis as long as they are capable of becoming pregnant (Ref. 1).

In the supplementary information accompanying its recommendation, the PHS noted that it is possible that lower intakes of folic acid may reduce the risk of neural tube defects, but that further research would be needed to learn the minimum effective level (Ref. 1). This issue is of importance not only because supplement doses lower than 0.4 mg (400 µg) have not been studied adequately, but because of the unknown contribution of dietary intake to the results reported in the available studies. Most of the studies of supplement use have not evaluated folate intake from foods. Thus, the base of dietary folate intake to which a folic acid-containing supplement was added is unknown. This complicates assessment of intake-response relationships.

Consideration of the minimum effective level of intake is also relevant because of the need for women to maintain good folate nutriture at least 1 month before conception and through the first 6 weeks of pregnancy. Given this fact and the high rate of unplanned pregnancies in the United States, women potentially must consume an effective amount of folic acid during all or most of their child-bearing years. This represents 30 years or more of chronic exposure for the target population. If the minimum effective

level is added to the conventional food supply, it represents a lifetime of exposure for the entire population.

The best available studies used daily intakes of folic acid of 0.8 mg (800 µg) or 4 mg (4,000 µg). These levels are outside of the range of folate provided by usual U.S. diets (100 to 500 µg/day). For example, the well-conducted Medical Research Council trial demonstrated that 4 mg of folic acid daily during the periconceptional period was effective in women at high risk of a recurrence of a neural tube defect-affected pregnancy (Ref. 6). Preliminary data from the recently closed Hungarian trial in women at risk of occurrence of a neural tube defect pregnancy showed that periconceptional use of 800 µg folic acid in a multivitamin/multimineral preparation significantly reduced these defects (Ref. 30). Under current regulations, products with these dosages are drugs.

Based on a synthesis of information from several studies, including those that recorded use of multivitamins containing folic acid at varying doses, the PHS inferred that folic acid at levels of 0.4 mg per day will reduce the risk of neural tube defects (Ref. 1). This level is currently regulated as a food.

Whether other vitamins have an impact on the effect of folic acid when taken at low doses is not known. For example, Smithells et al. (Ref. 8) used 360 µg folic acid with other vitamins, and the Hungarian study (Refs. 27 and 30) used a dose of 800 µg folic acid with other vitamins. The study of Milunsky et al. (1989) (Ref. 13) examined folic acid as a component of multivitamins, and Mulinare et al. (1988) (Ref. 12) studied vitamin use but there was no documentation of folic acid use. All preparations associated with reductions in risk of neural tube defects, with the exception of preparations used in the Medical Research Council trial, contained (at least) vitamin A, vitamin D, thiamin, riboflavin, pyridoxine, vitamin C, and niacin in addition to folic acid. The results of Mills et al. (1989) (Ref. 10) showed no effect of folic acid from multivitamins or fortified cereals at a level of 400 µg. Information from a recent case-control study in Boston, Philadelphia, and Toronto suggested that a daily intake of 300 to 400 µg/day of folates from conventional foods offered significant protection from risk of neural tube defects (Ref. 31). The interrelation between several vitamins and folic acid may be explored by the advisory committee.

The difficulties in identifying a minimal potentially protective intake of folic acid are related in part to observations that poor folic acid status per se is not directly related to neural tube defects (that is, a dietary insufficiency of folic acid has not been consistently associated with increased risk of neural tube defects or predictive of women who would be most likely to benefit from folic acid supplementation). Neural tube birth defects are not among adverse pregnancy outcomes that have been associated with clinical folate deficiency in humans. Inconsistent results have been obtained in clinical studies carried out to determine if mild to moderate folate deficiency is associated with adverse pregnancy outcomes (Ref. 28).

For example, Yates et al. (1987) (Ref. 16) reported that although erythrocyte folate levels were lower in women who had several infants with neural tube defects, there was no association between erythrocyte folate levels and dietary folate intake. Thus, the risk for recurrence of a neural tube defect pregnancy could not be attributed to lower dietary folate intakes by mothers of affected infants (Ref. 16). Mills et al. (1992) (Ref. 37) recently measured levels of folate, vitamin B_{12}, and retinol in maternal serum samples drawn early in 89 pregnancies resulting in neural tube defect offspring and in 178 control pregnancies. Samples were obtained within 8 weeks of neural tube closure. The results of this population-based study in Finland, a low prevalence area for neural tube defects, demonstrated no relationship between maternal serum folate, vitamin B_{12}, and retinol during pregnancy and the risk of neural tube defects.

Nutrition during early pregnancy is critical for normal embryonic development. Human intervention and observational studies have focused on the periconceptional interval as a time when maternal nutritional status is particularly important, and when intervention may be of greatest value. In human embryogenesis, the neural tube forms and closes within the first month of pregnancy, often before a women realizes that she is pregnant.

5. Options for implementation

The supplementary information accompanying the PHS recommendation stated that there are three potential approaches for the delivery of folic acid to the general population in the dosage recommended. These include: (1) Improvement of dietary habits, (2) fortification of the U.S. food supply, and (3) use of dietary supplements. Each option has certain advantages and disadvantages. A careful review of these options is warranted as the agency works toward deciding whether and how to authorize a health claim.

V. Role of the Advisory Committee

Given the significance of neural tube defects and the recommendation of the PHS, FDA convened an advisory committee to help resolve the outstanding concerns on the effects of food claims describing the effects of folic acid intake on neural tube defects. The process that the agency has instituted and the concerns that need to be addressed and resolved are described below.

In addition to convening the advisory committee, the agency will conduct an indepth analysis of consumption patterns for specific foods across all age groups and both genders. The agency will consider various possibilities for fortification of foods, and such analysis will facilitate a determination of the effects of fortification of specific foods on overall intake in selected groups in the population.

The advisory committee heard testimony from experts as well as from other interested parties and provided recommendations to the agency on four broad issues:

(1) What is the target population that needs to be reached regarding the effects of folic acid on neural tube defects?

(2) How does the available information on the effective level of intake affect options for implemenation?

(3) What are the safety concerns for persons in the target population and in the general population?

(4) If a claim is to be authorized, what is the most appropriate method for presenting it to the target population?

An announcement of the meeting of the advisory committee and an opportunity to participate was provided in a **Federal Register** notice (57 FR 52781, November 5, 1992). The agency is reviewing the recommendations provided by the advisory committee.

VI. Impact Statements

A. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was

published in the **Federal Register** of November 27, 1991 (56 FR 60856). The agency requested comments on the RIA along with the food labeling proposals.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

B. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

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PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (c) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(c) Folic acid and neural tube defects.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

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Table. Estimates of intakes resulting from fortification of foods with folic acid

Folate/folic acid source	Amount (µg)	Estimate of bio-availability[1] (percent)	Free folic acid equivalent (µg)
Estimate A:			
Usual diet	300	50	150
Add foods fortified to unit limit of 400 µg:			
Plus 1 supplement	400	100	400
Plus 5 servings breads and cereals	2,000	75	1,500
Plus 2 servings fruit juice	800	75	600
Plus 3 servings dairy products	1,200	75	900
Total µg/day	4,700		3,550
Estimate B:			
Usual diet	300	50	150
Add foods fortified to unit limit of 400 µg:			
Plus 2 supplements	800	100	800
Plus 10 servings breads and cereals	4,000	75	3,000
Plus 4 servings fruit juice	1,600	75	1,200
Plus 6 servings dairy products	2,400	75	1,800
Total µg/day	9,100		6,950

[1]Estimates of bioavailability used in FDA's calculation were 50 percent for food folates, 75 percent for folic acid added to foods, and 100 percent for folic acid in supplements.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0101]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements: Antioxidant Vitamins and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between antioxidant vitamins and cancer. However, FDA is authorizing a health claim relating substances in diets low in fat and high in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) to a reduced risk of cancer. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and was developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

Based on the totality of the publicly available scientific evidence, including recently available evidence, the agency has concluded that there is not significant scientific agreement among qualified experts that a claim relating antioxidant vitamins to reduced risk of cancer is supported. The publicly available evidence does indicate, however, that diets rich in fruits and vegetables, which are generally low in fat and high in vitamin A (as beta-carotene), vitamin C, and dietary fiber, are associated with decreased risk of several types of cancer and there is significant scientific agreement that the evidence supports this association. The evidence is not sufficient to attribute the reduction in risk specifically to vitamin A (as beta-carotene), vitamin C, or vitamin E, alone or in combination, or to other components of these diets. In order to evaluate further the relationship between antioxidant vitamins and cancer, FDA is planning to convene an advisory committee to review the available data and recommend whether a health claim for specific antioxidant vitamins and cancer should be authorized.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: John N. Hathcock, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 301-344-6006.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60624), FDA proposed to deny the use on food labeling of health claims relating antioxidant vitamins (specifically, vitamin C, vitamin E, and beta-carotene) to the risk of cancer. The proposed rule was issued in response to provisions of the 1990 amendments that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537). As amended by the 1990 amendments (Pub. L.101-535), the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or 343(r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether claims respecting 10 nutrient-disease relationships meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The relationship between antioxidant vitamins and cancer is one of the claims required to be evaluated. In carrying out this inquiry, FDA chose for consideration three antioxidant vitamins: vitamin C, vitamin E, and beta-carotene. Vitamins C and E were chosen because they are vitamins that function as antioxidants. FDA chose beta-carotene because it is an antioxidant, and because it is a provitamin and an important source of dietary vitamin A activity. FDA did not choose preformed vitamin A (retinol or retinoic acid) because its biological functions are not through an antioxidant role, and because vitamin A cannot function in an antioxidant fashion similar to that of beta-carotene (carotenoids) and vitamins C and E. FDA extended consideration of this topic area to all sources of antioxidant vitamins, i.e., both conventional foods and dietary supplements (56 FR 60624 at 60625).

FDA published a notice, in the **Federal Register** of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific health claim topic areas identified in the 1990 amendments, including antioxidant vitamins and cancer. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on antioxidant vitamins and cancer in the proposed rule. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed below.

In the proposed rule (56 FR 60624), FDA requested written comments on its tentative determination not to authorize a health claim for antioxidant vitamins and cancer. The agency specifically requested submission of data which directly bear on: (1) whether beta-carotene, vitamin C, and vitamin E per se, rather than some other component of food, decrease the risk of cancer in humans, and (2) the range of beta-carotene, vitamin C, and vitamin E intake that produce this effect. In addition, on January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments (57 FR 239, January 3, 1992).

In the **Federal Register** of July 23, 1992, FDA published a notice reopening the comment period for three specific health claim topics, including antioxidant vitamins and cancer (57 FR 32751). In that document, FDA noted that the agency had received or identified several new studies on the relationship between antioxidant vitamins and cancer, which appeared to present significant new information that was not identified in the studies that FDA reviewed in its proposal. FDA listed the new studies and requested comments on them. Using the same criteria as described in the proposed rule (56 FR 60624 at 60629), these new studies are reviewed below. Comments received on the new studies are incorporated into the discussion of comments that follows.

Altogether, the agency received approximately 100 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately answered in other companion food labeling documents, and these were forwarded to the appropriate docket for response.

The Dietary Supplement Act of 1992 (H.R. 6181) established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. The Dietary Supplement

Act says that FDA can grant health claims for foods, including dietary supplements, under section 403(r)(3)(B)(i) of the act. However, it may not act on such claims under section 403(r)(5)(D) of the act until it establishes a standard to implement that section of the act, which the Dietary Supplement Act says may not occur until December 1993. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to evaluate the antioxidant vitamins and cancer claim based on the standard that FDA is establishing for determining the reliability of health claims under section 403(r)(5)(D) of the act. In the November 27, 1991, proposal on general requirements for health claims, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that antioxidant vitamins are found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on antioxidant vitamins and cancer for any foods.

Because the Dietary Supplement Act provides that FDA may grant claims using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act, and given the breadth of FDA's November 1991 proposal on antioxidant vitamins, FDA has decided to move forward to determine whether it can authorize a claim under section 403(r)(3)(B)(i) of the act for antioxidant vitamins and cancer. However, this rule does not apply to dietary supplements. While a manufacturer of a dietary supplement can make a claim on antioxidant vitamins and cancer without rendering its product misbranded under section 403(r)(1)(B) of the act, the manufacturer should assure itself that the making of the claim will not misbrand the product under section 403(a).

II. Review of New Scientific Evidence: Beta-carotene, Vitamin C, and Vitamin E (Review of the Scientific Literature Available From 1991 Through February 1992, and Publications Submitted as Part of Comments)

A. New Studies

As noted in the **Federal Register** of July 23, 1992, results of several human studies have been reported in the scientific literature on the association between antioxidant vitamin intake and risk of cancer since the drafting of the proposed rule. Additionally, comments received in response to the proposed rule (56 FR 60624) noted some studies that FDA had overlooked in its proposal. FDA also identified some new studies through literature searches. Most of the new studies evaluated the effects of antioxidant vitamins in the larger context of diet and cancer, with some focusing primarily on the relationship of the antioxidant vitamins to fat and energy intakes. The recently available studies collectively addressed the relationship between antioxidant vitamins and a variety of types of cancer, including cancer of the breast, prostate, pancreas, uterine cervix, urinary bladder, colo-rectum, lung, and stomach.

Those studies submitted as comments which contributed to the totality of the scientific evidence on antioxidant vitamins and cancer are included in the following review. Those studies submitted as comments which were not germane to the topic or did not provide useful scientific information are addressed in the response to comments later in this final rule.

1. Overall cancer mortality rate

The relationship between vitamin C intake and total and cancer-related mortality rates in the United States was investigated through evaluation of the data from the National Health and Nutrition Examination Survey (NHANES I) (Ref. 1) (Table 1). The results indicated that higher vitamin C intakes are not significantly related to lower cancer mortality rates. The standardized mortality rate from all types of cancer collectively was a nonsignificant 0.78 for those taking supplemental vitamin C, compared with those who did not supplement with vitamin C.

2. Bladder cancer

A study of bladder cancer (Ref. 2) found that higher calculated vitamin E intake from foods was associated with slightly reduced risk of bladder cancer, after adjusting for smoking and total calories (Table 1). No association with cancer risk for the level of retinol or carotenoid intake was evident in this study. The participation rate was approximately 70 percent for the cases, the hospital-based controls, and the population-based controls. This study may have introduced bias by including prevalent cases (approximately 40 percent). Case-control studies usually select incident (newly diagnosed) cases. Prevalent cases are patients who have survived the disease for a period of time. Prevalent cases are generally not included in case control studies because the characteristics that contributed to their survival may modify potential risk factors of disease.

3. Breast cancer

In a recent study on breast cancer and foods that contain antioxidant vitamins (Ref. 3), dietary carotene and vitamin C intakes from foods were found to be associated with protection, but use of these constituents as dietary supplements had no effect on risk of breast cancer (Table 1). Patients with breast cancer tended to eat fewer than 10 fruits and vegetables per week. There was a low participation rate (56 percent of eligible cases and 46 percent of eligible controls), which may have introduced bias into the study. It is unclear why a large percentage of those identified as eligible did not participate, and this makes extrapolation of the results to the general population more difficult.

Another case-control study of breast cancer (Ref. 4) reported a marginal protective association between fruits rich in beta carotene and risk of breast cancer when premenopausal and postmenopausal women were evaluated together (Table 1). There was also a marginal protective association found for calculated preformed vitamin A (i.e., retinol) intake in postmenopausal women. When both premenopausal and postmenopausal women were analyzed together, the study found no significant association between antioxidant vitamin intake and the risk of breast cancer. There was also no evidence in this study that vegetable consumption was associated with reduced risk of breast cancer.

A case-control study in France (Ref. 5) found significantly higher intake and higher serum levels of vitamin E and higher serum vitamin E/total cholesterol ratio in breast cancer cases than in controls (Table 1). This effect remained after eliminating vitamin supplement users. Leukocyte vitamin E was elevated in cases; leukocyte vitamin C was also elevated in cases, but the elevation was not statistically significant. The report hypothesized that this effect may be the result of vitamin E-related metabolic alterations from breast cancer, rather than a cause of the disease.

Another case-control study on breast cancer (Ref. 6) found that diet was a more important risk factor for breast cancer in postmenopausal women than in premenopausal women (Table 1). After adjusting for energy intake, education, and age at menarche, the studies found that the intakes of dietary vitamin C, beta-carotene, total retinol equivalents and cellulose were positively associated with reduced risk of breast cancer in postmenopausal

women. The findings demonstrated that there was a marginally higher risk of breast cancer associated with high intake of nutrients from animal products and, after adjusting for the confounders described above, a lower risk associated with high intake of fruits and vegetables.

4. Cervical cancer

A recent case-control study of invasive cervical cancer (Ref. 7) reported that a slightly lower risk was associated with higher consumption of fruits and fruit juices (Table 1). No significant difference in risk of invasive cervical cancer was evident based on level of consumption of vegetables or legumes. There was decreased risk associated with higher intakes of vitamin C, beta-carotene, and other carotenoids. When vitamin C and beta-carotene were included in the same statistical model, the association for beta-carotene was attenuated, but the protective effect of vitamin C remained significant. This suggested that while beta-carotene and vitamin C are often present simultaneously in foods, the observed effect was more closely associated with vitamin C than beta-carotene. These results are difficult to interpret because there is generally more measurement error for beta-carotene intake than for vitamin C intake, and the strength of correlations may be affected by the size of the error variance.

A companion study in the same population (Ref. 8) focusing on serologic indicators of antioxidant vitamin intake found that intake of vitamin A (i.e., retinol), cryptoxanthin, lycopene, alpha-carotene, lutein, and vitamin E (alpha-tocopherol) did not significantly differ between cases of invasive cervical cancer and controls (Table 1). In addition, beta-carotene levels remained steady as cervical cancer progressed, arguing against an effect of disease progression on serum level. After adjusting for age, study site, reproductive history, socioeconomic status, and papilloma virus infection, higher serum beta-carotene and gamma-tocopherol levels were associated with decreasing risk of the disease. Considered together, the two studies found an association between beta-carotene intake, serum levels of beta-carotene, and decreasing risk of cervical cancer. In general, the protective effects were stronger for foods than for specific nutrients.

A clinical survey of patients with abnormal cervical cell types (cervicitis or dysplasia) in a recent study (Ref. 9) involved only 75 women and was confounded by smoking habits (Table 1). It did not have sufficient statistical power to find a significant difference in risk in relation to serum levels of antioxidant vitamins.

A case-control study of cervical intra-epithelial neoplasia in relation to dietary and serum carotenoids found ambiguous results for beta-carotene (Table 1) (Ref. 118). Protective associations were observed, however, for serum concentrations of the carotenoid lycopene and for dietary vitamin C.

5. Colorectal cancer

A study from the Balleric islands (Ref. 10) found no significant association between the risk of either colon or rectal cancer and the level of intake for vitamin A, retinol, carotene, vitamin C, or vitamin E (Table 1). There was a significant protective association for consumption of fiber from legumes and folic acid from cruciferous vegetables and reduced risk of cancer. The report stated that the findings support the recommendation for a diet high in vegetables as part of a lifestyle to reduce the risk of colorectal cancer.

6. Lung cancer

One of the new papers is a report of the results of a prospective cohort study (Ref. 11) regarding dietary intake of antioxidant vitamins and the risk of lung cancer in Finnish men (Table 1). The study found a protective effect associated with intake of foods rich in vitamins A, E, and C on the risk of lung cancer in nonsmokers. There was a strong protective association observed in this Finnish study between margarine intake and the risk of lung cancer in both smokers and nonsmokers. The report hypothesized that this finding was due to an effect of the vitamin E in margarine, although the researchers could not rule out an anticarcinogenic effect of some other constituent of margarine. Similarly, there was a lower incidence of lung cancer associated with consumption of foods that contributed 80 percent of the vitamin C in the Finnish diet (fruits, potatoes, and vegetables). The study could not separate the role of these nutrients from that of the foods which contain them in this association of reduced risk of lung cancer with diet, and could not rule out anticarcinogenic effects of other, nonnutritive constituents of fruits and vegetables, such as terpenes, flavones, and phenols. Also, behaviors possibly associated with intake of antioxidant-rich foods, such as exercise, not smoking, and decreased fat intake, may reduce cancer risk. The report concluded that studies focused on dietary patterns, intake levels, and protection against lung cancer by other constituents of antioxidant-rich foods are needed. Because the dietary estimate was based only on intake in the year preceding entry into the 20-year study, the estimate of antioxidant vitamin intake may not accurately represent the actual intake during the study duration, since changes in diet and supplement use were likely over the 20 years of the study.

Another new case-control study evaluated diet during the year preceding diagnosis and serum vitamin concentrations at diagnosis with lung cancer (Ref. 12) (Table 1). The calculated mean dietary intakes of beta-carotene were 24 percent lower for lung cancer cases than for controls, and 10 percent for other epithelial cancer cases than for controls. Serum concentrations of beta-carotene, retinol, and vitamin E were lower in the cancer patients than in the controls by 58, 30, and 31 percent, respectively, for lung cancer, and 33, 11, and 14 percent, respectively, for other epithelial cancer cases. The odds ratios for intakes of fruits and vegetables were rather irregular, and the associated trends were weaker than the trends for beta-carotene. The time period addressed in the dietary recall was the year prior to diagnosis. By comparison, cases in a 2-year period following sampling or interview are often excluded from prospective studies to help reduce the chance that the effects are a result of the cancer. Thus, the design of this study could have introduced bias related to deaths from preexisting cancer.

7. Oral and pharyngeal cancer

A population-based case-control study evaluated diet and dietary supplement use in relation to oral and pharyngeal cancer (Ref. 13) (Table 1). The results show decreased risk in association with higher consumption of fruits and vegetables and dietary supplements. In this four-State study, use of supplements was associated with being female, white, more highly educated, having a lower body mass, being a resident of California, and consuming more fruits and vegetables. Users of supplements of individual vitamin types were at lower risk after controlling for effects of tobacco, alcohol, and other risk factors. After adjustment for use of other supplements, vitamin E supplementation was the only one that remained associated with reduced risk.

8. Pancreatic cancer

A study on pancreatic cancer (Ref. 14) found a protective association between intake of dietary vitamin C and risk of pancreatic cancer after adjusting for

smoking and total calories (Table 1). Weak protective effects were also associated with vitamin A (i.e., retinol) and fiber intake and risk of cancer. Pancreatic cancer is characterized by a very rapid clinical course and deterioration of the pancreas, so dietary interviews and histopathologic confirmation are often not feasible. The Zatonski study may have introduced bias by using surrogates for assessing dietary history in 71 percent of cases. Reliance on a surrogate adds to the difficulty of recall. The spouse was sought as the surrogate in this study, because spouses generally provide reasonable dietary histories. Radiographic diagnosis of pancreatic cancer was used in 57 percent of the cancer cases. In lieu of a histologic diagnosis, the possibility of inaccurate diagnosis cannot be dismissed. This is a flaw in the study because noncases may have been included in the case group, and the signs of pancreatic cancer could have been confused with those of cancers of the upper gastrointestinal tract.

Another study on pancreatic cancer (Ref. 15) reported a statistically significant protective effect of vegetable consumption on the risk of pancreatic cancer after adjusting for smoking and total calories (Table 1). Protective effects were also demonstrated for consumption of both fresh vegetables and cooked cruciferous vegetables. This study did not separate the role of the food versus nutrients in the noted protective effects. A large percentage of dietary interviews relied on a proxy or substitute, which may have introduced errors in the estimates of food consumption. Proxies may not be aware of the complete dietary habits of the case that they represent.

9. Prostatic cancer

A study in Madrid, Spain, found no association between dietary vitamin A or C intake and the risk of prostate cancer (Ref. 16) (Table 1). However, the report noted that the customary Mediterranean diet is rich in fruits and vegetables. Any protective effect may have been pervasive at all levels of intake observed.

A case-control study of men in Utah (Ref. 17) found only a slight protective association between vitamin A intake in older men and the risk of prostate cancer (Table 1). Beta carotene had a nonsignificant protective association for prostate cancer in men aged 45 to 67 years. Dietary fat in men aged 68 to 74 years was the strongest association between a dietary risk factor and prostate cancer.

10. Skin cancer

A nested case-control study of serum micronutrients and low incidence cancer in Finland found a large decrease in risk of melanoma in association with higher serum beta-carotene concentrations (Ref. 18) (Table 1). There was a significant association, also, between higher serum alpha-tocopherol concentrations and reduced risk of melanoma. However, the small size of the study and wide confidence intervals prevent drawing strong conclusions from this study.

11. Stomach cancer

A case-control study of stomach cancer in high- and low-risk areas of Germany found a significant strong protective association between vitamin C from fruits and vegetables (RR = 2.32 for the lowest against the highest quintile of calculated intake) and risk of stomach cancer (Ref. 19) (Table 1). The results also implicated local water supply and smoked meat as possible sources of carcinogens or their precursors.

It has been suggested that vitamin C may reduce the risk for some cancers, particularly stomach cancer, through an antioxidant role in which the vitamin blocks formation in the stomach of carcinogens such as nitrosamines (Refs. 20 and 21). Most nitrosamines are mutagenic and carcinogenic in test systems, and, thus, many studies of the possible role of vitamin C in reducing the risk of cancer have focused on nitrate, nitrite, nitrosamines, and mutagenicity. Hence, several recent studies were directed toward relationships between vitamin C and formation of N-nitroso compounds, or between N-nitroso compounds and stomach cancer or precancerous pathology of the stomach. Data from such studies could prove useful in determining the specificity of vitamin C in relation to reduced risk of stomach cancer.

A case-control study in Shanghai, China, found that urinary ascorbic acid was lower and urinary nitrate higher in patients with gastric cancer than in normal controls (Ref. 22) (Table 1). The urine was not mutagenic (Ames test) in controls but the urine of subjects with dysplasia was somewhat mutagenic and that from gastric cancer patients was highly mutagenic. Normal controls had low levels of N-nitroso compounds in gastric juice, compared with the higher levels in patients with chronic atrophic gastritis, dysplasia or gastric cancer. The mutagenicity of the urine may have been related to synthesis of N-nitroso compounds in the stomach, and differences in this process may have been due to differences of ascorbic acid and nitrate. From studies of gastric cancer patients, without any other type of data, it is not clear whether the N-nitroso compounds are causal, predictive, or the result of gastric cancer.

The role of mutagenic/carcinogenic N-nitrosamides in stomach cancer was evaluated in a study with a complex, integrated design in China (Ref. 23) (Table 1). The study included: (1) Measures of mutagenicity of extract of local fish sauce before and after nitrosation, (2) determination of the carcinogenicity of these nitrosated products in the growing rat, (3) assaying the N-nitrosamides in these products, and (4) correlation of N-nitrosamides in gastric juice with the severity of precarcinogenic pathological changes in the stomachs of human subjects. In the absence of nitrosation, none of the fish sauce extracts was mutagenic. After nitrosation, all samples were mutagenic in common mutagenicity tests (Ames and sister chromatid exchange tests). The local fish sauce extracts from only two villages were mutagenic in the micronucleus test. Four weeks after treating newborn rats with fish sauce, only those treated with the sauce that was mutagenic in all three tests showed marked precancerous dysplasia. After 16 weeks, the same treatment groups had cancerous ulceration in the glandular stomach, with dysplastic glands and cells that had penetrated the mucosa and infiltrated into submucosa and muscular layers of the gastric wall. The mean concentrations of N-nitrosamides in the nitrosated fish products were more than 15 times higher in the samples from a high-risk area than in the samples from a low-risk area. The N-nitrosamide concentrations in gastric juice of human subjects had a strong positive correlation with the severity of pathological changes in the stomach.

A preliminary study in China (Ref. 24) found that N-nitroso compounds in the urine were higher in subjects with gastric dysplasia than in normal controls or subjects with chronic atrophic gastritis and/or intestinal-type metaplasia of the stomach (Table 1). The levels of N-nitroso compounds were lower in gastric juice than in the urine. With the small size and variability of this study, the N-nitroso compound levels in gastric juice could not be evaluated in relation to severity of stomach pathology.

The urinary concentrations of N-nitroso compounds and nitrate in urine of children from areas of low- and high-risk of stomach cancer in Costa Rica

have been studied (Ref. 25) (Table 1). The children were dosed with either 500 milligrams (mg) proline plus 200 mg ascorbic acid or 500 mg proline alone. [The proline was administered to assure that the quantities of N-nitrosoproline excreted were large enough to be chemically assayed in the 24-hour urine collected.] The amounts of N-nitrosoproline excreted were lower in the children from the low-risk area than from the high-risk area. In children from both areas, ascorbic acid treatment decreased the amount of N-nitroso-proline excreted. The N-nitrosoproline excretion had a highly significant positive correlation with the amount of nitrate excreted.

In a clinical trial involving English patients at high risk of stomach cancer (in this study, patients with atrophic gastritis, pernicious anemia, partial gastrectomy, or vagotomy), high doses of ascorbic acid (4 grams per day [g/day]) substantially decreased urinary N-nitroso compound excretion by all patients except those with pernicious anemia (Ref. 26) (Table 1). All patients received their normal diets, but avoided vegetable and fruit juices during the 4 weeks of the ascorbic acid treatment and 4 weeks of post-treatment observation. Serum ascorbic acid levels indicated excellent compliance with the ascorbic acid treatment.

A clinical trial of nitrosation of added L-proline by a high level of endogenous nitrate in test meals that were either low or high in endogenous ascorbic acid found that dietary levels of ascorbic acid significantly inhibit nitrosation of proline by dietary nitrate (Ref. 27) (Table 1). The results indicate that not all subjects synthesized nitrosoproline in vivo, and those who did not were the subjects who failed to show inhibition by ascorbic acid. Those who had in vivo nitrosation (13 of 19 subjects) showed strong inhibition of this process by ascorbic acid.

These results are supported by the results of a study that found lower excretion of nitrosoproline in subjects eating a lacto-vegetarian diet than in subjects eating a free-choice diet (Ref. 28). Supplementation with as little as 60 mg/day ascorbic acid decreased nitrosoproline excretion by the lacto-vegetarians, but not by those eating free choice diets. Supplementation with ascorbic acid at 300 or 3,000 mg/day decreased nitrosoproline excretion by both groups. Similarly, an earlier study found that dietary ascorbic acid (330 mg/day, principally from lemon juice) strongly decreased urinary excretion of two nitrosated products of the anthelmintic drug piperazine that are potent carcinogens in animals (Ref. 29). The inhibition of nitrosation by supplemental ascorbic acid decreases the mutagenicity of gastric juice (Ref. 30) and fecal mutagenicity (Refs. 31 and 32). Also, low concentrations of ascorbic acid in gastric juice are associated with chronic atrophic gastritis (Ref. 33) (Table 1), a condition widely considered to be premalignant (Ref. 34).

B. Conclusions From New Studies

1. Beta-carotene

Consistent with earlier studies reviewed in the proposed rule, these recent studies support findings that there is an inverse relationship between dietary intakes of green and yellow fruits and vegetables and the risk of cancer. This relationship is strongest for lung cancer. Intakes of the green and yellow fruits and vegetables have also been shown to be inversely associated with cervical cancer, but the evidence is not as consistent as with lung cancer. These studies were based on calculated intakes of nutrients from these foods. However, it is not possible to determine from these studies what substance or substances in these foods were responsible for the results. Beta-carotene may be responsible for the effect, or its presence in these foods may simply serve as a marker for some other unmeasured substances that are responsible for the protective effect of fruits and vegetables. Mechanistic studies provide a theoretical basis (singlet oxygen quenching) on which to postulate a protective antioxidant effect by beta-carotene, but the evidence from experimental animal carcinogenesis studies is less supportive. The evidence continues to be consistent with the conclusions of the major authoritative documents (e.g., "The Surgeon General's Report on Nutrition and Health" (Ref. 35) (the Surgeon General's report); the National Research Council's (NRC's) Report on Diet and Health: Implications for Reducing Chronic Disease Risk (Ref. 36) (the Diet and Health report); and the recent Life Sciences Research Office (LSRO) review (Ref. 37)) that the consumption of fruits and vegetables is inversely associated with risk of some cancers.

2. Vitamin C

Current data are compatible with the tentative conclusion in the proposed rule that consumption of fruits and vegetables rich in vitamin C may protect against some types of cancer. These data also provide additional indications of a mechanism to explain the relationship between vitamin C and reduced risk of stomach cancer. The relatively small number of studies reported since publication of the proposed rule are in agreement with earlier findings that consumption of fruits and vegetables is protective against cancer at several sites, particularly stomach cancer. The new studies, taken together with previous studies, indicate that consumption of fruits and vegetables is most consistently protective against cancers of the stomach, lung, and cervix, and less consistently protective at other sites. These data, however, are not sufficient to identify vitamin C versus other substances in these foods as being responsible for the observed protective effect.

The evidence from studies related to N-nitroso compounds is useful in identifying a mechanism, in human populations, whereby vitamin C could be responsible for decreasing the risk of some cancers, such as stomach cancer. The production of N-nitroso compounds with known carcinogenicity potential has been suggested as a cause of at least some stomach cancers in high-risk populations in China, Costa Rica, and Great Britain. The relevant data come from clinical trials showing the inhibition of nitrosation reactions in the stomachs of study populations, and epidemiological studies showing an association of N-nitroso compounds with precancerous and cancerous pathology of the stomach.

The results of the clinical trials on N-nitroso compound excretion, including new studies, indicate that levels of ascorbic acid from foods inhibit nitrosation reactions in humans by nitrite produced from dietary levels of nitrate, and that supplemental ascorbic acid within the range commonly obtained from foods (60 to 300 mg) can significantly decrease excretion of nitrosated products. Other new evidence shows that gastric juice and urinary nitrosamine concentrations are higher in normal persons in high-risk geographical areas than in normal persons living in low-risk areas, higher in persons with the more severe preneoplastic pathological changes in the stomach than in persons with less severe pathological changes, and higher in stomach cancer patients than in normal individuals. Ascorbic acid is only one determinant of endogenous nitrosation; dietary nitrate and its subsequent reduction to the nitrosating product nitrite by oral and gastric bacteria is also a strong determinant of endogenous nitrosation. Other determinants include nondietary influences such as smoking.

The carcinogenicity of N-nitroso compounds formed by endogenous nitrosation is determined by the amount of products formed and by their

chemical identities. The amounts formed are controlled by nitrate intake, nitrate reduction to nitrite, amounts of precursor amines available, and inhibition by ascorbic acid and other inhibitors of nitrosation. The identities of nitrosation products are determined by the identities of the precursor amines, available endogenously, in foods, or from other sources such as pharmaceutical products.

Although most of the several hundred nitrosamines and nitrosamides that have been tested are animal carcinogens, those used in evaluation of the potential for nitrosation in human subjects were selected because they are noncarcinogenic. Nevertheless, they provide a useful indicator of the effectiveness of vitamin C in decreasing the synthesis of carcinogenic members of the N-nitroso family of compounds. Studies of N-nitrosoproline, for example, must therefore be interpreted as indicators of nitrosation potential and associated risk of cancer, and not direct indicators of carcinogenic risk from that substance. It seems probable that the identities of precursor amines, and therefore of the N-nitroso compounds produced by endogenous nitrosation, will be different from one human population to another, depending on diet and other factors. Current scientific information is not sufficient to determine which specific mutagenic and carcinogenic N-nitroso compounds may be responsible for stomach cancer in various human populations, and it is reasonable to expect that these may vary from one population to another. Nonetheless, vitamin C is an inhibitor of the nitrosation reaction through its interaction with nitrite, regardless of the identify of the amine or amide being nitrosated and the corresponding identity of the resulting nitrosamine or nitrosamide.

The possible relationship of urinary and gastric juice N-nitroso compounds with stomach cancer is shown by the association of these compounds with precancerous pathological changes in the stomach and by the association of these pathologies with elevated risk of stomach cancer. The concentrations of N-nitroso compounds in gastric juice and urine are directly correlated with the degree of severity of the precancerous lesions in the stomach. The mutagenicity and carcinogenicity in test systems and experimental animals of N-nitroso compounds from food sources provide suggest a cause-and-effect relationship of N-nitroso compounds and stomach cancer in humans.

These effects cannot be interpreted as indicating that all stomach cancers are attributable to N-nitroso compounds or any other chemical carcinogens, or that vitamin C or other antioxidants can eliminate the risk of stomach cancer. Current data do not allow the exclusion of other mechanisms, such as general antioxidant effects, from the possible protective effects of vitamin C. Furthermore, the data from clinical trials showing inhibition of nitrosation reactions in the stomach, and epidemiological studies showing an association of N-nitroso compounds with precancerous and cancerous pathology of the stomach do not directly link vitamin C intakes with cancer risk or establish the validity of nitrosation reactions as a risk factor for stomach cancer in the U.S. population. These data provide a mechanistic basis for understanding a possible protective effect of vitamin C for stomach cancer risk. At this time, however, nitrosation has not been accepted by the general scientific community as a validated risk factor for stomach cancer. One of the unresolved questions is whether studies of this mechanism from the Chinese and other populations, which differ from the U.S. population in genetic, dietary, and environmental risk factors, adequately explain the etiology of stomach cancer in the United States.

3. Summary of vitamin C and cancer risk

Results from the newer data are similar to results of studies reviewed in the proposed rule, which showed that diets high in fruits and vegetables were associated with a reduced risk of some cancers. Additionally, the new data on the relationship of vitamin C in inhibiting nitrosation reactions in the stomach, resulting in reduced production of N-nitroso compounds with known carcinogenicity, provide a basis for a mechanism by which vitamin C may reduce the risk of some cancers such as stomach cancer in some people. However, these studies were done in populations outside the United States, so their relevance to the pathology and etiology of the types of stomach cancer in the United States is controversial. Furthermore, nitrosation has not received acceptance by many experts as a valid and quantifiable risk factor or surrogate marker for stomach cancer risk. Its validity and utility as an endpoint for evaluating the effect of nutrients on stomach cancer risk, therefore, warrants further discussion.

4. Vitamin E

The latest available information since the publication of the proposed rule is not sufficient to reach a definite conclusion about an association between vitamin E intake and the risk of cancer. Some studies provide suggestive evidence of an association of lower plasma/serum concentrations and lower dietary intake of vitamin E with increased risk of cancer. Mechanistic and animal studies provide a theoretical basis on which to expect a protective effect, but human studies are inconsistent and do not provide a convincing pattern of support for that conclusion. Even if an effect of vitamin E were assumed, it would not be clear from current data which specific chemical of the tocopherol family was responsible for the observed effect.

III. Summary of Comments and The Agency's Responses

Several comments supported the proposed rule to disallow a claim for antioxidant vitamins and cancer, without giving a rationale. Others supported the proposed rule, indicating that a cause-and-effect relationship of lowered risk has been established for fruits and vegetables, but that it is not clear that this relationship is due to the antioxidant vitamins in those foods.

The three final LSRO reports (Refs. 37 through 39) submitted as comments, which provided independent up-to-date reviews of the scientific evidence, also reached similar conclusions, except for vitamin C and stomach cancer. The LSRO report on vitamin C and cancer (Ref. 39) noted the consistency of epidemiological findings associating high intakes of vitamin C or vitamin C-rich foods with reduced risk of stomach cancer, but noted that vitamin C was either not related to other cancer sites or that study results were much less clear about such relationships. The LSRO report on Vitamin A and cancer (Ref. 37) concluded that, for foods containing beta-carotene, the associations with decreased cancer risk could not be attributed specifically to beta-carotene or to any other carotene compound. The LSRO report on vitamin E and cancer (Ref. 38) concluded that there was not a clear association of decreased cancer risk with consumption of foods high in vitamin E, and the tentative associations observed could not be attributed to vitamin E rather than to some other component. The report further stated that studies on vitamin E with animals and in vitro test systems provide a theoretical basis on which reduced risk of cancer can be hypothesized.

Many comments opposed the proposal not to allow a health claim for antioxidant vitamins and cancer. Issues raised in these comments are discussed below.

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A. Scientific Standard and its Application

In the proposed rule (55 FR 60624), FDA reviewed the evidence and conclusions reached in recent authoritative documents from the Federal Government and other sources. The agency updated the evidence reached in these documents by reviewing all human studies in the literature subsequent to these documents, and by contracting with the LSRO of the Federation of American Societies for Experimental Biology (FASEB) for an independent review. The agency considered the results of animal studies to the extent that they clarified human studies or suggested possible mechanisms of action. The agency evaluated the strengths and weaknesses of individual studies and then assessed the strength of the overall combined evidence, taking into account the strength of the association, the consistency of findings, specificity of the association, evidence for a biological mechanism, and presence or absence of a dose-response relationship.

1. A number of comments discussed the types and weighing of data used by FDA in reaching its tentative position. Several comments noted that the proposed rule repeatedly suggested that epidemiological data are not enough, and that complete clarity must await the completion of clinical trials. One comment stated that clinical trials should be undertaken only when feasible and likely to yield a definitive answer, and that this is not the case for antioxidant vitamins and cancer. Other comments stated a belief that FDA favored prospective over case-control studies because they are less subject to misclassification and recall bias. One of these comments argued that there are advantages to case-control studies in cancer research and that concurrent followup (prospective cohort) studies are too expensive and time-consuming to be done often. The comment further noted that followup studies usually cannot address interactions and confounding factors because the necessary information does not exist or because too few subjects develop the cancer of interest, and that the case-control study is uniquely well-suited to the study of cancer and other diseases of long duration. A comment stated that most epidemiological studies handle the issue of nutrient intake from dietary supplements in a manner that obscures their impact, that many studies have insufficient power for specific outcomes, and that many involve inadequate or inappropriate questionnaires. Another comment stated that the 1990 amendments do not set out a drug efficacy standard, but only require that there be significant scientific agreement that a claim is supported by the scientific evidence.

FDA disagrees that the proposed rule indicated that clinical trials are specifically required to support a health claim. FDA's proposed validity standards for health claims and conformance with these standards were discussed in the proposed rule on general requirements for health claims (56 FR 60537 at 60547 through 60549). In that document, FDA noted that, while intervention (i.e., clinical) studies are generally more reliable than observational studies for determining cause-and-effect relationships, the agency recognized that there are frequently reasons why the conduct of such studies is not feasible or ethical. FDA also noted that, in evaluating proposed claims, it would take into account the overall strengths and weaknesses of the available data, and that a combination of various types of studies can frequently compensate for deficiencies in individual studies and thus provide a stronger case to prove or disprove a hypothesis. Furthermore, regardless of the type study used (e.g., case-control versus prospective), study designs are most useful when they can determine whether or not an observed effect is due to the specific food component of interest.

In the proposed rule on health claims for antioxidant vitamins and cancer (56 FR 60624 at 60629 through 60630, 60633, 60636), FDA listed additional criteria used in evaluating the scientific evidence for each of the three antioxidant vitamins and risk of cancer. FDA again indicated that it assessed the weaknesses and strengths of individual studies; and then the agency assessed the strength of the overall evidence, taking into account the strength of the associations, the consistency of the findings, the specificity of the associations, the evidence for a biological mechanism, and the presence or absence of a dose-response relationship. FDA noted that the agency's tentative conclusions reflected the strength, consistency, and preponderance of the data as reported. FDA did not speculate about what the results of specific studies might have been if they had involved different designs, greater statistical power, or more specific questionnaires.

After reviewing the conclusions of the federal government and other authoritative reports and the updated literature review, FDA concluded that the evidence is strong that consumption of fruits and vegetables that are good sources of beta-carotene and vitamin C are associated with lowered risk of cancer at a number of sites (56 FR 60624 at 60631, 60635, and 60638). However, the agency tentatively concluded that the data were not sufficient to establish that these two vitamins themselves were responsible for this association. The agency also noted that it was aware of ongoing clinical trials that, when completed, would provide valuable data about the specific effect of the antioxidant vitamins on the risk of cancer. However, the agency did not intend that this statement should be interpreted to mean that the results of these or other studies were a necessary condition for authorizing a health claim for the antioxidant vitamins and risk of cancer. Rather, the agency simply stated this information to indicate its awareness of these studies and the rapidly evolving nature of the scientific evidence relative to the topic area. While FDA discussed the relative advantages and disadvantages and generally agreed upon weighting of various types of human studies in a generic sense, the agency did not intend to convey the impression that one type of study would be rejected or that clinical studies were required. Rather, it was the overall sufficiency of the available evidence that was important.

FDA has not required a drug efficacy standard for health claims on foods under the 1990 amendments. The requirements for demonstration of drug efficacy differ substantially from the scientific standard for authorization of health claims on foods. For example, clinical trials are necessary to gain approval of a new drug; as discussed above, they are not required for authorization of a health claim on food, if other types of available data are sufficient.

2. A comment expressed concern that the agency had used a more liberal standard in evaluating health claims for calcium and osteoporosis and lipids and cancer than for antioxidant vitamins and cancer. The comment cited the proposed rule on dietary lipids and cancer (56 FR 60764 at 60765 through 60766, November 27, 1991) in which FDA quoted from the diet and health report that data from epidemiological and experimental animal studies were sufficient to support a claim that dietary fat may influence the risk of some types of cancer, although the precise determination of the quantitative relationship and nature of the association between dietary fat and the overall risk of cancer has not been determined. The comment compared the proposed rule on antioxidant vitamins and cancer (56 FR 60624 at

60631 through 60632), arguing that FDA concluded that similar data are inadequate to support a claim for antioxidant vitamins and cancer. The comment claimed that distinctions between the arguments FDA used to accept a claim on lipids and cancer and reject a claim on antioxidant vitamins and cancer are illusory at best.

FDA disagrees with the assertion that the agency applied a variable standard for authorizing various health claims. For some topics such as calcium and osteoporosis, sodium and hypertension, lipids and heart disease, and lipids and cancer, there was a long history of review by expert panels from the Federal Government, the National Academy of Sciences, and other authoritative groups. These groups concluded that the science supports these nutrient/disease relationships, and this fact provides evidence for significant scientific agreement among qualified experts about the state of the evidence. In contrast, the authoritative reviews have concluded that the publicly available data do not support a conclusion that the antioxidant vitamins reduce cancer risk. In reviewing the recent human studies which became available subsequent to publication of these authoritative reports, FDA did not find compelling evidence that these nutrients were specifically responsible for reduced risk of cancer in persons consuming diets high in fruits and vegetables. Without such data, FDA could find no basis to conclude, counter to these previous conclusions of expert panels that, based on the totality of evidence, there is significant scientific agreement that an antioxidant vitamins/cancer claim is supported.

3. Some comments stated that FDA has relied on the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36) without considering all recent publications. These comments noted that the earlier authoritative reviews failed to consider all of the available data, and thus some of their conclusions may have rested on incomplete data. The comment also noted that the explosion of new research on the relationship between antioxidant nutrients and cancer has produced a large number of recently published studies which escaped the LSRO reviews. The comment also identified a number of studies included in the LSRO reviews that were not included in the tables published in the proposed rulemaking. The comment suggested that, while this may or may not have influenced the decisionmaking in this case, it might provide an incomplete picture to others who read the FDA proposal.

FDA disagrees with these statements. FDA considered not only the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36), but also all available recent publications that were relevant to the issue, including the recent review by the LSRO (Refs. 37 through 39). FDA recognizes that the authoritative review documents may not have considered and certainly did not cite every available publication related to the subject matter under consideration. FDA believes, however, that they authoritatively considered the original research publications and critical reviews necessary to reach accurate conclusions about the state of the scientific evidence on antioxidant vitamins and cancer.

The topics in the authoritative reports were evaluated by nationally recognized experts who would be expected to be familiar with all significant findings available at the time of the reports. Furthermore, except for the LSRO reports, these reports were subject to no requirements to list, as references, all available scientific literature. Most likely, they followed the common procedure of the scientific community and listed only those studies considered most relevant to the issues under review. FDA advises that any papers which were not cited in these reports but which commenters felt were important could have been submitted as comments to the public docket. Those that were submitted were included in FDA's review of new studies, or if not appropriate for inclusion in that section, are discussed in specific comments.

FDA also acknowledges that not every paper cited in the LSRO reviews was incorporated into the proposed rule. Conclusions from the LSRO preliminary reports were considered in developing FDA's proposed rule. Those relevant studies not included by FDA in the proposed rule, but cited by LSRO, have been included as new scientific evidence in this final rule (see section II. of this document).

The additional studies cited by one comment either are not sufficiently relevant to warrant their inclusion in the review of new scientific evidence, did not meet the inclusion criteria in the proposed rule, or are old enough to have been considered for inclusion in the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36) or the recent reviews by the LSRO (Refs. 37 through 39). There is broadly based scientific agreement of an association between dietary patterns high in fruits and vegetables and reduced risk of cancer, as acknowledged in the proposed rule, and in the Surgeon General's report (Ref. 35) and the Diet and Health report (Ref. 36). However, studies that identify or confirm the established relationship of protective effects of fruits and vegetables on cancer risk without providing data on the unresolved question of the specificity of one or more of the antioxidant vitamins in relation to reduced risk of cancer are not helpful in supporting a health claim on antioxidant vitamins and cancer. Those studies that are newer and more nearly relevant to the issue of antioxidant vitamins and cancer, in contrast to fruits and vegetables, are summarized and cited in Table 2 (Refs. 41 through 59). One study described and listed in Table 2 (Ref. 46) is a further description of a study already reported elsewhere and considered in the proposed rule. Those listed by the comment but not included in the review of new scientific evidence in an earlier section of this document, and not cited in Table 2, were reviewed and found either to be not sufficiently relevant, to not have found significant results, or to be old enough to have been included in earlier reviews if that had been considered appropriate (Refs. 60 through 109).

4. Some comments argued that the biochemical data on the effects of antioxidant vitamins on the probable mechanisms of chemical carcinogenesis are strong evidence, and could stand alone in support of an association between antioxidant vitamins and cancer. One comment suggested that numerous studies have shown antitumorigenic effects of antioxidant vitamins in animal models, and, although not showing protective effects from every nutrient in every animal model and in every dosage regimen, quite consistently show a strong and significant protective effect. However, no data were submitted to support this assertion.

FDA disagrees with these comments. Although biochemical data can indicate the possibility of a protective effect of the antioxidant vitamins against cancer, they cannot demonstrate that the effect is one of practical importance in humans, in the context of the total daily diet, alone, support a health claim. FDA recognized in the proposed rule that animal and mechanistic data provide a strong theoretical basis on which to postulate that the antioxidant vitamins decrease the risk of cancer in humans. FDA does not agree, however, that such evidence alone are sufficient to support the conclusion that the effect is necessarily of practical importance in humans, in the context of the total daily diet.

5. Some comments stated that FDA's fragmented approach to considering the

evidence has made it difficult to see the extraordinary consistency of the data. These comments state that, although the 1990 amendments directed FDA to consider a health claim regarding "antioxidant vitamins and cancer," the agency chose to consider three antioxidants (beta-carotene, vitamin C, and vitamin E) separately. The comments stated that this approach is counter to the requirements of the 1990 amendments and is inherently incapable of revealing the consistency of the data on the antioxidant vitamins. A few comments stated that FDA should have reviewed selenium.

FDA disagrees with these comments. The term "antioxidant" defines a functional characteristic of a substance rather than its specific identity. Antioxidant nutrients include the vitamins under consideration and the mineral selenium. FDA has not considered selenium, because the 1990 amendments specified "antioxidant vitamins and cancer," and, although it is an antioxidant, selenium is not a vitamin.

FDA reasonably interpreted the language of the 1990 amendments to refer either to an independent effect of one or more of the vitamins with antioxidant characteristics (i.e., vitamins C and E, and the provitamin A, beta-carotene) or to an effect of a combination of two or more of the antioxidant vitamins. Certainly, FDA did not interpret the language of the act to mean that the only effect to be considered was that of the three antioxidant vitamins in combination. FDA recognizes that much of the data from surveys of dietary patterns and intakes of specific foods involve consumption of combinations of the antioxidant vitamins. The agency notes, however, that the composition of fruits and vegetables includes many substances other than the antioxidant vitamins, such as dietary fiber, and believes that the results of studies of fruit and vegetable intake cannot be interpreted as demonstrating that a combination of the antioxidant vitamins is responsible for the observed protective effects. FDA advises, however, that a petition in support of a health claim for a combined effect of the three antioxidant vitamins may be submitted for evaluation.

6. Some comments stated that, in the proposed rule on antioxidant vitamins and cancer, FDA made a "Type II error" by failing to identify an effect when it exists. (In contrast, a Type I error is that of mistakenly identifying an effect when it does not exist.) The comments indicated that this type of error causes important health benefits that are justified by the available evidence to be denied. These comments also stated that a benefit/risk analysis could properly be used to allow health claims because the agency had stated in the proposed rule that "FDA will use its discretion to give greater weight to those studies that are more persuasive regardless of the nature or age of the studies."

FDA agrees that both types of error are possible. In general, decreasing the probability of a Type II error will increase the probability of a Type I error, and vice versa. In the proposed rule on general requirements for health claims (56 FR 60537 at 60547), FDA noted that the standard for conventional foods in the 1990 amendments required that the agency have a "high level of comfort that the claim is valid." FDA proposed that the same standard be used for both conventional foods and dietary supplements (56 FR 60357 at 60547). FDA believes that it has properly balanced the probabilities of making the two types of error by requiring that the totality of the data support the disease/nutrient relationship. Giving more weight to studies that are most persuasive, within the broader context of the strengths and weaknesses of individual studies and the types of evidence available, is appropriate in assessing the totality of the evidence. This approach does not, however, permit selective use of studies supporting a relationship at the expense of evaluating those studies which fail to support the relationship. Moreover, FDA's cited statement in the proposal does not support use of risk/benefit analysis to evaluate a health claim. Such an analysis would be inappropriate. FDA is responsible for ensuring a safe food supply, and thus foods bearing health claims must be demonstrated to be safe and lawful. (See § 101.14(b)(3)(ii)).

7. A comment stated that, in proposing not to authorize health claims for antioxidant vitamins and cancer, FDA was inconsistent with its cosponsorship, with the American Health Foundation, of a recent international conference on antioxidants and cancer. The comment stated that the overall content of the conference was to substantiate the protective effect of antioxidant vitamins against cancer.

FDA agrees that research discussed in the conference provided further evidence of the existence of plausible and substantiated mechanisms, including inhibition of nitrosation reactions, inhibition of free radical oxidations, and support of immune responses, through which antioxidant vitamins may decrease the risk of cancer. FDA also agrees that the conference provided evidence of the association of consumption of foods that are good sources of beta-carotene and vitamin C with protection against certain cancers. The research presented at the conference was generally consistent with a protective relationship between antioxidant vitamins and cancer, but the conference organizers and participants did not directly address whether the evidence met the standards and criteria specified in the 1990 amendments.

B. Relationships Between Antioxidant Vitamins and Cancer

8. Some comments asserted that a major problem with the proposal is that all cancers are referred to together. They further stated that the 1990 amendments do not specify or define antioxidant vitamins, and this makes it impossible for a regulation to be issued.

FDA disagrees. In the proposed rule (56 FR 60624 at 60633 through 60636), FDA broke out its review of vitamin C by type of cancer. There were insufficient data on beta-carotene and vitamin E for such an organizational structure. FDA does not believe that the organization of its review biased the conclusions. However, in the scientific review for this final rule, FDA organized its review of the effect of antioxidant vitamins by type of cancer. FDA's approach was again driven by the availability of data. As explained in the proposed rule, FDA selected beta-carotene, vitamin C, and vitamin E for review because they are vitamins (or, in the case of beta-carotene, a provitamin), they have antioxidant properties, and their known biological functions are through antioxidant activities.

9. Some comments disagreed with the statement by FDA that the amount of antioxidant vitamins needed to produce an effect must be identified. A comment also objected to the agency's statement that it would need to determine whether the food supply already provides that amount of the antioxidant vitamin, arguing that this is not a valid requirement because it does not consider variations in dietary intake. This comment stated that: (1) If FDA needs to know simply that effective levels may be obtained in a normal diet, the epidemiology can tell us that, and (2) if FDA is attempting to identify a specific amount, then this quest is misguided for several reasons. The reasons given included: (1) The required level is determined in part by the level of oxidant stress, (2) most of the epidemiologic data suggest that there is not a threshold, but rather a continuous trend of decreasing risk with increasing intake, and (3) the effective level may

well differ for different cancer sites. The comment stated that: (1) Protective levels are in the range attainable in the context of the total daily diet, and (2) in contrast to FDA statements or implications in the proposed rule, the antioxidant nutrient status of the U.S. population is not ample. No definition was given, however, for "ample."

FDA agrees that, if a cause-and-effect relationship has been shown for a particular type of cancer and a specific antioxidant vitamin, epidemiological data can be relied upon to indicate effective levels. FDA disagrees that any attempt to identify precise amounts of the antioxidant vitamins needed to decrease risk of cancer is misguided. The agency acknowledges the important considerations raised by the comment, but considers the rationale incomplete. Amounts of specific vitamins must be identified to provide a regulatory basis for the qualifying criteria for a health claim. In the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**, FDA has concluded that foods that bear a health claim must contain meaningful amounts of the targeted nutrient relative to the claimed effect (in this instance, potential for reduction in cancer risk) (§ 101.14 (21 CFR 101.14)). Any alternative approach would be misleading to the consumer.

FDA agrees, however, that, if the cause-and-effect relationship has been shown, protective levels might include the range most commonly obtained from the diet. Because protective levels of the antioxidant vitamins are not known, it seems futile to speculate as to whether protective levels, if and when identified, will be attainable within the context of the total daily diet. As is explained fully in the preamble of the final rule on the general requirements for health claims published elsewhere in this issue of the **Federal Register**, it would not be permissible for a health claim to imply that levels clearly beyond the range attainable in the context of the total daily diet would be effective in reducing the risk of a disease or health-related condition.

FDA acknowledges that its statements about the need for information on the current dietary status for the antioxidant vitamins in the proposed rule were not clear. The agency also agrees that high average intake and high intake in major population groups do not indicate that all individuals or population subgroups would have similarly high intakes. However, because of space limitations on food labels, it is not possible to provide information on the recommended nutrient intakes for major age and sex groupings or for all situations which might affect need. Rather, labels will show a reference value, and educational programs will help consumers understand the relevance of the reference value to their individual needs.

10. A comment stated that results from epidemiological studies are sufficient to show that the antioxidant vitamins per se decrease the risk of certain cancers. Some comments claimed that FDA's statement that the effects of fruits and vegetables cannot be specifically attributed to the antioxidant vitamins is not valid and is biased against dietary supplements in that the data on antioxidant vitamins and cancer are no more confounded than those on dietary fat and cancer. A comment stated that, although FDA documents note repeatedly that the evidence for fruits and vegetables is strong, FDA nevertheless rejected a health claim on the antioxidant vitamins and cancer on two grounds: (1) The association could be due to other factors associated with fruit/vegetable intake, and (2) even if the protective factor is an antioxidant, it is not clear which nutrient is effective. Several comments stated that FDA should allow a qualified claim such as "a diet high in fruits and vegetables containing antioxidant vitamins may help reduce the risk of certain cancers."

FDA agrees that the scientific evidence is strongly supportive that diets high in fruits and vegetables are associated with a reduced risk of several types of cancer. Theoretical considerations and some research findings have suggested that several common components of fruits and vegetables, or substances at low concentrations in diets containing large quantities of these plant foods, may be responsible for reduced risk of cancer, including vitamin C, beta-carotene, other carotenoids, vitamin E (alpha-tocopherol) or other tocopherols, dietary fiber, folic acid, and other substances such as the indoles in cruciferous vegetables. Fruits and vegetables may also provide a protective effect because they are generally low in fat and calories, and because they may displace higher fat foods in the total diet. In the final rule on general requirements for health claims (§ 101.14), FDA notes that labeling statements relating ingestion of general food groups (e.g., fruits and vegetables), in which a specific substance is not implied, to a disease or health-related condition will not be regulated as health claims under § 101.14, but will be subject to the requirement in section 403(a) of the act that they be truthful and not misleading.

FDA concludes that epidemiological studies of associations between food consumption and cancer, in which the antioxidant vitamins are provided almost entirely by fruits and vegetables, are not likely by themselves to establish a cause-and-effect relationship between antioxidant vitamins and cancer sufficiently to generate significant scientific agreement. It is not possible from these studies alone to identify the particular substances or combination of substances responsible for the effect. FDA recognizes that many studies have used multiple regression procedures to control for potential confounders and to attribute specificity to statistically significant relationships. However, unless all effective components are measured, it is not possible to differentiate between a measured variable which may be serving as a marker for other unmeasured components in the food and a real effect of the measured nutrient itself.

As to the concern expressed that FDA intentionally discriminated against dietary supplements, FDA disagrees. FDA, as stated in the proposed rule on general requirements for health claims (56 FR 60357), focused on the role of specific nutrients or foods as they relate to reduction in risk of a disease, regardless of source. The source of vitamin C, for example, could thus be naturally occurring vitamin C in foods, vitamin C added as a fortificant, or vitamin C obtained from dietary supplements. Consumers obtain their nutrients from a variety of sources. FDA's conclusions were driven by the nature of available evidence: for antioxidant vitamins and cancer, most of the available evidence is from studies on consumption of fruits and vegetables.

In regard to a health claim on conventional foods in which specific nutrients are named, such as "diets high in fruits and vegetables containing antioxidant vitamins may reduce the risk of cancer," FDA is persuaded by the comments that a similar claim may be useful, and that a similar claim is supported by the evidence. FDA, therefore, has decided to authorize a health claim relating low fat diets high in fruits and vegetables (which are low in fat and may contain vitamins A and C and dietary fiber) to a reduced risk of some types of cancer. Statements relating foods to cancer risk with acknowledgment of significant nutrient contributions of those foods to total diets are frequently the types of statements used in Federal Government and other dietary guidelines. The 1990 amendments clearly indicated that Congress intended that health claims on foods be a useful source of information to help Americans implement the U.S. Dietary Guidelines for Americans (Ref.

40). The authorized claim will provide such useful information.

11. One comment argued that time-release formulations of antioxidant vitamins are superior to standard formulations in their ability to decrease the risk of cancer, and that cancer clinics are using them successfully.

This comment did not provide scientific support for a conclusion that time-release formulations of the antioxidant vitamins have been shown to provide any special benefit or advantage over standard formulations. The literature submitted in support of the assertion consisted of general, nonscientific review and position statements, and was not useful in assessing the totality of the scientific evidence on the relationship between antioxidant vitamins and cancer. Moreover, FDA does not consider the issue of time-release formulation to be relevant to this rulemaking.

12. One comment submitted a copy of the entire April 1, 1992, issue of Cancer Research (Vol. 52, pp. 2091s through 2126s). Some comments submitted a review (Ref. 110) of carotenes, vitamin C, and vitamin E as protective antioxidants in human cancers.

One paper in the submitted issue of Cancer Research addressed antioxidant vitamins and cancer (Ref. 111) concluded that increased intakes of fruits, vegetables, and carotenoids, and elevated blood levels of beta-carotene are consistently associated with reduced risk of lung cancer. Nevertheless, this review concluded that, with current data, the effects of beta-carotene cannot be identified separately from those of other carotenoids, other constituents of fruits and vegetables, and associated dietary patterns.

The other review covered both animal experiments and epidemiologic research. Its overall conclusion was that antioxidant nutrients appear to play many important roles in protecting the body against cancer, but many important questions remain before dietary supplementation and/or food fortification can be recommended. In contrast, it concluded that there is a strong scientific basis for current dietary recommendations that emphasize frequent consumption of fruits and vegetables.

13. Another comment stated that the study on beneficial effects of dietary supplementation on longevity (Ref. 1) used inappropriate methods and therefore should not be used for identification of benefits from use of supplements. This comment stated that a major problem lies in the fact that cancers develop at different rates, thus requiring more time for conclusive studies.

FDA has indicated elsewhere in this document that this study did not find a significant effect of any antioxidant vitamin on cancer mortality. Thus, while the issue of the relevancy of the methods used may merit scientific review, it has no practical effect on the conclusions reached relative to health claims.

C. Safety Issues

14. Several comments disagreed with the statement by FDA in the proposed rule that high intakes of one vitamin without commensurate increases in the others may not support optimum status and functions for these nutrients. The comments stated that dietary supplements provide greater opportunity for deliberately balanced intakes of the antioxidant vitamins than do foods, and other comments asserted that FDA is wrong in stating that foods provide a better balance of antioxidant vitamins than do dietary supplements. The comments also suggested that interactions can be protective, as illustrated by data from animal experiments.

FDA agrees that dietary supplements allow the opportunity to provide a more controlled amount of nutrients than do foods. However, in the case of antioxidant vitamins and cancer, the scientific evidence from data that are customarily used in setting dietary goals and nutrition policy is not sufficient at present to identify an independent effect of these substances. Therefore, any attempt to define dosages or optimum balances among the three antioxidant vitamins is premature. The statement that foods may provide a better balance is consistent, therefore, with the limitation of current scientific evidence.

Additionally, FDA agrees with the statement that interactions can be either helpful or harmful. However, FDA's decision to propose not to authorize a health claim on antioxidant vitamins and cancer was not based on concern about toxicities or adverse interactions among nutrients, but, instead, on the insufficiency of the data available.

15. Some comments expressed concern that, if a health claim were permitted for vitamin C, the public might take supplemental doses far in excess of the Recommended Dietary Allowances, and that this could result in gastrointestinal disturbances, iron overload in some people, precipitation of calcium oxalate kidney stones, disruption of copper metabolism, and induction of postnatal bleeding in women. They also stated that dietary supplements should be required to list a warning statement regarding use of the supplement along with any health claim permitted.

FDA points out that most reports of possible adverse effects from ascorbic acid ingestion have involved dosages of 3 to 30 g per day (Ref. 112). The Surgeon General's report (Ref. 35) states that amounts of vitamin C in excess of the Recommended Dietary Allowance may cause rare adverse effects, but does not identify how far above the Recommended Dietary Allowance values adverse effects are observed. The adverse effects noted include gastrointestinal disturbances, iron overload in susceptible individuals, altered metabolism of certain drugs, precipitation of calcium oxalate kidney stones, altered absorption (both positive and negative) of several minerals, and interference with several laboratory tests. The review article cited as the source of this information (Ref. 112) concluded that, although the effects listed should be considered possible, consumption of supplemental vitamin C leads to no significant adverse health effects in humans in general, but nevertheless individuals who have a history of kidney stone formation and those who experience iron overload should exercise caution before using supplemental vitamin C.

The Diet and Health report (Ref. 36) recommends avoiding taking dietary supplements in excess of the Recommended Dietary Allowance in any one day. It states that several vitamins and minerals, if consumed in excess, can be toxic and cause numerous adverse health effects, but that there is no evidence that the public is harming itself by the use of low levels of supplements. This report did not discuss the possible adverse effects of vitamin C in detail, but instead reprinted a table from a review article in which the adult oral minimum toxic dose was estimated to be between 1 and 5 g. The NRC's "Recommended Dietary Allowances" 10th ed. (Ref. 113) stated that many persons habitually ingest 1 g. or more of ascorbic acid without developing apparent toxic manifestations, although a number of adverse effects have been reported.

Additionally, the LSRO report (Ref. 39) indicates that intakes of ascorbic acid of up to 1 g/day are well tolerated (Ref. 114). Occasionally, intakes above this may be associated with nausea and diarrhea. Ascorbic acid intakes of 4 g/day were used in a long-term intervention trial on rectal polyps without adverse effects in a population of adult men and women (Ref. 115).

FDA is not currently authorizing a health claim relating antioxidant vitamins and cancer. If such an authorization occurs in the future, these conclusions about vitamin C may be used in evaluation of its safety.

16. Some comments addressed the issue of possible iron overload as a result of high vitamin C intake. The comments stated that vitamin C added to foods can increase the amount of iron absorbed. These comments refer to a longstanding concern that persons carrying the genetic trait for idiopathic hemochromatosis, and perhaps also persons with the heterozygous trait, are at risk of earlier onset of the disease or more severe effects if the intake or bioavailability of dietary iron is increased. One comment, however, concluded that the effect, although likely to be insignificant in normal individuals, may be slightly greater in those who are heterozygous for the gene for hereditary hemochromatosis. This comment noted that an effect as great as doubling of iron stores might result, under very specific conditions of iron to ascorbic acid ratio in the food, from switching to a vitamin C-fortified food from a nonfortified food and continuing this practice for several years. Such a situation is presumably unlikely to occur frequently, making the potential impact on iron status much smaller.

FDA recognizes that the role of vitamin C in enhancing iron bioavailability under short-term test conditions is well established (Ref. 116). Studies in normal persons without the idiopathic hemochromatosis genetic trait show no increase in iron stores with chronic intakes of large amounts of supplemental ascorbic acid (Refs. 115 and 116). FDA, however, was not able to find similar studies in patients with hemochromatosis, and no such data were submitted as comments. Thus, the issue of safety of ascorbic acid intakes in enhancing iron uptake by hemochromatosis patients, and the dose-response relationship of ascorbic acid in this effect, cannot be resolved from current data.

17. A comment stated that FDA makes much of the need to determine precise intake levels of beta-carotene, vitamin C and vitamin E regarding potential benefits, but resorts to the broadest generalizations when it comes to possible detrimental actions of excessive intakes of vitamins. The comment pointed out that the amounts of vitamin C in diets recommended by the U.S. Department of Agriculture (USDA) and the National Cancer Institute exceed 200 mg, and that the situation is analogous for vitamin E.

FDA agrees that the proposed rule described the need to identify levels of antioxidant vitamins that are effective in reducing the risk of cancer, and that possibilities were discussed for adverse effects. The agency also is aware that current dietary patterns in the United States consistently result in average intake levels above current Recommended Dietary Allowances. The agency's discussions on effective intakes were presented because this issue can affect evaluations of safety. This information is also essential for determining qualifying criteria for foods bearing an authorized claim, and for deciding on the types of information needed to be included in a label statement. Estimates of current dietary intakes or intakes likely to occur if persons follow dietary guidelines are largely irrelevant to evaluating whether a nutrient/disease relationship exists.

IV. Decision Not to Authorize Health Claims Relating Antioxidant Vitamins and Cancer and to Authorize Health Claims Relating Substances in Fruits and Vegetables and Cancer

A. Scientific Evidence Regarding the Relationship between Antioxidant Vitamins and Cancer and Between Fruits and Vegetables and Cancer

FDA has reviewed numerous authoritative documents, including Federal Government reports, as well as recent research on diet and cancer risk. In addition, the agency considered all comments received in response to its proposed rule. The agency has concluded that the scientific evidence does not provide the basis for significant agreement among qualified experts that there is a relationship between antioxidant vitamins (specifically, beta-carotene, vitamin C and vitamin E) and a reduced risk of cancer. However, the publicly available scientific evidence does support an association between diets high in fruits and vegetables, which are good sources of two of the antioxidant vitamins (vitamin A as beta-carotene and vitamin C) and reduced risk of cancer.

Based on the scientific evidence in the proposed rule, the comments received, and new studies, FDA has reached the following decisions:

1. Vitamin E

Based on a review of the totality of the scientific evidence and comments received relative to the available evidence, FDA concludes that the data do not support a relationship of vitamin E to reduced risk of cancer and that there is not significant scientific agreement that vitamin E reduces the risk of cancer. Most studies on the possible protective effect of vitamin E have related plasma or serum levels of vitamin E (rather than fruit and vegetable consumption) to cancer risk. FDA recognizes that some evidence shows an association of low plasma/serum levels of vitamin E and reduced cancer risk, but finds that the inadequacies in the available data, as noted in the proposed rule (56 FR 60624), have not been adequately addressed by newer data; comments received in response to the proposed rule were not sufficiently convincing to reverse the proposed conclusion.

FDA recognizes that the animal and biochemical data provide a basis on which to hypothesize a protective effect by vitamin E (alpha-tocopherol) in humans, but the data from epidemiological studies, although providing some suggestion of an effect, are not sufficient to conclude that such effects are of importance in humans. Therefore, although vitamin E has been shown to have antioxidant effects in humans, the data are not sufficient to associate such effects with protection against cancer.

2. Beta-carotene

Based on a review of the totality of the scientific evidence and comments received relative to the available evidence, FDA concludes that data do not support the relationship of beta-carotene (provitamin A) to reduced cancer risk. FDA also concludes that there is not significant scientific agreement that beta-carotene reduces the risk of cancer. However, the available data show an association of consumption of fruits and vegetables and calculated beta-carotene intakes from these foods with reduced risk for some types of cancer. The scientific evidence is not sufficient to conclude that beta-carotene in these foods is responsible for the protective effect. Beta-carotene has been shown to protect against chemical carcinogenesis in some animal models, and the biochemical and mechanistic data provide a plausible scientific basis on which to hypothesize a protective effect in humans.

3. Vitamin C

In the proposed rule, FDA recognized that mechanistic and animal studies suggest that vitamin C may reduce the risk of cancer through the mechanism of inhibition of nitrosamine synthesis. Cancer of the stomach is the likely site of highest N-nitroso compound exposure, and is the site for which the data were the most complete. However, FDA found that the data available at the time of the proposed rule were not

sufficient to establish the relationship between inhibition of N-nitroso compound synthesis and stomach cancer in humans. FDA also recognized, in the proposed rule, that higher intakes of fruits and vegetables, higher calculated intakes of vitamin C, and increased blood levels of vitamin C are associated with lower risk of cancer of the stomach, and, more weakly, with cancers at other sites. New studies that are relevant to these issues are reviewed in previous sections of this document.

Epidemiological studies published since the review for the proposed rule further support the association of fruits and vegetables and calculated vitamin C intakes with protection against certain types of cancer, especially cancer of the stomach.

The studies showing the relationship of N-nitroso compounds (a class of compounds with known carcinogenicity) to stomach cancer provide evidence for a mechanism by which a specific vitamin C effect might occur for this and other cancers (e.g., esophageal and uterine cervical). Formation of N-nitroso carcinogens in the stomach would be expected to have the greatest effect at the site of production and greatest exposure, the stomach, and lesser effects at distal sites that require absorption and translocation of the putative carcinogen before an effect could occur. In animal test systems, preformed N-nitroso compounds are multitarget organ carcinogens. These conclusions are consistent with the conclusions of the recent LSRO review (Ref. 39).

When considered together, the different types of data are suggestive, but not conclusive, that vitamin C may be responsible for at least part of the reduction in risk of stomach cancer associated with consumption of diets high in fruits and vegetables. The evidence for specificity of vitamin C includes epidemiological associations of decreased risk with higher intakes of vitamin-C containing fruits and vegetables, clinical trials that show decreased concentrations of N-nitroso compounds after vitamin C supplements, and epidemiological associations of higher concentrations of N-nitroso compounds with higher risk of stomach cancer and precancerous pathology of the stomach. However, the N-nitroso compound data have not generally been validated as a basis for establishing a relationship between vitamin C and risk of stomach cancer in the U.S. population. At present there is not significant scientific agreement that this mechanism is an etiologic factor in stomach cancer risk in the United States, or that qualitative or quantitative changes in production and excretion of nitroso-compounds are a risk factor for stomach cancer.

In order to allow the issue of intermediate or surrogate markers (such as formation of N-nitroso compounds) for cancer risk to be more fully evaluated, FDA will be convening an advisory committee in the near future to make recommendations which can then be applied to evaluations of data for determining the scientific basis for health claims relating antioxidant vitamin intakes to cancer risk.

4. Fruits and vegetables

Dietary patterns that are low in fat and high in plant foods, including fruits and vegetables, are generally high in vitamin C and provitamin A (beta-carotene), and other nutrients such as dietary fiber, and are associated with a decreased risk of some types of cancer. The mechanisms responsible for this relationship are not known. Several factors could be important contributors to this protective effect. For example, fruits and vegetables are low in fat. FDA has reviewed the evidence supporting the relationship between low fat diets and reduced risk of cancer and has concluded that there is sufficient scientific evidence and significant scientific agreement among qualified experts to support this relationship. (See the final rule on health claims for lipids and cancer published elsewhere in this issue of the **Federal Register**). FDA is, therefore, authorizing a health claim for fat and cancer. Thus, one possible mechanism whereby fruits and vegetables may contribute to reduced cancer risk is through displacement of higher fat foods in a diet, with a net effect of reducing total fat intakes.

The subject of this final rule relates to the possible protective mechanism of vitamins with antioxidant functions in reducing cancer risk. Three antioxidant vitamins were considered: Beta-carotene, vitamin C and vitamin E. Fruits and vegetables are the major food source of beta-carotene (pro-vitamin A) and vitamin C in the U.S. diet. Vitamin E is more ubiquitously distributed, but some vegetable oils and whole grain products are significant sources. Fruits and vegetables are also good sources of dietary fiber. The possible protective role of dietary fiber in reducing cancer risk has been discussed in the final rule on health claims for dietary fiber and cancer published elsewhere in this issue of the **Federal Register**.

Finally, fruits and vegetables contain a number of nonnutritional substances (e.g., indoles, phenols, flavones, and terpenes) which have been hypothesized to be possibly protective against cancer risk through antioxidant or other functions. Fruits and vegetables also contain many carotenoid compounds in addition to beta-carotene, the carotenoid which has the greatest pro-vitamin activity. While the other carotenoids do not contribute significantly, if at all, to vitamin activity, they are antioxidants and, thus, may also provide a protective effect against cancer risk. The specific roles of these numerous, potentially protective substances in plant foods are not yet understood, and knowledge of their content in fruits and vegetables is lacking. Consequently, dietary intakes of these substances have not been estimated in human studies which show associations between fruit and vegetable intakes and cancer risk.

B. Conclusion Based on Scientific Evidence

In conclusion, while populations with diets rich in fruits and vegetables experience many health advantages, including lower rates of some types of cancers, it is not possible to specifically determine that the two antioxidant vitamins (i.e., beta-carotene and vitamin C) which are contained in fruits and vegetables are responsible for this effect, or to rule out the possibility of significant protective effects from nonmeasured components in these fruits and vegetables. Since many of these food substances (both nutritive and nonnutritive) coexist in fruits and vegetables, an observed correlation between a measured nutrient may be reflective of a "true" correlation between a coexistent, nonmeasured food substance. Currently, there is not significant scientific agreement as to whether the observed protective effects of fruit and vegetable consumption against cancer risk are due to a single or combined effect of the antioxidant vitamins and other nutrients with antioxidant functions (i.e., selenium), to other nutritive components of such foods (such as dietary fiber), to unmeasured components of such diets (for example, nonnutritive components such as carotenoids, indoles or flavonoids), or to displacement of other known risk components (such as fats and calories) within the total diet.

Thus, the conclusion that diets low in fat and high in fruits and vegetables (foods which are low in fat and are generally good sources of vitamins A and C and dietary fiber) are associated with a reduced risk of cancer, is consistent with the available scientific evidence.

Because dietary patterns which have high consumption of fruits and vegetables are not only low in fat but

can also be characterized by high intakes of dietary fiber and vitamins A and C, these nutrients can serve as useful markers for identifying the types of foods which contribute to a dietary pattern that is associated with a reduced cancer risk. Calculated intakes of vitamin C and vitamin A (often but not always identifying the fraction from beta-carotene) from diets high in fruits and vegetables have been correlated with reduced cancer risk. Although it is not known if it is the antioxidant vitamin components or some other components of these diets that provide the protective effects against cancer, these nutrients are characteristic of protective foods. Therefore, FDA is authorizing the use on labels and labeling of health claims regarding the association between diets low in fat and high in fruits and vegetables and a reduced risk of cancer with specific mention that these diets and foods are generally rich sources of vitamin A (as beta-carotene), vitamin C, and dietary fiber.

V. Rationale For Final Rule

A. Relationship and Significance sections

New § 101.78(a) is consistent with the conclusions reached in the science review that it is fruits and vegetables which relate to the reduced risk of cancer, not the antioxidant vitamins per se. Yet, because of the usefulness of vitamins A (as beta-carotene) and C and dietary fiber in identifying fruits and vegetables most likely to correlate with reduced cancer risk, these nutrients are specifically identified as being characteristic of the protective dietary pattern. Any one or a combination of these three nutrients can serve as the identifying marker. Since fruits and vegetables are also characterized by their absence of fat, and because of the identified relationship of low fat diets to reduced risk of cancer, this also is required to be a characterizing nutrient for the type of dietary pattern associated with decreased cancer risk. Other components of the relationship statement, for example, risk factors, have been indicated, similar to other authorized health claims.

In new § 101.78(b), on the significance of the relationship between consumption of diets low in fat and high in fruits and vegetables and reduced risk of cancer, the summary includes the information that U.S. diets tend to be high in fat and low in fruits and vegetables. Discussion of current dietary guidelines on recommended servings of fruits and vegetables, and dietary fiber intakes are also given. Because of the coexistence of all of these nutrients in fruits and vegetables, and because all have been associated with reduced risk of cancer, all four nutrients are indicated. Because the mechanism of the protective effect is not known and because it is not known which of these nutrients is effective, or if some combination of these nutrients is effective, the health claim is focused on fruits and vegetables as a product class and their relationship to cancer risk.

B. Nature of the Claim

In § 101.78(c)(2)(i), FDA is authorizing health claims relating substances in diets low in fat and high in fruits and vegetables to reduced risk of cancer. In new § 101.78(c)(2)(i)(A), the agency is requiring, similar to other authorized claims, that the relationship be qualified with the terms "may" or "might." These terms are used to indicate that not all persons will necessarily benefit from these dietary changes. In new § 101.78(c)(2)(i)(B), the agency, consistent with other authorized claims, is requiring that the claim not indicate that all cancers may be affected, but rather that the risk of "some types of cancer" or "some cancers" may be reduced. The relationship of dietary factors to various types of cancers appears to be variable; in many cases, the available data are inadequate to specifically identify which cancers will be affected.

In new § 101.78(c)(2)(i)(C), the agency is requiring that the claim characterize fruits and vegetables as foods that are low in fat and contribute vitamin A, vitamin C, and dietary fiber to the diet. All four nutrients must be identified as characteristic of this dietary pattern. As noted in the conclusions reached from the available scientific evidence, it is not known what substances in fruits and vegetables are responsible for their protective effect. The best documented relationship is for fat and cancer. Roles for dietary fiber and vitamins A and C have been speculated and intakes of these nutrients from fruits and vegetables are correlated with cancer risk. By requiring that all characterizing nutrients be identified as characteristic of dietary patterns rich in fruits and vegetables without specifically attributing reduced cancer risk to a single nutrient, the claim is consistent with the current scientific knowledge. The claim should also minimize consumer confusion, since its wording is similar to current dietary guidelines from the U.S. Government, including the National Cancer Institute. New § 101.78(c)(2)(i)(D) requires the claim to specify that the food bearing the claim contains at least one of the following: Dietary fiber, vitamin A, or vitamin C. This statement is required in order to identify the contribution of the labeled food to the diet in an accurate and nonmisleading manner. Only those nutrients for which the labeled food qualifies as a good source under § 101.54 may be identified in the health claim. Although the regulation does not restrict the manner in which these nutrient levels may be described, terms used must be consistent with other labeling regulations.

In new § 101.78(c)(2)(i)(E), FDA, consistent with other authorized health claims, is prohibiting the attribution of a specific reduction in risk to diets low in fat and high in fruits and vegetables. In new § 101.78(c)(2)(i)(F), (c)(2)(i)(G), (c)(2)(i)(H), and (c)(2)(i)(I), FDA is prohibiting, similar to other authorized health claims, more specific use of dietary terms than is warranted by the current state of the scientific evidence. These requirements also standardize use of these terms, thus minimizing consumer confusion as they compare food labels across products, or as they compare a health claim to the nutrition information panel. Section 101.78(c)(2)(i)(J) requires that health claims indicate that development of cancer is dependent on many factors. This requirement is intended to prevent consumers from being mislead that fruit and vegetable intake is the only factor connected with cancer risks.

C. Nature of the Food

New § 101.78(c)(2)(ii)(A) requires that the food bearing the authorized health claim be or contain a fruit or vegetable. Because the claim relates to diets high in those foods, it would not make sense for it to appear on the labeling of another type of food. A health claim that appears on a food that meets all the requirements in § 101.78(c)(2)(ii) but contains only a trivial amount of fruit or vegetables could be considered misleading and might misbrand the food under section 403(a) of the act.

FDA, consistent with the requirements for the health claim on fat and cancer (published elsewhere in this issue of the **Federal Register**), is requiring in new § 101.78(c)(2)(ii)(B) that foods bearing the authorized health claim be "low fat" foods or, alternatively, belong to a class of products that is "low in fat." Low fat diets are associated with reduced cancer risks. Low or negligible fat is also one of the characterizing nutrients for diets rich in fruits and vegetables. Since the effect of fat is not readily separated from the effect of other nutritive components of fruits and vegetables, it is required to be included as a qualifying nutrient.

In new § 101.78(c)(2)(ii)(C), FDA is requiring that fruits and vegetables bearing the health claim meet requirements for a "good source" (greater than or equal to 10 percent of the Reference Daily Intake (RDI)) for vitamin A and vitamin C, and greater than or equal to 10 percent of the Daily Reference Value (DRV) for dietary fiber. The requirement that these nutrients be present at 10 percent of the RDI or DRV is being established as a specific alternative to the 20 percent (i.e., "high") requirement for qualifying nutrients in the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**. (See § 101.14(d)(2)(vii)). This alternate level was deemed useful to assure that most fruits and vegetables would be eligible for this health claim, because fruits and vegetables in general are the product class for which correlations with reduced cancer risk have been observed as opposed to specific fruits and vegetables. Moreover, as a product class, fruits and vegetables are significant sources of vitamins A and C and fiber in the U.S. dietary pattern. Without this alternative level very few fruits and vegetables would qualify for the health claim. This seems contrary to the available evidence and to the purpose of health claims.

This section also requires that the qualifying nutrients be based on "natural" levels in foods. This means that foods which require modification, for example, fortification with vitamins A or C or dietary fiber, in order to meet the qualifying criteria for the health claim, cannot bear the claim. This requirement is consistent with the scientific basis for the claim; that is, that fruits and vegetables in their native form correlate with reduced cancer risk. Since there are not sufficient data to specifically identify vitamins A and C and dietary fiber as causal, and because these nutrients are being used as markers for the substance(s) in fruits and vegetables that provide the observed effect, it is the native nutritional composition of the foods that identifies their usefulness. At the same time, this requirement does not prohibit fortification of qualifying foods with the characterizing nutrients, once the qualifying criteria have been met.

D. Optional Information

Under new § 101.78(d), similarly to other authorized health claims, health claims may identify additional risk factors for cancer. The regulation specifies the factors that may be listed; all are risk factors about which there is general scientific agreement. This additional information can provide a context that is useful for an understanding of the relationship of the diet to the disease, but, manufacturers are cautioned that it should not be presented in a way that is misleading to the consumer. A health claim may also indicate that reductions in fat intake and consumption of fruits and vegetables are part of a total dietary pattern that is consistent with the latest "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 40) published jointly by the USDA and the Department of Health and Human Services (DHHS). Consistent with other health claim regulations, the claim may also include information on the prevalence of cancer in the United States. In order to ensure that this information is valid, the agency is requiring that it come from one of three specified authoritative sources.

Additionally, for the health claim relating substances in diets high in fruits and vegetables to reduced risk of cancer, the agency is allowing the use of the term "beta-carotene" in addition to the term vitamin A in listing nutrients that are characteristic of the protective dietary pattern. Beta-carotene is the form of the vitamin which has antioxidant functions. Therefore, the use of this term is consistent with a possible mechanism of action. On the other hand, if, after a food meets the qualifying criteria for a health claim, the food is fortified with vitamin A (as retinyl palmitate or another form of preformed vitamin A rather than with beta-carotene), then it would be misleading to indicate that its vitamin A content is primarily beta-carotene. Thus, FDA is permitting the term beta-carotene to be used in the claim only when the vitamin A in the food bearing the claim is beta-carotene.

E. Model Health Claims

In new § 101.78(e)(1) and (e)(2), FDA is providing several model health messages to help manufacturers understand the requirements of new § 101.78 and to help them understand the type of health claim that FDA considers to be appropriate. FDA is not prescribing specific language for claims, but certain elements are required, and these models include the required elements.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's disucssion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food lableing final rules. The final RFA will be placed on file with the dockts Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitues a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VIII. References

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6, of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (d) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(d) Antioxidant vitamins and cancer.

3. New § 101.78 is added to subpart E to read as follows:

§ 101.78 Health claims: fruits and vegetables and cancer.

(a) *Relationship between substances in diets low in fat and high in fruits and vegetables and cancer risk.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Although the specific roles of the numerous potentially protective substances in plant foods are not yet understood, many studies have shown that diets high in plant foods are associated with reduced risk of some types of cancers. These studies correlate diets rich in fruits and vegetables and nutrients from these diets, such as vitamin C, vitamin A, and dietary fiber, with reduced cancer risk. Persons consuming these diets frequently have high intakes of these nutrients. Currently, there is not scientific agreement as to whether the observed protective effects of fruits and vegetables against cancer are due to a combination of the nutrient components of diets rich in fruits and vegetables, including but not necessarily limited to dietary fiber, vitamin A (as beta-carotene) and vitamin C, to displacement of fat from such diets, or to intakes of other substances in these foods which are not nutrients but may be protective against cancer risk.

(b) *Significance of the relationship between consumption of diets low in fat and high in fruits and vegetables and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and low in fruits and vegetables. Studies in various parts of the world indicate that populations who habitually consume a diet high in plant foods have lower risks of some cancers. These diets generally are low in fat and rich in many nutrients, including, but not limited to, dietary fiber, vitamin A (as beta-carotene), and vitamin C. Current dietary guidelines from Federal Government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (less than 30 percent of calories), maintenance of desirable body weight, and increased consumption of fruits and vegetables (5 or more servings daily), particularly those fruits and vegetables which contain dietary fiber, vitamin A, and vitamin C.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating substances in diets low in fat and high in fruits and vegetables with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat and high in fruits and vegetables "may" or "might" reduce the risk of some cancers;

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(B) In specifying the disease, the claim uses the following terms: "some types of cancer", or "some cancers",

(C) The claim characterizes fruits and vegetables as foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber;

(D) The claim characterizes the food bearing the claim as containing one or more of the following, for which the food is a good source under § 101.54: dietary fiber, vitamin A, or vitamin C;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat and high in fruits and vegetables;

(F) In specifying the fat component of the labeled food, the claim uses the term "total fat" or "fat";

(G) The claim does not specify types of fats or fatty acids that may be related to risk of cancer;

(H) In specifying the dietary fiber component of the labeled food, the claim uses the term "fiber", "dietary fiber", or "total dietary fiber";

(I) The claim does not specify types of dietary fiber that may be related to risk of cancer; and

(J) The claim indicates that development of cancer depends on many factors.

(ii) *Nature of the food.* (A) The food shall be or shall contain a fruit or vegetable.

(B) The food shall meet the nutrient content requirements of § 101.62 for a "low fat" food.

(C) The food shall meet, without fortification, the nutrient content requirements of § 101.54 for a "good source" of at least one of the following: vitamin A, vitamin C, or dietary fiber.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets low in fat and high in fruits and vegetables and some types of cancer and the significance of the relationship.

(2) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(3) The claim may use the word "beta-carotene" in parentheses after the term vitamin A, provided that the vitamin A in the food bearing the claim is beta-carotene.

(4) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS), Government Printing Office.

(5) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to characterize the relationship between substances in diets low in fat and high in fruits and vegetables and cancer:

(1) Low fat diets rich in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) may reduce the risk of some types of cancer, a disease associated with many factors. Broccoli is high in vitamins A and C, and it is a good source of dietary fiber.

(2) Development of cancer depends on many factors. Eating a diet low in fat and high in fruits and vegetables, foods that are low in fat and may contain vitamin A, vitamin C, and dietary fiber, may reduce your risk of some cancers. Oranges, a food low in fat, are a good source of fiber and vitamin C.

Dated: November 3, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE 1

Human Studies. Antioxidant Vitamins and Cancer Through March 1, 1992

Study	Study Design	Subjects	Methods	Results	Comments
Basu et al., 1991. (Ref. 9)	Clinical survey of 75 subjects attending a referral clinic in the Bronx, New York for evaluation of abnormal screening Pap smear.	30 women with no cervicitis on pap smear, 45 women with histopathologically diagnosed dysplasia.	Pap smears, papilloma virus screening, age, parity, last menstrual period, contraceptive practice and duration, number of cigarettes per day and duration in years obtained from each patient. Venous sample obtained for micronutrient analysis: ascorbic acid, beta-carotene and retinol. Ascorbic acid levels were significantly lower in smokers, regardless of cervical status or detection of human papilloma virus infection.	Analysis directed at serum antioxidant levels in smokers versus nonsmokers. After dividing smokers and nonsmokers into groups, there was no significant difference in ascorbic levels in the women with cervical dysplasia and those without. Although not noted in the paper the serum retinol level was lower in smokers with cervical dysplasia than those without and serum beta-ocarotene levels were lower in smokers with cervical dysplasia than those without.	The study group was small, and both cigarette smoking and antioxidant level are continuous variables. The results do not show a significant association between cervical dysplasia and serum antioxidants.
Benito et al., 1991. (Ref. 10)	Case--control study; colorectal cancer in Majorca, Spain.	Cases - 386 histologically confirmed colorectal cancer cases, diagnosed between July 1984 and Feb. 1988 Controls--295 population controls and 203 hospital controls. Both cases and controls had to be residents of Majorca for previous 10 years.	A food frequency questionnaire with data on 99 food items was used. Average frequency of consumption in previous year assessed. Local food consumption tables used to estimate intake. Age, sex, weight 10 years prior to interview, meals per day, education in years, occupation, and physical activity in workplace (surrogate for energy expenditure) were used in regression model.	There was no significant association between the risk of either colon or rectal cancer and level of vitamin A, retinol, carotene, vitamin C, or vitamin E intake.	Based on the significant inverse association between fiber from legumes and folic acid in cruciferous vegetable, the findings support a recommendation for diets high in vegetables, along with a healthy lifestyle including moderate intake of calories and adequate physical activity.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Boeing and Frentzel-Beyme, 1991. (Ref. 19)	Environmental epidemiology study of stomach cancer; multicenter, hospital-based, case-control study in high- and low-risk areas for stomach cancer in Federal Republic of Germany.	An area with high stomach cancer mortality rate was compared with another area with a low rate. During the 3-year study period, 143 stomach cancer cases and 579 controls completed the interview.	Dietary information by recall was assessed for the last 5 years before onset of the disease. All interviews were coded by one person. Data were obtained on vitamin C intake, source of water supply, years of refrigerator use, and use of spruce for smoking meat at home. Risk estimates were obtained by unconditional logistic regression methods.	A low intake of vitamin C relative risk (RR) = 2.32, 95% confidence interval (CI) 1.22 to 4.43 for lowest against highest quintile), noncentralized water supply (RR = 2.17, CI 1.14 to 4.13 against central water supply), refrigerator use for less than 25 years (RR = 1.33, CI 0.82 to 2.15 against more than 30 years, and use of spruce for smoking (RR= 3.33, CI 1.56 to 71.2) against not smoking meat at home), were identified as factors possibly causally related to stomach cancer occurrence.	The results are consistent with the hypothesis that increased intake of vitamin C reduces the risk of stomach cancer by inhibiting nitrosation reactions in the stomach, or by decreasing the carcinogenicity of putative carcinogens in smoke (especially polyaromatic hydrocarbons and nitrosamines). Also, the data implicate possible sources of carcinogens or carcinogen precursors (smoked meat and local water supply) in the occurrence of stomach cancer.
Bravo et al., 1991. (16)	Case-control study, Madrid, Spain prostatic cancer	Cases-90 men with histologically diagnosed prostatic carcinoma between January 1983 and December 1987. Controls-180 male hospital patients with illnesses other than urologic disease or a primary tumor. Stratified by age and date of admission.	Standardized questionnaire covering occupation, medical, socioeconomic history, dietary factors including types and amounts of food eaten. Diet classified into five types; normal, rich in animal fat, rich in vegetable fat, deficient in vitamin A, and deficient in vitamin C. Food composition based on Madrid data. Odds ratio (OR) for diet, obesity and prostatic cancer calculated.	This study found no association between a diet deficient in vitamins A or C and the risk of prostatic cancer. The relationship between intake of vegetable fats and prostatic cancer was also not significant.	The diet of central Spain is rich in fruits and vegetables. It is possible that even the lowest quintile of intake for fruits and vegetables in Mediterranean areas are relatively high in relation to other cuisines. The results of this study may not be generalizable.
De Mesquita, et al., 1991. (Ref.15)	Case-control; Netherlands; Pancreatic (exocrine) cancer; study conducted 1984 to 1988	164 cases (surrogates interviewed for 50% males and 46% females); 480 controls (surrogates interviewed for 34% males and 26% females)	Interview using dietary questionnaire containing 116 food items; dietary assessment covered year before interview; 68% of cases were histologically confirmed; others diagnosed clinically.	Adjusted for smoking and total calories: Daily consumption of vegetables statistically significant Inverse association between intake of fresh vegetables, cooked cruciferous vegetables and pancreatic cancer.	Daily consumption of vegetables show a protective effect; large percentage of proxy interview of cases introduces bias

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Enstrom et al., 1992. (Ref. 1)	Population data base analysis, National Health and Nutrition Examination Survey (NHANES I) data and a median of 10 years of prospective followup mortality.	11,348 men and women, aged 25 to 74 years at time of NHANES I survey, wit a total of 1,809 deaths during the followup period.	Comprehensive nutritional status survey that included clinical, biochemical and dietary methods. The population was allocated into three groups: intake 50 <mg/day without supplements, intake ≥50 mg/day without supplements, and ≥50 mg/day with supplements. Followup mortality rates determined in total and for several specific causes, including cancer and heart disease.	Higher dietary intakes of ascorbic acid were associated with significant reduction total mortality rate and in the mortality from heart disease. These effects were enhances by supplements. The standardized mortality rate from cancer (total for all sites) was a nonsignificant 0.78 with supplemental ascorbic acid. In contrast with the results for total mortality and heart disease mortality, the results with cancer mortality were not significant because the standardized mortality rate was not a low and because the cohort size was decreased (heart disease produced approximately 40 percent of the total mortality, whereas cancer produced less than 25 percent).	These results do not provide support for a reduction in risk of any type of cancer by ascorbic acid. They cannot be interpreted, however, as contradicting that possibility. The mortality rate from cancer was not reduced as much with elevated vitamin C intake as were the total and heart disease rates, and the cohort size was substantially smaller. Any protective effect of vitamin C at one cancer site may have been masked by no effect at other sites, with the overall rate being apparently changed by a substantial but nonsignificant amount (22 percent) in a protective direction.
Gerber et al., 1991. (Ref. 5)	Montiplier, France observation of blood and cellular antioxidant levels in breast cancer cases and hospital controls	Cases: 48 women inpatients for breast cancer. Controls: 50 women first admission inpatient neurology without cancer or circulatory disease.	Blood levels of zinc, copper, selenium, vitamins E and C measured. Cellular levels of selenium, vitamins E and C evaluated in most subjects. Subject identity codes used.	Significantly higher mean levels of vitamin E, total cholesterol and E/total cholesterol ratio found in breast cancer cases than in controls. Effect lost when vitamin pill users excluded, except vitamin E. Leukocyte vitamin E level also significantly higher. Serum Zinc level sign higher. Elevated leukocyte vitamin C in cases borderline sign. Mean leukocyte vitamin E level sign after vitamin pill users excluded.	Sample size small. Elevated plasma vitamin E, leukocyte vitamin E, serum Zinc in breast cancer cases hypothesized to relate to facilitation of certain tumor growth by these antioxidants suggesting effect ultimately related to metabolic alteration. Future studies need to correlate tumor antioxidant level to resistance (chemo or natural) and tumor antioxidant level to blood level.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Graham et al., 1991. (Ref. 3)	Case-control; New York; Postmenopausal breast cancer	439 incident cases; 494 age-matched community controls	Interview using dietary questionnaire on 172 foods; diet assessed 2 years before interview; all cases were histologically confirmed; results adjusted for age, education, age at first pregnancy, number of pregnancies, age at menarche, relative with breast cancer, and benign breast disease.	Cases and controls consumed same number of calories. Dietary carotene, vitamin C protective but no effect shown for supplement use; dietary fiber borderline protective RR = 0.7 (0.5 to 1.1); adjustment for total calories did not change results. Cases ate less of 10 fruits and vegetables in questionnaire.	Low participation rates may introduce bias: 56% of eligible cases and 46% of eligible controls participated in study, thus may not be able to generalize the results.
Gridley et al., 1992. (Ref. 13)	A population-based case-control study of oral and pharyngeal cancer, conducted during 1984 to 1985 in four areas of the United States.	The subjects included 1,262 controls and 1,114 oral and pharyngeal cancer cases.	Interview were administered to obtain information on demographic variables, tobacco and alcohol use, diet, occupation, and medical history. Vitamin supplement use questions addressed years of use, age started, types of multivitamin products used (including brand) and uses of single nutrient supplements, vitamin shots obtained, and mineral products used.	Use of supplements was significantly associated with reduced risk of oral cancer. Use of supplements was associated with being female, white, more highly educated, being a California resident, having a lower body mass, and consuming more fruits and vegetables. Protracted use did not increase the apparent effects of supplements on cancer risk. Users of supplements of individual vitamins, including A, B-complex, C and E were at lower risk after controlling for effects of tobacco, alcohol and other risk factors. After adjustment for use of other supplements, vitamin E supplementation was the only one that remained associated with reduced risk.	It is not clear that the lower risk among consumers of vitamin E supplements was due to the vitamin itself, because the finding are also associated with higher intakes of fruits and vegetable among supplement users. The findings are consistent with evidence from experimental animals, and should prompt further research on vitamin E in reducing the risk of cancer.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Harris et al., 1991. (Ref. 12)	Case-control study during the year before diagnosis with cancer in Oxford, U.K.	The subjects included 96 men with lung cancer, 75 men with other epithelial cancers, and 97 hospital controls.	Interviews were conducted within 1 year of diagnosis by one experienced interviewer who was the same for all subjects. The interviewer was not blinded about diagnosis. The questionnaire covered smoking history and usual dietary intake during the year preceding diagnosis. The known carotene values for the foods are for beta-carotene.	Calculated mean dietary intakes of beta-carotene were 24% lower for lung cancer cases than for controls, 10% lower for other epithelial cancer cases than for controls. Serum concentrations of beta-carotene, retinol, and vitamin E were lower in the cancer patients than in the controls by 58, 30, and 31 percent, respectively, for lung cancer, and 33, 11, and 14 percent, respectively for other epithelial cancer cases. The OR's were less than 1.0 in the two upper thirds of dietary carotene, with the trends having borderline significance. The OR's for intakes of fruits and vegetables were rather irregular, and the associated trends were weaker than the trends for beta-carotene.	The period of concern in the recall was the year prior to diagnosis, a time. By comparison, cases in the 2-year period following sampling or interview are often excluded from prospective studies because differences may be caused by the cancer. The results suggest that beta-carotene is protective against epithelial cancers, including lung cancer.
Herrero et al, 1991. (Ref. 8)	Case-control study multiple sites in Mexico, Central America, and Colombia.	748 cases invasive cervical cancer, 1,411 inpatient controls from neurology wards at these sites.	Assessment of consumption of 98 foods, including major sources of vitamin A, C, carotenoids, and folacin as well as medical and behavioral characteristics related to cervical cancer. Adjusted for age, study site, sexual and reproductive history, socioeconomic status, screening practice, and detection of human papillomavirus.	Slightly lower risk for highest quartiles of consumption of fruit and fruit juice. Risk of cervical cancer not reduced in groups with highest consumption vegetables, foods of animal origin, complex carbohydrates, legumes, or folacin-rich foods. Evaluation of nutrient indices identified decreased risk associated with vitamin C, beta carotene, other carotenoids. Including vitamin C and beta carotene in the same model attenuated the association for beta carotene, but not for vitamin C.	Results consistent with other studies that support a protective effect of nutrients in fruits and vegetables against the development of invasive cervical cancer, however specific category of nutrient responsible not readily apparent. Associations were driven by relationships between diet and cervical cancer at two study sites. Higher socioeconomic status of subjects at these sites leaves open possibility of selection bias or an unidentified dietary pattern.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Knight et al., 1991. (Ref. 27)	Clinical trial of nitrosation of L-proline load by diet-derived nitrate, and inhibition by dietary ascorbic acid.	The first study had 16 subjects of both sexes, aged 23 to 56 years, all nonsmokers. The second study had 19 females aged 20 to 28 years, including 5 smokers. All subjects avoided known sources of the nitrosation product and vitamin supplements for 72 hours before test meal consumption.	Test Meal 1 was designed to supply a high level of dietary nitrate (172 mg/meal) accompanied by relative low levels of ascorbic acid (24 mg/meal). Test Meal 2 consisted of the same items as Test Meal 1, with the addition of foods rich in ascorbic acid (360 mg/meal). The nitrate level of Test Meal 2 was 197 mg. Both test meals contained 2.4 g dietary proline. In the first study, nitrosation was determined after consumption of low ascorbic acid meal (Test Meal 1) and, a week later, after consumption of the same meal with 500 mg of added L-proline. In the second study, all subjects had nitrosation determined with added proline, first with the low ascorbic acid meal and then a week later with the high ascorbic acid meal. Urine was collected for 24 hours after each test meal, and assayed for nitrosoproline (NPRO) and nitrate.	In the first study, the background excretion of NPRO was increased by addition of free L-proline. In the second study, a lower excretion of NPRO occurred with the high ascorbic acid meal. This occurred despite a slightly 13 higher nitrate intake from Test Meal 2, compared with that from Test Meal 1. Some subjects (Subgroup A) had a low NPRO excretion after Test Meal 1, this level was maintained with Test Meal 2. Subgroup B had high excretion of NPRO after Test Meal 1, and this was strongly decreased after Test Meal 2, containing high ascorbic acid foods.	Six subjects showed no change in NPRO after consumption of a test meal containing rich sources of ascorbic acid. These had low NPRO excretions with the low ascorbic acid meal. 13 subjects had much higher levels of NPRO excretion after the low ascorbic acid meal, but this was strongly inhibited by the inclusion of rich ascorbic acid sources in the meal, even though the ascorbic acid sources contributed some additional nitrate. The data suggest that not all individuals synthesized NPRO in vivo from the ingested precursors, and those who did not were the subjects who failed to show ascorbic acid inhibition of NPRO excretion. It was concluded that a normal western diet with plentiful content of fresh vegetables can provide sufficient nitrate to result in endogenous nitrosation, and that this process is substantially inhibited by inclusion of ascorbic acid rich foods.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Knekt et al., 1991. (Ref. 11)	Prospective cohort, 20-year followup for lung cancer in cancer free Finnish men.	4,538 cancer free men ages 20 to 69, baseline examination 1966 through 1972.	Dietary history estimated based on total habitual intake for previous year. Intake of antioxidant vitamins based on previously published analyses of Finnish foods.	Inverse relationship between intake of vitamins A, E, and C and incidence of lung cancer in nonsmokers. Relative risk between lowest and highest tertile of intake 2.5, 3.1 and 3.1 respectively. Inverse gradient between yellow, green and red vegetables (source of carotenoids) and lung cancer. No inverse gradient between preformed vitamin A and lung cancer. Strong inverse association for margarine intake (source of tocopherol) and incidence of lung cancer; significant inverse gradient for fruit intake (vitamin C source) despite low intake in this cohort.	Misclassification of intake and changes in intake were possible over followup, especially supplement use. Other substances in foodstuffs rich in antioxidant vitamin (e.g., terpenes, flavones, and phenols) may be anticarcinogenic. Studies needed on dietary patterns, intake levels, and protective effects of other constituents of diets.
Knekt et al., 1991. (Ref. 18)	A nested case-control study of serum micronutrients and cancers of low incidence in Finland.	The subjects were a total of 115 cases of cancer in 8 anatomical location categories (9 to 20 cases in each category) and 211 controls.	The site of primary cancer and date of diagnosis obtained from the cancer registry were linked to data obtained in the health examination data. Serum concentrations were determined form alpha-tocopherol, beta-carotene, retinol, retinol-binding protein, and selenium.	The crude mean level of serum alpha-tocopherol was 30% lower in persons with melanoma than in controls. The laryngeal and esophageal cases had alpha-tocopherol levels that were nonsignificantly lower. Accordingly for alpha-tocopherol, the relative risks of melanoma and was 0.2 (significant) and for cancers of the larynx and esophagus, 0.48 and 0.39 (nonsignificant). For beta-carotene, the relative risk of melanoma was 0.03 (highly significant).	Only melanoma patients had significantly lower serum alpha-tocopherol and beta-carotene levels than controls. Because the numbers of cases were small, no strong conclusions can be drawn from the results until they are confirmed in studies based on larger cohorts or on pooled data from several small samples.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Fotischman et al., 1991. (Ref. 7)	Case-control study 4 Latin American nations.	387 cases of invasive cervical cancer, 670 hospital controls.	Serum levels of eight micronutrients measured in cases and controls. Stage 1 and 2 cancer patients only included to minimize effects of disease on serologic markers.	Intake of retinol, cryptoxanthin, lycopene, alpha carotene, lutein and alpha tocopherol did not significantly differ between cases and controls. After adjustment for age, study site, sex and reproductive history, socioeconomic status, and papilloma virus higher serum beta carotene and gamma tocopherol levels associated with decreasing risk of disease.	Serum beta-carotene level constant as disease progressed, arguing against effect of disease progression on nutrient value, while gamma tocopherol level was higher in cases and progressed with disease. In this study dietary and serum effects of beta carotene concordant, both parameters indicate a possible association between intake of beta carotene and reduced risk of invasive cervical cancer.
Reed et al., 1991. (Ref. 26)	Clinical observations and ascorbic acid trial in patients at high-risk for stomach cancer.	Sixty-two English men and women with either atrophic gastritis, pernicious anemia (PA), partial gastrectomy, or vagotomy; ages ranged from 38 to 77 years.	Serum ascorbic acid and gastric juice nitrite and total extractable N-nitroso compounds were determined before treatment, weekly during 4 weeks of ascorbic acid treatment (4 g/day) and for 4 weeks after discontinuation of treatment. All patients consumed their normal diets, but avoided vegetable and fruit juices during the experiment.	Many patients had low baseline serum levels of ascorbic acid, and compliance with treatment was confirmed by a marked rise during treatment. The levels were still high 4 weeks after the patients had been instructed to stop taking ascorbic acid, implying that many of them had not discontinued treatment. Baseline levels of N-nitroso compounds were high in all groups compared with the levels previously found in normal controls, but a highly significant decrease was observed during treatment with ascorbic acid in all groups except those with PA. Treatment produced a marked decrease in gastric juice nitrite levels in all groups except those with PA.	These data support the conclusion that high-dose ascorbic acid treatment reduces the intragastric formation of nitrite and N-nitroso compounds.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Riboli et al., 1991. (Ref. 2)	Case-control; Spain; Bladder cancer	432 cases (all males); 792 controls; two sets of controls: population-based and hospital-based	Interview using dietary questionnaire containing 60 food groups; dietary assessment covered year before interview. Cases histologically confirmed.	Adjusted for smoking and total calories, a higher vitamin E intake was associated with a marginally significant reduction in risk of bladder cancer. No association found for retinol or carotene intake.	Slightly low participation rates (cases: 72% and controls: 71% hospital and 66% population); results possibly biased by inclusion of 208 prevalent cases who may represent survivors of bladder cancer.
Richardson et al., 1991. (4)	Case-control; France; Pre- and Postmenopausal breast cancer	409 incident cases; 515 hospital controls (348 premenopausal and 575 postmenopausal for total study population)	Interview using dietary questionnaire on 55 foods; current diet assessed, but if changed over past 12 months, former diet was used; all cases were histologically confirmed; results adjusted for age, menopausal status, family history of breast cancer, history of benign breast disease, alcohol consumption, and age at menarche.	Anticxidant vitamin intake had no significant effects on risk of breast cancer in premenopausal women and postmenopausal women; however, fruits rich in beta-carotene had a marginal protective effect (RR=1.4, CI=1.0-2.0) on breast cancer in this same group. In post-menopausal women retinol had a marginal protective effect (OR 1.8, CI=1.2-2.8), Beta-carotene and vitamin E intake had no significant effects on risk of breast cancer.	Study adds support to the hypothesis that fruit consumption may have a slight protective effect against breast cancer in all women (both premenopausal and postmenopausal women).

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Shi et al., 1991. (Ref. 22)	Case-control study in Shanghai, China comparing urinary ascorbic acid and nitrate in patients with gastric cancer and normal controls; urine mutagenicity in normal controls, dysplasia and gastric cancer; and gastric juice N-nitroso compounds in controls, chronic atrophic gastritis, and dysplasia/gastric cancer patients.	Thirty cases of gastric cancer were selected and paired with dysplastic patients and normal controls of the same sex and age group.	All cases were diagnosed by endoscopy. Urinary ascorbic acid and nitrate were determined chemically. Urine mutagenicity was determined in the Ames test using Salmonella typhimurium TA98 and TA100 strains, each with and without an activating S9 fraction. Four individual and the total N-nitroso compounds were chemically assayed in gastric juice.	The reduced ascorbic acid content of urine was lower in the gastric cancer group than in normal controls, while the content of nitrate was significantly higher in the cancer patients than in the controls. No mutagenicity was seen in the urines of the controls, whereas a low fraction of the urines from the dysplasia patients and a high fraction of the urines from the gastric cancer patients were mutagenic.	The lower excretion of ascorbic acid in the urine of gastric cancer patients could be either a cause or a result of the disease, but it is consistent with the hypothesis that this vitamin reduces the risk of this disease. The higher excretion of nitrate probably reflects a higher intake. Mutagenicity of the urine was directly associated with severity of pathology of the stomach. Normal controls had low levels of N-nitroso compounds in gastric juice, compared with chronic atrophic gastritis, dysplasia, or gastric cancer. The mutagenicity of the urine may have been related to synthesis of N-nitroso compounds in the stomach and differences in this process may have been due to differences in intakes of ascorbic acid and nitrate. These results support the hypothesis that N-nitroso compounds may be the cause of gastric cancer.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Sierra et al., 1991. (Ref. 25)	Comparison of urinary concentrations of nitrate and N-nitrosoamino acids in children from high- and low-risk areas for stomach cancer in Costa Rica.	One high-risk and one low-risk area for stomach cancer were chosen on criteria of rural location, large enough population of school age children and similar ethnic characteristics. From each area, 25 subjects aged 8 to 14 years were chosen at random for the oral treatments and urine collections.	Two samples of 12-hour overnight urine were collected from the children after they had ingested 500 mg proline with 200 mg ascorbic acid or 500 mg proline alone 1 hour after the evening meal. Urine samples were assayed for N-nitrosoproline and two other N-nitroso compounds, and nitrate.	All comparisons of levels of N-nitroso-proline were statistically significant. Thus, in both areas, the level was reduced by ingestion of ascorbic acid with proline, compared with that seen with proline alone. The level as higher in the high-risk area than in the low-risk area, for each type of dietary treatment. The N-nitrosoproline level correlated well with nitrate levels.	The results indicate that children living in a high-risk area have a higher potential for endogenous nitrosation than those living in the low-risk area. Nitrate exposure may explain at least part of this difference. The data confirm that proline nitrosation can be substantially inhibited by ascorbic acid supplementation.
Sobala et al., 1991. (Ref. 33)	Case control study 56 patients scheduled for stomach endoscopy in Lyon, France.	Fifty-six adult patients referred for endoscopic exam for possible gastritis with no previous stomach surgery.	Patients fasted overnight. Gastric juice aspirated for ascorbic acid, total vitamin C, total bile acid, nitrite, nitrate and total Nitroso compounds (NOC's), and an aliquot of plasma was collected for vitamin C levels. 2 stomach biopsies; 1 cultured for Helicobacter and 1 submitted for histopathology.	Of 56 patients, 12 completely normal on histopathology, 18 chronic superficial gastritis, 17 chronic gastritis with atrophy, and 9 had gastric reflux. 89% of chronic gastritis had Helicobacter infection. Intestinal metaplasia in this group significantly associated with gastric ascorbic acid, gastric vitamin C.	Age and gastric pH also significantly higher in chronic gastritis patients with intestinal metaplasia versus those without.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
VanRensvyk et al., 1991. (Ref. 118)	A case-control study of cervical intra-epithelial neoplasia and dietary and serum carotenoids.	The subjects were 103 nonpregnant, nonpostpartum cases and matched controls from women who had no cervical cytologic abnormalities greater or equal to those of benign atypia.	Cases were identified with biopsy-confirmed cervical intraepithelial neoplasia (CIN) of grades I, II, or III. Participants completed a food frequency questionnaire provided by the National Cancer Institute. The conversion of foods to nutrients was performed with and without an adjustment for energy intake.	For serum lycopene, the odds ratios for CIN were significantly increased in the three lower quartiles. The finding for lycopene-rich foods were consistent with this result. CIN was not associated with lutein. Finding for alpha-carotene, beta-carotene and cryptoxanthin were ambiguous. The lower quartiles of dietary vitamin C were associated with significantly increased odds ratios for CIN.	The relatively low response rates (approximately 60 percent for cases and 50 percent for controls) could have introduced bias. An inherent limitation of case-control studies is the determination of exposure after the onset of disease, especially for serum studies--dietary behavior may have changed after diagnosis and before blood sampling. The finding of a protective association for lycopene but not other carotenoids indicates that caution must be used in attributing the effects of carotenoid-containing fruits and vegetables to beta-carotene, at least for this type of cancer.
West et al., 1991. (17)	Case-control study, Utah. Prostatic cancer.	Cases-358 men with prostatic cancer diagnosed between 1984 and 1985. Controls-679 population based controls matched for age and county of residence.	Histologically confirmed cases and controls interviewed using quantitative food-frequency questionnaire. Data was analyzed separately for middle (45 to 67) and older (68 to 74) age categories and by tumor aggressiveness.	Beta carotene had a nonsignificant protective effect for prostatic cancer in younger males. In older males, total vitamin A had a slight positive association with all prostate cancer OR=1.6, CI=0.9 to 2.4). There was little association vitamin C and beta-carotene and prostate cancer in older men.	The most significant association were seen for older males with aggressive tumors. Dietary fat was the strongest risk factor for these males. It was not possible to blind interviewers to the case or control status of respondents.
Yoo et al., 1991. (Ref. 24)	Comparison of N-nitroso compounds concentrations in urine and gastric juice from subjects with different degrees of premalignant pathology of the stomach.	Twenty subjects with normal gastric mucosa, 20 subjects with chronic atrophic gastritis and/or intestinal metaplasia of the stomach, and 20 subjects with dysplasia of the gastric mucosa.	Twenty-four hour urine samples and gastric juice after an overnight fast were collected and assayed for N-nitroso-proline and two other N-nitroso compounds.	Levels of N-nitroso compounds in the urine were higher in subjects with gastric dysplasia than in normal controls or subjects with chronic atrophic gastritis/intestinal metaplasia. Levels of N-nitroso compounds were lower in gastric juice than in urine, and levels in gastric juice could not be evaluated by gastric pathology.	Persons with gastric dysplasia had elevated urinary levels of N-nitroso compounds, and these subjects are exceptionally prone to stomach cancer.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Karidze et al, 1991. (Ref. 6)	Case-control study, breast cancer, Moscow.	The subjects were 139 case-control pairs matched for age and neighborhood. Newly diagnosed cases of breast cancer between September 1987 to January 1989, and controls attending same clinics as cases for minor complaints.	Dietary assessment made with food frequency questionnaire for year prior to diagnosis of cases or attending clinic by controls. Assessment based on nutrient indices for 145 common food items. Data were analyzed separately for pre- and postmenopausal women.	Diet was a more important risk factor in breast cancer for postmenopausal women than for premenopausal women. After adjusting for age at menarche, energy intake, and education intake of vitamin C (OR 0.20), beta carotene (OR 0.09) retinol equivalent and cellulose were protective in postmenopausal women. Nonsignificant association for mono- and disaccharides. Increased risk of breast cancer with high intake of total fat. In general results indicate a high risk of breast cancer associated with nutrients from animal products, low risk associated with high intake of nutrients from vegetables and fruits.	Associations between dietary fat and breast cancer in postmenopausal women were nonsignificant. Socio-economic status and education were positively associated with higher risk. These confounding factors may relate to the access to health care, overestimation of intake based on serving sizes, and other influences which were not evaluated.
Ratonski et al., 1991. (Ref. 14)	Case-control; Poland; Pancreatic (Exocrine) Cancer; study conducted 1985 to 1988	110 cases (surrogates interviewed for 71%); 195 controls (all directly interviewed)	Interview using dietary questionnaire containing 80 food items assessed diet 1 to 2 years before diagnosis. 43% of cases were histologically confirmed, remainder diagnosed radiologically	Adjusted for smoking and total calories: Inverse association between intake of vitamin C and pancreatic cancer; nonsignificant protective effect association with retinol, fiber.	The statistically significant nutrients (and fiber) are associated with fruits and vegetables. Substantial use of proxy interview of cases introduces bias.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zhang et al., 1991. (Ref. 23)	The role of mutagenic/ carcinogenic N-nitrosamides in stomach cancer was studies by (1) measuring mutagenicity of extracts of a local fish sauce before and after nitrosation, (2) determining the carcinogenicity of these extracts in rats, (3) determining the N-nitrosamides in these extracts, and (4) correlation of N-nitrosamides in gastric juice with severity of pathological changes in the stomach of human subjects.	Fish similar fish sauces were collected from areas with high- and low-risk for stomach cancer, nitrosated, assayed for N-nitrosamides and mutagenicity, and fed to rats for 4 or 16 weeks. Gastric juice was collected from 12 normal control, 14 chronic atrophic gastritis, 13 gastric dysplasia patients, and assayed for N-nitrosamides.	Fish sauce samples were extracted with ethyl acetate and the extract was nitrosated with sodium nitrite under simulated gastric conditions. Mutagenicity was determined with the Ames test using Salmonella typhimurium strain TA100, a sister chromatic exchange assay, and a micronucleus test. The animal carcinogenicity assay was performed by gavaging for 3 days either nitrosated or nonnitrosated fish sauce extract to newborn rats and determining the effects in rats autopsied after 4 or 16 weeks. A total of 39 gastric juice samples were collected from patients after an overnight fast by fibroendoscopy.	In the absence of nitrosation, none of the fish sauce extracts was mutagenicity. After nitrosation, all samples had direct mutagenicity in the Ames test and induced sister chromatid exchange with a dose-response relationship. In the micronucleus test, fish sauce extracts from only two villages were active. Four weeks after treatment with fish sauce, only those rats treated with the sauce that was mutagenic in all three assays showed marked precancerous dysplasia. After 16 weeks, the same treatment group had cancerous ulceration in the glandular stomach, with dysplastic glands and cells that had penetrated the mucosa and infiltrated into submucosa and muscular layers of the gastric wall. The mean concentrations of N-nitrosamides in the nitrosated fish products were more than 15 times higher in the samples from a high-risk area than in the samples from a low-risk area. The N-nitrosamide concentrations in gastric juice were strongly positively correlated with the severity of pathological changes in the stomach.	These data strongly support the hypothesis that the etiology of human gastric cancer is closely related to intragastric formation of mutagenic/carcinogenic N-nitroso compounds, that the degree of pathological change is directly related to the exposure of these compounds, and that exposure to these carcinogens is higher in areas of high-risk for stomach cancer.

TABLE 2

Human Studies not Included in the Review of New Scientific Evidence.

Study	Study Design	Subjects	Methods	Results	Comments
Oranteich et al., 1991. (Ref. 41)	Case-control study in Northern California measuring sera beta-carotene levels 15 years prior to diagnosis of lung cancer versus sera levels collected from controls taken at same time.	The subjects were 263,000 individuals participating in routine Health Maintenance Organization check-ups; 151 lung cancer cases, 302 matched controls with similar sera storage time.	Comparisons were made with 123 case control triplets. Catalogued sera were stored at -40 C for 15 to 22 years and assayed using High Performance liquid chromatography. Relative risk of lung cancer was estimated by logistic regression, statistical significance of difference in mean calculated using single t test.	RR was 3.0 for lung cancer in lowest versus highest quintile of beta-carotene intake. Trend less evident for retinol and alpha-tocopherol.	Carotenoids are highly reactive, and decay may have varied in sera based on other substances present. It is also possible that the difference in sera carotenoid level in future lung cancer cases was not correlated with nutritional intake, but was associated with other factors such as smoking or alcohol use.
Tuyns et al., 1992. (Ref. 42)	A case-control study of gastric cancer in two provinces of Belgium.	Subjects were 449 cases 3,524 controls.	Diet data were obtained by interview using a validated dietary history questionnaire. Food were classified into groupings based source, such a vegetables, fruits, breads, meats, fish, and dairy products, and on raw versus cooked. RR and probability values were calculated.	Consumption of both raw and cooked vegetables, including leafy and root types, were associated with reduced risk. Consumption of raw fruit, but not stewed or canned fruit, was associated with reduced risk. Consumption of dairy products increased risk, and some types of meat and fish increased risk, whereas consumption of lean meats decreased risk. Consumption of high P/S ratio fats increased risk.	The results show that consumption of fruits and vegetables reduces risk. The destruction of protective effects by cooking of fruits, and the risk associated with polyunsaturated fat consumption suggest, but alone are not sufficient to demonstrate, that the antioxidant vitamins reduce the risk of stomach cancer.
Toma et al., 1992. (Ref. 43)	A clinical trial of beta-carotene (90 mg/day for three cycles of 3 months each) against oral, and evaluation after 24 months.	A total of 23 patients (aged 17 to 85) were included in the study and 18 (8 male and 10 female) were evaluated.	The leukoplakia lesions were examined macroscopically and microscopically at entry, and in the evaluated patients at the end of the study.	Among the 18 evaluated patients, 6 showed complete response, 2 partial response, 3 minimum response, and 6 stable disease.	The design examined the use of high-dose beta-carotene in treatment of preneoplastic conditions, and thus appear not to meet the 1990 amendments standards for dietary content or reduction of risk.
Swanson et al., 1992. (Ref. 44)	A case-control study of diet and lung cancer risk in Yunnan Province, China.	The subjects were 428 cases, aged 35 to 74 years, and 1,011 age-matched controls.	Interviews were conducted to obtain information about eating habits during adult life and to report usual intake frequency for 31 food items or groups.	The relative risk of lung cancer across increasing quartiles of food intake increased for consumption of meat. Cases tended to consume slightly more rice than controls. Risk decreased markedly across increasing quartiles dark green, leafy vegetables.	The specific constituent(s) responsible for the protective effects of vegetable consumption could not be identified, but carotenes other than beta-carotene, or compounds in cruciferous or Allium vegetables were stated to be possibilities.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Longnecker et al, 1992. (Ref. 45)	Pooled data from five previously published studies with serum alpha-tocopherol values were analyzed for reduced risk of several types of cancer.	The five studies, in Finland, Hawaii, Maryland, Switzerland, and the United Kingdom, included approximately 93,000 subjects, both male and female, but serum alpha-tocopherol assays were performed only on approximately 300 cases and 1,300 controls.	Blood specimens had been stored for 0 to 14 years at temperatures of -20 to -75° C when serum was analyzed for alpha-tocopherol.	In comparison of cases versus controls, alpha-tocopherol values were consistently nearly equal, and, when numerical difference occur, the cases tended to be slightly lower than the controls. The crude OR's for colon and rectum cancer were consistently lower for the highest quartile of serum alpha-tocopherol values than for the lowest quartile. The CI's of the collective data were quite wide, preventing significance of any real effects.	The results suggest that serum alpha-tocopherol concentration may be inversely related to risk of colorectal cancer. This is unclear, however, because the association between serum alpha-tocopherol level and decreased risk was modest, the confidence were wide, and the overall tests for trend in effect were not significant. Larger observational studies with dietary data are needed to determine whether vitamin E has a small but important effect on risk of colorectal cancer.
Fraser et al., 1991. (Ref. 46)	A prospective study with a 6-year followup from 1977 to 1982 on diet and lung cancer. California.	Subjects were 34,198 Seventh-Day Adventists, 61 of whom developed lung cancer in cohort.	A questionnaire was mailed to all subjects. Response exceeded 75% for non-Hispanic whites. Food frequency was determined for 51 different foods. Annual mailings in regard to hospitalization, and hospital record information were used to detect new cancer cases.	Fruit consumption had a strong protective effect for lung cancer; RR = 0.26 for highest tertile of consumption, CI = 0.10-0.70, p = 0.006.	This population is unique in that less than 4 percent admitted to smoking and approximately 50 percent are lacto-ovo vegetarians.
Stahelin et al., 1991. (Ref. 47)	A prospective study of men in Basel, Switzerland with a 12-year followup; plasma levels of antioxidant vitamins were correlated with mortality due to cancer at all sites.	The subjects were over 2,974 men from a cohort of 6,000 healthy volunteers employed in three pharmaceutical companies.	Serologic samples were collected from 2,974 men in 1971 to 1973 examination cycle. Information about deaths was obtained from employers and death certificates obtained. No vital statistics were obtained for eight individuals.	Overall cancer mortality was associated with low mean plasma carotene level adjusted for cholesterol, and vitamin C. Bronchus and stomach cancers were associated with low mean plasma carotene. Stomach cancer was associated with low mean vitamin C and lipid-adjusted vitamin A. Low levels of vitamin C increased the risk of stomach cancer (RR = 2.17, p = 0.05; and gastrointestinal cancer, RR = 2.46 in older subjects, significance lost in this group of subject with exclusion of first 2 years of followup.	Authors conclude that low serum antioxidant vitamin levels are associated with higher risk of subsequent cancer. Effects appear to be site specific. The role of nutrient intake, rather than serum levels, and other variables is unclear. Serum lipid, smoking, exercise, unidentified nutrients are associated with antioxidant vitamins may effect serum levels.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bagburst et al., 1991. (Ref. 48)	A case-control study of diet and pancreatic cancer, in Adelaide, Australia.	The subjects were 104 cases of pancreatic cancer and 253 community controls.	A quantitative food-frequency questionnaire was used to assess intakes of 179 food items. Amount and contribution to diet were compared for 48 nutrients.	Cases consumed more eggs, sweet,and fatty foods and less vegetables and fruits ($p < 0.01$ for dried grapes, lettuce, and broccoli consumption in females; $p < 0.01$ for dried grapes in males; $0.01 < p < 0.05$ for tomatoes, green beans, and coleslaw in males; and $0.01 < p < 0.05$ for brussels sprouts, cucumber, potato, and tomato in females). Cases consumed less beta-carotene, vitamin C, and vitamin E than controls.	Study supports view that fruit and vegetables have an important role in minimizing cancer of the pancreas, but provides information about relative, not quantitative, amounts of the antioxidant vitamins.
La Vecchia et al., 1991. (Ref. 49)	A case-control study of dietary indicators for pharyngeal and oral cancer in Northern Italy during 1987 to 1989.	The subjects were 105 cases of oral and pharyngeal cancer and 1,169 hospital controls with acute nonneoplastic conditions.	Data were collected on usual frequency of consumption of 10 indicator foods before onset of digestive illness. Subjective scores were given (low, medium, and high) for seven items including wholemeal bread, pasta, fats, condiments.	There was a significant protective association for consumption of six food items: milk, meat, cheese, carrots, green vegetables, and most strongly, for fruit (RR = 0.8 and 0.2, respectively, for two highest tertiles).	The associations may reflect poorer nutritional status in cases. The observation that fruit appeared to be particularly protective may be of significance in terms of etiology and protection.
Mu et al., 1991. (Ref. 50)	A case-control study of dietary indicators for colon and rectal cancer in Harbin City, Heilogjiang province, China during 1985 to 1988.	The subjects were 3,336 histologically confirmed cases of colorectal cancer (111 colon, 225 rectal) and an equal number of hospital controls with nonneoplastic diseases. Matched for sex, age, and residence.	Data on frequency and quantity of consumption of food items were collected. OR's and confidence limits were computed for intake and risk of disease.	Higher intakes of vegetables, especially green vegetables, chives, celery, were associated with a protective effect against colorectal cancer. Reduced intakes of meat, eggs, bean products, and grain were associated with increasing risk of rectal cancer.	The data are supportive of a protective effect of vegetable intake, especially green vegetables, against colorectal cancer. Protective effect of meat, eggs, bean products, and grain against rectal cancer may reflect lower level of nutrition in this region of China.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
De Vet et al., 1991. (Ref. 51)	A case-control study of dietary indicators for cervical dysplasia; a multicenter study in the Netherlands during 1984 to 1987.	The subjects were 257 cases of cervical dysplasia and 705 controls from the general population.	A questionnaire was mailed regarding frequency of consumption of various food items containing beta-carotene, retinol, vitamin C, and dietary fiber.	Increased risk of cervical dysplasia was associated with increased intake of beta-carotene; Relative Risk = 2.31, CI = 1.27 to 4.19. No relationship was found for retinol intake, but both vitamin C and dietary fiber intake showed a nonsignificant inverse relationship with cervical dysplasia.	The findings do not support hypothesis that beta-carotene protects against cervical dysplasia, but suggest a greater risk with higher intakes.
Graham et al., 1990. (Ref. 52)	A case-control study for gastric cancer in three counties in Western New York during 1975 to 1985.	The subjects were 293 histologically confirmed case and neighborhood-, age-, and sex-matched controls.	The cases came from hospital records in all but five hospitals in a three- county area. A 2.5-hour interview scheduled with each case and control was used to assess total nutrient intake. There were no surrogate interviews.	Carotene: there was substantial decrease in risk of male gastric cancer in the highest quartile of intake, but no dose-response relationship. There was no association in females. An increase in risk of gastric cancer occurred with higher retinol intake. No relationship to cancer was noted for vitamins C and E. Intake of specific vegetables had a significantly associated decreased risk of gastric cancer; male: cucumbers, tomatoes, green peppers, carrots, onions celery; female: onions, winter squash.	The study is supportive of a protective effect of specific vegetables against the risk of gastric cancer. Data does not provide specific support for a role of antioxidant vitamins in reducing the risk of gastric cancer.
Oreggia et al., 1991. (Ref. 53)	A case-control study cancer of the tongue in Uruguay, 1987 to 1989.	The subjects were 57 cases of lingual cancer and 353 hospital based controls. The study was restricted to males.	The subjects were interviewed with a standard questionnaire about the use of tobacco, alcohol, and dietary intake.	Infrequent consumption of vegetables was associated with tongue cancer; RR = 5.3, CI = 1.5-19.4. Tobacco and alcohol were the strongest risk factors.	The study does not provide direct support for a role of the antioxidant vitamins in cancer because of he limited data on nutrient intake presented.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Gridley et al., 1990. (Ref. 54)	A multicenter case-control study for oral and pharyngeal cancer in blacks in New Jersey, Atlanta, Los Angeles, and the San Francisco/ Oakland area during 1984 to 1985.	The subjects were 248 cases of oral cancer in blacks contacted and 190 participated in the study; all were identified from cancer registries. Of the 262 controls contacted, 201 participated. These were matched to cases on age, race, and sex. Those under 65 years of age were chosen from random digit dialing and over 65 from Health Care Financing Administration rosters.	Interviews were conducted on diet, occupation, tobacco, alcohol, demographics, and medical history. Questions were asked about 61 food frequencies, food preparation, and recent dietary changes. Indices and serving size data were obtained from NHANES II.	All fruits and vegetables, except legumes were associated with decreased risk of cancer in men. A significant protection was associated with intake of noncitrus fruits, green leafy vegetables, and vegetables eaten raw. All fruits and vegetables, except dark yellow vegetables, especially cruciferous vegetables, were associated with decreased risk of cancer in women, A protection was most evident for pharyngeal cancer. Intakes of carotene and vitamin C were associated with significantly reduced risk in men, while vitamin C was significant for reduced risk in women.	Lower consumption of fruits and vegetables in blacks may contribute to elevated rates of oral and pharyngeal cancer versus general population. The study is consistant with a protective role of the antioxidant vitamins and also for the inducer compounds in cruciferous vegetables.
Rossing et al., 1989. (Ref. 55)	A case-control study for antioxidant vitamins and pharyngeal cancer in Washington State, 1980-1983.	The subjects were 166 cases (of 292 identified cases) between 30 and 74 years old. Surrogate next-of-kin were interviewed for 86 cases; the controls were 547 of 552 individuals from a population who were sex- and age-matched to the cases.	The subjects were asked to estimate food frequency in a questionnaire interview for 48 food items and vitamin supplements during the 1970's. USDA nutrient indices were used to estimate intakes.	A significant increase in risk of pharyngeal cancer was associated with low intake of vitamin C; RR = 2.8, CI = 1.5 to 4.8. The role of vitamin C supplementation was difficult to assess because of discrepancies between next of kin reporting and the remaining case group.	The study suggests a potential protective effect of vitamin C against pharyngeal cancer. The authors conclude that the data are compatible with other research reporting a protective effect of fruits and vegetables against pharyngeal cancer.

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TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Ghadirian et al., 1991. (Ref. 56)	A case-control study for nutritional factors and pancreatic cancer in Montreal, Canada, 1984 to 1988.	The subjects were 179 clinically diagnosed cases from 19 French-speaking hospitals and 239 controls matched for age, sex and residence.	A core questionnaire about lifestyle, occupation, drinking, smoking, medical history, etc. was administered. A food frequency questionnaire was given concerning 200 different items for times 1 year and 10 years before diagnosis. The controls were matched individually for same period.	The associations for antioxidant vitamin intakes (beta-carotene, vitamins C and E) and retinol to the risk of cancer were nonsignificant.	The authors suggest need for larger studies of the relationship between nutrient intake and pharyngeal cancer.
Heilbrun et al., 1989. (Ref. 57)	A nested case-control study of diet and colorectal cancer in Oahu, Hawaii, 1965-1985.	The cohort was 8,006 American Japanese men aged 65 to 85 years in 1985; there were 102 cases of colon cancer and 60 cases of rectal cancer, and 361 cancer-free males from cohort randomly selected as controls.	Nutrient intake estimates were based on representative 24-hour recall of fiber, vitamins, minerals, macronutrients.	For colon cancer, the lowest quintile intake of vitamin C had RR = 1.87, CI = 1.03 to 3.37. There was a nonsignificant association between carotene, vitamin A intake and colon cancer. There was no association between rectal cancer and intake of any of the antioxidant vitamins.	With exception of vitamin C intake and colon cancer, the study does not support a protective effect of the antioxidant vitamins against colorectal cancer.
Kato et al., 1990. (Ref. 58)	A case-control study of colorectal cancer, and adenoma in Nagoya, Japan, 1986 to 1990.	The subjects were 221 cases of histologically diagnosed colorectal cancer, 525 cases of colorectal adenoma, and 578 neighborhood controls.	The cases attended Aichi Hospital; the neighborhood controls were matched for sex, age, and residence and were selected by random dialing.	Daily vegetable intake was associated with lower risk of distal colon adenoma; RR = 0.59, CI = 0.39 to 0.89, and rectal cancer; RR = 0.46, CI = 0.25 to 0.84.	The study supports a protective effect of vegetables against colorectal adenoma and carcinoma.
Graham et al., 1990. (Ref. 59)	A case-control study esophageal cancer and nutrition in three counties in Western New York, 1975 to 1986.	The subjects were 178 cases of histologically diagnosed esophageal cancer, matched with neighborhood controls for sex and age.	The cases came from hospital records in all but five hospitals in the three-county area. A 2.5-hour interview was scheduled with each case and control to assess total nutrient intake. No surrogate interviews.	Risk of cancer increased with increased consumption of foods containing retinol, not carotene.	The authors concluded that further studies are needed to distinguish risks of cancer of esophagus and elsewhere associated with retinol and carotene.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0102]

RIN 0905-AD08

Food Labeling: Health Claims; Zinc and Immune Function in the Elderly

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between ingestion of zinc and immune function in the elderly. This rule is issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and is developed in accordance with the final rule on general requirements for health claims, issued elsewhere in this issue of the Federal Register. The agency has concluded that, based on the totality of the scientific evidence, there is not significant scientific agreement among qualified experts that increased intake of zinc will enhance immune function in the elderly. Therefore, FDA has concluded that claims on foods relating to zinc and immune function in the elderly are not justified.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS-227), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5593.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 27, 1991 (56 FR 60652), FDA proposed not to authorize health claims relating to zinc and immune function in the elderly. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship of zinc and immune function in the elderly is one of the claims required to be evaluated. In the proposed rule (56 FR 60652), FDA reviewed the publicly available relevant data pertaining to zinc and immune function in the elderly and evaluated whether health claims relating zinc and immune function would be justified under the standard proposed in the companion document entitled "Food Labeling: General Requirements for Health Claims for Food" (56 FR 60537).

FDA published a notice in the Federal Register of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments, including zinc and immune function in the elderly. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on zinc and immune function, and were included in the proposed rule (56 FR 60652).

In the proposed rule (56 FR 60652), FDA requested written comments on its tentative determination not to authorize a health claim for zinc and immune function in the elderly. In addition, FDA held public hearings on January 30 and 31, 1992, on all aspects of the proposed rules published to effect the 1990 amendments (57 FR 239, January 3, 1992). The agency received approximately 20 comments in response to its proposal to deny health claims regarding zinc and immune function in the elderly. Several comments were received that were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

The relevant publicly available data evaluated by FDA in its proposed rule (56 FR 60652) included seven human studies (Refs. 29 through 35) in which elderly subjects were supplemented with zinc to determine its influence on immune system function. In the proposed rule (56 FR 60652 at 60661), the results of four of the earlier published studies (Refs. 29 through 32) suggested a zinc-associated enhancement of several measures of immune function. However, FDA noted that the reliability of three of these studies was limited due to inclusion of very few individuals, and the tested subjects were not representatives of the general elderly population. Moreover, FDA further noted that the results of these initial reports have not been substantiated by more recent, larger studies of more rigorous experimental design (Refs. 34 and 35).

FDA tentatively concluded that the later, larger studies showed no improvement of immunocompetence from zinc supplementation in the elderly. The agency also pointed out that zinc supplementation at levels in excess of 100 milligrams per day (mg/day) can result in suppression of immune system function (Ref. 48). For these reasons, FDA tentatively determined that claims on foods, including dietary supplements, relating to zinc and immune function in the elderly are not justified.

The Dietary Supplement Act of 1992 established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. The law says that FDA can grant health claims for foods, including dietary supplements, using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act. However, it may not act on such claims under section 403(r)(5)(D) of the act until it establishes a standard to implement that section of the act, which the new law says may not occur until December 1993. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to evaluate the zinc and immune function claim based on the standard that FDA is establishing for determining the reliability of health claims under section 403(r)(5)(D) of the act. In the November 27, 1991 proposal, on general requirements for health claims, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that zinc is found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on zinc and immune function in the elderly on any foods.

Because the Dietary Supplement Act provides that FDA may grant claims under section 403(r)(3)(B)(i) of the act, and given the breadth of FDA's November 1991 proposal, on zinc, FDA has decided to move forward to

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determine whether it can authorize a claim under section 403(r)(3)(B)(i) for zinc and immune function.

However, this rule does not apply to dietary supplements. While a manufacturer of a dietary supplement can make a claim on zinc and immune function in the elderly without rendering its product misbranded under section 403(r)(1)(B) of the act, the manufacturer should assure itself that the making of the claim will not misbrand the product under section 403(a) of the act.

II. Comments to the Proposal and the Agency's Responses

A. General

1. Nine comments representing State attorney generals, State agencies, associations of public health officials, and professional associations of people employed in nutrition-related fields agreed with FDA's assessment of the evidence on zinc and immune function, including FDA's proposed decision not to authorize a claim on this nutrient-disease relationship. Several comments stated opposition to allowing health claims in general.

The agency acknowledges those comments supporting its tentative position not to authorize a health claim on zinc and immune function in the elderly. In response to those comments that oppose all health claims, however, the agency points out that the 1990 amendments provide sufficient safeguards to ensure that health claims are scientifically valid and will provide consumers with information that will promote good health.

B. Comments on the Available Data

2. One comment from a consumer-oriented nutrition magazine noted that the small number of participants in some of the studies cited in the proposed rule (56 FR 60652) makes their inclusion questionable. This comment also noted that results from studies using supplemental zinc levels no higher than the Recommended Dietary Allowance would likely be of little value.

FDA concurs with this comment. In its proposed rule, FDA noted that small (5 to 8 subjects), uncontrolled studies (Refs. 30 through 32) were included among those that it found in its review of the publicly available scientific literature. However, in the proposed rule, the agency stated that the significance of these reports to the agency's decision was limited because of the small number of subjects and the lack of substantiation of their findings by larger studies.

Of the three studies in which supplemental zinc was provided at the Recommended Dietary Allowance level (12 to 15 mg/day), two studies (Refs. 34 and 35) also included substantially higher supplemental zinc levels (100 mg/day). FDA stated that the third study (Ref. 31), which used a 15 mg/day zinc supplement, was of low reliability because of the limited number of subjects, absence of control subjects with which to compare those supplemented with zinc, and lack of blinding as to treatment received.

3. One comment submitted a list of recently published scientific studies, not cited in the proposed rule, suggesting that they bear directly or indirectly on the issue.

FDA reviewed the submitted studies and determined that not one of the articles is relevant to the topic of zinc and immune function in the elderly. Of the six references listed, five were of studies of zinc metabolism or nutrition, but did not involve immune function. One reference listed did concern zinc and immune function, but was available only as an abstract. FDA did not consider abstracts in its evaluation as experimental design and data are presented too briefly for adequate evaluation.

C. Life Science Research Office Report

4. Among the authoritative documents considered in the proposed rule was a preliminary report (Ref. 26) from a 1991 review of the literature on the relationship between zinc and immune functions in the elderly conducted by the Life Sciences Research Office (LSRO) of the Federation of American Societies of Experimental Biology (FASEB). The final version of the LSRO report ("Evaluation of Publicly Available Scientific Evidence Regarding Certain Nutrient-Disease Relationships: 2. Zinc and Immune Function in the Elderly", W. R. Beisel) was released by LSRO in December 1991, and filed in the docket as a comment on the proposed rule. The final version was not changed from the preliminary version cited and discussed in the proposed rule. It fully supports FDA's conclusions on the lack of a relationship between zinc and immune function in the elderly.

D. Canada

5. In two comments, the Canadian Government (Bureau of Consumer Affairs, and Health and Welfare Canada) noted that, under the Canadian Food and Drug Act, Section 3, the advertising and sale of foods represented as a treatment, preventative, or cure for specified diseases and health problems is prohibited in Canada. Although immune function is not included among the list of specified disorders, health claims respecting zinc and immune function on food labels would likely result in the foods being classified as drugs in Canada by virtue of the definition for "drug" in the Canadian law.

These comments are essentially identical to a comment submitted by the Canadian Government in response to FDA's notice requesting scientific data or information on this topic, which published in the **Federal Register** of March 28, 1991 (56 FR 12932). In its proposed rule (56 FR 60652), FDA did not propose to authorize health claims for zinc and immune function on food labels. Thus, no change in the proposed rule is appropriate in response to this comment.

III. Conclusion

FDA reviewed the scientific data in conformity with the requirements of the 1990 amendments, as well as comments received regarding the proposed rule that published in the **Federal Register** of November 27, 1991 (56 FR 60652), and concluded that there is not a sufficient basis to support the use of health claims relating to the topic of zinc and immune function in the elderly.

The agency's examination of publicly available evidence found that, although it is well accepted that adequate dietary zinc is essential for normal immune function, a specific protective role of zinc supplementation of the elderly population has not been demonstrated. Although some small early clinical studies suggested such a relationship, these results were not substantiated in subsequent research using better study designs and larger samples. Therefore, there is no evidence that immune function in healthy persons can be enhanced by zinc supplementation. Zinc is considered to be relatively nontoxic, particularly if taken orally. However, adverse effects, which include impaired immune function, are known to occur with zinc intake in excess of Recommended Dietary Allowances. Thus, FDA has concluded that the publicly available data on the role of zinc in immune system function do not provide a sufficient scientific basis from which to conclude that immune function in the general elderly U.S. population can be improved by zinc supplementation. Moreover, based on the totality of this evidence, there is not significant scientific agreement among qualified experts that a health claim for zinc and immune function in the elderly is supported by the evidence.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354 , FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that, although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (e) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(e) Zinc and immune function in the elderly.

Dated: October 23, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31516 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N–0094]

RIN 0905–AB67

Food Labeling: Health Claims; Calcium and Osteoporosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use on the label and labeling of foods of health claims relating to an association between adequate calcium intake and osteoporosis. These rules are issued in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims and are developed in accordance with the general requirements in the health claims rule published elsewhere in this issue of the **Federal Register**. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific evidence and agreement among qualified experts that maintaining a diet adequate in calcium has a significant impact on bone health particularly during the critical bone forming years and after menopause and may help to reduce the risk of osteoporosis. The agency has therefore concluded that claims on foods relating the calcium content to a reduced risk of osteoporosis in susceptible populations are justified.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Mona S. Calvo, Center for Food Safety and Applied Nutrition (HFF–265), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5434.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60689), the agency proposed to authorize the use on foods, including dietary supplements, of health claims relating to the association between calcium and risk of osteoporosis. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101–535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537). With respect to health claims, the 1990 amendments amend the Federal Food, Drug, and Cosmetic Act (the act) by adding a new provision (section 403(r)(1)(B) (21 U.S.C. 343(r)(1)(B)) that provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act.

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether 10 nutrient/disease relationships meet the requirements of the section 403(r)(3) or (r)(5)(D) of the act. The relationship of calcium and osteoporosis was one of these areas. FDA published a notice in the **Federal Register** of March 28, 1991 (56 FR 12932), requesting scientific data and information on the 10 specific topic areas identified. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on calcium and osteoporosis and were included in the proposed rule (56 FR 60689). Because of time constraints, FDA addressed in that proposal only those comments submitted in response to the March 28,1991, notice that were in the form of scientific data. Comments of a more specific nature were not responded to at that time and are included among the comments responded to below.

Provisions of the proposed rule included qualifying and disqualifying criteria for the purpose of identifying foods eligible to bear a health claim. The proposal also specified mandatory content and label information for health claims statements and provided a model health claim and consumer summary statement. FDA also discussed potential safety issues relating to overfortification or oversupplementation with calcium. FDA requested written comments on the proposed rule, including comments on the issue of how to assess calcium bioavailability in products (conventional foods and supplements) to justify their eligibility to bear a health claim. Moreover, to ensure that calcium and osteoporosis claims will not mislead those individuals within the population for whom relatively higher calcium intake over a lifetime offers no apparent benefit to their bone health, FDA proposed that the subpopulations clearly at risk be identified on the label and solicited comments on how best to convey this information.

II. Summary of Comments and the Agency's Responses

In response to the proposed rule, the agency received more than 100 letters, each containing one or more comments, from consumers, consumer organizations, health care professionals, professional organizations, State and local governments, foreign governments, trade associations, and industry. In addition to these comments, the agency also considered statements made in a public hearing held on January 30 and 31, 1992 (57 FR 239, January 3, 1992) on a number of food labeling issues, including the proposed requirements for health claims. Some of the comments agreed with one or more provisions of the proposed rules without providing grounds for support other than those provided by FDA in the preamble to the proposal. Other comments disagreed with one or more provisions of the proposed rule without providing specific grounds for the disagreement. A few comments addressed issues outside of the scope of the regulations. Most of the comments provided specific support for their positions on the proposed regulations. The agency has summarized and addressed the relevant issues raised in all comments in the sections of this document that follow.

Before issuing the proposal, FDA contracted with the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology to evaluate independently the scientific literature on dietary calcium and osteoporosis. The preliminary draft of the LSRO report, "Calcium and Osteoporosis" (Ref. 13), was one of the authoritative documents reviewed by FDA in developing its proposal. After the proposal was issued, LSRO completed its evaluation of the scientific literature and submitted its final report in February 1992. The agency placed a copy of the final report in the administrative file (Ref. 138), and has considered the report as a comment on the proposal.

A. Validity Issues

1. No comments disputed FDA's tentative conclusion that a lifetime of adequate calcium intake is important for maintenance of bone health and may help reduce the risk of osteoporosis, particularly for individuals at greatest risk. Most comments supported the agency's position.

The LSRO report (Ref. 138) concluded that "the weight of the evidence supports the hypothesized relationship between calcium intake and bone health as expressed both in increased bone mass and in reduced fracture risk." According to LSRO, "the focus of calcium as a nutrient related to osteoporosis lies in its importance both for achieving genetically programmed bone mass during about the first 30 to 35 years of life and in maintaining that

bone during the remaining years of life." The report stressed that osteoporosis is a multifactorial disorder, and that inadequate calcium intake is only one of several interacting factors that determine whether low-trauma fracture will occur. The report also noted that "the data concerning level of [calcium] intake required for bone health can be safely generalized only to Caucasian females."

FDA acknowledges the significant agreement on this matter and reconfirms its position that adequate calcium intake is important for maintenance of bone health and may help reduce the risk of osteoporosis, particularly for individuals at greatest risk. FDA notes that the LSRO report is consistent with required health claim statements about the mechanism by which calcium works (proposed § 101.72(d)(3), finalized at § 101.72(c)(2)(i)(C)) and the population at greatest risk (§ 101.72(c)(2)(i)(B)). As discussed in the proposal (56 FR at 60698), FDA agrees that the general population is not at significant risk of developing osteoporosis. For example, despite their generally lower calcium intake, data show that African Americans have higher bone mass at maturity and a very low incidence of osteoporosis-related bone fracture.

B. Advisability of Permitting Claims

2. One comment asserted that health claims pertaining to calcium and osteoporosis should not be permitted because (1) the target population for the claim is too small, and (2) older people with the condition may be misled into thinking the rate of bone loss will be slowed or reversed with increased calcium consumption.

FDA disagrees with this comment, which provided no support for its assertions. First, a large number of American women are at risk of developing osteoporosis (Ref. 18). Further, many of the elderly have low bone mass, and they continue to lose bone mass with further aging. These individuals will clearly benefit from information about how they may reduce their risk of the disease.

Secondly, as explained fully in the preamble of the proposal (56 FR at 60689), adequate calcium intake does help to slow the rate of bone loss in the elderly. Thus, while under § 101.72, claims may not imply that adequate calcium intake will reverse bone loss, under § 101.72 (c)(2)(i)(C), when reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss. For these reasons, FDA disagrees that permitting claims to advise of the reduction in the rate of bone loss will mislead the elderly.

3. A few comments argued that a health claim should not be allowed because delay of the onset of osteoporotic fracture is not exclusively associated with adequate calcium intake. One of the comments justified this assertion by stating that many essential nutrients in addition to calcium, such as magnesium, copper, zinc, fluoride, and vitamins A, D, K, and C, are needed for normal bone growth and development.

FDA recognizes that many nutrients are essential for normal bone growth and development. However, FDA disagrees that this fact should preclude the agency from permitting a health claim pertaining to calcium and osteoporosis. The requirement in § 101.72(c)(2)(i)(A) that claims advise consumers of the importance of healthful diets is intended to alert consumers to the need to consume essential nutrients in addition to calcium. As the agency explained fully in the proposal (56 FR at 60689), national food intake surveys (Refs. 35, 54, and 105) provide evidence identifying calcium from dietary sources as a problem nutrient in a subpopulation at risk for osteoporosis, namely women between 11 and 35 years of age. Furthermore, FDA has concluded that based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that the evidence overwhelmingly supports the significance of calcium in maintaining bone health. Thus, FDA believes that the population at greatest risk of osteoporotic fracture in later life should be advised through food labeling of the benefits of adequate calcium intake.

C. Clarity of Provisions

4. A number of comments on the proposed rule on general requirements for health claims (November 27, 1991, 56 FR 60537) suggested that FDA revise provisions of all health claims rules to be more understandable.

FDA agrees that its regulations should be understandable. FDA has therefore made several nonsubstantive revisions in § 101.72 for the sake of clarity. For example, the provisions of the regulation have been grouped into general and specific requirements. The general requirements reference other regulations containing nutrition labeling requirements. The specific requirements are separated into requirements pertaining to the food and those pertaining to the claim. Finally, the model health claims have been simplified.

D. Qualifying Levels

5. A few comments addressed the issue of an appropriate qualifying level for calcium in a food. All of the comments strongly supported the requirement that a food bearing a calcium-osteoporosis claim be "high" in calcium (i.e., contain a minimum of 20 percent of the reference daily intake (RDI)). A number of the comments, however, asserted that the RDI was being set too low. One comment stated that the proposed RDI for calcium (800 mg) was an inadequate intake guideline for those individuals at greatest risk of osteoporosis. Another comment argued that there is substantial evidence that the population-weighted means used to establish the RDI's may seriously understate the nutritional needs of an estimated 52 million Americans.

For reasons explained fully in the preamble of the final rule on Reference Daily Intake and Daily Reference Values, which is published elsewhere in this issue of the Federal Register, FDA has adopted an RDI for calcium of 1,000 mg, the level in current § 101.9(c)(7)(iv). In view of the support for the proposal that only foods "high" in calcium qualify for calcium-osteoporosis claim, the agency has retained this requirement in the final rule in § 101.72(c)(2)(ii)(A) (proposed as § 101.72(c)(2)) with minor editorial revisions. Because the RDI for calcium is 1,000 mg, the reference amount customarily consumed for a food would need to contain at least 200 mg of calcium for it to qualify to bear the authorized calcium/ osteoporosis health claim.

E. Assimilability

All comments on this topic generally supported the concept of a requirement that the calcium content of the product be assimilable (proposed as § 101.72(c)(3) and finalized as § 101.72(c)(2)(ii)(B)). In response to an agency request in the proposal for comments about how to assess calcium assimilability (also referred to as "bioavailability"), a few comments suggested mechanisms to assess calcium bioavailability.

6. Several comments suggested that the agency establish a minimum standard that relates bioavailability to the amount of calcium actually absorbed from food. One comment cited the existence of a recognized data base describing the absorption of naturally occurring supplemental and fortified calcium in foods. However, the comment added that the cited data base

was actually a bibliography of various published articles describing calcium absorption from a variety of food sources. Another comment offered the following suggestion: "FDA should estimate the quantity of calcium in various foods that is rendered unavailable by oxalic acid, phytate, fiber, or other constituents and subtract this unavailable calcium from the amount of available calcium that the food would be expected to supply (which is usually only about half of the reported calcium content of food)." The comment suggested that FDA should not allow health claims on a given food if, after adjustment for oxalate and other constituents, the estimated quantity of "available" calcium is markedly lower than ordinarily expected, given the food reported calcium content. Similarly, another comment proposed the use of the indirect method of calciuric response to a calcium load as a convenient and reliable method of testing calcium absorbability and also proposed a test based on radiocalcium absorption.

FDA acknowledges these useful suggestions but notes that none of the proposed methods assesses calcium utilization. As discussed in the proposal, calcium bioavailability means both absorption and tissue utilization of calcium (56 FR at 60699). Appropriate tests for bioavailability need to include a measurement of the utilization of calcium by bone (calcium retention). A product that contains components that increase the urinary or fecal excretion of calcium or somehow impair the utilization of calcium by bone will not qualify for a calcium-osteoporosis claim. Monitoring only factors that alter absorption, such as the phytate content of a food, as suggested in the comment, would not allow estimation of the effects of factors that promote obligatory calcium loss such as increased urinary loss due to a high sulfate content. Both increased excretion and impaired utilization cause the decreased deposition of calcium in bone.

7. Some comments requested that FDA clarify an acceptable level of "assimilability," such as an acceptable percent bioavailability. The comments asserted that it would be unrealistic to require bioavailability data on all foods bearing a calcium claim, but that such a requirement might be a logical prerequisite for new sources of calcium used to fortify foods. A number of comments suggested that food and supplement manufacturers should bear the burden of proof of the bioavailability of calcium-fortified products and supplements in order to avoid indiscriminate fortification and marketing of poorly bioavailable supplements.

FDA reiterates that a product bearing a calcium-osteoporosis health claim must contain calcium that can be assimilated by the body. As noted in the proposal, it would be misleading to put a health claim for a substance on a food if consumption of that food will not provide the substance (56 FR at 60699). Such a food would be misbranded under section 403 (a) of the act (21 U.S.C. 343(a)). Given that most currently marketed products that are likely to bear a calcium-osteoporosis claim contain bioavailable calcium, FDA does not consider it necessary at this time to set a minimum acceptable level of bioavailability. If a food bearing a calcium osteoporosis claim does not contain calcium in a bioavailable form, the Government can take enforcement under the act against the product or its manufacturer. Calcium sources whose bioavailability has not been demonstrated would be at risk for such enforcement action.

There are sufficient scientific data in published literature to support the bioavailability of many sources of calcium in current use. However, instances may develop in which the bioavailability of the calcium source has not been shown, including the use of new fortificants or food products in which the combination of the component nutrients raises concerns about the assimilability of calcium from the product (e.g., a new bread rich in a novel high phytate fiber source and fortified with calcium).

As discussed in the previous comment, there are various ways of testing for bioavailability. FDA considers human or growing animal models to provide the most accurate assessments. One approach would involve collection of human data from calcium balance studies using stable isotopes or radioisotopes as evidence of reasonable or adequate bioavailability (assimilability), as well as evidence from well-controlled calcium supplementation or dietary intervention studies that measure calcium absorption and bone mass or density change over time. An appropriate standard reference would be calcium carbonate or milk.

FDA recognizes that establishing calcium retention in humans is a difficult and costly procedure. Another approach would use a growing animal model (rat) to demonstrate calcium retention in bone. Use of the growing rat model offers ease of bone mass or mineral content assessment, and, unlike human subjects, rats show limited between-subject variation in calcium absorption. There are a number of suitable studies in the literature that could serve as models and the basis for a study design (e.g., Refs. 139 through 141). The common end-measures shared by these animal studies include measures of apparent calcium absorption and determination of calcium content of bone, either directly by bone ashing and mineral analyses (Refs. 139 and 140) or indirectly by densitometric or histomorphometric methods (Ref. 141).

8. A number of comments proposed that superiority claims regarding the bioavailability or absorbability of calcium in a food or supplement compared to a reference food or supplement be permitted. One comment proposed milk as an ideal reference food against which to make the proposed comparisons and suggested the use of human bioavailability tests to provide evidence in support of superiority claims. Several comments suggested that a statistically significant difference in calcium absorption between two products using the proposed techniques should provide the basis for a superior absorbability comparative claim.

FDA advises that it is not appropriate to permit requested superiority claims under the provisions of the 1990 amendments that govern health claims. To the extent that the 1990 amendments provide for comparative claims, it is only with respect to claims that charaterize the level of a nutrient (section 403 (r)(1)(A) of the act). Regulations governing nutrient content claims, published elsewhere in this issue of the **Federal Register**, do not provide for superiority claims based on bioavailability. However, under § 10.30, an interested party can petition the agency to provide for superiority claims based on bioavailability. In considering such a petition, the agency would be concerned about ensuring that superiority claims are valid and nutritionally meaningful.

F. Disintegration and Dissolution of Calcium Supplements

9. The majority of comments concerned with the proposed requirement that calcium supplements meet the U.S. Pharmacopeia (U.S.P.) standards for disintegration and dissolution of calcium supplements (in proposed § 101.72(c)(4)) fully supported this aspect of the proposed regulation. The LSRO report strongly supported the proposed requirement noting that while the chemical form or solubility of the supplement makes little difference, the physical form of the salt and formulation of the tablet are critical. The comment stressed that "tablets so poorly formulated that they fail to disintegrate

under simulated gastric conditions appear to be widely distributed in the U.S. market." A public health advocacy group further suggested that since the U.S.P. is currently updating its standards for dietary supplements, the revised standards may include additional measures that FDA should adopt in the future. Two comments opposed this requirement. One argued that "the United States Pharmacopeia standards are not appropriately complete enough to be an exclusive condition for a product's health claim eligibility." The comment asserted that the U.S.P.'s are in vitro standards (meaning conducted in a test tube) and might not reflect human bioavailability of an individual calcium supplement, and they should therefore only establish a disqualifying presumption that would be rebuttable by the submission of human data supporting the product's bioavailability. Another comment emphasized the lack of justification for this testing, the inability to conduct all the tests since some of the calcium salts identified as safe for use as calcium supplements are not subject to U.S.P. dissolution requirements (calcium sulfate, and calcium oxide), the lack of fairness in that foods are not held to these criteria, the inappropriate application of drug standards set forth in the U.S.P. monographs to supplements, the "questionable expertise" of the U.S.P. convention members to judge nutritional property of compounds, and finally the lack of basis to require these standards in order to qualify for a health claim.

FDA has carefully considered these comments and agrees with several points. FDA agrees that disintegration and dissolution testing methods used to screen calcium supplements for bioavailability are imperfect, because these in vitro tests do not adequately mimic the physiologic environment of the human stomach, and U.S.P. standards are not available for all calcium-containing compounds. However, the agency considers the U.S.P. standards to provide sufficient assurance of dissolution and disintegration for those products where U.S.P. standards exist. A supplement that does not dissolve and disintegrate clearly does not provide calcium in an assimilable form and thus, a claim for such a supplement would be misleading because the supplement would not provide the nutrient that is the subject of the claim. Calcium supplements not in conventional food form can be formulated in a manner that prevents rapid dissociation and disintegration in the stomach, preventing assimilation. This unique aspect justifies the requirement in § 101.72(c)(2)(ii)(C) for supplements.

However, when U.S.P. standards do not exist, the agency recognizes, as pointed out by one comment, the need for an alternative method of establishing the bioavailability of supplements under the conditions of use stated on the product label. Demonstration of acceptable bioavailability in human or animal studies when conducted under the conditions of use stated on the product label (i.e, fed as an intact tablet, not crushed) would fulfill the requirement. Section 101.72(c)(2)(ii)(C) has been revised to require that dietary supplements meet the U.S.P. standards for disintegration and dissolution, except that dietary supplements for which no applicable U.S.P. standards exist shall exhibit appropriate assimilability under conditions of use stated on the product label. In order for a dietary supplement to bear the authorized calcium osteoporosis health claim, it must comply with all provisions of this final regulation.

G. Phosphorus Content

For reasons explained fully in the preamble of the proposal (56 FR 60689 at 60699 to 60700), FDA proposed that high levels of phosphorus (naturally occurring or added) in conventional foods or supplements that result in calcium to phosphorus ratios lower than 1:1 will disqualify the product from bearing a calcium/ osteoporosis health claim. FDA's tentative decision to place a limit on the amount of phosphorus that a food could have to be eligible to bear a claim was based on the ubiquitous distribution of this mineral in the food supply, the low ratio of calcium to phosphorus that typifies current intake patterns, and current evidence demonstrating that high levels of dietary phosphorus coupled with low dietary calcium adversely influence hormonal factors that regulate calcium and bone metabolism (Refs. 17, 21, 29, 32, 46, 93, 114, and 116). Many of the comments addressing this issue strongly supported the proposed phosphorus provision because of the reasons given by FDA in the proposal.

10. One comment questioned the need for any requirement that the phosphorus content not exceed the calcium content, asserting that "any reasonable fortified or enriched product will meet this condition."

The agency believes that it is incorrect to assume that all enriched, fortified, or modified products will contain more calcium than phosphorus, or even that products traditionally known to be rich sources of calcium will have lower levels of phosphorus than calcium. For example, a recent article (Ref. 142) on the reduction of fat in a newly developed processed cheese showed how processing techniques used to lower fat resulted in a calcium to phosphorus ratio lower than one to one. Some products naturally rich in phosphorus cannot meet this condition even after calcium fortification, and some products that are traditionally recognized as calcium rich foods, such as puddings, are now available in convenient instant versions in which the added phosphorus content far exceeds the calcium content. Therefore, FDA concludes that this comment does not provide a basis not to adopt a level of phosphorus that, if found in a food, would render the calcium osteoporosis claim misleading.

11. Several comments were in strong opposition to the requirement that a product not contain more phosphorus than calcium on a per weight basis. One comment contended that FDA relied on erroneous information relative to the consumption levels of dietary phosphorus supplied by food additives. The comment included data indicating little change in the estimated daily consumption of phosphorus from food additives from 1980 to 1990, based on the International Food Additives Council's estimated disappearance of food grade phosphorus in the United States. According to these data, the average per capita phosphorus consumption from food additives increased from 9.5 to more than 11 percent of the acceptable daily intake of phosphorus from 1980 to 1990.

FDA's statement in the proposal that phosphorus intake may be understated by as much as 15 to 20 percent due to phosphorus supplied by numerous additives was apparently misinterpreted by these comments. The agency did not intend to imply that phosphorus-containing food additive consumption had increased 15 to 20 percent. Rather, the agency was relying on the finding of Oenning et al. (Ref. 106), who demonstrated that nutrient estimates calculated from food intake records using current nutrient composition data bases underestimated phosphorus intake when compared to direct chemical analysis of the food from the dietary record. The underestimation of phosphorus content demonstrated in this study apparently was due to errors in the nutrient data bases, which have not kept abreast of changes in manufacturing techniques and in the use of phosphorus-containing food additives. FDA made this point to emphasize that currently in the United States, total phosphorus intake greatly

exceeds that of calcium, and that the levels may be even higher than surveys suggest because of flaws in the nutrient composition data bases used in these surveys.

The agency disagrees with the comment and interprets data presented by the comment as evidence of an important increase in phosphate food additive use over the last decade. These data indicate that estimated per capita daily consumption of phosphorus from food additives reported by the International Food Additive Council for 1990 was 470 milligrams (mg) phosphorus per day per capita as compared to an estimated 400 mg of phosphorus per day per capita for 1980, or approximately a 17 percent increase in per capita use over the last decade. Thus, more than one line of evidence points to the fact that the consumption of phosphorus-containing additives is on the rise and contributes to the high phosphorus intake observed in the United States population.

12. Another comment strongly opposed the proposed limit on phosphorus content for a number of reasons. The comment asserted that any health claim disqualifier must meet the same conditions as the claim itself, such as unanimous agreement among experts, and that no studies to date have demonstrated an adverse effect of excess phosphorus on bone in man or in monkeys or in calcium balance studies. This comment also asserted that there is a controversy over the effect of high phosphorus on calcium absorption and pointed to the fact that no single food contributes to the high phosphorus intake and to the remote possibility that reduction of phosphorus intake from one food will reduce total phosphorus intake.

The agency does not agree that any of these points warrants modification of the limit on phosphorus content in § 101.72(c)(2)(ii)(D). The limit on phosphorus is not a "disqualifying level" as that term is defined based on section 403(r)(3)(A)(ii) of the act. FDA is not limiting the phosphorus content because of its effect on the risk of a diet-related disease or health-related condition. FDA may have contributed to confusion in this regard by stating in the proposal that the level of phosphorus would disqualify a product from bearing a claim (56 FR at 60699). FDA is limiting the amount of phosphorus under the authority of section 403(a) of the act. As explained above, high levels of phosphorus when calcium intakes is low, would impair the utilization of calcium by bone. Thus, the presence of a calcium/osteoporosis claim on a food that does not have an appropriate calcium-phosphorus ratio would be misleading, because it would not be possible to get the full benefits of calcium from such a food.

In response to the criticism that no studies have demonstrated direct adverse effects of excess phosphorus on bone in humans or primate models, the agency points out that evidence in humans demonstrates that high levels of dietary phosphorus coupled with low dietary calcium intake adversely influence hormonal factors that regulate calcium and bone metabolism (Refs. 17, 21, 29, 32, 46, 93, 114, and 116). These changes were consistent with those observed in a variety of animal models where the hormonal changes were shown to induce bone resorption and ultimately bone loss (Ref. 46). The agency is particularly concerned about teens and young adults who typically consume more phosphorus than calcium (Ref. 105) and for whom such diets have recently been shown to produce changes in serum calcium and bone-regulating hormones that may adversely affect attainment of peak bone mass (Ref. 32). The health claim is an effective means of alerting this vulnerable population to foods that have the desired ratio of these two nutrients. Therefore the agency does not agree with the comment's suggestion that the limit on phosphorus content be dropped.

The agency does not disagree with the other assertions made in this comment. These points are minor and, given that health claims are authorized in the context of the total daily diet, not particularly relevant. The agency did not assert that excess phosphorus impaired calcium absorption and has maintained that phosphorus is ubiquitously distributed in the food supply. Given the effects of phosphorus on hormonal factors that regulate calcium and bone metabolism, FDA concludes that the limit on phosphorus content for a food that bears a calcium/osteoporosis claim is appropriate.

H. No Quantification of Reduction in Risk

13. One comment urged FDA to avoid any possible misinterpretation and potential abuse of the calcium/osteoporosis regulation by specifying in the regulation that "the claim shall not convey the misconception that dietary calcium intake can cure osteoporosis." The comment included examples of labels of dietary supplements found in health food stores.

The agency agrees with the comment's concern but remains confident that the claims being authorized will not mislead consumers into believing that calcium cures osteoporosis. This regulation authorizes a health claim that relates calcium intake to a reduction in the risk of osteoporosis. A statement that calciun cures osteoporosis would constitute a drug claim under section 201(g)(1)(B) of the act (21 U.S.C. 321(g)(1)(B)), and a product bearing such a claim would be subject to regulation as a drug. In addition, § 101.72(c)(2)(i)(D) bars health claims on calcium and osteoporosis from attributing any degree of reduction in risk of osteoporosis to maintaining an adequate calcium intake throughout life.

I. Limitations of Benefit to Bone Health

14. Several comments opposed the upper-limit-of-benefit statement proposed in § 101.72(d)(5), saying that this statement was an effort to limit the potency of supplements. A number of comments supported the statement but required that it be qualified. One comment requested that the statement only be placed on products in which the calcium level is greater than 50 percent of the originally proposed RDI of 900 mg or 450 mg of calcium (presumably per serving or per recommended daily dose). This comment reasoned that for products with lower levels of calcium, an unreasonable number of servings of food would need to be consumed to exceed 200 percent of the RDI, and thus the statement was not necessary.

FDA does not agree with the assertion that it is seeking to limit the potency of supplements. This regulation relates only to the type of health claim that a product may bear. It ensures that a material fact about the consequences of consumption of more than a specified level of calcium is presented as part of the claim. FDA agrees in principle with the suggested change in proposed § 101.72(d)(5) and believes that this modification may help curb overfortification. The agency has therefore added the following language to the proposed provision redesignated as § 101.72(c)(2)(i)(E)): "This requirement does not apply to foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day or 400 mg of calcium per reference amount customarily consumed or per total daily recommended supplement intake."

J. Safety

15. A public health advocacy association suggested that FDA require labels on high dose calcium supplements to disclose that high calcium intakes may increase the risk of kidney stones in susceptible people. The comment argued that levels greater than 1,000 to 2,500 mg calcium per day

may pose a risk to people with a history of kidney stones, and that, therefore, labels on supplements that contain 500 mg or more of calcium should inform consumers of this risk.

The agency does not agree that a warning is needed in addition to the statement on total dietary intakes greater than 200 percent of the RDI. Section § 101.72(c)(2)(i)(B) requires that the health claim identify the populations at greatest risk of osteoporosis, namely caucasian and Asian women in their bone forming years. Kidney stones are more prevalent in men than women. (With respect to calcium oxalate or mixed calcium stones, affected males outnumber affected females by three or four to one in the U.S. population (Ref. 143).) Thus, while men are at greater risk of the adverse affects of excess calcium intake due to their greater susceptibility to kidney stone formation, they are not at greater risk for osteoporosis and will not be targeted by the calcium-osteoporosis health claim. Consequently, there is no reason to expect that men will increase their consumption of calcium in response to the claim. Therefore, FDA concludes that the regulations offer sufficient protection without the proposed warning.

K. Consumer Summary

16. The comments specific to the proposed consumer summary were generally supportive, and some considered consumer summaries necessary to put any health claim into perspective as related to total diet. The use of the consumer summary on package inserts was suggested by several groups. Several comments suggested various ways to shorten the summary, while others suggested additional information to incorporate. One comment strongly opposed the consumer summary, stating that in light of the detailed, balanced information provided in the model claims, summaries are redundant, costly, and inconvenient to the manufacturer.

As discussed in the final rule on general requirements for health claims, consumer summaries are not required, although their use remains an option. For this reason, FDA has not included the proposed consumer summary on calcium and osteoporosis in this final rule.

L. Regulatory History of Calcium-containing Food Additive Use

The agency advised that, in order for calcium-containing food ingredients in conventional foods or calcium supplement products to be considered eligible to bear the authorized calcium/ osteoporosis health claim, they must meet the requirements in § 101.14, which include that they have been shown to FDA's satisfaction to be safe and lawful under the applicable safety provisions of the act (56 FR at 60699). Safety and lawfulness can be demonstrated in a number of ways, including through a showing that a food is generally recognized as safe (GRAS), affirmed as GRAS by FDA, listed in the food additive regulations, or subject to a prior sanction. Of the 36 or more calcium-containing ingredients identified by the agency as currently in use (Ref. 33), FDA advised that only the following 10 compounds had been demonstrated to be safe and lawful for use in a dietary supplement or as a nutrient supplement: calcium carbonate, calcium citrate, calcium glycerophosphate, calcium oxide, calcium pantothenate, calcium phosphate, calcium pyrophosphate, calcium chloride, calcium lactate, and calcium sulfate (56 FR at 60691).

17. One comment pointed out that the agency failed to include calcium ascorbate in this list of 10 compounds. The comment included also submitted an April 1989 letter from FDA stating the agency's lack of objection to the use of calcium ascorbate in dietary supplements. Another comment sought the addition of calcium hydroxide to the list of 10 calcium compounds discussed above, contending that "since calcium oxide is permitted and calcium hydroxide is simply the hydrate of the oxide formed on contact with water," calcium hydroxide should be included in the list.

As stated above, only 10 compounds have been demonstrated to FDA's satisfaction to be safe and lawful for use in a dietary supplement or as a nutrient supplement bearing a calcium/ osteoporosis health claim. In Ref. 33 of the proposal, the agency identified the calcium-containing ingredients currently in use, their functions, conditions of use, and limits on the levels at which they can be added to food. Only those ingredients with stated use as a nutrient supplement or in a dietary supplement are considered eligible for a health claim. Calcium ascorbate appears only under 21 CFR 182.3189 (Ref. 33) for use as a chemical preservative. Thus, FDA's failure to list it was not inadvertent. Calcium ascorbate is not eligible at this time for consideration for a health claim; however, a petition may be filed requesting a safety review for a new use of calcium ascorbate. Based on the outcome of this petition and review, calcium ascorbate may be considered eligible for a calcium/ osteoporosis health claim.

The agency declines to add calcium hydroxide to the list of 10 calcium-containing compounds that have been demonstrated to be safe and lawful for use in a dietary or nutrient supplement. In the list, FDA identified those ingredients with stated uses as a nutrient or dietary supplement, thus avoiding the use of potentially poorly suited or potentially harmful compounds. FDA's failure to include calcium hydroxide on the list does not imply that the agency considers the use of this substance to be unsafe for use as a calcium supplement, but rather reflects that it has not been demonstrated safe and lawful for this use. Manufacturers who would like to be abel to make a calcium/ osteoporosis health claim based on the presence of calcium hydroxide in their product should submit an appropriate petition to FDA.

M. Food Fortification

18. A public health and nutrition association expressed concern that manufacturers seeking a calcium/ osteoporosis health claim will fortify products of low nutritional value that do not naturally contain calcium. The comment recommended that FDA consider setting standards for the amount of fortification that is allowed and also suggested that FDA determine which products can be fortified.

Although the agency understands the concern expressed in the comment, the full implementation of these suggestions is beyond the scope of this rulemaking. The agency advises that fortification of foods to qualify for a health claim must comply with the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register.**

N. Nutrition Claims

19. One comment argued that claims relating to a nutrient's effect on the structure or function of the body are not health claims but nutrition claims. The comment suggested amending the proposed regulations to clarify the distinction between nutrition and health claims. In the event that FDA's rejected this proposal, the comment asked that the agency acknowledge that the relationship between calcium and bone health is a nutrition claim that is substantiated in the proposed calcium/ osteoporosis health claim regulation.

FDA rejects these suggestions. The distinction between nutritional guidance and health claims is discussed in the final rule on general requirements for health claims. The claim authorized

...nder this regulation re..ating calcium and osteoporosis is a health claim because it characterizes the relationship of a nutrient (calcium) to a disease or health-related condition (osteoporosis). A claim relating calcium to bone health would have to be evaluated on its own merits. Such a claim might be considered an implied health claim, rather than merely a statement about a food's effect on the structure or function of the body, and, if so, it would be subject to regulation under section 403(r) of the act.

O. Model Claim

20. Many comments discussed the length of the model health claim and its required components. Common to all comments was the complaint that the model message was too wordy. Comments were almost equally split between those supporting and those opposing the proposed model message. Supporting comments praised specific aspects of the model claim such as disclosure of other risk factors; the likely upper limit of beneficial calcium intakes; reflection of other factors that contribute to osteoporosis risk such as age, race, and sex; inclusion of the need for exercise; and disclosure of the mechanisms through which calcium may reduce the risk of osteoporosis. Opposing comments emphasized the burdensome length of the model claim. One comment stated that the length of the claim would not allow it to be translated into multiple languages on the label. Many comments requested that FDA remove the requirements that populations at special risk of osteoporosis and nondietary factors that can help prevent osteoporosis be identified. Several comments suggested that the length of the claim will limit its effectiveness and curtail manufacturers' incentives to make claims. An association of national advertisers asserted that no diet and disease relationship can be explained completely in one paragraph.

The agency agrees that the proposed model health claim was too long. However, as discussed in the proposal and elsewhere in this final rule, certain information is needed in the health claim in order for it to be truthful and not misleading to segments of the population that are not at high risk of developing osteoporosis or for whom no link between calcium and osteoporosis has been established. FDA notes that the proposed model claim contained optional as well as required information, and the example has been rewritten to demonstrate that all required information can be included in a model claim of less than 35 words: "Regular exercise and eating a healthful diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life." Foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day (400 mg calcium) per reference amount customarily consumed or per total daily recommended supplement intake may bear this claim. Other foods that contain higher levels of calcium must also carry an additional statement (see § 101.72(c)(2)(i)(E)).

Throughout FDA's responses to the comments in this preamble, the agency has presented various reasons that strongly support maintaining the requirements that make the claim lengthy. These points include the need not to mislead the public in thinking everyone is at risk for this disease, the need to identify those at greatest risk and thus to help individuals who are not at risk but who are susceptible to the adverse effects of oversupplementation with calcium avoid any problems, and the need to target the age group for which adequate calcium intake may have the greatest benefit for bone health and delayed risk of osteoporotic fracture.

P. Other Issues

21. One comment contended that FDA should permit health claims on OTC antacid products containing only calcium carbonate. Responding to a discussion on dual labeling in the proposal on general requirements for health claims (56 FR 60537), the comment asserted that FDA's objection to OTC drugs bearing health claims is not appropriate in the case of calcium-based antacids, because such products have been labeled for years with both food and drug labeling.

FDA has addressed the issues raised by this comment in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

22. Another comment urged that the regulation require disclosure about the relationship between calcium and protein and suggested disqualifying high protein products based on the effect of dietary protein on the urinary loss of calcium, which affects bone health.

As mentioned in the preamble of the proposal (56 FR at 60699), the agency recognizes that high levels of dietary protein typically found in the American diet have been shown to increase the obligatory loss of calcium, i.e., the amount of calcium that the body must lose daily. The agency, however, did not propose to disqualify high-protein products from bearing a calcium/osteoporosis claim or to disclose the effect of high protein intake on calcium retention on the label. Like calcium, protein is not ubiquitously distributed in our food supply and is richest in specific food sources (Refs. 27 and 110). Relatively few foods are sources of calcium and protein, forcing consumers to be selective to meet the nutritional needs for both calcium and protein. Some protein rich foods, such as lowfat milk or lowfat milk products, contribute more than half the calcium and protein intake of some individuals, notably children. It would be misleading to the public not to allow an important food such as lowfat milk to have a calcium/osteoporosis claim due to its high levels of protein. To disqualify a product that is both rich in calcium and protein, and that would not be disqualified because of its fat, saturated fat, cholesterol, or sodium levels, because of its protein content, would effectively prevent several major food sources of calcium from bearing a claim.

Several other considerations reinforce the agency's position that protein content should not be a basis for disqualification from bearing a calcium/osteoporosis claim or for a disclosure statement. The scientific evidence demonstrating a persistent increase in the urinary loss of calcium when high protein intakes are sustained for months is weak and controversial. In addition, different protein sources have been shown to elicit varying degrees of calciuria (increased loss of calcium in urine), thus making it incorrect for the agency to consider all dietary protein sources equally potent in their calciuric effect. Moreover, no clear evidence exists demonstrating that high protein intake alters any of the hormones that control bone formation and resorption, or that high protein intake impairs bone mineralization.

FDA is making several minor changes in the regulation to improve its readibility and to make it consistent with other regulations that FDA is adopting that authorize health claims. The most significant of these changes is the fact that FDA is adding to the paragraph on optional information a provision that will allow the declaration as part of the claim of the number of people who are affected by osteoporous (§ 101.72(d)(2)). This change makes § 101.72 consistent with the other regulations in Subpart E. Therefore, FDA is rejecting the comment's suggestion to require a statement about the relationship between calcium and protein or to establish a level of protein

that would disqualify a product from bearing a calcium/osteoporosis claim. The agency concludes that a product high in protein can still be an important source of calcium and that it cannot conclude that a claim would be misleading if it fails to reveal the relationship between calcium and protein.

III. Review of Scientific Evidence

FDA updated its review of the scientific literature by examining articles published since the proposed rule was issued. FDA's evaluation of recent human studies meeting the criteria outlined in the proposal (56 FR at 60693) is presented in Table 1 (Refs. 144 through 150). In addition, FDA also considered several review articles that were published since the proposal (Refs. 151 through 156). FDA sought to answer the same questions posed in the proposed rule.

First, do any of the recent studies present evidence documenting the role of calcium in achieving peak bone mass? A cross-sectional study examining spinal bone density in Caucasian girls 8 to 18 years of age demonstrated that calcium intake may be a major factor in achieving peak adult bone density (Ref. 148). Chan et al. (Ref. 145) also demonstrated higher bone mineral content in Caucasian boys and girls consuming greater than 1,000 mg of calcium per day. In this study 70 percent of the subjects younger than 11 years consumed at least their RDA of 800 mg of calcium per day, while 63 percent of the subjects older than 11 consumed less than their RDA of 1,200 mg per day. After adjustment for phosphorus and protein intake, multivariate analyses showed only calcium intake was related to bone mineral status of the children in this study. Thus, the most recent data, although not definitive, continue to strongly support the link between adequate calcium intake and optimal peak bone mass.

The second question asked in reviewing these studies is whether added calcium or high calcium intake reduces the risk of fracture or slows the rate of bone loss in younger or older subjects. Andon et al. (Ref. 144) showed, in a cross-sectional study, that Caucasian postmenopausal women consuming less than 600 mg calcium per day had significantly lower spinal bone mineral densities than women with higher calcium intakes. Because individuals who malabsorb lactose normally avoid dairy products, Wheadon et al. (Ref. 150) assessed lactose absorption and dietary calcium intake in elderly women with and without hip fractures and in young women. While 60 percent of the women with hip fractures were lactose malabsorbers, dietary calcium intakes did not differ significantly among the three groups. However, the authors cautioned against putting too much weight on the findings of the small study (n=31) since the aversion to milk and milk products ascribed to lactose intolerance may be shown to decrease calcium intake in a larger population.

As discussed in the earlier literature review, the responsiveness of postmenopausal women to calcium supplementation depends largely on their menopausal age. Calcium supplementation had no effect on spinal bone density early in menopause, but for women late in menopause, the rate of bone loss could be significantly reduced with calcium supplementation, if initial habitual calcium intakes were low (Refs. 47 and 151). Three recent prospective intervention studies (Refs. 146, 147, and 149) shed further light on this observation. Elders et al. (Ref 146) reported a high rate of lumbar vertebral bone loss in late and early postmenopausal subjects, with the highest loss occurring in early postmenopause. However, no significant interaction was observed between menopausal status of the subjects and the effect of calcium supplementation. These authors reported a significant decrease in lumbar bone loss after 2 years for women treated daily with 1,000 mg and 2,000 mg of elemental calcium relative to controls. The effect of calcium supplementation was significant after the first year of supplementation but not after the second year. The authors speculate that calcium supplementation probably reduced bone turnover.

In a double-blind, placebo controlled trial in Caucasian, postmenopausal women, with low initial forearm bone density, Prince et al. (Ref. 147) showed significantly less bone loss in the distal forearm in those women treated with calcium and regular exercise, while a group treated with estrogen and regular exercise gained significant bone density at this site relative to the control group with normal initial bone density and the group treated with exercise alone. Thus, calcium supplementation and exercise slowed bone loss relative to exercise alone but less effectively than exercise combined with estrogen.

In the third prospective study, this one a 3-year study in 622 Caucasian women, Tilyard and co-workers measured rate of vertebral fractures in women treated twice a day with either 0.25 micrograms of calcitriol (a synthetic form of the active metabolite of vitamin D) or 1 gram of elemental calcium (Ref. 149). After 2 and 3 years, a significant reduction in the rate of vertebral fracture was observed in calcitriol-treated women relative to those treated with calcium alone. This study clearly demonstrates that supplementation of calcium intake alone is not adequate to prevent vertebral fracture in postmenopausal women. In the absence of placebo-treated controls, the contribution of calcium supplementation to the reduction in vertebral fracture cannot be estimated. The results of these three prospective clinical trials support the hypothesis that adequate calcium intake helps to slow the rate of bone loss in postmenopausal women, but that calcium alone cannot effectively arrest this process, especially in early postmenopause.

The third question considered in evaluating the recent literature was whether any of the studies showed a threshold effect for the level of calcium intake associated with changes in bone mass. None of the findings from the recent studies were pertinent to this question.

To summarize, these new findings were consistent with and strengthened the conclusion that adequate calcium intake has a significant impact on bone health and risk of osteoporotic fracture.

IV. Decision to Authorize a Health Claim Relating Adequate Calcium Intake to Osteoporosis

The agency has reviewed recently published research articles and review articles relevant to calcium intake and osteoporosis (Refs. 144 through 156) and has concluded that the new studies are consistent with the tentative conclusions drawn in its proposed rule on calcium and osteoporosis (56 FR 60689) . The agency also considered all comments received in response to the proposal. The overwhelming concurrence among the experts in this area and the totality of publicly available evidence supports an association between adequate calcium intake and risk of osteoporosis. Based on the totality of the publicly available scientific evidence, FDA has determined that there is significant scientific agreement among qualified experts that a health claim for calcium and osteoporosis is supported by the evidence. Under § 101.72, an authorized health claim will convey the message that an adequate intake of calcium throughout life may delay the development of osteoporosis and ultimately reduce the risk of bone fracture in some individuals later in life.

V. Environmental Impact

The agency has determined that under 21 CFR 25.24(a)(11) this action is of a type that does not individually or cumulatively have significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.72 is added to subpart E to read as follows:

§ 101.72 Health claims: calcium and osteoporosis.

(a) *Relationship between calcium and osteoporosis.* An inadequate calcium intake contributes to low peak bone mass and has been identified as one of many risk factors in the development of osteoporosis. Peak bone mass is the total quantity of bone present at maturity, and experts believe that it has the greatest bearing on whether a person will be at risk of developing osteoporosis and related bone fractures later in life. Another factor that influences total bone mass and susceptibility to osteoporosis is the rate of bone loss after skeletal maturity. An adequate intake of calcium is thought to exert a positive effect during adolescence and early adulthood in optimizing the amount of bone that is

laid down. However, the upper limit of peak bone mass is genetically determined. The mechanism through which an adequate calcium intake and optimal peak bone mass reduce the risk of osteoporosis is thought to be as follows. All persons lose bone with age. Hence, those with higher bone mass at maturity take longer to reach the critically reduced mass at which bones can fracture easily. The rate of bone loss after skeletal maturity also influences the amount of bone present at old age and can influence an individual's risk of developing osteoporosis. Maintenance of an adequate intake of calcium later in life is thought to be important in reducing the rate of bone loss particularly in the elderly and in women during the first decade following menopause.

(b) *Significance of calcium.* Calcium intake is not the only recognized risk factor in the development of osteoporosis, a multifactorial bone disease. Other factors including a person's sex, race, hormonal status, family history, body stature, level of exercise, general diet, and specific life style choices such as smoking and excess alcohol consumption affect the risk of osteoporosis.

(1) Heredity and being female are two key factors identifying those individuals at risk for the development of osteoporosis. Hereditary risk factors include race: Notably, Caucasians and Asians are characterized by low peak bone mass at maturity. Caucasian women, particularly those of northern European ancestry, experience the highest incidence of osteoporosis-related bone fracture. American women of African heritage are characterized by the highest peak bone mass and lowest incidence of osteoporotic fracture, despite the fact that they have low calcium intake.

(2) Maintenance of an adequate intake of calcium throughout life is particularly important for a subpopulation of individuals at greatest risk of developing osteoporosis and for whom adequate dietary calcium intake may have the most important beneficial effects on bone health. This target subpopulation includes adolescent and young adult Caucasian and Asian American women.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating calcium with a reduced risk of osteoporosis may be made on the label or labeling of a food describe in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim makes clear that adequate calcium intake throughout life is not the only recognized risk factor in this multifactorial bone disease by listing specific factors, including sex, race, and age that place persons at risk of developing osteoporosis and stating that an adequate level of exercise and a healthful diet are also needed;

(B) The claim does not state or imply that the risk of osteoporosis is equally applicable to the general United States population. The claim shall identify the populations at particular risk for the development of osteoporosis. These populations include white (or the term "Caucasian") women and Asian women in their bone forming years (approximately 11 to 35 years of age or the phrase "during teen or early adult years" may be used). The claim may also identify menopausal (or the term "middle-aged") women, persons with a family history of the disease, and elderly (or "older") men and women as being at risk;

(C) The claim states that adequate calcium intake throughout life is linked to reduced risk of osteoporosis through the mechanism of optimizing peak bone mass during adolescence and early adulthood. The phrase "build and maintain good bone health" may be used to convey the concept of optimizing peak bone mass. When reference is made to persons with a family history of the disease, menopausal women, and elderly men and women, the claim may also state that adequate calcium intake is linked to reduced risk of osteoporosis through the mechanism of slowing the rate of bone loss;

(D) The claim does not attribute any degree of reduction in risk of osteoporosis to maintaining an adequate calcium intake throughout life; and

(E) The claim states that a total dietary intake greater than 200 percent of the recommended daily intake (2,000 milligrams (mg) of calcium) has no further known benefit to bone health. This requirement does not apply to foods that contain less than 40 percent of the recommended daily intake of 1,000 mg of calcium per day or 400 mg of calcium per reference amount customarily consumed as defined in § 101.12 (b) or per total daily recommended supplement intake.

(ii) *Nature of the food.* (A) The food shall meet or exceed the requirements for a "high" level of calcium as defined in § 101.54(c);

(B) The calcium content of the product shall be assimilable;

(C) Dietary supplements meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution applicable to their component calcium salts, except that dietary supplements for which no U.S.P. standards exist shall exhibit appropriate assimilability under the conditions of use stated on the product label;

(D) A food or total daily recommended supplement intake shall not contain more phosphorus than calcium on a weight per weight basis.

(d) *Optional information.* (1) The claim may include information from paragraphs (a) and (b) of this section.

(2) The claim may include information on the number of people in the United States who have osteoporosis. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Dietary Guidelines for Americans."

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between calcium and osteoporosis:

Model Health Claim Appropriate for Most Conventional Foods:

Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life.

Model Health Claim Appropriate for Foods Exceptionally High in Calcium and Most Calcium Supplements:

Regular exercise and a healthy diet with enough calcium helps teen and young adult white and Asian women maintain good bone health and may reduce their high risk of osteoporosis later in life. Adequate calcium intake is important, but daily intakes above about 2,000 mg are not likely to provide any additional benefit.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

Calcium and Osteoporosis: Effects of Calcium on Bone Status

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Andon, M., et al. (1991) (Ref. 144)	Cross-sectional measured: vertebral bone density (L2-L4) by dual photon absorption	131 women, Caucasian aged 53 to 92 years mean age: 64.7 years mean year post menopause: 10.1 years	N/A	Habitual diet	Dietary calcium intake estimated from food frequency questionnaire		Controlled for other factors including body weight, estrogen and alcohol use	Multiple regression analyses used to estimate effect of calcium intake on spinal bone density. Subjects grouped according calcium intake of < or >606 mg Ca/day	Significant correlation of body weight and dietary calcium with vertebral bone mineral density. Women consuming < 606 mg Ca per day had significant lower bone mineral density than those consuming > 606 mg/day	Study weakened by use of food frequency questionnaire not a reliable method of accurately estimating calcium intake
Chan, G. (1991) (Ref. 145)	Cross-sectional measured: bone mineral density of the distal third radius of nondominant side using single photon absorption and calcium intake Serum parameters also measured	166 healthy Caucasian children 90 boys 76 girls	N/A	Habitual Diet		Habitual Nutrient intake was estimated from two 2-day dietary histories		Correlation of age weight and height was significant to bone mineral content in all 166 children	70% of subjects < 11 years consumed at least 800 mg/day 63% of subjects > 11 consumed less than their Recommended Dietary Allowance of 1200 mg Ca/day mean intake =750 mg/girl While 53% of boys > 11 years consumed at least 1 200 mg/day Multivariate analyses showed only calcium intake related to children s bone mineral status (partial correlation coefficients 0 18 P<0 05)	Employed a weak method of determining calcium intake Children consuming > 1,000 mg of Ca/day had higher bone mineral content

TABLE--CONTINUED

Reference (author date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Elders P , et al (1991) (Ref 146)	Prospective Randomized Clinical Trial Measured: Bone mineral density of the lumbar spine (L2 L4) by dual photon absorption and combined metacarpal cortical thickness in second, third and fourth metacarpals of both hands	295 women, mostly Caucasian 46 to 55 years of age Menopausal status was ascerned by menstrual history and classified into four menopausal groups	2 years	Supplemental calcium source was effervescent tablet with 5 21 g of calcium lactogluconate and 0 9 g calcium carbonate	3 treatments no calcium supplements - 1 000 mg calcium at night - 2 000 mg calcium in two doses at night and in morning	Habitual Intake	47 295 of the original subjects dropped out 44 6% of the calcium treated group switched forms of calcium to calcium citrate due to GI upset		A significant decrease in lumbar bone loss observed after 2 years for the 1,000 and 2 000 mg supplemented groups relative to control (1 3% 0.7% and -3 5% mean loss after 2 years) The effect of calcium on lumbar bone loss was significant after the first year, but not after the second Calcium did not significantly effect metacarpal cortical bone oss	Authors concluded that calcium supplementation retards lumbar bone loss in the first year of supplementation, probably through reduced bone turnover Rate of lumbar bone loss was significantly more pronounced in late peri and early postmenopause and was highest in early postmenopause
Prince, R et al , (1991) (Ref 147)	Double blind Placebo Controlled Randomized Clinical trial Measured: Bone density at 3 forearm sites using single photon absorption every 3 months Urine and blood measurements every 6 months	120 women Caucasian mean age, 56.4 years All had low forearm bone density 42 women mean age 55 5.3 years All has normal forearm bone density	2 years	Exercise alone: n= 41 Exercise + 1 g Ca (calcium lactategluconate n=39 Exercise + progesterone and estrogen	2 5 mg/day medroxyprogesterone acetate and 0 625 mg/day estropipate for 1 month then 1 25 mg/day for 23 months	Habitual diet No significant difference observed between treatment groups Mean calcium intakes for all treatment groups > 650 mg	All exercise regimens consisted of one weekly class and two brisk [illegible] minutes walks per week Every 6 months, physical activity recorded over 4 days and scored Four day dietary records were recorded at beginning and end	All women in treatment groups had initial forearm bone density not lower than one standard deviation below mean for normal control Among 3 treatments no differences in baseline physical activity score calcium intake or forearm density observed	At the distal site both the normal control and the exercise alone group lost significant forearm bone (> -2 6%/y) while exercise + Calcium group lost significant bone (0 05 %/y) and the exercise + estrogen group gained significant bone density (+2 7%/y)	A combined therapy of estrogen and exercise was the most effective in increasing forearm bone mass but with more undesirable side effects Calcium and exercise slowed bone loss relative to exercise alone but less effective than exercise + estrogen Exercise alone was not effective

TABLE--CONTINUED

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Sentipal, J., et al (1991) (Ref 148)	Cross-sectional Measured: Vertebral bone density by dual X-ray absorption (L1 L4) and current calcium intake	49 adolescent girls 8 to 18 years Caucasians	N/A	Habitual diet	Current calcium intake estimated from 6-day diet records		3-day activity records used to determine average daily energy expenditure 16% of 11 to 18 year olds met their Recommended Dietary Allowance of 1200 mg for calcium, while 67% of the 8 to 10 year olds met their Recommended Dietary Allowance of 800 mg calcium	Relative contributions to difference in vertebral body density contributed by calcium intake, age weight height, total energy expenditure, SMR, were estimated by total linear regression SMR = Tanner Sexual Maturity Rating	81% of the variance in vertebral bone density was contributed by SMR, age, and calcium intake	Data suggest that calcium intake may influence peak bone mass and may be a major limiting factor in achieving adult bone density
Tilyard, M., et al., (1992) (Ref 149)	Prospective multicenter single-blind randomized intervention study measured: Rate of vertebral fracture, as defined as a decrease of 15% or more during any 1 year in the anterior or posterior height of the vertebral body from T4 through L4 estimated from early roentgenograms	622 women Caucasian aged 56 to 79 years All had one or more postmenopausic vertebral compression fracture None on estrogens 518 completed 1 year 476 completed 2 years, 432 completed 3 years	3 years	Calcitriol group n= 314 Calcium group n= 308	0.25 ug calcitriol, twice/day 1 gram calcium as 5.2 g calcium gluconate twice/day	Baseline dietary calcium intakes measured in both groups	Monitored serum chemistry changes relative to baseline over the 3 years of treatment	Measured incidence of nephrocalcinosis since both treatments are associated with it Measured calcium absorption status at 30 months	At year 1, fracture rate was 8.8 in Calcitriol and 10.3 in calcium groups At year 3, Fracture rates of spine were significantly reduced in Calcitriol and even more pronounced difference between treatments shown after 3 years Calcium group has a higher rate of vertebral fracture compared to Calcitriol treated subjects at all times	Study lacked a compliance assessment High patient attrition, 31% of women did not complete the study Study clearly shows that calcium supplementation alone is not adequate to prevent vertebral fractures in menopausal women Calcium absorption status did not affect rate of fracture in groups

TABLE--CONTINUED

Reference (author, date)	Study Design	Number and Description of Subjects	Duration of Study	Source and Identity of Test Material	Dosage of Test Material Used	Base Diet	Additional Treatments	Other Factors Affecting Interpretation of Data	Results	Comments
Rhoades, H., et al. (1991) (Ref. 156)	Assessed lactose absorption and dietary calcium intake in elderly women with and without hip fractures Measured: Lactose tolerance and dietary calcium	Women with hip fractures: n= 15, type II osteoporosis mean age = 64±10 years Control: Normal n= 16 mean age = 65±9 years			Dietary calcium intake was estimated from a food frequency questionnaire			Since bone density was not measured, there is a strong possibility that the elderly controls also had type II osteoporosis, but had not sustained a fracture	69% of elderly hip fracture group were lactose malabsorber 19/31 total elderly subjects were lactose malabsorber Dietary calcium intakes did not differ significantly among the 3 groups	Authors were not able to show a decreased dietary calcium intake associated with lactose malabsorption, but the aversion to milk and milk products ascribed to lactose malabsorption may be shown to decrease calcium intake in a larger population In elderly, decreased calcium intake may exacerbate calcium bone from loss

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N–0103]

RIN 0905–AB67

Food Labeling: Health Claims and Label Statements: Omega-3 Fatty Acids and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision not to authorize the use on the label or labeling of foods of health claims relating to an association between omega-3 fatty acids and coronary heart disease (CHD). The agency has determined, based on: (1) The totality of the publicly available scientific evidence; and (2) the agency's review of comments received in response to its November 27, 1991, proposed rule on omega-3 fatty acids and CHD, including scientific information included in those comments, that there is not significant scientific agreement among experts that such evidence supports a health claim for omega-3 fatty acids and CHD. Further, FDA has determined that the new information does not change the conclusions that the agency reached on the basis of the information reviewed in its proposal. Therefore, FDA has concluded that such a claim is not justified. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and is developed in accordance with the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: John C. Wallingford, Center for Food Safety and Applied Nutrition (HFS–465), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5461.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60663), FDA proposed not to authorize a health claim relating diets high in omega-3 fatty acids to reduced risk of heart disease. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101–535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (November 27, 1991, 56 FR 60537). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain good health through appropriate dietary patterns and to protect consumers from unfounded health claims. Section 3(b)(1)(A) of the 1990 amendments specifically requires the agency to determine whether health claims for 10 nutrient-disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship of omega-3 fatty acids and heart disease is one of the claims required to be evaluated. In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on omega-3 fatty acids and CHD and were included in the proposed rule.

In addition, on January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules (57 FR 239).

FDA requested in the **Federal Register** of November 27, 1991 (56 FR 60663), written comments in response to its proposed rule. FDA reviewed all of the comments it received, including new data submitted in the comments, and scientific articles referred to in the comments. FDA also reviewed additional scientific articles, reviews, and recommendations published from August 1991 through February 1992.

The Dietary Supplement Act of 1992 (DS Act) established a moratorium on the implementation of the 1990 amendments with respect to dietary supplements. The DS Act says that FDA can grant health claims for food, including dietary supplements, under section 403(r)(3)(B)(i) of the act. However, it may not act on such claims under section 403(r)(5)(D) of the act until it establishes a standard to implement that section of the act, which the DS Act says may not occur until December 1993. Section 3(b)(1)(A)(x) of the 1990 amendments directs the agency to evaluate the omega-3 fatty acids/CHD claims based on the standard that FDA is establishing for determining the reliability of health claims under section 403(r)(5)(D) of the act. In the November 27, 1991, proposal on general requirements for health claims, FDA proposed to adopt the standard that the 1990 amendments provide for conventional foods, which is set forth in section 403(r)(3)(B)(i) of the act, as the standard for dietary supplements. Given this fact, and the fact that omega-3 fatty acids are found in numerous conventional foods as well as in dietary supplements, FDA broadened its inquiry to a determination as to whether it should grant a health claim on omega-3 fatty acids and CHD for any foods.

Because the DS Act provides that FDA may grant claims using the significant scientific agreement standard specified in section 403(r)(3)(B)(i) of the act, and given the breadth of FDA's November 1991, proposal on omega-3 fatty acids, FDA has decided to move forward to determine whether it can authorize a claim under section 403(r)(3)(B)(i) for omega-3 fatty acids and CHD.

However, this rule does not apply to dietary supplements. While a manufacturer of a dietary supplement can make a claim on omega-3 fatty acids and CHD without rendering its product misbranded under section 403(r)(1)(B) of the act, the manufacturer should assure itself that the making of the claim will not misbrand the product under section 403(a).

II. Summary of Comments and the Agency's Response

FDA received 80 letters, each containing one or more comments, from consumers, health care professionals, universities and research institutes, health profession associations, consumer advocacy organizations, State and local governments, foreign governments, trade organizations, industry, and professional organizations. In addition to these comments, the agency also considered statements made on omega-3 fatty acids and CHD at the January 30 and 31, 1992, public hearings. Some of the comments agreed with one or more of the aspects of the proposed rule, without providing further grounds for support other than those provided by FDA in the preamble to the proposal. Other comments disagreed with one or more aspect of the proposal without providing specific grounds for the disagreement. A few comments addressed issues outside of the scope of this document and will not be discussed in this document. Most of the comments provided specific grounds in support of their positions concerning aspects of this health claim

as proposed. The agency has summarized and addressed the issues raised in the sections of this document that follow.

A. General Comments

1. Definition of omega-3 fatty acids and composition of omega-3 fatty acid supplements

1. One comment criticized the definition of omega-3 fatty acids used in the proposed rule, on the basis that omega-3 fatty acids were not distinguished from other polyunsaturated fatty acids (PUFA's).

In the proposed rule, FDA limited the term omega-3 fatty acids to eicosepentaenoic acid ((EPA), 20 carbons, 5 double bonds) and docosahexaenoic acid ((DHA), 22 carbons, 6 double bonds) (56 FR 60663 at 60664). FDA noted that most of the relevant research has used fish or fish oils rich in these two fatty acids.

FDA acknowledges that its statement defining omega-3 fatty acids did not explicitly refer to omega-3 fatty acids. The sentence: "Their unique characteristic is the location of the first double bond, which occurs at the third carbon from the methyl (or omega) end of the fatty acid." (56 FR 60663 at 60664) was intended to refer to omega-3 fatty acids. This definition distinguishes omega-3 fatty acids from other PUFA's, which have their first unsaturation at the sixth or ninth carbon from the omega end of the fatty acid.

2. One comment argued that the definition of omega-3 fatty acids should include land-based (primarily plant) omega-3 fatty acids (i.e., linolenic acid). (For the purposes of this document, the term linolenic acid is used to indicate the omega-3 fatty acid, alpha linolenic acid. In contrast, gamma linolenic acid has its first double bond at the sixth carbon from the omega end of the fatty acid, and is not an omega-3 fatty acid.)

FDA disagrees with this comment. FDA defined omega-3 fatty acids as EPA and DHA, primarily as a functional definition derived from the scientific literature. The hypothesis for a relationship between omega-3 fatty acids and CHD derived from correlations between low rates of CHD and high consumption of fish oils. Similarly, most of the intervention studies have used fish oil or fish as a source of EPA and DHA, not plant oils rich in linolenic acid. The comment provided no evidence that linolenic acid has biochemical effects comparable to EPA or DHA, nor has FDA found any evidence of a relationship between linolenic acid and CHD. Moreover, only a limited amount of linolenic acid is converted in the body to EPA and DHA (Ref. 100). Therefore, FDA believes it has represented the potential nutrient-disease relationship appropriately by limiting its attention to EPA and DHA.

3. Two comments stated that FDA's position on fish as opposed to the omega-3 fatty acids in fish was a tautology, because: "if polyunsaturated fatty acids have beneficial effects on CHD, and if fish oils are a member of this class of fatty acids, it should not be counted against their beneficial effects on CHD."

FDA disagrees with this comment. FDA considers the claim for omega-3 fatty acids to reflect the unique biochemistry of these fatty acids. In particular, the prevailing theory about the mode of action of omega-3 fatty acids is that they compete with omega-6 fatty acids (fatty acids with their first double bond at the sixth carbon from the methyl end, and which comprise the largest amount of dietary PUFA's). Thus, a clear separation of effects of omega-3 fatty acids from effects of other (primarily omega-6) PUFA's is needed to support a claim.

4. One comment stated that FDA did not consider the importance of the ratio of omega-3 fatty acids to arachidonic acid (AA), a 20 carbon omega-6 PUFA with four double bonds, and stated that evidence exists for a relationship between the saturated fat:unsaturated fat ratio in the diet and the omega-6:omega-3 fatty acid ratio in the diet and the risk of CHD.

FDA considers concerns about the ratio of AA to omega-3 fatty acids and the ratio of omega-6 fatty acids to omega-3 fatty acids to be reasonable in view of the competition between these classes of fatty acids in human biochemistry. FDA considered all types of foods and supplements used to provide omega-3 fatty acids in its evaluation of the claim. Although the AA content of the supplement was often reported, studies did not report data for total dietary AA. FDA is aware of only very limited data regarding the ratios of AA to omega-3 fatty acids, and of the omega-6 fatty acid:omega-3 fatty acid ratio in the diet and the risk of CHD. Therefore, it is not possible for FDA to draw any conclusions about these ratios and their possible modifying effects on the omega-3 fatty acids CHD health claim.

However, because the fish oils used contained high concentrations of omega-3 fatty acids, FDA believes that the amounts of fish oils supplemented to the various test diets would have affected the AA:omega-3 fatty acid ratio and the omega-6:omega-3 fatty acid ratio of the diets to some extent. FDA advises that interested persons may petition FDA under § 101.70 (21 CFR 101.70) to issue a regulation regarding a health claim that relates these ratios to the risk of CHD.

5. Another comment pointed out that supplements used currently have contained various amounts of short- and long-chain omega-3 fatty acids and that many supplements also contain saturated fat. The comment stated that some of the discrepancies in reported findings may be due to the type of supplement used.

FDA agrees that numerous supplements varying in fatty acid composition have been used, and that the variation in the fatty acid composition of supplements may have influenced the outcome. FDA reexamined the studies cited in its proposal and the new data submissions for evidence that the nature of the supplement used was related to the outcome. However, the agency found that the same results are observed regardless of the source of omega-3 fatty acids. For example, in eight well-designed studies cited in the proposal on the total serum cholesterol response among normal subjects (Refs. 6, 9, 14, 49, 54, 73, 156, and 166), six different sources of omega-3 fatty acids were used: Salmon oil, SuperEPA, MaxEPA, a fish oil triglyceride, Promega, and mackerel paste. None of these supplements produced a change in total serum cholesterol. Similarly, four different sources of omega-3 fatty acids (fresh water fish, salmon oil, purified EPA, MaxEPA) were shown in seven well-designed studies to reduce platelet aggregation in normal subjects (Refs. 2, 6, 24, 54, 96, 143, and 166).

FDA did note that some differences in response have been produced by supplements that vary in ratio of EPA to DHA. For example, one fish oil (pollock oil) with a high EPA:DHA ratio increased low-density lipoprotein (LDL) cholesterol, LDL triglyceride and apoprotein B (apoB) (a protein component of LDL) in comparison to a butter-rich diet, but two fish oils with a low EPA:DHA ratio (tuna oil, salmon oil with added palmitic acid) reduced apoB and LDL cholesterol, and increased LDL triglyceride to a smaller extent than the pollock oil in comparison to the butter-rich diet (Ref. 17). However, the effects of the two major omega-3 fatty acids have not yet been systematically investigated. FDA recognizes that purified EPA and DHA are now available for research; such supplements will enable the study of the individual effects of these fatty acids.

6. One comment stated that conservation of omega-3 fatty acids in

the body calls into question the importance of the amounts of omega-3 fatty acids used in scientific studies. However, the comment did not suggest any alternate method to describe intake.

FDA recognizes that fish is not ordinarily consumed daily. However, the 1990 amendments require that health claims on foods be stated in such a way as to enable the public to understand the relative significance of such information in the context of a total daily diet (section 403(r)(3)(B)(iii) of the act). Thus, a reasonable estimate of daily dietary intake of omega-3 fatty acids is needed when assessing the relationship between omega-3 fatty acids and the risk of CHD. Most of the studies reviewed by the agency used daily supplementation with a known amount of omega-3 fatty acids, but others estimated intake of omega-3 fatty acids from foods consumed in the daily diet. Both types of intake estimates are important. Daily supplementation is useful to relate changes to a carefully controlled amount of omega-3 fatty acids. The average daily intake of omega-3 fatty acids in nonintervention studies provides a basis upon which to determine whether the amounts of omega-3 fatty acids fed in supplementation studies are reasonable in the context of the total daily diet.

2. Criteria used in evaluating studies

In the proposed rule, FDA listed some of the criteria used in evaluating epidemiological studies on the relationship of omega-3 fatty acids to CHD: (1) The reliability and accuracy of the methods used in food intake analysis and measurements of disease endpoints, (2) the choice of control subjects, (3) the representativeness of the subjects, (4) the control of confounding factors in data analysis, (5) the potential for misclassification of individuals with regard to dietary exposure or disease endpoints, (6) the presence of bias, and (7) the degree of compliance and how compliance was assessed (56 FR 60667).

However, FDA stated that it considered randomized, double-blind, placebo-controlled trials to be more valuable than other types of human studies because they were less susceptible to bias, and because they allowed inference about the specific effects of omega-3 fatty acids. Studies in which the endpoint was CHD, by definition, provide the most persuasive type of evidence, but studies measuring CHD to date have not provided the specificity to show that the observed effects were due to omega-3 fatty acids.

7. Some comments expressed the concern that it was unlikely that additional clinical trials will be done due to their expense, and that, therefore, FDA should rely more heavily on epidemiologic studies, animal studies, and biochemical and physiological interventions that suggest an effect of omega-3 fatty acids on risk of CHD.

FDA has no basis upon which to agree or disagree with the comments' assertion that further clinical trials are unlikely. FDA disagrees that its emphasis on clinical trials was misplaced. Because the 1990 amendments addressed nutrient-disease relationships, FDA considered human studies that used CHD as the endpoint to be the most directly relevant studies, although these studies do not demonstrate that the effects are specifically due to omega-3 fatty acids. Human studies in which a surrogate marker for CHD risk was measured as the endpoint of the treatment were also considered carefully. The advantage of these studies is that they are able to demonstrate specificity of the effects due to omega-3 fatty acids. However, the relationships between many of these surrogate markers and risk of CHD are not well established, making it difficult to relate changes in these endpoints brought about by omega-3 fatty acids to the risk of disease. Biologic markers can serve as markers of a developing disease, but the relevance of such evidence depends directly on the strength of the association between the marker and the disease (Ref. 115).

FDA agrees that there are considerable additional data in animal studies, in vitro studies, and biochemical and physiological interventions regarding the effects of omega-3 fatty acids. However, it is not clear that the results of such studies are relevant to the risk of human disease. Thus, FDA believes that these other types of data are of secondary importance compared to clinical data that measure either CHD per se or established surrogate markers for CHD.

However, in response to the comments, FDA has provided a more thorough description of animal and in vitro studies that suggest a role for omega-3 fatty acids in reducing the risk of CHD, particularly with respect to the effects of omega-3 fatty acids on the development of atherosclerosis and with respect to the responsiveness of blood vessels to ischemia (see comments 38 and 49 and section II.C.3.a. of this document).

8. Many comments stated that the agency's position on omega-3 fatty acids and CHD was inconsistent with its position on other health claims, and argued that for each of the four claims proposed to be allowed by FDA, the data were no stronger than the data supporting the link between omega-3 fatty acids and CHD. The comments asserted that, by basing its decision on the relationship between the nutrient and a surrogate marker for the disease, or for a susceptible subpopulation, FDA held other claims to a less restrictive standard. One comment stated: "The FDA statement is internally consistent in denying health claims for omega-3 fatty acids, but this is only in the context of holding these food components to essentially impossible standards not required for other, allowable, claims."

Specific comparisons were made to the proposed claims on fat and CHD, fat and cancer, calcium and osteoporosis, and sodium and hypertension. Other comments indicated that qualified claims, such as that for calcium and osteoporosis, were appropriate models for the claim relating omega-3 fatty acids to CHD.

FDA disagrees with these comments. FDA believes that for these other claims there is significant scientific agreement among qualified experts regarding the relationship between the nutrient and the disease, whereas there is not such agreement regarding the relationship between omega-3 fatty acids and CHD, or between omega-3 fatty acids and agreed surrogate markers for risk of CHD. For example, based on the totality of the publicly available scientific evidence, FDA determined that there is significant scientific agreement about the role of calcium in maintaining bone mineral density (the relationship of the nutrient to the intermediate marker for the disease), and about the relationship between peak (maximal) bone mass and the risk of developing osteoporosis and related bone fractures later in life (the relationship between the intermediate marker and the disease itself) (see 56 FR 60689; see also the final rule on calcium and osteoporosis published elsewhere in this issue of the **Federal Register**). Similarly, FDA relied on a long history of Federal Government and other consensus statements to conclude that there is significant scientific agreement about the role of sodium as a causal factor in hypertension for a segment of the population. (See 56 FR 60825; see also the final rule on sodium and hypertension, published elsewhere in this issue of the **Federal Register**.) FDA also recognized the history of significant scientific agreement about the relationships between fat and cancer and between fat and CHD evidenced by statements in reports issued by Federal Government and other authoritative bodies. (See 56 FR 60764, 56 FR 60726; see also final rules on fat and cancer and

fat and CHD, published elsewhere in this issue of the **Federal Register**.).

Thus, these other nutrient-disease relationships have a history of being recognized in Federal Government and authoritative reports, indicating significant scientific agreement, whereas the relationship between omega-3 fatty acids and CHD has not been so recognized. For two of these other nutrient-disease relationships, the data relate to the disease itself, rather than to markers for the disease. In the other two, calcium and osteoporosis and fat and CHD, there is significant scientific agreement that the dietary factors are related to surrogate markers for the diseases, and that the surrogate markers are related to the diseases.

There is significant scientific agreement that serum cholesterol and blood pressure are risk factors for CHD, as indicated by the emphasis on these factors in Federal Government and other authoritative documents (Refs. 34 through 36, 100, 115, and 169). Data regarding the effects of omega-3 fatty acids on these endpoints have been carefully reviewed. However, the other endpoints measured in studies of the effects of omega-3 fatty acids, e.g., in vitro platelet aggregation, various growth factors, fibrinogen, have not achieved the same extent of scientific agreement.

Where authorized health claims include qualifications, the qualifications are intended to assure that the wording of allowed claims reflects those particular aspects of the substance-disease relationship for which there is significant scientific agreement, not to qualify the extent of agreement.

9. Some comments stated that FDA relied heavily on material published in the National Academy of Sciences 1989 report, "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 115) and the Surgeon General's 1988 report (Ref. 34), and did not place enough emphasis on information published since that time.

FDA acknowledges that the two reports in question were important to its assessment of the scientific evidence. However, the agency does not agree that it failed to give appropriate weight to subsequently published research. The 1990 amendments required the agency to consider the totality of publicly available scientific evidence in assessing nutrient-disease relationships. Given the time constraints imposed by the 1990 amendments for developing and publishing proposed regulations, FDA depended on Federal Government reports and reports of authoritative bodies (e.g. the National Academy of Sciences) for assessment of the scientific evidence published before 1988. The reports were also used as a way of determining whether there was significant scientific agreement among qualified experts that the evidence supports a relationship between omega-3 fatty acids and CHD. The agency's reliance on these reports is consistent with the 1990 amendments, which require the agency to consider reports from authoritative scientific bodies of the United States in assessing health claim petitions and to justify any decision rejecting the conclusions of such reports (section 403(r)(4)(C) of the act).

Recognizing, however, that considerable research had been published since these reports, and that these reports had not been updated, FDA also reviewed the available studies on humans published since 1988. FDA relied on its own review of individual studies rather than review articles, because review articles generally reflect the bias of the author and may not consider the totality of the evidence. FDA focused its independent review on primary papers published between January 1988 and August 1991. Surveys and cross-sectional or prospective studies that were published before 1988 and used to generate the hypothesis of a relationship between omega-3 fatty acids and CHD were also reexamined. Thus, by utilizing the two reports in question, supplemented with an independent review of the subsequently published research, FDA was able to assess the totality of the scientific evidence on omega-3 fatty acids and CHD in compliance with the statutory standard.

10. One comment suggested that FDA was inconsistent with the conclusions of the major reviews of this area, published after the Federal Government and other comprehensive reports. They stated that of the nine major reviews (excluding Kinsella, and Connor and Connor), eight concluded that omega-3 fatty acids played a beneficial role with factors affecting heart disease.

Although FDA did not rely on review articles to assess the strength of association between omega-3 fatty acids and CHD, each review was read, and the agency interprets these reviews as supporting the hypothesis in concept. However, each review contained reservations about the extent to which the relationship between omega-3 fatty acids and CHD was established. The cautionary statements suggest general agreement that the area of omega-3 fatty acids and CHD holds promise for further research along a number of lines, but that, at present, there are not sufficient data to have certainty about the relationship between omega-3 fatty acids and CHD. Placed in chronological order, the concluding sections from the cited review articles exemplify the lack of certainty as to the relationship between omega-3 fatty acids and risk of CHD.

The review of the relationship between omega-3 fatty acids and CHD by Leaf and Weber (Ref. 91) was considered in the National Academy of Sciences' "Diet and Health: Implications for Reducing Chronic Disease Risk" report (Ref. 115). FDA elected to include the Leaf and Weber review in its citations because it covered, in the most comprehensive manner of all available reviews, the state of scientific knowledge about omega-3 fatty acids in CHD at the time the Federal Government and other comprehensive reviews were published. Leaf and Weber wrote: "Despite claims that n-3 fatty acids can help prevent atherosclerosis, recommendations to the public on diet have been conservative; people have been advised to increase their consumption of fish by replacing two or three meals a week containing red meat with meals containing fish." Their concluding sentence was: "If prospective double-blind, placebo-controlled clinical trials *were to show* that n-3 fatty acids helped to prevent atherosclerosis, these agents apparently would represent one of the most benign interventions in our pharmacopeia." (Emphasis added.)

Bonaa (Ref. 10) wrote in his conclusion that the data on blood pressure:

> * * * provide some support for the hypothesis that dietary marine lipids influence blood pressure in man. Supplementation of n-3 PUFAs [polyunsaturated fatty acids] to Western diets consistently lowered systolic blood pressure, while results for diastolic blood pressure were conflicting * * *. There is no evidence of any substantial hypotensive response to marine lipids and further studies should be designed to detect small effects.

Lands (Ref. 89) did not review the relationship between omega-3 fatty acids and any specific disease, but presented the hypothesis that the balance of omega-3 and omega-6 fatty acids in the diet may be related to diseases associated with overproduction of eicosanoids from AA. He indicates in the introduction that, "We are now in an uncertain time of evaluating the benefits and risks of dietary n-6 and n-6 polyunsaturated fats."

Weber (Ref. 161) concluded:

> The promise of n-3 fatty acids deduced from biochemical and functional effects will have to be evaluated in ongoing and future carefully designed and conducted studies. So

far, published data of controlled clinical trials incorporating clinical endpoints after n-3 PUFAs are available only in abstract form. Therefore, the gap between biochemical and functional effects of dietary fatty acids *assumed to be* of clinical benefit in the prevention of atherothrombotic and allergic/inflammatory disorders is only beginning to be closed. (Emphasis added.)

Connor and Connor (Ref. 21) wrote in their summary:

The exact place of omega-3 fatty acids from fish and fish oil remains to be defined. However, this much seems certain. Fish provides an excellent substitute for meat in the diet. Fish is lower in fat, especially saturated fat, and contains the omega-3 fatty acids. Fish oil may have promise as a therapeutic agent in certain hyperlipidemic states, especially the chylomicronemia of type V hyperlipidemia. Fish oil has logical and well-defined antithrombotic and antiatherosclerotic activities since it depresses thromboxane A2 production and inhibits cellular proliferation responsible for the progression of atherosclerosis. As the years pass and more experiments are reported, it seems reasonable to place the omega-3 fatty acids from fish oil in a prominent position for specific hypolipidemic, antithrombotic and antiatherosclerotic activity.

Kinsella et al. (Ref. 82) wrote:

The cumulative findings concerning fish oils suggest that further amelioration of coronary heart disease may be feasible by dietary manipulation and by optimizing the intake of n-6 and n-3 PUFAs, not only to reduce plasma lipids but to ensure balanced eicosanoid metabolism—a prospect that deserves more research * * *. Overall, in view of the prevalence of coronary heart disease, consumption of n-3 PUFA oils should be considered as a useful complementary option for the amelioration of coronary vascular diseases.

Knapp (Ref. 84) introduced his paper stating: "The role of dietary polyunsaturated fats in the prevention of human vascular disease *has not been defined*, but population and intervention studies have *suggested* that w-3 fatty acids (FAs) from marine lipids *may have* a number of potentially beneficial effects." (Emphasis added.) And in conclusion he wrote: "The *proof of our hypotheses* must be derived from increasingly ambitious clinical trials, which assess the *potential* benefits of dietary polyunsaturates in particular clinical settings, the recent demonstration that three helpings of oily fish per week prolongs survival after MI (Ref. 16) is an example of this." (Emphasis added.)

Nestel (Ref. 111) concluded: "More basic understanding of the actions of fish oils is necessary before fish oils can be recommended widely to the public."

Nordoy and Goodnight (Ref. 112) cautioned that until additional data become available, "clinicians should be advised to follow the dietary recommendations of the National Cholesterol Education Program's expert panel," which is silent on omega-3 fatty acids and limits the total polyunsaturated fat to 10 percent of calories. These reviewers added their own recommendation that omega-6/omega-3 ratio of the PUFA's be approximately 3/1, with the omega-3 fatty acids from marine sources.

Weber and Leaf (Ref. 162) stated:

Despite all the laboratory, human, animal, and epidemiologic studies suggesting an anti-atheromatous action of w3 fatty acids, we have been lacking adequate clinical trials which will determine in prospective, placebo-controlled, randomized studies, whether all the above experimental and epidemiologic evidence adds up to a demonstrable effect of fish oils to prevent atherosclerosis, e.g., coronary heart disease in humans at high risk for heart attacks.

The Burr paper (Ref. 16) was described in Weber and Leaf's review, and thus was considered in the above summary statement.

In summary, these reviews indicate that what is agreed is that there is a plausible biochemical basis for a relationship between omega-3 fatty acids and CHD, and that there are some data supporting some of the hypothesized mechanisms by which omega-3 fatty acids might be related to CHD. What is not agreed, as indicated by the cautious tones of these concluding statements, is that such a relationship already has been established by the evidence.

11. A concern raised by many comments was that FDA's conclusions were different from the conclusions reached in the report from the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (Ref. 100), the most recent comprehensive review, and that FDA did not explain why it reached a different conclusion from that reached in the LSRO report.

The LSRO report was contracted for by FDA as an independent review of the scientific evidence about the relationship between omega-3 fatty acids and CHD. A draft of the tentative final report was received immediately prior to the publication of the proposed rule. Thus, there was insufficient time for the agency to prepare a detailed discussion of the report. The final report was submitted to FDA as a comment to the proposal. The LSRO report's conclusions on hypertension, thrombosis, the development of atherosclerotic plaque and intimal hyperplasia, plasma lipids and lipoproteins, diabetic and prediabetic patients, and epidemiologic observations are grouped with other comments on these topics and discussed in this document.

12. One comment considered FDA's caution against extrapolation of results from studies conducted in at-risk populations to the general population to be questionable, and possibly biased against hypertensives. The comment stated that the health claim should be allowed, based on data showing that omega-3 fatty acids reduce blood pressure among hypertensives.

FDA disagrees with this comment. FDA stated that, although it considered studies in the healthy population to be the most relevant, it also considered studies in a subpopulation with CHD or risk factors for CHD, in part because high risk populations may be more sensitive to showing a nutrient-disease relationship than the general population (56 FR 60663 at 60667). FDA stated that it extrapolated positive results from at-risk populations cautiously, and that comparable findings in the general population were needed to support a health claim.

13. Two comments discussed FDA's criteria for weighing various types of data. One comment stated that epidemiologic data are the "most significant class of evidence," and that FDA should give priority to various types of data in the same order that various types of data were reviewed in the proposal. One comment stated that FDA should not have considered epidemiological studies separately from clinical trials.

FDA considered the totality of publicly available scientific evidence in its assessment of the relationship of omega-3 fatty acids to CHD. However, some types of evidence were weighted more heavily than others because they were more useful in establishing whether or not the scientific basis of the claim was valid. In particular, the agency was concerned that both the substance (omega-3 fatty acids) and the disease (CHD) be carefully characterized. FDA also considered it important that the amount of omega-3 fatty acids tested was reasonably related to normal dietary intake, and that the findings apply to the general population. FDA agrees that epidemiologic studies in which the endpoint was CHD provide persuasive evidence for a relationship between fish consumption and CHD, but these studies did not provide the specificity to show that the observed effects were due to omega-3 fatty acids. Intervention trials using fish oil supplements often showed that the effects were specific to omega-3 fatty acids (by controlling with

other types of fatty acids) but typically did not measure the primary endpoint, CHD. Thus, these different types of data complement each other and must be considered together in assessing the totality of the scientific evidence.

14. One comment offered the services of the International Society for the Study of Fatty Acids and Lipids for the evaluation of the relationship between omega-3 fatty acids and CHD.

FDA appreciates this offer. In the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**, FDA advises that it welcomes the input of any professional organization that can provide expertise in reviewing data and in developing a thoughtful and well-organized petition for a health claim on a particular topic. In fact, FDA has added to § 101.70(b) the provision that information submitted with petitions may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area at issue. FDA, however, retains the authority to review such petitions and, through rulemaking, to decide whether or not to authorize the claim.

15. Two comments stated that it was contradictory for the U.S. Government to contract for research on the omega-3 fatty acids through the biologic test materials program but not to allow a health claim. Another comment pointed out that the Food and Agriculture Organization and the World Health Organization support research on omega-3 fatty acids. Other comments stated that the tone of FDA's proposed rule was unduly negative and that, by taking such a position, FDA may retard further research.

FDA disagrees that Federal Government sponsorship of a program to provide test materials for research on the effects of omega-3 fatty acids and the denial of the omega-3 fatty acid-CHD health claim are contradictory actions. The purpose of the biologic test materials program is to develop and standardize a source of omega-3 fatty acids and enable carefully controlled research on the effects of particular omega-3 fatty acids. In the proposed rule, FDA's intent was to examine the total available scientific evidence, some of which was generated using omega-3 fatty acids from the biologic materials test program, and to state its conclusions about the relationship between omega-3 fatty acids and CHD.

In its proposal and in this final rule, FDA has identified a number of areas where agreement is lacking that an observed effect of omega-3 fatty acids is related to the risk of CHD, or where there are ambiguities in the data that may be resolved by further research. Thus, FDA's analysis should provide guidance for additional research rather than inhibit it.

B. Relationship Between Omega-3 Fatty Acids and CHD

In the proposed rule, FDA tentatively concluded that the totality of the scientific evidence does not provide a basis upon which to authorize a claim that omega-3 fatty acids are associated with the risk of CHD (56 FR 60663). FDA noted that.

> the epidemiological research on this topic revealed that the available studies applied only to the consumption of fish, which contain omega-3 fatty acids, and * * * it was not possible to ascribe any effects specifically to the omega-3 fatty acids. Examination of data from clinical studies revealed that the effects on blood lipids of fish oils containing omega-3 fatty acids were primarily a reduction of blood triglycerides, a blood lipid variable not considered to be an independent risk factor for CHD, but they had no effect on serum cholesterol, low-density lipoprotein (LDL) cholesterol, or high density lipoprotein (HDL) cholesterol, the blood lipid variables most closely associated with risk of CHD The scientific data are ambiguous on the effects of omega-3 fatty acids on blood pressure and other risk factors for CHD.

(56 FR 60663.)

A number of comments supported the agency's position on this health claim, but without any specific reasons for that support. One comment agreed with the agency's position in principle, but contested the agency's interpretation of the scientific information in some areas. Other comments disagreed with the agency's review of the scientific information and its conclusion regarding the strength of the evidence supporting the proposed health claim. Specific comments are summarized below.

1. Epidemiologic evidence

In the proposed rule, FDA reviewed correlational and cross-sectional studies, prospective studies, and intervention studies available since 1988. (See 56 FR 60663 at 60667 through 60668). Except for the intervention studies (which were typically clinical trials) these studies used fish as a source of omega-3 fatty acids. FDA concluded that those studies that used fish as the source of omega-3 fatty acids were: "ambiguous, because they are not capable of distinguishing the effects that are specific to omega-3 fatty acids from those that are related to fish consumption." (56 FR 60663 at 60668.)

16. A number of comments considered the evidence from epidemiologic studies that relates the consumption of fish inversely to CHD to be sufficient to support a health claim, but did not supply any new information or arguments to support their position.

FDA disagrees with the comments. FDA found that:

> Only a few studies found an association between fish intake and CHD, while others have found no association. Thus there was not consistency of findings. None of the studies that reported a relationship distinguished fish consumption from other factors associated with fish consumption, and therefore they did not demonstrate specificity. Even in those studies reporting a relationship between fish consumption and CHD, it was not clear that the effects were because of the omega-3 fatty acids in fish. Also, the omega-3 fatty acid content of the fish diet associated with reduced CHD was so low that the importance of omega-3 fatty acids is questionable * * *

(56 FR 60663 at 60672.)

17. One comment described the results of the Dolecek and Grandits analysis of multiple risk factor intervention trial (MRFIT) data (Ref. 38) as indicating a greater protective effect against CHD due to consumption of 0 6 gram (g) omega-3 fatty acids than all other conventional efforts combined (reducing saturated fat, cholesterol, cigarette smoking, and hypertension).

FDA agrees with this comment that the association between omega-3 fatty acid consumption and CHD mortality reported in this study has the potential to make a very important public health impact. Notably, the results were obtained on data adjusted for age, race, smoking at entry to the study, diastolic blood pressure, and high-density lipoprotein (HDL) and LDL concentrations. Furthermore, the omega-3 fatty acids were obtained in the normal diet, providing evidence that the amount of omega-3 fatty acids consumed in a normal dietary intake is sufficient for the effect.

The researchers' adjustments for lipoprotein measurements should control for some other dietary variables that have been associated with CHD through their effects on these lipoproteins, e.g., saturated fat, but other dietary variables associated with CHD were not controlled, e.g., alcohol. The association between omega-3 fatty acid consumption and CHD mortality described in this study is among the most provocative findings to date in this area, and merits additional study using a design that will document that the active dietary component is or is not the omega-3 fatty acids (i.e., specificity of the effect).

18. One comment pointed out that the Burr paper (Ref. 16) deserved close consideration, because, in contrast to

trials on lipid lowering drugs, it showed that consumption of fish containing omega-3 fatty acids or dietary supplements of omega-3 fatty acids may reduce the risk of heart disease. One comment stated that it considered the Burr paper to be a positive finding, but gave no reason for this conclusion. The LSRO final report, submitted as a comment, also recognized the Burr paper as a very important trial. LSRO pointed out that, although separate results were not shown for those consuming fatty fish and those consuming supplemental fish oil, the results were dramatic, especially since all-cause mortality was reduced, in contrast to results from trials of plasma lipid-lowering drugs. LSRO concluded that "future research will be needed to define the amount and duration of w-3 fatty acid supplementation required to produce the beneficial effects."

FDA agrees that the Burr paper provides valuable evidence consistent with the hypothesized relationship between omega-3 fatty acids and CHD. However, FDA noted in its proposal (56 FR 60663 at 60668) that there are two specific shortcomings in this paper: the absence of separate data for subjects who consumed fish and those who consumed fish oil capsules, and the absence of dose-response data. These data would have provided evidence for a specific effect of omega-3 fatty acids. Ideally, other data regarding the subjects' diet would also show that there was no difference in consumption of other dietary factors related to CHD. The study design specifically included two such dietary factors, dietary fat and dietary fiber, and the lack of significant effects of these components argues against dietary factors other than omega-3 fatty acids as responsible for the association.

FDA does not consider the Burr paper to have established a beneficial effect of omega-3 fatty acids, although its results are consistent with such an action. The LSRO conclusion indicates that neither the amount of omega-3 fatty acids necessary for beneficial effects nor the duration of their intake has been established. The specificity of the substance responsible for the beneficial effects, the quantitative amount needed to produce the effect and the duration of intake needed to produce the effect need to be established before FDA can authorize a claim linking omega-3 fatty acids to reduction of risk of CHD.

19. Some comments stated that the amount of fish in the Zutphen and Burr studies was so low that the association between fish consumption and reduced CHD mortality could not be explained by the displacement by fish of other atherogenic foods from the diet.

FDA is not persuaded by these comments. The limitation in these studies is that they did not control for dietary factors associated with CHD, not that fish consumption displaced other atherogenic foods. FDA noted in its proposal that the Zutphen study found significant correlations between fish consumption and other dietary factors (i.e., alcohol, polyunsaturated fats) related to CHD. Comparable correlations were not addressed in the Burr paper because dietary intake data were not reported. Also, the design of the Burr paper was to encourage consumption of fish, which would likely have resulted in a reduction in the consumption of red meat (and, therefore, saturated fat).

20. Two comments discounted the Curb et al. study (Ref. 25), which showed no association between fish consumption and CHD mortality among subjects in Hawaii. The comments stated that the dietary source of fish was likely tropical fish, and since tropical fish feed on coral they have a high content of AA, which would counteract the effect of omega-3 fatty acids.

FDA disagrees with the comments. No data regarding the AA content of the diet in this study, or in other correlational studies; have been reported. Indeed, most epidemiologic correlation studies have not quantified the intakes of omega-3 fatty acids, a fundamental measurement to establish an association between omega-3 fatty acids and CHD. Finally, there is an abstract reporting that the omega-3 fatty acid to omega-6 fatty acid ratio of tropical fish is comparable to or greater than that of fish in higher latitudes (Ref. 237). Thus, the comments' explanation for a negative finding must be considered theoretical.

21. One comment argued that the lack of an association between fish consumption and CHD in two populations in Canada, a prairie province and a coastal province (Ref. 74), was because the prairie population consumed more alcohol and the coastal population smoked more. This comment criticized FDA for not pointing out the cautions raised by the authors about potential confounders like the difference in alcohol consumption.

FDA believes it presented the results of this paper fairly. While the authors reported small differences in smoking (more in the coastal population) and alcohol consumption (more in the prairie population), they stated, "It seems unlikely that these differences are sufficiently large to offset any strong effect of fish consumption." FDA is keenly aware that dietary and behavioral factors (e.g., smoking, alcohol) must be controlled before meaningful conclusions may be drawn about the effects of omega-3 fatty acids. FDA notes that alcohol consumption was also a confounding factor in a study that reported an association between fish consumption and CHD (Ref. 87).

22. A few comments stated that many of the reported effects come from studies on fish consumption, but that all measured biochemical changes related to CHD that are produced by fish have also been produced with fish oil concentrates.

FDA agrees in part with this comment. The fact that the same biochemical results have been obtained using fish oils rather than fish provides strong evidence that particular biochemical markers are affected specifically by omega-3 fatty acids. Also, since most studies have used fish oils, these results add consistency to the effects reported for studies that used fish. However, FDA disagrees that the comparable findings in studies that used fish oils and fish are sufficient to support the health claim that omega-3 fatty acids reduce the risk of CHD, because the particular biochemical markers affected by both fish and fish oils are not recognized with significant scientific agreement as useful surrogate risk factors for CHD in the general population.

23. One comment argued that the fact that Greenland Eskimos ate diets with half the saturated fat and more polyunsaturated fat than Danes and had much less CHD than Danes strengthens the case for fish oil-derived omega-3 fatty acids.

FDA agrees with the comment that diets lower in saturated fat are consistent with reduced CHD mortality (see the final rule on "Dietary Lipids and Coronary Vascular Disease" published elsewhere in this issue of the Federal Register). The differences in saturated fat intake, however, do not strengthen the case for omega-3 fatty acids, because they do not distinguish omega-3 fatty acids from polyunsaturated fats. Rather, the differences in dietary fat intakes strengthens the argument that saturated fat is associated with CHD mortality. The numerous dietary differences between the Greenland Eskimos and Danes make it difficult to ascribe to any single dietary factor the differences in CHD.

24. One comment pointed out that, of the ten prospective studies cited in the proposal (including three in Table 1 of the proposal), six support an inverse relationship between fish consumption and CHD. The comment noted that one

study only showed a relationship in men under 45, and argued that this result is promising because one might expect to find positive effects of long-term fish consumption on CHD in younger, relatively healthy men rather than in older men.

FDA agrees that some but not all reports find an inverse relationship between fish consumption and CHD. FDA does not agree, however, that this effect would more likely be noticed among younger, relatively healthy men. Older men would have had a greater duration of intake of omega-3 fatty acids and a greater incidence of CHD than younger men. Both these factors would favor finding an effect in older men rather than in younger men.

25 One comment noted that only two studies found a positive dose-response. Another comment stated that the studies that show no effect are those where the base group already consumed fish, whereas in studies that showed an effect, the base group did not consume fish A third comment stated that there were data that described an inverse dose-response relationship between serum EPA and CHD deaths among Japanese, but did not identify a particular study.

FDA disagrees that only two studies found a dose response correlation. Each study that reported a relationship between fish consumption (or, in one study, the calculated intake of omega-3 fatty acids) and CHD found a dose-response relationship. FDA agrees that most of the dose-response relationships reported suggest that the primary difference in rate of CHD is between those who consume no fish at all and those who consume a small amount of fish, and that there appears to be little additional benefit from consumption of large amounts of fish (Ref. 88). An alternate way of describing these data is that those who consume no fish have an increased risk of CHD. These data merit followup, because a showing that the relationship is due to the omega-3 fatty acids may provide evidence that the long-chain omega-3 fatty acids are essential in the diet.

In its proposal, FDA reviewed a study that described an inverse dose-response relationship between serum EPA and CHD mortality among two groups of Japanese (Ref. 78). FDA concluded that these cross-sectional, correlational data were useful in generating a hypothesis. Other notable dietary factors (including a difference in salt intake of 50 percent) and risk factors for CHD (prevalence of hypertension) also differed between the two groups, so it is not possible to conclude that differences in CHD mortality were due to differences in dietary omega-3 fatty acids.

26. Two comments stated that FDA had erred in stating that no biochemical data were reported in the Burr paper (Ref. 16).

FDA agrees with this comment, and stands corrected. Burr et al. (Ref. 16) did report that the geometric mean percentages of EPA were 0.59 percent and 0 46 percent in men given advice to consume more fish and those not so advised, respectively, a highly significant difference ($p < 0.01$). The fact that a geometric mean rather than an arithmetic mean was reported implies that there was substantial skewing of the data.

It is not clear from the article whether these differences were for the 6-month time into the trial, or for the end of the trial. The authors did not correlate plasma EPA concentrations directly with myocardial infarction (MI) or CHD deaths.

27. One comment argued that it was highly misleading to state in Table 1 that Kromhout et al. (Ref. 87) reported that, "lean fish, low in omega-3 fatty acids, had some protective effect against CHD," because Kromhout did not distinguish between the effects of lean and fatty fish.

FDA disagrees with this comment. The authors made two statements about lean fish that imply that additional data analyses were conducted, although (as the comment correctly notes) results of these analyses were not included in the paper. The authors wrote, "Lean fish was also inversely related to mortality from coronary heart disease," and "Thus, the inverse relation between lean fish and coronary heart disease cannot be explained by eicosapentaenoic acid."

FDA interprets these comments as a caution to the reader against assuming that EPA was the active component responsible for the observed reduction in CHD among fish-consuming subjects.

28. LSRO included in its report two studies that correlated plasma omega-3 fatty acids with dietary intake of these fatty acids (Refs. 213 and 225). Two other papers reviewed by LSRO but not included in the FDA proposal were correlation studies of mortality from different diseases among Greenlanders and Danes (Ref. 176) and diet-disease correlations in Japan (Ref. 284).

FDA agrees with LSRO's descriptions of these studies. FDA notes that the authors of the studies that correlated intake and plasma levels of omega-3 fatty acids did not relate their data to CHD The correlation studies of mortality did not provide any specific data regarding omega-3 fatty acids.

29. One comment provided new dose-response data from additional analyses of data of the Dart study, previously reported in part by Burr et al. (Ref. 16), that related the dietary intake of EPA at 6 months into the trial to the risk of CHD events (heart attacks, or MI's) or CHD mortality. The 947 subjects for whom dietary data were obtained were grouped according to EPA intake; 114 consumed less than 1 g per week (1 g/week), 373 consumed 1 to 2 g/week, and 460 consumed 2 or more g/week. The percentage of subjects that experienced either a nonlethal heart attack or died from a heart attack decreased as dietary EPA increased. For heart attacks the rates were 7.9 percent, 7.0 percent and 6.7 percent, for the less than 1 g/week, 1 to 2 g/week and 2 or more g/week groups, respectively. The percentages in each group who died were 6.1 percent, 5.1 percent, and 4.1 percent, respectively. There were no statistical analyses of these data reported.

FDA notes some limitations in these data as reported that caution against strong conclusions. Most notably, the analysis excluded the events and deaths during the first 6 months of the trial, when about half of all events and deaths occurred. This clearly diminishes the sensitivity of the analysis, and may result in an underestimation of the true effect, since the difference in survival between the group advised to eat more fish and the group not advised to eat more fish was most pronounced during the first 6 months. Alternatively, if the healthiest subjects were also the most compliant subjects, the reduced death rate in the highest EPA-consumption subjects may reflect the underlying health of those subjects, and the importance of dietary EPA may be overestimated.

Also, the unequal group sizes for this analysis places a greater weight on each subject in the smallest group (less than 1 g/week) than in the other groups. This may be particularly important because the smallest group includes those who consume no fish, and who may differ from fish consumers in other dietary or behavioral factors associated with CHD risk. The sensitivity of the results to small changes in outcomes is shown by example: one fewer death (6/114 rather than the reported number, 7/114) makes the CHD death rate of the less than 1 g/week group equal to the rate in the 1 to 2 g/week group.

Finally, although the dietary intake data at 6 months are useful, this study also assayed plasma fatty acids. Use of plasma EPA (or EPA plus DHA) in the dose-response analysis would have been a more powerful analysis, because it eliminates errors in the diet record data,

corrects for losses during food preparation and individual differences in bioavailability of the fatty acids, and integrates intake of omega-3 fatty acids over a longer period than the diet record data.

Therefore, FDA finds these dose-response data to be consistent with the hypothesis that omega-3 fatty acids reduce the risk of CHD, but the shortcomings discussed above limit their usefulness in establishing a relationship between omega-3 fatty acids and risk of CHD.

2. Evidence relating omega-3 fatty acids to intermediate or surrogate markers of CHD

In the proposed rule (56 FR 60663 at 60668), FDA stated that most information about the effects of omega-3 fatty acids on CHD has been derived from clinical trials using concentrated fish oils enriched in EPA and DHA, and in some cases purified methyl or ethyl esters of EPA and DHA. FDA concluded that:

> * * * there are a few established effects of omega-3 fatty acids from fish oils on thrombosis and hemostasis. Standardized bleeding times are increased, and platelet aggregation and function are reduced. However, direct relationships between the changes in bleeding times or platelet function and risk of CHD have not been established. While there is an established relationship between blood pressure and CHD, it has not been shown that omega-3 fatty acids specifically affect blood pressure in normal subjects in a way that would provide a protective benefit toward the risk of CHD. Effects of omega-3 fatty acids on other markers linked with CHD, e.g., fibrinogen or lipoprotein (a) have not been established.

(56 FR 60663 at 60671).

a. Atherosclerosis

i. Blood lipids

30. Numerous comments criticized FDA's focus on blood cholesterol as a surrogate marker for risk of CHD, although one comment noted that such an emphasis would be expected, given the importance of cholesterol in CHD. Another stated that the focus on cholesterol ignores other factors that determine blood cholesterol such as heredity, exercise, and stress, etc.

FDA disagrees with the comments that it overemphasized the importance of studies in which cholesterol was measured as a surrogate marker for CHD. The considerable attention given to blood cholesterol measurements (and measurements of other blood lipids and the protein components of blood lipoproteins) was the consequence of two factors: (1) There was a large number of studies on the effects of fish oils or fish containing omega-3 fatty acids on these blood lipid measures; and (2) there is general agreement that certain blood lipids are strongly associated with the risk of CHD.

FDA undertook to evaluate findings in these studies whether or not fish or fish oils were used as the source of omega-3 fatty acids and whether or not the outcome measures were generally recognized as predictive of CHD. This approach allowed the identification of biologic activities of omega-3 fatty acids that may be related at some point to risk of CHD, and identified areas where additional research is needed. FDA included in the summary of its proposed rule (56 FR 60663) only measures of generally recognized risk factors. FDA did not intend to imply that data on alternate markers were not considered in its decision.

FDA agrees that other factors contribute to blood lipid measures, but believes that randomization should control for these factors. In nonrandomized studies, these sources of potential bias limit the conclusions that can be inferred from the data. This is an important reason that data from correlation studies do not conclusively establish a relationship between omega-3 fatty acids and risk of CHD.

31. The LSRO report paid considerable attention to changes in blood lipids after increased consumption of omega-3 fatty acids, and reached some conclusions about effects of omega-3 fatty acids on blood lipids that differed from those reached by FDA. LSRO abstracted three studies from before the period covered by FDA review (Refs. 284a, 267, and 257). These studies were considered in Federal Government and other comprehensive reports reviewed in the proposed rule and not discussed further by FDA. LSRO also included three studies not reviewed by FDA in its proposal (Refs. 168, 226, and 301). Agren et al. (Ref. 168) studied healthy students randomly assigned to their normal diet (one fish meal per 2 weeks), a fish diet, or a fish diet low in saturated fat for 15 weeks. There was no change in total serum cholesterol on the control diet or fish diet, but the low-fat fish diet produced a reduction in total cholesterol. Jensen et al. (Ref. 226) studied 18 healthy subjects supplemented sequentially for 4-week periods with 4-week washouts between, with fish oils containing 1, 3, and 6 g EPA plus DHA, and found no change in total or LDL cholesterol. Wolmarans studied healthy subjects fed a meat diet or fish diet containing 6.1 g EPA plus DHA for 6 weeks each in a crossover design, and found reduced total cholesterol and LDL cholesterol during the fish diet phase. There was no difference in total fat of the two diets. However, there was significantly less saturated fat in the fish diet, so it is not certain that the omega-3 fatty acids were responsible for the decrease in the cholesterol measures.

FDA is concerned that the studies abstracted by LSRO do not accurately represent the totality of publicly available scientific evidence. For example, in its proposal, FDA included five studies among normal subjects (Refs. 2, 6, 24, 73, and 143) and three studies among subjects with preexisting lipid or lipoprotein abnormalities (Refs. 18, 73, and 93) not included in the LSRO report that had data for effects of omega-3 fatty acids on plasma lipids or lipoproteins. FDA determined that seven studies that reported changes in total cholesterol had the most rigorous designs and the largest numbers of normal subjects. None of these seven studies (Refs. 6, 9, 14, 49, 54, 73, and 166) in normal subjects found a significant change in total cholesterol after fish oil supplementation. FDA found similar results with regard to hyperlipidemic subjects.

Only two of these seven strongest studies in normal subjects were abstracted in the LSRO text, and two others were not cited at all by this report. LSRO did not distinguish between normal and hyperlipidemic subjects in its summary or conclusions. LSRO summarized the evidence on total cholesterol by stating, "Decreases in total cholesterol * * * have *also* been reported," (emphasis added), without mentioning that the predominant finding is that there is no effect on total cholesterol.

Similarly, FDA stated that the strongest studies among normal subjects (Refs. 6, 9, 14, 49, 54, 73, and 166) found no change in LDL cholesterol, and one reported an increase in LDL cholesterol (Ref. 54). Indeed, most studies on hypertriglyceridemic or hypercholesterolemic subjects reported an increase in LDL cholesterol following fish oil supplementation (56 FR 60663 at 60669). Consequently, FDA disagrees strongly with the summary statements in the LSRO report:

> Effects of fish oil upon LDL have been variable, in part because of different doses. In normolipidemic individuals, LDL has generally declined significantly. In *some* patients with primary hypercholesterolemia, consumption of fish (sic) has not resulted in altered plasma cholesterol levels; other studies have shown decreased cholesterol and LDL levels. (Emphasis added.)

32. Two comments stated that FDA had not considered all relevant data on HDL_2 cholesterol, and cited additional

studies that reported increased HDL_2 cholesterol after fish oil supplementation. One comment stated that overall HDL cholesterol tends to rise, and cited a review paper by Harris (Ref. 62). The LSRO report also concluded that HDL was increased by fish oil supplementation.

FDA disagrees with the comment regarding the overall HDL cholesterol change after fish oil supplementation. The agency considered HDL changes separately for normal, healthy subjects and for hyperlipidemic subjects (56 FR 60663 at 60669). Nearly all studies on normal subjects found no significant change in HDL cholesterol level. Some investigators reported increased HDL_2, but the data on HDL_2 were equivocal.

FDA also disagrees with the conclusions of the LSRO report regarding HDL cholesterol, because it does not represent the totality of publicly available scientific evidence. The LSRO summary states, "In *some* studies HDL concentrations have actually increased with consumption of fish oil" (emphasis added), not acknowledging that the balance of available scientific evidence on HDL indicates no change. In the review by Harris cited in the comment, the changes in HDL cholesterol in each study were weighted according to the number of subjects in the study, giving a per-subject change. This method of pooling data from different studies does not account for the variation of the response of subjects in each study, the amount of omega-3 fatty acids fed, the duration of feeding, or the source of the omega-3 fatty acids. Therefore, it must be considered only an estimate of the effects of omega-3 fatty acids on HDL cholesterol. Harris calculated the average HDL cholesterol change for normal subjects to be an increase of approximately 3 percent, a net change smaller than the usual variability in the test used to measure HDL.

The agency agrees with the comment that not all HDL_2 data were considered in the proposed rule, although FDA noted (56 FR 60663 at 60669) that some studies among normal subjects found increases in the HDL_2 fraction of HDL cholesterol, and that these reports were the most promising changes in blood lipids. Of the six references cited by the comments as not included among studies showing increased HDL cholesterol after omega-3 fatty acids, two were published after the time period covered in the proposed rule (Refs. 235 and 252). One other paper not cited by FDA in its proposal, although it was published during 1988 (Ref. 291), dealt with insulin-dependent diabetics. The other three papers were cited by FDA in other contexts, but data from these papers regarding HDL_2 cholesterol levels were not discussed (Refs. 1, 32, and 148).

FDA reexamined those papers that it cited but from which it did not present data regarding HDL_2, together with the newer papers. When fractions of HDL cholesterol have been reported, an increase has generally been found in the HDL_2 fraction (Refs. 1, 32, 148, 235, 251, and 291), with a comparable decrease in the HDL_3 fraction (Refs. 1, 235, and 251). This represents a shift within the HDL fractions toward a lipid-rich lipoprotein, and away from a protein-rich lipoprotein, similar to that reported for LDL, below. This shift has been reported when there is (Refs. 32, 148, 235, and 291) or is not (Refs. 1 and 251) a change in total HDL cholesterol. This raises the possibility that a shift occurred in other studies where total HDL was reported as not changed.

However, the importance of the shift in subfractions of HDL is not clear. FDA noted in its proposal (56 FR 60663 at 60669) that there is evidence that the HDL_2 fraction is the one most closely linked to risk of CHD. However, the agency was unable to find evidence that there was significant scientific agreement that HDL_2 was the fraction of HDL most closely associated with CHD. The National Institutes of Health's National Heart, Lung, and Blood Institute (NHLBI) consensus development conference on Triglyceride, High Density Lipoprotein and Coronary Heart Disease (Ref. 255), anticipated in the proposal (56 FR 60663 at 60664), concluded that, "It is not known to what extent these alterations of HDL contribute to atherogenesis."

Therefore, data on changes in HDL subfractions after increased consumption of omega-3 fatty acids do not provide a sufficient basis for a health claim, because there is not significant scientific agreement that HDL_2 is directly related to risk of CHD. If the risk of CHD becomes linked with HDL_2, these findings in normal subjects may be of great importance.

33. Many comments indicated that high triglycerides are causally related to decreased HDL, that triglycerides are an independent risk factor for CHD, or that statistical manipulations of data and imprecise measurements of triglycerides obscure the importance of triglycerides as a risk factor for CHD. One comment provided additional citations regarding the relationship between triglycerides and HDL, but these did not bear on risk of CHD. One comment stated that it was generally agreed that triglycerides were not independently associated with CHD.

FDA disagrees with all but the last comment. FDA is aware that there has been, and still is, substantial interest in the potential role of triglycerides in the etiology of CHD (e.g., Ref. 209). Because of the continued interest, the relationship between triglycerides and CHD was the topic of a consensus development conference sponsored by NHLBI on February 26 through 28, 1992. NHLBI had previously addressed this topic in 1983 and concluded at that time that the relationship was controversial. The recent conference (Ref. 255) concluded, "For triglyceride, the data are mixed; although strong associations are found in some studies, the evidence on a causal relation is still incomplete."

FDA agrees that the statistical methods previously used to study the relationship between triglycerides and CHD have lessened the likelihood that triglycerides would be found to be a significant, independent predictor of CHD. Furthermore, the agency believes that study design and analytic measurement methods have contributed to variation in triglycerides that may have resulted in reducing the statistical association between triglycerides and CHD. FDA believes that these sources of variation in triglycerides can be reduced by careful study design and standardized analytical measurement techniques, and also that clinical studies designed to lower triglycerides could provide a basis upon which to reconsider the importance of triglycerides in CHD.

34. Some comments stated that some very recent evidence from the Helsinki Heart Study supports a protective effect of lowering triglycerides, at least for a selected subpopulation of people with a high ratio of LDL cholesterol/HDL cholesterol and very high triglycerides.

FDA agrees that fish oils reduce plasma triglycerides. In its proposal FDA wrote, "The predominant blood lipid effects of fish oils * * * are decreased plasma triglycerides and VLDL." (56 FR 60663 at 60669.) In this regard FDA and LSRO were in agreement. The LSRO summary states, "The most striking effect is lowering of plasma triglyceride and VLDL concentrations."

FDA disagrees, however, that triglycerides have been established as an independent risk factor for CHD. The recent results from the Helsinki Heart Study (Ref. 242) were discussed at length at the NHLBI consensus development conference (Ref. 255). While the reduction in CHD mortality following drug intervention was dramatic (i.e., approximately 7-fold) for a particular subgroup with both elevated

triglycerides and elevated LDL to HDL ratio, this result was obtained by a post hoc analysis of earlier results. Because the combination of factors used to connote the high-risk group (i.e., high LDL cholesterol to HDL cholesterol ratio *and* high triglycerides) was determined after the data were collected, these results are not the results of the testing of a hypothesis, but are the origins of a new hypothesis. The authors indicate that the cut-off points for the ratio of LDL to HDL and triglycerides chosen were to some extent arbitrary. The actual number of cardiac events in the study was small (e.g., 18 events among 138 subjects in the highest risk subgroup), and the reduction in all-cause mortality due to the lipid-lowering drug, gemfibrozil, was not significant. Finally, independent of LDL to HDL ratio, increased triglycerides alone were not associated with an increased risk of heart attack.

The dramatic reduction of triglycerides by omega-3 fatty acids has resulted in their use in the treatment of a rare genetic hypertriglyceridemia (type V) to prevent noncardiovascular effects of high triglycerides (i.e., pancreatitis), but the usefulness of lowering triglycerides as a general strategy in prevention of CHD is not generally agreed. Therefore, FDA believes that the triglyceride-lowering effect of fish oils for some at-risk persons does not provide a basis for a health claim at this time.

35. Numerous comments indicated that postprandial triglyceridemia is a mechanism of action in the development of atherosclerosis. Some comments indicated that the relationship of elevated triglycerides to risk of CHD would be discussed at the NHLBI consensus development conference (Ref. 255). Others pointed out that LSRO had concluded that elevated very low density lipoproteins (VLDL) and triglycerides were atherogenic. LSRO stated that the reduction of postprandial hyperlipidemia is a "most important anti-atherogenic action." LSRO wrote in the summary that, "Since postprandial lipemia has been identified as an atherogenic risk factor, its prevention by w-3 fatty acids *would be* a most desirable effect" (emphasis added), and in its conclusions LSRO wrote:

> Fish oil has a generally accepted hypolipidemic effect without depressing HDL. This applies most to VLDL and triglyceride, lipids now believed to be atherogenic. There is little doubt that there is a reduction of postprandial hyperlipidemia following the ingestion of dietary fat if the background diet contains relatively small quantities of w-3 fatty acids. This may be a most important anti-atherogenic action.

FDA agrees that fish oils do not generally lower HDL. FDA also agrees that major blood lipid effects of omega-3 fatty acids are reductions of triglyceride and VLDL. The role of omega-3 fatty acids in the reduction of postprandial triglycerides was described in three papers abstracted by LSRO (Refs. 15, 59, and 163). While the first two papers used high levels of omega-3 fatty acids (30 and 9 g of EPA plus DHA/day, respectively), the recent paper used only 5 g of fish oil, containing 1.7 g EPA plus DHA. These studies showed that the concentration of plasma chylomicrons after a high-fat test meal was significantly less if the subjects had been consuming a fish oil diet than if they had been consuming a saturated fat or olive oil supplemented diet. Thus, FDA agrees that fish oils reduce postprandial lipemia.

However, FDA disagrees that there is significant scientific agreement that VLDL and triglycerides are atherogenic, or that the reduction in postprandial hyperlipemia is a most important anti-atherogenic action. Neither the Federal Government nor other authoritative reports have included these blood lipid measures among those they consider to be independent risk factors associated with CHD (Refs. 34 through 36, and 115). Furthermore, postprandial lipemia was discussed at the February 1992 NHLBI consensus development conference. The summary of that conference stated, "Postprandial triglyceride may be more important than the fasting triglyceride levels [to CHD], but little is known about this at the present time." (Ref. 255).

FDA notes that the only paper in the LSRO report cited in support of this hypothesized mechanism of action of omega-3 fatty acids in the prevention of CHD was a review paper published in 1979 (Ref. 305). Therefore, FDA believes that there is not significant scientific agreement at this time that postprandial triglycerides are related to the risk of CHD.

ii. Vessel wall effects

36. One comment indicated that two new studies support the use of omega-3 fatty acids to prevent restenosis, the closing of a mechanically opened blood vessel (Refs. 172 and 259). This comment suggested that FDA discounted the findings of the Dehmer study (Ref. 30) on the basis that it employed simultaneous treatment with drugs and fish oils.

FDA considered the use of omega-3 fatty acids to prevent restenosis to be a drug usage (56 FR 60663 at 60670), and notes that patients in these studies are under a physician's care. FDA's description of the Dehmer study points out a limitation of the data that is common in other reports of no effect of omega-3 fatty acids in restenosis (Refs. 56, 106, and 121), that the studies have not controlled for generalized effects of PUFA's that are not specific to omega-3 fatty acids. A better balanced experimental design would be comparison of drugs plus omega-3 fatty acids to drugs plus alternate PUFA's (e.g., corn oil).

FDA agrees that the new studies provide some support for the role of omega-3 fatty acids in prevention of restenosis, although neither was designed to distinguish effects of omega-3 fatty acids from effects of omega-6 PUFA's.

Nye et al. (Ref. 259) studied 79 men and 29 women who were referred for angina and underwent coronary percutaneous transluminal angioplasty (PCTA), i.e., a mechanical opening of a closed heart blood vessel. The subjects were randomly assigned to one of three treatments: (1) A combination of aspirin plus dipyridamole (an anti-platelet combination of drugs), (2) olive oil placebo, or (3) 12 milliliters (mL) fish oil containing 3.2 g EPA plus DHA/day. Subjects were restudied 1 year later or before if symptoms recurred, and 93 percent of all subjects were followed for the year. Although there was no significant difference in angina among the groups, the rate of restenosis, defined in this study as a loss of 50 percent or more of the luminal diameter increased by PCTA, was significantly less in the fish oil group (11 percent) than in the placebo group (30 percent).

The use of olive oil as the placebo did not control for effects due to PUFA's (omega-6). Also, it is notable that the restenosis rate in the aspirin group was somewhat higher (17 percent) than in the fish oil group, because aspirin is a much more potent inhibitor of platelet function than EPA in fish oil. Nonetheless, these results are consistent with an effect of omega-3 fatty acids in reducing restenosis.

The full "Quebec study" was published after the receipt of the comment, but because it was cited in the comment it will be discussed here. In this study, Bairati et al. (Ref. 172) conducted a double-blind, randomized intervention with either fish oil containing 4.5 g EPA plus DHA/day, or olive oil placebo in 205 patients undergoing first PCTA. The treatments were started 3 weeks before the procedure, and continued for 6 months after. Restenosis was assessed angiographically, using a quantitative

computer analysis program. Restenosis was reduced in the fish oil group compared to the olive oil group according to 3 of 4 definitions of restenosis. It was not reduced according to the clinical definition used by Nye et al. (Ref. 259), above, of a loss of 50 percent or more of the luminal diameter increased by PCTA.

This study also collected dietary data. The third of the subjects with the highest consumption of omega-3 fatty acids (0.15 g/day) and the third of the subjects with intermediate consumption of omega-3 fatty acids (0.033 to 0.15 g/day) had significantly lower rates of restenosis than the third consuming the least amount of omega-3 fatty acids. In fact, dietary omega-3 fatty acids (other than the supplement) were associated with a greater reduction in chance of restenosis than was the supplement. This result was somewhat surprising, since the supplement contained 30 times the amount of omega-3 fatty acids in the diet. No differences in rate of restenosis were found according to intake of total fat, polyunsaturated fat, monounsaturated fat, saturated fat, cholesterol, or total seafood consumption. These results suggest that chronic consumption of low amounts of omega-3 fatty acids may be as useful in preventing restenosis as much larger amounts consumed for a few weeks prior to and after PCTA.

In general, the results of Bairati et al. (Ref. 172) and Nye et al. (Ref. 259) are consistent, even though they obtained different results according to one identical definition of restenosis. The Bairati et al. study, like Nye et al. 1990, used olive oil as the control. If the mechanism of action of omega-3 fatty acids in restenosis is through competition with AA, this control is suitable, and an omega-6 fatty acid oil would have made the difference due to omega-3 fatty acids even more pronounced. If, however, the mechanism of action is through nonspecific effects of highly unsaturated fatty acids, then a control of a PUFA (e.g., corn oil) might have reduced the apparent effect of omega-3 fatty acids. It is notable that the only study of restenosis that has used a polyunsaturated fat control (an olive oil-corn oil mix) did not find an effect (Ref. 56).

37. Five studies in humans relevant to the actions of omega-3 fatty acids on the vessel wall were referenced in comments (Refs. 200, 213, 259, 268, and 277), including two published since the time period covered by FDA's review in its proposed rule (Refs. 200 and 268). Hamakazi et al. (Ref. 213) found a slower aortic pulse wave velocity (an electro-physiologic measurement) in persons from a Japanese fishing village compared to those from a farming village. Other data showed the populations differed in their intake of omega-3 fatty acids. Rapp et al. (Ref. 268) measured the amount of omega-3 fatty acids in the atherosclerotic lesion after consumption of omega-3 fatty acids at a high level (6 percent of calories, 16 to 21 g EPA plus DHA/day) for 6 to 120 days prior to planned surgical intervention, and found that the amount of omega-3 fatty acids in the lesion continued to increase throughout the time of ingestion. Force et al. (Ref. 200) studied the effects of fish oils and aspirin on the production of urinary metabolites of AA and EPA. Fish oil feeding resulted in a slight decrease in the amount of thromboxane A_2 made in the platelet, a decrease in the amount of AA-derived prostacyclin made in the endothelial cell, and an increase in the amount of EPA-derived prostacyclin made in the endothelial cell. Schmidt et al. (Ref. 277) described decreased monocyte chemotaxis among hypertensive patients after fish oil feeding. The Nye et al. study is discussed in comment 36 of this document.

FDA considers these studies to be observational, not clearly associating omega-3 fatty acids with risk of CHD. The correlation data of Hamakazi et al. do not indicate a specific role for omega-3 fatty acids. The Rapp et al. data verify that it is possible to incorporate omega-3 fatty acids into preexisting atherosclerotic plaque, but the relevance of incorporated omega-3 fatty acids has not been established. The studies of Force et al. and Schmidt et al. relate to a potential mechanism of action of omega-3 fatty acids, but the importance of these actions in reducing risk of CHD has not been established.

38. Many comments stated that the biochemical and physiological actions of omega-3 fatty acids are anti-atherogenic because they favor vasodilatation and inhibit vasoconstriction. One comment by a manufacturer of omega-3 fatty acids considered these actions have potential for future significance. Two comments cited a list of effects of omega-3 fatty acids, suggesting that each of the effects in the list was anti-atherogenic, and other comments referred to one or more of the components in the list. The listed changes were:
decreased thromboxane;
increased prostacyclin and leukotriene (LTB_4);
decreased fibrinogen;
decreased platelet activating factor (PAF);
decreased platelet-derived growth factor (PDGF);
decreased superoxide;
decreased interleukin-1 (TNF);
increased endothelium-derived relaxation factor (EDRF);
decreased lipoprotein (a) (Lp(a));
reduced inflammatory response; and
increased fibrinolytic activity.

The LSRO report stated that other mechanisms, such as cellular growth factors, interleukin-1 and cytokins, and EDRF may be important in the development of atherosclerosis, and be affected by omega-3 fatty acids. However, except for a single in vitro study on PDGF, no data are described in the report regarding these factors, nor is their relevance to human CHD discussed.

FDA addresses fibrinogen, Lp(a), and fibrinolytic activity in comment 46 and in section II.C.2. of this document. FDA does not agree that omega-3 fatty acids produce changes in all of the listed parameters. FDA has determined that for some of these endpoints the changes have not been shown to be specific to omega-3 fatty acids, but may be due to polyunsaturated fats instead. FDA disagrees that the changes brought about by omega-3 fatty acids will prevent atherosclerosis. Most of the data regarding changes in these endpoints brought about by omega-3 fatty acids have been derived from tissue culture or animal experiments, and the relevance to human atherosclerosis has not been demonstrated.

Thromboxanes and prostacyclins are compounds derived from omega-3 fatty acids and omega-6 fatty acids that affect the relaxed state of the blood vessels. Thromboxanes are produced primarily in platelets, and prostacyclins are produced primarily in the endothelial cells of the blood vessels. The thromboxane made from an omega-6 fatty acid called AA, thromboxane A_2, is a potent vasoconstrictor. EPA competes with AA for the enzyme that makes thromboxane A_2, and thereby diminishes the rate of production of thromboxane A_2; the thromboxane made from EPA is a much less potent vasoconstrictor. The prostacyclins made from AA or EPA in the endothelial cells are vasodilators. Thus, the relative amounts of AA and EPA in platelets and endothelial cells play a role in determining the form and amounts of the prostaglandins and thromboxanes that affect the tension of the vessel wall. Excessive constriction may lead to an occlusion, resulting in a heart attack. While there is general recognition that these vasoactive compounds may play a role in the formation of clots and thereby in heart attacks, there is no

agreement about the extent of changes needed in the concentrations of the vasoactive compounds in order to have an effect on heart disease. Changes in the amounts of these vasoactive compounds, produced by consumption of fish oil, are only useful as marker for CHD only insofar as there is significant scientific agreement that the magnitude of the changes is related to CHD. FDA is not aware of any such agreement, nor did the comments provide any evidence of agreement that particular changes in the levels of these vasoactive compounds were related to a reduction in risk of disease. Furthermore, the amount of omega-3 fatty acids needed to produce these changes in humans is not known.

For PDGF the evidence is confined to animal studies (Ref. 201), and the relevance to human disease has only been suggested, not demonstrated. The animal studies on PDGF also did not show that the effect was specific to omega-3 fatty acids. For example, the PDGF effect was observed also after polyunsaturated fats, and was abolished by anti-oxidants, suggesting that any highly unsaturated fatty acids prone to oxidation would have the effect. The experiments on EDRF (Ref. 181) also did not show that the effects were specific to omega-3 fatty acids, since the experiments were carried out in the presence of indomethacin, which blocks the eicosanoid effects of EPA. In fact, the authors consider changes in membrane fluidity to be a reasonable explanation for the effects. In yet other cases, e.g., TNF, there are conflicting results depending on the species (Refs. 41 and 236), and the findings must be considered preliminary.

FDA considered the effect of omega-3 fatty acids on chemotaxis, one aspect of inflammatory response (56 FR 60663 at 60670). A complete discussion of the role of fish oils in inhibition of the inflammatory process is outside of the scope of this rulemaking, but the relationship between omega-3 fatty acids and inflammatory response could be the subject of a petition for a health claim that includes the necessary information about this relationship.

FDA agrees that the biochemistry of the products formed from the omega-3 fatty acids in vivo (i.e., eicosanoids) have been shown under experimental conditions, usually in vitro, to have pronounced effects on the vessel wall. However, demonstration of isolated biochemical effects is not a sufficient basis upon which to make a claim regarding the outcome of a multifactorial process. Intermediate markers of CHD are useful only insofar as there is significant scientific agreement that changes in these markers produced by omega-3 fatty acids are causally related to CHD.

b. Thrombosis and hemostasis

39. A few comments stated that the mode of action of omega-3 fatty acids may be through stabilization of arrhythmia, and noted the reduced rate of death after heart attacks (MI's) in the Dart study (Ref. 16). This comment also stated that certain animal data were consistent with this hypothesis. The comments stated that the fibrillation mechanism suggested by DART was compelling, because 60 percent of sudden deaths are caused by ventricular fibrillation following reperfusion. Many commented that data from nonhuman primate models show that omega-3 fatty acids abolish arrhythmias, whereas polyunsaturated fat (safflower oil) had a lesser effect.

FDA disagrees with these comments. FDA's review of the literature regarding the usefulness of omega-3 fatty acids in arrhythmia and ventricular fibrillation found only one study on arrhythmias in humans, and it reported no significant effect of omega-3 fatty acids (Ref. 58). A review in 1989 also concluded that, even among the animal studies, there was no significant difference between omega-3 fatty acids and other polyunsaturated fats on arrhythmias (Ref. 269).

The data from the studies in nonhuman primates (i.e., the marmoset monkey) were published only as a nonpeer-reviewed paper in a book (Ref. 188). Two papers by the same author on the same topic were cited in 1990 as in press in a peer-reviewed journal, but have not yet been published. Therefore, FDA regards the data on nonhuman primates as preliminary only. Furthermore, the data for the marmoset monkey were obtained after prolonged feeding for 12 or 24 months with a supplement of DHA-rich fish oil at a level of 8 percent of the diet by weight. FDA calculates that this would provide 2.5 g of omega-3 fatty acids from fish oil/kilogram (kg), over 50 times the usual rate of supplementation in human studies (10 g fish oil or 3 g omega-3 fatty acids/day for a 70 kg subject), and over 300 times the amount of omega-3 fatty acids associated with reduced risk of CHD in the epidemiologic literature (Refs. 16, 38, and 87 report 300 to 660 milligrams (mg)/day). Thus, the relevance of these studies to omega-3 fatty acids in the human diet is questionable.

FDA is aware of in vitro data that show a specific protective effect of EPA against toxicity of heart muscle cells in culture. These results provide a biochemical basis for the hypothesized stabilization of cardiac arrhythmias by omega-3 fatty acids. Although this study (Ref. 212) was performed in vitro on heart cells from rats, it showed that the protective effect was specific to omega-3 fatty acids (EPA) because a similar effect was not obtained when a highly unsaturated omega-6 fatty acid (AA) was used instead.

FDA also regards the evidence from the Burr study of reduced death following a heart attack among those men advised to increase fish consumption as consistent with a stabilization of arrhythmias (Ref. 16). FDA agrees that this postulated mechanism of action is of great potential public health significance. However, the agency finds the clinical data available at this time are not in agreement with animal and in vitro data. Because the clinical data are not in agreement with these other types of data and because of the limitations in the animal studies, FDA concludes that there is not sufficient basis for protective effect specific to omega-3 fatty acids on arrhythmias, and, therefore, CHD in humans.

40. One comment criticized the 6-week clinical study by Hardarson et al. that found no effect of omega-3 fatty acids on arrhythmias (Ref. 58), arguing that the time for incorporation of omega-3 fatty acids into heart phospholipids was too short for an effect to be observed.

FDA agrees in part and disagrees in part with this comment. Generally, the time needed for incorporation of omega-3 fatty acids into cellular phospholipids is short; studies in animals show such incorporation in a period of weeks (Ref. 249). In the Hardarson study (Ref. 58), a substantial amount of cod liver oil was fed (20 mL/day) and a 230 percent increase in plasma phospholipid EPA was found. There was no trend toward reduced arrhythmias. Other data, however, show that although plasma phospholipids increase the omega-3 fatty acid content during the first few weeks of supplementation, the incorporation of omega-3 fatty acids in human atherosclerotic plaque continues to increase through 120 days (Ref. 268). Therefore, FDA agrees with the comment the supplementation period in the Hardarson study (Ref. 58) may have been too short to find an effect of fish oils on occurrence of arrhythmias. Also, the agency notes that the absence of a difference in CHD mortality during the first 6 weeks of the Burr study (Ref. 16) is consistent with the hypothesis that prolonged intake of omega-3 fatty acids (longer than 6 weeks) is needed to observe an effect on arrhythmias or

other mechanisms that reduce CHD mortality. FDA agrees that effects of long-term consumption of omega-3 fatty acids on arrhythmias, other platelet or vessel wall functions, and even some blood lipid measures have not been sufficiently studied.

i. Bleeding times

41. Two comments stated that there is no evidence of increased bleeding even among patients who had ingested 6 to 8 g of EPA plus DHA/day and underwent emergency surgery, coronary artery bypass surgery or angioplasty. The comments argued that increased bleeding has not a safety concern.

FDA agrees that there are few reports of excessive bleeding after ingestion of omega-3 fatty acids. However, FDA notes that the cited reports are for subjects with CHD, and evidence of the lack of excessive bleeding complications in this population is not sufficient to assure safety of omega-3 fatty acids in the general population. FDA believes that changes in bleeding due to consumption of omega-3 fatty acids remains a valid safety concern (see comment 52 of this document).

ii. Platelet aggregation

In the proposal, FDA stated:

> The relationship between platelet aggregation and the risk of heart attacks or CHD death in the general population is an important line of evidence that would support drug claims and perhaps health claims for omega-3 fatty acids. Although there is some evidence that changes in platelet aggregation may help prevent second heart attacks * * * it has not been shown that changes in platelet aggregation in the general population will reduce the risk of CHD.

(56 FR 60663 at 60670.)

The agency added: "What has not been established, however, is that platelet aggregation is a bona fide surrogate risk factor for CHD in the general population." (56 FR 60663 at 60672.)

42. Many comments argued that platelet aggregation is completely substantiated as a marker for risk of CHD, based on the results of the Physicians' Health Study (Ref. 66). One comment qualified this conclusion stating that the primary effect of omega-3 fatty acids in vivo was to reduce platelet deposition at sites of aortic lesions.

FDA acknowledges that aspirin studies provide evidence that platelet aggregation is a risk factor for CHD. The effect of aspirin in inhibiting platelet function has been shown. Among persons who have already had an MI, aspirin is effective in preventing a second infarction. FDA has proposed that aspirin be used to reduce the risk of death and/or nonfatal heart attack in patients with previous infarction or unstable angina pectoris as a professional labeling indication (provided to health professionals, but not to the general public), in the tentative final monograph for over-the-counter internal analgesic, antipyretic, and antirheumatic drug products (November 16, 1988, 53 FR 46204 at 46259). However, FDA does not consider the effects of aspirin in the Physicians' Health Study sufficient to establish that dietary omega-3 fatty acids would have the same effect in the general population. The Physicians' Health Study did not evaluate omega-3 fatty acids. The study population was highly selected; the rate of heart attacks was approximately 10-fold lower than in the general population, and cardiovascular mortality was only 15 percent of that expected for the general population of white men of the same age. Also, the results of the Physician's Health Study are not as straightforward as presented in the comments. The chairman of the Physicians' Health Study reported that there was a reduced risk of MI in the aspirin group, predominantly in nonfatal MI, but that there was no significant effect on overall cardiovascular mortality (a 2 percent reduction, not statistically significant) (Ref. 66). In addition, the aspirin group in this study had a greater number of sudden deaths (Ref. 282).

In the other primary prevention trial (Ref. 265), aspirin did not have any significant effect on heart attacks, on stroke, or on total vascular mortality. There was a significant increase in disabling stroke in the group taking aspirin.

On the basis of these studies there has not been an endorsement of the use of aspirin as a prophylactic measure against CHD by the general population by the American Heart Association or by the Canadian Medical Association (Ref. 187). Notably, "1992 Heart and Stroke Facts" published by the American Heart Association (Ref. 169) makes no reference to platelet aggregation as a risk factor for heart attacks (although sticky platelets are mentioned to be a consequence of cigarette smoking in the section on stroke), nor is aspirin discussed as an option for CHD prophylaxis, even though other drug and surgical treatments are discussed.

Therefore, FDA concludes that there is not significant scientific agreement at this time that platelet aggregation is a surrogate marker for CHD in the general population.

43. The LSRO report, submitted as a comment, contained abstracts of 19 studies in humans that contained data regarding changes in platelet function following omega-3 fatty acid consumption. LSRO concluded that omega-3 fatty acids prevented platelet aggregation.

In its proposal, FDA stated: "Platelet aggregation is generally considered to be decreased by fish oil consumption." (56 FR 60663 at 60670.) The agency also stated: "* * * platelet aggregation and function are reduced. However, direct relationships between the changes in * * * platelet function and risk or CHD have not been established." (56 FR 60633 at 60671.) Thus, FDA agrees with the conclusions of LSRO about effects of omega-3 fatty acids on platelet aggregation.

Two of the studies described by LSRO were not considered by FDA in its review, because they were published before 1988, and had been considered by Federal Government and other authoritative reports. One study (Ref. 227) used a large amount of fish oil (50 mL/day) not reasonably related to normal dietary intake. The other study (Ref. 211) involved 13 insulin-dependent diabetics, and therefore is of questionable relevance for the general population.

In its proposed rule, FDA considered 13 of the other 17 studies that were abstracted by LSRO. One of the four studies not addressed by FDA was a study on the effects of added vitamin E to fish oil on fibrinogen and fibrinolysis (Ref. 210). Two papers (Refs. 234 and 244) were published after the time period covered by FDA review. Marckmann et al. (Ref. 244) compared the effects of a fish diet and a lean meat diet on plasminogen activator (t-PA), plasminogen activator inhibitor (PAI–1) and the activity of the inhibitor (PAI–1 activity). Li and Steiner (Ref. 234) described changes in in vitro platelet adhesion after fish oil supplementation. The fourth paper was an uncontrolled observation study that found a high frequency of nosebleeds in adolescents supplemented with fish oils (Ref. 189).

Six other papers on thrombosis were not described in the LSRO text, but were included in the table (Refs. 203, 204, 209, 226, 245, and 254). Of these six, one was not relevant to the nutrient-disease relationship (Ref. 245) because it did not study EPA and DHA. Jensen et al. (Ref. 226) found no significant change in bleeding times in normal subjects after 1, 3, or 6 g EPA plus DHA/day in healthy subjects. Green et al. (Ref. 209) found no change in platelet aggregation or platelet count in 27 hyperlipidemic subjects in a randomized double-blind placebo controlled crossover trial. The treatments were 15 g/day fish oil

containing 4.3 g EPA plus DHA and a 50:50 mix of corn:olive oil, with each treatment lasting 8 weeks, and a 4-week washout between. Blood viscosity was decreased by fish oil. Gazso et al. (Ref. 204) found decreased platelet aggregation in healthy subjects after consumption of EFAmol-marine compared to olive oil in a double-blind randomized crossover study. These results of studies confirm others cited by FDA. The other studies (Refs. 203 and 254) pertained to regulators of bleeding and are discussed below.

Eight papers on platelet function were reviewed by FDA but not by LSRO (Refs. 2, 6, 18, 24, 73, 93, 131, and 143). Three studies were uncontrolled (Refs. 18, 93, and 143), while two were randomized (Refs. 2 and 131). Three were randomized, double-blind, placebo-controlled trials that used saturated vegetable oil (Ref. 6), vitamin E (Ref. 24) or wheat germ oil (Ref. 73) as the placebos. The two studies that used vegetable oil or vitamin E as controls found a reduction in platelet aggregation after omega-3 fatty acids, where no difference was reported in the trial that used a wheat germ oil placebo, although the data were not provided in this paper.

FDA and LSRO reached the same conclusions with regard to the effects of omega-3 fatty acids on platelet function. LSRO also concluded that platelet survival is also enhanced, but the only two studies published since 1987 that reported increased platelet survival (Refs. 94 and 144) were both uncontrolled, so the effect cannot be attributed specifically to omega-3 fatty acids.

44. One comment agreed in principle with the agency's assessment of the effects of omega-3 fatty acids on bleeding times, platelet aggregation, regulators of bleeding and blood pressure. The comment pointed out the extent of inhibition of platelet adhesion is as much as 60 percent, a marked reduction in adhesion.

FDA agrees that the reported extent of reduction of platelet adhesion from omega-3 fatty acid intake is remarkable (Ref. 234). The agency notes that this effect appears specific to omega-3 fatty acids at reasonable intake levels. FDA notes that animal studies (Refs. 230 through 233) published since the proposed rule provide evidence of reduced platelet adhesion to blood vessel endothalium in vivo in response to agents that provoke such adhesion. Because of the magnitude of the effect of omega-3 fatty acids on platelet adhesion, FDA considers this action of omega-3 fatty acids on blood platelet function to have great potential with regard to the development of atherosclerosis and the risk of CHD. However, as for platelet aggregation, FDA does not believe that there currently is significant scientific agreement that platelet adhesion is an accepted risk factor for CHD in the general population.

iii. Regulators of bleeding

In its proposal (56 FR 60663 at 60670 through 60671), FDA reviewed data on the effects of omega-3 fatty acids on other factors that are involved in the regulation of bleeding—fibrinogen, fibrinolytic activity and Lp(a)—and that have been associated with CHD.

45. Some comments, including the LSRO report, stated that omega-3 fatty acids increase fibrinolysis.

FDA disagrees with these comments. FDA found that there was no clear relationship between omega-3 fatty acids and factors involved in dissolving blood clots (56 FR 60663 at 60671). FDA noted that the data did not establish that omega-3 fatty acids reduced fibrinogen, because most studies did not control for other factors that might have reduced fibrinogen, e.g., other PUFA's.

FDA has reviewed the relevant studies again, as well as studies brought to its attention in the LSRO report. LSRO cited three papers on fibrinogen or fibrinolysis not cited by FDA. One placebo (vitamin E) controlled study found no change in fibrinolytic activity (Ref. 210). Mullertz et al. (Ref. 254) supplemented seven healthy adults with 0.55 g EPA plus DHA/day for 21 days and found increased levels of PAI–1, but no change in t-PA, suggesting that fish oil decreased fibrinolytic capability. Gans et al. (Ref. 203) reported no change in fibrinogen concentration after EFAmol-marine compared to corn oil, which is rich in polyunsaturated fat. These studies do not support the conclusion that omega-3 fatty acids reduce fibrinogen, or increase fibrinolysis.

The selection of studies abstracted by LSRO may not have represented the publicly available scientific evidence. For example, five papers abstracted found either a decrease in fibrinogen or an increase in fibrinolytic activity (Refs. 57, 71, 98, 104, and 117). In contrast, two studies found no change in fibrinolytic activity (Refs. 150 and 166), and only one found increased fibrinogen (Ref. 144), leaving the impression that omega-3 fatty acids usually have been reported to enhance fibrinolysis.

However, three other studies not abstracted by LSRO but included in their tables reported no effect of omega-3 fatty acids on fibrinogen compared to corn oil (Refs. 10, 118, and 203). One found a decrease compared to olive oil (Ref. 49) and one found a decrease compared to soybean oil only when 30 mL of fish oil were consumed, but not when 15 mL were consumed (Ref. 57). Additional well-designed studies not cited by LSRO, but considered in the FDA proposal, reported no change (Ref. 24) and an increase (Ref. 131) in fibrinolytic activity.

Therefore, FDA stands by its earlier conclusion that the publicly available scientific evidence does not support a relationship between omega-3 fatty acids and decreases in fibrinogen or increases in fibrinolysis. This conclusion is supported by findings that consumption of other PUFA's have effects comparable to those produced by consumption of omega-3 fatty acids.

46. Two comments cited unpublished data by Kostner and Herrmann, reporting reduced Lp(a) after fish oil consumption.

FDA was unable to find the full paper by these authors showing the decrease in Lp(a). FDA did find a paper by these researchers published in 1991 (Ref. 241) that reported no effect of fish oils on Lp(a) and did not cite conflicting work from their laboratory.

iv. Blood pressure

In its proposal, FDA considered the relationship between omega-3 fatty acids and blood pressure, one of the recognized risk factors for CHD. FDA stated:

> These results for effects of omega-3 fatty acids on blood pressure of normal subjects are ambiguous. Some studies found a reduction in systolic blood pressure after consumption of fish oils containing omega-3 fatty acids, whereas others did not. None of the studies found a significant reduction in diastolic blood pressure. Therefore, it also remains to be established that the normal, healthy population will reduce their risk of CHD via a reduction in blood pressure following consumption of omega-3 fatty acids.

(56 FR 60663 at 60671.)

FDA also stated that it was not known whether or not the magnitude and duration of the effect would persist after longer term supplementation. FDA recognized that studies among hypertensives found an effect more consistently than studies among normal subjects, although sometimes large amounts of fish oils were used.

47. Some comments considered the effects of omega-3 fatty acids on hypertension as evidence of a reduction in CHD risk. Other comments called for FDA to reassess the studies on blood pressure. One of these comments argued that the results of studies on blood pressure are not "completely"

ambiguous. One comment agreed in principle with the agency's assessment of the blood pressure studies. One comment considered a number of animal models to be relevant for hypertension. The LSRO report also considered the evidence relating omega-3 fatty acids to blood pressure to be important in relation to CHD. The LSRO report concluded that, "Fish oil probably has a mild hypotensive effect, especially in high doses."

FDA disagrees that the publicly available scientific evidence supports a relationship between omega-3 fatty acids and hypertension. At best, as stated in the proposal, the data are ambiguous. Qualifiers are needed to indicate that the reductions in blood pressure have not generally been shown to be specific to omega-3 fatty acids. Also, many valid studies have reported no effect.

LSRO reported a total of 13 studies on hypertension. Four were published before 1988, and were not reviewed by FDA in the proposed rule. Three of these studies used fish as the source of omega-3 fatty acids and therefore did not show the effect specifically to be due to omega-3 fatty acids. In fact, in one study (Ref. 292), the control diet of meat produced a decrease in blood pressure comparable to that of the fish diet. The study that used fish oils (Ref. 271) used an olive oil control, rather than an oil high in PUFA's. This study is the only study to show an effect of omega-3 fatty acids on diastolic blood pressure in normal subjects.

Of the other 10 studies on hypertension described in the LSRO report, 6 were also reviewed by FDA (Refs. 11, 57, 80, 85, 95, and 101). The LSRO and FDA interpretations of the results from these papers did not differ in any significant regard, except that FDA specifically noted that two of these studies (Refs. 85 and 95) used very high amounts (50 mL) of fish oil to show the effect. In fact, FDA singled out the Bonaa et al. (Ref. 11) and Kestin et al. (Ref. 80) studies as well-designed studies that showed an effect specific to omega-3 fatty acids in hypertensive and normal subjects, respectively (56 FR 60663 at 60671).

The LSRO report reviewed four papers not originally reviewed by FDA (Refs. 190, 285, and 299), including one study on linolenic acid outside of the scope of the definition of omega-3 fatty acids as used in this regulation (Ref. 262). Two other papers that appeared in the LSRO table but not in the text (Refs. 203 and 247) were also not reviewed by FDA in its proposal.

FDA agrees with the LSRO interpretation of the Wing et al. study (Ref. 299), where subjects remained on blood pressure lowering medications and no effects of added fish oils were observed.

FDA disagrees with the LSRO descriptions of the Singer and Cobiac studies. The placebo in the Singer study (Ref. 285) was olive oil, but this was not pointed out in the LSRO text. The reduction of blood pressure observed after fish oil, therefore, may have been due to a general unsaturated fatty acid effect not specific to omega-3 fatty acids. In the description of the Cobiac et al. study (Ref. 190), LSRO did not note that fish oil treatment alone (without simultaneous reduction of salt) had no effect on blood pressure.

Two other studies were cited in the LSRO tables but not in the text and were not included in the FDA review. Neither of these found an effect on blood pressure. Gans et al. (Ref. 203) used a randomized double-blind, placebo-controlled design and found a reduction in diastolic blood pressure for both fish oil and corn oil (placebo). Meland et al. (Ref. 247) carried out a randomized, double-blind multicenter trial among 40 mildly hypertensive subjects, using 6.8 g EPA plus DHA/day, but found no difference in blood pressure compared to a 50:50 olive:corn oil control.

Three other large and appropriately controlled studies not in the text of the LSRO report but included in its table were also reviewed by FDA. Two randomized studies on normal subjects (Refs. 9 and 49) and one controlled study among mildly hypertensive subjects (Ref. 20) reported no differences in blood pressure attributable to omega-3 fatty acids.

FDA reviewed in its proposal three other randomized, double-blind, placebo-controlled studies among healthy subjects that were not included in the LSRO review. Two of these studies were on normal, healthy subjects (Refs. 6 and 24) and found a decrease in systolic blood pressure compared to a saturated vegetable oil or vitamin E, respectively. The third study (Ref. 73) found that omega-3 fatty acids did not affect blood pressure in hypertensives or normal men compared to wheat germ oil.

Therefore, FDA concludes that the evidence of an effect of omega-3 fatty acids on blood pressure in normal subjects is ambiguous, because some studies reported a blood pressure lowering effect, whereas other equally well-designed studies found no specific effect. Studies among hypertensives found an effect more consistently than studies among normal subjects, although sometimes large amounts of fish oils were used, and many studies did not show that omega-3 fatty acids were more effective than other polyunsaturated fats.

48. Comments stated that other lines of evidence were not discussed in the proposal. Examples given were changes in plasma viscosity, increased vascular compliance, and reduced white blood cell (WBC) count.

FDA disagrees with the comment with respect to plasma viscosity and vascular compliance. In its proposed rule, FDA acknowledged that plasma viscosity was decreased and red cell deformability was increased by omega-3 fatty acids, but that the importance of these effects on the risk of CHD had not been established (56 FR 60663 at 60670).

The agency agrees that it did not systematically consider WBC count among the effects produced by omega-3 fatty acids. WBC count was not included among the actions of omega-3 fatty acids considered in major reviews. FDA notes that WBC count has only recently been identified as associated with risk of CHD by the Caerphilly Collaborative Heart Disease Study (Ref. 301a). Only two papers among literature from 1988 to present have reported a reduction of WBC count after fish oil supplementation (Refs. 183 and 253).

3. Other relevant information

a. Animal studies

49. Numerous comments asserted that animal studies did not receive an appropriate amount of discussion. One of these same comments stated that animal studies are not sufficient to support the claim, and that clinical trials on effects of omega-3 fatty acids directly on CHD are needed. One comment criticized FDA's review of animal studies because the negative findings have been in inappropriate models and should not have been discussed. Another comment stated that they did not believe that there is an appropriate animal model for human cardiovascular and CHD. The LSRO report considered animal studies to provide important evidence for an anti-atherogenic effect of fish oils, stating, "Omega-3 fatty acids have been shown to retard the development of the atherosclerotic plaque in experimental animals including the pig and rhesus monkey."

FDA agrees that the evidence from studies in animals warrants additional discussion. FDA has reviewed here those animal studies that were cited in its proposed rule and those that were cited in the LSRO report that were relevant to the development of atherosclerosis. Other animal studies relevant to the development of

atherosclerosis, and animal studies on aspects of CHD other than atherosclerosis are reviewed under section II.C.3.a. of this document.

In its proposal, FDA cited eight animal studies and one abstract on the development of atherosclerosis that were not included in the LSRO review (Refs. 19, 51, 65, 81, 97, 123, 126, and 151), seven of which reported either no beneficial effect or an adverse effect in fish oil supplemented animals. Only one animal study on the effects of omega-3 fatty acids on restenosis was abstracted by LSRO, although the others cited by FDA were described in the LSRO tables.

Three studies in nonhuman primates have been reported (Refs. 27, 47, and 116). In the Davis et al. (Ref. 27) and Parks et al. (Ref. 116) studies, the polyunsaturated fat intake was higher in the fish oil groups, and polyunsaturated fat is known to lower total plasma cholesterol. Also, the control diet of the Davis et al. study had more saturated fat than the fish oil diet. Thus, the effects on atherosclerosis may not have been specific for omega-3 fatty acids.

In these studies, the total cholesterol values for the fish oil groups were substantially lower than for the control group, which may explain the observed differences in atherosclerosis. In support of this interpretation, Parks et al. (Ref. 116) noted that one of monkeys fed the fish oil diet responded differently than the other 11 monkeys fed fish oil. This one monkey had a plasma cholesterol level comparable to that of the lard-fed control monkeys, and also had atherosclerosis comparable to the lard-fed monkeys.

Changes in total cholesterol levels were noted by authors of another study in pigs that showed a reduction in atherosclerosis concomitant with a reduction in time-weighted total cholesterol (Ref. 81). Since cholesterol concentrations are not changed by fish oils in humans, animal studies where fish oil treatment lowered total cholesterol levels are of questionable relevance to the role of omega-3 fatty acids in the development of human atherosclerosis.

A recent study (Ref. 47) in nonhuman primates (vervet) compared the effects of fish oil supplementation to sunflower oil supplementation in either an atherogenic diet (high fat, low polyunsaturated fat to saturated fat ratio, high cholesterol) or, following the atherogenic diet, in a therapeutic diet (low fat, high polyunsaturated fat to saturated fat ratio and low cholesterol). Animals in each diet group were matched for serum cholesterol. Sixteen separate measures of atherosclerosis were scored, including various measures of the extent of plaque, loss of endothelium, intimal thickening, and inflammation. Overall there was no benefit of fish oil; in some cases, the atherosclerotic measure indicated more disease in the fish-oil fed animals.

The LSRO report considered the amount of fish oil in the diets in this experiment (1.3 to 1.8 percent of calories) too low to observe an effect. In fact, FDA calculates a lower percent of calories from fish oil (1.0 to 1.5 percent) than calculated by LSRO. This level is about half the amount used in short-term human studies (i.e., 10 mL/day), and FDA agrees that the low level makes it less likely that an effect would be observed than if a higher amount had been used. However, diets were supplemented for a prolonged period of time (20 months) and in the therapeutic diet other dietary factors were also changed that might have made the effects of omega-3 fatty acids more noticeable (e.g., ratio of polyunsaturated to saturated fatty acids). Finally, the fact that there were differences between the fish oil-supplemented group and the polyunsaturated fat group while on either the atherogenic or therapeutic regimens suggests that there was sufficient sensitivity in the experimental design to detect protective effects of omega-3 fatty acids.

In some animal studies that showed a protective effect of fish oils, an invasive procedure was used to accelerate atherosclerosis, either mechanical injury (Ref. 122) or vein grafts (Refs. 90 and 186). These studies may be most relevant to the late stages of atherosclerosis, and to CHD in humans following invasive procedures. All of the animal studies cited in the LSRO report except Kim et al. (Ref. 81) and Fincham et al. (Ref. 47) did not control for PUFA's, so the effects observed have not been shown to be specific to omega-3 fatty acids. Additionally, the level of use of fish oils has been high, e.g., 22 percent of calories in Parks et al. (Ref. 116) and 25 percent of the diet in Davis et al. (Ref. 27), which limits the extrapolation of findings in these studies to levels that might be reasonably consumed by humans.

FDA disagrees with the summary of the literature in animals, as expressed in the LSRO report, because that report fails to mention important limitations in the data. FDA notes that most studies did not have an adequate design to show specificity of effects as due to omega-3 fatty acids. Furthermore, reductions in total cholesterol in the fish oil fed animals may explain the reported reductions in atherosclerosis. Since reasonable amounts of fish oils in human diets do not alter serum cholesterol concentrations, the results from these animal experiments are of questionable importance regarding human atherosclerosis. Finally, LSRO did not review numerous animal studies that found no effect or an adverse effect of supplementation with fish oils, and therefore the LSRO conclusion does not represent the totality of publicly available scientific information.

With these qualifications in mind, FDA notes that some of the reported effects of the dietary interventions with fish oils on the development of atherosclerosis have been dramatic. Also, FDA recognized that animal studies are of great importance for study of long-term effects on chronic diseases of consumption of amounts of omega-3 fatty acids, particularly in amounts that might be obtained in a reasonable diet. Therefore, FDA encourages further research in this area using rigorous study designs and amounts of omega-3 fatty acids reasonably available in a normal diet to elucidate any effects specific to these fatty acids.

After closer scrutiny of the animal studies cited in FDA's proposal and in the LSRO report, the agency has reached the same conclusion that it reached in its proposed rule: there are some data in studies from animals which suggest the possibility of a beneficial effect of omega-3 fatty acids on CHD; however, the data are equivocal. (56 FR 60663 at 60671.)

b. Safety considerations

50. One comment stated that the increases in LDL cholesterol observed were a chance occurrence, and another stated that increased LDL should not be considered an adverse finding in light of the results of the Burr study.

FDA disagrees with this comment. FDA found that increased LDL cholesterol was ordinarily found when hyperlipidemics or diabetics were given fish oil supplements. This may be due in part to the fact that fairly large amounts of omega-3 fatty acids (i.e., 5 g EPA plus DHA/day or more) were used in these studies. Increased LDL is not ordinarily seen in the studies on normal subjects.

FDA does not consider the Burr study (Ref. 16) to have established that omega-3 fatty acids reduce the risk of CHD, and therefore remains concerned that increases in LDL cholesterol could be adverse for some subjects. FDA notes that concern about increased LDL cholesterol was expressed in the report of the NHLBI consensus development conference (Ref. 255).

51. One comment stated that it was inappropriate to consider adverse effects

in subpopulations without describing the advantages of omega-3 fatty acids in those same populations.

FDA disagrees with this comment. As noted in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, it would be a violation of the agency's responsibility under the act to authorize a health claim about a substance without being satisfied that the use of the substance was safe. The agency attempted to examine all available scientific evidence regarding the effects of omega-3 fatty acids. FDA separated out the potential adverse effects discovered during its review, because it wanted to draw attention to these issues as impediments to a health claim for omega-3 fatty acids and CHD. Such potential adverse effects must be resolved, and may be important in setting the conditions under which FDA would allow a health claim to appear on the label and labeling of foods and food supplements.

52. Two comments stated that the safety issues raised in the Mitre Corp. report (Ref. 72) were outdated but did not indicate which issues, or suggest why they were outdated.

FDA recognizes that there has been considerable debate regarding the clinical importance of bleeding times since the publication of the Mitre Corp. report (Ref. 72). However, the agency believes that the issues raised in that report have been restated in subsequent literature, and that all issues of safety are important in deciding whether or not to authorize a health claim.

53. A few comments recommended that FDA balance the benefits of reduced risk of CHD against the risk of reduced glycemic control among diabetics when deciding whether or not to authorize a health claim. One comment stated that physicians could adjust the dose of insulin if omega-3 fatty acids reduced their glycemic control, but another comment stated that glycemic control must be considered a real adverse effect.

FDA agrees that limitations on the use of a substance by a subpopulation (e.g., diabetics) do not necessarily exclude a substance from bearing a health claim for the general population, because the claim may be appropriately restricted. However, FDA agrees that the loss of glycemic control is a potentially serious adverse effect that must be fully addressed before a health claim could be authorized.

54. Another comment stated that a major concern about omega-3 fatty acids not mentioned in the proposed rule is that they may be oxidized and, as oxidized products, may have adverse effects.

FDA agrees that oxidation of omega-3 fatty acids is a concern. In fact, there are many studies that have been reported since the publication of the proposed rule, or that were not included in FDA's literature review, that indicate such a concern (Refs. 184, 210, 217, 229, 240, 248, 263, 283, and 290).

Antioxidants have been successfully added to supplements and may be adequate to protect the omega-3 fatty acids in foods. It may be necessary to establish conditions that protect against oxidation of omega-3 fatty acids and incorporate those conditions into any future regulation authorizing health claims for omega-3 fatty acids.

55. A related comment indicated that the majority of the fish oil preparations that have been used are severely oxidized, including National Institutes of Health Fish Oil Test Materials. However, no data regarding the extent of oxidation, the nature of the oxidation products, or the physiologic action of these products was provided.

FDA agrees with this comment. Many of the biologically active products of omega-3 fatty acids are oxidation products. Oxidation of test materials may explain some contradictory findings in the literature.

56. One comment pointed out that increased prothrombin times and possibility of increased stroke were not discussed.

FDA agrees with this comment. FDA did not specifically review data on prothrombin times, although data on bleeding times as a measure of hemostasis were discussed for both normal subjects and for subjects with risk factors for CHD. The importance of the increase in bleeding time brought about by supplemental fish oils or increased fish consumption is not clear. FDA noted in the proposal that most reports suggest that serious bleeding is not an issue in patients supplemented with omega-3 fatty acids, and also that standardized bleeding times do not closely correlate with clinically significant bleeding. However, concerns about untoward bleeding after supplemental fish oils have been raised in the literature (Refs. 106, 120, and 189).

FDA did not discuss the possibility of increased occurrence of stroke as a consequence of increased consumption of omega-3 fatty acids. The papers that reported a correlation between high consumption of omega-3 fatty acids from fish and other marine animals and low rate of CHD mortality also noted an increase rate of stroke, particularly hemorrhagic stroke (Refs. 8 and 84). Also, the possibility of increased rates of stroke are raised by the data from studies on aspirin (Ref. 66).

Thus, FDA considers these potential adverse reactions to be legitimate concerns, primarily in the context of very high intakes of omega-3 fatty acids.

57. One comment stated that even if adverse effects were only suspected in a medical disorder, pronounced warnings or contraindications would be required.

As noted above, the agency must be satisfied that the use of a substance is safe before it will authorize a health claim about the substance. Thus, suspicions about potential adverse effects would need to be resolved prior to the authorization of a claim. Certain health claims may require appropriate qualification as a way of minimizing potential safety concerns.

C. New Scientific Data

To determine whether or not new scientific data published since the proposed rule provided a basis for modifying FDA's conclusions regarding the relationship between omega-3 fatty acids and risk of CHD, FDA conducted a search of the scientific literature for relevant studies. Reviews published since the period covered in the literature review in FDA's proposed rule were used to identify recently published studies.

1. Epidemiologic studies

a. Cross-sectional studies and surveys (Table 1)

Bulliyya et al. (Ref. 185) found lower total serum cholesterol and higher HDL cholesterol in a fish-consuming coastal village population than in a nonfish-consuming population from the interior of India. These correlational data are consistent with a beneficial effect of omega-3 fatty acids on blood lipids, but many possible confounding variables prevent strong conclusions regarding a specific role for omega-3 fatty acids.

In a retrospective study, Popeski et al. (Ref. 266) found that women from communities with higher marine oil consumption had significantly lower diastolic pressure in the last 6 hours of pregnancy than women from communities with low fish oil consumption. Pregnancy associated hypertension was 2.6 times more common in communities with low fish consumption. These correlational data are consistent with an effect of omega-3 fatty acids on blood pressure in this particular situation. Again, many possible confounding variables prevent strong conclusions regarding a specific role for omega-3 fatty acids.

b. Prospective studies (other than intervention studies) (Table 1)

Bjerregaard and Dyerberg (Ref. 176) reported age-standardized mortality rates per 10,000 person-years for CHD in men in Greenland settlements (5.3) as half of that reported for men in Denmark (10.0). There was an increasing rate of CHD from settlements to towns in Greenland. The difference in rates of CHD in women were less apparent, with lower rates in Denmark than in towns in Greenland. These studies do not have sufficient specificity to identify omega-3 fatty acids as causal in reducing CHD, but are consistent with the hypothesis that they are.

Van Houwelingen et al. (Ref. 294) found that, while men from a high fish consumption group had higher concentrations of plasma phospholipid EPA and DHA than men from a low fish consumption group, there was no significant difference in collagen-induced platelet aggregation, cutaneous bleeding time, ATP-release in whole blood, or platelet number between the two groups. This study suggests that the outcome measures found commonly to be affected in clinical studies may not be related to consumption of omega-3 fatty acids in the free-living population.

c. Intervention studies

There were no new prospective intervention studies measuring occurrence of heart attacks or CHD mortality.

2. Evidence relating omega-3 fatty acids to intermediate or surrogate markers of CHD (Table 2) .

a. Atherosclerosis

i. Blood lipids

Through its own literature review, FDA has found another 34 studies not reviewed in the proposal that report data for serum cholesterol after consumption of fish containing omega-3 fatty acids or fish oil concentrated in omega-3 fatty acids. Among these, 25 found no change in blood cholesterol levels, 3 found an increase, and 6 found a decrease.

Studies among normal healthy subjects generally reported no change in total cholesterol (Refs. 168, 196, 202, 210, 217, 220, 235, 241, 253, 254, and 277), although none of these studies was controlled for nonspecific effects of the omega-3 fatty acids as polyunsaturated fats.

One study among normal subjects found that feeding a high fish diet did not change total cholesterol, unless combined with a low total fat and low saturated fat diet (Ref. 168). Another study (Ref. 301) reported decreased total cholesterol after switching from a meat diet to a fish diet, but the fish diet had significantly less saturated fat than the meat diet. One study (Ref. 283) found a slight increase after 5.4 g EPA plus DHA/day from MaxEPA (with 30 percent saturated fatty acids), and one study (Ref. 224) found a slight reduction in total cholesterol after 2.7 g purified EPA/day, but neither study was placebo controlled for effects of polyunsaturated and saturated fat contained in the supplements.

Similarly, nearly all of the 17 studies on subjects in at-risk subpopulations, including all of the studies that controlled for PUFA's (Refs. 203, 209, 247, and 258), found no effect of supplemental omega-3 fatty acids on total cholesterol (except for a post hoc analysis of a subgroup in one study, (Ref. 209)). One study in diabetics (Ref. 252) found an increase in serum cholesterol, but the statistical significance of the result may have been due in part to a change in the opposite direction in the control group. One study among hyperlipidemics (Ref. 191) found decreased cholesterol after relatively high doses (4.6 to 6 g EPA plus DHA/day) but not after 3.6 g EPA plus DHA/day, and did not control for PUFA effects of the supplements. The other study that reported decreased cholesterol after supplemental omega-3 fatty acids (Ref. 268), similarly, found the effect after a high level (6 percent of calories, 16 to 21 g EPA plus DHA/day) and did not control for the polyunsaturated fat effects of the supplement.

These studies support the conclusion reached in the proposed rule, that among normal, healthy subjects there is no significant effect of omega-3 fatty acids from fish or fish oils on total serum cholesterol.

FDA concluded in the proposed rule that the best studies among normal subjects found no effect of fish oils on LDL cholesterol. All of the additional studies among normal healthy subjects obtained in FDA's updated literature search have reported no change in LDL cholesterol (Refs. 220, 253, 253, and 277).

One study (Ref. 224) reported that purified EPA produced a significant decrease in a subfraction of large, light LDL cholesterol (LDL_1), and a significant increase in small, dense LDL cholesterol (LDL_2), but FDA calculates no change for the sum of these two fractions of LDL cholesterol. Some clinical studies reviewed in the proposed rule (Refs. 1, 43, 53, and 129) described changes in the composition of LDL particle after consumption of fish oil.

The relative importance of various subfractions of LDL particles (and the associated composition of the particles), however, is still controversial. While Homma et al. (Ref. 224) suggest that large, light LDL are the fraction associated most closely with atherosclerosis, Austin et al. (Ref. 171) report that the phenotype of small, dense LDL is the fraction most closely related to increased CHD risk. The February 1992 NHLBI consensus development conference (Ref. 255) included among its recommendations for further research the identification of the atherogenic and anti-atherogenic subfractions that may be present in VLDL and HDL; the uncertainty about the relevance of changes in the amounts of subfractions of these two lipoproteins similarly applies to LDL.

In at-risk populations, there have been some additional reports of increased LDL cholesterol after fish oil supplementation (Refs. 170, 191, and 251), a concern raised in the proposal. However, most studies have found LDL cholesterol not changed by fish oils (Refs. 174, 189, 205, 209, 219, 258, and 278). Moreover, each of the studies that used a polyunsaturated fat placebo control group found no change in LDL cholesterol (Refs. 203, 209, and 258).

Therefore, FDA concludes that these most recently reviewed studies support the conclusion reached in the proposed rule, that for the general population, there is no significant effect of omega-3 fatty acids on LDL cholesterol. The results of recent studies among at-risk subjects, however, are not in complete agreement with the conclusions in the proposed rule, and suggest that omega-3 fatty acids may not uniformly increase LDL cholesterol. Additional study is needed to determine the conditions under which LDL cholesterol is increased by omega-3 fatty acids.

Among more recent studies in normal healthy subjects found in FDA's updated literature review, about half have found no effect of fish oils or fish on HDL cholesterol (Refs. 202, 206, 217, 219 (after 1.25 and 2.5 g/day EPA plus DHA), 226 (after 1 and 3 g/day EPA plus DHA), 241, and 244), but about half have found increased HDL (Refs. 210, 219 (after 3.75 and 5 g/day EPA plus DHA), 220, 226 (after 6 g/day EPA plus DHA), 235, 253 (compared to baseline, significant compared to olive oil control), 278, 283, and 301), including a metabolic ward study that very carefully controlled for total fat and saturated fat intake (Ref. 253). Weintraub et al. (Ref. 298) found decreased HDL after fish oil compared to a saturated fat diet.

FDA attempted to ascertain how those studies that reported an increase in HDL cholesterol after increased intake of omega-3 fatty acids differed from those studies in which no effect was found. However, there was no apparent difference between the studies that reported that omega-3 fatty acids reduced HDL cholesterol and those that reported no change. Most of the studies that found a change used supplements containing substantial amounts (e.g., 30 percent) of saturated fatty acids, raising the possibility that the saturated fatty acids in the supplements were responsible for the increase in HDL (Ref. 17). However, some supplements had low amounts of saturated fatty acids (Ref. 278) or saturated fat in the diet was specifically controlled (Ref. 235), and in one study the control diet was reported to have significantly more saturated fat than the fish diet (Ref. 301), so the saturated fat intake during omega-3 fatty acid supplementation cannot be the factor responsible for increased HDL.

The amounts of omega-3 fatty acids used in those studies that reported increased HDL tended to be high (e.g., more than 5 g EPA plus DHA/day), but some studies that found a change used lower amounts (Ref. 278) and some studies that used high amounts found no change (e.g., Ref. 241 (used 6.7 g EPA plus DHA/day) and 253 (used 8 g/day)). Some studies in which fish was fed, rather than fish oil, found an effect (Refs. 235 and 301), but others did not (Refs. 206 and 244). There was no systematic difference in sample sizes of the studies that found an effect and those that did not; seven of the negative studies reviewed in the proposed rule or in the present document had 30 or more subjects, compared to only one of the positive studies. Small studies (n = 10 or fewer) may not have observed a significant difference because of small sample size, but larger studies did not find a significant difference, even though some found a trend toward increased HDL after fish oil supplementation (Ref. 217).

Finally, the enrichment of plasma phospholipids with EPA and DHA tended to be higher for subjects in studies where increased HDL was found than that for subjects in the studies where no change in HDL was found, reflecting the tendency of higher doses to produce increased HDL. In particular, all studies in which the plasma phospholipid EPA value was 3.9 percent or more found increased HDL. However, the studies that fed the highest amounts of EPA but that did not find an effect on HDL did not report data for phospholipid EPA, so it is not clear whether high phospholipid EPA is uniformly associated with increased HDL. Comparable results were found after inspection of data on phospholipid DHA after supplementation, however, because not all studies reported phospholipid fatty acid values, no conclusion can be drawn about the relationship between phospholipid DHA and HDL concentration. Notably, recent data suggest a direct correlation between plasma EPA and HDL, but an inverse relationship between plasma DHA and HDL (Refs. 177 and 178), underscoring the importance of reporting these data in future studies.

Among subjects with risk factors for CHD fewer reports found increased HDL (Refs. 191 (for type IV on SuperEPA only), 195, 203, 209 (for type IIb), and 219) than found no change (Refs. 170, 174, 189, 191 (for type IIb and type IV on MaxEPA), 209 (type IV), 224, 258, 263, 277, and 299).

Few studies have controlled for effects of PUFA's by giving a PUFA supplement. Two papers found no change in HDL in normal subjects fed fish oil as Promega (Ref. 73) or MaxEPA (Ref. 166) compared to wheat-germ oil or safflower oil (Refs. 73 and 166, respectively). Cobiac et al. (Ref. 20) reported increased HDL for mildly hypertensive subjects fed salmon and sardines in sild oil compared to those given a safflower-olive oil mix, but in comparable subjects, Meland et al. (Ref. 247) found no change in HDL cholesterol after MaxEPA fish oil compared to when the subjects were given a corn-olive oil mix. Very recent results, also for a mildly hypertensive population, found increased HDL after either, ethyl esters of EPA and DHA, or after corn oil (Ref. 177). Thus, for normal and hypertensive subjects, the change in HDL appears to not be a specific effect of omega-3 fatty acids, but may be related nonspecifically to increased PUFA's, either omega-3 fatty acids or omega-6 fatty acids.

In contrast, there are two reports of increased HDL cholesterol in subjects with type IIb hyperlipidemia fed fish oil compared to safflower oil (Ref. 166) or a corn-olive oil mix (Ref. 209), and one report of increased HDL in type IIa hyperlipidemics after fish oil or olive oil compared to corn oil (Ref. 286). Others found fish oil did not change HDL in type IV hyperlipidemics (Refs. 166 and 209) or patients with CHD (Ref. 258) compared to PUFA controls.

Therefore, at this time, FDA concludes that there is some evidence that omega-3 fatty acids, in some form and amount and in some selected populations, may increase HDL cholesterol, but that current data are ambiguous because the conditions under which fish oils reliably increase (total) HDL cholesterol have not been established, either in a specific subpopulation, or in the general population.

When fractions of HDL cholesterol have been reported, an increase has generally been found in the HDL_2 fraction (Refs. 1, 9, 54, 148, 191, 202, 203, 220, 235, 251, and 286), with a comparable decrease in the HDL_3 fraction (Refs. 202, 235, 251, and 286). Interestingly, the two recent reports that failed to find increased HDL_2 both used esterified omega-3 fatty acids rather than the fish oil triglyceride (Refs. 191 and 224), although others using ethyl esters have found increased HDL_2 (Refs. 9 and 286).

These studies suggest that fish oils produce a shift within the HDL fractions toward a lipid-rich, and away from a protein-rich lipoprotein, as well as within the LDL fractions. This shift may occur whether or not there is any change in total HDL cholesterol. FDA noted (56 FR 60663 at 60669) that some studies among normal subjects found increases in the HDL_2 fraction of HDL cholesterol, and that these reports were the most promising changes in blood lipids. New studies published after the period covered in FDA's review of the literature, however, found that both HDL_2, and HDL_3 were correlated with reduced risk of MI (Refs. 185a and 287a), and the NHLBI consensus conference (Ref. 255) concluded that, "The current studies of HDL_2 and HDL_3 levels have not shown consistent associations with CHD." Therefore, data on changes in HDL subfractions after increased consumption of omega-3 fatty acids do not provide a sufficient basis for a health claim, because there is not significant scientific agreement that the endpoints are directly related to risk of CHD. If the risk of CHD becomes linked with particular subfractions of these lipoproteins, these findings in normal subjects may be of great importance.

However, FDA also notes that recently published data from a prospective study demonstrate an effect of aspirin consumption in reducing the incidence of first heart attacks among women (Ref. 243). Another study shows a relationship between spontaneous platelet aggregation in vitro and incidence of CHD (Ref. 288). Both studies were conducted in the general population and their results support the hypothesis that platelet aggregation is a useful marker for CHD risk in the general population. Additionally, preliminary data from the Caerphilly Collaborative Heart Disease Study (Ref. 302) supports a relationship between platelet aggregation and the incidence of

ischemic heart disease; final data from this study will be available in the near future. These recently published and forthcoming studies may provide the basis for significant scientific agreement regarding the use of platelet function as a surrogate marker for CHD risk among the general population.

ii. Vessel wall effects.

New human studies on the effects of omega-3 fatty acids on vessel wall effects were discussed in response to comments 35 through 37 of this document. A recent meta-analysis of studies on use of fish oils in the prevention of restenosis concluded that the most plausible interpretation of the results was that there was a small to moderate beneficial effect of fish oils, but that chance could not be ruled out as a cause of the results (Ref. 260). The authors noted a significant heterogeneity in the findings and concluded that data from a large clinical study are necessary to confirm their interpretation. No study of restenosis to date has compared fish oil to an alternate polyunsaturated oil to control for nonspecific effects of PUFA's.

b. Thrombosis and hemostasis

i. Bleeding times

A number of studies have reported data that show no significant effect of fish oils on standardized bleeding time tests (Refs. 179, 218, 253, 268, and 277). However, others have found a significant increase in bleeding time due to fish oil (Refs. 195, 219, 220, and 278) or salmon (Ref. 297) or have reported increased bleeding as a side effect of treatment (Refs. 189 and 295).

ii. Platelet aggregation.

Consistent with the literature previously reviewed, recent studies show that fish oil tends to decrease platelet aggregation to numerous stimuli including AA (Refs. 179 and 256), adenosine diphosphate (ADP) (Refs. 204, 256, and 297), collagen (Refs. 218, 241, 251, and 297), thrombin (Ref. 241), and PAF (Ref. 251). Only one of these studies controlled for effects due to PUFA's (Ref. 204). The importance of the polyunsaturated fat control is less critical for studies on platelet function than for studies on blood lipids, because nonomega-3 PUFA's (i.e., omega-6 fatty acids derived from plant oils) produce effects in the opposite direction in platelets as omega-3 fatty acids (whereas many of the blood lipid effects of these two classes of fatty acids are in the same direction). Thus, the effects of omega-3 fatty acids on platelet responsiveness are not likely to be produced by PUFA's in general.

The only new study among healthy subjects that reported no difference in responsiveness to ADP used EPA ethyl esters as the source of omega-3 fatty acids (Ref. 179). Furthermore, the data were not shown in this brief report, so it is not clear if there was a trend toward an effect that might not have been statistically significant due to small number of subjects (eight per group). Those studies in healthy subjects reviewed in the proposed rule that did not find statistically significant differences in platelet responsiveness to ADP did have trends in the direction of reduced responsiveness (Refs. 24 and 54).

Other studies found no effect of fish oils on platelet aggregation in response to collagen (Refs. 179, 256 and 277). Each of these studies had a relatively small number of subjects, and there was a trend toward decreased sensitivity toward collagen at a high dose of omega-3 fatty acids in one study (Ref. 277). However, in the recent metabolic ward study (Ref. 256) there was no trend toward decreased sensitivity toward collagen or thrombin. These findings contrast with the results described above (Refs. 218, 241, 251, and 297) and with studies in healthy subjects described in the proposed rule (Refs. 2, 24, 54, 96, 143, and 166).

Studies reporting no effect of fish oils on PAF or AA-induced platelet aggregation (Refs. 179 and 218) may not have had sufficient power to find a statistically significant difference; where the data were reported there was a trend toward decreased sensitivity for both agents (Ref. 218).

iii. Platelet adhesion

A provocative study by Li and Steiner (Ref. 234) showed a 60-percent decrease in the extent to which platelets prepared from subjects fed fish oils adhered to substrates in a laminar flow chamber. The high flow rates used in this experiment showed that the change in adhesiveness of the platelets was due to changes on the platelet surface, and not due to a difference in the amount of material released from platelets that subsequently caused adhesion (i.e., AA). Also, a dose-response relationship was observed, and the time to return to pre-fish oil adhesion values was related to the amount consumed.

However, another study found no effect on fish oils on in vitro platelet adhesion to everted rabbit aorta, although there was a trend toward increased adhesion after 2 and 4 weeks of supplementation (Ref. 264). The reperfusion assay used in this study does not distinguish platelet membrane effects from effects mediated by substances released from platelets. Neither of these studies used a nonomega-3 PUFA control.

iv. Regulators of bleeding

Two recent studies in normal subjects have reported that omega-3 fatty acids have no effect on the clotting protein fibrinogen (Refs. 183 and 210), although in one of these studies a large supplement of vitamin E was associated with a decrease (Ref. 210). An uncontrolled study in normal subjects found a decrease in fibrinogen after fish oil supplementation (Ref. 278).

Studies on subjects at risk for CHD have reported no change (Ref. 203), a decrease (Refs. 276 and 277), and an increase in fibrinogen (Ref. 287). In agreement with its tentative conclusion in the proposed rule, FDA finds that the data on the effects of omega-3 fatty acids on fibrinogen level are ambiguous, because they do not distinguish effects due to PUFA's from effects specific to omega-3 fatty acids.

Plasminogen is an enzyme that dissolves clots. Plasminogen activator is a substance that increases clot dissolving; plasminogen activator is specifically inhibited by another substance, the PAI–1. Thus, a high level of PAI–1 decreases the capability to dissolve clots.

Three recent studies reported increased concentrations of PAI–1 after fish oil supplementation (Refs. 254, 278, and 287), which would appear inconsistent with a clot-dissolving effect of fish oil. Two of these investigators also found no change in the amount of plasminogen activator (t-PA) after supplemental fish oil (Refs. 254 and 287) including one who used a very specific immunologic assay (Ref. 254), suggesting that fish oils do not increase clot dissolution by increasing the amount of this protein. The third group, however, found an increase in the activity of tissue plasminogen activator (Ref. 277), which suggests that fish oils might increase clot dissolution by a different mechanism than affecting the amount of activator. Another group found no effect of cod liver oil on t-PA activity or fibrinolysis measured directly (Ref. 216). These reports are in contradiction to a report of increased fibrinolytic activity after a fish or fish plus fish oil diet (Ref. 183). FDA has not been able to find a reason for this rather marked contradiction. Therefore, in agreement with the conclusion in its proposed rule, FDA finds there is no clear relationship between omega-3 fatty acids and factors involved in dissolving blood clots, or clot dissolution activity.

Numerous investigators (Refs. 174, 191, 210, 220, 235, 241, and 279) have

recently reported that fish oils do not affect the concentration of Lp(a), a lipoprotein correlated with the risk of CHD. One investigator reported that very high levels of fish oils (9 g EPA plus DHA/day) gave a trend toward lower values, but the response may have been due to the PUFA's (Ref. 279). One study reported no effect overall of fish oils on Lp(a) among hypertriglyceridemics, but Lp(a) was reduced in those whose initial values were high (Ref. 174). On the basis of these reports and those reviewed in the proposed rule, FDA concludes that omega-3 fatty acids do not affect the risk of CHD by lowering Lp(a).

v. Blood pressure

Most of the studies not reviewed in the proposed rule that report data on blood pressure after consumption of fish oils have not found a significant change. One study of 50 elderly, healthy subjects reported that fish oils in combination with a salt-restricted diet decreased both systolic and diastolic blood pressure, but that fish oil alone had no effect (Ref. 190). There was a reduction in blood pressure during the run-in period, when the polyunsaturated fat placebo, sunflower oil, was fed.

Most studies on subjects with mild hypertension also have reported no change (Refs. 247, 277, and 289), including one large, randomized, placebo-controlled, multicenter trial of various behavioral changes and dietary supplements (Ref. 289). One study in hypertensives found reduced systolic and diastolic blood pressure comparable to reductions after the hypertension medication propranolol (Ref. 285), and in some cases the combined treatment of fish oil plus propranolol gave a greater decrease than either treatment alone. This study was controlled by olive oil (which is predominantly monounsaturated fatty acids), and therefore does not distinguish effects of omega-3 fatty acids from other PUFA's. Another double-blind randomized, placebo-controlled study in hypertensives whose blood pressures were maintained by medications found comparable blood pressure lowering compared to pretreatment values by fish oil or olive oil placebo (Ref. 299).

One uncontrolled study among hyperlipidemics also found reduced systolic and diastolic blood pressure (Ref. 263), but no effect was found in uncontrolled trials in subjects with end-stage renal disease (Ref. 207) or diabetics (Ref. 215). In a polyunsaturated fat (corn oil) controlled study on subjects with stable claudication (Ref. 203) fish oil and corn oil both reduced diastolic blood pressure comparably, but systolic blood pressure was only reduced by the corn oil treatment.

The results of these studies support the tentative conclusions reached in the proposed rule, that omega-3 fatty acids reduce blood pressure to a small degree in hypertensive people, but that it is not clear if there is any specific effect among normal subjects.

3. Other relevant information

a. Animal studies

Animal studies are especially important for studying effects of long-term consumption of omega-3 fatty acids, where there are few data from human intervention studies. The animal studies cited in the proposed rule related to the ability of omega-3 fatty acids to inhibit the development of atherosclerosis, an area not readily available for study in humans. A more complete discussion of the previously cited studies, with emphasis on those studies in nonhuman primates, is given in response to comment 47 of this document. Other recent animal studies cited in the comments or found during FDA's updated literature search that provide data on the development of atherosclerosis (where atherosclerosis is measured directly) are reviewed here. Also reviewed are studies on effects of omega-3 fatty acids during experimental ischemia, obviously not available for human study.

i. Atherosclerosis

One recent study in rabbits found less atherosclerosis in fish oil-supplemented animals, but there was no control for PUFA's, and the fish oil-treated animals also had reduced serum cholesterol (Ref. 192). Because humans do not have reduced serum cholesterol after fish oil consumption, these results are of questionable relevance to humans. Furthermore, the effect cannot be attributed specifically to omega-3 fatty acids rather than to polyunsaturated fats in general.

Fish oil feeding has also been associated with reduced binding of LDL to the blood vessel endothelium in monkeys (Ref. 193), and purified EPA ethyl ester was reported to reduce susceptibility of LDL to oxidation (Ref. 273), but these studies did not control for PUFA's. The antioxidant levels in the diets with respect to the amount of omega-3 fatty acids may be as important in determining whether or not there is any effect of omega-3 fatty acids on the oxidation of LDL.

Three recent papers describe effects of fish oils fed before surgical grafting of a vein into an artery, a procedure associated with an accelerated development of atherosclerosis. Two papers (Refs. 275 and 303) each used a polyunsaturated fat control and studied fish oil effects after vein allografts in animals treated with the immunosuppressant cyclosporin. In one study (Ref. 303), six groups of rabbits received one of three amounts of fish oil (giving 29, 87 and 174 mg EPA plus DHA/kg, respectively, similar amounts to those used in most human studies) or comparable amounts of safflower oil. In this study, safflower oil was more effective at reducing cholesterol than fish oil, and there was a trend toward more protection from atherosclerosis in the safflower oil-fed group. In the other study (Ref. 275), rats received, in addition to cyclosporin, either fish oil (containing 210 mg EPA plus DHA/kg), or safflower oil with aspirin, or safflower oil only. The fish oil group had remarkably less atherosclerosis than the other two groups. The contradictory results in these two studies, both of which used the same model of vein allografts with cyclosporin immunosuppression and the same polyunsaturated fat control, may be related to dose and species differences.

A third study of vein allografts in dogs (Ref. 274) found significantly less atherosclerosis in fish oil-fed animals either fed the fish oil alone or in combination with aspirin or a thromboxane synthetase inhibitor. Other animals were treated with aspirin only or a thromboxane synthetase inhibitor only. There was no difference among groups for blood lipids, platelet function or eicosanoid metabolism. This study suggests that mechanisms of atherosclerosis other than those involving blood lipids and platelet function may be affected by omega-3 fatty acids.

These animal models are most relevant to comparable surgical procedures or other invasive procedures (e.g., angioplasty) that would be expected to activate platelets in humans. Use of omega-3 fatty acids in these settings is a drug usage, but provides information on the extent to which omega-3 fatty acids may modify platelet response in vivo. The very different results of omega-3 fatty acids in modifying the response to vein allografts in immune-suppressed animals indicates that the actions of omega-3 fatty acids in these settings are not yet well established.

ii. Response to ischemia

One major line of research on omega-3 fatty acids in animals is experimental ischemia (deficiency of blood flow to

the heart). Force et al. (Ref. 199) found that rats fed a diet containing a high amount of fish oil (20 percent of the diet) for 6 to 12 weeks had much greater blood flow once the occlusion was removed than rats fed diets enriched in corn oil or lard. There were no differences among diet groups in the amount of tissue damaged by ischemia. Increased blood flow after ischemia has also been reported in a pig model (Ref. 221). This study did not control for polyunsaturated fat and used a lower amount of omega-3 fatty acids, and the differences in blood flow were not as pronounced as in the Force study. Another study found evidence of less tissue damage during reperfusion when rats had been fed a diet with 12 percent fish oil compared to other rats fed the same level of corn oil (Ref. 223). Another study in yet a third animal species (Ref. 230) showed that the functional capillary density was preserved during reperfusion in hamsters fed 5 percent fish oil for 4 weeks prior to experimental ischemia.

A reperfusion study in dogs determined the effects of fish oil on the duration of time needed for drug-induced reperfusion following an electrically induced blockage, and on the occurrence of spontaneous reocclusion in the reopened vessel (Ref. 182). High amounts of fish oil (one-third of total calories) for 3 weeks before the surgery resulted in a shorter time needed for the drug-induced reperfusion, but did not affect the time necessary for the electrically mediated occlusion to occur, the occurrence of second occlusion, or the time it took for the second occlusions to appear. This study did not have a polyunsaturated fat control, and even at the high intake only a modest effect of omega-3 fatty acids on platelet function was seen, that being primarily an enhancement of the effects of the fibrinolytic drug.

Another possible consequence of ischemia is arrhythmia, when the heart fails to maintain its normal rhythmic beating. The effects of fish oils on arrhythmia in monkeys are discussed in response to comment 39 of this document. Similarly, data have been reported for experimental ischemia in rats that show that both fish oil and sunflower oil reduced the occurrence of arrhythmia during occlusion and reperfusion compared to a saturated fat diet (Ref. 246). Another study, done on isolated, cultured rat heart cells (myocytes) showed that EPA, but not AA, prevented a known toxin (ouabain) from disturbing the rhythmic contractions and killing the cells (Ref. 212). The effective amount of EPA was so low that the mode of action was proposed to be due to production of an active metabolite, rather than due to direct effects of EPA on the cell membranes. This study suggests a specific effect of EPA in stabilizing the heart myocytes during stress. Prevention of arrhythmia by stabilization of these heart cells has been proposed as a mechanism by which omega-3 fatty acids may increase the chances of survival following a heart attack as reported in the Dart study (Ref. 16).

These studies indicate that, in various animal models, dietary fish oils promote greater reestablishment of blood flow in heart tissues following a transient block, as occurs in an acute heart attack. Importantly, the results are consistent across many animal species, and in some cases have been shown to be specific for omega-3 fatty acids rather than simply due to any PUFA. Finally, the experimental designs included coronary occlusions in otherwise healthy animals who were not suffering from heart disease, a model relevant for use of omega-3 fatty acids in reducing the risk of CHD rather than in therapy for persons with preexisting heart disease. The studies remain limited in that ischemia was produced by an acute blockage produced by mechanical or electrical means rather than by chronic dietary means, and the response to these different types of block may not be the same.

Other studies have attempted to learn the mechanism by which the platelet-vessel wall interactions are modified by omega-3 fatty acids. One study (Ref. 240) found that aortas from rats fed fish oil or corn oil did not contract as much in response to agents that cause contraction as aortas from rats fed beef tallow (saturated fat). This was true both before and after oxygen deprivation. The aortas from fish oil-fed rats were more responsive to one of three tested chemical relaxers than aortas from corn oil-fed or beef tallow-fed rats. Another study found that EPA potentiated the release of an EDRF (Ref. 181), but the effect was thought to be related to the unsaturation of the EPA, because the experiments were carried out in the presence of inhibitors of EPA metabolism.

One research group has recently shown that leukotrienes, chemicals produced from AA, are important in the tissue injury that accompanies reperfusion (Refs. 230 and 232). Since EPA competes with AA for the enzyme that makes leukotrienes from AA, EPA could potentially reduce the amount of leukotriene formed from AA. This same group has shown that leukotrienes promote the adhesion of leukocytes to the vessel wall (Ref. 231), and that feeding hamsters fish oil at 5 percent of the diet for 4 weeks greatly reduced (over 60 percent) the adhesion of leukocytes to the vessel wall (Ref. 233). The reduced adhesion could be relevant for both the conditions during which atherosclerosis develops (indeed, the stimulus used to elicit leukocyte adhesion was oxidized LDL, a candidate for promoting atherosclerosis in humans), and the acute response to coronary ischemia.

These animal data suggest mechanisms by which omega-3 fatty acids could affect the development of atherosclerosis or the response of heart tissue after a transient occlusion of its blood flow. Both modes of action could make important contributions to the risk of CHD and, therefore, merit additional study. The reperfusion studies and the myocyte toxicity study have demonstrated specificity of the effect as to omega-3 fatty acids. However, the increase in reperfusion volume is not sufficient to ensure a reduced risk of CHD death. Omega-3 fatty acids may not affect the extent of tissue damaged during an occlusion, or the tendency for a second, spontaneous occlusion. Additionally, omega-3 fatty acids may not affect tissue vulnerability during reperfusion. Those studies where CHD deaths or second occlusions have been recorded used large amounts of fish oils, and do not indicate whether amounts of omega-3 fatty acids found in the diet would have the same effects. Thus, there are many possible avenues suggested by these animal studies for beneficial effects of omega-3 fatty acids on the development of CHD, but there are also important limitations in the study designs and models used that prevent drawing conclusions from these data about the importance of omega-3 fatty acids in reducing the risk of human CHD.

b. Safety concerns

i. Diabetes

Three additional papers (Refs. 170, 222, and 304) and one major review (Ref. 238) on the effects of fish oils in diabetics were published after the time period reviewed in the proposal. All three new studies found increased LDL cholesterol after fish oil consumption in type II diabetics. However, effects on fasting glucose varied, with no change (Ref. 170), a transient increase (Ref. 222) or an increase (Ref. 304) reported. Although fasting insulin concentration was unchanged after fish oil (Refs. 170 and 304), postprandial insulin response usually, but not always (Ref. 170), has been reported as reduced (Refs. 238 and 304).

These effects of fish oils on blood glucose appear to depend on the amount of fish oils fed. One study found no change in fasting blood glucose levels among type II diabetics treated with 3.0 g/day EPA plus DHA for 2 weeks (Ref. 170). Two other studies that used 3 or 2.7 g/day EPA plus DHA for 6 and 8 weeks (Refs. 222 and 79) only found transient increases in blood glucose halfway through their respective supplementation periods. A fifth study (Ref. 12) that used 3.0 g/day EPA plus DHA for 3 weeks found comparable increases in fasting blood glucose when either fish oil or safflower oil was fed, so the increase cannot be attributed specifically to the omega-3 fatty acids. Similarly, Vessby and Boberg (Ref. 157) fed 3 g/day EPA plus DHA and did not find a difference in fasting glucose or glycosylated hemoglobin after fish oil supplementation compared to baseline; they did find a significant difference compared to the olive oil treatment that produced changes in the opposite direction from fish oil. Studies on type II diabetics that reported increased glucose used higher amounts (4.5 to 8 g/day) of omega-3 fatty acids (Refs. 52, 55, 128, and 304). Thus, FDA concludes that glycemic control among diabetics remains a valid safety concern, but notes that restriction of the amount of supplemental omega-3 fatty acids may suitably address this concern.

ii. Increase in LDL cholesterol

Many studies published after 1987 with data for LDL or apoB report increased LDL cholesterol or apoB after fish oils, in hypercholesterolemic or hypertriglyceridemic subjects (Refs. 1, 26, 32, 55, 60, 61, 63, 73, 75, 94, 114, 119, 120, 129, 146, and 166). Virtually all the studies with 10 or more subjects supplemented with 5 g/day EPA plus DHA or more found increased LDL. Some studies on normal subjects (all of which were reviewed in the proposed rule) also report increased LDL or apoB after fish oil consumption (Refs. 54, 127, and 156). Many studies that found no effect may not have had sufficient sample size to detect a difference due to treatment. FDA concludes that increased LDL cholesterol among some populations already at increased risk of CHD remains a valid safety concern, but because most reports of increased LDL are in studies where large amounts of fish oils are given, it is possible that restriction of the amount of supplemental omega-3 fatty acids and/or changes in the fatty acid composition of omega-3 fatty acid supplements may suitably address this concern.

III. Overall Summary and Conclusions

FDA concludes that there is some evidence that supports a relationship between omega-3 fatty acids and CHD, but that the totality of scientific evidence available at this time does not provide an adequate basis for a health claim. In some cases, there is not significant scientific agreement that the changes that are specific to omega-3 fatty acids will reduce the risk of CHD. In other cases, the data do not demonstrate that the effect is specifically due to the omega-3 fatty acids and not due to other dietary variables. For yet other cases, the data are ambiguous because effects of omega-3 fatty acids are not consistently observed, which suggests that other variables are important in determining whether or not an effect is seen. Therefore, the agency does not consider the evidence sufficiently strong to draw a firm conclusion about the relationship between omega-3 fatty acids and risk of CHD, and therefore is not authorizing the claim at this time.

In the course of developing this regulation, FDA has identified some areas where greater agreement is needed that the effects produced by omega-3 fatty acids are directly related to the risk of CHD. Many surrogate markers have been hypothesized, on the basis of limited evidence, to be related to specific diseases, including CHD, but few have withstood the continued scrutiny of scientific investigation. Also, some markers may have scientific validity, but may not be applicable for use in the general population, because of technical limitations. Thus, FDA asserts that only when a surrogate marker for a disease has been accepted as a risk factor for the general population, as indicated by a statement by an unbiased, nationally representative authoritative scientific or medical body, can the agency authorize a health claim based on the relationship of a nutrient to the surrogate marker of the disease. Examples of potential surrogate measures for which validation is needed are in vitro platelet aggregation, in vitro platelet adhesion, elevated fasting triglycerides postprandial triglycerides (recently considered at the NHLBI consensus development conference, Ref. 255), and subfractions of LDL and/or HDL.

In some cases additional research is needed to determine whether hypothesized subpopulations, e.g., those with high LDL:HDL ratio and high triglycerides, are at increased risk of disease. The pronounced triglyceride lowering effects of omega-3 fatty acids might well have a protective effect against CHD in such a subpopulation.

There are other areas where additional research is needed to show, for agreed endpoints, that the effects are consistently produced, or are specifically due to omega-3 fatty acids. These areas require additional data to establish that the effect of omega-3 fatty acids is specific, or to further define the conditions under which omega-3 fatty acids have their effects. For example, data are needed to show a reduction in MI or CHD mortality among individuals fed supplemental omega-3 fatty acids (specifically) compared to a group fed omega-6 PUFA's. The critical failing of some recent studies associating omega-3 fatty acids and CHD is that specificity was not obtained. Future studies should carefully control for known confounders, particularly dietary variables.

Finally, the available data suggest that some set of conditions or population may exist for which omega-3 fatty acids will increase HDL. Additional research should be able to define the conditions under which omega-3 fatty acids have this effect.

Interested parties may choose to petition the agency for approval of other health claims about omega-3 fatty acids. For example, additional data may be developed to support an omega-3 fatty acids/hypertension health claim petition. Because the blood pressure-lowering effect of omega-3 fatty acids appears most marked against a background of very low dietary intakes of omega-3 fatty acids, the role of omega-3 fatty acids in the total diet would need clarification before such a petition could be adequately supported. Similarly, limitations of the effects of omega-3 fatty acids on the magnitude and duration of change in blood pressure, the quantitative amounts of omega-3 fatty acids required for the effects, and characterization of the sensitive subpopulation would require discussion in a petition. A petition should also address apparent conflicting pieces of information, e.g., high blood pressure among populations that have high intakes of omega-3 fatty acids. Safety concerns raised in this final rule will, of course, require resolution prior to the authorization of any petitioned claim.

IV. Decision Not to Authorize a Health Claim Relating Ingestion of Omega-3 Fatty Acids to Reduced Risk of CHD

In evaluating the scientific evidence, FDA considered: (1) The strength of the association of omega-3 fatty acids with CHD or surrogate markers for CHD, (2) the consistency of findings among the

many studies, (3) the specificity of the outcome to omega-3 fatty acids, (4) the presence or absence of a dose-response relationship, and (5) the biologic plausibility of an association. FDA has determined that there is inadequate evidence to show that increased consumption of omega-3 fatty acids will reduce the risk of CHD.

FDA sought to determine whether there was significant scientific agreement among qualified experts that the totality of publicly available scientific evidence supported the claim that omega-3 fatty acids reduce the risk of heart disease. FDA reviewed the position taken in numerous Federal Government reports and other authoritative scientific reports and evaluated the publicly available scientific evidence that has become available since those reports were written. The decision to deny a health claim is based on the conclusions reached following review of the following sources of information: (1) "The Surgeon General's Report on Nutrition and Health;" (2) the National Research Council's "Diet and Health: Implications for Reducing Chronic Disease Risk," and (3) the National Cholesterol Education Program's Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults. Each of these reports concluded that there was inadequate evidence of a relationship between consumption of omega-3 fatty acids and CHD. FDA has reviewed again all of the relevant cross-sectional data from which the hypothesized relationship between omega-3 fatty acids and CHD originated, and all clinical intervention data published since these Federal Government and other authoritative reports were issued to determine whether the additional evidence is adequate to support a health claim for omega-3 fatty acids.

The LSRO report reached a different conclusion from the other authoritative reports by finding a relationship between omega-3 fatty acids and CHD. The report used only selected evidence, and often did not distinguish effects specifically due to omega-3 fatty acids from effects due to PUFA's in general. The description of international epidemiologic findings of a relationship between fish consumption and CHD, similarly, was not shown to be specific to omega-3 fatty acids. In some instances, FDA disagreed with the interpretation of the studies reviewed by LSRO, or with LSRO's conclusions. Finally, the LSRO report also based its conclusions about the usefulness of omega-3 fatty acids, in part, on changes in blood lipid parameters that are not generally agreed to be risk factors for CHD. Therefore, FDA finds numerous reasons for not accepting all of the findings of the LSRO report. FDA's conclusions regarding the relationship between omega-3 fatty acids and CHD rely instead on FDA's independent review of the publicly available scientific information, and are consistent with the Federal Government and other comprehensive and authoritative reports except for the LSRO report.

The surveys, cross-sectional studies, and nonintervention prospective studies do not provide adequate support for a relationship between consumption of omega-3 fatty acids and CHD. Only a few studies found an association between fish intake and CHD, while others have found no association; thus, there was no consistency of findings. None of the studies that reported a relationship distinguished fish consumption from other factors associated with fish consumption, and therefore none demonstrates specificity. Even in those studies that reported a relationship between fish consumption and CHD, it is not clear that the observed effects were due to the omega-3 fatty acids in fish. Also, the omega-3 fatty acid content of the fish diet associated with reduced CHD in these studies was so low that the importance of omega-3 fatty acids is questionable, thus weakening the biologic plausibility of the relationship.

The data from intervention studies also do not establish a relationship between omega-3 fatty acids and risk of CHD. The most compelling type of evidence to support a diet-disease relationship is a prospective, double-blind, placebo-controlled intervention study, with CHD morbidity and mortality as endpoints. To date, there is only one such trial (Ref. 16). The results of that study showed that increased consumption of fish does not reduce the risk of a second heart attack but may reduce the risk that the attack will be fatal. This study provides evidence for a protective effect of fish consumption against second heart attacks. However, as with the nonintervention study data, this study did not provide evidence to attribute the benefit to omega-3 fatty acid intake rather than some other factor associated with fish consumption (specificity).

Less persuasive than prospective studies in which CHD per se is measured, but still very useful, are prospective clinical trials in which surrogate markers for CHD are measured. Recent studies have not found beneficial effects from omega-3 fatty acids on total cholesterol or LDL cholesterol in normal, healthy persons, or among persons at risk for CHD. Numerous studies, including some large or multicenter studies, have reported these results, demonstrating consistency in the findings and providing the agency confidence that they were not spurious. The data on HDL cholesterol are ambiguous. There appear to be other factors in the dietary interventions besides the omega-3 fatty acids that determine whether or not supplementation with fish or fish oils raises HDL.

An increase in bleeding times and a decrease in platelet aggregation have been observed frequently, but not always, after supplemental omega-3 fatty acids in normal healthy individuals as well as in diseased persons. Additionally, there is evidence that platelet adhesion is reduced by omega-3 fatty acids. The effects of decreased platelet aggregation and platelet adhesion appear to be related to the intake of omega-3 fatty acids in a dose-response relationship. What has not been established, however, is that in vitro platelet aggregation or platelet adhesion are bona fide surrogate risk factors for CHD in the general population.

Omega-3 fatty acids have been shown to reduce blood pressure in hypertensive people to a small degree, which may bear on a relationship between omega-3 fatty acids and CHD. This effect was not of large magnitude, but it is specific to omega-3 fatty acids, it has been reported by a number of investigators, a dose response was found, and the effect is biologically plausible through at least two mechanisms. However, it has not been established that omega-3 fatty acids reduce blood pressure in normal subjects (lack of consistency, weak effect, absence of dose-response relationship). Additionally, it has not been demonstrated that the magnitude and duration of changes in blood pressure observed in short-term studies will persist during long-term consumption of omega-3 fatty acids, or that these changes result in a reduced risk of CHD.

Finally, the potential that omega-3 fatty acids may increase LDL cholesterol and/or apoB among diabetics and hyperlipidemics, and the potential that omega-3 fatty acids may worsen control of blood glucose in diabetics are significant safety concerns that must be addressed before a claim may be made that consumption of omega-3 fatty acids by the general population will reduce the risk of CHD.

In conclusion, there are numerous effects of omega-3 fatty acids that may

be related to the risk of CHD, e.g., reduction in fasting and postprandial triglycerides, reductions in platelet aggregation and adhesion, changes in the composition of lipoproteins. However, at this time these endpoints are not generally agreed to be closely related to the risk of CHD. In other areas, additional data are needed to show that effects related to fish consumption are specifically due to the omega-3 fatty acids in the fish, and to define the conditions under which omega-3 fatty acids consistently increase HDL. These avenues may provide a reasonable basis for a future petition for a health claim relating omega-3 fatty acids to the risk of CHD.

V. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. References

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.71 is amended by adding new paragraph (f) to read as follows:

§ 101.71 Health claims: claims not authorized.

* * * * *

(f) Omega-3 fatty acids and coronary heart disease.

Dated: October 30, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160–01–F

TABLE 1

Epidemiologic Studies: Omega 3 Fatty Acids and CHD

Study	Study Design	Subjects	Methods	Results	Comments
Beswick et al. (Ref. 167).	Dietary counseling compared with survey data and platelet activity 6 months later. Men from Cardiff, Wales with history of myocardial infarction.	56 men, ages 36 to 71 (mean=58). 13 excluded for medication, 1 for inadequate blood sample. 18 smokers, 34 patients on cardiovascular medication, 19 on B blockers, 8 on antihypertensive drugs, and 24 on angina medication.	Questionnaire to estimate polyunsaturated to saturated fat ratio, percent calories from fat, and EPA intake. Platelet activity based on ADP added for aggregation of platelets in blood and plasma.	Significant inverse correlation between fat ratio and platelet activity. Nonsignificant trend for decreased platelet aggregation with increased EPA intake.	Study inconclusive on role of EPA in platelet activity. Small sample. In vitro assay not repeated for accuracy. Nutrient intake estimated. Health behaviors, medications, and other factors which may have influenced results not presented. Study population ill.
Bulliyya et al. (Ref. 185).	Dietary and serologic survey in Nellore and Chittor districts of India.	100 individuals in fish consuming populations and 109 individuals in nonfish consuming populations.	Dietary survey. Total serum and HDL-cholesterol, TG, and phospholipid measured. Clotting and bleeding times observed. Age, weight, pulse rate, blood pressure tabulated.	Total serum cholesterol was lower in the coastal village (152.7 mg/dL) than in the nonfish consuming village (214.9 mg/dL). HDL-cholesterol was higher in the coastal village.	Dietary survey methods not presented in paper. Dietary intake was presented as correlational data. The potential confounding effect of other components of diet on cholesterol level warrants explanation. Lower total cholesterol level in the fish eating population was observed.
Bjerregaard and Dyerberg, (Ref. 176).	Analysis of CHD mortality rates, Greenland.	All deaths due to CHD in Greenland from 1968 to 1983.	A register of deaths by cause was developed using information from death certificates, parish registers, and civil registration records. The register was computerized and brought under the management of the Danish Board of Health from 1975 to 1983.	Age standardized mortality rates per 10,000 person-years for CHD in men in Greenland settlements (5.3) were half those of men in Denmark (10.0). There was an increasing rate of CHD from settlements to towns in Greenland. The difference in rates of CHD in women were less apparent, with lower rates in Denmark than in towns in Greenland.	Genetic protection, exercise and confounding factors such as tobacco use cannot be eliminated as factors in this observation. These data support earlier observations of lower CHD rates in male Greenlanders versus Danes, but not for females. Note, the 50 percent difference is approximately the same as reported by Kromhout for comparing men eating no fish and those eating approximately 30 g/day.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bonaa et al. (Ref. 178).	Dietary and serologic survey of residents of Tromso, Norway.	156 subjects selected subjects from a survey population of 21,026 for an intervention trial.	Food consumption questionnaire, with separate questions for fatty and lean fish, also alcohol. Also, 2 unannounced 24-hour diet recalls. Analysis of covariance and multiple linear regression.	Fish consumption was inversely correlated with TG's, but no significant correlations between fish and cholesterol or apoprotein measures. EPA correlated with HDL until TG's were controlled. EPA correlated with TG even after HDL was controlled. DHA inversely correlated with HDL and apoA$_1$	Divergent relationships between EPA and HDL, and DHA and HDL, may explain discrepancies in the literature regarding the effect of various supplements on HDL.
Gerasimova et al. (Ref. 205).	Dietary and serologic survey of residents of Moscow and the Chukot peninsula.	Randomly selected men; Moscow n= 650 Chukot n= 261.	HDL by ultracentrifugation. A subsample was used for HDL phospholipids and apoproteins. 24-hour recall for dietary data.	Chukot residents had ↓ cholesterol, TG, LDL; ↑ HDL, ↑ consumption of omega-3 fatty acids, plasma lipid EPA.	Correlation between increased consumption of omega-3 fatty acids and serologic measures is consistent with the hypothesis of a relationship between omega-3 fatty acids and CHD, but many other dietary and behavioral factors could also be correlated and were not examined in this survey.
Innis et al. (Ref. 225).	Dietary and serologic survey.	Sample was selected as part of an unrelated dietary survey. 185 Canadian Inuit and 24 Vancouver residents.	Phospholipid fatty acid analyses.	Mean chain length and unsaturation index of the lipids in the two populations was very similar. The Inuit had greater EPA and lower AA than the Vancouver population. NS cholesterol	Observational data. Supports a dietary origin of phospholipids. Not directly relevant to CHD.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Popeski et al. (Ref. 266).	Retrospective survey of pregnancy induced hypertension in Inuit women and diet survey of women in these communities.	Hypertension study: 300 medical records from Inuit women in 7 communities in the Northwest Territories. Diet survey 27 Inuit women in the 7 communities above.	Retrospective study: Blood pressure measurements 6 hours before delivery, incidence of pregnancy induced hypertension. Diet survey: Reported diet, hunter interviews, cord serum phospholipid from 16 infants born in 6 months.	Communities with higher marine oil consumption ha significantly lower diastolic pressure in their women in the last 6 hours of pregnancy. Pregnancy associated hypertension was 2.6 times more common in communities with low fish consumption.	Ecologic data. Generates hypothesis for a relationship between the consumption of fish and blood pressure during pregnancy. Prospective study or clinical trial of diet and pregnancy needed.
Seidelin et al. (Ref. 281).	Correlation study of adipose tissue fatty acids and extent of coronary artery stenosis.	40 consecutive autopsies from subjects age 52 to 90 years.	Coronary artery disease was quantified by semi automatic image analysis, Degree of stenosis was used to divide subjects into three groups for correlations. Umbilical adipose lipids were extracted with methanol-chloroform, trans-methylated esters by gas chromotagraphy.	No correlation between extent of stenosis and 16:0, 18:0, 18:2n-6, 16:1n-9 or 18:1n-9, but a significant inverse correlation with 22:6n-3. Stenosis correlated with extent of body weight.	Limited data are presented for a limited number of subjects, i.e., no data for other fatty acids of interest are presented, e.g., EPA, AA.
Van Houwelingen et al. (Ref. 294).	Sample of clinical parameters from 40 healthy men selected from cohort in longitudinal study, Zutphen, Holland.	Men in low (n=15) and high (n=25) fish consumption groups. Low consumption group ate an average of 2 g fish/day while high consumption group ate an average of 33 g fish/day.	Individuals in this study where interviewed 4 times in 25 years using cross-check dietary methods for habitual fish consumption. Of 79 men selected for the study, 40 completed it. Blood collected for fatty acid composition, PAI activity, collagen-induced platelet aggregation, ATP release, and TXB_2.	There was significantly higher serum phospholipid concentration of omega-3 fatty acids EPA and DHA acid and no significant difference in collagen-induced platelet aggregation, cutaneous bleeding time, ATP-release in whole blood or platelet number between the two groups.	Small sample reflects inconsistency of fish consumption over time. Dose of omega-3 in high fish consumption group lower than in most clinical trials.

TABLE 1--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Van Houwelingen et al. (Ref. 293).	Sample of clinical parameters from 61 elderly male volunteers from longitudinal cohort. Zutphen, Holland.	61 healthy elderly male volunteers ages 67 to 82. Lowest quartile of fish consumption ate 0 g/day. Highest quartile ate 27 g/day.	Cross-check dietary history was taken to assess the habitual intake of polyunsaturated fatty acids. Blood was collected under controlled conditions for measurement of serum total lipids, phospholipids, TG's, and cholesterol esters.	Dietary history seemed to correlate with serum linoleic acid. The correlation between dietary history using the cross check method for fish consumption and serum level of fish-related fatty acids, however, seems less reliable.	The discrepancy between dietary history and serum level of fish-related fatty acid may be the result of large variation in the level of these fatty acids in the same foods.

TABLE 2

Intervention Trials of Omega-3 Fatty Acids and CHD

Study	Study Design	Subjects	Methods	Results	Comments
Agren et al. (Ref. 168).	Randomized parallel trial of fish, fish plus reduced fat (especially saturated fat) or usual diet (one fish meal per 2 weeks) for 15 weeks.	62 Normal, healthy female students.	Plasma lipids and lipoproteins at baseline, 7 and 15 weeks.	Controls: NS TG, cholesterol, $apoA_1$, apoB. Fish eaters: NS versus baseline TG, cholesterol, apoB; ↓ $apoA_1$; ↓ TG versus controls. Fish plus low fat: ↓ TG, cholesterol, $apoA_1$, apoB.	This study shows the importance of the balance of the diet, particularly regarding saturated fat, in determining the blood lipid response to omega-3 fatty acids. Changes were slight unless a low fat low saturated fat diet was used. Study would have been stronger with a control group eating a low fat low saturated fat diet matched with fish intake to the nonfish control.
Annussi et al. (Ref. 170).	Randomized double-blind crossover trial of 10 g fish oil/day (3.0 g EPA plus DHA, MaxEPA) versus olive, no wash out, 2 weeks each treatment.	Eight female NIDDM, without liver, kidney or any other disease known to influence lipid and/or carbohydrate metabolism.	One of the patients was treated by diet only; others on Glibenclamide (4) and metformin (3). The patients were under dietary control and they were in the metabolic ward.	↓ TG, VLDL; ↑ LDL; NS cholesterol, HDL FFA; NS LDL-TG, HDL-TG; NS fasting glucose, average glucose insulin response, sensitivity.	Duration period was very short and no fatty acid analysis on neither fish oil nor olive oil diet. There was no washout period between cross-over of the study.
Bairati et al. (Ref. 172).	Randomized, double-blind placebo-controlled trial of 15 g fish oil/day (MaxEPA, 4.5 g EPA plus DHA) versus olive oil from 3 weeks pre angioplasty to 6 months; concurrent aspirin.	119 Subjects undergoing first, successful, computer quantified percutaneous transluminal coronary angioplasty, evaluated also at 6 months.	Angiographic assessment, quantified by computer. diet by food frequency. Restenosis defined in four ways for analysis.	By three of four definitions of restenosis, and multivariate analysis to control for exclusions, fish oil reduced restenosis. NS ECG evidance of myocardial ischemia, but trend toward ↓ fish oil, also on exercise testing. Significant difference also according to dietary omega-3 fatty acids (highest, middle versus lowest tertile) although highest tertile intake was only 0.15 g/day, and dietary odds ratio comparable to fish oil odds ratio.	Comparable compliance. Olive oil control doesn't control for polyunsaturated fatty acids. The comparable magnitude of the effects of dietary omega-3 fatty acids and fish oil supplementation suggest long-term, low dose effects are as strong as short-term, larger amounts. No associations of restenosis with other dietary variables, total fat, classes of fat, cholesterol, or dietary seafood. Differences between groups use of blood pressure medications (see Bairati et al. Ref. 173)) was not discussed.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bairati et al. (Ref. 173).	Randomized double-blind, placebo-controlled trial with 15 g/day MaxEPA (4.5 g EPA plus DHA) versus olive oil.	125 patients undergoing first percutaneous transluminal coronary angioplasty, evaluated also at 6 months.	Recumbent blood pressure, blood lipids by commercial kits.	Blood pressure increased in the olive oil control group, and was unchanged in the fish oil group, possibly because greater number of patients in the olive oil group discontinued concurrent blood pressure medications. Fish oil ↓ TG's, NS in cholesterol, LDL or HDL versus control, but the change from baseline was different between groups with ↑ LDL and HDL in fish oil.	Multiple linear regression analysis used to control use of blood pressure medications reduced differences in LDL and HDL to borderline significance (p = 0.06), and inclusion of TG resulted in NS change in HDL.
Beil et al. (Ref. 174).	Randomized double-blind trial with 10.5 g/day fish oil (3.15 g EPA plus DHA, MaxEPA) versus 5.25 g/day fish oil plus 5.25 g oleic acid (low fish oil) versus 10.5 g oleic acid (placebo) 6 weeks.	30 Patients with primary hyper-triglyceridemia. Patients off lipid lowering drugs for 6 weeks, no beta blockers, diuretics or hormones. Fat restricted diet (30 percent, polyunsaturated fat:saturated fat ratio 1.5:1, cholesterol <250 mg/day).	Lipids by standard methods, Lp(a) by commercial kit.	↓ TG in high fish oil group versus placebo; NS cholesterol, LDL, HDL apoB; NS Lp(a), post-hoc analysis shows ↓ Lp(a) in those initially greater than 10 mg/dL.	Although randomized, there were large differences in initial Lp(a) levels, with only 1 of 10 in the placebo group over 6 mg/dL versus 6 and 8 of 10 in the low and high fish oil groups, respectively. Therefore, on the basis of Lp(a) the randomization was inadequate. Oleic acid does not control for polyunsaturated fatty acids.
Bhathena et al. (Ref. 175).	Noblinded, longitudinal design, 10 week run-in on placebo (15 g mixed fat); 10 weeks with 15 g fish oil (anchovy oil, 6.5 g EPA plus DHA); 8 weeks of 15 fish oil plus 200 mg vitamin E	40 healthy females, no history of metabolic disease, no medication, no smoking.	Diet for the placebo and test group was controlled, fish was eliminated from the menu. Forty percent of energy comes from dietary fat which was more than the level of current dietary guideline recommended.	Fish oil ↑ fasting glucose; ↓ TG, insulin, glucagon, GH, somatomedin-C; NS cholesterol, cortisol, dihydroepiandrosterone sulphate. Fish oil plus vitamin E gave no further change in glucose, TG, glucagon cortisol or cholesterol; but ↓ GH, insulin, increased somatomedin-C to placebo levels, and produced a ↓ in DHEA-S.	Unusual source and high level of omega-3 fatty acids. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bonaa et al. (Ref. 178).	Randomized, double-blind placebo-controlled trial of 6 g/day Norsk Hydro (4.5 g ethyl esters of EPA plus DHA) versus corn oil, 6 month observational run in, 10-week intervention.	146 healthy subjects.	Fasting blood samples at beginning and end of intervention, standard, commercial assays for lipids and apoproteins. Multiple linear regression.	Fish oil ↓ TG; In both groups NS cholesterol, LDL, apoB, ↑ HDL; ↑ apoA, in corn oil group. In fish oil group ↑ phospholipid EPA correlated with HDL, but not in corn oil group, whereas in corn oil group DHA was inversely correlated to HDL.	No change in dietary fat, alcohol or protein. Both groups had a small, significant weight gain. The divergent results underscore the need for studies on individual omega-3 fatty acids, that may help explain inconsistencies in results of fish oil effects on HDL.
Bordet et al. (Ref. 179).	Randomized, dose-response study to 300, 900, 2700 mg EPA (ethyl ester, MND-21, Mochida, Japan) 4 weeks plus 4-week washout.	33 healthy females.	Bleeding times by Simplate II.	NS platelet aggregation sensitivity to ADP, collagen, PAF; ↑ sensitivity to ate NS bleeding time.	Differences from other studies may be due to absence of DHA, and need for longer studies to allow DHA incorporation.
Brown and Roberts (Ref. 183).	Randomized 3 X 3 crossover of fish (0.6 g EPA plus DHA/day) versus fish plus fish oil (2.0 g EPA plus DHA/day) versus control (fish free) 6 weeks each with 6-week washout.	12 healthy females.	Clotting times on 2 samples taken 4 days apart at the end of each diet treatment. Fibrinolytic activity in pooled samples from each individual assayed by euglobulin activity versus fibrin.	↓ leukocytes on fish, fish plus fish oil diets. Platelet count ↓ on fish oil; NS fibrinogen, ↑ fibrinolytic activity on both fish and fish plus fish oil.	The authors review other reports on fibrinolytic activity and note the inconsistency in findings.
Brown and Wahle, (Ref. 184).	Crossover trial of 15 g fish oil (MaxEPA, 4.5 g/day EPA plus DHA) with or without 400 IU vitamin E for 4 weeks each with 2-week washout between.	11 healthy females.	Thiobarbituric acid reactive substances, total tocopherol by fluorometric assay, whole blood aggregation by electrival impedance after collagen stimulus.	NS conjugated dienes, creatine kinase, or TBARS in the platelet poor plasma; ↑ total plasma TBARS on both, but less with added vitamin E; ↑ glucose on fish oil without vitamin E.	Small number of subjects; considerable variance in many measures with the exception of plasma TBARS. The interaction between glucose suggests a mechanism to address potential adverse effect in diabetics.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Clarke et al. (Ref. 189).	Noncontrolled supplementation, 1 g fish oil/day (0.3 g EPA plus DHA, MaxEPA) increasing in 1 g increments monthly to 5 g/day for months 5 and 6.	7 male and 4 female adolescents with FHL type II (5 type IIa, 6 type IIb).	Usual low cholesterol, low saturated fat diets, 2 received colstipol.	MS TG's, cholesterol, LDL, HDL. Increased nose bleeds during fish oil treatment versus before and after.	Numbers of observations at each time per subject not given for blood lipids measurements, so fish oil amounts for "after" treatment not clear. Platelet count and other biochemistries described as normal, but no data of effects of fish oil are described.
Cobiac et al. (Ref. 190)	Randomized double-blind placebo-controlled, 2 week run-in on restricted Na intake plus 8 to 1 g sunflower oil capsules and 8 to 600 mg slow release NaCl. Then 4 weeks on fish oil (8 g MINMEGA, 4.2 g EPA plus DHA) on either lo or normal Na, and crossover to alternate Na for 4 weeks.	50 Elderly, healthy subjects.	Blood pressure in sitting position.	↓ sys, dias blood pressure on Na restricted diet plus fish oil; NS on fish oil only; NS on sunflower oil (the run-in treatment).	Note that sodium restriction alone had no effect. 55 elderly subjects started the experiment but only 50 completed the study. No explanation was given why some subjects were dropped out. Dietary intake and compliance were not controlled. No fatty acid analysis of the diet and/or the control and test oils. No washout period in between cross-over.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Davidson et al. (Ref. 191).	Three experiments: 1. Dose response study with fish oil, (7.2, 5.4, 3.6 g EPA plus DHA/day, SuperEPA) for 6 weeks sequentially, 6-week washout between doses; highest dose crossover to olive oil 2. Crossover of MaxEPA versus SuperEPA at 4.8 g EPA plus DHA/day each, 6 weeks, 6-week washout 3. Uncontrolled supplementation of cases from a 4 year period, 148 subjects treated for 6 week periods with various fish oil.	1. 16 Type II-B hyperlipidemic patients. 2. 12 Hyper triglyceridemic type IV. 3. 148 Patients of different hyperlipidemias.	1. Stable AHA phase 1 diet for 3 months prior to and during study. 3. Stable on AHA phase I or Phase II diets.	1. ↓ TG, cholesterol on 7.2, 5.6 g EPA plus DHA/day, NS cholesterol on 3.6 g EPA plus DHA/day; NS HDL; cholesterol ↑ on olive oil. 2. SuperEPA ↓ cholesterol more than MaxEPA; MaxEPA ↑ LDL, HDL, HDL_2 versus SuperEPA; NS HDL_2. 3. Each MaxEPA, SuperEPA, Promega ↓ TG's, cholesterol; ↑ HDL in Type IIb on SuperEPA only; ↓ LDL in familial hypercholesterolemia after SuperEPA. NS Lp(a).	Olive oil control increased TG cholesterol versus run-in diet. Design doesn't control for polyunsaturated fatty acids. Larger decrease in cholesterol by SuperEPA may be due to its reduced content of saturated fatty acids. Capsule counts were used to assess compliance.
Eritsland et al. (Ref. 195).	Randomized to aspirin (300 mg/g) for 1 week, followed by 4 week on fish oil (Norsk, 85 percent ethyl esters of EPA plus DHA, 3.4 g/day) or 4 week on fish oil followed by 1 week on aspirin.	22 female patients with stable CHD.	4 week run-in. Beta blockers used by 9 patients, nitrates allowed. Usual diet.	↓ TG's by fish oil; ↓ cholesterol by fish oil plus aspirin; ↑ HDL in fish oil only.	2 minor bleeding episodes on aspirin, none on fish oil. No wash out between treatments, small number of subjects makes differences in response to fish oil only and fish oil plus aspirin questionable.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Fahrer et al. (Ref. 196).	Self selected to treatment of fish (1.5 to 2.0 g EPA plus DHA/day), fish oil (Sancmega S18, 3.1 g EPA plus DHA/day), normal diet for 2 months.	21 female, 21 male healthy volunteers.	No run-in, fish was pink salmon, tuna, herring, mackerel, pilchard. Fish consumption recorded in daily diary.	↓ TG's in both fish and fish oil groups; NS cholesterol, HDL; decrease in TG correlated with increase in EPA.	Baseline blood lipid values were comparable in the self selected groups.
Ferretti et al. (Ref. 197).	Nonblinded, longitudinal design, 10 week run-in on placebo (15 g mixed fat); 10 weeks with 15 g fish oil (anchovy oil, 6.5 g EPA plus DHA); 8 weeks of 15 fish oil plus 200 mg vitamin E.	40 nonsmoking females.	PGE-M by a stable isotope dilution method developed in the authors' laboratories.	Fish oil alone and fish oil supplemented with vitamin E produced comparable results on average, with the mean values µg PGE-M excreted per 24 hours in control, fish oil and fish oil plus vitamin E of 15.41 ± 2.12, 12.51 ± 1.78 and 12.77 ± 1.85, respectively. Paired t-test showed a significant ($p < 0.002$) reduction between baseline and fish oil treatment.	PGE-M is the sum of PGE_1 plus PGE_2, derived from AA. The EPA-derived PGE_3 was not measured. Dietary intake was well controlled. Prolonged use of fish oil supplementation was not recommended. The range of baseline values was from 3.8 to 60.9 µg/24 hours. There was no apparent relationship between initial values and magnitude of the change, and there were many individuals who had substantial differences for the two fish oil treatments. Thus, the significance of an average change of about 20 percent is not clear.
Force et al. (Ref. 200).	12 g fish oil (n= 8)(6 g EPA plus DHA, Promega) or 16 g fish oil (n= 6) (8 g EPA plus DHA), 6 weeks. After 6 weeks on fish oil only, concurrent increasing daily dosages of ASA (50, 100, 225, 1,300 mg) 2 weeks each.	14 females, 2 males, clinically stable but advanced CHD.	Gas chromatography-mass spectroscopy	Fish oil ↓ TXA, 38 percent, with ASA ↓ 97 percent at each dose; fish oil and ASA each ↓ PGI_2 (ASA more than fish oil); fish oil ↑ PGI_3, but ASA did not increase PGI_3.	This is a study on the mechanism of action of fish oil. No concurrent placebo control. Dietary intake was not controlled.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Franceschini et al. (Ref. 202).	Uncontrolled supplementation study of 6 g/day fish oil (Norsk hydro, 2.8 g EPA plus 1.7 g DHA), 6 weeks.	5 Healthy subjects.	HDL subfractions assayed by nondenaturing polyacrylamide gel electrophoresis.	NS cholesterol, HDL, ↑ HDL_2, ↓ HDL_3, ↑ HDL_2/HDL_3 mass ratio.	Dietary intake was not controlled. Compliance was checked by plasma PL fatty acid composition. Small study.
Gans et al. (Ref. 203).	Randomized double-blind study (fish oil, source not specified, 1.8 g EPA plus 1.2 g DHA/day) versus corn oil, 4 months.	Stable claudication patients; 37 enrolled, 16 per group completed.	Supine blood pressure at rest and 1, 6, 10 min post exercise. Fibrinogen by commercial kit.	↓ Diastolic by both groups, ↓ systolic only in CO group; ↑ RBC deformability; NS cholesterol, LDL; fibrinogen; ↑ HDL, HDL_2; ↓ TG's; NS pain, walking distance.	Wide variation of age (18 to 80 years), Dietary intake was not controlled. Compliance was checked by plasma PL fatty acid composition. Blood pressure was lowered in both groups.
Gasso et al. (Ref. 204).	Randomized double-blind placebo-controlled Efamol-marine (1.2 g EPA) versus Efamol (v olive oil) 12 capsules/day 6 weeks.	17 normal healthy 6 males, 11 females 6-Efamol marine, 5-Efamol, 6-olive oil.	ic conversion, MDA, platelet aggregation to ADP.	↓ Platelet aggregation by Efamol-marine; ↓ MDA in all groups.	Groups differ in the endpoints at beginning of the experiment, so it is difficult to interpret changes. The MDA ↓ may be due to the vitamin E added.
Gerhard et al. (Ref. 206).	3-period crossover of three fish diets; Dover sole (2 g EPA plus DHA), Salmon (4 g EPA plus DHA), or sablefish (3.4 g EPA plus DHA), 18 d each with 3-week washout between.	21 normo-triglyceridemic females.	ApoB standardized to Centers for Disease Control standards. VLDL and LDL precipitated with magnesium phosphotungstate, HDL enzymatically in the supernatant.	Salmon, sablefish diets ↑ cholesterol, apoB, LDL. Sole ↓ HDL, ↑ LDL; Sablefish ↓ HDL.	Diets were comparable for total fat, saturated fat. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Goren et al. (Ref. 207).	Uncontrolled supplementation study, 150 to 200 mg/kg (EPAGIS) (0.86 to 2.3 g EPA plus DHA/day) 8 weeks.	16 Patients with end stage renal disease, 6 type IIb, 1 type IIa, 8 type IV.	Blood lipids before and after supplementation. cholesterol by microenzymatic method. Apoproteins by turbidity assays.	↓ TG; NS cholesterol, ↓ cholesterol/HDL in a subset of excessively hyperlipidemic subjects; NS blood pressure, platelet counts, $apoA_1$:apoB.	Fish oil dosage was adjusted to the body weight of chronic renal failure young patients (7 to 18 years).

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Green et al. (Ref. 209).	Randomized double-blind placebo-controlled crossover 15 g fish oil (EPAGIS, 4.3 g EPA plus DHA) versus corn:olive oil mix, 8 weeks each treatment with 4 week wash out.	27 Hyperlipidemic subjects, 15 type IIb, 12 type IV.	Cholesterol, HDL, TG by commercial kits. Apoproteins by immunoturbidity assay.	Overall NS cholesterol, LDL. Type IIb: ↓ TG, cholesterol; ↑ HDL; NS LDL. Type IV: ↓ TG; NS cholesterol, LDL, HDL. Both: NS platelet count, platelet aggregation, RBC deformability, apoB, $apoA_1$; ↓ blood viscosity.	Substantial amount of other omega-3 fatty acids in this supplement (0.50 g 18:3, 0.45 g 18:4 and 0.42 g 22:5) per day. Patients were on weight-maintenance diet but no cal. percent or wt percent of each component was given. Compliance was shown on blood lipid analysis.
Haglund et al. (Ref. 210).	Double-blind crossover study 30 mL/day of low vitamin E fish oil (9.6 g EPA plus DHA/day, Eskimo-3 or Inuit-3) or same oil supplemented with 1.5 IU vitamin E, 3 week.	12 Normal healthy subjects.	Lipids, glucose, Lp(a), fibrinogen.	Both fish oil ↓ TG's; ↑ HDL, glucose; NS cholesterol, Lp(a), apoB, insulin. Low vitamin E fish oil ↑ MDA, fructosamine; ↓ vitamin E. High vitamin E fish oil ↓ TG's, fibrinogen.	High vitamin E produced some effects independently of the fish oil, underscoring the need the control for polyunsaturated fatty acids, and have adequate vitamin E in the test substances.
Hamazaki et al. (Ref. 215).	Uncontrolled supplementation study, 1.8 g EPA ethyl ester/day, (laboratory purified), 6 months.	16 Diabetics, 5 IDDM, 11 NIDDM.	Albumin by radioimmunoassay with a commercial kit. HbA_{1c} by high performance liquid chromatography.	NS TG, cholesterol, glucose, HbA_{1c}, systolic, diastolic blood pressure, blood viscosity; ↓ albumin excretion, hematocrit.	NS body weight. Compliance was checked by blood EPA level. Dietary intake was not controlled. In IDDM fasting glucose was reduced, and barely missed statistical significance. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Hansen et al. (Ref. 216).	Crossover trial of 25 mL cod liver oil/day (6.25 g EPA plus DHA), 8 weeks versus no supplement.	20 healthy female and 20 healthy male subjects.	Whole blood clot (produced by added thrombin) lysis time to complete lysis. t-PA by commercial ELISA kit. Fibrinogen by spectrophotometric assay.	NS fibrinogen, fibrinolytic activity, t-PA; ↓ TXB_2.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Harats et al. (Ref. 217).	Parallel untreated controls versus 10 g MaxEPA/day (3 g EPA plus DHA), 4 weeks.	a. Smokers 6 MaxEPA, 5 controls. b. Smokers 3 control, 4 fish oil only, 4 fish oil plus 400 mg vitamin E smokers. c. Nonsmokers.	40 hour smoking abstinence and overnight fast prior to blood draw; 90 minutes 4 to 6 cigarettes smoked, for second blood draw.	↓ TG; NS cholesterol, HDL; fish oil ↑ TBARS in plasma presmoking ↑ TBARS after smoking.	TBARS in plasma, and LDL, more responsive to cigarettes than fish oils. Most, but not all of the increase due to fish oil alone could be blocked by the added vitamin E.
Harris et al. (Ref. 218).	Uncontrolled supplementation trial of fish oils plus aspirin; 325, 80, 80 mg aspirin for 3 days; 4 day wash out; 2 weeks on 4.5 g EPA plus DHA (SuperEPA); 325, 80 80 mg aspirin plus SuperEPA for 3 days.	8 healthy males.	Bleeding times by Simplate II. Platelet aggregation to AA, collagen, PAF and AA in combination with the other agonists.	Bleeding NS on fish oil; fish oil plus aspirin same as aspirin only; fish oil and fish oil plus aspirin NS on platelet sensitivity to AA, collagen, PAF, but fish oil ↓ extent of aggregation to collagen.	Medications were controlled but diet was not controlled. Short-term study with a small number of subjects may explain inconsistencies with other comparable studies. The study may not have had adequate statistical power to determine whether bleeding time increases of aspirin and fish oil are additive or greater than additive.
Harris and Windsor (Ref. 220).	Uncontrolled supplementation study on postprandial lipemia with of fish oil (2.2 g EPA plus DHA, Dale Alexander Omega-3), random assignment to capsules or emulsion for 4 weeks.	12 male and 4 female healthy normolipidemic subjects.	Bleeding times by Simplate. Background diets had 32 to 36 percent fat with 12 to 14 percent as saturated, 12 to 13 percent as monounsaturated, and 6 percent as polyunsaturated. Test meal provided 1 g fat/kg (61 percent of total calories: 32 percent of calories from saturated fatty acids; 13 percent from monounsaturated fatty acids, 7 percent from omega-3 fatty acids. Two hour blood samples through 10 hours post meal.	↓ TG's VLDL; NS cholesterol, LDL, apoB, $apoA_1$, HDL_2, vitamin E, Lp(a); ↑ HDL, HDL_3. ↑ Bleeding time; NS RBC deformability. Postprandial lipemia reduced about 40 percent.	No medications. No difference between capsules and emulsion in test meal, possibly because most fat was from other diet components.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Harris et al. (Ref. 219).	Randomized dose-response, 1.25 to 5 g EPA plus DHA/day (Promega) 6 months.	28 Hyperlipidemic patients.	Blood lipids, Simplate II for bleeding times.	↓ TG in dose-related manner 1 month and 6 months, except lowest dose NS at 6 months, ↓ VLDL on all but lowest dose; NS cholesterol, LDL, HDL, HDL_2, (except 2.5 g/day at 6 months ↑ LDL, HDL). ↑ Bleeding times on 2.5, 5 g/g RBC deformability largely unaffected.	Discrepancies among studies, methodologies were discussed. Irregularities may be due in part to small sample size. 4-week washout returned most values to pretreatment levels.
Sandra et al. (Ref. 222).	Randomized, double-blind, placebo-controlled trial of 10 g/day MaxEPA (3 g EPA plus DHA) versus olive oil, 6 weeks.	80 Noninsulin-dependent diabetic subjects.	Fibrinogen by Clauss, HDL by precipitation, LDL by calculation.	Transient ↑ glucose; NS HbA_1. ↓ TG; NS cholesterol, HDL; ↑ LDL (versus baseline). ↓ Spontaneous platelet aggregation, but NS responses to induced aggregation. ↓ blood pressure in both treatments.	Large, carefully controlled study in an at-risk population. Olive oil control doesn't allow conclusions about omega-3 fatty acid-specific effects.
Nozue et al. (Ref. 224).	Uncontrolled supplementation test of 2.7 g/day purified EPA ethyl ester (source not specified), 12 weeks.	15 Outpatients.	Ad libitum diets. Blood samples after 12 hour fast. Plasma lipids by ultracentrifugation every 4 weeks.	↓ cholesterol, TG, apoB, small dense LDL; ↑ large light LDL, lipid transfer protein activity; NS HDL, HDL_2, HDL_3, $apoA_1$, apoC, apoE.	Authors state the relative atherogenicity of large light LDL and small dense LDL is controversial.
Jensen et al. (Ref. 226).	Sequential dose-response with 1, 3, 6 g EPA plus DHA (Shaklee EPA), 4 weeks each with 3-week washout between.	14 healthy males and 4 healthy females.	1 Month run-in on fish free diet, otherwise diet not controlled. Bleeding times by Simplate II. Lipids by auto laboratory method.	↓ TG, VLDL on 6 g dose; ↑ HDL and HDL/LDL ratio on 6 g dose, but baseline HDL changed; NS cholesterol, LDL.	Changes in baseline HDL not shown.
Kremer et al. (Ref. 228).	Randomized double-blind placebo (olive oil) controlled trial of 3.25 or 6.5 g EPA plus DHA/day (ethyl esters, Pharmacaps), 24 weeks.	49 With rheumatoid arthritis completed the study.	IL-1 by bioassay.	↓ IL-1 38 percent 41 percent and 55 percent in olive oil, low and high fish oil groups, respectively; NS IL-2 in both fish oil groups.	Actual doses were adjusted per kg body weight.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Li and Steiner (Ref. 234).	Dose-response, parallel design: 4.8, 9.6, or 14.4 g EPA plus DHA/day, (source not specified), 3 weeks.	5 Normal healthy subjects each dose.	Platelet adhesion measured ex vivo in laminal flow chamber, using purified substrates.	↓ Platelet adhesion to collagen I and fibrinogen, near maximal response at 3 g EPA/day; speed of return to baseline values in the washout was directly related to dose.	This procedure reduces formation of thrombi, dilutes platelet derived factors. Measures direct interaction of platelets with surface matrix. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Lindgren et al. (Ref. 235).	Metabolic ward crossover of salmon versus prudent diet (30 percent fat). 20 day run-in, 40 days each diet. Salmon diet provided 2.1 percent of calories as omega-3 fatty acids, (approximately 5 g/day EPA plus DHA).	9 normolipidemic females.	Plasma proteins measured by competitive ELISA except $apoA_1$, by radioimmunodiffusion.	NS cholesterol, LDL, HDL_{2a}, HDL_{2b}, apoB, apoE, Lp(a); ↓ TG, HDL_3, HDL_{3b}, $apoA_1$, $apoA_2$; ↑ HDL, HDL_{3b}.	Carefully designed metabolic ward study, using practical level of omega-3 fatty acids, and Fat (saturated fatty acids and omega-6 polyunsaturated fatty acids) carefully controlled. Details on effects of lipoprotein subfractions. Two assay methods for Lp(a) gave same result.
Malle et al. (Ref. 241).	Uncontrolled supplementation with fish oil, (6.7 g EPA plus DHA/day, EPAX-5000), 6 weeks and 4-week washout.	Normolipemic subjects with very high (8) and very low, i.e., undetectable Lp(a) levels (7).	4 week run-in. Normal diets. Platelet aggregation to collagen, thrombin.	↓ TG, platelet aggregation; NS cholesterol, LDL, HDL, Lp(a).	Comparable lipid and platelet responses for the low Lp(a) and high Lp(a) groups.
Marckmann et al. (Ref. 244).	observational, sequential diets of fish (3.4 g/day EPA plus DHA, 10 d) uncontrolled (18 d), and meat (10 d).	12 healthy females.	Clauss fibrinogen assay, t-PA and PAI-1 antigens by ELISA.	NS cholesterol, HDL, TG, fibrinogen; TG ↓ on both diets; ↓ PAI-1 and t-PA antigen, PAI activity and ↑ t-PA activity on meat, but NS on fish.	Since both diets produced changes with respect to the initial diets (that were uncontrolled) it is difficult to ascribe any change to the omega-3 fatty acids. However, the changes on the meat diet are more in line with reduced CHD risk than the lack of change on the fish diet.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Meland et al (Ref. 247).	Double-blind, randomized multi-center placebo (corn oil- olive oil mix) controlled trial, 20 mL MaxEPA/day (6.8 g EPA plus DHA), 6 weeks.	40 females mild hypertension.	Calibrated instruments at 8 centers. Time of day for measurements was controlled.	NS blood pressure, cholesterol; ↓ TG's on fish oil; ↓ cholesterol/HDL ratio in both groups.	Power to detect a 5 mm blood pressure difference was 96 percent; a 10 percent cholesterol difference was 61 percent. Cholesterol/HDL ratio decrease in placebo was nearly more than that after fish oil ($p<0.07$). 11 of 14 subjects on fish oil guessed their assignment correctly.
Meydani et al (Ref. 248).	Uncontrolled supplementation study 2.4 g/day EPA plus DHA (Promega), 3 months.	25 males.	Blood at 1, 2, 3 months.	↓ TG's; ↑ lipid peroxides.	6 IU vitamin E may not be adequate.
Molvig et al. (Ref. 250).	Randomized, double-blind Placebo-controlled trial of 1.6, 3.2 g EPA plus DHA (Pikasol) versus fatty acid blend, 7 weeks.	25 Healthy subjects and 8 IDDM subjects.	Isolated monocyte cell cultures. TNF and IL-1 by commercial ELISA kits.	↓ IL-1B immunoreactivity on high dose only; NS after low dose. NS TNF-α; ↓ proliferative response.	Placebo had 20 percent polyunsaturated, 38 percent monounsaturated fatty acids. Spontaneous and LPS-stimulated leucotriene B_4 and PGE_2 secretion did not differ among groups at baseline or after 7 weeks of treatment. IL-1 returned to baseline with 3-week washout.
Mori et al. (Ref. 251).	Matched (age, weight) and randomized to 15 g MaxEPA/day (4.5 g EPA plus DHA) or olive oil, 4 weeks.	32 females with peripheral vascular disease.	No aspirin for 14 days prestudy platelet aggregation to PAF, collagen.	↑ cholesterol, LDL, HDL_2; ↓ TG by fish oil, (but olive oil ↓ cholesterol, LDL); ↓ platelet aggregation by fish oil, but olive oil ↑ aggregation.	Compliance by capsule count. Changes in control make interpretation difficult. Olive oil does not control for polyunsaturated fatty acids.
Mori et al. (Ref. 252).	Matched groups randomly assigned to 15 g/day MaxEPA (4.5 g EPA plus DHA), olive oil, or olive oil plus cholesterol.	27 normolipidemic insulin-dependent female diabetics.	HDL by heparin, manganese chloride precipitation, followed by separate precipitation of subfractions. LDL by calculation.	NS cholesterol, LDL, HDL; ↑ HDL_2, ↓ HDL_3, TG.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Mueller et al. (Ref. 253).	Randomized double-blind crossover trial of 8 g EPA plus DHA (Promega) versus olive oil, 21 d.	12 Healthy adults.	Bleeding times by Simplate II before and after administration of 325 mg aspirin. Excludes subjects with platelet or coagulation disorders, thrombocytopenia, ethanol.	Fish oil-MS bleeding time versus baseline but ↑ versus olive oil both before ($p < 0.02$) and after (NS) aspirin. ↓ TG on fish oil, platelet count, WBC count; NS cholesterol, LDL, HDL.	Trend toward ↑ HDL versus baseline, but olive oil in same direction, some order effects confound results.
Muller et al. (Ref. 253a).	Multicenter observational trial of 135 g canned mackerel paste (4.7 g/day EPA plus DHA) or meat paste.	84 healthy females.	Published methods for facror X, antithrombin III, alpha-antiplasmin, plasminogen. Fibrinogen by Clauss.	NS fibrinogen, other blood coagulation measures (only ↑ factor X), or fibrinolysis measures; meat ↓ plasminogen.	Compliance by lithium excretion. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Mullertz et al. (Ref. 254).	Uncontrolled supplementation, 0.55 g EPA plus DHA/day (Pikasol), 21 days.	7 Healthy adults.	Normal diets, PAI-1 and u-PA by ELISA kits.	↓ α-Tocopherol; NS cholesterol, TG's; ↑ PAI-1; NS t-PA, u-PA.	Suggests that differences reported for PAI-1 are due to the assay used, with the double antibody assay used in this study, and the monoclonal antibody used by Emeis et al. providing specificity. Concludes that fish oil decreases fibrinolytic activity.
Nelson et al. (Ref. 256).	Metabolic ward crossover of salmon, prudent diet (30 percent fat). 20 day run-in, 40 days each diet. Salmon diet gave 2.1 percent of calories as omega-3 fatty acids, (approximately 5 g/day EPA plus DHA).	9 normolipidemic females.	Platelet aggregation to ADP, AA, collagen, thrombin: threshold and maximum response. Bleeding time by Simplate II.	NS bleeding time; salmon diet ↓ platelet counts NS platelet response to collagen, thrombin but ↓ sensitivity to ADP.	Carefully designed metabolic ward study, using practical level of omega-3 fatty acids, and Fat (saturated fatty acids and omega-6 polyunsaturated fatty acids) carefully controlled.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Nikkila (Ref. 258).	Randomized, double-blind, placebo (corn oil) controlled, crossover, 2.4 g EPA plus DHA/day as ethyl ester (EPA X 6000EE, Almarin), two 4-week periods with a 4-week washout between, followed by open study of 3.6 g EPA plus DHA/day for 4 weeks.	32 females with CHD, increased TG and decreased HDL, 62 percent were overweight.	Lipid lowering diet for 4 weeks prior to study.	NS cholesterol, LDL, HDL, HDL/cholesterol ratio, $apoA_1$, apoB; ↓ TG's; During open phase those with severe hypertriglyceridemia had ↑ HDL/cholesterol.	HDL inversely related to TG in study group pretreatment.
Nye et al. (Ref. 259).	Randomized, fish oil and its placebo were double-blind 1. Aspirin 300 mg plus dipyridamole 75 mg. 2. 3.6 g EPA plus DHA (MaxEPA). 3. Olive oil, up to 1 year.	79 females, 29 males post PTCA referred for angina, none had grafts.	Angiography (blind) at one year or before in those with anginal symptoms; restenosis defined as a loss of 50 percent or more of the gain produced by PTCA.	NS angina (trend toward less in A/D and fish oil groups D restenosis by EPA (11 percent versus 30 percent for olive oil) MaxEPA not different in any regard versus A/D NS in any blood lipids in a subset (n= 42).	No deaths in any group through 1 year, 93 percent follow-up rate. Results suggest that MaxEPA is as useful or moreso than aspirin/dipyridamole.
Oh et al. (Ref. 261).	Randomized crossover of 4 normal eggs versus 4 omega-3 fatty acid-enriched eggs/day (4.5 g EPA plus DHA/day), 2 week run-in, 4 weeks each treatment.	9 female and 3 male healthy volunteers.	Recumbent blood pressure; VLDL by untracentrifugation, HDL by manganese-heparin precipitation.	Omega-3 fatty acid-enriched eggs did not ↑ cholesterol, but regular eggs did. Omega-3 fatty acid-enriched eggs ↓ TG in one group.	One of the groups used butter to prepare eggs, changing the P:S ratio. Pooled data were not given despite absence of order effects for most variables. ↓ LDL in one group; NS HDL in either treatment. Systolic blood pressure ↓ in both groups, diastolic only in one.
Olivieri et al. (Ref. 263).	Uncontrolled supplementation trial of 20 mL fish oil/day (3.0 g EPA plus DHA, source not specified), 8 weeks.	20 hyperlipidemic 16 female, 4 male.	No hypolipidemic drugs for 15 days pre trial. blood pressure by blinded nurse.	↓ Systolic diastolic blood pressure, TG; NS cholesterol, HDL, vitamin E; ↑ glutathione peroxidase activity in RBCs and platelets, ↓ MDA.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Owens and Cave, (Ref. 264).	Observational study, 15 g/day MaxEPA (4.5 g EPA plus DHA) 4 weeks.	6 normal females.	Simplate II for bleeding time. Platelet adhesion in Baumgartner chamber using everted rabbit aorta. Prothrombin time, WBC and platelet count by automated methods.	NS WBC, prothrombin time, platelet adhesion, bleeding time.	Trend toward increased adhesion with duration of feeding. Assay method measures platelet changes, but does not assay vessel wall changes. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Rapp et al. (Ref. 268).	Uncontrolled supplementation study of MaxEPA at 6 percent of calories (16 to 21.3 g EPA plus DHA/day), 6 to 120 days.	11 patients, 9 female, 2 male with obstructive atherosclerosis scheduled for peripheral vascular surgery.	Excludes subjects with habitual fish intake. 15 endarterectomy specimens. Control specimens from 18 nonfish consuming subjects undergoing vascular reconstruction.	Fish oil increased content of omega-3 fatty acids in atherosclerotic lesion linearly with duration of feeding, although plasma enrichment of omega-3 fatty acids plateaued by 2 to 3 weeks; ↓ cholesterol; NS TG's, platelet counts, bleeding times.	Shows incorporation of omega-3 fatty acids into plaque, especially DHA. Relevance to CHD not known. Not a specific effect of omega-3 fatty acids, but would be expected to polyunsaturated fatty acids. High amount of omega-3 fatty acids.
Saynor and Gillott (Ref. 276).	Uncontrolled long-term supplementation with 20 mL/day MaxEPA during year 1, 10 mL/day thereafter.	365 During 1 month to 40 at 84 months. 47 percent had survived a heart attack, 49 percent had angina.	Total cholesterol by enzymatic assay. HDL after precipitation.	↓ TG; ↓ cholesterol only for initial high cholesterol; ↑ HDL for total group; NS LDL; ↓ fibrinogen.	Large attrition makes it difficult to ascribe changes to fish oil (responders to treatment are more likely to stay in the study). Lack of blinding also may have contributed to bias. Some data were presented for all subjects only, other data only for subsets. Estimates of deviation from mean values not shown. Lack of control prevents conclusions regarding effects to omega-3 fatty acids.
Schmidt et al. (Ref. 277).	Dose-response study 1.3, 4, 9 g EPA plus DHA/day (Pikasol), 3 periods of 6 weeks/amount. Randomized to increasing or decreasing dose. 6-week washouts.	10 healthy females.	Simplate II for bleeding times; t-PA, PAI by commercial kits; fibrinogen by thrombin clotting time.	NS cholesterol, LDL, platelet aggregation; ↑ HDL, bleeding time on 4 and 9 g/day, PAI and t-PA antigen after 9 g/day; ↓ TG, fibrinogen.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Schmidt et al. (Ref. 278)	Uncontrolled supplementation with 4 g EPA plus DHA/day (Pikasol), 6 weeks.	10 Untreated hypertensives.	Supine blood pressure.	NS cholesterol, LDL, HDL, TG, platelet aggregation to collagen, ADP, systolic, diastolic blood pressure, bleeding time; ↓ cholesterol/HDL ratio, fibrinogen, monocyte chemotaxis.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects. Absence of significant change in plasma TG despite 25 percent decrease suggests inadequate sample size. Before and after compared by Pratt's test.
Schmidt et al. (Ref. 279).	Uncontrolled supplementation with 1.3 to 9.0 g EPA plus DHA/day (Pikasol, MaxEPA or cod liver oil), most for 6 weeks, angina subjects for 12 weeks.	Various at-risk subjects with angina (14), IDDM (10), hyperlipidemia (17), hypertension (10), and healthy subjects (46).	Normal diets. Lp(a) by two-site immunoradiometric test kit.	NS Lp(a) in any group.	Reports Lp(a) data for subjects from 5 previous Schmidt reports (Refs. 133 through 135), and the current refs above. Design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Shapiro et al. (Ref. 283).	Uncontrolled supplementation with 18 g MaxEPA/day (5.4 g EPA plus DHA/day), 6 weeks, 10-week washout.	10 normolipidemic, healthy females.	3 Samples per time point, 2 to 3 days apart.	↑ cholesterol, LDL, HDL, vitamin E, retinol versus presupplementation and washout; ↓ TG versus washout.	Multiple samples per treatment reduces day-to-day fluctuations, magnitude of changes: Cholesterol 6 percent; LDL 9 percent; HDL 11 percent versus average of pretreatment and washout values.
Singer et al. (Ref. 285).	Randomized to propranolol (P), or fish oil (2.9 g EPA plus DHA/day, source not specified), for 36 weeks, or (P) only (12 weeks) then P plus fish oil (12 weeks) then P plus olive oil placebo (12 weeks). Each followed by 4-week washout.	47 female patients with mild essential hypertension.	Two baseline blood pressure measures 4 weeks apart, blood pressure measured in triplicate at fixed time and post 2 hours of rest each 12 weeks.	P ↓ systolic, diastolic blood pressure, recumbent and upright; fish oil ↓ systolic, diastolic blood pressure in recumbent and upright; Some additive effects of P plus fish oil.	Olive oil control doesn't control for polyunsaturated fatty acids. Study duration and multiple measures (each 12 weeks) shows blood pressure lowering effect is persistent.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Hirtori et al. (Ref. 286).	Randomized, three-arm crossover of 6 g fish oil (Norsk Hydro, 4.5 g EPA plus DHA ethys esters) versus olive oil (middle arm for each sequence) versus corn oil for 6 weeks each. 1 month run-in and 4 week wash-out between each arm with low saturated fat diet.	12 Type IIa hyperlipidemics.	Lipids by enzymatic assays, apoproteins by immunoturbidity assay. Platelet aggregation versus AA. TXB_2 by radioimmunoassay. Superoxide by spectrophotometry.	Fish oil ↓ cholesterol, LDL, ↑ HDL; Olive oil ↓ LDL, ↑ HDL; Corn oil ↓ HDL, apoB. Platelet aggregation ↓ by all three oils. Fish oil ↓ superoxide in monocytes.	Excellent design. Divergent results from another recent study with comparable design (Ronaa et al. (Ref. 178) that used the same amount and form of fish oil supplement and same control (corn oil), suggesting that responses to supplemental oils may be different for different subpopulations. Absence of change in platelet aggregation may also be a population specific finding.
Spannagl et al. (Ref. 287).	Uncontrolled supplementation with 8.1 g EPA plus DHA/day (PGE-technology), 4 weeks.	13 (3 male 10 female) near normoglycemic type I diabetics.	Fibrinogen by turbidity assay. t-PA, PAI by test kits.	NS clotting tests, t-PA; ↑ PAI, fibrinogen; ↓ TG.	Design doesn't allow conclusions about omega-3 fatty acid-specific effects. Fairly high amount of omega-3 fatty acids in this nonnormal population.
Trials of Hypertension Prevention Collaborative Research Group (Ref. 289).	Randomized life style interventions and double-blind, placebo-controlled nutritional supplement interventions including 3.0 g omega-3 fatty acids/day (source not specified), 6 months.	2182 female and male with diastolic blood pressure 80 to 89 mm Hg.	Sitting blood pressure after 5 minute rest. Measurements for baseline, 3 and 6 months were made in triplicate on 3 different days. On the fish oil arm there were 161 active and 157 control subjects.	NS systolic, diastolic blood pressure.	Large, multicenter design with many internal comparisons.
Vandongen et al. (Ref. 291).	2 week run-in, observational trial of 15 g/day MaxEPA (4.5 g EPA plus DHA) versus no supplement.	22 female insulin-dependent diabetics.	Double precipitation for HDL subfractions.	↑ cholesterol, LDL, HDL, HDL_2; ↓ TG, HDL_3.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Virella et al. (Ref. 295).	Double-blind placebo (olive oil) controlled study of 2.4 g EPA (DHA not given) 6 weeks.	6 Normal subjects.	Blood samples at baseline, 3, 6, 14, 20, 28. Humoral immune response.	↓ TG in 3/4 on fish oil; variable in vivo response to tetanus toxoid booster; ↓ in vitro response to tetanus toxoid, ↓ IL-2 release.	Small number of subjects limits conclusions. Increase in bleeding reported in 2/4.
Vohwinkel et al. (Ref. 296).	Randomized, double-blind crossover of 6 g EPA plus DHA/day (source not specified) versus olive oil, 3 weeks.	48 Healthy subjects.	Glucose tolerance tests to 100 g oligosaccharides.	↑ Fasting glucose, insulin at 4 hours post load. Response of glucose to load affected differently by fish oil, depending on initial insulin response; among low responders fish oil increased insulin response and decreased glucose; among high insulin responders, fish oil reduced insulin response and lowered glucose response.	Complex results according to insulin responsiveness. Olive oil does;t control for effects of polyunsaturated fatty acids.
Wander and Patton, (Ref. 297).	3-period crossover of three fish diets; Dover sole (2 g EPA plus DHA), Salmon (4 g EPA plus DHA), or sablefish (3.4 g EPA plus DHA), 18 day each with 3-week washout between.	23 normo-triglyceridemic females.	Bleeding time by Simplate. Platelet aggregation versus collagen, ADP. TXB_2 by radioimmunoassay.	Salmon ↑ bleeding time. Sablefish ↓ platelet aggregation to collagen; Both sablefish and salmon ↓ aggregaton to ADP, ↓ TXB_2.	Diets were comparable for total fat, saturated fat. Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Weintraub et al. (Ref. 298).	Metabolic ward study. Crossover to 3 isocaloric diets:saturated fat; omega-6 fatty acids and omega-3 fatty acids (3.4 g/day EPA plus DHA), 25 days each with 5 to 7 day wash-out.	8 normolipidemic females.	Vitamin A fat load test in fasted subjects; HDL by precipitation, LDL by calculation. Lipolysis assay using human milk lipoprotein lipase.	Omega-3 diet ↓ cholesterol, TG, LDL, HDL, platelet count versus saturated fat. Omega-6 diet ↓ cholesterol, TG, LDL NS fasting glucose, postprandial insulin. Both omega-3 and omega-6 reduced postprandial lipemia versus saturated fat. NS in lipemia between omega-6 and omega-3.	Excellent design studies both chronic and acute fat effects. Many postprandial fat effects were larger on the omega-3 than the omega-6 diets, but not statistically significant.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Wing et al. (Ref. 299).	Double-blind, placebo (olive oil) controlled crossover trial of 15 g fish oil (Lipitac), 4.5 g EPA plus DHA, 8 weeks each.	20 Treated hypertensives maintained on blood pressure medications.	Supine and standing blood pressure. HDL after manganese chloride/heparin precipitation.	Blood pressure lower comparable on olive oil and fish oil. ↓ TG in fish oil; NS HDL on either treatment.	Study design doesn't allow conclusions about omega-3 fatty acid-specific effects.
Wojenski et al. (Ref. 300).	Sequential treatments with ethyl oleate (placebo), 6 g Res-Q1000 (3.6 g EPA plus DHA/day), or 4.0 g ethyl EPA. Washouts between phases of 5 weeks, 4 months, respectively, and 8 weeks posttreatment.	9 healthy female volunteers.	Bleeding time by Simplate II; HDL by hospital automated method, platelet aggregation to ADP, collagen. TXB$_2$ by radioimmunoassay. Fibrinogen binding by ^{125}I-Fibrinogen versus saline.	Bleeding time ↑ on ethyl EPA; Platelet count ↓ on Res-Q1000 and ethyl EPA; Ethyl EPA ↓ cholesterol, TG, platelet aggregation; NS fibrinogen binding.	No aspirin or ibuprofen. Evidence for a greater effect by the ethyl ester than for a comparable amount of omega-3 fatty acids in a mixed TG supplement.
Wolmarans et al. (Ref. 301).	Crossover comparison of red meat to fish, (6.1 g EPA plus DHA/day) 3 week baseline, 6 week treatment, 6 week posttreatment and 3-month washout.	Healthy subjects, 12 females, 16 males.	Habitual diet.	Fish diet ↓ cholesterol, LDL, VLDL; ↑ HDL.	NS total fat but ↓ saturated fat on fish diet. EPA was 1.91 g/day versus 0.06 g/day in baseline and 0.01 g/day on meat; total omega-3 fatty acids were 6.1 g/day on fish, and 0.9 g/day otherwise.

TABLE 2--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zambon et al. (Ref. 304).	Randomized crossover trial of fish oil 15 g/day SuperEPA (8 g EPA plus DHA ethyl esters), with and without glyburide 8 weeks on fish oil, 4 weeks on and 4 weeks off glyburide. Baseline treatment was glyburide alone, 4 weeks.	10 females with NIDDM.	Regular diets. Insulin by radioimmunoassay. Automated glucose analysis. Cholesterol by enzymatic methods.	Fish oil ↑ fasting glucose, NS fasting insulin, ↓ postprandial insulin. Fish oil ↑ LDL, NS cholesterol, HDL	High amount of omega-3 fatty acids may produce effects on glucose metabolism not seen with lower amounts. Effects are consistent with other reports, but absence of polyunsaturated fat control limits inferences about specificity of the effects.

Abbreviations used: apoA, apoprotein A (a protein in high-density liporpotein) apoE, apoprotein E (a protein in many lipoproteins, most notable VLDL and HDL); ASA, acetylsalicylic acid; ATP, adenosine triphosphate; CDC, Centers for Disease Control; CHD, coronary heart disease; ELISA, enzyme-linked immunosorbant assay; MDA, malondialdehyde; NIDDM, noninsulin dependent diabetes mellitus; NS, not statisticalluy significantly different; PGE-M, prostaglandin-M; TBARS, thiobarbituric acid reactive substances; TG's, triglycerides; TXB, thromboxane.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N-0096]
RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Dietary Saturated Fat and Cholesterol and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use on the label or labeling of certain foods of health claims relating to an association between dietary lipids (specifically, saturated fat and cholesterol) and cardiovascular disease (specifically, coronary heart disease (CHD)). The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets low in saturated fat and cholesterol may reduce the risk of heart disease. Therefore, FDA has concluded that claims on foods relating the reduction in dietary saturated fat and cholesterol to reduced risk of CHD are justified. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims and has been developed in accordance with the final rule on general requirements for health claims, which is published elsewhere in this issue of the Federal Register.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Paddy Wiesenfeld, Center for Food Safety and Applied Nutrition (HFS-465), Food and Drug Administration, 8301 Muirkirk Rd., Beltsville, MD 20708, 301-344-5825.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 27, 1991 (56 FR 60727), FDA proposed to authorize the use in food labeling of health claims relating diets low in saturated fat and cholesterol to decreased risk of CHD. The proposed rule was issued in response to provisions of the 1990 amendments (Pub. L. 101-535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended by the 1990 amendments, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship between dietary lipids and cardiovascular disease is one of the claims required to be evaluated. In the Federal Register of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on lipids and cardiovascular disease. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed in this document.

Because of the extremely large volume of scientific literature on this topic, FDA limited its scientific review to those aspects of the relationship for which the strongest scientific evidence and agreement already existed: dietary intakes of total saturated fats and cholesterol relative to risk of CHD. In addition to evaluating the scientific evidence relating saturated fat and cholesterol to cardiovascular disease, the proposed rule identified qualifying and disqualifying criteria for foods, specified mandatory and optional information for health claims statements, and provided model health claims. FDA also discussed potential safety issues associated with reducing current dietary intakes of saturated fat, cholesterol, and total fat.

FDA requested written comments in response to the proposed rule and solicited comments on several issues in particular. The agency asked how to restrict the use of these health claims to foods that are appropriately included as part of healthy diets, and whether there is a need for consumer summaries.

On January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for dietary saturated fat and cholesterol and heart disease (57 FR 239).

In response to its proposed health claim on lipids and cardiovascular disease, the agency received approximately 100 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately answered in other documents, and these were forwarded to the appropriate docket for response.

II. Comments on the Relationship Between Dietary Saturated Fats and Cholesterol and CHD

The majority of comments supported FDA's conclusion, noting that the scientific evidence that dietary saturated fat and cholesterol increase the risk of CHD is very strong and well accepted in the scientific community. Many of these comments provided little or no detail on their reasoning. One detailed comment that supported the saturated fat and cholesterol/heart disease relationship was the report of the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB), which evaluated recent scientific publications on this topic. The FASEB draft report was summarized by FDA in the November 27, 1991, proposal (Ref. 78). The final report was submitted to the docket as a comment (Ref. 196). The conclusions of the final LSRO report concur with previous dietary guideline recommendations that reducing intakes of saturated fat and cholesterol would lower total blood and low-density lipoprotein-cholesterol (LDL-cholesterol) levels and, thus, lower risks of CHD in the U.S. population.

A number of comments suggested modification and revision in various provisions of the proposal. A summary of the suggested changes and the agency's responses follows.

1. The agency received a number of comments focusing exclusively on dietary cholesterol as a risk factor for heart disease. Some comments suggested that the scientific evidence does not support a relationship between dietary cholesterol and blood cholesterol levels and suggested that the nutrient/disease linkage is primarily with saturated fat. The comments noted that most dietary cholesterol is not absorbed, and that individual responses to dietary cholesterol are highly variable. Conversely, many comments noted the compelling nature of the scientific evidence linking dietary cholesterol to risk of heart disease. The 1992 LSRO review of the science on this topic (Ref. 196) not only strongly supported the relationship between dietary cholesterol and increased blood

cholesterol levels but suggested that newer evidence increased the importance of dietary cholesterol as a risk factor for heart disease.

FDA agrees with those comments that suggested that there is adequate scientific evidence and significant scientific agreement that diets high in cholesterol increase the risk of heart disease. This conclusion is consistent with current dietary guidance and nutrition policy statements from the Federal Government (Refs. 29, 36, 136, and 150), the National Academy of Sciences (Ref. 20), and the recent LSRO report (Ref. 196). None of the comments that argued against such a link submitted either data or compelling logic to convince FDA that this conclusion is not correct. FDA recognize that there is some scientific disagreement about the relative importance of dietary cholesterol versus saturated fat intakes (56 FR 60730). However, there are strong and consistent data that support that saturated fat and cholesterol have independent effects on the risk of heart disease. Because the data support an independent effect for dietary cholesterol and for saturated fat, the relative importance of dietary cholesterol versus saturated fat on blood cholesterol levels and risk of heart disease really is irrelevant to the agency's conclusion that a health claim on both nutrients is appropriate. FDA recognizes that individual responses to dietary cholesterol are less consistent than to saturated fat. However, recent authoritative reviews (Refs. 20, 29, 31 through 36, 63, 71, 74, 98, 99, 129, 130, 136, 141, 150, 151, and 223) have concluded that the majority of persons in the United States will benefit from recommended dietary changes in cholesterol intake, even though the magnitude of the benefit varies among individuals.

2. Several comments stated that FDA did not address the issue of a beneficial role for dietary *cis*-monounsaturated fatty acids (MUFA's), a major source of dietary fat in the United States, in reducing the risk of heart disease. In this context, one comment noted that the Keys equation, which was used in several studies for predicting or explaining changes in blood total cholesterol based on dietary intakes of saturated and polyunsaturated fatty acids (PUFA's), was inadequate as a basis for evaluating the role of dietary lipids in reducing risk of heart disease, because it does not include a term for the amount of MUFA's. The comment further stated that, in light of newer data on possible beneficial effects of MUFA's, this equation may no longer adequately reflect the predictive value of changes in fat intakes to changes in blood cholesterol levels in the U.S. population.

The LSRO report (Ref. 196) evaluated the potential usefulness of oleic acid, the major *cis*-monounsaturated fatty acid, as a replacement for saturated fat in the American diet. The report concluded that recent research results are consistent with the conclusions that substitution of oleic acid for saturated fatty acids (SFA's) in the diet is safe and without adverse effects on blood LDL-cholesterol levels. The report stated that substitution of *cis*-monounsaturated fats for saturated fats can allow Americans to maintain customary intakes of total dietary fat without the negative effects of the more cholesterol-raising SFA's (i.e., lauric, myristic, and palmitic fatty acids). The LSRO report noted, however, that a diet high in monounsaturated fats (i.e., oleic acid) may contribute to development of obesity, a risk factor for heart disease.

FDA is aware of the recent and ongoing research efforts on the possible beneficial role of *cis*-forms of MUFA's in helping Americans to find a practical means of reducing saturated fat intake without changing total dietary fat intakes (Refs. 6, 37, 53, 57, 89, 93, 139, 144, 158, 159, 175, 180, 188, 192, 196, and 219). FDA, however, considers this issue outside the scope of this rule. In the proposed rule, the agency noted that, because of the extremely large volume of scientific research on lipids and cardiovascular disease and because of the extremely limited time constraints of the 1990 amendments, it had limited its science review to an evaluation of the relationship of saturated fat and cholesterol intakes to risk of CHD. Therefore, in both the proposed and final rules, FDA has limited the health claim to saturated fats and cholesterol.

FDA notes that the rapidly expanding science base may now, or in the future, be adequate to support that *cis*-monounsaturated fatty acids have a beneficial role in reducing blood total and LDL-cholesterol levels. However, because the question of whether this nutrient/disease relationship is appropriate for a health claim is outside the scope of this rulemaking, the question should be the subject of a petition for a health claim in accordance with the provisions of the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**.

3. One comment suggested that novel fats that affect a surrogate marker for the disease, such as lowering of blood LDL-cholesterol, should be allowed to carry a health claim.

FDA is aware that a large amount of research and development is being done on novel fats. Novel fats are those fats that are not commonly found in the food supply. Some examples of novel fats include those fats modified by rearrangement of fatty acids in triglyceride or by the addition of a cyclic or aromatic ring to a fatty acid. (The issue of "bioavailability" of novel fats is addressed elsewhere in this issue of the **Federal Register** in the final rules on mandatory nutrition labeling, nutrient content claims, and health claims.)

FDA did not have any scientific evidence on the possible effects of specific novel fats on risk of heart disease, or on other validated surrogate markers for heart disease, in developing this final rule. Therefore, FDA has not dealt with this issue in this final rule.

III. Qualifying Nutrients

The qualifying levels for saturated fat, cholesterol, and total fat are the maximum level at which these nutrients may be present in a food if it is to qualify to bear a claim. The levels of saturated fat, cholesterol, and total fat in a food must be less than those specified in the qualifying levels for the food to be eligible.

A. Saturated Fat and Cholesterol

In the proposed rule, FDA tentatively provided that, to bear a claim associating a diet low in saturated fat and cholesterol with reduced rate of coronary heart disease, the food must be "low saturated fat," "low cholesterol," and "low fat," as those terms are defined in new § 101.62. FDA also proposed to require that the food contain 1 g or less of saturated fat per 100 g of food.

4. A number of comments recommended that claims include information about the amount of saturated fat and cholesterol beyond the information contained on the nutrition panel. Some comments recommended the use of an index or "cholesterol-saturated fat index" (CSI) that integrates known relative effects of saturated fat and cholesterol intakes in predicting increased changes in total and LDL-cholesterol levels (Refs. 202 and 203). These comments pointed out that the CSI consists of a single score or number by which it would be possible to determine the relative cholesterol-raising propensity of a given food. The comments suggested that the CSI for a given food would be calculated from the experimentally-derived formula: (1.01 × g saturated fat) + (0.05 × mg cholesterol).

One comment included a detailed listing of CSI's for a wide variety of foods, including milk with 1-percent fat, which had a CSI of 2, and butter, which had a CSI of 37.

FDA agrees with the concept that consumers should have label information presented in a manner that enables them to evaluate an individual food relative to total dietary goals. However, the agency has not included any requirement for use of a CSI index in the final rule. The comments did not provide data to show that consumers would find use of a CSI index more helpful than the nutrition information currently required on food labeling. FDA is concerned that consumers might place undue emphasis on the CSI index in purchasing decisions and not concentrate on consuming healthful diets, which include a variety of foods.

FDA considers that a consistent approach to nutrition information on food labels will be less confusing to consumers than the use of a CSI index. FDA's general approach is to provide information that allows a consumer to construct a diet that is consistent with the particular health claim and with general dietary recommendations. The use of a CSI index, however, would be inconsistent with that approach because it would likely lead the consumer to place more emphasis on the specific food than on the entire diet. In addition, the larger scientific community has not generally agreed on a particular symbol or approach, such as the CSI index, for helping consumers to identify foods that will help lower their risk of heart disease.

Thus, FDA is retaining its proposed approach with respect to the label information that must appear on foods that qualify for a health claim on lipids and heart disease.

5. A few comments suggested that foods that contain eggs or egg products should be eligible to bear the authorized health claim.

The agency agrees that a food containing eggs or egg products should not be denied a health claim for saturated fat and cholesterol and heart disease, provided that the food is "low saturated fat," "low cholesterol," and "low total fat" and meets the other qualifying requirements for a health claim on this topic. The qualifying criterion for cholesterol is based on the final concentration of cholesterol in the food product and not on the cholesterol content of ingredients. Therefore, if eggs and egg products used as ingredients do not cause a food to exceed the definition of "low cholesterol," the food may qualify for a health claim.

6. Other comments suggested that the qualifying level for the saturated fat and cholesterol content of a serving of food be made less restrictive so that a larger number of wholesome foods can qualify for a health claim. Some of the comments stated that the permissible level of 1 g of saturated fat for a serving of food should be increased io 2 g. A few comments proposed that "foods that contain 20 milligrams or less of cholesterol per serving and 2 grams or less of saturated fat should be allowed to make a health claim." Other comments asserted that the saturated fat and cholesterol/heart disease health claims should be allowed on foods that qualify for the comparative claim, "reduced cholesterol." Some comments also objected to the per 100 g density criterion for qualifying levels of saturated fat and cholesterol, suggesting that it unfairly discriminates against foods that have a useful dietary role in reducing the risk of heart disease but that, because their servings sizes are less than 100 g, exceed the qualifying criterion on a per 100-g density basis.

Based on the large number of comments that the agency received, FDA has reassessed the qualifying levels for saturated fat, total fat, and cholesterol, including the density criterion. (See the final rule on general requirements for nutrient content claims published in this issue of the **Federal Register** for a more detailed discussion. FDA incorporates that discussion by cross reference. Based on this reanalysis and on the comments received, FDA has been persuaded that the second qualifying criterion based on per 100 g is too restrictive for "low fat" and "low cholesterol" claims. (The proposed definition for "low cholesterol" did not include a per 100-g criterion.) The agency has concluded that this criterion should be modified to more directly reflect the nutrient dence foods with small serving sizes that it was designed to address. Therefore, FDA has modified the density criterion from a per 100-g basis to a per 50-g basis for foods that have a reference amount customarily consumed of 30 g or of 2 tablespoons or less. With this modification, a larger number of wholesome foods may qualify for a health claim, including more brands of breakfast cereals and cereal grain products (Ref. 222).

The agency disagrees that "reduced cholesterol" and other comparative claims should be the basis for qualifying levels of nutrients. Many foods, even after meeting the requirements for "reduced" claims, contain significant amounts of saturated fat or cholesterol. When making substitute choices among similar types of foods (e.g., deciding upon which brand of vegetable oil to purchase), comparison claims are very useful in helping consumers to make a choice. However, when putting foods together within a total dietary context, the absolute amount of nutrient present in a food is important.

7. Some comments noted that FDA's proposed definition of saturated fat (i.e., the sum of lauric, myristic, palmitic, and stearic acids) is not consistent with the most recent evidence on cholesterol-raising fatty acids. The comments suggested that the cholesterol-raising characteristics of SFA's are due almost entirely to three SFA's: lauric, myristic and palmitic fatty acids. Conversely, stearic acid, which is a significant source of SFA's in the U.S. diet, has relatively little effect on blood cholesterol levels. The comments further note that this variability in cholesterol-raising potential opens new opportunities to replace cholesterol-raising saturates with other saturates that are not cholesterol-raisers (i.e., stearic acid).

The agency agrees that specific SFA's vary in their potential for an adverse effect on blood cholesterol levels and on other atherosclerotic risk factors. In the proposed rule (56 FR 60727 at 60734), FDA acknowledged that lauric, myristic, and palmitic SFA's have the greatest effect on blood cholesterol levels, and that, in this respect, stearic acid is relatively neutral. FDA disagrees, however, that the definition of saturated fat should be limited only to the sum of lauric, myristic, and palmitic fatty acids. In the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, and in response to comments, FDA has changed the definition of saturated fat to include the sum of all fatty acids containing no double bonds. This definition will apply to all references to saturated fat on the food label. Also, as noted in the preamble to the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**, this definition for saturated fat is consistent with dietary guidelines for diets to reduce risk of heart disease (i.e., consume less than 10 percent of calories as saturated fat; therefore, all four saturated fat (lauric, myristic, palmitic and stearic) plus less abundant saturated fats are included in the new definition.) Furthermore, FDA has noted that elevated blood cholesterol is not the only risk factor for cardiovascular disease (56 FR 60727 at 60734). Saturated fats have been implicated as possibly increasing the risk of cardiovascular disease through mechanisms other than adverse effects

on blood total and LDL-cholesterol (Ref. 20).

B. Total Dietary Fat as a Qualifying Criterion

In the proposal (56 FR 60727 at 60739), FDA proposed to prohibit health claims relating diets low in saturated fat or cholesterol to lower blood cholesterol levels and reduced risk of CHD unless the food also meets requirements for a "low" claim relative to total fat content (i.e., 3 g or less of fat per label serving size, per reference amount customarily consumed, and per 100 g). FDA notes that, while total fat is not as strongly or directly linked to increased risk of CHD as it may have significant indirect effects.

8. A number of comments supported the agency's position that a food must not only be low in saturated fat and low in cholesterol but must also be low in total fat, and that decreasing total fat intakes will generally aid in decreasing intakes of saturated fat and cholesterol. However, several comments opposed the additional "low fat" qualifying criterion, suggesting that foods recommended by public health authorities (such as fish, chicken, and lean beef and vegetable oils that are low in saturated fat and cholesterol) would not qualify for a health claim and that this would appear inconsistent with efforts to encourage an overall healthful diet.

FDA agrees that total fats are an appropriate qualifying criterion, and this provision is retained in new § 101.75(c)(2)(ii). (In the November 1991 proposed rules, FDA combined the regulations for lipids and cardiovasuclar disease (proposed § 101.73(a)) and lipids and cancer (proposed § 101.73(b)) into one section. In these final regulations, FDA has separated the two health claims into individual sections. New § 101.75 covers dietary saturated fat and cholesterol and coronary heart disease. New § 101.73 covers dietary fat and cancer.) FDA has retained this criterion because low fat foods generally help individuals in reducing their intake of saturated fat and cholesterol. In addition, excess calories, of which fat contributes more per g than the other energy nutrients, is associated with two health-related conditions (obesity and diabetes) that are risk factors for heart disease. These provisions now read in new § 101.75(c)(2)(ii): "The food shall meet all the requirements for a 'low saturated fat,' 'low cholesterol,' and 'low fat' food; * * *."

FDA agrees that lean meats, fish, and poultry, when eaten in moderation and prepared with little or no added fat, can play an important role in helping consumers to meet dietary guidelines. Meats, fish, and poultry play an important role in the U.S. dietary pattern, serving as entrees as well as rich sources of protein, bioavailable sources of many minerals, and rich sources of several vitamins. As proposed, the qualifying criteria virtually prohibit this category of foods from bearing health claims. As a result, the proposed criteria may inadvertantly interfere with the dietary guidance goals of encouraging consumption of a variety of foods and of increased use of lean meats, fish, and poultry instead of higher fat cuts.

In the final rule on general requirements for nutrient content claims published elsewhere in this issue of the **Federal Register**, FDA is defining the term "extra lean" as a claim for game meats and fish. Although this definition is not as stringent as the definition for "low fat," "low saturated fat," and "low cholesterol," it is consistent with the U.S. Department of Agriculture (USDA) definition for "extra lean" for meats and poultry.

The agency is persuaded that, to be consistent with the dietary guidence goals discussed above, health claims should be allowed on "extra lean" cuts of meat, fish, and poultry. FDA is therefore providing for saturated fat and cholesterol/CHD claims on "extra lean" game meats and fish that meet these requirements. This provision is added in new § 101.75(c)(2)(ii) which reads: "* * * except that fish and game meats (i.e., deer, bison, rabbit, quail, geese, and ostrich) may meet the requirements for 'extra lean' in § 101.62."

FDA disagrees with the comment suggesting that foods consisting entirely of fats and oils, but low in saturated fat and cholesterol, should qualify for heart disease health claims. Low fat diets are recommended in all Federal Government and National Academy of Sciences' dietary guidelines for reducing the risk of heart disease. Labeling of foods that are 100-percent fat with a message implying they are "heart healthy" is clearly inconsistent with dietary guidelines. FDA believes that the use of content claims is a more appropriate method for helping consumers make purchasing decisions about those oil products that they choose to include in their total daily diet than allowing those foods to bear health claims.

9. One comment suggested that total fat should be the basis for both the cancer and the heart disease health claims because these two diseases generally are considered together under a single dietary guidance goal for moderation in intakes of total fat and saturated fat.

The agency agrees that public health dietary guidelines generally focus on the reduction in total fat as a major, single goal when referring to both heart disease and cancer risks. However, health claims are specific for a nutrient-disease relationship. Heart disease and cancer relate to dietary factors through different mechanisms.

In the instance of CHD, dietary saturated fat and cholesterol are the major dietary risk factors because they increase blood LDL-cholesterol levels, which increase the risk of heart disease. As noted in the proposed rule (56 FR 60727 at 60739) and discussed above, total fat consumption affects risk of heart disease indirectly, through its effects on obesity and on facilitating dietary reductions in saturated fat and cholesterol. In contrast to the association between dietary fat and heart disease, the observed association between dietary fat and cancer has not been attributed to a specific type of lipid but has generally been linked to total fat intakes (see the final rule on dietary lipids and cancer published else where in this issue of the **Federal Register**.

Health claims must reflect current scientific understanding and agreement as to the basis of a diet-disease relationship. Thus, total fat is not listed as a causal dietary fat in the health claim. Instead, it is addressed as an additional criterion that must be met by a food before it may carry a health claim relating dietary saturated fat and cholesterol to risk of heart disease, because of the strong indirect effect of fat on heart disease risk. Of course, food labels may also include the claim "low fat" in addition to a health claim in accordance with the requirements for such claims, as discussed in the final rule on general requirements for nutrient content claims elsewhere in this issue of the **Federal Register**.

C. Other Qualifying Criteria

10. Some comments recommended that consumption of foods that alter other risk factors for CHD be included as qualifying nutrients relative to the fat/heart disease claim. For example, because foods high in salt or excess calories from sugars may be related to hypertension or obesity, respectively, the comments requested that limits be placed on the amount of salt or sugars that a food bearing this health claim may contain.

FDA recognizes that both hypertension and obesity are risk factors for heart disease and (see the final rule on sodium and hypertension, published elsewhere in this issue of the Federal

Register. As stated in the dietary guidelines, salt and sugars should be used in moderation. However, FDA believes that the arguments for making sugars content a qualifying criterion are considerably less compelling than those for total fat.

FDA has not established a Daily Reference Value for sugars because, other than dental caries, no public health concerns related to sugar have been substantiated (see final rule on Reference Daily Intakes and Daily Reference Values published elsewhere in this issue of the Federal Register). A cause-and-effect relationship between sugars intake and obesity is also not well established (Refs. 224 and 225). Conversely, the relationship of fat to obesity is based in part on the fact that fat is a more concentrated source of calories than sugars (9 calories per g versus 4 calories per g). Furthermore, new research suggests that, on a calorie-by-calorie comparison, fat calories may be more likely to be laid down as adipose (fat) tissue in the body than carbohydrate calories (including sugar) (Ref. 20).

Additionally, since saturated fat and cholesterol constitute part of the total fat content of foods, most dietary guidelines suggest that it is generally easier to reduce the target nutrients if total fat also is reduced (Refs. 20, 29, 33, 35, 36, 136, 150, and 151). High total fat intakes are also associated with the risk of cancer (see the final rule on dietary lipids and cancer, published elsewhere in this issue of the Federal Register. For these reasons, all current dietary guidelines include reduction of total fat as well as saturated fat and cholesterol when recommending dietary changes to reduce the risk of heart disease. Similar recommendations are not made for sugars (Refs. 20, 35, 136, and 151).

Thus, FDA concludes that the arguments to make sugars content a qualifying or disqualifying criterion are not convincing based on available data. FDA recognizes that all food nutrients, including sugars, have an appropriate role in the diet.

In the case of salt (and sodium), the issue is more difficult. FDA has found that sodium is a risk factor for hypertension (see the final rule on health claims for sodium and hypertension published elsewhere in this issue of the Federal Register). Furthermore, hypertension is considered to be a risk factor for cardiovascular disease, particularly for strokes and, to a lesser degree, for heart disease (Refs. 20 and 30 through 36). In choosing qualifying criteria for authorized health claims, FDA has tried to limit the number of qualifying nutrients to those nutrients that are most strongly linked to the nutrient/disease relationship, based on the current science. In the case of total fat, FDA concluded that it is appropriate to include it as a qualifying criterion because saturated fat is a subcomponent of total fat and because dietary guidelines consistently recommend moderate intakes of saturated fat, cholesterol, and total fat.

Sodium is a disqualifying nutrient for the dietary saturated fat and cholesterol/heart disease health claim, as for all health claims (i.e., as finalized, any health claim is prohibited on a food if the food contains 480 mg or more of sodium per reference amount customarily consumed, per label serving, or, if the reference amount is 30 g or less or 2 tablespoons or less per 50 g of food). The suggestion to make sodium a qualifying, rather than a disqualifying nutrient for this claim is less compelling than the argument for total fat. The link of salt to heart disease is not as direct as the link between saturated fat and cholesterol to heart disease. Dietary guidelines generally deal with sodium and fat separately. If sodium were changed from a disqualifying to a qualifying nutrient, that is, if foods were required to be low in sodium to be eligible for a saturated fat/cholesterol and heart disease claim, the number of foods that could bear such a claim would be greatly reduced. Foods excluded would include many foods in the following food categories that are generally found to be useful in meeting healthful diets: vegetable products, whole wheat breads, cereals, legume products, and some dairy products (Ref. 222). By retaining sodium as a disqualifying nutrient, not only will a much broader range of useful foods be allowed to qualify for a fat/heart disease claim, but foods in these and other food categories that contain large amounts of sodium will be disqualified. Examples of foods that will be excluded because their sodium content exceeds the disqualifying levels are certain vegetable products such as sauerkraut and some juices, many soups, and some sauces.

11. Several comments recommended that the agency drop the qualifying requirement for saturated fat in proposed § 101.73(a)(3)(iii), in which FDA proposed that the saturated fat content of the food must be less than 1 g per 100 g of food. One comment suggested that the agency instead require that the food be low in saturated fat or have "not more that 7 percent of calories from saturated fat."

The agency was persuaded by the comments that the additional density requirement (per 100 g) for saturated fat is not necessary. The agency was originally concerned that if it used only the definition for "low saturated fat" in the nutrient content claim proposal; the claim could appear on certain fats and oils. However, the agency has recognized that the requirement that a food meet the "low fat" criteria will prohibit foods that are 100 percent fat, such as oils, from bearing that health claim. The agency therefore has dropped the additional qualifying requirement for saturated fat that was in proposed § 101.73(a)(3)(iii). The agency has determined that the food or food product must meet the following qualifying criteria: "low in saturated fat, low in cholesterol, and low in total fat," as described in the rule on nutrient content claims published elsewhere in this issue of the Federal Register and stated in new § 101.75(c)(2)(ii).

IV. Safety Issues

In the proposed rule (56 FR 60727 at 60735), FDA noted that reductions in dietary intakes of saturated fat and cholesterol could result in higher intakes of other dietary components (e.g., monounsaturated and polyunsaturated fats, simple and complex carbohydrates, and commercially generated fats), because calories lost from decreased intakes of saturated fats would likely be "made up" by other energy-yielding nutrients. The availability of saturated fat and cholesterol/heart disease health claims will likely motivate manufacturers to alter the amount and type of fats added to foods, resulting in changes in composition of the U.S. food supply. As FDA discusses more thoroughly in the preamble of the final rule on general requirements for health claims, which appears elsewhere in this issue of the Federal Register, changes in consumption patterns may affect whether a food ingredient is safe and lawful under the act. Manufacturers should therefore assure themselves that such consumption changes will not affect the lawful status of the foods containing these ingredients. The agency, in its proposed rule (56 FR 60727 at 60735 to 60737), identified several areas of possible concern regarding changing American dietary patterns.

A. Trans-fatty Acids

One area of potential concern identified in the proposed rule is the potential for increased consumption of *trans*-fatty acids because of substitution of these fats for SFA's in foods. *Trans*-fatty acids (generally isomers of *cis*-monounsaturated fatty acids) are primarily constituents of commercially

hydrogenated or hardened natural vegetable oils used in formulating margarine, shortenings, and salad and cooking oils.

12. A number of comments were received, some agreeing and some disagreeing, on the agency's public health concern that *trans*-fatty acids may have cholesterol-raising characteristics, and, therefore, may increase the risk of heart disease. These concerns were raised in response to the published results of the Mensink and Katan study (Ref. 95). This study assessed the effects of a diet enriched in *trans*-fatty acid on blood lipids in 34 healthy women and 25 healthy men. The study results suggested that compared to an isocaloric diet enriched in oleic acid (a monounsaturated fat), the *trans*-fatty acid diet significantly increased LDL-cholesterol and significantly decreased high-density lipoprotein cholesterol (HDL-cholesterol) levels (two risk factors for heart disease (Refs. 1, 31, 33, 35, 48, 49, 74, 84, 112, 113, and 187)). (An evaluation of study design, results, and public health implications is found in the proposed rule (56 FR 60727 at 60736)).

In addition, the potential adverse health effects of *trans*-monounsaturated fatty acids were evaluated in the final version of the 1992 LSRO report on Lipids and Cardiovascular Disease (Ref. 196). This report states that:

> • • •until recently there was the general belief that *trans*-monounsaturates are "neutral" with respect to serum cholesterol levels. However, the recent findings of Mensink and Katan (1990) strongly suggest that these fatty acids have an adverse effect on serum lipoprotein levels, especially raising LDL-cholesterol levels. Still it hardly seems prudent to alter general dietary recommendations on the basis of a single study, albeit an excellent piece of investigation. Further carefully controlled studies thus appear to be in order before definitive recommendations can be made about *trans*-fatty acids for the American diet.

Other comments stated that "*trans*-fatty acids in foods may increase the risk of CHD equal to or greater than saturated fatty acids." Another comment suggested that "*trans*-fatty acids may increase the risk of coronary heart disease by a mechanism other than by increasing blood cholesterol." Another comment referred to *trans*-fatty acids as "deadly *trans*-fat pollution." Another comment suggested that the agency require a "warning" label for foods containing significant amounts of *trans*-fatty acids. Several comments suggested that *trans*-fatty acids should be included in the declaration of total SFA's content because they may have "cholesterol-raising" effects.

One comment on *trans*-fatty acids provided data that suggested that the *trans*-fatty acid content of some foods such as French fries was much higher than reported in commonly used food composition tables (i.e., that a medium serving of French fries from a fast food restaurant contained 7 g of *trans*-fatty acids, the upper daily limit of consumption suggested in several authoritative reports). Another comment criticized these data suggesting that proper sampling of the class of analyzed food had not been done.

One comment suggested that *cis*- and *trans*-monounsaturated fatty acids have similar metabolic actions. No data were provided in support of this comment, although it pointed out that the 1985 FASEB report on *trans*-fatty acid (Ref. 74) concluded that *trans*-fatty acids did not increase the risk of heart disease. One comment was concerned with the negative tone of the discussion on *trans*-fatty acids and suggested that the cited 1991 study by Mensink and Katan (Ref. 95) on adverse effects of *trans*-fatty acids was limited by its short duration (3 weeks), study population (healthy students), and processing techniques used to generate the hydrogenated *trans*-fatty acid isomers used in the test diets (varying catalyst and time) (Ref. 200). The comment expressed concern that the *trans*-fatty acids used in the test diets differed from those most commonly found in the U.S. food supply (i.e., different positional isomers), and that the *trans*-fatty acids may have been consumed in larger quantities in the test diets than they are generally consumed in the United States. The comment further suggested that a combination of these factors may have created a situation in which the study results suggesting that the consumption of diets enriched in *trans*-fatty acids increase blood LDL-cholesterol levels and decreased blood high density lipoprotein HDL-cholesterol; a blood cholesterol component for which low levels are associated with increased CHD risk (Refs. 1,47 through 49, 74, 75, 112, 113, and 187) were not necessarily applicable to the U.S. population. One comment referred to the report of Nestel (Ref. 177), which compared the effect of edible vegetable oil blends containing hydrogenated fatty acids on serum lipids. (The diets and study design are described in Table 1 of this document.) The results of this study showed that low saturated fat test diets containing *trans*-fatty acids from different oil sources lowered blood total cholesterol and LDL-cholesterol levels significantly as compared to control diets high in saturated fat.

Among the other comments on the study by Mensink and Katan (Ref. 95, 56 FR 60737 at 60736), was a referral to a published article written by Mensink and Katan (Ref. 201) which addressed criticisms of their 1990 study by noting that another study of longer duration (16 weeks), conducted in the same laboratory, found a similar effect on blood cholesterol levels, even after only 2 weeks on the diets (Ref. 201). One comment suggested a need for further research in the area of *trans*-fatty acids and blood cholesterol levels before policy decisions are made.

The agency agrees in general with the conclusions of the 1992 LSRO report that, while the available evidence to date is suggestive that *trans*-monounsaturated fatty acids may have LDL-cholesterol-raising characteristics, there is insufficient evidence upon which to make policy decisions at this time. FDA also notes that the requirement that foods be "low" in total fat before making a fat/heart disease health claim limits a manufacturer's ability to increase *trans*-fatty acid levels in foods, since any substitution of *trans*-fatty acids for SFA's must be done within the 3 g per reference serving size, or per 50 g, limit for total fat. This approach is unlikely to result in significantly increased levels of *trans*-fatty acids in foods qualifying for a health claim. The agency may reconsider the relationship of *trans*-fatty acid to heart disease claims at a later date if new data become available to confirm and strengthen the initial findings of an adverse effect of *trans*-fatty acids on blood LDL- and HDL-cholesterol levels. Results from well-designed scientific studies on the effect of *trans*-fatty acids at, or, slightly above, current U.S. consumption levels on blood lipids levels and on other risk factors for cardiovascular disease will aid the agency in reaching future decisions.

B. PUFA's

In the proposed rule, FDA expressed concerns about possible safety problems associated with consumption of diets enriched in polyunsaturated fats because of the substitution of these fats for SFA's (56 FR 60737 at 60736). Among concerns that FDA raised were potential adverse effects on cell membrane fluidity (a possible risk factor for cardiovascular disease (Ref. 20); decreasing levels of blood HDL-cholesterol; increase in formation of lipid hydroperoxides (oxidized LDL-cholesterol has a high atherogenic potential, Ref. 132); increasing blood

triglyceride levels (a possible risk factor for heart disease (Ref. 187); and increasing the risk of some types of cancer (see the proposed rule on dietary lipids and cancer at 56 FR 60764, November 27, 1991).

13. Many comments raised issues concerning the question of the safety of PUFA's in foods and supplements. Comments suggested that safety issues related to PUFA's included increased risk of cancer, coronary thrombosis, and osteoporosis in humans. A few comments also stated that PUFA's may adversely affect immune function. Conversely, others disagreed with the statement in the proposal that PUFA's may increase predisposition to or frequency of certain types of cancer because none of the dietary consensus documents of the Federal Government identified PUFA's as a risk factor for cancer in humans. One comment disagreed that diets enriched in PUFA's may decrease HDL-cholesterol levels but did agree with the description of results from the study by Wardlaw in Table 2 of the proposed rule (56 FR 60727 at 60764 (Ref. 144)) that, "High concentrations of PUFA's may have pharmacological effects on lowering HDL-cholesterol, however, diets containing 35 percent of calories from fat and a polyunsaturated:saturated fatty acid (P:S) ratio of less than 1.5 are not likely to lower HDL-cholesterol significantly." One comment suggested that diets high in PUFA's (greater than 10 percent of calories) cannot be achieved by the American public, so the potential safety concerns were overly emphasized.

The LSRO report on "Lipids and Cardiovascular Disease," submitted as a comment to the record, separated the evaluation of PUFA's into two categories: omega-6 polyunsaturates and omega-3 polyunsaturates (Ref. 196). Relative to linoleic acid (one of the major types of omega-6 fatty acids in the U.S. diet and an essential fatty acid), the report noted that while:

> * * * higher intakes may slightly reduce LDL-cholesterol * * * a higher consumption may increase risk for some cancers, promote LDL oxidation with the arterial wall, and possibly raise the risk for coronary thrombosis * * *. A reasonable recommendation may be to avoid both excessively low intakes of linoleic acid (below 4 percent of calories) and higher intakes (above 7 percent of calories).

Relative to the second type of PUFA's, the omega-3 fatty acids, the LSRO report noted that:

> Recommendations for increasing omega-3 fatty acids for the purpose of preventing common chronic diseases must be made with caution and only after more conclusive data are available * * *. Since these fatty acids are biologically active, they deserve intense investigation, but not premature recommendations for their consumption by the general public.

FDA agrees with the concern that high levels of intake of PUFA's have the potential for adverse effects in some persons. However, when consumed in amounts similar to current intakes, little or no risk is anticipated (Refs. 20, 29, 31, 33, 35, 74, 78, 136, and 196). Indeed, adequate intakes of essential fatty acids are needed to prevent nutrient deficiencies. By requiring that a food be low in total fat as a qualifying criterion, FDA has made it unlikely that excessively high intakes of PUFA's will be encouraged through the use of a health claim, because there is little room for manipulation of different fats within this range for total fat. Given current levels of intake of essential fatty acids by the U.S. population, deficiencies are not anticipated (56 FR 60727 at 60738; also, see document on dietary lipids and cancer published elsewhere in this issue of the **Federal Register**.

C. Other Safety Issues

14. One comment expressed concern about foods that qualify for a health claim for lipids and cardiovascular disease but that contain a nutrient that may increase the risk of cardiovascular disease or another disease or disorder. As an example, the comment suggested skim milk, which contains no or low fat and cholesterol but does contain casein. The comment suggested that casein has been reported to have atherosclerotic properties in some animals, but no data were provided to support this comment.

The basic concept of this comment, that the use of foods bearing health claims should not unduly increase the risk of disease because of the level of nutrients other than the nutrient that is the subject of the claim, is mandated by section 403(r)(3)(A)(ii) of the act. The preamble of the final rule concerning the general requirements for health claims, which appears elsewhere in this issue of the **Federal Register**, contains an extensive discussion of the agency's implementation of that section of the act through disqualifying nutrient levels.

FDA, however, disagrees with the specifics of this comment, i.e., that casein should be considered a negative component that would disqualify a food from bearing a fat/heart disease claim. FDA is aware of early research suggesting that casein has possible adverse effects on risk of heart disease (Ref. 20). However, these observations have never gained wide acceptance by the scientific community, and casein (a rich source of protein) is not considered to significantly contribute to the risk of heart disease.

V. Miscellaneous Issues

The proposal contained a number of additional provisions addressing both mandatory and optional aspects of claims about lipids and cardiovascular disease in proposed § 101.73(a)(4) and (a)(5). Proposed § 101.73(a)(4)(i) provided that a claim must state that a diet low in saturated fat and cholesterol will reduce high blood cholesterol and, thus, the risk of coronary heart disease. Proposed § 101.73(a)(4)(ii) provided that health claims must include the caveat that "some but not all individuals" would benefit from these dietary changes. Also the terminology for heart disease, blood lipid levels, and dietary fats were described in proposed § 101.73(a)(4)(iii)(A), (a)(4)(iii)(B), and (a)(4)(iii)(C). Furthermore, information on the multifactorial nature of the disease and other risk factors was included as a specific requirement in proposed § 101.73(a)(4)(iv), and optional information on the need for medical guidance and on the prevalence of heart disease in the U.S. population was provided in proposed § 101.73(a)(5)(i) and (a)(5)(ii), respectively. Many of these provisions are addressed in the following comments.

15. Some comments questioned the applicability of a claim relating diets low in saturated fat and cholesterol to reduced risk of heart disease in the general U.S. population. These comments asserted that only about 25 percent of the population may be responsive to reduction in dietary cholesterol and saturated fat. Thus, the comments argued, it would be misleading to imply that all persons would benefit. Conversely, the LSRO report concluded that "all people in the United States * * * will potentially benefit * * * from reductions in dietary saturated fat" (Ref. 196). Relative to dietary cholesterol, the LSRO report noted that "* * * avoidance of high intakes of dietary cholesterol for the whole population is prudent." Another comment suggested that the agency prescribe the term "most" individuals, persons, or people in referring to those people who may benefit from these dietary changes rather than "most but not all people."

As discussed in the proposed rule (56 FR 60727 at 60740), FDA recognizes that the beneficial effects from reduction of intakes of saturated fat and cholesterol are highly variable among individuals, particularly in terms of magnitude of effect. For this reason, FDA proposed to require that health claims make clear that the effects described in the claim

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are likely to be realized by "some but not all persons" (proposed § 101.73(a)(4)(ii)). At the same time, FDA does not wish to imply that a health claim on dietary lipids and heart disease in accordance with this rule is not useful information for the general population. Current dietary guidelines and the LSRO report cited above conclude that, even if responses among individuals are variable in magnitude, the majority of the population, including persons with normal blood cholesterol levels, will benefit from these dietary goals (Refs. 20, 29 through 36, 74, 136, and 151). Given the strong scientific agreement that the majority of persons in the U.S. will benefit from a reduction in intake of saturated fat and cholesterol, FDA has concluded that the proposed term "some persons but not all" is too conservative. FDA has thus not included any requirement for indicating that the nutrient/disease relationship is limited to "some persons but not all" in the final rule. Therefore, new § 101.75(c)(2)(i)(A) reads: "The claim states that diets low in saturated fat and cholesterol 'may' or 'might' reduce the risk of heart disease;".

16. Several comments recommended that the agency require that health claims include a statement on seeking medical advice for persons with multiple risk factors for heart disease. These comments suggested that the majority of the population at risk of cardiovascular disease may require medical advice and may need a combination of medication and diet and lifestyle changes. For these persons, adopting a diet low in saturated fat and cholesterol may not substitute for aggressive medical intervention.

FDA agrees that persons with blood LDL-cholesterol levels in the moderate to high risk ranges and with multiple risk factors for heart disease should seek medical advice. However, as noted above, dietary goals for intakes of saturated fat and cholesterol have been recommended for the general population as well as for persons with elevated blood cholesterol levels because of findings of benefit across the entire range of blood cholesterol levels (Refs. 31 and 33). FDA is concerned, therefore, that to require a statement that persons seek medical advice and guidance as part of the health claim might give the erroneous impression to consumers that there is no benefit for them in making the recommended dietary changes unless they have been identified as high risk patients. For this reason, FDA is not persuaded to change the status of information on medical advice from an optional to a mandatory requirement. Thus, the agency is retaining this provision as an optional statement in new § 101.75(d)(7), which states:

> The claim may state that individuals with elevated blood total- or LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- or LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

17. The agency proposed in § 101.73(a)(4)(iv) that the health claim may state that CHD is a multifactorial disease and listed major risk factors for the disease that may be used in the claim. This provision was worded so as to suggest that providing the above information was optional. However, this provision was included among the specific requirements in § 101.73(a)(4).

The agency received comments that both supported and opposed FDA requiring that any health claim describe CHD as a multifactorial disease. Several comments suggested that the multifactorial nature of the disease should be referred to indirectly, while other comments suggested that these multiple factors should be required to be identified in the health claim. Some comments identified a number of modifiable dietary risk factors for cardiovascular disease not included among those listed the proposed health claims such as: sodium (56 FR 60825), fiber (56 FR 60582), and antioxidant vitamins (56 FR 60624). Other comments recommended that the agency require that the most important risk factors for CHD, elevated LDL-cholesterol, high blood pressure, and cigarette smoking, be listed.

FDA recognizes that its proposal was inadvertantly ambiguous about whether the fact that CHD is a multifactorial disease would be a required element of the health claim on dietary lipids and this disease. As pointed out in the proposal (56 FR 60726 at 60740), given the multiple dietary, genetic, and lifestyle risk factors for this disease, consumers would be misled if they were to think that dietary factors are the only risk factors. Given this fact, FDA has concluded that the multifactorial nature of the disease should be a required element (§ 101.75(c)(2)(i)(E)).

The issue that is raised as a result is how the significant risk factors should be presented. FDA is concerned that encouraging an unrestricted listing of risk factors for heart disease could result in the listing on food labels of risk factors with relatively little importance or minimal scientific support or could be used to bypass other label requirements. For example, some comments listed several nutrient risk factors for heart disease, including sodium intake. While FDA is authorizing the use of sodium/hypertension health claims, the agency has not been presented with evidence that sodium intake is a risk factor for heart disease. A claim characterizing the relationship between sodium and heart disease is a health claim and would misbrand a food under section 403(r)(1)(B) of the act unless it is specifically authorized by the agency. Thus, the comments suggested that some would use a list of factors as a backdoor means of making unauthorized health claims. As a result, FDA concludes that only the significant risk factors should appear as part of a health claim. For example, those factors that identify the populations that are at risk, where the general population is not at risk, are appropriate for inclusion in the claim. Listing risk factors that are not significant would be false or misleading and could, as explained above, misbrand the food under section 403(r)(1)(B) of the act.

While FDA has decided that the fact that coronary heart disease is multifactorial should be a mandatory element of nutrition labeling, it has also decided that the specific risk factors need not be. As discussed below in conjunction with model health claims, FDA has received numerous comments that the shorter health claims are, the more likely it is that they will be used and understood. Therefore, given the information that it is requiring, FDA has decided, that on balance, it is not necessary to include the significant risk factors as mandatory elements of a claim.

The listing of risk factors provided in proposed § 101.73(a)(4)(iv) represented scientific consensus as to the most significant factors for heart disease. In this final rule, FDA has redesignated the list of risk factors in proposed § 101.73(a)(4)(iv) as new § 101.75(d)(1). This section provides a list of the factors that, based on general scientific agreement, are the major factors for heart disease. The agency has also provided that any list of risk factors included as part of a health claim may include one or more of these factors but must be limited to the factors on this list. Thus, new § 101.73(d)(1) states that:

> The claim may identify one or more of the following risk factors in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: a family history of coronary heart disease, elevated blood LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, and long-term physical inactivity.

18. Other comments pointed out that, while excessive intake of some nutrients such as fat may be harmful, there are also minimum intake levels which are essential. Some of the comments suggested that the agency identify minimum thresholds levels for SFA's, MUFA's, PUFA's, total fat, and other dietary nutrients below which intakes should not drop. The comments expressed concern that intakes below these levels would increase risk of nutrient deficiencies.

FDA recognizes that there are intake levels for nutrients below which there may be a risk of nutrient deficiencies that could present a risk of adverse effects. FDA disagrees, however, that these levels should be included in the health claim on dietary saturated fat/cholesterol and heart disease. In the proposed rule for a health claim on lipids and cardiovascular disease and as stated in the proposed rule on dietary lipids and cancer, FDA noted that:

> The requirement of linoleic acid to avoid essential fatty acid deficiency is 1 to 2 percent of total calorie intake. Currently, the average linoleic acid consumption in the U.S. ranges between 5 and 10 percent of total calorie intake, and deficiencies of essential fatty acids are rare in the U.S. Thus, a reduction of total fat consumption from the current 36 to 37 percent of total calorie intake to about 30 percent is not likely to cause essential fatty acid deficiencies in the general population.

(56 FR 60764 at 60712)

Furthermore, as previously noted in the response to comment 14 of this document, the reduction of saturated fat intakes to meet dietary goals for reduction in risk of heart disease is likely to result in increased intakes of PUFA—the source of the essential fatty acid, linoleic acid. Thus, FDA concludes, as was also concluded in several authoritative reports (Refs. 20, 29, 35, 136, and 150), that there is little likelihood of nutritional deficiencies resulting from changes in U.S. dietary patterns in response to health claims relative to saturated fat/cholesterol and heart disease.

19. One comment suggested that health claims not be allowed on foods that have been modified to meet the "low fat," "low saturated fat" or "low cholesterol" requirements unless the foods are nutritionally equivalent to the unmodified versions of those foods. FDA rejects this comment. The issue of the effects of a failure to maintain nutritional equivalency are fully addressed by § 101.3(e) of FDA's regulations, and in the final rule on standardized foods named by use of a nutrient content claim and a traditional standardized term, published elsewhere in this issue of the Federal Register. As long as a food meets the requirements of those regulations, § 101.14, and § 101.75, it may bear a health claim on the relationship of saturated fat and cholesterol and coronary heart disease.

20. One comment asked the agency to reconsider its position that health claims are inappropriate for foods intended to be consumed by infants and toddlers of less than 2 years of age; second, to reconsider the amount of total fat, saturated fat and cholesterol that meet requirements for health for infants and toddlers; third, to reconsider the age when infants and toddlers should start to consume "low fat" diets. The comment recommended that low saturated fat, low cholesterol, and low fat diets should be extended to even earlier ages, and that the percent of calories from fat for infants and toddlers should be less than 30 percent to reduce obesity, a risk factor for heart disease. The comment did not submit scientific data to support the proposition that a reduction in heart disease would occur if infants and toddlers consumed low fat diets (i.e., less than 25 percent of calories) earlier than 2 years of age.

FDA disagrees with the comment. In the 1990 amendments, Congress indicated that, if FDA's decision on a health claim petition deviated from recommendations of the Federal Government, those differences should be justified (section 403(r)(4)(C) of the act). The agency based its conclusions on the report from the National Cholesterol Education Program (NCEP) on population strategies for healthy children and adolescents (56 FR 60727 at 60731 (Ref. 34)). This report stated that general dietary recommendations for diets low in saturated fat, cholesterol, and total fat should be extended to cover toddlers and children 2 years and older. FDA has seen no compelling evidence to counter the conclusions of the NCEP report.

21. Several comments supported the agency's proposed limitation in proposed § 101.73(a)(4)(iii) on interchangeable terms for the disease, for lipids levels, and for the nutrients involved. Another comment suggested that the term "low density lipoprotein cholesterol" or the term "LDL-cholesterol" be used in place of the term "total blood cholesterol."

FDA agrees that the term "LDL-cholesterol" is more precise than the term "blood total cholesterol," but disagrees that it should be used in place of the term "total blood cholesterol" in § 101.75(d)(2) of the final rule. FDA, in proposing the term "total blood cholesterol" was using language commonly used in dietary guidance materials at the time of the proposal. Since the publication of the proposal, the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH) held a consensus conference on Triglycerides, High Density Lipoprotein, and Coronary Heart Disease in February 1992 (Ref. 187). As a result of that conference, a consensus panel draft report was published reconfirming that high levels of blood LDL-cholesterol are associated with high risk of CHD. The consensus conference panel draft report also concluded that low levels of another blood cholesterol component, HDL-cholesterol, in conjunction with high levels of LDL-cholesterol, were associated with a higher risk of heart disease. These two different cholesterol transport components of blood cholesterol when considered in combination are better predictors of risk than when considered independently.

The agency believes that the term "blood total cholesterol" should be retained to minimize consumer confusion, since that term is used in dietary guidance materials and many consumers know their blood total cholesterol levels. However, the agency believes that consumers will eventually learn that high LDL-cholesterol levels are strongly associated with risk of heart disease and are reduced by diets low in saturated fat and cholesterol in most people. The agency has therefore specified in new § 101.75(d)(2) that the term "LDL-cholesterol" may optionally be used in addition to the term "blood cholesterol," and states: "The claim may indicate that the relationship of saturated fat and cholesterol to heart disease is through the intermediate link of "blood cholesterol" or, "blood total- and LDL-cholesterol."

In other respects, the agency is carrying forward the terminology from the proposal in new § 101.75(c)(2)(i)(B), the agency is limiting the terms used to specify the disease to heart disease or coronary heart disease. This provision is consistent with proposed § 101.73(a)(4)(iii)(A). Furthermore, in new § 101.75(c)(2)(i)(C), the agency retains the limitations on specifying the nutrient in proposed § 101.73(a)(4)(iii)(C). However, § 101.75(c)(2)(i)(C) states that: "In specifying the nutrient, the claim uses the terms 'saturated fat' and 'cholesterol,' and lists both;".

22. One comment requested that health claims relating to lipids and cardiovascular disease be allowed for fruits and vegetables, which are naturally low in saturated fat, total fat, and cholesterol.

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FDA agrees that fruits and vegetables should be allowed to bear appropriate health claims. The agency notes that because most fruits and vegetables are naturally low in saturated fat and do not contain cholesterol, they will meet the qualifying criterion of new § 101.62 for "low saturated fat," "low cholesterol," and "low total fat," and thus will qualify under § 101.75(c) to bear this claim.

FDA advises that it has made a couple of additional minor changes in § 101.75. The agency has added § 101.75(a)(1), which, consistent with other regulations that the agency is adopting that authorize health claims, defines some of the terms in the regulation. These definitions are consistent with generally accepted science and with the discussion in the proposal. In addition in § 101.75(d)(5), FDA has added the National Institutes of Health and "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 29) in recognition that both are sources of information on the number of Americans with heart disease.

VI. Model Health Claims

23. Several comments suggested that the model health claims should be reduced in length. Some suggested that health claims should follow examples established by the Surgeon General's office, keeping the health claim in a precise, easily understandable text. One manufacturer submitted model health claims and examples of labeling. One comment submitted an example of a possible health claim: "Eating a healthful diet low in fat, saturated fat and cholesterol can help reduce the risk of heart disease." Another comment suggested that the health claim should state: "This ———— can be part of a total diet low in saturated fat and cholesterol, which can reduce risk of heart disease. Use in place of more saturated fats as part of a diet low in total fat. Contains ———— grams of saturated fat, ———— grams of total fat per serving." Another comment recommended an additional statement to be added to the health claim: "In vitro and animal data are often useful for formulating research hypotheses, but can be inappropriate and unreliable for making public policy."

FDA agrees with the comments that, to the extent possible, the model health claims should be shortened and made more understandable. They are more likely to be used by manufacturers if they take up as small an amount of label space as possible. Consumers will be more likely to read messages if they are stated simply and succinctly. However, section 403(r)(3)(B)(iii) of the act requires that health claim regulations ensure that claims accurately represent the nutrient/disease relationship and its significance and enable consumers to understand the information and its significance in the context of the total daily diet. Thus, there are constraints on FDA's authority to permit claims to be abbreviated.

The issue of shorter health claims has been discussed in detail in the preamble to the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**. As noted in comment 15 of this document, FDA has dropped the phrase "in some but not all." Additionally, FDA is making reference to the blood cholesterol linkage between dietary saturated fat and cholesterol and risk of heart disease optional. FDA reasons that this amount of detail is not necessary to motivate consumers to implement recommended dietary changes and contributes to wordiness. Thus, the minimum requirements can now be met with a statement as simple as "While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease." Additional provisions that were included in the proposed rule have been deleted or made optional to simplify health claims. Other model health claims are provided in new § 101.75(e). As discussed earlier in this preamble, FDA does, however, believe it is important for each model health claim to acknowledge that many factors affect heart disease.

Other changes incorporated into the final regulation include reorganization of paragraphs and clarification of requirements. The final regulation requires claims to use the word "may" or "might" rather than "can" or other words when describing the possible effect of a diet low in fat and cholesterol on risk of heart disease (§ 101.75(c)(2)(i)(A)). Although FDA recognizes that it cannot require preclearance of claims, it considers this and other restrictions on word choices to be necessary so that claims will accurately reflect the state of the science. All changes in the final regulation are a logical outgrowth of the proposal.

24. A few comments suggested that the agency amend the language of the health claim to include "very-low fat, low-cholesterol diets begin to reverse CHD in some patients." Accompanying the comments were six scientific publications describing six clinical trials. The comments thus suggested tighter criteria for the qualifying levels of fat and cholesterol, e.g., "very low," and a replacement of "may reduce the risk of" with a stronger statement about a "reversal" of CHD. In addition, the suggested claim would target one segment of the general population which is at increased risk for heart disease. The comments submitted a number of publications to justify use of the term "reversal" of heart disease.

FDA does not agree that the submitted publications justify the statement that heart disease may be reversed by very low fat, low saturated fat, and low cholesterol diets. Three of the randomized, controlled trials were previously reviewed (in Table 2 of the proposal) by the agency (56 FR 60727 at 60754 through 60755 and 60763) (Refs. 12, 14, and 106). The fourth was conducted in 1984 (Ref. 197) and therefore evaluated by Government and other public health authoritative reports, and the two remaining studies did not provide adequate information to be able to attribute beneficial results to specific dietary components (Refs. 198 and 199). Thus, while FDA finds these results very interesting and considers the studies to suggest a decrease in progression of heart disease from the combination of medical interventions used in these studies, FDA has concluded that these results are not applicable to health claims for several reasons. First, the treatment modality used to obtain results was primarily drugs that lower both blood lipids and blood pressure, in combination with dietary changes. Secondly, the treatment changes were quite severe, and their implementation in the general population is unlikely to be a reasonable goal. Finally, subjects were persons with serious preexisting CHD and under close medical supervision.

25. An association of medical professionals provided a number of references that suggest serum cholesterol goals for patients with noninsulin-dependent diabetes mellitus and patients with hyperlipidemia. The comment asked that the health claim be required to specifically identify and target this group of individuals as high-risk populations.

FDA disagrees that specific dietary advice and goals for persons with diseases such as noninsulin-dependent diabetes mellitus and hyperlipidemia should be required to be included as part of health claim messages. These are serious health conditions and require medical supervision. Health claims are intended for the general population. Foods bearing claims for conditions requiring medical supervision are more appropriately regulated as foods for special dietary use, as medical foods, or as drugs, depending upon the specifics of the food and the claims made for it.

VII. Consumer Summary

FDA also proposed to make available consumer summaries to provide additional information on the health claim. Comments from consumers, health care professionals, public health associations, and the food industry supported the use and availability of consumer summaries. FDA did not receive any comments that did not support the use of consumer summaries for this health claim regulation. Comments were received, however, for other health claim regulations suggesting that there was no need for consumer summaries.

As discussed in the final rule on general requirements for health claims published elsewhere in this issue of the **Federal Register**, consumer summaries are not required, although their use remains an option. For this reason, the proposed consumer summary has not been included in this final rule.

VIII. Summary of Updated Science Review

To ensure that significant new evidence had not become available subsequent to the proposal, FDA updated its review of the scientific evidence with human studies that were directly relevant to the proposed rule or that became available after publication of its proposal (Table).

A. Relationship of Dietary Saturated Fat and Cholesterol to Blood Cholesterol and, Therefore, to Risk of Heart Disease.

1. Saturated Fat

In the proposed rule (56 FR 60727 at 60728), FDA accepted the conclusions of consensus documents that serum cholesterol levels are a valid intermediate predictor of risk of heart disease (Refs. 20, 29 through 36, 74, 136, 150, and 151). FDA limited its evaluation of the nutrient/disease relationship to diets low in saturated fat and cholesterol and reduced risk of CHD. FDA additionally proposed that health claims should be prohibited on foods that are not low in fat because of strong indirect links between high fat diets and risk of heart disease.

A recent study supports the applicability of dietary modifications to children. A longitudinal study in 108 healthy Hispanic preschool children (Ref. 183) compared children in the highest tertile (a tertile is a comparison based on thirds, i.e., highest, middle and lowest tertile) of total fat and saturated fat consumption (36.2 percent and 14.6 percent of calories as fat and saturated fat, respectively) to children in the lowest tertile (30 percent and 11 percent of calories as fat and saturated fat). Higher total fat and saturated fat intakes were associated with higher blood total and LDL- cholesterol levels (Table).

Several new clinical trials provide additional support that reductions in intakes of dietary saturated fat and cholesterol reduce serum total and LDL-cholesterol levels, even though serum triglyceride and HDL-cholesterol levels do not change significantly.

Denke et al. (Ref. 162) compared the effects on blood cholesterol levels in 10 men, mean age 66, (Table) of isocaloric, liquid diets differing in type and amount of SFA. In the self controlled, cross-over study, the saturated fat was derived from either butter (25 percent SFA), beef (18 percent SFA), cocoa butter (23 percent SFA) or olive oil (8 percent SFA). These fat diets also differed in the amount of stearic acid: 4, 7.6, 13 and 1.2 percent, respectively. Diets enriched in saturated fat from butter, beef, or cocoa butter, significantly increased total cholesterol and LDL-cholesterol compared to diets containing less saturated fat. The higher concentration of stearic acid in both beef and cocoa butter diets did not negate the effect of saturated fat on blood cholesterol levels. Under the conditions of the study design, stearic acid was neutral in its ability to change blood cholesterol levels. This study should be repeated using more subjects, including healthy subjects, and with solid foods to provide nutritional data that is more applicable to the general public.

In another dietary intervention study, the effects of a low fat, low saturated fat, no cholesterol diet on serum cholesterol was reported (Ref. 184). Five familial hypercholesterolemic (FH) patients and four healthy control individuals consumed a diet that was very low fat (8.2 percent of calories), and high carbohydrate (80.5 percent of calories) for 1 month, following 1 month on a basal diet, and after 3 months on a wash-out diet (see Table). Both normal controls and FH patients responded similarly, with a significant decrease in total and LDL-cholesterol. HDL-cholesterol decreased nonsignificantly, but serum triglycerides increased significantly. One difference in response by FH patients and controls to the diets was observed in cholesterol synthesis. Cholesterol synthesis fell 24 percent (8.4 to 6.4 mg/kg/day) in controls and 58 percent (11.4 to 4.8 mg/kg/day) in FH patients.

Another dietary intervention study compared the effects of diets supplemented with saturated fat or linoleic acid on blood cholesterol levels (Ref. 180). This study of free-living subjects was conducted in 12 mildly hypercholesterolemic individuals (5 men and 7 women) ages 27 to 74 years, in a randomized, cross-over design that provided 2 weeks on the basal diet and 3 weeks on each of the test diets. Total fat composition of the diets is shown in the Table. The test diets contained an additional 17.3 percent SFA or 14.8 percent of PUFA (in the form of linoleic acid). The saturated fat-enriched diet significantly increased total cholesterol and LDL-cholesterol compared to the baseline diet. The linoleic-supplemented diet, which has a similar concentration of saturated fat as the basal diet, produced significantly lowered total cholesterol, 19 mg/decaliter (dL) (0.5 millimoles/Liter (mmol/L)) less compared to the basal diet and 39 mg/dL (1.0 mmol/L) less compared to the saturated fat-enriched diet. This study should be repeated using more subjects including healthy subjects and with solid foods to provide nutritional data that are more applicable to the general public. The study does suggest the possibility of more flexibility in dietary options available for the general public.

The effect of a "Western" diet rich in saturated fat and cholesterol (total fat, saturated fat and cholesterol: 43 percent, 21 percent, of calories, 1,020 mg/day, respectively) on blood cholesterol levels was measured in free-living subjects who normally consume a low fat, low saturated fat, Tarahumara diet (less than 20 percent of calories from total fat, 7 percent from saturated fat and less than 50 mg/day) (Ref. 176). The study included 12 adults (5 women) and one 12-year-old boy. After consumption of the "Western" diet for 5 weeks, total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides increased significantly in all subjects. Total cholesterol increased from 121 mg/dL at baseline to 159 mg/dL, and LDL-cholesterol went from 72 to 100 mg/dL. The "Western" diet as described by the study design contains a higher level of total fat, saturated fat, and cholesterol than consumed by the U.S. general population.

2. Dietary Cholesterol

In another recent study, the effect of dietary cholesterol (in the form of eggs) on serum cholesterol levels was measured in seventy 18 to 19 year old, free-living, healthy males (Ref. 190). A baseline diet containing 3 eggs per week was consumed by all subjects for 3 months (diet composition contained in the Table: total fat was 40 percent of approximately 3,350 calories per day). The subjects were divided into three groups of approximately equal numbers:

one group continued on the baseline diet, group 2 was supplemented with 7 eggs per week, and the third group was supplemented with 14 eggs per week for an additional 5 months. No significant differences were reported in total cholesterol, LDL-cholesterol, or triglycerides between groups.

The authors proposed several suggestions to explain these results. They stated that the relatively high levels of total fat compounded with a low content PUFA compared to SFA content may have canceled the potential serum cholesterol-raising effects of dietary cholesterol. Secondly, they suggested that the subjects may have adapted to the diet by decreasing cholesterol synthesis or by increasing the rate of cholesterol eliminated from the body.

Meta-analysis was used to examine the effects of dietary cholesterol on serum cholesterol from 76 studies that had reported completely controlled diets (Ref. 221). This meta-analysis, unlike previously reported studies, included baseline together with added dietary cholesterol data, PUFA and SFA content of the diet, and weighted the number of subjects in each trial. The diets used in the trials included formula diets, semipurified diets, and diets based on customary food. The baseline dietary cholesterol was a statistically stronger predictor of change in blood cholesterol than added dietary cholesterol. Thus when baseline dietary cholesterol was high, added dietary cholesterol resulted in diminished increases in total blood cholesterol. Therefore, when one to two eggs are added to a diet that already contain 350 to 400 mg/day of cholesterol, little increase in blood cholesterol would be expected.

B. Estimates of Change in Blood Cholesterol by Following Low Fat, Saturated Fat and Cholesterol Dietary Guidelines

In the following group of studies, the effectiveness of diets reduced in total fat, SFA, and cholesterol to levels suggested by national nutritional guidelines and health organizations were evaluated.

A diet referred to as "US74" (fat content was 38 percent of total calories, SFA 18 percent, MUFA's 14 percent, PUFA 4 percent, and cholesterol 600 mg/day) (Table, Ref. 168) was compared to the diet recommended by U.S. public health authorities (fat 30 percent and SFA, MUFA, and PUFA 10 percent of total calories, respectively, and cholesterol 300 mg/day and referred to as modified diet ("MOD" diet)) on total blood cholesterol levels. The study included 5 free-living women of Chinese origin and 14 of Caucasian origin, in a cross-over, randomized order design with each test diet lasting 3 weeks. Throughout the intervention study, the Chinese women had consistently higher total cholesterol, LDL-cholesterol, HDL-cholesterol and triglyceride levels than Caucasians, regardless of diet selected. Caucasian women showed a significant decrease in total cholesterol and LDL-cholesterol only when the US74 diet was compared to the MOD diet. Consumption of the US74 diet increased total cholesterol and very-low density lipoprotein-cholesterol (VLDL-cholesterol) in Chinese women compared to a self selected diet (in which fat was 34 percent of total calories and SFA was about 12 percent, MUFA was 13 percent (based on g of oleic acid/day), PUFA was 8 percent (based on g of linoleic acid/day), and cholesterol was 360 mg/day).

The second study evaluated the effectiveness of the American Heart Association (AHA) Step-1 diet in lowering blood cholesterol in free-living subjects (Ref. 154). (The AHA Step-1 diet contains 10 percent or less saturated fat; 30 percent or less of total calories from fat; and less than 300 mg/day cholesterol.) Forty-nine men and 38 women completed the 18 week dietitian-instructed study (they were hypercholesterolemic, total cholesterol 243 mg/dL. and LDL-cholesterol 169 mg/dL; and mean age of 50 years, Table). Modest, but significant, decreases were observed in total-cholesterol and LDL-cholesterol after 6 weeks. No further reductions in total- or LDL-cholesterol were observed at 12 or 18 weeks, and there was a tendency to return to or exceed baseline cholesterol levels. The authors suggested that since most of the participants knew they were hypercholesterolemic before the study, they may have already been following a self-developed, low saturated fat, low fat, low cholesterol diet. This conclusion was derived from analysis of self-administered food frequency questionnaires and 4-day food records, including 1 weekend day collected on baseline diet and AHA Step-1 diets.

The third study compared the effectiveness of the AHA Step-3 diet with a typical American diet. It pointed out additional considerations in implementing dietary changes to reduce blood cholesterol and CHD risk in women. In the study, 19 free-living premenopausal women consumed a typical American diet for 28 days prior to 5 months of the AHA Step-3 diet (Table, Ref. 161). In brief, self-reported dietary fat, saturated fat, and cholesterol for the American versus AHA Step-3 diet was 37 percent versus 21 percent; 15.7 percent versus 4.7 percent; and 271 versus 96 mg/day, respectively. Total cholesterol, LDL-cholesterol, and HDL-cholesterol decreased in these women consuming the AHA Step-3 diet. However, only after subdividing the women by body mass index were there significant decreases in total cholesterol, LDL-cholesterol, and HDL-cholesterol. Lean women, as determined by body mass index, had significant decreases in blood cholesterol, while moderate or grossly obese women did not. The authors suggest that results from this study with free-living individuals may imply that obese women may be more sensitive to dietary carbohydrates and therefore not as responsive to a diet low in total fat, saturated fat, and cholesterol and enriched in carbohydrate (43.8 versus 59.4 percent). Secondly, alternative diets that replace SFA by means other than carbohydrate exchange may be more effective in these individuals.

In a fourth study, the effectiveness of intensive dietary instruction on reduction of serum cholesterol level was evaluated as part of the Heart Tune Program (Ref. 169). Hypercholesterolemic patients (30 women and 19 men) attended 4 consecutive classes on heart disease, properties and definitions of fat, healthy food selections, and meal preparations for 2 1/2 hours per week. At baseline, the total and LDL-cholesterol levels of participants in the study were 268 mg/dL (6.95 mmol/L) and 180 mg/dL (4.68 mmol/L), respectively. After 4 weeks of enrollment in the program, there was a significant reduction in both total cholesterol and LDL-cholesterol to 240 mg/dL (6.30 mmol/L) and 161 mg/dL (4.16 mmol/L), respectively.

Additional confirmation and estimation of benefits associated with a reduction in serum cholesterol levels that are predictive of heart disease was provided using a computer model (Ref. 170). Subjects for the computer model system included both men and women with blood cholesterol levels ranging from 200 mg/dl (5.2 mol/L) to 300 mg/dL (7.8 mmol/L) at baseline. Data for the study incorporated updated estimates from both America (Framingham Heart Study) and Canada (Canadian Health Survey). Results suggested that, by reducing serum cholesterol levels by 5 to 33 percent, life expectancy could be lengthened by 0.03 to 3.16 years.

In summary, the updated literature review was consistent with and generally supported the tentative conclusions reached in the proposed rule (56 FR 60727 at 60735). That is,

diets low in saturated fat and cholesterol reduce blood cholesterol levels, particularly LDL-cholesterol levels.

C. Safety Issues

1. Trans-fatty Acids

One area identified in the proposed rule as a potential concern was the possibility of increased intake of *trans*-fatty acids as a result of changes in the fat composition of the U.S. food supply. One study that has been widely cited within the scientific community is the study by Mensink and Katan (Ref. 95).

Studies that examined the effects of *trans*-fatty acids on serum cholesterol levels are limited and report conflicting results and conclusions. One *trans*-fatty acid study discussed and evaluated in Table 2 of the proposed rule (56 FR 60727 at 60761, Ref. 95), reported that consumption of a diet enriched in *trans*-fatty acids (11 percent of total calories or 33 g/day) significantly increased total cholesterol and LDL-cholesterol and significantly reduced HDL-cholesterol levels in healthy subjects. The level of *trans*-fatty acids used was much higher than the level reported available for consumption by the U.S. population (3 to 4 percent of calories or 7 to 10 g/day).

In a recent study by Zock and Katan (Ref. 193), healthy, free-living, normolipidemic individuals (26 males and 30 females) consumed diets that compared the effect of C–18 fatty acids (saturated, trans-monoene, and unsaturated form) on serum lipids. Each diet, which did not differ in nutrient content, lasted for 3 weeks and was eaten as solid foods. In this multiple, cross-over design study, the *trans*-fatty acid level was set at 7.7 percent of total calories or 24 g/day. Both stearate and *trans*-fatty acid-enriched diets increased total cholesterol and LDL-cholesterol levels significantly, relative to the linoleate diet (a polyunsaturated fat). In addition, both stearate and *trans*-fatty acids significantly reduced HDL-cholesterol relative to linoleate. Lower HDL-cholesterol levels were observed in 46 of 56 subjects on the *trans*-fatty acid enriched diet. The authors concluded that, if the data from this study are combined with those from the previous study (Refs. 95 and 193), the results suggested that for every 1 percent of energy derived from *trans*-fatty acids, LDL-cholesterol would increase by 1.2 mg/dL and HDL-cholesterol would be lowered by 0.6 mg/dL relative to an equivalent amount of oleic or linoleate. The authors concluded that the current U.S. *trans*-fatty acid consumption level of about 3 to 4 percent of total calories may increase LDL-cholesterol by 4 mg/dL and decrease of HDL-cholesterol by 2 mg/dL.

2. Unsaturated Fatty Acids

In the following group of studies, the effect of diets reduced in total fat, SFA, and cholesterol to levels suggested by national nutritional guidelines and health organizations was evaluated with respect to the possibility of increased intake of unsaturated fatty acids, especially PUFA's. This issue was raised in the proposal as a result of possible changes in the fat composition of the U.S. food supply (56 FR 60727 at 60735).

In a randomized, blinded, controlled dietary intervention study, the effect of diets enriched in vegetable oils on serum cholesterol levels in 31 free-living mildly hypercholesterolemic men (Ref. 192) was reported. Two conditions were examined: Test diets, in which the saturated fat content was 7 percent (test) versus 15 percent in the control diets, were enriched in either MUFA (22 percent MUFA-test versus 14 percent-control) or PUFA (22 percent PUFA-test versus 9 percent PUFA-control) (refer to the Table). Total and LDL-cholesterol levels were reduced significantly by consumption of diets reduced in saturated fat and enriched (22 percent of calories) in either MUFA or PUFA (total cholesterol: -15 (PUFA) and -12 (MUFA) percent, and LDL-cholesterol: -20 (PUFA) and -12 (MUFA) percent, respectively).

3. PUFA-Enriched Diets Versus MUFA-Enriched Diets

A recent study by Mata et al. (Ref. 175) compared the long-term effects of PUFA-enriched diets versus MUFA-enriched diets, on blood cholesterol levels in 46 free-living, healthy men (mean age 33 years) and 32 women (mean age 42). The two diets were similar in all respects other than the content of the test unsaturated fatty acids (the PUFA-enriched diet content contained total fat 37 percent; SFA 12.5 percent; PUFA 13 percent; and MUFA 10 percent; while the MUFA-enriched diet had the same amount of total and saturated fat but 3.4 percent PUFA and 20 percent MUFA) (see Table). This controlled, solid food study, was conducted in two phases: phase 1, PUFA-enriched diets (for 16 weeks) followed by a second phase, the MUFA-enriched diet, which lasted for 28 weeks. The MUFA-enriched diet had no effect on blood total cholesterol in men but increased it in women. The MUFA-enriched diet increased HDL-cholesterol levels compared to the PUFA-enriched diet. HDL-cholesterol levels increased in both men (17 percent) and women (30 percent). No significant changes occurred in LDL-cholesterol or total triglycerides.

In summary, the updated literature review reveals relatively few new studies pertaining to possible unintended safety effects from reducing dietary intakes of saturated fat and cholesterol. Possible adverse effects on LDL-cholesterol and HDL-cholesterol from the consumption of large quantities of *trans*-fatty acids are supported by recent scientific reports. Most results are consistent with those of earlier reviews (Refs. 20, 30 through 36, 136, 150, and 151) and with comments received in response to the proposed rule.

Overall, the updated literature review provided no convincing evidence to suggest that the agency's tentative conclusions as to the relationship of saturated fat and cholesterol to risk of heart disease, as described in the proposal, required modification.

IX. Conclusions

FDA has responded to all comments received in response to the proposed saturated fat and cholesterol and CHD health claim regulation. In addition, the agency has reviewed all additional scientific studies received in comments or independently identified. The agency has determined that the new studies strengthen the tentative conclusions reached in the proposed regulation. After considering the comments and the new scientific studies, the agency concludes that there is significant scientific agreement based on the totality of publicly available scientific evidence that a claim that diets low in saturated fat and cholesterol may reduce the risk of CHD is supported by that evidence. Therefore, FDA is authorizing a claim.

The agency has decided that the regulations for the authorized health claims are most useful if they follow a consistent format and require only information that the agency considers essential. Therefore, the agency has made a number of editorial changes in the proposed codified material of the saturated fat and cholesterol and CHD health claim to make it more consistent with other authorized claims.

X. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XII. References

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224. Glinsmann, W. H., H. Irausquin, Y. Park, "Evaluation of Health Aspects of Sugar Contained in Carbohydrate Sweeteners," *Report on Sugar Task Force 1986*, Executive Summary, pp. s1–s16, 1986.

List of Subjects in 21 CFR Part 101

Food Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.75 is added to subpart E to read as follows:

§ 101.75 Health claims: dietary saturated fat and cholesterol and risk of coronary heart disease.

(a) *Relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Cardiovascular disease means diseases of the heart and circulatory system. Coronary heart disease is the most common and serious form of cardiovascular disease and refers to diseases of the heart muscle and supporting blood vessels. High blood total- and low density lipoprotein (LDL)- cholesterol levels are major modifiable risk factors in the development of coronary heart disease. High coronary heart disease rates occur among people with high blood cholesterol levels of 240 milligrams/deciliter (mg/dL) (6.21 millimoles per liter (mmol/L)) or above and LDL-cholesterol levels of 160 mg/dL (4.13 mmol/L) or above. Borderline high risk blood cholesterol levels range from 200 to 239 mg/dL (5.17 to 6.18 mmol/L) and 130 to 159 mg/dL (3.36 to 4.11 mmol/L) of LDL-cholesterol. Dietary lipids (fats) include fatty acids and cholesterol. Total fat, commonly referred to as fat, is composed of saturated fat (fatty acids containing no double bonds), and monounsaturated and polyunsaturated fat (fatty acids containing one or more double bonds).

(2) The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total- and LDL-cholesterol and, thus, with increased risk of coronary heart disease. Diets low in saturated fat and cholesterol are associated with decreased levels of blood total- and LDL-cholesterol, and thus, with decreased risk of developing coronary heart disease.

(b) *Significance of the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease.* (1) Coronary heart disease is a major public health concern in the United States, primarily because it accounts for more deaths than any other disease or group of diseases. Early management of risk factors for coronary heart disease is a major public health goal that can assist in reducing risk of coronary heart disease. There is a continuum of mortality risk from coronary heart disease that increases with increasing levels of blood LDL-cholesterol. Individuals with high blood LDL-cholesterol are at greatest risk. A larger number of individuals with more moderately elevated cholesterol also have increased risk of coronary events;

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such individuals comprise a substantial proportion of the adult U.S. population. The scientific evidence indicates that reducing saturated fat and cholesterol intakes lowers blood LDL-cholesterol and risk of heart disease in most individuals. There is also evidence that reducing saturated fat and cholesterol intakes in persons with blood cholesterol levels in the normal range also reduces risk of heart disease.

(2) Other risk factors for coronary heart disease include a family history of heart disease, high blood pressure, diabetes, cigarette smoking, obesity (body weight 30 percent greater than ideal body weight), and lack of regular physical exercise.

(3) Intakes of saturated fat exceed recommended levels in many people in the United States. Intakes of cholesterol are, on average, at or above recommended levels. One of the major public health recommendations relative to coronary heart disease risk is to consume less than 10 percent of calories from saturated fat, and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in saturated fat and cholesterol with reduced risk of coronary heart disease may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section provided that:

(A) The claim states that diets low in saturated fat and cholesterol "may" or "might" reduce the risk of heart disease;

(B) In specifying the disease, the claim uses the terms "heart disease" or "coronary heart disease;"

(C) In specifying the nutrient, the claim uses the terms "saturated fat" and "cholesterol" and lists both;

(D) The claim does not attribute any degree of risk reduction for coronary heart disease to diets low in dietary saturated fat and cholesterol; and

(E) The claim states that coronary heart disease risk depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.62 for a "low saturated fat," "low cholesterol," and "low fat" food; except that fish and game meats (i.e., deer, bison, rabbit, quail, wild turkey, geese, and ostrich) may meet the requirements for "extra lean" in § 101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors in addition to saturated fat and cholesterol about which there is general scientific agreement that they are major risk factors for this disease: A family history of coronary heart disease, elevated blood total and LDL-cholesterol, excess body weight, high blood pressure, cigarette smoking, diabetes, and physical inactivity.

(2) The claim may indicate that the relationship of saturated fat and cholesterol to heart disease is through the intermediate link of "blood cholesterol" or "blood total- and LDL cholesterol."

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between dietary saturated fat and cholesterol and risk of coronary heart disease, and the significance of the relationship.

(4) In specifying the nutrients, the claim may include the term "total fat" in addition to the terms "saturated fat" and "cholesterol".

(5) The claim may include information on the number of people in the United States who have coronary heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Health and Human Services (DHHS) and U.S. Department of Agriculture (USDA), Government Printing Office.

(6) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," DHHS and USDA, Government Printing Office.

(7) The claim may state that individuals with elevated blood total- or LDL-cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total- or LDL-cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(e) *Model health claims.* The following are model health claims that may be used in food labeling to describe the relationship between dietary saturated fat and cholesterol and risk of heart disease:

(1) While many factors affect heart disease, diets low in saturated fat and cholesterol may reduce the risk of this disease;

(2) Development of heart disease depends upon many factors, but its risk may be reduced by diets low in saturated fat and cholesterol and healthy lifestyles;

(3) Development of heart disease depends upon many factors, including a family history of the disease, high blood LDL-cholesterol, diabetes, high blood pressure, being overweight, cigarette smoking, lack of exercise, and the type of dietary pattern. A healthful diet low in saturated fat, total fat, and cholesterol, as part of a healthy lifestyle, may lower blood cholesterol levels and may reduce the risk of heart disease;

(4) Many factors, such as a family history of the disease, increased blood- and LDL-cholesterol levels, high blood pressure, cigarette smoking, diabetes, and being overweight, contribute to developing heart disease. A diet low in saturated fat, cholesterol, and total fat may help reduce the risk of heart disease; and

(5) Diets low in saturated fat, cholesterol, and total fat may reduce the risk of heart disease. Heart disease is dependent upon many factors, including diet, a family history of the disease, elevated blood LDL-cholesterol levels, and physical inactivity.

Dated: November 3, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

Dietary Saturated Fat and Cholesterol and Coronary Heart Disease

Study	Study Design	Subjects	Methods	Results	Comments
Hastel P. et al (Ref. 177)	Double blind, controlled, cross-over clinical trial of free-living subjects. Purpose: comparison of diets differing in concentration of SFA and PUFA (edible oil blends, containing hydrogenated oils and therefore trans fatty acids) on blood lipid levels. Trans fatty acid content was 4% of total calories. Study site: Australia	Twenty-six mildly hypercholesterolemic free-living men (5 to 7.5 mmol/L or 193 to 290 mg/dL), ages 20 to 65 years	Dietary instruction, food records for 3 consecutive days, total of 12 days. 14 weeks diet study: 2 weeks run-in; 4 weeks control diet and 4 weeks each test diet Composition of Diets: % of calories Control / Test 1 / Test 2 Fat 42 / 42 / 42 PUFA 6 / 10 / 11 MUFA 15 / 16 / 16 SFA 17 / 13 / 12 Chol (mg) 214 / 175 / 166 Test blend 1 contained 50% sunflower oil and a mixture of partially hydrogenated cottonseed and soybean oil. Test blend 2 contained 50% sunflower oil and partially hydrogenated canola and palm olein.	Total cholesterol (TC) and LDL-C were significantly reduced by consumption of diets containing oil blend 1 and 2 compared to controls. HDL-C and triglycerides (TG) were not significantly altered by consumption of test (oil blend diets) 1 and 2 compared to control diet. Results: (lipids in mg/dL) Control / Test 1 / Test 2 TC 221 / 216 / 212 LDL-C 154 / 150 / 147 HDL-C 42 / 42 / 42 When about 8% of energy from palmitic acid was exchanged for oleic acid, both LDL and HDL-cholesterol increased significantly. Therefore palmitic acid was either neutral or hypercholesterolemic dependent on the initial LDL receptor activity (subjects were hypercholesterolemic (>220 mg/dL) by malfunction in LDL-receptor activity).	Study suggests that edible oil blends that are lower in SFA (36 versus 21%) and higher in PUFA (21 versus 35%) than currently available in the market, can lower TC and LDL-C even when part of a diet in which fat is 42% of calories. Results of study were different than predicted by Keys equation. When trans fatty acid were treated as if they were SFA, then the Keys equation predicted closely the results observed.
Walden C. et al (Ref. 191)	Recruitment and design of dietary intervention study. Purpose: compare effectiveness of diets equivalent to NCEP Step I and Step II diets in lowering blood cholesterol on two different types of hyperlipidemia in free-living subjects. Study site: Washington State area.	320 hypercholesterolemic (HC) and 211 combined hyperlipidemia (CHL) men.	Initial dietary instruction provided, 8 weeks diet classes, 4 day food records maintained, evaluated at 6 month intervals. Four diet regimens compared: differing % fat, and amount of cholesterol. PUFA to SFA content held constant (ratio 1.0) % of Calories I / II / III / IV Fat 30 / 25 / 20 / 15 SFA 10 / 7 / 7 / 7 Chol (mg) 300 / 200 / 100 / 100	Out of 8,372 men screened for study, 47.7% were in the 60th percentile for elevated cholesterol and LDL-C, and elevated triglyceride (TG). Baseline lipid profiles for those classified as HC and CHL were similar. Fat was 36% of calories and cholesterol ranged from 279 to 316 mg/day in baseline diets.	Demonstrates the need for dietary intervention since a significant number of these industrial workers had elevated TC and LDL-C.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bonanome A. et al (Ref. 159)	Self-controlled clinical trial in Italy in free-living subjects. Purpose: compare effects of carbohydrate and MUFA diets on blood cholesterol level. Clinical, hospital out- patients	NIDDM patients whose diabetes was under control. 10 men and 9 women, average age 55 years. Free-living	Dietary counseling, 2 months on each diet. Three phases: carbo-MUFA-carb: isocaloric diets; MUFA from olive oil. % of calories Carb / MUFA Fat 25 / 40 MUFA 10 / 25 PUFA 5 / 5 Chol (mg) <300 / <300 Carb 60 / 45	Baseline glucose, insulin and lipid parameters showed NIDDM under control. No statistically significant difference in TC, LDL-C or HDL-C found between carbo and MUFA enriched diets. Slight increase in TC and HDL on MUFA diet. Plasma LDL-C, TG and HDL-C did not change significantly by changing from one dietary phase to another. Results: serum lipids (mg/dL) Carb / MUFA TC 239 / 251 LDL-C 163 / 166 HDL-C 42 / 51	Study suggests that it is possible to substitute SFA calories with either carbohydrate or MUFA and obtain similar results on blood cholesterol levels. This is especially important for NIDDM patients, because they were still able to maintain glycemic control on either diet.
Danko M. et al (Ref. 162)	Cross-over, controlled clinical trial. Purpose: compare effects on blood cholesterol of diets differing in type and amount of SFA. Study site: Texas Medical Center	Ten men, mean age 66 years, 5 of whom smoked, baseline TC 6 mmol/L (232 mg/dL); TG 1.5 mmol/L; free-living	Liquid diets: 3 weeks each diet. Cross-over 1 week ad libitum diet. Random order of diets. All diets: fat 40% of calories, 40% carbo., chol 120 mg/Mcal, PUFA <6%. Fat / % SFA / % Stearic Butter 25 / 4 Beef 18 / 7.6 Cocoa 33 / 13 Olive 0 / 1.2	High concentration of stearic in beef fat did not negate its cholesterol-raising properties. Cocoa butter not significantly less hypercholesterolemic than beef fat. Results: serum lipids (mg/dL) TC / LDL-C / HDL-C Butter 219 / 164 / 34 Beef 211 / 156 / 36 Cocoa 196 / 147 / 34 Olive 188 / 140 / 34	Possible differences due to liquid diet, comparisons to solid food diets would be helpful. The authors suggested that base line drops in TC and LDL-C (even on butter diets) was due to regression toward mean and/or hospitalization.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bierenbaum M. L. et al (Ref. 158)	Controlled clinical trial in free-living subjects. Purpose: measure effects of canola oil (enriched in PUFA) on serum lipids. Study sites: New Jersey /New York, hospitals	Thirty-six free-living hypercholesterolemic and/or hypertriglyceridimic patients. Twelve men and 15 women, average age 60.7 years. Four had diabetes, 14 post-CVD event, 2 post-MI Baseline lipids (mg/dL) TC 254 LDL-C 173 HDL-C 47 TG 214	Dietary instruction. 4 months on diet. 24-hour food diary prior to and during study. Diet: % of calories Basal: Fat 39%, SFA 19%, MUFA 11%, PUFA 9%, Chol 390 (mg/day) Test: 39%, 30 ml/day canola oil exchanged for basal dietary oil	Dietary adherence monitored by measuring w-3 fatty acid in RBC membranes before and after 4 months on diet. Both 18:3(w-3) 22:6(w-3) significantly increased from 1.4 to 39.8% and 0.7 to 10.2% respectively, while 18:0 decreased from 25 to 3.2%. No significant changes in total chol, HDL-C, TG, or BP. LDL-C was lowered significantly by the PUFA enriched diet. Blood lipid results (mg/dL) TC 248 LDL-C 160 HDL-C 51 TG 226 Serum a-tocopherol and B-carotene significantly decreased and retinol unchanged after 4 months on diet. Bleeding times increased significantly.	Dietary data not adequately described. Two types of hyperlipidemic may respond to differently to dietary changes. Response not necessarily equivalent to normal subjects. Study suggests a need for increased supplementation of antioxidant vitamins when increasing concentration of PUFA in the diet. One subfraction of HDL (HDL-2) decreased on PUFA enriched diet.
Garcia P. A. et al (Ref. 160)	Cross-over, controlled clinical trial in free-living subjects. Random order of diet treatment sequences. Purpose: measure effects of diets differing in fatty acid composition (SFA and PUFA) on serum lipids. Study site: Iowa and Nebraska	Twenty women; 10 from Nebraska, 10 from Iowa; 5 were Chinese and 14 Caucasian; average age 33 years; free-living. Baseline lipids (mg/dL): CA / CH TC 154 / 166 LDL-C 86 / 97 HDL-C 44 / 47 CA = caucasian CH = chinese	Dietary records self recorded: 28-day/diet total 70-day study. 3 diets: self selected (SS), two experimental diets: US74 and modified fat (MOD). Meals provided and food records maintained through study for US74 and MOD diets. Test Diet Composition US74 / MOD Fat (%) 40% / 30% PUFA 4 / 10 MUFA 14 / 10 SFA 14 / 10 Chol(mg) 400 / 300	Chinese women had consistently higher TC, LDL-C, HDL-C and TG levels that Caucasian women regardless of diet selected. Caucasian woman only showed significant decrease in TC, LDL-C, VLDL-C when effect of US74 to MOD diet compared. US74 diet increased TC, VLDL-C in Chinese women compared to self selected diet. Cross over diet effect on HDL levels of both groups of women. Blood lipids (mg/dL) US74: CA / CH MOD: CA / CH TC 163 / 195 — 139 / 159 LDL-C 89 / 104 — 75 / 85 HDL-C 46 / 51 — 44 / 49	Uneven numbers of subjects in each racial group. The Caucasian group from Iowa was significantly physically larger than the mixed racial group from Nebraska. Significant effects of experimental diets may have been masked by residual diet effects.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Wardlaw G. M. et al (Ref. 144)	Two-phase, randomized, blinded, free-living, controlled clinical trial. Purpose: measure effects of diets enriched in PUFA and MUFA, low in SFA on blood lipids while maintaining % energy from fat at 36%. Study site: Ohio	Thirty-one men completed the study. One criteria for selection of subjects was blood chol >5.16 mmol/L (199 mg/dL). Average age of free-living subjects was 33 years.	Baseline (BL) diet 3 weeks (phase 1), Test diets Mono (enriched MUFA) and Poly (enriched in PUFA), 8 weeks each (phase 2). All meals provided for study. Diets Composition (% of Calories) BL: Fat 39, SFA 15, MUFA 14, PUFA 9, Chol (mg) 360 MONO: Fat 40, SFA 7, MUFA 22, PUFA 11, Chol (mg) 320 POLY: Fat 39, SFA 7, MUFA 9, PUFA 22, Chol (mg) 320	TC fell from baseline significantly: -15% POLY and -9% MONO: LDL fell significantly from baseline by -20% POLY and -12% MONO enriched diets: apo B fell significantly from baseline by -21% POLY and -24% MONO enriched diets. Neither vegetable oil based diets resulted in a significant change in TG, HDL-C, HDL-2, or HDL-3, apo AI when compared baseline diet. Blood lipid results (mg/dL) BL: TC 208, LDL-C 143, HDL-C 42 MUFA: TC 169, LDL-C 123, HDL-C 39 PUFA: TC 178, LDL-C 116, HDL-C 42	Results indicate that consumption of diets low in SFA reduces blood cholesterol. Study also suggests that diets enriched in UFA do not necessarily decrease blood levels of HDL and/or increase TG. Study showed that when dietary energy from fat is 39% of calories (therefore higher than recommended by public health authorities), but the SFA content of the diet is reduced, it is possible to still achieve a reduction in blood cholesterol levels.
Reaven P. et al (Ref. 101)	Controlled dietary intervention clinical trial in free-living subjects. Purpose: compare effect of diets enriched in MUFA (18:1) with PUFA (18:2) on blood cholesterol levels and oxidative potential on LDL-C. Random diet assignment Study site: California university	Nine healthy volunteers, age 18 to 43 years. Gender not stated. Baseline lipids (mg/dL): oleа. linoleа. TC 166 147 LDL-C 96 69 HDL-C 46 42	Liquid diets (fat content less than 1%) to which test oils are added. Test oil one: Trisun 80 = >85% 18:1 (oleic acid). Test oil 2 sunflower oil, >60% 18:2 (linoleic acid). 5-week/diet. Diets enriched in (% of calories) Oleate: Fat 39.2, SFA <2, MUFA 34, PUFA 6, Chol 0 Linoleate: Fat 39.2, SFA <4, MUFA 9.6, PUFA 27, Chol 0 Fatty acid content for sunflower oil was not given by authors, and was as estimated here by using data from another publication, in order to evaluate study results.	No significant decrease in TC or LDL-C by either diet. HDL-C decreased significantly in linoleate (PUFA) supplement group. Blood lipid results (mg/dL) oleate: TC 147, LDL-C 77, HDL-C 46 linoleate: TC 113, LDL-C 58, HDL-C 49 Other results: Antioxidant (vitamin E) conc not significantly reduced by either diet. The amount and rate of formation of conjugated dienes (measure of degree of unsaturation) greater in linoleate group. No significant increase in TBAR (a measure of oxidization in LDL-C). However, significant increase in LDL-C degradation (measure of atherosclerotic potential) by macrophages in linoleate group.	Complete fatty acid analysis of oils used not provided in paper, especially important in case of Trisun 80. Preliminary study can not at this time apply results to general public health advise.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Cole T. G. et al (Ref. 161)	Dietary, clinical intervention trial. Purpose: effect of AHA Phase 3 diet (very low fat and cholesterol) diet on blood cholesterol levels Study site: Chicago	Nineteen free-living premenopausal women, mean age 32. Selection based on TC at or > than 50th percentile. . Healthy subjects. Six women were classified as grossly obese by body mass index (BMI > 30). Mean BMI for all subjects 28.2. Baseline lipids (mmol/L & mg/dL) TC 5.24 205 LDL-C 3.45 133 HDL-C 1.36 52	Stabilization diet: 28 days on typical American diet. 5 months on AHA Phase 3 diet. % of calories AMER AHA 3 Fat 37 21.6 Carb 43.8 59.4 Prot 19.2 19.2 SFA 15.7 4.7 MUFA 11.7 6.4 PUFA 6.7 8.4 Chol 371 96 (mg/day) meals provided on site	TC, LDL-C, HDL-C and HDL-2 decreased when all women were considered as a group. HDL-3, TG and VLDL-TG increased when all women considered as a group. Blood lipid results (all subjects in mg/dL) AMER AHA 3 TC 202 189 LDL-C 133 121 HDL-C 52 49 When women were divided into 3 groups based on BMI, leanest women had a significant decrease in TC, LDL-C and HDL-C. Blood lipid (mg/dL) response grouped by BMI <24 <30 >30 TC 169 202 199 LDL-C 106 130 120 HDL-C 49 57 40 Moderately and grossly obese women were nonresponders.	Results suggest that obesity, at least in women (n=6 BMI>30) had an influence on responsiveness to low-fat, low-cholesterol diet. Authors suggest that obese women may be carbohydrate-sensitive and therefore less responsive to low fat, low SFA diet.
Kwon, Jon-Sook et al (Ref. 172)	Controlled dietary, intervention study in free-living subjects. Purpose: study the effects of diets enriched in UFA from vegetable oils on platelet phospholipid (PL) fatty acid composition and function. Two phase diet design: phase 1, a 3-week baseline or control diet; followed by phase 2, an-8 week experimental diet. Study site: Ohio.	Thirty-four healthy males ages 21 to 50 years. All subjects had chol concentrations of 6.0 to 7.0 mmol/L (185 to 301 mg/dL) on self selected diet. All subjects consumed baseline diet. Sixteen assigned to diet enriched in PUFA and 18 assigned to diet enriched in MUFA.	Three diets: Baseline enriched in SFA, Canola enriched in MUFA and Safflower oil enriched in PUFA. Meals provided, eaten on site and dietitian monitored. % of Calories Base MUFA PUFA FAT 38.8 39.9 39.3 SFA 15.4 7.2 7.4 MUFA 13.0 22.0 8.1 PUFA 8.6 10.7 22.2	Compared to SFA enriched diet, platelet PL fatty acid composition was altered. MUFA enriched diet (canola) raised conc of oleic (MUFA) and linolenic (PUFA); there was a significant decrease in oleic and increase in linoleic with the PUFA enriched diet (safflower). Both vegetable oil diets produced increase in SFA (lauric and palmitic), a decrease in stearic acid of PL fatty acids of platelet compared to SFA diet. Both vegetable oil diets significantly increased platelet aggregation time compared to platelet from SFA diet. Data: Diet Aggregation. MUFA ↑ PUFA ↑ SFA ↓	Authors discussed the possible mechanism by which UFA from vegetable oils may platelet aggregation time. The authors suggest that vegetable oils: canola oil, may alter platelet aggregation by PG metabolism and membrane fluidity and safflower oil by membrane fluidity. The authors also suggested that the increased conc of 2 SFA (palmitic and stearic) in PL of platelet may not be prothrombic.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
McMurry P. et al (Ref. 176)	Dietary intervention study. Purpose: to measure the effects of an "industrialized, western, or affluent" diet on blood lipids levels of subjects who normally consume low fat, low SFA high fiber diets, the Tarahumara Indians Two phase design: phase 1, 1 week traditional diet, followed by phase 2, 5 weeks on test diet. Study site: Chihuahua, Mexico	Tarahumara Indians (Mexico) 12 adults (18 to 35 years), 1 boy (12 years). Five women (3 lactating) and 8 men. Baseline TC 121 mg/dL. Free-living	Tarahumara diet and test or westernized diet provided. Diet Composition Tarahumara "Western" Energy (kcal) 3,700 4,100 % of calories FAT 20 43 MUFA 10 15 PUFA 4 6 SFA 7 21 Dietary fiber 102 33 Chol (mg) <50 1,020	TC, LDL-C HDL-C and TG levels increased significantly in all subjects. Blood lipid results (mg/dL) Tarahumara "Western" TC 121 162 LDL-C 72 100 HDL-C 32 42 Increase in TC occurred very rapidly in response to the western diet. Women has a non-significantly higher increase in TC than men. Lactating women responded similar to non-lactating women. Adolescent boy had the highest initial and final TC level.	Test diet was 151 to 186% of estimated eucaloric needs. Response could be due to load response. Study complicated by large number of subgroups. Large percentage of SFA (21%) content in diet compared to US.
Rassias G. et al (Ref. 180)	Controlled, cross-over design dietary intervention clinical trial in free-living subjects. Purpose: compare the effects of diets supplemented with linoleic and SFA on serum lipids. Random order of diets; no wash-out between diets. 3 weeks on base line diet and 3 weeks on test diets Study site: Australia	Twelve mildly hypercholesterolemic individuals (five men seven women, ages 27 to 74 years. (5 subjects 20 to 30 and 7, 30 to 74 years). Baseline blood lipids mmol/L and (mg/dL) TC BMI Men 6.22 (240) 43 Women 6.17 (238) 56	Supplements provided in liquid form. 3-day food records maintained for each test period. Supplements-SFA and PUFA (linoleic) Diet composition (% of calories) BL SFA PUFA FAT 35.6 40.0 46.6 SFA 13.2 30.5 10.0 MUFA 11.6 9.2 10.0 PUFA 7.9 6.1 23.7	The linoleic-enriched diet significantly lowered TC 0.5 mmol/L compared to basal diet and 1.0 mmol/L compared to SFA-enriched diet. This decrease in TC occurred without a reduction in SFA content or replacement of SFA with PUFA. Comparing basal diet to PUFA enriched diet: the linoleic enriched diet did not decrease HDL-C levels. Data blood lipids mmol/L and (mg/dL) BL SFA PUFA TC 6.0(233) 6.5(251) 5.6(215) LDL 4.4(170) 4.6(177) 3.8(145) HDL 1.3(51) 1.6(63) 1.4(56)	Results suggest more alternatives in choosing nutrient substitutes for dietary saturated fat. Diets significantly lower in total or SFA but enriched in PUFA such as linoleic may also reduce TC levels.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Stacpoole P. W. et al (Ref. 184)	Dietary intervention clinical trial. Purpose: investigate the mechanism of cholesterol lowering action induced by high carbohydrate, very low fat feeding as reflected in changes in VLDL and LDL metabolism. Two phase dietary intervention: 1 phase basal diet for 1 month; wash-out 3 months, test diet 1 month. Study site: Shand Hospital, Florida	Four healthy controls (N=normal), four familial hypercholesterolemia (FH)-heterozygous, and one FH homozygous patients. Healthy volunteers 33 to 58 years, FH patients 20 to 65 years. Baseline blood lipids (mg/dL) N FH TC 186 460 LDL-C 101 400 HDL-C 47 51	Whole body cholesterol balance and tracer kinetics methods used. Lipid profile, fecal sterol balance, apo B synthesis and metabolism. Compartmental analysis. Diet provided and supervised. Basal diet (BL) solid food; test diet, continuous nasal gastric infusion. Diet composition (% of calories) BL Carb Carb 45% 90.5% Fat 40% 8.2% Prot 15% 1.3% P/S 1.0 Linoleic Chol (mg) 100 none	Both normal controls and FH patients total cholesterol and LDL-C decreased significantly (mean difference 43 mg/dl and 123 mg/dl respectively) by consumption of high carbohydrate diet. HDL-C decreased non-significantly in all subjects, serum TG increased significantly. Blood lipid data BL Carb N FH N FH TC 186 460 138 330 LDL-C 101 400 62 270 HDL-C 47 51 32 36 Other data: Decrease in fecal cholesterol and bile acid production and decrease in whole body cholesterol formation in all subjects. Cholesterol synthesis fell 24% (8.4 to 6.4 mg/kg per day) in controls and 58% (11.4 to 4.8 mg/kg/day) in FH subjects. Consumption of carbohydrate diet stimulated LDL-apo B clearance in all subjects.	As authors point out, there are still uncertainties whether frequent or continuous feeding of liquid formula containing mostly glucose is more effective in lowering total cholesterol than solid diets containing a variety of carbohydrates. Another possible issue is the safety of high carbohydrate extremely low fat diets as well as safety of liquid formula diets. For the above reasons application of study results, other than for suggestions of mechanism for control for cholesterol homeostasis, is not applicable to general public.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Dobs A. S. et al (Ref. 164)	Prospective, random, double blind, pravastatin and placebo- controlled clinical trial. Purpose: evaluation of drug and long-term dietary compliance, nutritional adequacy with a lipid-lowering diet. Subjects were randomly assigned to placebo or pravastatin (5, 10, 20 mg/day) for 12 weeks. After 12 weeks all subjects were placed on open-label pravastatin for the remaining 36 weeks. Multicenter trial Study sites: seven lipid treatment center in the United States	Two hundred and seventy-two adults: 206 men and 66 women; mean age 50 years (21 to 70 years); hypercholesterolemic (95th percentile) patients (76% men) aged.	Each subject had 6 weeks of dietary counseling. Basal diet (lipid lowering) for > 6 weeks. Seven, 1-day diet records kept for 1 year.	272 patients selected had elevated serum LDL after greater than 6 weeks of dietary counseling and as such were considered unresponsive to a diet lower in fat, SFA and cholesterol. Blood lipid data (mmol/L and mg/dL): Total cholesterol <1 week 0 weeks 48 weeks Men 6.6(176) 5.0(190) 92.9(186) Women 4.8(149) 3.1(116) 3.6(137) data from all subjects pooled: LDL-C decreased from 193 down to 150 mg/dL). Report given on 23 participants from John Hopkins in which pravastatin reduced TC 23% (about 265 down to 200 mg/dL) and LDL-C 30% (about 210 down to 150 mg/dL) over the year. TG and HDL did not change. Dietary compliance and evaluation given. 55% of men in study completed 7 diet records for 1 year. For both men and women the percentage of calories from total fat was (30%), SFA (8%), PUFA (9%) and MUFA (10%). Approximately two-thirds of participants ingested less that 67% of RDA of some essential mineral and vitamin nutrients.	Intervention with lipid lowering drug did not alter dietary compliance. Patients adhering to lipid lowering diets in which the fat content was similar to that recommended for general population (30% of calories), appeared to contain inadequate amounts of several essential nutrients (folic acid, vitamin B-6, calcium and zinc). Greater than 40% of women ingested less that 67% of the RDA for folic acid, vitamin B-6, vitamin D, calcium and Zn. Compared to general population the nutrient amounts were greater for zinc and calcium but less for vitamin B-6 and folic acid than that found in general population. In men the diet was inadequate in folic acid and zinc. Lipid lowering diet may be inadequate in several micronutrient. Other studies have however found these diets provide adequate amounts of these nutrients.
Todesco T. et al (Ref. 165)	Cross-over, random dietary intervention clinical trial in free-living subjects. Purpose: to test the effects of supplementation of short chain fatty acid (SCFA) on blood glucose and cholesterol levels 2 phases: control and test diet. Random order of diets Study site: medical school and hospital, Italy.	Six healthy volunteers, mean age 32 years; 3 males and 3 females; normal blood glucose and cholesterol levels. Baseline lipid data mmol/L mg/dL TC 5.0 193 LDL 3.2 123 HDL 1.25 48	Each diet period was 1 week including test diet. Diets similar except for supplementation of bread with propionate (9.9 g/150 g of carbohydrate). Maintained diet records day 0 and day 3 of each study. Diet composition (% of calories) Control Propionate Carb 52 53 Prot 17 18 Fat 29 29.5 Fiber 19.2 19.6	A significant decrease in blood glucose response was observed with use of propionate-supplemented bread compared to control bread. No significant changes were observed in total cholesterol, LDL-C, HDL-C or triglycerides. 5 subjects however showed a reduced level of HDL-C and increased triglycerides with propionate-supplemented bread use. Data: mmol/L (mg/dL) Control Propionate TC 5.0 (193) 4.8 (185) LDL-C 3.2 (123) 2.0 (77) HDL-C 1.3 (50) 1.1 (42) TG 1.3 1.8	Short dietary test period, non-steady state conditions, no wash-out between diets. No indication of other confounders for glucose or lipid response (concentration of PUFA, MUFA SFA or cholesterol). Does not confirm previous reports which suggest SCFA decrease total cholesterol by inhibiting HMGCoA reductase (or the synthesis of cholesterol).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Ullman D. et al (Ref. 186)	Metabolic ward, dietary intervention clinical trial in free-living subjects. Purpose: First: to determine if carbohydrate-induced hypertriglyceridemia is avoided with 10-day phase in of 65% carbohydrate and 20% fat diet. Second: to determine if hypertriglyceridemia can be induced by an acute challenge of same diet. Study site: Oregon	Eight healthy nondiabetic adults (two women, six men) mean age 51. Mean Baseline blood lipid (mg/dL) TC 228 LDL-C 147 HDL-C 44 TG 254	Meals provided and compliance observed. Each diet period lasted 10 days. Study 1. Baseline (American) diet. Test diets increased in carbohydrate (65%) while decreasing in fat (20%). Study 2. (American) diet followed by acute 4 diet. Diet composition (% of calories) Amer 1 2 3 4 Carb 45 50 55 60 65 Prot 15 15 15 15 15 Fat 40 35 30 25 20 SFA 15 11 8 6 5 PUFA 6 8 8 8 8 MUFA 19 16 14 11 7 Chol 179 143 107 71 36	Study 1. Triglyceride or VLDL-TG did not significantly increase when carbohydrate concentration of diet was gradually phased in. TC was reduced significantly by phase 3 and phase 4. LDL-C was significantly reduced at all phases. HDL-C was significantly reduced at phase 4 of the diet. Study 1 data (mg/dL) Amer 1 2 3 4 TC 232 223 216 209 198 LDL-C 161 144 141 134 126 HDL-C 43 41 44 42 36 TG 213 232 237 230 230 Study 2. An acute switch to high carbohydrate diet significantly increased both TG and VLDL-TG in 6 of 8 patients. Study 2 data (mg/dL) Amer 65% Carb TC 243 233 LDL-C 174 143 HDL-C 43 41 TG 204 296	At least in some people, a gradual approach of phased increase in carbohydrate as replacement of calories from SFA, total fat and cholesterol may allow for better control of hypertriglyceridemia than previously reported.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bae, C-Y et al (Ref. 154)	Clinical dietary intervention in free-living subjects. Purpose: to determine the effectiveness of American Heart Association Step 1 Diet (% of calories-fat 30% or less, SFA 10% or less and cholesterol less than 300 mg/day in lowering blood cholesterol. Study site: Minnesota Hospital and Medical Center	Eighty-seven (49 men and 38 women) completed the study. Mean age 50.1 years. Baseline lipid data: TC 243 mg/dl; LDL-C 169 mg/dl.	Dietician instructed and followups, food records maintained. Analysis of 4-day food records every 6 weeks. Blood lipid analysis at 6, 12 and 18 weeks. Diet Composition at Baseline (% of calories) Fat 31.6 SFA 10.6 PUFA 6.0 MUFA 11.5 Carbo 50 Prot 16.6 Chol (mg/d) 233 Fiber-soluble 5.9 Calories 1,975	Modest but significant decreases in TC (-3.6%) and LDL-C (-3.5%) were observed at 6 weeks. No further reduction in TC or LDL-C were found at 12 or 18 weeks. By 18 weeks, TC and LDL-C levels showed a tendency to return to and even exceed baseline levels. Small increase in HDL-C (2.1%) and TG (3.8%) at 18 weeks. Blood lipid data in mg/dL at (6 weeks) and (18 weeks) BL AHA(6) AHA(18) TC 242 235 245 LDL-C 169 163 170 HDL-C 49 49 48 Diet results: 1. total dietary fat decreased at 6, 12 and 18 weeks (minus 2.7, 2, and 2.4% respectively). 2. SFA and cholesterol consumption decreased also at 6, 12 and 18 weeks for SFA (minus -1.6, -1.5, and -2.6) and -46% and -50% for cholesterol at 12 and 18 weeks.	The AHA Step 1 diet was not effective in improving plasma lipids of these subjects. This may be due to fact that most participants had already achieved a low level of SFA and cholesterol intake at baseline. All participants knew they were hypercholesterolemic prior to the study and were already following a self developed diet. Those subjects who responded the best were older, had higher LDL-C levels and had higher intake of total and PUFA at baseline.
Groth K et al (Ref. 169)	Clinical intervention by dietary instruction. Purpose: to evaluate the effectiveness of dietician instruction on reduction of blood cholesterol levels. Study site: Spokane Washington	Thirty women and 19 men, mean age 55 years. Mean baseline blood lipids: TC 6.95 mmol/L (268 mg/dL) LDL-C 4.48 mmol/L (174 mg/dL).	Four consecutive classes, 1 1/2 hr per/week. Class topics: (1) CHD the disease; (2) meal preparation; (3) fat definition and properties of specific foods; and (4) healthy food choices. Blood cholesterol levels determined prior to and after dietary instruction. Dietary instructional recommendations: total fat 20% of energy, cholesterol 100 mg/day, soluble fiber 30 g/day. Food recommendations few or lean cuts of meat, few or no dairy products, vegetables, whole grain products. Diet composition:	A significant reduction in TC and LDL-cholesterol before and last class (week 6). Reduction in TC and LDL-C was maintained 1 year after instruction. Blood lipid data: mmol/L (mg/dL) Pre 4 week 1 year TC 6.9(266) 6.3(243) 6.2(249) LDL 4.7(177) 4.2(162) 4.4(170) HDL 1.3 (50) 1.2(46) 1.3(50)	The measure of understanding of the study is evident by helping individuals realize an immediate (6 weeks) and sustained reduction in blood cholesterol levels (1 year). Study suggests that once dietary recommendations are understood, changes will be maintained. Nutritional instruction, therefore, could be instrumental in reducing blood cholesterol levels in the general population.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Maron D. J. et al (Ref. 174)	Cross-sectional study. Purpose: Evaluate the effect of diet (SFA) on insulin levels in nondiabetic (obese) men with heart disease. Study site: Stanford University	Two hundred and fifteen nondiabetic free-living men, 32 to 74 years with angiographically proven coronary artery disease (CAD). Baseline lipids mmol/L (mg/dL) TC 4.4 (170) LDL 2.8 (108) HLD 1.3 (50) other: BMI 26.7	4-day food records and physical activity records maintained (4 years). Index of obesity: BMI; change in BMI, and waist to hip ratio (WHR). Fasted and response glucose and insulin levels measured. Diet Composition (% of calories) Total Fat 32 SFA 10 MUFA 12 PUFA 7.5 Chol 279 (mg/day)	SFA and cholesterol correlated positively with all three indexes of obesity and with fasted and insulin response. Data for correlation of diet and response in various indexes: SFA Chol BMI 0.18 0.16 change in BMI 0.23 0.18 Waist/hip 0.21 0.22 Fast insulin 0.26 0.23 Insulin response 0.17 0.21 Carbohydrate consumption correlated negatively with all measures of obesity and with both measures of insulin. Multivariant analysis showed that SFA, MUFA and cholesterol, positively and significantly correlated with fasting insulin	Limitation of study: dietary data self reported. Study demonstrated that SFA consumption is positively related to insulin concentration independently of obesity in nondiabetic man with heart disease.
Vorster H. H. et al (Ref. 190)	Dietary intervention study. Random and controlled. Purpose: measure effect of 3, 7, or 14 eggs per week on serum lipid levels in subjects who followed a Western diet. Study site: South Africa	Seventy 18 to 19 year-old healthy male university students. Free-living subjects Baseline lipids mmol/L (mg/dL) TC 4.4 (170) LDL-C 2.8 (108) HDL-C 1.3 (50) other: BMI 22.3, nonsmokers	All subjects consumed baseline diet containing three eggs/week for 3 months. One group continued this diet for additional 5 months and remainder either consumed 7 eggs or 14 eggs/week for 5 months. Diet composition Run-in Experimental Cal 3190-3429 3230-3540 Fat% 38-40 39-41 P/S .7-.8 .7-.8 Chol 380 403, 556, or 800 (mg) Fatty acids C16:0 22.5 mg same C18:0 12.4 C18:1 14.5 C18:2 32 C20.4 .26 Group 1 = 3 egg/week Group 2 = 7 eggs/week Group 3 = 14 eggs/week	All subjects at steady state due to consumption of baseline diet for 3 months as determined by multiple blood lipid analysis over 3 month period. Only small differences within groups and no significant differences in total cholesterol, LDL-cholesterol or triglycerides between groups. Group 3 (14 egg/day) had high creatine value (119 versus 86 umol/L). Group 3 had significantly higher total protein, total phospholipid and arachidonic acid. Blood lipid data at 7 months mmol/L (mg/dL) Group 1 2 3 TC 4.3(162) 4.7(175) 4.3(160) LDL 2.6(98) 2.8(104) 2.6(97) HDL 1.2(45) 1.3(48) 1.2(45) There was a significant increase in with in all subjects (4.6 kg from baseline).	Egg intake in the range consumed did not increase blood cholesterol levels in self selected diet. Authors suggested several reasons for the above results such as a high fat diet with a, relatively low P/S ratio may cancel effects of additional cholesterol, second that there was a metabolic adaptation to compensate for increase in consumption of dietary Chol decrease in Chol synthesis or increase in Chol elimination and third that the phospholipid content may be hypocholesterolemic and thus counter act hypercholesterolemic effect of added cholesterol.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Grover S. A. et al (Ref. 170)	CHD primary prevention computer model to estimate lifetime benefit of risk factor modification. Purpose: To evaluate lifetime benefits of reducing total cholesterol to prevent CHD through dietary modification or medical intervention. Study site: Canada	Men and women, age 35 to 65 years of age, free of CHD. Blood cholesterol levels at baseline range 5.2 to 7.8 mmol/L or (200-low risk to 300 mg/dL-high risk) with and without additional CHD risk factor.	Computer model based on Framingham Heart Study, Canadian Life Tables, Canada Health Survey Data. Program estimate average expectancy associated with modifying one or more CHD risk factors. Into model following factors are incorporated: age, sex, diastolic blood pressure, total cholesterol, left ventricular hypertrophy, glucose intolerance and cigarette smoking. Adjustments also made for HDL using gender specific HDL modification for men and women.	Ability to forecast lifetime benefits depends on baseline levels, age, sex, and presence and absence of other risk factors. Reducing serum cholesterol levels 5 to 33% increases the average life expectancy 0.03 year or 11 days to 3.16 years. The average onset of symptomatic CHD would be delayed by 0.06 or 22 days to 4.98 years. Among 35 year old men and women, without other risk factors, reducing cholesterol from 300 to 200 mg/dL with diet or medication would increase life expectancy 1.64 year (men) and 0.98 year (women).	Computer model used is based on relatively short term clinical data - 5 to 10 year to predict lifetime benefits. Wide variation in results from reduction of blood cholesterol in men and women of various ages. Results similar to other models used to estimate benefit from lowering blood cholesterol. For example Taylor model: a 6.7% decline in total cholesterol increased life expectancy 3 days to 3 months for low-risk men and women age 30 to 60 years.
Ekstedt B. et al (Ref. 165)	Diet and exercise intervention study. Controlled study in free- living subjects. Purpose: to determine the effect of low calorie, fat, and cholesterol diet on blood cholesterol and triglyceride levels. Study site: Sweden	Seven healthy males, age 21 to 37 years. Nonsmokers. Study included statement that subjects had normal cholesterol and triglyceride levels but blood lipid data not provided.	Stabilization diet (fat 26 to 30% of calories) and exercise (run 5 to 10 km, 2 to 4 times per week) for 1 month prior to study. Four different diets compared: 8 days each diet (solid food), one test per year, while cross country skiing 160 Km. Low calorie (LCa); High fat and high chol (HF/HC); high chol (HC) Std / LCa / HF/HC / HC Cal 3800 / 2300 / 3800 / 3800 Fat (%) 36 / 21 / 52 / 29 Chol (mg) 360 / 110 / 480 / 410 Carb (%) 57 / 68 / 34 / 56	A significant decrease in both total cholesterol and LDL-C by consumption of each of the test diets compared to levels at baseline. No significant change in HDL-C with standard or low energy diet. Significant increase in HDL-C with high fat/high cholesterol diet (18%) and high cholesterol diet (30%). Serum triglyceride decreased by more than 30% but no difference due to diet. Blood lipid data (actual values not provided); data presented as percent increase or decrease: Std / LCa / HF/HC / HC TC -26 / -35 / -20 / -31 LDL -38 / -50 / -41 / -58 HDL 6 / 8 / 19 / 30 Body weight decreased significantly on low calories diet (3 kg).	Other results not shown in table were: heavy exercise, irrespective of fat, calorie, or cholesterol content of diet, decreased LDL-C levels in healthy men. Loss in short term body weight did not increase cholesterol lowering effect of low calorie, low fat and cholesterol diet. Short term heavy physical activity had stronger influence on blood cholesterol levels, than did fat or cholesterol content of diet. Large variance in triglyceride levels among individuals. Can only apply results to short term heavy exercise - diet and not moderate exercise and diet effects as may be common in general public.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Rok F. J. et al (Ref. 171)	Case-control study conducted 1986 to 1987. Purpose: to determine the levels of a trace element, antioxidant and PUFA levels in patients with atherosclerosis. Study site: Netherlands	Ninety-one CHD (cases) and 72 control male subjects, average age 53 years. Other confounders-proportion: alcohol (65%), smoke (28%), hypertension (35%), MI (36% in cases and 15% in controls). All subjects has coronary angiography. Stenosis in at least one coronary vessel: case subjects >85% and < 50% of controls.	Plasma selenium measured by neutron activation; tocopherol by high pressure liquid chronography; gas chromatography of methyl ester derivative of lipid extract of plasma PUFA.	Cases, compared to controls had significantly high levels of total cholesterol and LDL-cholesterol and lower levels of diastolic blood pressure and HDL-cholesterol. Plasma selenium was significantly lower in cases compared to controls. No significant differences in tocopherol or PUFA's. In subgroup of case where tocopherol is low (less than 1452 ug/dL), there is a corresponding significant lower ratio of selenium/PUFA.	Dietary history, which could impact on these results, was not provided in study. Study lacks a control group which had no previous history of or who had no MI or atherosclerosis. Also subjects had many other risk factors which may relate to the results i.e., smoking and not directly to atherosclerosis. The reason for evaluating the study was because of safety concerns with proposed changes dietary composition due to a decrease in SFA consumption and replacement with other nutrients such as PUFA and micronutrient status (such as antioxidants) have been expressed. Some previous reports suggested that selenium was significantly lower in acute MI or those who died from CVD.
Shea S. et al (Ref. 163)	Longitudinal, survey. Purpose: survey of Hispanic preschool children in New York, measurements include serum lipids, dietary index and body mass index (BMI).	One hundred and eight healthy (57 boys and 51 girls) Hispanic children, average age 4.5 years. Mean serum total cholesterol (TC) for 108 children was 156 mg/dL and LDL-cholesterol was 97 mg/dL.	Four 24-hour dietary record, 3 months apart. Two Willett semiquantitative food frequency questionnaires approximately 6 months apart.	Boys had slightly higher serum TC and LDL-cholesterol than the total group or the girls. Children in the highest tertile of total fat consumption (36.2% of total calories) compared to the lowest tertile (30.2% of calories) had significantly higher TC and LDL-cholesterol Furthermore, children in the highest tertile of SFA consumption (14.6 % of calories) compared to lowest tertile (11.2% of calories) had significantly higher TC and LDL-cholesterol levels. Blood lipid data (mg/dL): Nutr. SFA Tertiles 1st 2nd 3rd TC 152 152 172 LDL-C 92 91 108 Nutr. TF (total fat) TC 154 161 171 LDL-C 93 96 106	Findings suggest that dietary fat, particularly SFA, is increases blood cholesterol, especially LDL-Chol in preschool children. Correlation R^2 TC LDL-C SFA 0.12 0.16 TF 0.08 0.10 Data adjusted in multiple linear regression models for caloric intake, age, sex, and body mass index.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Prewitt T. E., et al (Ref. 170)	Controlled clinical trial, diet intervention in free-living subjects. Purpose: to compare effects of high (37% of calories) and low fat (20% of calories) diet on a. insulin like growth factor and b. blood cholesterol levels study site: Chicago, IL.	Eighteen healthy premenopausal women, mean age 32 years. Subjects had higher than average levels of blood cholesterol (50th) percentile. Baseline blood lipid data other than range notated above was not provided in the paper. Other: mean BMI 30; n=12 BMI 23; n=6 BMI 38.4.	All subjects consumed the 37% fat diet for 4 weeks, followed by 20 weeks of a the 20% fat diet. Diet composition (% of calories) High fat / Low fat Fat 37% / 20% P/S 0.5 / 1.0 Chol (mg/d) 266 / 94 Meals provided and monitored on site. Absolute amount of SFA and PUFA dietary data not provided in study; no data on MUFA content provided.	When all subjects were considered, total cholesterol (TC) and LDL-cholesterol tended to decrease by consumption of low fat, low cholesterol diet Consumption of low fat diet by the obese group, decreased TC and LDL-cholesterol. Blood lipid data: Entire group versus Obese (mg/dL) 37% / 20% / 37% / 20% TC 200 / 185 / 205 / 193 LDL 127 / 120 / 143 / 127 HDL 46 / 50 / 40 / 41 No relationship was observed between BMI and TC or LDL-cholesterol when all subjects were considered together or divided into normal weight or obese groups.	There was no run-in or diet stabilization period. The study did not use a wash-out period between diets or alternatively use cross over design. In premenopausal, obese women consumption of a diet in which fat was 20% of calories and 94 mg/day reduced TC and LDL-cholesterol, Variance in absolute amounts of PUFA, SFA, MUFA complicates interpretation and applicability of results to general public or a subpopulation.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Berlin E. et al (Ref. 157)	Clinical trial, dietary intervention, free-living, controlled, randomized study. Purpose: To compare the effects of high fat diet (40% of calories) and low fat diet (20% of calories), on blood cholesterol levels and lipoprotein fluidity in premenopausal women. Diets also varied in amount of PUFA and SFA. Study site: BHNRC, Beltsville Maryland.	Thirty-seven healthy women between 20 and 40 years of age selected, 31 finished the study.	Free choice dietary period for one menstrual cycle. All women were then placed on high fat diet for 4 months (4 menstrual cycles) and then switched to low fat diet for 4 months. Food was provided, eaten on site or prepared for home consumption. Approximately 2,200 kcal per day. Diet composition data (% of energy): Nutrient and diet intervention groups 1 2 3 4 Carb 45 45 64 64 Fat 39 39 19 19 Chol (mg) 374 269 230 199 SFA (g) 44 27 21 12 C18:1 (g) 30 33 15 17 C18:2 (g) 15 26 7 13 Fluidity measured by fluorescence anisotropies using the probe 1,6 diphenyl 1,3,5 hexatriene (DPH).	Plasma cholesterol levels were lower during luteal phase of menstrual cycle regardless of diet. Blood total cholesterol data (mg/dL): Diet groups 1 2 3 4 Follicle 160 152 157 154 Luteal 148 140 152 149 In general low-fat, and higher portion of PUFA in the diet increased lipoprotein fluidity. Fluidity of VLDL was related to oleate and linoleate. Fluidity of LDL and HDL, however, showed an inverse relationship to oleate and linoleate content.	It is difficult to evaluate study based on P/S ratio, without grams or percent of SFA, PUFA, and MUFA in the diet. It is possible that the SFA content of the diet was the same throughout the study. This was not the case in this study as shown by composition in g of SFA content. No consistent relationship emerged from the study to indicate that lipoprotein fatty acid content determined either LDL-C or HDL-C fluidity. The dietary cholesterol content was more significant than fatty acid content in determining LDL fluidity. This result would suggest another important role of dietary cholesterol separate from its effect on blood cholesterol levels. Changes in fluidity of lipoprotein particles may in turn alter their interaction with receptors and therefore alter the fate of blood cholesterol levels

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Bassarre T. L. et al (Ref. 155)	Cross-sectional Purpose: to examine the relationship of several cardiovascular disease risk factors (CDRF) such as blood pressure (BP), total cholesterol (TC), HDL-C, BMI and percent of fat with daily energy intakes (EI) and daily energy expenditure (EE). Study site: North Carolina	Farmers and farm wives. 84 men (mean age 53) 74 women (mean age 51). BMI for men was 62 and 43 for woman.	Dietary data and activity records collected for 4 days. Subjects were instructed to maintain their normal diet and activities. No dietary composition provided in the study.	For both males and females, at every age group, energy expenditure (EE) was greater than energy intake (EI). Mean EI and EE were statistically less from females than for males. Mean systolic BP, diastolic BP, TC, HDL-C were within normal limits. Mean TC, HDL-C and diastolic BP was slightly higher in females than in males. Blood lipid data mmol/L (mg/dL) Males / Females TC 5.4(206) / 5.45(210) LDL 3.98(154) / 3.87(149) HDL 1.36(52) / 1.58(61) When EI compared to EE, farm men consumed and expended more energy than farm women. Energy data: Males / Females EI 2413 / 1761 EE 4300 / 2919 Balance(EI-EE) -1886 / -1158	EE obtained from a reliable activity record may be a more practical tool for assessing the possible relationship of energy metabolism to CHD risk factors such as total and LDL cholesterol. Males who expend energy (exercise) may reduce risk of CHD.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Demacker P. N. M. et al (Ref. 163)	Dietary intervention study. Cross-over design, in free-living subjects. Purpose: To compare the effect to two diets: one enriched in SFA and the other enriched in PUFA on postprandial lipoprotein metabolism Study site: Netherlands	Twelve normalipidaemic subjects (six males and six females), ages 21 to 26 years. Subjects had fixed pattern of daily activities, none smoked. Other: mean BMI was 22.	Subjects consumed each test diet 9 days with a 4-week wash-out with habitual diet. Lunch was prepared in hospital kitchen. Meals consumed at fixed time intervals. Dietary instruction was given and dietary records maintained for breakfast and dinner meals. Rate of absorption of retinyl palmitate was used as a marker to measure rate of fat absorption was added to lunch meal on day 9 of the study. Diets: contained 2,400 kcal; fat 36.5% and Carbo 47.5% of calories; and Chol 294 mg/day. [% of calories - diets:] SFA 21 10 MUFA 12 9 PUFA 3 18	Consumption of the PUFA enriched diet resulted in a significant decrease in TC and LDL-C compared to SFA enriched diet. HDL-C was not significantly altered by diet. Blood lipid data (mg/dL) SFA PUFA TC 118 108 LDL-C 71 59 HDL-C 38 36 Other results: There was a 43% decrease in chylomicron and their ruminants as well as a 20% decrease in VLDL due to consumption of the PUFA enriched diet. Chylomicron remnants were 43% more rapidly removed on diet rich in PUFA compared to diet rich in SFA. Since the rate of absorption is the same, an increase in the rate of clearance of triglyceride and cholesterol rich particles may explain the significant decrease in blood levels of these lipoprotein particles by PUFA-enriched diet.	Because of the short duration of the study (9 days), applicable results refer to short half-lived lipoprotein particles [chylomicron, VLDL and their remnants]. Under these circumstances cannot conclude whether or not the PUFA enriched diet altered the level of HDL. Second, the PUFA enriched diet was also reduced in SFA (about 10% of calories). This decrease in SFA content may account for decrease in TC and LDL-C observed. Thus added PUFA when substituted of SFA did not negate the cholesterol lowering effect of decreasing the SFA content of the diet. If future studies support these results such that a PUFA enriched diet increases the rate of clearance for chylomicron remnants, this could suggest a decrease in a lipoprotein particle of atherogenic potential.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Seidell, J. C. et al (Ref. 102)	Cross-sectional survey Purpose: To determine is there is a relationship between linoleic and linolenic content in gluteal fat tissue and serum lipids. Study site: five populations in Europe (Sweden, Netherlands, Belgium, Italy and Poland)	Three hundred and twenty-seven men aged 38 from five European towns, Specific details of general health, except for smoking habits were not presented in the paper. No dietary data was available for evaluation.	Fat biopsies taken from the upper outer quadrant of the left buttock. Serum lipids [total cholesterol, HDL-cholesterol and triglycerides] were determined enzymatically after an overnight fast. LDL-cholesterol determined by the Fridewald equation.	Adipose linoleic content, which varied widely was lowest in men from Poland (8.6%) and highest in men from Belgium (16.7%). Linolenic acid content was lowest in men from Italy (0.5%) and highest in men from Sweden and the Netherlands (0.9%). Linoleic acid was negatively correlated with LDL-C (-0.15, $p<0.01$) and total cholesterol ($r=-0.17$, $p<0.01$). Linolenic acid was negatively correlated with serum triglycerides ($r=-.14$, $p<0.05$). There was a significant difference in HDL-C levels , with the highest level in men from Italy, Belgium, and Sweden and the lower concentration in men from Poland. Total cholesterol and LDL-C was highest in Italian males [TC= 6.2 mmol/L and LDL-C= 4.2 mmol/L] but lowest in Swedish men [TC= 5.7 mmol/L and LDL-C= 3.9 mmol/L].	The authors concluded that there were major differences in these adipose unsaturated fatty acids from different European communities which correlated with some, but not all serum lipids. Adipose linoleic and linolenic content did not adequately explain the significant differences observed in serum HDL-C and triglycerides.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Brown, S. A., et. al. (Ref. 160)	Dietary intervention; dietician-instructed and multiple interviews; free-living; meals provided; food consumption supervised; dietary records maintained and checked. Purpose: measure effect of dietary cholesterol on blood lipids. Study site: Austria.	Study 1: 81 normolipidemic [less than 240 mg/dL fasting TC, 175 mg/dL LDL-C]; healthy outpatient males (aged 20 to 50 years, mean age 29.6 year). Study 2: 14 of the 81 males participated.	Study 1. Two diets (3 weeks each) of 6-week study. First 3 weeks: low chol diet (fat 40%; Carb 45%; protein 15% of total calories; Chol less than 300 mg/day). Second 3 weeks: similar to first 3 weeks plus 6 eggs per day (1,300 mg Chol/day). Diet fat composition estimated based on percent of C-16 and C-18 for SFA, C-18:1 for MUFA and C:18:2 for PUFA. Study 1 fat content (% of calories) total fat 38% SFA 11% MUFA 13% PUFA 6% Study 2. Four diets compared, 3 weeks/diet, for a total 12 weeks. Percent of Carb and protein same as above. Estimate of fat distribution for study 2. Test diets 1 2 3 4 TF 45 44 45 44 SFA 11 11 8 8 MUFA 20 20 10 10 PUFA 7 7 20 21 chol 300 1,300 300 1,300 (mg/d)	Study 1. In the 81 normotensive males, dietary cholesterol consumption increased total (12%), LDL-C (17%) and HDL-C (5%) significantly. Blood lipid data (mg/dL) 300 mg 1,300 mg TC 171 192 LDL-C 102 120 HDL-C 52 55 Study 2. LDL-C levels increased significantly (27%) on the high SFA-high cholesterol diet (diet 2) compared to SFA enriched diet with low cholesterol (diet 1). When subjects switched from SFA enriched, cholesterol rich diet to PUFA enriched low cholesterol diet; TC and LDL-C decreased significantly (31%) and HDL-C was unchanged (to diet 3). LDL-C was lowest on the PUFA enriched-low cholesterol diet. Adding cholesterol to PUFA increased LDL-C (25%) (diet 4). Study 2. Blood lipid (mg/dL) 1 2 3 4 TC 152 178 137 160 LDL-C 88 112 77 96 HDL-C 51 54 48 53	Results demonstrated that both dietary SFA and cholesterol increase total and LDL-C levels in normolipidemic males. The study included the use higher levels of total fat, dietary cholesterol and PUFA than is recommended for the general public.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Valsta, L. M. et al (Ref. 188)	Dietary intervention in free-living subjects. Cross-over design. Conventual mixed solid foods, meals provided and consumption monitored. Food records maintained. Duplicate portions of each diet collected daily and analyzed. Purpose: to compare effect of diets enriched in either MUFA or PUFA on serum lipoprotein Study site: Finland.	Fifty-nine healthy volunteers (30 men, 29 women), aged 18-65 years (median 25 years). At baseline subjects TC was 4.82 mmol/L or 186 mg/dL (men) and 5.23 mmol/L or 201 mg/dL (women). Subjects maintained normal lifestyle (same smoking habits, alcohol consumption, and exercise).	Study lasted 63 days. Baseline diet 2 weeks (SFA enriched), followed by two test diets (PUFA or MUFA enriched) for 25 days each. MUFA enriched diet used rapeseed oil and contained 5% SFA, 58% MUFA, 24% PUFA [n-6] and 13% PUFA [n-3]. PUFA enriched diet used sunflower oil and contained: 12% SFA, 23% MUFA, 65% PUFA [n-6]. Diets as % of total calories: BASE PUFA MUFA Fat 36 38 38 SFA 19 13 12 MUFA 11 10 16 PUFA 4 13 8 Chol (mg/d) 356 315 360	Dietary compliance assessed by plasma phospholipid fatty acids composition. Both PUFA and MUFA enriched diets significantly reduced TC and LDL-C from baseline. The MUFA enriched diet reduced TC and LDL-C more than PUFA enriched diet. Blood lipid data: mmol/L (mg/dL) BASE PUFA MUFA TC 5.3(205) 4.6(178) 4.5(174) LDL 3.2(123) 2.6(100) 2.4 (93) HDL 1.3 (51) 1.3 (50) 1.3 (51) The differences between test diets in TC and triglyceride (TG) were more pronounced in women but statically insignificant from men. Conversely, the test diets effected LDL-C and HDL-2 of men more than women.	MUFA enriched diets were shown to be equally effective as PUFA enriched diet in reducing TC and LDL-C levels in men and women. HDL-C was not significantly reduced by consumption of PUFA or MUFA enriched diet. If PUFA is at or below 10 to 13% calories, HDL-C levels do not appeared to be lowered. Study results suggest cannot rely on Key equation to predict the effect of MUFA and PUFA on serum cholesterol levels.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zock P. L. and Katan M. B. (Ref. 193)	Dietary intervention. Random, multiple cross-over design in healthy free- living subjects; uses three consecutive periods; three test diets lasting 3 weeks each. Meals provided. Duplicate portions of each diet were analyzed each day. Food dairies maintained. Purpose: To compare the effects of C-18 fatty acids on serum cholesterol levels: SFA (stearic acid); trans MUFA (elaidic acid); PUFA, (linoleate acid) Study site: Netherlands	Twenty-six men, 30 women normolipidemic, completed study. Equal number of men and women in each test group. Mean total cholesterol men and women was 157 mg/dL; HDL-C was 53 mg/dL. Age ranged 19 to 46 years for men, mean 25 years; Age ranged 18 to 49 years, mean 24 years for women.	Diets did not differ from one another other than test fatty acid which was 8% of total energy. Trans fatty acid (TFA) prepared from high oleic acid sunflower oil; hydrogenated with sulfurized nickel catalyst, and mixed 75 parts of TFA to 25 parts oleic acid rich oil. Stearate (S.A.) inter-esterified from a mixture of 41 parts of hydrogenated high linoleic acid sunflower oil to 50 parts high oleic sunflower oil and 9 parts of unmodified high linoleic sunflower oil. Diets as % of total calories: L.O.= linoleate; Trans= trans elaidic; S.A.= stearate L.O. S.A. TRANS Fat 41 43 40 SFA 11 20 10 MUFA 16 17 23* PUFA 12 4 4 Chol 33 33 33 (mg/MJ) *7.7% as trans MUFA	Compared to levels of serum cholesterol on linoleate diet both stearate and trans fatty acid enriched diet significantly increased TC and LDL-C levels. In addition, both stearate and trans fatty acid enriched diet significantly reduced HDL-C compared to linoleate enriched diet. Blood lipid data (mg/dL) L.O S.A. TRANS TC 183 189 189 LDL 109 116 119 HDL 57 54 53	Consumption of trans fatty acid enriched diet which is closer to some subpopulation groups in U.S. increased blood risk factors for CHD. Broader spectrum of subjects than in earlier Mensink and Katan study. Trans fatty acid consumption of total calories and g/day: Current U.S. 3 to 4% or 7 to 10 g/day; Zock and Katan study 7.7% or 24 g/day; Mensink and Katan study 11% or 33 g/day. The authors suggest that every one percent of energy from trans fatty acids increases LDL-C 1.2 mg/dL and lowers HDL-C 0.6 mg/dL relative to oleic and linoleic acid. Therefore at current U.S. consumption of 3 to 4 % of calories, contributions from trans fatty acid could increase LDL-C by 4 mg/dL and decrease HDL-C by 2 mg/dL.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Mata P. et al (Ref. 175)	Dietary intervention in free-living healthy men and women. Controlled, cross-over design. Dietary diaries maintained. Compliance assessed by questionnaire and observation. Consumed solid foods. Purpose: determine long- term effects of MUFA versus PUFA enriched diets on risk factors for CHD. Study site: Spain	Seventy-eight subjects from 2 urban closed communities (46 men mean age 33 years and 32 women mean age 42 years). Plasma cholesterol levels above 90th percentile and below 10th percentile were excluded from study (specific baseline data not provided in the study). Subjects maintained habitual lifestyle throughout study.	Maintained usual diets [men: fat 37% and Carb 43% of calories (2,540) and women: fat was 36% and carb 46% of 2,000 calories] with exception of type of dietary oil. Phase 1: subjects consumed PUFA enriched diet (sunflower oil- enriched in linoleic acid) for 12 weeks. Phase 2: subjects consumed MUFA enriched diet (olive oil- enriched in oleic acid) for 20 weeks. Vegetable oils comprised 44% of dietary fat (16% of total calories) for men and 50% of dietary fat (18% of calories for women). Diet composition as % of total calories PUFA / MUFA FAT 37 / 36 SFA 12 / 12.5 MUFA 11 / 20 PUFA 12.8 / 3.4 CHOL 460 / 337 (mg/day)	Blood lipids were analyzed in week 10 and 12 of the PUFA enriched diet and weeks 4, 8, 12, 16, 20 weeks of the MUFA enriched diet. In this study the PUFA is the baseline of comparative diet. Phase I. Blood lipid data at 12 weeks (expressed in mmol/L and mg/dL) Men / Women TC 4.93(190) / 5.2(201) LDL 3.3(126) / 2.48(96) HDL 1.0(39) / 1.3 (51) In Phase 2 (at week 16 for men and 20 for woman respectively, on the MUFA enriched diet): nonsignificant reduction in TC and LDL-C, but HDL-C increased significantly for men. In women: TC increased significantly (to 5.7 mmol/L (220 mg/dL or by 9%), LDL-C was unchanged (2.4 mmol/L or 94 mg/dL) and HDL-C increased significantly (to 1.7 mmol/L or 66 mg/dL or by 30%). No blood lipid data was provided for men at week 20 of study. The authors used an atherogenic index defined as (TC:HDL-C) to compare the effects of PUFA to MUFA diets: in men the atherogenic index fell 12% and 17% in women.	Larger and longer dietary intervention study than many of previous studies. The paper did not report baseline cholesterol values. Study which lasted up to 20 weeks allows for some estimation of possible long-term effects of MUFA compared to PUFA on blood lipids. Compared to the PUFA diet, the MUFA enriched diet significantly increased HDL-C levels without increasing TC or LDL-C for both men and women. The increase in HDL-C due to consumption of the MUFA enriched diet was larger in females than males. Public health significance: diets were similar in the total fat content to the American diet, but had a higher percentage of MUFA suggest that longer term consumption may reduce total and LDL-C without reducing and perhaps increasing HDL-C levels.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Garry P. J. et al (Ref. 167)	Longitudinal, nonrandom, free-living study design. Purpose: to estimate the effect of dietary intake from protein, fat carbohydrate, and total energy on plasma lipid levels in healthy, elderly men and women. Length of study 9 years. Study site: New Mexico and the United States	One hundred and fifty-seven healthy elderly men (n=65) and women (n=92) outpatients from Albuquerque, NM. All subjects > 60 years (medium age 70 years). Subjects were caucasians, who for the most part were health conscious and educated.	Dietician instructed, maintained food records. Nutrient content of diets analyzed. Analysis of blood was at the same time annually. Nutritional and clinical data collected from 1969 to 1989. Analyzed nutritional status also grouped by age (cross-sectional or cohort differences).	No significant cross-sectional differences in energy, protein total fat and carbohydrates intake with age was noted. There was a significant longitudinal decrease in total fat, saturated and PUFA and cholesterol intakes in men and women. Significant decreases in total, HDL-C and LDL-C plasma cholesterol concentrations were reported in both women and men. Blood lipid data mmol/L (mg/dL) Women / Men TC 6.3(243) / 5.6(217) LDL 4.1(158) / 3.8(139) HDL 1.5(59) / 1.3(52) Longitudinal predicted changes (mg/dL) Women / Men TC -1.5 / -2.2 LDL -0.9 / -1.1 HDL -0.9 / -1.1 The decrease in total fat and cholesterol intakes were significantly correlated with the decrease in total plasma cholesterol.	Study found significant associations between changes in dietary intake and changes in plasma lipids over time. When both SFA and PUFA intakes decreased over time, HDL-C was also reduced (therefore HDL-C reduced even when PUFA does not substitute for SFA).

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Nguyen, L. B. et al (Ref. 194)	Dietary and drug intervention study. Controlled study in free- living subjects. Purpose: to determine the effects of cholesterol lowering drug and restriction of dietary cholesterol on synthesis and serum lipoprotein levels in two families with a lipid storage disease. Study site: New York and New Jersey	Two homozygous (male 28 years and female 9 years) and 2 obligate heterozygous subjects (female 25 years and male 47 years) with sitosterolemia, and 17 healthy control subjects (10 males and 7 females ranging between 19 and 60 years of age.	The metabolic ward diet consisted of: carbohydrate 53%, protein 17% and fat 30% of total calories, and cholesterol 223 mg/2,000 calories. Drug regiments consisted of: lovastatin (15 mg twice daily) and cholestyramine (15 g/day). The effect of diet alone on paired test subjects in a metabolic ward (one homozygous and one heterozygous), diet in combination with drug regiments was conducted for 3 weeks each followed by a 2-week wash-out on the basal diet. A second pair of test subjects were on free-living diets (contained the similar caloric profiles but differed in sterol content (high= 400/500 g/day cholesterol and 100 to 150 mg/day plant sterols: low =100 g/cholesterol and 50 mg plant sterol/day). One free-living heterozygous subject received no drug treatment.	Both homozygous subjects had elevated cholesterol levels compared to controls [>300 vs 185 mg/dl respectively]. Dietary sterol restriction was ineffective in lowering serum cholesterol levels in homozygous subjects. Neither lovastatin or low sterol diet produces a significant effect on reduced mononuclear leukocyte HMG-CoA reductase activity in homozygous or heterozygous subjects while lovastatin increased HMG CoA reductase 30% in controls.	Small study due to nature and rarity of the disease. Not all test subjects complied with both diet and drug treatments. Many confounders in study design and therefore difficult to make conclusions. There are marked abnormalities in cholesterol homeostasis in patients with homozygous sisterolemia. The results suggested a depressed cellular cholesterol synthesis due to a deficiency in HMG-CoA reductase that cannot be up regulated by a low sterol diet. Can not make public health conclusions from this study.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Meinerts H. et al (Ref. 195)	A controlled dietary intervention study in free-living subjects. Purpose: to compare the effects of two sources of dietary protein (plant and animal) with dietary cholesterol on serum lipoproteins in healthy subjects. Study site: Denmark	Twenty-one healthy active individuals (11 women and 10 men). Subjects had normal body weight, and normal cholesterol levels. Age range of subjects was 28 to 55 years.	All subjects received both the soy protein and the casein diets, with or without cholesterol enrichment in a cross-over design. Each dietary period lasted 31 days. The study included a 30-day wash-out period on a self selected diet. Diet composition (% total calories) Protein: Cas(g) Soy(g) (20%) 139 140 Fat (27%) Carbohydrate (53%) Cholesterol (mg) Low animal 72 12 plant 214 251 Cholesterol (mg) High animal 549 486 plant 579 637 casein = CAS soy protein = SOY Caloric intake from protein and fatty acid composition of both diets were very similar. SFA and stearic acids together was 11% of calories.	Body weight decreased on both diets casein and soy diets and on both low and high cholesterol diets. TC, triglycerides and VLDL-C levels were similar on casein and soy, regardless of the cholesterol content of the diets. On a low-cholesterol diets, the mean plasma levels of LDL-C and HDL-C were identical and not dependent on source of dietary protein. On a cholesterol enriched diet, however, LDL-C levels were significantly lower on the soy protein diet and HDL-C was significantly higher. Blood lipid data (mg/dL) Low Chol / Enriched Chol CAS SOY CAS SOY TC 124 127 138 133 LDL 68 66 81 68 HDL 42 43 47 53	Results suggest an interaction between source of dietary protein (plant and/or animal) and dietary cholesterol on levels of blood LDL-C and HDL-C concentrations. On cholesterol enriched diet, the source of dietary protein appears to be more important in determining serum cholesterol levels than on a low cholesterol diet. This study is of public health significance, since the results suggest that on a cholesterol enriched diet, such as found in the U.S., casein (animal protein) increased LDL-cholesterol while simultaneously reducing the HDL- cholesterol.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Barr S. L. et al (Ref. 220)	Dietary intervention study. Randomized, double blind and controlled study in free-living subjects. Purpose: to compare the effects of a low fat diet and a low fat diet that is reduced in saturated fat on blood cholesterol levels in healthy males. Study site: New York	Forty-eight healthy males ages 21 to 32 years. Subjects with extreme dietary habits or ethanol intake were excluded. Other: men BMI 24 Baseline lipids (mg/dL): ADD Step 1 Sat TC 185 185 179 HDL 46 49 49 LDL 139 136 130 n=17 n=15 n=16	All subjects consumed baseline diet (3 weeks) equivalent to average American diet (AAD). Meals provided throughout 10-week study. Randomly assigned to three isocaloric diet groups (7 weeks). Group 1 (ADD); group 2 (AHA Step 1); group 3 (AHA + SFA). Diet composition: % of total calories AAD Step 1 SAT Fat 36 29 29 SFA 16 8.6 12 MUFA 14 12.0 10.6 PUFA 7 7.6 6.3 Chol (mg/d) 491 303 347	Refer to baseline data: Overall the switch to Step 1 diet significantly decreased total cholesterol by 0.36 mmol/L or 14 mg/dL (7.5%). Men on SFA/Step 1 diet had non-significant decrease in total cholesterol of 0.08 mmol/L or 3.1 mg/dL (1.6%) compared to AAD diet. Switch to Step 1 diet significantly decreased LDL-cholesterol 0.25 mmol/L or 9.6 mg/dL (0.1%). Consumption of SFA diet was associated with a decrease of 0.03 mmol/L or 1.1 mg/dL (1.1%). Switch to Step 1 diet significantly decreased HDL-cholesterol 0.11 mmol/L or 4.2 mg/dL (8.6%). Switch to SFA diet decreased HDL-cholesterol by 0.06 mmol/L or 2.3 mg/dL (4.6%.)	No significant decreases in total or LDL-cholesterol were observed in healthy males when total calories from fat was reduced from 37% to 30%. Significant reductions in total and LDL-cholesterol were observed in healthy males when both total fat and saturated fat content of the diet was reduced.
Lahtimaki, T. et al (Ref. 221)	Dietary intervention study. Controlled, switch-back in free-living subjects. Purpose: to compare the effect of dietary cholesterol on blood lipids and apolipoprotein E phenotypes in healthy males and females. Study site: Finland	Thirty-six normolipidemic students (16 female and 20 males, average age 23.9 years). Apo phenotypes were: E3/2 (n=9); E3/3 (n=11); E4/4 (n=3). Baseline lipids for all subjects estimated from figure of data at zero time: TC range (4.5 to 5.2 mmol/L (174 to 201 mg/dL)); LDL-C (2.4 to 2.9 mmol/L (93 to 112 mg/dL)) and HDL-C (1.4 to 1.7 mmol/L (54 to 66 mg/dL)]) Other: All participants were nonsmokers, used minimal alcohol, mean 21.9 BMI.	Baseline diet (3 weeks), followed by 3 week diet intervention which was followed by 3 week return to baseline diet. No eggs consumed on baseline diets. Dietary intervention included addition of three eggs (yolks)/day or addition of 750 mg extra dietary cholesterol. Energy intake was not measured during intervention. Body weights unchanged during the study.	There were no significant differences between males and females either during intervention or switchback. Three week of cholesterol enriched diet induced significant increase in total and LDL-cholesterol, and apo B concentration in all 4 phenotypes. In all phenotype groups, HDL-cholesterol increased with dietary cholesterol consumption. All lipid classes returned to original concentrations after switchback. The response in blood LDL-cholesterol and apo B to the cholesterol rich diet was greater in apo E4/4 subjects. The above statements on response to dietary cholesterol are the authors and supported by figures of the data in the paper.	Insufficient dietary data provided to evaluate study accurately. Did not record saturated fat and cholesterol contents in the baseline and intervention diets. Stronger responses by apo E4/4 phenotypes, suggests these individuals are more sensitive to dietary cholesterol (increased two-fold over other phenotypes). In Finland about 6% of the population is of the apo E4/4 phenotype.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Tremblay, A. et al (Ref. 217)	Diet and exercise intervention study in free-living subject. Individual recorded dietary records for 1 day /week throughout study. Meet once per week with dietitian and exercise specialist. Purpose: to determine the effect of a low fat diet and exercise on metabolic profiles (including blood lipids) in obese women. Study site: Canada	Four obese women, average age 42 years. On an average body weight was 92 kg, and % body fat 49. Baseline blood lipids (mg/dL): TC 214 LDL 157 HDL 38 TG 126	29-month study which included two experimental periods (period one (15 months) involved supervised aerobic exercise and the second period involved exercise plus low fat diet). The dietary intervention by instruction was to maintain protein (0.9 g/kg body weigh) and carbohydrate intake but to reduce lipid consumption to 26 to 28% of total calories (no indication of what baseline macronutrient intake was).	Lipid intake in period 1 and 2 was 29 and 30% of total calories. A significant decrease in body weight, fat mass and percent body fat occurred in period 1. Substantial reductions in plasma cholesterol (from 214 down to 174 mg/dL) and LDL-cholesterol (157 down to 116 mg/dL) were observed in period 1 and 2. Plasma HDL-cholesterol was not changed (38 compared to 40 mg/dL) but apo A-1 (HDL) was significantly increased by exercise (105 compared to 122 mg/dL).	At end of 29 months subjects lost 11 kg (but were still obese). Plasma glucose and insulin response to oral glucose similar to nonobese subjects. Interventions appeared to normalize level of risk for diabetes which is also a risk factor for CHD. Results (med) suggested that long-term exercise program can reduce plasma total and LDL-cholesterol levels in obese subjects.
Bonanome, A. et al (Ref. 219)	A randomised, cross-over design, dietary intervention study in free-living subjects. Purpose: To compare the effects of MUFA and PUFA on blood lipids and the susceptibility of LDL-cholesterol to oxidation. Study site: Pauda Italy.	Eleven healthy males, mean age 22 years, body weight 76 kg and body mass index of 25. Blood lipid profile of subjects: blood cholesterol (4.60 mmol/L or 181 mg/dL); LDL-cholesterol of 3.2 mmol/L or 125 mg/dL and HDL-cholesterol of 1.1 mmol/L or 44 mg/dL..	Two solid food diets with each diet lasting 3 weeks separated by washout period of 7 days. Phase 1 was enriched in MUFA and phase 2 was enriched in PUFA. Dietary composition (% of total calories) MUFA PUFA Fat(45%) SFA 10 10 MUFA 30 5 PUFA 5 30 chol <200 <200 (mg/day) Grapeseed oil supplied most of PUFA in diet. Olive oil supplied most of MUFA in diet. Other: susceptibility to oxidative modification was measure in 2, 2'azobis (2-aminopropane) dihydro-chloride (AAPH). AAPH is a water-soluble diazo compound that generates free radicals by spontaneous thermal decomposition.	Both diets significantly lowered total and LDL-cholesterol. Blood lipid data mmol/L (mg/dL) Baseline MUFA PUFA TC 4.7(181) 3.8(148) 3.5(136) LDL 3.2(125) 2.6(100) 2.3 (90) HDL 1.1(44) 1.0 (40) 0.98(38) TG 1.1 0.8 0.7 Other: The peroxidation rate was significantly higher when patients were on PUFA diet compared to MUFA diet. No significant differences were observed for inhibition of peroxidation by either diet.	Replacement of calories from SFA by either MUFA or PUFA induced a significant hypocholesterolemic effect. In addition, the results of the study support the hypothesis that diets rich in MUFA increase resistance of LDL-cholesterol to oxidative modification, independent of their content of antioxidants. Changes in peroxidation rate suggest that once LDL-cholesterol is depleted of antioxidant content, a diet enriched in MUFA may allow LDL-cholestgrol to resist oxidative stress. Ratio of oleic to linoleic in LDL was inversely correlated with the peroxidation rate.

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Zimetbaum, P. et al (Ref. 218)	Epidemiological, prospective study. Purpose: to access the correlation of lipid and lipoproteins levels on CVD risk, stroke, dementia, and death in the elderly. Study site: New York, (10-year follow-up of the Bronx Aging Study (BAS))	Mean age of entry into BAS study was 79 years, who did not have any diagnosed terminal illness or dementia. From BAS enrollment of 488, 350 had two lipid determinations at 10 years. Subjects had about a 7 to 9 th grade education, 60% were men and 25% of women were smokers, 49% of subjects took diuretics.	Extensive medical and psychosocial histories taken, laboratory screening, neurological and neuropsychiatric testing. CVD included MI, stroke and other heart related deaths. All events verified by reviewing medical records and/or death certificates.	Mean blood lipid values: (mg/dL) Total Men Women chol 207 234 LDL-C 140 158 HDL-C 38 46 Proportional hazards analysis showed that men with consistently low HDL-cholesterol levels (<30 mg/dL) were independently associated with the development of MI, CVD and /or death. For women, elevated LDL-cholesterol (>171 mg/dL) was associated with MI.	Using both univariant and multivariant analysis, only a consistently low HDL-cholesterol was significantly and independently associated with MI or all cause mortality in elderly men even after controlling for smoking and hypertension. For elderly women only a consistently elevated LDL-cholesterol was associated with MI. No significant associations between lipids and dementia were observed for either men or women. These results are in contrast to Framingham report which reported that baseline low HDL-cholesterol levels was associated with increased risk of MI and or death in both elderly and middle aged men and women. Elevated total cholesterol was not found to be an independent risk factor for MI or death.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N–0097]

RIN 0905–AD08

Food Labeling: Health Claims and Label Statements: Dietary Fat and Cancer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is authorizing the use on the labels and labeling of certain foods of health claims relating to an association between dietary fat and cancer. This final rule is issued under provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and was developed in accordance with the final rule on general requirements for health claims, which is published elsewhere in this issue of the **Federal Register**. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets low in fat may reduce the risk of some cancers. Therefore, FDA has concluded that claims on certain foods relating fat reduction to reduced risk of cancer are justified.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Helen HsiChong Lee, Center for Food Safety and Applied Nutrition (HFS–226), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5558.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60764), FDA proposed to authorize the use on food labeling of health claims relating diets low in fat to reduced risk of some types of cancer, particularly breast, colon, and prostate, in the general population (hereafter referred to as the lipids/cancer proposal). The lipids/cancer proposal was issued under provisions of the 1990 amendments (Pub. L. 101–535) that bear on health claims and in accordance with the proposed general requirements for health claims for foods (November 27, 1991, 56 FR 60537). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or 343(r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or 403(r)(5)(D) of the act. The relationship between lipids and cancer is one of the claims required to be evaluated. In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on lipids and cancer and were included in the lipids/cancer proposal. Comments received in response to the notice and not specifically addressed in the lipids/cancer proposal are summarized and addressed below.

In addition to evaluating the scientific evidence, the lipids/cancer proposal identified qualifying and disqualifying nutrient levels for foods bearing health claims on fat and cancer. The lipids/cancer proposal also specified mandatory and optional information for health claim statements and provided sample messages. FDA requested written comments in response to its proposed rule. In addition, FDA held public hearings on January 30 and January 31, 1992, on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for lipids and cancer.

II. Summary of Comments and the Agency's Responses

In response to its proposed health claim regulation on lipids and cancer, the agency received approximately 80 letters, each containing one or more comments, from consumers, consumer groups, health care professionals, professional organizations, State and local governments, a foreign government, trade associations, and industry. A number of comments received on this proposed rule were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

A. Validity Issues

1. Many comments addressed the basic issue of whether FDA should permit any health claims about total fat and/or any particular type of fat and cancer on food labeling. Several comments objected to the lipids/cancer claim and suggested that results from epidemiologic studies are often inconclusive and do not provide the information necessary to identify the type of fat that is responsible for cancer. Some comments felt that claims about saturated fat and cancer, but not about total fat and cancer, may be justified, but did not provide any data to document this conclusion. Other comments noted that results from animal studies suggest that dietary lipids do not affect noncarcinogen-induced tumorigenesis. Some comments suggested that animal studies reported conflicting results on the relationship between dietary lipids and cancer. Other comments expressed concern that rodent studies were extrapolated to humans without considering species differences.

Conversely, there was widespread support from organizations of nutritionists, organizations of health professionals, scientific societies, consumers, and food manufacturers for the agency's proposed rule. Most of these comments took the position that there was adequate scientific evidence to support claims about total fat and cancer, and concurred that these claims should be permitted. Some of these comments stressed that the recommendations from Federal government agencies and other authoritative scientific organizations, which concluded that diets high in fat increase the risk of cancer, are widely accepted in the scientific community.

FDA agrees that the totality of scientific evidence provides considerable support for a claim about the relationship between high intakes of dietary fat and increased risk of some cancers and that the conclusions and recommendations reached in a number of Federal government and other authoritative documents about this relationship demonstrate the existence of significant scientific agreement among experts qualified by experience and training to evaluate such evidence. In developing its proposed regulation, FDA has reviewed Federal government reports and other review documents as well as recent research articles relevant to dietary lipids and cancer risk. Authoritative documents consistently and independently conclude that dietary fat contributes to the risk of some cancers. Among human studies, results of international correlational studies consistently and strongly show that dietary fat may play a role in cancer. Also, the independent review by the Life Sciences Research Office (LSRO) concurred with FDA's conclusion that high fat intake increases

the risk of developing cancers. Furthermore, as discussed in section III of this preamble, new studies that became available for review after the publication of the lipids/cancer proposal are consistent with the agency's conclusion that high fat intake is associated with increased risk of some cancers.

FDA considers it appropriate to permit health claims about fat and cancer without identification of the type of fat that is responsible for the cancer. As the agency explained in the preamble of the proposal (56 FR 60764 at 60773), the available scientific evidence is inconclusive in linking a specific type of fat to cancer risk. As presented in the proposal, some evidence has been found in both human studies and animal studies that all three types of fat (saturated, monounsaturated, and polyunsaturated) may be associated with the risk of some types of cancer. Because it was not possible to clearly identify a particular type of fat or fatty acid, and because several types of fatty acids have been implicated in cancer risk, the agency based its claim on the total fat content of the diet, rather than on any specific type of fat or fatty acid. Further, as explained in section III of this preamble, the evidence from new animal studies generally supports the conclusion drawn in the proposal that total dietary fat is associated with the risk of cancer. Of course, if more conclusive evidence becomes available about specific roles of different types of fat, any interested person may submit a petition under the provisions of new § 101.71 to revise the regulation on identification of the specific types of fat that affect cancer risk, or FDA may itself initiate action to revise the regulation.

The agency does not consider the absence of evidence from noncarcinogen-induced tumorigeneses in animal studies to be a major flaw in determining the adequacy of the scientific evidence to support a relationship between dietary fat and cancer. The data, which indicate that fats cannot initiate tumorigenesis (tumor growth), do not call into question the validity of FDA's evaluation of animal studies. The current understanding of the process of tumorigenesis involves a two stage model: initiation of the carcinogenic process, followed by promotion of tumor growth. During initiation, a normal cell is altered to become a latent cancer cell. This is presumably accomplished when a carcinogen interacts with and subsequently alters the genetic apparatus of the cell. During tumor promotion, the altered genes are expressed to make new cells, a process leading ultimately to autonomous cell growth that is no longer responsive to normal physiologic growth regulatory signals. As FDA explained in the preamble of the lipids/cancer proposal, current knowledge about tumor growth shows that dietary fat affects the promotional stage, not the initiation stage, of carcinogenesis (56 FR 60764 at 60768). Substances affecting the promotional stage of carcinogenesis are appropriate subjects of health claims because, in the promotion stage, the ultimate development of cancer that cannot be controlled by the body is still in question. Thus, risk of cancer may still be reduced in the promotion stage.

As described in the lipids/cancer proposal, FDA agrees that extrapolation of the data from animal studies to humans is limited by differences in metabolism and physiology between species. However, experiments in different animal species permit more intensive observation under controlled experimental conditions. The agency believes that a careful evaluation of animal studies provides useful information and can provide valuable insight into mechanisms involved and specificity of fat versus other nutrients. Thus, the agency critically evaluated animal studies using the evaluation criteria found in the lipids/cancer proposal (56 FR 60764 at 60767). Furthermore, the rodents, which are used in most of the studies reviewed, have digestive and/or metabolic systems that are similar to humans and have been widely used in cancer studies. The agency did not include studies that utilized cell culture techniques because cells can be genetically transformed during the in vitro culture phase, thus generating data that are substantially different from findings in human physiology.

B. Cancer Sites

2. Although most comments took the position that claims about total fat and cancer should be permitted, a number of comments expressed differing opinions about whether claims should specifically address the types of cancer affected by a diet that is low in total fat. Several comments supported the agency's proposed § 101.73(b)(1)(iii) (56 FR 60764 at 60779) to restrict claims to cancer of the breast, colon, and prostate. One explained that, without some identification of affected cancers, the claims may be misinterpreted as meaning that all types of cancer are affected. The comment suggested that FDA require the phrase, "particularly colon, breast, and prostate cancer" in the health claim.

On the other hand, several comments suggested that FDA exclude the designation of specific cancer for the sake of simplicity or because of the inconclusiveness of the relevant scientific evidence. Some comments stated that the magnitude of the association between dietary fat and the risk of various cancers such as breast cancer, colon cancer, and prostate cancer varies so widely that it is misleading to presume that strong evidence supports each site. The comments asserted that claims should therefore not be site-specific.

FDA has reconsidered the issue of requiring claims to identify the specific sites of cancer that may be affected by total fat content in the daily diet. The agency no longer believes that the current state of the scientific evidence on this issue justifies such specific identification. As is fully discussed in the preamble of the lipids/cancer proposal (56 FR 60764 at 60772 and 60773), when FDA proposed such identification, the agency did so because an international correlation study found an association between fat intake and cancer of the breast, colon, and prostate, but not of cervical or lung (Ref. 38). The agency, therefore, concluded that the effect of fat on cancer may be site-specific. In view of the lack of evidence for other types of cancer, the agency believed health claims would not be justified unless the claims pertained only to cancer of the breast, colon, and prostate.

However, additional studies that were not available for review at the time of the lipids/cancer proposal contain further evidence that cancers of additional sites may also be affected by dietary fat intake. Further, the evidence for an association of an increased risk of breast cancer with dietary lipids appears not to be as strong as previously thought from the findings in many case-control and cohort studies (See section III of this document). Thus, FDA now concludes that the identification of specific sites of affected cancers is no longer as appropriate as FDA believed when it issued the proposal. In view of the weaker data on breast cancer and the possibility of a wider variety of affected sites, and taking into account comments received, FDA believes that health claims should not be permitted to refer to specific cancer sites. At the same time, the agency feels that it would be misleading to imply that risk of all cancers may benefit from low fat diets. Accordingly, FDA has included a provision in § 101.73(c)(2)(B) of the rule set forth below requiring that health claims use the terms "some types of cancer" or "some cancers" in specifying

the disease. All provisions in the rule addressing specific sites of cancer have also been revised accordingly.

FDA points out that the lack of consistency of more recent studies with earlier studies concerning the relationship between breast cancer and fat intakes does not bring into question the more general validity of conclusions pertaining to dietary fat intake and cancer that were discussed in the agency's response to the previous comment. The absence of clear evidence of a strong association between fat and breast cancer in many case-control studies may be due to the dietary homogeneity of the population studied. International correlation studies, which have the greatest variability in dietary fat intakes among the populations examined, have consistently found an association. But correlational studies cannot control for important confounding factors, such as family history of cancer and reproductive history, which may also explain the correlations found between fat intake and cancer mortality in these studies.

C. Advisability of Permitting Claims

3. Some comments asserted that, regardless of whether claims about total fat and cancer may be valid, such claims should not be permitted because of safety considerations. A number of comments maintained that health claims about total fat may increase the risk of heart disease from reduced intakes of certain nutrients (i.e., essential fatty acids and fat soluble vitamins). One of the comments stated that the polyunsaturated and monounsaturated fats in vegetable oils have well-documented advantages, particularly in beneficially affecting the ratio of blood total cholesterol to HDL-cholesterol (i.e., raising the level of HDL-cholesterol relative to total cholesterol levels). The comment also pointed out that vegetable fats are the primary source of vitamin E in U.S. diets, and asserted that half of the U.S. population is below the recommended level of consumption of this vitamin. The comment stated that there is emerging evidence for a protective role of vitamin E in cardiovascular and other important diseases.

The agency does not foresee that a health claim relating diets low in fat to reduced risk of cancer will increase the risk of coronary heart disease because of reductions in HDL cholesterol. Under the provision of 1990 amendments, FDA evaluated scientific evidence on the relationships between dietary fat intakes and the development of two chronic diseases, cancer, and cardiovascular disease, separately. FDA's evaluation of the lipids/cardiovascular disease relationship is found in a companion document elsewhere in this issue of **Federal Register**. In that document, FDA is requiring that foods bearing a saturated fat and cholesterol/heart disease claim be "low in fat" in addition to being low in saturated fat and cholesterol. All current dietary guidelines from the Federal government and other authoritative reports include recommendations for diets low in fat when dealing with diet and heart disease relationships. Diets containing 30 percent or less of calories from total fat are deemed helpful in reducing the risk of heart disease because they facilitate meeting dietary goals for saturated fat and cholesterol. Furthermore, these diets are useful in maintaining moderate calorie intakes and desirable body weights. None of the authoritative reports or guidelines have noted concerns or evidence for inadvertent safety problems if Americans were to follow general dietary guidelines for reducing fat intakes to 30 percent of calories or less. Admittedly, diets very low in fat may pose a risk. However, given current fat intakes in the U.S. population of approximately, on average 37 percent of calories from fat, and given the difficulty in lowering this level significantly within the context of dietary patterns in the United States, FDA has concluded that it is highly unlikely that the U.S. population will be able or motivated to lower total fat intakes to levels low enough to have adverse health effects. Indeed, reductions in total fat intakes, consistent with dietary guidelines, are likely to have a beneficial effect on blood HDL-to total-cholesterol ratios.

With respect to assertions that the lipids/cancer health claims will adversely affect the nutritional status of vitamin E or essential fatty acids or will have a negative impact on coronary heart disease because of decreased vitamin E consumption, FDA does not foresee that the lipids/cancer health claim will adversely affect the status of essential fatty acids and vitamin E. Deficiencies of essential fatty acids and vitamin E are very rare in the United States at this time. Furthermore, there is extensive epidemiologic evidence that low fat diets providing fat at 30 percent of calories or less are consumed by many population groups without apparent adverse effects (Ref. 141). Current dietary guidelines, which target no more than 30 percent of calories from fat to reduce coronary heart disease and cancer risks, are generally regarded as practical in controlling fat, saturated fat, cholesterol, and calorie intakes, and yet as more than adequate for providing adequate intakes of essential fatty acids, for facilitating absorption of fat-soluble vitamins, and for maintaining growth and development in children and adolescents 2 years of age and older (Ref. 141). Furthermore, the recommended approach to reducing intake of total fat is to increase consumption of vegetables, fruits, and whole grain products, choose lean meats, fish, and poultry, and low fat dairy products, and use fats and oils sparingly. These diets generally are not only low in fat, saturated fat, cholesterol, and calories, but also tend to be high in vitamins (including vitamin E and provitamin A). Additionally, essential fatty acid requirements can be adequately met with only about 1 percent to 5 percent of calories from fat, an intake level well below the recommended levels, and not practical to achieve in the United States. Thus, FDA sees little, if any possibility, that consumption of diets consistent with current dietary guidelines for fat intake will result in significant reductions in intakes of essential fatty acids or fat-soluble vitamins. Consequently, an adverse effect on risk of coronary heart disease is unlikely. Furthermore, scientific evidence is not clear, as yet, regarding the postulated, protective role of vitamin E in preventing the autoxidation of polyunsaturated fatty acids, a possible risk factor for heart disease.

4. A comment stated that the lipids/cancer claim ignores the positive role of fats in a healthy diet.

FDA agrees with the comment that dietary fats have important functions in foods and as a source of essential fatty acids and other nutrients. In the proposed rule, FDA acknowledged the physiologic functions of dietary fats. As described above, the agency foresees beneficial effects of reducing fat intakes relative to cancer risk, but does not foresee that nutritional deficiencies or harmful effects to health will occur. The agency does not consider it necessary to include statements in the health message as to the beneficial role of fats. The purpose of health claims is to provide useful information to consumers on nutrient/disease relationships. However, as noted in the final rule on general principles for health claims published elsewhere in this **Federal Register**, certain statements, including general statements about the role of nutrients in maintenance of good health, are considered to be dietary guidance outside the scope of the 1990 amendments. These types of dietary

guidance would be permitted as long as the information contained in them is truthful and not misleading.

D. Other Issues

5. A few comments stated that the proposed rule focuses only on fat and does not require that claims discuss other dietary components (e.g., complex carbohydrates or dietary fiber). These comments asserted that such a narrow focus is misleading and would not serve to educate the public about the broad issue of diet and cancer. The comments emphasized that health claims should be presented in the context of a total diet.

FDA agrees that health claims should be presented in a manner that enables the public to comprehend the relative significance of the claim in the context of the total daily diet. In fact, section 403(r)(3)(B)(iii) of the act specifically requires that a regulation that authorizes a claim require that the claim be stated in such a manner.

However, a review of the relationships of other dietary factors and cancer risk (apart from antioxidant vitamins and dietary fiber, which are discussed in final rules published elsewhere in this issue of **Federal Register**), is beyond the scope of the Congressional mandate. Thus, FDA does not agree that the lipids/cancer claim must specifically address the significance of other nutrients such as complex carbohydrates, dietary fiber, saturated fat, or cholesterol in relation to cancer risk. However, any interested party may petition the agency, in accordance with criteria described in the final rule on general requirements for health claims published elsewhere in this **Federal Register**, for additional nutrient/cancer claims to be authorized. As proposed, the fat/cancer health claim must include a statement that the development of cancer depends on many factors. This information is essential for understanding the context of the nutrient/disease relationship.

6. A few comments urged FDA to require health claims to advise that reductions in fat intake to less than 30 percent of total calories may be needed to reduce the risk of cancer. The comment argued that such information is needed because consumers may otherwise believe they are making meaningful reductions in fat intake when that is not the case. This comment pointed to FDA's observation in the proposal (56 FR 60764 at 60773) that studies with small differences in fat intakes among test groups (from 32 to 37 percent of total calories) failed to find a significant reduction in cancer risk.

FDA does not agree that it would be appropriate to require this information in the lipids/cancer health claim. This information would unduly add to the length and complexity of the health claim. However, FDA concurs that this information could be very useful to consumers. Thus FDA has provided for optional use of this type of information as part of a health claim, because it is contained in the significance statement of the final rule (new § 101.73(b)), and information from this section of the rule is permitted to be used on the label (new § 101.73(d)(1)).

7. In its proposed rule, the agency requested comments on whether a food that qualifies for a "reduced fat" or other comparative claim should be permitted to bear a health claim relating dietary lipids and cancer. Several comments supported FDA's proposal that foods must be "low fat" or "fat free" in order to carry this health claim. However, some comments objected to FDA's definition of "low fat." In addition to comments specifically addressing the proposed "low fat" or "fat free" requirement, FDA received a large number of similar comments on the "low fat" requirement that appeared in the general requirements for health claims, proposal (56 FR 60537).

FDA advises that the final rule is retaining the "low fat" qualifying criterion for health claims concerning fat and cancer. ("Fat free" foods necessarily meet the definition of "low fat;" therefore, to avoid redundancy, the agency is requiring only that a food meet the "low fat" definition.) Because the issue of "low" qualifying requirements is of a general nature (e.g., this criterion also pertains to the fat and heart disease health claim), most of the comments on this issue were filed in the docket of the proposal on general requirements for health claims. FDA has responded to all comments about this issue in the preamble of the final rule on general requirements for health claims, which appears elsewhere in this issue of the **Federal Register**. Discussions of FDA's definition of "low fat" are published elsewhere in this issue of the **Federal Register** in the final rule on requirements for nutrient content claims.

8. A few comments requested that FDA develop identical criteria for health claims on lipids and cancer and on lipids and cardiovascular disease, because the proposed criteria for these two topics are similar but not totally consistent, and any differences may be confusing to consumers. The comments further suggested that total fat be used as the "common denominator" because "consumers who reduce total fat intake are likely to be concurrently reducing saturated fat intake as well as cholesterol, even if not making a conscious attempt at either."

The agency will allow manufacturers to formulate their own claim combining the fat and cancer and the saturated fat/cholesterol and heart disease claim if the food meets the criteria for both claims. However, at this time, it is not appropriate to set identical requirements for health claims for dietary fat and cancer and for dietary saturated fat and cholesterol and risk of heart disease, because the two diseases differ in the nature of their relationship to dietary fat components. Current evidence demonstrates that it is total fat, rather than individual fat components, that is associated with an increased risk of cancer. However, there is a substantial body of evidence that demonstrates that high levels of saturated fat and cholesterol, rather than total fat, are associated with an increased risk of cardiovascular disease. For this reason, FDA has decided to maintain separate criteria for the fat/cancer and the saturated fat and cholesterol/heart disease health claims.

9. Several comments stated that the lipids/cancer health claim should identify energy intake as an independent factor for cancer rather than reduced fat intake, because energy excess, not fat, is the factor that increases risk of carcinogenesis. Another comment stated that, if fat has an independent effect on carcinogenesis, the need to reduce fat intake becomes more important, because by reduction of fat intake, reductions in intakes of energy and fat could be efficiently achieved.

FDA agrees that the scientific evidence on the association between dietary lipids and cancer includes studies that demonstrate that total energy intake may be an independent risk factor for cancer (Refs. 11, 17, and 23). However, the 1990 amendments instructed the agency to determine whether claims respecting dietary lipids and cancer, not energy intake and calories, meet the requirements of section 403(r)(3) of the act. The agency found that, currently, there is adequate evidence from animal studies and from human studies that total fat is a risk factor for some cancers, independent of the effect of total calories. Furthermore, decreasing the fat content of the diet appears to be a practical approach to reducing energy intakes and maintaining desirable body weights. However, if a health claim regarding energy intake and cancer is desired, such a claim can be handled by the petition process set forth in the general

requirements for health claims final rule published elsewhere in this issue of the Federal Register.

10. One comment suggested that FDA exclude omega-3 fatty acids from the calculation of total fat for deciding whether a food is "low fat" relative to cancer risk, because the effect of omega-3 fatty acids may be neutral or, even, tumor-suppressing.

The agency does not agree that the scientific evidence is adequate to establish that omega-3 fatty acids are neutral with respect to cancer risk. Most animal studies, although concluding that a diet high in fish oil suppresses tumorigenesis, have methodologic problems which make it difficult to extrapolate results to humans. Specifically, the diets used in most of these studies provided insufficient amounts of the essential fatty acid, linoleic acid, to support optimal tumor growth. Therefore, it is not possible to determine whether the observed tumor-suppression by the fish oil diets was caused by an insufficiency of essential fatty acids (linoleic acid) to support tumor growth, or by a direct inhibitory effect of the omega-3 fatty acids contained in the fish oils. FDA is, therefore, not persuaded to exclude omega-3 fatty acids from the calculation of total fat for deciding whether a food is "low fat" with regard to cancer risk.

However, interested persons who believe there is adequate scientific evidence to support a beneficial relationship between omega-3 fatty acids and cancer risk, may use the petition process described in the final rule on general requirements for health claims, published elsewhere in this Federal Register.

11. A number of comments on the general requirements proposal for health claims (56 FR 60537) suggested that FDA revise provisions of all health claims rules to be more understandable.

The agency agrees that all health claims rules should be made more understandable wherever practicable. FDA has, therefore, made a variety of nonsubstantive revisions of provisions of the regulations set forth below for clarity. For example, provisions have been grouped into general and specific requirements. The general requirements reference other regulations containing nutrition labeling requirements. The specific requirements are separated into requirements pertaining to the food and those pertaining to the claim. The model health claims have been simplified. The regulation has also been modified to permit fish and game meats that meet the requirements for "extra lean" in § 101.62 to bear the health claim. This change is in response to comments on the proposed fat and cardiovascular disease health claim, and will make both final rules consistent with each other. "Extra lean" fish and meats can play an important role in a low fat diet. Consistent with other health claims regulations, this regulation also permits the claim to indicate the prevalence of cancer in the United States.

12. A comment suggested that the final rule include a requirement that, in order to qualify for the lipids/cancer health claim, a food must contain a minimum amount of dietary fiber, because fiber intake is another dietary risk factor for cancer.

The agency disagrees that dietary fiber should be required to be included in a fat/cancer health claim, but does agree that diets rich in foods containing dietary fiber and many other nutrients are associated with reduced cancer risk. Dietary components that have been implicated in cancer development include fat, antioxidant vitamins, and fibers. Among these dietary components, fat intake has been reported as the most strongly associated component. Under the 1990 amendments, FDA evaluated scientific evidence on three separate health claim topics relevant to cancer: Fat and cancer, antioxidant vitamins and cancer, and fiber and cancer. Of these three topics, FDA has concluded that there is significant agreement about the relationship between fat and cancer. FDA's evaluation and decision about the other two health claims (published elsewhere in this issue of Federal Register) is that diets rich in fruits, vegetables and grain products, which are generally low in fat and high in dietary fiber and vitamins A and C, are associated with reduced cancer risk. However, the agency did not find the evidence sufficient to attribute this relationship to a specific nutrient contained in plant foods. Furthermore, the agency's review of scientific evidence found that almost all animal studies of fat and cancer employed defined experimental diets containing the same amounts of vitamins and fibers. Animal studies on the association of dietary fat with cancer development provide substantial support for the conclusion that the effect of fat intake on cancer development is independent of the effects of fiber and antioxidant vitamins. Therefore, the agency is not persuaded to add fiber content as a required qualifying criterion for the fat and cancer claim.

III. Review of New Scientific Evidence

In addition to its evaluation of the comments, FDA has evaluated the scientific literature that has become publicly available since the issuance of the proposal. The following represents a summary of the agency's evaluation of this literature.

A. Human Studies

1. Studies Submitted as/with Comments

No new human studies that meet the criteria for selecting articles to review, which are described in the lipids/cancer proposal, were submitted with comments.

2. Update of the Scientific Literature

Studies that became available after publication of the lipids/cancer proposal are discussed below and described in Table 1.

A new correlational study on cancers of the colon, rectum, prostate, and breast was reviewed (Ref. 92). Incidence rates for these cancers and food consumption data were compared among Chinese in Shanghai, Chinese Americans in San Francisco, and Americans in Connecticut. The study demonstrated that the incidence rates for the four types of cancer were much higher among Americans and Chinese Americans than for Shanghai Chinese and that the Americans and Chinese Americans consumed much more meat and milk products than the Shanghai Chinese. The authors interpreted the results of the study to demonstrate that low fat diets were associated with the lower incidence rates of the four types of cancer found among the Shanghai Chinese. However, because the design of this study allowed correlations to be made only between a population's cancer incidence rates and its per capita food consumption, rather than studying individuals who actually have cancer, inferences cannot be made about the causal nature of diet on risk of cancer. The study was unable to control for important risk factors for these cancers, such as lifestyle factors, family history, reproductive and endocrine factors, total energy intake, and differences in body weight.

A new correlational study that compared dairy fat and lard intake data from 36 countries with cause-specific cancer mortality rates was also reviewed (Ref. 93). World Health Organization (WHO) mortality statistics for 1985–1987 were correlated with intake data obtained from 1979–1981 Food and Agricultural Organization (FAO) food balance sheets. FAO's food balance sheets are approximations of actual consumption and are not separated by age and sex. The authors were able to adjust for total caloric intake but were not able to adjust for potential confounding factors, such as smoking

and family history. The study demonstrated highly significant correlations between intakes of dairy fat or lard fat and mortality from all causes, total cancer, and colon and rectal cancer among both men and women and from lung cancer and prostate cancer for men and breast cancer for women.

a. *Pancreatic cancer.* The agency reviewed two new case-control studies on diet and pancreatic cancer, which were published in 1991 (see Table 1). One study conducted in Poland (Ref. 94) demonstrated no association between risk of pancreatic cancer and total dietary fat or saturated fat. The highest intake of dietary cholesterol measured in the study was associated with a statistically significant relative risk (the incidence of cancer of the exposed group/the incidence of cancer of the unexposed group) of 4.3 for pancreatic cancer. However, the highest intakes of monounsaturated fatty acids and of polyunsaturated fatty acids were associated with statistically significant decreased risks (see Table 1). The second case-control study, which was conducted in the Netherlands, did not analyze for total dietary fat or for saturated fat (Ref. 95). Consumption of eggs was associated with a statistically significant increased risk and daily consumption of vegetables showed a protective effect in this study.

b. *Bladder cancer.* One case-control study on bladder cancer conducted in Spain was reviewed (Ref. 96 and Table 1). An increased risk of bladder cancer was found with dietary saturated fat but not with total fat. The results of this study may be biased by the inclusion of 208 prevalent cases of bladder cancer, approximately half of the cancer cases. Case-control studies usually select incident cases of cancer for participation, which are new cases, i.e., those not previously diagnosed. Prevalent cases are patients who have survived the disease for at least some amount of time and are generally not included in case-control studies of cancer because the traits contributing to their survival may modify potential risk factors of the disease.

c. *Lung cancer.* A prospective cohort study on lung cancer published in 1991 was reviewed (Ref. 97 and Table 1). The cohort consisted of 1,878 men employed by the Western Electric Company in Chicago. The men were 40 to 55 years old in 1958 when enrolled in the study and were followed for 24 years. Dietary information was collected in 1958 and in 1959 when all the men were clinically free of cancer. After adjusting the results for smoking and percent of calories from fat, an increment of dietary cholesterol of 500 mg per day was associated with a relative risk of lung cancer of 1.9.

d. *Breast cancer.* Five new case-control studies on diet and breast cancer were reviewed (see Table 1). One study that examined only postmenopausal breast cancer found no association with dietary fat (Ref. 99). However, the study suffered from low participation rates among both the cases and controls, which prohibits generalization of the study results to the total population.

A case-control study of both premenopausal and postmenopausal breast cancer among Singapore Chinese showed no effect of diet on postmenopausal women (Ref. 100). No effect on breast cancer risk for premenopausal women was found for total fat, for saturated fat, for monounsaturated fatty acids or for cholesterol; polyunsaturated fatty acids demonstrated a protective effect. The median level of dietary total fat consumed on a daily basis was 33 grams (g) for cases and 34 g for controls; total fat intake ranged from 26 g to 41 g in this study. The authors did not adjust the results for total calories.

A French case-control study found limited evidence that fat is associated with breast cancer risk when the results were analyzed by menopausal status (Ref. 101). However, for all women analyzed together regardless of menopausal status, total fat was associated with a relative risk of 1.6, saturated fat was associated with a relative risk of 1.9 and monounsaturated fatty acids were associated with a relative risk of 1.7. Polyunsaturated fatty acids were not associated with risk of breast cancer. The results were not adjusted for total calories; thus, the increased risk associated with the fats may actually be due to a higher caloric intake by the cancer cases. Several food items were associated with an increased risk of breast cancer among all women, including high fat cheese, fruits rich in beta-carotene, and desserts and chocolate.

A case-control study conducted in Moscow found that dietary fat was not associated with risk of breast cancer in either premenopausal or postmenopausal women (Ref. 102). Gram levels of daily total fat intake were not provided. Several nutrients were associated with a protective effect, including polyunsaturated fatty acids, beta-carotene, vitamin C, calcium, and cellulose. Risks associated with food items were not examined in this study.

A large case-control study conducted in Italy examined the risk of breast cancer associated with fat intake from seasonings (Ref. 103). A moderate association was found for total fat seasonings and for butter and oil, but no association was found for margarine. The results were not adjusted for total calories and very limited dietary information was collected.

e. *Colorectal cancer.* Three new studies on colorectal cancer were reviewed (see Table 1). The most informative study of the three was conducted in Majorca (Ref. 104). An increased risk of colorectal cancer was found to be associated with total calories, and, after adjustment for total calories, an increased risk was also associated with cholesterol, protein, and carbohydrates (Ref. 104). A protective effect was demonstrated with fiber from legumes. Colorectal cancer risk was not found to be associated with high consumption of total dietary fats or saturated fats. However, this lack of association between colorectal cancer and dietary fat may be a result of the population's consumption of primarily monounsaturated fatty acids rather than animal fats.

f. *Prostate cancer.* Two additional case-control studies on the association between dietary factors and risk of prostate cancer were reviewed (Refs. 105 and 106 and Table 1). One study conducted in Spain from 1983 to 1987 found that risk of prostate cancer was increased by a diet rich in animal fats but not by a diet rich in vegetable fats (Ref. 105). Also, meat consumption was associated with increased risk, but different types of meat were not significantly linked to prostate cancer. The study did not adjust for total calories; however, the relative risks associated with animal fats and with meat consumption were large enough (see Table 1) that after adjustment for calories the relative risk estimate would most likely remain elevated.

A case-control study of prostate cancer conducted in Utah demonstrated that dietary factors were not associated with risk of prostate cancer among young men (aged 45 to 67 years) (Ref. 106). However, among men aged 68 to 74 years, risk was increased for total calories, and after adjustment for total calories, an increased risk was associated with total fat, protein, and also for monounsaturated fatty acids and polyunsaturated fatty acids. For both age groups, the baseline level of total fat intake was about or less than 66 g per day.

In addition to the studies in Table 1, several review articles on the relationship between dietary fat and cancer were published recently (Refs. 107, 108, 109, and 110). Two of these review articles stated that the evidence for a putative effect of dietary fat on breast cancer risk is based primarily on

international correlational studies, whereas case-control studies and cohort studies have found only weak associations or no association between dietary fat and breast cancer risk (Refs. 107 and 108). Kinlen (Ref. 107) suggests that the international correlations with fat may be a reflection of the effects of calorie restriction in poor countries or over-nutrition in affluent countries during the years of growth which directly influences known risk factors for breast cancer, such as age at menarche and body size.

A recent review on prostate cancer (Ref. 109) stated that, overall, the epidemiology studies on diet and prostate cancer implicate fat as the main dietary component associated with increased risk. Specifically, recent case-control studies are supportive of an association of fat to prostate cancer, whereas cohort studies have shown either an equivocal and no effect.

B. Animal studies

1. Studies Submitted as/with Comments

No new animal studies that meet the criteria for selecting articles to review, which is described in the lipids/cancer proposal, were submitted with comments.

2. Update of the Scientific Literature

FDA reviewed 22 new animal studies dealing with the relationship between dietary fat and cancer that were not available for review in the proposed rule (see Table 2). Dietary fat and mammary tumorigenesis was the subject of nine studies. The role of fat in colon tumorigenesis was evaluated in five studies, while the role of fat in tumorigenesis at pancreas, skin, or lymph were evaluated in two studies for each tumor site. Fat and leukemia or fat and liver tumor was the subject of one report for each tumor site.

a. *Role of total dietary fat.* Six mammary tumor studies examined the effects of total fat on tumorigenesis. Among these, three studies (Refs. 112, 113, and 114) reported a significant association of high dietary fat with the development of mammary tumors. For example, Kumaki and Noguchi (Ref. 112) measured the influence of high dietary fat on the malignant intensity and hormone receptors of 7,12-dimethylbenzanthracene (DMBA)-induced mammary tumor in female rats fed either a low fat (0.5 percent corn oil) or a high fat (20 percent corn oil) diet after DMBA administration. Tumor incidences in the high fat fed group were significantly higher than in the low fat fed group (86 percent versus 46 percent, respectively) and tumors were significantly larger in the high fat fed group than in the low fat fed group (13.9 millimeters (mm) versus 7.9 mm, respectively). In this study, the 0.5 percent corn oil diet provided inadequate linoleic acid (about 0.3 percent by weight) for growth of the mammary tumors. The deficiency of linoleic acid, rather than decreased total fat, could have reduced tumorigenesis.

Cohen et al. (Ref. 113) examined the effects of dietary fat and fiber in the N-nitrosomethylurea (NMU)-induced rat mammary tumor model. The number of tumor-bearing rats and the mean number of tumors per rat were significantly higher in rats fed a high fat diet (23.5 percent corn oil) than in those fed a low fat diet (5 percent corn oil). The latent period was also significantly prolonged in the low fat fed group. The diets used by Cohen et al. were not isocaloric and body weights were significantly lower in the 5 percent corn oil group from weeks 11 to 15 of the study. Therefore, the results could have been caused by differences in energy intake rather than fat per se.

Gonzalez et al. (Ref. 114) studied the effects of different amounts and types of fat on the growth of human breast carcinoma in athymic nude mice. They reported that a diet with 20 percent corn oil by weight significantly elevated the volume of transplanted mammary tumors (estrogen-dependent MDA–MB231 and nonestrogen-dependent MCF–7) in mice, compared to effects of a diet containing 5 percent corn oil. Diets used in this study were not isocaloric and the differential intakes among groups confound an attribution of the dietary fat to the results per se. The MDA–MB23 cell line was estrogen-dependent and estrogen provided in the drinking water and implanted pellets may have affected tumor growth in these groups.

Studies by Zhu et al. (Ref. 115), Aksoy et al. (Ref. 116), and Khoo et al. (Ref. 117) reported no association between dietary total fat and tumorigenesis in rodents. Zhu et al. (Ref. 115) measured the effect of total dietary fat and dietary energy restriction on growth of methylnitrosourea (MNU)-induced mammary tumorigenesis in female rats. When the diets were isocaloric (50 kilocalories (kcal) per day or 35 kcal per day), tumor yield (number or weight) was not different between the two diet groups (45 percent fat diet by energy and 25 percent fat diet by energy). In this study, diets differed in the provision of linoleic acid: The 25 percent fat diet provided about 1.7 percent linoleic acid by weight. This amount was most likely inadequate for tumor growth.

Aksoy et al. (Ref. 116) attempted to identify effects of different levels of dietary fat on MNU-induced rat mammary tumorigenesis. These authors reported no difference in the incidence, yield, or mortality among groups fed diets containing 12 percent, 25 percent, and 45 percent fat by energy. The 12 percent or the 25 percent fat diets (which provided about 0.7 percent or 1.9 percent linoleic acid by weight) may not have provided adequate linoleic acid for tumor growth. In this study, rats consumed the same amount of calories, and body weights were not different among groups even though the experimental diets were not isocaloric.

Khoo et al. (Ref. 117) tested the anticancer effect of dietary stearic acid. In this study, mammary tumors were induced by NMU and cultured in vitro. The cultured, tumor cells were implanted in the flank of rats. Rats were fed either a powdered control diet or a diet containing 20 percent stearic acid by weight. Feeding was continued for 5 weeks before and 25 days after tumor implantation. The stearic acid-supplemented diet did not affect the growth (size or weight) of the transplanted tumors. The adequacy of dietary linoleic acid for tumor growth in this study cannot be determined because the fatty acid composition in the diet was not reported.

Six new studies examined the effects of dietary fat on development of chemically-induced colon tumors in rodents. Two studies measured the effect of total fat (Refs. 118 and 119). Nicholson et al. (Ref. 118) measured the influence of dietary fat (beef suet, rich in saturated fats and corn oil, rich in linoleic acid) on colorectal tumorigenesis. Wistar rats were fed diets containing 5 percent or 20 percent fat (beef suet or corn oil) by weight. The 5 percent beef suet diet significantly reduced azoxymethane-induced colon adenocarcinoma compared to the 20 percent beef suet diet (12 carcinomas versus 28 carcinomas, respectively, in the 5 percent and 20 percent beef suet groups). The difference in tumor yield between the 5 percent corn oil and 20 percent corn oil diets was not statistically significant (1 carcinoma versus 2 carcinomas, respectively, between the 5 percent and 20 percent corn oil groups). The beef suet diets provided limited linoleic acid (0.6 percent to 1 percent).

Behling et al. (Ref. 119) measured the effects of varying levels of dietary calcium and butter fat on lipid utilization and development of colon tumors in dimethylhydrazine dihydrochloride (DMH)-initiated rats. These authors found no difference in

intestinal tumors in rats fed either a diet with 5 percent butter fat plus 1 percent corn oil or a diet with 20 percent butter fat plus 1 percent corn oil. The experimental diets provided limited linoleic acid (about 0.6 percent by weight), and this may have decreased the possibility of identifying effects of total dietary fat.

Hietanen et al. (Ref. 120) measured modulation by quantity and degree of saturation of dietary fat of oxidative stress and chemically-induced liver tumors in rats. These authors found a significantly increased incidence of liver tumors in rats fed a diet containing high levels of polyunsaturated fatty acids (PUFA; 25 percent sunflower seed oil by weight) compared to rats fed a diet containing low concentrations of polyunsaturated fatty acids (2 percent sunflower seed oil by weight). Tumor incidences were 80 percent versus 42 percent for groups fed 25 percent or 2 percent sunflower seed oil, respectively. The 2 percent PUFA diet in this study provided about 1.6 percent linoleic acid, which may not have been adequate for tumor growth. Body weight changes were not significantly different among groups, although diets were not isocaloric.

Smith et al. (Ref. 121) measured the effects of a high fat diet and a CCK-receptor antagonist on growth of a human pancreatic tumor cell line in nude mice. In this study, a high fat diet (20.3 percent fat by weight: 4.3 percent chow fat plus 16 percent corn oil) significantly increased tumor volume and protein content compared to values for tumors from mice fed a chow diet. Fatty acid composition of the chow diet was not reported. However, the chow diet may not have provided adequate linoleic acid for tumor growth, and a limitation of linoleic acid, rather than low total fat, could have reduced tumor growth.

Longnecker et al. (Ref. 122) studied the development of pancreatic neoplasms in elastase-1-simian virus transgenic mice. The authors reported no difference in incidence of tumor between groups of mice fed a 5 percent corn oil diet or a 20 percent corn oil diet. The applicability of the results of this study in genetically transformed mice to human cancer studies is not clear.

Thus, among the 11 studies that examined the effect of dietary fat on tumorigenesis, 6 studies (3 mammary tumor studies, 1 colon tumor study, 1 pancreatic tumor study, and 1 liver tumor study) reported significant reductions in the risk of tumorigenesis, measured by incidence, multiplicity, or latency, by reducing fat intakes from about 20 percent to about 5 percent. However, the evaluation of the studies was difficult because many studies suffered a critical and a common limitation in the methodology: diets were limited in linoleic acid, which is necessary for optimal tumor growth.

b. *Effects of types of fat.* Four studies examined the effects of different types of fat on mammary tumorigenesis (Refs. 117, 123, 124, and 125). All four studies reported inconsistent or insignificant effects of different types of fat.

Buckman et al. (Ref. 123) studied whether oleate influences the linoleate-enhanced metastasis of murine mammary tumors. Diets contained 13.5 percent to 61 percent linoleic acid and 12 percent to 47 percent oleic acid. Total fat was 20 percent by weight. Diets did not significantly affect latent period, incidence, or yield of tumors. These diets provided adequate linoleic acid for optimal tumor growth at the mammary gland. The authors reported that a low linoleic acid to low oleic acid diet reduced lung metastasis compared to the other three diets (low linoleic acid to high oleic acid, high linoleic acid to moderate oleic acid, and high linoleic acid to low oleic acid). Values were 10 nodules, 62 nodules, 78 nodules, and 90 nodules, respectively, for mice fed these four diets. The low linoleic acid to low oleic acid suppressed tumorigenesis, in terms of metastasis, in lung but not in liver.

Lasekan et al. (Ref. 124) fed rats diets with 20 percent fat by weight and examined DMBA-induced mammary tumorigenesis. The concentrations of linoleic acid and oleic acid, respectively, in the dietary fat were 72.9 percent and 12.4 percent linoleic acid-rich safflower oil diet (SL diet), 17.2 percent and 71.1 percent safflower oil diet (SO diet), 5.6 percent and 6.7 percent olive oil diet (OO diet), and 16.9 percent and 67.9 percent linoleic acid-rich olive oil diet (OL diet). The concentrations of linoleic acid in the diets were 14.6 percent (SL diet), 3.4 percent (SO diet), 1.1 percent (OO diet), and 3.4 percent (OL diet) by weight. Dietary concentrations of linoleic acid, oleic acid, or linoleic acid to oleic acid ratio did not consistently affect latent period, incidence, or yield of mammary tumors. The OO diet showed a significant tumor-lowering effect, which disappeared when linoleic acid was added. Tumors per rat were 3.0, 5.1, 3.5, and 5.0 in rats fed the OO, OL, SL, and SO diet, respectively. Because the OO diet was limited in linoleic acid, the findings support the "about 4 percent linoleic acid requirement" for mammary tumorigenesis in rodents (Refs. 20 and 71).

Khoo et al. (Ref. 117) also showed that 20 percent supplementation of stearic acid to a control diet did not affect mammary tumor growth in rats. Fatty acid composition of the control diet was not reported for this study, and the adequacy of linoleic acid content cannot be determined. Hirose et al. (Ref. 125) also reported no difference in mammary tumor yields between the 10 percent soybean oil group and the 10 percent safflower oil group. Both of these diets contained sufficient linoleic acid for optimal tumor growth.

Three studies (Refs. 118, 125, and 126) examined the effects of different types of fat on colon tumorigenesis. One study (Ref. 118) reported that a diet containing 20 percent beef suet produced significantly more tumor than a diet containing 20 percent corn oil (28 carcinoma versus 2 carcinoma, respectively). The 5 percent beef suet diet also elevated tumor yield compared to the 5 percent corn oil diet (12 carcinoma versus 1 carcinoma, respectively). The beef suet diets, although providing limited linoleic acid, nevertheless increased colon tumor development. The findings suggest that the effects of saturated fatty acids (SFA) may be promoting and those of polyunsaturated fatty acids (PUFA) may be protective for colorectal tumorigenesis.

Conversely, Nutter et al. (Ref. 126) measured the effects of dietary fat and protein on DMH-induced tumor development and immune responses in male mice. These authors reported that 4.7 percent beef tallow (BT) diets were protective for colon tumorigenesis in mice compared to 4.7 percent corn oil (CO) diets (3.2 tumor per tumor-bearing mouse versus 12.3 tumor per tumor-bearing mouse, BT versus CO, respectively). This study suffers limitations in methodology: the total fat level, 4.7 percent, was too low, and the beef tallow diet was limited in content of linoleic acid (about 0.3 percent by weight).

The other study by Hirose et al. (Ref. 125) reported that incidence or yield of experimental tumorigenesis at the colon was not different between the 10 percent soybean oil group and the 10 percent safflower oil group in rats. The diets provided adequate linoleic acid for optimal tumor growth.

Two studies on skin tumors (Refs. 127 and 128) were also reported. Locniskar et al. (Ref. 127) compared the effects of fish, coconut, and corn oils on skin tumors induced by DMBA and benzoylperoxide in mice. Leyton et al. (Ref. 128) measured the effects of different types of dietary fat on DMBA- and phorbolester (12–O-

tetradecanoylphorbol-13-acetate, TPA)-elicited tumorigenesis at mouse skin. Both studies found a significant protective effect of PUFA (corn oil) and a significant promoting effect of SFA (coconut oil) on skin tumorigenesis. In both of these studies, diet groups with the highest dietary corn oil (15 percent by weight in one study and 10 percent by weight in the other study as the sole fat source) showed the lowest yield of papilloma (3.4 tumors versus 11.7 tumors, 1 percent CO versus 15 percent CO in SENCAR mice) or carcinoma. The results differ from the "about 4 percent linoleic acid requirement" for optimal tumorigenesis for mammary tumorigenesis in rodents (Refs. 129 and 130) and suggest that the linoleic acid requirement may be different for tumors at different sites.

The results of the recently reported studies show that, when the requirement of linoleic acid for optimal tumor growth is met, types of dietary fat do not have specific effects on tumorigenesis of the mammary gland. The study results on colon tumor are equivocal: dietary PUFA was promoting in one study and was protective in the other. The two studies in skin tumor consistently reported a protective role of dietary PUFA, which suggests a different level of linoleic acid requirement for tumorigenesis at different sites.

c. *Fat intake versus energy intake.* Because energy intake and fat intake are highly correlated, it is possible that the association between dietary fat and cancer is confounded by energy intake. It also has been demonstrated in animal and human studies that energy intake in excess of an essential requirement is of primary importance in determining the incidence of induced and spontaneous tumors. During the preparation of the proposal on the lipids and cancer health claim, FDA carefully reviewed studies with isocaloric diets or similar energy provisions. The agency reached the tentative conclusion that the totality of the evidence from both animal and human studies showed that the effect of dietary fat on tumorigenesis is independent of the effect of energy (Refs. 11, 17, and 23).

Two new animal studies examined the relationship between fat and cancer with isocaloric diets or similar energy provisions (Refs. 115 and 116). One study (Ref. 115) reported that calorie restriction, rather than fat content, significantly reduced tumor growth in this study. Another study by Aksoy et al. (Ref. 116) reported no difference in the growth of mammary tumors among 12 percent, 25 percent, and 45 percent fat-fed groups. However, both of these negative studies suffered from the same methodological problem: diets were limited in linoleic acid (about 1.7 percent linoleic acid in one study and about 0.7 percent to 1.9 percent linoleic acid in the other). Because of this common limitation that linoleic acid in the diet was not sufficient for optimal tumor growth, the studies cannot be adequately evaluated for the effect of fat on cancer. In conclusion, although the newly reported studies were not adequate to evaluate the energy-independent effect of fat on cancer development, from several studies previously reviewed, the agency found adequate evidence to conclude that the effect of fat is independent of the effect of energy.

d. *Omega-3 fatty acids and fish oil.* In one study (Ref. 125), mammary tumor was induced by dimethylbenzanthracene and dimethylhydrazine, and the effects of perilla oil (an omega-3 fatty acid rich plant seed oil), soybean oil, and safflower oil were tested at 10 percent by weight. Incidence rates were not different among groups but the tumor yield was significantly lowered by perilla oil feeding, compared to soybean oil or safflower oil feeding (4.4 tumors, 6.5 tumors, and 5.7 tumors per rat: perilla oil, soybean oil, and safflower oil, respectively). Perilla oil is rich in linoleic acid (13.7 percent) compared to soybean and safflower oils, which contain 1.7 percent and 0.1 percent linoleic acid, respectively. Perilla oil is also relatively low in linoleic acid (15.9 percent) compared to soybean and safflower oils, which contain 52.6 percent and 74 percent linoleic acid, respectively. This study suffers the common methodological limitation in that perilla oil diet containing about 1.6 percent linoleic acid may have provided inadequate linoleic acid for tumor growth.

One recent study on colon tumorigenesis (Ref. 129) also reported a protective effect of omega-3 fatty acid. In this study, mice were fed a 19.2 percent fat diet with various sources: beef tallow, soybean oil, and a commercial fish oil product (MaxEPA). The MaxEPA diet significantly lowered and the beef tallow diet significantly elevated the yield of adenocarcinoma of the colon, compared to other groups (mean tumor per animal was 1.23 mean tumor, 0.47 mean tumor, and 0.23 mean tumor for the beef tallow, soybean oil, and fish oil group, respectively). Diets provided adequate linoleic acid for optimal tumor growth. This result suggests that the high fish oil diet (MaxEPA) may have a protective role in dimethylhydrazine-induced colon tumorigenesis in Swiss-Webster mice.

Another study (Ref. 125) found an inconsistent effect of different types of fat on tumorigenesis at the colon. A 10 percent perilla oil diet significantly lowered incidence of colon tumors compared to a 10 percent soybean oil diet or a 10 percent safflower oil diet in rats. Tumor incidences were 4 percent, 9 percent, or 9 percent for the perilla oil, soybean oil, or safflower oil diets, respectively. Tumor yield was not different among groups. In this study, the perilla oil diet provided about 1.6 percent linoleic acid by weight, which might have been limiting for optimal tumor growth.

There were two lymphoma studies (Refs. 130 and 131), which showed an adverse effect of omega-3 rich fatty acid on tumorigenesis. Both studies used AKR mice and examined the growth of xenograft lymphoma. The composition of dietary fat tested were fish oil versus beef tallow in one study and fish oil versus hydrogenated beef tallow in the other. Diets in both of these studies were severely limited in linoleic acid (0.01 percent to 0.48 percent by weight in one study and 0.004 percent to 0.18 percent by weight in the other study). Due to this methodological problem, the results are not useful for evaluating the effect of fat.

Hence, results of the recently reported studies are contradictory for the effect of omega-3 fatty acid on tumor development. One (Ref. 129) of the four studies studied the development of colon tumor with an adequate linoleic acid provision in the diet. In this study, the fish oil (MaxEPA) at 19.2 percent by weight significantly reduced tumor yield. The study, however, suffers from the limitation that the amount of dietary fish oil used was impractically high. Overall, the recent studies failed to adequately refute or support the effects of fish oil on tumorigenesis. Further studies are required to elucidate the effects and mechanism of omega-3 fatty acids on tumorigenesis.

e. *Mechanisms of carcinogenesis.* Although several mechanisms have been proposed, the biochemical mechanism by which fat affects tumorigenesis has not been definitely established. As discussed in the lipids/cancer proposal, hypotheses include fat-induced alteration in membrane peroxidation, immune function, gene expression, metabolism of chemical carcinogens, metabolism of hormones, metabolism of eicosanoids, and turnover rate of intestinal mucosal cells (56 FR 60764). Recent studies have not further elucidated the mechanisms for the effect of fat on tumorigenesis.

After reviewing the animal studies, Schatzkin et al (Ref. 132) concluded that increasing the amount of dietary fat increases mammary tumorigenesis, whether measured in terms of incidence, multiplicity, or latency; the production of tumors is enhanced when a high level of fat is fed after, not before, initiation, suggesting a promotional effect of dietary fat; the tumor-enhancing effects of high levels of saturated or polyunsaturated fat are similar when the diets contain a minimal amount of polyunsaturated fat to provide essential fatty acids; and that dietary fat and total calorie intake seem to have separate tumor enhancing effects.

On the other hand, Kritchevsky (Ref. 133) noted that all of the studies relating to fat and experimental carcinogenesis show that increasing levels of dietary fat increases tumor incidence; the effect seems to be exerted principally in the promotion phase and plateaus at between 5 and 10 percent of fat in the diet; and energy from the fat-rich diets, rather than fat per se, may be the factor enhancing tumorigenesis. He concluded that:

> The possibility that the problem may be energy rather than fat permits us to make broader dietary choices without excluding specific nutrients. * * * The call for reductions in fat intake to 15 percent or 20 percent of energy may be considered drastic, but a modest reduction (perhaps to 30 percent of energy) might not be out of order.

Another comprehensive review of studies (Ref. 134) reached conclusions similar to those of Kritchevsky. The authors concluded that:

> High dietary fat (20 percent by weight or 40 percent by energy) significantly elevates incidence and multiplicity of mammary gland tumors induced chemically in rodents. High dietary total fat also clearly promotes tumorigenesis at the colon and pancreas. On the other hand, moderate to severe dietary restriction in animals yields fewer neoplasms, particularly in the mammary gland. Intake of a high-fat diet even at moderate restriction would not lead to promotion because the dietary restriction would have the opposite effect. This finding could obviously be transformed to humans. However, most human populations do not voluntarily undergo lifelong dietary restriction but rather eat ad libitum.

Therefore,

> A diet which is high in complex carbohydrate (65 percent to 70 percent by energy) and moderate in fat (20 percent to 25 percent) and protein (10 percent to 15 percent) would be recommended.

C. Conclusions About New Evidence

The agency has reviewed several new research articles, and several review papers, which were published since the proposal. Among the human studies, one correlational study was supportive of the hypothesis that high fat diets increase the risk of cancers of the colon, rectum, prostate and breast (Ref. 92), and another correlational study supported the relationship between increased cancer risk and dairy fat and lard fat (Ref. 93). A new case-control study on pancreatic cancer was consistent with the earlier reports that this cancer is not associated with dietary fat (Refs. 94). A study on bladder cancer suggested that an increased risk was associated with saturated fat but not with total fat (Ref. 96).

The results of several new human case-control studies on breast cancer demonstrated no effect of total dietary fat on postmenopausal breast cancer risk (Refs. 99, 100, and 102). Moreover, the evidence for an effect of dietary fat on premenopausal risk was extremely limited in the new studies reviewed, and the study that found an increased risk associated with fat for all women (not separated by menopausal status) did not adjust for total calories (Ref. 101). The case-control studies on breast cancer which examined associations with food found increased risks from total food (Ref. 101) and from fats used as seasonings (Ref. 103), but not from meat (Ref. 101).

However, for a number of reasons, case-control studies are at a disadvantage compared to correlational studies in their ability to detect an association between dietary fat and cancer risk. The range of dietary fat intake is usually narrow in case-control studies because the populations studied are homogenous in terms of dietary parameters. It is extremely difficult for an epidemiology study to detect an increase in cancer risk associated with dietary fat when the difference in fat intake between cases and controls is minimal. Also, the average fat content of the diet in Western countries is seldom less than 30 percent to 35 percent of total calories. Although it is not known for certain how low the fat content of a diet needs to be before a reduction in cancer risk is achieved, it is at least less than 30 percent of total calories. Thus, it is not surprising that the results of case-control studies investigating the relation between dietary fat and cancer are often equivocal.

A new study on colorectal cancer did not demonstrate an increased risk associated with total dietary fat or saturated fat but did show an increased risk with total calories and with cholesterol (Ref. 104). Two new case-control studies on prostate cancer both found an increased risk associated with dietary fat (Refs. 105 and 106).

The evidence from the new animal studies generally supports the conclusion drawn in the lipids/cancer proposal that dietary total fat is associated with the risk of cancer. Among eleven animal studies, six studies (three in mammary tumor, one in colon tumor, one in pancreatic tumor, and one in liver tumor) reported significant reductions in the risk of tumorigenesis, measured by incidence, multiplicity, or latency, by reducing fat intakes from about 20 percent to about 5 percent.

Regarding types of fat, the new studies provide the same conclusion as the one that the agency drew in the proposal: currently, there is not enough evidence to delineate specific roles of different types of fat on tumorigenesis. The new studies show that when the requirement of linoleic acid for optimal tumor growth is met, various types of dietary fat do not affect tumorigenesis at the mammary gland differently. The study results on colon tumor are equivocal; dietary PUFA was promoting in one study and was protective in the other. The two studies on skin tumor consistently reported a protective role of dietary PUFA, which suggests a different level of linoleic acid requirement for tumorigenesis at different sites.

It is difficult to disassociate the effect of fat from the effect of total energy. The two new animal studies did not provide further evidence that dietary fat has an energy-independent effect on carcinogenesis. There are two new studies that utilized isocalorie or similar calorie provisions (Refs. 115 and 116). One of these studies reported that energy intake rather than fat intake affects cancer development. However, both studies suffered the common methodologic limitation that linoleic acid in the diet was insufficient and were not adequate to evaluate the effect of fat. However, several studies previously reviewed by the agency (Refs. 11, 17, and 23) provided adequate evidence to conclude that the effect of fat is independent of the effect of energy.

As was the case with studies reviewed in the proposal, new studies on omega-3 fatty acid and tumor development do not provide conclusive evidence. Among the four new studies of omega-3 fatty acid and cancer, only one study (Ref. 129) in colon tumor provided adequate linoleic acid in the diet. The fish oil (MaxEPA) at 19.2 percent by weight significantly reduced tumor yield, suggesting that the fish oil may reduce DMH-induced colon tumor risk. The study, however, suffered from the limitation that the amount of dietary

fish oil used was unpractically high. Additional studies are required to elucidate the effects and mechanisms of omega-3 fatty acids on tumorigenesis.

The new studies reviewed did not further elucidate the mechanisms for the effect of fat on tumorigenesis. The existing hypotheses include alterations in membrane peroxidation, membrane fluidity and microenvironment, immune function, gene expression, metabolism of chemical carcinogens, metabolism of hormones, metabolism of eicosanoids, and turnover rate of intestinal mucosal cells (as discussed in the lipids/cancer proposal).

Thus, new animal studies provide some, although inconclusive, evidence that dietary total fat is associated with risk of some cancers. Mammary tumor, colon tumor, pancreatic tumor, and liver tumor may be affected. Evidence is inconclusive regarding specific roles of different types of fat including fish oils. The evaluation of the new studies was greatly hampered by the common limitation in the experimental design of limited linoleic acid in the diet.

As discussed previously in this preamble, several comments suggested that FDA drop the specification of types of cancer affected from the health claim. In view of the new evidence, FDA believes that the scientific evidence on lipids and risk of specific cancers is not as yet definitive. Further evidence has to be accumulated to draw clear conclusions regarding effects of different types of fat, effects at different tumor sites, effects of omega-3 fatty acids, the quantitative relationship between fat and energy, and mechanisms by which fat affects cancer development. Methodological limitations in the human and animal studies on dietary lipids and cancer are discussed in the lipids/cancer proposal and elsewhere in this document.

In conclusion, the evidence found in the new studies in humans and animals supports the agency's tentative conclusion in the proposal that the totality of publicly available scientific evidence supports an association between dietary fat and cancer risk. Evidence is also accumulating that total energy intake is an additional risk factor for cancer. However, the evidence for which types of cancer are affected is equivocal. Therefore, the agency is not authorizing the phrase "particularly cancers of the colon, breast, and prostate" or any other site to be included in the health claim.

IV. Environmental Impact

FDA has determined that under 21 CFR 25.24(a)(11), this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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142. O'Neill, I. K., M. T. Goldberg, E. E. I. Ghissassi, and M. Rojas-Moreno, "Dietary Fiber, Fat, and Beef Modulation of Colonic Nuclear Aberrations and Microcapsule-trapped Gastrointestinal Metabolite of Benzo[a]pyrene-treated C57/B6 Mice Consuming Human Diets," *Carcinogenesis*, 12:175–180, 1991.

143. Jenski, L. J., L. Sturdevant, W. D. Ehringer, and W. Stillwell, "Omega-3 Fatty Acids Increase Spontaneous Release of Cytosolic Compounds from Tumor Cells," *Lipids*, 26:353–358, 1991.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.73 is added to subpart E to read as follows:

§ 101.73 Health claims: dietary fat and cancer.

(a) *Relationship between fat and cancer.* (1) Cancer is a constellation of more than 100 different diseases, each characterized by the uncontrolled growth and spread of abnormal cells. Cancer has many causes and stages in its development. Both genetic and environmental risk factors may affect the risk of cancer. Risk factors include a family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) Among dietary factors, the strongest positive association has been found between total fat intake and risk of some types of cancer. Based on the totality of the publicly available scientific evidence, there is significant scientific agreement among experts, qualified by training and experience to evaluate such evidence, that diets high in total fat are associated with an increased cancer risk. Research to date, although not conclusive, demonstrates that the total amount of fats, rather than any specific type of fat, is positively associated with cancer risk. The mechanism by which total fat affects cancer has not yet been established.

(3) A question that has been the subject of considerable research is whether the effect of fat on cancer is site-specific. Neither human nor animal studies are consistent in the association of fat intake with specific cancer sites.

(4) Another question that has been raised is whether the association of total fat intake to cancer risk is independently associated with energy intakes, or whether the association of fat with cancer risk is the result of the higher energy (caloric) intake normally associated with high fat intake. FDA has concluded that evidence from both animal and human studies indicates that total fat intake alone, independent of energy intake, is associated with cancer risk.

(b) *Significance of the relationship between fat intake and risk of cancer.* (1) Cancer is ranked as a leading cause of death in the United States. The overall economic costs of cancer, including direct health care costs and losses due to morbidity and mortality, are very high.

(2) U.S. diets tend to be high in fat and high in calories. The average U.S. diet is estimated to contain 36 to 37 percent of calories from total fat. Current dietary guidelines from the Federal Government and other national health professional organizations recommend that dietary fat intake be reduced to a level of 30 percent or less of energy (calories) from total fat. In order to reduce intake of total fat, individuals should choose diets which are high in vegetables, fruits, and grain products (particularly whole grain products), choose lean cuts of meats, fish, and poultry, substitute low-fat dairy products for higher fat products, and use fats and oils sparingly.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in fat with reduced risk of cancer may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in fat "may" or "might" reduce the risk of some cancers;

(B) In specifying the disease, the claim uses the following terms: "some types of cancer" or "some cancers";

(C) In specifying the nutrient, the claim uses the term "total fat" or "fat";

(D) The claim does not specify types of fat or fatty acid that may be related to the risk of cancer;

(E) The claim does not attribute any degree of cancer risk reduction to diets low in fat; and

(F) The claim indicates that the development of cancer depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.62 for a "low fat" food; except that fish and game meats (i.e., deer, bison, rabbit, quail, wild turkey, geese, ostrich) may meet the requirements for "extra lean" in § 101.62.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of cancer: Family history of a specific type of cancer, cigarette smoking, alcohol consumption, overweight and obesity, ultraviolet or ionizing radiation, exposure to cancer-causing chemicals, and dietary factors.

(2) The claim may include information from paragraphs (a) and (b) of this section which summarize the relationship between dietary fat and cancer and the significance of the relationship.

(3) The claim may indicate that it is consistent with "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office.

(4) The claim may include information on the number of people in the United States who have cancer. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," USDA and DHHS, Government Printing Office.

(e) *Model health claims.* The following model health claims may be used in food labeling to describe the relationship between dietary fat and cancer:

(1) Development of cancer depends on many factors. A diet low in total fat may reduce the risk of some cancers.

(2) Eating a healthful diet low in fat may help reduce the risk of some types of cancers. Development of cancer is associated with many factors, including a family history of the disease, cigarette smoking, and what you eat.

Dated: October 30, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following tables will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

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TABLE 1
Lipids and Cancer: Human Studies 1991 to Present

Study	Study Design	Subjects	Methods	Results	Comments
Zatonski et al., 1991 (Ref. 94)	Case-Control; Poland; Pancreatic (Exocrine) Cancer; study conducted 1985 to 1988	110 cases (surrogates interviewed for 71%); 195 controls (all directly interviewed)	Interview using dietary questionnaire containing 80 food items; diet assessed 1 to 2 years before interview; 43% of cases were histologically confirmed and remainder diagnosed radiologically	Adjusted for smoking and total calories: Total fat: RR=0.3 (0.1-1.0) SFA: RR=0 3 (0.1-1.0) MUFA: RR=0.1 (0.3-0.6) PUFA: RR=0.2 (0.1-0.6) Cholesterol: RR=4.3 (1.6-11 6)	Only cholesterol showed a positive relation with pancreatic cancer; substantial use of proxy interview of cases introduces bias; median daily total fat intake was 113 g for cases and 105 g for controls
de Nesquita, et al., 1991 (Ref. 95)	Case-Control; Netherlands; Pancreatic (Exocrine) Cancer; study conducted 1984 to 1988	164 cases (surrogates interviewed for 50% males and 46% females); 480 controls (surrogates interviewed for 34% males and 26% females)	Interview using dietary questionnaire containing 116 food items; diet assessed 1 year before interview; 68% of cases were histologically confirmed; others diagnosed clinically	Adjusted for smoking and total calories: Oil and Fats: RR=1.1 for highest quintile (NS) Total meat: RR=1.6 for highest quintile (NS) Cheese: RR=0.8 (NS) Milk: RR=0.8 (NS) Eggs: RR=2 3 and daily consumption of vegetables RR=0.3 for highest quintile (statistical significance and test for trend significance for both)	Total fat and saturated fat not analyzed in this study; consumption of eggs is associated with a statistically significant increased risk and daily consumption of vegetables show a protective effect; large percentage of proxy interview of cases may introduce bias
Riboli, et al., 1991 (Ref. 96)	Case-Control; Spain; Bladder Cancer; Study conducted 1985 to 1986	432 cases (all males); 792 controls; 2 sets of controls: population-based and hospital-based	Interview using dietary questionnaire containing 60 food groups; diet assessed 1 year before interview; all cases histologically confirmed	Adjusted for smoking and total calories: Total fat: No association Saturated Fat: RR=2.2 (1.4-3.6) for highest quintile and trend highly significant (p=.0005) PUFA, MUFA: No associations Cholesterol: RR=1.4 (0.9-2.2) P/S Ratio: RR=0.7 (0.5-1.0)	Increased risk associated only with saturated fat; no association with total fat. Mean daily total fat intake was 99 g for cases and 95 g for controls Slightly low participation rates (cases: 72%; controls: 71% hospital and 66% population); results possibly biased by inclusion of 208 prevalent cases because they are survivors
Shekelle, et al., 1991 (Ref. 97)	Prospective Cohort; Western Electric Co. employees, Chicago; Lung Cancer	1,878 men aged 40 to 55 years in 1958 followed 24 years	Dietary information on foods and beverages consumed preceding 28 days collected at exam 1 and exam 2, 1 year later (all clinically free of cancer)	Adjusted for smoking and percent calories from fat: Dietary Cholesterol: 605-794 mg/day RR=1.3 795-1,909 mg/day RR=1.9 (results similar when adjusted for energy intake) Multivariable model implicated cholesterol from eggs but not from other sources	Increment of dietary cholesterol of 500 mg/day associated with RR=1.9 (1 1-3.4) Followup data not available so cannot assess changes in dietary cholesterol after baseline measurement

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Graham, et al., 1991 (Ref. 99)	Case-Control: New York: Postmenopausal Breast Cancer: Study conducted 1986 to 1989	439 incident cases: 494 age-matched community controls	Interview using dietary questionnaire on 172 foods: diet assessed 2 years before interview: all cases were histologically confirmed: results adjusted for age, education, age at first pregnancy, number of pregnancies, age at menarche, relative with breast cancer, benign breast disease, and Quetelet index	Cases and controls consumed same calories. No association found between breast cancer risk and total fat or saturated fat: Fat RR= 0.9 (0.6-1.4); SFA RR=1.0 (0.7-1.5). Dietary carotene, vitamin C protective but no effect shown for supplement use; dietary fiber borderline protective RR=0.7 (0.5-1.1); adjustment for total calories did not change results	No association found between breast cancer risk and dietary fat. Mean daily total fat consumption was 82 g for cases and 83 g for controls. Low participation rates may introduce bias: 56% of eligible cases and 46% of eligible controls participated in study, thus results may not be generalizable to total population
Lee, et al., 1991 (Ref. 100)	Case-Control: Singapore Chinese; Pre- and Postmenopeusal Breast Cancer: Study conducted 1986 to 1988	203 incident cases (109 premenopausal and 91 postmenopausal); 420 age-matched hospital controls (207 premenopausal and 213 postmenopausal)	Interview using dietary questionnaire on 90 foods; diet assessed 1 year before interview; all cases were histologically confirmed; results adjusted for age and age at birth of first child for premenopausal women and for age, height, education, nulliparity, family history of breast cancer for postmenopausal women	Postmenopausal women: no significant effects for any dietary variable Premenopausal women: Total fat, SFA, MUFA, and cholesterol showed no significant effect; P/S Ratio: RR=0.4 (0.2-0.8); Decreased risks found for PUFA: RR=0.5 (0.3-0.8); increased risk found for red meat after controlling for all other dietary variables: RR=4.0 (1.9-8.5)	Results not adjusted for total calories. No effect of diet on postmenopausal women. No effect found for total fat, SFA, MUFA, cholesterol and protective effect found for PUFA on premenopausal women. Median daily fat consumption was 33 g for cases and 34 g for controls. Hospital controls may have misrepresented their usual diet if preclinical symptoms (1 year before interview) affected diet
Richardson, et al., 1991 (Ref. 101)	Case-Control: France: Pre- and Postmenopausal Breast Cancer: Study conducted 1983 to 1987	409 incident cases: 515 hospital controls (348 premenopausal and 575 postmenopausal for total study population)	Interview using dietary questionnaire on 55 foods; current diet assessed, but if changed over past 12 months, former diet was used; all cases were histologically confirmed; results adjusted for age, menopausal status, family history of breast cancer, history of benign breast disease, alcohol consumption, and age at menarche	Multivariate Model: All women: Fat 1.6 (1.1-2.2) SFA 1.9 (1.3-2.6) MUFA 1.7 (1.2-2.5) PUFA, cholesterol no significant effects Premenopausal women: MUFA 2.0 (1.1-3.7) SFA, MUFA, retinol, beta-carotene, fat, vitamin E no significant effects Postmenopausal women: SFA: 2.0 (1.2-3.1) Retinol: 2.8 (1.2-2.8) Total fat, MUFA, beta-carotene, vitamin E no significant effects Food Associations (all women): Total Food RR=1.7 (1.1-2.6); High fat cheese RR=1.4 (1.0-1.9); Desserts and chocolate RR=1.7 (1.2-2.5); Meat, Olive Oil, Nuts - nonsignificant	Results not adjusted for total calories or for body size. Limited evidence that fat is associated with breast cancer risk when analyzed by menopausal status. Total food was positively associated. Use of hospital controls could lead to selection of controls whose diseases are associated with high fat diets, although study excluded cardiovascular disease controls

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Zarídze, et al., 1991 (Ref. 102)	Case-Control; Moscow; Pre and postmenopausal Breast Cancer; Study conducted 1987 to 1989	139 incident cases (58 premenopausal and 81 postmenopausal); 139 clinic controls (54 premenopausal and 85 postmenopausal) matched by age and neighborhood	Dietary questionnaire on 145 food items; diet assessed for average consumption during year prior to diagnosis for cases and for year prior to interview for controls. Data analyzed for pre- and postmenopausal women separately. Adjusted for total energy for all analyses; weight, height and Quetelet's index were assessed but none had a significant effect so results were not adjusted for these variables	Premenopausal women: Adjusted for total energy, age at menarche, age at first birth: Magnesium intake: RR=.02 (.0005-.08) only significant finding Postmenopausal women: adjusted for total energy, age at menarche, and education: Total fat, SFA, MUFA, cholesterol, protein: Nonsignificant PUFA: RR=0.1 (0.03-0.7) Mono- and disaccharides: RR=0.02 (0.002-0.3) Cellulose: RR=0.04 (0.01-0.3) Beta-carotene, vitamin C, potassium, calcium, magnesium, and retinol equivalents all showed significant protective effects	Dietary fat not associated with breast cancer risk in either pre- or postmenopausal women. Results showing protective effects of some nutrients are difficult to interpret due to multiple comparisons and multiple models used in analysis, especially in light of the small number of study participants
D'Avanzo, et al., 1991 (Ref. 103)	Case-Control; Italy; Pre- and postmenopausal Breast Cancer; Study conducted 1983 to 1989	2,663 incident cases (1,122 premenopausal and 1,541 postmenopausal); 2,344 controls (884 premenopausal and 1,460 postmenopausal)	Dietary questionnaire on few selected indicator foods to obtain data on fat intake in seasonings (butter, margarine and oil); current diet assessed; all cases histologically confirmed; results adjusted for age, area of residence, education, history of benign breast disease, family history of breast cancer, nulliparity, age at first birth, age at menarche, menopausal status, age at menopause, body mass index, oral contraceptive and other female hormone use	Total Fat (from seasonings) RR=1.5 (1.2-1.7) Butter RR=1.6 (1 2-2.1) Oil RR=1.2 (1.0-1 6) No effect shown with margarine consumption	Results not adjusted for total calories. Moderate association between intake of added fat in seasonings and breast cancer risk. Use of hospital controls could lead to selection of controls whose diseases are associated with high fat diets, although gastrointestinal diseases were excluded. Assessment of current diet rather than diet before onset of illness could bias results. Very limited dietary information available
Benito, E., et al., 1991 (Ref. 104)	Case-Control; Majorca; Colorectal Cancer; Study conducted 1984 to 1988	286 incident cases; 295 population controls and 203 hospital (ophthalmology and orthopedic); controls matched to cases by age and sex	Interview using dietary questionnaire on 99 food items; diet assessed in year preceding interview; all cases histologically confirmed; results adjusted for total calories and for age, sex, estimated weight 10 years prior to interview, number of meals per day, education, job category, and activity in the workplace	RR's for quartiles of consumption: Total Calories: RR=1.0, 1.6, 1 6, 2.6 After adjustment for total calories: Cholesterol: RR=1.0, 0.9, 1.7, 1 7 Fiber from legumes: RR=1.0, 0.8, 0.5, 0.4 Protein: RR=1.0, 1.1, 1 7, 2.5 Carbohydrate: RR=1.0, 1.5, 1 4, 2 2 No effects found for total fat or saturated fats	Increased risk of colorectal cancer found for total calories, cholesterol, protein, and carbohydrates and protective effect found for fiber from legumes. No effect on colorectal cancer risk was found for increased consumption of total fats or saturated fats. This lack of association may be due to the population's consumption mainly of MUFAs rather than animal fats. Mean percentage of calories from fat was 37% for colon cancer cases, for rectal cancer cases and for controls

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Yeung, et al., 1991 (Ref. 138)	Correlational (Biochemical) Study: China and American; Colorectal Cancer	42 male and 50 female Chinese and 34 male and 33 female Chinese Americans; the two populations have fourfold difference in colorectal cancer risk	24-hour food, urine and stool samples analyzed; all subjects were randomly selected from volunteers	Chinese American diets were higher in fat and protein and lower in carbohydrates, stools contained more cholesterol and bile acids, and no difference in fatty acids, and urine contained more 3-methyl-histidine and malonaldehyde. Authors interpreted results to demonstrate that high fat, high protein, low carbohydrate diets are associated with increased colorectal cancer risk	Authors interpretation does not follow from study's findings due to methodological flaws: results are correlational only--no cases of colorectal cancer actually existed among participants; diet was assessed for 24 hours only; Chinese had higher participation rate than Americans; confounding by environmental and lifestyle factors were not controlled for in study
Geltner-Allinger, et al., 1991 (Ref. 139)	Case-Control; Sweden; Colon Cancer	35 cases (16 men, 19 women); 46 population controls (26 men, 20 women)	Limited dietary intake information, diet assessed for preceding year; stool samples analyzed for bile acids and lipid concentrations; rectal biopsies collected for colonic epithelial cell proliferation rate analysis	No differences found in the concentration of fecal bile acids or in colonic cell proliferation rates. No differences found in dietary intake of fat and fiber; female cases consumed slightly more calcium than controls (574 mg versus 370 mg)	Biological marker study; very small numbers of participants and very limited dietary assessment. No conclusions can be drawn from this study
Clausen, et al., 1991 (Ref. 140)	Clinical Study; Denmark; Colon Cancer	17 patients with colonic adenomas, 17 patients with colon cancer, and 16 healthy controls	Analyzed stool samples for short chain fatty acids; compared molar production velocities of short chain fatty acids from glucose, ispagule, wheat bran, and albumin in fecal incubations; no dietary assessment conducted	Fecal concentrations of total short chain fatty acids and concentrations and ratios of the individual fatty acids did not differ among the two sets of patients and controls. Molar production velocities did not differ except for the ratio of butyrate production to total short chain fatty acid production from fiber was reduced in colon cancer and adenoma patients compared to controls	Authors speculate that the low ratios of colonic butyrate formation combined with low fiber diets may increase the risk of colonic neoplasia. Study provides very limited evidence that high fiber diets may reduce the risk of colon cancer, and no information is provided by study as to type of fiber responsible

TABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
Yu, et al., 1991 (Ref. 92)	Correlational Study: China and U.S.: Colon, Rectal, Prostate and Breast Cancer	Chinese in Shanghai, Chinese Americans and Americans compared	Incidence rates of cancers of the colon, rectum, female breast, and prostate compared using Connecticut SEER data for White Americans, San Francisco SEER data for Chinese Americans, and data from the cancer registry at the Shanghai Tumor Institute for Shanghai Chinese. Incidence rates were standardized to the 1970 age distribution of the world population. Food consumption data compared using FAO data for U.S. and from two Chinese publication sources for China	Incidence rates for colon cancer among Americans were 4 times the Chinese rates, for rectal cancer among Americans were 2 times the Chinese rates, for prostate cancer among Americans were 26 times Chinese rates, and for postmenopausal breast cancer among Americans were 10 times the Chinese rates. Americans consumed 6 times more meat and eggs, 55 times more milk, slightly more fats and oils, and 3 times more fruit than Chinese	Study was correlational in design; there is no way to determine by this study if the persons who actually have these cancers also eat the putative diet. Study did not control for the very important known risk factors of these cancers such as lifestyle factors, family history, reproductive factors, and endocrine factors
Kesteloot, et al., 1991 (Ref. 93)	Correlational Study: 36 countries: Total Cancer and several types of cancer	Men and Women in 36 countries	Cause-specific cancer mortality rates using 1985 to 1987 WHO data were compared with dairy and lard fat intake obtained from food balance sheets from 1979 to 1981 FAO data	Highly significant correlations were found between dairy fat plus lard fat intake and mortality from all causes, total cancer, colon, and rectal cancer among both men and women and from lung cancer and prostate cancer for men only and breast cancer for women only. Correlations remained significant when adjusted for total caloric intake or for total caloric intake minus total fat intake	Study was correlational in design: thus, the diet of the persons with the diseases studied are not being analyzed directly. Study did not control for the very important known risk factors of these cancers such as lifestyle factors (e.g., smoking), family history, reproductive factors, and endocrine factors. Food balance sheet data from FAO are approximations of actual consumption and these data are not separated by age and sex
Bravo, et al., 1991 (Ref. 105)	Case-Control: Spain: Prostate Cancer: study conducted 1983 to 1987	90 cases: 180 controls from same hospital matched by age and date of hospital admission: controls were those with diseases other than urologic diseases or a primary tumor	Interview on types and amounts of foods usually consumed: obesity measured by body mass index: all cases were histologically confirmed: results were not adjusted for total calories	Risk of prostate cancer was increased by a diet rich in animal fats: RR=2.6 (1.3-5.0) Diets rich in vegetable fats, and vitamins A and C deficiencies were not associated with increased risk of prostatic cancer. Meat consumption was associated with increased risk: RR=2.3 (1.2-4.4) but different types of meat were not significantly associated with increased risk. No risk associated with obesity	Study demonstrates an increased risk of prostate cancer with diets rich in animal fats and with meat consumption. Results were not adjusted for total calories which severely limits the validity of the results. Hospital controls used, some with gastrointestinal diseases, and usual diet was assessed so that disease may have affected diet

ABLE 1--continued

Study	Study Design	Subjects	Methods	Results	Comments
West, et al., 1991 (Ref. 106)	Case-Control; Utah; Prostate Cancer; Study conducted 1984 to 1985	358 incident cases (179 aged 45 to 67 and 179 aged 68 to 74); 679 population-based controls (387 aged 45 to 67 and 292 aged 68 to 74), matched by county of residence	Interview using dietary questionnaire containing 183 foods; cases' diet assessed for 3-year period prior to diagnosis or prior to symptoms; controls' diet assessed 3 year prior to interview; all cases histologically confirmed; interviewers not blinded to case or control status of respondent. Results were adjusted for total calories. Interaction and confounding between dietary variables and demographic and lifestyle factors were assessed but none found; therefore, authors reported only crude relative risks	No associations between dietary variables and prostate cancer found for men 45 to 67 years of age, either for all tumors combined or when subdivided by tumor aggressiveness. Males aged 68 to 74: For all tumors: Total Fat RR=1.7 (1.0-3.1) Protein RR=1.7 (1.0-2.9) For aggressive tumors: Total Calories RR=2.5 (1.0-6.5) Total Fat RR=2.9 (1.0-8.4) MUFA RR=3.6 (1.3-9.7) PUFA RR=2.7 (1.1-6.8) No dose-response seen; cholesterol not associated with prostate cancer risk for either age group	Study demonstrates that dietary fat is associated with prostate cancer risk among older men. Bias may have been introduced due to low participation rates: 77% of eligible cases and 77% of eligible controls participated. Interviewers were not blinded as to case or control status of respondent; this may have introduced bias if the interviewers were aware of the association between dietary factors and prostate cancer

TABLE 2
Lipids and Cancer: Animal Studies

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Cohen et al., 1991 (Ref. 113)	Tested effects of fats and fiber in the N-nitromethylurea-induced rat mammary tumor model	Virgin female F-344 rats 5-day old 30/groups	Diet: varied in fat and fiber I 23.5% CO II 23.5% CO plus 10% fiber III 5% CO IV 5% CO plus 10% fiber The fiber was soft white wheat bran. Base diet was AIN-76A Rats received intravenous N-nitrosomethylurea (NMU) and fed diets for 15 weeks Tumor incidence and development measured. Blood levels of 17B-estradiol and progesterone also measured	5% CO diet sign reduced incidence (63 versus 90%) and multiplicity (1.1 versus 2.5 tumors per rat) and significance prolonged latency period compared to 23.5% CO diet Fiber significance reduced incidence and multiplicity of tumors in the 23.5% CO group but not in the 5% CO group No difference in hormone levels	Nonisocaloric diets used; food consumption not reported; significantly decreased body weight in the low fat, compared to other groups
Gonzalez et al., 1991 (Ref. 114)	To measure effects of different amounts and types of fat on growth of human breast carcinoma in athymic nude mice	Athymic nude mice Female 5 to 13 weeks old	Diet I 5% CO, 3.87 kcal/g II 20% CO, 4.55 kcal/g III 20% butter, 4.55 kcal/g IV 19% BT + 1% CO, 4.55 kcal/g V 19% FO (MO) + 1%, 4.55 kcal/g linoleic acid level (wt %) I 2.8 II 11.2 III 0.36 IV 0.9 V 0.75 After tumor transplantation, mice were fed the diets for 6 to 8 weeks. Tumor growth (number and volume of carcinoma) measured as well as lipid peroxidation in carcinoma Human breast cancer cell lines, MCF-7 and MDA-MB231, were used	Higher tumor volume in the high CO group (V) than low CO group (I); significant in the MDA-MB23 cell line transplanted mice. (0.4-4 cm3 versus 0.2-3.4 cm3, II versus I) Among high fat groups (II-V), high CO significantly raised and FO significantly lowered tumor volume Tumor volume was intermediate in the BT and butter groups MCF-7 carcinoma MDA-MB231 carcinoma mean carcinoma volume (cm3) (A) (B) I 3.4 0.5 0.2 II 4.0 1.5 0.4 III 2.4 1.2 0.1 IV 2.4 0.8 V 0.2 0.6 0.0 Significance: I II III IV versus II I versus II versus V I versus III II versus V II vs V V vs V	Diets III, IV, and V did not provide adequate linoleic acid for tumor growth The carcinoma cell line MDA-MB23, but not the MCF-7, was estrogen-dependent, and mice in this group was provided with exogenous estrogen in the drinking water; biologic plausibility to extrapolate the result to human is questioned

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Zhu et al., 1991 (Ref. 115)	To measure effects of dietary calorie restriction and fat reduction on growth of mammary carcinoma in rats	Female Sprague-Dawley rats 50-day old 19 to 23/groups	Diet: calorie restriction versus fat I 50kcal/day, 45 energy % fat II 35 kcal/day, 45 energy % fat III 50 kcal/day, 25 energy % fat IV 35 kcal/day, 25 energy % Diet I & II III & IV (wt%) PO 16.28 7.8 lard 3.04 1.46 SSO 2.39 1.14 Rats were injected with methylnitrosoures (MNU) and fed Diet I until tumor size was approximately 1 cm3 then fed with the experimental diets for 10 ± 2 weeks. Tumor development and liver glutathione measured	No difference in tumor number and weight between diets I and III, and II and IV 30% caloric reduction significantly reduced tumor yield (I versus II, and III versus IV)	Linoleic acid in diets III and IV may not have been adequate for tumor growth: therefore, comparisons between I and III or II and IV are not valid to test the effect of total fat
Buckman et al., 1990 (Ref. 123)	To measure whether oleate influences the linoleate-enhanced metastasis of murine mammary tumor	Weanling Female BALB/cAnN mice 12/groups	Diet: 20 wt% total fat I II III IV (wt %) SO 15.5 15.5 2.6 2.6 Triolein 0 4.5 11.5 [illegible] CCO 4.5 0 5.9 17.4 18:2n-6/oil 61 .5 15.5 13.5% 18:2n-6/diet 12.2 12.3 .1 2.7% 18:1n-9/oil 10.5 24.5 47 12 Spontaneous tumor cell line (4526 murine mammary tumor cell line) was injected into mammary fat pad of mice and metastasis to lung, kidney, and liver measured	No difference in latency period, incidence, or yield of tumors among groups Most metastasis found in lung, some in liver, none in kidney Lung metastasis was significantly higher in the low linoleic acid to low oleic acid group (IV) compared to the other three groups (10, 62, 78, & 90 nodules: low linoleic to low oleic, low linoleic to high linoleic, high linoleic to moderate oleic, & high linoleic to low oleic, respectively No difference in liver metastasis among groups	Tumor cells grown in vitro were used; ability to extrapolate to humans is limited The effect of total fat not tested The effect of oleic acid not consistent Diets provided adequate linoleic acid and were isocaloric
Khoo et al., 1990 (Ref. 117)	To test the anticancer effect of stearic acid in transplanted mammary tumorigenesis in rats	Female F344 rats 4 to 6-week old 30/groups	Diet Control powdered diet (fat content not reported) and the control diet plus 20% stearic acid by weight Rats were fed the diets for 6 weeks before and 25 days after tumor implantation. Mammary tumor was induced in the rats by nitrosomethylurea and maintained in passage. The 8th passage cells were implanted in the flank of rats	Dietary stearic acid did not significantly affect the growth (size or weight) of transplanted tumor. Dietary stearic acid did not affect FA composition in tissues	Composition or level of dietary fat not provided; adequacy of linoleic acid cannot be judged. If the control diet was common chow or fat free diet both diets contained insufficient linoleic acid for tumor growth

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Aksoy et al., 1990 (Ref. 116)	To identify effects of different levels of dietary fat on MNU-induced rat mammary carcinogenesis	Female Sprague-Dawley rats 50 day-old 90/3 groups	Diet g/100g I II III PO 3 7.8 16.3 lard 0.56 1.46 3.04 SSO 0.44 1.14 2.39 Total fat 12 25 45 (energy %) Rats were fed experimental diets for 6 months and methylnitrosourea (MNU) -induced tumor development and plasma lipids measured	No difference in tumor incidence, or yield, or in mortality among groups	Diet I and II may not have provided adequate linoleic acid for mammary tumor growth Nonisocaloric diets used; however, rats consumed the same amount of calories and body weights were not different among groups
Lasekan et al., 1990 (Ref. 124)	To compare effects of safflower and olive oils on DMBA-induced mammary tumorigenesis	Female Weanling Sprague-Dawley rats 25/groups	Diet: 20 wt% fat High linoleic acid SO: SL diet High oleic acid SO: SO diet Olive oil: OO diet OO diet w/ linoleic acid supplementation : OL diet Linoleic content (wt%) SL 14.6 SO 3.4 OO 1.1 OL 3.4 Rats were fed the diets for 16 weeks, and 7, 12-DMBA-induced tumorigenesis measured	No difference in lag time or incidence OO diet significantly lowered tumor yield compared to SO or OL diets Linoleic supplementation of the OO diet (makes OL diet) significantly enhanced the yield: no difference in yield between OO and OL diets Diet / Tumors /rat statistics SL 3.5 a,b SO 5.0 a OO 3.0 b OL 5.1 a (statistical: different letters in the statistics column show a significant difference)	Isocaloric diets: no difference in body weight or food intakes among groups OO diet which was limited in linoleic acid content resulted in a significantly lower tumor yield. This result was abolished by supplemental linoleic acid; the results support a linoleic acid requirement of about 4% by weight for induced mammary tumor genesis in rodents
Hirose et al., 1990 (Ref. 125)	The effects of diets supplemented with perilla oil (n-3 linoleic rich) and soybean and safflower oils (n-6, linoleic-rich) on DMBA-induced mammary and colon carcinogenesis	Female SD rats 5-week old 10/groups	Diet: 10% perilla oil 10% SBO 10% SO SO SBO perilla oil 18:2n-6 74 52.6 15.9% 20:4n-6 - 0.3 0.1% 18:3n-3 0.1 .7 13.7 Rats were fed the diets for 33 weeks after the injection of initiator (7, 12-DMBA) and promotor (1, 2-dimethylhydrazine, DMH). Incidence and development of tumor measured	Mammary Perilla oil significantly lowered tumor yield compared to SBO or SO (4.4, 6.5, 5.7, tumors per rat: perilla oil, SBO, or SO, respectively) No difference in yield between SBO and SO. No difference in incidence among groups Colon perilla oil significantly lowered tumor incidence compared to SOB or SO (4, 9, or 9% incidence: perilla oil, SBO, or SO). No difference in incidence between SO and SBO No difference in yield among groups	Perilla oil may not have provided adequate linoleic acid for tumor growth

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Kumaki and Noguchi, 1990 (Ref. 112)	To measure the influence of high dietary fat on malignant intensity and hormone receptors of DMBA-induced mammary carcinoma	Female 50-day old Virgin Sprague-Dawley rats 36 to 38/groups	Diet I 0.5% CO II 20% CO Rats were fed diets for 20 weeks, and 7, 12-DMBA-induced incidence and growth of tumor tested. DNA index, S-phase fraction and hormonal receptors for estrogen, progesterone were also tested.	High fat diet significantly elevated incidence (86 versus 46%), size (13.9 versus 7.9 mm diameter) and shortened latency period (10.0 versus 13.9 weeks) compared to low fat diet No difference in hormonal receptors	Low fat diet did not provide adequate linoleic acid for growth of tumor or the animal Nonisocaloric diets used; however, body weight was not different between groups
Wan et al., 1991 (Ref. 136)	To compare effects of fish oil or safflower oil on protein synthesis and catabolism of mammary tumor grown in the peritoneal cavity	Female Pathogen-free F344 rats 60 ± 5 g	Diet I 19.5% MO + 0.5% SO II 20% SO Rats were fed the diets for 5 weeks, inoculated with mammary ascites tumor cells (13762 MAT) and fed the diets for 2 weeks Tumor size, protein turnover, and plasma lipids were measured	No difference in tumor weight between groups Significant decrease in tumor volume by FO feeding Significantly increased w-6 FA and significantly reduced w-3 FA in plasma lipids No difference in protein turnover rate in tumor or in whole body between two diet groups Significantly prolonged liver protein turnover in FO group compared to SO group	Rats were pair-fed and diets were isocaloric FO diet did not provide adequate linoleic acid for tumor growth Additional antioxidants (vitamin E and tertiary butylhydroquinone) were used
Takata et al., 1990 (Ref. 137)	To measure the effects of two different types of unsaturated FA on NMU-induced mammary carcinogenesis	Female Sprague-Dawley rats 6-week old 10 (control) and 30 (test)/groups	Diet: 5 wt% I) 4.7 wt% EPA plus 0.3 wt % linoleate II) 5 wt% linoleate Rats fed the diets for 20 weeks, N-nitroso-N-methylurea (NMU) -induced tumor incidence and yield tested	Significantly lower tumor incidence and yield (weight or number) in the EPA group EPA diet reduced prostaglandins (PGE2, TXB2, and 6-keto PGF1) in tumor, compared to linoleic acid diet	EPA diet did not provide adequate linoleic acid for tumor growth or animal growth. Unrealistically low total fat

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Bunce and Abou-El-Ela, 1990 (Ref. 135)	To measure eicosanoid synthesis and ornithine decarboxylase activity in mammary tumors in rats fed varying levels of n-3 and n-6 fatty acids	Virgin female Sprague-Dawley rats 50-day old 25/groups	Diet CO PO BCO BO MO (wt% per diet) I 20 - - - - II - 20 - - - III - - 20 - - IV - - - 20 - V 15 - - - 5 VI 10 - - - 10 VII 5 - - - 15 VIII - - - 10 n-6FA U-3FA (% per diet) I 12.1 0 II 16.8 0 III 11.3 .3 IV 12.6 0 V 9.3 1.4 VI 6.5 2.9 VII 3.6 1.2 VIII 6.7 2.9 Rats were administered i.g. 7, 12-DMBA and fed diets for 112 days Incidence and multiplicity of the tumor examined. Prostaglandin (PGE, LTB4, and LTC4) synthesis and ornithine decarboxylase (ODC) activity also tested	Incidence of adenocarcinoma: significantly lower in groups III, VI, and VII than groups II, IV, and VIII; n-3 FA level or n-6 FA/n-3FA ratio did not consistently affect the incidence Tumor yield (number/rat) was significantly lower in group II than groups IV and III; n-3 or n-6 FA did not consistently affect the yield No difference in latency period among groups	Diets provided adequate linoleic acid for growth of the animal as well as the tumor
O'Neill et al., 1991 (Ref. 142)	To measure modulation of colonic nuclear aberrations and microcapsule-trapped gastro-intestinal metabolism in benzopyrene treated mice consuming human diets	Male C57/B6 mice 6-week old 36/6 groups	Diet: I & II III IV V fat 15 45 15 energy % Protein 2.7 .1 2.7 2.7 wt% Fiber 2.1 2.1 2.1 5.6 wt% Fiber: nonstarch polysaccharide. Protein: beef protein Mice were fed the diets for 3 weeks and received benz(a)pyrene by gavage. Colonic nuclear aberration was examined histologically and by using HPLC	Benz(a)pyrene increased the nuclear aberrations by 8-fold The extent of benz(a)pyrene-induced nuclear aberrations was decreased to 2-to 3-fold by increased fiber or fat in the diet	FA composition in the diet not reported and the adequacy of dietary EFA is not known Nuclear aberration, not cancer development, was measured

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Nutter et al., 1990 (Ref. 126)	To measure effects of dietary fat and protein on DMH-induced tumor development and immune responses	Weanling, BALB/c mice Male 280/10 groups	Diet: varied in fat and protein Total fat: 5 wt% Total protein: 11 wt% Diet CO BT Casein NFDM Lyophilized beef (wt%) I 4 7 31.5 II 2.9 - 13 4 III 4 7 31.5 IV 5 12.1 - V 5 20 - Diet V was AIN-76A diet Mice were fed until 51 weeks of age. Incidence and development of the dimethylhydrazine (DMH)-induced tumor as well as immune response was measured. DMH was injected subcutaneously for 10 weeks	CO plus NFDM diet significantly elevated tumor yield compared to other groups Number of tumors per tumor-bearing mouse I 12.3 II 2.6 III 3.2 IV 5.3 V 4.4	Total fat levels in the diets do not match between the levels described in the Methods and the levels found in authors' Table 1 BT diets may not have provided adequate linoleic acid for growth of tumor The effect of CO on tumor yield was not consistent
Nicholson et al., 1990 (Ref. 118)	To measure the influence of dietary fats (beef suet rich in saturated fat and corn oil rich in linoleic acid) on colorectal carcinogenesis	Wistar rats Male 5-week old 57/groups	Diet 5% beef suet (BS) 20% beef suet 5% corn oil 20% corn oil FA composition in diet linoleic (%) arachidonic 5%bs 12.7 2.3 20%bs 5.4 0.5 5%CO 42.4 0.9 20%CO 48.6 0.5 Animals were fed the diets for 16 weeks before and 6 weeks after azoxymethane, which was injected once a week for 6 weeks. Yield (#) of adenoma and carcinoma measured. Mucosal and tumor FA composition also measured	No difference in adenoma yields The BS diets produced significantly more carcinoma than CO diets (1 versus 12 carcinoma, 5% CO versus 5% BS; 2 versus 28 carcinoma, 20% CO versus 20% BS) 20% BS produced significantly more carcinoma than 5% BS (28 versus 12 carcinoma; 20% BS versus 5% BS); difference for CO was nonsignificant (2 versus carcinoma; 20% CO versus 5% CO) Arachidonic acid was higher in tumors than in colonic mucosa regardless of fat source N-6 FA may suppress the development of colorectal carcinoma. The data also suggest an association of prostaglandins with colorectal tumor development	Nonisocaloric diets used; however, no difference in food consumption or in body weight BS diets, which may have provided insufficient linoleic acid for tumor growth, had elevated tumorigenesis. The results suggest linoleic acid requirements may be different for different tumor sites

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Behling et al , 1990 (Ref. 119)	To measure the effect of varying levels of dietary calcium and butterfat on cecal enzyme activity and development of DMH-initiated colon tumors in rats	Weanling male Sprague-Dawley rats 112/4 groups	Diet: I 1% CO + 5% butter fat + 2.5 g Ca/kg II 1% CO + 5% butter fat + 10 g Ca/kg III 1% CO + 20% butter fat + 2.5 g Ca/kg IV 1 CO + 20% butter fat + 10 g Ca/kg Diets fed for 2 weeks before and 31 to 34 weeks after the injection of DMH Incidence and development of intestinal tumor examined. Enzymic activity in cecum and lipid extraction in feces also measured	No difference in tumor yield among groups High Ca increased fecal lipids	All diets may not have provided adequate linoleic acid for tumor growth The study focused on the effect of Ca, not lipids
Lindner, 1991 (Ref. 129)	The effect of n-3 PUFA on colon cancer in mice. Effects of high fat and high cholesterol diets and low fat cholesterol free diets in mice	Swiss-Webster mice 6 to 7-week old 174/4 groups	Diet BT SO FO MaxEPA Low fat (wt%) Tot fat 19.2 19.2 19.2 3.5 n-6FA 3.5 14.3 .8 2.0 n-3FA 0 4.4 0 MUFA 7.5 2.8 5.2 1.0 Mice were fed the diets for 4 weeks, received 1.2-DMH for 11 weeks Tumor development in the intestinal tract (from esophagus to rectum) was examined. Plasma lipids also examined	Significantly higher body weight in BT group than low fat or FO groups and in SO group than low fat group No difference in mortality Higher colon tumor incidence in the BT groups; significance between BT and FO group. Tumor incidence in other sites (kidney, liver, skin, and scrotum) was lower in the BT group (significance between BT and low fat group) Colon tumor No difference in adenoma yield. Significantly higher adenocarcinoma in BT group than SO or FO group. FO was protective: adenocarcinoma yield was the lowest in the FO group; significance between FO and BT group. (Mean tumors per animal 1.23, 0.47 and 0.23; BT, SO and FO) Oleic acid and MUFA content (%) in the plasma or in colon mucosa were linearly correlated with tumor yield; dietary MUFA was reflected in plasma but not in colon mucosa n6 PUFA or linoleic acid was not associated w/ tumor yield: dietary level of linoleic acid was reflected in plasma and colon mucosa n-3 PUFA and EPA level in plasma or colon mucosa was significantly, negatively correlated w/ tumor production	The FO (MaxEPA) may have a protective role in DMH-induced colon tumorigenesis in Swiss-Webster mice The effect of carcinogen, DMH, was different among sites of tumorigenesis and the findings cannot be generalized to cancer sites beyond colon

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Smith et al., 1990 (Ref. 121)	The effects of high fat diet and CCK-receptor antagonist on growth of human pancreatic tumor cells in nude mice	Male 5 to 6-week old Athymic nude mice 15/groups	Diet 4.3% fat chow diet 20.3% fat diet: 4.3% fat in the chow + 16% CO Mice were injected w/ SW-1990 human pancreatic adenocarcinoma cell line and fed the diets for 23 days. The effects of dietary fat and CCK-receptor antagonist L364718 on pancreatic tumor development examined	Among L364718 untreated animals, the high fat diet significantly increased tumor volume and protein content in tumor, compared to the chow diet L364718 significantly decreased tumor yield; endogenous CCK (cholecystokinin) may promote the growth of pancreatic tumor in mice	FA composition of chow diet not reported. The chow diet may have provided insufficient linoleic acid for tumor growth Tumor cells, assayed in vitro, were used
Longnecker et al., 1990 (Ref. 122)	To measure the development of pancreatic neoplasms in elastase-1-simian virus transgenic mice	Elastase 1 simian virus transgenic mice Strain Tg (Ela-1, SV40E) Bril 18 Female and male 11 to 23/groups	Diet chow: 5-6% fat AIN-76A: 5% CO Hi-fat: 20% CO Diets were fed for 22 to 23 weeks. At autopsy, incidence and multiplicity of the tumor examined	Incidence of exocrine carcinoma: significantly reduced by chow diet No difference between AIN-76A and high fat diets Incidence of islet cell tumor: no difference among groups	Genetically transformed, transgenic mice were used: extrapolation of results to human is questionable Extremely low total fat Linoleic acid content of the chow diet is not known
Oth et al., 1990 (Ref. 131)	The modulation of CD4 expression in lymphoma transplanted to mice fed n-3 PUFA	Adult AKR mice	Diet No fat, basal diet I 1% FO II 1% BT III 4% FO IV 4% BT V 6% FO VI 6% BT VII 8% FO VIII 8% BT IX 16% FO X 16% BT FO: 23 7% SFA, 30.3% n-3 FA, 1.3% linoleic acid Experimental diets were fed for 6 weeks before and 2 weeks after tumor xenograft by intraperitoneal transplantation. RDM-4 tumors in ascites were harvested and examined. Cell surface markers tested as well	Considerably (statistics not tested) faster tumor growth in the FO-fed donor than in the BT- or no-fat-fed donors Significantly reduced CD4 cell surface marker in the FO groups than BT groups; other markers such as CD8, H2K, Thy-1, and LFA-1 markers were not affected No effect of total fat	Both BT and FO diets may not have provided adequate linoleic acid for tumor growth

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Ayachi et al., 1990 (Ref. 130)	To test the suspectibility of lymphome cells to lymphokine-activated killer (LAK) cells in mice fed high fat, fish oil diets	AKR mice	Diet 4% FO 4% HBT 8% FO 8% HBT 16% FO 16% HBT n-6 FA content HBT: 0.1 wt% FO: 2.2 wt% Mice were fed the diets for 6 weeks before and 12 to 15 weeks after the intraperitoneal graft of RDM4 lymphoma cells	Tumor yield was significantly greater in the FO group than in the HBT group FO increased resistance of lymphoma cells to lysis by lymphokine activated killer cells in vitro No effect of total fat	Experimental diets may not have provided adequate linoleic for growth of tumor and the mice Total fat in 4 to 8% fat diets was unrealistically low Due to the limitation in dietary linoleic acid, results are not useful for evaluating the effect of fat
Locniskar et al., 1991 (Ref. 127)	To compare the effects of fish, coconut, and corn oils on skin tumor promotion by benzoyl peroxide in mice	Weanling Female SENCAR mice 30/groups	Diet: 10% total fat CCO / CO / MO (wt%) A 8.5 / 1.5 / - B 7.5 / 1.5 / 1.0 C 4.5 / 1.5 / 4.0 D - / 1.5 / 8.5 E - / 10.0 / - Mice were fed 5% CO diet for 3 weeks, treated with an initiator, 7,12-DMBA, fed 10% CO diet for 2 weeks, fed the experimental diets (A-E) for 52 weeks, and treated with benzoylperoxide (promoter) biweekly. Latency, incidence, and yield of papilloma and carcinoma examined. Ornithine decarboxylase (ODC), vascular permeability, and hyperplasia of the dorsal skin were also examined	Papilloma Significantly higher cumulative tumor probability in Diet A than Diet B, D, and E, but not C. Papilloma yield was significantly greater in Diet A or Diet C than Diet B, D, and E (Tumor probability was mathematically calculated) Carcinoma Significantly higher tumor incidence and cumulative tumor probability in Diet A and Diet E: no difference in incidence among Diet B, C and D. Carcinoma yield not reported No difference in ODC activities or vascular permeability among groups. Significantly greater hyperplasia in Diets B and C than Diets A, D, and E	Low total fat in the diets Except Diet E, all the diets may have provided inadequate linoleic acid for tumor growth. Diet E with adequate linoleic acid resulted in the longest latency period, lowest tumor incidence, and least tumor yield The results suggest that growth of skin tumor may not require 4% dietary linoleic acid and that the effect of dietary fat on tumorigenesis is site-specific In the 10% fat diet, high PUFA in the diet showed a protective effect and high SFA in the diet showed a promoting effect while the effect of n3 FA-rich diet was intermediate

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Leyton et al., 1991 (Ref. 128)	To measure effects of type of dietary fat on phorbol-ester-elicited tumor promotion in mouse skin	Female SENCAR and DBA/2 mice 4-week old 30 mice/groups	Diet Initiation period: 5 wt% total fat Co CCO C18:2n-6 all 1.7% 3.3% 1.0% promotion period: 15 wt% total fat CO CCO C18:2n-6 I 1.0 14 0.8 II 3.6 11.4 2.2 III 6.0 9.0 3.5 IV 7.9 7.1 4.5 V 9.9 5.1 5.6 VI 12.5 2.5 7.0 VII 15. 0. 8.4 7,12-DMBA initiated and 12-O-tetradecancyl-phorbol-13-Acetate(TPA)-promoted papilloma development determined	Papilloma incidence: No difference among groups Significant inverse correlation between CO level and papilloma yield (r = 0.92), 5.4 tumors versus 11.7 tumors per mouse; 15% CO versus 10% CO in SENCAR mice). Similar results found in DBA/2 mice The results suggest that increasing dietary CO or decreasing SFA may suppress skin tumor in mice TPA'elevated epidermal PGE2 in all diet groups: the extent was negatively correlated with dietary CO	The effect of total fat not tested Low PUFA/high SFA diet significantly enhanced DMBA- and TPA-induced skin tumor yield than high PUFA/low SFA diet; this result is inconsistent with the 4 to 5 wt% linoleic acid requirement found in mammary and pancreatic tumorigenesis in rats. The results suggest that the effect of dietary fat may be specific for tumor sites
Jenski et al., 1991 (Ref. 143)	To measure the release of cytosolic components from leukemic cells inoculated into mice fed menhaden oil or coconut oil	BALB/c mice Female and male 4/groups	Diet I 10% MO + basal chow diet II 10% CCO + basal chow diet III 20% MO + ICN fat free diet IV 20% HCO + ICN fat free diet Mice were fed the diets for 5 weeks, inoculated intraperitoneally with murine leukemia cell line T27A, and fed the diets for 1 week Membrane permeability of tumor cells was examined in vitro by examining 51CR release from the cells	Increased membrane permeability in the MO groups The enhanced membrane permeability was correlated with n-3 FA (DHA and EPA) incorporated into the tumor cells	Diets may not have provided adequate linoleic acid for optimal tumor growth Tumor development not measured. Eradication of tumor was measured indirectly by measuring cell permeability intravenously

TABLE 2--continued

Study	Objectives/ Tumor Types	Experimental Animals	Methods	Results	Comments
Nielsen et al., 1990 (Ref. 120)	To test the modulation of dietary fat, varied in the quality and the quantity, of the oxidative stress and chemical-induced liver tumors in rats	Male wister rats 4-week old	Diet SSO lard (wt%) I 2 0 II 1 III 12.5 0 IV 1 11.5 V 25 0 VI 1 24 Rats were fed for 10 weeks prior and 33 weeks after the N-nitrosodimethylamine (NDMA) administration by gavage Tumor prevalence as well as plasma lipids and lipid peroxidation were measured	High-PUFA diet (25% SSO) significantly elevated tumor incidence compared to low PUFA diet (2% SSO), (80% versus 42%; 25% SSO versus 2% SSO) Fat type did not significantly affect tumor incidence High-PUFA diets (25% or 12.5% SSO) reduced plasma cholesterol and TG concentration compared to high SFA diets (25% or 12.5% lard diets)	Except 12.5% SSO and 25% SSO diets, all diets may have provided inadequate linoleic acid for tumor growth Monisoceleric diets used: body weight changes were not significantly different among groups Due to limitations in study design, the effect of dietary fat on cancer development cannot be evaluated

Abbreviations
BCO: black currant seed oil
CO: corn oil
EFA: essential fatty acid
i.p.: intraperitoneal
PUFA: polyunsaturated fatty acid
SBO: soybean oil
BO: borage oil
CCO: coconut oil
FO: fish oil
MO: menhaden oil
PrO: primrose oil
SO: safflower oil
BS: beef suet
DMBA: 7, 12-dimethylbenzanthracene
FA: fatty acid
MUFA: monounsaturated fatty acid
RR: relative risk
BT: beef tallow
DMH: 1, 2-dimethylhydrazine
HBT: hydrogenated beef tallow
NFDM: nonfat dried milk
SSO: sunflower seed oil
Ca: calcium
EPA: eicosapentaenoic acid
HCO: hydrogenated corn oil
PO: palm oil
SFA: saturated fatty acid

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N–0095]

RIN 0905–AB67

Food Labeling: Health Claims and Label Statements; Sodium and Hypertension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to authorize the use on the label or labeling of certain foods of health claims relating to an association between dietary sodium and high blood pressure. The agency has concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets low in sodium may help lower blood pressure in many people. Therefore, FDA has concluded that claims on certain foods relating sodium reduction to reduced risk of high blood pressure are justified. This action is in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) that bear on health claims, and is developed in accordance with the final rule on general requirements for health claims, which is published elsewhere in this issue of the **Federal Register**.

EFFECTIVE DATE: May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Ellen M. Anderson, Center for Food Safety and Applied Nutrition (HFF–266), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5375.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60825), FDA proposed to authorize the use on food labeling of health claims relating diets low in sodium to lower blood pressure in some people. The proposed rule was issued under provisions of the 1990 amendments (Pub. L. 101–535) that bear on health claims and in accordance with the proposed general requirements for health claims for food (56 FR 60537, November 27, 1991). As amended in 1990, the Federal Food, Drug, and Cosmetic Act (the act) provides that a food is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition unless the claim is made in accordance with section 403(r)(3) or (r)(5)(D) of the act (21 U.S.C. 343(r)(3) or (r)(5)(D)).

Section 3(b)(1)(A) of the 1990 amendments specifically requires that the agency determine whether claims respecting 10 nutrient/disease relationships meet the requirements of section 403(r)(3) or (r)(5)(D) of the act. The relationship between sodium and hypertension is one of the claims required to be evaluated. In the **Federal Register** of March 28, 1991 (56 FR 12932), FDA published a notice requesting scientific data and information on the 10 specific topic areas identified in the 1990 amendments. Relevant scientific studies and data received in response to this request were considered as part of the agency's review of the scientific literature on sodium and hypertension and were included in the proposed rule. Comments received in response to the notice and not specifically addressed in the proposed rule are summarized and addressed below.

In addition to evaluating the scientific evidence, the proposed rule identified qualifying and disqualifying criteria for foods bearing health claims on sodium and hypertension. The proposed rule also specified mandatory and optional information for health claim statements and provided a sample claim. FDA requested written comments in response to its proposed rule and solicited comments on several issues in particular. The agency asked whether foods with minimal nutritional value should be allowed to bear health claims and whether a statement of the recommended range of sodium intake (500 to 2,400 milligrams (mg) per day) should be required or remain optional. The agency requested comments on requiring the use of the terms "sodium" rather than "sodium chloride" and "high blood pressure" rather than "hypertension," and on allowing the terms "salt" in addition to "sodium" and "hypertension" in addition to "high blood pressure." The agency also requested comments on whether a statement indicating that identified hypertensives should consult their physicians should be allowed or required, on the safety of the recommendations to reduce sodium and salt intake, and on the proposed "Consumer Summary on Sodium and High Blood Pressure."

On January 30 and 31, 1992, FDA held public hearings on all aspects of the proposed rules published in response to the 1990 amendments, including health claims for sodium and high blood pressure (57 FR 239).

In response to its proposed health claim regulation on sodium and hypertension, the agency received approximately 100 comments from consumers, consumer advocacy groups, State health departments, organizations of health professionals, the food industry, and Government agencies. A number of comments were received that were more appropriately addressed in other documents, and these comments were forwarded to the appropriate docket for response.

II. General Comments

1. One comment noted that it is difficult to find a variety of foods that meet recommended dietary sodium levels and expressed the hope that this regulation would encourage industry to provide more low sodium foods.

FDA strongly encourages innovation in providing consumers with a wider variety of choices. FDA's labeling and education initiatives in the early eighties resulted in a 60 percent increase in sodium content labeling from 1978 to 1988 (Ref. 46) and the introduction of additional low sodium products (Ref. 56). The current initiatives include not only sodium/hypertension health claims, but also mandatory sodium labeling, a daily value (DV) for sodium, sodium disqualifying levels for health claims, and sodium disclosure levels for nutrient content claims. FDA anticipates that these regulations will motivate manufacturers to develop and market a broader range of lower salt products for the American consumer.

2. Another comment argued that consumers will wrongly believe that consumption of foods with too much sodium to qualify for a sodium/hypertension health claim will necessarily lead to exceeding current dietary guidelines.

FDA disagrees. Rather, the agency believes that health claims will encourage the availability and consumption of foods that will help consumers meet dietary guidelines. Furthermore, auxiliary educational programs, consistent with the dietary guidelines philosophy, can help consumers understand that, by consuming a variety of foods, some higher in sodium and some lower in sodium, they can meet total dietary intake goals.

3. One comment opposed sodium restrictions on foods, arguing that restrictions would be likely to hinder the development of low fat foods and that reducing fat in the diet is more important than reducing sodium. The comment submitted supporting data from surveys in which nutritionists and

physicians rated their most important health concerns (Refs. 137 and 142). Although reduction in sodium intake was ranked as a "high priority" for good health (Ref. 142) and a "moderate priority" for improved heart health (Ref. 137), the comment noted that the survey results indicate that reducing fat was considered a higher priority than reducing sodium.

It was not clear whether the comment objected to sodium/hypertension health claims, to disqualifying levels for sodium on other health claims, or to both. In the 1990 amendments, Congress specifically identified sodium and hypertension as one of ten topics to be evaluated for health claims and did not limit claims to the highest priority health issues. FDA evaluated the totality of the scientific information and the extent of the scientific agreement among qualified experts and concluded that claims for sodium and hypertension should be allowed. In addition, the provisions of the 1990 amendments state that health claims may not be made on a food that contains a nutrient that increases the risk of a disease or health-related condition. Sodium was one of four nutrients identified by the agency as increasing the risk of a disease or health-related condition.

FDA disagrees that these survey results are relevant to its duty under the 1990 amendments with regard to health claims for sodium and hypertension. FDA need only establish that a relationship between sodium and hypertension is supported by the totality of the scientific evidence and by significant scientific agreement among experts qualified by experience and training to evaluate such evidence. A poll of scientists ranking sodium/hypertension concerns relative to fat/heart disease concerns does not contribute to this process.

FDA recognizes the importance of encouraging the development and use of more low fat foods. The agency has authorized two health claims that may appear only on foods low in fat (final rules on lipids and cardiovascular disease and on lipids and cancer health claims, published elsewhere in this issue of the **Federal Register**). Sodium is a disqualifying nutrient for these and other health claims, because diets high in sodium increase blood pressure in many people and, therefore, increase the risk of high blood pressure and associated risks of heart disease and stroke. (See the final rule on general requirements for health claims, published elsewhere in this **Federal Register**).

4. Several comments asserted that the agency adequately considered safety concerns regarding reductions in sodium intake in the proposed regulation. The Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) prepared a final independent evaluation of the scientific evidence on sodium and hypertension (Ref. 138) and submitted this as a comment. An earlier draft of the report (Ref. 108) was discussed in the proposed rule (56 FR 60825 at 60829). The FASEB report (Ref. 138) concluded that severe sodium chloride restriction (less than 20 milliquivalents (meq) or 460 mg sodium per day) may have adverse consequences, but that, in the absence of obvious salt-losing disorders, there is no evidence that avoiding high sodium chloride intakes would be deleterious to health. Other comments, including a review article (Ref. 144), disagreed with FDA's assessment, arguing that there is inadequate scientific evidence that curtailing sodium will safely reduce the risk of hypertension; that there is a growing body of scientific evidence that reducing sodium may put some healthy people at risk, that no populations with free access to salt choose such low levels and the risks of these levels have not been considered; that severe restriction in animals results in some risks; that in the older literature, extremely low sodium intake in humans resulted in some symptomatic distresses; and that FDA has no studies that demonstrate safety and efficacy of universal sodium restriction, especially in normotensives. The comments submitted no data demonstrating that daily dietary intakes of 2,400 mg sodium are unsafe.

The agency has considered and addressed the safety concerns and believes that the recommended goal of 2,400 mg per day is safe. The National Academy of Sciences, which recommended the 2,400 mg daily goal, is considering dropping the current target goal to 1,800 mg sodium per day (Ref. 62). Furthermore, the 1989 Recommended Dietary Allowances (Ref. 63) identify 500 mg sodium as a safe minimum daily intake for adults, and 2,400 mg is well above this safe minimum intake level. Other authoritative documents also agree that a moderate sodium intake is safe (Refs. 38, 43, and 62). Numerous experiments with low sodium diets have been conducted with no serious consequences. Finally, dietary guidelines since the early eighties (Refs. 9, 22, and 85) have recommended moderation in sodium intake with no ill effects. Given these conclusions, the lack of data demonstrating safety concerns with daily consumptions of 2,400 mg sodium, and the extreme difficulty in achieving an intake of sodium at or below the 500 mg per day minimum safe level in the U.S. diet, FDA concludes that there are no safety risks associated with use of the sodium/hypertension health claim.

5. A few comments from health professionals supported FDA's description of the special considerations and risks involving sodium losses during sustained exercise or training in hot temperatures. One comment specifically supported responding to these risks with education efforts as proposed by the agency.

FDA acknowledges these comments.

6. Some comments supported FDA's conclusion in the proposed rule that the study results (Refs. 33 and 72) that suggest some individuals may respond to sodium reduction with blood pressure increases rather than decreases may be due to random variations and require additional research to determine if the results of these few studies are significant and reproducible. Other comments disagreed. One comment stated that many people believe that the results of the INTERSALT study (Ref. 37) confirm this heterogeneous blood pressure response.

FDA acknowledges that there is wide variability in blood pressure response to changes in sodium intake, but disagrees that recommended sodium intake goals pose safety risks. The INTERSALT (Ref. 37) and other study results (Refs. 41, 44, 45, 76, 80, 94, 97, 100, 106, 107, 109, 121, 122, and 123), in spite of large background fluctuations and a dilution effect of including nonresponsive individuals, clearly show that reducing sodium intake has a measurable and beneficial effect on reducing average blood pressure. The agency encourages additional studies under controlled conditions; however, FDA disagrees that this normal variability, which commonly occurs with physiological measurements, calls into question the safety of current intake recommendations of 2,400 mg per day.

7. A few comments supported FDA's conclusion in the proposed rule that the possible adverse changes in plasma lipids in response to sodium restriction (Refs. 2, 40, 49, and 89) do not pose safety concerns for the general public consuming recommended intakes of sodium. One comment indicated that the sodium intakes in these studies were very low and that the observed effects could have been due to dehydration. Other comments disagreed. One comment, accompanied by three studies, accused FDA of failure to give

the plasma lipid studies proper consideration.

In preparing its proposal, FDA reviewed the plasma lipid studies submitted. Sodium intake levels in these studies were very low (460 and 780 mg daily) relative to current U.S. intakes (approximately 3,000 to 6,000 mg daily) and dietary guidelines (2,400 mg daily). Also, the intervention periods were very short (one week or less). The agency encourages additional research, but disagrees that a few studies involving sodium intakes of 460 to 780 mg daily are relevant or raise safety concerns for the general public consuming well in excess of this amount or for public health agency recommendations encouraging moderate sodium intakes of 2,400 mg per day.

8. One comment included recent study data (Ref. 91), which the comment believed linked reduced sodium intake to high plasma renin levels and risk of myocardial infarction.

FDA reviewed the study data submitted and located a review article associated with the original study (Ref. 96). The incidence of myocardial infarction was low (27 instances in 1,717 subjects over 8.3 years) in a narrow and limited population group (predominantly nonwhite, hypertensive males with 20 percent excluded for renin levels outside the limits established for the study). Furthermore, sodium intakes per se were not evaluated in relationship to potential risk. It is unclear whether there is a causal relationship or whether renin levels simply serve as a marker for high risk. It is clearly premature to extrapolate the results of one study with a variety of limitations to the effects that a modest reduction in dietary sodium may have on the general population.

9. One comment mentioned that sodium restriction might precipitate sodium depletion in people with "wasting" nephropathy or chronic renal failure, but that it might also ameliorate their hypertension. The comment noted further that, at this time, there is not enough information to know what might occur and that patients with these diseases need specific advice from their physicians.

FDA agrees that there is not enough information to know if sodium restriction to 2,400 mg would pose any concern or be of any benefit with regard to "wasting" nephropathy or chronic renal failure. These are serious diseases and persons with these conditions should be under a physician's supervision and monitoring. Should these persons need to be concerned about their sodium intake, mandatory nutrition labeling of sodium content on all foods can help them meet specific dietary goals set by their physicians and health care consultants.

10. A couple of comments expressed concern that, in consuming low sodium foods, individuals might be missing important nutrients.

FDA disagrees. Many nutrient-rich foods are relatively low in sodium and will qualify for sodium/hypertension health claims (e.g., fruits, vegetables, and some dairy products). Additionally, substitute foods formulated to be low in sodium must be nutritionally equivalent to the foods that they are intended to replace (21 CFR 101.3(e)). Failure to maintain nutritional equivalency results in identification of the substitute food as an "imitation" product. With the mandatory labeling of a core set of nutrients, including sodium, for foods generally (see the final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**), people consuming low sodium foods as part of a total diet can select a variety of foods and meet nutrient needs.

11. One comment stated that FDA has determined that current U.S. intakes of sodium are not safe. The comment argued, therefore, that current levels are not generally recognized as safe (GRAS), that the food industry should bear the burden of proof that current levels are safe, and that, in the absence of such proof, FDA is obligated to require that salt levels be reduced and the food industry is obligated to lower the levels of salt currently being added to foods.

FDA disagrees. Salt has traditionally and historically been regarded as a GRAS substance (21 CFR 182.1), and the GRAS safety review in 1982 (47 FR 26590, June 18, 1982) deferred regulatory action until the impact of the sodium labeling initiatives (47 FR 26580, June 18, 1982; 49 FR 15510, April 18, 1984) could be assessed. The agency is not aware of any new data that would raise significant additional safety concerns. There is thus no basis for reopening the question of salt's GRAS status at this time.

III. Statement of the Relationship of Sodium and Hypertension

In the proposed rule (56 FR 60825), FDA tentatively concluded that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that there is a relationship between sodium intake and high blood pressure. Some comments agreed with this conclusion, often providing no evidence. A few comments disagreed and provided specific reasons for their objections.

12. Several comments supported FDA's conclusion that there is sufficient evidence of and significant agreement about a relationship between sodium and hypertension. The FASEB report (Ref. 138) concluded that "both observational data and intervention trials document a small, but consistent effect of dietary sodium chloride on blood pressure." The report further noted that the association between sodium intake and blood pressure may be more meaningfully extrapolated to a population than applied to an individual, that additional studies are necessary to assess the dose-response relationship, and that human data provide no evidence that blood pressure at one age is related to salt intake at an earlier age. A submitted study by Espinel (Ref. 143) identified specific patients and levels of salt intake that triggered hypertension. The results were repeated between 2 months and 1 1/2 years later and remained stable and reproducible.

A few comments and a review article (Ref. 144) disagreed and noted that the scientific data on sodium and hypertension are variable, complex, inconsistent, and more complicated than previously accepted. These comments argued that the epidemiological (i.e., observational) evidence is weak and that information from a natural setting where individuals select their own diets provides no information on how alterations would affect blood pressure. They also argued that modification studies have been short-term, that there are few long-term maintenance studies and data, and that the data are insufficient to support significant long-term effects, including long-term blood pressure changes and reduced rates of stroke and cardiovascular disease. These comments noted that, in contrast, clinical trials of lifesaving drugs often last several years. They suggested that FDA erroneously cited the INTERSALT study to establish that a lifetime lowering of sodium chloride would lower risk of hypertension, and that FDA should avoid giving prescriptive recommendations on weak observational data.

These comments argued further that there is significant controversy regarding the relationship between sodium and hypertension and, therefore, insufficient scientific agreement to support a health claim. The comments noted that the FASEB Report (Ref. 108) concluded that the within-population study data were inconclusive or showed low correlation, and that there was only sparse or inconclusive long-term information

about the relationship. They observed that no consensus was reached at the Workshop on Salt and Hypertension (Ref. 103), and noted that the Dietary Guidelines Advisory Committee (Ref. 135) reported that such a lack of consensus, especially relative to guidance for nonhypertensives, was apparent. (Other comments indicated that, even though consensus was not an aim of the workshop, a large degree of consensus was exhibited.) The comments observed that FDA acknowledged in its proposal the highly polarized views at the Hypertension Workshop (Ref. 103) and the controversy over the interpretation of the INTERSALT results (Ref. 37). The comments argued that the intense and continuing nature of the debate over the relationship between sodium and hypertension evidences lack of significant scientific agreement. The comments accused FDA of not attempting to understand the controversy and change its public health policies, but rather simply dismissing new studies and asserting that there is significant agreement among scientists.

FDA agrees with the FASEB report that there is a small but significant effect of sodium on blood pressure and with the Espinel study results demonstrating that sodium intake can trigger hypertension. This position is consistent with the tentative conclusions reached in the proposal. FDA noted in the proposed rule that the science is complicated by the multifactorial nature of the blood pressure response and that blood pressure varies for each individual and among different individuals. Nonetheless, in spite of large average fluctuations in confounding variables and the resultant impact on blood pressure response, there continues to be a small, significant, and independent impact of sodium on blood pressure, which is supported by the FASEB report (Ref. 138), the National Academy of Sciences' Report (Ref. 62), the Surgeon General's Report (Ref. 43), the INTERSALT study (Ref. 37), and other recent studies (Refs. 41, 44, 45, 55, 71, 76, 80, 90, 94, 97, 100, 106, 107, 109, 121, 122, and 123).

FDA recognizes that data from carefully controlled clinical trials are stronger than data from human observational studies. The methodologic problems in observational studies are more difficult to address adequately, and there are more individually negative observational studies than trials. Furthermore, pooling of studies is more difficult for observational studies, because of the need to control for confounding variables. Finally, most observational studies are cross-sectional, so they do not establish time-orders (i.e., cause precedes effect). However, despite these limitations, FDA contends that, in general, the human observational data support a relationship between sodium and hypertension. The recent, multinational INTERSALT study (Ref. 37) used carefully standardized methodologies and comprehensive data analysis. The study reported a significant relationship between sodium intake and systolic blood pressure (SBP) for the pooled within-center data and for changes in blood pressure with age for the across-center data. This conclusion is likewise supported by other authoritative reports (Refs. 43 and 62) and is consistent with and strengthened by the experimental evidence provided by randomized clinical trials.

FDA acknowledges that long-term, prospective study data are limited and sometimes inconclusive. However, obtaining definitive, long-term human data on the development of hypertension may be difficult due to a wide variety of factors: (1) the long time necessary for the development of the disease, (2) the large sample and control populations needed for statistical significance, (3) the small absolute magnitude of the effect of sodium on blood pressure, (4) the wide variations in salt content in foods and food products, (5) the large day-to-day and year-to-year variability in dietary sodium intake, (6) the large fluctuations in blood pressure response in the individual, (7) the multifactorial response of blood pressure to a wide variety of nutritional and environmental factors, and (8) the ethical considerations of encouraging or maintaining long-term, high-sodium diets in a control population. The feasibility of obtaining definitive study data was discussed in greater detail in the proposed rule on general requirements for health claims (56 FR 60537 at 60548 through 60549). Nonetheless, although three long-term intervention studies were inconclusive (Refs. 42, 70, and 124), the abstract (Ref. 123) and the recently reported final study results (Ref. 145) of the 18-month Trials of Hypertension Prevention (TOHP) Collaborative Research Group, which were published subsequent to the proposed regulation, reported conclusively that a reduction in sodium intake reduced blood pressure in the sodium intervention group and also showed a trend towards a reduced incidence of hypertension. The 18-month followup of the Koopman study (Ref. 76) also documented reduced blood pressure in response to reduced sodium intake. The results of these clinical trials are thus consistent with and strengthen the INTERSALT results (Ref. 37), which are cross-sectional. Additionally, the INTERSALT study provides useful information for making limited inferences on long-term effects of sodium reductions on blood pressure. The INTERSALT study reported a statistically significant relationship between sodium intake and the slope of SBP and diastolic blood pressure (DBP) with age; i.e., the difference in blood pressure of older individuals in a population relative to younger individuals in the same population is greater in populations with high sodium intake than in populations with low sodium intake. The lack of definitive long-term studies is, therefore, not sufficiently problematic to disallow sodium/hypertension health claims, given the strength of the short-term clinical data relating sodium intake and blood pressure, the difficulties associated with obtaining long-term sodium/hypertension data, and the long history of support by authoritative bodies for public health policies encouraging all people to reduce their sodium intake.

Finally, FDA recognizes that, as is typical in science, there is a wide range of opinion regarding the relationship between sodium and hypertension, and consensus is rarely reached. A requirement for "significant scientific agreement" has not been interpreted by FDA to mean a requirement for consensus. (See final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.) FDA believes that there is sufficient scientific evidence to provide strong support for a relationship between dietary sodium intake and high blood pressure, and that there is significant scientific agreement that the evidence supports the relationship. In the proposed rule, FDA summarized Government and authoritative reports that concluded that the evidence was sufficiently strong to support a relationship between salt or sodium and high blood pressure, and many of these reports recommended that sodium intake be decreased (Refs. 38, 43, 62, 63, and 85). The interim and final FASEB reports (Refs. 108 and 138) concluded that the totality of the data supports a relationship between dietary sodium chloride and blood pressure. The INTERSALT study (Ref. 37) reported evidence of a relationship between sodium and high blood pressure. Most authors supported the INTERSALT findings and favored sodium restriction

(Refs. 50, 52, 60, 69, 75, 111, and 114), whereas only a few authors considered the effect to be too small and opposed sodium restriction (Refs. 90 and 120). The other scientific studies evaluated in the proposed sodium/hypertension health claim regulation generally supported a relationship between sodium and high blood pressure, although a few were inconclusive or not supportive. Finally, most of the reports at the Hypertension Workshop (Ref. 103) supported reductions in dietary sodium intake (Refs. 94, 95, 97, 98, 102, 104, 105, and 113), while only a few were in opposition (Refs. 110 and 112). Vigorous, spirited debate is necessary to the scientific process and should be encouraged. However, despite the existence of differences of opinion, FDA concludes that, based on the totality of the scientific evidence, there is significant scientific agreement among qualified experts that diets high in sodium are associated with high blood pressure.

13. One comment questioned FDA's evaluation of the INTERSALT data (Ref. 37), indicating it was possibly serious abuse of the scientific data, including a possibly intentionally misleading interpretation. The comment stated that the INTERSALT authors, in their abstract, concluded both that there was no relationship between sodium intake in a society and the prevalence of hypertension within that society, and that there was a positive association between the level of sodium in a society's diet and the rate of rise in blood pressure with age. The comment argued that, if both statements are correct, then the societies with higher sodium intakes must have had lower blood pressures earlier in life, could not have had more hypertension even after 40 years, and must have had lower blood pressures from 20 to 60 years of age.

The FASEB report (Ref. 138) summarized the results of the INTERSALT study, noting that, after adjustments for age and gender, sodium was significantly correlated with SBP in 39 of the 52 centers and with DBP in 33 of the 52 centers, and that there was a significant linear relationship between average sodium excretion and the slope of SBP with age for all 52 centers, which remained significant when four populations with low salt intakes were excluded.

FDA disagrees with the comment criticizing FDA's evaluation of the INTERSALT study. The conclusions of both the FASEB report (Ref. 138) and the authors of the INTERSALT study are consistent with FDA's interpretation and not with those of the objecting comment. In the discussion, the INTERSALT study authors noted that some of the results across the centers were no longer statistically significant when the results from four centers with low sodium excretion were excluded. They attributed this to diminished statistical power due to an upper limit of sodium intake that was lower than anticipated, which resulted in a range of intakes too narrow to provide adequate detection sensitivity. They also noted that multiple confounding factors, such as climate, physical activity, and acculturation, would affect results across several centers but would be less likely to confound results within centers. The authors concluded by emphasizing that the data across the centers showed a significant positive association between sodium intake and the slope of increasing blood pressure with age for all 52 centers, which remained significant when the 4 populations with low salt intakes were excluded. These results are consistent with the findings within the centers. FDA believes that it has presented an accurate summary of the INTERSALT results that neither intentionally nor unintentionally misrepresented the authors' findings. FDA also believes that the INTERSALT study provides a useful piece of evidence for supporting the sodium/hypertension relationship that is consistent with and strengthens conclusions in recent consensus and authoritative reports (Refs. 43, 85, 62, and 63).

14. A couple of comments contended that, because there is controversy surrounding the interpretation of the INTERSALT data, FDA is legally and scientifically obligated to independently review the primary data tapes and to make the original data publicly available.

FDA disagrees and notes that it is not reviewing primary data for any of the studies it is evaluating. Rather, the agency reviewed and summarized publicly available scientific reports and publications of results from the INTERSALT study, including both significant and inconclusive findings (56 FR 60825 at 60829 through 60830). FDA considered all these results in determining whether the totality of scientific evidence supported a relationship between sodium and hypertension. This satisfied the agency's legal obligation to evaluate the publicly available scientific evidence and determine whether, based on the totality of that evidence, there is significant scientific agreement among qualified experts that a health claim for sodium and hypertension is supported. Since the primary data tapes from the INTERSALT study are not publicly available, the agency did not review that evidence. The agency does not have the authority to compel the release of these data.

15. One comment objected to the findings of the TOHP Collaborative Research Group study (Ref. 145) (see section VIII.A.5. of this document), which reported significant average decreases in blood pressure (1.7 millimeters of mercury (mm Hg) SBP; 0.9 mm Hg DBP) with average daily reductions in sodium of 55.19 millimoles (mmol) or 1,270 mg in 2,182 normotensives over an 18-month period. The comment suggested that the study methodology was flawed because the sodium reduction intervention group was compared with unmasked nonintervention controls, because the sodium reduction group was compared with a subset (417 subjects) of the "usual care" control group (589 subjects), and because the authors failed to explain the drop in blood pressure of the control group, which was two-thirds of the decrease noted in the sodium reduction intervention group.

FDA disagrees. As the authors noted, achieving sodium reduction via dietary changes requires active and conscious cooperation of the intervention participants in changing shopping, cooking, and food selection behaviors. Therefore, it would not have been feasible to blind the study participants to the dietary changes necessary to reduce sodium intake. In addition, it would have been impractical to follow free-living participants who are blinded to sodium intake for an 18-month period. Most importantly, the study included blinding at the critical point, blood pressure measurement, that is, trained, certified observers, who were blinded to the dietary sodium status of the participants, took the blood pressure measurements of participants at 3, 6 12, and 18 months. In addition, the success of the dietary sodium intervention and possible confounding factors were independently monitored at 6, 12, and 18 months by collecting 24-hour urine samples for sodium analysis, and weighing participants. With regard to the number included in the control group systematically and randomly assigned, the total cumulative number of controls was 589 generated as a result of conducting three separate intervention studies. Furthermore, as noted in Figure 1 in the article, the number of control subjects available for respective comparisons varied due to stratification by clinic and body mass index, and as noted on page 1,214 of the article, in clinics where both weight reduction and sodium reduction were

studied, a higher number of subjects were assigned to the control group to provide sufficient high-weight controls for comparison with the weight reduction intervention. Thus, it is inaccurate to conclude that 172 controls were excluded, since none of the three intervention groups had a control group of all 589 controls. Finally, although both the sodium reduction intervention and the control group experienced decreases in blood pressure, the sodium reduction intervention group's decrease in blood pressure relative to the control group was statistically significant. Furthermore, although the control group was not specifically instructed in ways of reducing sodium intake, the independent measures indicated that, at 18 months, the sodium intake of the control group had decreases by 11.33 mmol (260 mg) sodium as compared with 55.19 mmol (1,270 mg) in the sodium reduction intervention group. This reduction in sodium could account for some of the decrease in blood pressure observed in the control group. In conclusion, the epidemiologic study design was rigorous. The study results provide important insight into the relationship between sodium intake and blood pressure in a normotensive population and also into the long-term impact of sodium reduction on both blood pressure and the development of hypertension over time.

16. One comment objected to FDA's definition of normotension, SBP below 140 mm Hg and DBP below 90 mm Hg, arguing that this implies that blood pressures below 90 mm Hg are without risk. The comment noted that those with DBP between 80 and 90 mm Hg account for one third of cardiovascular disease response. The comment suggested that labels state that blood pressure should ideally be no more than 120 mm Hg SBP and 80 mm Hg DBP.

FDA disagrees. In the proposed rule, the agency acknowledged that the definitions of hypertension and normotension are based on correlations with risk of heart disease and stroke, differ by organization and purpose (Refs. 4, 17, 27, and 38), and are currently under review by the Joint National Committee of the National Heart, Lung, and Blood Institute at the National Institutes of Health. The definitions were changed in 1984 (Ref. 23) based on Public Health Service recognition that there is substantial risk associated with blood pressure levels between 140 and 160 mm Hg SBP and between 90 and 95 mm Hg DBP. These definitions will continue to be monitored; however, it would be very confusing to consumers if various government agencies used different definitions of hypertension and normotension. Consequently, FDA adopted the current Public Health Service definitions.

IV. Statement of the Significance of the Sodium and Hypertension Relationship

17. A few comments argued that the general population should be considered to be the general normotensive population, and that studies on hypertensives would, therefore, not be relevant. The comments suggested also that the data on normotensives are sparse, heterogeneous, and short-term, and that there is no clear, persuasive scientific evidence that healthy people in the general population would benefit from sodium reduction or that sodium increases the risk of hypertension in the general population. The comments concluded that the data do not support a recommendation that 200 million normotensives should reduce their daily sodium intake by half.

FDA disagrees with this assessment. Under new § 101.14(b)(1), set out in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**, to qualify for a health claim a "substance must be associated with a disease or health-related condition for which the general U.S. population, or an identified U.S. population subgroup (e.g., the elderly) is at risk." The general population is at risk for hypertension, and sodium consumption is associated with hypertension. One third of the adult, U.S. population is hypertensive (Ref. 85) and many of these are expected to benefit from sodium reduction. Furthermore, many normotensives are likely to benefit as well, because even in the range of normal blood pressures, mortality risk from stroke and heart disease decreases as blood pressures drop (Refs. 68, 69, and 114).

18. One comment opposed the sodium/hypertension claim, arguing that high blood pressure affects a large segment of the population, but that only a minority are salt sensitive and that this fact should be stated if claims are permitted. Other comments argued that there is wide variation among individuals in salt sensitivity, that many patients are not responsive to sodium, and that health claims should not be allowed because only 12.5 percent of the population, the salt-sensitive hypertensives, would benefit. Another comment said that sodium restriction would benefit a large portion of the population, 20 to 40 percent, and one comment argued that FDA should change its statement to indicate that "many" people, rather than "some," would be likely to benefit. One submitted study (Ref. 143) reported that 13 of 30 well-established hypertensive patients (DBP greater than 90 mm Hg) could control their blood pressure (DBP below 90 mm Hg) on a low salt diet (2 g salt or 780 mg sodium per day). The blood pressures of the remaining patients were reduced as well (SBP: from 173.3 to 164.1 mm Hg; DBP: 102.9 to 98.2 mm Hg) but not enough to return to normotensive levels. The FASEB report (Ref. 138) noted that, "[al]though it is clear that there is a marked heterogeneity of blood pressure responses to alterations of dietary NaCl in both the experimental animal and in man, currently, there is not a uniform definition of salt sensitivity of blood pressure." The report concluded that, "until more information is available, caution is recommended before arbitrarily classifying individuals as NaCl sensitive or NaCl resistant."

FDA recognized in its proposed rule that not all persons may be sensitive to salt. However, all salt-sensitive individuals, those with high blood pressures as well as those with normal blood pressures, are likely to benefit from sodium reductions, since mortality risk from stroke and heart disease drops as blood pressures decrease. Even within the range of normal blood pressures, the lower the blood pressure, the lower the risk (Refs. 68, 69, and 114).

Recognizing that the response varies widely between individuals and that not all people are likely to benefit, FDA originally proposed that health claims indicate that a low sodium diet is associated with lower blood pressure in "some people" (proposed § 101.74(c)(2)). Upon reconsideration, the agency agrees with the comment that suggests that more than "some" individuals are likely to profit from reducing sodium intake. The word "some" may erroneously lead consumers to believe that only a small percentage of the population will benefit and may discourage many people from following this dietary goal. Some scientists have estimated that 30 to 60 percent of hypertensives and 15 to 45 percent of normotensives are salt sensitive (Ref. 116) and would thus benefit from sodium reduction. Taken together, this represents a significant segment of the U.S. adult population. FDA is persuaded that these numbers may not be accurately conveyed by noting that "some" people may benefit from sodium reduction. The agency has therefore dropped the use of the qualifier from the regulation. The agency believes that requiring the use of "may" or "might" (new

§ 101.74(c)(2)(i)(A)) to describe the relationship between sodium intake and blood pressure conveys the meaning that not all individuals respond to sodium restriction with lower blood pressure levels. The statement of the significance of sodium in relation to high blood pressure now includes the following sentences at new § 101.74(b)(1): "The scientific evidence indicates that reducing sodium intake lowers blood pressure and associated risks in many but not all hypertensive individuals. There is also evidence that reducing sodium intake lowers blood pressure and associated risks in many but not all normotensive individuals as well." Consistent with other health claim regulations, the final rule specifically permits the inclusion in a claim of information on the number of people in the United States who have high blood pressure.

19. A few comments contended that moderate reductions of less than 100 mmol sodium (2,300 mg) sodium would have limited impact. A couple of these comments noted that the relationship between sodium and hypertension in the INTERSALT study was significant when all 52 centers were included, but not when only 48 centers were considered. The comment considered the sodium intake range in the 48 centers to be comparable to sodium intakes of Western diets, and argued that since the results were not significant in this group, sodium intake changes in this range would not have any significant effect. A few comments also stated that no populations with free access to salt voluntarily choose such low levels. A few comments suggested that reducing sodium intake significantly was not feasible in Western populations. Others disagreed. One comment noted that the public health benefit could be substantial because food habits are linked to preventable diseases. Another comment extrapolated its clinical findings to the total population and estimated that FDA's reference value of 2,400 mg for sodium could result in cost savings of $2.1 billion per year by reducing costs of hypertension medications for patients who can control their blood pressure by diet alone. They further noted that additional cost savings could be expected through reductions in medication dosages, medication side effects, hospitalization, and costs associated with stroke, heart disease, and kidney disease.

FDA agrees with the comments that suggest sodium restriction will have a significant impact. Average estimates of the effect of a reduction in sodium intake of 100 mmol (2,300 mg) per day on SBP range from 2.2 mm Hg (Ref. 37) to 5 to 10 mm Hg (Ref. 108). Since these are population averages and therefore composite figures, the individual impact for many people will be greater than average. Furthermore, estimates suggest that over a 30-year age span (i.e., 25 to 55 years of age), this reduction of 100 mmol per day corresponds to a reduction in mortality rate of 16 percent for heart disease and 23 percent for stroke (Refs. 69 and 114). Other estimates indicate that a 1,150 mg daily change in sodium intake over a 10-year age span (i.e., 50 to 59 years of age) would result in a 26 percent reduction in stroke and a 15 percent reduction in heart disease in Western populations (Ref. 107).

FDA agrees that there is significant potential benefit if moderate sodium intakes in the U.S. population can be achieved and maintained. This is a feasible goal, because it has been estimated that 90 percent of dietary sodium is from salt added during food processing and manufacturing (75 percent) and during food preparation and consumption (15 percent). Thus, only 10 percent of sodium is naturally occurring in food. The agency notes that populations that voluntarily choose to consume high levels of sodium also have high prevalence of hypertension and greater increases of blood pressure with age. FDA continues to believe that encouraging reductions in sodium intake will benefit millions of Americans.

20. One comment objected to health claims listing ways of reducing sodium without noting that the majority (75 percent) is added to foods in processing, and the most effective strategy to reduce sodium intake is to avoid high-sodium, processed foods.

In the proposed rule, FDA included ways to reduce sodium intake as part of the significance statement, § 101.74(b): "In order to reduce sodium intake, individuals can choose foods with less sodium and salt, reduce the amount of sodium and salt used in food preparation and cooking, and reduce the amount of salt added at the table." This information has been deleted from the final rule in order to make it consistent with the final rules authorizing other health claims. However, the same information is included in "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 85). This information is truthful and correct, and manufacturers may provide this or similar information as long as it is presented in a truthful and nonmisleading manner. Furthermore, FDA agrees that most sodium is added in manufacturing and processing; however, the agency has restricted sodium/hypertension health claims to foods naturally low or processed to be low in sodium and salt.

V. Requirements

FDA received many comments about its proposed disqualifying criteria for sodium and hypertension health claims. Some of these comments supported and some opposed the concept of disqualifying criteria, the selected nutrients, the proposed levels, and the per 100-gram (g) criterion.

FDA has made several changes that affect disqualifying criteria, and these changes are discussed more fully in the final rules on general requirements for nutrient content claims, general requirements for health claims, Reference Daily Intakes (RDI's) and Daily Reference Values (DRV's), and serving sizes, which are published elsewhere in this issue of the Federal Register. FDA has retained sodium, fat, saturated fat, and cholesterol as disqualifying and disclosure nutrients, but the levels have changed due to changes in serving sizes, in the caloric basis for DV's (from 2,360 to 2,000 kilocalories), in the cutoff percentage for disqualifying nutrients (from 15 percent to 20 percent of the DV), and in the density criteria for disqualifying nutrients (from per 100 g to per 50 g for foods with reference amounts of 30 g or less or two tablespoons or less). As discussed below, these changes have resulted in additional foods qualifying for sodium/hypertension health claims.

The requirement that foods meet the "low sodium" content claim requirements was inadvertently removed from the proposed regulation and a notice to that effect appeared in Corrections to Proposed Regulations (57 FR 8180, March 6, 1992). It has been added to the final rule as new § 101.74(c)(2)(ii).

21. Several comments supported FDA's requirement that, in order to qualify for sodium/hypertension health claims, foods must meet the qualifying criterion for "low sodium" foods. Comments also favored allowing health claims only on foods that make a nutritional contribution to the diet. One comment supported requiring foods to meet the "very low sodium" (35 mg sodium) rather than the "low sodium" (140 mg sodium) criterion before being allowed to bear sodium/hypertension health claims. It argued that this would be consistent with prior FDA practices and with scientific evidence that only primitive societies with sodium intake levels at or below this level can avoid developing hypertension. The comment further argued that the only appropriate

target population for sodium/hypertension health claims is individuals on medically restricted diets, that the medical evidence suggests that only salt-sensitive hypertensives would benefit from sodium restriction, and that the INTERSALT (Ref. 37) data showed no effect for diets between 2,300 mg and 4,600 mg sodium per day. The comment concluded that 15 to 26 servings of "very low sodium" foods would provide a daily intake of only 525 to 910 mg sodium, and that this intake level corresponds to the intakes of low sodium populations that had little or no hypertension, and would, therefore, be low enough to have an impact on blood pressure.

FDA disagrees with these comments and contends that restricting sodium/hypertension health claims to "low sodium" foods is consistent with prior agency initiatives that emphasized developing and maintaining policies appropriate for the general public (47 FR 26580, June 18, 1982; and 49 FR 15510, April 18, 1984). The agency does not agree that the only appropriate target population is individuals on medically restricted diets. Furthermore, as discussed in comments 17 and 18 of this document, FDA disagrees that only hypertensives would benefit from reduced sodium intakes. Estimates suggest that 15 to 45 percent of normotensives are likely to benefit from salt (sodium) reduction (Ref. 116). Even within "normal ranges," lower blood pressures are generally associated with reduced mortality risk for the normotensive population as well as for the hypertensive population (Refs. 68, 69, and 114). In addition, 15 to 26 servings of "low sodium" foods would provide from 2,100 to 3,640 mg sodium per day. This is consistent with the DV for sodium of 2,400 mg, published elsewhere in this issue of the Federal Register. This is also consistent with FDA's policy that health claims are intended for the general population. Conversely, requiring foods bearing health claims to meet requirements for "very low sodium" could result in a sodium intake from 525 to 910 mg sodium per day, a value more appropriate for therapeutic diets than for diets for the general population. FDA is encouraging the entire population to moderate sodium intake, but the goal for the United States is not to try to reach the sodium intake levels of primitive societies. Although the INTERSALT data cited in the comment on the relationship between sodium and blood pressure were generally inconclusive when the four populations with the lowest sodium intakes were excluded, the data on the relationship between sodium intake and trends in blood pressure with age remained positive and significant.

The definition of "low sodium" requires that foods contain less than 140 mg sodium per reference amount and per 50 g for foods with reference amounts of 30 g or less or 2 tablespoons or less. The "per 50 g" criterion is a change from the proposed criterion of "per 100 g," and this change is discussed in further detail in the final rule on general requirements for nutrient content claims, which is published elsewhere in this issue of the Federal Register.

In the companion document on general requirements for health claims, FDA is also prohibiting claims on foods lacking naturally occurring nutrients (i.e., in order to bear health claims, foods must naturally contain a minimum of 10 percent of the RDI or DRV for one of six specified nutrients: Protein, fiber, vitamin A, vitamin C, calcium, and iron). The changes in the qualifying criteria for "low sodium," in the disqualifying levels for fat, saturated fat, and cholesterol, and in the restrictions to foods with naturally occurring nutrients have resulted in the qualification of some additional foods for sodium/hypertension health claims and the disqualification of foods lacking significant naturally occurring nutrients. Examples of foods that may bear sodium/hypertension claims include several additional fish and shellfish products, egg substitutes, and a few skim milk cheeses. Examples of foods that would have qualified for health claims under the proposed rules but no longer qualify include beverages such as carbonated soft drinks, coffees, and teas; most candies, cookies, baked goods, and icings; margarines and salad dressings; sweeteners; most jams and jellies; a few canned fruits; and a few canned and raw vegetables.

22. One comment argued that foods allowed to bear sodium/hypertension health claims should have a calorie restriction, since obesity is a risk factor for high blood pressure.

FDA disagrees. Sodium/hypertension health claims are intended for the general population and not merely for those who need to restrict their caloric intake. It would be a disservice to restrict health claims to low calorie foods, since many people who are at risk for high blood pressure and can benefit from consuming foods that are low in sodium may not need to consume foods low in calories. In addition, although everyone is encouraged to consume a diet low in sodium, individuals can select a variety of foods with different sodium and calorie contents to meet their dietary needs.

23. Some comments approved of the model health claim message. Others expressed concern that, by including too much information, claims would become overly burdensome and ineffective and would discourage manufacturers from using them and consumers from reading them. One comment suggested a simpler claim: "A low sodium diet can help to lower blood pressure in some people with high blood pressure."

FDA appreciates the concern about long and burdensome messages and has discussed this issue in the final rule on general requirements for health claims published elsewhere in this issue of the Federal Register. Upon reconsideration, the agency has made several changes that will simplify claims and limit the amount of required information, while assuring that claims are clear and nonmisleading to consumers. The proposed regulation would have imposed the following requirements on health claims: "The health claim states that a low sodium diet is associated with or related to lower blood pressure in some people. Alternatively, the health claim can state that a high sodium diet is associated with or related to higher blood pressure in some people" (proposed § 101.74(c)(2)); and "The health claim identifies the populations at greatest risk of developing high blood pressure as being the elderly and those with family histories of high blood pressure and states that other dietary risk factors associated with high blood pressure include alcohol consumption and excess weight" (proposed § 101.74(c)(3)).

These requirements have been simplified to require that claims use the words "may" or "might" (§ 101.74(c)(2)(i)(A)) (see comment 18 of this document); that the disease and nutrient terms be "high blood pressure" (§ 101.74(c)(2)(i)(B)), and "sodium" (§ 101.74(c)(2)(i)(C)), respectively [this is consistent with the proposed rule]; and that claims not state any degree of risk reduction (§ 101.74(c)(2)(i)(D)) (see comment 26 of this document). The agency believes that simplifying the relationship statement will make the message shorter and easier for consumers to understand. In order to be consistent with other regulations, FDA has used wording associating diets low in sodium "to reduced risk of high blood pressure" rather than the wording suggested in the comment "to lower blood pressure." This phrasing more accurately captures the relationship

between sodium intake and high blood pressure than the proposal, which would have permitted claims to note the "association" or "relation" of sodium to blood pressure. In addition, as discussed in comment 18 of this document, the wording "in some people" has been deleted.

24. One comment opposed identifying specific risk populations in health claims and argued that other populations would assume they do not need to be concerned. Others argued that the inclusion of risk populations and dietary risk factors made claims too long and burdensome. Still others provided data on other dietary factors, such as the potassium, calcium, magnesium, or chloride ion content or the ratio of sodium to potassium (Refs. 15, 19, 21, 24, 26, 28, 32, 36, 39, 61, 65, 66, 67, 73, 77, 86, 88, 101, 110, and 115) or suggested that these other dietary factors should be discussed and acknowledged in health claims as dietary risk factors.

FDA recognizes that high blood pressure is a multifactorial disease and that research has indicated that other nutrients may be associated with high blood pressure. However, in the 1990 amendments, Congress directed the agency to evaluate, within a short period of time, the relationship between sodium and hypertension. Thus, FDA's present assessment of the scientific evidence is limited to this relationship. References in a sodium/hypertension health claim to other specified nutrients would constitute a health claim for these nutrients and would not be allowed unless authorized through the petition process set out in the final rule on general requirements for health claims, published elsewhere in this issue of the **Federal Register**.

FDA is concerned that allowing the unrestricted listing of risk factors for high blood pressure other than sodium intakes could result in risk factors of little relative importance or with minimal scientific support being included on labels. Depending on the context in which they are discussed, information on risk factors other than sodium can be misleading. However, the agency is also concerned that consumers could be misled into overemphasizing the impact of sodium on blood pressure or into believing that high blood pressure can be controlled by sodium restriction alone. Proposed § 101.74(c)(3) would have required health claims to include information identifying populations at greatest risk of developing hypertension and other risk factors associated with high blood pressure.

Upon reconsideration, FDA has chosen to limit the mandatory health claim requirement for sodium and hypertension to a short statement containing the minimum essential information and to allow additional information on an optional basis. Under the final regulation, claims must indicate that the development of high blood pressure depends on many factors. This requirement is intended to prevent consumers from being misled that sodium intake alone is connected with high blood pressure. However, in order to permit shorter claims, the final regulation dose not require that specific risk factors be identified. FDA has listed major risk factors for which there is general scientific agreement in § 101.74(d)(1). Under that section, a claim "may identify one or more of the following risk factors for development of high blood pressure in addition to dietary sodium consumption: family history of high blood pressure, growing older, alcohol consumption, and excess weight." FDA encourages manufactures to provide useful and accurate information on risk factors, but advises that, if specific information about disease risk is included in health claims, then the information must of course be presented in a truthful and nonmisleading manner.

VI. Optional Information

25. One comment supported encouraging 2,400 mg sodium as a maximum intake recommendation for the public at large, and another agreed that current intakes of sodium are well in excess of need and recommendations. Another comment strongly opposed including a statement that sodium intake should not exceed 2,400 mg, indicating that this value is a reference level, not a maximum intake level.

In response to comments urging the agency to shorten health claims and to provide more consistent regulations, FDA has decided to retain this information, but to move it to the significance statement. While most people should target their sodium intakes within the 500 to 2,400 mg range, a very few individuals may need more than the minimum because of excessive sweat losses, and some high calorie consumers may find 2,400 mg impossible to meet. Section 101.74(d)(2) will permit the inclusion of information from the significance statement in a health claim. Consequently, proposed § 101.74(d)(1) has been deleted, and the following sentence has been added to the significance statement in § 101.74(b)(4): "Sodium is an essential nutrient, and experts have recommended a safe minimum level of 500 mg sodium per day and a upper level of 2,400 mg sodium per day, the FDA Daily Value for sodium."

26. Comments from both health professionals and trade associations strongly supported requiring that sodium/hypertension health claims contain a statement that individuals with high blood pressure should consult their physicians for medical advice and treatment. There were no comments opposing this statement or requesting that it remain optional, as proposed, although some comments expressed general objections to the length of health claims.

In the proposal, FDA expressed concern that some people might attempt to use the ready availability of sodium labeling, and in particular sodium/hypertension health claims, to self-medicate or treat their hypertension without consulting a physician, especially since many people are aware of the dangers of hypertension (Ref. 56) and can easily learn their blood pressure levels by visiting a health professional or using "do it yourself" machines in grocery stores or shopping malls. Requiring the statement about physician consultations as part of the health claim might give consumers the erroneous impression that there is no benefit in making recommended dietary changes unless they have been identified as hypertensive. On the other hand, FDA remains concerned about hypertensives foregoing needed medical diagnosis and treatment. Specifically, definitions of hypertension or normotension in terms of blood pressure readings could encourage self-diagnosis, and information relating specific sodium intakes to specific reductions in blood pressure could encourage self-treatment. To decrease the likelihood of self-diagnosis or treatment based on health claims, in new § 101.74(c)(2)(i)(D) FDA has specifically prohibited claims from including any information on the degree of risk reduction for high blood pressure associated with sodium reduction. The agency has also has removed the following quantitative statements from the significance statement in new § 101.74(b):

> Estimates suggest that reducing sodium intake by 100 millimoles (mmol) per day (2,300 mg of sodium or approximately one rounded teaspoon of salt) would correspond to an average lowering of blood pressure of approximately 2.2 mm Hg systolic and 0.1 mm Hg diastolic. Because these are population-wide estimates, the magnitude of the effect for sensitive individuals would be greater. Estimates suggest that, for the age range from 25 to 55, a 100 mmol per day (2,300 milligrams (mg) per day) lower lifetime intake of sodium would correspond to a reduction in mortality rates of

approximately 16 percent for coronary heart disease and 23 percent for stroke.

FDA has decided to limit the information required in health claims to that which is essential. Therefore, the agency has retained the physician consultation statement as optional information, § 101.74(d)(7). However, should manufacturers choose to include information that could increase the likelihood of consumers self-diagnosing or self-treating their hypertension, that information must be presented in a clear and nonmisleading manner. For example, claims should not overemphasize the importance of sodium in reducing blood pressure. In addition, should manufacturers include specific information that would assist consumers in self-diagnosing their hypertension, such as definitions of either high or normal blood pressure, then the physician consultation statement would be mandatory, and this requirement has been included in new § 101.74(d)(7):

> The claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment. If the claim defines high or normal blood pressure, then the health claim must state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

Because high blood pressure is a serious disease that often has no outwardly observable symptoms, FDA encourages manufacturers to include a physician referral statement as a public service, and requires it when health claims include information that could encourage self-diagnosis or treatment.

27. The agency proposed to permit the optional use of the term "salt" in addition to the term "sodium" in health claims. However, because of recent studies, and the increasing body of evidence identifying sodium chloride rather than sodium alone as the active substance in affecting blood pressure, the agency specifically requested comments regarding the appropriateness of selecting sodium rather than sodium chloride as the specified nutrient and on allowing the term "salt" in addition to the term "sodium" in health claims. One comment objected to allowing the term "salt" in addition to the term "sodium," arguing that FDA policies have been based on sodium, that the 1990 amendments specify sodium, that it would be arbitrary and capricious to indicate sodium chloride without providing a scientific basis, that consumers would consider the two interchangeably, and that it would undermine previous education efforts. Other comments provided data on sodium salts other than sodium chloride and argued that the effect of sodium on blood pressure was due not to sodium alone but rather to sodium in combination with chloride. One comment noted that only studies involving sodium as the chloride salt have resulted in demonstrable increases in blood pressure. The comment urged the agency to permit salt/hypertension health claims and not sodium/hypertension health claims. The FASEB report (Ref. 138) concluded that "the impact of dietary sodium on blood pressure depends on the provision of sodium as the chloride."

After considering the comments and data submitted in response to the proposed rule, FDA has concluded that these issues are very complex. Salt or sodium chloride is the major source of sodium in foods, and over the years most of the studies investigating the effect of sodium on blood pressure have involved either increasing or decreasing sodium chloride intake (56 FR 60825, Table 2, Refs. 44, 45, 80, 109, 121, 122). Many dietary guidance discussions, policies, and recommendations refer to both sodium and salt (Refs. 43, 62, and 85), and the use of the term "salt" would make claims more understandable to many people. For these reasons, the agency has decided to make final its proposal to permit the optional use of the term "salt" in addition to "sodium."

FDA acknowledges that some studies and reviews indicate that sodium chloride and other sodium salts have distinct effects on blood pressure (Refs. 31, 43, 48, 79, 87, and 92). The agency recognizes that, if it is true that "salt" and not "sodium" is implicated in high blood pressure, products containing other sources of sodium may be incorrectly considered to promote high blood pressure. At present, however, there is not significant scientific agreement that only sodium chloride affects blood pressure, as evidenced by the fact that authoritative documents have not limited their recommendations to salt. Limiting health claims to "salt" would represent a significant policy change and would have implications for many other regulations. FDA has therefore concluded that a thorough review of all the data and an opportunity for public comment are required before such a shift. If concerned parties believe that, based on the totality of the publicly available scientific evidence, there is significant scientific agreement that sodium chloride, and not just sodium, is associated with high blood pressure, they should petition the agency for a change in the regulation.

28. No comments were received regarding FDA's tentative decision to allow the term "hypertension" in addition to the term "high blood pressure." Consequently, FDA has retained this provision in the optional information section of the regulation, although the numbering has changed from § 101.74(d)(4) to (d)(5).

29. Comments to the public docket on sodium and hypertension strongly supported Consumer Summaries. One comment recommended developing additional summaries to target specific audiences. A few comments suggested specific changes in the wording provided in the proposed rule. However, comments to the public docket for the general requirements for health claims generally opposed Consumer Summaries.

FDA acknowledges the interest expressed by comments in the consumer summaries. However, the agency has been persuaded by the comments received overall relative to health claims (See the general requirements for health claims final rule published elsewhere in this Federal Register). FDA notes that considerable educational efforts are planned and Consumer Summaries as part of the preamble and not in the codified language had limited utility.

VII. Model Health Claims

30. Several comments approved the model health claim for sodium and hypertension. Others objected to its length or to specific required information, and these comments have been addressed in comments 18, 23, 24, and 27 of this document. FDA has provided new model health claims to illustrate changes made in the proposed regulations.

VIII. Additional Scientific Data

To assure that significant new evidence had not become available subsequent to the proposal, FDA updated its review of the scientific evidence with human studies that were directly relevant to the proposed rule or became available after publication of its proposal (see Table).

A. Review of Scientific Studies and Data

1. Relationship of sodium intake to blood pressure

Pavek and Pavek (Ref. 146) conducted an intervention study in 35 mild, untreated hypertensives (15 males, 20 females) to determine the blood pressure sensitivity to 72-hour salt depletion achieved through a low salt diet consisting of unprocessed rice, potatoes, fruits, vegetables, and 2 liters (L) of tap water. Oscillometric,

auscultatory, and ambulatory blood pressure measurements were taken, and sodium intake was determined by 24-hour urine collections. Average 24-hour urinary sodium decreased by 17.5 mmol (400 mg), and average body weight by 3.1 percent. Average SBP decreased significantly (Oscillometric: 147.3 to 134.8 mm Hg; Auscultatory: 148.0 to 134.4 mm Hg; and Ambulatory Oscillometric: 138.6 to 130.4 mm Hg). Average DBP changed little, and only oscillometric measurements were statistically significant. Determination of individual salt sensitivity varied greatly and depended on the type of blood pressure measurement considered.

Dustan and Kirk (Ref. 125) investigated the effect of sodium depletion (9 meq or 210 mg sodium diet) followed by sodium loading (9 meq or 210 mg sodium plus 3.88 meq or 90 mg sodium per kilogram (kg)) in 51 normotensive white (19 male, 32 female), 18 normotensive black (7 male, 16 female), and 21 hypertensive black (5 male, 16 female) patients and the effect of sodium loading followed by sodium depletion in 11 normotensive white (2 male, 9 female), 16 normotensive black (6 male, 10 female), and 19 hypertensive black (4 male, 15 female) patients. The order of sodium loading and depletion did not affect mean arterial pressure in normotensive white patients (blood pressure did not vary) or in hypertensive black patients (blood pressure rose during sodium loading and fell during sodium depletion). Mean arterial pressure in normotensive black patients did not vary when sodium depletion was followed by sodium loading, but when the order was reversed, mean arterial pressure fell during sodium depletion and rose during sodium loading.

A study by Elliott et al. (Ref. 126) analyzed data collected as part of a random sample of 58 subjects aged 40 or above (29 male, 29 female) from a North London population that included diabetics (6 subjects) and individuals taking antihypertensive medication (5 subjects) or diuretics (3 subjects). SBP was significantly and positively related to 24-hour urinary sodium excretion and remained significant after adjustment for age, sex, and body mass index. DBP was significantly related to 24-hour urinary sodium excretion; however, the significance was borderline after adjustment for age and sex and insignificant after additional adjustment for body mass index. The reliability of complete 24-hour urine collection was monitored by para-aminobenzoic acid, and the significance of the results was greater in the subgroup identified as having the most complete urine collections. The within-individual variation in sodium intake was estimated from data on 11 subjects who completed two 24-hour collections. A reduction of 50 mmol (1,150 mg) sodium was associated with lower SBP and DBP of 5.3 and 1.4 mm Hg, respectively.

Khaw and Barrett-Conner (Ref. 128) examined the relationship between blood pressure and sodium estimated from dietary recall data in upper middle class white Southern Californian subjects (584 men and 718 women). Age-adjusted SBP and DBP correlated significantly with dietary sodium intake in men but not in women and with the sodium/potassium ratio in both men and women. The relationship persisted over the entire range of blood pressures and dietary intakes. The authors concluded that the results support the hypothesis that dietary sodium and potassium are related to blood pressure within a population.

He et al. (Ref. 139) investigated the relationship of 4 dietary ions, including sodium, to blood pressure in 4 population groups of Southern Chinese men from the Sichuan Province: 119 Yi farmers from remote villages in the high mountains, 114 Yi farmers from lower elevation, mountainside villages, 89 Yi people who had migrated to the county seat, and 97 Han people who were native residents of the county seat. Dietary and urinary sodium were significantly and positively correlated with SBP and DBP, even after controlling for age, body mass index, heart rate, alcohol, and total energy intake. Analysis at the individual level confirmed these results.

Forte et al. (Ref. 132) studied the effect of a health education program on salt reduction and blood pressure response in two matched rural Portuguese communities (150 of approximately 800 subjects studied in each community) with initially high daily salt intakes (360 mmol or 8,300 mg sodium). The health education program in the intervention community emphasized adding less salt in the kitchen, eating less cod fish and fewer sausages, and adding less salt to home-baked bread. In addition, local bakers were asked to reduce the salt added to bread by 50 percent during the 2-year trial. Mean sodium intake fell in the intervention community (364 mmol or 8,370 mg to 202 mmol or 4,640 mg) and rose slightly in the control community (352 mmol or 8,100 mg to 371 mmol or 8,530 mg). In the intervention community, average blood pressure decreased (SBP: decrease of 3.6 mm Hg at one year and 5.0 mm Hg at 2 years, DBP: decrease of 5.0 mm Hg at 1 year and 5.1 mm Hg DBP at 2 years); however, in the control community, average SBP rose and DBP remained constant.

2. Risk factors for high blood pressure

Beretta-Piccoli (Ref. 134) studied total exchangeable sodium in 62 normotensive (SBP < 130 mm Hg, DBP < 90 mm Hg) Swiss males with and without a family history of hypertension (31 subjects each, matched by age, height, and weight) on a normal daily sodium intake (150 mmol or 3,400 mg) and, in a subgroup of 23 subjects (13 with and 10 without a family history of hypertension), Beretta-Piccoli studied the adaptation of exchangeable sodium to variations in dietary sodium intake (low urinary sodium of 17 mmol or 390 mg versus high urinary sodium of 270 mmol or 6,200 mg). In the first, matched study, blood pressures tended to be higher in the group with a family history of high blood pressure. In the second, subgroup study, blood pressures increased with sodium intake in all subjects, but the magnitude of increase was greater in subjects with a family history of hypertension (SBP: 119 to 126 mm Hg, DBP: 76 to 80 mm Hg) than in those without (SBP: 112 to 113 mm Hg, DBP: 69 to 71 mm Hg).

3. Hypertensives versus normotensives

In addition to the Dustan study (Ref. 125) considered above, two additional studies investigated differences in responses for hypertensives and normotensives. Gill et al. (Ref. 127) investigated various hormonal changes in response to various dietary sodium levels. The study classified 19 patients with normal renin idiopathic hypertension as salt-sensitive (mean arterial pressure increases of 8 to 14 percent) (8 patients) or salt-resistant (mean arterial pressure changes from −7 to +7 percent) (11 patients) as compared with 5 normotensive subjects (mean arterial pressure changes from −3 to +7 percent). Subjects were fed a constant isocaloric diet supplemented with sodium chloride to provide 3 dietary levels of sodium intake: 9 meq (200 mg), 109 meq (2,500 mg), and 249 meq (5,700 mg). Average mean arterial blood pressures on the low sodium relative to the high sodium diet changed from 79 to 83 mm Hg in the normotensive subjects, from 104 to 114 mm Hg in the salt-sensitive hypertensive patients, and remained balanced at 114 mm Hg in the salt-resistant hypertensive patients.

Weinberger and Fineberg (Ref. 141) conducted 3 studies in Indiana. The first investigated the reproducibility of determining salt-sensitivity in 28

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normotensive (BP < 140/90) and hypertensive (antihypertension therapy or BP ≤ 140/90 on at least 3 occasions) subjects. Salt-sensitivity was defined in terms of response to sodium chloride infusion (change from 2 L of 0.9 percent sodium chloride to 10 mmol or 230 mg sodium per day) where mean arterial blood pressure responses of 10 mm Hg or greater, of 5 mm Hg or less, and of 6 to 10 mm Hg were classified as salt-sensitive, salt-resistant, and indeterminant, respectively. The authors reported that the majority (18 of 28) were consistent in their responses. The second study investigated the influence of age on blood pressure response to the salt-sensitivity procedure described above in 430 normotensive and 230 hypertensive subjects. Sodium sensitivity increased progressively with age in hypertensive subjects but not in normotensive subjects until they reached 60 years of age and older. The third study assessed changes in blood pressure over 10 or more years in subjects classified initially using the salt-sensitivity procedure described above: 13 hypertensives (10 salt-senstive, 3 salt-resistant) and 18 normotensives (6 salt-sensitive, 12 salt-resistant).

4. Salt sensitivity

In addition to the Gill study (Ref. 127) and the Weinberger study (Ref. 141) considered above, two other studies investigated the salt sensitivity issue. Sullivan et al. (Ref. 130) studied 65 borderline hypertensive (DBP generally below 90 mm Hg but greater than 90 mm Hg on at least 3 occasions) and 92 normotensive subjects to investigate different characteristics of sodium-sensitive and sodium-resistant individuals. Many parameters were studied while subjects followed their usual diets, 10 meq (230 mg) sodium/60 meq potassium diets, and 200 meq (4,600 mg) sodium per 60 meq potassium diets. Sodium sensitivity was defined as a 5 percent increase in blood pressure between the low sodium and the high sodium states; the prevalence of sodium sensitivity was higher in blacks (27 percent of normotensives and 50 percent of borderline hypertensives) than in whites (15 percent of normotensives and 29 percent of borderline hypertensives). Sodium depletion and repletion had a variable effect on blood pressure, and mean blood pressure rose 6.5 percent in those identified as sodium sensitive as compared with 0 percent in those identified as sodium resistant.

Espinel (Ref. 143) conducted a 3-phase dietary salt intervention trial to characterize the response of 30 well-established adult hypertensive patients (DBP greater than 90 mm Hg) to dietary salt. The unrestricted-salt phase certified the presence of hypertension and documented the customary salt intake. The restricted-salt phase (2 g salt) (<34 mmol salt or 780 mg sodium) identified 13 patients, who were considered salt-sensitive, who could control their DBP (below 90 mm Hg) on a salt-restricted diet containing less than 2 g salt per day (SBP: from 177.1 to 145.1 mm Hg; DBP: from 105.4 to 82.0 mm Hg). The blood pressures of the remaining patients were reduced as well (SBP: from 173.3 to 164.1 mm Hg; DBP: from 102.9 to 98.2 mm Hg) but not enough to return to normotensive levels. In the salt-step phase, salt was added to the diet established during the restricted-salt phase in a stepwise manner (increases of 1 g salt or 390 mg sodium; each step lasting at least 3 days) to determine the level of salt that triggered hypertension in individual patients. This level was termed the Salt Hypertension Threshold for that patient and in the 13 patients ranged from 3 to 16 g salt (1,200 to 6,200 mg sodium) per day. The test was repeated between 2 months and 1 1/2 years later and the results remained stable and reproducible.

5. Long-term effect

The results of an 18-month trial on normotensives, the TOHP Collaborative Research Group study abstract (Ref. 123) was included in the proposed regulation, and the final study results are summarized here (Ref. 145). The TOHP Collaborative Research Group study included 7 nonpharmacologic interventions, 3 life-style changes (weight reduction, sodium reduction, and stress management), and 4 nutritional supplements (calcium, magnesium, potassium, and fish oil) in 2,182 normotensive (DBP from 80 to 89 mm Hg) subjects (70 percent male). The sodium-reduction intervention emphasized shopping, cooking, and food selection behavior aimed at reducing sodium intake, and at 18 months had achieved average daily reductions of 55.19 mmol sodium (1,270 mg) as compared to 11.33 mmol sodium (260 mg) in the control group from initial baseline values of 154.6 mmol (3,550 mg) and 156.4 mmol (3,600 mg) in the two groups, respectively. Statistically significant average decreases in blood pressure were reported in the intervention group as compared with the control group for both DBP (decrease of 0.9 mm Hg) and SBP (decrease of 1.7 mm Hg).

Joosens and Kesteloot (Ref. 147) reanalyzed data from 3,328 subjects collected as part of 6 Belgian surveys conducted between 1967 and 1986. Six of the surveys included blood pressure data and five included 24-hour sodium excretion data. Between 1967 and 1986, the mean standardized sodium excretion decreased from 265 to 160 mmol in men (6,100 to 3,700 mg) and from 208 to 160 mmol in women (4,800 to 3,700 mg). Mean SBP decreased from 169 to 142 mm Hg in men and from 171 to 147 mm Hg in women. The prevalence of hypertension (SBP > 159 mm Hg) decreased from 51 to 21 percent in men and from 66 to 22 percent in women, and severe hypertension (SBP > 220 mm Hg) nearly disappeared. During the same period, body mass index increased 1.1 kg/m^2 in men and was unchanged in women. Since increased weight is associated with increases in blood pressure, the observed decreases in blood pressure could not be ascribed to changes in weight. The proportion of subjects receiving treatment for hypertension increased from 10 to 36 percent in men and from 18 to 41 percent in women. The increased treatment would account for some of the observed decreases in blood pressure, but the authors concluded that treatment alone could not account for all of the observed changes in blood pressure. The authors used the correlation between sodium intake and blood pressure from the INTERSALT study (Ref. 37) and the observed decrease in sodium intake in Belgium from 1967 to 1986 in order to estimate the expected corresponding decrease in SBP. Considered together, the increase in treatment and the decrease in sodium intake were considered sufficient to explain the observed decreases in blood pressure. Methodologies in the six studies were similar but not identical, adding to the uncertainties.

6. Sodium chloride versus other sodium salts

Shore et al. (Ref. 129) conducted a randomized, crossover study to investigate the blood pressure response of six hypertensives (DBP between 90 to 110 mm Hg) on low sodium diets of 10 mmol (230 mg) sodium and 80 mmol potassium with the addition of either sodium chloride (120 mmol or 2,760 mg total daily sodium) or sodium potassium (122 mmol or 2,800 mg total daily sodium). Urinary sodium excretion was similar during both periods. However, blood pressures increased when sodium chloride was added to the diet, but not when sodium phosphate was added.

7. Effect on medication requirements

Weinberger et al. (Ref. 131) investigated whether free-living

hypertensive patients could reduce their medication by individualized dietary counseling aimed at moderately reducing their dietary sodium intake. Only 98 of the original 114 individuals completed the study and maintained significant reductions in mean sodium intake for 30 weeks. Those who achieved the 80 mmol (1,800 mg) sodium goal were more likely to have a reduction in a number of medications than those not reaching the goal.

In an observer-blind, controlled trial, Little et al. (Ref. 140) compared the effect of a low sodium, low fat, high fiber diet against the individual components of the diet in reducing the amount of antihypertensive medication required by 196 patients with established hypertension. Medication reductions were 64 percent and significant on the combination diet, 45 percent and insignificant on the low sodium diet, and 33 percent on the control diet; 57.5 percent of patients on the combination diet stopped all medication as compared with 24 percent on the control diet.

8. Effect of sodium intake on medicated patients

Carney et al. (Ref. 136) used a randomized, double-blind, crossover study design to investigate the effect of 100 mmol (2,300 mg) of sodium chloride on blood pressure control in 11 patients with mild to moderate hypertension successfully treated with various hypotensive agents. No significant changes in supine or erect blood pressure were observed in these medicated patients.

9. Studies in children

An intervention study by Ellison et al. (Ref. 148) involved reducing the sodium intake of students by 15 to 20 percent through changes in food purchasing and preparation practices in two boarding high schools. Each school served alternately as the control or the intervention school for one school year. Early in the year, blood pressures increased above baseline; however, as the year progressed blood pressures in the intervention school dropped and remained below baseline. The average SBP and DBP, adjusted for sex and initial blood pressure, were reduced by 1.7 and 1.5 mm Hg, respectively, on the low sodium diet when measured from the beginning to the end of the school year. Changes in sodium intake were calculated from 24-hour food diaries completed periodically during the year, and no independent measurements were made to document changes in sodium intake.

A longitudinal study by Geleijnse et al. (Ref. 149) collected blood pressure and electrolyte data annually from 233 Netherlands children ranging in age from 5 to 17 years old (108 boys, 125 girls) for an average period of 7 years in order to investigate the association between sodium and potassium intake and the change in blood pressure over time. No significant association between sodium intake and the change in blood pressure over time was observed. Mean 24-hour sodium intakes were calculated values and were based on six timed, overnight urine collections.

Miller et al. (Ref. 150) conducted an intervention study in Indiana with 64 male and 84 female white, normotensive children to determine if modest dietary restriction in childhood results in heterogeneous changes in blood pressure response. Families received instruction to assist them in restricting their dietary sodium to 60 mmol (1,380 mg) per day. Average sodium decreased from 112.9 mmol (2,600 mg) to 53.4 mmol (1,230 mg) in boys and from 91.1 mmol (2,090 mg) to 41.1 mmol (940 mg) in girls. Changes in SBP were not significant for either boys or girls, but girls showed a decrease in DBP ($p<0.05$) and in mean arterial pressure.

Rocchini et al. (Ref. 133) studied blood pressure changes in 60 obese and 18 nonobese adolescents (10 to 16 years of age) on high salt diets (> 250 mmol or 5,700 mg sodium) per day and low salt diets (< 30 mmol or 700 mg sodium) per day with the caloric content held constant. In the obese adolescents, there was a statistically significant decrease in blood pressure on the low sodium diet (mean arterial pressure change from 92 to 80 mg Hg), but no significant change was observed in the nonobese adolescents (mean arterial pressure change from 76 to 77 mm Hg). The study was repeated on 51 of the obese adolescents after 20-week weight loss program. The 36 subjects who lost at least 1 kg of body weight (average weight loss 7.5 kg) had a reduced sensitivity of blood pressure to sodium (mean arterial pressure change from 82 to 81 mm Hg) as compared to the 15 subjects who lost less than 1 kg of body weight (mean arterial pressure change from 89 to 79 mm Hg).

B. Conclusions from Scientific Studies and Data

In assessing the new scientific evidence, FDA has considered whether the evidence significantly challenges any of its tentative conclusions presented in the proposed rule.

The agency has determined that, although one study was inconclusive (Ref. 125), the scientific evidence continues to support a relationship between sodium and hypertension in adults (Refs. 123, 126, 127, 128, 132, 134, 139, 141, 146, and 147). In particular, the 3-year study on nonpharmacologic interventions (Ref. 145) strengthens previously limited evidence on the benefits of long-term sodium reduction in reducing blood pressure. In addition, the Espinel study (Ref. 143) demonstrates the wide variability in blood pressure response to sodium and the long-term individual reproducibility. The studies on children sometimes showed an effect (Ref. 148), sometimes showed no effect (Ref. 149), and sometimes showed an effect in certain population subgroups but not in others (Refs. 133 and 150). The one study involving a nonchloride sodium salt (Ref. 129) showed an effect for sodium chloride but not for sodium phosphate, which supports the contention that sodium chloride and not sodium per se is important in blood pressure response (see comment 27 of this document).

In conclusion, the new scientific evidence strengthens the conclusion reached in the proposed regulation that, based on the totality of the scientific evidence, there is significant scientific agreement that the evidence supports health claims that diets low in salt and sodium may help lower blood pressure in many people.

IX. Conclusions

FDA has responded to all comments received in response to the proposed sodium/hypertension health claim regulation. In addition, the agency has reviewed all additional scientific studies received in comments or independently identified and has determined that the new studies strengthen the conclusions reached in the proposed regulation. After considering the comments and the new scientific studies, the agency concludes that health claims for sodium and hypertension should be authorized.

The agency has decided that the regulations for the authorized health claims are most useful if they follow a consistent format and require only information that the agency considers essential. Therefore, the agency has made a number of editorial changes in the proposed codified material of the sodium and hypertension health claim to make it more consistent with other authorized claims.

X. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole,

would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XI. Environmental Impact

The agency has determined that, under 21 CFR 25.24(a)(11), this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6, of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.74 is added to subpart E to read as follows:

§ 101.74 Health claims: sodium and hypertension.

(a) *Relationship between sodium and hypertension (high blood pressure).* (1) Hypertension, or high blood pressure, generally means a systolic blood pressure of greater than 140 millimeters of mercury (mm Hg) or a diastolic blood pressure of greater than 90 mm Hg. Normotension, or normal blood pressure, is a systolic blood pressure below 140 mm Hg and diastolic blood pressure below 90 mm Hg. Sodium is specified here as the chemical entity or electrolyte "sodium" and is distinguished from sodium chloride, or salt, which is 39 percent sodium by weight.

(2) The scientific evidence establishes that diets high in sodium are associated with a high prevalence of hypertension or high blood pressure and with increases in blood pressure with age, and that diets low in sodium are associated with a low prevalence of hypertension or high blood pressure and with a low or no increase of blood pressure with age.

(b) *Significance of sodium in relation to high blood pressure.* (1) High blood pressure is a public health concern primarily because it is a major risk factor for mortality from coronary heart disease and stroke. Early management of high blood pressure is a major public health goal that can assist in reducing mortality associated with coronary heart disease and stroke. There is a continuum of mortality risk that increases as blood pressures rise. Individuals with high blood pressure

are at greatest risk, and individuals with moderately high, high normal, and normal blood pressure are at steadily decreasing risk. The scientific evidence indicates that reducing sodium intake lowers blood pressure and associated risks in many but not all hypertensive individuals. There is also evidence that reducing sodium intake lowers blood pressure and associated risks in many but not all normotensive individuals as well.

(2) The populations at greatest risk for high blood pressure, and those most likely to benefit from sodium reduction, include those with family histories of high blood pressure, the elderly, males because they develop hypertension earlier in life than females, and black males and females. Although some population groups are at greater risk than others, high blood-pressure is a disease of public health concern for all population groups. Sodium intake, alcohol consumption, and obesity are identified risk factors for high blood pressure.

(3) Sodium intakes exceed recommended levels in almost every group in the United States. One of the major public health recommendations relative to high blood pressure is to decrease consumption of salt. On a population-wide basis, reducing the average sodium intake would have a small but significant effect on reducing the average blood pressure, and, consequently, reducing mortality from cardiovascular disease and stroke.

(4) Sodium is an essential nutrient, and experts have recommended a safe minimum level of 500 milligrams (mg) sodium per day and an upper level of 2,400 mg sodium per day, the FDA Daily Value for sodium.

(c) *Requirements.* (1) All requirements set forth in § 101.14 shall be met.

(2) Specific requirements. (i) *Nature of the claim.* A health claim associating diets low in sodium with reduced risk of high blood pressure may be made on the label or labeling of a food described in paragraph (c)(2)(ii) of this section, provided that:

(A) The claim states that diets low in sodium "may" or "might" reduce the risk of high blood pressure;

(B) In specifying the disease, the claim uses the term "high blood pressure";

(C) In specifying the nutrient, the claim uses the term "sodium";

(D) The claim does not attribute any degree of reduction in risk of high blood pressure to diets low in sodium; and

(E) The claim indicates that development of high blood pressure depends on many factors.

(ii) *Nature of the food.* The food shall meet all of the nutrient content requirements of § 101.61 for a "low sodium" food.

(d) *Optional information.* (1) The claim may identify one or more of the following risk factors for development of high blood pressure in addition to dietary sodium consumption: Family history of high blood pressure, growing older, alcohol consumption, and excess weight.

(2) The claim may include information from paragraphs (a) and (b) of this section, which summarizes the relationship between dietary sodium and high blood pressure and the significance of the relationship.

(3) The claim may include information on the number of people in the United States who have high blood pressure. The sources of this information must be identified, and it must be current information from the National Center for Health Statistics, the National Institutes of Health, or "Nutrition and Your Health: Dietary Guidelines for Americans," U.S. Department of Health and Human Services (DHHS) and U.S. Department of Argiculture (USDA), Government Printing Office.

(4) The claim may indicate that it is consistent with "Nutrition and Your Health: U.S. Dietary Guidelines for Americans, DHHS and USDA, Government Printing Office.

(5) In specifying the nutrient, the claim may include the term "salt" in addition to the term "sodium."

(6) In specifying the disease, the claim may include the term "hypertension" in addition to the term "high blood pressure."

(7) The claim may state that individuals with high blood pressure should consult their physicians for medical advice and treatment. If the claim defines high or normal blood pressure, then the health claim must state that individuals with high blood pressure should consult their physicians for medical advice and treatment.

(e) *Model health claims.* The following are model health claims that may be used in food labeling to describe the relationship between dietary sodium and high blood pressure:

(1) Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors.

(2) Development of hypertension or high blood pressure depends on many factors. [This product] can be part of a low sodium, low salt diet that might reduce the risk of hypertension or high blood pressure.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

Note: The following table will not appear in the annual Code of Federal Regulations.

BILLING CODE 4160-01-F

TABLE

Sodium/Hypertension

Study	Study Design	Subjects	Methods	Results	Comments
Beretta-Piccoli (1990) (Ref. 136)	Survey of exchangeable body sodium (Na) in normotensive men with and without a family history of hypertension Study done in Switzerland	62 healthy, normotensive males (SBP < 130 mm Hg, DBP < 90 mm Hg) (31 with a family history of hypertension, 31 without a family history of hypertension) Subjects matched by age, height, and weight Subgroup of 23 (13 with and 10 without a family history of hypertension)	Mean total exchangeable Na was measured by isotope dilution The study of exchangeable Na in the total group was carried out with subjects on a normal Na intake (150 mmol or 3,400 mg per day) The adaptation of exchangeable Na to variations in dietary Na intake, carried out in the study subgroup, involved taking measurements at the end of a 7-day low-salt phase (17 mmol or 390 mg per day) and of a 7-day high-salt phase (270 mmol or 6,200 mg per day)	Investigation of 62 subjects on normal Na intake: Blood pressure (BP) was higher in the group of normotensive men with a family history of hypertension ($p < 0.005$), but age, urinary Na excretion, plasma renin activity, and aldosterone levels or creatine clearance were comparable Exchangeable Na did not differ significantly between the two groups and was unrelated to arterial pressure or to plasma renin activity Investigation of subgroup of 23 subjects varying the Na intake: At the end of the low-Na phase, there was no significant difference in BP, heart rate, body weight, exchangeable Na, plasma Na and potassium, or creatinine clearance between subjects with and without a family history of hypertension The change from a low-Na diet to a high-Na diet resulted in significant and comparable rises in body weight and exchangeable Na in the two groups, comparable values for Na-dependent suppression of renin, angiotensin II, aldosterone, and plasma catecholamines, and no changes in heart rate, plasma Na and potassium, or creatine clearance Supine SBP and DBP increased with Na intake in all subjects but more in subjects with a family history of hypertension (SBP: from 119 to 126 mm Hg, DBP: from 76 to 80 mm Hg) as compared to those without a family history of hypertension (SBP: from 112 to 113 mm Hg, DBP: from 69 to 71 mm Hg)	Findings suggest that exchangeable body Na is normal and adapts normally to variations in dietary Na intake in normotensive subjects with familial predisposition to hypertension The authors concluded that exchangeable body Na depletion in early hypertension appears to be a secondary rather than a primary event

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Carney (1991) (Ref 136)	Randomized double-blind crossover study to evaluate the effect of additional sodium chloride (NaCl) compared with a placebo on BP control over a 6 week period before changing to the other trial arm for an additional 6 week period	11 patients with mild to moderate essential hypertension satisfactorily treated with diverse hypotensive agents (BP stable and well controlled for at least 6 months with no evidence of renal, cardiac, hepatic, or endocrine disease) (5 men, 6 women) Age range: 30 to 65 years	Patients were kept on normal diets and randomly assigned to 6 week periods of additional Na (100 mmol or 2,300 mg slow Na (10 NaCl tablets per day) or a placebo with a subsequent crossover Body weight, pulse, and supine and erect BP (mean of two readings) were measured at 1, 2, 4, and 6 weeks of each trial arm Blood collections and 24-hour urine collections were taken at study commencement, and 1, 6, 7, and 12 weeks	Tablet compliance was excellent There were no significant changes in mean supine or erect BP with increased NaCl in patients on various hypotensive drugs	Findings suggest that excess dietary Na does not jeopardize BP control in patients on various hypotensive drugs
Dustan (1988) (Ref. 125)	Intervention study to investigate the quantitative importance of Na balance to arterial pressure changes produced by changes in Na intake Conducted at the University of Alabama Hospital	Protocol 1: 51 normotensive white patients (19 males, 32 females) 18 normotensive black patients (7 males, 11 females) 21 hypertensive black patients (5 males, 16 females) Protocol 2: 11 normotensive white patients (2 males, 9 females) 16 normotensive black patients (6 males, 10 females) 19 hypertensive black patients (4 males, 15 females)	Protocol 1: A 3-day control period (150 meq or 3,600 mg Na intake per day) followed by 4 days of salt depletion (SD) (low-Na diet of 9 meq or 210 mg Na per day) and furosemide (1 mg/kg given on the first day) followed by 3 days of salt loadingPABA (SL) (low-Na diet continued plus 25 mL/kg of isotonic NaCl solution or 3.88 meq or 90 mg per kg per day) given intravenously Protocol 2: Same as Protocol 1 except the sequence of Na intake changes was reversed For both protocols, Na balance was calculated by subtracting urinary Na excretion from Na intake and expressed in meq per Kg, either positive or negative	Protocol 1: Mean arterial pressures of the two normotensive groups were comparable in the control period and varied little during SD and SL Mean arterial pressures of the hypertensive group fell during SD and returned toward control values during SL Na balance data were comparable for the three groups, except the hypertensives lost more Na during SD than the normotensives Protocol 2: Mean arterial pressures of the normotensive white group varied little during SD and SL Mean arterial pressures of both the normotensive and the hypertensive black groups fell during SD and rose during SL Na balance data were comparable for the two normotensive groups; the black hypertensives retained less Na during SL and did not lose more Na during SD than the normotensives Spearman correlation coefficients indicated that there was no significant relationship between arterial pressure changes and Na losses during SD or Na retention during SL in either protocol or any group	The authors noted that group averages obscured the heterogeneity of the BP responses Spearman correlations suggest that salt-sensitive (SS) hypertension results not from the magnitude of Na retention, but from the pressor mechanisms evoked

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Elliott (1988) (Ref. 126)	Data collected as part of a 1983 to 1984 survey in North London, England Random sample of survey population selected for study of Na versus BP	50 subjects (29 men, 29 women) Age: 40 years and above Age range: 41 to 87 years Mean age: 57.9 years Diabetics (6 subjects) and people taking antihypertensive medication (5 subjects) and diuretics (3 subjects) were included in the study	Na determined by 24-hour urinary Na excretion BP determined as the average of 2 measurements, 1 at each of 2 visits an average of 8 1/2 months apart	SBP significantly related to 24-hour Na excretion, and results remained significant after adjustment for age, sex, and body mass index DBP significantly related to 24-hour Na excretion, and results were borderline after adjustment for age and sex and not significant after adjustment for age, sex, and body mass index Para-aminobenzoic acid (PABA) was used to monitor reliability of complete 24-hour urine collection and the statistical significance was greater for the subgroup of "complete collectors" as monitored by PABA	Eleven subjects provided two 24-hour urine collections to estimate the within-individual variability Only 50% of subjects were classified as "complete collectors" by PABA excretion
Ellison (1989) (Ref. 140)	Nonrandomized, concurrently controlled, longitudinal study Application of intervention in two boarding high schools Each school served alternatively as the control or the intervention school for 1 school year	BP monitored among 341 subjects during control years and 309 subjects during intervention years	The Na intake of students was reduced by 15 to 20% through changes in food purchasing and preparation practices Students were not asked to change their usual eating habits Changes in Na intake were determined by 24-hour food diaries which the students completed periodically during the study BP determined weekly as the average of 2 of 3 measurements	Average SBP reduced by 1.7 mm Hg (95% confidence intervals (CI) = -0.6, -2.9, p=0.003) on low-Na diet Average DBP reduced by 1.5 mm Hg (95% CI = -0.6, -2.5, p=0.002) on low-Na diet Values were adjusted for gender and initial BP	There was no control for possible differences in exercise levels among students at two schools There was no independent measurement of urinary Na excretion from the beginning to the end of the year to document changes in Na intake BP increased above baseline early in the year and then fell and remained below baseline later in the year

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Espinal (1992) (Ref. 143)	Three-phase dietary salt intervention trial to characterize the response of hypertensive patients to dietary salt	30 well-established adult hypertensives (DBP > 90 mm Hg on 3 visits)	Salt-Step Test in three Phases (medications and substances that might alter BP or salt balance were discontinued during the three phases) Phase 1: Unrestricted-salt phase: No restrictions on salt intake to certify the presence of hypertension and to document customary salt intake Phase 2: Restricted-salt phase: Low salt diet (2 g salt per day, i.e. < 34 mmol or 780 mg Na per day) to identify SS patients who could maintain DBP < 90 mm Hg on 2 g salt per day Phase 3: Salt-step phase: Diet established in Phase 2 (2 g salt per day) continued and salt added stepwise (each step lasting at least 3 days) in 1 g increments (390 mg Na) to determine the level of salt that triggered hypertension in individual patients (Salt Hypertension Threshold)	The 13 patients classified as SS (DBP < 90 mm Hg on salt-restricted diet) experienced large BP decreases between Phases 1 and 2 (SBP: from 177.1 to 145.1 mm Hg; DBP: from 105.4 to 82.0 mm Hg) The Salt Hypertension Threshold for the 13 SS patients ranged from 3 to 16 g salt (1,200 to 6,200 mg Na) per day, and the results, which were repeated in 11 patients at intervals between 2 months and 1 1/2 years later, remained stable and reproducible (i.e., they agreed for each patient within 2 g salt or 780 mg Na per day) The remaining 17 patients experience smaller BP decreases between Phases 1 and 2 (SBP: from 173.3 to 164.1 mm Hg; DBP: from 102.9 to 98.2 mm Hg) Body weight decreased in all but 2 patients in the restricted-salt phase and increased in all patients until thresholds were reached	The independent contribution of weight changes was not evaluated, thus, it is not clear whether the observed BP changes are the result of lower salt intake, lower weight, or a combination of the two The author noted that the individuality of responses and the broad range of thresholds could explain why some patients respond to fixed salt dosages and others do not and concluded that the Salt-Step Test may be useful in providing specific, individualized guidelines for dietary salt restriction
Forte (1989) (Ref. 132)	Study to evaluate the effect of a health education program on salt reduction and BP in two matched rural communities in Portugal Initial salt intake was high (about 360 mmol or 8,300 mg Na per day) and 30% of individuals were hypertensive (DBP = or > 95 mm Hg)	2 villages, each with about 800 inhabitants A stratified random sample of 150 people was drawn from each village, comprised of 25 subjects of each gender in each of 3 age groups (15 to 34, 35 to 54, and 55 to 69 years)	In the intervention community there was a vigorous health education effort to reduce salt intake Duplicate BP readings were obtained from each individual at the beginning of the study, at 12 months, and at 24 months	In the intervention community, average SBP and DBP fell by 3.6 and 5.0 mm Hg, respectively, at 1 year and by 5.0 and 5.1 mm Hg, respectively, at 2 years In the control community, average SBP rose and DBP remained stable	The authors noted that the difference in trends between the two communities was highly significant and seemed to indicate that, at least in this high-intake population, a decrease in salt consumption seemed to have resulted in a sizeable decrease in average BP

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Geleijnse (1990) (Ref. 149)	Longitudinal study of a cohort of children in a suburban town in the Netherlands to assess the association between Na and potassium intake and BP	233 children (108 boys, 125 girls) Age range: 5 to 17 years at entry Randomly selected from participants in an epidemiological population survey for determining risk factors for cardiovascular disease Children with established hypertension were excluded	At least 6 yearly examinations were made during an average followup period of 7 years Mean 24-hour Na and potassium was calculated from 6 timed overnight urine samples during the year, and the sodium/potassium ratio was calculated BP was determined at each visit as the average of 2 readings Individual slopes of BP over time were calculated by linear regression analysis	No significant association was observed between Na excretion and the change in BP over time Figures were adjusted for gender, initial age, change in height, change in body weight, and potassium intake Boys mean 24-hour Na ranged from 61.5 to 251.5 mmol (1,400 to 5,800 mg) Girls mean 24-hour Na ranged from 60.5 to 215.3 mmol (1,600 to 4,900 mg) The mean yearly rise in SBP for the whole group was 1.93 mm Hg	Dietary potassium and the ratio of dietary Na to potassium were related to the rise in BP in children, and the authors concluded that these values may be important in the early pathogenesis of primary hypertension Higher potassium levels were associated with lower mean SBP slopes over time Higher sodium/potassium ratios were associated with greater changes in SBP
Gill (1988) (Ref. 127)	Intervention trial in which patients with normal renin, idiopathic hypertension were compared with normotensive subjects after consuming Na intakes of 9, 109, and 249 meq (200, 2,500, and 5,700 mg) per day for 7 days	19 patients with normal renin idiopathic hypertension (antihypertensive medications discontinued) (14 women, 10 men) (20 to 75 years of age) 5 normotensive subjects without a family history of hypertension (3 women, 2 men) (20 to 62 years of age)	All subjects housed on a metabolic unit and fed a constant isocaloric diet containing 9 meq (200 mg) Na Supplements of NaCl were given as follows: 100 meq (2,300 mg Na) per day for 7 days (normal Na intake of 109 meq or 2,500 mg Na); no supplement for 7 days (low Na intake of 9 meq or 200 mg Na); and 240 meq (5,500 mg) per day for 8 days (high Na intake of 249 meq or 5,700 mg Na)	Hypertensive subjects were classified as SS (mean arterial pressure increases of 0 to 16%) or salt-resistant (SR) (mean arterial pressure changes of -7 to +7%) as compared with normotensive subjects (mean arterial pressure changes of -3 to +7%) in response to changes in Na intake Mean BP on the low-Na relative to the high-Na diet increased in the SS hypertensive subjects (from 104 to 114 mm Hg), and the normotensive subjects (from 79 to 83 mm Hg), and remained balanced in the SR hypertensive subjects (114 mm Hg) (due to classification scheme in which BP increases and decreases were set to be equal)	The authors noted that supernormal Na retention and a failure to suppress adrenergic activity may explain, in part, the phenomenon of salt sensitivity of BP in SS patients and may also be factors in the pathogenesis of hypertension in this subset of individuals

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
He (1991) (Ref. 139)	Study to investigate the relationship of Na, potassium, calcium, and magnesium to BP in 4 groups of Southern Chinese men with a wide range of electrolyte intakes Study conducted in Puge County, Sichuan Province, People's Republic of China	4 groups of men: 119 high-mountain Yi farmers, 114 mountainside Yi farmers, 99 Yi people who had migrated to the county seat, 97 Han people who were native residents of the county seat	Four electrolytes were measured in the diet, blood serum, and urine	Na excretion was 73.9 mmol (1,700 mg) per 24 hours in high-mountain Yi farmers, 117.9 mmol (2,700 mg) per 24 hours in mountainside Yi farmers, 159.4 mmol (3,700 mg) per 24 hours in Yi migrants, and 186.0 mmol (4,300 mg) per 24 hours in the Han people In ecological correlation analysis, dietary and urinary Na were significantly and positively correlated with both SBP and DBP, whereas serum Na showed no relationship to BP Analysis at the individual level confirmed the results seen at the ecological level These findings persisted after controlling for age, body mass indices, heart rate, alcohol, and total energy intake In multiple regression analysis, an increase in Na intake of 100 mmol (2,300 mg) per day corresponded to an increase of 2.3 mm Hg SBP and 1.0 mm Hg DBP	The authors noted that the results are consistent with the view that a diet low in Na may prevent the development of hypertension

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Joossens (1991) (Ref. 147)	SBP data from 6 Belgian surveys conducted between 1967 and 1986 were reanalyzed	3,320 subjects 1967 study: 510 subjects 1972 study: 366 survivors of 1967 study 1973 to 1977 study: 143 subjects 1980 to 1984 study: 1,803 subjects 1979 to 1986 study: 344 subjects 1986 study: 162 subjects Range of mean ages of 6 groups: 70 to 81 years	All Na determinations from 24-hour urine samples were performed using the same methods and in the same laboratory used in the INTERSALT study (Ref. 37) Data were analyzed by age groups and the age groups used were the same as those used in the INTERSALT study	Values are for the change between 1967 and 1986: The mean standardized 24-hour Na excretion decreased from 265 to 188 mmol (6,100 to 3,700 mg) in men and from 200 to 160 mmol (4,800 to 3,700 mg) in women Mean SBP decreased from 159 to 142 mm Hg in men and from 171 to 147 mm Hg in women The prevalence of hypertension (SBP above 159 mm Hg) decreased from 51% to 21% in men and 66% to 22% in women, and severe hypertension (SBP > 220 mm Hg) nearly disappeared The proportion of subjects receiving treatment for hypertension increased from 10% to 36% in men and from 10% to 41% in women SBP was significantly and independently related to Na excretion in the 1967 and 1972 studies	Methodologies were similar but not identical between the studies, and differences would increase variability Only SBP was considered because DBP decreases with age in the elderly During the same period, body mass index increased 1.1 kg/m^2 in men and remained unchanged in women, therefore decreases in BP cannot be ascribed to changes in body mass index Treatment for hypertension increased, and Na intake decreased The authors calculated that the increase in hypertension treatment and the decrease in Na intake, taken together, could account for the observed changes in SBP, but that neither factor alone was sufficient The authors concluded that the decrease in SBP in Belgium was influenced by the combined effects of more and better treatment for hypertension and a decrease in Na intake

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Study	Study Design	Subjects	Methods	Results	Comments
Khaw (1988) (Ref. 120)	Cross-sectional examination of the relationship between dietary Na and potassium intake and BP estimated from 24-hour dietary recall among members of a defined geographical region in Southern California	584 men and 710 women Age: 30 to 79 years Geographically defined, upper middle class, white population	A 24-hour dietary recall was obtained by a certified dietician The raw 24-hour dietary recall data were coded for nutrient intake by the Nutrition Coordinating Center, University of Minnesota, using their 1983 computerized data base	Age-adjusted SBP and DBP correlated significantly with dietary Na intake in men, but not in women, and with the sodium/potassium ratio in both men and women The relationship was apparent over the whole range of BP and dietary intakes A marked age gradient was apparent in men; the regression slope for BP versus sodium/potassium ratio increasing with increasing age, suggesting increasing sensitivity to dietary sodium/potassium ratio with age Adjustments for intakes of other dietary variables; including calories, protein, carbohydrates, saturated fat, alcohol, calcium, and fiber; did not alter the relationship. Adjustments for body mass index reduced the strength of the association in women but not in men	The authors noted that the results support the hypothesis that Na and potassium are related to BP within a population
Little (1991) (Ref. 140)	Observer-blind, controlled trial studying the effect of a low-Na, low-fat, high-fiber diet in allowing a reduction of antihypertensive medication as compared with the effect produced by the individual components of this diet Study conducted in the United Kingdom	196 patients with established hypertension (DBP > 95 mm Hg on at least 3 occasions)	Patients were allocated to the following groups, keeping the observer blind to group allocation: Group A (control): no change in diet (n=41) Group B (high-fiber diet): 40 to 45 g soluble and insoluble fiber per day (n=42) Group C (low-Na diet): 40 to 50 mmol (920 to 1,150 mg) Na per day (n=30) Group D (low-fat diet): 23 to 25% calories as fat per day with no change to the P/S or M/S ratios (n=43) Group E (combination low-Na, low-fat, high-fiber diet) 40 to 45 g fiber, 40 to 50 mmol (920 to 1,150 mg) Na, 23 to 25% calories as fat per day (n=40)	In the control group, a 33% reduction in medication was possible, with 24% of patients off medication altogether The low-fat, high-fiber, and low-Na groups showed larger reductions in medication (38%, 47%, and 45%, respectively, but the results were not significant when compared with the control group The combination group had the largest medication reduction (64%) and the difference was highly significant when compared with the control group, and significantly more patients in this group stopped their medication altogether (57.5%) when compared with the control group	The authors noted that the findings are significant because negative side effects of drug treatment may be reduced by lowering drug doses and making corresponding changes in diet

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Study	Study Design	Subjects	Methods	Results	Comments
Miller (1988) (Ref. 150)	Intervention study to determine whether modest dietary Na restriction in childhood results in heterogeneous changes in BP response Study conducted in Indiana	169 healthy, normotensive children (84 boys, 85 girls)	Baseline BP and 24-hour urinary Na were determined prior to Na restriction to serve as control data Families received instructions designed to aid them in restricting their dietary Na intake to a goal of 60 mmol (1,380 mg) per day Families were encouraged to maintain their usual dietary practices so that other dietary constituents (i.e. potassium and calories) would not be altered Dietary restrictions lasted for 3 months	Na excretion was decreased during the study period in both boys (from 112.9 mmol or 2,600 mg to 53.5 mmol or 1,230 mg) and girls (from 91.1 mmol or 2,090 mg to 41.1 mmol or 940 mg) Changes in SBP were not significant in either sex but females showed a decrease ($p < 0.05$) in DBP and mean actual pressures Because BP in children is correlated with age and body size, multiple linear regression was used to adjust BP levels for age and weight, and these analyses yielded small but significant decreases in SBP, DBP, and arterial pressures	The authors noted that the results suggest that compliance with modest Na restriction does not consistently lower BP in normotensive children
Pavek (1990) (Ref. 146)	Intervention study Objective measures of BP sensitivity to a 72-hour salt depletion were evaluated Salt-sensitivity was defined as a decrease in DBP after salt depletion and was estimated by both 24-hour ambulatory and office BP measurements Study conducted in Sweden	35 mild hypertensives (15 men and 20 women) Mean age: 48 years Mean body mass index: 25.2 Active, working patients with mild, untreated hypertension were recruited from a screening of public health service employees The duration of known increase of BP was 7.3 years	Salt depletion started with a morning furosemide (40 mg) tablet and continued for 72 hours with a low-salt diet consisting of unprocessed rice, potatoes, fruits, vegetables, and about 2 L of tap water Na determined by 24-hour urine collection BP determined before and after salt depletion; 24-hour ambulatory BP was recorded 3 times per hour on the left arm using an oscillometric monitor; and 6 pairs of sitting auscultatory and oscillometric pressures were recorded in random order in the mornings, at the start, and at the end of the 24-hour BP recordings	Average 24-hour Na decreased by 17.5 mmol (400 mg) Average body weight decreased by 3.1% Average SBP decreased significantly using all 3 types of BP measurements Average DBP changed little, and a statistically significant decrease was observed only by the oscillometric method.	Study duration was short (72 hours) Individual estimates of salt-sensitivity varied widely and were dependent on the type of BP measurement employed

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Study	Study Design	Subjects	Methods	Results	Comments
Rocchini (1989) (Ref. 133)	Study to measure BP response in obese and nonobese adolescents after successive 2-week periods of a high-salt diet and a low-salt diet, and to compare results for a subset of the obese adolescents before and after a 20-week weight-loss program	60 obese adolescents (10 to 16 years old) (Mean age: 13 years) 10 nonobese adolescents (10 to 16 years old) (Mean age: 12.5 6 years)	Sensitivity to Na was evaluated by giving all subjects a high-salt diet (> 250 mmol or 5,700 mg Na per day) for two weeks, followed by a low-salt diet (< 30 mmol or 700 mg Na per day) for two weeks The low-salt diet was formulated to contain the same caloric intake as the high-salt diet To assess compliance with the diets, 24-hour food records were reviewed and 24-hour urine samples were collected on the day before the outpatient testing A subset of the obese adolescents (51 subjects) were also studied before and after a 20-week weight-loss program	When changed from the high-salt to the low-salt diet, the obese group had a significant decrease in mean arterial pressure (from 92 to 88 mm Hg) relative to insignificant change in the nonobese group (from 76 to 77 mm Hg)($p < 0.001$) After the weight-loss program, the 36 subjects who lost more than 1 kg of body weight (average weight loss 7.5 kg) had a reduced sensitivity of BP to Na	The authors noted that the results support the hypothesis that the BP of obese adolescents is sensitive to dietary Na intake, and that this sensitivity may be due to the combined effects of hyperinsulinemia, hyperaldosteronism, and increased activity of the sympathetic nervous system that are characteristic of obesity
Shore (1988) (Ref. 129)	Randomized, crossover study to investigate the effect of supplementing a low-Na diet with either NaCl or sodium phosphate Study conducted in the United Kingdom	6 hypertensive outpatients (DBP between 90 to 110) with no history of, and no clinical, or biochemical evidence of renal or heart disease Patients had either received no antihypertensive medication or such medication had been withdrawn for at least 2 weeks prior to the study Patients had DBP between 90 and 110 mm Hg when receiving no medication	A low-salt diet (10 mmol or 230 mg Na and 80 mmol potassium) was provided After 5 days on the low-salt diet, the diet was supplemented with Na for an additional period of 5 days, followed by another 5-day period of the low-salt diet alone, and a second supplementation period of 5 days The Na load was given as NaCl (daily Na intake 120 mmol or 2,760 mg) or as Na in the presence of other anions, mainly phosphate (daily Na intake 122 mmol or 2,800 mg) Three patients received NaCl supplementation first	With both Na salts, urinary Na excretion increased The calculated amount of Na retained was similar for both the NaCl and the sodium phosphate periods Increases in BP occurred with the addition of NaCl to the low-salt diet; however, no change in BP occurred with the addition of sodium phosphate	Differences in the distribution of the retained Na may have contributed to the BP responses The authors noted that these findings suggest that the anion may be important in the BP response to Na loading in patients with essential hypertension

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Study	Study Design	Subjects	Methods	Results	Comments
Sullivan (1988) (Ref. 130)	Dietary intervention study to identify normotensive and borderline hypertensive individuals whose BP rose in response to increased dietary Na, to determine the hemodynamic mechanism causing the increase in BP, to identify other characteristics of the Na-or salt-sensitive (SS) individual, and to determine if the Na-induced increases in BP persisted with time	65 borderline hypertensive subjects (DBP generally < 90 mm Hg, but > 90 mm Hg on at least 3 occasions) 92 normotensive subjects	Subjects were studied while following their usual diets followed by 4 days of a 10 meq (230 mg) Na and 60 meq potassium diet, and again after 2 days of their usual diets followed by 4 days of a 200 meq (4,600 mg) Na and 60 meq potassium diet After examining the distribution of responses, a 5% increase in BP from the 230 mg Na to the 4,600 mg Na state was selected as a measure of SS A subset of normotensive subjects, chosen from the Na-resistant normotensive subjects who agree to participate, followed a daily diet containing about 200 meq (4,600 mg) Na and were followed for 12 months	The prevalence of SS was higher in blacks than in whites and greater in hypertensives than in normotensives Mean BP rose on the high-salt diet as compared with the low-salt diet in the SS population (increase of 6.5%) as compared with the Na-resistant population (0%) BP was not found to rise during the long-term study because total peripheral resistance fell proportionately	The authors speculated that there may be a genetic basis for the response to Na, because the observed changes resembled those reported in the Dahl SS rat
Trials of Hypertension Prevention (TOHP) Collaborative Research Group (1992) (Ref. 123)	Randomized control, multicenter trials	2,182 normotensive (DBP: 80 to 89 mm Hg) subjects (70% men) Age: 30 to 54 years Average age: 43 years	Three life-style change groups (weight reduction, Na reduction, and stress management) were each compared with unmasked nonintervention controls over 18 months Four nutritional supplement groups (calcium, magnesium, potassium, and fish oil) were each compared singly, in double-blind fashion with placebo controls over 6 months The primary outcome measure was change in DBP from baseline to final followup, measured by blinded observers Secondary outcome measures were changes in SBP and intervention compliance measures Na reduction interventions focused on shopping, cooking, and food selection behaviors aimed at reducing intake of Na No recommendations regarding Na were given to weight reduction participants	In the Na-reduction and weight-reduction groups, both DBP and SBP were consistently reduced in the active intervention groups when compared to the controls In the Na-reduction group, the mean decrease in Na excretion was constant at about 55 to 60 mmol (1,300 to 1,400 mg) per 24 hours at 6, 12, and 18 months At the end of the study, the BP decreases in the Na-reduction group were 0.9 mm Hg DBP ($p<0.05$) and 1.7 mm Hg SBP ($p<0.01$), while in the weight reduction group, they were 2.3 mm Hg DBP and 2.9 mm Hg SBP ($p<0.01$ for both) Changes in BP for stress management were small and inconsistent in direction	Compliance with the three life-style interventions was satisfactory, both in terms of attendance at counseling sessions and in reaching specific goals The authors concluded that the magnitude of the BP reductions with changes in body weight and Na intake could have a substantial benefit in reducing the incidence of hypertension, and on cardiovascular morbidity and mortality

TABLE--CONTINUED

Study	Study Design	Subjects	Methods	Results	Comments
Weinberger (1991) (Ref. 161)	Three studies to classify subjects as SS or SR, to evaluate the relationship of SS and SR to age, and the evaluate the changes in BP over time of individuals classified as SS or SR Used a Na and volume expansion and contraction protocol in making both cross-sectional and longitudinal observations Study conducted in Indiana	Study 1: 28 hypertensive (antihypertensive medication or BP > 140/90) and normotensive (BP < 140/90) subjects Study 2: 230 hypertensive and 430 normotensive subjects Study 3: 13 hypertensive (10 SS, 3 SR) and 10 normotensive (6 SS, 12 SR)	Rapid Na-sensitivity test described: Comparison of BP response after rapid increase in extracellular fluid volume and Na balance using an intravenous infusion of 2 L saline (0.9%) over 4 hours versus Na and volume depletion induced by intake of 10 mmol or 230 mg Na and furosemide over 1 day A SS response was defined as a decrease in mean arterial pressure of 10 mm Hg or greater, and a SR response was defined as a change in mean arterial pressure of 5 mm Hg or less Study 1: The BP response was studied twice within a 12-month period Study 2: The BP response was studied to evaluate the influence of age Study 3: BP changes over a period of 10 years or more were studied	Study 1: The BP response was reproducible in 20 individuals who were tested twice within a 12-month period (r=.56; p < 0.002) Study 2: Salt-sensitivity of BP increased significantly with increasing age in the entire population (n=660; r= -0.38; p < 0.001) and was more striking in hypertensive subjects in whom a progressive increase in SS with decades was seen than in the normotensives in whom SS was not seen until the sixth decade Study 3: SS subjects had a significantly greater increase in SBP and DBP over time than SR subjects	The authors noted that salt-sensitivity appears to be a reproducible phenomenon that is related to the age-associated increase in BP which is characteristic of industrialized societies The authors noted that salt-sensitivity can be shown to be a predictor of subsequent, age-related BP increase

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 102, 130, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169

[Docket No. 90N-0361]

RIN 0905-AD08

Food Labeling; Declaration of Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its food labeling regulations to make ingredient labeling more useful for consumers. The agency is also responding to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), which amended the Federal Food, Drug, and Cosmetic Act (the act) by requiring the listing of the common or usual names of: (1) All ingredients in standardized foods and (2) all color additives required to be certified by FDA.

In addition, this document will: (1) Permit inclusion of the food source in the names of the sweeteners defined by the food standards in §§ 168.110 and 168.111 (21 CFR 168.110 and 168.111) (i.e., "corn sugar anhydrous" and "corn sugar monohydrate" would be permitted in addition to names already provided for in § 168.110(b) ("dextrose anhydrous" or "anhydrous dextrose") and § 168.111(c) ("dextrose monohydrate" or "dextrose")); (2) require the declaration of all protein hydrolysates (hydrolyzed vegetable protein and others), including the identification of the food source, e.g., "hydrolyzed corn protein," in the list of ingredients; (3) require identification of a caseinate (e.g., sodium caseinate) as a milk derivative when used in foods that claim to be nondairy foods; (4) provide a uniform format for voluntary declaration of percentage ingredient information; (5) require label declaration of sulfiting agents that have a functional effect in a standardized food or that are present in a standardized food at a detectable level of 10 parts per million (ppm) or more; and (6) provide certain exemptions from the requirements for listing the specific common or usual names of preservative coatings on fresh fruits and vegetables. Elsewhere in this issue of the **Federal Register**, the agency is publishing a final rule under the provisions of section 701(e) of the act (21 U.S.C. 371(e)) to establish and amend the ingredient labeling requirements within the standards of identity for dairy products (parts 131, 133, and 135 (21 CFR parts 131, 133, and 135)) and maple sirup (syrup) (§ 168.140 (21 CFR 168.140)). Also in this issue of the **Federal Register**, the agency is publishing a proposed rule to: (1) Amend the ingredient labeling requirements within the standard of identity for canned tuna (§ 101.190); (2) amend the common or usual name regulations for protein hydrolysates (§ 102.22) to require the term "contains glutamate" as a part of the common or usual name of autolyzed yeast extracts and certain hydrolyzed proteins; and (3) amend the food labeling regulations in § 101.22 (21 CFR 101.22) to allow "and/or" labeling for the declaration of sweeteners in soft drinks.

DATES: The effective date of the provisions in this final rule for ingredient listing of standardized foods and declaration of certified color additives is May 8, 1993 (§ 101.4(a) and (b)(2)(i), § 101.22(k), and parts 130 through 169). The effective date of all other provisions in this regulation is May 8, 1994. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a certain publication at 21 CFR 130.9, effective May 8, 1993.

FOR FURTHER INFORMATION CONTACT: Betty Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 21, 1991 (56 FR 28592), FDA published a proposed rule (hereinafter referred to as the June 21, 1991, proposal) to implement amended sections of the act in accordance with section 7 of the 1990 amendments (Pub. L. 101-535) to require the listing of the common or usual names of all ingredients in standardized foods and of all color additives required to be certified by FDA under section 706(c) of the act (21 U.S.C. 376(c)) that were used in the food.

In response to written and oral comments received on an advance notice of proposed rulemaking (ANPRM) published in the **Federal Register** of August 8, 1989 (54 FR 32610), FDA also proposed in the June 21, 1991, proposal to: (1) Require that when more than one sweetener is used in a product, all sweeteners be listed together in the ingredient list under the collective term "sweeteners"; (2) permit inclusion of the food source in the names of the sweeteners defined by the food standards in §§ 168.110 and 168.111; (3) require the declaration of protein hydrolysates used for flavor-related purposes, including the identification of the food source in the list of ingredients; (4) require identification of caseinate as a milk derivative when used in a food that claims to be a nondairy food; (5) require that label statements explain that the list of ingredients is arranged in descending order of predominance; (6) provide a uniform format for voluntary declaration of percentage ingredient information; and (7) permit certain exemptions from requirements for listing the specific common or usual names of preservative coatings on fresh fruits and vegetables.

FDA also reproposed labeling requirements for sulfiting agents in standardized foods that it had first proposed in the **Federal Register** of December 19, 1988 (53 FR 51062). In 1988, FDA proposed to require that any sulfiting agent (or combination of sulfiting agents) that is present in a standardized food and is functional and provided for in the standard of identity, or that is present in the finished food at a detectable level of 10 ppm or more, must be declared on the label of the food by its common or usual name. Under the proposal, label declaration of sulfites meeting these criteria would be required regardless of whether the sulfite is directly added or indirectly added to the food via one or more of the ingredients of the food. The preamble to the December 19, 1988, proposal was incorporated in the June 21, 1991, proposal. In this final rule, FDA is responding to the comments received on the proposal and on the reproposal.

The agency received over 700 letters about the June 21, 1991, proposal. Each letter contained one or more comments. The letters were from a wide range of sources, including consumers, consumer organizations, professional associations, State and local government agencies, industry, and industry trade associations. Many comments generally supported the proposal or various provisions of the proposal. Other comments addressed issues outside the scope of the proposal (e.g., nutrition labeling, State petitions for exemption from preemption) and will not be discussed here. Many of the comments suggested modifications, revisions, or revocations of various provisions of the proposal. A summary of the comments, the agency's responses to the comments,

and a complete discussion of the agency's conclusions with respect to ingredient labeling, follow.

II. Ingredients of Standardized Foods

Before the 1990 amendments were enacted, FDA had authority under section 403(g) of the act (21 U.S.C. 343(g)) to require the declaration of optional ingredients in standardized foods. The act did not make any provision, however, for the declaration of mandatory ingredients (21 U.S.C. 343(g) and (i)). In the absence of statutory authority, FDA could not require the complete listing of all ingredients in standardized foods. However, the 1990 amendments revised section 403(i) of the act to treat standardized foods like all other foods and require the listing of all ingredients.

In addition, section 8 of the 1990 amendments removed most rulemakings on food standards from the coverage of section 701(e) of the act. Thus, they are subject to section 701(a) of the act. Actions for the amendment or repeal of food standards for dairy products and maple sirup, however, remain subject to section 701(e) of the act, which prescribes formal rulemaking procedures for the issuance, amendment, or repeal of regulations. Under formal rulemaking procedures, there is an opportunity to object to a final rule and to request a public hearing based upon such objection. Such an opportunity is not provided as part of the notice-and-comment rulemaking procedures followed by the agency under section 701(a) of the act. The agency is publishing the regulations set forth below under section 701(a) of the act. Elsewhere in this issue of the **Federal Register**, the agency is amending the standards of identity for dairy products in parts 131, 133, and 135 and for maple sirup in § 168.140 under the formal rulemaking provisions of section 701(e) of the act.

A. General Labeling of Standardized Foods

To make its ingredient labeling regulations consistent with the 1990 revision of section 403(i) of the act that pertains to standardized foods, FDA proposed in the June 21, 1991, proposal, to add new § 130.3(e) (21 CFR 130.3(e)). The proposed paragraph specified that all mandatory and optional ingredients of standardized foods must appear on food labels in accordance with the requirements of part 101 (21 CFR part 101), except that where a definition and standard of identity contains a specific provision with respect to the declaration of optional ingredients, the optional ingredients may be declared in accordance with that provision. FDA also proposed to amend all the standards of identity to require that all ingredients be declared on the label in accordance with the applicable sections of part 101 and part 130 (21 CFR part 130).

1. International Implications

1. Two comments from foreign governments opposed the declaration of mandatory ingredients of standardized foods. These comments maintained that listing mandatory ingredients would place an undue burden on the manufacturer without a noticeable advantage to the consumer and would cause confusion among foreign manufacturers, because in most other countries, manufacturers are required only to provide optional ingredient labeling in standardized foods. These comments argued that this regulation would require foreign companies to use separate labels just for the U.S. market, consequently increasing costs and discouraging free trade. They further maintained that consumer education would be more beneficial than ingredient declaration because standardized foods are prepared according to regulations.

The agency advises that foreign companies that market their products in the United States will have to comply with this requirement. The agency does not have the authority to provide a general exemption from this statutory provision for foreign manufacturers. The 1990 amendments amended section 403(i) of the act to require that the labeling of products marketed in the United States declare all ingredients used to make a food including a standardized food. Congress adopted this amendment with full recognition that it would eliminate a significant exception to the mandatory ingredient labeling requirements in section 403 of the act. See 136 Congressional Record H5842 (July 30, 1990). Consequently, FDA finds that there is no basis to make any changes in the regulations that it proposed in response to these comments.

2. Declaration of Noncharacterizing Optional Ingredients

2. Some comments, objecting to the proposed revocation of § 101.6, requested that provisions in § 101.6(d) be retained. This provision exempts manufacturers who declare all of the ingredients in a standardized food in the ingredient list from declaring certain optional ingredients on the principal display panel or wherever the name of the standardized food appears on the label, as required by certain individual standards. These comments asserted that without this provision, a 1"double declaration" of certain optional ingredients would be required which would overemphasize the optional ingredients, overcrowd the label, and may be confusing and misleading to the consumer.

These comments also responded to the question raised in the June 21, 1991, proposal on the need for the requirement in some standards of identity that certain optional ingredients be declared in conjunction with the name of the food wherever it appears on the label (e.g., the principal display panel), and that the declaration be so conspicuous as to be easily seen under customary conditions of purchase. The comments recommended that declaration of these ingredients in this manner be voluntary because all ingredients will now be required to be declared on the information panel.

The agency agrees with the comments. In most cases, the declaration of certain optional ingredients in conjunction with the name would be duplicative and unnecessary now that the 1990 amendments require that all ingredients of standardized foods be declared in the ingredient list. It is not the agency's intent to require dual declaration of noncharacterizing optional ingredients. However, the agency notes that in some instances, the optional ingredients provided for in the individual standards of identity are characterizing in the food. In such instances, the optional ingredient must be declared in accordance with the provisions of the specific standard, as required by § 101.3(f) and new § 130.11.

With regard to retaining § 101.6, the agency recognizes that, in the absence of § 101.6, several of the standards of identity (e.g., Macaroni products (21 CFR 139.110)) would require that all optional ingredients in the food, whether characterizing or not, be declared wherever the name of the standardized food appears on the label. The agency considers such dual declaration of noncharacterizing optional ingredients in standardized foods to be unnecessary and inappropriate. Nonetheless, the agency finds that it is not appropriate simply to retain § 101.6(d).

Section 101.6(d) includes guidance on the voluntary listing of ingredients in standardized foods. Such guidance is no longer necessary under the new ingredient listing requirements. The agency finds that rather than retaining § 101.6(d), it is more appropriate to establish general provisions regarding label declaration of optional ingredients

of standardized foods in part 130, where the other general regulations for food standards are set forth.

Accordingly, the agency is revoking § 101.6 and establishing new § 130.11 to prescribe requirements for the declaration of characterizing ingredients and an exemption from such requirements for noncharacterizing ingredients. The requirements in new § 130.11 are intended to provide manufacturers the same options regarding declaration of noncharacterizing ingredients of standardized foods that were provided by § 101.6(d). The basic difference between new § 130.11 and § 101.6(d) is that the requirements in the latter section were based on voluntary declaration of all ingredients in standardized foods, whereas new § 130.11 reflects the requirements that all ingredients in standardized foods must be declared, as provided in the 1990 amendments.

The agency finds that the adoption of new § 130.11 in this final rule is a logical outgrowth of the proposal. The proposed revocation of § 101.6 created ambiguity between the agency's position not to require dual declaration of certain optional ingredients and the requirements of some of the existing standards of identity. Thus, the agency is adopting new § 130.11 to remove this ambiguity.

3. Ingredients of Standardized Juices

3. One comment requested that the agency provide an exemption under § 101.100(a)(3)(ii)(b) for naturally occurring constituents or components of fruit juice from ingredient declaration requirements. The comment expressed the opinion that substances that are ingredients of standardized foods, and thus subject to the new ingredient listing requirements, should be differentiated from those that, in the comment's view, are naturally occurring constituents of the raw food from which the standardized food is made and that, therefore, should not be subject to these requirements. The comment maintained that the distinction between "ingredients" and "constituents" is clearly recognized by the act, and that the distinction is made clearer in § 101.100(a)(3)(ii)(b), which provides for an exemption from ingredient declaration for processing aids that are "substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food."

The comment noted that several of the standards of identity for various forms of orange juice and grapefruit juice in part 146 (21 CFR part 146) require that all "optional ingredients" be listed on the label in the statement of ingredients. The comment further stated that each of the standards that refers to "optional ingredients" uses the term to apply to added ingredients such as sweeteners or concentrated juice products. The comment also noted that these standards provide for the removal, addition, and adjustment of certain naturally occurring constituents or components of the juice, such as the oil, pulp, and essence.

FDA does not agree with this interpretation of § 101.100(a)(3)(ii)(b). The exemption from ingredient declaration provided by § 101.100(a)(3)(ii)(b) pertains to "incidental additives," substances that are present in a food at insignificant levels and that do not have any technical or functional effect in that food. Oil, pulp, and essence are not incidental additives under this definition for the following reasons:

First, fruit oils, pulp, and essence are added to fruit juice products to accomplish specific technical functions in the manufactured juice products and are, therefore, not processing aids. These constituents are added to the juice to replace constituents or components (oil, pulp, and essence) of the juice that are intentionally or unavoidably removed during processing. Their addition enables manufacturers to adjust the organoleptic characteristics of the juice as needed because of natural variations in the fruit from which it is derived and to achieve uniform quality and organoleptic properties in the finished products from lot to lot and season to season (Ref. 44).

Secondly, the level of use of the added ingredients is not insignificant. For example, in the manufacture of frozen concentrated orange juice, most of the pulp of orange juice is removed to facilitate concentration. Pulp, obtained from oranges, is later added to the concentrate in amounts sufficient to yield levels in the finished product that are comparable to the pulp levels of the raw juice. Therefore, these ingredients cannot qualify as incidental additives or as processing aids under § 101.100(a)(3)(ii)(*b*).

However, FDA notes that when these naturally occurring constituents (oil, pulp, and essence) are removed from the juice for purposes of efficient processing, and these constituents, from the same types of fruit provided by the standard (including any limits on fruit species) are added to the juice later in the manufacturing process, there is no need to declare these constituents as "ingredients" under section 403(i)(2) of the act. The agency believes that this approach is reasonable because when the constituents of the juice are added to the juice, in the same proportions as in the original juice, the basic composition of the juice is not changed. Further, FDA believes that it may be misleading to consumers if these constituents are listed in the ingredient statement of the juice when their addition has not altered the basic composition of the juice. Consumers might be led to believe that the juice has been fabricated from the individual juice components, or that the juice contains substantially higher levels of these constituents than would be the case if the ingredients had not been added.

Thus, FDA advises that only if pulp, oil, or essence are added at levels significantly in excess of those found in the raw juice from which the juice is derived, or if they are obtained from an extraneous source, i.e., from sources other than the fruit from which the juice is obtained (e.g., produced synthetically or purchased through a flavor supplier for artificially adding flavor or texture to the juice), would they be ingredients subject to the ingredient labeling requirements for standardized foods, as set forth in part 130.

4. One comment expressed the opinion that orange juice from different species of orange should continue to be permitted to be declared as "orange juice" on the label. The comment noted that the standards of identity for pasteurized orange juice (§ 146.140), canned orange juice (§ 146.141), orange juice from concentrate (§ 146.145), and frozen concentrated orange juice (§ 146.146) provide that the finished juices are made from the juice of oranges of the species *Citrus sinensis*, with up to 10 percent of the juice from the species *C. reticulata* or hybrids thereof. Similarly, the comment noted, the standard of identity for grapefruit juice (§ 146.132) provides for juice from the species *C. paradisi Macfadyen*, with up to 10 percent of the juice coming from mature hybrids of grapefruit.

In this context, FDA notes that the standard for frozen concentrated orange juice (§ 146.146) also provides for the addition of up to 5 percent of the juice of mature oranges of the species *C. aurantium*. By cross-reference to this standard, the standards of identity for orange juice from concentrate (§ 146.145), reduced acid frozen concentrated orange juice (§ 146.148), concentrated orange juice for manufacturing (§ 146.151), and frozen concentrated orange juice with

preservative (§ 146.153) also provide for the juice of oranges of *C. aurantium*.

FDA agrees with the comment that juice from different species of orange (*C. sinensis*, *C. reticulata*, and *C. aurantium*) may be declared as a single food. The labeling regulations in part 101 (§ 101.4(a)) require that food ingredients be declared by their common or usual names. There is no requirement that the scientific species names be used on the food label.

In addition, FDA recognizes that the need to blend juices, as well as juice constituents, will vary depending on the quality of the oranges used and the desired characteristics of the finished juice product. For example, the juice of mandarin oranges (*C. reticulata*) or sour oranges (*C. aurantium*) may be blended with the juice of the sweet oranges (*C. sinensis*) to adjust the color or degree of sweetness to compensate for differences arising from seasonal variations or the lack of availability of specific varieties. Such variations in formulation of the processed orange juice products could require multiple labels for products with essentially the same composition and organoleptic properties. The agency believes that in such cases, requiring multiple labels for the same juice product is impractical and needlessly burdensome. FDA, therefore, is not requiring that the specific orange species or varietal names be listed in the ingredients statement of orange juice products when manufacturers comply with the limits on the species of orange specified in the standards of identity in part 146. FDA takes the same position for standardized grapefruit juice products.

4. Addition of Water to Tomato Concentrates

5. One comment opposed the current exemption in § 155.191(a)(3)(iv) (21 CFR 155.191(a)(3)(iv)) for label declaration of water added to adjust the tomato soluble solids content of tomato concentrates within the range of soluble solids levels permitted for these foods. The comment stated that some manufacturers make tomato concentrate with an approximate Brix value of 31° and, at a later date and typically in a geographically different location, add 2.5 to 3.5 parts water to 1 part tomato concentrate to make a tomato product with a significantly lower Brix value. Thus, the comment asserted that water added to tomato concentrates is an ingredient and should be required to be declared in the ingredient statement.

The intent of this exemption was to allow for the adjustment, within the range of concentrations for the particular finished tomato product being made, of the soluble solids content of the tomato concentrate products during the production of these tomato products from fresh tomatoes. For example, if the product being manufactured is tomato puree, and the resulting tomato concentrate has a soluble solids content in the range provided by the standard of identity for tomato puree, i.e., not less than 8 percent but less than 24 percent, manufacturers would be allowed to add water to the puree to adjust the tomato soluble solids content within the standardized range and not have to declare the added water. Similarly, manufacturers of tomato paste would be allowed to add water to a tomato concentrate containing more than 24 percent soluble solids without having to list the added water as an ingredient, as long as the finished tomato paste contained at least 24 percent soluble solids as required by the standard.

FDA provided the labeling exemption codified in § 155.191(a)(3)(iv) in response to an industry comment (49 FR 15071, April 17, 1984). The exemption was intended to eliminate confusion as to whether, for example, a manufacturer of a tomato puree of 12.0 percent soluble solids that is prepared from a tomato puree of 18 percent soluble solids would have to state "tomato concentrate and water" in the ingredients statement.

Differences in raw ingredients and difficulty in obtaining a precise endpoint during the evaporation process in manufacturing tomato concentrates justify addition of the water to adjust the soluble solids level. The addition of water enables manufacturers to obtain a uniform product concentration from batch to batch and facilitates production of products that are designed to meet specific needs and that fall within the ranges provided by the standard. Therefore, FDA has not deleted the current exemption in § 155.191(a)(3)(iv).

However, when tomato paste is converted to tomato puree, by the addition of water, the label of the puree, and of any food in which that puree is used, must show the ingredients used, namely, tomato paste and water (Refs. 45 and 46). This result is required by section 403(i)(2) of the act, which states that when a food is fabricated from two or more ingredients each such ingredient must be declared by its common or usual name, except that spices, flavorings, and color not required to be certified under section 706(c) of the act may be declared as such without naming each. In addition, it would be false and misleading to make a food (tomato puree) from two ingredients (water and tomato paste) and not disclose that fact on the label. It is true that both tomato paste and tomato puree are provided for in the general standard for tomato concentrates (§ 155.191). However, this fact does not mean that a manufacturer can transform one food with an established common or usual name into another without disclosing that fact on the label.

With regard to labeling standardized and nonstandardized tomato products made by diluting previously processed tomato concentrates with 2.5 to 3.5 parts of water, one comment contended that consumers and purchasers of these tomato products need a label statement on the principal display panel to disclose when that tomato product has been "made from concentrate" because consumers do not take time to read ingredient statements. The agency has also received several letters in support and in opposition to the position stated in this comment.

The intent of this rulemaking is to deal with ingredient issues, not how reconstituted products should be labeled. This issue was not raised in the proposal, nor can it be viewed as the logical outgrowth of any issues that were. Therefore, these comments are outside the scope of this rulemaking.

5. Optional Ingredients of Canned Tuna

6. One comment suggested that the optional ingredients listed in the standard of identity for canned tuna in § 161.190(a)(6) (21 CFR 161.190(a)(6)) need only be declared in the ingredient statement. The comment asserted that these optional ingredients are "minor" and "noncharacterizing." Therefore, the comment continued, the agency should not require that they be declared wherever the name of the standardized food appears on the label.

FDA disagrees that all of the optional ingredients listed in § 161.190(a)(6) are noncharacterizing in canned tuna. In many instances the optional ingredients, provided for in this paragraph on how the food may be flavored and seasoned, will in fact, be characterizing, depending upon the level and specific conditions of use of the ingredient in the food.

For example, added to canned tuna at low levels, lemon flavoring, one of the optional ingredients provided for in § 161.190(a)(6), would not impart any characteristic flavor of its own but would merely subtly alter the flavor profile of canned tuna. However, above a certain level, this ingredient would contribute a distinctive lemon flavor to the canned tuna.

In the former case, the agency requires that the optional ingredient be declared only in the ingredient statement as "natural flavor." Such ingredients need

not be declared in conjunction with the name of the standardized food on the label because they are not significant characterizing ingredients in the food (see § 130.11).

In the latter situation, because "lemon flavoring" would be a significant characterizing ingredient, it would need to be declared on the food label, in accordance with the provisions of § 101.3 and § 102.5(c) (21 CFR 102.5(c)), as a characterizing ingredient to distinguish lemon-flavored canned tuna from other types of canned tuna. Therefore, in this instance, in addition to the declaration of "flavoring" in the ingredient statement on the food label, the words "lemon flavored" or "with lemon flavoring" would need to appear in conjunction with the name of the standardized food as required by new § 130.11 and by new § 161.190(a)(8)(vi) and (a)(8)(viii).

When FDA proposed the revocation of § 101.6 in the June 21, 1991, proposal, the agency did not intend to alter its policy concerning the naming of canned tuna on the food label. As previously discussed, FDA is revoking § 101.6 and establishing new § 130.11 as a replacement for § 101.6(d). The latter action will correct the unanticipated effects that the revocation of § 101.6 would have had on the naming of canned tuna and other standardized foods. In accordance with new § 130.11, an optional ingredient listed in the standard of identity for canned tuna will have to be declared wherever the name of the food appears on the label only if the use of the optional ingredient in the food significantly distinguishes the food from the same standardized food that does not contain the optional ingredient as a significant characterizing ingredient.

7. One comment stated that vegetable broth used in canned tuna is a flavoring and falls under the definition of flavoring ingredients in § 101.22.

In claiming that vegetable broth is a flavoring, this comment is pointing to the fact that vegetable broth contains vegetable extractives that may provide flavor to the canned tuna. However, this effect may be outweighed by the flavor-enhancing effect that this ingredient may have in canned tuna. Flavor enhancers are used to supplement, enhance, or modify the original taste or aroma of a food without imparting a characteristic taste or aroma of their own (§ 170.3(o)(11) (21 CFR 170.3(o)(11)), while flavoring agents and adjuvants impart or help impart a taste or aroma in food (§ 170.3(o)(12)).

According to information available to FDA, vegetable broth used in canned tuna may serve to enhance the basic flavor of the tuna and to make it appear less bland when it is packed in water, as in dietetic packs where it supplements the flavor of the product, without imparting a flavor of its own (Refs. 47, 48, and 49). It also aids in suppressing the bitter flavors that may develop during the canning operation (Ref. 47). Because vegetable broth is not generally used at levels at which it would impart a characteristic flavor or aroma of its own to the tuna, FDA concludes that flavor-enhancement may be a significant function of vegetable broth in canned tuna.

Flavor enhancers are not exempt from the ingredient declaration requirement in section 403 of the act. Therefore, they must be listed by their common or usual names in the ingredient statement on the food label. Where vegetable broth functions to enhance the basic flavor of the tuna, it must be declared by its common or usual name in the ingredient statement of the food label, even though it may, at certain levels of use and depending on the flavoring potential of vegetable sources used in making the broth, also act as a flavoring in the food.

Where the effect of the addition of vegetable broth is such that it adds a characterizing flavor to the tuna, the standard of identity, in new § 161.190(a)(8)(vi) and (a)(8)(viii), requires that the term "seasoned with vegetable broth" appear in close proximity to the name of the standardized food wherever that name occurs on the principal display panel of the label. In this situation, the vegetable broth would be properly declared in the ingredient statement as "flavoring" provided that it does not serve a flavor enhancing function in the food. Where the vegetable broth serves both as a flavor enhancer and a flavor, it must be declared by it common or usual name in the ingredient statement, as well as in conjunction with the name of the food when it serves as a characterizing ingredient, in accordance with new § 161.190(a)(8)(vi) and (a)(8)(viii).

8. One comment stated that, traditionally, the individual vegetable extractives used in the preparation of vegetable broth have not been declared on the label of canned tuna. This comment interpreted the agency's implementation of the 1990 amendments to mean that FDA will require the listing of each vegetable that is in the vegetable broth in order of predominance parenthetically following the term "vegetable broth" in the ingredient statement on the label of canned tuna. The comment stated its opposition to this approach. In support of its position, the comment pointed out that this method of listing the ingredients comprising vegetable broth in canned tuna would "intensify label crowding" and "create confusion as to whether or not whole pieces of vegetables are contained therein." This comment also stated that if FDA requires the listing of the components of vegetable broth in canned tuna, then the agency should generate an alternative labeling scheme that would be flexible, economically feasible, and protective of trade secrets.

FDA agrees that the listing of each ingredient comprising vegetable broth on the label of canned tuna could be lengthy and cumbersome. New § 130.3(e) provides that:

> All ingredients must be listed in accordance with the requirements of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

The standard of identity for canned tuna permits the optional ingredient defined in renumbered new § 161.190(a)(6)(v) to be called "vegetable broth" on the label of canned tuna, as specified in new § 161.190(a)(8)(vi). Hence, the optional ingredient vegetable broth may be listed as "vegetable broth" in the list of ingredients on the label of canned tuna. The new regulations do not require full declaration of all of the ingredients of which the vegetable broth is comprised.

However, for reasons discussed in another document that appears elsewhere in this issue of the **Federal Register**, the agency is proposing to amend the standard of identity for canned tuna to require the declaration of soybeans when the ingredient vegetable broth contains soybean extractives. If the agency adopts this proposal, the ingredient will have to be listed as "vegetable broth (includes soybeans)."

9. Although the agency did not receive any other comments with respect to canned tuna, FDA, as set forth in new § 161.190(a)(6)(ii), is amending the standard of identity for this food to eliminate the term "purified" in conjunction with "monosodium glutamate" (MSG) for consistency with the terminology for MSG in the food additive regulation in 21 CFR 182.1 and in the food labeling regulation in § 101.22(h)(5). The term "purified" had been used in the name in § 101.35 to distinguish between three types of ingredients, "monosodium glutamate," "hydrolyzed proteins," and "hydrolyzed proteins with reduced monosodium glutamate content." Elsewhere in this document (See section VIII. of this document), FDA is revoking

§ 101.35 because the regulation is obsolete and does not include many of the protein hydrolysates used in foods.

In addition, consistent with the establishment of new § 102.22, as set forth below, to provide for the declaration of protein hydrolysates by a common or usual name that is specific to the ingredient and that identifies the food source from which the protein was derived, the agency is amending the standard of identity in new § 161.190(a)(6)(iii) to require labeling of the source of protein in the optional ingredient "hydrolyzed protein."

Furthermore, to reflect the agency's decision to revoke § 101.35, the agency is amending the standard of identity for canned tuna in new § 161.190(a)(6) to remove "hydrolyzed protein with reduced monosodium glutamate content" from the list of optional ingredients permitted in canned tuna. As discussed in the June 21, 1991, proposal (56 FR 28592 at 28600 et seq.), all hydrolyzed protein contains MSG, and this MSG is not itself an ingredient that is subject to the ingredient declaration requirements of the act. In that document, FDA stated that after carefully considering the information available concerning the safe use of protein hydrolysates and whether the presence of MSG is a material fact that needs to be disclosed on the label for health reasons, it tentatively concluded that the information does not provide an appropriate basis to require declaration of MSG as a component of protein hydrolysates. However, for the reasons discussed in another document elsewhere in this issue of the **Federal Register**, the agency has reconsidered this issue and is proposing to require the declaration of glutamate as part of the common or usual name when a component of certain hydrolyzed proteins. Therefore, it will no longer be necessary to distinguish between "hydrolyzed protein" and "hydrolyzed protein with reduced monosodium glutamate content" in the manner currently provided for in this standard.

Accordingly, new § 161.190(a)(6)(i) through (a)(6)(ix) have been renumbered to reflect the elimination of "hydrolyzed protein with reduced monosodium glutamate content" from the list of optional ingredients permitted in canned tuna. "Hydrolyzed protein" will be retained in the list of optional ingredients, as specified in § 161.190(a)(6) below (see section VIII. of this document).

6. Other Related Actions

10. The agency did not receive any comments that objected to its proposal to require that the ingredient declaration for fruit butter in § 150.110 conform to the regulations in part 101. Thus, the agency is removing § 150.110(e)(2)(ii) (21 CFR 150.110(e)(2)(ii)), which states that if sugar or invert sugar is the sweetener used, the term "sugar" may be used, and if the sweetener used is derived from corn, the term "corn sweetener" may be used. The agency is also requiring that the ingredient declaration for fruit butter conform to the regulations in part 101. In this rule, the agency is terminating the rulemaking to permit the use of the terms "sugar" and "corn syrup" as collective ingredient designations. The agency has determined that declaration of specific names for sweeteners within these collective categories is practicable. Consistent with this action, the agency has concluded that declaration of the specific names of sweeteners is also practicable for standardized foods and is deleting the requirements of § 150.110(e)(2)(ii).

The agency is also deleting the requirements in the standards for mixed nuts and peanut butter in §§ 164.110 and 164.150 (21 CFR 164.110 and 164.150) that provide for the use of the term "hydrogenated vegetable oil" or "vegetable oil" with the optional use of the name of the vegetable source, and the requirement in § 164.110 for label declaration of chemical preservatives. Required label declarations for these types of ingredients are clearly delineated in §§ 101.4(b)(14) and 101.22(j), respectively. Moreover, the "and/or" labeling exemption in § 101.4(b)(14) should effectively eliminate the need for collective names for vegetable oils on these standardized foods.

The agency did not receive any other comments with respect to proposed changes to specific standards of identity. Thus, the agency is finalizing the amendments to the individual standards as proposed.

In the July 21, 1991, proposal on Declaration of Ingredients, FDA withdrew the proposed amendment to § 101.4 (formerly § 1.10) pertaining to the establishment of the terms "sugar" and "corn syrup" as collective ingredient designations that was published in the **Federal Register** of June 14, 1974 (39 FR 20888); terminated the rulemaking proceeding initiated by that proposal; and denied the petitions commenting on that proposal from the Canada Dry Corp. (June 27, 1975—Docket No. 75P–0144), the Canners League of California (January 19, 1977—Docket No. 77P–0051), the Independent Bakers Association (September 22, 1977—Docket No. 77P–0357), the California Milling Corp. (June 19, 1978—Docket No. 77P–0051 CP0002), the Orth Co. (July 31, 1978—Docket No. 77P–0357), and L. Karp & Sons, Inc. (August 11, 1978—Docket No. 77P–0357 CP0003).

B. Labeling of Sulfites in Standardized Foods

In the **Federal Register** of December 19, 1988 (53 FR 51062), FDA published a proposed rule to require that any standardized food that contains a sulfiting agent that has a functional effect or that is present at a level of 10 ppm or more is misbranded if the presence of the sulfiting agent is not declared on the label by its common or usual name. The agency proposed to codify this requirement in new § 130.9. The agency also solicited comments regarding sulfite-sensitive consumers' ability to recognize and avoid foods labeled with the six common or usual names for sulfites (sulfur dioxide, sodium sulfite, sodium and potassium bisulfite, and sodium and potassium metabisulfite). In addition, the agency requested comments on whether any final rule should contain a requirement that the common or usual name of a labeled sulfiting agent should be followed by the term "sulfiting agent." The comments received on these and other aspects of this part of the proposal, and the agency's response, follow.

11. The majority of comments from consumers and industry supported adoption of § 130.9. These comments stated that sulfite labeling of standardized foods would decrease allergic type reactions by increasing consumer awareness, while allowing the vast majority of consumers, who are not sensitive to sulfites, to continue to consume foods containing sulfiting agents. A few consumers' comments, however, requested that all unnecessary uses of sulfites be banned, or, in the alternative, that principal display panel warnings be required. Citing the large number of people adversely affected by sulfites, the comments asserted that there was no established safe threshold for sulfites, and that they are one of the few food ingredients known to cause anaphylactic shock and death.

The agency recognizes that sulfites present a significant health problem for a small segment of the population, particularly some asthmatics. However, sulfiting agents do not appear to present a problem for most people, and the declaration of sulfiting agents in the list of ingredients will provide sufficient information for those people who need or want to avoid unexpected exposure to these ingredients. Thus, FDA does not believe that it is necessary to require

a warning statement on food labels or to ban all uses of sulfites. In addition, the comments did not provide any data to support banning current uses of sulfites.

The agency believes that the action that it is taking in this final rule will afford more effective protection for sulfite-sensitive individuals than is currently provided. This provision for label declaration of sulfites for standardized foods is consistent with the provisions for label declaration of sulfites for nonstandardized foods in § 101.100(a).

Thus, FDA is adopting new § 130.9, as proposed, in this final rule. As a result, all foods containing sulfiting agents that are functionally active or present at 10 ppm or more in the finished food are now required to declare the presence of the sulfiting agent in the ingredient statement.

12. Some comments expressed the opinion that the term "sulfiting agent" should be used instead of the common or usual name of the particular substance because it is more recognizable by consumers. None of these comments, however, offered any data to show the extent of consumer knowledge about the common or usual names for sulfiting agents.

Lacking data, and reflective of the small number of comments from consumers on this issue, FDA is not persuaded that requiring a descriptive or collective term to be used with the common or usual name of the sulfiting agent is necessary because the declaration of the sulfiting agent by its common or usual name will adequately inform the consumer of its presence.

Furthermore, sulfite sensitive consumers know to look for sulfiting agents in the ingredient statement. However, the agency will not object if manufacturers choose to make this dual declaration.

Moreover, the agency is not persuaded that the term "sulfiting agent" should be used in place of the common or usual name for sulfiting agents added directly to the standardized food or for sulfiting agents that have a technical or functional effect. FDA addressed this issue with respect to label declaration of sulfites in nonstandardized foods in the **Federal Register** of July 9, 1986 (51 FR 25012). At that time the agency adopted § 101.100(a)(4) which requires sulfiting agents present at 10 ppm or more in a nonstandardized food be declared on the label. Furthermore, sulfiting agents that are directly added to, or that have a technical or functional effect in, food should be declared by the name of the specific sulfiting agent. However, the agency also established the policy that sulfiting agents that are indirectly added to a food, and that have no technical or functional effect in the food, could be declared by a collective term. FDA considered the term "sulfiting agent" to be the most accurate and informative collective term. The agency still believes that this position is appropriate for nonstandardized foods and is also appropriate for standardized foods. Thus, when indirectly added sulfiting agents remain in a standardized food in a significant amount, but no longer have a technical or functional effect, they may be declared by the term "sulfiting agents."

FDA also continues to hold that if a food contains a sulfiting agent that has a technical or functional effect in the standardized food and that is declared in the list of ingredients by its common or usual name, as required by § 130.9(a), any nonfunctional sulfiting agents present in the standardized food need not be declared separately in the list of ingredients. In such circumstances, sulfite sensitive individuals will be alerted to avoid the food by the declaration of the former sulfiting agent. However, FDA emphasizes that this flexibility applies only if the sulfite does not perform a technical or functional effect in the standardized food.

13. Several comments from industry and trade associations objected, for various reasons, to the use of the Monier-Williams method of sulfite analysis. These comments requested that firms should have the freedom to choose between "state-of-the-art" methods and the Monier-Williams method in determining the amount of sulfite present.

FDA has selected the Monier-Williams method as the method that it will use for enforcement of the sulfite labeling requirements because this method is an official method of the Association of Official Analytical Chemists and is the standard against which the accuracy of new procedures has been judged. Moreover, this method will measure the free sulfite plus a reproducible portion of the bound sulfites in the food. However, the agency advises that processors and food manufacturers are under no obligation to use the Monier-Williams method for quality control or any other purpose. Processors are free to, and frequently do, determine the correlation between the official FDA-designated enforcement method, i.e., the Monier-Williams method, and their method of choice. They may then use their method of choice as they see fit, recognizing that FDA will rely on the Monier-Williams method in any enforcement action.

14. A few comments suggested that the concentration of the sulfite should be declared on the label, thereby allowing the consumer to decide whether to purchase the product based on this information. The comments stated that this would absolve the manufacturers of liability, as long as the product did not exceed the limit.

The agency rejects this suggestion. Although the agency is aware that limited studies have been performed on sulfite-sensitive individuals to determine dose response reactions, the agency finds that the available evidence does not establish that a threshold level exists for sulfite-sensitive individuals. Furthermore, the agency does not believe that sulfite-sensitive individuals should be expected to determine their tolerance levels. Therefore, FDA finds that, given currently available information, there is no reason to require manufacturers to declare the concentration of sulfites on the label. Declaration of the sulfiting agent in the ingredient list will adequately inform all individuals who are sensitive to sulfites that sulfites are present in the food.

15. One comment asked for clarification of the "written agreement" exception to the labeling requirement as it applies to bulk shipment of ingredients that will be further processed into consumer products by other manufacturers. The comment stated that it is impractical for ingredient manufacturers of sulfiting agents to enter into written bilateral contracts with each customer. The comment proposed an alternative such as a "pure food" guarantee, indicating that the food is not adulterated or misbranded within the meaning of the act (e.g., a letter of guarantee from the manufacturer that the product contains less than the maximum residual limit of sulfites that is consistent with the generally recognized as safe (GRAS) regulations or the inclusion of information on an invoice that specifies the maximum residual level of sulfites contained in the product).

Section 101.100(d) provides an exemption from the labeling requirements for foods shipped in bulk when there is a written agreement between the shipper and the consignee. The written agreement must, among other things, contain specifications for the processing, labeling, or repacking of the food by a designated establishment that will ensure that the food will not be adulterated or misbranded within the meaning of the act. The exemption provided in § 101.100(d) applies to all foods shipped under the prescribed provisions without full labeling and not just those foods containing sulfites.

Furthermore, § 101.100(d) is not a subject of this rulemaking. In addition, sulfite manufacturers have not provided reasons to persuade the agency that they should be treated differently from manufacturers of other ingredients. The alternative proposed in the comment is welcome additional information but is not a substitute for written agreements for interstate shipment of partially labeled food for further processing.

III. Label Declaration—Statement that Ingredients are Listed in Descending Order of Predominance by Weight

FDA proposed in the June 21, 1991, proposal to adopt proposed § 101.4(a)(3) to require that food labels bear a statement explaining that the list of ingredients is in descending order of predominance by weight. The proposed requirement was in response to comments received on the 1989 ANPRM that suggested that consumers were not aware of the requirement in new § 101.4(a)(1) that ingredients be declared in descending order of predominance by weight. FDA cited, as an example of an appropriate statement: "Ingredients (in descending order of predominance by weight): ———————, ———————, and ———————."

16. Although a few industry and consumer comments on the June 21, 1991, proposal supported proposed § 101.4(a)(3), the majority of industry comments requested that it be deleted from a final rule. Industry comments maintained that consumers have been made aware that ingredients are declared in descending order of predominance by weight through the food industry's advertisements. According to these comments, such advertisements highlight ingredient statements when comparing the quantity of various ingredients among competitive products. The comments said that, therefore, an explanatory statement would be demeaning to many consumers. These comments further argued that the proposed model statement, "Ingredients (in descending order of predominance by weight)," uses sophisticated terminology unlikely to be understood by those consumers who remain unaware of the listing requirement. These comments suggested that this issue could be more appropriately addressed through public education efforts by FDA and the food industry.

Other opposing comments on this issue emphasized that the labeling exemption in proposed § 101.4(a)(2) for ingredients that are present in amounts of 2 percent or less by weight allows listing the ingredients without regard to order of predominance. These comments maintained that the proposed statement would contradict the 2 percent rule and lead to consumer confusion.

Some comments further stated that the parenthetical statement, as proposed, would use valuable label space, especially on small packages, and would add to label clutter without significant benefit to the consumer. Of particular concern was ingredient labeling for chewing gum packages. Comments from the chewing gum industry stated that the addition of this statement on the ingredient label in conjunction with all of the other labeling changes required by the 1990 amendments and proposed by FDA could require the development of new packaging.

Comments from foreign governments stated that there was no requirement to include such a statement in their countries. They contended that if FDA established the requirement for such a statement, additional labeling difficulties and costs would be borne by both United States and foreign food manufacturers wishing to use a single label for both markets. These comments stressed that any additional costs would ultimately be passed on to consumers.

The agency has carefully considered all of the comments and has been persuaded to reconsider its position. The agency agrees that in some cases, educational efforts by the industry and FDA may better inform the public that ingredients are listed in descending order of predominance by weight than requiring the statement on the label. The agency also recognizes that with the implementation of other labeling requirements mandated by the 1990 amendments, label space, especially on smaller packages, may be limited. Finally, comments from consumers demonstrated little support for the proposal. Accordingly, the agency is not requiring that food labels bear a statement explaining that the list of ingredients is in descending order of predominance by weight and is deleting proposed § 101.4(a)(3) from this final rule. However, the agency encourages manufacturers to provide this information voluntarily when practicable.

IV. Declaration of Sweeteners in the Ingredient List

A. General

The June 21, 1991, proposal discussed several issues regarding labeling of sweeteners. Consumers had complained of not being able to determine the relative amounts of added sweeteners because sweeteners are listed at various positions throughout the ingredient list. In response, the agency proposed that all sweeteners be grouped together parenthetically following the term "sweeteners" when more than one sweetener is present in a product and be declared in the ingredient list in the order of predominance appropriate for the sum of all sweeteners in the product. The agency also withdrew a previous proposal, published in the **Federal Register** of June 14, 1974 (39 FR 20888), to establish the term "sugar" as a collective ingredient designation for sucrose and invert sugar and "corn sweeteners" as a collective ingredient designation for sweeteners derived from corn. With this action, the agency denied several industry petitions requesting the use of these collective terms.

17. One consumer comment strongly disagreed with allowing the ingredient sucrose to be labeled as "sugar" while other caloric sweeteners are labeled by their proper names. This comment also expressed the belief that manufacturers mislead consumers by using the term "No sugar added" when the product is sweetened by a caloric sweetener other than sucrose. The comment urged that all sweeteners be labeled by their proper names, and that the term "sugar" be prohibited.

FDA has traditionally held that the term "sugar" in an ingredient list refers to sucrose as defined in § 184.1854 (21 CFR 184.1854). Although the agency proposed in 1974 to permit the term "sugar" to also include invert sugar, the agency never acted on that proposal and subsequently withdrew it in the June 21, 1991, proposal. In addition, the agency believes that sucrose is the only sweetener that has traditionally been referred to as "sugar" by industry and consumers, and that the use of this term in the ingredient list is not misleading. Thus, the agency is not granting the request to prohibit the use of the term "sugar" as defined in § 184.1854. To promote greater consumer awareness of § 184.1854, FDA has specifically referenced it in new § 101.4(b)(20) (§ 101.4(b)(22) in the proposed rule).

With regard to the statement "no sugar added" when sweeteners other than sucrose are used in a food, the agency's position (21 CFR 105.66) has been that label declaration claims such as "no sugar added" may reasonably be expected to convey to consumers that the food contains no added nutritive sweeteners, such as high fructose corn syrup, malt syrup, or honey. Claims such as "no sugar added" refer not only to sucrose but to a class of sweeteners of which sucrose is just one. The agency addressed this issue in detail in its

proposal on nutrient content claims (56 FR 60421 at 60437, November 27, 1991). At that time, FDA proposed that claims for the absence of added sugars apply only to those foods to which sugar or other nutritive sweeteners have not been added directly or indirectly during processing or packaging. This issue is further addressed in the nutrient content claims final rule published elsewhere in this issue of the Federal Register.

18. Comments from consumers, consumer groups, and some State governments supported the agency's proposal that all sweeteners be listed together in the ingredient list under the collective term "sweeteners." They expressed the belief that current regulations permit manufacturers to hide the actual amount of added sweeteners in a product by dispersing them in the ingredient statement. In addition, several of these comments requested more complete information on the total amount of sugars present in a finished food and suggested that such information be required in nutrition labeling.

However, comments from industry opposed grouping sweeteners in the ingredient list. The comments questioned FDA's authority to require grouping sweeteners in the ingredient list and stated that there was no scientific or public health rationale for singling out sweeteners for distinctive treatment in the ingredient list. These comments argued that total sugars declaration is the function of the nutrition label and not the ingredient label. They further argued that sweeteners may be added to foods for other than sweetening purposes (e.g., as bulking agents, firming agents, cryoprotectants, and fermenting agents), and that grouping sweeteners in the ingredient list could obscure the intended function of the sweetener in the food, thereby generating consumer confusion. In addition, several comments raised concerns regarding labeling requirements of foods that: (1) Are themselves sweeteners, (2) contain a standardized multicomponent ingredient that had a sweetener as one of its ingredients, and (3) contained sweeteners that perform functions for which "and/or" labeling is permitted under current regulations (§ 101.4(b)(19)).

One comment from industry argued that inclusion of the term "sweeteners" in the ingredient list of food products that are themselves sweeteners is unnecessary. The comment asserted that a sweetener with two ingredients, both of which are "sweeteners," would have to list under this regulation "Ingredients: Sweeteners (dextrose, aspartame)," rather than a simpler and more straightforward listing of "Ingredients: dextrose, aspartame." This comment requested an exemption for products that are themselves sweeteners.

Other industry comments maintained that where manufacturers declare a multicomponent ingredient (e.g., a standardized or nonstandardized food for which there is a common or usual name and that is fabricated from two or more ingredients) of a food by its common or usual name followed by a parenthetical listing of the two or more ingredients in the multicomponent ingredient, sweeteners would either: (1) Have to be listed twice, first in the parenthetical list following the name of the multicomponent ingredient and second in the list of combined sweeteners contained in the finished food; or (2) have to be removed from the parenthetical list of the multicomponent ingredient and added to the parenthetical list of sweeteners. These comments contended that such a practice would be misleading because it would, in the first case, over-represent the amount of the sweetener by declaring it twice, or, in the second case, give the impression that the multicomponent ingredient is "sugar free."

The comments stated that, in the alternative, the parenthetical listing of the ingredients of the multicomponent ingredient, as provided in proposed § 101.4(b)(2)(i), would no longer be an option. Sweeteners would have to be removed from the multicomponent ingredient declaration and grouped with other sweeteners. The other ingredients in the multicomponent ingredient would then have to be dispersed in the ingredient list in descending order of predominance, as provided in proposed § 101.4(b)(2)(ii), without naming the multicomponent ingredient. As a result, common, readily identifiable multicomponent ingredient names such as "milk chocolate" or "marshmallows" would not appear in the ingredients statement, and the consumer would be misled.

Several other industry comments requested clarification regarding label declaration of sweeteners, such as sugar alcohols, that may be used as firming agents and that are currently declared parenthetically using "and/or" labeling following the collective term "firming agents." These comments asserted that manufacturers who may not adhere to a constant pattern of use of a particular firming agent that is a sweetener would be at a competitive disadvantage because of the additional expense of maintaining label inventories for every possible formulation.

Additional comments that opposed the grouping of sweeteners stated that consumers will avoid foods unnecessarily if the grouped sweeteners appear first or second in the ingredient list and thereby imply that such foods are "bad." These comments further stated that when low calorie or intense sweeteners are used, they would most likely be the only sweetening ingredient in a food and therefore would be exempt from this requirement because the group declaration of sweeteners is only triggered when more than one added sweetener is present. These comments asserted that consumers would be given the impression that a food containing an intense or low calorie sweetener contained less sugar and therefore, was more nutritious than a food that contained, for example, five sweeteners. In fact, the comment continued, the food containing five sweeteners may contain other essential nutrients not present in the food with the intense sweetener. Another comment asserted that the grouping of sweeteners in the ingredient list would lead to deceptive and unfair practices because manufacturers may manipulate formulations so that ingredients that are valued by consumers, such as honey and concentrated fruit juice, would appear to be more predominant when grouped with other sweeteners than they would under current labeling regulations.

Finally, two comments from foreign manufacturers that opposed grouping sweeteners in the ingredient list maintained that such a requirement would be a barrier for foreign trade because foreign manufacturers are not required to group sweeteners on labels. These comments further stated that foreign manufacturers would be required to use separate labels just for the U.S. market, consequently increasing costs and discouraging free trade.

The agency has carefully reviewed all of the comments and, as stated above, has been persuaded to reconsider its proposal to require grouping of sweeteners in the ingredient statement. As stated in the final rule on mandatory nutrition labeling published elsewhere in this issue of the Federal Register, in response to section 403(q) of the act, FDA is requiring the declaration of total sugars in the nutrition label. The agency believes that information on the quantity of sugars in a finished food is more effectively conveyed as part of nutrition labeling, than ingredient labeling. The total amount of sugars, including both added and indigenous

sugars, is declared in the nutrition label, whereas the information on sugars content provided through ingredient labeling includes only added sweetening ingredients in order of predominance by weight. The ingredient label does not give information regarding the amounts of those sugars.

It is true that in the June 21, 1991, proposal, the agency stated that even if it were to require the declaration of total sugars, there was still a significant need for grouping sweeteners in the ingredient list to prevent consumers from being misled by the practice of dispersing sweetener names throughout the ingredient list. FDA has reconsidered this position, however, and concludes that from a nutritional standpoint, the placement of added sugars in the ingredient statement is not relevant.

For FDA to require the grouping of sweeteners in the ingredient list, it would have to find that listing them in order of predominance is false or misleading (section 403(a) of the act). Clearly, the applicable finding would have to be that the current method of listing sweeteners results in consumer deception, that is, as argued by the consumer and state government comments, by dispensing sweeteners throughout the ingredient list, manufacturers hide the total amount of sweetening ingredients added to a food. FDA has concluded, however, that this practice will not result in deception for two reasons.

First, because nutrition labeling will include a listing of total sugars, this practice will no longer provide a means of hiding the amounts of sweeteners added to the food. The consumer will be able to determine if a product has a high amount of sugars by looking at the nutrition label.

Secondly, from a nutritional standpoint, the amount of added sugars is not significant information when considering overall sugar content. It is the total sugars content that has nutritional importance. Again, this amount will be determinable from the nutrition label. Thus, FDA agrees with the comments that there is no scientific or public health reasons for singling out sweeteners for special treatment in the ingredient list. For these reasons FDA concludes that grouping of sweeteners is not necessary to prevent consumers from being misled and, therefore, FDA is not requiring such a step. Accordingly, FDA has deleted the proposed requirement for aggregate declaration of sweeteners (proposed § 101.4(b)(21)) from this final rule.

FDA points out that it has considered the other objections raised by industry to its proposal. As explained above, FDA clearly has authority under section 403(a) of the act to take the step it proposed. FDA advises that there would be alternative ways of addressing each of the other concerns that the industry comments raised. Because the agency has decided not to adopt proposed § 101.4(b)(21), however, it finds that there is no need to address each of those concerns in detail.

The agency received several other supporting and opposing comments addressing its definition of sweeteners (i.e., list of ingredients to be included in the definition of sweeteners for the purpose of this regulation) as discussed in the June 21, 1991, proposal (56 FR 28592 at 28608). Because the agency has reconsidered its position on the aggregate declaration of sweeteners in the ingredient statement, the issues raised in those comments are no longer pertinent and need not be addressed in this rulemaking.

19. Other comments recommended that FDA require the disclosure of artificial sweeteners on the principal display panel in addition to the ingredient list. These comments suggested that the label should read "Artificially sweetened" and should also bear warnings about artificial sweeteners being harmful to children and pregnant women. However, the comments did not provide information supporting their assertion that artificial sweeteners are specifically harmful to children and pregnant women.

The agency will not object to manufacturers voluntarily declaring on the principal display panel that the product is artificially sweetened. This voluntary declaration, however, only applies in those instances where "artificially sweetened" is not a part of the statement of identity of the food (e.g., artificially sweetened canned apricots) and, therefore, required to appear on the principal display panel. The agency is not aware of any evidence to support the assertion in the comments that artificial sweeteners are more harmful to children and pregnant women than to the general population. FDA has considered the safety of these ingredients as part of the food additive listing process. Where it has been presented with evidence that shows that it is necessary for the safe use of an artificial sweetener, FDA has required declarations. Such a declaration is provided for in 21 CFR 172.804, which requires that labels on foods that contain aspartame bear the statement "PHENYLKETONURICS: CONTAINS PHENYLALANINE." In addition section 403(o)(1) of the act requires that labels of foods containing saccharin bear the warning statement "USE OF THIS PRODUCT MAY BE HAZARDOUS TO YOUR HEALTH. THIS PRODUCT CONTAINS SACCHARIN WHICH HAS BEEN DETERMINED TO CAUSE CANCER IN LABORATORY ANIMALS." Both provisions require that such statements shall be located in a conspicuous place on the label as proximate as possible to the name of the food and shall appear in conspicuous and legible type in contrast to other printed matter on the label. As other artificial sweeteners are permitted for use in foods, the agency will prescribe the conditions under which those sweeteners may be safely used, including labeling or packaging requirements if deemed necessary by the agency to ensure the safety of such use. See section 409(c)(1)(A) of the act (21 U.S.C. 348(c)(1)(A)).

B. Lactose Labeling

In the June 21, 1991, proposal, the agency restated its policy on the declaration of lactose and advised that ingredient labeling regulations require the listing of lactose whenever it is used as an ingredient of food (56 FR 28592 at 28608).

20. One comment supported FDA's position against requiring label declaration of lactose when present as a component of an ingredient (e.g., whey, nonfat dry milk), because lactose intolerant consumers know to avoid milk and milk products. Another comment requested the establishment of regulations to require labeling products as "lactose free." This comment stated that the high percentage of the population that suffers from lactose intolerance warrants such a requirement.

The agency does not agree that the requested statement is needed because lactose intolerant consumers know to avoid milk and milk products. Furthermore, the comment did not present data to substantiate that lactose intolerant consumers need a "lactose free" declaration to determine which foods they can safely consume. Such information would be necessary for FDA to require a statement that a product is "lactose free." Thus, FDA is not requiring a "lactose free" declaration on products that do not contain lactose. However, the agency advises that manufacturers may voluntarily label a food as "lactose free," provided, of course, that the statement is true. Any product labeled as "lactose free" must not contain lactose as an ingredient or as a component of an ingredient and

should adhere to the provisions of 21 CFR 105.62 on hypoallergenic foods.

V. Labeling of Fresh Fruits and Vegetables

A. Pesticides

21. The majority of comments, citing concerns about health risks and the consumer's right to know, requested that the agency require manufacturers to disclose preharvest and postharvest pesticide use on fresh fruits and vegetables at the retail level. The comments expressed concern that, in the absence of pesticide labeling at the retail level, growers, packers, repackers, or distributors may indiscriminately use pesticides that are not permitted or are permitted only on specific fruit and vegetable commodities.

As discussed in the preamble to the June 21, 1991, proposal (56 FR 28592 at 28611), section 403(l) of the act only requires declaration of postharvest pesticides on the shipping container. Moreover, section 403(l) of the act specifically precludes the agency from requiring declaration of postharvest pesticides at the retail level. The comments favoring disclosure of preharvest and postharvest pesticide use did not provide any information not considered by the agency at the time of the proposal, nor did they provide viable solutions to the many compliance and enforcement problems that would arise if the agency acquired statutory authority to require pesticide labeling at the retail level. Moreover, the agency advises that the indiscriminate use of pesticides is illegal. Only uses specifically permitted by the Environmental Protection Agency under the Federal Insecticide, Fungicide and Rodenticide Act of 1988 (7 U.S.C. 136a-1) are legal. Thus, FDA has concluded that it will not seek statutory authority to require pesticide labeling by the retailer at this time.

B. Wax or Resin Coatings

The agency proposed to permit retailers to use appropriate collective (generic) names for ingredient labeling of wax or resin coatings on fresh produce (56 FR 28592 at 28611). Section 403(i) of the act provides for exemption from specific ingredient labeling when such labeling is impracticable or results in deception or unfair competition. Because of the constant change of produce items in retail establishments, FDA tentatively concluded that specific ingredient labeling of waxes and resins was impracticable (56 FR 28592 at 28613). In addition, under the proposal, packers and repackers unable to adhere to a constant pattern of wax or resin use on produce would be permitted to use collective names in ingredient labeling. Also in the June 21, 1991, proposal, FDA responded to a citizen petition (Docket No. 90P-0404) requesting the agency to permit: (1) Collective labeling of fresh produce by shippers; (2) ingredient labeling on plastic bags; and (3) the term "may" in ingredient labeling of wax or resin coating on fresh produce.

22. Although a number of comments supported the agency's proposal, several comments requested specific wax or resin coating ingredient declaration at the retail level because of health and safety considerations and because of the right of consumers to know what is in the foods they eat.

The agency recognizes that consumers have expressed health and safety concerns as they relate to the consumption of waxes and resins. Waxes and resins used on fresh produce have been accepted as food grade and therefore are considered by the agency to be safe ingredients. If the agency becomes aware that a particular wax or resin may be harmful to consumers, it will take appropriate action to ensure safe use of the wax or resin.

The agency further acknowledges that some consumers desire specific ingredient declaration of waxes and coatings, and that such declarations are generally required under section 403(i) of the act. However, section 403(i) of the act does not provide a "right to know" the ingredients of every food. It qualifies the requirement that each ingredient be listed (section 403(i)(2) of the act) by saying that to the extent that compliance with that requirement is impracticable or results in deceptive or unfair competition, FDA is to establish exemptions from the requirement by regulation (section 403(i)(2)). The comments did not provide evidence regarding retail marketing practices that contradicted the agency's tentative conclusion that specific ingredient labeling at the retail level is impracticable. Therefore, FDA has not been persuaded to change its tentative finding that specific ingredient declaration is impracticable, at the retail level. Accordingly, the agency concludes that specific ingredient declaration of waxes and coatings on fresh produce is impracticable and that the proposed exemption permitting use of collective terms by the retailer is appropriate.

23. Some of the comments that requested specific wax or resin coating label declaration also requested declaration of the fungicides applied in the waxes or coatings. These comments asserted that information on fungicides is important for health and safety considerations.

As discussed above, section 403(l) of the act specifically precludes FDA from issuing regulations requiring retail labeling for postharvest use of pesticides. Fungicides that may be applied with or without waxes or coatings are included in the category of postharvest-use pesticides, as provided in section 201(q) of the act (21 U.S.C. 321a(q)) and therefore are exempt from required declaration at the retail level. As previously stated, the agency does not plan to seek statutory authority to require pesticide labeling by retailers.

24. Many comments requested that domestic and foreign packers and repackers be exempted from specific ingredient labeling and allowed to use collective (generic) terms without first having to determine whether there is a "constant pattern" of wax or resin use on the produce. Several of the comments asserted that seasonal variation, product variation, coating variability, product destination, cost and availability of wax or resin coating, and the practice of commingling lots of variously coated fresh fruits and vegetables from different suppliers occur so frequently that packers and repackers would rarely, if ever, adhere to a "constant pattern" of use.

In addition, the comments stated that the packer or repacker who adheres to a "constant pattern" of use, and, therefore, is required to use specific wax or resin coating ingredient declarations, is at a competitive disadvantage when compared to packers or repackers who do not adhere to a constant pattern of use. The comments contended that unfair competition results because of the labeling and inventory costs required to maintain specific ingredient labeling as well as collective ingredient labeling for those instances when the packer does not adhere to a constant pattern of use. The comments further stated that the ordinary practice in the packing industry is to use prestenciled shipping containers that are labeled before they are packed. Thus, packers and repackers who adhere to a constant pattern of use and are required to list individual wax or resin ingredients would have to maintain a separate inventory of boxes prestenciled with the required ingredient information. The comments argued further that most packers often run two or three shifts per day, each with multiple lines packing various types of produce simultaneously. These comments concluded that the packers who adhere to a constant pattern of use would not only have to increase their packaging costs and inventory space but also

would have to increase their workforce and reorganize the packing process.

Other comments stated that the requirement to list specific ingredients on shipping containers if a "constant pattern" of use is determined is at odds with the proposal to use collective names at retail. Such a requirement would compel retail store personnel to categorize the specific wax or resin coating, because retail establishments will always be able to use generic labeling. These comments further maintained that it is unreasonable to expect produce clerks and store managers to understand ingredient label classification of waxes and resins and to label accurately the products with the appropriate collective name. These comments also contended that requiring produce personnel to classify waxes and resins for labeling purposes may ultimately cause erroneous labeling, resulting in misbranding of the product and misleading the consumer.

The agency requires ingredient labeling for wax or resin coatings on both domestic and imported fresh fruits and vegetables. The agency finds, based on information provided in the comments regarding industry practices, that the loss of specific lot identification because of commingling of variously coated produce while in bulk storage at the wholesale distributor level makes specific ingredient declaration impracticable. Proposed § 101.4(b)(25) (redesignated as new § 101.4(b)(22) in this final rule) provided for the use of collective terms by packers and repackers when a "constant pattern" of wax or resin ingredient use is not practicable. In light of information regarding industry practice provided in several of the comments, the agency concludes that it is likely that the great majority of packers and repackers, both foreign and domestic, will satisfy the conditions of impracticability required for exemption from specific ingredient labeling for wax and resin coatings. The agency further concludes that the small number of manufacturers who adhere to a constant pattern of use of wax or resin coatings may be at a competitive disadvantage because they will incur additional labeling and inventory costs in order to provide specific wax or resin ingredient labeling for a variety of fruits and vegetables. Similar costs will not be borne by the majority of packers and repackers, who do not adhere to a constant pattern of wax or resin use.

Section 403(i)(2) of the act provides that, in cases where specific ingredient labeling would be impracticable or result in deception or unfair competition, the packer or repacker may be exempted from such labeling. Because of industry practices previously discussed, the majority of packers and repackers will meet the requirements for exemption from specific ingredient declaration because of impracticability. In the agency's opinion, however, the few packers and repackers that would not be exempt from specific ingredient declaration due to impracticability would be placed at a competitive disadvantage if required to comply with section 403(i) of the act. Accordingly, the agency is revising proposed § 101.4(b)(22) to exempt all packers and repackers from specific ingredient labeling of wax and resin coatings. In reaching this conclusion, FDA also considered that consumers would not be disadvantaged by any loss of information if packers and repackers use collective term labeling of waxes and resins because retailers are permitted to use collective terms. Therefore, specific ingredient labeling of waxes and resins by the packer or repacker would not be provided to the consumer by the retailer.

25. Several comments requested that the agency revise proposed § 101.4(b)(25) to include dairy-based waxes within the category of animal-based waxes, e.g., "animal-based or milk-based" or "coated with animal-based wax (may include dairy product-based wax)." The comments cited the possibility of allergic reaction to products containing small amounts of dairy products and religious, ethnic, or dietary restrictions as the reasons for the request.

The agency advises that dairy-based waxes are included in the animal-based wax category. The agency believes that consumers understand that dairy products are animal-based, and that any dairy-based ingredients in waxes or resins would be included in an "animal-based wax" declaration. The agency further believes that the prescribed term "coated with animal-based wax" is adequate to provide the requested information to consumers wishing to avoid dairy-based products. The comments did not provide any basis for finding that the use of the term "animal-based" is not adequate to advise consumers with all the information they would need to avoid the product. Accordingly, FDA has not made the requested revision of the regulation.

26. Some comments objected to the term "food grade," stating that all ingredients are food grade, and that this term may give the consumer the impression that other ingredients are not "food grade." These comments also objected to the optional use of functional phrases, e.g., "to maintain freshness," in conjunction with the words "wax" and "coatings," because the comments believed that such terms are misleading or redundant.

The agency points out that the term "food grade" is an optional term and concludes that it should remain as such. The agency is not convinced that consumers will perceive that ingredients not designated as "food grade" are not food grade. On the contrary, the agency believes that the use of the optional term "food grade" will assure consumers who are concerned about wax or resin coatings that these ingredients have been accepted by the agency as "food grade" and, therefore, are considered to be safe ingredients.

The agency disagrees that the phrase "to maintain freshness" is misleading. Waxes and coatings do perform a preservative function, and this phrase is an acceptable means of stating that fact. Although the agency is not requiring the phrase "to maintain freshness" to describe the preservative function of waxes and resins (FDA believes that consumers generally recognize that this function is associated with the terms "wax" and "resin;" thus, for produce, the terms "wax" and "resin" fulfill the requirements of new § 101.22(j) and section 403(k) of the act with respect to the declaration of the preservative function), the agency will permit the phrase to be included in the wax or resin ingredient declaration.

27. A few comments suggested that the term "no wax and/or resin coating" should be required instead of no labeling when no wax or resin coating is present, to assure the consumer that the absence of labeling is not the result of the retailer's failure to label the presence of wax or resin coating.

The agency has the authority to require declaration of the absence of an ingredient in cases where it is implied that the ingredient has been used when in fact it has not been used. In such instances the lack of specific information would be misleading under sections 403(a) and 201(n) of the act. However, the comment did not provide information to substantiate that in the absence of a wax or resin declaration, consumers would believe that a wax or resin coating had been applied. Thus, the agency does not have the authority, in this instance, to require a "no wax or resin" declaration. However, the agency will not object to use of a "no wax or resin" declaration but does require that the statement is factual in all respects. Furthermore, the agency expects that packers, repackers, and retailers will comply with the statutory requirements and correctly label wax or resin coated fresh fruits and vegetables.

28. Other comments requested that the agency revise proposed § 101.4(b)(25) to: (1) Establish shellac or lac-based coatings as a separate category of wax or resin coatings; (2) modify the term shellac with the phrase "a coating made up of a secretion of the lac insect" to alert strict vegetarians; and (3) combine the categories beeswax and shellac-based because they are both insect-derived.

The agency has not been persuaded by the comments that the prescribed terms are inadequate to inform the consumer about wax and resin coatings, or that an additional category should be established to alert a limited population of consumers. FDA selected the collective terms that it proposed in the June 21, 1991, proposal to assist the consumer in avoiding certain products for reasons of religious, cultural, or ethnic dietary restrictions. These collective terms allow consumers to avoid certain foods, while providing the flexibility needed by retailers in prevailing market conditions to comply with the ingredient labeling requirement. Thus, the agency is not creating an additional category for beeswax and shellac (or lac-) based waxes. However, should a packer, repacker, or retailer voluntarily choose to use a more narrow descriptive term such as "vegetable based" or "beeswax and shellac based," or to name the specific wax or resin coating, the agency will not object to such use but does require that the declaration be factual.

29. Some comments suggested use of the term "petroleum based" as opposed to "mineral based" because it is factual, it is understood by consumers, and the term "mineral" may be misleading if associated with vitamins and minerals, particularly if nutrition labeling is provided by the retailer.

The agency agrees with the comments. Currently, in part 172 (21 CFR part 172), there are at least four multipurpose direct food additives that may be applied to fresh fruits and vegetables as a protective coating, and that the agency considers to be in the category "petroleum based." These are: White mineral oil (liquid petrolatum), § 172.878; petroleum wax, § 172.886; synthetic petroleum wax, § 172.888; and petrolatum, § 172.880. With the exception of white mineral oil, all have the term "petroleum" as part of their common or usual name. Therefore, the agency concludes that the term "petroleum based" is more accurate and informative in describing the nature and source of the wax coating than the term "mineral," which may be associated with inorganic substances rather than organic substances. Accordingly, FDA has revised new § 101.4(b)(22) (formerly § 101.4 (b)(25)) to reflect this change.

30. Two comments expressed concern that growers, packers, and repackers may begin to use coatings derived from certain gluten containing foods (i.e., wheat, barley, rye, oats, or millet), and that the prescribed generic terms would not adequately inform persons who must avoid these foods. The comments further asserted that retailers should not be allowed to treat cut-up fruits or vegetables with a gluten-based coating to enhance color and preserve freshness without declaring the use of such coating.

The agency is not aware of any commercially used coating derived from wheat, barley, rye, oats, or millet that may contain gluten. However, should such a coating be developed in the future, FDA would decide what measures are necessary to adequately protect those consumers who need to avoid gluten and to ensure the safe use of the coating.

In addition, retailers who coat fruits or vegetables are required to declare such ingredients in accordance with the provisions of section 403(k) of the act and § 101.4(b)(22).

31. Some comments that supported the use of self-serve plastic bags to identify wax or resin coating ingredients saw no difference between prepacked plastic bags with ingredient labeling and those plastic bags to be used by consumers from a roll. Further, they argued that, as opposed to information on signs, the information on plastic bags would give consumers added time for review during shopping and after leaving the store. Other comments opposed the use of self-serve plastic bags to provide ingredient declaration of wax or resin coatings because: (1) The consumer would not have the information before making the purchase decision; (2) it is difficult to read print on bags in a roll; (3) the consumer may not use the plastic bags specific to the produce or to the actual waxes applied to the products being purchased; and (4) the practice is not ecologically sound.

The comments supporting use of self-serve plastic bags to declare wax or resin coatings on produce at retail have not persuaded the agency that self-serve plastic bags available in the produce department meet statutory labeling requirements for ingredient declaration, meet expressed consumer needs, or can reasonably be managed at the retail store. As stated in the June 21, 1991, proposal, ingredient information on plastic bags available in the produce department would not provide consumers with this information at the time they actually make purchase decisions (56 FR 28592 at 28614). Further, the agency doubts that consumers would notice ingredient information because the bags are usually distributed in rolls. Thus, because the ingredient information would not be placed conspicuously and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, the produce would be misbranded under section 403(f) of the act.

Furthermore, the agency believes that ingredient declaration on plastic bags could result in misleading consumers, especially when consumers may commingle different brands of the same produce or puzzle over which plastic bag to use for which produce. Unlike ingredient declaration on prepackaged fruits and vegetables, which is specific to the contents of that package, the agency cannot ensure that ingredient declaration placed on self-serve plastic bags would be used for the specific fruit or vegetable for which the bags were intended. Thus, FDA affirms its tentative finding and concludes that wax or resin coating ingredient labeling limited to self-serve rolls of plastic bags in the produce department does not meet the statutory requirement of section 403(f) of the act and, therefore, is not an acceptable alternative of ingredient declaration of waxes and resins.

32. Several comments requested that the agency reconsider its decision and permit retailers to use the term, "may have been treated with wax or resin coatings," on produce labels. The comments compared the concept to "and/or" labeling of fats and oils.

The agency believes that there is an inherent difference between the terms "may have been treated * * *," with its inherent suggestion that the food may or may not contain the wax, and "and/or." As discussed in the June 21, 1991, proposal, the suggestion that a food may contain a wax would be of virtually no use to consumers because it does not advise them whether the produce has a wax or resin coating or identify the coating used. On the other hand, "and/or" labeling informs the consumer that one or more of the ingredients declared is definitely present in the product. Thus, the agency is not granting the request to allow the term "may have been treated * * *" in the declaration of wax or resin coatings. However, the agency points out that it has allowed in new § 101.4(b)(22) for the use of "and/or" labeling in declaration of wax or resin coatings (e.g., "coated with vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin") because it

adequately informs the consumer of the generic category of wax or resin coating as well as provides the flexibility needed by industry. These prescribed terms are sufficiently general that if several different kinds of wax or resin coatings become commingled in different lots, the produce would still be factually and informatively labeled.

33. Several comments requested that the agency establish more rigid requirements with respect to format, terminology, and letter size for wax or resin label declaration. These comments expressed the belief that the proposed requirements were not adequate to inform the consumer.

The comments did not provide any evidence to support their claim that the requirements as proposed will not result in labeling that will adequately inform the consumer regarding wax or resin coating. Consequently, the agency disagrees with these comments and concludes that the requirement that labeling be displayed prominently and in a conspicuous manner with lettering at least one-fourth of an inch high is adequate to inform the consumer.

34. A few comments requested that FDA require that the sign for each commodity be placed next to the bin bearing that commodity. These comments contended that one sign in the produce department covering all affected produce would not adequately provide point-of-purchase information for the various items sold throughout the department. Comments opposing the requirement of individual signs next to each commodity stated that such a practice would ultimately lead to misbranding because of the retail practice of moving bins, rearranging produce displays, and the likelihood of consumers knocking down such signs.

In the June 21, 1991, proposal, the agency proposed in § 101.4(f) to require that ingredients that must be declared in labeling because there is no label for the food (display of written, printed, or graphic matter upon the immediate container of any article), be listed prominently and conspicuously by their common or usual name. The agency did not, however, propose requirements with regard to the number of signs or countercards or the placement of such labeling in produce departments because the arrangement and size of produce departments is not consistent from one retail establishment to another. In cases where the produce department is confined to a small area, one sign or counter card may be sufficient to adequately inform the consumer regarding the use of wax or resin coatings as produce ingredients. However, where the produce department covers a large area, one sign may not be adequate. The agency believes that retailers should be permitted to determine the appropriate placement of signs and counter cards to meet ingredient labeling requirements in each particular establishment. However, the agency advises that enforcement action may be taken against retail establishments where wax or resin ingredient declarations are not prominently and conspicuously displayed.

35. One comment stated that the agency should not specify the manner of labeling for wax or resin coated produce or set rigid type size requirements for sign lettering placed on bulk bins, i.e., one-fourth inch type size, as proposed in § 101.100(a)(2)(ii). The comment asserted that such rigid standards would stifle innovation and limit the creativity of grocers in finding new ways to provide useful information to consumers.

The agency disagrees with the comment that the proposed labeling requirements would stifle retail creativity. The proposed minimum type size requirement will help to ensure that consumers with a wide range of visual acuities will be able to read the written information. Moreover, such written information will comply with requirements provided under section 403(f) of the act. Further, the type size requirement does not preclude retailers from providing brochures, electronic signs, computer screen displays, or using other media and methods to inform consumers in addition to the sign required in § 101.100(a)(2).

36. One comment requested clarification on whether the minimum letter size requirement of one-fourth of an inch referred to upper case or lower case when both lettering types are used.

The agency advises that, as with other minimum lettering size requirements, the minimum size requirement of one-fourth of an inch for labeling of wax or resin coating ingredient labeling refers to the height of the lower case "o" when both upper and lower case lettering is used, as established in § 101.105(h)(2).

VI. Source Labeling

A. General

FDA stated in the June 21, 1991, proposal that declaration of the food source in the common or usual name of all foods would not be required.

37. Many consumer comments responding to the proposal requested that the agency reconsider its position and require that the specific source of an ingredient be declared as part of its common or usual name in the list of ingredients.

These comments repeated requests that the agency had already evaluated when developing the June 21, 1991, proposal and did not present new information. As previously discussed (56 FR 28592 at 28603), several of these comments expressed a desire to avoid certain ingredients (e.g., corn-derived sweeteners), while others stated that consumers should be fully aware of what is in the food they eat.

FDA appreciates consumer needs and concerns about source labeling and points out that source labeling is required as part of the common or usual name in instances where such information has a material bearing on the purchase of a food, where such information describes the basic nature of the food, or where consumers may be misled without such information (§ 101.4(a)(1) and 102.5(a)). For FDA to require declaration of the source of all ingredients, it would have to amend the common or usual name of those ingredients that do not currently include their source. As explained in the June 21, 1991, proposal (56 FR 28592 at 28603), such a requirement would require enormous resources, and the agency does not have such resources available. Moreover, many of these ingredients are so well known that most consumers understand the source of the ingredient from its name. Consequently, FDA reaffirms its conclusion that it is not feasible or necessary to establish a general requirement for source information in the common or usual names of all foods.

B. For Specific Foods—Gluten Labeling

38. FDA received several comments from consumers affected with celiac sprue, a medical condition that results in damage to the absorptive surface of the intestine when gluten (a protein fraction of cereal grains) is ingested. These comments strongly requested source declaration, particularly for all protein hydrolysates (i.e., flavor-related and nonflavor-related protein hydrolysates) and modified food starches produced from wheat, barley, rye, oats, and millet which commonly contain gluten. Alternatively, these comments requested that FDA establish regulations that would allow manufacturers to state that a product is "gluten free" without misbranding the food.

The agency acknowledges the desire of those individuals affected with celiac sprue to know what products contain gluten. As with other ingredients combined to make a finished food, declaration of gluten when added as an

ingredient to a food is required. Literature reviewed by the agency suggests that the two most commonly used forms of gluten are derived from corn and wheat (Ref. 45). Sections 184.1321 and 184.1322 (21 CFR 184.1321 and 184.1322) establish the terms "corn gluten" and "wheat gluten," respectively, as the common or usual names for declaration of these ingredients.

In this final rule, FDA is requiring source declaration in the common or usual name of all protein hydrolysates, including those that are made from sources that may contain gluten, because the source is essential to describe the basic nature of the ingredient. In the June 21, 1991, proposal, the agency advised that protein hydrolysates used for nonflavor-related purposes should also be declared by appropriate common or usual names in accordance with the provisions of proposed § 101.22(h)(7), which describes requirements for the declaration of protein hydrolysates used for flavor-related purposes (56 FR 28592 at 28600). For reasons discussed in section VIII.A. of this document, the agency is incorporating that position into the regulation. Therefore, the requirement for source declaration in the common or usual name of protein hydrolysates used for flavor-related purposes has been transferred from § 101.22(h)(7) to new § 102.22(a) and now applies to declaration of protein hydrolysates used for flavor-related as well as nonflavor-related purposes. The agency believes that this requirement will assist consumers who wish to avoid gluten.

With respect to modified food starch, the agency does not believe that source declaration is required to inform consumers about gluten content. Modified food starches (21 CFR 172.892) are products of the treatment of any of several grain- or root-based starches with small amounts of chemical agents, which modify the physical characteristics of the source starches to produce desirable properties. Corn starches are the dominant starches used in the United States (Ref. 50). As stated in the comments, consumers with celiac sprue must abstain primarily from gluten derived from wheat, oats, barley, millet, and rye. Corn as a source of gluten was not mentioned in the comments as one to be avoided.

More importantly, the starch component of the source food is separated from the protein (i.e., gluten) component through starch isolation techniques (Ref. 50). Once the starch has been isolated, it is modified and added to food as an ingredient. Therefore, irrespective of the source of the modified food starch, the gluten (protein) component is removed and therefore should not be a problem for gluten intolerant consumers. The comments did not provide evidence that modified food starch causes adverse health consequences as currently used. Therefore, the agency is not requiring source declaration for modified food starch.

The agency advises that even though it has not specifically defined "gluten free," this phrase can be used on foods provided that when as used it is not false or misleading. The term "gluten free" may be misleading when the food ordinarily contains no gluten (e.g., modified food starch). Further, it is the agency's understanding that "gluten free" foods labeled as such may be found in the special dietary sections of some food stores and on a very limited number of products more generally available. Therefore, the agency has advised (Refs. 51 and 52) that foods labeled "gluten free" that purport to be or are represented for special dietary use should adhere to the provisions for hypoallergenic foods in § 105.62 by declaring the common or usual name, and the quantity or proportion, of each ingredient (including spices, flavorings and noncertified color additives) when the food is fabricated of two or more ingredients. Additionally, under § 105.62(b), the name of the food or of its ingredients must be qualified to reveal clearly the specific plant or animal source of the food or ingredient. Moreover, an informative statement of the nature and effect of any treatment or processing of the food or any ingredient thereof must be declared if a change in the allergenic property results from such treatment or processing (§ 105.62(c)).

FDA will consider establishing a definition for "gluten free" if petitioned with sufficient information, including an adequate analytical methodology for food analysis.

C. Labeling of Foods Characterized as "Nondairy" that Contain Caseinates

In the June 21, 1991, proposal, the agency identified some food products that are marketed as dairy product substitutes and that bear labels that include the statement "nondairy," but that contain a caseinate milk derivative. FDA believes that the labeling of such products may lead consumers to think that the caseinates are not milk derived. Thus, the agency proposed in § 101.4(d) that wherever "nondairy" statements appear on the label of a product that contains a milk derivative, the source of the milk derivative must be declared in the ingredient statement.

39. The majority of comments that addressed this issue supported the agency's proposal. However, several comments recommended that the agency revise § 101.4(d) to require that the term "caseinate milk derivative" be declared after the term "nondairy" on the principal display panel, as well as in the ingredient list.

The agency disagrees with the latter comments. The agency does not believe that requiring the additional declaration on the principal display panel is justified. FDA believes that the proposed requirement to declare the source of the milk derivative in the ingredient list will adequately protect consumers who wish to avoid milk-derived ingredients. The comments in question did not provide evidence to show that the ingredient list declaration would not be adequate. Therefore, the agency is not requiring source declaration on the principal display panel.

40. One comment recommended that the source identification requirement of caseinates as milk derivatives in foods labeled as "nondairy" be extended to foods that do not bear a "nondairy" label. However, the comment offered no rationale for this recommendation.

The agency disagrees with the recommendation. In the absence of a "nondairy" label declaration, there is no basis to suggest that the consumer would be led to believe that the food was nondairy. The declaration of the specific name of the caseinate in the ingredient statement would not be misleading and complies with regulations for ingredient labeling. Thus, the agency is not requiring source information in the name of the caseinate if the product does not bear a "nondairy" claim.

41. Other comments recommended that State laws that require "nondairy" labeling of products with caseinates be preempted for health reasons.

The agency disagrees with this suggestion. The comments did not provide information on which the agency could make a finding that the term "nondairy" on products that contain caseinates would create health concerns if the products' labeling also declares, in the ingredient statement, that the caseinate is milk-derived. The latter statement would adequately inform consumers, wishing to avoid milk-derived products, of the presence of a milk-derived ingredient. Accordingly, the agency is requiring, as proposed, that products that bear a "nondairy" claim and contain caseinates, must declare in the ingredient statement that the caseinate is milk-derived.

D. Nomenclature for Sweeteners

42. One comment requested source labeling for sweeteners. This comment stressed that source labeling would allow persons with specific food allergies to avoid these ingredients in finished foods. This comment further stated that corn, specifically, is of concern to Jews observing dietary laws during Passover.

The evidence presented by the comment lacked supportive scientifically verifiable data and thus, has not persuaded the agency to modify its tentative finding that allergic reactions to sweeteners, particularly corn-derived sweeteners, do not represent a major health concern in the United States. In the absence of such evidence, the agency is not requiring inclusion of the food source in the names of sweeteners. However, the agency acknowledges the concern expressed by consumers about source labeling, particularly for corn sweeteners, for other than health reasons. Accordingly, as proposed, the agency is amending §§ 168.110(b) and 168.111(c) to provide for voluntary declaration of the food source in the naming of these sweeteners, as is currently allowed for glucose sirup (§ 168.120 (21 CFR 168.120)) and dried glucose sirup (§ 168.121 (21 CFR 168.121)). Because the agency is not requiring declaration of the food source in the naming of these sweeteners, it encourages consumers wishing to avoid certain sweeteners for religious or other reasons to familiarize themselves with the names of these sweeteners and look for these names in the ingredient lists.

43. Another comment requested clarification regarding nomenclature appropriate for commonly used nonstandardized sweeteners, such as corn sirups with varying degrees of sweetness intensity (dextrose equivalence) and in varying forms (dried, powdered, and liquid). The comment requested that names such as "corn sirup" and "corn sirup solids" be permitted instead of the common or usual name of the ingredient or the precise form in which the ingredient was incorporated into the food. The comment maintained that "corn sirup" and "corn sirup solids" would be better understood and more recognizable by consumers than the technical common or usual names.

The agency rejects this comment. The requested terms "corn sirup" and "corn sirup solids" are currently used as alternative names, designating source, for standardized sweeteners provided in §§ 168.120 and 168.121. They are specific to those ingredients and, therefore, not appropriate for collective declaration of nonstandardized sweeteners. Furthermore, consumers have consistently requested specific ingredient labeling information rather than the use of collective terms when asked to comment on several food labeling issues, including labeling of sweeteners.

Moreover, under section 403(i) of the act, a food that is fabricated from two or more ingredients is misbranded unless the label bears the common or usual name of each such ingredient. The act also states that the agency is to provide for exemptions if compliance with this requirement is impracticable or results in deception or unfair competition. The comment did not present evidence upon which FDA could make a finding that the declaration of nonstandardized sweeteners, by their common or usual names, would be impracticable or would result in deceptive or unfair competition. Accordingly, the agency is denying the comment's request to permit such names as "corn sirup" instead of the common or usual name of the nonstandardized sweetener. As discussed in the proposal, persons interested in further guidance on appropriate names for nonstandardized sweeteners should refer to parts 172, 180, 182, and 184 (21 CFR parts 172, 180, 182, and 184).

VII. Percentage Ingredient Labeling

FDA proposed in the June 21, 1991, proposal to codify in § 101.4(e) its voluntary percentage labeling policy, which permits manufacturers to declare voluntarily percentages of ingredients if the information is not misleading and is truthful in all respects.

44. Several industry comments acknowledged that in instances where an ingredient is prominently declared, either through identity or other label information, or where the ingredient has a market appeal or is used to make a claim, percent ingredient labeling should be required. However, these comments also suggested that voluntary percentage ingredient labeling has the potential to confuse and mislead the consumer because too much information can distract consumers from the more important nutrient content information now mandated for all food labels. These comments further stated that confusion could be generated if only some manufacturers declare ingredient percentages. These comments asserted that voluntary percent labeling is unnecessary in light of the new nutrition labeling regulations and is not important to consumers. One comment further expressed concern that percentage ingredient labeling will eventually become mandatory for all foods. This comment requested assurance from FDA that voluntary percentage ingredient labeling would not become mandatory.

The agency is not convinced that voluntary percentage ingredient declaration would lead to consumer confusion. FDA has permitted manufacturers to declare voluntarily the percentage of ingredients, and it does not have information to indicate that consumer confusion has occurred as a result of such declarations. In addition, the majority of comments on this issue stated that it was appropriate for FDA to establish a uniform method of declaration for those manufacturers who choose to use percent ingredient labeling.

Furthermore, the agency believes that this information could educate consumers as to the individual contribution of a particular ingredient in the finished food, thereby assisting them in planning their diets. Consumers have the ability to discern and understand labeling information that is presented in a uniform, clear, and concise manner. Therefore, the agency is issuing new § 101.4(e) to establish a uniform method for voluntary percentage declaration of ingredients.

FDA is not requiring general percentage labeling of all ingredients in all foods. Although the agency cannot give assurances regarding the future, it is not at this time seeking authority to require such percentage ingredient labeling. The agency emphasizes, however, that the percentage of characterizing ingredients must be declared, as provided in § 102.5(b), when the proportion of such ingredients has a material bearing on the price or consumer acceptance of the food, or when there may be an erroneous impression that the ingredients are present in an amount greater than is actually the case.

VIII. Flavors, Colors, and Spices

A. Label Declaration of Protein Hydrolysates

Protein hydrolysates, which include acid hydrolyzed and enzyme hydrolyzed proteins from plant and animal sources, and autolyzed yeast extracts, are used in many foods for a variety of functions, including as formulation aids, leavening agents, stabilizers, thickening agents, nutrient supplements, protein sources, flavorings, and flavor enhancers. Current regulations do not exempt protein hydrolysates from ingredient declaration when used for purposes other than flavoring. The practice

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among some in industry has been to declare protein hydrolysates used for flavor-related purposes, such as flavor enhancement, as "flavorings" or "natural flavors."

In the June 21, 1991, proposal, the agency reached several tentative conclusions with regard to label declaration for protein hydrolysates used for flavor-related purposes. After reviewing available literature and technical data, FDA concluded that when protein hydrolysates are added to foods as flavorings, they also function as flavor enhancers. The agency pointed out that the act does not exempt flavor enhancers from required label declaration. Consequently, the June 21, 1991, proposal provided that any protein hydrolysate used in a food as a flavoring must be declared by its common or usual name.

As required by § 102.5(a), the common or usual name of a food should adequately describe its basic nature or characterizing properties or ingredients. The agency believes that some terms currently used for declaration of protein hydrolysates, e.g., "hydrolyzed vegetable protein" or "hydrolyzed animal protein," do not adequately describe their basic nature or characterizing properties because protein hydrolysates from different sources have different functional characteristics. Accordingly, in the June 21, 1991, proposal, FDA tentatively concluded that declaration of the protein source is necessary to describe accurately the nature of the protein hydrolysate, and proposed that it be included in the common or usual name. Furthermore, the agency stated that source declaration of protein hydrolysates is a material fact for consumers wishing to avoid certain foods for religious or cultural reasons.

In addition, FDA responded to the citizen petition submitted by the International Hydrolyzed Protein Council (the Council) in 1985. This petition requested that the agency revoke § 101.35 because the regulation is obsolete and does not include many of the protein hydrolysates presently used in foods. The agency agreed with the Council and proposed to delete § 101.35 from the regulations in the June 21, 1991, proposal.

FDA also tentatively found that there was no public health basis for requiring the declaration of free glutamates that occur as components of protein hydrolysates. However, comments on the June 21, 1991, proposal have raised other issues not related to public health concerning the declaration of glutamates. FDA did not consider these issues in the June 21, 1991, proposal. After evaluating the information presented in these comments, FDA has tentatively concluded that the phase "(contains glutamate)" is necessary to describe adequately the basic nature of certain protein hydrolysates and, thus, is proposing elsewhere in this issue of the Federal Register that this phrase be part of the common or usual name of certain protein hydrolysates. This action will, consequently, provide for the declaration of free glutamates as components of certain protein hydrolysates.

In the June 21, 1991, proposal, the agency did not include regulations for determining appropriate common or usual names for protein hydrolysates used for nonflavor-related purposes. Nevertheless, the agency did advise that protein hydrolysates used for nonflavor-related purposes should be declared in accordance with the provisions of proposed § 101.22. After reviewing the comments, however, the agency concluded that it is more appropriate to establish regulations that provide general requirements for the declaration of all protein hydrolysates and not just those used for flavor-related purposes. This will minimize confusion regarding appropriate common or usual names for the various kinds of protein hydrolysates. The agency also concluded that establishing general requirements for protein hydrolysates used for nonflavor-related purposes was a logical outgrowth of the June 21, 1991, proposal. Accordingly, the agency has transferred provisions of proposed § 101.22 regarding the common or usual name designation of protein hydrolysates used for flavor-related purposes to new § 102.22, and extended the requirements to include protein hydrolysates used for nonflavor-related purposes.

The agency has also concluded that highly hydrolyzed protein hydrolysates can be differentiated (as discussed below) from protein hydrolysates that may be mildly, lightly, or partially hydrolyzed (i.e., those types used for nonflavor-related purposes). Unlike highly hydrolyzed protein hydrolysates, protein hydrolysates that are not highly hydrolyzed may retain the functional effects and allergenic potential of the source protein because the source protein is still structurally intact to a substantial degree. Therefore, the agency has concluded that the inclusion of the protein source in the common or usual name of mildly, lightly, or partially hydrolyzed protein hydrolysates is also a material fact because this information is required by certain (allergic) individuals in order to make purchase decisions.

The agency's evaluation and summary of the comments received in response to the June 21, 1991, proposal follow.

45. The agency did not receive any comments objecting to the required ingredient declaration of protein hydrolysates when added to foods for flavor-related purposes. Therefore, as proposed, the agency is establishing in new § 101.22 a requirement for declaration of a hydrolyzed protein by its common or usual name in the ingredient list in order of predominance by weight when added to a food for flavoring or flavor-related functions. The agency points out, however, that provisions for specific declaration and acceptable names for protein hydrolysates have been transferred from proposed § 101.22(h)(7) to new § 102.22(a).

46. A number of comments requested more detailed source declaration, such as identification of milk-derived ingredients and specific origin of vegetable-derived protein hydrolysates. The two primary reasons cited in the comments for requesting source declaration were: (1) Religious or cultural dietary concerns; and (2) allergy, food intolerance, or sensitivity to the source protein. Other comments expressed the belief that the source of the protein should also be required in the declaration of the protein hydrolysate used for nonflavor-related purposes to protect those individuals who are allergic to certain source proteins. These comments stated that the potential for an allergic reaction is greater for nonflavor-related protein hydrolysates because these protein hydrolysates may be partially, mildly, or lightly hydrolyzed proteins. Unlike highly hydrolyzed proteins; partially, mildly, or lightly hydrolyzed proteins retain their capacity to induce allergic reactions because peptides from their source protein are significantly longer than those present in highly hydrolyzed proteins.

Several comments stated that source declaration should be limited to the terms "animal" or "vegetable," and that these generic terms would be sufficient for individuals wishing to avoid certain foods for religious or cultural reasons. These comments further stated that individuals wishing to avoid specific ingredients of animal or vegetable origin could do so by relying on the generic source declaration of "animal" or "vegetable."

The agency believes that the requirements set forth in §§ 101.22 and 102.22 are sufficient to inform consumers about the nature of the protein hydrolysate and, therefore, concludes that additional declarations

(e.g., milk-derived) are not necessary. However, the agency finds significant merit in those comments requesting that the source declaration be required for protein hydrolysates used for nonflavor-related purposes. The agency agrees with the comments that protein hydrolysates used for nonflavor-related purposes (i.e., partially hydrolyzed protein hydrolysates) may retain the allergenic potential of the source protein. Thus, the agency concludes that the inclusion of the name of the source in the common or usual name of the ingredient represents a material fact under section 201(n) of the act because individuals who are allergic to a specific food need to know when it is present as an ingredient in a food in order to make informed purchase decisions.

Furthermore, as the agency determined that source declaration as part of the common or usual name of highly hydrolyzed proteins is necessary to describe the basic nature of the ingredient because of inherent differences in the nature (amino acid profiles) of the source protein, it also finds that source declaration as part of the common or usual name of partially hydrolyzed proteins is necessary to describe the basic nature of the ingredient. Further, in order to provide additional guidance on the declaration of nonflavor-related protein hydrolysates, the agency is also advising that it is appropriate to use optional terms such as "partially," "lightly," or "mildly" in the declaration of protein hydrolysates that are not highly hydrolyzed. For example, the common or usual name of a protein hydrolysate that is not highly hydrolyzed may be declared as "hydrolyzed (source) protein" or "partially hydrolyzed (source) protein."

As stated in the June 21, 1991, proposal, the agency has advised that manufacturers should determine appropriate common or usual names for protein hydrolysates used for nonflavor-related purposes according to the provisions of proposed § 101.22. Upon consideration of the comments, however, the agency finds that it is necessary to establish regulations for the common or usual names of protein hydrolysates used for nonflavor-related purposes to ensure accurate, uniform, concise, and appropriate ingredient declarations for all protein hydrolysates. Accordingly, the agency has extended provisions for specific declaration and acceptable names for protein hydrolysates in proposed § 101.22 to cover all protein hydrolysates, and has transferred the provisions to new § 102.22.

With regard to the use of generic terms, the agency believes that generic terms like "animal" or "vegetable" do not adequately describe the basic nature or characterizing properties of the protein hydrolysate nor distinguish between the several types of source proteins in each general class of ingredients; therefore, they do not comply with § 102.5(a). As required by § 102.5(a), the common or usual name of an ingredient must describe, in as simple terms as possible, the basic nature of the food or its characterizing properties. As discussed in the proposal, hydrolyzed protein from wheat gluten and hydrolyzed protein from soy are different proteins, with significantly different amino acid profiles and functional properties. The amino acid profile, or composition, of the source protein describes the basic nature of the protein hydrolysate and determines the different levels of free amino acids released upon hydrolysis. In addition, the specific amino acids present in a source protein influence the flavoring ability of the protein hydrolysate at different stages of hydrolysis. Therefore, hydrolyzed wheat protein and hydrolyzed soy protein would not be distinguished accurately by a generic name.

Thus, generic source labeling using the terms "animal" or "vegetable" would not fully comply with § 102.5(a). The agency concludes that the declaration of the food source of a protein hydrolysate is essential to describe the basic nature of the protein hydrolysate, and that the food source is a significant determinant in the hydrolysate's eventual use in a food. Therefore, the food source should be a part of the common or usual name. The agency concludes further that the failure to identify the specific food source in the declaration of a protein hydrolysate causes the food to be misbranded because the declaration would not comply with the requirements of § 102.5(a) of the regulations and sections 201(n) and 403(a) of the act. The requirement for identification of the food source of a protein hydrolysate in proposed § 101.22(h)(7) is codified in new § 102.22(a).

47. One industry comment requested that FDA modify proposed § 101.22(h)(7) by providing that protein hydrolysates obtained from wheat gluten and other wheat sources be called "hydrolyzed wheat protein." The comment argued that once hydrolyzed, wheat gluten loses its specificity and is no longer wheat gluten because the carbon and nitrogen bonds holding the amino acids together are broken, leaving small peptides and amino acids. Therefore, the comment asserted, the term "hydrolyzed wheat protein" is more factual, adequately describes the nature of the ingredient, and is not misleading to consumers.

FDA recognizes that the hydrolysis of any protein source will produce small peptides and release certain amino acids, such that the hydrolyzed protein will not be identical structurally and functionally to the source protein. The amino acid profiles of the source protein and its hydrolyzed product, however, will be the same. Although wheat gluten is the principal protein component of wheat, there are other proteinaceous components of wheat that may not be defined specifically, as is gluten, but can serve as sources for hydrolyzed proteins. Furthermore, the agency believes that wheat gluten is generally accepted by consumers and industry as a differentiated wheat protein that meets the requirements of § 184.1322. Therefore, in the agency's opinion, when wheat gluten is used as a source of a hydrolyzed protein, the correct name of the ingredient is "hydrolyzed wheat gluten." Accordingly, the agency is not granting the comment's request. However, when other wheat components are used as sources of hydrolyzed proteins, the ingredient shall be declared as "hydrolyzed wheat protein."

48. Several comments asserted that source declaration for highly hydrolyzed proteins is not necessary because the source protein is so decharacterized in these products that its allergenic potential is no longer present.

The agency concurs with the comments' assertion that allergic, food intolerant, or sensitivity reactions are unlikely to occur from consumption of highly (acid) hydrolyzed proteins used in foods primarily for flavoring and flavor enhancement because the high degree of hydrolysis generally employed in the manufacture of these protein hydrolysates is likely to destroy the allergenic potential of the source protein (Ref. 4). Thus, the agency concludes that source declaration for highly hydrolyzed proteins is not necessary for the protection of individuals who are allergic, food intolerant, or sensitive to the source protein. However, as stated earlier, the food source of a protein hydrolysate is basic to describing the nature of the protein hydrolysate and, therefore, the agency is requiring the declaration of the food source as part of the common or usual name.

49. Many comments urged the agency to require declaration of the MSG (glutamate) component in protein hydrolysates for various reasons.

Because the agency is proposing, elsewhere in this issue of the Federal Register, to require, in specific situations, the declaration of glutamate as a component of protein hydrolysates, these comments and the agency's response will not be discussed here. However, a full discussion of this issue is presented in the above-referenced proposal.

50. In responding to the June 21, 1991, proposal, several comments indicated that differences exist among acid-hydrolyzed protein hydrolysates, enzyme-hydrolyzed protein hydrolysates, partially hydrolyzed protein hydrolysates, and autolyzed yeast extracts. These comments argued that the agency should make distinctions in the labeling of these different substances because some are used almost exclusively for flavor enhancement, sometimes substituting for MSG; others are primarily flavors rather than flavor enhancers but act in both capacities; and still others are neither flavors nor flavor enhancers but function as formulation aids, leavening agents, stabilizers, thickening agents, nutrient supplements, and protein sources. In conjunction with the nonflavor-related functions, some comments stated that the agency should address separately the labeling of a class of protein hydrolysates variously termed "partially," "mildly," or "lightly" hydrolyzed proteins, which primarily serve functions in food other than as flavor enhancers and/or flavorings.

The agency believes that the requirements in § 102.22 provide ample guidance for label declaration of protein hydrolysates in instances where confusion may have existed. As provided, the common or usual name of any protein hydrolysate will include the protein source. This requirement is necessary to describe the basic nature or characterizing property of the ingredient. The agency will also permit manufacturers to use such terms as "partially," "mildly," or "lightly" to describe protein hydrolysates that are not highly hydrolyzed. The agency believes that appropriate standards exist to allow it to distinguish between commercially-available highly hydrolyzed protein hydrolysates and those protein hydrolysates; variously termed "partially," "mildly," or "lightly" hydrolyzed; that are not used for flavor-related purposes. Highly hydrolyzed proteins can be defined as those whose ratio of α-amino nitrogen (AN) to total nitrogen (TN), determined by using the tests for "Acid Hydrolyzed Proteins" set forth in the "Food Chemicals Codex", 3d ed., 1st Supp. (1983), is greater than 0.62 (AN:TN > 0.62) (Ref. 53). Proteins that are not highly hydrolyzed would have an AN:TN ratio of less than 0.62 (AN:TN < 0.62) and may be declared by using such terms as "partially," "mildly," or "lightly" (e.g., "Partially hydrolyzed (source) protein"). The comments did not offer any analytical information or methodology, however, to assist the agency in distinguishing between partially, mildly, or lightly hydrolyzed proteins.

51. The agency did not receive any comments objecting to the proposed deletion of § 101.35, which provides guidelines for label declaration of MSG and other hydrolyzed vegetable proteins. Therefore, as proposed, the agency is deleting § 101.35 from its regulations.

B. Labeling of Other Flavors, Color Additives, and Spices

Before passage of the 1990 amendments, the act provided that flavorings, colorings, and spices could be declared collectively using the terms "flavorings," "colorings," and "spices." However, the 1990 amendments amended section 403(i) of the act to require that certified color additives be declared by their common or usual names and not be designated by the collective term "colorings." As a result of this change in the statute, each certified color additive used in or on a food must be declared by its common or usual name, but noncertified color additives may still be declared collectively. Congress did not revoke the exemption from required declaration for flavorings and spices.

In response to this new statutory authority, FDA proposed § 101.22(k) which details how color additives are to be declared in the ingredient list. The agency also proposed to permit the use of abbreviated names for certified color additives. Over the last several years, FDA has allowed manufacturers who voluntarily declare certified color additives to use abbreviated names. Although the agency believed that the common or usual names by which the color additives are listed in parts 74 and 82 (21 CFR parts 74 and 82) were the most appropriate names for identifying these color additives, it also felt that a provision that permitted the use of abbreviated names might encourage more manufacturers to voluntarily declare these color additives. The agency concluded that such a practice would provide more information to consumers than use of the collective term, which before the 1990 amendments, satisfied the requirements of the act.

On January 28, 1983, FDA issued an advisory opinion permitting the use of abbreviated names of certified color additives in response to a citizen petition submitted by the Grocery Manufacturers of America, Inc. (Docket No. 78P–0164). FDA subsequently proposed, in the **Federal Register** of June 6, 1985 (50 FR 23815), to incorporate that advisory opinion into its regulations. A final rule, however, has not yet published.

With the passage of 1990 amendments including the requirement that certified color additives used in foods be declared by their common or usual names FDA saw an opportunity to finalize the 1985 rulemaking. Given that under section 403(i)(2) of the act the listing of certified color additives will be required on food labels, the agency tentatively concluded that manufacturers should have the option to use abbreviated names for declaring the certified color additives. Accordingly, in the June 21, 1991, proposal, the agency proposed to continue the option to use abbreviated names because consumers have come to recognize and understand these names for color additives. Furthermore, the agency recognized that the use of abbreviated names has some advantage for industry because they consume less label space.

In the proposal, the agency solicited comments on whether certified color additive lakes should also be permitted to be declared using abbreviated names.

52. A comment from the Canadian government requested that the agency modify proposed § 101.22(k) to provide for the use of alternative names (such as tartrazine, allura red, erythrosine, sunset yellow FCF, brilliant blue FCF, indigotine, and fast green FCF) instead of the U.S. names (FD&C Yellow No. 5, FD&C Red No. 40, FD&C Red No. 3, FD&C Yellow No. 6, FD&C Blue No. 1, FD&C Blue No. 2, and FD&C Green No. 3, respectively) or to allow alternative names to be included in parentheses after the U.S. names. The comment stated that this approach would be consistent with provisions of the U.S. Canada Free Trade Agreement.

The agency believes that the common or usual names of certified color additives used in food, such as FD&C Blue No. 1 and FD&C Yellow No. 5, are recognized by consumers and broadly understood to be names of artificial colorings when they appear in an ingredient list. In addition, the certified color additives meet certain specifications, as provided in parts 74 and 82. The alternative names suggested in the comment may not represent the certified form of the specific color. For example, tartrazine may not be the U.S.

certified product, while FD&C Yellow No. 5 is the certified form of tartrazine.

Furthermore, the alternatives suggested in the comment have not been used in ingredient lists in the United States and are not recognized by FDA (part 74 (21 CFR part 74)) as the common or usual names of certified color additives. Accordingly, the agency is not persuaded that such names should be used at this time in place of common or usual names in the declaration of certified color additives.

However, the agency acknowledges the need, under the Free Trade Agreement, to accommodate Canadian labeling requirements where feasible. Declaration of both names for the U.S. certified color additives may facilitate familiarity with the alternative names for U.S. consumers. Therefore, manufacturers may voluntarily declare generally accepted alternative names, as suggested in the comment, in parentheses after the required U.S. name of the FDA certified color additive.

53. Another comment requested that the agency clarify that when several certified color additives are used in a food, they would have to be declared in descending order of predominance. The comment stated that proposed § 101.22(k) does not specifically address this issue. The comment was concerned that in instances where a combination of certified color additives and noncertified color additives is used in a food, the consumer would be confused because of the specific declaration of certified color additives and the use of a functional descriptor for noncertified color additives. The comment recommended that, when a combination of certified color additives and noncertified color additives is used in a food, the agency require both a functional descriptor and the listing of the specific names of all the color additives (certified and noncertified) in their order of predominance.

Declaration of certified color additives by their common or usual name must be done in a manner that complies with § 101.4. If more than one certified color additive is added to the food, the color additive present in the greatest amount must be declared first, unless the certified color additives are present at 2 percent or less and are, therefore, exempt from listing in order of predominance as provided in § 101.4(a)(2). With the exception of FD&C Yellow No. 5, current regulations have permitted collective declaration of certified and noncertified color additives, such that both "FD&C Yellow No. 5" and "artificial coloring" may appear on a food label. The agency has no evidence to indicate that consumers have been misled or confused by such a declaration. Consequently, the agency has no basis to conclude that declaration of certified and noncertified color additives as proposed would cause consumers confusion when both types of color additives are present in a food.

54. Another comment requested that FDA clarify whether dietary supplement manufacturers who comply with section 403(i) of the act, and have been permitted to list only those nutrients contained in the product for which a U.S. Recommended Daily Allowance (U.S. RDA) has been established, will be required to conform their ingredient listing to the regulation on color additives.

The agency acknowledges that a 1942 letter identified as TC–387 (Ref. 54) exempted "excipients, fillers, binders, and other fabricating ingredients" from complete ingredient declaration when used in manufacturing dietary supplements. Although TC–387 has not been officially revoked, the agency advises that its current policy, as stated in the **Federal Register** of August 2, 1973 (38 FR 20730), the **Federal Register** of March 16, 1979 (44 FR 16005), and in subsequent correspondence with industry (Refs. 55 and 56), is that the label for dietary supplements must contain a list of nutrients and a full statement of ingredients, except those exempted by section 403(i)(2) of the act, declared by the common or usual name. This policy is consistent with the ingredient declaration requirements for other types of products.

With regard to declaration of certified color additives, the 1990 amendments amended section 403(i)(2) of the act to require certified color additives be declared by their common or usual names. This requirement applies to all foods. However, in the Dietary Supplement Act of 1992, Congress imposed a moratorium on the implementation of the 1990 amendments with respect to dietary supplements with only very limited exceptions. Thus, FDA will not bring regulatory action against such products whose labels fail to declare the presence of certified color additives by their common or usual names until December 15, 1993.

55. Most comments responding to this issue strongly supported the use of abbreviated names for certified color additives. However, one comment maintained that certified color additives should be declared by their common or usual names as required in parts 74 and 82 and not by an abbreviated name unless there is a phase-in period of approximately 3 years during which both names would be used. The comment stated that this would allow consumers time to become familiar with the abbreviated name.

Because abbreviated names for certified color additives have been permitted and used by manufacturers since January 1983, the agency believes that consumers have a general understanding of these names, and are adequately informed about color additives. Consequently, an additional phase-in period is not necessary. Therefore, as proposed, the agency is providing the option to use abbreviated names for certified color additives in new § 101.22(k).

56. Several comments requested that the agency clarify the phrasing of the permitted abbreviated names. They pointed out that an FDA advisory opinion dated January 28, 1983, permitted the use of abbreviated names for color additives and the proposal of June 6, 1985 (50 FR 23815), permitted omission of not only "FD&C" but also "No." However, proposed § 101.22(k)(1) in the June 21, 1991, proposal only allowed the omission of the "FD&C" prefix from the declaration of a certified color additive in the ingredient list.

The agency acknowledges that proposed § 101.22(k)(1) in the June 21, 1991, proposal inadvertently omitted addressing the term "No." The agency intended to say that the abbreviated name need not include both "FD&C" and "No." FDA is revising new § 101.22(k)(1) accordingly.

57. The agency received several comments on the declaration of color additive lakes. Some of these comments recommended that abbreviated names should also apply to color additive lakes, so that their declaration would be consistent with that of certified color additives, e.g., "Blue 1 Lake." Other comments suggested that a single declaration (e.g., FD&C Blue No. 1) be used for both a certified color additive and its lake, or that the declaration of lakes of certified color additives follow the same requirements as certified color additives. These comments maintained that the difference between a certified color additive and its lake is one of technical functionality, and that consumers are unaware of the distinction. One comment argued that declaration of color additives and color additive lakes on the same information panel would lead to confusion and raise unnecessary questions in the consumer's mind. As an alternative, the comment recommended declaring lakes as dyes.

The agency agrees with those comments that stated that abbreviated names should also apply to certified

color additive lakes. Because this final rule provides for use of abbreviated names for certified color additives in foods, the agency finds that label declaration would be inconsistent and ultimately lead to consumer confusion if abbreviated names were not also allowed for certified color additive lakes. Accordingly, the agency is adopting, in § 101.22(k)(1), the option to declare the lake of a certified color additive using the abbreviated name of the certified color additive followed by the term "Lake." For example, a lake of FD&C Blue No. 1 would be "Blue 1 Lake."

The agency has no evidence to indicate that declaration of certified color additives and certified color additive lakes on the same information panel would lead to consumer confusion, and the comment did not present any evidence to substantiate this assertion. Furthermore, the agency believes that the use of the term "dye" for a lake would create an inappropriate distinction between a certified color additive and its lake by suggesting to consumers that certified color additive lakes are dyes, but that certified color additives are something other than dyes.

The agency is deferring rulemaking on the use of abbreviated names for color additives and lakes in drugs, cosmetics, and medical devices to separate action on the 1985 proposal.

58. One comment urged FDA to require that noncertified color additives be declared by name, so that consumers are provided with labeling information on noncertified color additives that is consistent with the labeling information on certified color additives. These comments asserted that noncertified color additives should also be declared by their common or usual names and not by collective terms, so that hypersensitive consumers can avoid foods to which they have chemical sensitivities.

Although the 1990 amendments modified section 403(i) of the act to require complete declaration of certified color additives, it did not revoke the exemption from ingredient labeling for noncertified color additives. Consequently, the agency does not have the authority to require specific declaration of noncertified color additives unless such declaration is necessary to ensure the safe use of the additive. Traditionally, the agency has encouraged manufacturers to list voluntarily, when practical, the specific names of all color additives following the functional descriptor. FDA has even provided guidance in new § 101.22(k)(2) for such a declaration.

The comment did not present any evidence to substantiate that there is a public health need for the specific declaration of all noncertified color additives. As with flavors and spices, FDA will consider requiring declaration of a noncertified color additive if such a need is demonstrated.

59. One comment stated that, although the proposal provided examples of specific declaration of noncertified color additives (e.g., caramel (color)), there appeared to be no reason to require the term "color" to be enclosed in parentheses. This comment requested clarification on whether parentheses were required, and if the term "caramel color" was an acceptable alternative.

The agency advises that the specific examples cited in the June 21, 1991, proposal for declaration of noncertified color additives were not intended to be all-inclusive. As discussed in the proposal, FDA will allow any informative term that clearly indicates to the consumer that a noncertified color additive has been added to the food. The agency advises that the term "caramel color" without parentheses adequately informs the consumer that caramel has been added to the food as a color additive.

60. Most comments generally supported FDA's recommendation, in proposed § 101.22(k)(3), for the voluntary declaration of all color additives in butter, cheese, and ice cream. These comments maintained that this practice would provide consumers with information for these three foods consistent with that now required for all other foods. No comments objected to this recommendation.

The agency is, therefore, finalizing its recommendation in new § 101.22(k) that when manufacturers add color additives to butter, cheese, or ice cream, they should voluntarily declare all color additives in the ingredient list.

61. Several comments from consumer interest groups requested that FDA require specific declaration of all flavors and spices on food labels. These comments contended that this information is important to individuals who have sensitivities to certain flavors and spices. The comments asserted that declaration of each spice and flavoring would enable these individuals to avoid foods that contain ingredients to which they are allergic.

Although the 1990 amendments required specific declaration of certified color additives, they did not amend the act to require specific declaration of flavorings or spices or of color additives that are not subject to certification. In the proposal, the agency tentatively concluded that, without such an amendment, it does not have the authority to generally require specific declaration of flavorings and spices. The comments summarized above were similar to the comments on the 1989 ANPRM that FDA reviewed when it was developing the June 21, 1991, proposal, and they did not provide any new information to justify their requests. However, if FDA determines that specific declaration of a flavor or spice is necessary to ensure its safe use, the agency will consider establishing requirements for label declaration of that flavor or spice by its common or usual name.

62. One comment requested clarification with respect to labeling of spices whose primary function is to color, e.g., paprika, a noncertified color additive. The comment argued that such an ingredient should not be labeled as a spice.

The agency encourages manufacturers to declare voluntarily specific spices and color additives they use in a food when practical. As for the label declaration of ingredients such as paprika (i.e., ingredients that have been declared GRAS as a spice and approved as a color additive), the agency expects manufacturers to declare such ingredients in a manner consistent with the ingredient's intended use in the food as provided in part 70 (21 CFR part 70). Section 70.3(f) provides that food ingredients that may contribute their own natural color when added to a food are not regarded as color additives, but when the ingredient is deliberately used as a color, it is a color additive. Therefore, if the intended use of an ingredient such as paprika is to color the food, it must be declared as an added color.

IX. Use of "And/Or" Labeling

FDA allows the use of "and/or" labeling in certain situations when manufacturers are unable to adhere to a consistent pattern of use of specific ingredients in their products (§ 101.4(b)). Such labeling provides a manufacturer with the flexibility to list together in the ingredient list of a food product all the ingredients of a particular type (e.g., fats or oils) that it sometimes uses to make the product, without having to specify the ingredients that are actually present in the product. To make clear that not all of the ingredients identified are actually present, the entry in the ingredient list must include the words "or," "and/or," or "contains one or more of the following." For example, the ingredient list on a package of crackers may include an entry, "partially

hydrogenated vegetable shortening (soybean oil, canola oil, and/or palm oil)."

In the June 21, 1991, proposal, FDA tentatively decided to continue to permit the use of "and/or" labeling for fats and oils. However, the agency requested any available scientific data on adverse reactions to fats or oils that would warrant a reconsideration of this decision.

The agency also discussed industry petitions that requested the use of "and/or" labeling of sweeteners, primarily for soft drinks (sodas) in the June 21, 1991, proposal. At that time, the agency denied the request for "and/or" labeling for sweeteners.

63. The majority of consumer comments addressing this issue opposed the continued use of "and/or" labeling for fats and oils for reasons already addressed in the June 21, 1991, proposal. These comments requested that the agency reconsider its position and revoke § 101.4(b)(14). These comments, however, did not offer any information that had not already been considered in developing the June 21, 1991, proposal.

In light of the 1990 amendments, which mandate declaration of the saturated fatty acid content of a food, and the revisions in nutrition labeling regulations proposed on November 27, 1991 (56 FR 60366), the agency does not believe that the potential benefits from requiring more specific labeling of fats and oils outweigh the possible impact of higher food costs that accrue when manufacturers are forced to change food labels in response to marketplace price fluctuations of fats and oils. In addition, the mandatory declaration of saturated fatty acid content grants the consumers' primary request regarding more information on saturated fats. Accordingly, FDA is not revoking § 101.4(b)(14).

It should be noted that § 101.4(b)(14) restricts "and/or" labeling to situations in which fats and oils are not the predominant ingredient. The agency is not changing this restriction.

64. One comment requested the option to use an "and/or" statement to list specific protein hydrolysates in canned tuna. The comment asserted that "and/or" labeling would give tuna processors the flexibility to select protein hydrolysates for use as flavor enhancers in canned tuna, based on cost considerations and the availability of these ingredients, without having to change labels.

FDA is not granting this request. Designation of the specific source of protein when protein hydrolysate is listed in the ingredient statement of the label alerts consumers to the exact identity of this ingredient. Such declaration of protein hydrolysates provides a tangible benefit to consumers who may be avoiding a particular protein source because of religious or cultural beliefs or other personal reasons. While FDA recognizes the need for flexibility in the selection of the protein hydrolysates used for flavor enhancing purposes in canned tuna, the agency believes that a provision for "and/or" labeling of the protein hydrolysate would defeat the purpose of this declaration.

As stated elsewhere in this document, FDA believes that consumers have a right to be able to choose between products on the basis of the ingredients contained in the foods. Disjunctive labeling on canned tuna, i.e., "and/or" labeling, limits consumers' choices because they must avoid all tuna products that may contain a certain protein hydrolysate when this ingredient is listed as one of several alternative protein hydrolysates on the label. Even though most protein hydrolysates used for flavor enhancement are highly hydrolyzed and unlikely to cause adverse reactions, FDA believes that manufacturers should continue to provide specific source information on protein hydrolysates to enable consumers to make choices based on their personal, cultural, or religious beliefs. Therefore, FDA is not making the requested change in the standard of identity for canned tuna.

FDA acknowledges that "and/or" labeling is used for fats and oils to provide a measure of flexibility in the selection and use of these ingredients in foods. In such cases, however, FDA notes that there is potential for cost savings which can be passed on to consumers when manufacturers have the option of selecting oils suitable for a particular food operation, based on cost and availability. This is particularly significant because food oils are used in large volumes in food production; protein hydrolysates generally are not. Moreover, no information on the magnitude of potential costs savings was presented in the comment. In addition, the use of "and/or" labeling with fats and oils is augmented by information concerning the fat, fatty acid, and cholesterol contents of the foods in nutrition labeling, thus providing further information to enable consumers to avoid foods that contain levels of cholesterol, total fat, or saturated fat that are inconsistent with their nutrition goals.

65. Comments requesting that the agency reconsider its position on the use of "and/or" labeling for sweeteners argued that, while present price relationships between sugar and corn sweeteners may be relatively constant, there is no guarantee that either sugar processing costs or the impact of the U.S. sugar program on prices will remain static. The comments further stated that advances in processing technologies may cause changes in traditional price relationships, and that manufacturers will need the flexibility of "and/or" labeling to remain competitive.

The agency acknowledges that price fluctuations between sugar and corn sweeteners may eventually occur. If and when FDA is provided evidence that significant price fluctuations occur among different sweeteners, or the flexibility of "and/or" labeling otherwise becomes necessary, the agency will consider initiating rulemaking to permit this labeling exemption.

66. Comments from the soft drink industry requested that the agency reconsider the citizen petition of the National Soft Drink Association (NSDA) (January 20, 1984—Docket No. 84P–0029) and provide for use of "and/or" labeling for sweeteners in soft drinks. The agency has reconsidered the citizen petition of the NSDA and is proposing, as discussed elsewhere in this issue of the **Federal Register**, to allow "and/or" labeling for sweeteners in soft drinks.

X. Other Labeling Issues

A. Ingredient List Format

In the June 21, 1991, proposal, the agency discussed several ways that the readability of the ingredient list might be enhanced. However, the agency was not aware of any evidence that the current ingredient labeling format was not adequate to meet the labeling requirements provided in section 403(f) of the act. Without such evidence, the agency had no basis to propose new format requirements for ingredient labeling. Hence, the agency requested that if there is a need to revise the ingredient list format, comments provide data to substantiate the need and to describe what changes would improve the label.

67. A number of comments opposed separation of ingredient declaration of major and minor ingredients and expressed concern that such a separation might lead consumers to pay less attention than is merited to those ingredients listed as minor, which may include chemicals that have a significant health effect. Some comments also expressed concern that such a requirement could result in a further division between the United

States and the European Economic Community labeling requirements and create a barrier to trade. Finally, one comment stated that proposed § 101.4(a)(2) allows the option of separate declaration for ingredients present at two percent or less when preceded by an appropriate quantifying statement. Thus, the comment saw no reason to require the separation of major and minor ingredients. On the other hand, a few comments supported separation of the ingredient statement.

The agency has considered the positions presented in all of the comments. As stated in the June 21, 1991, proposal, the agency believes that separation of the ingredient statement into major and minor ingredients, would improve readability. However, the comments supporting separation of the ingredient list did not present evidence that the current labeling format did not fully satisfy section 403(f) of the act. Thus, the agency is not requiring separation of major and minor ingredients in this final rule.

68. The comments addressing increased type size requirements on the ingredient label generally recommended that readability would be enhanced by the use of capital and lower case letters without right margin justification printed in distinct contrast to other printed or graphic matter on an appropriate background. One of the comments reported that labels with black lettering on blue background or black lettering on red background are difficult to read.

The agency allows manufacturers to print ingredient lists in capital and lower case letters. The agency has no requirements with respect to right margin justification and allows use of this format. Furthermore, the agency allows the manufacturer flexibility in choosing specific color schemes for labeling and packaging. However, the agency emphasizes that the color schemes and printing used in ingredient labeling must comply with the provisions of section 403(f) of the act, which require that the information be conspicuous and have sufficient contrast to its background as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. Furthermore, in § 101.2(c) with § 101.105(h), the agency requires that information appearing on the ingredient label shall appear prominently and conspicuously in easily legible boldface print or type in distinct contrast to other printed or graphic matter on the label. Thus, the agency has concluded that several of the recommendations presented in the comments are incorporated in current labeling requirements. The agency has further concluded that current labeling requirements with respect to format, except as discussed in the wax and resin section of this document, are adequate to meet the requirements of the act and, therefore, finds no basis to revise them at this time.

B. Restaurant Foods

In the June 21, 1991, proposal, the agency requested comments on the practicability and feasibility of requiring ingredient labeling of restaurant foods. In addition, the agency also requested suggestions for appropriate ingredient labeling formats for restaurant foods if such labeling were required.

69. Several comments from consumers and consumer interest groups supported full ingredient disclosure for restaurants that maintain standardized menus (e.g., chain or fast food restaurants). In support of their position, these comments argued that because standardized menu items are all prepared in the same manner, they are conducive to ingredient labeling. One comment recommended, however, that ingredient labeling for chain restaurants be done on a trial basis before instituting regulations. Another comment from a chain pizza restaurant opposed ingredient labeling for restaurants. The comment asserted that it would be impossible for restaurants to use ingredient labeling because it would: (1) Hinder work on new formulations; (2) require a standardized menu; (3) limit menu items; and (4) escalate prices. In the alternative, the comment recommended that restaurants distribute a brochure providing ingredient information for any food item that might be used in their products. The brochures would be distributed at point of purchase or available upon request through a toll-free number. This comment urged the agency not to require ingredient labeling for chain restaurants.

The agency believes that it may be feasible for certain types of restaurants (e.g., chain or fast food restaurants with standardized food preparation and ingredient specifications) to provide ingredient information. However, the agency has not received enough information about the industry to determine the appropriateness and manner of requiring ingredient labeling by restaurants. While it is not adopting requirements at this time for ingredient labeling of restaurant foods, FDA encourages such declarations on a voluntary basis.

As discussed in the June 21, 1991, proposal, the agency cannot reasonably expect restaurants that frequently change their menu items to provide information on ingredients. The agency concurs with the comment that a brochure would be helpful to consumers in providing information on ingredients used in prepared foods when it is impractical for a restaurant to provide ingredient information for all menu items. The agency encourages restaurants to provide written information regarding ingredients used in prepared foods when practical.

C. Vendor Foods

70. Several comments from the vending industry requested that the agency exempt foods sold from automatic vending machines from ingredient declaration requirements. These comments did not, however, provide information to substantiate their request that the agency had not already considered in developing the June 21, 1991, proposal.

In the absence of information not already considered by the agency, and for the reasons discussed in the proposal, FDA reaffirms its previous decision not to exempt vendor foods from full ingredient labeling requirements.

D. Warning Statements

71. One of the issues addressed in the June 21, 1991, proposal was the practicality and desirability of requiring warning statements on foods to announce the presence of specific ingredients. At that time, the agency tentatively decided not to require the broad use of warning statements with respect to ingredients.

Comments on this issue generally supported FDA's position not to require warning statements in the absence of clear evidence of a health hazard. The comments warned that an overabundance of warning statements may desensitize the general public to safety concerns and subsequently cause warning statements to lose some of their value as a means of informing the consumer about potential health hazards.

The agency affirms its tentative position and does not intend to require warning statements except in specific instances where there is scientifically based evidence of a potential health hazard.

E. Simplified Names for Ingredients

72. The agency discussed, in the June 21, 1991, proposal, the various criteria that must be met before a new simplified name for an ingredient can supplant an established name in the ingredient list. Specifically, the new

name must be descriptive of the ingredient, must not provide misleading label information, and must be shown to be recognized by consumers.

The agency did not receive any comments addressing this issue. Therefore the agency does not plan to change any of the criteria discussed in the proposal.

F. Statements of Ingredients' Functions

73. In the June 21, 1991, proposal the agency said that it would consider any suggestions for declaration of the function of a particular ingredient or group of ingredients that are supported by appropriate evidence and that can be justified under one of the relevant statutory standards (i.e., sections 409(c) and 201(n) of the act). Since the comments did not provide evidence to support the declaration of the function of a particular ingredient or group of ingredients, the agency is not adopting any new requirements to list the function or purpose of food ingredients.

G. Irradiated Ingredients

74. One comment opposed declaration of irradiated foods by their common or usual names without specific declaration of irradiation and argued that consumers should be informed about the processing of the food. The comment did not present information not already considered by the agency in developing the June 21, 1991, proposal.

As stated in the proposal, the agency addressed the issue of declaration of irradiated ingredients in the **Federal Register** of December 30, 1988 (53 FR 53176). At that time, the agency concluded that irradiated ingredients should be declared by their common or usual name without additional information on processing. The agency finds no basis on which to revise its 1988 decision.

XI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

XII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in the June 21, 1991, proposal the agency determined that under 21 CFR 25.24(a)(11), this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

XIII. Effective Date

Several comments from the food industry strongly urged FDA to reconsider the effective date for ingredient labeling regulations for standardized foods and certified color additives. The comments argued that a November 8, 1991, effective date would not allow the food industry enough time to develop the required labeling and would significantly increase costs, because inventory would have to be discarded. These comments strongly urged FDA to establish a uniform effective date, for all proposed changes in ingredient labeling, to comply with the effective date for section 403(q) of the act (mandatory nutrition labeling) and section 403(r) (claims), which were added by the 1990 amendments.

Section 10(c) of the 1990 amendments established an effective date of November 8, 1991, for ingredient labeling of standardized foods and color additives required to be certified. However, Congress changed that effective date on August 17, 1991, and established a new effective date of May 8, 1993. In the November 27, 1991, **Federal Register** (56 FR 60877), the agency published information on this change in the effective date for standardized foods and certified color additives. As stated in that document, labels attached to food after May 8, 1993, will be subject to amended section 403(i) of the act and to this final rule. However, labels printed after July 1, 1991, but before the effective date of this final rule and applied before May 8, 1993, must comply with the June 21, 1991, proposal. Thus, the effective date of the final provisions in this regulation for standardized foods and certified color additives is May 8, 1993. The other final provisions in this regulation become effective on May 8, 1994.

XIV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Congressional Record—House, July 30, 1990, H5842.

2. FDA Compliance Policy Guide 7127.01.

3. FDA advisory opinion on Grocery Manufacturers of America Petitions (Docket Nos. 77N–0009 and 78P–0164), Joseph P. Hile, to Laurie Burg, January 28, 1983.

4. International Hydrolyzed Protein Council, 1977, comments with additional data by IHPC on SCOGS tentative evaluation of the health aspects of protein hydrolysates as food ingredients—Report 37b, International Hydrolyzed Protein Council, Washington, DC.

5. FDA opinion letter, Daniel D. Jones, GRAS Review Branch, to Charles L. Noland, October 18, 1978.

6. FDA opinion letter, Duane G. Groth, Advisory Opinions Branch, Division of Industry Advice, to Mrs. Betty B. Horn, May 4, 1965.

7. FDA opinion letter, Mary I. Snyder, Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition, to Ellen J. Flannery, April 29, 1988.

8. Heath, H. B., and G. Reineccius, "Flavor Chemistry and Technology," Van Nostrand Reinhold Co., Inc., New York, pp. 319–331, 259–261, 1986.

9. Pease, H., "Protein Hydrolysates and Flavor Enhancers," a paper given October 29, 1970, at Columbia University, to the graduate course in food product development, pp. 43.

10. Prendergast, K., "Versatility of Protein Hydrolysates," *Food Manufacture*, pp. 37, 39, and 57, April 1973.

11. FDA opinion letter, Taylor M. Quinn, Bureau of Foods, to Patrick L. Weidner, July 21, 1978.
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List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Fruit juices, Oils and fats, Onions, Potatoes, Seafood.

21 CFR Part 130

Food additives, Food grades and standards, Incorporation by reference.

21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

21 CFR Part 136

Bakery products, Food grades and standards.

21 CFR Part 137

Cereals (food), Food grades and standards.

21 CFR Part 139

Food grades and standards.

21 CFR Part 145

Food grades and standards, Fruits.

21 CFR Part 146

Food grades and standards, Fruit juices.

21 CFR Part 150

Food grades and standards, Fruits.

21 CFR Part 152

Bakery products, Food grades and standards, Frozen foods, Fruits.

21 CFR Part 155

Food grades and standards, Vegetables.

21 CFR Part 156

Food grades and standards, Vegetable juices.

21 CFR Part 158

Food grades and standards, Frozen foods, Vegetables.

21 CFR Part 160

Eggs and egg products, Food grades and standards.

21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

21 CFR Part 163

Cacao products, Food grades and standards.

21 CFR Part 164

Food grades and standards, Nuts, Peanuts.

21 CFR Part 166

Food grades and standards, Food labeling, Margarine.

21 CFR Part 168

Food grades and standards, Sugar.

21 CFR Part 169

Food grades and standards, Oils and fats, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA is amending 21 CFR parts 101, 102, 130, 135, 136, 137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163, 164, 166, 168, and 169 as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.4 is amended by revising paragraphs (a)(1), and (b)(2)(i), and by adding new paragraphs (b)(20) through (b)(22), (d), (e), and (f) to read as follows:

§ 101.4 Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that comply with standards of identity, except those ingredients exempted by § 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of § 101.2.

* * * * *

(b) * * *

(2) * * *

(i) By declaring the established common or usual name of the ingredient followed by a parenthetical listing of all ingredients contained therein in descending order of predominance except that, if the ingredient is a food subject to a definition and standard of identity established in subchapter B of this chapter that has specific labeling provisions for optional ingredients, optional ingredients may be declared within the parenthetical listing in accordance with those provisions.

* * * * *

(20) For purposes of ingredient labeling, the term "sugar" shall refer to sucrose, which is obtained from sugar cane or sugar beets in accordance with the provisions of § 184.1854 of this chapter.

(21) [Reserved]

(22) Wax and resin ingredients on fresh produce when such produce is held for retail sale, or when held for other than retail sale by packers or repackers shall be declared collectively by the phrase "coated with food-grade animal-based wax, to maintain freshness" or the phrase "coated with food-grade vegetable-, petroleum-, beeswax-, and/or shellac-based wax or resin, to maintain freshness" as appropriate. The terms "food-grade" and "to maintain freshness" are optional. The term "lac-resin" may be substituted for the term "shellac."

* * * * *

(d) When foods characterized on the label as "nondairy" contain a caseinate ingredient, the caseinate ingredient shall be followed by a parenthetical statement identifying its source. For example, if the manufacturer uses the term "nondairy" on a creamer that contains sodium caseinate, it shall include a parenthetical term such as "a milk derivative" after the listing of sodium caseinate in the ingredient list.

(e) If the percentage of an ingredient is included in the statement of ingredients, it shall be shown in parentheses following the name of the ingredient and expressed in terms of percent by weight. Percentage declarations shall be expressed to the nearest 1 percent, except that where ingredients are present at levels of 2 percent or less, they may be grouped together and expressed in accordance with the quantifying guidance set forth in paragraph (a)(2) of this section.

(f) Except as provided in § 101.100 ingredients that must be declared on labeling because there is no label for the food, including foods that comply with standards of identity, shall be listed prominently and conspicuously by common or usual name in the manner prescribed by paragraph (b) of this section.

§ 101.6 [Removed]

3. Section 101.6 *Label designation of ingredients for standardized foods* is removed from subpart A.

4. Section 101.22 is amended by adding new paragraphs (h)(7) and (k) to read as follows:

§ 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.

* * * * *

(h) * * *

(7) Because protein hydrolysates function in foods as both flavorings and flavor enhancers, no protein hydrolysate used in food for its effects on flavor may be declared simply as "flavor," "natural flavor," or "flavoring." The ingredient shall be declared by its specific common or usual name as provided in § 102.22 of this chapter.

* * * * *

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to §§ 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

(1) A color additive or the lake of a color additive subject to certification under 706(c) of the act shall be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter, except that it is not necessary to include the "FD&C" prefix or the term "No." in the declaration, but the term "Lake" shall be included in the declaration of the lake of the certified color additive (e.g., Blue 1 Lake). Manufacturers may parenthetically declare an appropriate alternative name of the certified color additive following its common or usual name as specified in part 74 or part 82 of this chapter.

(2) Color additives not subject to certification may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes

clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with ————————" or "———————— color", the blank to be filled with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

(3) When a coloring has been added to butter, cheese, or ice cream, it need not be declared in the ingredient list unless such declaration is required by a regulation in part 73 or part 74 of this chapter to ensure safe conditions of use for the color additive. Voluntary declaration of all colorings added to butter, cheese, and ice cream, however, is recommended.

§ 101.35 [Removed]

5. Section 101.35 *Notice to manufacturers and users of monosodium glutamate and other hydrolyzed vegetable protein products* is removed from subpart B.

6. Section 101.100 is amended by revising paragraph (a)(2) to read as follows:

§ 101.100 Food; exemptions from labeling.

(a) * * *

(2) A food having been received in bulk containers at a retail establishment, if displayed to the purchaser with either:

(i) The labeling of the bulk container plainly in view, provided ingredient information appears prominently and conspicuously in lettering of not less than one-fourth of an inch in height; or

(ii) A counter card, sign, or other appropriate device bearing prominently and conspicuously, but in no case with lettering of less than one-fourth of an inch in height, the information required to be stated on the label pursuant to section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act).

* * * * *

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

7. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: Secs. 201, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371).

8. New § 102.22 is added to subpart B to read as follows:

§ 102.22 Protein hydrolysates.

The common or usual name of a protein hydrolysate shall be specific to the ingredient and shall include the identity of the food source from which the protein was derived.

(a) "Hydrolyzed wheat gluten," "hydrolyzed soy protein," and "autolyzed yeast extract" are examples of acceptable names. "Hydrolyzed casein" is also an example of an acceptable name, whereas "hydrolyzed milk protein" is not an acceptable name for this ingredient because it is not specific to the ingredient (hydrolysates can be prepared from other milk proteins). The names "hydrolyzed vegetable protein" and "hydrolyzed protein" are not acceptable because they do not identify the food source of the protein.

(b) [Reserved]

PART 130—FOOD STANDARDS: GENERAL

9. The authority citation for 21 CFR part 130 continues to read as follows:

Authority: Secs. 201, 306, 401, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 336, 341, 343, 371).

10. Section 130.3 is amended by adding new paragraph (e) to read as follows:

§ 130.3 Definitions and interpretations.

* * * * *

(e) Section 403(i) of the act requires the listing of all ingredients in standardized foods. All ingredients must be listed in accordance with the requirements of part 101 of this chapter, except that where a definition and standard of identity has specific labeling provisions for optional ingredients, optional ingredients may be declared in accordance with those provisions.

11. New § 130.9 is added to subpart A to read as follows:

§ 130.9 Sulfites in standardized food.

(a) Any standardized food that contains a sulfiting agent or combination of sulfiting agents that is functional and provided for in the applicable standard or that is present in the finished food at a detectable level is misbranded unless the presence of the sulfiting agent or agents is declared on the label of the food. A detectable amount of sulfiting agent is 10 parts per million or more of the sulfite in the finished food. The level of sulfite in the finished food will be determined using sections 20.123 through 20.125, "Sulfurous Acid (Total) in Food Modified Monier-Williams Method Final Action" in "Official Methods of Analysis of the Association of Official Analytical Chemists," 14th ed. (1984), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, and the refinements of the "Total Sulfurous Acid" procedure in the "Monier-Williams Procedure (with Modifications) for Sulfites in Foods," which is appendix A to part 101 of this chapter. A copy of sections 20.123 through 20.125 of the "Official Methods of Analysis of the Association of Official Analytical Chemists" is available from AOAC International, 1111 North 19th St., Suite 210, Arlington, VA 22209, or available for inspection at the Office of the Federal Register, 800 North Capitol St. NW., Suite 700, Washington, DC.

(b) Any standardized food that, as a result of actions that are consistent with current good-manufacturing practice, contains an indirectly added sulfiting agent that has no functional effect in the food and that would, in the absence of § 101.100(a)(4) of this chapter, be considered to be an incidental additive for purposes of § 130.8, conforms to the applicable definition and standard of identity if the presence of the sulfiting agent is declared on the label of the food.

12. New § 130.11 is added to subpart A to read as follows:

§ 130.11 Label designations of ingredients for standardized foods.

Some definitions and standards of identity for foods set forth below require that designated optional ingredients such as spices, flavorings, colorings, emulsifiers, flavor enhancers, stabilizers, preservatives, and sweeteners be declared in a specified manner on the label wherever the name of the standardized food appears on the label so conspicuously as to be easily seen under customary conditions of purchase. Such requirements shall apply to a manufacturer, packer, or distributor of a standardized food only if the words or statements on the label of the standardized food significantly differentiate between two or more foods that comply with the same standard by describing the optional forms or varieties, the packing medium, or significant characterizing ingredients present in the food.

PART 135—FROZEN DESSERTS

13. The authority citation for 21 CFR part 135 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

14. Section 135.160 is amended by revising paragraph (a) to read as follows:

§ 135.160 Water ices.

(a) *Description.* Water ices are the foods each of which is prepared from the same ingredients and in the same manner prescribed in § 135.140 for sherbets, except that the mix need not

be pasteurized, and complies with all the provisions of § 135.140 (including the requirements for label statement of ingredients), except that no milk or milk-derived ingredient and no egg ingredient, other than egg white, is used.

* * * * *

PART 136—BAKERY PRODUCTS

15. The authority citation for 21 CFR part 136 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

16. Section 136.110 is amended by revising paragraph (f) to read as follows:

§ 136.110 Breads, rolls, and buns.

* * * * *

(f) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

17. The authority citation for 21 CFR part 137 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

18. Section 137.105 is amended by revising paragraph (b)(1) to read as follows:

§ 137.105 Flour.

* * * * *

(b)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

19. Section 137.155 is revised to read as follows:

§ 137.155 Bromated flour.

Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for flour by § 137.105, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished bromated flour, and is added only to flours whose baking qualities are improved by such addition.

20. Section 137.160 is revised to read as follows:

§ 137.160 Enriched bromated flour.

Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for enriched flour by § 137.165, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished enriched bromated flour, and is added only to enriched flours whose baking qualities are improved by such addition.

21. Section 137.165 is amended by revising the introductory text to read as follows:

§ 137.165 Enriched flour.

Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for flour by § 137.105, except that:

* * * * *

22. Section 137.170 is amended by revising paragraph (a) to read as follows:

§ 137.170 Instantized flours.

(a) Instantized flours, instant blending flours, and quick-mixing flours, are the foods each of which conforms to the definition and standard of identity and is subject to the requirement for label statement of ingredients prescribed for the corresponding kind of flour by §§ 137.105, 137.155, 137.160, 137.165, 137.175, 137.180, and 137.185, except that each such flour has been made by one of the optional procedures set forth in paragraph (b) of this section, and is thereby made readily pourable. Such flours will all pass through a No. 20 mesh U.S. standard sieve (840-micron opening), and not more than 20 percent will pass through a 200 mesh U.S standard sieve (74-micron opening).

* * * * *

23. Section 137.175 is amended by revising the introductory text to read as follows:

§ 137.175 Phosphated flour.

Phosphated flour, phosphated white flour, and phosphated wheat flour, conform to the definition and standard of identity, and are subject to the requirements for label declaration of ingredients, prescribed for flour by § 137.105, except that:

* * * * *

24. Section 137.180 is amended by revising paragraph (b) to read as follows:

§ 137.180 Self-rising flour.

* * * * *

(b) Label declaration. Each of the ingredients used in the food, shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

25. Section 137.185 is amended by revising the introductory text to read as follows:

§ 137.185 Enriched self-rising flour.

Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for self-rising flour by § 137.180, except that:

* * * * *

26. Section 137.200 is amended by revising paragraph (b)(1) to read as follows:

§ 137.200 Whole wheat flour.

* * * * *

(b)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

27. Section 137.205 is revised to read as follows:

§ 137.205 Bromated whole wheat flour.

Bromated whole wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for whole wheat flour by § 137.200, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.

28. Section 137.225 is revised to read as follows:

§ 137.225 Whole durum flour.

Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for whole wheat flour by § 137.200, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.

29. Section 137.235 is amended by adding new paragraph (c) to read as follows:

§ 137.235 Enriched corn grits.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

30. Section 137.260 is amended by adding new paragraph (c) to read as follows:

§ 137.260 Enriched corn meals.

* * * * *

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

31. Section 137.270 is amended by adding new paragraph (c) to read as follows:

§ 137.270 Self-rising white corn meal.

* * * * *

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

32. Section 137.305 is amended by revising paragraph (b)(1) to read as follows:

§ 137.305 Enriched farina.

* * * * *

(b)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

33. Section 137.350 is amended by adding new paragraph (g) to read as follows:

§ 137.350 Enriched rice.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 139—MACARONI AND NOODLE PRODUCTS

34. The authority citation for 21 CFR part 139 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

35. Section 139.110 is amended by adding new paragraph (g) to read as follows:

§ 139.110 Macaroni products.

* * * * *

(g) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

36. Section 139.115 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.115 Enriched macaroni products.

(a) Description: Enriched macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f), and (g), except that:

* * * * *

37. Section 139.117 is amended by revising paragraph (e) to read as follows:

§ 139.117 Enriched macaroni products with fortified protein.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

38. Section 139.120 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.120 Milk macaroni products.

(a) Milk macaroni products are the class of food, each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

39. Section 139.121 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.121 Nonfat milk macaroni products.

(a) Each of the macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), (f)(4), and (g), except that:

* * * * *

40. Section 139.122 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.122 Enriched nonfat milk macaroni products.

(a) Each of the enriched macaroni products made with nonfat milk for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), (f)(4), and (g), except that:

* * * * *

41. Section 139.125 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.125 Vegetable macaroni products.

(a) Vegetable macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

42. Section 139.135 is amended by revising paragraph (a) to read as follows:

§ 139.135 Enriched vegetable macaroni products.

(a) Each of the macaroni products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for macaroni products by § 139.110(a), (f), and (g), and in addition is enriched to meet the requirements prescribed for enriched macaroni products by § 139.115 and contains a vegetable ingredient in compliance with the requirements prescribed for vegetable macaroni products by § 139.125.

* * * * *

43. Section 139.138 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.138 Whole wheat macaroni products.

(a) Whole wheat macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

44. Section 139.140 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.140 Wheat and soy macaroni products.

(a) Wheat and soy macaroni products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients, prescribed for macaroni products by § 139.110(a), (f)(2), (f)(3), and (g), except that:

* * * * *

45. Section 139.150 is amended by adding new paragraph (i) o read as follows:

§ 139.150 Noodle products.

* * * * *

(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

46. Section 139.155 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 139.155 Enriched noodle products.

(a) Enriched noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for noodle products by § 139.150(a), (g), and (i), except that:

* * * * *

47. Section 139.160 is amended by revising paragraph (a) to read as follows:

§ 139.160 Vegetable noodle products.

(a) Vegetable noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for noodle products by § 139.150(a), (g), and (i), except that tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof are not less than 3 percent by weight of the finished vegetable noodle product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste).

* * * * *

48. Section 139.165 is amended by revising paragraph (a) to read as follows:

§ 139.165 Enriched vegetable noodle products.

(a) Each of the noodle products for which a definition and standard of identity is prescribed by this section conforms to the definition and standard of identity and is subject to the requirements for label declaration of ingredients prescribed for noodle products by § 139.150(a), (g), (h), and (i), and in addition is enriched to meet the requirements prescribed for enriched noodle products by § 139.155 and, except as hereinafter provided, contains a vegetable ingredient in compliance with the requirements prescribed for vegetable noodle products by § 139.160. Because they are apt to impart an egg-yolk color, carrots are not used in enriched vegetable noodle products.

* * * * *

49. Section 139.180 is amended by revising paragraph (a) to read as follows:

§ 139.180 Wheat and soy noodle products.

(a) Wheat and soy noodle products are the class of food each of which conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed for noodle products by § 139.150(a), (g), and (i), except that soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom).

* * * * *

PART 145—CANNED FRUITS

50. The authority citation for 21 CFR part 145 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

51. Section 145.110 is amended by revising paragraph (a)(4) to read as follows:

§ 145.110 Canned applesauce.

(a) * * *

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. However, when ascorbic acid (vitamin C) is added as provided for in paragraph (a)(2)(viii)(*b*) of this section, after the application of heat to the apples, preservative labeling requirements do not apply.

* * * * *

52. Section 145.115 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.115 Canned apricots.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

53. Section 145.116 is amended by revising paragraph (b)(2) to read as follows:

§ 145.116 Artificially sweetened canned apricots.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned apricots by § 145.115(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

54. Section 145.120 is amended by revising paragraph (a)(5)(iv) to read as follows:

§ 145.120 Canned berries.

(a) * * *

(5) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

55. Section 145.125 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.125 Canned cherries.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

56. Section 145.126 is amended by revising paragraph (b)(2) to read as follows:

§ 145.126 Artificially sweetened canned cherries.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned cherries by § 145.125(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

57. Section 145.130 is amended by revising paragraph (d)(4) to read as follows:

§ 145.130 Canned figs.

* * * * *

(d) * * *

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

58. Section 145.131 is amended by revising paragraph (b)(2) to read as follows:

§ 145.131 Artificially sweetened canned figs.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned figs by § 145.130. If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

59. Section 145.134 is amended by adding new paragraph (f) to read as follows:

§ 145.134 Canned preserved figs.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

60. Section 145.135 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.135 Canned fruit cocktail.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

61. Section 145.136 is amended by revising paragraph (b)(2) to read as follows:

§ 145.136 Artificially sweetened canned fruit cocktail.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned fruit cocktail by § 145.135(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

62. Section 145.140 is amended by revising paragraph (d)(4) to read as follows:

§ 145.140 Canned seedless grapes.

* * * * *

(d) * * *

(4) Label declaration Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

63. Section 145.145 is amended by revising paragraph (a)(4)(iii) to read as follows:

§ 145.145 Canned grapefruit.

(a) * * *

(4) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

64. Section 145.170 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.170 Canned peaches.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

65. Section 145.171 is amended by revising paragraph (b)(2) to read as follows:

§ 145.171 Artificially sweetened canned peaches.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned peaches by § 145.170(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

66. Section 145.175 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.175 Canned pears.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

67. Section 145.176 is amended by revising paragraph (b)(2) to read as follows:

§ 145.176 Artificially sweetened canned pears.

* * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned pears by § 145.175(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin". When any organic salt or acid or any mixture of two or more of these is added, the label shall bear the common or usual name of each such ingredient.

68. Section 145.180 is amended by revising paragraph (a)(5)(iii) to read as follows:

§ 145.180 Canned pineapple.

(a) * * *

(5) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

69. Section 145.181 is amended by revising paragraph (b)(2) to read as follows:

§ 145.181 Artificially sweetened canned pineapple.

* * * * *

(b) * * *

(2) The artificially sweetened food is subject to the requirements for label statement of ingredients used, as prescribed for canned pineapple by § 145.180(a). If the packing medium is thickened with pectin, the label shall bear the statement "thickened with pectin".

70. Section 145.185 is amended by revising paragraph (a)(4)(iv) to read as follows:

§ 145.185 Canned plums.

(a) * * *

(4) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

71. Section 145.190 is amended by revising paragraph (c)(4) to read as follows:

§ 145.190 Canned prunes.

* * * * *

(c) * * *

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the

applicable sections of parts 101 and 130 of this chapter.

PART 146—CANNED FRUIT JUICES

72. The authority citation for 21 CFR part 146 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

73. Section 146.113 is amended by adding new paragraph (h) to read as follows:

§ 146.113 Canned fruit nectars.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

74. Section 146.114 is amended by revising paragraph (a)(3)(ii) to read as follows:

§ 146.114 Lemon juice.

(a) * * *

(3) * * *

(ii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

75. Section 146.120 is amended by revising paragraph (c) to read as follows:

§ 146.120 Frozen concentrate for lemonade.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

76. Section 146.121 is amended by adding new paragraph (f) to read as follows:

§ 146.121 Frozen concentrate for artificially sweetened lemonade.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

77. Section 146.126 is amended by revising paragraph (c) to read as follows:

§ 146.126 Frozen concentrate for colored lemonade.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

78. Section 146.132 is amended by revising paragraphs (a)(3)(iii) to read as follows:

§ 146.132 Grapefruit juice.

(a) * * *

(3) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

79. Section 146.140 is amended by adding new paragraph (g) to read as follows:

§ 146.140 Pasteurized orange juice.

* * * * *

(g) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

80. Section 146.141 is amended by adding new paragraph (f) to read as follows:

§ 146.141 Canned orange juice.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

81. Section 146.145 is amended by adding new paragraph (f) to read as follows:

§ 146.145 Orange juice from concentrate.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

82. Section 146.146 is amended by adding new paragraph (g) to read as follows:

§ 146.146 Frozen concentrated orange juice.

* * * * *

(g) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

83. Section 146.148 is amended by revising paragraph (a) to read as follows:

§ 146.148 Reduced acid frozen concentrated orange juice.

(a) Reduced acid frozen concentrated orange juice is the food that complies with the requirements for composition and label declaration of ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it may not contain any added sweetening ingredient. A process involving the use of anionic ion-exchange resins permitted by § 173.25 of this chapter is used to reduce the acidity of the food so that the ratio of the Brix reading to the grams of acid, expressed as anhydrous citric acid, per 100 grams of juice is not less than 21 to 1 or more than 26 to 1.

* * * * *

84. Section 146.150 is amended by revising paragraph (a) to read as follows:

§ 146.150 Canned concentrated orange juice.

(a) Canned concentrated orange juice is the food that complies with the requirements of composition, definition of dilution ratio, and labeling of ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it is not frozen and it is sealed in containers and so processed by heat, either before or after sealing, so as to prevent spoilage.

* * * * *

85. Section 146.152 is amended by revising paragraph (d) to read as follows:

§ 146.152 Orange juice with preservative.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. In addition, the name of each preservative shall be proceeded by a statement of the percent by weight of the preservative used. If the food is packed in container sizes that are less than 19 liters (5 gallons), the label shall bear a statement indicating that the food is for further manufacturing use only.

* * * * *

86. Section 146.153 is amended by revising paragraph (a) to read as follows:

§ 146.153 Concentrated orange juice for manufacturing.

(a) Concentrated orange juice for manufacturing is the food that complies with the requirements of composition and label declaration of ingredients prescribed for frozen concentrated orange juice by § 146.146, except that it is either not frozen or is less concentrated, or both, and the oranges from which the juice is obtained may deviate from the standards for maturity in that they are below the minimum Brix and Brix-acid ratio for such oranges: *Provided*, however, that the concentration of orange juice soluble solids is not less than 20° Brix.

* * * * *

87. Section 146.154 is amended by revising paragraph (d) to read as follows:

§ 146.154 Concentrated orange juice with preservative.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. In addition, the name of each preservative shall be preceded by a statement of the percent by weight of the preservative used. If the food is packed in container sizes that are less than 19 liters (5 gallons), the label shall bear a statement indicating that the food is for further manufacturing use only.

* * * * *

88. Section 146.185 is amended by revising paragraph (a)(3) to read as follows:

§ 146.185 Pineapple juice.

(a) * * *

(3) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

89. Section 146.187 is amended by adding new paragraph (d) to read as follows:

§ 146.187 Canned prune juice.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 150—FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

90. The authority citation for 21 CFR part 150 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

91. Section 150.110 is amended by revising the introductory text of paragraph (e)(1) and by removing paragraph (e)(2)(ii) and reserving it, to read as follows:

§ 150.110 Fruit butter.

* * * * *

(e)(1) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

(2) * * *

(ii) [Reserved]

92. Section 150.140 is amended by revising the introductory text of paragraph (e)(2) to read as follows:

§ 150.140 Fruit jelly.

* * * * *

(e)(2) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

93. Section 150.141 is amended by adding new paragraph (h) to read as follows:

§ 150.141 Artificially sweetened fruit jelly.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

94. Section 150.160 is amended by revising the introductory text of paragraph (e)(2) to read as follows:

§ 150.160 Fruit preserves and jams.

* * * * *

(e) * * *

(2) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

95. Section 150.161 is amended by adding new paragraph (h) to read as follows:

§ 150.161 Artificially sweetened fruit preserves and jams.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 152—FRUIT PIES

96. The authority citation for 21 CFR part 152 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

97. Section 152.126 is amended by revising paragraph (a)(4)(i) to read as follows:

§ 152.126 Frozen cherry pie.

(a) * * *

(4)(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 155—CANNED VEGETABLES

98. The authority citation for 21 CFR part 155 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

99. Section 155.120 is amended by revising paragraph (a)(5) to read as follows:

§ 155.120 Canned green beans and canned wax beans.

(a) * * *

(5) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

100. Section 155.130 is amended by revising paragraph (a)(5) to read as follows:

§ 155.130 Canned corn.

(a) * * *

(5) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

101. Section 155.131 is amended by revising paragraph (a)(1) to read as follows:

§ 155.131 Canned field corn.

(a) *Identity.* (1) Canned field corn conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for canned corn by § 155.130(a), except that the corn ingredient consists of succulent field corn or a mixture of succulent field corn and succulent sweet corn.

* * * * *

102. Section 155.170 is amended by revising paragraph (a)(4) to read as follows:

§ 155.170 Canned peas.

(a) * * *

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

103. Section 155.172 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 155.172 Canned dry peas.

(a) *Identity.* Canned dry peas conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for canned peas by § 155.170(a), except that:

* * * * *

104. Section 155.191 is amended by revising paragraph (a)(3)(iv) to read as follows:

§ 155.191 Tomato concentrates.

(a) * * *

(3) * * *

(iv) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

105. Section 155.194 is amended by revising paragraph (a)(3)(iii) to read as follows:

§ 155.194 Catsup.

(a) * * *

(3) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter; except that the name "tomato concentrate" may be used in lieu of the names "tomato puree," "tomato pulp," or "tomato paste" and when tomato concentrates are used, the labeling requirements of § 155.191(a)(3)(ii)(*a*) and (a)(3)(ii)(*b*) do not apply.

* * * * *

106. Section 155.200 is amended by revising paragraph (h) to read as follows:

§ 155.200 Certain other canned vegetables.

* * * * *

(h) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

107. Section 155.201 is amended by revising paragraph (a)(4)(ii) to read as follows:

§ 155.201 Canned mushrooms.

(a) * * *

(4) * * *

(ii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 156—VEGETABLE JUICES

108. The authority citation for 21 CFR part 156 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371).

109. Section 156.145 is amended by revising paragraph (a)(2)(ii) to read as follows:

§ 156.145 Tomato juice.

(a) * * *

(2) * * *

(ii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 158—FROZEN VEGETABLES

110. The authority citation for 21 CFR part 158 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371).

111. Section 158.170 is amended by revising paragraph (a)(4) to read as follows:

§ 158.170 Frozen peas.

(a) * * *

(4) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 160—EGGS AND EGG PRODUCTS

112. The authority citation for 21 CFR part 160 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

113. Section 160.105 is amended by adding new paragraph (e) to read as follows:

§ 160.105 Dried eggs.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

114. Section 160.110 is amended by adding new paragraph (d) to read as follows:

§ 160.110 Frozen eggs.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

115. Section 160.115 is amended by redesignating the existing text as paragraph (a) and by adding new paragraph (b) to read as follows:

§ 160.115 Liquid eggs.

* * * * *

(b) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

116. Section 160.140 is amended by adding new paragraph (c) to read as follows:

§ 160.140 Egg whites.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

117. Section 160.145 is amended by adding new paragraph (f) to read as follows:

§ 160.145 Dried egg whites.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

118. Section 160.150 is amended by adding new paragraph (c) to read as follows:

§ 160.150 Frozen egg whites.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

119. Section 160.180 is amended by redesignating the existing text as paragraph (a) and by adding new paragraph (b) to read as follows:

§ 160.180 Egg yolks.

* * * * *

(b) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

120. Section 160.185 is amended by adding new paragraph (e) to read as follows:

§ 160.185 Dried egg yolks.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be

declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

121. Section 160.190 is amended by redesignating the existing text as paragraph (a) and by adding new paragraph (b) to read as follows:

§ 160.190 Frozen egg yolks.

* * * * *

(b) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 161—FISH AND SHELLFISH

122. The authority citation for 21 CFR part 161 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

123. Section 161.145 is amended by adding new paragraph (a)(4) to read as follows:

§ 161.145 Canned oysters.

(a) * * *

(4) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

124. Section 161.170 is amended by revising paragraph (a)(5)(iii) to read as follows:

§ 161.170 Canned Pacific salmon.

(a) * * *

(5) * * *

(iii) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

125. Section 161.173 is amended by revising paragraph (a)(5)(ix) to read as follows:

§ 161.173 Canned wet pack shrimp in transparent or nontransparent containers.

(a) * * *

(5) * * *

(ix) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

126. Section 161.175 is amended by adding new paragraph (i) to read as follows:

§ 161.175 Frozen raw breaded shrimp.

* * * * *

(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

127. Section 161.190 is amended by revising paragraphs (a)(6)(ii) through (a)(6)(viii), by removing paragraph (a)(6)(ix), and by revising paragraph (a)(8)(vi) to read as follows:

§ 161.190 Canned tuna.

(a) * * *

(6) * * *

(ii) Monosodium glutamate.

(iii) Hydrolyzed protein declared in accordance with the applicable provisions of § 101.22.

(iv) Spices or spice oils or spice extracts.

(v) Vegetable broth in an amount not in excess of 5 percent of the volume capacity of the container, such broth to consist of a minimum of 0.5 percent by weight of vegetable extractives and to be prepared from two or more of the following vegetables: Beans, cabbage, carrots, celery, garlic, onions, parsley, peas, potatoes, green bell peppers, red bell peppers, spinach, and tomatoes.

(vi) Garlic.

(vii) Lemon flavoring to be prepared from lemon oil and citric acid together with safe and suitable carriers for the lemon oil which are present at nonfunctional and insignificant levels in the finished canned food. When lemon flavoring is added, a safe and suitable solubilizing and dispersing ingredient may be added in a quantity not exceeding 0.005 percent by weight of the finished food. A substance used in accordance with this paragraph is deemed to be suitable if it is used in an amount no greater than necessary to achieve the intended flavor effect, and is deemed to be safe if it is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if it is a food additive as so defined, it is used in conformity with regulations established pursuant to section 409 of the act.

(viii) Edible vegetable oil or partially hydrogenated vegetable oil, excluding olive oil, used alone or in combination in an amount not to exceed 5 percent of the volume capacity of the container, with or without any suitable form of emulsifying and suspending ingredients that has been affirmed as GRAS or approved as a food additive to aid in dispersion of the oil, as seasoning in canned tuna packed in water.

* * * * *

(8) * * *

(vi) Where the canned tuna contains one or more of the ingredients provided for in paragraph (a)(6) of this section, the label shall bear the statement "Seasoned with ————————", the blank being filled in with the name or names of the ingredient or ingredients used, except that if the ingredient designated in paragraph (a)(6)(v) of this section is used, the blank shall be filled in with the term "vegetable broth", and if the ingredients designated in paragraph (a)(6)(viii) of this section are used, the blank may be filled in with the term "oil", and if the ingredient designated in paragraph (a)(6)(iv) of this section is used alone, the label may alternatively bear either the statement "spiced" or the statement "with added spice"; and if salt is the only seasoning ingredient used, the label may alternatively bear any of the statements "salted", "with added salt", or "salt added". If the flavoring ingredients designated in paragraph (a)(6)(vii) of this section are used, the words "lemon flavored" or "with lemon flavoring" shall appear as part of the name on the label; for example, "lemon flavored chunk light tuna". Citric acid and any optional solubilizing and dispersing agent used as specified in paragraph (a)(6)(vii) of this section in connection with lemon flavoring ingredients or emulsifying and suspending ingredients used as specified in paragraph (a)(6)(viii) of this section shall be designated on the label by their common or usual name.

* * * * *

PART 163—CACAO PRODUCTS

128. The authority citation for 21 CFR part 163 continues to read as follows:

Authority: Secs. 201, 301, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 341, 343, 348, 371, 376).

129. Section 163.110 is amended by adding new paragraph (c) to read as follows:

§ 163.110 Cacao nibs.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

130. Section 163.111 is amended by adding new paragraph (c) to read as follows:

§ 163.111 Chocolate liquor.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

131. Section 163.112 is amended by adding new paragraph (c) to read as follows:

§ 163.112 Breakfast cocoa.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

132. Section 163.113 is revised to read as follows:

§ 163.113 Cocoa.

Cocoa, medium fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for breakfast cocoa by § 163.112, except that it contains less than 22 percent but not less than 10 percent of cacao fat as determined by the method referred to in § 163.112(a).

133. Section 163.114 is revised to read as follows:

§ 163.114 Lowfat cocoa.

Lowfat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients for breakfast cocoa in § 163.112, except that the cacao fat content is less than 10 percent by weight, as determined by the method prescribed in § 163.112(a).

134. Section 163.117 is amended by revising paragraph (a) to read as follows:

§ 163.117 Cocoa with dioctyl sodium sulfosuccinate for manufacturing.

(a) Description. Cocoa with dioctyl sodium sulfosuccinate for manufacturing is the food additive complying with the provisions in § 172.520 of this chapter. It conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, for breakfast cocoa in § 163.112, or for cocoa in § 163.113, or for lowfat cocoa in § 163.114, except that the food additive contains dioctyl sodium sulfosuccinate (complying with the requirements of § 172.810 of this chapter, including the limit of not more than 0.4 percent by weight of the finished food additive).

* * * * *

135. Section 163.123 is amended by adding new paragraph (i) to read as follows:

§ 163.123 Sweet chocolate.

* * * * *

(i) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

136. Section 163.130 is amended by adding new paragraph (f) to read as follows:

§ 163.130 Milk chocolate.

* * * * *

(f) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

137. Section 163.135 is amended by adding new paragraph (c) to read as follows:

§ 163.135 Buttermilk chocolate.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

138. Section 163.140 is amended by adding new paragraph (c) to read as follows:

§ 163.140 Skim milk chocolate.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

139. Section 163.145 is amended by adding new paragraph (c) to read as follows:

§ 163.145 Mixed dairy product chocolates.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

140. Section 163.150 is amended by adding new paragraph (d) to read as follows:

§ 163.150 Sweet cocoa and vegetable fat (other than cacao fat) coating.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

141. Section 163.153 is amended by adding new paragraph (c) to read as follows:

§ 163.153 Sweet chocolate and vegetable fat (other than cacao fat) coating.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

142. Section 163.155 is amended by adding new paragraph (c) to read as follows:

§ 163.155 Milk chocolate and vegetable fat (other than cacao fat) coating.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by applicable sections of parts 101 and 130 of this chapter.

PART 164—TREE NUT AND PEANUT PRODUCTS

143. The authority citation for 21 CFR part 164 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

144. Section 164.110 is amended by revising the introductory text of paragraph (e), by removing paragraphs (e)(3) and (e)(4), and by revising paragraph (f) to read as follows:

§ 164.110 Mixed nuts.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

(f) The words and statements specified in paragraph (e) of this section showing the ingredients present shall be listed on the principal display panel or panels or any appropriate information panel without obscuring design, vignettes, or crowding. The declaration shall appear in conspicuous and easily legible letters of boldface print or type the size of which shall be not less than one-half of that required by part 101 of this chapter for the statement of net quantity of contents appearing on the label, but in no case less than one-sixteenth of an inch in height. The entire ingredient statement shall appear on at least one panel of the label. If the label bears any pictorial representation of the mixture of nuts, it shall depict the relative proportions of the nut ingredients of the food. If the label bears a pictorial representation of only one of each nut ingredient present, the nuts shall be depicted in the order of decreasing predominance by weight. A factual statement that the food does not contain a particular nut ingredient or ingredients may be shown on the label if the statement is not misleading and does not result in an insufficiency of label space for the proper declaration of information required by or under

authority of the act to appear on the label.

145. Section 164.150 is amended by revising paragraph (e) to read as follows:

§ 164.150 Peanut butter.

* * * * *

(e) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 166—MARGARINE

146. The authority citation for 21 CFR part 166 continues to read as follows:

Authority: Secs. 201, 401, 403, 407, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 347, 348, 371, 376).

147. Section 166.110 is amended by revising paragraph (d) to read as follows:

§ 166.110 Margarine.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter. For the purposes of this section the use of the term "milk" unqualified means milk from cows. If any milk other than cow's milk is used in whole or in part, the animal source shall be identified in conjunction with the word milk in the ingredient statement. Colored margarine shall be subject to the provisions of section 407 of the Federal Food, Drug, and Cosmetic Act as amended.

PART 168—SWEETENERS AND TABLE SIRUPS

148. The authority citation for 21 CFR part 168 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

149. Section 168.110 is amended by revising paragraph (b) to read as follows:

§ 168.110 Dextrose anhydrous.

* * * * *

(b) The name of the food is "Dextrose anhydrous" or "Anhydrous dextrose" or alternatively, "———— sugar anhydrous" or "Anhydrous sugar", with the blank to be filled with the name of the food source, for example, "Corn sugar anhydrous".

150. Section 168.111 is amended by revising paragraph (c) to read as follows:

§ 168.111 Dextrose monohydrate.

* * * * *

(c) The name of the food is "Dextrose monohydrate" or "Dextrose" or alternatively, "———— sugar monohydrate" or "———— sugar", with the blank to be filled with the name of the food source, for example, "Corn sugar monohydrate" or "Corn sugar".

* * * * *

151. Section 168.130 is amended by revising paragraph (d) to read as follows:

§ 168.130 Cane sirup.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

152. Section 168.160 is amended by revising paragraph (d) to read as follows:

§ 168.160 Sorghum sirup.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

153. Section 168.180 is amended by revising paragraph (d)(1) to read as follows:

§ 168.180 Table sirup.

* * * * *

(d)(1) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

* * * * *

PART 169—FOOD DRESSINGS AND FLAVORINGS

154. The authority citation for 21 CFR part 169 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

155. Section 169.115 is amended by revising paragraph (e) to read as follows:

§ 169.115 French dressing.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

156. Section 169.140 is amended by revising paragraph (f) to read as follows:

§ 169.140 Mayonnaise.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

157. Section 169.150 is amended by revising paragraph (g) to read as follows:

§ 169.150 Salad dressing.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

158. Section 169.175 is amended by adding new paragraph (c) to read as follows:

§ 169.175 Vanilla extract.

* * * * *

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

159. Section 169.176 is amended by revising paragraph (a) to read as follows:

§ 169.176 Concentrated vanilla extract.

(a) Concentrated vanilla extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by § 169.175, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in § 169.3(c). The content of ethyl alcohol is not less than 35 percent by volume.

* * * * *

160. Section 169.177 is amended by revising paragraph (a) to read as follows:

§ 169.177 Vanilla flavoring.

(a) Vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by § 169.175, except that its content of ethyl alcohol is less than 35 percent by volume.

* * * * *

161. Section 169.178 is amended by revising paragraph (a) to read as follows:

§ 169.178 Concentrated vanilla flavoring.

(a) Concentrated vanilla flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla flavoring by § 169.177, except that it is concentrated to remove part of the solvent, and each gallon contains two or more units of vanilla constituent as defined in § 169.3(c).

* * * * *

162. Section 169.179 is amended by adding new paragraph (d) to read as follows:

§ 169.179 Vanilla powder.

* * * * *

(d) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

163. Section 169.180 is amended by revising paragraph (a) to read as follows:

§ 169.180 Vanilla-vanillin extract.

(a) Vanilla-vanillin extract conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla extract by § 169.175, except that for each unit of vanilla constituent, as defined in § 169.3(c), contained therein, the article also contains not more than 1 ounce of added vanillin.

* * * * *

164. Section 169.181 is amended by revising paragraph (a) to read as follows:

§ 169.181 Vanilla-vanillin flavoring.

(a) Vanilla-vanillin flavoring conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla-vanillin extract by § 169.180, except that its content of ethyl alcohol is less than 35 percent by volume.

* * * * *

165. Section 169.182 is amended by revising paragraph (a) to read as follows:

§ 169.182 Vanilla-vanillin powder.

(a) Vanilla-vanillin powder conforms to the definition and standard of identity and is subject to any requirement for label statement of ingredients prescribed for vanilla powder by § 169.179, except that for each unit of vanilla constituent as defined in § 169.3(c) contained therein, the article also contains not more than 1 ounce of added vanillin.

* * * * *

Dated: October 22, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 131, 133, 135, and 168

[Docket No. 90N-361D]

RIN 0905-AD06

Food Labeling; Declaration of Ingredients for Dairy Products and Maple Sirup

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA), in accordance with the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) (the 1990 amendments) is amending the U.S. standards of identity for dairy products (parts 131, 133, and 135 (21 CFR parts 131, 133, and 135)) and maple sirup (21 CFR 168.140) to require the listing of the common or usual names of all ingredients in these standardized foods.

Section 701(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)), as amended by the 1990 amendments, requires formal rulemaking for the amendment or repeal of standards of identity for dairy products and maple sirup. The 1990 amendments removed food standards rulemaking for all other foods from the coverage of section 701(e) of the act. Because of the procedural differences between amending the standards for dairy products and maple sirup and amending other food standards, the agency is publishing two separate final rules amending food standards. This final rule on dairy products and maple sirup is issued under formal rulemaking procedures. A companion document for other foods is published elsewhere in this issue of the **Federal Register**.

DATES: Effective May 8, 1993, except as to any provisions that may be stayed by the filing of proper objections; compliance may begin January 6, 1993, written objections and requests for a hearing by February 5, 1993.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5106.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 21, 1991 (56 FR 28592), FDA published a proposed rule concerning the declaration of ingredients (hereinafter referred to as the June 21, 1991, proposal) and solicited public comment on ingredient labeling issues. The June 21, 1991, proposal addressed several current requirements that bear on ingredient labeling. Most significantly, section 403(i) of the act (21 U.S.C. 343(i)) requires, with certain specific exceptions, that ingredients be listed by their common or usual names on food labels. Before the 1990 amendments, the act provided FDA with authority under section 403(g) of the act to require the declaration of optional ingredients in standardized foods, but mandatory ingredients were exempt from such a requirement under section 403(i) of the act. In the absence of statutory authority, FDA could not require the complete listing of all ingredients in standardized foods. However, the 1990 amendments removed the portion of section 403(i) of the act that excluded mandatory ingredients used in standardized foods from the requirement for label declaration.

In the June 21, 1991, proposal, the agency proposed revisions of § 101.4(a)(1) and (b)(2)(i) (21 CFR 101.4(a)(1) and (b)(2)(i)) and proposed to adopt new § 130.3(e) (21 CFR 130.3(e)) to implement the new ingredient listing requirements for standardized foods prescribed by amended section 403(i) of the act. Proposed § 130.3(e) provides that all mandatory and optional ingredients of standardized foods must appear on food labels in accordance with the requirements of part 101 (21 CFR part 101), except where a definition and standard of identity contains a specific provision with respect to the declaration of optional ingredients. In addition, the agency proposed to amend specific standards of identity either by changing the existing language for label declaration of ingredients or by adding a new paragraph, to require that all ingredients be declared on the label in accordance with the applicable sections of parts 101 and 130 (21 CFR part 130).

The agency notes that several standards of identity define foods by cross-referencing other standardized foods. For example, § 133.114 *Cheddar cheese for manufacturing* describes a food that, with certain exceptions, "conforms to the definition and standard of identity prescribed for cheddar cheese by § 133.113." Similar language is contained in §§ 133.109, 133.119, 133.137, 133.145, 133.157, 133.161, and 133.196. FDA advises that conformance with a cross-referenced definition and standard of identity includes compliance with the labeling provisions in the referenced standard. Thus, except where existing standards contained language contrary to the ingredient labeling requirements prescribed by amended section 403(i) of the act, it was not necessary for the June 21, 1991, proposal to change the wording of standards of identity that define foods by cross-reference. These standards are being amended by modifying the standards they cross-reference.

The 1990 amendments removed food standards rulemakings, except for actions for the amendment or repeal of food standards for dairy products or maple sirup, from the coverage of section 701(e) of the act. Section 701(e) of the act establishes formal rulemaking procedures that must be followed for the issuance, amendment, or repeal of regulations under certain sections of the act. Under formal rulemaking procedures, there is an opportunity to object to any final rule and to request a public hearing upon such objection. Such an opportunity is not provided as part of the notice and comment rulemaking procedures followed by the agency under section 701(a) of the act.

Because of the procedural differences between amending the standards for dairy products and maple sirup and amending other food standards, the agency is publishing two separate final rules. This final rule, issued under formal rulemaking procedures, amends the requirements for label declaration of ingredients in the standards of identity for dairy products (parts 131, 133, and 135) and for maple sirup (§ 168.140). A companion document amending declaration of ingredient regulations in part 101, establishing ingredient labeling requirements in part 102 (21 CFR part 102) and part 130 for nonstandardized and standardized foods, respectively, and amending the labeling requirements for standardized foods under the provisions of section 701(a) of the act appears elsewhere in this issue of the **Federal Register**. In addition, elsewhere in this issue of the **Federal Register**, FDA is publishing a proposal on other ingredient labeling issues that arose from the June 21, 1991, proposal.

The 1990 amendments gave the Secretary the authority to extend the applicability of certain of its provisions. However, the provision of the amendments that established a requirement that all ingredients in standardized foods be listed on the label is not among those provisions for which

an extension is permitted. Thus, this new labeling requirement is effective May 8, 1993.

II. Comments and Agency Response

In response to the June 21, 1991, proposal, the agency received over 700 letters containing one or more comments from a wide range of sources, including consumers, consumer organizations, professional associations, government agencies, industry, and industry trade associations. None of the comments specifically addressed ingredient labeling of maple sirup or dairy products. In addition, many comments were not relevant to these foods. However, a few of the comments, and of the agency's conclusions on the issues raised by the comments, bear generally on dairy product and maple sirup standards. A summary of comments and the agency's responses follow. The comments are discussed in more detail in the companion document on declaration of ingredients published elsewhere in this issue of the **Federal Register**.

A. Declaration of Mandatory Ingredients in Standardized Foods

The majority of comments from consumers and the food industry generally supported the declaration of mandatory as well as optional ingredients in foods in the ingredient list. In support of their position, consumers asserted that they had a right, and in many cases a need, to know the identity of all of the ingredients in the food they consume. Moreover, some comments expressed the belief that the average consumer has no idea of what mandatory ingredients go into a standardized food and, therefore, is unable to make informed decisions.

The agency agrees with these comments. FDA is amending its ingredient labeling regulations to require that all mandatory and optional ingredients of standardized foods appear on food labels in accordance with the requirements of part 101, except where a definition and standard of identity contains a specific provision with respect to the declaration of optional ingredients. In such instances, certain ingredients may be declared in accordance with that provision. Accordingly, FDA is codifying this requirement, as proposed, in new § 130.3(e). (New § 130.3(e) is being issued as part of the general final rule on declaration of ingredients, published elsewhere in this issue of the **Federal Register**.) The exceptions for certain ingredients in specified standards of identity permit continued use of alternatives to the labeling requirements of part 101 where compliance with those requirements would be impracticable.

In the June 21, 1991, proposal, the agency proposed revisions of § 101.4(a)(1) and (b)(2)(i) to reflect the new ingredient listing requirements in amended section 403(i) of the act. The proposed revisions clarify that: (1) All standardized foods must comply with § 101.4, rather than only those foods specifically required to do so by the standards; and (2) a standardized food is subject to the same treatment as any other food, except that, where the food is subject to a standard that makes specific provisions for the labeling of optional ingredients, the optional ingredients may be declared in accordance with those provisions. The agency did not receive any comments objecting to these changes. Therefore, FDA is finalizing these revisions as proposed. (New § 101.4(a)(1) and (b)(2)(i) are being issued as part of the general final rule on declaration of ingredients, published elsewhere in this issue of the **Federal Register**.)

The agency is also amending the dairy product and maple sirup standards of identity, as proposed, to require that all ingredients be declared on the label in accordance with the applicable sections of parts 101 and 130. Many of the standards already provide for declaration of all optional ingredients used in accordance with the applicable sections of part 101, and the wording in these standards has been amended to require the declaration of all ingredients. Where there is no existing provision for ingredient labeling, FDA has added a paragraph to the standard to include the new labeling provisions.

As proposed, FDA is retaining a number of existing optional ingredient listing provisions in the dairy standards that permit collective terms to be used rather than specific ingredient names where similar provisions are not present in part 101. Thus, the agency is retaining the provisions for listing the term "enzymes" rather than the specific name of the enzyme and the terms "milkfat and nonfat milk" or "nonfat milk and milkfat" for dairy ingredients in standards such as § § 133.106 *Blue cheese*, 133.133 *Cream cheese*, and 133.164 *Nuworld cheese*.

B. Labeling Exemptions

As discussed in the June 21, 1991, proposal (56 FR 28592 at 28593), part 101 provides for a number of labeling exemptions. The agency does not believe that these exemptions need to be duplicated in individual standards. For instance, several of the dairy standards in part 133 contain exemptions that provide for the declaration of the use of bacterial cultures on the label by the word "cultured" followed by the name of the substrate, e.g., "cultured cream" or "made from cultured skim milk." Other cheese standards provide for the use of terms such as "cream" for plastic cream and dried cream, "milk" for concentrated milk and dried milk, "skim milk" for concentrated skim milk and nonfat dry milk, and "whey" for cheese whey, concentrated cheese whey, and dried cheese whey. Section 101.4(b) currently provides for these labeling exemptions, and FDA concludes that the language does not need to be repeated in each standard of identity. To do so would only add needlessly repetitive language to the standards. In proposing to update the language of the standards in part 133 to require the listing of the common or usual name of all ingredients, these provisions were deleted from several of the proposed standards. There were no objections to this change. Accordingly, FDA is deleting these provisions as proposed.

III. Economic Impact

In accordance with the Regulatory Flexibility Act (Pub. L. 96–354) (5 U.S.C. 601), FDA has reviewed the final rule to amend the standards of identity for dairy products and maple sirup to determine its impact on small entities, including small businesses. The amendments will require label declaration of ingredients used in these foods in accordance with the ingredient labeling requirements of parts 101 and 130. FDA has determined that because the effect of the amendments is to require declaration of mandatory ingredients primarily (as most optional ingredients are already required to be declared on labels), and because most manufacturers already declare all ingredients on labels of these products, this action will not result in a significant impact on a substantial number of small entities. FDA has not received any new information or comments that would alter this determination. Therefore, in accordance with section 605(b) of the Regulatory Flexibility Act, FDA certifies that no significant impact on a substantial number of small entities will derive from this action.

In accordance with Executive Order 12291, FDA has carefully analyzed the economic effects of this final rule, and the agency has determined that the rule, if promulgated, will not be a major rule as defined by that order.

IV. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 5, 1993, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

List of Subjects

21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

21 CFR Part 133

Cheese, Food grades and standards, Food labeling.

21 CFR Part 135

Food grades and standards, Food labeling, Frozen foods, Ice cream.

21 CFR Part 168

Food grades and standards, Sugar.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 131, 133, 135, and 168 are amended as follows:

PART 131—MILK AND CREAM

1. The authority citation for 21 CFR part 131 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

2. Section 131.110 is amended by revising paragraph (f) to read as follows:

§ 131.110 Milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

3. Section 131.111 is amended by revising paragraph (h) to read as follows:

§ 131.111 Acidified milk.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

4. Section 131.112 is amended by revising paragraph (g) to read as follows:

§ 131.112 Cultured milk.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

5. Section 131.115 is amended by revising paragraph (f) to read as follows:

§ 131.115 Concentrated milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

6. Section 131.120 is amended by revising paragraph (e) to read as follows:

§ 131.120 Sweetened condensed milk.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

7. Section 131.122 is amended by revising paragraph (e) to read as follows:

§ 131.122 Sweetened condensed skimmed milk.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

8. Section 131.123 is amended by revising paragraph (f) to read as follows:

§ 131.123 Lowfat dry milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

9. Section 131.125 is amended by revising paragraph (e) to read as follows:

§ 131.125 Nonfat dry milk.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

10. Section 131.127 is amended by revising paragraph (f) to read as follows:

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

11. Section 131.130 is amended by revising paragraph (f) to read as follows:

§ 131.130 Evaporated milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

12. Section 131.132 is amended by revising paragraph (f) to read as follows:

§ 131.132 Evaporated skimmed milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

13. Section 131.135 is amended by revising paragraph (f) to read as follows:

§ 131.135 Lowfat milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

14. Section 131.136 is amended by revising paragraph (h) to read as follows:

§ 131.136 Acidified lowfat milk.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

15. Section 131.138 is amended by revising paragraph (g) to read as follows:

§ 131.138 Cultured lowfat milk.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

16. Section 131.143 is amended by revising paragraph (f) to read as follows:

§ 131.143 Skim milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

17. Section 131.144 is amended by revising paragraph (h) to read as follows:

§ 131.144 Acidified skim milk.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

18. Section 131.146 is amended by revising paragraph (g) to read as follows:

§ 131.146 Cultured skim milk.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

19. Section 131.147 is amended by revising paragraph (f) to read as follows:

§ 131.147 Dry whole milk.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

20. Section 131.149 is amended by revising paragraph (e) to read as follows:

§ 131.149 Dry cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

21. Section 131.150 is amended by revising paragraph (e) to read as follows:

§ 131.150 Heavy cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

22. Section 131.155 is amended by revising paragraph (e) to read as follows:

§ 131.155 Light cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

23. Section 131.157 is amended by revising paragraph (e) to read as follows:

§ 131.157 Light whipping cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

24. Section 131.160 is amended by revising paragraph (e) to read as follows:

§ 131.160 Sour cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

25. Section 131.162 is amended by revising paragraph (e) to read as follows:

§ 131.162 Acidified sour cream.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

26. Section 131.170 is amended by revising paragraph (h) to read as follows:

§ 131.170 Eggnog.

* * * * *

(h) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

27. Section 131.180 is amended by revising paragraph (e) to read as follows:

§ 131.180 Half-and-half.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

28. Section 131.185 is amended by revising paragraph (e) to read as follows:

§ 131.185 Sour half-and-half.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

29. Section 131.187 is amended by revising paragraph (e) to read as follows:

§ 131.187 Acidified sour half-and-half.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

30. Section 131.200 is amended by revising paragraph (g) to read as follows:

§ 131.200 Yogurt.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

31. Section 131.203 is amended by revising paragraph (g) to read as follows:

§ 131.203 Lowfat yogurt.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

32. Section 131.206 is amended by revising paragraph (g) to read as follows:

§ 131.206 Nonfat yogurt.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

33. The authority citation for 21 CFR part 133 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

34. Section 133.102 is amended by revising paragraph (e) to read as follows:

§ 133.102 Asiago fresh and asiago soft cheese.

* * * * *

(e) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

35. Section 133.103 is revised to read as follows:

§ 133.103 Asiago medium cheese.

Asiago medium cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 35 percent moisture, its solids contain not less than 45 percent of milkfat, and it is cured for not less than 6 months.

36. Section 133.104 is revised to read as follows:

§ 133.104 Asiago old cheese.

Asiago old cheese conforms to the definition and standard of identity and is subject to the requirements for label statement of ingredients prescribed by § 133.102 for asiago fresh cheese, except that it contains not more than 32 percent moisture, its solids contain not less than 42 percent of milk fat, and it is cured for not less than 1 year.

37. Section 133.106 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.106 Blue cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

38. Section 133.108 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.108 Brick cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that.

* * * * *

39. Section 133.111 is amended by revising paragraph (f) to read as follows:

§ 133.111 Caciocavallo siciliano cheese.

* * * * *

(f) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

40. Section 133.113 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.113 Cheddar cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

41. Section 133.118 is amended by adding new paragraph (f) to read as follows:

§ 133.118 Colby cheese.

* * * * *

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

42. Section 133.121 is amended by revising the introductory text to read as follows:

§ 133.121 Low sodium colby cheese.

Low sodium colby cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.118 for colby cheese and complies with all the provisions of § 133.118, including the requirements for label statement of ingredients, except that:

* * * * *

43. Section 133.123 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.123 Cold-pack and club cheese.

* * * * *

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, may be designated as "American cheese".

* * * * *

44. Section 133.124 is amended by revising paragraph (h) to read as follows:

§ 133.124 Cold-pack cheese food.

* * * * *

(h) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these, may be designated as "American cheese".

45. Section 133.125 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.125 Cold-pack cheese food with fruits, vegetables, or meats.

(a) Cold-pack cheese food with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label declaration of ingredients, prescribed for cold pack cheese food by § 133.124, except that:

* * * * *

46. Section 133.127 is amended by revising paragraph (d) to read as follows:

§ 133.127 Cook cheese, koch kase.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

47. Section 133.128 is amended by revising paragraph (e) to read as follows:

§ 133.128 Cottage cheese.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that milk-clotting enzymes may be declared by the word "enzymes"

48. Section 133.129 is amended by revising paragraph (e) to read as follows:

§ 133.129 Dry curd cottage cheese.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that milk-clotting enzymes may be declared by the word "enzymes"

49. Section 133.131 is amended by revising the introductory text to read as follows:

§ 133.131 Lowfat cottage cheese.

Lowfat cottage cheese is the food prepared from the same ingredients and in the same manner prescribed in § 133.128 for cottage cheese and complies with all the provisions of § 133.128 (including requirements for the label statement of ingredients), except that:

* * * * *

50. Section 133.133 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.133 Cream cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be

declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

51 Section 133.134 is amended by revising the introductory text paragraph (d) to read as follows:

§ 133.134 Cream cheese with other foods.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

52. Section 133.136 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.136 Washed curd and soaked curd cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

53. Section 133.138 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.138 Edam cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

54. Section 133.140 is amended by revising paragraph (c) to read as follows:

§ 133.140 Gammelost cheese.

* * * * *

(c) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

55. Section 133.141 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.141 Gorgonzola cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

56. Section 133.144 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.144 Granular and stirred curd cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

57. Section 133.146 is amended by revising the introductory text of paragraph (e) to read as follows:

§ 133.146 Grated cheeses.

* * * * *

(e) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

58. Section 133.147 is amended by revising paragraph (e) to read as follows:

§ 133.147 Grated American cheese food.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated "American cheese".

59. Section 133.148 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.148 Hard grating cheeses.

* * * * *

(f) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

60. Section 133.149 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.149 Gruyere cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

61. Section 133.150 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.150 Hard cheeses.

* * * * *

(f) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

62. Section 133.152 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.152 Limburger cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

63. Section 133.153 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.153 Monterey cheese and monterey jack cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

64. Section 133.154 is revised to read as follows:

§ 133.154 High-moisture jack cheese.

High-moisture jack cheese conforms to the definition and standard of identity and is subject to the requirement for label statement of ingredients prescribed for monterey cheese by § 133.153, except that its moisture content is more than 44 percent but less than 50 percent.

65. Section 133.155 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.155 Mozzarella cheese and scamorza cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

66. Section 133.156 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.156 Low-moisture mozzarella and scamorza cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

67. Section 133.158 is revised to read as follows:

§ 133.158 Low-moisture part-skim mozzarella and scamorza cheese.

Low-moisture part-skim mozzarella cheese and low-moisture part-skim scamorza cheese conform to the definition and standard of identity and comply with the requirements for label declaration of ingredients prescribed for low-moisture mozzarella cheese and low-moisture scamorza cheese by § 133.156, except that their milkfat content, calculated on the solids basis, is less than 45 percent but not less than 30 percent.

68. Section 133.160 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.160 Muenster and munster cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

69. Section 133.162 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.162 Neufchatel cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

70. Section 133.164 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.164 Nuworld cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

71. Section 133.165 is amended by revising paragraph (e) to read as follows:

§ 133.165 Parmesan and reggiano cheese.

* * * * *

(e) Label declaration: Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that enzymes of animal, plant, or microbial origin may be declared as "enzymes".

72. Section 133.167 is amended by revising the introductory text to read as follows:

§ 133.167 Pasteurized blended cheese.

Pasteurized blended cheese conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese by § 133.169, except that:

* * * * *

73. Section 133.168 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.168 Pasteurized blended cheese with fruits, vegetables, or meats.

(a) Pasteurized blended cheese with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized blended cheese by § 133.167, except that:

* * * * *

74. Section 133.169 is amended by revising paragraph (g) to read as follows:

§ 133.169 Pasteurized process cheese.

* * * * *

(g) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as "American cheese".

75. Section 133.170 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.170 Pasteurized process cheese with fruits, vegetables, or meats.

(a) Unless a definition and standard of identity specifically applicable is established by another section of this part, a pasteurized process cheese with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese by § 133.169, except that:

* * * * *

76. Section 133.171 is amended by removing paragraph (f) and revising the introductory text to read as follows:

§ 133.171 Pasteurized process pimento cheese.

Pasteurized process pimento cheese is the food which conforms to the definition and standard of identity for pasteurized process cheese with fruits, vegetables, or meats, and is subject to the requirement for label statement of ingredients, except that:

* * * * *

77. Section 133.173 is amended by revising paragraph (h) to read as follows:

§ 133.173 Pasteurized process cheese food.

* * * * *

(h) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as "American cheese".

78. Section 133.174 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.174 Pasteurized process cheese food with fruits, vegetables, or meats.

(a) Pasteurized process cheese food with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese food by § 133.173, except that:

* * * * *

79. Section 133.175 is revised to read as follows:

§ 133.175 Pasteurized cheese spread.

Pasteurized cheese spread is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese spread by § 133.179, except that no emulsifying agent as prescribed by § 133.179(e) is used.

80. Section 133.176 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.176 Pasteurized cheese spread with fruits, vegetables, or meats.

(a) Pasteurized cheese spread with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized cheese spread by § 133.175, except that:

* * * * *

81. Section 133.178 is amended by revising paragraph (d) to read as follows:

§ 133.178 Pasteurized neufchatel cheese spread with other foods.

* * * * *

(d) Each of the ingredients used in the food shall be declared on the label as

required by the applicable sections of parts 101 and 130 of this chapter.

82. Section 133.179 is amended by revising paragraph (i) to read as follows:

§ 133.179 Pasteurized process cheese spread.

* * * * *

(i) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that cheddar cheese, washed curd cheese, colby cheese, granular cheese, or any mixture of two or more of these may be designated as "American cheese".

83. Section 133.180 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 133.180 Pasteurized process cheese spread with fruits, vegetables, or meats.

(a) Pasteurized process cheese spread with fruits, vegetables, or meats, or mixtures of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of ingredients, prescribed for pasteurized process cheese spread by § 133.179, except that:

* * * * *

84. Section 133.181 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.181 Provolone cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

85. Section 133.182 is amended by adding paragraph (f) to read as follows:

§ 133.182 Soft ripened cheeses.

* * * * *

(f) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

86. Section 133.183 is amended by revising the introductory text of paragraph (f) to read as follows:

§ 133.183 Romano cheese.

* * * * *

(f) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

87. Section 133.184 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.184 Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

88. Section 133.185 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.185 Samsoe cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

89. Section 133.186 is amended by revising paragraph (d) to read as follows:

§ 133.186 Sap sago cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

90. Section 133.187 is amended by adding new paragraph (g) to read as follows:

§ 133.187 Semisoft cheeses.

* * * * *

(g) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

91. Section 133.188 is amended by adding new paragraph (g) to read as follows:

§ 133.188 Semisoft part-skim cheeses.

* * * * *

(g) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

92. Section 133.189 is amended by adding new paragraph (e) to read as follows:

§ 133.189 Skim milk cheese for manufacturing.

* * * * *

(e) Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

93. Section 133.190 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.190 Spiced cheeses.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

94. Section 133.191 is revised to read as follows:

§ 133.191 Part-skim spiced cheeses.

Part-skim spiced cheeses conform to the definition and standard of identity, and are subject to the requirements for label statement of ingredients prescribed for spiced cheeses by § 133.190, except that their solids contain less than 50 percent, but not less than 20 percent, of milkfat.

95. Section 133.193 is amended by revising paragraph (a) to read as follows:

§ 133.193 Spiced, flavored standardized cheeses.

(a) Except as otherwise provided for herein and in applicable sections in this part, a spiced or flavored standardized cheese conforms to the applicable definitions, standard of identity and requirements for label statement of ingredients prescribed for that specific natural cheese variety promulgated pursuant to section 401 of the Federal Food, Drug, and Cosmetic Act. In addition a spiced and/or flavored standardized cheese shall contain one or more safe and suitable spices and/or flavorings, in such proportions as are reasonably required to accomplish their intended effect: Provided, That, no combination of ingredients shall be used to simulate the flavor of cheese of any age or variety.

* * * * *

96. Section 133.195 is amended by revising the introductory text of paragraph (d) to read as follows:

§ 133.195 Swiss and emmentaler cheese.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that:

* * * * *

PART 135—FROZEN DESSERTS

97. The authority citation for 21 CFR part 135 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

98. Section 135.110 is amended by revising paragraph (f) to read as follows:

§ 135.110 Ice cream and frozen custard.

* * * * *

(f) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that the sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of all the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in § 101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used or, alternatively, as permitted in § 101.4 of this chapter. Under section 403(k) of the Federal Food, Drug, and Cosmetic Act, artificial color need not be declared in ice cream, except as required by § 101.22(c) or (k) of this chapter. Voluntary declaration of all colors used in ice cream and frozen custard is recommended.

99. Section 135.115 is amended by revising paragraph (d) to read as follows:

§ 135.115 Goat's milk ice cream.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

100. Section 135.120 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 135.120 Ice milk.

(a) *Description.* Ice milk is the food prepared from the same ingredients and in the same manner prescribed in § 135.110 for ice cream and complies with all the provisions of § 135.110 (including the requirements for label statement of ingredients), except that:

* * * * *

101. Section 135.130 is amended by revising paragraph (e) to read as follows:

§ 135.130 Mellorine.

* * * * *

(e) *Label declaration.* Each of the ingredients used shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter, except that sources of milkfat or milk solids not fat may be declared in descending order of predominance either by the use of the terms "milkfat and nonfat milk" when one or any combination of two or more of the ingredients listed in § 101.4(b)(3), (b)(4), (b)(8), and (b)(9) of this chapter are used, or alternatively as permitted in § 101.4 of this chapter.

102. Section 135.140 is amended by revising paragraph (i) to read as follows:

§ 135.140 Sherbet.

* * * * *

(i) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

PART 168—SWEETENERS AND TABLE SIRUPS

103. The authority citation for 21 CFR part 168 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

104. Section 168.140 is amended by revising paragraph (d) to read as follows:

§ 168.140 Maple sirup.

* * * * *

(d) *Label declaration.* Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

Dated: October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101 and 102

[Docket No. 80N–0140]

RIN 0095–AC48

Food Labeling; Declaration of Ingredients; Common or Usual Name For Nonstandardized Foods; Diluted Juice Beverages

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food labeling regulations to establish requirements for the declaration of the percentage of juice in foods that purport to be beverages containing fruit or vegetable juice. The agency is also revising the existing common or usual name regulation for diluted fruit or vegetable juice beverages. FDA is also revoking the common or usual name regulations for noncarbonated beverage products that contain no fruit or vegetable juice and for diluted orange juice beverages. This final rule responds to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and is part of FDA's ongoing rulemaking on juices and juice beverages.

EFFECTIVE DATE: May 8, 1993, except that amendments to part 102 become effective May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS–155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 2, 1991 (56 FR 30452), FDA proposed requirements for the declaration of the percentage of juice in foods that purport to be beverages containing fruit or vegetable juice (hereinafter referred to as the July 2, 1991, proposal). There had been a longstanding controversy over percentage juice declaration in diluted fruit and vegetable juice beverages. The 1990 amendments (Pub. L. 101–535) settled the question of whether, and where, a declaration of the percentage of juice in a fruit or vegetable juice beverage must be included on the product's label. Section 7 of the 1990 amendments amends section 403(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(i)) to require, that "if the food purports to be a beverage containing vegetable or fruit juice, it bear a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food." In the preamble to the July 2, 1991, proposal, FDA discussed questions remaining about the exact meaning and the implementation of this provision (56 FR 30452 at 30453). The agency proposed to add new § 101.30 to establish requirements for the percentage declaration, and to delete the similar provision from the existing common or usual name regulation for diluted fruit or vegetable juice beverages in § 102.33 (21 CFR 102.33)). The agency also proposed to make revisions to the requirements in § 102.33 pertaining to the product name. FDA also proposed to revoke the common or usual name regulations for noncarbonated beverage products containing no fruit or vegetable juice in § 102.30 (21 CFR 102.30) and for diluted orange juice beverages in § 102.32 (21 CFR 102.32). Because these products would be covered under proposed § 101.30 and the revised § 102.33, the agency tentatively found that separate regulations for these products are no longer needed. In addition, the agency withdrew its July 16, 1987, proposal to revoke the existing regulations on common or usual names for diluted fruit or vegetable juice beverages (52 FR 26690).

The agency received over 200 responses to the July 2, 1991, proposal from a wide range of sources, including consumers, consumer organizations, professional associations, State and local government agencies, manufacturers, and trade associations. Each of the responses contained one or more comments. Several comments addressed issues outside the scope of the July 2, 1991, proposal and will not be discussed here. A number of comments suggested modification of various provisions of the July 2, 1991, proposal. A summary of the relevant issues raised in the comments and the agency's responses follow.

II. Percentage Juice Labeling

A. Applicability (Covered Products)

Section 403(i) of the act requires that the label of any food that purports to be a beverage containing fruit or vegetable juice bear a percent juice declaration on the information panel. In the July 2, 1991, proposal, FDA described this requirement for percentage juice declaration as applying to full-strength juices and to various other standardized and nonstandardized fruit and vegetable beverages. The scope of the proposed regulation included waters, carbonated and noncarbonated beverages containing juice, juice nectars, diluted juices, wine coolers containing juice, and any beverage that contains no juice but whose labeling, color, or flavor represents, suggests, or implies that fruit or vegetable juice may be present.

1. One comment stated that the agency should not determine for consumers when a beverage purports or does not purport to contain juice. The comment stated that consumers will come to recognize the presence or absence of juice in a beverage by the presence or absence of a percent juice declaration.

The agency points out that the statute requires percentage declaration of fruit or vegetable juice on the label of a food if it "purports" to be a beverage containing vegetable or fruit juice. The agency is therefore obliged to base its requirements on whether or not the product purports to contain juice. FDA is applying its longstanding policy on whether a food purports to contain an ingredient, i.e., a food purports to contain an ingredient if it conveys, implies, or professes outwardly that it contains that ingredient; or the food has the appearance of being, intending, or claiming to contain that ingredient. The term "purports" is used in its ordinary sense, and includes what the food is accepted as by the average consumer under ordinary conditions of purchase as well as what it appears or is represented to be by labeling or other means. (*United States* v. *306 Cases Containing Sandford Tomato Catsup with Preservative*, 55 F. Supp. 725, 727 (E.D.N.Y. 1944); *United States* v. *30 Cases, More or Less, labeled in part: "Leader Brand Strawberry Fruit Spread,"* 93 F. Supp. 764 (S.D. Iowa 1950). Accordingly, a beverage purports to contain juice if it states or implies on the label that it contains juice or has the appearance of being juice or containing juice. New § 101.30(a) applies this policy for beverages.

2. Several comments said that FDA should be able to use extra-label sources of information, such as advertisements and store promotions as well as the beverage label, in determining whether percent juice declaration requirements apply. Several comments stated that percent juice declaration requirements should apply to carbonated soft drinks if a manufacturer uses advertising to represent that the firm's beverage contains juice. On the other hand, one comment opposed the use of extra-label sources of information to determine whether a product purports to contain

juice because there is no precedent for it.

The agency agrees that advertisements in the form of store promotions or other extra-label information stating or implying that the particular beverage contains juice result in the advertised beverage purporting to contain juice, and therefore percentage juice declaration is required. While FDA is not attempting to regulate advertising or claims made in advertising, contrary to the second comment, statements made in advertising have long affected the labeling of food products. FDA has given similar significance to advertising in the regulations on nutrition labeling (§ 101.9 (21 CFR 101.9)) and on the characterizing flavor labeling requirements (§ 101.22 (21 CFR 101.22)). In both of these instances, an advertising claim for a nutrition or flavor characteristic of a food invokes the requirement for nutrition labeling or flavor characterization labeling on the basis that the consumer who wants the food because of its particular nutrient content or flavor is entitled to examine a label that reveals facts material in light of the representations made, including those made in advertising, at the time of purchase. Similarly, FDA concludes that once a juice content claim is made for a beverage, the consumer who wants the product because of claims about its juice content is entitled to examine a label that provides juice content information at the time of purchase. Therefore, the agency is providing in new § 101.30(a) that advertising is a means by which a beverage purports to contain juice.

3. One comment expressed the belief that the requirement in the 1990 amendments for percent declaration of juice content does not apply to full-strength juice (including 100 percent juice prepared from concentrate). It stated that the 1990 amendments mandated this information for beverages that contain fruit or vegetable juices and not those that are 100 percent fruit or vegetable juice.

The agency disagrees with this interpretation of the statute. The statute states, "* * * if the food purports to be a beverage containing vegetable or fruit juice * * *." A single-strength juice product may contain a single juice as its only ingredient. A beverage that is a single-strength juice made from concentrate and water contains 100 percent juice. Likewise, a beverage that is a blend of more than one single-strength juice may contain 100 percent juice. The agency believes that using the interpretation in the comment would result in inconsistent requirements, e.g., the second and third types of products described above would bear percentage juice declarations, while the beverage consisting of one single-strength juice as its only ingredient would not.

The legislative history for this provision is not helpful in determining congressional intent. It states only: "Section 7(2) would require statements as to the percentage of fruit or vegetable juice contained in products sold as such juice." (136 Congressional Record—H5842 (July 30, 1990)). Thus, FDA finds no basis to conclude that Congress intended such an inconsistent outcome and therefore concludes that the interpretation of the statute in the comment is incorrect. Accordingly, the agency finds that beverages that contain only a single-strength juice are subject to the percentage juice declaration requirements.

4. A number of comments requested that juice flavored waters and seltzers be exempted from the requirement for declaration of percent of juice. They stated that the juice ingredient in these beverages is present in minor amounts (usually less than 2 percent) for flavoring, and that the beverages are not considered by consumers to be sources of juice. They stated further that naming the juice used as a flavor in the ingredient list should not be considered as purporting to be a beverage that contains juice. Several of the comments stated that a product should not have to declare percent of juice if the label states that it is flavored with the fruit juice, e.g., "———— flavored drink" or "A-B drink with a touch of lemon." The comments explained that the term "flavored" used with the common or usual name of the beverage informs the consumer that the juice is present in minor amounts for flavoring or taste, and that the beverage does not contain a significant amount of fruit or vegetable juice.

The agency agrees with the comments that a beverage flavored with a small amount of juice may not "purport to be a beverage containing juice" as that phrase is meant in the 1990 amendments. FDA believes that declaration of juice content provides information essential to the consumer in determining the nature of the product and reveals facts material in light of any representation made that the beverage contains juice. The agency considers that where a beverage contains a small amount of juice (usually less than 2 percent) for flavoring purposes, the label makes clear that the juice is present for flavoring, the word "juice" is not used on the label except in the ingredient list, the beverage is not represented as containing a significant amount of juice. In such a case, information on the amount of juice present would not be essential to describe the nature of the product. The agency concludes that such a product does not purport to contain juice within the meaning of the statute, and that therefore declaration of percent of juice is not required.

However, the label statement describing the flavor role of the small amount of juice must include the term "flavor" or "flavored" or otherwise indicate that the amount of juice is small and not use the word "juice." When a beverage contains a fruit or vegetable juice but does not use a form of the word "flavor" or otherwise indicate that the amount of juice is small, e.g., "lemon iced tea" or "lemon drink," the combination of the name of the fruit in the name of the product and declaration of the juice in the ingredient list implies that the beverage not only derives its flavor from the juice, but that it contains the juice. Thus, the product would purport to contain juice. In addition, use of the word "juice" in the flavor designation or elsewhere on the label, except in the ingredient list, would convey a similar impression. The statute requires the declaration of the percent of the juice in such circumstances.

In addition, the overall impression of the label, packaging, and physical characteristics of the beverage taken together may give the consumer the impression that the beverage contains juice and not just minor amounts of juice for flavor. For example, vignettes, such as one depicting juice flowing or oozing from a fruit or vegetable, or the physical characteristics of juice, such as the presence of pulp, would give the impression that the beverage contains juice. As described in new § 101.30(a), beverages bearing such representations purport to contain juice and are therefore required to bear the percent juice declaration.

Accordingly, the agency is including in the final regulation as new § 101.30(c) (proposed § 101.30(c) and (d) are deleted in response to comment 10 of this document) an exemption from percentage juice declaration for juice flavored beverages such as waters or seltzers provided that the beverage is labeled with a juice flavor description using the term "flavor," "flavored," or "flavoring" or otherwise makes clear that the juice is present in a small amount. To be exempt, the product's advertising, label, and labeling must not bear: (1) The term "juice" on the label other than in the ingredient statement, e.g., "seltzer water flavored with raspberry" or "seltzer water with a touch of raspberry;" (2) a vignette, e.g., depicting juice exuding from a fruit or vegetable; or (3) specific resemblance to

a juice, e.g., via distinctive juice characteristic such as pulp.

5. In the preamble to the July 2, 1991, proposal, FDA tentatively concluded that wine coolers and similar beverages containing less than 7 percent alcohol by volume that purport to contain unfermented fruit or vegetable juice are covered by proposed § 101.30 and are required to bear a percentage juice declaration (56 FR 30452 at 30454). While several comments supported this position, others objected, stating that wine coolers do not purport to contain juice but are juice flavored wine. The comments stated that many brands of wine coolers and some sangrias currently sold in the United States contain natural and artificial juice flavors rather than juice or pulp and are labeled in compliance with § 101.22, indicating that they contain flavors rather than juice. One of the comments stated that brands representing approximately 93 percent of all wine coolers sold in the United States are manufactured with fruit flavors rather than fruit juice. Several comments stated that wine coolers, including sangrias, should be treated in the same fashion as juice flavored soft drinks because consumers purchase wine coolers as alternatives to other alcoholic beverages, the same as soda drinkers who drink cherry cola when they want a change from regular cola.

The agency points out that wine coolers that do not contain unfermented juice are not covered by this regulation unless they purport to contain juice by means of advertising, labeling statements, vignettes, or physical characteristics. Thus, if a wine cooler does not contain any juice, has labeling that makes clear that it contains flavors rather than juice, and does not bear a vignette that implies fruit juice content, it is not subject to new § 101.30. In addition, FDA advises that noncarbonated beverages that purport to contain juice but do not, in fact, contain any juice were required by § 102.30 to state that they contain no juice. FDA concludes that this new regulation does not appreciably change the requirements for juice content declaration for the wine coolers referred to in these comments. Accordingly, no change in the regulation or its applicability is warranted by these comments.

6. Several comments stated that requiring percentage juice declaration on wine coolers is unfair because the same requirement does not apply to most other alcoholic beverages including spirits-based and malt-based coolers, which compete directly against wine coolers.

The agency advises that the labels of alcoholic beverages (those that contain 7 percent or more alcohol by volume and malt beverages) are regulated in accordance with the Federal Alcohol Administration Act (27 U.S.C. 205) administered by the Bureau of Alcohol, Tobacco and Firearms and are controlled differently from wine coolers. The labeling of wine coolers, like other beverages that contain less than 7 percent alcohol by volume, are regulated under the act. To the extent that these statutes differ, the products are regulated differently in other labeling aspects as well as in declaration of percentage juice content. It is not up to FDA, but to Congress, to decide that the same requirements must apply to wine coolers, other alcoholic beverages, and malt based beverages.

7. Some comments agreed with the agency proposal that traditional carbonated fruit-flavored soft drinks (sodas) have a substantial history of marketing as products with fruit flavor and are recognized as containing only fruit flavor and not necessarily fruit juice. These comments recommended that carbonated fruit flavored soft drinks be exempted from percentage juice declaration. However, several other comments said that the percent juice declaration regulation should apply if a soft drink manufacturer uses labeling to represent that a carbonated beverage does contain juice, such as vignettes depicting juice dripping from a fruit.

These comments are consistent with the preamble to the July 2, 1991, proposal, in which FDA stated that the label and labeling of soft drinks (sodas) generally do not give the impression through words or explicit vignettes that these beverages contain juice (56 FR 30452 at 30454). FDA therefore concludes that if a soft drink (soda) does not represent or suggest in the name, labeling statement, or ingredient statement that it contains fruit or vegetable juice, there is no basis to find that it purports to contain juice. Accordingly, for clarity the agency is adding a statement to that effect to the regulation in § 101.30(a). However, FDA also concludes that, as discussed in the preamble to the July 2, 1991, proposal, a soft drink (soda) that contains ingredients, such as pulp, that give the impression that it contains juice or that bears an explicit vignette that gives the impression of juice content, purports to contain juice (56 FR 30452 at 30454). Such a product would be required under § 101.30(d) to declare juice content. In addition, those soft drinks that do contain juice usually make that fact known. These products purport to contain juice and are subject to the percentage juice declaration requirement.

8. In the July 2, 1991, proposal, FDA also addressed requests for exemption from percentage declaration for bulk juice concentrates for institutional use. The agency stated that it was not proposing to exempt these bulk concentrates because of a lack of information substantiating the need or value of such an exemption. Some comments requested exemption from percent juice declaration for bulk juice concentrates for institutional use because they claimed this information is provided to consumers in other ways by the institution, and the institution specifies the juice content of the product in contracts and purchasing agreements.

Because these comments provided no additional information to support their assertions, the agency still does not have information that demonstrates a need for an exemption from percentage juice declaration for bulk juice concentrates for institutional use. Therefore, FDA is not including such an exemption in this final rule.

However, those requesting an exemption from percentage juice declaration for bulk juice concentrates for institutional use may petition for such an exemption under § 10.30 (21 CFR 10.30), providing the agency with information such as actual contracts or purchasing agreements specifying juice content and verifiable instances and examples of the percentage juice content presentation provided to consumers served the juice derived from the bulk juice concentrates by specific institutions, as well as data demonstrating the extent of use of these products by institutions.

9. Some comments requested exemption from percent juice declaration for bulk concentrates intended for further processing because consumers would not see the labeling, and manufacturers require bulk concentrate that meets their specifications from their suppliers.

The agency advises that bulk concentrates for further processing are covered by the exemptions provided in § 101.100(d) (21 CFR 101.100(d)). That regulation specifies criteria for exemption from labeling requirements including those of section 403(i) of the act. Therefore, there is no need to grant a new exemption.

B. What Percentage Must be Declared

Section 403(i) of the act, as modified by section 7(2) of the 1990 amendments, requires that if a food purports to be a beverage containing fruit or vegetable juice, it must bear a statement of "* * *

the total percent of such fruit or vegetable juice contained in the food * * *." In the July 2, 1991, proposal, FDA tentatively concluded that this statement could be read two ways, one to require declaration of percent of total juice and the other to require declaration of percent of each juice represented to be in the beverage. The agency found that under either reading a material fact would not be disclosed. Reading section 403(i) of the act together with section 201(n) of the act (21 U.S.C. 321(n)) and section 403(a) of the act, FDA proposed to require declaration of both the percent of total juice and the percent of each juice represented to be in a multiple-juice beverage.

10. Many comments opposed the requirement for declaration of percent of individual juices in multiple-juice beverages. They cited the following reasons for their opposition: (1) The statutory language of the 1990 amendments does not require declaration of percent of individual juice in multiple-juice beverages; (2) proprietary formula information would be revealed by a 1-percent increment declaration of individual juices; (3) variable (least cost) juice blend formulation driven by fluctuations in cost or availability of individual juices would be eliminated with the proposed 1-percent increment label declaration requirement as labels would have to be changed to reflect formulation changes; (4) the requirement is unenforceable with current analytical methodology; (5) there are no data or information that demonstrate consumer interest in or benefit from the requirement; and (6) label clutter on the information panel would be increased.

In contrast, other comments supported the proposed requirement for individual juice percentage declaration, stating: (1) The 1990 amendments clearly require a total percent juice declaration, and it does not follow that Congress did not intend for the consumer to be fully apprised of the identity and amount of the juices that make up the declared total amount of juice; (2) some juice beverages have misleading labels in that high cost/value or intense flavor juices are given greatest label prominence but are present in minor amounts; (3) some manufacturers misrepresent the juice content of their beverage through the use of added pulp, clouding agents, and thickening agents which mislead consumers into believing that these beverages have more juice than is actually present; (4) more precise, direct information on relative amounts of specific juices in multiple-juice beverages is needed by consumers to make in-store purchasing decisions; (5) among multiple-juice beverages with the same total juice percentage, a juice's order of predominance in the ingredient statement does not directly translate to its percentage in the beverage; and (6) enforcement actions by Federal, State, and local consumer protection agencies will be needed less often because the percent of individual juice declaration will remove possible ambiguity as to whether a product label may be misleading to the consumer.

The agency has reconsidered its interpretation of the amendment to section 403(i) of the act in light of the arguments presented in the comments. The agency notes the contrast in language in section 403(i)(2) of the act, which, on the one hand, requires the declaration of the common or usual name of "each such ingredient" when a product is fabricated from two or more ingredients but only the declaration of the total juice percentage of "such" fruit or vegetable juice contained in the food, not "each" fruit or vegetable juice contained in the food. Thus, had the intent of Congress been to require percent individual juice declaration, it clearly knew how to do so. Based on the face of the law, it is reasonable to expect that Congress would have used the word "each" in place of, or preceding, the word "such" in the phrase "such fruit or vegetable juice," as it did in the phrase "each such ingredient." Without relevant legislative history on the provision, FDA now finds that the better reading of section 7 of the 1990 amendments is that it requires declaration of percent of total juice but not declaration of percent of individual juices in a multiple-juice beverage.

Nor is it clear that the percent of each individual juice represented on the label is a material fact under section 201(n) of the act for all multiple-juice beverages. In the July 2, 1991, proposal, FDA stated that if the label of a beverage declared the presence of one or more juices by representation (i.e., word or vignette) and declared the total percentage of juice in the product, but did not declare the percentage of each individual represented juice, the label would be misleading (56 FR 30452 at 30456). The agency tentatively found that such a label would create an impression that overstates the amount of the represented juices in the beverage if not all the juice in the beverage is supplied by the represented juices.

While beverage labels clearly are misleading if they misrepresent the contribution of one or more individual juices to the total amount of juice, the agency acknowledges that not all multiple-juice beverage labels that bear representations of individual juices misrepresent the contribution of the individual juices to the total. For example, a vignette that depicts all the fruits or vegetables in the product may not misrepresent an individual juice contribution. In addition, declaration as a part of the product name of all juices present (in descending order by volume of single-strength juice) would generally not be misleading.

Accordingly, FDA is not including in the final regulation the requirements in proposed § 101.30(c) and (d) for the declaration of the percent of juice for all juices in multiple-juice beverages that are declared in the label or labeling, by word, vignette, or other means, other than inclusion in the statement of ingredients, to be present in the beverage. The agency is also deleting proposed § 101.30(e), which provided for optional declaration of percent of individual juices not represented on the label. Instead, the agency has included in the final regulation on the common or usual name of such beverages, provisions for adequately descriptive names that will inform the consumer of the nature of the product. As discussed in detail in Section III. of this document, for beverages where one or more but not all the juices are named and the named juice is not the predominant juice, the agency is providing two alternatives for describing the contribution of the named juice. The label must either state that the beverage is flavored by the named juice (e.g., "raspberry flavored juice drink") or declare the content of the named juice in a 5 percent range (e.g., "raspberry juice drink 2 to 7 percent raspberry juice"). The agency believes that this approach will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups.

Because FDA is deleting the requirement for declaration of percent of individual juice content in multiple-juice beverages, a number of comments are no longer relevant. Such comments include those regarding which juices should be included in the percent of individual juice declaration and the impracticability of declaring individual juices in 1-percent increments. The agency is not addressing these comments because the concerns they express are moot. In addition, allegations that this regulation would result in a compensable taking of private property are no longer relevant. These allegations were based on the contention that a requirement for declaration of percent of individual juices would be a mandatory disclosure of proprietary information and would thereby constitute a taking. Because the

requirement in question has been deleted, there is no need for FDA to address the issue.

11. No comments objected to the requirement that the declaration of percent of total juice be in 1-percent increments. However, several comments pointed out that the regulation should provide for beverages that contain less than 1 percent juice. They stated that to have a "0 percent juice" declaration on a product with juice declared in the ingredient list would be confusing to the consumer. One comment suggested that FDA provide for a statement such as "less than 1 percent juice" instead of requiring "0 percent juice" for those products that contain juice at a volume of less than 1 percent.

The agency agrees that a declaration of juice content of less than 1 percent may be appropriate if it accurately describes the amount of juice in the product. Therefore, FDA is revising the provisions in new § 101.30(b) for percentage juice declaration to allow for this declaration.

C. How Declarations Should Be Made—Placement and Prominence

Section 403(i)(2) of the act requires "a statement with appropriate prominence on the information panel" of the percentage of juice. The agency proposed requirements that it believed would provide appropriate prominence for the percentage juice declaration and still allow room for other required information. The agency proposed in § 101.30(g) that if the beverage is sold in a package that has an information panel, the percentage juice declaration is to be prominently placed near the top of the information panel, with no other printed label material appearing above it. Additionally, the agency proposed to require that the declaration be in easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the product name, and in lines generally parallel to the base on which the package rests.

The agency also proposed in § 101.30(h) that the percentage juice declaration may also be placed on the principal display panel if the declaration is consistent with that presented on the information panel. Further, the agency proposed in § 101.30(i) that if the beverage package does not include an information panel, the percentage juice declaration must be placed on the principal display panel: (1) In type size not less than that required for the declaration of net quantity of contents statement, (2) located near the name of the food, and (3) in lines generally parallel to the base on which the package rests. (Paragraph designations of new § 101.30 have been changed to paragraphs (e), (f), and (g), respectively, as a result of changes discussed in response to comment 10 of this document.)

12. Some comments suggested that the total juice content should be required to be placed at the top of the principal display panel with the common or usual name. They stated that otherwise the declaration of total juice would not have appropriate conspicuousness or prominence, because many consumers do not routinely, or cannot easily, read fine print, i.e., one-sixteenth of an inch minimum height, on the information panel.

The agency advises that the act requires that the percent juice declaration be on the information panel. The comments did not provide a legal basis on which the agency could require an additional declaration on the principal display panel. However, as provided in new § 101.30(f), the agency is permitting percent total juice on the principal display panel as an optional declaration.

13. Several comments stated that in addition to the percent juice declaration on the information panel, percent juice declaration should be allowed on the principal display panel.

As stated in response to the previous comment, the agency does not object to the additional declaration of percent juice content on the principal display panel, provided that it is consistent with the declaration on the information panel. This additional declaration is provided for in new § 101.30(f).

14. Although no comments objected to the requirement that a total percent juice declaration appear on the principal display panel in the absence of an information panel, some comments objected to the requirement that placement of the percent juice declaration on the principal display panel be near the name of the food. These comments asserted that there is no compelling reason for such placement, and that there should be more flexibility in the location of the declaration.

The agency disagrees with the comments. Consumer use of the percent juice content declaration will be facilitated if it is in a consistent, prominent location on the food label. The comments did not recommend alternative placement criteria.

Currently, some juice beverage labels bear percent juice statements such as "100 percent juice" or "100 percent juice blend" on the principal display panel near the name of the juice product. Because of the longstanding industry tradition of marketing food products bearing percentage claims near the name of the food on the principal display panel, and because of agency regulations providing for such percentage declarations in association with the common or usual names of nonstandardized foods (§ 102.5(b) (21 CFR 102.5(b))), consumers have become accustomed to seeing such percent juice information, when it appears on the principal display panel, near the name of the food. Therefore, the agency concludes that the proposed requirement for placement of the percent juice declaration on the principal display panel near the name of the food, if there is no information panel, provides appropriate prominence as required by the statute. This requirement is set forth below as new § 101.30(g).

15. Several comments objected to the proposed requirement that the percent juice declaration be near the top of the information panel with no printed information appearing above it. These comments wanted more flexibility to use available label space efficiently and to minimize label clutter that they said would result from declaration of percent juice statements near the top of the information panel. The comments stated that the 1990 amendments did not mandate that the percentage juice declaration be the most prominent or conspicuous item on the information panel. Finally, the comments said that the July 2, 1991, proposal gives the declaration more prominence than health and safety statements such as those required for saccharin section 403(o) and (p) of the act (codified at 21 CFR 100.130(d)(2), 101.11, 105.66(b) and 180.37) or phenylalanine (21 CFR 172.804(e)(2)), and other statements concerning storage, preparation, recycling, and deposit information. The comments requested that they have, at a minimum, the option of placing such information as the brand name, product name, product logos, and the universal product code (UPC) above the percentage juice declaration.

The suggestion in the comments that required information on the information panel is not more important than optional information, and should have equal but not greater prominence, is contrary to existing regulatory requirements that have not been changed by the 1990 amendments. The agency is not requiring that the percent juice declaration be the most prominent and conspicuous item on the information panel by virtue of its placement near the top of the

information panel. FDA considered that the same regulations that currently apply to labeling information appearing on the information panel (§ 101.2 (21 CFR 101.2)) will also apply to the total percent juice declaration and did not wish to unduly disrupt the customary sequence of required information on the information panel, i.e., nutrition information, ingredient statement, and name and place of business of the distributor (§ 101.2(b)). Further, because the percentage juice declaration is now required information, the agency believes it must be at least as prominent as other required information to have the "appropriate prominence" required by the statute (21 CFR 101.2(c) and 101.15).

Consistent with these considerations, the agency finds that placing optional information such as storage instructions and recipes, which need not appear on the information panel at all, above the total percentage declaration, and consequently above all other required information on the information panel, will not give the percentage declaration "appropriate prominence." The comments did not provide any examples or information to substantiate a need for additional flexibility, and the agency is not convinced by the comments' assertions that the prominence and placement of the required total percent juice declaration is unreasonably restrictive.

However, having considered all the comments on this issue, the agency concludes that since the product name or brand name or logo often appear at the top of the information panel, they may continue to appear above the percentage juice declaration on the information panel. However, any additional printed material, other than product name or brand name or logo that appears above the percentage juice declaration will render the percent juice declaration so inconspicuous that the "appropriate prominence" required by the 1990 amendments will not be provided. Consistent with past agency practice, foods whose labeling omits or fails to prominently or conspicuously convey required information, and instead utilizes available label space to give prominence and conspicuousness to nonmandatory information, will be subject to legal action.

Finally, FDA considers the UPC to be a sufficiently distinctive label feature that it does not affect the prominence and conspicuousness of other information on the label. The agency has therefore not seen a need to regulate its location on the label in relation to required information. Consequently, the final regulation does not prohibit the UPC from appearing above the percentage declaration on the information panel.

Accordingly, the agency is revising the regulation in new§ 101.30(e)(1) to include the words "except the brand name, product name, logo, or universal product code" after the word "statement."

16. Several comments objected to the requirement that the percent total juice declaration be not less than the largest type on the information panel except that used for the product name because it gave the percent declaration undue prominence. These comments asserted that the type size requirements should not be any greater than for other required information, i.e., a minimum one-sixteenth of an inch in height unless exempted pursuant to § 101.2(f). Additionally, the comments asserted that type size requirements should relate only to type size of the required information on the information panel and not to the brand name, product name, UPC, or any other nonmandatory information on the information panel. One comment suggested a minimum 3/32 of an inch type size instead of the proposed one-sixteenth of an inch on large containers such as half-gallon cartons, so that the print size would be more proportional to other printed material on the carton.

In the July 2, 1991, proposal, the agency attempted to strike a balance between "appropriate prominence" for the percent juice declaration and that of other required information and of nonmandatory information on the information panel. The agency believes that the total percentage juice declaration should be at least as prominent as any other information on the same panel, whether required or not. However, because the agency also recognized that manufacturers may desire to place the product name prominently on the information panel, it proposed to exclude the name from consideration relative to the type size for the total percent juice declaration. Consistent with the decision above to permit brand name, product name, logo, or UPC to be located above the percent juice declaration, the exclusion from type size comparison should also apply to the brand name and the logo. The agency also did not intend to include the UPC among the label information on which type size for the percent juice declaration is based. As stated above, it considers that the UPC is sufficiently distinctive in appearance that it does not interfere with the prominence or conspicuousness of other label information.

In meeting the mandate of the 1990 amendments for appropriate prominence of the percentage juice declaration, FDA did not wish to deviate unnecessarily from existing type size requirements or to establish new type size requirements such as the requested 3/32 of an inch type size for large containers. The comment requesting larger minimum type size for large containers did not provide information to substantiate a need for larger type or to demonstrate that the 3/32-inch type size would be appropriate to meet such a need. Therefore, FDA is retaining the one-sixteenth of an inch minimum type size provision in the final rule.

To summarize, the type size requirement of not less than the largest type on the information panel with the exception of product or brand name, the logo, and the UPC ensures a certain proportionality of type size for required and nonmandatory statements. This proportionality of type size both provides for "appropriate prominence" of the percentage juice declaration and helps to curb instances of inappropriate prominence of nonmandatory information over required information on the information panel.

Therefore, the agency is requiring in new § 101.30(e)(2) that the declaration of percentage juice be prominently placed on the information panel, appearing in easily legible boldface type, in distinct contrast to other printed or graphic matter, in a height not less than the largest type on the information panel except for that used for the brand name, product name, logo, or UPC.

17. Some comments objected to the requirement in proposed § 101.30(g)(2) that the percentage juice declaration on the information panel be in lines generally parallel to the base upon which the package rests. They stated that the requirement limits the flexibility of beverage manufacturers in placement of the required declaration and other required information on the information panel. Several other comments suggested that the percent juice declaration be in lines generally parallel to other required information, whether or not this information is also parallel to the base on which the package rests.

The agency advises that placing required information on the principal display panel in lines other than generally parallel to the base upon which the package rests requires the consumer to unnecessarily manipulate the package to read the required information, making it less likely to be read. Consistent with this fact,

statements of identity and net quantity of contents are required to appear on the principal display panel in lines generally parallel to the base upon which a package rests (§ § 101.3(d) and 101.105(f) (21 CFR 101.3(d) and 101.105(f)), respectively).

However, the agency agrees with the comments that requiring that the percent juice declaration be on the information panel in lines generally parallel to the base is not justified because other mandatory information on the information panel is not required to be in lines generally parallel to the base of the package. The regulations in § 101.2 do not include specific orientation requirements for mandatory declarations such as the ingredient statement, nutrition labeling, or name and place of business of the manufacturer, packer, or distributor.

Accordingly, FDA concludes that because it does not have substantial justification for this additional orientational requirement and in light of objections from comments, the proposed requirement should be withdrawn. Therefore, FDA has deleted the phrase "and in lines generally parallel to the base on which the package rests" from proposed § 101.30(g)(2) (redesignated as new § 101.30(e)(2) in this final rule).

The agency, however, is persuaded by the suggestion in the comments that the percent juice declaration should be in lines generally parallel to other required information, whether or not this information is also parallel to the base on which the package rests. Because existing § 101.2(e) provides that all information appearing on the information panel pursuant to this section must appear in one place without intervening material, it is reasonable that the percent juice declaration should be in lines generally parallel with this information, so that the consumer will not have to manipulate the package to read all the required information. This orientational requirement will ensure that appropriate prominence of the percent juice declaration is maintained. Therefore, the agency has inserted the phrase "in lines generally parallel to other required information" after the word "panel" in new § 101.30(e).

D. Associated Label Statements

In the July 2, 1991, proposal, FDA discussed declarations that use a percentage (usually 100) to describe a term other than juice, such as "100 percent pure" or "100 percent natural" (56 FR 30452 at 30457). The agency stated that these declarations have a great potential to mislead the consumer into believing that the product is 100 percent juice. FDA advised that such statements should not be used. In addition, the agency requested comments as to whether FDA should adopt regulations specifically providing that declarations such as "100 percent pure" or "100 percent natural" or "100 percent" to describe a term other than juice are misleading, particularly when used on the principal display panel of diluted juice beverages.

18. Several comments stated that the terms "pure" and "natural" are ambiguous and tend to mislead consumers about the nature of a product. These comments stated that at times, the terms "pure" and "natural" mislead a consumer into believing that the product consists entirely of juice. A number of comments stated that using the term "100 percent" with the terms "pure" and "natural" exaggerates and exacerbates the already ambiguous and misleading nature of the terms "pure" and "natural" on diluted juice beverages. These comments said that consumers are consistently confused and misled by such statements into believing that the beverages are all juice with no additional ingredients or are full-strength (100 percent) juice. These comments stated that the use of these phrases should be restricted by FDA because most juice beverages are not 100 percent juice, or they are processed, i.e., reconstituted with water and ingredients other than juice such as sweeteners, preservatives, flavors, colors, pulp, and thickening and clouding agents to restore the juice to its original expressed juice state, to compensate for seasonal or regional variations, or to create a unique juice based beverage.

Opposing comments stated that the terms "pure" and "natural" can be used in some contexts in which they would not be misleading. These comments argued that consumers read the terms "pure" and "natural" to mean that the product is made of natural ingredients such as fruit juices, water, natural sweeteners, and flavors. They recommended that labels bearing the terms "pure" and "natural" be evaluated on a case-by-case basis.

Several comments were of the opinion that use of a percentage to describe an undefined attribute on products required to bear a percent juice declaration could potentially be misleading to consumers. They stated that therefore, any use of "100 percent" on the label in conjunction with an undefined term should be prohibited unless the product is a full-strength (100 percent) juice product. However, these comments stated that this policy should not restrict use of a percentage declaration that is clearly defined as not being related to juice content, i.e., "contains 100 percent of U.S. Recommended Daily Allowance (U.S. RDA) for Vitamin C."

The agency advises that while there is no specific prohibition against the use of the terms "pure" and "natural," it has discouraged the use of these terms because they are ambiguous and may be misleading. For example, "orange juice," "pure orange juice," and "100 percent pure orange juice" are identical foods, but "pure" as applied to the food implies that other identical products are "impure" or "not pure" if they do not bear the same term on their label. The term "natural" is similarly ambiguous when applied to any food except flavors and flavorings.

The agency concludes that this rulemaking is not the appropriate vehicle to consider whether terms such as "pure" and "natural" should be permitted on juice product labels. The comments presented opinions on the word "pure," but they did not provide sufficient information on which to base a regulation. The term "natural" is included in another agency rulemaking. In the **Federal Register** of November 27, 1991 (56 FR 60421 at 60466), FDA published a proposal entitled "Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms" that included, among other things, a discussion of various aspects of defining the term "natural." A final rule based on that proposal is published elsewhere in this issue of the **Federal Register**. In that rulemaking, however, the agency decided not to define the term "natural."

However, FDA also concludes that the use of a percentage, particularly 100 percent, in conjunction with terms other than "juice," such as "pure" and "natural," on a beverage that is not full-strength juice can be misleading, particularly where the 100 percent figure appears near the name of the product but not in close proximity to a prominent declaration of the percentage of juice. On the other hand, FDA agrees with those comments that stated that statements clearly unrelated to juice content, e.g., "provides 100 percent of U.S. RDA of vitamin C," are not misleading.

Therefore, to clarify these matters, under sections 403(a) and 701(a) of the act (21 U.S.C. 371(a)), the agency is including in the final regulation a prohibition on the use of "100 percent" or any other percentage unrelated to juice content that could be misunderstood to represent the percent of juice in the beverage. This provision in the final regulation, designated new

§ 101.30(l), states: "A beverage required to bear a percentage juice declaration on its label shall not bear any other percentage declaration that describes the juice content of the beverage in its label or in its labeling (e.g., "100 percent natural" or "100 percent pure"). However, the label or labeling may bear percentage statements clearly unrelated to juice content (e.g., "provides 100 percent of U.S. RDA of vitamin C").

E. Calculation of Percentage Juice

1. Juice From Concentrate

The agency proposed that in enforcing the act and in ensuring that percentage juice declarations are truthful and not misleading, it would calculate the percentage juice from concentrate in a juice or juice beverage using the minimum Brix levels that were listed in proposed § 101.30(j)(1). (Because of revisions to the final regulation proposed § 101.30(j) is redesignated as new § 101.30(h)). In the July 2, 1991, proposal, the agency strongly recommended that manufacturers use this method in calculating the percentage juice from concentrate. The agency also advised that if the July 2, 1991, proposal were adopted, while manufacturers may use any appropriate alternate method, they should ensure that this alternate method produces similar results.

In the preamble to the July 2, 1991, proposal, FDA listed proposed minimum Brix values for a number of fruit and vegetable juice products and minimum anhydrous citric acid contents for two fruit juices, based primarily on data from the National Juice Products Association (NJPA) in December of 1989 and May of 1990 (56 FR 30452 at 30466).

FDA received comments on 13 of the 51 proposed minimum Brix values for 100 percent juice and comments regarding minimum Brix values for two other juice products not listed in the proposed regulation. Most comments claimed that one or more of the 13 values were too high and offered information or data to support their claims. Several comments simply objected to the proposed Brix values as being too high without suggesting more appropriate values. Brix data in the comments were provided in several forms: Individual values, ranges of values, monthly or yearly averages, and mean values with designated standard deviations. A presentation of the data submitted, and the agency's review and conclusions, follow.

a. Evaluation of Brix data in comments.

FDA acknowledges that much of the Brix data in agency files is old and may be out of date. The Brix data used in establishing the fruit or fruit juice content in the standards of identity for fruit butter and fruit jelly (§§ 150.110 and 150.140 (21 CFR 150.110 and 150.140)) were obtained from authentic fruit samples collected before 1940. Although the data were used for many years without question for fruit butters and fruit jelly, when these data were incorporated in the standard of identity for canned nectars, FDA received an objection that questioned the applicability of the single-strength juice values to canned nectars and suggested that they be reevaluated in light of current commercial practice in the manufacture of nectars. Thus, the standard for canned nectars (§ 146.113 (21 CFR 146.113)) was stayed in 1968 (33 FR 10713, July 27, 1968).

Differences in juice composition that result from factors such as horticultural practices, processing operations, and geographical origin, as well as the use of new varieties of certain species, may account for differences in Brix values obtained on juice products prior to 1940 and values obtained for fruit juices currently produced under current good manufacturing practice. In reviewing the data submitted in comments, FDA has consulted published references on juice composition, e.g., U.S. Department of Agriculture (USDA) Food Composition Tables (Handbook 8–9: Fruits and Fruit Products and Handbook 8–11: Vegetables and Vegetable Products) (Refs. 5 and 6). FDA has also reviewed Brix data in files that were used in support of existing standards of identity and data contained in published articles on juice research and composition. In instances where there are established values in standards of identity that appear to be too high compared to newer information, and the data submitted in support of lower values seem reasonable in light of this newer information, FDA has adopted a lower value in new § 101.30(h)(1). Where FDA has adopted a lower Brix value for 100 percent juice than is currently listed for the fruit juice in an existing standard of identity, FDA intends to consider revision of the standard of identity at a later date to make it consistent with the Brix value that the agency is adopting in this regulation.

b. Use of Brix data.

19. Several comments supported FDA's proposal to calculate the labeled percentage of juice from concentrate in a reconstituted juice or in a diluted juice beverage based on the minimum Brix standards. One comment expressed the opinion that the Brix concept represents the most workable method for accurately and consistently calculating the percentage of juice. A comment from the Government of Canada also expressed support for specifying minimum Brix values for use in calculating the percentage of juice included in diluted juice beverages and reconstituted juices. However, the comment stated that it does not support the proposed Brix values because they would effectively exclude Canadian products from the U.S. market. Other comments in the letter from the Government of Canada on specific juices are discussed below. One comment opposed the proposed method of calculating the percentage of juice based on minimum Brix values, established by regulation, instead of requiring the percentage of juice to be calculated in terms of the actual soluble solids content of the original juice. The comment maintained that use of the table of fixed Brix values in proposed § 101.30(j)(1) (redesignated as new § 101.30(h)(1)), which, the comment contended, contains values well below the Brix of sound ripe fruit, gives food processors a license to overstate the quantity of juice in their products.

FDA recognizes that when a minimum Brix value based on the mean or a range of values for a particular fruit or vegetable juice is established by regulation, there will always be some juices that will have Brix values above the minimum, and some juices that will be below the minimum because of natural variations in the source fruits and vegetables. The agency also acknowledges that, in some instances, producers of lower Brix juices will have to use more juice to meet the minimum soluble solids requirements for reconstituted full-strength juice. However, use of standardized Brix levels in preparing and labeling blended juice products and diluted juice products from concentrates will ensure that consumers obtain products with a reliably determined minimum juice soluble solids content. As a result consumers will be able to make meaningful value comparisons between brands of such products based on the labeled juice content. Use of actual Brix levels of the original juice used to manufacture the concentrates could lead to variations in the levels of soluble solids on labels of products that bear the same percentage juice declaration. Therefore, FDA is not modifying its proposed use of standardized minimum Brix levels to determine the percent juice in juice products made from

concentrate, as requested by the comment.

c. Approaches other than use of Brix.

20. One comment proposed an alternative to Brix calculation for percentage juice in the case of orange juice and other citrus juices that have been modified by the removal of the naturally occurring sugars that are then replaced partially or wholly by intense sweetening agents. The proposed method would use citric acid content or the ascorbic acid content consistent with FDA's proposal for lemon juice and lime juice.

The comment provided guide values of 8.0 grams per liter citric acid and 200 milligrams per liter ascorbic acid for orange juice as an alternative for the determination of percentage juice for orange juice with sugars removed and referenced methods for determination of the citric acid and ascorbic acid content ("RSK–Values, The Complete Manual, Guide Values and Ranges of Specific Numbers, Including the Revised Methods of Analysis," Verband der deutschen Fruchtsaftindustrie e.V., Bonn, 1987). However, the comment did not include any data to correlate and verify these values and methods as they apply to an "artificially sweetened, sugars-reduced orange juice."

The agency is not incorporating the suggested alternative method for determining the percentage of "juice" contributed by modified juices in which the native sugars have been removed and have been replaced wholly or partially by intense sweetening agents. As discussed in section II. F. of this document, these products are not considered to be juice. Under new § 101.30(h)(1), FDA is establishing minimum Brix values for fruit and vegetable juices based on the soluble solids content (i.e., primarily sugars content of the juice), with the exception of lemon juice and lime juice that are defined by citric acid content, for use in percent juice labeling. Therefore, such modified juices cannot be included in the percent juice calculation or depicted as juice in the vignette on a beverage. The description of the modification (e.g., "sugar-reduced orange juice") as part of the common or usual name of the product makes clear that the change in the product is such that it no longer purports to be juice. The product may substitute for juice, but it is not juice. Although the suggested alternative methodology may be useful for validating claims about modified juice products, the agency is not aware of acceptable methodology to confirm the content of any modified juice products, e.g., "reduced sugars" or "sugars removed" juice products.

d. Meaning of Brix standards.

21. One comment stated that from the proposed single-strength Brix standards, it is not clear whether the standards are intended to represent mean values, or whether they are minimum values. In some instances, e.g., in normalizing compositional data of juice concentrates, the comment stated, it may be appropriate to use mean values. In other instances, minimum values may be more appropriate, e.g., regulations for 100 percent fruit juice made from concentrate.

The agency advises that the Brix values set out in new§ 101.30(h)(1) are minimum values that are based on average values for the respective juice products. As stated in the preamble to the July 2, 1991, proposal, the purpose of establishing these Brix values for 100 percent juice is to provide a "minimum" acceptable level for determining whether a juice should be considered to be full-strength (56 FR 30452 at 30459).

e. How Brix values are set.

22. One comment stated that it is desirable to take a statistical approach in revising or establishing the Brix values. The comment stated that in some instances, it may be appropriate to use "mean" values, e.g., normalizing compositional data of juice concentrates; and in other instances, minimum values may be more appropriate, e.g., in establishing minimum Brix requirements to define 100 percent fruit juice from concentrate. The comment added that where minimum Brix values are appropriate, the minimum value could be one standard deviation below the mean if 66 percent confidence limits were applied, or two standard deviations if 95 percent confidence limits were thought to be more appropriate. For some juices, e.g., orange juice and apple juice, the comment maintained that there should be adequate data bases available for such statistical applications. For many commodities, the data will need to be developed. The comment also maintained that there needs to be agreement on the sample protocol for developing such data bases.

FDA agrees that a statistical approach should be used to establish the minimum Brix values when adequate data bases are available. However, because of the limited amount of data available to FDA for most juice products for which minimum values were proposed, a statistical approach could not be used. Where comments supplied Brix data in statistical terms, means and standard deviations, FDA used these data in evaluating the proposed Brix values and in some instances has incorporated these values in new § 101.30(h)(1). In other instances, FDA has adopted the Brix values established in the standards of identity for fruit products because they represent consensus values that are acceptable to both consumers and food processors.

Although the comment stated that there should be adequate data bases for orange juice and apple juice for statistical calculation to determine the minimum Brix value, no data bases for these juices were provided in the comment.

FDA agrees that a statistical analysis could be used to establish a Brix value for the single-strength juices. However, in the case of orange juice, the proposed Brix value of 11.8° for orange juice from concentrate is consistent with the Brix value established in the standard of identity for orange juice from concentrate (§ 146.145 (21 CFR 146.145)). In the absence of new data or information that demonstrates that the established Brix value is no longer representative of the soluble solids content of orange juice used to make frozen concentrated orange juice in this country, the agency has no reasonable basis to revise the Brix value for orange juice in new § 101.30(h)(1). A discussion on information received in comments on apple juice follows.

Because the Brix values represent minimum values, food processors are free to pack to higher soluble solids contents to meet consumers expectations when making juice products from concentrate. FDA points out, however, that should food processors use higher levels of soluble solids than is required by new § 101.30(h)(1) in reconstituting a juice to single-strength (100 percent juice) to meet consumer expectations for a sweeter juice, for example, FDA still considers the product to be 100 percent juice and not a higher percentage, such as 110 percent juice, when the additional soluble solids are the result of added juice.

23. Several of the comments cited the German RSK Brix values in support of the modifications that they suggested in the minimum Brix values listed in the July 2, 1991, proposal. One comment requested that these values be considered in establishing U.S. standards so as to achieve worldwide uniformity.

FDA agrees with the comment that the use of the German RSK Brix values may serve as useful guidelines in establishing Brix values in this country. The RSK values (termed Richwerte und Schwankungsbreiten bestimmter Kennzahlen or RSK–WERTE) are used by the German fruit juice industry as

reference points or guidelines for specified constituents in fruit juices. They assist food processors in determining whether fruit juices have been produced lawfully without adulteration. Factors influencing juice composition, such as growing region, variety, and production year, are considered in their establishment. Soluble solids content (Brix value) is one of the quality parameters defined by the RSK–WERTE guidelines. Other parameters include density, titratable acidity, sugars, acids, and amino acids. Mean values, standard values, ranges, and commentary are provided for each parameter.

A standard RSK value is usually a "minimum" or a "maximum" value, with data seldom falling above or below this value. In other words, the standard Brix value would be the minimum value in the range of values and not the mean or average Brix value. The mean RSK Brix value is not the arithmetic mean value but the value around which most of the values of industrially manufactured juice products congregate. RSK Brix values cited by the agency in this document are from "Adulteration of Fruit Juice Beverages," edited by S. Nagy, et al. (Ref. 7).

24. Several comments stated that the Brix calculation is only valid for juices to which sweeteners have not been added, and that other methods should be used to test for adulteration.

The agency agrees that the Brix calculation is only valid for juices to which sweeteners have not been added. Further, the Brix calculation to determine the percent juice content can only be used before sweeteners are added to the juice beverage in instances where the beverage is not 100 percent juice. The agency does not use Brix measurements by themselves to test for adulteration. Brix measurements can be used in conjunction with the results of other analytical methodologies and inspectional observations to support charges of product adulteration.

25. Other comments stated that the percent juice declaration should be calculated on weight/weight basis utilizing reference Brix levels because that is the manner in which the concentrates are sold.

The agency disagrees with these comments. The purpose of the regulation was not to prescribe how concentrates should be sold but to ensure that when reconstituted juice or juice from concentrate is used to produce a single-strength juice or a multiple-juice beverage, there is a standardized criterion for determining the percentage juice in the finished product. The standardized criterion allows consumers to make price and value comparisons across the range of juice beverages. Because the juice beverages are sold on a single-strength volume basis to the consumer, and percentage juice declaration is based on this standardized criterion, it would be inappropriate to utilize a weight/weight basis.

26. One comment requested that manufacturers be allowed to reconstitute concentrated juice back to the Brix in original expressed juice if the Brix of the expressed juice is known, and records are kept for the purpose of percent juice calculation and declaration. For example, expressed apple juice with a Brix value of 9.0° could be reconstituted and declared as 100 percent apple juice even though the Brix value provided by proposed § 101.30(j)(1) for 100 percent apple juice from concentrate is 12.5°.

The agency made an exception to the use of Brix values in calculating percentage juice for expressed juices because these juices have a naturally occurring range of Brix beyond the control of the manufacturer. Similarly, in consideration of existing industry conditions, the agency's decision to use Brix value for calculation of percent juice from concentrate was derived from the industry practice of commingling juice concentrates whose original Brix is unknown.

The agency differentiated between percent juice calculation for expressed juices and juice concentrates on the basis of industry practice and out of fairness to the expressed juice segment of the industry, which is subject to the vagaries of nature. While the agency does not object to reconstituting of concentrated expressed juice to the Brix level of the original juice if that Brix value level is known, the agency finds that once a juice has been concentrated, for the purpose of percent juice calculation and subsequent percent juice declaration, the Brix value as prescribed in the regulation must be used. Use of the same minimum Brix value level in labeling juice content for a specific juice from concentrate will enhance consumer comparisons between competing brands of that juice.

Therefore, the agency is denying the comment's request to reconstitute juice to its original Brix as expressed juice and declare it as 100 percent juice from concentrate although it does not have the minimum Brix value as prescribed in the regulation. This policy is consistent with Brix value requirements established in standards of identity for juice products made from concentrate.

f. Provisions to revise Brix values.

27. Many comments urged FDA to establish a mechanism to amend the table of Brix values because it may be necessary to include juices in the table that are not included now, and revised brix values may be needed in response to changes in technology, new crop varieties, and other matters.

The agency agrees that periodic amendments to the Brix value table will be necessary. However, the agency believes that adequate provisions exist in the regulation for citizen petitions, (§ 10.30). Therefore, the agency is not proposing any additional mechanisms to amend the Brix value table as adequate provisions already exist.

g. Individual juices.

28. Many comments submitted information to revise 1 or more of 13 proposed Brix values for various juices, such as apple, apricot, carrot, celery, cherry, grape, guava, lemon, orange, passion fruit, peach, pear, and raspberry (red). One comment submitted data to establish a Brix value for pomegranate juice.

i. Apple juice.

In the preamble to the July 2, 1991, proposal, FDA specifically requested comment on the proposed Brix value for apple juice, 12.5°, which the agency selected using values in the lower portion of the range of Brix values available to the agency (56 FR 30452 at 30459). NJPA had suggested that FDA adopt a Brix value of 11.0° for apple juice, based on USDA standards for grades (7 CFR 52.301 through 52.301) for U.S. Grade A apple juice.

Several comments contended that the proposed Brix value of 12.5° for apple juice is too high and urged FDA to adopt a Brix value of 11.0° as originally submitted by NJPA in comments to the agency in December 1989 and May 1990. In a comment on the July 2, 1991, proposal, NJPA stated that its suggested Brix value of 11.0° for apple juice reflects a consensus not only of NJPA's member companies but also of members of the National Food Processors Association (NFPA), with which NJPA coordinated the adoption of its December 1989 voluntary percent juice labeling policy. NJPA also pointed out that much of the concentrated apple juice used by its members is imported from foreign countries, and that any Brix value established should take into consideration the Brix value of juice produced in these countries. It noted that over 35 percent of all imported apple juice products during 1990 cam from Argentina, and that the majority of the remainder came from European Community (EC) countries. According to the comment, there is no enforceable minimum Brix value requirement for

single-strength apple juice in Argentina but, in Germany and EC countries, the minimum Brix value for single-strength apple juice is 11.18°. The comment also noted that the Codex Alimentarius Commission has recommended a Brix value of 10.0° for reconstituted apple juice.

NJPA stated that Brix data from a major U.S. processor for juice expressed from apples grown in the State of Washington reflects an average Brix value of 11.58°, with a monthly range of 10.38° to 12.62° Brix (n=51) for two processing seasons (1989 to 1990 and 1990 to 1991). It claimed that similar data obtained from Michigan for the period November 1986 through November 1990 showed that monthly average Brix values ranged from 9.6° to 13.09°. The mean of the monthly Brix averages in Michigan for the 4-year period was 11.47°, with a standard deviation of 0.876°. The comment pointed out that the average Brix would have met FDA's proposed Brix value of 12.5° in only 6 months of the 4-year period, while the suggested Brix value of 11.0 would have been met in 26 months during the 4-year period. According to the comment, average monthly Brix values obtained from New York, for the period January 1987 through July 1991, ranged from a low of 9.5° to a high of 11.8°. The comment noted that, generally, juice from apples grown in the northwestern region of the United States has a higher average Brix and a lower acid content than juice produced from apples grown in the midwestern and eastern regions.

A comment from one firm noted that production records from their Austrian supplier showed that the Brix value of Austrian apple juice ranges from about 10° to 12° over the apple juice processing season. Another of the firm's suppliers provided information on apple juice from Germany, showing that in September the Brix value range of apple juice is from 9.8° to 11.0°, in October 10.5° to 11.5°, and in November 11.5° to 12.3°. It noted that most of the apple juice from Germany is processed during September and October. The comment recommended that FDA establish a minimum Brix value of 11.0° for apple juice. To establish a higher value, the comment added, would be to establish an artificially high Brix level that would impose an unfair trade barrier.

A comment suggested a minimum Brix value of 10.5° for apple juice. The comment noted that minimum Brix level for U.S. Grade B apple juice is set at 10.5° in the USDA standards for grades for apple juice (7 CFR 52.308). The comment maintained that the proposed Brix value of 12.5° would effectively exclude Canadian products from the U.S. market.

Other comments supported a Brix value of 11.5° for apple juice. One comment recommended a minimum Brix of 11.5° for apple juice reconstituted from apple concentrate, based on available data including records collected at 21 apple processing facilities, operated by 13 companies. According to the comment, the average Brix level reported by 17 of 21 plants fell in the range of 11.1° to 11.8°, with 11 of the plants reporting data in the 11.3° to 11.7° Brix range. Thus, the comment concluded, a Brix value of 11.5° is more representative of the Brix level of expressed apple juice than is the Brix value of 12.5° proposed by FDA.

Several comments contended that increasing the Brix value of apple juice to 12.5° would result in a Brix higher than normal for the expressed juices commonly used and would force food processors to produce a product that is incompatible with consumer expectations. They maintained that apple juice at a Brix of 12.5° is too sweet, especially in the Northeastern region where the taste preference for apple juice is a tart product (lower Brix/acid ratio). One comment stated that the proposed higher Brix value level of 12.5° would result in a 9 percent increase in soluble solids content over that of the currently marketed apple juice which contains from 11.0 to 11.5 soluble solids. It estimated that the increase would cost consumers of reconstituted juice products approximately $25 million annually. It further contended that the cost of some single-strength apple juice that contains added apple juice concentrate to achieve a preferred flavor profile would be increased as well if a Brix value of 12.5° is adopted. Another comment stated that changing the Brix from 11° to 12.5° would increase the ingredient cost by 14 percent and would further serve to put the product out of reach of many mothers who have been using apple juice for their babies.

After reviewing the data on the soluble solids content of apple juice submitted in the comments on the July 2, 1991, proposal, FDA has reconsidered its position regarding the proposed Brix value of 12.5° for 100 percent apple juice from concentrate. Data provided by industry in comments showed that mean Brix values for individual lots of apple juice range from 8.9° to 13.4°, with summary mean values (averaged monthly and yearly mean values) ranging from 11.0° to 11.58. NJPA pointed out that the minimum RSK Brix of apple juice is 11.18° and recommended that FDA adopt a minimum value of 11.0°. The agency notes, however, that the RSK mean Brix value for apple juice is 12.06°. With respect to the comment that requested that FDA adopt the minimum Brix of 10.5° for U.S. Grade B apple juice, FDA believes that this value is too low and does not reflect average Brix values of apples produced and processed in this country, as evidenced in the comments cited above.

In response to the comment requesting adoption of the USDA U.S. Grade A Brix value of 11.0° for apple juice, FDA points out that the USDA lowered the Brix value of U.S. Grade A apple juice from 11.5° to 11.0° in response to a request from the Processed Apple Institute (47 FR 5875, February 6, 1982). At that time, USDA stated that the change was being made to include differences in growing conditions in various parts of the country, increased use of more varieties of apples in the manufacture of canned apple juice, consumer preference for a less sweet product, and differences in processing techniques. However, comments summarized in the USDA rule noted that northwest apples have a Brix average of 12.5° or higher, to which USDA responded that the Brix requirements provided for in their standards for grades are minimum standards for each grade. It also stated that lowering the Brix by one-half of a degree will accommodate apple processors using varieties that have lower soluble solids compared with other varieties processed in other parts of the country.

FDA points out that the USDA standard (7 CFR 52.308), referenced by the comments, applies to canned single-strength apple juice, in which no more than one-fourth of the juice may have been concentrated. In the case of the USDA standard in 7 CFR 52.6221 et seq., for frozen concentrated apple juice, the minimum Brix value for a concentrate that is to be diluted 1 plus 1 is 22.9°. Such a product on dilution would have a Brix value of approximately 11.45°.

FDA acknowledges that there are differences in Brix values of apples depending on geographical growing regions, and that consumers may have developed certain preferences based on these regional differences. However, FDA believes that it should set the minimum Brix for apple juice at a level that is toward the middle of the range of Brix values for apple juice in order not to penalize producers of freshly expressed apple juice, which may have a higher solids content, to the benefit of those producers who sell reconstituted

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or diluted apple juice products. It would also be fairer to consumers because they would be assured of getting reconstituted juices that more closely resembled the juice from which it was made. Consumers who prefer a less sweet juice can dilute the juice further by adding water. However, consumers who find that a reconstituted juice tastes weak because of a lower apple juice soluble solids content cannot rectify this condition by adding more apple juice solids.

Although most of the apple juice may be sold at Brix levels ranging from 11.0° to 11.5°, according to industry-based standards established by USDA, the agency believes that in establishing a minimum value for reconstituted apple juice or diluted apple juice, the minimum should reflect the average Brix value of expressed apple juice. Thus, consideration must be given to the higher Brix apple juice produced in the northwestern areas of the United States as well as to the lower Brix value juices produced in the midwestern and eastern areas. As noted in the July 2, 1991, proposal, a study by Mattick and Moyer (Ref. 2) of the Brix of 93 authentic apple samples collected from many different areas of the country and representing many apple varieties demonstrated average Brix values of 12.60°, 12.80°, 12.83°, and 12.74° (56 FR 30452 at 30459). The German RSK value noted in the comment provides for a range of Brix values from 11.18° to 14.01° with a mean Brix value of 12.08°. In view of these higher values, FDA believes that the minimum Brix value of 11.0° suggested by several comments from industry is too low, and that a minimum Brix value of 11.5° for apple juice is more appropriate because it takes into account the apples with the higher Brix values. Further, it is consistent with the Brix of reconstituted apple juice made in compliance with the USDA standard for grades for frozen concentrated apple juice. It also represents a value on the low side of the mean Brix value established for German apple juice, as well.

Accordingly, FDA has revised the minimum Brix value for apple juice by reducing it from 12.5° to 11.5°.

ii. Apricot juice.

FDA proposed a minimum Brix value of 14.0°, based on the data submitted by NJPA. According to NJPA, this value was derived from the USDA File code 147–A–2 (March 1988), Inspection of 50 percent Juice Drinks and Juice Drink Products under the Child Nutrition Labeling Program (Food and Nutrition Service).

One comment from a fruit and vegetable processing and marketing cooperative stated that their analyses of apricot juice over the period 1986 to 1990 showed an average Brix of 11.7° with a standard deviation of 0.8°. This average value was derived from a total of 502 measurements. The comment stated that it believed that the data were adequate because they include five different growing seasons, several varieties, and various weather conditions and cultural practices.

FDA notes that a National Canners Association report on the Brix values of authentic samples of apricots, as reported by Nelson and Tressler (Ref. 10), lists the Brix values of whole Blenheim apricots and Tilton apricots as ranging from 10.7° to 17.1°, with means of 14.1° for Blenheim apricots (n=6) and 12.6° for Tilton apricots (n=6). In this same reference, the Brix value of whole apricot pulp was 11.5°, and apricot nectar was 14.3° (n=6 in both cases). Thus, the Brix value of apricot juice appears to be dependent on the source of the extracted juice used in the analysis. Based on these data, FDA finds that the suggested Brix value of 11.7°, as provided in the comment, is reasonable. Use of the lower Brix value would permit use of an important variety, Tilton, which has a much lower Brix value than the proposed Brix value, 14.3°, from the canned nectars standard. In addition, the lower value would be representative of the Brix values currently encountered in industry as cited in the comment. Therefore, FDA is incorporating the Brix value of 11.7°, as suggested by the comment, in new § 101.30(h)(1) in place of the proposed Brix value of 14.3°. Because this amendment is based primarily on a single submission, FDA requests comments and data submitted in the form of a petition to amend this regulation if data are available that would support a different and more appropriate value.

iii. Carrot juice.

FDA proposed a minimum Brix value of 11.0° for carrot juice based on the NJPA Brix value submitted in December 1989. Subsequently, in May 1990, NJPA submitted a lower Brix value of 9.0° for carrot juice, based on data from NFPA. NJPA did not provide any justification as to why this value was more appropriate than the earlier submission. Thus, FDA published the Brix value of 11.0° because it was based on Government data rather than solely on industry practice. FDA specifically sought comments on the appropriateness of the proposed value and also requested justification for any suggested lower number.

Several comments were received on the Brix value of carrot juice that claimed that the proposed Brix level of 11.0° was too high. One comment provided 31 average Brix values (one average for each date of measurement) for the carrot juice produced during the period January 31, 1991, through June 12, 1991. The overall average Brix level from these data is 7.0° with a range of 5.4° to 8.0°.

Later, a trade association provided additional information concerning average Brix levels for carrot juice in a memorandum, dated January 22, 1992. This information consisted of the following: (1) An average Brix value of 8.6°, with a Brix value range from 7.0° to 9.3° and a standard deviation of 0.5°, based on 72 measurements, for the period of January 1, 1990, through December 12, 1990; and (2) an average Brix value of 8.1° with a Brix value range from 6.9° to 9.8° and a standard deviation of 0.5°, based on 39 measurements during the period of January 1, 1991, through July 31, 1991. No specific value was suggested for a minimum Brix for carrot juice in this comment.

A comment from a manufacturer of concentrated carrot juice recommended a Brix value of 8.0° for the reconstituted carrot juice. The comment provided information on daily average Brix value levels of freshly expressed carrot juice (each day's volume was between 30 to 50 tons) showing that: (1) The daily Brix average values (n = 31) ranged from 5.4° to 8.0° with an overall average of 7.0° during the period of January 31, 1991, through June 12, 1991, and (2) the average daily values (n = 20) ranged from 6.9° to 8.3° with an average of 7.6° during the period of October 1, 1991, through January 21, 1992. The comment stated that the firm has processed in excess of 3,000 tons of carrots for juice and concluded that the values submitted are indicative of the true Brix value of single-strength carrot juice.

Only two comments provided data on the Brix of carrot juice. The average Brix values from both sources and the industry recommended Brix are considerably lower than the proposed Brix of 11.0°. The Brix averages of the four data sets received are 7.0°, 8.6°, 8.1°, and 7.6°, with an overall average Brix value of 7.8°. The proposed Brix value of 11.0° was based on data from USDA Handbook 8–11, which lists 11.12 percent of total solids in canned carrot juice, of which 9.9 percent is total carbohydrate (Ref. 6). Because the Brix measures soluble solids content, and not all of the total solids or total carbohydrate content of carrot juice is expected to be soluble (e.g., insoluble cellulose or fiber), the use of these values as the Brix value would result in

a figure that is higher than would result from measurement of the Brix by refractometer. Therefore, based on this information, FDA is adopting the value of 8.0° in new § 101.30(h)(1). The Brix value of 8.0°, set out in the regulation below, was recommended by the manufacturer of carrot juice and is very close to the calculated overall average Brix in the data supplied to the agency in the comments.

iv. Celery juice.

FDA proposed to establish a minimum Brix value of 4.5° for celery juice based on the NJPA Brix value submitted in December 1989. Subsequently, in 1990, NJPA submitted a lower Brix value of 3.6° for celery juice, based on data from NFPA. NJPA did not provide justification as to why this value was more appropriate than the earlier submission. As in the case with carrots, FDA published the higher Brix value of 4.5° because it was based on Government data rather than solely on industry practice.

Two comments received in response to the July 2, 1991, proposal claimed that the proposed Brix value level of 4.5° for celery juice, based on NJPA's December 1989 submission to the agency, was too high, but these comments did not provide any data in support of the claim. One of these comments, from a trade association, stated that members had expressed concern over the proposed minimum level of 4.5°, and that it is soliciting data on levels for celery juice. However, no data were received on the Brix of celery juice from the trade association during the comment period.

A comment from a food processor recommended a Brix value of 3.0° for reconstituted celery juice. The comment stated that daily average Brix levels of freshly expressed celery juice, during the period of April 9, 1991, through May 10, 1991, ranged from 2.95 to 3.4° (n=10), with an overall Brix value average of 3.1°; and for December 23, 1991, the 1-day average Brix value was 2.64°. The mean of the 11 average Brix values is 3.09°.

NJPA suggested Brix value of 4.5° for celery juice was based on information from USDA Handbook 8–11, which reflects the total solids content of celery, and thus may be too high. The data on the Brix of celery juice from the food processor and NJPA's May 1990 submission also suggest that proposed minimum Brix value of 4.5° is too high. USDA Handbook 8–11 lists the total carbohydrate content of celery as 3.63 g/100 g (per edible portion), of which 0.80 g is crude fiber (Ref. 6). Thus, the soluble carbohydrates (sugars) content would comprise approximately 2.83 percent by weight. FDA recognizes that the other constituents may affect the Brix determination by refractometer, and that the use of the soluble solids, determined by difference, from Handbook 8–11 can only serve as a rough approximation. However, in view of this calculation and the data supplied by the food processor, both values supplied by NJPA appear to be too high for celery juice. Because neither NFPA or NJPA provided a basis for the Brix value of 3.6° for celery juice, FDA concludes that for the purpose of labeling the content of celery juice from concentrate that a more appropriate Brix value is 3.1°, based on the mean of the data submitted by the food processor. Therefore, FDA is revising new § 101.30(h)(1), accordingly.

v. Cherry juices.

FDA proposed a single Brix value of 14.0° for juice from both sour cherry and sweet cherry varieties, based on the data submitted by NJPA.

A comment from a firm that processes juice beverages stated that it has encountered large variations in Brix between the varieties of sweet cherries and sour cherries, and that the single-strength Brix values should reflect these differences. The comment maintained that the proposed Brix value of 14.0° is a compromise that does not reflect the actual situation for either cherry classification. In support of this contention, the comment included summary data from its U.S. supplier for dark sweet cherries and for red sour cherries obtained from the Pacific northwest.

Data from the supplier for the dark sweet cherries, collected during the years 1982 to 1990, showed a mean Brix value of 20.0°, a median of 19.9°, with a standard deviation of 3.0° (n=120) and a Brix value range from 14.0° to 30.0°. Using these data, the comment suggested that the minimum Brix value for dark sweet cherries be set at one standard deviation below the mean Brix value or 17.0°.

With respect to the red sour cherries, the comment supplied data for the years 1983 to 1990 that showed a mean Brix value of 15.8, a median of 14.0°, with a standard deviation of 3.4° (n=23) and a range from 11.2° to 22.9°. Using these data, the comment suggested that the minimum Brix value for sour cherries be set at one standard deviation below the mean Brix value or 12.4°. The comment also supplied data for five other mean Brix values or ranges for red sour cherries. These Brix values were for products obtained from Germany, Austria, and the United States, and ranged from a low Brix value of 10.0° to a high Brix value of 13.0°. This comment also pointed out that the German RSK Brix values (Ref. 7) for sour cherry juice are as follows: 14.71° mean Brix value, 12.36° minimum Brix value, and a Brix value range of 12.36° to 19.30°.

The comment also noted that food processors generally do not find that sweet cherry and sour cherry varieties are interchangeable in their beverage products.

FDA concurs with the comment that it should establish specific Brix values for sweet cherry and for sour cherry varieties because of the differences between the two types of cherries. Sweet cherries are higher in sugar and lower in acid than sour cherries. Accordingly, FDA has amended new § 101.30(h)(1) to reflect the differences, based in part of the data supplied by the comment.

In making this determination, FDA compared the suggested Brix value of 12.4° for sour cherries to data collected by FDA in 1962 (Ref. 11) for red sour pitted cherries that show a mean Brix value of 14.3° (n=15, std. dev. = 0.96° and range = 12.7° to 16.0°). FDA believes that the suggested Brix value of 12.4° may be too low in view of the FDA data, the median value of 14.0° cited by the comments and the RSK mean value, 14.71°. In keeping with establishing Brix values close to the mean Brix value, but in the lower portion of the Brix range, FDA believes that a more appropriate Brix value for sour cherries is 14.0°, as proposed. This value is slightly lower than the RSK mean value, the mean from the FDA data, and the mean value submitted by the comment. It is also consistent with the median value for sour cherries submitted in the comment. Therefore, FDA is retaining the proposed Brix value of 14.0° for sour cherries in new § 101.30(h)(1).

In the case of sweet cherries, FDA compared the suggested Brix value for dark sweet cherries of 17.0° (mean=20°, median=19.9°, std. dev.=3°) to data collected by FDA in 1962 on authentic sweet cherries (Ref. 11) that show a Brix range of 18.0° to 21.9° for sweet cherries (n=3). Because the mean values from the comment and the FDA data, as well as the median value supplied by the comment, cluster around 20.0°, the agency believes that the Brix value of 20° is more representative of the Brix value of sweet cherries than is the value of 17.0° suggested by the comment or the value of 14.0° for all types of cherries proposed by FDA. Therefore, FDA is modifying § 101.30(h)(1) to include a Brix value of 20.0° for sweet cherries.

FDA notes that the new Brix values are inconsistent with the single

requirement established for cherries in the standard of identity for fruit jelly, i.e., 14.3°, the reciprocal of the factor, 7, in § 150.140(b)(1) (21 CFR 150.140(b)(1)). The information that FDA has received suggests that there may be a need to revise the standard of identity for fruit jelly to reflect the separate values for the two classes of cherries, sour cherries and sweet cherries. In consideration of amending the standard of identity for fruit jelly, FDA requests information as whether substantial amounts of sweet cherries are being used in the manufacture of fruit jelly, and whether it should incorporate a specific value for sweet cherries in the standard.

vi. Coconut juice.

In the July 2, 1991, proposal, FDA stated that it has no data to support a specific Brix level for juice from coconut and requested comments on, and data for, an appropriate Brix level. The agency also noted that there are two portions of the coconut that can conceivably be used to produce a juice, i.e., the coconut water (liquid from coconut) and the coconut meat. FDA asked for information on the feasibility of using both portions of the coconut to produce juice and comments on whether there should be one or two Brix value levels for coconut.

According to one comment, there are no data to support a specific Brix value level for juice from coconut. The comment also noted that the method used for determining the Brix value of other juices may be inappropriate for use with coconut juice because of coconut juice's fat and oil content and their effects on refractometer readings. The comment stated that when data become available that might be useful to FDA in establishing a Brix or other value for determining what constitutes 100 percent coconut juice, it will submit such data.

In the absence of data on the soluble solids content of single-strength coconut juice, FDA is not establishing a minimum value for the food. Diluted or blended beverages made with coconut juice should be labeled with the percentage of coconut juice based on the content of the full-strength juice used. If made from coconut juice concentrate, the dilution should be based on the composition of the juice used in making the concentrate.

vii. Grape juice.

NJPA submitted a Brix value of 16° for grape juice in December 1989, based on information obtained from the Concord Grape Association. Subsequently, in May of 1990, NJPA suggested a lower Brix value of 13° based on the USDA File code 147–A–2 (March 1988). FDA proposed the higher Brix value of 16° for grape juice and solicited comments on the appropriate Brix level.

A comment from NJPA supported the proposed Brix value of 16.0° for grape juice. The comment stated that the higher Brix level for single-strength grape juice, recommended in its May 1990 comments, was based on comments it received from NFPA and the Concord Grape Association. NJPA stated that this level is the appropriate level.

A comment from a distributor and processor of juice products stated that in this country, no one in the industry is using a Brix level of 16.0° for grape juice, as set out in proposed § 101.30(j)(1), and urged that the final rule establish a minimum Brix level of 13.0° for single-strength grape juice. Citing two Federal regulations, the comment argued that FDA already recognizes 14.3° as the appropriate Brix value for grape juice in the standard of identity for fruit jelly in § 150.140, and that USDA uses a Brix value of 13° in the USDA standards for grades for frozen concentrated sweetened grape juice in 7 CFR 52.2460(b)(1) which, the comment maintained, is closer to reality.

FDA disagrees with this comment. The comment from the juice distributor cited the value for grape juice in USDA grade standard for frozen concentrated "sweetened" grape juice (7 CFR 52.2451 through 52.2464). FDA does not consider this Brix value to be applicable in defining the appropriate Brix for 100 percent grape juice. The USDA standard in 7 CFR 52.2452(a) states that not less than 50 percent of the total soluble solids of the finished concentrate shall be derived from Concord type grapes of the Labrusca species. In 7 CFR 52.2453, USDA requires a minimum Brix value of the finished concentrate including added sweetening ingredients to be 24.8° when the concentrate is made to be diluted 1 to 1 before consumption. The standard further states that in grading the prepared "grape juice beverage" from frozen concentrated sweetened grape juice, the Brix value of the beverage is not less than 13.0°. This "beverage" is the sweetened diluted grape juice product and thus is not relevant in determining the Brix of unsweetened, undiluted grape juice.

FDA notes, however, that the current USDA standards for grades for canned grape juice, in 7 CFR 52.1341–52.1351, list Brix values for two types of "unsweetened grape juice." Type I juice is from the Concord type grapes of the Labrusca species (slip skin varieties), and type II juice is from any type of grape other than the Concord type. The standard requires a minimum Brix value of 15.0° for both types of Grade A unsweetened grape juice and a minimum Brix value of 14.0° for both types of U.S. Grade B unsweetened grape juice. When the canned grape juice is sweetened, the minimum Brix value for each grade is increased by 2° to 17.0 and 16.0°, respectively (7 CFR 52.1350(a) and (b)).

The agency recognizes that much of the grape juice in the marketplace may have been sweetened or diluted because the strong and somewhat astringent flavor of freshly expressed grape juice may not appeal to some individuals. However, consumers have a right to know when the juice has been sweetened or diluted. Thus, FDA must establish a minimum Brix for the unsweetened full-strength grape juice to serve as the basis for the percent juice declaration on diluted juice beverages and reconstituted grape juice products.

FDA notes that the proposed Brix value of 16.0°, in accordance with the NJPA submission, was based on information from the Concord Grape Association. This value is also supported by information in the literature. Data reported by C.S. Pederson on grape juice support that the Brix value of the juice is around 16° for *Vitis labrusca* (Concord grapes) (Ref. 10). Average soluble solids levels for Concord grapes were 15.1, 16.4, and 16.7 for three regions in New York State in a 1949 publication by Robinson, et al., cited by Pederson (Ref. 10). The ranges for these three average Brix values were 12.9° to 17.8°, 13.1° to 19.5°, and 22.7° to 20.0°, respectively. Pederson also stated that nearly all grape juice prepared in the United States is from Concord grapes. The German RSK minimum Brix value for grape juice is 15.88°, based on a range of 15.88° to 19.30° and a mean of 17.03° (Ref. 7).

Based on these observations, FDA concludes that the minimum Brix value for grape juice should be at least 16.0°. Therefore, FDA is retaining the proposed Brix value of 16.0° for grape juice in new § 101.30(h)(1).

According to one comment, approximately 20 million gallons of 68 degree Brix grape juice concentrate (worth $130 million) is used annually in juice blends. The comment stated that because much of the juice is used at the 13° to 14° Brix level, an increase in the Brix level to 16.0° for purposes of juice percentage declaration, would have devastating economic effects. At an average cost of $6.50 per gallon, the comment claimed, this would represent a loss of $32.5 million which when passed on to consumers would become

much larger. The comment further stated that calorie conscious consumers will shy away from higher Brix juices in favor of others with lower Brix levels. Thus, a Brix value of 16.0° could also result in substantial losses in market volume that would be impossible to calculate.

FDA does not agree with the cost analysis in the comment. If the minimum Brix value is set at a higher level than food processors are currently using, food processors can still maintain the same diluted juice blend formulations. They simply will have to label the percentage of juice in the beverage appropriately.

viii. Grapefruit juice.

FDA proposed to adopt a minimum Brix value of 10.0° for grapefruit juice. This value was submitted by NJPA in December 1989 and is the same as that established in the standard of identity in § 146.132 (21 CFR 146.132) for grapefruit juice made from concentrated grapefruit juice exclusive of any added sweeteners.

A comment from a foreign government expressed support for a minimum Brix value of 9.0° for fresh or reconstituted grapefruit juice. The comment stated that this value would be consistent with the USDA standards for grades for unsweetened U.S. Grade A and U.S. Grade B grapefruit juice (7 CFR 52.1228, Table I).

FDA notes that the Brix value of 9.0° for fresh single-strength grapefruit juice is not applicable to "grapefruit juice from concentrate" (i.e., reconstituted grapefruit juice) in the United States or for use in calculating the percentage of juice contained in a juice blend in accordance with new § 101.30(h)(1). The standard of identity for grapefruit juice in § 146.132, as noted above, and the USDA standards for grades for grapefruit juice in 7 CFR 52.1228 (Table II, U.S. Grade A and U.S. Grade B), list a Brix value of 10.0° for unsweetened grapefruit juice from concentrate. The Brix value of freshly expressed grapefruit juice is not specifically designated in the standard of identity nor in the regulation (new § 101.30(h)(1)) set forth below. The Brix value for freshly expressed grapefruit juice is the Brix of the particular lot of grapefruit juice, before the addition of any water, sweetener, or any other additives, as determined by refractometer and corrected for acidity in accordance with § 146.132(a).

FDA is not revising the proposed Brix value of 10.0° for grapefruit juice because it was established by formal rulemaking (47 FR 43364, October 1, 1982). At the time that FDA adopted the standard, citrus processors and growers indicated that the preponderance of grapefruit juice produced in the United States contains, on average, 10.0 percent soluble solids or greater. Comments on the proposed standard of identity at that time also maintained that to establish a minimum soluble solids content of 9.0 percent would be to allow dilution of the finished product to a level substantially below that of the juice from the grapefruit fruit from which the concentrate is made. Therefore, FDA is adopting the 10.0° Brix value as proposed.

ix. Guava juice.

FDA proposed a minimum Brix value of 7.7° for guava juice, as suggested by NJPA. This value is consistent with the Brix value in the standards of identity for canned nectars (§ 146.113 and fruit jelly (21 CFR 146.140), the U.S. Customs Service requirements (19 CFR 151.91), and USDA File code 147–A–2 (March 1988).

One comment stated that using a statistical approach, it had calculated a standard Brix value of 6.6° for guava juice. The comment explained that its Brix data (mean of 7.1°, standard deviation of 0.5, a minimum of 6.0 and a maximum of 8.0°, median 7.1°, 20 data points, and mean minus 1 standard deviation to yield 6.6°) came from a single supplier of Hawaiian guava juice, who forwarded the weighted mean Brix values for each month's production. Using these data, the comment recommended a Brix value of 6.6° as the minimum level for a single-strength guava juice.

FDA has been unable to corroborate the suggested lower Brix value for guava juice in the published studies. FDA notes that one reference states that the Brix of guava averages around 9° (Ref. 12). Another reference lists soluble solids for the fruit from selected Hawaiian guava seedlings, which range from 8.0 to 11.5° Brix, and total soluble solids contents that range from 7.80 to 10.53 percent (n=10)(Ref. 10). In view of the published data on the Brix value of guava juice, FDA is adopting the proposed Brix value of 7.7°, which reflects FDA and U.S. Customs Service regulations, as well as USDA specifications. FDA recognizes that this value is higher than the mean and median in the comment's data, but the Brix published in the literature support a higher value than that suggested by the comment.

FDA is open to submission of information on the appropriateness of this value for 100 percent guava juice as a basis of a proposal to amend the standards of identity for fruit butter and fruit jelly. Any petition submitted to amend the fruit butter or fruit jelly standards (§ 150.110 (21 CFR 150.110)) and § 150.140) should be accompanied by data representative of the varieties of guava used in the manufacture of these products, as well as data on possible effects of factors such as maturity, growing conditions, and processing on the Brix of the fruit.

x. Orange juice.

FDA proposed a Brix value of 11.8° based on the requirement in the standard of identity for orange juice from concentrate in § 146.145. This value is also consistent with the Brix value submitted by NJPA.

A comment from a foreign government opposed the proposed Brix value of 11.8° for reconstituted orange juice and suggested a minimum Brix value of 9.7°. The comment stated that its suggested value would be consistent with the regulation in that country which establishes a minimum Brix value of 9.7° for orange juice (B.11.128 Food and Drugs Regulations, Canada).

FDA is not making the requested change. FDA notes that the Brix value of 11.8° set forth in new § 101.30(h)(1) for orange juice is the same as that established in the standard of identity for orange juice from concentrate in § 146.145. This value was established after a public hearing (28 FR 10900, October 11, 1963), by formal rulemaking, and represents a consensus of what interested parties believed to be appropriate at the time. A Brix value of 11.8° seemed reasonable and practical because it was equivalent to the approximate soluble solids content of reconstituted orange juice made in the home by consumers by diluting frozen concentrated orange juice. Frozen concentrated orange juice (§ 146.146 (21 CFR 146.146)) is generally made to 42° Brix and is diluted before consumption by adding 3 parts water, such that the resulting Brix value ranges from not less than 11.8° to 12.4°. FDA sees no reason for different values in the standard of identity for orange juice from concentrate and the regulation for defining "100 percent juice" for percent juice labeling purposes in new § 101.30(h)(1). Therefore, FDA is not revising the minimum Brix value of 11.8° for orange juice in new § 101.30(h)(1), as requested by the comment.

xi. Passion fruit juice.

NJPA suggested a Brix value of 12.0° for passion fruit juice based on the USDA File code 147–A–2 (March 1988). However, FDA proposed a minimum Brix value of 14.5° based on the Brix of passion fruit juice in the stayed canned nectar standard of identity (§ 146.113). FDA noted the variation in the two Federal specifications and expressed the

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opinion that if there was justification for the lower suggested value, that it would be forthcoming in comments on the July 2, 1991, proposal.

A comment from NJPA stated that its original May 1990 suggestion of 12.0° as the minimum Brix value for passion fruit juice was based on a USDA data base, and that it has been unable to locate any other differing data except for the German RSK "guide" value for passion fruit juice of 13.5°. Noting that the FDA proposed Brix value of 14.5° was based on the canned nectar standard in § 146.113, which has been stayed for many years, the comment maintained that industry believes that the Brix levels contained in that standard are too high.

Another comment provided data obtained from its suppliers in 1990 on the soluble solids content of single-strength (unconcentrated) passion fruit juice from Ecuador (average Brix value of 14°) and Peru (Brix value range of 14° to 16°). The comment recommended that FDA adopt a minimum Brix level of 14.0° for the single-strength (100 percent) passion fruit juice.

FDA notes that the German RSK Brix value is based on a data range of 12.0° to 18.0° with a mean Brix of 14.0° and a standard value (minimum value) of 13.5°. Wallrauch, et al., (Ref. 7) stated that the data on passion fruit juice were based on extensive analyses of all industrially important varieties and provenances (South America, Africa, Australia, New Zealand, Fiji Islands, Sri Lanka, Taiwan, and Hawaii). It further stated with respect to the Brix of passion fruit juice, that only rarely and only for Brazilian juice has a Brix value for passion fruit juice been found to be as low as 11.5°. Wallrauch et al., also noted that a mean Brix value of 14° can be used in the dilution of concentrate to single-strength so as to maintain all of the organoleptic and analytical features of passion fruit juice.

FDA is adopting a Brix value of 14.0° for passion fruit juice based on the analytical data provided in the comments and supported by Wallrauch, et al. This value also is the same as the mean RSK Brix value reported by the German fruit industry (Ref. 7).

xii. Peach juice.

NJPA suggested a Brix value of 11.8° for peach juice which was published in the proposed § 101.30(j)(1). This Brix value is incorporated in the standards of identity for fruit butters (§ 150.110 (21 CFR 150.110)) and fruit jelly (§ 150.140) on September 5, 1940 (5 FR 3558) and in the standard of identity for canned nectars (§ 146.113) on May 7, 1968 (33 FR 6862) which was stayed because of objections on July 27, 1968 (33 FR 10713). It was based on the analysis of 33 authentic samples during the period 1924 to 1935 (Ref. 2). This Brix value is also used by the U.S. Customs (19 CFR 151.91) and by USDA in its specifications for its diluted juice products (USDA File code 147–A–2, March 1988).

One comment stated that its analyses of peaches over a 5-year period (1986–1990) showed an average Brix value of 10.5°, with a standard deviation of 0.9°. The average value was based on a total of 1,190 measurements. The comment recommended adoption of a Brix value of 10.5° in the final rule.

Based on its review of the data in the comment, FDA is adopting a Brix value of 10.5 as the minimum level for a single-strength peach juice because it is based on the data from over 1,000 samples obtained during a recent 5-year period. Thus, FDA has revised new § 101.30(h)(1) to reflect this minimum Brix value for peach juice.

FDA is open to additional information on the appropriateness of this value for 100 percent peach juice as a basis for a proposal to amend the standards of identity for fruit butter and fruit jelly. Any petition submitted to amend the fruit butter or fruit jelly standards (§§ 150.110 and 150.140) should be accompanied by data representative of the varieties of peaches used in the manufacture of these products, as well as data on possible effects of factors such as maturity, growing conditions, and processing on the Brix value of the fruit.

xiii. Pear juice.

NJPA suggested a Brix value of 11.0° for pear juice based on the USDA File code 147–A–2 (March 1988). FDA believed that this value may be too low and proposed a minimum Brix value of 15.4° based on the Brix value of pear juice in the stayed canned nectar standard of identity (§ 146.113). FDA noted the variation in the two Federal specifications and anticipated receipt of data in support of an appropriate Brix value for pear juice.

Seven comments stated that the proposed Brix value level of 15.4° for pear juice is unrealistically high. A comment from a university professor stated that it is common commercial practice to use a Brix value of 12.0° to represent single-strength pear juice. The comment stated that the RSK Brix values, which are widely applied as typical compositional indices for single-strength juice, list a Brix value range of 11.18° to 13.54° and mean of 12.13° for pear juice. According to the comment, pears are high in sugar content, even when harvested at the green and hard, but full-sized, stage of maturity. It noted that in one university study of changes in sugars and acids during the ripening of Bartlett pears, the data showed that green, hard pears contain 12.0 g of sugars per 100 g (12 percent) which increases to a maximum of 13.5 percent and then decreases to 12.4 percent at the fully ripe stage. The comment also stated that juice is easier to express from the green, hard fruit, and that processors often prefer to press at that stage of maturity. The comment reported a Brix range of 11.7° to 14.2° for pilot-plant processed pear juice (three varieties, unripe and ripened fruit, n=8). This comment did not recommend a specific Brix value.

One comment from a trade association stated that data from its members show that the proposed Brix value of 15.4° for pear juice is clearly excessive and recommended that the agency adopt a Brix value of 11.5° for pear juice from concentrate. According to the comment, the majority of pear concentrate is prepared from Bartlett pears. Other varieties may have a higher Brix, but they are normally marketed as fresh pears and have only limited use in the juice market. Therefore, the comment contended, other varieties should not be considered when establishing a minimum Brix level for pear juice from concentrate.

A comment from a juice products distributor provided data on unconcentrated pear juice that it collected from worldwide suppliers. The data included yearly average Brix values from Australia (1960), central and northern Argentina (1988 to 1991), and the northwestern United States (1988 to 1991). The overall weighted average Brix was 12.1° and the average Brix values ranged from a low of 10.5° to a high of 13.4°, with a standard deviation of 0.8°. Based on these data, the comment recommended that FDA adopt the Brix value of 12.2° as the minimum level of single-strength pear juice.

A comment from a fruit and vegetable processing and marketing cooperative stated that for the past 5 years, they have tested Brix levels in pear juice, and their results are much lower than FDA's proposed Brix value. The comment presented a summary of the data of Brix analyses for the years 1986 through 1990 (n = 2,446 measurements, mean Brix = 12.0°, and standard deviation = 0.8°). Based on these data, the comment recommended a Brix value of 12.0° as the minimum Brix level of single-strength pear juice.

One comment provided a summary of Brix data for more than 1,800 measurements on pear juice samples. The Brix averages for the last 3 years

were 11.7°, 11.6°, and 11.7°. The comment stated that many canners have been packing pears in pear juice for many years, and that the juice consistently runs between 11° and 12° Brix. No specific Brix level was suggested for the final rule.

A comment from a firm that imports apple and pear juice stated that data obtained from its research on pear juice suppliers in both the Northern and Southern Hemisphere showed that concentrate is produced from pears having a maximum Brix value not exceeding 12.3°, with a seasonal Brix value range of 11.3° to 12.3°. The comment recommended adoption of a Brix value of 11.0° for reconstituted single-strength pear juice.

One comment from a trade association expressed the opinion that a Brix value of 15.4° is too high and should be lowered. The comment cited a report showing that Brix values for unripe, fined Bartlett, Comice, and d'Anjou pear juice ranged from 11.7° to 14.1°, and that the majority of pear juice is produced from hard winter pears which generally average 11.0° Brix (Ref. 7). According to the comment, although some ripened Bartlett pears are juiced, they would have to be extremely ripe to approach even 15.0° Brix, and in that condition, they would be virtually impossible to press.

FDA agrees with the comments that a Brix of 15.4° for pear juice is too high. In proposing this value, which was based on the stayed canned nectar standard (§ 146.113), FDA acknowledged that the values had been challenged and specifically requested information on what values would be appropriate. NJPA's recommended Brix value of 11.0° was based on the USDA procedure for inspection of 50 percent juice drinks and juice drink products under the Child Nutrition Labeling Program (USDA file code 147§ A§ 2). According to USDA, this Brix value was recognized by industry as being appropriate in 1980. As far as this agency can determine, there is no identifiable data base that supports the USDA value.

Having reviewed the data in the comments, FDA concludes that the proposed Brix of 15.4° is not consistent with current commercial practice. The reported Brix values in the comments ranged from a low of 10.5° to a high of 14.1°. Industry recommendations for the minimum Brix value range from a low of 11.0° from a trade association to a high of 12.2° from a juice processor, with a mean recommended Brix value of 11.7°.

FDA acknowledges that the information provided consistently points to a lower Brix value for pear juice than the FDA proposed value of 15.4°. As stated above, however, one standard deviation below the mean is too low and is not in the best interest of the consumer. In this case, most of the data point to a mean Brix value around 12°. In fact, one comment recommended a minimum value of 12.2°, another 12°, and the university professor observed a Brix of 12.0° in his research. In addition, the German RSK "mean" Brix value is 12.13°. Use of a mean value of 12.0° would facilitate processing of pear juice which, according to the comments, is done most efficiently at the hard, green stage when the Brix of the juice is lower. Therefore, FDA is revising the minimum Brix for pear juice by lowering the level from 15.4° to 12.0°.

xiv. Pomegranate.

In the July 2, 1991, proposal, the agency solicited comments, as well as data, on any additional fruits and vegetables whose Brix values should be added to the final rule (56 FR 30452 at 30460). In response to this request, NJPA submitted data on the Brix value of pomegranate juice based on data from one of its members and suggested that a minimum Brix value of 16.0° be established as the Brix for 100 percent pomegranate juice. The suggestion was based on the firm's production records for the 1988, 1990, and 1991 processing seasons. Of the 257 samples taken during these seasons, the Brix values of samples ranged from 13.3° to 18.8°, with a weighted average of 15.9°. NJPA stated that the wide range in values is related to early season low Brix fruit versus late season high Brix fruit, varietal differences, and seasonal (climatic) variations.

FDA notes that the comment requested a minimum Brix value of 16.0° based on the firm's analyses over a 3-year period. FDA has an established Brix for pomegranate in the standard of identity for fruit jelly of 18.2°, expressed as the reciprocal by the designated factor of 5.5 for pomegranate (§ 150.140(b)(1)). This value was taken from data obtained before 1940 from authentic samples of pomegranates. According to USDA Handbook 8–9, pomegranates contain 17.17 percent total carbohydrate and 0.20 percent of fiber, or approximately 17.0 percent of sugars and other carbohydrate substances (Ref. 5). The agency recognizes that total carbohydrate content is only a rough approximation of the soluble solids content, and that other constituents of the juice may affect the refractometer readings.

Thus, FDA concludes that it is reasonable to adopt the comment's suggested lower value of 16.0° for pomegranate juice, which was based on actual analyses, instead of the higher value of 18.2° in the standard of identity for fruit jelly. In addition, the information from Handbook 8–9 suggests that a value lower than 18.2 would be more representative of the average Brix of pomegranate juice. Therefore, FDA is including the suggested minimum Brix of 16.0 for pomegranate juice in new § 101.30(h)(1) as set out below.

xv. Red raspberry juice.

In its 1989 submission of Brix data, NJPA suggested a Brix value of 9.0° for 100 percent red raspberry juice based on current industry practice. However, in evaluating the NJPA suggested value for red raspberry juice, FDA found that single-strength red raspberry juice can range between 5.6° and 10.7° (Ref. 3 at page 390). Other reports show Brix levels of 8.9°, 11.3°, and 10.8° (Ref. 3). Because these data (median value 10.7°) were not inconsistent with the Brix value set out in the standard of identity for fruit jelly (the reciprocal of the designated factor, 9.5, that equates to a Brix value of 10.5°) in § 150.140, FDA proposed a minimum Brix value for red raspberry juice from concentrate of 10.5°.

Four comments maintained that the proposed Brix value of 10.5° is too high for red raspberry juice. Two comments, one from a food processor and one from a trade association provided data on the Brix level for red raspberry juice obtained from three sources: (1) Lots of Pacific northwest red raspberries processed by the firm from 1985 to 1990 (mean Brix of 10.1°; standard deviation = 1.0°; n = 124); (2) 1988 European suppliers (mean Brix of 9.7°, standard deviation = 1.8, n = 16); and (3) 1990 European suppliers (mean Brix = 9.4°, standard deviation = 1.1°, n = 242). The comment from the food processor also included another compilation of seven average Brix values or Brix ranges provided by other juice suppliers from four countries (Austria—2 suppliers: mean Brix value of 8.5° and 6.3°; Belgium—mean Brix of 8.8°, with a range of 6.8 to 12.0°; Germany—Brix range of 7° to 8°; and United States—3 suppliers: Brix of 9° to 9.5°, 8.5°, and 8.5°). The comment also noted that the average RSK mean Brix value for raspberry juice is 8.7° with a range of 5.3° to 13.6°. Based on these data, both comments recommended a minimum Brix value of 8.4° for red raspberry juice.

Another comment, from a university professor, requested that the mean Brix values for red raspberry juice obtained from his research be considered in adopting a new standard. A statistical

summary of the Brix values resulting from the study are as follows: Mean of 9.95° (n = 41); std. dev. of 1.93°; and a range from 7.0° to 15.0°. The comment stated that if data for the underripe and overripe samples are excluded from the data base, the following summary values are obtained: mean of 9.50° Brix (n=26); standard deviation of 1.65°; and a range from 7.0° to 13.2°. Although the sampling protocol was not designed for the purpose of determining the "true" mean Brix value for single-strength red raspberry juice, the comment stated that these new data are relevant to the proposed regulations because the major commercial varieties from the Pacific Northwest and from Poland predominate in the sample set. Fall-bearing raspberries and several unusual varieties such as Golden are also included. The comment concluded that the proposed Brix level of 10.5° is too high and suggested that the 9.5° to 9.95° Brix values from the current research be considered in adopting the new standard.

One comment from a distributor of 100 percent fruit juice blends stated that the Brix value proposed by FDA for red raspberry fruit is incorrect and is not consistent with establishing a minimum acceptable value for a juice to be considered full-strength. The comment provided a brief summary of the Brix values collected from suppliers in northwestern United States (1990) and Europe (1991). It provided two average Brix values, 10.1° (range 9.0° to 12°) and 8.5° (no range provided) for the United States and an average Brix of 8.0° and a range of Brix values, 7.0° to 9.0° Brix for Europe, resulting in an overall average Brix value of 9.1° with standard deviation of 0.7°. The comment recommended 9.1° as the minimum Brix level of single-strength (100 percent juice) red raspberry.

FDA has reconsidered its proposed value of 10.5° Brix for red raspberries and agrees, based on the data submitted in the comments, that this value should be revised.

FDA also notes that soluble solids analyses conducted by the agency in 1964 and 1965 on five types of authentic red raspberries resulted in an average Brix of 8.91° (range 8.13° to 10.9° Brix; standard deviation 0.68°) (Ref. 14). In deciding to lower the proposed Brix value, FDA noted that most values cited in the comments tend to cluster between 8.5° and 9.7° Brix. Thus, FDA concludes that the suggested value of 8.4° is too low. The agency believes that a more appropriate minimum Brix value would be 9.2°, a Brix value in the lower portion of the range of suggested values provided in the comments. Accordingly, FDA has incorporated the value of 9.2° in new § 1.30(h)(1).

xvi. Other comments on specific values.

29. Several comments from the juice canning industry noted that FDA did not list any Brix values for beets, parsley, bell peppers, garlic, and onion. However, the comments did not propose any values or provide any information as to appropriate Brix values for these foods.

The July 2, 1991, proposal requested comments on, and data for, any additional fruits and vegetables whose Brix values should be added to the regulation. Because the comments provided no information or data, the agency is not placing these foods in the Brix value table. If a percentage juice determination is made for any fruit or vegetable juice not found in the Brix table in the regulation, the calculation for percentage juice declaration is to be made on the basis of the soluble solids content of the single-strength (unconcentrated) juice used to produce such a concentrated juice.

30. One comment proposed calculating the percentage juice at a Brix level equal to the average of the single-strength (unconcentrated) juice produced from that fruit in the United States.

Because the comment provided no data for the agency to review or evaluate, the agency cannot evaluate the comment's suggestion. Therefore, the percentage juice declaration will continue to be determined by using the Brix values in the table as revised in this final rule.

31. Several comments stated that acid correction of the Brix value in the calculation of percentage juice should be provided for certain juices, e.g., cranberry, lemon, lime, and raspberry as is currently provided in the standards of identity for grapefruit and pineapple juice (§§ 146.132 and 146.185 (21 CFR 146.185)). However, the comments stated that the methodology to do this correction at present is complex and not widely distributed. The comments suggested that Government and industry work together under the auspices of the Association of Official Analytical Chemists (AOAC) to determine the proper reliable methodology.

NJPA commented that the Brix values submitted by them in December 1989 and May 1990 were based on the assumption that the refractometric readings of Brix values were corrected for acidity to obtain the total soluble solids. They also stated that a footnote should be added to the table of values in new§ 101.30(h)(1), stating that the Brix value, if determined by refractometer, is corrected for acidity by the method set forth in the grapefruit juice standard. Another comment that supported the NJPA suggested Brix values recommended that a correction for acid content be applied in the Brix value determination for all juices, and that this correction be based on the predominant acid type inherent to the individual juice (e.g., corrected on a citric acid, malic acid, or tartaric acid basis). NJPA suggested that the predominant acid type be identified as part of new § 101.30(h)(1) to provide a clear and consistent means for the determination of the Brix values. A comment from another trade association also stated that any method used to calculate the Brix value level of the juice should provide for an acidity correction factor in determining the actual Brix value level.

FDA notes that the correction factors in the grapefruit standard are specific to citric acid. Yeatman, et al., developed two correction factors based on percent of citric acid to be added to the sucrose values obtained by the refractometer to yield true soluble solids and true Brix for grapefruit juice (Ref. 8). The data used to develop the correction factors were based on data collected by Stevens and Baier (Ref. 9) for citric acid content in citrus juice products. There are other predominant acids in fruit juices, but data, similar to that for citric acid, would have to be collected for these other fruit acids before a correction factor could be established.

Consequently, the above suggestions are not workable because these correction factors are applicable only to citric acid.

FDA notes that NJPA's list of Brix values cited references that predate the 1976 date of the Yeatman publication on the citric acid correction factors. In addition, Brix values for the fruit butter and fruit jelly standards were proposed in September 1940, and the fruit nectars standard was stayed in 1968. Thus, FDA does not believe that all of the proposed Brix values would have been corrected for acidity. The suggestion of a joint Government and industry effort to determine reliable methodology will be considered. Until acid correction factors are established for other juices, FDA will use the Brix values as specified in new § 101.30(h)(1).

32. One comment mentioned that FDA had not addressed the need for temperature correction when determining the percent soluble solids by refractometer.

FDA disagrees with this comment. The cited method of analysis (56 FR 36452 at 30458), published by AOAC, for determining the percent soluble

solids by refractometer includes a temperature correction (AOAC Official Methods of Analysis, 15th ed., 1990, sections 976.20 and 983.17).

33. Some comments stated that a "100 percent juice" claim should mean that only juice is present, and that no preservatives or other ingredients have been added. On the other hand, one comment stated that the percentage juice calculation should be a function of total juice solids in the final product, and that any added ascorbic acid, natural flavors, and acidulents should be treated as ingredients that do not affect the 100 percent juice claim as long as there are sufficient juice solids present to substantiate the juice content declaration. Another comment asked whether the Brix measurement included salt added to vegetable juices. It requested clarification as to whether adding salt to a 100 percent juice would prohibit declaration of the juice as 100 percent.

The juice content declaration is based on the percent by volume of single-strength (100 percent) juice in the product. It is intended to provide information on whether a juice is diluted and if so, by how much. For example, a declaration of 10 percent juice means one part juice plus nine parts water, 50 percent juice means 1 part juice plus 1 part water, and 100 percent juice means 1 part juice and no water.

Further, the agency recognizes that certain ingredients, such as salt, are used to affect flavor, and that others may be added, for example, as nutrients or as preservatives. In most instances, these additives, excluding bulky ingredients such as carbohydrate sweeteners, are not added in volumes significant enough to result in a diminution of the juice's soluble solids content and therefore do not affect the percent juice calculation. The juice products in the beverage must contain sufficient juice soluble solids to meet the minimum Brix level for 100 percent juice where established by regulation, before the addition of any non-juice ingredients, where such requirements have been established. For example, under the standard of identity for grapefruit juice, when the juice product is made from concentrate, and liquid sweeteners are added, the Brix value of the juice must comply with the required Brix of 10° (and corrected for acidity) exclusive of any added sweetener.

The agency believes that limiting the 100 percent juice declaration to juice beverages that contain no additives, such as vitamin C would discourage some manufacturers from producing beverages that contain such useful added ingredients.

However, FDA agrees that it is necessary to clarify the issue of a 100 percent juice declaration on a product that includes non-juice ingredients because it may be interpreted by some to mean the beverage contains juice and no other ingredients. The agency has advised repeatedly for a number of years that an unqualified 100 percent juice declaration on the principal display panel is misleading when the juice also contains non-juice ingredients (Ref. 16). The agency believes that the industry is already in substantial compliance with this policy. Particularly for a beverage made from only one fruit or vegetable juice, the "100% juice" declaration introduces a precision to the description of the product that can result in the consumer concluding that the juice is the only ingredient. Because an ingredient statement is required only if a product contains two or more ingredients the consumer would not likely look for an ingredient statement under these circumstances. A 100 percent juice declaration appearing on the information panel is not likely to similarly mislead the consumer because it is in reasonable proximity to the ingredient statement, so that it will be read by the ordinary consumer in conjunction with that statement under normal conditions of purchase. Similarly, if there is no information panel, and the principal display panel bears an ingredient statement, a 100 percent juice declaration would not likely be misleading. In addition, the agency recognizes that some of these products declare the presence of the non-juice ingredients as part of the statement of identity (e.g., "prune juice with added vitamin C").

Accordingly, FDA is requiring in § 101.30(b)(3) that for those products that do not declare the presence of the non-juice ingredient in the statement of identity, when a "100% juice" declaration appears on a panel of a juice beverage that does not also bear the ingredient statement, and the product contains a non-juice ingredient, the 100 percent juice declaration shall be accompanied by the qualifying phrase "with added ————," the blank filled in with the generic term "ingredient" or a term such as "preservative" or "sweetener." For example, a beverage blend containing 100 percent juice with an added sweetener in any or all the juices would bear the phrase "100% juice with added sweetener" when the declaration appears on a panel that does not also bear the ingredient statement.

Therefore, the agency is not granting the comments' request but is permitting a qualified 100 percent juice declaration on the principal display panel of 100 percent juice beverages that contain non-juice ingredients that do not significantly affect product volume, such as preservatives, provided that these ingredients do not result in a diminution of the juice soluble solids content or otherwise adulterate the beverage.

The agency advises that in this discussion, it is not evaluating the appropriateness of any of these low volume ingredients for addition to specific juices. Determinations of whether a substance is suitable as an ingredient in a food are beyond the scope of this rulemaking. This discussion addresses only the effect on the declaration of 100 percent juice of the presence of suitable ingredients that do not have a significant effect on product volume. Further, FDA advises that the presence of such ingredients in these beverages may require specific label declaration.

2. Juice Not From Concentrate

FDA proposed in § 101.30(k), (redesignated as new § 101.30(i)) that juices expressed directly from a fruit or vegetable, i.e., not concentrated and reconstituted, be considered to be 100 percent juice and be declared as "100 percent juice." Likewise, the percentage of expressed juice, and not Brix level, is to be used in calculating the percentage of juice in diluted juice beverages made directly from expressed juice. Therefore, FDA proposed in § 101.30(l) (redesignated as new § 101.30(j)) to require that calculations of the percentage of juice in a juice beverage made directly from expressed juice (not from concentrate) be based on the percentage of the expressed juice in the product computed on a volume/volume basis.

34. One comment stated that expressed juice products should not be excluded from the Brix method of calculating percentage juice. The comment expressed concern that if manufacturers were not required to meet a specified Brix level, some might dilute high solids content expressed juice with water to a lower Brix level and sell the product as full-strength (100 percent) juice.

As FDA stated in the July 2, 1991, proposal, diluting expressed juice to a lower Brix level but still calling it 100 percent juice would constitute adulteration and misbranding. Such a product would be misbranded under section 403(a) of the act because its labeling would be false and misleading

in that it failed to reveal the material fact that the juice was diluted. It would also be adulterated under section 402(b) of the act (21 U.S.C. 342(b)) because it had been diluted with water.

The agency discussed in the July 2, 1991, proposal that it was necessary to exclude expressed juices from the requirement for a single Brix level because such a provision would result in high solid content juice being diluted to the standard Brix level (56 FR 30452 at 30460). FDA stated that such dilution was not acceptable, and that expressed juice had to be declared as 100 percent with the solids content of the juice as expressed. The agency believes that the adulteration and misbranding provisions cited above will deter manufacturers from diluting expressed juice with water. Thus, FDA concludes that the concerns expressed in the comment are unfounded. Accordingly, as proposed, § 101.30(i) and (j) exclude expressed juice from the provision that percent of juice is to be calculated using specified Brix levels.

35. Another comment expressed concern that allowing expressed juice to have a different Brix value than juice of the same fruit made from concentrate could lead to organoleptic as well as nutritional inconsistencies in the product.

The agency recognizes that organoleptic as well as nutritional inconsistencies may be created by requiring that manufacturers of juice products that consist solely of expressed juice base their calculation of the juice content of the product on the juice as expressed rather than on a Brix level. The agency has concluded that Brix values are the best standardized criteria for calculating percentage of juice from concentrate primarily because of the industry practice of commingling large quantities of concentrated fruit juice, often from foreign sources, with differing and possibly unknown soluble solids values.

However, because the actual percentage of the source expressed juice is known, the percentage of expressed juice, and not Brix level, must be used in calculating the percentage of juice in full-strength and in diluted juice products made directly from expressed juice. Additionally, because the Brix levels of expressed juice from the same fruit or vegetable grown in different regions may vary within a large range, e.g., the Brix value for expressed apple juice ranges from 9° to 14°, it would be economically unfair to penalize producers of expressed juice from fruit or vegetables grown in regions that have a lower Brix value by not allowing them to declare 100 percent fruit or vegetable juice, when in fact the juice was directly expressed from the fruit or vegetable as it occurred in nature.

Also, FDA finds that consumers will not be misled by the differences between juices made from concentrate and expressed juices. While consumers expect juice from concentrate to be processed into a uniform product, they understand that expressed juice may vary because of variation in the fruit. For example, a particular brand of frozen concentrated orange juice will taste a the same from purchase to purchase, but fresh squeezed, home prepared orange juice will vary in sweetness and taste, depending on the maturity and quality of the oranges used to prepare the juice.

Therefore, the agency is finalizing the provision that juices expressed directly from fruits or vegetables be considered 100 percent juice.

36. One comment stated that the proposed method of calculating the juice content based on the Brix value was not applicable to blends of full-strength juice and concentrated juice because the total amount of juice in the product may be greater than 100 percent. The comment suggested that the final rule be amended to state that the Brix values are to be used for labeling purposes only when the product is a single juice beverage that is derived from concentrate.

FDA acknowledges that the total soluble solids content exceeds the minimum level necessary to declare that the juice is full-strength (100 percent) when concentrates are blended with single-strength juices. FDA does not intend that these products be exempt from declaration of the percent of juice. The agency recognizes that strongly flavored juice concentrates may be blended with single-strength juices to provide flavor and color in blended juice products. As a result, the total level of juice soluble solids in the blend will be greater than the total of such juices if the concentrate were diluted to single-strength before its use in the blend. In such cases, unless the blended juice is to be further diluted by the consumer, FDA considers a declaration of more than 100 percent juice to be misleading. Thus, the juice should be labeled as 100 percent juice. The agency has no objection to manufacturers making a truthful statement on the label concerning the actual level of juice soluble solids contained in the blend provided that it is made in a manner that is not misleading to consumers.

37. Several comments requested that the fruit component of nectars not be required to be declared as percent of fruit juice. They stated that pulp and puree are the fruit ingredients in nectars, not fruit juice. Comments suggested alternate fruit content declarations, such as "apricot nectar—contains 45 percent apricot pulp" or "————————percent fruit + juice." The comments expressed concern that consumers might be confused by a declaration, for example, of 100 percent juice on a beverage in which only two of the ingredients are declared as juice while the other two ingredients are declared as fruit puree.

The agency acknowledges that there is generally more fruit or vegetable fiber or pulp present in nectars than in juice, which is otherwise processed, clarified, or filtered. However, the Brix values listed in the July 2, 1991, proposal were calculated to take into consideration that some of the starting materials may be puree or pulp, e.g., banana, papaya, or guava. Further, many comments expressed support for the agency's position that standardized criteria are needed to facilitate consistency in calculating percentage of juice. The Brix concept for percent juice calculation, while not without limitations, is a standardized criterion and provides a consistent and equitable frame of reference for manufacturers in determining percent juice in beverages derived from concentrates. The agency is unaware of a comparable standardized criterion for fruit content as opposed to fruit juice content. Therefore, FDA rejects the suggested alternative percent fruit content declaration or declarations such as "contains 45 percent apricot pulp" or "————— percent fruit + juice" in lieu of the prescribed percentage juice content declaration based on Brix for nectars. However, the agency does not object to voluntary disclosure of such fruit component information provided that it is factual. These comments did not provide alternative standardized criteria for consistently determining fruit content in nectars or purees by themselves and in combination with other fruit juice in beverages as opposed to fruit juice content based on Brix values.

F. Modified Juice

The agency proposed in § 101.30(m) (redesignated as new § 101.30(k)) that if major modifications (i.e., changes in the color, taste, or other organoleptic properties) are made to a juice to the extent that the original juice is not recognizable, or if its nutrient profile has been diminished, then the juice may not be included in the total juice percentage declaration. However, in the July 2, 1991, proposal, FDA pointed out that it is appropriate to include in the

total percentage juice declaration juices with minor modifications, such as acid-reduced orange juice, that are easily recognizable to consumers (56 FR 30452 at 30461).

38. One comment suggested that the industry work with FDA to develop information and data that will provide normal ranges for the constituents in juice, such as minerals, acids, and sugars. Such data would be used to determine at what point in the process modification of the juice is beyond the normal range of these constituents. According to the comment, a project has been initiated to develop these parameters for apple juice obtained from sources throughout the world. Additional juices are to be added to the project in the future.

FDA is aware of this information development project and is providing guidance as to the kind of information that would be useful in making agency decisions. The agency encourages industry to develop data bases that would be helpful in establishing reasonable guidelines for juices, in particular, the levels and types of nutrients, ranges for these levels, and effects of processing on nutrient content. Such data bases would facilitate decisions that promote fairness to both consumers and the industry.

39. Several comments expressed concern that the description of major modifications in § 101.30(k) would not be interpreted appropriately. One comment stated that if the phrasing "if its nutrient profile has been diminished" is strictly interpreted, juice made from concentrate would be excluded from the juice content declaration. The comment explained that there is some difference in nutrient content in any juice that is filtered and concentrated. Some comments stated that the language of § 101.30(k) should be clarified by adding: "at the time processing is complete" after "recognizable;" and "to a level below the naturally occurring nutritional range for the juice" after "diminished," so that minor modifications of juices do not preclude the juice from being included in the percentage juice calculation and declaration. They cited as examples of such minor changes acid adjustments and removal of naringin from navel oranges to facilitate production of a more uniform product.

The agency agrees with the comments and is clarifying the provision because it was intended to address significant modifications of organoleptic properties and significant modifications of nutritional values. Significant modifications in organoleptic properties would include removal of the typical color, taste or flavor, or aroma such that the juice is no longer recognizable as the typical juice of the fruit or vegetable. In the case of nutrient content of modified juices, significant nutritional modifications would include decreases in the content of any essential nutrient that is present in a measurable amount (excluding fat or calories), i.e., present at a level of 2 percent or more of the Reference Daily Intake (RDI) for any vitamin or mineral listed under § 101.9(c)(7)(iv). However, FDA recognizes that some nutrient losses can be expected as a result of heat treatment, filtration, and clarification used to make the modified juice product. FDA expects that such losses would be minor, and that the resulting modified juices will provide levels of essential nutrients comparable to the naturally occurring nutritional range published in recognized data bases, such as the USDA Handbooks on Food Composition (Refs. 5 and 6), for the unmodified juice product.

The agency is adopting the suggested changes to the regulation with one exception. It believes that the term "normal nutrient range" is more appropriate than "naturally occurring nutritional range." As stated in the comment, the naturally occurring nutrient range, i.e., nutrient levels in expressed juice, may be slightly different from the range of nutrients normally present in juice that has been processed, for example, filtered and concentrated. FDA believes these differences should be taken into account in determining which changes in a juice constitute major modifications.

Accordingly, FDA has revised new § 101.30(k) by adding the phrase "at the time processing is complete" after "recognizable" and the phrase "to a level below the normal nutrient range for the juice" after "diminished," to specify that comparisons of the organoleptic properties of the original juice and the modified juice will be made "at the time processing is complete" and to specify that the nutritional profile must not be diminished "to a level below the normal nutrient range."

40. Some comments requested clarification of how the percentage juice content of dehydrated juices should be determined. One requested that dehydrated fruit and vegetable powders be treated similarly to fruit and vegetable juice concentrates, i.e., based on the Brix value, and therefore, the percent of juice should be based on the soluble solids content of the rehydrated product.

Another comment questioned the status of dry drink mixes which are prepared from spray dried juices that have not been modified in any way other than that the water has been largely removed. The comment expressed the opinion that when these products are properly reconstituted, they should be considered to be a juice.

FDA is not providing for the declaration of the percent of juice from dehydrated fruit or vegetable juices. At this time, the agency does not have information on the manufacture of such products or on the properties of the finished products with which to determine whether dehydration is a minor modification that does not significantly change the juice. The agency believes that many dehydrated juices may contain ingredients other than simply juice solids. Maltodextrins are often added to prevent stickiness during juice drying operations. Fruit essence or flavors may be added to compensate for volatile flavor components lost during processing. However, according to the literature, processes are being developed in which juices may be dehydrated without the addition of additives such as maltodextrins or glucose syrups (Ref. 15).

The agency requests information on how the specific dehydrated juices are made, so that it can determine appropriate means of labeling dehydrated juice products in juice beverages. Until such time as FDA can establish rules governing the declaration of dehydrated juices in juice beverages, it will evaluate the labeling of such dehydrated products on a case-by-case basis to determine if it is misleading. However, FDA advises that in the meantime, any declaration of percent of juice made on a rehydrated juice should be based on the fruit or vegetable solids before any other soluble substances are added to the product.

41. One comment stated that it is possible to remove some or most of the sugar from a juice and not otherwise change the nutrient profile of the juice. The comment stated that, with an alternative sweetener, the product will have the color, taste, and other organoleptic properties consumers associate with the original juice. The reduced-sugars juice will have levels of ascorbic acid, citric acid, and minerals that are equivalent to those of the standard juice. The comment maintained that an alternate method to the Brix calculation will have to be used in calculating juice content for such products. Thus, the comment suggested that the regulation recognize this possibility and permit manufacturers to use an alternative method to calculate

the juice content, provided they have data to substantiate the method.

FDA recognizes that current technology is such that sugars or other components may be removed from juice. The agency recognizes that the reduction of sugars from a juice or a standardized juice, and the subsequent sweetening of the juice with a sweetener that provides an insignificant amount of calories, results in a modified juice. If the juice is a standardized juice, e.g., orange juice, that has been reduced in sugars so that it qualifies for use of a nutrient content claim and complies in all other aspects to new § 130.10, then the product is a food defined by new § 130.10 and must be labeled accordingly. The actual name of the food will depend on its nutrient content. Similarly, if the original juice is not a standardized juice, it may qualify to bear a nutrient content claim defined in part 101.

However, as stated above, when sugars are removed, the resulting product is a modified juice and not juice. Therefore, like other modified juices, it cannot be included in calculating the percent juice in the product.

III. Common or Usual Name Regulation

The 1990 amendments require that the percentage juice declaration for fruit or vegetable juice beverages be on the information panel of the label. Accordingly, FDA proposed to delete from the common or usual name regulation for diluted fruit or vegetable juice beverages (§ 102.33) the provisions that deal with percentage juice declaration as a part of the name of the product and to amend the regulation to pertain only to how these beverages should be named. The agency also proposed changes in the provisions for naming diluted juice beverages. The proposed regulation included a requirement that the name of a beverage that contains juice but that is less than 100 percent juice include a qualifying term like "beverage," "cocktail," or "drink," to indicate that the product is not 100 percent juice. In addition, the agency requested comment on whether the term "diluted" should be required for these products. Further, the proposed regulation addressed such issues as how individual juices in a multiple-juice beverage should be declared, and how modified juices should be declared.

42. One comment requested clarification of the applicability of § 102.33. It noted that there were differences in phrasing in proposed § 102.33(a), (b), and (c) with respect to the products covered. It said that in § 102.33(a), FDA addressed diluted juice beverages by saying, "* * * beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice." On the other hand, in § 102.33(b) the product is described as a "diluted, multiple-juice beverage or blend of single-strength juices," and in § 102.33(c), as a "multiple-juice beverage or blend of single-strength juices * * *." The comment stated that it was clear that § 102.33(a) applies to dilute beverages and does not apply to nondilute beverages, but that it was not clear whether both § 102.33(b) and (c) apply to dilute and nondilute beverages, or whether § 102.33(c) applies only to nondilute beverages.

The agency advises that the difference in phrasing in § 102.33(b) and (c) was inadvertent. Both provisions are intended to apply to both dilute and nondilute beverages. Accordingly, § 102.33(c) has been revised to refer to a "diluted multiple-juice beverage or blend of single-strength juices."

A. Identity of Diluted Juice Beverages

The agency proposed in § 102.33(a) that if a product contains less than 100 percent juice and uses the word "juice" in the common or usual name, then the word "juice" must be qualified by a term that indicates dilution, such as "beverage," "cocktail," or "drink," appropriate to advise the consumer that the product is less than 100 percent juice. In addition, FDA requested comments on whether the term "diluted," or a similar term, should be required as part of the common or usual name for juices that are less than full-strength (100 percent) juice.

43. Several comments supported the July 2, 1991, proposal to qualify the term "juice" on products containing less than 1080 percent juice, and none objected. However, the majority of comments addressing the issue objected to a requirement for the term "diluted" in the name of beverages containing less than 100 percent juice. The comments stated that the term would give consumers the impression that the product was "watered down." On the other hand, several comments expressed the belief that the term "diluted" should be used. Alternatively, these comments suggested that if the term "diluted" is not used, a declaration of the total percent of juice should appear on the principal display panel if the beverage is not 100 percent juice.

The comments requesting that the term "diluted" be required did not provide information to demonstrate that such a declaration was needed or would be useful to the consumer. Consequently, the agency has no grounds on which to base such a requirement at this time. Therefore, in accord with most of the relevant comments, while requiring use of a term that indicates dilution, FDA is not requiring that the term "diluted" be included in the name of juice products that contain less than 100 percent juice and is adopting § 102.33(a) as proposed.

Further, the agency disagrees with the alternative suggestion to require total percent juice declaration on the principal display panel of the juice beverage if it is not 100 percent juice and does not bear the term "diluted." Percentage juice is required to be declared on the information panel, and, as discussed in comment 12 of this document, the agency does not have an appropriate legal basis for requiring an additional percentage juice declaration on the principal display panel.

44. One comment stated that soft drinks (sodas) that purport to contain real fruit juice should have a common or usual name such as "imitation grape drink." This comment said that such a name is applicable when a product named "grape soda" bears vignettes or words indicating the presence of grape juice.

The agency disagrees. Under § 101.3(e), a food is an imitation if it is a substitute for, and resembles another food, and is nutritionally inferior to that food. However, if the food is not nutritionally inferior to the food for which it substitutes, it is permitted to be labeled descriptively and need not bear the term "imitation."

The requirements for labeling a beverage as an imitation are not evoked by use of vignettes or words suggesting that grape juice is present. These vignettes or words would, however, make the beverage subject to the requirements in § 101.30 for declaration of juice content. The agency finds that such a product with a percent of juice declaration would be informatively labeled and would not be misleading. Accordingly, FDA is not requiring beverages which purport to contain fruit juice to be labeled "imitation" unless the criteria in § 101.3(e) are met.

B. Identity of Multiple-Juice Beverages

FDA proposed to require in § 102.33(b) that if a product is a diluted, multiple-juice beverage or a blend of single-strength juices and declares, names, implies, or represents on the label, other than in the ingredient statement, one or more of the individual juices (represented juices), then the names of the represented juices must be included in the common or usual name in descending order of predominance by volume, unless the common or usual

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name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink).

In the July 2, 1991, proposal, the agency noted that blends or mixtures of several juices, with one or two juices present in only minor amounts giving them flavor, are difficult to label (56 FR 30452 at 30462). Therefore, FDA did not propose an exact labeling format for such products. The agency proposed in § 102.33(c) that if a diluted multiple-juice beverage or blend contains a represented juice and one or more that are not represented, i.e., not named or implied through words or vignettes other than in the ingredient statement, then the common or usual name for the product must state that the nonrepresented juices are present (e.g., "Raspcranberry: raspberry and cranberry juice in a blend of two other fruit juices").

45. Comments addressing the issue of which juices should be declared in the common or usual name when more than one juice is present in the product were markedly different. Some comments asserted that all juices (represented and nonrepresented) should be included in the common or usual name because consumers may be confused when the common or usual name reflects certain juices and the ingredient statement declares additional juices. One of these comments disagreed with FDA's proposed position that it was appropriate to exclude from the category of represented juices (and consequently from the requirement for declaration in the name) those juices whose presence in the product is disclosed only in the ingredient statement. The comment stated that the agency had offered no legal justification for this position. The comment provided no justification for its position that the presumption should be that juices declared only in the ingredient list are "represented."

Other comments stated that it would be unreasonably cumbersome for products that include many juices to list them all in the statement of identity. They said that the combination of a truthful, descriptive statement of identity, the ingredient list, the percentage total juice declaration and, optionally, a vignette would provide enough information about the juices present.

The first comments are not persuasive. The agency stated in the July 2, 1991, proposal that because all ingredients of a product must be declared in the ingredient statement, if the criteria for what is a "represented juice" included being listed anywhere on the label, all juices would be considered to be represented (56 FR 30452 at 30456). FDA stated that it was more appropriate to exclude juices listed only in the ingredient statement from the category of represented juices, so that a distinction can be made between those juices represented as being present in the product, through word or vignette, and those not so represented. The comment did not provide any information that would justify different position.

The basis for the agency's position is provided by the basic principles for common or usual names in § 102.5. It is not necessary to list all juices in the name of a beverage to adequately describe the product. The basic nature of the product can be described in various ways, e.g., as a blend of five juices, with a declaration of the name of the juice or juices that provide the characterizing flavor, as long as it is clear from the name that other juices are present. Under sections 201(n) and 403(a) of the act, the name of the food must not omit any material facts. The names of all the juices in the five-juice beverage example, however, are not necessarily material facts in this context. Consequently, FDA concludes that its position that a juice whose presence in the product is disclosed only in the ingredient list of a beverage product is not a "represented" juice is appropriate and consistent with the act.

The agency also concludes that it is not necessary to require that each juice in a beverage be named to ensure that the label is not be misleading. As discussed in the response to comment 10 of this document and in response to subsequent comments, there are several ways in which a multiple-juice beverage can be appropriately labeled. For example, for a product containing apple, grape, raspberry, and cranberry juice, the names "Raspberry and cranberry flavored juice beverage in a blend of two other juices" or "Raspcranberry; Raspberry and cranberry juice beverage, 10 to 15 percent cranberry juice and 3 to 8 percent raspberry juice" would be acceptable under the act.

However, while FDA is not requiring that each juice in a beverage be declared in the name of the product, it encourages such declarations. They may provide useful information for the consumer, provided that the declaration does not misrepresent the contribution of any individual juice to the product.

46. One comment suggested that for a multiple-juice beverage, the principal display panel should display by words, vignette, or other means each juice ingredient or the number of juices in the beverage. It stated that such a requirement would remove the need to distinguish between represented and nonrepresented juices and would assure clarity and uniformity in labeling.

The agency agrees that such labeling would be informative and encourages manufacturers to identify on the principal display panel each juice ingredient or the number of juices in the beverage. FDA is not convinced that it is necessary or appropriate to limit label declarations for all multiple-juice beverages to those described in this comment because there are other ways to adequately name these beverages. The agency has provided in response to other comments in this document, examples of other nonmisleading ways to name a multiple-juice beverage. Consequently, FDA is not adopting the requested requirement.

47. A number of comments objected to the requirement in proposed § 102.33(b) that each juice represented on the label be named in the statement of identity in descending order of predominance by volume. Some suggested that where all juices in a multiple-juice beverage are depicted in a vignette, naming all those juices in the common or usual name would not provide significant benefit to the consumers. They said that instead, naming all such represented juices would require excessive label space. A number of comments stated that in those instances where a blended juice product includes a juice that imparts the predominant flavor but that does not predominate by volume, the declaration of the name of the prominent or characterizing juice flavor should be made first, rather than being declared in order of predominance by volume, because the consumer needs to know the flavor to be expected in the product.

The agency has evaluated these comments and others discussed below and is revising the provisions of new § 102.33(b) so that it does not require declaration of all represented juices in the common or usual name of the beverage. Consistent with the approach discussed in response to comment 10 of this document, FDA concludes that while beverage labels are clearly misleading if they misrepresent the contribution of one or more individual juices to the nature of the product, not all multiple-juice beverage labels that bear representations of individual juices misrepresent their contribution to the total product. For example, a vignette that depicts all the fruits or vegetables in the product may not misrepresent the contribution of an individual juice to the nature of the product. Accordingly, the agency has revised new § 102.33(b) to clarify that all represented juices need not be named. In addition, FDA is

retaining the provision that juices that are declared in the name must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). The name of the characterizing juice may therefore be declared first although it is not the most predominant juice. However, as discussed below, this provision does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner. The agency believes that this revision of new § 102.33 along with the others discussed below are adequate to prevent misleading labels on multiple-juice beverages.

48. Several comments supported proposed § 102.33(c), which states that when the represented juice is not the only juice present, the common or usual name of a multiple-juice beverage should reflect that fact. No comments objected. The agency is therefore retaining this provision. However, given other changes in the final regulation, FDA has used a different example to illustrate the requirement, so that there will not be confusion as to the completeness of the name provided in the example.

49. One comment noted the requirement in § 101.22(i) that the term "flavor" or "flavored" accompany the name of certain foods containing added flavors. The comment requested that juice products labeled as "———— flavor" be exempt from common or usual name requirements in proposed § 102.33. It requested clarification with respect to naming a diluted juice product containing three juices (cranberry, grape, and lemon) and a juice flavor (cranberry flavor). This comment stated that § 101.22(i)(1)(iii) requires such a product to be labeled as "cranberry flavor," however the proposed regulations in § 102.33 require the statement: "in a blend of ———— other juices." The comment stated that requiring this statement is not reasonable because the term "cranberry flavor" adequately informs the consumer in accordance with § 101.22, and the percent total juice and percent cranberry juice would be on the information panel.

The agency advises that an acceptable description of the product described in the comment would be "cranberry flavored juice in a blend of two other juices." Another adequately descriptive term would be "cranberry juice in a blend of two other juices, with added cranberry flavor." The agency has not specified the precise wording that must be used as the name of such a beverage. However, both §§ 101.22 and 102.33 are intended to ensure that the label communicates essential information to consumers. These provisions are intended to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the product. The agency concludes that both kinds of label information discussed here are essential to adequately describe the nature of the product. One type of information informs the consumer when flavoring substances have been added to the product. The other type describes other aspects of the basic nature of the product. Thus, FDA is not making the requested revision.

In addition, the suggestion in the comment included mandatory declaration of the percent of cranberry juice in addition to percent of total juice. As discussed in comment 10 of this document, declaration of percentage of individual juices represented on the label is not required as a part of the juice content declaration under this final rule. Therefore, not all the label information discussed in the comment's alternative approach will be required on the product.

50. Some comments that objected to mandatory declaration of the percentage of each individual juice represented on the label of a multiple-juice beverage suggested alternatives in the form of labeling schemes centered around the common or usual name of the product that they said would adequately describe multiple-juice beverages. These label schemes included statements of identity that: name the characterizing juice where needed to provide information on taste or flavor of the product; where appropriate, declare that the product was prepared from concentrate; and include terminology like "blended" or "blend of juices" to convey the multiplicity of juice ingredients. In addition, declaration of the presence of added flavors in accordance with § 101.22(i) would be required. The comments said that this information, together with the percentage of total juice and declaration in the ingredient list of all juices (or juice concentrates) in descending order of predominance by weight, would provide the consumer with sufficient information to make a product selection.

The agency agrees that the labeling schemes suggested by the comment would provide adequately descriptive labeling for some products and, as discussed in other comments, is requiring in the final regulation the declarations suggested. However, it does not agree that this scheme would ensure that all multiple-juice beverages would bear labels that are not misleading.

As discussed above, FDA finds that it is not necessary that all multiple-juice beverages identify each represented juice in the name of the product and declare the percentage of each represented juice. The agency has given examples of label statements that would not be misleading. However, FDA is not persuaded that the recommended schemes would ensure the labeling of multiple-juice beverages in which the named juice is not the predominant juice would provide enough information to describe the product for the consumer. FDA agrees with those comments that expressed concern that consumers are being misled into believing that named juices are present in greater amounts than is actually the case. The agency is aware of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount.

The agency notes that the regulation on the general principles for common and usual names provides in § 102.5(b) (21 CFR 102.5(b)) that when the proportion of a characterizing ingredient in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient is present in an amount greater than is actually the case, the percentage such characterizing ingredient shall be declared as a part of the common or usual name of the food. This provision formed the basis for the requirement in the previous version of § 102.33 for declaration of percent of juice, both for total juice and for each individual juice represented on the label.

FDA agrees with comments that stated that declaration of the percentage of individual juices will provide informative labeling. While the agency has decided not to require percentage declaration of represented individual juices in all multiple-juice beverages, it concludes that for multiple-juice beverages that name one or more but not all of the juices present other than in the ingredient list, there is great potential for the label to misrepresent the contribution of the named juice to the product. When the named juice is the predominant juice in the product, FDA considers that the consumer will not be misled with regard to its contribution because naming it will not over emphasize its contribution. However, when the named juice is not the predominant juice, the consumer can be

misled. Therefore the final regulation, in § 102.33(d), requires that the common or usual name of the product specifically describe the contribution of the named juice if it is not the predominant juice. The agency has provided two ways for the common or usual name to include this information.

In § 102.33(d)(1), the agency has provided that manufacturers can use a product name that identifies the juice that provides the characterizing flavor and specifically shows that that juice is used to flavor the product (e.g., "raspberry flavored apple and pear juice drink" or "apple and pear juice drink flavored with raspberry juice"). The agency believes that using the term "flavor" with the name of the characterizing juice will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case. This alternative is consistent with the agency's approach of not requiring percentage total juice declaration for bottled waters that contain juice for flavoring in small amounts (usually less than 2 percent) (see comment 4 of this document). Accordingly, FDA is providing in § 102.33(d)(1) that a multiple-juice beverage may use a product name that specifically shows that the named juice is used as a flavor.

Alternatively, consistent with § 102.5(b), the agency is providing in § 102.33(d)(2) for the declaration of the amount of the named juice in multiple-juice beverages that name one or more but not all of the juices in the product. As explained in the **Federal Register** of March 14, 1973 (38 FR 6964), the disclosure of the amount of a characterizing ingredient is a material fact.

Among the reasons given in comments that disagreed with the proposed requirement for declaration of percentage of individual juices was the need to have flexibility in the formulation of the beverage to accommodate variations in raw material juices and price changes. The comments included a report that documented that changes in formulation occur frequently and in a significant number of products. The agency is persuaded by the comments that an accommodation is warranted. It agrees that declaration of individual juice content in 1-percent increments is not practicable. Accordingly, FDA is providing in § 102.33(d)(2) that the juice content declaration of individual juices may be made using a 5 percent range, e.g., 2 to 7 percent raspberry juice or 5 to 10 percent cranberry juice. The agency considers that a 5 percent range is large enough to provide for changes in formulation for juices that are present in small amounts.

Comments did not provide specific information on individual juice content, but it is reasonable to assume that a minor juice in a multiple-juice beverage would not be present at greater than about 25 percent of the total product. The 5 percent range is one-fifth of this amount. The agency concludes that a 5 percent range would provide this kind of flexibility to accommodate minor fluctuations in amounts of juice needed to compensate for differences in raw material. In addition, some comments contended that declaration of percent of individual juices in 1-percent increments constitutes an inappropriate disclosure of proprietary formulation information. The agency believes that declaration of individual juice content in 5 percent ranges would in any case not reveal the product formula. Finally, the 5 percent range declaration will provide enough information for consumers to be able to understand the contribution to the product made by the named juice and not be misled into believing that the juice is present in an amount greater than is actually the case.

Accordingly, FDA has provided these two labeling alternatives for multiple-juice beverages that name one or more but not all of the juices in the product in new § 102.33(d). In addition, the final regulation requires in new § 102.33(d) that the percent individual juice declaration be a part of the name of the product and meet the type size requirements in § 102.5(b)(2).

51. Several comments stated that juice beverages may be made from dehydrated as well as fresh fruits and vegetables in products such as vegetable cocktail, vegetable juice cocktail, juice cocktail, and bloody mary mix. One comment requested clarification that the names "vegetable juice cocktail," "vegetable cocktail juice," and "vegetable cocktail" can be used interchangeably on such products, when they are made from any combination of expressed juice, juice concentrate, and dehydrated fruits and vegetables.

The agency does not have information with which to determine whether beverages made from dehydrated fruits or vegetables differ from beverages made from concentrated or expressed juice. The agency welcomes any data or other information on the nature of beverages made from dehydrated fruits and vegetables, particularly on how they differ from beverages made from expressed or concentrated juice. The agency advises that it will evaluate the labels of such products on a case-by-case basis to determine whether the labeling is misleading. However, FDA advises that irrespective of the form of the vegetable ingredients, the term "vegetable cocktail juice" may not be interchangeable with the other two terms. It uses the word "juice" without a term indicating dilution. Accordingly, it can be used only on beverages that are not diluted juice products. The terms "vegetable juice cocktail" and "vegetable cocktail" would apply to diluted vegetable juice beverages.

C. Vignettes

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a label vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate.

52. Some comments, from both consumers groups and manufacturers, stated that vignettes should depict all juices in a product. Other comments stated that such a provision is not necessary because a descriptive name together with declaration of each juice by order of predominance in the ingredient list and the percent of total juice would provide enough information to ensure that the consumer is adequately informed.

The agency agrees that it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette. The agency believes that a vignette that pictures only some of the fruit or vegetables in the beverage would not be misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice. For example, for a 100 percent juice product consisting of apple, grape, and raspberry juices, in which the raspberry juice provides the characterizing flavor, a vignette depicting raspberries would not necessarily be misleading if the statement of identity were "raspberry juice in a blend of apple and grape juice." Similarly, the vignette would not be misleading if the beverage were named "raspberry flavored fruit juice blend" or "raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice." Moreover, if these three juices were in a beverage containing 50 percent total juice, a vignette picturing raspberries would not be misleading in the presence of a name like "raspberry flavored juice beverage."

Accordingly, FDA is not requiring that vignettes depict the fruits or vegetables for all juices present. However, FDA believes that a vignette that pictures the fruit or vegetable

sources of all juices present in a product would provide useful information and thus encourages manufacturers to use such vignettes.

Conversely, vegetables or fruits not present in the beverage cannot be depicted in vignettes or other pictorial representations on the label. The agency considers that depicting a fruit or vegetable in a vignette on a juice beverage implies that the fruit or vegetable is in the product, either in the form of a juice or of a natural or artificial flavor of the depicted fruit or vegetable. A vignette that pictures a fruit or vegetable that is not present in the product results in a label that is false and misleading and therefore in violation of section 403(a) of the act.

53. Some comments that wanted all fruits and vegetables pictured in the vignette also requested that the fruits and vegetables be depicted in proportion to the amount of each juice present. However, most comments requested that the agency not impose a specific requirement regarding the relative amounts of the various fruits or vegetables because the relative size and shape of various fruits and vegetables make it difficult to portray by vignette. They stated that both the relative size and the quantity of these fruits and vegetables are difficult to represent in a manner that would allow the consumer to readily recognize the quantity relationship.

The agency did not propose a specific requirement regarding the relative amounts of the various fruits depicted in a vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate. While information in comments emphasized the difficulties in displaying fruits and vegetables quantitatively, there was no information on how useful quantitative displays could be devised. The agency, therefore, is not requiring that fruits and vegetables pictured in vignettes be depicted in proportion to the amount of each juice present.

54. Several comments requested that the agency not make specific requirements regarding flavor characterizations in vignettes. They stated that the taste of a product is best communicated to the consumer through means other than the label vignette alone, and that any requirement should rely on wording to describe product flavor, e.g., "raspberry (flavor) in a blend of ———— other juices."

The agency agrees with the comments that vignettes alone should not be required to communicate the flavor characteristics of the beverage and is not establishing such requirements. It also agrees that more explicit information is provided by the wording on the label, especially in the statement of identity of the product. However, FDA advises that in order for a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way. The agency has discussed above the circumstances under which the name of the beverage may be misleading. It will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information or for other reasons.

D. Modified Juices

In the July 2, 1991, proposal, the agency stated that the consumer must not be misled as to the nature of the juices used to make a juice or diluted juice beverage (56 FR 30452 at 30461). FDA stated that the appropriate common or usual name for a modified juice or a beverage containing a modified juice should be determined by the nature and extent of modification. For example, the appropriate common or usual name for frozen orange juice concentrate in which the acid content is reduced is "reduced acid frozen concentrated orange juice" (21 CFR 146.148).

However, FDA also acknowledged that beverages may contain modified juices that are markedly altered and added to beverages to increase the declared juice content but are actually "stripped" juices, i.e., juice derived, rather than sugar derived, sweetening ingredients, e.g., deflavored, decolored white grape juice.

The agency proposed in § 102.33(d) (redesignated as new § 102.33(e)) to permit a juice that has been modified to be referred to by a common or usual name that includes the word "juice" so long as the exact nature of the modification is specified in the common or usual name. The description of the modification would therefore appear as part of the name wherever it is used.

Further, the agency proposed that a product would be misbranded if a label vignette depicts the source fruit or vegetable of a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable, or if its nutrient profile has been diminished.

55. One comment suggested three classifications for juice as the basis for developing labeling policy for modified juices:

First, minor modifications that do not alter the basic characteristics of the juice outside the normal range for that juice.

Secondly, more significant modifications that alter one or more basic characteristic of the juice but not to the extent that the juice would not still be acceptable if offered as a single juice product. The comment stated that such products would require a descriptive term as part of the product name to indicate the nature of the change but could still be identified as "juice."

Thirdly, products that have undergone major modifications that remove virtually all significant nutrients, resulting essentially in a sugar water product. The comment stated that while such products are acceptable as sweeteners, they should not be identified as juice or counted toward the juice content declaration.

The agency agrees that modified juices could be considered in three categories. It used a similar approach in the July 2, 1991, proposal (56 FR 30452 at 30460). The comment's first category is essentially the group of products that have undergone modifications so minor as to be within the normal range of properties of the original juice. These products do not require a modification of the name "———— juice," where the blank is filled with the name of the source fruit or vegetable.

The second category is illustrated in the July 2, 1991, proposal using "reduced acid frozen concentrated orange juice" and "acid-reduced pineapple juice" (56 FR 30452 at 30461). These products would require a name that describes the modification (§ 102.33(e)) but would not be prohibited under new § 101.30(k) from being included in the calculation of total juice percentage.

The third category described in the comment is clearly within the description in proposed § 102.33(e) (redesignated as new § 102.33(f)) and requires a name that fully describes the major modification. In suggesting that these products not be identified as "juice," the comment would prohibit the use of the word "juice" in the name of these modified juices. As discussed in the July 2, 1991, proposal and in response to comment 56 of this document, which follows, FDA disagrees and concludes that a name that fully describes the modifications made in the juice may include the word "juice" and its source.

56. A number of comments disagreed with the proposed provisions for naming juices that had undergone major modifications. They referred to these products as "stripped juices" and

"sugar water." They stated that the term "juice" should not be included in the name of such modified products. Some comments suggested alternative names such as "grape syrup," "apple syrup," or a similar term.

The agency proposed in § 102.33(d) (redesignated as new § 102.33(e)) that the common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "deflavored, decolored grape juice"). The agency believes that there is enough information in the description of the modification that consumers will be able to recognize the ingredient as different from the original juice.

Further, since juices with major modifications may not be included in the total percentage juice declaration, and the source fruit or vegetable from which the modified juice was derived may not be depicted on the label or other pictorial representation, consumers should not be misled by inclusion of the word "juice" in the name of juices in the ingredient list. Therefore, the agency is not granting the comments' request.

In addition, the suggestions for alternative names covered only some of the products in the category of juices that have undergone significant modifications. For example, other comments (comments 20 and 41 of this document) addressed juices from which the sugars had been removed. As discussed in response to those comments "reduced sugar ——— juice" may be an appropriately descriptive term for such a product with the name of the alternative sweetening ingredient appropriately declared.

Comments that addressed the issue supported the provision in proposed § 102.33(e) (redesignated as new § 102.33(f)) that the fruit or vegetable source of a modified juice may not be depicted on the label by vignette or other pictorial representation.

Accordingly, FDA concludes that except for conforming the wording of § 102.33(f) to reflect the decision made with respect to modified juices in comment 39 of this document, the provision should be retained. The agency wishes to clarify that the provision addresses juice products that have undergone major modification and as a result are no longer recognizable at the time processing is complete, or whose nutrient profile has been diminished to a level below the normal nutrient range for the juice. The prohibition against depicting the fruit or vegetable on the label does not apply to juices that have been slightly modified but that still retain the basic properties of the original juice, e.g., acid-reduced grape juice.

IV. Other Issues

57. One comment stated that where a beverage is prepared from one or more juice concentrates this fact should be declared as part of the common or usual name.

The agency agrees. FDA's longstanding policy with regard to juice beverages made from concentrate is that a term such as "from concentrate" or "reconstituted" must be a part of the name of the juice, in letters not less than one-half the height of the letters in the name of the juice, e.g., lemon juice (§ 146.114) and orange juice from concentrate (§ 146.145). Accordingly, FDA has added as § 102.33(g) a requirement that when one or more of the juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such term may either be included in the name of each individual juice where appropriate, or it may be stated once adjacent to the product name so that it applies to all the juices (e.g., "cherry juice (from concentrate) in a blend of 2 other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in type size no less than one-half the height of the letters in the name of the fruit or vegetable juice. This type size requirement is consistent with similar provisions in existing regulations (e.g., §§ 146.114 and 146.145).

58. One comment pointed out that under § 101.22(i)(1)(iii) the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors. It requested that § 102.33(b) be amended to clarify this.

The agency agrees that the requested clarification may be helpful to readers of the regulation and is revising § 102.33(b) accordingly. Because the provision is already a part of FDA's food labeling regulations, this amendment is not substantive. It simply conforms § 102.33(b) to § 101.22(i)(1)(iii).

59. Comments supported the proposal to revoke the common or usual name regulations for noncarbonated beverage products that contain no fruit or vegetable juice (§ 102.30) and for diluted orange juice beverages (§ 102.32). They agreed with FDA's position that because these products would be covered under new § 101.30 and the revised § 102.33, the separate regulations are no longer needed. Accordingly, as proposed, FDA is revoking these two regulations.

V. Effective Date

FDA proposed to make the percent juice labeling regulations effective on the same date as the mandatory nutrition labeling final rule (i.e., May 8, 1993). However, the agency pointed out that the 1990 amendments state in section 10(c) of the 1990 amendments that percent juice labeling was to take effect 1 year after enactment. Thus, on November 8, 1991, the statutory provision for percent juice declaration was to go into effect.

In response to the July 2, 1991, proposal many comments from the food industry strongly urged FDA to reconsider the effective date for percent juice labeling regulations. The comments argued that a November 8, 1991, effective date would not allow the food industry enough time to develop the required labeling and would significantly increase costs because present inventory would have to be discarded. The comments strongly urged FDA to establish a uniform effective date for the requirement for percent juice declaration with section 403(q) of the act (mandatory nutrition labeling) and section 403(r) of the act (health and nutrient content claims), which were added to the act by the 1990 amendments. Although FDA agreed with these comments, it had no authority to provide the requested exemptions or extend the effective date.

A technical amendment (Pub. L. 102–108) was enacted on August 17, 1991, in which Congress amended the 1990 amendments to delay the effective date of the percent juice labeling requirements. Notice of this change in the effective date was given in the Federal Register of November 27, 1991 (56 FR 60877). Under this amendment the new percent juice labeling requirements for fruit and vegetable juice beverages apply to labels attached to these products after May 8, 1993.

60. Many comments responding to this proposal objected to the proposed effective date of November 8, 1991, for compliance with the requirements of the percentage juice declaration provisions because of the cost and time involved in making the necessary labeling changes. The agency also received a comment requesting a temporary exemption from the May 8, 1993, statutory effective date established by the technical amendment. The comment requested that the requirement for percentage juice declaration on the labels of beverages purporting to contain juice be implemented concurrently with any later applicability date that the agency

may prescribe for the nutrition labeling regulations pursuant to section 10(a)(3)(B) of the 1990 amendments. The comment suggested that the effective date for the percent juice declaration be delayed until May 8, 1994, on the basis of the proviso in section 403(i) of the act which states that: "* * * to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary." The comment cited case law and previous FDA policy as precedent for the requested temporary exemption.

The agency is not persuaded by the arguments and assertions presented in the request for a temporary exemption from the statutory compliance date of May 8, 1993, for the requirement of percentage juice declaration. The agency acknowledges that section 403(i) of the act provides authority for exemption, and some such exemptions have been temporary. However, in light of the specific date (May 8, 1993) established by the technical amendment, and the failure of Congress to include provisions for a delay of the application of this provision, in contrast to the provision that it made for such a delay for the nutrition labeling and nutrient content claims provisions in the 1990 amendments, and without any indication in the legislative history that Congress wished to delay any longer the implementation of percentage juice declaration on beverages purporting to contain juice, the agency finds that a temporary exemption based on section 403(i) of the act is not sustainable. Therefore, the agency is not granting a temporary exemption from compliance with the percent juice declaration requirements or extending the effective date until May 8, 1994. However, because the amendments to part 102 are not directly responsive to section 7 of the 1990 amendments, and in order to minimize costs, FDA is making the amendments to part 102 effective on May 8, 1994.

VI. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the **Federal Register** of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the **Federal Register**. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857 and a notice will be published in the **Federal Register** announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

VII. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in July 2, 1991, proposal, the agency determined that under 21 CFR 25.24(a)(11), that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required. No new information or comments have been received that would effect the agency's previous determination.

VIII. References

The following references have has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Lake, Robert L., letter to NFPA, March 16, 1988.

2. Mattick, Leonard R., and S. C. Moyer, *Journal Association of Official Analytical Chemistry*, Vol. 66, No. 5, pp. 1251–1255, 1983.

3. Wrolstad, Ronald E., "Detection of Adulteration in Several Fruit Berry Drinks and Concentrates," in "Adulteration of Fruit Juice Beverages," ed., S. Nagy, J. A. Attaway, M. E. Rhodes, Marcel Dekker, Inc., New York, p. 390, 1988.

4. Snyder, Carl S., and Lester D. Hammond, "Weights per U.S. Gallons and Weights per Cubic Foot of Sugar Solution," National Bureau of Standards, Circular 457, Table 1, pp. 3–26, 1946.

5. USDA Handbook 8–9: Composition of Foods: Fruits and Fruit Products, Raw, Processed Prepared, Rev. August, 1982.

6. USDA Handbook 8–11: Composition of Foods: Vegetables and Vegetable Products, Raw, Processed Prepared, Rev. August, 1984.

7. Wallrauch, S. and W. Faethe, "Germany: RSK Values—Guidelines and Tolerances for Specified Constituents in Fruit Juices," in "Adulteration of Fruit Juice Beverages," ed., S. Nagy, J. A. Attaway, M. E. Rhodes, Marcel Dekker, Inc., New York, pp. 424–429, 446–452, 1988.

8. Yeatman, Senzel, and Springer, "Correction of Refractometer Readings for Citric Acid Content in Frozen Concentrate for Lemonade," *Journal of the Association of Official Analytical Chemists*, vol. 59, p. 368, 1976.

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10. Nelson, P. E. and D. K. Tressler, "Fruit and Vegetable Juice Processing Technology," 3d ed., The AVI Publishing Co., Inc., Westport, Connecticut, pp. 279, 360–361, 441–443, 1980.

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13. Sale, J. W., "Interpretation of Chemical Analyses of Preserves and Jams," *Journal of the Association of Official Analytical Chemists*, vol. 21, No. 8, pp. 502–515, 1938.

14. Frederick E. Boland, Victor H. Blomquist, and Ben Estrin, "Chemical Composition of Fruits," *Journal of the Association of Official Analytical Chemists*, vol. 51, No. 6, pp. 1203–1205, 1968.

15. Monzini, A. and E. Maltini, "Production of Juice Powders without Additives by Vacuum Belt Drying," Flussiges Obst, vol. 57, No. 2, pp. 89–90, 1990.

16. Food and Drug Administration, State Cooperation Information Letter No. 48, June 26, 1950. Stutsman, Martin J., letter to City of Los Angeles Department of Aging, April 18, 1989. Scheineson, Marc J., letter to Bob Graham, United States Senator, May 14, 1992.

List of Subjects

21 CFR Part 101

Food Labeling, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Fruit juices, Oils and fats, Onions, Potatoes, Seafood.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101 and 102 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.30 is added to subpart B to read as follows:

§ 101.30 Percentage juice declaration for foods purporting to be beverages that contain fruit or vegetable juice.

(a) This section applies to any food that purports to be a beverage that contains any fruit or vegetable juice (i.e., the product's advertising, label, or labeling bears the name of, or variation on the name of, or makes any other direct or indirect representation with respect to, any fruit or vegetable juice), or the label or labeling bears any vignette (i.e., depiction of a fruit or vegetable) or other pictorial representation of any fruit or vegetable, or the product contains color and flavor that gives the beverage the appearance and taste of containing a fruit or vegetable juice. The beverage may be carbonated or noncarbonated, concentrated, full-strength, diluted, or contain no juice. For example, a soft drink (soda) that does not represent or suggest by its physical characteristics, name, labeling, ingredient statement, or advertising that it contains fruit or vegetable juice does not purport to contain juice and therefore does not require a percent juice declaration.

(b)(1) If the beverage contains fruit or vegetable juice, the percentage shall be declared by the words "Contains ———— percent (or %) ———— juice" or "———— percent (or %) juice," or a similar phrase, with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the juice and the second blank (if used) filled in with the name of the particular fruit or vegetable (e.g., "Contains 50 percent apple juice" or "50 percent juice").

(2) If the beverage contains less than 1 percent juice, the total percentage juice shall be declared as "less than 1 percent juice" or "less than 1 percent ———— juice" with the blank filled in with the name of the particular fruit or vegetable.

(3) If the beverage contains 100 percent juice and also contains non-juice ingredients that do not result in a diminution of the juice soluble solids or, in the case of expressed juice, in a change in the volume, when the 100 percent juice declaration appears on a panel of the label that does not also bear the ingredient statement, it must be accompanied by the phrase "with added ————," the blank filled in with a term such as "ingredient(s)," "preservative," or "sweetener," as appropriate (e.g., "100% juice with added sweetener"), except that when the presence of the non-juice ingredient(s) is declared as a part of the statement of identity of the product, this phrase need not accompany the 100 percent juice declaration.

(c) If a beverage contains minor amounts of juice for flavoring and is labeled with a flavor description using terms such as "flavor", "flavored", or "flavoring" with a fruit or vegetable name and does not bear:

(1) The term "juice" on the label other than in the ingredient statement; or

(2) An explicit vignette depicting the fruit or vegetable from which the flavor derives, such as juice exuding from a fruit or vegetable; or

(3) Specific physical resemblance to a juice or distinctive juice characteristic such as pulp then total percentage juice declaration is not required.

(d) If the beverage does not meet the criteria for exemption from total juice percentage declaration as described in paragraph (c) of this section and contains no fruit or vegetable juice, but the labeling or color and flavor of the beverage represents, suggests, or implies that fruit or vegetable juice may be present (e.g., the product advertising or labeling bears the name, a variation of the name, or a pictorial representation of any fruit or vegetable, or the product contains color and flavor that give the beverage the appearance and taste of containing a fruit or vegetable juice), then the label shall declare "contains zero (0) percent (or %) juice". Alternatively, the label may declare "Containing (or contains) no ———— juice", or "no ———— juice", or "does not contain ———— juice", the blank to be filled in with the name of the fruits or vegetables represented, suggested, or implied, but if there is a general suggestion that the product contains fruit or vegetable juice, such as the presence of fruit pulp, the blank shall be filled in with the word "fruit" or "vegetable" as applicable (e.g., "contains no fruit juice", or "does not contain fruit juice").

(e) If the beverage is sold in a package with an information panel as defined in § 101.2, the declaration of amount of juice shall be prominently placed on the information panel in lines generally parallel to other required information, appearing:

(1) Near the top of the information panel, with no other printed label information appearing above the statement except the brand name, product name, logo, or universal product code; and

(2) In easily legible boldface print or type in distinct contrast to other printed or graphic matter, in a height not less than the largest type found on the information panel except that used for the brand name, product name, logo, or universal product code.

(f) The percentage juice declaration may also be placed on the principal display panel, provided that the declaration is consistent with that presented on the information panel.

(g) If the beverage is sold in a package that does not bear an information panel as defined in § 101.2, the percentage juice declaration shall be placed on the principal display panel, in type size not less than that required for the declaration of net quantity of contents statement in § 101.105(i), and be placed near the name of the food.

(h)(1) In enforcing these regulations, the Food and Drug Administration will calculate the labeled percentage of juice from concentrate found in a juice or juice beverage using the minimum Brix levels listed below where single-strength (100 percent) juice has at least the specified minimum Brix listed below:

Juice	100 percent juice[1]
Acerola	6.0
Apple	11.5
Apricot	11.7
Banana	22.0
Blackberry	10.0
Blueberry	10.0
Boysenberry	10.0
Cantaloupe Melon	9.6
Carambola	7.8
Carrot	8.0
Casaba Melon	7.5
Cashew (Caju)	12.0
Celery	3.1
Cherry, dark, sweet	20.0
Cherry, red, sour	14.0
Crabapple	15.4
Cranberry	7.5
Currant (Black)	11.0
Currant (Red)	10.5
Date	18.5
Dewberry	10.0
Elderberry	11.0
Fig	18.2
Gooseberry	8.3

Juice	100 percent juice[1]
Grape	16.0
Grapefruit	10.0
Guanabana (soursop)	16.0
Guava	7.7
Honeydew melon	9.6
Kiwi	15.4
Lemon	[2]4.5
Lime	[2]4.5
Loganberry	10.5
Mango	13.0
Nectarine	11.8
Orange	11.8
Papaya	11.5
Passion Fruit	14.0
Peach	10.5
Pear	12.0
Pineapple	12.8
Plum	14.3
Pomegranate	16.0
Prune	18.5
Quince	13.3
Raspberry (Black)	11.1
Raspberry (Red)	9.2
Rhubarb	5.7
Strawberry	8.0
Tangerine	11.8
Tomato	5.0
Watermelon	7.8
Youngberry	10.0

[1] Indicates Brix value unless other value specified.
[2] Indicates anhydrous citrus acid percent by weight.

(2) If there is no Brix level specified in paragraph (h)(1) of this section, the labeled percentage of that juice from concentrate in a juice or juice beverage will be calculated on the basis of the soluble solids content of the single-strength (unconcentrated) juice used to produce such concentrated juice.

(i) Juices directly expressed from a fruit or vegetable (i.e., not concentrated and reconstituted) shall be considered to be 100 percent juice and shall be declared as "100 percent juice."

(j) Calculations of the percentage of juice in a juice blend or a diluted juice product made directly from expressed juice (i.e., not from concentrate) shall be based on the percentage of the expressed juice in the product computed on a volume/volume basis.

(k) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then that juice to which such a major modification has been made shall not be included in the total percentage juice declaration.

(l) A beverage required to bear a percentage juice declaration on its label shall not bear any other percentage declaration that describes the juice content of the beverage in its label or in its labeling (e.g., "100 percent natural" or "100 percent pure"). However, the label or labeling may bear percentage statements clearly unrelated to juice content (e.g., "provides 100 percent of U.S. RDA of vitamin C").

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

3. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: Secs. 201, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371).

§ 102.30 [Removed]

4. Section 102.30 Noncarbonated beverage products containing no fruit or vegetable juice is removed from subpart B.

§ 102.32 [Removed]

5. Section 102.32 Diluted orange juice beverages is removed from subpart B.

6. Section 102.33 is revised to read as follows:

§ 102.33 Beverages that contain fruit or vegetable juice.

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of § 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit.")

(d) In a multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5- percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in § 102.5(b)(2).

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

(f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.

(g) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.

Dated: October 27, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 5, 20, 100, 101, 105, and 130

[Docket No. 91N–0219]

RIN 0905–AD08

Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Regulatory impact analysis statement.

SUMMARY: The Food and Drug Administration (FDA) is publishing the final regulatory impact analysis (RIA) that it has prepared under Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). This study presents the costs and benefits of the food labeling regulations that FDA is issuing. FDA is issuing these final rules (published elsewhere in this issue of the **Federal Register**) in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and as part of the Secretary of Health and Human Services' (the Secretary's) food labeling reform initiative. The agency has prepared this comprehensive RIA document for these regulations because, when taken together, they constitute a major rule.

FOR FURTHER INFORMATION CONTACT: Richard A. Williams, Jr., Center for Food Safety and Applied Nutrition (HFF–303), Food and Drug Administration,200 C St. SW., Washington, DC 20204, 202–205–5271.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 27, 1991 (56 FR 60366 et seq), FDA published a number of proposed food labeling regulations to implement the provisions of the 1990 amendments (Pub. L. 101–535). In the same issue of the **Federal Register** (56 FR 60856, November 27, 1991), FDA published an RIA (hereinafter referred to as the 1991 RIA proposal) which preliminarily estimated the costs and benefits of the various proposed regulations and on which FDA asked for comments. Interested persons were given until February 25, 1992, to comment. FDA received approximately 350 letters, each containing one or more comments, from health professionals, trade associations, Federal and State Governments, foreign governments, consumer advocacy organizations, consumers, professional societies, food manufacturers and distributors, and academia. Many of the issues addressed in the 1991 RIA proposal are covered in the separate final rules issued concurrently with this document.

Comments have not altered FDA's preliminary finding that the food labeling reform initiative, taken as a whole, will have associated costs in excess of the $100 million threshold that defines a major rule. Therefore, in accordance with Executive Order 12291, FDA has developed one comprehensive final RIA that presents the costs and benefits of all of the food labeling proposals taken together.

In addition, FDA is publishing elsewhere in this issue of the **Federal Register** a final rule to announce its decision to delay the application of the nutrition labeling and nutrient content claims provisions of the Federal Food, Drug, and Cosmetic Act (the act). In that rule FDA concluded that requiring compliance with section 403(q) or (r)(2) of the act (21 U.S.C. 343(q) or (r)) on May 8, 1993, would cause an "undue economic hardship" on the food industry in that there would be costs to the food industry that are excessive and more than Congress intended. All comments regarding the applicability date are addressed in that document.

FDA also published, as a component of the 1991 RIA proposal, a preliminary regulatory flexibility analysis which addressed the issue of small businesses. The 1990 amendments granted an exemption from mandatory nutrition labeling for small businesses. Under section 403(q)(5)(D) of the act, a small business is defined as a business with less than $500,000 annual gross sales or a business with annual gross sales of more than $500,000 but less than $50,000 in food sales. The exemption does not apply to those products that make nutritional claims or voluntarily provide nutrition information.

Comments concerning this exemption stated that this exemption was too low and are discussed more thoroughly in the mandatory nutrition labeling final rule published elsewhere in this issue of the **Federal Register**. FDA, in response to these comments, participated in a series of public forums that had been scheduled by the U.S. Department of Agriculture (USDA) to discuss the small business issue. In addition, FDA published a notice in the **Federal Register** asking for comments on this issue. As of publication of these rules and the final RIA, the exemption has not been changed. FDA will discuss in more detail the affect of the 1990 amendments on small businesses in a final Regulatory Flexibility Analysis published subsequent to these final rules.

II. Regulatory Options

Under the Regulatory Flexibility Act, FDA is required by law to consider ways to reduce the regulatory burden on small businesses. One conceivable regulatory option would be to allow product lines with fewer than 500,000 unit sales annually produced by small firms (firms with less than 500 employees) to make reasonable estimates of mean nutrient content rather than complying with the 80/100/120 rules.

Under the regulatory option currently selected, class I nutrients (added nutrients) including vitamins, minerals, protein, dietary fiber, and potassium are required to have at least 100 percent of the listed value within specified variances. Class II nutrients (naturally occurring), including vitamins, minerals, proteins, total carbohydrates, dietary fiber, other carbohydrates, polyunsaturated or monounsaturated fat, or potassium must have at least 80 percent of the value for the nutrient declared on the label within specified variances. Finally, a food with a label declaration of calories, sugars, total fat, saturated fat, cholesterol, or sodium is misbranded under section 403(a) of the act if the nutrient content of the composite sample is greater than 20 percent more than the declared amount, again within the variance specified for the appropriate test. In addition, in new § 101.9(g)(6), reasonable excesses over or under the labeled amounts are allowed where current good manufacturing practices (CGMP's) are used. This option would replace these values with a requirement to list the mean value within variances established for specific nutrient tests and allowing reasonable excesses over or under the labeled amounts where CGMP's are used. This option could either exist as a blanket exemption for small firms or one that is made by special request on a per firm basis to the agency.

Thus small firms could determine nutrient levels by analysis, by calculation using nutrient data bases of ingredients and recipes, or by other reasonable means that provide assurance that the value declared is the mean value of a particular nutrient in the food product. This option would reduce the burden on small business by allowing the use of means rather than values determined by analytical testing in the declaration of nutrient content.

Approximately 59 percent of all food products have fewer than 500,000 units sold annually and are produced by

small firms. This option would significantly reduce analytical costs by between $235 and $600 million depending upon the rate of retesting that would otherwise be done. In addition, this option will prevent small business failure which may occur for small firms with very low product volume. This option would result in virtually no loss in benefits because the occasional errors in labeling may offset one another. In addition, although this type of exemption would represent a large number of products, it represents only about 2 percent of the diet. Thus, for example, if these manufacturers were to approximate wrong (or intentionally misrepresent their products) concerning the amount of total fat in their product such that all of the products in this category underreported the amount of fat by 50 percent, and if all consumers were 100 percent mislead by such underreporting, it would only result in a 1 percent error in fat consumption. Given that such errors in reporting are: (1) Likely to balance out; (2) will probably be corrected by enforcement over time; and, (3) that it is unlikely that all consumers would be misled by gross errors, a significant loss of benefits as they have been calculated in this regulatory impact analysis seems unlikely.

An alternate standard for coverage of this option, such as exempting small firms (500 or less employees) with less than 100,000 units could also be chosen. This would exempt 51 percent of the products covered by the 1990 amendments, but it would exempt less than 2 percent of the diet.

Although FDA is allowing the "reasonable basis" standard in food service establishments making nutrient content claims and health claims, FDA believes that there is a significant difference between the criteria used to determine whether or not a claim is justified, and the criteria used to determine the quantified level of a nutrient to be reported on a food label. In addition, FDA believes that the option that it has chosen is also consistent with the other relevant sections of the act including sections 402(b) and 403(a) (21 U.S.C. 342(b) and 343(a)).

III. Costs of the Regulations

A. General

In the 1991 RIA proposal, FDA determined that about 17,000 domestic food manufacturers and 260,000 labels would be affected by the regulations promulgated in response to the 1990 amendments. Of these, approximately 160 dietary supplement manufacturers would alter approximately 3,400 unique dietary supplement products. In addition, 96,000 food service establishments would also be required to alter their menus if they are not in compliance with nutrient content and health claims regulations.

Categories of costs include administrative, analytical, printing, inventory disposal, and reformulation. In all cost categories, except administrative costs, the costs of relabeling products produced and labeled in foreign countries cannot be separated from those products produced and labeled domestically. Thus, the administrative costs considered are domestic costs only, whereas the printing, inventory, and analytical costs considered are multinational.

In the 1991 RIA proposal, mandatory ingredient labeling for standardized foods and certified colors were separated from the other actions because it was to take effect in November of 1991. Costs for these provisions, as proposed, were $128 million.

In the **Federal Register** of July 2, 1991 (56 FR 30452), FDA published a proposal on the declaration of percentage juice. FDA determined that the costs which would occur as a result of those proposed requirements would be $40 million, based on an effective date of November 8, 1991. When the 1991 RIA proposal was published, the proposed requirements regarding the declaration of percentage juice were to become effective concurrently with the requirements for mandatory nutrition labeling which would have resulted in lowering the incremental costs to $1 million. However, because those provisions are subject to being enforced 9 months before the agency will enforce the requirements for mandatory nutrition labeling, the costs are appropriately determined to be the original assessment of $40 million. FDA received no comments to the original proposal objecting to its determination of the costs. Therefore, the agency is not amending its original estimate of the costs of declaring percentage juice.

Voluntary nutrition labeling of raw fruit, vegetables, and fish is also separable from all other provisions of the 1990 amendments because it affects supermarkets, not food manufacturers. The agency estimated these costs to be between $117 to $155 million.

The costs to food manufacturers for all other labeling regulations, including percent juice labeling, mandatory nutrition labeling, nutrient content claims definition, health claim labeling, format changes, and others, were estimated in the 1991 RIA proposal to be as high as $1.3 billion, depending on the compliance period chosen.

In addition, FDA estimated that the costs to restaurants and other food service establishments to reprint menus not in conformance with nutrient content or health claim proposed regulations would be $116 million.

FDA estimated that total costs of the proposed rules to implement the 1990 amendments, excluding voluntary supermarket labeling, would be approximately $1.5 billion. The agency also determined that if the agency opted to allow an additional 6 months or an additional year to the compliance period provided for by the statute, total costs would decrease to $.8 billion and $.6 billion, respectively.

In October 1992, Congress passed the Dietary Supplement Act of 1992 (DS Act). This act prevents the agency from implementing the 1990 amendments as they apply to dietary supplements until December 1993. This act requires the agency to issue proposed regulations applicable to dietary supplements by June 15, 1993. Because this document is intended to determine the costs and benefits of all regulations implementing the 1990 amendments, the agency is responding to the comments regarding dietary supplements with tentative conclusions and is presenting preliminary estimates of those costs. The agency will address any alterations to these estimates when it issues regulations on the labeling of dietary supplements.

In response to its assessment of the costs in the 1991 RIA proposal, FDA also received several comments regarding costs from firms whose products are regulated by USDA, not FDA. The agency has forwarded these comments to USDA for consideration in their RIA.

1. One comment stated that FDA's cost analysis could not be correct because it is impossible to accurately estimate costs.

The agency disagrees with the comment. The agency recognizes that costs of regulation are complex and often difficult to measure with 100 percent accuracy. However, after studying the industries affected and considering the comments, FDA is confident that it has determined the costs of the regulations with reasonable accuracy. The agency will not amend its cost estimates based on this comment.

2. One comment stated that because it would take up to 30 years to see the benefits of the regulations, FDA should calculate the costs of nutrition labeling for 30 years. The comment criticized FDA for limiting the costs to a 5-year period.

FDA disagrees with this comment. FDA has determined that the benefits will occur sooner than 30 years. For calculation purposes, FDA assumed that the lag time for cancer is 10 years. Beyond 20 years, the discount rate drives the benefits too low to be significant. FDA, therefore, calculated benefits over 20 years for ease of computation. For the sake of consistency, FDA also calculated the costs over 20 years. FDA did not limit its determination of costs to 5 years as the comment mistakenly understood. FDA is calculating the final costs and benefits similarly.

B. Administrative Costs

In the 1991 RIA proposal, FDA determined that administrative costs would be approximately $177 million, of which $16 million are attributable to mandatory ingredient labeling of standardized foods and certified colors. FDA received one comment from an industry association that stated that FDA provided a fairly reasonable assessment of the administrative portion of total cost. This judgment was based on the association's evaluation of such costs for the firms it represents. However, FDA received several other comments criticizing its estimates.

3. Two comments stated that administrative costs are more closely related to the number of products or labels than to the number of firms. One firm stated that administrative costs will be high because of the number of units involved and the fact that the product is packaged at many different locations by third-party vendors. This situation, the comment stated, will necessitate additional administrative costs in the nature of man-hours for coordination.

FDA acknowledges that the comment may be correct but has no additional information to support this claim. In its original analysis, FDA assumed that administrative costs differed based on firm size. In part, this assumption is based not only on the bureaucratic difficulties inherent in larger companies, but also on the assumption that larger firms produce a greater number of products. The comment did not state nor supply data as to whether changing this assumption would increase or decrease administrative costs. Thus, FDA is not amending its final administrative cost estimates based on this comment.

4. Several comments stated the cost of increased errors should be included in administrative costs, especially for smaller firms. The comment stated that error rates will increase because of: (1) The unreasonably short timeframes in which all label changes will be made, (2) inexperienced short-term personnel hired to relieve the enormous strains on capacity, and (3) the novelty and magnitude of the changes themselves.

FDA agrees that firms may experience increased error rates which may increase administrative costs. FDA also agrees that these costs will be significantly reduced by allowing firms additional time to comply with labeling regulations. However, FDA is not amending its final cost estimates to account for increased errors because the final rule allows additional time, and the comments did not provide information regarding either the rate at which errors would be increased or the cost of such errors. Also, FDA believes that the cost of increased errors would not significantly increase total costs. Finally, by delaying the date that it will apply section 403(q) and (r)(2) of the act, the agency is relieving the time pressures that the comments said would contribute to the error rates.

5. Several comments provided estimates of administrative costs. FDA received only one estimate for small firms, $3,000 per firm. Estimates for medium to large firms range from approximately $6,500 to over $1 million per firm. One manufacturer of both FDA and USDA regulated products stated that additional man-hours and a part-time consultant would be required to implement the proposed label requirements at a total cost of $53,300. Some comments provided separate estimates for internal administrative costs and external administrative costs. Internal administrative costs include travel expenses, overtime expenses, and payroll expenses and benefit costs for added employees. External administrative costs include such items as legal fees, temporary help, and consultants.

FDA recognizes that the factors that determine administrative costs are very complicated. In the 1991 RIA proposal, FDA estimated that administrative costs for intricate regulations would be $9,000 for small/medium firms and $68,450 for large firms, assuming a compliance date of May 8, 1993. Administrative costs would be less with longer compliance periods. Final administrative estimates are based on a compliance period ending in May 1994. Administrative costs would be $3,375 for small/medium firms and $25,700 for large firms. The range of administrative cost estimates submitted in the comments was extremely broad. Also, there were no identifiable patterns to the estimates given. Therefore, FDA is not altering its original estimates. In the future, FDA would be interested in obtaining more detailed data concerning the nature and level of the marginal administrative costs of regulation.

6. One comment stated that the cost of reading, analyzing, and commenting on the proposals should be addressed. The comment stated that thousands of people are spending many hours reading, analyzing, discussing, and explaining FDA proposals and writing, typing, copying, collating, and sending comments.

FDA recognizes that many resources are spent in the process of reviewing and responding to proposals. Whether these costs should be attributed to the regulation or considered normal costs of doing business in a regulated industry is debatable. Nevertheless, FDA has no information to determine the amount and value of resources spent in reviewing regulations and is, therefore, not amending its estimates based on this comment.

7. One comment argued that FDA should consider the cost that the implementing regulations would have on the Government, e.g., extra FDA personnel, laboratory supplies, and tax increases to the American consumer.

FDA agrees with this comment. FDA estimates that approximately 85 Full-Time Equivalents (FTE's) have been utilized in the 2 years of development of the implementing regulations. In addition, FDA estimates that 135 FTE's will be used each year during the next 20 years in recurring activities related to the implementing regulations, e.g., enforcement and petition review. Each FTE is currently valued at $75,000. Therefore, FDA's labor costs are about $6.4 million for start-up and $127 million in recurring costs (discounted at 5 percent). In addition, FDA estimates that other costs to the Government to implement the 1990 amendments are approximately $4.4 million in start-up costs and an additional $2 million per year over the next 20 years, or $25 million (discounted at 5 percent). Therefore, total estimated costs to the Federal Government are $163 million. FDA notes, however, that these costs do not constitute increased cost to either consumers or industry in that they do not represent an increase in funding to the Federal Government. The development and enforcement of these regulations is funded primarily by replacing other Government programs.

8. One dietary supplement manufacturer stated that FDA should take into account the total cost of administrative time rather than incremental costs associated with the regulatory action being taken.

FDA disagrees with this comment. Executive Order 12291 requires that FDA calculate the cost of this regulatory

action. Therefore, only incremental costs—those costs associated with the additional administrative effort required to comply with the implementing regulations—are relevant. Accordingly, FDA rejects the comment on this point.

9. One dietary supplement manufacturer stated that FDA's estimate of administrative costs for supplement manufacturers was incorrect. The comment suggested that if one mid-level executive spends 1 week trying to read and understand these regulations, the cost would be in excess of the $850 per firm estimated by FDA.

FDA neither agrees nor disagrees with this comment. Although the assumptions FDA made regarding administrative costs for dietary supplements may have resulted in underestimates, comments did not provide FDA with information with which reasonable estimates could be made. FDA will continue to study the supplement industry and will alter its estimates, if necessary, when the regulations regarding dietary supplements are issued. FDA is not currently altering its original estimate based on this comment.

C. Analytical Costs

In the 1991 RIA proposal, FDA estimated analytical costs to be $195 million, of which $112 million are initial one-time costs. Although one firm stated that its cost estimates verify the numbers reported by FDA in its 1991 RIA proposal, several other comments argued FDA's estimates were too low.

10. Several comments questioned FDA's assumption that some products are already tested. These comments stated that the agency's assumption that 20 percent of products are already performing all newly required tests and would require no additional testing is arbitrary and not based on survey or other data. These firms argued that no products are currently undergoing all testing that would be necessary for compliance because the definitions for some nutrients or food components will significantly change.

FDA is persuaded by this argument. In its final estimate, the agency is assuming that all products will undergo at least some analytical testing and is adjusting the costs for analytical tests accordingly. FDA is assuming that the 40 percent of foods that currently provide nutrition information will require testing for only the newly required nutrients. The remaining 60 percent of foods are not currently undergoing testing for any nutrients. Therefore, the incremental costs for this 60 percent of foods will be the cost of performing all required tests. This change in assumptions also affects administrative costs because the regulation will be complex (requiring testing) for all firms, rather than for 80 percent of firms as originally assumed.

11. One comment requested that FDA make its laboratories available for testing at a small or no fee in order that firms may offset at least some of the cost of the regulations.

FDA does not have the resources to make its laboratories available to do testing, nor can FDA charge a fee to do testing. Therefore, FDA rejects this request. Although the choice may affect the company's expenses, whether testing is performed in-house, by independent laboratories, or by FDA laboratories, the societal costs of the regulation are the same.

12. Many comments stated that testing costs per product may increase because of the increased demand on laboratories. One firm estimated that analytical work on a priority basis will add about $2,000 per product. Similarly, many comments suggested that an increase in demand for printing services would create additional costs.

FDA agrees that the price of testing may increase in the short run because of increased demand. However, because firms will have 15 months to comply, not six months as assumed by the comments, any increase in costs will not be significant. FDA is not considering these costs in its final estimate.

13. One comment argued that FDA's estimate of the cost of analytical testing is wrong because it is based on the number of products, rather than the number of labels. The comment stated that it is not clear that a correlation exists between the number of labels needed to test and the number of products. For example, the comment stated that "manufacturing for private labels may require more testing of essentially the same product due to ingredient demands for retailers."

FDA believes that the comment did not understand FDA's definition of products and labels. FDA defined a product as an individual formulation regardless of size of container. Any change in ingredients constitutes a separate product formulation. When a private label manufacturer changes a product's ingredients in order to meet different demands of retailers, a different product is created, and additional testing is required. However, if the manufacturer merely changes the packaging for different retailers but does not change the product formulation, there is no new product, only a new label. FDA concludes after consideration of the contractor's (Research Triangle Institute (RTI)) report and comments to the 1991 RIA proposal, that for each distinct product formulation a separate analytical test must be performed. Tests for each individual label are unnecessary. Therefore, FDA is not modifying its estimate of analytical testing in response to this comment.

14. Many comments suggested that analytical costs as originally calculated are too low because the number of products on which they were based is too low.

FDA agrees that the estimate of the number of products contained in the 1991 RIA proposal was too low. FDA also agrees with comments that some firms use different formulations of the same product for different geographical areas because of varying ingredient demands. FDA's count of products and labels is based on Universal Product Code (UPC) codes that may not pick up these variations. Also, certain specialty items that are not sold through distribution channels using UPC codes would not be counted. Comments did not provide adequate information from which FDA can amend its original assessment of the number of products based on these considerations. However, FDA reviewed its source of the number of products (A. C. Nielsen) and found that its estimate was incorrect.

FDA originally used data collected in 1987 that was derived from grocery store warehouses. Because many products are not distributed through warehouses, FDA undercounted the number of products. A. C. Nielsen has since revised its method of data collection to account for this problem. Therefore, FDA now estimates that there are 196,000 products. The estimate of the number of labels, which was based on an up-to-date count of UPC codes, remains unchanged at 257,000. However, FDA recognizes that these estimates are still understated because Nielsen surveys 3,000 grocery stores and does not extrapolate to the remaining stores. FDA does not have any information with which such an extrapolation could be made. FDA also recognizes that these are still underestimates because: (1) Some firms use different formulations of the same product for different geographical areas due to varying ingredient demands; (2) FDA's count of products and labels is based on UPC codes which may not pick up these variations; and (3) certain specialty items which are not sold through distribution channels using UPC codes would not be counted. However, FDA does not have any better data, nor did the comments provide

better data. Therefore, the final estimates are based on these figures.

15. One comment argued that FDA's calculation of testing costs for those 32 percent of firms already performing the currently required tests was wrong. This comment argued that subtracting the $135 for tests not required was wrong because this is a sunk cost that was already being imposed by FDA. The comment did not object to the subtraction of $135 from the $354 cost required for analysis under the current regulations because this portion of the $354 will not be incurred by first-time testers.

FDA disagrees with the first point. FDA is not reimposing the costs for tests no longer required. The marginal cost is the cost of required tests ($376) less the cost of tests previously required by regulations but not required by these final rules ($135). FDA agrees with the second point made by the comment. The costs per test is not changed.

16. One comment argued that FDA's analytical cost estimates should have included employee time to prepare samples for testing, review laboratory reports, interpret the results, and determine resulting nutrition values that can be placed on labels. The comment stated an appropriate estimate would be 2–1/2 hours per product at an average salary and benefits figure of $85.

FDA agrees that the employee's time for preparing samples should be included as part of the analytical costs. However, the other activities cited by the comment are not analytical costs but administrative costs and are considered in that section of the document. Having concluded that the cost of preparing the sample should be added to its initial analysis, the agency, using the average hourly earnings calculated by the Department of Labor, has determined that an appropriate cost would be 1/2 hour per sample at an average salary and benefits figure of $19 per hour. These costs are included in the agency's final estimate.

17. One comment suggested that analytical costs should include the value of lost products and packages destroyed to run analyses, as well as the cost of freight to ship to the laboratory.

FDA agrees that for those products not undergoing any testing, the cited activities should be included in the analytical costs of complying with these regulations. Although FDA has no specific information on the amount of product and packaging that would be destroyed, or on the cost of that product, FDA can make crude estimates. These estimates suggest that such costs will be small relative to total costs. For example, if the cost of manufactured food products is approximately $2 per unit, and approximately 12 units per product are destroyed to conduct analytical testing, the total cost would be $4.7 million. Because these costs represent less than 1 percent of total costs, FDA is not attempting to accurately determine the cost of lost product and package and is not including these costs in its final estimates.

18. Several comments disagreed with FDA's assumptions regarding the frequency of retesting. One comment stated that partial, if not full, retesting will occur each time a product is reformulated. The comment noted that this occurs more frequently than every 5 years. Another comment stated that retesting would occur quarterly. A third comment was told by a laboratory that FDA would require testing 3 or 4 times a year. This latter comment recommended that FDA recommend laboratory analysis no more than once every 5 years or when the recipe changes.

FDA does not have a set number of times a product must be tested in a year, nor does FDA determine the frequency with which analytical information should be verified. The agency simply requires that the information on the label conforms to the regulations. Therefore, if a product is reformulated, the manufacturer should retest the product. The agency has no information regarding the average frequency of reformulation, nor was such information submitted by the comments. However, FDA is persuaded that many firms may retest their products more frequently than every 5 years. FDA, for its final estimates, calculated analytical costs based on a retesting frequency ranging from annual retesting to once every 5 years.

19. One comment stated that testing would almost always be duplicated and, in many cases, triplicated.

FDA believes that this comment confirms its assumption in the 1991 RIA proposal that initial tests will be performed three times to confirm the results. Thus, no change in the agency's original assumptions are necessary in response to this comment.

20. One comment suggested that analytical testing for new product introductions under the new proposals would be more expensive than otherwise.

FDA disagrees with this comment. Although initial testing costs to firms may go up because of queuing, FDA is not convinced that demand for testing will ultimately exceed the supply of testing services. However, FDA is including the incremental additional cost of testing new products in its final estimates of analytical testing costs which the agency did not do in the 1991 RIA proposal.

21. One comment suggested that the added cost of analysis would burden small companies because their work would be done by already overworked commercial laboratories which charge high fees for services, sometimes in excess of $900 for a full nutritional profile. Another comment agreed, arguing that the cost per product, estimated at $1,482, represents approximately 3 percent of the gross revenue per product for the average small/medium firm.

FDA agrees that because of the smaller volume under which small firms operate, the additional analytical testing could cause a burden on smaller firms. FDA believes that giving firms a longer time to comply with regulations, until May 8, 1994, will alleviate some but not all of this burden by reducing the impact of queuing costs. In addition, FDA believes that allowing firms the option of using nutritional data bases, instead of requiring analytical testing, will reduce the burden on small firms by providing a low-cost alternative to analytical testing.

22. One large firm stated that all costs incurred would be passed along to consumers almost immediately, not over a 20-year period. That comment explained that the cost of analytical work cannot be financed over a 20-year period.

FDA does not agree with this comment. The comment misinterpreted the agency's calculations. FDA did not state in the 1991 RIA proposal that costs would be financed over a 20-year period. FDA analyzed costs that will be incurred immediately. In addition, FDA also determined that firms would retest their products periodically, even without reformulating, to verify the accuracy of the nutrition information reported on the label and calculated the costs of this retesting over the next 20 years.

23. Several comments provided estimates of the costs of analytical testing. Estimates of analytical testing per product ranged from $500 to $2,000.

FDA, in the 1991 RIA proposal, calculated the analytical cost per product to be $723 for those products that have been tested and $1,785 for those products that have not been tested. Because these estimates are within the range reported by comments, FDA is using them in the final RIA.

24. One large firm stated that because testing for protein quality would be changed under FDA's proposed rules, the cost of this test should be included

with testing for cholesterol, fiber, fatty acids, and sugars. The comment also stated that under FDA's definitions, analysis for complex carbohydrate content would also be required.

FDA agrees with this comment that the cost of testing for protein quality would increase under FDA's rules. FDA has determined, based on information from existing independent testing laboratories' price lists, that a change in the definition of protein quality will add approximately $540 per product to the cost of analytical testing. Therefore, total costs would increase by approximately $159 million over the next 20 years assuming products would be retested every 5 years or $440 million assuming annual retesting (discounted at 5 percent). (FDA notes that these are maximum estimates. The agency is providing values in the final rule on mandatory nutrition labeling, published elsewhere in this issue of the **Federal Register**, that should significantly reduce the costs of calculating protein quality for many foods.) FDA is not, however, adding complex carbohydrates to the list of nutrients required to be listed in the nutrition label (see final rule on mandatory nutrition labeling published elsewhere in this issue of the **Federal Register**). Therefore, no analysis for this nutrient is necessary.

25. One comment stated that the changeover to new Reference Daily Intake (RDI) values will require that all data bases be completely reprogrammed to reflect the new values, and that therefore the cost of reprogramming all data bases should be included as a cost to the regulations.

FDA agrees with this comment. Because RDI's differ from Recommended Dietary Allowance's and Daily Reference Value's, on which the nutrition label is based, data bases would need some new programming if the agency were to switch to RDI's. The comment did not provide any data regarding the additional costs resulting from such changes. FDA is not aware of the number of such data bases but notes that it would take a large number coupled with significant reprogramming costs to affect this cost estimate. Therefore, FDA believes that such costs will be small relative to the total costs of the regulation. However, because the DS Act prevents FDA from adopting revised RDI's at this time, the costs associated with switching to new RDI values will not occur.

26. One large firm commented that for most nutritionally-modified products, and for the foods for which they substitute, it is necessary to conduct a complete nutritional analysis to determine nutritional equivalence. The comment estimated the cost of testing for complete nutritional equivalence for one product to be $2,300 for the first lot and $1,200 for the remaining two confirmatory lots. Also, the comment stated that the agency's proposals require testing for several micronutrients not previously included in nutritional equivalency testing, such as Vitamin K and molybdenum.

The point of the comment is unclear. If the comment is referring to tests conducted when using nutrient content claims, FDA disagrees that such costs have not been considered. The costs associated with the use of nutrient content claims are the costs of obtaining the information to insure that the claim meets the definitions provided by FDA. All firms will obtain that information when performing analyses for the nutrition panel. Therefore, there are no incremental costs for using nutrient content claims. If, however, the comment is referring to substitute products, that policy is not changing, and the comment has no relevance. Finally, because of the moratorium under the DS Act, FDA has not adopted RDI's for Vitamin K or molybdenum. Therefore, no testing for these nutrients is necessary at this time. For these reasons, FDA will not change its estimates based on this comment.

27. Manufacturers of dietary supplements objected to FDA's assumption that, because of the nature of the product, full analytical testing is already performed on supplements. Comments stated that because full analytical testing is not currently done on dietary supplements, all dietary supplement products will undergo full nutrient content analysis.

FDA is persuaded by the comment. In the 1991 RIA proposal, FDA conceded that this assumption was merely supposition and requested information from industry sources on this point. FDA will develop an appropriate estimate of cost of analytical testing for dietary supplements as part of the rulemaking that the agency will complete in accordance with the DS Act.

28. Several dietary supplement manufacturers also stated that FDA's estimate of analytical costs was understated because the number of products was understated.

The agency's original analysis was based on a count of the number of unique supplement products reported in use during a small survey of consumers. Because of the small number of consumers sampled, FDA agrees that this was not an accurate source to determine the number of dietary supplement products. In comments to the 1991 RIA proposal, one association reported 25,000 products and 75,000 labels in use in the supplement industry. The association was unclear as to how these numbers were calculated, and how "supplement" was defined in order to arrive at these numbers. The agency believes these estimates seem large. However, because no better information currently exists, FDA is using these figures in calculating costs to dietary supplement manufacturers. FDA will further study the supplement industry and make any necessary changes to its estimates when regulations are issued in accordance in the DS Act.

D. Printing Costs

In the 1991 RIA proposal, FDA preliminarily determined that firms would spend approximately $112 million on printing costs to comply with mandatory ingredient labeling of standardized foods and certified colors, and approximately $750 million to comply with all other provisions, except labeling of raw fruit, vegetables, and fish. FDA received several comments criticizing the agency's calculation of printing and redesign costs.

29. One comment was concerned that FDA assumed that changes will occur only to the principle display panel (PDP) and to the information panel.

FDA is aware that mandated changes are so significant that the entire label will be changed. FDA accounted for this fact in the 1991 RIA proposal. In the model supplied by the contractor and used by FDA, label redesign was denoted as a "complex" label change which was used for all labels.

30. Several comments stated that capital costs associated with label printing are underestimated. The comments stated that for many firms, new labeling devices will be needed. One comment, for example, stated that food manufacturers may have to install new packaging or labeling systems if existing labels are not large enough to accommodate the new information. Comments stated labeling equipment would cost approximately $65,000.

FDA agrees that some firms may require new labeling devices but does not have enough information to determine how many new devices will be needed. Whether firms will need to increase package or label size to accommodate the new information will depend largely on the format selected. FDA is allowing a reduced format for small packages and very small packages may be exempt from nutrition information. The decision to purchase new machinery will also depend on how lengthy health claims are. FDA

does not believe that health claims will cause many firms to increase package size because health claims are voluntary. If a firm must increase package size and order new packaging equipment to accommodate a claim, many firms will not make the claim. Although FDA does agree that capital costs may be significant, inadequate information regarding the number of devices needed prevents the agency from quantifying these costs.

31. Several comments stated that FDA should include the cost of the first labels ordered under the new requirements because these initial label orders replace those labels that will not be in compliance.

In determining the impact of regulations, FDA is only concerned with incremental costs only. The cost of initial label orders is incremental only in the sense that labels are ordered to replace existing labels that are no longer in compliance. FDA included these costs in its calculation of the cost of label inventory disposal because disposed label inventory is valued at its replacement cost. To include both initial label orders and inventory disposal costs would be double counting. Therefore, FDA rejects these comments on this point.

32. One comment claimed that, as the compliance date nears, additional costs will be incurred as firms find it necessary to request smaller, less efficient print runs.

FDA agrees with this comment. However, the agency does not have information with which it can estimate these costs nor does it believe they will significantly add to the costs. FDA believes that giving firms a longer time to comply with these regulations will alleviate this burden.

33. Several comments provided estimates of printing costs ranging from $500 to $5,500 per label.

FDA believes its calculation of printing costs fits within this range. FDA calculated the cost of redesigning 257,000 labels within a 6-month compliance period at $862 million, or an average of $3,400 per product. FDA is using these same estimates, adjusted for a longer compliance period, in the final RIA.

34. Manufacturers of dietary supplements objected to FDA's analysis of printing costs as described in the 1991 RIA proposal. One manufacturer estimated redesign costs for all of its products to be $363,250 but did not provide the agency with the number of products that would be covered under this estimate. Other firms estimated relabeling costs per product to be between $400 and $5,000.

FDA tentatively concludes that its assessment of the redesign cost per label for dietary supplements was underestimated. FDA assumed that labels on supplement products were more similar to drug labels than conventional food labels. However, the comments were successful in convincing the agency that supplement labels are more similar to conventional food labels and would incur a similar cost of printing and redesign. FDA will revise its estimates for redesign cost per label for dietary supplements as part of the rulemaking that FDA will complete in accordance with the DS Act.

E. Label Inventory Disposal Costs

35. Many comments stated that FDA's estimate of inventory disposal costs were too low. One very large firm estimated its own cost of inventory disposal to be in excess of $10 million. Another comment estimated disposal costs for the dairy industry to be approximately $125 million. This comment stated that if the dairy industry represents 15 percent of food sales, then FDA's estimate must be understated.

FDA does not believe that it is possible to extrapolate disposal costs from one firm or industry to the aggregate. Inventory disposal costs are subject to too many different variables to make such comparisons. For example, smaller firms are known to hold larger inventories than large firms. However, large firms hold smaller inventories for a greater number of labels. The cost of inventory disposal is the value of replacing inventories. Costs will be higher per label for products for which the package is the label than for products with stick-on labels. Also, costs will be higher for those labels that are produced using expensive printing processes. Therefore, although an industry or firm may represent a certain percentage of food sales, that industry or firm will not necessarily represent the same percentage of label inventory disposal costs. FDA does not believe it understated label inventory disposal costs except in the case of dietary supplements as described below. Therefore, FDA is not amending its final estimates based on this comment.

36. One comment from a food manufacturer disagreed with the assumption that industry label inventories would not exceed 6 months.

The comment misunderstood FDA's calculations. Although FDA did make such an assumption in regard to manufacturers of dietary supplements, FDA used data provided in a study conducted by RTI to calculate inventory disposal costs applicable to conventional food manufacturers. These data showed that most firms would require longer than 6 months to deplete label inventories. Therefore, FDA is not changing its final estimates based on this comment.

37. Dietary supplement manufacturers objected to the assumption that existing label stock could be used up within the proposed compliance period. An association of supplement manufacturers stated that "the on-going recession has meant that production levels have been cut, resulting in greater than normal stocks of labels." The association stated that the cost of discarding inventory would be over $25 million in order to implement the new requirements by May 1993, $15 million by November 1993, and $8 million by May 1994.

FDA tentatively concludes that its estimates of inventory disposal for dietary supplement manufacturers were incorrect. FDA, in the 1991 RIA proposal, made an ad hoc assumption regarding disposal of dietary supplement labels. Based on information supplied by comments, the cost of inventory disposal for dietary supplement manufacturers is valued at $11.5 million for a compliance period ending May 1994. However, because the DS Act imposed a moratorium on implementation of the 1990 amendments with respect to dietary supplements, FDA is not including these costs in the final RIA.

F. Reformulation

38. Several firms criticized FDA for not including the costs of evaluating and executing changes in marketing strategies, searching and testing new brand names, and reformulating products. One association for supplement manufacturers estimated reformulation costs at $20,000 per product but did not state how many products would be reformulated. Another comment stated that new product introductions, of which there were 12,000 in 1991, typically cost between $5 and $7 million.

In the 1991 RIA proposal, FDA acknowledged that reformulation would take place because of these regulations but stated that it could not determine the costs of reformulation because of a lack of adequate information. FDA agrees that because of the changes in the market that these regulations induce, some products will be reformulated. However, FDA is not estimating either the costs or the benefits of such reformulation. The comments did not provide the agency with enough information to calculate the marginal costs of reformulation caused by these

regulations. Although it is known that new product introductions have grown at an annual rate of 15 percent since 1986, FDA cannot predict how these regulations might affect that rate. However, it seems likely that these regulations will encourage firms to offer more nutritious foods to consumers. FDA also questions the cost of $5 to $7 million as an average cost of new product introductions. FDA notes that many small gourmet and confectionery products reformulate often during the year and may have annual sales much lower than these figures. FDA believes the costs and benefits of reformulation will be significant but is unable to estimate either based on the comments received.

G. Costs to Food Service Establishments

39. One comment stated that the cost of providing nutrition information in food service establishments would be prohibitive. The comment stated that for a typical establishment offering 80 items, the cost of analytical testing would be $136,000.

FDA agrees that providing nutrition information in food service establishments would be costly and prohibitive for many firms. The 1990 amendments exempt food service establishments from providing nutrition information. However, the 1990 amendments do not exempt food service establishments that use nutrient content claims or health claims from meeting FDA definitions for nutrient content claims or health claims. FDA is not amending its final cost estimates based on this comment because the agency is not requiring nutrition labeling in food service establishments.

40. FDA received several comments stating that the estimates of costs to the food service industry is understated for the following reasons: (1) The number of establishments affected is understated, (2) the number of menus and menu boards is understated, and (3) the cost per menu is underestimated. An association for the restaurant trade stated that approximately 262,000 commercial establishments and 36,000 institutions have approximately 406,384 printed menus. The association determined that, based on analysis of entries in its annual menu contest, 89 percent of all printed menus include at least one nutrient content or health claim. Thus, nearly 362,000 individual menus and 233,000 establishments in the commercial sector are potentially affected by the regulations. Further, the association determined that at least 18 percent of printed menus would require revision of an entire section or symbol program. According to the association, the cost of changing printed menus requiring changes in terminology or individual menu items would be $500 per menu or $144 million. The cost of changing printed menus requiring changes to alter or replace sections or symbols would be $5,000 per menu, including the cost of analysis or data base use, or $366 million. Therefore, the costs to food service establishments would be $510 million. These cost estimates did not include costs associated with development of new menu items, costs of compliance for 178,355 commercial establishments likely to use menu boards, and costs of compliance for institutional establishments.

FDA has reviewed the calculations, data, and assumptions and is persuaded by the comments that certain costs to the food service industry as described in the 1991 RIA proposal were not accurately estimated. However, FDA notes that the association's estimates are overstated because of three issues: (1) The agency is requiring that food service establishments have only a reasonable basis to support nutrient content or health claims—no analyses or data bases are necessary; (2) the agency is deferring enforcement for small food service firms (10 or less individual establishments) for an additional year to facilitate compliance by this segment of the industry; and (3) the agency does not intend to include menus within its regulatory coverage.

The association estimated that analyses will cost between $700 and $950 for each of 4 recipes for 73,149 menus, or a total of $241 million. Total costs to food service establishments should be reduced by this amount. In the 1991 RIA proposal, FDA assumed that 30 percent of the establishments would normally change their food items during the proposed 6-month compliance period. FDA received no comments refuting this assumption. Extrapolating this assumption to account for the 9-month extension of the date of application of section 403(q) and (r)(2) of the act, indicates that 75 percent of all food offerings would normally be revised during the compliance period. For ease of calculation, the agency assumes that food service establishments make nutrient content claims only, not health claims for which the date of applicability has not been extended. In addition, the agency has determined that enforcement will be deferred on 75 percent of food service establishments. Therefore, the costs of compliance for food service establishments, adjusting for normal revisions and analytical testing, are $17 million. This cost is assumed to be an upper bound estimate as many claims made by restaurants may be consistent with the new definitions.

H. Other Costs

41. One comment stated that FDA overlooked the cost of advertising changes and related marketing expenditures that will be necessitated by these regulations. The comment stated that because most advertising in the visual media includes a picture of the product, the advertising will become obsolete because the label on the product will change. Also, marketing material such as recipe booklets, materials provided to the trade, and shelf tags will require revision or destruction.

FDA acknowledges that some firms may incur costs of changing advertising and marketing campaigns because of changes to the label required by these regulations. For example, in any instance in which a photograph of the product is shown in an advertisement, that advertisement will be made misleading if the label changes but the advertisement does not. Although advertising comes under the jurisdiction of the Federal Trade Commission, such changes will occur as an indirect result of FDA's regulatory actions, and the costs are attributable to these regulations. According to "Food Retailing Review" (The Food Institute, 1992 ed.) advertising budgets for food at home in 1991 were approximately $12 billion, or 4 percent of the total cost. It is unclear how much, if at all, advertising expenditures will increase because of these regulations. Also, it is likely that, within the 15 months firms have to comply with the mandatory nutrition labeling and nutrient content claims regulations, many of those advertisements would have been changed for other reasons. Therefore, FDA believes that the marginal costs of changing advertising because of these labeling regulations will not add significantly to total costs. Therefore, FDA is not amending its final estimates based on this comment.

42. One comment stated that FDA should include the costs of consumer education campaigns.

FDA agrees with this comment. Although not a direct component of these regulations, consumer education campaigns are an essential element of the 1990 amendments. In 1991, FDA and USDA initiated a multiyear food labeling education campaign to increase consumers' knowledge and effective use of the new food label and to assist consumers in making accurate and sound dietary choices. FDA and USDA themselves do not have adequate

resources to inform and educate the public effectively about the new food label and how to use it to plan a healthy diet. The agencies are working with other public and private sector organizations. FDA interprets its role as one of providing leadership in developing, and encouraging others to develop, programs that enable diverse audiences to use food labels effectively. The agency estimates that its efforts in this role may cost as much as $3 million in the next 5 years and in excess of 50 person-years. The agency, due to inadequate information, is not able to predict the costs to other Government agencies nor the multiplier effect on consumer groups, educators, mass media, the food industry, and other public and private sector organizations.

43. One comment concluded that much of the costs will be passed on to consumers, not borne by industry.

FDA does not have sufficient demand and supply information to estimate the amount of cost shifting that may occur as a result of the labeling costs. However, FDA has always considered costs to society without regard to who bears those costs. Therefore, FDA does not believe that it is important for the purposes of societal cost and benefit estimation to estimate the amount of cost shifting. However, for the purposes of estimating whether there is an "undue economic hardship" to industry, FDA does believe that this question is relevant, and this question has been addressed in the final rule published elsewhere in this issue of the **Federal Register** on the date of applicability of section 403(q) and (r)(2) of the act.

I. Summary of Costs

After examining the comments, FDA has recalculated the costs of the final rules. These final estimates are based on a 15-month compliance period ending in May 1994. Although some provisions of the 1990 amendments, i.e., health claims, will become effective on May 8, 1993, FDA received no comments regarding the separate costs of those provisions. Further, in the 1991 RIA proposal, FDA preliminarily determined that the costs of the labeling of ingredients in standardized foods and certified colors were $16 million for administrative costs and $112 million for printing. The costs of percent juice labeling have been estimated at $40 million. Comments did not result in a recalculation of these costs.

The comments mentioned many costs that FDA agrees could be included in the costs of food labeling regulations but cannot calculate because of a lack of information. These costs include the cost of increased errors, the resources spent in reviewing and commenting on proposed regulations, the cost of lost products and packages destroyed to run analyses, the capital costs associated with label printing, the costs associated with smaller, less efficient print runs, and the costs of reformulation. FDA believes that, with the exception of reformulation, these costs represent a small portion of the total costs and that not including them in the final estimates does not significantly alter FDA's conclusions.

Based on the information provided by the comments and the contractor's cost study, FDA now finds that administrative costs are $9,000 for small/medium firms and $68,450 for large firms when the compliance period is 6 months. Because FDA is extending the compliance to 15 months, costs will be $3,375 for small/medium firms and $25,700 for large firms, or $56 million for the 8,900 medium and large firms affected. Similarly, administrative costs to manufacturers of dietary supplements are $850 per firm with a 6-month compliance period. Adjusted to a 15-month compliance period, administrative costs to dietary supplement manufacturers are $320 per firm or $52,000. However, these costs may be greatly reduced depending upon the outcome of the proposals to be issued at a later date, as discussed above, in response to the DS Act. Thus, the costs to dietary supplement manufacturers are not being included at this time.

FDA has agreed with the comments that the costs to the Federal Government for implementing the 1990 amendments should be considered in its final estimates. As previously described in comment 7 of this document, FDA estimates that implementing the 1990 amendments will cost the Federal Government approximately $163 million in labor and capital over the next 20 years (5 percent discount rate). These costs will most likely not be incurred by increasing taxes on either consumers or industry as the food labeling information program will be funded by substituting efforts away from other Government programs. FDA did not attempt to estimate the costs to other governmental units or State governments.

FDA has determined that all products produced by medium and large firms will undergo some analytical testing. Approximately 40 percent of products will require full nutrient testing at a cost of $1,785 per product. The remaining 60 percent of products will require only partial testing because they have already been tested for some nutrients. The cost for testing these products is $723 per product. FDA is assuming a range of retesting from once every year to every 5 years on average. Analytical costs for mandatory nutrition labeling are $228 million in the first year. Total discounted analytical costs range from $466 million assuming retesting every 5 years and $1.1 billion assuming annual retesting (5 percent discount rate). The cost of collecting samples is between $17.9 and 22.8 million over the next 20 years (discounted at 5 percent) In addition, FDA estimates the cost of protein quality testing will be $540 per product or $185 million over the next 20 years assuming retesting every 5 years or $440 million assuming annual retesting.

The assumptions used to calculate printing costs for conventional foods remain unchanged by the comments. The cost of printing 257,000 food labels is estimated at $518 million for a compliance period ending in February 1994.

Review of the comments did not lead to any changes in the assumptions used to calculate inventory disposal costs except that FDA no longer assumes dietary supplement manufacturers will have enough time to dispose of all labels. Total costs for inventory disposal of conventional food labels is $6 million for a May 8, 1994, compliance date.

FDA has reviewed the calculations provided by food service establishments and has adjusted those calculations to account for a longer compliance period and normal menu revision. FDA is allowing food service firms the option of using a reasonable basis rather than analytical testing to support claims, further reducing costs. In addition, FDA is deferring enforcement for restaurants with 10 or less individual establishments. The cost to food service establishments, reflecting all adjustments, is $17 million.

The total costs of food labeling regulations range from $1.4 billion to $2.3 billion (discounted at five percent), depending on the frequency of reanalyzing products, excluding the cost of labeling raw fruit, vegetables, and fish, and assuming a 15-month compliance period ending in May 1994. In addition, costs of Government activities are estimated at $163 million.

IV. Benefit Estimation

As part of the 1991 RIA proposal, FDA published a labeling benefits model that examined the health benefits from consumer response to food labeling. In this model, FDA used economic theory to quantify the value of the reduction in coronary heart disease (CHD) and three types of cancer that

would result from modified diets in response to nutrition labeling. FDA received approximately 20 comments directly related to the benefits of nutrition labeling. Many comments addressed the benefits of specific rules. The agency is responding to these comments in the relevant individual final rules.

A. Benefits—General

44. Several comments questioned the credibility of the health benefit estimate, particularly as to whether risk reduction through change of dietary habits can be quantified.

FDA does not agree with this comment although FDA stresses that it views the benefit estimation of the 1990 amendments as a preliminary investigation into quantification of mandatory information disclosure. In addition, FDA notes that the agency is required by Executive Order 12291 to quantify benefits where possible and to use such estimates to select regulatory policy options that generate the largest net benefits. Therefore, FDA is not changing its estimate of the benefits based on this comment. FDA will continue to refine the methodology employed here as well as to seek alternative methodologies to measure these effects.

45. One comment noted that there will be reductions in health care and insurance costs that will result in cost savings to all consumers, whether disease afflicted or not.

FDA notes that health care estimates were included in the 1991 RIA proposal. FDA agrees that as demand for health care resources decreases, there will be price decreases that will affect all consumers and consequent reductions in insurance costs. However, benefit estimates are societal benefits which are real resource savings to all members of society, without regard to incidence. For example, estimates of the willingness-to-pay to reduce risk of illness and death reflect total societal values. Therefore, the benefits estimated in the 1991 RIA proposal reflect savings to all of society, whether disease afflicted or not, but this fact does not alter the quantitative total societal benefits and does not affect the final estimate of the benefits.

46. Another comment noted that there may be significant benefits from reduction in allergic responses to food.

The agency believes that the most significant additional ingredient information resulting from the 1990 amendments is the listing of ingredients in standardized foods. The agency believes, however, that the labeling of almost all standardized foods already contained this information before the passage of the 1990 amendments. Although the agency agrees that the required labeling of allergens such as hydrolyzed corn protein will have some benefits for preventing allergic responses, these benefits are expected to be small relative to the nutritional benefits of the final rules.

47. One comment suggested that because the agency accounted for the costs of product reformulations, it should estimate the benefits of reformulation.

Although FDA agrees that product reformulation will occur as a result of the 1990 amendments, FDA did not estimate either costs or benefits of product reformulation (see comment 38 of this document). The assumption underlying the benefit estimate is that firms did not reformulate foods just to participate in the shelf flag study (the FDA/Giant Special Dietary Alert (SDA) study cited in the 1991 RIA proposal) because the relative size of the market used in the study is small, and the time span was relatively short (1 year). The agency noted in the 1991 RIA proposal how difficult it would be to estimate the amount of reformulation that would take place.

48. Some comments addressed the purpose of the food label with respect to the projected benefits of the new labeling. One comment stated that the purpose of the food label is to inform consumers (presumably about nutritional values), while another stated that the purpose of the food label is to sell a product.

Compliance with the final regulations that respond to the 1990 amendments as well as with other regulations governing food labels will make the label, both the PDP and the information panel, more informative for consumers. Thus, estimated benefits derived from compliance with the 1990 amendments are not benefits to manufacturers from selling food but rather are benefits to consumers because manufacturers must comply with the law.

49. Another comment expressed concern that diet deficiencies might be a possible response to the new labeling information. This comment noted that some consumers may have negative benefits because they use food labels to modify their diet in a detrimental way. According to the comment, this result would occur because food nutrients are grouped in foods such that, for example, a product substitution may decrease fat intake slightly but result in a large increase in sodium intake.

As mentioned in the 1991 RIA proposal, FDA was aware of the possibility that these effects may occur and represent a potential bias towards overestimating benefits. However, FDA believes that it is unlikely that the provision of more information on food labels will lead to such effects. It is difficult to construe the labeling changes that respond to the 1990 amendments as being the cause of many ill-considered food choices. The disqualifying disclosure levels are intended to prevent such effects from occurring. Further, FDA believes that the consumer information campaigns now underway in response to the 1990 amendments will serve to further mitigate the chances of any such effect.

50. One comment stated that the only benefits that would arise from requiring restaurants to carry nutritional information would be for the chemical laboratories that do the testing.

The agency advises that it is not requiring full nutrition labeling for restaurants in these final rules. However, restaurants will be required to ensure that their judgments that a food has an appropriate level of a nutrient to qualify for a health claim or a nutrient content claim have a reasonable basis. There is no requirement for laboratory testing of such foods. Moreover, FDA does not agree that no other parties will benefit from these rules with respect to restaurants. Consumers will now have consistent, reasonably based signals from restaurant menus with regard to health claims and nutrient content claims that they can use to control their diets.

B. Consumer Response to Labeling

51. One comment contended that FDA's estimate of the consumer response to labeling was low. The comment argued that FDA's estimate of the percentage of consumers that read and understand labels, 45 percent, should be used as a measure of consumer behavior change in response to new labeling.

The agency rejects this view. The agency's estimate was based on actual consumer behavior measured in response to new labeling information (the FDA/Giant SDA study). As for the estimate of consumers who read and understand labeling, the agency notes that the cost of changing dietary behavior is greater than the cost of simply reading and understanding labels. The cost of changing dietary behavior includes search costs, costs of giving up some elements of taste, and possibly paying higher prices for the more nutritious foods. For this reason, it is likely that only a small percentage of consumers actually change their purchases in any meaningful way. In addition, FDA acknowledged factors

that would cause the benefit projections to be overestimated. For example, as noted in the 1991 RIA proposal, FDA does not have evidence that changes made in the FDA/Giant SDA program were lasting. Although FDA expects that consumers' diet/health link awareness will increase over time, it is not clear how much of an effect this increased awareness will have.

52. Other comments questioned whether consumers will use labels to actually change purchase behavior.

FDA believes that the SDA study supports its view that some consumers, although a small percent, will use labels to change their purchase behavior. In this study, shelf flags were used to alert consumers to the presence of desirable nutrient attributes. Netting out price changes, there were measurable shifts to more nutritious foods. Moreover, the SDA categories covered less than one-fourth of all of the food categories, and FDA believes it is likely that there will be responses in other categories of food because of the addition of other nutrients of concern as part of the 1990 amendments.

53. One comment to the RIA stated that the shelf flag highlighting in the SDA study overestimates benefits of the 1991 initiative because they do not apply to information required on the food label. The comment noted that, since shelf flag highlighting may have been used in addition to highlighting the product characteristics on the label, similar results will not be obtained unless retailers use shelf flags. The comment went on to say that it is unlikely that retailers will use shelf flags given disclosure requirements, type-size and placement requirements, and density-based requirements.

The agency notes that these final rules do not prohibit shelf flags from being used by manufacturers exactly as they were used by Giant Foods during the SDA study. The agency is announcing in the final rule on nutrient content claims, published elsewhere in this issue of the **Federal Register**, that it is encouraging retailers to use such devices consistent with the nutrient content claim definitions provided in that final rule. Thus, the agency believes that similar results will occur as a result of the 1990 amendments and is not changing its estimate based on this comment.

54. One comment expressed the view that the shelf flags in the SDA study are best related to regulations allowing health claims and nutrient content claims on labels, and that benefit estimates should be related to those provisions of the 1990 amendments.

FDA believes that all implementing regulations of the 1990 amendments will have benefits, although the bulk of such benefits may come with changes to the PDP where nutrient content claims and some health claims will be displayed. However, FDA is unable to separate the effects of the various aspects of the 1990 amendments on the basis of this comment or any other of the comments received. Therefore, FDA is not changing the benefits estimate based on this comment.

55. Another comment on the SDA study noted that FDA did not separate the effects of the shelf flags from other marketplace events such as price changes, advertising campaigns, price reductions, or couponing.

The agency notes that price changes were accounted for in the SDA study, although the other events mentioned represent a possible bias in the study. To the extent that such effects caused consumer purchase changes independent of the shelf flags, the agency agrees that such changes would result in the benefit estimate being an overestimate. However, no information was presented that would allow the agency to calculate the extent of this bias. The agency points out that this is one of several biases in the analysis that were noted in the 1991 RIA proposal.

56. One comment suggested that FDA examine microdata from SDA to determine whether Giant stores had a disproportionate number of people at risk for developing chronic diet-related diseases. They pointed out that if so, it would bias the outcome when the study is extrapolated to the entire U.S. population. Other comments noted that the Washington D.C. metropolitan area may not be representative based on demographic data.

The agency acknowledges these limitations of the data presented in the SDA study and recognizes that the benefit estimates provided in both the preliminary and the final RIA are soft because of the many assumptions made and the tenuous support for many of these assumptions. The agency believes, however, that it has made a novel first attempt at estimating the effects of this type of mandatory label information. A number of comments addressed the viability of the agency's assumptions in estimating these benefits but offered no data upon which to fashion better assumptions. The agency agrees that the Washington D.C. area may not be representative of the U.S. population as a whole but does not have any way to make the study representative. Thus, FDA is very aware of the imprecision of these benefit estimates. From these comments FDA has received no information that would alter its assessment of the expected change in dietary behavior from that reported in the 1991 RIA proposal.

C. Health Response to Improved Diet

57. One comment noted that FDA's estimate of the maximum preventable cases of cancer and CHD prevention from dietary changes was low relative to what was predicted by "significant scientific agreement." The comment used Table 13 in FDA's 1991 RIA proposal (56 FR 60856 at 60871, November 27, 1991), and estimated that, of the total cases estimated to be avoided, cancer cases represent 89.7 percent, and CHD the remaining 10.3 percent. Eliminating the years where 0 cases are expected to be prevented, the first 10 years for cancer and 2 years for CHD, the above percentages were applied to the total cases, 503,448 (Table 16, 56 FR 60856 at 60872). From these calculations, the comment noted that FDA's figures appear to show only 45,310 cancer cases and 2,797 heart disease cases are preventable through dietary intervention per year. These numbers were compared by the comment with other published numbers. For total preventable cancers, the comment updated a 1991 published estimate of 1,100,000 cases (per year in the United States) with an annual growth rate of 0.9 percent to obtain an average over the 10th to 20th years from the 1990 amendments of 1,258,230. The comment noted that FDA's estimate of preventable cancers (45,310) was only 3.6 percent of this figure, less than the 5 percent to 35 percent of cases preventable through diet. Another comment noted that the 2,797 estimated cases of CHD that would be prevented represent only 0.9 percent of the total cases, which it said was extremely low.

The agency disagrees that its figures are low. First, the agency's estimates were based on the difference between current dietary intakes and DRV's. DRV's are the U.S. Government recommendations for an achievable diet, not a maximal diet. A maximal diet would be much lower in fat content, for example, as well as containing other nutrient values much "stricter" than the RDI diet. The RDI diet might be construed to be "perfect," however, in the sense that it does not involve giving up all desirable foods to meet a reasonable health goal.

In addition, FDA notes that although there is significant scientific agreement that reductions in fat intake will reduce the risk of some cancers, the precise quantitative relationship has not been firmly established. It is unlikely, however, that the relationship between

fat intake and cancer will prove to be false.

Finally, it should be noted that FDA's figures from Table 16 in the 1991 RIA proposal (56 FR 60856 at 60872) are from reducing fat intake for FDA foods only, which does not include meat and poultry (regulated by USDA). Reductions of fat from consuming those foods will save additional lives and cases. Thus, FDA disagrees that its estimates are low and has not changed the benefit estimate of the 1990 amendments based on this comment.

58. One comment requested that FDA explain an apparent discrepancy. The comment took the number of total cases of illness estimated to be avoided for each scenario and divided them by the total number of deaths estimated to be avoided. The comment stated that the discrepancy arose because the total number of cases (cancer and CHD) avoided in the maximal FDA diet, approximately 42 percent resulted in lives saved, whereas in the scenario that applies to the benefit estimate, only 32 percent of cases avoided will result in lives saved.

The agency does not believe that this difference is a discrepancy. The explanation is that both total cases avoided and total lives saved are based on cancer and CHD. In the Browner model, which was used as a component of the FDA labeling benefits model, reducing fat intake changes the ratio of saturated fat to cholesterol intake. In the maximum health benefits scenario, this ratio is 2. As the amount of fat intake is reduced in response to labeling, this ratio declines to 1.3. The ratio of saturated fat to cholesterol changes are based on actual intake changes measured in the SDA study. In turn, as the ratio of saturated fat to dietary cholesterol decreases, the rate of CHD cases avoided (based on saturated fat) will decline relative to that of cancer cases avoided (based on total fat).

In the Browner model, it is assumed that all CHD cases result in death, but that only 45 percent of the cancer cases result in death. Thus, as there is no discrepancy, FDA concludes that no changes in the agency's benefit estimate are necessary in response to this comment.

59. One comment argued that it makes no sense to postulate that a perfect diet would only prevent 3.6 percent of cancer cases, but 42 percent of cancer deaths. Similarly, the comment stated that it is unlikely that there would be only a 0.9 percent reduction in incidence of heart disease but 4.5 percent reduction in deaths.

The agency disagrees with this comment. The comment is referring to the agency's estimate of the number of preventable cases of cancer and cases of death that would result from adoption of a perfect diet by all consumers (Table 15, 56 FR 60872). The comment appears to have incorrectly calculated the percentage of cancer deaths that will be avoided as a result of a perfect diet relative to the total number of cancer deaths in the United States. Rather than 42 percent as calculated by the comment, the agency calculates that 3.5 percent of all cancer deaths in the United States would be avoided if consumers adopt a perfect diet. This number, 3.5 percent, is calculated as follows: On average, it is expected, based on FDA calculations (56 FR 60872), that there would be approximately 18,985 cancer deaths avoided per year (following the 10-year lag from the beginning of a perfect diet). This number is obtained by multiplying the total number of deaths avoided (212,596) by 89.3 percent (the proportion of cancer deaths avoided) and dividing by 10, the number of years for which the model estimates cancer deaths being avoided. Therefore, if there are 545,718 total cancer deaths per year, then 18,985 deaths per year (3.5 percent) can be avoided as a result of adoption of a perfect diet. A similar calculation determines that CHD deaths avoided as a percent of CHD deaths per year (500,000) is about 0.3 percent.

60. Another comment states that the "total impact of the approved health claim on lipids and cancer will be a reduction of 0.28 percent of all cancer cases and an estimated prevention of 1,188 cancer deaths per annum, a total decline of 0.23 percent."

The agency's estimate of the benefits of the 1990 amendments apply to the whole of the 1990 amendments. Changes in dietary behavior, such as lipid reduction, are likely to be made by consumers in response to changes in the information panel including new nutrient and ingredient information, as well as to PDP changes such as new definitions for nutrient content claims and health claims. The agency is unable to separate out, based on this or any other comment received, the marginal change in consumer behavior solely in response to health claims and the resulting health effect. Thus, no change to the agency's benefit analysis has been made in response to this comment.

61. One comment noted that FDA has estimated a reduction in the consumption of fats by men and women to be 1.4 and 1.1 percent which translates to 1.49 and 0.67 grams, respectively. The comment went on to say that given that a "less" fat item will have a minimum of 3 grams less fat than a comparable choice, FDA's estimate would amount to only one improved serving choice every other day for an average male and every 4.5 days for an average female. The comment contended that this appears to underestimate the potential impact. The comment also noted that:

> The apparent use of a typical consumer, rather than of a bell distribution, would dramatically skew the impacts of the reduction on health * * * as minor reductions (1.1 to 1.4 percent) * * * cannot be expected to have a significant impact on risk reduction. Because actual reduction would be distributed across a curve, those whose reduction in cholesterol would be significant would experience a significant reduction in risk unrevealed by the FDA single, typical consumer model.

The agency did not use a typical consumer to estimate the benefits of the proposed regulations. In the Browner model, all age groups were used in 5-year increments (e.g., 40-to 45-year-olds) which would approximate the full distribution of age groups, not collapse all age groups into a typical consumer. This data (the actual distribution of intakes) came from the Continuing Survey of Food Intakes by Individuals. Furthermore, the agency is not persuaded by the argument concerning food choices. FDA agrees with the comment that rather than all consumers making small changes, what is more likely is that a small subset of consumers will make dietary changes, or that some consumers will only change a small portion of their diets. This pattern of response would explain the relatively modest changes that occurred in the SDA study. FDA notes that consumer response to new information has been shown to be modest in other studies, such as response to radon information provided by the Environmental Protection Agency. However, the agency believes that reformulation of foods, which were not estimated in this benefit analysis, will increase the size of the total benefits. FDA acknowledges that this bias exists in the estimate but, as noted elsewhere in this document, FDA does not have sufficient information to estimate these effects and FDA is not altering its estimate based on this comment.

Although the estimate of the number of deaths avoided will not be adjusted based on the comments received, FDA acknowledges that a letter to the Department of Labor from the Office of Management and Budget (OMB) returning a rule which would lower permissible exposure limits for 375 substances in the construction and maritime industries has implications for

its estimate of the number of lives saved (Ref. 2). In that letter, OMB took note of a series of papers and books that estimated the effect of wealth on health. They noted that, "Richer workers on average buy more leisure time, more nutritious food, more preventive health care, and smoke and drink less than poorer workers." Thus, money spent by society to improve nutrition labeling will not be spent in other areas such as smoke detectors and airbags which will reduce risk. OMB cited a U.S. Court of Appeals decision which in turn cited research showing that each $7.5 million in additional regulatory expenditures may result in one additional death from lowered income.

The relationship between income and death is still somewhat controversial. In a recent article, researchers found that the effect is likely if the income reduction is permanent, as opposed to transitory (Ref. 3). Keeney has examined the extent to which the mortality effects on income changes are greater for poorer people than for richer people (Ref. 7). As the expenditure on nutrition labeling is a one-time expenditure affecting all consumers very slightly, it is likely that it is a transitory expenditure. On the other hand, because food expenditures account for a significantly larger share of the family budget for poorer families, the cost of these regulations are likely to have larger impacts on those families. Thus, it is unclear whether or not these expenditures will, in fact, increase some deaths while saving others. Nevertheless, FDA has estimated the possible effects this potential bias could have on the benefit estimate.

FDA's final estimate of additional regulatory costs resulting from the 1990 amendments is $1.6 to $2.7 billion. This would result in between 216 and 360 additional deaths which should be subtracted from FDAs estimate. Based on the Keeney estimate of one death for each $7.5 million of cost, the final estimates for the total deaths avoided as a result of the 1990 amendments are between 12,542 and 12,689 (from 12,902 estimated in the 1991 RIA proposal, Table 13, 56 FR 60856 at 60871). Life-years gained are reduced to between 78,672 and 79,577 (from 80,930, also in Table 13). The results of these changes affect the total benefits very slightly with the new range being $4.5 to $21 billion.

D. Quantification of Health Response

62. One comment argued that the average medical care costs estimated in Table 14 (56 FR 60856 at 60871) should not be discounted at a 5 percent inflation rate because the rising costs of medical care have been increasing 10.5 percent in recent years.

The agency agrees that the costs of medical care have been rising at approximately 10.5 percent. If this trend were to continue, however, a net of 5.5 percent increase (10.5 percent medical care cost inflation minus 5 percent general inflation) could be added to these costs, although future cost increases are difficult to predict, and the agency does not wish to infer that great precision accompanies these estimates. The agency notes that medical care costs estimated in the 1991 RIA proposal may be over or underestimates of actual medical care costs. That is, because some people who will not get cancer or CHD will get other illnesses that will result in medical care costs, using the total cost savings from reduced cancer and CHD cases is an overestimate. Because the agency was unable to net out increases in medical care from other diseases, it overestimated medical care cost savings. Thus, the agency acknowledges that there is a bias in both directions for the medical care cost estimate. Because it is not possible to estimate the net direction of these biases, however, the agency will not make further adjustments in these numbers. Finally, the agency's estimates of the benefits of nutrition labeling derive primarily from the willingness-to-pay for increased longevity, not from nonfatal medical care costs.

63. One comment expressed the view that the willingness-to-pay generated benefits of the 1990 amendments of $3.6 to $21 billion are for nonmedical outlays only.

FDA disagrees with this comment. In fact, the willingness-to-pay estimates of health benefits in the 1991 RIA proposal are individual dollar amounts that market studies demonstrate consumers (and workers) will pay to reduce the probability of death from these illnesses. Many people are willing to pay to reduce the probability of death and illness, and these payments include expected expenditures on medical care as well as other types of disability, such as pain and sickness. As noted earlier in this document, however, the total benefit estimates do not cover the cost savings from illnesses that do not result in death, which are estimated in the section on medical care cost savings. Thus, no change in the benefit estimate will be made as a result of this comment.

64. One comment pointed out that a willingness-to-pay model is not anchored in any real occurrence in the marketplace and reflects only a subjective valuation of good health. This comment added that risk is not traded in the marketplace.

The agency disagrees with this comment. The agency believes that willingness-to-pay estimates represent the individual's valuation of loss of productivity, medical care costs, pain and suffering, and other utility losses as demonstrated in economic literature. In this case, the decisions reflect payments to reduce the risk of death rather than using those resources for other goods.

FDA also believes that risk, including health risk, is ubiquitously traded in the marketplace. For example, expenditures on seatbelts, airbags, airline safety, safety caps on medicine, preventive check-ups, suntan lotion, and a multitude of other factors represent market expenditures on risk reduction. Many of the studies conducted to estimate willingness-to-pay to avoid death were based on the workplace transactions by estimating wage differentials for jobs with varying levels of risk and wages. Therefore, the willingness-to-pay figures for reductions in the probability of death are strongly grounded in economic theory such that the agency will not change the benefit estimate based on this comment.

65. One comment suggested that "hard figures" such as lost productivity should be used instead of willingness-to-pay estimates.

FDA disagrees with this comment because the use of such "hard figures" alone (productivity) will ultimately undervalue the total utility of reducing risk to the individual as it does not include the utility derived from reduced medical care costs and pain and sickness. The agency believes that the willingness-to-pay methodology is strongly grounded in economic theory and is the conceptually correct method to estimate these health benefits. Therefore, no change will be made to the benefit estimates based on this comment.

66. One comment contended that the quantitative estimate provided in the 1991 RIA proposal for the amount and value of reduced risk were too low because: (1) The estimate chosen for the value of risk reduction (value of life) from secondary studies was low because the mean of these type of studies was not chosen; (2) the estimate for value of risk reduction did not include the impact of recent inflation; (3) the estimate for the value of risk reduction did not include growth in real income before 1990; and (4) the estimate for value of risk reduction did not include future real growth of income.

FDA does not agree that the estimates chosen for the value of risk reduction, $1.5 to $3 million, from secondary

studies is necessarily low. Market studies of willingness-to-pay to avoid death have produced a range of values—some higher and some lower than the values used in this study. In order to capture this diversity, FDA used a wide range of benefits. Thus, FDA is unconvinced that sufficient data are either available in the literature or were in the comments to warrant changing these estimates.

As to the second point, FDA agrees that some inflation has occurred since the publication of the study that the agency used to estimate the value of risk reductions. The study's results were calculated in 1986 dollars (Ref. 4) and inflation from 1986 to 1991 was 16.5 percent (not 15.5 percent as mentioned in the comment). In addition, the comment noted that there have been increases in real personal disposable income since 1986. Real personal disposable income has increased from 1986 to 1990 by 8.5 percent, not 10 percent as cited in the comment (Table B–25 in the Economic Report to the President (Ref. 6)). To the extent that individuals can now purchase 8.5 percent more goods than they could in 1986, it is likely that they would be willing to pay more for risk reduction as well. Updating the range of estimates noted above of $3.5 to $21 billion to account for inflation and real personal disposable income yields the new range of $4.4 to $26.5 billion.

The comment also noted that FDA should include in the benefits estimates future real growth of income because if income continues to grow, people in the future will purchase more risk reduction. FDA disagrees with using long-term real growth of income to increase benefits. The benefits estimate derives from the choice that is made by individuals today. That choice reflects the amount of money people are willing to give up today to reduce risk in the future. Those estimates reflect individuals subjective evaluation of both their future health states as well as their assessment of their future income changes that will occur as a result of the regulation. If FDA were to forecast future growth in personal income and estimate the income/risk trade-offs (income elasticity of demand for risk reduction) that would be made for each future period, it would result in double counting. Again, this would be true as people implicitly account for future income growth in decisions made today. Furthermore, as income rises, people may choose to add even more labeling information at some time in the future but that would represent a separate choice with separate marginal costs and benefits.

FDA concedes, however, that choices that are made in most, if not all, willingness-to-pay studies associated with risk reduction are reflective of individuals valuation of their own change in probability of risk of death. They do not include the individual's altruistic expenditures to reduce risk for future generations. This effect is expected to be small for this regulation, however, as benefits and costs are estimated for over 20 years.

E. Health Claims

67. One comment expressed concern that FDA had ignored some fundamental findings from consumer behavior studies and the economics of information. It also stated that approval of health claims should be done on a cost-benefit basis rather than by consensus. The comment noted that allowing partial information produces a more efficient marginal adjustment process in the market than requiring full information. The comment noted that it did not believe there was such a thing as "Gresham's Law" (which essentially says that "bad" money drives out "good" money) of health claims in advertising.

The agency does not necessarily disagree with this assessment of the state of the economics of information. However, section 403(r)(3) of the act requires "substantial scientific agreement" for approval of a health claim for conventional food. The standard for substances in dietary supplements under section 403(r)(5)(D) of the act will be determined in accordance with the DS Act. The agency believes that the final rules for health claims are as flexible as is possible. Also, the agency notes that there is a set period of time for Government review of petitions for authorization to make additional health claims.

On the issue of whether or not there is a "Gresham's Law" with respect to advertising, the agency notes the widespread persistent use of the misleading "percent fat free" advertising. Thus, it is not clear whether or not "good" advertising in terms of being truthful and not misleading will ultimately drive "bad" advertising from the marketplace without regulation. Thus, FDA does not believe that this comment affects the ultimate benefits from the 1990 amendments and will not change its assessment based on the comment.

There is an opportunity cost of the choices made with respect to health claims and nutrient content claims. Opportunity costs of the regulation of these claims include the benefits foregone by not choosing an alternative option. Some of these costs arise from the statute itself, and some arise from the interpretations made in these regulations. If firms are either prohibited from making certain kinds of claims, or if the incentives are such that firms make fewer valid health claims or nutrient content claims, there is a cost imposed on society in that some valuable information may not be conveyed to consumers. For instance, if firms find that the required disclosures surrounding health claims are too cumbersome, they may find that this adversely affects the marketing of their product and fail to make a valid health claim.

In fact, FDA has no data to evaluate the potential market outcomes that would arise with alternative regulatory choices with respect to health and nutrient content claims. Although FDA has benefited from numerous comments on the subject, including a lengthy comment from the Federal Trade Commission, no comments have been able to show the quantitative outcomes of allowing more health claims in a different format or allowing more flexible use of nutrient content claims. However, although these rules are final, FDA will continue to evaluate information that will help refine these rules and encourages interested parties to submit such information.

V. Summary

FDA has evaluated comments on the costs and benefits of the impact of the changes in the food label occurring as a result of the 1990 amendments. The benefits of the 1990 amendments and the implementing regulations include decreased rates of cancer, CHD, osteoporosis, obesity, hypertension, and allergic reactions to food. As consumers are given more informative labeling in an improved format, uncertainty and ignorance concerning the ingredient and nutrient content of the foods they eat will decrease, and some consumers will select more nutritious, healthier foods. Also, the creation of consistent metrics and definitions, such as standardized serving sizes and nutrient content claim definitions, that consumers can use to judge the nutritional aspects of foods will encourage manufacturers through competition to reformulate their products into healthier foods. Thus, even those consumers who may be unaware of the effects of diet on health will inadvertently eat a better diet.

The model chosen to estimate these benefits focused on the two largest health problems, cancer and CHD (Ref. 5). This model involved the following three-step estimation process:

(1) Estimate changes in consumer purchase behavior and resulting changes in nutrient intakes as a result of receiving new nutrient information about foods. Some comments stated that consumers will not use labels at all, and some comments asserted that many more changes will come about than those that FDA estimated. A number of comments noted particular bias in the FDA/Giant SDA study. Although FDA agrees that there is bias both in the SDA study and in applying the results of the SDA study to the benefits of the 1990 amendments, no comments provided a sufficient basis either to replace or amend the study's result in this RIA.

(2) Estimate the changes in health states that would result from consumers' changes in nutrient intakes, particularly for reduced incidence of cancer and CHD. Again, FDA was presented with a number of comments on the changes that will result from changed diets, but none were convincing. Many comments were directed at the Browner model which was incorporated into FDA's benefit estimate in this section of FDA's analysis. The comments focused on the fact that nutrition labeling and other components of the 1990 amendments are estimated in FDA's model to make only a relatively small decrease in the number of cases of CHD and cancer and the deaths associated with them. However, FDA is unpersuaded by these arguments. The Browner model is well documented and contains realistic health assumptions. However, FDA did account for studies cited by OMB that demonstrated that regulatory expenditures may cause increased death. This resulted in FDA's estimate of lives saved and life-years saved decreasing by very small amounts, to between 12,542 and 12,689 (from 12,902 estimated in the 1991 RIA proposal, Table 13, 56 FR 60856 at 60871) and to between 78,672 and 79,577 (from 80,930, also in Table 13) for the number of life-years saved.

(3) Estimate the value of changes in health states in terms of life-years gained, number of cases and deaths avoided, and the dollar value of such benefits. FDA has been persuaded by some of the arguments that the benefits are underestimated in this component of the analysis. Specifically, the agency has adjusted for inflation and for the growth of real personal disposable income that occurred in the 4 years between when the estimates were cited in the economic literature and the time the 1991 RIA proposal was concluded. Coupled with changes made to the number of life-years and lives saved mentioned above, these adjustments change the benefits to $4.4 to $26.5 billion (discounted at 5 percent over a 20-year period).

FDA also evaluated comments on costs of the 1990 amendments and has amended its cost estimates based on these comments. The total costs of food labeling regulations range from $1.4 billion to $2.3 billion (discounted at 5 percent), depending on the frequency of reanalyzing products, excluding the cost of labeling raw fruit, vegetables, and fish, and assuming a 15-month compliance period for nutrition labeling and nutrient content claims ending in May 1994. If a discount rate of ten percent is used, total costs are estimated between $1.3 and $1.8 million. These costs include costs to food manufacturers and food service establishments. Costs to Government entities are estimated to be $163 million. Costs to dietary supplement manufacturers were not included in this estimate because of the moratorium imposed by the DS Act.

FDA believes that the study of the costs and benefits of food labeling is as accurate as possible for a forward looking study of the costs and benefits of regulatory action. FDA published the initial study in the **Federal Register** and received over 300 comments on it. As a result of the comments and new information, FDA revised its figures upward for both costs and benefits. In addition, FDA acknowledges that many deficiencies remain in these estimates because there are elements of both costs and benefits that remain unquantified. Nonetheless, the purpose of the RIA is to estimate the general magnitude of these effects in accordance with Executive Order 12291 and to determine whether the benefits of this action exceed the costs, and FDA has met that burden. With the exception of reformulation, FDA has examined the unquantified costs and benefits and believes that they are likely to be small relative to those that have been quantified and are not likely to change the estimates significantly.

Furthermore, the analysis contains assumptions that are subject to challenge, and many of the comments did so. However, where neither data nor convincing evidence were submitted to contradict the assumptions, FDA has not changed them. Finally, FDA advises that the dollar amounts estimated in the final RIA are not exact amounts but rather reasonable estimates of the impacts of nutrition labeling on U.S. society. The final RIA demonstrates that although this action is expensive, the likely benefits to U.S. consumers substantially exceed the costs that shareholders, taxpayers, and consumers will ultimately bear.

VI. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Peto, Richard, "Cancer Around the World: Evidence for Avoidability," in *Diet and Prevention of Coronary Heart Disease and Cancer*, B. Hallgren et al., editors, Raven Press, New York, 1986.

2. MacRae, James, B. Jr., Acting Administrator and Deputy Administrator of the Office of Information and Regulatory Affairs, OMB, letter to the Honorable Nancy Risque-Rohrbach, Assistant Secretary for Policy, Department of Labor, March 10, 1992.

3. Graham, John D., Bei-Hung Chang, and John S. Evans, "Poorer is Riskier," *Risk Analysis*, vol. 12, No. 3, 1992.

4. Fisher, A., L. Chestnut, and D. Violette, "The Value of Reducing Risk of Death: A Note on New Evidence," *Journal of Policy Analysis and Management*, vol. 8, No. 1, 1989.

5. RTI, "Estimating Health Benefits of Nutrition Label Changes," April 1991.

6. Economic Report of the President, transmitted to Congress February 19, 1992, p. 327, U.S. Government Printing Office, Washington DC.

7. Keeney, R.L., "Mortality Risks Induced by Economic Expenditures," *Risk Analysis*, vol. 10, No. 1, 1990.

Dated: December 17, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

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Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 101, et al.
Food Labeling; Misleading Containers; Proposed Rules

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 91N–384H]

RIN 0905–AD08

Food Labeling: Nutrient Content Claims, Definition of Term: Healthy

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its food labeling regulations to establish a definition for the term "healthy" under the Federal Food, Drug, and Cosmetic Act. Elsewhere in this issue of the **Federal Register**, the agency is publishing a final rule to revise 21 CFR part 101 which establishes provisions for general principles, petitions, and definition of terms for nutrient content claims. This proposal will provide a definition for the implied nutrient content claim "healthy" for individual foods and for meals and main dish products and provide for its use on the food label. This action is in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments).

DATES: Written comments by March 8, 1993. The agency intends that any final rule that may issue based on this proposal become effective on the same date as the final regulations for the General Principles for Nutrient Content Claims, promulgated under the provisions of the 1990 amendments and published elsewhere in this issue of the **Federal Register**.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS–155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5229.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 27, 1991 (56 FR 60421), FDA published a proposal entitled, Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms (hereinafter referred to as the general principles proposal) that would, among other things, establish general principles for the use of claims describing the nutrient content of foods and define certain nutrient content claims and provide for their use on food labels.

In the same issue of the **Federal Register** (56 FR 60478), FDA also published a proposed rule entitled "Food Labeling: Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food" (hereinafter referred to as the fat/cholesterol proposal) to define and provide for the proper use of the nutrient content claims for fat, saturated fatty acids, and cholesterol.

Both the general principles proposal and the fat/cholesterol proposal were issued in response to the 1990 amendments (Pub. L. 101–535). With respect to nutrient content claims, the 1990 amendments amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 403(r)(1)(A) (21 U.S.C. 343(r)(1)(A)), which states that a food is misbranded if it bears a claim on its label or in its labeling that either expressly or implicitly characterizes the level of any nutrient of the type required to be declared as part of the nutrition labeling, unless such claim is made in accordance with section 403(r)(2) of the act.

In the general principles proposal, the agency proposed that an implied nutrient content claim is one that describes the food or an ingredient therein in such a manner that leads a consumer to assume that a nutrient is absent or present in a certain amount (e.g., "high in oat bran"), or that the food because of its nutrient content may be useful in achieving a total diet that conforms to current dietary recommendations (e.g., "healthy") (56 FR 60421 at 60423).

The agency stated that because of the large variety of statements that could be considered to make implied claims and because of the resource constraints and strict timeframes under which the rulemaking was proceeding, it was not proposing to adopt regulations that authorize any implied claims at that time. However, the agency solicited comments and information concerning specific implied claims. The agency stated that if it received sufficient information in comments, it would consider providing for specific implied claims in the final regulation. Alternatively, it said, the agency might defer action on implied claims until after the rulemaking required by the 1990 amendments was complete.

In response to the general principles proposal, the agency received a number of comments on implied claims, including some specifically on the term "healthy." Elsewhere in this issue of the **Federal Register** FDA is publishing a final rule (the general principles final rule) based on the general principles proposal and the fat/cholesterol proposal. In the general principles final rule, the agency has determined that the term "healthy" is an implied nutrient content claim when it appears on the label or in labeling in a nutritional context, that is, when it appears in association with an explicit or implicit claim or statement about a nutrient, such as "healthy, contains less than 3 g of fat." Alternatively, use of the term "healthy" when not an implied claim will be reviewed under the general misbranding privisions. Such a statement suggests that the food may be useful in maintaining healthy dietary practices. Because of the complex nature of the term, the agency has determined that it was not possible to arrive at a final regulation for a definition of the term "healthy." Therefore, the agency is proposing a definition of the term. The agency advises that it intends to make any final rule that derives from this rulemaking effective on the same date as the general principles final rule and the final rule on mandatory nutrition labeling. If for some reason, however, the final rule has not been issued, "healthy" would be subject to the general nutrient content claim requirements for implied claims or the general misbranding clause.

II. Comments and Agency Response

1. Some comments asserted that the term "healthy" may be understood by consumers in some contexts to convey an implied health claim and should, in those instances, be regulated as an implied health claim. One of these comments asserted that the extent to which the term "healthy" implies health benefits depends on the context of the entire label. The comment specifically asserted that the term "healthy," when it is standing alone or is in a brand name, definitely implies to the consumer that the food has a direct beneficial effect on one's health.

Many other comments asserted that the term "healthy" is an implied nutrient content claim. Some comments stated that the context surrounding the use of the term "healthy" frequently conveys a strong message to consumers about the nutrient content of a food. However, one of these comments further stated that the term "healthy" can also appear in a context that does not imply nutrient content. The comment urged FDA, therefore, to consider the textual use of the term when determining whether it constitutes an implied nutrient content claim.

A similar comment asserted that the term "healthy" is misleading when it appears in a brand name of a food but is combined with a descriptor (nutrient content claim) or used in a context that is susceptible to a "unique" inference (e.g., "Healthy One"). The comment stated that the implication is not only that this labeled food is healthy, but that it is the only healthy product and other products of a similar type are unhealthy. The comment supported this argument by citing the results of a poll in which people were presented with two brand names of soup and asked which soup was "better for you." The soups were equivalent in nutritional content. When presented with one brand name that contained the term "healthy" in conjunction with a descriptor implying that the product was unique and one brand name that made no reference to "health" or "healthy," 67.7 percent of the respondents stated the soup whose brand name contained "healthy" was "better for you." The comment suggested that the term "healthy" not be allowed to appear in any context that suggests that the food is uniquely "healthy" as compared to similar products, unless such a claim is true.

FDA agrees with the comments that asserted that the context in which the term "healthy" is used is a critical factor in determining whether the term constitutes an implied nutrient content claim. As discussed in the general principles final rule, FDA believes that the term "healthy" constitutes an implied nutrient content claim only when it appears in a nutritional context. Such a context is established when the term "healthy" appears in association with an explicit or implicit claim or statement about a nutrient. Accordingly, the label or labeling statement "a healthy, low fat meal" would constitute an implied nutrient content claim. Likewise, the statement "low in saturated fat" on the label of a food with the brand name "Healthy Mountain" would place the term "healthy" into a nutritional context and subject it to the provisions of section 403(r) of the act.

On the other hand, FDA believes that in a context that refers to general dietary guidance, "healthy" is not an implied nutrient content claim. For example, in the statement "eat lots of fruit and vegetables for a healthy diet," the term "healthy" does not imply the absence of a nutrient or the presence of a nutrient in a particular amount and would therefore not be a claim subject to the requirements of section 403(r) of the act.

Further, FDA is not convinced that brand names in which "healthy" appears in a phrase with a term that suggests that the product is uniquely healthy, such as "Healthy One," invariably imply that the specified product is superior to products of a similar type, or that the consumer should choose that product because it conforms to current dietary guidelines. The comment's interpretation of its survey is that some brand names that include the term "healthy" should be prohibited because of their context. However, FDA is not convinced that this interpretation of the study is appropriate. Because the study included only one sample involving "healthy," the agency has no way to distinguish between uses of "healthy" in various names. Accordingly, FDA is not granting the comment's request that "healthy" not be allowed to appear in a context that suggests that the food is uniquely healthy. FDA will evaluate such uses of the term on a case-by-case basis and take appropriate action if a particular use is false or misleading.

In addition, FDA advises that a statement containing references to both nutrient levels and a disease or health-related condition would constitute a health claim. As discussed in the final rule on general principles for health claims, published elsewhere in this issue of the **Federal Register**, a health claim is made when a label or labeling statement refers explicitly or by implication both to a nutrient present in the food and to a disease or health-related condition. The agency does not believe that the term "healthy" inherently implies that a food contains certain nutrients, or that the term inherently implies that the consumption of the product may reduce the risk of a disease or health-related condition. Instead, such implications are likely to be made only if the term "healthy" is accompanied by additional language or graphic material (e.g., logos, symbols, vignettes) that explicitly or implicitly suggests both a disease-related benefit and a nutrient context. For example, the statement "a low fat, heart-healthy food" on a food label or labeling implies that the food is useful in reducing the risk of heart disease because of its low fat content and would, therefore, be considered an implied health claim.

Consequently, the agency concludes that when the term "healthy" appears on a food label without the additional label statements that render it either a health claim or a nutrient content claim, it is not subject to the requirements of section 403(r) of the act. Instead, under such conditions, the use of the term "healthy" is subject to section 403(a) of the act, and whether it is misleading will be determined on a case-by-case basis. However, FDA advises that even though it is not establishing a regulation on use of the term "healthy" on labels and in labeling of foods under section 403(a) of the act, it believes that there are some foods on which the term would be misleading. These include foods in which the level of a nutrient exceeds the disclosure level established in new § 101.13(h) published elsewhere in this issue of the **Federal Register**. The agency considers that it is misleading for a label to include the term "healthy" when the food contains a nutrient at a level such that the food would not assist consumers in maintaining healthy dietary practices.

FDA seeks comment on whether it should adopt a regulation using its authority under the general misbranding sections of the act (201(n) (21 U.S.C. 321(n)), 403(a), and 701(a) (21 U.S.C. 371(a))), that provides further guidance on the circumstances under which use of the term "healthy" might be false or misleading and thus misbrand the product. The agency is concerned that when a label bears the term "healthy," even in the absence of statements that render the term an implied claim subject to the requirements of section 403(r) of the act, its implications about the consequences of consumption of the food will be misleading unless the food complies with some understood criteria. If comments support adopting such a regulation, FDA will consider doing so in the final rule that results from this proposal.

2. Some comments asserted that the term "healthy" should either be clearly defined or be prohibited to ensure that the term is used consistently and truthfully. Others asserted that the word "healthy" should be prohibited on food labels because it is misleading to consumers. One of these comments asserted that establishing a definition for "healthy" is impractical because what is "healthy" for one individual is not necessarily "healthy" for another. The comment noted that many of the nutritional needs of children are markedly different than the needs of adults. The comment also asserted that the scientific understanding of "healthy" is continually evolving.

Many comments suggested that the agency should define the term "healthy." A comment from industry stated that the term "healthy" should be defined to curtail the wide variety of products that are marketed as "healthy," when in fact the benefits that they provide in comparison to benchmark products are minimal. One comment asserted the agency should define and allow the use of the term "healthy" to give manufacturers who wish to use the term an incentive to improve the nutritional quality of their products.

One comment asserted that use of the word "healthy" as a descriptor should be encouraged and facilitated because it allows an evaluation of a total product, while it precludes unjustified focus on one nutritive aspect. The comment stated that promulgation of a standard will ensure a quality product, used in an informed way, by a consumer who has accurate information and justified reliance on the product as labeled.

A number of comments stated that there is little or no consistency in the way the term "healthy" is used in the marketplace today. One of these comments asserted that the term is used to describe a low sodium content in some instances and a low fat or saturated fat content in others. The comment noted that some products described as "healthy" may in fact contain a low level of one of these nutrients but still contain high levels of another (e.g., a peanut butter which contains less sodium than other brands but just as many calories and just as much fat). The comment further noted that, in some instances, the nutrient of concern is actually present in greater amounts than it is in similar products that are not described as "healthy" (e.g., one brand of frozen desserts labeled as "healthy" contains more sodium than regular ice creams and more fat than fat free ice creams). Another comment pointed out that the term "healthy" is also understood by some consumers to indicate that a food is free of pesticides.

Some comments stated that the uncontrolled use of the term "healthy" diminishes consumer confidence in FDA and in the truthfulness of the food label. One of these comments cited the results of a national survey conducted in February 1992, in which 1,007 individuals were interviewed concerning their interpretation of the word "healthy" as it appears on food labels. The comment reported that when asked what the word "healthy" on a food label says about an unspecified product, 33 percent responded that it means nothing, 24 percent responded that it means the product is good for you, 9 percent responded that it is an advertising ploy. Additionally, 9 percent of the respondents indicated that they don't believe that the product is actually healthy.

Several comments objected that the grandfathering of brand names that include the term "healthy" would create additional confusion in the marketplace. Some of these comments stated that unevenly restricting usage of the term "healthy" would allow one company to use a term like "healthy" in a brand name and preclude other manufacturers with equivalent or superior products from using the term. One comment also asserted that allowing the use of the term "healthy" through the grandfathering process would perpetuate a "good food/bad food" distinction. Another comment stated that such a policy would allow manufacturers of products with grandfathered brand names to continue to mislead consumers. One comment stated that leaving the term "healthy" undefined allows companies that used the claim in brand names before October 25, 1989, to continue using the term on foods that may not meet appropriate standards.

Some comments encouraged FDA to define "healthy" in a separate supplemental proceeding on an expedited basis, with an effective date that coincides with other implementing regulations. One comment suggested that such a rulemaking be done in conjunction with the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service.

FDA has carefully reviewed these comments and tentatively concludes that a definition of the term "healthy" should be included in the implied nutrient content claim regulations. The number and variety of comments received in response to the appearance of the term "healthy" in the proposed definition of "implied nutrient content claim" has made the agency aware of the overwhelming interest that both consumers and industry have in regulating the use of this term. The agency agrees with those comments that asserted that there is little consistency in the way the term "healthy" is currently used in the marketplace and is concerned that this inconsistency is confusing to consumers. Because concern over the use of the term "healthy" is so great, and because there is a wide divergence of opinion on appropriate criteria, the agency is proposing a definition for this term.

In reaching this tentative conclusion, FDA considered the option of not defining the term "healthy." Under section 403(r)(2)(C) of the act, all undefined nutrient content claims will be prohibited except when they appear in the brand names of products that were initially marketed before October 25, 1989. Thus, if FDA did not define "healthy," it could continue to be used in grandfathered brand names as long as such use was not false or misleading under section 403(a) of the act. This would have meant that the inconsistent use of this term among grandfathered brand name foods would also continue. The agency believes that the situation that would have resulted would not only not be in the interest of consumers but would be inequitable, because one product would be able to bear the claim but a nearly identical product could not. (The agency emphasizes that this discussion does not apply to uses of "healthy" that are not implied nutrient content claims.)

FDA tentatively concludes that a more appropriate resolution to the problems cited by the comments is to define the term "healthy." The agency believes that, by providing a definition, it will ensure that the term is used consistently by various manufacturers, and that all manufacturers who market similar products are able to use the term "healthy" if the product meets the definition.

3. Some comments asserted that the term "healthy" is more appropriately applied to overall diets which include fresh fruits, vegetables, low fat dairy products, and grains rather than an individual food or "meal/main dish" product. These comments suggested that FDA prohibit the use of the term on food labels. One such comment stated that allowing the use of the term "healthy" on individual foods contradicts the Department of Health and Human Services and USDA "Nutrition and Your Health, Dietary Guidelines for Americans" 1990 (Dietary Guidelines) which states that almost any food that supplies calories and nutrients can be incorporated into a nutritious diet, and that it is the overall diet that is significant. While most comments that discussed "healthy" did not distinguish between its use on individual foods and its use on meals and main dishes, other comments asserted that allowing individual foods to be described as "healthy" perpetuates a "good food/bad food" image. A comment from a foreign government advised that its policy is not to allow food products to be described as "healthy," although their labeling may bear statements that the food can be consumed as part of a healthy overall diet. Another comment expressed concern that the representation of single foods or "meal/main dish" products as "healthy" could easily lead a consumer to over consume those products rather than consuming a variety of foods and thereby reduce the nutrient quality of his/her diet.

The agency tentatively concludes that it should not limit the use of the term "healthy" to reference the total diet. FDA believes that foods labeled with the term "healthy," whether they are individual foods, main dishes, or meals, can be used with a variety of foods to assist consumers in maintaining healthy dietary practices, that is, to achieve a total diet that conforms to current

dietary guidelines. One of the goals of the 1990 amendments was to encourage manufacturers to provide a wider selection of foods with improved nutrient content to facilitate diets that conform to guidelines. The agency tentatively concludes that appropriate criteria for use of the term "healthy" can be established to both encourage innovation and ensure that the term is not misleading.

While FDA is proposing a definition for "healthy" that includes the same criteria for all types of foods, the agency requests comments on whether it is more appropriate to establish criteria for the use of "healthy" on individual foods that are different from those for meals and main dishes, or whether use of "healthy" should be limited to meals and main dishes. Comments should suggest criteria appropriate for the recommended use and include data or other information to substantiate their recommendations.

4. The agency received numerous comments that suggested definitions for use of the term "healthy" on food labels. Several of those comments addressed the issue of what the term "healthy" is understood to mean or should be defined to mean when it appears on food labels. One comment stated that consumers associate the term "healthy" with fat, saturated fat, cholesterol, and sodium. The comment cited the results of a national survey that showed that 81 percent of the respondents thought that a food labeled as "healthy" was low in sodium and fat, 79 percent thought it was low in cholesterol, and 74 percent thought it was low in saturated fat and calories. Many of the comments that offered definitions for the term "healthy" included requirements for the levels of fat, saturated fat, cholesterol, and sodium. One of these comments stated that foods labeled with the term "healthy" should contain no more than 30 percent calories from fat, 10 percent calories from saturated fat, 60 milligrams (mg) or a significantly reduced amount of cholesterol, and 480 mg or a significantly reduced amount of sodium. A few comments suggested that FDA allow the term "healthy" to appear on foods that do not contain nutrients at levels exceeding the disclosure levels for sodium, fat, saturated fat, and cholesterol. Many comments asserted that a product labeled as "healthy" should additionally be "low" in at least one of these nutrients.

Many other comments suggested a stricter definition of "healthy" that would require that a product meet the "low" definition for sodium, fat, saturated fat, and cholesterol. Some comments also suggested additional criteria that a "healthy" product should be required to meet. One of these comments suggested that such a product be "low" in calories. Another suggested that such a product meet the "low" definition for sugars.

The agency has evaluated these comments. It tentatively agrees with those comments that stated that FDA should define the term "healthy" in a way that restricts the levels of those nutrients whose consumption should be limited in the total daily diet to levels that do not exceed the Daily Reference Values (DRV's) for those nutrients. The agency also tentatively agrees with those comments that suggested that the definition for "healthy" should focus on restrictions for fat, saturated fat, sodium, and cholesterol because these nutrients are of particular significance to public health. High intake of total dietary fat is associated with increased risk for obesity, some types of cancer, and possibly gall bladder disease. Excessive saturated fat consumption is a major contributor to total blood cholesterol levels, and the consumption of dietary cholesterol also contributes to total blood levels. An extensive body of evidence has established a relationship between high blood cholesterol and increased coronary heart disease. Accordingly, many health organizations have made recommendations for modifying dietary intake of fat, saturated fat, and cholesterol for the purpose of improving the public health (56 FR 60478 at 60482). According to the Dietary Guidelines, excessive dietary intake of sodium is one of several factors that may increase the risk of hypertension in some individuals. Hypertension currently affects one in three Americans and is associated with heart disease and stroke when uncontrolled (56 FR 60825 at 60834).

The agency has tentatively concluded that a definition of "healthy" that allows the term to appear on foods that contain amounts of fat, saturated fat, sodium, and cholesterol above the disclosure level would not assist consumers in maintaining healthy dietary practices and could result in an overall diet inconsistent with current dietary guidelines. Accordingly, FDA has tentatively concluded that a definition of "healthy" that permits levels of fat, saturated fat, sodium, and cholesterol that are above the disclosure levels would not be approiate. FDA believes that labeling of such products as "healthy" would be misleading to consumers.

Likewise, the agency is concerned that a definition of "healthy" that requires that a food be "low" in fat, saturated fat, sodium, and cholesterol may be too restrictive. Such a definition could disqualify many products that would be useful in maintaining a diet that conforms to current dietary guidelines. FDA also believes that although restricting the percentage of calories derived from fat and saturated fat to no more than 30 percent and less than 10 percent, respectively, is appropriate for overall diets, it is not appropriate for individual foods and is, therefore, not appropriate as a criterion for "healthy" on individual foods. However, as discussed in the general principles final rule in the definition for "low fat" and "low saturated fat" for meal and main dish products, no more than 30 percent of calories from fat and less than 10 percent of calories from saturated fat are used as a second criterion for the definitions for "low fat" and "low saturated fat," respectively. Therefore, under this proposal the criterion of no more than 30 percent of calories from fat or less than 10 percent of calories from saturated fat will apply to meal and main dish products bearing the term "healthy."

FDA is therefore proposing to amend new § 101.65 by redesignating paragraph (d) as paragraph (d)(1) and by adding new paragraph (d)(2) which provides that for the purposes of new § 101.65, the term "healthy" may be used to describe foods that do not exceed the disclosure level for sodium or cholesterol and are "low" in fat and saturated fat. This proposed definition of "healthy" limits fat and saturated fat in a "healthy" food because of the recommendations from leading health authorities that lowered consumption of fat and saturated fat is of importance in reducing the risk of certain diet-related diseases that are discussed above.

The agency believes that the foods that will be able to bear the term "healthy" under this definition will be of a sufficient number and variety to help consumers achieve a total diet that is consistent with current dietary recommendations.

FDA specifically solicits comments for evaluating whether this definition of "healthy" is appropriate.

The agency requests comments on whether the definition for "healthy" should include a requirement that the food be "low" in a third nutrient, i.e., cholesterol or sodium. Among other things, comments should address: whether a "low cholesterol" criterion is needed; if such a requirement is included in the definition will such foods as shellfish and crustaceans qualify to be labeled "healthy;" should such foods be labeled "healthy" in light of their cholesterol content?

In addition, comments should consider whether a "low calorie" criterion should be a part of the definition of "healthy." The agency has not included a calorie criterion in its proposed definition because there was not enough information in comments for FDA to determine that such a criterion is needed. However, dietary guidelines recommend that Americans maintain appropriate caloric intake for their body weight, and that overweight is a major public health problem. In light of these facts, FDA is seeking comment on what, if any, calorie criterion should be included. Should calories be a part of a requirement for a third nutrient at a "low" level, i.e., the food must be "low" cholesterol, sodium, or calories in addition to fat and saturated fat? Alternatively, should a "low calorie" criterion be required in addition to "low" in cholesterol or sodium?

FDA acknowledges that the definition of the term "healthy" that it is proposing in this document differs from the definition for the term proposed elsewhere in this issue of the **Federal Register** by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), which regulates the labeling of meat and poultry products. The Dietary Guidelines for Americans recommend choosing lean meat and poultry as part of a balanced diet. The agency requests comments on whether a definition of healthy which excludes lean meat and poultry will help consumers to achieve a total diet that is consistent with current dietary recommendations. Comments should suggest appropriate criteria for a single definition for all foods or separate definitions for foods of animal origin such as meat and poultry and provide rationale and other information to substantiate their suggestions. The agency also requests comment on whether it is necessary that the two agencies provide uniform criteria for use of this term or whether different definitions may be appropriate.

5. Some comments suggested that a product labeled as "healthy" should provide key nutrients in addition to being "low" in sodium, fat, saturated fat, and cholesterol. Another such comment specified that the product should be "high" in two of the four micronutrients (i.e., Vitamin A, Vitamin C, calcium, and iron). Another of these comments suggested that a "healthy" food contain either at least 5 percent of the Reference Daily Intake (RDI) of at least two vitamins or minerals required to be included in the nutrition label or at least 10 percent of the RDI of at least one such vitamin or mineral. One such comment suggested that FDA require that the food provide 10 percent of the reference levels of fiber and two other vitamins or minerals. The concept that a definition for the term "healthy" should include a requirement for fiber was also supported by the results of the national survey that is discussed above in greater detail. That survey found that 72 percent of the respondents believed that the term "healthy" implied that the food was a source of fiber.

FDA specifically requests comments on the appropriateness of including a requirement in the definition of "healthy" that the food supply a certain amount of specified essential vitamins, minerals, or other nutrients (e.g., protein). There is not significant agreement among the comments as to the specific nutrients that should be included in such a requirement. The agency does not believe that it currently has enough information to conclude that such a requirement would be useful if a definition for use of the term "healthy" were to be adopted.

6. Some comments specifically addressed use of the term "healthy" to describe meals and main dish products (referred to in the general principles proposal as meal-type products). One comment suggested that the term "healthy" be allowed to appear in the labeling of a meal-type product that contains not more than 19 grams (g) of fat, 6 g of saturated fat, 75 mg of cholesterol, or 600 mg of sodium per product. The comment also stated that these criteria would reflect 25 percent of the proposed DRV for each of the nutrients and would provide an adequate amount of nutrients when considering that consumers have approximately four important eating occasions on a daily basis.

Another comment asserted that in addition to nutrient criteria, the use of the term "healthy" to describe meal products should be restricted to foods that: (1) Provide at least 500 calories per serving, and (2) are composed of foods from at least three of the major food groups.

After reviewing these comments, the agency has tentatively concluded that there is a need to provide for use of the term "healthy" to describe the levels of multiple nutrients in a meal or main dish product.

FDA tentatively agrees with those comments that suggested that the definition for "healthy" on meals and main dish products should focus on restrictions for fat, saturated fat, sodium, and cholesterol, because these nutrients are of particular significance to public health. Moreover such a definition is consistent with the definition of "healthy" that FDA is proposing for individual foods. The agency does not agree, however, with the comment that suggested that the definition for "healthy" on meal products should be restricted to those products that provide at least 500 calories per serving and are composed of foods from at least three of the major food groups. Such a criterion would preclude many products that otherwise meet the requirements for "healthy" and are beneficial in assisting consumers in maintaining diets within current dietary guidelines from bearing a "healthy" claim. Thus, the agency has tentatively concluded that the proposed definition for "healthy" on individual foods can also be applied to meal and main dish products, because, as discussed in section II. of this document (comment 4) such a definition places emphasis on the limitation of fat and saturated fat in a "healthy" meal or main dish product. Therefore, the proposed definition conforms to recommendations from leading health authorities to limit total daily consumption of fat and saturated fat. Accordingly, FDA is proposing to define the term "healthy" in new § 101.65(d)(2) to describe a meal product as defined in new § 101.13(l) or main dish product as defined in new § 101.13(m) that meets the definition for "low" for fat and saturated fat and that does not exceed the disclosure level for cholesterol or sodium.

The agency believes that the meal and main dish products that will be able to bear the term "healthy" under this definition will be of a sufficient number and variety to help consumers achieve a total diet that is consistent with current dietary recommendations. FDA specifically solicits comments for evaluating whether this definition of "healthy" is appropriate for meal and main dish products.

In addition, as discussed in the general principles final rule, because of the unique nature of restaurant foods, the agency requests information on the extent to which such a definition for "healthy" would be appropriate for meals, main dishes, and individual foods served in restaurants. Specifically, the agency requests information on: (1) Whether such foods have characteristics which would make such a definition for "healthy" difficult to meet, and (2) if a different definition for "healthy" on such foods would be confusing to consumers.

7. One comment requested that FDA specifically include in the language of the regulation on "healthy" that a food need not be specially processed, altered, formulated, or reformulated to qualify for use of the term on its labeling.

The agency advises that the requirement that a food be specially processed, altered, formulated, or reformulated compared to other foods applies to "free" and "low" claims (new § 101.13(e)). The requirement is triggered when these claims appear before the name of the food to prevent the consumer from being led to believe the product differs from others of that type when that is not the case. FDA is not aware of a similar use of the term "healthy." The comment did not provide information on or examples of misleading labels. Therefore, the agency tentatively concludes that a provision similar to that in new § 101.13(e) is not needed for "healthy." However, it requests comments on this issue. If information in comments demonstrates that such a provision is warranted, FDA will consider including it in the final regulation.

III. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (address above), and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

Because any changes that result from this proposal will not need to be made until the same date as the other changes required by the nutrient content claims final rule (May 8, 1994), this proposal will not add any additional meal costs to those considered in the RIA.

IV. Environmental Impact

The agency previously considered the environmental effects of the action being taken in this final rule. As announced in its nutrition labeling proposed rules published in the Federal Register of November 27, 1991 (56 FR 60366 et al.), the agency determined that under 21 CFR 25.24(a)(8) and (a)(11), these actions are of a type that do not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement was required.

V. Request for Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.65 is amended by adding new paragraph (d)(2) to read as follows:

§ 101.65 Implied nutrient content claims and related label statements.

* * * * *

(d) * * *

(2) For purposes of this section, the term "healthy" may be used on the label or in labeling of a food, including a meal as defined in § 101.13(l) or a main dish as defined in § 101.13(m), provided:

(i) It meets the definition of "low" for fat and saturated fat;

(ii) Neither cholesterol nor sodium is present at a level exceeding the disclosure levels as described in § 101.13(h) for an individual food, meal product, or main dish product, as appropriate; and

(iii) The food complies with definitions and declaration requirements established in this part for any specific nutrient content claim on the label or in labeling.

Dated. October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31526 Filed 12–28–92; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 101, 102, and 161

[Docket No. 90N-361M]

RIN 0905-AD08

Food Labeling; Declaration of Ingredients—Common or Usual Name Declaration for Protein Hydrolysates and Vegetable Broth in Canned Tuna; "and/or" Labeling for Soft Drinks

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to: (1) Amend the standard of identity for canned tuna (21 CFR 161.190) to require the term "(includes soybeans)" as part of the name used to declare the ingredient vegetable broth when soybeans are one of the vegetable extractives used to make the vegetable broth; (2) amend the common or usual name regulations for protein hydrolysates (new § 102.22) to require the term "contains glutamate" as a part of the common or usual name of autolyzed yeast extracts and certain hydrolyzed proteins; and (3) amend the food labeling regulations in § 101 4 (21 CFR 101.4) to allow "and/or" labeling for the declaration of sweeteners in soft drinks. These proposed requirements are in response to issues that were raised in comments to the proposed rule on ingredient labeling that was published in the **Federal Register** of June 21, 1991 (56 FR 28592).

DATES: Written comments by March 8, 1993. The agency proposes that any final rule that may issue based on this proposal, become effective May 8, 1994.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Campbell, Center for Food Safety and Applied Nutrition (HFS-155), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5229.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 21, 1991 (56 FR 28592), FDA published a proposed rule (hereinafter referred to as the 1991 ingredient labeling proposal) to implement certain amendments to the Federal Food, Drug, and Cosmetic Act (the act) that were made in section 7 of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535). These amendments require the listing of the ingredients of standardized foods and the declaration of certified color additives in foods. In the 1991 ingredient labeling proposal, FDA also proposed other actions concerning ingredient labeling in response to written and oral comments received on an advance notice of proposed rulemaking published in the **Federal Register** of August 8, 1989 (54 FR 32610), as part of the food labeling initiative of the Secretary of the Department of Health and Human Services. The agency received over 700 letters in response to the 1991 ingredient labeling proposal, each containing one or more comments. Elsewhere, in this issue of the **Federal Register**, the agency is publishing a final rule (the declaration of ingredients final rule) responding to the majority of those comments. However, some comments to the 1991 ingredient labeling proposal presented new information on two matters that the agency had addressed in the 1991 ingredient labeling proposal: the declaration of glutamate when a component of certain protein hydrolysates and the use of "and/or" labeling for sweeteners in soft drinks. Other comments raised a new issue that had not been addressed in the 1991 ingredient labeling proposal: the declaration of vegetable extractives in vegetable broth in canned tuna.

After reviewing the information provided in these comments, as well as other information available to the agency, FDA has tentatively concluded that additional labeling requirements are necessary and appropriate to ensure that ingredient labeling with regard to these issues is accurate, not misleading, and assists the consumer in making informed purchase decisions. With respect to each of the three issues, however, FDA has concluded that it would not be appropriate to simply include the regulations that it is proposing in the final rule on declaration of ingredients. The agency had not specifically addressed the appropriate declaration of the vegetable extractives in vegetable broth when present in canned tuna in the 1991 ingredient labeling proposal. Moreover, in that proposal, FDA had flatly asserted that declaration of glutamate would not be possible, and its only action with regard to the use of "and/or" labeling of sweeteners in soft drinks was to deny a longstanding petition. Thus, the agency determined that the best approach to addressing these issues was to publish a proposed rule and to permit an opportunity for comment on its tentative decisions to establish additional labeling requirements with regard to these three matters.

II. The Proposal

A. Declaration of Soybeans as Ingredients of Vegetable Broth Used in Canned Tuna

The standard of identity for canned tuna (§ 161.190 (21 CFR 161.190)) permits the inclusion of several optional ingredients. One of the optional ingredients provided for in § 161.190(a)(6)(v) is designated as "vegetable broth" and is permitted to be declared in the ingredient list as "vegetable broth." As required by the standard, vegetable broth consists of two or more of the vegetable extractives as specified in § 161.190(a)(6)(v). In accordance with the 1990 amendments, FDA proposed in the 1991 ingredient labeling proposal to amend the standard of identity for canned tuna (56 FR 28592 at 28634) to require that all mandatory and optional ingredients be declared in the ingredient list in accordance with the requirements of the applicable sections of parts 101 and 130 (21 CFR parts 101 and 130). Previously, only declaration of optional ingredients in standardized foods was required by the act.

One comment interpreted the agency's implementation of the 1990 amendments to mean that FDA will require the listing of each vegetable that is in the vegetable broth in the order of predominance parenthetically following the term "vegetable broth" in the ingredient statement on the label of canned tuna. The comment stated its opposition to this approach. In support of its position, the comment pointed out that this method of listing the ingredients comprising vegetable broth in canned tuna would "intensify label crowding" and "create confusion as to whether or not whole pieces of vegetables are contained therein." This comment also stated that FDA should not require the listing of the components of vegetable broth in canned tuna.

As discussed in the declaration of ingredients final rule, FDA agrees that the listing of each ingredient comprising vegetable broth on the label of canned tuna could be lengthy and cumbersome. Furthermore, as stated above, the standard of identity for canned tuna permits the ingredient vegetable broth to be listed as "vegetable broth." Hence, the new regulations do not require full declaration of all of the ingredients of which the vegetable broth is comprised

However, the agency notes that some manufacturers have interpreted the provision in § 161.190(a)(6)(v) that permits the use of "beans" as one of the vegetables extractives in making the vegetable broth used in canned tuna as including soybeans (Ref. 57). Soybeans generally are not classified as "vegetables" but as grains and belong to the general category of oilseeds. Thus, it is not likely that the term "vegetable broth" would be understood by most consumers to be a product that has been made from soybeans. Because some individuals have food sensitivities (including possible life-threatening reactions) to soy proteins (Ref. 58), consumers should be informed of the presence of soybean extractives in the broth. Therefore, FDA is proposing to amend the standard of identity in § 161.190(a)(6)(vi) to require that when soybeans are used in vegetable broth, this fact be declared parenthetically following the listing of "vegetable broth" in the ingredient statement of the label, as follows: "vegetable broth (includes soybeans)". If the vegetable broth serves as a flavor and has no flavor enhancing function in the food, the vegetable broth containing soybean extractives will be listed in the ingredient statement as "flavoring (includes soybeans)." (In the declaration of ingredients final rule the agency discusses its conclusions with respect to the functional effect of vegetable broth as a flavoring or flavor enhancer when used in canned tuna and the appropriate label declarations for such use.)

The proposed requirement to list soybeans as a constituent of vegetable broth is consistent with FDA's past policy regarding the listing of soybeans on canned tuna labels. In a letter to Protein Technologies International, FDA stated that when soybeans are used in the vegetable broth, their presence must be identified parenthetically following the term vegetable broth because of possible allergic reactions in some individuals to soy proteins (Ref. 57). FDA continues to believe that such information is essential to individuals with sensitivities to soybeans, and that the industry should continue to list soybeans on the label when it is contained in the vegetable broth.

FDA encourages, where practicable, the full disclosure of all ingredients on the labels of food products to promote clarity and to prevent confusion and misunderstanding on the part of consumers. The agency believes that listing of all the components of vegetable broth would be informative and useful to consumers.

B Label Declaration of Glutamate as a Component of Protein Hydrolysates

FDA stated in the 1991 ingredient labeling proposal that the agency was not aware of scientific evidence establishing that monosodium glutamate (MSG) causes severe adverse or life-threatening reactions (56 FR 28592 at 28600). Therefore, the agency tentatively found that there was no public health basis for requiring the declaration of free glutamates (i.e., salts of free glutamic acid such as MSG, monopotassium glutamate, etc.) that occur as components of protein hydrolysates.

Many comments to the ingredient labeling proposal urged the agency to reconsider its position and require declaration of the MSG component in protein hydrolysates for health reasons. (The agency notes that the glutamic acid portion of a protein hydrolysate may be present as salts other than the monosodium salt. Hence, the agency will use the generic term, "glutamate," to refer to all the salts of glutamic acid.) Most of these comments alleged that many people have allergic reactions, food intolerance, or sensitivity to glutamate and, therefore, want to avoid consumption of any amount of glutamate in food. One comment stated that its request for declaration of glutamate in hydrolyzed protein was based on some of the same information on which the agency had relied. The comment disagreed, however, with the agency's conclusion that glutamate as a component of a protein hydrolysate is safe. The comment also disagreed with the agency's belief that there is no scientific evidence to support a finding that glutamate in such amounts as may result from the hydrolysis of a protein can cause or trigger an allergic reaction, food intolerance, sensitivity, or any other measurable adverse health effect.

The agency disagrees with these comments. As the agency indicated in the 1991 ingredient labeling proposal, there is some evidence in case reports and in the scientific literature that dose-dependent, mild reactions to glutamate occur in a limited portion of the population. However, no verifiable scientific data have been presented to the agency that establish that low doses of glutamate, as found in protein hydrolysates, cause severe adverse or allergic reactions in sensitive individuals. Further, none of the comments provided scientific data to support allegations of allergic reactions, food intolerance, or sensitivity responses due to the ingestion of glutamate as a component of protein hydrolysates.

Thus, there is no public health basis for requiring declaration of glutamate present in a food as a component of hydrolyzed protein and the agency's tentative decision to require the declaration of glutamate is not based on any failure of the labeling to reveal material facts regarding consequences that may result from the customary or usual use of the ingredient.

However, some comments to the 1991 ingredient labeling proposal raised other issues not related to public health concerning the declaration of glutamates. These comments urged that FDA require declaration of the glutamate component in protein hydrolysates because of public confusion, misunderstanding, and suspicion caused by lack of informative labeling of protein hydrolysates. Most of the comments expressed concern that foods that do not have glutamate declared in the ingredient label or are labeled "no added MSG" do indeed contain some form of glutamate. Several comments stated that MSG could conceivably be a component of any ingredient in the finished food. Other comments stated that all protein hydrolysates, regardless of the degree of hydrolysis, contain high levels of glutamate. Finally, some comments indicated that consumers believe manufacturers add protein hydrolysates that contain high levels of glutamate to food but do not declare the presence of glutamate on the label.

FDA did not consider these issues in the 1991 ingredient labeling proposal. After evaluating the information presented in these comments, FDA has tentatively concluded that the phrase "(contains glutamate)" is necessary to describe adequately the basic nature of certain protein hydrolysates and, thus, is proposing that this phrase be part of the common or usual name of certain protein hydrolysates.

The agency has tentatively decided to define specific situations (i.e., when the protein hydrolysate used is an autolyzed yeast extract or a highly hydrolyzed protein hydrolysate) in which the label declaration of free glutamate formed during the production of protein hydrolysates is required.

The tentative decision to require declaration of glutamate as a component of certain protein hydrolysates is in response to information reviewed by the agency that suggests that the proposed common or usual name for protein hydrolysates used for flavor-related purposes does not accurately describe the basic nature or characterizing properties of the ingredient. Specifically, some protein hydrolysates with high levels of glutamate are

functionally equivalent to MSG when added to food, while other protein hydrolysates, added to food for nonflavor related purposes, contain inadequate levels of glutamate to mimic MSG in food.

Literature reviewed by the agency (Ref. 4) indicates that protein hydrolysates from different sources may contain very different levels of free glutamate based on the amino acid profile of the source protein and the degree of hydrolysis of the protein hydrolysate. These technical differences are important in deciding which protein hydrolysates will be used in which foods.

Two basic methods for producing protein hydrolysates used for flavor-related purposes were identified in the 1991 ingredient labeling proposal (56 FR 28592 at 28596): Acid hydrolysis and enzyme hydrolysis (including hydrolysis by endogenous proteolytic enzymes as occurs in the preparation of autolyzed yeast extract). The high degree of hydrolysis that occurs as a result of the acid digestion of the source protein results in a 75 to 95 percent free amino acid content. Enzyme hydrolysis, on the other hand, is less complete, and the resulting free amino acid content can be as little as 45 percent (Ref. 4).

The major contributors to the flavor and flavor enhancement properties of protein hydrolysates are the many amino acids and their derivatives (Ref. 4). Glutamic acid, although well-known for its flavor enhancing properties, is only one of several amino acids contributing to the desirable flavor profile of a hydrolyzed protein. Nevertheless, it is the predominant amino acid in all of the protein sources currently subjected to hydrolysis for flavor-related uses (i.e., autolyzed yeast extracts and highly hydrolyzed proteins) (Ref. 4). Furthermore, data show that, as the free glutamate component of the protein hydrolysate is increased, the effectiveness of the protein hydrolysate as a flavor enhancer is also increased (Refs. 4, 59, and 60). Moreover, the amount of free glutamate in protein hydrolysates commonly used for flavor-related purposes is at a level such that the glutamate is capable of functioning as a flavor enhancer independently of the protein hydrolysate (Refs. 4 and 60).

The concern expressed in the comments by consumers who desire to know whether a protein hydrolysate has a significant glutamate functionality, but are unable to determine the nature of the protein hydrolysate from the information in the ingredient list, led the agency to consider further current labeling practices as they relate to commonly used levels of highly hydrolyzed proteins and autolyzed yeast extracts. In addition, the comments the agency has received on the various types of protein hydrolysates used in foods (i.e., flavor and nonflavor types) and the consumer confusion that surrounds the current terms used to declare protein hydrolysates have convinced the agency that additional provisions for common or usual name declaration of flavor type protein hydrolysates are required in the regulations to ensure that the common or usual names accurately describe the nature and characterizing properties of these ingredients.

Under the declaration of ingredients final rule, for example, both a highly and a partially hydrolyzed soy protein may be declared as "hydrolyzed soy protein." This form of declaration provides no means of distinguishing between the lightly hydrolyzed ingredient, which does not contain a level of free glutamate sufficient to cause the ingredient to function as a flavor enhancer; and the highly hydrolyzed ingredient, which does contain functionally effective free glutamate. In order to ensure that the common or usual names of protein hydrolysates used for flavor-related purposes accurately describe the basic nature of the particular ingredient and its characterizing property distinction as required by § 102.5(a), the agency tentatively concludes that the common or usual names of protein hydrolysates used for flavor-related purposes (i.e., autolyzed yeast extracts and highly hydrolyzed proteins) should include the parenthetical phrase "contains glutamate." Highly hydrolyzed proteins can be defined as those with a ratio of α-amino nitrogen (AN) to total nitrogen (TN), determined by using the tests for "Acid Hydrolyzed Proteins" set forth in the "Food Chemicals Codex", 3d ed., 1st Supp. (1983), greater than 0.62 (AN:TN ≤ 0.62) (Ref. 53). Proteins that are not highly hydrolyzed would have an AN:TN ratio of less than 0.62 (AN:TN < 0.62) and may be declared by using such terms as "partially," "mildly," or "lightly" (e.g., "Partially hydrolyzed (source) protein"), as discussed in the declaration of ingredients final rule.

Thus, FDA is proposing to require declaration of glutamate in the common or usual names of highly hydrolyzed proteins and autolyzed yeast extracts because it is essential to describe accurately the basic nature and characterizing property of the particular ingredient. The agency is proposing to add new § 102.22(b) to include this requirement. For example, a common or usual name required by this proposed regulation would be "hydrolyzed soy protein (contains glutamate)" or "autolyzed yeast extract (contains glutamate)." The agency believes that this provision will provide fully informative labeling for hydrolyzed proteins used for flavor-related purposes. It will also preclude the misleading practice, alleged in many comments, of manufacturers using protein hydrolysates as substitutes for MSG in order to circumvent the requirement that MSG be declared in the ingredient list.

The agency requests comments on its tentative decision to require "contains glutamate" as part of the common or usual name of these protein hydrolysates.

C. Use of "and/or" Labeling

The food labeling regulations allow the use of "and/or" labeling in certain situations when manufacturers are unable to adhere to a consistent pattern of use of specific ingredients in their products (§ 101.4(b)). Such labeling provides a manufacturer with the flexibility to list together in the ingredient list of a food product all the ingredients of a particular type (e.g., fats or oils) that it sometimes uses to make the product, without having to specify the ingredients that are actually present in the product. To make clear that not all of the ingredients identified are actually present, the entry in the ingredient list must include the words "or," "and/or," or "contains one or more of the following."

In the 1991 ingredient labeling proposal, the agency denied the citizen petition of the National Soft Drink Association (NSDA) (January 20, 1984—Docket No. 84P–0029) that had requested that FDA allow for the use of "and/or" labeling for sweeteners in soft drinks.

NSDA submitted a comment and additional information requesting that FDA reconsider its denial of its petition and provide for the use of "and/or" labeling for sweeteners in soft drinks. These comments maintained that the option of using different sweetener formulations (e.g., sucrose, high fructose corn syrup (HFCS), or a blend of the two), in conjunction with meeting consumer demands during peak selling periods, obtaining product labels from a national supplier, and the huge sales volume of the bottler system, necessitates the flexibility of an "and/or" labeling system. These comments asserted that, in contrast to sweeteners used in other foods, sugar and HFCS are used in soft drinks exclusively to produce desired sweetness. Furthermore, in contrast to other foods, nondiet soft drinks contain only these

two sweeteners. A single intense (i.e., artificial) sweetener is used solely in diet soft drinks. The comments did not request inclusion of intense sweeteners in "and/or" labeling. They stated that HFCS and sugar are completely interchangeable in soft drinks. One sweetener can be substituted for the other without otherwise altering the formulation or changing the order of predominance of the total amount of the two sweeteners in the ingredient label. The comments reported that, consequently, a current practice in the soft drink industry is for different bottlers of the same brand of soft drink to use different sweetener formulations (i.e., either HFCS, sugar, or a blend of HFCS and sugar) when HFCS, the primary sweetener used, is in short supply for the bottler.

Furthermore, the comments reported that the franchise company typically provides "standard copy" labels to all of the bottlers of a particular brand of soft drink. This practice ensures consistency, uniformity, and accuracy for all of a company's product labels throughout the nation. The comments asserted that because the franchise company provides labels to the bottlers, each individual bottler does not have the flexibility of using labels specific to its unique formulation of HFCS, sugar, or an HFCS-sugar blend. Without "and/or" labeling, problems with compliance may arise when these bottlers need to change their labels in response to necessary adjustments in their specific sweetener formulations. The comments contended that, furthermore, without the flexibility of "and/or" labeling, many bottlers would be forced to maintain, at a minimum, dual inventories of packages (for soft drinks packaged in cans, the label is printed on the can during can manufacture) and labels, which could not only double or triple their operating cost but also make it unlikely that soft drink can manufacturers which, commonly, already operate at 97 percent of capacity would be able to meet the demand for additional packaging.

These comments stated that even though problems of availability of HFCS do not occur routinely, situations do arise from time to time every year in many different parts of the country that necessitate altering the sweetener formulation or completely substituting sugar for HFCS. The comments stated that the demand for soft drinks is seasonal, and that there is not enough flexibility in the supply system to accommodate spot shortages of HFCS during peak demand season. They stated that there were limits to the ability to stockpile HFCS in anticipation of shortages. The storage life of HFCS is only 90 to 120 days. After that period of time, it changes color, decreases in sweetness, and is not suitable for use. Without "and/or" labeling, the flexibility of using sugar to compensate for shortages in HFCS would be lost unless multiple inventories of labels were maintained.

These comments further stated that "and/or" labeling would allow certain soft drink manufacturers to use "kosher for Passover" claims on shrink wrap, bottle lids and caps, or cardboard enclosures, without changing the ingredient label, to indicate to the consumer that the product has been sweetened with sugar rather than HFCS and meets kosher requirements. Without "and/or" labeling, bottlers wishing to market kosher soft drinks would have to obtain completely new packaging, listing only sugar in the ingredient list. The comments contended that the considerable expense associated with maintaining different packaging in order to offer a product in conformity with religious requirements would discourage bottlers from producing such products.

The comments strongly urged FDA to reconsider its position and to allow the use of "and/or" labeling of sweeteners in soft drinks.

At the time that the agency developed the ingredient labeling proposal, it was"not aware that sweetener formulations may be different for the same soft drink brand. In light of this information, FDA has reconsidered its denial of NSDA's petition on the use of "and/or" labeling for sweeteners in soft drinks. Based on its reconsideration, FDA finds substantial merit on both sides of this issue.

The petition and comments allege that a constant pattern of use of sweeteners does not exist among soft drink bottlers because individual bottlers are sometimes required to change their sweetener formulation in response to shortages in supply. FDA finds, however, that this reason does not justify establishing a provision for "and/or"labeling. The agency has traditionally dealt with such emerging shortages by informally granting temporary labeling exceptions to the manufacturers. This approach fully addresses this aspect of the problem.

The second basis for "and/or" labeling that the petition and comments assert is that different bottlers around the country use different formulas. As a result, the labels for some would need to list only HFCS in the ingredient list, the labels for others HFCS and sugar. Moreover, at Passover, a third label would be required that lists only sugar. Having to prepare and maintain three labels would add to the costs of the franchise company and would limit its ability to ensure the consistency and uniformity of its product labels throughout the nation. The individual bottlers would have the costs of maintaining a label that reflects their regular formula plus the Passover label. Thus, the question that the agency must consider is whether the additional costs to the franchise company and bottler make it impracticable for soft drinks to satisfy section 403(i)(2) of the act (21 U.S.C. 343(i)(2)) and to declare each ingredient by its common or usual name.

Granting an exemption for sweeteners in soft drinks would represent a significant departure from the circumstances in which FDA has granted "and/or" exemptions in the past. FDA has only granted "and/or" exemptions when the manufacturer has been unable to adhere to a constant pattern of ingredient use. As explained above, FDA questions whether the claim has credibly been made here. Moreover, all "and/or" labeling exemptions in § 101.4(b) have been for minor ingredients, such as leavening agents, yeast nutrients, dough conditioners, firming agents, and ingredients that are less than 2 percent of the foods. Furthermore, such "and/or" labeling exemptions are provided for these ingredients in all foods and is not restricted to a specific food type. Thus, FDA has significant concerns about the precedent that it would create by granting this exemption.

However, in the interests of advancing the administrative process in the most expeditious manner, FDA is proposing to grant the exemption. The agency is proposing to add § 101.4(b)(21) to allow the use of "and/or" labeling for sweeteners in soft drinks.

The agency wishes to make clear, however, that its final decision on the exemption will be based largely on the comments that it receives. To justify adoption of proposed § 101.4(b)(21), industry will have to produce data to demonstrate that it is in fact impracticable to produce the very limited number of versions of a label that would be necessary if an exemption is not granted. Those who oppose granting the exemptions will have to come forward with strong reasons why the requested exemption should not be granted in the face of data from the industry that establishes significant costs from strict compliance with section 403(i)(2) of the act. Is there data to show, for example, that consumers are less willing to buy a product that contains HFCS than sugar? Is there

reason to believe that the use of "and/or" labeling in this instance is to obscure the nature of the sweetener used rather than to minimize labeling costs? FDA will consider the comments that it receives.

III. Economic Impact

In its food labeling proposals of November 27, 1991 (56 FR 60366 et seq.), FDA stated that the food labeling reform initiative, taken as a whole, would have associated costs in excess of the $100 million threshold that defines a major rule. Thus, in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354), FDA developed one comprehensive regulatory impact analysis (RIA) that presented the costs and benefits of all of the food labeling provisions taken together. That RIA was published in the Federal Register of November 27, 1991 (56 FR 60856), and along with the food labeling proposals, the agency requested comments on the RIA.

FDA has evaluated more than 300 comments that it received in response to the November 1991 RIA. FDA's discussion of these comments is contained in the agency's final RIA published elsewhere in this issue of the Federal Register. In addition, FDA will prepare a final regulatory flexibility analysis (RFA) subsequent to the publication of the food labeling final rules. The final RFA will be placed on file with the Dockets Management Branch (address above) and a notice will be published in the Federal Register announcing its availability.

In the final RIA, FDA has concluded, based on its review of available data and comments, that the overall food labeling reform initiative constitutes a major rule as defined by Executive Order 12291. Further, the agency has concluded that although the costs of complying with the new food labeling requirements are substantial, such costs are outweighed by the public health benefits that will be realized through the use of improved nutrition information provided by food labeling.

Because any changes that result from this proposal will not need to be made until the same date as the other changes required by the other rulemakings undertaken in response to the 1990 amendments (May 8, 1994), this proposal will not add any additional costs to those considered in the RIA.

IV. Environmental Impact

The agency has previously considered, in the 1991 ingredient labeling proposal, the environmental effects of the type of action being taken in this proposed rule. No new information or comments have been received that would affect the agency's previous determination under 21 CFR 25.24(a)(8) and (a)(11) that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Effective Date

The proposed effective date of any final rule based on this proposal is May 8, 1994. FDA intends to publish the final rule on this proposal as soon as possible after the comment period to ensure that any labeling changes necessitated by the final rule can be accomplished by the proposed effective date.

VI. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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5. FDA opinion letter, Daniel D. Jones, GRAS Review Branch, to Charles L. Noland, October 18, 1978.
6. FDA opinion letter, Duane G. Groth, Advisory Opinions Branch, Division of Industry Advice, to Mrs. Betty B. Horn, May 4, 1965.
7. FDA opinion letter, Mary I. Snyder, Division of Regulatory Guidance, Center for Food Safety and Applied Nutrition, to Ellen J. Flannery, April 29, 1988.
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23. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Diet and Health, Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.
24. U.S. Department of Agriculture (USDA) and DHHS, "Nutrition and Your Health, Dietary Guidelines for Americans," *Home and Garden Bulletin*, No. 232, U.S. Government Printing Office, Washington, DC, 1985.
25. National Heart, Lung, and Blood Institute, "National Cholesterol Education Program Report of the Expert Panel on Population Strategies for Blood Cholesterol Reduction (Population Panel)," draft, February 2, 1990.
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52. FDA opinion letter, Kay Holcombe, Acting Associate Commissioner for Legislative Affairs, to David Tabar, July 29, 1991.
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VII. Comments

Interested persons may, on or before March 8, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

21 CFR Part 102

Beverages, Food grades and standards, Food labeling, Frozen foods, Fruit juices, Oils and fats, Onions, Potatoes, Seafood.

21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 101, 102, and 161 are amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.4 is amended by adding new paragraph (b)(21) to read as follows:

§ 101.4 Food; designation of ingredients.

* * * * *

(b) * * *

(21) Each individual sweetener in a soft drink (soda) shall be declared by its specific common or usual name in its order of predominance in the soft drink (soda) except that, if the manufacturer is unable to adhere to a constant pattern of nutritive sweeteners in the soft drink (soda), the nutritive sweeteners may be designated in their order of predominance in the soft drink (soda) by words indicating that the sweeteners may not be present, such as "and/or," "or," or "contains one or more of the following:".

* * * * *

PART 102—COMMON OR USUAL NAME FOR NONSTANDARDIZED FOODS

7. The authority citation for 21 CFR part 102 continues to read as follows:

Authority: Secs. 201, 403, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 343, 371).

8. Section 102.22 is amended by adding new paragraph (b) to read as follows:

§ 102.22 Protein hydrolysates.

* * * * *

(b) The parenthetical declaration "(contains glutamate)" when the protein hydrolysate is an autolyzed yeast extract, or a highly hydrolyzed protein (i.e., hydrolyzed proteins whose ratio of α-amino nitrogen (AN) to total nitrogen (TN), using the tests for "Acid Hydrolyzed Proteins" set forth in the "Food Chemicals Codex", 3d ed., First Supp. (1983), is greater than 0.62). "Hydrolyzed soy protein (contains glutamate)" or "autolyzed yeast extract (contains glutamate)" are examples of acceptable names.

PART 161—FISH AND SHELLFISH

9. The authority citation for 21 CFR part 161 continues to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 376).

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10. Section 161.190 is amended by adding two sentences to the end of paragraph (a)(8)(vi) to read as follows:

§161.190 Canned tuna.

(a) * * *

(8) * * *

(vi) * * * If the vegetable extractives used in manufacturing the vegetable broth include extractives of soybeans, the designation of vegetable broth in the ingredient statement shall be followed by a parenthetical listing as follows: "vegetable broth (includes soybeans)." Alternatively, if vegetable broth containing soybean extractives serves as a flavor and has no flavor enhancing function, it may be listed in the ingredient statement as: "flavoring (includes soybeans)."

* * * * *

Dated: October 26, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92-31527 Filed 12-28-92; 8:45 am]

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21 CFR P

[Docket No

Misleadin
Slack-Fill

AGENCY: F
HHS.

ACTION: P

SUMMARY:
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 100

[Docket No. 92N–0383]

Misleading Containers; Nonfunctional Slack-Fill

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA), in accordance with the Nutrition Labeling and Education Act of 1990 (the 1990 amendments), is proposing to amend its regulations to define the circumstances in which a food is misbranded under section 403(d) of the Federal Food, Drug, and Cosmetic Act (the act). Among other things, the proposed regulation defines the circumstances in which the slack-fill within a package is nonfunctional and, therefore, misleading. FDA is taking this action to remedy the inadequate implementation of section 403(d) of the act.

DATES: Written comments by March 8, 1993. The agency intends to issue a final rule by May 8, 1993.

ADDRESSES: Written comments may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5106.

SUPPLEMENTARY INFORMATION:

I. Background

A. Section 403(d) of the Act

Section 403 of the act (21 U.S.C. 343) defines conditions under which a food is deemed to be misbranded. Section 403(d) of the act deals with misleading containers. This section states that a food is misbranded "if its container is so made, formed, or filled as to be misleading." The misleading container provisions in section 403(d) of the act may be triggered by misleading packaging practices, misleading containers themselves, or by misleading fill. Examples of packaging and filling practices that would cause a food to be misbranded under section 403(d) of the act include: (1) Packages made of yellow cellophane that make plain or water noodles appear to be rich in egg; (2) containers formed with a false bottom, ridges, or other device whose sole purpose is to create empty space (i.e., space devoid of product) within a container; and (3) opaque packages filled to substantially less than capacity, i.e., packages containing an unnecessary amount of empty space (slack-fill) that is significant in proportion to the volume of the container, and that consumers may not be aware of when they purchase the product. The first two examples refer to containers that are "made" or "formed" as to mislead consumers regarding the quality or quantity of the contents of such container (hereinafter referred to as "deceptive packaging"). The third example refers to deceptive fill even though the net quantity of contents may be accurately stated.

B. The 1990 Amendments

The 1990 amendments (Pub. L. 101–535) provide, among other things, for the Federal preemption of certain food standards and other labeling requirements issued by a State or political subdivision of a State. Section 6 of the 1990 amendments, entitled "National Uniform Nutrition Labeling," adds new section 403A to the act (21 U.S.C. 343–1). Section 403A(a)(3) of the act prohibits States from directly or indirectly establishing any requirement for the labeling or packaging of any food in interstate commerce of the type required by sections 403(b) (offered for sale under the name of another food), 403(d) (misleading container), 403(f) (appropriate prominence of information), 403(h) (standards of quality and fill), 403(i)(1) (common or usual name), or 403(k) (declaration of artificial flavoring, coloring, or preservatives) of the act that is not identical to the requirement of such section. However, sections 6(b)(3) and 10(b)(1)(C) of the 1990 amendments provide that the six provisions listed in section 403A(a)(3) of the act do not become preemptive until FDA determines that each is being adequately implemented by Federal regulations.

To implement section 403A of the act, section 6(b) of the 1990 amendments mandates that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) contract for a study to determine whether the above six misbranding sections of section 403 of the act are adequately being implemented by Federal regulations. The 1990 amendments further mandate that FDA publish in the **Federal Register** lists of sections that are (or are not) being adequately implemented by Federal regulations. Finally, the 1990 amendments require that FDA propose revisions to its regulations for any sections that the agency determines are not being adequately implemented.

C. The IOM Report

In accordance with section 6(b) of the 1990 amendments, FDA entered into a contract with the National Academy of Sciences, Institute of Medicine, Food and Nutrition Board (hereinafter referred to as "the IOM") to conduct a study of State and local food labeling and packaging requirements of the types required by section 403(b), (d), (f), (h), (i)(1), and (k) of the act and to report on whether these sections of the act, and the regulations issued by FDA to enforce them, adequately implement the purposes of such sections. On April 23, 1992, the IOM submitted to FDA the final draft manuscript reporting its findings. A copy of the report, entitled "Food Labeling: Toward National Uniformity" (hereinafter referred to as "the IOM report"), is on file with the Dockets Management Branch (address above) under the above-referenced docket number. Copies of the IOM report may be purchased from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418.

Based on information collected at a public meeting (May 8, 1991), written comments to the public meeting notice, and discussions with State and local regulators, industry representatives, and consumer groups, the IOM reported that all but section 403(d) of the act (misleading container) are being adequately implemented.

The IOM report acknowledged that there was a wide divergence of views among State officials, industry, and consumer groups as to whether section 403(d) of the act is being adequately implemented. All groups that expressed an opinion to the IOM about the adequacy of implementation of 403(d) of the act felt very strongly about their position.

Industry generally supported the adequacy of implementation of 403(d) of the act. However, some State officials and consumer groups testified that the absence of Federal regulations and the small number of enforcement actions under section 403(d) of the act are evidence that this section is not being adequately implemented.

The IOM found that relatively few States have taken independent action to establish more specific requirements related to container fill or deceptive packaging. One State official testified that his State has not encountered problems with container fill and deceptive packaging, and that, if it did, section 403(d) of the act was more than adequate if enforced. Of the States with

regulations prohibiting misleading containers, two have adopted "formed or filled" language similar to section 403(d) of the act.

One State regulation cited by the IOM addresses variance from net weight which may be more relevant to section 403(e) than to 403(d) of the act. Another State regulation cited by the IOM deals with the practice of "downsizing," i.e., reducing the amount of product in a container without a substantial change in the size or shape of the container. For example, a manufacturer may decide (with an appropriate change in the declared net weight) to sell 14 ounces (oz) of coffee in a container similar in appearance to one that has traditionally held 16 oz of product. The potential problem with downsizing lies in the fact that consumers, familiar with a product and its packaging, may receive an amount of product that is less than they expect based on a history of purchases.

FDA notes that reducing the amount of product in a container without reducing the volume of the container will increase the amount of slack-fill in that container. To the extent that some portion of this slack-fill would be nonfunctional, the practice would constitute misleading fill under § 100.100, as proposed. However, proliferation of sizes, of which downsizing may be a part, comes under the jurisdiction of the Department of Commerce as provided for in section 5(d) of the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1454). Therefore, the practice of downsizing is outside the scope of this proposed rulemaking, although the package that results is not.

Four States have chosen to issue regulations that establish specific fill-of-container provisions or that define misleading fill beyond the provisions of section 403(d) of the act. Several State officials provided the IOM with examples of packaged foods that are currently being marketed and that represent, in their view, objectionable practices that have occurred under FDA's current policies.

The IOM reported that there was disagreement among the members of the committee that it used to study about the adequacy of the implementation of 403(d) of the act. According to the IOM report, some members of the committee saw no problem with implementation of section 403(d) of the act and did not feel consumers were being disadvantaged by deceptive packaging or slack-filled containers. These members believed that the more blatant examples of misleading containers presented to the IOM could be addressed quite readily under current law. In addition, these members maintained that, because the IOM had determined that the level of enforcement activity was not a criterion in determining adequacy of implementation, new regulations should not be suggested to FDA on the basis of the level of enforcement of this section.

The IOM report stated that other committee members were impressed by the examples of packaging presented by State officials and believed that deceptive or slack-filled containers should be considered a matter of national importance. One example cited in the IOM report involved two varieties of a hot beverage mix in single-serving packages within an outer container. One variety was a "light" version of the regular mix. It contained 40 percent less product by weight but was packaged in the same size envelopes and external package as the regular mix. The IOM believed that packaging the "light" product in the same way as the regular product could potentially mislead consumers as to the quantity of food that they were purchasing. Ultimately, the IOM decided that the perception of inadequacy on the part of some State officials and consumer groups was sufficiently strong to justify a finding that section 403(d) of the act is not being adequately implemented.

D. Agency Determination of Adequacy of Implementation of Section 403(d) of the Act

In a document published in the **Federal Register** of July 28, 1992 (57 FR 33283), based on the IOM report, the agency proposed to find that of the six misbranding sections listed in section 403A(a)(3) of the act, all but section 403(d) are being adequately implemented. The document provided for the submission of comments by interested persons by September 28, 1992.

In a final rule published elsewhere in this issue of the **Federal Register**, the agency is announcing its conclusion, based on comments submitted in response to the July 28, 1992, proposal and other relevant material, that all but section 403(d) of the act are being adequately implemented. The agency notes that three of the six letters received in response to the July 28, 1992, proposal maintained that section 403(d) of the act is being adequately implemented. However, as discussed in the final rule, none of the comments provided a factual basis to support a determination that 403(d) of the act is being adequately implemented.

In its consideration of whether section 403(d) of the act is (or is not) being adequately implemented, the agency gave significant weight to evidence cited by the IOM that a number of States have addressed fill-of-container matters that are not addressed by FDA's regulations. As discussed in the final rule, FDA believes that a strong Federal regulatory system is a prerequisite of the Congressional mandate for uniformity. FDA currently has no regulations to implement the provisions of section 403(d) of the act. The agency determination that section 403(d) of the act is not being adequately implemented is discussed further in the final rule.

FDA acknowledges the lack of consensus expressed in the IOM report with respect to section 403(d) of the act (see section I.C. of this document) and in the comments to the proposed list. The agency is also concerned that, because of the time constraints imposed by the 1990 amendments, there may not have been sufficient time for interested parties to fully develop evidence to support a determination that section 403(d) is being adequately implemented.

FDA advises that, should it receive evidence during the comment period on this proposal that establishes that section 403(d) is being adequately implemented, the agency would be willing to reconsider its contrary determination. Thus, one possible outcome of this rulemaking would be a determination that section 403(d) is adequately being implemented by FDA and is thus preemptive, even in the absence of a new regulation. However, absent information to support such a finding, FDA advises that it tentatively concludes that the regulation proposed in this document would ensure adequate implementation of section 403(d) of the act.

II. The Issue of Slack-Fill

A. Introduction—The IOM Report

Most of the discussion in the IOM report, and much of the information that the IOM received, regarding the adequacy of section 403(d) of the act centered around whether consumers are being adequately protected against slack-filled containers. Furthermore, of the States cited by the IOM that have established more specific requirements than section 403(d) of the act related to misleading containers, most have chosen to focus on misleading fill.

The IOM cited the California Sherman Food, Drug, and Cosmetic Law (California Health and Safety Code Section 26437) that adopted the language of section 5(c)(4) of the FPLA as an approach for prohibiting misleading fill. The IOM also stated that no single State regulation was adequate for adoption as a Federal standard. The IOM suggested that FDA consider

promulgating regulations to prohibit misleading fill based on the definition of nonfunctional slack-fill provided for in the FPLA. The IOM report concluded that the definition of nonfunctional slack-fill in the FPLA provides FDA with a means of implementing the intent of section 403(d) of the act and suggested that FDA consider promulgating regulations to prohibit misleading fill based on that definition. In concluding that section 403(d) of the act was not being adequately implemented, the IOM did not recommend that the agency promulgate regulations with regard to the deceptive packaging ("made" or "formed" as to be misleading) provisions of section 403(d) of the act.

B. Definition of "Slack-fill"

For the purposes of this rulemaking, "slack-fill" is defined as the difference between the actual capacity of a container and the volume of product contained therein. For example, when a round or cup-shaped candy bar is packaged in a square container, the empty space in the corners of the package is considered slack-fill. In the case of cereal or potato chips, the empty space external to the bulk of the product (i.e., at the top of the bag or box) would be considered slack-fill. Slack-fill includes space within a container that is empty of product but that may contain secondary packaging materials (e.g., bag-in-box packaging, cardboard dividers, or molded plastic trays).

Air space within the bulk of the food (e.g., the space between adjacent corn flakes, the "holes" in swiss cheese, or the air in whipped cream) is generally not considered to be slack-fill, although a portion of this space could become slack-fill as some products settle. The agency tentatively concludes that interstitial space in a food that results from the physical characteristics of the food (e.g., the shape of the food particles), that would be included in any common household measure of the food (e.g., a cup of sugar or a cup of corn flakes), and that cannot be excluded from the food without changing its physical characteristics is part of the body of the food rather than slack-fill. The agency believes that it is both inappropriate and impracticable to quantify as slack-fill the interstitial space that can not be separated from the bulk of a food without altering the character of the food. The agency invites comment on this interpretation.

C. The Fair Packaging and Labeling Act

The FPLA was promulgated, in part, to elaborate on and to reinforce the misbranding provisions in section 403 of the act. In section 2 of the FPLA (15 U.S.C. 1451), Congress clearly states that "Informed consumers are essential to the fair and efficient functioning of a free market economy. Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons." Section 5(c)(4) of the FPLA provides for the promulgation of regulations necessary to prevent the deception of consumers or to facilitate value comparisons of consumer commodities, including regulations to prevent nonfunctional slack-fill. Section 5 of the FPLA states:

> For the purposes of paragraph (4) of this subsection, a package shall be deemed to be nonfunctionally slack-filled if it is filled to substantially less than its capacity for reasons other than (A) protection of the contents of such package or (B) the requirements of machines used for enclosing the contents in such package.

During 1970 and 1971, following enactment of the FPLA, FDA contracted with 11 State regulatory agencies to determine the extent to which slack-fill occurs in food packages at the retail level. Analysis of 11,000 samples revealed many packages with significant levels of slack-fill. In some instances, the empty space occupied as much as 80 percent of the volume of the container. However, this survey did not differentiate between functional and nonfunctional slack-fill.

The agency subsequently (from 1974 through 1976) initiated surveys at the manufacturing level to determine the extent to which slack-fill was justified by factors such as: Requirements of the filling machine, physical properties of the product, and normal product settling. These surveys focused on commodities that had: (1) Exhibited substantial slack-fill in the earlier State surveys, (2) significant production volumes, and (3) the highest incidence of consumer complaints. The commodities surveyed included: Candy, cookies, crackers, pretzels, potato chips, macaroni, spaghetti, cereal, dry dessert mixes, and prepared mixes.

Agency personnel, in cooperation with industry, observed various commercial manufacturing and filling operations and measured the degree to which product settled during shipping. They also collected data on variations in bulk density (weight per unit volume) for individual products and for product classes. In some instances (e.g., cereal and dry dessert mixes), FDA field personnel adjusted filling equipment or manually added additional product to containers in order to determine the effect of "overfill" on product quality. In other instances (e.g., a candy bar on a cardboard support with an outer wrap), the level of slack-fill was reduced by increasing the dimensions of the product. Overfilling packages to various degrees allowed FDA to identify the levels of slack-fill necessary for proper package closure and protection of the product and to determine the amounts of slack-fill that were likely to result from variations in the physical characteristics of the product and normal product settling. For the purposes of these studies, it was often easier to reduce slack-fill by increasing the fill of the container rather than altering the dimensions of the container.

Although the study was terminated before slack-fill had been fully studied in all the target commodities cited above, and no formal report was published, FDA collected sufficient data to determine that it is possible to distinguish between functional and nonfunctional slack-fill on a plant-by-plant basis for specific products in given container sizes.

At the same time, the agency noted that differences in the physical characteristics of a given product, including the need to protect the product from breakage, and precision of filling equipment result in a high degree of variability in the level of functional slack-fill within commodity classes. For example, functional slack-fill for macaroni products ranged from a low of 3.7 percent at manufacture and packaging to as much as 23.0 percent after shipping. Functional slack-fill levels for cereal products after shipping were even higher, ranging from 8.6 to 43.1 percent of the container volume. FDA concluded that many consumer commodities may have large levels of slack-fill that, although justified, might appear to be deceptive to consumers. FDA also observed that some products had greater slack-fill than could be justified by protection of the food or by requirements of the filling machine. A copy of the draft Compliance Program Evaluation for fiscal years 1975 and 1976 nonfunctional slack-fill surveys (7320.40 and 7320.65) is on file with the Dockets Management Branch (address above) under the above-referenced docket number.

The agency notes that some manufacturers employ label statements such as "Contents may settle during shipping" or "Contents sold by weight, not volume" to inform consumers that a package will probably appear to be less than full. Statements such as "A certain amount of air is packaged in each bag to act as a cushion against breakage" alert consumers as to the presence of slack-fill and provide

information on the function of the slack-fill.

Although section 5(c)(4) of the FPLA provides for the promulgation of regulations to prevent nonfunctional slack-fill in packages containing consumer commodities, FDA chose not to promulgate such regulations. Based on the preceding studies, FDA believed that establishing specific limits on the level of slack-fill of consumer commodities would, in many cases, involve values that were so high (e.g., as much as 63.8 percent for candy bars) that the regulations would serve no useful purpose. FDA also believed that such regulations could, in fact, encourage or legitimize a failure to minimize slack-fill on the part of some manufacturers. For example, a manufacturer with sophisticated equipment, capable of producing a product with a relatively low level of slack-fill, might decide to increase slack-fill in the product, taking advantage of a maximum slack-fill level that had been established based on less sophisticated packaging equipment. The agency also concluded that determining maximum allowable levels for functional slack-fill on a commodity-by-commodity basis would require considerable agency resources. Based on the preceding studies, FDA determined that it would not be appropriate to expend limited agency resources to develop regulations that would probably contribute little to improve implementation of section 403(d) of the act.

However, as stated above, the 1990 amendments require FDA to promulgate regulations to implement any provision listed in section 403A(a)(3) of the act that it determines is not being adequately implemented. Thus, in light of its determination that section 403(d) of the act is not being adequately implemented (see I.D. of this document), FDA has reconsidered its position on the need for regulations on nonfunctional slack-fill.

III. FDA Proposed Response

A. Introduction

As mentioned in section I.D. of this document, FDA has determined that section 403(d) of the act is not being adequately implemented. That section states that a food is misbranded if its container is so made, formed, or filled as to be misleading. Although FDA is addressing each of these aspects of section 403(d) of the act in proposed § 100.100, this rulemaking is primarily concerned with defining the circumstances in which the slack-fill within a package is nonfunctional and, therefore, constitutes misleading fill. The agency has tentatively decided not to elaborate on ways in which a container may be "made" or "formed" as to be misleading. The agency has tentatively concluded that these terms are straightforward and thus require little elaboration. This approach is consistent with that of several States that have chosen to establish regulations prohibiting misleading containers by elaborating only on what constitutes misleading fill. Furthermore, the IOM did not point to any particular problems emanating from the "made" or "formed" aspects of 403(d) of the act, nor did it recommend that the agency promulgate regulations with regard to these provisions. The agency invites comment on its approach and on whether it is necessary to elaborate on when a container is so made or formed as to be misleading to fully implement section 403(d) of the act.

B. Misleading Fill

The agency has long been aware of consumer dissatisfaction with slack-filled containers. FDA advises that, in many products, a certain level of slack-fill has a functional purpose (e.g., protecting the product) and, therefore, can be justified even though some consumers may perceive it to be misleading. The agency acknowledges that some products being marketed under existing Federal regulations may contain amounts of slack-fill exceeding that necessary to protect the product or required by the filling machine. The agency also acknowledges that in the cases that it has brought to enforce section 403(d) of the act, such as the *United States* v. *174 Cases * * * Delson Thin Mints*, 195 F. Supp. 326 (D.N.J. 1961), aff'd 302 F.2d 724 (3d. Cir. 1962), the phrase "misleading fill" has proven to be too vague to permit successful resolution.

Although FDA has established fill-of-container standards for a number of standardized foods such as canned oysters (21 CFR 161.145) and canned wet pack shrimp in transparent or nontransparent containers (21 CFR 161.173), the agency believes that standards of fill are not a practical way to implement the intent of section 403(d) of the act for all consumer commodities. Establishing specific limits on the level of slack-fill on a commodity-by-commodity basis would require considerable agency resources, much more than the agency has available. On the other hand, FDA believes that the action suggested by the IOM, i.e., to establish by regulation a general definition for nonfunctional slack-fill using the FPLA for guidance, has merit.

FDA believes that by establishing under section 701(a) of the act (21 U.S.C. 371(a)) a regulation that implements section 403(d), it could provide a general definition for nonfunctional slack-fill that would serve to define the circumstances in which fill is misleading under the act. By doing so, the agency would provide the guidance about the meaning of misleading fill that was requested by State officials and consumer groups in testimony before the IOM. This approach would also allow enforcement based on the capabilities of individual processing and packaging facilities and on the specific physical properties (e.g., bulk density, uniformity, tendency to settle, and need for protection) of individual products, rather than establishing maximum slack-fill values for classes of commodities that are necessarily too high to have any meaning. The agency believes that this proposed action will: (1) Provide guidance for consumers and manufacturers regarding what is functional slack-fill and what is not, (2) encourage industry to evaluate the amount of slack-fill in existing products and aid it in choosing the most appropriate processing and packaging methods for new products, and (3) increase consumer confidence that the amount of slack-fill in consumer commodities has a function. By ensuring adequate implementation of section 403(d) of the act, the proposed regulation will reduce those instances of misleading fill that may exist under current Federal regulations.

FDA tentatively finds that appropriate levels of slack-fill are those no greater than necessary to accomplish the intended functional effect in the packaged food product. For example, a candy bar may be packaged so that it is resting on a cardboard support with both candy bar and support within an outer wrapper. The support will determine the minimum length and width of the outer packaging, while the height of the package is determined by the height of the candy bar. The dimensions of the cardboard support and the outer wrapper must be such as to accommodate normal variations in the size and shape of the product. The cardboard support needs to be of sufficient size and strength to protect the product during shipping and handling. It may also be necessary for the outer wrapper to be longer than the support, so that neither the support nor the candy bar interferes with the efficient closure of the outer wrapper.

When a candy bar is packaged in this manner, some slack-fill is inevitable. The amount of slack-fill in the package will vary depending on factors such as the uniformity of the product and the capabilities of the packaging equipment. The proposed regulation is not intended to require manufacturers who are operating under current good manufacturing practices to change the physical characteristics of a food, nor is it intended to require manufacturers to purchase more sophisticated packaging equipment (proposed § 100.100(a)(2)).

FDA tentatively finds that slack-fill or the practice that results in slack-fill is justified to the extent that it performs such appropriate functions as protecting the contents of the container or meeting the necessary requirements of the filling machine. Slack-fill in excess of that required to perform a function, e.g., using a 6-inch cardboard support to hold a candy bar that is 3 inches long, however, is nonfunctional slack-fill and, therefore, misleading fill, even though the support may continue to perform a function such as protecting the product.

To address this situation, FDA is proposing to define "nonfunctional slack-fill." The agency tentatively finds that the definition of this term that appears in section 5(c) of the FPLA is adequate to differentiate between functional and nonfunctional slack-fill of the types described above. However, slack-fill may serve additional purposes (e.g., allowing a package to accommodate tamper resistant devices or modified atmosphere packaging to extend shelf-life) that were not anticipated when the FPLA was enacted. FDA believes that slack-fill related to modified atmosphere or tamper resistant packaging is covered by that portion of the proposed definition that allows slack-fill to protect the contents of a container (proposed § 100.100(a)(1)).

FDA notes that some slack-fill, e.g., slack-fill resulting from normal product settling, does not perform a function in a food. As such, it could be considered nonfunctional slack-fill. However, product settling is a normal, unavoidable process for many types of food (e.g., cereal and potato chips). Thus, slack-fill that results from product settling is a function of the physical properties of the product (e.g., the shape of the pieces of food), and of the way in which the product is filled into the container (e.g., loosely packed). For the purposes of this proposed rule, FDA tentatively proposes to exclude unavoidable slack-fill that results from normal product settling from the definition of nonfunctional slack-fill (proposed § 100.100(a)(3)).

In addition, advances in food technology and product development have resulted in a number of products with slack-fill that may be justifiable (i.e., performs a specific function) but may not be addressed by the definition of nonfunctional slack-fill in the FPLA. For example, consumer demand for convenience has led to the development of food products that may be cooked in, or eaten out of, the containers in which they are purchased. Thus, packaging for an instant soup must not only allow efficient closure of the package and protect the product during shipping, it must also have sufficient empty space to hold the hot water added by the consumer to hydrate the product. A package of microwavable brownies may contain a disposable tray in which the product is both mixed and cooked. Thus, the package would need to be large enough to accommodate a tray whose size was based, in part, on the size of the cooked brownies, not the amount of dry mix in the container.

FDA notes that convenience foods often require an increase in the size of the container relative to the amount of product within the container. For example, a box containing hot chocolate in single serving packages is usually larger than a box containing the same amount of bulk product without the secondary packaging. In addition, such products would be clearly labeled as to their contents (e.g., "Contains 6 single-serve packages" or "Package contains baking tray"). Therefore, the agency tentatively concludes that reasonable levels of slack-fill resulting from the practices described above perform a function in that they are necessary for convenient preparation or consumption of the product. However, such functions are not covered by the definition of nonfunctional slack-fill in the FPLA. Therefore, the agency is proposing to exclude, from the definition of "nonfunctional slack-fill," slack-fill that results from practices that are necessary for a package to perform a particular function (e.g., to aid in the preparation and consumption of a specialty food product), where such function is clearly declared on the label and is an integral part of the nature of the food (proposed § 100.100(a)(4)).

Gift products represent another category where packaging may serve functions other than to simply contain and protect the food. For example, some gift products (e.g., cheese and jellies in a basket or assorted biscuits in a teapot) consist of a food contained in a reusable household article that is itself part of the gift. In some instances, the food component of the gift product is packaged in a predetermined or standardized quantity before being placed in the reusable gift container. At the same time, the size of the reusable gift container (e.g., a teapot) may be a function of its intended use after the food component of the gift has been consumed.

Depending on the nature of the food and the type of gift container used, manufacturers will have varying degrees of control over the amount of slack-fill in such containers. For example, baskets are available in a wide range of shapes and sizes, allowing manufacturers to choose a basket that is appropriate for the amount of food contained therein. Other household items that may be desirable gift containers (e.g., coffee cups or teapots) are available in a more limited number of sizes. Furthermore, because part of the purchase of a gift product is the continued utility of the reusable container, and part of the purchase may include intangibles (e.g., aesthetics or sentiment resulting from the way in which the product is packaged), it is more difficult to differentiate between functional and nonfunctional slack-fill in these items as compared to conventional foods.

FDA tentatively finds that, in the case of such gift products, reasonable differences between the volume of the reusable gift container and the amount of food contained therein that result from the role of the gift container in the presentation of the food would not constitute misleading fill, even though such slack-fill might not have a specific functional effect such as protecting the product. FDA tentatively finds that exempting reasonable amounts of slack-fill in such gift products (i.e., food packaged in a reusable household item) from the definition of nonfunctional slack-fill would provide manufacturers with flexibility in packaging such products, while providing consumers with product choices. The agency invites comment on these tentative findings. Specifically, FDA requests comment on the appropriateness of establishing an exemption from the definition of nonfunctional slack-fill for gift products consisting of a food item combined with a gift container (i.e., a reusable household item) where the gift container serves to contain and protect the food, is part of the presentation of the food, and is to be usable after the food is consumed (proposed § 100.100(a)(5)).

FDA advises that the preceding discussion is concerned only with gift products that are packaged in reusable containers. The agency acknowledges that other types of gift products may also be packaged in containers that are designed to do more than simply

contain and protect the food. For example, when candy is packaged in a heart-shaped box, the shape of the box conveys a message to the receiver. Other products, e.g., chocolate covered cherries, may be packaged in a decorative plastic tray that not only protects the product but plays a role in the presentation of the food. The agency believes that manufacturers of such products have greater control over package design and filling operations with respect to minimizing slack-fill in these products as opposed to gift products in a reusable container whose size and shape is, in part, a function of its intended use after the food has been consumed. The agency also notes that, in the absence of a reusable gift container, the distinction between gift products, luxury items, and conventional food products appears to be subjective. Furthermore, although packaging such as a heart shaped box appears to play a role in the presentation of a food, the agency lacks sufficient information to establish criteria for distinguishing between functional and nonfunctional slack-fill in such products.

The agency invites comment on whether it would be appropriate to provide more latitude in determining that slack-fill in gift products is functional if the slack-fill is attributable to packaging that serves to contain the food and that plays a role in the presentation of the food but that is not intended for reuse after the food is consumed. The agency invites comment on criteria that it could use to distinguish between functional and nonfunctional slack-fill in such products and for such purposes. Comments should provide specific examples of products whose packaging includes slack-fill associated with the presentation of a food that should, or should not, be excluded from the definition of nonfunctional slack-fill as misleading fill. Comments should provide substantive arguments for or against such an exclusion and, if appropriate, contain criteria to be used in determining such exclusion.

FDA notes that product reformulations may change the density, weight, or volume of a product, sometimes drastically. For example, a package of gelatin mix sweetened with sugar may contain 3 oz of product. The same product sweetened with a high intensity sweetener may weigh only 0.5 oz. If the manufacturer uses the same package for both products, the package containing gelatin sweetened with the high intensity sweetener will contain a significantly greater amount of slack-fill. The agency notes that the increased slack-fill in the package containing 0.5 oz of product exceeds the amount of slack-fill that is required to perform such necessary functions as protecting the product and ensuring proper package closure in the package that contains 3 oz of product. At the same time, the agency notes that both packages of gelatin contain sufficient mix to provide the same amount of finished product. The agency tentatively concludes that, absent a functional effect, the portion of slack-fill within a container resulting from product reformulation (e.g., removal of a macronutrient such as sucrose) that reduces the volume of product in that container constitutes nonfunctional (misleading) slack-fill. The agency invites comment on this tentative conclusion and on the criteria that could be used to distinguish between functional (justifiable) and nonfunctional (misleading) slack-fill in a case such as this.

The agency also invites comment on the appropriateness of establishing an exemption from the definition of nonfunctional slack-fill for packages containing slack-fill that results from an inability to further reduce the size of the package. The agency notes that some food products (e.g., saffron and saccharin) are frequently sold in very small quantities for various reasons, including: Limited shelf-life, high cost per unit volume, or the need to use only a small amount of the product at any one time. To the extent that such foods must be sold in a package of some minimum size to accommodate required food labeling excluding any vignettes or other nonmandatory designs or label information, discourage pilfering, or facilitate handling, the resulting slack-fill may be a function of a minimum package size requirement. Comments on the need for an exemption for such packages should present specific examples of products that have a minimum package size requirement and whose packaging includes slack-fill that should, or should not, be excluded from the proposed definition of nonfunctional slack-fill. Comments should provide substantive arguments for or against such an exclusion and, if appropriate, contain criteria to be used in determining such an exclusion.

The agency invites comment on any other practices or developments that may result in slack-fill and that are not addressed by the language of the proposed definition of nonfunctional slack-fill. Comments should provide specific examples of containers that represent functional slack-fill versus nonfunctional slack-fill or misleading fill. When appropriate, comments should also include suggested wording to be used in this rulemaking to ensure that the examples are adequately covered by any regulation that FDA adopts. The agency also invites comment on the phrase "filled to substantially less than capacity" in proposed § 100.100(a). FDA intends this phrase to mean that any packages containing levels of nonfunctional slack-fill that are significant in proportion to the volume of the container would be misbranded. FDA requests comment on the appropriateness of this standard. The agency also requests comment on how to define "significant" in this context.

Finally, the agency invites comment on whether it makes a difference if a product is packaged in a container that allows consumers to fully view the contents of the container. Specifically, would nonfunctional slack-fill be misleading when consumers can clearly see what they are purchasing?

The agency believes that several factors, such as the cost of packaging materials, space required for storage and transport, and increased national interest in efficient packaging to reduce solid waste, will serve to reduce slack-fill in many commodities.

The agency believes that the proposed regulation will ensure adequate implementation of section 403(d) of the act, thereby, providing additional consumer protection against misleading fill and facilitating value comparisons on the part of consumers. Thus, section 403(d) of the act will become preemptive upon adoption of proposed § 100.100. This regulation, if adopted, will also provide State regulatory agencies, as well as FDA, with a uniform means of taking action against misleading containers. The agency also notes that section 4 of the 1990 amendments (21 U.S.C. 337) provides for State enforcement of section 403(d) of the act in Federal court. Consequently, manufacturers can expect that packaging will be treated uniformly throughout the States with regard to misleading containers.

Therefore, FDA is proposing § 100.100 *Misleading containers* in part 100 (21 CFR part 100) within a newly proposed subpart of part 100 to be entitled "Subpart F—Misbranding for Reasons Other Than Labeling." The proposed regulation states that food is misbranded if its container is so made, formed, or filled as to be misleading. It defines misleading fill as nonfunctional slack-fill. Finally, the proposed regulation includes criteria for use in determining whether slack-fill is functional versus nonfunctional.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(11) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Although not a labeling requirement per se, this action is closely related to food labeling and arises out of the misbranding sections of the act. In all other respects, this action comes within the exemption in § 25.24(a)(11). Moreover, although this action is not specifically designated in 21 CFR 25.22(a) and does not fall within the scope of the general provision (21 CFR 25.22(a)(19)), it could not significantly affect the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Economic Impact

FDA has examined the economic implications of the proposed rule on misleading containers and nonfunctional slack-fill as required by Executive Orders 12291 and 12612 and the Regulatory Flexibility Act. Executive Order 12291 compels agencies to use cost-benefit analysis when making decisions, and Executive Order 12612 requires Federal agencies to ensure that Federal solutions, rather than State or local solutions, are necessary. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (Pub. L. 96–354), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses. Finally, any federalism issues that would require an analysis under Executive Order 12612 are resolved as a matter of law by section 6 of the 1990 Amendments.

A. Market Failure

FDA believes the current proposal cannot be justified on the grounds of market failure. Required net weight figures already provide information on package contents. Furthermore, if consumers object to the level of slack-fill in a given package, they can easily identify that product by brand name and refrain from purchasing that particular product in the future. However, FDA believes that the IOM report and comments on whether section 403(d) of the act is being adequately implemented establish that a situation in which rulemaking is required under section 6 of the 1990 amendments exists.

There are three primary alternatives available to FDA with respect to ensuring adequate implementation of section 403(d) of the act.

(1) Adopt a regulation that does not define nonfunctional slack-fill but only repeats the language of section 403(d) of the act.

(2) Define nonfunctional slack-fill as proposed, with possible additional exemptions such as the following: (a) Gift products in nonreusable containers, (b) new products, initially introduced, where appropriate packaging material and equipment are not already available, and (c) small businesses.

(3) Define not only misleading fill but also when a container has been made or formed to be misleading.

B. Costs

1. Repeat the language of section 403(d) of the act

This alternative serves as the benchmark for estimating the costs and benefits of the other alternatives; therefore, no costs or benefits will be estimated for this alternative.

2. Define nonfunctional slack-fill as proposed, with possible additional exemptions

Potential compliance costs to industry include designing and manufacturing new packages. FDA currently has no information on the number of firms that would be affected or on the cost, if any, of required package changes. FDA requests information on compliance costs to firms resulting from this alternative beyond the costs that would occur if FDA promulgates a regulation that repeats the language of section 403(d) of the act.

In addition, consumers may undergo a utility loss from a reduction in the variety of packages currently available. Although the utility loss per product is probably small, FDA believes this utility loss may be significant in the aggregate, compared to the utility loss from the reduction in the variety of packages that would occur if FDA promulgates a regulation that repeats the language of section 403(d) of the act. FDA requests information on consumer valuation of packaging variety.

This alternative includes a possible exemption for gift products in nonreusable containers. The cost of this alternative with this exemption is as above, less the compliance cost to manufacturers of these products and the utility loss to consumers from reducing the current level of variety in the packaging of these products. FDA cannot estimate this cost at this time because FDA has been unable to specify an operational definition of gift product. FDA requests comments on whether it would be appropriate to provide this exemption, on defining gift product, and on consumer dissatisfaction with the fill of these products.

This alternative also includes a possible temporary exemption for new products, initially marketed, where appropriate packaging material and equipment (that is, material and equipment that eliminate nonfunctional slack-fill) are not already available. The cost of this alternative with this exemption is as above, less the compliance cost to manufacturers of these products and the utility loss to consumers from the reduction in the current rate of introduction of new products onto the market. FDA cannot estimate this cost at this time and requests information on the effect of this proposal on the rate of introduction of new products onto the market in the absence of this exemption, and on consumer valuation of any change in the rate at which new products are introduced onto the market. FDA also requests information on whether it would be appropriate to provide this exemption.

In addition, this alternative includes a possible exemption for small businesses. Under the Regulatory Flexibility Act of 1990, FDA is required to consider relief for small businesses from regulation where feasible. The cost of this alternative with this exemption is as above, less the compliance cost to small businesses and the utility loss to consumers from a possible reduction in the competitiveness of small businesses. The fixed cost of developing and introducing new packaging and purchasing new packaging equipment is a significant cost for small businesses. In the absence of this exemption, small businesses will be less able to produce a wide variety of products and product sizes than large businesses. FDA cannot estimate this cost at this time. FDA requests information on the effect of this alternative on small business in the absence of a small business exemption. FDA also requests information on whether it would be appropriate to provide this exemption.

3. Define not only misleading fill but when a producthas been made or formed to be misleading

The costs of this alternative are identical in kind to the costs of defining nonfunctional slack-fill as proposed. FDA cannot estimate these costs without specifying the conditions under which a product has been made or formed to be misleading. However, since this alternative would place

additional restrictions on packaging beyond the restrictions that would occur if FDA promulgates a regulation that repeats the language of section 403(d) of the act or defines nonfunctional slack-fill as proposed, the compliance cost of this alternative will be greater than that of either of these other two alternatives. FDA requests comments on potential specifications of when a product is made or formed to be misleading, as well as on the costs of such specifications to industry, consumers, and society in general.

C. Benefits

1. Repeat the language of section 403(d) of the act

This alternative serves as the benchmark for estimating the costs and benefits of the other alternatives; therefore, no costs or benefits will be estimated for this alternative.

2. Define nonfunctional slack-fill as proposed, withpossible additional exemptions

Potential benefits of this alternative include a reduction in the incidence of differing interpretations of the language of section 403(d) of the act that might occur if FDA promulgated a regulation repeating the language of section 403(d). FDA cannot estimate this benefit at this time and requests information on the likely incidence and cost of differing interpretations of the language of section 403(d) of the act that might occur if FDA promulgated a regulation repeating the language of section 403(d).

Potential benefits of this alternative to consumers will result from the possible reduction in the incidence of consumer dissatisfaction with the fill of food containers. A certain amount of consumer dissatisfaction with slack-fill is likely to remain since the amount of slack-fill in general will continue to vary between packages of the same products (because of settling, product breakage, etc.), between different brands of the same product (because of different packaging technology and product characteristics), and between different products. FDA currently has no information on the level of consumer dissatisfaction with the fill of containers, or on the degree to which current consumer dissatisfaction concerns nonfunctional slack-fill rather than slack-fill in general. Thus, FDA cannot estimate this benefit at this time.

However, since consumers can identify offending packages by brand name and refrain from purchasing that product in the future (even when complaints of slack-fill cannot be addressed by current Federal or State law), it is unlikely that utility losses from this source are significant. The benefit to consumers from changes in the regulations addressing slack-fill should therefore be quite modest.

The benefit of this alternative with any of the three possible additional exemptions will be as above, less the value of the reduction in consumer dissatisfaction with the fill of the products covered in the exemptions. FDA cannot estimate the benefit of this alternative with the possible exemptions at this time and requests information on consumer dissatisfaction with the fill of the products specified in the possible exemptions.

3. Define not only misleading fill but when a producthas been made or formed to be misleading

The benefit of this alternative is a reduction in consumer dissatisfaction with the form or construction of packaging. FDA cannot estimate this benefit without specifying the conditions under which a product has been made or formed to be misleading beyond the current provisions of section 403(d) of the act. FDA requests comments on potential specifications of when a product is made or formed to be misleading, as well as on the benefits of such specifications to consumers.

D. Conclusion

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this proposed rule and has determined that this rule, if promulgated, will not be a major rule as defined by that order.

In accordance with the Regulatory Flexibility Act, the agency has requested information that will allow the agency to consider a small business exemption. FDA requests information on the effect of this proposed rule on packaging costs of small businesses.

Finally, FDA requests information on any other economic functions slack-fill might fulfill other than facilitating the test marketing of new products and the preservation of packaging variety for gift products.

VI. Comments

Interested persons may on or before January 11, 1993, submit to the Dockets Management Branch (address above) written comments regarding this regulation. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 100

Administrative practice and procedures, Food labeling, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 100 be amended as follows:

PART 100—GENERAL

1. The authority citation for 21 CFR part 100 continues to read as follows:

Authority Secs. 201, 301, 307, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 337, 342, 343, 348, 371).

2. New subpart F, consisting of § 100.100, is added to read as follows:

Subpart F—Misbranding for Reasons Other Than Labeling

§ 100.100 Misleading containers.

In accordance with section 403(d) of the act, a food shall be deemed to be misbranded if its container is so made, formed, or filled as to be misleading.

(a) A container shall be considered to be filled as to be misleading if it contains nonfunctional slack-fill. "Slack-fill" is the difference between the actual capacity of a container and the volume of product contained therein. "Nonfunctional slack-fill" is the empty space in a package that is filled to substantially less than its capacity for reasons other than:

(1) Protection of the contents of the package;

(2) The requirements of the machines used for enclosing the contents in such package;

(3) Normal product settling during shipping and handling;

(4) The need for the package to perform a specific function (e.g., where packaging plays a role in the preparation or consumption of a food), where such function is inherent to the nature of the food and is clearly labeled; or

(5) The fact that the product is a gift product consisting of a food or foods combined with a reusable gift container, where the container is intended for further use after the food is consumed.

(b) [Reserved]

Dated: November 5, 1992.

David A. Kessler,

Commissioner of Food and Drugs.

Louis W. Sullivan,

Secretary of Health and Human Services.

[FR Doc. 92–31528 Filed 12–28–92; 8:45 am]

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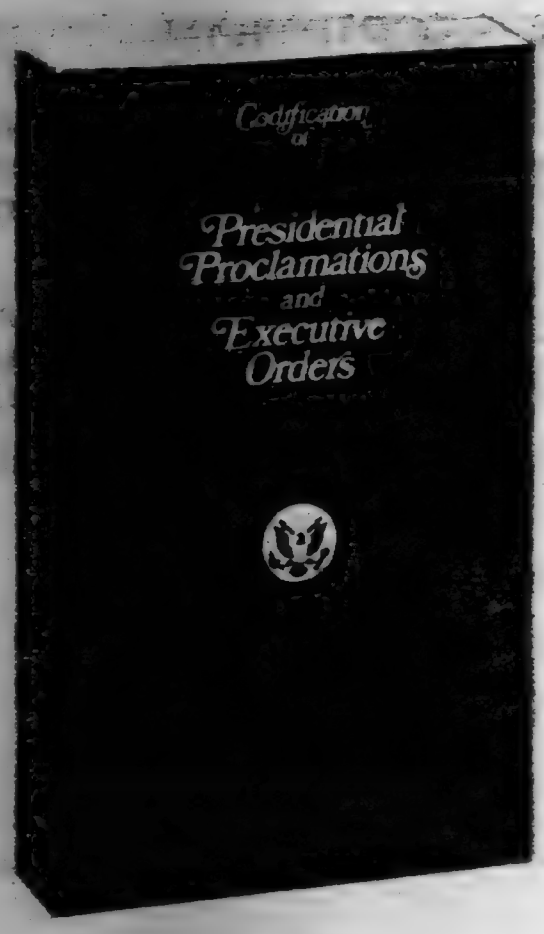

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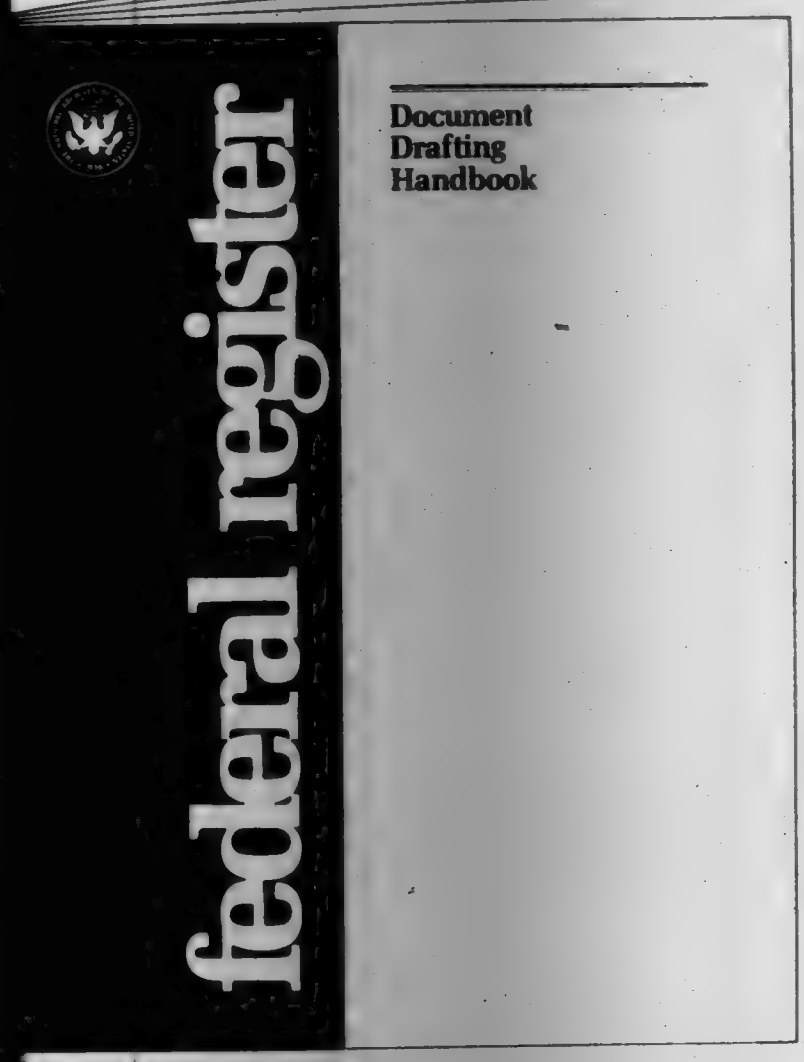

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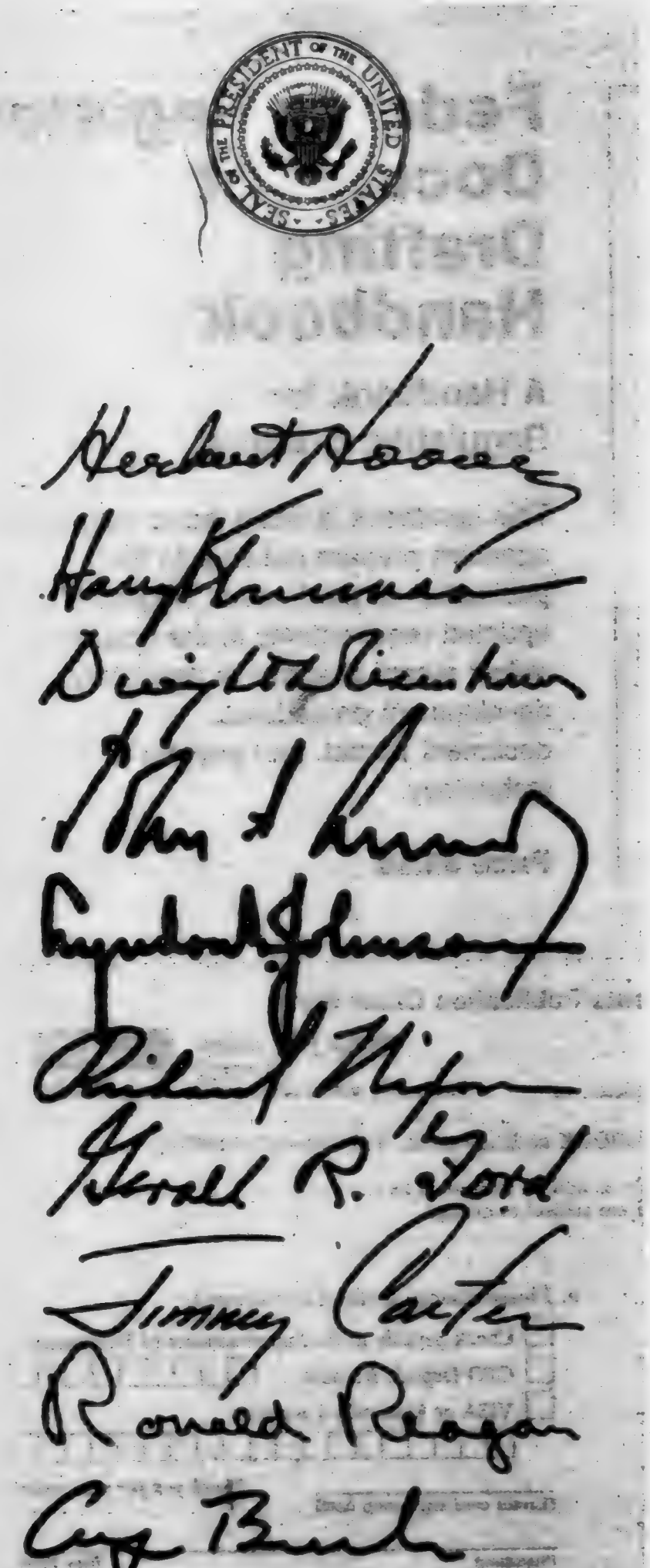

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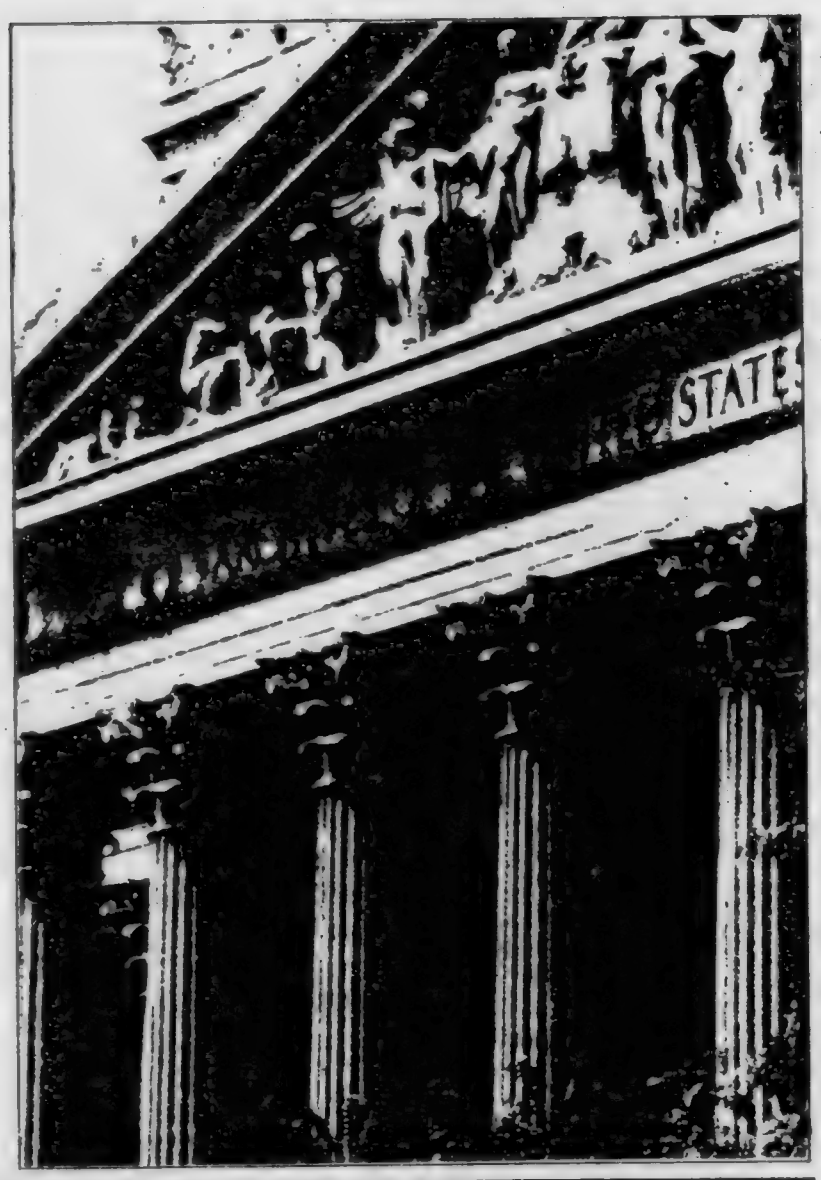

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Presidential Documents

Title 3—

The President

Executive Order 12828 of January 5, 1993

Delegation of Certain Personnel Management Authorities

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3 of the United States Code and sections 3502(e), 4505a(e), and 5377(i)(2) of title 5 of the United States Code, it is hereby ordered as follows:

Section 1. The Office of Personnel Management is designated and empowered to exercise, without the approval, ratification, or other action of the President, the following:

(1) The authority of the President under 5 U.S.C. 3502(e), as added by section 4433 of Public Law 102–484, to shorten the period of advance notice otherwise required by law with respect to reductions in force.

(2) The authority of the President under 5 U.S.C. 4505a(e), as added by section 2(19) of Public Law 102–378, to permit performance-based cash awards to be paid to categories of employees who would not otherwise be eligible.

Sec. 2. The Director of the Office of Management and Budget is designated and empowered to exercise, without the approval, ratification, or other action of the President, the authority of the President under 5 U.S.C. 5377(i)(2), as added by section 2(34) of Public Law 102–378, to designate one or more categories of positions within an agency to be treated as critical positions within the meaning of 5 U.S.C. 5377(a)(2).

Sec. 3. This order shall be effective immediately.

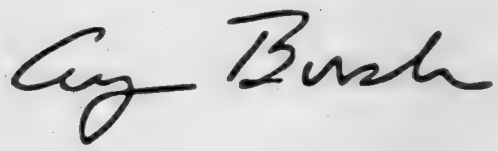

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SMALL BUSINESS ADMINISTRATION

13 CFR Part 101

Administration; Delegation of Authority, Claims Review Committees

AGENCY: Small Business Administration.

ACTION: Final rule.

SUMMARY: The Small Business Administration (SBA) is amending its regulations delegating authority to its claims review committees. Presently, claims review committees exist at the District, Regional, and Central Office level and have the authority to approve settlement on primary obligations or other evidence of an indebtedness owed the SBA for an amount less than the total amount due thereon. This rule sets forth authority by which claims review committees may be established at the Branch Office level.

DATE: This rule is effective January 7, 1993.

FOR FURTHER INFORMATION CONTACT: Earl Chambers, Director, Office of Portfolio Management, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416, (202) 205–6481.

SUPPLEMENTARY INFORMATION: SBA is amending its regulations setting forth the authority delegated to its various claims review committees. Claims reviews committees are established at the District, Regional, and Central Office level for the purpose of determining the action SBA will take with respect to debts owed the Agency. Specifically, the various claims review committees have authority, at differing amounts depending upon their organizational level, to reach settlement on primary obligations or other evidence of an indebtedness owed the SBA for an amount less than the total amount due thereon. This rule provides authority by which a claims review committee may be constituted at the Branch Office level.

In each qualified SBA Branch Office, a Branch Claims Review Committee may be established. The membership of the Committee shall consist of three incumbents (or those officially acting in their behalf) in the following order of position classification: Assistant Branch Manager for Finance and Investment (F&I); Portfolio Management (PM) Chief or Senior PM Staff Member; Branch Counsel; Finance Division (FD) Chief or Senior FD Staff Member; and Business Development Specialist. The first person available in the above order shall serve as chairperson of the committee. The regulation sets forth the degree of concurrence required of committee members in order to undertake certain action as well as the level of authority, in specific dollar amounts, which may be exercised by the Branch Claims Review Committee. Finally, the rule states that split decisions and reconsiderations (appeals) of actions taken by the Branch Claims Review Committee are to be taken directly to the Regional Claims Review Committee. A split decision for purposes of this rule means less than unanimity on those matters which require unanimity.

The establishment of a Branch Claims Review Committee pursuant to this authority shall require publication of a notice in the **Federal Register**. This regulation states that Branch Claims Review Committees will not be organized in each SBA Branch Office. Rather, this rule describes the authority that a Branch Claims Review Committee may exercise and requires that, in order to create a Branch Claims Review Committee in a particular SBA Branch Office, a notice must be published specifically designating such office. This system ensures that only those SBA Branch Offices with sufficient personnel and loan volume have the authority to undertake compromise activities.

Due to the fact that this rule governs matters of agency organization, management, and personnel and makes no substantive change to the current regulation, SBA is not required to determine if it constitutes a major rule for purposes of Executive Order 12291, to determine if it has a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), to do a Federalism Assessment pursuant to Executive Order 12612, or to determine if this rule imposes an annual recordkeeping or reporting requirement on 10 or more persons under the Paperwork Reduction Act (44 U.S.C. ch. 35).

SBA is publishing this regulation governing agency organization, practice, and procedure as a final rule without opportunity for public comment pursuant to 5 U.S.C. 553(b)(A).

List of Subjects in 13 CFR Part 101

Administrative practice and procedure; Authority delegation; Organization and function, Government agency; Reporting and recordkeeping requirement.

For the reasons set forth above, SBA is amending part 101 of Title 13, Code of Federal Regulations, as follows.

PART 101—[AMENDED]

1. The authority citation for part 101 continues to read as follows:

Authority: Secs. 4 and 5 of Pub. L. 85–536, 72 Stat. 384 and 385 (15 U.S.C. 633 and 634, as amended); sec. 308, Pub. L. 85–699, 72 Stat. 694 (15 U.S.C. 687, as amended); sec. 5(b)(11), Pub. L. 93–386 (Aug. 23, 1974); and 5 U.S.C. 552.

2. Part V of Section 101.3–2, Delegation of authority to conduct program activities in field offices, is amended by redesignating paragraphs (a) through (d) as paragraphs (b) through (e) and by adding a new paragraph (a) to read as follows:

§ 101.3–2 Delegation of authority to conduct program activities in field offices.

* * * * *

PART V—CLAIMS REVIEW COMMITTEE

Committee Authority

No authority has been delegated within SBA to take final action in compromise settlement of any Agency claim except through the established Claims Review Committees. Actions taken by such Committees must be in compliance with the provisions of this regulation.

a. *Branch Claims Review Committee.* A Branch Claims Review Committee (BCRC) may be established in each qualified branch office. Membership shall generally consist of three available incumbents (or those acting officially on their behalf) in the following order of position classification. The first member

available in this order shall serve as chairperson:

Assistant Branch Manager/Finance and Investment Portfolio Management Chief or Senior Portfolio Management Staff Member
Branch Counsel
Finance Division Chief or Senior Finance Division Staff Member
Business Development Specialist

In the face of limited staffing availability, the Branch Manager may authorize a different committee structure if such structure is monitored to ensure that each member of the committee is free to give independent opinions regarding the matters at hand. This committee structure must be approved by the District Director overseeing the particular Branch Office at issue.

1. Authority is delegated to this Committee to take final approval action on:

(A) Claims not in excess of $200,000 (excluding interest), upon the majority vote of its members.

(B) Claims exceeding $200,000 but not in excess of $300,000 (excluding interest), upon the unanimous vote of its members.

(C) Claims of any size when the amount offered represents the full principal balance due (thereby forgiving only accrued interest), upon the majority vote of its members.

(D) Claims of any size involved in insolvency proceedings (bankruptcies, state and Federal receiverships, USDA Certified Mediation cases, assignments for the benefit of creditors, etc.) or which are under the administrative control of the U.S. Department of Justice, upon the unanimous vote of its members.

(E) Requests to reduce or eliminate the interest rate charged and/or the interest accrued by the Agency when authority for such action is not otherwise delegated to the line supervisor or the Central Office Claims Review Committee, upon the majority vote of its members.

(F) Private sales of collateral and collateral purchased which exceed the delegated authority of the line supervisor, upon the unanimous vote of its members.

(G) Bid proposals responding to an authorized Request For Proposals for annual auctioneering services, upon the unanimous vote of its members.

2. Committee recommendations to sell a loan or other evidence of indebtedness owed the Agency for less than the principal amount due, or to compromise an Agency claim against a "going" business which is not involved in insolvency proceedings or under the administrative control of U.S. Department of Justice, must be forwarded through channels, with Branch and Regional Committee comments, to the Central Office Claims Review Committee for final action.

3. Settlement offers on claims of any size may be declined by majority vote of its members.

4. Split decisions and reconsiderations (appeals) of actions taken by this Committee must go directly to the Regional Claims Review Committee.

5. A Branch Claims Review Committee will not be organized in each SBA Branch Office. Rather, a Branch Claims Review Committee may be established at an SBA Branch Office only pursuant to a specific designation of a particular branch office, published as a notice in the **Federal Register**. Such designation will be based upon the sufficiency of that office's personnel as well as its loan volume.

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Dated: December 28, 1992.

Patricia Saiki,

Administrator.

[FR Doc. 93–15 Filed 1–6–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 346 and 381

[Docket No. RM92–17–000]

Elimination of Filing Fees

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is amending its regulations to eliminate certain filing fees. The Commission will retain filing fees for petitions for issuance of a declaratory order and the fees for blanket certificate applications made by Hinshaw pipelines and local distribution companies, for petitions for rate approval pursuant to § 284.123(b)(2), and for initial or extension reports for title III transactions, in addition to the six filing fees proposed for retention in the notice of proposed rulemaking. The Commission also is revising the current methodology for annual adjustments to its filing fees and direct billing.

EFFECTIVE DATE: This rule is effective January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Julia Lake White, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 208–0457.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission has made this document available so that all interested persons may inspect or copy its contents during normal business hours in room 3104, 941 North Capitol Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to use 300, 1200, 2400 baud, full duplex, no parity, 8 data bits and 1 stop bit. The full text of this document will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in room 3104, 941 North Capitol Street, NE., Washington, DC 20426.

Before Commissioners:
Martin L. Allday, Chairman;
Charles A. Trabandt, Elizabeth Anne Moler,
Jerry J. Langdon and Branko Terzic.

Elimination of Certain Filing Fees in Parts 346 and 381

[Docket No. RM92–17–000; Order No. 548]

Issued January 4, 1993.

I. Introduction

The Federal Energy Regulatory Commission (Commission) is amending its regulations in parts 346 and 381 to eliminate certain filing fees. The Commission will retain the filing fees for petitions for issuance of a declaratory order in § 381.302 and the fees in § 381.207(a)(1) for blanket certificate applications made by Hinshaw pipelines and local distribution companies, in § 381.403 for petitions for rate approval pursuant to § 284.123(b)(2), and in § 381.404 for initial or extension reports for Title III transactions, in addition to the six filing fees proposed for retention in the Notice of Proposed Rulemaking. The Commission also is revising the current methodology for annual adjustments to its filing fees in § 381.104(c) and direct billing in § 381.107(a) of the regulations.

This rule will be effective upon issuance.

II. Background

The Commission is authorized under the Independent Offices Appropriation Act of 1952 (IOAA) to establish fees for the services and benefits it provides.[1] In addition, the Omnibus Budget Reconciliation Act of 1986 (OBRA) authorizes the Commission to "assess and collect fees and annual charges in any fiscal year in amounts equal to all of the costs incurred by the Commission in that fiscal year."[2]

On October 15, 1992, the Commission issued a Notice of Proposed Rulemaking (NOPR) proposing to eliminate most filing fees, with the exception of six.[3] The Commission proposed to recover costs associated with filings for which fees are being eliminated in the annual charges assessed pursuant to part 382 of the Commission's regulations. The Commission reserved the option to order direct billing for filings that may be unusually extensive in scope and that present complex factual, legal, or policy issues requiring an extraordinary amount of time and effort to process them. The Commission also sought comments on whether to substitute a different approach for the current methodology for annual adjustment of the retained filing fees.

Twenty-four comments were received in response to the NOPR.[4] Thirteen commenters generally supported the Commission's proposal because it will simplify the filing process, expedite the consideration of filings, eliminate barriers to actions that may be economically efficient and in the public interest, and to some extent reduce the Commission's administrative costs.[5] At the same time, some of these commenters expressed concerns with the final rule's potential impact on certain types of transactions and services.[6]

Eleven commenters opposed the elimination of filing fees.[7] These commenters argued that elimination of the Commission's filing fees will not result in either simplifying the filing process or expediting the review and consideration of filings. According to commenters, the Commission has not shown that elimination of the filing fees will reduce the Commission's administrative costs.

Commenters also proposed modifications to the annual charges assessment methodology, retention of additional filing fees, and modifications to direct billing procedures and the methodology for updating the filing fees.

For the reasons discussed below, the Commission is adopting as final its proposal to eliminate certain filing fees, with some modifications.

III. Discussion

A. Comments Supporting Elimination of Filing Fees

The Commission received thirteen comments that supported this rulemaking, recognizing its procompetitive and public interest aspects. Commenters noted that the proposed rule would reduce overall administrative costs for the Commission and the companies it regulates.[8] This in turn will benefit consumers since public utilities and pipelines generally pass on the fees and the costs associated with filings to purchasers and consumers.[9] They also noted that filing fees discourage otherwise economically advantageous and efficient jurisdictional transactions.[10]

One commenter identified two market-distorting effects of the Commission's current filing fees system for the electric industry: (1) utilities may forgo transactions or structure them inefficiently in order to avoid fees; and (2) utilities may design transactions to maximize filing fees passed through to customers/competitors, seeking to gain a competitive advantage or to block competitors from participating in the bulk power and coordination markets.[11]

According to commenters, removing filing fees will eliminate the cost of filing as a consideration in determining whether to engage in certain transactions, allowing those decisions to be made on their merits.[12] Commenters also noted that the Commission's existing filing fees system is not clear and leaves filing parties uncertain as to the fee, if any, that is due.[13]

Commenters supporting the rule also pointed out that the final rule will eliminate market barriers for some participants, especially smaller entities.

B. Impact of Elimination of Filing Fees on Annual Charges Assessments

1. Perceived Impacts on Jurisdictional Companies

The Commission proposed to eliminate most filing fees and to recover the Commission's costs associated with these filings as part of the annual charges assessed each year. The Commission noted in the NOPR that the resulting increase in annual charges would be modest and have no effect on the financial health or competitive viability of any jurisdictional company.[14]

Commenters opposing the elimination of the filing fees, apparently believing that the increase in annual charges will be much higher than will actually be the case, argued that the Commission must accurately allocate costs and eliminate or avoid cross-subsidies. According to these commenters, the Commission should require pipelines to pay regulatory costs in proportion to, or to compensate for, their regulatory activities.[15] One commenter argued that the proposed collection method would move further away from the theory that those who incur the costs of

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[1] 31 U.S.C. 9701.

[2] 42 U.S.C. 7178.

[3] Elimination of Certain Filing Fees in parts 346 and 381, Docket No. RM92–17–000, 57 FR 48005 (Oct. 21, 1992), IV FERC Stats. & Regs. ¶32,488. The six filing fees to be retained are: reviews of Department of Energy remedial orders in § 381.303; reviews of Department of Energy denials of adjustment in § 381.304; five Megawatt exemption applications under section 405 of the Public Utility Regulatory Policy Act (PURPA) in § 381.601; reviews of jurisdictional agency determinations in § 381.402; certifications of qualifying status as small power production facility or cogeneration facility in § 381.505; and interpretations by the Office of the General Counsel in § 381.305.

[4] A list of the commenters is in the Appendix.

[5] See, e.g., Columbia Gas Transmission Corporation and Columbia Gulf Transmission Company (Columbia), Commonwealth Edison Company (Edison); Edison Electric Institute (EEI); Enron Interstate Pipelines (Enron); Green Mountain Power Corporation (Green Mountain); National Fuel Gas Supply Corporation (National Fuel); New England Power Company; Pacific Gas Transmission Company (Pacific Gas); Public Systems; Tennessee Gas Pipeline Company (Tennessee Gas); Northern Distributor Group; Florida Power & Light Company (Florida); and UtiliCorp United Inc. (UtiliCorp).

[6] See, e.g., Columbia Gas; Edison; EEI; Enron; and Tennessee Gas.

[7] See, e.g., Arizona Public Service Company (Arizona); Arkla Energy Resources and Mississippi River Transmission Corporation (AER and MRT); ANR Pipeline Company and Colorado Interstate Gas Company (ANR and CIG); El Paso Natural Gas Company (EL Paso); Iowa-Illinois Gas & Electric (Iowa-Illinois); JMC Power Projects; Philadelphia Electric Company; PEC Pipeline Group; Transok Gas; Washington Water Power Company (Washington Water); and Williston Basin Interstate Pipeline Company (Williston).

[8] See, e.g., Public Systems at 2; Northern Distributor Group at 1; and Pacific Gas Transmission at 2.

[9] See, e.g., Public Systems at 2; Northern Distributor Group at 2,

[10] See, e.g., New England Power at 1; Northern Distributor Group at 2.

[11] Public Systems at 5.

[12] See, e.g., Edison Electric Institute at 1; New England Power at 1; Pacific Gas Transmission at 2; Northern Distributor Group at 2–4.

[13] See, e.g., Commonwealth Edison at 4; Green Mountain Power Corporation at 1–2; Pacific Gas Transmission at 2.

[14] See Notice of Proposed Rulemaking, slip op. at 6–9.

[15] See, e.g., AER and MRT; JMC Power Projects; ANR and CIG; and El Paso.

Commission services should pay for them.[16]

Arizona Public Service Co. (Arizona) argued that the elimination of filing fees would penalize jurisdictional utilities that collect applicable filing fees directly from the entity causing the filing. Arizona also fears that annual charges would be increased as the filing fees now recovered on an individual basis are spread out and recovered from all applicable jurisdictional utilities. Arizona noted that a utility may be required to seek a rate increase to absorb the increase in the annual charges assessments (ACA).[17]

Jurisdictional utilities that collect applicable filing fees directly from the entity causing the filing will not be penalized by this final rule. The increase in annual charges paid by utilities will be modest. Utilities may file to recover the increased annual charges if they choose to do so. Utilities may also seek to have these adjusted annual charges allocated to the customers who use those kilowatt hours.

Commenters also noted that, under the current ACA methodology, jurisdictional entities are not guaranteed recovery of annual charges payments to the Commission. According to one commenter, under current market conditions, merely having the right to collect the ACA does not guarantee that regulated entities will actually collect the ACA on volumes of natural gas transported. This commenter noted that, when the pipeline is forced to offer a discounted rate that includes the full ACA surcharge, the pipeline shareholders, not customers, would fund a portion of the Commission's activities.[18] According to two joint commenters, the annual charges element in a pipeline's rate may constitute a significant portion in a deeply discounted transportation arrangement. They alleged that, in a low margin transaction, the annual charge increase may render the transaction uneconomic.[19]

The Commission has considered these comments but nonetheless believes that eliminating filing fees will have a moderate impact on annual charges for jurisdictional companies. To the extent that these commenters believe that the elimination of filing fees will vastly increase their annual charges assessments, they are mistaken.

In 1992, the total annual charges assessments to oil companies were $2,589,000; if filing fees had been eliminated, the total annual charges would have been $2,675,000, a difference of $86,000, which will be spread out over 137 companies. The largest annual charges assessed against an oil pipeline in 1992 were $164,000 and the smallest annual charges assessed against an oil pipeline were $18. If filing fees had been eliminated, the largest annual charges that would have been assessed against an oil pipeline would have been $170,000 and the smallest annual charges that would have been assessed would have been $19. This is a difference of $6,000 and $1, respectively.

In 1992, the total annual charges assessments to electric public utilities were $29,083,000; if the filing fees other than for small power and co-generation had been eliminated, the annual charges would have been $31,306,000, which is a difference of $2,223,000, which would be spread out over 182 companies. The largest annual charges assessed against a public utility in 1992 were $1,330,174[20] and the smallest annual charges assessed against a public utility were $2. If filing fees had been eliminated, the largest annual charges that would have been assessed against a public utility would have been $1,431,799 and the smallest annual charges that would have been assessed would have been $2. This is a difference of $101,625 and zero, respectively.

In 1992, the total annual charges assessments to gas companies were $61,018,000; if the filing fees had been eliminated, the annual charges would have been $68,265,000, which is a difference of $7,247,000, which will be spread out over 115 companies. The largest annual charges assessed against a gas company in 1992 were $3,951,147 and the smallest annual charges assessed against a gas company were $145. If filing fees other than producer fees had been eliminated, the largest annual charges that would have been assessed against a gas company would have been $4,420,543 and the smallest annual charges that would have been assessed would have been $162. This is a difference of $469,396 and $17, respectively.

The benefits that will accrue as a result of this rule will not be counterbalanced by burdensome increases in annual charges. If the proposal to eliminate most filing fees had been in effect in 1992, there would have been no increase in annual charges for hydro-electric companies and an increase of only about 3 percent for oil pipelines. For electric utilities and natural gas pipelines, there would have been overall increased annual charges of about 7.64 and 11.88 percent, respectively.

The largest assessments and the smallest assessments are both being affected equally; the effect is a low percentage increase in annual charges. The highest increase in annual charges would have occurred with respect to the gas pipelines and this increase would only have been 11.88 percent.

Of equal importance to the modest increase in annual charges occasioned by this rule is the fact the increase in annual charges does not result in any additional revenue to the Commission. The increases in annual charges are offset, dollar for dollar, by decreases in filing fees. Those filing fees are generally paid by the very same entities that are paying annual charges. For example, in 1992, Texas Eastern Transmission Corporation (Texas Eastern) paid annual charges of $2,292,048 and filing fees for all its various filings of $589,618, or total charges of $2,881,666. If the rule had been in place for 1992, Texas Eastern would have paid annual charges of $2,564,343. While as an industry the offset will be dollar-for-dollar, for any given company in any given year the effect of the rule change may cause its total charges to be higher or lower than without the change. This would occur because the Commission offsets total program costs with total fees paid before assessing annual charges, rather than offsetting individual companies' annual charges with individual fees paid. The Commission would expect differentials to balance out over time.

The Commission does not anticipate that the removal of filing fees will result in a large number of frivolous filings by companies that were inhibited from making such filings prior to the fees' removal. To expect such behavior on the part of regulated entities is to anticipate that they will act in an economically irrational manner. The Commission cannot presume that this will be the case.

Recovering costs through annual charges rather than filing fees has the advantage of enhanced convenience and certainty for jurisdictional companies. Fees for specific types of regulatory action are, by their nature, subject to greater fluctuation than is a single annual charge based on a pro rata share of the Commission's costs for an entire regulatory program.[21]

[16] Williston Basin at 1.
[17] Arizona Public Service Co. at 2–3.
[18] Columbia at 5–6.
[19] AER and MRT at 4.
[20] New England Power Co. This utility supports this rulemaking.
[21] For example, certain pipeline tariff filing fees (under 18 CFR 381.205(a)(1)) increased from $6,600 in 1990 to $8,080 in 1992; pipeline certificate

The commenters who questioned a possible increase in annual charges that could result from elimination of most filing fees did not properly account for the fact that, to some extent, entities that pay annual charges are always cross-subsidizing activities at the Commission in which they do not actively participate or as to which they are not necessarily direct beneficiaries. The cross-subsidy to which some commenters allude is not unique to this proposal and is to some extent inherent in annual charges. Thus, raising the possibility of problems that occur with respect to annual charges to oppose elimination of filing fees is an impermissible and untimely collateral attack on the annual charges methodology.

2. Perceived Impact on Companies With Little Direct Involvement With FERC.

Iowa-Illinois is concerned that the Commission's proposal to shift recovery of costs from filing fees to annual charges assessments will adversely impact companies who have little direct involvement with the Commission. Iowa-Illinois pointed out that it generates few filings and the Commission therefore expends little time and resources processing Iowa-Illinois' filings. According to Iowa-Illinois, movement away from direct assessment methodology raises the possibility that Iowa-Illinois will be assessed a portion of the charges for the multitude of filings made by interstate natural gas pipelines and other entities.[22]

Iowa-Illinois' contentions lack merit. First, as previously noted, no jurisdictional company that presently pays annual charges will experience a significant increase in its annual charges. Second, Iowa-Illinois' arguments are a collateral attack on annual charges. Filing fees may actually distort the economic costs of doing business with the Commission more than annual charges and may also inhibit smaller companies, with a lesser ability to pay, from making beneficial filings.

Perhaps most significantly, based on this year's data, Iowa-Illinois actually will benefit from the rule change. According to Commission records, Iowa-Illinois paid electric annual charges for 1992 in the amount of $34,854 (disregarding an adjustment for the prior year's overpayment). If the rule change had been in effect, the annual charges would have been $37,517. In fiscal year 1992, Iowa-Illinois also paid $4,850 in filing fees—meaning that, under the rule change, Iowa-Illinois would have paid over $2,000 less than it did under the current system. Iowa-Illinois' fear of a dramatic increase in the amount of its annual charges is unfounded.

Finally, its contention that it has had relatively few filings in recent years does not signify that it should be given a waiver from the annual charges that jurisdictional companies must pay, according to statute.

C. Collateral Attack on Annual Charges Assessments Methodology

In addition to objecting to a perceived increase in the amount of annual charges that they will be required to pay, certain commenters identified problems with the Commission's current methodology for assessing annual charges pursuant to Part 382 of the Commission's regulations, including: (1) The proposal to eliminate filing fees is inconsistent with Order No. 636's policy initiatives[23]; (2) ACA charges should not be collected on interstate pipeline sales under blanket certification[24]; (3) pipelines should be able to recover ACA charges in their demand charges[25]; (4) pipelines should be able to recover ACA charges in a "50–50 demand/commodity split,"[26]; (5) pipelines should be allowed to recover increased ACA charges by changing their method of collecting annual charges from a cost-of-service item to a surcharge, or vice-versa[27]; (6) pipelines should be allowed to recover increased ACA charges by adjusting their base tariff rates in limited Section 4(e) filings to reflect the increase in annual charges[28]; (7) pipelines should be allowed to recover increased ACA charges by continuing to collect the existing level of annual charges in their base tariff rates, and collecting the increase in annual charges resulting from this rule through an interim surcharge[29]; (8) pipelines should be allowed to recover increased ACA charges by maintaining the status quo and continuing to pay filing fees in lieu of the increase in annual charges, until the pipelines make their next general Section 4 rate filing[30]; (9) pipelines should be allowed to recover annual charges through a reservation surcharge[31]; (10) the ACA charge should only be collected by the pipeline at the end of the transaction chain[32]; (11) annual charges must be assessed only once[33]; (12) the Commission should include a true-up mechanism whereby an entity is assured of remitting only the annual charges amounts actually collected[34]; (13) increased annual charges assessments should be billed by the Commission on a quarterly basis[35]; (14) the ACA methodology will result in regional inequities that will create a substantial and unrecoverable cost burden on companies operating where pipeline construction has slowed due to an excess of capacity[36]; (15) increased annual charges will have deleterious consequences for "incremental shippers"[37]; and (16) the Commission should expand of the types of companies assessed annual charges[38].

First, the Commission will not address in this docket the commenters' attacks on the way annual charges are assessed and collected. These issues are irrelevant to the question of eliminating certain filing fees. As the Commission repeatedly has noted, shifting the recovery of the Commission's costs from filing fees to annual charges will not substantially increase any one company's costs—and on an industry-wide basis, the change is zero. The incremental increase in the pipelines' annual charges should have negligible consequences, particularly when these consequences are balanced against the administrative burden of maintaining two different collection systems. Moreover, because this action is being taken in mid-year, the impact of doing away with filing fees will be spread over two years.

Second, questions that have been raised with respect to the Commission's annual charges adjustment (ACA) mechanism are beyond the scope of this rulemaking. The Commission nevertheless acknowledges that several of the commenters have raised issues that deserve further consideration. Revisitation of the ACA mechanism may be appropriate, particularly as a result of the policy initiatives in Order No. 636.[39]

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application fees rose in the same period from $26,260 to $39,440; and curtailment filing fees increased from $6,270 to $11,432.

[22] See Iowa-Illinois at 1–2.

[23] See PEC Pipeline Group at 1–2 and 5–7.

[24] Tennessee Gas Pipeline Company at 4.

[25] *Id.*

[26] Columbia at 6–7.

[27] ANR and CIG at 4.

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] The PEC Pipeline Group at 11–12.

[32] Williston at 3.

[33] Enron at 6–7.

[34] Columbia at 7.

[35] Enron at 5–6

[36] JMC Power Projects at 3 and 5.

[37] JMC Power Projects at 3–4.

[38] PEC Pipeline Group at 9–10.

[39] Pipeline Service Obligations and Revisions to Regulations Governing Self-Implementing Transportation; and Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol, 57 FR

Cont'nued

The Commission therefore will issue a notice of inquiry in the near future seeking comments on the ACA mechanism and current market conditions. That notice will take into account the comments that were filed by all commenters in this case and will seek additional comments from entities that are affected by the Commission's annual charges assessments.

D. Retention of Certain Filing Fees

The Commission proposed to retain six filing fees including: (1) reviews of Department of Energy remedial orders in § 381.303; (2) reviews of Department of Energy denials of adjustment in § 381.304; (3) five megawatt exemption applications under Section 405 of the Public Utility Regulatory Policy Act (PURPA) in § 381.601; (4) reviews of jurisdictional agency determinations in § 381.402; (5) certifications of qualifying status as a small power production facility or cogeneration facility in § 381.505; and (6) interpretations by the Office of the General Counsel in § 381.305.

Commenters generally supported retention of these filing fees. However, several commenters proposed retention of other filing fees. Two commenters requested that the Commission retain the filing fee for petitions for issuance of a declaratory order in § 381.302.[40] These commenters noted that non-jurisdictional entities may file requests for a declaratory order disclaiming jurisdiction and that these filings are of specific interest and benefit to the party making the filing. According to Tennessee, the number of these petitions seems to be increasing as more companies seek gathering status determinations for various facilities.[41]

The Commission will retain the filing fee for petitions for issuance of a declaratory order in § 381.302, as Arizona and Tennessee requested. This is consistent with the Commission's intention to retain filing fees assessed against nonjurisdictional entities. The Commission recognizes, in the case of petitions for declaratory orders for gathering status determinations or for other determinations of nonjurisdictional status, that these filings are made by entities that may well not pay annual charges.

The Commission will retain a filing fee for blanket certificate applications made by Hinshaw pipelines and local distribution companies in § 381.207(a)(1). The PEC Pipeline Group pointed out that elimination of the filing fee for all certificate applications will allow intrastate pipelines that are not subject to annual charges assessments to avoid paying for Commission services.[42] The PEC Pipeline Group argues that interstate pipelines should not be required to pay for filings made by intrastate pipelines when interstate pipelines do not enjoy the same benefits as do the intrastate pipelines providing section 311 service.

The PEC Pipeline Group's arguments do not warrant retention of this filing fee. Since 1989, the Commission has processed only 23 applications pursuant to § 381.207(a)(1). Those applications are routine in nature, are now acted upon pursuant to delegated authority, and do not require significant expenditures of Commission resources. Since 1989, these applications have not once been protested. Retention of the current level of filing fees for this category of applicant (now $39,440) would result in disproportionately high costs, however, because the applications would be considered on the same base that is discussed in section F, herein.

On the other hand, the Commission believes that these categories of filers, who do not pay annual charges and therefore do not defray the costs applicable to consideration of their applications, should pay a filing fee for applications filed under § 381.207(a)(1). Based on recent experience with these types of filings, the Commission has determined that a comparable category in terms of resources expended is in § 381.208, requests under the blanket certificate notice and protest procedures. Presently, these filing fees are $490. However, the applications filed pursuant to § 381.207(a)(1) require preparation of an order, which should add to the fee that the applicant will pay. The Commission therefore has determined to retain an application fee for these applications, but will change § 381.207(b) to reflect the reduced filing fee. The fee that the Commission will charge for such filings in the future, to be updated on an annual basis based on the data available with respect to these transactions in the Commission's data base, as explained in section F herein, will initially be $1,000.

The Commission also will retain the filing fees under §§ 381.403 and 381.404, that are applicable to petitions for rate approval pursuant to § 284.123(b)(2) and initial or extension reports for Title III transactions for intrastate pipelines, respectively. These fees are charged for filings that are made by nonjurisdictional companies that do not pay annual charges. The volume of these filings, which are made on a continuous and routine basis, can be significant. The Commission has determined to continue to charge filing fees in these circumstances and will therefore retain §§ 381.403 and 381.404 intact.

Philadelphia Electric Company (PECo) requested the Commission to exempt rate filings to effect transmission services under the Federal Power Act from the NOPR's proposal to eliminate filing fees. PECo did not specify the provision(s) that it wanted the Commission to retain, but noted that a number of the filing fees incurred by PECo arise from customer requests for new transmission services and the accompanying new rate schedules. PECo alleges that it and a number of other electric power companies recover these filing fees directly from the customer. According to PECo, without a separately identified filing fee, it would be unlikely that electric power companies could assess the costs caused by each rate filing to the party that is responsible for the expense. Annual charges for public utilities are based, in part, on the amount of power they transmit. Thus, PECo alleges, inclusion of annual charges in the regulatory expense portion of their base rates would be one way for PECo to recover these costs.

Edison Electric Institute (EEI) requested the Commission to charge filing fees for preliminary permit applications, and original license applications filed under part I of the Federal Power Act (FPA).[43] EEI noted that a large percentage of these applications do not result in licensed projects, so the applicants never pay annual charges for back charges to cover their share of the Commission's administrative costs.[44] EEI also noted that few preliminary permits and

13267 (Apr. 16, 1992), III FERC Stats. & Regs. Preambles ¶ 30,939 (Apr. 8, 1992); *order on reh'g*, Order No. 636–A, 57 FR 36128 (Aug. 12, 1992), III FERC Stats. & Regs. Preambles ¶ 30, 950 (Aug. 3, 1992); *order denying reh'g and clarifying*, 57 FR 57911 (Dec. 8, 1992), 61 FERC ¶ 61,272 (Nov. 27, 1992).

[40] See Arizona Public Service Co. at 4; and Tennessee Gas Pipeline Co. at 3.

[41] Tennessee Gas Pipeline Co. at 3. Commission records indicate that 10 petitions for declaratory orders for gathering determinations were filed in FY 91, 11 petitions were filed in FY 92, and to date 4 petitions have been filed in FY 93.

[42] The PEC Pipeline Group at 9–10.

[43] EEI at 2.

[44] EEI cited testimony by Dick Hunt, former Director of the Commission's Office of Hydropower Licensing to the Senate Energy Committee in February 1991, that only 54% of permit, license, and exemption applications filed with FERC between 1980 and 1990 were approved and only 13% of the approved projects resulted in operating power plants. See EEI at 2.

original license applications are filed by owners of existing projects.

The costs of administering part I of the Federal Power Act are collected pursuant to section 10(e) of the Act. Changes to the manner in which part I costs are collected are beyond the scope of this rulemaking.

E. Direct Billing

The Commission proposed to retain the option to order a direct billing procedure at the beginning of processing a filing or at any time up to one year after receiving a complete filing for extraordinary filings.

Several commenters requested the Commission to clarify what constitutes an "extraordinary filing," to implement objective standards for determining when and how the direct billing mechanism will be applied, and to provide for notice to an affected applicant as soon as possible after an extraordinary filing is submitted, including an estimate of the fee.[45] Tennessee and Williston requested the Commission to place a cap on direct billing charges.[46] UtiliCorp requested the Commission to simplify the direct billing mechanism by replacing the periodic assessment of costs provision with a one-time standardized complexity surcharge.[47] The PEC Pipeline Group reserved the right to comment further on the direct billing test because the NOPR did not suggest a test.[48]

The PEC Pipeline Group also requested the Commission to clarify its intent regarding the direct billing alternative. According to the PEC Pipeline Group, once filing fees are eliminated, it is unclear whether the Commission intends to direct bill for an extraordinary filing that no longer requires a filing fee to be remitted. The PEC Pipeline Group interprets § 381.107(a) as indicating that direct billing will occur only on applications associated with payment of a filing fee. The PEC Pipeline Group requested clarification if this interpretation is not the Commission's interpretation.[49] Contrary to the PEC Pipeline Group's interpretation, the direct billing mechanism is not restricted to situations where a filing fee would otherwise be paid.

The Commission expects that the occasions on which it will resort to direct billing will be extremely rare. The direct billing procedures will be utilized, at the Commission's discretion, only in those cases involving complex factual, technical, environmental, procedural and/or legal issues that involve a disproportionate expenditure of Commission resources. One such situation is a large LNG project that is unrelated to any class of domestic customers or domestic rate payers and thus would not pay annual charges.[50]

F. Annual Adjustment of Fees

The Commission invited comments on whether it should continue the current annual recalculation process on the fees being retained. Few comments were submitted on the current annual recalculation process in § 381.104(c).[51] EEI noted that, although the Commission's current method of updating filing fees may be the most cumbersome of those identified in the NOPR, it also appears to be the most accurate. EEI requested the Commission to ensure that any alternative other than the current method selected to recalculate the filing fees produce accurate results.[52] EEI also suggested that filing fees should be "spot checked" periodically to ensure that they reflect actual costs for processing specific filings.[53]

EEI specifically requested that, if the Commission uses a constant number of employee hours for each type of filing to calculate filing fees, the constants should be developed using a sufficiently large data base to ensure that they accurately represent typical filings. EEI also requested that, if fees are updated by applying an inflation factor to base year fees, the "base year" should be carefully chosen to ensure that it reflects the level and nature of filings for which fees will be charged.[54]

The Commission is substituting a new formula for the present annual adjustment. The formula for determining each fee will use a constant base. That base will be the total number of actual workmonths dedicated to a given fee category for all years for which the Commission has data, through FY 92[55], divided by the total number of actual completions in those years for which the Commission has data, through FY 92. This base will be multiplied by the average cost per workmonth in the most recent complete fiscal year.[56]

This methodology for computing the annual adjustment of fees is preferable to other proposed methodologies because this method will simplify the Commission's procedures while retaining an accurate update of the fees. Using five or six years' data rather than the present three-year base will reduce year-to-year fluctuations. At the same time, using the most current cost factor will allow fees to reflect Commission costs more accurately than would an inflation factor, which would increase the fees yearly based on the rate of inflation only for that year.

If this formula for determining the filing fees had been in effect for FY 92, it would have affected the fees that the Commission proposed originally to retain in the following manner[57]: (1) Reviews of Department of Energy remedial orders would have been $12,940 instead of $13,400; (2) reviews of Department of Energy denials of adjustment would have been $6,940 instead of $5,760; (3) the fee for five Megawatt exemptions would have been $19,900 instead of $20,650; (4) reviews of jurisdictional agency determinations would have been $90 instead of $85; (5) the fee for certification as a qualifying small power production facility would have been $8,120 instead of $9,100 and the fee for certification as a qualifying cogeneration facility would have been $9,560 instead of $10,540; and (6) the fee for interpretations by the Office of the General Counsel would have been $2,450 instead of $2,310.

The Commission is revising § 381.104(c) to reflect its new formula.

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[45] See AER and MRT at 7–8; Commonwealth Edison at 1 and 4–6; Tennessee at 5; and Williston Basin at 2.

[46] Tennessee Gas Pipeline Company at 5 and Williston at 2.

[47] UtiliCorp at 2.

[48] PEC Pipeline Group at 13–14.

[49] PEC Pipeline Group at 13.

[50] See Yukon Pacific Co. L.P., 59 FERC ¶ 61,153 (1992), order on reh'g 60 FERC ¶ 61,132 (1992), appeal pending sub nom. Yukon Pacific Co. L.P. v. FERC, No. 92–1503 (D.C. Cir. filed Oct. 7, 1992).

[51] 18 CFR 381.104(c).

[52] EEI at 2.

[53] Id. at 3.

[54] EEI at 2.

[55] Two fees, those for certifications of qualifying status as a small power production facility and cogeneration facilities, will use data for only five years (1988–1992) because prior to 1988 these fees were combined, and no data are available for 1987. All other fees will use data for the six fiscal years 1987 through 1992.

[56] Under this formula, the number of workmonths reported for a class of docketed activity is added to that class's pro rata share of the workmonths reported for relevant support activities. This figure, representing the total number of workmonths dedicated to a class of docketed activity for the indicated years, is divided by the number of completions for those six years for the given activity. The resulting quotient will be a constant factor used each year which represents the average number of workmonths required to complete one proceeding in that given class of docketed activity. Next, the average cost of a workmonth is calculated based on the Commission's most recent fiscal year actual costs. Then, in order to determine the fee for a given class of activity, the average cost per workmonth is multiplied by the constant factor. After rounding, according to current practice, this number will represent the fee in that category.

[57] These numbers for the filing fees being retained have been calculated without workmonth and completion data for FY 92, which are not yet available.

The Commission has determined to retain the filing fees for blanket certificate applications filed by Hinshaw pipelines and local distribution companies in § 381.207(a)(1). The data base that currently exists takes into account all pipeline certificate applications, however, not just these less substantial certificate applications. The present fee therefore is based on inclusion of larger and more complex transactions that are filed by jurisdictional companies. The Commission henceforth will rely on the data generated with respect to only the Hinshaw and LDC applicants in updating the filing fees that will be applicable to these transactions, which are made pursuant to section 7(c) of the Natural Gas Act filed in accordance with § 284.224 of the Commission's regulations. For the first year, the Commission will make the filing fee $1,000, based on the § 381.208 filing fee and its own experience. The Commission will add each succeeding year's information to create a data base for the filing fees for these applications.

G. Miscellaneous Comments

1. AER and MRT requested the Commission to expand the scope of this docket to re-examine all aspects of its cost collection methodology including: (1) Assigning costs directly to entities that cause the costs through their regulatory activity; (2) giving pipelines a reasonable opportunity to recover any annual charges allocated to discounted transactions; and (3) addressing the problem of multiple collections of annual charges for transactions that traverse more than one interstate pipeline.[58]

The Commission will not expand the scope of this docket to accommodate AER's and MRT's interests in order to re-examine all aspects of the cost collection methodology. AER's and MRT's first request, that the Commission assign costs directly to entities that cause the costs through their regulatory activities, would result in the Commission's abandoning the annual charges concept and potentially could overburden smaller companies, with a lesser ability to pay, with disproportionate costs. In any event, this request is beyond the scope of this rulemaking.

The Commission is not honoring in this docket AER's and MRT's request that the Commission consider giving pipelines a reasonable opportunity to recover any annual charges allocated to discounted transactions. First, this request appears to be premised on the false assumption that there will be a significant increase in annual charges as a result of the elimination of the filing fees at issue. As the Commission has previously explained, however, filing fees overall constitute less than 12 percent of the revenues; annual charges are the vast majority. Second, the annual charges adjustment mechanism set out in § 154.38(d)(6) of the Commission's regulations is not mandatory, but rather is one option by which pipelines may recover their annual charges.[59] Such charges may also be included and recovered as a part of regulatory expense in the pipelines' base rates. In any event, the Commission will be pursuing possible revisions to the ACA methodology in the near future.

The last problem that AER and MRT identified, multiple collections of annual charges for transactions that traverse more than one interstate pipeline, is similarly inappropriate for the Commission to address in the instant rulemaking. To the extent that the problem exists at all (and AER and MRT did not quantify the extent to which it allegedly exists), it is not unique to this case and will not be significantly exacerbated by the modest increase in annual charges that might occur after the elimination of the filing fees.

2. UtiliCorp United Inc. (UtiliCorp) proposed that the Commission should consider three refinements to the filing fees mechanism if the Commission should retain a filing fees approach to cost recovery.[60] The three proposals are: (1) within each currently existing category of filing, distinctions should be drawn based upon the type of application being made; (2) more of the existing filing fee categories should be broken down based on the dollar amount involved; and (3) the Commission must streamline its direct billing provision.

There is no need to address UtiliCorp's proposal because the Commission is eliminating most filing fees in this final rule.

3. In assessing annual charges under Part I of the FPA to recover the cost of other agencies participating in the hydro licensing process, EEI requested the Commission to set standards for documentation that other agencies must provide to substantiate their costs. EEI also requested the Commission to screen and occasionally audit the bills submitted by those other agencies.[61]

The Commission declines EEI's request to set standards for documentation that other agencies must provide to substantiate their costs in this rulemaking. EEI's request is beyond the scope of this rulemaking docket. The Commission intends to address this issue in a future rulemaking proceeding.

4. Filing Fee for Persons Seeking Exempt Wholesale Generator Status

On November 10, 1992, the Commission issued a notice of proposed rulemaking in Docket No. RM93–1–000 implementing section 32 of the Public Utility Holding Company Act of 1935 (PUHCA), as added by section 711 of the Energy Policy Act of 1992.[62] PUHCA section 32 requires persons seeking a determination of exempt wholesale generator (EWG) status to file for a determination with the Commission. The Commission requested comments in the NOPR concerning whether to create a separate fee category for applications for EWG status for non-public utility EWGs. The Commission noted that comments received in Docket No. RM93–1–000 would be placed in the record of this rulemaking docket. Comments are due in Docket No. RM93–1–000 on or before December 24, 1992.

Florida Power & Light Company (FPL) filed comments in support of the proposal to establish a filing fee for non-public utility EWG applicants in this rulemaking docket. FPL also raised several concerns with the Commission's proposal. The Commission will address FPL's comments along with the other comments filed in Docket No. RM93–1–000 separately from this rulemaking eliminating certain filing fees.

IV. Regulatory Flexibility Certification

The Regulatory Flexibility Act of 1980 (FRA)[63] generally requires a description and analysis of final rules that will have significant economic impact on a substantial number of small entities.[64] Pursuant to section 605(b) of the RFA, the Commission hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

[58] AER and MRT at 6–7.

[59] 18 CFR 154.38(d)(6).

[60] See UtiliCorp at 7–11.

[61] EEI at 3.

[62] Filing Requirements and Ministerial Procedures for Persons Seeking Exempt Wholesale Generator Status, Docket No. RM93–1–000, 57 FR 55195 (Nov. 24, 1992), IV FERC Stats. & Regs. ¶ 32,490 (Nov. 10, 1992).

[63] 5 U.S.C. 601–612.

[64] Section 601(c) of the RFA defines a "small entity" as a small business, a small not-for-profit enterprise, or a small governmental jurisdiction. A "small business" is defined by reference to section 3 of the Small Business Act as an enterprise which is "independently owned and operated and which is not dominant in its field of operation." 15 U.S.C. 632(a).

V. Environmental Statement

The Commission concludes that issuance of this rule would not represent a major federal action having a significant adverse effect on the human environment under the Commission regulations implementing the National Environmental Policy Act.[66] This rule would be procedural in nature and therefore falls within the categorical exemptions provided in the Commission's regulations. Consequently, neither an environmental impact statement nor an environmental assessment is required.[66]

VI. Information Collection Statement

The Office of Management and Budget's (OMB) regulations require that OMB approve certain information collection requirements imposed by agency rule.[67] However, this proposed rule contains no information collection requirements and therefore is not subject to OMB approval.

VII. Effective Date

Public Systems requested the Commission to make the final rule effective immediately, rather than 30 days after publication in the **Federal Register**. Pursuant to 5 U.S.C. 553(d)(1), Public Systems noted that a rule that grants an exemption may be placed into immediate effect. Public Systems argued that the Commission's rule would exempt certain filings from fees and that significant savings may be effected if filing fees can be eliminated by year's end. According to Public Systems, parties can begin their transactions in the new year with considerably more flexibility and without the anti-competitive impediments created by the present regulation.[68]

The Commission will make this rule immediately effective on the date of issuance. The Commission is eliminating a regulatory burden in the form of filing fees and does not foresee that those affected by the change will need time to make adjustments to comply with this rule.

This final rule, therefore, is effective January 4, 1993.

List of Subjects

18 CFR Part 346

Pipelines, Reporting and recordkeeping requirements.

18 CFR Part 381

Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission is amending parts 346 and 381, chapter I, title 18, Code of Federal Regulations, as set forth below.

By the Commission. Commissioner Langdon dissented with a separate statement attached.

Lois D. Cashell,

Secretary.

PART 346—FEES

1. Part 346 is removed in its entirety.

PART 381—FEES

2. The authority citation for Part 381 is revised to read as follows:

Authority: 15 U.S.C. 717–717w; 16 U.S.C. 791–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; and 49 U.S.C. 1–27.

3. In § 381.104, paragraph (c) is revised to read as follows:

§ 381.104 Annual adjustment of fees.

* * * * *

(c) *Formula.* (1) Except as provided in paragraph (c)(2) of this section, the formula for determining each fee is the workmonths dedicated to the given fee category for the six fiscal years 1987 through 1992 or all years prior to FY 93 for which data are available divided by the number of actual completions in the six fiscal years 1987 through 1992 or all years prior to FY 93 for which data are available multiplied by the average monthly employee cost in the most recent fiscal year for which data are available.

(2) With respect to the fees charged to pipelines filing pursuant to § 381.207(a), the fee for the first year will be $1,000. The formula for the fee in future years will be the workmonths from the immediately prior year divided by the number of actual completions in that year multiplied by the average monthly employee cost in the most recent fiscal year for which data are available. With the addition of future years, the formula for § 381.207(a) fees will be updated to include that year as part of the base period.

* * * * *

4. In § 381.107, paragraph (a) is revised to read as follows:

§ 381.107 Direct billing.

(a) *Applicability.* If a filing presents an issue of fact, law, policy, procedural difficulty, or technical complexity that requires an extraordinary amount of expense to process, the Commission may institute a direct billing procedure for the direct and indirect costs of processing that filing. The Commission will make a direct billing determination under this paragraph not later than one year after receiving a complete filing from an applicant.

* * * * *

5. Sections 381.201 through 381.206 are removed, §§ 381.207(a) and (b) are revised, §§ 381.208, 381.209, 381.301, and 381.401 are removed, § 381.404 is revised, §§ 381.405, 381.502 through 381.504, and 381.506 through 381.512, are removed to read as follows:

§ 381.207 Pipeline certificate applications.

(a) *Definition.* For purposes of this section, "pipeline certificate application" means any application for authorization or exemption, any substantial amendment to such an application, and any application, other than an application for a temporary certificate, for authorization to amend an outstanding authorization or exemption, by any person, made pursuant to section 7(c) of the Natural Gas Act filed in accordance with § 284.224 of this chapter.

(b) *Fee.* Unless the Commission orders direct billing under § 381.107 or otherwise, the fee established for a blanket certificate application is $1,000. The fee filed under this paragraph must be submitted in accordance with § 284.224 of this chapter.

* * * * *

§ 381.404 Initial or extension reports for Title III transactions.

The fee established for an initial or extension report is $120. The fee must be submitted in accordance with subpart A of this part and §§ 284.126(c), 284.148(e), and 284.165(d).

Note: The following Appendix will not be published in the Code of Federal Regulations.

Appendix—Commenters

1. Arizona Public Service Company.
2. Arkla Energy Resources and Mississippi River Transmission Corporation (filed joint comments).
3. ANR Pipeline Company and Colorado Interstate Gas Company.
4. Columbia Gas Transmission Corporation and Columbia Gulf Transmission Company.
5. Commonwealth Edison Company.
6. Edison Electric Institute.
7. El Paso Natural Gas Company.
8. Enron Interstate Pipelines (consisting of Northern Natural Gas Company, Transwestern Pipeline Company and Florida Gas Transmission Company).
9. Florida Power & Light Company.
10. Green Mountain Power Corporation.
11. Iowa-Illinois Gas and Electric Company.
12. JMC Power Projects (consisting of Ocean State Power, Ocean State Power II,

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[65] See Order No. 486, 52 FR 47897 (Dec. 17, 1987), FERC Stats. & Regs., Regulations Preambles 1986–1990 ¶ 30,783 (Dec. 10, 1987) (codified at 18 CFR Part 380).

[66] See 18 CFR 380.4(a)(1).

[67] 5 CFR part 1320.

[68] Public Systems at 6.

Selkirk Cogen Partners, L.P., and MASSPOWER).

13. National Fuel Gas Supply Corporation.

14. New England Power Company.

15. Northern Distributor Group (consisting of the Great Plains Natural Gas Company, Interstate Power Company, Iowa Electric Light & Power Company, Iowa Southern Utilities Company, Metropolitan Utilities District of Omaha, Michigan Gas Company, Midwest Gas, a division of Midwest Power Systems, Inc., Northern Minnesota Utilities, Northern States Power Company (Minnesota), Northern States Power Company (Wisconsin), Northwestern Public Service Company, Peoples Natural Gas Company, Division of UtiliCorp, Inc., Wisconsin Gas Company, and Wisconsin Power & Light Company).

16. Pacific Gas Transmission Company.

17. Philadelphia Electric Company.

18. Public Systems (consisting of the American Public Power Association, Belmont, Massachusetts Municipal Light Department, the City of Burlington, Vermont Electric Light Department, the Connecticut Municipal Electric Energy Cooperative, the Florida Municipal Power Agency, the Indiana Municipal Power Agency, the Massachusetts Municipal Wholesale Electric Company, the Michigan Municipal Cooperative Group, the Northern California Power Agency, the City Utilities of Springfield, Missouri, the City of Westfield, Massachusetts Gas and Electric Department, and the City of Riverside, California).

19. Tennessee Gas Pipeline Company.

20. Texas Eastern Transmission Corporation, Panhandle Eastern Pipe Line Company, Trunkline Gas Company, and Algonquin Gas Transmission Company (the "PEC Pipeline Group") (filed joint comments).

21. Transok, Inc. and Transok Gas Transmission Company.

22. UtiliCorp United Inc.

23. Washington Water Power.

24. Williston Basin Interstate Pipeline Company.

Elimination of Certain Filing Fees in Parts 346 and 381

[Docket No. RM92-17-000]

Issued January 4, 1993.

Jerry J. Langdon, Commissioner, *dissenting.*

In light of the many negative comments received in response to the NOPR in this Docket, I will dissent from this order's departure from the time-honored principle of "cost responsibility stems from cost incurrence." In my concurrence to the NOPR, I noted that we were well down the road toward this departure by already having a large portion of our budget be recovered through annual charges. Nevertheless, I still believe that, despite the small percentage of our revenue that it recovers, the filing fee structure has multiple benefits.

Filing fees force parties to make more complete filings at the Commission. For example, rather than piecemealing tariff provision changes through the soon-to-be cost-free filing process, a pipeline, under our current provisions, has an incentive to put these provisions together into a rate case.[1] This allows its customers and the Commission to view the issues more globally.

In addition, individual filing fees are good indications to parties about the relative amount of Commission effort needed to process an application. This Final Rule would limit such instances to extraordinary direct bill situations.

Also, filing fees are a good check on our own efficiency. By having our employees allocate their time to projects (much as a law firm does for its lawyers), we have a useful way of tracking employee efficiency, if necessary. By having filing fees, the ratepaying public can look over our shoulder to see how we're doing.

The statutory language relied upon in this order to support a further move away from filing fees is selectively quoted. A review of the statute reveals that both fees and annual charges were envisioned. I see no reason to eliminate them altogether here; the statute, certainly, does not require it.

In response to the NOPR, some parties complained about the seeming inadequacy of the present filing fee structure to accommodate various levels of complexity within filings. This should be addressed by *reforming* the filing fee structure, not by eliminating it!

I am pleased that parties responded to the concerns I raised in my NOPR concurring statement about problems with the ACA charge, particularly in multiple pipeline transactions. I welcome the Commission's decision to examine this issue in the near future through a Notice of Inquiry. In my review of the legislative history of the statute, I discovered that this precise point was of concern to its drafters.

This Final Rule is a step backward from our progress toward implementing "good government" procedures at the Commission; therefore, I will dissent from its issuance.

Jerry J. Langdon,

Commissioner.

[FR Doc. 93-286 Filed 1-6-93; 8:45 am]

BILLING CODE 6717-01-M

[1] The order mistakenly views the arguments in this vein as asserting that such filings will be "frivolous." *Mimeo* at page 11. Although I suppose they could be "frivolous," piecemealed filings are not necessarily so by definition.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 89F-0115]

Indirect Food Additives; Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the additional use of Nylon 12 in coatings for repeated use in contact with food. This action responds to a petition filed by Huls America, Inc.

DATES: Effective January 7, 1993; written objections and requests for a hearing by February 8, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9500.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 10, 1989 (54 FR 20203), FDA announced that a food additive petition (FAP 9B4137) had been filed by Huls America, Inc., 80 Centennial Ave., Piscataway, NJ 08855-0456, proposing that § 177.1500 *Nylon resins* (21 CFR 177.1500) be amended to provide for the additional use of Nylon 12 in coatings intended for repeated use in contact with food.

FDA has evaluated data in the petition and other relevant material and concludes that the proposed use of the food additive is safe. The agency further concludes that § 177.1500 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of

this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the* **Federal Register**), file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 177.1500 is amended in the table in paragraph (b) by revising entry "9" in the first column under the heading "Nylon resins" to read as follows. The text under the remaining headings is unchanged.

§ 177.1500 *Nylons resins.*

* * * * *

(b)

Nylon resins	Specific gravity	Melting point (degrees Fahrenheit)	Solubility in boiling 4.2*N* HCl	Viscosity No. (mL/g)	Maximum extractable fraction in selected solvents (expressed in percent by weight of resin)			
					Water	95 percent ethyl alcohol	Ethyl acetate	Benzene
9. Nylon 12 resins for use only:	.....	.....	.....	.....	.....	.....	.....	.....
a. In food-contact films having an average thickness not to exceed 0.0016 inch intended for use in contact with nonalcoholic food under the conditions of use A (sterilization not to exceed 30 minutes at a temperature not to exceed 250° F), and B through H of Table 2 of § 176.170(c) of this chapter, except as provided in § 177.1390(d)..	.....	.....	.....	.....	.....	.....	.....	.....
b. In coatings intended for repeated use in contact with all food types described in Table 1 of § 176.170(c) of this chapter, except those containing more than 8 percent alcohol, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter..	.....	.....	.....	.....	.....	.....	.....	.....

* * * * *

Dated: December 15, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–240 Filed 1–6–93; 8:45 am]

BILLING CODE 4160–01–F

PEACE CORPS

22 CFR Part 309

Claims Collection

AGENCY: Peace Corps of the United States (Peace Corps).

ACTION: Final rule.

SUMMARY: The Peace Corps revises its regulations regarding the Collection of Claims by Administrative Offset. These changes are made to enhance Peace Corps' ability to collect its debts by providing guidance to officers and employees charged with debt collection responsibilities. The rule implements the collection procedures authorized by the Federal Claims Collection Act of 1966, as amended by the Debt Collection Act of 1982 (31 U.S.C. 3701–3719 and 5 U.S.C. 5514) (Pub. L. 97–365, 96 Stat. 1749). In addition, the rule implements 31 U.S.C. 3720A, which authorizes Federal agencies to notify the Internal Revenue Service of a past-due legally enforceable debt for the purpose of offsetting the debtor's tax refund. These laws have been implemented by the Federal Claims Collection Standards issued jointly by the General Accounting Office and the Department

of Justice, regulations issued by the Office of Personnel Management, the procedures prescribed by the Office of Management and Budget in Circular A–129, and by the Internal Revenue Service procedures.

On November 24, 1992, the Peace Corps published for comment in the **Federal Register** a proposed regulation for claims collection, 57 FR 55202–55212. Interested parties were invited to submit comments within 30 days. The Peace Corps received no comments by the deadline of December 24, 1992. Except for some editorial changes, the final rule is the same as the proposed regulation.

EFFECTIVE DATE: January 7, 1993.

FOR FURTHER INFORMATION CONTACT: Stephen Rademaker, Peace Corps General Counsel, or Daniel Bosco, Assistant General Counsel at (202) 606–3114 (Voice) or (202) 606–1313 (TDD).

SUPPLEMENTARY INFORMATION: The Debt Collection Act of 1982 authorizes procedures for the collection of debts owed to the United States including: (1) Salary offset, (2) administrative offset, (3) contracting for collection services to recover debts. In addition, section 3720A of title 31 U.S.C. authorizes agencies to notify the Internal Revenue Service of a past-due legally enforceable debt for the purpose of offsetting the debtor's tax refund. Although these are separate procedures, any procedure may be used by itself or in conjunction with other procedures.

Salary Offset. Section 5 of the Debt Collection Act (codified at 5 U.S.C. 5514) establishes the procedures to be used when an agency collects money owed it by offsetting the salary of a federal employee. Agencies of the Government may cooperate with one another in order to effectuate recovery of the claim. Salary offset procedures permit an employee to review the determination of indebtedness before offset is implemented, and an employee against whom an offset is sought is automatically entitled to a hearing on matters surrounding the determination of the debt, or the percentage of disposable pay to be deducted each pay period.

Administrative Offset. The procedures authorized for administrative offset are contained in section 10 of the Debt Collection Act (codified at 31 U.S.C. 3716). The Act requires that notice procedures be observed by the agency. The debtor is also afforded an opportunity to inspect and copy government records pertaining to the claim, enter into an agreement for repayment, and to a review of the claim (if requested). Like salary offset, agencies may cooperate with one another in order to effectuate recovery of the claim.

Collection Services. Section 13 of the Debt Collection Act (codified at 31 U.S.C. 3718) authorizes agencies to enter into contracts for the collection services to recover debts owed the United States. The Act requires that certain provisions be contained in such contracts including:

(1) The agency retains the authority to resolve a dispute, including the authority to terminate a collection action or refer the matter to the Attorney General for civil remedies; and

(2) The contractor is subject to the Privacy Act of 1974, as it applies to private contractors, as well as subject to State and Federal laws governing debt collection practices.

Tax Refund Offset. Title 31 U.S.C. 3720A authorizes the Internal Revenue Service (IRS) to reduce a refund of a taxpayer's overpayment of tax by the amount of any legally enforceable debt which is owed to a Federal agency and is at least three months overdue. This section also requires the agency to give taxpayer-debtors at least 60 days notice of the agency's intention to use the provisions of this section. Under this authority, the Peace Corps may refer to the IRS for collection by tax refund offset from refunds otherwise payable, past-due legally enforceable debts owed to the Peace Corps if: (i) the debts are eligible for offset pursuant to 31 U.S.C. 3720A, section 6402(d) of the Internal Revenue Code, 26 CFR 301.6420T, and the agreement between the Peace Corps and the IRS, and (ii) the Peace Corps provides the information required by the agreement for each debt.

Executive Order 12291

This rule is not a "major rule" as defined under Executive Order 12291 because it will not result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographical regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, no regulatory impact analysis is required.

Regulatory Flexibility Act of 1980

The Director of the Peace Corps certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. The economic impact of the rule is expected to be minimal. In this regard, measures would be triggered only by a failure to pay debts owed the United States and, therefore, are avoidable. Peace Corps has no reason to believe that small entities, in particular, would be seriously effected by this rule.

Paperwork Reduction Act of 1980

In accordance with the Paperwork Reduction Act (Pub. L. 96.511, 44 U.S.C. Chapter 35), any reporting or recordkeeping provisions that are included in this rule will be submitted for approval to the Office of Management and Budget (OMB).

Environmental Impact

This rule does not require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321, *et seq.*), because it is not a major Federal action significantly affecting the quality of the human environment.

Executive Order 12778

This final rule has been reviewed under the principles set forth in section 2 of Executive Order 12778 (56 FR 55195) on Civil Justice Reform. The Peace Corps has determined that this rule meets the applicable standards of section 2 of Executive Order 12778.

List of Subjects in 22 CFR Part 309

Administrative practice and procedure, Claims collection, Government employees, Salary offset, Tax refund offset, Volunteers, and Trainees.

Accordingly, the Peace Corps hereby amends title 22 of the Code of Federal Regulations chapter III by revising part 309 to read as follows:

PART 309—CLAIMS COLLECTION

Subpart A—General Provisions

Sec.

309.1 General purpose.
309.2 Scope.
309.3 Definitions.
309.4 Interest, penalties, and administrative costs.
309.5 Designation.

Subpart B—Salary Offset

309.6 Purpose.
309.7 Scope.
309.8 Applicability of regulations.
309.9 Waiver requests and claims to the General Accounting Office.
309.10 Notice requirements before offset.
309.11 Review.
309.12 Certification.
309.13 Voluntary repayment agreements as an alternative to salary offset.
309.14 Special review.

309.15 Notice of salary offset.
309.16 Procedures for salary offset.
309.17 Coordinating salary offset with other agencies.
309.18 Interest, penalties and administrative costs.
309.19 Refunds.
309.20 Request for the services of a hearing official from the creditor agency.
309.21 Non-waiver of rights by payments.

Subpart C—Tax Refund Offset

309.22 Applicability and scope.
309.23 Past-due legally enforceable debt.
309.24 Definitions.
309.25 Peace Corps participation in the IRS tax refund offset program.
309.26 Procedures.
309.27 Referral of debts for offset.
309.28 Notice requirements before offset.

Subpart D—Administrative Offset

309.29 Applicability and scope.
309.30 Definitions.
309.31 General.
309.32 Demand for payment—notice.
309.33 Debtor's failure to respond.
309.34 Agency review.
309.35 Hearing.
309.36 Written agreement for repayment.
309.37 Administrative offset procedures.
309.38 Civil and Foreign Service Retirement Fund.
309.39 Jeopardy procedure.

Subpart E—Use of Consumer Reporting Agencies and Referrals to Collection Agencies

309.40 Use of consumer reporting agencies.
309.41 Referrals to collection agencies.

Subpart F—Compromise, Suspension or Termination and Referral of Claims

309.42 Compromise.
309.43 Suspending or terminating collection.
309.44 Referral of claims.

Authority: 31 U.S.C. 3701–3719; 5 U.S.C. 5514; 22 U.S.C. 2503(b); 31 U.S.C. 3720A; 4 CFR parts 101–105; 5 CFR part 550; 26 CFR 301.6402–6T.

Subpart A—General Provisions

§ 309.1 General purpose.

This part prescribes the procedures to be used by the Peace Corps of the United States (Peace Corps) in the collection of claims owed to Peace Corps and to the United States.

§ 309.2 Scope.

(a) Applicability of Federal Claims Collection Standards (FCCS). Except as set forth in this part or otherwise provided by law, Peace Corps will conduct administrative actions to collect claims (including offset, compromise, suspension, termination, disclosure and referral) in accordance with the Federal Claims Collection Standards of the General Accounting Office and the Department of Justice, 4 CFR parts 101 through 105.

(b) This part is not applicable to: (1) Claims against any foreign country or any political subdivision thereof, or any public international organization.

(2) Claims where the Peace Corps Director (or designee) determines that the achievement of the purposes of the Peace Corps Act, as amended, 22 U.S.C. 2501 *et seq.*, or any other provision of law administered by the Peace Corps require a different course of action.

§ 309.3 Definitions.

As used in this part (except where the context clearly indicates, or where the term is otherwise defined elsewhere in this part) the following definitions shall apply:

(a) *Agency* means: (1) An Executive Agency as defined by section 105 of title 5, United States Code, including the U.S. Postal Service and the U.S. Postal Rate Commission;

(2) A military department as defined by section 102 of title 5, United States Code.

(3) An agency or court of the judicial branch including a court as defined in section 610 of title 28, United States Code, the District Court for the Northern Mariana Islands and the Judicial Panel on Multidistrict Litigation;

(4) An agency of the legislative branch, including the U.S. Senate and the U.S. House of Representatives; and

(5) Other independent establishments that are entities of the Federal Government.

(b) *Certification* means a written debt claim form received from a creditor agency which requests the paying agency to offset the salary of an employee.

(c) *Consumer reporting agency* means a reporting agency as defined in 31 U.S.C. 3701(a)(3).

(d) *Creditor agency* means the agency to which the debt is owed.

(e) The term *debt and claim* refers to an amount of money or property which has been determined by an appropriate agency official to be owed to the United States from any person, organization or entity, except another Federal agency. A debtor's liability arising from a particular contract or transaction shall be considered a single claim for purposes of monetary ceilings of the FCCS.

(f) *Delinquent debt* means any debt which has not been paid by the date specified by the Government in writing or in an applicable contractual agreement for payment or which has not been satisfied in accordance with a repayment agreement.

(g) *Disposable pay* means that part of current basic pay, special pay, incentive pay, retired pay, retainer pay, or, in the case of an employee not entitled to basic pay, other authorized pay remaining after the deduction of any amount required by law to be withheld. These deductions are described in 5 CFR 581.105(b) through (f). These deductions include, but are not limited to: Social Security withholdings; Federal, State and local tax withholdings; retirement contributions; and life insurance premiums.

(h) *Employee* means a current or former employee of the Peace Corps or other agency, including a member of the Armed Forces or Reserve of the Armed Forces of the United States.

(i) *FCCS* means the Federal Claims Collection Standards jointly published by the Department of Justice and the General Accounting Office at 4 CFR parts 101 through 105.

(j) *Hearing official* means an individual responsible for conducting any hearing with respect to the existence or amount of a debt claimed, and rendering a decision on the basis of such hearing. Except in the case of an administrative law judge, a hearing official may not be under the supervision or control of the Peace Corps when the Peace Corps is the creditor agency.

(k) *Paying agency* means the agency which employs the individual and authorizes the payment of his or her current pay. In some cases, the Peace Corps may be both the creditor and the paying agency.

(l) *Notice of intent to offset* or *notice of intent* means a written notice from a creditor agency to an employee which alleges that the employee owes a debt to the creditor agency and apprising the employee of certain administrative rights.

(m) *Notice of salary offset* means a written notice from the paying agency to an employee after a certification has been issued by a creditor agency, informing the employee that salary offset will begin at the next officially established pay interval.

(n) *Payroll office* means the payroll office in the paying agency which is primarily responsible for the payroll records and the coordination of pay matters with the appropriate personnel office with respect to an employee.

(o) *Salary offset* means an administrative offset to collect a debt under 5 U.S.C. 5514 by deduction at one or more officially established pay intervals from the current pay account of an employee, without the employee's consent.

(p) *Salary Offset Coordination Officer* means an official designated by the Director who is responsible for

coordinating debt collection activities for the Peace Corps.

(q) *Waiver* means the cancellation, remission, forgiveness, or nonrecovery of a debt or debt related charge as permitted or required by law.

§ 309.4 Interest, penalties, and administrative costs.

(a) Except as otherwise provided by statute, contract or excluded in accordance with FCCS, Peace Corps will assess:

(1) Interest on unpaid claims in accordance with existing Treasury rules and regulations, unless the agency determines that a higher rate is necessary to protect the interests of the United States.

(2) Penalty charges at a rate of 6 percent a year on any portion of a claim that is delinquent for more than 90 days.

(3) Administrative charges to cover the costs of processing and handling the debt beyond the payment due date.

(b) Late payment charges shall be computed from the date of mailing or hand delivery of the notice of the claim and interest requirements.

(c) When a debt is paid in partial or installment payments, amounts received shall be applied first to outstanding penalty and administrative cost charges, second to accrued interest, and then to outstanding principal.

(d) Waiver. Peace Corps will consider waiver of interest, penalties and/or administrative costs in accordance with the FCCS, 4 CFR 102.13(g).

§ 309.5 Designation.

The Chief Financial Officer and his or her delegates, or any person discharging the functions presently vested in the Chief Financial Officer, are designated to perform all the duties for which the Director is responsible under the foregoing statutes and Joint Regulations: Provided, however, That no compromise of a claim shall be effected or collection action terminated except with the concurrence of the General Counsel. No such concurrence shall be required with respect to the compromise or termination of collection activity on any claim in which the unpaid amount of the debt is $300 or less.

Subpart B—Salary Offset

§ 309.6 Purpose.

The purpose of the Debt Collection Act of 1982 (Pub. L. 97–365), is to provide a comprehensive statutory approach to the collection of debts due the United States Government. This subpart implements section 5 thereof which authorizes the collection of debts owed by Federal employees to the Federal Government by means of salary offsets. No claim may be collected by salary offset if the debt has been outstanding for more than 10 years after the agency's right to collect the debt first accrued, unless facts material to the Government's right to collect were not known and could not reasonably have been known by the official or officials who were charged with the responsibility for discovery and collection of such debts.

§ 309.7 Scope.

(a) This subpart provides Peace Corps' procedures for the collection by salary offset of a Federal employee's pay to satisfy certain past due debts owed the United States Government.

(b) This subpart applies to collections by the Peace Corps from:

(1) Federal employees who owe debts to the Peace Corps; and

(2) Employees of the Peace Corps who owe debts to other agencies.

(c) This subpart does not apply to debts or claims arising under the Internal Revenue Code of 1954, as amended (26 U.S.C. 1 *et seq.*); the Social Security Act (42 U.S.C. 301 *et seq.*); the tariff laws of the United States; or to any case where collection of a debt by salary offset is explicitly provided for or prohibited by another statute (e.g., travel advances in 5 U.S.C. 5705 and employee training expenses in 5 U.S.C. 4108).

(d) This subpart does not apply to any adjustment to pay arising out of an employee's election of coverage or a change in coverage under a Federal benefits program requiring periodic deductions from pay, if the amount to be recovered was accumulated over four pay periods or less.

(e) Nothing in this subpart precludes the compromise, suspension, or termination of collection actions where appropriate under the standards implementing the Federal Claims Collection Act (31 U.S.C. 3711 *et seq.*; 4 CFR parts 101 through 105).

§ 309.8 Applicability of regulations.

The provisions of this subpart are to be followed in instances where:

(a) The Peace Corps is owed a debt by an individual currently employed by another agency;

(b) The Peace Corps is owed a debt by an individual who is a current employee of the Peace Corps; or

(c) The Peace Corps currently employs an individual who owes a debt to another Federal agency. Upon receipt of proper certification from the creditor agency, the Peace Corps will offset the debtor-employee's salary in accordance with these regulations.

§ 309.9 Waiver requests and claims to the General Accounting Office.

The provisions of this subpart do not preclude an employee from requesting waiver of an overpayment under 5 U.S.C. 5584 or 8346(b), 10 U.S.C. 2774, 32 U.S.C. 716, or in any way questioning the amount or validity of a debt by submitting a subsequent claim to the General Accounting Office in accordance with the procedures prescribed by the General Accounting Office. This subpart also does not preclude an employee from requesting a waiver pursuant to other statutory provisions pertaining to the particular debts being collected.

§ 309.10 Notice requirements before offset.

(a) Deductions under the authority of 5 U.S.C. 5514 shall not be made unless the creditor agency first provides the employee with written notice that he/she owes a debt to the Federal Government at least 30 calendar days before salary offset is to be initiated. When Peace Corps is the creditor agency this notice of intent to offset an employee's salary shall be hand-delivered or sent by certified mail to the most current address that is available. The written notice will state:

(1) That Peace Corps has reviewed the records relating to the claim and has determined that a debt is owed, its origin and nature, and the amount of the debt;

(2) The intention of Peace Corps to collect the debt by means of deduction from the employee's current disposable pay account until the debt and all accumulated interest is paid in full;

(3) The amount, frequency, approximate beginning date, and duration of the intended deductions;

(4) An explanation of the Peace Corps' policy concerning interest, penalties and administrative costs, including a statement that such assessments must be made unless excused in accordance with § 309.4(d);

(5) The employee's right to inspect and copy all records of the Peace Corps pertaining to the debt claimed or to receive copies of such records if personal inspection is impractical;

(6) The right to a hearing conducted by a hearing official (an administrative law judge, or alternatively, a hearing official not under the supervision or control of the Peace Corps) with respect to the existence and amount of the debt claimed, or the repayment schedule (i.e., the percentage of disposable pay to be deducted each pay period), so long as a petition is filed by the employee as prescribed in § 309.11;

(7) If not previously provided, the opportunity (under terms agreeable to the Peace Corps) to establish a schedule for the voluntary repayment of the debt or to enter into a written agreement to establish a schedule for repayment of the debt in lieu of offset. The agreement must be in writing, signed by both the employee and the creditor agency (4 CFR 102.2(e));

(8) The name, address and telephone number of an officer or employee of the Peace Corps who may be contacted concerning procedures for requesting a hearing;

(9) The method and time period for requesting a hearing;

(10) That the timely filing of a petition for hearing within 15 calendar days after delivery of the notice of intent to offset will stay the commencement of collection proceedings;

(11) The name and address of the office to which the petition should be sent;

(12) That the Peace Corps will initiate certification procedures to implement a salary offset, as appropriate, (which may not exceed 15 percent of the employee's disposable pay) not less than 30 calendar days from the date of delivery of the notice of debt, unless the employee files a timely petition for a hearing;

(13) That a final decision on the hearing (if one is requested) will be issued at the earliest practical date, but not later than 60 calendar days after the filing of the petition requesting the hearing, unless the employee requests and the hearing official grants a delay in the proceedings;

(14) That any knowingly false or frivolous statements, representations or evidence may subject the employee to:

(i) Disciplinary procedures appropriate under chapter 75 of 5 U.S.C., 5 CFR 752, or any other applicable statutes or regulations;

(ii) Penalties under the False Claims Act, §§ 3729–3731 of title 31, United States Code, or any other applicable statutory authority; and

(iii) Criminal penalties under 18 U.S.C. sections 286, 287, 1001, and 1002 or any other applicable authority;

(15) Any other rights and remedies available to the employee under statutes or regulations governing the program for which the collection is being made;

(16) That unless there are applicable contractual or statutory provisions to the contrary, amounts paid on or deducted for the debt which are later waived or found not owed to the United States will be promptly refunded to the employee; and

(17) That proceedings with respect to such debt are governed by section 5 of the Debt Collection Act of 1982 (5 U.S.C. 5514).

(b) The Peace Corps is not required to comply with paragraph (a) of this section for any adjustment to pay arising out of an employee's election of coverage or a change in coverage under a Federal benefits program requiring periodic deductions from pay if the amount to be recovered was accumulated over four pay periods or less.

§ 309.11 Review.

(a) *Request for review.* Except as provided in paragraph (b) of this section, an employee who desires a review concerning the existence or amount of the debt or the proposed offset schedule must send a request to the office designated in the notice of intent. See § 309.10(a)(8). The request for review must be received by the designated office not later than 15 calendar days after the date of delivery of the notice as provided in § 309.10(a). The request must be signed by the employee and should identify and explain with reasonable specificity and brevity the facts, evidence and witnesses which the employee believes support his or her position. If the employee objects to the percentage of disposable pay to be deducted from each check, the request should state the objection and the reasons for it. The employee must also specify whether an oral hearing or a review of the documentary evidence is requested. If an oral hearing is desired, the request should explain why the matter cannot be resolved by review of the documentary evidence alone.

(b) *Failure to timely submit.*

(1) If the employee files a petition for a review after the expiration of the 15 calendar day period provided for in paragraph (a) of this section, the designated office may accept the request if the employee can show that the delay was the result of circumstances beyond his or her control, or because of a failure to receive the notice of the filing deadline (unless the employee has actual knowledge of the filing deadline).

(2) An employee waives the right to a review, and will have his or her disposable pay offset in accordance with Peace Corps' offset schedule, if the employee fails to file a request for a hearing unless such failure is excused as provided in paragraph (b)(1) of this section.

(3) If the employee fails to appear at an oral hearing of which he or she was notified, unless the hearing official determines failure to appear was due to circumstances beyond the employee's control, his or her appeal will be decided on the basis of the documents then available to the hearing official.

(c) *Representation at the hearing.* The creditor agency may be represented by a representative of its choice. The employee may represent himself or herself or may be represented by an individual of his or her choice and at his or her expense.

(d) *Review of Peace Corps records related to the debt.*

(1) An employee who intends to inspect or copy creditor agency records related to the debt in accordance with § 309.10(a)(5), must send a letter to the official designated in the notice of intent to offset stating his or her intention. The letter must be sent within 15 calendar days after receipt of the notice.

(2) In response to a timely request submitted by the debtor, the designated official will notify the employee of the location and time when the employee may inspect and copy records related to the debt.

(3) If personal inspection is impractical, copies of such records shall be sent to the employee.

(e) *Hearing official.* Unless the Peace Corps appoints an administrative law judge to conduct the hearing, the Peace Corps must obtain a hearing official who is not under the supervision or control of the Peace Corps.

(f) *Obtaining the services of a hearing official when the Peace Corps is the creditor agency.*

(1) When the debtor is not a Peace Corps employee, and in the event that the Peace Corps cannot provide a prompt and appropriate hearing before an administrative law judge or before a hearing official furnished pursuant to another lawful arrangement, the Peace Corps may contact an agent of the paying agency designated in appendix A to part 581 of title 5, Code of Federal Regulations or as otherwise designated by the agency, and request a hearing official.

(2) When the debtor is a Peace Corps employee, the Peace Corps may contact any agent of another agency designated in appendix A to part 581 of title 5, Code of Federal Regulations or otherwise designated by that agency, to request a hearing official.

(g) *Procedure.* (1) If the employee requests a review, the hearing official or administrative law judge shall notify the employee of the form of the review to be provided. If an oral hearing is authorized, the notice shall set forth the date, time and location of the hearing. If the review will be on documentary evidence, the employee shall be notified that he or she should submit arguments in writing to the hearing official or administrative law judge by a specified

date, after which the record will be closed. This date shall give the employee reasonable time (not less than 14 calendar days) to submit documentation.

(2) *Oral hearing.* An employee who requests an oral hearing shall be provided an oral hearing if the hearing official or administrative law judge determines that the matter cannot be resolved by review of documentary evidence alone (e.g. when an issue of credibility or veracity is involved). The hearing is not an adversarial adjudication, and need not take the form of an evidentiary hearing. Oral hearings may take the form of, but are not limited to:

(i) Informal conferences with the hearing official or administrative law judge, in which the employee and agency representative will be given full opportunity to present evidence, witnesses and argument;

(ii) Informal meetings with an interview of the employee; or

(iii) Formal written submissions, with an opportunity for oral presentation.

(3) *Paper review.* If the hearing official or administrative law judge determines that an oral hearing is not necessary, he or she will make the determination based upon a review of the available written record.

(4) *Record.* The hearing official must maintain a summary record of any hearing provided by this subpart. See 4 CFR 102.3. Witnesses who testify in oral hearings will do so under oath or affirmation.

(h) *Date of decision.* The hearing official or administrative law judge shall issue a written opinion stating his or her decision, based upon documentary evidence and information developed at the hearing, as soon as practicable after the hearing, but not later than 60 calendar days after the date on which the petition was received by the creditor agency, unless the employee requests a delay in the proceedings. In such case the 60 day decision period shall be extended by the number of days by which the hearing was postponed.

(i) *Content of decision.* The written decision shall include:

(1) A statement of the facts presented to support the origin, nature, and amount of the debt;

(2) The hearing official's findings, analysis and conclusions; and

(3) The terms of any repayment schedules, if applicable.

(j) *Failure to appear.* In the absence of good cause shown (e.g., excused illness), an employee who fails to appear at a hearing shall be deemed, for the purpose of this subpart, to admit the existence and amount of the debt as described in the notice of intent. If the representative of the creditor agency fails to appear, the hearing official shall schedule a new hearing date upon the request of the agency representative upon showing of good cause. Both parties shall be given the time and place of the new hearing.

§ 309.12 Certification.

(a) The Peace Corps salary offset coordination officer shall provide a certification to the paying agency in all cases where:

(1) The hearing official determines that a debt exists;

(2) The employee admits the existence and amount of the debt by failing to request a review; or

(3) The employee admits the existence of the debt by failing to appear at a hearing.

(b) The certification must be in writing and must state:

(1) That the employee owes the debt;

(2) The amount and basis of the debt;

(3) The date the Government's right to collect the debt first accrued;

(4) That the Peace Corps' regulations have been approved by OPM pursuant to 5 CFR part 550, subpart K;

(5) The amount and date of any lump sum payment;

(6) If the collection is to be made in installments, the number of installments to be collected, the amount of each installment, and the date of the first installment, if a date other than the next officially established pay period is required; and

(7) The date the action was taken and that it was taken pursuant to 5 U.S.C. 5514.

§ 309.13 Voluntary repayment agreements as alternative to salary offset.

(a) In response to a notice of intent, an employee may propose a written agreement to repay the debt as an alternative to salary offset. Any employee who wishes to repay a debt without salary offset shall submit in writing a proposed agreement to repay the debt. The proposal shall admit the existence of the debt and set forth a proposed repayment schedule. Any proposal under this paragraph must be received by the official designated in that notice within 15 calendar days after receipt of the notice of intent.

(b) When the Peace Corps is the creditor agency, in response to a timely proposal by the debtor the agency will notify the employee whether the employee's proposed written agreement for repayment is acceptable. It is within the agency's discretion to accept a repayment agreement instead of proceeding by offset.

(c) If the Peace Corps decides that the proposed repayment agreement is unacceptable, the employee will have 15 calendar days from the date he or she received notice of the decision to file a petition for a review.

(d) If the Peace Corps decides that the proposed repayment agreement is acceptable, the alternative arrangement must be in writing and signed by both the employee and a designated agency official.

§ 309.14 Special review.

(a) An employee subject to salary offset or a voluntary repayment agreement, may at any time request a special review by the creditor agency of the amount of the salary offset or voluntary payment, based on materially changed circumstances such as, but not limited to, catastrophic illness, divorce, death, or disability.

(b) In determining whether an offset would prevent the employee from meeting essential subsistence expenses (costs for food, housing, clothing, transportation and medical care), the employee shall submit a detailed statement and supporting documents for the employee, his or her spouse and dependents indicating:

(1) Income from all sources;

(2) Assets;

(3) Liabilities;

(4) Number of dependents;

(5) Expenses for food, housing, clothing and transportation;

(6) Medical expenses; and

(7) Exceptional expenses, if any.

(c) If the employee requests a special review under this section, the employee shall file an alternative proposed offset or payment schedule and a statement, with supporting documents, showing why the current salary offset or payments result in significant financial hardship to the employee.

(d) The Peace Corps shall evaluate the statement and supporting documents, and determine whether the original offset or repayment schedule imposes significant financial hardship on the employee. The Peace Corps shall notify the employee in writing of such determination, including, if appropriate, a revised offset or payment schedule.

(e) If the special review results in a revised offset or repayment schedule, the Peace Corps salary offset coordination officer shall provide a new certification to the paying agency.

§ 309.15 Notice of salary offset.

(a) Upon receipt of proper certification of the creditor agency, the Peace Corps payroll office will send the employee a written notice of salary offset. Such notice shall, at a minimum:

(1) Contain a copy of the certification received from the creditor agency; and

(2) Advise the employee that salary offset will be initiated at the next officially established pay interval.

(b) The payroll office shall provide a copy of the notice to the creditor agency and advise such agency of the dollar amount to be offset and the pay period when the offset will begin.

§ 309.16 Procedures for salary offset.

(a) The Director (or designee) shall coordinate salary deductions under this subpart.

(b) The payroll office shall determine the amount of the employee's disposable pay and will implement the salary offset.

(c) Deductions shall begin within 3 official pay periods following receipt by the payroll office of certification.

(d) Types of collection. (1) *Lump-sum payment.* If the amount of the debt is equal to or less than 15 percent of disposable pay, such debt generally will be collected in one lump-sum payment.

(2) *Installment deductions.* Installment deductions will be made over a period not greater than the anticipated period of employment. The size and frequency of installment deductions will bear a reasonable relation to the size of the debt and the employee's ability to pay. However, the amount deducted from any period may not exceed 15 percent of the disposable pay from which the deduction is made unless the employee has agreed in writing to the deduction of a greater amount.

(3) *Lump-sum deductions from final check.* A lump-sum deduction exceeding the 15 percent of disposable pay limitation may be made from any final salary payment pursuant to 31 U.S.C. 3716 in order to liquidate the debt, whether the employee is being separated voluntarily or involuntarily.

(4) *Lump-sum deductions from other sources.* Whenever an employee subject to salary offset is separated from the Peace Corps, and the balance of the debt cannot be liquidated by offset of the final salary check, the Peace Corps, pursuant to 31 U.S.C. 3716, may offset any later payments of any kind against the balance of the debt.

(e) *Multiple debts.* In instances where two or more creditor agencies are seeking salary offsets, or where two or more debts are owed to a single creditor agency, the payroll office may, at its discretion, determine whether one or more debts should be offset simultaneously within the 15 percent limitation.

(f) *Precedence of debts owed to the Peace Corps.* For Peace Corps employees, debts owed to the agency generally take precedence over debts owed to other agencies. In the event that a debt to the Peace Corps is certified while an employee is subject to a salary offset to repay another agency, the payroll office may decide whether to have that debt repaid in full before collecting its claim or whether changes should be made in the salary deduction being sent to the other agency. If debts owed the Peace Corps can be collected in one pay period, the payroll office may suspend the salary offset to the other agency for that pay period in order to liquidate the Peace Corps' debt. When an employee owes two or more debts, the best interests of the Government shall be the primary consideration in the determination by the payroll office of the order of the debt collection.

§ 309.17 Coordinating salary offset with other agencies.

(a) *Responsibility of the Peace Corps as the creditor agency.*

(1) The Director or Director's designee shall coordinate debt collections and shall, as appropriate:

(i) Arrange for a hearing upon proper petition by a federal employee; and

(ii) Prescribe such practices and procedures as may be necessary to carry out the intent of this subpart.

(2) Designate a salary offset coordination officer who will be responsible for:

(i) Ensuring that each notice of intent to offset is consistent with the requirements of § 309.10;

(ii) Ensuring that each certification of debt sent to a paying agency is consistent with the requirements of § 309.12;

(iii) Obtaining hearing officials from other agencies pursuant to § 309.11(f); and

(iv) Ensuring that hearings are properly scheduled.

(3) Request recovery from current paying agency. Upon completion of the procedures established in these regulations and pursuant to 5 U.S.C. 5514, the Peace Corps must:

(i) Certify, in writing, that the employee owes the debt, the amount and basis of the debt, the date on which payments are due, the date the Government's right to collect the debt first accrued, and that the Peace Corps' regulations implementing 5 U.S.C. 5514 have been approved by the Office of Personnel Management;

(ii) Advise the paying agency of the actions taken under 5 U.S.C. 5514(a) and give the dates the actions were taken (unless the employee has consented to the salary offset in writing or signed a statement acknowledging receipt of the required procedures and the written consent or statement is forwarded to the paying agency);

(iii) Except as otherwise provided in paragraph (a)(3) of this section, submit a debt claim containing the information specified in paragraphs (a)(3) (i) and (ii) of this section and an installment agreement (or other instruction on the payment schedule), if applicable, to the employee's paying agency;

(iv) If the employee is in the process of separating, the Peace Corps must submit its debt claim to the employee's paying agency for collection as provided in § 309.16. The paying agency must certify the total amount of its collection and notify the creditor agency and the employee as provided in paragraph (b)(4) of this section. If the paying agency is aware that the employee is entitled to payments from the Civil Service Retirement and Disability Fund, or other similar payments, it must provide written notification to the agency responsible for making such payments that the debtor owes a debt (including the amount) and that the provisions of this section have been fully complied with. However, the Peace Corps must submit a properly certified claim to the agency responsible for making such payments before the collection can be made.

(v) If the employee is already separated and all payments due from his or her former paying agency have been paid, the Peace Corps may request, unless otherwise prohibited, that money due and payable to the employee from the Civil Service Retirement and Disability Fund (5 CFR 831.1801 *et seq.*) or other similar funds, be administratively offset to collect the debt (See 31 U.S.C. 3716 and 41 CFR 102.4).

(4) When an employee transfers to another paying agency, the Peace Corps need not repeat the due process procedures described in 5 U.S.C. 5514 and this subpart to continue the collection. The Peace Corps must review the debt upon receiving the former paying agency's notice of the employee's transfer to make sure the collection is continued by the new paying agency.

(b) *Responsibility of the Peace Corps as the paying agency.*

(1) *Complete claim.* When the Peace Corps receives a certified claim from a creditor agency, deductions should be scheduled to begin at the next officially established pay interval. The employee must receive written notice that the Peace Corps has received a certified debt claim from the creditor agency (including the amount) and written

notice of the date salary offset will begin and the amount of such deductions.

(2) *Incomplete claim.* When the Peace Corps receives an incomplete certification of debt from a creditor agency, the Peace Corps must return the debt claim with notice that procedures under 5 U.S.C. 5514 and this subpart must be followed and a properly certified debt claim received before action will be taken to collect from the employee's current pay account.

(3) *Review.* The Peace Corps is not authorized to review the merits of the creditor agency's determination with respect to the amount or validity of the debt certified by the creditor agency.

(4) *Employees who transfer from one paying agency to another.* If, after the creditor agency has submitted the debt claim to the Peace Corps, the employee transfers to another agency before the debt is collected in full, the Peace Corps must certify the total amount collected on the debt. One copy of the certification must be furnished to the employee and one copy to the creditor agency along with notice of the employee's transfer.

§ 309.18 Interest, penalties and administrative costs.

The Peace Corps shall assess interest, penalties and administrative costs on debts owed pursuant to 31 U.S.C. 3717 and 4 CFR 102.13.

§ 309.19 Refunds.

(a) In instances where the Peace Corps is the creditor agency, it shall promptly refund any amounts deducted under the authority of 5 U.S.C. 5514 when:

(1) The debt is waived or otherwise found not to be owed to the United States; or

(2) An administrative or judicial order directs the Peace Corps to make a refund.

(b) Unless required or permitted by law or contract, refunds under this subpart shall not bear interest.

§ 309.20 Request for the services of a hearing official from the creditor agency.

(a) The Peace Corps will provide a hearing official upon request of the creditor agency when the debtor is employed by the Peace Corps and the creditor agency cannot provide a prompt and appropriate hearing before an administrative law judge or before a hearing official furnished pursuant to another lawful arrangement.

(b) The Peace Corps will provide a hearing official upon request of a creditor agency when the debtor works for the creditor agency and that agency cannot arrange for a hearing official.

(c) The salary offset coordination officer will appoint qualified personnel to serve as hearing officials.

(d) Services rendered under this section will be provided on a fully reimbursable basis pursuant to the Economy Act of 1932, as amended, 31 U.S.C. 1535.

§ 309.21 Non-waiver of rights by payments.

An employee's involuntary payment of all or any portion of a debt being collected under this subpart shall not be construed as a waiver of any rights which the employee may have under 5 U.S.C. 5514 or any other provision of a written contract or law unless there are statutory or contractual provisions to the contrary.

Subpart C—Tax Refund Offset

§ 309.22 Applicability and scope.

This subpart implements 31 U.S.C. 3720A which authorizes the Internal Revenue Service (IRS) to reduce a tax refund by the amount of a past-due legally enforceable debt owed to the United States.

§ 309.23 Past-due legally enforceable debt.

For purposes of this subpart, a past-due legally enforceable debt referable to the IRS is a debt which is owed to the United States and:

(a) Except in the case of a judgment debt, has been delinquent for at least 3 months and will not have been delinquent more than 10 years at the time offset is made;

(b) Cannot be currently collected pursuant to the salary offset provisions of 5 U.S.C. 5514;

(c) Is ineligible for administrative offset under 31 U.S.C. 3716(a) by reason of 31 U.S.C. 3716(c)(2) or cannot be collected by administrative offset under 31 U.S.C. 3716(a) by the Peace Corps against amounts payable to the debtor by the Peace Corps;

(d) With respect to which the Peace Corps has given the taxpayer at least 60 days to present evidence that all or part of the debt is not past-due or legally enforceable, has considered evidence presented by such taxpayer, and determined that an amount of such debt is past-due and legally enforceable;

(e) Has been disclosed by the Peace Corps to a consumer reporting agency as authorized by 31 U.S.C. 3711(f), unless the consumer reporting agency would be prohibited from reporting information concerning the debt by reason of 15 U.S.C. 1681c, or unless the amount of the debt does not exceed $100;

(f) Is at least $25; and

(g) With respect to which the Peace Corps has notified or has made a reasonable attempt to notify the taxpayer that:

(1) The debt is past due, and

(2) Unless repaid within 60 days thereafter, the debt will be referred to the IRS for offset against any overpayment of tax. For the purposes of paragraph (g) of this section, in order to make a reasonable attempt to notify the debtor, Peace Corps must use such address for the debtor as may be obtainable from IRS pursuant to section 6103(m)(2), (m)(4), or (m)(5) of the Internal Revenue Code.

§ 309.24 Definitions.

For purpose of this subpart:

Commissioner means the Commissioner of the Internal Revenue Service.

Memorandum of Understanding (MOU or agreement) means the agreement between the IRS and the Peace Corps which prescribes the specific conditions the Peace Corps must meet before the IRS will accept referrals for tax refund offsets.

§ 309.25 Peace Corps' participation in IRS tax refund offset program.

(a) The Peace Corps will provide information to the IRS within the time frame prescribed by the Commissioner of the IRS to enable the Commissioner to make a final determination as to the Peace Corps' participation in the tax refund offset program. Such information will include a description of:

(1) The size and age of the Peace Corps' inventory of delinquent debts;

(2) The prior collection efforts that the inventory reflects; and

(3) The quality controls the Peace Corps maintains to assure that any debt that may be submitted for tax refund offset will be valid and enforceable.

(b) In accordance with the timetable specified by the Commissioner, the Peace Corps will submit test magnetic media to the IRS, in such form and containing such data as the IRS shall specify.

(c) The Peace Corps will provide the IRS with a telephone number which the IRS may furnish to individuals whose refunds have been offset to obtain information concerning the offset.

§ 309.26 Procedures.

(a) The Chief Financial Officer (or designee) shall be the point of contact with the IRS for administrative matters regarding the offset program.

(b) The Peace Corps shall ensure that:

(1) Only those past-due legally enforceable debts described in § 309.23 are forwarded to the IRS for offset; and

(2) The procedures prescribed in the MOU between the Peace Corps and the

IRS are followed in developing past-due debt information and submitting the debts to the IRS.

(c) The Peace Corps shall submit a notification of a taxpayer's liability for past-due legally enforceable debt to the IRS on magnetic media as prescribed by the IRS. Such notification shall contain:

(1) The name and taxpayer identifying number (as defined in section 6109 of the Internal Revenue Code) of the individual who is responsible for the debt;

(2) The dollar amount of such past-due and legally enforceable debt;

(3) The date on which the original debt became past due;

(4) A statement accompanying each magnetic tape certifying that, with respect to each debt reported on the tape, all of the requirements of eligibility of the debt for referral for the refund offset have been satisfied. See § 309.23.

(d) The Peace Corps shall promptly notify the IRS to correct data submitted when the Peace Corps:

(1) Determines that an error has been made with respect to a debt that has been referred;

(2) Receives or credits a payment on such debt; or

(3) Receives notification that the individual owing the debt has filed for bankruptcy under title 11 of the United States Code or has been adjudicated bankrupt and the debt has been discharged.

(e) When advising debtors of an intent to refer a debt to the IRS for offset, the Peace Corps shall also advise the debtors of all remedial actions available to defer or prevent the offset from taking place.

§ 309.27 Referral of debts for offset.

(a) The Peace Corps shall refer to the IRS for collection by tax refund offset, from refunds otherwise payable, only such past-due legally enforceable debts owed to the Peace Corps:

(1) That are eligible for offset under the terms of 31 U.S.C. 3720A, section 6402(d) of the Internal Revenue Code, 26 CFR 301.6402–6T and the MOU; and

(2) That information will be provided for each such debt as is required by the terms of the MOU.

(b) Such referrals shall be made by submitting to the IRS a magnetic tape pursuant to § 309.26(c), together with a written certification that the conditions or requirements specified in 26 CFR 301.6402–6T and the MOU have been satisfied with respect to each debt included in the referral on such tape. The certification shall be in the form specified in the MOU.

§ 309.28 Notice requirements before offset.

(a) The Peace Corps must notify, or make a reasonable attempt to notify, the individual that:

(1) The debt is past due; and

(2) Unless repaid within 60 days thereafter, the debt will be referred to the IRS for offset against any refund of overpayment of tax.

(b) The Peace Corps shall provide a mailing address for forwarding any correspondence and a contact name and telephone number for any questions.

(c) The Peace Corps shall give the individual debtor at least 60 days from the date of the notification to present evidence that all or part of the debt is not past due or legally enforceable. The Peace Corps shall consider the evidence presented by the individual and shall make a determination whether any part of such debt is past due and legally enforceable. For purposes of this subpart, evidence that collection of the debt is affected by a bankruptcy proceeding involving the individual shall bar referral of the debt to the IRS.

(d) Notification given to a debtor pursuant to paragraphs (a), (b), and (c) of this section shall advise the debtor of how he or she may present evidence to the Peace Corps that all or part of the debt is not past due or legally enforceable. Such evidence may not be referred to, or considered by, individuals who are not officials, employees, or agents of the United States in making the determination required under paragraph (c) of this section. Unless such evidence is directly considered by an official or employee of the Peace Corps, and the determination required under paragraph (c) of this section has been made by an official or employee of the Peace Corps, any unresolved dispute with the debtor as to whether all or part of the debt is past due or legally enforceable must be referred to the Peace Corps for ultimate administrative disposition, and the Peace Corps must directly notify the debtor of its determination.

Subpart D—Administrative Offset

§ 309.29 Applicability and scope.

The provisions of this subpart apply to the collection of debts owed to the United States arising from transactions with the Peace Corps. Administrative offset is authorized under section 5 of the Federal Claims Collection Act of 1966, as amended by the Debt Collection Act of 1982 (31 U.S.C. 3716). These regulations are consistent with the Federal Claims Collection Standards on administrative offset issued jointly by the Department of Justice and the General Accounting Office as set forth in 4 CFR part 102.

§ 309.30 Definitions.

(a) *Administrative offset*, as defined in 31 U.S.C. 3701(a)(1), means withholding money payable by the United States Government to, or held by the Government for, a person to satisfy a debt the person owes the Government.

(b) *Person* includes a natural person or persons, profit or nonprofit corporation, partnership, association, trust, estate, consortium, or other entity which is capable of owing a debt to the United States Government except that agencies of the United States, or of any State or local government shall be excluded.

§ 309.31 General.

(a) The Director of the Peace Corps (or designee) will determine the feasibility of collection by administrative offset on a case-by-case basis for each claim established. The Director (or designee) will consider the following issues in making a determination to collect a claim by administrative offset:

(1) Can administrative offset be accomplished?

(2) Is administrative offset practical and legal?

(3) Does administrative offset best serve and protect the interest of the U.S. Government?

(4) Is administrative offset appropriate given the debtor's financial condition?

(b) The Director (or designee) may initiate administrative offset with regard to debts owed by a person to another agency of the United States Government, upon receipt of a request from the head of another agency or his or her designee, and a certification that the debt exists and that the person has been afforded the necessary due process rights.

(c) The Director (or designee) may request another agency that holds funds payable to a Peace Corps debtor to offset the debt against the funds held and will provide certification that:

(1) The debt exists; and

(2) The person has been afforded the necessary due process rights.

(d) No collection by administrative offset shall be made on any debt that has been outstanding for more than 10 years unless facts material to the Government's right to collect the debt were not known, and reasonably could not have been known, by the official or officials responsible for discovering the debt.

(e) Administrative offset under this subpart may not be initiated against:

(1) A debt in which administrative offset of the type of debt involved is

explicitly provided for or prohibited by another statute;

(2) Debts owed by other agencies of the United States or by any State or local Government; or

(3) Debts arising under the Internal Revenue Code of 1954; the Social Security Act; or the tariff laws of the United States.

(f) The procedures for administrative offset in this subpart do not apply to the offset of Federal salaries under 5 U.S.C. 5514.

§ 309.32 Demand for payment—notice.

(a) Whenever possible, the Peace Corps will seek written consent from the debtor to initiate immediate collection before starting the formal notification process.

(b) In cases where written agreement to collect cannot be obtained from the debtor, a formal notification process shall be followed, 4 CFR 102.2. Prior to collecting a claim by administrative offset, the Peace Corps shall send to the debtor, by certified or registered mail with return receipt, written demands for payment in terms which inform the debtor of the consequences of failure to cooperate. A total of 3 progressively stronger written demands at not more than 30 day intervals will normally be made unless a response to the first or second demand indicates that a further demand would be futile or the debtor's response does not require rebuttal, or other pertinent information indicates that additional written demands would be unnecessary. In determining the timing of the demand letters, the Peace Corps should give due regard to the need to act promptly so that, as a general rule, if necessary to refer the debt to the Department of Justice for litigation, such referral can be made within 1 year of the final determination of the fact and the amount of the debt. When appropriate to protect the Government's interests (for example, to prevent the statute of limitations from expiring), written demand may be preceded by other appropriate actions, including immediate referral for litigation.

(c) Before offset is made, a written notice will be sent to the debtor. This notice will include:

(1) The nature and amount of the debt;

(2) The date when payment is due (not less than 30 days from the date of mailing or hand delivery of the notice);

(3) The agency's intention to collect the debt by administrative offset, including asking the assistance of other Federal agencies to help in the offset whenever possible, if the debtor has not made payment by the payment due date or has not made an arrangement for payment by the payment due date;

(4) Any provision for interest, late payment penalties and administrative charges, if payment is not received by the due date;

(5) The possible reporting of the claim to consumer reporting agencies and the possibility that Peace Corps will forward the claim to a collection agency;

(6) The right of the debtor to inspect and copy Peace Corps' records related to the claim;

(7) The right of the debtor to request a review of the determination of indebtedness and, in the circumstances described below, to request an oral hearing from the Peace Corps;

(8) The right of the debtor to enter into a written agreement with the agency to repay the debt in some other way; and

(9) In appropriate cases, the right of the debtor to request a waiver.

(d) Claims for payment of travel advances and employee training expenses require notification prior to administrative offset as described in this section. Because no oral hearing is required, notice of the right to a hearing need not be included in the notification.

§ 309.33 Debtor's failure to respond.

If the debtor fails to respond to the notice described in § 309.32 (c) by the proposed effective date specified in the notice, the Peace Corps may take further action under this part or the FCCS under 4 CFR parts 101 through 105. Peace Corps may collect by administrative offset if the debtor:

(a) Has not made payment by the payment due date;

(b) Has not requested a review of the claim within the agency as set out in § 309.34; or

(c) Has not made an arrangement for payment by the payment due date.

§ 309.34 Agency review.

(a) A debtor may dispute the existence of the debt, the amount of the debt, or the terms of repayment. A request to review a disputed debt must be submitted to the Peace Corps official who provided notification within 30 calendar days of the receipt of the written notice described in § 309.32(c).

(b) The Peace Corps will provide a copy of the record to the debtor and advise him/her to furnish available evidence to support his or her position. Upon receipt of the evidence, the Peace Corps will review the written record of indebtedness and inform the debtor of its findings.

(c) Pending the resolution of a dispute by the debtor, transactions in any of the debtor's accounts maintained by the Peace Corps may be temporarily suspended. Depending on the type of transaction the suspension could preclude its payment, removal, or transfer, as well as prevent the payment of interest or discount due thereon. Should the dispute be resolved in the debtor's favor, the suspension will be immediately lifted.

(d) During the review period, interest, penalties, and administrative costs authorized under the Federal Claims Collection Act of 1966, as amended, will continue to accrue.

§ 309.35 Hearing.

(a) A debtor will be provided a reasonable opportunity for an oral hearing when:

(1)(i) By statute, consideration must be given to a request to waive the indebtedness;

(ii) The debtor requests waiver of the indebtedness; and

(iii) The waiver determination rests on an issue of creditability or veracity; or

(2) The debtor requests reconsideration and the Peace Corps determines that the question of indebtedness cannot be resolved by reviewing the documentary evidence.

(b) In cases where an oral hearing is provided to the debtor, the Peace Corps will conduct the hearing, and provide the debtor with a written decision.

§ 309.36 Written agreement for repayment.

If the debtor requests a repayment agreement in place of offset, the Peace Corps has discretion and should use sound judgment to determine whether to accept a repayment agreement in place of offset. If the debt is delinquent and the debtor has not disputed its existence or amount, the Peace Corps will not accept a repayment agreement in place of offset unless the debtor is able to establish that offset would cause undue financial hardship or be unjust. No repayment arrangement will be considered unless the debtor submits a financial statement, executed under penalty of perjury, reflecting the debtor's assets, liabilities, income, and expenses. The financial statement must be submitted within 10 business days of the Peace Corps' request for the statement. At the Peace Corps' option, a confess-judgment note or bond of indemnity with surety may be required for installment agreements. Notwithstanding the provisions of this section, any reduction or compromise of a claim will be governed by 4 CFR part 103 and 31 CFR 5.3.

§ 309.37 Administrative offset procedures.

(a) If the debtor does not exercise the right to request a review within the time

specified in § 309.34, or if as a result of the review, it is determined that the debt is due and no written agreement is executed, then administrative offset shall be ordered in accordance with this subpart without further notice.

(b) *Travel advance.* The Peace Corps will deduct outstanding advances provided to Peace Corps travelers from other amounts owed the traveler by the agency whenever possible and practicable. Monies owed by an employee for outstanding travel advances which cannot be deducted from other travel amounts due that employee, will be collected through salary offset as described in subpart B of this part.

(c) *Volunteer allowances.* The Peace Corps may deduct through administrative offset amounts owed the U.S. Government by Volunteers and Trainees from the readjustment allowance account.

(1) Overseas posts will obtain written consent from Volunteers or Trainees who are indebted to the agency upon close of service or termination, to deduct amounts owed from their readjustment allowances. Posts will immediately submit the written consent to Volunteer and Staff Payroll Services Division (VSPS).

(2) In cases where written consent from indebted Volunteers or Trainees cannot be obtained, overseas posts will immediately report the documented debts to VSPS. VSPS may then initiate offset against the readjustment allowance. Prior to offset action, VSPS will notify the debtor Volunteer or Trainee of their rights as required in § 309.32.

(d) *Requests for offset to other Federal agencies.* The Director or his or her designee may request that a debt owed to the Peace Corps be administratively offset against funds due and payable to a debtor by another Federal agency. In requesting administrative offset, the Peace Corps, as creditor, will certify in writing to the Federal agency holding funds of the debtor;

(1) That the debtor owes the debt;

(2) The amount and basis of the debt; and

(3) That the Peace Corps has complied with the requirements of 31 U.S.C. 3716, its own administrative offset regulations and the applicable provisions of 4 CFR part 102 with respect to providing the debtor with due process.

(e) *Requests for offset from other Federal agencies.* Any Federal agency may request that funds due and payable to its debtor by the Peace Corps be administratively offset in order to collect a debt owed to such Federal agency by the debtor. The Peace Corps shall initiate the requested offset only upon:

(1) Receipt of written certification from the creditor agency:

(i) That the debtor owes the debt;

(ii) The amount and basis of the debt;

(iii) That the agency has prescribed regulations for the exercise of administrative offset; and

(iv) That the agency has complied with its own administrative offset regulations and with the applicable provisions of 4 CFR part 102, including providing any required hearing or review.

(2) A determination by the Peace Corps that collection by offset against funds payable by the Peace Corps would be in the best interest of the United States as determined by the facts and circumstances of the particular case, and that such offset would not otherwise be contrary to law.

§ 309.38 Civil and Foreign Service Retirement Fund.

(a) Unless otherwise prohibited by law, Peace Corps may request that monies that are due and payable to a debtor from the Civil Service Retirement and Disability Fund, the Foreign Service Retirement Fund or any other Federal retirement fund be administratively offset in reasonable amounts in order to collect in one full payment or a minimal number of payments, debts owed the United States by the debtor. Such requests shall be made to the appropriate officials of the respective fund servicing agency in accordance with such regulations as may be prescribed by the Director of that agency. The requests for administrative offset will certify in writing the following:

(1) The debtor owes the United States a debt and the amount of the debt;

(2) The Peace Corps has complied with applicable regulations and procedures;

(3) The Peace Corps has followed the requirements of the FCCS as described in this subpart.

(b) Once Peace Corps decides to request offset under paragraph (a) of this section, it will make the request as soon as practical after completion of the applicable procedures in order that the fund servicing agency may identify and flag the debtor's account in anticipation of the time when the debtor requests or becomes eligible to receive payments from the fund. This will satisfy any requirements that offset will be initiated prior to expiration of the statute of limitations.

(c) If Peace Corps collects part or all of the debt by other means before deductions are made or completed pursuant to paragraph (a) of this section, Peace Corps shall act promptly to modify or terminate its request for offset.

(d) This section does not require or authorize the fund servicing agency to review the merits of Peace Corps' determination relative to the debt.

§ 309.39 Jeopardy procedure.

The Peace Corps may effect an administrative offset against a payment to be made to the debtor prior to the completion of the procedures required by § 309.32(c) of this subpart if failure to take the offset would substantially jeopardize the Peace Corps' ability to collect the debt, and the time available before the payment is to be made does not reasonably permit the completion of those procedures. Such prior offset shall be promptly followed by the completion of those procedures. Amounts recovered by offset but later found not to be owed to the Peace Corps shall be promptly refunded.

Subpart E—Use of Consumer Reporting Agencies and Referrals to Collection Agencies

§ 309.40 Use of consumer reporting agencies.

(a) The Peace Corps may report delinquent debts to consumer reporting agencies (see 31 U.S.C. 3701(a)(3)). Sixty days prior to release of information to a consumer reporting agency, the debtor shall be notified, in writing, of the intent to disclose the existence of the debt to a consumer reporting agency. Such notice of intent may be separate correspondence or included in correspondence demanding direct payment. The notice shall be in conformance with 31 U.S.C. 3711(f) and the Federal Claims Collection Standards.

(b) The information that may be disclosed to the consumer reporting agency is limited to:

(1) The debtor's name, address, social security number or taxpayer identification number, and any other information necessary to establish the identity of the individual;

(2) The amount, status, and history of the claim; and

(3) The Peace Corps program or activity under which the claim arose.

§ 309.41 Referrals to collection agencies.

(a) Peace Corps has authority to contract for collection services to recover delinquent debts in accordance with 31 U.S.C. 3718(c) and the FCCS (4 CFR 102.6).

(b) Peace Corps will use private collection agencies where it determines that their use is in the best interest of

the Government. Where Peace Corps determines that there is a need to contract for collection services, the contract will provide that:

(1) The authority to resolve disputes, compromise claims, suspend or terminate collection action, and refer the matter to the Department of Justice for litigation or to take any other action under this Part will be retained by the Peace Corps;

(2) Contractors are subject to the Privacy Act of 1974, as amended, to the extent specified in 5 U.S.C. 552a(m) and to applicable Federal and State laws and regulations pertaining to debt collection practices, such as the Fair Debt Collection Practices Act, 15 U.S.C. 1692;

(3) The contractor is required to strictly account for all amounts collected;

(4) The contractor must agree that uncollectible accounts shall be returned with appropriate documentation to enable Peace Corps to determine whether to pursue collection through litigation or to terminate collection;

(5) The contractor must agree to provide any data in its files relating to paragraphs (a) (1), (2) and (3) of section 105.2 of the Federal Claims Collection Standards upon returning the account to Peace Corps for subsequent referral to the Department of Justice for litigation.

(c) Peace Corps will not use a collection agency to collect a debt owed by a current employed or retired Federal employee, if collection by salary or annuity offset is available.

Subpart F—Compromise, Suspension or Termination and Referral of Claims

§ 309.42 Compromise.

Peace Corps may attempt to effect compromise in accordance with the standards set forth in part 103 of the FCCS (4 CFR part 103).

§ 309.43 Suspending or terminating collection.

Suspension or termination of collection action shall be made in accordance with the standards set forth in Part 104 of the FCCS (4 CFR 104)

§ 309.44 Referral of claims.

Claims on which an aggressive collection action has been taken and which cannot be collected, compromised or on which collection action cannot be suspended or terminated under parts 103 and 104 of the FCCS (4 CFR parts 103 and 104), shall be referred to the General Accounting Office or the Department of Justice, as appropriate, in accordance with the procedures set forth in part 105 of the FCCS (4 CFR part 105).

Barbara Zartman,

Acting Director, Peace Corps of the United States.

[FR Doc. 93-239 Filed 1-6-93; 8:45 am]

BILLING CODE 6051-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

Office of the Assistant Secretary for Fair Housing and Equal Opportunity

24 CFR Part 100

Discriminatory Conduct Under the Fair Housing Act

CFR Correction

In title 24 of the Code of Federal Regulations, parts 1-199, revised as of April 1, 1992, on page 786, in § 100.135, paragraph (c) was incorrectly printed and paragraph (d) was inadvertently omitted. The correct paragraphs (c) and (d) appear as follows:

§ 100.135 Unlawful practices in the selling, brokering or appraising of residential real property.

* * * * *

(c) Nothing in this section prohibits a person engaged in the business of making or furnishing appraisals of residential real property from taking into consideration factors other than race, color, religion, sex, handicap, familial status, or national origin.

(d) Practices which are unlawful under this section include, but are not limited to, using an appraisal of residential real property in connection with the sale, rental, or financing of any dwelling where the person knows or reasonably should know that the appraisal improperly takes into consideration race, color, religion, sex, handicap, familial status or national origin.

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP St. Louis Regulation 92-10]

Safety Zone Regulations; Upper Mississippi River Mile 202.1 through 202.6

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the Upper Mississippi River, from Mile 202.1 through 202.6, to protect commercial traffic and private vessels from hazards associated with construction of the Clark Highway Bridge. Entry into this zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATES: This regulation is effective daily, from November 6, 1992 through April 30, 1993 between the hours of 7 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Commander Scott Cooper, Captain of the Port, St. Louis, Missouri at 314-539-3823.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective less than 30 days after publication in the Federal Register. Publishing an NPRM and delaying the effective date would be contrary to the public interest since immediate action is necessary to ensure the safety of vessels operating in the regulated area.

Drafting Information

The drafter of this regulation is MSTC M.G. Bryan, project officer for the Captain of the Port.

Discussion of Regulation

This regulation is required to protect commercial traffic and private vessels from hazards associated with construction of the Clark Highway Bridge spanning the Mississippi River. The event requiring this regulation will begin on November 6, 1992 and will conclude on April 30, 1993. Entry into this zone between 7 a.m. and 5 p.m. will be prohibited at various times and dates during the construction period. The M/V MISS JAN will be on scene to update closure periods as conditions warrant. Questions can be directed to the M/V MISS JAN on VHF channels 13 and 16. Reopening broadcasts will be made by M/V MISS JAN. This regulation is issued pursuant to 33 U.S.C. 1231 as set out in the authority citation for all of 33 CFR part 165.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

Regulation

In consideration of the foregoing, subpart C of part 165 of title 33, Code of Federal Regulations, is amended as follows:

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 49 CFR 1.46 and 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5

2. A new § 165.T0255 is added to read as follows:

§ 165.T0255 Safety zone: Upper Mississippi River.

(a) *Location.* The following area is a safety zone: Upper Mississippi River from Mile 202.1 through 202.6.

(b) *Effective Date.* This regulation is effective daily on November 6, 1992 through April 30, 1993 between the hours of 7 a.m. and 5 p.m.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port or his on scene representative, the M/V MISS JAN.

Dated: November 3, 1992.

Scott P. Cooper,

Commander, U.S. Coast Guard, Captain of the Port, St. Louis, Missouri.

[FR Doc. 93–270 Filed 1–6–93; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

42 CFR Part 1001

[RIN 0991–AA59]

Medicare and State Health Care Programs; Fraud and Abuse; Safe Harbors for Protecting Health Plans—Extension of Comment Period

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Interim final rule with request for comment; extension of comment period.

SUMMARY: On November 5, 1992, we published an interim final rule establishing two new safe harbors, and amended one existing safe harbor, to provide protection for certain health care plans, such as health maintenance organizations and preferred provider organizations (57 FR 52723). We are extending the comment period at the request of several organizations.

DATES: Comments may be submitted until March 5, 1993.

ADDRESSES: Comments should be submitted to: Office of Inspector General, Department of Health and Human Services, Attention: LRR–28–FC, room 5246, 330 Independence Avenue, SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of Inspector General, (202) 619–0089.

SUPPLEMENTARY INFORMATION: These safe harbors specifically set forth various standards and guidelines that, if met, will result in the particular arrangement being protected from criminal prosecution or civil sanctions under the anti-kickback provisions of the statute. Although this rule was issued in final form and became effective on the date of publication, we indicated in the preamble of that document that we were allowing a 60-day public comment period during which time interested parties could submit their comments and concerns regarding these safe harbors to the Office of Inspector General. The OIG agreed to consider all comments received on or before January 4, 1993.

Since publication of that final rule, we have received requests from several outside organizations to extend the existing comment period beyond the 60-day period. Specifically, because of our desire to work with affected outside groups in considering innovative suggestions and ideas in establishing practical and workable safe harbors, and concerns made known to us by some parties that the holiday season has hampered their ability to poll their constituents in a timely and effective manner to provide necessary and comprehensive information, we have agreed to extend the public comment period on this interim final rulemaking until March 5, 1992. We note that even though we are formally extending the comment period by an additional 60 days, these managed care safe harbor provision regulations have the effect of a final rule and such extension will not have an effect on the current implication of this rule.

Dated: December 18, 1992.

Approved: December 31, 1992.

Bryan B. Mitchell,

Principal Deputy Inspector General.

Louis W. Sullivan,

Secretary.

[FR Doc. 93–272 Filed 1–4–93; 11:52 am]

BILLING CODE 4150–04–M

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 665

[Docket No. 89–B]

RIN 2132–AA30

Bus Testing Program; Reopening of Comment Period

AGENCY: Federal Transit Administration, DOT.

ACTION: Interim final rule; reopening of comment period.

SUMMARY: On July 28, 1992, the Federal Transit Administration (FTA) published interim procedures for its bus testing program. The comment period ended on December 14, 1992. Because of the complexity of the issues involved and the desire of the FTA to give interested parties the maximum opportunity to comment, the FTA has found reasonable cause to extend the comment period of FTA Docket 89–B for an additional forty-five (45) days from the December 14, 1992, closing date.

DATES: Comments must be submitted by January 29, 1993. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments should be addressed to: Federal Transit Administration, Department of Transportation, Office of the Chief Counsel, Docket 89–B, 400 Seventh Street SW., room 9316, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: For technical issues, Steven A. Barsony, Director, Office of Engineering Evaluations, Office of Technical Assistance and Safety, (202) 366–0090; for legal issues, Richard L. Wong, Attorney-Advisor, General Law Division, Office of the Chief Counsel, (202) 366–1936 (voice); (202) 366–2979 (TDD).

SUPPLEMENTARY INFORMATION: On July 28, 1992, the Federal Transit Administration (FTA) published an Interim Final Rule (IFR), implementing section 12(h) of the Federal Transit Act (FT Act), which in turn implements section 317 of the Surface Transportation and Uniform Relocation Assistance Act of 1987 (STURAA). Section 12(h) of the FT Act states that no Federal funds * * * may be obligated or expended for the acquisition of a new bus model (including any model using alternative fuels) unless a bus of such model has been tested [at the Federal bus testing facility at Altoona, Pennsylvania]. The IFR adds two categories of vehicles to the three existing categories of vehicles which must be tested before a recipient of Federal funds could expend those funds for a vehicle. The IFR also proposes a partial testing program for those vehicles which have already completed testing at the Federal bus testing facility at Altoona, Pennsylvania. (57 FR 33394, July 28, 1992).

The IFR had an effective date of August 27, 1992, thirty days after publication. Allowing only thirty days between the publication date and the

effective date raised unforeseen issues regarding the effect of the regulation on the small bus industry, affecting both operators and manufacturers. To address this problem, the FTA amended the IFR, temporarily postponing the effective date of the regulation as it applies to the two categories of vehicles until February 10, 1993, and extending the comment period until December 14, 1992. (57 FR 46814, October 13, 1992). Given the complexity of the issues involved and the desire of the FTA to give interested parties the maximum opportunity to comment, the FTA has found reasonable cause to extend the comment period of FTA Docket 89–B for an additional forty-five (45) days from the December 14, 1992, closing date to January 29, 1993.

Issued: December 31, 1992.

Brian W. Clymer,

Administrator.

[FR Doc. 93–228 Filed 1–6–93; 8:45 am]

BILLING CODE 4910–57–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 227

[Docket No. 910779–2317]

Sea Turtle Conservation; Shrimp Trawling Requirements

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule, technical amendment.

SUMMARY: The Secretary of Commerce issues this final rule to amend the regulations requiring shrimp trawlers in the Gulf of Mexico and the Atlantic Ocean off the southeastern United States to use Turtle Excluder Devices (TEDs) to reduce incidental captures of endangered and threatened sea turtles during shrimp fishing operations. This rule removes out-dated language concerning temporary exemptions from the requirement that shrimp trawlers equip their nets with TEDs.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Phil Williams, (301) 713–2319 or Charles A. Oravetz, (813) 893–3366.

SUPPLEMENTARY INFORMATION:

Background

All sea turtles that occur in U.S. waters are listed as either endangered or threatened under the Endangered Species Act (ESA).

Pursuant to its authority under the ESA, NMFS issued a final rule to revise sea turtle conservation measures effective December 1, 1992 (57 FR 57348, December 4, 1992). The specific requirements, their background and rationale, including comments and responses, and summaries of relevant biological opinions, were included in the initial publication of the rule (57 FR 57348, December 4, 1992) and are not repeated here.

This final rule technical amendment removes the language in the Code of Federal Regulations concerning two temporary exemptions that expire on January 1, 1993.

Classification

This final rule, technical amendment, is issued under 50 CFR part 227. Because this rule makes only minor, non-substantive changes, it is unnecessary under 5 U.S.C. 553(b)(B) to provide for prior public comment and there is good cause under 5 U.S.C. 553(d) not to delay for 30 days its effective date.

Because this rule is being issued without prior comment, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act and none has been prepared.

This rule makes minor technical changes to a rule that has been determined not to be a major rule under Executive Order 12291, does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612, and does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act. There is no change in the regulatory impacts previously reviewed and analyzed.

List of Subjects in 50 CFR Part 227

Endangered and threatened species, Exports, Imports, Marine mammals, Transportation.

Dated: December 31, 1992.

Samuel W. McKeen,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 227 is amended as follows:

PART 227—THREATENED FISH AND WILDLIFE

1. The authority citation for part 227 continues to read as follows:

Authority: 16 U.S.C. 1531 et seq.

2. In § 227.72, paragraphs (e)(2)(ii)(A)(5) and (e)(2)(ii)(A)(6) are removed and paragraph (e)(2)(ii)(A)(7) is redesignated (e)(2)(ii)(A)(5).

[FR Doc. 93–249 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–22–M

50 CFR Parts 611 and 663

[Docket No. 921253–2353]

Foreign Fishing; Pacific Coast Groundfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of 1993 groundfish fishery specifications and management measures, and request for comments.

SUMMARY: NMFS announces the 1993 fishery specifications and management measures for groundfish taken in the U.S. exclusive economic zone and state waters off the coasts of Washington, Oregon, and California as authorized by the Pacific Coast Groundfish Fishery Management Plan (FMP). The specifications include the level of the acceptable biological catch, harvest guidelines and quotas, and their distribution between domestic and foreign fishing operations. The management measures for 1993 are designed to keep landings within the harvest guidelines or quotas, if any, and to achieve the goals and objectives of the FMP and its implementing regulations. The intended effect of these actions is to establish allowable harvest levels of Pacific coast groundfish and to implement management measures designed to achieve but not exceed those harvest levels.

EFFECTIVE DATE: January 1, 1993, until modified, superseded, or rescinded. Comments will be accepted until February 8, 1993.

ADDRESSES: Comments on these actions should be sent to Mr. Rolland A. Schmitten, Director, Northwest Region, National Marine Fisheries Service, 7600 Sand Point Way NE., BIN C15700—Bldg. 1, Seattle, WA 98115–0070; or Dr. Gary Matlock, Acting Director, Southwest Region, National Marine Fisheries Service, 501 West Ocean Blvd., Suite 4200, Long Beach, CA 90802–4213. Information relevant to these specifications and management measures has been compiled in aggregate form and is available for public review during business hours at the office of the NMFS Northwest Regional Director or may be obtained from the Pacific Fishery Management Council (Council), by writing Pacific Fishery Management Council, Metro Center, Suite 420, 2000 SW. First Avenue, Portland, OR 97201.

FOR FURTHER INFORMATION CONTACT: William L. Robinson (Northwest Region, NMFS) 206–526–6140; or Rodney R. McInnis (Southwest Region, NMFS) 310–980–4040.

SUPPLEMENTARY INFORMATION: The FMP requires that fishery specifications for groundfish be evaluated each calendar year, that harvest guidelines or quotas be specified for species or species groups in need of additional protection, and that management measures designed to achieve the harvest guidelines or quotas be published in the **Federal Register** and implemented by January 1, the beginning of the next fishing year.

These final fishery specifications and management measures have been recommended by the Council and approved by the Secretary of Commerce (Secretary) for implementation on January 1, 1993. The acceptable biological catches (ABCs) and harvest guidelines announced herein are the basis for the management measures recommended for 1993, and may be modified during the year as provided in the FMP. All of the management measures announced in this notice are considered "routine," and have been so designated at 50 CFR 663.23. A proposed rule to designate trip landing and frequency limits for Pacific whiting as "routine" was published on December 1, 1992 (57 FR 56897). A final rule is expected imminently.

The FMP provides for announcement of the final fishery specifications in the **Federal Register** after consideration at two Council meetings. The process for adopting ABCs, harvest guidelines and quotas for 1993 was initiated early in 1992 so that preliminary specifications could be adopted by the Council at its September 1992 meeting. New stock assessments, the basis for changes to the 1992 ABCs, were distributed to the public prior to the September Council meeting. The documents were reviewed and commented upon by the Council's scientific and industry advisory committees and by the public. After receiving comments, the Council adopted preliminary ABCs and harvest guidelines at its September meeting, which were subsequently made available to the public. Comments were requested before and at the November Council meeting. The final recommendations of harvest specifications, and management measures designed to achieve those specifications, adopted at the November Council meeting were forwarded to the Secretary for implementation by January 1, 1993.

I. Final Specifications of ABC, Harvest Guidelines or Quotas, and Apportionments to DAP, JVP, DAH, and TALFF

The fishery specifications include the ABC, the designation and amounts of harvest guidelines or quotas for species that need individual management, and the apportionment of the harvest guidelines or quotas between domestic and foreign fisheries. For those species needing individual management that will not be fully utilized by domestic processors or harvesters, and that can be caught without severely impacting species that are fully utilized by domestic processors or harvesters, the harvest guidelines or quotas may be apportioned to domestic annual harvest (DAH, which includes domestic annual processing (DAP) and joint venture processing (JVP)) and the total allowable level of foreign fishing (TALFF).

The final 1993 management specifications are listed in Tables 1 and 2, followed by a discussion of each species with an ABC, harvest guideline, or quota that differs from 1992 levels. As in the past, these specifications include fish caught in state ocean waters (0–3 nautical miles offshore) as well as fish caught in the exclusive economic zone (EEZ, 3–200 nautical miles offshore).

TABLE 1.—FINAL SPECIFICATIONS OF ABC FOR 1993 FOR WASHINGTON, OREGON, AND CALIFORNIA BY MANAGEMENT SUBAREAS DEFINED IN 50 CFR PART 663 (THESE CORRELATE WITH INTERNATIONAL NORTH PACIFIC FISHERIES COMMISSION—INPFC—AREAS)

[In thousands of metric tons]

Species	Subarea					Total
	Vancouver[1]	Columbia	Eureka	Monterey	Conception	
Groundfish:						
Lingcod	1.0	4.0	0.5	1.1	0.4	7.0
Pacific cod	.....	.....	(2)	(2)	(2)	3.2
Pacific whiting	.....	.....	.....	.....	(3)	177.0
Sablefish	.....	.....	.....	0.425	(4)	5.0–7.0
Jack mackerel	.....	.....	.....	.....	(2)	52.6
Rockfish:						
Pacific ocean perch	0.0	0.0	(2)	(2)	(2)	0.0
Shortbelly	.....	.....	.....	.....	(2)	13.0
Widow	.....	.....	.....	.....	(2)	7.0
Thornyheads:						
Shortspine	.....	(2)	(2)	(2)	.....	1.9
Longspine	.....	(2)	(2)	(2)	.....	10.1
Sebastes complex:						
Bocaccio	(2)	(2)	(2)	(2)	(2)	1.54
Canary	0.8	1.5	0.6	(2)	(2)	2.9
Chilipepper	.....	.....	.....	.....	(2)	3.6
Yellowtail	1.3	3.1	0.3	(2)	(2)	4.7
Remaining rockfish	0.8	3.7	1.9	4.3	3.3	14.0
Flatfish:						
Dover sole	2.4	4.0	3.5	5.0	1.0	15.9
English sole	.....	.....	.....	.....	(2)	1.9
Petrale sole	0.6	1.1	0.5	0.8	0.2	3.2
Arrowtooth	.....	.....	.....	.....	.....	5.8
Other flatfish	0.7	3.0	1.7	1.8	0.5	7.7
Other fish[5]	2.5	7.0	1.2	2.0	2.0	14.7

[1] U.S. portion, except for Pacific whiting.
[2] These species are not common or important in the areas footnoted. Rockfish species with this footnote are included in the "remaining rockfish" category for the areas footnoted only. Other groundfish species with this footnote are included in the "other fish" category for the areas footnoted.
[3] ABC for the U.S. and Canada combined.
[4] The 7,000-mt sablefish ABC applies only to the Vancouver, Columbia, Eureka, and Monterey subareas. There is a separate 425-mt ABC for the Conception subarea.

[5] Total—all areas off Washington, Oregon, and California.
[6] Includes areas beyond the EEZ (200 nm), and in the EEZ north of 39° N. latitude. The FMP governs only jack mackerel in the EEZ north of 39° N. latitude.
[7] The ABC is for these areas combined. For bocaccio, the Eureka subarea contribution is small.
[8] "Other fish" includes sharks, skates, rays, ratfish, morids, grenadiers, and groundfish species (except rockfish) in those areas designated by footnote 2.

TABLE 2.—FINAL HARVEST GUIDELINE (HG) SPECIFICATIONS AND THEIR APPORTIONMENT TO DAP, JVP, DAH, AND TALFF IN 1993

[In thousands of metric tons]

Species	HG	DAP	JVP[1]	DAH	Reserve	TALFF[1]
Pacific whiting[2]	142.0	142.0	0.0	142.0	0.0	0.0
Shortbelly rockfish	13.0	13.0	0.0	13.0	0.0	0.0
Jack mackerel[3]	46.5	46.5	0.0	46.5	0.0	0.0
Sablefish[4]	7.0	7.0	0.0	7.0	0.0	0.0
Pacific ocean perch[5]	[5]1.55	1.55	[5]0.0	1.55	0.0	0.0
Widow rockfish	7.0	7.0	0.0	7.0	0.0	0.0
Bocaccio[6]	1.54	1.54	0.0	1.54	0.0	0.0
Yellowtail rockfish[7]	4.4	4.4	0.0	4.4	0.0	0.0
Thornyheads[8]	7.0	7.0	0.0	7.0	0.0	0.0
Dover sole[4]	17.9	17.9	0.0	17.9	0.0	0.0
Sebastes: Complex[7]	11.2	11.2	0.0	11.2	0.0	0.0
Rockfish[9]						

[1] In the event of foreign trawl or joint venture fisheries for Pacific whiting, incidental catch allowance percentages (based on TALFF) and incidental retention allowance percentages (based on JVP) are: Sablefish 0.173 percent; Pacific ocean perch 0.062 percent; rockfish excluding Pacific ocean perch 0.738 percent; flatfish 0.1 percent; jack mackerel 3.0 percent; and other species 0.5 percent. In foreign trawl and joint venture fisheries, "other species" means all species, including nongroundfish species, except Pacific whiting, sablefish, Pacific ocean perch, other rockfish (that is, rockfish excluding Pacific ocean perch), flatfish, jack mackerel, and prohibited species. In a foreign trawl or joint venture fishery for species other than Pacific whiting, incidental allowance percentages will be stated in the conditions and restrictions to the foreign fishing permit. See 50 CFR 611.70(c) for application of incidental retention allowance percentages to joint venture fisheries.
[2] U.S. only, based on 80 percent of the 177,000-mt ABC for the United States and Canada combined.
[3] The harvest guideline for jack mackerel north of 39° N. latitude is derived by subtracting the potential harvest outside of 200 nm (6,100 mt) from the 52,600-mt ABC that applies both inside and outside of 200 nm.
[4] Sablefish, thornyheads, and Dover sole may be managed together as the "deepwater complex." The harvest guideline for sablefish does not apply to the Conception subarea. The sablefish trawl and nontrawl allocations also are harvest guidelines. (See the section on trawl and nontrawl sablefish management for 1993.) The 17,900 mt coastwide harvest guideline for Dover sole includes a 6,000-mt harvest guideline for the Columbia subarea.
[5] The harvest guideline for Pacific ocean perch applies to the Vancouver and Columbia subareas combined.
[6] The harvest guideline for bocaccio applies to the Eureka, Monterey, and Conception subareas.
[7] The harvest guideline for yellowtail rockfish is 4,400 mt for the Vancouver and Columbia subareas. The harvest guideline for the *Sebastes* complex (including yellowtail rockfish) in the Vancouver and Columbia subareas is 11,200 mt.
[8] The harvest guideline for thornyheads includes both shortspine and longspine thornyheads in the Columbia, Eureka, and Monterey subareas.
[9] Harvest guidelines for commercial harvests of all species of rockfish by members of the Makah, Quileute, Hoh, and Quinault Indian tribes are established as follows: 51,000 pounds (23.1 mt) for the area between the U.S.-Canada border and Cape Alava (48°09'30" N. latitude); and 10,000 pounds (4.5 mt) for the area between Destruction Island (47°40'00" N. latitude) and Leadbetter Point (46°38'10" N. latitude).

Changes to the ABCs and Harvest Guidelines

The 1993 final ABCs are changed from the 1992 levels for the following species: Pacific whiting, sablefish, bocaccio, Dover sole. A numerical ABC is established for arrowtooth flounder for the first time. These changes are based on the best available scientific information.

Information considered in determining these specifications is available from the Council (see **ADDRESSES**) and was distributed to the public in the Council's stock assessment and fishery evaluation (SAFE) document. The SAFE document, required under the Guidelines for Fishery Management Plans at 50 CFR part 602, summarizes the best available scientific information concerning the past, present, and possible future condition of the stocks and fisheries being managed under Federal regulation.

Those species or species groups with harvest guidelines in 1992 will continue to be managed with harvest guidelines in 1993. As in 1992, no quotas are established. The harvest guidelines are changed in 1993 for Pacific whiting, sablefish, bocaccio, Dover sole, yellowtail rockfish, and the *Sebastes* complex.

The changes to the ABCs and harvest guidelines are announced below. All other specifications announced in 1992 (57 FR 1654, January 15, 1992) continue in effect for 1993.

Pacific Whiting

Based on the 1992 stock assessment, the Council recommended a coastwide 1993 ABC for the United States and Canada combined of 177,000 mt, 24 percent lower than the 232,000-mt combined ABC in 1992. This ABC is based on a hybrid fishing strategy that combines the features of a constant fishing mortality (F) strategy at higher levels of biomass, and, at lower levels of biomass, a variable F strategy where fishing mortality for a particular year is proportional to the level of female spawning biomass. Although the Council has assumed a moderate harvest rate in setting the U.S. harvest guideline for the past 2 years, lack of agreement with Canada over the sharing of this transboundary stock has resulted in combined catches exceeding the ABC. If recruitment remains near the 1960–1989 median recruitment of 0.678 billion fish, the outlook for the immediate future is for a continuing decline in annual yield. This decline will steepen if the combined catch for the United States and Canada continues above the ABC for both countries. The recruitment of a strong year class would substantially increase the projected yields.

Pacific whiting is a transboundary stock and the U.S. and Canadian governments do not yet agree on the appropriate levels of harvest by each country. In 1992, the combined U.S. and Canadian catch is expected to exceed the ABC for both countries by 29 percent. The 1992 U.S. harvest guideline of 208,800 mt was 90 percent of the U.S.-Canada ABC of 232,000 mt, whereas Canada based its quota of 90,000 mt on 30 percent of the expected total catch. In bilateral negotiations with Canada, the United States indicated that it would ask the Council to recommend lowering the U.S. harvest guideline to 80 percent of the U.S.-Canada ABC in 1993. Subsequently, the Council recommended that the 1993 U.S. harvest guideline be set at 142,000 mt, 80 percent of the 177,000-mt coastwide ABC for the United States and Canada.

If Canada continues to calculate its share in the same manner as in 1992, the U.S. and Canadian total harvest would be 15 percent above the coastwide ABC in 1993. If fishing occurs at this level in 1993, future ABCs will be reduced but the overfishing level for whiting will not be reached.

Sablefish

The ABC is decreased from 8,900 mt coastwide in 1992 to 5,000–7,000 mt north of the Conception subarea (north of 36°00′ N. latitude) in 1993. Coastwide landings in 1991 were 9,454 mt, and in 1992 are expected to be close to the 8,900-mt 1992 ABC. The sablefish stock was assessed in 1992 through application of a stock synthesis model to fishery size and age composition data from 1986–1991 and trawl and pot survey data. However, it was not possible to satisfactorily reconcile differences in the results of the slope trawl surveys and the pot surveys. Consequently, an ABC range of 5,000–7,000 mt was selected to protect the stock until more certainty can be achieved. Trawl discards have been estimated to be about 1,220 mt in recent years and are already subtracted from the ABC range.

For the first time, the harvest guideline for sablefish will apply only to the Vancouver, Columbia, Eureka, and Monterey subareas. The 1993 harvest guideline is 7,000 mt, the same as the ABC for those areas. The trawl and nontrawl gear allocations for sablefish also will continue to be specified as harvest guidelines. This is done so that the Council's goal of providing very small trip limits until the end of the year will not be compromised by premature closure of the fishery due to difficulties in estimating landings, as occurred in the nontrawl sablefish fishery in 1991.

A separate ABC of 425 mt is designated for sablefish in the Conception subarea, which is approximately the amount landed in that area in recent years. The Conception subarea is excluded from the stock assessment because of smaller size-at-age and delayed maturity in that area. In addition, sablefish larvae are rare in that area, suggesting that any spawning in that area makes a minimal contribution to coastwide recruitment.

Bocaccio

A new stock assessment was completed for bocaccio in the Eureka-Monterey-Conception subareas, resulting in an increase in the ABC from 800 mt in 1992 to 1,540 mt in 1993. The new assessment incorporates improved estimates of historical catch, including trawl, set net, hook-and-line, and recreational data. The stock synthesis model indicates that biomass has declined substantially since 1980 due to low recruitment, and is approaching 20 percent of its estimated unfished level. (Unfished level means the biomass that would exist if no fishing occurred.) Landings are substantially lower than they were before trip limits were imposed in 1991. However, weak recruitment since 1979 is expected to cause the stock to continue to decline unless the total harvest is kept closer to 1,100 mt, the 1991 harvest guideline. Landings in 1992 are projected to be less than 1,300 mt, and the overfishing level in 1993 is 1,840 mt. The Council supported its Groundfish Management Team's (GMT) recommendation for setting the ABC at 1,540 mt, because it is consistent with the current harvest policy for most of the groundfish species which assumes a fishing mortality rate that would reduce egg production per female to 35 percent of its unfished level. This ABC also includes an estimate of expected discards (160 mt) in the trawl and set net fisheries that often fish to the 2-week cumulative vessel limit for bocaccio.

The 1993 harvest guideline for bocaccio is equal to the ABC for the same areas.

Dover Sole

A new stock assessment for Dover sole was conducted in 1992. As a result, the 1993 ABC is reduced from 6,100 to 4,000 mt in the Columbia subarea, and from 4,900 mt to 3,500 mt in the Eureka subarea, and the coastwide ABC is reduced from 19,400 mt to 15,900 mt. There are no changes to the ABCs for the Vancouver, Monterey, and Conception subareas. The 1993 coastwide ABC is close to the level of landings in 1990 and 1992, but is lower than the 1991 landings of 18,203 mt. Recent landings are close to the recommended area ABC's for 1993 except for the Columbia subarea where landings were approximately 8,000 mt annually in 1988–1991, twice the recommended ABC for that area.

To mitigate the economic impact of abrupt reductions in ABC, the Council has recommended phasing in reductions by setting the harvest guideline higher than the ABC and decreasing the harvest guideline gradually over a few years. Consistent with this policy, the Council recommended a separate harvest guideline of 6,000 mt for Dover sole in the Columbia subarea in 1993, intermediate between the 4,000-mt 1993 ABC and the 8,000-mt projected landings for 1992. As a result, the coastwide harvest guideline, which includes the Columbia subarea harvest guideline, is 17,900 mt, 2,000 mt higher than the sum of the ABCs.

Arrowtooth Flounder

A stock assessment on arrowtooth flounder currently is underway, and a separate ABC is specified because of the growing importance of this fishery. Landings in 1991 declined to 4,960 mt from 5,824 mt in 1990. Pending completion of the new stock assessment, the ABC for arrowtooth flounder is set equal to the highest recent catch of 5,800 mt.

Yellowtail Rockfish and the Sebastes Complex

The 1993 ABCs for yellowtail rockfish and the other components of the *Sebastes* complex in the Vancouver and Columbia subareas are the same as in 1992. However, the harvest guideline applies to different areas in 1993. Before 1992, the harvest guidelines applied only to the Vancouver-Columbia area. However, in 1992, the Columbia subarea was divided at Cape Lookout, Oregon, and the harvest guidelines for yellowtail rockfish and the *Sebastes* complex applied to the Vancouver-northern Columbia area, and a separate harvest guideline was established for yellowtail in the southern Columbia-Eureka area. There was no separate trip limit for yellowtail in the southern area. The 1992 areas were difficult to monitor and high catch rates in the southern area suggested that management should be the same throughout the Columbia subarea. By July 29, 1992, trip limits were changed to be the same throughout the Vancouver and Columbia subareas. Consequently, the 1993 harvest guidelines for yellowtail rockfish of 4,400 mt and the *Sebastes* complex of 11,200 mt will be assigned only to the Vancouver and Columbia subareas combined, as they were in 1991.

Setting Harvest Guidelines Greater Than ABC

In most cases, harvest guidelines equal the ABCs, or prorated ABCs, for specific areas. However, for 1993 the Council recommended harvest guidelines that exceed the ABCs for two species, Pacific ocean perch (POP) and Dover sole. The FMP requires that the Council consider certain factors when setting a harvest guideline above an ABC. These factors were considered in establishing the 20-year rebuilding schedule for POP in the 1981 FMP, and were considered again for POP and Dover sole in the most recent stock assessment in the Council's August 1992 SAFE document, which provides the basis for the 1993 ABCs.

POP

POP currently is managed under a 20-year rebuilding schedule specified in the original 1981 FMP. The 1993 harvest guideline for POP is the same as in 1992, 1,550 mt, even though the ABC

remains at zero. As for the last several years, the harvest guideline, in conjunction with a very small trip limit, is necessary to accommodate only incidental catches of POP. Landings in 1992 are projected to be 1,023 mt. This harvest guideline is consistent with the 1,550-mt quota established in the original FMP to allow for incidental catches while achieving the 20-year rebuilding schedule for POP.

Dover Sole

The Council's GMT recommended that the 1993 harvest guideline for the Columbia subarea be set 2,000 mt above the area's ABC, and that the harvest guideline in 1994 and 1995 for the Columbia subarea be stepped down 1,000 mt each year so that it equals the ABC in 1995. This recommendation was based on the need to resolve uncertainty in the stock assessment and to mitigate the economic impact on the fishing industry. The risk of overfishing Dover sole in the Columbia subarea is not appreciably increased by a harvest guideline that exceeds the ABC during 1993 and 1994.

Overfishing

The FMP defines "overfishing" as a fishing mortality rate that would reduce spawning biomass per recruit to 20 percent of its unfished level (unless the species is above the level that would produce the maximum sustainable yield (MSY)). If the overfishing level is reached, the Guidelines for Fishery Management Plans at 50 CFR part 602 require the Council to identify actions to be undertaken to alleviate overfishing. No groundfish species are believed to have been overfished in 1992, and none, with the possible exception of POP, are expected to be overfished in 1993.

POP was depleted off Washington, Oregon, and California, mainly by foreign fishing during the 1960's and early 1970's. In 1981, a rebuilding program was established for POP in the Vancouver and Columbia subareas. (POP is neither common nor important in the more southern areas.) A new comprehensive review of fishery and survey data does not indicate any significant rebuilding. The stock is estimated to be about 50 percent of its MSY level and the recent harvests of about 1,000 mt are near the level of overfishing (1,100 mt). The review also indicates that strong year classes, which are necessary to rebuild the stock, occur infrequently so the lack of rebuilding is not unexpected. The Council's GMT recognized that, as long as trawling occurs in these areas, incidental catches of POP will result. The GMT recommended that trip limits continue to be set to discourage targeting on POP while allowing landings of incidental catches. It is not anticipated that lowering the level of the trip limit or the harvest guideline will reduce the fishing mortality of POP. The level of catch will vary with effort in the Vancouver-Columbia area, and it is possible that the overfishing level will be reached in 1993. Under the same harvest guideline and trip limit (3,000 pounds (1,361 kg) or 20 percent of all groundfish per trip, whichever is less), the total landed catch was 1,378 mt in 1991 and is projected at 1,023 mt in 1992.

Two species (bocaccio and shortspine thornyheads) reached their overfishing levels in 1991, and a number of restrictions were imposed to minimize this possibility in 1992. These appear to have been successful because they did not reach their respective levels of overfishing in 1992.

Although landings of bocaccio in 1992 are greater than in 1991, a new stock assessment has increased the ABC significantly, from 800 mt in 1992 to 1,540 mt in 1993. In 1993, the harvest guideline is equal to the ABC, and the overfishing level is 1,840 mt. Landings in 1992 are projected to be 1,268 mt, higher than the 1,000-mt harvest guideline. As discussed in the next section on management measures, the 1992 trip limit for bocaccio still is appropriate and is continued in 1993.

As in 1992, a 7,000-mt combined harvest guideline is recommended in 1993 for shortspine and longspine thornyheads because they are caught together and are difficult to tell apart. The ABC for shortspine thornyheads (1,900 mt) is much smaller than for longspines (10,100 mt). The harvest guideline is less than the combined ABCs for the two species because if it were equal to the sum of the ABCs for both species it would likely result in overfishing of shortspine thornyheads which contribute only 16 percent of the available yield. Thus, the shortspine ABC is expected to be exceeded in 1992 and 1993, while the ABC for longspine thornyheads will not be reached. The catch of shortspine thornyheads is projected to be 2,530 mt in 1992, above its ABC of 1,900 mt and well below its overfishing level of 3,500 mt. Thornyheads are projected to exceed their harvest guideline by 9 percent in 1992, and there is some uncertainty as to whether the increase in trawl mesh size (57 FR 12212, April 9, 1992, effective May 11, 1992) will increase the proportion of shortspine thornyheads in the catch. The more productive longspine thornyheads contributed about 75 percent of the landed catch during the first half of 1992, but if both species are caught in roughly equal proportions in 1993, the overfishing level of shortspine thornyheads could be reached. Consequently, the trip limits in January 1993 are lower than in January 1992 (as discussed in the section on management measures).

Discards

Stock assessments and in-season catch monitoring are designed to account for all fishing mortality, including that discarded at sea. Discards of rockfish and sablefish in the fishery for whiting processed at sea are well-monitored and are accounted for in-season as they occur. In the other fisheries, discards caused by trip limits are not monitored, so discard factors have been developed to reasonably account for this extra catch. These discard factors are applied in one of two ways. In some cases (trawl sablefish, widow rockfish, bocaccio, Dover sole), the discard factor was used in the stock assessment and in the setting of the ABC. Therefore the ABC and harvest guideline are defined in terms of landed catch, with the understanding that the discard factor is not applied for in-season catch monitoring. In other cases (yellowtail rockfish, POP, thornyheads), a discard factor was not anticipated in the stock assessment leading to the setting of the ABC because it was developed before the trip limits became low enough to induce discards. Therefore, an estimate of discards caused by trip limits is included in the in-season landing estimates.

Apportionment to DAP, JVP, DAH, and TALFF

In 1993, there are no surplus groundfish available for joint venture or foreign fishing operations. Consequently, the entire harvest guidelines in 1993 are designated entirely for DAP (which also equals DAH), and JVP and TALFF are set at zero.

II. 1993 Management Measures

The 1993 management measures announced in this notice have been designated as "routine" under the procedures contained in Amendment 4 to the FMP. This means that the measure is likely to need adjustment on an annual or more frequent basis, the effects of the particular management measure have been analyzed previously, and it may be implemented and adjusted for a specified species or species group and gear type after consideration at a single Council meeting and after a notice is published in the **Federal Register**, as long as the

purpose of the measure is the same as when it was designated as routine.

The Sebastes Complex (Including Yellowtail Rockfish and Bocaccio)

In 1993, the cumulative trip limit for yellowtail rockfish of 8,000 pounds (3,629 kg) in a 2-week period is the same as at the beginning of 1992. However, it applies to the larger area north of Coos Bay, Oregon, rather than north of Cape Lookout, Oregon. In 1992, for the first time, different trip limits and harvest guidelines were set for yellowtail rockfish in the northern area (Vancouver-Columbia north of Cape Lookout) and the southern area (Eureka-Columbia south of Cape Lookout). Because landings of yellowtail rockfish from the southern area were expected to be small, they were restricted only by the trip limit for the *Sebastes* complex. However, landings in the southern area have grown and it became apparent that management should be the same throughout the Columbia subarea. On July 29, 1992, the trip limits for yellowtail rockfish were again applied to the Vancouver-Columbia area, as has been the case since 1985. This practice is continued in 1993.

The 1992 cumulative trip limit for bocaccio of 10,000 pounds (4,536 kg) in a 2-week period caught, south of Cape Mendocino (the Monterey and Conception subareas), is not changed for 1993, except that it will be applied the same as for yellowtail rockfish: that is, if a vessel is used to fish south of Cape Mendocino at any time during the 2-week period, the more restrictive trip limit for bocaccio caught south of Cape Mendocino will apply to all landings by that vessel during the 2-week period, even if some fishing occurred north of Cape Mendocino. This change is not expected to affect fishing operations since few bocaccio fishers, if any, operate both north and south of Cape Mendocino.

The 1993 coastwide cumulative trip limit for the *Sebastes* complex of 50,000 pounds (22,680 kg) in a 2-week period, which includes yellowtail rockfish and bocaccio as well as most other rockfish species, is the same as in 1992.

Widow Rockfish

The 1993 cumulative trip limit for widow rockfish is 30,000 pounds (13,608 kg) in a 4-week period, the same as at the beginning and end of 1992. On whatever date during the 1993 fishing season it is determined necessary to extend the fishery to the end of the year, a 3,000 pound (1,361 kg) trip limit may be imposed. If imposed, the 3,000-pound (1,361 kg) trip limit will apply per trip, not cumulatively.

POP

The 1993 trip limit for POP is the same as in 1991 and 1992: 3,000 pounds (1,361 kg) or 20 percent of all fish on board, whichever is less, in landings of POP above 1,000 pounds (454 kg). This is not a cumulative limit because it is intended to accommodate only incidental catches. It therefore applies to each fishing trip.

Deepwater Complex (Thornyheads, Dover Sole, and Trawl-Caught Sablefish)

The cumulative trip limits for the deepwater complex and thornyheads are reduced from January 1992 levels, but the sablefish trip limit is unchanged. This is intended to reduce landings of thornyheads which are expected to exceed their harvest guideline by 9 percent in 1992. It also is intended to reduce landings of Dover sole, which is projected to be 6 percent below its coastwide harvest guideline in 1992, but must be reduced further to accommodate the lower harvest guideline in the Columbia area in 1993. Consequently, the cumulative trip limit for the deepwater complex is reduced from 55,000 pounds (24,948 kg) in a 2-week period in January 1992 to 45,000 pounds (20,412 kg) in a 2-week period in January 1993. Similarly, the cumulative trip limit for thornyheads, which is included in the trip limit for the deepwater complex, will be lower in January 1993 than in January 1992, reduced from 25,000 pounds (13,340 kg) to 20,000 pounds (9,072 kg) for each 2-week period. As in 1991 and 1992, sablefish cannot exceed 25 percent of any landing of the deepwater complex containing more than 1,000 pounds (454 kg) of sablefish, and, in any landing, no more than 5,000 pounds (2,268 kg) of sablefish may be smaller than 22 inches. Even though the sablefish harvest guideline applies only to the Vancouver, Columbia, Eureka, and Monterey subareas, these trip limits are applied coastwide to avoid effort shifts into the Conception subarea.

Nontrawl Trim Limits for Sablefish

In 1993, a 250-pound (113 kg) daily trip limit will apply until the first 72-hour closure before the start of the regular season, and again on the date necessary to extend the harvest guideline to the end of the year without exceeding it. In 1993, the regular season is expected to begin on May 12. If fishing rates are similar to 1992, the 1993 regular season will be shorter than 3 weeks.

The level of trip limits in the nontrawl sablefish fishery prior to the regular season was the subject of considerable debate in 1991 and 1992. These limits are intended to allow small incidental catches to be landed and to allow small fisheries to operate year-round. In 1992, the year began with a 500-pound (227 kg) daily trip limit which was increased to 1,500 pounds (680 kg) daily on March 1. Because the sablefish catch continued at a more rapid rate than the Council intended, the trip limit was reduced to 500 pounds on March 20, 1992, and to 250 pounds on April 17, 1992, until the regular season opened on May 12, 1992. The regular season lasted only 15 days, after which the 250-pound (113 kg) daily trip limit was reimposed. Nontrawl landings are expected to be close to the 1992 nontrawl allocation of 3,612 mt by the end of the year.

More restrictive trip limits are necessary in 1993 because the nontrawl harvest guideline is smaller than in 1992 due to the reduction in ABC. A trip limit larger than 250 pounds (113 kg) per day most likely would result in a shorter open season, which already is expected to be 3 weeks or less.

Management Measures Recommended as "Routine" in 1993 or Under Amendment 7

The Council recommended that trip limits for Pacific whiting be designated as routine during the time periods before and after the large-scale target season that starts in the spring, and also for whiting caught shoreward of 100-fathoms in the Eureka subarea. Routine trip limits are listed in the Federal regulations at 50 CFR 663.23(c). A proposed rule to designate whiting trip limits as routine before and after the main season was published at 57 FR 56897 (December 1, 1992). A final rule is expected imminently. The Council recommended that Pacific whiting trip limits be set at 10,000 pounds (4,536 kg) per trip for 1993.

If approved, the routine designation for the trip limit for whiting caught inside of 100 fathoms in the Eureka subarea will be combined in the same rule with a number of other recommended nonroutine actions that would impose restrictions to minimize the bycatch of salmon in the whiting fishery. These restrictions include: no fishing for whiting at night south of 42° N. latitude; no at-sea processing operations south of 42° N. latitude; no fishing for whiting in the Columbia River and Klamath River salmon conservation zones; no fishing for whiting inside the 100-fathom contour in the Eureka subarea, except for a small "routine" trip limit, if any; and opening of the whiting season on March 1

between 42°00′ and 40°30′ N. latitude. These actions are contingent on approval of Amendment 7 to the FMP and, if approved, may not be effective before the spring of 1993.

Secretarial Actions

The Secretary concurs with the Council's recommendations and announces the following management actions, including those that have not been changed (for POP, widow rockfish, sablefish caught with nontrawl gear, and recreational bag and size limits).

A. General Definitions and Provisions

The following definitions and provisions apply to the 1993 management measures, unless otherwise specified in a subsequent notice:

(1) *A trip limit* is the total allowable amount of a groundfish species or species complex, by weight, or by percentage of fish on board, that may be taken and retained, possessed, or landed per vessel from a single fishing trip.

(2) *A daily trip limit* is the maximum amount that may be taken and retained, possessed or landed per vessel in 24 consecutive hours, starting at 0001 hours local time. Only one landing of groundfish may be made in that 24-hour period.

(3) *A cumulative trip limit* is the maximum amount that may be taken and retained, possessed or landed per vessel in a specified period of time, without a limit on the number of landings or trips. Cumulative trip limits for 1993 initially apply to 2-week and 4-week periods.

The 2-week and 4-week periods in 1993 are as follows, and start at 0001 hours Wednesday and end at 2400 hours Tuesday (local time), except for the first period which is short 2 days, and the last period which includes an extra 3 days to extend to the end of the year:

Two-week periods: 1/1–1/12; 1/13–1/26; 1/27–2/9; 2/10–2/23; 2/24–3/9; 3/10–3/23; 3/24–4/6; 4/7–4/20; 4/21–5/4; 5/5–5/18; 5/19–6/1; 6/2–6/15; 6/16–6/29; 6/30–7/13; 7/14–7/27; 7/28–8/10; 8/11–8/24; 8/25–9/7; 9/8–9/21; 9/22–10/5; 10/6–10/19; 10/20–11/2; 11/3–11/16; 11/17–11/30; 12/1–12/14; 12/15–12/31.

Four-week periods: 1/1–1/26; 1/27–2/23; 2/24–3/23; 3/24–4/20; 4/21–5/18; 5/19–6/15; 6/16–7/13; 7/14–8/10; 8/11–9/7; 9/8–10/5; 10/6–11/2; 11/3–11/30; 12/1–12/31.

(4) Unless the fishery is closed, a vessel which has landed its 2-week (or 4-week) limit may continue to fish on the limit for the next 2-week (or 4-week) period so long as the fish are not landed (offloaded) until the next 2-week (or 4-week) period.

(5) All weights are round weights or round weight equivalents.

(6) Percentages are based on round weights, and, unless otherwise specified, apply only to legal fish on board.

(7) Legal fish means fish taken and retained, possessed, or landed in accordance with the provisions of 50 CFR part 663, the Magnuson Act, any notice issued under subpart B of part 663, and any other regulation promulgated or permit issued under the Magnuson Act.

(8) Closure, when referring to closure of a fishery, means that taking and retaining, possessing or landing the particular species or species group is prohibited. (See the regulations at 50 CFR 663.2.)

(9) The fishery management area for these species is the EEZ off the coasts of Washington, Oregon, and California between 3 and 200 nautical miles offshore, and bounded on the north by the Provisional International Boundary between the United States and Canada, and bounded on the south by the International Boundary between the United States and Mexico. All groundfish possessed 0–200 nautical miles offshore, or landed in, Washington, Oregon, or California are presumed to have been taken and retained from the fishery management area, unless otherwise demonstrated by the person in possession of those fish.

(10) Inseason changes to trip limits are announced by notices published in the **Federal Register.** Information concerning changes to trip limits also is available from the NMFS Northwest and Southwest regional offices [see ADDRESSES above]. Changes to trip limits are effective at the times stated in the **Federal Register** notices. Once a change is effective, it is illegal to take and retain, possess, or land more fish than allowed under the new trip limit.

B. Widow Rockfish

No more than 30,000 pounds (13,608 kg) cumulative may be taken and retained, possessed, or landed per vessel in a 4-week period. (Widow rockfish also are called brownies.)

C. Sebastes Complex (Including Yellowtail and Bocaccio Rockfish)

(1) General. (a) *Sebastes* complex means all rockfish managed by the FMP except Pacific ocean perch (*Sebastes alutus*), widow rockfish (*S. entomelas*), shortbelly rockfish (*S. jordani*), and *Sebastolobus* spp. (thornyheads, idiot, or channel rockfish). Yellowtail rockfish (*S. flavidus*) are commonly called greenies. Bocaccio (*S. paucispinis*) are commonly called rock salmon.

(b) Coos Bay means 43°21′34″ N. latitude, the north jetty at Coos Bay, Oregon.

(c) Cape Mendocino means 40°30′00″ N. latitude.

(2) Cumulative trip limits. Coastwide, no more than 50,000 pounds (22,680 kg) cumulative of the *Sebastes* complex may be taken and retained, possessed or landed per vessel in a 2-week period. Of this 50,000 pounds (22,680 kg), no more than 8,000 pounds (3,629 kg) cumulative may be yellowtail rockfish taken and retained north of Coos Bay, and no more than 10,000 pounds (4,536 kg) cumulative may be bocaccio taken and retained south of Cape Mendocino.

(3) If any vessel is used to fish north of Coos Bay during a 2-week period, then that vessel is subject to the trip limit for yellowtail rockfish taken and retained north of Coos Bay, no matter where the fish are possessed or landed. Similarly, if a vessel is used to take and retain yellowtail rockfish south of Coos Bay and possesses or lands yellowtail rockfish north of Coos Bay, that vessel is subject to the northern trip limit.

(4) If any vessel is used to fish south of Cape Mendocino during a 2-week period, then that vessel is subject to the trip limit for bocaccio taken and retained south of Cape Mendocino, no matter where the fish are possessed or landed. Similarly, if a vessel is used to take and retain bocaccio north of Cape Mendocino and possesses or lands bocaccio south of Cape Mendocino, that vessel is subject to the southern trip limit.

D. Pacific Ocean Perch (POP)

The trip limit for Pacific ocean perch coastwide is 3,000 pounds (1,361 kg) or 20 percent of all legal fish on board, whichever is less. If less than 1,000 pounds (454 kg) of Pacific ocean perch are landed, the 20 percent limit does not apply.

[Note: Twenty percent of all legal fish on board including Pacific ocean perch is equivalent to 25 percent of all legal groundfish on board other than Pacific ocean perch.]

E. Sablefish and the Deepwater Complex (Sablefish, Dover Sole, and Thornyheads

(1) *1993 Management Goal.* The sablefish fishery will be managed to achieve the 7,000 mt harvest guideline in 1993.

(2) *Washington Coastal Tribal Fisheries.* An estimate will be made of the catch to the end of the year for the Washington coastal treaty tribes. It is anticipated that these tribes will regulate their fisheries so as not to exceed their estimated catch. There will

be no Federally imposed tribal allocation or quota. In 1993, the estimated tribal catch is 300 mt, the same as in 1991 and 1992.

(3) *Gear Allocations.* After subtracting the tribal-imposed catch limit, the remaining harvest guideline will be allocated 58 percent to the trawl fishery and 42 percent to the nontrawl fishery.

[Note: The 1993 harvest guideline for sablefish is 7,000 mt. After subtracting the 300-mt tribal-imposed catch limit, the remaining 6,700 mt is allocated 3,886 mt to the trawl fishery and 2,814 mt to the nontrawl fishery. The trawl and nontrawl gear allocations are harvest guidelines in 1993, which means the fishery will be managed so that the harvest guidelines are not exceeded, but will not necessarily be closed if they are reached.]

(4) *Trawl Trim and Size Limits.* (a) *Trawl gear.* Trawl gear includes bottom trawls, roller or bobbin trawls, pelagic trawls, and shrimp trawls.

(b) "Deepwater complex" means sablefish (*Anoplopoma fimbria*), Dover sole (*Microstomus pacificus*), and thornyheads (*Sebastolobus* spp.). Sablefish also are called blackcod. Thornyheads also are called idiots, channel rockfish or hardheads.

(c) *Trip limits.* Coastwide, no more than 45,000 pounds (20,412 kg) cumulative of the deepwater complex may be taken and retained, possessed, or landed per vessel in a 2-week period. Within this 45,000 pounds (20,412 kg), no more than 20,000 pounds (9,072 kg) cumulative may be thornyheads. In any landing of the deepwater complex, no more than 25 percent of the deepwater complex may be sablefish, unless less than 1,000 pounds (454 kg) of sablefish are landed, in which case the percentage does not apply. In any landing, no more than 5,000 pounds (2,268 kg) of sablefish may be smaller than 22 inches (56 cm) (total length).

[Note: Twenty-five percent of the deepwater complex (including sablefish) is equivalent to 33.333 percent of the legal thornyheads and Dover sole.]

(5) *Nontrawl trip and size limits.* (a) Nontrawl gear means all legal commercial groundfish gear other than trawl gear (see 50 CFR 663.2), including set nets (gill and trammel nets), traps or pots, longlines, commercial vertical hook-and-line gear, and troll gear.

(b) The coastwide daily trip limit for sablefish caught with nontrawl gear is 250 pounds (113 kg). This trip limit, which applies to sablefish of any size, remains in effect until the regular season begins, as specified at 50 CFR 663.23(b)(2).

[Note: Currently, the regular season begins on April 1. However, the Council has recommended, and NMFS has proposed (57 FR 53313, November 9, 1992) that the regular season be changed so that it begins 3 days prior to the first sablefish opening in Alaska, with 72-hour closures immediately before and after the regular season. If the Council's recommendation is approved by the Secretary, and Alaska opens its sablefish fishery on May 15, 1993, as currently expected, the 250-pound (113 kg) daily trip limit would be in effect from 0001 hours January 1 through 2400 hours May 8; the first 72-hour closure would occur from 0001 hours May 9 through 2400 hours May 11; and the regular season would start at 0001 hours May 12.]

(c) During the "regular" season, the only trip limit in effect applies to sablefish smaller than 22 inches (56 cm) (total length) which may comprise no more than 1,500 pounds (680 kg) or 3 percent of all legal sablefish on board, whichever is greater. (See paragraph (6) regarding length measurement.)

(d) Following the regular season, on a date to be announced in the **Federal Register**, the 250-pound (113 kg) daily trip limit may be reimposed for sablefish (of any size) caught with nontrawl gear.

(6) *Length measurement.* (a) Total length is measured from the tip of the snout (mouth closed) to the tip of the tail (pinched together) without mutilation of the fish or the use of additional force to extend the length of the fish.

(b) For processed ("headed") sablefish,

(i) the minimum size limit is 15.5 inches (39 cm) measured from the origin of the first dorsal fin (where the front dorsal fin meets the dorsal surface of the body closest to the head) to the tip of the upper lobe of the tail; the dorsal fin and tail must be left intact; and,

(ii) the product recovery ratio (PRR) established by the state where the fish is or will be landed will be used to convert the processed weight to round weight for purposes of applying the trip limit. (The PRR currently is 1.6 in Washington, Oregon, and California. However, the state PRRs may differ and fishermen should contact fishery enforcement officials in the state where the fish will be landed to determine that state's official PRR.)

(7) No sablefish may be retained which is in such condition that its length has been extended or cannot be determined by the methods stated above in paragraph (6).

III. Recreational Fishing

(1) *California.* The bag limit for each person engaged in recreational fishing seaward of the State of California is 5 lingcod which may be no smaller than 22 inches (56 cm) (total length) and 15 rockfish per day. Multi-day limits are authorized by a valid permit issued by the State of California and must not exceed the daily limit multiplied by the number of days in the fishing trip.

(2) *Washington (South of Leadbetter Point) and Oregon.* The bag limit for each person engaged in recreational fishing seaward of the States of Washington south of Leadbetter Point (46°38'10" N. latitude) and Oregon is 3 lingcod per day and 15 rockfish per day.

(3) *Washington (North of Leadbetter Point).* The bag limit for each person engaged in recreational fishing seaward of the State of Washington north of Leadbetter Point (46°38'10" N. latitude) is 3 lingcod per day and 12 rockfish per day.

IV. Inseason Adjustments

At subsequent meetings, the Council will review the best data available and recommend modifications to these management measures if appropriate. The Council intends to examine the progress of these fisheries during the year in order to avoid overfishing and to achieve the goals and objectives of the FMP and its implementing regulations.

V. Other Fisheries

A. Foreign Vessels

Receipt or retention of groundfish by foreign fishing or foreign processing vessels, if any, is limited by incidental allowances established under 50 CFR 611.70.

B. Experimental Fisheries

U.S. vessels operating under an experimental fishing permit issued under 50 CFR 663.10 also are subject to these restrictions unless otherwise provided in the permit.

C. Shrimp and Prawn Fisheries

Landings of groundfish in the pink shrimp, spot and ridgeback prawn fisheries are governed by regulations at 50 CFR 663.24, which state:

Section 663.24(a) Pink Shrimp

The trip limit for a vessel engaged in fishing for pink shrimp is 1,500 pounds (680 kg) (multiplied by the number of days of the fishing trip) of groundfish species other than Pacific whiting, shortbelly rockfish, or arrowtooth flounder (which are not limited under this paragraph).

Section 663.24(b) Spot and Ridgeback Prawns

The trip limit for a vessel engaged in fishing for spot or ridgeback prawns is 1,000 pounds (454 kg) of groundfish species per fishing trip.

However, if fishing for groundfish and pink shrimp, spot or ridgeback prawns in the same fishing trip, the groundfish restrictions in this notice apply.

Classification

The final specifications and management measures for 1993 are issued under the authority of and in accordance with the regulations implementing the FMP at 50 CFR parts 611 and 663.

An Environmental Impact Statement (EIS) was prepared for the FMP in 1982 and a Supplemental EIS was prepared for Amendment 4 in accordance with the National Environmental Policy Act (NEPA). The alternatives considered and environmental impacts of the actions contained in this notice are not significantly different than those considered in either the EIS or SEIS for the FMP. Therefore this action is categorically excluded from the NEPA requirements to prepare an environmental assessment in accordance with paragraph 6.02c3(f) of the NOAA Administrative Order 216–6 because the alternatives and their impacts have not changed significantly and this action falls within the scope of the EIS and SEIS.

This action is in compliance with Executive Order 12291 and the Regulatory Flexibility Act.

This action does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under Executive Order 12612.

Much of the data necessary for these specifications and management measures comes from the current fishing season. Because of the timing of the receipt, development, review, and analysis of the fishery information necessary for setting the initial specifications and management measures, and the need to have these specifications and management measures in effect at the beginning of the fishing year, there is good cause to waive the publication of proposed specifications in the **Federal Register** and a 30-day comment period on the proposed specifications. Amendment 4 to the FMP, implemented on January 1, 1991, recognized these timeliness considerations, and set up a system by which the interested public was notified, through **Federal Register** notice and Council mailings, of meetings and of the development of these measures, and was provided the opportunity to comment during the Council process. The public participated in GMT, Groundfish Advisory Subpanel, Scientific and Statistical Committee, and Council meetings in August, September, October, and November 1992 that resulted in these recommendations from the Council. Additional public comments will be accepted for 30 days after publication of this notice in the **Federal Register**. The Assistant Administrator for Fisheries, NOAA, will consider all comments made during the public comment period and may propose modifications as appropriate.

The Administrative Procedure Act requires that publication of an action be made not less than 30 days before its effective date unless the Secretary finds and publishes with the rule good cause for an earlier effective date. Good cause for waiving the delay in effectiveness is found if the delay is impracticable, unnecessary, or contrary to the public interest. These specifications announce the harvest goals and the management measures designed to achieve those harvest goals in 1993. A delay in implementation could compromise the management strategies that are based on the projected landings from these trip limits. Therefore, a delay in effectiveness is contrary to the public interest and these actions are effective on January 1, 1993.

List of Subjects

50 CFR Part 611

Fisheries, Foreign relations, Reporting and recordkeeping requirements.

50 CFR Part 663

Administrative practice and procedure, Fisheries, Fishing, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 31, 1992.

Samuel W. McKeen,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 92–31957 Filed 12–31–92; 4:53 pm]

BILLING CODE 3510–22–M

Proposed Rules

Federal Register
Vol. 58, No. 4
Thursday, January 7, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 270

[Release Nos. 33-6871, IC-18192; File No. S7-41-92]

RIN 3235-AF60

Revision of Certain Annual Review Requirements of Investment Company Boards of Directors

AGENCY: Securities and Exchange Commission.

ACTION: Proposed amendments to rules and guidelines, and requests for comment.

SUMMARY: The Commission is proposing for public comment amendments to five rules under the Investment Company Act of 1940. The proposed amendments would eliminate requirements in these rules that directors annually review certain arrangements and procedures, and require instead that directors make and approve changes only when necessary. The proposals are intended to substitute more meaningful requirements for the current annual review requirements, which are not necessary to further the purposes of the rules or protect investors. The proposals would also make conforming changes to the Guidelines to Forms N-1A and N-3.

DATES: Comments must be received on or before March 8, 1993.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Stop 6-9, Washington, DC 20549. All comment letters should refer to File No. S7-41-92. All comments received will be available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549.

FOR FURTHER INFORMATION CONTACT: Edward J. Rubenstein, Attorney, or Diane C. Blizzard, Deputy Chief of Office, both at (202) 272-2048, Office of Regulatory Policy, Division of Investment Management, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission today is requesting public comment on proposed amendments to rules 10f-3, 17a-7, 17e-1, 17f-4, and 22c-1 [17 CFR 270.10f-3, 270.17a-7, 270.17e-1, 270.17f-4, and 270.22c-1] under the Investment Company Act of 1940 [15 U.S.C. 80a-1, *et seq.*] (the "Act").[1] The proposed amendments implement recommendations made in chapter 7 of the Division of Investment Management's recently issued report, Protecting Investors: A Half Century of Investment Company Regulation (the "Protecting Investors Report").[2]

I. Background

In connection with the *Protecting Investors Report*, the Division examined ways to relieve investment company boards of directors from tasks that perform little useful purpose and that actually interfere with the ability of boards to operate efficiently. The Division concluded that these goals would be furthered by the elimination of the requirements in rules 10f-3, 17a-7, 17e-1, 17f-4, and 22c-1 that the boards of directors annually review certain procedures and arrangements.[3] These requirements may take up a substantial amount of the boards' time and attention and increase costs, and are unnecessary because, generally, the arrangements do not change from year to year.[4] Consequently, these annual review requirements do not materially strengthen the rules or add to the protection of investors. The Division concluded that a more appropriate approach would be to require the boards to make and approve changes only as warranted by circumstance.[5]

The Commission agrees with these recommendations, and proposes to amend rules 10f-3, 17a-7, 17e-1, 17f-4, and 22c-1 to eliminate the annual review requirements, and to require instead that the boards make and approve changes to the various arrangements as the boards deem necessary. These proposed amendments would remove unnecessary regulatory burdens without diminishing investor protection, and should permit the directors to devote time and attention to more important matters.

II. Discussion

A. Rules 10f-3, 17a-7, and 17e-1

Rules 10f-3 and 17a-7 permit certain otherwise prohibited, affiliated transactions to go forward if the transactions meet the conditions enumerated in the rules.[6] Rule 17e-1

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[1] The proposals also make conforming changes to the Guidelines to Forms N-1A [17 CFR 239.15A and 274.11A] and N-3 [17 CFR 239.17a and 274.11b].

[2] Sec, Division of Investment Management, Protecting Investors: A Half Century of Investment Company Regulation, *Corporate Governance* 251-289 (May 1992) [hereinafter the Protecting Investors Report].

[3] In response to the Commission's Request for Comment on Reform of the Regulation of Investment Companies, Investment Company Act Release No. 17534 (June 15, 1990), 55 FR 25322, several commenters also suggested the deletion of the annual review requirements in one or all of these rules. *See, e.g.*, Letter from Davis Polk & Wardwell to Jonathan G. Katz, Secretary, SEC (March 7, 1991) File No. S7-11-90 [hereinafter Davis Polk Study Comment]; Letter from Dechert Price & Rhoads to Jonathan G. Katz, Secretary, SEC 36-44 (Oct. 10, 1990), File No. S7-11-90; and Letter from R. James Gormley to Jonathan G. Katz, Secretary, SEC 16-19 (Oct. 9, 1990), File No. S7-11-90. The Act contains other board of directors annual review requirements that neither the commenters nor the Division recommended eliminating. *See, e.g.*, rule 17g-1 [17 CFR 270.17g-1] (annual approval of fidelity bonds).

In the future, the Commission anticipates considering an amendment to rule 17f-5 [17 CFR 270.17f-5] to revise a requirement in that rule that directors annually approve foreign custody arrangements after considering numerous factors, and an amendment to rule 12d3-1 [17 CFR 270.12d3-1] that, among other things, would delete the requirement that directors determine that any debt security of an issuer in which the investment company intends to invest is "investment grade," if the issuer derived more than fifteen percent of its gross revenues from securities-related activities in its most recent fiscal year. Both of these rule proposals would implement recommendations contained in the Protecting Investors Report. *See id.* at 270-271.

[4] See, e.g., Davis Polk Study Comment, *supra* note 3, at 2.

[5] See Protecting Investors Report at 251-271.

[6] Section 10(f) (15 U.S.C. 80a-10(f)) generally prohibits a registered investment company from acquiring securities during the existence of an underwriting syndicate if a principal underwriter of that syndicate is an affiliate of the investment company. Rule 10f-3 (17 CFR 270.10f-3) provides a limited exemption, permitting a registered investment company to purchase securities in a transaction prohibited by section 10(f) as long as the transaction complies with certain conditions. The purpose of these provisions, and the rule's conditions, is to prevent underwriters from "dumping" unmarketable securities on affiliated investment companies, or from earning excessive underwriting fees in connection with such transactions. See Investment Company Acquisition of Securities Underwritten by an Affiliate of that Company, Investment Company Act Release No. 14924 (Feb. 4, 1986), 51 FR 4386.

Continued

provides a safe harbor from the Act's restriction on affiliated brokers' compensation in connection with the sale of securities.[7] All three rules require that the full board and a majority of the independent directors must adopt procedures designed to assure that all relevant conditions and standards have been satisfied, review the procedures at least annually for "continuing appropriateness," and determine at least quarterly that all relevant transactions during the preceding quarter were effected in compliance with the established procedures.[8]

Annual review of these operating procedures should not be necessary to achieve the purposes that give rise to these rules. The conditions in rules 10f–3, 17a–7, and 17e–1 are intended to prevent overreaching,[9] or assure fair compensation.[10] Annual review of the operating procedures do not advance these purposes because, ordinarily, the procedures do not change after they are adopted.[11] In the case of rules 10f–3 and 17a–7, the procedures are virtually prescribed by the rules and thus generally are unlikely to change unless the rules change.

The Commission thus proposes to amend these rules to delete the annual review requirements, and to require instead that the board make and approve any changes to the procedures as the board deems necessary.[12] Careful attention to the required quarterly reviews of transactions,[13] which are retained in these rules, should enable boards to monitor the procedures and identify any problems that might require an adjustment to procedures. Boards should also take note of any other information about the effectiveness of the procedures that is presented or observed.

B. Rule 17f–4

Section 17(f)[14] permits an investment company or its custodian to deposit the company's securities in a securities depository that complies with Commission requirements. Under rule 17f–4,[15] the depository must be either a clearing agency registered with the Commission under section 17A of the Securities Exchange Act of 1934 (15 U.S.C. 78q–1) or the Federal Reserve book-entry system.[16] In addition, the arrangement with the depository must comply with several conditions, which include initial approval and annual review by the board of directors.[17] The purpose of the rule is "to enable investment companies to participate, with minimum risks, in the potential benefits incident to the deposit of securities in securities depositories."[18]

Annual review of depository arrangements does not appear necessary. The use of domestic securities depositories has become an integral part of securities investing; most funds investing in United States securities could not conduct business without using them. The eligible depositories are either registered with the Commission or, in the case of the book-entry system, operated by the Federal Reserve,[19] and the depository arrangements must comply with substantive conditions intended to minimize risks.[20] Most of the key elements of the arrangements are prescribed by the rule, leaving the boards of directors very little discretion, other than to make sure that the arrangements continue to comply with the rule. Accordingly, once established, the essential terms of the arrangements remain unchanged from year to year unless the rule changes. The annual review becomes perfunctory. At the same time, this requirement consumes time and attention that could be better spent on other matters.

The Commission proposes to amend rule 17f–4 to delete the annual review requirement.[21] Directors would only be required to approve depository arrangements initially, and any subsequent changes proposed by the adviser.

C. Rule 22c–1

Rule 22c–1 generally requires that the purchase and redemption of a redeemable security be effected at the current net asset value next computed after receipt of a purchase or redemption request.[22] Current net asset value must be computed at least once daily, subject to limited exceptions, and, at least annually, the board of directors must set the time or times each day that the company will calculate current net asset value.[23] The purpose of section 22(c) and rule 22c–1 is to address the problem of "dilution" and to curb certain speculative trading practices.[24]

Requiring the directors annually to set the time of day does not materially advance the purpose of the rule. This is accomplished by the fundamental requirement of forward pricing. In addition, the pricing time is not something that normally needs to be changed annually. The proposed rule amendments would delete this requirement, and require instead that the board initially set the pricing time or times, and thereafter make and approve any changes as it deems necessary.[25] For example, it may be

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Section 17(a) (15 U.S.C. 80a–17(a)) generally prohibits an affiliated person of a registered investment company (or an affiliated person of such person) from engaging in a purchase, sale, or loan transaction with such registered investment company (or any company controlled by such registered investment company). Rule 17a–7 (17 CFR 270.17a–7) provides an exemption from section 17(a) for purchases and sales of securities between funds that are considered affiliates because of a common adviser, director, or officer, subject to conditions that are intended to limit the exemption to those situations where there is no likelihood of overreaching with respect to the participating investment companies. See Exemption of Certain Purchase or Sale Transactions Between Affiliated Registered Investment Companies, Investment Company Act Release No. 4697 (Sept. 16, 1966), 31 FR 12092. The rule permits funds under common management to trade securities with each other and thus to avoid brokerage commissions. The rule also limits the prices at which inter-fund transfers may occur in order to prevent inequitable pricing practices that could benefit one fund at the expense of another.

[7] Section 17(e)(2)(A) (15 U.S.C.80a–17(e)(2)(A)) prohibits an affiliated broker-dealer from receiving a commission that exceeds the usual and customary broker's commission where the sale is effected on a securities exchange. Rule 17e–1 (17 CFR 270.17e–1) provides, in part, that a commission will not be considered as exceeding the usual and customary broker's commission if the board has adopted procedures designed to ensure that the commissions paid are reasonable and fair compared to commissions paid to brokers in connection with comparable transactions involving similar securities being sold on a securities exchange during a comparable period. The purpose of the rule's conditions is to ensure compliance with this standard. See Agency Transactions by Affiliated Persons on a Securities Exchange, Investment Company Act Release No. 10605 (Mar. 6, 1979), 44 FR 12202.

[8] Rules 10f–3(h), 17a–7(e), and 17e–1(b) (17 CFR 270.10f–3(h), .17a–7(e), and .17e–1(b)).

[9] See supra note 6.

[10] See supra note 7.

[11] See, e.g., Davis Polk Study Comment, supra note 3, at 2.

[12] The Commission also proposes to amend rules 10f–3 and 17e–1 to make technical, non-substantive language changes.

[13] See rules 10f–3(h)(3), 17a–7(e)(3), and 17e–1(b)(3).

[14] 15 U.S.C. 80a–17(f).

[15] Rule 17f–4(b) (17 CFR 270.17f–4(b)).

[16] See 31 CFR Part 306, subpart O; and 31 CFR Part 350.

[17] See rule 17f–4(c)(3) and (d)(5), (17 CFR 270.17f–4(c)(3) and .17f–4(d)(5)).

[18] Deposits of Securities in Securities Depositories, Investment Company Act Release No. 10453 (Nov. 1, 1978), 43 FR 50869.

[19] See rule 17f–4(b).

[20] See rules 17f–4(c) and (d).

[21] The Commission also proposes to amend rule 17f–4 to make technical, non-substantive language changes.

[22] 17 CFR 270.22c–1(a).

[23] See rule 22c–1(b)(1) [17 CFR 270.22c–1(b)].

[24] See Pricing of Redeemable Securities for Distribution, Redemption and Repurchase and Time-Stamping of Orders by Dealers, Investment Company Act Release No. 5519 (Nov. 7, 1968), 33 FR 16331.

[25] This would require amending rule 22c–1(b)(1), and adding a new paragraph (e). There is already pending a proposal to add a new paragraph (d) to rule 22c–1. See Periodic Repurchases By Closed-End Management Investment Companies; Redemptions by Open-End Management Investment Companies and Registered Separate Accounts at

necessary for the board to change the pricing time in response to new developments, such as twenty-four hour trading, or changes in the nature of the investment company's investments.

In connection with the proposed amendments to rule 22c–1, the Division would make conforming amendments to the Guidelines to Forms N–1A [17 CFR 239.15A, 274.11A] and N–3 [17 CFR 239.17a, 274.11b]. The revision to the Guidelines to Form N–1A would delete the words "at least once a year" in the eleventh paragraph of Guide 28. The revision to the Guidelines to Form N–3 would delete the words "no less frequently than annually" in the last paragraph of Guide 27.

III. Cost/Benefit of Proposed Action

Proposed amendments to rules 10f–3, 17a–7, 17e–1, 17f–4, and 22c–1 would not impose any significant burdens on investment companies. These proposed amendments would benefit investment companies by reducing the burdens on directors and freeing their time for more important matters. Comment is requested, however, on these matters and on the costs or benefits of any other aspect of the proposed actions. Commenters should submit estimates of any costs and benefits perceived, together with any supporting empirical evidence available.

IV. Summary of Initial Regulatory Flexibility Analysis

The Commission has prepared an Initial Regulatory Flexibility Analysis in accordance with 5 U.S.C. 603 regarding amendments to rules 10f–3, 17a–7, 17e–1, 17f–4, and 22c–1. The Analysis explains that the proposed amendments would eliminate the requirement in these rules that directors annually review certain arrangements and procedures, and require instead that directors make and approve changes only when necessary.[25] The Analysis states that the proposed amendments are intended to delete those annual review requirements that are more form than substance, and that are not necessary to further the purposes of the rules or to protect investors, and to substitute more meaningful requirements. The Analysis states that the proposed amendments are intended to maintain the highest level of investor protection. It also states that the proposed amendments contain no reporting or recordkeeping requirements. By eliminating the annual review requirements, the proposed amendments will reduce the costs incurred by investment companies. The Commission considered a number of significant alternatives to the proposed amendments, but prefers the proposed approach because it eliminates unnecessary burdens while preserving investor protection. A copy of the Initial Regulatory Flexibility Analysis may be obtained by contacting Edward J. Rubenstein, Esq. or Diane C. Blizzard, Esq., both at Mail Stop 10–4, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

V. Statutory Authority

The Commission is proposing the amendments to rules 10f–3, 17a–7, 17e–1, 17f–4, and 22c–1 pursuant to sections 6(c), 10(f), 17(e), 17(f), 22(c), and 38(a) of the Act.

List of Subjects in 17 CFR Part 270

Investment Companies, Reporting and recordkeeping requirements, Securities

Text of Proposed Rule Amendments

For the reasons set out in the preamble, title 17, chapter II of the Code of Federal Regulations is proposed to be amended as follows:

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

1. The authority citation for part 270 continues to read, in part, as follows:

Authority: 15 U.S.C. 80a–1 *et seq.*, 80a–37, 80a–39 unless otherwise noted:

* * * * *

Section 270.22 c–1 also issued under secs. 6(c), 22(c), and 38(a) [15 U.S.C. 80a–6(c), 80a–22(c), and 80a–37a].

2. Section 270.10f–3 is amended by revising paragraph (h) to read as follows:

§ 270.10f–3 Exemption of acquisition of securities during the existence of underwriting syndicate.

* * * * *

(h) The board of directors, including a majority of the directors of the investment company who are not interested persons with respect thereto:

(1) Has adopted procedures, pursuant to which such purchases may be effected for the company, which are reasonably designed to provide that all the conditions of this section in paragraphs (a) through (g) have been complied with;

(2) Makes and approves such changes as the board deems necessary; and

(3) Determines no less frequently than quarterly that all purchases made during the preceding quarter were effected in compliance with such procedures; and

* * * * *

3. Section 270.17a–7 is amended by revising paragraph (e)(2) to read as follows:

§ 270.17a–7 Exemption of certain purchase or sale transactions between an investment company and certain affiliated persons thereof.

* * * * *

(e) * * *

(2) Makes and approves such changes as the board deems necessary, and

* * * * *

4. Section 270.17e–1 is amended by revising paragraph (b) to read as follows:

§ 270.17e–1 Brokerage transactions on a securities exchange.

* * * * *

(b) The board of directors, including a majority of the directors of the investment company who are not interested persons thereof:

(1) Has adopted procedures which are reasonably designed to provide that such commission, fee, or other remuneration is consistent with the standard described in paragraph (a) of this section;

(2) Makes and approves such changes as the board deems necessary; and

(3) Determines no less frequently than quarterly that all transactions effected pursuant to this section during the preceding quarter were effected in compliance with such procedures; and

* * * * *

5. Section 270.17f–4 is amended by revising paragraphs (b), (c)(3), and (d)(5) to read as follows:

§ 270.17f–4 Deposits of securities in securities depositories.

* * * * *

(b) A registered management investment company (investment company) or any qualified custodian may deposit all or any part of the securities owned by the investment company in a foreign securities depository or clearing agency in accordance with rule 17f–5 (17 CFR 270.17f–5) or in:

(1) A clearing agency registered with the Commission under section 17A of the Securities Exchange Act of 1934 (clearing agency), which acts as a securities depository, or

(2) The book-entry system as provided in subpart O of Treasury Circular No. 300, 31 CFR part 306, subpart B of 31 CFR part 350, and the book-entry regulations of federal agencies substantially in the form of subpart O,

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Periodic Intervals or with Extended Payment, Investment Company Act Release No. 18860 (August 6, 1992), 57 FR 34701, 34721.

[25] The Analysis also notes that the proposals would make certain technical, non-substantive language changes to rules 10f–3, 17e–1, and 17f–4, as well as conforming changes to the Guidelines to Forms N–1A [17 CFR 239.15A, 274.11A] and N–3 [17 CFR 239.17a, 274.11b].

in accordance with the following paragraphs of this section.

(c) * * *

(3) The investment company, by resolution of its board of directors, initially approved the arrangement, and any subsequent changes thereto.

(d) * * *

(5) The investment company, by resolution of its board of directors, initially approved the arrangement, and any subsequent changes thereto.

6. Section 270.22c–1 is amended by revising paragraph (b)(1) and adding paragraph (e) to read as follows:

§ 270.22c–1 Pricing of redeemable securities for distribution, redemption and repurchase.

* * * * *

(b) * * *

(1) The current net asset value of any such security shall be computed no less frequently than once daily, Monday through Friday, at the specific time or times during the day that the board of directors of the investment company sets, in accordance with paragraph (e) of this section, except on:

(i) Days on which changes in the value of the investment company's portfolio securities will not materially affect the current net asset value of the investment company's redeemable securities;

(ii) Days during which no security is tendered for redemption and no order to purchase or sell such security is received by the investment company; or

(iii) Customary national business holidays described or listed in the prospectus and local and regional business holidays listed in the prospectus; and

* * * * *

(e) The board of directors shall initially set the time or times during the day that the current net asset value shall be computed, and shall make and approve such changes as the board deems necessary.

Text of Proposed Changes to Guidelines

Note: The Guides to Forms N–1A and N–3 are not codified in the Code of Federal Regulations.

1. Guide 28 to Form N–1A (239.15A and 274.11A) is amended by revising the first three sentences of paragraph eleven (unnumbered) to read as follows:

Guide 28. Valuation of Securities Being Offered

* * * * *

Item 7 requires a statement in the prospectus as to when calculations of net asset value are generally made. The current net asset value of redeemable securities should be computed at least once each day whenever there is enough trading in the investment company's portfolio securities to materially affect the current net asset value of the investment company's redeemable securities and on which an order for purchase, redemption, or repurchase of its securities is received. Calculations of net asset values should be made at such time or times during the day as set by the directors of the investment company. * * *

* * * * *

2. Guide 27 to Form N–3 (239.17a and 274.11b) is amended by revising the first three sentences of the last paragraph (unnumbered) to read as follows:

Guide 27. Valuation of Securities Being Offered

* * * * *

The prospectus must disclose when calculations of accumulation unit value are generally made. The current accumulation unit value of redeemable securities should be computed in accordance with rule 22c–1 under the 1940 Act [17 CFR 270.22c–1], i.e., at least once daily on each weekday (except for customary national and local business holidays listed in the prospectus) in which there is sufficient trading in the separate account's portfolio securities so that the current accumulation unit value might be materially affected by changes in the value of these portfolio securities and on which an order for purchase or redemption of its securities is received. These calculations of accumulation unit value should be made at such specific time or times during the day as determined by a majority of the board of managers of the separate account. * * *

By the Commission.

Dated: December 30, 1992.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–291 Filed 1–6–93; 8:45 am]

BILLING CODE 8010–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Ch. I

[FRL–4552–9]

Change in Meeting Location for the January 13–14 Disinfection By-products Negotiated Rulemaking Advisory Committee Meeting

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Disinfection By-products Negotiated Rulemaking Advisory Committee's January 13–14 meeting to continue to develop consensus that can be used as the basis of a proposed rule will be held at the Quality Hotel, 415 N. Jersey Ave, NW, Washington, D.C., NOT at "Resolve" on 24th Street as Noticed earlier.

DATES: The meeting will take place on January 13–14. On January 13 the meeting will start at 9:30 a.m. and end at 5:00 p.m. On January 14, it will start at 8:30 a.m. and end by 4:00 p.m.

ADDRESSES: The Committee will meet at the Quality Hotel, 415 N. Jersey Ave NW, Washington, D.C. [202] 638–1616.

FOR FURTHER INFORMATION CONTACT: For further information on substantive aspects of the rule, call Stig Regli of EPA's Water Office at [202] 260–7379. For further information on the meeting, call Gail Bingham, the Committee Co-Chair, at [202] 293–4800.

Chris Kirtz,

Director, Consensus and Dispute Program.

Dated: January 4, 1993.

[FR Doc. 93–300 Filed 1–6–93; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 92–304; FCC 92–557]

Renewal Reporting Requirements

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission initiates this Notice of Proposed Rule Making to consider whether to require licensees of certain types of broadcast stations to report on their license renewal applications the status of their operations. Specifically, the Commission proposes to modify Form 303–S to require licensees of full power commercial AM, FM and TV stations to report, at the time of license renewal, whether their stations are on the air or have discontinued operations.

DATES: Comments are due on or before February 23, 1993, and reply comments are due on or before March 10, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: David E. Horowitz, Policy and Rules Division, Mass Media Bureau, (202) 632–7792.

SUPPLEMENTARY INFORMATION: The following collection of information requirements contained in these proposed form changes have been

submitted to the Office of Management and Budget for review under Section 3504(h) of the Paperwork Reduction Act. Copies of the submission may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–2422, 1990 M Street, NW., Suite 640, Washington, DC 20036. Persons wishing to comment on this information should direct their comments to Jonas Neihardt, (202) 395–4814, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503. A copy of any comments should also be sent to the Federal Communications Commission, Office of Managing Director, Washington, 20554. For further information contact Judy Boley, Federal Communications Commission, (202) 632–7513.

OMB Number: 3060–0110.

Title: Application for Renewal of License for Commercial and Noncommercial AM, FM or TV Broadcast Station.

Form: FCC 303–S.

Action: Revised Collection.

Respondents: Businesses or other for-profit, small businesses or organizations.

Frequency of Response: Once every 5 years for TV; once every 7 years for radio.

Estimated Annual Response: 144 noncommercial TV licensees, 0.666 per response; 330 commercial TV licensees, 3.166 per response; 6 off-the-air commercial TV licensees, 4.166 per response, 1,166 hours total.

Needs and Uses: FCC 303–S is a data collection device filed by licensees of commercial and noncommercial AM, FM and TV station licensees. The data are used to assure that the necessary forms connected with the renewal application have been filed and that the licensee continues to meet basic statutory requirements to remain a licensee of a broadcast station. The following is a synopsis of the Commission's Notice of Proposed Rule Making, in MM Docket No. 92–304, adopted December 18, 1992, and released December 30, 1992. The complete text of this Notice of Proposed Rule Making is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1990 M Street, NW., Suite 640, Washington, DC 20036.

Synopsis of Notice of Proposed Rule Making

1. The Commission initiates this Notice of Proposed Rule Making ("Notice") on its own motion, to consider whether to require licensees of certain types of broadcast stations to report on their license renewal applications the status of their operations. Specifically, the Commission proposes to modify Form 303–S to require licensees of full power commercial AM, FM and TV stations to report whether, at the time of license renewal, their stations are on the air or have discontinued operations.

2. Section 73.1740(a)(4) of the Commission's Rules permits commercial AM, FM, and TV licensees to limit or discontinue operations for a period of thirty days without authority from the Commission. However, licensees are required to notify the Commission of limited or discontinued operations not later than the tenth day of such operation. Licensees are also required to request additional time if operations are not resumed within thirty days. In addition, 73.1750 requires commercial licensees to tender their license authorizations to the Commission for cancellation when discontinuance of station operations are permanent.

3. Preliminary information gathered by the Commission indicates that commercial AM, FM, and TV stations may not be complying fully with the requirements of §§ 73.1740 and 73.1750. The Commission is aware of an increasing number of stations that have discontinued operation. Many of these stations did not notify the Commission of discontinued operations in a timely manner, and few that have permanently discontinued operations have tendered the license to the Commission for cancellation.

4. When a licensee discontinues operations for a long period of time, the public is harmed through diminished service. Allowing licensees to preserve their exclusive right to use the frequency precludes the provision of service to the public by another interested party that would resume station operations. Unjustified prolonged suspension of station operations disserves the public interest, and the information which the Commission proposes to seek would promote the expeditious restoration of service to the public. Accordingly, the Commission seeks comment on its proposal to add to FCC Form 303–S the following questions: "Is the station off the air as of the date of this filing?" and "If yes, attach as Exhibit No. _____a statement of explanation, including the steps the applicant intends to take to restore service to the public."

Ex Parte Rules—Non-Restricted Proceeding

4. This is a non-restricted notice and comment rulemaking proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in Commission Rules. See generally 47 CFR 1.1202, 1.1203 and 1.1206(a).

Comment Information

5. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, interested parties may file comments on or before February 23, 1993, and reply comments on or before March 10, 1993. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding. To file formally in this proceeding, participants must file an original and four copies of all comments, reply comments, and supporting comments. If participants want each Commissioner to receive a personal copy of their comments, an original plus nine copies must be filed. Comments and reply comments should be sent to the Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center (room 239) of the Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

Initial Regulatory Flexibility Analysis

6. As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared the following Initial Regulatory Flexibility Analysis (IRFA) of the expected impact on small entities of the proposals suggested in this document. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the Regulatory Flexibility Analysis. The Secretary shall send a copy of this Notice of Proposed Rule Making, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981)).

I. Reason for the Action: The purpose of this Notice is to consider whether to

solicit information at renewal time as to the status of licensees' broadcast operations.

II. Objective of This Action: This action is intended to determine whether soliciting such information would be in the public interest.

III. Legal Basis: Authority for the actions proposed in this Notice may be found in sections 4 and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 154 and 303.

IV. Reporting, Recordkeeping, and Other Compliance Requirements Inherent in the Proposed Rule: Licensees would be required to report as to the status of their broadcast operations at renewal time.

V. Federal Rules Which Overlap, Duplicate, or Conflict With the Proposed Rule: None.

VI. Description, Potential Impact and Number of Small Entities Involved: Approximately 10,000 existing commercial broadcasters of all sizes would be affected by the proposals contained in this Notice.

VII. Any Significant Alternatives Minimizing the Impact on Small Entities and Consistent With the Stated Objectives: None.

List of Subjects in 47 CFR Part 73

Radio broadcasting and Television broadcasting.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93-311 Filed 1-6-93; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 92-305; FCC 92-556]

TV Transmission Standards

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to amend its television technical standards to provide for enhanced closed-captioning service and the transmission of a ghost-cancelling reference signal. This action is necessary to respond to respective petitions filed by the Electronic Industries Association and the American Television Systems Committee and to update the TV technical rules to provide for new service made possible by advancements in television technology. The intended effect of the action is to significantly improve the performance and versatility of television receivers.

DATES: Comments must be filed by March 1, 1993. Reply comments must be filed by March 16, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: James E. McNally, Jr., Mass Media Bureau, Engineering Policy Branch, (202) 632-9660.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making in MM Docket No. 92-305 adopted December 18, 1992, and released on December 31, 1992. The complete text of this Notice of Proposed Rule Making is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M St., NW., Washington, DC, and may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1114 21st Street, NW., Washington, DC 20036.

Synopsis of Notice of Proposed Rule Making

1. By this Notice of Proposed Rule Making, the Commission proposes to amend §§ 73.682 and 73.699 of its rules to permit optional transmission of expanded closed-captioning and other types of information using all of line 21, field 2, of the vertical blanking interval (VBI) of broadcast television signals. This action is being taken in response to a petition for rule making (RM-8066) which was filed by the Consumer Electronics Group of the Electronic Industries Association (EIA/CEG) on July 7, 1992.

2. Additionally, the Commission, in response to a petition for rule making (RM-8067) filed by the Advanced Television Systems Committee (ATSC) on August 14, 1992, proposes to reserve use of line 19 of the VBI for the optional use of a ghost-canceling reference (GCR) signal. Because each of the petitions is directed at improving the quality of television service through new or modified uses of the VBI, and because neither of the two petitions appears to involve any significant technical difficulty, the Commission believes that a consolidated rulemaking proceeding would expedite their resolution and facilitate introduction of these new technologies to the American public.

3. The Commission believes that the proposals and rationale presented in both the EIA/CEG Petition and the ATSC Petition have merit. Of particular importance in the former petition is the fact that the first half of line 21, field 2 has not been utilized in its current technical configuration. The Commission agrees with the petitioner that reconfiguration of line 21, field 2 to provide enhanced closed-captioning (whether it be for a second language or a higher level of captioning quality) would appear to serve the public interest. This change may not only enhance closed-captioning for hearing-impaired persons, but may also expand various captioning uses for non hearing-impaired person as well. It also believes that EIA/CEG's proposed distinction in the priority of use (with non-captioning uses permitted only on a secondary basis) of line 21 may be appropriate.

4. The second half of line 21, field 2 is ostensibly in the visible portion of the TV signal. The Commission believes that this is not cause for concern, however, because the scanning beam in every TV receiver available to date "overscans" the visible picture by several lines on the top and the bottom of the screen. (Overscanning is the deflection of the scanning beam beyond the mask on a television picture tube. The mask is usually part of the television cabinet and it covers the edges of the picture. Line 22, also part of the active video, has been used for several years for program source identification signaling. Since initiation of this use, no complaints of picture degradation have been received.)

5. In sum, both EIA/CEG's petition and the Commission's experience indicate that there is no likely adverse impact if it assigns all of line 21, field 2 for enhanced closed-captioning and, on a secondary basis, other broadcast-related uses. The Commission seeks comment on this proposal and on any unforeseen or overlooked problems or circumstances that exist which would argue for or against this use of line 21, field 2. Comments also are solicited on whether or not any adverse interaction may occur between line 21 and line 22 from the standpoint of line identification and decoding circuitry. If so, should use of line 22, which may be used for "special signals" (see 22 FCC 2d 779 (1970)), be made secondary to that of line 21?

6. With respect to ATSC's petition, the Commission believes that while many advances in NTSC television quality have been made over the years, picture degradation through ghosting may be the most significant reception defect yet to be eliminated or minimized. Therefore, an effective system of reducing or eliminating ghosts would be a significant technical improvement which would be of direct benefit to viewers.

7. There are several issues requiring exploration in this matter. First, is there any significant use of the VIR signal today? As ATSC notes in its petition:

For the VIR signal to be maximally effective for the consumer, the VIR signal must be added at the time the program is created and must remain unchanged during distribution of that program in a television distribution system. It was difficult for television stations to consistently apply the VIR signal given the complexities of program production and distribution. And a misapplied VIR signal could actually change the consumer's received color rendition for the worse. (ATSC Petition, p. 5.)

This statement indicates that VIR implementation has been far from complete. Nevertheless, the Commission solicits additional comment on any current uses of the VIR and whether they should preclude its abandonment in favor of a GCR signal.

8. Second, ATSC asks that the Commission embody the definition of the Philip's Laboratory GCR signal in an OET Bulletin with a reference to it being placed in the rules, inasmuch as ATSC membership agreed on the selection of Philip's GCR system as being the best of those tested. By this action the Commission would clearly ratify the industry's selection. The Commission has taken similar action in the past, most notably when it adopted standards for TV stereo. (Reference is made to the "BTSC system of stereophonic sound transmission" in § 73.682(c)(3) of the Rules, the specifications of which are described in detail in OST Bulletin No. 60.) Comment is requested on this proposal. The Commission also asks whether or not flexibility and future improvements in ghost-cancelling technology would be hindered by this approach. Alternatively, it could simply reserve all of line 19 for use by ghost-cancelling reference signals without specifying any particular system. Lastly, comment is solicited on any other relevant circumstances or potential problems that may be associated with the implementation of the GCR reference signal on line 19.

9. Significant benefits can be derived by prompt action in this rule making. TV manufacturers currently are designing receivers equipped with closed-captioning circuitry mandated by the Television Decoder Circuitry Act of 1990 (Pub. L. 101–431) as implemented in § 15.119 of the Commission's Rules. The earlier action can be taken on the proposals discussed herein, the less disruptive it will be for manufacturers already planning their compliance with this requirement and the sooner televisions equipped with these features can be made available to the public. Therefore, to bring these improvements to the public with a minimum of delay, relatively short deadlines for filing comments and reply comments are specified below. Extensions of the comment and reply comment deadlines will require substantial justification, as the Commission desires to proceed to the Report and Order phase of this proceeding as soon as possible.

Initial Regulatory Flexibility Analysis

10. As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared the following Initial Regulatory Flexibility Analysis (IRFA) of the expected impact on small entities of the proposals suggested in this document. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice, but they must have a separate and distinct heading designating them as responses to the Regulatory Flexibility Analysis. The Secretary shall send a copy of this Notice of Proposed Rule Making, including the IRFA, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act (Pub. L. No. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981)).

11. *Reason for Action:* The purpose of this Notice is to consider changes in the use of the vertical blanking interval of broadcast television signals.

12. *Objectives of This Action:* This action is intended to improve the general quality of television service by providing for enhanced closed-captioning service and, secondary to that, other broadcast-related information services capable of depiction in an alpha-numeric format. Additionally, the rules proposed would permit the transmission of a special ghost-cancelling reference signal that when used with TV receivers having the proper decoding circuitry, could eliminate much, if not all, picture degradation due to the reception of reflected, low amplitude TV signals.

13. *Legal Basis.* Authority for the actions proposed in this Notice may be found in sections 4 and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 154 and 303.

14. *Reporting, Recordkeeping, and Other Compliance Requirements:* None.

15. *Federal Rules Which Overlap, Duplicate, or Conflict With the Proposed Rule:* None.

16. *Description, Potential Impact and Number of Small Entities Involved:* The services permitted by the new rules are entirely optional in character. However, their appeal to the public is likely to be such that most TV broadcast licensees will want to obtain the equipment with which to provide them. Thus, as a practical matter, the new rules would have an impact on some 1,500 licensees.

17. *Any Significant Alternatives Minimizing the Impact on Small Entities and Consistent With the Stated Objectives:* There are none.

Ex Parte

18. This is a non-restricted notice and comment rulemaking proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in Commission rules. See generally 47 CFR 1.1202, 1.1203 and 1.1206(a).

Comment Information

19. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, interested parties may file comments on or before March 1, 1993 and reply comments on or before March 16, 1993. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding. To file formally in this proceeding, participants must file an original and four copies of all comments, reply comments, and supporting comments. If participants want each Commissioner to receive a personal copy of their comments, an original plus nine copies must be filed. Comments and reply comments should be sent to the Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the Dockets Reference Room (room 239) of the Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–271 Filed 1–6–93; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 76

[MM Docket No. 92–306, FCC 92–561]

Cable Television Services; List of Major Television Markets

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission invites comments on its proposal, initiated by a request filed by Press Broadcasting Company, Inc. (Press), to amend the Commission's Rules to change the

designation of the Orlando-Daytona Beach-Melbourne-Cocoa, Florida television market to include the community of Clermont, Florida. This action is taken to test the proposal for market hyphenation through the rulemaking process and through the record established based on comments filed by interested parties.

DATES: Comments are due by February 22, 1993, and reply comments are due by March 9, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Alan E. Aronowitz, Mass Media Bureau, Policy and Rules Division (202) 632–7792.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making in MM Docket No. 92–306, FCC 92–561, adopted December 21, 1992, released December 31, 1992. The complete text of this document is available for inspection and coping during normal business hours in the FCC Reference Center, 1919 M Street, NW., Washington, DC, and also may be purchased from the Commission's copy contractor, Downtown Copy Center, at (202) 452–1422, 1990 M Street, NW., room 640, Washington, DC 20554.

Synopsis of the Notice of Proposed Rule Making

1. The Commission, in response to a Petition for Rulemaking filed by Press, licensee of WKCF (TV), Clermont, Florida, proposed to amend § 76.51 of the Rules (47 CFR 76.51) to change the designation of the Orlando-Daytona Beach-Melbourne-Cocoa, Florida, television market to include the community of Clermont, Florida. In previous decisions, the Commission granted a Press request for waiver of § 73.658(m) of the Rules to allow WKCF to be included in the subject market for territorial exclusivity purposes (4 FCC Rcd 8799 (1989), *aff'd on recon.*, 6 FCC Rcd 6563 (1991)), and granted Press' Petition for Extraordinary Relief, ruling that WKCF was a "local signal" in the market for mandatory cable carriage (and thus copyright) purposes for the period between December 11, 1989, and November 13, 1991 (FCC 92–460, released November 9, 1992).

2. The Commission, based on the facts presented, believes that a sufficient case for market hyphenation has been set forth to justify testing this proposal through the rulemaking process and notice and comment procedures. Therefore, comment is requested on this proposal to amend § 76.51 of the Commission's Rules by adding Clermont to the Orlando-Daytona Beach-Melbourne-Cocoa, Florida, market designation.

Administrative Matters

Initial Regulatory Flexibility Analysis

3. We certify that the Regulatory Flexibility Act of 1980 does not apply to this rulemaking proceeding because if the proposed rule amendment is promulgated, there will not be a significant economic impact on a substantial number of small business entities, as defined by section 601(3) of the Regulatory Flexibility Act. A few number of television licensees and permittees will be affected by the proposed rule amendment. The Secretary shall send a copy of this Notice of Proposed Rule Making, including the certification, to the chief counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act. Pub. L. No. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981).

Ex Parte

4. This is a non-restricted notice and comment rule-making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's Rules. See generally 47 CFR 1.1202, 1.1203, and 1.1206(a).

Comment Dates

5. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before February 22, 1993, and reply comments on or before March 9, 1993. To file formally in this proceeding, you must file an original plus four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center of the Federal Communications Commission, room 239, 1919 M Street, NW., Washington, DC 20554.

6. Authority for this proposed Rule Making is contained in sections 4 (i) and (j), and 303 of the Communications Act of 1934, as amended.

List of Subjects in 47 CFR Part 76

Cable television.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–269 Filed 1–6–93; 8:45 am]

BILLING CODE 6712–01–M

Notices

Federal Register
Vol. 58, No. 4
Thursday, January 7, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Agency Forms Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposals for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: National Marine Sanctuary Permits.

Agency Form Number: None.

OMB Approval Number: 0648–0141.

Type of Request: Extension of the expiration date of a currently approved collection.

Burden: 273 hours.

Number of Respondents: 140.

Avg Hours Per Response: Ranges between 30 minutes and 2 hours.

Needs and Uses: Individuals who wish to conduct research or other regulated activities in National Marine Sanctuaries must submit a written permit request. Following permit issuance, a cruise log report and an annual report of activities must be submitted.

Affected Public: Individuals, state or local governments, businesses or other for–profit institutions, federal agencies, non–profit institutions, and small businesses or organizations.

Frequency: On occasion, annually.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Ron Minsk, (202) 395–3084.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Atlantic Bluefin Tuna Dealer Reports.

Form Number: NOAA 88–144.

OMB Approval Number: 0648–0239.

Type of Request: Revision.

Burden: 983 hours.

Number of Respondents: 360.

Avg Hours Per Response: Ranges between 3 and 33 minutes.

Needs and Uses: The U.S. is a member of the International Commission for the Conservation of Atlantic Tunas (ICAAT). As a member nation, the U.S. is required to take part in the collection of biological statistics and adhere to specific quotas assigned to it by ICAAT. The purpose of this collection is to satisfy both these requirements by obtaining information for stock assessments and to monitor the catch so that the U.S. quota is not exceeded.

Affected Public: Businesses or other for–profit institutions, small businesses or organizations.

Frequency: Daily and bi–weekly.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Ron Minsk, (202) 395–3084.

Copies of the above information collection proposals can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collections should be sent to Ron Minsk, OMB Desk Officer, room 3019, New Executive Office Building, Washington, DC 20503.

Dated: January 4, 1993.

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR DOC 93–252 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–CW–F

International Trade Administration

Export Trade Certificate of Review

ACTION: Notice of Issuance of an Export Trade Certificate of Review, Application No. 92–00012.

SUMMARY: The Department of Commerce has issued an Export Trade Certificate of Review to Balmac International, Inc., effective December 29, 1992. This notice summarizes the conduct for which certification has been granted.

FOR FURTHER INFORMATION CONTACT: George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration, 202–482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001–21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. The regulations implementing Title III are found at 15 CFR part 325 (1991) (50 FR 1804, January 11, 1985).

The Office of Export Trading Company Affairs is issuing this notice pursuant to 15 CFR 325.6(b), which requires the Secretary of Commerce to publish a summary of a Certificate in the **Federal Register**. Under section 305(a) of the Act and 15 CFR 325.11(a), any person aggrieved by the Secretary's determination may, within 30 days of the date of this notice, bring an action in any appropriate district court of the United States to set aside the determination on the ground that the determination is erroneous.

DESCRIPTION OF CERTIFIED CONDUCT:

Export Trade

1. Products

Cold storage warehouses, ice flakers, ice machines, block ice machines, commercial and industrial mechanical refrigeration equipment and accessories.

2. Services

Design and modification of the above listed products pursuant to foreign buyers' specifications.

Export Markets

The Export Markets include all parts of the world except Canada and the United States (the fifty states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, and the Trust Territory of the Pacific Islands).

Export Trade Activities and Methods of Operation

1. With respect to the sale of Products and Services, BALMAC, subject to the terms and conditions listed below, may:

(a) Enter into and terminate exclusive independent agreements with Bally Engineered Structures, Inc. and other Supplier separately wherein:

(1) BALMAC agrees not to represent any competitors of such Supplier as an Export Intermediary unless authorized by the Supplier;

(2) The Supplier agrees not to sell, directly or indirectly, through any other intermediary, into the Export Markets in which BALMAC represents the Supplier

as an Export Intermediary and, if such sales do occur to pay a commission to BALMAC; or

(3) Both (1) and (2) above

(b) Enter into and terminate exclusive agreements with Export Intermediaries wherein:

(1) BALMAC agrees to deal in Products in the Export Markets only through that Export Intermediary;

(2) That Export Intermediary agrees not to represent BALMAC's competitors in the Export Markets or not to buy from BALMAC's competitors for resale in the Export Markets; or

(3) Both (1) and (2) above.

(c) Enter into exclusive or nonexclusive agreements with an individual buyer in the Export Markets to act as a Purchasing Agent with respect to a particular transaction.

(d) On behalf of BALMAC itself, or while acting as an Export Intermediary for separate Suppliers:

(1) Establish prices and quantities at which Products will be acquired, sold or resold for or in the Export Markets;

(2) Establish the price and other terms of sale at which Services will be acquired, sold or resold for or in the Export Markets;

(3) Allocate foreign territories or customers among BALMAC's Export Intermediaries or to a Supplier and that Supplier's Export Intermediaries; or

(4) Any combination of (1), (2), and (3) above.

BALMAC may engage in the activities in (d) above by agreement with BALMAC's Export Intermediaries, by independent agreement with separate Suppliers, by agreement with that Supplier's Export Intermediaries, or on the basis of its own determination.

(e) Disclose to an individual buyer in the Export Market prices and other terms of export marketing or sale.

Terms and Conditions of Certificate

1. In engaging in Export Trade Activities and Methods of Operation, BALMAC will not intentionally disclose, directly or indirectly, to any Supplier any information about any other Supplier's costs, production, capacity, inventories, domestic prices, domestic sales, or U.S. business plans, strategies, or methods that is not already generally available to the trade or public.

2. BALMAC will comply with requests made by the Secretary of Commerce on behalf of the Secretary of Commerce or the Attorney General for information or documents relevant to conduct under the Certificate. The Secretary of Commerce will request such information or documents when either the Attorney General or the Secretary of Commerce believes that the information or documents are required to determine whether the Export Trade, Export Trade Activities, and Methods of Operation of a person protected by this Certificate continue to comply with the standards of Section 303(a) of the Act.

Definitions

For purposes of this certificate, the following terms are defined:

(a) "Export Intermediary" means:

(1) "Broker"—a person that locates buyers in the Export Markets for the Supplier or that locates Suppliers for buyers in the Export Markets on a straight commission or cost-plus commission basis and that, in so acting, offers, provides or engages in some or all Services;

(2) "Distributor"—a person that purchases Products for its own account from a Supplier, that may establish the resale price or maintain an inventory of Products for perspective, unidentified sales and that, in so acting, offers, provides or engages in some or all Services; or

(3) "Sales Representative or Agent"—a person that identifies and locates Products for sale; gives advice on, or chooses among prospective buyers in the Export Markets, advises on or negotiates prices, quantities, and other sale terms and conditions, sells Products for its own account or for the account of others; and that, in so acting, offers, provides or engages in some or all Services.

(b) "Purchasing Agent" means an intermediary who identifies and locates Products for purchase; gives advice on, or chooses among prospective Suppliers; advises on or negotiates prices, quantities, and other purchase terms and conditions; and purchases Products for its own account or for the account of others; and who, in so acting, offers, provides or engages in some or all Services.

(c) "Supplier" means a person who produces or sells Products or Services to be exported from the United States.

Protection Provided by Certificate

This Certificate protects BALMAC, its partners, officers, and employees acting on its behalf from private treble damage actions and government criminal and civil suits under U.S. federal and state antitrust laws for the export conduct specified in this Certificate and carried out during its effective period in compliance with its terms and conditions.

Effective Period of Certificate

This Certificate continues in effect from the effective date until it is relinquished, modified, or revoked as provided in the Act and Regulations.

Other Conduct

Nothing in this Certificate prohibits BALMAC from engaging in conduct not specified in this Certificate, but such conduct is subject to the normal application of the antitrust laws.

Disclaimer

The issuance of this Certificate of Review to BALMAC by the Secretary of Commerce with the concurrence of the Attorney General under the provisions of the Act does not constitute, explicitly or implicitly, an endorsement or opinion by the Secretary of Commerce or by the Attorney General concerning either (a) the viability or quality of the business plans of BALMAC or (b) the legality of such business plans of BALMAC under the laws of the United States (other than as provided in the Act) or under the laws of any foreign country.

The application of this Certificate to conduct in export trade where the United States Government is the buyer or where the United States Government bears more than half the cost of the transaction is subject to the limitations set forth in Section V.(D.) of the "Guidelines for the Issuance of Export Trade Certificates of Review (Second Edition)," 50 FR 1786 (January 11, 1985).

A copy of each certificate will be kept in the International Trade Administration's Freedom of Information Records Inspection Facility, room 4102, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

Dated: December 29, 1992.

George Muller,

Director, Office of Export Trading Company Affairs.

[FR Doc. 93–304 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–DR–M

National Oceanic and Atmospheric Administration

[Docket No. 91–6133]

Endangered and Threatened Wildlife and Plants: Steller Sea Lion Recovery Plan

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Response to comments on Draft Plan and notice of availability of Final Plan.

SUMMARY: NMFS published an emergency ruling listing the Steller sea lion as threatened under the Endangered

Species Act (ESA) on April 5, 1990 (55 FR 12645), and a final rule on November 26, 1990 (55 FR 49204).

Section 4(f) of the ESA requires that NMFS develop and implement plans for the conservation and survival of endangered and threatened species. Accordingly, the Assistant Administrator for Fisheries appointed a Steller Sea Lion Recovery Team (hereafter referred to as the Recovery Team) who submitted a draft Steller Sea Lion Recovery Plan (referred to as the Recovery Plan) to NMFS on February 15, 1991. NMFS released the draft Recovery Plan for public review and comment on March 15, 1991 (56 FR 11204). The Recovery Team, to the maximum extent possible, incorporated all comments that were submitted to NMFS during the technical review process into the draft Recovery Plan. The final draft of the Recovery Plan by the Recovery Team was submitted to NMFS for review on October 3, 1991. This notice summarizes and responds to comments received on the draft Recovery Plan. The draft Recovery Plan was reviewed and finalized by NMFS, and a final Recovery Plan is now available upon request.

ADDRESSES: Requests for the Steller Sea Lion Recovery Plan should be addressed to Steller Sea Lion Recovery Plan, either at the National Marine Fisheries Service, Office of Protected Resources/PR2, 1335 East-West Highway, Silver Spring, MD 20910, or the NMFS, Alaska Regional Office, POB 21668, Juneau, AK 99802.

FOR FURTHER INFORMATION CONTACT: Michael Payne at (301) 713–2322.

SUPPLEMENTARY INFORMATION: NMFS received nine sets of comments regarding the draft Recovery Plan. Generally, the draft Recovery Plan was considered (by consensus of those who provided comments) to be comprehensive and exceedingly well done, providing good suggestions regarding specific management actions, as well as future research activities, required for assuring the recovery of Steller sea lions. Comments received by NMFS during the technical review process focused on the following issues: a Recovery Plan Coordinator, reclassification criteria suggested by the Recovery Team in the draft Recovery Plan, critical habitat and habitat protection, disturbance at rookeries and haulout sites, determining prey requirements (and protecting prey species) of Steller sea lions, commercial fisheries impacts on Steller sea lions, and public education. The following section addresses comments received on each of these issues.

Reclassification Criteria

The draft Recovery Plan described criteria, and an application of these criteria, for determining whether the species should be reclassified from a threatened to an endangered status under the ESA. Several commenters commended the Recovery Team for attempting to develop a framework for making decisions regarding the status of Steller sea lions. One commenter suggested that the approach (for reclassification) seemed reasonable and that it be adopted. However, two other commenters questioned whether there was any biological or theoretical bases for the threshold values recommended by the Recovery Team, stating that there was no explanation given for the value of "17 percent of a benchmark population" threshold point for the endangered cutoff value in the draft Recovery Plan. A commenter continued by stating that "it is hard to argue for or against the specific trigger points recommended (in the draft Recovery Plan) without further information." Several commenters agreed that a biological justification must be provided for the threshold values used in the reclassification criteria for Steller sea lions, and that these should be adopted by appropriate review. The same comment regarding biological justification of the threshold criteria was extended by one commenter to the "40 percent of a benchmark population" value suggested in the draft Recovery Plan as a cutoff determination for listing or delisting the species as threatened.

Another commenter suggested that this section should be expanded to address the removal of the species from the list of depleted species under the Marine Mammal Protection Act (MMPA). That is, if the population data on Steller sea lions satisfy the recommended delisting criteria and the species is removed from the list of threatened species, it is possible, if not likely, that it could still be considered depleted under the MMPA. Therefore, to ensure that this plan also meets the planning requirements of the MMPA when Steller sea lions are not listed as endangered or threatened under the ESA, the commenter recommended that either: (a) This section be expanded to describe the threshold at which Steller sea lions would no longer be considered depleted under the MMPA; or (b) a new task be added to define this point as and when necessary.

Response: The draft Recovery Plan suggested that an objective evaluation of whether and how Steller sea lions should be listed under provisions of the ESA could be made by comparing the most recent data available with the measurable criteria which were described in the draft Recovery Plan. In the draft Recovery Plan the Recovery Team recommended that evaluation criteria should be applied based on a percent of a benchmark population value in the Trend Count study area (for example if the adult/juvenile Trend Count in the Kenai-Kiska area is less than 17 percent of the benchmark value, the species should be listed as endangered), or based on trends of the adult/juvenile Trend Count or a Pup Production Index from the survey data (see Part II, Section 1.C, draft Recovery Plan).

It is the intent of NMFS to support the recovery activities outlined in the Recovery Plan. However, concerns associated with the proposed evaluation criteria regarding the quantitative measures for changing status under the ESA require further analysis and discussion. Thus, NMFS has not adopted Part II, Section 1.C of the draft Recovery Plan at this time. NMFS believes that the strategy in this section focuses on small, short-term changes (e.g., in II.1.C(3), a 10-percent decline over three years) but neglects an analysis of long-term trends and the effects of stochastic variability. NMFS supports and will evaluate a combination of techniques, like population viability analysis and analysis of data on historical trends, to provide a more robust estimation of the likelihood of extinction. At the conclusion of these analyses, NMFS will reconsider the threshold levels proposed by the Recovery Team, as well as other criteria which emerge as part of the analytical procedure.

However, section 4 of the ESA requires that objective, measurable criteria be incorporated into each Recovery Plan which, when met, would result in a determination that the species be removed from the list. The data currently available on Steller sea lion relative abundance come from aerial photographic surveys of adults and juveniles and land-based counts of pups (section II.E.3 of Recovery Plan). Preliminary simulation studies conducted at an April 1992 workshop indicated that the confidence interval around the recent estimates of adult and juvenile numbers of sea lions from aerial surveys is quite small; therefore, NMFS has adopted the delisting criteria proposed in the draft Recovery Plan. However, these criteria will also be evaluated as part of the risk analysis to determine their adequacy for long-term protection of the species.

The Recovery Team believed that the goal of this Recovery Plan will be met

when the Steller sea lion population has recovered to the extent that it can be removed from ESA listings. As previously suggested, it is possible that at that point the species would still qualify as depleted under terms of the MMPA. In that case, the conservation plan requirements of the MMPA would apply. At present, the Recovery Plan acts as both an ESA and an MMPA Plan. When the Steller sea lion is removed from ESA listing, the Recovery Plan, at that time, will be reviewed and revised as necessary to reflect MMPA requirements, and the biological and ecological situations.

Steller Sea Lion Recovery Plan Coordinator

Several commenters recommended that NMFS immediately take steps to appoint or hire a full-time Steller sea lion Recovery Plan coordinator to implement the Recovery Plan.

Response: The draft Recovery Plan recognized the need for a full-time Recovery Plan coordinator to facilitate recovery activities outlined in the Plan (draft Recovery Plan, Stepdown Outline, Item 7(1)). Accordingly NMFS employed such a position. Some of the duties of the Recovery Plan coordinator include evaluating and developing regulations, designation of critical habitat, ESA section 7 consultations, providing liaison between NMFS Steller sea lion recovery efforts and the fishery management councils, enforcement agencies, researchers and other interested parties.

Habitat Requirements and Protection

The ESA requires that critical habitat be identified and designated, to the extent possible, in conjunction with or shortly after a species is listed. Section 15, page 59, of the draft Recovery Plan recognized the need to identify critical habitat for Steller sea lions. Several commenters noted that recommendations for critical habitat have been submitted to NMFS by the Recovery Team and recommended that NMFS (1) review the Recovery Team's recommendation; (2) complete the necessary economic impact analyses, environmental assessments, and other supporting documentation; and (3) propose a critical habitat designation.

One commenter questioned why, in the draft Recovery Plan, buffer areas around rookeries and haulout sites were not considered. The commenter made reference to a 30-mile no fishing zone that has been established around Steller sea lion rookeries in the Kuril Islands and suggested that the important, large rookeries [in Alaska] should have buffers considerably larger than the 3-nautical mile (nm) zone established in the listing regulations. Another commenter also recommended that the buffer zones be increased significantly as it has been well documented that Steller sea lions move considerable distances beyond 3-miles from the rookeries.

Response: The Recovery Team recommended to NMFS terrestrial and aquatic areas which they believed should be considered as critical habitat for the Steller sea lion. These areas included all rookeries, major haulout sites, and important feeding areas identified in Sections 111, 112, and 113 of the draft Recovery Plan. The Recovery Team further indicated that when areas are designated they should be large enough to ensure that potential impacts can be controlled and minimized, and that seasonal-use patterns by Steller sea lions (Section 12) should, if applicable, be documented when critical habitat designation is made. NMFS is reviewing the recommendations of the Recovery Team and is developing a proposed rule to designate critical habitat for Steller sea lions.

Disturbance at Rookeries and Haulout Sites and Intentional Takes

Several commenters stated that disturbances of animals at rookeries and on haulouts must be diminished, including restricting water and air traffic. Several commenters also stated that intentional takes must cease. Shooting at or near Steller sea lions must be stopped.

Response: Information on the possible effects of disturbance caused by human activities was summarized in the draft Recovery Plan. The draft Recovery Plan suggested that information about the causes and impacts on sea lions of disturbance caused by human activities (e.g., noise from aircraft, boats, or other vehicles; shooting; habitat alterations; etc.) should be archived and summarized, and an effort made to document the response of sea lions to disturbance in areas where such observations can be made (e.g., at rookeries in California and Oregon). Instances of disturbance should also be recorded by observers who are now in place on commercial fishing vessels.

The draft Recovery Plan also suggested that (1) regulations and guidelines should be developed and/or revised to minimize potential impacts of human activities, and that buffer zones may be the best way to limit disturbance around rookeries and major haulouts; (2) major feeding areas at sea need to be protected from human disturbance through the prohibition or control of certain activities (e.g., shooting); and (3) specific guidelines or regulations should address disturbance that may be caused by vessels (commercial and sport fishing, tourist, research, and recreational), aircraft (private, charter, and military), and activity on the ground (tourists, researchers, motorized vehicles, and industrial activities).

Several of these issues were addressed at the time the species was listed as threatened. The discharge of firearms was prohibited within 100 yards (91.4 meters) of a Steller sea lion; and (2) no-entry buffer zones of 3 nautical miles (5.5 kilometers) were established around the principal Steller sea lion rookeries in the GOA and BSAI specifically to reduce disturbance and possible intentional takes at those sites. No vessels are allowed to operate within the buffer zones, with exceptions outlined in the final rule (FR 55 49209, Nov. 26, 1990).

NMFS continues to monitor and limit disturbances around Steller sea lion rookeries and haulouts, and the possible impacts of commercial fishery activities through the ESA section 7 consultation review process, and the review process associated with obtaining permits to conduct research, or to approach Steller sea lion rookeries at a distance less than that specified at the time of listing.

Prey Requirements of Steller Sea Lions and Commercial Fisheries

The draft Recovery Plan recognized that commercial fisheries may remove millions of metric tons of main prey species of the Steller sea lion. It further suggests that this may cause nutritional stress due to large-scale changes in food abundance, localized prey depletion, and disrupting fish behavior causing the Steller sea lion to expend more energy to obtain food (page 26, draft Recovery Plan). The draft Recovery Plan recognized that if a fishery is having a detrimental effect on prey availability, then regulation of the fishery will be necessary.

In light of this, one commenter suggested that the handling of this issue in the draft Recovery Plan was inadequate, and that the final Recovery Plan should suggest stronger measures to limit fishing in critical areas to ensure adequate prey availability. Another commenter suggested that in order to require sufficient quality of food at all times, fishing should be restricted using quotas and time/area closures to see if this speeds [sea lion] recovery. Several comments discussed the need for reviewing data on commercial fishing activities in Steller sea lion feeding areas, and another recommended establishing procedures to evaluate

whether fisheries compete for Steller sea lion prey, including listing explicit criteria for determining when a fishery becomes a limiting factor.

Response: Although the data available on abundance of Steller sea lions, and changes that have occurred over time, are not as comprehensive as is desirable, it is certain that a major population decline has occurred. Both natural and human-caused factors have been hypothesized as contributing to these declines. The Recovery Team recognized that for the Steller sea lion population to grow (i.e., recover) measures must be taken to ensure that food availability is not limiting. A large combined biomass of assorted prey species does not necessarily indicate an adequate food supply, since some of the species may be nutritionally poor at times or energetically costly to catch. The draft Recovery Plan stated that if a fishery is having detrimental effects on prey availability, either through removals of target species or bycatch, additional regulation of the fishery may be necessary. In some instances it may be possible to reduce competition between commercial fisheries and sea lions by changing fishing areas, seasons, time of day, and types of operations. Where alterations in operations can reduce competition, the Recovery Team recommended that appropriate changes should be initiated and the sea lions monitored for responses (see Section 621). Quotas for catches should be set on a regional and seasonal basis for each stock of each prey species identified as important (Section 614).

Since the final listing, NMFS has developed under the MFCMA additional fishery management regulations to further reduce the potential adverse effects of the walleye pollock fishery on Steller sea lions. By emergency rule (56 FR 28112, June 19, 1991), NMFS established restrictions to ensure that the 1991 GOA walleye pollock fishery would not jeopardize the continued existence or recovery of Steller sea lions. Concurrent with specification of the 1991 GOA walleye pollock harvest levels, NMFS (a) prohibited groundfish trawling within 10 nm of 14 GOA and 4 BSAI Steller sea lion rookeries (rookeries are listed at 56 FR 28116, June 19, 1991); (b) spatially allocated the walleye pollock harvest to divert fishing effort away from sea lion foraging areas; and (c) placed further restrictions on the amount of walleye pollock that could be harvested in any quarter of the year. On November 18, 1991, NMFS issued a proposed rule to make the above emergency fishery management measures permanent (56 FR 58214). The final rule was issued on January 23, 1992 (57 FR 2683) and expanded the proposed rule to (1) prohibit trawling year-round within 10 nm of 37 rookeries in the GOA and BSAI; and (2) expand the 10 nm buffer zone around five of the rookeries (Akutan Island, Akun Island, Sea Lion Rocks, Seguam Island, and Adligadak Island) to 20 nm from January 1 through April 15 of each year. These closures are intended to further reduce any effects that groundfish trawling may have on the Steller sea lions, particularly to their foraging success.

NMFS will continue to research the condition and required foraging range of Steller sea lions through research activities specified in the Recovery Plan. If certain age/sex classes of sea lions are found to be especially food limited, then special efforts should be made to regulate total allowable catches in their feeding areas. Where prey abundance is low, or where the sea lions show signs of nutritional stress, prey availability must be increased, if possible. NMFS recognizes that the types of prey available and the energetic cost of obtaining the prey should be acceptable at required times in all critical feeding areas.

Education

One commenter emphasized the need for public education and awareness. They continued by stating that an aggressive campaign of producing posters illustrating identifying features and closely related species [i.e. California sea lions] and bulletins identifying the minimal impact by Steller sea lions on selected commercially valuable species are just some of the education related activities that are of great importance.

Response: Steller sea lion public information/education efforts to date have included mass mailings, press releases, and public presentations of ongoing research and management activities at Fishery Management Council meetings and at symposia and public hearings in affected communities. Mass mailings to vessel operators, other affected parties, and government agencies that included a description of the regulations and maps depicting buffer zones have accompanied each rulemaking. A public information poster was developed and placed in strategic locations throughout Alaska.

NMFS held a meeting of the Recovery Team in November 1992 and appropriate directions for the information and education program objectives specified in the Recovery Plan were discussed. The Recovery Team recommended that (a) an Alaska Department of Fish and Game (ADFG) video on the Steller sea lion be distributed to Marine Advisory Program offices; (b) NMFS-funded subsistence studies be used as a possible education avenue to Alaska coastal communities; (c) a Steller sea lion brochure be developed for distribution at government and tourist facilities; (d) a Steller sea lion newsletter and other marine mammal issues be developed; and (e) greater emphasis on the rationale behind management actions taken need to be included in information packages to affected parties. NMFS recognizes the need and importance of these information and education programs. NMFS, ADFG and Alaska Sea Grant have agreed to work cooperatively on the implementation of these actions.

Recovery Plan Summary

The stated goal of the Recovery Team was to develop a Steller Sea Lion Recovery Plan which would promote recovery of the Steller sea lion population to a level appropriate to justify its removal from ESA listings. Immediate objectives of the Recovery Plan were to identify factors that limit the population, to propose a set of actions that minimize any human-induced activities considered detrimental to the survival or recovery of the population, and actions necessary to cause the population to increase. The Recovery Team recognized that, although it is not clear what factors have contributed to the Steller sea lion population decline and that a great deal of information vital to the effective management of the species is lacking, there was an urgent need to take immediate actions to safeguard against further population declines, and to provide for recovery of the species. The Recovery Team recommended that immediate actions should be taken to reduce human-caused mortality to the lowest level practicable, to protect important habitats through buffer zones and other means, and enhance population productivity by ensuring that there is an ample food supply available. Conservation and management measures implemented when Steller sea lions were listed under the ESA, and since, have addressed some of these needs. Additional management actions are described in the final Steller Sea Lion Recovery Plan.

The final Steller Sea Lion Recovery Plan has been approved by NMFS and is available upon request. The Recovery Plan was prepared by the Recovery Team but does not necessarily represent official positions nor approvals of all the Recovery Team members, or cooperating agencies, other than NMFS, involved in

the plan formulation. The final Recovery Plan represents the official position of NMFS only after it has been signed by the Assistant Administrator for Fisheries as approved. The approved Recovery Plan is still subject to modification as dictated by new findings, changes in species status and completion of tasks described in the plan. Goals and objectives will be attained and funds expended contingent upon agency appropriations and priorities.

References

References in this notice can be found in the Steller Sea Lion Recovery Plan, or provided upon request.

Dated: December 29, 1992.

William W. Fox, Jr.,

Assistant Administrator for Fisheries.

[FR Doc. 93–254 Filed 1–6–93; 8:45 am]

BILLING CODE 3510-22-M

Atlantic Mackerel, Loligo and Illex Squid, and Butterfish Under U.S. Jurisdiction, Excluding the Gulf of Mexico and Caribbean Sea

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of intent to prepare a supplemental environmental impact statement (SEIS) and request for scoping comments.

SUMMARY: NOAA announces its intention to prepare, in cooperation with the Mid-Atlantic Fishery Management Council (Council), an SEIS pursuant to the National Environmental Policy Act, to assess effects of any changes to the management regime of Atlantic mackerel (*Scomber scrombrus*), two squid species, *Loligo pealei* and *Illex illecebrosus*, and butterfish (*Peprilus triacanthus*) pursuant to the Magnuson Fishery Conservation and Management Act of 1976, as amended (MFCMA). The Council is considering amending the Atlantic Mackeral, Squid, and Butterfish Fishery Management Plan (FMP) by developing appropriate management measures to be contained in Amendment 5. The SEIS will analyze the potential impacts of any proposed new measures in the amendment, and the fishery, itself, on the human environment. If such an amendment to the FMP is approved by the Secretary of Commerce (Secretary), implementation of such action is expected no sooner than 1994.

In addition, the Council announces a public process for determining the scope of issues to be addressed and for identifying the significant issues relating to revising management of Atlantic mackerel, *Loligo* and *Illex* squid, and butterfish. The intended effect of this notice is to alert the interested public of the commencement of a scoping process and to provide for public participation. This action is necessary to comply with Federal environmental documentation requirements.

DATES: Scoping comments are invited until January 7, 1993, when the scoping process will end at the conclusion of a scoping meeting that will begin at 1:00 p.m. on January 7, 1993, at the Ramada Inn, 76 Industrial Highway, Essington, PA 19029, (215–521–9600).

FOR FURTHER INFORMATION CONTACT: Mr. John C. Bryson, Room 2115 Federal Building 300 South New Street, Dover, Delaware 19901–6790 (Phone 302–674–2331) (FAX 302–674–5399).

SUPPLEMENTARY INFORMATION:

Problems Discussed for this Amendment

1. Overcapitalization Should be Avoided

The fishery currently has more than sufficient capacity to harvest all the allowable biological catch (ABC) for each species. This FMP was initially designed to encourage U.S. fishermen to harvest underutilized resources. The U.S. fishery may have grown to where there is no need for foreign harvests, and additional investment by U.S. fishermen could only dissipate any profits for existing fishermen who have invested heavily to build this fishery.

2. Additional Management Measures Are Necessary for Loligo and Illex

Both of these fisheries have become completely Americanized. No foreign harvests of either of these species of squid have occurred since 1987. Domestic harvests for both species are approaching the maximum sustainable yield (MSY) levels. At present, the Regional Director can only close the fishery if the quotas are reached. This management alternative may not be the best solution for the continued smooth and efficient operation of these fisheries.

3. Butterfish Bycatch Discard Mortality May be Inhibiting Sufficient Growth Such That Achievement of Maximum Sustainable Yields is Prevented

Sea sampling data for 1989, 1990, and 1991 indicate that as much butterfish (by weight) is discarded as is landed. This may be a partial explanation for why there have been relatively low levels of butterfish landings over the past several years in light of very favorable stock assessments. The MSY is 16,000 metric tons. However, actual landings have only been around one quarter this level. The lack of availability of butterfish for fishermen was thought to have been the explanation in the past. However, the new sea sampling data indicate that discards may be having a significant impact on the resource.

4. Lack of Data

National standard 2 states that "measures shall be based upon the best scientific information available." Although recreational and commercial catch data have been adequate to formulate and implement management measures, data collection should be improved, in order to allow for better management in the future. An improved data base will allow the Council to more finely tune the management system to the needs of the fishery. These data are necessary to assess the impact and effectiveness of management measures, as well as monitor fishing mortality and increases in stock size to determine if additional amendments to the FMP will be necessary.

5. Mixed-Species Fishery

The Mid-Atlantic mixed-species fishery relies principally on summer flounder, scup, black sea bass, yellowtail flounder, butterfish and *Loligo*, as either directed or bycatch in other directed fisheries. Many of these species are also components of the southern New England trawl areas. Generally, fishing activities follow these species as they make annual migrations from south to north and from offshore to inshore waters. Many of the species identified above that are in this mixed fishery are overexploited. Directed effort from some of the species has been switched to species managed in this FMP. These factors complicate the identification of appropriate and effective management strategies, thus requiring close coordination of regulatory measures for the different species in order to manage properly this species assemblage.

Possible Management Measures

Part of this scoping is the possible reevaluation of the existing objectives. Current management objectives of the FMP are:

1. Enhance the probability of successful (i.e., the historical average) recruitment to the fisheries.
2. Promote the growth of the U.S. commercial fishery, including the fishery for export.
3. Provide the greatest degree of freedom and flexibility to all harvesters of these resources consistent with the

attainment of the other objectives of this FMP.

4. Provide marine recreational fishing opportunities, recognizing the contribution of recreational fishing to the national economy.

5. Increase understanding of the conditions of the stocks and fisheries.

6. Minimize harvesting conflicts among U.S. commercial, U.S. recreational, and foreign fishermen.

POSSIBLE COMMERCIAL FISHERY MANAGEMENT MEASURES INCLUDE

	Atlantic Mackerel	Loligo	Illex	Butterfish
Minimum fish size	X	X	X	X
Minimum mesh size	X	X	X	X
Closed seasons	X	X	X	X
Closed areas	X	X	X	X
Quotas	X	X	X	X
Moratorium on vessels	X	X	X	X
ITQs	X	X	X	X
Dealer and vessel permits	X	X	X	X
Dealer and vessel reports	X	X	X	X
Operator permits	X	X	X	X
Gear restrictions & limits	X	X	X	X

POSSIBLE MANAGEMENT MEASURES FOR THE ATLANTIC MACKEREL RECREATIONAL FISHERY INCLUDED

	Atlantic Mackerel
Minimum fish size	X
Maximum possession limit	X
Closed seasons	X
Closed areas	X
Gear restrictions & limits	X
Quotas	X
Restrictions on the ability to sell recreational caught fish.	X
Dealer and vessel permits	X
Dealer and vessel reports	X
Operator permits	X

It is likely that any of these measures would be implemented through a frameworking procedure. That is, a Monitoring Committee, made up of representatives of the three Councils and NMFS, would annually review the condition of the resource and fishery and recommend adjustment of the measures (e.g., possession limit, quota, etc.) to achieve the desired goals.

Permitting and Reporting

It is anticipated that vessels landing squid, mackerel, and butterfish for sale would be required to have permits, and that party and charter boats in the Atlantic mackerel fisheries would be required to have permits.

It is anticipated that operators of commercial vessels (vessels with permits to sell squid, mackerel, and butterfish) and operators of party and charter boats would be required to obtain permits.

It is anticipated that vessels landing squid, mackerel, and butterfish for sale would be required to submit logbook reports. It is anticipated that dealers purchasing these species from permitted commercial vessels would be required to submit reports. It is anticipated that dealers purchasing these species from permitted commercial vessels would need to submit reports. It is anticipated that operators of charter and party boats would need to submit logbooks.

Under the Paperwork Reduction Act, in the SF–83 forms prepared by NMFS for Amendment 2 to the Summer Flounder FMP, the dealer purchase report was estimated to involve 1,255 respondents and 26+responses per respondent per year, for a total of 33,135 responses at 0.0448 hours per response, for a total of 1,485 hours. The vessel logbook was estimated at 1,314 respondents, 12 responses per respondent, at 0.08 hours per response, for a total of 1,261 burden hours. The vessel permit was estimated at 24,943 annual responses at 0.2878 hours per response, for a total of 7,179 burden hours. Similar burden hours per respondent should be expected through squid, mackerel, and butterfish management.

Timetable for SEIS Preparation and Decisionmaking

The Council has adopted a tentative amendment preparation, review, and approval schedule for Amendment 5. Under this schedule, the draft SEIS is planned for completion prior to the Council's October 1993 meeting. If an acceptable draft is completed, the Council would decide at that meeting whether to submit the draft SEIS for public review. Oral comments to the Council on their decision could be made at that meeting. If the Council's decision is affirmative, public review of the draft SEIS would occur during 45 days in November and December, 1993. At its February, 1994, meeting, the Council would decide on the revisions to the management of Atlantic mackerel, *Loligo* and *Illex* squid, and butterfish. Again, oral comments on this decision could be made to the Council at that meeting. If the Council's decision is affirmative, the SEIS would be made final and submitted with the amendment recommendation and other rulemaking documents to the Secretary for review and approval. The Council reserves the right to modify or abandon this schedule if determined necessary.

Under the Magnuson Act, Secretarial review and approval of a proposed amendment is completed in no more than 95 days and includes concurrent public comment periods on the amendment and proposed regulations. If approved by the Secretary under this schedule, the revised Atlantic mackerel, squid, and butterfish management measures would be effective late in 1994.

Dated: January 4, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–305 Filed 1–4–93; 8:45 am]

BILLING CODE 3510–22–M

[Docket No. 921248–2348]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of Yellowfin tuna embargo.

SUMMARY: The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), announces that yellowfin tuna and products derived from yellowfin harvested by Panamanian purse seine vessels operating in the eastern tropical Pacific Ocean (ETP) are prohibited from entry into the United States until further notice.

EFFECTIVE DATES: This finding was effective December 22, 1992, and remains in effect until further notice.

FOR FURTHER INFORMATION CONTACT: Dr. Gary Matlock, Acting Director, Southwest Region, NMFS, 501 W. Ocean Blvd., suite 4200, Long Beach, CA 90802–4213, telephone 310/980–4000.

SUPPLEMENTARY INFORMATION: The Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*) requires a ban on the importation of commercial fish or products from fish that have been caught with commercial fishing technology that results in the incidental kill or serious injury of ocean mammals in excess of U.S. standards. In the case of yellowfin tuna from the ETP, the MMPA requires the ban unless nations have met standards comparable to those of the United States. Regulations at 50 CFR 216.24(e)(5) provide, consistent with the MMPA, specific criteria for issuing initial and subsequent affirmative findings to a harvesting nation that implements a prohibition against the intentional deployment of nets to encircle marine mammals by its purse seine vessels.

On January 9, 1992, NMFS published a finding in the **Federal Register** (57 FR 883), that Panama had enacted by Presidential Decree No. 111 a marine mammal regulatory program that prohibited its vessels from intentionally deploying purse seine nets on or to encircle marine mammals in the course of harvesting yellowfin tuna in the ETP.

The Assistant Administrator has determined that this finding must now be revoked on the basis that a Panamanian purse seine vessel greater than 400 short tons (362.9 metric tons) carrying capacity caused dolphin mortalities in purse seine sets intentionally deployed to encircle marine mammals on two successive trips within 180 days of each other during the 1992 fishing season. An observer approved by the Assistant Administrator accompanied both trips. Regulations at 50 CFR 216.24(e)(5)(x)(A)(1) provide that a nation enters into probationary status for 180 days, effective upon the date the vessel returns to port to unload, if the vessel made an intentional purse seine set on marine mammals. Section 216.24(e)(5)(x)(A)(2) provides that the Assistant Administrator will immediately revoke an affirmative finding if there are any additional intentional purse seine sets made on marine mammals during the 180-day probationary period by any vessel operating under the flag of that nation.

In addition, the Assistant Administrator has determined that Panama has enacted Presidential Decree No. 70, dated October 20, 1992, that modifies Presidential Decree No. 111, to allow Panamanian purse seine vessels operating under the Inter-American Tropical Tuna Commission (IATTC) dolphin mortality reduction program to intentionally deploy their nets on, or to encircle, marine mammals. Decree No. 70 substantively changes the regulatory program upon which the 1991 and 1992 affirmative findings to allow importation of Panamanian yellowfin tuna was based.

The MMPA's import ban under section 101(a)(2) also applies to intermediary nations, nations that export yellowfin tuna or yellowfin tuna products to the United States and that import yellowfin tuna and yellowfin tuna products that are subject to a direct ban on importation into the United States. All yellowfin tuna and yellowfin tuna products from such nations will be prohbiited unless such nations certify and provide reasonable proof that they have not imported, within the preceding 6 months, any yellowfin tuna or yellowfin tuna products that are subject to a direct ban on importation to the United States.

Therefore, in adherence with the regulations implementing the MMPA, the Assistant Administrator announces that the importation of yellowfin tuna, or products derived from yellowfin tuna harvested with purse seine in the ETP by the Republic of Panama is prohibited until further notice. Under 50 CFR 216.24(e)(xiv), all intermediary nations that export yellowfin tuna and yellowfin tuna products to the United States and also import yellowfin tuna and yellowfin tuna products harvested in the ETP by Panamanian purse seine vessels of greater than 400 short tons (362.9 metric tons) carrying capacity, must certify and provide reasonable proof to the Assistant Administrator that they have not imported yellowfin tuna or yellowfin tuna products subject to a U.S. import prohibition within the preceding 6 months. Yellowfin tuna and yellowfin tuna products from intermediary nations that fail to provide such certification will not be allowed to enter the United States.

Dated: December 31, 1992.

Samuel W. McKeen,

Program Management Officer.

[FR Doc. 93–248 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–22–M

[Docket No. 921249–2349]

Taking and Importing of Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce

ACTION: Notice of affirmative findings.

SUMMARY: The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), announces that the Republic of Ecuador has submitted documentation that it is in compliance with the yellowfin tuna importation regulations for nations that have acted to ban purse seine sets on marine mammals in the eastern tropical Pacific Ocean (ETP). In addition, the Republic of Vanuatu has submitted documentary evidence which establishes under the yellowfin importation regulations that the average rate of incidental taking of marine mammals by vessels of the harvesting nation is comparable to the average rate of incidental taking of marine mammals by U.S. vessels in the course of harvesting yellowfin tuna by purse seine in the ETP, and that other requirements for an affirmative finding have been met. Affirmative findings have been made that will allow yellowfin tuna and yellowfin tuna products to be imported into the United States from Vanuatu and Ecuador through December 31, 1993.

DATES: This finding is effective January 1, 1993, and remains in effect through December 31, 1993, or until further notice.

FOR FURTHER INFORMATION CONTACT: Gary Matlock, Acting Director, NMFS Southwest Region, NOAA, 501 W. Ocean Blvd., suite 4200, Long Beach, CA 90802–4213, or by telephone at 310/980–4000, or by FAX at 310/980–4018.

SUPPLEMENTARY INFORMATION: On November 18, 1992, NMFS published a final rule (57 FR 54334) that established a provision for timely consideration and granting of an affirmative finding under the yellowfin tuna import regulations to a nation which prohibits its vessels from intentionally setting on marine mammals in the course of harvesting yellowfin tuna by purse seine in the ETP. With an affirmative finding, yellowfin tuna and tuna products from the harvesting nation can be imported into the United States.

On March 30, 1990, NMFS promulgated a final rule (55 FR 11921) to implement portions of the Marine Mammal Protection Act Amendments of 1988. This rule governs the importation of yellowfin tuna caught by purse seining in the ETP and requires submission of an annual report to include, among other things, the

number, by species, of marine mammals killed and seriously injured, and the number of sets made. With an affirmative finding under this section, yellowfin tuna and tuna products from the harvesting nation can be imported into the United States.

The Assistant Administrator, after consultation with the Department of State, finds that the Republic of Ecuador and the Republic of Vanuatu have submitted documentary evidence that establishes that their regulatory programs comply with the tuna importation provisions of 50 CFR 216.24(e). As a result of these affirmative findings, yellowfin tuna and products derived from yellowfin tuna harvested by Ecuadorian-flag and Vanuatuan-flag purse seine vessels operating in the ETP may be imported into the United States from Ecuador and Vanuatu, either directly or through another nation, through December 31, 1993.

Dated: December 31, 1992.

Samuel W. McKeen,

Program Management Officer.

[FR Doc. 93–245 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–22–M

National Marine Fisheries Service; Marine Fisheries Advisory Committee; Notice of Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), NOAA.

TIME AND DATE: Meeting will convene at 8:45 a.m., February 2, and adjourn at 3:30 p.m., February 3, 1993.

PLACE: The Le Pavillon Hotel, 833 Poydras Street, New Orleans, Louisiana.

STATUS: As required by section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1982), notice is hereby given of a meeting of the Marine Fisheries Advisory Committee (MAFAC). MAFAC was established by the Secretary of Commerce on February 17, 1971, to advise the Secretary on all living marine resource matters which are the responsibility of the Department of Commerce. This Committee ensures that the living marine resource policies and programs of this Nation are adequate to meet the needs of commercial and recreational fishermen, and environmental, state, consumer, academic, and other national interests.

MATTERS TO BE CONSIDERED: February 2, 1993, 8:45 a.m.—5:30 p.m., (1) Magnuson Act issues and reauthorization, (2) in season management of fishery resources, (3) Gulf long line fisheries, (4) bycatch effort mandated by Magnuson Act amendment, and (5) overview of fishery data programs.

February 3, 1993, 9 a.m.—3:30 p.m., (1) health and preservation of wetlands, (2) marine mammal exemption program, (3) NMFS habitat office, and (4) budget and program planning.

FOR FURTHER INFORMATION CONTACT: Ann Smith, Executive Secretary, Marine Fisheries Advisory Committee, Policy and Coordination Office, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910. Telephone: (301) 713–2252.

Dated: December 30, 1992.

Samuel W. McKeen,

Program Management Officer, National Marine Fisheries Service, NOAA.

[FR Doc. 93–255 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–06–M

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The New England Fishery Management Council (Council) will hold a public meeting on January 13–14, 1993, at the King's Grant Inn, Route 128 at Trask Lane, Danvers, MA; telephone: (508) 774–6800. The Council will begin its meeting at 10 a.m. on January 13. The meeting will reconvene on January 14 at 9 a.m.

The meeting will open on the first day with a Lobster Committee report and discussion on Amendment #4 to the Lobster Fishery Management Plan (FMP). The Large Pelagic Committee report will follow which will include ICCAT meeting highlights and discussion of the NMFS Shark FMP. In the afternoon, the Groundfish Committee will discuss progress on Amendment #5 of the Groundfish FMP.

On the second day of the meeting, discussion of the Groundfish Amendment #5 will continue. Reports from the Council Chairman and Executive Director, the NMFS Regional Director, Northeast Fisheries Science Center Liaison, Mid-Atlantic Council liaison, and representatives for the Department of State, Coast Guard, Fish and Wildlife Service and Atlantic States Marine Fisheries Commission will follow.

For more information contact Douglas G. Marshall, Executive Director, New England Fishery Management Council, 5 Broadway, Saugus, MA 01906; telephone: (617) 231–0422.

Dated: December 31, 1992.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–246 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–22–M

North Pacific Fishery Management Council; Revision to Public Meeting Agenda

AGENCY: National Marine Fisheries Service, NOAA, Commerce. The meeting agenda for the North Pacific Fishery Management Council (Council) and its Committees, which are scheduled to meet January 18–21, 1993, has been revised. Notice of the meeting was published in the **Federal Register** at 57 FR 62303 on December 30, 1992.

Revision

Council: Delete agenda item 7, final review of plan amendments for the Pribilof Island trawl closure and an amendment to separate Atka mackerel from the "Other Species" category in the Gulf of Alaska. This item will be rescheduled for review in April, 1993.

For more information contact the North Pacific Fishery Management Council, P.O. Box 103136, Anchorage, AK 99510, (907) 271–2809.

Dated: December 31, 1992

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–247 Filed 1–6–93; 8:45 am]

BILLING CODE 3510–22–M

COMMODITY FUTURES TRADING COMMISSION

New York Cotton Exchange: Proposed Amendments Relating to the Grade Standards and Price Differentials for Cotton Certificated for Delivery on the Cotton No. 2 Futures Contract

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed contract market rule change.

SUMMARY: The New York Cotton Exchange (NYCE) has submitted proposed amendments to the cotton No. 2 futures contract. The proposed amendments will change the contract's grade standards to conform with new official U.S. grade standards for cotton promulgated by the Agricultural Marketing Service of the United States Department of Agriculture (USDA–AMS) which will become effective

beginning on August 5, 1993. The proposal also will establish special quality price differentials applicable to the delivery of certain new qualities of cotton that will become deliverable on the futures contract under the proposed amendments. The proposed amendments will apply to all cotton certificated for delivery on and after August 5, 1993.

Acting pursuant to the authority delegated by Commission Regulation 140.96, the Director of the Division of Economic Analysis (Division) of the Commodity Futures Trading Commission (Commission) has determined that publication of the proposed amendments is in the public interest and will assist the Commission in considering the views of interested persons.

DATES: Comments must be received on or before February 8, 1993.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Reference should be made to the proposed changes in grade standards for cotton certificated for the cotton No. 2 futures contract.

FOR FURTHER INFORMATION CONTACT: Fred Linse, Division of Economic Analysis, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581, telephone (202) 254–7303.

SUPPLEMENTARY INFORMATION: The existing rules of the cotton No. 2 futures contract provide for the delivery of 11 cotton grades. The par delivery grade of cotton is strict low middling white. The contract also provides for the delivery of the following additional grades of cotton at price differentials to the par grade: Good middling white; strict middling white; middling plus white; middling white; strict low middling plus white; low middling plus white; low middling white; good middling light spotted; strict middling light spotted; and middling light spotted cotton. The existing price differentials applicable to the delivery of the above-noted non-par grades of cotton are based on actual commercial differences in value which are published by the USDA–AMS.

The USDA–AMS recently amended the official U.S. grade standards for American Upland Cotton to become effective with the 1993 cotton marketing year, beginning August 5, 1993.[1] Under the new grade standards, each bale of cotton will be given two separate grades: one grade for the color of the cotton and another grade for the leaf content of the cotton. The current grading system, by contrast, assigns one grade to each cotton bale that represents a composite grade reflecting the combination of color and leaf content of the cotton. The new U.S. standards will consist of 30 color grades and seven leaf grades.

The proposed amendments will revise the contract's existing list of deliverable grades of cotton to conform with the new USDA–AMS cotton classification system; that is, the proposed amendments will establish a list of deliverable color grades and deliverable leaf grades of cotton. For color, the proposed amendments will provide for the delivery of the following eight grades: Good middling white; strict middling white; middling white; strict low middling white; low middling white; good middling light spotted; strict middling light spotted, and middling light spotted cotton.[2] Each of the new color grades has the same color ranges set forth in the corresponding standards for the existing U.S. grades of American Upland Cotton. The proposed amendments will allow delivery of cotton in these color grades that also meets leaf grades 1 through 5, provided that the cotton is one of the deliverable white grades of cotton, and leaf grades 1 through 3 for cotton meeting the standards for the light spotted color grades.

Table 1 below indicates the color and leaf grade combinations which correspond to those cotton grades from the existing grading system that presently are deliverable on the futures contract, and the color and leaf grade combinations from the new grading system that will be deliverable under the proposed amendments.

TABLE 1.—DELIVERABLE COLOR AND LEAF GRADES UNDER THE CURRENT AND PROPOSED TERMS OF THE COTTON NO. 2 FUTURES CONTRACT

Color grade	Leaf grade	
	Deliverable under current system	Deliverable under new system
Good middling white.	1,2	1,2,3,4,5.
Strict middling white.	1,2,3	1,2,3,4,5.
Middling white.	2,3,4	1,2,3,4,5.
Strict low middling white.	3,4,5	1,2,3,4,5.

[1] See the August 5, 1992, **Federal Register** notice of final rules issued by the USDA–AMS concerning "Grade Standards for American Upland Cotton" (57 FR 34495).

[2] The new US standards eliminate certain existing grade categories, including all "plus" grades, because they are no longer needed to describe special color and leaf combinations.

TABLE 1.—DELIVERABLE COLOR AND LEAF GRADES UNDER THE CURRENT AND PROPOSED TERMS OF THE COTTON NO. 2 FUTURES CONTRACT—Continued

Color grade	Leaf grade	
	Deliverable under current system	Deliverable under new system
Low middling white.	4,5	1,2,3,4,5.
Good middling light spotted.	1,2	1,2,3.
Strict middling light spotted.	1,2,3	1,2,3.
Middling light spotted.	2,3	1,2,3.

Under the proposed revised grade standards, cotton which is classed as strict low middling white (color grade), and number 4 (leaf grade) will be deliverable at par. All of the non-par combinations of color grades in the left-hand column and corresponding leaf grades shown in the right-hand column of Table 1 will be deliverable at quality price differentials which are equivalent to the commercial price differences published by the USDA–AMS for these grade combinations, with the exception of certain combinations discussed below.

Certain color and leaf grade combinations will become deliverable under the proposed amendments at special price differentials that are equal to the commercial price differences published by the USDA–AMS for cotton of certain other specified color and leaf grade combinations. Table 2 indicates these grade combinations and the assigned color and leaf grade combinations whose price differentials will be used in determining the futures delivery value of these certain specified grades of cotton.[3] In Table 2, the left-hand column indicates the grade combinations that will be deliverable at special price differentials and the right-hand column shows the corresponding color and leaf grade combinations whose price differentials will be used to determine the delivery value of such cotton.[4]

[3] Some of the newly deliverable cotton grade combinations indicated in Table 1 will be delivered at published commercial price differences for those particular combinations and therefore are not included in Table 2.

[4] The NYCE notes that, under existing U.S. standards, the cotton grade combinations noted in the left hand column of Table 2 would have been classified as "Average Rule Used (ARU)" cotton. The NYCE notes, however, that ARU cotton is not tenderable under existing Exchange rules. The NYCE further notes that, under the new standards, the ARU designation will be eliminated since the new standards for color and leaf will provide a more precise method of classifying cotton.

TABLE 2.—PROPOSED PRICE DIFFERENTIALS FOR CERTAIN COLOR AND LEAF GRADE COMBINATIONS

Actual color and leaf grade combination	Assigned color and leaf grade combination for purposes of calculating price differential
Good middling white color, No. 3 leaf.	Strick middling white color, No. 3 leaf.
Good middling white color, No. 4 leaf.	Middling white color, No. 4 leaf.
Good middling white color, No. 5 leaf.	Strict low middling white color, No. 5 leaf.
Good middling light spotted color, No. 3 leaf.	Middling light spotted color, No. 3 leaf.
Strict middling white color, No. 4 leaf.	Middling white color, No. 4 leaf.
Strict middling white color, No. 5 leaf.	Strict low middling white color, No. 5 leaf.
Middling white color, No. 5 leaf.	Strict low middling white color, No. 5 leaf.

The NYCE proposes to implement the proposed amendments simultaneously with the introduction of the new U.S. standards by the USDA–AMS, effective for all cotton classified on and after August 5, 1993. A NYCE spokesperson has represented that cotton that had been classified under the old standards and certificated for delivery on the cotton No. 2 futures contract prior to August 5, 1993 will continue to be deliverable on the futures contract after August 5, 1993, with no requirement that such cotton be regraded under the new standards before delivery. To facilitate the delivery of cotton that has been classified and certificated prior to August 5, 1993, the NYCE proposes to permit delivery of such cotton using the below conversion chart (Table 3) between the old and new grade standards.

TABLE 3.—CONVERSION CHART FOR COTTON CLASSIFIED AND CERTIFICATED PRIOR TO AUGUST 5, 1993

Current grade designation	New grade designation	
	Color grade	Leaf grade
Good middling	Good middling	1
Good middling light spotted.	Good middling light spotted.	1
Strict middling	Strict middling	2
Strict middling light spotted.	Strict middling light spotted.	2
Middling plus	Strict middling	3
Middling	Middling	3
Middling light spotted	Middling light spotted.	3
Strict low middling plus.	Middling	4
Strict low middling	Strict low middling	4
Low middling plus	Strict low middling	5
Low middling	Low middling	5

The Commission is requesting comments on the proposed amendments and proposed implementation plan. Specifically, the Commission is requesting comment on the extent to which the proposed price differentials described in Table 2 above reflect commercial price differences for the cotton color and grade combinations shown in the left-hand column of that table. In addition, the Commission is requesting comment on the adequacy of the conversion chart shown above (Table 3) in assuring that cotton which meets the standards for the existing grades shown in the left-hand column has the same economic value as cotton that meets the standards for the corresponding specified new grades for color and leaf shown in the right-hand columns.

Copies of the proposed amendments will be available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, at the above address. Copies of the amended terms and conditions can be obtained through the Office of the Secretariat by mail at the same address or by telephone at (202) 254–6314.

The materials submitted by the NYCE in support of the proposed amendments may be available upon request pursuant to the Freedom of Information Act (5 U.S.C. 552) and the Commission's regulations thereunder (17 CFR part 145 (1987)). Requests for copies of such materials should be made to the FOI, Privacy and Sunshine Act Compliance Staff of the Office of the Secretariat at the above address in accordance with 17 CFR 145.7 and 145.8.

Any person interested in submitting written data, views, or arguments on the proposed amendments should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, at the above address by the specified date.

Issued in Washington, DC on January 4, 1993.

Gerald Gay,

Director.

[FR Doc. 93–279 Filed 1–6–93; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF DEFENSE

Public Information Collection Requirements Submitted to OMB for Review.

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title, Applicable Form, and Applicable OMB Control Number: Department of Defense Personnel Security Questionnaire (PSQ); DD Form 398, DD Form 398–INST, DD Form 1879; OMB Control No. 0704–0299.

Type of Request: Revision.

Average Burden Hours/Minutes Per Response: 1.5 Hours.

Responses Per Respondent: 1.

Number of Respondents: 310,000.

Annual Burden Hours: 465,000.

Annual Responses: 310,000.

Needs and Uses: The information collected by the DD Form 398 is used by the Defense Investigative Service to conduct Single Scope Background investigations (SSBI), Periodic Reinvestigations (PR), and Special Investigative Inquiries (SII). These provide the basis for determination of a person's eligibility for access to classified information, appointment to a sensitive position, assignment to duties that require a personnel security or trustworthiness determination, continuing eligibility for retention of a security clearance, or assignment to other sensitive duties. The DD Form 398–INST provides guidance for completing the DD Form 398. The DD Form 1879 is used to request an SSBI, PR, or SII, and accompanies the DD Form 398.

Affected Public: Individuals or households; Federal agencies or employees.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, Room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. William P. Pearce.

Written requests for copies of the information collection proposal should be sent to Mr. Pearce at WHS/DIOR, 1215 Jefferson Davis Highway, suite 1204, Arlington, Virginia 22202–4302.

Dated: January 4, 1993.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–268 Filed 1–6–93; 8:45 am]

BILLING CODE 3810–01–M

Department of the Navy

CNO Executive Panel; Meeting

Notice was published Thursday December 24, 1992, at 57 FR 61401, that

the Chief of Naval Operations Executive Panel will meet on January 12, 1993, from 9:00 am to 5:00 pm, in Alexandria, Virginia. That Meeting has been rescheduled and will be held on January 21, 1993. All other information in the previous notice remains effective. In accordance with 5 U.S.C. section 552b(e)(2), the meeting change is publicly announced at the earliest time.

For further information concerning this meeting contact: Judith A. Holden, Executive Secretary to the CNO Executive Panel, 4401 Ford Avenue, Room 601, Alexandria, Virginia 22302-0268, Phone (703) 756-1205.

December 29, 1992.

Michael P. Rummel

LCDR, JAGC, USN, Federal Register Liaison Officer.

[FR Doc. 93-256 Filed 1-6-93; 8:45 am]

BILLING CODE 3810-AE-F

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Management Service, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before February 8, 1993.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok: Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place, NW., room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Cary Green, Department of Education, 400 Maryland Avenue, SW., room 5624, Regional Office Building 3, Washington, DC 20202-4651.

FOR FURTHER INFORMATION CONTACT: Cary Green (202) 708-5174.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Management Service, publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following:

(1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Cary Green at the address specified above.

Dated: December 30, 1992.

Wallace McPherson,

Acting Director, Information Resources Management Service.

Office of Special Education and Rehabilitative Services

Type of Review: Reinstatement.

Title: Traumatic Brain Injury Effective Practices Study.

Frequency: One time.

Affected Public: Businesses or other for-profit.

Reporting Burden:

Responses: 46.

Burden Hours: 50.

Recordkeeping Burden:

Recordkeepers: 0.

Burden Hours: 0.

Abstract: This evaluation will identify current Vocational Rehabilitation (VR) agency policy and practice in serving clients with Traumatic Brain Injury (TBI), describe their strengths and weaknesses, and identify effective practices that RSA may suggest for implementation. The Department uses the information for program evaluation and to make recommendations for improvement of services.

[FR Doc. 93-280 Filed 1-6-93; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER93-85-000, and EL93-7-000]

Connecticut Yankee Atomic Power Co.; Initiation of Proceeding and Refund Effective Date

December 31, 1992.

Take notice that on December 22, 1992, the Commission issued an order in the above-indicated dockets initiating an investigation in Docket No. EL93-7-000 under section 206 of the Federal Power Act.

The refund effective date in Docket No. EL93-7-000 will be 60 days after publication of this notice in the **Federal Register.**

Lois D. Cashell,

Secretary.

[FR Doc. 93-287 Filed 1-6-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. ER93-86-000, and EL93-11-000]

Delmarva Power & Light Co.; Initiation of Proceeding and Refund Effective Date

December 31, 1992.

Take notice that on December 31, 1992, the Commission issued an order in the above-indicated dockets initiating an investigation in Docket No. EL93-11-000 under section 206 of the Federal Power Act.

The refund effective date in Docket No. EL93-11-000 will be 60 days after publication of this notice in the **Federal Register.**

Lois D. Cashell,

Secretary.

[FR Doc. 93-288 Filed 1-6-93; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4552-9]

Meetings of the Science Advisory Board and Environmental Financial Advisory Board and the Executive Committee

Pursuant to the Federal Advisory Committee Act, Public Law 92-463, notice is hereby given that the Science Advisory Board and the Environmental Financial Advisory Board (SAB/EFAB) will conduct a meeting on Wednesday, January 27, 1993. The purpose of the meeting is to explore the utility of

blending scientific, engineering and financial advice to the Administrator. The issues of nitrates in ground water and treatment of surface waters by filtration will be examined as case studies.

Also, January 28–29, the Executive Committee will meet. The purpose of this meeting is to review reports from the following Committees:

Environmental Economics Advisory Committee: Commentary on the possible trade-off between health benefits and disbenefits from regulation.

Environmental Engineering Committee: Review of underground storage tank (UST) research and Review of indoor air research.

Environmental Health Committee: Review of Dermal Exposure Assessment document and Review of Risk Assessment Guidance for Superfund: Human Health Evaluation Manual (RAGS/HHEM).

Radiation Advisory Committee: Commentary on radiation exposure models and assessment of uncertainty and Review of release of C–14 Carbon Dioxide from High Level Radioactive Waste Sites.

Additional items on the agenda will likely include the following:

A briefing on State and Local Risk Reduction projects

A report on the Resources for the Future Conference featuring the SAB's Reducing Risk report.

A discussion on the plans of the new Administration as they relate to the SAB.

An update on the project joint project with the Environmental Financial Advisory Board (EFAB) to investigate the utility of melding scientific, engineering, and financial advice to the Administrator.

On the afternoon of January 29 the Executive Committee's Subcommittee on RCRA Regulatory Impact Analysis review will meet to coordinate plans for that review during the spring.

Both meetings are being held at the Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. SAB/EFAB will take place in the Administrator's Conference room 1103W, from 9 a.m. to 12 noon. The Executive Committee will meet the first day in the Administrator's Conference Room from 8: 30 a.m. to 5 p.m. and continue its deliberation on the 29th in the Washington Information Center, Room 17 from 8:30 a.m. to 5:00 p.m.

The meeting is open to the public. Any member of the public wishing further information concerning the meeting or who wishes to submit comments should contact Darlene Sewell-Oliver, A–101, U.S. Environmental Protection Agency, Washington, DC 20460, at (202) 260–4126 or by Fax at (202) 260–9232. Limited unreserved seating available at the meeting.

Dated: December 29, 1992.

Donald G. Barnes,

Staff Director, Science Advisory Board.

[FR Doc. 93–301 Filed 1–6–93; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL RESERVE SYSTEM

Report to Congressional Committees Regarding Differences in Capital and Accounting Standards Among the Federal Banking and Thrift Agencies

December 19, 1992.

AGENCY: Board of Governors of the Federal Reserve System.

ACTIONS: Report to the Committee on Banking, Housing, and Urban Affairs of the United States Senate and to the Committee on Banking, Finance and Urban Affairs of the United States House of Representatives regarding differences in capital and accounting standards among the Federal banking and thrift agencies.

SUMMARY: This report has been prepared by the Federal Reserve Board pursuant to section 121 of the Federal Deposit Insurance Corporation Improvement Act of 1991. Section 121 requires each Federal banking and thrift agency to report annually to the above specified Congressional Committees regarding any differences between the accounting or capital standards used by such agency and the accounting or capital standards used by other banking and thrift agencies. The report must also contain an explanation of the reasons for any discrepancy in such accounting or capital standards. The report must be published in the **Federal Register**.

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Introduction and Overview

This report addresses the question of what differences in capital standards and accounting practices currently exist among the three banking agencies (The Board of Governors of the Federal Reserve System (FRB), The Office of the Comptroller of the Currency (OCC), and the Federal Deposit Insurance Corporation (FDIC)) and the Office of Thrift Supervision (OTS). Section One of the report focuses on differences that exist in capital standards; Section Two discusses differences in accounting standards. The remainder of this introduction provides, in turn, an overview of the discussion of each of the following sections.

Capital Standards

As stated in reports [1] the FRB has submitted to the Congress in previous years, the three bank regulatory agencies [2] have, for a number of years, employed a common regulatory framework that establishes minimum capital adequacy ratios for commercial banking organizations. Throughout the 1980's, the banking agencies utilized a common standard that required banking organizations to maintain a level of primary capital (principally, permanent shareholders' equity, general loan loss reserves, and certain mandatory convertible securities) equal to at least 5.5 percent of total assets. Banking organizations also were required to maintain a level of total capital (primary capital plus secondary capital, such as subordinated debt) equal to at least 6.0 percent of total assets.

In 1989, all three banking agencies and the OTS adopted a risk-based capital framework that was based upon the international capital accord developed by the Basle Committee on Banking Regulations and Supervisory Practices (Basle Accord) and endorsed by the central bank governors of the G–10 countries. This framework establishes minimum ratios of total and Tier 1 (core) capital to risk-weighted assets. The Basle Accord requires banking organizations to have total and core capital equal to at least 7.25 percent and 3.625 percent, respectively, of risk-weighted assets during a phase-in period which began at the end of

[1] The previous report prepared by the Federal Reserve Board was made pursuant to section 1215 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) which was superseded by section 121 of the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA).

[2] At the federal level, the Federal Reserve System has primary supervisory responsibility for state-chartered banks that are members of the Federal Reserve System as well as all bank holding companies. The FDIC has primary responsibility for state nonmember banks and FDIC-supervised savings banks. National banks are supervised by the OCC. The OTS has primary responsibility for savings and loan associations.

1990. This interim transition standard will expire at the end of 1992, when banking and thrift organizations will be required to maintain total capital equal to at least 8 percent of risk-weighted assets. At least one half of the total capital requirement, or a minimum of 4 percent by the end of 1992, must consist of Tier 1 capital (principally, common shareholders' equity and qualifying perpetual preferred stock, less disallowed intangibles such as goodwill). The other half, Tier 2, may include certain supplementary capital items, such as general loan loss reserves and subordinated debt. The risk-based capital requirements are viewed by the three banking agencies and the OTS as minimum standards, and most institutions are expected to, and generally do, maintain capital levels well above the minimums.

In addition to specifying identical ratios, the risk-based framework being implemented by the three banking agencies and the OTS includes a common definition of regulatory capital and a uniform system of risk weights and categories. While the minimum standards and risk weighting framework are common to all the banking agencies, there are some technical differences in language and interpretation among the agencies that are discussed in Section One. Also discussed in Section One are the banking agencies' guidelines relating to the treatment of identifiable intangible assets, which are not entirely uniform at the present time. All four of the agencies have issued coordinated proposals designed to achieve uniformity with respect to the treatment of identifiable intangible assets for capital purposes. Section One also discusses the three banking agencies' revised leverage standards that were adopted in the second half of 1990 and in early 1991, and are based upon the common definition of Tier 1 capital contained in the risk-based capital guidelines.

Several sections of FDICIA had the effect of codifying the risk-based capital and leverage requirements adopted by the Federal Reserve and the other agencies. During 1992, the three banking agencies and the OTS adopted uniform prompt corrective action regulations, as mandated by section 131 of FDICIA, which required the establishment of specific capital categories based on risk-based capital and leverage measures. Also, pursuant to section 308, the Federal Reserve has adopted a regulation to limit certain interbank liabilities which is keyed to risk-based capital levels. The FDIC adopted risk-based insurance premiums, pursuant to section 302, and has set limits on the acceptance of brokered deposits, pursuant to section 301. Both of these regulations entail reliance upon capital categories.

The agencies are continuing their efforts to revise the risk-based capital requirements to ensure that those standards take account of interest-rate risk. Section 305 of FDICIA mandates that the risk-based capital standards consider interest rate risk, as well as concentration of credit risk and the risks of nontraditional activities. At this writing, the OTS is contemplating issuing in the near term an approach for requiring that adequate capital be maintained against interest rate risk. The three banking agencies have sought comment on a proposed approach for incorporating interest-rate risk into the risk-based capital standards. The approach ultimately adopted by the banking agencies could differ from that taken by the OTS.

The differences in the capital standards between the three banking agencies and the OTS are set forth in Section One. The staffs of the agencies have been meeting regularly to identify and address differences and inconsistencies in their capital standards. The agencies are committed to continuing this process in an effort to achieve full uniformity in their capital standards.

Accounting Standards

Over the years, the three banking agencies, under the auspices of the Federal Financial Institutions Examination Council (FFIEC), have developed Uniform Reports of Condition and Income (Call Reports) for all commercial banks and FDIC-supervised savings banks. The reporting standards followed by the three banking agencies are substantially consistent, aside from a few limited exceptions, with generally accepted accounting principles (GAAP) as they are applied by commercial banks.[3] The uniform bank Call Report serves as the basis for calculating risk-based capital and leverage ratios, as well as for other regulatory purposes. Thus, material differences in regulatory accounting and reporting standards among commercial banks and FDIC-supervised savings banks do not exist.

The OTS requires each thrift institution to file the Thrift Financial Report (TFR), which is consistent with GAAP as it is applied by thrifts. The TFR differs in some respects from the bank Call Report. One reason is that thrift GAAP is different in a few limited areas from GAAP as it is applied by banks; another, as previously mentioned, is that there are a few minor areas in which the bank Call Report departs from bank GAAP. A summary of the differences between the bank Call Report and the TFR is presented in Section Two.

Over the past year, the three banking agencies and the OTS have continued to undertake projects that seek to simplify and reduce differences in reporting standards between commercial banks and thrift institutions. As a compromise, the OTS has adopted some of the policies of the three banking agencies where differences had previously existed.[4] In addition, all four agencies have issued uniform accounting and reporting guidance governing assets held for trading or for sale and high risk mortgage derivative products. All four agencies have also been discussing ways of establishing conformity in reporting requirements (and capital treatment) for recourse arrangements. Furthermore, the staffs of the agencies are meeting regularly to review their approaches in evaluating the allowance for loan and lease losses and the valuation of real estate collateral in order to improve their practices in these areas and promote consistency among them.

The agencies have also jointly requested public comment on the accounting and reporting treatment for deferred tax assets, in response to new accounting standards issued by the Financial Accounting Standards Board (FASB). The agencies are currently studying the comments received and expect to announce a uniform policy on deferred tax assets by the end of this year.

The FASB recently issued a proposed accounting standard on the accounting for loan impairment. If adopted, this standard will narrow the differences in GAAP between bank and thrift accounting for measuring and reporting the effects of impairment on troubled loans. In addition, the American Institute of Certified Public Accountants (AICPA) has recently issued standards governing the accounting for and reporting of foreclosed assets, which became effective for fiscal years ending

[3] In those cases where bank Call Report standards are different from GAAP, the regulatory reporting requirements are intended to be more conservative than GAAP.

[4] The main area of accounting policy that the OTS has adopted involves a new OTS requirement that savings associations maintain general valuation allowances (GVAs) for all assets, including the loan portfolio, in addition to specific valuation allowances. This requirement for a GVA for the loan portfolio is essentially equivalent to the allowance for loan and lease losses required in regulatory financial reports for banks. In addition, certain minor accounting policies of the banking agencies have been adopted this year by the OTS.

after December 15, 1992. These accounting changes, will promote greater uniformity of regulatory reporting requirements in these two areas.

Section One

Differences in Capital Standards Among Federal Banking and Thrift Supervisory Agencies

Leverage Capital Ratios

Throughout most of the 1980's, the three banking agencies required banking organizations to meet minimum capital to total assets (leverage) ratios. In the past, these requirements included a minimum 5.5 percent primary capital ratio and a minimum 6.0 percent total capital ratio.

In the second half of 1990 and in early 1991, the three banking agencies developed revised leverage standards based upon the common definition of Tier 1 capital contained in their risk-based capital guidelines. These standards require the most highly-rated institutions to meet a minimum Tier 1 capital ratio of 3 percent, and for all other institutions, these standards generally require an additional cushion of at least 100 to 200 basis points, i.e., a minimum leverage ratio of at least 4 to 5 percent, depending upon an organization's financial condition.

As required by FIRREA, the OTS has established a 3 percent core capital ratio and a 1.5 percent tangible capital leverage requirement for thrift institutions. However, the OTS is in the process of finalizing a new leverage rule that will generally conform to the rules of the three banking agencies. The differences that will exist after the OTS has adopted its new standard pertain to the definition of core capital. While this definition generally conforms to Tier 1 bank capital, certain adjustments discussed below apply to the core capital definition used by savings associations. In addition, core capital as currently defined by the OTS includes qualifying supervisory goodwill. Such goodwill is to be phased out of thrift core capital by the end of 1994, after which time the treatment of goodwill for thrift institutions will be consistent with that of the banking agencies.

Risk-based Capital Ratios

The three banking agencies have adopted risk-based capital standards consistent with the Basle Accord. These standards require all commercial banking organizations to maintain a minimum ratio of total capital (Tier 1 plus Tier 2) to risk-weighted assets of 7.25 percent by year-end 1990; this minimum standard increases to 8 percent as of year-end 1992. Tier 1 capital comprises common stockholders' equity, qualifying perpetual preferred stock, and minority interests in consolidated subsidiaries, less goodwill. (The treatment of other intangible assets is discussed below.) Tier 1 capital must comprise at least 50 percent of the total risk-based capital requirement. Tier 2 capital includes such components as general loan loss reserves, subordinated term debt, and certain other preferred stock and convertible debt capital instruments, subject to appropriate limitations and conditions. Risk-weighted assets are calculated by assigning risk weights of 0, 20, 50, and 100 percent to broad categories of assets and off-balance sheet items based upon their relative credit risks.

The banking agencies view the risk-based capital standard as a minimum supervisory benchmark. In part, this is because the risk-based capital standard focuses primarily on credit risk; it does not take full or explicit account of certain other banking risks, such as exposure to changes in interest rates. The full range of risks to which depository institutions are exposed are reviewed and evaluated carefully during on-site examinations. In view of these risks, most banking organizations are expected to operate with capital levels well above the minimum risk-based and leverage capital requirements.

The Federal Reserve is working with the other U.S. banking agencies and the regulatory authorities on the Basle Supervisor's Committee to develop possible methods to measure and address certain market and price risks. These risks include exposures resulting from foreign exchange positions, imbalances between the maturity of debt instruments held as assets and issued as liabilities, and holdings of traded debt and equity securities. One important reason for addressing these risks on an international level is to develop supervisory approaches that do not undermine the competitiveness of U.S. banking organizations.

OTS has adopted a risk-based capital standard that in most respects is similar to the framework adopted by the banking agencies. The OTS standard currently requires a minimum risk-based capital ratio equal to 7.20 percent of risk-adjusted assets, and this minimum required ratio will increase to 8 percent at year-end 1992. The OTS has proposed an additional element for interest rate risk. Differences between the risk-based capital guidelines by the OTS and the other agencies are discussed below.

Equity Investments

In general, commercial banks that are members of the Federal Reserve System are not permitted to invest in equity securities, nor are they generally permitted to engage in real estate investment or development activities. To the extent that commercial banks are permitted to hold equity securities (for example, in connection with debts previously contracted), the three banking agencies generally assign such investments to the 100 percent risk category for risk-based capital purposes.

The three banking agencies' guidelines permit, on a case-by-case basis, a deduction of equity investments from the parent bank's capital or other options, if necessary, to assess an appropriate capital charge above the minimum requirement. The banking agencies' treatment of investments in subsidiaries is discussed below.

The OTS risk-based capital standards require that thrift institutions deduct certain equity investments from capital over a phase-in period, which ends on July 1, 1994, as explained more fully below in the section on subsidiaries.

FSLIC/FDIC—Covered Assets (Assets Subject to Guarantee Arrangements by the FSLIC or FDIC)

The three banking agencies generally place these assets in the 20 percent risk category, the same category to which claims on depository institutions and government-sponsored agencies are assigned.

The OTS places these assets in the zero percent risk category.

Repossessed Assets and Assets More Than 90 Days Past Due

The three banking agencies require that foreclosed real estate be written down to fair value (see Section Two of this appendix, "Specific Valuation Allowances for, and Charge-Offs of, Troubled Real Estate Loans not in Foreclosure" for further details) with the resulting asset assigned to the 100 percent risk category. The write-down effectively results in a reduction of capital. Assets 90 days or more past due, including 1- to 4-family mortgages, are assigned to the 100 percent risk category. If and when such assets are eventually charged-off, capital is effectively adjusted for any resulting loss.

Consistent with the Basle Accord, the 100 percent risk category is the highest risk category under the risk-based capital guidelines of the three banking agencies. As noted above, however, the bank risk-based capital standards represent minimum ratios.

Consequently, organizations with high levels of risk, including a significant volume of nonperforming or past due assets, are expected to maintain capital ratios above minimum levels. Accordingly, the risk-based capital framework of the banking agencies provides the latitude to place a higher than minimum capital charge on assets of this type.

The OTS risk-based capital framework assigns a 200 percent risk weight to repossessed assets (generally referred to as REO) and assets more than 90 days past due. An exception exists for 1- to 4-family mortgages more than 90 days past due, which are assigned to the 100 percent risk category. The OTS intends to change the risk weight for all REO to 100 percent in conjunction with recent changes in the accounting for REO.

Limitation on Subordinated Debt and Limited-Life Preferred Stock

Consistent with the Basle Accord, the three banking agencies limit the amount of subordinated debt and limited-life preferred stock that may be included in Tier 2 capital. This limit, in effect, states that these components together may not exceed 50 percent of Tier 1 capital. In addition, maturing capital instruments must be discounted by 20 percent in each of the last five years prior to maturity.

Neither of these capital components is a permanent source of funds, and subordinated debt cannot absorb losses while the bank continues to operate as a going concern. On the other hand, both components can provide a cushion of protection to the FDIC insurance fund. Thus, this limitation permits the inclusion of some subordinated debt in capital, while assuring that permanent stockholders' equity capital remains the predominant element in bank regulatory capital.

The OTS has no limitation on the total amount of limited-life preferred stock or maturing capital instruments that may be included within Tier 2 capital. In addition, the OTS allows thrifts the option of: (1) Discounting maturing capital instruments, issued on or after November 7, 1989, by 20 percent a year over the last 5 years of their term—the approach required by the banking agencies; or (2) including the full amount of such instruments provided that the amount maturing in any of the next seven years does not exceed 20 percent of the thrift's total capital.

Subsidiaries

Consistent with the Basle Accord and long-standing supervisory practices, the three banking agencies generally consolidate all significant majority-owned subsidiaries of the parent organization for capital purposes. This consolidation assures that the capital requirements are related to all of the risks to which the banking organization is exposed.

As with most other bank subsidiaries, banking and finance subsidiaries generally are consolidated for regulatory capital purposes. However, in the case of banking and finance subsidiaries that are not consolidated, the Federal Reserve, consistent with the Basle Accord, generally deducts investments in such subsidiaries in determining the adequacy of the parent bank's capital.

The Federal Reserve's risk-based capital guidelines provide a degree of flexibility in the capital treatment of unconsolidated subsidiaries (other than banking and finance subsidiaries) and investments in joint ventures and associated companies. For example, the Federal Reserve may deduct investments in such subsidiaries from an organization's capital, may apply an appropriate risk-weighted capital charge against the proportionate share of the assets of the entity, may require a line-by-line consolidation of the entity, or otherwise may require that the parent organization maintain a level of capital above the minimum standard that is sufficient to compensate for any risks associated with the investment.

The guidelines also permit the deduction of investments in subsidiaries that, while consolidated for accounting purposes, are not consolidated for certain specified supervisory or regulatory purposes. For example, the Federal Reserve deducts investments in, and unsecured advances to, section 20 securities subsidiaries from the parent bank holding company's capital. The FDIC accords similar treatment to securities subsidiaries of state nonmember banks established pursuant to § 337.4 of the FDIC regulations.

Similarly, in accordance with § 325.5(f) of the FDIC regulations, investments in, and extensions of credit to, certain mortgage banking subsidiaries are also deducted in computing the parent bank's capital. (The Federal Reserve does not have a similar requirement with regard to mortgage banking subsidiaries. The OCC does not have requirements dealing specifically with the capital treatment of either mortgage banking or securities subsidiaries. The OCC, however, does reserve the right to require a bank, on a case-by-case basis, to deduct from capital investments in, and extensions of credit to, any nonbanking subsidiary.)

The deduction of investments in subsidiaries from the parent's capital is designed to ensure that the capital supporting the subsidiary is not also used as the basis of further leveraging and risk-taking by the parent banking organization. In deducting investments in, and advances to, certain subsidiaries from the parent's capital, the Federal Reserve expects the parent banking organization to meet or exceed minimum regulatory capital standards without reliance on the capital invested in the particular subsidiary. In assessing the overall capital adequacy of banking organizations, the Federal Reserve may also consider the organization's fully consolidated capital position.

Under OTS capital guidelines, a distinction, mandated by FIRREA, is drawn between subsidiaries that are engaged in activities that are permissible for national banks and subsidiaries that are engaged in "impermissible" activities for national banks. Subsidiaries of thrift institutions that engage only in permissible activities are consolidated on a line-for-line basis if majority-owned and on a pro rata basis if ownership is between 5 percent and 50 percent. As a general rule, investments, including loans, in subsidiaries that engage in impermissible activities are deducted in determining the capital adequacy of the parent. However, investments, including loans, outstanding as of April 12, 1989 to subsidiaries that were engaged in impermissible activities prior to that date are grandfathered and will be phased-out of capital over a transition period that expires on July 1, 1994. During this transition period, investments in subsidiaries engaged in impermissible activities that have not been phased out of capital are to be consolidated on a pro rata basis.

Presold Residential Construction Loans

As mandated under section 618(a) of the Resolution Trust Corporation Refinancing, Restructuring, and Improvement Act of 1991 (RTCRRIA), the banking and thrift agencies are amending the risk-based capital guidelines to lower the risk weight to 50 percent for loans to finance the construction of 1- and 4-family residential properties that have been presold. Prior to this amendment, these loans were considered to be construction and land development loans and generally assigned to the 100 percent risk weight category.

This section of the statute required the three banking agencies and the OTS to assign to the 50 percent risk category any presold residential construction loan that meets the following criteria: (1) The loan is for the construction of a 1- to 4-family residential property, (2)

the bank has sufficient documentation, as may be required by the appropriate federal banking agency, to demonstrate the intent and ability of the buyer to purchase the property, (3) the purchaser has provided to the builder a nonrefundable deposit in an amount determined by the appropriate federal banking agency, but not less than one percent of the principal amount of the mortgage, and (4) the loan satisfies prudent underwriting standards as established by the appropriate federal banking agency.

The OTS and OCC have already issued final rules implementing this change. The FDIC is in the process of adopting a final rule. The FRB is planning to issue an interim rule amending its risk-based capital guidelines. There is a difference between the OTS and OCC rules and those under consideration by the FDIC and FRB. Under the OTS and OCC rules, a requirement is in place that the property be presold before the construction loan is extended in order for the loan to qualify for the 50 percent risk weight. The FDIC and FRB amendments would allow loans for the construction of such properties to qualify for the 50 percent risk weight once the property is presold, even if that sale occurs after the construction loan was made.

Qualifying Multifamily Mortgage Loans

The three banking agencies place multifamily mortgage loans (five units or more) in the 100 percent risk weight category. Historically, when compared to loans secured by mortgages on 1- to 4-family residences, which generally are assigned to the 50 percent risk category, the credit risk associated with multifamily mortgage loans, unless conservatively underwritten and seasoned, is more akin to that experienced on commercial property loans, which are assigned to the 100 percent risk category. The OTS allows certain multifamily mortgage loans to qualify for the 50 percent risk category. This would apply, for example, to loans secured by buildings with 5–36 units, provided these loans have a maximum 80 percent loan-to-value ratio and an 80 percent occupancy rate.

Pursuant to section 618(b) of the RTCRRIA, the three banking agencies and the OTS were directed to amend their risk-based capital guidelines to lower the risk weight of certain multifamily housing loans, and securities backed by such loans, from 100 percent to 50 percent. The section specifies several criteria that a multifamily housing loan must satisfy in order to qualify for a 50 percent risk weight. These criteria are: (1) The loan is secured by a first lien, (2) the ratio of the principal obligation to the appraised value of the property, that is, the loan-to-value ratio, does not exceed 80 percent (75 percent if the loan is based on a floating interest rate), (3) the annual net operating income generated by the property (before debt service) is not less than 120 percent of the annual debt service on the loan (115 percent if the loan is based on a floating interest rate), (4) the amortization of principal and interest occurs over a period of not more than 30 years and the minimum maturity for repayment of principal is not less than7 years, and (5) all principal and interest payments have been made on time for a period of not less than one year.

In addition, section 618(b) also provides that multifamily housing loans accorded a 50 percent risk weight must meet any underwriting characteristics that the appropriate federal banking agency may establish, consistent with the purposes of the minimum acceptable capital requirements to maintain the safety and soundness of financial institutions.

The agencies have proposed revisions to their capital standards to meet the requirement of section 618(b). The comments received in response to these proposals are currently under review and consideration.

Nonresidential Construction and Land Loans

The three banking agencies assign loans for real estate development and construction purposes to the 100 percent risk category. Reserves or charge-offs are required, in accordance with examiner judgment, when weaknesses or losses develop in such loans. The banking agencies have no requirement for an automatic charge-off when the amount of a loan exceeds the fair value of the property pledged as collateral for the loan.

The OTS generally assigns these loans to the 100 percent risk category. However, if the amount of the loan exceeds 80 percent of the fair value of the property, that excess portion must be deducted from capital in accordance with a phase-in arrangement, which ends on July 1, 1994.

Mortgage-Backed Securities (MBS)

The three banking agencies, in general, place privately-issued MBS in a risk category appropriate to the underlying assets but in no case to the zero percent risk category. In the case of privately-issued MBSs where the direct underlying assets are mortgages, this treatment generally results in a risk weight of 50 percent or 100 percent. Privately-issued MBSs that have government agency or government-sponsored agency securities as their direct underlying assets are generally assigned to the 20 percent risk category.

The OTS assigns privately-issued high quality mortgage-related securities to the 20 percent risk category. These are, generally, privately-issued MBSs with AA or better investment ratings.

At the same time, both the banking and thrift agencies automatically assign to the 100 percent risk weight category certain MBSs, including interest-only strips, residuals, and similar instruments that can absorb more than their pro rata share of loss. The Federal Reserve, in conjunction with the other banking agencies and the OTS, is in the process of developing more specific guidance as to the types of "high risk" MBSs that will qualify for a 100 percent risk weight.

Intangible Assets

The federal banking agencies do not allow banks or FDIC-supervised savings banks to include goodwill in the calculation of Tier 1 capital for either risk-based or leverage capital purposes. Bank holding companies may include goodwill acquired prior to March 12, 1988 in Tier 1 for risk-based capital purposes (although not for leverage capital purposes), until the end of the 1992. After 1992, all goodwill is to be deducted from bank holding company capital.

Pursuant to FIRREA, the OTS allows "qualifying supervisory goodwill" to be included as part of core capital through year-end 1994. After this date, thrift institutions must meet their minimum core capital requirement without reliance on goodwill.

Presently, the three banking agencies and the OTS differ somewhat with regard to the treatment of identifiable intangible assets (that is, intangible assets other than goodwill) in the calculation of regulatory capital ratios. The FDIC and OCC fully deduct all intangibles other than limited amounts of purchased mortgage servicing rights (PMSRs) from Tier 1 capital. The Federal Reserve does not automatically deduct any identifiable intangible assets from Tier 1 capital, but determines the appropriateness of their inclusion in an organization's capital position on a case-by-case basis. The OTS deducts all intangibles other than limited amounts of PMSRs unless an institution can document that its holdings of other intangibles meet certain criteria, in which case certain limited amounts of these qualifying intangibles may be included in capital.

All of the agencies have some means of limiting the amount of intangibles that institutions can include in capital. The OCC permits PMSRs to account for up to 25 percent of Tier 1 capital, while the FDIC permits them to account for up to 50 percent of Tier 1. The OTS also permits PMSRs to be included up to 50 percent of Tier 1 capital and limits other qualifying intangibles to 25 percent of Tier 1 capital. The Federal Reserve's current risk-based capital guidelines indicate that identifiable intangible assets in excess of 25 percent of Tier 1 capital are subject to particularly close scrutiny. The FDIC and the OTS also subject PMSRs to certain valuation and discounting requirements.

In order to develop a uniform capital treatment for identifiable intangible assets, the agencies issued separate proposals, on a coordinated basis, for public comment in 1992. The Federal Reserve's proposal stated that banking organizations would be permitted to include PMSRs and purchase credit card relationships (PCCRs) in capital, provided that, in the aggregate, the amount included does not exceed 50 percent of an organization's Tier 1 capital. PCCRs would be subject to a separate sublimit of 25 percent of Tier 1. Amounts of PMSRs and PCCRs in excess of these amounts, as well as all other identifiable intangible assets, including core deposit intangibles, would be deducted from Tier 1 for purposes of calculating regulatory capital ratios.

The proposal also addresses the valuation of identifiable intangible assets included in capital in a manner that is consistent with section 475 of FDICIA. Section 475 requires the agencies to determine the appropriate capital treatment to be given to PMSRs, where the fair market value of the PMSRs is calculated at least quarterly and the amount of PMSRs included in capital is discounted to no more than 90 percent of fair market value. The proposal also states that, for purposes of calculating regulatory capital (but not for financial statement purposes), the amount of PMSRs and PCCRs reported on the balance sheet would be reduced to the lesser of:

(i) 90 percent of the fair market value of the PMSRs; or

(ii) 90 percent of the original purchase price paid for the PMSRs; or

(iii) 100 percent of the remaining unamortized book value of the PMSRs.

Similarly, the FDIC and the OTS also currently require state nonmember banks and savings associations to discount their holdings of PMSRs.

The proposal also states that, in accordance with current FDIC and OTS rules, institutions wishing to include PMSRs and PCCRs in capital must carry them at a book value that does not exceed the discounted value of their future net servicing income. The proposal further requires that the discount rate used for this purpose not be less than the original discount rate derived at the time of acquisition, based upon the estimated cash flows and the price paid for the asset at the time of purchase.

The Federal Reserve and the other agencies have received public comments on the proposal and are reviewing these comments in preparation for issuing their final rules.

Assets Sold With Recourse

In general, recourse arrangements allow the purchaser of an asset to "put" the asset back to the originating institution under certain circumstances, for example if the asset ceases to perform satisfactorily. This, in turn, can expose the originating institution to any loss associated with the asset. As a general rule, the three banking agencies require that sales of assets involving any recourse be reported as financings and that the assets be retained on the balance sheet. This effectively requires a full leverage and risk-based capital charge whenever assets are sold with recourse, including limited recourse. The Federal Reserve generally applies a capital charge to any off-balance sheet recourse arrangement that is the equivalent of a guarantee, regardless of the nature of the transaction that gives rise to the recourse obligation.

An exception to this general rule involves pools of 1- to 4-family residential mortgages and to certain farm mortgage loans. Certain recourse transactions involving these assets are reported in the bank Call Report as sales, thereby removing these transactions from leverage ratio calculations. These transactions, which are the equivalent of off-balance sheet guarantees, involve the type of credit risk that is addressed by bank risk-based capital requirements, although some questions in this regard have been raised because of the treatment afforded these transactions for leverage purposes. The Federal Reserve has clarified its risk-based capital guidelines to ensure that recourse sales involving residential mortgages are to be taken into account for determining compliance with risk-based capital requirements. The FDIC is also in process of clarifying its guidelines.

In general, the OTS also requires a full capital charge against assets sold with recourse. However, in the case of limited recourse, the OTS limits the capital charge to the lesser of the amount of recourse or the actual amount of capital that would otherwise be required against that asset, that is, the normal full capital charge.

Some securitized asset arrangements involve the issuance of senior and subordinated classes of securities against pools of assets. When a bank originates such as transaction by placing loans that it owns in a trust and retaining any portion of the subordinated securities, the banking agencies require that capital be maintained against the entire amount of the asset pool. When a bank acquires a subordinated security in a pool of assets that it did not originate, the banking agencies assign the investment in the subordinated piece to the 100 percent risk-weight category. The Federal Reserve carefully reviews these instruments to determine if additional reserves, asset write-downs, or capital are necessary to protect the bank.

The OTS requires that capital be maintained against the entire amount of the asset pool in both of the situations described in the preceding paragraph. Additionally, the OTS applies a capital charge to the full amount of assets being serviced when the servicer is required to absorb credit losses on the assets being serviced.

In 1990, the three banking agencies and the OTS, under the FFIEC, issued for public comment a fact finding paper pertaining to the wide range of issues relating to recourse arrangements. These issues include the definition of "recourse" and the appropriate reporting and capital treatments to be applied to recourse arrangements, as well as so-called recourse servicing arrangements and limited recourse. The objective of this effort was to develop a comprehensive and uniform approach to recourse arrangements for capital adequacy, reporting, and other regulatory purposes. The comments received were very extensive and generally illustrated the extreme complexity of the subject. In view of the project's significance and complexity, the FFIEC in December 1990 decided to narrow the scope of the initial phase of the recourse project to credit-related risks, including the appropriate treatment of credit-related recourse arrangements that involve limited recourse or that support a third party's assets.

A recourse working group, composed of representatives from the member agencies of the FFIEC, presented a report and recommendations to the FFIEC in August 1992 and were directed

to carry out a study of the impact of their recommendations on depository institutions, financial markets, and other affected parties. Plans to carry-out this study are being developed by the interagency working group.

Agricultural Loan Loss Amortization

In the computation of regulatory capital, those banks accepted into the agricultural loan loss amortization program pursuant to Title VIII of the Competitive Equality Banking Act of 1987 are permitted to defer and amortize losses incurred on agricultural loans between January 1, 1984 and December 31, 1991 The program also applies to losses incurred between January 1, 1983 and December 31, 1991, as a result of reappraisals and sales of agricultural Other Real Estate Owned (OREO) and agricultural personal property. These losses must be fully amortized over a period not to exceed seven years and, in any case, must be fully amortized by year-end 1998. Thrifts are not eligible to participate in the agricultural loan loss amortization program established by this statute.

Treatment of Junior Liens on 1- to 4-Family Properties

In some cases, a banking organization may make two loans on a single residential property, one loan secured by a first lien, the other by a second lien. In such a situation, the Federal Reserve views these two transactions as a single loan, provided there are no intervening liens. This could result in assigning the total amount of these transactions to the 100 percent risk weight category, if, in the aggregate, the two loans exceeded a prudent loan-to-value ratio and, therefore, did not qualify for the 50 percent risk weight. This approach is intended to avoid possible circumvention of the capital requirements and capture the risks associated with the combined transactions.

The FDIC, OCC, and the OTS generally assign the loan secured by the first lien to the 50 percent risk-weight category and the loan secured by the second lien to the 100 percent risk-weight category.

Pledged Deposits and Nonwithdrawable Accounts

The capital guidelines of OTS permit thrift institutions to include in capital certain pledged deposits and nonwithdrawable accounts that meet the criteria of the OTS. Income Capital Certificates and Mutual Capital Certificates held by the OTS may also be included in capital by thrift institutions. These instruments are not relevant to commercial banks, and, therefore, they are not addressed in the three banking agencies' capital guidelines.

Mutual Funds

The three banking agencies assign all of a bank's holdings in a mutual fund to the risk category appropriate to the highest risk asset that a particular mutual fund is permitted to hold under its operating rules. The purpose of this is to take into account the maximum degree of risk to which a bank may be exposed when investing in a mutual fund in view of the fact that the future composition and risk characteristics of the fund's holdings cannot be known in advance.

The OTS applies a capital charge appropriate to the riskiest asset that a mutual fund is actually holding at a particular time. In addition, the OTS guidelines also permit, on a case-by-case basis, investments in mutual funds to be allocated on a pro rata basis in a manner consistent with the actual composition of the mutual fund.

Section Two

Differences in Accounting Standards Among Federal Banking and Thrift Supervisory Agencies

Under the auspices of the FFIEC, the three banking agencies have developed uniform reporting standards for commercial banks which are used in the preparation of the Call Report. The FDIC has also applied these uniform Call Report standards to savings banks under its supervision. The income statement and balance sheet accounts presented in the Call Report are used by the bank supervisory agencies for determining the capital adequacy of banks and for other regulatory, supervisory, surveillance, analytical, and general statistical purposes. The reporting standards set forth in the Call Report are based almost entirely on GAAP for banks, and, as a matter of policy, deviate from GAAP only in those instances where statutory requirements or overriding supervisory concerns warrant a departure from GAAP. Thus, in so far as the federal bank supervisory agencies are concerned, material differences in accounting standards for regulatory purposes do not exist.

The OTS has developed and maintains a separate reporting system for the thrift institutions under its supervision. The TFR, is based on GAAP as applied by thrifts, which differs in some respects from GAAP for banks. The following discussion addresses the differences in reporting standards among the federal banking agencies and the OTS.

Futures and Forward Contracts

The banking agencies, as a general rule, do not permit the deferral of losses by banks on futures and forwards whether or not they are used for hedging purposes. All changes in market value of futures and forward contracts are reported in current period income. The banking agencies adopted this reporting standard as a supervisory policy prior to the adoption of FASB Statement No. 80, which allows hedge or loss deferral accounting, under certain circumstances. Contrary to this general rule, hedge accounting in accordance with FASB Statement No. 80 is permitted by the three banking agencies only for futures and forward contracts used in mortgage banking operations.

The OTS practice is to follow FASB Statement No. 80 for futures contracts. In accordance with this statement, when hedging criteria are satisfied, the accounting for the futures contract is related to the accounting for the hedged item. Changes in the market value of the futures contract are recognized in income when the effects of related changes in the price or interest rate of the hedged item are recognized. Such reporting can result in deferred losses which would be reflected as assets on the thrift's balance sheet in accordance with GAAP.

Excess Servicing Fees

As a general rule, the three banking agencies do not follow GAAP for excess servicing fees, but require a more conservative treatment. Excess servicing results when loans are sold with servicing retained and the stated servicing fee rate is greater than the normal servicing fee rate. With the exception of sales of pools of residential mortgages for which the banking agencies' approach is consistent with FASB Statement No. 65, excess servicing fee income in banks must be reported as realized over the life of the transferred asset, not recognized up front as required by FASB Statement No. 65.

The OTS allows the present value of the future excess servicing fee to be treated as an adjustment to the sales price for purposes of recognizing gain or loss on the sale. This approach is consistent with FASB Statement No. 65.

In-substance Defeasance of Debt

The banking agencies do not permit banks to report defeasance of their debt obligations in accordance with FASB Statement No. 76, Defeasance involves a debtor irrevocably placing risk-free monetary assets in a trust solely for satisfying the debt. Under FASB

Statement No. 76, the assets in the trust and the defeased debt are removed from the balance sheet and a gain or loss for the current period can be recognized. Commercial banks are not permitted to defease their debt obligations for reporting or supervisory purposes. Thus, banks may not remove assets or liabilities from their balance sheets or recognize resulting gains or losses. The banking agencies have not adopted FASB Statement No. 76 because of uncertainty regarding the irrevocable trusts established for defeasance purposes. Furthermore, defeasance would not relieve the bank of its contractual obligation to pay depositors or other creditors.

OTS practice is to follow FASB Statement No. 76.

Sales of Assets With Recourse

In accordance with FASB Statement No. 77, a transfer of receivables with recourse is recognized as a sale if: (1) The transferor surrenders control of the future economic benefits, (2) the transferor's obligation under the recourse provisions can be reasonably estimated, and (3) the transferee cannot require repurchase of the receivables except pursuant to the recourse provisions.

The practice of the three banking agencies is generally to permit commercial banks to report transfers of receivables with recourse as sales only when the transferring institution (1) retains no risk of loss from the assets transferred and (2) has no obligation for the payment of principal or interest on the assets transferred. As a result, virtually no transfers of assets with recourse can be reported as true sales. However, this rule does not apply to the transfer of 1- to 4-family or agricultural mortgage loans under certain government-sponsored programs (including the Federal National Mortgage Association and the Federal Home Loan Mortgage Corporation). Transfers of mortgages under these programs are generally treated as sales for Call Report purposes.

Furthermore, private transfers of mortgages are also reported as sales if the transferring institution retains only an insignificant risk of loss on the assets transferred. However, the seller's obligation under recourse provisions related to sales of mortgage loans under the government programs is viewed as an off-balance sheet exposure. Thus, for risk-based capital purposes, capital is generally expected to be held for recourse obligations associated with such transactions.

The OTS policy is to follow FASB Statement No. 77. However, in the calculation of risk-based capital under the OTS guideline, off-balance sheet recourse obligations generally are converted at 100 percent. This effectively negates the sale treatment recognized on a GAAP basis for risk-based capital purposes, but not for leverage capital purposes. Thus, by making this adjustment in the risk-based capital calculation, the differences between the OTS and the banking agencies for capital adequacy measurement purposes, are substantially reduced.

During the past year, the three banking agencies and the OTS have continued to discuss the possibility of conforming the reporting practices of the banking agencies and the OTS in this area.

Specific Valuation Allowances for and Charge-offs of Troubled Loans

Currently, the OTS uses net realizable value (NRV) to determine the level of specific valuation allowances or charge-offs for troubled, collateral-dependent loans. Existing OTS policy requiring the use of NRV may be more or less stringent than that required by the banking agencies. The OTS has proposed a new policy for the classification and valuation of troubled collateral-dependent real estate loans that relies on the use of fair value rather than NRV of the collateral.

Push-Down Accounting

When a depository institution is acquired by a holding company in a purchase transaction, the holding company is required to revalue all of the assets and liabilities of the depository institution at fair value at the time of acquisition. When push-down accounting is applied, the same revaluation made by the parent holding company is made at the depository institution level.

The three banking agencies require push-down accounting when there is at least a 95 percent change in ownership. This approach is generally consistent with interpretation of the Securities and Exchange Commission.

The OTS requires push-down accounting when there is at least a 90 percent change in ownership.

Negative Goodwill

The three banking agencies require that negative goodwill be reported as a liability, and not be netted against goodwill assets. Such a policy ensures that all goodwill assets are deducted in regulatory capital calculations, consistent with the Basle Accord.

The OTS permits negative goodwill to offset goodwill assets reported in the financial statements.

Other Real Estate Owned—Other Than Primary Residences

The three banking agencies require that receivables resulting from sales of OREO that cannot be accounted for under the full accrual method be reported as OREO when the buyer's initial investment is less than 10 percent.

The OTS follows GAAP which does not provide explicit guidance on this issue. Thus, GAAP may permit the receivable to be reported as a loan when the buyer's initial investment is less than 10 percent.

Board of Governors of the Federal Reserve System, December 31, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93–273 Filed 1–6–93; 8:45 am]

BILLING CODE 6210–01–M

GENERAL SERVICES ADMINISTRATION

[GSA Bulletin FPMR D–232]

Public Buildings and Space

December 11, 1992.

To: Heads of Federal agencies.

Subject: Limitation on expenditures for Presidential appointees' offices.

1. *Purpose.* This bulletin cancels GSA Bulletin FPMR D–222 and informs agencies and departments of new guidelines limiting the obligation and expenditure of monies used for offices of Presidential appointees to the Federal Government.

2. *Expiration date.* This bulletin contains information of a continuing nature and will remain in effect until canceled.

3. *Background.* GSA Bulletin FPMR–222, February 16, 1990, informed agencies that the Joint Resolutions making continuing appropriations each year prohibited agencies and departments from spending or obligating more than $5,000 to furnish or redecorate, or to purchase furniture or make improvements for Presidential appointees' offices. This limitation applied during the appointee's term of office. Advance notification and express approval by the House and Senate Committees on Appropriations were required where the expenditures exceeded the $5,000 limitation. The Treasury, Postal Service, and General Government Appropriations Act, 1993, Pub. L. No. 102–393, Sec. 618, 106 Stat. 1729 (1992) amended the previous

language by defining "office" as "the entire suite of offices assigned to the individual, as well as any other space used primarily by the individual or the use of which is directly controlled by the individual."

4. *Summary.* In accordance with the language of the Treasury, Postal Service, and General Government Appropriations Act, 1992, Pub. L. No. 102–393, Sec. 618, 106 Stat. 1729 (1992), agencies and departments may not obligate or expend in excess of $5,000 to furnish or redecorate, or to purchase furniture or make improvements for Presidential appointees' offices. This limitation applies during the appointee's term of office. Advance notification and express approval by the House and Senate Committees on Appropriations are required where the expenditures exceed the $5,000 limitation.

For the purposes of this section the word "office" shall include the entire suite of offices assigned to the individual, as well as any other space used primarily by the individual or the use of which is directly controlled by the individual.

Earl E. Jones,

Commissioner, Federal Property, Asset Management Service.

[FR Doc. 93–257 Filed 1–6–93; 8:45 am]

BILLING CODE 6820–23–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92F–0382]

Hoechst Aktiengesellschaft; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Hoechst Aktiengesellschaft has filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyhydric alcohol esters and calcium salts of oxidatively refined (Gersthofen process) montan wax acids as lubricants for all polymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2B4344) has been filed by Hoechst Aktiengesellschaft, c/o 1001 G St. NW., Washington, DC 20001. The petition proposes to amend the food additive regulations in § 178.3770 *Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids* (21 CFR 178.3770) to provide for the safe use of polyhydric alcohol esters and calcium salts of oxidatively refined (Gersthofen process) montan wax acids as lubricants for all polymers intended for use in contact with food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: December 15, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–243 Filed 1–6–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92F–0432]

Victorian Chemical Co., Pty. Ltd.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Victorian Chemical Co., Pty. Ltd., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of: ethyl esters of fatty acids in aqueous emulsions for dehydrating corn, cereal grains, and beans and sulfated butyl oleate and sulfated ethyl oleate alone or in combination for dehydrating grapes to raisins, cereal grains, and beans.

FOR FURTHER INFORMATION CONTACT: Gerald J. Buonopane, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9519.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 2A4340) has been filed by Victorian Chemical Co., Pty. Ltd., P.O. Box 71, Richmond, Victoria 3121, Australia. The petition proposes to amend the food additive regulations in § 172.225 *Methyl and ethyl esters of fatty acids produced from edible fats and oils* (21 CFR 172.225) (57 FR 12709, April 13, 1992) and § 172.270 *Sulfated butyl oleate* (21 CFR 172.270) (57 FR 12709, April 13, 1992) to provide for the safe use of: (1) ethyl esters of fatty acids in aqueous emulsions for dehydrating corn, cereal grains, and beans and (2) sulfated butyl oleate and sulfated ethyl oleate alone or in combination in aqueous emulsions for dehydrating grapes to raisins, cereal grains, and beans.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: December 15, 1992.

Fred R. Shank,

Director Center for Food Safety and Applied Nutrition.

[FR Doc. 93–241 Filed 1–6–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0469]

Lyphomed, Division of Fujisawa USA, Inc.; Withdrawal of Approval of 10 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 10 abbreviated new drug applications (ANDA's) held by Lyphomed, Division of Fujisawa USA, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160–1002 (Lyphomed). FDA is withdrawing approval of these applications because of questions raised about the reliability of the data and information submitted to FDA in support of the applications. Lyphomed has waived its opportunity for hearing.

EFFECTIVE DATE: January 7, 1993.

FOR FURTHER INFORMATION CONTACT: Jean M. Olson, Center for Drug Evaluation and Research (HFD–366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8041.

SUPPLEMENTARY INFORMATION: Recently, FDA became aware of discrepancies concerning the data used to support approval of the following ANDA's held by Lyphomed:

ANDA 70–751, Nalbuphine Hydrochloride Injection, 10 milligrams

per milliliter (mg)/(mL) - 2 and 10 mL vials;

ANDA 70–752, Nalbuphine Hydrochloride Injection, 20 mg/mL - 2 and 10 mL vials;

ANDA 70–962, Dacarbazine for Injection, 100 mg/vial;

ANDA 70–990, Dacarbazine for Injection, 200 mg/vial;

ANDA 70–992, Droperidol Injection, 2.5 mg/mL - 2 and 5 mL vials;

ANDA 70–993, Droperidol Injection, 2.5 mg/mL - 10 mL vials;

ANDA 71–187, Haloperidol Injection, 5 mg/mL - 2 and 10 mL vials;

ANDA 71–188, Ritodrine Hydrochloride Injection, 10 mg/mL - 5 mL vial;

ANDA 71–189, Ritodrine Hydrochloride Injection, 15 mg/mL - 10 mL vial; and

ANDA 86–754, Mannitol Injection, 25% - 50 mL vial.

Lyphomed has identified discrepancies in data submitted to obtain approval of the applications listed above which have raised questions about the reliability of the data. Subsequently, in letters dated June 1, 1992, and September 15, 1992, Lyphomed requested withdrawal of these ANDA's. Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of the ANDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective January 7, 1993. Distribution of drug products in interstate commerce without an approved application is unlawful.

Dated: December 15, 1991.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 93–242 Filed 1–6–93; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[OIS–019–N]

Medicare and Medicaid Programs; Quarterly Listing of Program Issuances and Coverage Decisions

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: General notice.

SUMMARY: This notice lists HCFA manual instructions, substantive and interpretive regulations and other **Federal Register** notices, and statements of policy that were published during July, August, and September of 1992 that relate to the Medicare and Medicaid programs. Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, we are including all Medicaid issuances and Medicare and Medicaid substantive and interpretive regulations (proposed and final) published during this timeframe.

We also are providing the content of revisions to the Medicare Coverage Issues Manual published between July 1 and September 30, 1992. On August 21, 1989 (54 FR 34555), we published the contents of the Manual and indicated that we will publish quarterly any updates. Adding the Medicare Coverage Issues Manual changes to this listing allows us to fulfill this requirement in a manner that facilitates identification of coverage and other changes in our manuals.

FOR FURTHER INFORMATION CONTACT:

Margaret Cotton, (410) 966–5260 (For Medicare Instruction Information)

Sam DellaVecchia, (410) 966–5395 (For Medicare Coverage Information)

Dusty Kowalewski, (410) 965–3377 (For Medicaid Instruction Information)

Margaret Teeters, (410) 966–4678 (For All Other Information)

SUPPLEMENTARY INFORMATION:

I. Program Issuances

The Health Care Financing Administration (HCFA) is responsible for administering the Medicare and Medicaid programs, which pay for health care and related services for 35 million Medicare beneficiaries and 31 million Medicaid recipients. Administration of these programs involves (1) providing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public; and (2) effective communications with regional offices, State governments, State Medicaid Agencies, State Survey Agencies, various providers of health care, fiscal intermediaries, and carriers who process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under authority granted the secretary under sections 1102, 1871, and 1902 and related provisions of the Social Security Act (the Act) and also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish in the **Federal Register** at least every 3 months a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during this timeframe. Since the publication of our quarterly listing on June 12, 1992 (57 FR 24797), we decided to add Medicaid issuances to our quarterly listings. Accordingly, we are listing in this notice, Medicaid issuances and Medicaid substantive and interpretive regulations published from July 1 through September 30, 1992.

II. Medicare Coverage Issues

We receive numerous inquiries from the general public about whether specific items or services are covered under Medicare. Providers, carriers, and intermediaries have copies of the Medicare Coverage Issues Manual, which identifies those medical items, services, technologies, or treatment procedures that can be paid for under Medicare. On August 21, 1989, we published a notice in the **Federal Register** (54 FR 34555) that contained all the Medicare coverage decisions issued in that manual.

In that notice, we indicated that revisions to the Coverage Issues Manual will be published at least quarterly in the **Federal Register.** We also sometimes issue proposed or final national coverage decision changes in separate **Federal Register** notices. Table IV of this notice contains the text of the revisions to the Coverage Issues Manual published between July 1 and September 30, 1992. Readers should find this an easy way to identify both issuance changes to all our manuals and the text of changes to the Coverage Issues Manual.

Revisions to the Coverage Issues Manual are not published on a regular basis but on an as needed basis. We publish revisions as a result of technological changes, medical practice changes, responses to inquiries we receive seeking clarifications, or the resolution of coverage issues under Medicare. If no Coverage Issues Manual revisions were published during a particular quarter, our listing will reflect that fact.

Not all revisions to the Coverage Issues Manual contain major changes. As with any instruction, sometimes minor clarifications or revisions are made within the text. We have reprinted manual revisions as transmitted to

manual holders. The new text is shown in italics. We will not reprint the table of contents, since the table of contents serves primarily as a finding aid for the user of the manual and does not identify items as covered or not.

We issued updates that included the text of changes to the Coverage Issues Manual in the following issues of the **Federal Register:**

- March 20, 1990 (55 FR 10290).
- February 6, 1991 (56 FR 4830).
- July 5, 1991 (56 FR 30752).
- November 22, 1991 (56 FR 58913).
- January 22, 1992 (57 FR 2558).
- March 16, 1992 (57 FR 9127).
- June 12, 1992 (57 FR 24797).
- October 16, 1992 (57 FR 47468).

The issuance updates found in Table IV of this notice, when added to material from the manual published on August 21, 1989, and the updates listed above constitute a complete manual as of September 30, 1992. Parties interested in obtaining a copy of the manual and revisions should follow the instructions in section IV of this notice.

III. How To Use the Listing

This notice is organized so that a reader may review the subjects of all manual issuances, memoranda, substantive and interpretive regulations, or coverage decisions published during this timeframe to determine whether any are of particular interest. We expect it to be used in concert with previously published notices. Most notably, those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577); those desiring information on the Medicare Coverage Issues Manual may wish to review the August 21, 1989 publication; and those seeking information on the location of regional depository libraries may wish to review Table IV of our first notice. We have divided this current listing into four tables.

Table I describes where interested individuals can get a description of all previously published HCFA Medicare and Medicaid manuals and memoranda.

Table II of this notice lists, for each of our manuals or Program Memoranda, a transmittal number unique to that instruction and its subject matter. A transmittal may consist of a single instruction or many. Often it is necessary to use information in a transmittal in conjunction with information currently in the manuals.

Table III lists all substantive and interpretive Medicare and Medicaid regulations and general notices published in the **Federal Register** during the quarter covered by this notice. For each item, we list the date published, the **Federal Register** citation, the title of the regulation, and the Parts of the Code of Federal Regulations (CFR) which have changed.

Table IV sets forth the revisions to the Medicare Coverage Issues Manual that were published during the quarter covered by this notice. For the revisions, we give a brief synopsis of the revisions as they appear on the transmittal sheet, the manual section number, and the title of the section. We present a complete copy of the revised material, no matter how minor the revision, and identify the revisions by printing in italics the text that was changed. If the transmittal includes material unrelated to the revised section, for example, when the addition of revised material causes other sections to be repaginated, we do not reprint the unrelated material.

IV. How To Obtain Listed Material

A. Manuals

An individual or organization interested in routinely receiving any manual and revisions to it may purchase a subscription to that manual. Those wishing to subscribe should contact either the Government Printing Office (GPO) or the National Technical Information Service (NTIS) at the following addresses:

Superintendent of Documents, Government Printing Office, ATTN: New Order, P.O. Box 371954, Pittsburgh, PA 15250–7954, Telephone (202) 783–3238, Fax number (202) 512–2250 (for credit card orders); or

National Technical Information Service, Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, Telephone (703) 487–4630.

In addition, individual manual transmittals and Program Memoranda listed in this notice can be purchased from NTIS. Interested parties should identify the transmittal(s) they want. GPO or NTIS can give complete details on how to obtain the publications they sell.

B. Regulations and Notices

Regulations and notices are published in the daily **Federal Register**. Interested individuals may purchase individual copies or subscribe to the **Federal Register** by contacting the GPO at the same address indicated above for manual issuances. When ordering individual copies, it is necessary to cite either the date of publication or the volume number and page number.

C. Rulings

Rulings are published on an infrequent basis by HCFA. Interested individuals can obtain copies from the nearest HCFA Regional Office or review them at the nearest regional depository library. We also sometimes publish Rulings in the **Federal Register**.

V. How to Review Listed Material

Transmittals or Program Memoranda can be reviewed at a local Federal Depository Library (FDL). Under the Federal Depository Library Program, government publications are sent to approximately 1400 designated libraries throughout the United States. Interested parties may examine the documents at any one of the FDLs. Some may have arrangements to transfer material to a local library not designated as an FDL. To locate the nearest FDL, individuals should contact any library.

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of nearly every Federal Government publication, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library.

Superintendent of Documents numbers for each HCFA publication are shown in Table II, along with the HCFA publication and transmittal numbers. To help FDLs locate the instruction, use the Superintendent of Documents number, plus the HCFA transmittal number. For example, to find the Hospital Manual (HCFA—Pub. 10) transmittal entitled "Advance Directive Requirements," use the Superintendent of Documents No. HE 8/2 and the HCFA transmittal number 641.

VI. General Information

It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. Individuals are expected to purchase copies or arrange to review them as noted above.

Questions concerning Medicare items in Tables I or II may be addressed to Margaret Cotton, Office of Issuances, Health Care Financing Administration, room 688, East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–5260.

Questions concerning Medicaid items in Tables I or II may be addressed to Dusty Kowalewski, Medicaid Bureau, Office of Medicaid Policy, Health Care Financing Administration, Room 233

East High Rise, 6325 Security Blvd., Baltimore, MD 21207. Telephone (410) 965–3377.

Questions concerning Medicaid items in Table IV may be addressed to Sam DellaVecchia, Office of Coverage and Eligibility Policy, Health Care Financing Administration, Room 445 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–5395.

Questions concerning all other information may be addressed to Margaret Teeters, Regulations Staff, Health Care Financing Administration, Room 132 East High Rise, 6325 Security Blvd., Baltimore, MD 21207, Telephone (410) 966–4678.

Table I—Description of Manuals, Memoranda, and HCFA Rulings

An extensive descriptive listing of Medicare manuals and memoranda was previously published on June 9, 1988 at 53 FR 21730 and supplemented on September 22, 1988 at 53 FR 36891 and December 16, 1988 at 53 FR 50577. Also, a complete description of the Medicare Coverage Issues Manual was published on August 24, 1989 at 54 FR 34555. A brief description of the various Medicaid manuals and memoranda that we maintain was published on October 16, 1992 at 57 FR 47468.

TABLE II.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS

[July through September 1992]

Trans. No.	Manual/Subject/Publication No.
Intermediary Manual Part 1—Fiscal Administration (HCFA—Pub. 13–1) (Superintendent of Documents No. HE 22.8/6–3)	
123	• General information about termination costs—vouchering procedures.
Intermediary Manual Part 3—Claims Process (HCFA—Pub. 13–3 (Superintendent of Documents No. HE 22.8/6)	
1575	• Swing-bed services.
1576	• Application of fee schedule and determining payments and patient liability.
1577	• Federal government's right to sue and collect double damages. Excise tax penalties for contributors to nonconforming group health plans.
1578	• Review of form HCFA–1450 for inpatient and outpatient bills. Addendum C—coding structures.
1579	• Claims processing timeliness. Review of the form HCFA–1450 for inpatient and outpatient bills. Addendum C—coding structures.
Intermediary Manual Part 4—Audit Procedures (HCFA—Pub. 13–4) (Superintendent of Documents No. HE 22.8/6–4)	
29	• Standards for audits under medicare. Field work standards. Internal control questionnaire.
Carriers Manual Part 1—Fiscal Administration (HCFA—Pub. 14–1) (Superintendent of Documents No. HE 22.8/7–2)	
117	• General information about termination costs.
Carriers Manual Part 2—Program Administration (HCFA—Pub. 14–2) (Superintendent of Documents No. HE 22.8/7–3)	
120	• Beneficiary services.
121	• Claims processing timeliness.
Carriers Manual Part 3—Claims Process (HCFA—Pub. 14–3) (Superintendent of Documents No. HE 22.8/7)	
1428	• Medicare carriers manual index, part 3.
1429	• Evidence of medical necessity for home oxygen therapy. Completion of form HCFA–484. Completion oxygen prescribed. Testing under conditions other than at room air Explanation of need for ambulatory or portable equipment. Evidence of medical necessity—oxygen claims. Initial certifications. Revised certification. Scheduling and documenting recertification of medical necessity for oxygen. First recertification required at 3 months. First recertification for long-term therapy. Options in requesting recertifications. Attending physician of record no longer involved with the patient.
1430	• National standard EMC format maintenance procedures. National standard EMC change request procedures.
1431	• Physician and supplier overpayment reporting system, data entry. PSOR user instructions.
1432	• Establishing extended repayments. Documentation required to support a request for extended repayments. Referral of requests for extended repayment schedule to RO. Execution of promissory note. Monitoring an approved extended repayment schedule. Protocol for reviewing extended repayment schedule. Statement of source and application of funds period covered. Cash flow statement period covered.

TABLE II.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July through September 1992]

Trans. No.	Manual/Subject/Publication No.
1433	Projected cash flow statement cash from operations (schedule A) period covered. Promissory note containing agreement for judgment. • Completing page eleven of the carrier performance report. Checking reports prior to submittal to HCFA.
1434	Carrier workload report. • Part D—claims processing timeliness. Part E—interest payment date. Claims reduced and denied. Part D—selected claim data by participation status. Checking HCFA–1565C prior to submittal to HCFA.
1435	• Payment for extracorporeal shock wave lithotripsy.
1436	• Federal government's right to sue and collect double damages. Excise tax penalties for contributors to nonconforming group health plans.
1437	• 1992 CPT–4 additional procedure codes.
1438	• Coding type of supplier. Inter-fields verification of BMAD files.
1439	• Rebundling of CPT–4 codes.
	Program Memorandum Intermediaries (HCFA—Pub 60 A) (Superintendent of Documents No. HE 22.8/6–5)
A–92–3	• Prohibition against admission deposits.
A–92–4	• Financial arrangements between hospitals and hospital-based physicians.
A–92–5	• Health care financing administration's audit and cost report settlement expectations.
A–92–6	• Adjusting interim payments for capital-related costs for hospitals paid under the medicare prospective payment system.
	Program Memorandum Intermediaries/Carriers (HCFA—Pub. 60A/B) (Superintendent of Documents No. HE 22.8/6–5)
AB–92–1	• HMO directory.
AB–92–2	• 1992 HCPCS update and corresponding payment instructions.
AB–92–3	• Temporary codes for new drugs.
AB–92–4	• Current status of medicare program memorandums and letters issued before calendar year 1992.
	State Operations Manual (HCFA)—Pub. 7) (Superintendent of Documents No. HE 22.8/12)
253	• Federal minimum qualification standards for long-term care facility surveyors. Test administration. Test-related activities. State test administration plan.
254	• Screening mammography, citations, and description. Interim certification process. Site of screening mammography services. Survey process. Screening mammography services data report. Interpretive guidelines, screening mammography suppliers. Screening mammography services data report.
	Regional Office Manual Medicare (HCFA—Pub. 23–2) (Superintendent of Documents No. HE 22.8/8)
322	• Instructions for completing the regional office all trunks busy report.
323	• Annual contractor evaluation report. Target dates in preparing ACERs/service area reports. ACERs for multi-regional contractors. Evaluation of contractors under other-than-standard cost reimbursement contracts. Evaluation of contractors under budget-flexibility contracts. Scoring methodology. Corrective action. ACER format. Contractor profile. Performance criteria. Regional home health intermediary performance evaluation program.
324	• General information about termination costs—vouchering procedures.
	Regional Office Manual Standards and Certification (HCFA)—Pub. 23–4) (Superintendent of Documents No. HE 22.8/8–3)
IM–92–1	• Medicare approval of federally qualified health centers. Interim approval process.
52	Federal minimum qualification standards for long-term care facility surveyors. Test administration. Test-related activities State test administration plan. Model letter announcing to state survey agency the requirements for administering the long term care surveyor minimum qualifications test.
	Health Maintenance Organization/Competitive Medical Plan Manual (HCFA—Pub. 75) (Superintendent of Documents No. HE 22.8/21:989)
11	• General Requirements

TABLE II.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[July through September 1992]

Trans. No.	Manual/Subject/Publication No.
	Plan operating experience requirements. Composition of enrollment. Open enrollment. Additional open enrollment periods. Enrollment application procedures. Processing applications. Effective date of enrollment and disenrollment. General requirements. How to process applicants with ESRD. Hospice patients. Reenrollments. Conversion enrollments. Failure to pay premium. Permanent move out of geographic area. Retention of enrollees who temporarily leave geographic area. Beneficiary chooses to disenroll. Disenrollment for cause.
12	• Basic contract requirements for HMOs/CMPs. Basic requirements under HCPP agreement. Types of contract and agreement cessations. Supplemental policy coverage (HMOs and CMPs only). Systems issues. Model beneficiary notice. Model public notice.
	Hospital Manual (HCFA—Pub. 10) (Superintendent of Documents No. HE 22.8/2)
638	• Note: See Transmittal No. 640.
639	• Swing-bed services.
640	• Fraud and abuse—general. Definition and examples of fraud. Definition and examples of abuse. Responsibility for combatting fraud, waste, and abuse. Federal government administration of the health insurance program.
641	• Advance directive requirements.
642	• Completion of form HCFA–1450 FOR inpatient and/or outpatient billing.
643	• Claims processing timeliness requirement.
	Peer Review Organization Manual (HCFA—Pub. 19) (Superintendent of Documents No. HE 22.8/15)
1	Authority. Purpose of PRO review. PRO responsibilities. Health care financing administration's role. Background. MOAs with FIs and carriers. Background. Objective development. Problem identification. Required elements. Monitoring PRO performance. Contract modification. Record and documentation of review activities. Retention of review documentation. Review documentation. Retention of medical records. Electronic data retention requirements. Contractor records retention. Disposal of records. Background. Provisions of the notice. Uses of evaluation criteria. Background. Purpose. Timing. Methods of evaluation. Report of findings.
	Home Health Agency Manual (HCFA—Pub. 11) (Superintendent of Documents No. HE 22.8/5)
253	• Fraud and Abuse—General Definition and examples of fraud. Definition and examples of abuse. Responsibility for combatting fraud, waste, and abuse. Federal government administration of the health insurance program.
254	• Advance directive requirements.
255	• Completion of form HCFA–1450 for home health agency billing. Addendum C—coding structures.

TABLE II.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued
[July through September 1992]

Trans. No.	Manual/Subject/Publication No.
256	• Completion of form HCFA–1450 for home health agency billing.
	Skilled Nursing Facility Manual (HCFA—Pub. 12) (Superintendent of Documents No. HE 22.8/3)
311	• Fraud and abuse—general.
	Definition and examples of fraud.
	Definition and examples of abuse.
	Responsibility for combatting fraud, waste, and abuse.
	Role of health care financing administration.
	Role of the public health service.
312	• Advance directive requirements.
313	• Completion of form HCFA–1450 for inpatient and/or outpatient billing.
	Addendum C—coding structures.
314	• Completion of form 1450 for inpatient and/or outpatient billing.
315	• Prohibition against "Rules of Thumb" in medical review determinations.
	Rural Health Clinic Manual (HCFA—Pub. 27) (Superintendent of Documents No. HE 22.8/19:985)
46	• Completion of form HCFA–1450 by independent rural health clinics.
47	• Completion of form HCFA–1450 by independent rural health clinics.
	Renal Dialysis Facility Manual (HCFA—Pub. 29) (Superintendent of Documents No. HE 22.8/13)
54	• Fraud and abuse—general.
	Definition and examples of fraud.
	Definition and examples of abuse.
	Responsibility for combatting fraud, waste, and abuse.
55	• Completion of form HCFA—1450 by independent facilities for home dialysis items and services billed under the composite rate (method I).
56	• Completion of form HCFA—1450 by independent facilities for home dialysis items and services billed under the composite rate (method I).
	Hospice Manual (HCFA—Pub. 21) (Superintendent of Documents No. HE 22.8/18)
29	• Note: see transmittal No. 30.
30	• Fraud and abuse—general.
	Definition and examples of fraud.
	Definition and examples of abuse.
	Responsibility for combatting fraud, waste, and abuse.
	Federal government administration of the health insurance program.
31	• Advanced directive requirements.
	Outpatient Physical Therapy and Comprehensive Outpatient Rehabilitation Facility Manual (HCFA—Pub. 9) (Superintendent of Documents No. HE 22.8/9)
106	• Completion of form HCFA—1450 for billing comprehensive outpatient rehabilitation facility, outpatient physical therapy, occupational therapy or speech pathology services.
	Addendum C—coding structures.
107	• Completion of form HCFA—1450 for billing CORF, outpatient physical therapy, occupational therapy or speech pathology services.
	Coverage Issues Manual (HCFA—Pub. 6) (Superintendent of Documents No. HE 22.8/14)
59	• Apheresis (Therapeutic pheresis).
60	• Adult liver transplantation.
61	• General anesthesia in cataract surgery endothelial cell photography.
	Provider Reimbursement Manual Part 1 (HCFA—Pub. 15–1) (Superintendent of Documents No. HE 22.8/4)
367	• Nonowners compensation.
	Transportation costs.
368	• Costs of approved nursing and paramedical education programs.
	Provider Reimbursement Manual Part 1—Chapter 27 Reimbursement for ESRD and Transplant Services (HCFA—Pub. 15–1–27) (Superintendent of Documents No. HE 22.8/4)
20	• Exception to present method selection of payment method on the form HCFA—382 (ESRD beneficiary selection form).
	Provider Reimbursement Manual Part II—Provider Cost Reporting Forms and Instructions (HCFA—Pub. 15–IIN) (Superintendent of Documents No. HE 22.8/4)
3	• Obsoletes chapter 14, freestanding hospice cost report.

TABLE II.—MEDICARE AND MEDICAID MANUAL INSTRUCTIONS—Continued

[July through September 1992]

Trans. No.	Manual/Subject/Publication No.
State Medicaid Manual Part 3—Eligibility (HCFA—Pub. 45–3) (Superintendent of Documents No. HE 22.8/10)	
59	• Requirements of state CSE agency and cooperative agreements. Funding.
State Medicaid Manual Part 5—Early and Periodic Screening, Diagnosis, and Treatment (HCFA—Pub. 45–5) (Superintendent of Documents No. HE 22.8/10)	
5	• Screening service content.
State Medicaid Manual Part 7—Quality Control (HCFA—Pub. 45–7) (Superintendent of Documents No. HE 22.8/10)	
46	• Definitions of key terms. Cases which are not reviewed. Review of SSI cash cases in SSI-criteria and 209(b) states. Field investigation. Hold harmless provision of the immigration reform and control act. Systematic alien verification of entitlement documentation. Verification standards. Basic program requirements (100). Resources (200)—Element 212. Verification guide. Hierarchy of MEQC errors. Cases to be reviewed. Case record review. Resources (200)—element 211. Income (300)—elements 312, 321, 322, 323, 331, and 350. Medicaid eligibility quality control review. In-person interview. Basic program requirements (100)—element 185. Income (300)—element 311. Computation of financial eligibility (500)—elements 530 and 550. Instructions for integrated review schedule—form HCFA 301. Administrative period. Classification of errors. Technical errors. Eligible with ineligible services. Computation of liability errors. Determining final misspent dollar amounts of cases containing initial liability understated errors. Federal monitoring.
Program Memorandum Medicaid State Agencies (HCFA—Pub. 17)	
92–5	• Current status of medicaid program memorandums and action transmittals issued before calender year 1992.
92–6	• Preadmission screening and annual resident review requirement.
Regional Office Manual Medicaid (HCFA—Pub. 23–6) (Superintendent of Documents No. 22.8/8–4)	
34	• Title XIX compliance policies.
Medicare/Medicaid Sanction—Reinstatement Report (HCFA—Pub. 69)	
92–8	• Report of physicians/practitioners, providers and/or other health care suppliers excluded/reinstated (July 1992).
92–9	• Report of physicians/practitioners, providers and/or other health care suppliers excluded/reinstated (August 1992).

TABLE III.—REGULATIONS AND NOTICES PUBLISHED JULY THROUGH SEPTEMBER 1992

Publication date/citation	42 CFR Part	Title
FINAL RULES		
07/31/92 (57 FR 33878)	405, 410, 412, 413, 482	Medicare Program; Fee Schedules for the Services of Certified Registered Nurse Anesthetists (Correction Published 09/01/92 (57 FR 39743)).
07/31/92 (57 FR 33992)	493, 498	Clinical Laboratories Improvement Act Program; Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of CLIA exemption Under State Laboratory Programs.
08/12/92 (57 FR 36006)	405, 406, 409, 410, 411, 412, 413, 418, 489	Medicare Program; Self-Implementing Coverage and Payments Provisions: 1990 Legislation (Correction Published 09/30/92 (57 FR 45112)).
08/26/92 (57 FR 38616)	403	Medicare Program; Beneficiary Counseling and Assistance Grants Program.

TABLE III.—REGULATIONS AND NOTICES PUBLISHED JULY THROUGH SEPTEMBER 1992—Continued

Publication date/citation	42 CFR Part	Title
08/27/92 (57 FR 38778)	433	Medicaid Program; Medicaid Management Information System (MMIS) Performance Review; Notification Procedures for Changes in Requirements, Performance Standards, and Reapproval Conditions (Correction Published 09/30/92 (57 FR 45112)).
09/01/92 (57 FR 39746)	412, 413	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1993 Rates; Final Rule.
09/23/92 (57 FR 43922)	431, 442, 447, 483, 488, 489, 498	Medicare and Medicaid Programs; Requirements for Long Term Care Facilities.
09/23/92 (57 FR 43906)	413, 447	Medicare and Medicaid Programs; Revaluation of Assets.
PROPOSED RULES		
07/09/92 (57 FR 30301)	412, 413	Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal year 1993 Rates.
08/17/92 (57 FR 36968)	435, 436	Medicare Program; Qualified Family Members.
08/28/92 (57 FR 39278)	431, 442, 488, 489	Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities.
09/22/92 (57 FR 43659)	413	Medicare Program; Payment for Nursing and Allied Health Education.
Publication date/citation	Title	
NOTICES		
07/01/92 (57 FR 29410)	Medicare Program; Schedule of Limits on Home Health Agency Costs Per Visit for Cost Reporting Periods Beginning On or After July 1, 1992 (Correction Notices Published 09/27/92 (57 FR 38959) and 09/17/92 (57 FR 43004)).	
07/17/92 (57 FR 31664)	Medicare Program; Clinical Laboratory Improvement Act Program Fee Collection; Correction.	
07/27/92 (57 FR 33202)	Health Maintenance Organizations; HMO Qualification Determinations and Compliance Actions (Correction Notice Published 09/11/92 (57 FR 41810)).	
08/11/92 (57 FR 35760)	Medicare Program; Carrier Jurisdiction for Claims for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and Standards for Evaluating Regional DMEPOS Carriers; Correction.	
08/11/92 (57 FR 35760)	Medicare Program; Medicare and Laboratory Certification Program; Enforcement Procedures for Laboratories; Correction.	
08/11/92 (57 FR 35836)	Medicare Program; Update of Ambulatory Surgical Center Payment Rates and Additions to and Deletions From the Current List of Covered surgical Procedures; Correction.	
08/11/92 (57 FR 35837)	Medicare Program; Peer Review Organizations: Revised Scopes of Work for the District of Columbia, Puerto Rico, the Virgin Islands, and All States Except Delaware, Florida, Missouri, Montana, Nebraska, Nevada, Oklahoma, Rhode Island, South Carolina, Washington and Wyoming; Correction.	
08/21/92 (57 FR 37980)	Medicare Program; HHS' Recognition of NAIC Model Standards for Regulation of Medigap Policies.	
09/15/92 (57 FR 4291)	Medicare Program; Fee Schedule for Physicians' Services; Correction Notice.	
09/18/92 (57 FR 43230)	Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During FY 1993.	

Table IV—Medicare Coverage Issues Manual

(For the reader's convenience, new material and changes to previously published material are in italics. If any part of a sentence in the manual instruction has changed, the entire line is shown in italics. The transmittal includes material unrelated to revised sections. We are not reprinting the unrelated material.) Transmittal No. 59; section 35–60, Apheresis (Therapeutic Pheresis)

CHANGED IMPLEMENTING INSTRUCTIONS—EFFECTIVE DATE: For services performed on or after 07/30/92.

Section 35–60, Apheresis (Therapeutic Pheresis), is updated and revised to provide that apheresis may now be covered when performed either in a hospital setting (inpatient or outpatient) or in a nonhospital setting if the patient is under the care of a physician and a physician is also present to direct and supervise the nonphysician services. Also, while indications for the procedure remain unchanged, obsolete references to specific dates of coverage were removed.

35–60 Apheresis (Therapeutic Pheresis)

A. General.—Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken.

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

B. Indications.—Apheresis is covered for the following indications:

- *Plasma exchange for acquired myasthenia gravis;*
- *Leukapheresis in the treatment of leukemia;*
- *Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);*
- *Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;*

- *Plasmapheresis or plasma exchange as a last resort treatment of thromobotic thrombocytopenic purpura (TTP);*
- *Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;*
- *Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease;*
- *Plasma exchange in the treatment of Goodpasture's Syndrome;*
- *Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;*
- *Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;*
- *Treatment of life threatening schleroderma and polymyositis when the patient is unresponsive to conventional therapy;*
- *Treatment of Guillain-Barre Syndrome; and*
- *Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.*

C. Settings.—Apheresis is covered only when performed in the following settings:

- *In a hospital setting (either inpatient or outpatient). Nonphysician services furnished to hospital patients are covered and paid for as hospital services. When covered services are provided to hospital patients by an outside provider/supplier, the hospital is responsible for paying the provider/supplier for the services.*
- *In a nonhospital setting, e.g., a physician directed clinic (see HCFA Pub. 14–3, § 2050.4) when the following conditions are met:*

—A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
—Each patient is under the care of a physician; and
—All nonphysician services are furnished under the direct, personal supervision of a physician.

Transmittal No. 60; section 35–53, Adult Liver Transplantation.

CLARIFICATION—EFFECTIVE DATE: Not Applicable.

Section 35–53, Adult Liver Transplantation.—This section is revised to add International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9–CM) codes not included with previous revision.

35–53 Adult Liver Transplantation

A. General.—Adult liver transplantation is covered under Medicare when performed in a facility which is approved by HCFA as meeting institutional coverage criteria, and for patients with one of the following conditions:

- *Primary biliary cirrhosis (ICD–9–CM 571.6);*
- *Primary sclerosing cholangitis (ICD–9–CM 576.1);*
- *Postnecrotic cirrhosis, hepatitis B surface antigen negative (ICD–9–CM 571.5);*
- *Alcoholic cirrhosis (ICD–9–CM 571.2);*
- *Alpha-1 antitrypsin deficiency disease (ICD–9–CM 277.6);*
- *Wilson's disease (ICD–9–CM 275.1);*

or

- *Primary hemochromatosis (ICD–9–CM 275.0).* Coverage of adult liver transplantation is effective as of the date of the facility's approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See **Federal Register** 56 FR 15006 dated April 12, 1991.)

B. Follow-up Care.—Follow-up care or retransplantation (ICD–9–CM 996.82, Complications of Transplanted Organ, Liver) required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving a noncovered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines. (See Intermediary Manual § 3101.14 and Carriers Manual § 2300.1.)

C. Immunosuppressive Drugs.—See Intermediary Manual § 3660.8 and Carriers Manual §§ 2050.5, 4471 and 5249.

Transmittal No. 61; section 35–44, General Anesthesia in Cataract Surgery, and section 50–38, Endothelial Cell Photography.

CHANGED IMPLEMENTING INSTRUCTONS—EFFECTIVE DATE: Services performed on or after 08/31/92

Section 35–44, General Anesthesia in Cataract Surgery.—This section has been renamed to indicate more clearly its subject matter. The new title is "Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery." Section 50–38, Endothelial Cell Photography.—This section has been revised to include a paragraph that stipulates that endothelial cell photography is subject to the limitation on coverage of visual tests prior to cataract surgery as described in § 35–44.

35–44 Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery

50–38 Endothelial Cell Photography (Effective for Services Rendered on and After August 19, 1983)

Endothelial cell photography involves the use of a specular microscope to determine the endothelial cell count. It is used by ophthalmologists as a predictor of success of ocular surgery or certain other ocular procedures. Endothelial cell photography is a covered procedure under Medicare when reasonable and necessary for patients who meet one or more of the following criteria:

- Have slit lamp evidence of endothelial dystrophy (cornea guttata),
- Have slit lamp evidence of corneal edema (unilateral or bilateral),
- Are about to undergo a secondary intraocular lens implantation,
- Have had previous intraocular surgery and require cataract surgery,
- Are about to undergo a surgical procedure associated with a higher risk to corneal endothelium; i.e., phacoemulsification, or refractive surgery (see § 35–54 for excluded refractive procedures),
- With evidence of posterior polymorphous dystrophy of the cornea or irido-corneal-endothelium syndrome, or
- Are about to be fitted with extended wear contact lenses after intraocular surgery.

When a pre-surgical examination for cataract surgery is performed and the conditions of this section are met, if the only visual problem is cataracts, endothelial cell photography is covered as part of the presurgical comprehensive eye examination or combination brief/intermediate examination provided prior to cataract surgery, and not in addition to it. (See § 35–44.)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.714, Medical Assistance Program)

Dated: December 29, 1992.

William Toby, Jr.,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 93–276 Filed 1–6–93; 8:45 am]

BILLING CODE 4120–01–M

National Institutes of Health

National Cancer Institute; Meetings of the Board of Scientific Counselors, Division of Cancer Prevention and Control and its Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, Division of Cancer Prevention and Control (DCPC), National Cancer Institute, and its Subcommittees on January 7–8, 1993. The full Board will meet in Conference Room 10, 6th Floor, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. Meetings of the Subcommittees of the Board will be held at the times and places listed below. Except as noted below, the meetings of the Board and its Subcommittees will be open to the public to discuss issues relating to committee business as indicated in the notice. Attendance by the public will be limited to space available.

A portion of the Board meeting will be closed to the public in accordance with the provisions set forth in section 552B(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, for the critique and evaluation of individual DCPC intramural and extramural programs and projects, including the consideration of personnel qualifications and performance, the competence of individual investigators and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Committee Management Office, National Cancer Institute, National Institutes of Health, room 10A06, Building 31, 9000 Rockville Pike, Bethesda, Maryland 20892 (301/496–5708), will provide a summary of the meeting and a roster of committee members, upon request.

Other information pertaining to this meeting can be obtained from the Executive Secretary, Linda M. Bremerman, National Cancer Institute, Executive Plaza-North, room 318, National Institutes of Health, Bethesda, Maryland 20892 (301–496–8526), upon request.

Name of Committee: Board of Scientific Counselors, Division of Cancer Prevention and Control.
Executive Secretary: Mrs. Linda M. Bremerman, Building—EP–N, room 318 Bethesda, MD 20892; (301) 496–8526.
Dates of Meeting: January 7–8, 1993.
Place of Meeting: Building 31, Conference Room 10.
Open: January 7—8:30 a.m. to 8:45 a.m.; 10:30 a.m. to 3 p.m.
Agenda: Review progress of programs within the Division and review of concepts being considered for funding.
Closed: January 7—3 p.m. to recess.
Agenda: For review and discussion of individual grant applications.
Open: January 8—8:30 a.m. to approximately 5 p.m.
Agenda: Review progress of programs within the Division and review of concepts being considered for funding.
Name of Committee: Subcommittee on Surveillance.
Executive Secretary: Mrs. Linda M. Bremerman, Building—EP–N, room 318 Bethesda, MD 20892; (301) 496–8526.
Date of Meeting: January 7, 1993.
Place of Meeting: Building 31C, Conference Room 10.
Open: 8:45 a.m. to 10:30 a.m.
Agenda: Discuss current and future programs of the Surveillance Subcommittee and review of concepts being considered for funding.
Name of Committee: Subcommittee on Early Detection and Community Oncology.
Executive Secretary: Mrs. Linda M. Bremerman, Building—EP–N, room 318 Bethesda, MD 20892; (301) 496–8526.
Date of Meeting: January 7, 1993.
Place of Meeting: Building 31C, Conference Room 8.
Open: 8:45 a.m. to 10:30 a.m.
Agenda: Discuss current and future programs of the Early Detection and Community Oncology Subcommittee and review of concepts being considered for funding.
Name of Committee: Subcommittee on Cancer Control Science.
Executive Secretary: Mrs. Linda M. Bremerman, Building—EP–N, room 318 Bethesda, MD 20892; (301) 496–8526.
Date of Meeting: January 7, 1993.
Place of Meeting: Building 31C, Conference Room 9.
Open: 8:45 a.m. to 10:30 a.m.
Agenda: Discuss current and future programs of the Cancer Control Science Subcommittee and review of concepts being considered for funding.
Name of Committee: Subcommittee on Cancer Prevention Research.
Executive Secretary: Mrs. Linda M. Bremerman, Building—EP–N, room 318 Bethesda, MD 20892; (301) 496–8526.
Date of Meeting: January 7, 1993.
Place of Meeting: Building 31C, Conference Room 7.
Open: 8:45 a.m. to 10:30 a.m.
Agenda: Discuss current and future programs of the Cancer Prevention Research Subcommittee and review of concepts being considered for funding.

CATALOG OF FEDERAL DOMESTIC ASSISTANCE PROGRAM NUMBERS: (93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control.)

Dated: December 24, 1992.

Susan K. Feldman,
Committee Management Officer, NIH.

[FR Doc. 93–427 Filed 1–6–93; 8:45 am]
BILLING CODE 4140–01–M

Public Health Service

Office of the Assistant Secretary for Health; Office of Disease Prevention and Health Promotion; Cooperative Agreements to Coordinate Healthy People 2000 Implementation

The Office of Disease Prevention and Health Promotion (ODPHP) announces the availability of funds for Fiscal Year 1993 for cooperative agreements to coordinate implementation of Healthy People 2000: National Health Promotion and Disease Prevention Objectives and related prevention policy initiatives.

ODPHP was established by Pubic Law 94–317, the National Consumer Health Information and Health Promotion Act of 1976, and functions under the provisions of title XVII of the Public Health Services Act, as amended. Located within the Office of the Assistant Secretary for Health, the mission of ODPHP is to provide leadership for prevention policy and program undertaken by the Public Health Service, to coordinate prevention policy and program among Public Health Service agencies, and to undertaken prevention initiatives on behalf of the Assistant Secretary for Health. ODPHP undertakes this mandate through the formulation and management of national health goals and objectives, contained in Healthy People 2000 and through the stimulation of public and private programs and strategies to enhance the health of the Nation through preventive approaches. ODPHP is organized around four areas: Prevention policy, clinical preventive services, nutrition policy, and health communication.

The Public Health Service is committed to achieving the health promotion and disease prevention goals

and objectives of Healthy People 2000, a national activity to reduce morbidity and mortality and improve the quality of life. This program announcement is related specifically to priority areas of Healthy People 2000 on clinical preventive services and nutrition. [Copies of Healthy People 2000 may be ordered from the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (telephone 202–783–3238), stock number 017–001–00474–0].

FY 1993 Priorities

ODPHP uses cooperative agreements with national membership organizations in order to support its mandate to provide leadership to promote health and prevent disease among Americans through management and coordination of the implementation of Healthy People 2000. Through these cooperative agreements, ODPHP has forged public-private partnerships to extend the reach and effectiveness of its work. In Fiscal Year 1993, ODPHP intends to establish, or renew existing, cooperative agreements specifically in the areas of clinical preventive services and nutrition policy. Support for prevention policy and health communication is provided principally through collaborations among Public Health Service lead agencies for the priority areas of Healthy People 2000 (for prevention policy) and contracted services (for health communication).

For clinical preventive services, ODPHP intends to provide financial assistance, up to a total of $400,000 per year, for one or two cooperative agreements. National professional membership organizations wishing to enter into a cooperative agreement with ODPHP to collaborate in carrying out its clinical preventive services efforts must demonstrate their ability to address the following activities:

- Implementation of the Public Health Service's national professional and public education program, entitled "Put Prevention into Practice," by primary health care providers. "Put Prevention into Practice" includes a package of materials for use by clinicians, office practices, and patients related to age- and sex-specific
- Work with the U.S. Preventive Services Task Force to revise the Guide to Clinical Preventive Services, first published in 1989 and due to be released in a second edition in 1994.
- Work with a consortium of societies of teachers of primary health care and preventive medicine to continue the process of selecting and managing the Luther L. Terry Fellowship in Clinical Preventive Services, begun in 1985 and involving the Society for General Internal Medicine, the Ambulatory Pediatrics Association, the Society of Teachers of Family Medicine, and the Association of Teachers of Preventive Medicine.
- Support for preventive medicine residents (and residents in other relevant specialties) to experience residency rotations in a health policy setting as a part of their residency programs.

For nutrition policy, ODPHP intends to provide financial assistance, up to $150,000, for one cooperative agreement. A national professional membership organization wishing to enter into a cooperative agreement with ODPHP to collaborate in carrying out its nutrition policy efforts must demonstrate its ability to address the following activity:

- Serve as a communication forum for development of effective nutrition policy by Federal and non-Federal nutrition scientists, addressing issues such as definition of "healthy" weight, assessment of nutritional status of high-risk populations, translation of nutrition science into dietary guidance that is understandable by the lay public, and provision of leadership to the nutrition professional community in defining new nutrition policy issues and using federally generated nutrition-related research and policy.

Eligibility Requirements

Cooperative agreements awarded to address the ODPHP priorities outlined above are limited to national membership organizations, due to limitations on availability of funds and as a function of the kinds of public-private collaboration which the priorities entail. Requests to Congress for funds for the National Health Promotion Program have specified this limitation of applicant eligibility. ODPHP has a history of facilitating Public Health Service work with national membership organizations to implement national health promotion and disease prevention programs and policies. As representatives of special constituencies, membership organizations are in a unique position to be able to identify realistic, appropriate, and effective strategies for reaching their members or the populations that their members represent.

In order to be eligible to participate in these cooperative agreements, an organization must meet all of the following requirements:

- Be a national, private, nonprofit organization;
- Have a national membership, state/local chapters, and/or otherwise well-defined affiliate structure;
- Demonstrate an understanding of the current and potential role of the membership in health promotion and disease prevention efforts;
- Have in place a variety of communication channels that are appropriate for informing members and other constituents about how to become involved in meeting the objectives of the cooperative agreement; and
- Demonstrate top level support within the organization for the project and, where appropriate, demonstrate similar support from the membership.

For purposes of this announcement, national membership organizations are defined as organizations with individual or institutional members in more than one state and region of the United States. "Members" must voluntarily and expressly associate themselves with the organization as through payment of a membership fee or other declaration of association (i.e. request and receipt of membership card or certificate of membership).

Period of Performance

Contingent on the availability of funds and satisfactory performance, cooperative agreements will be awarded to national membership organizations for a period of four years. Awards will be made for 12-month budget periods. To obtain funding after the initial budget period, continuation applications and approvals will be required for each subsequent 12-month period. Continuation applications will not be subject to competitive review but will be subject to review for satisfactory progress and availability of funds. The award of funds for any budget period is not a legal commitment to award funds in any subsequent budget period.

Terms and Conditions

Federal funds allocated for cooperative agreements are not intended to cover all of the costs that will be incurred in the process of completing the proposed projects. Applicants should demonstrate a commitment of financial or in-kind resources to their support. Organizations participating in the cooperative agreement program may use awarded funds to support salaries of individuals assigned to the project. Award recipients are encouraged to seek additional sources of funds to complement the activities of the proposed project.

ODPHP Involvement

ODPHP will:

• Provide a significant portion of the time of one or two professional staff persons to work with the award recipient on the cooperative agreement and to coordinate its activities with the work of ODPHP.

• Make available the resources of the ODPHP National Health Information Center and other access to Federal information resources, as needed and appropriate.

• Make available technical assistance from other Federal agencies and sources, as needed and appropriate.

• Provide liaison with other Federal agencies, as needed and appropriate.

Application Process

1. All applications must be submitted with a signed copy of PHS Form 5161, with the required information filled in appropriately. The required application form with instructions will be mailed to potential applicants who make telephone requests to Ms. Delores Flenoury at (202) 205–8583 or write to her at ODPHP/PHS, Department of Health and Human Services, Switzer 2132, Washington, DC 20201.

2. All applications must be either received or postmarked on or before 5 p.m. on March 8, 1993. Applications received or postmarked later than 5 p.m. (E.S.T.) on that day will be ineligible. Applications postmarked but not received by March 8, 1993, will be eligible only if they are received in time for orderly process and review.

3. Application packages should be mailed or delivered to: Ms. Delores Flenoury, ODPHP/PHS/DHHS, 2132 Switzer Building, 330 C Street, SW, Washington, DC 20201.

4. Applications must be typed on one side of the page only.

5. The original and two copies of each application, with attachments and documentation, must be submitted.

6. Applications for projects which are national in scope or note required to carry out the provisions of Executive Order 12372.

Application Requirements

Applications must include the following information:

• A description of the organization and its membership and documentation that it meets all the eligibility requirements, with examples of the organization's prior efforts and activities as needed to substantiate its capability to undertake the proposed project.

• A description of how the project will contribute to the Public Health Service's efforts to promote health, prevent disease, and improve the quality of life.

• A detailed delineation of the tasks that will be undertaken in the first budget period and the outcomes expected at the end of that period.

• A detailed budget for the first budget period.

• A brief delineation of the tasks that will be undertaken in each of the remaining budget periods, as appropriate, and how they will contribute toward accomplishing the project's goals and objectives.

• A timetable for each budget period of the project.

• An evaluation plan which will show how the conduct of the project will be assessed on an ongoing basis.

• The background and qualifications of individuals who will manage and staff the project. If the individuals are not now known, provide a list of the qualifications that will be sought.

• If it is anticipated that any individuals or other organizations will be subcontracted in the first budget period, information about the role they will play and their qualifications.

• If organizations are collaborating on a proposal, information about the role each will play, along with complete eligibility information and specification of which will have leadership responsibility for overall project management. One organization should be identified as the lead to receive and manage funds.

Review and Selection Process

Applications will be screened by ODPHP upon receipt to assure that all eligibility requirements have been met. Applications meeting these requirements will be reviewed by a Federal panel of reviewers using the criteria outlined below. The results of the review will be recommended to the Director of ODPHP for FY 1993 cooperative agreement awards. ODPHP intends to make awards between March and July 1993.

Evaluation Criteria

1. Understanding the Project—20

Understanding of the issues and the program priority that the project proposes to address. Clarity, feasibility, and practicality of the objectives of the project and the plan to meet them.

2. Methodology and Approach—30

Soundness, practicality, and feasibility of the technical approach to the work, including how the tasks are to be carried out, anticipated problems and proposed solutions. The potential for the project to make an innovative, significant impact and contribution to health promotion and disease prevention.

Feasibility and appropriateness of the proposed ongoing assessment of project activities.

3. Organizational Capability—25

Commitment of financial or in-kind resources to support the proposed project. Relevant experience of the organization in conducting similar projects. Adequacy of project management to keep project on track and on schedule. Demonstrated capacity for reaching key audiences to project.

4. Project Direction, Management, and Staffing—25

Management plan, advisory and supervisory structure, and qualifications and relevant experience of proposed staff both in the content and execution of proposed project.

Further Information

This Notice contains information collections required from respondents for the subject cooperative agreements.

The information collection is approved under OMB control number 0937–0189.

To request additional copies of this notice or for further clarification, contact: Ms. Delores Flenoury, (202) 205–8583, Switzer 2132, 330 C Street, SW., Washington, DC.

For technical or program assistance, contact James A. Harrell, whose telephone number is (202) 205–8611. For business management questions, contact Ms. Martha Frazier, on (202) 205–8583.

J. Michael McGinnis,

Deputy Assistant Secretary for Health, Director, Office of Disease Prevention and Health Promotion.

[FR Doc. 93–275 Filed 1–6–93; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Fair Housing and Equal Opportunity

[Docket No. N–93–3559; FR–3429–N–01]

Establishment of a Task Force on Occupancy Standards in Public and Assisted Housing

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice of establishment of an Advisory Committee.

SUMMARY: HUD is establishing a Task Force on Occupancy Standards in Federally Assisted Housing as required by section 643 of the Housing and

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Community Development Act of 1992 (Pub. L. 102–550), and in accordance with the provisions of the Federal Advisory Committee Act [5 U.S.C. App 2]. The Task Force will review all existing standards, regulations and guidelines governing lease provisions and occupancy and tenant selection policies in public and assisted housing, and make recommendations for revisions of such standards, regulations and guidelines to provide accurate and complete guidance to owners and managers of public and assisted housing as authorized by section 643.

The Task Force will continue to exist for a period of 12 months from the date its charter becomes effective unless the charter is sooner amended or revoked.

DATE: The charter of the Occupancy Standards Task Force will become effective on the date the Secretary of Housing and Urban Development files it with the Senate Committee on Banking, Housing and Urban Affairs, and the House Committee on Banking, Finance and Urban Affairs which are the standing committees of Congress having legislative jurisdiction over the Department.

FOR FURTHER INFORMATION CONTACT: Barbara Capozzola, Committee Management Officer, Telephone (202) 708–3123, room 5168, or Laurence D. Pearl, Telephone (202) 708–3727, (TDD) (202) 708–0113, room 5226, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: Section 643 of the Housing and Community Development Act of 1992 (Pub. L. 102–550) directs the Secretary of HUD to establish a task force to review all rules, policy statements, handbooks, and technical assistance memoranda issued by the Department on the standards and obligations governing residency in public and assisted housing and make recommendations to the Secretary for the establishment of reasonable criteria for occupancy. The charter of the task force is being published with this notice.

The membership of the Task Force will consist of no more than 35 people. Members will include representatives of owners, managers and tenants of federally assisted housing, public housing agencies, owner and tenant advocacy organizations, persons with disabilities and disabled families, organizations assisting homeless individuals, and social service, mental health and other nonprofit service providers who serve federally assisted housing.

The Task Force will continue to exist for a period of 12 months from the date its charter becomes effective as provided in the Federal Advisory Committee Act, unless the charter is amended or revoked sooner. All meetings of the Task Force will be open to the public.

The time, place, and agenda for the first Task Force meeting and for each subsequent meeting, will be published in the **Federal Register** at least 15 days prior to the meeting. At the time the first meeting is announced, the names of the members of the Task Force will be published.

Dated: December 31, 1992.

Gordon H. Mansfield,

Assistant Secretary for Fair Housing and Equal Opportunity.

Charter of the HUD Task Force on Occupancy Standards in Public and Assisted Housing

Section 1. Purpose. The purpose of this document is to establish a Charter for a Task Force on Occupancy Standards in Public and Assisted Housing, as required under the provisions of the Federal Advisory Committee Act (FACA).

Section 2. Authority. The Task Force is established by the Secretary pursuant to section 643 of the Housing and Community Development Act of 1992 (Pub. L. 102–550), and implements the determination of the Secretary of Housing and Urban Development to establish an Advisory Committee in accordance with section 9(a)(1) of the FACA.

Section 3. Objectives, Scope of Activities and Duties. The Task Force will (1) review all existing standards, regulations and guidelines governing occupancy and tenant selection policies, and lease provisions and other rules of occupancy in public and assisted housing; (2) propose criteria for occupancy, standards for reasonable behavior of tenants, compliance standards consistent with reasonable accommodation and other requirements of civil rights laws and procedures for eviction of tenants who fail to comply with the standards; and (3) report to the Secretary and the Congress on its findings and recommendations.

Section 4. Membership. The Task Force will be composed of no more than 35 members, and will include representatives of owners, managers and tenants of federally assisted housing, public housing agencies, owner and tenant advocacy organizations, persons with disabilities and disabled families, organizations assisting homeless individuals, and social service, mental health and other nonprofit service providers who serve federally assisted housing. The members will be selected on the basis of personal experience and expert knowledge.

Section 5. Appointments. The Task Force members will be appointed by the Secretary to serve a term of 12 months from the effective date of the charter. Members will serve at the pleasure of the Secretary.

Section 6. Chair. The Chair will be elected by the Task Force from among its members. The Chair is responsible for:

a. Establishing the informal organization of the Task Force and appointing such subcommittees as may be necessary;

b. Developing, with the advice and consent of the Task Force, procedures for its effective and efficient operation;

c. Ensuring that procedures for public participation in Task Force meetings are established in accordance with the FACA;

d. Taking other actions required to facilitate the discharge of Task Force duties.

Section 7. Task Force Organization. The organization and agenda of the Task Force will be established at its first full meeting. Once established, the organization of the Task Force may be modified as appropriate by the Chair. Any subcommittee appointed by the Chair will be subordinate and advisory to the full Task Force. Subcommittees may meet at such times and places as the subcommittee Chair has approved for the performance of Task Force business. The results of all subcommittee meetings will be reported to the Task Force for its review.

Section 8. Meetings. The Task Force will meet at least twice during its term. The Task Force Chair may call special meetings as needed. The Task Force and any of its subcommittees will convene under the following conditions:

a. A notice of each Task Force or subcommittee meeting will be published in the **Federal Register** at least 15 days in advance of the meeting. Shorter notice is permissible in cases of emergency, but the basis for the declaration of an emergency must be reported in the notice.

b. Detailed minutes of each meeting of the Task Force will be kept, and the accuracy of the minutes will be certified to by the Task Force Chair, submitted to the Secretary of HUD, and filed with the Departmental Committee Management Officer. The minutes will include:

(1) The time and place of the meeting;

(2) A list of Task Force members and staff and department employees present at the meeting;

(3) A complete summary of matters discussed and the conclusions reached;

(4) Copies of all reports received, issued or approved by the Task Force;

(5) A description of the extent to which the meeting was open to the public;

(6) A description of public participation, including a list of members of the public who attended the meeting and a list of those who presented oral or written statements.

c. In accordance with the FACA, an employee designated by the Secretary will attend every meeting of the Task Force. The employee, or his or her designee, must call or approve the calling of each meeting, and is authorized to adjourn any Task Force meeting whenever he or she determines that adjournment is in the public interest.

Section 9. Support Services. The Assistant Secretary for Fair Housing and Equal Opportunity, to the extent permitted by law and subject to the availability of funds, will provide the Task Force with administrative services, funds, facilities, staff and other support necessary for the effective performance of its functions.

Section 10. Estimated Support and Cost. The Department estimates that the operating cost of the Task Force will not exceed $45,000, including staff support costs.

Section 11. Travel and Compensation. Members of the Task Force will serve without compensation, but are entitled to be paid for travel and subsistence in the performance of duties as authorized by 5 U.S.C. 5703(b).

Section 12. Reports. The Task Force will submit a written report to the Secretary, describing its membership, functions and actions before its termination. The Task Force will submit other written reports from time to time to the Secretary and the Congress as required by section 643.

Section 13. Expiration. The Task Force established under this Charter will terminate 12 months after the charter is filed, unless sooner extended.

Dated: December 31, 1992.

Approved:

Frank Keating,

Acting Secretary.

[FR Doc. 93-264 Filed 1-6-93; 8:45 am]

BILLING CODE 4210-32-M

[Docket No. N-93-3558; FR-3429-N-01]

Task Force on Occupancy Standards in Public and Assisted Housing; Meeting

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity.

ACTION: Notice of open meeting.

SUMMARY: The Task Force on Occupancy Standards in Public and Assisted Housing was established on December 31, 1992 in accordance with the provisions of section 643 of the Housing and Community Development Act of 1992 (Pub. L. 102-550), the Task Force's charter and the Federal Advisory Committee Act (FACA). The Task Force was created to review all rules, policy statements, handbooks, and technical assistance memoranda issued by the Department on the standards and obligations governing residency in public and assisted housing and make recommendations to the Secretary for the establishment of reasonable criteria for occupancy. This is a notice announcing the first meeting of the Task Force.

TIME AND PLACE: The Task Force will meet on Friday, January 15, 1993 from 10 a.m. to approximately 3 p.m. The meeting will take place in room 10233 (10th floor) of the Department of HUD Building, 451 Seventh Street, SW., Washington, DC. This is an open meeting. Fifteen days advance notice of this meeting could not be provided because of the necessity to schedule the organizational meeting of the Task Force before the congressionally mandated date for an interim report on the progress of the Task Force (January 28, 1993).

AGENDA: The Task Force will address the following during its initial meeting:

Introduction of Task Force Members and HUD Staff
Overview of Section 643—Background on the Creation of the Task Force
Review of material relating to occupancy and tenant selection
Task Force Methodology
  Study of Materials
  Public Hearings
  Written Comments
  Preliminary and Final Reports
Perspectives of Task Force members
Plans for Next Meeting/Public Hearings
Election of Chair and Vice Chair

PUBLIC PARTICIPATION: The public is invited to submit written comments on any aspect of the Task Force's mandate or activities. The Task Force will plan for subsequent public hearings as required by section 643(a)(5) of the Housing and Community Development Act of 1992.

FOR FURTHER INFORMATION CONTACT: Laurence D. Pearl, Office of Fair Housing and Equal Opportunity, room 5226, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Telephone: (202) 708-3727. (TDD) (202) 708-0113 (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Federal Advisory Committee Act and section 643(a)(2) of the Housing and Community Development Act of 1992, the Secretary has appointed a balanced and diverse Task Force consisting of representatives of owners, managers and tenants of federally assisted housing, public housing agencies, owner and tenant advocacy organizations, persons with disabilities and disabled families, organizations assisting homeless individuals, and social service, mental health and other nonprofit service providers who serve federally assisted housing.

The Task Force members are:

Charles Achilles, Vice President, Institute of Real Estate Management, Chicago, IL.
Lynn Aronson, Director of Housing, Connecticut Department of Mental Health, Hartford, CT.
John Bohm, Executive Director, National Assisted Housing Management Association, Alexandria, VA.
Conrad Egan, Chairman, Multifamily Housing Management Committee, National Association of Home Builders, Reston, VA.
Diane Engster, Esq., Northern Virginia Alliance for the Mentally Ill, Alexandria, VA.
Mike Finkle, On Our Own, Baltimore, MD.
Joseph Finnegan, Government Affairs Specialist, Walpole, MA.
Kimi Gray, President, Kenilworth-Parkside Resident Management Corporation, Washington, DC.
Jon Gutzman, National Association of Housing and Redevelopment Officials, Washington, DC.
Loretta Hall, Manager, Carr Square Tenant Management Corporation, St. Louis, MO.
Fred Karnas, Jr., Executive Director, National Coalition for the Homeless, Washington, DC.
Thomas L. Kenyon, Executive Director, National Alliance to End Homelessness, Washington, DC.
Ruth Lowenkron, Esq., New York Lawyers in the Public Interest, New York, NY.
Kathy McGinley, The Association for Retarded Citizens, Washington, DC.
Larry McNicol, Director of Housing Policy, American Association of

Homes for the Aging, Washington, DC.
Bonnie Milstein, National Mental Health Law Project, Washington, DC.
Bill Mitchell, National Association of Protection and Advocacy Systems, Washington, DC.
Denise Muha, Executive Director, National Leased Housing Association, Washington, DC.
Gerald Nicely, Public Housing Agencies Directors' Association, Washington, DC.
Debby Pilch, Esq., Disability Law Center, Boston, MA.
Don Redfoot, American Association of Retired Persons (AARP), Washington, DC.
Greg Russ, Advocate for Mixed Housing, Odenton, MD.
MaryAnn Russ, Council of Large Public Housing Agencies, Washington, DC.
Kim Savage, Esq., National Senior Citizens Law Center, Los Angeles, CA.
Susan Silverstein, Esq., Monroe County Legal Assistance, Rochester, NY.
Harry Thomas, Executive Director, Seattle Housing Authority, Seattle WA.
Steve Townsend, National Council of Community Menal Health Centers, Rockville, MD.
Larry Volk, Director of Programs, National Council of State Housing Finance Agencies, Washington, DC.
Ramsey Weit, Esq., Office of Commissioner Polly Casterline, Portland, OR.
Dorinda Wider, Esq., Minneapolis Legal Aid Society, Minneapolis, MN.
Daniel Wuenschel, Executive Director, Cambridge Housing Authority, Cambridge, MA.
Roberta Youmans, National Housing Law Project, Washington, DC.
Mildred Zanditon, Vinfen Corporation, Boston, MA.

Dated: December 31, 1992.

Gordon H. Mansfield,

Assistant Secretary for Fair Housing and Equal Opportunity, United States Department of Housing and Urban Development.

[FR Doc. 93–265 Filed 1–6–93; 8:45 am]

BILLING CODE 4210-28-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[ID–943–4210–05; IDI–17811C]

Order Providing for Opening of Public Land; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of cancellation of classification and opening of public lands.

SUMMARY: This Order revokes the suitable and unsuitable classification for the lands in a desert land application which is considered to have lapsed with the death of the applicant, pursuant to IBLA Order 86–643, dated May 21, 1992. This order opens the lands to the land, mining and mineral leasing laws.

EFFECTIVE DATE: February 8, 1992.

FOR FURTHER INFORMATION CONTACT: Larry L. Lievsay, BLM, Idaho State Office, 3380 Americana Terrace, Boise, Idaho 83706, 208–384–3166.

1. The suitable classification for desert land entry on the following described land is hereby revoked.

Boise Meridian, Idaho

T. 2 N., R. 3 W.,
Sec. 21, E½SW¼NE¼, E½W½SE¼, NE¼NW¼ and NW¼NE¼;
Sec. 28, W½NE¼, NW¼NW¼NW¼, S½NE¼NW¼, S½NE¼NW¼ and E½SE¼NW¼.

2. The unsuitable classification for desert land entry on the following described land is hereby revoked.

Boise Meridian, Idaho

T. 2 N., R. 3 W.,
Sec. 28, N½NE¼NW¼ and NE¼NW¼NW¼.

The area described contains 300 acres in Canyon County.

3. At 9 a.m. on February 8, 1993, the lands described in paragraphs 1 and 2 will be opened to the operation of the land laws generally, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid applications received at or prior to 9 a.m. on February 8, 1993, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

4. At 9 a.m. on February 8, 1993, the lands described in paragraphs 1 and 2 will be opened to location and entry under the United States mining laws and to applications and offers under the mineral leasing laws. Appropriation of any of the lands described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: December 15, 1992.

Bill R. LaVelle,

Acting State Director.

[FR Doc. 93–253 Filed 1–6–93; 8:45 am]

BILLING CODE 4310-06-M

[MT–930–4210–06; SDM 79849]

Opening of Land in a Proposed Withdrawal; South Dakota

Correction

In notice document 92–29642 appearing on page 58025 in the issue of Tuesday, December 8, 1992, make the following corrections:

1. In the first line, the serial number "MTM 79849" should read "SDM 79849."

2. In the second line of the document heading, "Montana" should read "South Dakota."

Dated: December 28, 1992.

John A. Kwiatkowski,

Deputy State Director, Division of Lands and Renewable Resources.

[FR Doc. 93–259 Filed 1–6–93; 8:45 am]

BILLING CODE 4310-DN-M

National Park Service

General Management Plan; Great Basin National Park; Notice of Availability of Final General Management Plan and Environmental Impact Statement

SUMMARY: In accordance with section 102(2)(C) of the National Environmental Policy Act of 1969, Public Law 91–190, and National Park Service (NPS) planning guidelines, the NPS has prepared a Final General Management Plan/Environmental Impact Statement (GMP/EIS) for Great Basin National Park, established in 1986.

The Draft General Management/Environmental Impact Statement (GMP/EIS) was circulated for public review between October 11 and December 31, 1991 (56 FR 50924). Both the Draft and Final GMP/EIS describe and analyze a proposal and three alternatives, for future management and use of the park. The proposal would provide a diversity of visitor opportunities by expanding interpretation, improving access to and within the park, construction of a new visitor center, adding new camping and trail facilities and moving administrative support facilities outside the park. Alternatives include: (A) Minimal improvements and no relocation of support facilities; (B) maximizing natural resource protection with concentration and restriction of visitor facilities and relocation of

support facilities; and (C) providing more extensive visitor development and accessibility to the park with support facilities remaining in the park.

The 30 day no action period on the Final GMP/EIS will end February 8, 1993. Requests for additional information and/or copies of the Final GMP/EIS should be directed to: Superintendent, Great Basin National Park, Baker NV 89311, telephone number (702) 234–7331.

Copies of the Final GMP/EIS are available at the park headquarters and at the following libraries: Lincoln and White Pine county libraries, NV; Beaver and Millard county libraries, UT; Harold E. Lee Library, Brigham Young University; and Southern Utah University Library. Copies also are available for inspection at the following address: Western Regional Office, National Park Service, Division of Planning, Grants and Environmental Quality, 600 Harrison St., suite 600, San Francisco, CA 94107–1372.

Dated: November 4, 1992.

Lewis Albert,

Acting Regional Director, Western Region.

[FR Doc. 93–309; Filed 1–6–93; 8:45 am]

BILLING CODE 4310–70–M

Chesapeake and Ohio Canal National Historical Park Commission Meeting

Notice is hereby given in accordance with Federal Advisory Committee Act that the meeting that was scheduled for December 12, 1992, and postponed due to inclement weather, has been rescheduled for January 23, 1993, at 10:30 a.m. at J. Paul's Restaurant, 3218 M Street, Georgetown, Washington, DC.

The Commission was established by Public Law 91–664 to meet and consult with the Secretary of the Interior on general policies and specific matters related to the administration and development of the Chesapeake and Ohio Canal National Historical Park.

This will be an orientation meeting for the nine newly appointed Commission members and the ten members who were reappointed. Robert Stanton, Regional Director, National Capital Region, will swear the new commissioners.

The members of the Commission are as follows:

Mrs. Sheila Rabb Weidenfeld, Chairman, Washington, DC
Ms. Diane C. Ellis, Brunswick, Maryland
Brother James T. Kirkpatrick, F.S.C., Cumberland, Maryland
Ms. Anne L. Gormer, Cumberland, Maryland
Ms. Elise B. Heinz, Arlington, Virginia
Mr. George M. Wykoff, Jr., Cumberland, Maryland
Mr. Rockwood H. Foster, Washington, DC
Mr. Barry A. Passett, Washington, DC
Mrs. Jo Reynolds, Potomac, Maryland
Ms. Nancy C. Long, Glen Echo, Maryland
Ms. Mary Elizabeth Woodward, Shepherdstown, West Virginia
Dr. James H. Gilford, Frederick, Maryland
Mr. Edward K. Miller, Hagerstown, Maryland
Mrs. Sue Ann Sullivan, Williamsport, Maryland
Mr. Terry W. Hepburn, Hancock, Maryland
Mr. Laidley E. McCoy, Charleston, West Virginia
Ms. Jo Ann M. Spevacek, Burke, Virginia
Mr. Charles J. Weir, Falls Church, Virginia
Ms. Donna Pope, Alexandria, Virginia

The agenda for this meeting includes discussion of the legislative process that created the C&O Canal Commission by former Commission Chairman, Carrie Johnson; Planning of the Park by John Parsons, Associate Regional Director, National Capital Region; the Role of the Commission, Overview of Park Operations, Update of the Vail Agenda and Superintendent's Report by Superintendent Thomas Hobbs.

The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning the matters to be discussed. Persons wishing further information concerning this meeting, or who wish to submit written statements, may contact Thomas O. Hobbs, Superintendent, C&O Canal National Historical Park, P.O. Box 4, Sharpsburg, Maryland 21782.

Minutes of the meeting will be available for public inspection six (6) weeks after the meeting at Park Headquarters, Sharpsburg, Maryland.

Dated: December 29, 1992.

Robert Stanton,

Regional Director, National Capital Region.

[FR Doc. 93–308 Filed 1–6–93; 8:45 am]

BILLING CODE 4310–70–M

Gettysburg National Military Park Advisory Commission; Meeting

AGENCY: Gettsburg National Military Park Advisory Commission.

ACTION: Notice of Meeting.

SUMMARY: This notice sets forth the date of the sixth meeting of the Gettysburg National Military Park Advisory Commission.

DATE: January 28, 1993.

TIME: 2 p.m.–4 p.m.

INCLEMENT WEATHER RESCHEDULE DATE: None.

ADDRESS: Holiday Inn, 516 Baltimore Street, Gettysburg, Pennsylvania 17325.

AGENDA: Sub-Committee Reports, presentation on Memorial Landscape, update on removal of overhead utility lines in the Park, status of Land Protection Plan, release of the Eisenhower Statement for Management, report on the status of the fast food directional signs on Taneytown Road, and an operational update on the park.

FOR FURTHER INFORMATION CONTACT: Jose A. Cisneros, Superintendent, Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325.

SUPPLEMENTAWRY INFORMATION: The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning agenda items. The statement should be addressed to the Advisory Commission, Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325. Minutes of the meeting at the permanent headquarters of the Gettysburg National Military Park located at 95 Taneytown Road, Gettysburg, Pennsylvania 17325.

John McKenna,

Acting Regional Director, Mid-Atlantic Region.

[FR Doc. 93–307 Filed 1–6–93; 8:45 am]

BILLING CODE 4310–70–M

Gettysburg National Military Park Advisory Commission; Meeting

AGENCY: Gettysburg National Military Park Advisory Commission.

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the date of a special meeting of the Gettysburg National Military Park Advisory Commission.

DATES: January 30, 1993.

TIME: 8:30 a.m.–9:30 a.m.

INCLEMENT WEATHER RESCHEDULE DATE: None.

ADDRESSES: Hotel Gettysburg, Lincoln Square, Gettysburg, Pennsylvania 17325.

AGENDA: Update on Gettysburg National Military Park to the Civil War Sites Advisory Commission.

FOR FURTHER INFORMATION CONTACT: Jose A. Cisneros, Superintendent, Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning agenda items. The statement should be addressed to the Advisory Commission, Gettysburg National Military Park, P.O. Box 1080, Gettysburg, Pennsylvania 17325. Minutes of the meeting will be available for inspection four weeks after the meeting at the permanent headquarters of the Gettysburg National Military Park located at 95 Taneytown Road, Gettysburg, Pennsylvania 17325.

John McKenna,

Acting Regional Director, Mid-Atlantic Region.

[FR Doc. 93–306 Filed 1–6–93; 8:45 am]

BILLING CODE 4310–70–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32227]

Louisiana & Delta Railroad, Inc.; Trackage Rights Exemption; Southern Pacific Transportation Co.

Southern Pacific Transportation Company (SP) has agreed to grant trackage rights to Louisiana & Delta Railroad, Inc. (LDR) over approximately 3 miles between SP's mileposts 128.0 at New Iberia, LA, and 131.0 west of the Ara Spur, LA. The trackage rights were to become effective on December 30, 1992.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Charles D. Crampton, 700 Midtown Tower, Rochester, NY 14604.

As a condition to the use of this exemption, any employees adversely affected by the trackage rights will be protected under *Norfolk and Western Ry. Co.—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.—Lease and Operate*, 360 I.C.C. 653 (1980).

Decided: December 31, 1992.

By the Commission, Donald J. Shaw, Acting Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–278 Filed 1–6–93; 8:45 am]

BILLING CODE 7035–01–M

MERIT SYSTEM PROTECTION BOARD

Call for Riders for the U.S. Merit Systems Protection Board Report, "A Question of Equity: Women and the Glass Ceiling in the Federal Government"

AGENCY: U.S. Merit Systems Protection Board.

ACTION: Notice of call for riders for the Board's report, "A Question of Equity: Women and the Glass Ceiling in the Federal Government".

SUMMARY: The purpose of this notice is to inform Federal departments and agencies that the U.S. Merit Systems Protection Board's report, "A Question of Equity: Women and the Glass Ceiling in the Federal Government," will be available on a rider basis from the Government Printing Office. Departments and agencies may order this publication by riding the Board's requisition number 3–00106.

DATES: Agency requisitions must be received by the Government Printing Office on or before February 22, 1993.

ADDRESSES: Interested departments and agencies should send requisitions from their headquarter offices authorized to procure printing to the Government Printing Office, Requisition Section, room C–836, Washington, DC 20401.

FOR FURTHER INFORMATION CONTACT: Annette Johnson, Office of Policy and Evaluation, U.S. Merit Systems Protection Board, 1120 Vermont Avenue, NW., Washington, DC 20419, 202–254–8014.

SUPPLEMENTARY INFORMATION: This report examines the reasons that so few women are in top-level positions in the Civil Service. The Board finds that the underrepresentation of women in senior career positions and, particularly, the slower promotion rates in GS–9 through GS–12 ranks are only partially explained by such factors as education, experience, and mobility. The report discusses these barriers and offers recommendations for ways to achieve greater equity for women.

In making this report available, the Board intends to provide useful information on this issue to Federal managers as they consider ways to effectively manage Federal employees.

The Board is unable to fill large volume orders from agencies for this publication; therefore, agencies are urged to take advantage of this opportunity to order copies directly from the Government Printing Office. Because of budgetary constraints, the Board is uncertain when and if there will be another reprinting of this publication in the current fiscal year. This requisition is for reprinting the first edition of the report, dated October 1992.

Dated: January 4, 1993.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 93–289 Filed 1–6–93; 8:45 am]

BILLING CODE 7400–01–M

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration, Office of Records Administration.

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Records schedules identify records of sufficient value to warrant preservation in the National Archives of the United States. Schedules also authorize agencies after a specified period to dispose of records lacking administrative, legal, research, or other value. Notice is published for records schedules that (1) propose the destruction of records not previously authorized for disposal, or (2) reduce the retention period for records already authorized for disposal. NARA invites public comments on such schedules, as required by 44 U.S.C. 3303a(a).

DATES: Request for copies must be received in writing on or before February 22, 1993. Once the appraisal of the records is completed, NARA will send a copy of the schedule. The requester will be given 30 days to submit comments.

ADDRESSES: Address requests for single copies of schedules identified in this notice to the Records Appraisal and Disposition Division (NIR), National Archives and Records Administration, Washington, DC 20408. Requesters must cite the control number assigned to each schedule when requesting a copy. The control number appears in the parentheses immediately after the name of the requesting agency.

SUPPLEMENTARY INFORMATION: Each year, U.S. Government agencies create billions of records on paper, film, magnetic tape, and other media. In order to control this accumulation, agency records managers prepare records

schedules specifying when the agency no longer needs the records and what happens to the records after this period. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. These comprehensive schedules provide for the eventual transfer to the National Archives of historically valuable records and authorize the disposal of all other records. Most schedules, however, cover records of only one office or program or a few series of records, and many are updates of previously approved schedules. Such schedules also may include records that are designated for permanent retention.

Destruction of records requires the approval of the Archivist of the United States. This approval is granted after a thorough study of the records that takes into account their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and historical or other value.

This public notice identifies the Federal agencies and their subdivisions requesting disposition authority, includes the control number assigned to each schedule, and briefly describes the records proposed for disposal. The records schedule contains additional information about the records and their disposition. Further information about the disposition process will be furnished to each requester.

Schedules Pending

1. Department of the Air Force (N1–AFU–93–4). Environmental Training Records.
2. Department of the Air Force (N1–AFU–93–5). Depot Maintenance Records.
3. Department of the Army (N1–AU–93–2). Medical Malpractice Records.
4. Department of Commerce, Office of Environmental Affairs (N1–40–92–4). Environmental Impact Statements and other environmental records.
5. Department of Commerce, International Trade Administration (N1–151–92–8). Canadian lumber export notices.
6. Defense Investigative Service (N1–446–92–2). Routine and facilitative records relating to recurring reports, leave slips and port security.
7. Defense Investigative Service (N1–446–92–3). Export license forms received from Department of State.
8. Defense Logistics Agency (N1–361–93–1). Publications background files from field activities.
9. Defense Logistics Agency (N1–361–93–2). Flight operations records.
10. Department of Health and Human Services, Indian Health Service (N1–513–92–5). General program and administrative records.
11. Federal Bureau of Investigation (N1–65–93–1). Sound recordings which are duplicative, lack historical value, or exhibit poor quality.
12. Department of State, All Foreign Service Posts (N1–84–93–1). Personnel folders of uncompensated non-Americans.
13. Department of State, All Foreign Service Posts (N1–84–93–2). Cash receipts and records of fees.
14. Department of State, All Foreign Service Posts (N1–84–93–3). Legal inquiries.
15. Department of State, All Foreign Service Posts (N1–84–93–4). American citizens services precedent case files.
16. Office of Thrift Supervision (N1–483–92–9). Records relating to data processing and management information systems.
17. Panama Canal Commission (N1–185–92–2). Routine civilian personnel records.
18. Panama Canal Commission (N1–185–92–3). Police and Convict Records.
19. White House Conference on Library and Information Science (N1–220–92–2). Facilitative and housekeeping records.

Dated: December 23, 1992.

Don W. Wilson,

Archivist of the United States.

[FR Doc. 93–260 Filed 1–6–93; 8:45 am]

BILLING CODE 7515–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Agency Information Collection Under OMB Review

AGENCY: National Endowment for the Humanities, NFAH.

ACTION: Notice.

SUMMARY: The National Endowment for the Humanities (NEH) has sent to the Office of Management and Budget (OMB) the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

DATES: Comments on this information collection must be submitted on or before February 8, 1993.

ADDRESSES: Send comments to Ms. Susan Daisey, Assistant Director, Grants Office, National Endowment for the Humanities, 1100 Pennsylvania Avenue, NW., room 310, Washington, DC 20506 (202–606–8494) and Mr. Steve Semenuk, Office of Management and Budget, New Executive Office Building, 726 Jackson Place, NW., room 3002, Washington, DC 20503 (202–395–6880).

FOR FURTHER INFORMATION CONTACT: Ms. Susan Daisey, Assistant Director, Grants Office, National Endowment for the Humanities, 1100 Pennsylvania Avenue, NW., room 310, Washington, DC 20506 (202) 606–8494 from whom copies of forms and supporting documents are available.

SUPPLEMENTARY INFORMATION: All of the entries are grouped into new forms, revisions, extensions, or reinstatements. Each entry is issued by NEH and contains the following information: (1) the title of the form; (2) the agency form number, if applicable; (3) how often the form must be filled out; (4) who will be required or asked to report; (5) what the form will be used for; (6) an estimate of the number of responses; (7) the frequency of response; (8) an estimate of the total number of hours needed to fill out the form; (9) an estimate of the total annual reporting and recordkeeping burden. None of these entries are subject to 44 U.S.C. 3504(h).

Category: Revisions

Title: Guidelines and Application Forms for the Division of Preservation and Access
Form Number: Not Applicable
Frequency of Collection: Semi-annual
Respondents: Humanities researchers and institutions
Use: Application for funding
Estimated Number of Respondents: 250
Frequency of Response: Once
Estimated Hours for Respondents to Provide Information: 40 per respondent
Estimated Total Annual Reporting and Recordkeeping Burden: 12,500 hours

Thomas S. Kingston,

Assistant Chairman for Operations.

[FR Doc. 93–261 Filed 1–6–93; 8:45 am]

BILLING CODE 7536–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Mathematical Sciences; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and Time: January 25–26, 1993 9 a.m.–5 p.m.

Place: National Science Foundation, 1800 'G' Street, NW., room 1243, Washington, DC 20550.

Type of Meeting: Closed.

Contact Person: Alvin Thaler, Program Director, Division of Mathematical Sciences, Room 338, National Science Foundation, 1800 G St. NW., Washington, DC 20550. Telephone: (202) 357–3691.

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Grants for Scientific Computing Research Environments of the Mathematical Sciences proposals as part of the selection process for awards.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: January 4, 1993.

Modestine Rogers,

Acting Committee Management Officer.

[FR Doc. 93-310 Filed 1-6-93; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the OMB review of information collection.

SUMMARY: The NRC has recently submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

1. Type of submission, new, revision or extension: Revision.

2. The title of the information collection: Proposed Rule, "10 CFR Part 110: Requirements for the Specific Licensing of Exports of Certain Alpha-Emitting Radionuclides and Byproduct Material".

3. The form number if applicable: NRC Form 7.

4. How often the collection is required: On occasion.

5. Who will be required or asked to report: Some exporters of bulk tritium, americium-242m, californium-249, californium-251, curium-245, curium-247 and certain alpha-emitting radionuclides.

6. An estimate of the number of reporting responses annually: 9.

7. An estimate of the total number of hours annually needed to complete the requirement or request: 28. 22 hours of reporting burden is estimated (an average of 2.4 hours per response) and 6 hours of recordkeeping burden is estimated.

8. An indication of whether section 3504(h), Public Law 96-511 applies: Applicable.

9. Abstract: 10 CFR part 110 provides application, reporting, and recordkeeping requirements for exports and imports of nuclear equipment and material. The proposed revision would require that specific licenses be obtained for certain exports of byproduct materials and some alpha-emitting radionuclides.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC 20555.

Comments and questions may be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs (3150-0036 and 3150-0027), NEOB-3019, Office of Management and Budget, Washington, DC 20503.

Comments may also be communicated by telephone at (202) 395-3084.

The NRC clearance officer is Brenda Jo Shelton, (301) 492-8132.

Dated at Bethesda, Maryland, this 23rd day of December 1992.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 93-267 Filed 1-6-93; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-31673; File No. SR-DTC-92-16]

Self-Regulatory Organizations; The Depository Trust Company; Order Approving Proposed Rule Change Relating to the Deposit of Nontransferable Securities

December 30, 1992.

On October 14, 1992, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR-DTC-92-16) pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] The proposed rule change will establish procedures that will enable DTC to provide expanded safekeeping and depository services for nontransferable securities. The Commission published notice of the proposed rule change in the **Federal Register** on November 18, 1992.[2] No comments were received. For the reasons discussed below, the Commission is approving the proposed rule change.

[1] 15 U.S.C. 78(b)(1).

[2] Securities Exchange Act Release No. 31439 (November 12, 1992), 57 FR 54432.

I. Description

The proposed rule change will establish procedures for the deposit of nontransferable securities at DTC. Securities may become nontransferable for a number of reasons, including the bankruptcy or insolvency of the issuer, the failure to pay fees to a transfer agent, a final or complete liquidation of the issuer, the filing of a certificate of dissolution, the placement of the issuer in receivership, or the revocation of the issuer's charter. Currently, nontransferable securities are eligible for limited clearing and depository services.

A. Background

In prior years, when a depository eligible security became nontransferable, depositories declared the security "ineligible" and distributed certificates to participants to the extent properly denominated certificates were available. When such certificates were unavailable, remaining participant positions were "frozen" in some fashion within the depositories to prevent further processing activities. This presented a variety of problems. Because no clearing or book-entry services were available, settlement could occur only by physical delivery or by a cumbersome process which debited a delivering participant and credited a receiving participant within the depository. In this environment, failed deliveries occurred regularly and remained outstanding as the result of trading and account transfer activity. Participants were burdened with the expense of safekeeping certificates exited by the depositories and monitoring the ongoing transferability status of the securities. Participants forced to assume these responsibilities individually developed procedures and practices to address this burden.

Over the past two years, depositories and clearing corporations have ameliorated this situation somewhat. Instead of declaring a security "ineligible," securities can now be designated as "inactive." This designation permits a more flexible determination of the specific types of services to be provided. Most depositories and clearing corporations now act to restrict continuous-net-settlement, deposit, withdrawal, and transfer activity for nontransferable securities, while permitting book-entry deliveries. This action has stopped the outflow of nontransferable securities from the depositories and permitted the settlement of fails to the extent a

deliverer has a sufficient position within the depository at the time a security is designated inactive. Participants must continue, however, to safekeep certificates exited by depositories in prior years, in addition to safekeeping those securities registered in customer or firm name that the depositories will not currently accept as deposits, because they cannot be registered in the name of the depositories' nominees.

DTC currently has two ongoing programs for the deposit of nontransferable securities. The first is for the redeposit of nontransferable securities registered in DTC's nominee name, Cede & Co., and was introduced primarily to allow participants to make book-entry deliveries of these redeposited securities. The second allows participants to cover short positions, and permits deposits of securities registered in Cede & Co., customer, or street name. The procedures, forms, and loss allocation method of the proposed rule change, as described below, will replace those in the two ongoing programs and permit participants to deposit all DTC-eligible nontransferable securities at DTC, regardless of purpose, and allow them to make book-entry deliveries to one another where deliveries of physical certificates may not be possible.

B. Deposit Procedures

When DTC announces to participants that an issue is "nontransferable," DTC will change the transfer agent number on DTC's records, which may be viewed by participants via DTC's Participant Terminal System, to reflect the fact that the issue is nontransferable. Participants will then be permitted to deposit their DTC-eligible nontransferable securities by adhering to several procedures. Specifically, participants will be asked to:

(1) Send to their Participant Services representative a copy of the Blanket Indemnification executed by an authorized officer. Procedures set forth in the Indemnification will, among other things, require the participant to verify with the Securities Information Center ("SIC") that the certificate has not been reported to SIC as lost, stolen, missing, or counterfeit;

(2) Use a Legal deposit ticket clearly marked "N/T." No more than ten certificates may be included in each individual deposit. Participants will also be asked not to commingle different types of registrations on a single deposit ticket (*i.e.*, all nominee-name and street-name registrations will be deposited under separate tickets); and

(3) Check the certificates for assignment to Cede & Co., New York State tax waiver, endorsements, and other requirements, and provide the appropriate signature guarantees.

C. Procedures for Sharing of Loss Related to Deposit of Nontransferable Securities

Under the proposed rule change, DTC has developed a loss allocation method in the event that a certificate that represents a nontransferable security is deposited at DTC and later, most likely after the reinstatement of transfer services and presentation of the certificate for transfer, is found to be stolen, counterfeit, or otherwise defective. If the depositing/indemnifying participant is still in business or if DTC is holding the participant's Participants Fund deposit in an amount sufficient to cover the loss, DTC will first seek to charge the participant or its deposit. In the event, however, in which at the time that DTC becomes aware of the loss: (1) The depositing participant has transferred the underlying securities by book-entry; (2) the participant does not itself cover the loss because it is not in business or for some other reason; and (3) the participant's deposit to the Participants Fund is insufficient to cover the loss, then the loss will be allocated as follows.[3]

The loss will be shared *pro rata* among all participants that have a position in such issue on the date that DTC determines that the certificate is defective, excluding participants' positions, however, to the extent that positions existed on the day that DTC first announced to participants that the issue was "nontransferable."[4] For example, if a participant already held a position of 1,000 shares in an issue at the time that the issue was identified by DTC as being nontransferable and then acquires 500 additional shares later, any proportionate loss calculation would be only against the additional 500 shares and not against the 1,500 share total position. DTC will first seek to charge the participant's Participants Fund deposit in an amount sufficient to cover the loss. If the deposit will not cover the total amount of the loss, DTC will then charge the participant directly for the remaining amount. In the event, however, that the loss allocation method as described above does not cover the total amount of the loss related to the deposit of the nontransferable securities, DTC will then charge the loss in accordance with its current loss allocation scheme.[5]

II. Discussion

The Commission believes that DTC's proposed rule change is consistent with section 17A of the Act and specifically, with sections 17A(b)(3) (A) and (F) thereunder.[6] Sections 17A(b)(3) (A) and (F) of the Act require that a clearing agency be organized and its rules be designed to enable it to facilitate the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in its custody or control or for which it is responsible. In addition, section 17A(a)(1) encourages the adoption of efficient and effective procedures for the clearance and settlement of securities transactions.

The Commission believes that DTC's proposal will reduce the costs and inefficiencies associated with the clearance and settlement of nontransferable securities by bringing the benefits of centralized, automated book-entry clearance and settlement to nontransferable issues. At the present time, there are approximately 4,200 DTC-eligible nontransferable issues at DTC.[7] As a result of the proposed rule, which would enable participants to deposit these nontransferable issues at DTC, participants will be able to reduce their physical vault inventory, which will in turn allow them to reduce processing expense, audit time and interest expense that results from outstanding fails to deliver. This will eventually allow participants to

[3] Assuming that book-entry transfers have been made, it would not be feasible for DTC to trace the transfers and attribute the security positions represents by the defective certificate to particular participants. According to DTC, in order to trace the transfers, DTC would have to keep records relating to these transactions indefinitely. At the present time, DTC retains records for a period not longer than 10 years. In the absence of a procedure to allocate losses, therefore, any such loss would be shared by all participants. Telephone conversation between Jack R. Wiener, Associate Counsel, DTC, and Ari Burstein, Law Clerk, Commission (October 26, 1992).

[4] To assure that the effect of this proposal is prospective, this procedure applies to issues that become "non-transferable" at DTC subsequent to the Commission's approval of this procedure. In the event that the issue is already "non-transferable" as of the date of the Commission's approval order, DTC will instead exclude participants' positions to the extent that positions existed on the date of the approval order.

[5] Conversation between Richard Nesson, General Counsel and Senior Vice President, DTC, and Ari Burstein, Law Clerk, Commission (November 9, 1992).

For further details see Rules of The Depository Trust Company, Rule 4 (Participants Fund).

[6] 15 U.S.C. 78q–1(b)(3) (A) and (F).

[7] Telephone conversation between Jack R. Wiener, Associate Counsel, DTC, and Ronald Burns, Vice President, Operations, DTC, and Ari Burstein, Law Clerk, Commission (October 26, 1992).

minimize their total overhead by reducing staff and insurance costs.

The proposed procedure is also consistent with industry efforts toward greater immobilization of securities certificates and with industry efforts to maximize efficiency in securities processing. The proposal, therefore, is consistent with the requirement of section 17A(b)(3)(F) of the Act requiring that the rules of a clearing agency be designed to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.

DTC received ten comment letters from participants regarding the proposed rule change.[8] Six of the letters were in favor of the program as proposed by DTC to accept nontransferable securities and stated interest in participating in the program when it was approved.[9] One letter stated that there was no need for the proposed rule change in light of the two programs that DTC currently has in place for the deposit of transferable securities.[10] The remaining three letters had no objection to the rule change as proposed by DTC but instead provided several suggestions, as discussed below, relating to potential improvements to the nontransferable securities program.[11]

Two commenters expressed concern about the process by which DTC will notify participants of a security's nontransferable status.[12] These participants stated that because their current systems are completely automated, it would not be possible to extract the nontransferable issues from the regular daily transmissions of securities. These participants suggested that a special coding system be implemented to allow their automated systems to differentiate between a legal deposit and a regular deposit, which in turn will prevent their automated systems from becoming more manual in nature.

DTC stated that they are currently exploring the feasibility of implementing the suggested special coding system.[13] Under the proposed rule, once DTC announces that an issue is nontransferable, DTC will change the transfer agent number on DTC's records to "2400," which is a special transfer agent number assigned to nontransferable securities. Participants can then determine which issues are nontransferable by keying in the security's CUSIP number over DTC's Participant Terminal System and examining the transfer agent number assigned to the issue by DTC.

The Commission believes that the proposed system for notifying participants of the nontransferable status of an issue is consistent with the requirement of section 17A(b)(3)(F) of the Act that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions. The Commission, however, encourages DTC to explore ways, including the suggested special coding system, to allow participants to process nontransferable deposits in the same manner as those currently employed for other DTC deposits.

Two other participants expressed concerns to DTC regarding the proposed loss allocation scheme.[14] The participants urged that the loss allocation procedure was inequitable and will unjustly penalize a participant for merely having a position in a security in which losses will result from deposits made by other participants. They suggested that DTC set up a reserve which would be funded by a portion of the nontransferable deposit fee, against which future losses could be allocated. In the absence of a reserve, the participants suggested that the loss be allocated among all participants in the nontransferable securities program, instead of merely against the participants in the particular nontransferable issue.

Under the proposed loss allocation procedure for the nontransferable securities program, DTC will first seek to charge the depositing/indemnifying participant for an amount sufficient to cover the loss. DTC will not charge the loss to participants that have positions in the nontransferable issue unless the depositing participant cannot cover the loss. Moreover, as described above, DTC will not allocate the loss to participants whose positions in a nontransferable issue predate the nontransferable status. Given these conditions and in the absence of identified losses to date, the Commission believes DTC's decision not to establish a specific reserve by raising or allocating nontransferable deposit fees is consistent with sections 17A(b)(3) (D) and (F) of the Act which require that the rules of the clearing agency provide for the equitable allocation of reasonable dues, fees and other charges among its participants and that the rules of the clearing agency are not designed to permit unfair discrimination among participants in the use of the clearing agency.

Commenters also expressed concern about the amount of the deposit fee that DTC is proposing to charge per deposit. One participant stated that because the securities are nontransferable, there should not be any transfer costs associated with the deposit except for expenses which are storage related. The participants claimed that the cost of the deposit fee is therefore excessive for the amount of service required.[15] DTC explained that since all of the deposits must be fully examined and indemnifications verified by DTC, it is necessary to charge the full service legal examination fee per deposit.

The deposit fee to be charged under the proposed nontransferable securities program is identical to that charged for other similar DTC services. In addition, the fee is needed to cover the additional safeguards DTC is required to implement under the proposed rule. Accordingly, the Commission believes that the amount of the deposit fee is consistent with the requirements of section 17A(b)(3)(D) of the Act which requires that the rules of the clearing agency provide for the equitable allocation of reasonable dues, fees and other charges among its participants.

The restrictions on the number of certificates that can be deposited per deposit ticket and the requirement that

[8] See letter from Louis Chiaccheri, Vice President, The Bank of New York, to Ronald Burns, Vice President, DTC (September 18, 1992); letter from Jan Fenty, President, Cashiers' Association of Wall Street, Inc., to Val Stevens, Director, DTC (September 25, 1992); letter from Linda M. Rushlow, Vice President, Chase Lincoln First Bank, N.A., to Gerry Marotta, Participant Services Representative, DTC (September 29, 1992); letter from John Bertuzzi, Vice President, Dean Witter Reynolds Inc., to Ronald Burns, Vice President, DTC (September 17, 1992); letter from Philip Fox, Associate Vice President, A.G. Edwards & Sons, Inc., to Ronald Burns, Vice President, DTC (September 16, 1992); letter from Claude Schmook, Assistant Vice President, The First National Bank of Chicago, to Tony Gazzola, DTC (October 1, 1992); letter from Frank Delia, Vice President, Kidder Peabody & Co., to Everett Smith, Participant Services Representative, DTC (September 30, 1992); letter from Albert Howell, Vice President, Merrill Lynch, to Valentine Stevens, Director, DTC (September 29, 1992); letter from Maureen G. Tomshack, Vice President, NBD Bank, N.A., to Michael Miklas, Senior Securities Officer, DTC (October 1, 1992); and letter from Joe Ricca, Vice President, Pershing, to Valentine Stevens, Director, DTC (October 1, 1992).

[9] See supra, note 8, letters from Cashiers' Association of Wall street; Chase Lincoln First Bank; Kidder, Peabody; Merrill Lynch; NBD Bank; and Pershing.

[10] See supra, note 8, letter from First National Bank of Chicago.

[11] See supra, note 8, letters from The Bank of New York, Dean Witter Reynolds; and A.G. Edwards & Sons.

[12] See supra, note 8, letters from Dean Witter Reynolds and the Bank of New York.

[13] Telephone conversation between Jack R. Wiener, Associate Counsel, DTC, and Ron Burns, Vice President, Operations, DTC, and Ari Burstein, Law Clerk, Commission (October 28, 1992).

[14] See *supra*, note 8, letters from A.G. Edwards & Sons and The First National Bank of Chicago.

[15] See *supra*, note 8, A.G. Edwards & Sons letter.

registrations cannot be commingled was addressed in two comment letters from participants.[16] The participants stated that the restrictions can result in costly deposit fees and asked DTC to eliminate the restrictions to minimize costs. DTC believes that the restrictions are necessary to minimize the problems associated with the manual balancing of those deposits and to help safeguard the nontransferable program in general. In addition to the restrictions on the amount of certificates that can be deposited, other safeguards implemented by DTC include the requirement that participants, through the procedures set forth in the Blanket Indemnification, verify with the Securities Information Center ("SIC") that the certificate has not been reported as lost, stolen, missing, or counterfeit. Participants will also be asked to check the certificates for proper assignment, endorsements, and other requirements, and provide the appropriate signature guarantees.

The Commission believes that the safeguards and controls DTC has established under the nontransferable securities program are reasonable and that the proposal is consistent with the requirements of sections 17A (b)(3)(A) and (b)(3)(F) of the Act in that it promotes the prompt and accurate clearance and settlement of securities transactions and assures the safeguarding of funds and securities which are in DTC's custody or control or for which it is responsible.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the Act, and in particular with section 17A of the Act, and with the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[17] that the proposed rule change (File No. SR–DTC–92–16) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[18]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–292 Filed 1–6–93; 8:45 am]

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[16] See *supra*, note 8, letters from The Bank of New York and A.G. Edwards & Sons.

[17] 15 U.S.C. 78s(b)(2).

[18] 17 CFR 200.30–3(a)(12).

[Release No. 34–31674; File No. SR–MSTC–92–07]

Self-Regulatory Organizations; Midwest Securities Trust Company; Order Approving Proposed Rule Change Relating to the Deposit of Nontransferable Securities

December 30, 1992.

On August 19, 1992, the Midwest Securities Trust Company ("MSTC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR–MSTC–92–07) pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] The proposed rule change will establish procedures that will enable MSTC to provide safekeeping and limited depository services for nontransferable securities.[2] The Commission published notice of the proposed rule change in the **Federal Register** on October 14, 1992.[3] The Commission received one comment letter supporting the proposal.[4] For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The proposed rule change will establish procedures for the safekeeping and limited depository services of nontransferable securities at MSTC. Securities may become nontransferable for a number of reasons, including the bankruptcy or insolvency of the issuer, failure to pay fees to a transfer agent, a final or complete liquidation of the issuer, the filing of a certificate of dissolution, placement of the issuer in receivership, or revocation of the issuer's charter. Currently, nontransferable securities are eligible for limited clearing and depository services.

A. Background

In prior years, when a depository eligible security became nontransferable, depositories declared the security "ineligible" and distributed certificates to participants to the extent properly denominated certificates were available. When such certificates were unavailable, remaining participant positions were "frozen" in some fashion within the depositories to prevent further processing activities. This presented a variety of problems. Because no clearing or book-entry services were available, settlement could occur only by physical delivery or via a cumbersome process which debited a delivering participant and credited a receiving participant within the depository. In this environment, failed deliveries occurred regulatory and remained outstanding as the result of trading and account transfer activity. Participants were burdened with the expense of safekeeping certificates exited by the depositories and monitoring the ongoing transferability status of the securities. Participants forced to assume these responsibilities individually developed procedures and practices to address this burden.

Over the past two years, depositories and clearing corporations have ameliorated this situation somewhat. Instead of declaring a security "ineligible," securities can now be designated as "inactive." This designation permits more flexible determination of the specific types of services to be provided. Most depositories and clearing corporations now act to restrict continuous-net-settlement, deposit, withdrawal, and transfer activity for nontransferable securities, while permitting book-entry deliveries. This action has stopped the outflow of nontransferable securities from the depositories and permitted the settlement of fails to the extent a deliverer has a sufficient position within the depository at the time a security is designated inactive. Participants must continue, however, to safekeep certificates exited by depositories in prior years, in addition to safekeeping those securities registered in customer or firm name that the depositories will not currently accept as deposits, because they cannot be registered in the name of the depositories' nominees.

The problem of adequately monitoring nontransferable securities to identify a change in transferable status is also of concern to participants. Because of tax considerations, it is often necessary for participants to verify whether a nontransferable security is worthless. Moreover, verification is important because it will allow participants to strike the position from their records. Under current procedures, it is extremely time consuming and cumbersome for participants to verify that a security is nontransferable and to ascertain whether the security has, to the best of anyone's knowledge, been declared worthless. As each participant

[1] 15 U.S.C. 78s(b)(1).

[2] On December 10, 1992, MSTC amended the proposed rule change by providing the indemnification agreement to be signed by participants in the nontransferable securities program. Letter from George T. Simon, Foley & Lardner, MSTC, to Ester Saverson, Jr., Branch Chief, Division of Market Regulation, Commission (December 10, 1992).

[3] Securities Exchange Act Release No. 31290 (October 6, 1992), 57 FR 47148.

[4] See letter from Albert Howell, Vice President, Merrill Lynch, to the Commission (June 1, 1992).

is verifying and validating nontransferable securities independently, enormous amounts of time, money, and resources are wasted. In response to these concerns, MSTC has developed a method of providing safekeeping and limited depository services for nontransferable securities.

B. Deposit Procedures

The proposed rule change, in conjunction with the implementation of new procedures, will allow nontransferable securities to be deposited in MSTC either through physical delivery or by book-entry. In the case of physical deliveries, MSTC will physically inspect the security to verify that no notorials [5] are attached to the security and that the appropriate NASD Ownership Transfer Indemnification Stamp is properly executed.[6] At the time of delivery, participants will provide a warranty and indemnification to MSTC to protect MSTC against the possibility that a defect in any documentation or ownership rights causes MSTC a financial loss in the event the security becomes transferable in the future but the transfer agent rejects the specific certificates held by MSTC.[7] Specifically, each participant will warrant that there are no defects in title in a security delivered to or deposited with MSTC, that they have inquired of the Securities Information Center ("SIC") regarding the particular security and that, as of the date of the deposit with MSTC, the security has not been reported to the SIC as lost, stolen, missing or counterfeit. In addition to physical deposits, all incoming interdepository book-entry movements of the nontransferable securities will be permitted. Once deposited, MSTC will make sure that the security has a CUSIP number and if not, MSTC will obtain one for the security.[8]

Under new procedures, MSTC will revalidate the continuing nontransferable status of each issue on a simi-annual basis and provide participants with the last date of revalidation, thereby reducing the cost that participants currently incur in monitoring the status of each nontransferable issue. In addition, MSTC will promptly restore an issue to full eligibility status for normal depository processing once it again becomes transferable, so long as it meets the current eligibility requirements for normal depository processing. Finally, at the time of regained transferability, MSTC will forward all prior participant deposits to the transfer agent for re-registration into the name of the depository's nominee. Rejected transfers would be reclaimed to the original depositing participant in accordance with MSTC's current reclamation procedures.

C. Procedures for Sharing of Loss Related to Deposit of Nontransferable Securities

Under the proposed rule change, in the event that a certificate that represents a nontransferable security is deposited at MSTC and later, most likely after the reinstatement of transfer services and presentation of the certificate for transfer, is found to be stolen, counterfeit, or otherwise defective, MSTC will initially seek to charge the depositing participant for the amount of the loss. In the event, however, that the depositing participant is no longer in business or for some other reason cannot cover the loss, the loss will then be charged to the individual who has signed the NASD indemnification accompanying the certificate, assuming they are also not the depositing participant.

If the loss allocation method as described above still does not cover the total amount of the loss related to the deposit of the nontransferable securities, MSTC will then charge the loss in accordance with MSTC's standard loss provision rules.[9]

II. Discussion

The Commission believes that MSTC's proposed rule change is consistent with section 17A of the Act and, specifically, with section 17A(b)(3)(A) and (F) thereunder.[10] Sections 17A(b)(3)(A) and (F) of the Act require that a clearing agency be organized and its rules be designed to enable it to facilitate the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in its custody or control or for which it is responsible. In addition, section 17A(a)(1) encourages the adoption of efficient and effective procedures for the clearance and settlement of securities transactions.

The Commission believes that MSTC's proposal will reduce the costs and inefficiencies associated with the clearance and settlement of nontransferable securities by bringing the benefits of centralized, automated book-entry clearance and settlement to nontransferable issues. At the present time, there are approximately 1,500 nontransferable issues at MSTC.[11] As a result of the proposed rule, which would enable the participants to deposit these nontransferable issues at MSTC, participants will be able to reduce their physical vault inventory, which will in turn allow them to reduce processing expense, audit time and interest expense that results from outstanding fails to deliver. This, in turn, will eventually allow participants to minimize their total overhead by reducing staff and insurance costs.

The proposed procedure also promotes industry efforts to immobilize securities certificates and to maximize efficiency in securities processing. Under the new procedures, MSTC will provide participants with uniform information regarding the status of nontransferable issues through a central database of information. This will eliminate the need for each participant to individually determine the status of an issue and will reduce the time and cost currently incurred by individual monitoring. The change, therefore, is consistent with section 17A(b)(3)(F) in that it removes impediments to and perfects the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.

MSTC has established several safeguards under the nontransferable securities program to minimize the risk of loss in the event that a certificate is found to have a defect in title or is reported as lost, stolen, missing or

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[5] A "notorial" is a legal form which is used to validate a signature when a security ceases to be active.

[6] The NASD Ownership Transfer Indemnification Stamp acknowledges that the transfer books for a specific stock issue have been closed and indemnifies future parties holding the certificate against claims on the security.

[7] See supra, note 2, amendment to proposed rule change providing the indemnification agreement to be signed by participants in the nontransferable securities program.

[8] Telephone conversation between George T. Simon, Attorney, Foley & Lardner, MSTC, and Jonathan Kallman, Associate Director, Division of Market Regulation, Commission (December 28, 1992).

[9] Letter from George T. Simon, Foley & Lardner, MSTC, to Ari Burstein, Law Clerk, Commission (December 1, 1992).

For further details, see Rules of the Midwest Securities Trust Company, Article VI, Rule 2 (Participants Fund).

Today, the Commission is also approving a proposed rule change by The Depository Trust Company ("DTC") concerning safekeeping and depository services for nontransferable securities. See Securities Exchange Act Release No. 31873 (December 30, 1992). MSTC and DTC have proposed different procedures for the sharing of losses resulting from the deposit of nontransferable securities. The Commission believes that nothing in the Act explicitly requires uniform loss allocation schemes, as long as each such scheme is consistent with the Act.

[10] 15 U.S.C. 78q–1(b)(3) (A) and (F).

[11] Telephone conversation between David Rusoff, Attorney, Foley & Lardner, MSTC, and Ari Burstein, Law Clerk, Commission (November 10, 1992).

counterfeit. As previously discussed, in the case of physical deliveries, MSTC will physically inspect the security to verify that no notorials are attached to the security and that the appropriate NASD stamp is properly executed. In addition, each participant will warrant that there are no defects in title in a security delivered to or deposited with MSTC, that they have inquired of SIC regarding the particular security and that, as of the date of the deposit with MSTC, the security has not been reported to the SIC as lost, stolen, missing or counterfeit. Accordingly, the Commission believes that the safeguards and controls MSTC has established under the nontransferable securities program are reasonable and that the proposal is consistent with the requirements of sections 17A(b)(3)(A) and (F) of the Act in that it promotes the prompt and accurate clearance and settlement of securities transactions and assures the safeguarding of funds and securities which are in MSTC's custody or control or for which it is responsible.

MSTC received three comment letters from participants regarding the proposed rule change.[12] All of the letters were in favor of the program to accept nontransferable securities as proposed by MSTC. In addition, the Commission received one letter from a participant expressing support for the proposed rule change.[13]

One comment letter expressed concern that the deposit charge for nontransferable securities will be prohibitive and will discourage brokers from using the depository.[14] MSTC has stated that the higher deposit charge is necessary to cover the additional cost of manually checking and examining each nontransferable securities deposit. The Commission believes that the amount of the deposit charge is consistent with the requirements of section 17A(b)(3)(D) of the Act, which requires that the rules of the clearing agency provide for the equitable allocation of reasonable dues, fees and other charges among its participants, because the higher deposit charge will be allocated to processing the nontransferable securities deposits.

[12] See letter from Francis X. Hughes, Senior Vice President, United States Trust Company of New York, to Lou Klobuchar, Jr., Senior Vice President, MSTC (June 8, 1992); letter from Jan Fenty, President, The Cashiers' Association of Wall Street, to Lou Klobuchar, Jr., Senior Vice President, MSTC (June 12, 1992); and letter from Robert J. Petrizzo, Director, New York Operations, Charles Schwab & Co., Inc. to Lou Klobuchar, Jr., Senior Vice President, MSTC (June 15, 1992).

[13] See letter from Albert Howell, Vice President, Merrill Lynch, to the Commission (June 1, 1992).

[14] See supra, note 12, Cashiers' Association of Wall Street letter.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the Act, and in particular with section 17A of the Act, and with the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[15] that the proposed rule change (File No. SR–MSTC–92–07) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–293 Filed 1–6–93; 3:45 am]

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[Release No. 34–31675; File No. SR–MSTC–92–09]

Self-Regulatory Organizations; Midwest Securities Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to the Adoption of Fees for the Nontransferable Securities Program

December 30, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on December 3, 1992, the Midwest Securities Trust Company ("MSTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change (File No. SR–MSTC–92–09) as described in Items I, II and III below, which Items have been prepared primarily by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

MSTC has amended its rules to provide for the deposit, safekeeping and monitoring of nontransferable securities.[2] The proposed rule change sets forth the fees (*see Exhibit A*) to be charged under the nontransferable securities program.

[15] 15 U.S.C. 78s(b)(2).

[16] 17 C.F.R. 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] For further details concerning the nontransferable securities program, see Securities Exchange Act Release No. 31674 (December 30, 1992).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of the proposed rule change is to establish fees for the deposit, safekeeping and monitoring of nontransferable securities in connection with MSTC's nontransferable securities program. Under the proposal, MSTC will charge a deposit fee of $3.70 per deposit with a maximum of ten certificates permissible per deposit. MSTC also will charge a safekeeping fee per CUSIP per month. There are two types of safekeeping fees that will be charged under the proposed rule change. Every nontransferable CUSIP will be charged a "Position Fee" of $0.45 per CUSIP per month. In addition, where applicable, a "less active issue surcharge" will be imposed. If eight participants or less hold a position in a particular equity or corporate issue, a surcharge of $0.22 will be charged per CUSIP per month in addition to the Position Fee. If two participants or less hold a position in a particular municipal issue, a surcharge of $0.72 will be charged per CUSIP per month in addition to the Position Fee.[3]

MSTC also will divide nontransferable securities into monitored and nonmonitored classifications. For those securities that will be monitored, participants will have the option of subscribing to a service for a charge of $0.32 per CUSIP per month which will provide them with an on line inquiry of major events occurring with respect to that security, listed in chronological order. Other fees, where applicable, will be charged at existing rates.

[3] The "less active issue surcharge" is identical to the fee charged for transferable securities that are deemed "less active." Telephone conversation between David Rusoff, Attorney, Foley & Lardner, MSTC and Ari Burstein, Staff Attorney, Commission (December 11, 1992).

MSTC believes that the proposed rule change is consistent with the requirements of section 17A(b)(3)(D) of the Act, and the rules and regulations thereunder, which requires that the rules of a clearing agency provide for the equitable allocation of reasonable dues, fees and other charges among its participants.

(B) Self-Regulatory Organization's Statement on Burden on Competition

MSTC does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

MSTC has not solicited written comments with respect to the proposed rule change, and none have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b–4 thereunder, because the proposed rule change establishes or changes a due, fee, or other charge imposed by the self-regulatory organization. At any time within 60 days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of MSTC. All submissions should refer to the File No. SR–MSTC–92–09 and should be submitted by January 28, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

EXHIBIT A.—NONTRANSFERABLE FEES

Activity	Fee
Deposits[1]	$3.70
Safekeeping (per CUSIP/per month)	
Position Fee	.45
Less Active Issue Surcharges	
Less Active Equity or Corporate Issue Surcharge	[2].22
Less Active Municipal Issue Surcharge	[3].72
Optional On Line Monitoring[4] (per CUSIP/per month)	.32
Street withdrawals (COD's), Depository Delivery Instructions (DO's), and other fees, where applicable, are at existing rates.	

[1] Maximum of ten certificates permissible per deposit.
[2] Less active, in this context, is defined as 6 or less participants holding a position in the CUSIP. This fee is in addition to the Position Fee.
[3] Less active, in this context, is defined as 2 or less participants holding a position in the CUSIP. This fee is in addition to the Position Fee.
[4] MSTC will divide securities into monitored and nonmonitored classifications. For those securities that will be monitored, participants will have the option of subscribing to a service providing them with an on line inquiry of major events occurring with respect to that security, listed in chronological order.

[FR Doc. 93–294 Filed 1–6–93; 8:45 am]

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[Release No. 34–31677; File No. SR–NASD–92–59]

Self-Regulatory Organizations; Notice and Order Granting Accelerated Approval of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to an Interim Extension of the OTC Bulletin Board Service through March 31, 1993

December 31, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 21, 1992, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons, and simultaneously approving the proposal.

[4] 17 C.F.R. 200.30–3(a)(12).

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

On June 1, 1990, the NASD initiated operation of the OTC Bulletin Board Service ("OTCBB Service" or "Service") in accord with the Commission's approval of File No. SR–NASD–88–19, as amended.[1] The OTCBB Service provides a real-time quotation medium that NASD member firms can elect to use to enter, update, and retrieve quotation information (including unpriced indications of interest) for securities traded over-the-counter that are neither included in the Nasdaq System nor listed on a registered national securities exchange (collectively referred to as "unlisted securities"). Essentially, the Service supports NASD members' market making in unlisted securities through authorized Nasdaq Workstation™ units. Real-time access to quotation information captured in the Service is available to subscribers of Level 2/3 Nasdaq service as well as subscribers of vendor-sponsored services that now include OTCBB Service data. The Service is currently operating under an interim approval that expires on December 31, 1992.[2]

The NASD hereby files this proposed rule change, pursuant to section 19(b)(1) of the Act and Rule 19b–4 thereunder, to obtain authorization for an interim extension of the Service through March 31, 1993. During this interval, there will be no material change in the OTCBB Service's operational features.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

[1] Securities Exchange Act Release No. 27975 (May 1, 1990), 55 FR 19124 (May 8, 1990).

[2] Securities Exchange Act Release No. 31264 (September 30, 1992), 57 FR 46215 (October 7, 1992).

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The purpose of this filing is to ensure continuity in the operation of the OTCBB Service while the Commission considers an earlier NASD rule filing (File No. SR–NASD–92–7) that requested permanent approval of the Service. For the month of October 1992, the service reflected 12,130 market making positions based on 304 NASD member firms displaying quotations/indications of interest in 4,074 unlisted securities.[3]

During the proposed extension, foreign securities and American Depositary Receipts (collectively, "foreign/ADR issues") will remain subject to the twice-daily, update limitation that traces back to the Commission's original approval of the OTCBB Service's operation. As a result, all priced bids/offers displayed in the Service for foreign/ADR issues will remain indicative.

In conjunction with the start of the Service in 1990, the NASD implemented a filing requirement (under Section 4 of Schedule H to the NASD By-Laws) and review procedures to verify member firms' compliance with Rule 15c2–11 under the Act. During the proposed extension, this review process will continue to be an important component of the NASD's self-regulatory oversight of broker-dealers' market making in unlisted securities. The NASD also expects to work closely with the Commission staff in developing further enhancements to the Service to fulfill the market structure requirements mandated by the Securities Enforcement Remedies and Penny Stock Reform Act of 1990 ("Reform Act"), particularly section 17B of the Act.[4] The NASD notes that implementation of the Reform Act entails Commission rulemaking in several areas, including the development of mechanisms for gathering and disseminating reliable quotation/transaction information for "penny stocks."

The NASD believes that this proposed rule change is consistent with sections 11A(a)(1), 15A(b) (6) and (11), and section 17B of the Act as the statutory basis for the instant rule change proposal. Section 11A(a)(1) sets forth the Congressional findings and policy goals respecting operational enhancements to the securities markets. Basically, the Congress found that new data processing and communications techniques should be applied to improve the efficiency of market operations, broaden the distribution of market information, and foster competition among market participants. Section 15A(b)(6) requires, *inter alia*, that the NASD's rules promote just and equitable principles of trade, facilitate securities transactions, and protect public investors. Subsection (11) thereunder authorizes the NASD to adopt rules governing the form and content of quotations for securities traded over-the-counter for the purposes of producing fair and informative quotations, preventing misleading quotations, and promoting orderly procedures for collecting and disseminating quotations. Finally, section 17B contains Congressional findings and directives respecting the collection and distribution of quotation information on low-priced equity securities that are neither Nasdaq nor exchange-listed.

The NASD believes that extension of the Service through March 31, 1993 is fully consistent with the foregoing provisions of the Act.

B. Self-Regulatory Organization's Statement on the Burden on Competition

The NASD does not believe any burden will be placed on competition as a result of this filing.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The NASD requests that the Commission find good cause, pursuant to section 19(b)(2) of the Act, for approving the proposed rule change prior to the 30th day after its publication in the **Federal Register** to avoid any interruption of the Service. The current authorization for the Service extends through December 31, 1992. Hence, it is imperative that the Commission approve the instant filing on or before that date. Otherwise, the NASD will be required to suspend operation of the Service pending Commission action on the proposed extension.

The NASD believes that accelerated approval is appropriate to ensure continuity in the Service's operation pending a determination on permanent status for the Service, as requested in File No. SR–NASD–92–7. Continued operation of the Service will ensure the availability of an electronic quotation medium to support member firms' market making in approximately 4,100 unlisted equity securities and the widespread dissemination of quotation information on these securities. The Service's operation also expedites price discovery and facilitates the execution of customer orders at the best available price. From a regulatory standpoint, the NASD's capture of quotation data from participating market makers supplements the price and volume data reported by member firms pursuant to Section 2 of Schedule H to the NASD By-Laws.

The Commission finds good cause for approving the proposed rule change prior to the 30th day after the date of publishing notice of the filing thereof. Accelerated approval of the NASD's proposal is appropriate to ensure continuity in the Service's operation as an electronic quotation medium that supports NASD members' market making in these securities and that facilitates price discovery and the execution of customer orders at the best available price. Additionally, continued operation of the Service will materially assist the NASD's surveillance of trading in unlisted securities that are eligible and quoted in the Service.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by January 28, 1993.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act, that the

[3] These are average daily figures calculated for the entire month.

[4] On November 24, 1992, the NASD filed an application with the Commission for interim designation of the Service as an automated quotation system pursuant to section 17B(b) of the Act.

proposed rule change be, and hereby is, approved for a three month period, inclusive of March 31, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–295 Filed 1–6–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–31672; File No. SR–PHLX–92–4]

Self-Regulatory Organizations; Order Granting Temporary Approval of Proposed Rule Change by the Philadelphia Stock Exchange, Inc., To Amend Certain Rules to Facilitate the Trading of NASDAQ/NMS Securities on the PHLX

December 30, 1992.

On February 26, 1992, the Philadelphia Stock Exchange, Inc. ("PHLX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] The proposed rule change is designed to facilitate the trading of NASDAQ/National Market System ("NMS") securities on the PHLX pursuant to unlisted trading privileges ("UTP") or the listing of those securities on the PHLX. Notice of the proposed rule change appeared in the **Federal Register** on August 12, 1992.[2] The Commission received no comments on the proposed rule change. This order grants approval of the proposed rule change on a temporary basis through December 31, 1993.

I. Description of the Proposed Rule Change

On June 26, 1990, the Commission approved a transaction reporting plan submitted by the National Association of Securities Dealers, Inc. ("NASD"), the American Stock Exchange ("Amex"), the Boston Stock Exchange ("BSE"), the Midwest Stock Exchange ("MSE"), and the PHLX.[3] The Joint Industry Plan ("Plan") governs the collection, consolidation, and dissemination of quotation and transaction information for NASDAQ/NMS securities listed on an exchange or traded on an exchange pursuant to a grant of UTP.[4] The PHLX represented to the Commission that it has complied with the requirements and standards of the Plan, enabling the PHLX to trade NASDAQ/NMS securities pursuant to UTP.[5] The purpose of the proposed rule change is to accommodate the trading of NASDAQ/NMS securities on the PHLX pursuant to the grant of UTP or the listing of those securities on the PHLX.

The proposed rule change makes several amendments to the PHLX rules conforming the rules to the granting of UTP. These changes were described in the notice of proposed rule change,[6] and are restated below.

The proposed rule change adds Rule 233, to enable the trading of NASDAQ/NMS securities pursuant to the listing of those securities or the granting of UTP. The proposed rule change also amends existing PHLX rules to accommodate the trading of NASDAQ/NMS securities on a UTP basis:

Rule 102: Specifies that all NASDAQ/NMS securities transactions must be conducted during the applicable Exchange floor hours.

Rule 104: Provides authority for appropriate members to trade NASDAQ/NMS securities with non-floor persons under rule 233.

Rule 105: Declares that NASDAQ/NMS quotations displayed by competing markets shall have no standing in the trading crowds on the floor under the PHLX recognized quotation rule.

Rule 132: Exempts NASDAQ/NMS securities from off-board trading restrictions.

Supplementary Material .01: Includes language requiring that in the event of unusual market conditions, as determined by the Floor Procedure Committee, quotations in a given issue will not be subject to firmness provided that the Exchange also notifies the processor for NASDAQ/NMS securities.

Rule 216: Requires that every specialist trading NASDAQ/NMS securities keep records in accordance with the Commission and Exchange recordkeeping rules.

Rule 225: Incorporates provisional language for dealing with odd-lot orders in NASDAQ/NMS securities.

Rule 226: Incorporates provisional language for dealing with round-lot orders in NASDAQ/NMS securities.

Rule 229: Enables specialists trading in NASDAQ/NMS securities to receive orders over the Philadelphia Stock Exchange Automated Communication and Execution System ("PACE"), but provides that such orders will not be subject to automatic parameters set forth by the PACE rule.

Rule 455: Exempts NASDAQ/NMS securities from the short-sale rule.[7]

Rule 606: Enables telephone access to the PHLX assigned specialist for any NASDAQ system market maker.

II. Discussion

Section 12(f)(2) of the Act granted the Commission explicit authority to approve UTP in over-the-counter ("OTC") securities. Section 12(f)(2) requires the Commission, prior to approving UTP, to determine that the granting of UTP is consistent with the maintenance of fair and orderly markets and the protection of investors. The Commission believes that the proposed rule change is consistent with these goals and thus, the Commission is approving the proposed rule change on a temporary basis subject to the PHLX complying with the requirements of the Plan.

In 1985, the Commission published its policy to extend UTP to national securities exchanges in certain OTC securities provided certain terms and conditions are satisfied.[8] The

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[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 30984 (July 31, 1992), 57 FR 36114.

The PHLX initially filed the proposed rule change for immediate effectiveness, pursuant to section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b–4 thereunder. On March 13, 1992, the PHLX amended the rule change by withdrawing its request for immediate effectiveness and agreed to abide by the procedure specified in section 19(b)(2) of the Act. See letter to Christine A. Sakach, Branch Chief, National Market System Branch, Division of Market Regulation ("Division"), Commission from Michele R. Weisbaum, Assistant General Counsel, PHLX dated March 13, 1992.

On March 24, 1992, the PHLX amended the proposed rule change to clarify the exemption to the PHLX's short sale rule, Rule 455. The amended proposed rule change adopts language based on the Commission's short sale rule, Rule 10a–1. See letter to Christine A. Sakach, Branch Chief, National Market System Branch, Division, Commission, from William W. Uchimoto, General Counsel, PHLX, dated March 24, 1992.

On June 30, 1992, the PHLX submitted a request for accelerated approval of the proposed rule change. See letter to Elizabeth MacGregor, Branch Chief, National Market System Branch, Division, Commission, from William W. Uchimoto, General Counsel, PHLX, dated June 30, 1992.

[3] Securities Exchange Act Release No. 28146 (June 26, 1990), 55 FR 27917.

[4] The Plan also superseded an interim transaction reporting plan filed by the NASD and the MSE and approved by the Commission on April 29, 1987. See Securities Exchange Act Release No. 24407 (April 29, 1987), 52 FR 17349.

[5] See letter to Kathryn Natale, Assistant Director, Division, Commission, from William Uchimoto, General Counsel, PHLX, dated June 18, 1992.

[6] See Securities Exchange Act Release No. 30984 (July 31, 1992), 57 FR 36114.

[7] See SR–NASD–92–12 (April 9, 1992), the NASD's proposed rule change to limit short sales of NASDAQ/NMS securities. Securities Exchange Act Release No. 31003 (August 6, 1992), 57 FR 36421.

The PHLX has filed a comment letter with the Commission in connection with the NASD's proposed short sale rule (File No. SR–NASD–92–12), expressing opposition to the proposal. Among other things, the PHLX asserted that the NASD's proposed short sale rule would not be effective and would result in unequal regulation between NASD market makers and exchange option market makers in NASDAQ/NMS securities. The PHLX represented, however, that if the Commission approves the NASD's proposed short sale rule, the PHLX would cooperate in good faith to create comparable short sale regulations applicable to exchange trading in NASDAQ/NMS securities pursuant to Commission approval of OTC/UTP. See letter to Anthony R. Bosch, Attorney, Division, Commission, from William W. Uchimoto, General Counsel, PHLX, dated December 11, 1992.

[8] Securities Exchange Act Release No. 22412 (September 16, 1985), 50 FR 38040.

Commission's policy stated that UTP approval would be conditioned, in part, on the approval of a plan to consolidate and disseminate exchange and OTC quotation data and transaction data upon which UTP is granted.[9] As noted above, the Commission approved a Plan to provide for the collection, consolidation, and dissemination of quotation and transaction information for NASDAQ/NMS securities listed on an exchange or traded on an exchange pursuant to a grant of UTP.[10] Securities approved for UTP on the PHLX pursuant to section 12(f)(1)(C) will be reported in the consolidated transaction reporting system established under the Plan.[11]

In approving the Plan, the Commission noted that the Plan should enhance market efficiency and fair competition, avoid investor confusion, and facilitate regulatory surveillance of concurrent exchange and OTC trading. The Commission believes that the proposed rule change will further promote these goals and the development of a National Market System.

The Commission reasserts the obligation of the UTP participants to evaluate the effect of OTC/UTP trading on the OTC market. The UTP participants should evaluate the quality of execution of customer orders and whether the Plan facilitates the goals of a National Market System. The UTP participants also should develop an intermarket trading linkage and an accompanying trade-through rule.

Recently, the PHLX filed a separate proposed rule change to prevent the potential abuse of the informational advantage that options traders could acquire from the equity floor.[12] The Commission is approving the instant proposed rule change for one year, through December 31, 1993, while it monitors the side-by-side trading concerns.

Approval of the proposed rule change also is limited to providing the PHLX authority to submit applications for securities for OTC/UTP in 100 NASDAQ/NMS securities. The PHLX must submit OTC/UTP applications to the Commission for specific securities for approval pursuant to section 12(f) of the Act. In considering an application for extension of UTP to an OTC security under section 12(f)(1)(C), the Commission is required to consider, among other matters, the public trading activity in the security, the character of that trading, the impact of an extension of UTP on the existing markets for the security, and the desirability of removing impediments to and the progress that has been made toward the development of a National Market System.

III. Conclusion

For the reasons stated above, the Commission believes that it would be appropriate, pursuant to sections 11A and 12 of the Act and under the terms of the Plan, for the PHLX to trade NASDAQ/NMS securities pursuant to UTP, assuming those securities otherwise meet the requirements of OTC/UTP.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act, that the proposed rule change be, and hereby is, approved, on a temporary basis through December 31, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–296 Filed 1–6–93; 8:45 am]

BILLING CODE 8010–01–M

[9] The Commission determined that an intermarket trading linkage, accompanied by a trade-through rule, was not necessary during the initial stages of trading of OTC/UTP securities. The Commission, however, encouraged the NASD and exchanges to develop through their own initiatives an intermarket trading linkage and a trade-through rule. The Commission also noted that despite a formal linkage the Plan participants are subject to fiduciary obligations to seek best execution of customer orders and to the requirements of the firm quote rule, Rule 11Ac1–1. *Id.*

[10] See note 3.

[11] As noted above, the PHLX represented to the Commission that it has complied with its requirements under the Plan. *See supra* note 5. The Commission emphasizes the PHLX specialists trading NASDAQ/NMS securities pursuant to the grant of UTP will be subject to Plan requirements as well as PHLX By-Laws and Rules. For example, PHLX specialists will be required to display limit orders that better the market. PHLX Rules, Rule 118. This requirement is similar to the requirement imposed on MSE specialists under MSE rules.

[12] See Securities Exchange Act Release No. 31453 (November 11, 1992), 57 FR 54884.

[Investment Company Act Rel. No. 19201; 812–8178]

The Munder Funds, Inc., et al.; Notice of Application

December 31, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 ("Act").

APPLICANTS: The Munder Funds, Inc., (the "Fund") and Ascher/Decision Services, Inc. (the "Distributor").

RELEVANT ACT SECTIONS: Exemption requested pursuant to section 6(c) from the provisions of sections 2(a)(32), 2(a)(35), 22(c), and 22(d) and rule 22c–1.

SUMMARY OF APPLICATION: Applicants seek an order that would permit them to impose a contingent deferred sales charge ("CDSC") on the redemption of certain shares and to waive the CDSC in certain specified instances.

FILING DATE: The application was filed on November 20, 1992 and amended on December 29, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street, NW., Washington, DC 20549. Applicants, 777 South Figueroa, 38th Floor, Los Angeles, California 90017.

FOR FURTHER INFORMATION CONTACT: James E. Anderson, Staff Attorney, at (202) 272–7027, or C. David Messman, Branch Chief, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. The Fund, a Maryland corporation, is an open-end management investment company registered under the Act. Munder Capital Management, Inc. serves as investment adviser to the Fund. Distribution services for the Fund are presently provided by the Distributor.

2. Initially the Fund intends to offer one class of shares in The Munder Multi-Seasons Growth Fund (the "Portfolio"). The Fund intends to seek regulatory authority to issue one or more additional classes of shares of the Portfolio. Applicants seek an order that would permit the Fund, and any existing or future open-end investment company which is or may become a member of the Munder "group of investment companies" as that term is

defined in rule 11a–3 under the Act and which employs a CDSC under the same terms and conditions as those described in this application, to impose a CDSC on certain redemptions of shares.

3. Under the proposed CDSC arrangement, the amount of the CDSC will depend on the number of years since the purchase of the shares being redeemed. The amount of the CDSC will range from 5% for redemptions made during the first year after purchase to 1% for redemptions made in the sixth year after purchase. No CDSC will be charged on shares of a Portfolio purchased prior to the date that an order is issued pursuant to this application.

4. No CDSC will be imposed on shares representing capital appreciation or purchased with reinvested income dividends or capital gains distributions. In determining the applicability and rate of any CDSC, it will be assumed that a redemption is made first of shares representing capital appreciation, next of shares representing payment of dividends, and finally of other shares held by the shareholder for the longest period of time. As a result, any charge will be imposed at the lowest possible rate. The applicants will not impose a CDSC on shares issued prior to receipt of the requested relief.

5. Applicants request the ability to waive the CDSC in the case of redemptions in connection with: (a) Redemptions by investors who have invested $1 million or more in the Portfolio; (b) redemptions by the officers, directors, and employees of Munder Capital Management, Inc. or the Distributor and such persons' immediate families; (c) dealers or brokers who have a sales agreement with the Distributor, for their own accounts, or for retirement plans for their employees or sold to registered representatives or full-time employees (and their families) that certify to the Distributor at the time of purchase that such purchase is for their own account (or for the benefit of their families); and (d) involuntary redemptions effected pursuant to the Portfolio's right to liquidate shareholder accounts having an aggregate net asset value of less than $500.

6. The applicants propose to provide a *pro rata* credit for any CDSC paid in connection with a redemption of shares followed by a reinvestment effected within 90 days of the redemption. The credit will allow investors who erroneously redeemed or otherwise had second thoughts about having redeemed their shares to reinvest the proceeds plus the amount of any CDSC paid. The credit will be paid for by the Distributor.

Applicants' Legal Conclusion

Applicants believe that implementation of the CDSC in the manner and under the circumstances described above would be fair and in the best interests of the shareholders of the Fund. Thus the granting of the requested order would be appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Consequently, applicants request an order of the Commission pursuant to section 6(c) of the Act for an exemption from the provisions of sections 2(a)(32), 2(a)(35), 22(c), and 22(d) of the Act and rule 22c-1 thereunder to the extent necessary to permit the proposed CDSC arrangement.

Applicants' Condition

Applicants agree that any order granting the requested relief will be subject to the following condition:

Applicants will comply with the provisions of proposed rule 6c-10 under the Act, Investment Company Act Release No. 16619 (Nov. 2, 1988), as such rule is currently proposed, and as it may be reproposed, adopted, or amended.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–297 Filed 1–6–93; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–19202; 811–4877]

Titan Institutional Investments, Inc.; Notice of Application

December 31, 1992.

AGENCY: Securities and Exchange Commission ("SEC" or "Commission").

ACTION: Notice of application for deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: Titan Institutional Investments, Inc.

RELEVANT ACT SECTION: Section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on January 28, 1992 and amended on November 27, 1992.

HEARING OR NOTIFICIATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. and January 25, 1993, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street, NW., Washington, DC 20549. Applicant, 31 West 52nd Street, New York, NY 10019.

FOR FURTHER INFORMATION CONTACT: Elaine M. Boggs, Staff Attorney, at (202) 272–3026, or Nancy M. Rappa, Branch Chief, at (202) 272–3030 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end diversified investment company that was organized as a corporation under the laws of Maryland. On October 20, 1986, applicant filed a notification of registration pursuant to section 8(a) of the Act. Applicant has not filed any registration statement pursuant to the Securities Act of 1933.

2. On September 4, 1991, applicant's board of directors approved a plan of complete liquidation and dissolution and recommended it be approved by shareholders. At a meeting held on September 19, 1991, applicant's shareholders approved the liquidation.

3. A notice of liquidating distribution was mailed by on July 31, 1992 to applicant's shareholders of record and a notice of liquidating distribution was published in The New York Times on August 13, August 20, and August 27, 1992. Such notices indicated that shareholders of record of applicant had until October 31, 1992 to prove their interests in assets of applicant to be distributed.

4. On November 20, 1992, applicant made a liquidating distribution to its shareholders in an amount equal to $3,884, representing a net asset value of $20.90 per share for each of the 185.862 shares outstanding.

5. There were seven shareholders whose whereabouts applicant could not ascertain after diligent efforts, to whom checks were mailed in complete liquidation of their interests at their respective addresses of record. Those

checks that are returned unclaimed will be held by Investors Bank and Trust Company, applicant's transfer and dividend disbursing agent, and will remain there during the applicable escheatment period.

6. Applicant incurred approximately $172,525 in liquidation-related expenses, consisting primarly of legal, accounting, and transfer agent fees.

7. There are no securityholders to whom distributions in complete liquidation of their interests have not been made. Applicant has no debts or other liabilities that remain outstanding. Applicant is not a party to any litigation or administrative proceeding.

8. On July 20, 1992, articles of dissolution were filed and approved by the State Department of Assessments and Taxation of Maryland.

9. Applicant is not now engaged, nor does it purpose to engage, in any business activities other than those necessary for the winding up of its affairs.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–298 Filed 1–6–93; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 101

Administration; Delegation of Authority, Branch Claims Review Committee

AGENCY: Small Business Administration.

ACTION: Notice Delegating Authority to Establish a Branch Claims Review Committee.

SUMMARY: This notice delegates authority to certain specific Small Business Administration (SBA) branch offices to establish a Branch Claims Review Committee. The authority to constitute a claims review committee in the enumerated branch offices is based upon the education, training, and experience of such office's personnel as well as its staffing level and loan volume.

EFFECTIVE DATE: This notice is effective January 7, 1993.

FOR FURTHER INFORMATION CONTACT: Earl L. Chambers; Director, Office of Portfolio Management; U.S. Small Business Administration; 409 Third Street, SW.; Washington, DC 20416; Tel. (202) 205–6481.

SUPPLEMENTARY INFORMATION: Elsewhere in today's **Federal Register**, SBA is publishing a final rule amending Section 101.3-2 of part 101, title 13, Code of Federal Regulations, to set forth a standard delegation of authority to SBA branch offices for the establishment of a Branch Claims Review Committee. However, this regulation states that Branch Claims Review Committees will not be organized in each SBA Branch Office. Rather, the rule provides that, in order to create a Branch Claims Review Committee in a particular SBA Branch Office, a notice must be published in the **Federal Register** specifically designating such office. This system ensures that only those SBA Branch offices with sufficient staff and portfolio volume have the authority to undertake compromise activities.

The Agency believes that, when appropriate, delegating increased levels of authority to field office personnel yields increased benefits for program participants and SBA. SBA claims review committees are established for the purpose of determining the action SBA will take with respect to debts owed the Agency. Specifically, the various claims review committees have authority, at differing amounts depending upon their organizational level, to reach settlement on primary obligations or other evidence of an indebtedness owed the SBA for an amount less than the total amount due thereon. It is essential that the Agency have qualified field personnel process expeditiously and accurately the matters submitted to the various claims review committees. Only certain designated Agency branch offices are authorized to establish Branch Claims Review Committees in light of its personnel and the large size of its portfolio. This system allows for loan debt and compromise cases being processed by the office servicing the account. In this fashion, the borrower is provided quicker and more accurate claims processing, while the Agency is benefited by maximizing its recovery on defaulted loans.

This notice delegates authority to specific SBA branch offices to constitute a Branch Claims Review Committee. The SBA branch offices in Sacramento, California; Springfield, Illinois; and Milwaukee, Wisconsin have sufficient loan volume and personnel. Thus, these offices are delegated authority to establish a Branch Claims Review Committee pursuant to the authority set forth at paragraph (a) of part V of 13 CFR 101.3-2.

This delegation of authority to establish a Branch Claims Review Committee is contingent upon the above named branch offices maintaining their current level of loan approval authority.

Dated: December 28, 1992.

Charles R. Hertzberg,

Assistant Administrator for Financial Assistance.

[FR Doc. 93–16 Filed 1–6–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF STATE

Bureau of Oceans and International Environmental and Scientific Affairs

[Public Notice 1750]

Conservation Measures for Antarctic Fishing Under the Auspices of the Commission for the Conservation of Antarctic Marine Living Resources

AGENCY: Bureau of Oceans and International Environmental and Scientific Affairs, State.

ACTION: Notice.

SUMMARY: At its Eleventh Annual Meeting in Hobart, Tasmania, October 26 to November 6, 1992, the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR), of which the United States is a member, adopted the conservation measures and the resolution listed below, pending countries' approval, pertaining to fishing in the CCAMLR Convention Area in Antarctic waters. These were agreed upon in accordance with article IX, paragraph 6(A) of the Convention for the Conservation of Antarctic Marine Living Resources. The measures restrict overall catches of certain species of fish, prohibit the taking of certain species of fish, list the fishing seasons, and define reporting requirements.

DATES: Persons wishing to comment on the measures or desiring more information should submit written comments within 30 days of the publication of this notice in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Ray Arnaudo, Chief, Division of Polar Affairs, Office of Oceans Affairs (OES/OA), room 5801, Department of State, Washington, DC 20520, (202) 647–3262.

SUPPLEMENTARY INFORMATION:

Conservation Measures Adopted at the Eleventh Annual Meeting of CCAMLR.

At its Eleventh Annual Meeting in Hobart, Tasmania, October 26 to November 6, 1992, the Commission for the Conservation of Antarctic Marine Living Resources (CCAMLR) adopted the following conservation measures and one resolution. The conservation measures addressing catch limitations

were adopted in accordance with Conservation measure 7/V and therefore enter into force immediately.

Conservation Measures Adopted This Year

Conservation Measure 44/XI

Limitation of the Total Catch of *Dissostichus eleginoides* in Statistical Subarea 48.4 in the 1992/93 Season

The Commission,

Endorsing the application of Chile to conduct a new fishery on *Dissostichus eleginoides* in Statistical Subarea 48.4 in accordance with Conservation Measure 31/X,

Welcoming the invitation of Chile for one scientist to participate as an observer onboard the vessel fishing for *Dissostichus eleginoides*,

Noting that no other Member has notified the Commission of proposals to establish a new fishery for this species and Statistical Subarea,

Agrees that no other fishing shall occur for *Dissostichus eleginoides* in Statistical Subarea 48.4 in the 1992/93 season,

Hereby adopts the following Conservation Measure in accordance with Article IX of the Convention:

1. The new fishery by Chile for *Dissostichus eleginoides* in Statistical Subarea 48.4 in 1992/93 shall be limited to 240 tons.

2. For the purposes of this new fishery for *Dissostichus eleginoides* in Statistical Subarea 48.4 the 1992/93 fishing season is defined as the period from 6 November 1992 to the close of the Commission meeting in 1993.

3. Full data shall be provided to the CCAMLR Secretariat for consideration by the Working Group on Fish Stock Assessment and Scientific Committee, as specified in CCAMLR–XI/7, supplemented by SC–CCAMLR–XI, paragraph 3.45.

Conservation Measure 45/XI

Precautionary Catch Limitation on *Euphausia superba* in Statistical Division 58.4.2

The total catch of *Euphausia superba* in Statistical Division 58.4.2 shall be limited to 390,000 tons in any fishing season. A fishing season begins on 1 July and finishes on 30 June of the following year.

This limit shall be kept under review by the Commission, taking into account the advice of the Scientific Committee. For the purposes of implementing this Conservation Measure, the catches shall be reported to the Commission on a monthly basis.

Conservation Measure 46/XI

Allocation of Precautionary Catch Limit on *Euphausia superba* in Statistical Area 48 (Conservation Measure 32/X) to Statistical Subareas

If the total catch of *Euphausia superba* in Statistical Subareas 48.1, 48.2 and 48.3 in any fishing season exceeds 620,000 tons, then catches in the following Statistical Subareas shall not exceed the precautionary catch limit prescribed below:

	Subarea	Tons
Antarctic Peninsula	48.1	420,000
South Orkney Islands	48.2	735,000
South Georgia	48.3	360,000
South Sandwich Islands	48.4	15,000
Weddell Sea	48.5	75,000
Bouvet Island region	48.6	300,000

Notwithstanding these subareal limits, the total sum of catches in any fishing season in all Subareas shall not exceed the precautionary catch limit of 1.5 million tons for the whole of Statistical Area 48 prescribed by Conservation Measure 32/X. A fishing season begins on 1 July and finishes on 30 June of the following year.

The above precautionary catch limits shall apply to the fishing seasons 1992/93 and 1993/94 after which time they will be reviewed by the Commission, taking into account the advice of the Scientific Committee.

For the purpose of implementing this Conservation Measure, the catches shall be reported to the Commission for each Statistical Subarea on a monthly basis.

Conservation Measure 47/XI

Scientific Research Exemption Provisions

This Conservation Measure is adopted in accordance with article IX of the Convention.

1. Catches taken during fishing for research purposes by commercial fishing or fishery support vessels, or vessels of a similar catching capacity, will be considered as part of any catch limit.

2. For the purposes of implementing this conservation measure, the catch reporting procedure set out in Conservation Measure 51/XI shall apply whenever the catch within any five-day reporting period exceeds 5 tons, unless more specific regulations apply to the particular species.

Conservation Measure 48/XI

Prohibition of Directed Fishery on *Notothenia gibberifrons*, *Chaenocephalus aceratus*, *Pseudochaenichthys georgianus*, *Notothenia squamifrons* and *Patagonotothen guntheri*, in Statistical Subarea 48.3 for the 1992/93 and 1993/94 Seasons

This Conservation Measure is adopted in accordance with Conservation Measure 7/V:

Directed fishing on *Notothenia gibberifrons*, *Chaenocephalus aceratus*, *Pseudochaenichthys georgianus*, *Notothenia squamifrons* and *Patagonotothen guntheri* in Statistical Subarea 48.3 is prohibited in the 1992/93 and 1993/94 seasons, defined as the period from 6 November 1992 to the end of the Commission meeting in 1994.

Conservation Measure 49/XI

Limitation of the Total Catch of *Champsocephalus gunnari* in Statistical Subarea 48.3 in the 1992/93 Season

This Conservation Measure is adopted in accordance with Conservation Measure 7/V:

1. The total catch of *Champsocephalus gunnari* in the 1992/93 season, which shall commence on 6 November 1992 shall not exceed 9 200 tons in Statistical Subarea 48.3.

2. The fishery for *Champsocephalus gunnari* in Statistical Subarea 48.3 shall close if the by-catch of any of the species listed in Conservation Measure 50/XI reaches their by-catch limit or if the total catch of *Champsocephalus gunnari* reaches 9 200 tons, whichever comes first.

3. if, in the course of the directed fishery for *Champsocephalus gunnari*, the by-catch of any one haul of any of the species named in Conservation Measure 50/XI exceeds 5%, the fishing vessel shall move to another fishing ground within the subarea.

4. The use of bottom trawls in the directed fishery for *Champsocephalus gunnari* in Statistical Subarea 48.3 is prohibited.

5. The fishery for *Champsocephalus gunnari* in Statistical Subarea 48.3 shall be closed from 1 April 1993 until the end of the Commission meeting in 1993.

6. For the purpose of implementing paragraphs 1 and 2 of this Conservation Measure:

(i) The Five-day Catch and Effort Reporting System set out in Conservation Measure 51/XI shall apply in the 1992/93 season commencing on 6 November 1992.

(ii) The Monthly Effort and Biological Data Reporting System set out in

Conservation Measure 50/XI shall apply for *Champsocephalus gunnari* and all by-catch species listed in Conservation Measure 50/XI in the 1992/93 season, commencing on 6 November 1992.

Conservation Measure 50/XI

Limitation of the By-catch of *Notothenia gibberifrons, Chaenocephalus aceratus, Pseudochaenichthys georgianus, Notothenia rossii* and *Notothenia squamifrons*, in Statistical Subarea 48.3 for the 1992/93 Season

This Conservation Measure is adopted in accordance with Conservation Measure 7/V:

In any directed fishery in Statistical Subarea 48.3, during the 1992/93 season commencing 6 November 1992, the by-catch of *Notothenia gibberifrons* shall not exceed 1470 tons; the by-catch of *Chaenocephalus aceratus* shall not exceed 2200 tons; and the by-catch of *Pseudochaenichthys georgianus, Notothenia rossii* and *Notothenia squamifrons* shall not exceed 300 tons each.

Conservation Measure 50/XI

Five-day Catch and Effort Reporting System

This Conservation Measure is adopted in accordance with Conservation Measure 7/V where appropriate:

1. For the purposes of this Catch and Effort Reporting System the calendar month shall be divided into six reporting periods, viz: day 1 to day 5, day 6 to day 10, day 11 to day 15, day 16 to day 20, day 21 to day 26 and day 26 to the last day of the month. These reporting periods are hereinafter referred to as periods A, B, C, D, E and F.

2. At the end of each reporting period, each Contracting Party shall obtain from each of its vessels its total catch and total days and hours fished for that period and shall, by cable or telex, transmit the aggregated catch and days and hours fished for its vessels so as to reach the Executive secretary not later than the end of the next reporting period.

3. The catch of all species, including by-catch species, must be reported.

4. Such reports shall specify the month and reporting period (A, B, C, D, E or F) to which each report refers.

5. Immediately after the deadline has passed for receipt of the reports for each period, the Executive Secretary shall notify all Contracting Parties engaged in fishing activities in the area, of the total catch taken during the reporting period, the total aggregate catch for the season to date together with an estimate of the date upon which the total allowable catch is likely to be reached for that season. The estimate shall be based on a projection forward of the trend in daily catch rates, obtained using linear regression techniques from a number of the most recent catch reports.

6. At the end of every six reporting periods, the Executive Secretary shall inform all Contracting Parties of the total catch taken during the five most recent reporting periods, the total aggregate catch for the season to date together with an estimate of the date upon which the total allowable catch is likely to be reached for that season.

7. If the estimated date of completion of the TAC is within five days of the date on which the Secretariat received the report of the catches, the Executive Secretary shall inform all Contracting Parties that the fishery will close on that estimated day or on the day on which the report was received, whichever is the later.

Conservation Measure 52/XI

Monthly Effort and Biological Data Reporting System for Trawl Fisheries

This Conservation Measure is adopted in accordance with Conservation Measure 7/V, where appropriate:

1. Specification of "target species" and "by-catch" species referred to in this Conservation Measure shall be made in the Conservation Measure to which it is attached.

2. At the end of each month each Contracting Party shall obtain from each of its vessels the data required to complete the CCAMLR fine-scale catch and effort data form for trawl fisheries (Form C1, latest version). It shall transmit those data to the Executive Secretary not later than the end of the following month.

3. The catch of all species, including by-catch species, must be reported.

4. At the end of each month each Contracting Party shall obtain from each of its vessels representative samples of length composition measurements of the target species and by-catch species from the fishery (Form B2, latest version). It shall transmit those data to the Executive Secretary not later than the end of the following month.

5. Failure by a Contracting Party to provide the fine-scale catch and effort data or length composition data for three consecutive months shall result in the closure of the fishery to vessels of that Contracting Party. If the Executive Secretary has not received length composition data for two consecutive months he shall notify the Contracting Party that the fishery will be closed to that Contracting Party unless those data (including arrears of data) are provided by the end of the next month. If at the end of the next month those data have still not been provided, the Executive Secretary shall notify all Contracting Parties of the closure of the fishery to vessels of the Contracting Party which has failed to supply the data as required.

6. For the purpose of implementing this Conservation Measure;

(i) Length measurements of fish should be of total length, to the nearest centimeter below;

(ii) Representative samples of length composition should be taken from a single fishing ground. In the event that the vessel moves from one fishing ground to another during the course of a month, then separate length compositions should be submitted for each fishing ground.

Note: Pending the provision of a more appropriate definition, the term fishing ground is defined here as the area within a single fine-scale grid rectangle (0.5° latitude by 1° longitude).

Conservation Measure 53/XI

Limitation of the Total Catch of *Electrona carlsbergi* in Statistical Subarea 48.3 for the 1992/93 Season

This Conservation Measure is adopted in accordance with Conservation Measure 7/V:

1. For the purposes of this Conservation Measure the fishing season for *Electrona carlsbergi* is defined as the period from 6 November 1992 to the end of the Commission meeting in 1993.

2. The total catch of *Electrona carlsbergi* in the 1992/93 season shall not exceed 245,000 tons in Statistical Subarea 48.3.

3. In addition, the total catch of *Electrona carlsbergi* in the 1992/93 season shall not exceed 53,000 tons in the Shag Rocks region, defined as the area bounded by 52°30′S, 40°W; 52°30′S, 44°W, 54°30′S, 40°W and 54°30′S, 44°W.

4. The directed fishery for *Electrona carlsbergi* in Statistical Subarea 48.3 shall close if the by-catch of any of the species detailed in Conservation Measure 50/XI reaches their by-catch limit or if the total catch of *Electrona carlsbergi* reaches 245,000 tons, whichever comes first.

5. The directed fishery for *Electrona carlsbergi* in the Shag Rocks region shall close if the by-catch of any of the species detailed in Conservation Measure 50/XI above reaches their by-catch limit or if the total catch of *Electrona carlsbergi* reaches 53,000 tons, whichever comes first.

6. If, in the course of the directed fishery for *Electrona carlsbergi*, the by-

catch of any one haul of any of the species named in Conservation Measure 50/XI exceeds 5%, the fishing vessel shall move to another fishing ground within the subarea.

7. For the purpose of implementing this Conservation Measure:

(i) The Catch Reporting System set out in Conservation Measure 41/X shall apply in the 1992/93 season; and,

(ii) The Data Reporting System set out in Conservation Measure 54/XI shall apply in the 1992/93 season.

Conservation Measure 54/XI

Biological Data Reporting System for *Electrona carlsbergi* in Statistical Subarea 48.3.

This Conservation Measure is adopted in accordance with Conservation Measure 7/V.

Each month the length composition of a minimum of 500 fish, randomly collected from the commercial fishery, will be measured and the information passed to the Executive Secretary not later than the end of the month following.

Conservation Measure 55/XI

Catch Limit on *Dissostichus eleginoides* in Statistical Subarea 48.3 for the 1992/93 Season

This Conservation measure is adopted in accordance with Conservation measure 7/V:

1. The total catch of *Dissostichus eleginoides* in Statistical Subarea 48.3 caught in the 1992/93 season shall be limited to 3 350 tons.

2. For the purposes of the fishery for *Dissostichus eleginoides* in Statistical Subarea 48.3, the 1992/93 fishing season is defined as the period from 6 December 1992(1) to the end of the Commission meeting in 1993, or until the TAC is reached, whichever is sooner.

3. For the purpose of implementing this Conservation Measure:

(i) The Five-day Catch and Effort Reporting System set out in Conservation Measure 50/XI shall apply in the 1992/93 season, commencing on 6 December 1992.

(ii) The Effort and Biological Data Reporting System set out in Conservation Measure 56/XI shall apply in the 1992/93 season, commencing on 6 December 1992.

4. There will be no increase over the 1991/92 season in the number of vessels of Members who have been fishing in the 1991/92 season for *Dissostichus eleginoides* in Subarea 48.3

Note: The December 6 date allows one month to elapse from the end of the Commission meeting in order for notification of this measure to be transmitted to the fishing vessels.

Conservation Measure 56/XI

Effort and Biological Data Reporting System for *Dissostichus eleginoides* in Statistical Subarea 48.3 for the 1992/93 Season

This Conservation Measure is adopted in accordance with Conservation Measure 7/V:

1. The end of each month, each Contracting Party shall obtain from each of its vessels the haul-by-haul data required to complete the CCAMLR fine-scale catch and effort data form for longline fisheries (Form C2, latest version). It shall transmit those data to the Executive Secretary not later than the end of the following month.

2. At the end of each month, each Contracting Party shall obtain from each of its vessels a representative sample of length composition measurements from the fishery (Form B2, latest version). It shall transmit those data to the Executive Secretary not later than the end of the following month.

3. Failure by a Contracting Party to provide either/or both of the haul-by-haul and length composition data for three consecutive months shall result in the closure of the fishery to vessels of that Contracting Party. If the Executive Secretary has not received either/or both of the haul-by-haul and length composition data for two consecutive months he shall notify the Contracting Party that the fishery will be closed to that Contracting Party unless those data (including arrears of data) are provided by the end of the next month. If at the end of the next month those data have still not been provided, the Executive Secretary shall notify all Contracting Parties of the closure of the fishery to vessels of the Contracting Party which has failed to supply the data as required.

Conservation Measure 57/XI

Prohibition of Directed Fishing for Finfish in Statistical Subarea 48.2 for the 1992/93 Season

Taking of finfish, other than for scientific research purposes, in Statistical Subarea 48.2 is prohibited in the 1992/93 season, defined as the period from 6 November 1992 to the end of the Commission meeting in 1993.

Conservation Measure 58/XI

Prohibition of Directed Fishing for Finfish in Statistical Subarea 48.1 for the 1992/93 Season

Taking of finfish, other than for scientific research purposes, in Statistical Subarea 48.1 is prohibited in the 1992/93 season, defined as the period from 6 November 1992 to the end of the Commission meeting, in 1993.

Conservation Measure 59/XI

Limitation of Total Catch of *Notothenia squamifrons* in Statistical Division 58.4.4 (Ob and Lena Banks) in the 1992/93 and 1993/94 Season

1. The total catch of *Notothenia squamifrons* for the entire two year period shall not exceed 1150 tons, which shall be made up of 715 tons on Lena Bank and 435 tons on Ob Bank.

2. The two year period shall be from 6 November 1992 to the end of the Commission meeting in 1994.

3. For the purpose of implementing this Conservation Measure:

(i) The Five-day Catch and Effort Reporting System set out in Conservation Measure 51/XI shall apply in the period 1992 to 1994 commencing, on 6 November 1992;

(ii) The Monthly Effort and Biological Data Reporting System set out in Conservation Measure 52/XI shall apply for *Notothenia squamifrons* commencing on 6 November 1992;

(iii) Age frequency and age/length keys for *Notothenia squamifrons* and any other species forming a significant part of the catch shall be collected and reported to each annual meeting of Working Group on Fish Stock Assessment for each Bank separately; and

(iv) The fishery for *Notothenia squamifrons* will be subject to review at the 1993 annual meeting of the Scientific Committee and the Commission.

Conservation Measure 60/XI

Limits on the Exploratory Crab Fishery in Statistical Area 48 in the 1992/93 Season

The following measures apply to all crab fishing within Statistical Area 48:

1. The crab fishery is defined as any harvest activity in which the target species is any member of the crab group (Order Decapoda, Suborder Reptantia).

2. The crab fishery in Statistical Area 48 shall be closed from 15 November 1992 until the CCAMLR Workshop to develop the Longterm Management Plan for crabs (planned for April or May, 1993) has met, revised the data reporting forms and provided modified forms to Members who have notified the Secretariat of their intention to fish for crabs.

3. The crab fishery shall be limited to one vessel per Member; however, if the Secretariat is notified that more than three vessels intend to fish for crabs, no more than 1000 tons shall be taken during the period from the start of the

fishery until the end of the next meeting of the Commission in 1993.

4. Each Member intending to participate in the crab fishery shall notify the CCAMLR Secretariat at least three months in advance of starting fishing of the name, type, size, registration number and radio call sign and fishing plan of the vessel that the Member has authorized to participate in the crab fishery.

5. The following data shall be reported to CCAMLR by 30 August 1993 for crabs caught prior to 30 July 1993:

(i) The location, date, depth, fishing effort (number and spacing of pots) and catch (numbers and weight) of commercially sized crabs (reported on as fine a scale as possible, but no coarser than 1° longitude by 0.5° latitude) for each 10-day period;

(ii) The species size and sex of a representative subsample of crabs and by-catch caught in traps; and

(iii) Other relevant data, as possible, according to the logbook formats already being used in the crab fishery (SC-CCAMLR-XI, Annex 5, Appendix F).

6. For the purposes of implementing this Conservation Measure the 10-day catch and effort reporting system set out in Conservation Measure 61/XI shall apply.

7. Data identified by the Workshop that are required to determine the appropriate harvest levels shall be collected during the 1993 season by all vessels fishing for crabs. These data shall be reported to CCAMLR in the form specified by the Workshop. Data on catches taken before 30 August 1993 shall be reported to the CCAMLR Secretariat by 30 September to enable the data to be available to Working Group on Fish Stock Assessment.

8. Crab fishing gear shall be limited to the use of crab pots (traps). The use of all other methods of catching crabs (e.g., bottom trawls) shall be prohibited.

9. The crab fishery shall be limited to sexually mature male crabs—all female and undersized male crabs caught shall be released unharmed. In the case of *Paralomis spinosissima* and *P. formosa*, males with a minimum carapace width of 102 mm and 90 mm, respectively, may be retained in the catch; and

10. Crab processed at sea shall be frozen as crab sections (minimum size of crabs to be determined when using crab sections).

Conservation Measure 61/XI

Ten-day Catch and Effort Reporting System

This Conservation Measure is adopted in accordance with Conservation Measure 7/V where appropriate:

1. For the purposes of this Catch and Effort Reporting System the calendar month shall be divided into three reporting periods, viz: day 1 to day 10, day 11 day 20, day 21 to the last day of the month. These reporting periods are hereinafter referred to as periods A, B and C.

2. At the end of each reporting period, each Contracting Party shall obtain from each of its vessels its total catch and total days and hours fished for that period and shall, by cable or telex, transmit the aggregated catch and days and hours fished for its vessels so as to reach the Executive Secretary not later than the end of the next reporting period.

3. The retained catch of all species and by-catch species, must be reported.

4. Such reports shall specify the month and reporting period (A, B and C) to which each report refers.

5. Immediately after the deadline has passed for receipt of the reports for each period, the Executive Secretary shall notify all Contracting Parties engaged in fishing activities in the area, of the total catch taken during the reporting period, the total aggregate catch for the season to date together with an estimate of the date upon which the total allowable catch is likely to be reached for that season. The estimate shall be based on a projection forward of the trend in daily catch rates, obtained using, linear regression techniques from a number of the most recent reports.

6. At the end of every three reporting periods, the Executive Secretary shall inform all Contracting Parties of the total catch taken during, the three most recent reporting periods, the total aggregate catch for the season to date together with an estimate of the date upon which the total allowable catch is likely to be reached for that season.

1. If the estimated date of completion of the TAC is within ten days of the date on which the Secretariat received the report of the catches, the Executive Secretary shall inform all Contracting Parties that the fishery will close on that estimated day or on the day on which the report was received, whichever is the later.

Conservation Measure 62/XI

Protection of the Seal Islands CEMP Site

1. The Commission noted that a program of longterm studies is being undertaken at the Seal Islands, South Shetland Islands, as part of the CCAMLR Ecosystem Monitoring Program (CEMP). Recognizing that these studies may be vulnerable to accidental or willful interference, the Commission expressed its concern that this CEMP site, the scientific investigations, and the Antarctic marine living resources therein be protected.

2. Therefore, the Commission considers it appropriate to accord protection to the Seal Islands CEMP site, as defined in the Seal Islands management plan.

3. Members are required to comply with the provisions of the Seal Islands CEMP site management plan, which is recorded in Annex B of Conservation Measure 18/IX.

4. To allow Members adequate time to implement the relevant permitting procedures associated with this measure and the management plan, Conservation Measure 62/XI shall become effective as of 1 May 1993.

5. In accordance with article X, the Commission shall draw this Conservation Measure to the attention of any State that is not a Party to the Convention and whose nationals or vessels are present in the Convention Area.

Conservation Measure 29/XI

Minimization of the Incidental Mortality of Seabirds in the Course of Longline Fishing or Longline Fishing Research in the Convention Area

The Commission,

Noting the need to reduce the incidental mortality of seabirds during longline fishing by minimizing their attraction to the fishing vessels and by preventing them from attempting to seize baited hooks, particularly during the period when the lines are set.

Recognizing that successful techniques for reducing the mortality of albatrosses have been employed in the longline fishery for tuna immediately to the north of the Convention Area.

Agrees to the following measures to reduce the possibility of incidental mortality of seabirds during longline fishing.

1. Fishing operations shall be conducted in such a way that the baited hooks sink as soon as possible after they are put in the water.

2. During the setting of longlines at night, only the minimum ship's lights necessary for safety shall be used.

3. Trash and offal are not to be dumped while longline operations are in progress.

4. A streamer line designed to discourage birds from settling, on baits during deployment of longlines shall be towed. The specification of the streamer line and its method of deployment is given in the Appendix to this Measure.

5. This Measure shall not apply to designated research vessels investigating better methods for

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reducing incidental mortality of seabirds.

Appendix to Conservation Measure 29/XI

1. The streamer line is to be suspended at the stern from a point approximately 4.5 m above the water and such that the line is directly above the point where the baits hit the water.

2. The streamer line is to be approximately 3 mm diameter, have a minimum length of 150 m and be weighted at the end so that it streams directly behind the ship even in cross winds.

3. At 5 m intervals commencing from the point of attachment to the ship five branch streamers each comprising two strands of approximately 3 mm diameter cord should be attached. The length of the streamer should range between approximately 3.5 m nearest the ship to approximately 1.25 m for the fifth streamer. When the streamer line is deployed the branch streamers should reach the sea surface and periodically dip into it as the ship heaves. Swivels should be placed in the streamer line at the towing point, before and after the point of attachment of each branch streamer and immediately before any weight placed on the end of the streamer line. Each branch streamer should also have a swivel at its attachment to the streamer line.

Resolution 9/XI

Scientific Research Exemption Provisions for Finfish

In accordance with Conservation Measure 47/XI, the Commission adopts the following resolutions:

1. (i) Any member planning to use commercial fishing or fishery support vessels or vessels of a similar catching capacity to conduct fishing for research purposes when the estimated catch may exceed 50 tons, shall notify and provide the opportunity for other members to review and comment on their research plans. Such plans shall be provided to the Secretariat for distribution to members at least six months in advance of the planned starting date for the research. In the event of any request for a review of such plans, the Executive Secretary shall notify all members and submit the plan to the Scientific Committee for review. Based on the submitted research plan and any advice provided by the appropriate Working Group, the Scientific Committee will provide advice to the Commission where the review process will be concluded. Until the review process is complete the planned fishing for research purposes should not proceed.

(ii) The Scientific Committee, in consultation with its Working Groups, shall develop standardized guidelines and formats for research plans.

2. (i) Until such time as the Scientific Committee, in consultation with its Working Groups, develops standardized guidelines and formats for research plans, the member planning to undertake research fishing in accordance with 1(i) above should provide the following information:

Vessel details

(a) Name of vessel;
(b) Name and address of vessel owner;
(c) Port of registration, registration number and radio call sign;
(d) Vessel type, size, fish processing and storage capacity; and
(e) Gear type, fishing capacity and anticipated catch.

Research plan

(a) A statement of the planned research objectives;
(b) A description of when, where, and what activities are planned including a fishing plan which includes the number and duration of hauls and the fishing gear to be used: and
(c) The name(s) of the chief scientific(s) responsible for the planning and coordinating the research, and the number of scientists and crew expected to be aboard the vessel(s).

3. (i) A summary of the results of any research fishing subject to the research exemption provisions shall be provided to the Secretariat within 180 days of the completion of the research fishing. A full report should be provided within 12 months.

(ii) Catch and effort data resulting, from the research fishing in accordance with I (1) should be reported to the Secretariat according to the haul-by-haul reporting format for research vessels (C4).

Other Conservation Measures in Force

The Commission agreed that conservation measures 2/III (as amended by Conservation Measure 19/IX to delete the reference to *Champsocephalus gunnari*), 3/IV 4/V, and 7/V and 18/IX, 19/IX, 29/IX (as at this year, see above), 30/X, 31/X, 32/X, and 40/X should remain in force as they stand.

Cathch Reporting

Catches of *E. superba* shall be reported on a monthly basis, as set out in Conservation Measure 45/XI and 46/XI.

Catches of *E. carlsbergi* shall be reported to the Secretariat at the end of each calendar month, according to the system described in Conservation measure 40/X. In addition, biological data should be reported every month in accordance with Conservation Measure 54/XI.

Catches of *D. eleginoides* shall be reported to the Secretariat at the end of five-day intervals, according to the system described in Conservation Measure 51/XI. In addition, biological data should be reported every month in accordance with Conservation Measure 56/XI.

Catches of *C. gunnari* and *N. squamifrons* shall be reported to the Secretariat at the end of five-day intervals, according to the system described in Conservation Measure 51/XI. In addition, biological data should be reported every month in accordance with Conservation Measure 52/XI.

Catches of crabs shall be reported to the Secretariat at the end of ten-day intervals, according to the system described in Conservation Measure 61/XI. In addition, data on all crabs caught before June 30 shall be reported to CCAMLR by August 30, in accordance with Conservation Measure 60/XI.

Catches for scientific research shall be reported to the Secretariat at the end of each five-day period whenever the catch within that period exceeds five tons.

Dated: December 24, 1992.

Raymond Arnaudo,

Chief, Division of Polar Affairs, Office of Oceans Affairs.

[FR Doc. 93-261 Filed 1-6-93; 8:45 am]
BILLING CODE 4710-09-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Environmental Impact Statement: Kitsap County, WA

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement (EIS) will be prepared for a proposed highway project in Kitsap County, Washington Telephone.

FOR FURTHER INFORMATION CONTACT: Barry F. Morehead, Division Administrator, Federal Highway Administration, 711 South Capitol Way, suite 501, Olympia, Washington, 98501. Telephone: (206) 753-2120; or Gary Demich, District Administrator, Washington State Department of Transportation, District 3, P.O. Box 9327, Olympia, Washington, 98504, Telephone: (206) 357-2605; or Dan

Elsass, City of Bremerton, 239 4th Street, Bremerton, Washington, Telephone: (206) 478-5272.

SUPPLEMENTARY INFORMATION: The FHWA, the Washington State Department of Transportation (WSDOT), and the City of Bremerton, in cooperation with Kitsap County, the U.S. Department of Defense, and Kitsap Transit, will prepare an EIS on a proposal to improve a 5.25 mile portion of SR 3 and SR 304. The proposed improvement will include adding two to four lanes on SR 3 from the Gorst railroad bridge to the SR 304 junction, and improving traffic flow on SR 304 to the ferry terminal using one-way couplets or a four lane two-way route.

Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand. The primary purpose of the proposed project is to improve transportation access to and throughout downtown Bremerton, which includes the Puget Sound Naval Shipyard and the State ferry terminal, both major regional destinations. The existing peak hour traffic volumes in the corridor result in congestion and delay for traffic associated with these destinations. Future traffic volumes are expected to rise due to the high growth rate of the region, expansion of the Puget Sound Naval Shipyard and increased ferry system usage by commuters.

Alternatives under considered on the SR 3 portion include (1) taking no action; (2) widening SR 3 along Sinclair Inlet adjacent to the roadway from the existing four lanes to six or eight lanes; or (3) adding new lanes in one direction on a higher grade then the existing roadway. Alternatives under consideration for the SR 304 portion include (1) taking no action; (2) a one way couplet; (3) a four lane facility from SR 3 to the ferry terminal. Included in all of the build alternatives are the replacement of the Gorst railroad bridge, consideration of including provisions for high occupancy vehicles (HOV), and consideration of adding a southbound to eastbound movement at the SR 3/SR 304 interchange.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, affected Indian tribes, and to private organizations and citizens who have previously expressed or are known to have interest in this proposal. A series of public meetings will be held between November 1992 and May 1993. In addition, a public hearing will be held. Public notice will be given of the time and place of the meetings and hearing. The draft EIS will be available for public and agency review prior to the public hearing.

To ensure that the full range of issues related to this proposed project are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation of federal peograms and activities apply to this program.)

Issued on: December 30, 1992.

Richard Schimelfenyg,

Area Engineer, Washington Division.

[FR Doc. 93-262 Filed 1-6-93; 8:45 am]

BILLING CODE 4910-22-M

Environmental Impact Statement: Stillwater County, MT

AGENCY: Federal Highway Administration [FHWA], DOT.

ACTION: Notice of intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an Environmental Impact Statement (EIS) will be prepared for a proposed highway project in Stillwater County, Montana.

FOR FURTHER INFORMATION CONTACT: Dale Paulson, Environmental Coordinator, Federal Highway Administration, 301 South Park, Drawer 10056, Helena, MT 59626-0056; Telephone: (406) 449-5310; or Edrie L. Vinson, Chief, Environmental and Hazardous Waste Bureau, Montana Department of Transportation, 2701 Prospect Street, Helena, MT 59620; Telephone: (406) 444-7632.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the Montana Department of Transportation (MDT), is preparing an Environmental Impact Statement for a proposal to improve the Montana Highway Route 78 corridor from the East Rosebud Creek Bridge south of Absarokee, Montana to the Yellowstone River Bridge south of Columbus, Montana.

Improvements to the corridor are considered necessary to provide for the existing and projected traffic demand. During the development of an environment assessment for this project it was determined that an environmental impact statement was required. Comments are being solicited from appropriate Federal, State, and local agencies and from private organizations and citizens who have previously expressed or are known to have interest in this proposal. Public meetings will be held in the project area and in addition a public hearing will be held. Public Notice will be given of the time and place of the meetings and hearings. The draft EIS will be available for public and agency review and comment prior to the public hearing.

To ensure that the full range of all issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments, or questions concerning this proposed action and the EIS should be directed to the FHWA, or the MDT at the addresses listed previously.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this proposed action.)

Issued on: December 29, 1992.

Hank D. Honeywell,

Division Administrator Montana Division, Helena.

[FR Doc. 93-263 Filed 1-6-93; 8:45 am]

BILLING CODE 4910-22-M

National Highway Traffic Safety Administration

[Docket No. 93-01; Notice 1]

Ford Motor Company; Receipt of Petition for Temporary Exemption From 14 Federal Motor Vehicle Safety Standards

Ford Motor Company of Dearborn, Michigan, has petitioned for a temporary exemption from 14 Federal motor vehicle safety standards for an electric panel delivery van. The basis of the petition is that an exemption will facilitate the development and field evaluation of low-emission motor vehicles.

Notice of receipt of the petition is published in accordance with agency regulations on the subject (49 CFR part 555) and does not represent any judgment of the agency of the merits of the petition.

Ford intends to manufacture up to 105 low emission experimental electric panel delivery vans, including prototypes, to be called the Ford Ecostar. The Ecostar will be leased to test fleets operated by Ford's electric vehicle development partners in the U.S. and Europe for up to three years of cooperative field testing, thus, an exemption would facilitate the development and field evaluation of it in the United States.

There appear to be three versions of the Ecostar, which will be classified as a truck for purposes of the standards. The first is a hybrid internal combustion-electric vehicle. The second is an electric vehicle with a fuel-fired heating and defrosting system. Both versions are being designed to meet the California Air Resource Board (CARB) requirements for ultra-low emissions. The third type, an electric vehicle with an electric heating/defrosting system would meet CARB's zero emission requirements. Components of these vehicles have been developed in cooperation with the United States Department of Energy, General Electric, and other suppliers.

The Ecostar is based upon an Escort delivery van manufactured by Ford of England which was designed to meet all applicable European (EEC and ECE) regulations. The van bodies would be shipped to the U.S. where the electric motor, inverter, transaxle drivetrain, batteries, controls, and other components unique to the Ecostar would be installed in the U.S. Electrical/electronic controls handling high current/voltage would be packaged outside the passenger compartment, with the exception of a fully enclosed electric heater/defroster core on those vehicles so equipped. an "advanced design battery would be located in the fuel tank space under the load floor. Hybrid vehicles would have a small, gasoline-fueled engine/alternator assembly mounted under the load floor. A hydraulic/regenerative braking system would be employed. "Limited testing" of converted Escorts indicates that the Ecostar continues to meet the EEC/ECE regulations.

Differences between U.S. and European standards, as well as the increased vehicle weight would result in noncompliances with the U.S. standards. However, in Ford's view, these noncompliances are minor in nature and would not unreasonably degrade the safety of the vehicle.

The standards, or portions thereof, from which Ford requests a 2-year exemption, are:

1. Standard No. 101 *Controls and Displays*

2. Standard No. 105 *Hydraulic Brake Systems*

S5.2.3 of Standard No. 101 and S5.3.5(b) of Standard No. 105 require a brake warning light labeled "BRAKE". The Ecostar uses the ISO brake symbol instead. Neither the heating/defrosting/air conditioning fan switch, nor the horn control, is identified as required by Standard No. 101, although the horn control is conventionally located in the center of the steering hub, and its size, shape, and location should make its function obvious to most operators. The fan switch is located with the other heating/defrosting/air conditioning controls in the center of the instrument panel. The fan speed markings (0, I, II, III), combined with location of the fan control between the temperature control and the air distribution control, have proven adequate to identify the function of the fan control switch to a European multilingual customer base without the addition of the fan ISO symbol.

In addition, some hybrid Ecostars use the ISO oil can symbol to indicate low oil level, rather than low oil pressure. Ford believes that it is appropriate to use the symbol to indicate low oil level on vehicles that do not have a pressurized internal combustion lubrication system.

Finally, certain right hand drive models to be tested by the U.S. Postal Service do not meet the requirement of S5.3.3 of Standard No. 101 for variable illumination of the displays. The right hand drive vehicle model was designed to meet only European regulations which do not have an adjustability requirement. The interest of the Postal Service came too late in the development process to add adjustment of display illumination, as Ford found there was no available space to package a dimming control without a major change to the instrument panel and wiring system. Ford believes that the fixed level of illumination provided raises no daylight or night vision issues. Only a minimal number of vehicles, six in all, would be covered by the exemption requested.

3. *Standard No. 106—Brake Hoses*

The brake hoses will not be labeled and certified according to SF.2 of the standard. However, they "appear to meet the design and performance requirements" of the standard.

4. *Standard No. 108—Lamps, Reflective Devices, and Associated Equipment*

The headlamps on the Ecostar meet European and not U.S. requirements for beam pattern photometrics. Further, the vehicles would not be equipped with side marker lamps.

Ford argues that exemptions from the photometric requirements will not unduly degrade the safety of the vehicles because the only difference is that the European beam pattern does not provide the lighting above the horizontal that U.S. headlamps provide to illuminate passive and reflectorized overhead signs. This should not have adverse safety implications because the limited fleet of Ecostars will be operated in urban areas with generally high nighttime ambient lighting. Although the Ecostars do not have front and rear side marker lamps, the taillamps "are very visible from the side of the vehicle, although they probably do not meet all of the Standard 108 detailed photometric requirements for side marker lamps."

5. *Standard No. 120—Tire Selection and Rims for Motor Vehicles Other Than Passenger Cars*

As permitted by S5.1.1 of Standard No. 120, Ford plans to use a passenger car tire on its "light truck" Ecostar, specifically, a tire that has been developed especially for use on electric vehicles. The tire will meet Standard No. 109's requirements, except for maximum allowable inflation pressure. The pressure will be 350 Kpa (51 psi). Recommended tire pressure will be 50 psi for both front and rear tires. The load rating will be based on an inflation pressure of 240 Kpa (35 psi), then derated by 10% as specified by S5.1.2. Ford notes that both the Rubber Manufacturers Association and the European Tyre and Rim Technical Organization have petitioned NHTSA for rulemaking to amend Standard No. 109 to include a maximum tire pressure of 350 Kpa.

6. *Standard No. 115—Vehicle Information Number (VIN)*

Without being specific, Ford states that the VIN "may not meet certain U.S. requirements." It notes that any recall would be facilitated through Ford's retention of title to the vehicles.

7. *Standard No. 204—Steering Column Rearward Displacement*

Frontal barrier tests indicate that "some versions of the experimental Ecostar, particularly the hybrid-electric vehicles equipped with internal combustion engines," may not meet the requirements of this standard because of the added weight of the internal combustion engine. However, an Ecostar tested at a weight similar to the Standard No. 204 test weight met the displacement criterion. Although that test is an insufficient basis upon which to certify compliance of the hybrid vehicles, any deviation from compliance by the hybrids is likely to be small. Considering the Ford intends to produce only 26 hybrid vehicles, "the vehicle operating characteristics, and the expected operating pattern of these vehicles, Ford believes that the steering columns of these vehicles would not represent any meaningful degradation in operating safety."

8. *Standard No. 207—Seating Systems*

9. *Standard No. 210—Seat Belt Assembly Anchorages*

Seats, seat anchorages, and seat belt anchorages "meet U.S. anchorage strength specifications when tested by the European strength test procedure, but may not meet when tested with the longer loading and holding periods of the U.S. test procedure." However, "seats and safety belts that meet the EEC/ECE strength test have proven to be very effective over many years of highway experience."

10. *Standard No. 208—Occupant Crash Protection*

Paragraph S4.6.1 requires that instrumented dummies meet various criteria in 30 mph frontal barrier crashes. Ford has not tested the Ecostar with instrumented dummies. The Ecostar, however, is derived from the European Escort car and its panel delivery van, both of which have been designed to meet Standard No. 208's dummy criteria. Further, the electric vehicle modifications to the van structure have been designed to maintain crash integrity, although tests indicate that the heaviest versions may not meet U.S. standards for steering column displacement and windshield zone intrusion.

Ford believes that the Ecostar may be able to meet requirements of Standard No. 208 that differ from EEC/ECE requirements (e.g., belt contact force, latchplate access, and retraction) but it has no plans to conduct testing because of "our inability to certify compliance" with other sections of Standard No. 208, especially S4.6.1.

In addition, the European restraint system does not have the audible seat belt reminder, as required by S7.3.

Standard No. 208 also requires that vehicles be equipped with seat belt assemblies that conform to Standard No. 209. Ford states that the belts may not have the marking required by S4.1(j) but meet all other requirements.

11. Standard No. 212—Windshield Mounting

A frontal barrier impact of a maximum weight Ecostar showed a windshield retention of 73.4 percent, a minor deviation from the required minimum of 75 percent. However, retention was not measured until about 2 months after the test, following removal and storage of the vehicle. Thus, Ford is unsure whether the hybrid Ecostar conforms, but that it appears that most Ecostars will.

12. Standard No. 216—Roof Crush Resistance

This standard becomes effective for light trucks beginning September 1, 1993. Ford has not tested the Ecostar for compliance with the standard, and believes that assembly of most Ecostars will be completed by then. In its comments to the notice of proposed rulemaking on extension of the standard, Ford raised the issue of inapposite test platen placement, which remains unresolved. Because Ford does not know how the agency would conduct a test on the Ecostar, it cannot judge the complaince status of its vehicle.

13. Standard No. 219—Windshield Zone Instrusion

The hybrids may also not comply with Standard No. 219, though "[l]imited testing indicates that the electric Ecostar probably meets EEC/ECS requirements." The frontal barrier tests were not performed primarily to determine compliance with Standard No. 219, and hence did not use the styrofoam form on the windshield to determine intrusion into the windshield zone. The test of the Hybrid Ecostar showed light contact between the hood and the lower portion of the windshield, and thus Ford could not certify compliance without further testing. The contact noted was "so near the lower edge of the windshied that the contacted area is quite unlikely to be approached by an occupant's head in a frontal collision".

14. Standard No. 301—Fuel system Integrity

Rear structural modifications will be made to protect fuel system components of the hybrid-electric vans and the electric vans equipped with fuel-fired heater/defrosters. Tests conducted to date indicate that the Ecostar would probably meet the front (S6.1) and rear (S6.2) impact criteria, although the tests were conducted without dummies. However, its limited test program is inadequate "to certify that all versions of the Ecostar meet the rear impact requirements of S6.2, the lateral impact requirements of S6.3, or the static rollover requirements of S6.4 after rear or lateral impact."

Not all the Ecostars are equipped with fuel systems, so an exemption would cover only about half the Ecostars. About 25 percent of the vehicles will be hybrid-electric vehicles that are to be equipped with small gasoline powered engines to extend their driving range. Another 25 percent will be electric vehicles equipped with diesel-fuel-fired heater/defroster systems. Ford has no reason to believe that the vehicles would fail to meet the lateral impact requirements. Exemptions from S6.2, S6.3, and S6.4 would not degrade safety "because of the excellent performance of the fuel system in front and rear development crash tests and the use of widely accepted design and production practices for protecting the fuel system from lateral impacts."

Ford argues that an exemption would be in the public interest because of their potential reduction in emissions, as well as the requirements of some States that manufacturers sell a percentage of zero-emission motor vehicles by the 1998 model year. Half the Ecostars tested will be zero-emission vehicles. To provide the best possible vehicles, Ford must " invent and refine" technology for such vehicles, and an exemption would allow field testing and demonstration of electric and hybrid-electric vehicles equipped with advanced battery and electronic technologies. A principal issue to be resolved with the half of the Ecostar fleet that is not composed of zero-emission vehicles is to determine whether the emission standards for an ultra-low emission vehicle can practicably be met, although the emission levels of these Ecostars are well below the current limits established under the Clean Air Act.

A temporary exemption would also be consistent with the objectives of the National Traffic and Motor Vehicle Safety Act in Ford's view because the Ecostar provides a level of safety substantially equivalent to that required by the safety standards.

Interested persons are invited to submit comments on the petition described above. Comments should refer to the docket number and be submitted to: Docket Section, NHTSA, room 5109, 400 Seventh Street, SW., Washington, DC 20590. It is requested but not required that 10 copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: February 8, 1993.

Authority: 15 U.S.C. 1410; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: January 4, 1993.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 93–282 Filed 1–6–93; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF THE TREASURY

Office of the Secretary

[Supplement to Department Circular—Public Debt Series—No. 40–92]

Treasury Notes, Series AH–1994

Washington, December 23, 1992.

The Secretary announced on December 22, 1992, that the interest rate on the notes designated Series AH–1994, described in Department Circular—Public Debt Series—No. 40–92 dated December 16, 1992, will be 4⅝ percent. Interest on the notes will be payable at the rate of 4⅝ percent per annum.

Marcus W. Page,

Fiscal Assistant Secretary.

[FR Doc. 93–284 Filed 1–6–93; 8:45 am]

BILLING CODE 4810–40–M

[Supplement to Department Circular—Public Debt Series—No. 41–92]

Treasury Notes, Series U–1997

Washington, December 24, 1992.

The Secretary announced on December 23, 1992, that the interest rate on the notes designated Series U–1997, described in Department Circular—Public Debt Series—No. 41–92 dated December 16, 1992, will be 6 percent. Interest on the notes will be payable at the rate of 6 percent per annum.

Marcus W. Page,

Fiscal Assistant Secretary.

[FR Doc. 93–285 Filed 1–6–93; 8:45 am]

BILLING CODE 4810–40–M

DEPARTMENT OF VETERANS AFFAIRS

Information Collection Under OMB Review

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document lists the following information: (1) The title of the information collection, and the Department form number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collections and supporting documents may be obtained from Janet G. Byers, Veterans Benefits Administration (20A5), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3021.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMB Desk Officer.

Dated: December 30, 1992.

By direction of the Secretary.

Frank E. Lalley,

Associate Deputy, Assistant Secretary for Information, Resources Policies and Oversight.

1. Notice of Past Due Payment, VA Form 29–389e

2. The form is used by veterans as a temporary measure to restore continuous protection until a final decision is made on their application for benefits. The information collected is used to determine the insured's eligibility for continued protection.

3. Individuals or households

4. 484 hours

5. 15 minutes

6. On occasion

7. 1,936 respondents

Extension

1. Request to Creditor Regarding Applicant's Indebtedness, VA Form Letter 26–250

2. The form letter is used to obtain credit information from landlords and other creditors of veteran-applicants for guaranteed and direct loans, potential purchasers of VA-acquired properties, and potential assumers of guaranteed and direct loans to determine applicant's eligibility for the loan.

3. Individuals or households—Businesses or other for-profit—Small businesses or organizations

4. 15,833 hours

5. 10 minutes

6. On occasion

7. 95,000 respondents

Extension

1. Request for Postponement of Offsite or Exterior Onsite Improvements—Home Loan, VA Form Letter 26–1847

2. The form serves as the lender's and veteran's request for guaranty of home loan for which offsite or exterior onsite improvements are incomplete to permit the veteran's occupancy of the property.

3. Individuals or households—Businesses or other for-profit—Small businesses or organizations

4. 2,500 hours

5. 30 minutes

6. On occasion

7. 5,000 respondents

[FR Doc. 93–302 Filed 1–6–93; 8:45 am]

BILLING CODE 8320–01–M

VOL 58 ISS 4 JA 7 1993 UMI

Sunshine Act Meetings

Federal Register
Vol. 58, No. 4
Thursday, January 7, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10:00 a.m. on Tuesday, January 12, 1993, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Reports of actions approved by the standing committees of the Corporation and by officers of the Corporation pursuant to authority delegated by the Board of Directors.

Discussion Agenda:

Memorandum and resolution re: Proposed amendments to Part 362 of the Corporation's rules and regulations, entitled "Activities and Investments of Insured State Banks," which would require insured state banks to obtain the prior consent of the Corporation before directly, or indirectly through a subsidiary, engaging "as principal" in any activity that is not permissible for a national bank.

Memorandum and resolution re: Proposed amendments to Part 333 of the Corporation's rules and regulations, entitled "Extension of Corporate Powers," which would eliminate section 333.3, which makes certain prohibitions applicable to state chartered savings associations applicable to state banks that are members of the Savings Association Insurance Fund.

Memorandum and resolution re: Proposed amendments to the Corporation's rules and regulations, which would eliminate Part 332, entitled "Powers Inconsistent with Purposes of Federal Deposit Insurance Law."

Memorandum and resolution re: Final amendments to Part 325 of the Corporation's rules and regulations, entitled "Capital Maintenance," which would allow limited amounts of mortgage servicing rights and purchased credit care relationships to be recognized for regulatory capital purposes.

Memorandum re: Information Resources Management Plan.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC.

The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should contact Llauger Valentin, Equal Employment Opportunity Manager, at (202) 898–6745 (Voice); (202) 898–3509 (TTY), to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898–6757.

Dated: January 5, 1993.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 93–441 Filed 1–5–93; 2:49 pm]

BILLING CODE 6714-01-M

FEDERAL ELECTION COMMISSION

* * * * *

DATE AND TIME: Tuesday, January 12, 1993 at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

* * * * *

DATE AND TIME: Thursday, January 14, 1993 at 10 a.m.

PLACE: 999 E Street NW., Washington, DC (ninth floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes

Title 26 Certification Matters

Advisory Opinion 1992–42: Ms. Arlene M. Willis of Lewis for Congress Committee.

Legislative Recommendations, 1993 (continued from the meeting of January 7, 1993)

Routine Administrative Matters

* * * * *

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Press Officer, Telephone: (202) 219–4155.

Delores Hardy,

Administrative Assistant.

[FR Doc. 93–452 Filed 1–5–93; 3:55 pm]

BILLING CODE 6715-01-M

FEDERAL MARITIME COMMISSION

TIME AND DATE: 10 a.m.—January 13, 1993.

PLACE: Main Hearing Room—800 North Capitol Street, NW., Washington, DC 20573–0001.

STATUS: Part of the meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTER(S) TO BE CONSIDERED:

Portion open to the public:

1. Docket No. 92–33—Marine Terminal Facilities Agreements—Exemption—Consideration of comments.
2. Docket No. 92–37—Financial Responsibility for Non-Vessel-Operating Common Carriers—Consideration of comments.

Portion closed to the public:

1. Trans-Atlantic Agreement Rate Activity.
2. Docket No. 91–17—*Consumer Electronics Shippers Associations, Inc. v. ANERA*—Consideration of the record.
3. Special Docket No. 2306—Application of Star Shipping A/S (d.b.a. Atlanticargo) for the Benefit of Economy Freight Services Ltd.—Review of Initial Decision.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 93–380 Filed 1–5–93; 11:57 am]

BILLING CODE 6730-01-M

NATIONAL SCIENCE BOARD EXECUTIVE COMMITTEE

DATE AND TIME:

January 15, 1993 8:30 a.m. Open Session.

January 15, 1993 8:35 a.m. Closed Session

January 15, 1993 9:05 a.m. Open Session

PLACE: The Franklin Institute, Benjamin Franklin Parkway at 20th Street, Philadelphia, PA 19103–1194.

STATUS: Part of this meeting will be open to the public. Part of this meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Friday, January 15, 1993.

Open Session (8:30 a.m.–8:35 a.m.)

1. Approval of Minutes, November Executive Committee Meeting

Closed Session (8:35 a.m.–9:05 a.m.)

2. Future NSF Budget

Open Session (9:05 a.m.–4:00 p.m.)

3. Chairman's Items
4. Director's Items
5. Policy Environment
6. Report of the NSB Commission on the Future of the NSF
7. NSB Issues/Actions for the Coming Year
8. NSF Actions and Planning
9. Adjourn

Marta Cehelsky,

Executive Officer.

[FR Doc. 93–413 Filed 1–5–93; 1:57 pm]

BILLING CODE 7555-01-M

VOL 58 ISS 4 JA 7 1993 UMI

Corrections

Federal Register
Vol. 58, No. 4
Thursday, January 7, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 920

[Docket No. FV–92–060IFR]

Kiwifruit Grown in California; Relaxation of Quality Requirements

Correction

In rule document 92–22043 beginning on page 41853 in the issue of Monday, September 14, 1992, make the following correction:

§ 920.302 [Corrected]

On page 41854, in the second column, in § 920.302(b)(1), in the eighth line, after "misshapen" insert "and an additional tolerance of 7 percent is provided for kiwifruit that is "badly misshapen." "

BILLING CODE 1505–01–D

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

36 CFR Part 1191

[Docket No. 92–2]

RIN 3014 AA12

Americans With Disabilities Act (ADA) Accessibility Guidelines for Buildings and Facilities; State and Local Government Facilities

Correction

In proposed rule document 92–30559 beginning on page 60612 in the issue of Monday, December 21, 1992, make the following corrections:

1. On page 60612, in the third column, in the fourth paragraph, in the ninth line, "FR 38174" should read "56 FR 38174".

2. On page 60613, in the first column, in the third footnote, in the last line, "airport terminal" should read "airport passenger terminal".

3. On page 60619, in the first column, in the first full paragraph, in the eighth line, "what" should read "that".

4. On page 60620, in the first column, in the second line, "and (3) and also contain" should read "and (3) also contain".

5. On page 60629, in the first column, in the heading, *"11.90"* should read *"11.9"*.

6. On the same page, in the same column, in the first full paragraph, in the fifth line, "comply" should read "complying".

7. On the same page, in the same column, in the 2nd full paragraph, in the 12th line, "this" should read "This".

8. On the same page, in the same column, in the 3rd full paragraph, in the 10th line, "trail" should read "trial".

9. On the same page, in the second column, in the first full paragraph, in the fourth line, "trail" should read "trial".

10. On page 60631, in the third column, in the first full paragraph, in the last line, "female minimum housing units" should read "female minimum and maximum housing units".

11. On page 60637, in the 3rd column, in the 14th line, "shred" should read "shared".

12. On page 60639, in the second column, in the second full paragraph, in the last line, "by" should read "for".

13. On page 60645, in the first column, in the first full paragraph, in the seventh line, "1:12," should read "1:12."

14. On page 60646, in the 2nd column, in the 4th full paragraph, in the 11th line, "As population," should read "As a population,".

BILLING CODE 1505–01–D

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 327

RIN 3064–AA37, 3064–AA96, 3064–AB14

Assessments

Correction

In rule document 92–23514 beginning on page 45263 in the issue of Thursday, October 1, 1992, make the following corrections:

§ 327.3 [Corrected]

1. On page 45285, in the first column, in § 327.3(d)(i)(B)*(1)*, in the fourth line, "of" should read "for".

§ 327.7 [Corrected]

2. On page 45286, in the first column, in § 327.7(a)(1)(ii)(A), in the second line, "paid by the bank" should read "paid by a bank".

BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR

Office of Surface Mining and Reclamation

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

Correction

In notice document 92–30240 appearing on page 59126 in the issue of Monday, December 14, 1992, in the third column, the text from "*Abstract:*" through "*Estimated Completion Time:* 16 mins" was printed incorrectly. It should read as follows:

"*Abstract:* This Part requires the regulatory authority to conduct periodic inspections of coal mining activities, and prepare and maintain inspection reports for public review. This information is necessary to meet the requirements of the Surface Mining Control and Reclamation Act of 1977.
Bureau Form Number: None
Frequency: Monthly
Description of Respondents: State Regulatory Authorities
Estimated Completion Time: 4 hours
Annual Responses: 170,580
Annual Burden Hours: 622,500"

BILLING CODE 1505–01–D

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

Correction

In notice document 92–30239 appearing on page 59126 in the issue of Monday, December 14, 1992, the text

from "*Abstract:*" through "*Annual Burden Hours:* 622,500" was printed incorrectly. It should read as follows:

"*Abstract:* In order to ensure compliance with 30 CFR part 870, a quarterly report is required of coal produced for sale, transfer or use nationwide. Individual reclamation fee payment liability is based on this information.

Bureau Form Number: OSM–1

Frequency: Quarterly

Description of Respondents: Coal mine and coal preparation plant operators

Annual Responses: 15,000

Annual Burden Hours: 4,089

Estimated Completion Time: 16 mins"

BILLING CODE 1505-01-D

VOL 58 ISS 4 JA 7 1993 UMI

federal register

Thursday
January 7, 1993

Part II

Environmental Protection Agency

40 CFR Part 61
National Emission Standards for Hazardous Air Pollutants; Benzene Waste Operations; Final Rule

VOL 58 ISS 4 JA 7 1993 UMI

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 61

[AD-FRL-4534-2]

National Emission Standards for Hazardous Air Pollutants; Benzene Waste Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is clarifying widely misunderstood provisions to the national emission standards for hazardous air pollutants (NESHAP) for benzene emissions from benzene waste operations, subpart FF of 40 CFR part 61. Sources affected by subpart FF of this part include chemical manufacturing plants, coke by-product recovery plants, petroleum refineries, and facilities at which waste management units are used to treat, store, or dispose of waste generated by chemical manufacturing plants, coke by-product recovery plants, or petroleum refineries.

The final amendments clarify points on which there has been confusion and provide additional options for compliance that give owners and operators increased flexibility in meeting the requirements of the rule while still meeting the NESHAP goals for health risk protection.

DATES: *Effective Date:* January 7, 1993.

Judicial Review. Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of the clarifying amendments to the NESHAP is available only by filing a petition for review in the U.S. Court of Appeals for the District of Columbia Circuit on or before March 8, 1993. Under section 307(b)(2) of the CAA, the requirements that are the subject of today's notice may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements. Judicial review is not available for aspects of subpart FF that are not addressed by today's amendments.

ADDRESSES: *Docket.* Information related to the development of the amendments to subpart FF promulgated today is contained in categories XI through XIV of Docket No. A-89-06. The docket is available for public inspection and copying between 8:30 a.m. and 3:30 p.m., Monday through Friday, at the EPA's Air Docket Section, Waterside Mall, room 1500, 1st Floor, 401 M Street, SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: For information on the rule amendments, contact Robert B. Lucas, Chemicals and Petroleum Branch (MD-13), telephone (919) 541-0884 or Gail Lacy, Standards Development Branch (MD-13), telephone (919) 541-5261, Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711. For information on the waiver policy for Subpart FF, contact Eric Crump, Chemicals and Petroleum Branch (MD-13), telephone (919) 541-5032, Office of Air Quality Planning and Standards, Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

SUPPLEMENTARY INFORMATION: The information presented in this preamble is organized as follows:

I. Background.
II. Overview of Final Rule Clarifications and Implementation.
III. Facility Applicability.
IV. Control Requirements.
V. Additional Exemption for Small Benzene Quantity Wastes.
VI. Alternative Compliance Options.
VII. Monitoring, Recordkeeping, and Reporting.
VIII. Policy for Granting Waivers of Compliance.
IX. General.
X. Administrative Requirements.

I. Background

On March 7, 1990 (55 FR 8292), the EPA promulgated under section 112 of the Clean Air Act (as it was written prior to the Clean Air Act Amendments of 1990), 42 U.S.C. 7412, NESHAP controlling emissions of benzene to the ambient air from waste operations (subpart FF of 40 CFR part 61). The NESHAP for benzene waste operations is applicable to owners or operators of chemical manufacturing plants, coke by-product recovery plants, and petroleum refineries. In addition, this subpart applies to owners and operators of facilities at which waste management units are used to treat, store, or dispose of waste generated by chemical plants, coke by-product recovery plants, or petroleum refineries.

Due to widespread confusion among affected industries concerning key provisions of the rule, the EPA issued a stay of effectiveness of subpart FF on March 5, 1992 (57 FR 8012). The stay was to remain in effect until the EPA took final action on clarifying amendments to subpart FF. Clarifying amendments to the rule were also proposed on March 5, 1992. The EPA agreed to take final action on these amendments or before December 1, 1992 in a settlement agreement filed in connection with litigation on subpart FF. See *API* v. *EPA*, No. 90-1238 (D.C. Circuit) (Settlement Agreement).

With today's notice, the EPA is promulgating clarifying amendments to subpart FF and removing the stay. In accordance with section 112(q) of the Clean Air Act, as amended in 1990, these amendments are being promulgated under the authority of the Clean Air Act prior to enactment of the Clean Air Act Amendments of 1990. They are intended to clarify existing provisions of subpart FF and to provide additional flexibility to owners and operators who must comply with the rule while still meeting the NESHAP goals for health risk protection.

The comment period on the proposed clarifying amendments was from March 5, 1992 to May 4, 1992. Thirty-three comment letters were received. The commenters included companies affected by the rule, trade associations, and an environmental group. Most comment letters contained multiple comments. Commenters generally supported the proposed amendments, although many offered specific criticisms and suggested changes. The EPA considered all comments on the proposed rule amendments in developing the final amendments promulgated today.

In the March 5, 1992 notice of proposed rulemaking, the EPA requested specific comments on potential alternative structures for the rule that would encourage reclamation and recycling without compromising the NESHAP risk protection goals. To inform the affected public of the suggested alternative rule structures and major rule clarifications being considered, the EPA held a series of meetings, between proposal and promulgation of the rule amendments, with industry and an environmental group. A written record of each meeting was placed in the rulemaking docket for subpart FF. During and following these meetings, additional comments were submitted on the major rule clarifications and alternative rule structures. These comments were also considered by the EPA in developing the final rule amendments.

The clarifying amendments to subpart FF that are being promulgated today are discussed below. Comments received on the proposed amendments and the EPA's responses to those comments are also discussed.

Some commenters submitted comments on aspects of the original rule that were unaffected by the proposed amendments. These comments are outside the scope of the rulemaking for

the proposed amendments. Therefore, these comments, although mentioned, are not addressed in this rulemaking.

II. Overview of Final Rule Clarifications and Implementation

The EPA proposed clarifying amendments to several provisions of subpart FF to resolve confusion. Several clarifications related to facility applicability including: (1) Clarifying which wastes are included in the calculation of total annual benzene quantity in all aqueous waste streams (TAB); (2) elaboration on the definition of point of waste generation; and (3) making clear that waste treatment cannot be used to lower facility TAB. Other proposed amendments included a 1.0 megagram per year (Mg/yr) of benzene exemption from controls for small quantity benzene wastes, a requirement that facilities prepare and implement a maintenance turnaround plan, and other miscellaneous clarifications. Comments were specifically requested on the need for a maintenance turnaround plan, the risks associated with organic wastes, and on possible alternative structures for the rule that would encourage recycling and reclamation while still meeting the NESHAP risk protection goals.

The EPA carefully considered comments received on the proposed clarifying amendments, and has made several changes in the final rule. These changes include the following:

(1) Raising the proposed 1.0 Mg/yr of benzene exemption to 2.0 Mg/yr of benzene, and removing the proposed restrictions on which wastes are eligible for this exemption;

(2) Deleting the requirement for a maintenance turnaround plan;

(3) Adding an elective option for averaging the benzene in process unit turnaround wastes in the calculation of facility TAB;

(4) Establishing separate control requirements based on containment controls for certain organic wastes that are managed in tanks; and

(5) Including an additional compliance option for facilities that are above the 10 Mg/yr applicability threshold.

Other more minor changes were also made based on comments received. All changes made to the clarifying amendments between proposal and promulgation are discussed in detail beginning in section III of this preamble.

Facilities subject to the rule are required to be in compliance with all provisions of the amended rule within 90 days from today, unless a waiver of compliance is obtained under §§ 61.10 and 61.11 of the General Provisions to 40 CFR part 61. Additional information on the policy for granting waivers of compliance for subpart FF, as amended, is discussed in section VIII of this preamble. Detailed guidance on the waiver policy is provided in a separate document, "Benzene Waste Operations—NESHAP Waiver Guidance." No waiver of compliance issued will extend beyond 2 years from today's date.

All facilities subject to Subpart FF are required to submit a report that summarizes the regulatory status of each waste stream covered by the rule to the appropriate EPA regional office or delegated State or local agency. A facility that has previously submitted this report to the EPA or to the delegated State or local agency and, after reviewing the clarifying amendments promulgated today, believes that the previous report is accurate, may submit a statement to this effect rather than resubmitting the entire previous report.

In an advance notice of proposed rulemaking (ANPR), the EPA is announcing the intent to propose an additional compliance option, based on site-specific risk assessment, for public comment. Facilities that may want to utilize this alternative compliance option if it is added to the rule are eligible to apply for a waiver of compliance. Additional information on waivers of compliance for facilities that may want to utilize site-specific risk assessment as a compliance option is presented in section VIII of this preamble.

III. Facility Applicability

Subpart FF is applicable to petroleum refineries, chemical plants, and coke by-product recovery facilities. It also is applicable to treatment, storage, and disposal facilities (TSDF) that receive wastes from petroleum refineries, chemical plants, and coke by-product recovery facilities.

The calculation of TAB determines whether a facility is subject to the control requirements of the rule. A facility at or above the TAB threshold in the rule of 10 Mg/yr is required to control each benzene waste stream at the facility or demonstrate that the waste stream meets a criterion in the rule for exemption from control. A facility with a TAB below 10 Mg/yr is only subject to the rule's reporting and recordkeeping provisions, unless the facility receives a waste from offsite that must be controlled to meet subpart FF, in which case that waste must be controlled.

Following promulgation of subpart FF on March 7, 1990, it was evident that many members of the regulated community were either confused about or had misunderstood the EPA's intent on how the applicability of control requirements in the rule to facilities should be determined. Given the critical importance of this determination of facility applicability, the EPA proposed amendments in the March 5, 1992 notice to clarify how facility applicability is determined. Comments received on the proposed clarifications related to facility applicability, and the EPA's responses to them, are discussed in the following sections.

A. Wastes Included in the TAB Calculation to Determine Applicability of Control Requirements

The proposed amendments sought to clarify the EPA's general intent that the benzene in all aqueous wastes and wastes that become aqueous be included in the TAB calculation. To resolve prior confusion, discussion in the preamble and proposed clarifying language in the regulation specifically stated that the following wastes are among those whose benzene should be included in the calculation of facility TAB: Organic wastes that become aqueous (i.e., are mixed with water or other aqueous wastes such that the water content of the waste exceeds 10 percent); materials subject to subpart FF that are sold; and wastes that may be exempted from control under the rule based on low benzene concentration, low benzene quantity, or low total waste quantity.

The proposed amendments also included a clarification to address how wastes generated on an infrequent basis, such as wastes from process unit turnarounds, are counted in the TAB calculation. Under the proposed clarifications, these wastes would have been counted in a facility's TAB for the year in which they are generated.

To avoid creating a disincentive for facilities to undertake voluntary remediation activities, the proposal included an exception for remediation wastes. The proposed clarification would exclude these wastes from the facility TAB calculation but require that they are subject to control if the facility TAB is 10 Mg/yr or greater. Thus, the benzene content of remediation wastes would not affect whether a facility is subject to the control requirements of the rule.

Industry representatives commented on several aspects of the proposed clarifications related to facility applicability. After consideration of these comments, the EPA is proceeding with all of the clarifications as proposed with the exception of the proposed language for process unit turnarounds.

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The final amendments allow facilities to average the benzene in wastes generated by process unit turnarounds in the calculation of TAB. Further discussion of the comments received and the EPA's responses is presented below.

Materials Subject to Subpart FF That Are Sold

One commenter claimed that the EPA had created additional confusion with the proposed clarification in § 61.342(a)(2) that the benzene in a material subject to subpart FF that is sold is included in the calculation of TAB if the material meets the definition of a waste and has an annual average water content greater than 10 percent. The commenter further states that with this proposed change, the EPA has raised questions concerning the status of materials that have never been regarded as wastes.

It has always been the EPA's intent that if a material meets the definition of a waste in the rule, then the benzene in that material should be included in the calculation of TAB based on its benzene content at the point of generation. The purpose of the proposed amendment was to clarify more specifically that the act of selling a material does not, by itself, mean that the material is not subject to subpart FF. The definition of waste in the rule is intentionally broad and does not differentiate between materials based on their ultimate end use. This is because any material containing benzene that meets the rule's definition of waste has the potential to be a source of benzene emissions. Further, materials that meet the definition of waste are generally not subject to other rules that limit benzene air emissions.

Although not explicitly stated by the commenter, the EPA sees two potential concerns by industry associated with materials subject to Subpart FF that are sold. One concern might be that including the benzene in these materials in facility TAB causes facilities otherwise below 10 Mg/yr to exceed this TAB threshold for the applicability of subpart FF control requirements. However, the commenter gave no indication to what extent this may be a problem.

A second potential concern might be from the perspective of facilities with TAB's above 10 Mg/yr. The owners or operators of these facilities may not understand the control requirements at the generator site and at the site receiving them for materials that are sold. Since these materials are potential sources of benzene emissions, the EPA has always intended that they be controlled as are other materials that meet the definition of waste in subpart FF. At the generator site, these materials must be managed in units equipped with emission controls prior to shipment offsite as specified in the rule. As required under § 61.342(f), the generator is required to include with each shipment offsite of waste, a notice stating that the waste must be managed and treated in accordance with the requirements of subpart FF. In the case of materials that are sold, the receiving site may be purchasing them for input to another process as a raw material. In that case, at the receiving site, materials subject to subpart FF would have to be managed in units meeting the subpart FF requirements for benzene air emission control up to the point the materials reenter a process; at the process reentry point the sold materials would no longer be subject to subpart FF. In meetings following the proposal of the clarifying amendments, the EPA asked for additional supporting information from industry to indicate the extent of concern regarding materials subject to subpart FF that are sold and to aid in evaluating the impact of the proposed clarification. No additional information has been received by the EPA.

Without additional information submitted to support the comment on materials subject to subpart FF that are sold, the EPA is not persuaded that these wastes should be excluded from the rule or the TAB calculation. Therefore, the promulgated clarification is unchanged from proposal.

Remediation Activities

The EPA received comments from industry in support of and in opposition to the proposed clarification on remediation wastes. Those supporting the proposed amendments believed that the EPA had correctly recognized that without this clarification, there would be a disincentive for facilities to undertake voluntary remediation activities. Those opposing the proposed clarification objected to inclusion of these wastes in the rule at all. One commenter argued that remediation wastes are already controlled under the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and thus should not be controlled by subpart FF. Another commenter claimed that the control requirement for remediation wastes would create a disincentive to conduct remediation activities and that solid waste remediation (e.g., contaminated soils) should be removed from the scope of the rule because control of these wastes is best left to the regulatory agency directing the cleanup, and because these wastes may require controls and equipment dissimilar to the controls discussed in the rule. The commenter noted that few solid waste remediation activities are voluntary, citing RCRA and CERCLA as statutes driving many such remediation activities.

The EPA disagrees with the commenters opposed to the proposed clarification. While the EPA believes it is reasonable to exclude the benzene in remediation wastes from facility applicability determination (in order not to create a disincentive for voluntary remediation actions), there is a strong rationale to control these wastes at a facility to which the control requirements apply. Materials generated by remediation actions fall within the definition of waste in the rule and can contain significant amounts of benzene. In general, these materials would be expected to be managed with other wastes at a facility. If these materials were excluded from the control requirements of the rule, benzene air emissions from remediation actions could be left uncontrolled, resulting in the remediation activity transferring benzene contamination from another media into the air. Consequently, the EPA believes that at facilities with a TAB above the control threshold in the rule of 10 Mg/yr, wastes from remediation activities should be subject to the control requirements of the rule as are other wastes containing benzene.

The EPA also disagrees that the proposed change would create a disincentive for facilities to undertake remediation activities. To the contrary, by proposing that the benzene in remediation wastes not be included in the TAB calculation, the proposed change would remove the potential disincentive in the original rule for a facility with a TAB below 10 Mg/yr to undertake voluntary remediation actions. That the proposed change would accomplish this is supported by some commenters. Further, to the extent that benzene emissions from these wastes are controlled by CERCLA or RCRA, no additional effort would be required under subpart FF. For these reasons, remediation wastes are excluded from TAB, but are subject to the control requirements of the rule. At facilities whose TAB's are at or above 10 Mg/yr, remediation wastes are subject to the rule's control requirements in the same manner as any other wastes.

Regarding the types of controls needed for soil remediation wastes, the EPA believes that these wastes can be managed and treated in units that meet

the control requirements of subpart FF. The rule does not apply to the act of excavating benzene-contaminated soil, a point perhaps misunderstood by the commenter. However, after the contaminated soil is excavated, it then meets the definition of a waste, and is subject to the rule. Once excavated, waste containing 10 ppmw or greater benzene is required to be handled in waste management units (e.g., containers) for which the controls specified in the rule are applicable and appropriate. The treatment requirement in the rule is a performance standard (i.e., reduce concentration of benzene in the waste to below 10 ppmw, or by 99 percent) and does not specify the method of treatment. Methods such as solvent extraction and thermal treatment are demonstrated technologies that are available to meet this performance standard for soil remediation wastes. The requirement in subpart FF for the control of air emissions from a treatment technology that is used is also a performance standard (reduce organic emissions by 95 percent or benzene by 98 percent). This level of control has been demonstrated to be achievable and is comparable to what is required for the control of air emissions from treatment units permitted under the RCRA.

One company asked whether the benzene in a remediation waste that is sent offsite to a TSDF is counted towards the TAB of the TSDF. The benzene in all wastes (including remediation wastes) received by a TSDF from chemical plants, petroleum refineries, and coke by-product recovery plants and that contain 10 percent or greater of water count towards the TAB of the TSDF. This is discussed further in section III.C of this preamble.

Infrequently Generated Wastes

The proposed rule amendments included a clarification that the benzene in waste streams generated on an infrequent basis, such as wastes from process unit turnarounds (also referred to as maintenance turnarounds) that occur only once every 2 to 5 years or less frequently, is counted in the TAB calculation for the year in which the wastes are generated. The proposed clarification specifically stated that the benzene in these wastes is not averaged over the time period between occurrences of the activities that generate the wastes. The EPA received a number of comments on this proposed clarification.

Most of the comments received on this proposed clarification addressed process unit turnaround wastes. Commenters specifically opposed the proposed inclusion of the benzene in process unit turnaround wastes in the TAB calculation for the year in which the waste is generated. The concern expressed by commenters was that, because of the potentially significant amount of benzene in process unit turnaround wastes, the proposed clarification could cause facilities with a TAB otherwise below 10 Mg/yr to go above this level in the year that process unit turnaround occurs.

One commenter cited an example where wastes containing 2.5 tons of benzene were generated during process unit turnaround at a facility with a TAB that in other years is just below 10 Mg/yr. In this situation, process unit turnaround wastes would trigger applicability of the control requirements of the rule to all wastes at the facility, but only in the years that process unit turnaround occurs. As a remedy for this, commenters suggested that the EPA allow the averaging of infrequently generated wastes in the TAB calculation over the period between occurrences.

The EPA agrees with commenters that the clarification as proposed would create the potential for a facility to exceed the 10 Mg/yr TAB threshold only in those years when a process unit turnaround occurs. Previously, the EPA was not aware of the extent to which the benzene in process unit turnaround wastes could influence the applicability of control requirements at facilities subject to the rule. Based on the comments received, it is clear that the proposed clarification would substantially impact some smaller facilities, requiring them to purchase and install controls for use only in years in which process unit turnaround occurs or face penalties for noncompliance in those years. This is not the EPA's intent.

The EPA considers the suggestion made by commenters that, for the purpose of the TAB calculation, the benzene in intermittently generated wastes be averaged over the period between occurrences to be a reasonable one for process unit turnaround wastes generated as infrequently as once every 2 years or longer. Consequently, the final rule clarifications include an elective option in § 61.355(b)(4) for averaging the benzene in process unit turnaround wastes in the calculation of facility TAB. To compute a yearly contribution to facility TAB under this option, the benzene in process unit turnaround wastes generated during the most recent turnaround is divided by the period of time between the two most recent turnarounds. A facility selecting this approach will report an annual contribution to facility TAB for the process unit regardless of whether the unit had a turnaround in the reporting year. If turnaround occurs separately for individual process units within a facility, the annual contribution to facility TAB shall be computed separately for each process unit.

For example, assume there is a process unit for which turnaround occurred in 1988 and in 1991, and the facility does not anticipate turnaround again until 1995. In 1993, the first year of compliance with the amended rule, the annual contribution to TAB from turnaround of the process unit would be the benzene quantity from the 1991 turnaround divided by three (because the period from 1988 to 1991 covers three years). This same value would be used in the calculation of TAB for 1994 and 1995. If the process unit turns around again in 1995, as anticipated, the value would change in 1996 to be the quantity generated from the 1995 turnaround divided by four (4-years between 1991 and 1995). Subsequent TAB calculations would use this value until the next turnaround of the process unit.

Owners and operators are not required to average process unit turnaround wastes. For most facilities, it will simplify the TAB calculation to record the benzene in process unit turnaround wastes only in the year that a turnaround occurs. The option of averaging the benzene in process unit turnaround waste is expected to be elected by a facility whose TAB is just below 10 Mg/yr and where the benzene in process turnaround waste could cause the facility to exceed 10 Mg/yr in the year that turnaround occurs if averaging were not allowed. A facility with a TAB significantly below 10 Mg/yr is not likely to average the benzene in process unit turnaround waste unless averaging is necessary to maintain the facility TAB below 10 Mg/yr. Facilities whose TAB is above 10 Mg/yr based on the benzene in wastes other than process unit turnaround wastes, are not likely to elect this option.

Commenters also requested that wastes associated with process upsets should be excluded from the TAB calculation. No information was supplied by the commenters on the possible magnitude of the benzene in these wastes or the potential impact of these wastes on facility applicability determinations. Without such information, the EPA has no basis for assessing the impact on benzene emissions and risk basis for assessing the impact on benzene emissions and risk if these wastes were excluded. Consequently, these wastes are covered by the rule and must be included in a

facility's TAB calculation if the waste contains greater than 10 percent water, or is mixed with water or other wastes at any time and has an annual average water content over 10 percent. Further, since process upsets are random events that do not occur at predictable intervals (as do process unit turnarounds), the development of a methodology whereby the benzene in these wastes could be averaged in the calculation of TAB is not appropriate. Therefore, the benzene in a waste generated by a process upset must be included in the facility's TAB calculation in the year the waste is generated.

B. Clarifications on Point of Waste Generation

Subpart FF requires that the characteristics of waste streams at their "point of generation" be used for the purposes of calculating a facility's TAB, which in turn determines applicability of Subpart FF control requirements to a facility. For a limited number of facilities that are subject to the rule, in particular for those whose TAB is just below or above 10 Mg/yr, the definition of the point of generation of waste streams can affect facility applicability.

Due to confusion over the rule's original language related to point of generation, the EPA proposed to simplify the definition of point of generation in § 61.341 and also clarify in §§ 61.355 (b) and (c) where waste quantity and flow-weighted annual benzene concentration are determined for the purpose of calculating TAB. Comments received on these proposed changes are discussed below.

Definition of Point of Generation

The proposed definition of point of generation in § 61.341 focused on the difference between process and waste management units and emphasized that the point of waste generation is before any waste treatment. Numerous comments were received on the proposed definition.

Several commenters argued that the point of generation should be where a waste is first exposed to the atmosphere. These commenters claimed that relating the point of generation to the point of exposure to the atmosphere was essential to simplifying applicability of the rule and promoting recycling and source reduction of wastes.

The EPA explained in the preamble to the proposed rule amendments that its intent in specifying the point of generation was (1) to establish the true emission potential of a stream, prior to any losses that occur through volatilization to the atmosphere and prior to any waste treatment, and (2) to have affected facilities calculate their TAB in a manner consistent with the EPA's intended structure for the rule; that is, consistent with how the EPA determined which facilities should be controlled to meet the NESHAP risk goals. To adopt the commenters' suggestion would be contrary to these stated intentions for the rule as originally structured. A definition entirely based on where waste is exposed to the atmosphere would allow waste treatment as a means of reducing facility TAB. If this were allowed, facilities could simply treat wastes such that facility TAB was lowered to just below 10 Mg/yr, thereby avoiding the control requirements of the rule. Further, there would be no assurance that treatment processes would be controlled for benzene air emissions. As discussed in the proposal preamble, this was not the EPA's intent in the original rule structure and may not achieve the NESHAP risk goals (see 57 FR 8021 and 8022). Therefore, the EPA has not adopted the commenters suggested definition of point of generation for the original rule structure.

Moreover, the purpose for these amendments is to clarify the original intent of the rules with respect to the point of waste generation. If this rulemaking was just being initiated, the EPA may have considered a different regulatory approach to meet the NESHAP risk policy goals.

However, as discussed in section VI of this preamble, the EPA has included in the final rule amendments an additional compliance option for facilities subject to the control requirements of subpart FF (i.e., those facilities with TAB's above 10 Mg/yr). This option is being promulgated specifically in response to commenters who requested an additional compliance option that would further promote reclamation and recycling of wastes at facilities affected by the rule and that must install controls. Under this option, a facility owner or operator may selectively manage wastes such that the mass of benzene in wastes after management in units equipped with air emission controls (or after treatment in devices equipped with air emission controls), plus the mass of benzene in wastes not managed in controlled units (at their point of generation) is less than 6 Mg/yr (see section VI of this preamble). For waste streams that are managed from their point of generation in units controlled at least to the level required by the rule or that are treated to reduce benzene, the benzene quantity is determined before the waste enters the first unit uncontrolled for air emissions. Thus, this option does, in effect, allow compliance with the rule for controlled waste streams to be determined based on the characteristics of the waste at the point where it is first exposed to the atmosphere.

One commenter stated that rarely is there a "bright line" between equipment that is integral to a process and equipment that is nonintegral in refinery processes. The commenter expressed concern about how the EPA would make case-by-case decisions on integral versus nonintegral equipment and whether these decisions would be published. Other commenters described site-specific equipment configurations claimed to be processes that promote resource recovery and requested that the EPA clarify the location of the point of generation for these configurations.

The EPA believes that through the definitions of waste, waste management unit, and point of generation, the rule provides adequate direction to determine the distinction between a waste management unit and a process unit. The definition of waste determines which materials at a facility comes under potential coverage by subpart FF. Which facilities are subject to the control requirements of subpart FF, and which waste streams must be controlled at those facilities is determined based on the characteristics of waste streams at their point of generation. The point of generation of a stream is after it has left a process and prior to handling or management in a unit that is not integral to the process, including prior to processes that promote resource recovery.

In general, and as discussed in the proposal preamble, the distinction between what is a waste management unit and what is a process unit is based on the material managed in the unit (see 57 FR 8020). If the material meets the definition of waste in the rule, then the unit is a waste management unit and the point of generation would be at a location prior to where the waste enters this unit. This is a primary criterion for distinguishing waste management units from process units for the purposes of subpart FF.

In limited situations, a material may meet the definition of a waste, but because it never leaves a process unit component, there may not be a point for that material that technically meets the definition of point of generation in the rule. This may be the case where materials are recycled within a process (e.g., product distillation reflux streams) or where materials are directly hardpiped from one process to another without accumulation, storage, or treatment. If a material never leaves a process, it is not covered by the rule,

even though it may meet the definition of waste. The burden, however, will be on owners and operators to demonstrate that the material does not leave the process, and that units claimed to be process units are, in fact, integral to the process. Additional discussion on materials recycled to a process or within a process is presented in section III.E of this preamble.

Where site-specific determinations on the point of generation are requested, they will be made by the EPA regional offices and delegated State and local agencies consistent with the final rule amendments. Regions, States, or local agencies that get applicability determinations that may be precedent setting or have nationwide importance will work with the EPA Headquarters in making the determinations. The EPA Headquarters will then distribute these determinations to other EPA regional offices, and State and local agencies as appropriate.

Listed Exceptions in § 61.355 for Sour Water Streams and Wastes at Coke By-Product Plants

The proposed rule amendments, clarify that for the purpose of a facility's TAB calculation, all determinations of waste stream annual quantity and benzene concentration are made at the point of generation with three exceptions. The listed exceptions are for wastes at coke by-product recovery plants handled in units subject to subpart L of 40 CFR part 61, sour water streams treated in sour water strippers, and wastes received by a TSDF from offsite. Due to the special circumstances explained in the proposal preamble, the quantity and benzene concentration of these wastes are determined at a location different from the point of generation (and described in §§ 61.355 (b) and (c) of the proposed rule amendments).

Several commenters supported this proposed clarification. One commenter asked the EPA to accord natural gas strippers and other strippers inherently controlled for air emissions the same status in the rule as sour water strippers. The EPA does not believe that the exception should apply to natural gas and other strippers.

In general, in the analysis performed to support subpart FF, the EPA evaluated waste streams based on their benzene content at the point of generation, and prior to any waste treatment. Certain exceptions were made, however, based on unique circumstances.

Although sour water strippers are considered by the EPA to be waste treatment devices, the benzene content of each sour water stream treated in a sour water stripper was assumed in the analysis based on its benzene concentration at the exit of the stripper. This is because information supplied to the EPA by industry at the time the analysis was performed was for the characteristics of waste streams at the exit of sour water strippers. The analysis showed that for these streams, assuming benzene content at the exit of the stripper, and assuming inherent control for air emissions of the treatment device, the NESHAP risk protection goals would be met. This was explained in the preamble to the proposed amendments (see 57 FR 8021). Similar assumptions could not be made for other strippers based on the limited information available at the time of the analysis. Further, the application of sour water strippers is limited to the treatment of sour water streams, not any waste containing benzene.

For these reasons, the EPA considers sour water strippers to be unique relative to other treatment devices, not comparable to natural gas strippers and other strippers inherently controlled for air emissions. To accord natural gas strippers and other strippers the same status in the rule as sour water strippers would imply a general allowance of waste treatment as a means of lowering facility TAB. As discussed in the notice of proposed rulemaking for the clarifying amendments, this is clearly not the EPA's intention. Generically allowing waste treatment to lower facility TAB would be inconsistent with the EPA's intended rule structure in a way that could jeopardize attainment of the NESHAP risk protection goals for several reasons. For example, if waste treatment were generically allowed to lower TAB such that a facility is no longer subject to the control requirements of the rule, there would be no assurance that the treatment process was controlled for air emissions, there would be no control of benzene emissions from organic wastes, and facilities could treat wastes such that facility TAB was lowered only to 10 Mg/yr. All of these results would be inconsistent with the EPA's intended structure for the rule. Based on this, the commenter's suggestion was not adopted in the final rule amendments. It should be pointed out, however, that natural gas strippers and other strippers inherently controlled for air emissions are likely in compliance with the control requirements of the rule for those sources, although other waste management sources at the same facility may require additional control.

C. Applicability of the Rule to TSDF

The preamble to the proposed amendments described how control of wastes received by TSDF from chemical plants, petroleum refineries, and coke by-product recovery plants can be required under the rule in two ways (see 57 FR 8021). Control of these wastes is required at the TSDF if either (1) the TAB calculated for the TSDF is 10 Mg/yr or greater (based on the characteristics of the wastes at the point they enter the TSDF), or (2) if the waste would have been required to be controlled to meet the rule by the generator if it had not been shipped offsite (i.e., the generator's TAB is 10 Mg/yr or greater and the waste contains 10 ppmw or more of benzene).

Although no changes were proposed to the specific rule requirements that address the shipment of wastes offsite in the second case, comments were received that the "need to control" a waste should not accompany the waste when it is shipped from a generator with a TAB of 10 Mg/yr to a TSDF with a TAB below 10 Mg/yr. Two commenters specifically stated that this could restrict the number of TSDF willing to accept refinery wastes.

It is the EPA's intent that wastes generated by any facility subject to the rule with a TAB of 10 Mg/yr or greater be controlled, regardless of whether the waste is sent offsite or not. Consistent with this intent, the rule requires that wastes sent to any offsite facility (including TSDF) by a generator with a TAB of 10 Mg/yr continue to be subject to the control requirements of subpart FF until they are treated to the level required by the rule or they reenter a process at the offsite facility.

Dispersal of wastes to offsite facilities where controls may not be required is not an acceptable means of reducing the potential health risks associated with these wastes for two reasons. First, if the "need to control" a waste did not go with it when it is shipped offsite as suggested by the commenters, this could lead to the distribution of significant quantities of benzene wastes to uncontrolled facilities (e.g., to TSDF's with TAB's significantly below 10 Mg/yr currently). This would result in an increase in benzene emissions and risk and conflict with the NESHAP risk protection goal of minimizing the population at a risk of greater than one in one million.

Secondly, there would be no guarantee that potential benzene emissions and risk would actually be dispersed. For example, even if a TSDF were under separate ownership, it could be located contiguous to a facility

generating the waste. In this case, "offsite" may simply be across the street. For these reasons, the final rule as amended still requires wastes shipped to a TSDF from a generator with a TAB of 10 Mg/yr to be controlled at the TSDF, even when the TSDF's TAB is below 10 Mg/yr.

As mentioned earlier, a question was raised after proposal of the rule amendments as to whether the benzene in a remediation waste that is sent offsite to a TSDF is counted towards the TAB of the TSDF. The benzene in all wastes (including remediation wastes) that are received by a TSDF from chemical plants, petroleum refineries, and coke by-product recovery plants and that contain greater than 10 percent water or that are mixed with water or other wastes and have over 10 percent water content count towards the TAB of the TSDF. The benzene in remediation wastes generated offsite are not excluded from the calculation of TAB (see § 61.342 (a) (3)) for a TSDF or any other facility subject to the rule (although it is still not included in the TAB for the generator site) for two reasons.

First, the objective in excluding remediation wastes from facility TAB is to remove the potential influence that concern over facility applicability might have on a facility owner or operator's decision whether or not to undertake a voluntary remediation action. That is, would the benzene in remediation wastes, if generated, cause facility TAB to go from below 10 Mg/yr to above 10 Mg/yr, triggering the possible need for controls? This consideration does not apply to facilities receiving wastes from offsite where the owners are not making decisions on whether to generate wastes.

Second, if the benzene in remediation wastes were excluded from the TAB calculation at a TSDF, there would be no limit on the amount of remediation wastes that could be received before facility controls would be required. This could potentially result in an unacceptable increase in the maximum individual risk or the population exposure. (As explained in section III.C of this preamble, however, any waste that is subject to the control requirements of the Subpart at a generator site must also be controlled if sent to a TSDF, regardless of the TAB of the TSDF.) Thus, under the final rule amendments, if remediation wastes are sent offsite to a TSDF or other facility, the benzene in these wastes does count towards the TAB of the TSDF.

D. Wastes Exempt From the Rule

The EPA proposed to remove confusion over what wastes are exempt from the rule by removing paragraph (c)(3) of § 61.340. This section identified intermediate and product distillation reflux streams as examples of materials that could meet the definition of waste but are not subject to subpart FF because they are not discharged from a process. This section had caused confusion and, in the EPA's view is unnecessary since other provisions in the rule clearly indicate that materials that never leave a process are not subject to the rule. A commenter objected to the complete removal of § 61.340(c)(3), claiming that if it is removed, the EPA will be bringing streams under the rule that would have been exempt.

The EPA considered this comment but is proceeding with the deletion of § 61.340(c)(3). The exemption in this section was originally designed to apply to a narrow population of wastes that included primarily intermediate and product reflux streams, but the examples provided in the rule had been misinterpreted by some affected facilities to mean that a wider population of wastes were not subject to the rule. The EPA believes that the focus in determining which materials are subject to the rule such as identified in the commenters example should be on the definition of waste. Under this definition, waste means "any material resulting from industrial, commercial, mining, or agricultural operations, or from community activities that is discarded or is being accumulated, stored, or physically, chemically, thermally, or biologically treated prior to being discarded, recycled or discharged."

The prior wording of § 61.340(c)(3) was unclear in that it did not adequately tie the status of materials under subpart FF to the definition of waste in the rule, and as such, led some to believe that even if a material were accumulated or stored prior to waste treatment, it might be exempt from the rule. A proper focus on the definition of waste makes § 61.340(c)(3) in the original rule unnecessary. Applying the test of whether a material is accumulated, stored, or treated prior to being discharged or recycled will resolve uncertainty about the status of a material under subpart FF in most cases.

Examples provided by commenters reinforced the need to clarify coverage of the rule in a more general way than through the limited examples previously provided in § 61.340(c)(3). For instance, a refinery example cited by one commenter was overhead condensate from a distillation column that is recycled in enclosed piping to the crude desalter. This operation is not integral to the process. However, it is an example of voluntary direct recycle from one process to another (i.e., the material never leaves the process). As discussed in the next section, if a material never leaves a process, it is not within the scope of subpart FF.

E. Materials Recycled to a Process or Within a Process

The proposal included a revision to § 61.342(c)(1)(iii) to clarify the EPA's intent that waste streams that are recycled be managed and treated according to the requirements in § 61.342(c) up to the point that the waste reenters the process, including entry to a tank used for the storage of production process feed, product, or product intermediates. Commenters did not specifically object to this proposed clarification, but stated that further rule language was needed to clarify that materials recycled within a process or directly to another process are outside the scope of subpart FF. One commenter claimed that in the preamble to the proposed rule amendments, the EPA had indicated that recycled or reclaimed materials that are recycled within a process or directly recycled to another process are not within the scope of the rule. This commenter believes that similar language should be added to the regulation in order that there be a clear understanding on this point by both enforcement officials and the regulated community.

After consideration of these comments, the EPA believes that further clarification in the rule on materials recycled within a process or directly to another process is unnecessary. In the preamble to the proposed rule amendments, the EPA stated that "recycled or reclaimed materials will generally be subject to subpart FF unless they are recycled within a process or are directly recycled to another process." The basis for this statement was not the EPA's intent that materials recycled within a process or directly recycled to another process should by definition be exempt from the rule, but an assumption by the EPA that these materials generally would not meet the definition of waste in the rule.

To meet the definition of waste in the rule, a material must either be discarded or accumulated; stored, or physically, chemically, thermally, or biologically treated prior to being discarded, recycled or discharged. The test for whether materials recycled within a process or that are recycled directly to

another process are subject to the rule is whether they are accumulated, stored, or treated prior to recycling: If they are, they are subject to the rule.

F. Definition of Waste

Although the EPA did not propose to amend the definition of waste in the original rule, several commenters suggested that the EPA take action on this. Commenters criticized the definition of waste in the rule as overly broad, discouraging pollution prevention, and covering non-waste materials. Two commenters objected to the EPA's use of spent caustic in the proposal preamble, stating that it is not always a waste. One commenter requested that the EPA redefine waste to reflect the end use of a material.

As noted, the EPA did not propose any change to the definition of waste in the original rule. The definition of waste that was promulgated in the original rule was the same as proposed on September 14, 1989 (54 FR 38083). The EPA responded to comments on the proposed definition of waste in the notice of final rulemaking issued on March 7, 1990 (see 55 FR 8318). Therefore, comments on the definition of waste in the rule that were received following publication of the proposed rule amendments are outside the scope of this rulemaking.

Regarding spent caustic, the EPA acknowledges that this material is not always subject to subpart FF. In the example presented in the proposal preamble, it was assumed that spent caustic met the definition of waste. If spent caustic does not meet the definition of waste in the rule, then it is not subject to subpart FF.

IV. Control Requirements

Several comments were received on proposed clarifying amendments affecting control requirements that apply at facilities with TAB's of 10 Mg/yr or greater. These comments and the EPA's responses are discussed below.

A. Control Requirements for Organic Wastes

A clarification to § 61.342(c)(1) was proposed to reflect the EPA's intent that all wastes (that contain benzene at a concentration of 10 ppmw or more and do not meet other exemption criteria) at a facility with a TAB of 10 Mg/yr or more are subject to the control requirements of the rule. For the purpose of the TAB calculation, aqueous wastes are those containing 10 percent or more total water and nonaqueous (i.e., organic) wastes are those containing less than 10 percent total water. Only the benzene in aqueous wastes counts towards facility TAB. Once it is determined that a facility must install controls, the original rule made no distinction between aqueous and organic wastes. The same level of control was required for all wastes except those containing less than 10 ppmw benzene or those meeting other criteria for exemption from controls. In the proposal preamble, the EPA specifically solicited comments on the risks associated with organic waste streams.

The EPA did not propose that the benzene in organic wastes be included in facility TAB, a point apparently misunderstood by one commenter. Rather, language was included in § 61.342(a) of the proposed amendments to clarify the EPA's original intent that the benzene in organic wastes that become aqueous during waste management are included in TAB. If organic wastes are not mixed with water or with other wastes such that they become aqueous, the benzene in them is not included in TAB and, therefore, does not affect determinations of which facilities are subject to the control requirements in the rule.

Several comments were received on the need to control organic wastes and the level of control required. Most of the commenters requested that the EPA raise the threshold level for control for organic wastes in the final rule to 1,000 ppmw (i.e., not require controls for organic wastes containing benzene below this concentration level). This request was based on the commenters' assertion that the emission potential of benzene dissolved in organic waste is much lower than the emission potential of benzene dissolved in aqueous waste. One commenter presented calculations on the basis of which it was suggested that the control level concentration for organic wastes could be raised to 1,000 ppmw with no increase in emissions. Another commenter argued that organic wastes are already adequately controlled under the RCRA and that control by subpart FF was redundant.

The EPA has always acknowledged that when benzene is dissolved in organics, it is much less volatile than benzene in aqueous waste at the same concentration. This is a major reason why the benzene in organic wastes that are not mixed with aqueous wastes is excluded from the TAB calculation in the rule. However, the benzene in organic wastes can contribute to benzene emissions and risk, and further, if organic wastes are not controlled at facilities with TAB's at or above 10 Mg/yr, attainment of the NESHAP risk goals could be jeopardized. Therefore, the EPA concluded that organic wastes should not be excluded from control at facilities with TAB's at or above 10 Mg/yr. The rule promulgated on March 7, 1990 reflected this conclusion.

In the preamble to the final rule in the March 7, 1990 **Federal Register** notice, the EPA also responded to commenters on the original proposed rule (proposed on September 14, 1989) who had commented that other regulations promulgated under the Clean Air Act and other Federal statutes (including the RCRA) already adequately controlled benzene emissions from waste operations. In its response, the EPA explained in detail why existing regulations are not adequate for controlling benzene emissions from benzene waste operations (see 45 FR 8321, March 7, 1990). These reasons are still valid.

After reviewing information submitted by commenters on the proposed rule amendments and other information, the EPA still believes, as discussed below, that organic wastes can be a source of significant benzene emissions and risk and, therefore, should be subject to control at facilities above the threshold for applicability of controls. In addition to the concentration of benzene in a waste and its volatility in that medium, potential benzene emissions and risk are also affected by the quantity of the waste and the manner in which the waste is managed. Commenters did not address these factors.

Although no information on the quantity of organic wastes managed at facilities subject to subpart FF was submitted by commenters on the proposed rule amendments, information supplied by facilities to comply with the reporting requirements of the original rule (in § 61.357) suggests that the quantities of organic wastes, and the benzene contained in them, may be substantial. For example, in a report summarizing the regulatory status of each waste stream submitted as required in § 61.357(a) of the original rule, one facility reported over 42,000 Mg of slop oil containing less than 10 percent total water. The average benzene reported for this organic waste was 500 ppmw, which yields an annual benzene quantity of 21 Mg/yr. Another facility reported a waste that was 19 percent benzene with a benzene quantity of almost 20 Mg/yr.

With these large amounts of benzene in organic wastes, it is critical that they be properly managed or else significant benzene emissions may result. If they are managed in covered tanks, benzene emissions can be minimal. However, if at some point the wastes are managed in tanks, aerated units, or heated units (for

example, to break emulsions) that are uncontrolled for air emissions, the benzene emissions would be much higher than if the waste is managed only in covered tanks. In addition, if the waste is splash loaded into open containers several times before final disposition or recycle, much of the benzene could be emitted.

Once a facility is subject to the control requirements of the rule on the basis of the benzene in their aqueous wastes, organic wastes are also subject to control. Organic wastes are eligible for the exemption from control promulgated in today's final rule amendments for wastes containing up to a total of 2.0 Mg/yr of benzene. However, because the potential benzene emissions and risk associated with organic wastes in certain waste management scenarios could be significant, the EPA continues to believe that organic wastes not meeting other exemption criteria in the rule should be controlled for air emissions.

At the same time, the EPA also believes that due to the acknowledged lower volatility of benzene contained in organic wastes, the level of control required for organic wastes does not need to match the level of control required for aqueous wastes. The EPA considered the suggestion by commenters to establish a control threshold specifically for organic wastes based on a benzene concentration of 1,000 ppmw. However, this suggestion puts no limit on the quantity of wastes below the control threshold or on how these wastes are managed. Consequently, if this suggestion were adopted, there could be no assurance that potential benzene emissions would be limited below a level that would not jeopardize attainment of the NESHAP risk goals. On this basis, the commenters' suggestion was rejected.

As an alternative, the EPA has retained the concentration threshold for control for all wastes at 10 ppmw benzene, but has established separate control requirements for organic wastes that have not been mixed such that they become aqueous. Considering the lower volatility of benzene contained in organic wastes and the typical fate of these wastes (generally returned to a process or incinerated), the EPA has determined that controls that suppress benzene emissions are adequate for organic wastes.

Organic wastes are managed primarily in tanks and containers. The existing requirements in the rule for containers are for covers only (unless treatment occurs in the container, in which case a closed-vent system and control device are also required) and, therefore, no change is necessary. For tanks, however, the original rule required a fixed-roof plus a closed-vent system and control device (or the alternative controls for tanks described in § 61.351). Based on the considerations discussed above, the final rule amendments promulgated today include separate requirements for tanks in which organic wastes are managed. These separate requirements, in § 61.343(b) of the amended rule, specify that under certain conditions, a tank in which organic wastes are managed need only be equipped with a fixed roof. The vapor pressure and tank size cutoffs from the new source performance standards for volatile organic liquids in storage tanks (subpart Kb of 40 CFR part 60) have also been adopted in § 61.343(b) as additional eligibility criteria for the less stringent control requirements for tanks. For tanks above these size and vapor pressure cutoffs, the control requirements in the originally promulgated subpart FF are reasonable and typical. Most organic wastes will have vapor pressures below the specified limits or be managed in tanks smaller than the size cutoffs. Therefore, the vapor pressure and tank size cutoffs should not limit the utility of this new provision.

The new provisions for the management of organic wastes in tanks also include language that limits the conditions under which tank venting to the atmosphere may occur (see § 61.343(b)(3)). This language, in effect, means that tanks in which wastes are agitated, treated, or heated must also be equipped with a closed-vent system and control device.

B. Alternative Control Devices

Two comments were received on the proposed amendments to § 61.349 regarding alternative control devices. The original rule (§ 61.349(a)) specified requirements for closed-vent systems and control devices used to comply with the rule's control requirements. Requirements were specified for enclosed combustion devices, vapor-recovery systems, and flares. The EPA proposed to amend this section to allow owners and operators to use alternative control devices, provided that it is demonstrated, prior to the installation of the alternative device, that it will achieve 95 percent control of organic compounds or 98 percent control of benzene.

One commenter supported the proposed amendment as a positive one that would provide flexibility and provide a means to make the rule more cost effective. However, this and another commenter were also concerned that the language of proposed § 61.349(a)(2)(iv)(E) could be interpreted to mean that an alternative control device could not be operated until approval was received from the EPA Administrator. The commenters claimed this interpretation could discourage use of this provision and the development of innovative controls. The commenters suggested options to limit the time available to the Administrator for approval or denial of an alternative device or to allow operation of an alternative control device during the approval period, with the risk that if approval is denied, a facility may be cited for violation for the period it operated the device.

It is the EPA's intent that the performance of an alternative control device be demonstrated and that information documenting that a device will meet the requirements of the rule be submitted before it is installed and operated.

If facilities were prohibited from installing and operating alternative control devices before approval is received from the Administrator, the EPA agrees that owners and operators could be discouraged from attempting to develop and use alternative control devices. However, this is not the case. After the documentation has been submitted to the EPA, the owner or operator may install and operate the device before receiving the EPA's approval. Nevertheless, the owner or operator may be subject to enforcement action beginning from the time the control device began operation. For example, if the EPA disapproves of the device, the facility may be cited for violation for the period it operated the device. Even if the EPA approves of the use of the device, an owner or operator may not have operated the device in accordance with § 61.349 for a portion of the time period before approval was granted. In such a case, the EPA may cite the facility for a violation during that period.

The EPA considered placing a limit in the rule on the time available to the EPA to review information submitted on alternative control devices and to issue approval or denial. However, the review of each device proposed will be different, and the level and complexity of information that will be submitted to document performance cannot be predicted. For this reason, the EPA concluded that it is not reasonable to limit the amount of time available to the EPA to review the information submitted and to issue approval or denial.

The EPA does not, however, want concern about the possible time

required to receive approval from the EPA to discourage the development of alternative control devices that will meet or exceed the performance requirements of the rule. This was the EPA's original intent, but apparently, it was unclear in the language proposed. Therefore, the EPA has included language in the rule that will allow owners and operators at their risk to install and operate alternative control devices, pending approval by the Administrator, provided information and data on the device have been submitted as required by the rule. If an owner or operator chooses to install and operate an alternative control device prior to receiving approval and the EPA determines that the control device did not achieve the emission limitations or was not properly operated, the owner or operator may be cited for noncompliance with subpart FF during the period after the compliance date that the device was operated.

C. Other Comments on Control Requirements

The EPA received comments on the proposed amendment to § 61.349(a)(1)(ii) that would allow, as an alternative to flow indicators required in the original rule, the use of car-seals to indicate the position of any valves that might be used to divert the flow of emissions from a control device. One commenter supported the proposed amendment, and suggested that small connections (e. g., low-point drains and high-point bleeds) on the closed-vent system be excluded from requirements for flow indicators, car-sealed valves, and recordkeeping. Another commenter suggested plugging, capping, or blinding as an alternative to car-sealed valves for some vents and drains installed for maintenance around control devices.

The EPA believes that it is essential that air pollution control systems installed to meet the rule be equipped such that it can easily be determined if emissions are being routed to a control device. Any opening that allows emissions to by-pass a control device for an extended period of time can be a potential source of significant air emissions. It is the EPA's intent that routine opening of potential avenues of control device by-pass be prevented and monitored. It should be pointed out, however, that not all openings are prevented. Openings such as emergency venting of pressure relief devices are permitted to prevent physical damage to the closed-vent system and control device. Opening of low-point drains as described by the commenter would also be allowed as long as the drain does not permit diversion of the vent stream away from the control device.

Flow indicators and car-sealed valves provide easily observable visual evidence that control systems are not being by-passed, are widely used in industry, and are required in other NESHAP. These devices also provide recordable evidence that emissions may be escaping, whereas plugs and caps can be removed with no evidence visible that emissions are actually escaping. Although plugging and capping can be effective in controlling fugitive emissions that result from equipment leaks when used in combination with valves, the commenters do not make a strong argument why these would be as effective as flow indicators or car seals in demonstrating the integrity of a closed-vent system, especially without the valve before the cap or plug. For these reasons, § 61.349(a)(1)(ii) is not changed from proposal.

The EPA also received comments on the need for dilution air to prevent explosive mixtures in the headspace of waste management units. The EPA agrees with the commenters and the final rule has been amended to allow the addition of dilution air into waste management units that are maintained at less than atmospheric pressure. Facilities must do annual monitoring to demonstrate no detectable emissions from the opening. Also, the pressure must be monitored continuously to ensure that the pressure remains below atmospheric pressure.

One commenter asked the EPA to recognize that there are equipment cleaning and waste removal activities that are not feasible to control, and requested that these be excluded from the control requirements of the rule. Examples cited were routine pipe, strainer, and equipment cleaning; and tank and vessel cleaning.

When tanks and other equipment are opened for cleaning, the emissions from the tank opening are not covered by subpart FF. However, cleaning activities generate wastes subject to subpart FF. If the wastes have 10 ppmw or greater benzene, then the wastes must be controlled and treated in accordance with the rule. To simply exempt these wastes from control without any cap that would limit potential emissions would jeopardize attainment of the NESHAP risk goals. Therefore, these activities are not, by definition, exempted from the control requirements of the rule.

However, the EPA has included an option in the rule amendments promulgated today, as described in the next section of this preamble, that is specifically designed to provide an option for facilities to exclude from control wastes that contain benzene in small quantities, such as those cited by the commenter. Under this option, in § 61.342(c)(3), owners and operators may exclude wastes containing up to a total of 2.0 Mg/yr of benzene from the control requirements of the rule. There are no limits on which wastes are eligible. The EPA believes that with this option, and other compliance options provided in the rule as amended, owners and operators have flexibility in deciding which waste streams to control while the EPA limits the maximum possible emissions.

Since proposal of the clarifying rule amendments, questions have been submitted to the EPA concerning the definition of "water seal controls" in § 61.341 of the rule. Water seal controls are identified as acceptable controls for drains and junction boxes in the alternative standards for individual drain systems specified in § 61.346(b).

In the original rule, "water seal controls" is defined as "a seal pot, p-leg trap, or other type of trap filled with water that has a design capacity to create a water barrier between the sewer line and the atmosphere." The EPA has been asked if the examples cited in this definition are the only acceptable types of water seal controls. Other potential types of water seal controls identified by questioners were flooded sewers and baffle plates on junction boxes that extend to below the liquid surface.

The objective of the controls specified for drains and junction boxes in an individual drain system is to isolate them such that the free flow of vapors within the system is prevented. The examples cited in the original definition of water seal controls in the rule were not intended to be limiting. Other types of seals that achieve this objective are also acceptable. More specifically, flooded sewers are an acceptable control technique for individual drains and junction boxes, provided that the liquid level in the seal is maintained in the vertical leg of the drain. A baffle plate is an acceptable control for a junction box, provided each plate extends below the liquid level. In the final rule amendments, additional examples of acceptable controls have been added to the definition of water seal controls in § 61.341 to clarify this point. It is also clarified that for all water seals for drains, the water level must be maintained in the vertical leg of the trap for it to be considered a water' seal.

V. Additional Exemption for Small Benzene Quantity Wastes

Numerous commenters addressed the proposed additional option for

exempting wastes that contain small quantities of benzene from the control requirements of the rule. The EPA proposed (in § 61.342(c)(3)) that wastes containing a total of up to 1.0 Mg/yr of benzene, on an annual basis, could be exempted from control, with certain restrictions. The proposed restrictions on the use of this exemption option were that (1) the annual quantity of benzene in any waste stream exempted under this provision, except for process wastewater, could not exceed 25 kilograms per year (kg/yr); (2) if this option were elected by a facility, it would be as an alternative to the low-flow or mass quantity cutoffs for process wastewater in § 61.342(c)(3); and (3) tank drawdown and wastes from purging prior to sampling ("sample purge") would not be eligible for the proposed exemption.

In general, commenters supported the concept of providing an additional option in the rule for exempting small benzene quantity wastes from control. However, numerous commenters objected to the proposed limits on the use of the option. Commenters also requested that the EPA raise the amount of benzene that can be exempted from 1.0 to 2.0 Mg/yr. Some commenters argued that there should be no limit on either the quantity or type of streams that could qualify for the exemption, as long as the cap on the total amount of benzene was not exceeded. Other commenters specifically requested that the restrictions placed on tank drawdown and sample purge be removed. One commenter suggested that tank drawdown should not be excluded from the proposed exemption option if the tank drawdown were equipped with an oil/water monitoring device that can detect the presence of hydrocarbon in the water phase and automatically close the tank draw. Some commenters requested additional clarifying language in the regulation on which wastes would not be excluded from the proposed option.

After reviewing the comments submitted, the EPA has concluded that providing an additional option for exempting small benzene quantity wastes from the control requirements of the rule is still appropriate. However, in the final rule amendments, several changes have been made to the proposed exemption option based both on an assessment of the comments and on concerns the EPA has related to the tracking of wastes exempted under this provision. These are discussed below.

Specifically, the 25 kg per stream quantity limit and the exclusion of tank drawdown and sample purge from eligibility in the proposed exemption provisions have been removed. The cap on total benzene that may be exempted has also been raised to 2.0 Mg/yr.

The EPA's intent in proposing the additional exemption option was to expand the range of options available to owners and operators in seeking the most cost effective control strategy at each facility that must install controls to comply with the rule. In developing the proposed amendments, concerns related to tank drawdown and sample purge led the EPA to propose that these wastes would not be eligible for the new small quantity benzene exemption. Specifically, the volume and benzene content of waste streams generated through tank drawdown are highly dependent on the techniques of individual operators, making the monitoring of compliance by enforcement agencies difficult for these streams. Sample purge is required to be controlled under certain conditions by other NESHAP applicable to facilities also subject to subpart FF, and the EPA did not want to imply that the requirements of other standards would be overridden by allowing sample purge to be excluded from control under subpart FF.

Commenters argued forcefully that the restrictions proposed on use of the exemption option and the 1.0 Mg/yr of benzene proposed cap could severely limit its utility. After weighing these arguments against the EPA's earlier concerns, as discussed below, the EPA concluded that to accomplish its goal of providing a viable additional option for exempting small benzene quantity wastes, there should be no limits on which waste streams are eligible for the exemption. Further, a reevaluation of the cap indicated that the NESHAP risk goals would still be met if the cap were raised to 2.0 Mg/yr. The increase to 2.0 Mg/yr does allow benzene emissions to increase but it would not allow any facility to exceed one in ten thousand and it still results in significant reductions in population exposed to greater than one in one million risk. Thus, in the final rule amendments, any stream is eligible as long as the total benzene in all streams exempted under this provision is less than 2.0 Mg/yr.

As in the proposal, however, if this option were elected by a facility, the facility would not also be able to take advantage of the low-flow or mass quantity cutoffs for process wastewater in § 61.342(c)(3). Further, any facility electing to comply with the alternative compliance option for the rule would not also be able to exempt streams from control under the small quantity exemption options (please see section VI of this preamble).

Although the restrictions proposed for the exemption option have been removed in the final rule amendments, the EPA remains concerned about the potential for facilities to underestimate the quantity of benzene in an exempted stream. Incorrect determinations could cause the actual risk to be higher than the risk associated with 2.0 Mg/yr if the incorrect determinations result in greater than 2.0 Mg/yr of benzene in exempted wastes.

This is of particular concern for tank drawdown. As mentioned previously, the quantity of tank drawdown waste generated during each tank water draw and the benzene content of this waste is determined by individual operators and can be highly variable. Further, tank drawdown can be a multiple phase waste, making determination of the average benzene concentration difficult and subject to error. These factors make the quantity and benzene concentration of tank drawdown highly variable and difficult to predict. This creates a significant potential for the benzene in these wastes to be severely underestimated by facilities. Although less variable than tank drawdown, the quantity and benzene concentration of other small quantity wastes can also be difficult to predict.

Due to the variability in tank drawdown, the difficulty inherent in estimating the benzene content of these and other small quantity wastes, and without the restrictions on use of the option that were in the proposal, the EPA believes that it is critical that wastes exempted under this option be tracked separately and be easily identifiable by enforcement agencies. Facilities subject to subpart FF generally must already identify and characterize all benzene-containing waste streams in order to prepare the initial and annual reports required by the rule summarizing the regulatory status of each waste stream. For the purpose of tracking wastes exempted under § 61.342(c)(3), this general requirement has been clarified in the final rule amendments to specify that waste streams exempted under § 61.342(c)(3) must be separately identified in these reports. Further, the mass of benzene in these streams must be separately totaled to demonstrate compliance with the 2.0 Mg/yr benzene limit. Finally, although owners and operators are still allowed to use knowledge of the waste to estimate the concentration of benzene in these streams, it is clarified in the rule that the Administrator may require measurements to verify estimated concentrations in the case of disputes.

Due to the concerns the EPA has about tank drawdown, the suggestion by

a commenter to require a device that would automatically shut off tank draw when organic material is detected was considered. A device such as this could minimize the amount of tank drawdown waste generated by eliminating the potential for operator error. The EPA did not, however, adopt this suggestion. While at least one facility has found shut-off devices helpful in controlling tank drawdown, these devices are not widely demonstrated to be technically feasible. In addition, the cost of equipping all tanks that must be controlled under this rule with these devices may be prohibitive. Consequently, the commenter's suggestion was not adopted in the final rule amendments.

It should be noted that although the exemption option in the final rule amendments contains no restrictions on which streams may be exempted under this provision, this does not override the requirements of other NESHAP that may require control of specific streams. In particular, subpart L, applicable to coke by-product recovery facilities, and subpart J, applicable to equipment leaks of benzene, contain requirements to control benzene emissions during sampling that apply under conditions specified in those standards.

VI. Alternative Compliance Options

In the March 5, 1992 notice of proposed rulemaking, the EPA specifically solicited suggestions from the public for other structures for the rule, including supporting information, that would encourage reclamation and recycling without compromising attainment of the NESHAP risk protection goals (57 FR 8022). The EPA stated that any rule structures suggested would be considered as an alternative compliance option to the structure of the rule originally promulgated on March 7, 1990.

In the notice of proposal, the EPA set forth several criteria that must be met for suggested alternative rule structures to be considered. First, the supporting information submitted must clearly describe the suggested structure and level of protection it would provide. Secondly, any structure suggested should address the benzene emission concerns including, but not limited to, characterizing and assuring adequate control of the benzene emissions that would result from aqueous waste treatment processes, nonaqueous wastes, treatment residuals, or materials sold offsite. Thirdly, the structure should be generic in that it should be able to be applied at any facility and result in achievement of the NESHAP risk protection goals. The proposal specifically stated that the EPA was not seeking suggestions for structures based on site-specific control or risk protection. The last criterion for suggested structures was that any structure suggested should be one that can be developed and evaluated for the level of protection it provides within the timeframe of this rulemaking.

A. Compliance Options Suggested by Commenters

In response to the EPA's request in the notice of proposal, several alternative compliance options were suggested by commenters. Four general types of options were suggested. These can generally be described as (1) site-specific risk assessment, (2) emissions averaging, (3) a structure based on other existing rules that would not require calculation of TAB, and (4) treat to a target benzene quantity in waste. The suggestions made by commenters are referred to as compliance options rather than alternative rule structures because they would not change the fundamental way that facilities become subject to the control requirements in the rule, but rather would provide an alternative way to comply with these requirements.

There were also commenters who argued that the EPA should not promulgate any alternative compliance options, but require all facilities subject to the rule to comply with the rule as originally structured. These commenters contend that for the EPA to provide a more cost effective compliance option at this time would reward those facilities that did not meet the original schedule for compliance and penalize those facilities that did comply on schedule with the original rule by putting them at a competitive disadvantage.

After consideration of these comments and additional analysis, the EPA determined that a treat to a target benzene quantity compliance option would best meet the criteria set forth in the notice of proposal. Consequently, an alternative compliance option of this type is included in the final rule amendments promulgated today. A brief discussion of each compliance option suggested by commenters, and the rationale for selecting the compliance option promulgated today, is presented below.

As noted earlier, the EPA is publishing an ANPR in the **Federal Register** announcing the EPA's intent to propose for public comment an additional compliance option based on site-specific risk assessment.

Site-Specific Risk Assessment

Several commenters suggested that the EPA should allow any facility above the facility control applicability threshold of 10 Mg/yr TAB to conduct a site-specific risk assessment to demonstrate either that controls were not needed or that controls less than mandated by the rule would meet the NESHAP risk goals. Although suggested by several commenters, site-specific risk assessment as an alternative compliance option does not meet two of the criteria set forth in the March 5, 1992 notice of proposed rulemaking. As noted earlier, the EPA's solicitation of suggestions for alternative rule structures specifically stated that the EPA was not seeking suggestions for structures based on site-specific control or risk protection. The suggestion of site-specific risk assessment as an alternative compliance option clearly does not meet this criterion. Further, it was stated in the March 5, 1992 notice of proposed rulemaking that any structure suggested should be one that could be developed within the timeframe of this rulemaking (i.e., by today's date). Due to the need to resolve risk assessment policy issues and to prepare guidance for both facilities and regulatory agency personnel on how to conduct and evaluate risk assessments for benzene waste sources, the development of an alternative compliance option for subpart FF involving site-specific risk assessment would have been impossible within the timeframe of this rulemaking. For these reasons, site-specific risk assessment was not considered by the EPA as a viable alternative compliance option to be included in the rule amendments promulgated today.

Emissions Averaging

Three commenters suggested that control strategies involving benzene emissions averaging, or "bubbling," across all benzene emission sources at a facility, be allowed by the EPA as a compliance option for subpart FF. Commenters contend that at some facilities, reductions in benzene emissions from sources not covered by subpart FF (e.g., process vents or vehicles) can be achieved at less cost than controlling low-flow, low-concentration benzene waste streams. Further, commenters argue that the EPA should not be concerned about which sources at a facility are controlled if the total benzene emission reduction achieved at the entire facility is equivalent to what would have been achieved with controls as specified in the rule for benzene waste sources.

One suggestion made by commenters to implement emissions averaging is for the EPA not to change the language of § 61.353 of the rule, "Alternative Means of Emission Limitation," as proposed in

the March 5 notice. Commenters contend that without the proposed change, the EPA may approve emissions averaging strategies under this section. Emissions averaging was also indirectly suggested by other commenters who criticized the proposed change to § 61.353 as limiting consideration of emissions to those "from the source."

The EPA does not view emissions averaging as suggested by commenters to be a viable candidate for promulgation at this time as an alternative compliance option for subpart FF. Similar to the compliance option based on site-specific risk assessment suggested by other commenters, emissions averaging does not meet the criteria set forth for an alternative rule structure for subpart FF in the March 5 notice. Emissions averaging is also an inherently site-specific compliance option that would require consideration and analysis by the EPA of proposals from facilities on a case-by-case basis, with each proposal based on the unique characteristics of benzene emission sources at individual plants. Further, some commenters suggest that they be allowed to control benzene emissions from sources outside of the scope of applicability of this rule as an alternative to controlling some benzene waste sources. This raises regulatory and other issues that cannot be resolved within the timeframe of the current rulemaking. For these reasons, the EPA did not select emissions averaging as an alternative compliance option for subpart FF at this time.

The change proposed to § 61.353 by the EPA was to correct an inadvertent omission of language that would make this section consistent with the language of the General Provisions to part 61. Based on the decision not to adopt emissions averaging as an alternative compliance option for Subpart FF at this time, § 61.353 is promulgated in today's rule amendments as proposed.

Compliance Option Based on Other Existing Rules That Would Not Require Calculation of TAB

One commenter suggested an alternative compliance option incorporating the requirements of other new source performance standards (NSPS) and NESHAP, that, if elected by a facility, would not require a facility to perform or document the calculation of TAB. This commenter claimed that the control requirements of subpart Kb of part 60, and subparts Y, V, and BB of part 61 would, for example, provide adequate emissions limitation if also applied to low-concentration benzene waste streams. The commenter provided detailed regulatory language to implement this suggestion and contended that this alternative compliance option would be widely used by industry and would result in equal or better emissions reduction at a much lower cost to both industry and government agencies as a result of more uniform regulatory provisions.

For several reasons, the EPA did not adopt this suggested alternative compliance option in the final rule promulgated today. One of the criteria set out in the proposal notice is not met in that the commenter provided no estimates of benzene emissions and risk associated with the suggested alternative, and not enough information was submitted for the EPA to make these estimates. There are substantive differences in the technical requirements in the suggested regulatory language provided by the commenter as compared to the requirements in subpart FF (and in the proposed amendments) that could jeopardize attainment of the NESHAP risk protection goals. For example, the regulatory language suggested by the commenter exempts from control all waste streams that contain less than 10 kg/yr of benzene, with no cap on total mass of benzene exempted.

Also, there are no requirements in the suggested regulatory language that facilities keep records of the quantity and benzene concentration individual waste streams or of how wastes are managed. The EPA views the identification and tracking of wastes through proper recordkeeping as an essential element of the original rule and of any alternative compliance option. The need to keep records of wastes subject to the rule is particularly critical for wastes claimed to be exempt from control by owners and operators on the basis of low benzene concentration, benzene quantity, or under other compliance options provided in the rule. Without recordkeeping requirements to identify, characterize, and track the management of these wastes, there can be no assurance that the requirements of the rule are met.

The EPA disagrees that other NSPS and NESHAP provide adequate emission limitation for waste streams. Although many aspects of the control requirements of subpart FF are very similar to the control requirements of other rules, there are distinct differences in the sources and materials covered by each rule that warrant separate standards. This was discussed in the EPA's response to a similar comment submitted when subpart FF was originally proposed (see 55 FR 8321, March 7, 1990).

Although the commenter claimed that the suggested alternative compliance option would be widely used, there was no evidence supplied supporting this contention. Based on the considerations discussed above, and given the time and resources that would be required to evaluate all elements of the commenter's suggested regulatory language, the EPA did not adopt this commenter suggested alternative compliance option in the final rule amendments.

One motivation for the commenter's suggested alternative appears to be to avoid the calculation of TAB. The EPA does not view the requirement that TAB be calculated by sources affected by the rule as overly burdensome. As described in § 61.355, direct measurement of flow rate and benzene concentration of waste streams is not required, although it is acceptable. For example, the flow rate of wastes through a waste management unit can be determined based on the unit's maximum design capacity, and the concentration of benzene in a waste stream can be determined based on knowledge of the waste. Further, the initial calculation of TAB should have already been completed by facilities since its promulgation on March 7, 1990. The amendments promulgated today do not substantively change the way TAB is calculated. Therefore, the resubmission of the TAB calculation and the periodic update of the TAB calculation by facilities as required in today's final rulemaking should require minimal additional expenditures beyond what is required to characterize changes since the last update.

Treat to a Target Benzene Quantity

Four commenters suggested that the rule should include an alternative under which facilities could treat only those streams necessary to lower the total benzene in waste to a specified target level. Three commenters, without providing any details of how such an option would be implemented, suggested that the target level should be 10 Mg/yr, the same as the TAB threshold in the rule for facility control.

In the most detailed description of an alternative compliance option of this type, one commenter suggested that only the benzene in wastes not recycled or recovered should be counted in the calculation of TAB. Materials sent offsite for recycling or resale would also not count towards facility TAB provided that these wastes were not exposed to the atmosphere. Coupled with the TAB calculation that would exclude recycled, recovered, or resold materials, this commenter suggested that the facility applicability threshold be

lowered to 6 Mg/yr in the alternative compliance option. The commenter claims that his suggested compliance option would encourage pollution prevention approaches and estimates that typically 40 percent of the benzene waste contained in refinery waste streams is technologically capable of being reclaimed or recycled.

The EPA agrees that an alternative compliance option based on a target benzene quantity would encourage recycling and reclamation. Further, it meets the criteria set out in the March 5 notice for an alternative structure. However, there are two concerns about the specifics of the suggestions made by commenters. First, as noted above, some commenters suggested that the target level should be equal to the facility threshold control level, based on TAB, of 10 Mg/yr. The EPA stated in the preamble to the proposed rule amendments published on March 5, 1992, and in the preamble to the final rule issued March 7, 1990, that the 10 Mg/yr control threshold was not intended to be a target level, and that a target level, if established, would need to be less than 10 Mg/yr to guarantee attainment of the NESHAP risk protection goals.

Second, the descriptions of the treat to a target alternatives suggested by some of the commenters imply that if a facility met the target level, then it would not be subject to the monitoring, reporting, and recordkeeping provisions of the rule. Facilities would, in effect, be able to "treat out" of the rule. Because facilities above the 10 Mg/yr TAB control threshold level have been identified as potentially not meeting the NESHAP risk protection goals if controls are not installed, operated, and maintained properly, the EPA believes that all facilities subject to control requirements should also be subject to monitoring, reporting, and recordkeeping requirements.

Based on the considerations described above, the EPA has developed and included in the final rule amendments promulgated today an alternative compliance option based on treatment to a target benzene quantity. The proposal solicited alternative compliance options that would encourage reclamation and recycling. This structure is conceptually based on responses of commenters to that solicitation, with specific variations to address concerns of the EPA.

B. Description of Alternative Compliance Option Selected by the EPA for Promulgation

As discussed above, the EPA selected treat-to-a-target benzene quantity as the format for an alternative compliance option. This compliance option is available to facilities who are subject to the control requirements of the rule. To demonstrate compliance under this new alternative, a facility determines its benzene quantity. The facility benzene quantity is determined by summing the mass of benzene in all aqueous wastes subject to the rule at the point where each waste first enters a waste management unit that is not controlled for air emissions to at least the same degree required by §§ 61.343 through 61.348(a). The benzene in wastes that are aqueous at their point of generation and the benzene in wastes that become aqueous through mixing are included in the target benzene quantity. Wastes that are organic (and remain organic) must be managed in controlled units under this option. The facility target benzene quantity alternative compliance option is an alternative within the general standards. A facility choosing this option is not allowed to use the process wastewater exemption or the 2.0 Mg/yr small benzene quantity exemption.

To determine the target benzene quantity level for this alternative, the EPA used the same modeling and exposure analysis performed to support development of the original rule. The analysis indicated that a target benzene quantity of 6.0 Mg/yr, even under reasonable worst-case assumptions, would meet the NESHAP goals for maximum individual risk and total population risk.

In the final rule amendments, the alternative compliance option is set forth in § 61.342(e). Under this provision, the owner or operator may choose to control or treat any combination of aqueous waste streams that contain benzene provided that the target benzene quantity is maintained below 6.0 Mg/yr. Organic wastes are required to be managed in units controlled for benzene air emissions as they would be without the target benzene quantity alternative compliance option.

The rule specifies that under this alternative compliance option, the target benzene quantity is calculated by summing the mass of benzene in all waste streams managed in units that do not comply with §§ 61.343 through 61.348(a). The mass of benzene is determined at the point of generation for a waste stream if the first unit in which the waste is managed is not equipped with air emission controls as specified in the rule. If the first unit after the point of generation is controlled, the mass of benzene in each waste stream is determined at a point before the waste enters the first unit that is not controlled for benzene air emissions in accordance with §§ 61.343 through 61.348(a).

The EPA recognizes that in some waste management scenarios, wastes may be mixed in ways that could result in multiple counting of benzene in the determination of the target benzene quantity. For example, where controlled and uncontrolled wastes are combined in a controlled unit and then later managed in an uncontrolled unit, the benzene quantity determined in the resultant stream would contain benzene previously counted toward the target benzene quantity, since, as described in this example, some of the wastes were managed in uncontrolled units prior to combination. In this situation, the final rule requires that the total benzene quantity in the combined stream be determined to count towards the target benzene quantity. However, if this approach results in a benzene quantity that exceeds the 6.0 Mg/yr target benzene quantity, and a portion of the benzene has previously been included in the benzene quantity, the benzene quantity determined for the combined stream may be corrected to not double count the portion of the benzene that had been counted previously. In this correction, losses of benzene due to emissions, removal, or destruction in management units prior to the determinations for the combined streams shall be calculated and considered in the target benzene quantity. All calculations must be documented.

Similar to the determination of facility TAB, the benzene in all materials that meet the definition of waste in the rule and that contain 10 percent or more of water (or that are combined with other streams such that they contain 10 percent or more of water) must be included in the target benzene quantity determination except for those materials exempted from all aspects of subpart FF in § 61.340(c). Wastes transferred offsite must also be included in the target benzene quantity determination. For the purpose of determining the target benzene quantity, the benzene in an aqueous waste managed entirely in units uncontrolled for air emissions is counted at the waste's point of generation. The benzene in an aqueous waste managed in units equipped with air emission controls is counted at the point where the waste enters the first waste management unit not controlled for air emissions to the level required by the applicable control requirements of §§ 61.343 through 61.348(a). The benzene in an aqueous waste that is treated to reduce benzene is counted after the treatment device when the

waste first enters a unit not controlled to the level required by §§ 61.343 through 61.348(a), provided that the treatment device and the units in which the waste is managed prior to treatment are controlled for air emissions. If each waste stream entering an enhanced biodegradation unit is less than 10 ppmw on a flow-weighted annual average basis and all prior units are controlled, then the benzene entering the enhanced biodegradation unit is not included in the determination.

Organic wastes (i.e., those containing less than 10 percent water) are not included in the target benzene quantity unless they are mixed with other materials such that they become aqueous. For example, the benzene in an organic waste managed in a wastewater system not controlled to the level required by §§ 61.343 through 61.348(a) where the waste becomes mixed with aqueous waste is included in the target benzene quantity based on the benzene content of the waste at its point of generation or if an organic waste is managed in controlled units, where the waste enters the first unit not controlled to the level required by §§ 61.343 through 61.348(a).

However, the control requirements for organic wastes that remain organic during waste management are still applicable under this alternative. That is, organic wastes containing 10 ppmw or greater of benzene must be managed in units equipped with air emission controls to the level required by subpart FF. Further, an owner or operator who selects this alternative compliance option may not also take advantage of any other compliance option in the rule under which wastes may be exempted from control such as the option for exempting wastes containing up to 2.0 Mg/yr of benzene in § 61.342(c)(3).

There are three key differences in how the benzene quantity is determined under the new alternative compliance option as opposed to how facility TAB is determined. First, as already mentioned under the target benzene quantity alternative compliance option, if a waste stream is continuously managed beyond the point of generation in waste management or treatment units equipped with air emission controls, benzene concentration and quantity are not determined at the waste's point of generation, as would be done for TAB, but at a point before the waste enters the first unit not controlled to the level required by §§ 61.343 through 61.348(a). Second, the benzene in remediation wastes, which is not included in TAB, is included in the target benzene quantity determination. Third, the benzene in process unit turnaround wastes, which may be averaged over the period between turnarounds in the calculation of TAB, is included in the target benzene quantity determination in the year in which the wastes are generated.

Remediation wastes are not included in the calculation of TAB to not discourage voluntary remediation actions by facilities whose TAB's are below 10 Mg/yr by not subjecting them to the control requirements of the rule. Since treatment to lower TAB is not allowable, these facilities have no options that would keep the remediation wastes from possibly affecting facility applicability.

In contrast, the target benzene quantity alternative compliance option is an optional means of compliance available to facilities determined to be subject to the control requirements of the rule. Facilities have flexibility to take actions (such as treating wastes) that affect the calculation of the benzene quantity that they do not have with TAB. Due to the flexibility available under the target benzene quantity alternative compliance option, the EPA believes it is appropriate that the benzene in all aqueous wastes, including the benzene in aqueous remediation wastes, be included in the benzene quantity.

Similarly, the benzene in process unit turnaround wastes may be averaged over the period between turnarounds in the calculation of TAB due to a facility applicability concern, namely to reduce the impact on small facilities whose TAB would go above 10 Mg/yr only in years that turnaround occurs if averaging were not allowed. With the flexibility provided under the target benzene quantity option, a facility may treat process unit turnaround wastes if necessary to keep its benzene quantity below 6.0 Mg/yr. Considering this flexibility, the EPA sees no need to provide an averaging option for process unit turnaround wastes under the target benzene quantity alternative compliance option.

A facility that selects the target benzene quantity alternative compliance option must also account for wastes that are sent offsite. The benzene in wastes sent offsite that contain 10 percent or more of water at their point of generation counts towards the target benzene quantity of the facility from which the waste is transferred (e.g., the generating facility). The benzene quantity of these wastes is determined at the point before the waste enters the first unit that is not controlled according to §§ 61.343 through 61.348(a). This point may be at the offsite facility provided that documentation of the benzene quantity is obtained from the offsite facility and the documentation also indicates that the waste is managed in controlled units up to the point the benzene quantity is determined. The benzene in wastes that are input to another process at an offsite facility may be counted as zero in the determination of target benzene quantity for the generating facility, provided the waste is managed in units controlled according to §§ 61.343 through 61.348(a) prior to reentering a process and documentation is obtained. A generating facility without documentation from the offsite facility determines benzene quantity of these wastes at the point where the waste leaves the generating facility, assuming the waste is managed in units controlled according to §§ 61.343 through 61.348(a) up to that point. All organic wastes sent offsite must also be controlled at the receiving facility in units that meet subpart FF control requirements, and documentation of these controls must be obtained by the generating facility.

Similar to the notification requirements in the rule for other wastes required to be controlled under subpart FF that are sent offsite, the rule requires the generator to include, with each shipment of waste that must be controlled under the target benzene quantity alternative compliance option, a notice to the receiving facility indicating that the waste is subject to subpart FF and how it must be controlled at the offsite facility.

The target benzene quantity alternative compliance option is also available to a TSDF that is subject to the control requirements of subpart FF because the facility has a TAB of 10 Mg/yr or greater. However, any wastes received by the TSDF that have been designated for control under a generator's compliance plan under §§ 61.342(e) or (f) are not eligible for less stringent control at the TSDF under the target benzene quantity compliance option.

As noted earlier, the EPA held several meetings following proposal of the clarifying amendments to discuss possible alternative compliance options for subpart FF with representatives of individual companies, trade associations, and an environmental group. At these meetings, the EPA presented a tentative description of the target benzene quantity alternative compliance option.

Following these meetings, members of industry suggested that streams containing less than 10 ppmw benzene not be included in the determination of benzene quantity. However, no information was submitted on the total

mass of benzene in these streams, or on their impact on their contribution to facility benzene emissions and risk.

The EPA intended that the target benzene quantity alternative compliance option encompass all waste streams managed at a facility, including those containing less than 10 ppmw of benzene. This provides the maximum degree of flexibility to owners and operators in choosing a compliance approach while still limiting benzene emission to ensure that the NESHAP risk goals will be met. For example, an owner or operator may find that it is more cost effective to treat certain high volume waste streams containing less than 10 ppmw benzene than controlling numerous other low volume streams, such as maintenance wastes, containing higher concentrations of benzene. The target benzene quantity alternative compliance option would allow this.

Further, the benzene in all waste streams, including the benzene in less than 10 ppmw benzene streams, was counted towards the benzene quantity in the analysis that identified 6.0 Mg/yr as a target benzene quantity level that would meet the NESHAP risk goals. If streams containing less than 10 ppmw of benzene were to be excluded from the target benzene quantity, the target level would be substantially lower than 6.0 Mg/yr to ensure that the NESHAP risk protection goals would be met. For these reasons, the benzene in waste streams with less than 10 ppmw benzene must be included in benzene quantity as it is determined under the final rule amendments.

VII. Monitoring, Recordkeeping, and Reporting

Comments were received on specific monitoring, recordkeeping, and reporting requirements included in the proposed clarifying amendments. In addition, general comments on the reporting and recordkeeping burden associated with the entire rule were received. These comments and the EPA's responses are presented below.

A. Proposed Clarification on Monitoring Requirement for Wastewater Treatment Systems

In the March 5, 1992 notice, the EPA proposed that § 61.354(b) of the rule be changed to require that the flow rate and benzene concentration of each stream entering the first unit not controlled for air emissions (an "exempt unit") be continuously monitored, except for biodegradation units. For each enhanced biodegradation unit that is the first exempt unit in a treatment train, it was proposed that the benzene concentration of waste streams entering the unit be continuously monitored. These changes were proposed to make the § 61.354(b) monitoring requirements consistent with the control requirements for wastewater treatment systems complying with § 61.348(b). Section 61.354(b) in the original rule required monitoring of the flow rate of each wastewater stream exiting the wastewater treatment system. The EPA's intent, as explained in the preamble to the proposed clarifying amendments, was that monitoring be conducted of both the flow rate and benzene concentration of streams entering the first exempt unit, and of the benzene concentration of streams entering enhanced biological treatment units.

Numerous commenters objected to the proposed change to § 61.354(b). Many commenters stated that the continuous monitoring of benzene in waste streams is unduly expensive. Cost estimates cited by commenters ranged from $300,000 capital costs for an entire plant to over $350,000 for each waste stream. One commenter estimated that between 10 and 40 analyzers would be necessary at the typical refinery, resulting in annual costs ranging from $3.5 million to $14 million for continuous benzene monitoring at a single facility.

Some commenters argued that monitoring requirements were unnecessary. Others suggested that other less frequent techniques, such as periodic grab sampling, would provide information comparable to continuous monitors.

After an evaluation of the comments received and further investigation, the EPA has revised the monitoring requirements for wastewater treatment systems in § 61.354(b) in the final rule amendments. Monitoring of the flow rate and benzene concentration of the streams entering the first exempt unit is required, as well as monitoring of the benzene concentration of the streams entering an enhanced biological treatment unit. However, the proposed requirement for continuous monitoring has been deleted. Instead, monthly determinations are required.

Since compliance with the wastewater treatment system provisions of § 61.348(b) is based on a determination of the total mass of benzene in streams entering exempt units, and the benzene concentration of streams entering both exempt units and enhanced biological treatment units, the EPA believes that monitoring of these parameters is reasonable and appropriate. Although compliance is based on annual flow rates and annual average benzene concentration of streams managed in the wastewater treatment system, monitoring of these parameters on a more frequent basis will track fluctuations in flow rate and concentration. Data obtained through this monitoring will provide an early indication of whether compliance will be achieved on an annual basis and allow owners and operators to make changes in process or waste management operations if necessary.

Although, for these reasons, the EPA believes that monitoring is reasonable and appropriate, further investigation of the cost of continuous monitoring systems led the EPA to agree with commenters that the costs of these systems outweigh the benefits for the purposes of this rule. Vendor estimates obtained by the EPA of the capital cost of a system to continuously monitor benzene concentration ranged from $40,000 to $125,000 per stream monitored. In addition to the initial cost of the system, maintenance costs can be significant. For example, the EPA estimates that the annual costs of the weekly calibration required could be about $10,000 per monitoring device. While these costs are lower than those estimated by commenters, the EPA considers these costs to be high when compared to other available options.

The EPA believes that for the purposes of monitoring compliance with § 61.348(b), monthly determinations of benzene concentration and flow rate are adequate. Units that are expected to be exempt from control are likely to be near the end of the wastewater treatment system, after the mixing of many waste streams and management in units that tend to dampen out variation in flow and concentration. Therefore, frequent fluctuation in the benzene concentration is not expected. This sampling frequency is consistent with the requirements contained in § 61.354(a) for monitoring the effluent from waste treatment systems. Therefore, in the final rule amendments, § 61.354(b) requires monthly monitoring using grab sampling to determine benzene concentration and the procedures of § 61.355(b) to determine flow rate.

Some comments on the monitoring requirements for wastewater treatment systems complying with § 61.348(b) suggested misunderstanding of the EPA's intent. For example, many commenters focused only on the need to monitor benzene concentration. These commenters are reminded that under § 61.348(b), there are two criteria that must be met before a waste management unit is exempt from control. A unit does not have to be equipped with benzene air emission controls if (1) the benzene content of each stream entering the unit

is less than 10 ppmw benzene on a flow-weighted annual average basis, and (2) the total annual benzene quantity contained in all waste streams managed in exempt units in the wastewater treatment system is less than 1 Mg/yr. To determine if the second criterion is met, the flow rate of streams must be estimated and hence the need to monitor this parameter as well as benzene concentration.

Misunderstanding is also evident in comments made on the number of waste streams that must be monitored, and on the costs associated with monitoring these streams. Wastewater treatment systems typically are comprised of a combination of waste management units (e.g., oil/water separators, DAF units, equalization basins, activated sludge tanks, and clarifiers) configured in series to form a wastewater treatment train. Facilities typically have one treatment train, although larger plants may have two parallel trains. Prior to entering a wastewater treatment system, individual wastewater streams are normally combined to facilitate treatment in a treatment train. The intent of proposed § 61.354(b) is to monitor the benzene concentration and flow of this combined wastewater stream at the point where it enters the first exempt unit in a treatment train. This requirement should require a limited number of monitoring devices. Commenters who claimed that many streams would have to be monitored apparently misinterpreted § 61.354(b) to mean that the flow and benzene concentration of each waste stream that is eventually combined and managed in an exempt unit in a wastewater treatment system must be monitored at its point of generation. This is not a correct interpretation of the rule. Monitoring of the combined stream at the point where it enters an exempt unit is what is intended.

B. Maintenance Turnaround Plan

In the notice of proposal, the EPA asked for comments on several aspects of the proposed requirement for a maintenance turnaround plan in § 61.356(m) (see 57 FR 8023).

Several commenters argued that because maintenance turnaround wastes were already subject to the control requirements of the rule at facilities with a TAB of 10 Mg/yr or greater, the requirement for a plan to minimize air emissions from maintenance turnaround wastes at these facilities was redundant and unnecessary. The recordkeeping burden associated with preparing a plan was criticized as excessive by some commenters who requested a reduction in the level of detail required. One commenter said that the language of the proposal preamble suggested that a separate plan would be required for each turnaround and asked that it be clarified that a single generic plan was required at a facility.

Many commenters asked that the proposed requirement that the maintenance turnaround plan be in the plant operating record by the effective date of the rule amendments be modified such that the plan was not required until 60 to 90 days before turnaround actually occurs. One commenter supported the need for a maintenance turnaround plan in conjunction with a suggested alternative compliance option.

The maintenance turnaround plan, as proposed, has been interpreted to apply to benzene emissions generated during activities associated with process unit turnarounds. However, subpart FF is intended to apply only to the wastes generated by process unit turnarounds. The EPA considers the turnaround activities, even though they generate the wastes, to be part of process unit operations, rather than waste management operations.

The EPA considered all of the comments on the turnaround plan and has deleted the plan from the requirements. Because wastes generated during a turnaround are subject to the requirements of the rules, there is an incentive for facilities to minimize the amount of wastes generated. Wastes that are generated must be accounted for in the TAB determination. Further, not all wastes generated during turnarounds require control due to the small quantity exemptions and the alternative compliance option. Finally, there appears to be some confusion over the scope of the plan. For these reasons, the EPA has deleted the requirement for the process unit turnaround plan in the final rule amendments.

C. Other Comments on Monitoring, Reporting, and Recordkeeping

Comments were also received on other aspects of the monitoring, reporting, and recordkeeping requirements of the rule. These are discussed below.

Several comments were received on the monitoring, reporting, and recordkeeping requirements associated with wastes that are sent offsite by a generator to a TSDF. One commenter stated that no rationale had been presented by the EPA for requiring the generator to include a notice with wastes shipped offsite that they must be managed and treated to meet subpart FF. Another commenter claimed that the inspection, monitoring, recordkeeping and reporting requirements will be a heavy burden for handlers of a large number of containers such as drums that are filled once and then sent to a TSDF. This commenter proposed an alternative that would allow initial monitoring of containers for detectable emissions after the containers are filled. Containers certified to have no detectable emissions would be labeled as such. No additional monitoring or inspection of these containers would be required until the containers were reopened.

These comments are outside of the scope of the proposed clarifying amendments. Further, they are not questions for clarification; rather they are requests to change the original rule requirements.

Commenters noted that § 61.357(d)(1) in the proposed amendments requiring a compliance certification "within 90 days after March 5, 1992" was in error. The proposed language of this section should have read "within 90 days after (date of promulgation of clarifying amendments)." A notice was issued by the EPA on May 20, 1992 (57 FR 21368) to correct this error.

One commenter suggested that if there have been no changes to a report previously submitted that summarizes the regulatory status of each waste stream (as described in proposed § 61.357(a)) then only a statement that the previous report is still valid should be required, rather than the submission of a copy of the previous report. The EPA agrees with the commenter on this point and § 61.357 has been amended as suggested.

One commenter stated that there should be no reporting requirements for facilities that do not have any benzene in process or waste materials. The EPA views the reporting requirements in the rule for these facilities as minimal and necessary. Chemical plants, petroleum refineries, coke by-product recovery plants, and TSDF that receive wastes from these industries are subject to subpart FF. Under § 61.357(a), a facility subject to subpart FF that has no benzene onsite in wastes, products, by-products, or intermediates is required to submit only a statement to this effect. The EPA believes that this minimal reporting is necessary to identify all plants potentially subject to the rule and to differentiate those facilities that must install controls from those that do not have to install controls. Therefore, there is no change to this requirement from proposal.

Two comments were received by the EPA on recordkeeping and reporting requirements promulgated in the original rule for subpart FF, although

the EPA did not propose changes to these requirements in the clarifying rule amendments. Commenters requested that the EPA consider the overlap of recordkeeping and reporting requirements under subpart FF with recordkeeping and reporting requirements under the new standards developed under Section 112 of the Clean Air Act as amended in 1990, including, in particular, the proposed NESHAP for Source Categories: Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry and Seven Other Processes NESHAP. One commenter recommended specifically that the EPA require reporting for subpart FF on a semiannual basis to be consistent with the new operating permit program requirements (57 FR 32250).

In the clarifying amendments, the EPA did not propose any change to the recordkeeping and reporting requirements of the original rule. These requirements were proposed on September 14, 1989, and opportunity for public comment occurred at that time. The EPA responded to comments on the proposed recordkeeping and reporting requirements in the notice of final rulemaking issued on March 7, 1990 (see 55 FR 8318). Therefore, these comments on the original recordkeeping and reporting requirements are outside the scope of this rulemaking. However, one of the commenters requested corrections of some errors in the cross-referencing in the rule requirements and also suggested minor changes. The EPA made the suggested corrections and minor changes to the recordkeeping and reporting requirements and they do not change the burden associated with the recordkeeping and reporting.

One commenter claimed that hundreds of hours per year per response would be required to collect information necessary to comply with the reporting and recordkeeping requirements of subpart FF as opposed to the EPA's estimate of 11.9 hours per response. This commenter claimed that additional review is called for under the Paperwork Reduction Act.

The estimate of 11.9 hours per response presented in the preamble to the proposed clarifying amendments is for the information collection requirements in the proposed amendments, and not for the information collection requirements of the entire rule. The information collection requirements of the original rule were approved by the Office of Management and Budget at the time the original rule was promulgated. Based on changes to the clarifying amendments since proposal, the public reporting burden for the rule amendments has been reestimated and is presented in the next section of this preamble.

VIII. Policy for Granting Waivers of Compliance

Owners and operators of existing sources subject to a NESHAP promulgated under the Clean Air Act prior to the 1990 Clean Air Act Amendments must be in compliance with the rule within 90 days of the rule's effective date, unless a waiver of compliance is granted by the Administrator. The period for a waiver may not exceed 2 years beyond the effective date of the rule. For a NESHAP, the effective date is the date of promulgation in the **Federal Register**.

To resolve confusion about subpart FF, the EPA chose to stay the effectiveness of the rule while clarifying amendments were developed. The effective date for the amended rule is today's date, and existing sources must be in compliance within 90 days of today's date unless a waiver of compliance is granted by the Administrator.

The owner or operator of an existing source unable to come into complete compliance with the NESHAP for existing waste operations within 90 days of the effective date of this rule may apply for a waiver of compliance in accordance with the procedures described in 40 CFR §§ 61.10 and 61.11. One requirement of these provisions is to demonstrate that the additional time is necessary for the installation of controls. In addition, as the EPA stated in the March 5, 1992 proposal, the EPA believes that it is essential that the risk to human health from benzene emissions be mitigated. The EPA believes that the best way to mitigate the benzene emission reductions that will be lost due to delayed compliance during the waiver period is to reduce benzene emissions elsewhere at the facility. However, in some instances it may not be technically or economically feasible to achieve such benzene emission reductions. Accordingly, in the preamble to the proposed rule, the EPA indicated that it would consider various other types of environmentally beneficial activities that could be credited (on a discounted basis) towards the mitigation goal. In the preamble to the proposed rule amendments, the EPA set forth a hierarchy of activities (see 57 FR at 8026).

One commenter objected to the broad degree of available mitigation options. The commenter expressed concern over the ability of the EPA to determine whether the mitigation made up for the lost benzene emission reductions where the mitigation included emission reduction of nonhazardous air pollutants, nonair emission reductions and nonquantifiable pollution reduction projects. The commenter requested that only benzene emissions be credited for mitigation or at least that mitigation be limited to reductions of other hazardous air pollutants with a weighting factor included.

The EPA understands the concern about the uncertainty in equating one type of emissions reduction with a reduction of another pollutant or in another media, and, as a result, the final mitigation policy is somewhat narrower than outlined in the proposed rule.

It remains the EPA's policy that a source should seek to reduce other benzene emissions first, where such reductions are technically and economically feasible. However, because of (1) the unique nature of this rule; (2) the efforts made thus far by sources seeking to comply with the benzene waste NESHAP; (3) the relatively short period of time that remains for submitting waiver applications; (4) the conditions for granting a waiver are more restrictive than announced in the proposal notice; and (5) the departure set forth herein is consistent with efforts to resolve litigation brought by both environmental and industry parties, the EPA is providing opportunities to achieve the mitigation goal through projects involving the reductions of pollutants other than benzene when projects to reduce benzene emissions are not technically and economically feasible.

Thus, the EPA has determined that a source seeking a waiver must determine and achieve its mitigation objective as follows. First, the source must determine the additional amount of benzene emissions that will be emitted to the air from emission points subject to subpart FF as compared with the emissions expected if the source complied with that standard without a waiver. Second, the source must multiply that amount by 1.5. This quantity, expressed in kilograms, becomes the source's mitigation goal. Then a source must identify how it will achieve that goal.

The EPA will continue to give the highest priority to obtaining reductions of other benzene air emissions to meet this mitigation goal. Thus, a source must include in its waiver application all emission reduction projects for benzene, where it is technically and economically feasible to achieve such benzene reductions. If a source undertakes a benzene project (having determined it to

be technically and economically feasible based on the benzene reductions to be achieved) that also achieves coincidental reductions of other hazardous air pollutants (HAP's) or volatile organic compounds (VOC's), the source may include as a mitigation credit those coincidental reductions on a discounted basis as described below.

If a source demonstrates that there are no other technically and economically feasible projects to reduce benzene emissions and that as a result of those projects it still cannot achieve its mitigation goal, the EPA will accept additional projects supplying reductions of other HAP's listed under section 112 of the Clean Air Act as amended in 1990 at a ratio of 1.1 kilograms of other such pollutants per kilogram of the source's unmet mitigation goal.

If a source demonstrates that emission reduction projects supplying sufficient reductions of other NAP's are not available, the EPA will accept additional projects resulting in reductions of VOC's, at a ratio of 2.2 kilograms of such pollutant per kilogram of the source's unmet goal.

Mitigation may not be credited if the reduction is to meet any other regulatory requirement. However, if a source achieves early compliance with some future regulatory requirement, it can be credited with the reductions which occur up to the time the requirement goes into effect.

Finally, the EPA will consider waiver applications for up to three projects involving reductions of sulfur oxides (SO_x), if the sources seeking these reductions demonstrate that adequate reductions of benzene, other NAP's, and VOC's are not available at their facilities. These sources must provide at least 2.2 kilograms of SO_x for each kilogram of credit towards the mitigation goal. The EPA believes it is appropriate to consider these projects in this case only because the planning for these projects may already be far advanced, and it may not be feasible for such sources to develop other mitigation projects in time to apply for a waiver.

The EPA is adopting the mitigation principles set forth above for this rule because of the reasons outlined above. The interpollutant provisions of this action do not establish any precedent for future actions.

For subpart FF, the EPA believes the waiver policy described in the March 5, 1992 notice of proposed rulemaking is a legitimate exercise of the Administrator's discretionary authority to grant waivers of compliance under section 112 of the CAA. This policy was discussed in the preamble to provide information to potential waiver applicants and not to indicate that the policy was part of the proposed rule amendments proposed for comment. The only requirement related to waiver applications in the proposed rule amendments was that waiver applicants include, with their applications under § 61.10, a plan that is an enforceable commitment to obtain environmental benefits to mitigate the benzene emissions that result from delayed compliance. This requirement is retained in the final rule. The criteria for judging whether an application for a waiver of compliance for subpart FF is acceptable have been established by the Administrator under his discretionary authority for granting waivers. These criteria are fully explained in the waiver guidance document prepared since proposal of the rule, as discussed in the following section.

A. Waiver Application and Review Process

A number of other comments addressed issues related to the waiver. Several commenters urged the EPA to make the waiver application and review process simple and expeditious. Some suggested that the rule require the EPA to make determinations within 30 or 45 days of receipt of an application. One commenter stated that the EPA had failed to substantively describe the waiver process. Another commenter urged the EPA to solicit industry comment during development of waiver guidance and to release the guidance as soon as possible.

The general waiver application and review process for NESHAP was previously established in §§ 61.10 and 61.11 of the General Provisions to part 61. Due to the special circumstances of subpart FF, and to expedite the application and review process for waivers under subpart FF, the EPA prepared a draft guidance document, "Benzene Waste Operations—NESHAP Waiver Guidance Document." This guidance document describes the waiver application and review process, articulates the policy to be followed by the EPA in reviewing waiver applications for subpart FF, and describes in detail the information that should be included in a waiver application for this rule, with examples provided. The draft guidance document was circulated to trade associations representing companies affected by subpart FF (including the commenter who stated that the EPA had failed to substantively describe the waiver process), and an environmental group for comment on the document's clarity and readability. The document will soon be published and made available to the public. The basic principles to be included in the document were outlined above. The EPA believes that this guidance document, plus the general procedures already established in §§ 61.10 and 61.11, will expedite the process for waiver approval to the extent possible for this rule. The EPA or the delegated authority will make every effort to review promptly all waiver applications. However, the EPA will not limit in advance the amount of time available for review as suggested by commenters because the EPA cannot anticipate with certainty such variables as the complexity of each application received (related to site-specific factors) and the number of applications that may be received by an individual EPA regional office or delegated authority.

One commenter asked the EPA to consider a less onerous, less detailed demonstration for granting a waiver of several additional months in cases where the control equipment is operating, but the monitoring, recordkeeping, and other procedural requirements are not yet in place.

The EPA believes that a situation in which a facility is able to be in compliance with all of the control requirements but is not able to comply with the monitoring and recordkeeping requirements is unlikely. However, if this situation were to arise, there is no reason to make the waiver application different. The basic information required relates to how and when the facility will be in compliance. The mitigation plan is based on the estimated benzene emissions that will be lost due to delayed compliance. In the situation described by the commenter, few, if any, benzene emissions may be required to be mitigated.

B. Mitigation Requirements

Several comments were received related to the proposed requirement that facilities submit, with a waiver application, a plan that is an enforceable commitment to obtain environmental benefits to mitigate the benzene emissions that result from extending the compliance date. One commenter argued that the waiver policy should not require offsetting mitigation actions because this requirement would penalize facilities that are taking additional time to implement comprehensive multimedia compliance programs. Finally, a commenter specifically supported allowing reductions of other pollutants and non-air media actions to count towards a facility's mitigation goal and pointed to other rules that require control of sources of benzene (other than benzene

waste sources) at coke by-product recovery plants, thus limiting the opportunity to reduce benzene air emissions from other sources at these facilities.

The granting of waivers of compliance by the EPA Administrator is discretionary. That is, the Administrator may grant a waiver of compliance, but is not obligated to do so. Nothing in the language of the statute limits the EPA's ability to make the granting of waivers for a particular rule conditional on terms that the Administrator, in his sole judgement, determines to be necessary for that rule.

One commenter, also a litigant on subpart FF, contends that they should not be required to provide for mitigating environmental benefits because their settlement agreement makes no mention of such a requirements. The commenter also contends that the waiver policy is inconsistent with the settlement statement that compliance waivers will be on a refinery-by-refinery basis.

The EPA disagrees with the commenter's contentions. The settlement agreement to which the commenter refers in no way precludes a requirement that the commenter (or any other source) obtain mitigating environmental benefits if it seeks a waiver of compliance following promulgation of the amendments to clarify 40 CFR part 61, subpart FF. Nor does it preclude any other condition of the waiver. The criteria and requirements for seeking a waiver will apply to all applicants. The settlement agreement merely provides that when considering whether to grant a waiver, it will not penalize the commenter for its good faith belief that its refinery was not subject to the standard when it was promulgated in 1990. Requiring it to obtain mitigation for the benzene emissions that will be lost during the pendency of the waiver period is not a penalty for the source not achieving compliance by March 1992; rather, it is a condition for a waiver beyond the new effective date of the revised subpart FF standard.

The settlement agreement addresses the question of whether the EPA would find that an applicant is making every effort to comply with the standard but that it is unable to comply by the compliance date where it did not make any effort from March 1990 to December 1991 because it did not think it was covered by the rule. The settlement agreement made clear that the EPA would not penalize the commenter because prior to the signing of the settlement it believed that it was not subject to the standard. It did not purport to provide the commenter special treatment vis-a-vis all other sources with respect to the requirement to undertake mitigation to make up for the benzene emissions lost if a waiver is granted.

Finally, the waiver policy is not inconsistent with the statement that the waiver applications will be considered on a refinery-by-refinery basis. In 1990, when the EPA promulgated subpart FF, it granted a 2-year compliance waiver to all sources affected by the rule. It did not require each source individually to make the demonstration of need for a waiver as required by 40 CFR 61.10. In contrast, the EPA wanted to make clear that this time it would not issue a generic waiver. Rather, each source seeking a waiver must file its own request for a waiver; each application will be considered on its own merits. The language cited by the commenter can in no way be read to suggest that there would be different criteria for waivers for different sources or that some sources would not be required to provide mitigating environmental benefits.

One commenter contends that the EPA lacks the statutory and regulatory authority to require waiver applicants to provide mitigating environmental benefits in the absence of a finding that such conditions are necessary to protect the health of persons from imminent endangerment.

Section 112(c)(1)(B) of the Clean Air Act (CAA), prior to passage of the Clean Air Act Amendments of 1990, provides that the Administrator may grant a waiver if he finds additional time is necessary for installation of controls and that "steps will be taken to assure that the health of persons will be protected from imminent endangerment." The regulations implementing this statutory waiver provision further provide that the Administrator may "[s]pecify any additional conditions which the Administrator determines necessary * * * to assure protection of the health of persons during the waiver period" (40 CFR 61.11(a) (4)).

This regulatory provision is very broad and affords the Administrator wide discretion in granting waivers. Waivers themselves are available at the discretion of the Administrator; no source is entitled to a waiver. The EPA believes this broad regulatory authority affords the Administrator the discretion to condition a waiver on an assurance that the source will undertake activities to benefit the environment and to protect human health. The mitigation policy that seeks, in the first instance, to obtain other benzene air reductions, is an effort to effectuate the waiver provisions in 40 CFR 61.11.

The opportunity to mitigate, and thereby protect human health and the environment, by reducing pollutants other than benzene air emissions, was an effort to provide a source an opportunity to satisfy the conditions of 40 CFR 61.11 where it was not feasible to otherwise reduce benzene emissions at a particular facility.

C. Special Requirements for Waiver Applicants Awaiting Development of a Compliance Option Based on Site-Specific Risk Assessment

As previously noted, the EPA is planning to propose an additional compliance option for subpart FF based on site-specific risk assessment. Owners or operators who plan to use this option, if it becomes available, are eligible to apply for waivers of compliance. The EPA plans to take final action on the additional compliance option by August 1993.

Mitigation goals and credits under the waiver policy must be calculated based on a plan to comply with subpart FF, as amended by today's final rulemaking, and not based on using the alternative compliance option. If an additional compliance option is promulgated, facilities may modify the enforceable commitment to reduce the mitigation goal, based from that date forward on lost benzene emission reductions under the new compliance option. However, the goal for mitigation of lost benzene emission reductions, based on the amended rule promulgated today, that occurred prior to the effective date of the new compliance option, shall not change.

Waiver applications by applicants awaiting the development of an additional compliance option should reflect a two-phase compliance path. The first phase would outline how compliance will be achieved with a site-specific risk assessment-based compliance option. In the first phase of the waiver application, the applicant shall demonstrate how, and on what schedule, compliance under this option would be expeditiously achieved. This phase of the compliance path would not have to show installation of control equipment necessary for compliance with §§ 61.343 through 61.349 of subpart FF, if that control equipment would not be required under a compliance option based on site-specific risk assessment.

The second phase of the compliance plan shall document, how the applicant will comply with §§ 61.343 through 61.349 of subpart FF, as amended by today's final rulemaking. This compliance path would then be implemented by the applicant if a

compliance option based on site-specific risk assessment is not promulgated (presently final action is scheduled for August 1993, as discussed above).

Finally, applicants awaiting development of an additional compliance option for subpart FF should recognize that they will not receive additional time beyond the waiver period for compliance, and that waiver period shall not extend more than 2 years beyond the effective date of today's amended rule.

IX. General

A variety of comments in addition to those discussed in previous sections were received in response to the proposal of clarifying amendments to subpart FF. These additional comments, and the EPA's responses are discussed below.

A. Risk Assessment Supporting the Original Rule

Many comments were received criticizing the EPA's risk assessment that was performed to support development of the original rule promulgated on March 7, 1990. This risk assessment had been performed to demonstrate both that the original rule was necessary and that the NESHAP risk protection goals would be met under the final rule. Several commenters claimed that the original analysis was flawed because the model used grossly overstates emissions and risk. Some commenters stated that benzene emission estimates for specific sources were overestimated in the analysis. These commenters stated that the risk assessment should be redone using more recent exposure models developed by the EPA and incorporating more site-specific information. A few commenters had performed their own risk assessments for several facilities and claimed that the results showed controls were not needed to the level required by the rule.

These commenters incorrectly assumed that with the proposal of clarifying amendments to subpart FF, the EPA was reopening the entire rule, and the original analyses supporting it, to further public comment and possible change. To the contrary, the amendments proposed were narrow in scope, designed to clarify only those specific points on which there had been confusion following promulgation of the original rule. They also were designed to provide additional flexibility to owners and operators who must comply with the control requirements of the rule.

The appropriate time for comments concerning the technical basis of the original rule was following proposal of the rule on September 14, 1989 (54 FR 38083). The need for the controls required by the rule was discussed in the preamble to the proposed rule and the technical analyses supporting the proposed rule were placed in the docket prior to proposal and were available for public review. Comments received on the need for the rule and the analyses supporting the rule were carefully considered, and changes in the analyses and the rule were made as appropriate before promulgation of the final rule on March 7, 1990.

In the notice of final rulemaking, the EPA presented thorough and extensive responses to comments on the risk assessment methodology used to evaluate sources of benzene wastes and other sources of benzene emissions (see 55 FR 8301 to 8307). The proposal of clarifying amendments does not reopen those parts of the rule unaffected by the amendments (and the technical analyses supporting them) for public comment.

B. Costs of Controls

Several comments were received claiming that the EPA had understated the costs of the benzene waste NESHAP. Commenters stated that the capital cost of complying with the rule is several billion dollars based on industry surveys. Because of this, commenters say the benzene waste NESHAP is a major rule and that a Regulatory Impact Analysis (RIA) must be performed. One commenter stated that this rule is a prime candidate for review under the President's regulatory review initiative.

As discussed earlier, the proposal of clarifying amendments to subpart FF did not reopen the entire rule for public comment. While it is possible that the EPA may have underestimated the cost of complying with subpart FF as originally promulgated, it is also possible that facilities may be overstating the cost of compliance. Many facilities subject to subpart FF are implementing multi-media compliance strategies designed to meet the requirements of many regulations to control pollution, including subpart FF. The EPA believes that these facilities, in some cases, may be overstating the portion of total compliance costs that are attributable to subpart FF.

Under Executive Order 12291, an RIA is required if the economic impacts of a rulemaking would exceed $100 million. The rule amendments clarify, but do not change, the basic requirements of the rule. Therefore, there is no additional compliance cost associated with the rule amendments. The clarifying amendments promulgated today include additional options for compliance. The additional options provided would reduce the cost of complying with subpart FF at some facilities. Hence, any impact of the rule amendments on the costs of complying with subpart FF would be to reduce compliance costs.

The EPA therefore believes that the costs associated with the rule amendments do not exceed the $100 million threshold, the amendments will not significantly increase process or production costs, and the amendments will not cause significant adverse effects on domestic competition, employment, investment, productivity, innovation, or competition in foreign markets. Consequently, the rule amendments do not constitute a major rule and an RIA is not required.

Further, the EPA also views the rule amendments as consistent with the President's regulatory review initiative. A primary objective of the regulatory review initiative is to improve the clarity of regulations. The amendments to subpart FF are designed to clarify provisions of the original rule and, therefore, are consistent with this objective. The amendments are also consistent with the regulatory review initiative in that they provide additional options for compliance that (1) may be more cost-effective for some facilities; (2) encourage recycling, reclamation, and pollution prevention, and (3) encourage comprehensive multi-media compliance programs.

C. Legal Aspects

One commenter, a trade association, contends that it and its members' companies will have the right to obtain full judicial review of the total NESHAP when the final rule is issued.

The commenter is incorrect in this assertion. The assertion is without foundation in the law. The Clean Air Act limits the right to petition for judicial review of a rule to a 60-day period following publication of the final rule in the **Federal Register:**

> Any petition for review under this subsection must be filed within 60 days from the date notice of such promulgation, approval, or action appears in the **Federal Register**, except that if such petition is based solely on grounds arising after such sixtieth day, then any petition for review under this subsection shall be filed within 60 days after such ground arise.

CAA, § 307(b)(1), 42 U.S.C. 7607(b)(1).

The notice of proposed rulemaking issued on March 5, 1992 states throughout that it only proposes clarifying amendments and minor revisions to limited provisions of

subpart FF. The entire basis of the rule was not reopened. If commenters objected to the aspects of the rule when it was promulgated, then they had the opportunity to file a petition for review at that time. By making minor amendments to a few provisions of 40 CFR part 61, subpart FF, the EPA does not override the directives of section 307(b) and reopen the entire rule. Moreover, the one petitioner that did challenge the final rule negotiated a settlement agreement whereby the EPA committed to propose the clarifying changes set forth in the March notice. By issuing a final rule today that is consistent with those changes, the EPA has satisfied its obligations with respect to the settlement agreement. As a result, the petitioner, by terms of the settlement agreement, has committed to dismiss its original petition for review.

One commenter stated that the EPA may not apply these amendments to sources that already expended efforts to comply with the rule if the company used a good faith interpretation of the rules in developing its compliance plan. This commenter asked the EPA to provide a "grandfather" exemption from the amended rule for facilities that spent money in good faith and complied with the original rule by March 7, 1990. The commenter contends that under the holding of *United States* v. *Narragansett Improvement Company*, 571 F. Supp. 688 (D.R.I. 1983) it would be unlawful to apply the proposed amendments (once made final) to its facility.

The EPA commends the commenter for its efforts to achieve timely compliance with requirements of subpart FF when it was promulgated in 1990. Moreover, the EPA recognizes that there was substantial confusion about certain provisions of the rule following its promulgation. Indeed, as the EPA noted at the time it proposed clarifying amendments, the amendments were to help reduce the confusion. The intent and scope of the rule, however, remain essentially the same. The amendments promulgated today become part of the subpart FF requirements. Unless a source receives a waiver of compliance pursuant to 40 CFR 61.10 and 61.11, it must comply with the provisions of subpart FF, as amended, within 90 days of the effective date.

The application of these rules to an affected facility is not precluded by the decision on *United States* v. *Narragansett, supra*. In *Narragansett*, the court held that a regulation defining when certain reconstruction activity was subject to a new source performance standard could not apply to activity undertaken before the EPA had issued the regulation. In this situation, the EPA would not be seeking to retroactively apply the amended rule to the source. The source need only comply with the amended standard on the new compliance date. In *Narragansett*, the determination of whether a source was new was based on a one-time determination, which is made at the time the construction activity occurs. All the court said in *Narragansett* was that the regulations on the book at the time the facility undertook its construction activity was determinative of whether the source was new. Thus, subsequently promulgated regulations could not alter the determination of whether a particular activity triggered new source applicability. Here the EPA is not saying that the source should be in compliance with the revised standards as of the original compliance date of March 1992. Rather, the source must be in compliance with the amended rule as of the new compliance date.

Further, as stated in the March 5, 1992 notice of proposed rulemaking, the amendments do not change the basic requirements of subpart FF. Rather, they clarify the EPA's original intent on those provisions of the original rule where confusion was evident. By staying the rule while clarifying amendments were proposed and promulgated, the EPA provided additional time for facilities who did misinterpret the original rule to come into compliance. Facilities that correctly understood and complied with the requirements of the original rule previously should be in compliance with the amended rule.

D. Compliance Aspects

One commenter suggested that the EPA amend the proposal to extend the compliance date for the amended rule to March 1994 or to 1 year after the final amended rule is promulgated, whichever is later. This commenter said that this would prevent facilities from installing needless controls while uncertainty on the final rule still exists. Another commenter asked the EPA to announce that it will allow sufficient time for compliance after the final amended rule is issued to allow the use of possible alternative approaches.

The compliance time available to existing facilities following promulgation of a NESHAP under the Clean Air Act prior to the 1990 Clean Air Act Amendments is established by law as 90 days from the effective date of a rule, unless a waiver of compliance is obtained (see section 112(c)(1)(B) of the Clean Air Act as amended in 1977). The effective date of a NESHAP is the date of promulgation.

Subpart FF was originally promulgated on March 7, 1990. The original rule provided a blanket waiver of compliance to facilities such that controls were to be installed no later than March 7, 1992. Prior to March 7, 1992, subpart FF was stayed pending final action by the EPA on clarifying amendments to the rule. In a settlement agreement with litigants on subpart FF, the EPA committed to taking final action on clarifying amendments to the rule by December 1, 1992.

Given that the effectiveness of subpart FF was stayed until final action was taken on the clarifying amendments proposed March 5, 1992, the EPA does not believe that there is the need to take the unusual step of issuing a blanket waiver of compliance for subpart FF as amended. Therefore, the compliance date for the amended rule is 90 days from today's date unless a waiver of compliance is obtained. Applications for waivers of compliance will be considered on a case-by-case basis by the Administrator according to §§ 61.10 and 61.11 of the General Provisions to 41 CFR part 61.

Finally, a commenter stated that if the TAB of a facility goes below the control threshold of 10 Mg/yr in the future, the facility should only be required to continue to comply with the rule provisions for facilities with comparable TAB's (i.e., below 10 Mg/yr).

The EPA agrees with this comment. If, at some point in the future, a facility's TAB (as determined according to the rule) is reduced to below 10 Mg/yr, then the facility would no longer be subject to the control requirements of the rule, but must continue to comply with the reporting and recordkeeping requirements. This was allowed in the original rule and is still allowed under the amended rule. The commenter is reminded, however, that while means such as benzene waste minimization are acceptable to reduce facility TAB, waste treatment is not acceptable to reduce TAB.

E. Points for Sampling and Analysis

One commenter claimed that the proposed rule language could cause confusion on where the benzene concentration of treated waste streams should be determined. This commenter asked that it be stated in the rule that if the treatment standards of § 61.348(a) are met, then the determination is made at the exit of the treatment process.

The EPA agrees with the commenter on this point. It is the EPA's intent that, for the purpose of demonstrating compliance with the standards for treatment processes in § 61.348(a), benzene concentration should be

determined at the exit of the treatment process. This regulatory language can be found in § 61.355(d).

Another commenter recommended that the rule provide flexibility on sampling locations for waste streams at a plant already determined to have a TAB above 10 Mg/yr. The commenter cited cases where, due to safety concerns, it was preferable to sample at a common collection point to which wastes had been hardpiped, rather than at the point of generation.

Although it is not clear from the comment what the purpose for the sampling described is (e.g., to compute TAB or demonstrate that a stream contains less than 10 ppmw benzene and, therefore does not have to be controlled), the EPA believes that the rule provides the flexibility that the commenter is recommending. To calculate TAB for a facility requires that the annual mass of benzene in each waste stream at its point of generation be estimated. The mass of benzene in each stream is estimated through a determination of benzene concentration and waste quantity. The determination of benzene concentration and waste quantity through direct measurement at the point of generation is not required by the rule for the purpose of estimating facility TAB, but is an acceptable option.

To determine waste quantity, historical records or the maximum design capacity of the waste management unit handling the waste may also be used (see §§ 61.355(b) (5) through (7)). To determine benzene concentration (for TAB or for other purposes), use of knowledge of the waste is acceptable (see § 61.355(c)(2)). Direct measurement of benzene concentration at a location other than the point of generation may be used to support a determination based on knowledge of the waste.

Facilities acknowledging that they are above the 10 Mg/yr threshold for the applicability of control requirements will not be expected to document their estimate of TAB as rigorously as those who are claiming they are below 10 Mg/yr and therefore do not need to apply controls. However, facilities claiming that either the entire facility or individual waste streams within the facility are exempt based on the results of sampling of waste streams at locations other than their point of generation will be expected to document that benzene concentration has not been reduced through dilution or volatilization.

In case of disputes, the Administrator may require direct measurement of waste characteristics at the point of generation. However, in cases where facility applicability is not an issue (i.e., at facilities over 10 Mg/yr on the basis of other streams), evidence such as that suggested by the commenter would likely be acceptable to support a TAB calculation.

Finally, a commenter requested that the rule specify that a Method-27 leak test is an acceptable alternative to Method 21 for trucks and rail cars.

Under § 61.345, the cover and all openings of containers in which benzene-containing wastes subject to the control requirements of the rule are managed must be designed to operate with no detectable emissions as indicated by an instrument reading of less than 500 ppmv above background, initially and thereafter at least once per year by the methods specified in § 61.355(h) of the rule. Section 61.355(h) specifies EPA Reference Method 21. Section 61.355(h) was not affected by the proposed amendments and, therefore, it was not appropriate for the EPA to change this section in the final rule without proposal and comment. However, an owner or operator may request that the Administrator approve the use of an alternative method under § 61.13 of the General Provisions to 40 CFR part 61.

F. Requests for Site-Specific Clarifications

Two comments were received requesting determinations on how the rule would apply to their specific facilities. One commenter requested clarification of the definition of "petroleum refinery" as it applied to the commenter's facility. Another commenter requested a determination on how the rule would apply to part of a coke by-product recovery plant that is under separate ownership from the coke oven and the rest of the by-product recovery plant, where materials (including wastes) are hard piped between them.

The EPA considers these requests for site-specific determinations on the applicability of subpart FF to be outside of the scope of this rulemaking. Determinations on the applicability of the final rule to specific facilities will be made by the EPA Regional offices or delegated State or local agencies. Requests for site-specific clarifications should, therefore, be directed to the appropriate EPA Regional Office or delegated State or local agency.

X. Administrative Requirements

A. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in subpart FF under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0183. The OMB approved the requirement in the proposed clarifying amendments for a compliance waiver, but did not approve the proposed requirement for a maintenance turnaround plan. The promulgated rules do not include the requirement for a maintenance turnaround plan for the reasons stated in section VII. B. of this preamble.

The public reporting burden for the compliance waiver is estimated to be a one time burden of 15 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch (PM–223Y); U.S. Environmental Protection Agency; 401 M St., SW.; Washington DC 20460; and the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

B. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires the EPA to consider potential impacts of regulations on small business "entities." If a preliminary analysis indicates that a regulation would have a significant economic impact on 20 percent or more of small entities, then a Regulatory Flexibility Analysis must be prepared.

The amendments to 40 CFR part 61, subpart FF, are intended to clarify the rule and will not affect the number of facilities subject to the rule or the controls that must be installed to comply. I therefore certify that this rule will not have significant economic impact on a substantial number of small entities.

C. Docket

The docket is an organized and complete file of all the information submitted to or otherwise considered by the EPA in the development of this rulemaking. The docketing system is intended to allow members of the public and industries involved to readily identify and locate documents so that they can effectively participate in the rulemaking process. Along with the statement of basis and purpose of the proposed and promulgated revisions, and the EPA's responses to significant

comments, the contents of the docket, except for interagency review materials, will serve as the record in case of judicial review [Section 307(d)(7)(A)].

D. Executive Order 12291

Under Executive Order 12291, the EPA is required to judge whether this regulation is a "major rule" and therefore subject to certain requirements of the Order. The EPA has determined that the clarifying amendments to subpart FF would result in none of the adverse economic effects set forth in section I of the Order as grounds for finding a regulation to be a "major rule." The EPA does not believe these amendments to the regulation are major because the economic effects of the amendments do not meet the $100-million threshold, the amendments will not significantly increase process or production costs, and the amendments will not cause significant adverse effects on domestic competition, employment, investment, productivity, innovation, or competition in foreign markets.

The EPA has not conducted a RIA of this regulation because this action does not constitute a major rule.

List of Subjects in 40 CFR Part 61

Air pollution control, Arsenic, Asbestos, Benzene, Beryllium, Coke oven emissions, Hazardous substances, Intergovernmental relations, Mercury, Radionuclides, Reporting and recordkeeping requirements, Vinyl chloride, Volatile hazardous air pollutants.

Dated: December 1, 1992.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, title 40, chapter 1, part 61 of the Code of Federal Regulations is amended as follows:

1. The authority citation for part 61 continues to read as follows:

Authority: Sections 101, 112, 114, 116, 301 of the Clean Air Act as amended (42 U.S.C. 7401, 7412, 7414, 7416, 7601).

§ 61.340 [Removed]

2. In § 61.340, paragraph (c)(3) is removed.

3. Section 61.341 is amended by revising the definitions for "point of waste generation" and "water seal controls," and by adding definitions in alphabetical order to read as follows:

§ 61.341 Definitions.

* * * * *

Car-seal means a seal that is placed on a device that is used to change the position of a valve (e.g., from opened to closed) in such a way that the position of the valve cannot be changed without breaking the seal.

* * * * *

Flow indicator means a device which indicates whether gas flow is present in a line or vent system.

* * * * *

Maximum organic vapor pressure means the equilibrium partial pressure exerted by the waste at the temperature equal to the highest calendar-month average of the waste storage temperature for waste stored above or below the ambient temperature or at the local maximum monthly average temperature as reported by the National Weather Service for waste stored at the ambient temperature, as determined:

(1) In accordance with § 60.17(c); or

(2) As obtained from standard reference texts; or

(3) In accordance with § 60.17(a)(37); or

(4) Any other method approved by the Administrator.

* * * * *

Point of waste generation means the location where the waste stream exits the process unit component or storage tank prior to handling or treatment in an operation that is not an integral part of the production process, or in the case of waste management units that generate new wastes after treatment, the location where the waste stream exits the waste management unit component.

* * * * *

Process unit turnaround means the shutting down of the operations of a process unit, the purging of the contents of the process unit, the maintenance or repair work, followed by restarting of the process.

Process unit turnaround waste means a waste that is generated as a result of a process unit turnaround.

* * * * *

Sour water stream means a stream that:

(1) Contains ammonia or sulfur compounds (usually hydrogen sulfide) at concentrations of 10 ppm by weight or more;

(2) is generated from separation of water from a feed stock, intermediate, or product that contained ammonia or sulfur compounds; and

(3) requires treatment to remove the ammonia or sulfur compounds.

Sour water stripper means a unit that:

(1) Is designed and operated to remove ammonia or sulfur compounds (usually hydrogen sulfide) from sour water streams;

(2) has the sour water streams transferred to the stripper through hard piping or other enclosed system; and

(3) is operated in such a manner that the offgases are sent to a sulfur recovery unit, processing unit, incinerator, flare, or other combustion device.

* * * * *

Water seal controls means a seal pot, p-leg trap, or other type of trap filled with water (e.g., flooded sewers that maintain water levels adequate to prevent air flow through the system) that creates a water barrier between the sewer line and the atmosphere. The water level of the seal must be maintained in the vertical leg of a drain in order to be considered a water seal.

4. Section 61.342 is amended by revising paragraphs (a), (b), (c)(1) introductory text, (c)(1)(iii), (c)(2), (c)(3), and (d) introductory text; by redesignating paragraphs (e), (f), and (g) as (f), (g), and (h); and by adding paragraph (e) to read as follows:

§ 61.342 Standards: General.

(a) An owner or operator of a facility at which the total annual benzene quantity from facility waste is less than 10 megagrams per year (Mg/yr) shall be exempt from the requirements of paragraphs (b) and (c) of this section. The total annual benzene quantity from facility waste is the sum of the annual benzene quantity for each waste stream at the facility that has a flow-weighted annual average water content greater than 10 percent or that is mixed with water, or other wastes, at any time and the mixture has an annual average water content greater than 10 percent. The benzene quantity in a waste stream is to be counted only once without multiple counting if other waste streams are mixed with or generated from the original waste stream. Other specific requirements for calculating the total annual benzene waste quantity are as follows:

(1) Wastes that are exempted from control under §§ 61.342(c)(2) and 61.342(c)(3) are included in the calculation of the total annual benzene quantity if they have an annual average water content greater than 10 percent, or if they are mixed with water or other wastes at any time and the mixture has an annual average water content greater than 10 percent.

(2) The benzene in a material subject to this subpart that is sold is included in the calculation of the total annual benzene quantity if the material has an annual average water content greater than 10 percent.

(3) Benzene in wastes generated by remediation activities conducted at the facility, such as the excavation of contaminated soil, pumping and treatment of groundwater, and the recovery of product from soil or groundwater, are not included in the calculation of total annual benzene

quantity for that facility. If the facility's total annual benzene quantity is 10 Mg/yr or more, wastes generated by remediation activities are subject to the requirements of paragraphs (c) through (h) of this section. If the facility is managing remediation waste generated offsite, the benzene in this waste shall be included in the calculation of total annual benzene quantity in facility waste, if the waste streams have an annual average water content greater than 10 percent, or if they are mixed with water or other wastes at any time and the mixture has an annual average water content greater than 10 percent.

(4) The total annual benzene quantity is determined based upon the quantity of benzene in the waste before any waste treatment occurs to remove the benzene except as specified in § 61.355(c)(1)(i) (A) through (C).

(b) Each owner or operator of a facility at which the total annual benzene quantity from facility waste is equal to or greater than 10 Mg/yr as determined in paragraph (a) of this section shall be in compliance with the requirements of paragraphs (c) through (h) of this section no later than 90 days following the effective date, unless a waiver of compliance has been obtained under § 61.11, or by the initial startup for a new source with an initial startup after the effective date.

(1) The owner or operator of an existing source unable to comply with the rule within the required time may request a waiver of compliance under § 61.10.

(2) As part of the waiver application, the owner or operator shall submit to the Administrator a plan under § 61.10(b)(3) that is an enforceable commitment to obtain environmental benefits to mitigate the benzene emissions that result from extending the compliance date. The plan shall include the following information:

(i) A description of the method of compliance, including the control approach, schedule for installing controls, and quantity of the benzene emissions that result from extending the compliance date;

(ii) If the control approach involves a compliance strategy designed to obtain integrated compliance with multiple regulatory requirements, a description of the other regulations involved and their effective dates; and

(iii) A description of the actions to be taken at the facility to obtain mitigating environmental benefits, including how the benefits will be obtained, the schedule for these actions, and an estimate of the quantifiable benefits that directly result from these actions.

(c) * * *

(1) For each waste stream that contains benzene, including (but not limited to) organic waste streams that contain less than 10 percent water and aqueous waste streams, even if the wastes are not discharged to an individual drain system, the owner or operator shall:

* * * * *

(iii) Each waste management unit used to manage or treat waste streams that will be recycled to a process shall comply with the standards specified in §§ 61.343 through 61.347. Once the waste stream is recycled to a process, including to a tank used for the storage of production process feed, product, or product intermediates, unless this tank is used primarily for the storage of wastes, the material is no longer subject to paragraph (c) of this section.

(2) A waste stream is exempt from paragraph (c)(1) of this section provided that the owner or operator demonstrates initially and, thereafter, at least once per year that the flow-weighted annual average benzene concentration for the waste stream is less than 10 ppmw as determined by the procedures specified in § 61.355(c)(2) or § 61.355(c)(3).

(3) A waste stream is exempt from paragraph (c)(1) of this section provided that the owner or operator demonstrates initially and, thereafter, at least once per year that the conditions specified in either paragraph (c)(3)(i) or (c)(3)(ii) of this section are met.

(i) The waste stream is process wastewater that has a flow rate less than 0.02 liters per minute or an annual wastewater quantity of less than 10 Mg/yr; or

(ii) All of the following conditions are met:

(A) The owner or operator does not choose to exempt process wastewater under paragraph (c)(3)(i) of this section.

(B) The total annual benzene quantity in all waste streams chosen for exemption in paragraph (c)(3)(ii) of this section does not exceed 2.0 Mg/yr as determined in the procedures in § 61.355(j), and

(C) The total annual benzene quantity in a waste stream chosen for exemption, including process unit turnaround waste, is determined for the year in which the waste is generated.

(d) As an alternative to the requirements specified in paragraphs (c) and (e) of this section, an owner or operator of a facility at which the total annual benzene quantity from facility waste is equal to or greater than 10 Mg/yr as determined in paragraph (a) of this section may elect to manage and treat the facility waste as follows:

* * * * *

(e) As an alternative to the requirements specified in paragraphs (c) and (d) of this section, an owner or operator of a facility at which the total annual benzene quantity from facility waste is equal to or greater than 10 Mg/yr as determined in paragraph (a) of this section may elect to manage and treat the facility waste as follows:

(1) The owner or operator shall manage and treat facility waste with a flow-weighted annual average water content of less than 10 percent in accordance with the requirements of paragraph (c)(1) of this section; and

(2) The owner or operator shall manage and treat facility waste (including remediation and process unit turnaround waste) with a flow-weighted annual average water content of 10 percent or greater, on a volume basis as total water, and each waste stream that is mixed with water or wastes at any time such that the resulting mixture has an annual water content greater than 10 percent, in accordance with the following:

(i) The benzene quantity for the wastes described in paragraph (e)(2) of this section must be equal to or less than 6.0 Mg/yr, as determined in § 61.355(k). Wastes as described in paragraph (e)(2) of this section that are transferred offsite shall be included in the determination of benzene quantity as provided in § 61.355(k). The provisions of paragraph (f) of this section shall not apply to any owner or operator who elects to comply with the provisions of paragraph (e) of this section.

(ii) The determination of benzene quantity for each waste stream defined in paragraph (e)(2) of this section shall be made in accordance with § 61.355(k).

5. Section 61.343 is amended by revising the first sentence of paragraph (a) introductory text; by redesignating paragraphs (b) and (c) as (c) and (d); by adding paragraphs (a)(1)(i)(C) and (b); and by revising newly redesignated paragraph (c) to read as follows:

§ 61.343 Standards: Tanks.

(a) Except as provided in paragraph (b) of this section and in § 61.351, the owner or operator shall meet the following standards for each tank in which the waste stream is placed in accordance with § 61.342 (c)(1)(ii). * * *

(1) * * *

(i) * * *

(C) If the cover and closed-vent system operate such that the tank is maintained at a pressure less than atmospheric pressure, then paragraph (a)(1)(i)(B) of this section does not apply to any opening that meets all of thefollowing conditions:

(1) The purpose of the opening is to provide dilution air to reduce the explosion hazard;

(2) The opening is designed to operate with no detectable emissions as indicated by an instrument reading of less than 500 ppmv above background, as determined initially and thereafter at least once per year by the methods specified in § 61.355(h); and

(3) The pressure is monitored continuously to ensure that the pressure in the tank remains below atmospheric pressure.

* * * * *

(b) For a tank that meets all the conditions specified in paragraph (b)(1) of this section, the owner or operator may elect to comply with paragraph (b)(2) of this section as an alternative to the requirements specified in paragraph (a)(1) of this section.

(1) The waste managed in the tank complying with paragraph (b)(2) of this section shall meet all of the following conditions:

(i) Each waste stream managed in the tank must have a flow-weighted annual average water content less than or equal to 10 percent water, on a volume basis as total water.

(ii) The waste managed in the tank either:

(A) Has a maximum organic vapor pressure less than 5.2 kilopascals (kPa) (0.75 pounds per square inch (psi));

(B) Has a maximum organic vapor pressure less than 27.6 kPa (4.0 psi) and is managed in a tank having design capacity less than 151 m^3 (40,000 gal); or

(C) Has a maximum organic vapor pressure less than 76.6 kPa (11.1 psi) and is managed in a tank having a design capacity less than 75 m^3 (20,000 gal).

(2) The owner or operator shall install, operate, and maintain a fixed roof as specified in paragraph (a)(1)(i).

(3) For each tank complying with paragraph (b) of this section, one or more devices which vent directly to the atmosphere may be used on the tank provided each device remains in a closed, sealed position during normal operations except when the device needs to open to prevent physical damage or permanent deformation of the tank or cover resulting from filling or emptying the tank, diurnal temperature changes, atmospheric pressure changes or malfunction of the unit in accordance with good engineering and safety practices for handling flammable, explosive, or other hazardous materials.

(c) Each fixed-roof, seal, access door, and all other openings shall be checked by visual inspection initially and quarterly thereafter to ensure that no cracks or gaps occur and that access doors and other openings are closed and gasketed properly.

* * * * *

6. Section 61.344 is amended by redesignating paragraph (a)(1)(i)(C) as (a)(1)(i)(D), and by adding paragraph (a)(1)(i)(C) to read as follows:

§ 61.344 Standards: Surface impoundments.

(a) * * *

(1) * * *

(i) * * *

(C) If the cover and closed-vent system operate such that the enclosure of the surface impoundment is maintained at a pressure less than atmospheric pressure, then paragraph (a)(1)(i)(B) of this section does not apply to any opening that meets all of the following conditions:

(1) The purpose of the opening is to provide dilution air to reduce the explosion hazard;

(2) The opening is designed to operate with no detectable emissions as indicated by an instrument reading of less than 500 ppmv above background, as determined initially and thereafter at least once per year by the methods specified in § 61.355(h) of this subpart; and

(3) The pressure is monitored continuously to ensure that the pressure in the enclosure of the surface impoundment remains below atmospheric pressure.

* * * * *

7. Section 61.345 is amended by revising paragraphs (a)(1)(ii), (a)(2), and (a)(3) introductory text; and by adding paragraph (a)(4) to read as follows:

§ 61.345 Standards: Containers.

(a) * * *

(1) * * *

(ii) Except as provided in paragraph (a)(4) of this section, each opening shall be maintained in a closed, sealed position (e.g., covered by a lid that is gasketed and latched) at all times that waste is in the container except when it is necessary to use the opening for waste loading, removal, inspection, or sampling.

(2) When a waste is transferred into a container by pumping, the owner or operator shall perform the transfer using a submerged fill pipe. The submerged fill pipe outlet shall extend to within two fill pipe diameters of the bottom of the container while the container is being loaded. During loading of the waste, the cover shall remain in place and all openings shall be maintained in a closed, sealed position except for those openings required for the submerged fill pipe, those openings required for venting of the container to prevent physical damage or permanent deformation of the container or cover, and any openings complying with paragraph (a)(4) of this section.

(3) Treatment of a waste in a container, including aeration, thermal or other treatment, shall be performed by the owner or operator in a manner such that whenever it is necessary for the container to be open while the waste is being treated, the container is located under a cover (e.g. enclosure) with a closed-vent system that routes all organic vapors vented from the container to a control device, except for cover and closed-vent systems that meet the requirements in paragraph (a)(4) of this section.

* * * * *

(4) If the cover and closed-vent system operate such that the container is maintained at a pressure less than atmospheric pressure, the owner or operator may operate the system with an opening that is not sealed and kept closed at all times if the following conditions are met:

(i) The purpose of the opening is to provide dilution air to reduce the explosion hazard;

(ii) The opening is designed to operate with no detectable emissions as indicated by an instrument reading of less than 500 ppmv above background, as determined initially and thereafter at least once per year by methods specified in § 61.355(h); and

(iii) The pressure is monitored continuously to ensure that the pressure in the container remains below atmospheric pressure.

* * * * *

8. Section 61.346 is amended by adding paragraph (a)(1)(i)(C) to read as follows:

§ 61.346 Standards: Individual drain systems.

(a) * * *

(1) * * *

(i) * * *

(C) If the cover and closed-vent system operate such that the individual drain system is maintained at a pressure less than atmospheric pressure, then paragraph (a)(1)(i)(B) of this section does not apply to any opening that meets all of the following conditions:

(1) The purpose of the opening is to provide dilution air to reduce the explosion hazard;

(2) The opening is designed to operate with no detectable emissions as indicated by an instrument reading of less than 500 ppmv above background, as determined initially and thereafter at

least once per year by the methods specified in § 61.355(h); and

(3) The pressure is monitored continuously to ensure that the pressure in the individual drain system remains below atmospheric pressure.

* * * * *

9. Section 61.347 is amended by adding paragraph (a)(1)(i)(C) to read as follows:

§ 61.347 Standards: Oil-water separators.

(a) * * *

(1) * * *

(i) * * *

(C) If the cover and closed-vent system operate such that the oil-water separator is maintained at a pressure less than atmospheric pressure, then paragraph (a)(1)(i)(B) of this section does not apply to any opening that meets all of the following conditions:

(1) The purpose of the opening is to provide dilution air to reduce the explosion hazard;

(2) The opening is designed to operate with no detectable emissions as indicated by an instrument reading of less than 500 ppmv above background, as determined initially and thereafter at least once per year by the methods specified in § 61.355(h); and

(3) The pressure is monitored continuously to ensure that the pressure in the oil-water separator remains below atmospheric pressure.

* * * * *

10. Section 61.348 is amended by adding a new sentence at the end of paragraph (a)(5); by revising the introductory text of paragraphs (b) and (e); by redesignating paragraphs (f) and (g) as (e)(1) and (e)(2); by adding paragraph (e)(3); and by redesignating paragraphs (h) and (i) as (f) and (g).

§ 61.348 Standards: Treatment Processes.

(a) * * *

(5) * * * These provisions apply to above-ground wastewater treatment systems as well as those that are at or below ground level.

(b) Except for facilities complying with § 61.342(e), the owner or operator that aggregates or mixes individual waste streams as defined in paragraph (a)(5) of this section for management and treatment in a wastewater treatment system shall comply with the following requirements:

* * * * *

(e) Except as specified in paragraph (e)(3) of this section, if the treatment process or wastewater treatment system unit has any openings (e.g., access doors, hatches, etc.), all such openings shall be sealed (e.g., gasketed, latched, etc.) and kept closed at all times when waste is being treated, except during inspection and maintenance.

* * * * *

(3) If the cover and closed-vent system operate such that the treatment process and wastewater treatment system unit are maintained at a pressure less than atmospheric pressure, the owner or operator may operate the system with an opening that is not sealed and kept closed at all times if the following conditions are met:

(i) The purpose of the opening is to provide dilution air to reduce the explosion hazard;

(ii) The opening is designed to operate with no detectable emissions as indicated by an instrument reading of less than 500 ppmv above background, as determined initially and thereafter at least once per year by the methods specified in § 61.355(h); and

(iii) The pressure is monitored continuously to ensure that the pressure in the treatment process and wastewater treatment system unit remain below atmospheric pressure.

* * * * *

. Section 61.349 is amended by revising paragraphs (a)(1)(ii), (a)(2)(i)(B), (a)(2)(ii), and (e); and by adding paragraphs (a)(1)(iv), and (a)(2)(iv) to read as follows:

§ 61.349 Standards: Closed-vent systems and control devices.

(a) * * *

(1) * * *

(ii) Vent systems that contain any bypass line that could divert the vent stream away from a control device used to comply with the provisions of this subpart shall install, maintain, and operate according to the manufacturer's specifications a flow indicator that provides a record of vent stream flow away from the control device at least once every 15 minutes, except as provided in paragraph (a)(1)(ii)(B) of this section.

(A) The flow indicator shall be installed at the entrance to any bypass line that could divert the vent stream away from the control device to the atmosphere.

(B) Where the bypass line valve is secured in the closed position with a car-seal or a lock-and-key type configuration, a flow indicator is not required.

* * * * *

(iv) For each closed-vent system complying with paragraph (a) of this section, one or more devices which vent directly to the atmosphere may be used on the closed-vent system provided each device remains in a closed, sealed position during normal operations except when the device needs to open to prevent physical damage or permanent deformation of the closed-vent system resulting from malfunction of the unit in accordance with good engineering and safety practices for handling flammable, explosive, or other hazardous materials.

(2) * * *

(i) * * *

(B) Achieve a total organic compound concentration of 20 ppmv (as the sum of the concentrations for individual compounds using Method 18) on a dry basis corrected to 3 percent oxygen; or

* * * * *

(ii) A vapor recovery system (e.g., a carbon adsorption system or a condenser) shall recover or control the organic emissions vented to it with an efficiency of 95 weight percent or greater, or shall recover or control the benzene emissions vented to it with an efficiency of 98 weight percent or greater.

* * * * *

(iv) A control device other than those described in paragraphs (a)(2) (i) through (iii) of this section may be used provided that the following conditions are met:

(A) The device shall recover or control the organic emissions vented to it with an efficiency of 95 weight percent or greater, or shall recover or control the benzene emissions vented to it with an efficiency of 98 weight percent or greater.

(B) The owner or operator shall develop test data and design information that documents the control device will achieve an emission control efficiency of either 95 percent or greater for organic compounds or 98 percent or greater for benzene.

(C) The owner or operator shall identify:

(1) The critical operating parameters that affect the emission control performance of the device;

(2) The range of values of these operating parameters that ensure the emission control efficiency specified in paragraph (a)(2)(iv)(A) of this section is maintained during operation of the device; and

(3) How these operating parameters will be monitored to ensure the proper operation and maintenance of the device.

(D) The owner or operator shall submit the information and data specified in paragraphs (a)(2)(iv) (B) and (C) of this section to the Administrator prior to operation of the alternative control device.

(E) The Administrator will determine, based on the information submitted

under paragraph (a)(2)(iv)(D) of this section, if the control device subject to paragraph (a)(2)(iv) of this section meets the requirements of § 61.349. The control device subject to paragraph (a)(2)(iv) of this section may be operated prior to receiving approval from the Administrator. However, if the Administrator determines that the control device does not meet the requirements of § 61.349, the facility may be subject to enforcement action beginning from the time the control device began operation.

* * * * *

(e) The Administrator may request at any time an owner or operator demonstrate that a control device meets the applicable conditions specified in paragraph (a)(2) of this section by conducting a performance test using the test methods and procedures as required in § 61.355, and for control devices subject to paragraph (a)(2)(iv) of this section, the Administrator may specify alternative test methods and procedures, as appropriate.

* * * * *

12. Section 61.353 is amended by revising paragraph (a) to read as follows:

§ 61.353 Alternative means of emission limitation.

(a) If, in the Administrator's judgment, an alternative means of emission limitation will achieve a reduction in benzene emissions at least equivalent to the reduction in benzene emissions from the source achieved by the applicable design, equipment, work practice, or operational requirements in §§ 61.342 through 61.349, the Administrator will publish in the **Federal Register** a notice permitting the use of the alternative means for purposes of compliance with that requirement. The notice may condition the permission on requirements related to the operation and maintenance of the alternative means.

* * * * *

13. Section 61.354 is amended by revising paragraphs (a)(1), (b), (c)(6)(i), (c)(7)(i), (c)(8), and (d) and by adding paragraphs (c)(9), (f), and (g) to read as follows:

§ 61.354 Monitoring of operations.

(a) * * *

(1) Measure the benzene concentration of the waste stream exiting the treatment process complying with § 61.348(a)(1)(i) at least once per month by collecting and analyzing one or more samples using the procedures specified in § 61.355(c)(3).

* * * * *

(b) If an owner or operator complies with the requirements of § 61.348(b), then the owner or operator shall monitor each wastewater treatment system to ensure the unit is properly operated and maintained by the appropriate monitoring procedure as follows:

(1) For the first exempt waste management unit in each waste treatment train, other than an enhanced biodegradation unit, measure the flow rate, using the procedures of § 61.355(b), and the benzene concentration of each waste stream entering the unit at least once per month by collecting and analyzing one or more samples using the procedures specified in § 61.355(c)(3).

(2) For each enhanced biodegradation unit that is the first exempt waste management unit in a treatment train, measure the benzene concentration of each waste stream entering the unit at least once per month by collecting and analyzing one or more samples using the procedures specified in § 61.355(c)(3).

(c) * * *

(6) * * *

(i) A monitoring device equipped with a continuous recorder to measure either the concentration level of the organic compounds or the concentration level of benzene in the exhaust vent stream from the condenser; or

* * * * *

(7) * * *

(i) A monitoring device equipped with a continuous recorder to measure either the concentration level of the organic compounds or the benzene concentration level in the exhaust vent stream from the carbon bed; or

* * * * *

(8) For a vapor recovery system other than a condenser or carbon adsorption system, a monitoring device equipped with a continuous recorder to measure either the concentration level of the organic compounds or the benzene concentration level in the exhaust vent stream from the control device.

(9) For a control device subject to the requirements of § 61.349(a)(2)(iv), devices to monitor the parameters as specified in § 61.349(a)(2)(iv)(C).

(d) For a carbon adsorption system that does not regenerate the carbon bed directly on site in the control device (e.g., a carbon canister), either the concentration level of the organic compounds or the concentration level of benzene in the exhaust vent stream from the carbon adsorption system shall be monitored on a regular schedule, and the existing carbon shall be replaced with fresh carbon immediately when carbon breakthrough is indicated. The device shall be monitored on a daily basis or at intervals no greater than 20 percent of the design carbon replacement interval, whichever is greater. As an alternative to conducting this monitoring, an owner or operator may replace the carbon in the carbon adsorption system with fresh carbon at a regular predetermined time interval that is less than the carbon replacement interval that is determined by the maximum design flow rate and either the organic concentration or the benzene concentration in the gas stream vented to the carbon adsorption system.

* * * * *

(f) Owners or operators using a closed-vent system that contains any bypass line that could divert a vent stream from a control device used to comply with the provisions of this subpart shall do the following:

(1) Visually inspect the bypass line valve at least once every month, checking the position of the valve and the condition of the car-seal or closure mechanism required under § 61.349(a)(1)(ii) to ensure that the valve is maintained in the closed position and the vent stream is not diverted through the bypass line.

(2) Visually inspect the readings from each flow monitoring device required by § 61.349(a)(1)(ii) at least once each operating day to check that vapors are being routed to the control device as required.

(g) Each owner or operator who uses a system for emission control that is maintained at a pressure less than atmospheric pressure with openings to provide dilution air shall install, calibrate, maintain, and operate according to the manufacturer's specifications a device equipped with a continuous recorder to monitor the pressure in the unit to ensure that it is less than atmospheric pressure.

14. Section 61.355 is amended by revising paragraphs (a)(1) introductory text, (a)(1)(i), (a)(1)(ii), (a)(2), (a)(3), (b), (c) introductory text, the first sentence of (d), (e)(3), (e)(4), (f)(3), the first sentence of (g), (i) introductory text, (i)(3) introductory text, (i)(3)(ii)(C), (i)(3)(iii), (i)(3)(iv), and (i)(4); by adding paragraph (a)(6); by redesignating paragraphs (c)(1) and (c)(2) as (c)(2) and (c)(3) respectively; by adding (c)(1) and a new sentence to the end of the newly redesignated paragraph (c)(2); and by adding paragraphs (j) and (k) to read as follows:

§ 61.355 Test methods, procedures, and compliance provisions.

(a) * * *

(1) For each waste stream subject to this subpart having a flow-weighted annual average water content greater

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than 10 percent water, on a volume basis as total water, or is mixed with water or other wastes at any time and the resulting mixture has an annual average water content greater than 10 percent as specified in § 61.342(a), the owner or operator shall:

(i) Determine the annual waste quantity for each waste stream using the procedures specified in paragraph (b) of this section.

(ii) Determine the flow-weighted annual average benzene concentration for each waste stream using the procedures specified in paragraph (c) of this section.

* * * * *

(2) Total annual benzene quantity from facility waste is calculated by adding together the annual benzene quantity for each waste stream generated during the year and the annual benzene quantity for each process unit turnaround waste annualized according to paragraph (b)(4) of this section.

(3) If the total annual benzene quantity from facility waste is equal to or greater than 10 mg/yr, then the owner or operator shall comply with the requirements of § 61.342 (c), (d), or (e).

* * * * *

(6) The benzene quantity in a waste stream that is generated less than one time per year, except as provided for process unit turnaround waste in paragraph (b)(4) of this section, shall be included in the determination of total annual benzene quantity from facility waste for the year in which the waste is generated unless the waste stream is otherwise excluded from the determination of total annual benzene quantity from facility waste in accordance with paragraphs (a) through (c) of this section. The benzene quantity in this waste stream shall not be annualized or averaged over the time interval between the activities that resulted in generation of the waste, for purposes of determining the total annual benzene quantity from facility waste.

(b) For purposes of the calculation required by paragraph (a) of this section, an owner or operator shall determine the annual waste quantity at the point of waste generation, unless otherwise provided in paragraphs (b) (1), (2), (3), and (4) of this section, by one of the methods given in paragraphs (b) (5) through (7) of this section.

(1) The determination of annual waste quantity for sour water streams that are processed in sour water strippers shall be made at the point that the water exits the sour water stripper.

(2) The determination of annual waste quantity for wastes at coke by-product plants subject to and complying with the control requirements of §§ 61.132, 61.133, 61.134, or 61.139 of subpart L of this part shall be made at the location that the waste stream exits the process unit component or waste management unit controlled by that subpart or at the exit of the ammonia still, provided that the following conditions are met:

(i) The transfer of wastes between units complying with the control requirements of subpart L of this part, process units, and the ammonia still is made through hard piping or other enclosed system.

(ii) The ammonia still meets the definition of a sour water stripper in § 61.341.

(3) The determination of annual waste quantity for wastes that are received at hazardous waste treatment, storage, or disposal facilities from offsite shall be made at the point where the waste enters the hazardous waste treatment, storage, or disposal facility.

(4) The determination of annual waste quantity for each process unit turnaround waste generated only at 2 year or greater intervals, may be made by dividing the total quantity of waste generated during the most recent process unit turnaround by the time period (in the nearest tenth of a year) between the turnaround resulting in generation of the waste and the most recent preceding process turnaround for the unit. The resulting annual waste quantity shall be included in the calculation of the annual benzene quantity as provided in paragraph (a)(1)(iii) of this section for the year in which the turnaround occurs and for each subsequent year until the unit undergoes the next process turnaround. For estimates of total annual benzene quantity as specified in the 90-day report, required under § 61.357(a)(1), the owner or operator shall estimate the waste quantity generated during the most recent turnaround, and the time period between turnarounds in accordance with good engineering practices. If the owner or operator chooses not to annualize process unit turnaround waste, as specified in this paragraph, then the process unit turnaround waste quantity shall be included in the calculation of the annual benzene quantity for the year in which the turnaround occurs.

(5) Select the highest annual quantity of waste managed from historical records representing the most recent 5 years of operation or, if the facility has been in service for less than 5 years but at least 1 year, from historical records representing the total operating life of the facility;

(6) Use the maximum design capacity of the waste management unit; or

(7) Use measurements that are representative of maximum waste generation rates.

(c) For the purposes of the calculation required by §§ 61.355(a) of this subpart, an owner or operator shall determine the flow-weighted annual average benzene concentration in a manner that meets the requirements given in paragraph (c)(1) of this section using either of the methods given in paragraphs (c)(2) and (c)(3) of this section.

(1) The determination of flow-weighted annual average benzene concentration shall meet all of the following criteria:

(i) The determination shall be made at the point of waste generation except for the specific cases given in paragraphs (c)(1)(i)(A) through (D) of this section.

(A) The determination for sour water streams that are processed in sour water strippers shall be made at the point that the water exits the sour water stripper.

(B) The determination for wastes at coke by-product plants subject to and complying with the control requirements of §§ 61.132, 61.133, 61.134, or 61.139 of Subpart L of this part shall be made at the location that the waste stream exits the process unit component or waste management unit controlled by that subpart or at the exit of the ammonia still, provided that the following conditions are met:

(*1*) The transfer of wastes between units complying with the control requirements of Subpart L of this part, process units, and the ammonia still is made through hard piping or other enclosed system.

(*2*) The ammonia still meets the definition of a sour water stripper in § 61.341.

(C) The determination for wastes that are received from offsite shall be made at the point where the waste enters the hazardous waste treatment, storage, or disposal facility.

(D) The determination of flow-weighted annual average benzene concentration for process unit turnaround waste shall be made using either of the methods given in paragraph (c)(2) or (c)(3) of this section. The resulting flow-weighted annual average benzene concentration shall be included in the calculation of annual benzene quantity as provided in paragraph (a)(1)(iii) of this section for the year in which the turnaround occurs and for each subsequent year until the unit undergoes the next process unit turnaround.

(ii) Volatilization of the benzene by exposure to air shall not be used in the

determination to reduce the benzene concentration.

(iii) Mixing or diluting the waste stream with other wastes or other materials shall not be used in the determination—to reduce the benzene concentration.

(iv) The determination shall be made prior to any treatment of the waste that removes benzene, except as specified in paragraphs (c)(1)(i)(A) through (D) of this section.

(v) For wastes with multiple phases, the determination shall provide the weighted-average benzene concentration based on the benzene concentration in each phase of the waste and the relative proportion of the phases.

(2) * * * when an owner or operator and the Administrator do not agree on determinations of the flow-weighted annual average benzene concentration based on knowledge of the waste, the procedures under paragraph (c)(3) of this section shall be used to resolve the disagreement.

* * * * *

(d) An owner or operator using performance tests to demonstrate compliance of a treatment process with § 61.348 (a)(1)(i) shall measure the flow-weighted annual average benzene concentration of the waste stream exiting the treatment process by collecting and analyzing a minimum of three representative samples of the waste stream using the procedures in paragraph (c)(3) of this section. * * *

(e) * * *

(3) The mass flow rate of benzene entering the treatment process (E_b) shall be determined by computing the product of the flow rate of the waste stream entering the treatment process, as determined by the inlet flow meter, and the benz ene concentration of the waste stream, as determined using the sampling and analytical procedures specified in paragraph (c)(2) or (c)(3) of this section. Three grab samples of the waste shall be taken at equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of 3 runs conducted over a 3-hour period. The mass flow rate of benzene entering the treatment process is calculated as follows:

$$E_b = \frac{K}{n \times 10^6} \left[\sum_{i=1}^{n} V_i C_i \right]$$

Where:

E_b=Mass flow rate of benzene entering the treatment process, kg/hour.

K=Density of the waste stream, kg/m³.

V_i=Average volume flow rate of waste entering the treatment process during each run i, m³/hour.

C_i=Average concentration of benzene in the waste stream entering the treatment process during each run i, ppmw.

n=Number of runs.

(4) The mass flow rate of benzene exiting the treatment process (E_a) shall be determined by computing the product of the flow rate of the waste stream exiting the treatment process, as determined by the outlet flow meter or the inlet flow meter, and the benzene concentration of the waste stream, as determined using the sampling and analytical procedures specified in paragraph (c)(2) or (c)(3) of this section. Three grab samples of the waste shall be taken at equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of 3 runs conducted over the same 3-hour period at which the mass flow rate of benzene entering the treatment process is determined. The mass flow rate of benzene exiting the treatment process is calculated as follows:

$$E_a = \frac{K}{n \times 10^6} \left[\sum_{i=1}^{n} V_i C_i \right]$$

Where:

E_a=Mass flow rate of benzene exiting the treatment process, kg/hour.

K=Density of the waste stream, kg/m³.

V_i=Average volume flow rate of waste exiting the treatment process during each run i, m³/hour.

C_i=Average concentration of benzene in the waste stream exiting the treatment process during each run i, ppmw.

n=Number of runs.

* * * * *

(f) * * *

(3) The mass flow rate of benzene entering the combustion unit shall be determined by computing the product of the flow rate of the waste stream entering the combustion unit, as determined by the inlet flow meter, and the benzene concentration of the waste stream, as determined using the sampling procedures in paragraph (c)(2) or (c)(3) of this section. Three grab samples of the waste shall be taken at equally spaced time intervals over a 1-hour period. Each 1-hour period constitutes a run, and the performance test shall consist of a minimum of 3 runs conducted over a 3-hour period. The mass flow rate of benzene into the combustion unit is calculated as follows:

$$E_b = \frac{K}{n \times 10^6} \left[\sum_{i=1}^{n} V_i C_i \right]$$

Where:

E_b=Mass flow rate of benzene into the combustion unit, kg/hour.

K=Density of the waste stream, kg/m³.

V_i=Average volume flow rate of waste entering the combustion unit during each run i, m³/hour.

C_i=Average concentration of benzene in the waste stream entering the combustion unit during each run i, ppmw.

n=Number of runs.

* * * * *

(g) An owner or operator using performance tests to demonstrate compliance of a wastewater treatment system unit with § 61.348(b) shall measure the flow-weighted annual average benzene concentration of the wastewater stream where the waste stream enters an exempt waste management unit by collecting and analyzing a minimum of three representative samples of the waste stream using the procedures in paragraph (c)(3) of this section. * * *

* * * * *

(i) An owner or operator using a performance test to demonstrate compliance of a control device with either the organic reduction efficiency requirement or the benzene reduction efficiency requirement specified under § 61.349(a)(2) shall use the following procedures:

* * * * *

(3) The mass flow rate of either the organics or benzene entering and exiting the control device shall be determined as follows:

* * * * *

(ii) * * *

(C) The organic concentration or the benzene concentration, as appropriate, in the vent stream entering and exiting the control shall be determined using Method 18 from Appendix A of 40 CFR part 60.

(iii) The mass of organics or benzene entering and exiting the control device during each run shall be calculated as follows:

$$M_{aj} = K\,V_{aj}\left[\sum_{i=1}^{n} C_{ai}\,MW_i\right](10^{-6})$$

$$M_{bj} = K\,V_{bj}\left[\sum_{i=1}^{n} C_{bi}\,MW_i\right](10^{-6})$$

Where:

M_{aj}=Mass of organics or benzene in the vent stream entering the control device during run j, kg.

M_{bj}=Mass of organics or benzene in the vent stream exiting the control device during run j, kg.

V_{aj}=Volume of vent stream entering the control device during run j at standard conditions, m^3.

V_{bj}=Volume of vent stream exiting the control device during run j at standard conditions, m^3.

C_{ai}=Organic concentration of compound i or the benzene concentration measured in the vent stream entering the control device as determined by Method 18, ppm by volume on a dry basis.

C_{bi}=Organic concentration of compound i or the benzene concentration measured in the vent stream exiting the control device as determined by Method 18, ppm by volume on a dry basis.

MW_i=Molecular weight of organic compound i in the vent stream or the molecular weight of benzene, kg/kg-mol.

n=Number of organic compounds in the vent stream; if benzene reduction efficiency is being demonstrated, then n=1.

K=Conversion factor for molar volume=0.0416 kg-mol/m^3 (at 293°K and 760 mm Hg).

10^{-6}=Conversion from ppm, ppm^{-1}.

(iv) The mass flow rate of organics or benzene entering and exiting the control device shall be calculated as follows:

$$E_a = \left(\sum_{j=1}^{n} M_{aj}\right) / T$$

$$E_b = \left(\sum_{j=1}^{n} M_{bj}\right) / T$$

Where:

E_a=Mass flow rate of organics or benzene entering the control device, kg/hour.

E_b=Mass flow rate of organics or benzene exiting the control device, kg/hour.

M_{aj}=Mass of organics or benzene in the vent stream entering the control device during run j, kg.

M_{bj}=Mass of organics or benzene in vent stream exiting the control device during run j, kg.

T=Total time of all runs, hour.

n=Number of runs.

(4) The organic reduction efficiency or the benzene reduction efficiency for the control device shall be calculated as follows:

$$R = \frac{E_a - E_b}{E_a} \times 100$$

Where:

R=Total organic reduction efficiency or benzene reduction efficiency for the control device, percent.

E_a=Mass flow rate of organics or benzene entering the control device, kg/hr.

E_b=Mass flow rate of organics or benzene exiting the control device, kg/hr.

(j) An owner or operator shall determine the benzene quantity for the purposes of the calculation required by § 61.342 (c)(3)(ii)(B) according to the provisions of paragraph (a) of this section, except that the procedures in paragraph (a) of this section shall also apply to wastes with a water content of 10 percent or less.

(k) An owner or operator shall determine the benzene quantity for the purposes of the calculation required by § 61.342(e)(2) by the following procedure:

(1) For each waste stream that is not controlled for air emissions in accordance with §§ 61.343. 61.344, 61.345, 61.346, 61.347, or 61.348(a), as applicable to the waste management unit that manages the waste, the benzene quantity shall be determined as specified in paragraph (a) of this section, except that paragraph (b)(4) of this section shall not apply, i.e., the waste quantity for process unit turnaround waste is not annualized but shall be included in the determination of benzene quantity for the year in which the waste is generated for the purposes of the calculation required by § 61.342(e)(2).

(2) For each waste stream that is controlled for air emissions in accordance with §§ 61.343. 61.344, 61.345, 61.346, 61.347, or 61.348(a), as applicable to the waste management unit that manages the waste, the determination of annual waste quantity and flow-weighted annual average benzene concentration shall be made at the first applicable location as described in paragraphs (k)(2)(i), (k)(2)(ii), and (k)(2)(iii) of this section and prior to any reduction of benzene concentration through volatilization of the benzene, using the methods given in (k)(2)(iv) and (k)(2)(v) of this section.

(i) where the waste stream enters the first waste management unit not complying with §§ 61.343, 61.344, 61.345, 61.346, 61.347, and 61.348(a) that are applicable to the waste management unit,

(ii) For each waste stream that is managed or treated only in compliance with §§ 61.343 through 61.348(a) up to the point of final direct discharge from the facility, the determination of benzene quantity shall be prior to any reduction of benzene concentration through volatilization of the benzene, or

(iii) For wastes managed in units controlled for air emissions in accordance with §§ 61.343, 61.344, 61.345, 61.346, 61.347, and 61.348(a), and then transferred offsite, facilities shall use the first applicable offsite location as described in paragraphs (k)(2)(i) and (k)(2)(ii) of this section if they have documentation from the offsite facility of the benzene quantity at this location. Facilities without this documentation for offsite wastes shall use the benzene quantity determined at the point where the transferred waste leaves the facility.

(iv) Annual waste quantity shall be determined using the procedures in paragraphs (b)(5), (6), or (7) of this section, and

(v) The flow-weighted annual average benzene concentration shall be determined using the procedures in paragraphs (c)(2) or (3) of this section.

(3) The benzene quantity in a waste stream that is generated less than one time per year, including process unit turnaround waste, shall be included in the determination of benzene quantity as determined in paragraph (k)(6) of this section for the year in which the waste is generated. The benzene quantity in this waste stream shall not be annualized or averaged over the time interval between the activities that resulted in generation of the waste for purposes of determining benzene quantity as determined in paragraph (k)(6) of this section.

(4) The benzene in waste entering an enhanced biodegradation unit, as defined in § 61.348(b)(2)(ii)(B), shall not be included in the determination of benzene quantity, determined in paragraph (k)(6) of this section, if the following conditions are met:

(i) The benzene concentration for each waste stream entering the enhanced biodegradation unit is less than 10 ppmw on a flow-weighted annual average basis, and

(ii) All prior waste management units managing the waste comply with §§ 61.343, 61.344, 61.345, 61.346, 61.347 and 61.348(a).

(5) The benzene quantity for each waste stream in paragraph (k)(2) of this section shall be determined by multiplying the annual waste quantity of each waste stream times its flow-weighted annual average benzene concentration.

(6) The total benzene quantity for the purposes of the calculation required by § 61.342(e)(2) shall be determined by adding together the benzene quantities determined in paragraphs (k)(1) and (k)(5) of this section for each applicable waste stream.

(7) If the benzene quantity determined in paragraph (6) of this section exceeds 6.0 Mg/yr only because of multiple counting of the benzene quantity for a waste stream, the owner or operator may use the following procedures for the purposes of the calculation required by § 61.342(e)(2):

(i) Determine which waste management units are involved in the multiple counting of benzene;

(ii) Determine the quantity of benzene that is emitted, recovered, or removed from the affected units identified in paragraph (k)(7)(i) of this section, or destroyed in the units if applicable, using either direct measurements or the best available estimation techniques developed or approved by the Administrator.

(iii) Adjust the benzene quantity to eliminate the multiple counting of benzene based on the results from paragraph (k)(7)(ii) of this section and determine the total benzene quantity for the purposes of the calculation required by § 61.342(e)(2).

(iv) Submit in the annual report required under § 61.357(a) a description of the methods used and the resulting calculations for the alternative procedure under paragraph (k)(7) of this section, the benzene quantity determination from paragraph (k)(6) of this section, and the adjusted benzene quantity determination from paragraph (k)(7)(iii) of this section.

15. Section 61.356 is amended by redesignating paragraph (b)(4) as (b)(6); by revising newly redesignated (b)(6); by adding paragraphs (b)(4) and (b)(5); by revising paragraph (b)(2), (c), (d), (e)(2), and the introductory text of (f)(2); by removing (f)(2)(i); by redesignating paragraph (f)(2)(ii) as (f)(2)(i); by revising newly redesignated paragraphs (f)(2)(i) introductory text and (f)(2)(i) (E) through (G); by adding paragraph (f)(2)(i)(H); by redesignating (i)(4) as (i)(5); by adding paragraph (i)(4); by revising paragraphs (j)(3), (j)(6), (j)(8), (j)(9), and (j)(11); and by adding paragraphs (j)(12), (m), and adding and reserving paragraph (f)(2)(ii) to read as follows:

§ 61.356 Recordkeeping requirements.

* * * * *

(b) * * *

(2) For each waste stream exempt from § 61.342(c)(1) in accordance with § 61.342(c)(3), the records shall include:

(i) All measurements, calculations, and other documentation used to determine that the continuous flow of process wastewater is less than 0.02 liters per minute or the annual waste quantity of process wastewater is less than 10 Mg/yr in accordance with § 61.342(c)(3)(i), or

(ii) All measurements, calculations, and other documentation used to determine that the sum of the total annual benzene quantity in all exempt waste streams does not exceed 2.0 Mg/yr in accordance with § 61.342(c)(3)(ii).

* * * * *

(4) For each facility where waste streams are controlled for benzene emissions in accordance with § 61.342(e), the records shall include for each waste stream all measurements, including the locations of the measurements, calculations, and other documentation used to determine that the total benzene quantity does not exceed 6.0 Mg/yr.

(5) For each facility where the annual waste quantity for process unit turnaround waste is determined in accordance with § 61.355(b)(5), the records shall include all test results, measurements, calculations, and other documentation used to determine the following information: identification of each process unit at the facility that undergoes turnarounds, the date of the most recent turnaround for each process unit, identification of each process unit turnaround waste, the water content of each process unit turnaround waste, the annual waste quantity determined in accordance with § 61.355(b)(5), the range of benzene concentrations in the waste, the annual average flow-weighted benzene concentration of the waste, and the annual benzene quantity calculated in accordance with § 61.355(a)(1)(iii) of this section.

(6) For each facility where wastewater streams are controlled for benzene emissions in accordance with § 61.348(b)(2), the records shall include all measurements, calculations, and other documentation used to determine the annual benzene content of the waste streams and the total annual benzene quantity contained in all waste streams managed or treated in exempt waste management units.

(c) An owner or operator transferring waste off-site to another facility for treatment in accordance with § 61.342(f) shall maintain documentation for each offsite waste shipment that includes the following information: Date waste is shipped offsite, quantity of waste shipped offsite, name and address of the facility receiving the waste, and a copy of the notice sent with the waste shipment.

(d) An owner or operator using control equipment in accordance with §§ 61.343 through 61.347 shall maintain engineering design documentation for all control equipment that is installed on the waste management unit. The documentation shall be retained for the life of the control equipment. If a control device is used, then the owner or operator shall maintain the control device records required by paragraph (f) of this section.

(e) * * *

(2) If engineering calculations are used to determine treatment process or wastewater treatment system unit performance, then the owner or operator shall maintain the complete design analysis for the unit. The design analysis shall include for example the following information: Design specifications, drawings, schematics, piping and instrumentation diagrams,

and other documentation necessary to demonstrate the unit performance.

* * * * *

(f) * * *

(2) If engineering calculations are used to determine control device performance in accordance with § 61.349(c), then a design analysis for the control device that includes for example:

(i) Specifications, drawings, schematics, and piping and instrumentation diagrams prepared by the owner or operator, or the control device manufacturer or vendor that describe the control device design based on acceptable engineering texts. The design analysis shall address the following vent stream characteristics and control device operating parameters:

* * * * *

(E) For a condenser, the design analysis shall consider the vent stream composition, constituent concentration, flow rate, relative humidity, and temperature. The design analysis shall also establish the design outlet organic compound concentration level or the design outlet benzene concentration level, design average temperature of the condenser exhaust vent stream, and the design average temperatures of the coolant fluid at the condenser inlet and outlet.

(F) For a carbon adsorption system that regenerates the carbon bed directly on-site in the control device such as a fixed-bed adsorber, the design analysis shall consider the vent stream composition, constituent concentration, flow rate, relative humidity, and temperature. The design analysis shall also establish the design exhaust vent stream organic compound concentration level or the design exhaust vent stream benzene concentration level, number and capacity of carbon beds, type and working capacity of activated carbon used for carbon beds, design total steam flow over the period of each complete carbon bed regeneration cycle, duration of the carbon bed steaming and cooling/drying cycles, design carbon bed temperature after regeneration, design carbon bed regeneration time, and design service life of carbon.

(G) For a carbon adsorption system that does not regenerate the carbon bed directly on-site in the control device, such as a carbon canister, the design analysis shall consider the vent stream composition, constituent concentration, flow rate, relative humidity, and temperature. The design analysis shall also establish the design exhaust vent stream organic compound concentration level or the design exhaust vent stream benzene concentration level, capacity of carbon bed, type and working capacity of activated carbon used for carbon bed, and design carbon replacement interval based on the total carbon working capacity of the control device and source operating schedule.

(H) For a control device subject to the requirements of § 61.349(a)(2)(iv), the design analysis shall consider the vent stream composition, constituent concentration, and flow rate. The design analysis shall also include all of the information submitted under § 61.349 (a)(2)(iv).

(ii) [Reserved]

* * * * *

(i)* * *

(4) If measurements of waste stream benzene concentration are performed in accordance with § 61.354(b), the owner or operator shall maintain records that include the date each test is performed and all test results.

* * * * *

(j)* * *

(3) Periods when the closed-vent system and control device are not operated as designed including all periods and the duration when:

(i) Any valve car-seal or closure mechanism required under § 61.349(a)(1)(ii) is broken or the by-pass line valve position has changed.

(ii) The flow monitoring devices required under § 61.349(a)(1)(ii) indicate that vapors are not routed to the control device as required.

* * * * *

(6) If a boiler or process heater is used, then the owner or operator shall maintain records of each occurrence when there is a change in the location at which the vent stream is introduced into the flame zone as required by § 61.349(a)(2)(i)(C). For a boiler or process heater having a design heat input capacity less than 44 MW, the owner or operator shall maintain continuous records of the temperature of the gas stream in the combustion zone of the boiler or process heater and records of all 3-hour periods of operation during which the average temperature of the gas stream in the combustion zone is more than 28°C below the design combustion zone temperature. For a boiler or process heater having a design heat input capacity greater than or equal to 44 MW, the owner or operator shall maintain continuous records of the parameter(s) monitored in accordance with the requirements of § 61.354(c)(5).

* * * * *

(8) If a condenser is used, then the owner or operator shall maintain records from the monitoring device of the parameters selected to be monitored in accordance with § 61.354(c)(6). If concentration of organics or concentration of benzene in the control device outlet gas stream is monitored, then the owner or operator shall record all 3-hour periods of operation during which the concentration of organics or the concentration of benzene in the exhaust stream is more than 20 percent greater than the design value. If the temperature of the condenser exhaust stream and coolant fluid is monitored, then the owner or operator shall record all 3-hour periods of operation during which the temperature of the condenser exhaust vent stream is more than 6 °C above the design average exhaust vent stream temperature, or the temperature of the coolant fluid exiting the condenser is more than 6 °C above the design average coolant fluid temperature at the condenser outlet.

(9) If a carbon adsorber is used, then the owner or operator shall maintain records from the monitoring device of the concentration of organics or the concentration of benzene in the control device outlet gas stream. If the concentration of organics or the concentration of benzene in the control device outlet gas stream is monitored, then the owner or operator shall record all 3-hour periods of operation during which the concentration of organics or the concentration of benzene in the exhaust stream is more than 20 percent greater than the design value. If the carbon bed regeneration interval is monitored, then the owner or operator shall record each occurrence when the vent stream continues to flow through the control device beyond the predetermined carbon bed regeneration time.

* * * * *

(11) If an alternative operational or process parameter is monitored for a control device, as allowed in § 61.354(e) of this subpart, then the owner or operator shall maintain records of the continuously monitored parameter, including periods when the device is not operated as designed.

(12) If a control device subject to the requirements of § 61.349(a)(2)(iv) is used, then the owner or operator shall maintain records of the parameters that are monitored and each occurrence when the parameters monitored are outside the range of values specified in § 61.349(a)(2)(iv)(C), or other records as specified by the Administrator.

* * * * *

(m) If a system is used for emission control that is maintained at a pressure less than atmospheric pressure with openings to provide dilution air, then

the owner or operator shall maintain records of the monitoring device and records of all periods during which the pressure in the unit is operated at a pressure that is equal to or greater than atmospheric pressure.

* * * * *

16. Section 61.357 is amended by revising paragraphs (a) introductory text and (a)(4); by adding a new sentence at the end of paragraph (c) and a new sentence at the end of paragraph (d)(2); by removing paragraph (d)(4); by redesignating paragraph (d)(3) as (d)(4); by adding paragraph (d)(3); by redesignating paragraphs (d)(5), (d)(6) and (d)(7) as (d)(6), (d)(7) and (d)(8) respectively; by redesignating the newly redesignated paragraph (d)(7)(iii) as (d)(7)(iv); by adding paragraphs (d)(5), (d)(7)(iii), (d)(7)(iv)(J) and (d)(7)(V); and by revising paragraph (d)(1), the newly redesignated paragraphs (d)(4)(iii), (d)(7)(iv)(D) and (d)(8) to read as follows:

§ 61.357 Reporting requirements.

(a) Each owner or operator of a chemical plant, petroleum refinery, coke by-product recovery plant, and any facility managing wastes from these industries shall submit to the Administrator within 90 days after January 7, 1993, or by the initial startup for a new source with an initial startup after the effective date, a report that summarizes the regulatory status of each waste stream subject to § 61.342 and is determined by the procedures specified in § 61.355(c) to contain benzene. Each owner or operator subject to this subpart who has no benzene onsite in wastes, products, by-products, or intermediates shall submit an initial report that is a statement to this effect. For all other owners or operators subject to this subpart, the report shall include the following information:

* * * * *

(4) The information required in paragraphs (a) (1), (2), and (3) of this section should represent the waste stream characteristics based on current configuration and operating conditions. An owner or operator only needs to list in the report those waste streams that contact materials containing benzene. The report does not need to include a description of the controls to be installed to comply with the standard or other information required in § 61.10(a).

* * * * *

(c) * * * If the information in the annual report required by paragraphs (a)(1) through (a)(3) of this section is not changed in the following year, the owner or operator may submit a statement to that effect.

(d) * * *

(1) Within 90 days after January 7, 1993, unless a waiver of compliance under § 61.11 of this part is granted, or by the date of initial startup for a new source with an initial startup after the effective date, a certification that the equipment necessary to comply with these standards has been installed and that the required initial inspections or tests have been carried out in accordance with this subpart. If a waiver of compliance is granted under § 61.11, the certification of equipment necessary to comply with these standards shall be submitted by the date the waiver of compliance expires.

(2) * * * If the information in the annual report required by paragraphs (a)(1) through (a)(3) of this section is not changed in the following year, the owner or operator may submit a statement to that effect.

(3) If an owner or operator elects to comply with the requirements of § 61.342(c)(3)(ii), then the report required by paragraph (d)(2) of this section shall include a table identifying each waste stream chosen for exemption and the total annual benzene quantity in these exempted streams.

(4) * * *

(iii) For each process wastewater stream identified as being controlled for benzene emissions in accordance with the requirements of this subpart, the table shall report the following information for the process wastewater stream as determined at the exit to the treatment process: Annual waste quantity, range of benzene concentrations, annual average flow-weighted benzene concentration, and annual benzene quantity.

(5) If an owner or operator elects to comply with the alternative requirements of § 61.342(e), then the report required by paragraph (d)(2) of this section shall include a table presenting the following information for each waste stream:

(i) For each waste stream identified as not being controlled for benzene emissions in accordance with the requirements of this subpart; the table shall report the following information for the waste stream as determined at the point of waste generation: annual waste quantity, range of benzene concentrations, annual average flow-weighted benzene concentration, and annual benzene quantity;

(ii) For each waste stream identified as being controlled for benzene emissions in accordance with the requirements of this subpart; the table shall report the following information for the waste stream as determined at the applicable location described in § 61.355(k)(2): Annual waste quantity, range of benzene concentrations, annual average flow-weighted benzene concentration, and annual benzene quantity

* * * * *

(7) * * *

(iii) If a treatment process or wastewater treatment system unit is monitored in accordance with § 61.354(b), then each period of operation during which the flow-weighted annual average concentration of benzene in the monitored waste stream entering the unit is equal to or greater than 10 ppmw and/or the total annual benzene quantity is equal to or greater than 1.0 mg/yr.

(iv) * * *

(D) Each 3-hour period of operation during which the average concentration of organics or the average concentration of benzene in the exhaust gases from a carbon adsorber, condenser, or other vapor recovery system is more than 20 percent greater than the design concentration level of organics or benzene in the exhaust gas.

* * * * *

(J) Each 3-hour period of operation during which the parameters monitored are outside the range of values specified in § 61.349(a)(2)(iv)(C), or any other periods specified by the Administrator for a control device subject to the requirements of § 61.349(a)(2)(iv).

(v) For a cover and closed-vent system monitored in accordance with § 61.354(g), the owner or operator shall submit a report quarterly to the Administrator that identifies any period in which the pressure in the waste management unit is equal to or greater than atmospheric pressure.

(8) Beginning one year after the date that the equipment necessary to comply with these standards has been certified in accordance with paragraph (d)(1) of this section, the owner or operator shall submit annually to the Administrator a report that summarizes all inspections required by §§ 61.342 through 61.354 during which detectable emissions are measured or a problem (such as a broken seal, gap or other problem) that could result in benzone emissions is identified, including information about the repairs or corrective action taken.

* * * * *

§ 61.359 [Removed]

17. Section 61.359 is removed and reserved.

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Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 227

Threatened Fish and Wildlife; Listing of the Gulf of Maine Population of Harbor Porpoise as Threatened; Proposed Rule

Endangered Fish and Wildlife: Gray Whale; and Listing Endangered and Threatened Species: Northern Offshore Spotted Dolphin; Notices

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 227

[Docket No. 921232-2332]

Threatened Fish and Wildlife; Listing of the Gulf of Maine Population of Harbor Porpoise as Threatened under the Endangered Species Act (ESA)

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule.

SUMMARY: NMFS was petitioned to list the Gulf of Maine (GME) population of harbor porpoise as threatened under the ESA due, primarily, to the level of incidental bycatch of harbor porpoise in the GME sink-gillnet fishery. The best available scientific information indicates that the incidental bycatch of harbor porpoise in this fishery is unsustainable. Furthermore, regulations or other provisions to reduce or limit the level of incidental bycatch by this fishery do not exist. Based on this information, and the criteria established by the ESA, NMFS has determined that the petitioned action is warranted. NMFS, therefore, proposes that the GME harbor porpoise population be listed as threatened under the ESA. The GME population includes all harbor porpoise whose range extends throughout waters of eastern North America from (and including) the Bay of Fundy (BOF), Nova Scotia south to eastern Florida.

DATES: Comments and information must be received by April 7, 1993. Requests for public hearings must be received by February 22, 1993.

ADDRESSES: Comments should be addressed to the Director, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Michael Payne, NOAA/NMFS, Office of Protected Resources, 1335 East-West Highway, Silver Spring, MD 20910 (303/713–2322).

SUPPLEMENTARY INFORMATION:

Background

The GME is bounded on the west by the coastline of the northeastern United States, and on the northeast by the Bay of Fundy (BOF) and Nova Scotia, Canada. There has been incidental catch of harbor porpoise in GME gillnet fisheries for a number of years. Gilbert and Wynne (1983, 1984, 1985, 1988) provided early reports regarding the incidental take of harbor porpoise and other marine mammals. Because of the bycatch of harbor porpoise, the multispecies sink-gillnet fishery in the GME (and adjacent waters) was classified as a Category I fishery under section 114 of the Marine Mammal Protection Act (MMPA) (54 FR 16072, April 20, 1989). Under the 1988 amendments to the MMPA a Category I fishery involves "frequent incidental takes of marine mammals." To determine the extent of the harbor porpoise bycatch by the sink-gillnet fishery in the GME, NMFS initiated an observer program in August 1989 (Payne, Power and Yustin 1990; Power and Drew 1991). NMFS has also conducted field studies to determine the best methods to assess the abundance of GME harbor porpoise (Polacheck and Thorpe 1990; Polacheck 1991a, 1991b; Polacheck and Smith 1989).

Harbor porpoise bycatch data collected by observers between August 1989 and July 1990 were reported at a NMFS/International Whaling Commission (IWC) workshop, October 22–25, 1990 (IWC 1991). The data indicated that the rate of harbor porpoise bycatch in the gillnet fishery was large relative to available estimates of harbor porpoise abundance in the GMW. On February 12, 1991, NMFS announced that a status review of harbor porpoise throughout their North American range would be conducted and requested information pertaining to the species (56 FR 5684).

On September 18, 1991, NMFS received a petition from the Sierra Club Legal Defense Fund on behalf of the International Wildlife Coalition and 12 other organizations to list the GME harbor porpoise population as "threatened" under the ESA. NMFS determined that the petition presented substantial information that the petitioned action may be warranted (56 FR 65044, Dec. 13, 1991). To ensure that the status review was comprehensive and based on the best available scientific data, NMFS again solicited information and comments regarding the status of the harbor porpoise, this time focusing only on the GME. This review was conducted in conjunction with the status review initiated by NMFS on February 12, 1991. Comments regarding the petition were accepted by NMFS until February 11, 1992.

NMFS convened a workshop on May 5–8, 1992, to evaluate the status of the GME harbor porpoise and adjacent populations (as described in Gaskin 1984) in eastern North America (NMFS 1992a). Information was reviewed on population structure, reproductive rates, population size, and levels of bycatch for each of the populations considered. Workshop participants reached conclusions regarding the status of harbor porpoise populations in eastern North America based on information pertaining to: (1) Removals relative to population size; (2) adequacy of existing regulations; and (3) the ecological role of the species in the GME. The information received during the comment periods mentioned above, and the results of the harbor porpoise workshop, provided the scientific information necessary to complete the status review (NMFS 1992a) and respond to the petition.

Comments Received

NMFS received comments on both the February 12, 1991, notice initiating a status review of harbor porpoise throughout U.S. waters, and the December 13, 1991, notice of receipt of the petition to list the harbor porpoise in the GME as threatened under the ESA. NMFS received information regarding the status of the harbor porpoise in the GME and BOF regions from individuals at the following organizations: National Fisheries Institute, Washington, DC; New England Aquarium, Boston, Mass; members of the New England Harbor Porpoise Working Group; Manomet Bird Observatory, Marine Mammal and Seabird Studies, Manomet, Mass; Center for Marine Conservation, Washington, DC; New England Gillnetters Association, Marshfield, Mass; Marine Gillnetters Association, Stonington, Maine; South Carolina Association for Marine Mammal Protection, Myrtle Beach SC; International Wildlife Coalition, N. Falmouth, Mass.; Woods Hole Oceanographic Institute, Woods Hole, Mass.; Center for Coastal Studies, Provincetown, Mass; National Aquarium in Baltimore, Md.; South Shore Gillnetters Association, Norwell, Mass.; and New Hampshire Commercial Fishermens Association, Rye, NH.

Comment: One comment referred to the petition as inappropriate in light of the most recent data on harbor porpoise abundance estimates released by NMFS (the abundance estimates available in Smith *et al.* (1991)).

Response: The comment cited only the preliminary abundance estimate, which was a result of analyses of sighting data from the 1991 harbor porpoise surveys (see Listing Procedures: B in this preamble). However, the commenter did not consider the revised estimate of incidental take, which was also discussed in Smith *et al.* (1991). Both of these estimates were greater than the earlier estimates that were cited in the petition, and both were considered

preliminary. The ratio of the estimated incidental take to estimated population size used in this proposed rule (at NMFS 1992a) supports NMFS' determination that the petition is warranted (see Listing Procedures: B in this preamble).

Comment: One commenter asserted that the primary basis for the petition "is the alarming level of fishery kill to which the Gulf of Maine/Bay of Fundy population is subject." The commenter went on to note that the petition arrived at a figure of 1,530 harbor porpoise killed annually incidental to gillnet fishing in the GME. This figure was based on a study that included interviewing fishermen in 1987 to determine the average annual kill per boat. This figure was then multiplied by the number of vessels registered in the sink-gillnet fishery as part of the Interim Exemption for Commercial Fisheries. Although the exact number of active (as opposed to registered) gillnetters is not known, the commenter suggested that the level of effort was overestimated and that the estimate of bycatch was overestimated as well.

Response: NMFS was required to determine whether the petition presented substantial information indicating that listing may be warranted prior to the analyses of sighting data collected during the dedicated harbor porpoise survey conducted in the summer of 1991. Analyses of the data from these surveys have resulted in the best available estimate of harbor porpoise abundance in the GME (NMFS 1992a). The population estimates used in the petition ranged from approximately 3,000 to 15,000 (estimates from Gaskin *et al.* 1985; and Kraus, Gilbert and Prescott 1983). These estimates were considered by many likely to underestimate the true abundance of harbor porpoise in the GME to some unknown degree.

The petition also preceded the completion of analyses on the level of bycatch of harbor porpoise associated with gillnets in the sink-gillnet fishery. The mortality considered by the petitioners ranged from 280–800 per year (from Polacheck 1989) to approximately 1,000 per year (from Kraus 1990). The bycatch estimate used by the petitioners was based, at least in part, on the 1989–1990 data collected during a systematic observer program initiated by NMFS to determine the number of harbor porpoise taken in the GME.

Comment: Several comments addressed the issue of fishing effort as it relates to a bycatch estimator. The commenters maintained that total bycatch cannot be estimated by extrapolation using the estimates of total effort due to the seasonality of the fishery or biases in the database. One commenter suggested that the estimate of fishing effort used by the petitioners to extrapolate a total kill was too large.

Another commenter focused on trends in the gillnet fishery effort. The petition stated that "recent trends in fishery effort suggest that these numbers cannot be expected to slacken off anytime in the near future." The commenter replied that this is not true, and cited the development of a groundfish management plan by the New England Fishery Management Council (NEFMC) which may propose a 50-percent reduction in fishing effort in the GME. Therefore, the commenter continued, in 1992 there will likely be a marked decrease in gillnetting effort due to the effort reduction plans.

Response: Most gillnet fishery effort is recorded in a NEFSC weighout database, and several measures of fishing effort that can be used for estimating total bycatch of harbor porpoise are included in the database. The petitioners used the number of days fished (trip-based estimator) to determine fishing effort. There are, however, as mentioned by the commenters biases inherent in the weighout data (Bisack and Dinardo 1991; Bisack 1992b) which affect this estimator. these biases were addressed at the Thirteenth Northeast Regional stock Assessment Workshop (NMFS 1992b). Based on discussion at the Stock Assessment Workshop, Bisack (1992a) considered two effort estimators from the weighout database, trips (days absent) and landings (bycatch per total fish landed), to calculate estimates of harbor porpoise bycatch in the GME (see Listing Procedures: B in this preamble). NMFS concluded that total landings in the sink-gillnet fishery are more completely and accurately monitored than is fishing effort based on trips (the number of days absent) (NMFS 1992b), and is therefore a better indicator of effort than that used by the petitioners.

Several management plans are being considered that may decrease overall fishing effort throughout the GME in an attempt to rebuild selected fish stocks. At this time it is not known what plan may be implemented, or to what extent any plan will impact the gillnet fishery, or how it might result in a shift of the gillnet effort into other portions of the harbor porpoise range. It is also not clear whether measures used to reduce fishery effort in an attempt to rebuild fish stocks will also reduce the bycatch of harbor porpoise in the GME. Therefore, given the best information available at this time, it is not reasonable to predict the level of effort that will occur in the GME during the next few years, or the effect any plan will have on the bycatch of harbor porpoise.

Comment: Several commenters mentioned and supported the activities of the Harbor Porpoise Working Group, which has been meeting regularly since 1990. the group membership consists of gillnet fishermen throughout New England coastal states, NMFS and NEFMC representatives, environmental organizations, and several biologists from non-governmental organizations who have studied the biology and fishery-interaction issues of harbor porpoise throughout the GME and BOF areas. This group has made an effort to encompass all concerned parties. The group has been working to provide accurate information for the NMFS status review, and workable solutions to the problem of harbor porpoise incidental take in GME gillnets.

Response: NMFS supports the activities of the working group and has been an active participant. NMFS has used the working group meetings as a forum to discuss all issues related to harbor porpoise and the sink-gillnet fishery in the GME.

Determination of "Species" under the ESA

To consider the GME harbor porpoise population for listing, it must qualify as a "species" under the ESA. Section 3(15) of the ESA defines "species" to include "any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature." Although this definition of "species" under the ESA is in part a legal interpretation, species and populations are biological concepts that must be defined on the basis of the best scientific data available (NMFS has adopted a policy to determine whether stocks of Pacific salmon can be considered a species under the ESA (described at 56 FR 58612, Nov. 20, 1991 and at Waples 1991). However this policy was specific to Pacific salmon and not of general applicability to other species. NMFS has not adopted a similar policy for marine mammals).

NMFS uses all available lines of evidence regarding the population structure of harbor porpoise in the western North Atlantic, recognizing the limitations of each and taking advantage of the complementary nature of the different types of information. Some of the factors which have been used in making population determinations are distribution and migration patterns; isolation at the time of reproductive

activity; potential geographical and oceanographic barriers (e.g. broad stretches of open ocean) which may limit genetic exchange; the distribution of known prey; and pollutant and parasite loads (Gaskin 1984; Dizon *et al.* 1992).

Based on the best available information, NMFS issues this proposed determination that the GME harbor porpoise population qualifies as a "species" as defined by the ESA and is, therefore, eligible for listing as threatened. The bases for this determination are provided below.

Distribution of Harbor Porpoise in the North Atlantic

The harbor porpoise is confined to the Northern Hemisphere, and Gaskin (1984) suggested that there were three isolated, populations: (1) A North Pacific population; (2) a Black Sea-Sea of Azov population; and (3) a North Atlantic population. Yurick and Gaskin (1977) presented evidence for western and eastern regional populations of harbor porpoise in the North Atlantic, and Gaskin (1984) suggested that smaller, functional population units occur within each of these regions. Gaskin (1984) divided the western North Atlantic region into the following four populations: (1) West Greenland; (2) Eastern Newfoundland-Western Davis Strait; (3) St. Lawrence Estuary; and (4) Southern Nova Scotia-North Carolina.

The largest concentrations of the Southern Nova Scotia-North Carolina population occur during summer in the BOF and the northern GME. The petitioner referred to this population as the Gulf of Maine/Bay of Fundy, or more simply, the Gulf of Maine population. NMFS will use the petitioner's language and refer to harbor porpoise that occur throughout waters of eastern North America from (and including) the Bay of Fundy (BOF), Nova Scotia south to eastern Florida, but whose greatest concentrations occur in the GME and BOF, as the "GME" population.

Seasonal Distribution of the GME Population of Harbor Porpoise

Available sighting data indicate that GME harbor porpoise are highly mobile, with strong seasonal north/south movements throughout shelf waters of the BOF and the northeastern United States (CeTAP 1982; Payne, Power and Yustin 1990).

The greatest density of harbor porpoise occurs during late summer in a "high-density" area north of 43°N. latitude in the northern GME/BOF. Between the putative GME population and the adjacent populations of porpoise, there is a distinct density gradient during later summer which decreases rapidly from the high-density areas of the northern GME and BOF to near-zero density around the southern tip of Nova Scotia north to Cape Breton, Nova Scotia.

By late autumn, most harbor porpoise in this population migrate south from the BOF towards the lower GME. The winter distribution of the GME population of harbor porpoise is poorly known. There are records of winter strandings from New England to Cape Hatteras, and rarely to Florida (Polacheck and Wenzel 1990). Limited sighting and bycatch data also indicate a population that is dispersed in shelf waters south to at least North Carolina. Although strandings occur south of Cape Hatteras during winter, the available information indicates that the southern limit to large concentrations of harbor porpoise is Cape Hatteras, North Carolina.

The number of harbor porpoise sightings in the southern GME increases in spring (CeTAP 1982). Sightings between April and June in the southern GME indicate that the animals are moving in a northerly direction—further evidence that a large percentage of the GME population winters south of the GME. The distribution of porpoise sightings shifts from the southern GME in spring, to the northern GME/BOF by mid- to late summer (CeTAP 1982).

Evidence of Reproductive Isolation

Periods of reproductive activity for cetacea species can be inferred, generally, from direct observations of mating behavior, from the distribution of the annual peak of births, and from studies of the state of the testes of adult males (Gaskin *et al.* 1984). Throughout the North Atlantic, harbor porpoise mate and give birth from May to August (Fisher and Harrison 1970; Harrison 1970; Gaskin *et al.*, 1984; Read 1990a). Evidence that the reproductive activity in the GME is seasonal and does not occur during other periods of the year was provided by Gaskin *et al.* (1984), who demonstrated that seminiferous tubule diameter and the percentage of tubules containing sperm declined between July and September. This indicates a seasonal cycle of spermatogenesis in the GME, and agrees with data presented by Fisher and Harrison (1970), who concluded that testicular activity in North Atlantic harbor porpoise increased from May onwards (reaching a peak in the latter half of July), and then decreased dramatically by mid-August. Decreasing testicular volume from July through September was considered further evidence of the existence of an annual reproductive cycle in the male harbor porpoise (Gaskin *et al.*, 1984). Female harbor porpoise also display significant reproductive seasonality in the timing of ovulation (late June through early August) (Read 1990a). Generally, therefore, peak reproduction activity (and genetic exchange) does not occur outside the summer range of the harbor porpoise, where populations are most discrete.

The summer arrival times within all of the four proposed populations in the western North Atlantic coincide closely with each other (mother-calf pairs begin to arrive in the BOF coastal waters in June, or rarely in late May). This also indicates that, while more than one population of harbor porpoise may occur seasonally in the GME, the likelihood of these populations mixing during the period of greatest reproductive activity is thought to be very low, and supports the population structure in the western North Atlantic characterized by Gaskin (1984).

Each of these population concentrations has large areas of zero or near-zero harbor porpoise density between them at this time of the year. Although these "density troughs" (Dizon *et al.*, 1992) imply a high degree of segregation and an extremely limited exchange rate, it cannot be ruled out that some interchange may occur, and this population cannot be considered completely allopatric. However, reproductive isolation does not have to be absolute for a population to be considered distinct (FR 56 58612, Nov. 20, 1991). Considering (1) the limited seasonality of peak reproductive activity, and (2) the average distance and "density troughs" that segregate the northwest Atlantic into obvious, discrete reproductive groupings during peak reproductive activity, the degree of genetic exchange between the harbor porpoise population in the GME, and adjacent populations, is considered to be minimal.

Evidence of Site-Fidelity (Population) Between Years

Gaskin, Smith and Watson (1975), Read and Gaskin (1985) and Gaskin *et al.* (1985) found no evidence that harbor porpoise caught and radio-tagged in the western BOF range into adjacent waters (such as the GME and southwest Nova Scotia) during the summer months. Gaskin and Watson (1985) determined that recognizable animals returned each year to re-establish "specific ranges in virtually the same locations in the western BOF each summer."

These authors were able to resight individual animals during the summers of 1973–1975 and in 1977. Gaskin and Watson (1985) suggested that possible "home-ranges" in harbor porpoise should not be surprising. Similar patterns, although sometimes on very different geographical scales, have been recorded for other species of small cetaceans.

It is also worth noting that three recognizably marked females studied by Watson (1976) in the Fish Harbour region (western BOF) not only returned several years in succession (3 years, 2 years and 2 years), but in each year had newborn calves with them.

These demonstrated "specific ranges" and annual returns by individual harbor porpoises in the BOF further suggest geographic isolation (therefore reproductive isolation) between the GME population and other porpoise in the western North Atlantic during the peak reproductive season.

Population Response Data

A self-sustained population's life histories may be modified through density-dependent responses to over-exploitation. Such responses have been used to distinguish populations. Read and Gaskin (1988) demonstrated significant differences between the frequency distribution of body lengths of porpoises retrieved from gillnets during 1981–1986, and of porpoises collected in 1969–1973 by Smith *et al.* (1983). The observed changes had two main components: An increase in the length of calves from the earlier collection to the 1980s, and an absence of large animals during the 1980s. The increased mean calf length could have been caused by increased prey resources, concomitant with a decline in local density, allowing females to invest more energy in their offspring during pregnancy and/or lactation, resulting in larger calves. The authors concluded that the observed differences between the gillnet samples in the 1980s and samples collected from 1969–1973 reflected real changes in body size that have occurred in the population between the sampling periods. The authors further suggested that sustained incidental mortality from gillnets makes it unlikely that porpoises lived long enough to reach large sizes, and population resilience to exploitation is limited (female harbor porpoise in the 1969–1973 sample reached sexual maturity at age 4, and few animals lived more than 7 years, Gaskin and Blair 1977).

It was recognized by Read and Gaskin (1988) that gillnets possibly catch certain size classes of porpoises and do not catch small or large animals. Therefore Read and Gaskin also examined a small sample of porpoise caught in herring weirs during the two different time periods. The frequency distributions of body length of porpoises captured in herring weirs in 1981–1986 and in 1969–1973 were also significantly different, further suggesting that the differences observed in samples from the gillnets reflected real changes in the population.

The May 1992 harbor porpoise assessment workshop discussed these data and suggested that harbor porpoise abundance in the BOF could have been reduced by incidental catches, or other factors, leading to an increased per-capita food consumption (as suggested by Read and Gaskin 1988); or that changes in prey biomass may have led to an increase in per-capita food consumption, regardless of the trajectory of the porpoise population.

Contaminants

Nearshore marine mammals such as pinniped and small cetaceans are long-lived and feed high on the food chain; therefore they tend to accumulate chlorinated hydrocarbons in their blubber layers which serve as stable repositories for these lipophilic contaminants (Calambokidis and Barlow 1991). As such, pollutant ratios in the blubber of coastal marine mammals are useful as indicators of population or regional discreteness, and useful in evaluating the extent of movement and interchange between regions.

Calambokidis and Barlow (1991) found very strong pollutant ratio gradients with latitude in harbor porpoise from the west coast of the United States. Because chlorinated hydrocarbons accumulate over long periods of time (the entire lifespan of male harbor porpoise), the authors inferred, based on the significant differences in levels of pollutants in the blubber samples by region, that most harbor porpoises remain in a region for extended periods, if not most of their lives. This implies long-term geographical and genetic isolation from other porpoise from other regions. If the population(s) were panmictic (randomly mixed), homogeneous pollutant ratios between samples from all areas should exist.

Gaskin (1984) used the lack of any significant differences in mercury and polychlorinated biphenyl levels in animals from different parts of the GME and BOF (data at Gaskin 1982; Gaskin, Frank and Holdrinet 1983), combined with data on the migration patterns and movements of radio-tagged porpoise in the BOF, to suggest that the harbor porpoise from the BOF, south into U.S. waters, represented a single, functional population unit.

Genotypic Data

Evidence obtained from genetic methods is often considered by resource managers as the most unequivocal means for differentiating species and their intraspecific population structure. The mitochondrial genome (mtDNA) exhibits several features that make it particularly useful for comparing closely related taxa: (1) It is inherited maternally (Brown, George and Wilson 1979) and does not undergo recombination during replication, thus allowing for clearer inferences of phylogenetic relationships; (2) the lack of recombination allows mtDNA genotypes to persist through generations without disruption; and (3) mtDNA evolves faster than nuclear DNA (Brown, George and Wilson 1979), which means that differences among local populations leading to population differentiation will accumulate more rapidly, allowing for higher resolution in the differentiation of recently diverged taxa. These features have made the analysis of mtDNA, through DNA sequencing and restriction fragment length polymorphism (RFLP) studies, a powerful tool for determining patterns of geographic variation in natural populations (Avise *et al.* 1987; Slatkin and Maddison 1989; Stoneking *et al.* 1990; Thomas *et al.* 1990).

Recent comparisons of the mtDNA of harbor porpoise from different areas were presented at the May 1992 workshop. Rosel (1992) presented the results of sequencing the mtDNA from samples taken from the eastern and western North Atlantic. This analysis could not detect population differentiation between eastern and western North Atlantic populations. Wang, Gaskin and White (1992) presented preliminary results from RFLP analysis to assess the levels of mtDNA differentiation between three of the putative populations (eastern Newfoundland, Gulf of St. Lawrence, and the GME) in the western North Atlantic. The amount of genetic diversity found within each of the populations was greater than that found between populations (i.e. the analyses did not detect differences between the putative populations). Thus, results of genetic analyses obtained thus far do not support reproductive isolation between the population structure proposed by Gaskin (1984).

Due to limitations in the interpretation of the genetic analyses, however, the inability to detect genetic differences among these groups does not

rule out the possibility that they are distinct populations. Where genetic barriers are "leaky" (no more than a few individuals per generation) mtDNA genomes can rapidly penetrate neighboring populations, independent of the adaptive chromosomal genome (Ferris *et al.* 1983). These mtDNA genomes are considered neutral, and not selectively removed from the population. The presence of these foreign genomes may argue for the presence of "homogenizing" gene flow and lumping the separate population as one stock, when they may be separate stocks.

Dowling *et al.* (1992) further stated that the failure to find diagnostic molecular charactistics among distinct forms does not necessarily imply conspecificity, but rather indicates that the available genetic data (typically representing only a small fraction of the genome) do not allow rejection of the null hypothesis (i.e., no difference). Read (at the May 1992 workshop) noted that a preliminary study using protein electrophoresis failed to differentiate *P. phocoena* from *P. spinipinnis*. Speciation could conceivably result from very few genetic changes (or even one); therefore, levels of genetic divergence alone are not valid measures of specific status. Dowling *et al.* (1992) further suggested that it is important to realize that two adjacent forms (or, in this case, populations of harbor porpoise) should not be discriminated against because of their lack of genetic "purity." The dismissal of distinct entities (i.e., forms, or populations) due solely to lack of "purity" or apparent lack of genetic devergence is unacceptable (Dowling *et al.* 1992).

Dizon *et al.* (1992) described four operational categories of populations based on the degree of response to differential selection likely to have occurred in one population relative to another. Under their scheme, differences found in demographic, morphological, or mtDNA measures are taken to be proxies indicating that selection (potential gene flow) may be operating differentially on one population relative to another. Their categories I–IV represent gradients from the easiest situation demonstrating separate populations (category I-allopatric populations with significant genetic differences) to a situation where there are no geographical barriers between populations, there is considerable intermixing on the breeding range, and the potential for extensive gene interchange is great (category IV). The latter category demonstrates the weakest evidence for differentiation between populations.

Following the classification criteria considered by Dizon *et al.*, harbor porpoise in the GME most closely resemble a Category III population (i.e., there is strong geographic partitioning at the reproductive season indicating reproductive isolation to some degree; however, the geographically separated assemblages are characterized by little or no genetic differentiation). Dizon *et al.* suggested that a Category III population should be considered and managed separately due, at a minimum, to the geographic partitioning of the breeding assemblages.

Participants at the harbor porpoise workshop also recognized that, even though rates of exchange between harbor porpoise in the northwest Atlantic may be great enough to eliminate genetic differences, groups could still be sufficiently distinct to justify management as separate stocks or populations (NMFS 1992a). Recent separation or very low levels of mixing would hamper attempts to detect genetic differences. Therefore, participants at the May 1992 workshop suggested that Gaskin's proposed population structure of the northwest Atlantic be used as the working hypothesis (NMFS 1992a).

Although the direct genetic evidence for consideration of the GME harbor porpoise as a distinct population is inconclusive, all other lines of biological evidence strongly support a species status recognition under the ESA. Seasonal movements into the northern GME/BOF during summer, the known summer reproductive periodicity and spatial segregation from other conspecific groups at that time, and the subsequent dispersal during late fall and winter from the GME south to at least North Carolina, strongly suggests a unified, single breeding assemblage. The best scientific information available indicate that the viability of harbor porpoise in shelf waters of the eastern U.S. is dependent upon harbor porpoise in the GME and BOF. Therefore, based on this information, NMFS proposes that the harbor porpoise that occur in the GME and BOF represent a distinct population, and therefore a "species" under section 3(15) of the ESA.

Listing Procedures: Summary of Factors Affecting the Species

Section 3 of the ESA (16 U.S.C. 1532(19)) defines a threatened species as "any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range."

To determine whether a species should be listed as endangered or threatened, section 4(a)(1) of the ESA (16 U.S.C. 1533(a)(1)) sets forth the following five criteria:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

A. *The Present or Threatened Destruction, Modification, or Curtailment of Habitat or Range:* Although the nearshore habitat of this species along the eastern U.S. coastline is potentially threatened with destruction or physical modification (see E. of this preamble), there is no evidence that such modification or destruction to date has contributed to a decline of harbor porpoise in the GME.

There is no evidence that the range of this subspecies has changed significantly (see E. of this preamble), or has contributed to a decline of harbor porpoise in the GME.

B. *Overutilization for commercial, recreational, scientific, or educational purposes:* Information on the bycatch of harbor porpoise in the GME has been obtained from several sources throughout the 1980s. Some of this information has been from scientific, but not systematic surveys. Gilbert and Wynne (1988) documented relative levels of marine mammal bycatch (including harbor porpoise) in GME fisheries. These data were used by NMFS to classify the GME sink-gillnet fishery as a Category I fishery (54 FR 16072, April 20, 1989). However, due to an inability to place observers systematically aboard domestic fishing vessels prior to the implementation of section 114(f) of the MMPA, it was not possible, until recently, to obtain the temporal and spatical sampling required for a reliable estimate of harbor porpoise bycatch in GME fisheries from rate-of-take data such as that collected by Gilbert and Wynne.

Vessels operating in a Category I fishery are required, under section 114(e) of the MMPA, to take onboard an observer to obtain information on the species and number of marine mammals taken incidental to the fishery. This latter requirement has been implemented in the GME multispecies sink-gillnet fishery through the NMFS/NEFSC Sea Sampling Program (SSP).

(i) Observer Effort

The SSP observer effort has been allocated by month and NMFS fishery statistical areas within the GME, based

on the total number of days that fishing vessels were absent from port (as indicated in the NEFSC weighout database) for the previous year (Power and Drew 1991; Bisack 1992a). Bisack (1992a) partitioned the GME into a northern component (NMFS statistical areas 511 and 512) and a southern component (statistical areas 513–515). Most of the sink-gillnet fishery effort (based on the weighout database) in the GME occurs in these statistical areas.

(ii) Bycatch Estimators From Weighout Database

The porpoise rate-of-take information collected by SSP observers needs to be combined with some measure of total fishing effort to calculate a total bycatch for the GME. Several measures of fishing effort that can be used for estimating total bycatch are available in the weighout database. Smith *et al.* (1991) presented preliminary estimates of bycatch based on the product of the mean bycatch rate per fishing trip from the SSP database and the total number of fishing trips in the sink-gillnet fishery as estimated by NEFSC port agents and recorded in the weighout database (i.e. a trip-based effort indicator). There are, however, biases inherent in the weighout data (Bisack and DiNardo 1991; Bisack 1992b). These were discussed at the Thirteenth Northeast Regional Stock Assessment Workshop (NMFS 1992b). It is known, for example, that for some vessels, the number of days absent or days at sea (trip estimator) are underestimated in the weighout data. Vessels under 5 tons represent one-third of the weighout trips, but they cannot be tracked in the database; therefore, little information is available about the number of these participating vessels and the association between the number of days absent and total fishing effort (Bisack and DiNardo 1991). Also, the weighout database is intended to provide catch data through port interviews with the fishermen. The amount of interview effort from the northern GME reported in the weighout database has not been adequate and significantly underestimates the amount of fishing effort in that region. Since total effort estimates from the weighout database are needed to estimate marine mammal bycatch, the bycatch estimates may be downwardly biased as a result of underestimating effort in northern GME ports (Bisack and DiNardo 1991).

An alternative method of estimating total bycatch of harbor porpoise killed in the fishery from the weighout data could be determined based on the number of harbor porpoise taken per ton of fish landed (based on SSP sampling data), expanded by the total tons of fish landed from the weighout database (i.e. a landings estimator). The participants of the Stock Assessment Workshop (NMFS 1992b) suggested that estimates of total landings in the grillnet fishery are more accurate than estimates of total fishing effort.

(iii) Estimates of Harbor Porpoise Bycatch in the GME

The present estimates are based on data collected from June 1989 through the second half of 1991. SSP observers reported 67 harbor porpoise taken by gillnet vessels from June 1989, through 1991. Most (58/67) of the harbor porpoise bycatch occurred in the southern GME, primarily from October through May (fall and winter, Bisack 1992). In the northern GME, the bycatch occurred primarily in the summer and fall (Table 1). The timing and location of takes are consistent with known seasonal movements of harbor porpoise between the southern GME and the northern GME/BOF.

There were no harbor porpoise takes reported during the summers of 1989 or 1990 (Table 1). During these periods the distribution of sampling effort was often disjunct with the known distribution of harbor porpoise (i.e., SSP observers were allocated to the southern GME at a time when harbor porpoise were primarily in the northern GME (Payne, Power and Yustin 1990). It is only since June 1991, when SSP effort increased throughout the GME, that statistically reliable bycatch estimates can be made for all regions and seasons within the GME (Bisack 1992b).

The bycatch estimates using trips and landings as estimators are similar, except in the fall of 1990 and the winters of 1990 and 1991 (Table 2). During these periods, the bycatch estimates using landings as the effort estimator were substantially higher than the trip-based estimates (NMFS 1992a). The differences in the trip-based and landings-based estimates could be due to several known difficulties with the databases (discussed previously, and in DiNardo and Bisack 1991; Bisack 1992b).

Given the recommendations of the Stock Assessment Workshop participants that estimates of total landings in the gillnet fishery are more accurate than estimates of total fishing effort, a landings-based bycatch estimator is considered more accurate than one based on total fishing effort. The best estimate of the average annual bycatch of harbor porpoise in the entire GME gillnet fishery (northern and southern GME) is 2,000 (95 percent confidence interval (CI)=1,200–2,800) (Bisack 1992a). The landings-based estimates ranged from 2,396 to 1,672 for 1990 and 1991, respectively (NMFS 1992a). The 95-percent CI in 1990 ranged from 1,600 to 3,500, and in 1991 from 1,100 to 2,500 (NMFS 1992a)

These estimates are not likely to be biased upward because landings were overestimated. Landings would only be overestimated if there were incorrect gear assignments, that is, if other gear types were recorded as sink gillnet gear. It is more likely that sink gillnet gear has been incorrectly assigned to other gear types (Bisack 1992b), which would result in trips and landings being underestimated; therefore, bycatch would also be underestimated.

TABLE 1.—ANNUAL SEA SAMPLING (SSP) TRIPS, TOTAL OBSERVED HARBOR PORPOISE BYCATCH, WEIGHOUT (WO) TRIPS, AND WO LANDINGS (TONS) BY YEAR AND SEASON (SUMMER, FALL AND WINTER) FOR THE NORTHERN GULF OF MAINE (UPPER) THE SOUTHERN GULF OF MAINE (LOWER).

[Northern Gulf of Maine]

Year	Season	SSP trips	Porpoise bycatch	WO trips	WO landings
1989	S	2	0	888	1641
	F	1	0	378	529
	W	2	0	154	186
1990	S	6	0	856	1269
	F	2	1	433	392
	W	2	0	235	215
1991	S	91	5	1033	1975
	F	33	3	429	668

[Southern Gulf of Maine]

Year	Season	SSP trips	Porpoise bycatch	WO trips	WO landings
1989	S	7	0	2158	4945
	F	1	0	3821	6214
	W	56	9	3062	2916
1990	S	21	0	3602	7969
	F	36	7	3848	5564
	W	36	10	2693	2229
1991	S	325	2	2871	5483
	F	328	30	3055	3005

TABLE 2.—ESTIMATED BYCATCH (K) AND STANDARD DEVIATION OF THE ESTIMATE (SD) WITH TRIPS AND LANDINGS AS AN ESTIMATOR BY REGION AND SEASON.

Year	Season	Trip Estimator				Landings Estimator			
		N. GME		S. GME		N. GME		S. GME	
		K	SD	K	SD	K	SD	K	SD
1989	S								
	F			372	170			337	174
	W			495	217			1264	159
1990	S								
	F	217	216	748	298	67	400	1045	347
	W			748	294			1201	331
1991	S	57	28	18	17	65	28	19	17
	F	39	209	281	56	48	22	339	61

It should be re-emphasized that the incidental bycatch estimates are only for the multispecies sink-gillnet fishery in the GME. The harbor porpoise bycatch estimates do not include known bycatch from this population that also occurs in the BOF, and in U.S. waters below the GME (during the winter-spring) by other gillnet fisheries.

(iv) Estimate of Bycatch in the BOF

Harbor porpoise from the GME population are taken incidentally by several fisheries in the BOF.

The size of the gillnet fleet in the western BOF, and the level of porpoise bycatch, remained relatively stable between 1986 and 1989, when approximately 100 porpoises were reported killed each summer in the groundfish gillnet fishery (Read and Gaskin 1988, 1990). Incidental takes of harbor porpoise are also likely to occur in the eastern BOF but have not been quantified (NMFS 1992a).

Smith, Read and Gaskin (1983) also estimated that approximately 70 porpoises are trapped each summer in herring weirs in the western BOF, and that, on average, approximately 27 die annually as a result of entrapment. Small numbers of harbor porpoises are also taken in herring weirs scattered along southwestern Nova Scotia (Smith, Read and Gaskin 1983).

Based largely on the magnitude of the incidental take in the western BOF gillnet fishery, and changes in local density and life history parameters of harbor porpoise in that region, the harbor porpoise was listed as a threatened species by the Committee on the Status of Endangered Wildlife in Canada (Gaskin 1989).

(v) Other Harbor Porpoise Bycatch in U.S. Waters

Harbor porpoise takes in the sink-gillnet fishery south of the GME have also been reported in the SSP database, but not considered in this estimate of total bycatch for the GME. There is increasing evidence that harbor porpoise have been taken incidental to gillnet fisheries for anadromous fish species, such as herring and shad, in coastal southern New England/Mid-Atlantic waters (south of the GME), winter through spring (57 FR 1900, Jan. 16, 1992). Fourteen harbor porpoises, some of which had net marks and full stomachs (characteristics indicative of gillnet mortality) washed up on New Jersey beaches in the spring of 1991, in the vicinity of shad gillnets (57 FR 1900, Jan. 16, 1992). Increased enforcement inquiries in southern New Jersey in late March, 1991, resulted in reports from coastal gillnet fishermen of two lethal and two live takes in the shad gillnet fishery in that area. During this same time period six harbor porpoises also stranded on Virginia beaches, including four with net marks on the leading edge of the flukes and dorsal fins. The first was found the day after the opening of the Virginia nearshore gillnet fishery for shad. Harbor porpoises have also been taken in shad gillnets in the Chesapeake Bay (57 FR 1900, Jan. 16, 1992).

The magnitude of the bycatch in these coastal and nearshore gillnet fisheries is not known. Observer coverage of the sink-gillnet fleet in southern New England only started in August 1992, and therefore, insufficient data are available to estimate the total extent of this bycatch.

(vi) Harbor Porpoise Abundance

Field and analytical experiments to determine the best method of assessing harbor porpoise abundance in the GME have been conducted by the NEFSC since 1988 (Polacheck and Thorpe 1990; Polacheck 1991a, 1991b; Polacheck and Smith 1990). Previous harbor porpoise surveys or abundance estimates (Gaskin 1977; Prescott *et al.* 1981; CeTAP 1982; Kraus, Gilbert and Prescott 1983; Gaskin *et al.* 1985) provided survey coverage for only a limited part of the range of the harbor porpoise, and resulted in minimum abundance estimates, which are considered dated and inadequate. During July and August 1991, NMFS conducted sighting surveys in the offshore waters of the GME/lower BOF/southern Scotian Shelf (Palka 1992a), and GME inshore waters (Read and Kraus 1992). Preliminary estimates from these surveys were presented by Smith *et al.* (1991). Several commenters referred to these estimates in their comments to NMFS regarding the petition to list GME harbor porpoise as threatened under the ESA. These estimates were considered preliminary by NMFS in that further review of the data was needed to confirm the following areas of uncertainty:

(a) Two teams of observers were used in the offshore survey. Each team

searched simultaneously for harbor porpoise, but recorded all sightings separately (Palka and Potter 1992). The use of two observer teams allowed abundance to be estimated in several manners (Palka 1992a, 1992b; NMFS 1992a). The sighting data for the two observer teams were combined to calculate a 1991 estimate (following a technique described at Butterworth and Borchers 1988), correcting for the fraction of the sightings missed by both teams. An uncertainty in the number of duplicative sightings between the two observer teams needed to be further addressed.

(b) The preliminary estimates assumed the density of porpoise in nearshore areas to be the same as the density of porpoise immediately offshore. Rather than assuming that the densities were the same in the two areas, the participants at the May 1992 workshop suggested a different and perhaps better approach. The participants suggested using the measured ratio of porpoises seen in the two areas as an estimate of density in the nearshore area (NMFS 1992a).

(c) Finally, previous survey data suggested that these animals avoid research vessels, at least at close ranges. The distributions of observed swimming directions indicated that harbor porpoise were reacting to the vessel prior to (Palka 1992c) and after (Polacheck and Thorpe 1990) being observed. Significant bias can be introduced into density estimates if animals react to a survey vessel (Polacheck and Thorpe 1990). However, there was no indication from the distribution of perpendicular sighting distances to the harbor porpoises that they were avoiding the survey vessel. Given available data, the workshop participants concluded that it was impossible to assess the effect of animal movement in reaction to the vessel on abundance estimates (NMFS 1992a).

Detailed descriptions of the survey methodology and the sighting data analyses used in the 1991 surveys are provided in Palka (1992 a, b, c, d), Palka and Potter (1992) and Read and Kraus (1992). Participants at the 1992 workshop agreed that the 1991 harbor porpoise survey provided reliable density estimates using the best available survey techniques (NMFS 1992a). Methods of estimating confidence limits around the abundance estimate are also provided in Palka (1992a) and NMFS (1992a). The average abundance estimate produced from the 1991 survey, 45,000 (95-percent CI: 23,000–80,000), is considered the best estimate of the GME harbor porpoise population.

(vii) Harbor Porpoise Productivity versus Bycatch in the GME

Woodley and Read (1991) used demographic models to evaluate the effects of different rates of incidental removal of animals from the harbor porpoise population in the GME/BOF. Woodley and Read (1991) estimated the potential intrinsic rate of increase (r_{max}) of the GME harbor porpoise population using empirical data on reproductive rates (at Read 1990c) and several hypothetical survival schedules. Survival schedules were calculated to maximum ages of 12 and 15 years using estimates of natural mortality combined with the following rates of incidental mortality: 0.0183, 0.0352, 0.0523, and 0.1006. The incidental mortality rates were estimated assuming that the proportion of all age classes of porpoise greater than age 0 are equally affected by incidental mortality, and by calculating ratios from estimates of bycatch to total population size. The range of the bycatch to abundance ratios calculated by Woodley and Read (1991) is identical to the range of the 95 percent CI values around the average bycatch to abundance ratios in the GME using the results of bycatch data presented in Bisack (1992a), and abundance estimates from Palka (1992a) (the 95-percent CI values around the bycatch to abundance ratio range from 0.018 to 0.109 (NMFS 1992a).

The model used by Woodley and Read (1991) incorporates the best available scientific information on the range of life history parameters of harbor porpoise in the GME and BOF, and has resulted in the best available estimate of maximum net productivity for harbor porpoise in the GME. Woodley and Read (1991) found that the model population could not sustain levels of incidental mortality greater than 0.04. At the two higher levels of incidental mortality (0.0523 and 0.1006), only negative population growth rates were possible (i.e., population could only decrease). Woodley and Read concluded, in agreement with Barlow (1986), that harbor porpoises have a limited capacity for population increase, and cannot sustain even moderate levels of incidental mortality.

The IWC reviewed net reproductive rates of harbor porpoise and related species in an attempt to place an upper limit on the range of R_{max}. Theoretical upper limits to phocoenid R_{max} have approached 10 percent (IWC 1990; Barlow and Boveng 1991); therefore R_{MNPL} could theoretically approach 0.05. It should be re-emphasized, however, that the IWC Committee concluded that "it had no firm basis" for estimating a net reproductive rate for harbor porpoise, and none of the calculated estimates of R_{max} for any phocoenid population have been as large as 10 percent (IWC 1990). Barlow and Boveng (1991) envisioned the primary use of their modeling efforts as exploratory, and recommended that their approach (and the resulting survival parameters) not be used for estimating the actual growth rates for any population.

The IWC (1990) concluded that any estimate of acceptable harvest and incidental take rates of harbor porpoise should be conservative, i.e., lower than half of the estimated value of the maximum rate of increase. Therefore, r_{max} values in the range of 4 percent per year indicate a porpoise population that could possibly sustain a level of incidental take that approaches, but does not exceed, 2 percent of the population estimate. Annual human-induced mortality exceeding two percent is not considered sustainable for other species of small cetaceans (MMC 1979, reviewed by Hammond 1991).

(C) *Disease or predation:* There is no indication from stranding data, or tissue analyses from harbor porpoises taken in gillnets, that disease has had an impact on harbor porpoise in the GME. Likewise, harbor porpoise are known to be preyed upon by sharks and killer whales. However, killer whales are not common enough in the GME/BOF to have a measurable effect on the abundance of porpoise, and there is no evidence that shark predation has contributed to the decline of harbor porpoise in the GME.

Harbor porpoise in the GME are know to carry high levels of heavy metals and organochlorines in their tissues (Gaskin, Holdrinet and Frank 1982). Of particular concern are the polychlorinated biphenyls (PCBs) and their lipophilic organichlorines found in harbor porpoise (Gaskin, Holdrinet and Frank 1982; Gaskin, Frank and Holdrinet 1983). These organochlorine residues are known to be mobilized and transferred from adult females to their calves during lactation (Gaskin *et al.* 1982). However, at the present time, the presence of these contaminants in harbor porpoise tissues does not appear to pose a serious threat to this population (Read and Kraus 1991).

(D) *The inadequacy of existing regulatory mechanisms:* One of the strongest recommendations from the May 1991 harbor porpoise assessment workshop was that the present level of bycatch of porpoise in the GME sink-gillnet fishery needs to be reduced. The 1988 Amendments to the MMPA, as

amended, established the Marine Mammal Exemption Program (MMEP). The MMEP allows commercial fisheries to take harbor porpoise without a timely mechanism for control. However, the amendments do not contain emergency provisions that can be employed. It was indicated at the harbor porpoise assessment workshop that the harbor porpoise bycatch levels may not appropriately be considered an "emergency" at this time. However, the workshop results did determine that the bycatch levels may "have a significant adverse impact over a period of time longer than one year". Therefore, independent of the ESA, NMFS is proceeding under section 114(g)(3) of the MMPA to address the bycatch problem. Pursuant to the MMPA, NMFS requested that the New England Fishery Management Council (NEFMC) introduce measures in Amendment 5 to the Northeast Multispecies Fishery Management Plan (FMP) that will reduce harbor porpoise mortality to acceptable levels.

The NEFMC is considering proposals to amend the FMP to reduce fishing to levels that would allow selected stocks of groundfish to recover. One of the proposals being considered is a reduction in fishing effort through reductions in allowable fishing time. For vessels participating in the gillnet fishery, the NEFMC has proposed that gillnets be removed from the water for specific periods of time. The NEFMC will also request comment on a proposal that would allow changes to this management measure in subsequent years. This seconds proposal would allow for annual review of more recent information on areal and seasonal distributions of harbor porpoise and possible measures to mitigate their takings. It is envisioned that this process will be able to respond in a more timely fashion to new information or increased understanding of the interactions of marine mammals and this fishery. Public hearings are planned for both proposals early in 1993. After receipt of public comment, the NEFMC will determine what measures are to be included in amendment 5, then submit the amendment to them for submission to the Secretary for approval. Further data regarding the species status, and the final amendment 5 measures will be considered in the decision for final listing.

The FMP restrictions may not address bycatch in state-regulated fisheries/state waters. However, under section 114(g)(3), NMFS could request the states to take such action within their authority (such as imposing restrictions on state-regulated fisheries) as it considers necessary to mitigate the bycatch.

NMFS could also, pursuant to section 114(g)(2) of the MMPA, consult with NEFMC and state fishery managers to prescribe emergency regulations to prevent, to the maximum extent possible, any further taking of harbor porpoise. Such emergency regulations must also, to the maximum extent possible, avoid interfering with existing state or regional FMPs. While this option would provide immediate relief to harbor porpoise in the GME, it would only be a temporary solution since emergency regulations promulgated under section 114(g)(2) would be effective for only 180 days or until the end of the fishing season, whichever is earlier. Further, the results of the harbor porpoise assessment workshop indicate that the situation may not appropriately be considered an "emergency."

(E) *Other natural or manmade factors affecting its continued existence:* Although incidental catches in gillnet fisheries are believed to pose the greatest threat to harbor porpoises in the GME, Read and Kraus (1991) listed several other factors that may influence this population, including the following: Loss of habitat (see A. in this preamble), coastal pollution and environmental pollution (see C. in this preamble), and competition with fisheries for prey resources.

The most important prey of harbor porpoises in the GME/BOF is Atlantic herring (Smith and Gaskin 1974; Recchia and Read 1989). Between 1967 and 1976, there was a 75-percent reduction in herring biomass on Georges Bank (Sissenwine, Overholtz and Clark 1984), and in 1977 the commercial fishery for herring failed completely. There was virtually no evidence of a Georges Bank herring population between 1977–1983, despite considerable sampling by research vessels during that period. Kenney *et al.* (1991) suggested that, in response to the complete collapse of a Georges Bank herring stock, harbor porpoise may have shifted their distribution nearshore during the early 1980s, away from Georges Bank. Such a response to a human-induced prey depletion might result in local increases in harbor porpoise abundance, an increased density in areas of the GME and BOF where reduced prey are concentrated, and increased opportunities for fishery-harbor porpoise interactions in the GME and BOF.

Connor (1971) and Ulmer (1977) reported harbor porpoise (in small groups) in the summer months (during the 1940s) in lower New York Bay. It is difficult to determine what "a small number" implies; however, harbor porpoise, at present, are rarely observed outside the northern GME and BOF during summer. Therefore, it does seem possible that the distribution and seasonal occurrence of harbor porpoise have shifted in recent decades. Although cause and effect can rarely be demonstrated, such a seasonally-reduced sighting distribution may be precipitated by a change in the availability of prey.

Recent fishery conservation measures are allowing herring stocks to recover from previous low levels, and fishing pressure on these stocks is currently light. Therefore, there is no evidence at this time that harbor porpoises are affected by prey densities.

Vessel traffic has also been documented to have a negative impact on harbor porpoise behavior. Flaherty and Stark (1982) suggested that harbor porpoise abandoned areas of the Washington coastline because of vessel traffic. Polacheck and Thorpe (1991) demonstrated ship avoidance to a research vessel by harbor porpoise in the GME. If ship avoidance were a widespread phenomenon, harbor porpoises might be expected to abandon areas of heavy vessel activity in the GME. Most of the summer range of the GME population occurs in areas of light vessel traffic, and it is unlikely that porpoise are affected by vessel traffic at this time. During the winter and spring, the distribution shifts into the southern GME and adjacent southern New England waters. It is during this period that porpoise behavior may be influenced by increased vessel traffic. The petitioners have demonstrated that vessel traffic has increased in the GME in recent years. However, it is not known to what extent, if any, this increased vessel density has affected harbor porpoise in the GME.

Determination

Based on the assessment of available scientific information, NMFS proposes that harbor porpoise in the GME is a "species" under the ESA.

The best estimate of the average annual bycatch of harbor porpoise in the entire GME gillnet fishery (northern and southern GME) is a minimum of 2,000 (95-percent CI=1,200–2,800) (Bisack 1992a). This estimate is based only on data for the multispecies sink-gillnet fishery in the GME, and does not include known bycatch from this population which occurs in the BOF, or in U.S. waters below the GME (during the winter-spring range of the GME harbor porpoise population).

The best estimate of the size of the GME harbor porpoise population from

the 1991 survey is 45,000. Therefore, the minimum bycatch of the GME population is approximately 4.5 percent of the best estimate of its abundance.

Harbor porpoises have a limited capacity for population increase, and are unlikely to sustain even moderate levels of incidental mortality. The best available estimate of maximum net productivity (r_{max}) for harbor porpoise in the GME does not exceed 4 percent (Woodley and Read 1991). At greater levels of incidental take, the population will likely decline. The IWC (1990) believes that any estimate for acceptable harvest and/or incidental take rates of harbor porpoise should be conservative, i.e., lower than half of the estimated value for r_{max}. Therefore, r_{max} values in the range of 4 to 5 percent per year indicate a porpoise population that could sustain a level of incidental take no greater than 2 percent of the population estimate. NMFS believes that annual human-induced mortality exceeding this value for other species of small cetaceans is unsustainable. The best available information indicates that the bycatch of the GME population of harbor porpoise must be reduced by more than 50 percent to be sustained by the present GME population. This includes a reduction in bycatch by the GME multispecies sink-gillnet fishery as well as the southern New England/Mid-Atlantic gillnet fisheries for herring, shad and other coastal species. At present the extent of bycatch in the gillnet fisheries is considered a threat to the continued existence of the GME harbor porpoise. NMFS concludes that the GME population of harbor porpoise is likely to become endangered within the foreseeable future throughout all or a significant portion of its range and determines that the petitioned action is warranted. NMFS, therefore, proposes to list the GME population of harbor porpoise as threatened under the ESA.

Proposed Protective Regulations

Until more comprehensive regulatory or other action can be implemented to reduce sources of harbor porpoise mortality (e.g., bycatch), NMFS is proposing to adopt the ESA section 9 prohibitions applicable to endangered species to prohibit taking, interstate commerce, possession, sale, receipt, transport, or shipping of harbor porpoises. Generally, then, the prohibitions of § 9 that are applicable to endangered species would be applicable to harbor porpoises, with certain exceptions.

NMFS is proposing to adopt the following exceptions to the general prohibitions: (1) Taking of harbor porpoise incidental to commercial fishing operations if the incidental takings are consistent with the following bycatch reduction program; (2) taking in a humane manner (including euthanasia) by federal, state and local officials and employees, and others designated by the Assistant Administrator pursuant to § 112(c) of the MMPA, in the course of their official duties; and (3) taking for purposes of scientific research pursuant to § 104 of the MMPA and § 10 of the ESA. These exceptions are more fully discussed below.

Exceptions—Commercial fishing: Under this proposed rule, the general prohibitions would not apply to the taking of harbor porpoise incidental to commercial fishing operations if the take complies with the harbor porpoise bycatch reduction program. NMFS is proposing to adopt a bycatch reduction program aimed at progressively reducing total harbor porpoise bycatch in all gillnet fisheries, including bycatch from other gillnet fisheries that impact this population outside the GME. Programs to reduce bycatch must be initiated within the next 18 months with a goal of reducing bycatch to an amount not exceeding 2 percent of the best estimate of population abundance within a period of time not to exceed 4 years beginning in 1993. This would require, at a minimum, a reduction in incidental take in the GME by at least 50 percent of the present take level. To achieve the necessary reduction in bycatch, protective regulations need to be implemented. NMFS is considering area closures, seasonal restrictions, incidental take allocations and other measures to reduce bycatch. Comments are specifically requested concerning the best management measures to achieve the bycatch reduction goal. Since takings incidental to commercial fishing operations would not be prohibited by this rule, separate incidental take authorization pursuant to Sections 7(b)(4) or 10(a)(1)(B) of the ESA would not be required.

In order to monitor the bycatch, the Assistant Administrator of Fisheries (Assistant Administrator) may require the placement of an observer on any gillnet fishing vessel operating in U.S. waters in order to conserve a species listed under the ESA. Therefore, NMFS may notify owners and operators of gillnet vessels operating within the known range of the Gulf of Maine population of harbor porpoise that they must carry a NMFS-approved observer on board such vessel(s) if requested to do so. If the observer data indicate a need, the Assistant Administrator may take actions including, but not restricted to, the issuance of emergency rules to establish closed areas from further fishing, the allocation of the "incidental take" among NMFS statistical areas, or other actions(s) to ensure that commercial fishing operations do not jeopardize the continued existence of the species. NMFS is also requesting comments and recommendations concerning the implementation and seasonal timing of an observer program to monitor bycatch of the GME population of harbor porpoise throughout their range, specifically in Southern New England and Mid-Atlantic coastal waters south to Cape Hatteras, North Carolina.

Official Activities—Under this proposed rule, the general prohibitions would not apply to the taking of harbor porpoises by federal, state or local government officials or employees, or persons designated by the Assistant Administrator under section 112(c) of the MMPA, in the course of their duties as officials, employees or designees, if the taking is for the protection or welfare of the harbor porpoise, is for the protection of the public health or welfare, or the non-lethal removal of nuisance animals. Any such taking would have to be done humanely, which could include euthanasia in some cases. The primary purpose of this exception to the general prohibitions is to provide for the activities of Marine Mammal Stranding Networks, which perform important services in rescuing and rehabilitating stranded marine mammals. In cases where it is determined that stranded harbor porpoises cannot be saved, euthanasia would be authorized. This exception also provides flexibility for responding to unlikely situations where a dead or diseased harbor porpoise could be considered a threat to the public health or welfare, or where harbor porpoises are perceived as public nuisances. It should be stressed, however, that this exception is not intended to authorize lethal takes or harassment of harbor porpoises to stop or dissuade them from interfering with commercial fishing operations.

Permits—Finally, under this proposed rule, the general prohibitions would not preclude scientific research currently authorized under section 104 of the MMPA for a period of one year following final listing of harbor porpoise as threatened. After that one year period, a scientific research permit or a permit to enhance the propagation or survival of the species issued pursuant to section 10 of the ESA would be required. Takes of harbor porpoise incidental to other lawful activities may also be authorized under section 10.

Critical Habitat

NMFS has not completed the analysis necessary for the designation of critical habitat, but has decided to proceed with the proposed listing determinations now and to proceed with the designation of critical habitat in a separate rulemaking. NMFS believes that this action is consistent with the intent of the 1982 amendments to the ESA: "The Committee feels strongly, however, that where the biology relating to the status of the species is clear, it should not be denied the protection of the Act because of the inability of the Secretary to complete the work necessary to designate critical habitat" (H. Report No. 567, 97th Congr., 2nd Sess. 19, 1982).

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Classification

The 1982 amendments to the ESA (Pub. L. 97–304), in section 4(b)(1)(A), restricted the information that may be considered when assessing species for listing. Based on this limitation of criteria for a listing decision and the opinion in *Pacific Legal Foundation* v. *Andrus*, 657 F. 2d 829 (6th Cir., 1981), these decisions are excluded from the requirements of the National Environmental Policy Act.

The Conference Report on the 1982 amendments to the ESA notes that economic considerations have no relevance to determinations regarding the status of species, and that E.O. 12291 economic analysis requirements, the Regulatory Flexibility Act, and the Paperwork Reduction Act are not applicable to the listing process. Similarly, listing actions are not subject to the requirements of E.O. 12612, or the President's Memorandum of January 28, 1992.

List of Subjects in 50 CFR Part 227

Endangered and threatened species, Exports, Imports, Marine mammals, Transportation.

Dated: December 30, 1992.

William W. Fox, Jr.,

Assistant Administrator, Fisheries.

For the reasons set out in the preamble, 50 CFR part 227 is proposed to be amended as follows:

PART 227—THREATENED FISH AND WILDLIFE

1. The authority citation for part 227 continues to read as follows:

Authority: 16 U.S.C. 1531 *et seq.*

2. In § 227.4, new paragraph (i) is added to read as follows:

§ 227.4 Enumeration of threatened species.

* * * * *

(i) Gulf of Maine (GME) population of harbor porpoise *(Phocoena (phocoena))*. The GME population includes all harbor porpoise whose range extends throughout waters of eastern North America from (and including) the Bay of Fundy (BOF), Nova Scotia south to eastern Florida.

3. A new § 227.13 is added to subpart B to read as follows:

§ 227.13 Gulf of Maine harbor porpoise.

(a) *Prohibitions.* The prohibitions of section 9 of the Act (16 U.S.C. 1538) relating to endangered species apply to the threatened species of harbor porpoise listed in § 227.4(i) of this part, except as provided in paragraph (b) of this section.

(b) *Exceptions*—(1) General exceptions. The exceptions of section 10 of the Act (16 U.S.C. 1539) and other exceptions under the Act relating to endangered species, and the provisions of regulations issued under the Act relating to endangered species (such as 50 CFR part 222, subpart C—Endangered Fish or Wildlife Permits) also apply to the threatened population of harbor porpoise listed in § 227.4(i) of this part, except as otherwise provided in subsections (b)(2), (b)(3) and (b)(4). This section supersedes other restrictions on the applicability of 50 CFR part 222, including, but not limited to, the restrictions specified in §§ 222.2(a) and 222.22(a).

(2) Official activities—The prohibitions of paragraph (a) of this section do not restrict a Federal, state or local government official, his or her designee, or other person authorized by the Assistant Administrator pursuant to regulations at 50 CFR part 216, subpart C, who is acting in the course of official duties, from taking a harbor porpoise in a humane manner, including euthanasia, if the taking is for the protection or welfare of the animal, the protection of the public health and welfare, or the nonlethal removal of nuisance animals.

(3) Permits—The prohibitions of paragraph (a) of this section do not apply to scientific research activities authorized pursuant to section 104 of the Marine Mammal Protection Act and regulations at 50 CFR part 216, subpart D—Special Exceptions, for a period of one year from the final listing of the GOM harbor porpoise as threatened. After that period, such activities must be authorized by the Assistant Administrator in accordance with and subject to the provisions of 50 CFR part 222, subpart C—Endangered Fish or Wildlife Permits.

(4) Commercial fishing exemptions. The prohibitions of paragraph (a) of this section, insofar as they relate to the taking of harbor porpoise incidental to commercial fishing operations, do not apply to incidental takings that are consistent with the by-catch reduction program under paragraph (3)(c). Intentional lethal taking of harbor porpoise for any reason is not authorized under this paragraph (b)(4).

(c) *Bycatch Reduction Program.* The bycatch reduction program will progressively reduce total harbor porpoise bycatch in all gillnet fisheries, including bycatch from other gillnet fisheries that impact this population throughout U.S. waters outside the Gulf of Maine, to an amount not exceeding 2 percent of the best estimate of population abundance within a period of time not to exceed 4 years from the effective date of this section.

(1) Bycatch Reduction Program Methodology. [Reserved].

(2) Observer Requirements. [Reserved].

[FR Doc. 93–39 Filed 1–6–93; 8:45 am]

BILLING CODE 3510-22-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[Docket No. 921233–2333]

Endangered Fish and Wildlife; Gray Whale

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of determination.

SUMMARY: Under the Endangered Species Act (ESA), NMFS has determined that the eastern North Pacific (California) stock of gray whale should be removed from the List of Endangered and Threatened Wildlife (the List). This determination is based on evidence showing that this stock has recovered to near its estimated original population size and is neither in danger of extinction throughout all or a significant portion of its range, nor likely to again become endangered within the foreseeable future throughout all or a significant portion of its range. NMFS believes that the western Pacific gray whale stock, which is geographically isolated from the eastern stock, has not recovered and should remain listed as endangered. In accordance with section 4(a)(2)(B) of the ESA, NMFS is recommending that the Department of the Interior implement this action by amending the List accordingly.

EFFECTIVE DATE: This determination is effective on January 7, 1993.

ADDRESSES: Copies of the references used in this document are available from: Office of Protected Resources, National Marine Fisheries Service, 1331 East-West Highway, Silver Spring, Maryland 20910.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth R. Hollingshead, Office of Protected Resources, NMFS, at (301) 713–2055.

SUPPLEMENTARY INFORMATION:

Background

The Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) is administered jointly by the U.S. Fish and Wildlife Service (FWS), Department of the Interior, and NMFS. NMFS has jurisdiction over most marine species and makes determinations under section 4(a) of the ESA as to whether the species should be listed as endangered or threatened. The FWS maintains and publishes the List of Endangered and Threatened Wildlife (the List) in 50 CFR part 17 for all species determined by NMFS or FWS to be endangered or threatened. A list of threatened and endangered species under the jurisdiction of NMFS is contained also in 50 CFR 227.4 and 50 CFR 222.23(a), respectively.

Section 4(c)(2) of the ESA requires that, at least once every 5 years, a review of the species on the List be conducted to determine whether any species should be (1) removed from the List; (2) changed in status from an endangered species to a threatened species; or (3) changed in status from a threatened species to an endangered species. NMFS completed its first 5-year review on the status of endangered whales in 1984 (Breiwick and Braham 1984). Based upon that status review, NMFS concluded that although no longer in danger of extinction, because of limited calving grounds and coastal habitat which is being subjected to increasing development, the eastern Pacific gray whale (*Eschrichtius robustus*) stock should not be delisted but should be upgraded to threatened (49 FR 44774, November 9, 1984). No further action was taken, however.

On January 3, 1990 (55 FR 164), NMFS announced that it was conducting status reviews on certain listed species (including the gray whale) under its jurisdiction, and solicited comments and biological information. That status review was completed and made available to the general public on June 27, 1991 (56 FR 29471). The **Federal Register** notice also stated that NMFS intended to publish a proposed determination that the listing status of the eastern North Pacific population of gray whale should be changed. That proposed determination and rule was completed and published in the **Federal Register** on November 22, 1991 (56 FR 58869).

In the proposed rule, NMFS gave notice that the comment period would close on January 21, 1992. However, as provided under section 4(b)(5)(E) of the ESA, NMFS received and accepted a request for a public hearing on the proposal (57 FR 3040, January 27, 1992). Public hearings were held in Silver Spring, Maryland, on February 14, 1992 and Long Beach, California on February 25, 1992. The comment period was extended until March 6, 1992 (57 FR 2247, January 21, 1992) in order to allow the public sufficient time to attend the hearings and complete their written comments.

Petition

Coincident with completion of the status review (but prior to its availability to the public), under section 4(c)(2) of the ESA and after work was initiated on the proposed determination and rule, the Secretary of Commerce (Secretary) received, on March 7, 1991, a petition from the Northwest Indian Fisheries Commission and others, which requested, under section 4(b)(3)(A) of the ESA, the removal of the eastern stock of the North Pacific gray whale from the ESA. On March 27, 1991, the Under Secretary for Oceans and Atmosphere, NOAA, acknowledged, the petition and NMFS began a review to determine whether the petition presented "substantial scientific or commercial information" that would support such an action.

NMFS completed that review and made a determination on December 10, 1991 (56 FR 64498), that the petition presented substantial information indicating that the requested action was warranted. The notice stated, however, that, because the status review had been completed, published, and made available to the general public, it had been determined that conducting another status review under section 4(b)(3)(A) would be duplicative and unnecessary. The notice concluded that the November 22, 1991, proposal could be accepted as the finding action required by section 4(b)(3)(B) for petitions found to contain substantial information.

Comments and Responses

During the 104-day comment period, NMFS received 103 letters and 612 photocopied form letters from the general public, all either opposing the delisting or recommending upgrading the status to threatened. Most of those commenting stated they opposed changing the status of the gray whale because of increased coastal pollution and development and boating activities. Oil and gas development, an increase in pressure to resume whaling, and "low genetic diversity" were other reasons given to oppose the proposed action.

In addition to the above, 30 letters were received within the comment period that substantially discussed the science upon which the proposal was based. Letters were received from the Governments of Canada, Russia and Mexico. Although all three governments chose not to comment on the internal decisions of another nation, the Government of Mexico submitted comments on behalf of its fisheries agency. These comments are addressed below. Comments and recommendations were received from the Marine Mammal Commission (MMC) on May 15, 1992. As provided by section 202(d) of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 *et seq.*), NMFS will respond in detail to the MMC's specific recommendations by a separate letter. However, their

comments and recommendations and the comments of others are discussed below.

General Comments: Population Estimates

Comment: Two commenters questioned the accuracy of the population estimates given in the proposed rule, in particular the difference in population estimates between the United States and those supplied by the Government of Mexico in its submitted comments.

Response: The Mexican estimate of 15,000 (± 2,000) was obtained through aerial surveys of Mexican waters and is contained in a document submitted to the International Whaling Commission (IWC) Scientific Committee on the Assessment of Gray Whales. As the Document analyzed only raw data, the IWC Committee concluded it was not valid for indexing either abundance or trends (IWC 1990). In addition, the Mexican surveys, while limited to the breeding grounds, did not include all breeding lagoons and offshore waters. There was general agreement among scientists at the IWC meeting that the shore censuses along the migratory route are at present the appropriate way to estimate absolute abundance for this stock (IWC 1990). Reilly (1984) provides a more detailed explanation of the methods, assumptions and biases encountered with both aerial surveys and shore censuses of gray whales.

Comment: Two commenters noted that the U.S. population estimate for the eastern Pacific stock of gray whales is over 4 years old. They recommended that no action should be taken until new population estimates are made.

Response: The population estimate used in the proposed rule (21,113 (± 688) was made in 1987/88. Although a revision of the 1987/88 estimate was presented at the 1992 IWC meeting (*i.e.* 23,859, CV=0.0536, 95% CI 21,500–26,500), a stock size of 21,113 has been accepted by the IWC as the best estimate available (IWC 1990). That latter number is accepted also by NMFS as the best estimate available for the population size in 1987/88. Considering that previous population estimates indicated that the stock has been increasing at a rate of 3.2 percent (± 0.5 percent) annually between 1967 and 1988 (IWC 1990), it is considered neither necessary nor appropriate, to delay the action in order to accrue more data on the population. Monitoring required by section 4(g) of the ESA will include biennial surveys to continue the assessment of the stock and emergency provisions that could be imposed if the stock declined precipitously.

Comment: Several commenters questioned NMFS' estimate that carrying capacity was in the range of 24,000 animals. Three commenters cited Reilly (in press) indicating that the carrying capacity may be as high as 35,000 which would affect the NMFS calculation that the population was about 88 percent of carrying capacity.

Response: The recent paper by Reilly was not available prior to completion of the proposed rule. The status review in this final determination has been modified to address the carrying capacity issue.

General Comments: Consideration as a Species Under the ESA

Comment: One commenter questioned the accuracy of the statement that there are two stocks in the Pacific Ocean and stated that unless it can be demonstrated that the populations are separate, then the western stock remains vulnerable as recolonization is dependent upon the eastern stock. Therefore, protection of the eastern stock is required. The commenter recommended that NMFS conduct photo-identification and skin biopsy studies to determine "the degree of isolation and/or possible genetic exchange between these two stocks."

Response: Section 4 of the ESA provides for listing (and therefore delisting) at different evolutionary levels (i.e., species, subspecies, or "distinct population segment") on the basis of the best scientific and commercial data available. For the reasons detailed below, NMFS concludes that the best available scientific evidence supports the finding that the stocks are geographically and reproductively isolated (see for example, IWC 1990). The basis for determining stock discreetness for gray whales was fully addressed in the proposed rule and continued in this determination. However, it should be recognized that as the western stock of gray whales will remain listed under the ESA and as gray whales will remain protected also under the MMPA and the International Convention on the Regulation of Whaling, implementation of this action will not affect the ability of the eastern Pacific stock to repopulate the western Pacific if research later were to demonstrate that the two stocks are in fact a single stock. The research proposed by the commenter, while useful, is neither necessary prior to implementing this action, as populations do not need to be totally isolated genetically in order to be listed or delisted, nor assured of success considering the extremely low numbers of the western Pacific stock sighted in recent years. However, NMFS scientists will strongly encourage their Russian counterparts at IWC to collect and analyze appropriate samples from gray whales stranded in and around the Sea of Okhotsk for comparison with whales in their harvest. U.S. scientists plan to collect skin biopsy samples as part of the marine mammal stranding program and these samples will be available for comparison with any biopsy samples taken by Russia.

Comment: One commenter at the Silver Spring, Maryland, hearing objected to removing the eastern stock of gray whales from the List until the stock outgrows its (food) resources enough to trigger an expansion into its former range (i.e., the western North Pacific and Atlantic Oceans).

Response: As the proposal indicated, there are three distinct stocks of gray whales. One is extinct, a second near extinction and the third, the eastern Pacific stock, has recovered and is close to carrying capacity. Physical barriers (*e.g.* summer ice limits) prevent the eastern Pacific stock of gray whales from recolonizing habitat of the extinct Atlantic Ocean stock. It is also possible that a physical oceanographic barrier along the Kamchatka coast discourages intermingling of eastern and western Pacific stocks. To wait, as the commenter suggests, until these barriers are breached before removing the eastern Pacific stock from the List is not practical and is not required by section 4 of the ESA, which provides for listing (and therefore delisting) at different evolutionary levels (i.e., species, subspecies, or "distinct population segment").

General Comments: Use of Personnel

Comment: Two commenters were concerned that NMFS was spending time on this proposal that would be better utilized in listing species and designating critical habitats.

Response: NMFS is required under section (4)(c)(2) of the ESA, at least once every 5 years, to review the status of the species on the List to determine whether any species status warrants change. NMFS completed this review in 1991 and, based upon that status review, and as required by section 4(c)(2)(B) of the ESA, concluded that the gray whale stock had recovered to near its estimated original population size and is neither in danger of extinction throughout all or a significant portion of its range, nor likely to become endangered again within the foreseeable future throughout all or a significant portion of its range. Based on that review, NMFS determined that the status of the eastern gray whale stock

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should be changed (56 FR 29471, June 27, 1991).

Furthrmore, on March 7, 1991, the Secretary was petitioned under section 4(b)(3)(A) of the ESA to remove the eastern stock of the North Pacific gray whale from the List. Thus, NMFS has a statutory obligation to review and take appropriate action on the status of listed species and also to take appropriate action upon receipt of a petition to amend the List.

General Comments: Monitoring

Comment: Several commenters expressed concern over NMFS' monitoring program and offered suggestions on the composition of the Task force, the types of research to be carried out and coordination with appropriate foreign governments. One organization recommended that the gray whale not be delisted unless their recommended extensive research and monitoring program can be conducted. Another suggested that the monitoring program be conducted but that the stock only be upgraded to threatened status.

Response: Because they will be advising the Assistant Administrator on grants and on internal NMFS research on gray whales, including budgetary actions, the gray whale task force will be composed of NMFS marine mammal scientists. The final determination has been modified to make this issue more clear. Also, some types of research suggested for NMFS to conduct, either alone or within a multilateral agreement, but as part of its monitoring program, are viewed by NMFS as not being within the scope of requirements for monitoring under section 4(g) of the ESA. For example, one commenter's suggested research would require long-term monitoring of the coastal environment of the Bering Sea (feeding grounds), central and southern California (migratory route) and Baja California (calving grounds). Such research would be prohibitively expensive, taking away funds needed elsewhere and, without establishing a control, would not likely be successful. While baseline data might prove useful in the future, a direct cause-and-effect link between environmental conditions and the health of the marine mammal stocks would be difficult to prove. NMFS believes that monitoring the eastern Pacific gray whale stock in compliance with section 4(g) of the ESA can be accomplished through biennial shore-side surveys along the California coast, and a cooperative research program with Mexico to monitor trends and abundances in the lagoons in Baja California. Additional research would be funded if, during (or after) the mandated monitoring period, the stock indicates signs of environmental stress. Additional research proposed to be conducted on gray whales (i.e., photo-identification studies on isolated subpopulations, genetic diversity studies, analysis of tissue samples for contaminants from stranded animals, etc.) that is not considered part of the described monitoring program will be required to compete with other funding requirements for marine mammal research or could be funded by other sources (e.g., MMC, Minerals Management Service (MMS), or the National Science Foundation).

General Comments: Section 7 Consultations

Comment: One commenter recommended that NMFS provide a more complete review of those biological opinions which determined that the action could result in jeopardizing gray whales and an explanation on whether the findings of those biological opinions are no longer valid based upon new information or on a reevaluation of information originally considered in the opinions. Another commenter at the Silver Spring MD hearing recommended that NMFS reexamine the biological opinion(s) which contain(s) a jeopardy determination for gray whales and to remove that finding if the gray whale is delisted.

Response: NMFS has expanded the discussion on the impacts of oil and gas activities on gray whales. NMFS has also reexamined the findings in the earlier biological opinions, and concluded that, while the cumulative impacts from oil and gas activities may have the potential to affect adversely the eastern North Pacific gray whale stock, these impacts are not likely to jeopardize its continued existence. A copy of this reanalysis is available upon request (see **ADDRESSES**). See also the discussion of oil and gas development under Factor (A) below.

Comments on the Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Comment: Several commenters were concerned that should the gray whale be delisted, habitat protection will be lost. On a closely related issue, several commenters were concerned about increasing development throughout the gray whales' range but particularly over tourist facilities and oil and gas development, in the coastal breeding lagoons. Two were concerned about the potential loss of benthic food sources by development in these coastal lagoons. Another was concerned about the potential loss of food resources in the Bering Sea if an oil spill were to occur.

Response: The final determination has been modified and expanded to discuss, in greater detail, habitat concerns in the Bering Sea, along the Northwest Coast migration pathway and in the coastal lagoons in Baja California. However, as the benthic resources available to gray whales appear to be minimal in the coastal lagoons, and as the feeding which does occur (see Summary of Status Review) is probably opportunistic on pelagic organisms (Nerini 1984), coastal development does not appear to constitute a significant impact on gray whale food sources in the southern grounds at this time.

Comment: Several commenters expressed concern that the proposal did not adequately address the impact of general onshore development along the California coast, including the loss of wetlands, on the gray whales. One of these commenters was also concerned about the potential for intensive coastal development along the Washington/Oregon coast, especially in the Gray's Harbor area, should offshore oil development commence.

Response: The issue of onshore coastal development is not discussed in any depth since, other than in the breeding/calving lagoons in Baja, a direct relationship between the two is largely speculative. However, as impacts from agricultural and industrial runoff and sewage may have some impacts on that portion of the stock that enters the enclosed embayments along the Pacific coasts, this impact was discussed in the proposed rule and is continued in this final determination.

Comment: Several commenters were concerned that bioaccumulation of toxic compounds in gray whales may pose jeopardy to the continued existence of the gray whale. One commenter was particularly concerned about increased strandings in Puget Sound and related them to their feeding in the "chemical soup" of the Sound.

Response: Although the November 22, 1991 proposal addressed this concern in some detail, the final determination has been updated with more recent analyses. These commenters did not dispute NMFS' findings cited in the proposed rule, and did not provide data or references, other than ancedotal, contrary to NMFS' cited research results (NMFS 1990) that chlorinated hydrocarbon and heavy metal contamination did not appear to be significant enough to cause deleterious effects to gray whales (see also Factor C: Disease or Predation). For that reason, a finding different from the one presented in the proposal is not warranted.

Comment: Some commenters were of the opinion that NMFS seriously underplayed the potential impacts from oil and gas activities, including the extent of activities along the Pacific coasts of Mexico, Canada and Russia.

Response: Although there is a possibility of joint-venture oil and gas operations between Russia and international oil companies, especially as recently reported for the Navarin Basin, no specific information is available to NMFS on scheduling of offshore oil activities off Russia, Mexico, or Canada at this time. As the commenters did not submit data supporting their contention, this issue cannot be addressed in any greater detail than was supplied in the proposal. Discussion of future oil and gas activities within U.S. waters, which was mentioned under the section 7 consultation portion of the proposal, has been moved and expanded in this part of the final determination (see the discussion under Factor (A) below). A description of present-day oil and gas activities and anticipated future events has been added to this section.

Comments on Overutilization for Commercial, Recreational, Scientific or Educational Purposes

Comment: One commenter expressed concern that delisting could lead to an increase in subsistence use of gray whales including use by the Makah Tribe for subsistence or ceremonial purposes.

Response: Native Americans in Washington, Oregon and California currently do not intentionally take gray whales. Should Native Americans in these States wish to begin taking gray whales, it would be necessary for them to gain access to the IWC's quota for subsistence takes. The IWC quota for the eastern gray whale stock is 169, which is taken by Russia for its Chukchi Natives. There is no indication from Russia that there is a need for a higher subsistence quota, although one could be authorized if documented as necessary, since the current subsistence quota is less than sustained yield (IWC 1990). More detailed information on both issues can be found elsewhere in the preamble.

Comment: One commenter was concerned that whale-watching activities might drive gray whales from critical habitat.

Response: While critical habitat has not been formally designated for gray whales, consideration of breeding, feeding, and migratory areas as important components for gray whale survival is appropriate. Whale-watching activities on the breeding grounds and along the migratory route, in addition to general recreational boating, are identified impacts on gray whales, which we readdressed in the November 22, 1991, proposal and in this action.

Comments on Disease or Predation

Comment: Two commenters were concerned that cumulative impacts from anthropogenic contaminants, biotoxins, noise, and disturbance could cause stress-induced immunosuppression resulting in non-natural mortality. One commenter was concerned that the proposed rule did not consider the potential future effects of biotoxins on gray whales.

Response: The proposed rule discussed these impacts in some detail. The conclusion was that individual and cumulative impacts, while they may have the potential to affect adversely the eastern North Pacific gray whale stock, are not likely to jeopardize its continued existence. Immunosuppression response in gray whales remains hypothetical at this time. There is no evidence outside of the captive environment that such a reaction occurs, although it is alleged to have occurred in certain odontocetes. Also, a link between biotoxins caused by phytoplankton and gray whales has not been shown to exist and at this time can be assumed to be unlikely (at least on primary feeding grounds) since gray whales, unlike previously identified impacted marine mammal species such as humpback whales and bottlenose dolphins on the U.S. East Coast, do not feed on those species of fish likely to contain the biotoxin. It bears watching whether that small portion of the population inhabiting Puget Sound becomes affected by the domoic acid outbreak in shellfish. A monk seal die-off in 1978/79 mentioned by the commenter was likely due to ciguatoxin and maitotoxin, both caused by ingesting reef fish, not a normal component of the gray whale diet.

Comments on Inadequacy of Existing Regulatory Mechanisms

Comment: Several commenters were concerned that changing the status of the gray whale could encourage other nations to request a change in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) or for whaling nations or subsistence users to request the IWC to increase the quota. One commenter expressed concern that if the stock is delisted, other nations might ease their protective laws for gray whales and in this venue, NMFS should describe all applicable laws and assess their provisions.

Response: The issue of increasing the subsistence quota on gray whales has been discussed above and elsewhere in the preamble. Any actions taken under CITES or the IWC would be determined based upon the status of the gray whale stock, not by NMPS' delisting action. Under both international agreements, the status of the gray whale is subject to change depending upon a majority vote of their members independent of any action the United States takes under the ESA. The IWC, for example, establishes a gray whale quota based upon the status of the stock. The gray whale was changed from a "Protected Stock" to a "Sustained Management Stock" in 1978 on the basis that under a relatively constant harvest, the stock had apparently remained stable over a period of 11 years (IWC 1979). Recent exercises within the IWC to determine whether the stock should be reclassified as an "Initial Population Stock" (a step necessary in order for a commercial harvest quota to be established), have not been successful. The subsistence quota is set presently at 169 and there is no indication that a higher quota is warranted, although it is possible one could be authorized, since the current subsistence quota is less than sustained yield (IWC 1990). As mentioned later under the Factor, any increases in the subsistence take of the eastern stock of gray whales, by itself, is not likely to impact that stock significantly.

As stated in the proposed rule, existing national laws are considered adequate at this time and, under this Factor, it is existing regulatory measures that must be taken into account when determining impacts on a species.

While NMFS has determined that it is not necessary to publish a list of appropriate national laws and regulations and evaluate their effectiveness, the final determination has been expanded to more fully describe regulations pertaining to the protection of gray whales within their coastal lagoons.

Comment: Under this Factor, one commenter also wanted NMFS to "conduct and provide a more comprehensive assessment of present and foreseeable threats to the principal breeding lagoons, feeding grounds, and other areas of special biological importance to the species * * *" prior to making a determination that laws are adequate to protect gray whales.

Response: Although NMFS does not consider it appropriate to provide a comprehensive assessment of threats to gray whales under this Factor, such an assessment was provided under Factor A.

Comment: Several commenters were concerned that the regulatory mechanisms provided under CITES, IWC, and the MMPA could not prevent habitat degradation, or a resumption of whaling. In addition, concern was made by several reviewers over the loss of section 7 consultations if the stock was removed from the List.

Response: While section 7 consultations would cease for the gray whale if the eastern Pacific stock was removed from the List, other laws and activities would protect the coastal habitat. The final determination has been expanded to incorporate these concerns.

Comment: Several commenters recommended that if the species is delisted, NMFS establish an international conservation plan under the MMPA. One commenter recommended that this international research be conducted under multilateral treaties and agreements under the monitoring requirements of section 4 of the ESA. In addition, this commenter wanted NMFS to undertake, or cause to be undertaken, research recommended by the IWC in 1990.

Response: NMFS has included as part of its monitoring program a proposed cooperative research effort with the Government of Mexico. NMFS will also continue to conduct gray whale research under the aegis of the IWC. While cooperative research programs with other Pacific Rim nations would likely result in improved knowledge on the gray whale, implementation of an international conservation plan under the MMPA for a non-depleted species, independent of the IWC, is viewed as being neither likely to be successful, nor an efficient use of Agency resources, since other marine mammal species, including seriously depleted or endangered species, could benefit from this attention and funding. However, NMFS will continue, through participation in the IWC, to encourage other Pacific Rim nations to conduct research on gray whales, particularly the western Pacific gray whale stock, which will remain listed as endangered.

Comments on Other Natural or Man-made Factors Affecting Its Continued Existence

Comment: Several commenters were concerned that the species was reduced to such low levels early in the century that its genetic diversity is limited, which may impact the species' future viability, in particular making it more vulnerable to disease.

Response: There is no evidence that the eastern Pacific gray whale stock's genetic composition was compromised by its reduction to approximately 4–5,000 in the mid-19th century. While an analysis of skin biopsy samples from gray whales taken in harvests or strandings, for the degree of heterozygosity would be informative, and may provide some insight into the degree of severity of the harvest reduction, it is not clear that it would provide much help in determining whether the eastern North Pacific gray whale is either in danger of extinction throughout all or a significant portion of its range, or likely to again become endangered within the foreseeable future throughout all or a significant portion of its range.

Comment: One commenter expressed concern that the proposal did not adequately address the impact of commercial fisheries on gray whales, including the deterrence of high penalties under the ESA in comparison to the MMPA, the reluctance of fishermen to report "takes" of endangered and threatened species, the low observer coverage in fisheries and the relationship between the ESA and state fishery regulations.

Response: While NMFS considers the discussion on the relationship between commercial fisheries and the eastern North Pacific stock of gray whales in the proposal to be adequate, the final determination has been expanded to address these additional concerns.

Comment: One commenter recommended that the discussion of this Factor address other issues in addition to commercial fishing, including vessel traffic, whale-watching, pollution, coastal development, and other activities that may affect gray whales and their habitat.

Response: The activities mentioned by the commenter were all addressed under Factors 1 through 4 in the proposed rule and in this document as Factors A through D and need not be repeated under this Factor. NMFS recognizes that categorizing an impact within a specific Factor is not always clear. However, in order to reduce repetition of text, NMFS has chosen to discuss a specific impact in its entirety under the first Factor wherein the impact is mentioned, for example, under Factor A, discussion of the impacts of oil spills on gray whale habitat is appropriate, therefore discussion of oil impacts on the gray whale as a individual, is also discussed under this Factor rather than delaying discussion until Factor E. This also facilitates comprehension and understanding of the impact.

Status Review

The gray whale is confined to the North Pacific Ocean. Two stocks occur in the North Pacific: the eastern North Pacific or "California" stock, which breeds along the west coast of North America, and the western Pacific or "Korean" stock which apparently breeds off the coast of eastern Asia (Rice 1961). Because it uses coastal habitats extensively, the gray whale was especially vulnerable to shore-based whaling operations and both stocks were severely depleted by the early 1900s. Under legal protection since 1946, the eastern North Pacific stock has recovered to its estimated original, pre-commercial exploitation population size (Rice *et al.* 1984), but apparently remains below the ecosystem's carrying capacity for that stock (Reilly 1992).

The estimated stock size in 1987/88 (21,113 ± 688; Breiwick *et al.* 1989) is above Henderson's (1972, 1984) estimated initial (1846) stock size of 15,000–20,000, but below Reilly's (1981) estimate for carrying capacity of 24,000 gray whales. Between 1967 and 1988, the stock increased at a rate of 3.2 percent (± 0.5 percent) per year (IWC 1990; see Reilly *et al.* 1983 and Reilly 1987, for analysis of the 1967–1980 data; Rugh *et al.* 1990, for the 1985–1986 data; Breiwick *et al.* 1989, for the 1988 population estimate). Using Reilly's (1981) estimate with Breiwick *et al.*'s (1989) estimate of population size, it is likely that the gray whale population is within its optimum sustainable population (OSP) size or at about 88 percent of estimated historic carrying capacity (21,113/24,000 = 88 percent).

More recently however, Reilly (1992) stated that it is not entirely clear where the population is in relation to its current carrying capacity. He noted that if early aboriginal kills were 50 percent higher than documented, estimates of carrying capacity would range from 23,000 to about 35,000 and the population would be between 60 percent and about 90 percent of carrying capacity. However, Reilly (1992) noted also that the possible recent decline in pregnancy rates (see also IWC 1990) and possible signs of overexploitation of the benthic fauna upon which gray whales feed in the Bering and Chukchi Seas (see also Stoker 1990, IWC 1990), if verified, may be evidence that the stock is nearing the limits of its environment and therefore approaching carrying capacity. Another indication implying that the stock may be approaching carrying capacity is the increased observation of females with newborn calves in areas outside the calving

lagoons, especially during the southbound migration (Jones and Swartz 1989, Swartz 1990). Alternatively, the fact that the calving lagoons do not appear to be saturated (Swartz 1990) may indicate that gray whales continue to reoccupy their former range. However, since early calving has been observed previously (for example off Mission Bay California in 1963/64 by Gilmore and McIntyre where the birth was observed (McIntyre, pers. comm. 1991) and off Monterey California in 1974 (Sund 1975)), this may be a normal event and the calving lagoons are neither a factor limiting the increasing size of the gray whale population, nor, considering their geologically transient nature, as critical a component of the gray whale's habitat as previously assumed (see for example, Rice *et al.* 1984 and 49 FR 44774, November 8, 1984). However, data on the mortality rate of newborn calves outside the calving lagoon environment in comparison to mortality within the lagoons (approximately 5 percent) are needed to verify this hypothesis.

The eastern Pacific stock has increased in spite of increased human use of the coastal habitat (i.e., nearshore migration route where mating and calving occur), and a subsistence catch of 167 (±3.5) whales per year by the former Soviet Union during the past 30 years (calculated from data in Ivashin in press).

Most of the eastern North Pacific stock spends the summer feeding in the northern Bering and southern Chukchi Seas (Rice and Wolman 1971, Rice *et al.* 1984). In the northwestern Bering Sea, they have been noted in recent years to be extending their range west of Cape Olyutorisky on the Chukchot Peninsula. Unless this is simply an artifact of increased observation effort, gray whales may be extending their range in search of additional food resources. In the Beaufort Sea, sightings have been made of individuals as far east as long. 130°W during August (Rugh and Fraker 1981) and in the East Siberian Sea, gray whales were found along the Siberian coast as far west as 174°08'E in late September (Marquette *et al.* 1982). Berzin (1984) believes these distributions are probably limited by pack ice in the summer. Although actual timing depends upon feeding conditions and patterns of ice formation, during October and November the stock begins leaving the Chukchi Sea (Braham 1984). Moving at about 125 km/day (Braham 1984), they exit the Bering Sea through Unimak Pass, Alaska, mainly in November and December (Rugh and Braham 1979, Braham 1984, Rugh 1984). The whales migrate near shore along the coast of North America from Alaska all the way to central California (92 percent pass within 1.6 km of Cape Sarichef, Unimak Pass (Rugh 1984), and 94 percent pass within 1.6 km of the Monterey-Point Sur area of central California (Sund and O'Connor 1974)). After passing Point Conception, California, Rice *et al.* (1984) believed the majority of the animals took a more direct offshore route across the southern California Bight to northern Baja California. This route passes Santa Rosa and San Nicolas islands, the Tanner and Cortes banks and into Mexican waters (MMS 1992). Other routes include the nearshore route which follows the mainland coast of California, and the inshore route which passes through the northern Channel Island chain to Santa Catalina or San Clemente Island and on into Mexico. Bursk (1988) contends that gray whales have moved further offshore recently and Graham (1989) estimates that 14, 15, and 25 percent of the estimated population size passed west of San Clemente Island during the southbound migration in 1986/87, 1987/88 and 1988/89, respectively. Off California, southbound migrating gray whales swim at about 5.5–7.7 km/hour, and thus travel about 132–185 km per day with day and night speeds not statistically different (Pike 1962, Jones and Swartz 1987, Swartz *et al.* 1987).

Migrating gray whales are temporally segregated according to sex, age, and reproductive status (Rice and Wolman 1971). During the southward migration, the sequence of passage off California is as follows: Females in late pregnancy, followed by females that have recently ovulated, adult males, immature females, and then immature males (Rice *et al.* 1984). The earliest southbound migrants (mostly late-pregnant females) usually travel singly, whereas later migrants usually are in pods of two or more. The mean pod size through Unimak Pass is about two (Rugh 1984).

The eastern Pacific stock winters mainly along the west coast of Baja California. The pregnant females assemble in certain shallow, nearly landlocked lagoons and bays where, after a 418-day gestation period (Rice *et al.* 1981), the calves are born from early January to mid-February. The majority of gray whales in Baja California (including some cows with calves) spend the winter outside the major breeding/calving lagoons along the outer coast apparently from Bahia de Sebastian Vizcaino to Boca de las Animas. Recent research indicates that females with calves do not necessarily restrict themselves to a single lagoon, but may move between and among lagoons and the outer coast during the winter (Jones and Swartz 1984). While calving was assumed to occur only rarely during the southbound migration north of Baja California (Rice and Wolman 1971), more recently, Swartz (IWC, 1990) noted that in the Channel Islands "calves of the season comprised 13.3% of all whales counted * * *." These observations suggest that calves may be born as far north as Washington State (Jones and Swartz 1987). A few calves are also born on the eastern side of the Gulf of California at Yavaros, Sonora, and Bahia Reforma, Sinaloa, Mexico (Gilmore 1960; Gilmore *et al.* 1967).

The northbound migration begins in mid-February and continues through May with the earliest northbound migrants passing San Diego before the last of the southbound migrants (Rice *et al.* 1981). By April, the early migrating whales begin showing up in the southern Bering Sea, which they enter through Unimak Pass. This migration is completely coastal, at least to the east of central Bering Sea (Nunivak Island). Most of the animals in Alaska travel within one km of the coast, avoiding embayments, especially in the southeastern Bering Sea, and at least some apparently feed during migration (Braham 1984). However, because suitable feeding habitat is relatively uncommon south of the Bering Sea, few gray whales remain south of Unimak Pass to spend the summer along the west coast of North America in apparently isolated locations as far south as Baja California, Mexico (Nerini 1984). During the northward migration, the sequence, in two phases, is as follows: Newly pregnant females, followed by other mature females, adult males, and immature males and females Cows with calves are the last animals to leave the lagoons, and most migrate after the other whales (Rice *et al.* 1984) with a more protracted period of migration (Swartz 1990). The cow/calf phase of the spring migration generally peaks 7 to 9 weeks after the peak of the first migration phase (Poole 1984). On the northern grounds, primary feeding locations appear to be in the Chirikov Basin, the north side of the Chukchi Peninsula, nearshore waters of the western Bering Sea, and the southern capes of St. Lawrence Island (Nerini 1984). These benthic foraging areas are all underlain by dense infaunal communities of crustaceans (Nerini 1984).

The western Pacific stock formerly occupied the northern Sea of Okhotsk in the summer, as far north as Penzhinskaya Bay, and south to Akademii and Sakhalinskiy Gulfs on the west and the Kikhchik River on the east

Southbound whales migrated along the coast of eastern Asia from Tatarskiy Strait to South Korea (Rice and Wolman 1971) to winter breeding/calving grounds, which probably lie along the coast of southern China in Gwangxi and Gwangdong provinces, and around Hainan Island (Wang 1984). Until the turn of this century, another migration route led down the eastern side of Japan to winter grounds in the Seto Inland Sea, Japan (Omura 1974). The status of the western Pacific stock of gray whales is uncertain (Brownell and Chun 1977). Sightings of 24 animals in the Okhotsk Sea and nine off the tip of Kamchatka in 1983 (Blokhin *et al.* 1985, Votrogov and Bogoslovskaya 1986), and 34 in 1989 in the Okhotsk Sea (Berzin in press) suggest that the stock is small. There is no evidence that it has reoccupied its entire former range (Omura 1984) and initial stock size may have been only a few thousand (Omura 1988). Although Rice *et al.* (1984) concluded that it is likely that the stock is below a critical population size sufficient for recovery and may be almost extinct, Berzin (in press) suggests that the stock is increasing slowly.

The gray whale formerly occurred in the North Atlantic, but has been extinct there for several centuries (Mead and Mitchell 1984).

Consideration as a Species Under the ESA

The ESA defines "species" to include any subspecies of fish, wildlife, or plants, and any distinct population segment of any species or vertebrate fish or wildlife which interbreeds when mature.

Two stocks of gray whales remain extant, both in the North Pacific Ocean: (1) The western stock, which migrates between feeding grounds in the Sea of Okhotsk and breeding/calving grounds along the South China Coast; and (2) the eastern stock, which migrates between breeding/calving grounds along the West Coast of Mexico and feeding grounds in the Bering and Chukchi Seas (Rice and Wolman 1971). These stocks appear to be significantly isolated both geographically and reproductively from each other. Recent strandings of gray whales on the Commander Islands are believed to be from the eastern stock, while gray whales reported along the Kamchatka coast are believed to be from the Okhotsk-South China population (IWC 1990). Alternatively, all strandings may be from the Korea stock (Rice 1981, IWC 1986). Since gray whales mate during their autumnal southward migration, rare vagrants would make interbreeding between the California and western Pacific population possible. However, that possibility would be greatly reduced if, as Rice (1981) believes likely, most vagrants are immature animals. The absence of sightings between the Okhotsk Sea and the Commander Islands suggests the stocks are separate (IWC 1990). Mitchell suggests that an absence of aboriginal whale hunting records along the Pacific coast of the Kamchatka Peninsula may indicate a lack of abundance of gray whales in the area and a hiatus in distribution between eastern and western stocks (IWC 1990). In addition, Yablokov and Bogoslovskaya (1984) after reanalyzing data collected by earlier investigators, found that, in addition to differences in cranial measurements indicating the Okhotsk-Korea stock to be statistically larger in size than the Chukotka-California stock, the latter stock had fewer throat grooves and a smaller number of baleen plates. These authors believe that these differences may indicate the existence of two distinct groups which may allow them to be designated as subspecies. After reviewing the data available to it, the IWC Scientific Committee on the Assessment of Gray Whales (IWC 1990) agreed that the eastern and western populations of gray whales probably represent geographically isolated stocks, although recognizing that the existing data are not conclusive.

Based on the above discussion, NMFS believes that the best scientific and commercial data available supports the determination that there are two separate stocks of gray whales in the North Pacific Ocean and that the eastern North Pacific gray whale stock can be considered a distinct population and hence a species under the ESA.

Summary of Factors Affecting the Species

Section 4(a)(1) of the ESA and the NMFS' listing regulations (50 CFR part 424) set forth procedures for listing, reclassifying or removing species. The Secretary of either the Interior or Commerce, depending upon the species involved, must determine if any species is endangered or threatened based upon any one or a combination of the following factors: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific or educational purposes; (C) disease or predation; (D) inadequacy of existing regulatory mechanisms; or (E) other natural or man-made factors affecting its continued existence. Under section 4(a)(2) of the ESA, if the Secretary of Commerce determines that a species under her jurisdiction should be removed from the List or changed in status from endangered to threatened, the Secretary then recommends such action to the Secretary of the Interior. If the Secretary of the Interior concurs with the action, he must implement the action by amending the List. However, if a species is removed from the List, the Secretary, under section 4(g) of the ESA, must implement a system in cooperation with the states to monitor effectively, for a period not less than 5 years, the status of the species and must use the emergency authority provisions under paragraph (b)(7) of section 4 to prevent a significant risk to the well-being of any recovered species. These factors and subsequent consultation with the Department of the Interior are discussed below.

Factor (A)—The Present or Threatened Destruction, Modification or Curtailment of Its Habitat or Range.

Two potential threats to the eastern North Pacific gray whale population are increasing vessel traffic (including whale watching activities), and industrial development (including oil and gas exploration and development), in the breeding/calving lagoons, feeding grounds, and along the migration route.

Commercial vessel traffic may result in the death of gray whales through collision or by harassment when both vessel and whale are confined to narrow passages. Heyning and Dahlheim (in press) documented 7 cases of gray whale/ship collisions; 5 in southern California, one each in Alaska and Washington. They surmised that gray whales may be unable to detect large ships in time to avoid collisions due to the size and speed of the vessels. However, because large vessels are restricted to certain travel lanes while in inshore waters (where gray whales are predominantly located) and the low period of vulnerability to large commercial vessels due to the whale's migratory nature, NMFS believes that few gray whales are killed annually by collisions with vessels.

Activities of commercial cruise boats and small pleasure craft may result in harassment of gray whales, especially in the breeding/calving lagoons in Baja California and along their migration route off California. As whale-watching activities increase rapidly in southern California and on the Baja Peninsula, harassment occurrences are increasing proportionally, particularly on weekends and holidays. Whale watching by recreational and commercial craft may negatively impact migrating gray whales by interrupting swimming patterns, altering migratory routes, and displacing cow/calf pairs from inshore waters, thereby increasing

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every consumption (CMC/NMFS 1988, IWC 1990). Bursk (1988) contends that gray whales have moved further offshore recently due to whale-watching activities in southern California. Graham (1989) has noted a similar decrease in nearshore gray whales but attributed it to sea surface temperature anomalies in late 1988/early 1989. Others, such as Rice (1965), and Gilmore (1978), noted this offshore migration route earlier and Rice and Wolman (1971) considered the offshore passage to be a normal migratory route.

Vessels in the breeding/calving lagoons may cause short-term flight reactions by gray whales when the vessel is moving at high speeds or erratically, but gray whales will show little response to slow moving or anchored vessels. Gray whales have been reported to avoid vessels at ranges of roughly 0.5 km and less, with no documented responses at further distances (IWC 1990). However, Jones and Swartz (1984), in a study of gray whales in Bahia San Ignacio, found that data suggest that gray whales possess sufficient resiliency to tolerate the physical presence and activities of whale-watching vessels and skiffs and the noise produced by this level of activity without major disruption. This finding was supported by a noted increase in usage of the lagoons by gray whales, especially females with calves. Jones and Swartz (1984) believe a key factor responsible for maintaining a stable population within their study lagoon (*i.e.*, San Ignacio) was: (1) The establishment of the gray whale refuge, which provided an area free of all vessel activity to which whales could retreat and (2) the behavior of commercial whale watch operators to minimize disturbance.

Under the MMPA, gray whale harassment is considered a "take" and is prohibited. NMFS has established guidelines for whale watching in order to avoid harassment of gray whales on their migration path in U.S. waters and may implement regulations to limit approaches to marine mammals in 1993. In this regard, a proposed rule was published on August 3, 1992 (57 FR 34101) with a comment period due to expire on December 31, 1992. These regulations, if implemented, would be effective within waters under U.S. jurisdiction and for U.S. citizens except when within waters under the jurisdiction of another nation (*e.g.* Canada and Mexico). These regulations would, if implemented as proposed, establish minimum approach distances for large cetaceans (100 yards) and will require procedures to avoid disrupting the normal movement or behavior of marine mammals. It is anticipated that these regulations would strengthen protective measures for gray whales principally during migratory periods. Enforcement of these regulations will be accomplished through onboard monitoring of activities, citizen complaints and aerial and shipboard reconnaissance.

The main gray whale calving grounds in Mexico are Laguna Ojo de Liebre (Scammon's Lagoon with 53 percent of calves), Estero Soledad (12 percent), Laguna San Ignacio (11 percent) and Laguna Guerrero Negro (9 percent) in Mexico (Rice *et al.* 1984). However, the number of whales present at any one time is subject to fluctuations due to the interchange of whales between the lagoons (Jones and Swartz 1984). Minor calving areas, each with less than 6 percent of the calves, are San Juanico Bight, Bahia Magdalena, Bahia Almejas, and Bahia Santa Marina (Rice *et al.* 1981, 1984). A few calves are also born on the eastern side of the Gulf of California at Yavaros, Sonora, and Bahia Reforma, Sinola, Mexico (Gilmore 1960, Rice *et al.* 1984). Between 1972 and 1979, the Mexican Government designated three (Laguna Ojo de Liebre, Laguna Guerrero Negro, and Laguna San Ignacio) of the four major calving lagoons in Baja California as gray whale refuges. These are the lagoons that most of the U.S. tour boats and private tourists visit. The number of vessels allowed in these lagoons at any one time is limited by the Mexican Government by permit, which all commercial vessels are required to obtain, and entry into certain areas, such as the upper lagoon in Laguna Ojo de Liebre and the middle and upper lagoons in Laguna San Ignacio (Jones and Swartz 1984), is forbidden. Apparently, because of Mexico's policy of revoking permits if there are any transgressions, this system is generally self-policed effectively (Stinson 1988). However, Jones and Swartz (1984) found that in Laguna San Ignacio, where regulations limit the number of vessels to two at any one time, 3 or 4 vessels may occupy the lower lagoon for about ½ day when departing vessels overlap with arriving vessels.

To provide additional protection of gray whales within Mexican waters, the Government of Mexico is in the process of implementing its own standards for governing whale watching activities.

A second potential threat to the eastern North Pacific gray whale stock and its habitat is oil and gas exploration and development and related activities along its migration route, in the breeding/calving lagoons in Baja and in or near its feeding grounds in the Bering and southern Chukchi Seas. Oil and gas exploration, which may result in a short-term loss of habitat for gray whales through displacement by seismic and other activities, is contemplated or under way on the outer continental shelf (OCS) from California to the Beaufort Sea, and west into Russian waters of the Bering Sea throughout the migration range of this species. (In addition, other types of mineral resource development (e.g., gold mining) are under consideration within possible gray whale feeding areas in the Bering Sea). Annually, the gray whale population migrates by or through at least eight oil lease areas within U.S. waters (Rice *et al.* 1984).

Between 1964 and January 1, 1990, over 358 exploration and 692 development wells, have been drilled on the Pacific Region OCS (MMS 1992). All of the development wells and all but 31 of the exploration wells were in the Southern California Bight. In Southern California, 21 platforms have been installed and approximately 135 miles of pipeline have been laid in Federal waters. There are no platforms or pipelines in the Central California, Northern California, and Washington-Oregon OCS.

Nominal exploration and development work will continue in southern California as the number of leases has dropped dramatically to only 116 as of July 1990 (MMS 1991). MMS (1992), for its baseline studies, anticipates that in southern California, approximately 3–4 exploratory and/or delineation wells could be drilled annually, for a total of 25 wells over an eight year period. Approximately 7 development platforms (and pipelines) would be built under this scenario. It appears that only two large and ongoing development projects, the Point Arguello Field and the Santa Ynez units will be placed into production within the next 5 years (MMS 1991). Oil and gas development activities will likely result in a long-term, but considering the small amount of ocean bottom utilized by platforms and pipelines an insignificant, loss of habitat for gray whales.

In Alaska, 87 wells have been drilled, including 2 ongoing wells in the Chukchi Sea and 14 test wells. Thirty-three wells were drilled in the Gulf of Alaska, 30 in the Bering Sea, and 24 in the Arctic. None of these wells resulted in the discovery of hydrocarbons in commercially producible amounts. However, while subeconomic, eight wells demonstrated the positive hydrocarbon bearing potential of the Beaufort Sea area (MMS 1991).

At this time there does not appear to be a high degree of industry interest in the Gulf of Alaska/Cook Inlet area and unless new leases are issued, there will be little operational activity in that area in the next 5- to 10-year period (MMS 1991). Past drilling activity in the St. George, Norton and Navarin Basins has not resulted in any announced discoveries of oil or gas and leases in the North Aleutian Basin have been suspended pending completion of congressionally mandated studies. Although there may be some scattered exploratory activity on existing leases in the St. George, Norton and Navarin Basins, any production is at least 10 to 15 years away, even if a major field were to be discovered (MMS 1991). If a major field is not discovered, little activity would be expected because of the high costs involved and the unproven geologic potential of the area.

In the Chukchi Sea, it is likely that 2 to 3 exploration wells will be drilled each year for the next 5- to 10-year period contingent on results of early wells. One or more major discoveries might accelerate activity while few or no discoveries will curtail activity. While there are some significant discoveries of oil and gas in the Beaufort Sea, whether or not they are developed further may well depend on new discoveries to support the enormous costs of infrastructure to produce and transport oil and gas from Alaska (MMS 1992).

No new lease sales are proposed for Washington, Oregon, or central and northern California before 1997. In southern California no lease sales are contemplated until at least 1996, when 86 blocks in the Santa Maria Basin and Santa Barbara Channel will be considered (MMS 1991). In Alaska, two lease sales in the Beaufort Sea (1993 and 1996), two for the Chukchi Sea (1994 and 1997), two in the Bering Sea (1995 and 1996) and one each in Cook Inlet (1994) and Gulf of Alaska (1995) are proposed, although several additional sales are possible (MMS 1991).

On the winter breeding/calving grounds, oil and gas exploratory areas include sites within and adjacent to present calving and nursery areas, such as the offshore waters of Sebastian Vizcaino Bay, where seismic exploration for gas deposits took place during 1981. To date, no development activities are known to be underway but may take place in the future.

Potential impacts from oil and gas exploration and development include noise disturbance, contact with spilled oil, habitat degradation and possible loss or destruction of benthic prey populations upon which gray whales depend.

Noise disturbance to gray whales has been studied during their migrations along the California coast (Malme *et al.* 1983 and 1984) and on their breeding/calving grounds in Baja California Sur, Mexico (Dahlheim 1983, 1984; Dahlheim *et al.* 1984). Reactions of gray whales to recordings of industrial noise and to a seismic airgun source during migration have shown that avoidance behavior occurs only at relatively close ranges at decibels greater than 120 dB for continuous noise and 160–170 dB for pulsed sounds such as from airguns (Tyack 1988). Malme *et al.* (1984) for example, found a 50 percent probability of an avoidance response of 2.5 km off central California for a seismic airgun array, 1.1 km for a drillship, and 400 m for a single airgun. However, because noise from oil and gas activities occurs at frequencies that overlap gray whale calling (and assumed hearing) frequencies, they may also influence other behavior causing, for example, interference with socialization, reproductive behavior and communication. For oil and gas activities subject to U.S. jurisdiction, NOAA requires companies under an MMPA 101(a)(5) Small Take Letter of Authorization to take specified precautions to avoid disturbing whales including grays.

Reactions to industrial noises by gray whales studied in their breeding/calving grounds were more pronounced than those found off central California, including vacating the study area during the projection of industrial noises (Jones *et al.* 1991), and changes in the acoustical and observed surface behavior and distribution (Dahlheim 1988). Dahlheim (1988) found that gray whales responded to vessels and to playbacks of vessel noise by: (1) An increase in calling rates; (2) an increase in received levels of sounds; (3) an increase in frequency modulation, number of pulses per series, and repetition rates; and (4) a distinct change in movement, both away from and toward the sound source. In response to a playback of oil drilling noise, calling rates were reduced, direct movements away from the sound source were documented, milling rates decreased, and major changes in distribution and a decrease in local whale abundance were documented. Dahlheim (1988) hypothesized that gray whales engaged in acoustical communication circumvented noise in the acoustical channel by the structure and timing of their calls.

Gray whales may also be sensitive to noise disturbance on their feeding grounds and might temporarily abandon productive feeding areas if excessively disturbed. MMS (1992) estimates that seismic exploration activities off Alaska would take place from June to September, the same time period gray whales occupy their northern feeding grounds. Reliance on less-productive areas could leave the animals with insufficient body reserves for their successful migration and reproduction. However, because of the gray whale's abundance and range, (and the apparent abundance and range (one million km^2) of its primary food source in the Bering Sea), the present gray whale population could likely tolerate without significant effects the short-term and non-recurring local impacts brought on by seismic exploration (NMFS Biological Opinion for Lease Sale 100, dated December 21, 1984).

Another potential threat is the possibility of a major oil spill that would affect a large portion of the gray whale population and/or its habitat; although the temporal and spatial segregation of the stock would tend to expose different segments of the population to oil at any given time. Assuming an oil spill, caused either by a tanker accident, pipeline break, or an oil well blowout, were to occur and contact gray whales, the worst adverse impacts to whales from contact would include death or illness caused by ingestion or inhalation of oil, irritation of skin and eyes, fouling of feeding mechanisms, and reduction of food supplies through contamination or losses of food organisms. Although no data exist at this time, likely direct adverse impacts include: (1) Conjunctivitis and corneal eye inflammation leading to reduced vision and possible blindness; (2) development of skin ulcerations from existing eroded areas on the skin surface with subsequent possibility of infection; (3) compromising of tactile hairs as sensory structures; and (4) development of bronchitis or pneumonia as a result of inhaled irritants (Albert 1981). In general, however, the results of Geraci and St. Aubin (1982, 1985) and Geraci (1990) indicate that whales are likely to suffer only minor impacts if they contact oil spills, and that they are likely to recover from these effects. It is recognized that natural oil seeps have long been a part of the ecosystem that gray whales inhabit. In southern California for example, there are 54 natural seeps, with an approximate discharge of 30,000 tons (7.03×10^6 gal.) released annually in the Santa Barbara Channel alone (Fischer 1978 as cited in Neff 1990a). Studies on gray whales in

these seeps (Evans 1982), and on bottlenose dolphins in an experimental setting (Geraci 1990), although inconclusive, tend to indicate that cetaceans can detect oil on the surface. When entering oil-contaminated environs, gray whales tend to spend less time on the surface, blowing less frequently, but faster, which may be interpreted as an avoidance behavior, although more testing would be necessary to verify the observation (Geraci 1990). The inhalation of the hydrocarbon products at the water surface is believed unlikely because the breathing mechanism of the whale which prevents inhalation of water would likely also prevent inhalation of oil (Geraci and St. Aubin 1980). However, if the whales enter the immediate vicinity of a recent spill, toxic fumes could be inhaled (Dahlheim n.d.), although 50 percent of the aromatic hydrocarbons (*e.g.* toluene and benzene) evaporate within a few days of the discharge (Neff 1990a), greatly reducing the toxicity in the spill area.

Because the probable effects on whales from contacting oil include temporary fouling of baleen and toxic effects from ingestion of oil, oil spills may pose a greater problem for the gray whale on its feeding grounds than during its migration. In a laboratory study on bowhead whales (*Balaena mysticetus*), baleen plates fouled by oil had decreased filtering efficiency for at least 30 days, but 85 percent of the efficiency was restored within 8 hours (Braithwaite *et al.* 1983). Due to its coarser and shorter baleen, Geraci and St. Aubin (1982, 1985) demonstrated similar, but somewhat faster, recovery rates for gray whales. Although the toxic effects of ingesting oil remain generally unknown, Geraci and St. Aubin (1990) believe that marine mammals have the liver enzymes required to metabolize and excrete hydrocarbon compounds. This ability limits the accumulation of residues in body tissues and minimizes the probability of residual harm following a spill.

A recent computer model simulating an oil spill projected that gray whales would not contact oil in the Navarin Basin, but would contact oil in the Beaufort Sea (<=0.2% of the population), the St. George Basin (<=1.5%) and Chukchi Sea (<=0.8%). In the St. George Basin, gray whales would contact oil while navigating to and from their feeding grounds in the spring and fall, while in the Chukchi Sea, they would contact oil during summer feeding months. No more than 1.5 percent of the whales passing through Unimak Pass would contact oil. In general there was a 6.3 percent chance that at least one gray whale would encounter oil in the Bering Sea during the 30- to 40-year lifespan of an individual oil field (Neff 1990b). MMS (1992) projects the probability of one or more oil spills of 10,000 barrels or greater occurring in the gray whale areas to range from 14 percent in southern California, 21–27 percent in the Bering Sea, 18–34 percent in the Gulf of Alaska to 96 percent in the Chukchi Sea, provided commercially producible amounts of hydrocarbons are discovered and developed.

MMS (1992) gives the probabilities of one or more pipeline or platform spills of 1,000 bbl and greater, and 10,000 bbl and greater as a result of activity in the Chukchi Sea as 92 and 57 percent respectively. In addition, because Chukchi Sea oil will be transported by tanker, there is a 93 and 81 percent probability of one or more spills of 1,000 bbl or greater and one or more spills of 10,000 bbls or greater respectively occurring; although tanker spills would occur outside the Chukchi Sea area since all transport within the area will be by pipeline (MMS 1992). In areas such as the Norton, Navarin and St. George Basins, oil will be transported by tanker to shore facilities in Alaska or other West Coast states. For its base case projections, MMS (1992) predicts one tanker spill for each of these areas developed (over the 30- to 40-year life span of an oil field) but no platform or pipeline spills.

In southern California, MMS (1992) projects a single pipeline spill of 7,000 bbl will result from exploration and development activities in the Santa Maria Basin or the Santa Barbara Channel. In addition, as a result of oil and gas activities in Alaska, 3 tanker oil spills of 30,000 bbl each are projected to occur along the tanker route on the Pacific coast over the 30- to 40-year life span of an oil field: One off Washington, one off northern California and one off southern California. A northern California spill is projected by MMS to occur 80 km or more from the coast with no shore contact.

MMS (1992) anticipates that an oil spill of 10,000 bbl or greater could result in the death of a few individuals and the displacement of gray whales from areas of up to 1,500 km^2 in the Chukchi and Bering Sea feeding grounds for all or part of a season. (For comparison purposes, the Chirikov Basin is approximately 3.7×10^4 km^2).

MMS (1991) reports that out of a total of 6.2 billion barrels of OCS oil produced from 1971 through 1988, only 900 barrels were spilled from blowouts. However, this statistic excludes the Union Oil spill in Santa Barbara in January 1969. That spill resulted in a loss of about 3 million gal of oil which eventually covered 800 mi^2. Surveys conducted as a result of that spill discovered 6 gray whales stranded between January 28 and March 31, 1969. Although these counts were higher than normal, it is unclear whether this was due to the spill or to the increased survey effort (Brownell 1971).

Based upon data resulting from the exploratory wells drilled in recent years in the Bering Sea, MMS (1992) has reevaluated and lowered its estimate of the potential for discovering an exploitable field in the Bering Sea. Based upon MMS' reanalysis, NMFS has determined that the expectation of an oil well blowout occurring and impacting gray whales is low. Essentially, in order for gray whales to be seriously impacted by an oil spill due to oil and gas exploration and development activities, the following events need to occur: (1) A lease sale takes place; (2) exploratory activities determine that economically exploitable quantities of oil can be recovered; (3) development occurs which (4) results in a blowout with a significant loss of oil and (5) the spilled oil intercepts a significant portion of the gray whale population or its food source.

Oil spills, the chemicals used to break up and sink surface oil, and other anthropogenic materials from either oil platforms, (such as drilling muds, discharged materials and produced water), or shore-side discharges from industrial, residential or agricultural point and non-point sources, could also harm gray whales by reducing or contaminating their food resources. Gray whales are opportunistic feeders on a wide variety of benthic ampeliscid amphipods and other bottom dwelling organisms (Nerini 1984). Most feeding takes place between May and September in the northern waters of the Bering and Chukchi seas, especially in the Chirikov Basin. Some food consumption also occurs during migration and a small portion of the population remains south of Unimak Pass, Alaska, to exploit that resource. Little is believed consumed on the calving grounds (Nerini 1984).

The feeding strategy of gray whales could lead to ingestion of oil from oil-contaminated food, if the prey organisms accumulate petroleum hydrocarbons in their tissue, or from contaminated sediments associated with food sources. The effect of pollutants on the benthic organisms on which these whales feed is relatively unknown, but may result in either direct mortality or sublethal effects that inhibit growth, longevity and reproduction. Benthic organisms could ingest either heavy

metals or hydrocarbons which could bioaccumulate up through the food web. According to sources cited in Neff (1990a), benthic crustaceans have a well-developed mixed-function oxidase (MFO) system to eliminate petroleum hydrocarbons. If amphipods have the ability to detoxify hydrocarbons, these hydrocarbons are less likely to persist and biomagnify in the gray whale food web. Another factor inhibiting bioaccumulation may be the short life span of the amphipods (i.e. <2 years). Therefore, while gray whales probably have a low risk of ingesting petroleum hydrocarbons from their source (see also the earlier discussion on baleen fouling from sediment contamination), benthic amphipods have proven to be quite sensitive to spilled oil and are among the first animals killed after an oil spill (Neff 1990a), which could in turn affect that portion of the gray whale stock feeding in the contaminated area. If they are unable to locate alternative areas with sufficient food resources, they may have insufficient reserves to make the 8,000 km migration to southern grounds, overwintering there and returning the following spring. These animals likely would either remain in waters north of Baja California or succumb from the effects.

Because discharges of drilling muds from offshore platforms may contain heavy metals and other contaminants, all discharges from platforms are regulated by EPA under section 402 of the Clean Water Act. EPA's proposed regulations recommend zero discharges of drilling muds and cuttings and filtration of produced waters. Drilling muds, however, are relatively non-toxic and the metals associated with drilling muds are virtually unavailable for bioaccumulation by marine organisms (Neff 1987). The National Research Council (1985) concluded that the risks to most OCS benthic communities from exploratory drilling discharges are small and result primarily from physical benthic effects. Since ampeliscid amphipods predominate in disturbed bottoms (Nerini and Oliver 1983, Nerini 1984, Oliver *et al.* 1985), are highly motile, and good colonizers, and amphipod recovery is likely to take place within 1 year (Oliver *et al.* 1985), NMFS believes that the gray whale's food source is unlikely to be impacted seriously by the establishment of platforms and pipelines in the OCS.

Preliminary results from the study by NMFS (1990) on contaminants found in gray whales stranded near Puget Sound indicated that heavy metal levels appear to be too low to cause any deleterious effects. In addition, the concentrations of PCBs and DDT were very low compared to levels in other whales and are below levels known to cause impairment (NMFS 1990). More recent analyses (Varanasi *et al.* in prep.) of 22 gray whales stranded at various locations along the U.S. West Coast, which included those mentioned above, showed no apparent significant differences, between stranding sites, for chlorinated hydrocarbons in the blubber and liver. Analyses of 16 elements in liver, kidney and stomach contents of gray whales were generally low. However, high concentrations of aluminum (1,700 ±450 ppm), iron (320 ±250 ppm), manganese (23 ± 15 ppm), and chromium (3.4 ±1.3 ppm), were discovered in stomachs, although no significant differences were observed between whales stranded in Puget Sound compared to whales stranded at more pristine sites. Varanasi *et al.* (in prep.) noted that the relative proportions of these 4 elements in stranded whales were similar to the relative proportions in sediments, which is consistent with a geological source of these elements from the ingestion of sediment during feeding. The results of their study suggest that the concentrations of anthropogenic chemicals in stranded gray whales show little relation to the level of pollution at the stranding site, and further, showed that the concentrations of potentially toxic chemicals were relatively low when compared to the concentrations in marine mammals feeding on higher trophic level species, such as fish. They noted, however, the lack of data from apparently healthy gray whales limits the understanding of the susceptibility or hardiness of this species with respect to levels of anthropogenic contaminants found in tissues.

According to Brownell and O'Shea (in press), levels of organochlorine pollutants that may cause reproductive problems in other mammals are higher than those reported in baleen whales. In addition, the vast majority of the eastern Pacific gray whale stock feeds mostly in colder waters that have been less exposed to organochlorine pollutants (IWC 1990).

Coastal development and coastal and offshore industrial activities may also result in some impacts to the gray whale and its habitat. For example, in the calving lagoon of Guerrero Negro, daily dredging and vessel traffic between 1957 and 1967 for a salt extraction plant reportedly caused the whales to abandon the area. In 1967, the plant was closed and moved to Laguna Ojo de Liebre (Bryant *et al.* 1984). Six years after the dredging and barge activity in Guerrero Negro ceased, gray whales began to return to the lagoon (Gard 1974, Bryant and Lafferty 1980). Since the salt works at Laguna Ojo de Liebre appear to be an environmentally clean industry, with no adverse impacts on the biota of the lagoon (Rice *et al.* 1981), and since the whales appear to tolerate the daily salt-barge traffic and have not abandoned Laguna Ojo de Liebre, daily dredging in the confined Guerrero Negro is more likely the cause of abandonment than the vessel traffic. In addition, exploitation of phosphorus (Cordoba 1981) and the development of a large resort in and near the minor calving lagoons of Bahia Almejas and Bahia Magdalena, if constructed, may be cause for concern. Because of the scarcity of suitable isolated calving and nursery areas for gray whales and the whales' specialized feeding habits, gray whales need to be monitored to determine the effects of future coastal or shallow-water development on any critical stages of the gray whale's life cycle.

The recovery of the gray whale population has occurred concurrent with extensive OCS geophysical exploration off the California coast and other activities throughout its range, and these levels of activity are unlikely to increase significantly in the near future. NMFS, therefore, concludes that current and anticipated levels of human activities do not pose a danger of extinction to this species now or in the foreseeable future. NMFS does not rule out the possibility that parts or all of this stock and certain components of its habitat have been and/or are being stressed or that the effects will not be manifested over time as changes in productivity, mortality or distribution.

Factor (B)—Overutilization for Commercial, Recreational, Scientific or Educational Purposes

As a result of commercial whaling operations, the gray whale was severely depleted by the early 1900's. After 1946, commercial harvesting of gray whales was banned by the International Convention for the Regulation of Whaling. Between 1959 and 1969, a total of 316 gray whales were killed under Special Scientific Permits off California. (A significant amount of gray whale life history data came from these animals (see for example, Rice and Wolman 1971).)

Eskimos living on the shores of the northern Bering Sea and the Chukchi Sea have hunted whales for perhaps several thousand years. Estimated aboriginal takes of the eastern Pacific stock prior to depletion of gray whales ranged from about 156 per year (years 1600–1750) to 186 per year (years 1850–1860) with a period high of 263 per year (years 1751–1850). Subsequent declines

after 1850 were due to reductions in native populations, loss of traditional native cultures under the influence of Western society and reduction of the gray whale stock due to commercial whaling (Mitchell and Reeves 1990, IWC 1990).

In Alaska recently, the catch consists mostly of bowhead whales, with few gray whales being intentionally taken (Marquette and Braham 1992). However, on the Chukotka coast of Russia, the catch has consisted almost entirely of gray whales. Since 1969, when the aboriginal hunt ceased as a result of a large number of "struck-and-lost" whales (Yablokov *et al.* 1984), gray whales have been taken by the Russian Government for the Chukchi Eskimos using one modern catcher boat. The total aboriginal catch in Russia has averaged about 165 gray whales per year since 1967. The current catch limit set by the IWC is 179 per year, 10 of which the United States informed the IWC at the 1991 plenary session that ". . . it is not requesting and will not in future years request an allocation or use of 10 gray whales" (IWC 1992). In 1990, the Soviet Union requested a three year extension of their quota indicating that this level would satisfy local needs (IWC 1992). This authorized subsistence catch of gray whales is believed to be well below the sustainable yield estimated to be approximately 670 (95 percent confidence: 490–850; IWC 1990) and therefore is not likely to be significantly impacting the stock.

The question has arisen whether non-Alaskan natives would, in the near future, pursue traditional whaling and sealing activities. To date, only the Makah Tribe has expressed such an interest, but it is unclear at this time whether they would be interested in pursuing open-boat whaling or could satisfy subsistence and/or cultural needs by other means. For any Native American group to begin harvesting large whales, they would need to demonstrate a subsistence need and request (through the Bureau of Indian Affairs) the U.S. Commissioner to the IWC to petition that body for a portion of the subsistence quota for gray whales. Such a scenario is considered unlikely at this time.

The question of whether commercial whaling on gray whales would resume in the near future has also been raised. In order for commercial whaling to resume, the IWC would need to reclassify the gray whale as an "initial population stock" (see discussion elsewhere in the preamble), and terminate its whaling moratorium. NMFS concludes that current and anticipated uses for commercial, recreational, scientific or educational purposes do not pose a danger of extinction to this species now or in the foreseeable future.

Factor (C)—Disease or Predation

The natural mortality rate of the gray whale is low, approximately 0.056 for adults and 0.132 for juveniles (Reilly 1981). There is no information indicating that disease or predation constitutes a threat to the continued welfare of the species.

The killer whale (*Orcinus orca*) appears to be the only non-human predator on gray whales. Evidence from the necropsy of 39 gray whales that stranded on St. Lawrence Island indicated that 16 had been killed by killer whales (Fay *et al.* 1978). The mortality rate from killer whale attacks is unknown. However, the frequency of tooth scars on gray whale carcasses indicates that killer whale attacks are often not fatal.

Moderate numbers of gray whale calves strand in and near the nursery lagoons and along the southern California coast (Swartz and Jones 1983). In addition, a few adults strand every year throughout their range, but the numbers appear low compared with the size of the population (Rice *et al.* 1984). While mortality rates due to stranding cannot be calculated (Rice *et al.* 1984) stranding data may provide insights whether strandings are due to natural or anthropogenic factors.

In 1989, 29 (three possible recounts) gray whales were reported stranded in Alaska from the area from Prince William Sound to the Alaskan Peninsula and into Bristol Bay around the time of the Exxon Valdez oil spill; nine (two possible recounts) of those animals were reported stranded near the southern end of Kodiak Island, southwest and down-current of the oil spill area. While this number was significantly greater than earlier years when only six were documented between Kayak Island and Unimak Pass (Zimmerman 1989), this may be attributed to the timing of the search effort coinciding with the northern migration of gray whales augmented by the increased search effort in the oil spill area (Loughlin, in prep.). In 1990, 26 gray whales were counted off the southern end of Kodiak Island. Surveys of the other areas were not conducted that year. Although some gray whales were reported in 1989 to have oil on their baleen, apparently none had oil in the digestive tract (Moore and Clark as reported in IWC 1990). This is not unexpected considering that dead whales at sea generally float with the ventral surface up and the mouth open. The relationship between these strandings to the oil spill remains conjectural at this time.

Recent strandings reported along the Washington/Oregon coast have also been higher than the mean for the past 2 years, but as indicated in Table 1 below, not higher than historic records (AFSC stranding data). The majority of the animals stranding in Washington waters in 1990 and 1991 apparently died outside Puget Sound and were carried by currents to the outer coast of Washington and the Straits of Juan de Fuca.

NMFS concludes that disease or predation do not pose a danger of extinction to this species now or in the foreseeable future.

TABLE 1. RECENT STRANDING ALONG THE WASHINGTON/OREGON COAST

Year	Number	Year	Number	Year	Number
1983	8	1984	15	1985	2
1986	2	1987	9	1988	10
1989	4	1990	15	1991	12
1992	*3				

*To date.

Factor (D)—Inadequacy of Existing Regulatory Mechanisms

Existing laws and regulations are considered adequate for the conservation of the gray whale. Under the protection of the IWC, the MMPA and the ESA, the eastern North Pacific gray whale stock has recovered to near or above its estimated pre-commercial exploitation population size. Most of the protective measures for the gray whale would remain even without listing under the ESA. The gray whale would remain protected in the United States under the MMPA and the Whaling Convention Act, internationally under the International Convention for the Regulation of Whaling, as well as under national legislation in Canada, Mexico, and Russia, although the effectiveness of this legislation is not fully known.

Mexico has particularly detailed legislation protecting the calving lagoons from disturbance (Klinowska 1991). In 1972, 1975, and 1979 respectively, the Mexican Government designated the major calving lagoons of Laguna Ojo de Liebre, Laguna Guerrero Negro, and Laguna San Ignacio in Baja California as gray whale refuges. These refuges account for approximately 73 percent of calf productivity and are the lagoons that most of the U.S. tour boats and private tourists visit. The number of vessels allowed in these lagoons at any one time is limited by permit to two vessels at a time, and entry into the middle and upper (Ojo de Liebre and

San Ignacio) and upper (Guerrero Negro) lagoon areas is forbidden from December 15 to March 15, although as documented by Jones and Swartz (1984) at Laguna San Ignacio, compliance is not absolute. Mexico issues individual permits to each vessel which specify the number of days a vessel may remain within the lagoon, the number of passengers it may carry, the number of skiffs it may launch and the kinds of activities permitted, such as whale watching, shore exploration, etc. (Jones and Swartz 1984). Violation of the permit requirements leads to a revocation of the permit. In order to provide additional protection for gray whales within Mexico waters, the Government of Mexico is in the process of implementing its own standards for governing whale watching activities. However, the level of enforcement in the Mexican lagoons is not fully known at this time.

Although unclassified in the "Red Book" (i.e. not listed as threatened) by the International Union for the Conservation of Nature (see Klinowska 1991), additional protection is afforded internationally under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). CITES was created to prevent species from becoming threatened through international trade (Wells and Barzdo, 1991) and prohibits commercial trade in seriously threatened species, which are listed in CITES Appendix I. Trade in Appendix I species, such as the gray whale, may be authorized only in exceptional circumstances (*e.g.*, scientific research), and provided the import is not for commercial purposes. All international shipments must be covered by an export permit from the country of origin and an import permit from the country of destination. There is no indication that any change in the gray whale's status under CITES is contemplated by any of its members and any change in status would require a majority vote of the member nations.

In the United States, irrespective of the outcome of this action, activities that take marine mammals are prohibited unless authorized or exempted under the MMPA. The incidental take of marine mammals may be authorized in limited circumstances under an MMPA small take exemption. Oil and gas exploration activities, for example, are eligible to apply for a small take exemption under section 101(a)(5) of the MMPA. Under a Small Take Exemption, NMFS requires the oil and gas industry to take appropriate measures to minimize impacts to gray whales and to conduct exploration activities in such a way as to reduce the likelihood of adversely affecting the gray whale. The Letters of Authorization also include requirements for monitoring and reporting. For the 1991/92 exploration season, NMFS issued five Letters of Authorization (50 FR 47742, Sept. 20, 1991) but only one for the 1992/93 season. NMFS annually reviews the conditions under which these Letters are issued to ensure that gray whales, other marine mammals and their habitats remain adequately protected.

While section 7 consultations under the ESA would cease for the gray whale once the eastern stock is delisted, coastal habitat critical for the continued well-being of the gray whale would be protected within waters under the jurisdiction of the United States through other laws such as the National Environmental Policy Act, the Clean Water Act, MARPOL (the Anti-Dumping Act), the Marine Protection, Research and Sanctuaries Act, (ocean dumping), sections 10 and 404 of the Rivers and Harbors Act of 1899 and the Oil Pollution Act of 1990 which will require, among other things, double-hulled tankers within U.S. waters by 2015. Consultations will also continue under the Outer Continental Shelf Lands Act Amendments.

NFMS concludes that the anticipated regulatory mechanisms are adequate for the conservation of this species.

Factor (E)—Other Natural or Man-made Factors Affecting its Continued Existence

In addition to those man-made factors affecting the gray whale's continued existence which were discussed under Factors A and C above, gray whales are also impacted by incidental take in commercial fishing operations.

The fact that gray whales migrate in a narrow, nearshore corridor where commercial fishing activities are concentrated leads to encounters and entanglement in gear from several commercial fisheries. Norris and Prescott (1961) document entanglement in gillnets since the late 1950s. Data from the NMFS-administered stranding networks document that commercial gillnet fisheries take gray whales incidental to fishing. NMFS' Southwest Region has maintained records of reported gray whale entanglements in California gillnet fisheries since the 1984/85 migration. The number of entanglements has varied from a low of seven entanglements and no mortality during the 1985/86 migration to a high of 15 entanglements and three mortalities during the 1986/87 migration. The number of entanglements and deaths declined during the 1987/88 migration to seven entanglements and one mortality. This reduction in entanglements may have been due to regulations implemented by the State of California in the fall of 1987 that require fishermen to construct their nets so that whales can break through them and that prohibit fishing near major whale concentrations. However, no study was conducted to quantify the effectiveness of these regulations and the decline in entanglement could be due to natural variation. In 1990 and 1991, no gray whales were reported entangled in gillnet fisheries in California (Perkins and Barlow 1992).

It should be recognized that under the MMPA, the incidental taking of endangered, threatened or depleted species was illegal until 1989, making the fisherman subject to penalty. It is presumed that the potential for prosecution may lead to underreporting of incidental takings. In 1988, amendments to the MMPA authorized the incidental (but not intentional) taking of depleted species during commercial fishing operations under section 114 of the MMPA until October 1, 1993. However, under the ESA, takings of endangered species incidental to commercial fishing operations cannot be authorized under section 7 of the ESA, leaving the issue unresolved. The NMFS legislative proposal to Congress to govern fisheries after October 1, 1993 (see 56 FR 23958, May 24, 1991) proposes to authorize a limited incidental take of depleted, threatened or endangered species and to amend the MMPA to authorize takes incidental to commercial fishing activities under section 101(a)(5). Under that proposal, all provisions of the ESA would apply as well. That proposal, if implemented by law, however, would not likely result in an increase in gray whale mortality, since commercial fisheries would be regulated through seasonal, area or gear restrictions to reduce marine mammal mortality to insignificant levels approaching a zero rate. In addition, observers could be placed onboard vessels operating in any fishery that takes marine mammals and quotas would be enforced through fishery restrictions based upon observer reports.

The California Department of Fish and Game (CDF&G) observed one entangled balaenopterid (probably a minke whale) during 177 observer days spent monitoring the shark and swordfish drift net fishery in 1980. CDF&G's southern California set-net monitoring program monitored about 5 percent of the fishing effort from 1983 through 1986 and observed no gray whale entanglements (Collins *et al.* 1984, 1985, 1986; Vojkovich *et al.* 1987).

Likewise, CDF&G set-net observers in northern California reported no gray whale entanglements during monitoring of about 1 percent of the fishing effort from 1984 through 1987 (Wild 1985, 1986).

In the Pacific Northwest, gray whales have been observed entangled in salmon set-nets off northern Washington and in crab pot lines off Oregon. These entanglements are infrequent, occurring once every 1 to 3 years in the set-net fishery and once every 3 to 5 years in the crab fishery (NMFS 1991).

Heyning and Dahlheim (in press) reported on strandings and incidental takes of gray whales from Alaska to Mexico for the years 1975–1988. Gray whale strandings were examined carefully to document whether the animal had been entangled in fishing gear. Some known fishery kills of gray whales bore no evidence of entanglement after stranding, despite thorough examination (Heyning and Lewis 1990). Data from the Heyning and Lewis study suggested that (1) sexually immature animals represented 90 percent of all strandings; and (2) gray whale mortality related to fisheries interactions is likely insignificant relative to the present population size.

Minimal estimates of fisheries-related mortality for stranded gray whales ranged from 8.7 to 25.8 percent (Heyning and Dahlheim in press). None of the 20 animals documented in that report from Alaskan feeding grounds had indications of entanglement in fishing gear. In the Gulf of Alaska and Alaskan Peninsula area, four animals out of 29 (13.8 percent) that stranded were involved in fishing gear. Baird *et al.* (1990) reviewed the available information for British Columbia and found four animals out of 39 strandings (11.1 percent) were involved in fishing gear. They noted that if they included only the 15 strandings that were carefully examined, then 26.7 percent of mortalities were fisheries related.

The fisheries related mortality for Washington, Oregon and northern California are eight out of 50 (16 percent), two out of 23 (8.7 percent), and six out of 47 (12.8 percent), respectively. In southern California, more carcasses have been examined thoroughly and 25 out of 92 (25.8 percent) were mortalities related to fishing operations. Heyning and Lewis (1990) have reviewed baleen whale entanglements in this region and found that the majority of gray whale entanglements involved immature animals but not calves. Almost two-thirds of these entanglements occurred during the northbound migration.

Based upon the information acquired to date, but recognizing the scarcity of that information, NMFS concludes that gray whale mortality related to fisheries interactions is likely insignificant relative to the present population size.

NMFS concludes that there are no known or anticipated other natural or man-made factors that pose a danger of extinction to this species either now or in the foreseeable future.

Consultations under Section 7 of the ESA

A chronology of consultations with MMS on oil and gas activities and NMFS' assessed impacts on gray whales was published in the proposed rule (56 FR 58869, November 22, 1991). Please refer to that document for further information on this subject. A copy of the reanalysis of the biological opinions on the impacts of oil and gas activities, which was based on information and data described in this final determination, is available upon request (see **ADDRESSES**). See also the discussion under Factor (A) above.

Discussion

An endangered species is any species that is in danger of extinction throughout all or a signficiant portion of its range; a threatened species is any species that is likely to become an endangered species within the foreseeable future. The ESA requires that any determination that a species is endangered or threatened be made solely on the basis of the best available scientific and commercial information concerning that species relative to the five factors discussed above.

The eastern North Pacific stock of the gray whale has recovered to near or above its estimated pre-commercial exploitation population size. It is estimated to be between 60 and 90 percent of its carrying capacity and will probably continue to increase until density dependent factors slow the rate of growth. NMFS therefore believes that this stock is not currently in danger of extinction throughout all or a significant portion of its range. Moreover, even though the eastern Pacific gray whale stock inhabits coastal waters that are increasingly impacted by human activities, the stock continues to increase and, therefore, is not likely to become an endangered species again within the foreseeable future throughout all or a significant portion of its range. Based upon the assessments discussed above, NMFS believes that individual and cumulative impacts, while they may have the potential to affect adversely the eastern North Pacific gray whale stock, are not likely to jeopardize its continued existence. Therefore, NMFS believes the eastern North Pacific stock of the gray whale should be removed from the List of Endangered and Threatened Species under the ESA.

Some commenters contend that although the stock is not currently threatened, human activities have the potential to threaten the stock in the future. For the most part, they fear that the IWC may allow the resumption of commercial whaling; that oil and gas exploration either planned or under way along the continental shelf could seriously harm whales that use these coastal areas; and that potential cumulative impacts may, in the future, threaten the gray whale's survival. However, potential future threats, as opposed to actual, present-day threats, are neither sufficient to justify listing a species nor sufficient for retaining a recovered species on the List according to the factors that must be considered under the ESA. If they were, then, as noted by Brownell *et al.* (1989), "* * * the majority of the world's animals would have to be included on the List, as large numbers of species are potentially threatened by the growth of human populations, current rates of habitat destruction, and other harmful activities." NMFS believes that the increasing abundance of this stock, in close proximity to human coastal development, industrial activity and vessel traffic, suggests that this stock has the resiliency to adjust to human activities with few apparent adverse effects.

However, because the gray whale is exposed frequently to human activities, and cumulative impacts may result in some indirect effects, long-term monitoring of the status of the gray whale stock will be conducted (see Monitoring below).

Removing the eastern North Pacific gray whale stock from the List will not result in a major reduction in protection. While the protections and prohibitions of the ESA, including the consultation requirements of section 7, will cease to apply, the gray whale will remain subject to prohibitions against taking under the MMPA. Habitat concerns will continue to be addressed under several other laws. In addition, because the species also remains protected under the U.S. Whaling Convention Act and the International Convention for the Regulation of Whaling, the number of gray whales authorized to be taken for subsistence purposes will continue to be limited by the IWC.

NMFS also believes that the western Pacific gray whale stock, which is geographically isolated from the eastern

stock, has not recovered and should remain listed as endangered.

Coordination

In accordance with section 4(a)(2) of the ESA, NMFS requested the concurrence of the Department of the Interior on this proposal when it was published on November 22, 1991. Concurrence on the proposal was received in a letter dated March 4, 1992. As the FWS maintains and publishes the List in 50 CFR part 17 for all species determined by NMFS or FWS to be endangered or threatened, the FWS is encouraged to promulgate a rule amending the List by removing the "gray whale" and replacing it with the "Western Pacific (Korean) gray whale." Upon completion, NMFS will implement a rule to remove the gray whale from the list of species found in 50 CFR 222.23. NMFS encourages the FWS to take timely action on this request and will assist the FWS to the greatest extent possible.

Monitoring

Section 4(g) of the ESA requires that whenever a species is removed from the List, the Secretary must implement a system, in cooperation with the states, to monitor effectively the status of any species that has recovered to the point where the protective measures provided under the ESA are no longer necessary. This monitoring program will continue for at least 5 years and, if at any time during that period the Secretary finds that the species' well-being is at significant risk, the ESA (section 4(b)(7)) provides that emergency protective regulations must be issued to ensure the conservation of any recovered species.

As part of its monitoring program, NMFS intends to create an internal Task Group responsible for monitoring activities potentially impacting gray whales. This Task Group will consist of NMFS marine mammal scientists familiar with either gray whale biology or related subject matter and will be expected to coordinate internal research on gray whales, encourage independent research in areas not currently funded or investigated by NMFS, and serve as a quick response advisory team in the event of any catastrophic event impacting gray whales. The Task Group will also recommend to the Assistant Administrator for Fisheries, NOAA (Assistant Administrator) appropriate steps, necessary to mitigate any catastrophic event, including the reimposition of emergency protective measures. Finally, within 6 months following the conclusion of the first 5-year monitoring program, the Task Group will conduct a comprehensive "status review" of the gray whale that will be forwarded to the Assistant Administrator for approval and release to the general public for review and comment. The Task Group will review and address the comments in drafting a final report. Included in that report will be a recommendation on whether (1) to continue the monitoring program for an additional 5 years; (2) terminate the monitoring program; or (3) reconsider the status of the gray whale under the ESA. In the intervening year between the conclusion of the first 5-year monitoring program and release of the final report, NMFS will continue with its monitoring program.

Although recognizing current budgetary restraints, NMFS encourages the MMS and other Federal agencies to continue studies on gray whale distribution, abundance, and habitat use in the Bering, Chukchi, and Beaufort Seas and on the impacts of seismic exploration, offshore drilling activities, oil spills, and vessel traffic. In addition to research on gray whales conducted in the United States through independently funded sources and in Mexico by the Government of Mexico, NMFS plans to conduct the following as part of its monitoring program:

(1) Monitor the status of the gray whale and habitats essential to its survival;

(a) Conduct a biennial population assessment to include:

(i) A census of the southbound migration for comparison with historical research;

(ii) Carry out research as needed to determine any potential biases in the estimation of procedures (e.g., offshore distribution, tails of the migration, night-time migration rates);

(iii) Estimate population productivity using data obtained from (i) and (ii) above, and from life history studies, as may be appropriate, such as calf production; and

(iv) A determination of the shape of the production curve of the population—that is, the "point" or series of estimates that suggest that the population has reached its carrying capacity.

(2) Continue monitoring the level and frequency of gray whale mortality through small take and commercial fishery exemptions, stranding programs and other activities.

(3) As part of the stranding network, monitor trends in the levels of contaminants, including hydrocarbons, organochlorines, heavy metals and DDT, in gray whales by conducting bioassays of all available stranded animals.

In addition to its required monitoring program, NMFS anticipates taking the following actions to ensure the continued well-being of gray whales:

(1) Implement whale watching regulations for U.S. citizens and others within the U.S. EEZ and promote with Mexico and Canada the use of similar standards for whale watching within their waters.

(2) To the extent possible, encourage MMS to continue studies to determine the impacts of oil spills; vessel traffic, including noise; seismic exploration; and offshore drilling activities on gray whales and their benthic food resources.

(3) To the extent possible, continue and promote increased cooperative studies with Mexico to monitor habitat use and the impacts of whale watching on the Mexican breeding/calving grounds; encourage the enforcement of gray whale sanctuary regulations in Mexico; and encourage operators of U.S. whale watch vessels to observe Mexican sanctuary regulations.

(4) Continue participation in the IWC and its Subcommittee on Protected Species and Aboriginal Subsistence Whaling, in order (among other things), to coordinate research on gray whales by member nations, in particular surveys of western Pacific areas for estimating abundance of the Okhotsk stock, photo-identification studies, and DNA/carbon isotope work.

References

A copy of the references used in this document is available upon request (see **ADDRESSES**).

Determination

Based upon the assessments discussed above, NMFS has determined that the eastern North Pacific gray whale stock has recovered to near its estimated original population size and, while individual and cumulative impacts may have the potential to affect adversely the eastern stock, that stock is neither in danger of extinction throughout all or a significant portion of its range, nor likely to again become endangered within the foreseeable future throughout all or a significant portion of its range. Therefore, NMFS has determined that the eastern North Pacific stock of the gray whale should be removed from the List of Endangered and Threatened Species under the ESA. NMFS has also determined that the western Pacific gray whale stock, which is geographically isolated from the eastern stock, has not recovered and should remain listed as endangered.

Dated: December 30, 1992.

William W. Fox, Jr.,

Assistant Administrator for Fisheries.

[FR Doc. 93–40 Filed 1–6–92; 8:45 am]

BILLING CODE 3510–22–M

[Docket No. 920544–2324]

Listing Endangered and Threatened Species; Northern Offshore Spotted Dolphin

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of Determination; Status Review.

SUMMARY: NMFS determines that a proposal to list the northern offshore spotted dolphin, *Stenella attenuata*, as "threatened" under the Endangered Species Act (ESA) is not warranted at this time. This determination follows an NMFS announcement indicating that the geographic boundaries which have delineated the stock structure for spotted dolphins in the eastern Tropical Pacific (ETP) should be revised. The petition received by NMFS to list the northern offshore spotted dolphin as threatened addressed the status (abundance and fishery-induced mortality) of this stock using previously accepted geographic boundaries, and not the currently accepted boundaries for stock structure in the ETP. Changes in the stock structure indicate that the northern offshore stock of spotted dolphin as identified in the petition is no longer a valid biological or management unit. Based on the best available information, NMFS believes that the northern offshore spotted dolphin does not fall within the definition of "species" under the ESA and, therefore, is not eligible for listing under the Act.

DATES: Comments and information concerning the status of the northeastern stock and the western/southern stock of offshore spotted dolphins must be received by NMFS by February 17, 1993.

ADDRESSES: Comments can be forwarded to Dr. Michael F. Tillman, Acting Director, Office of Protected Resources, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Michael Payne, NOAA/NMFS, Office of Protected Resources, 1335 East-West Highway, Silver Spring, MD 20910 (301/713–2322).

SUPPLEMENTARY INFORMATION:

Background

On October 31, 1991, the Center for Marine Conservation (CMC) petitioned NMFS to add the northern offshore spotted dolphin (*S. attenuata*) to the U.S. List of Endangered and Threatened Wildlife as a threatened species. Under section 4(b)(3)(A) of the ESA, a determination must be made whether the petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted. If a petition is found to present such information, a review of the status of the species concerned is mandated. NMFS determined that the petition presented substantial information, and that the petitioned action may be warranted (56 FR 65724, Dec. 18, 1991). To ensure a comprehensive review, NMFS solicited information and comments concerning the petition. Comments and further information on this petition were accepted by NMFS until January 17, 1992.

NMFS was also petitioned by the Defenders of Wildlife and Environmental Solutions International to designate the northern offshore spotted dolphin as threatened under the ESA on January 23, 1992. However, this petition, received by NMFS on January 29, 1992, was formally denied for the following reasons: (1) NMFS had already received the petition from CMC to designate the northern offshore spotted dolphin as threatened under the ESA, and had determined that this petition presented information indicating that listing may be warranted, and (2) the latter petition essentially duplicated the previously accepted petition. NMFS considered the information provided in the denied petition during the review and evaluation of the original petition.

At the time the original petition was received on October 31, 1991, NMFS was in the process of reviewing new scientific information regarding this species. On November 13–14, 1991, NMFS conducted a workshop on the status of ETP dolphin stocks (referred to as the Status of Porpoise Stocks (SOPS) Workshop) to review these data (DeMaster *et al.*, 1992). Two reports presented at the SOPS workshop, Dizon, Perrin and Akin (1992) (referred to by the commenters and workshop participants as SOPS–9), and Perrin *et al.* (1991) (referred to as SOPS–15), presented new information on the stock structure of ETP dolphins and are the basis for this determination.

Comments and Responses

NMFS received comments in response to the petition to list the northern offshore spotted dolphin as threatened under the ESA that addressed the following issues: Abundance and trends of the northern offshore spotted dolphin, quality of assessment data, overutilization and fishery-induced mortality, stock boundaries between the offshore populations of spotted dolphin, quality of the habitat, and regulations governing the take of dolphins in the purse-seine fishery. This notice focuses only on those comments addressing stock structure, and the definition of stock boundaries for offshore spotted dolphins, as they relate to the status of the northern offshore spotted dolphin.

Comments: The data indicating geographical separation of the northern and southern offshore spotted stocks were questioned by several commenters. One commenter cited SOPS–15 as follows: "present management units are inconsistent with patterns of cranial variation; spotted dolphin west of 120 degrees W. probably should not be pooled with those to the east as they show closer affinity with the southern offshore unit. In addition, the boundary between the northern and southern units should probably be moved north to about 5 degrees N." The commenter continued, "Perrin noted that managing both southern and western offshore spotted dolphins as one stock was consistent. He concluded that combining the southern and western areas into a single management unit should be considered provisional."

Several commenters noted that the participants of the SOPS workshop recommended that the distribution plots for each stock be updated from those prepared for the 1984 status review.

Regarding the status of ETP spotted dolphin stocks, and the question of where to draw the lines delineating the boundaries for the northern and southern offshore stocks, one of the commenters cited S.T. Buckland, a workshop participant, as follows: "Buckland commented that (1) the geographically defined management units (previous stock boundaries) are not necessarily biologically meaningful; (2) That abundance can be estimated for a management unit, but trends in abundance must often be determined by pooling stocks that are thought to mix or overlap in distribution; and (3) where quota management is considered appropriate, quotas should be established for each management unit." The commenter continued that until such time as NMFS can determine the correct boundary lines to separate the northern and southern offshore spotted dolphin stocks, no estimate of the relative abundance of either stock can be made. Further, no reliable estimates of the ratio of the current population size to historical size can be made.

To correct these deficiencies in the data and the analysis, two commenters suggested that the comment period to respond to the petitions to list the northern spotted dolphin as threatened under the ESA [or as depleted under the Marine Mammal Protection Act], should be extended for at least 6 months. Alternatively, one commenter suggested that NMFS should determine that the petitioner failed to provide substantial information indicating that the petitioned action is warranted.

Response: The documents presented at the November 1991 SOPS workshop have subsequently received further review by NMFS. Based on these studies NMFS believes that the following changes in the stock structure for spotted dolphins in the ETP are warranted:

Previous stock structure	New stock structure
northern	northeastern.
southern	western/southern.
coastal	coastal.

The petition to list the northern offshore spotted dolphin as threatened addressed the status (abundance and fishery-induced mortality) of the northern offshore spotted dolphin using previously accepted stock structure and geographic boundaries, and not the revised boundaries for the "northeastern" offshore spotted dolphin. Section 4(b)(3)(B) of the ESA requires that, after receiving a petition found to present substantial information, the Assistant Administrator for Fisheries must make a finding within 12 months that either the petitioned action is warranted and then publish a proposed regulation to implement the petitioned action, or that the petitioned action is not warranted. The ESA has no provision which allows an extension of the 12 month period following the receipt of a petition if a proposed implementing regulation cannot be published because new information results in substantial disagreement regarding the accuracy of the available data relevant to the petitioned action. Even given the recent changes in the delineation of the stock boundaries of offshore spotted dolphins, and the potential impact that such a restructuring has on the petitioned action, NMFS cannot extend the 12 month period prior to a determination to allow for additional comments, or to allow for reanalyses of the status of offshore spotted dolphins using current geographical stock boundaries.

Furthermore, section 4(b) of the ESA requires that determinations concerning listings be made solely on the best scientific and commercial data available after conducting a review of the status of the species. As a preliminary matter, and considering recent changes in the stock structure of ETP offshore spotted dolphins, the northern offshore spotted dolphin must first fit within the definition of a "species" under the ESA before it can be considered for listing.

Determination of "Species" Status Under the ESA

Section 3(15) of the ESA defines "species" to include "any subspecies of fish or wildlife or plants, and any distinct population segment of any species of vertebrate fish or wildlife which interbreeds when mature." Although this definition of "species" under the ESA is in part a legal interpretation, species and populations are biological concepts that must be defined on the basis of the best scientific data available. Based on the best available information regarding the stock structure of ETP dolphins, NMFS believes that the petitioned stock (the northern offshore spotted dolphin), which was defined by now-rejected geographic boundaries, does not fall within the definition of "species" under the ESA. Therefore, the northern offshore spotted dolphin is not eligible for listing under the ESA. The basis for this determination is provided in Dizon, Perrin and Akin (1992), and Perrin *et al.* (1991).

Determination of Listing the Northern Offshore Spotted Dolphin Under the ESA

After a thorough analysis of all information available, including information and comments received in response to the notices referenced above, and based on the best available scientific information presented at the November 1991 SOPS workshop, and published since, NMFS has determined that a proposed rule to list the northern offshore spotted dolphin as threatened under the ESA is not warranted at this time. This determination is based on the interpretation of "species" under the ESA, and not the five factors considered in section 4(A)(1) of the ESA.

Conclusion

NMFS and the IATTC are re-assessing the status of ETP offshore stocks of spotted dolphin using the redefined stock boundaries. NMFS is soliciting information and comments concerning the status of the northeastern and western/southern stocks of offshore spotted dolphin to ensure that the review is complete and based on the best scientific and commercial data available. In a previous **Federal Register** notice (57 FR 40166, Sep. 2, 1992), NMFS delayed, until February 17, 1992 (6 months from the close of the comment period on the proposed rule), issuance of a final rule on whether the northeastern stock, or the western/southern stock, of offshore spotted dolphins were depleted under the MMPA. NMFS will also accept comments and information germane to the "threatened" status of these dolphin stocks until this date.

If the current status review concludes that a listing of either population of offshore spotted dolphin as threatened is warranted under the ESA, or a listing of either population of offshore spotted dolphin as depleted is warranted under the MMPA, a proposed listing will be published in the **Federal Register**.

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Perrin, W. P., G. D. Schnell, D. J. Hough, J. W., Gilpatrick and J. V. Kashiwada. 1991. Re-examination of geographical cranial variation in the pantropical spotted dolphin, *Stenella attenuata*, in the eastern Pacific. NMFS SWRSC Admin. Rept. LJ–91–93.

Dated: December 29, 1992.

Nancy Foster,

Acting Deputy Assistant Administrator for Fisheries.

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Final Revision of National Park Service Standard Concession Contract; Notice

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DEPARTMENT OF THE INTERIOR

National Park Service

Final Revision of National Park Service Standard Concession Contract

SUMMARY: The National Park Service (NPS) authorizes private businesses known as concessioners to provide necessary and appropriate visitor facilities and services in areas of the national park system. The authorizations for larger concessions primarily are in the form of standard language NPS concession contracts. NPS has amended its standard language concession contract (hereinafter the "old standard contract") in the form of a new standard concession contract (hereinafter the "new standard contract") to clarify certain provisions and to implement certain new contract terms in the public interest. NPS will utilize this form contract as a guide in its concession contracting process but each concession contract contains terms unique to it and NPS frequently alters standard provisions as needed to implement particular contract objectives. The new standard contract is set forth below.

EFFECTIVE DATE: January 7, 1993.

FOR FURTHER INFORMATION CONTACT: Lee Davis, Chief, Concessions Division, National Park Service, Washington, D.C. 20013–7127. Tele. (202) 343–3784.

SUPPLEMENTARY INFORMATION: On September 3, 1992, NPS published for public comment in the **Federal Register** proposed amendments to the old standard concession contract. The changes were proposed to implement certain aspects of the Secretary of the Interior's reform of the NPS concessions program and otherwise to make certain needed changes to the old standard contract. (See the preamble to the proposed amendments at 57 FR 40508 for a description of the premises and objectives of the Secretary's concessions reform initiative. Interested persons should also review the preambles to both the proposed and final new NPS concession regulations (56 FR 41894 and 57 FR 40496) for further information).

NPS received 61 public comments on the proposed amendments to the old standard contract, including a number of comments from environmental organizations, individual concessioners, and, the Conference of National Park Concessioners (on behalf of its membership which includes some but not all NPS concessioners). Approximately 4% of existing concessioners individually commented on the proposal. Approximately 13% of existing concessioners with concession contracts individually commented on the proposal. The substance of these comments, as well as certain changes NPS has made in its proposal, are discussed below. Additionally, NPS has made a number of clarifying, editorial and technical changes to the new standard contract as proposed consistent with its purposes.

Section-by-Section Analysis

General Comments

Several commenters have suggested that NPS reduce the size of some of the paragraphs in the new standard contract to make it easier for readers to refer to specific contractual provisions. In response to this concern NPS has broken down some of the longer paragraphs into smaller paragraphs, and renumbered these "new" paragraphs accordingly.

A few commenters discussed issues relating to NPS concession contracting regulations which were recently amended by NPS in furtherance of the objectives of the Secretary's concession reform initiative. These issues are not further discussed here as they were the subject of public comment in the adoption of the amended regulations. The amended regulations were published in final in the **Federal Register** on September 3, 1992 (57 FR 40496).

One commenter asserted that NPS has violated applicable law in publishing the proposed changes to the old standard contract as a public notice with opportunity for comment rather than as a regulation. NPS disagrees and considers that the process used to obtain public comment on its proposed changes to the old standard contract is lawful. In fact, NPS solicited public comment on the proposed changes as a matter of policy to assure a full discussion of the issues involved. It was not required by law to do so.

Several commenters urged NPS to increase the length of concession contract terms. Others supported shorter term contracts. Neither of these views deal with the substance of the new standard contract as the term of a contract is not a matter determined by the new standard contract. However, in determining the appropriate length of a concession contract, NPS takes into account various considerations. These include the need to encourage competition for concession contracts and the level of investment required by the contract. These factors necessarily vary from contract to contract.

Whereas Clauses

The new standard contract deletes the whereas clause in the old standard contract which references the concessioner's investment and risk of loss. Some commenters objected to the removal of this clause from the contract, claiming that it serves to balance the interests of concessioners against those of the government.

NPS disagrees. The clause contains language that is too specific for a standard language contract. It concerns only those concessioners that are required to make "substantial investments of capital." Moreover, the new standard contract does retain the whereas clause that reiterates the statutory obligation of the Secretary to "exercise his authority * * * in a manner consistent with a reasonable opportunity for the Concessioner to realize a profit."

Other commenters asserted that the whereas clauses should contain some acknowledgement of NPS's duty under the Concessions Policy Act (16 U.S.C. 20 et seq.) (hereinafter the "Act") to ensure that concession development is limited to that which is "necessary and appropriate for the public use and enjoyment of the parks." NPS agrees. Consistent with the Act, NPS has added the "necessary and appropriate" phrase to a whereas clause in the new standard contract.

Section 1—Term of Contract

Some commenters opposed paragraph (b) of this section, which gives the Secretary the authority to shorten the term of the contract if the concessioner does not timely complete a building and improvement program. These commenters claimed that this provision is unfair, since many of the causes for delay in the completion of a building and improvement program are beyond a concessioner's control.

NPS recognizes that in some cases concessioners may not have total control over the performance of building and improvement programs. That is why paragraph (d) of this section allows the Secretary to relieve a concessioner from its building and improvement obligations when delays in the completion of the program are determined to be beyond the concessioner's control.

One commenter asked NPS to set up procedures through which a concessioner can ask for this type of relief. NPS believes further contract language in this regard is unnecessary as paragraph (d) details the procedure to be followed to the extent necessary for contract purposes.

Section 2—Accommodations, Facilities and Services

One commenter stated that this section should state that if an Operating Plan requirement conflicts with the contract, the contract governs. NPS believes this is unnecessary as the final sentence of this section states that "such Operating Plan shall not amend or alter the material rights and liabilities of the parties to this CONTRACT."

Some commenters opposed the elimination from this section of the optional "preferential right to additional services" provision. They contended, essentially, that inclusion of this provision is necessary because it gives NPS greater control over concessions operations and serves to lessen the impact that concession operations have on park resources.

NPS disagrees with these arguments. NPS has full authority to strictly monitor concession operations and does not need this provision to achieve these purposes. The provision may be included in concession contracts where it is determined in a particular circumstance to be in the public interest. The provision was deleted because in the experience of NPS it served to impede fair competition in concession contracting.

One commenter stated that Operating Plans should include the requirement that concessioners use state-of-the-art environmental technology. NPS disagrees. NPS has adequate authority to require concessioners to adopt new technology as appropriate without including a specific contract term to this effect.

Section 3—Plant, Personnel and Rates

The new standard contract omits the following sentence from the old standard contract: "The Secretary shall exercise his decision making authority with respect to the concessioner's rates and prices in a manner consistent with a reasonable opportunity for the concessioner to realize a profit on its operations hereunder as a whole commensurate with the capital invested and the obligations assumed."

Some commenters objected to the removal of this sentence as they consider it an appropriate limitation to place on the NPS rate approval process. However, NPS considers that the sentence distorts the meaning of the Act as Section 3(c) of the Act requires rates to be judged "primarily by comparison with those current for facilities and services of comparable character under similar conditions." The new standard contract does include a whereas clause which appropriately reflects NPS statutory responsibilities with respect to a concessioner's reasonable opportunity for profit.

One commenter suggested that the contract should prohibit concessioners from providing complimentary goods or services to government officials. NPS disagrees. This type of prohibition is more properly the subject of law or regulation independent of the concession contract. NPS, in this connection, has several requirements limiting NPS officials from accepting benefits from concessioners or other contractors.

One commenter suggested that the contract should give park superintendents "the right to direct the concessioner to dismiss any concessioner employee whose actions or judgements have proven to be inimical to the proper and lawful operation of the park or safety of visitors". NPS considers that termination of concession employment is the responsibility of the concessioner, not the NPS. However, NPS, under Section 3(b)(2) of the new standard contract, does have the ability to bring such circumstances to the attention of the concessioner for appropriate action to be taken.

One commenter contended that the new standard contract improperly describes the requirements of the Rehabilitation Act of 1973. The description of the meaning of this law has been deleted from the new standard contract to avoid any confusion in this regard.

Additionally, NPS has added language to this section to clarify that by agreeing to the concession contract, the concessioner acknowledges that its terms provide the concessioner with a reasonable opportunity for profit.

Section 4—Government Land and Improvements

One commenter considered that this section should require a specific listing of government improvements. NPS agrees. Exhibits B and C to the contract, as referenced in this section, list the parcels of land and government improvements that are assigned to the concessioner under the contract.

Section 5—Maintenance

One commenter was concerned that NPS may require concessioners to undertake major repairs under this section without providing the concessioner with any corresponding consideration. However, the first sentence of this section provides that its requirements are subject to section 4(e) of the contract. Section 4(e) requires concessioner repair expenditures to be consistent with a reasonable opportunity for a concessioner to realize a profit on its operations.

Section 7—Utilities

This section provides that if NPS is unable to provide the concessioner with utilities, the concessioner shall secure utilities at its own expense. Several commenters stated that this provision is unfair because it places a new burden—the expense of securing utilities—on concessioners. NPS disagrees with these comments. This section is substantially similar to the "Utilities" section of the old standard contract which also does not require NPS to provide utilities to the concessioner.

Several commenters opposed the requirement that upon contract termination concessioners must assign to the United States, without further compensation, any water rights they have acquired under the contract. However, the water rights relate to NPS land and are needed to fulfill NPS purposes. The concessioner obtains no permanent interest in the right under the new standard contract as a condition of the contract.

One commenter asked NPS to clarify the kinds of utility costs it will charge concessioners under this section. However, the scope of utility costs to be charged concessioners under this provision is a matter of NPS policy independent of the new standard contract.

Section 8—Accounting Records and Reports

One commenter stated that this section should require the concessioner to provide NPS with a list of the members of its Board of Directors, as well as the names and addresses of all owners and part-owners of the concession. NPS currently accomplishes this to the extent appropriate by requiring businesses to provide this information when they submit an offer for a concession contract.

NPS, in response to a comment, has amended this section to clarify that the concessioner's system of account classification must be directly related to the Concessioner Annual Financial Report form prescribed by the Secretary. Further, NPS has added a sentence to paragraph (a) of this section to clarify that concessioners earning less than $250,000 may submit financial statements that have been prepared without the involvement of an independent certified, or licensed public accountant, unless otherwise determined by the Secretary. In addition, NPS has added to this paragraph the clarifying requirement that concessioners which must have

their annual financial statements audited or reviewed are to use the accrual accounting method and include in their statements a footnote that reconciles their financial statements to their Federal income tax returns.

Section 9—Fees

Paragraph (a)(1) of this section as proposed provides that building use fees shall be adjusted annually by the Secretary to equal the fair annual value of government improvements assigned to the concessioner. Several commenters stated that it is unfair to adjust building use fees every year. NPS disagrees. This section merely requires building use fees to be reviewed annually to determine that they continue to reflect the fair annual value of park buildings. If the value has not changed, no amendments to the fees will be made. The word "shall" has been changed to "may" in the final document to reflect this intent.

One commenter stated that NPS should take into account maintenance and capital improvement obligations when setting building use fees. This is present NPS policy.

One commenter stated that franchise fees should not be reconsidered on a more frequent basis than every five years. NPS disagrees. The level of franchise fee is based on NPS's determination of the probable value of the privileges granted by the contract. As a concession operation's financial circumstances change over time, so does the probable value of the contract privileges. NPS believes that under many contracts a five year interval between fee reconsiderations is appropriate, as it is unlikely that the probable value of these contracts will dramatically change prior to the end of this five year period. Under other contracts, however, the probable value could change a great deal in two or three years, thereby warranting reconsideration. NPS notes that the reconsideration provision is a two way street. Fees may go down as well as up under its terms.

The proposed new standard contract also stated that fees "may" be reconsidered. One commenter suggested that the term "may" should be changed to "shall" since the Act requires the reconsideration of franchise fees. NPS agrees with this comment. The language in this section has been changed to provide that fees shall be reconsidered at the time intervals set forth in the contract. In reconsidering fees, however, NPS will not seek to adjust a fee that continues to reflect the probable value of a particular concession contract.

This section also provides that receipts from the sale of genuine United States Indian and native handicraft are excluded from NPS franchise fee calculations. A few commenters objected to this exclusion, which has been included in concession contracts for many years, claiming that it is no longer necessary to stimulate the sale of Indian and native handicraft. NPS disagrees with these objections. It considers that this exclusion continues to represent sound public policy.

Section 9(e) of the contract provides for advisory arbitration to resolve fee reconsideration disputes. One commenter objected to the advisory nature of this procedure. As a matter of law, however, NPS cannot allow itself to be party to a binding arbitration proceeding.

NPS, however, has clarified and made more specific the dispute resolution procedure of Section 9(e). First, instead of referring to this procedure as an "advisory arbitration", the new language refers to it as a "mediation" and includes appropriate procedural requirements in this regard. The term "mediation" is a better description of the process involved in this section, as the goal of the process is to advise, rather than bind, the Secretary. Second, to the mutual benefit of the government and concessioners, the time deadlines of this section have been streamlined to expedite the reconsideration process.

Section 10—Accounts

This section authorizes as optional provisions two types of accounts for building and improvement programs. The optional section 10(a) requires the concessioner to remit funds into a "Government Improvement Account" in consideration of the right to use and occupy government-owned buildings. The concessioner accesses this account to fund the repairs and improvements of government improvements which directly support concession services.

Optional section 10(b) requires the concessioner to remit a portion of its revenues into a "Capital Account" as partial consideration for the privileges granted under the contract. The concessioner accesses this account to fund improvements which directly support concession services.

Several commenters claimed that this section violates the Act's requirement that concessioners receive possessory interest for the improvements they make to structures on park lands as improvements funded from the accounts are not eligible for possessory interest. NPS disagrees with this contention for the reasons discussed below in connection with the general discussion of possessory interest.

For a variety of reasons, several commenters objected to using the National Park Foundation as a trustee for the funds concessioners deposit in the Section 10 accounts. NPS has eliminated this role for the National Park Foundation from the new standard contract.

Other commenters urged that Section 10 account funds should not be restricted to funding only improvements that directly support concession services. They asked that NPS make these funds available for resource protection, interpretation, research, and other park purposes. NPS, however, is required by law to restrict the use of these funds to improvements that directly support concession operations.

Another commenter suggested that NPS further define the term "routine operational maintenance." NPS disagrees with this suggestion. What is routine maintenance in one park may not be routine in another. The Maintenance Agreement allows for appropriate definition of these requirements on a case-by-case basis.

Section 11—Bond and Lien

One commenter stated that while he supports the general thrust of this provision, he would prefer it to include a "financial penalty clause" which would impose financial penalties on a party for failing to comply with the contract. NPS is presently studying this suggestion for possible future implementation.

Section 12—Termination

The terms of the new standard contract clarify the Secretary's authority to terminate or suspend operations under a concession contract. Several commenters stated that they support the general thrust of this clarification to the authority contained in the old standard contract.

Section 13—Compensation

The aspect of the new standard contract most criticized by the NPS concessioners that submitted comments is its amendment to the measure of compensation due a concessioner for possessory interest. (As noted, approximately 4% of concessioners individually commented and approximately 13% of contract concessioners commented.) The amendment, however, was supported strongly by the environmental groups which submitted comments.

The general objective of the amendment is to change, in certain circumstances, the compensation

standard for a concessioner's possessory interest in improvements it constructs from one based on the appreciated value of the improvements to our based on the actual cost to a concessioner of constructing an improvement, less depreciation. The fundamental reason for this change is to eliminate from concession contracts in the public interest an unnecessary and otherwise detrimental liability for payment of compensation to concessioners.

"Possessory interest" is the legal term for the compensable interest in real property a concessioner obtains pursuant to a concession contract when it makes capital improvements on park lands or to government buildings. Under the old standard contract, a concessioner is entitled to receive compensation for possessory interest in capital improvements it makes either in the amount of the "sound value" of the improvement or the book value of the improvement, depending on the circumstances. Sound value (referred to hereinafter as "sound value compensation") is defined generally as "reconstruction cost less depreciation," but, "not to exceed fair market value." Sound value, in effect, provides the concessioner compensation for the appreciated value of its buildings as the compensation is based on either the reconstruction cost or fair market value of a building, calculated as of the time it is transferred by a concessioner, not as of the time of construction.

The major difference in possessory interest compensation between the old and the new standard contract is that the new standard contract generally provides for a redefined "fair value" possessory interest compensation instead of sound value. (The new standard contract also changes book value to fair value in most circumstances but this is a technical change for consistency purposes as fair value, except for possible differences in depreciation schedules, generally equates to book value.)

Fair value compensation is redefined in the new standard contract as the "original construction cost of the improvement less straight line depreciation over the estimated useful life of the improvement according to Generally Accepted Accounting Principles." For NPS purposes, such useful life is not to exceed thirty years. Fair value compensation under the new standard contract provides the concessioner compensation for the improvements it makes at actual cost less depreciation, but, unlike sound value compensation, does not provide compensation for the appreciated value of concessioner improvements.

The NPS concessioners which commented individually and the Conference of National Park Concessioners objected to this amendment, contending that replacing sound value compensation with fair value compensation is detrimental and not authorized by the Act. NPS, however, after thorough examination of these views, continues to consider that the change to fair value compensation in the new standard contract is in the public interest and authorized by law. Particularly, NPS considers that the sound value possessory interest compensation provision contained in the old standard contract is no longer a prudent term to include in concession contracts for a variety of reasons, as follows: (1) Sound value compensation is an unnecessary financial liability borne directly or indirectly by the government; (2) sound value compensation inhibits fair competition in the award of concession contracts; and, (3) sound value compensation impairs the ability of NPS to undertake changes in the location and uses of concession facilities otherwise required for the preservation of park resources and their enjoyment by park visitors.

Unnecessary Financial Incentive

As stated, sound value compensation provides a concessioner with compensation for the appreciated value of the improvements it constructs in a park area. Sound value compensation, accordingly, is likely always to be a higher level of compensation than fair value as contained in the new standard contract. Depending on the circumstances under the old standard contract, either NPS or a successor concessioner has the liability to pay the concessioner sound value compensation. For example, NPS must pay sound value compensation if it requires the concessioner to remove and replace an existing facility in which it has a possessory interest, and, a successor concessioner must pay sound value compensation to the previous concessioner as a condition of receiving a concession contract which replaces one containing sound value compensation. Currently, almost all major NPS concession contracts contain sound value possessory interest provisions.

Provisions for sound value possessory interest compensation, accordingly, place direct or indirect financial burdens on the government. As such, as a matter of fiscal prudence and sound contract administration, they should be contained in concession contracts only if necessary in order to attract qualified concessioners or if they otherwise provide offsetting benefits to the government. NPS considers sound value compensation is not necessary to attract qualified concessioners for the reasons discussed below. Also, as discussed below, NPS considers that sound value compensation, rather than providing offsetting benefits to the government, has detrimental consequences to NPS.

Sound value compensation, in the abstract, is attractive to business persons as they may be expected to seek appreciation in the value of improvements they make. Based on its experience, however, NPS considers that many business persons interested in concession contracts look to the return they expect to make on the revenues of a concession operation over the term of the contract in deciding whether an investment should be made. The possibility of selling buildings at their appreciated value at the expiration of a contract is not as significant a factor. In fact, even under the old standard contract, there is no assurance that the concessioner will receive sound value compensation upon contract expiration or otherwise. For example, under the old standard contract, if the concession operation is to be discontinued upon contract expiration, the concessioner is entitled only to book value compensation.

For these reasons, NPS now does not consider that sound value compensation is needed in order to attract qualified concessioners. A prospective concessioner, of course, does seek to be assured that it will be able to recover the investment it makes in concession buildings. The fair value compensation provision included in the new standard contract achieves this objective. NPS also appreciates that continuity in concession operators is of benefit to NPS and park visitors. In certain circumstances, sound value compensation may encourage continuity in operations. However, the Act contains a specific provision to achieve this objective (the preference in renewal for existing satisfactory concessioners) and NPS considers that the detrimental aspects of sound value compensation as discussed below outweigh any benefit it may provide with respect to continuity of operations.

NPS also notes that, in its experience, lenders generally do not make decisions on loans to concessioners for construction of buildings or otherwise based on an expectation that a concessioner's buildings will appreciate in value due to increased building costs or other external market forces. Rather, lenders generally make concession loans based on an estimate that the net revenues of the business will be

sufficient to repay the loan. Possessory interest in a concession building to be constructed with borrowed funds is used as security for a loan, but, the estimated value of this security generally is based on construction cost, not on an assumption that the value of the concession building will appreciate. In this regard, as discussed above, there is, in fact, no assurance of possessory interest compensation at sound value under the old standard contract. Book value is all that is assured. Lenders presumably are aware of the terms of the old standard contract in this respect and yet frequently make loans to concessioners.

NPS considers that the fair value compensation provisions included in the new standard contract will be more than a sufficient level of compensation to attract qualified concessioners and to induce lenders to make loans to concessioners. The fair value compensation in the new concession contract is, as a practical matter, almost the functional equivalent of a government guarantee that a lender will receive security in an improvement based on actual construction cost less specified depreciation. This may be considered as better security than is obtainable in usual business circumstances as the security provided, although it has a fixed maximum amount, concomitantly has a fixed minimum amount as well. In fact, in terms of potential down-side, it may be considered as better security than sound value possessory interest compensation.

In this connection, NPS notes its recent award of a new concession contract for hotel and other facilities at Yosemite National Park, the largest concession operation in the national park system with the largest sound value possessory interest in the system. NPS, through a public solicitation under which six companies made competitive offers, was able to select a qualified new concessioner for the operations that has agreed to amortize the existing sound value compensation of the former concessioner (worth multiple millions of dollars) over a fifteen year period, and, in addition, to invest over $100 million dollars in new concession facilities. The contract does not contain sound value compensation provisions, but, rather, consistent with the new standard contract, provides fair value compensation for improvements constructed with concessioner funds and for no possessory interest in improvements constructed with funds from what are the equivalent of the new standard contract's Section 10 accounts.

NPS concessioners that commented on the new standard contract generally argued that sound value possessory interest compensation is needed in order to attract qualified concessioners. NPS disagrees for the reasons discussed above and points out that it will soon find out whether the terms of the new concession contract are such that qualified businesses generally will accept the new standard contract for park concession operations. If this does not prove to be the case, NPS will alter the new standard contract on a case-by-case basis or generally to the extent needed to procure qualified concessioners. The "marketplace" ultimately will determine the validity of the financial assumptions of the new standard contract.

Comments from concessioners also take the position that concessioners are entitled to sound value compensation under what may be characterized as the principles of free enterprise. This position is based on the proposition that in free enterprise a business person is able to sell a building it constructs for its appreciated value. However, the NPS concession contract program is hardly a free enterprise model. In fact, it contains several features benefiting existing concessioners that are not to be found in a free enterprise system, e.g., the statutory preference in renewal and the effective monopolies exercised by many concession operations with substantial possessory interest. In any event, however, the concept of fair value compensation is very much a "free enterprise" concept. Landlords in the private sector, when leasing property upon which a tenant is to make improvements, for good business reasons seek to include lease provisions that require improvements made by tenants to belong to the landlord upon lease expiration. This "free enterprise" practice is mirrored by the fair value compensation provisions of the new standard contract.

Finally, concessioners argued that the absence of sound value compensation will discourage concessioners from maintaining their buildings as they will no longer be compensated for buildings based in part on their physical condition. There is some logic to this argument, but, it boils down to the proposition that a purpose of sound value compensation is to induce concessioners to maintain their buildings properly. However, such inducement should not be needed as this obligation is otherwise contained in the concession contract, and, moreover, is a matter of good business practice if the concessioner wishes to please its customers and retain its preference in contract renewal as a satisfactory concessioner. NPS will rely on the terms of the contract and the good business sense of its concessioners to assure that concession buildings are properly maintained.

Impairing Fair Competition

Another reason to replace sound value possessory interest compensation is its negative impact on fair competition in concession contracting. By "fair" in this sense, NPS means competition for concession contract renewals under a process which encourages continuity of operations through an existing satisfactory concessioner's right of preference, but, also, which allows a competitor a reasonable opportunity to make and be awarded an offer advantageous to NPS. A balance of these interests is required under the Act. The problem presented by sound value compensation in this regard is that a prospective concessioner seeking to be awarded a contract for an existing concession operation (with a possessory interest) under the present contracting system, is, as a practical matter, required to offer to "buy a pig in a poke" when applying for the contract. This is because sound value compensation, based as it is on the estimated cost to reconstruct a building (or a building's fair market value, whichever is less), is always an unknown dollar amount until the completion of engineering studies and appraisals, and, if necessary, completion of a negotiation or binding arbitration to reconcile differing appraisals. NPS, under the terms of the old standard contract, requires a prospective new concessioner to agree to compensate the existing concessioner for applicable possessory interest at sound value, but, the prospective concessioner does not know at the time it must make this commitment what the amount will eventually turn out to be. Binding arbitration determines the final value.

Needless to say, few business persons submit offers for concession contracts in these circumstances. In fact, to the best of the institutional memory of NPS, a new concessioner has never, either before or after the passage of the Act in 1965, been awarded a concession contract in the place of an existing concessioner which sought contract renewal and had substantial possessory interest assets at the sound value level of compensation. For the most part, NPS does not receive competing offers at all, but, even if received, a competing offer may be expected to be conservative with respect to financial terms of importance to NPS in light of the unknown possessory interest purchase price the offeror faces. The incumbent concessioner, of course, is able to

submit a more favorable offer as it does not have to pay the sound value compensation or estimate the actual dollar amount.

The key elements of the Secretary's reform initiative with respect to enhancing competition in concession contracting are the amendment of NPS concession regulations, accomplished as of October 3, 1992, and the implementation of the new standard contract. Under the new regulations, it is made clear that an incumbent satisfactory concessioner is entitled to a right to meet the terms of a better offer received, but, is also required to be responsive to the contract terms as proposed by NPS. Under the new standard contract, a prospective concessioner will know in advance its liability to the incumbent concessioner for possessory interest compensation. NPS, accordingly, expects to receive more competing offers under the new regulations and new standard contract, and, expects to receive more favorable competing offers, to the ultimate benefit of the national park system.

NPS considers that the new regulations and the change to fair value compensation achieve a proper balance between the desirability of encouraging continuity of operations and the desirability of fair competition. As discussed below, satisfactory incumbent concessioners will still have substantial advantages over competitors in the award of a new concession contract but, the competitive process should no longer be a "rubber stamp" exercise.

Resource Preservation

A more subtle but very serious consequence of sound value compensation is the fact that it tends to impede the ability of NPS to make necessary changes in the types and locations of concession facilities in park areas as visitor needs and resource concerns change over time. Under sound value compensation, if NPS wishes to have a concessioner relocate a concession facility (an objective that occurs frequently in light of the prime resource locations of many major concession facilities constructed decades ago), NPS must obtain and pay the concessioner compensation in the amount of the sound value of the structures to be removed. Such compensation can be a very large and increasing sum of money, effectively making difficult or impossible what otherwise may be a necessary step in the preservation of the resources of a park area. NPS, of course, can seek to obtain appropriated funds to provide the required compensation, but, the reality of budget priorities is that funds simply are not available for all the situations where they may be needed. The shift to fair value compensation and consequent reduction in possessory interest liabilities over time will assist significantly the ability of NPS to carry out its primary mission, the preservation of park resources for their enjoyment by visitors. NPS points out that its concern with sound value possessory interest in this regard is not meant to be a criticism of NPS concessioners, most of which fully share and assist in achieving NPS resource management goals, but, merely reflects economic reality.

These are the reasons why NPS has adopted fair value compensation in the new concession contract. The proposal was supported strongly by environmental groups that commented on the proposal. However, the NPS concessioners that commented, in addition to the business concerns they expressed as discussed above, also argued that the fair value compensation provision in the new standard contract is not authorized by the Act (or, even, that it is unconstitutional as a taking of property without just compensation). NPS has reviewed these positions carefully and disagrees with them.

The general position of the concessioners which asserted a lack of legal authority for the fair value compensation provisions of the new standard contract is their view that the Act in Section 6 "requires" that compensation for possessory interest be at sound value. However, this view overlooks the fact that the Act states that compensation for possessory interest is to be at sound value "unless otherwise agreed by the parties." NPS, of course, cannot enter into a concession contract containing the fair value compensation provision unless the concessioner signing the contract also agrees to it. NPS, however, does acknowledge that the Congress, in deliberating upon the legislation which led to the Act, considered, as a matter of factual expectation, not law, that NPS would continue to include sound value compensation provisions in concession contracts, in part because of the perception of the Congress in 1965 that sound value compensation would be necessary in order to attract investment in concession operations by qualified concessioners. This perception may have been accurate in 1965, but is not considered by NPS to be the case today as discussed above. As stated, NPS considers that it will have no general difficulty in attracting qualified concessioners under the terms of the new concession contract. If it does, it will revert to sound value compensation as necessary.

In this regard, the legislative history of the Act specifically acknowledges in a number of places the continuing authority of NPS (under the "unless otherwise agreed by the parties" phrase of Section 6 of the Act and otherwise) to include possessory interest compensation in concession contracts at other than sound value. For example, Congressman Aspinall, a principal author of the legislation which became the Act, stated as follows in House floor debate (as a rebuttal to a colleague's criticism of sound value compensation):

> The Secretary is free [under Section 6] both to require the concessioner to waive any possessory interest he might otherwise have in this sort of improvement [concessioner improvements] and to adapt the valuation formula to suit the circumstances of such improvement as sees fit. (Congressional Record, September 14, 1965 at p. 22787.)

In addition to its clear authority under the Act of contract for possessory interest compensation at other than sound value, NPS also points out that there is nothing new about a provision for less than sound value possessory interest compensation in NPS concession contracts. In fact, each and every NPS concession contract entered into since passage of the Act in 1965 (with possessory interest provisions) has contained terms which limit possessory interest compensation to less than sound value in certain circumstances. For example, it has always been NPS policy under the Act and the old standard contract to provide book value compensation when a concession facility is no longer used for concession operations. In addition, NPS implemented, shortly after passage of the Act, a policy still reflected in both the old and the new standard contracts, to the effect that possessory interest compensation in government buildings improved by a concessioner is at book value. This latter policy was adopted formally in 1979 after public notice and opportunity for comment on the then new standard language concession contract.

In short, the commenters cannot reconcile their position that the Act does not authorize anything but sound value compensation with the administrative practice of NPS under the Act. In this connection, NPS also notes that all concession contracts grossing more than $100,000 are required to be submitted to Congress for a sixty day period prior to execution. In order for the commenters' to sustain the validity of their legal position, they would have to argue that Congress has chosen to ignore the fact that each and

every concession contract submitted to the Congress since 1965 (with possessory interest provisions) is illegal under the Act.

One commenter did acknowledge the "unless otherwise agreed to by the parties" phrase of section 6 of the Act. The commenter, however, tried to explain this phrase away by arguing that the phrase means that a potential concessioner for a new concession contract has a right to agree or disagree "in advance" to a contract which does not contain sound value compensation. The Act, of course, simply does not read this way. Further, it is self-evident that no one is required to apply for an NPS concession contract if he or she disagrees with the terms of the contract. In fact, it appears that this "advance agreement" legal argument, if carried to its logical conclusion, would mean that a third party somehow has a right to veto the inclusion of a less than sound value compensation provision in a concession contract which otherwise has been agreed to by both parties to the contract, NPS and the selected concessioner. NPS does not believe that the Act can be read to achieve this anomalous result.

Although NPS considers that it has legal authority to adopt the fair value compensation provision, it does not seek to deprive existing concessioners which are entitled to sound value compensation the full measure of compensation due under existing contracts or to deprive existing concessioners of a fair opportunity to apply for a new contract. In this regard, NPS will include in each concession solicitation utilizing the new standard contract its estimate, where applicable, of the value of an existing concessioner's possessory interest and require the successful applicant (if it is not the existing concessioner) to pay the existing concessioner all possessory interest compensation (including sound value and book value, as applicable) and other compensation due the existing concessioner under the expired contract. If the existing concessioner chooses to seek to continue its operations under the new contract, it will be entitled to apply for the new contract containing the fair value compensation provision, and, if it is a satisfactory concessioner, it will have a right of preference in the new contract in accordance with the Act and 36 CFR part 51.

In either circumstance, the specific amount of money to be included in the new contract with respect to existing sound value possessory interest will be calculated in accordance with the terms of the expired contract. If this amount should change as a result of a required arbitration or otherwise, NPS will make appropriate adjustments to the terms of the new contract to reflect the adjusted actual dollar value of the existing sound value compensation.

Existing concessioners may argue that it is not within the authority of NPS to propose a contract which, in effect, requires an incumbent concessioner to amortize its sound value possessory interest under its terms. NPS, however, has carefully considered this argument and considers it to be unpersuasive. In the first instance, although an existing satisfactory concessioner has a right of preference to a new contract, this right does not extend to setting the terms of a new contract with respect to possessory interest compensation or otherwise. NPS has the statutory responsibility to establish such terms in fulfillment of its obligations to preserve areas of the national park system and to provide for their enjoyment by park visitors.

In any event, however, an existing concessioner in fact has the choice under the new standard contract either to agree to the terms of the new contract as offered equally to all applicants, or, to obtain immediately the full compensation which is due under the expired contract. In this regard, NPS points out that the overall financial benefits of a new concession contract, will be, as a matter of business necessity, at least equal to the compensation due an incumbent concessioner under an expired contract, or else, no one, including the incumbent concessioner, will make a responsive offer for the new contract. NPS, to this end, will take into account in its internal decisions regarding proposed contract terms (e.g., building programs, term, franchise fees, etc.) the economic consequences of amortizing existing sound value possessory interest as required by the new standard contract. A new concessioner will not offer to pay the existing concessioner the sound value and other compensation due under the expired contract and thereafter amortize this expense as required by the new standard contract unless the terms of the new contract are considered attractive enough to warrant such payments as a matter of business judgment. In fact, the incumbent concessioner has substantial advantages over competitors in this regard because the incumbent is not required to pay cash up front for the sound value compensation (as is a new concessioner), and, the incumbent will have a better estimate of the value of the new contract because of its detailed knowledge of past expenses and revenues.

An example of this is as follows. If an existing concessioner has sound value possessory interest in the amount of $1,000,000, a fifteen year new contract proposal would state that compensation for this existing possessory interest is initially set at $1,000,000 and will decrease by one thirtieth each year of the contract. If a new concessioner is awarded this contract, it would be required to pay the existing concessioner the $1,000,000 up front (in accordance with the expired contract) and would then amortize this payment under the terms of the new contract. If an existing concessioner is awarded the contract, this amount likewise would be amortized under the terms of the new contract. At the expiration of the fifteen year contract, accordingly, one-half of the initial amount would be due the concessioner if it is not awarded a subsequent new contract. Under a subsequent new fifteen year contract, the concessioner thereunder would amortize the balance of the initial $1,000,000.

In summary, under the new standard contract, an incumbent concessioner with existing sound value possessory interest either may obtain immediate full payment for this interest, or, may seek to enter into a new concession contract which is intended through its terms to compensate the concessioner, whether a new concessioner or the existing concessioner, for the amortization of the existing possessory interest and provide, taking the amortization into account, a reasonable opportunity for profit. The existing concessioner is given the choice in this regard, and, the liability of the government thereafter to pay sound value compensation (and related detrimental consequences) is eliminated as required in the public interest.

Several commenters also questioned the validity of the optional Section 10 account provisions of the new standard contract which do not provide possessory interest in improvements constructed with funds from Section 10 accounts. As a legal matter, the Act allows for the assignment, transfer or extinguishment of possessory interest and thus the section 10 provision is lawful for the same reasons as discussed above with respect to fair value compensation. NPS also notes that commenters generally accepted the fairness of this Section 10 account limitation with respect to possessory interest. In fact, the provision is of economic benefit to concessioners as they will profit from the use of improvements constructed with funds

from the accounts which otherwise may be an expense to the concessioner under the contract (e.g., increased franchise or building use fees) without corresponding benefit.

NPS finally notes in connection with section 13 that it received a comment which stated that section 13(d) is confusing because it appears that it merely restates Section 13(d). In this regard, section 13(f) is included in the new standard contract by NPS pursuant to statutory requirements. However, section 13(d) has been modified to be consistent with the intentions of the fair value provisions of the new standard contract and statutory requirements.

Section 14—Assignment or Sale of Interests

Several commenters asserted generally that section 14 is contrary to the principles of free enterprise, as it restricts a concessioner's ability to sell its business. NPS disagrees. This provision properly allows NPS to carry out its duty of ensuring that assignees of concessions contracts are capable of conforming to NPS's policies and procedures and that the terms of a concession contract, upon transfer, will continue to reflect the probable value of the privileges granted by the contract so that the interests of the government are protected. The fundamental premise of Section 14, as reflected in both the old and new standard contracts, is that there is no inherent right to assign or sell to a third party the rights and obligations of a government contract. This concept is not new. It has been in effect since well before the passage of the 1965 Act. Section 14 as proposed has been amended to reflect the related requirements of 36 CFR part 51.

One commenter stated that NPS approval of a sale or transfer should not be unreasonably withheld. This is present NPS policy, and does not change under the new standard contract.

Section 15—Approval of Subconcession Contracts

One commenter objected to this section, claiming that the Act does not allow subconcessioners to operate concession facilities and services. NPS believes that the Act authorizes subconcessioners, and, although NPS generally discourages subconcessioners, it has allowed their operation in certain circumstances for many years.

Section 17—Procurement of Goods, Equipment and Services

One commenter urged that this section specify that if NPS determines that a diversion or concealment of profits has occurred, the concessioner is to be terminated immediately. NPS disagrees with this suggestion. All diversions or concealments are not alike. Those that are unintentional or of a minor nature may not warrant immediate termination. Others, however, may deserve this action. For this reason, NPS needs the flexibility in the language of this section to take whatever action may be appropriate in these circumstances.

The Former "Disputes" Section

Several commenters objected to the removal of the "Disputes" section from the old standard contract. They considered, essentially, that this section is necessary to protect the rights of concessioners. NPS disagrees. The "Disputes" Section was deleted from the contract because independent statutory provisions now achieve the purposes of the Disputes clause.

NPS has determined that this document is categorically excluded from the NEPA process pursuant to applicable Departmental and NPS guidelines. NPS, in light of comments received regarding the fair value compensation provision, also reviewed this document in connection with the policies and criteria of Executive Order No. 12630 and has determined, for the reasons discussed above, that this document is consistent with applicable provisions of the Executive order.

Dated: December 30, 1992.

James M. Ridenour,

Director, National Park Service.

Standard Language To Be Used, Where Applicable in Concession Contracts

United States Department of the Interior, National Park Service

_____

(Name of Concessioner)

_____

(Name of Area)

Contract No. _____
Executed _____
Covering the Period _____
Through _____

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EXHIBITS

Exhibit "A": Nondiscrimination
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Corporation

THIS CONTRACT made and entered into by and between the United States of America, acting in this matter by the Secretary of the Interior, through the Director of the National Park Service, hereinafter referred to as the "Secretary," and _____, a corporation organized and existing under the laws of the State of _____doing business as _____hereinafter referred to as the "Concessioner":

Partnership

THIS CONTRACT made and entered into by and between the United States of America, acting in this matter by the Secretary of the Interior, through the Director of the National Park Service, hereinafter referred to as the "Secretary", and _____of _____, _____, and _____of _____, partners, doing business as _____, pursuant to a partnership agreement dated _____, with the principal place of business at _____, hereinafter referred to as the "Concessioner":

Sole Proprietorship

THIS CONTRACT made and entered into by and between the United States of America, acting in this matter by the Secretary of the Interior, through the Director of the National Park Service, hereinafter referred to as the "Secretary," and _____, an

individual of _____, doing business as _____, hereinafter referred to as the "Concessioner"

Witnesseth

That whereas, *(Name of Park, Recreation Area, etc.)* (hereinafter referred to as the "Area") is administered by the Secretary to conserve the scenery and the natural and historic objects and the wildlife therein, and to provide for the public enjoyment of the same in such manner as will leave such area unimpaired for the enjoyment of future generations; and

Whereas, the accomplishment of these purposes requires that facilities and services that have been determined to be necessary and appropriate for the public use and enjoyment of the area be provided for the public visiting the area; and

Whereas, the United States has not itself provided such necessary facilities and services and desires the Concessioner to establish and operate certain of them at reasonable rates under the supervision and regulation of the Secretary; and

Whereas, pursuant to law the Secretary is required to exercise his authority hereunder in a manner consistent with a reasonable opportunity by the Concessioner to realize a profit on the operations conducted hereunder as a whole commensurate with the capital invested and the obligations assumed:

Now, Therefore, pursuant to the authority contained in the Acts of August 25, 1916 (39 Stat. 535; 16 U.S.C. 1, 2–4), and October 9, 1965 (79 Stat. 969; 16 U.S.C. 20 et seq.), and other laws supplemental thereto and amendatory thereof, the Secretary and the Concessioner agree as follows:

Sec. 1. Term of Contract (a) This Contract shall [supersede and cancel Contract No. _____ effective upon the close of business _____ 19_____, and shall][1] be for the term of _____ (_____) years from _____, 19_____,[2] [conditioned upon the Concessioner's completion of the improvement and building program set forth in subsection (b) hereof. In the event the Concessioner fails to complete this program to the satisfaction of the Secretary within the time allotted therefor, then this Contract shall be for the term of _____ (_____) years from _____.]

[1] To be used when existing contract is to be replaced, before expiration date.

[2] To be used where there is an improvement and building program. The shortened term of contract should generally not exceed 10 years.

(b)[3] The Concessioner shall undertake and complete an improvement and building program (hereinafter "Improvement Program") costing not less than $_____ as adjusted per project to reflect par value in the year of actual construction in accordance with the appropriate indexes of the Department of Commerce's "Construction Review." It is agreed that such investment is consistent with Section 3(a) hereof. The Improvement Program shall include:

(Provide detailed description of the Improvement Program.)

(c) The Concessioner shall commence construction under the Improvement Program on or before _____ in such a manner as to demonstrate to the satisfaction of the Secretary that it is in good faith carrying the Improvement Program forward reasonably under the circumstances. After written approval of plans and specifications, the Concessioner shall provide the Secretary with such evidence or documentation, as may be satisfactory to the Secretary, to demonstrate that the Improvement Program duly is being carried forward, and shall complete and have the improvements and buildings available for public use on or before _____.

(d) The Concessioner may, in the discretion of the Secretary, be relieved in whole or in part of any or all of the obligations of the Improvement Program for such stated periods as the Secretary may deem proper upon written application by the Concessioner showing circumstances beyond its control warranting such relief.

(e) In addition to the Improvement Program described above, the Concessioner shall accomplish such additional improvement projects as may be funded from the account(s) established in Section 10 hereof.

Sec. 2. Accommodations, Facilities and Services (a) The Secretary hereby requires and authorizes the Concessioner during the term of this Contract to provide accommodations, facilities and services for the public within the Area, as follows:

(Provided detailed description of services which are required and/or only authorized to be undertaken. Broad generalizations such as "any and all facilities and services customary in such operations" or "such additional facilities and services as may be required" are not to be used. A provision stating "The Concessioner may provide services incidental to the operations authorized hereunder at the request of the Secretary" is acceptable.)

[3] (b), (c) and (d) Are to be used where improvement programs are included in the contract. *Note: Do not use* Sec. 1, (b), (c) or (d), if there is no building program.

(b) The Secretary reserves the right to determine and control the nature, type and quality of the merchandise and services described herein to be sold or furnished by the Concessioner within the Area.

(c) This Contract and the administration of it by the Secretary shall be subject to the law of Congress governing the Area and rules, regulations and policies promulgated thereunder, whether now in force or hereafter enacted or promulgated, including but not limited to United States Public Health Service requirements. The Concessioner must also comply with applicable requirements promulgated by the United States Department of Labor's Occupational Safety and Health Act of 1970 (OSHA) and those provisions outlined in the National Park Service's Safety and Occupational Health Policy associated with visitor safety and health.

(d) In order to implement these requirements the Secretary, acting through the Superintendent and in consultation with the Concessioner, shall establish and revise as circumstances warrant, specific operating requirements in the form of an Operating Plan which shall be adhered to by the Concessioner. The Operating Plan established by the Superintendent shall not amend or alter the material rights and liabilities of the parties to this Contract.

Sec. 3. Plant, Personnel and Rates (a)(1) The concessioner shall maintain and operate the accommodations, facilities and services described above to such extent and in such manner as the Secretary may deem satisfactory, and shall provide the plant, personnel, equipment, goods, and commodities necessary therefor, provided that the Concessioner shall not be required to make investments inconsistent with a reasonable opportunity to realize a profit on its operations under this Contract commensurate with the capital invested and the obligations assumed. The Concessioner agrees that the terms of this Contract provide the Concessioner this reasonable opportunity to realize a profit.

(a)(2) All rates and prices charged to the public by the Concessioner for accommodations, services or goods furnished or sold shall be subject to regulation and approval by the Secretary. Reasonableness of rates and prices will be judged generally by comparison with those currently charged for comparable

accommodations, services or goods furnished or sold outside of the areas administered by the National Park Service under similar conditions, with due allowance for length of season, provision for peak loads, [average percentage of occupancy] [4] accessibility, availability and cost of labor and materials, type of patronage, and other conditions customarily considered in determining charges, but due regard may also be given to such other factors as the Secretary may deem significant.

(a)(3) The Concessioner shall require its employees to observe a strict impartiality as to rates and services in all circumstances. The Concessioner may, subject to the prior approval of the Secretary, grant complimentary or reduced rates under such circumstances as are customary in businesses of the character conducted hereunder. The Concessioner will provide Federal employees conducting official business reduced rates for lodging, essential transportation and other specified services in accordance with procedures established by the Secretary.

(b)(1) The Concessioner may be required to have its employees who come in direct contact with the public, so far as practicable, to wear a uniform or badge by which they may be known and distinguished as the employees of the Concessioner. The Concessioner shall require its employees to exercise courtesy and consideration in their relations with the public.

(b)(2) The Concessioner shall review the conduct of any of its employees whose action or activities are considered by the Concessioner or the Secretary to be inconsistent with the proper administration of the Area and enjoyment and protection of visitors and shall take such actions as are necessary to fully correct the situation.

(b)(3) The Concessioner shall, in addition to other laws and regulations which may be applicable to its operations, comply with applicable requirements of (i) Title VII of the Civil Rights Act of 1964, as well as Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, (ii) Title V, sections 503 and 504 of the Rehabilitation Act of September 26, 1973, Public Law 93–112 as amended in 1978, (iii) 41 CFR part 60–2 which prescribes affirmative action requirements for contractors and subcontractors, (iv) the Age Discrimination in Employment Act of December 15, 1967 (Pub. L. 90–202), as amended by (Pub. L. 95–256) of April 6, 1978, and (v) the Architectural Barriers Act of 1968 (Pub. L. 90–480). The Concessioner shall also comply with regulations heretofore or hereafter promulgated, relating to nondiscrimination in employment and providing accessible facilities and services to the public including those set forth in Exhibit "A" attached hereto and made a part hereof.

Sec. 4. Government Land and Improvements (a)(1) The Secretary hereby assigns for use by the Concessioner during the term of this Contract, certain parcels of land, if any (as described in Exhibit "B" hereto), and Government Improvements, if any (as described in Exhibit "C" hereto), appropriate to conduct operations hereunder.

(a)(2) The Secretary reserves the right to withdraw such assignments or parts thereof at any time during the term of this Contract if, in his judgement, (i) such withdrawal is for the purpose of enhancing or protecting area resources or visitor enjoyment or safety, or (ii) the operations utilizing such assigned lands or buildings are terminated pursuant to Section 12 hereof.

(a)(3) Any permanent withdrawal of assigned lands or Government Improvements which are essential for conducting the operation authorized hereunder will be considered by the Secretary as a termination of this Contract pursuant to Section 12 hereof. The Secretary shall compensate the Concessioner for any Possessory Interest it may have in such properties permanently withdrawn pursuant to section 13 hereof.

(b)(1) "Government Improvements" as used herein, means the buildings, structures, utility systems, fixtures, equipment, and other improvements affixed to or resting upon the lands assigned hereunder in such manner as to be part of the realty, if any, constructed or acquired by the Secretary and assigned to the Concessioner by the Secretary for the purposes of this Contract.

(b)(2) The Concessioner shall have a Possessory Interest to the extent provided elsewhere in this Contract in capital improvements (as hereinafter defined) it makes to Government Improvements (excluding improvements made from funds from any Section 10 accounts) with the written permission of the Secretary. In the event that such Possessory Interest is acquired by the Secretary or a successor concessioner at any time, the Concessioner will be compensated for such Possessory Interest pursuant to section 13 hereof.

(c) The Secretary shall have the right at any time to enter upon the lands and improvements utilized by the Concessioner hereunder for any purposes he may deem reasonably necessary for the administration of the Area.

(d) The Concessioner may construct or install upon assigned lands such buildings, structures, and other improvements as are necessary for operations hereunder, subject to the prior written approval by the Secretary of the location, plans, and specifications thereof. The Secretary may prescribe the form and contents of the application for such approval. The desirability of any project as well as the location, plans and specifications thereof will be reviewed in accordance with applicable provisions of the National Environmental Policy Act of 1969 and the National Historic Preservation Act of 1966, among other requirements.

(e) If, during the term of this Contract, a Government Improvement requires capital improvement (major repairs and/or improvements that serve to prolong the life of the Government Improvement to an extent requiring capital investment for major repair), such capital improvements shall be made by the Concessioner at its expense if consistent with a reasonable opportunity for the Concessioner to realize a profit as described above. Where capital improvements to other Government facilities which directly support the Concessioner's operations under this Contract are determined by the Secretary to be necessary for the accommodation of Area visitors, such improvements shall be made by the Concessioner at its expense unless the Secretary determines that expenditures for such improvements are inconsistent with a reasonable opportunity for the Concessioner to realize a profit as described above.

Sec. 5. Maintenance (a) Subject to section 4(e) hereof, the Concessioner will physically maintain and repair all facilities (both Government Improvements and Concessioner Improvements) used in operations under this Contract, including maintenance of assigned lands and all necessary housekeeping activities associated with such operations, to the satisfaction of the Secretary.

(b) In order to implement these requirements, the Secretary, acting through the Superintendent, shall undertake appropriate inspections, and, in consultation with the Concessioner, shall establish and revise as circumstances warrant a Maintenance Plan consisting of specific maintenance requirements which shall be adhered to by the Concessioner. However, such Maintenance Plan shall not amend or

[4] This should be used only in contracts involving lodging.

alter the material rights and liabilities of the parties to this Contract.

Sec. 6. Concessioner's Improvements (a)(1) "Concessioner Improvements," as used herein, means buildings, structures, fixtures, equipment, and other improvements, affixed to or resting upon the lands assigned hereunder in such manner as to be a part of the realty, provided by the Concessioner for the purposes of this Contract (excluding improvements made to Government Improvements and improvements made from funds in any Section 10 accounts), as follows: (i) Such improvements upon the lands assigned at the date hereof as described in Exhibit "D" hereto; and (ii) all such improvements hereafter constructed upon or affixed to the lands assigned to the Concessioner with the written consent of the Secretary.

(a)(2) Concessioner Improvements do not include any interest in the land upon which the improvements are located.

(a)(3) Any salvage resulting from the authorized removal, severance or demolition of a Concessioner Improvement or any part thereof shall be the property of the Concessioner.

(a)(4) In the event that a Concessioner Improvement is removed, abandoned, demolished, or substantially destroyed and no other improvement is constructed on the site, the Concessioner, at its expense, shall promptly, upon the request of the Secretary, restore the site as nearly as practicable to its original condition.

(b)(1) The Concessioner shall have a Possessory Interest, as defined herein, in Concessioner Improvements to the extent provided by the Contract.

(b)(2) Possessory Interest in Concessioner Improvements or Government Improvements shall not be extinguished by the expiration or other termination of this Contract, and may not be terminated or taken for public use without just compensation as determined in accordance with Section 13. Performance of the obligations assumed by the Secretary under Section 13 hereof shall constitute just compensation with respect to the taking of Possessory Interest.

(c)(1) Possessory Interest, as the term is used in this Contract, shall consist of all incidents of ownership in capital improvements made by the Concessioner, except legal title which shall be vested in the United States and subject to other limitations as set forth in this Contract. Particularly, among other matters, the existence of Possessory Interest shall not be construed to include or imply any authority, privilege, or right to operate or engage in any business or other activity, and the use or enjoyment of any structure, fixture or improvement in which the Concessioner has a Possessory Interest shall be wholly subject to the applicable provisions of this Contract and to the laws and regulations relating to the Area.

Sec. 7. Utilities (a) The Secretary may furnish utilities to the Concessioner for use in connection with the operations authorized under this Contract when available at reasonable rates to be fixed by the Secretary in his discretion. Such rates which shall at least equal the actual cost of providing the utility or service unless a reduced rate is provided for in an established policy of the Secretary in effect at the time of billing.

(b) Should the Secretary not provide such utilities, the Concessioner shall, with the written approval of the Secretary and under such requirements as the Secretary shall prescribe, secure necessary utilities at its own expense from sources outside the Area or shall install the same within the Area with the written permission of the Secretary, subject to the following conditions:

(i) Any water rights deemed necessary by the Concessioner for use of water on Federal lands shall be acquired at its expense in accordance with applicable State procedures and law. Such water rights, upon expiration or termination of this Contract for any reason shall be assigned to and become the property of the United States without compensation;

(ii) Any utility service provided by the Concessioner under this Section shall, if requested by the Secretary, be furnished to the Secretary to such extent as will not unreasonably restrict anticipated use by the Concessioner. The rate per unit charged the Secretary for such service shall be approximately the average cost per unit of providing such service; and

(iii) All appliances and machinery to be used in connection with the privileges granted in this Section, as well as the plans for location and installation of such appliances and machinery, shall first be approved by the Secretary.

Sec. 8. Accounting Records and Reports (a) The Concessioner shall maintain an accounting system whereby its accounts can be readily identified with its system of accounts classification. The Concessioner shall submit annually as soon as possible but not later than _____(_____) days after the _____day of _____a financial statement for the preceding year or portion of a year as prescribed by the Secretary, and such other reports and data, including, but not limited to, operations information, as may be required by the Secretary. Such information are subject to public release to the extent authorized by law or established policies and procedures of the Secretary. The Concessioner's system of accounts classification shall be directly related to the Concessioner Annual Report Form issued by the Secretary. If the annual gross receipts of the Concessioner are in excess of $1,000,000, the financial statements shall be audited by an independent certified public accountant or by an independent licensed public accountant certified or licensed by a regulatory authority of a State or other political subdivision of the United States on or before December 31, 1970, in accordance with the auditing standards and procedures promulgated by the American Institute of Certified Public Accountants. If annual gross receipts are between $250,000, and $1,000,000, the financial statements shall be reviewed by an independent certified public accountant or by a licensed public accountant certified or licensed by a regulatory authority of a State or other political subdivision of the United States on or before December 31, 1970, in accordance with the auditing standards and procedures promulgated by the American Institute of Certified Public Accountants. If annual gross receipts are less than $250,000, the financial statements may be prepared without involvement by an independent certified or licensed public accountant, unless otherwise directed by the Secretary.

If the Concessioner is required to have its annual financial statement (Concessioner Annual Financial Report) audited or reviewed, the Concessioner must use the accrual accounting method. In addition, it must include in its annual financial statement (Concessioner Annual Financial Report) a footnote that reconciles its annual financial statement to its Federal income tax returns.

(b) [5] Within ninety (90) days of the execution of this Contract or its effective date, whichever is later, the Concessioner shall submit to the Secretary a balance sheet as of the beginning date of the term of this Contract. The balance sheet shall be audited by an independent certified public accountant or by an independent licensed public accountant, certified or licensed by a regulatory authority of a

[5] Optional: Subsection 8(b), in its entirety, may be excluded where the Concessioner has no acquired possessory interest assets involved and no balance sheet is required.

State or other political subdivision of the United States on or before December 31, 1970. The balance sheet shall be accompanied by a schedule that identifies and provides details for all assets in which the Concessioner claims a Possessory Interest. The schedule must describe these assets in detail showing for each such asset the date acquired, useful life, cost and book value.

(c) The Secretary and Comptroller General of the United States, or any of their duly authorized representatives, shall at any time up until the expiration of five (5) calendar years after the expiration of this Contract, have access to and the right to examine any of the Concessioner's pertinent books, documents, papers, and records, including Federal and State income tax returns (collectively "documents"), and such documents of any subconcessioner related to this Contract, and, such documents of any proprietary or affiliate companies of the Concessioner.

Sec. 9. Fees For the term of this Contract, the Concessioner shall pay to the Secretary for the privileges granted herein, fees as follows:

(a)(1)[6] An annual fee for the use of Government Improvements assigned to the Concessioner, if any. Such fee and related Government Improvement shall be identified in Exhibit "C" hereto, and the fee may be adjusted annually by the Secretary to equal the fair annual value of the related Government Improvement as determined by the Secretary.

(a)(2) In addition to the foregoing, a franchise fee equal to _____ percent (_____%) of the Concessioner's gross receipts, as herein defined, for the preceding year or portion of a year.

(b) The franchise fee shall be due on a monthly basis at the end of each month and shall be paid by the Concessioner in such a manner that payment shall be received by the Secretary within 15 days after the last day of each month that the Concessioner operates. Such monthly payment shall include the annual use fee for assigned Government Improvements, as set forth in Exhibit "C" hereto, divided by the expected number of operating months, as well as the specified percentage of gross receipts for the preceding month. The payment of any additional amounts due at the end of the operating year as a result of adjustments shall be paid at the time of submission of the Concessioner's annual financial statement. Overpayments shall be offset against the following year's franchise fees due. All franchise fee payments consisting of $10,000 or more, shall be deposited electronically by the Concessioner using the Treasury Financial Communications System.

(c) An interest charge will be assessed on overdue amounts for each 30-day period, or portion thereof, that payment is delayed beyond the 15-day period provided for above. The percent of interest charged will be based on the current value of funds to the United States Treasury as published quarterly in the Treasury Fiscal Requirements Manual.

(d)(1) The term "gross receipts" as used in this Contract shall be mean the total amount received or realized by, or accruing to, the Concessioner from all sales for cash or credit, of services, accommodations, materials, and other merchandise made pursuant to the rights granted by this Contract, including gross receipts of subconcessioners as herein defined and commissions earned on contracts or agreements with other persons or companies operating in the Area, and excluding gross receipts from the sale of genuine United States Indian and native handicraft, intracompany earnings on account of charges to other departments of the operation (such as laundry), charges for employees' meals, lodgings, and transportation, cash discounts on purchases, cash discounts on sales, returned sales and allowances, interest on money loaned or in bank accounts, income from investments, income from subsidiary companies outside of the Area, sale of property other than that purchased in the regular course of business for the purpose of resale, and sales and excise taxes that are added as separate charges to approved sales prices, gasoline taxes, fishing license fees, and postage stamps, provided that the amount excluded shall not exceed the amount actually due or paid government agencies,[7] and amounts received as a result of an add-on to recover utility costs above comparable utility charges. All monies paid into coin operated devices, except telephones, whether provided by; the Concessioner or by others, shall be included in gross receipts. However, only revenues actually received by the Concessioner from coin-operated telephones shall be included in gross receipts.

(d)(2) The term "gross receipts of subconcessioners" as used in this Contract shall mean the total amount received or realized by, or accruing to, subconcessioners from all sources, as a result of the exercise of the rights conferred by subconcession contracts hereunder without allowances, exclusions or deductions of any kind or nature whatsoever and the subconcessioner shall report the full amount of all such receipts to the Concessioner within 45 days after the _____day of _____each year or portion of a year. Subconcessioners shall maintain an accurate and complete record of all items listed in Subsection (d)(1) of this Section as exclusions from the Concessioner's gross receipts and shall report the same to the Concessioner with the gross receipts. The Concessioner shall be entitled to exclude items listed in subsection (d)(1) in computing the franchise fee payable to the Secretary as provided for in subsection (a) hereof.

(e)(1) Immediately following the end of _____, _____, _____, and _____, year of this Contract, the amount and character of the franchise fees described in this Section and/or contributions to any accounts described in Section 10 hereof (Section 10 contributions) shall be reconsidered for a period of one hundred and eighty (180) days. During this reconsideration period, the Secretary or the Concessioner may propose adjustments to such franchise fees and/or section 10 contributions (which shall reflect their position as to the then current probable value of the privileges granted by this Contract based upon a reasonable opportunity for profit in relation to both gross receipts and capital invested) by mailing written notice to the other party of such proposal before the end of the reconsideration period. If no such notices are duly mailed, the reconsideration shall end and the fees and contributions shall remain the same until the occurrence of the next reconsideration period.

(e)(2) If the Secretary or the Concessioner duly makes a proposal to adjust the franchise fees and/or Section 10 contributions before the end of the reconsideration period, they shall, commencing the day after the end of the reconsideration period, undertake a good faith negotiation of the proposal. If such negotiation does not result in an agreement as to adjustments to the fees and/or contributions within sixty (60) days of its commencement, this negotiation period shall end and any adjustments determined by the Secretary as of that time shall go into effect, provided that, the Concessioner

[6] This subsection should be used if a building use fee is to be charged. If a special account is to be established under section 10(a) in lieu of a building use fee, this subsection should be deleted.

[7] Note to Preparer: This means, for example, if fishing licenses are sold, $2.00 goes to State or Federal agency, $.25 goes to Concessioner. Only $2.00 can be excluded from gross receipts, i.e. fishing license cost to user $2.00 but concessioner sells them and charges $.25 for services.

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may extend this negotiation period by appealing such adjustments to the Secretary. Such appeal must be received by the Secretary within thirty (30) days after the end of the sixty day negotiation period. The appeal must be in writing and include the Concessioner's detailed position as to the validity of such adjustments to the fees and/or contributions. The Secretary, acting through a designee other than the official who determined the adjustments from which the Concessioner duly has appealed, shall consider the position of the Concessioner and related documents as appropriate, and, if applicable, the written views of the mediator as described below. The Secretary shall then make a written final determination of appropriate adjustments to franchise fees and/or Section 10 contributions consistent with the probable value to the concessioner of the privileges granted by this contract based upon a reasonable opportunity for profit in relation to both gross receipts and capital invested. This final determination, or, where applicable, a determination as to adjustments made at the end of the sixty day negotiation period described above from which the Concessioner fails to timely appeal, shall be conclusive and binding upon the parties to this Contract.

(e)(3) Adjustments to franchise fees and/or Section 10 contributions resulting from the process described herein shall be retroactive to the commencement of the applicable contract period for which a notice of reconsideration was given. Payments or contributions made in arrears shall include interest at a per cent based on the current value of funds to the United States Treasury as published quarterly in the Treasury Fiscal Requirements Manual. The adjustments shall also be effective for the remaining term of this Contract, subject to the results of any further reconsideration periods. If an adjustment to franchise fees and/or Section 10 contributions results in higher fees and/or contributions, the Concessioner will pay all back franchise fees due (with applicable interest) and make all section 10 contributions due (with applicable interest) at the time of the next regular franchise fee payment or Section 10 contribution respectively. If an adjustment results in lower fees and/or contributions, the Concessioner may withhold the difference from future franchise fee payments or Section 10 contributions until the Concessioner has recouped the overpayment. Adjustments to franchise fees and/or section 10 contributions will be embodied in an amendment to this Contract unless resulting from a determination of the Secretary without the agreement of the Concessioner in which event a copy of such determination shall be attached to this Contract and become a part hereof as if originally incorporated herein. During the pendency of the process described herein, the Concessioner shall continue to make the established franchise fee payments and/or Section 10 contributions required by this Contract.

(e)(4) In connection with an appeal to the Secretary hereunder, the Concessioner may request mediation of appropriate adjustments to franchise fees and/or Section 10 contributions by providing a written request for mediation with its appeal to the Secretary as described above. The mediation will be conducted by the American Arbitration Association (AAA) or a similar organization chosen by the Secretary and take place in Washington, DC. The purpose of the mediation shall be to provide for the Secretary's consideration during such appeal the views of the mediator as to appropriate adjustments of franchise fees and/or Section 10 contributions consistent with the probable value to the Concessioner of the privileges granted by this Contract based upon a reasonable opportunity for profit in relation to both gross receipts and capital invested. The written views of the mediator shall be provided to the Secretary within ninety (90) days of the request for mediation unless, because of extenuating circumstances, the Secretary determines that an extension of this time period is warranted. If such views are not provided within this time period (or a duly extended time period), the advisory mediation shall terminate and the Secretary shall make a determination on the appeal as if the mediation had not been requested. The Concessioner and the Secretary shall cooperate in good faith to permit the views of the mediator to be provided within the applicable time period. The Secretary and the Concessioner shall share equally the costs of the services of the mediator and the mediation organization. The views of the mediator are advisory only.

(e)(5) The mediator shall be selected by agreement between the Concessioner and the Secretary from a list provided by the mediation organization within ten (10) days of receipt. Promptly following the selection, the Secretary shall schedule a date for the mediation meeting to take place at which time the written positions of the Concessioner and the Secretary shall be presented to the mediator along with appropriate oral presentations unless advance submissions are agreed upon. The mediator shall not have the power to compel the production of documents or witnesses and shall not receive or take into account information or documents concerning positions taken by the Concessioner or the Secretary in the negotiations which preceded the request for mediation. The mediator shall consider the written submissions and any oral presentations made and provide his or her written views as described above to the Secretary within ninety (90) days of the request for mediation, or, if applicable, by the last day of a duly extended time period.

Sec. 10. Accounts [Two alternatives are presented for Section 10.]

*No Government Improvement or Capital Improvement Accounts are included in this Contract. [or]

(a) Government Improvement Account* (1) As consideration for the use and occupancy of Government Improvements herein provided, the Concessioner shall establish and manage a "Government Improvement Account." The funds in this account belong to the Concessioner, including interest earned thereon, but will be used by the Concessioner only to undertake on a project basis repairs and improvements to Government Improvements listed in Exhibit "C" to this Contract, as directed by the Superintendent in writing and in accordance with project priorities established by the Regional Director of the National Park Service. Expenditures from this account for repair and/or improvement projects in excess of $1,000,000 must receive the written approval of the National Park Service Director.

(a)(2) Projects paid for from the Government Improvement Account will not include routine, operational maintenance of facilities or housekeeping activities. Nothing in this Section shall lessen the responsibility of the Concessioner to carry out the maintenance and repair of Government Improvements as otherwise required by this Contract from Concessioner funds exclusive of funds contained in the Government Improvement Account, and, specifically, funds from such account shall not be used for the purposes of fulfilling the Concessioner's obligations under Sections 4 and 5 of this Contract. The Concessioner shall have no ownership, Possessory Interest, or other interest in improvements made

*This subsection should be used only when no special accounts are included in the contract.

*To be used in lieu of building use fee requirement in Section 9(a)(1) if a special account is to be established.

from funds from the Government Improvement Account.

(a)(3) The Concessioner shall deposit within fifteen (15) days after the last day of each month a sum equal to one-twelfth of the amount of the Government Improvement Account Allocation as established in Exhibit "C" into an interest bearing account(s) at a Federally insured financial institution(s). The account(s) shall be maintained separately from all other Concessioner funds, and, copies of monthly account statements shall be provided to the Secretary. The Concessioner shall submit annually, no later than _____ of the year following the Concessioner's accounting year, a statement reflecting total activity in the Government Improvement Account for the preceding accounting year. The statement shall reflect monthly credits, expenses by project, and the interest earned. The balance in the Government Improvement Account shall be available for projects in accordance with the account's purpose. Advances or credits to the account by the Concessioner will not be allowed. Projects will be carried out by the Concessioner as the Superintendent shall direct in writing in advance of any expenditure being made. For all expenditures made for each project from the account, the Concessioner shall maintain auditable records including invoices, billings, cancelled checks, and other documentation satisfactory to the Secretary. An interest charge will be assessed on overdue deposits for each thirty (30) day period, or portion thereof, that the deposit is delayed beyond the fifteen (15) day period provided for herein. The per cent of interest charged will be based on the then current value of funds to the U.S. Treasury as published in the Treasury Fiscal Requirements Manual.

(a)(4) Upon the expiration or termination of this Contract, or upon assignment or sale of interests related to this Contract, the unexpended balance remaining in the Government Improvement Account shall be expended by the Concessioner for approved projects, or, shall be remitted by the Concessioner to the Secretary in such a manner that payment shall be received by the Secretary within fifteen (15) days after the last day of the Concessioner's operation. Any payment consisting of $10,000 or more shall be deposited electronically by the Concessioner using the Treasury Financial Communications System. An interest charge will be assessed on overdue amounts for each thirty (30) day period, or portion thereof, that payment is delayed beyond the fifteen (15) day period provided for herein. The percent of interest charged will be based on the then current value of funds to the United States Treasury which is published quarterly in the Treasury Fiscal Requirements Manual.

(b) Capital Account (1) As partial consideration for the privileges granted by this Contract, the Concessioner shall establish a "Capital Account" by which it will undertake, on a project basis, improvements which directly support the Concessioner's operations hereunder. Funds in the Capital Account, including interest earned thereon, belong to the Concessioner but shall be used by the Concessioner only for construction of qualified improvements approved by the Superintendent in accordance with priorities established by the National Park Service Regional Director. Projects estimated to cost over $1,000,000 must be approved by the Director.

(b)(2) Improvements paid for with funds from the Capital Account will not include routine, operational maintenance of facilities or housekeeping activities. Nothing in this Section shall lessen the responsibility of the Concessioner to carry out the maintenance and repair of Government Improvements as required by Sections 4 and 5 of this Contract, or otherwise, from Concessioner funds exclusive of those funds contained in the Capital Account. Funds in the Capital Account shall not be used for purposes for which those Sections would apply. The Concessioner shall have no ownership, Possessory Interest or other interest in improvements made from Capital Account funds.

(b)(3) The Concessioner shall deposit within fifteen (15) days after the last day of each month that the Concessioner operates a sum ("SUM") equal to _____. Percent (_____%) of the Concessioner's Gross Receipts for the previous month, as defined in this Contract, into an interest bearing account(s) at a Federally insured financial institution(s). The account(s) shall be maintained separately from all other Concessioner funds and copies of monthly account statements shall be provided to the Secretary. An interest charge will be assessed on overdue deposits for each thirty (30) day period, or portion thereof, that the deposit is delayed beyond the fifteen (15) day period provided for herein. The percent of interest charged will be based on the then current value of funds to the U.S. Treasury as published in the Treasury Fiscal Requirements Manual.

(b)(4) The Concessioner shall submit annually, no later than _____, of the year following the Concessioner's accounting year a statement reflecting total activity in the Capital Account for the preceding accounting year. The statement shall reflect monthly credits, expenses by project, and the interest earned.

(b)(5) Advances or credits to the Capital Account by the Concessioner are not permitted. Projects will be carried out by the Concessioner as the Superintendent shall direct in writing and in advance of any expenditure being made. For all expenditures made for each project from Capital Account funds, the Concessioner shall maintain adaptable records including invoices, billings, canceled checks, and other documentation satisfactory to the Secretary.

(b)(6) Upon the expiration or termination of this Contract, or upon assignment or sales of interests related to this Contract, the unexpended balance remaining in the Capital Account shall be expended by the Concessioner for approved Projects, or, shall be remitted by the Concessioner to the Secretary in such a manner that payment shall be received by the Secretary within fifteen (15) days after the last day of the Concessioner's operation. Any payment consisting of $10,000 or more shall be deposited electronically by the Concessioner using the Treasury Financial Communications System. An interest charge will be assessed overdue amounts for each thirty (30) day period, or portion thereof, that payment is delayed beyond the fifteen (15) day period provided for herein. The percent of interest charged will be based on the current value of funds to the United States Treasury which is published quarterly in the Treasury Fiscal Requirements Manual.

Sec. 11. Bond and Lien. The Secretary may, in his discretion, require the Concessioner to furnish a surety bond acceptable to the Secretary conditioned upon faithful performance of this Contract, in such form and in such amount as the Secretary may deem adequate, not in excess of _____ Dollars ($_____).[10] As additional security for the faithful performance by the Concessioner of all of its obligations under this Contract, and the payment to the Government of all damages or claims that may result from the Concessioner's failure to observe such obligations, the Government shall have at all times the first lien on all assets of the Concessioner within the Area.

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[10] *Note to Preparer:* If a bond is required it should not, under normal conditions, exceed the amount of franchise fees which may be due. Leave blank where there has been no past operator because no dollar amount can be determined.

Sec. 12. Termination. (a)(1) The Secretary may terminate this Contract in whole or part for default at any time and may terminate this Contract in whole or part when necessary for the purpose of enhancing or protecting Area resources or visitor enjoyment or safety.

(a)(2) Operations under this Contract may be suspended in whole or in part at the discretion of the Secretary when necessary to enhance or protect Area resources or visitor enjoyment or safety.

(a)(3) Termination or suspension shall be by written notice to the Concessioner and, in the event of proposed termination for default, the Secretary shall give the Concessioner a reasonable period of time to correct stated deficiencies.

(a)(4) Termination for default may be utilized in circumstances where Concessioner has breached any requirement of this Contract, including, but not limited to, failure to maintain and operate accommodations, facilities and services to the satisfaction of the Secretary in accordance with the Secretary's requirements hereunder.

(b) In the event of termination or expiration of this Contract, the total compensation to the Concessioner for such termination or upon expiration shall be as described in Section 13 ("Compensation") of this Contract.

(c) In the event it is deemed by the Secretary necessary to suspend operations under this Contract in whole or in part to enhance or protect Area resources or visitor enjoyment or safety, the Secretary shall not be liable for any compensation to the Concessioner for losses occasioned thereby, including but not limited to, lost income, profit, wages, or other monies which may be claimed.

(d) To avoid interruption of services to the public upon the expiration or termination of this Contract for any reason, the Concessioner, upon the request of the Secretary, shall (i) continue to conduct all operations hereunder for a reasonable period of time to allow the Secretary to select a successor concessioner, or (ii) consent to the use by a temporary operator, designated by the Secretary, of Concessioner Improvements and personal property, if any, not including current or intangible assets, used in operations hereunder upon fair terms and conditions, provided that the Concessioner shall be entitled to an annual fee for the use of such improvements and personal property, prorated for the period of use, in the amount of the annual depreciation of such improvements and personal property, plus a return on the book value of such improvements and personal property equal to the prime lending rate, effective on the date the temporary operator assumes managerial and operational responsibilities, as published by the Federal Reserve System Board of Governors or as agreed upon by the parties involved. In such circumstances, the method of depreciation applied shall be either straight line depreciation or depreciation as shown on the Concessioner's Federal income tax return.

SEC. 13. Compensation (a) Just Compensation: The compensation described in this Section shall constitute full and just compensation to the Concessioner from the Secretary for all losses and claims occasioned by the circumstances described below.

(b) Contract expiration or termination where operations are to be continued: (b)(1) If, for any reason, including Contract expiration or termination as described herein, the Concessioner shall cease to be required by the Secretary to conduct operations hereunder, or substantial part thereof, and, at the time of such event the Secretary intends for substantially the same or similar operations to be continued by a successor, whether a private person, corporation or an agency of the Government; (i) the Concessioner shall sell and transfer to the successor designated by the Secretary its Possessory Interest in Concessioner Improvements and Government Improvements, if any, as defined under this Contract, and all other tangible property of the Concessioner used or held for use in connection with such operations; and, (ii) the Secretary will require such successor to purchase from the Concessioner such Possessory Interest, if any, and such other property, and to pay the Concessioner the fair value thereof.

(b)(2) The initial fair value of any Possessory Interest in Concessioner Improvements in existence before the effective date of this Contract shall be $_____as of the effective date of this Contract. This initial fair value amount shall annually decrease by _____[11] of this amount. In the event of Contract termination or expiration, the Concessioner's right to fair value for such Possessory Interest shall be the amount not yet so decreased. The fair value of any Possessory Interest in Government Improvements in existence before the effective date of this Contract shall be the book value of the improvements as of the last day of the contract under which such Possessory Interest was obtained, subject to further reduction pursuant to the applicable depreciation schedule of such improvements.

(b)(3) The fair value of Possessory Interest in Concessioner Improvements and Government Improvements made after the effective date of this Contract shall be, unless calculated in accordance with section 13(d) hereof, the original cost of the improvements less straight line depreciation over the estimated useful life of the asset according to Generally Accepted Accounting Principles, provided, however, that in no event shall any such useful life exceed 30 years. In the event that such Possessory Interest is acquired by a successor, the successor will not be permitted to revalue such Possessory Interest, or, alter its depreciation schedule or useful life.

(b)(4) The fair value of merchandise and supplies shall be actual cost including transportation.

(b)(5) The fair value of equipment shall be its book value.

(c) Contract expiration or termination where operations are to be discontinued: If for any reason, including Contract expiration or termination as described herein, the Concessioner shall cease to be required by the Secretary to conduct operations hereunder, or substantial part thereof, and the Secretary at the time chooses to discontinue such operations, or substantial part thereof, within the Area, and/or to abandon, remove, or demolish any Concessioner Improvements, if any, then the Secretary will take such action as may be necessary to assure the Concessioner of compensation for (i) its Possessory Interest in Concessioner Improvements and Government Improvements, if any, in the applicable amount as set forth in Section 13(b) hereof; (ii) the cost to the Concessioner of restoring any assigned lands to a natural condition, including removal and demolition, (less salvage) if required by the Secretary; and (iii) the cost of transporting to a reasonable market for sale such movable property of the Concessioner as may be made useless by such determination. Any such property that has not been removed by the Concessioner within a reasonable time following such determination shall become the property of the United States without further compensation therefor.

(d) Contract Termination for Default for Unsatisfactory Performance. Notwithstanding any other provision of

[11] In usual circumstances, the amount by which possessory interest will be reduced annually will be 1/30th (i.e., over 30 years). However, as our policy is to extinguish possessory interests as quickly as possible, taking into consideration the useful life of the facilities, a shorter period of time should be established when the economic conditions permit.

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this Contract to the contrary, in the event of termination of this Contract for default for failure to maintain and operate accommodations, facilities and services hereunder to the satisfaction of the Secretary in accordance with the Secretary's requirements, compensation for Possessory Interest in Concessioner Improvements, if any, except for Possessory Interest in Concessioner Improvements in existence before the effective date of this Contract, shall be as set forth in Section 13(b) hereof or at book value, whichever is less.

Sec. 14. Assignment, Sale or Encumbrance of Interests. (a) Pursuant to this section and 36 CFR part 51, the Concessioner and/or any person or entity which owns a controlling interest (as is or as may be defined in 36 CFR part 51) in a Concessioner's ownership, (collectively defined as the "Concessioner" for the purposes of this Section) shall not assign or otherwise sell or transfer responsibilities under this Contract or concession operations hereunder, or the Concessioner's assets in the concession operation, nor sell or otherwise assign, transfer or encumber (including, without limitation, mergers, consolidations, reorganizations, other business combinations, mortgages, liens or collateral) a controlling interest in such operations, this Contract, or a controlling interest in the Concessioner's ownership or assets (as is or as may be defined in 36 CFR part 51), without the prior written approval of the Secretary.

(a)(2) Such approval is not a matter of right and is further subject to the requirements of 36 CFR part 51 (as are or as may be set forth therein). The Secretary will exercise his discretion as to whether and/or under what conditions a proposed transaction will be approved in accordance with established policies and procedures.

(a)(3) Failure to comply with this provision or the procedures described herein shall constitute a material breach of this Contract for which this Contract may be terminated immediately by the Secretary without regard to the procedures for termination for default described in Section 12 hereof, and, the Secretary shall not be obliged to recognize any right of any person or entity to an interest in this Contract or to own or operate operations hereunder acquired in violation hereof.

(b) The Concessioner shall advise the person(s) or entity proposing to enter into a transaction which is subject to this Section that the Secretary shall be notified and that the proposed transaction is subject to review and approval by the Secretary. The Concession shall request in writing the Secretary's approval of the proposed transaction prior to consummation and shall promptly provide the Secretary all relevant documents related to the transaction, and the names and qualifications of the person(s) or entity involved in the proposed transaction. The relevant documents shall be as described in 36 CFR Part 51 but shall also include other documents as the Secretary may require.

(c) The Concessioner may not enter into any agreement with any entity or person except employees of the Concessioner to exercise substantial management responsibilities for operations hereunder or any part hereof without the written approval of the Secretary given at least thirty (30) days in advance of such transaction.

(d) No mortgage shall be executed, and no bonds, shares of stock or other evidence of interest in, or indebtedness upon, the rights and/or properties of the Concessioner, including this Contract, in the Area, shall be issued without prior written approval of the Secretary. Approval of such encumbrances shall be granted only for the purposes of installing, enlarging or improving, plant equipment and facilities, provided that, such rights and/or properties, including possessory interests, or evidences of interests therein, in addition, may be encumbered for the purposes of purchasing existing concession plant, equipment and facilities. In the event of default on such a mortgage, encumbrance, or such other indebtedness, or of other assignment, transfer, or encumbrance, the creditor or any assignee thereof, shall succeed to the interest of the Concessioner in such rights and/or properties but shall not thereby acquire operating rights or privileges which shall be subject to the disposition of the Secretary.

Sec. 15. Approval of Subconcession Contracts. All contracts and agreements (other than those subject to approval pursuant to Section 14 hereof) proposed to be entered into by the Concessioner with respect to the exercise by others of the privileges granted by this Contract in whole or part shall be considered as subconcession contracts and shall be submitted in advance of execution to the Secretary for his approval and shall be effective only if approved. However, agreements with others to provide vending or other coin-operated machines shall not be considered as subconcession contracts. In the event any such subconcession contract or agreement is approved the Concessioner shall pay to the Secretary within _____ days after the _____ day of _____ each year or portion of a year a sum equal to Fifty Percent (50%) of any and all fees, commissions or compensation payable to the Concessioner thereunder, which shall be in addition to the franchise fee payable to the Secretary on the gross receipts of subconcessioners as provided for in Section 9 of this contract.

Sec 16. Insurance and Indemnity. (a)(1) General. The Concessioner shall save, hold harmless, defend and indemnify the United States of America, its agents and employees for losses, damages or judgments and expenses on account of fire or other peril, bodily injury, death or property damage, or claims for bodily injury, death or property damage or any nature whatsoever, and by whomsoever made, arising out of the activities of the Concessioner, his employees, subcontractors or agents under this Contract.

(a)(2) The types and amounts of insurance coverage purchased by the Concessioner shall be approved by the Secretary.

(a)(3) At the request of the Secretary, the Concessioner shall annually, or at the time insurance is purchased, provide the Secretary with a Statement of Concessioner Insurance and Certificate of Insurance as evidence of compliance with this section and shall provide the Secretary thirty (30) days advance written notice of any material change in the Concessioner's insurance program hereunder.

(a)(4) The Secretary will not be responsible for any omissions or inadequacies of insurance coverages and amounts in the event the insurance purchased by the Concessioner proves to be inadequate or otherwise insufficient for any reason whatsoever.

(b) Property Insurance. (b)(1) The Concessioner will, in the event of damage or destruction, repair or replace those buildings, structures, equipment, furnishings, betterments and improvements and merchandise determined by the Secretary to be necessary to satisfactorily discharge the Concessioner's obligations under this Contract and for this purpose shall provide fire and extended insurance coverage on both Concessioner Improvements and Government Improvements in such amounts as the Secretary may require during the term of the Contract. Those values currently in effect are set forth in Exhibit "E" to this Contract. This exhibit will be revised at least every 3 years, or sooner, if there is a substantial increase in value.

(b)(2) Such insurance shall provide for the Concessioner and the United States of America to be named insured as their interests may appear. In the

event of loss, the Concessioner shall use all proceeds of such insurance to repair, rebuild, restore or replace Concessioner Improvements and Government Improvements, equipment, furnishings and other personal property hereunder, as directed by the Secretary. The lien provision of Section 11 shall apply to such insurance proceeds.

The Concessioner shall purchase the following additional property coverages in the amounts set forth in Exhibit "E":

1. Boiler and machinery
2. Sprinkler leakage
3. Builders' risk
4. Flood
5. Earthquake
6. Hull
7. Extension-of-coverage endorsement

(c) Additional Property Damage Requirements—Government Improvements, Property and Equipment. The following additional requirements shall apply to structures all or any part of which are Government Improvements as defined in this Contract.

(c)(1) The insurance policy shall contain a loss payable clause approved by the Secretary which requires insurance proceeds to be paid directly to the Concessioner without requiring endorsement by the United States.

(c)(2) The use of insurance proceeds for repair or replacement of Government Improvements will not alter their character as Government Improvements and, notwithstanding any provision of this Contract to the contrary, the Concessioner shall gain no Possessory Interest therein.

(d) Public Liability. (d)(1) The Concessioner shall provide Comprehensive General Liability insurance against claims occasioned by actions or omissions of the Concessioner in carrying out the activities and operation authorized hereunder.

(d)(2) Such insurance shall be in the amount commensurate with the degree of risk and the scope and size of such activities authorized herein, but in any event, the limits of liability shall not be less than ($_____) per occurrence covering both bodily injury and property damage. If claims reduce available insurance below the required per occurrence limits, the Concessioner shall obtain additional insurance to restore the required limits. An umbrella or excess liability policy, in addition to a Comprehensive General Liability Policy, may be used to achieve the required limits.

(d)(3) From time to time, as conditions in the insurance industry warrant, the Secretary reserves the right to revise the minimum required limits.

(d)(4) All liability policies shall specify that the insurance company shall have no right of subrogation against the United States of America or shall provide that the United States of America is named an additional insured.

(d)(5) The Concessioner shall also obtain the following additional coverages at the same limits as required for Comprehensive General Liability insurance unless other limits are specified below:

(1) *Product Liability*—Amount ($_____)
(2) *Liquor Legal Liability*—Amount ($_____)
(3) *Protection and Indemnity (Watercraft Liability)*—Amount ($_____)
(4) *Automobile Liability*—To cover all owned, non-owned, and hired vehicles—Amount ($_____)
(5) *Garage Liability*—Amount ($_____)
(6) *Workers' Compensation*
(7) *Aircraft Liability*—Amount ($_____)
(8) *Fire Damage Legal Liability*—Amount ($_____)
(9) Other

Sec. 17. Procurement of Goods, Equipment and Services. In computing net profits for any purposes of this Contract, the Concessioner agrees that its accounts will be kept in such manner that there will be no diversion or concealment of profits in the operations authorized hereunder by means of arrangements for the procurement of equipment, merchandise, supplies or services from sources controlled by or under common ownership with the Concessioner or by any other device.

Sec. 18. General Provisions. (a) Reference in this Contract to the "Secretary" shall mean the Secretary of the Interior, and the term shall include his duly authorized representatives.

(b) The concessioner is not entitled to be awarded or to have negotiating rights to any Federal procurement or service contract by virtue of any provision of the contract.

(c) Notwithstanding any other provision hereof, the Secretary reserves the right to provide directly or through cooperative or other non-concession agreements with non-profit organizations, any accommodations, facilities or services to Area visitors which are part of and appropriate to the Area's interpretive program.

(d) That any and all taxes which may be lawfully imposed by any State or its political subdivisions upon the property or business of the Concessioner shall be paid promptly by the Concessioner.

(e) No member of, or delegate to, Congress or Resident Commissioner shall be admitted to any share or part of this Contract or to any benefit that may arise herefrom but this restriction shall not be construed to extend to this Contract if made with a corporation or company for its general benefit.

(f) This Contract may not be extended, renewed or amended in any respect except when agreed to in writing by the Secretary and the Concessioner.

In witness whereof, the parties hereto have hereunder subscribed their names and affixed their seals.

Dated at _____, this _____ day of 19 ___.

UNITED STATES OF AMERICA

By _____,
Regional Director, National Park Service.

Corporations

Attest:
By _____
By _____
Title _____
Date _____

_____
(Concessioner)

By _____
By _____
Title _____
Date _____

Sole Proprietorship

Witnesses:
Name _____
Address _____
Name _____
Address _____
Date _____

_____
(Concessioner)

_____
(Name)

_____
(Title)

Partnership

Witnesses as to each:
Name _____
Address _____
Name _____
Address _____

_____
(Concessioner)

_____
(Name)

_____
(Name)
Date _____

Exhibit "A"

Nondiscrimination

Section I—Requirements Relating to Employment and Service to the Public

Concession Authorization No.: ———

A. Employment: During the performance of this Contract the Concessioner agrees as follows:

(1) The Concessioner will not discriminate against any employee or applicant for employment because of race, color, religion, sex, age, national origin or disabling condition. The Concessioner will take affirmative action to ensure that applicants are employed, and that employees are treated during employment, without regard to their race, color, religion, sex, age, national origin or disabling condition. Such action shall include, but not be limited to, the following: Employment upgrading, demotion or transfer: recruitment or recruitment advertising; layoff or termination; rates of pay or other forms of compensation; and selection for training, including apprenticeship. The Concessioner agrees to post in conspicuous places available to employees and applicants for employment, notices to be provided by the Secretary setting forth the provisions of this nondiscrimination clause.

(2) The Concessioner will, in all solicitations or advertisements for employees placed by or on behalf of the Concessioner, state that all qualified applicants will receive consideration for employment without regard to race, color, religion, sex, age, national origin or disabling condition.

(3) The Concessioner will send to each labor union or representative of workers with which the Concessioner has a collective bargaining agreement or other contract or understanding, a notice, to be provided by the Secretary, advising the labor union or workers' representative of the Concessioner's commitments under Section 202 of Executive Order 11246 of September 24, 1965, as amended by Executive Order 11375 of October 13, 1967, and shall post copies of the notice in conspicuous places available to employees and applicants for employment.

(4) Within 120 days of the commencement of a contract every Government contractor or subcontractor holding a contract that generates gross receipts which exceed $50,000 or more and having 50 or more employees shall prepare and maintain an affirmative action program at each establishment which shall set forth the contractor's policies, practices and procedures in accordance with the affirmative action program requirement.

(5) The Concessioner will comply with all provisions of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and of the rules, regulations, and relevant orders of the Secretary of Labor.

(6) The Concessioner will furnish all information and reports required by Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and by the rules, regulations, and orders of the Secretary of Labor, or pursuant thereto, and will permit access to the concessioner's books, records, and accounts by the Secretary of the Interior and the Secretary of Labor for purposes of investigation to ascertain compliance with such rules, regulations, and orders.

(7) In the event of the Concessioner's noncompliance with the nondiscrimination clauses of this Contract or with any of such rules, regulations, or orders, this Contract may be canceled, terminated, or suspended in whole or in part and the Concessioner may be declared ineligible for further Government concession contract in accordance with procedures authorized in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, and such other sanctions may be imposed and remedies invoked as provided in Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, or by rule, regulation, or order of the Secretary of Labor, or as otherwise provided by law.

(8) The Concessioner will include the provisions of paragraphs (1) through (7) in every subcontract or purchase order unless exempted by rules, regulations, or orders of the Secretary of Labor issued pursuant to Section 204 of Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, so that such provisions will be binding upon each subcontractor or vendor. The Concessioner will take such action with respect to any subcontract or purchase order as the Secretary may direct as a means of enforcing such provisions, including sanctions for noncompliance: Provided, however, that in the event the Concessioner becomes involved in, or is threatened with, litigation with a subcontractor or vendor as a result of such direction by the Secretary, the Concessioner may request the United States to enter into such litigation to protect the interest of the United States.

B. Construction, Repair, and Similar Contracts: The preceding provisions A (1) through (8) governing performance of work under this Contract, as set out in Section 202 of Executive Order No. 11246, dated September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, shall be applicable to this Contract, and shall be included in all contracts executed by the Concessioner for the performance of construction, repair, and similar work contemplated by this contract, and for the purpose the term "Contract" shall be deemed to refer to this instrument and to contracts awarded by the Concessioner and the term "Concessioner" shall be deemed to refer to the Concessioner and to contractors awarded contracts by the Concessioner.

C. Facilities: (1) Definitions: As used herein: (i) Concessioner shall mean the Concessioner and its employees, agents, lessees, subleases, and contractors, and the successors in interest of the Concessioner; (ii) facility shall mean any and all services, facilities, privileges, and accommodations, or activities available to the general public under this Contract.

(2) The Concessioner is prohibited from: (i) publicizing facilities operated hereunder in any manner that would directly of inferentially reflect upon or question the acceptability of any person because of race, color, religion, sex, age, national origin or disabling condition; (ii) discriminating by segregation or other means against any person because of race, color, religion, sex, age, national origin or disabling condition in furnishing or refusing to furnish such person the use of any such facility.

(3) The Concessioner shall post a notice in accordance with Federal regulations to inform the public of the provisions of this subsection, at such locations as will ensure that the notice and its contents will be conspicuous to any person seeking accommodations, facilities, services, or privileges. Such notice will be furnished the Concessioner by the Secretary.

(4) The Concessioner shall require provisions identical to those stated in subsection C herein to be incorporated in all of the Concessioner's contracts or other forms of agreement for use of land made in pursuance of this Contract.

Section II—Accessibility

Title V, Section 504 of the Rehabilitation Act of 1973, as amended in 1978, requires that action be taken to assure that any "program" or "service" being provided to the general public be provided to the highest extent reasonably possible to individuals who are mobility impaired, hearing

impaired, and visually impaired. It *does not* require architectural access to every building or facility, but only that the service or program can be provided somewhere in an accessible location. It also allows for a wide range of methods and techniques for achieving the intent of the law and calls for consultation with disabled persons in determining what is reasonable and feasible.

No handicapped person shall, because a Concessioner's facilities are inaccessible to or unusable by handicapped persons, be denied the benefits of, be excluded from participation in, or otherwise be subject to discrimination under any program or activity receiving Federal financial assistance or conducted by any Executive agency or by the U.S. Postal Service.

Part A—Discrimination Prohibited

A Concessioner, in providing any aid, benefit, or service, may not directly or through contractual, licensing, or other arrangements, on the basis of handicap:

1. Deny a qualified handicapped person the opportunity to participate in or benefit from the aid, benefit, or service;

2. Afford a qualified handicapped person an opportunity to participate in or benefit from the aid, benefit, or service that is not equal to that afforded others;

3. Provide a qualified handicapped person with an aid, benefit, or service that is not as effective as that provided to others;

4. Provide different or separate aids, benefits, or services to handicapped persons or to any class of handicapped persons unless such action is necessary to provide qualified handicapped persons with aid, benefits, or services that are as effective as those provided to others;

5. Aid or perpetuate discrimination against a qualified handicapped person by providing significant assistance to any agency, organization, or person that discriminates on the basis of handicap in providing any aid, benefit, or services to beneficiaries of the recipient's program;

6. Deny a qualified handicapped person the opportunity to participate as a member of planning or advisory boards; or

7. Otherwise limit a qualified handicapped person in the enjoyment of any right, privilege, advantage or opportunity enjoyed by others receiving an aid, benefit, or service.

Part B—Existing Facilities

A Concessioner shall operate each program or activity so that the program or activity, when viewed in its entirety, is readily accessible to and usable by handicapped persons. This paragraph does not require a Concessioner to make each of its existing facilities or every part of a facility accessible to and usable by handicapped persons.

Exhibit "B"

Land Assignment

Note to Preparer: The land assignment may be described in narrative form and, if possible, should include a map showing the area(s) to be assigned.

Exhibit "C"

Government-owned Structures (Government Improvements) Assigned to

_____

(Concessioner)
Pursuant To
Concession Contract No.

Building No.	Description	Annual fee
		$

Total amount due pursuant to subsection —
Approved, effective _____
By:

Name of Concessioner

By _____
Title _____
United States of America

_____

Regional Director

_____

Region

Exhibit "D"

Pursuant to Subsection 6(a)(1)

Note to preparer: If the Concessioner has no Possessory Interest assets, put *"NONE"* on this page. You will *ALWAYS* use this EXHIBIT, either with a schedule of possessory interest assets, or with the words "NONE", but *NEVER LEAVE THIS EXHIBIT OFF THE CONTRACT.*

Exhibit "E"

Building Replacement Cost for Insurance Purposes

Concessioner:
Concession Contract No.: _____

The replacement costs set forth herein are established for the sole purpose of assuring property insurance coverage and shall not be construed as having application for any other purpose.

I. Government Buildings

Building No.	*Description*	*Insurance replacement value*[1]

II. Concessioner Buildings

Building No.	*Description*	*Insurance replacement value*[1]

[1] or "Not to be replaced," where applicable.

* * *

By _____
(Name of Concessioner)
Title _____
Date _____

United States of America

_____

Regional Director

[FR Doc. 93–89 Filed 1–6–93; 8:45 am]

BILLING CODE 4310–70–M

Federal Register

Thursday
January 7, 1993

Part V

Department of Housing and Urban Development

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Part 961
Public and Indian Housing Drug Elimination Program; Final Rule

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Part 961

[Docket No. R-92-1541; FR-2992-F-02]

RIN-2577-AA97

Public and Indian Housing Drug Elimination Program

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Final rule.

SUMMARY: This rule amends 24 CFR part 961, the Public and Indian Housing Drug Elimination Program, as authorized by chapter 2, subtitle C, title V of the Anti-Drug Abuse Act of 1988 (42 U.S.C. 11901 *et seq.*), and amended by section 581 of the National Affordable Housing Act (NAHA) (approved November 28, 1990, Pub. L. 101–625) and the Housing and Community Development Act of 1992 (HCDA 1992) (Pub. L. 102–550, approved October 28, 1992). The program authorizes HUD to make grants to public housing agencies (PHAs) and Indian Housing Authorities (IHAs), for use in eliminating drug-related crime and/or the problems associated with it.

EFFECTIVE DATE: February 8, 1993.

FOR FURTHER INFORMATION CONTACT: Malcolm E. Main, Drug Free Neighborhoods Division, Office of Resident Initiatives, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW., room 4118, Washington, DC 20410, telephone (202) 708–1197 or 708–3502. A telecommunications device for speech and hearing impaired persons (TDD) is available at (202) 708–0850. (These are not toll-free telephone numbers.) To obtain copies of OMB Circulars No. A–87 Cost Principles for State and local Governments or A–102 Grants and Cooperative Agreements with State and local Governments, contact: Executive Office of the President (EOP), Publications Services, 725 17th Street NW., room 2200, Washington, DC 20503 (202) 395–7332. [This is not a toll-free telephone number.]

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act Statement

The information collection requirements contained in this final rule have been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1980. Pending approval of these requirements by OMB and the assignment of an OMB control number, no person may be subjected to a penalty for failure to comply with these information collection requirements. Upon approval by OMB, a Notice containing the OMB approval number will be published in the **Federal Register**.

Public reporting burden for the collection of information requirements contained in this final rule are estimated to include the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Information on the estimated public reporting burden is provided under the Preamble heading, *Other Matters*. Send comments regarding this burden estimate, or any other aspect of this collection of information, including suggestions for reducing this burden, to the Department of Housing and Urban Development, Rules Docket Clerk, 451 Seventh Street, SW., room 10276, Washington, DC 20410; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, room 3001, 725 17th Street, NW., Washington, DC 20503, Attention: Desk Officer for HUD. At the end of the public comment period, the Department may amend the information collection requirements to reflect the public comments received concerning the collection of information requirements.

I. Background

The Public Housing Drug Elimination Program was first authorized by chapter 2, subtitle C, title V of the Anti-Drug Abuse Act of 1988 (42 U.S.C. 11901–11908). Implementing regulations for this program were issued by HUD at 55 FR 27598 (July 3, 1990), codified at 24 CFR 961. Applicants eligible to receive grants under this program were public housing agencies (PHAs), including Indian housing authorities (IHAs). (For the sake of convenience, IHAs and PHAs will both be referred to as HAs.)

Section 581 of the National Affordable Housing Act (NAHA) (approved November 28, 1990, Pub. L. 101–625) amended the Drug Elimination Program in a number of ways, and the Department published a proposed rule in the **Federal Register** on July 1, 1991 to implement these amendments (56 FR 30176).

Two additional amendments to the Drug Elimination Program were made by the Housing and Community Development Act of 1992 (HCDA 1992) (Pub. L. 102–550, approved October 28, 1992). One amendment would permit grants to be used to eliminate drug-related crime in housing owned by HAs that is not housing assisted under the United States Housing Act of 1937 and is not otherwise federally assisted. However, these grants are available only if two conditions are met. The housing must be located in a high intensity drug trafficking area designated pursuant to section 1005 of the Anti-Drug Abuse Act of 1988, and the HA owning the housing demonstrates that drug-related activity, and the problems associated with it, at the housing has a detrimental affect on or about the real property comprising any public or other federally assisted low-income housing. The Department intends to permit this demonstration to be made on the basis of information normally submitted in accordance with the requirements of a Notice of Funding Availability (NOFA) for this program.

The second amendment would make resident management corporations (RMCs) eligible, along with PHAs and IHAs, to receive Drug Elimination Program grants. The statutory language requires eligible RMCs to be those that are principally managing, as determined by the Department, housing developments owned by HAs. The existing rule at 24 CFR 961 and the proposed rule to amend it both included a definition of RMC, and this final rule includes the same definition. Any RMC that meets the definition and that is managing developments owned by HAs will be considered eligible to receive Drug Elimination Program grants.

The Department has determined that language to implement each of these statutory amendments may be included in this final rule without the usual notice and comment procedures because neither of the two amendments requires any new discretion to be exercised on the part of the Department.

The present Drug Elimination Program regulation at 24 CFR part 961 applies to both public and Indian housing, and this final rule does also. The requirements for both PHAs and IHAs are virtually identical, except for basic programmatic differences such as the applicability of the Indian Civil Rights Act. Relevant differences are noted in the rule, which uses the designation HA to apply to both an IHA and a PHA. There were no public comments received on the issue of separate public housing and Indian housing rules in response to the proposed rule.

II. Public Comments

The Department received a total of nine comments on the proposed rule, four of which were from housing

authorities (HAs), two each from city and state agencies, and one from a professional association. The following discussion summarizes the comments received and the Department's responses to them. In general, the Department has attempted to streamline the rule, placing emphasis on the statutory requirements. Additional, specific guidance will be provided to applicants in the annual Notices of Funding Availability (NOFAs) for the program.

Two comments questioned the definition of the term "in and around" and its effect of limiting program activities, particularly drug treatment, to activities within, or adjacent to, the physical boundaries of a public or Indian housing development. The Department has determined that this definition is appropriate to make certain that program funds and program activities are targeted to benefit, as directly as possible, public and Indian housing developments, the intended beneficiaries of the program under the authorizing statute. While it may be argued that many actions taken elsewhere would have an impact on these developments, for example, the interdiction of drugs before they can be distributed among the general population, the goals of this program are best served by focusing its resources directly upon public and Indian housing developments. The same reasoning applies to the inquiry in this comment concerning the use of program funds at sites not federally assisted. The most efficient use of program funds that will result in a consistent, beneficial impact on public and Indian housing is achieved by focusing program activities on the public or Indian housing developments themselves.

One comment asked why the definition of "controlled substance" in the proposed rule did not include alcohol, thereby excluding alcohol from being considered in the definition of "drug-related crime" and from being eligible for program funding. The authorizing statute for the Drug Elimination Program specifies the definitions of both "controlled substance" and "drug-related crime." Neither statutory definition includes alcohol and, therefore, alcohol-related problems may not be addressed in this program.

A comment suggested that the rule provide examples of model drug treatment programs and their characteristics. HUD will not be providing specific examples of programs by name, because it does not want to be interpreted as endorsing any specific program.

One comment asked why the proposed rule eliminated drug detoxification as an eligible activity, and another requested that the Department consider funding under the program for specific treatment beds/slots in detoxification, residential, and methadone treatment programs. Drug detoxification, residential, and methadone treatment programs have never been eligible, funded activities under this program. Funds for these purposes are, however, available through programs funded by the Department of Health and Human Services, which has taken the lead in this area.

There was a request for clarification in one comment of the prohibition, included in the proposed rule at § 961.10 as an ineligible activity, against using, in any way, grant funds to pay for expenses incurred in the preparation of a grant application. The Department has concluded that in some limited circumstances, grant funds would unavoidably be used, in an incidental way, in the preparation of a grant application. For example, records kept for activities funded by a grant would probably form part of the basis for a future grant application, yet it would not be argued that these record-keeping costs were not eligible for program funding. The significant factors here are that (1) the use of grant funds for grant application preparation purposes is only incidental to a current, approved program use, and (2) the grant funds are not being used retroactively to pay for expenses incurred before the funds were awarded. The final rule clarifies this issue by specifying that funding is not permitted for costs incurred prior to the effective date of the grant agreement, including, but not limited to, consultant fees for surveys related to the application or for the actual writing of the application. The underlying rationale is to maximize the use of funds for the purpose of implementing program activities.

A request was received to permit the position of a paid coordinator for volunteer tenant foot patrols under the Drug Elimination Program. The Department has considered this comment and determined that the employment of an individual to coordinate a grantee's activities is a valid and reasonable use of program funds. The final rule explicitly permits the use of program funds for a grant coordinator, who could function, for example, as the coordinator for volunteer tenant foot patrols.

One comment asked why the proposed rule, at § 961.10(b)(3), would permit the use of program funds for the acquisition of certain equipment if used primarily in the provision of additional services, but, at § 961.10(b)(6), would forbid the purchase or lease of other items including "police cars, vans, buses, motorcycles or motorbikes." Section 961.10(b)(2) of the final rule deals with the eligible program activity of "reimbursement of local law enforcement agencies for additional security and protective services." The emphasis here is on providing additional services, not equipment. It is expected that program grantees would contract for additional security and protective services with a service provider that comes completely equipped to provide the service. The exception is in the case of equipping a facility not usually available from a service provider, such as a police substation on the premises of the housing development (project) being assisted.

The prohibition at § 961.10(f)(11) of the proposed rule against using grant funds for administrative costs related to screening or evicting residents for drug-related crime prompted one commenter to ask if screening of applicants is permitted. Eviction and screening costs for either residents or applicants are not permitted under the Drug Elimination Program. The Department has determined that these activities are more appropriately a part of the routine operating expenses of public or Indian housing developments. However, Drug Elimination Program funds may be used to employ individuals to investigate drug-related crime on or about the real property comprising any public or Indian housing development and to provide evidence relating to this crime in any judicial or administrative proceeding, including eviction proceedings.

Clarification of the term "projects" as it is used in the rule was requested in one comment. The comment pointed out that "projects" was used to refer to both program activities and to a HA's buildings and facilities. In response to this comment, the final rule has been changed to read "activity" or "program" rather than "project" where the intent is to refer to plans and actions funded under a Drug Elimination Program grant. In addition, for the purposes of this rule, the term "development" is defined as having the same meaning as "project" in reference to a HA's buildings and facilities. This change in nomenclature is made to reflect current usage within the Department.

The comment also questioned whether the plan for addressing the problem of drug-related crime which must be included with every application

had to be prepared separately for each development. The plan does not have to address each of a HA's developments separately if the same activities will apply to each development, and the rule now states this. Only where program activities differ from one development to another must the applicant prepare the plan separately from each development.

Another comment on the plan objected to the apparent preference given in the proposed rule to objective data, such as crime statistics, over subjective and narrative data. As indicated above, this final version of the rule is omitting much of the detail contained in the proposed rule. HUD will provide guidance to applicants on the specifics of the plan that must be included with the application in NOFAs published for this program. However, the Department generally believes that the consistent use of objective data as identified in the proposed rule permits more valid comparisons and assessments to be made among applicants. On the other hand, it is also recognized that objective data may not be equally available to all applicants. Because of these considerations, the Department intends to permit applicants to submit relevant information, other than strictly objective data, that has a direct bearing on drug-related crime problems in the developments proposed for assistance. This option would only be permitted to the extent that objective data may not be available, or to complement objective data. If other relevant information is to be used in place of, rather than to complement, objective data, the application must indicate the reasons why objective data could not be obtained and what efforts were made to obtain it. Examples of permissible other relevant information would be included in the NOFA.

It was pointed out in one comment that the certification requirement at § 961.20(a)(5)(iv) of the proposed rule that, "the locality is meeting its obligations under the cooperation agreement with the HA, particularly with regard to law enforcement services," appears to conflict with the format of the application form (HUD Form 52353, section 4 B). The Department appreciates such observations and intends to make all references in the final rule and application forms consistent.

The suggestion was made in a comment that the selection criteria should not include any item that assesses the program after the grant period, since any projections made at the application stage would be too speculative to be used for selection purposes. This item must be included in the selection criteria because one of the statutory criteria for the selection of applications is "the extent to which the plan includes initiatives that can be sustained over a period of several years." In addition, projection is a vital component of good planning, and well-supported projections would be an indication that the program to be funded is a good investment for the future. For these reasons, the selection criteria that will be used in NOFAs for this program will require some assessment of applicants' programs beyond the grant period.

One comment suggested awarding grants that ran longer than the 24 month maximum permitted by § 961.26(f) of the proposed rule with grant agreements conditioned on future appropriations and HUD evaluations of grantee performance. The Department disagrees with this approach because it would take funds out of the competitive awards process established for this program. The amount of funding for this much-needed program is limited, and all eligible applicants should have the opportunity to compete for all of the funds that are made available in each funding cycle. An applicant whose program has been funded previously may reapply for a continuation of funding, and at that time, its program will be assessed in relation to the programs of other applicants also seeking funding.

Two comments pointed out that the rule did not implement the provisions of section 581 of NAHA that expanded the Drug Elimination Program to include federally-assisted low income housing developments (projects). As was explained in its preamble, the proposed rule only addressed the NAHA amendments that affected HAs because these were the only entities that were eligible for funding in FY 1991. The appropriation for the Program in FY 1992 and FY 1993 specifically included $10 million each for federally assisted housing, and the Department has made these funds available in separate notices.

On the issue of the time permitted for the preparation of program applications, one comment stated that the period of time from the date that a Notice of Funding Availability (NOFA) for the Drug Elimination Program is published in the Federal Register and the application is to be submitted to HUD should be no less than ninety days, and another comment suggested a period of no less than nine weeks. This is an issue that is not specifically addressed in either the proposed rule or the final rule. The date by which applications for funds are due is specified in the NOFA itself. It is the Department's intention to provide applicants with a reasonable amount of time in which to prepare applications within the annual funding cycle of this program.

Other Changes in the Final Rule

To provide guidance for applicants for activities such as security personnel or additional law enforcement that are required to be "over and above" services already being received, the final rule specifies the procedure for demonstrating "over and above." The application must first identify the services currently being received and then identify the increased services for which funding is sought.

To promote a more efficient use of the limited grant funds, the final rule also requires that if additional security personnel (in the form of HA police) or investigators are to be employed for a service that is also provided by a local law enforcement agency, the applicant must provide a cost analysis that demonstrates the employment of the additional HA police or investigators is more cost efficient than obtaining the service from the local law enforcement agency.

The final rule also clarifies the grant administration requirements for the Drug Elimination Program. These additions do not add any new requirements to the rule, but make explicit, for the convenience of program participants, the administrative requirements that have always applied to the program.

A definition of "problems associated with drug-related crime" has been added to the rule to convey the sense, which the Department has determined to be implicit in the authorizing statute, that this program is intended to address more than the narrowly-defined problem of "drug-related crime." "Problems associated with drug-related crime" is defined to mean the negative physical, social, educational and economic impact of drug-related crime on public housing residents, and the deterioration of the public housing environment because of drug-related crime.

Similarly, a definition of "program income" and a new paragraph in the grants administration section referencing the part 85 program income requirements have been added.

II. Other Matters

Environmental Impact

Grants under this program are categorically excluded from review under the National Environmental

Policy Act of 1969 (NEPA) in accordance with 24 CFR part 50.20(p). However, prior to an award of grant funds, HUD will perform an environmental review to the extent required by HUD's environmental regulations at 24 CFR part 50, including the applicable related authorities at 24 CFR 50.4.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this rule before publication and by approving it certifies that this rule does not have a significant economic impact on a substantial number of small entities. The rule would provide grants to HAs and RMCs to eliminate drug-related crime in public and Indian housing developments. In certain instances, the HA can provide grant funds under the program to nonprofit Resident Management Corporations, Resident Councils, or Resident Organizations for certain eligible program activities. Although small entities could participate in the program, the rule would not have a significant economic impact on them.

Economic Impact

This rule does not constitute a "major rule" as that term is defined in section 1(b) of the Executive Order on Federal Regulations issued on February 17, 1969. Analysis of the rule indicates that it does not: (1) Have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises in domestic or export markets.

Family Impact

The General Counsel, as the Designated Official for Executive Order 12606, the Family, has determined that the provisions of this rule have the potential for a positive, although indirect, impact on family formation, maintenance and general well-being within the meaning of the Order. The proposed rule would implement a program that would encourage HAs and RMCs to develop a plan for addressing the problem of drug-related crime, and to make available grants to help HAs and RMCs to carry out this plan. As such, the program is intended to improve the quality of life of public and Indian housing development residents, including families, by reducing the incidence of drug-related crime.

Federalism Impact

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government and, therefore, the provisions of this rule do not have "federalism implications" within the meaning of the Order. The rule implements a program that encourages HAs and RMCs to develop a plan for addressing the problem of drug-related crime, and makes available grants to HAs and RMCs to help them carry out their plans. As such, the program would help HAs and RMCs combat serious drug-related crime problems in their developments, thereby strengthening their role as instrumentalities of the States. In addition, further review under the Order is unnecessary, since the rule generally tracks the statute and involves little implementing discretion.

This final rule was listed as Item No. 1250 in the Department's Semiannual Agenda of Regulations published on April 27, 1992 (57 FR 16804, 16845) under Executive Order 12291 and the Regulatory Flexibility Act.

The Public Housing Drug Elimination Program is listed in the Catalog of Federal Domestic Assistance as number 14.854.

The collection of information requirements contained in this rule have been approved by OMB for review under section 3504 (h) of the Paperwork Reduction Act of 1980. Certain sections of this rule have been determined by the Department of contain collection of information requirements. Information on these requirements is provided as follows:

Section	Number of respondents	Frequency of responses	Est. Avg. response time (in hours)	Estimated annual burden hours
961.15	800	1	64	51,200
961.18	5,000	1	1	5,000
961.28(a)	800	2	24	38,400
961.28(b)	800	1	1	800
Total reporting burden				95,400

List of Subjects in 24 CFR Part 961

Drug abuse, Drug traffic control, Grant programs—housing and community development, Grant programs—Indians, Grant programs—low and moderate income housing, Public housing, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, title 24, chapter IX, of the Code of Federal Regulations is amended by revising 24 CFR part 961, consisting of §§ 961.1 through 961.29, to read as follows:

PART 961—PUBLIC HOUSING DRUG ELIMINATION PROGRAM

Subpart A—General

Sec.
961.1 Purpose and scope.
961.3 Encouragement of resident participation.
961.5 Definitions.

Subpart B—Use of Grant Funds

961.10 Applicants and activities.

Subpart C—Application and Selection

961.15 Application selection and requirements.
961.18 Resident comments on grant application.

Subpart D—Grant Administration

961.26 Grant administration.
961.28 Periodic reports.
961.29 Other Federal requirements.

Subpart E—Reserved

Authority: 42 U.S.C. 3535(d) and 11901 et seq.

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Subpart A—General

§ 961.1 Purpose and scope.

The purposes of the Public and Indian Housing Drug Elimination Program are to:

(a) Eliminate drug-related crime and the problems associated with it in and around the premises of public and Indian housing developments;

(b) Encourage HAs and RMCs to develop a plan that includes initiatives that can be sustained over a period of several years for addressing drug-related crime and/or the problems associated with it in and around the premises of public and Indian housing developments proposed for funding under this part; and

(c) Make available Federal grants to help HAs and RMCs carry out their plans.

§ 961.3 Encouragement of resident participation.

The elimination of drug-related crime and the problems associated with it in public housing developments requires the active involvement and commitment of public housing residents and their organizations. To enhance the ability of HAs to combat drug-related criminal activity in their developments, Resident Councils (RCs), Resident Management Corporations (RMCs), and Resident Organizations (ROs) will be permitted to undertake management functions specified in this part, notwithstanding the otherwise applicable requirements of 24 CFR parts 905 and 964. The Department encourages HAs to make Resident Management Corporations (RMCs), Resident Councils (RCs), and Resident Organizations (ROs) full partners in this effort.

§ 961.5 Definitions.

Act means The United States Housing Act of 1937.

Chief executive officer of a State or a unit of general local government means the elected official, or the legally designated official, who has the primary responsibility for the conduct of that entity's governmental affairs. Examples of the "chief executive officer" of a unit of general local government are: the elected mayor of a municipality; the elected county executive of a county; the chairperson of a county commission or board in a county that has no elected county executive; or the official designated pursuant to law by the governing body of the unit of general local government. The chief executive officer of an Indian tribe is the tribal governing official.

Controlled substance means a drug or other substance or immediate precursor included in schedule I, II, III, IV, or V of section 102 of the Controlled Substances Act (21 U.S.C. 802). The term does not include distilled spirits, wine, malt beverages or tobacco as those terms are defined in subtitle E of the Internal Revenue Code of 1954.

Drug intervention means a process to identify public housing resident drug users and assist them in modifying their behavior and/or refer them to drug treatment to eliminate drug abuse.

Drug prevention means a process to provide goods and services designed to alter factors, including activities, environmental influences, risks and expectations, that lead to drug abuse.

Drug-related crime means the illegal manufacture, sale, distribution, use, or possession with intent to manufacture, sell, distribute, or use, a controlled substance.

Drug treatment means a program for the residents of an applicant's development that strives to end drug abuse and to eliminate its negative effects through rehabilitation and relapse prevention.

Governmental jurisdiction means the unit of general local government, State, or area of operation of an Indian tribe in which the housing development administered by the applicant is located.

HUD or *Department* means the United States Department of Housing and Urban Development.

In and around means within, or adjacent to, the physical boundaries of a housing development.

Indian means any person recognized as being an Indian or Alaska Native by an Indian tribe, the Federal Government, or any State.

Indian Housing Authority (IHA) means any entity that:

(1) Is authorized to engage in or assist in the development or operation of lower income housing for Indians; and

(2) Is established either by exercise of the power of self-government of an Indian tribe independent of State law, or by operation of State law providing specifically for housing authorities for Indians, including regional housing authorities in the State of Alaska.

For the purposes of this part, the term HA includes IHA.

Indian tribe means any tribe, band, pueblo, group, community, or nation of Indians or Alaska Natives.

Local law enforcement agency means a police department, sheriff's office, or other entity of the governmental jurisdiction that has law enforcement responsibilities for the community at large, including the housing developments administered by the applicant. In Indian jurisdictions, this includes tribal prosecutors that assume law enforcement functions analogous to a police department or the BIA. More than one law enforcement agency may have these responsibilities for the jurisdiction that includes the applicant's developments.

Problems associated with drug-related crime means the negative physical, social, educational and economic impact of drug-related crime on public and Indian housing residents, and the deterioration of the public and Indian housing environment because of drug-related crime.

Program income means gross income received by a grantee and directly generated from the use of program funds. When program income is generated by an activity only partially assisted with program funds, the income shall be prorated to reflect the percentage of program funds used. Program income includes, but is not limited to: Proceeds from the disposition by sale or long-term lease of real property purchased or improved with program funds; proceeds from the disposition of equipment purchased with program funds; gross income from the use or rental of real or personal property acquired by a grantee with program funds, less costs incidental to the generation of the income; and, interest earned on funds held in a program fund account.

Project means low income housing and all necessary appurtenances developed, acquired, or assisted by a HA under the United States Housing Act of 1937 (other than under section 8). A project encompasses those buildings identified in the Annual Contributions Contract (ACC) that is executed between HUD and the HA. For the purposes of this part, the term "development" means the same as "project."

Public housing agency (PHA) means any State, county, municipality or other governmental entity or public body (or agency or instrumentality thereof) that is authorized under the United States Housing Act of 1937 (other than under section 8) to engage in or assist in the development or operation of housing for low income families and that has entered into both an Annual Contributions Contract (ACC) with HUD and a Cooperation Agreement with the local jurisdiction. For the purposes of this part, the term HA includes PHA.

Resident Council (RC) means an incorporated or unincorporated nonprofit organization or association that meets each of the following requirements:

(1) It must be representative of the residents it purports to represent;

(2) It may represent residents in more than one development or in all of the developments of an HA, but it must fairly represent residents from each development that it represents;

(3) It must adopt written procedures providing for the election of specific officers on a regular basis (but at least once every three years);

(4) It must have a democratically elected governing board. The voting membership of the board must consist of residents of the development or developments that the resident organization or resident council represents.

Resident Management Corporation (RMC) means the entity that proposes to enter into, or that enters into, a management contract with a PHA under 24 CFR part 964 in accordance with the requirements of that part, or with an IHA under 24 CFR part 905, or with an IHA in accordance with the requirements of this part. The corporation must have each of the following characteristics:

(1) It must be a nonprofit organization that is incorporated under the laws of the State or the Indian tribe in which it is located.

(2) It may be established by more than one resident organization or resident council, so long as each such organization or council:

(i) Approves the establishment of the corporation and;

(ii) Has representation on the Board of Directors of the corporation.

(3) It must have an elected Board of Directors.

(4) Its by-laws must require the Board of Directors to include representatives of each resident organization or resident council involved in establishing the corporation.

(5) Its voting members must be residents of the development or developments it manages.

(6) It must be approved by the resident council or resident organization. If there is no council or organization, a majority of the households of the development must approve the establishment of such an organization to determine the feasibility of establishing a corporation to manage the development.

(7) It may serve as both the resident management corporation and the resident council or the resident organization, so long as the corporation meets the requirements of part 964 of this chapter for a resident council or the requirements of this part for a resident organization.

Resident Organization (RO) means an incorporated or unincorporated nonprofit organization or association that meets each of the following requirements:

(1) It must be representative of the residents it purports to represent;

(2) It may represent residents in more than one development or in all of the developments of an IHA, but it must fairly represent residents from each development that it represents;

(3) It must adopt written procedures providing for the election of specific officers on a regular basis (but at least once every three years);

(4) It must have a democratically elected governing board. The voting membership of the board must consist of residents of the development or developments that the resident organization represents.

Single State Agency means an agency responsible for licensing and monitoring State or tribal drug abuse programs.

State means any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments. The term does not include any public or Indian housing agency under the United States Housing Act of 1937.

Unit of general local government means any city, county, town, municipality, township, parish, village, local public authority (including any public or Indian housing agency under the United States Housing Act of 1937) or other general purpose political subdivision of a State.

Subpart B—Use of Grant Funds

§ 961.10 Applicants and activities.

(a) *Eligible applicants.* PHAs, IHAs, and RMCs that manage developments owned by HAs are eligible applicants under this program.

(b) *Eligible activities.* An application for funding under this program may be for one or more of the following eligible activities, although an applicant may submit only one application under each Notice of Funding Availability (NOFA). In general, compensation for personnel (including supervisory personnel, such as a grant administrator or drug program coordinator, and support staff, such as counselors and clerical staff) hired for grant activities is permitted and may include wages, salaries, and fringe benefits. The following is a listing of eligible activities:

(1) *Employment of security personnel.*

(i) *Security Guard Personnel.* Contracting for security guard personnel services in the developments proposed for funding is permitted under this program.

(A) Contract security personnel funded by this program must perform services not usually performed by local law enforcement agencies on a routine basis, such as, patrolling inside buildings, providing guard services at building entrances to check for ID's, or patrolling and checking car parking lots for appropriate parking decals.

(B) Contract security personnel funded by this program must meet all relevant tribal, State or local government insurance, licensing, certification, training, bonding, or other similar requirements.

(C) The applicant, the cooperating local law enforcement agency, and the provider (contractor) of the security personnel are required, and as a part of the security personnel contract, to enter into and execute a written agreement that describes the following:

(1) The activities to be performed by the security personnel, their scope of authority, and how they will coordinate their activities with the local law enforcement agency;

(2) The types of activities that the security personnel are expressly prohibited from undertaking.

(ii) *Employment of HA Police.* Employment of additional HA police in the developments proposed for funding is permitted under this program.

(A) If additional HA police are to be employed for a service that is also provided by a local law enforcement agency, the applicant must provide a cost analysis that demonstrates the employment of HA police is more cost efficient that obtaining the service from the local law enforcement agency.

(B) Additional HA police services to be funded under this program must be over and above those that the existing HA police, if any, provides, and the tribal, State or local government is contractually obligated to provide under its Cooperation Agreement with the applying HA (as required by the HA's Annual Contributions Contract). An applicant seeking funding for this activity must first establish a baseline by describing the current level of services provided by both the local law enforcement agency and the HA police, if any (in terms of the kinds of services provided, the number of officers and equipment and the actual percent of their time assigned to the developments proposed for funding), and then demonstrate to what extent the funded activity will represent an increase over this baseline.

(C) HA police funded by this program must meet all relevant tribal, State or local government insurance, licensing, certification, training, bonding, or other similar requirements.

(D) The applicant and the cooperating local law enforcement agency are required to enter into and execute a written agreement that describes the following:

(1) The activities to be performed by the HA police, their scope of authority, and how they will coordinate their activities with the local law enforcement agency;

(2) The types of activities that the HA police are expressly prohibited from undertaking.

(2) *Reimbursement of local law enforcement agencies for additional security and protective services.*

(i) Additional security and protective services to be funded under this program must be over and above those that the tribal, State or local government is contractually obligated to provide under its Cooperation Agreement with the applying HA (as required by the HA's Annual Contributions Contract). An application seeking funding for this activity must first establish a baseline by describing the current level of services (in terms of the kinds of services provided, the number of officers and equipment and the actual percent of their time assigned to the developments proposed for funding) and then demonstrate to what extent the funded activity will represent an increase over this baseline.

(ii) Communications and security equipment to improve the collection, analysis, and use of information about drug-related criminal activities in a public housing community, such as computers accessing national, tribal, State or local government security networks and databases, facsimile machines, telephone equipment, bicycles, and motor scooters may be eligible items if used exclusively in connection with the establishment of a law enforcement substation on the funded premises or scattered site developments of the applicant. Funds for activities under this section may not be drawn until the grantee has executed a contract for the additional law enforcement services.

(3) *Physical improvements to enhance security.* (i) Physical improvements that are specifically designed to enhance security are permitted under this program. These improvements may include (but are not limited to) the installation of barriers, lighting systems, fences, bolts, locks; the landscaping or reconfiguration of common areas so as to discourage drug-related crime; and other physical improvements in public housing developments that are designed to enhance security and discourage drug-related activities.

(ii) An activity that is funded under any other HUD program, such as the modernization program at 24 CFR part 968, shall not also be funded by this program.

(iii) Funding is not permitted for physical improvements that involve the demolition of any units in a development.

(iv) Funding is not permitted for any physical improvements that would result in the displacement of persons.

(v) Funding is not permitted for the acquisition of real property.

(vi) All physical improvements must also be accessible to persons with disabilities. For example, some types of locks, buzzer systems, etc., are not accessible to persons with limited strength, mobility, or to persons who are hearing impaired. All physical improvements must meet the accessibility requirements of 24 CFR part 8.

(4) *Employment of investigators.* (i) Employment of one or more individuals is permitted under this program to:

(A) Investigate drug-related crime in or around the real property comprising any public housing development; and

(B) Provide evidence relating to any such crime in any administrative or judicial proceedings.

(ii) If one or more investigators are to be employed for a service that is also provided by a local enforcement agency, the applicant must provide a cost analysis that demonstrates the employment of investigators is more cost efficient than obtaining the service from the local law enforcement agency.

(iii) Investigators funded by this program must meet all relevant tribal, State or local government insurance, licensing, certification, training, bonding, or other similar requirements.

(iv) The applicant, the cooperating local law enforcement agency, and the investigator(s) are required, before any investigators are employed, to enter into and execute a written agreement that describes the following:

(A) The nature of the activities to be performed by the investigators, their scope of authority, and how they will coordinate their activities with the local law enforcement agency;

(B) The types of activities that the investigators are expressly prohibited from undertaking.

(5) *Voluntary tenant patrols.* (i) The provision of training, communications equipment, and other related equipment (including uniforms), for use by voluntary tenant patrols acting in cooperation with officials of local law enforcement agencies is permitted under this program. Members must be volunteers and must be tenants of the development that the tenant (resident) patrol represents. Patrols established under this program are expected to patrol for drug-related criminal activity in the developments proposed for assistance, and to report these activities to the cooperating local law enforcement agency and relevant tribal, State and Federal agencies, as appropriate. Grantees are required to obtain liability insurance to protect themselves and the members of the voluntary tenant patrol against potential liability for the activities of the patrol under this program. The cost of this insurance will be considered an eligible program expense.

(ii) The applicant, the cooperating local law enforcement agency, and the members of the tenant patrol are required, before putting the tenant patrol into effect, to enter into and execute a written agreement that describes the following:

(A) The nature of the activities to be performed by the tenant patrol, the patrol's scope of authority, and how the patrol will coordinate its activities with the local law enforcement agency;

(B) The types of activities that a tenant patrol is expressly prohibited from undertaking, to include but not limited to, the carrying or use of firearms or other weapons, nightsticks, clubs, handcuffs, or mace in the course of their duties under this program;

(C) The type of initial tenant patrol training and continuing training the members receive from the local law enforcement agency (training by the local law enforcement agency is required before putting the tenant patrol into effect);

(iii) Tenant patrol members must be advised that they may be subject to individual or collective liability for any actions undertaken outside the scope of their authority and that such acts are not covered under a HA's or RMC's liability insurance.

(iv) Communication and related equipment eligible for funding under this program shall be equipment that is reasonable, necessary, justified and related to the operation of the tenant patrol and that is otherwise permissible under tribal, State or local law.

(v) Under this program, bicycles and uniforms (caps and other clothing items that identify voluntary tenant patrol members, including patrol t-shirts and jackets) to be used by the members of the tenant patrol are eligible items.

(vi) Drug elimination grant funds may not be used for any type of financial compensation, such as wages, salaries, and stipends, for voluntary tenant patrol participants. However, the use of program funds for a grant coordinator

for volunteer tenant foot patrols is permitted.

(6) *Drug prevention, intervention and treatment programs to reduce the use of drugs.* Programs that reduce the use of drugs in and around the premises of public housing developments, including drug abuse prevention, intervention, referral and treatment programs are permitted under this part. The program should facilitate drug prevention, intervention and treatment efforts, to include outreach to community resources and youth activities, and facilitate bringing these resources onto the premises, or providing resident referrals to treatment programs or transportation to out-patient treatment programs away from the premises. Funding is permitted for reasonable, necessary and justified leasing of vehicles for resident youth and adult education and training activities directly related to "Programs to reduce the use of drugs" under this section. Alcohol-related activities/programs are not eligible for funding under this part. Notices of Funding Availability (NOFAs) published in the **Federal Register** for this program will provide more extensive guidance as to the elements that are to be included in a drug treatment program.

(7) *Resident management corporations (RMCs), resident councils (RCs) and resident organizations (ROs).* Funding under this part is permitted for HAs that receive grants to contract with RMCs and incorporated RCs and ROs to develop security and drug abuse prevention programs involving site residents. Such programs may include voluntary tenant patrol activities, drug education, drug intervention, youth programs, referral, and outreach efforts.

(8) *Continuation of current program activities.* Current or previous PHDEP grant holders may apply, on the same basis as other applicants, for grants to continue their PHDEP activities or implement other program activities. The Department will evaluate an applicant's performance under any previous Drug Elimination Program grants within the past five years. Subject to evaluation and review are the applicant's financial and program performance; reporting and special condition compliance; accomplishment of stated goals and objectives under the previous grant; and program adjustments made in response to previous ineffective performance. If the evaluation discloses a pattern under past grants of ineffective performances with no corrective measures attempted, it will result in a deduction of points from the current application. Since this is a competitive program, HUD does not guarantee continued funding of any previously funded Drug Elimination Program Grant.

(9) *HA-owned housing.* Funding may be used for the activities described in § 961.10(b) (1) through (7), to eliminate drug-related crime in housing owned by housing agencies that is not housing assisted under the United States Housing Act of 1937 and is not otherwise federally assisted, but only if:

(i) The housing is located in a high intensity drug trafficking area designated pursuant to section 1005 of the Anti-Drug Abuse Act of 1988; and

(ii) The HA owning the housing demonstrates, on the basis of information submitted in accordance with the requirements of any NOFA issued under this program, that drug-related activity, and the problems associated with it, at the housing has a detrimental affect on or about the real property comprising any public or other federally assisted low-income housing.

(c) *Ineligible activities.* Funding is not permitted under this program for any of the activities listed in this paragraph (c) or those specified as ineligible elsewhere in this part. Notices of Funding Availability (NOFAs) published under this program will provide specific guidance concerning other ineligible activities.

(1) *Joint applications are not eligible* for funding under this program.

(2) Indirect costs as defined in OMB Circular A–87 are not permitted under this program.

(3) Funding is not permitted for costs incurred before the effective date of the grant agreement, including, but not limited to, consultant fees for surveys related to the application or the actual writing of the application.

(4) Funding is not permitted for the costs (e.g., attorney's fees, court costs, etc.) related to screening or evicting residents for drug-related crime. However, investigators funded under this program may participate in judicial and administrative proceedings as provided in paragraph (b)(4)(i)(B) of this section.

Subpart C—Application and Selection

§ 961.15 Application selection and requirements.

(a) *Selection criteria.* HUD will review each application that it determines meets the requirements of this part and assign points in accordance with the selection criteria. The number of points that an application receives will depend on the extent to which the application is responsive to the information requested in Notices of Funding Availability (NOFAs) published for this program. Each application submitted for a grant under this part will be evaluated on the basis of the following selection criteria:

(1) First criterion: The extent of the drug-related crime problem in the applicant's development or developments proposed for assistance.

(2) Second criterion: The quality of the plan to address the crime problem in the developments proposed for assistance, including the extent to which the plan includes initiatives that can be sustained over a period of several years.

(3) Third criterion: The capability of the applicant to carry out the plan.

(4) Fourth criterion: The extent to which tenants, the local government and the local community support and participate in the design and implementation of the activities proposed to be funded under the application.

(b) *Plan requirement.* Each application must include a plan for addressing the problem of drug-related crime and/or the problems associated with drug-related crime on the premises of the housing for which the application is being submitted. For applications that cover more than one development, the plan does not have to address each development separately if the same activities will apply to each development. Only where program activities will differ from one development to another must the plan address each development separately.

(c) *Notice of Funding Availability.* HUD will publish Notices of Funding Availability (NOFAs) in the **Federal Register**, as appropriate, to inform the public of the availability of grant amounts under this part. NOFAs will provide specific guidance with respect to the grant process, including the deadlines for the submission of grant applications; the limits (if any) on maximum grant amounts; the information that must be submitted to permit HUD to score each of the selection criteria; the maximum number of points to be awarded for each selection criterion; the contents of the plan for addressing the problem of drug-related crime that must be included with the application; the listing of any certifications and assurances that must be submitted with the application; and the process for ranking and selecting applicants. NOFAs will also include any additional information, factors, and requirements that the Department has determined to be necessary and appropriate to provide for the implementation and administration of the program under this part.

(d) *Environmental review.* Grants under this part are categorically

excluded from review under the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321), in accordance with 24 CFR 50.20(p). However, prior to an award of grant funds under this part, HUD will perform an environmental review to the extent required by HUD's environmental regulations at 24 CFR part 50, including the applicable related authorities at 24 CFR 50.4.

§ 961.18 Resident comments on grant application.

The applicant must provide the residents of developments proposed for funding under this part, as well as any RMCs, RCs, or ROs that represent those residents (including any HA-wide RMC, RC or RO), with a reasonable opportunity to comment on its application for funding under this program. The applicant must give these comments careful consideration in developing its plan and application as well as in the implementation of funded programs. Copies of all written comments submitted must be maintained by the grantee for three years.

Subpart D—Grant Administration

§ 961.26 Grant administration.

(a) *General.* Each grantee is responsible for ensuring that grant funds are administered in accordance with the requirements of this part, any Notice of Funding Availability (NOFA) issued for this program, 24 CFR part 85, applicable laws and regulations, applicable OMB circulars, HUD fiscal and audit controls, grant agreements, grant special conditions, the grantee's approved budget (SF-424A), budget narrative, plan, and activity timetable.

(b) *Grant term extensions.* (1) *Grant term.* Terms of the grant agreement may not exceed 24 months, unless an extension is approved by the local Field Office or the local HUD Office of Indian Programs. The maximum extension allowable for any grant is 6 months. Any funds not expended at the end of the grant term shall be remitted to HUD.

(2) Grantees may be granted an extension of the grant term in response to a written request for an extension stating the need for the extension and indicating the additional time required.

(3) The request must be received by the local HUD Field Office or the local HUD Office of Indian Programs prior to the termination of the grant, and requires approval by the local HUD Field Office or the local HUD Office of Indian Programs with jurisdiction over the grantee.

(4) The maximum extension allowable for any program period is 6 months. Requests for retroactive extension of program periods will not be considered. Only one extension will be permitted. Extensions will only be considered if the extension criteria of paragraph (b)(5) of this section are met by the grantee at the time the request for the extension of the deadline is submitted for approval.

(5) *Extension criteria.* The following criteria must be met by the grantee when submitting a request to extend the expenditure deadline for a program or set of programs.

(i) *Financial status reports.* There must be on file with the local HUD Field Office or the local HUD Office of Indian Programs, current and acceptable Financial Status Reports, SF-269As.

(ii) *Grant agreement special conditions.* All grant agreement special conditions must be satisfied except those conditions that must be fulfilled in the remaining period of the grant. This also includes the performance and resolution of audit findings in a timely manner.

(iii) A narrative justification must be submitted with the program extension request. Complete details must be provided, including the circumstances which require the proposed extension, and explanation of the impact of denying the request.

(6) The local HUD Field Office or the local HUD Office of Indian Programs will take action on any proposed extension request within 15 days after receipt of the request.

(c) *Duplication of funds.* To prevent duplicate funding of any activity, the grantee must establish controls to assure that an activity or program that is funded by other HUD programs, such as modernization or CIAP, or programs of other Federal agencies, shall not also be funded by the Drug Elimination Program. The grantee must establish an auditable system to provide adequate accountability for funds that it has been awarded. The grantee is responsible for ensuring that there is no duplication of funds.

(d) *Employment preference.* A PHA grantee under this program shall give preference to the employment of public housing residents, and comply with section 3 of the Housing and Urban Development Act of 1968 and 24 CFR part 135, to carry out any of the eligible activities under this part, so long as such residents have comparable qualifications and training as non-public housing residents. Except where the labor standards requirements of § 961.29(a)(1) are applicable, a public housing resident employed under this section may choose to receive compensation for his or her services either in the form of payment, as a credit to the resident's account, or as payment of back rent owed to the grantee. An IHA grantee under this program shall give preference to the employment of Indians, in accordance with 25 U.S.C. 450(e) and 24 CFR 905.165, to carry out any of the eligible activities under this part, to the greatest extent feasible. The Indian preference must be used first before any resident preference may be allowed. Except where the labor standards requirements of § 905.1109(a)(1) of this chapter are applicable, an Indian housing resident employed under this section may choose to receive compensation for his or her services either in the form of payment, as a credit to the resident's account, or as payment of back rent owed to the grantee. Voluntary tenant patrol participants are not eligible for compensation from Drug Elimination Program funds.

(e) *Insurance.* Each grantee is required to obtain adequate insurance coverage to protect itself against any potential liability arising out of the eligible activities under this part. In particular, applicants are required to assess their potential liability arising out of the employment or contracting of security personnel, law enforcement personnel, investigators, and drug treatment providers, and the establishment of voluntary tenant patrols; to evaluate the qualifications and training of the individuals or firms undertaking these functions; and to consider any limitations on liability under tribal, State or local law. Grantees are required to obtain liability insurance to protect the members of the voluntary tenant patrol against potential liability as a result of the patrol's activities under § 961.10(b)(5). Voluntary tenant patrol liability insurance costs *are eligible program expenses.* Subgrantees are required to obtain their own liability insurance.

(f) *Program income.* The requirements of 24 CFR 85.25 apply to program income as defined at § 961.5, except that program income must be used for eligible Drug Elimination Program activities.

(g) *Failure to implement program.* If the grant plan, approved budget and timetable, as described in the approved application, are not operational within 60 days of the grant agreement date, the HA must report by letter to the local Field Office or the local Office of Indian Programs the steps being taken to initiate the plan and timetable, the reason for the delay, and the expected starting date. Any timetable revisions which resulted from the delay must be included. The Field Office or the Office of Indian Programs will determine if the

delay is acceptable, approve/disapprove the revised plan and timetable and take any additional appropriate action.

(h) *Sanctions.*

(1) HUD may impose sanctions if the grantee:

(i) Is not complying with the requirements of 24 CFR part 961 or of other applicable Federal law;

(ii) Fails to make satisfactory progress toward its drug elimination goals, as specified in its plan and as reflected in its performance and financial status reports under § 961.28;

(iii) Does not establish procedures that will minimize the time elapsing between drawdowns and disbursements;

(iv) Does not adhere to grant agreement requirements or special conditions;

(v) Proposes substantial plan changes to the extent that, if originally submitted, would have resulted in the application not being selected for funding;

(vi) Engages in the improper award or administration of grant subcontracts;

(vii) Does not submit reports; or

(viii) Files a false certification, for example, in response to a certification request contained in a funding notice.

(2) HUD may impose the following sanctions:

(i) Temporarily withhold cash payments pending correction of the deficiency by the grantee or subgrantee;

(ii) Disallow all or part of the cost of the activity or action not in compliance;

(iii) Wholly or partly suspend or terminate the current award for the grantee's or subgrantee's program;

(iv) Require that some or all of the grant amounts be remitted to HUD;

(v) Condition a future grant and elect not to provide future grant funds to the grantee until appropriate actions are taken to ensure compliance;

(vi) Withhold further awards for the program or

(vii) Take other remedies that may be legally available.

§ 961.26 Periodic reports.

In accordance with 24 CFR 85.40, grantees are responsible for managing the day-to-day operations of grant and subgrant supported activities. Grantees must monitor grant and subgrant supported activities to assure compliance with applicable Federal requirements and that performance goals are being achieved. Grantee monitoring must cover each program, function or activity of the grant.

(a) *Semi-annual (nonconstruction) performance reports.*

(1) In accordance with 24 CFR 85.40(b)(1)(2) and 85.50(b), grantees are required to provide the local HUD Field Office or the local Office of Indian Programs with a semi-annual performance report that evaluates the grantee's performance against its plan. These reports shall include in summary form (but are not limited to) the following: Any change or lack of change in crime statistics or other indicators drawn from the applicant's plan assessment (such as vandalism, etc.) and an explanation of any difference; successful completion of any of the strategy components identified in the applicant's plan; a discussion of any problems encountered in implementing the plan and how they were addressed; an evaluation of whether the rate of progress meets expectations; a discussion of the grantee's efforts in encouraging resident participation; a description of any other programs that may have been initiated, expanded or deleted as a result of the plan, with an identification of the resources and the number of people involved in the programs and their relation to the plan.

(2) *Reporting period.* Semi-annual performance reports (for periods ending June 30 and December 31) are due to the local HUD Field Office or the local Office of Indian Programs on July 30 and January 31 of each year. If the reports are not received by the Field Office or the local Office of Indian Programs on or before the due date, grant funds will not be advanced until the reports are received.

(b) *Final performance report.* (1) In accordance with 24 CFR 85.40(b)(1) and 85.50(b), grantees are required to provide the local HUD Field Office or the local Office of Indian Programs with a final cumulative performance report that evaluates the grantee's overall performance against its plan. This report shall include in summary form (but is not limited to) the following: any change or lack of change in crime statistics or other indicators drawn from the applicant's plan assessment (such as vandalism, etc.) and an explanation of any difference; successful completion of any of the strategy components identified in the applicant's plan; a discussion of any problems encountered in implementing the plan and how they were addressed; an evaluation of whether the rate of progress meets expectations; a discussion of the grantee's efforts in encouraging resident participation; a description of any other programs that may have been initiated, expanded or deleted as a result of the plan, with an identification of the resources and the number of people involved in the programs and their relation to the plan.

(2) *Reporting period.* The final performance report shall cover the period from the date of the grant agreement to the termination date of the grant agreement. The report is due to the local HUD Field Office or the local Office of Indian Programs within 90 days after termination of the grant agreement.

(c) *Semi-annual financial status reporting requirements.*

(1) The grantee shall provide a financial status report in accordance with 24 CFR part 85.41 (b) and (c). The grantee shall use the SF–269A, Financial Status Report-Long Form, to report the status of funds for non-construction programs. The grantee shall use SF–269A, block 12, "Remarks," to report on the status of programs, functions or activities within the program.

(2) *Reporting period.* Semi-annual (for periods ending June 30 and December 31) financial status reports (SF–269A) must be submitted to the local HUD Field Office or the local Office of Indian Programs by July 30 and January 31 of each year. If the SF–269A is not received on or before the due date by the Field Office or the local Office of Indian Programs, grant funds will not be advanced until the reports are received.

(d) *Final financial status report (SF–269A).* (1) The final report will be a cumulative summary of expenditures to date and must indicate the exact balance of unexpended funds. If any amount of grant funds owed to HUD have not been remitted by the grantee, the local Field Office or the local Office of Indian Programs shall notify the grantee, in writing, to remit the excess funds to HUD. The grantee shall remit all Drug Elimination Program funds owed to HUD, including any unexpended funds prior to or upon receipt of the notice.

(2) *Reporting period.* The final financial status report shall cover the period from the date of the grant agreement to the termination date of the grant agreement. The report is due to the local HUD Field Office or the local Office of Indian Programs within 90 days after the termination of the grant agreement.

(e) *Report submission.* The grantee shall submit all required reports to the local HUD Field Office, Attention: Director, Public Housing Division or to the local HUD Office of Indian Programs, Attention: Director, Indian Housing Division.

§ 961.28 Other Federal requirements.

Use of grant funds requires compliance with the following additional Federal requirements:

(a) Labor standards. (1) Where grant funds are used to undertake physical improvements to increase security under § 961.10(b)(3), the following labor standards apply:

(i) The grantee and its contractors and subcontractors must pay the following prevailing wage rates, and must comply with all related rules, regulations and requirements:

(A) For laborers and mechanics employed in the program, the wage rate determined by the Secretary of Labor pursuant to the Davis-Bacon Act (40 U.S.C. 276a *et seq.*) to be prevailing in the locality with respect to such trades;

(B) For laborers and mechanics employed in carrying out non-routine maintenance in the program, the HUD-determined prevailing wage rate. As used in this paragraph (a), non-routine maintenance means work items that ordinarily would be performed on a regular basis in the course of upkeep of a property, but have become substantial in scope because they have been put off, and that involve expenditures that would otherwise materially distort the level trend of maintenance expenses. Non-routine maintenance may include replacement of equipment and materials rendered unsatisfactory because of normal wear and tear by items of substantially the same kind. Work that constitutes reconstruction, a substantial improvement in the quality or kind of original equipment and materials, or remodeling that alters the nature or type of housing units is not non-routine maintenance.

(ii) The employment of laborers and mechanics is subject to the provisions of the Contract Work Hours and Safety Standards Act (40 U.S.C. 327–333).

(2) The provisions of paragraph (a)(1) of this section shall not apply to labor contributed under the following circumstances:

(i) Upon the request of any resident management corporation, HUD may, subject to applicable collective bargaining agreements, permit residents of a program managed by the resident management corporation to volunteer a portion of their labor;

(ii) An individual may volunteer to perform services if:

(A) The individual does not receive compensation for the voluntary services, or, is paid expenses, reasonable benefits, or a nominal fee for voluntary services; and

(B) Is not otherwise employed at any time in the work subject to paragraphs (a)(1)(i) (A) or (B) of this section.

(b) *Nondiscrimination and equal opportunity.* The following nondiscrimination and equal opportunity requirements apply to this program:

(1) The requirements of The Fair Housing Act (42 U.S.C. 3601–19) and implementing regulations issued at 24 CFR part 100; Executive Order 11063 (Equal Opportunity in Housing) and implementing regulations at 24 CFR part 107; and title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d–2000d–4) (Nondiscrimination in Federally Assisted Programs) and implementing regulations issued at 24 CFR part 1;

(2) The prohibitions against discrimination on the basis of age under the Age Discrimination Act of 1975 (42 U.S.C. 6101–07) and implementing regulations at 24 CFR part 146, and the prohibitions against discrimination against handicapped individuals under section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) and implementing regulations at 24 CFR part 8;

(3) The requirements of Executive Order 11246 (Equal Employment Opportunity) and the regulations issued under the Order at 41 CFR chapter 60;

(4) The requirements of section 3 of the Housing and Urban Development Act of 1968, 12 U.S.C. 1701u (Employment Opportunities for Lower Income Persons in Connection with Assisted Projects); and

(5) The requirements of Executive Orders 11625, 12432, and 12138. Consistent with HUD's responsibilities under these Orders, recipients must make efforts to encourage the use of minority and women's business enterprises in connection with funded activities.

(c) *Use of debarred, suspended or ineligible contractors.* Use of grant funds under this program requires compliance with the provisions of 24 CFR part 24 relating to the employment, engagement of services, awarding of contracts, or funding of any contractors or subcontractors during any period of debarment, suspension, or placement in ineligibility status.

(d) *Flood insurance.* Grants will not be awarded for proposed activities that involve acquisition, construction, reconstruction, repair or improvement of a building or mobile home located in an area that has been identified by the Federal Emergency Management Agency (FEMA) as having special flood hazards unless:

(1) The community in which the area is situated is participating in the National Flood Insurance Program in accordance with 44 CFR parts 59 through 79; or

(2) Less than a year has passed since FEMA notification to the community regarding such hazards; and

(3) Flood insurance on the structure is obtained in accordance with section 102(a) of the Flood Disaster Protection Act of 1973 (42 U.S.C. 4001).

(e) *Lead-based paint.* The provisions of section 302 of the Lead-Based Paint Poisoning Prevention Act, 42 U.S.C. 4821–4846, and implementing regulations at 24 CFR part 965, subpart H apply to activities under this program as set out below. This section is promulgated pursuant to the authority granted in 24 CFR 35.24(b)(4) and supersedes, with respect to all housing to which it applies, the requirements (not including definitions) prescribed by subpart C of 24 CFR part 35.

(1) *Applicability.* The provisions of this section shall apply to all developments constructed or substantially rehabilitated before January 1, 1978, and for which assistance under this part is being used for physical improvements to enhance security under § 961.10(b)(3).

(2) *Definitions.* The term "applicable surfaces" means all intact and nonintact interior and exterior painted surfaces of a residential structure.

(3) *Exceptions.* The following activities are not covered by this section:

(i) Installation of security devices;

(ii) Other similar types of single-purpose programs that do not involve physical repairs or remodeling of applicable surfaces of residential structures; or

(iii) Any non-single purpose rehabilitation that does not involve applicable surfaces and that does not exceed $3,000 per unit.

(f) *Conflicts of interest.* In addition to the conflict of interest requirements in 24 CFR part 85, no person, as described in paragraphs (f) (1) and (2) of this section, may obtain a personal or financial interest or benefit from an activity funded under this program, or have an interest in any contract, subcontract, or agreement with respect thereto, or the proceeds thereunder, either for himself or herself or for those with whom he or she has family or business ties, during his or her tenure, or for one year thereafter:

(1) Who is an employee, agent, consultant, officer, or elected or appointed official of the grantee, that receives assistance under the program and who exercises or has exercised any functions or responsibilities with respect to assisted activities; or

(2) Who is in a position to participate in a decision making process or gain inside information with regard to such activities.

(g) *Drug Free Workplace Act of 1988.* The requirements of the Drug-Free

Workplace Act of 1988 at 24 CFR part 24, subpart F apply to this program.

(h) *Anti-lobbying provisions under section 319.* The use of funds under this part is subject to the disclosure requirements and prohibitions of section 319 of the Department of the Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352), and implementing regulations at 24 CFR part 87. These authorities prohibit recipients and subrecipients of Federal contracts, grants, cooperative agreements and loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific contract, grant, or loan. The prohibition also covers the awarding of contracts, grants, cooperative agreements, or loans unless the recipient has made an acceptable certification regarding lobbying. Under 24 CFR part 87, applicants, recipients, and subrecipients of assistance exceeding $100,000 must certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance. However, since grantees sometimes may expect to receive additional grant funds through reallocations, all potential grantees are required to submit the certification, and to make the required disclosure if the grant amount exceeds $100,000. The law provides substantial monetary penalties for failure to file the required certification or disclosure. IHAs established by an Indian tribe as a result of the exercise of the tribe's sovereign power are excluded from the coverage of 31 U.S.C. 1352, but IHAs established under State law are not excluded from the statute's coverage.

(i) For IHAs, § 905.115 of this chapter, "Applicability of civil rights requirements", and § 905.120 of this chapter, "Compliance with other Federal requirements", of this title apply and control to the extent they may differ from other requirements of this section;

(j) *Indian preference.* Applicants are subject to the Indian Civil Rights Act (24 U.S.C. 1301), the provisions of section 7(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450e(b)), and the Indian preference rules in the IHA procurement regulations at 24 CFR 905, subpart B. These provisions require, to the greatest extent feasible, that preference and opportunities for training and employment be given to Indians and that preference in the award of subcontracts and subgrants be given to Indian Organizations and Indian Owned Economic Enterprises.

(k) *Intergovernmental Review.* The requirements of Executive Order 12372 and the regulations issued under the order at 24 CFR part 52, to the extent provided by **Federal Register** notice in accordance with 24 CFR 52.3 apply to this program.

Subpart E—[Reserved]

Dated: December 23, 1992.

Joseph G. Schiff,

Assistant Secretary for Public and Indian Housing.

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Department of Education

34 CFR Part 682
Federal Family Education Loan Program; Final Regulations

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DEPARTMENT OF EDUCATION

34 CFR Part 682

RIN 1840–AB41

Federal Family Education Loan Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations for the Federal Family Education Loan Program (FFELP), formerly the Guaranteed Student Loan (GSL) program (34 CFR part 682). The final regulations are needed to implement further the Secretary's Default Reduction Initiative. The effect of the regulatory change would be to require certain schools to establish one or more prescribed alternative closure plans that would offer relief to borrowers if the school terminates teaching activities in a particular program of study before students complete that program of study.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments, with the exception of § 682.600. The amendments to § 682.600 will become effective after the information collection requirements contained in that section have been submitted by the Department of Education and approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the **Federal Register**.

See also "Compliance" under the supplementary information section.

FOR FURTHER INFORMATION CONTACT: Pat Newcombe, FFELP Section, Loans Branch, Division of Policy Development, Policy, Training, and Analysis Service, Office of Student Financial Assistance, Department of Education, 400 Maryland Avenue, SW., (room 4310, ROB #3), Washington, DC 20202–5449, Telephone (202) 708–8242. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8399 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION:

Compliance

Each school currently participating in the FFEL program that is covered by these regulations must have a school closure plan in place no later than six months from the effective date of these regulations. A school that submits an application to participate in the FFEL program on or after the effective date of these regulations must submit its school closure plan with its application to participate in the FFEL program. A school that has an application pending to participate in the FFEL program on the effective date of these regulations must add the required school closure plan documentation to its application before the Secretary will approve it to participate in the FFEL program.

Background

On June 5, 1989, the Secretary published a notice of proposed rulemaking (NPRM) in the **Federal Register** (54 FR 24128) proposing, in part, a measure to ensure that students attending a private postsecondary school that closes have the opportunity to complete their program of study through a "teachout" arrangement. Based on the Department's review of the serious concerns about the teachout proposal raised by the commenters, the Secretary decided to issue a new NPRM that would require private postsecondary schools that offer an undergraduate nonbaccalaureate program designed to prepare students for a particular vocational, trade or career field to select and adopt one or more of several alternative approaches to deal with a potential school closing. This new NPRM was published in the **Federal Register** on September 5, 1991 (56 FR 43978). The second NPRM included a detailed discussion of the proposed changes to § 682.600, and the discussion will not be repeated here.

The regulations are needed to put in place an element of the Secretary's Default Reduction Initiative for the FFEL program. The Default Reduction Initiative was prompted when FFELP default costs in fiscal year (FY) 1988 totalled almost $1.4 billion, representing a 200 percent increase in defaults during the previous five years and approximately 40 percent of the Department's FY 1988 expenditures for the FFEL program. The default problem continues, with costs reaching $3.6 billion in FY 1991. The Secretary believes that a factor contributing to the high default rate is the large number of borrowers who are stranded by school closings. These borrowers are unable to gain employment due to an incomplete education but still owe a large FFELP debt that some feel no obligation to repay since the services paid for were not delivered. The effect of the regulatory change would be to require certain schools to establish one or more prescribed alternative closure plans that would offer relief to borrowers if the school terminates teaching activities in a particular program of study before students complete that program of study.

The most significant change to the proposed regulations is to limit the application of these regulations to schools with the greatest probability of closing. The Secretary's examination of data from FYs 1987 to 1990 reveals that private nonprofit institutions that qualify as institutions of higher education are overwhelmingly less likely to close than are proprietary postsecondary schools. The number of closed proprietary schools has increased sharply each year from 22 in FY 1987 to 187 in FY 1990 (the last full year for which data are available). During this four-year period, fewer than 1 percent (26 out of 2,641) of private nonprofit institutions that qualify as institutions of higher education participating in the FFEL program closed. By contrast, during the same period, 9.3 percent (361 out of 3,876) of participating proprietary schools closed. The majority of these school closures have not been end-of-the-term, orderly closures. During FY 1990, only seven private nonprofit institutions that qualify as institutions of higher education closed compared with 187 proprietary schools. The Department estimates the number of borrowers attending those 187 closed proprietary schools to be sixteen times greater than the number of borrowers attending the seven closed private nonprofit schools. Each year the cumulative rate has increased as the number of schools closures has increased at a faster rate than the number of participating schools; thus, based on this trend, when the FY 1991 data become available, we expect the FY 1987 through FY 1991 rate—especially for proprietary schools—to be substantially higher than the FY 1987 through FY 1990 rate. An examination of this data leads the Secretary to believe that private nonprofit postsecondary schools that qualify as institutions of higher education under 34 CFR 600.4 have a much smaller likelihood of mid-session closure than proprietary postsecondary schools, so he has exempted such schools from the requirement to have a school closure plan.

Reauthorization of the Higher Education Act of 1965, as amended by Public Law 102–325, changed the definition of *pro rata* refund as used for the Title IV student aid programs. See section 484B of the HEA. The Department's general provisions regulations for the student financial aid

programs will be amended to reflect this change in definition. Publication of the amended regulations will change the regulatory reference to *pro rata* refund in this regulation.

The purpose of these regulations is to improve the efficiency of Federal student aid programs and, by so doing, to improve their capacity to enhance opportunities for postsecondary education. Encouraging students to graduate from high school and to pursue high quality postsecondary educations are important elements of the President's AMERICA 2000 strategy to move the Nation toward achieving the National Education Goals.

The public comments received in response to the second NPRM have resulted in several changes in the regulations. A discussion of those changes follows.

Analysis of Comments and Changes

In response to the NPRM, 63 parties submitted comments on the proposed revision to § 682.600 of the regulations. Substantive issues raised by the commenters are discussed below.

Section 682.600 Agreement between an eligible school and the Secretary for participation in the Federal Family Education Loan Program

Comments: The majority of commenters favored the Secretary's proposal to require a private postsecondary school participating in the FFEL program to establish a school closure plan under which the borrower and the Federal fiscal interest would be protected if the school terminates teaching activities in a particular program before the student completes that program. However, some commenters argued that certain categories of schools should be exempted from the requirement. The commenters argued that some private postsecondary schools, particularly hospital-based nursing schools that grant diplomas and are required by State law or State Boards of Registration to complete the training of any students who begin their programs, should be exempt from the requirement that they maintain a school closure plan. The commenters cited two examples of hospital-based nursing programs that fit this criterion: (1) One State requires schools offering those programs to make provisions to protect students in the event of school closure, and (2) another State requires that a school offering such a program graduate the last class that was admitted to its program so its graduates can sit for the State licensure exam.

Some commenters believed that the scope of institutions covered by the proposed regulations was too broad. Other commenters believed that the term "private," as used in the NPRM, was not clear. For example, a commenter from a major private university noted that his school was a "private" institution under the definition in the NPRM, but the likelihood of a program being terminated before completion of a student's program of study was nonexistent.

Discussion: The Secretary agrees with the commenters that if a certain type of private school very rarely closes, that type of school should not be required to have a school closure plan. The Secretary has examined historical data from the FY 1990 FFELP guarantee agency cumulative Tape Dump files and the records from the Department's Division of Audit and Program Review to determine the probability of certain types of schools closing. The data from FYs 1987–1990 reveal that the number of closed proprietary postsecondary schools has increased sharply each year from 22 in FY 1987 to 187 in FY 1990. The annual closure rate for this type of school increased from 0.7 percent in FY 1987 to 5.6 percent in FY 1990. On the other hand, few private nonprofit institutions that qualify as institutions of higher education have closed during this period and there is no trend toward an increase in the closure rate. For each of the four years in this period, the annual closure rate was well below 1 percent for this type of school. During FY 1990, there were approximately 26 proprietary school closings for every private nonprofit institution that qualifies as an institution of higher education that closed.

Based on this data, the Secretary has concluded that private nonprofit institutions that qualify as institutions of higher education are highly unlikely to close. Therefore, the Secretary has decided that a private postsecondary school that qualifies as an institution of higher education under 34 CFR 600.4 should be exempt from the requirement to have a school closure plan. Generally, a private, nonprofit school that provides (1) a degree program, (2) at least a two-year program acceptable for full credit toward a bachelor's degree, or (3) at least a one-year training program that leads to a certificate, degree, or other recognized educational credential and prepares students for gainful employment in a recognized occupation, qualifies as an institution of higher education under 34 CFR 600.4. This category would include many hospital-based nursing programs that satisfy these requirements.

Changes: The Secretary has revised the proposed regulations to provide that a private nonprofit school that qualifies as an institution of higher education under 34 CFR 600.4 is exempt from the requirement to have a school closure plan.

Comments: Several commenters expressed concern that the NPRM mandated the creation of a school closure plan as a requirement for participation in the FFEL program. They argued that the Department should provide schools with sufficient time to develop school closure plans to submit to the Secretary before establishing the plan as a requirement.

Discussion: The Secretary agrees that schools currently participating in the FFEL program should have a reasonable period of time to develop and submit a school closure plan to the Secretary, the principal guarantee agency, and the appropriate accrediting commission. Therefore, the Secretary has decided to permit schools currently participating in the FFEL program to establish and submit school closure plans within six months from the date the regulations become effective. The Department will notify schools of the address that they should use to submit documentation concerning their plans to the Secretary and the deadline for submission. A school not currently participating in the FFEL program as of the effective date of these regulations must submit its school closure plan with its application to participate in the FFEL program. A school that has an application pending to participate in the FFEL program at the time this regulatory requirement becomes effective must add the required school closure plan documentation to its application before the Secretary will approve it to participate in the FFEL program.

Changes: A change has been made in the date school closure plans must be established and submitted. The Department will permit a school currently participating in the FFEL program to submit a school closure plan to the Secretary, its principal guarantee agency, and its accrediting agency within six months of the date the regulations become effective.

Comments: One of the options for a school closure plan permits coverage under a State-administered tuition-recovery plan. Commenters from one State pointed out that when their State recovery plan is put in place in the near future, it will be State-approved, not State-administered. These commenters asked if this plan would satisfy the regulations.

Discussion: The Secretary believes that a State-administered plan would be audited by State auditors or subject to review by the State legislature and administrators, or both and would best meet his goals of ensuring the fiscal and administrative viability of the tuition recovery plan. However, the Secretary has concluded that a State-approved plan could provide these same protections in some cases. Therefore, a State-approved plan will be acceptable under the regulations if the plan is subject to State audit or review by the State legislature and administrators and is backed by the full faith and credit of the State.

Changes: The Secretary has revised the proposed regulations to provide that a State-approved tuition recovery plan will be an acceptable school closure plan if the plan is subject to State audit or review by the State legislature and administrators and is backed by the full faith and credit of the State.

Comments: Many commenters expressed concern that several existing State tuition-recovery plans do not permit refunds to be made to anyone but the student. State plans with this requirement would not qualify to be part of approved school closure plans under the proposed regulations.

Discussion: In the case of a school closure, the Secretary believes that, to prevent student loan defaults and protect the Federal fiscal interest, FFELP refunds must be paid to the lenders on behalf of the borrowers rather than to the borrowers directly. The proposed regulations are consistent with current Department regulations that require schools to pay FFELP refunds to lenders. See 34 CFR 668.22(e), 682.606 and 682.607. Therefore, the Secretary has retained the requirement that, to qualify as an approved part of a school closure plan, a tuition-recovery plan must pay refunds to the lenders.

Changes: None.

Comments: Many commenters expressed concern that the refund amounts paid under several existing State tuition-recovery plans might not refund an amount as large as the amount calculated under the definition of a *pro rata* refund in 34 CFR 682.606(c)(1) as required by the proposed regulations.

Discussion: The Secretary wishes to ensure that a refund made under this provision is equal to or greater than the amount calculated under 34 CFR 682.606(c)(1). Therefore, any State tuition-recovery plan that results in a refund equal to or greater than what would result if the refund were calculated in accordance with 34 CFR 682.606(c)(1) would satisfy the requirement of this provision of the regulations.

Changes: The language of the regulations has been clarified to provide that an acceptable school closure plan may include coverage under a State tuition-recovery plan that mandates a refund at least as large as a *pro rata* refund as defined in 34 CFR 682.606(c)(1).

To establish a consistent standard for refunds made as a result of any option selected as a school closure plan, the Secretary has also revised the language in 34 CFR 682.600(d)(2)(ii), (iii)(B), and (v) to reflect the same level of refund provided for in revised § 682.600(d)(2)(i).

Comments: Many commenters indicated that the level of third-party financial guarantees that would be required to satisfy the school closure plan obligation was too high, would impose a financial burden on already overburdened schools, and might, in fact, trigger school closures.

Discussion: The Secretary is aware that some schools might have difficulty meeting the level of third-party financial guarantees required under the surety bond or letter of credit option. However, the Secretary believes that the requirement that the bond or letter of credit be in an amount equal to at least 50 percent of one academic year's tuition, fees, and other charges for all enrolled students on whose behalf a FFELP loan is made for the current period of enrollment is needed to protect the interests of the students and the Federal government. Moreover, since the third-party financial guarantee is only one of several options a school may select, the Secretary does not agree with the commenters that it is unduly onerous and should be modified.

Changes: None.

Comments: Many commenters stated that accrediting commissions might be prohibited legally from administering or sponsoring teachout or pooled-risk programs as proposed as part of the alternatives in the NPRM because of a possible conflict of interest that might exist in their administration of the funds.

Discussion: On the basis of interest expressed by accrediting bodies after the original NPRM was published on June 5, 1989, the Secretary included proposals in the revised NPRM that would allow a school to participate in a school closure plan administered by its accrediting agency. The Secretary understands that each accrediting agency will have to determine its legal authority to administer such a program. However, the Secretary has retained the option of accrediting-agency administration of a school closure plan for those agencies that are able to administer one.

Changes: None.

Comments: A number of commenters suggested that the regulations should require that any school closure plan offer the borrower the option of a *pro rata* refund or a teachout.

Discussion: While the Secretary supports the idea of borrower choice inherent in the commenter's proposal, comments on the original June 5, 1989 NPRM indicated that not all schools are in a position to offer students the option of a teachout. Therefore, other options for school closure plans are being offered. However, the Secretary has determined that, in some circumstances, the Federal fiscal interest should be protected by requiring that a teachout must be the primary option. For example, the Secretary believes that in the case of a school closure plan administered by a school's accrediting commission, a teachout must be made available if possible. Only if teachout is not available under these plans must the *pro rata* refund be provided.

Changes: None.

Comments: Some commenters were concerned about the information that would need to be disclosed to a "competitor" for a school to arrange for a valid teachout agreement. Questions also were raised about the potential financial liabilities faced by the teachout school taking on the educational responsibilities of the closed school.

Discussion: The Department is not mandating specific information to be included in a teachout agreement. However, the teachout school must be an eligible institution that participates in the FFEL program and the agreement itself must comply with any other applicable laws and regulations.

In general, the Department will *not* require the teachout institution to assume the liabilities of the original school relating to the administration of the FFEL program. Moreover, the Department will not include in the calculation of the teachout school's cohort default rate any defaults that might occur on loans received by students to pay the costs at the school that closed. If, however, the students receive additional loans to cover the cost of attendance at the teachout school, any subsequent defaults will be included in the teachout school's cohort default rate.

Changes: None.

Comments: Several commenters stated that the provision for *pro rata* refunds as part of a school closure plan was inadequate and proposed that the

Secretary require full refunds be paid to students in attendance at a school at the time it terminates full teaching activities.

Discussion: While the Secretary understands the argument that an incomplete vocational education is of questionable value, it is unlikely that a total refund would be available in most closure situations. Moreover, the Secretary believes that a *pro rata* refund is generally appropriate and that, in most cases, students received some benefit from the training. Nonetheless, the Secretary encourages States and accrediting agencies, when possible, to provide full refunds for students; such a plan would satisfy these regulations.

Changes: None.

Comments: Several commenters urged the Secretary to monitor compliance with these regulations.

Discussion: The Secretary agrees that it is necessary to have systematic, ongoing monitoring of compliance with these regulations once initial compliance has been established.

Changes: No change has been made to the regulations. However, the Secretary will revise current audit and institutional review guides to ensure that school compliance with this requirement is monitored systematically.

Comments: Some commenters were concerned about the requirement that teachout agreements would not be permitted between schools that have a business connection.

Discussion: The Secretary believes that a teachout arrangement between schools that share a business connection might not adequately protect student consumers. A teachout agreement with another school with which the original school has a business connection is generally of questionable value as the financial difficulties encountered by the original school also might affect the teachout school. However, the Secretary wishes to clarify that while a school may not enter into a teachout agreement with a school with whom it shares a business connection to comply with the regulations, such a school will not be prohibited from teaching out the students from the original school as part of an orderly, planned closing.

For example, some entities that own a group of "related" schools might elect to close one of the schools to continue to maintain the financial health and quality of the other schools in the group. The teachout agreement with a school with which the original school has no business connection must be in place and capable of being implemented should such a school close. However, should a "related" school elect to teach out students of the closing school, instead of the official teachout school, the Department would not prohibit such a teachout as it might be the least disruptive method for a student to complete his or her program of study.

Changes: None.

Comments: A few commenters objected to the proposal that schools selecting the teachout alternative must make the information public in their catalogs or brochures and their enrollment contracts.

Discussion: The Secretary believes that potential students should be informed of the school's plans to protect them in case of a school closure. Information regarding such an arrangement must be available in the school's catalog or its equivalent and the enrollment contract if one is used.

Changes: The Secretary has revised the regulations to allow a school to meet this requirement by briefly describing its teachout arrangement in its catalog (or equivalent) and its enrollment contract, if one is used. The description in the catalog (or equivalent), or enrollment contract, may summarize the arrangement, but a detailed description must be available to a student or potential student upon request.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed regulations and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 682

Administrative practices and procedure, Colleges and universities, Loan programs-education, Reporting and recordkeeping requirements, Student aid, Vocational education.

Dated: December 24, 1992.

Lamar Alexander,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number 84.032, Guaranteed Student Loan Program and PLUS Program.)

The Secretary amends part 682 of title 34 of the Code of Federal Regulations as follows:

PART 682—FEDERAL FAMILY EDUCATION LOAN (FFEL) PROGRAM

1. The authority citation for part 682 continues to read as follows:

Authority: 20 U.S.C. 1071 to 1087–2, unless otherwise noted.

2. Section 682.600 is amended by redesignating paragraph (d) as paragraph (e) and adding a new paragraph (d) to read as follows:

§ 682.600 Agreement between an eligible school and the Secretary for participation in the Federal Family Education Loan Program.

* * * * *

(d)(1) A private school that does not qualify as an institution of higher education under 34 CFR 600.4, and that offers an undergraduate nonbaccalaureate program designed to prepare students for a particular vocational, trade, or career field, shall, as a condition for participation in the Federal Stafford, Federal PLUS, and Federal Supplemental Loans for Students (SLS) programs, have in effect at all times a plan, containing one or more of the elements in paragraph (d)(2) of this section, that provides for the equitable treatment of enrolled students and the Secretary in the event that the school terminates teaching activities in a particular program of study before the students complete the program of study.

(2) A school is considered to have a plan in effect that meets the requirements of this section only if its plan includes one or more of the following elements:

(i) Coverage under a State-administered tuition-recovery fund, or a State-approved tuition recovery plan that is subject to State audit or review by the State legislature or administrators and is backed by the full faith and credit of the State, that provides for payment of a refund from the fund directly to the lender that is at least as large as a *pro rata* refund, as defined in § 682.606(c)(1) of the tuition, fees, and other institutional charges assessed an enrolled student on whose behalf a Federal Stafford, Federal SLS, or Federal PLUS loan was made for the period of enrollment during which the school terminated teaching activities in a particular program of study.

(ii) A surety bond or letter of credit payable on demand to the Secretary posted by the school or another entity on behalf of the school in an amount equal to at least 50 percent of one academic year's tuition, fees, and other charges for all enrolled students on whose behalf a Federal Stafford, Federal SLS, or Federal PLUS loan will be made for the current period of enrollment at that school and that provides for the payment of a refund to lenders that is at least as large as a *pro rata* refund as defined in § 682.606(c)(1).

(iii) Coverage under a program and fund administered by the school's accrediting commission that includes—

(A) Written procedures for arranging a teachout, including the provisions in paragraph (d)(2)(iv) of this section for teachouts performed by a participating school under a teachout agreement, for enrolled students on whose behalf a Federal Stafford, Federal SLS, or Federal PLUS loan has been made who are in attendance at the school when the school terminates teaching activities in a particular program of study; and

(B) If no such teachout is provided when the school terminates teaching activities in a particular program of study, the payment of a refund at least as large as a *pro rata* refund as defined in § 682.606(c)(1) to the lender for each enrolled student on whose behalf a Federal Stafford, Federal SLS, or Federal PLUS loan was made for the period of enrollment during which the school terminated teaching activities in a particular program of study.

(iv) A teachout agreement with one or more other participating schools (the teachout school or schools) offering similar educational programs and with which the original school has no business connection that contains the following provisions:

(A) Each teachout school shall agree that, if the original school terminates its teaching activities in a particular program of study in which it enrolls a student to whom or on whose behalf a Federal Stafford, Federal SLS, or Federal PLUS loan is made for attendance at the original school, the teachout school will offer each such student enrolled in that course of study at the original school when the teaching activities are terminated a reasonable opportunity to promptly resume and complete his or her course of study, or a substantially similar course of study, in the same geographic area as that in which the original school provided the course of study.

(B) The teachout school shall agree to provide this opportunity without additional charge to the student, except that the teachout school may charge the student for periods of enrollment that the student is required to undertake to complete the course of study undertaken at the original school, as the student incurs those charges, up to the amount not yet paid by the student, that the original school would have been entitled to collect for those periods of enrollment from the student had the original school not terminated teaching activities in the program of study prior to the student's completion of the program of study.

(C) The original school shall agree that, in the event a teachout becomes necessary, it will arrange, in a timely manner, for individual notice to each student of the availability of the teachout and diligently advertise the availability of the teachout. Such arrangements may provide that the teachout notices be sent by the teachout school.

(v) Coverage under a "pooled risk" arrangement administered by the school's accrediting commission that ensures that a refund will be paid directly to the lender that is at least as large as a *pro rata* refund as defined in § 682.606(c)(1) for each enrolled student on whose behalf a Federal Stafford, Federal SLS, or Federal PLUS loan was made for the period of enrollment during which the school terminates teaching activities in a particular program of study.

(3) A school shall submit written evidence acceptable to the Secretary, its accrediting commission, and its principal guarantee agency that it has been selected and adopted an acceptable closure plan containing one or more of the elements under this paragraph. A school that selects the teachout alternative under paragraph (d)(2)(iv) of this section shall submit, as required written evidence of the teachout arrangement, a copy of its catalog or the equivalent and of its enrollment contract, both including a brief description of the teachout plan, and shall make details of such arrangement available to students and prospective students upon request.

* * * * *

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Part VII

Department of Education

34 CFR Part 668

Student Assistance General Provisions; Final Regulations

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DEPARTMENT OF EDUCATION

34 CFR Part 668

RIN 1840–AB30

Student Assistance General Provisions

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the Student Assistance General Provisions regulations to put in place a procedure for determining the immigration status of noncitizen applicants for student financial assistance under Title IV of the Higher Education Act of 1965, as amended (Title IV, HEA). The purpose of the immigration-status confirmation procedure is to relieve substantially most institutions from the burden of manually inspecting the immigration-status documents of all noncitizen applicants for Title IV, HEA financial assistance.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the Federal Register, or later if Congress takes certain adjournments, with the exception of §§ 668.133, 668.134, and 668.135. Sections 668.133, 668.134, and 668.135 will become effective after the information collection requirements contained in those sections have been submitted by the Department of Education and approved by the Office of Management and Budget under the Paperwork Reduction Act of 1980. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Claude Denton, General Provisions Branch, Division of Policy Development, U.S. Department of Education, 400 Maryland Avenue, SW. (Regional Office Building 3, room 4318), Washington, DC 20202–5444, Telephone (202) 708–7888. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION: The Student Assistance General Provisions regulations put in place requirements that apply to all institutions that participate in the Title IV, HEA student financial assistance programs. For purposes of this subpart, the Title IV, HEA programs include the Federal Pell Grant, Federal Stafford Loan, Federal PLUS Loan, Federal Supplemental Loans for Students (SLS), State Student Incentive Grant (SSIG), Federal Perkins Loan, Federal Work-Study (FWS), and Federal Supplemental Educational Opportunity Grant (FSEOG) programs.

On April 29, 1991, the Secretary published a notice of proposed rulemaking in the Federal Register (56 FR 19782) with regard to the immigration-status confirmation procedure. The Secretary believes that this procedure will assure that Federal student financial assistance dollars are used to provide educational opportunities only to U.S. citizens, U.S. nationals, or noncitizens who prove that they possess an immigration status that satisfies the eligibility criteria for Title IV, HEA financial assistance set forth in 34 CFR 668.7(a) (4). Specifically, 34 CFR 668.7(a)(4)(ii) provides that a student is eligible for Title IV, HEA assistance if the student provides evidence from the U.S. Immigration and Naturalization Service (INS) that he or she is a permanent resident of the United States or is in the United States for other than a temporary purpose with the intention of becoming a citizen or permanent resident.

The immigration-status confirmation procedure will relieve most institutions of a substantial portion of the administrative burden currently associated with identifying the immigration status represented on immigration documents and determining whether those documents are authentic. At the same time, the procedure will reduce the potential for fraud and abuse in the Title IV, HEA programs by improving the institutions' ability to determine whether noncitizen applicants are eligible for Title IV, HEA assistance under § 668.7(a)(4)(ii).

The confirmation procedure will improve the efficiency of the Title IV, HEA programs and, by so doing, improve their capacity to enhance opportunities for postsecondary education. Encouraging students to graduate from high school and to pursue high quality postsecondary education are important elements of the President's AMERICA 2000 strategy to move the Nation toward achieving the National Education Goals.

These regulations establish procedures for institutions to use in determining the eligibility of noncitizen applicants for Title IV, HEA benefits. The term "confirmation" of immigration status as set forth in Subpart I is equivalent to the term "verification" of immigration status that commonly is used by the INS and other agencies using the INS's immigration-status verification system. The Secretary substituted the term "confirmation" in place of the INS term "verification" to avoid confusion with the process of verifying the student's Expected Family Contribution in 34 CFR 668, Subpart E. Immigration-status confirmation under Subpart I and verification under Subpart E are two separate procedures and institutions may not count confirmations under Subpart I toward the 30 percent verification ceiling mandated by section 484(f) of the Higher Education Act of 1965, as amended (HEA).

Analysis of Comments and Changes

In response to the Secretary's invitation in the NPRM, 68 parties submitted comments on the proposed regulations. An analysis of the comments and of the changes in the regulations since publication of the NPRM follows.

Substantive issues are discussed under the section of the regulations to which they pertain. Technical and other minor changes—and suggested changes that the Secretary is not legally authorized to make under the applicable statutory authority—are not addressed.

Section 668.132 Institutional Determinations of Eligibility Based on Primary Confirmation

Comments: Several commenters supported these provisions and several others objected. Many commenters disagreed with the Secretary's contention that use of the primary confirmation process to replace determining immigration status by inspecting documents manually would reduce administrative burden on institutions. Two commenters expressed concern that some student records that successfully matched with INS data in a previous award year did not match in the current award year and questioned the need to impose secondary confirmation on institutions because of Federal data errors. Other commenters suggested that current primary confirmation performance is poor, that the INS data base is not adequately updated and maintained, and that the Secretary's claim that 80 percent of noncitizen applications would match with INS data using primary confirmation is unrealistic. Several commenters perceived a conflict in that this section prohibits institutions from requiring documentation if the message on the output document confirms the student's eligible noncitizen status, while § 668.133 of the proposed regulations requires an institution to request document and follow secondary confirmation procedures if the output document confirms the student's eligibility but the institution has conflicting information.

Discussion: The Secretary agrees with those commenters who maintain that the primary confirmation process reduces the burden on institutions. At the same time, the Secretary is aware that the percentage of primary confirmation matches was abnormally low during the 1990–91 award year because the primary confirmation system was taken out of operation for several months while the Department and INS brought the matching program into compliance with the Computer Matching and Privacy Protection Act of 1988, that became effective in January 1990. The Secretary believes that this operations hiatus explains why some applicants who matched in a previous award year did not match in the current award year. The Secretary expects that continuous operation of the matching system during the entire 1991–92 award year and thereafter should alleviate much of the concern expressed about institutional burden and the quality of the INS data base. Indeed, recent analysis of 1991–92 data reveals that the percentage of noncitizen applicants confirmed through the primary confirmation process is approximately 70 percent.

The Secretary disagrees that there is a conflict between instructions given in § 668.132(a) and § 688.133. Section 668.132(a) states that "except as provided in § 668.133(a)(1)(ii)," the institution must determine a student to be an eligible noncitizen if the institution receives an output document that confirms the student's immigration status. An institution cannot determine a student to be an eligible noncitizen in accordance with § 668.132(a) if it has conflicting information concerning the student's immigration status. Under § 668.133(a)(1)(ii), if the institution has conflicting information, the institution must obtain, from the applicant, documentation of immigration status and submit that documentation to the INS for secondary confirmation.

Changes: None.

Section 668.133 Conditions Under Which an Institution Shall Require Documentation and Request Secondary Confirmation

Comments: Several commenters protested that secondary confirmation is an INS enforcement exercise that is being inappropriately assigned to educational institutions and that exchanges of data should take place only between the student and INS. One commenter questioned why the burden of processing secondary confirmation requests should be placed on the institution when the student can obtain such information directly from INS or the Secretary's central processing system. Many commenters questioned whether the problem of citizenship fraud and abuse in the Title IV, HEA programs is serious enough to warrant mandatory secondary confirmation. Many others were concerned that secondary confirmation procedures are administratively burdensome and will delay processing of Title IV, HEA assistance for many eligible noncitizen students. Two commenters questioned why secondary confirmation is needed when the institution can make a reasonable determination of the student's eligibility using documents submitted by the student. Several commenters expressed their desire to have secondary confirmation available as an option and to be permitted to continue the current practice of determining noncitizen eligibility through a manual examination of the student's immigration-status documents. A number of commenters suggested that secondary confirmation should be required only in cases of conflicting or irreconcilable documentation. One commenter suggested that institutional confirmation of a student's immigration status be required only once during the student's enrollment at the institution. Another commenter proposed that, prior to issuing final regulations, the Secretary should conduct a study to compare the costs and benefits of the proposed regulations. Another commenter questioned how an output document could be incorrect unless the Secretary suspects inadequacies in the INS data base. One commenter questioned whether § 668.133(b)(1) is intended to prohibit the use of secondary confirmation to identify fraudulent documentation in cases where the student changes his response on the application from "eligible noncitizen" to "U.S. citizen" or "U.S. national."

Discussion: With regard to comments concerning mandatory use of secondary confirmation, the Secretary no longer has authority to prescribe regulations limiting use of this process. Section 484(h)(4)(B) of the Higher Education Act of 1965, as amended, now requires an institution to request secondary confirmation if a student's claim of eligible noncitizen status is not confirmed using primary confirmation and if that student submits documents that the institution determines constitute reasonable evidence of the student's immigration status.

The Secretary is carefully considering the suggestion of a one-time-only confirmation of the immigration status of a student during the student's enrollment at a given institution. For the 1993–94 award year, the Secretary is investigating the possible use of an automatic renewal of the primary confirmation message on the output documents of individuals having an eligible noncitizen status that is confirmed using primary confirmation.

The commenter's suggestion that a cost-benefit analysis be undertaken before putting in place these regulations is well taken. The Secretary has performed a recent analysis, as required by the Compute Matching and Privacy Protection Act of 1988, that indicates that the operational costs of this computer match to the Federal Government are $35,400, as compared to $650,000 in administrative savings to institutions that are no longer required to examine the immigration-status documents of 70% of noncitizen applicants. Secondary confirmation is not monitored at the Federal level, however, so the costs of secondary confirmation are not factored into this analysis. The Secretary must rely on information, such as that provided by the commenters, to gain a rough assessment of the total costs and benefits of this program.

The Secretary disagrees with the commenter who presumes that any possibility of conflicting information in the message on the output document is an indication that the INS data base used for primary confirmation is inadequate. The regulations recognize that the immigration status of an individual might change and that conflicts of information are inevitable when either documentation or data base information becomes outdated. Since § 668.14(f) of the existing regulations requires an institution to "identify and resolve discrepancies in the information it receives from different sources," these regulations offer the secondary confirmation process as a way of reconciling these conflicts.

The Secretary does not believe that § 668.133(b) would prohibit an institution from requesting secondary confirmation for a student who changes his or her response on an application from "eligible noncitizen" to "U.S. citizen" or to "U.S. national." If the institution has reason to believe the student's citizenship claim is incorrect or that a student's citizenship documentation may be fraudulent, the institution must obtain additional information through secondary confirmation. Furthermore, any information related to a false claim of citizenship should be referred to the appropriate authorities for investigation in accordance with § 668.14(g).

Changes: None.

Section 668.134 Institutional Policies and Procedures for Requesting Documentation and Receiving Secondary Confirmation

Comments: Several commenters suggested that establishing additional policies and procedures is overly burdensome and unwarranted. One commenter questioned why institutions were being required to establish their own policies and procedures instead of complying with guidelines already set by the Secretary. Several others commented that it is unnecessary to have a deadline for submitting documents and requested guidance concerning the actions to be taken if documents are submitted after the deadline has passed. One commenter requested that the Secretary provide institutions with sample explanations of the needed documentation. Another commenter requested clarification concerning whether the phrase "a clear explanation" means that an institution would be required to provide instructions to students in their native languages.

Discussion: The Secretary disagrees that the requirement for institutional policies and procedures is unwarranted and burdensome or that the Secretary should impose standard policies and procedures for all institutions. This section is similar to requirements set forth in § 668.53 of existing regulations, which provides guidance to institutions in establishing policies and procedures that deal with verifying information provided by a student that is used to calculate the student's eligibility for financial aid. In the same fashion, the Secretary intends to permit significant institutional discretion in designing procedures for requesting documentation and confirming a student's immigration status. For example, an institution will need to give a student written instructions that are clear and complete, but it need not interpret this provision as a requirement for the instructions to be provided in an applicant's native language. By requiring that an institution establish written policies and procedures, the Secretary seeks to ensure that the institution establishes each student's immigration status and eligibility for Title IV HEA financial assistance in an equitable and consistent manner.

To preserve as much institutional discretion as possible, the Secretary has chosen not to set arbitrary deadlines for the submission of documents. Rather, the Secretary has created parameters within which institutions may set their own deadlines. These parameters are necessary because of existing statutory requirements and practical considerations regarding the time needed to process Title IV, HEA applications. Specifically, in accordance with the Computer Matching and Privacy Protection Act of 1988, an institution must allow a student a minimum of 30 days to collect and submit documentation to the institution in support of his or her claim of eligible noncitizen status.

Sample documentation of immigration status already has been provided by the Secretary in Chapter 2 of the Federal Student Financial Aid Handbook, which is published annually. These regulations are not introducing any changes in the immigration-status documents that institutions examined in the past to determine noncitizen eligibility.

Changes: None.

Section 668.135 Institutional Procedures for Completing Secondary Confirmation

Comments: Several commenters supported the procedure. Many commenters, however, protested that the 10-business-day deadline for institutions to initiate secondary confirmation after receiving immigration-status documentation from the student is unrealistic during peak workload periods. Two commenters questioned why the regulations require institutions to comply with the 10-business-day deadline and only "expect" INS to meet its 10-business-day turnaround time to respond to requests for secondary confirmation. Two commenters questioned whether institutions are required to initiate secondary confirmation for students who applied to the institution but have not been admitted and whether the 10-business-day countdown should begin if the institution has received immigration-status documents for a student but no output document for that student. One commenter requested guidance concerning the consequences if an institution fails to meet the deadline for submitting documentation to INS.

Discussion: The Secretary does not agree that 10 business days is insufficient time to complete the request portion of the G–845 and to submit it to INS. The 10-business-day deadline represents a balance between the need for sufficient time to confirm and authenticate a student's immigration status with INS and the need to avoid undue delays in assistance to eligible students.

With regard to the comment concerning a double standard assigned to INS and institutions in complying with 10-business-day deadlines, the Secretary cannot regulate another Federal agency, but can enter into agreements with another agency stating that certain standards of performance are expected by both parties. Accordingly, the Secretary has an operational computer matching agreement in which INS has agreed to the 10-business-day turnaround time to respond to requests from institutions for secondary confirmation.

The 10-business-day deadline for institutional initiation of secondary confirmation after receiving documentation from the student applies whether or not the student has been admitted.

With regard to when the 10-business-day countdown begins, if the institution receives immigration-status documentation without an output document, an institution should not consider the 10-business-day period to begin until it has received both the student's immigration-status documents and the output document. The output document is a required component of that documentation as it contains important information related to the results of primary confirmation. The requirements in § 668.135 apply only when a student is required to undergo secondary confirmation. An institution will not be able to determine whether secondary confirmation is mandatory until the institution has received the student's output document.

Institutional penalties for missing this deadline will be consistent with program review policy to enforce all applicable regulatory provisions.

Changes: None.

Section 668.136 Institutional Determination of Eligibility That Are Not Based on Primary Confirmation

Comments: One commenter suggested that it invites abuse to have a policy permitting institutional disbursements of Title IV, HEA assistance prior to the institution obtaining a response from INS concerning secondary confirmation. Several commenters were concerned that the need to track the 15-business-day period subsequent to initiation of secondary confirmation would add to institutional burden. A number of commenters felt that any disbursement of assistance prior to obtaining a response from INS would place potential liability on the institution and, for this reason, few institutions would use this option. Several commenters expressed concern that the preamble's statement that "an INS determination of a student's immigration status * * * should precede any decision by the institution with regard to the student's

eligibility for Title IV, HEA assistance" would prevent the institution from making routine preliminary decisions about student eligibility in areas other than immigration status. Two commenters suggested that the term "sufficient documentation" in proposed § 668.136(b)(2) be clarified as "documentation that, if valid, demonstrates that the applicant is an eligible noncitizen." One commenter suggested that to avoid delays to students institutions should be allowed to telephone INS when the 15-business-day period is exceeded. Another commenter suggested that the 15-business-day period be lengthened to 20 or 30 business days to allow more time for postal delivery.

Discussion: The Secretary does not agree that provisions providing for disbursement of assistance pending receipt of INS responses to secondary confirmation requests invite abuse. An institution will continue to be responsible for making certain that noncitizen applicants provide acceptable evidence of eligible noncitizen status before disbursing Title IV, HEA assistance.

The Secretary also wishes to emphasize that these regulations do not impose liabilities on institutions for erroneous grant payments or loan disbursements to a student discovered to be ineligible as a result of secondary confirmation if the institutions can show documented evidence of immigration status that meets the requirements of § 668.7(a)(4)(ii).

The Secretary believes that the 15-business-day limitation subsequent to initiation of secondary confirmation is necessary to prevent unnecessary delays in processing the student financial aid applications of eligible noncitizens.

Contrary to one commenter's concern, the Secretary's desire to obtain an INS determination of a student's immigration status prior to the institution's determination of eligibility does not prevent an institution from engaging in an activity such as providing preliminary estimates of financial aid eligibility.

The Secretary disagrees with the commenter who requested that the proposed use of the term "sufficient documentation" be changed to "documentation that, if valid, demonstrates that the applicant is an eligible noncitizen." "Sufficient" indicates that the institution has in its possession documents with which it is able to make a decision that a student satisfies the requirements of § 668.7(a)(4)(ii). The commenter's proposed revision presupposes that the institution will determine the student to be eligible when, in fact, the institution may determine that the documents are insufficient to determine eligibility and, as a result, may deny Title IV, HEA assistance to the student.

The Secretary does not agree with the suggestion that institutions should be allowed to telephone INS to obtain status information when the 15-business-day period is exceeded. Although procedures differ somewhat among INS field offices, the Secretary recognizes that institutional access to INS by telephone has become more limited in recent years because of the large increase in immigrants and other groups seeking INS services. The Secretary wishes to cooperate with INS, to the fullest extent possible, in developing a more automated and efficient means of gaining access to information than is possible if the institution must await responses to telephone calls or inquiries by letter.

Finally, the Secretary does not agree with the suggestion that the 15-business-day period be lengthened to 20 or 30 business days. Fifteen business days, or three calendar weeks, should be the maximum amount of time allowed given INS's commitment to a 10-business-day response and the Secretary's desire not to delay assistance to eligible noncitizens undergoing secondary confirmation.

Changes: None.

Section 668.137 Deadlines for Submitting Documentation and the Consequences of Failure To Submit Documentation

Comments: One commenter sought clarification from the Secretary concerning whether this section is limited in scope to immigration-status confirmation or if it has broader application. Two commenters questioned the need for an institutionally set deadline for the student to submit immigration-status documents to the institution, and they also questioned whether the institution has the right to deny assistance if this deadline is not met. Another commenter suggested that this section is inconsistent with the Computer Matching and Privacy Protection Act of 1988, which requires a minimum period of time for the student to submit documents as a way of contesting the results of the computer matching program.

Discussion: The Secretary assures the commenter seeking clarification regarding applicability of this section that the regulations are limited in scope to institutions considering claims by students to be eligible noncitizens under § 668.7(a)(4)(ii). With regard to the need for an institutionally set deadline, the Secretary believes that the institution, which is being given responsibility for initiating secondary confirmation requests, also should be given the flexibility for setting a deadline that is consistent with its own procedures.

The Secretary does not agree with the commenter who expressed doubt that the institution has authority to deny assistance to an applicant who does not meet this deadline. The Secretary points out that § 668.60 already has given an institution similar authority when an applicant fails to provide requested documentation with regard to verification of the student's application data for purposes of calculating the student's award.

The Secretary agrees with the commenter that there is a statutory requirement setting a minimum time period for the student to submit evidence of eligible noncitizen status; it is required by section 2 of the Computer Matching and Privacy Protection Act of 1988.

Changes: Paragraph (a) is revised to allow the student a minimum of 30 days from the date the output document is submitted to the institution to submit documentation of eligible noncitizen status to the institution. Because this revision conflicts with the remainder of proposed paragraph (a) to the extent that the 30-day period would allow an applicant to submit immigration-status documents after the end of the award year or period of enrollment, the Secretary is deleting the remainder of this paragraph.

Section 668.138 Liability

Comments: Several commenters expressed concern that this section would hold institutions liable for disbursements made as a result of eligibility determinations that subsequently are found to be in error after receipt of secondary confirmation responses. One commenter requested that the Secretary explain how an institution could make an error when the immigration-status documentation satisfies existing regulations. Another commenter suggested that, since the institution would be relying on documentation supplied by the student, the student should be liable unless the institution had reason to believe the documents do not support the student's claim to be an eligible noncitizen.

Discussion: The Secretary agrees with the commenters' assertions that liability should not be imposed on the institution for the institution's erroneous determination that a student is an eligible noncitizen as long as the institution can justify a disbursement by

showing documented evidence of eligible immigration status as required by § 668.7(a)(4)(ii). The intent of this section was to impose liability on an institution that disburses Title IV, HEA assistance despite having immigration-status documentation, or an INS response to a secondary confirmation request, that does not support the student's eligibility claim.

Changes: Section 668.138(c)(3) is added to clarify the Secretary's intent concerning institutional liability.

Section 668.139 Recovery of Payments and Loan Disbursements to Ineligible Students

Comments: Two commenters suggested that § 668.139(d) be rephrased to require the institution to repay the "ineligible portion of a loan disbursement" to the lender and to notify the guarantee agency when the institution makes a disbursement to an ineligible student. These commenters suggested that the Secretary include provisions authorizing the institution to obtain the promissory note for the purpose of loan collection and that the Secretary should address repayment of interest and special allowances paid on the "ineligible portion." One commenter proposed that for Federal PLUS loans institutions should be permitted to accept a statement attesting to the eligible noncitizen status of the parent of an eligible noncitizen applicant. Another commenter requested clarification about whether loans to ineligible students could be reinsured as exempt claims as provided in § 682.405(a)(2).

Discussion: The Secretary does not agree that § 668.139(d) should be revised to assign institutions the responsibility for repaying the "ineligible portion" of a Federal Stafford, Federal SLS, or Federal PLUS loan to the lender. An institutional determination of a student's eligible noncitizen status affects the student's eligibility for all Title IV, HEA assistance. The student will be liable for repayment of the entire disbursement should the institution's determination of eligibility prove to be in error. Any discussion of repayment of a portion of the disbursement is not relevant in this situation.

The comments with regard to guarantee agency notification and refunds of interest and special allowances are valid comments and should be addressed within the context of all recipients of Title IV, HEA assistance who subsequently are determined to be ineligible. Noncitizens represent only small fraction of the population that might be affected.

The Secretary does not agree that statements of eligible noncitizen status from Federal PLUS loan parents should be accepted in lieu of actual INS immigration-status documents and believes that such statements do not provide satisfactory evidence of immigration status.

With regard to the comment concerning reinsurability, the Secretary holds the position that the amount of the disbursement to an ineligible student is not reinsured.

Changes: Paragraph (d) is revised to insert "repay" in place of "restore."

Waiver of Proposed Rulemaking

In accordance with section 431(b)(2)(A) of the General Education Provisions Act (20 U.S.C. 1232(b)(2)(A)) and the Administrative Procedure Act (5 U.S.C. 553), it is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations. Most of the changes in these final regulations were published for public comment on April 29, 1991 at 56 FR 19782. However, some of these changes are needed to conform the regulations to statutory changes made by Public Law 102–325, and public comment would have no effect on the content of these changes. Therefore, the Secretary has determined that publication of a proposed rule is unnecessary and contrary to the public interest under 5 U.S.C. 553(b)(B).

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 668

Administrative practice and procedure, Colleges and universities, Consumer protection, Education, Grant programs—education, Loan programs—education, Reporting and recordkeeping requirements, Student aid.

Dated: December 30, 1992.

Lamar Alexander,

Secretary of Education.

(Catalog of Federal Domestic Assistance Numbers: Supplemental Educational Opportunity Grant Program, 84.007; Stafford Loan Program, 84.032; College Work-Study Program, 84.033; Perkins Loan Program, 84.038; Income Contingent Loan Program, 84.226; Pell Grant Program, 84.063; State Student Incentive Grant Program, 84.069)

The Secretary amends part 668 of title 34 of the Code of Federal Regulations by adding a new Subpart I to read as follows:

PART 668—STUDENT ASSISTANCE GENERAL PROVISIONS

* * * * *

Subpart I—Immigration-Status Confirmation

668.130 General.
668.131 Definitions.
668.132 Institutional determinations of eligibility based on primary confirmation.
668.133 Conditions under which an institution shall require documentation and request secondary confirmation.
668.134 Institutional policies and procedures for requesting documentation and receiving secondary confirmation.
668.135 Institutional procedures for completing secondary confirmation.
668.136 Institutional determinations of eligibility based on INS responses to secondary confirmation requests.
668.137 Deadlines for submitting documentation and the consequences of failure to submit documentation.
668.138 Liability.
668.139 Recovery of payments and loan disbursements to ineligible students.

Authority: 20 U.S.C. 1091, 1092, and 1094, unless otherwise noted.

* * * * *

Subpart I—Immigration-Status Confirmation

§ 668.130 General.

(a) *Scope and purpose.* The regulations in this subpart govern the responsibilities of institutions and students in determining the eligibility of those noncitizen applicants for Title IV, HEA assistance who must, under § 668.7(a)(4)(ii), produce evidence from the United States Immigration and Naturalization Service (INS) that they are permanent residents of the United States or in the United States for other than a temporary purpose with the intention of becoming citizens or permanent residents.

(b) *Student responsibility.* At the request of the Secretary or the institution at which an applicant for Title IV, HEA financial assistance is

enrolled or accepted for enrollment, an applicant who asserts eligibility under § 668.7(a)(4)(ii) shall provide documentation from the INS of immigration status.

(Authority: 20 U.S.C. 1091, 1094)

§ 668.131 Definitions.

The following definitions apply to this subpart:

Eligible noncitizen: An individual possessing an immigration status that meets the requirements of § 668.7(a)(4)(ii).

Immigration status: The status conferred on a noncitizen under the Immigration and Nationality Act of 1952, as amended, 8 U.S.C. 1182.

Output document: The Student Aid Report (SAR), Electronic Student Aid Report (ESAR), other document, or automated data generated by the Department of Education's central processing system as the result of processing the data provided in an Application for Federal Student Aid or multiple data entry application.

Primary confirmation: A process by which the Secretary, by means of a matching program conducted with the INS, compares the information contained in an Application for Federal Student Aid or a multiple data entry application regarding the immigration status of a noncitizen applicant for Title IV, HEA assistance with records of that status maintained by the INS in its Alien Status Verification Index (ASVI) system for the purpose of determining whether a student's immigration status meets the requirements of § 668.7(a)(4)(ii) and reports the results of this comparison on an output document.

Secondary confirmation: A process by which the INS, in response to the submission of INS Document Verification Form G–845 by an institution, searches pertinent paper and automated INS files, other than the ASVI database, for the purpose of determining a student's immigration status and the validity of the submitted INS documents, and reports the results of this search to the institution.

(Authority: 20 U.S.C. 1091)

§ 668.132 Institutional determinations of eligibility based on primary confirmation.

(a) Except as provided in § 668.133(a)(1)(ii), the institution shall determine a student to be an eligible noncitizen if the institution receives an output document for that student establishing that—

(1) The INS has confirmed the student's immigration status; and

(2) The student's immigration status meets the noncitizen eligibility requirements of § 668.7(a)(4)(ii).

(b) If an institution determines a student to be an eligible noncitizen in accordance with paragraph (a) of this section, the institution may not require the student to produce the documentation otherwise required under § 668.7(a)(4)(ii).

(Authority: 20 U.S.C. 1091, 1094)

§ 668.133 Conditions under which an institution shall require documentation and request secondary confirmation.

(a) *General requirements.* Except as provided in paragraph (b) of this section, an institution shall require the student to produce the documentation required under § 668.7(a)(4)(ii) and request the INS to perform secondary confirmation for a student claiming eligibility under § 668.7(a)(4)(ii), in accordance with the procedures set forth in § 668.135, if—

(1) The institution—

(i) Receives an output document indicating that the student must provide the institution with evidence of the student's immigration status required under § 668.7(a)(4)(ii); or

(ii) Receives an output document that satisfies the requirements of § 668.132(a)(1) and (2), but the institution—

(A) Has documentation that conflicts with immigration-status documents submitted by the student or the immigration status reported on the output document; or

(B) Has reason to believe that the immigration status reported by the student or on the output document is incorrect; and

(2) The institution determines that the immigration-status documents submitted by the student constitute reasonable evidence of the student's claim to be an eligible noncitizen.

(b) *Exclusions from secondary confirmation.* An institution may not require the student to produce the documentation required under § 668.7(a)(4)(ii) and may not request that INS perform secondary confirmation, if—

(1) The student—

(i) Demonstrates U.S. citizen or national status; or

(ii) Demonstrates eligibility under the provisions of § 668.7(a)(4) (iii) or (iv); and

(2) The institution does not have conflicting documentation or reason to believe that the student's claim of citizenship or immigration status is incorrect.

(Authority: 20 U.S.C. 1091, 1094)

§ 668.134 Institutional policies and procedures for requesting documentation and receiving secondary confirmation.

(a) An institution shall establish and use written policies and procedures for requesting proof and securing confirmation of the immigration status of applicants for Title IV, HEA student financial assistance who claim to meet the eligibility requirements of § 668.7(a)(4)(ii). These policies and procedures must include—

(1) Providing the student a deadline by which to provide the documentation that the student wishes to have considered to support the claim that the student meets the requirements of § 668.7(a)(4)(ii);

(2) Providing to the student information concerning the consequences of a failure to provide the documentation by the deadline set by the institution; and

(3) Providing that the institution will not make a determination that the student is not an eligible noncitizen until the institution has provided the student the opportunity to submit the documentation in support of the student's claim of eligibility under § 668.7(a)(4)(ii).

(b) An institution shall furnish, in writing, to each student required to undergo secondary confirmation—

(1) A clear explanation of the documentation the student must submit as evidence that the student satisfies the requirements of § 668.7(a)(4)(ii); and

(2) A clear explanation of the student's responsibilities with respect to the student's compliance with § 668.7(a)(4)(ii), including the deadlines for completing any action required under this subpart and the consequences of failing to complete any required action, as specified in § 668.137.

(Authority: 20 U.S.C. 1091, 1092, 1094)

§ 668.135 Institutional procedures for completing secondary confirmation.

Within 10 business days after an institution receives the documentary evidence of immigration status submitted by a student required to undergo secondary confirmation, the institution shall—

(a) Complete the request portion of the INS Document Verification Request Form G–845;

(b) Copy front and back sides of all immigration-status documents received from the student and attach copies to the Form G–845; and

(c) Submit Form G–845 and attachments to the INS District Office.

(Authority: 20 U.S.C. 1091, 1094)

§ 668.136 Institutional determinations of eligibility based on INS responses to secondary confirmation requests.

(a) Except as provided in paragraphs (b) and (c) of this section, an institution that has requested secondary confirmation under § 668.133(a) shall make its determination concerning a student's eligibility under § 668.7(a)(4)(ii) by relying on the INS response to the Form G–845.

(b) An institution shall make its determination concerning a student's eligibility under § 668.7(a)(4)(ii) pending the institution's receipt of an INS response to the institution's Form G–845 request concerning that student, if—

(1) The institution has given the student an opportunity to submit documents to the institution to support the student's claim to be an eligible noncitizen;

(2) The institution possesses sufficient documentation concerning a student's immigration status to make that determination;

(3) At least 15 business days have elapsed from the date that the institution sent the Form G–845 request to the INS;

(4) The institution has no documentation that conflicts with the immigration-status documentation submitted by the student; and

(5) The institution has no reason to believe that the immigration status reported by the applicant is incorrect.

(c) An institution shall establish and use policies and procedures to ensure that, if the institution has disbursed or released Title IV, HEA funds to the student in the award year or employed the student under the Federal Work-Study Program, and the institution determines, in reliance on the INS response to the institution's request for secondary confirmation regarding that student, that the student was in fact not an eligible noncitizen during that award year, the institution provides the student with notice of the institution's determination, an opportunity to contest the institution's determination, and notice of the institution's final determination.

(Authority: 20 U.S.C. 1091, 1094)

§ 668.137 Deadlines for submitting documentation and the consequences of failure to submit documentation.

(a) A student shall submit before a deadline specified by the institution all documentation the student wishes to have considered to support a claim that the student meets the requirements of § 668.7(a)(4)(ii). The deadline, set by the institution, must be not less than 30 days from the date the institution receives the student's output document.

(b) If a student fails to submit the documentation by the deadline established in accordance with paragraph (a) of this section, the institution may not disburse to the student, or certify the student as eligible for, any Title IV, HEA program funds for that period of enrollment or award year; employ the student under the Federal Work-Study Program; or certify a Federal Stafford, Federal PLUS, or Federal SLS loan application for the student for that period of enrollment.

(Authority: 20 U.S.C. 1091, 1094)

§ 668.138 Liability.

(a) A student is liable for any SSIG, Federal SEOG, or Federal Pell Grant payment and for any Federal Stafford, Federal SLS, or Federal Perkins loan made to him or her if the student was ineligible for the Title IV, HEA assistance.

(b) A Federal PLUS loan borrower is liable for any Federal PLUS loan made to him or her on behalf of an ineligible student.

(c) The Secretary does not take any action against an institution with respect to an error in the institution's determination that a student is an eligible noncitizen if, in making that determination, the institution followed the provisions in this subpart and relied on—

(1) An output document for that student indicating that the INS has confirmed that the student's immigration status meets the eligibility requirements for Title IV, HEA assistance;

(2) An INS determination of the student's immigration status and the authenticity of the student's immigration documents provided in response to the institution's request for secondary confirmation; or

(3) Immigration-status documents submitted by the student and the institution did not have reason to believe that the documents did not support the student's claim to be an eligible noncitizen.

(d) Except as provided in paragraph (c) of this section, if an institution makes an error in its determination that a student is an eligible noncitizen, the institution is liable for any Title IV, HEA disbursements made to this student during the award year or period of enrollment for which the student applied for Title IV, HEA assistance.

(Authority: 20 U.S.C. 1091, 1094)

§ 668.139 Recovery of payments and loan disbursements to ineligible students.

(a) If an institution makes a payment of a grant or a disbursement of a Federal Perkins loan to an ineligible student for which it is not liable in accordance with § 668.138, it shall assist the Secretary in recovering the funds by—

(1) Making a reasonable effort to contact the student; and

(2) Making a reasonable effort to collect the payment or Federal Perkins loan.

(b) If an institution causes a Federal Stafford, Federal SLS, or Federal PLUS loan to be disbursed to an ineligible student or Federal PLUS loan borrower for which it is not liable in accordance with § 668.138, it shall assist the Secretary in recovering the funds by notifying the lender that the student has failed to establish eligibility under the requirements of § 682.201(d).

(c) If an institution is liable for a payment of a grant or Federal Perkins loan to an ineligible student, the institution shall restore the amount equal to the payment or disbursement to the institution's Federal Perkins loan fund or Federal Pell Grant, Federal SEOG, or SSIG amount, even if the institution cannot collect the payment or disbursement from the student.

(d) If an institution is liable for a Federal Stafford, Federal SLS, or Federal PLUS loan disbursement to an ineligible student, the institution shall repay an amount equal to the disbursement to the Federal Stafford, Federal SLS, or Federal PLUS lender and provide written notice to the borrower.

(Authority: 20 U.S.C. 1091, 1094)

[FR Doc. 93–134 Filed 1–6–93; 8:45 am]

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Federal Register

Thursday
January 7, 1993

Part VIII

Department of Education

34 CFR Part 99
Family Educational Rights and Privacy; Rule

VOL 58 ISS 4 JA 7 1993 UMI

DEPARTMENT OF EDUCATION

34 CFR Part 99

RIN 1880–AA54

Family Educational Rights and Privacy

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations for the Family Educational Rights and Privacy Act (FERPA). These amendments are needed to implement a disclosure provision of the Crime Awareness and Campus Security Act of 1990. Additionally, the amendments are needed to (1) reflect a change in the enforcement provisions of the existing regulations, including designation of a new review authority; and (2) incorporate a number of technical amendments. The principal change resulting from these regulations is establishment of another condition under which an institution of postsecondary education may, without prior consent, disclose information from an education record.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the Federal Register or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Ellen Campbell, Family Policy Compliance Office, Office of Human Resources and Administration, U.S. Department of Education, 400 Maryland Avenue, SW., Washington, DC 20202–4605. Telephone: (202) 732–1807. Individuals who are hearing impaired may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION: The current FERPA regulations allow educational agencies and institutions to disclose personally identifiable information from a student's education records without the student's consent only under certain conditions. These final regulations allow institutions of postsecondary education to disclose the results of a disciplinary proceeding conducted by the institution against an alleged perpetrator of a crime of violence to the alleged victim of that crime without the prior written consent of the alleged perpetrator. This new condition was created by section 203 of the Crime Awareness and Campus Security Act of 1990 (Public Law 101–542, title II, section 203; 20 U.S.C. 1232g(b)(6)), which amended FERPA to allow for this disclosure.

Additionally, these final regulations reflect changes in the enforcement provisions under 34 CFR part 99, subpart E. Specifically, FERPA provides that the Secretary shall designate a review board within the Department for the purpose of reviewing and adjudicating violations of FERPA. In the current regulations, the Education Appeal Board (EAB) serves as the designated review board. Because the EAB is being phased out, the Secretary designates the Office of Administrative Law Judges to act as the review board for the purpose of reviewing and adjudicating under FERPA.

Further, several amendments are included in these final regulations for reasons of clarification. A change has been made to the provision that describes the conditions under which an educational agency or institution must obtain prior consent in order to disclose information. The change will allow an educational agency or institution to disclose information from a student's education records if the parent or eligible student has provided written consent to the party seeking access to the records, rather than require that the educational agency or institution obtain written consent directly from the parent or eligible student.

These final regulations also include a definition of what is considered to be a "timely complaint" of an alleged violation of FERPA. Historically, the office designated to administer FERPA has had to determine on a case-by-case basis what it considered to be a "timely complaint." Based on this historical experience and comparison with similar limitation periods for filing complaints, the Secretary has determined that a complaint brought within 180 days of the alleged violation should be considered timely.

On August 11, 1992, at 57 FR 35964 the Secretary published a notice of proposed rulemaking (NPRM). Except for minor technical revisions, there are no differences between the NPRM and these final regulations.

Public Comment

In the NPRM the Secretary invited comments on the proposed regulations. Two parties submitted comments endorsing the proposed regulations. The only substantive comment the Secretary received suggested a change the Secretary is not legally authorized to make under the applicable statutory authority.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Paperwork Reduction Act of 1980

These regulations have been examined under the Paperwork Reduction Act of 1980 and have been found to contain no information collection requirements.

Assessment of Educational Impact

In the NPRM, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects in 34 CFR Part 99

Administrative practice and procedure, Education, Family educational rights, Parents, Privacy, Reporting and recordkeeping requirements, Students.

Dated: December 18, 1992.

Lamar Alexander,

Secretary of Education.

(Catalog of Federal Domestic Assistance Number does not apply.)

The Secretary amends part 99 of title 34 of the Code of Federal Regulations as follows:

PART 99—FAMILY EDUCATIONAL RIGHTS AND PRIVACY

1. The authority citation for part 99 is revised to read as follows:

Authority: 20 U.S.C. 1232g, unless otherwise noted.

2. Section 99.5 is amended by revising the section heading to read as follows:

§ 99.5 What are the rights of students?

* * * * *

§ 99.6 [Amended]

3. In § 99.6, paragraph (a)(5) is amended by removing "maintained" and adding, in its place, "maintained".

4. Section 99.30 is amended by revising the section heading and paragraph (a) to read as follows:

§ 99.30 Under what conditions is prior consent required to disclose information?

(a) The parent or eligible student shall provide a signed and dated written consent before an educational agency or institution discloses personally identifiable information from the student's education records, except as provided in § 99.31.

* * * * *

5. Section 99.31 is amended by adding a new paragraph (a)(13), revising paragraph (b), and revising the authority citation to read as follows:

§ 99.31 Under what conditions is prior consent not required to disclose information?

(a) * * *

(13) The disclosure is to an alleged victim of any crime of violence, as that term is defined in section 16 of title 18, United States Code, of the results of any disciplinary proceeding conducted by an institution of postsecondary education against the alleged perpetrator of that crime with respect to that crime.

(b) This section does not forbid an educational agency or institution to disclose, nor does it require an educational agency or institution to disclose, personally identifiable information from the education records of a student to any parties under paragraphs (a)(1) through (11) and (13) of this section.

(Authority: 20 U.S.C. 1232g(a)(5)(A), (b)(1), (b)(2)(B) and (b)(6))

6. Section 99.60 is amended by revising the heading and paragraphs (a) and (c) to read as follows:

§ 99.60 What functions has the Secretary delegated to the Office and to the Office of Administrative Law Judges?

(a) For the purposes of this subpart, "Office" means the Family Policy Compliance Office, U.S. Department of Education.

* * * * *

(c) The Secretary designates the Office of Administrative Law Judges to act as the Review Board required under the Act to enforce the Act with respect to all applicable programs. The term "applicable program" is defined in section 400 of the General Education Provisions Act.

7. Section 99.63 is revised to read as follows:

§ 99.63 Where are complaints filed?

A person may file a written complaint with the Office regarding an alleged violation under the Act and this part. The Office's address is: Family Policy Compliance Office, U. S. Department of Education, Washington, D.C. 20202–4605.

(Authority: 20 U.S.C. 1232g(g))

8. Section 99.64 is amended by adding new paragraphs (c) and (d) to read as follows:

§ 99.64 What is the complaint procedure?

* * * * *

(c) A timely complaint is defined as an allegation of a violation of the Act that is submitted to the Office within 180 days of the date of the alleged violation or of the date that the complainant knew or reasonably should have known of the alleged violation.

(d) The Office extends the time limit in this section if the complainant shows that he or she was prevented by circumstances beyond the complainant's control from submitting the matter within the time limit, or for other reasons considered sufficient by the Office.

9. Section 99.65 is revised to read as follows:

§ 99.65 What is the content of the notice of complaint issued by the Office?

(a) The Office notifies the complainant and the educational agency or institution in writing if it initiates an investigation of a complaint under § 99.64(b). The notice to the educational agency or institution—

(1) Includes the substance of the alleged violation; and

(2) Asks the agency or institution to submit a written response to the complaint.

(b) The Office notifies the complainant if it does not initiate an investigation of a complaint because the complaint fails to meet the requirements of § 99.64.

(Authority: 20 U.S.C. 1232g(g))

10. Section 99.67 is amended by revising paragraph (a) and the authority citation to read as follows:

§ 99.67 How does the Secretary enforce decisions?

(a) If the educational agency or institution does not comply during the period of time set under § 99.66(c), the Secretary may, in accordance with part E of the General Education Provisions Act—

(1) Withhold further payments under any applicable program;

(2) Issue a compliant to compel compliance through a cease-and-desist order; or

(3) Terminate eligibility to receive funding under any applicable program.

* * * * *

(Authority: 20 U.S.C. 1232g(f); 20 U.S.C. 1234)

[FR Doc. 93–133 Filed 1–6–93; 8:45 am]
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January 7, 1993

Part IX

Department of Transportation

Federal Aviation Administration

Explosive Detection Systems; Notice

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 27026; Notice No. 92–16A]

RIN 2120–AE77

Explosive Detection Systems

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed Criteria for Certification; extension of comment period.

SUMMARY: This document announces an extension of the comment period on Notice 92–16 entitled, "Explosive Detection Systems; Proposed Criteria for Certification" (57 FR 52698; November 4, 1992). This comment period is extended from January 4, 1993, until February 4, 1993. The extension responds to the request of the Air Transport Association of America (ATA) and is needed to permit ATA, and other affected parties, additional time to develop comments responsive to Notice 92–16.

DATES: The comment period is being extended from January 4, 1993, to February 4, 1993.

ADDRESSES: As stated in Notice 92–16, comments should be mailed, in triplicate, to: Federal Aviation Administration, Office of Chief Counsel, Attention: Rules Docket (AGC–10), Docket No. 27026, 800 Independence Avenue, SW., Washington, DC 20591. All comments must be marked: "Docket No. 27026." Comments on this Notice may be examined in room 915G on weekdays, except on Federal holidays, between 8:30 a.m. and 5 p.m.

Comments that include or reference national security information or sensitive security information should not be submitted to the public docket. Such comments should be sent to the following address in a manner consistent with applicable requirements and procedures for safeguarding sensitive security information: Federal Aviation Administration, Office of Civil Aviation Security Operations, Attention: FAA Security Control Point (ACO–320A), Docket No. ACP–27026–C, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Mr. Bruce Butterworth, Director (ACP–1), Office of Civil Aviation Security Policy and Planning, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8058.

SUPPLEMENTARY INFORMATION: On November 4, 1992, the FAA issued Notice No. 92–16, entitled "Explosive Detection Systems; Proposed Criteria for Certification." Notice 92–16 proposed to establish criteria for the certification of explosives detection systems to screen checked baggage for international flights.

By a request dated December 1, 1992, ATA asked that the comment period be extended 60 days. Because of the technical and operational complexities of the proposed criteria, ATA indicated that it, and its member air carriers, had not completed analyzing the potential effects of the criteria proposed in Notice 92–16.

In order to give ATA and its members additional time to complete this analysis and prepare comments reflecting the knowledge gained from it, the FAA finds that it would be in the public interest to extend the comment period. The FAA finds that an extension of 30 days, however, is sufficient for careful analysis and the preparation and submission of comments to the docket. An extension until March 4 would unduly delay FAA's efforts to comply with sections 107 and 108 of the Aviation Security Improvement Act of 1990, Public Law 101–604, which require an accelerated research and development program with proper testing and certification of equipment prior to deployment. Any such comments submitted before the close of the extended comment period are likely to provide additional substantive information, which will be helpful in developing the criteria, without unduly delaying issuance of the criteria in final (or interim final) form. Accordingly, the comment period is extended to February 4, 1993, to afford all interested persons the opportunity to comment on Notice 92–16.

Issued in Washington, DC, on January 4, 1993.

O.K. Steele,

Assistant Administrator for Civil Aviation Security.

[FR Doc. 93–379 Filed 1–5–93; 12:31 pm]

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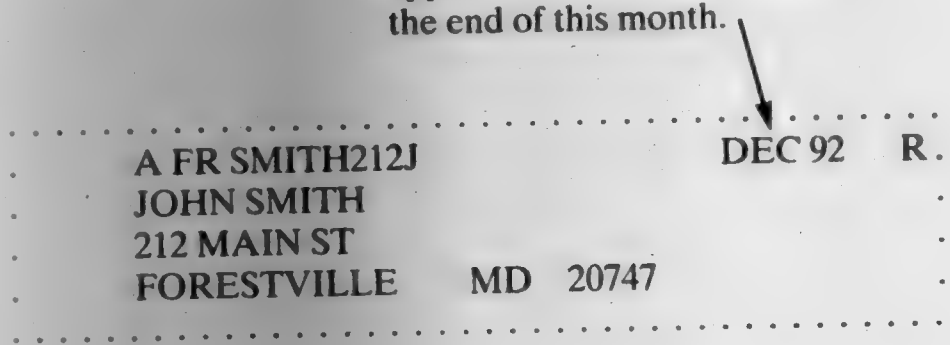

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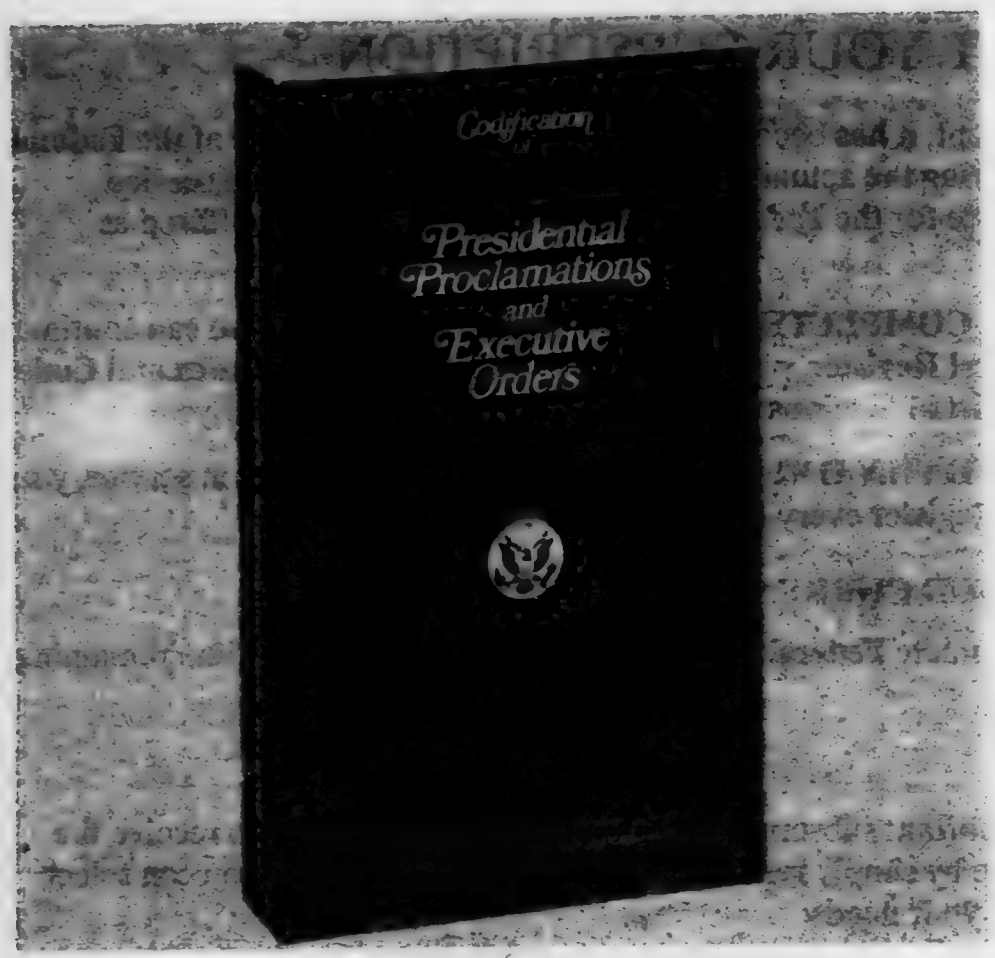

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Electronic Bulletin Board
Free Electronic Bulletin Board service for Public Law Numbers and Federal Register finding aids is available on 202–275–1538 or 275–0920.

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Title 3—

The President

Memorandum of December 30, 1992

Delegation of Responsibilities Under Title XIV of Public Law 102–484 and Title V of Public Law 102–511

Memorandum for the Secretary of State, the Secretary of Defense [and] the Director, Office of Management & Budget

By the authority vested in me by the Constitution and the laws of the United States of America, including section 301 of title 3 of the United States Code, I hereby delegate:

1. to the Secretary of State the authority and duty vested in the President under section 1412(d) of the Former Soviet Union Demilitarization Act of 1992 (title XIV of the National Defense Authorization Act for Fiscal Year 1993, Public Law 102–484) and section 502 of the Freedom Support Act (Public Law 102–511).

2. to the Secretary of Defense the authorities and duties vested in the President under sections 1412(a), 1431, and 1432 of Public Law 102–484 and sections 503 and 508 of Public Law 102–511.

The Secretary of Defense shall not exercise authority delegated by paragraph 2 hereof with respect to any former Soviet republic unless the Secretary of State has exercised his authority and performed the duty delegated by paragraph 1 hereof with respect to that former Soviet Republic. The Secretary of Defense shall not obligate funds in the exercise of authority delegated by paragraph 2 hereof unless the Director of the Office of Management and Budget has determined that expenditures during fiscal year 1993 pursuant to such obligation shall be counted against the defense category of discretionary spending limits for that fiscal year (as defined in section 601(a)(2) of the Congressional Budget Act of 1974) for purposes of Part C of the Balanced Budget and Emergency Deficit Control Act of 1985.

The Secretary of State is directed to publish this memorandum in the **Federal Register**.

George Bush

THE WHITE HOUSE,
Washington, December 30, 1992.

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Presidential Documents

Proclamation 6522 of January 5, 1993

Braille Literacy Week, 1993

By the President of the United States of America

A Proclamation

Standardized for use in the United States in 1932, braille is the primary tactile system for reading and writing used by blind individuals today. The braille system uses raised dots to represent the letters of the alphabet, symbols of punctuation, mathematic and scientific characters, music and computer notation, and foreign language signs.

Through braille, a person who is visually impaired is given the key to unlock the power of the written word. Braille enables blind individuals to achieve the many rewards of literacy, including educational advancement, personal independence, and economic opportunity and security. Braille also enables its users to enjoy the full form, structure, and beauty of printed poetry and prose.

Over the past 60 years, the braille system has continued to open doors of learning and opportunity for blind Americans. This week we acknowledge the importance of braille and recognize the many dedicated individuals who teach and promote this system as a tool of achievement.

The Congress, by House Joint Resolution 353, has designated the week of January 3 through January 9, 1993, as "Braille Literacy Week" and has authorized and requested the President to issue a proclamation in observance of this week.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the week of January 3 through January 9, 1993, as Braille Literacy Week and invite all Americans to observe this week with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of January, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

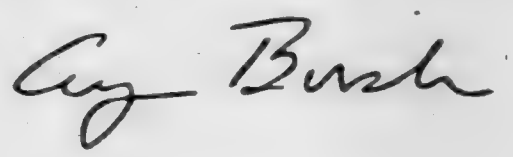

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Presidential Documents

Proclamation 6523 of January 5, 1993

National Law Enforcement Training Week, 1993

By the President of the United States of America

A Proclamation

The effectiveness of any Federal, State, or local law enforcement agency depends on knowledgeable, well-trained, and highly qualified personnel. Building such a force requires rigorous education and training, not only before an officer earns the badge, but also throughout his or her career.

Whether intervening in a violent domestic dispute, apprehending a suspected drug dealer, or assisting at the site of a traffic accident, law enforcement officers are often required to make split-second decisions that could mean the difference between life and death. Therefore, in addition to knowledge of criminal statutes and fundamental rules of procedure, law enforcement training encompasses basic skills on which an officer's survival and other human lives depend. From physical conditioning and self-defense techniques to the safe use of firearms, such training ensures that an officer is prepared to maintain law and order while, at the same time, protecting the rights and safety of individual citizens.

As law enforcement agencies employ increasingly sophisticated technology and techniques in the fight against crime, the need for highly specialized education and training continues to increase as well. Today an officer's training in traditional investigative methods may also include more advanced studies in ballistics, toxicology, computer science, psychology, and other complex fields. For the veteran as well as the rookie, for the administrator behind the desk as well as the officer on the beat—continuing education and training are essential to meeting new challenges in police work.

All Americans benefit from programs that contribute to the knowledge, professionalism, and skill of our Nation's law enforcement officers, and this week we gratefully salute the dedicated individuals whose instruction and guidance assist officers in the performance of their duties. We also recognize the many rewarding career opportunities that are available to young people in law enforcement and related occupations, and encourage parents and teachers to make the observance of this week a rewarding learning opportunity for children—one that instills in them a healthy respect for the law and for the courageous men and women who are pledged to defend it.

In order to heighten public awareness of the importance of law enforcement training and its related fields, the Congress, by Senate Joint Resolution 304, has designated the week of January 3 through January 9, 1993, as "National Law Enforcement Training Week" and has authorized and requested the President to issue a proclamation in observance of this week.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, do hereby proclaim the week beginning January 3, 1993, as National Law Enforcement Training Week. I invite all Americans to observe this week with appropriate programs and activities.

IN WITNESS WHEREOF, I have hereunto set my hand this fifth day of January, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

George Bush

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Rules and Regulations

Federal Register
Vol. 58, No. 5
Friday, January 8, 1993

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Parts 531, 532, 550, and 575

RIN 3206–AE23

Special Pay Entitlements for Law Enforcement Officers

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management (OPM), in conformance with amendments to the Federal Employees Pay Comparability Act of 1990 (FEPCA) made by the "Technical and Miscellaneous Civil Service Amendments Act of 1992" (Pub. L. 102–378, October 2, 1992), is issuing interim regulations to (1) amend the definition of "law enforcement officer" for certain pay purposes, (2) authorize the payment of a special pay adjustment for law enforcement officers in addition to a nationwide or worldwide special salary rate, and (3) expand coverage of the special maximum limitation on relocation bonuses for law enforcement officers to five additional categories of law enforcement employees.

DATES: The amendments to 5 CFR 531.304 are effective on the first day of the first pay period beginning on or after January 8, 1993. The amendments to 5 CFR 532.509 and 575.205(b)(2) are being made effective on October 2, 1992. The amendments to 5 CFR part 550 and the remaining amendments to 5 CFR parts 531 and 575 are being made effective on the first day of the first pay period beginning on or after October 2, 1992. Comments must be received on or before March 9, 1993.

ADDRESSES: Send or deliver written comments to Barbara L. Fiss, Assistant Director for Compensation Policy, U.S. Office of Personnel Management, room 6H31, 1900 E Street NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Belva MacDonald, (202) 606–2858.

SUPPLEMENTARY INFORMATION: The "Technical and Miscellaneous Civil Service Amendments Act of 1992" (Pub. L. 102–378, October 2, 1992) includes (1) an expanded definition of law enforcement officer under section 5541 of title 5, United States Code (with conforming amendments in 5 U.S.C. 4521, 5542, and 5547, and section 402 of FEPCA); (2) an amendment to section 404 of FEPCA to provide OPM with the authority to determine the extent to which a special pay adjustment for law enforcement officers may be paid to an employee receiving a special salary rate under 5 U.S.C. 5305 or a similar provision of law; and (3) an amendment to section 405 of FEPCA to extend application of the special maximum limitation on relocation bonuses for law enforcement officers to the categories of law enforcement employees listed in section 405 of FEPCA—i.e., Park Police officers, Secret Service Uniformed Division officers, special agents in the Diplomatic Security Service, and probation and pretrial services officers. The regulatory changes resulting from the technical amendments are summarized below.

Expanded Definition of Law Enforcement Officer

The technical amendments provide a new definition of law enforcement officer effective on the first day of the first pay period beginning on or after the date of enactment of Public Law 102–378. For most agencies, this effective date was October 4, 1992. The expanded definition is codified in 5 U.S.C. 5541(3) and has been added to 5 CFR 550.103. The expanded definition also has been incorporated into the definition of law enforcement officer in section 402 of FEPCA for purposes of special salary rates and special pay adjustments for law enforcement officers. For these purposes, a law enforcement officer must meet the premium pay definition in § 550.103 *and* must also be subject to the provisions of chapter 51 of title 5, United States Code (Classification).

The expanded definition of law enforcement officer in 5 U.S.C. 5541(3) includes law enforcement officers within the meaning of section 8331(20) or section 8401(17) of title 5, United States Code (i.e., law enforcement officers covered under the special law enforcement retirement provisions of the Civil Service Retirement System (CSRS) or the Federal Employees' Retirement System (FERS)). The expanded definition also includes certain individuals who are covered by CSRS or FERS, but who do not meet the strict definitions of the term law enforcement officer in 5 U.S.C. 8331(20) or 8401(17) because they did not transfer directly to a supervisory or administrative position (i.e., a "secondary position") after serving in a position as a law enforcement officer (i.e., a "primary position"). (This amendment does not authorize coverage of these employees under the special law enforcement retirement provisions of CSRS or FERS.)

In addition, the expanded definition permits OPM to include within the meaning of law enforcement officer an employee not under CSRS or FERS who is in a position that OPM determines would otherwise satisfy the requirements of the definition. The interim regulations include a provision that permits OPM, on its own motion or at the request of the head of an agency or an official who has been delegated authority to act for the head of the agency in this matter, to determine that an individual would meet the definition if the individual were under CSRS or FERS. Finally, the definition includes special agents in the Diplomatic Security Service within the meaning of law enforcement officer for premium pay purposes.

The definition of law enforcement officer has been amended in the following sections of title 5, Code of Federal Regulations:

- § 531.301 (special pay adjustments for law enforcement officers);
- § 550.103 (premium pay);
- § 550.105(b)(3) (biweekly maximum earnings limitation);
- § 550.106(e)(2) (annual maximum earnings limitation for work in connection with an emergency);
- § 550.107 (special maximum earnings limitation for law enforcement officers);
- § 575.102(a)(4) (delegation of authority to pay a recruitment bonus to law enforcement officers);
- § 575.202(a)(4) (delegation of authority to pay a relocation bonus to law enforcement officers);

§ 575.205(b) (special maximum limitation on relocation bonuses for law enforcement officers); and
§ 575.302(a)(4) (delegation of authority to pay a retention allowance to law enforcement officers).

Special Pay Adjustments for Law Enforcement Officers

A scheduled annual rate of pay is the rate of basic pay on which a special pay adjustment for law enforcement officers under section 404 of FEPCA is computed. As originally enacted, section 404(a) of FEPCA provided that special pay adjustments for law enforcement officers would be reduced by any applicable special rate of pay under 5 U.S.C. 5305. Section 3(7) of Public Law 102–378 amends section 404(a) of FEPCA to provide that OPM may determine the extent to which special pay adjustments for law enforcement officers may be paid to employees receiving special rates of pay under 5 U.S.C. 5305 or any similar provision of law (other than special salary rates under section 403 of FEPCA).

OPM has determined that special law enforcement adjusted rates of pay will be based on a nationwide or worldwide special salary rate under 5 U.S.C. 5305, but not on a local special salary rate. This change will make the administration of special pay adjustments for law enforcement officers consistent with the administration of interim geographic adjustments under section 302 of FEPCA. These regulations amend 5 CFR 531.301 by adding a definition of local special salary rate and by including a nationwide or worldwide special salary rate under the definition of scheduled annual rate of pay.

Relocation Payments

Section 407 of FEPCA authorizes the payment of relocation bonuses of up to $15,000 to law enforcement officers whose rates of basic pay are less than $60,000. Section 575.205(b) of title 5, Code of Federal Regulations, allows for the payment of a relocation bonus not to exceed the greater of $15,000 or 25 percent of the rate of basic pay to certain law enforcement officers. The technical amendments extend the coverage of this special maximum limitation on relocation bonuses for law enforcement officers to law enforcement employees defined in section 405(b) of FEPCA—i.e., (1) members of the United States Secret Service Uniformed Division; (2) members of the United States Park Police; (3) special agents within the Diplomatic Security Service; (4) probation officers (referred to in section 3672 of title 18, United States Code); and (5) pretrial service officers (referred to in section 3153 of title 18, United States Code). Section 575.205(b) has been expanded to include a reference to law enforcement employees under section 405(b) of FEPCA.

Finally, the interim regulations amend 5 CFR 532.509 (Pay for Sunday Work) to conform to an amendment made by Public Law 102–378, which strikes 5 U.S.C. 5550 and adds a new paragraph (c) to 5 U.S.C. 5544 that provides for the payment of Sunday pay and overtime pay for prevailing rate (wage) employees of nonappropriated fund instrumentalities on the same basis as for other wage employees.

Waiver of Delay in Effective Date

Pursuant to 5 U.S.C. 553(d)(3), I find that good cause exists for making these rules effective in less than 30 days. The amendment to 5 CFR 531.304 is being made effective on the first day of the first pay period beginning on or after January 8, 1993, in order to make this benefit available to employees on the earliest practicable date. The amendments to 5 CFR part 532, 550, and 575 and the remaining amendments to 5 CFR part 531 are being made effective on the effective dates required by statute.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities, since it applies only to Federal employees and agencies.

List of Subjects in 5 CFR Parts 531, 532, 550, and 575

Administrative practice and procedure, Claims, Government employees, Wages.

U.S. Office of Personnel Management.
Douglas A. Brook,
Acting Director.

Accordingly, OPM is amending parts 531, 532, 550, and 575 of title 5 of the Code of Federal Regulations as follows:

PART 531—PAY UNDER THE GENERAL SCHEDULE

1. The authority citation for part 531 is revised to read as follows:

Authority: 5 U.S.C. 5115, 5307, 5338, and chapter 54; E.O. 12748, 56 FR 4521, February 4, 1991, 3 CFR 1991 Comp., p. 316;

Subpart A issued under section 302 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509), 104 Stat. 1462, and E.O. 12786, 56 FR 67453, December 30, 1991, 3 CFR 1991 Comp., p. 376;

Subpart B also issued under 5 U.S.C. 5303(g), 5333, 5334(a), 5402, and 7701(b)(2);

Subpart C also issued under section 404 of Public Law 101–509, 104 Stat. 1466, and section 3(7) of Public Law 102–378 (October 2, 1992);

Subpart D also issued under 5 U.S.C. 7701(b)(2) and 5 U.S.C. 5335(g);

Subpart E also issued under 5 U.S.C. 5336.

2. In § 531.301, the definitions of "law enforcement officer" and "scheduled annual rate of pay" are revised, and a definition of "local special salary rate" is added to read as follows:

§ 531.301 Definitions.

* * * * *

Law enforcement officer means a law enforcement officer as defined in § 550.103 of this part with respect to whom the provisions of chapter 51 of title 5, United States Code, apply, including members of the Senior Executive Service.

Local special salary rate means a special salary rate established under part 530 of this chapter for one or more locations, but not for all locations nationwide or worldwide.

* * * * *

Scheduled annual rate of pay means—

(1) The rate of basic pay for a law enforcement officer's grade or pay level and step (or relative position in the rate range), including special rates for law enforcement officers under section 403 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509) and a nationwide or worldwide special salary rate under part 530 of this chapter, where applicable, but not including local special salary rates or additional pay of any kind, such as premium pay;

(2) For a law enforcement officer covered by the Performance Management and Recognition System who is receiving a local special salary rate under 5 U.S.C. 5305 or a similar provision of law (other than section 403 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509)), the rate of pay resulting from the following computation—

(i) Using the local special salary rate schedule established under 5 U.S.C. 5305, subtract the dollar amount for step 1 of the law enforcement officer's grade from the dollar amount for the law enforcement officer's local special salary rate; and

(ii) Add the result of paragraph (b)(1) to the dollar amount for step 1 of the employee's grade on the General Schedule; or

(3) The retained rate of pay under part 536 of this chapter or 5 CFR 359.705, where applicable, exclusive of additional pay of any kind.

* * * * *

3. In § 531.304, paragraphs (a)(3) and (f)(5) are revised to read as follows:

§ 531.304 Administration of special law enforcement adjusted rates of pay.

(a) * * *

(3) Any applicable local special salary rate for the employee's grade and step (or relative position in the rate range).

* * * * *

(f) * * *

(5) An employee's local special salary rate exceeds his or her special law enforcement adjusted rate of pay.

* * * * *

PART 532—PREVAILING RATE SYSTEMS

4. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552. Freedom of Information Act, Public Law 92–502.

§ 532.509 [Amended]

5. In § 532.509, the words "sections 5544 and 5550" are removed, and the words "section 5544" are added in their place.

PART 550—PAY ADMINISTRATION (GENERAL)

Subpart A—Premium Pay

6. The authority citation for subpart A continues to read as follows:

Authority: 5 U.S.C. 5547, 5548, and 6101(c).

7. In § 550.103, paragraph (t) is added to read as follows:

§ 550.103 Definitions.

* * * * *

(t) *Law enforcement officer* means an employee who—

(1) Is a law enforcement officer within the meaning of section 8331(20) or section 8401(17) of title 5, United States Code;

(2) In the case of an employee who holds a secondary position, as defined in 5 CFR 831.902, and is subject to the Civil Service Retirement System, but who does not qualify to be considered a law enforcement officer within the meaning of section 8331(20), would so qualify if such employee had transferred directly to such position after serving as a law enforcement officer within the meaning of such section;

(3) In the case of an employee who holds a secondary position, as defined in 5 CFR 842.802, and is subject to the Federal Employees Retirement System, but who does not qualify to be considered a law enforcement officer within the meaning of section 8401(17), would so qualify if such employee had transferred directly to such position after performing duties described in section 8401(17) (A) and (B) for at least 3 years; and

(4) In the case of an employee who is not subject to either the Civil Service Retirement System or the Federal Employees Retirement System—

(i) Holds a position that the Office of Personnel Management, on its own motion or at the request of the head of an agency or an official who has been delegated authority to act for the head of the agency in this matter, determines would satisfy paragraph (t) (1), (2), or (3) of this definition if the employee were subject to the Civil Service Retirement System or the Federal Employees Retirement System; or

(ii) Is a special agent in the Diplomatic Security Service.

8. In § 550.105, paragraph (b)(3) is revised to read as follows:

§ 550.105 Biweekly maximum earnings limitation.

* * * * *

(b) * * *

(3) A law enforcement officer.

9. In § 550.106, paragraph (e)(2) is revised to read as follows:

§ 550.106 Annual maximum earnings limitation for work in connection with an emergency.

* * * * *

(e) * * *

(2) A law enforcement officer.

10. In § 550.107, the introductory paragraph is revised to read as follows:

§ 550.107 Special maximum earnings limitation for law enforcement officers.

A law enforcement officer may be paid premium pay under this subpart only to the extent that the payment does not cause the total of his or her basic pay and premium pay for any period to exceed the lesser of—

* * * * *

PART 575—RECRUITMENT AND RELOCATION BONUSES; RETENTION ALLOWANCES; SUPERVISORY DIFFERENTIALS

11. The authority citation for part 575 is revised to read as follows:

Authority: 5 U.S.C. 1104(a)(2), 5753, 5754, and 5755; sec. 302 and 404 of the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509) 104 Stat. 1462 and 1466, respectively; E.O. 12748, 56 FR 4521, February 4, 1991, 3 CFR 1991 Comp., p. 316.

12. In § 575.102, paragraph (a)(4) is revised to read as follows:

§ 575.102 Delegation of authority.

(a) * * *

(4) A position as a law enforcement officer, as defined in § 550.103 of this chapter.

* * * * *

13. In § 575.202, paragraph (a)(4) is revised to read as follows:

§ 575.202 Delegation of authority.

(a) * * *

(4) A position as a law enforcement officer, as defined in § 550.103 of this chapter.

* * * * *

14. In § 575.205, paragraph (b) is revised to read as follows:

§ 575.205 Payment of relocation bonus.

* * * * *

(b) The amount of a relocation bonus may not exceed the greater of $15,000 or 25 percent of a law enforcement officer's rate of basic pay in the case of—

(1) A law enforcement officer, as defined in § 550.103 of this chapter, with respect to whom the provisions of chapter 51 of title 5, United States Code, apply;

(2) A member of the United States Secret Service Uniformed Division;

(3) A member of the United States Park Police;

(4) A special agent within the Diplomatic Security Service;

(5) A probation officer (referred to in section 3672 of title 18, United States Code); and

(6) A pretrial services officer (referred to in section 3153 of title 18, United States Code).

* * * * *

15. In § 575.302, paragraph (a)(4) is revised to read as follows:

§ 575.302 Delegation of authority.

(a) * * *

(4) A position as a law enforcement officer, as defined in § 531.301 of this chapter;

* * * * *

[FR Doc. 93–350 Filed 1–7–93; 8:45 am]
BILLING CODE 6325–01–M

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5 CFR Part 838

Correction of Regulations Concerning Court Orders Affecting Retirement Benefits

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is correcting four

nonsubstantive errors in its recently published regulations concerning court orders affecting retirement benefits of Federal employees covered by the Civil Service Retirement System and the Federal Employees Retirement System. These regulations are necessary to add an inadvertently omitted definition, to correct typographical errors, and to provide the complete address to which court orders should be sent.

EFFECTIVE DATE: August 28, 1992.

FOR FURTHER INFORMATION CONTACT: Harold L. Siegelman, (202) 606–0299.

SUPPLEMENTARY INFORMATION: On July 29, 1992, we published (at 57 FR 33570) final regulations concerning court orders affecting retirement benefits. The regulations contained typographical errors in §§ 838.135(a) (the reference to § 838.725 should have been to § 838.806) and 838.806(c)(1) (the second "of" should have been "or"). This final rule corrects those errors. It also replaces the five-digit zip code in the mailing address stated in appendix A to subpart A of part 838 with the applicable nine-digit zip code. In addition, it adds to § 838.103 the inadvertently omitted definition of "self-only annuity" that is referenced in § 838.306; the definition is the same as the definitions in the current survivor election regulations at §§ 831.603 and 842.602 of title 5, Code of Federal Regulations.

Under sections 553(b)(3)(B) and 553(d)(3) of title 5, United States Code, I find that good cause exists for waiving the general notice of proposed rulemaking and for making these amendments effective in less than 30 days. Notice of proposed rulemaking is unnecessary because this final rule only corrects nonsubstantive errors in the recently published regulations. The amendments are effective August 28, 1992, the same date as the regulations published on July 29, 1992. This date is appropriate because the changes merely correct nonsubstantive errors and provide the complete address for mailing court orders to OPM.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined under section 1(b) of E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the regulation only makes nonsubstantive, technical corrections in regulations that only affect payments of retirement benefits to Federal employees and retirees, and their families.

List of Subjects in 5 CFR Part 838

Administrative practice and procedure, Claims, Disability benefits, Government employees, Income taxes, Pensions, Retirement, Court.

Office of Personnel Management.

Douglas A. Brook,

Acting Director.

Accordingly, OPM is amending part 838 of title 5, Code of Federal Regulations, as follows.

PART 838—COURT ORDERS AFFECTING RETIREMENT BENEFITS

1. The authority citation for part 838 continues to read as follows:

Authority: 5 U.S.C. 8347(a) and 8461(g). Subparts B, C, D, E, and J also issued under 5 U.S.C. 8345(j)(2) and 8467(b). Sections 838.221, 838.422, and 838.721 also issued under 5 U.S.C. 8347(b).

Subpart A—Court Orders Generally

2. Section 838.103 is amended by adding in alphabetical order the new definition of the term "self-only annuity" to read as follows:

§ 838.103 Definitions.

* * * * *

Self-only annuity means the recurring unreduced payments under CSRS or FERS to a retiree with no survivor annuity payable to anyone.

* * * * *

§§ 838.135, 838.806, Appendix A to Subpart A of Part 838 [Amended]

3. In the list below, for each section and paragraph indicated in the left two columns, remove the words or numbers indicated in the third column where it appears in the paragraph, and add the words or numbers indicated in the fourth column:

Section	Paragraph	Remove	Add
838.135	(a)	838.725	838.806.
Appendix A to Subpart A.	(a)	20044	20044–0017.
838.806	(c)(1)	"of death" .	"or death".

[FR Doc. 93–351 Filed 1–7–93; 8:45 am]

BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 401

[Amendment No. 46 Doc. No. 0006S]

General Crop Insurance Regulations; Corn, Grain Sorghum, and Soybean Endorsements

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) amends the General Crop Insurance Regulations, effective for the 1994 and succeeding crop years, by adding Late Planting and Prevented Planting provisions to the Corn Endorsement, Grain Sorghum Endorsement and the Soybean Endorsement. The intended effect of this rule is to replace the current optional coverages for late and prevented planting with more effective provisions that are a required part of the basic coverage.

DATES: This rule is effective on November 30, 1993.

FOR FURTHER INFORMATION CONTACT: Mari Dunleavy, Acting Director, Office of Regulatory Development, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (202) 254–8314.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512–1. This action does not constitute a review as to the need, currency, clarity, and effectiveness of the Corn, Grain Sorghum, and Soybean Endorsement regulations affected by this rule under those procedures. The sunset review date established for Corn is April 1, 1996; Soybeans, October 1, 1996; and Grain Sorghum, July 1, 1996.

James E. Cason, Manager, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, Federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

James E. Cason, Manager, FCIC, certifies that this action will not increase the federal paperwork burden

for individuals, small businesses, and other persons. The action will not have a significant economic effect on a substantial number of small entities. This program is strictly voluntary. This regulation adds coverage to the policy already in place which had been previously optional. The increase in premium is minimal and no additional record keeping is required by the insured or the insurance company. If anything, a net decrease in the paperwork burden will occur since the companies will no longer have to carry the additional policy for prevented planting coverage and all of the tables and sales matters that the separate policy entailed. Therefore, this action is determined to be exempt from the provisions of the Regulatory Flexibility Act and no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

The Manager, FCIC, has certified to the Office of Management and Budget (OMB) that these final regulations meet the applicable standards provided in section 2(a) and 2(b)(2) of Executive Order 12778.

This final rule has been reviewed in accordance with Executive Order 12778. These provisions do preempt state and local laws to the extent such state and local laws are inconsistent with the provisions of this final rule.

FCIC amends the General Crop Insurance Regulations (7 CFR part 401) by adding Late Planting and Prevented Planting provisions to the Corn Endorsement (§ 401.111), Grain Sorghum Endorsement (§ 401.113), and the Soybean Endorsement (§ 401.117), effective for the 1994 and succeeding crop years. The intended effect of this rule is to replace the current optional coverage for late and prevented planting with more effective provisions that are an integral part of the basic coverage.

The current optional coverage for late and prevented planting lack the desired degree of effectiveness due to both coverage deficiencies and the volume of paperwork required. The additional paperwork required includes the prevented planting application and acreage report, and an option form for late planting coverage. Adding to the administrative burden of the current coverage is tracking the dates for submission of these forms.

To improve the coverage provided for late and prevented planting, an analysis of the weaknesses of the current program and concepts on which new policy provisions could be based, was prepared. A summary of changes, based on these concepts are as follows:

1. For the 1994 and subsequent crop years, coverage for late and prevented planting are incorporated into the provisions of the corn, grain sorghum, and soybean endorsements. The 1994 crop year will serve as an evaluation period. Other crops may be considered for the 1995 crop year.

2. Coverage for prevented planting will be for the peril of excess moisture. In cases of drought, the insured or the company may petition FCIC to permit coverage under the prevented planting provisions. FCIC may permit insureds to bypass planting where successful production appears improbable and still remain qualified for a prevented planting production guarantee. Irrigated acreage will not be eligible for a prevented planting production guarantee due to drought.

3. When the insured is prevented from planting the insured crop by the final planting date, the insured may choose to:

(a) Plant the insured crop after the final planting date and have coverage under the late planting or prevented planting provisions;

(b) Plant and insure an alternative crop with a later final planting date, if the insured has the proper crop endorsements;

(c) Plant a salvage crop for its value;

(d) Leave the acreage unplanted and receive a prevented planting production guarantee; or

(e) Plant any uninsured, non-conserving crop, and terminate insurance protection.

4. The late planting period begins the day after the final planting date of the insured crop and extends for 25 days thereafter. The production guarantee will be reduced at the rate of 1% per day for days 1 through 10 and 2% per day for days 11 through 25.

5. When the insured crop is planted more than 25 days after the final planting date for the insured crop, but not later than 55 days after the latest final planting date, the value of any production will be production to count against the prevented planting guarantee. When a salvage crop is planted during the same period, the value of the salvage crop will be deducted from the applicable indemnity payment. In this case, the liability will be 60% of the guarantee.

6. If the insured is prevented from planting the insured crop and a salvage crop is not planted within 55 days after the latest final planting date for the current crop year, a prevented planting guarantee may be applicable.

7. The guarantee for prevented planting will be 50% of the guarantee for timely planted acreage and applies to acreage not planted within 55 days of the latest final planting date. The current prevented planting endorsement provides for liability for 35% of the guarantee. The increase to 50% will provide additional protection to insureds.

8. If the unit is planted prior to 55 days after the latest final planting date, with any non-conserving crop maturing in the same crop year, a prevented planting indemnity will not be paid.

9. For corn and grain sorghum, the maximum acreage eligible for prevented planting coverage will be equal to the greater of the previous year's planted acreage, or the Agricultural Stabilization and Conservation Service (ASCS) base acreage applicable to the farm, less any acreage reduction necessary to comply with the current year's ASCS price support program. The maximum eligible acreage for soybeans will be 100 percent of the soybean acreage planted the previous year.

10. To be eligible for a prevented planting production guarantee, the acreage that was prevented from being planted must exceed the lesser of 20 acres or 20 percent of the unit.

11. Prevented planting coverage will not be provided for:

(a) High risk land, unless we agree to such coverage in writing;

(b) Land used for acreage conservation (ASCS's Acreage Reduction Program (ARP));

(c) Land on which any crop has been harvested in the same crop year;

(d) Land entered into any program administered by the United States Department of Agriculture that provides a payment for not planting the acreage, e.g., the 0/92 or Conservation Reserve programs.

12. When the insured is prevented from timely planting and plants a crop subject to salvage provisions, the premium for the acreage will be the same as for timely planted acreage. When the farmer paid premium for late or prevented planting exceeds the liability, coverage will not be provided but conversely no premium will be due since insurance did not attach.

13. This coverage will require an appropriate premium charge.

On Friday, January 10, 1992, FCIC published a notice of proposed rulemaking in the **Federal Register** at 57 FR 1116, replacing the current optional coverage for late and prevented planting with more effective provisions that are an integral part of the basic coverage.

In the proposed rule, FCIC stated that the late planting/prevented planting coverage would be offered as an option for the 1992 crop year if the process of publishing proposed and final rule was completed timely. Upon further review, FCIC determined that there would not be sufficient time to implement the rule to be effective for the 1992 crop year.

Following publication of the proposed rule, the public was given 15 days to submit written comments, data, and opinions. Comments were received from several insurance companies who generally agreed that implementation of the rule as an option for the 1992 crop year would not be feasible. FCIC agrees with such comments, and will make the rule effective for the 1994 crop year.

A summary of other concerns expressed by the commenters are as follows:

1. *Comment:* The companies generally agreed with the concept of including these provisions in the basic endorsements but suggest that such incorporation into the basic policy will increase paperwork since policyholders who choose not to accept the late and prevented planting provisions will be required to submit written notification to that effect. The companies also questioned the amount of additional premium required and what change in final planting dates would be required.

FCIC Response: FCIC anticipates this approach will reduce paperwork for both the insured and the agent. The current coverage for late planting requires the completion of an option form while the new coverage will be an integral part of the policy. The current prevented planting coverage requires an application and acreage report while the proposed coverage incorporates this into present information gathering. The new coverage is much more comprehensive. FCIC has eliminated the option to decline late planting and prevented planting coverage due to adverse selection problems and servicing workload conditions.

A final rate analysis has not been completed. A sufficient in the premium rate will be made if the analysis indicates that need. No changes in final planting dates are being considered because of the addition of the new late and prevented planting coverage. The normal review process for changes in final planting dates will continue. This process includes evaluation of the impacts of the current late planting coverage.

For the insured with the new coverage in place, the risk of not being able to plant the desired crop is reduced. The amount of insurance available for prevented planting approximates the costs already incurred. The new late planting coverage extends by five days (from 20 to 25) the amount of time coverage is available. The reduction in the production guarantee does not advance as quickly, therefore, the insured will have a larger guarantee if planting must be delayed by only a few days. The insured does not incur the large yield reduction on the first, sixth, eleventh, and sixteenth days of the current late planting option.

2. *Comment:* By incorporating these provisions the policy forces insureds to insure for a loss that may never be collected.

FCIC Response: All insurance policies provide coverage for an event that may not happen during the insurance period. The crop insurance program has experienced considerable criticism due to failure to cover these situations. Premium rates will now reflect risks associated with late or prevented planting.

3. *Comment:* Many companies will be reluctant to bear the risk associated with such mandatory coverage without being allowed to actually "underwrite" these risks.

FCIC Response: Properly rated, this provision does not represent unusual risk to policy issuing companies. The FCI Act requires that FCIC establish coverage and rates. This coverage and the corresponding risk imposes no greater risk to the company than do the present provisions.

4. *Comment:* Rates for coverage are not actuarially sound and this change will make them more unsound.

FCIC Response: FCIC reviews premium rates on an ongoing basis to improve actuarial soundness. A review to determine the effect of including late and prevented planting on premium rates is in progress. The FCIC is required to establish the rates for this coverage on an actuarially sound basis.

5. *Comment:* After the 20-day extension, it is too late to have a normal harvest. The current 20-day optional coverage (available separately) allows sufficient time to plant a crop. Extending this to 25 days will increase both the amount and number of losses paid, resulting in increased paperwork on late planted acreage.

FCIC Response: Because the late planting provisions will be incorporated in the respective crop policies, the overall amount of paperwork per insured will remain approximately equal. Improved policy protection may result in a slightly larger number of claims for loss adjustment. Extending the late planting period by five days will not be detrimental as long as the production guarantee is sufficiently reduced. The opportunity to make a normal crop does not suddenly cease on the 21st day. The continual acceleration of the guarantee reduction is sufficient to cover the increased risks of insufficient growing season.

6. *Comment:* Making these provisions an integral part of the regulations was questioned. The commenting company stated they have never paid a prevented planting claim, and under the previous procedures, never expected to pay one. Assuming FCIC has to give permission to insureds, the commenter inquired about the method FCIC will use to handle requests from reinsured companies.

FCIC Response: Making the provisions an integral part of the policies will reduce the number of problems experienced with previously available coverage. The new coverage eliminates the need for separate applications, acreage reports, and option forms required under current procedures. The fact that the commenting company has never paid a claim under the current coverage would indicate that policy coverage is not adequate. This would account, in part, for the extremely low participation rates in the current prevented planting coverage. FCIC's permission is only required if drought is the reason that planting is prevented. We do not consider that drought will normally be a prevented planting cause of loss.

7. *Comment:* Companies opposed the use of the producer's option to reject prevented planting coverage. Not only was it thought that this would increase paperwork but it was thought that the necessity of an affirmative request could lead to insureds confusion.

FCIC Response: FCIC agrees and has eliminated the option to decline coverage.

8. *Comment:* Prevented planting should not be part of the policy because of its complexity and the need to explain it in detail to the insured.

FCIC Response: All insurance policies include provisions that are somewhat complex and require explanation to insureds. Establishing separate forms because a provision is new or complex does not establish a desirable precedent.

9. *Comment:* In all three endorsements, calendar year should be changed to read crop year (Texas cotton

is not harvested until January of the following year thus eliminating a prevented planting for the following year).

FCIC Response: FCIC agrees with this comment and has revised each crop endorsement to indicate crop year rather than calendar year.

10. *Comment:* Drought should not be an insurable peril for prevented planting purposes. Drought is difficult to measure or define and would not prevent a crop from being planted. The only insurable peril should be excess moisture. The final planting date is too early to allow an insured the option not to plant and collect a prevented planting payment.

FCIC Response: FCIC agrees that drought is difficult to measure and define. Administration of this coverage will be difficult, especially since agreement as to the severity of the drought and determination of the area to be covered must be determined during the insurance period. FCIC will review requests, on a case by case basis, to determine whether circumstances are sufficiently adverse to grant prevented planting coverage in cases of drought. Policy issuing companies, on behalf of insureds, must obtain written concurrence from FCIC prior to invoking prevented planting coverage in a drought situation. In order for the insured to be indemnified under the prevented planting provisions after the final planting date they must not plant the insured acreage to the insured crop or a substitute crop. If the insured crop or a salvage crop is planted within the periods designated in the provisions, there will be no prevented planting coverage, and the salvage value of the crop will be counted against the production guarantee. The amount of insurance available for prevented planting is designed to approximate the costs already incurred if it is not possible to plant the desired crop. There will be little incentive for the insured to idle ground for the entire crop year only to recover fixed costs. FCIC does not anticipate farmers idling acreage after the final planting date when there is still time to plant another crop.

List of Subjects in 7 CFR Part 401

Crop insurance; Corn, Grain sorghum, and Soybeans.

Final Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 et seq.), the Federal Crop Insurance Corporation hereby amends the crop insurance regulations (7 CFR part 401) effective for the 1994 and subsequent crop years as follows:

PART 401 [AMENDED]

1. The authority citation for 7 CFR part 401 continues to read as follows:

Authority: 7 U.S.C. 1506, 1516.

2. 7 CFR 401.111 is amended by redesignating section 10 of the Corn Endorsement as a revised section 11 and adding a new section 10 to read as follows:

§ 401.111 Corn endorsement.

* * * * *

10. Late and Prevented Planting

a. You are automatically covered under the late planting, salvage crop, and prevented planting provisions of this endorsement, whichever is applicable. If you are prevented from planting due to excess moisture conditions (and drought, if agreed to in writing by us) you may choose to plant late; or you may choose to plant a salvage crop; or you may choose to receive a prevented planting payment if you are unable to plant a crop. For the provisions concerning "Late Planting" guarantee, see subsection b; for the provisions concerning "Coverage Provided for Planting After the Late Planting Period", see subsection c; for the provisions concerning "Prevented Planting" guarantee, see subsection d. If drought is general in the area, we may consider drought an insurable cause of loss under this section in limited circumstances. Drought will not be considered an insurable cause of loss for late or prevented planting for acreage insured under an irrigated practice. You may elect to plant corn for up to 25 days after the final planting date (with a reduction in guarantee), even if you are not prevented from planting.

b. Late Planting

(1) If you were prevented from planting by the final planting date or if you elect to plant later than that date, you may plant corn during the late planting period, subject to the provisions of subsection c or d as applicable. If the acreage is planted later than the twenty-fifth day after the final planting date it will be subject to subsection c or subsection d which contains additional coverage provisions for acreage you were prevented from planting by the final planting date and did not plant during the late planting period.

(2) If you select to plant later than the final planting date, you must provide notice of such election to us, on or before the final planting date. You must note the dates of actual planting on your acreage report if you plant during the late planting period. Failure to provide timely notice will result in reduced coverage or cancellation of your policy coverage.

(3) If you were prevented from planting by the final planting date, you must:

(i) Plant the acreage with corn during the late planting period, subject to the terms of this endorsement;

(ii) Plant the acreage with an alternative crop with a later final planting date which, if insurable, is separately insured under the policy and endorsement for the alternative crop;

(iii) Leave the acreage unplanted and obtain a prevented planting production guarantee, (see subsection d); or

(iv) Plant the acreage to any non-conserving crop not insured under your policy and endorsement for that crop leaving the crop without insurance protection.

(4) The premium for corn planted during the late planting period will be the same as the premium for timely planted acreage. If the farmer paid premium (gross premium less our subsidy) for late planted acreage exceeds our liability on the acreage, then coverage will not be provided (no premium will be due and no indemnity will be paid).

(5) The production guarantee for corn for each acre planted during the late planting period will be reduced for each day after the final planting date by:

(i) One percent (1%) for each of the first ten days after the final planting date; and

(ii) Two percent (2%) each day for the eleventh through the twenty-fifth day after the final planting date.

(6) Subsection 2e(4) of the General Crop Insurance Policy does not apply to corn insured under this endorsement.

c. Planting After the Late Planting Period (Salvage Crop)

(1) You may plant a salvage crop (including corn) during the salvage crop period if you were prevented from planting corn by the final planting date and you did not plant a crop during the late planting period. If the acreage is not planted to corn or a salvage crop during this period (the salvage crop period) the acreage may be subject to subsection d, which contains additional coverage provisions.

(2) The acreage covered will be limited to the greater of (a) the number of acres planted to corn for the previous crop year on the ASCS farm serial number (adjusted for any reconstitution which may have occurred prior to the sales closing date) or (b) the ASCS base acreage for corn reduced by any acreage reduction applicable to the farm under any program administered by the United States Department of Agriculture. Irrigated acreage is limited to a maximum of 100 percent of the acres planted for corn and irrigated during the previous crop year. Coverage for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented. When prevented planting occurs and the ASCS farm serial number covers more than one unit, the covered acres will be allocated based on the cropland acres in each unit or your planting intentions if supported by verifiable records or planting history. Acreage planted with a salvage crop must meet all applicable policy requirements for insurability. You must have been prevented from planting on a minimum of 20 acres or 20 percent of the eligible acres in the unit, whichever is smaller.

(3) If acreage insured for corn production could not be planted by the final planting

date and was not planted by the end of the late planting period, you have the option to:

(i) Plant the acreage to corn and retain coverage at 60% of the guarantee for timely planted acreage;

(ii) For its salvage value plant the acreage to another crop insured under your policy and the endorsement for that crop and retain the insurance coverage remaining (60% of the original liability) on your corn endorsement;

(iii) Leave the acreage unplanted and retain a prevented planting production guarantee subject to the applicable provisions of subsection d; or

(iv) Plant the acreage to an uninsured non-conserving crop, which will terminate the insurance offer on that acreage and result in no premium due nor indemnity paid for that acreage.

(4) You must report the number of acres you were prevented from planting no later than 15 days after planting to a salvage crop or 55 days after the latest final planting date, whichever comes first. This report will be your notice of loss for the purpose of determining coverage under this section. All non-irrigated acreage may be reported, subject to the limitations contained in 10c(2) of this part.

(5) If the farmer paid premium (gross premium less our subsidy) exceeds our liability, then coverage is not provided on the affected acreage (no premium will be due and no indemnity will be paid).

(6) When a salvage crop is planted during the salvage crop period, any production on the acreage will be counted against the policy guarantee. The value of the salvage crop will be the amount received if the crop has been marketed, or the amount which could have been received if the crop has not been marketed. The value will be established on the day the loss is determined.

(7) The prevented planting indemnity for a unit, if the acreage was planted to a salvage crop, will be calculated as follows:

(i) Separate the unit into three parts:

(A) Acreage that was timely planted;

(B) Acreage that was late planted; and

(C) Acreage that was prevented from being planted timely and was planted to a salvage crop during the salvage crop period;

(ii) Multiply the per acre production guarantee for timely planted acreage by the eligible number of acres where planting was prevented (paragraph 10c(7)(i)(C)) and then multiply this result by sixty percent (60%);

(iii) Multiply the per acre production guarantee for timely planted acreage by the eligible number of acres timely planted (paragraph 10c(7)(i)(A));

(iv) Multiply the applicable production guarantee for acreage late planted (subsection 10b(5)) by the eligible number of acres planted late (paragraph 10c(7)(i)(B)); and

(v) Add the production guarantee determinations from 10c(7)(ii), 10c(7)(iii) and 10c(7)(iv);

(vi) Divide the value of production from any salvage crop by your price election;

(vii) Add the amount determined in 10c(7)(vi) above to the production to count established for timely and late planted acreage and acreage planted to corn during the salvage crop period and subtract the total from the production guarantee determined in 10c(7)(v) above;

(viii) Multiply the remainder (10c(7)(vii)) by your price election; and

(ix) Multiply the result of 10c(7)(viii) by your share.

(8) If any crop (salvage or other) is planted 56 or more days after the latest final planting date of corn, grain sorghum, or soybeans in the county, no value will count against the policy guarantee.

d. Prevented Planting

(1) If you were prevented from planting corn by the final planting date, you elected not to plant corn during the late planting period, and you have not planted a salvage or any non-conserving crop prior to the 56th day after the latest final planting date, you may be eligible for a prevented planting production guarantee.

(2) The acreage covered will be limited to the greater of (a) the number of acres planted to corn for the previous crop year on the ASCS farm serial number adjusted for any reconstitution which may have occurred prior to the sales closing date, or (b) the ASCS base acreage for corn reduced by any acreage reduction applicable to the farm under any program administered by the United States Department of Agriculture. Irrigated acreage is limited to a maximum of 100 percent of the acres planted for corn and irrigated during the previous crop year. Coverage for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented. When prevented planting occurs and the ASCS farm serial number covers more than one unit, the covered acres will be allocated based on the cropland acres in each unit or your planting intentions if supported by verifiable records or planting history. Acreage insured for prevented planting must meet all applicable policy requirements for insurability. A minimum of 20 acres or 20 percent of the acres in the unit, whichever is smaller, must be subject to the conditions set out in subsection 10d(2) which prevented planting on that acreage in order to be eligible for this provision.

(3) A prevented planting production guarantee will not be provided for:

(i) High risk land unless we agree to prevented planting coverage, in writing, prior to the sales closing date for corn in the county;

(ii) Land used for acreage conservation under any acreage reduction program administered by the United States Department of Agriculture;

(iii) Land that is entered into any program administered by the United States Department of Agriculture that provides a payment for not planting the acreage (such as the Conservation Reserve Program); or

(iv) Land where any crop has been harvested in the same crop year.

(4) You must report the number of acres eligible for prevented planting coverage no later than 55 days after the latest final planting date in order to receive a prevented planting indemnity. This report will be your notice of loss for the purpose of determining coverage under this section. All non-irrigated acreage may be reported, subject to the limitations in 10d(2) above. No more than 100 percent of the number of acres planted for corn production and irrigated during the previous crop year will be eligible for a prevented planting indemnity as irrigated. A prevented planting indemnity for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented.

(5) The premium for acreage eligible for a prevented planting indemnity is included in the premium for this endorsement. If the farmer paid premium for this coverage exceeds our liability, then coverage will not be provided (no premium will be due and no indemnity will be paid).

(6) The indemnity for a unit adversely impacted by a prevented planting situation, if the impacted acreage is left unplanted, will be calculated as follows:

(i) Separate the acreage of the unit into four parts:

(A) Acreage that was timely planted;

(B) Acreage that was late planted;

(C) Acreage that was prevented from being planted and was planted to a salvage crop or corn during the salvage crop period; and

(D) Acreage that was prevented from planting;

(ii) Multiply the applicable production guarantee for timely planted acreage by the eligible number of acres where planting was prevented (10d(6)(i)(D)) and then multiply that result by fifty percent (50%);

(iii) Multiply the applicable production guarantee for timely planted acreage (10d(6)(i)(A)) by the number of eligible acres timely planted;

(iv) Multiply the applicable production guarantee for late planted acreage (10d(6)(i)(B)) by the number of eligible acres late planted (10b); and

(v) Multiply the applicable production guarantee for acreage planted to a salvage crop (10d(6)(i)(C)) by the number of eligible acres planted to a salvage crop;

(vi) Add the production guarantee determinations from 10d(6) (ii), (iii), (iv), and (v) above;

(vii) Subtract the production to count established for the unit from the production guarantee determined in (10d(6)(vi)) above;

(viii) Multiply the result of (vii), if greater than zero, by your price election;

(ix) Multiply the result of (viii) by your share.

11. Meaning of Terms

a. *Cropland*—arable land in a unit.

b. *Days*—calendar days.

c. *Distinctly Low Quality*—(1) Exceeding 8.0 percent kernel damage (excluding heat damage); (2) Having a musty, sour, or commercially objectionable foreign odor which causes the corn to grade U.S. Sample grade; or (3) Graded as "Garlicky."

d. *Drought*—a lack of precipitation which is general in the county, occurs after planting the insured crop and before harvest, and results in adverse impacts on the production of the insured crop. For prevented planting purposes only, drought occurring prior to the

final planting date and before planting may be considered.

e. *Final planting date*—the date contained in the actuarial table by which the insured crop must initially be planted in order to be insured for the full production guarantee.

f. *Harvest*—completion of combining or picking corn for grain.

g. *High risk land*—land on which crop damage occurs more frequently than is normal in the county and may be characterized by frequent flooding or excess moisture, or soil classified in other than an "R" classification on the actuarial table.

h. *Irrigated practice*—applying adequate water at the proper time to produce at least the yield used to establish the guarantee on the irrigated corn.

i. *Late planting period*—the period which begins the day after the final planting date for corn and ends twenty five (25) days after the final planting date.

j. *Latest final planting date*—the latest final planting date, as established by the actuarial table, for any insurable crop in the county to be planted for harvest in the same crop year as the insured corn. When determining the latest final planting date associated with corn, exclude planting dates related to tobacco, fresh market sweet corn, fresh market peppers, and fresh market tomatoes.

k. *Non-conserving crop*—any food, feed, or fiber crop planted for harvest in the same crop year as the insured corn crop, which is not insured under your policy and its endorsements.

l. *Prevented planting*—you were unavoidably prevented from planting corn by the final planting date due to excess moisture [or drought, if drought is general in the county and we determine in writing that drought will be an insurable cause of loss].

m. *Prevented planting indemnity*—the payment provided for qualifying acreage where corn planting by the final planting date was prevented and the acreage remained unplanted until after the salvage crop period had expired.

n. *Production to count*—the actual appraised or harvested production on insured acreage.

o. *Replanting*—performing the cultural practices necessary to replace the corn seed in the insured acreage with the expectation of growing a successful crop.

p. *Salvage crop*—any crop which has a final planting date equal to or later than corn, is insured under your policy and its endorsements, that is planted during the salvage crop period on acreage where corn planting was prevented by the final planting date. When an insurable crop is planted that may qualify as a salvage crop, the insured crop may be considered to be the crop with the highest applicable liability.

q. *Salvage crop period*—the period which begins the day after the corn late planting period and ends 55 days after the latest final planting date.

r. *Section*—a unit of measure under the rectangular survey system describing a tract of land generally one mile square, usually containing approximately 640 acres.

s. *Silage*—corn harvested by severing the stalk from the land and chopping the stalk and the ear for the purpose of livestock feed.

t. *Timely planted*—corn planted by the final planting date, as established by the actuarial table, for corn in the county to be planted for harvest in the crop year.

2. 7 CFR 401.113 is amended by redesignating section 10 of the Grain Sorghum Endorsement as a revised section 11 and adding a new section 10 to read as follows:

§ 401.113 Grain sorghum endorsement.

* * * * *

10. Late and Prevented Planting

a. You are automatically covered under the late planting, salvage crop, and prevented planting provisions of this endorsement, whichever is applicable. If you are prevented from planting due to excess moisture conditions (and drought, if agreed to in writing by us) You may choose to plant late; or you may choose to plant a salvage crop; or you may choose to receive a prevented planting payment if you are unable to plant a crop. For the provisions concerning "Late Planting" guarantee, see subsection b; for the provisions concerning "Coverage Provided for Planting After the Late Planting Period", see subsection c; for the provisions concerning "Prevented Planting" guarantee, see subsection d. If drought is general in the area, we may consider drought an insurable cause of loss under this section in limited circumstances. Drought will not be considered an insurable cause of loss for late or prevented planting for acreage insured under an irrigated practice. You may elect to plant grain sorghum for up to 25 days after the final planting date (with a reduction in guarantee), even if you are not prevented from planting.

b. Late Planting

(1) If you were prevented from planting by the final planting date or if you elect to plant later than that date, you may plant grain sorghum during the late planting period, subject to the provisions of subsection c or d as applicable. If the acreage is planted later than the twenty-fifth day after the final planting date it will be subject to subsection c or subsection d which contains additional coverage provisions for acreage you were prevented from planting by the final planting date and did not plant during the late planting period.

(2) If you elect to plant later than the final planting date, you must provide notice of such election to us, on or before the final planting date. You must note the dates of actual planting on your acreage report if you plant during the late planting period. Failure to provide timely notice will result in reduced coverage or cancellation of your policy coverage.

(3) If you were prevented from planting by the final planting date, you must:

(i) Plant the acreage with grain sorghum during the late planting period, subject to the terms of this endorsement;

(ii) Plant the acreage with an alternative crop with a later final planting date which, if insurable, is separately insured under the policy and endorsement for the alternative crop;

(iii) Leave the acreage unplanted and obtain a prevented planting production guarantee, (see subsection d); or

(iv) Plant the acreage to any non-conserving crop not insured under your policy and endorsement for the crop leaving the crop without insurance protection.

(4) The premium for grain sorghum planted during the late planting period will be the same as the premium for timely planted acreage. If the farmer paid premium (gross premium less our subsidy) for late planted acreage exceeds our liability on the acreage, then coverage will not be provided (no premium will be due and no indemnity will be paid).

(5) The production guarantee for grain sorghum for each acre planted during the late planting period will be reduced for each day after the final planting date by:

(i) One percent (1%) for each of the first ten days after the final planting date; and

(ii) Two percent (2%) each day for the eleventh through the twenty-fifth day after the final planting date.

(6) Subsection 2.e(4) of the General Crop Insurance Policy does not apply to grain sorghum insured under this endorsement.

c. Planting After the Late Planting Period (Salvage Crop)

(1) You may plant a salvage crop (including grain sorghum) during the salvage crop period if you were prevented from planting grain sorghum by the final planting date and you did not plant a crop during the late planting period. If the acreage is not planted to grain sorghum or a salvage crop during this period (the salvage crop period) the acreage may be subject to subsection d, which contains additional coverage provisions.

(2) The acreage covered will be limited to the greater of (a) the number of acres planted to grain sorghum for the previous crop year on the ASCS farm serial number (adjusted for any reconstitution which may have occurred prior to the sales closing date) or (b) the ASCS base acreage for grain sorghum reduced by any acreage reduction applicable to the farm under any program administered by the United States Department of Agriculture. Irrigated acreage is limited to a maximum of 100 percent of the acres planted for grain sorghum and irrigated during the previous crop year. Coverage for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented. When prevented planting occurs and the ASCS farm serial number covers more than one unit, the covered acres will be allocated based on the cropland acres in each unit or your planting intentions if supported by verifiable records or planting history. Acreage planted with a salvage crop must meet all applicable policy requirements for insurability. You must have been prevented from planting on a minimum of 20 acres or 20 percent of the eligible acres in the unit, whichever is smaller.

(3) If acreage insured for grain sorghum production could not be planted by the final planting date and was not planted by the end

of the late planting period, you have the option to:

(i) Plant the acreage to grain sorghum and retain coverage at 60% of the guarantee for timely planted acreage;

(ii) For its salvage value plant the acreage to another crop insured under your policy and the endorsement for that crop and retain the insurance coverage remaining (60% of the original liability) on your grain sorghum endorsement;

(iii) Leave the acreage unplanted and retain a prevented planting production guarantee subject to the applicable provisions of subsection d; or

(iv) Plant the acreage to an uninsured non-conserving crop, which will terminate the insurance offer on that acreage and result in no premium due nor indemnity paid for that acreage.

(4) You must report the number of acres you were prevented from planting no later than 15 days after planting to a salvage crop or 55 days after the latest final planting date, whichever comes first. This report will be your notice of loss for the purpose of determining coverage under this section. All non-irrigated acreage may be reported, subject to the limitations contained in 10c(2) of this part.

(5) If the farmer paid premium (gross premium less our subsidy) exceeds our liability, then coverage is not provided on the affected acreage (no premium will be due and no indemnity will be paid).

(6) When a salvage crop is planted during the salvage crop period, any production on the acreage will be counted against the policy guarantee. The value of the salvage crop will be the amount received if the crop has been marketed, or the amount which could have been received if the crop has not been marketed. The value will be established on the day the loss is determined.

(7) The prevented planting indemnity for a unit, if the acreage was planted to a salvage crop, will be calculated as follows:

(i) Separate the unit into three parts:

(A) Acreage that was timely planted;

(B) Acreage that was late planted; and

(C) Acreage that was prevented from being planted timely and was planted to a salvage crop during the salvage crop period;

(ii) Multiply the per acre production guarantee for timely planted acreage by the eligible number of acres where planting was prevented (paragraph 10c(7)(i)(C)) and then multiply this result by sixty percent (60%);

(iii) Multiply the per acre production guarantee for timely planted acreage by the eligible number of acres timely planted (paragraph 10c(7)(i)(A));

(iv) Multiply the applicable production guarantee for acreage late planted (subsection 10b(5)) by the eligible number of acres planted late (paragraph 10c(7)(i)(B)); and

(v) Add the production guarantee determinations from 10c(7)(ii), 10c(7)(iii) and 10c(7)(iv);

(vi) Divide the value of production from any salvage crop by your price election;

(vii) Add the amount determined in 10c(7)(vi) above to the production to count established for timely and late planted acreage and acreage planted to grain sorghum during the salvage crop period and subtract the total from the production guarantee determined in 10c(7)(v) above;

(viii) Multiply the remainder (10c(7)(vii)) by your price election; and

(ix) Multiply the result of 10c(7)(viii) by your share.

(8) If any crop (salvage or other) is planted 56 or more days after the latest final planting date of corn, grain sorghum, or soybeans in the county, no value will count against the policy guarantee.

d. Prevented Planting

(1) If you were prevented from planting grain sorghum by the final planting date, you elected not to plant grain sorghum during the late planting period, and you have not planted a salvage or any non-conserving crop prior to the 56th day after the latest final planting date, you may be eligible for a prevented planting production guarantee.

(2) The acreage covered will be limited to the greater of (a) the number of acres planted to grain sorghum for the previous crop year on the ASCS farm serial number adjusted for any reconstitution which may have occurred prior to the sales closing date, or (b) the ASCS base acreage for grain sorghum reduced by any acreage reduction applicable to the farm under any program administered by the United States Department of Agriculture. Irrigated acreage is limited to a maximum of 100 percent of the acres planted for grain sorghum and irrigated during the previous crop year. Coverage for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented. When prevented planting occurs and the ASCS farm serial number covers more than one unit, the covered acres will be allocated based on the cropland acres in each unit or your planting intentions if supported by verifiable records or planting history. Acreage insured for prevented planting must meet all applicable policy requirements for insurability. A minimum of 20 acres of 20 percent of the acres in the unit, whichever is smaller, must be subject to the conditions set out in subsection 10d(2) which prevented planting on that acreage in order to be eligible for this provision.

(3) A prevented planting production guarantee will not be provided for:

(i) High risk land unless we agree to prevented planting coverage, in writing, prior to the sales closing date for grain sorghum in the county;

(ii) Land used for acreage conservation under any acreage reduction program administered by the United States Department of Agriculture;

(iii) Land that is entered into any program administered by the United States Department of Agriculture that provides a payment for not planting the acreage (such as the Conservation Reserve Program); or

(iv) Land where any crop has been harvested in the same crop year.

(4) You must report the number of acres eligible for prevented planting coverage no later than 55 days after the latest final planting date in order to receive a prevented planting indemnity. This report will be your notice of loss for the purpose of determining coverage under this section. All non-irrigated acreage may be reported, subject to the limitations in 10d(2) above. No more than 100 percent of the number of acres planted for grain sorghum production and irrigated during the previous crop year will be eligible for a prevented planting indemnity as irrigated. A prevented planting indemnity for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented.

(5) The premium for acreage eligible for a prevented planting indemnity is included in the premium for this endorsement. If the farmer paid premium for this coverage exceeds our liability, then coverage will not be provided (no premium will be due and no indemnity will be paid).

(6) The indemnity for a unit adversely impacted by a prevented planting situation, if the impacted acreage is left unplanted, will be calculated as follows:

(i) Separate the acreage of the unit into four parts:

(A) Acreage that was timely planted;

(B) Acreage that was late planted;

(C) Acreage that was prevented from being planted and was planted to a salvage crop or grain sorghum during the salvage crop period; and

(D) Acreage that was prevented from planting;

(ii) Multiply the applicable production guarantee for timely planted acreage by the eligible number of acres where planting was prevented (10d(6)(i)(D)) and then multiply that result by fifty percent (50%);

(iii) Multiply the applicable production guarantee for timely planted acreage (10d(6)(i)(A) by the number of eligible acres timely planted;

(iv) Multiply the applicable production guarantee for late planted acreage (10d(6)(i)(B) by the number of eligible acres late planted (10b); and

(v) Multiply the applicable production guarantee for acreage planted to a salvage crop (10d(6)(i)(C)) by the number of eligible acres planted to a salvage crop;

(vi) Add the production guarantee determinations from 10d(6)(ii), (iii), (iv), and (v) above;

(vii) Subtract the production to count established for the unit from the production guarantee determined in (10d(6)(vi) above;

(viii) Multiply the result of (vii), if greater than zero, by your price election;

(ix) Multiply the result of (viii) by your share.

11. Meaning of Terms

a. *Cropland*—arable land in a unit.

b. *Days*—calendar days.

c. *Distinctly Low Quality*—(1) Exceeding 8.0 percent kernel damage (excluding heat damage); (2) Having a musty, sour, or commercially objectionable foreign odor which causes the grain sorghum to grade U.S. Sample grade; or (3) Graded as "Garlicky."

d. *Drought*—a lack of precipitation which is general in the county, occurs after planting the insured crop and before harvest, and results in adverse impacts on the production

of the insured crop. For prevented planting purposes only, drought occurring prior to the final planting date and before planting may be considered.

e. *Final planting date*—the date contained in the actuarial table by which the insured crop must initially be planted in order to be insured for the full production guarantee.

f. *Harvest*—completion of combining or threshing grain sorghum for grain.

g. *High risk land*—land on which crop damage occurs more frequently than is normal in the county and may be characterized by frequent flooding or excess moisture, or soil classified in other than an "R" classification on the actuarial table.

h. *Irrigated practice*—applying adequate water at the proper time to produce at least the yield used to establish the guarantee on the irrigated grain sorghum.

i. *Late planting period*—the period which begins the day after the final planting date for grain sorghum and ends twenty five (25) days after the final planting date.

j. *Latest final planting date*—the latest final planting date, as established by the actuarial table, for any insurable crop in the county to be planted for harvest in the same crop year as the insured grain sorghum. When determining the latest final planting date associated with grain sorghum, exclude planting dates related to tobacco, fresh market sweet corn, fresh market peppers, and fresh market tomatoes.

k. *Non-conserving crop*—any food, feed, or fiber crop planted for harvest in the same crop year as the insured grain sorghum crop, which is not insured under your policy and its endorsements.

l. *Prevented planting*—you were unavoidably prevented from planting grain sorghum by the final planting date due to excess moisture [or drought, if drought is general in the county] and we determine in writing that drought will be an insurable cause of loss.

m. *Prevented planting indemnity*—the payment provided for qualifying acreage where grain sorghum planting by the final planting date was prevented and the acreage remained unplanted until after the salvage crop period had expired.

n. *Production to count*—the appraised or harvested actual production on insured acreage.

o. *Replanting*—performing the cultural practices necessary to replace the grain sorghum seed in the insured acreage with the expectation of growing a successful corp.

p. *Salvage crop*—any crop which has a final planting date equal to or later than grain sorghum, is insured under your policy and its endorsements, is planted during the salvage crop period on acreage where grain sorghum planting was prevented by the final planting date. When an insurable crop is planted that may qualify as a salvage crop, the insured crop may be considered to be the crop with the highest applicable liability.

q. *Salvage crop period*—the period which begins the day after the grain sorghum late planting period and ends 55 days after the latest final planting date.

r. *Section*—a unit of measure under the rectangular survey system describing a tract of land generally one mile square, usually containing approximately 640 acres.

s. *Silage*—grain sorghum harvested by severing the stalk from the land and chopping the stalk and the grain for the purpose of livestock feed.

t. *Timely planted*—grain sorghum planted by the final planting date, as established by the actuarial table, for grain sorghum in the county to be planted for harvest in the crop year.

5. 7 CFR 401.117 is amended by redesignating section 10 of the Soybean Endorsement as a revised section 11 and adding a new section 10 to read as follows:

§ 401.117 Soybean endorsement.

* * * * *

10. Late and Prevented Planting

a. You are automatically covered under the late planting, salvage crop, and prevented planting provisions of this endorsement, whichever is applicable. If you are prevented from planting due to excess moisture conditions (and drought, if agreed to in writing by us) You may choose to plant late; or you may choose to plant a salvage crop; or you may choose to receive a prevented planting payment if you are unable to plant a crop. For the provisions concerning "Late Planting" guarantee, see subsection b; for the provisions concerning "Coverage Provided for Planting After the Late Planting Period", see subsection c; for the provisions concerning "Prevented Planting" guarantee, see subsection d. If drought is general in the area, we may consider drought an insurable cause of loss under this section in limited circumstances. Drought will not be considered an insurable cause of loss for late or prevented planting for acreage insured under an irrigated practice. You may elect to plant soybean for up to 25 days after the final planting date (with a reduction in guarantee), even if you are not prevented from planting.

b. Late Planting

(1) If you were prevented from planting by the final planting date or if you elect to plant later than that date, you may plant soybean during the late planting period, subject to the provisions of subsection c or d as applicable. If the acreage is planted later than the twenty-fifth day after the final planting date it will be subject to subsection c or subsection d which contains additional coverage provisions for acreage you were prevented from planting by the final planting date and did not plant during the late planting period.

(2) If you elect to plant later than the final planting date, you must provide notice of such election to us, on or before the final planting date. You must note the dates of actual planting on your acreage report if you plant during the late planting period. Failure to provide timely notice will result in reduced coverage or cancellation of your policy coverage.

(3) If you were prevented from planting by the final planting date, you must:

(i) Plant the acreage with soybean during the late planting period, subject to the terms of this endorsement;

(ii) Plant the acreage with an alternative crop with a later final planting date which, if insurable, is separately insured under the policy and endorsement for the alternative crop;

(iii) Leave the acreage unplanted and obtain a prevented planting production guarantee, (see subsection d); or

(iv) Plant the acreage to any non-conserving crop not insured under your policy and endorsement for that crop leaving the crop without insurance protection.

(4) The premium for soybean planted during the late planting period will be the same as the premium for timely planted acreage. If the farmer paid premium (gross premium less or subsidy) for late planted acreage exceeds our liability on the acreage, then coverage will not be provided (no premium will be due and no indemnity will be paid).

(5) The production guarantee for soybean for each acre planted during the late planting period will be reduced for each day after the final planting date by:

(i) One percent (1%) for each of the first ten days after the final planting date; and

(ii) Two percent (2%) each day for the eleventh through the twenty-fifth day after the final planting date.

(6) Subsection 2.e(4) of the General Crop Insurance Policy does not apply to soybean insured under this endorsement.

c. Planting After the Late Planting Period (Salvage Crop)

(1) You may plant a salvage crop (including soybeans) during the salvage crop period if you were prevented from planting soybeans by the final planting date and you did not plant a crop during the late planting period. If the acreage is not planted to soybean or a salvage crop during this period (the salvage crop period) the acreage may be subject to subsection d, which contains additional coverage provisions.

(2) The acreage covered will be limited to the greater of (a) the number of acres planted to soybeans for the previous crop year on the ASCS farm serial number (adjusted for any reconstitution which may have occurred prior to the sales closing date) or (b) the ASCS base acreage for soybean reduced by any acreage reduction applicable to the farm under any program administered by the United States Department of Agriculture. Irrigated acreage is limited to a maximum of 100 percent of the acres planted for soybeans and irrigated during the previous crop year. Coverage for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented. When prevented planting occurs and the ASCS farm serial number covers more than one unit, the covered acres will be allocated based on the cropland acres in each unit or your planting intentions if supported by verifiable records or planting history. Acreage planted with a salvage crop must meet all applicable policy requirements for insurability. You must have been prevented from planting on a minimum of 20 acres or 20 percent of the eligible acres in the unit, whichever is smaller.

(3) If acreage insured for soybean production could not be planted by the final planting date and was not planted by the end

of the late planting period, you have the option to:

(i) Plant the acreage to soybean and retain coverage at 60% of the guarantee for timely planted acreage;

(ii) For its salvage value plant the acreage to another crop insured under your policy and the endorsement for that crop and retain the insurance coverage remaining (60% of the original liability) on your soybean endorsement;

(iii) Leave the acreage unplanted and retain a prevented planting production guarantee subject to the applicable provisions of subsection d; or

(iv) Plant the acreage to an uninsured non-conserving crop, which will terminate the insurance offer on that acreage and result in no premium due nor indemnity paid for that acreage.

(4) You must report the number of acres you were prevented from planting no later than 15 days after planting to a salvage crop or 55 days after the latest final planting date, whichever comes first. This report will be your notice of loss for the purpose of determining coverage under this section. All non-irrigated acreage may be reported, subject to the limitations contained in 10c(2) of this part.

(5) If the farmer paid premium (gross premium less our subsidy) exceeds our liability, then coverage is not provided on the affected acreage (no premium will be due and no indemnity will be paid).

(6) When a salvage crop is planted during the salvage crop period, any production on the acreage will be counted against the policy guarantee. The value of the salvage crop will be the amount received if the crop has been marketed, or the amount which could have been received if the crop has not been marketed. The value will be established on the day the loss is determined.

(7) The prevented planting indemnity for a unit, if the acreage was planted to a salvage crop, will be calculated as follows:

(i) Separate the unit into three parts:

(A) Acreage that was timely planted;

(B) Acreage that was late planted; and

(C) Acreage that was prevented from being planted timely and was planted to a salvage crop during the salvage crop period;

(ii) Multiply the per acre production guarantee for timely planted acreage by the eligible number of acres where planting was prevented (paragraph 10c(7)(i)(C) and then multiply this result by sixty percent (60%);

(iii) Multiply the per acre production guarantee for timely planted acreage by the eligible number of acres timely planted (paragraph 10c(7)(i)(A));

(iv) Multiply the applicable production guarantee for acreage late planted (subsection 10b(5)) by the eligible number of acres planted late (paragraph 10c(7)(i)(B)); and

(v) Add the production guarantee determinations from 10c(7)(ii), 10c(7)(iii) and 10c(7)(iv);

(vi) Divide the value of production from any salvage crop by your price election;

(vii) Add the amount determined in 10c(7)(vi) above to the production to count established for timely and late planted acreage and acreage planted to soybean during the salvage crop period and subtract the total from the production guarantee determined in 10c(7)(v) above;

(viii) Multiply the remainder (10c(7)(vii) by your price election; and

(ix) Multiply the result of 10c(7)(viii) by your share.

(8) If any crop (salvage or other) is planted 56 or more days after the latest final planting date of corn, grain sorghum, or soybeans in the county, no value will count against the policy guarantee.

d. Prevented Planting

(1) If you were prevented from planting soybean by the final planting date, you elected not to plant soybean during the late planting period, and you have not planted a salvage or any non-conserving crop prior to the 56th day after the latest final planting date, you may be eligible for a prevented planting production guarantee.

(2) The acreage covered will be limited to the greater of (a) the number of acres planted to soybean for the previous crop year on the ASCS farm serial number adjusted for any reconstitution which may have occurred prior to the sales closing date, or (b) the ASCS base acreage for soybean reduced by any acreage reduction applicable to the farm under any program administered by the United States Department of Agriculture. Irrigated acreage is limited to a maximum of 100 percent of the acres planted for soybean and irrigated during the previous crop year. Coverage for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented. When prevented planting occurs and the ASCS farm serial number covers more than one unit, the covered acres will be allocated based on the cropland acres in each unit or your planting intentions if supported by verifiable records or planting history. Acreage insured for prevented planting must meet all applicable policy requirements for insurability. A minimum of 20 acres or 20 percent of the acres in the unit, whichever is smaller, must be subject to the conditions set out in subsection 10d(2) which prevented planting on that acreage in order to be eligible for this provision.

(3) A prevented planting production guarantee will not be provided for:

(i) High risk land unless we agree to prevented planting coverage, in writing, prior to the sales closing date for soybean in the county;

(ii) Land used for acreage conservation under any acreage reduction program administered by the United States Department of Agriculture;

(iii) Land that is entered into any program administered by the United States Department of Agriculture that provides a payment for not planting the acreage (such as the Conservation Reserve Program); or

(iv) Land where any crop has been harvested in the same crop year.

(4) You must report the number of acres eligible for prevented planting coverage no later than 55 days after the latest final planting date in order to receive a prevented planting indemnity. This report will be your notice of loss for the purpose of determining coverage under this section. All non-irrigated acreage may be reported, subject to the limitations in 10d(2) above. No more than 100 percent of the number of acres planted for soybean production and irrigated during the previous crop year will be eligible for a prevented planting indemnity as irrigated. A prevented planting indemnity for irrigated acreage will only be approved if the acreage prevented from planting is prepared for irrigation, and if sufficient irrigation equipment and water was and is available to carry out an irrigated practice on the acreage where planting was prevented.

(5) The premium for acreage eligible for a prevented planting indemnity is included in the premium for this endorsement. If the farmer paid premium for this coverage exceeds our liability, then coverage will not be provided (no premium will be due and no indemnity will be paid).

(6) The indemnity for a unit adversely impacted by a prevented planting situation, if the impacted acreage is left unplanted, will be calculated as follows:

(i) Separate the acreage of the unit into four parts:

(A) Acreage that was timely planted;

(B) Acreage that was late planted;

(C) Acreage that was prevented from being planted and was planted to a salvage crop or soybean during the salvage crop period; and

(D) Acreage that was prevented from planting;

(ii) Multiply the applicable production guarantee for timely planted acreage by the eligible number of acres where planting was prevented (10d(6)(i)(D)) and then multiply that result by fifty percent (50%);

(iii) Multiply the applicable production guarantee for timely planted acreage (10d(6)(i)(A)) by the number of eligible acres timely planted;

(iv) Multiply the applicable production guarantee for late planted acreage (10d(6)(i)(B)) by the number of eligible acres late planted (10b); and

(v) Multiply the applicable production guarantee for acreage planted to a salvage crop (10d(6)(i)(C)) by the number of eligible acres planted to a salvage crop;

(vi) Add the production guarantee determinations from 10d(6)(ii), (iii), (iv), and (v) above;

(vii) Subtract the production to count established for the unit from the production guarantee determined in (10d(6)(vi)) above;

(viii) Multiply the result of (vii), if greater than zero, by your price election;

(ix) Multiply the result of (viii) by your share.

11. Meaning of Terms

a. *Cropland*—arable land in a unit.

b. *Days*—calendar days.

c. *Distinctly Low Quality*—(1) Exceeding 8.0 percent kernel damage (excluding heat damage); (2) Having a musty, sour, or commercially objectionable foreign odor which causes the beans to grade U.S. Sample grade; or (3) Graded as "Garlicky."

d. *Drought*—a lack of precipitation which is general in the county, occurs after planting the insured crop and before harvest, and results in adverse impacts on the production of the insured crop. For prevented planting purposes only, drought occurring prior to the

purposes only, drought occurring prior to the final planting date and before planting may be considered.

e. *Final planting date*—the date contained in the actuarial table by which the insured crop must initially be planted in order to be insured for the full production guarantee.

f. *Harvest*—completion of combining or threshing of soybeans on the unit.

g. *High risk land*—land on which crop damage occurs more frequently than is normal in the county and may be characterized by frequent flooding, excess moisture, or soil classified in other than an "R" classification on the actuarial table.

h. *Irrigated practice*—applying adequate water at the proper time to produce at least the yield used to establish the guarantee on the irrigated soybeans.

i. *Late planting period*—the period which begins the day after the final planting date for soybeans and ends twenty five (25) days after the final planting date.

j. *Latest final planting date*—the latest final planting date, as established by the actuarial table, for any insurable crop in the county to be planted for harvest in the same crop year as the insured soybeans. When determining the latest final planting date associated with soybeans, exclude planting dates related to tobacco, fresh market sweet soybean, fresh market peppers, and fresh market tomatoes.

k. *Non-conserving crop*—any food, feed, or fiber crop planted for harvest in the same crop year as the insured soybeans crop, which is not insured under your policy and its endorsements.

l. *Prevented planting*—you were unavoidably prevented from planting soybeans by the final planting date due to excess moisture [or drought, if drought is general in the county and we determine in writing that drought will be an insurable cause of loss].

m. *Prevented planting indemnity*—the payment provided for qualifying acreage where soybean planting by the final planting date was prevented and the acreage remained unplanted until after the salvage crop period had expired.

n. *Production to count*—the actual appraised or harvested production on insured acreage.

o. *Replanting*—performing the cultural practices necessary to replace the soybeans seed in the insured acreage with the expectation of growing a successful crop.

p. *Salvage crop*—any crop which has a final planting date equal to or later than soybeans, is insured under your policy and its endorsements, is planted during the salvage crop period on acreage where soybeans planting was prevented by the final planting date. When an insurable crop is planted that may qualify as a salvage crop, the insured crop may be considered to be the crop with the highest applicable liability.

q. *Salvage crop period*—the period which begins the day after the soybeans late planting period and ends 55 days after the latest final planting date.

r. *Section*—a unit of measure under the rectangular survey system describing a tract of land generally one mile square, usually containing approximately 640 acres.

s. *Timely planted*—soybeans planted by the final planting date, as established by the actuarial table, for soybeans in the county to be planted for harvest in the crop year.

Done in Washington, DC, on November 17, 1992.

David L. Brecht,

Associate Manager, Federal Crop Insurance Corporation.

[FR Doc. 93-412 Filed 1-7-93; 8:45 am]

BILLING CODE 3410-08-M

Federal Grain Inspection Service

7 CFR Part 800

Certification of Additive-Treated Grain

AGENCY: Federal Grain Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Federal Grain Inspection Service (FGIS) is revising the regulations under the United States Grain Standards Act (USGSA) to require the showing of a statement on official inspection and weight certificates whenever water is applied to export grain at export port locations. This action will ensure that buyers are informed when water has been applied.

EFFECTIVE DATE: February 8, 1993.

FOR FURTHER INFORMATION CONTACT: George Wollam, FGIS, USDA, room 0632 South Building, P.O. Box 96454, Washington, DC, 20090-6454; (202) 720-0292.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This final rule has been issued in conformance with Executive Order 12291 and Departmental Regulation 1512-1. This action has been classified as nonmajor because it does not meet the criteria for a major regulation established in the Order.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. The United States Grain Standards Act provides in section 87g that no State or subdivision may require or impose any other requirements or restrictions concerning the inspection, weighing, or description of grain under the Act. Otherwise, this final rule will not preempt any State or local laws, regulations, or policies,unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act Certification

John C. Foltz, Administrator, FGIS, has determined that this final rule will not have a significant economic impact on a substantial number of small entities because most users of the inspection and weighing services and those persons that perform these services do not meet the requirements for small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Information Collection Requirements

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the information collection requirements contained in the rule being amended have been previously approved by the Office of Management and Budget under control number 0580-0013.

Background

Eight years ago, in the November 26, 1984, **Federal Register** (49 FR 46414), FGIS proposed to revise the regulations under the United States Grain Standards Act (USGSA) to establish provisions for officially inspecting and weighing additive-treated grain. These provisions were developed to offer the grain industry the opportunity to utilize available dust suppression technology, apply insect and fungi controls, and mark grain for identification purposes with Food and Drug Administration (FDA) approved additives.

A total of 15 comments were received on the changes proposed in the November 26, 1984, **Federal Register**. Three commenters were in favor of the proposed regulations without any reservations. Two commenters were opposed to the proposed additive provisions, as related to dust-suppressing agents. They asserted, in part, that water may be added just to increase the weight of the grain. The remaining 10 commenters were in favor of the proposed additive policy, but expressed concerns about certain parts of the regulations. Three of these 10 commenters noted the potential for improper addition of additives for the purpose of adding weight to the grain.

The final rule, published in the March 4, 1987, **Federal Register** (52 FR 6493), specified that if additives are applied during loading to outbound grain after sampling or weighing for the purpose of insect or fungi control, dust suppression, or identification, the inspection and/or weight certificate must show a statement that describes the type and purpose of the additive application. A statement is not required to be shown when additives are applied prior to sampling and weighing

outbound grain or after sampling and weighing inbound grain. All incidents or suspected incidents of unapproved additive usage or improper additive application would be reported to the appropriate Federal, State, or local authorities for action.

Recently, FGIS received several complaints from both foreign and domestic grain merchants concerning the application of water to grain. The complainants expressed concern over potential quality degradation due to water application, emphasized that alternative dust control techniques are available that are practical and effective, and contended that the primary purpose of applying water is to increase the weight of the grain and, thereby, gain a market advantage. They further expressed concern about possible negative market reaction by both domestic and foreign buyers of U.S. grain. That is, buyer confidence in U.S. grain quality will decline if concerns develop over potential quality degradation and "paying grain prices for water." Those who support allowing the application of water to grain contend that it is an effective method for reducing dust emissions.

In the July 17, 1992, **Federal Register** (57 FR 31668), FGIS proposed to revise the regulations under the USGSA to require a statement to be shown on all official export inspection and weight certificates whenever additives (except fumigants applied for the purpose of insect control) are applied to export grain, at export port locations, regardless of whether the additives are applied before or after sampling and weighing. According to the proposal, the statement would describe the type of additive that was applied, the point in the handling process where it was applied, and the specific reason for application. FGIS also proposed to revise the regulatory language concerning the use of fumigants as an additive. Fumigants are gaseous in nature and will not adversely affect the physical condition of grain. Therefore, the proposal did not require a statement to be shown on official inspection and weighing certificates when the additive is a fumigant applied for the purpose of insect control.

Comment Review

FGIS received a total of 39 comments during the 15-day comment period. Fourteen commenters supported the changes to the regulations as proposed. Supporters included foreign trade groups, U.S. producer organizations, and grain companies. Many of those that voiced support for this action also urged FGIS to initiate action to prohibit the addition of water to grain in both export and domestic markets.

Six commenters representing grain handlers recommended that the proposed action be limited to the addition of water to grain. These commenters indicated that additives, such as mineral oil, vegetable oil, and insecticides, are already adequately controlled. Many of these commenters also stated that water is the only currently available additive for which there is an economic incentive to increase the weight of grain.

Nine commenters opposed the proposal as written. Two commenters recommended that the statement only be required when an excessive amount of additive is applied. One commenter suggested that the statement not be required for insecticides unless it is also required for fumigants. Other commenters expressed fear that the proposed statement could disrupt the export grain market or result in the misapplication of additives. One commenter urged FGIS to conduct further studies before taking any action.

Ten commenters did not address the proposed action, but indicated that they opposed any prohibition on the use of water for suppressing dust. Five of these comments were from individuals or groups affiliated with one grain company. Most of these commenters wrote about their own positive experiences with water-based dust suppression systems. They indicated that water is a cheap and effective material for controlling dust, and that FGIS should allow elevators to continue to use it.

Final Action

On the basis of the comments that were received and other available information, FGIS has determined that the regulations under the USGSA should be revised to require a statement on official inspection and weight certificates whenever water is applied to export grain at export port locations. FGIS is taking this action because sufficient concern exists among many producers, exporters, and foreign buyers regarding the application of water to grain, and the potential effect of this practice on the marketing of U.S. grain and the integrity of U.S. grain merchants. FGIS believes that this action will alleviate these concerns and improve the confidence of foreign buyers regarding the quality of U.S. grain.

FGIS decided not to require a statement on certificates when additives, other than water, are applied to export grain before sampling and weighing because such information could be disruptive to marketing and because additives, such as dyes, insecticides, and fungicides are:

(1) Typically applied to export grain only when stipulated by the purchase contract and

(2) Commercially recognized as safe when used properly. In addition, these additives do not present the same incentive to increase grain weight as does water.

Also, the proposed rulemaking action did not address limiting or prohibiting the addition of water to domestic and export grain. FGIS is very concerned about potentially improper water applications and is reviewing this issue separately.

List of Subjects in 7 CFR Part 800

Administrative practice and procedure, Exports, Grain.

For reasons set out in the preamble, 7 CFR Part 800 is amended as follows:

PART 800—GENERAL REGULATIONS

1. The authority citation for part 800 continues to read as follows:

Authority: Pub. L. 94–582, 90 Stat. 2867, as amended, (7 U.S.C. 71 *et seq.*).

2. Section 800.88(d) is revised to read as follows:

§ 800.88 Loss of identity.

* * * * *

(d) *Additives.*[1]

(i) *General.* If additives are applied during loading to outbound, including export, grain after sampling or during unloading to inbound grain before sampling for the purpose of insect or fungi control, dust suppression, or identification, the inspection certificate shall show a statement showing the type and purpose of the additive application, except that no statement is required to be shown when the additive is a fumigant applied for the purpose of insect control.

(ii) *Export grain.* If water is applied to export grain, at export port locations, the inspection certificate shall show a statement indicating the purpose and location of the water application.

3. Section 800.96(c)(2) is revised to read as follows:

§ 80.96 Weighing procedures.

* * * * *

(c) * * *

(2) *Additives.*[1]

(i) *General.* If additives are applied during loading to outbound, including

[1] Elevators, other handlers of grain, and their agents are responsible for the additive's proper usage and application. Compliance with this section does not excuse compliance with applicable Federal, State, and local laws.

export, grain after weighing or during unloading to inbound grain before weighing for the purpose of insect or fungi control, dust suppression, or identification, the weight certificate shall show the actual weight of the grain after the application of the additive for inbound grain or the actual weight of the grain prior to the application of the additive for outbound or export grain and a statement showing the type and purpose of the additive application, except that no statement is required to be shown when the additive is a fumigant applied for the purpose of insect control.

(ii) *Export grain.* If water is applied to export grain, at an export port location, the weight certificate shall show a statement showing the purpose and location of the water application.

* * * * *

Dated: December 14, 1992.

John C. Foltz,

Administrator.

[FR Doc. 93–120 Filed 1–7–93; 8:45 am]

BILLING CODE 3410–EN–M

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7 CFR Part 800

Fees for Official Inspection and Official Weighing Services

AGENCY: Federal Grain Inspection Service, USDA.

ACTION: Interim rule with request for comment.

SUMMARY: The Federal Grain Inspection Service (FGIS) is increasing its fees by 3.7 percent for official inspection and weighing services performed in the United States under the United States Grain Standards Act (USGSA), as amended. The Office of Management and Budget inflation factor for the Federal pay raise effective in January 1993 is 3.7 percent. The same factor was used in arriving at the FY 1993 President's budget. The change is intended to cover, as nearly as practicable, the FGIS operating costs, including related supervisory and administrative costs. The change does not include an increase in fees for administration and supervision of Official Agencies or for inspection and weighing services in Canada.

DATES: Effective February 1, 1993. Comments must be submitted on or before March 3, 1993.

ADDRESSES: Written comments must be submitted to George W. Wollam, Federal Grain Inspection Service, USDA, room 0624, South Building, P.O. Box 96454, Washington, DC 20090–6454 and telecopy users may send responses to the automatic telecopier machine at (202) 720–4628.

All comments received will be made available for public inspection during regular business hours in room 0632, South Building, 1400 Independence Avenue, SW., Washington, DC (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: George W. Wollam, Federal Grain Inspection Service, USDA, room 0624, South Building, P.O. Box 96454, Washington, DC 20090–6454; Telephone (202) 720–0292.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This interim rule has been issued in conformance with Executive Order 12291 and Departmental Regulation 1515–1. This action has been classified as non-major because it does not meet the criteria for a major regulation established in the Order.

Executive Order 12778

This interim rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. The United States Grain Standards Act provides in section 87g that no State or subdivision may require or impose any requirements or restrictions concerning the inspection, weighing, or description of grain under the Act. Otherwise, this final rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act Certification

John C. Foltz, Administrator, FGIS, has determined that this interim rule will not have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because most users of the official inspection and weighing services do not meet the requirements for small entities. FGIS is required by statute to make services available and to recover, as nearly as practicable, the costs of providing such services.

Paperwork Reduction

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the information collection requirements contained in the rule being amended have been previously approved by OMB under control number 0580–0013.

Background

The USGSA, as amended (7 U.S.C. 71 *et seq.*), provides that FGIS shall charge and collect reasonable fees that cover its estimated cost for performing official inspection, weighing, reinspection, and appeal inspection services. The fees are to cover, as nearly as practicable, the FGIS costs for performance of these official services, including related administrative and supervisory costs.

FGIS costs include personnel compensation, personnel benefits, travel, rent, communications, utilities, contractual services, supplies, and equipment. The current USGSA fees for original inspection and weighing services performed in the U.S. became effective May 20, 1991 (56 FR 15803). The fees were designed to cover, as nearly as practicable, the level of operating costs as projected for fiscal year 1991. They presently appear in 800.71 on Schedule A of the regulations, Fees for Official Inspection, Weighing, and Appeal Inspection Services Performed in the United States (7 CFR 800.71) (Schedule A).

Costs for fiscal year 1991 exceeded revenues by $1.646 million requiring FGIS to draw from its limited retained earnings. FGIS continually monitors its costs, revenue, and operating reserve level to assure that there are sufficient resources for operations. Revenue for fiscal year 1991 decreased by $1.896 million when compared to the previous fiscal year. FGIS reduced its costs by $2.803 million in fiscal year 1991 when compared to the previous fiscal year.

In fiscal year 1992, FGIS further reduced its costs by $347,000 resulting in a positive margin for the year of $261,000. The Office of Management and Budget has published an inflation factor of 3.7 percent covering Federal pay raises effective in January 1993. Based on fiscal year 1992 costs of $18.813 million, the inflation factor for federal pay will increase costs for fiscal year 1993 by $522,000 (9 months for the fiscal from January through September 1993). FGIS is proposing to continue its cost reduction efforts along with adjusting its fees for inflation in order to break-even for fiscal year 1993.

Final Action

FGIS believes it is necessary to increase fees on February 1, 1993, for official grain inspection and weighing, reinspection, and appeal inspection services performed in the U.S. by 3.7 percent, including both the contract hourly rates and noncontract hourly rates for original inspection and official weighing if FGIS is to break even in its revenue for fiscal year 1993. The official

inspection and weighing services hourly rates include, but are not limited to: grading, weighing, sampling, stowage examination, equipment testing, test weight reverification, evaluation of inspection and weighing equipment, demonstrating official inspection and weighing functions, furnishing standard illustrations, and certifying inspection and weighing results, and other services requested by the applicant when performed at the point of service. Accordingly, this interim rule increases fees by 3.7 percent and revises the fee tables to reflect the increase.

Pursuant to 5 U.S.C. 553, it is found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the Federal Register.

This interim final rule is needed because FGIS has determined that (1) the Inspection and Weighing Program is generating insufficient funds under current schedules to break-even in Fiscal Year 1993, and (2) to enhance the possibility of breaking-even, revenues generated under the new schedules, must be effective February 1, 1993. A 30-day comment period is provided to allow interested persons to comment on this interim final rule prior to its finalization.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads and in Executive Orders 12291 and 12498. The Department applies this principle to the fullest extent possible, consistent with law.

The Department has developed and reviewed this regulatory action in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the rule. Comments suggesting less burdensome or more efficient alternatives should be addressed to FGIS as provided in this rule.

List of Subjects in 7 CFR Part 800

Administrative practice and procedure; Grains.

For the reasons set out in the preamble, 7 CFR Part 800 is amended as follows:

PART 800—GENERAL REGULATIONS

1. The authority citation for part 800 continues to read as follows:

Authority: Pub. L. 94–582, 90 Stat. 2867, as amended (7 U.S.C. 71 *et seq.*).

2. In § 800.71, Schedule A, is revised to read as follows:

§ 800.71 Fees assessed by the Service.

(a) * * *

SCHEDULE A. FEES FOR OFFICIAL INSPECTION, WEIGHING, AND APPEAL INSPECTION SERVICE PERFORMED IN THE UNITED STATES [1]

Inspection & weighing service (bulked or sacked grain)	Regular workday (Monday to Saturday)	Nonregular workday (Sunday and Holiday)
(1) Original Inspection Official Weighing:		
(i) Contract (per hour per Service Representative)	$32.80	$44.80
(ii) Noncontract (per hour per Service Representative)	43.60	59.20
(2) Reinspection, Appeal Inspection, Board Appeal Inspection, and Review of Weighing Services: [2] [3]		
(i) Grading Service:		
(a) Grade & Factors (per sample)	63.40	82.60
(b) Protein Test (per sample)	16.00	20.80
(c) Factor Determination (per sample)	31.80	41.40
(ii) Sampling Services (per hour per Service Representative)	63.40	82.60
(iii) Review of Weighing Service (per Service Representative)	63.40	82.60
(3) Extra copies of certificates (per copy)	3.20	3.20
(4) Official Track Scale Testing Service	45.80	62.20

[1] Official inspection and weighing services include, but are not limited to, grading, weighing, sampling, stowage examination, equipment testing, scale testing and certification, test weight reverification, evaluation of inspection weighing equipment, demonstrating official inspection and weighing functions, furnishing standard illustrations, and certifying inspection and weighing results.

[2] Fees for reinspection and appeal inspection services performed at locations where FGIS is providing original inspection service shall be assessed at the applicable contract or noncontract hourly rate as the original inspection. However, if additional personnel are required to perform the reinspection or appeal inspection service, the applicant will be assessed the noncontract original inspection hourly fee.

[3] If at the request of the Service, a file sample is located and forwarded by an agency for an official appeal, the agency may, upon request, be reimbursed at the rate of $2.60 per sample by the Service.

* * * * *

Dated: December 14, 1992.

John C. Foltz,

Administrator.

[FR Doc. 93–283 Filed 1–7–93; 8:45 am]

BILLING CODE 3410-EN-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 35

[Docket No. 92–ANE–46; Special Conditions No. SC–92–02–NE]

Special Conditions: Hamilton Standard Model 247F–1 Propeller

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Hamilton Standard Model 247F–1 propeller. This propeller is constructed using all composite blades, a novel and unusual design feature. These special conditions contain the additional safety standards which the Administrator considers necessary to establish a level of safety equivalent to that established by the airworthiness standards of part 35 of the FAR.

EFFECTIVE DATE: February 8, 1993.

FOR FURTHER INFORMATION CONTACT: Martin Buckman, Engine and Propeller Standards Staff, ANE–110, Engine and Propeller Directorate, Aircraft Certification Service, FAA, New England Region, 12 New England Executive Park, Burlington, Massachusetts 01803–5229; (617) 273–7079; Fax (617) 270–2412.

SUPPLEMENTARY INFORMATION:

Background

On May 24, 1991, Hamilton Standard applied for type certification for a new Model 247F–1 propeller. This propeller is constructed using all composite blades, a novel and unusual design features. Propellers constructed entirely of composite material have additional airworthiness considerations not currently addressed by part 35 of the FAR. Those additional airworthiness considerations associated with propellers constructed using all composite blades are propeller integrity following a bird strike, propeller

integrity following a lightning strike, and propeller fatigue strength when exposed to the deteriorating effects of in-service use and the environment.

Type Certification Basis

Under the provisions of § 21.17 of the FAR, Hamilton Standard must show that the Model 247F–1 propeller meets the requirements of the applicable regulations in effect on the date of the application. Those Federal Aviation Regulations are § 21.21 and part 35, effective February 1, 1965, as amended.

The Administrator finds that the applicable airworthiness regulations in part 35, as amended, do not contain adequate or appropriate safety standards for the Model 247F–1 propeller because it is constructed using composite material. Therefore, the Administrator prescribes special conditions under the provisions of Section 21.16 of the Federal Aviation Regulations to establish a level of safety equivalent to that established in part 35.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR after public notice and opportunity for comment, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2).

Novel or Unusual Design Feature

The Hamilton Standard 247F–1 propeller incorporates propeller blades constructed using composite material. This material has fibers that are woven, or aligned, in specific directions to give the material directional strength properties. These properties depend on the type of fiber, the orientation and concentration of fiber, and the matrix material. Composite materials exhibit multiple modes of failure. Propellers constructed of composite material must demonstrate continued airworthiness when considering these novel design features not associated with propeller blades constructed using other materials.

The requirements of part 35 of the FAR were established to address the airworthiness considerations associated with wood and metal propellers used primarily on reciprocating engines. Propeller blades of this type are generally thicker than composite blades installed on turbine engines and have demonstrated good service experience following a bird strike. Propeller blades constructed using composite material are generally thinner when used on turbine engines, and are typically installed on high performance aircraft. Further, high performance aircraft generally fly at high airspeeds with correspondingly high impact forces associated with a bird strike. Thus, composite propellers must demonstrate propeller integrity following a bird strike.

In addition, part 35 of the FAR does not currently require a demonstration of propeller integrity following a lightning strike. No safety considerations arise from lightning strikes on propellers constructed of metal because the electrical current is safely conducted through the metal blade, without damage to the propeller. Fixed pitched, wooden propellers are generally used on engines installed on small, general aviation aircraft that typically do not encounter flying conditions conducive to lightning strikes. Composite propeller blades, however, may be used on turbine engines and high performance aircraft that have an increased risk of lightning strikes. Composite blades may not safely conduct or dissipate the electrical current from a lightning strike. Severe damage can result if the propellers are not properly protected. Therefore, composite blades must demonstrate propeller integrity following a lightning strike. Information on testing for lightning protection is set out in SAE Report AE4L, entitled, "Lightning Test Waveforms and Techniques for Aerospace Vehicles and Hardware," dated June 20, 1978.

Lastly, the current certification requirements only address fatigue evaluation of metal propeller blades or hubs and those metal components of non-metallic blade assemblies. Allowable design stress limits for composite blades must consider the deteriorating effects of the environment and in-service use, particularly those effects from temperature, moisture, erosion and chemical attack. Composite blades also present new and different considerations for retention of the blades in the propeller hub.

Discussion of Comments

Interested persons have been afforded the opportunity to participate in the making of these special conditions. Due consideration has been given to comments received.

One commenter supports the special conditions as proposed.

After careful review of the available data, including the comments noted above, the FAA determined that air safety and the public interest require the adoption of the special conditions as proposed.

Conclusion

This action affects only the Hamilton Standard Model 247F–1 propeller and future propeller models within this series. It is not a rule of general application, and it affects only the manufacturer who applied to the FAA for approval of this propeller model.

List of Subjects in 14 CFR Part 35

Air Transportation, Aircraft, Aviation Safety, Safety.

The authority citation continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421, 1423; 49 U.S.C. 106(g).

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Hamilton Standard Model 247F–1 Propeller:

(a) For purposes of these special conditions, a hazardous condition is considered to exist for each of the following conditions:

(1) Loss of the propeller blade, or a major portion of a blade.

(2) Overspeed of the propellers.

(3) Unintended movement of the blade below the established minimum inflight blade angle, or to an angle that results in excessive drag.

(4) The inability to feather the propeller when necessary.

(b) In addition to the requirements of FAR Part 35, it must be shown that for propellers of composite construction:

Bird Strike

The propeller can withstand a four pound bird strike at the blade's critical radial location, when operating at takeoff RPM and liftoff (Vr) speed of a typical aircraft, without giving rise to a hazardous condition, and while maintaining the capability to be feathered.

Lightning Strike

A lightning strike on a propeller of a composite construction shall not result in a hazardous condition. The propeller shall be capable of continued safe operation.

Fatigue Evaluation

A fatigue evaluation must be provided and the fatigue limits determined for each propeller hub, blade, and each primary load carrying component of the propeller. The fatigue evaluation must consider all known and reasonable foreseeable vibration and cyclic load patterns that may be encountered in service. The fatigue limits must account for the effects of in-service deterioration, such as, impact damage, nicks, grooves, galling, or bearing wear; for variations in production material properties; and for environmental effects, such as, temperature, moisture, erosion,

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chemical attack, etc., that cause deterioration. Issued in Burlington, Massachusetts, on December 29, 1992.

Jack A. Sain,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 93-360 Filed 1-7-93; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 92-ANM-17]

Amendment of Transition Area; Livingston, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the 700-foot and 1200-foot transition areas at Livingston, Montana, to provide additional controlled airspace for aircraft executing a revised instrument approach procedure at Mission Field Airport, Livingston, Montana. The airspace will be depicted on aeronautical charts for pilot reference.

EFFECTIVE DATE: 0901 UTC, April 1, 1993.

FOR FURTHER INFORMATION CONTACT: James E. Riley, ANM-537, Federal Aviation Administration, Docket No. 92-ANM-17, 1601 Lind Avenue, SW., Renton, Washington 98055-4056, Telephone: (206) 227-2537.

SUPPLEMENTARY INFORMATION:

History

On September 2, 1992, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Livingston, Montana 700-foot and 1200-foot Transition Areas (57 FR 40156). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. This amendment is the same as that proposed in the NPRM, except the 4.4 nautical miles radius centered on Mission Field Airport has been corrected to read 4.1 nautical miles; and the statement "excluding that airspace within the Livingston, Montana, Control Zone during the specific dates and times it is in effect," has been added. The coordinates in the proposal were North American Datum 27; however, these coordinates have been updated to North American Datum 83. Transition areas are published in § 71.181 of FAA Order 7400.7A dated November 2, 1992, and effective November 27, 1992, which is incorporated by reference in 14 CFR 71.1. The transition areas listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations amends the Livingston, Montana, 700-foot and 1200-foot transition areas to provide controlled airspace for aircraft executing a revised instrument approach procedure to the Mission Field Airport, Livingston, Montana.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Incorporation by reference, Transition areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p.389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.7A Compilation of Regulations, dated November 2, 1992, and effective November 27, 1992, is amended as follows:

Section 71.181 Designation of Transition Areas

* * * * *

ANM MT TA Livingston, MT [Revised]

Livingston, Mission Field, MT (lat. 45°42'09"N, long. 110°26'50"W)

Livingston VORTAC (lat. 45°42'09"N, long. 110°26'33"W)

That airspace extending upward from 700 feet above the surface within 8 nautical miles west and 4 nautical miles east of the Livingston VORTAC 340 degree radial, extending from the VORTAC to 20 nautical miles north of the VORTAC, and within 2.2 nautical miles each side of the Livingston 085 degree radial, extending from a 4.1 nautical mile radius circle centered on Mission Field Airport, Livingston, Montana, to 7.9 nautical miles east of the VORTAC; that airspace extending upward from 1200 feet above the surface within 5.3 nautical miles south and 8.3 nautical miles north of the Livingston VORTAC 085 and 265 degree radials, extending from 6.1 nautical miles west to 18.3 nautical miles east of the VORTAC, excluding that airspace within the Livingston, MT, Control Zone during the specific dates and times it is in effect.

* * * * *

Issued in Seattle, Washington, on December 23, 1992.

Temple H. Johnson, Jr.,

Manager, Air Traffic Division.

[FR Doc. 93-365 Filed 1-7-93; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 91-ASW-23]

Establishment of Transition Area; Oakdale, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a new transition area at Oakdale, LA. The development of a new standard instrument approach procedure (SIAP) to the Allen Parish Airport has made this action necessary. The intended effect of this action is to provide adequate controlled airspace for aircraft executing the new Nondirectional Radio Beacon (NDB) Runway 35 SIAP. This action changes the status of the Allen Parish Airport from visual flight rules (VFR) only, to include operations under instrument flight rules (IFR).

EFFECTIVE DATE: 0901 UTC, April 1, 1993.

FOR FURTHER INFORMATION CONTACT: Alvin E. DeVane, System Management Branch, Air Traffic Division, Southwest Region, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193-0530, telephone (817) 624-5535.

SUPPLEMENTARY INFORMATION:

History

On October 24, 1991, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish a transition area at Oakdale, LA (56 FR 55101).

Interested persons were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. One comment objecting to the proposal was received from the United States Air Force (USAF). The Allen Parish Airport is located within the lateral limits of the Hotrock 2 military operations area (MOA). The USAF objection centered on perceived traffic conflicts between aircraft operating in the MOA and aircraft inbound to the Oakdale Allen Parish Airport utilizing the new SIAP. The establishment of a transition area is an airspace action that has little, if any, effect on the volume of air traffic operating at the airport. The USAF objection concerned the establishment of the new SIAP. Although the two actions are interrelated, the establishment of a transition area merely provides controlled airspace from 700 feet to 1200 feet above ground level and does not establish any different priorities among the users of the airspace or facilitate an influx of additional traffic. A significant operational advantage will be gained for those users of the Allen Parish Airport by converting the airport from VFR only to include IFR operations.

Since the Notice of Proposed Rulemaking was published on October 24, 1991, the criteria used in the development of transition areas has changed. The new criteria became effective on October 15, 1992. Since the effective date of these changes, mileage is expressed in terms of nautical miles rather than statute miles. The transition area in this final rule has been amended to conform to this new standard. Except for these changes, the amendment is adopted as proposed. Additionally, the coordinates in the proposal were North American Datum 27; however, these coordinates have been updated to North American Datum 83. Transition areas are published in § 71.181 of FAA Order 7400.7A dated November 2, 1992, and effective November 27, 1992, which is incorporated by reference in 14 CFR 71.1. The transition area listed in this document will be published subsequently in the Order.

The Rule

The FAA is amending part 71 of the Federal Aviation Regulations to establish a 700-foot transition area located at Oakdale, LA. The development of a new NDB runway 35 SIAP to the Allen Parish Airport, LA, has necessitated this action. The intended effect of this action is to provide adequate controlled airspace for aircraft executing the new SIAP. The status of the Allen Parish Airport, LA, will also be changed from VFR only to include IFR operations.

The FAA has determined that this regulation only involves an established body of technical regulations that needs frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Incorporation by reference, Transition areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.7A, Compilation of Regulations, dated November 2, 1992, and effective November 27, 1992, is amended as follows:

Section 71.181 Designation of Transition Areas

* * * * *

ASW LA TA Oakdale, LA [New]

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of the Allen Parish Airport (latitude 30°45'03" N., longitude 092°41'21" W.) excluding that airspace within restricted area R–3806.

* * * * *

Issued in Fort Worth, TX, on December 18, 1992.

Larry L. Craig,

Manager, Air Traffic Division, Southwest Region.

[FR Doc. 93–364 Filed 1–7–93; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 91–ASW–26]

Revision of Control Zones; Lafayette, LA; New Iberia, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revises the control zones at Lafayette and New Iberia, LA, and revises the coordinates used to describe the Lafayette Regional Airport. The very high frequency omnidirectional range/tactical air navigation (VORTAC) was relocated to a site on the Lafayette Regional Airport. This action is necessary to revise the control zone located at Lafayette, LA, due to revisions to the standard instrument approach procedures (SIAP) at Lafayette Regional Airport and the development of a new VOR Runway 4R SIAP. Additionally, this action is necessary to revise the control zone located at New Iberia, LA, due to revisions to the SIAP's at the Acadiana Regional Airport and the discontinuance of the nondirectional radio beacon (NDB) Runway 16 SIAP. The intended effect of this action is to provide adequate controlled airspace for aircraft executing SIAP's at the Lafayette Regional Airport and the New Iberia/Acadiana Regional Airport and revise the coordinates used to describe the Lafayette Regional Airport.

EFFECTIVE DATE: 0901 u.t.c., April 1, 1993.

FOR FURTHER INFORMATION CONTACT: Alvin E. DeVane, System Management Branch, Air Traffic Division, Southwest Region, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530, telephone (817) 624–5535.

SUPPLEMENTARY INFORMATION:

History

On October 29, 1991, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the control zones at Lafayette and New Iberia, LA (56 FR 55637).

Interested persons were invited to participate in this rulemaking proceeding by submitting written

comments on the proposal to the FAA. No comments objecting to the proposal were received.

Since the Notice of Proposed Rulemaking was published on October 29, 1991, the criteria used in the development of control zones has changed. The new criteria became effective on October 15, 1992.

Since the effective date of these changes, mileages are expressed in nautical miles rather than statute miles and a standard control zone has an upper altitude limit of 2500 feet above ground level (AGL). Previously, the standard control zone extended to the base of the Continental Control Area at 14,500 feet mean sea level (MSL) and had no upper limit when it did not underlie the Continental Control Area. The control zones in this final rule have been amended to conform to these new standards.

Additionally, the coordinates in the proposal were North American Datum 27; however, these coordinates have been updated to North American Datum 83. Except for these changes, this amendment is adopted as proposed. Control zones are published in § 71.171 of FAA Order 7400.7A dated November 2, 1992, and effective November 27, 1992, which is incorporated by reference in 14 CFR 71.1. The control zones listed in this document will be published subsequently in the Order.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations revises the control zones located at Lafayette and New Iberia, LA. The Lafayette VORTAC was relocated to a site on the Lafayette Regional Airport. SIAP's that derive information from this navigational aid were revised making this action necessary. The coordinates used to describe the Lafayette Regional Airport are also revised. The intended effect of this action is to provide adequate controlled airspace for aircraft executing SIAP's at the Lafayette Regional and New Iberia/Acadiana Regional Airports.

The FAA has determined that this regulation only involves an established body of technical regulations that needs frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Control zones, Incorporation by reference.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.7A, Compilation of Regulations, dated November 2, 1992, and effective November 27, 1992, is amended as follows:

Section 71.171 Designation of control zones.

* * * * *

ASW LA CZ Lafayette, LA. [Revised]

That airspace extending upward from the surface to and including 4,000 feet MSL within a 5-mile radius of the Lafayette Regional Airport (latitude 30°02'19"N., longitude 091°59'15"W.) and within 2.4 miles each side of the Lafayette VORTAC (latitude 30°11'38"N., longitude 091°59'33"W.) 238° radial, extending from the 5-mile radius zone to 7.7 miles southwest of the airport.

* * * * *

ASW LA CZ New Iberia, LA. [Revised]

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.4-mile radius of the Acadiana Regional Airport (latitude 30°02'16"N. longitude 091°53'02"W.) excluding the Lafayette Regional Airport, LA, Airport Radar Service Area. The control zone is effective during the specific dates and times established in advance by a Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Director.

* * * * *

Issued in Fort Worth, TX, on December 18, 1992.

Larry L. Craig,

Manager, Air Traffic Division, Southwest Region.

[FR Doc. 93–361 Filed 1–7–93; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 97

[Docket No. 27096; Amdt. No. 1524]

Standard Instrument Approach Procedures: Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: *Effective:* An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination— 1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which affected airport is located; or

3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, US Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (AFS–420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal

Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC) /Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviations Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the Federal Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction of charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The Provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAM for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been cancelled. The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPs criteria were applied to only these specific conditions existing at the affected airports.

This amendment to part 97 contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice Airmen (NOTAM) as an emergency action to immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the US Standard for Terminal Instrument Approach Procedures (TERPs). Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC, on December 18, 1992.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 u.t.c. on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. App. 1348, 1354(a), 1421 and 1510; 49 U.S.C. 106(g) (revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33 and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

NFDC Transmittal Letter

Effective	State	City	Airport	FDC number	SIAP
11/09/92	MO	Columbia	Columbia Regional	FDC 2/6736	ILS RWY 2 AMDT 12A.
11/09/92	MO	Columbia	Columbia Regional	FDC 2/6737	NDB RWY 2 AMDT 8.
12/02/92	TX	Mineral Wells	Mineral Wells	FDC 2/7191	VOR RWY 31 AMDT 9.
12/02/92	WA	Seattle	Boeing Field/King County Intl	FDC 2/7210	ILS RWY 13R MIN 5.
12/03/92	GA	Augusta	Daniel Field	FDC 2/7216	NDB RWY 10, AMDT 2.
12/03/92	GA	Augusta	Daniel Field	FDC 2/7217	RNAV RWY 10, AMDT 5.
12/03/92	GA	Cedartown	Cornelius-Moore Field	FDC 2/7214	RNAV RWY 10, AMDT 2.
12/03/92	GA	Cedartown	Cornelius-Moore Field	FDC 2/7218	VOR-A, AMDT 12.
12/03/92	GA	Griffin	Griffin-Spalding County	FDC 2/7215	VOR/DME RWY 13, AMDT 4A.
12/03/92	GA	Statesboro	Statesboro Muni	FDC 2/7227	LOC RWY 32 AMDT 3A.
12/03/92	LA	Baton Rouge	Baton Rouge Metropolitan/Ryan Field.	FDC 2/7223	LOC BC RWY 4L AMDT 4.
12/03/92	MA	Pittsfield	Pittsfield Muni	FDC 2/7224	NDB RWY 26 AMDT 3.
12/03/92	MA	Pittsfield	Pittsfield Muni	FDC 2/7225	LOC RWY 26 AMDT 4.
12/04/92	ME	Presque Isle	Northern Maine Regional Arpt at Presque Isle.	FDC 2/7236	VOR/DME RWY 1 AMDT 11.

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Effective	State	City	Airport	FDC number	SIAP
12/04/92	ME	Presque Isle	Northern Maine Regional Arpt at Presque Isle.	FDC 2/7237	VOR RWY 19 AMDT 8.
12/04/92	MN	Austin	Austin Muni	FDC 2/7246	VOR RWY 36 ORIG A.
12/04/92	MN	Austin	Austin Muni	FDC 2/7247	VOR/DME-A AMDT 1.
12/04/92	MN	Austin	Austin Muni	FDC 2/7252	VOR RWY 18 ORIG.
12/04/92	MN	Pipestone	Pipestone Muni	FDC 2/7248	NDB RWY 36 AMDT 5.
12/04/92	MN	Willmar	Willmar Muni-John L. Rice Field	FDC 2/7249	VOR RWY 28 AMDT 1.
12/04/92	MN	Willmar	Willmar Muni-John L. Rice Field	FDC 2/7250	VOR RWY 10 AMDT 1.
12/04/92	MT	Butte	Bert Mooney	FDC 2/7238	LOC/DME RWY 15 AMDT 6.
12/04/92	MT	Butte	Bert Mooney	FDC 2/7239	ILS RWY 15 AMDT 4.
12/04/92	MT	Butte	Bert Mooney	FDC 2/7240	VOR/DME-A AMDT 3.
12/04/92	MT	Butte	Bert Mooney	FDC 2/7241	VOR-B AMDT 1.
12/07/92	MT	Glendive	Dawson Community	FDC 2/7276	NDB RWY 12 AMDT 4.
12/08/92	MD	College Park	College Park	FDC 2/7302	VOR/DME RNAV RWY 15 AMDT 1.
12/08/92	TX	Houston	Houston-Southwest	FDC 2/7282	RNAV RWY 10 AMDT 1.
12/08/92	TX	Houston	Houston-Southwest	FDC 2/7283	RNAV RWY 28 AMDT 2.
12/08/92	TX	Houston	Houston-Southwest	FDC 2/7286	NDB RWY 10 AMDT 4.
12/08/92	TX	Houston	Houston-Southwest	FDC 2/7299	NDB RWY 28 AMDT 3.
12/09/92	AR	Crossett	Crossett Z. M. Jack Stell Field	FDC 2/7371	VOR/DME-A ORIG A.
12/09/92	VI	Charlotte Amalie/St Thomas	Cyril E King	FDC 2/7345	ILS RWY 10 ORIG.
12/11/92	FL	Jacksonville	Jacksonville Intl	FDC 2/7438	LOC RWY 25, AMDT 6.
12/11/92	FL	Quincy	Quincy Muni	FDC 2/7444	VOR/DME-A ORIG.
12/11/92	FL	Tallahassee	Tallahassee Regional	FDC 2/7441	ILS RWY 36, AMDT 22.
12/11/92	FL	Tallahassee	Tallahassee Regional	FDC 2/7442	NDB RWY 36, AMDT 18.
12/11/92	GA	Americus	Souther Field	FDC 2/7429	LOC RWY 22 AMDT 2A.
12/11/92	GA	Americus	Souther Field	FDC 2/7430	NDB RWY 22 AMDT 2A.
12/14/92	GA	Macon	Middle Georgia Regional	FDC 2/7491	VOR RWY 13 AMDT 7.
12/14/92	GA	Macon	Middle Georgia Regional	FDC 2/7492	VOR RWY 23 AMDT 1.
12/14/92	GA	Macon	Middle Georgia Regional	FDC 2/7493	RADAR-1 AMDT 13.
12/15/92	MI	East Tawas	Iosco County	FDC 2/7507	
12/15/92	MN	Detroit Lakes	Detroit Lakes	FDC 2/7508	VOR RWY 31 AMDT 3A.
12/15/92	MN	Detroit Lakes	Detroit Lakes	FDC 2/7509	VOR RWY 13 AMDT 5A.
12/16/92	KS	Manhattan	Manhattan Muni	FDC 2/7546	VOR-F AMDT 4.
12/17/92	KY	Louisville	Standiford Field	FDC 2/7561	RADAR-1, AMDT 24.

[FR Doc. 93-363 Filed 1-7-93, 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 97

[Docket No. 27095; Amdt. No. 1523]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: *Effective:* An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA-200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20401.

FOR FURTHER INFORMATION CONTACT: Paul J. Best, Flight Procedures Standards Branch (A-420), Technical Programs Division, Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8277.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Forms are identified as FAA Forms 8260-3, 8260-4, and 8260-5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure

identification and the amendment number.

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air traffic control, Airports, Incorporation by reference, Navigation (Air), Standard instrument approaches, Weather.

Issued in Washington, DC, on December 18, 1992.

Thomas C. Accardi,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 u.t.c. on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. App. 1348, 1354(a), 1421 and 1510; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

Effective February 4, 1993

Lake Havasu City, AZ, Lake Havasu City, VOR/DME–A, Orig.
Monterey CA, Monterey Peninsula, LOC/DME RWY 28L, Amdt. 2
Kokomo, IN, Kokomo Muni, ILS RWY 23, Amdt. 7
Pella, IA, Pella Muni, NDB RWY 34, Amdt. 6
Greenville, MI, Greenville Muni, VOR/DME–A, Orig., Cancelled
Hastings, MI, Hastings, VOR RWY 12, Amdt. 7, Cancelled
Manistee, MI, Manistee Co-Blacker, VOR RWY 9, Amdt. 10
Manistee, MI, Manistee Co-Blacker, VOR RWY 27, Amdt. 10
Plymouth, MI, Mettetal-Canton, VOR–A, Amdt. 10
Monroe, MI, Custer, VOR RWY 21, Orig.
Monroe, MI, Custer, VOR/DME RNAV RWY 21, Amdt. 4 Cancelled
Port Huron, MI, St. Clair County Intl, NDB RWY 4, Amdt. 1
Port Huron, MI, St. Clair County Intl, ILS RWY 4, Amdt. 1
Silver Bay, MN, Silver Bay Muni, NDB RWY 25, Orig.
Princeton, MN, Princeton Muni, NDB RWY 15, Orig.
Farmington, MO, Farmington Regional, VOR/DME–A, Orig.
Farmington, MO, Farmington Regional, VOR–A, Amdt. 4, Cancelled
Fredericktown, MO, Fredericktown Muni, VOR/DME RWY 1, Amdt. 2
Fredericktown, MO, Fredericktown Muni, VOR RWY 19, Orig.
Fredericktown, MO, Fredericktown Muni, VOR–B, Amdt. 1, Cancelled
Perryville, MO, Perryville Muni, VOR/DME–A, Amdt. 4
Perryville, MO, Perryville Muni, VOR/DME RNAV RWY 19, Amdt. 2
St. Charles, MO, St. Charles, VOR RWY 9, Amdt. 3
St. Charles, MO, St. Charles County Smartt VOR RWY 18, Orig.
St. Charles, MO, St. Charles County Smartt VOR–A, Amdt. 3, Cancelled
St. Louis, MO, Arrowhead, VOR RWY 2, Amdt. 5
St. Louis, MO, Arrowhead, VOR–B, Amdt. 3
St. Louis, MO, Creve Coeur, VOR–A, Amdt. 4
St. Louis, MO, Lambert/St. Louis Intl, RNAV RWY 6, Amdt. 1A, Cancelled
St. Louis, MO, Lambert/St. Louis Intl, RNAV RWY 12R, Amdt. 1A Cancelled
St. Louis, MO, Lambert/St. Louis Intl, RNAV RWY 24, Amdt. 2A, Cancelled
St. Louis, MO, Lambert/St. Louis Intl, RNAV RWY 30L, Amdt. 11A Cancelled
St. Louis, MO, Lambert/St. Louis Intl, RNAV RWY 30R, Amdt. 2A Cancelled
St. Louis, MO, Spirit of St. Louis, RNAV RWY 26L, Amdt. 3A Cancelled
St. Louis, MO, Weiss, VOR–C, Amdt. 5
Sidney, MT, Sidney-Richland Muni, NDB RWY 1, Amdt. 2
Sidney, MT, Sidney-Richland Muni, NDB RWY 19, Amdt. 3
Corry, PA, Corry-Lawrence, VOR RWY 32, Amdt. 4
Gallatin, TN, Sumner County Regional VOR/DME–A, Amdt. 1
Gallatin, TN, Sumner County Regional, NDB RWY 35, Amdt. 1
Gallatin, TN, Sumner County Regional, RADAR–1, Amdt. 2
Huntingdon, TN, Carroll County, NDB RWY 1, Amdt. 1
Nashville, TN, John C. Tune, LOC/DME RWY 19, Amdt. 2
Nashville, TN, Nashville International, VOR/DME RWY 13, Amdt. 12
Nashville, TN, Nashville International, VOR RWY 31, Amdt. 26 Cancelled
Nashville, TN, Nashville International, NDB RWY 2L, Amdt. 6
Nashville, TN, Nashville International, NDB RWY 20R, Amdt. 7
Nashville, TN, Nashville International, ILS RWY 2L, Amdt. 7
Nashville, TN, Nashville International, ILS RWY 02R, Amdt. 2
Nashville, TN, Nashville International, ILS RWY 20R, Amdt. 6
Nashville, TN, Nashville International, ILS RWY 20L, Amdt. 3
Nashville, TN, Nashville International, ILS RWY 31, Amdt. 7
Smyrna, TN, Smyrna, VOR/DME RWY 32, Amdt. 12
Smyrna, TN, Smyrna, VOR/DME RWY 14, Amdt. 6
Smyrna, TN, Smyrna, NDB RWY 32, Amdt. 8
Smyrna, TN, Smyrna, ILS RWY 32, Amdt. 5
Waverly, TN, Humphrey's County, NDB RWY 22, Amdt. 3
Austin, TX, Robert Meuller Muni, RADAR–1, Amdt. 13, Cancelled
Reading, PA, Reading Regional/Carl A. Spaatz Field, NDB RWY 36, Amdt. 23
Reading, PA, Reading Regional/Carl A. Spaatz Field, ILS RWY 36, Amdt. 28
Murfreesboro, TN, Murfreesboro Muni, NDB RWY 18, Amdt. 2
Burlington, WI, Burlington Muni, VOR–A, Orig.

East Troy, WI, East Troy Muni, VOR–A, Orig.

Effective January 7, 1993

West Memphis, AR, West Memphis Muni, ILS RWY 17, Orig.
Pittinstown, NJ, Alexandria, VOR RWY 8, Amdt. 1
Pembina, ND, Pembina Muni, VOR RWY 33, Amdt. 6
Bowling Green, OH, Wood County, VOR RWY 18, Amdt. 11

Effective December 16, 1992

Phoenix, AZ, Phoenix Sky Harbor Intl., VOR/DME RWY 8R, Amdt. 1
Phoenix, AZ, Phoenix Sky Harbor Intl., VOR/DME RWY 26L, Amdt. 1
Phoenix, AZ, Phoenix Sky Harbor Intl., LOC BC RWY 26L, Amdt. 8

Effective December 15, 1992

Phoenix, AZ, Phoenix Sky Harbor Intl., ILS RWY 8R, Amdt. 9

Effective December 10, 1992

Crossville, TN, Crossville Memorial, ILS RWY 26, Amdt. 10

Effective December 4, 1992

Auburn-Lewiston, ME, Auburn-Lewiston Muni, VOR–A, Amdt. 1
Auburn-Lewiston, ME, Auburn-Lewiston Muni, NDB RWY 4, Amdt. 9

[FR Doc. 93–362 Filed 1–7–93; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 770 and 786

[Docket No. 921083–2283]

Shipper's Export Declaration

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) to conform with the changes in the Foreign Trade Statistics Regulations (15 CFR part 30) that were published by the Bureau of the Census in the **Federal Register** on November 30, 1990 (55 FR 49613). The November 30 rule announced that the United States is eliminating the requirement of filing SEDs for most direct shipments from the U.S. to Canada. However, an SED continues to be required for certain shipments, including those subject to a Department of Commerce validated export license and shipments under the authority of some other U.S. Government agencies.

This final rule amends the EAR by revising the definition of Schedule B Numbers and clarifying which exports are exempt from Shipper's Export Declaration (SED) requirements.

EFFECTIVE DATE: This rule is effective January 8, 1993.

FOR FURTHER INFORMATION CONTACT: Dennis Kerner, Export Enforcement, Bureau of Export Administration, Telephone: (202) 482–0297.

SUPPLEMENTARY INFORMATION:

Ruemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule involves collections of information subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). These collections have been approved by the Office of Management and Budget under control numbers 0607–0001, 0607–0018, and 0607–0152.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553) or by any other law, under section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a delay in effective date, are inapplicable because this regulation involves a foreign and military affairs function of the United States. No other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

Therefore, this regulation is issued in final form. Although there is no formal comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Nancy Crowe, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

List of Subjects

15 CFR Part 770

Administrative practice and procedure, Exports.

15 CFR Part 786

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 770 and 786 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

1. The authority citation for 15 CFR parts 770 and 786 continues to read as follows:

Authority: Pub. L. 90–351, 82 Stat. 197 (18 U.S.C. 2510 *et seq.*), as amended; sec. 101, Pub. L. 93–153, 87 Stat. 576 (30 U.S.C. 185), as amended; sec. 103, Pub. L. 94–163, 89 Stat. 877 (42 U.S.C. 6212), as amended; secs. 201 and 201(11)(e), Pub. L. 94–258, 90 Stat. 309 (10 U.S.C. 7420 and 7430(e)), as amended; Pub. L. 95–223, 91 Stat. 1626 (50 U.S.C. 1701 *et seq.*); Pub. L. 95–242, 92 Stat. 120 (22 U.S.C. 3201 *et seq.* and 42 U.S.C. 2139a); sec. 208, Pub. L. 95–372, 92 Stat. 668 (43 U.S.C. 1354); Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. App. 2401 *et seq.*), as amended; sec. 125, Pub. L. 99–64, 99 Stat. 156 (46 U.S.C. 466c); E.O. 11912 of April 13, 1976 (41 FR 15825, April 15, 1976); E.O. 12002 of July 7, 1977 (42 FR 35623, July 7, 1977), as amended; E.O. 12056 of May 11, 1978 (43 FR 20947, May 16, 1978); E.O. 12214 of May 2, 1980 (45 FR 29783, May 6, 1980); E.O. 12730 of September 30, 1990 (55 FR 40373, October 2, 1990), as continued by Notice of September 25, 1992 (57 FR 44649, September 28, 1992); and E.O. 12735 of November 16, 1990 (55 FR 48587, November 20, 1990), as continued by Notice of November 14, 1991 (56 FR 58171, November 15, 1991).

PART 770—[AMENDED]

2. Section 770.2 is amended by revising the definition for the term "Schedule B Numbers" as follows:

§ 770.2 Definitions of terms.

* * * * *

Schedule B numbers. The commodity numbers appearing in the current edition of the Bureau of the Census publication, Schedule B Statistical Classification of Domestic and Foreign Commodities Exported from the United States.

* * * * *

3. Section 770.4 is revised to read as follows:

§ 770.4 Shipments to territories, dependencies, and possessions of the United States, and to Trust Territories.

No license is required for shipments from the United States to the Commonwealth of Puerto Rico or to any territory, dependency, or possession of the United States as listed in Schedule C, Classification of Country and Territory Designations for U.S. Foreign Trade Statistics, issued by the Bureau of the Census.

4. Section 786.1 is amended:

a. By revising the phrase "Under the Export Administration regulations" in the first sentence of paragraph (a) to read "Under the Export Administration Regulations and the Bureau of the Census' Foreign Trade Statistics Regulations (15 CFR Part 30)";

b. By revising footnote 1 in paragraph (b)(1);

c. By revising paragraph (b)(2)(i);

d. By revising the second sentence in paragraph (c)(1);

e. By removing the phrase", in those instances when a license is required," in the third sentence of paragraph (c)(2), introductory text;

f. By revising the phrase "at $2,500 or less" in paragraph (c)(2)(i) to read "at $2,500 or less per Schedule B Number";

g. By revising the phrase "under a single seven-digit Schedule B Number" in paragraph (c)(2)(i) to read "under a single Schedule B Number";

h. By adding within the parenthesis the sentence "See Supplement No. 1 to part 786." after the first sentence in the parenthesis in paragraph (c)(2)(iii); and

i. By revising paragraph (c)(3) to read as follows:

§ 786.1 General export clearance requirements.

* * * * *

(b) * * *

(1) * * *

[1] The Shipper's Export Declaration (U.S. Department of Commerce form 7525–V) may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, or it may be privately printed. Form 7525–V–ALT. (Intermodal) must be privately printed. Privately printed forms must strictly conform to the official form in all respects. Samples of these forms may be obtained from the Bureau of the Census, Washington, DC 20233, local Customs offices, and U.S. Department of Commerce District Offices.

(2) * * *

(i) *Declaration required.* Unless otherwise set forth specifically by the Export Administration Regulations or by the Bureau of the Census' Foreign Trade Statistics Regulations (see subpart D for exceptions), the sender shall present to the post office at the place of mailing a duly executed Declaration for each shipment to any destination under a general license, from one business concern to another business concern, when the value of the commodity(ies) to be shipped exceeds $500. Declarations are not required for noncommercial shipments nor are they required for shipments to Canada for consumption therein when no validated license is required. See paragraph (c)(3) of this section regarding declaration requirements for destinations not requiring a license.

* * * * *

(c) * * *

(1) * * * The exporting carrier is responsible for the accuracy of the following items of information (where required) on the Declaration: Name of carrier (including flag of vessel), U.S. Customs port of export, method of transportation, foreign port of unloading, bill of lading or air waybill number, and whether or not containerized. * * *

(2) * * *

(3) *Exports not requiring a license.* Unless otherwise exempt under the Export Administration Regulations or the Bureau of the Census Trade Statistics Regulations (see subpart D), a Shipper's Export Declaration is required for export to destinations not requiring either a validated or a general license, except that a Declaration is not required for shipments to Canada for consumption therein.

* * * * *

5. Section 786.3 is amended:

a. By revising paragraph (f)(1);

b. By revising paragraph (i)(1);

c. By revising paragraph (i)(2);

d. By revising the phrase "seven-digit Schedule B number" to read "Schedule B number" in paragraph (i)(3):

e. By revising the phrase "The license number" in the first sentence of paragraph (j)(1) to read "The license number and expiration date";

f. By revising footnote 3 in paragraph (p)(1), introductory text;

g. By revising paragraph (p)(1)(i);

h. By revising paragraph (p)(1)(ii);

i. By revising the first sentence in paragraph (r)(1);

j. By revising the phrase "file a monthly report" in the third sentence of paragraph (r)(1) to read "file electronically";

k. By revising the phrase "file monthly reports" to read "file electronically" in paragraphs (r)(3), (r)(4), and (r)(6); and

l. By revising the phrase "filing monthly reports" in paragraph (r)(7) to read "filing electronically", as follows:

§ 786.3 Shipper's export declaration.

* * * * *

(f) * * *

(1) *Exports by means other than by mail.* Two copies of the declaration are required, except:

(i) Only one copy is required for shipments from the United States to Puerto Rico, from Puerto Rico to the United States, from the United States or Puerto Rico to the U.S. Virgin Islands, and to Canada, when required.

(ii) An additional copy may be required by paragraph (f)(3) of this section.

* * * * *

(i) * * *

(1) *Schedule B number.* The Schedule B number, as shown in the current edition of Schedule B, Statistical Classification of Domestic and Foreign Commodities Exported from the United States, must be entered in the designated column of the Declaration regardless of whether the shipment is being exported under a validated or general license.

(2) *Commodity description for validated license shipment.* The commodity description on the Declaration for a shipment under a validated license shall be that shown on the related validated license. However, where part of the description on the license is underlined, only the underlined portions need be included on the Declaration. The commodity description on the license will be stated in Commerce Control List terms, which may be inadequate to meet Census Bureau requirements. In this event, the commodity description on the Declaration shall give enough additional detail to permit verification of the Schedule B number (e.g. size, material, or degree of fabrication).

* * * * *

(p) * * *

(1) * * *

(i) Commodities departing the United States by vessel, which transited through or transshipped in ports of the United States, destined from one foreign country or area to another.

(ii) Foreign merchandise exported from a General Order Warehouse and the reexport of merchandise that was rejected after government inspection or examination. Shipments in bond transiting the United States being exported by means of any carrier other than a vessel may be cleared for export without presenting a Form 7513, unless a validated license is required for the export.

* * * * *

(r) * * *

(1) * * * An alternate procedure for reporting exports to Canada (when required) and to Country Groups Q, T, V, W, and Y is available under which qualified exporters may be authorized to file monthly Shipper's Export Declarations with the Bureau of the Census in lieu of individual Declarations. * * *

* * * * *

Supplement No. 1 to Part 786—[Amended]

6. Supplement No. 1 to part 786 is amended by revising the title to read as follows:

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[3] Form 7513 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, the local Customs offices, or may be privately printed.

Supplement No. 1 to Part 786

FOREIGN TRADE STATISTICS REGULATIONS OF THE BUREAU OF THE CENSUS; SUBPART D—EXEMPTIONS FROM THE REQUIREMENTS FOR THE FILING OF SHIPPER'S EXPORT DECLARATION (15 CFR 30.50–30.58)

* * * * *

Dated: January 4, 1993.

James M. LaMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93–303 Filed 1–7–93; 8:45 am]

BILLING CODE 3510-DT-M

FEDERAL TRADE COMMISSION

16 CFR Part 305

RIN 3084–AA26

Rules for Using Energy Cost and Consumption Information Used in Labeling and Advertising of Consumer Appliances Under the Energy Policy and Conservation Act; Ranges of Comparability for Refrigerators, Refrigerator-freezers, and Freezers

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission amends its Appliance Labeling Rule by revising the ranges of comparability used on required labels for refrigerators, refrigerator-freezers, and freezers.

Under the rule, each required label on a covered appliance must show a range, or scale, indicating the range of energy costs or efficiencies for all models of a size or capacity comparable to the labeled model. This notice publishes the new range figures, which, under §§ 305.10, 305.11 and 305.14 of the rule, must be used on labels on refrigerators, refrigerator-freezers, and freezers manufactured on and after April 8, 1993 and in advertising of refrigerators, refrigerator-freezers, and freezers in catalogs printed after April 8, 1993. Properly labeled refrigerators, refrigerator-freezers, and freezers manufactured prior to the effective date need not be relabeled. Catalogs printed prior to the effective date in accordance with 16 CFR 305.14 need not be revised.

EFFECTIVE DATE: April 8, 1993.

FOR FURTHER INFORMATION CONTACT: James Mills, Attorney, 202–326–3035, Division of Enforcement, Federal Trade Commission, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: On November 19, 1979, the Commission issued a final rule,[1] pursuant to section 324 of the Energy Policy and Conservation Act of 1975,[2] covering certain appliance categories, including refrigerators, refrigerator-freezers, and freezers. The rule requires that energy costs and related information be disclosed on labels and in retail sales catalogs for all refrigerators, refrigerator-freezers, and freezers presently manufactured. Certain point-of-sale promotional materials must disclose the availability of energy usage information. If a refrigerator, refrigerator-freezer or freezer is advertised in a catalog from which it may be purchased by cash, charge account or credit terms, then the range of estimated annual energy costs for the product must be included on each page of the catalog that lists the product. The required disclosures and all claims concerning energy consumption made in writing or in broadcast advertisements must be based on the results of test procedures developed by the Department of Energy, which are referenced in the rule.

Section 305.8(b) of the rule requires manufacturers, after filing an initial report, to report annually by specified dates for each product type.[3] Because the costs for the various types of energy change yearly, and because manufacturers regularly add new models to their lines, improve existing models and drop others, the data base from which the ranges of comparability are calculated is constantly changing.

To keep the required information in line with these changes, the Commission is empowered, under section 305.10 of the rule, to publish new ranges (but not more often than annually) if an analysis of the new data indicates that the upper or lower limits of the ranges have changed by more than 15%.

The new figures for the estimated annual costs of operation for refrigerators, refrigerator-freezers, and freezers, which were calculated using the 1992 representative average energy cost for electricity (8.25 cents per kilowatt-hour) published by DOE on January 14, 1992,[4] have been submitted and have been analyzed by the Commission. New ranges based upon them are herewith published.

In consideration of the foregoing, the Commission amends Appendices A–1, A–2 and B of its Appliance Labeling Rule by publishing the following ranges of comparability for use in the labeling and advertising of refrigerators, refrigerator-freezers, and freezers beginning April 8, 1993.

List of Subjects in 16 CFR Part 305

Advertising, Energy conservation, Household appliances, Labeling, Reporting and recordkeeping requirements.

Accordingly, 16 CFR part 305 is amended as follows:

PART 305—[AMENDED]

1. The authority citation for part 305 continues to read as follows:

Authority: Sec. 324 of the Energy Policy and Conservation Act (Pub. L. 94–163) (1975), as amended by the National Energy Conservation Policy Act, (Pub. L. 95–619) (1978), the National Appliance Energy Conservation Act, (Pub. L. 100–12) (1987), and the National Appliance Energy Conservation Amendments of 1988, (Pub. L. 100–357)(1988), 42 U.S.C. 6294; sec. 553 of the Administrative Procedure Act, 5 U.S.C. 553.

2. In Appendices A1, A2 and B, Paragraph 1 of each and the introductory text in Paragraph 2 of each are revised to read as follows:

Appendix A1 to Part 305—Refrigerators

1. Range Information:

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
Less than 2.5	$23	$30
2.5 to 4.4	5	35
4.5 to 6.4	23	51
6.5 to 8.4	34	37
8.5 to 10.4	9	39
10.5 to 12.4	40	41
12.5 to 14.4	40	46
14.5 to 16.4	19	19
16.5 and over	36	59

2. Yearly Cost Information: Estimates on the scale are based on a national average electric rate of 8.25¢ per kilowatt hour.

* * * * *

Appendix A2 to Part 305—Refrigerators-Freezers

1. Range Information:

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
Less than 10.5	$17	$59
10.5 to 12.4	55	79
12.5 to 14.4	25	71
14.5 to 16.4	31	72
16.5 to 18.4	47	86
18.5 to 20.4	57	106
20.5 to 22.4	60	108
22.5 to 24.4	64	121

[1] 44 FR 66466, 16 CFR Part 305.

[2] Pub. L. 94–163, 89 Stat. 871 (Dec. 22, 1975).

[3] Reports for refrigerators, refrigerator-freezers and freezers are due by August 1.

[4] 57 FR 1461. The Commission published these figures on February 20, 1992, at 57 FR 6071.

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
24.5 to 26.4	77	125
26.5 to 28.4	102	128
28.5 and over	109	133

[1] No data submitted.

2. Yearly Cost Information: Estimates on the scale are based on a national average electric rate of 8.25¢ per kilowatt hour.

* * * * *

Appendix B to Part 305—Freezers

1. Range Information:

Manufacturer's rated total refrigerated volume in cubic feet	Ranges of estimated yearly energy costs	
	Low	High
Less than 5.5	$14	$53
5.5 to 7.4	28	45
7.5 to 9.4	28	46
9.5 to 11.4	30	58
11.5 to 13.4	33	80
13.5 to 15.4	36	82
15.5 to 17.4	48	89
17.5 to 19.4	50	92
19.5 to 21.4	52	89
21.5 to 23.4	46	59
23.5 to 25.4	(*)	(*)
25.5 to 27.4	53	66
27.5 to 29.4	(*)	(*)
29.5 and over	139	222

2. Yearly Cost Information: Estimates on the scale are based on a national average electric rate of 8.25¢ per kilowatt hour.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 93–118 Filed 1–7–93; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. 89C–0480]

Listing of Color Additives For Coloring Contact Lenses; Vinyl Alcohol/Methyl Methacrylate-C.I. Reactive Red 180 Reaction Product

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use in coloring contact lenses of the reaction product formed by chemically bonding the dye C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl) sulfonyl]-2-naphthalenyl]azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114–32–0) to the vinyl alcohol/methyl methacrylate copolymeric lens material. This action is in response to a petition filed by Ciba Vision Corp.

DATES: Effective February 9, 1993, except as to any provisions that may be stayed by the filing of proper objections; written objections by February 8, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of December 19, 1989 (54 FR 51945), FDA announced that a color additive petition (CAP 9C0217) had been filed by Ciba Vision Corp., P.O. Box 105069, Atlanta, GA 30348. The petition proposed that the color additive regulations be amended to provide for the safe use of six vinyl sulfone reactive dyes to color contact lenses prepared from a copolymer that is the reaction product of the dye and a polyvinyl alcohol/methyl methacrylate copolymer. The dyes are as follows:

(1) C.I. Reactive Black 5 (2,7-naphthalenedisulfonic acid, 4-amino-5-hydroxy-3,6-bis[(4-((2-(sulfooxy)ethyl]sulfonyl]phenyl]azo)-, tetrasodium salt], CAS Reg. No. 17095–24–8);

(2) C.I. Reactive Blue 21 (copper, [29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32)-,sulfo((4-((2-(sulfooxy) ethyl]sulfonyl]phenyl]amino)sulfonyl derivatives, CAS Reg. No. 73049–92–0);

(3) C.I. Reactive Orange 78 (2-naphthalenesulfonic acid, 7-(acetylamino)-4-hydroxy-3-((4-((2-(sulfooxy)ethyl]sulfonyl]phenyl]azo)-, CAS Reg. No. 68189–39–9);

(4) C.I. Reactive Yellow 15 (benzenesulfonic acid, 4-[4,5-dihydro-4-((2-methoxy-5-methyl-4-((2-(sulfooxy)ethyl)sulfonyl)phenyl)azo)-3-methyl-5-oxo-1H-pyrazol-1-yl)-, CAS Reg. No. 60958–41–0);

(5) C.I. Reactive Blue No. 19 (2-anthracenesulfonic acid, 1-amino-9,10-dihydro-9,10-dioxo-4-((3-((2-(sulfooxy)ethyl)sulfonyl)phenyl)amino)-, disodium salt, CAS Reg. No. 2580–78–1); and

(6) C.I. Reactive Red 180 (5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl]sulfonyl)-2-naphthalenyl]azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt, CAS Reg. No. 98114–32–0).

Ciba Vision Corp. has changed its address to 11460 Johns Creek Pkwy., Duluth, GA 30136–1518.

The petitioner has also requested that, at this time, the agency regulate separately the color additive formed by the reaction of C.I. Reactive Red 180 with vinyl alcohol/methyl methacrylate copolymer. The safety of the other five vinyl alcohol/methyl methacrylate-dye reaction products is still under review, and the agency's decision with regard to regulation of these color additives will be addressed in a later **Federal Register** document. The petition was filed under section 706 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376).

II. Applicability of The Act

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive comes in direct contact with the body for a significant period of time (21 U.S.C. 376(a)). The use of the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product as a color additive in contact lenses is subject to this listing requirement. The color additive is added to contact lenses in such a way that at least some of the color additive will come in contact with the eye when the lenses are worn. In addition, the lenses are intended to be placed on the eye for several hours a day, each day, for 1 year or more. Thus, the color additive will be in direct contact with the body for a significant period of time. Consequently, the use of the color additive currently before the agency is subject to the statutory listing requirement.

III. Identity

The color additive is the reaction product of the reactive dye C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-((1-sulfo-6-((2-(sulfooxy)ethyl]sulfonyl)-2-naphthalenyl]azo)-2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114–32–0) and the vinyl alcohol/methyl methacrylate copolymer. The dye is reacted with contact lenses fabricated from the vinyl alcohol/methyl methacrylate copolymer. During the reaction, the sulfate groups

of the dye are replaced by other linkages to the copolymeric lens material. As a result, a thin layer of colored copolymeric material forms on the surface of the lenses and colors the contact lenses. As part of the manufacturing process, the lenses are thoroughly washed to remove unbound dye.

IV. Safety Evaluation

The agency believes that because the reactive dye C.I. Reactive Red 180 has a significantly lower molecular weight than the vinyl alcohol/methyl methacrylate-dye copolymer, it would be more readily absorbed into the body than the copolymeric color additive and would thus be expected to show a greater toxic effect. Therefore, the safety evaluation of the subject color additive focused primarily on C.I. Reactive Red 180.

FDA concludes from the data submitted in the petition and from other relevant information that the exposure to C.I. Reactive Red 180 from its use to produce the color additive in the contact lenses is 3.3 nanograms (ng) per person per day. The exposure calculated by the agency was based on two factors. First, from extraction studies conducted by the petitioner on contact lenses colored with the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product, the agency has determined that the amount of dye that could migrate from the colored contact lenses is no more than 0.6 micrograms (µg) per lens. Secondly, the agency made two worst-case assumptions that: (1) A user will replace lenses colored with the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product once each year with a new pair of lenses tinted with the same color additive; and (2) 100 percent of the extractible reactive dye will migrate from the lenses into the eyes over the 1-year period. Because these assumptions are worst-case estimates, exposure to C.I. Reactive Red 180 from its use to produce the color additive in contact lenses is likely to be less than 3.3 ng per person per day (Ref. 1).

In evaluating the safety of the reactive dye C.I. Reactive Red 180, the agency considered two in-vitro cytotoxicity studies contained in its files on C.I. Reactive Red 180 by the direct-contact method. From these studies, the maximum noncytotoxic concentration for the reactive dye was determined to be 10 µg per milliliter (mL) using mouse fibroblast cells. In addition, the petitioner conducted toxicity tests to establish that the vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product is safe for use in coloring contact lenses. These tests included in-vitro cytotoxicity studies on the lenses and on lens extracts using mouse fibroblast cells and the agar-overlay method. The petitioner also conducted an acute systemic toxicity test on mice using lens extracts and 21-day ocular irritation studies on rabbits using the colored lenses. The above referenced studies demonstrated no evidence of cytotoxicity, acute systemic toxicity, or ocular irritation.

To relate the no-effect level of 10 µg/mL, established in the direct-contact cytotoxicity studies on C.I. Reactive Red 180, to the 3.3 ng per person per day exposure from wearing the colored lenses, the agency calculated the maximum concentration level of reactive dye in each eye that would result from the use of the contact lens. The agency estimated that the daily exposure to reactive dye in each eye would be 1.65 ng and that this would be diluted by the average daily tear film of 1.2 mL produced in each eye. This concentration is equal to a maximum daily concentration in the tear flow of the eye of 1.38 ng/mL. When this concentration is compared with the no-effect level of 10 µg/mL, this represents a 7,300-fold safety factor for this proposed use of C.I. Reactive Red 180.

Based upon the available toxicity data, the small amount of vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product in the contact lenses, and the agency's exposure calculation, FDA finds that the reaction product formed by chemically bonding the dye C.I. Reactive Red 180 to vinyl alcohol/methyl methacrylate copolymer is safe for use as a color additive in contact lenses. FDA further concludes that the use of the color additive shall not exceed the minimum amount reasonably expected to accomplish the intended coloring effect. Batch certification is not required to ensure safety.

V. Conclusions

Based on data contained in the petition and other relevant information, FDA concludes that there is a reasonable certainty that no harm will result from the petitioned use of vinyl alcohol/methyl methacrylate-C.I. Reactive Red 180 reaction product as a color additive in contact lenses, and that the additive is safe and suitable for the intended use. Therefore, the agency is amending the regulations by adding new § 73.3127.

VI. Inspection of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in § 71.15, the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Food and Color Additives Review Section to the Indirect Additives Branch, "CAP's 8C0212 and 9C0217 - Ciba Vision Corp. Remazol Red 180 for Use in Colored Contact Lenses. Validation of Limit of Detection. Submission dated 7–8–91," February 24, 1992.

IX. Objections

Any person who will be adversely affected by this regulation may at any time on or before February 8, 1993, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the

objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: Secs. 201, 401, 402, 403, 408, 501, 502, 505, 601, 602, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 376).

2. New § 73.3127 is added to subpart D to read as follows:

§ 73.3127 Vinyl alcohol/methyl methacrylate-dye reaction products.

(a) *Identity.* The color additive is formed by reacting a dye with a vinyl alcohol/methyl methacrylate copolymer, so that the sulfate groups of the dye are replaced by ether linkages to the vinyl alcohol/methyl methacrylate copolymer. The dye is: C.I. Reactive Red 180 [5-(benzoylamino)-4-hydroxy-3-[(1-sulfo-6-[(2-(sulfooxy)ethyl]sulfonyl)-2-naphthalenyl]azo)- 2,7-naphthalenedisulfonic acid, tetrasodium salt] (CAS Reg. No. 98114-32-0).

(b) *Uses and restrictions.* (1) The substance listed in paragraph (a) of this section may be used to color contact lenses in amounts not to exceed the minimum reasonably required to accomplish the intended coloring effect.

(2) As part of the manufacturing process, the lenses containing the color additive are thoroughly washed to remove unbound reactive dye.

(3) Authorization and compliance with this use shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act (the act). A person intending to introduce a device containing a vinyl alcohol/methyl methacrylate-dye reaction product listed under this section into commerce shall submit to the Food and Drug Administration either a premarket notification in accordance with subpart E of part 807 of this chapter, if the device is not subject to premarket approval, or submit and receive approval of an original or supplemental premarket approval application if the device is subject to premarket approval.

(c) *Labeling.* The label of the color additive shall conform to the requirements of § 70.25 of this chapter.

(d) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore, this color additive is exempt from the certification requirements of section 706(c) of the act.

Dated: December 31, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-317 Filed 1-7-93; 8:45 am]

BILLING CODE 4160-01-F

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21 CFR Part 888

[Docket No. 89P-0367]

Medical Devices; Reclassification and Codification of Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the reclassification and codification of the hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis. FDA issued an order in the form of a letter to two manufacturers reclassifying the device from class III into class II. Accordingly, FDA is amending the regulations as set forth below.

DATES: The reclassification was effective February 21, 1992. This final rule becomes effective February 8, 1993.

FOR FURTHER INFORMATION CONTACT: Nirmal K. Mishra, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1036.

SUPPLEMENTARY INFORMATION: On September 12, 1989, FDA filed a reclassification petition submitted by Richards Medical Co. (Richards) and Intermedics Orthopedics, Inc. (Intermedics), requesting reclassification of the hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis from class III into class II. FDA consulted with the Orthopedic and Rehabilitation Devices Panel (the Panel). During an open public meeting on September 22, 1989, the Panel recommended that FDA reclassify the hip joint metal/polymer/metal semi-constrained porous-coated prosthesis from class III into class II and that FDA assign a low priority for the establishment of a performance standard for the generic type of device under section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d).

FDA fully considered the Panel's recommendations and tentatively agreed that the generic type of device should be reclassified from class III into class II and that the promulgation of a performance standard for the device should be a low priority.

The Safe Medical Devices Act of 1990 (the SMDA) amended the act to change the definition of a class II device. Under the SMDA, class II devices are those devices for which there is insufficient information to show that general controls themselves will ensure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of a performance standard. Thus, the definition of a class II device was changed from "performance standards" to "special controls." FDA's final determination was made under the standard set forth in the SMDA.

It is the agency's position that the SMDA does not require the agency to obtain new reclassification recommendations from a panel which had recommended reclassification under the previous standards. The Panel recommended the hip joint metal/polymer/metal semi-constrained porous coated prosthesis be reclassified from class III (premarket approval) into class II (performance standards). Under the SMDA, FDA may establish a performance standard, as well as establish other special controls, including postmarket surveillance, patient registries, guidelines, and other appropriate actions it believes necessary to provide reasonable assurance of the safety and effectiveness of the device.

In the Federal Register of July 15, 1991 (56 FR 32145), FDA published a notice of the Panel's recommendations and invited public comment. FDA received eight comments regarding the reclassification proposal for the generic type of device. All of the comments supported reclassification, although six of them expressed concern about various aspects of the device description, e.g., the materials, pore morphology, and specifications. Each comment was addressed in the order, which is available for examination in the Docket Management Branch (HFA-

305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

After reviewing the data in the petition and presented before the Panel, and after considering the Panel's recommendation and the comments received, FDA ordered the reclassification of the generic type of device from class III into class II. As required by 21 CFR 860.134(b)(7) of the regulations, FDA is announcing the reclassification of this generic type of device. In addition, FDA is issuing a final rule that codifies the reclassification of this device by adding new § 888.3358 *Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis* (21 CFR 888.3358).

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

After considering the economic consequences of approving this reclassification, FDA certifies that this final rule requires neither a regulatory impact analysis, as specified in Executive Order 12291, nor a regulatory flexibility analysis, as specified in the Regulatory Flexibility Act (Pub. L. 96–354). This reclassification will not have a significant economic impact on a substantial number of small entities. The petitioners and all future manufacturers of the generic type of device are relieved of the costs of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e).

There are no offsetting costs that manufacturers would incur from reclassification into class II other than those associated with complying with special controls under section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)), or meeting a performance standard if established. The actual cost of complying with these requirements cannot be determined in advance. The magnitude of the economic savings from approval of this petition depends on the extent of studies the petitioners would have conducted in support of new premarket approval applications (PMA's), or supplements to existing PMA's, and the number of future competitors satisfying the requirements of premarket approval. None of these parameters can be reliably calculated to permit quantification of the economic savings.

List of Subjects in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 888.3358 is added to subpart D to read as follows:

§ 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis.

(a) *Identification.* A hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device limits translation and rotation in one or more planes via the geometry of its articulating surfaces. It has no linkage across the joint. This generic type of device has a femoral component made of a cobalt-chromium-molybdenum (Co-Cr-Mo) alloy or a titanium-aluminum-vanadium (Ti-6Al-4V) alloy and an acetabular component composed of an ultra-high molecular weight polyethylene articulating bearing surface fixed in a metal shell made of Co-Cr-Mo or Ti-6Al-4V. The femoral stem and acetabular shell have a porous coating made of, in the case of Co-Cr-Mo substrates, beads of the same alloy, and in the case of Ti-6Al-4V substrates, fibers of commercially pure titanium or Ti-6Al-4V alloy. The porous coating has a volume porosity between 30 and 70 percent, an average pore size between 100 and 1,000 microns, interconnecting porosity, and a porous coating thickness between 500 and 1,500 microns. The generic type of device has a design to achieve biological fixation to bone without the use of bone cement.

(b) *Classification.* Class II.

Dated: December 24, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–316 Filed 1–7–93; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 580

Haitian Transactions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Policy statement.

SUMMARY: The Office of Foreign Assets Control ("FAC") is extending all current licenses issued under § 580.515 of the Haitian Transactions Regulations, 31 CFR part 580. These licenses, which authorize transactions in connection with both the exportation to Haiti of articles containing specified parts or materials, and the importation into the United States of specified articles assembled in Haiti containing materials or parts exported from the United States, are extended to January 31, 1994. Additionally, to clarify the reporting requirements with respect to such licenses FAC is instructing licensees to refer to specific language in preparing the transaction summary sections of their required quarterly reports.

EFFECTIVE DATE: January 6, 1993.

FOR FURTHER INFORMATION CONTACT: Steven I. Pinter, Chief of Licensing (tel.: 202/622–2480), or William B. Hoffman, Chief Counsel (tel.: 202/622–2410), Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

Accordingly, under the authority of 50 U.S.C. 1701 *et seq.*, E.O. 12775 (56 FR 50641, Oct. 7, 1991), and E.O. 12779 (56 FR 55975, Oct 30, 1991), the Office of Foreign Assets Control gives notice that:

1. All licenses issued and in effect pursuant to § 580.515 of the Haitian Transactions Regulations, 31 CFR part 580, are extended to January 31, 1994.

2. Holders of such licenses need not file requests for renewal with the Office of Foreign Assets Control.

3. Quarterly reports filed pursuant to such licenses shall describe all exports and imports of authorized articles, components and materials by referencing the descriptive labels given to these items in § 1 (a) and (b) of the licenses. Items not on the prescribed list are to be separately grouped, and persons engaged in transactions involving these items should contact the Licensing Division of the Office of Foreign Assets Control (202/622–2480) to seek clarification or an appropriate license amendment.

Dated: December 16, 1992.
R. Richard Newcomb,
Director, Office of Foreign Assets Control.
Approved: January 4, 1993.
Nancy L. Worthington,
Acting Assistant Secretary (Enforcement).
[FR Doc. 93–416 Filed 1–6–93; 9:28 am]
BILLING CODE 4810–25–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6955

[OR–943–4210–06; GP2–396; OR–21783 (WASH)]

Partial Revocation of Bureau of Land Management Order Dated June 18, 1947; Washington

AGENCY: Bureau of Land Management, Interior.
ACTION: Public land order.

SUMMARY: This order revokes a Bureau of Land Management order insofar as it affects 680 acres of public lands withdrawn for Bureau of Reclamation's Columbia River Basin Project. The lands are no longer needed for reclamation purposes. The revocation is needed to permit disposal of the lands through land exchange under section 206 of the Federal Land Policy and Management Act of 1976. This action will open the lands to surface entry and mining subject to other segregations of record. The lands have been and will remain open to mineral leasing.

EFFECTIVE DATE: February 8, 1993.
FOR FURTHER INFORMATION CONTACT: Donna Kauffman, BLM Oregon State Office, P.O. Box 2965, Portland, Oregon 97208–2965, (563)–280–7162.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), it is ordered as follows:

1. Bureau of Land Management Order dated June 18, 1947, which withdrew public lands for use by the Bureau of Reclamation for reclamation purposes in connection with the Columbia River Basin Project, is hereby revoked insofar as it affects the following described lands:

Willamette Meridian

T. 23 N., R. 27 E.,
Sec. 12, SE¼SW¼ and SW¼SE¼;
Sec. 14, S½NE¼, NE¼SW¼, and S½SW¼;
Sec. 22, NE¼NE¼, S½NE¼, SE¼NW¼, E½SW¼, and W½SE¼;
Sec. 24, N½NW¼.

The areas described aggregate 680.00 acres in Grant County.

2. At 8:30 a.m. on February 8, 1993, the lands will be opened to the operation of the public land laws generally, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. All valid applications received at or prior to 8:30 a.m. on February 8, 1993, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

3. At 8:30 a.m. on February 8, 1993, the lands will be opened to location and entry under the United States mining laws, subject to valid existing rights, the provisions of existing withdrawals, other segregations of record, and the requirements of applicable law. Appropriation of any of the lands described in this order under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38 (1988), shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

Dated: December 22, 1992.
Dave O'Neal,
Assistant Secretary of the Interior.
[FR Doc. 93–396 Filed 1–7–93; 8:45 am]
BILLING CODE 4310–33–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 572

[Docket No. 91–27; Notice 3]

RIN 2127–AC87

Anthropomorphic Test Dummies; Newborn Infant Test Dummy

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.
ACTION: Final rule.

SUMMARY: This notice amends regulations on Anthropomorphic Test Dummies, by establishing specifications for a newborn infant test dummy to be used in testing infant restraints. NHTSA believes standardizing the dummy used to test infant restraints will enable NHTSA and the child passenger safety community to evaluate those restraints in a fuller and more uniform manner. Adding the dummy to the agency regulations is a first step toward possibly specifying the dummy for use in testing the compliance of infant restraints with Federal Motor Vehicle Safety Standard (FMVSS) No. 213, Child Restraint Systems. The issue of amending FMVSS 213 to specify use of the dummy in compliance testing under that standard will be explored in future rulemaking.

DATES: The amendment is effective on July 1, 1993. The incorporation by reference of certain publications listed in the regulation is approved by the Director of the Federal Register as of July 1, 1993.

Petitions for reconsideration of the final rule must be received by February 8, 1993.

ADDRESSES: Petitions for reconsideration should refer to the docket number and notice number of the notice and be submitted to: Administrator, room 5220, National Highway Traffic Safety Administration, 400 Seventh St., SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Charles Hott, NHTSA Office of Vehicle Safety Standards, room 5320C, 400 Seventh St., SW., Washington, DC 20590 (202–366–0247).

SUPPLEMENTARY INFORMATION: This notice amends part 572, Anthropomorphic Test Dummies, to establish specifications for a test dummy representing a newborn infant. (49 CFR part 572). The regulatory text adopted today is identical in all significant respects to that proposed by the notice of proposed rulemaking (NPRM).

Child test dummies specified in part 572 enable NHTSA to dynamically test child restraint systems in a manner that is both measurable and repeatable. The addition of the newborn infant dummy will encourage testing of infant restraint systems in a fuller and more uniform manner.

NHTSA already has four child dummies specified in Part 572 for testing child restraint systems. Two of the dummies, a six-month-old and three-year-old child dummy, are incorporated into the compliance test procedures of FMVSS 213, Child Restraint Systems (49 CFR 571.213; S7.1, 7.2). In other words, these two dummies are used by NHTSA to determine whether restraints comply with the dynamic performance requirements of FMVSS 213. The other two dummies, a nine-month-old and six-year-old child dummy, are not yet

incorporated into FMVSS 213, and thus are not used in compliance testing.

The nine-month-old and six-year-old dummies were recently added to part 572. The specifications for both became effective in 1992 (see, 56 FR 41077 (nine-month-old dummy); 56 FR 57830 (six-year-old dummy)). The new dummies were adopted to improve the testing of child restraints for research purposes. These new dummies more closely represent the size, weight and mass distribution of the children for whom some restraints are designed than do the present six-month-old and three-year-old dummies. With more representative dummies, real world crashes can be better simulated, and the performance of the restraints better evaluated. For example, restraints are usually recommended for children of certain weight ranges, such as from 30 to 60 pounds. A restraint recommended for such a weight range is currently tested with a single size of dummy: The three-year-old, 33-pound part 572 dummy. Testing the restraint with not only that dummy, but also the six-year-old, 47-pound dummy, would provide a fuller evaluation of the safety provided by the restraint for the range of children recommended for it.

While the newly specified dummies are currently used only for research, NHTSA plans to propose rulemaking on the issue of incorporating them into the test procedure of FMVSS 213. The newborn infant dummy specified in today's rule would be included in that rulemaking.

Summary of the Final Rule

The newborn infant test dummy, commercially known as SA100N, is based on a simple design representing the dimensions and mass distribution characteristics of a 50th percentile newborn infant. It is 20 inches long and weighs 7.5 pounds. The dummy is scaled down from the design of the six-month-old test dummy currently specified in part 572. The six-month-old dummy, developed by the Federal Aviation Administration's Civil Aeronautical Institute (CAMI), has been used successfully to test child restraint systems since the mid-1970's. NHTSA's tests have shown that the newborn dummy's kinematic responses in a dynamic test are repeatable and reproducible.

The newborn infant dummy is used to assess the ability of infant restraints to retain their occupants and maintain their structural integrity during dynamic testing. Because of its construction, the dummy cannot be instrumented to measure the forces exerted on it during a crash.

The newborn dummy is specified by descriptive design specifications that ensure that each dummy will vary little from other newborn dummies in its construction and performance. The specifications for the newborn infant dummy consist of a drawing package that: Shows the component parts, the subassemblies, and the assembly of the complete dummy; and defines the materials and sets the specifications for the dummy's component parts. The drawings for the newborn dummy are available for inspection in NHTSA docket 91–27–N02. In addition, NHTSA has developed a construction manual for the dummy, which is based on the manual for the six-month-old dummy. The construction manual for the newborn dummy is available for inspection in NHTSA docket 91–27–N03. Copies of the drawings and construction manual can be obtained from Reprographic Technologies, Inc., 1111 14th St., NW., Washington, DC 20005, telephone (202) 628–6667 or (202) 408–8789.

Background

NHTSA published the NPRM for the newborn infant dummy on August 12, 1991 (56 FR 38108). The agency issued the proposal for the new dummy to enable NHTSA and others to obtain a more accurate evaluation of restraints designed for newborn infants, than that obtained by use of the six-month-old dummy alone. The proposal responded to a petition for rulemaking from Mr. D. Friedman requesting NHTSA to revise FMVSS 213 and part 572 to specify use of the newborn dummy in FMVSS 213 compliance tests.

The proposed newborn infant dummy had to be newly developed by NHTSA. NHTSA surveyed the dummies that were available in the marketplace and did not find one suitable for the agency's purposes. These dummies were the "P-O" dummy developed by Institute Voor Wegtransportmiddelen (TNO) of the Netherlands, and the "Baby Anne" dummy that is used for training obstetric nurses in the care and feeding of newborns. NHTSA's reasons for concluding that the dummies were unsuitable were fully discussed in the NPRM. (See, 56 FR at 38109.) Briefly stated, NHTSA's main concerns related to both dummies' biofidelity (i.e., how human-like they would have been in an impact), and to Baby Anne's capability to provide repeatable results. (Repeatability refers to the repetition of similar impact responses by the same dummy.)

NHTSA developed the newborn infant dummy by scaling down the design of the six-month-old CAMI dummy. The agency determined that the dummy's kinematic responses in a dynamic test are repeatable and reproducible. (Reproducibility refers to the variation of impact responses among different dummies.) *Id.*

In December 1991, NHTSA reopened the comment period for the newborn infant proposal. The reason for the action was to provide interested persons the opportunity to inspect the drawings and construction manual for the dummy, which were not available during the original comment period. 56 FR 63922, December 6, 1991.

Comments on the NPRM

NHTSA received eleven comments on the proposal. Commenters included Arkansas' health department, consumer coalition groups, the University of Michigan, child restraint manufacturers and motor vehicle manufacturers. The commenters generally supported establishing specifications for a newborn infant dummy. However, some commenters had concerns about NHTSA's choice of the SA100N dummy.

Alternative Dummies

The Center for Auto Safety stated the SA100N dummy is acceptable for now, but asked whether NHTSA made a "comprehensive survey of possible sources" for infant dummy candidates. The answer is that NHTSA asked all the anthropomorphic test dummy manufacturers and a number of child passenger safety researchers about the availability of a newborn infant dummy. The inquiry identified the TNO P-O dummy and the Baby Anne dummy as the possible candidates. As mentioned above, neither of the dummies was suitable.

For Motor Company suggested that NHTSA consider another dummy rather than SA100N. Ford said that First Technology Safety Systems and the Society of Automotive Engineers have just finished the initial prototype of an instrumented, six-month-old infant dummy. Ford believed that "a down-size version of this new dummy would offer more potential for meaningful safety testing of infant restraints" than the SA100N dummy.

The agency does not agree another dummy should be considered at this time. The prototype six-month-old dummy described in Ford's comment has not yet been fully evaluated to determine its suitability as an anthropomorphic test device. If the six-month-old dummy were determined to be suitable, the dummy would then have to be scaled down to the newborn size. The scaled down model would

then have to be evaluated for its suitability. Each of these steps would be time consuming, and would result in delays in incorporating specifications for the newborn dummy in part 572. NHTSA does not believe those delays are warranted, given the adequacy of the SA100N dummy. Of course, the part 572 specifications can be amended if necessary, at any time. If a preferred newborn dummy is developed in the future, rulemaking can be initiated to determine whether such dummy should replace the SA100N dummy.

Advocates for Highway and Auto Safety (Advocates) recommended that NHTSA should work on developing a dummy whose head-neck design replicates the "highly undeveloped neck musculature" of an infant. NHTSA will keep abreast of the developments in the anthropomorphic test dummy field. As better dummies become available, the agency will consider the desirability of modifying part 572.

Material Specifications

The University of Michigan (UM) said that the canvas skin specified for covering the exterior of the proposed dummy is too heavy, coarse and stiff for the dummy's small structure. UM suggested that lighter weight synthetic materials could be used in place of the canvas, and in place of the material used for the dummy's skeleton.

NHTSA is not aware of any problems with the dummy's canvas or skeleton. The dummy has demonstrated its suitability as a test device in dynamic tests. NHTSA concludes there is insufficient reason to change the material specifications that had been proposed for the dummy.

Size and Weight

Advocates stated that the dummy is of a "reasonable size and weight that accommodates a high percentage of full-term infants." However, Advocates stated that a significant proportion of newborn infants released from the hospital weigh less than 7.5 pounds, due to increasing numbers of premature infants surviving birth and full-term low birth weight infants. The commenter suggested that a higher percentage of newborns could be represented by the dummy if its weight and length were below 7.5 pounds and 20 inches.

The agency believes the SA100N dummy adopted today appropriately represents newborns. The median birth weight newborn infant in 1988, which has not changed since 1984, was seven pounds, seven ounces. (National Center for Health Statistics, Vol. 39, No. 4, August 1990.) The dummy's weight at 7.5 pounds is in the 50th percentile for newborn weights. If the dummy were to weight less than 7.5 pounds, it would not be as representative of newborn infants in the higher weight ranges. NHTSA also notes that the ratio of low birth weight newborn infants to other newborn infants is decreasing. In 1975, it was 7.39 percent; in 1987, 6.9 percent. (National Center for Health Statistics, Trends in Low Birth Weight: United States, 1975–85, October 1989.) Given this trend, reducing the weight of the SA100N dummy might reduce the percentage of newborns represented by the dummy in the future.

UM and Century compared the newborn dummy to anthropometric data for infants from zero to three months and concluded that the dummy is too small in the head and waist and too large in the chest.

NHTSA designed the dummy to conform to anthropometric data for a 50th percentile newborn infant, rather than to data for infants from zero to three months, which is what UM used. The agency decided that the dummy should represent a newborn infant rather than an older infant because it may be more difficult for some restraints to prevent the ejection of the smaller body than the larger one. The newborn dummy could be used to test infant restraints in conjunction with the six-month-old infant and nine-month-old child dummies currently specified in subparts D and J of 49 CFR part 572. The newborn dummy would ensure that the restraint is able to protect the very young infant as well as older infants and children for whom the restraint is designed.

The data NHTSA used for the newborn infant dummy were obtained from "Growth and Development of Children," eighth edition, Year Book Medical Publishers, Inc. The data are as follows:

Weight	7.5 pounds.
Head circumference	13.8 inches.
Chest circumference	13.7 inches.
Height	19.9 inches.

The SA100 dummy's measurements are as follows:

Weight	7.5 pounds.
Head circumference	13.9 inches.
Chest circumference	14.0 inches.
Height	20.5 inches.

The SA100N dummy compares favorably with these data. Since the dummy is pliable and will be used as an inertial loading device, the slight increase in chest circumference and the slight differences in torso shape should have little effect on its dynamic performance.

Knee Flexibility

Advocates was concerned about the flexibility of the dummy's knees. The dummy has less joint articulation than a newborn infant. The dummy was designed to be stiffer to improve its durability for repeated testing. Advocates believed that the dummy's knees should be more flexible because "stiff knees help to restrain the dummy in both front and rear impacts." Advocates was concerned that some infants could be asphyxiated by a "cross-tie" on a restraint if the infant "submerges" in the system. Advocates believed stiff knees can prevent the dummy from sliding down into the restraint, which reduces the use of the dummy to evaluate the risk of asphyxiation.

NHTSA does not believe that the dummy's knees would artificially restrain the dummy. Its legs are relatively straight and flex at the hip. When placed in a rear-facing child restraint, it positions correctly into the restraint without bending its knees (unlike the TNO dummy, whose knees are permanently molded into the flexed position). During a frontal impact the dummy is free to shift toward the back of the child restraint without its knees "hooking" on the restraint. The hooking phenomenon is more likely to occur with the TNO dummy, with its flexed knees, than with the SA100N dummy.

Construction Manual

No commenter objected to the agency's proposal to use the six-month-old dummy's construction manual for the newborn dummy. However, NHTSA has decided that the newborn infant dummy should have its own construction manual, because use of a different dummy's construction manual might be confusing. The new construction manual is also clearer than the six-month-old dummy manual, in that it references the specific drawings for the newborn infant dummy.

This final rule does not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (Safety Act; 15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. Section 105 of the Safety Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking

Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The agency has analyzed the economic and other effects of this rule and has determined that they are neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department of Transportation regulatory policies and procedures. The specifications for the newborn dummy are intended to facilitate the evaluation of crash protection for newborn children for research purposes only. The rule would not require any manufacturer to produce or use the dummy. Further, the addition of the newborn infant dummy to part 572 will not require any manufacturer to make any changes to any child restraint system. The dummy would not be used in Standard 213 compliance testing unless the agency decided to do so after thoroughly evaluating and discussing such use and its costs and other impacts in a separate rulemaking.

The agency estimates that the newborn test dummy can be manufactured for $2,500 to $5,000 per unit, depending on the manufacturer. Since the dummy is designed to be reusable, its cost can be amortized over a number of tests. The materials used in the dummy are obtainable readily and are similar to the materials used in the six-month-old dummy described in subpart D of part 572. For these reasons, the agency has determined that the economic effects of the amendments are so minimal that a full regulatory evaluation is not required.

Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, NHTSA has evaluated the effects of this action on small entities. There are several child anthropomorphic test device manufacturers currently operating in this country. Any of these manufacturers could fabricate this dummy. However, only one manufacturer, First Technology Safety Systems, currently has direct experience in fabrication. This notice neither requires newborn dummies to comply with the specifications, nor requires the use of the specified dummy in child restraint testing. However, the agency anticipates that the existence of the specifications would cause purchasers seeking newborn dummies to select only those newborn dummies that meet those specifications. NHTSA believes that use of the dummy would not affect the sales or use of other currently-specified part 572 child dummies, since those dummies would continue to be used in testing child restraint systems. Small organizations and small governmental jurisdictions that deal with automotive child safety would not be significantly affected since the potential cost increments associated with this proposed action would have negligible effects on the purchase price of applicable child restraint systems, if at all.

Based upon the above evaluation, I certify that today's amendment to part 572 would not have a significant economic impact on a substantial number of small entities. Accordingly, no final regulatory flexibility analysis has been prepared.

Executive Order 12612

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been tentatively determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

National Environmental Policy Act

The agency has also analyzed this rule for the purpose of the National Environmental Policy Act, and tentatively determined that it would not have any significant impact on the quality of the human environment.

Regulatory Information Number (RIN)

A RIN is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 572

Motor vehicle safety, Incorporation by reference.

In consideration of the foregoing, NHTSA amends 49 CFR part 572 as follows:

PART 572—[AMENDED]

1. The authority citation for part 572 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, and 1407; delegation of authority at 49 CFR 1.50.

2. Subpart K, consisting of §§ 572.90 through 572.91, is added to read as follows:

Subpart K—Newborn Infant

572.90 Incorporated materials
572.91 General description

Subpart K—Newborn Infant

§ 572.90 Incorporation by reference.

(a) The drawings and specifications referred to in § 572.91(a) are hereby incorporated in subpart K by reference. These materials are thereby made part of this regulation. The Director of the Federal Register approved that materials incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the materials may be inspected at NHTSA's Docket Section, 400 Seventh Street, SW., room 5109, Washington, DC, or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(b) The incorporated material is available as follows:

(1) Drawing numbers 126–0000 through 126–0015 (sheets 1 through 3), 126–0017 through 126–0027, and a parts list entitled "Parts List for CAMI Newborn Dummy," are available from Reprographic Technologies, 1111 14th Street, NW., Washington, DC 20005. (202) 628–6667.

(2) A construction manual entitled, "Construction of the Newborn Infant Dummy" (July 1992) is available from Reprographic Technologies at the address in paragraph (b)(1) of this section.

§ 572.91 General description.

(a) The representative newborn infant dummy consists of a drawings and specifications package that contains the following materials:

(1) Drawing numbers 126–0000 through 126–0015 (sheets 1 through 3), 126–0017 through 126–0027, and a parts list entitled "Parts List for CAMI Newborn Dummy"; and,

(2) A construction manual entitled, "Construction of the Newborn Infant Dummy" (July 1992).

(b) The structural properties of the dummy are such that the dummy conforms to this part in every respect both before and after being used in dynamic tests specified in Standard No. 213 of this chapter (§ 571.213).

Issued on January 5, 1993.

Marion C. Blakey,

Administrator.

[FR Doc. 93–440 Filed 1–7–93; 8:45 am]

BILLING CODE 4910-59-M

Proposed Rules

Federal Register
Vol. 58, No. 5
Friday, January 8, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

Agricultural Stabilization and Conservation Service

7 CFR Part 29

[Docket No. TB–92–42]

Subpart A—Policy Statement and Regulations Governing the Extension of Tobacco Inspection and Price Support Services to New Markets and to Additional Sales on Designated Markets

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Department is proposing to expand the geographical area of a designated tobacco auction market from 3 miles to 5 miles of the boundaries of the city or town. This would allow more flexibility in building new warehouses. In many markets zoning laws and the cost of land make it impossible to build new warehouses within the 3-mile limit. With the spread of residential development and other businesses seeking lower cost advantages, it has become necessary for new warehouses to locate further outside the city limits.

DATES: Comments should be received on or before February 8, 1993.

ADDRESSES: Send comments to the Director, Tobacco Division, Agricultural Marketing Service (AMS) United States Department of Agriculture (USDA), Room 502 Annex Building, P.O. Box 96456, Washington, DC 20090–6456. Comments will be available for public inspection at this location during regular business hours.

FOR FURTHER INFORMATION CONTACT: Director, Tobacco Division, AMS, USDA, Room 502 Annex Building, P.O. Box 96456, Washington, DC 20090–6456. Telephone (202) 205–0567.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Department proposes to make minor revisions of the definition "Designated market" in subpart A, § 29.1(e).

The amendment would expand the geographical boundaries of tobacco auction markets designated by the Secretary under section 5 of the Tobacco Inspection Act to that geographical area within 5 road miles of the boundary of that town or city. It would also allow warehouses in existence and which received price support and inspection services during the 1992 marketing season to continue to operate at the same location. This change would allow more flexibility in building new warehouses. In many markets the spread of residential development, zoning laws, and the cost of land make it difficult to build new warehouses within the 3-mile limit.

This proposed rule has been reviewed under USDA procedures established to implement Executive Order 12291 and Departmental Regulation 1512–1 and has been determined to be "nonmajor" because it does not meet any of the criteria established for major rules under the Executive Order.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This proposed rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Additionally, in conformance with the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), full consideration has been given to the potential economic impact on small business. Most of the firms which would be affected by this rule are small businesses. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having gross annual revenues for the last 3 years of less than $500,000, and small agricultural service firms are defined as those whose gross annual receipts are less than $3,500,000. The Administrator, Agricultural Marketing Service, has determined that this action would not have a significant economic impact on a substantial number of small entities. This proposed rule would not substantially affect the normal movement of the commodity in the marketplace. Compliance with this proposed rule would not impose substantial direct economic cost, recordkeeping, or personnel workload changes on small entities, and would not alter the market share of competitive positions of small entities relative to the large entities and would in no way affect normal competition in the marketplace.

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this Notice.

All persons who desire to submit written data, views, or arguments for consideration in connection with the proposal may file them with the Director, Tobacco Division, Agricultural Marketing Service, United States Department of Agriculture, Room 502 Annex Building, P.O. Box 96456, Washington, D.C. 20090–6456, not later than February 8, 1993.

List of Subjects in 7 CFR Part 29

Administrative practice and procedure, Advisory committees,

Government publications, Imports, Pesticides and pests, Reporting and recordkeeping requirements, Tobacco.

For the reasons set forth in the preamble, it is proposed that the regulations of 7 CFR part 29 be amended as follows:

PART 29—TOBACCO INSPECTION

Subpart A—Policy Statement and Regulations Governing the Extension of Tobacco Inspection and Price Support Services to New Markets and to Additional Sales on Designated Markets

1. The authority citation for subpart A continues to read as follows:

Authority: Sec. 14, 49 Stat. 734, as amended; sec. 4, 62 Stat. 1070, as amended, 7 U.S.C. 511m, 15 U.S.C. 714b. Interpret or apply sec. 5, 62 Stat. 1072 secs. 101, 401, 403, 63 Stat. 1051, as amended, 1054 as amended, 15 U.S.C. 714c, 7 U.S.C. 1441, 1421, 1423.

2. Paragraph (e) of § 29.1 would be revised to read as follows:

§ 29.1 Definitions

* * * * *

(e) *Designated market* means an auction market designated by the Secretary under section 5 of the Tobacco Inspection Act including the town or city which is the population center of the market and whose name the market bears and all of the geographical area within 5 road miles of the boundaries of said city or town as they are constituted on January 1, 1993. *Provided,* That any warehouse beyond these boundaries which received tobacco inspection and price support services during the 1992 marketing season shall continue to receive such services at the same location regardless of any prohibition contained herein: *And further provided,* That this geographical limitation may be waived by the Secretary after a hearing held pursuant to §§ 29.2 and 29.3.

* * * * * *

Dated: December 29, 1992.

Daniel D. Haley,

Administrator Agricultural Marketing Service.

Keith D. Bjerk,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 93–201 Filed 1–7–92; 8:45 am]

BILLING CODE 3410–02–M

7 CFR Parts 56 and 59

[Docket No. PY–92–001]

RIN 0581–AA66

Refrigeration and Labeling Requirements for Shell Eggs

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On October 27, 1992, the Agricultural Marketing Service (AMS) published a proposed rule with request for comments in the **Federal Register** (57 FR 48569). The proposal would require shell eggs to be stored at an ambient temperature at 45 °F (7.2 °C) or below after packing, and transported under refrigeration at an ambient temperature of 45 °F (7.2 °C) or below. The proposal also contains egg carton labeling requirements to remind consumers to keep eggs refrigerated. AMS is extending the comment period to March 29, 1993, because an industry organization requested additional time to evaluate the proposed rule.

DATES: Written comments must be received on or before March 29, 1993.

ADDRESSES: Send written comments, in duplicate, to Janice L. Lockard, Chief, Standardization Branch, Poultry Division, Agricultural Marketing Service, U.S. Department of Agriculture, room 3944–South, P.O. Box 96456, Washington, DC 20090–6456. Comments received may be inspected at this location between 8 a.m. and 4:30 p.m., Eastern Time, Monday through Friday, except holidays. State that your comments refer to Docket No. PY–92–001. Comments concerning the information collection requirements contained in this action should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20603, Attn: Desk Officer for the Agricultural Marketing Service, USDA.

FOR FURTHER INFORMATION CONTACT: Janice L. Lockard, Chief, Standardization Branch (202) 720–3506.

SUPPLEMENTARY INFORMATION: On October 27, 1992, AMS published a proposed rule in the **Federal Register** (57 FR 48569) to amend 7 CFR parts 56 and 59. The amendments would require refrigeration of eggs at or below 45 °F (7.2 °C) after they are packed into containers destined for the ultimate consumer. The proposed regulations would also require that such containers be labeled to indicate that refrigeration is required.

Since the publication of the proposed rule, an industry organization has requested additional time to evaluate the proposed rule and make comments. The United Egg Producers (UEP) is initiating an independent survey of egg production facilities to determine the most efficient and cost-effective refrigeration methods. Various time/temperature devices, insulation materials, and cooling units are being studied, as well as usage of holding and pre-cooling areas. Also, UEP plans to conduct trial runs on refrigerated transport vehicles.

UEP has requested an additional 90 days to evaluate the results of the survey before submitting comments. AMS has determined that there is sufficient justification for extending the comment period to March 29, 1993.

Dated: December 31, 1992.

Daniel D. Haley,

Administrator.

[FR Doc. 93–326 Filed 1–7–93; 8:45 am]

BILLING CODE 3410–02–M

7 CFR Part 958

[Docket No. FV–92–093PR]

Onions Grown in Certain Designated Counties in Idaho and Malheur County, OR; Reopening of Comment Period on Proposed Rule

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Reopening of the comment period.

SUMMARY: Notice is hereby given that the time period for filing comments is reopened on the proposed rule for Idaho-Eastern Oregon onions published in the October 6, 1992, issue of the **Federal Register.** That action proposed amending the handling regulation to change the term "pearl onion" and reduce the maximum size of exempt pearl onions. This action provides additional opportunity for comments, including submitting alternative proposals to the proposed rule.

DATES: Comments must be received by January 22, 1993.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for further public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Gary Olson, Northwest Marketing Field Office, 1220 SW. Third Avenue, room 369, Portland, Oregon, 97204, telephone (503) 326–2724, or Robert F. Matthews, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456, telephone (202) 690–0464.

SUPPLEMENTARY INFORMATION: The proposed rule was proposed under Marketing Agreement No. 130 and Order No. 958, both as amended, (7 CFR part 958) (order), regulating the handling of onions grown in Idaho and Malheur County, Oregon. The marketing agreement and order are authorized by the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

The proposed rule was issued on October 1, 1992, and published in the October 6, 1992, **Federal Register** (57 FR 45993). It proposed to amend the handling regulation to change the term "pearl onions" to "pickler onions" and reduce the maximum size exemption for such onions from 1¾ inches to 1 inch in diameter. Comments were requested from October 6 through November 5, 1992. Under the current handling regulation, pearl onions as large as 1¾ inches in diameter are exempt from grade, size, maturity, assessment and inspection requirements, while other white onions more than 1 inch in diameter must meet minimum requirements in these areas. The action was proposed to cover onions competing with regulated onions and to eliminate the ambiguity over which onions are exempt and which onions are regulated by establishing a new, smaller, size range for exempt pearl onions that more closely follows current industry practice.

One comment was received from a pearl onion producer/handler in Idaho objecting to the proposed change for several reasons. The commentor contends that: The industry does not generally consider pearl onions to be ¾ inch to 1 inch in diameter; that smaller-sized pearl onions do not lend themselves well to mechanical topping and packing procedures, and do not store well; that most of the pearl onion market is for sizes from 1 to 1¼ inches in diameter; that "pearl onions" should not be redefined as "pickler onions"; that pearl onions up to 1¾ inches in diameter do not compete with other, regulated, onion supplies in the market; and that the proposed regulation could prevent shipment of smaller-sized red and yellow pearl onions. The commentor also disagreed with explanations in the proposed rule regarding the justification for a 1990 rulemaking action which increased the size of exempt pearl onions to 1¾ inches in diameter, and regarding cultural practices employed in the production of pearl onions.

The U.S. Department of Agriculture has determined that it is in the public interest to reopen the comment period for this proposed rule. Such action will provide interested persons more time to review this proposed rule and submit additional written views and information pertinent to the proposed changes and on any alternative proposals. Accordingly, the comment period is reopened to January 22, 1993.

List of Subjects in 7 CFR Part 958

Marketing agreements, Onions, Reporting and recordkeeping requirements.

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

Dated: December 31, 1992.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 93–325 Filed 1–7–93; 8:45 am]

BILLING CODE 3410-02-M

FEDERAL RESERVE SYSTEM

12 CFR Parts 208, 211, and 225

[Regulations H, K and Y; Docket No. R–0792]

Membership of State Banking Institutions in the Federal Reserve System; International Banking Operations; Bank Holding Companies and Change in Bank Control; Criminal Referral Report

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice of proposed rulemaking.

SUMMARY: An interagency task force has designed a uniform multiagency criminal referral form in order to facilitate compliance with financial institutions' criminal activity reporting requirements, to enhance law enforcement agencies' ability to investigate and prosecute the matters reported in the criminal referrals, and to develop and maintain a new interagency database. This uniform criminal referral form will replace the various criminal referral forms that are currently being used by federal bank, thrift and credit union regulatory agencies and by financial institutions. The purpose of the proposed regulation is to create a uniform criminal referral reporting requirement for all domestic and foreign financial institutions operating in the United States.

DATES: Comments on this proposed regulation must be received by February 8, 1993.

ADDRESSES: Comments should be sent to: Board of Governors of the Federal Reserve System, Mr. William Wiles, Secretary of the Board, 20th and C Streets, NW., Washington, DC 20551, attention Docket No. R–0792.

FOR FURTHER INFORMATION CONTACT: Herbert A. Biern, Deputy Associate Director, (202) 452–2620, Richard A. Small, Special Counsel, (202) 452–5235, or Mark Leemon, Senior Attorney, (202) 452–5206, Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), Dorothea Thompson, (202) 452–3544, Board of Governors of the Federal Reserve System, 20th and C Streets, NW. Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

Background

The federal financial institutions regulatory agencies are the Office of the Comptroller of the Currency (the "OCC"), the Board of Governors of the Federal Reserve System (the "Board"), the Federal Deposit Insurance Corporation (the "FDIC"), the Office of Thrift Supervision (the "OTS"), and the National Credit Union Administration (the "NCUA"). These agencies are charged with safeguarding the safety and soundness of financial institutions with operations in the United States, including national banks, credit unions, savings associations, state-chartered banks, bank and thrift holding companies and their nonbank subsidiaries, Edge and Agreement corporations, and all U.S. offices of foreign banks. Pursuant to their respective enabling statutes, these agencies are responsible for ensuring that financial institutions apprise federal law enforcement authorities of any violation or suspected violation of a criminal statute. Fraud, abusive insider transactions, check kiting schemes, money laundering and other crimes can cause significant financial losses, pose serious threats to a financial institution's continued viability and, if unchecked, may undermine the public confidence in the financial services industry. The law enforcement community needs to receive timely information regarding criminal and suspected criminal activity that is sufficiently detailed to determine whether investigations and prosecutions are warranted.

The Interagency Bank Fraud Working Group (the "Working Group") was formed in 1984 to promote interagency cooperation toward the goal of improving the federal government's response to white collar crime in financial institutions. The Working Group now consists of representatives from twelve federal agencies, including the Board, the other federal financial institutions regulators, the Federal Bureau of Investigation, the U.S. Secret Service, the Department of Justice and the U.S. Department of the Treasury. A subcommittee of the Working Group studied the criminal referral process and developed a new uniform criminal referral form (the "Form"). The purpose of the Form is to standardize criminal referral data and to facilitate its automation. It is anticipated that the resulting interagency criminal referral database will provide information, *inter alia*, to the OCC, the Board, the FDIC, the OTS, the NCUA, the Department of Justice and the U.S. Department of the Treasury. In order to promote use of the Form, each of the federal financial institutions regulatory agencies has decided to adopt similar regulations relating to the filing of criminal referral reports in specific situations and the use of the same Form in the making of such criminal referral reports. The new regulations would replace requirements mandating the filing of criminal referrals and designating separate agency forms for such referrals.

Comments are sought on all the provisions contained in the proposed regulation.

Regulatory Flexibility Act

The Board certifies that this proposed regulation will not have a significant financial impact on a substantial number of small banks or other small entities.

Executive Order 12291

The Board has determined that this proposed regulation is not a "major rule" and therefore does not require a regulatory impact analysis.

Paperwork Reduction Act

In accordance with section 3507 of the Paperwork Reduction Act of 1980, the criminal referral report regulation was approved under authority delegated to the Board by the Office of Management and Budget. The Board has determined that the regulation does not significantly increase the burden of the reporting institutions. The estimated average burden associated with the collections of information contained in a criminal referral report is approximately .5 hour per respondent. The burden per respondent will vary depending on the nature of the criminal activity being reported.

Comments concerning the accuracy of this burden estimate should be directed to the Herbert A. Biern, Deputy Associate Director, Division of Banking Supervision and Regulation, Mail Stop 175, Federal Reserve Board, 20th and Constitution Avenue, NW., Washington, DC 20551.

List of Subjects

12 CFR Part 208

Accounting, Agriculture, Banks, Banking, Confidential business information, Currency, Federal Reserve System, Reporting and recordkeeping requirements, Securities.

12 CFR Part 211

Exports, Federal Reserve System, Foreign banks, Holding companies, Investments, Reporting and recordkeeping requirements.

12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and requirements, Securities.

For the reasons set forth in the preamble, parts 208, 211, and 225 of chapter II of title 12 of the Code of Federal Regulations are amended as follows:

PARTS 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM

1. The authority citation for 12 CFR part 208 continues to read as follows:

Authority: Sections 9, 11(a), 11(c), 19, 21, 25 and 25(a) of the Federal Reserve Act (12 U.S.C. 321–338, 248(a), 248(c), 461, 481–486, 601, and 611); sections 4, 13(j) and 38 of the Federal Deposit Insurance Act, as amended (12 U.S.C. 1814, 1823(j), and 1831o).

2. Section 208.20 is added to read as follows:

§ 208.20 Reports of crimes and suspected crimes.

(a) *Purpose.* This section applies to known or suspected crimes involving state member banks. This section ensures that law enforcement agencies are notified by means of criminal referral reports when unexplained losses or known or suspected criminal acts are discovered. Based on these reports, the federal government will take appropriate measures and will maintain an interagency database that is derived from these reports.

(b) *Institution-affiliated party. Institution-affiliated party* means any institution-affiliated party as that term is defined in Sections 3(u) and 8(b)(3) and (4) of the FDIA (12 U.S.C. 1813(u) and 1818(b)(3) and (4)).

(c) *Reports required.* A state member bank shall file a criminal referral report using a standardized form (the "Form"),[1] in accordance with instructions for the Form, in every situation where:

(1) The state member bank suspects one of its directors, officers, employees, agents, or other institution-affiliated parties of having committed or aided in the commission of a crime;

(2) There is an actual or potential loss to the state member bank (before reimbursement or recovery) of more than $1,000 where the state member bank has a substantial basis for identifying a possible suspect or group of suspects and the suspect(s) is not an director, officer, employee, agent, or institution-affiliated party of the state member bank;

(3) There is an actual or potential loss to the state member bank (before reimbursement or recovery) of $5,000 or more and where the state member bank has no substantial basis for identifying a possible suspect or group of suspects; or

(4) The state member bank suspects that a monetary transaction uses the financial institution as a conduit for criminal activity, such as money laundering or structuring transactions to evade the Bank Secrecy Act reporting requirements.

(d) *Time for reporting.* (1) A state member bank shall file the report required by paragraph (c) of this section no later than 30 calendar days after the date of detection of the loss or the known or suspected criminal violation or activity. If no suspect has been identified within 30 calendar days after the date of the detection of the loss or the known, attempted or suspected criminal violation or activity, reporting may be delayed an additional 30 calendar days or until a suspect has been identified; but in no case shall reporting of known or suspected crimes be delayed more than 60 calendar days after the date of the detection of the loss or the known, attempted or suspected criminal violation or activity. When a report requirement is triggered by the identification of a suspect or group of suspects, the reporting period commences with the identification of each suspect or group of suspects.

(2) When a state member bank detects a pattern of crimes committed by an identifiable individual, the state member bank shall file a report no later

[1] Copies of the Form are available from the Federal Reserve Banks.

than 30 calendar days after the aggregated amount of the crimes exceeds $1,000.

(3) In situations involving violations requiring immediate attention or where a reportable violation is ongoing, the state member bank shall immediately notify by telephone the appropriate law enforcement agency and the appropriate Federal Reserve Bank in addition to filing a timely written report.

(e) *Reporting to State and local authorities.* State member banks are encouraged to file copies of the Form with State and local authorities where appropriate.

(f) *Exceptions.* A state member bank need not file the Form:

(1) For those robberies and burglaries that are reported to local law enforcement authorities; and

(2) For lost, missing, counterfeit or stolen securities if a report is filed pursuant to the reporting requirements of 17 CFR 240.17f–1.

(g) *Retention of records.* A state member bank shall maintain copies of any Form that it filed and the originals of all related documents for a period of 10 years from the date of the report.

(h) *Notification to Board of Directors.* The management of a state member bank shall promptly notify its board of directors of any report filed pursuant to this section.

(i) *Penalty.* Failure to file a report in accordance with the instructions on the Form and this regulation may subject the state member bank, its directors, officers, employees, agents, or other institution-affiliated parties to supervisory action.

PART 211—INTERNATIONAL BANKING OPERATIONS

1. The authority citation for 12 CFR part 211 continues to read as follows:

Authority: Federal Reserve Act (12 U.S.C. 221 *et seq.*); Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841 *et seq.*); the International Banking Act of 1978, as amended (12 U.S.C. 3101 *et seq.*); the International Lending Supervision Act (12 U.S.C. 3901 *et seq.*); and the Export Trading Company Act Amendments of 1988 (title III, Pub. L. 100–418, 102 Stat. 1384 (1988).

2. Section 211.8 is added to read as follows:

§ 211.8 Reports of crimes and suspected crimes.

An Edge corporation or any subsidiary or an Agreement corporation or any subsidiary shall file a criminal referral form in accordance with the provisions of § 208.20 of the Board's Regulation H, 12 CFR 208.20.

3. Section 211.24 is amended by adding a new paragraph (i) to read as follows:

211.24 Nonbanking activities of foreign banking organizations.

(i) *Reports of crimes and suspected crimes.* A branch or agency or representative office of foreign bank operating in the United States shall file a criminal referral form in accordance with the provisions of § 208.20 of the Board's Regulation H, 12 CFR 208.20.

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. The authority citation for 12 CFR part 225 continues to read as follows:

Authority: Section 5(b) of the Bank Holding Company Act of 1956, as amended (12 U.S.C. 1844(b)); section 8 and 13(a) of the International Banking Act of 1978 (12 U.S.C. 3106 and 3108); section 7(j)(13) of the Federal Deposit Insurance Act, as amended by the Change in Bank Control Act of 1978 (12 U.S.C. 1817(j)(13)); section 8(b) of the Federal Deposit Insurance Act (12 U.S.C. 1818(b)); and the International Lending Supervision Act of 1983 (Pub. L. 98–181, title IX).

2. Section 225.4 is amended by adding a new paragraph (g) to read as follows:

§ 225.4 Corporate practices.

* * * * *

(g) *Criminal referral report.* A bank holding company or any nonbank subsidiary thereof, or a foreign bank that is subject to the BHC Act or any nonbank subsidiary of such foreign bank operating in the United States, shall file a criminal referral form in accordance with the provisions of § 208.20 of the Board's Regulation H, 12 CFR 208.20.

Board of Governors of the Federal Reserve System, December 28, 1992.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93–454 Filed 1–7–93; 8:45 am]

BILLING CODE 6210–01–M

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 353

RIN 3064–AA60

Reports of Apparent Crimes Affecting Insured Nonmember Banks

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Proposed rule.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC), in conjunction with an interagency task force, has designed a uniform multi-agency criminal referral form. The form will facilitate financial institutions' compliance with criminal activity reporting requirements and will enhance law enforcement agencies' ability to investigate the matters reported in criminal referrals. The information from the form also will be entered into a new interagency data base which will enhance the regulatory and law enforcement agencies' ability to track criminal and administrative cases. The uniform criminal referral form, which will require substantially the same information as is now collected, is intended to replace the various criminal referral forms currently used by Federal bank, thrift and credit union regulatory agencies and by financial institutions. The purpose of this proposed rule is to implement the new procedures for completion and submission of the uniform criminal referral form. Appendix A of the current rule is being eliminated to avoid the necessity of updating the regulation with each change in the form. Additionally, under the new rule, descriptions of situations requiring reporting are contained in the body of the regulation rather than on the form. This action is intended to improve reporting of crimes relating to financial institutions and to provide uniform data which can be entered into the new interagency computer data base.

DATES: Comments must be received on or before March 9, 1993.

ADDRESSES: Send comments to Hoyle L. Robinson, Executive Secretary, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429. Comments may be hand-delivered to room F–400, 1776 F Street, NW., on business days between 8:30 a.m. and 5 p.m., and may be inspected in room F–457 between 8:30 a.m. and 5 p.m., on business days. (Fax number: (202) 898–3838).

FOR FURTHER INFORMATION CONTACT: Eugene Seitz, Review Examiner, Special Activities Section, Division of Supervision, (202) 898–6793, FDIC, 550 17th Street, NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act. The collection of information contained in this rule has been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) under control number 3064–0077, said clearance in effect through June 30, 1994.

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The estimated annual reporting burden for the collection of information in the regulations is summarized as follows:

Number of Respondents: 6,500.

Number of Responses Per Respondent: 1.

Total Annual Responses: 6,500.

Hours Per Response: 0.6.

Total Annual Burden Hours: 3,900.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Assistant Executive Secretary (Administration), room F–400, Federal Deposit Insurance Corporation, Washington, DC 20429, and to the Office of Management and Budget, Paperwork Reduction Project (3064–0077), Washington, DC 20503.

Background Information. The FDIC is responsible for safeguarding the safety and soundness of insured nonmember banks, including insured state-licensed branches of foreign banks.

Pursuant to the enabling statutes, the FDIC is responsible for ensuring that insured nonmember banks apprise Federal law enforcement authorities of any violation or suspected violation of a criminal statute. Fraud, abusive insider transactions, check kiting schemes, money laundering and other crimes can pose serious threats to a financial institution's continued viability and, if unchecked, may undermine the confidence in the financial services industry. The law enforcement community needs to receive timely information regarding criminal and suspected criminal activity that is sufficiently detailed to determine whether investigations and prosecutions are warranted.

An Interagency Bank Fraud Working Group (Working Group) was formed in 1984 to address problems and to promote cooperation toward the goal of improving the Federal government's response to white collar crime in financial institutions. The Working Group now consists of representatives from 12 Federal agencies, including the Federal financial institution regulatory agencies, the Federal Bureau of Investigation, the Secret Service, the Department of Justice, and the Department of the Treasury.

A subcommittee of the Working Group studied the criminal referral process and developed a new uniform criminal referral form (the Form). The purpose of the Form is to standardize criminal referral data and to facilitate its automation. The new form will take the place of the existing "short" and "long" forms, but, in substance, will require the same information.

The information contained in the criminal referral forms, and in the agencies' existing computer systems, will serve as the data base for a new computer system to be developed and maintained by the Financial Crimes Enforcement Network (FinCEN) within the Department of the Treasury. It is anticipated that the resulting interagency criminal referral data base will provide information to the FDIC, Resolution Trust Corporation (RTC), Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), the Office of Thrift Supervision (OTS), the National Credit Union Administration (NCUA), the Department of Justice and the Department of the Treasury.

Proposal. The FDIC and the other Federal financial institution regulatory agencies propose to create a single uniform criminal referral form to take the place of the existing long and short criminal referral forms. This should simplify the reporting requirements of insured nonmember banks under 12 CFR part 353. In addition, the agencies have designed the form so that the information collected can be readily entered into a new criminal referral data base to be developed and maintained by FinCEN. This system will enhance the regulatory and law enforcement agencies' ability to track information pertaining to criminal referrals made to the law enforcement agencies, as well as administrative actions taken by the Federal financial institution regulatory agencies.

Following is a section-by-section analysis showing the modifications to the existing regulation:

Section 353.0—Purpose and scope.

Only minor changes have been made in this section.

Section 353.1—Reports and records.

This section has been modified to more clearly identify the circumstances requiring reports and to add the requirement that the bank's board of directors be notified of any report filed pursuant to this section.

Appendix A—Form 6710/06 and 6710/06A, Report of Apparent Crime (Short Form and Long Form), and Instructions for Its Preparation and Filing.

Appendix A of the current rule is being eliminated to avoid the necessity of updating the regulation with each change in the form. Additionally, under the new rule, descriptions of situations requiring reporting are contained in the body of the regulation rather than on the form.

Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), the FDIC certifies that the proposed amendment will not have a significant economic impact on a substantial number of small entities. Small entities already are required to comply with the reporting requirements established in the existing regulation, and this proposed amendment only clarifies those requirements.

List of Subjects in 12 CFR Part 353

Banks, Banking, Crime, Reporting and recordkeeping requirements.

For reasons set out in the preamble, title 12, part 353, of the Code of Federal Regulations is proposed to be revised as follows:

PART 353—REPORTS OF APPARENT CRIMES AFFECTING INSURED NONMEMBER BANKS

Sec.

353.0 Purpose and scope.
353.1 Reports and records.

Authority: 12 U.S.C. 1818, 1819.

§ 353.0 Purpose and scope.

The purpose of this part is to reduce losses to insured nonmember banks resulting from criminal violations of the United States Code by requiring prompt and systematic reports by such banks of such crimes or attempted crimes. This part applies to known, attempted or suspected crimes involving or affecting the assets or affairs of insured nonmember banks. For purposes of this part, the phrase "known, attempted or suspected crimes" implies that there is a reasonable basis for believing that a crime has occurred, is occurring, or may occur. This part ensures that law enforcement authorities are notified by means of criminal referral reports when unexplained losses or known, attempted or suspected criminal acts are discovered. Based on these reports, the Federal government will take appropriate measures and will maintain an interagency data base that is derived from these reports.

§ 353.1 Reports and records.

(a) Supplies of the Interagency Criminal Referral Form (the Form) may be obtained from the FDIC regional office (Division of Supervision), which will provide, if needed, the addresses of the investigatory and prosecuting authorities with which reports required by this part are to be filed. An insured nonmember bank shall file a criminal referral report using the Form, in

accordance with the instructions for the Form, in every situation where:

(1) The insured nonmember bank suspects one of its employees, officers, directors, agents, or other institution-affiliated parties (as defined in section 3(u) of the Federal Deposit Insurance Act (12 U.S.C. 1813(u)) of having committed or aided in the commission of a crime involving the insured nonmember bank;

(2) There is an actual or potential loss to the insured nonmember bank (before reimbursement or recovery) involving $1,000 or more where the insured nonmember bank has a substantial basis for identifying a possible suspect or group of suspects and the suspect(s) is not an employee, officer, director, agent, or institution-affiliated party of the insured nonmember bank;

(3) There is an actual or potential loss to the insured nonmember bank (before reimbursement or recovery) involving $5,000 or more and where the insured nonmember bank has no substantial basis for identifying a possible suspect or group of suspects; or

(4) The insured nonmember bank suspects the existence of a monetary transaction involving the use of the insured nonmember bank as a conduit for criminal activity (such as money laundering or structuring transactions to evade the Bank Secrecy Act reporting requirements).

(b)(1) An insured nonmember bank shall file the report required by paragraph (a) of this section no later than 30 calendar days after the date of the detection of the loss or the known, attempted or suspected criminal violation or activity. If no suspect has been identified within 30 calendar days after the date of the detection of the loss or the known, attempted or suspected criminal violation or activity, reporting may be delayed an additional 30 calendar days or until a suspect has been identified; but in no case shall reporting of unidentified suspects be delayed more than 60 calendar days after the date of the detection of the loss or the known, attempted or suspected criminal violation or activity.

(2) When an insured nonmember bank detects a pattern of crimes committed by an identifiable individual, as set forth in paragraph (a)(2) of this section, the insured nonmember bank shall file a report no later than 30 calendar days after the aggregate amount of the crimes exceeds $1,000.

(3) In situations involving violations requiring immediate attention or where a reportable violation is ongoing, the insured nonmember bank shall immediately notify by telephone, or other expeditious means, the appropriate law enforcement agency and the appropriate FDIC regional office (Division of Supervision) in addition to filing a timely report.

(c) Insured nonmember banks are encouraged to file copies of the Form with state and local authorities where appropriate.

(d) An insured nonmember bank need not file the Form:

(1) For those robberies, burglaries and larcenies that are reported to law enforcement authorities and for which the insured nonmember bank maintains records under 12 CFR 326.3(a)(2)(i); and

(2) For lost, missing, counterfeit or stolen securities if a report is filed pursuant to the reporting requirements of 17 CFR 240.17f–1.

(e) An insured nonmember bank shall maintain copies of any Form that it filed and the originals of all related documents.

(f) The management of an insured nonmember bank shall promptly notify its board of directors [1] of any report filed pursuant to this section. The board of directors shall make a note of such reports in the minutes of the board of directors' meetings.

By order of the Board of Directors.

Dated at Washington, DC, this 27th day of October 1992.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 93–453 Filed 1–7–93; 8:45 am]

BILLING CODE 6714–01–M

[1] The term "board of directors" includes the managing official of an insured state-licensed branch of a foreign bank for purposes of 12 CFR 353.0–353.1.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21 and 29

[Docket No. 93–ASW–1; Notice No. SC–93–1–SW]

Special Condition: European Helicopter Industries, Ltd. Model EH–101 Helicopter, Electronic Instrument System

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed special condition.

SUMMARY: This notice proposes a special condition for the European Helicopter Industries, Ltd. Model EH–101 helicopter. This helicopter will have a novel or unusual design feature associated with the Electronic Instrument System. The applicable regulations do not contain adequate or appropriate safety standards for the protection of critical function systems from the effects of external high intensity radiated fields (HIRF). This notice contains proposed additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the airworthiness standards of part 29 of the Federal Aviation Regulations (FAR).

DATES: Comments must be submitted on or before April 8, 1993.

ADDRESSES: Submit comments in duplicate to the FAA, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–ASW–1, Forth Worth, Texas 76193–0007, or deliver in duplicate to the Office of the Assistant Chief Counsel, Building 3B, room 158, 4400 Blue Mound Road, Forth Worth, Texas.

Comments must be marked Docket No. 93–ASW–1. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 8 a.m. and 4 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Carroll Wright, FAA, Rotorcraft Standards Staff, Regulations Group, Fort Worth, Texas 76193–0111; telephone (817) 624–5120.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed special condition by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator before taking action on this proposal. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 93–ASW–1." The postcard will be date/time stamped and returned to the commenter.

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Background

European Helicopter Industries, Ltd., which consists of Westland Helicopters of England and Agusta Helicopters of Italy, submitted applications for type certificates dated September 20, 1988, to the FAA Brussels Certification Office through the Civil Airworthiness Authorities of the United Kingdom for the passenger carrying version of the EH–101 and through the Registro Aeronautico Italiano of Italy for the utility version. The passenger version is a 30 passenger, long range helicopter powered by three GE CT 7–6A engines with a maximum takeoff weight of 31,000 lbs. The utility version is a cargo or mixed passenger and cargo helicopter that differs principally from the passenger version in having a ramp door incorporated in the rear fuselage.

Type Certification Basis

The certification basis established for the Model EH–101 helicopter consists of FAR 29, including Amendments 29–1 through 29–24, and 14 CFR parts 21 and 36; Amendment 21–61 and 36–14.

If the Administrator finds that the applicable airworthiness regulations do not contain adequate or appropriate safety standards for the Model EH–101 because of novel or unusual design features, special conditions are prescribed under the provisions of § 21.16 to establish a level of safety equivalent to that established in the regulations.

Special Conditions, as appropriate, are issued in accordance with § 11.49 after public notice, as required by §§ 11.28 and 11.29(b), effective October 14, 1980, and become a part of the type certification basis, as provided by 21.101(b)(2).

Discussion

The European Helicopter Industries, Ltd. Model EH–101 helicopter, at the time of application, was identified as incorporating one and possibly more electrical/electronic systems that will be performing functions critical to the continued safe flight and landing of the helicopter. The Electronic Instrument System displays attitude, flight data, navigation data, engine, and transmission information. The display of attitude, altitude, and airspeed is critical to the continued safe flight and landing of the helicopter for instrument flight rules (IFR) operations in instrument meteorological conditions. When the design is finalized, European Industries, Ltd. will provide the FAA with a preliminary hazard analysis that will identify any other critical functions performed by electrical/electronic systems.

Recent advances in technology have given rise to the application in aircraft designs of advanced electrical/electronic systems that perform functions required for continued safe flight and landing. These advanced systems are responsive to the transient effects of induced electrical current and voltage caused by radiated fields incident on the external surface of the helicopter. These induced transient currents and voltages can degrade the performance of electrical/electronic systems by damaging the components or by upsetting the systems' functions.

Furthermore, the electromagnetic environment has undergone a transformation not envisioned by the current application of the § 29.1309(a) requirement. Higher energy levels radiate from operational transmitters that are currently used for radar, radio, and television. Also, the number of transmitters has increased significantly.

Existing aircraft certification requirements are inappropriate in view of these technological advances. In addition, the FAA has received reports of some significant safety incidents and accidents involving military aircraft equipped with advanced electrical/electronic systems when they were exposed to electromagnetic radiation.

The combined effects of the technological advances in helicopter design and the changing environment have resulted in an increased level of vulnerability of the electrical/electronic systems required for the continued safe flight and landing of the helicopter. Effective measures to protect these helicopters against the adverse effects of exposure to HIRF must be provided by the design and installation of these systems. The following primary factors contribute to this increased concern:

(1) The increasing use of sensitive electronics that perform critical functions,

(2) The reduced electromagnetic shielding afforded helicopter systems by advanced technology airframe materials,

(3) The adverse service experience of military aircraft using these technologies, and

(4) The increase in the number and power of radio frequency emitters and the expected increase in the number of these transmitters in the future.

The FAA has recognized the need for aircraft certification standards to keep pace with the developments in technology and environment and, in 1986, initiated a high priority program to (1) determine and define the electromagnetic energy levels; (2) develop and describe guidance material for design, test, and analysis; and (3) prescribe and promulgate regulatory standards. The FAA participated with industry and airworthiness authorities of other countries to develop internationally recognized standards for certification.

The FAA and airworthiness authorities of other countries have established a level of HIRF environment that a helicopter could be exposed to during IFR operations.

While the HIRF requirements are being finalized, the FAA is adopting special conditions for the certification of aircraft that employ electrical/electronic systems performing critical functions. The accepted maximum energy levels in which civilian helicopter system installations must be capable of operating safely are based on surveys and analysis of existing radio frequency emitters. This special condition will require that the helicopter's electrical/electronic systems and its associated wiring harness be protected from these energy levels. These external threat levels are believed to represent the worst-case exposure for a helicopter operating IFR.

The defined HIRF environment specified in this proposed special condition is based on many critical assumptions; among these is that, with the exception of takeoff and landing at an airport, the aircraft would be not less than 500 feet above ground level (AGL). Helicopters operating under visual flight rules (VFR) routinely operate at less than 500 feet AGL and perform takeoffs and landings at locations other than controlled airports. Therefore, it would be expected that the HIRF environment experienced by a helicopter operating VFR may exceed the given environment by 100 percent or more.

This special condition will require electrical/electronic systems that perform critical functions to meet either a defined HIRF environment or a fixed value using laboratory tests.

In order to meet a defined HIRF environment, the applicant may demonstrate that the operation and the operational capability of the installed electrical/electronic systems that perform critical functions are not adversely affected when the aircraft is exposed to the HIRF environment. The FAA has determined that the environment defined in Table I is acceptable for critical functions in helicopters operating not less than 500 feet AGL. For critical functions in helicopters operating at altitudes less than 500 feet AGL, additional factors must be considered.

The applicant may also demonstrate by a laboratory tests that the electrical/electronic systems that perform critical functions will withstand a peak

electromagnetic field strength in a frequency range of 10 KH_z to 18 GH_z. If laboratory tests are used to show compliance with the HIRF requirements, no credit would be given for signal attenuation due to installation. A level of 100 v/m and further considerations, such as an alternate technology backup immune to HIRF, are appropriate for critical functions during IFR operations. A level of 200 v/m and further considerations, such as an alternate technology backup immune to HIRF, are more appropriate for critical functions during VFR operations.

A preliminary hazard analysis must be performed by the applicant for approval by the FAA to identify electrical/electronic systems that perform critical functions. The term "critical" means those functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the helicopter. The systems identified by the hazard analysis that perform critical functions are the ones required to have HIRF protection.

A system may perform both critical and noncritical functions. Primary electronic flight display systems and their associated components perform critical functions such as attitude, altitude, and airspeed indication. The HIRF requirements would only apply to the critical functions.

Compliance with HIRF requirements will be demonstrated by tests, analysis, models, similarity with existing systems, or a combination of these methods. Service experience alone will not be acceptable since such experience in normal flight operations may not include an exposure to HIRF. Reliance on a system with similar design features for redundancy as a means of protection against the effects of external HIRF is generally insufficient since all elements of a redundant system are likely to be concurrently exposed to the fields.

The modulation should be selected for the signal most likely to disrupt the operation of the system under test, based on its design characteristics. For example, flight control systems may be susceptible to 3 H_z square wave modulation while the video signals for electronic display systems may be susceptible to 400 H_z sinusoidal modulation. If the worst-case modulation is unknown or cannot be determined, default modulations may be used. Suggested default values are a 1 KH_z sine wave with 80 percent depth of modulation in the frequency range from 10 KH_z to 400 MH_z and 1 KH_z square wave with greater than 90 percent depth of modulation from 400 MH_z to 18 GH_z.

For frequencies where the unmodulated signal would cause deviations from normal operation, several different modulating signals with various waveforms and frequencies should be applied.

Acceptable system performance would be attained by demonstrating that the critical aspects of the system under consideration continue to perform its intended function during and after exposure to required electromagnetic fields. Deviations from system specifications may be acceptable but need to be independently assessed by the FAA for each application.

TABLE 1.—FIELD STRENGTH VOLTS/METER

Frequency	Peak	Average
10–100 KH_z	50	50
100–500	60	60
500–2000	70	70
2–30 MH_z	200	200
30–70	30	30
70–100	30	30
100–200	150	30
200–400	70	70
400–700	4020	935
700–1000	1700	170
1–2 GH_z	5000	990
2–4	6680	840
4–6	6850	300
6–8	3600	670
8–12	3500	1270
12–18	3500	360
18–40	2100	750

Conclusion

This action affects only certain unusual or novel design features on one series of helicopters. It is not a rule of general applicability and affects only the manufacturer who applied to the FAA for approval of these features on the affected helicopter.

List of Subjects in 14 CFR Parts 21 and 29

Aircraft, Air transportation, Aviation safety, Rotorcraft, Safety.

The authority citation for this special condition is as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2); 42 U.S.C. 1857f–10, 4321 et seq.; E.O. 11514; 49 U.S.C. 106(g).

The Proposed Special Condition

Accordingly, the Federal Aviation Administration (FAA) proposes the following special condition as a part of the type certification basis for the European Helicopter, Ltd. Model EH–101 helicopter.

Protection for Electrical/Electronic Systems From High Intensity Radiated Fields.

Each system that performs critical functions must be designed and installed to ensure that the operation and operational capabilities of these critical functions are not adversely affected when the helicopter is exposed to high intensity radiated fields external to the helicopter.

Issued in Fort Worth, Texas, on December 11, 1992.

Henry A. Armstrong,

Acting Manager, Rotorcraft Directorate Aircraft Certification Service.

[FR Doc. 93–366 Filed 1–7–93; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 92–AWP–19]

Proposed Establishment of Transition Area; Aubrey Cliffs, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to establish a 9000 foot mean sea level (MSL) and above transition area near the Grand Canyon Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC), AZ. This transition area would provide controlled airspace for aircraft being vectored to the final approach fix at the Grand Canyon Airport.

DATES: Comments must be received on or before February 15, 1993.

ADDRESSES: Send comments on the proposal in triplicate to: Federal Aviation Administration, Attn: Manager, System Management Branch, AWP–530, Docket No. 92–AWP–19, Air Traffic Division, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009.

The official docket may be examined in the Office of the Assistant Chief Counsel, Western-Pacific Region, Federal Aviation Administration, room 6W14, 15000 Aviation Boulevard, Lawndale, CA 90261.

An informal docket may also be examined during normal business hours at the Office of the Manager, System Management Branch, Air Traffic Division at the above address.

FOR FURTHER INFORMATION CONTACT: Gene Enstad, Airspace Specialist, System Management Branch, AWP–530, Air Traffic Division, Western–Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 297–0010.

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SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with the comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 92–AWP–19." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the System Management Branch, Air Traffic Division, at 15000 Aviation Boulevard, Lawndale, California, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish a 9,000 foot Mean Sea Level (MSL) and above transition area near the Grand Canyon VORTAC, AZ. This transition area would be known as the Aubrey Cliffs transition area. This proposed transition area would provide controlled airspace for aircraft being vectored to the final approach fix at the Grand Canyon Airport. Transition areas are published in Section 71.181 of FAA Order 7400.7A, dated November 2, 1992, and effective November 27, 1992, which is incorporated by reference in 14 CFR 71.1. The transition area listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore (1) is not a "major rule" under Executive order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 10034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Incorporation by reference, Transition areas.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS, JET ROUTES, AND AREA HIGH ROUTES

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

71.1—(Amended)

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.7A, Compilation of Regulations, dated November 2, 1992, and effective November 27, 1992, is amended as follows:

Section 71.181 Designation of Transition Areas

* * * * *

AWP CA TA Aubrey Cliffs, AZ [NEW]

That airspace extending upward from 9,000 feet mean sea level (MSL) and above bounded on the north by the southern edge of Victor Airway 208/210 (V–208/210), on the east by the western edge of V–257, and on the south by the northern edge of V–291.

* * * * *

Issued in Los Angeles, California, on December 14, 1992.

Richard R. Lien,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 93–367 Filed 1–7–93; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 71

[Airspace Docket No. 91–ASW–27]

Proposed Revision of Transition Areas: Lafayette, LA; Bunkie, LA; Eunice, LA; Opelousas, LA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: This notice withdraws the Notice of Proposed Rulemaking (NPRM), Airspace Docket No. 91–ASW–27, which was published in the **Federal Register** on November 5, 1991. That notice proposed to revise the transition areas located at Lafayette, Bunkie, Eunice, and Opelousas, LA. That proposal was necessitated due to the revisions to the standard instrument approach procedures (SIAP), caused by the relocation of the Lafayette Very High Frequency Omninavigational radio Range/Tactical Air Navigation (VORTAC) to a site on the Lafayette Regional Airport.

Since the NPRM was published in the **Federal Register** on November 5, 1991, (56 FR 56481), the Terminal Airspace Reclassification Final Rule, published in the **Federal Register** August 27, 1992 (57 FR 38962), effected the necessary revisions to the transition areas to provide adequate controlled airspace for aircraft utilizing instrument approach procedures at the Lafayette Regional, Bunkie Municipal, Eunice, and Opelousas/St. Landry Parish—Ahart Field Airports, making this proposal unnecessary.

FOR FURTHER INFORMATION CONTACT: Alvin E. DeVane, System Management Branch, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530; telephone: (817) 624–5535.

The Proposed Rule

On November 5, 1991, an NPRM was published in the **Federal Register** to revise the transition areas located at Lafayette, Bunkie, Eunice, and Opelousas, LA. This proposal was necessitated due to the revisions to the SIAP's, caused by the relocation of the Lafayette VORTAC to a site on the Lafayette Regional Airport. The Terminal Airspace Reclassification Final Rule, published in the **Federal Register** August 27, 1992 (57 FR 38962), effected the necessary revisions to the transition areas, making this proposal unnecessary.

List of Subject in 14 CFR Part 71

Aviation safety, Incorporation by reference, Transition areas.

The Withdrawal

Accordingly, pursuant to the authority delegated to me, the NPRM, Airspace Docket No. 91–ASW–27, as published in the **Federal Register** on November 5, 1991 (56 FR 56481), is hereby withdrawn.

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

Issued in Forth Worth, TX on December 15, 1992.

Larry L. Craig,

Manager, Air Traffic Division Southwest Region.

[FR Doc. 93–369 Filed 1–7–93; 8:45 am]

BILLING CODE 4910–13–M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 270

[Release No. IC–19204, International Series Release No. 517; File No. S7–1–93]

RIN 3235–AE47

Exemption of Acquisitions of Securities Issued by Persons Engaged in Securities Related Businesses

AGENCY: Securities and Exchange Commission.

ACTION: Proposed rule amendments and request for comment.

SUMMARY: The Commission is publishing for comment proposed rule amendments that would eliminate a number of conditions that today must be for acquisitions by a registered investment company of the securities of securities related businesses, both domestic and foreign, thus simplifying the conditions for exemptive relief that would be required to be met under the rule. The revised rule amendments would provide investment companies more flexibility in making such acquisitions and would permit companies to pursue a broader range of investment objectives.

DATES: Comments must be received on or before March 9, 1993.

ADDRESSES: Comments should be submitted in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. All comment letters should refer to File No. S7–1–93. All comments received will be available for public inspection and copying in the Commission's Public Reference Room, 450 Fifth Street, NW., Washington, DC 20549.

FOR FURTHER INFORMATION CONTACT: L. Bryce Stovell, Senior Special Counsel, or Diane Blizzard, Deputy Chief, both at (202) 272–2048, Office of Regulatory Policy, Division of Investment Management, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: The Commission is seeking public comment on revised proposed amendments to rule 12d3–1 (17 CFR 270.12d3–1) under the Investment Company Act of 1940 (15 U.S.C. 80a). These amendments would eliminate certain "qualitative" conditions that the rule now imposes on acquisitions by registered investment companies, and companies they control, of the securities of businesses engaged in securities related activities, both domestic and foreign. The rule, however, would continue not to exempt a registered investment company's acquisition of a general partnership interest, or of any security issued by the investment adviser, promoter, or principal underwriter of the company, or any affiliated person of such adviser, promoter, or underwriter. In addition, the rule would retain certain "quantitative" conditions on investments in securities related businesses.

Executive Summary

Section 12(d)(3) (15 U.S.C. 80a–12(d)(3)), with limited exceptions, prohibits a registered investment company and companies it controls from acquiring any security of, or any other interest in, a securities related business, such as a broker, dealer, underwriter, or investment adviser. Rule 12d3–1 exempts certain acquisitions. Businesses that have derived fifteen percent or less of their gross revenues in their most recent fiscal year from securities related activities are deemed by the rule not to be securities related businesses. Acquisitions of securities issued by businesses that exceed the fifteen percent limitation are exempt under the rule provided that the acquisition meets certain "qualitative" conditions: The securities acquired, if equity securities, must be "margin securities" under Federal Reserve Board Regulation T (17 CFR 220.1) or, if debt securities, must be investment grade as determined by the acquiring company's board of directors. In addition, such acquisitions must meet "quantitative" conditions; they must involve not too large a percentage of the acquiring company's assets, or of the acquired business' equity or debt securities.

The rule, however, does not exempt the acquisition of a general partnership interest in a securities related business, or any security issued by an investment adviser, promoter, or principal underwriter of the acquiring company or any affiliated person thereof.

In 1989, the Commission proposed amendments to rule 12d3–1 that were designed to facilitate the acquisition of the equity securities of foreign securities related businesses by registered investment companies.[1] The amendments provided alternative conditions for the equity securities of foreign securities related businesses that could not meet the qualitative "margin securities" requirement of rule 12d3–1 in its current form. While all five commenters on the proposed rule amendments generally supported the Commission's initiative to ease the rule's requirements, they criticized the specific qualitative conditions.

In response to the comments, the Commission has re-examined the conditions of rule 12d3–1 in light of the purposes underlying section 12(d)(3), and changes in the manner in which the securities business has been conducted, both in the United States and in foreign countries, since 1940. As a result of this re-examination, the Commission is proposing revised amendments to rule 12d3–1 that would greatly simplify the rule. The revised proposed amendments would eliminate entirely the qualitative conditions of the rule. The qualitative conditions primarily reflected a concern with certain risks of investments in securities related businesses which, we believe, is adequately addressed by the requirement that a registered investment company may not purchase a general partnership interest in a securities related business. To a lesser extent, the qualitative conditions also reflected an

[1] See Acquisitions by Registered Investment Companies of the Equity Securities of Foreign Securities Firms, Investment Company Act Release No. 17096 (Aug. 3, 1989) [54 FR 33027, Aug. 11, 1989] ("1989 Proposal").

attempt to minimize any harm that could occur through the risks of reciprocal practices and conflicts of interest The Commission believes that such risks may be addressed adequately by the quantitative conditions, by the condition prohibiting the acquisition of any security issued by persons with certain business relationships with the acquiring company, and by existing disclosure requirements for registered investment companies.

I. Background

Section 12(d)(3) makes it unlawful for any registered investment company and any company or companies controlled by such registered investment company to purchase or otherwise acquire any security issued by or any other interest in the business of any person who is a broker, a dealer, is engaged in the business of underwriting, or is either an investment adviser of an investment company or an investment adviser registered under the Investment Advisers Act of 1940.[2]

Rule 12d3–1 provides a conditional exemption from section 12(d)(3). The rule exempts purchases of the securities of any entity that derived fifteen percent or less of its gross revenues from securities related activities[3] in its most recent fiscal year, unless the acquiring company would control the person after the acquisition.[4] The rule also exempts acquisitions of the securities of a person that derived more than fifteen percent of its gross revenues from securities related activities in its most recent fiscal year, if certain qualitative and quantitative conditions are met.

The qualitative conditions differ depending on whether the security to be acquired is an equity security or a debt security. Any equity security must, at the time of acquisition, be a "margin security" as defined in Regulation T promulgated by the Board of Governors of the Federal Reserve System.[5] Any debt security of the issuer must, at the time of acquisition, be investment grade as determined by the acquiring company's board of directors.[6]

Under the quantitative conditions, immediately after the acquisition the acquiring company may own not more than five percent of any class of the issuer's equity securities, nor more than ten percent of the outstanding principal amount of the issuer's debt securities.[7] In addition, immediately after the acquisition the acquiring company may have invested not more than five percent of the value of its total assets in the securities of an issuer.[8]

Certain other conditions apply to any acquisition, even where an issuer is engaged in only a limited amount of securities related activities. The rule does not exempt the acquisition of a general partnership interest in a securities related business, nor does it exempt the acquisition of any security issued by the company's investment adviser, promoter, or principal underwriter or any affiliated person of such investment adviser, promoter, or principal underwriter that is a securities related business (unless otherwise permitted under sections 12(d)(3) (A) and (B)).[9]

The Commission's 1989 proposal attempted to address the situation of registered investment companies that wished to acquire the equity securities of foreign securities firms by providing an alternative to the qualitative condition that any equity security be a margin security at the time of acquisition. This requirement in most cases would not have been met by the equity securities of foreign securities firms. The proposed amendments sought to permit such acquisitions by allowing acquiring companies to comply with the margin security requirement, or with a substitute set of criteria patterned after the margin requirements but tailored to foreign markets. These criteria related to the nature of the equity security, its issuer, and the market for the security.

First, the proposed amendments would have imposed alternative conditions related to the security's marketability, requiring, among other things, the equity security to have been listed on an exchange for at least six months prior to the acquisition.

Second, the proposed amendments would have required that the issuer of the equity security have made public all information that was required to make public in its home country since the beginning of its last fiscal year, and have filed with any stock exchange on which its securities were traded the filings required by that exchange during that period. The proposed amended rule set out several other conditions concerning the nature of the equity security, its issuer, and the market in which the security was traded.

Third, the proposed amendments would have required that an equity security of a foreign securities related business be listed on a "qualified foreign exchange" meeting certain requirements as to structure, size, and stability. For example, to assure a depth of market comparable to that of United States national securities exchanges, the qualified foreign exchange would have been required to have had an annual trading volume in stocks totalling at least $7.5 billion in the year preceding the acquisition.

All five commenters on the 1989 proposal generally supported the Commission's initiative, but argued that several of the proposed conditions would be burdensome and unworkable. Some argued that the Commission should not impose any specific qualitative conditions. In response, the Commission has re-examined the scope of the proposal in light of the purposes of section 12(d)(3) and now proposes to delete the qualitative conditions.

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[2] These prohibitions do not apply to the acquisition of the securities of a corporation all the outstanding securities of which (other than short-term paper, securities representing bank loans, and directors qualifying shares) are, or after such acquisition will be, owned by one or more registered investment companies, if such corporation is primarily engaged in the business of underwriting and distributing securities issued by other persons, selling securities to customers, or any one or more of such or related activities, and the gross income of such person normally is derived principally from such business or related activities. *See* sections 12(d)(3)(A), (B) (15 U.S.C. 80a–12(d)(3)(A), –12(d)(3)(B). Thus, section 12(d)(3) does not prohibit an investment company from acquiring securities of a wholly-owned underwriting subsidiary.

[3] Rule 12d3–1(d)(1) defines "securities related activities" as a person's activities as a broker, as a dealer, from the business of underwriting, as an investment adviser registered under the Investment Advisers Act of 1940, as amended, or as an investment adviser to a registered investment company.

[4] Rule 12d3–1(a).

[5] Rule 12d3–1(b)(4). In 1990, Regulation T was amended to permit the marginability of certain foreign equity and debt securities. *See* Credit by Brokers and Dealers; Accommodation of Settlement and Clearance of Foreign Securities, 55 FR 11158 (Mar 21, 1990). Under these amendments, foreign equity securities are eligible for margin treatment if they have been traded for at least six months on an exchange or in a recognized foreign securities market and if they meet certain requirements as to availability of price information, market value, trading volume and the like. Foreign debt securities are marginable if they meet certain criteria as to size of the original issue, if the issue is not in default as to payments of principal or interest, and if the issue meets certain rating criteria.

[6] Rule 12d3–1(b)(5).

[7] *See* rule 12d3–1(b)(1) and (b)(2).

[8] *See* rule 12d3–1(b)(3). The quantitative conditions of rule 12d3–1 are derived from the proviso in a predecessor rule, rule 12d–1, that the registered investment company and certain related companies together own no more than 10% of the total outstanding voting stock of, or proprietary interest in, a company engaged in securities related activities. *See* Conditional Exemption of Certain Purchases or Acquisitions of Securities from the Prohibitions of section 12(d)(3) of the Investment Company Act of 1940, Investment Company Act Release No. 4044 (Sept. 4, 1964) (29 FR 12915, Sept. 15, 1964) (adopting rule 12d–1).

[9] Rule 12d3–1(c). The exemption for acquisitions of the securities of a wholly-owned underwriting subsidiary in sections 12(d)(3) (A) and (B) is discussed *supra* note 2.

II. Discussion

A The Purposes of Section 12(d)(3)

While the reasons for Congress prohibiting investment company investments in securities related businesses are not addressed in much detail in the Act's legislative history, it appears that Congress had two purposes. First, Congress wished to limit, at least to some extent, the exposure of registered investment companies to entrepreneurial risks peculiar to securities related businesses. In 1940, securities related businesses, for the most part, were organized as privately held general partnerships. By investing in such businesses, investment companies exposed themselves to potential losses which were not present in other types of investments, if the business failed, the investment company as a general partner was held accountable for the partnership's liabilities.[10]

A second purpose appears to have been to prevent potential conflicts of interest and reciprocal practices. Section 12(d) also contains restrictions on the ownership of one investment company by another, as well as on the ownership of insurance companies by registered investment companies. The provisions of the section generally are intended to prevent "pyramiding" and other cross-control situations which might result in investment companies being organized, operated, managed, or their portfolio securities selected in the interests of brokers, dealers, underwriters, and investment advisers, whether or not these entities are affiliated persons of the companies.[11] The practical effect of the section is to eliminate the possibility of certain conflicts of interest and reciprocal practices between investment companies and securities related businesses.

As a result of its re-examination of section 12(d)(3)'s purposes, the Commission is now proposing more extensive changes than in 1989, based on our belief that the qualitative conditions of rule 12d3–1 are not necessary to ensure that the rule is consistent with Congress's intent in enacting the section. The revised amendments would eliminate the qualitative conditions. The reasons for and the effects of these changes are discussed more fully below.

B Elimination of the Qualitative Conditions of Rule 12d3–1

The qualitative conditions (subparagraphs (b)(4) and (b)(5)) require that the securities being acquired by the registered investment company be margin securities, if equity, or investment grade, if debt. These conditions were included in rule 12d3–1 in 1984 primarily to address a perceived Congressional concern with certain investment risks associated with securities issued by securities related businesses.[12] In addition, the Commission stated that placing a floor on the "quality" of securities that could be acquired by an investment company would lessen the harm from investment company—broker-dealer reciprocal practices.[13]

The Commission now believes that, in light of changes in the ownership structure of most securities related businesses since 1940, the concern regarding the unusual risks of investment in such businesses is adequately addressed by prohibiting the acquisition of general partnership interests. Today, many if not most securities firms are organized not as general partnerships but in corporate form. Aside from general partnership interests, investments in securities issued by securities related business need not be subject to any special standards not applicable to investments in other businesses, except to address the potential for conflicts of interest and reciprocal practices.[14]

The Commission believes that the risks of conflicts of interest and reciprocal practices are adequately addressed by the other conditions of rule 12d3–1. Such risks are greatest when an investment company acquires the securities of a securities related business that performs a significant level of services for the investment company or where the investment company has a large investment in the securities related business. Accordingly, the Commission proposes to retain the condition that provides that the rule does not exempt an investment company's acquisition of any security issued by its investment adviser, promoter, or principal underwriter, or any affiliated person of such investment adviser, promoter, or principal underwriter. In addition, the Commission proposes to retain the quantitative conditions of the rule, which minimize the potential for conflicts of interest and reciprocal practices by preventing an investment company from acquiring a significant stake in any particular broker or dealer. The Commission, however, requests comment on whether the quantitative conditions are necessary to effectuate the purposes of section 12(d)(3) or whether the concerns about reciprocal practices could be addressed by other conditions.[15]

Any investment company that acquires securities issued by securities related businesses would be subject to the disclosure provisions in various registration forms under the Act that require that an investment company disclose acquisitions of the securities of its "regular brokers or dealers."[16] In

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[10] In testimony before Congress, a Commission representative testified to the effect that the Commission had concerns about subjecting all the assets of the investment trust to the risks of the underwriting business, but that the Commission did not see any difficulty if the trusts availed themselves of the corporate fiction and limited their liabilities to the amount of money they wanted to invest. Accordingly, the representative noted that there would not be a problem if an investment trust went into the underwriting business through a wholly owned subsidiary *See Investment Trusts and Investment Companies: Hearing before a Subcomm. of the Senate Comm. on Banking and Currency*, 76th Cong., 3rd. Sess. 243 (1940) (testimony of David Schenker Chief Counsel, Investment Trust Study).

[11] *See* Pacific Coast Mortgage Co., 22 SEC 832 (1946), in which the Commission expressed its view that section 12(d)(3) is obviously intended to prevent operating investment companies from engaging in diverse financial activities in conjunction with persons other than investment companies.

[12] Exemption for Acquisitions by Registered Investment Companies of Securities Issued by Persons Engaged Directly or Indirectly in Securities Related Businesses, Investment Company Act Release No. 14036 (July 13, 1984) (49 FR 29362 (July 20, 1984) ("Congress in prohibiting investment in securities related businesses under section 12(d)(3) was apparently concerned, among other things, with an investment company's maintaining the liquidity of its portfolio").

[13] *Id.* at no. 4.

[14] Obviously, a margin security or an investment grade debt instrument generally will be more liquid than a security that does not meet those standards, but this will be true regardless of the nature of an issuer's business. In any event, the liquidity requirements for registered investment companies exist independently from the provisions of section 12(d)(3) and elimination of the qualitative conditions would not implicate the overall liquidity requirements for investment companies. *See* Guide 4 to Form N–1A, Revision of Guidelines to Form N–1A, Investment Company Act Release No. 18612 (March 12, 1992), 57 FR 9828 (stating that the usual limit on aggregate holdings of illiquid assets by an open-end company is fifteen percent of its net assets).

[15] The Commission recently received an application for exemption from section 12(d)(3) for a unit investment trust that, among other things, seeks to invest more than five percent of its assets in equity securities issued by unaffiliated securities related businesses. *See* Defined Asset Funds—Equity Income Fund, Select Ten Portfolio (File 812–8134). Arguably, the threat of reciprocal practices is minimized in the case of unit investment trusts, which are not managed.

[16] Forms N–1A, N–2, N–3, N–5, N–8B–2, and N–8B–4 each require the investment company to disclose its acquisitions of securities of its regular brokers or dealers as defined in rule 10b–1 (17 CFR 270.10b–1), or their parents. Rule 10b–1 defines regular broker or dealer to mean one of the ten brokers or dealers that received the greatest dollar

Continued

addition, investment companies are required to disclose acquisitions of the securities of their regular brokers or dealers semi-annually on Form N–SAR.[17] Form N–SAR requires investment companies to list the name of any of their regular brokers or dealers or the parents of such brokers or dealers (if such parents derived more than fifteen percent of their gross revenues from securities related activities) whose securities they owned at the end of the current period. By alerting the Commission and existing and prospective investors to possible conflicts of interest, these disclosures would provide a check against the conflicts of interest arising from investment company ownership of the securities of the company's significant brokers or dealers.

The effect of the elimination of qualitative conditions for investment in securities-related businesses would be to permit a broader range of discretion to portfolio managers of registered investment companies. Among other things, it would permit them to invest more freely in the securities of foreign securities related businesses, and thus would respond to the criticisms voiced in the comment letters concerning the conditions in the 1989 proposal. It also would remove a requirement that company directors determine that debt securities issued by securities related businesses are investment grade, enabling directors to focus their attention on more critical issues.[18]

In connection with the proposed elimination of the qualitative conditions, the Commission is proposing to restate certain of the conditions of the rule. These changes are intended to improve the clarity of the rule; they are not intended to effect any substantive changes.

III. Cost/Benefit of Proposed Action

The revised proposed rule amendments would benefit acquiring companies by facilitating acquisitions of the securities of domestic and foreign securities related businesses. In particular, by omitting the margin security requirement, the revised proposed rule amendments would remove the most significant obstacle to acquiring the equity securities of foreign securities related businesses. In addition, the boards of directors of acquiring companies no longer would have to determine that debt securities issued by securities related businesses are investment grade. The Commission would benefit because its staff would have to review fewer applications for exemption in this area.

IV. Summary of Initial Regulatory Flexibility Analysis

The Commission has prepared an Initial Regulatory Flexibility Analysis in accordance with 5 U.S.C. 603 regarding the revised proposed amendments. The Analysis explains that the revised proposed amendments are intended to simplify rule 12d3–1, by eliminating conditions that are unnecessary, in light of the Congressional purposes underlying section 12(d)(3), to permissible investment company acquisitions of the securities of securities related businesses. The Analysis states that the proposed amendments provide flexibility and investor protection in a way that should minimize any impact on, or cost to, small business. A copy of the Initial Regulatory Flexibility Analysis may be obtained from L. Bryce Stovall, at Mail Stop 10–6, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

V. Statutory Authority

The Commission is proposing the amendments to rule 12d3–1 pursuant to sections 6(c) and 38(a) of the Act (15 U.S C. 80a–6(c), –37(a)). The authority citations for these actions precede the text of the actions.

List of Subjects in 17 CFR Part 270

Investment companies, Reporting and recordkeeping requirements, Securities.

Text of Proposed Rule Amendments

For the reasons set out in the preamble, the Commission is proposing to amend chapter II, title 17 of the Code of Federal Regulations as follows:

PART 270—RULES AND REGULATIONS, INVESTMENT COMPANY ACT OF 1940

1. The general authority citation for part 270 is revised to read as follows:

Authority: 15 U.S.C. 80a–1 *et seq*, unless otherwise noted;

2. Section 270.12d3–1 is revised to read as follows:

§ 270.12d3–1 Exemption of acquisitions of securities issued by persons engaged in securities related businesses.

(a) Notwithstanding section 12(d)(3) of the Act, a registered investment company, or any company or companies controlled by such registered investment company ("acquiring company") may acquire any security issued by any person that, in its most recent fiscal year, derived 15 percent or less of its gross revenues from securities related activities unless the acquiring company would control such person after the acquisition.

(b) Notwithstanding section 12(d)(3) of the Act, an acquiring company may acquire any security issued by a person that, in its most recent fiscal year, derived more than 15 percent of its gross revenues from securities related activities, *provided that*.

(1) Immediately after the acquisition of any equity security, the acquiring company owns not more than five percent of the outstanding securities of that class of the issuer's equity securities;

(2) Immediately after the acquisition of any debt security, the acquiring company owns not more than ten percent of the outstanding principal amount of the issuer's debt securities; and

(3) Immediately after any such acquisition, the acquiring company has invested not more than five percent of the value of its total assets in the securities of the issuer.

(c) Notwithstanding paragraphs (a) and (b), this section does not exempt the acquisition of a general partnership interest or a security issued by the acquiring company's investment adviser, promoter, or principal underwriter, or any affiliated person of such investment adviser, promoter, or principal underwriter.

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amount of brokerage commissions by virtue of direct or indirect participation in the company's portfolio transactions during the company's most recent fiscal year; one of the ten brokers or dealers that engaged as principal in the largest dollar amount of portfolio transactions of the investment company during the company's most recent fiscal year; or one of the ten brokers or dealers that sold the largest dollar amount of securities of the investment company during the company's most recent fiscal year.

In particular the investment company must identify each such broker or dealer and state the value of its aggregate holdings. Each of these registration forms also provides that the registrant need only disclose information with respect to an issuer that derived more than 15% of its gross revenues from the business of a broker, a dealer, an underwriter, or an investment adviser during its most recent fiscal year

[17] Form N–SAR is the combined reporting form used for semi-annual and annual reports by all investment companies that have filed a registration statement that has become effective under the Securities Act of 1933 (15 U.S.C. 77a).

[18] In the Division of Investment Management's report on investment company regulation, the Division recommended that several rules under the Act, including rule 12d3–1, be amended to eliminate inappropriate burdens on investment company directors. Division of Investment Management, SEC, *Investment Company Governance*, Protecting Investors: A Half Century of Investment Company Regulation (1992). The proposed amendments would effect that recommendation with respect to rule 12d3–1 The Commission proposed amendments to rules 10f–3, 17a–7, 17e–1 17f–4, and 22c–1 in Investment Company Release No. 19192 (Dec. 30, 1992).

(d) For purposes of this section,

(1) "Securities related activities" are a person's activities as a broker, a dealer, an underwriter, an investment adviser registered under the Investment Advisers Act of 1940, as amended, or as an investment adviser to a registered investment company.

(2) An issuer's gross revenues from its own securities related activities and from its ratable share of the securities related activities of enterprises of which it owns 20 percent or more of the voting or equity interest should be considered in determining the degree to which an issuer is engaged in securities related activities. Such information may be obtained from the issuer's annual report to shareholders, the issuer's annual reports or registration statement filed with the Commission, or the issuer's chief financial officer.

(2) "Equity security" is as defined in § 240.3a–11 of this chapter.

(4) "Debt security" includes all securities other than equity securities.

(5) Determination of the percentage of an acquiring company's ownership of any class of outstanding equity securities of an issuer shall be made in accordance with the procedures described in the rules under § 240.16 of this chapter (17 CFR part 240)

(6) Where an acquiring company is considering acquiring or has acquired options, warrants, rights, or convertible securities of a securities related business, the determination required by paragraph (b) of this section shall be made as though such options, warrants, rights, or conversion privileges had been exercised.

(7) The following transactions will not be deemed to be an acquisition of securities of a securities related business:

(i) Receipt of stock dividends on securities acquired in compliance with this section;

(ii) Receipt of securities arising from a stock-for-stock split on securities acquired in compliance with this section;

(iii) Exercise of options, warrants, or rights acquired in compliance with this section;

(iv) Conversion of convertible securities acquired in compliance with this section; and

(v) Acquisition of puts, as defined in § 270.2a–7(a)(12), provided that, immediately after the acquisition of any put, the company will not, with respect to seventy-five percent of the total value of its assets, have invested more than five percent of the total value of its assets in securities underlying puts from the same institution. An unconditional put shall not be considered a put from that institution, *provided that,* the value of all securities issued or guaranteed by the same institution and held by the investment company does not exceed ten percent of the total value of the company's assets. For purposes of this section, a put will be considered to be from the party to whom the company will look for payment of the exercise price and an unconditional put, as defined in § 270.2a–7(a)(19), will be considered to be a guarantee of the underlying security or securities.

(8) Any class or series of an investment company that issues two or more classes or series of preferred or special stock, each of which is preferred over all other classes or series with respect to assets specifically allocated to that class or series, shall be treated as if it is a registered investment company.

Note: It is not intended that this rule should supersede the requirements prescribed in Investment Company Act Release No. 13005 (Feb. 2, 1983) with respect to repurchase agreements with brokers or dealers.

Dated: January 4, 1993.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–391 Filed 1–7–93; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 290

[Notice No. 764; Re. Notice No. 754]

RIN 1512–AA03

Reopening of Comment Period on Revision of Regulations for Exportation of Tobacco Products and Cigarette Papers and Tubes, Without Payment of Tax, or With Drawback of Tax

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Advance notice of proposed rulemaking; reopening of comment period.

SUMMARY: This notice announces the reopening of the written comment period for Notice 754, an advance notice of proposed rulemaking (ANPRM) published in the **Federal Register** on September 8, 1992. In Notice No. 754, ATF proposed the revision and recodification of the regulations pertaining to the exportation of tobacco products and cigarette papers and tubes. As a result of recent changes in Customs regulations regarding duty-free stores and the potential impact on the exportation of tobacco products, industry members have requested that AFT reopen the comment period to provide sufficient time to coordinate and submit comments.

DATES: Comments must be filed on or before March 9, 1993.

ADDRESSES: Send written comments to: Chief, Distilled Spirits and Tobacco Branch, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, DC 20091–0221; ATTN: Notice No. 754.

FOR FURTHER INFORMATION CONTACT: Mary A. Wood, Distilled Spirits and Tobacco Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, telephone (202) 927–8210.

SUPPLEMENTARY INFORMATION:

Background

On September 8, 1992, ATF published Notice No. 754, an advance notice of proposed rulemaking, in the **Federal Register** (57 FR 40889). In this notice ATF solicited comments on its proposal to update and reissue the regulations pertaining to the exportation of tobacco products and cigarette papers and tubes. ATF is planning to revise the regulations now contained in 27 CFR part 290, and reissue the revised regulations as part 44 of the same chapter. The comment period for Notice No. 754 closed on October 8, 1992.

On August 20, 1992, the U.S. Customs Service published T.D. 92–81 which gave approximately 125 duty-free stores official status as Class 9 Customs Bonded Warehouses (CBW's). As such they could receive domestic tobacco products for export. The regulations in Part 290 have no provisions for the exportation of domestic tobacco products through Class 9 CBW's. On October 16, 1992, Customs published a notice delaying indefinitely the effective date of T.D. 92–81 Industry members have advised us of their need to consider these matters further before they could comment on any changes to Part 290.

In consideration of this request, ATF has determined that, in addition to the 30 days already allowed, an extension of an additional 60 days is appropriate. Therefore, the comment period has been reopened until March 9, 1993.

Drafting Information

The principal authors of this document are Mary A. Wood and Daniel J. Hiland of the Distilled Spirits and Tobacco Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 290

Administrative practice and procedure, Aircraft, Authority delegations (Government agencies), Cigarette papers and tubes, Claims, Customs duties and inspection, Excise taxes, Exports, Foreign trade zones, Labeling, Packaging and containers, Penalties, Surety bonds, Tobacco products, Vessels, Warehouses.

Authority

This notice is issued under the authority in 26 U.S.C. 7805.

Signed: January 4, 1993.

Stephen E. Higgins,

Director.

[FR Doc. 93-377 Filed 1-17-93; 8:45 am]

BILLING CODE 4810-31-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 840 and 842

RIN 1029-AB60

Surface Coal Mining and Reclamation Operations; Initial and Permanent Regulatory Programs; Abandoned Sites

AGENCY: Office and Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; extension of public comment period and rescheduling of date for public hearing.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the U.S. Department of the Interior (DOI) extends until February 22, 1993, the public comment period on the proposed rule published in the December 18, 1992 **Federal Register** (57 FR 60410). Further, the date of the public hearing is being rescheduled. The proposed rule would amend OSM's regulations governing the inspection of surface coal mining and reclamation operations to change the minimum inspection frequency for minesites defined as "abandoned sites" under the existing regulations.

DATES: *Written Comments:* OSM will accept written comments on the proposed rule until 5 p.m. Eastern time on February 22, 1993.

Public Hearings: Upon request, OSM will hold a public hearing on the proposed rule in Washington, DC on February 10, 1993. Upon request, OSM will also hold public hearings in the States of California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington at times and dates to be announced prior to the hearings. OSM will accept requests for public hearings until 5 p.m. on January 19, 1993. Individuals wishing to attend, but not testify at the hearing should contact the person identified under **FOR FURTHER INFORMATION CONTACT** beforehand to verify that the hearing will be held.

ADDRESSES: *Written Comments:* Hand deliver to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 660, 800 North Capitol St., Washington, DC; or mail to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, room 660 NC, 1951 Constitution Avenue NW., Washington, DC 20240.

Public Hearings: Department of the Interior Auditorium, 18th and C Streets NW., Washington, DC. The addresses for any hearings scheduled in the States of California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington will be announced prior to the hearings.

Request for Public Hearings: Submit orally or in writing to the person and address specified under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Daniel Stocker, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Avenue NW., Washington, DC 20240: Telephone: 202-208-2550 (Commercial or FTS).

SUPPLEMENTARY INFORMATION: OSM published a proposed rule on December 18, 1992 (57 FR 60410), that would amend its regulations governing the inspection of surface coal mining and reclamation operations to change the minimum inspection frequency for minesites defined as "abandoned sites" under the existing regulations. An abandoned site is an incompletely reclaimed surface coal mining and reclamation operation where mining and reclamation activities have permanently ceased. In most instances the operators of these sites have filed for bankruptcy or can not be located and either will not or can not comply with corrective measures ordered in State or Federal enforcement actions which mine inspectors have issued to compel abatement of violations of environmental performance standards or to compel completion of reclamation obligations. The proposed revisions would enable regulatory authorities to eliminate a significant number of ineffective inspections which waste inspection resources and thus, would allow the regulatory authorities to redirect those resources to operations where inspection and enforcement would achieve intended results.

The comment period for the proposed rule was scheduled to close on January 19, 1993. However, in order to provide more time for interested persons to comment on the proposed rule, OSM is extending the comment period. Comments will now be accepted until 5 p.m. local time on February 22, 1993. The date of the public hearing in Washington, DC, if one is requested, has been rescheduled for February 10, 1992. OSM will accept requests for public hearings until 5 p.m. on January 19, 1993. Individuals wishing to attend, but not testify at the hearing should contact the person identified under **FOR FURTHER INFORMATION CONTACT** beforehand to verify that the hearing will be held.

Dated: January 4, 1993.

Brent Wahlquist,

Assistant Director, Reclamation and Regulatory Policy.

[FR Doc. 93-320 Filed 1-7-93; 8:45 am]

BILLING CODE 4310-05-M

Notices

Federal Register
Vol. 58, No. 5
Friday, January 8, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

[CN 92-006]

Proposal to Re-establish the National Advisory Committee on Cotton Marketing

AGENCY: Office of the Secretary, USDA.

ACTION: Proposal to re-establish the National Advisory Committee on Cotton Marketing.

SUMMARY: The U.S. Department of Agriculture (USDA) proposes to re-establish the advisory committee on cotton marketing to review federal programs administered by USDA that impact on the cotton marketing system and to recommend ways of improving their effectiveness and efficiency.

DATES: Comments must be received by January 15, 1993.

ADDRESSES: Send written comments to: Jesse F. Moore, Director, Cotton Division, AMS, USDA, P.O. Box 96456, Washington, DC 20090-6456.

FOR FURTHER INFORMATION CONTACT: Jesse F. Moore, (202) 720-3193.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (Pub. L. No. 92-463), notice is hereby given that the Secretary of Agriculture intends to re-establish the National Advisory Committee on Cotton Marketing. The purpose of the committee is to review the cotton marketing system and to make recommendations to improve its effectiveness and efficiency, with special emphasis on Federal programs administered by USDA, which impact on the marketing system. Great strides were made in this regard during the previous two terms of this committee, but dramatic changes in the marketing system continue to develop. The input of all cotton industry segments represented on the advisory committee remains necessary to relate effectively USDA policy to the rapidly changing marketing system.

The Secretary has determined that the work of the committee is in the public interest and is in connection with the duties of USDA. No other advisory committee in existence is capable of advising and assisting the Department on the task assigned, nor does the Department have an alternate means to obtain the technical and practical expertise needed from private industry.

Balanced committee membership will be continued through appointment by the Secretary of Agriculture of one grower representative from each of the four general areas of cotton production and two representatives each from the ginner, cooperative, merchant, manufacturer and academic/research segments of the industry. One alternate member for every two regular members will also be appointed. Each member will have one vote.

Equal opportunity practices, in line with USDA policies, will be followed in all appointments to the committee. To ensure that the recommendations of the committee have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

Dated: January 4, 1993.

Charles R. Hilty,

Assistant Secretary for Administration.

1. Purpose

a. The National Advisory Committee on Cotton Marketing is hereby re-established. The purpose of the committee is to review the Federal programs administered by the U.S. Department of Agriculture (USDA) that impact on the cotton marketing system and to recommend ways of improving their effectiveness and efficiency. Much progress was made in the previous two terms of this committee, but ongoing changes in cotton marketing as a result of technological advancements in textile manufacturing, changes in grade standards and methods of measuring quality, the establishment of premiums and discounts for additional quality factors under the price support program, and other factors create the need to continue the review.

b. USDA must communicate with and obtain the cooperation and expertise of the cotton industry in conducting the review. The re-establishment of this committee is the most effective means to that end.

2. Special Instructions/Cancellations

The functions of this committee cannot be completed in less than two years. No other existing committee can complete the review function. In accordance with the regulations for Federal advisory bodies, the committee, unless renewed, shall terminate two years from the date of appointment. This regulation will expire two years from the date of signing.

3. Membership

a. Committee members shall be appointed by the Secretary of Agriculture for the two-year life of the committee. Membership shall consist of one grower from each of the four general areas of production and two representatives each from the ginner, cooperative, warehouse, merchant, manufacturer, and academic/research areas. One alternate member for every two regular members shall also be appointed.

b. Equal Opportunity practices in accordance with USDA policies will be followed in all appointments to the committee. To ensure that the recommendations of the committee have taken into account the needs of the diverse groups served by the Department, membership shall include, to the extent practicable, individuals with demonstrated ability to represent minorities, women, and persons with disabilities.

c. The Director of the Cotton Division, Agricultural Marketing Service (AMS) shall serve as Executive Secretary.

4. Duties

a. The committee shall review the federal programs administered by USDA that impact on the cotton marketing system and recommend ways of improving their effectiveness and efficiency. The review will include but will not be limited to the cotton classification program, cotton standards, spot quotations, and the establishment of quality factors for price support loan purposes.

b. The committee reports to the Secretary of Agriculture through the Administrator of AMS and the Administrator of ASCS.

c. The disposition of the recommendations shall be the sole responsibility of the Department, in accordance with Federal laws and regulations.

5. Estimated Annual Operating Cost

a. Members shall serve without pay, but with reimbursement of travel costs and per diem for attendance at committee meetings.

b. Annual operating costs are estimated at $33,000. Federal staff support is estimated at 0.5 staff years.

c. The estimate of costs is based on an assumption that two meetings will be held during the two-year life of the committee. These costs shall be paid from user fees for classification services collected from cotton growers under the Cotton Statistics and Estimates Act (7 U.S.C. 473a), as amended by Public Law 102–37.

6. Number and Frequency of Meetings

The Advisory Committee on Cotton Marketing will meet once annually, or as often as the Secretary deems necessary. All meetings are open to the public.

7. Administrative/Support

Support to the committee will be provided by the Agricultural Marketing Service (AMS) and the Agricultural Stabilization and Conservation Service (ASCS).

[FR Doc. 93–398 Filed 1–7–93; 8:45 am]

BILLING CODE 3410-02-M

Agricultural Marketing Service

[TR–93–01]

Program Continuation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice inviting applications for fiscal year 1993 grant funds under the Federal-State Marketing Improvement Program (FSMIP).

SUMMARY: Notice is hereby given that the Federal-State Marketing Improvement Program was allocated $1,250,000 in the Federal Budget for Fiscal Year 1993. Funds remain available for this program. States interested in obtaining funds under the program are invited to submit proposals for marketing studies. Only State Departments of Agriculture or State Agencies are eligible for funds.

DATES: Applications will be accepted through June 1993.

ADDRESSES: Proposals may be sent to Dr. Harold S. Ricker, Assistant Director, Transportation and Marketing Division, AMS, USDA, room 4006-South Building, P.O. Box 96456, Washington, DC 20090–6456.

FOR FURTHER INFORMATION CONTACT: Dr. Harold S. Ricker, (202) 720–2704.

SUPPLEMENTARY INFORMATION: The Federal-State Marketing Improvement Program is authorized under section 204(b) of the Agricultural Marketing Act of 1946 (7 U.S.C. 1621 *et seq.*). The program is a matching fund program designed to assist State Departments of Agriculture in conducting feasibility studies related to the marketing of agricultural products. Organizations interested in conducting a marketing study should contact their State Department of Agriculture Marketing Division to discuss their proposal.

Mutually acceptable proposals must be submitted through the State Office and be accompanied by a completed SF 424 and detailed budget statement. FSMIP funds may not be used for advertising or the purchase of equipment or facilities. Guidelines may be obtained from your State Departments of Agriculture or the above AMS contact.

In terms of objectives, the States are encouraged to submit proposals regarding: (1) Studies to identify new crops, markets, and marketing systems for agricultural products, both domestically and internationally; (2) Studies to improve efficiency of the marketing system to enhance competitiveness and profitability; (3) Studies to help maintain product quality through new handling, processing, and distribution techniques; and, (4) studies identifying agricultural products that might have potential for new alternative market uses. Proposals addressing other marketing objectives will also receive consideration.

The Federal-State Marketing Improvement Program is listed in the "Catalog of Federal Domestic Assistance" under NO. 10.156 and subject agencies must adhere to title VI of the Civil Rights Act of 1964 which bars discrimination in all Federally assisted programs.

Dated: December 31, 1992.

Daniel D. Haley,

Administrator.

[FR Doc. 93–324 Filed 1–7–93; 8:45 am]

BILLING CODE 3410-02-M

Farmers Home Administration

Recipients of Fiscal Year 1992 Section 515 Loan Funds

AGENCY: Farmers Home Administration, USDA.

ACTION: Notice.

SUMMARY: The Farmers Home Administration (FmHA) has compiled a list of all recipients of FY 1992, section 515 loan funds. This action is taken to inform the public of recipients of FY 92 Section 515 funds. The intended effect is public awareness.

FOR FURTHER INFORMATION CONTACT: Cynthia L. Reese-Foxworth, Loan Assistant, Rural Rental Housing Branch, Multi-Family Housing Processing Division, Farmers Home Administration (FmHA), USDA, room 5337, South Agriculture Building, Washington, DC 20250, telephone (202) 720–1608 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

Programs Affected

This program is listed in the Catalog of Federal Domestic Assistance under Number 10.415, Rural Rental Housing Loans.

Discussion of Notice

The information available is an 84 page compilation that lists borrower names, names of the general partners, project name and location, number of units developed, and FmHA loan amount. This information is available to all interested parties and can be obtained by writing the following address: USDA, FmHA, Multi-Family Housing Processing Division, room 5337–S, Washington, DC, 20250. The request must be accompanied by a self-addressed, self-stamped envelope. Envelopes must be a minimum of 11" x 9" in size, and bear first class postage of $1.67. Requests without the required return envelope and postage will not be acknowledged or responded to.

Dated: December 11, 1992.

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 93–323 Filed 1–7–93; 8:45 am]

BILLING CODE 3410-07-M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget (OMB)

DOC has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: International Trade Administration, Commerce.

Title: Quality Assurance Survey Catalog Exhibition Evaluation.

Form Numbers: Agency—ITA—4017P. OMB—0625–0202.

Type of Request: Revised Collection.

Burden: 1,100 respondents; 183 reporting hours.

Average Hours per Response: 10 minutes.

Needs and Uses: The International Trade Administration's U.S. and Foreign Commercial Service (US&FCS) develops and operates catalog and video-catalog exhibition projects. The average Catalog Exhibition includes U.S. company participants, each of which sends material for display and promotion to overseas sites. A Video-Catalog Exhibition normally includes company participants whose video presentation is combined into an overall tape in various language versions and also includes participant company full product catalogs for display and promotion in overseas sites. Each hosting overseas post, at the conclusion of the promotional event, conveys to participants a list of visitors and any trade interest leads expressed by those visitors respecting individual U.S. firm presentations or product catalogs. This survey will allow participants to comment on the effectiveness with which the program serves their overseas marketing objectives. The information will be used by US&FCS for program evaluation and strategic planning. It will enable the staff to better direct the limited resources available and to administer these exhibition programs more effectively and efficiently, determining if the targeted industry groups are being reached.

Affected Public: Businesses or other for profit; small businesses or organizations.

Frequency: On occasion;

Respondent's Obligation: Voluntary.

OMB Desk Officer: Gary Waxman, 395–7340.

Copies of the above information collection proposal can be obtained by calling or writing DOC Clearance Officer, Edward Michals, (202) 482–3271, Department of Commerce, room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Gary Waxman, OMB Desk Officer, room 3208 New Executive Office Building, Washington, DC 20503.

Dated: January 4, 1993.

Edward Michals,

Departmental Clearance Officer, Office of Management and Organization.

[FR Doc. 93–355 Filed 1–7–93; 8:45 am]

BILLING CODE 3510-CW-M

Bureau of Export Administration

Regulations and Procedures Technical Advisory Committee; Open Meeting

A meeting of the Regulations and Procedures Technical Advisory Committee will be held January 27, 1993, 9:30 a.m., in the Herbert C. Hoover Building, room 1617M(2), 14th Street and Pennsylvania Avenue, NW., Washington, DC. The Committee advises the Office of Technology and Policy Analysis on implementation of the Export Administration Regulations (EARs), and provides for continuing review to update the EARs as needed.

Agenda

1. Opening Remarks by the Chairman.
2. Presentation of Papers or Comments by the Public.
3. Review of the Revised TAC Charter and Related Requirements for 1993 Work Plan.
4. Report of the Non-Proliferation Working Group.
5. Status of Refinement of EPCI End-Use Controls.

The meeting will be open to the public and a limited number of seats will be available. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials, two weeks prior to the meeting date, to the following address: Ms. Lee Ann Carpenter, TAC Unit/OAS–EA/BXA, Room 1621, U.S. Department of Commerce, 14th & Pennsylvania Ave., NW., Washington, DC 20230.

For further information or copies of the minutes, contact Lee Ann Carpenter on (202) 482–2583.

Dated: January 5, 1993.

Lee Ann Carpenter,

Acting Director, Technical Advisory Committee Unit.

[FR Doc. 93–424 Filed 1–7–93; 8:45 am]

BILLING CODE 3510-DT-M

INTERNATIONAL TRADE ADMINISTRATION

[A–533–806]

Final Determination of Sales at Less than Fair Value: Sulfanilic Acid from India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 8, 1993.

FOR FURTHER INFORMATION CONTACT: Mary Jenkins, Office of Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 482–1756.

FINAL DETERMINATION: The Department of Commerce (the Department) determines that sulfanilic acid from India is being, or is likely to be, sold in the United States at less than fair value, as provided in section 735 of the Tariff Act of 1930 (the Act), as amended. The Department also determines that critical circumstances exist.

Case History

Since the publication of our preliminary determination on October 22, 1992 (57 FR 48207), the following events have occurred.

We published a preliminary affirmative determination of critical circumstances on December 7, 1992 (57 FR 57729). This determination was in response to petitioner's October 14, 1992, allegation.

On November 4, 1992, John D. Wilson, Consultation Services, sent us a fax informing us that an Indian producer of sulfanilic acid, Kokan Synthetics, was not contacted when we sent out our questionnaires.

On December 21, 1992, an *ex parte* meeting was held with Rolf Th. Lundberg, Deputy Assistant Secretary for Impact Administration, and representatives of certain Indian sulfanilic acid producers and U.S. importers. During this meeting the representatives challenged our preliminary determinations in both the antidumping and countervailing duty investigations. As Mr. Lundberg stated at the meeting, these arguments were too late to be considered for the final determinations in either case. (See, *Ex parte* Memorandum dated December 22, 1992.) In addition, certain arguments which were contained in a November 11, 1992, brief submitted by these parties in the countervailing duty case, were discussed. For a further discussion of this issue, see, Final Affirmative Countervailing Duty Determination:

Sulfanilic Acid From India (CVD Final), published concurrently with this notice.

Scope of the Investigation

The products covered by this investigation are all grades of sulfanilic acid, which include technical (or crude) sulfanilic acid, refined (or purified) sulfanilic acid and sodium salt of sulfanilic acid (sodium sulfanilate).

Sulfanilic acid is a synthetic organic chemical produced from the direct sulfonation of aniline with sulfuric acid. Sulfanilic acid is used as a raw material in the production of optical brighteners, food colors, specialty dyes, and concrete additives. The principal differences between the grades are the undesirable quantities of residual aniline and alkali insoluble materials present in the sulfanilic acid. All grades are available as dry, free flowing powers.

Technical sulfanilic acid, currently classifiable under the subheading 2921.42.24.20 of the Harmonized Tariff Schedule of the United States (HTSUS), contains 96 percent minimum sulfanilic acid, 1.0 percent maximum aniline, and 1.0 percent maximum alkali insoluble materials. Refined sulfanilic acid, also currently classifiable under the HTSUS subheading 2921.42.24.20, contains 98 percent minimum sulfanilic acid, 0.5 percent maximum aniline, and 0.25 percent maximum alkali insoluble materials. Refined sodium salt of sulfanilic acid (sodium sulfanilate), currently classifiable under the HTSUS subheading 2921.42.70, is a granular or crystalline material containing 75 percent minimum equivalent sulfanilic acid, 0.5 percent maximum aniline, and 0.25 percent maximum alkali insoluble materials based on the equivalent sulfanilic acid content.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is December 1, 1991, through May 31, 1992.

Best Information Available

We have determined, in accordance with section 776(c) of the Act, that the use of best information available (BIA) is appropriate for valuing the sales of the subject merchandise in this investigation. Section 776(c) provides that the Department may use BIA when a respondent refuses or is unable to produce information requested in a timely manner and in the form required.

We sent questionnaires to seven companies who were identified as producers to determine who would be the appropriate recipients of the full antidumping questionnaire. We received questionnaire responses from four companies: Golden Dyes Corp. (India) Private Ltd., Synthetic Dyestuff (India) Corp., Atul Products, and Hickson & Dadajee Ltd. indicating that they had no sales or exports during the POI. The remaining three companies, Beta Napthol (P) Ltd. (Beta), Kanoria Chemicals & Industries Ltd. (Kanoria), and Chemco International (Chemco), did not respond to our questionnaire. Because we have not received any response with which to perform our antidumping analysis for the latter three companies, we are making our determination on the basis of BIA. We selected as BIA the highest margin in the petition, in accordance with the two-tiered BIA methodology outlined in the Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From France; et al.; Final Results of Antidumping Duty Administrative Reviews (57 FR 28360, 28379, June 24, 1992).

Fair Value Comparisons

To determine whether sales of sulfanilic acid from India to the United States were made at less than fair value, we compared the "United States price to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We based U.S. price on BIA, which was information supplied by the petitioner. Petitioner based U.S. price on exporter's sales price (ESP) methodology because sulfanilic acid was sold to unrelated purchasers in the United States after the importation of the subject merchandise into the United States.

Petitioner calculated ESP based on packed, C&F U.S. port of entry price quotations. Petitioner deducted foreign inland freight, foreign handling, ocean freight, U.S. brokerage and handling charges, and commissions incurred in the United States.

Foreign Market Value

We based FMV on BIA, which was information supplied by the petitioner. Petitioner based FMV on f.o.b. observed prices in India for all three grades of sulfanilic acid. No adjustments have been made to the observed Indian prices.

Final Affirmative Determination of Critical Circumstances

Petitioners alleged that "critical circumstances" exist with respect to imports of sulfanilic acid from India. Section 735(a)(3) of the Act provides that critical circumstances exist if we determine that there is a reasonable basis to believe or suspect the following:

"(A)(i) There is a history of dumping in the United States or elsewhere of the class or kind of merchandise which is the subject of the investigation, or

(ii) The person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the merchandise which is the subject of investigation at less than fair value, and

(B) There have been massive imports of the merchandise which is the subject of the investigation over a relatively short period."

Regarding criterion (A) above, we normally consider either an outstanding antidumping order in the United States or elsewhere on the subject merchandise, or margins of 25 percent or more in the case of purchase price comparisons, and 15 percent or more in the case of exporter sales price comparisons, sufficient to impute knowledge of dumping under section 735(a)(3) of the Act. The dumping margin found in this final determination is sufficiently high so that the importer of the merchandise knew, or should have known, that dumping was occurring.

Regarding criterion (B) above, pursuant to 19 CFR 353.16(f), we generally consider the following factors in determining whether imports have been massive over a short period of time: (1) The volume and value of the imports; (2) seasonal trends (if applicable); and(3) the share of domestic consumption accounted for by imports. Because shipment data for Beta, Kanoria and Chemco was not reported, as BIA, we determine that imports were massive over a relatively short period of time. Accordingly, we find that critical circumstances exist for all manufacturers, producers and exporters of the subject merchandise.

With respect to Golden Dyes Corp. Private Ltd., Synthetic Dyestuff Corp., Atul Products, and Hickson & Dadajee Ltd., we make no specific determination with respect to the issue of critical circumstances because it is moot.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(4)(A) of the Act, for Beta, Kanoria, and Chemco, we are directing the Customs Service to continue to suspend liquidation of all entries of sulfanilic acid from India that are entered, or withdrawn from warehouse, for consumption on or after July 24,

1992, which is 90 days retroactive from the date of publication of our preliminary determination notice in the Federal Register. For all others, we are directing Customs to suspend liquidation of all entries of sulfanilic acid from Indian that are entered, or withdrawn from warehouse, for consumption on or after July 24, 1992.

The Customs Service shall continue to require a cash deposit or posting of a bond equal to the estimated amounts by which the foreign market value of sulfanilic acid exceeds the United States price as shown below. The suspension of liquidation on sulfanilic acid will remain in effect until further notice. The dumping margin in this case is 114.8 percent for all manufacturers/producers/exporters. However, section 772(d)(1)(D) of the Act prohibits assessing dumping duties on the portion of the margin attributable to an export subsidy. In this case, the product under investigation is subject to a countervailing duty investigation (see, CVD Final). We are subtracting the cash deposit rate attributable to the export subsidies found, 43.71 percent. Accordingly, for duty deposit purposes, the net estimated antidumping duty deposit rate is shown below.

Manufacturers/producers/exporters	Margin (percentage)
Bola, Kanoria and Chemco	71.09
All Others	71.09

ITC Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission (ITC) of our determination. If the ITC determines that material injury, or threat of material injury, does not exist with respect to sulfanilic acid, the proceeding will be terminated and all securities posted will be refunded or cancelled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing Customs officials to assess antidumping duties on all sulfanilic acid from India, entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

This determination is published pursuant to section 735(d) of the Act (19 U.S.C. 1673(d) and 19 CFR 353.20).

Dated: December 29, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 93–356 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–DS–M

International Trade Administration

[A–412–809]

Final Determination of Sales at Less Than Fair Value: Sulfur Dyes, Including Sulfur Vat Dyes, From the United Kingdom

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 8, 1993.

FOR FURTHER INFORMATION CONTACT: Shawn Thompson, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–1776.

FINAL DETERMINATION: We determine that sulfur dyes, including sulfur vat dyes, from the United Kingdom are being, or are likely to be, sold in the United States at less than fair value, as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the publication of our affirmative preliminary determination on September 24, 1992 (57 FR 44163), the following events have occurred:

We received requests for a public hearing from Sandoz Chemicals Corporation, the petitioner, on October 2, 1992, and from James Robinson Limited (JR), the respondent, on October 5, 1992.

From October 5 through October 8, 1992, we conducted verification in the Untied Kingdom of JR's responses to the Department's questionnaire.

On October 8, 1992, JR requested a postponement of the final determination. We granted this request, and on October 16, 1992, we postponed the final determination until not later than December 31, 1992 (57 FR 48356 (Oct. 23, 1992)).

Both petitioner and JR filed case briefs on November 17, 1992, and rebuttal briefs on November 25, 1992. A public hearing was held on December 2, 1992.

Class or Kind of Merchandise

On August 31, 1992, respondent requested that the Department of Commerce (the Department) determine that there are two separate classes or kinds of merchandise under investigation—conventional sulfur dyes and solubilized sulfur dyes. Respondent further requested that the Department either rescind the investigation with respect to solubilized sulfur dyes, as there was no less-than-fair value (LTFV) allegation in the petition regarding this type of dye, or, at a minimum, calculate separate dumping margins for each type of dye. For the reasons outlined below, we determine that conventional and solubilized sulfur dyes do not constitute separate classes or kinds of merchandise.

In past cases where the Department has been called upon to determine the number of classes or kinds of merchandise under investigation, we have based our analysis on the criteria set forth by the Court of International Trade in *Diversified Products* v. *United States*, 6 CIT 155, 572 F. Supp. 883 (1983) ("*Diversified Products*"). According to *Diversified Products*, the Department may rely upon the following factors in determining whether products belong to the same class or kind of merchandise: (1) The general physical characteristics of the merchandise; (2) the ultimate use of the merchandise; (3) the expectations of the ultimate purchaser; (4) the channels of trade in which the product is sold; and (5) the manner in which the product is advertised and displayed. (See, *e.g.*, Final Determinations of Sales at Less Than Fair Value: Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof From the Federal Republic of Germany, 54 FR 18992 (May 3, 1989)).

Regarding four of the five *Diversified Products* criteria (*i.e.*, ultimate use, expectations of the ultimate purchasers, channels of trade, and manner of advertising), we find that there is significant overlap between the two types of dyes. Although it is true that one type of solubilized sulfur dye (the type formulated to dye leather) cannot be used in the same applications as conventional sulfur dyes (and vice versa), we find that another type (the type formulated to dye textiles) can be, and is ultimately used in the same applications (*i.e.*, to dye textiles). Accordingly, we find that the ultimate use and expectations of the ultimate purchasers for one type of solubilized sulfur dye are similar to the use of, and expectations for, conventional sulfur dyes. Moreover, it appears that the type of solubilized sulfur dye formulated to dye textiles moves in the same channels of trade as conventional sulfur dyes. Along the same lines, we find that advertising for this type of solubilized sulfur dye, like that for conventional sulfur dyes, is directed towards textile dyers.

Regarding the remaining *Diversified Products* criterion (the general physical characteristics of the merchandise), we note that, when examining differences

in physical characteristics in the context of a class or kind analysis, the Department looks for clear dividing lines between product groups, not merely the presence or absence of physical differences between certain products. In this specific instance, although there are physical differences between certain types of solubilized sulfur dyes (*i.e.*, those formulated for use on leather) and conventional sulfur dyes, we find that the physical differences between the two product groups in question (*i.e.*, conventional sulfur dyes and solubilized sulfur dyes taken as a whole) are not so great or so clearly delineated as to form the sole basis for determining that they fall within separate classes or kinds of merchandise. In other words, physical differences among these products alone are not *ipso facto* proof of different classes or kinds.

In making its arguments that separate classes or kinds of merchandise exist, respondent relies heavily on a recent determination issued by the Department. (See, Pure and Alloy Magnesium From Canada: Final Affirmative Determination; Rescission of Investigation and Partial Dismissal of Petition, 57 FR 30,939, (July 13, 1992) ("Magnesium"). In that determination, the Department found not only that the two products in question had clearly defined differences in physical characteristics, but also that they were ultimately used for distinctly different purposes by purchasers who had completely different expectations. We find that respondent's reliance on Magnesium is misplaced, however, because in this investigation we find no clearly defined differences in any of the five *Diversified Products* criteria.

In sum, our analysis of conventional and solubilized sulfur dyes in light of the *Diversified Products* criteria supports a finding that these products should not be separate classes or kinds of merchandise. Accordingly, we have not rescinded the investigation with respect to solubilized sulfur dyes. In addition, in accordance with the Department's practice of calculating one weighted-average margin for the class or kind of merchandise, we have calculated a single margin for solubilized and conventional sulfur dyes. (For a more detailed discussion of this issue, see Memorandum from David L. Binder, Acting Director, Office of Antidumping Investigations, to Richard W. Moreland, Acting Deputy Assistant Secretary for Investigations, dated December 22, 1992.)

Scope of Investigation

The merchandise subject to this investigation is sulfur dyes, including sulfur vat dyes. Sulfur dyes are synthetic, organic, coloring matter containing sulfur. Sulfur dyes are obtained by high temperature sulfurization of organic material containing hydroxy, nitro or amino groups, or by reaction of sulfur and/or alkaline sulfide with aromatic hydrocarbons. For purposes of this investigation, sulfur dyes include, but are not limited to, sulfur vat dyes with the following color index numbers: Vat Blue 42, 43, 44, 45, 46, 47, 49, and 50 and Reduced Vat Blue 42 and 43. Sulfur vat dyes also have the properties described above. All forms of sulfur dyes are covered, including the reduced (leuco) or oxidized state, presscake, paste, powder, concentrate, or so-called "pre-reduced, liquid ready-to-dye" forms. The sulfur dyes subject to this investigation are classifiable under subheadings 3204.15.10, 3204.15.20, 3204.15.30, 3204.15.35, 3204.15.40, 3204.15.50, 3204.19.30, 3204.19.40 and 3204.19.50 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Period of Investigation

The period of investigation (POI) is November 1, 1991, through April 30, 1992.

Such or Similar Comparisons

We have determined that all the products covered by this investigation constitute a single category of such or similar merchandise. Where there were no sales of identical merchandise in the home market to compare to U.S. sales, we made comparisons on the basis of: (1) Category; (2) color; (3) color index number; (4) type; (5) form; and (6) strength. We made adjustments for differences in the physical characteristics of the merchandise, in accordance with section 773(a)(4)(C) of the Act.

Fair Value Comparisons

To determine whether sales of sulfur dyes, including sulfur vat dyes, from the United Kingdom to the United States were made at less than fair value, we compared the United States price (USP) to the foreign market value (FMV), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

United States Price

We calculated USP using the methodology described in the preliminary determination, with the following exception: We disregarded U.S. sample sales in our analysis, because these sales accounted for a very small percentage of U.S. sales by volume. (For further discussion, see *Comment 5* in the "Interested Party Comments" section of this notice.)

Foreign Market Value

We calculated FMV using the methodology described in the preliminary determination, with the following exceptions:

1. We excluded from our analysis one large volume sale, as we determined that this sale was made outside the ordinary course of trade. (For further discussion, see *Comment 3.*)

2. We reclassified payments to one of respondent's customers, characterized by respondent as post-sale rebates, as commission expenses because the payments in question were made in return for the customer's performance of the functions of a sales agent (including the function of finding buyers). Because JR neither reported U.S. indirect selling expenses nor paid commissions in the U.S. market, we used best information available (BIA) to determine the amount of the commission offset for these sales. As BIA, we used the amount of the commission itself. (For further discussion, see *Comment 9.*)

3. We corrected JR's reported difference in merchandise adjustments (difmers) for errors found at verification. In addition, for one product comparison we excluded sales of one product from the calculation of FMV, as we find that the variable cost difference between the product sold in the home market and that sold in the United States is too large to allow a reasonable price-to-price comparison (*i.e.*, the revised difmer for this product comparison exceeded 20 percent of the cost of manufacture (COM) of the product sold in the United States, and no party to this proceeding provided any basis to depart from the 20 percent guideline).

4. We made a circumstance-of-sale adjustment for credit expenses using revised U.S. credit expenses. We recalculated these expenses using respondent's home market interest rate, because this was the rate that respondent actually used to finance its U.S. accounts receivables. (See *Comment 7.*) In our recalculation, we also used updated payment information for certain U.S. sales, provided at verification.

5. We added to FMV an additional U.S. packing expense, based on our findings at verification.

Currency Conversion

We made currency conversions in accordance with 19 CFR 353.60(a) based on the official exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Verification

As provided in section 776(b) of the Act, we verified information provided by respondent by using standard verification procedures, including the examination of relevant sales and financial records, and selection of original source documentation containing relevant information.

Critical Circumstances

Petitioner alleges that "critical circumstances" exist with respect to imports of sulfur dyes, including sulfur vat dyes, from the United Kingdom. Section 735(a)(3) of the Act provides that critical circumstances exist if we determine that there is a reasonable basis to believe or suspect that:

(A)(i) There is a history of dumping in the United States or elsewhere of the class or kind of merchandise which is the subject of the investigation, or

(ii) The person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the merchandise which is the subject of the investigation at less than its fair value, and

(B) There have been massive imports of the class or kind of merchandise which is the subject of the investigation over a relatively short period.

With respect to the first criterion, we note that there are no outstanding antidumping orders on sulfur dyes, including sulfur vat dyes, from the United Kingdom, and, thus, no history of dumping. Moreover, because the final dumping margin for JR and all other exporters is less than 25 percent, we cannot impute knowledge under section 735(a)(3)(A)(ii) of the Act. Since the criteria necessary to find the existence of critical circumstances under section 735(a)(3)(A) are not present, we do not need to determine whether imports of subject merchandise have been massive over a relatively short period, in accordance with section 735(a)(3)(B) of the Act.

Accordingly, we determine that critical circumstances do not exist with respect to imports of sulfur dyes, including sulfur vat dyes, from the United Kingdom. (For further discussion of this issue, see *Comment 10.*)

Interested Party Comments

Comment 1

Petitioner alleges that JR incorrectly calculated its adjustments for differences in the physical characteristics of the merchandise. According to petitioner, JR's use of direct labor costs as a basis for allocating overhead constitutes the least accurate method of measuring overhead, as JR's production involves a highly capital-intensive, low-labor manufacturing process. Petitioner maintains that the individual elements comprising JR's variable overhead costs will increase or decrease proportionally with the amount of goods produced, while the amount of labor will not necessarily vary at all. Consequently, petitioner argues that the most accurate basis of allocating variable overhead costs is the volume of goods produced. To this end, petitioner provided the Department with recalculated overhead amounts, as well as revised difmers.

Respondent contends that its method of allocating overhead costs on the basis of labor is the best method available for measuring the work necessary to take raw materials through to finished products, because its factory is not automated and still is relatively labor-intensive. According to respondent, using petitioner's suggested methodology of reallocating overhead costs based on production volume is inappropriate in this investigation because JR's processes and product range is so diverse (*i.e.*, each unit produced by JR does not require the same amount of overhead inputs).

Respondent asserts that the Department has accepted this allocation methodology in other investigations, citing Television Receivers, Monochrome & Color, From Japan: Final Results of Antidumping Duty Administrative Review, 56 FR 34177 (July 26, 1991) and Final Determination of Sales at Less than Fair Value: Cell Site Transceivers From Japan, 49 FR 43080 (Oct. 26, 1984). Finally, respondent notes that the Department verified JR's overhead costs and allocations and found no significant discrepancies.

DOC Position

We agree with respondent and have accepted JR's allocation methodology for purposes of the final determination. After evaluating JR's allocation methodology, we find that, while the company's costs do not correlate perfectly with the amount of labor used, its methodology is more accurate than the alternative put forth by petitioner, in that JR's methodology at least assigns higher costs to products which have more production steps or have more complex processes (and therefore use more labor). In this particular instance, petitioner's methodology of allocating overhead based on production volume would be distortive and inaccurate, because JR's costs would not vary proportionally with the volume produced. Petitioner's recalculated numbers show that the overhead amounts vary by an insignificant amount between the different product groups produced by JR. However, we noted at verification that it is more costly to produce subject merchandise as a powder than as a liquid (these are classified as separate product groups in JR's accounting system), because powder production requires additional machinery and has several additional production steps. Therefore, we have used JR's verified overhead costs for purposes of the final determination.

Comment 2

Petitioner alleges that all of JR's home market sales of certain products were made at prices below the cost of production (COP) and should be excluded from the Department's analysis for purposes of the final determination. In order to support this allegation, petitioner provided its own COP calculations for these products, using respondent's data after revising them to take into account its proposed methodology for reallocating overhead expenses. (See *Comment 1*, supra.) Petitioner then compared the revised COPs to the gross unit prices for the products in question, less any reported rebates. According to petitioner, because (1) the total volume of all below-cost sales is greater than ten percent of the JR's total home market sales of subject merchandise, and (2) all of the sales of the specific products in question are below-cost, the Department should apply its "10/90/10" rule and exclude the below-cost sales from the margin analysis. Accordingly, petitioner states, the Department should base FMV for the U.S. sales previously compared to the below-cost sales on the constructed value (CV) for one of products sold in the home market. Petitioner reasons that, of the below-cost products sold in the home market, this product is the only one having a revised difmer of less than 20 percent of the COM of the comparison products sold in the United States.

Finally, petitioner submits that its COP allegation should not be rejected on timeliness grounds, as not only did petitioner previously submit an allegation, but it is not now either realleging sales below cost or requesting

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that the Department initiate a COP investigation. Rather, petitioner argues that the facts on the record, verified by the Department, establish that JR's sales were below COP. Moreover, petitioner maintains that it did not have complete access to these facts, used in its case brief for the first time, as (1) petitioner did not receive sufficient information on one of the products in question until JR filed its second deficiency response (which was submitted after the deadline for filing a cost allegation) and (2) much of JR's cost information was revised during verification.

Respondent contends that the Department should reject petitioner's COP allegation, as it is 106 days past the regulatory deadline. Respondent states that the Department afforded petitioner numerous opportunities to submit an adequate allegation prior to the deadline, yet petitioner declined to do so. Moreover, respondent states that petitioner had sufficient information in its possession prior to the deadline to make substantially the same allegation, as almost all of the data used by petitioner in its case brief was contained in JR's pre-deficiency questionnaire responses. Finally, respondent argues, regardless of the timing involved, petitioner's allegation is without merit because it relies on an incorrect reallocation of overhead costs.

DOC Position

We agree with respondent that petitioner's cost allegation is untimely. We find that petitioner had access to all of the necessary information two weeks prior to the preliminary determination, and that, had petitioner chosen to make a cost allegation earlier than in its case brief, it had the raw data to do so. We also note that the "deadline" set out in 19 CFR 353.31(c)(1)(i) does not require the Department to reject cost allegations received after the deadline date in all cases. Rather, it states that the deadline will be 45 days before the scheduled date for the preliminary determination "unless a relevant response is untimely or incomplete." Because JR's original response was deficient, the Department requested that JR submit new information after the regulatory "deadline." Had this new information directly led petitioner to believe or suspect that any of JR's home market sales were made at prices below COP, petitioner could have made a cost allegation at that point in the investigation and we would not necessarily have considered it to be untimely. Accordingly, because petitioner had access to the relevant information well before the date on which it submitted its case brief, we have rejected petitioner's cost allegation as untimely.

Comment 3

Petitioner contends that one large volume sale should be excluded from the calculation of FMV because it (1) was not made within the POI; (2) was not made in the ordinary course of trade; and (3) constituted a pretended/fictitious sale. Should the Department disagree, petitioner argues, this sale should be disregarded in any event, because it was made at a price below its COP.

Regarding the first argument, petitioner states that a contract analysis is relevant in determining when a sale occurs for purposes of the antidumping duty law. According to petitioner, the methodology that respondent used to determine the date of sale for the order in question conflicted with one of the provisions in the agreement between respondent and its customer. Accordingly, petitioner asserts that the date that a binding commitment was made under the terms of the agreement (in this case the date of shipment) should be controlling for date of sale purposes. As the sale was shipped outside the POI, petitioner asserts that it should be excluded from the calculation of FMV.

Regarding the second argument, petitioner contends that, because (1) the sale was priced below the COM of the product in question and (2) the circumstances surrounding the sale patently deviated from the conditions and practices applicable to other home market sales reported by JR, it is clear that the sale was not made in the ordinary course of trade.

Regarding the argument that this sale was fictitious, petitioner contends that both the timing of the sale (*i.e.*, after the filing of the petition) and the price at which it was made (*i.e.*, below the price then in effect between JR and its customer), when taken in conjunction with the fact that its shipping pattern was markedly different from that for JR's other sales to this customer, lead to the conclusion that the sale was contrived for the purpose of serving as the basis for a more favorable FMV calculation. Petitioner states that this sale should therefore be disregarded for purposes of the final determination and section 773(a)(1) of the Act, which states that, "[I]n the ascertainment of foreign market value for the purposes of this title no pretended sale or offer for sale, and no sale or offer for sale intended to establish a fictitious market, shall be taken into account."

Respondent contends that the sale was properly reported as a sale made within the POI. Respondent notes that its order record card, used to establish the date of sale for all other home market transactions, shows that both price and quantity were fixed on the date reported in the home market sales listing. Moreover, respondent asserts, the customer in question was obligated to, and in fact did, accept and pay for all merchandise sold pursuant to this sale, and it did so in the same manner as JR's other sales. Respondent further states that this sale was not made outside the ordinary course of trade, because there were other large sales made by JR during the POI. Therefore, respondent states that the size of this sale was not uncommon. Finally, respondent argues that this sale was not a fictitious sale, as it was made in order to assist the customer to develop a market for the product in certain areas of the United Kingdom.

DOC Position

We agree with respondent that the date of sale for this transaction was within the POI. At verification, we reviewed respondent's documentation on this sale and found that the binding commitment between the parties as to price and quantity was made on the date that respondent reported in its sales listing.

However, we agree with petitioner that this sale was made outside the ordinary course of trade. We note that not only was this sale at a greater quantity and lower price than other sales to the same customer, but it was also out of line with the prices and quantities of the vast majority of respondent's other sales transactions in the home market during the POI. In addition, we note that the agreement between respondent and the customer in question was concluded in a manner noticeably different from respondent's other sales during the POI (*i.e.*, the sale involved a "special agreement" between the parties in order to promote the product at issue).

Based on our determination that this sale was not made in the ordinary course of trade, we have excluded it from our calculation of FMV for purposes of the final determination.

Accordingly, we do not need to address the issue of whether this sale was made in order to establish a fictitious market.

Comment 4

Petitioner contends that one of JR's home market sales should be treated as a consignment sale, even though it was not reported as such. Petitioner further contends that the gross unit price for this sale should be revised upward to

equal JR's "scheduled price" for this product, with the difference between the scheduled and reported prices treated as a commission. As support for its contention that this sale should be classified as a consignment sale, petitioner notes that the sale was made to a customer who acts as a consignment agent for other products. In addition, petitioner claims that this transaction appears to have been handled in a manner similar to that in which JR's consignment sales to this agent were handled.

Respondent contends that petitioner's argument should be rejected because the sale in question was not a consignment sale. Respondent notes that JR's consignment agreement with its agent covered a different product entirely. Therefore, respondent maintains that this sale should be treated as a non-consignment sale for purposes of the final determination.

DOC Position

We agree with respondent. The Department normally accepts a respondent's assertions, which the respondent has certified as factually correct, unless either there is conflicting information on the record or the information is found to be factually inaccurate during verification. In this instance, we examined the circumstances surrounding this sale at verification and saw no evidence that it was shipped to the customer in question as consignment stock. Moreover, it would be inappropriate to classify all sales to a customer, who acts at times as a consignee, as consignment merchandise, based solely on the fact that the parties have an agent/principal relationship governing sales of certain (but not all) products. Accordingly, we have not reclassified this sale as a consignment sale for purposes of the final determination.

Comment 5

Respondent argues that the Department should exclude sample and trial orders from its analysis, because the overriding goal of the antidumping statute is to make apples-to-apples comparisons. (See, *e.g., American Permac, Inc.* v. *United States*, 783 F. Supp. 1,421 (CIT 1992) ("*American Permac*").) According to respondent, in *American Permac*, the court recognized that in antidumping investigations the Department may exclude U.S. sales when they are unrepresentative of a company's U.S. selling practices and when such sales would result in an unfair comparison.

Respondent states that examining the sales at issue results in unfair pricing comparisons because JR did not have the same type of sales in the home market during the POI. Moreover, respondent contends that to examine these sales is contrary to the Department's practice, citing Final Determination of Sales at Less Than Fair Value: Coated Groundwood Paper From the United Kingdom, 56 FR 56,403 (Nov. 4, 1991) (where the Department determined that including trial sales in only one market would be unfair).

Petitioner argues that the Department should continue to include these sales in its analysis because they are not outside the ordinary course of trade. Petitioner states that the quantities of these sales indicates that these orders were placed by the customer for the purpose of conducting full mill production trials and that JR had the expectation of follow-up sales. According to petitioner, this fact alone is sufficient to support the Department's determination that these sales were of usual commercial quantities and in the ordinary course of trade. Therefore, petitioners assert that they should be matched with home market sales for purposes of the final determination.

DOC Position

In performing its LTFV analysis, the Department is not required to examine every sales transaction made by a respondent during the POI. See 19 CFR 353.42(b)(1). (See also *e.g.*, Final Determination of Sales at Less Than Fair Value: New Minivans From Japan, 57 FR 21,937 (May 26, 1992).) Accordingly, we have disregarded sample sales in our LTFV calculations for purposes of the final determination, because we find that these sales accounted for a very small percentage of U.S. sales by volume and we have adequate sales coverage without examining them. (See, *e.g.*, Final Determination of Sales at Less Than Fair Value: Coated Groundwood Paper From France, 56 FR 56,380, 56,384 (Nov. 4, 1991).)

Regarding respondent's trail sales, however, we find that these sales were not made in unusually small quantities (*i.e.*, the quantities were comparable to the quantities of other U.S. sales transactions reported by respondent, and were actually larger than the quantities of respondent's home market sales of the identical merchandise). Because respondent has provided no compelling reason to disregard these sales, we determine that it is appropriate to include them in our LTFV analysis.

Regarding respondent's argument that the Department should exclude both sample and trail sales because to not do so would result in the Department's making unfair comparisons, we find that this argument is without merit. The Department makes price-to-price comparisons based on the requirements set forth in both the antidumping statute and its regulations. We evaluate the information used in our LTFV analysis in light of these requirements, as well as in light of the commercial practices in the industry in question. Based on our evaluation of the circumstances surrounding the particular transactions at issue, we find that our actions are consistent with both the statute and the regulations. Consequently, respondent's argument does not alter our analysis in any way.

Comment 6

Respondent contends that the Department should exclude from its analysis JR's home market sales of "excess, left over, or odd lot" merchandise, because this merchandise was not sold in the ordinary course of trade. Respondent notes that, unlike other products sold in the home market which were produced to order for home market customers, the merchandise in question was produced solely for one U.S. end user. Consequently, respondent states, the excess produced from each batch was inventoried and sold infrequently in the home market as an incidental, "odd lot" product.

According to respondent, the Department has realized in other cases that excess or left over merchandise is out of the ordinary course of trade and has therefore excluded such merchandise from its calculation of FMV. As support for this contention, respondent cites Certain Fresh Cut Flowers From Colombia: Final Results of Antidumping Duty Administrative Review, 55 FR 20,491 (May 17, 1990) ("Flowers").

Alternatively, respondent argues that the Department should disregard JR's home market sales of the product in question and base FMV on CV. Respondent argues that its home market sales do not provide a meaningful basis for price-to-price comparisons because of the extreme differences in individual sales quantities between the two markets. Respondent cites 19 CFR 353.55(a), which states that in "comparing the United States price with foreign market value, the Secretary normally will use sales of comparable merchandise." In this case, respondent contends that "comparable" refers to price comparability, not similarity of physical characteristics. As evidence that the prices for these two products are not comparable, respondent offers the fact that a significant percentage of

its preliminary dumping margin was attributable to these comparisons.

Petitioner maintains that the Department was correct in basing FMV on JR's home market sales of the product in question. Petitioner asserts that these sales were made to the same customer and in similar quantities as other home market sales, and that respondent's argument amounts to little more than an eleventh hour claim for an adjustment for pre-sale warehousing expenses. Petitioner further asserts that accepting respondent's argument that these sales were outside the ordinary course of trade would therefore necessitate making a similar determination for a number of other home market sales not at issue. Where there exist contemporaneous sales of identical merchandise in the home market, petitioner states, it is appropriate to rely on such sales, rather than CV, as the basis for determining FMV.

DOC Position

We agree with petitioner. The antidumping law requires the Department to disregard individual home market sales made outside the ordinary course of trade. This section of the law does not appear to apply in the current investigation, however, as JR's home market sales were made to the same customers, and in similar quantities, as other home market sales. Moreover, there is no indication that this particular merchandise is not sold to the same types of purchaser in the same manner as other sulfur dyes in the home market.

Regarding JR's argument that the real issue is price comparability between markets, we note that JR incorrectly cited 19 CFR 353.55. That section relates to adjustments for price differences in the merchandise due to differences in the commercial quantity of sales. This provision states that the Department "normally will use sales of comparable quantities of merchandise * * * (and) * * * will make a reasonable allowance for any difference in quantities, to the extent that the Secretary is satisfied that the amount of any price differential is wholly or partly due to that difference in quantities." JR did not attempt to claim that its price differential between the U.S. and home market sales of this product resulted from a difference in quantities. Thus, we find that this provision in the Department's regulations does not apply in this instance.

Finally, with regard to respondent's argument that the Department has disregarded sales of left over merchandise in the past, we note that the case cited by respondent, *Flowers*, dealt with a perishable good. Thus, we find that the circumstances here are factually different from those in the *Flowers* case. Accordingly, we have included respondent's sales of the product in question in our final margin analysis.

Comment 7

Petitioner argues that the Department should calculate U.S. credit expenses using the actual interest rate incurred by JR during the POI on its U.S. dollar-denominated bank account. Petitioner asserts that the Department determined at verification that the actual interest rate paid on this account was substantially higher than the theoretical interest rate reported in JR's questionnaire response. According to petitioner, it is preferable to use an actual verified rate rather than a theoretical rate, particularly in view of the fact that at verification JR presented the Department with two different sets of rates from its bank.

Respondent argues that it was unable to provide the Department with the accurate short-term interest rate on its U.S. dollar-denominated account because its bank would not cooperate with JR. Respondent contends, however, that it is inappropriate to use the "verified actual" rate to calculate U.S. credit expenses, as JR did not actually pay this rate. Moreover, respondent notes that using this "actual" rate is especially unreasonable in light of the fact that the rates provided by the bank in response to JR's second request were so much lower than either the "actual" rate or the reported rate.

Rather, respondent argues, the Department should calculate U.S. credit expenses using JR's home market interest rate. Respondent points out that it rarely used its U.S. dollar-denominated account because the interest rate that JR would receive on positive balances was higher in its pounds sterling account. Thus, respondent contends that any financing of its U.S. dollar-denominated receivables was done primarily through its pounds sterling account and that, consequently, using JR's verified home market interest rates would lead to the most accurate measurement of the opportunity cost associated with holding U.S. receivables.

DOC Position

We agree with respondent and have recalculated U.S. credit expenses using JR's home market interest rate. We noted at verification that JR did not pay interest on its U.S. dollar-denominated receivables in the ordinary course of its business, as it only incurred interest expenses for a very few days during the POI and then only by accident (*i.e.*, any interest paid on negative balances was due to the company's overestimation of the funds available in the account because the company attempted to maintain a zero or slightly positive balance there). We also determined at verification that JR borrowed from its home market bank in the ordinary course of its business, and we reviewed the interest rates applicable to those borrowings. Thus, our use of JR's home market interest rate is consistent with the instructions of the Court of Appeals for the Federal Circuit in a recent case, *La Metalli Industriale, S.p.A.* v. *United States*, 912 F.2d 455 (Fed. Cir. 1990), where the court directed the Department to consider the commercially reasonable business practice of respondents in determining the interest rate used in the calculation of imputed credit.

Comment 8

Respondent argues that the Department should deduct from FMV imputed credit expenses related to the prepayment of value added taxes (VAT). Specifically, respondent argues that it incurred an opportunity cost for the period in which it had paid VAT to the U.K. government for a particular sale, but had not yet received payment from its home market customers. As Department precedent on this issue, respondent cites Final Results of Administrative Review of Antidumping Duty Order: Color Television Receivers From Korea, 49 FR 50,420 (Dec. 28, 1984) ("CTVs"), in which the Department allowed a similar claim.

Respondent notes that, although it is not the Department's current practice to impute credit expenses related to VAT prepayments, in a recent case the Department implied that it would allow such an adjustment if it were properly quantified. (See, Preliminary Determination of Sales at Less Than Fair Value: Dynamic Random Access Memory Semiconductors of One Megabyte and Above From the Republic of Korea, 57 FR 49,066 (Oct. 29, 1992) ("DRAMs"), where the Department disallowed credit expenses related to VAT payments because respondent did not take into account the saving gained from early payment of VAT by the customer.) Respondent states that its claim in this case was correctly quantified, as it took into account not only the opportunity cost associated with its prepayments of VAT to the U.K. government, but also the opportunity gain associated with early payment of VAT by its customers.

DOC Position

We disagree. After further reflection, we have reconsidered the position taken in *DRAMs*. We find that there is no statutory or regulatory basis for making the adjustment suggested by respondent. While there may be an opportunity cost associated with the prepayment of VAT, that fact alone is not a sufficient basis for the Department to make an adjustment in price-to-price comparisons. We note that virtually every charge or expense associated with price-to-price comparisons is either prepaid or paid for at some point after the cost is incurred. Accordingly, for each pre- or post-service payment, there is also an opportunity cost (or gain). Thus, to allow the type of adjustment suggested by respondent would imply that in the future the Department would be faced with the impossible task of trying to determine the opportunity cost (or gain) of every freight charge, rebate and selling expense for each sale reported in a respondent's database. In order to make a price-to-price comparison, this exercise would make our calculations inordinately complicated, placing an unreasonable and onerous burden on both respondents and the Department. Consequently, we have not deducted from FMV the imputed credit expense in question.

Comment 9

Respondent argues that JR's post-sale payments to its consignment agent were properly treated in the preliminary determination as rebates, rather than commissions, because the agent often resells the merchandise for a higher price than the price it paid JR.

DOC Position

We disagree. For purposes of the final determination, we are treating these payments as commissions, rather than as rebates, because they were made in return for the consignee's performing the functions of a sales agent (including the function of finding buyers). Because JR neither paid commissions in the U.S. market nor reported U.S. indirect selling expenses as an offset to commissions paid in the home market (as requested in section C of the Department's questionnaire), we have used BIA to determine the amount of the commission offset for JR's sales in question. As BIA, we have used the amount of the commission itself (thereby resulting in a net reduction to FMV of zero). We note that, although JR was aware that the Department could potentially reclassify these expenses as commissions, it opted not to report offsetting expenses.

Comment 10

Petitioner argues that critical circumstances exist with respect to imports of subject merchandise from the United Kingdom, because imports of Sulfur Black 1 were massive over a relatively short period during the POI. Petitioner bases its analysis on the Bureau of Census' import statistics for Sulfur Black 1 (the type of sulfur dye which petitioner states accounts for a "significant portion" of the domestic sulfur dye market). Petitioner states that these statistics show that imports of Sulfur Black 1 increased by between 40 and 75 percent during April through June 1992 when compared to the period January through March 1992.

Respondent argues that petitioner's critical circumstances analysis is invalid because it is based on imports of only one product, rather than the entire range of products subject to investigation. According to respondent, a comparison of the volume of all of JR's products exported to the United States during the period January through March with the volume of its exports made during the period April through June shows that JR's exports of subject merchandise to the United States have actually decreased. Finally, respondent notes that, before the Department will find critical circumstances, the dumping margin must exceed 25 percent. Respondent notes that the preliminary margin in this case was lower than that amount.

DOC Position

We agree with respondent. As the final dumping margin calculated for JR is less than 25 percent and there is no "history" of dumping of the merchandise subject to this investigation, this issue is moot. For a discussion of the criteria used to determine the existence of critical circumstances, see the "Critical Circumstances" section of this notice.

Continuation of Suspension of Liquidation

We are directing the Customs Service to continue to suspend liquidation of all entries of sulfur dyes, including sulfur vat dyes, that are entered, or withdrawn from warehouse, for consumption on or after September 24, 1992, the date of publication of our affirmative preliminary determination in the **Federal Register**. The Customs Service shall require a cash deposit or the posting of a bond equal to the estimated amount by which the FMV of the merchandise subject to this investigation exceeds the USP, as shown below. This suspension of liquidation will remain in effect until further notice. The weighted-average dumping margins are as follows:

Producer/manufacturer/exporter	Weighted-average margin percentage
James Robinson Limited	19.97
All Others	19.97

ITC Notification

In accordance with section 735(d) of the Act, we have notified the ITC of our determination.

Notification to Interested Parties

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 353.34(d). Failure to comply is a violation of the APO.

This determination is published pursuant to section 735(d) of the Act and 19 CFR 353.20(a)(4).

Dated: December 31, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 93–357 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–DS–M

[C–533–807]

Final Affirmative Countervailing Duty Determination; Sulfanilic Acid From India

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 8, 1993.

FOR FURTHER INFORMATION CONTACT: Rick Herring, Office of Countervailing Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC 20230; telephone: (202) 482–3530.

FINAL DETERMINATION:

Case History

Since our preliminary determination on August 11, 1992 (57 FR 35784), the following events have occurred. On August 24, 1992, we received a supplemental response from the Government of India. On August 25, 1992, we aligned the final countervailing duty determination with the final determination in the companion antidumping duty

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investigation (57 FR 38485). On November 16, 1992, we received a submission from PMC Specialities, an importer of sulfanilic acid from India.

Scope of Investigation

The products covered by this investigation are all grades of sulfanilic acid, which include technical (or crude) sulfanilic acid, refined (or purified) sulfanilic acid and sodium salt of sulfanilic acid (sodium sulfanilate).

Sulfanilic acid is a synthetic organic chemical produced from the direct sulfonation of aniline with sulfuric acid. Sulfanilic acid is used as a raw material in the production of optical brighteners, food colors, specialty dyes, and concrete additives. The principal differences between the grades are the undesirable quantities of residual aniline and alkali insoluble materials present in the sulfanilic acid. All grades are available as dry, free flowing powders.

Technical Sulfanilic acid, currently classifiable under the subheading 2921.42.24.20 of the Harmonized Tariff Schedule of the United States (HTSUS), contains 96 percent minimum Sulfanilic acid, 1.0 percent maximum aniline, and 1.0 percent maximum alkali insoluble materials. Refined sulfanilic acid, also currently classifiable under the HTSUS subheading 2921.42.24.20, contains 98 percent minimum Sulfanilic acid, 0.5 percent maximum aniline, and 0.25 percent maximum alkali insoluble materials. Refined sodium salt of sulfanilic acid (sodium sulfanilate), currently classifiable under the HTSUS subheading 2921.42.70, is a granular or crystalline material containing 75 percent minimum equivalent sulfanilic acid, 0.5 percent maximum aniline, and 0.25 percent maximum alkali insoluble materials based on the equivalent sulfanilic acid content.

Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Analysis of the Programs

We did not receive timely or complete responses to our questionnaire from any of the producers or exporters of Sulfanilic acid from India. Therefore, in accordance with section 776(c) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 355.37 (1992), we used the best information available to calculate the estimated net subsidy conferred upon the production and exportation of sulfanilic acid from India.

We used information provided by the petitioner as the best information available. Petitioner asserted that the net subsidy conferred on the production and exportation of Sulfanilic acid was 43.71 percent *ad valorem*.

Comment

As previously noted, we received one submission from a U.S. importer. The portion of that submission relevant to this proceeding can be summarized as follows. The U.S. importer argues that there are three different grades of sulfanilic acid and that each of these grades should be considered separate products. In support of its position, the importer points to differences in the physical characteristics of various grades of sulfanilic acid due to purity levels. Further, the importer maintains that the different grades of sulfanilic acid are not always interchangeable for reasons associated with price and use of the product.

The U.S. importer also points out that the U.S. industry no longer manufactures the "pure" grade of sulfanilic acid and that the imposition of import duties would ultimately injure the domestic consumer. Accordingly, the importer requests that the Department promptly terminate the investigation.

DOC Position

The importer requests that the Department terminate this investigation, apparently based on a standing argument and on U.S. consumer's interests. To the extent that the importer is alleging that the petitioner does not have standing, the allegation is untimely pursuant to 19 CFR 355.31(c)(2)(1992). With respect to the effect of countervailing duties on domestic prices, there is no provision in the statute which permits the Department to take into account the interests of consumers in reaching a determination of whether the foreign producers are being subsidized. For these reasons, we have no basis to terminate this proceeding.

Verification

Due to the lack of timely and complete responses from any of the Indian producers or exporters of sulfanilic acid, we did not conduct verification.

Suspension of Liquidation

In accordance with our affirmative preliminary determination, we instructed the Customs Service to suspend liquidation of all entries of sulfanilic acid from India which were entered, or withdrawn from warehouse, for consumption, on or after August 11, 1992, the date of publication of our preliminary determination in the Federal Register. As noted above, however, this final countervailing duty determination was postponed from December 9, 1992, to December 29, 1992, to coincide with the final determination in the companion antidumping investigation.

Under Article 5, paragraph 3 of the General Agreement on Tariffs and Trade Subsidies Code, provisional measures cannot be imposed beyond a period of four months. Therefore, we have instructed the Customs Service to discontinue the suspension of liquidation of the subject merchandise entered on or after December 9, 1992, the date that falls four months after the preliminary determination in this case. We will reinstate suspension of liquidation under section 703(d) of the Act, if the ITC issues a final affirmative injury determination, and will require a cash deposit of estimated countervailing duties equal to 43.71 percent *ad valorem* for all manufacturers, producers, and exporters in India of sulfanilic acid.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. If the ITC determines that material injury, or the threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or cancelled. If, however, the ITC determines that such injury does exist, we will issue a countervailing duty order, directing Customs officers to assess countervailing duties on all entries of sulfanilic acid from India entered, or withdrawn from warehouse, for consumption, as described in the "Suspension of Liquidation" section of this notice.

Return or Destruction of Proprietary Information

This notice serves as the only reminder to parties subject to an Administrative Protective Order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 355.34(d). Failure to comply is a violation of the APO.

This determination is published pursuant to section 705(d) of the Act (19 U.S.C. 1671(d)) and 19 CFR 355.20(a)(4) (1992).

Dated: December 29, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 93–358 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–DR–M

President's Export Council; Meeting

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of open meeting.

SUMMARY: The President's Export Council (PEC) is holding an open meeting to address the following: PEC accomplishments, export promotion resource allocation, and export controls. The Export Administration Subcommittee will present its report, and the Council will discuss a report to the President on outstanding trade issues. The President's Export Council was established on December 20, 1973, and reconstituted May 4, 1979, to advise the President on matters relating to U.S. export trade.

DATES: January 11, 1993, from 10 a.m. to 12 noon.

ADDRESSES: The Willard Hotel, The Pierce Room, 1401 Pennsylvania Avenue, NW., Washington, DC. Seating is limited and will be a first come, first serve basis.

FOR FURTHER INFORMATION CONTACT: Ms. Sylvia Lino Prosak, President's Export Council, room 2015B, Washington, DC 20230.

Dated: January 4, 1993.

Wendy H. Smith,

Director, President's Export Council.

[FR Doc. 93–359 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–DR–M

Minority Business Development Agency

Business Development Center Applications: U.S. Virgin Islands (Service Area)

AGENCY: Minority Business Development Agency, DOC.

ACTION: Notice.

SUMMARY: The Minority Business Development Agency (MBDA) is cancelling the announcement to solicit competitive applications under its Minority Business Development Center program to operate a U.S. Virgin Islands MBDC for a three (3) year period, starting April 1, 1993 to March 31, 1994, in the U.S. Virgin Islands SMSA (Closing date November 23, 1992). Refer to the **Federal Register** dated October 7, 1992, 57 FR 46149.

Dated: December 29, 1992.

William R. Fuller,

Deputy Regional Director.

[FR Doc. 93–345 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–21–M

National Oceanic and Atmospheric Administration

Marine Mammals

AGENCY: National Marine Fisheries Service (NMFS) NOAA, Commerce.

ACTION: Issuance of Modification to Permit No. 787 (P444A).

SUMMARY: On November 16, 1992, notice was published in the **Federal Register** (57 FR 221) that a request had been filed by the Center for Coastal Studies, Provincetown, MA, 02657, for a modification to Scientific Research Permit No. 787. The applicants requested to extend their study of humpback whales (*Megaptera novaeangliae*) along the eastern U.S. Coast south to Miami.

Notice is hereby given that on December 31, 1992, as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407) and Endangered Species Act of 1973 (16 U.S.C. 1531–1543), the National Marine Fisheries Service issued a Modification to this Permit for the above taking, subject to certain conditions set forth therein.

Issuance of this Modification, as required by the Endangered Species Act of 1973, is based on the finding that such Permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which is the subject of the Permit; and (3) will be consistent with the purposes and policies set forth in Section 2 of the Act. This Modification was also issued in accordance with and is subject to parts 220–222 of the National Marine Fisheries Service regulations governing endangered fish and wildlife permits.

Documents submitted in connection with this permit are available, by appointment, in the Permits Division, Office of Protected Resources, National Marine Fisheries Service, NOAA, 1335 East-West Highway, room 7324, Silver Spring, MD 20910;

Director, Northeast Region, National Marine Fisheries Service, NOAA, One Blackburn Drive, Gloucester, MA 01930 (508/281–9200); and

Director, Southeast Region, National Marine Fisheries Service, NOAA, 9450 Koger Blvd., St. Petersburg, FL 33702 (813/893–3141).

This modification is requested to expand the study area to include U.S. waters as far south as Miami, FL.

Dated: December 31, 1992.

Michael F. Tillman,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–352 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–22–M

Marine Mammals

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

ACTION: Issuance of Modification to Permit No. 496 (P79D).

Notice is hereby given that pursuant to the provisions of § 216.33(d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), Scientific Research Permit No. 496 issued to Center for Coastal Marine Studies, University of California at Santa Cruz, Santa Cruz, California 95064, is modified to extend the authority to take elephant seals (*Mirounga angustirostris*) for scientific research purposes until March 31, 1993. This modification became effective on December 31, 1992.

The Permit, as modified, is available for review by appointment in the Permits Division, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Hwy., suite 7324, Silver Spring, MD 20910 (301/713–2289); and

Director, Southwest Region, National Marine Fisheries Service, NOAA, 501 W. Ocean Blvd., Long Beach, CA 90802–4213 (310/980–4015).

Dated: December 31, 1992.

Michael F. Tillman,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–353 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–22–M

Marine Mammals

AGENCY: National Marine Fisheries Service, NMFS, NOAA, Commerce.

ACTION: Issuance of Permit Modification (P319A).

Notice is hereby given that pursuant to the provisions of § 216.33 (d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), Scientific Research Permit No. 638 issued to Dr. Randall S. Wells, Dolphin Biology Research Associates, Inc., 163 Siesta Drive, Sarasota, Florida 34242, on June 14, 1988, to take up to 3000 Atlantic bottlenose dolphins (*Tursiops truncatus*) by potential harassment during the conduct of scientific research. This Permit is modified to

extend the date of expiration through January 31, 1993. This modification becomes effective upon signature by the Assistant Administrator for Fisheries or his designee.

Documents submitted in connection with this Permit, as modified, are available for review, by appointment, in the Permits Division, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, suite 7324, Silver Spring, MD 20910 (301/713–2289); and Director, Southeast Region, National Marine Fisheries Service, NOAA, 9450 Koger Boulevard, St. Petersburg, FL 33702 (813/893–3141).

Dated: December 31, 1992.

Michael F. Tillman,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–354 Filed 1–7–93; 8:45 am]

BILLING CODE 3510–22–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to Procurement List.

SUMMARY: This action adds to the Procurement List commodities and a service to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: February 8, 1993.

ADDRESSES: Committee for Purchase from People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: On October 9 and November 20, 1992, the Committee for Purchase from People Who Are Blind or Severely Disabled published notices (57 FR 46543 and 54774) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to produce the commodities and provide the service, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the commodities and service listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities or service to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities or service.

3. The action will result in authorizing small entities to furnish the commodities or service to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities or service proposed for addition to the Procurement List.

Accordingly, the following commodities and service are hereby added to the Procurement List:

Commodities

Trousers, Men's Medical Assistant
8405–00–110–8290
8405–00–110–8291
8405–00–110–8292
8405–00–110–8293
8405–00–110–8294
8405–00–110–8295
8405–00–110–8296
8405–00–110–8297
8405–00–110–8298
8405–00–110–8299
8405–00–110–8301
8405–00–110–8302
8405–00–110–9468
8405–00–110–9469
8405–00–110–9470
8405–00–110–9471
8405–00–110–9472
8405–00–110–9473
8405–00–110–9474
8405–00–110–9475
8405–00–110–9476
8405–00–110–9477
8405–00–110–9478
8405–00–110–9479
8405–00–110–9480
8405–00–110–9481
8405–00–110–9482
8405–00–110–9483
8405–00–110–9484
8405–00–110–9485
8405–00–110–9486
8405–00–110–9487
8405–00–110–9488
8405–00–110–9489
8405–00–110–9490
8405–00–110–9697
8405–00–113–5418
8405–01–008–8848
(One-time addition of 50,000 pairs)

Service

Janitorial/Custodial, Libby Ranger Station, Kootenai National Forest, Libby, Montana.

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 93–414 Filed 1–7–93; 8:45 am]

BILLING CODE 6820–33–M

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List commodities to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete commodities previously furnished by such agencies.

COMMENTS MUST BE RECEIVED ON OR BEFORE: February 8, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

Additions

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodities listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following commodities to the Procurement List for production by the nonprofit agencies listed:

DOE This Month, 7690–00–NSH–0033 (Requirements for the Department of Energy), Nonprofit Agency: Lt. Joseph P. Kennedy Institute, Washington, DC

Newsletter, Smithsonian Institution Women's Council, 7690–00–NSH–0037 (Requirements for the Smithsonian Institution), Washington, DC

Newsletter, VA Medical Center, 7690–00–NSH–0042 (Requirements for the Department of Veterans Affairs), Nonprofit Agency: Lt. Joseph P. Kennedy Institute, Washington, DC

Deletions

It is proposed to delete the following commodities from the Procurement List:

Strap, Chin, Steel Helmet
8470–00–032–2737
Strap, Steel Helmet
8970–00–030–8003

Beverly L. Milkman,

Executive Director.

[FR Doc. 93–415 Filed 1–7–93; 8:45 am]

BILLING CODE 6820–33–M

CONSUMER PRODUCT SAFETY COMMISSION

Technical Advisory Group for Cigarette Fire Safety; Meeting

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of meeting.

SUMMARY: The Technical Advisory Group for Cigarette Fire Safety will meet on January 28–29 1993, in Washington, DC. The purpose of the meeting is to discuss current research to develop a test method to measure cigarette ignition propensity and matters related to implementation of the Fire Safe Cigarette Act.

DATES: The meeting will be from 9 a.m. to 4 p.m. on January 28–29, 1993.

ADDRESSES: The meeting will be in room 432, Federal Trade Commission, 6th and Pennsylvania Avenue, NW., Washington, DC.

FOR A RECORDED MESSAGE CONTAINING THE LATEST INFORMATION ABOUT THE TIME AND LOCATION OF THE MEETING CALL: (301) 504–0709.

FOR FURTHER INFORMATION CONTACT: Beatrice M. Harwood, Directorate for Epidemiology, Consumer Product Safety Commission, Washington, DC 20207; telephone: (301) 504–0470.

SUPPLEMENTARY INFORMATION: The Fire Safe Cigarette Act of 1990 (FSCA) (Pub. L. 101–352, 104 Stat. 405) directs the Commission, with assistance from the National Institute of Standards and Technology (NIST) and the Department of Health and Human Services, to conduct research concerning the feasibility of a performance standard to address the propensity of cigarettes to act as an ignition source. The FSCA also establishes an advisory committee, the Technical Advisory Group for Cigarette Fire Safety, to advise and work with the Commission and NIST in the implementation of that act.

The Technical Advisory Group for Cigarette Fire Safety will meet on January 28–29, 1993, to discuss current research to develop a test method to measure cigarette ignition propensity; the status of a cigarette fire incident study; plans to evaluate the possible health effect of cigarettes with reduced ignition propensity; and other administrative and operational plans to implement the FSCA.

The meeting will be open to observation by members of the public, but only members of the Technical Advisory Group for Cigarette Fire Safety may participate in the discussion. Persons who desire to submit written statements or questions for consideration by the Technical Advisory Group, before or after the meeting, should address them to the Technical Advisory Group for Cigarette Fire Safety, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

Dated: January 4, 1993.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 93–438 Filed 1–7–93; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Per Diem, Travel and Transportation Allowance Committee

AGENCY: Per Diem, Travel and Transportation Allowance Committee, DoD.

ACTION: Publication of changes in per diem rates.

SUMMARY: The Per Diem, Travel and Transportation Allowance Committee is publishing Civilian Personnel Per Diem Bulletin Number 167. This bulletin lists changes in per diem rates prescribed for U.S. Government employees for official travel in Alaska, Hawaii, Puerto Rico, the Northern Mariana Islands and Possessions of the United States. Bulletin Number 167 is being published in the **Federal Register** to assure that travelers are paid per diem at the most current rates.

EFFECTIVE DATE: January 1, 1993.

SUPPLEMENTARY INFORMATION: This document gives notice of changes in per diem rates prescribed by the Per Diem Travel and Transportation Allowance Committee for non-foreign areas outside the continental United States. Distribution of Civilian Personnel Per Diem Bulletins by mail was discontinued effective 1 June 1979. Per Diem Bulletins published periodically in the **Federal Register** now constitute the only notification of change in per diem rates to agencies and establishments outside the Department of Defense. The text of the Bulletin follows:

Maximum Per Diem Rates for Official Travel in Alaska, Hawaii, the Commonwealths of Puerto Rico and the Northern Mariana Islands and Possessions of the United States by Federal Government Civilian Employees

Locality	Maximum lodging amount (A)	+	M&IE rate (B)	=	Maximum per diem rate (C)	Effective date
Alaska:						
Adak[5]	$10		$34		$44	10-01-91
AnaktuvukPass	83		57		140	12-01-90
Anchorage:						
05-15—09-15	174		71		245	05-15-93
09-16—05-14	81		66		147	12-01-92
Aniak	73		36		109	07-01-91
Atqasuk	129		86		215	12-01-90
Barrow	86		73		159	06-01-91
Bethel	82		64		146	01-01-93
Bettles	65		45		110	12-01-90
Cold Bay	71		54		125	12-01-90
Coldfoot	95		59		154	10-01-92
Cordova	66		77		143	12-01-92
Craig	67		35		102	07-01-91
Dillingham	76		38		114	12-01-90
Dutch Harbor-Unalaska	113		67		180	05-01-92
Eielson AFB:						
05-15—09-15	100		66		166	05-15-93
09-16—09-14	65		67		132	12-01-92
Elmendorf AFB:						
05-15—09-15	174		71		245	05-15-93
09-16—09-14	81		66		147	12-01-92
Fairbanks AFB:						
05-15—09-15	100		66		166	05-15-93
09-16—09-14	65		67		132	12-01-92
False Pass	80		37		117	06-01-91
Ft. Richardson:						
05-15—09-15	174		71		245	05-15-93
09-16—09-14	81		66		147	12-01-92
Ft. Wainwright:						
05-15—09-15	100		66		166	05-15-93
09-16—09-14	65		67		132	12-01-92
Homer:						
05-01—09-30	71		60		131	05-01-93
10-01—04-30	53		62		115	12-01-92
Juneau:						
05-01—10-01	88		74		162	05-01-92
10-02—04-30	75		73		148	1-01-92
Katmai National Park	89		59		148	12-01-90
Kenai-Soldotna:						
04-02—09-30	94		68		162	04-02-93
10-01—04-01	57		66		123	12-01-92
Ketchikan:						
05-14—10-14	77		61		138	05-14-93
10-15—05-13	68		71		139	12-01-92
King Salmon[3]	75		59		134	12-01-90
Klawock	75		36		111	07-01-91
Kodiak	71		61		132	01-01-92
Kotzebue	125		72		197	01-01-92
Kuparuk Oilfield	75		52		127	12-01-90
Metlakatla	79		44		123	07-01-91
Murphy Dome:						
05-15—09-15	100		66		166	05-15-93
09-16—05-14	65		67		132	12-01-92
Nelson Lagoon	102		39		141	06-01-91
Noatak	125		72		197	01-01-92
Nome	71		58		129	01-01-93
Noorvik	125		72		197	01-01-92
Petersburg	72		64		136	05-01-92
Point Hope	99		61		160	12-01-90
Point Lay[6]	106		73		179	12-01-90
Prudhoe Bay-Deadhorse	64		57		121	12-01-90
Sand Point	75		36		111	07-01-91
Seward:						
05-01—09-30	107		53		160	05-01-92
10-01—04-30	61		48		109	01-01-92
Shungnak	125		72		197	01-01-92
Sitka-Mt. Edgecombe	72		69		141	01-01-92
Skagway:						
05-14—10-14	77		61		138	05-14-93
10-15—05-13	68		71		139	12-01-92
Spruce Cape	71		61		132	01-01-92
St. George	100		39		139	06-01-91
St. Paul Island	81		34		115	12-01-90
Tanana	71		58		129	01-01-93
Tok	48		55		103	12-01-92
Umiat	97		63		160	12-01-90

MAXIMUM PER DIEM RATES FOR OFFICIAL TRAVEL IN ALASKA, HAWAII, THE COMMONWEALTHS OF PUERTO RICO AND THE NORTHERN MARIANA ISLANDS AND POSSESSIONS OF THE UNITED STATES BY FEDERAL GOVERNMENT CIVILIAN EMPLOYEES—Continued

Locality	Maximum lodging amount (A)	+	M&IE rate (B)	=	Maximum per diem rate (C)	Effective date
Valdez:						
05-01—09-01	98		53		151	05-01-93
09-02—04-30	82		70		152	12-01-92
Wainwright	90		75		165	12-01-90
Walker Lake	82		54		136	12-01-90
Wrangell:						
05-14—10-14	77		61		138	05-14-93
10-15—05-13	68		71		139	12-01-92
Yakutat	70		40		110	12-01-90
Other [3 4 6]	63		48		111	01-01-93
American Samoa	85		47		132	12-01-91
Guam	112		75		187	05-01-92
Hawaii:						
Island of Hawaii: Hilo	65		61		126	06-01-92
Island of Hawaii: Other	80		61		141	06-01-92
Island of Kauai	99		55		154	06-01-92
Island of Kure[1]	.....		13		13	12-01-90
Island of Maui	79		64		143	06-01-92
Island of Oahu	105		55		160	06-01-92
Other	59		47		106	12-01-90
Johnston Atoll[2]	20		20		40	10-01-92
Midway Islands	.....		13		13	12-01-90
Northern Mariana Islands:						
Rota	68		55		123	01-01-93
Saipan	100		69		169	01-01-93
Tinian	50		55		105	01-01-93
Other	20		13		33	12-01-90
Puerto Rico:						
Bayamon:						
04-16—12-14	93		67		160	06-01-92
12-15—04-15	116		69		185	12-15-92
Carolina:						
04-16—12-14	93		67		160	06-01-92
12-15—04-15	116		69		185	12-15-92
Fajardo (including Luquillo):						
04-16—12-14	90		57		147	06-01-92
12-15—04-15	134		61		195	12-15-92
Ft. Buchanan (including GSA Service Center, Guaynabo):						
04-16—12-14	93		67		160	06-01-92
12-15—04-15	116		69		185	12-15-92
Mayaguez	85		65		150	06-01-92
Ponce	106		65		171	06-01-92
Roosevelt Roads:						
04-16—12-14	90		57		147	06-01-92
12-15—04-15	134		61		195	12-15-92
Sabana Seca:						
04-16—12-14	93		67		160	06-01-92
12-15—04-15	116		69		185	12-15-92
San Juan (including San Juan Coast Guard units):						
04-16—12-14	93		67		160	06-01-92
12-15—04-15	116		69		185	12-15-92
Other.						
Virgin Islands of the U.S.:						
05-02—12-15	100		68		168	06-01-92
12-16—05-01	144		73		217	12-16-92
Wake Island[2]	4		17		21	12-01-90
All Other Localities	20		13		33	12-01-90

[1]Commercial facilities are not available. The meal and incidental expense rate covers charges for meals in available facilities plus an additional allowance for incidental expenses and will be increased by the amount paid for Government quarters by the traveler.

[2]Commercial facilities are not available. Only Government-owned and contractor operated quarters and mess are available at this locality. This per diem rate is the amount necessary to defray the cost of lodging, meals and incidental expenses.

[3]On any day when U.S. Government or contractor quarters are available and U.S. Government or contractor messing facilities are used, a meal and incidental expense rate of $19.65 is prescribed to cover meals and incidental expenses at Shemya AFB, Clear AFS, Galena APT and King Salmon APT. This rate will be increased by the amount paid for U.S. Government or contractor quarters and by $4 for each meal procured at a commercial facility. The rates of per diem prescribed herein apply from 0001 on the day after arrival through 2400 on the day prior to the day of departure.

[4]On any day when U.S. Government or contractor quarters are available and U.S. Government or contractor messing facilities are used, a meal and incidental expense rate of $34 is prescribed to cover meals and incidental expenses at Amchitka Island, Alaska. This rate will be increased by the amount paid for U.S. Government or contractor quarters and by $10 for each meal procured at a commercial facility. The rates of per diem prescribed herein apply from 0001 on the day after arrival through 2400 on the day prior to the day of departure.

[5]On any day when U.S. Government or contractor quarters are available and U.S. Government or contractor messing facilities are used, a meal and incidental expense rate of $25 is prescribed instead of the rate prescribed in the table. This rate will be increased by the amount paid for U.S. Government or contractor quarters.

[6]The meal rates listed below are prescribed for the following locations in Alaska: Cape Lisburne RRL, Cape Newenham RRL, Cape Romanzof APT, Fort Yukon RRL, Indian Mtn RRL, Spernewohn RRL, Tanana RRL, Tin City RRL, Barter Island AFS, Point Barrow AFS, Point Lay AFS and Oliktok AFS. The amount to be added to the cost of government quarters in determining the per diem will be $3.50 plus the following amount:

DOD Personnel $13

Non-DOD Personnel (Daily Rate) $30

Dated: January 4, 1993.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–378 Filed 1–7–93; 8:45 a.m.]

BILLING CODE 3810–01–M

Air Force

USAF Scientific Advisory Board; Meeting

The Cruise Missile Panel of the USAF Scientific Advisory Board's Committee on Options for Theater Air Defense will meet on 27–28 January 1993, at The ANSER Corporation, 1215 Jefferson Davis Highway, Arlington, VA from 8 a.m. to 5 p.m. This meeting was originally scheduled for January 19, 1993.

The purpose of this meeting will be to receive briefings and gather information on issues related to theater air defense.

The meeting will be closed to the public in accordance with section 552b(c) of title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the Scientific Advisory Board Secretariat at (703) 697–4811.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 93–425 Filed 1–7–93; 8:45 am]

BILLING CODE 3910–01–M

USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board of the Air Force and Other Services Initiatives Panel (Information Architecture) will meet on January 28–29, 1993 from 8 a.m. to 5 p.m. at ANSER Corporation, Arlington, VA.

The purpose of this meeting is to receive briefings, hold discussions and begin report writing on projects related to Information Architectures. This meeting will involve discussions of classified defense matters listed in section 552b(c) of title 5, United States Code, specifically subparagraph (1) thereof, and accordingly will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at (703) 697–4648.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 93–426 Filed 1–7–93; 8:45 am]

BILLING CODE 3910–01–M

DEPARTMENT OF ENERGY

DOE Response to Recommendation 92–5 of the Defense Nuclear Facilities Safety Board Concerning Discipline of Operations Throughout the Defense Nuclear Facilities Complex

AGENCY: Department of Energy.

ACTION: Notice and Request for public comment.

SUMMARY: Pursuant to section 315(b) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2286d(b), the Department of Energy (DOE) hereby publishes notice of a response of the Secretary of Energy (Secretary) to Recommendation 92–5 of the Defense Nuclear Facilities Safety Board, published in the **Federal Register** on August 28, 1992, (57 FR 39191) concerning discipline of operations in a changing defense nuclear facilities complex.

DATES: Comments, data, views, or arguments concerning the Secretary's response are due on or before February 8, 1993.

ADDRESSES: Send comments, data, views, or arguments concerning the Secretary's response to: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW., suite 700, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Mr. Donald K. Knuth, Deputy Assistant Secretary for Operations, Defense Programs, Department of Energy, 1000 Independence Avenue SW., Washington DC 20585.

Issued in Washington, DC, on January 4, 1993.

Mario Fiori,

Departmental Representative to the Defense Nuclear Facilities Safety Board.

[FR Doc. 93–404 Filed 1–7–93; 8:45 am]

BILLING CODE 6450–01–M

Office of Arms Control and Nonproliferation Policy

Proposed Subsequent Arrangement

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of a proposed "subsequent arrangement" under the Additional Agreement for Cooperation America and the European Atomic Energy Community (EURATOM) concerning Peaceful Uses of Atomic Energy, as amended, and the Agreement for Cooperation between the Government of the United States of America and the Government of Japan concerning Peaceful Uses of Nuclear Energy.

The subsequent arrangement to be carried out under the above-mentioned agreements involves approval for the following retransfer: RTD/JA(EU)–63 for the transfer of 2 grams of uranium enriched to 93 percent in the isotope uranium-235 from Belgium to Japan for use in measurements of fission rates in the fast critical assembly at the Tokai Research Establishment.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that this subsequent arrangement will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

Issued in Washington, DC on January 5, 1993.

Salvador N. Ceja,

Acting Director, Office of Nonproliferation Policy.

[FR Doc. 93–409 Filed 1–7–93; 8:45 am]

BILLING CODE 6450–01–M

Office of Energy Research

Energy Research Financial Assistance Program Notice 93–11; Experimental Program To Stimulate Competitive Research (EPSCoR)

AGENCY: Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Office of the Science and Technology Advisor (STA) of the Department of Energy (DOE), in keeping with its energy-related mission to assist in strengthening the Nation's human resource infrastructure through the support of science, engineering, and mathematics education at all levels of education, announces its interest in receiving grant applications from eligible States for the support of the EPSCoR Program. The purpose of the DOE/EPSCoR Program is to enhance the capabilities of the National Science Foundation (NSF) designated States to conduct nationally competitive energy-related research and to develop science and engineering manpower in energy-rated areas to meet current and future needs in those areas. Approximately $5.0 million will be available for grant awards under the DOE/EPSCoR Program in FY 1993 for collaborative research and manpower development in energy-related science and engineering disciplines.

DATES: Applications for grants under this Notice should be received by 4:30

p.m. Eastern Standard Time, March 1, 1993.

ADDRESSES: Application materials are available from the Office of University and Science Education Programs, ST–50, 1000 Independence Avenue, SW., Washington, DC 20585. Telephone requests for application materials may be made by calling (202) 586–8949. The completed applications must be submitted to: U.S. Department of Energy, Office of Energy Research, Divisions of Acquisition and Assistance Management, ER–64, Washington, DC 20585. The personal or courier delivery address is: U.S. Department of Energy, Division of Acquisition and Assistance Management, ER–64, Office of Energy Research, 19901 Germantown Road, Germantown, MD 20874. Each application submitted must reference Notice No. 93–11. Telephone and telefax numbers must also be included in any application.

FOR FURTHER INFORMATION CONTACT: Ms. Donna J. Prokop, Education Programs Manager, Office of University and Science Education Programs, Office of the Science and Technology Advisor, ST–511, Department of Energy, Washington, DC 20585. She may be reached by telephone on (202) 586–8949.

SUPPLEMENTARY INFORMATION: The House and Senate reports accompanying the FY 1993 Energy and Water Development Appropriations Act (H.R. Rep. No 555, 102nd Cong., 2nd Sess., pg. 74 and S. Rep. No. 344, 102nd Cong., 2nd Sess., pg. 90, respectively) mentioned that the pertinent committees were impressed with the progress of the DOE/EPSCoR program. In addition, the language in the two reports recommend that $5.0 million be committed to continuing the program in the States designated by NSF as EPSCoR States. In accordance with 10 CFR 600.7(b)(1), and to be consistent with the Congressionally recommended limitations, DOE has decided to continue to restrict eligibility for these grants to the following States and Territory: Alabama, Arkansas, Idaho, Kansas, Kentucky, Louisiana, Maine, Mississippi, Montana, Nebraska, Nevada, North Dakota, Oklahoma, South Carolina, South Dakota, Vermont, West Virginia, Wyoming, and the Commonwealth of Puerto Rico.

Awards issued under this Notice will implement approved and selected plans formulated under the DOE/EPSCoR planning grants awarded in FY 1991. It is estimated that approximately $5.0 million will be available for awards that will provide for state management, coordination, research collaboration and human resource development activities. It is expected that up to 5 new awards will be issued up to a maximum of $1.250 million each. Any remaining balance of the estimated $5.0 million will be used to award funds to sustain unsuccessful DOE/EPSCoR state committees to refine state energy-related plans. Awards will range from $5,000 up to a maximum of $1.250 million.

In addition, as a tangible measure of an applicant's commitment to the objectives of the DOE/EPSCoR program, cost-sharing on a one-to-one ratio is a requirement of this program. Therefore, each application submitted requesting support from DOE under this Notice must provide, from non-Federal funds, an amount equal to the amount awarded by the DOE; i.e., for every dollar provided by DOE, the recipient must provide a dollar from non-Federal sources for the project.

General information about development and submission of applications, eligibility, limitations, evaluation, and selection processes, and other policies and procedures are contained in the Office of Energy Research Special Research Grant Application Kit and Guide. This Notice requests further that the "Detailed Description of Research Work Proposed" component of a complete grant application, as established by 10 CFR part 605, should not exceed 20 double-spaced, typed pages excluding curriculum vitae. The Catalog of Federal Domestic Assistance Number of this program is 81.049.

Issued in Washington, DC., on December 30, 1992.

D.D. Mayhew,

Director, Office of Management, Office of Energy Research.

[FR Doc. 93–206 Filed 1–7–93; 8:45 am]

BILLING CODE 6450–01–M

Energy Research Financial Assistance Program Notice 93–08; University Reactor Instrumentation Program

AGENCY: Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Office of Energy Research (ER) of the Department of Energy, in keeping with its energy-related mission to strengthen the Nation's support of science, engineering and mathematics education at all levels of education, announces its interest in receiving grant applications for the support of the University Reactor Instrumentation Program. The purpose of this program is to support needs of U.S. academic communities in modernizing and improving their nuclear reactors which are used for training and research. Approximately $1 million from fiscal year 1993 funds has been allocated for grant awards to those eligible colleges and universities with operating nuclear reactors dedicated to research, training and service. Future year funding will be contingent upon the availability of appropriated funds.

DATES: Applications for grants under this notice must be received by 4:30 p.m., Eastern Standard Time, March 10, 1993.

ADDRESSES: Application kits and guides are available from the Office of University and Science Education Programs, ST–50, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–8949. The completed applications must be submitted to: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER–64, Washington, DC, 20585. The personal or courier delivery address is: U.S. Department of Energy, Acquisition and Assistance Management Division, ER–64, Office of Energy Research, 19901 Germantown Road, Germantown, MD 20874. Each application submitted must reference Notice No. 93–08. Telephone and telefax numbers must also be included in any application.

FOR FURTHER INFORMATION CONTACT: Dr. Larry Barker, Program Manager, Office of University and Science Education Programs, ST–50, Office of Science and Technology Advisor, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC., 20585, (202) 586–8947.

SUPPLEMENTARY INFORMATION: The University Reactor Instrumentation Program was developed to provide support for modernization and improvement of the research and training reactors at U.S. colleges and universities. In accordance with 10 CFR 600.7(b)(1), it has been determined that eligibility for these grants is restricted to U.S. colleges and universities with operating nuclear reactors dedicated to research, training and service to the scientific community. The purpose for restricting eligibility to these applicants only is derived from the intent of the program, which is to provide funds for modernizing and improving research and training reactors, and the fact that reactors are general purpose laboratory facilities, useful in teaching nuclear science at all levels from pre-college through graduate school. In addition, this support will facilitate training for various reactor operating skills required by industry and the government.

Two general categories of equipment and instrumentation will be considered

under this program. They include: (1) equipment and instrumentation relating to the performance, operating capability and control of the reactor including radiation detection or monitoring equipment; and (2) equipment or instrumentation that will significantly improve or expand the research/training capability of the facility. Applications may include more than one item of equipment or instrumentation; however, they must be listed in order of priority. Detailed information regarding the cost or price of equipment or instrumentation must be included as part of the required budget narrative section of the application. Applications may also be broken into phases for funding at a later date dependent upon availability of resources. Support will not be provided for faculty or staff salaries, facility operating costs, fees or profit. The project description portion of the application must include information on the following activities (items 1 and 2 are the most critical): (1) The potential of the new equipment or instrumentation to increase the quality and/or efficiency of operation of the reactor facility; (2) the potential of the new equipment or instrumentation to significantly improve or expand the research or training capability of the facility; (3) the potential of the new equipment or instrumentation to enhance and/or modernize safety related systems within the reactor facility; (4) the number of students pre-college through graduate and faculty using as well as supported by the facility; and (5) the amount and type of research or service being provided by the facility to other departments, universities, industry or U.S. Government Agencies during the past five years. A brief description and statement of qualifications of the reactor facility staff should also be provided. Selection for award decisions by DOE will take into consideration information provided regarding the applicant's willingness to share in the total cost of the project.

It is anticipated that $1 million will be available for this activity. Awards may range from $5,000 to $250,000 per year. The number of awards will be determined from the number of approved applications submitted under this notice and the funds available at time of award. However, DOE reserves the right to fund, in whole or in part, any, all, or none of the applications submitted. Additional information may be subsequently requested by DOE during evaluation of a submitted application. General information about development and submission of applications, eligibility, limitations, evaluation and selection processes, and other policies and procedures are contained in the ER Special Research Grant Application Kit and Guide, and in 10 CFR part 605. The catalog of Federal Domestic Assistance Number for this program is 81.049.

Issued in Washington, DC, on December 23, 1992.

D. D. Mayhew,

Director, Office of Management, Office of Energy Research.

[FR Doc. 93-207 Filed 1-7-93; 8:45 am]

BILLING CODE 6450-01-M

Financial Assistance Program Notice 93-09; University Reactor Sharing Program

AGENCY: Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Office of Science and Technology Advisor (STA) of the Department of Energy, in keeping with its energy-related mission to strengthen the Nation's support of science, engineering and mathematics education at all levels of education, announces its interest in receiving grant applications for the support of the University Reactor Sharing Program. The purpose of this program is to provide funds to U.S. colleges or universities with nuclear reactor facilities (host institutions) that cover reactor operating costs when the facilities are utilized by regional affiliates (user institutions) for student instruction or for student or faculty research. In accordance with 10 CFR part 600.7(b)(1), eligibility for these grants is restricted to U.S. colleges and universities with nuclear reactor facilities because they provide a unique opportunity to address important aspects of the Nation's nuclear science and engineering educational programs. It is anticipated that approximately $500,000 will be available for support of this program during fiscal year 1993.

DATES: Applications for grants under this notice should be received by 4:30 p.m., Eastern Standard Time, March 31, 1993.

ADDRESSES: Application kits and guides are available from: U.S. Department of Energy, Office of University and Science Education Programs, St-50, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-8949. Completed applications must be submitted to: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER-64, Washington, DC 20585. The following address must be used when submitting applications by U.S. Postal Service Express, any commercial mail delivery service, or when handcarried by the applicant: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER-64, 19901 Germantown Road, Germantown, MD 20874. Each application must reference Notice No. 93-09. Telephone and telefax numbers must also be included in any application.

FOR FURTHER INFORMATION CONTACT: Dr. Larry Barker, Program Manager, U.S. Department of Energy, Office of Energy Research, University and Science Education Programs, ST-511, Washington, DC 20585, (202) 586-8947.

SUPPLEMENTARY INFORMATION: This program provides funding to host institutions to cover expenses associated with operation of their nuclear reactor facility for the benefit of user institutions to promote education, training or research opportunities. University reactors are extremely versatile neutron sources and research facilities; thus the availability of a nuclear reactor contributes particularly and significantly to research and educational opportunities at both the graduate, undergraduate and precollege levels. Any U.S. educational institution which operates a research or training reactor may submit an application for a new or renewal award. However, those host institutions applying that have a substantial number of user institutions indicating continued or new interest in the project are more likely to be selected than those applicants who do not have sufficient numbers of user institutions. User groups affiliated with the host institution are not considered eligible for participation in this program. Projects may range from tours, demonstrations, experiments, workshops and seminars for middle school and high school groups to faculty research projects and MS/Ph.D. thesis or dissertation research. Reactor utilization may range from simple service irradiations and analytical support to basic research studies requiring the facility's most sophisticated equipment. Each application must include under the "Project Description" portion information on the relative availability of the reactor to outside users, an assessment on a regional basis of the colleges, universities and/or precollege institutions that can be served by the proposing institution's reactor facility and provide evidence of interest on the part of potential or former user institutions to utilize the applicant's

reactor facility during the proposed grant period. Allowable costs under this program include:

(1) Payments for irradiation services not to exceed the established, published schedule of the host institution;

(2) Payments for use of the reactor and related facilities based upon established rates of the host institution;

(3) Cost of technical assistance furnished by the host institution for conduct of studies by a user institution; and

(4) Costs of materials and supplies consumed in user institution projects. Unallowable costs under this program include:

(1) Normal operating expenses of the facility;

(2) Laboratory apparatus and instrumentation;

(3) Costs that are covered by existing grant or contract; and

(4) Indirect or overhead costs. Funds for individual or group travel or subsistence will not allowed except in highly unusual situations.

During fiscal year 1993, DOE anticipates that the number of awards to be issued and the amount of each award will depend upon the number of approved applications, the amount of funds requested and the total DOE funds made available for this program. It is anticipated that $500,000 will be available from DOE's Office of Energy Research. Awards may range from $5,000 to $100,000 per year.

DOE reserves the right to fund, in whole or in part, any, all, or none of the applicants submitted. Additional information may be subsequently requested by DOE during evaluation of a submitted application. General information about development and submission of applications, eligibility, limitations, evaluation and selection processes, and other policies and procedures are contained in the ER Special Research Grant Application Kit and Guide, and in 10 CFR part 605. The catalog of Federal Domestic Assistance Number for this program is 81.049.

Issued in Washington, DC, on December 23, 1992.

D.D. Mayhew,

Director, Office of Management, Office of Energy Research.

[FR Doc. 93–208 Filed 1–7–93; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

Memorandum of Understanding Between the Federal Energy Regulatory Commission and the Department of the Interior, Bureau of Reclamation

January 4, 1993.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of Memorandum of Understanding.

SUMMARY: On November 6, 1992, the Chairman of the Federal Energy Regulatory Commission and the Department of the Interior's Assistant Secretary for Water and Science signed a Memorandum of Understanding that establishes a process for the early resolution of issues related to the development of non-federal hydrodevelopment at the Bureau of Reclamation facilities.

EFFECTIVE DATE: November 6, 1992.

FOR FURTHER INFORMATION CONTACT: Barbara Christin, Office of the General Counsel, Federal Energy Regulatory Commission, 825 N. Capitol Street, NE., Washington, DC 20426, Phone: (202) 208–0773.

SUPPLEMENTARY INFORMATION:

Memorandum of Understanding Between the Federal Energy Regulatory Commission and the Bureau of Reclamation, Department of the Interior for Establishment of Processes for the Early Resolution of Issues Related to the Timely Development of Non-Federal Hydroelectric Power at the Bureau of Reclamation Facilities

In the interest of mutual cooperation for the expeditious non-Federal development of hydroelectric energy, the Memorandum of Understanding is executed between the Federal Energy Regulatory Commission (Commission), pursuant to the authority contained in the Federal Power Act (FPA), 16 U.S.C. 791a *et seq.*, section 210 of the Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 824a–3, and the Electric Consumers Protection Act of 1986, Public Law 99–495, and the Bureau of Reclamation (Reclamation), pursuant to the Reclamation Act of 1902, 43 U.S.C. 391 *et seq.*, as amended and supplemented, and the interdepartmental work provision of 47 Stat. 417, 31 U.S.C. 1535.

Whereas, the Commission is authorized to issue preliminary permits and licenses to non-Federal entities for the development of hydroelectric powerplants under its jurisdiction, including powerplants utilizing Federal dams or other facilities where hydroelectric power has not been reserved exclusively for Federal development under Federal reclamation law, either congressionally or administratively, where hydroelectric power development has been reserved for non-Federal development under reclamation law; and

Whereas, Reclamation is authorized both administratively and congressionally to construct water resources projects throughout the 17 Western States, including hydroelectric power facilities; and

Whereas, Reclamation is authorized to grant leases of power privilege to non-Federal entities for the development of hydroelectric powerplants under its jurisdiction; and

Whereas, Reclamation is agreeable to the development of hydroelectric power by non-Federal entities under the FPA on Reclamation projects where hydroelectric power development has not been reserved exclusively for development under Federal reclamation law, either congressionally or administratively,or where hydroelectric power development has not been reserved for non-Federal development under reclamation law, and where such hydroelectric power developments are compatible with the purposes for which the Reclamation projects were authorized; and

Whereas, Reclamation and the Commission recognize the need to establish criteria and guidelines to assist in determining whether the Commission or Reclamation has jurisdiction over non-Federal hydroelectric power development at particular Reclamation projects; and

Whereas, the process of non-Federal development of hydroelectric power at Federal facilities often begins informally with early consultations with either or both agencies by prospective applicants, and begins formally either with an application to the Commission for a preliminary permit or license or a request to Reclamation for a lease of power privilege; and

Whereas, from time to time issues arise between the Commission and Reclamation concerning whether the Commission has authority to license non-Federal hydroelectric power development at a particular Reclamation project; and

Whereas, both agencies desire to establish administrative processes and joint guidelines by which such issues can be resolved in a timely and legally sound fashion;

Now Therefore, because it is in the public interest that the agencies work together to ensure timely development of renewable hydroelectric power resources at existing Reclamation facilities, the Commission and Reclamation agree to the following:

Article 1. *Commission Procedures.* Upon the filing with the Commission of an application for a preliminary permit or a license for a hydroelectric power development located at or within a Reclamation project, the following procedures will be used:

A. Distribution of Applications

Commission staff will ensure that Reclamation receives a copy of the filed application within 15 calendar days of such filing.

B. Reclamation Review of Permit Applications

Reclamation shall preliminarily review each permit application and, if it objects to the proposed hydroelectric power development on the ground that it is reserved for development under Federal reclamation law, shall, within 45 days of the filing date of the application, so advise the applicant and the Commission in writing and, to the extent possible at this stage of review, give to the applicant and the Commission the reasons therefor, with citations to and, where feasible, copies of relevant statutory texts, legislative history, administrative authorizations, and feasibility reports.

C. Reclamation Review of License Applications

Reclamation shall review each license application and, if it objects to the proposed hydroelectric power development on the ground that it is reserved for development under Federal reclamation law, shall, within 60 days of the filing of the application, so advise the applicant and the Commission in writing, giving both the applicant and the Commission the reasons therefor, with citations to and, where feasible, copies of relevant statutory texts, legislative history, administrative authorizations, and feasibility reports.

D. Preliminary Determination on Jurisdiction

Commission staff preliminarily review each license or preliminary permit application proposing hydroelectric development at or within a Reclamation project to determine whether the Commission's authority to license non-Federal hydroelectric power development has been withdrawn.

(1) If Commission staff, after reviewing the information submitted by Reclamation, concludes that the Commission's authority has been withdrawn, it shall then take appropriate action on the application and state the grounds therefor.

(2) If Commission staff is unable to determine conclusively that the Commission's authority to license a non-Federal hydroelectric power development at the facility or site has been withdrawn, or preliminarily determines that the Commission's authority to license a non-Federal hydroelectric power development at the facility or site has not been withdrawn, it shall so advise the applicant and Reclamation in writing, providing the rationale for its determination, with citations to and, where feasible, copies of relevant statutory texts, legislative history, administrative authorizations, and feasibility reports.

(3) Staff of either agency may, within 30 days of Commission staff's notification to Reclamation and the applicant under D(2) above, request a meeting to discuss and attempt to resolve any differences between the agencies. If Reclamation changes its position after the meeting, it shall, within 30 days of the meeting, so notify the Commission and the applicant, in writing. Commission staff shall proceed to issue public notice of the acceptance of such application for processing only after any such meetings that have been requested have taken place.

E. Formal Reclamation Comments

If after issuance of public notice of the acceptance of a preliminary permit or license application for processing (both pursuant to paragraph D of this Article 1), Reclamation continues to object to the proposed hydroelectric power development on the ground that it has been reserved for development under Federal reclamation law, it shall, within the comment period and deadline for intervention established in the public notice of the acceptance of the permit or license application, either file formal comments or a motion to intervene (which motion will include formal comments). In either event, Reclamation shall submit its final position on the issue, giving reasons therefor, with citations to and, where feasible, copies of relevant statutory texts, legislative history, administrative authorizations, and feasibility reports. In the case of a license application, Reclamation shall also, either in response to the public notice of the license application or in response to the public notice that the application is ready for environmental review, whichever comes later, submit (through the Interior Department) conditions for inclusion in the license pursuant to section 4(e) of the FPA.

F. Final Commission Action

After completion of the above-described procedures, the Commission, or its staff, will review all the information in the record of the preliminary permit or license proceeding on the issue of the Commission's authority and take whatever action on the preliminary permit or license application it deems appropriate.

Article 2. *Reclamation Procedures.* Upon receipt by Reclamation of a request for a lease of power privilege for a hydroelectric power development located at or within a Reclamation project, the following procedures will be used:

A. Distribution of Applications

Reclamation will ensure that the Commission receives a copy of the request within 15 calendar days of its receipt.

B. Reclamation Review

Before proceeding in any manner to act upon a request for a lease of power privilege, Reclamation shall make a determination as to whether hydroelectric power development is reserved at the project in question under Federal reclamation law.

(1) If Reclamation determines that hydroelectric power development is not reserved under Federal reclamation law, and that the Commission's authority to license such hydroelectric development has not been withdrawn, then Reclamation shall deny the request for a lease of power privilege, so notify the requestor in writing, and provide a copy of this notification to the Commission.

(2) If Reclamation preliminarily determines that hydroelectric power development is reserved under Federal reclamation law, then it shall, in writing, so notify the requestor and the Commission and give to the Commission the reasons therefor, with citations to and, where feasible, copies of relevant statutory text, legislative history, administrative authorizations, and feasibility reports.

C. Commission Review and Response

Commission staff shall review all requests for leases of power privilege for which Reclamation has made a determination under paragraph B(2) above.

(1) If, within 60 days of receipt of the information provided by Reclamation pursuant to paragraph B(2) above, Commission staff does not submit comments, or submits comments stating that it does not object to Reclamation's determination under paragraph B(2) above, then Reclamation will proceed to act upon the request for a lease of power privilege according to its procedures.

(2) If it preliminarily determines that the Commission's authority to license such hydroelectric development has not been withdrawn, Commission staff shall, within 60 days of receipt of the information provided by Reclamation pursuant to paragraph B(2) above, so advise Reclamation and the requestor in writing, providing the appropriate rationale to explain its conclusion. Staff of either agency may, within 30 days of Commission staff's notification to Reclamation and the requestor under this paragraph, request a meeting to discuss and attempt to resolve any differences between the agencies. If Commission staff changes its position after the meeting, it shall, within 30 days of the meeting, so notify Reclamation and the requestor, in writing. If Commission staff and Reclamation cannot, after a reasonable effort and period of time, reach agreement on which agency has jurisdiction, then Reclamation will notify the requestor that Reclamation will not act upon the request for a lease of power privilege. The requestor will be advised by Reclamation to file a preliminary permit application or a declaration of intention with the Commission in order to obtain a final determination as to which agency has jurdiction. The Commission and Reclamation will then follow the procedures in Article 1, paragraphs E and F.

Article 3. *Hydroelectric Developments Located Both Inside and Outside of Reclamation Projects.* In the event that non-Federal hydropower facilities would be located inside and outside of the boundaries of a Reclamation project, and if hydroelectric power development is reserved under reclamation law, then the Commission shall have jurisdiction over the portion of the facilities located outside the boundaries of the Reclamation project and Reclamation shall have jurisdiction over the portion of the facilities located inside the boundaries of the Reclamation project. If hydroelectric power development is not reserved under reclamation law, then the Commission shall have jurisdiction over the entire non-Federal hydroelectric development. If the Commission and Reclamation agree that hydroelectric power development has been reserved under reclamation law, then the two agencies shall coordinate their respective processes for acting on license applications

and requests for leases of power privilege. If Commission staff and Reclamation disagree, then the procedures set forth in Article 2, paragraph B will be followed:

Article 4. *Application of Guidelines.* (1) Both agencies agree to apply the guidelines attached to this Memorandum of Understanding as Exhibit A to all applications to develop non-Federal hydroelectric powerplants and facilities at or within Reclamation projects and to all applications to surrender licenses authorizing such development that are pending as of the date of execution of this Memorandum of Understanding or that are filed thereafter. Final authorizations for non-Federal hydroelectric powerplants and facilities at or within Reclamation projects are not affected by this Memorandum of Understanding; except for a situation where any request for lease of power privilege has been granted by Reclamation at a site where (a) at the time the lease was granted, a license or preliminary permit application for the site was pending before the Commission; (b) the license or preliminary permit application is pending before the Commission as of the date of execution of this Memorandum of Understanding; and (c) construction under the lease of power privilege has not commenced as of the date of execution of this Memorandum of Understanding.

(2) In reviewing, pursuant to Articles 1, 2, and 3 above, the authorizations under which a Reclamation project or facility was constructed to determine if the Commission's jurisdiction to license non-Federal hydroelectric projects at the site has been withdrawn, both agencies agree to apply the guidelines attached to this Memorandum of Understanding as Exhibit A. Authorizations not addressed by the attached guidelines will be reviewed and interpreted by each agency in the manner it deems appropriate.

Article 5. *Environmental Compliance.* For non-Federal hydroelectric powerplants and facilities involving Reclamation projects, facilities, and lands which are, in whole or in part, subject to the Commission's jurisdiction, the Commission shall, to the extent permitted by law, be the lead agency for the purposes of compliance with the National Environmental Policy Act (NEPA) and other applicable regulatory statutes. At Reclamation's request, the Commission will grant Reclamation cooperating agency status in the preperation of environmental impact statements pursuant to NEPA.

Article 6. Nothing in this Memorandum of Understanding shall be interpreted as modifying or limiting the legal rights and authorities of either agency, including the applicability of administrative procedures under the FPA and the Administrative Procedure Act (5 U.S.C. 522 *et seq.*), and the availability of judicial review of a final Commission order under Section 313 of the FPA.

Article 7. Nothing in this Memorandum of Understanding shall be construed as limiting or modifying Reclamation's rights to intervene in Commission proceedings, in accordance with applicable law and regulations, on grounds other than jurisdictional conflicts.

Article 8. Nothing in this Memorandum of Understanding shall be construed as interpreting or modifying the requirements of Section 2402 of the Energy Policy Act of 1992 or impairing the authorities of the National Park Service at Reclamation projects administered as part of the National Park system or of other agencies of the Interior Department not party to this agreement.

Article 9. This Memorandum of Understanding shall remain in effect until terminated by either party in writing.

Martin L. Allday,

Chairman, Federal Energy Regulatory Commission.

John M. Sayre,

Assistant Secretary for Water and Science, Department of the Interior.

Exhibit A

I. Congressional Authorization

In determining which agency has jurisdiction over the development of non-Federal hydropower at sites within congressionally authorized Reclamation projects, the Commission and Reclamation will apply, to the maximum extent practicable, the following presumptions. These presumptions may be challenged. The challenging agency,which bears the burden of proof, may offer evidence from any source. Some evidence will be deemed more persuasive than other evidence. The following evidence is listed in descending order of persuasiveness: (1) Statutory language; (2) materials incorporated by reference into the statute; (3) House and Senate documents and reports; (4) documents submitted to Congress, such as Feasibility Reports and Definite Plan Reports; (5) other legislative history, such as floor debates or hearing transcripts; (6) Definite Plan Reports, or supplements thereto, that are issued after the administrative or statutory authorization; and (7) any other information.

Presumption 1

If neither the authorizing statute, as amended, nor any documents incorporated by reference in the statute, mention hydropower development as a project purpose, then the Commission is presumed to have jurisdiction.

Example: *Baker Project, Upper Division,* Pub. L. No. 87–706, 76 Stat. 634 (1962). "That for the purposes of providing irrigation water, controlling floods, conserving and developing fish and wildlife, and providing recreational benefits, the Secretary of the Interior, * * * is authorized to construct, operate, and maintain the facilities of the upper division of the Baker Federal Reclamation project, Oregon. The principal works of the project shall consist of a dam and reservoir, pumping plans, and related facilities."

Presumption 2

If the authorizing statute, as amended, or any documents incorporated by reference in the statute, appear to specifically reserve hydropower development exclusively to the United States or to specifically withdraw the Commission's jurisdiction, then Reclamation is presumed to have jurisdiction.

Example: *Palo Verde Diversion Project,* Public Law No. 83–752, section 2(c), 68 Stat. 1045 (1954). "* * * *Provided,* That there shall be and is hereby reserved to the United States or there shall be made available to it, as the case may require, the exclusive right to utilize * * * said dam, appurtenant works, lands, and interests in land for such development, generation, and transmission of electric power and energy as may hereafter be authorized by law * * *."

Uncompahgre Valley Project, Public Law No. 75–698, 52 Stat. 941 (1938). "* * * That whenever a development of power is necessary for the irrigation of lands under the Uncompahgre Valley reclamation project, Colorado, or an opportunity is afforded for the development of power under said project, the Secretary of the Interior is authorized to enter into a contract for a period not exceeding forty years for the sale or development of any surplus power * * *"

All American Canal, Boulder Canyon Project Act, Section 7, 45 Stat. 1057, 1062 (1928). "The said districts or other agencies shall have the privilege at any time of utilizing by contract or otherwise such power possibilities as may exist upon said canal * * *."

Presumption 3

If the authorizing statute, as amended, or any documents incorporated by reference in the statute, only list hydropower as one of several project purposes, without further detail, then the Commission is presumed to have jurisdiction.

Example: *Central Valley Project,* Rivers and Harbors Act of 1937, 50 Stat. 850 (subsequently amended). "That the entire Central Valley Project * * * is hereby reauthorized and declared to be for the purposes of improving navigation, regulating the flow of the San Joaquin River and the Sacramento River, controlling floods, providing for storage and for the delivery of the stored waters thereof, for the reclamation of arid and semiarid lands and lands of Indian reservations, and other beneficial uses, and for the generation and sale of electric energy as a means of financially aiding and assisting such undertakings and in order to permit the full utilization of the works constructed to accomplish the aforesaid purposes * * *."

Presumption 4

If the authorizing statute, as amended, or any documents incorporated by reference in the statute, specifically authorize Reclamation to construct, operate, or maintain hydroelectric facilities or powerplants, then Reclamation is presumed to have jurisdiction even though the authorizing statute does not specifically withdraw the Commission's authority over all hydropower development within the project.

Example: *Colorado River Storage Project,* Colorado River Storage Project Act, Public Law No. 84–485, 70 Stat. 105 (1956). "Secretary is hereby authorized (1) to construct, operate, and maintain the following initial units * * * consisting of dams, reservoirs, powerplants, transmission facilities, and appurtenant works: Curecanti. Flaming Gorge, Navajo (dam and reservoir only), and Glen Canyon * * * and (2) to

construct, operate, and maintain the following additional reclamation projects (including power-generating and transmission facilities related thereto), hereinafter referred to as participating projects: [Initial authorization listed eleven projects—other projects added from time to time]."

Presumption 5

If the authorizing statute, as amended, or any documents incorporated by reference in the statute, specify the number, capacity, or location of powerplants authorized for federal development, then Reclamation is presumed to have jurisdiction for that specified development. Beyond the specified development, the Commission is presumed to have jurisdiction.

Example: *Central Valley Project, Trinity River Division,* Public Law No. 84–386, 69 Stat. 719 (1955). "[T]he Secretary of the Interior * * * is authorized to construct, operate, and maintain * * * the Trinity River division consisting of * * * hydroelectric powerplants with a total generating capacity of approximately two hundred thirty-three thousand kilowatts * * *."

Central Valley Project, American River Division, 63 Stat. 852 (1949). "A hydroelectric powerplant with a generating capacity of approximately one hundred and twenty thousand kilowatts, and necessary hydroelectric afterbay powerplants * * *."

Columbia Basin Project, Grand Coulee Dam, Public Law No. 89–448, 80 Stat. 200 (1966). "[T]he Secretary of the Interior is hereby authorized to construct, operate, and maintain a third powerplant with a rated capacity of approximately three million six hundred thousand kilowatts * * * at Grand Coulee Dam * * *."

II. Administrative Authorizations

If the Reclamation project was administratively authorized, the agencies must examine the authorizing feasibility reports that were adopted in accordance with the approval procedures governing at the time to determine appropriate jurisdiction. In reviewing the feasibility reports, the reasoning set out in Section I above shall apply.

Example: *Baker Project, Lower Division,* approved by the President March 18, 1931.

Boise Project, except for Black Canyon Dam and Powerplant in Payette Division. Arrowrock Dam authorized by the Secretary January 6, 1911.

Deadwood Dam and Reservoir approved by the President October 19, 1928. *Payette Division* approved by the President December 19, 1935.

Anderson Ranch Dam and Reservoir authorized by the Secretary August 12, 1940.

Orland Project, authorized by the Secretary October 5, 1907.

Rio Grande Project, except for Elephant Butte Dam and Powerplant and Caballo Dam, authorized by the Secretary December 2, 1905.

III. Congressional and Administrative Authorizations

In some cases, Reclamation projects were initially authorized administratively, but then legislation was subsequently passed that, for example, re-authorized the project, authorized additional project features, modified the previously authorized project, or affected some other aspect of the project such as authorization to dispose of surplus power produced at the project. For projects having both administrative and congressional authorizations, in order to determine which documents must be examined, we must first determine whether only one type of authorization applies to the particular site in question. If the site in question: (1) is or is not mentioned in any of the administrative authorizations, and was subsequently authorized by legislation, then the relevant statutory texts and legislative history will prevail over the administrative authorization; or (2) was administratively authorized, but none of the congressional authorizations apply, then the authorizing feasibility reports must be examined. In either case, the reasoning set out in Section I above shall apply.

Example: *Uncompahgre Project.* Authorized (originally called Gunnison Project) by the Secretary March 14, 1903. Rehabilitation work and construction of Taylor Park Dam approved by the President November 6, 1935. Statute authorizing sale and development of surplus power enacted June 22, 1938, 52 Stat. 941.

Salt River Project. Authorized by the Secretary March 14, 1903. Rehabilitation and betterment authorized by act of October 7, 1949, 63 Stat. 724. Statute authorizing sale of surplus power enacted September 18, 1922, 42 Stat. 847.

Boise Project, Black Canyon Dam and Powerplant in Payette Division. Black Canyon Dam authorized by the Secretary June 26, 1922. Payette Division authorized by the Secretary December 19, 1935. Power development restrictions, 43 Stat. 390, 415 (June 5, 1924). Revenues from Black Canyon powerplant, 45 Stat. 1562 (March 4, 1929). Authorization for feasibility studies for additional power, 94 Stat. 1505.

This Memorandum of Understanding was signed by the Chairman of the Federal Energy Regulatory Commission and the Assistant Secretary for Water and Science, Department of the Interior, on November 6, 1992.

Lois D. Cashell,

Secretary.

[FR Doc. 93–335 Filed 1–7–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. RS92–5–000 and RS92–6–000]

Columbia Gas Transmission Corporation and Columbia Gulf Transmission Company; Deadline for Protests and Comments on Compliance Filings

December 31, 1992.

Take notice that on December 30, 1992, Columbia Gas Transmission Corporation and Columbia Gulf Transmission Company made filings pursuant to § 284.14 of the Commission's regulations (18 CFR 284.14) to comply with Order No. 636. Under the procedures established by notice issued May 22, 1992, any protests to, or comments on, these compliance filings must be filed with the Commission within 21 days of the date of the filings. Because the Commission's offices will be closed on January 20, 1993, for Inauguration Day, protests and comments in these proceedings will be due on January 21, 1993.

Lois D. Cashell,

Secretary.

[FR Doc. 93–381 Filed 1–7–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP91–188–000]

El Paso Natural Gas Company; Compliance Filing

December 31, 1992.

Take notice that on December 29, 1992, El Paso Natural Gas Company ("El Paso") filed pursuant to part 154 of the Federal Energy Regulatory Commission ("Commission") Regulations Under the Natural Gas Act, and in compliance with the Commission's order issued December 23, 1992 at Docket No. RP91–188–000 certain tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1–A to become effective December 29, 1992.

El Paso states that ordering paragraph (B) of the Commission's December 23, 1992 order directs El Paso to file, within fifteen (15) days of the date of the order, tariff sheets revising § 20.12(e), Unauthorized Overpull Penalty, contained in the transportation General Terms and Conditions of El Paso's Volume No. 1–A Tariff.

El Paso states that the December 23, 1992 order directed El Paso to: (i) Reflect that the Unauthorized Overpull Penalty amounts attributable to each day be allocated on a *pro rata* basis to customers that receive less than their scheduled quantities of gas on that day; (ii) define a qualified Shipper as one that did not receive its scheduled volumes due to El Paso's inability to make deliveries on days when El Paso has provided notice that an overpull penalty exists; and (iii) change the word "month" with the word "day" where appropriate. El Paso further states that the tendered tariff sheets were filed in compliance with said directives.

El Paso respectfully requested that the Commission grant such waivers of its applicable rules and regulations as may be necessary to permit the tendered tariff sheets to become effective on December 29, 1992, the date on which the filing was made with the

Commission, as authorized by ordering paragraph (B) of the December 23, 1992 order.

El Paso states that copies of the filing were served upon all parties of record at Docket No. RP91–188–000 and all interested state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 8, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of the filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–382 Filed 1–7–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. TQ93–5–4–000 and TM93–10–4–000]

Granite State Gas Transmission, Inc.; Proposed Changes in Rates

December 31, 1992.

Take notice that on December 29, 1992, Granite State Gas Transmission, Inc. (Granite State), 300 Friberg Parkway, Westborough, Massachusetts 01581 filed the revised tariff sheets listed below in its FERC Gas Tariff, Second Revised Volume No. 1, containing changes in sales rates for effectiveness on January 1, 1993.

Twenty-third Revised Sheet No. 21
Ninth Revised Sheet No. 22

According to Granite State, it filed its Annual Purchased Gas Cost Adjustment on November 7, 1992 proposing revised sales rates and revised surcharges applicable to deferred gas costs for effectiveness on January 1, 1993, applicable to its sales to its two affiliated distribution company customers, Bay State Gas Company (Bay State) and Northern Utilities, Inc. (Northern Utilities). It is further stated that, subsequent to the annual filing on November 17, 1992. Granite State filed a compliance filing in Docket No. CP92–552–000 to reflect a certificate authorizing Granite State to provide a Rate Schedule SS–NE storage service for Bay State and Northern Utilities and to reduce its sales obligations to these customers in quantities equivalent to the maximum daily deliveries from the storage service. Prior to the compliance filing, Granite State and reflected in its sales rates the costs for the Rate Schedule SS–NE service which was rendered for Granite State's account by Tennessee Gas Pipeline Company (Tennessee). It is stated that in a contemporaneous out-of-cycle filing on November 17, 1992 in Docket No. TQ93–4–4–000, *et al.*, Granite State removed the Rate Schedule SS–NE costs from its sales rates.

According to Granite State, the instant out-of-cycle purchased gas cost adjustment is submitted to revise the sales rates included in the annual purchased gas cost adjustment filed on November 7, 1992 to reflect the following:

1. Reductions in the contract demand billing determinants for its sales obligations to Bay State and Northern Utilities to conform with the certificate issued in Docket No. CP92–552–000 and the compliance filing on November 17, 1992;

2. Removal of the Tennessee Rate Schedule SS–NE costs from the sales rates to conform with the out-of-cycle purchased gas cost adjustment in TQ93–4–4–000, *et al.*, also filed November 17, 1992;

3. Adjustments to demand charges to the rates for gas purchases from and transportation services rendered by Tennessee and Algonquin Gas Transmission Company to reflect the addition of the demand charge component of the Gas Research Institute interim funding unit approved by the Commission in Docket No. RP92–133–000 (Phase 1) for 1993; and

4. Revisions in projected spot market gas purchase costs to reflect lower prices that will be in effect on January 1, 1993.

Granite State further states that copies of its filing were served upon its customers and the regulatory commissions of the states of Maine, Massachusetts and New Hampshire.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 8, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–383 Filed 1–7–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–20–002]

Northwest Pipeline Corporation; Proposed Change in FERC Gas Tariff

December 31, 1992.

Take notice that on December 29, 1992, Northwest Pipeline Corporation (Northwest) tendered for filing and acceptance the following tariff sheets

Second Revised Volume No. 1

First Revised Sheet No. 153

First Revised Volume No. 1–A

Substitute First Revised Sheet No. 425

Northwest states that the purpose of the filing is to correct two minor errors that were contained in Northwest's November 6, 1992 filing that was filed in the referenced docket. First Revised Sheet No. 153 is filed to eliminate section 21.7 of the General Terms and Conditions of Northwest's Volume No. 1 Tariff, which relates to the abandoned Gas Inventory Charge Provision. Substitute First Revised Sheet No. 425 is filed to eliminate language from section 15.3 of the General Transportation Terms and Conditions, which is also contained on Original Sheet No. 424 of Northwest's currently effective Volume No. 1–A Tariff.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 8, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–384 Filed 1–7–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP91-166-019]

Northwest Pipeline Corporation; Proposed Change in FERC Gas Tariff

December 31, 1992.

Take notice that on December 29, 1992, Northwest Pipeline Corporation (Northwest) tendered for filing and acceptance the following tariff sheets:

Second Revised Volume No. 1

Third Revised Twentieth Revised Sheet No. 10
Third Revised Nineteenth Revised Sheet No. 11
Second Revised Fourteenth Revised Sheet No. 13
First Revised Original Sheet No. 138

First Revised Volume No. 1-A

First Revised Original Sheet No. 2
Second Revised Fifteenth Revised Sheet No. 201
First Revised Original Sheet No. 406
First Revised First Revised Sheet No. 437

Original Volume No. 2

First Revised Fifteenth Revised Sheet No. 2
First Revised Seventh Revised Sheet No. 2.1
First Revised Thirteenth Revised Sheet No. 2-A
First Revised Seventh Revised Sheet No. 2-A.1
First Revised Substitute Twenty-Fifth Revised Sheet No. 2-B
First Revised First Revised Sheet No. 2-C

Northwest states that the purpose of this filing is to file revised rates and tariff provisions which reflect the conveyance of Northwest's gathering and processing facilities, at the close of business on December 31, 1992, to Williams Gas Processing Company. Northwest requests an effective date of January 1, 1993 for all tariff sheets included in this filing.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 8, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-385 Filed 1-7-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. MT88-6-005]

Texas Gas Transmission Corp.; Notice of Filing

December 31, 1992.

Take notice on December 21, 1992, Texas Gas Transmission Corporation ("Texas Gas") tendered for filing the following revised tariff sheets to its First Revised Volume No. 2-A of its FERC Gas Tariff to be effective within 30 days:

First Revised Sheet No. 118
First Revised Sheet No. 175
Original Sheet No. 175A

Texas Gas states that this filing is being made to revise its tariff to reflect organizational changes that are (1) designed to consolidate all gas merchant functions of Texas Gas and its affiliates within a single company that can serve gas consumers more efficiently and (2) comply with the requirements of Order Nos. 636, *et seq.*, as well as Order Nos. 497 *et seq.* Texas Gas further states that consolidation of Texas Gas' gas merchant service will not be completed until its blanket sales certificate pursuant to Order No. 636 is effective.

Texas Gas states that copies of its filing are available for inspection at its principal place of business in Owensboro, Kentucky and have been mailed to all affected customers and state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211. All such protests should be filed on or before January 8, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-386 Filed 1-7-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. MT88-3-008]

Transcontinental Gas Pipe Line Corp.; Notice of Filing

December 31, 1992.

Take notice on December 21, 1992, Transcontinental Gas Pipe Line Corporation ("TGPL") tendered for filing the following revised tariff sheet to its Third Revised Volume No. 1 of its FERC Gas Tariff to be effective within 30 days:

Second Revised Sheet No. 344

TGPL states that this filing is being made to revise its tariff to reflect organizational changes that are (1) designed to consolidate all gas merchant functions of TGPL and its affiliates within a single company that can serve gas consumers more efficiently and (2) comply with the requirements of Order Nos. 636 *et seq.*, as well as Order Nos. 497 *et seq.*

TGPL states that copies of its filing are available for inspection at its principal place of business in Houston, Texas, and have been mailed to all affected customers and state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NW., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211. All such protests should be filed on or before January 8, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-387 Filed 1-7-93; 8:45 am]

BILLING CODE 6717-01-M

Office of Fossil Energy

[FE Docket No. 92-130-NG]

The Montana Power Co.; Order Granting Long-Term Authorization To Export Natural Gas to Canada and Terminating Existing Authorization

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of order.

SUMMARY: The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Montana Power Company (MPC) long-term authorization to export up to 475 Mcf per day, and up to 173,375 Mcf per year, of natural gas to Canada, at Sweetgrass, Montana, for an initial term beginning on the date of first delivery through October 13, 1994, consistent with the terms of the gas purchase contract between MPC and Canadian Western Natural Gas Company Limited dated September 3, 1992, on file in this docket. The authorization shall be automatically extended from month to month until the date the parties terminate the contract.

This order is available for inspection and copying in the Office of Fuels Programs docket room, 3F–056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 24, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 93–495 Filed 1–7–93; 8:45 am]

BILLING CODE 6450–01–M

[FE Docket No. 90–05–NG]

Rochester Gas and Electric Corp.; Order Amending Conditional Order To Grant Final Long-Term Authorization To Import Natural Gas From Canada

AGENCY: Office of fossil Energy, DOE.

ACTION: Notice of Order.

SUMMARY: The Office of Fossil energy of the Department of Energy gives notice that it has issued a final order granting Rochester Gas and Electric Corporation authorization to import near Grand Island, New York, up to 16,000 Mcf of Canadian natural gas per day. The authorization is for a term of 10 years beginning on the date that the pipeline to be built by Empire State Pipeline Company, Inc. in New York State is placed in service.

This order is available for inspection and copying in the Office of Fuels Programs Docket Room, room 3F–056, at 1000 Independence Avenue, SW., Washington, DC 20585. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on December 31, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 93–403 Filed 1–7–93; 8:45 am]

BILLING CODE 6450–01–M

Cases Filed During the Week of December 11 Through December 18, 1992

Office of Hearings and Appeals

During the week of December 11 through December 18, 1992, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Dated: December 29, 1992.

George B. Breznay,

Director, Office of Hearings and Appeals.

LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS

[Week of December 11 through December 18, 1992]

Date	Name and location of applicant	Case No.	Type of submission
Dec. 11 1992	Walter J. Scott & Benjamin J. Agajanian, Oil Producers et al., Washington, DC.	LEF–0053	Implementation of special refund procedures. *If granted:* The Office of Hearings and Appeals would implement Special Refund Procedures pursuant to 10 C.F.R., Part 205, Subpart V, for distributing the crude oil overcharge funds obtained in settlements with Walter J. Scott and Benjamin J. Agajanian Oil Producers, et al.
Dec. 14, 1992	Ferenc M. Szasz, Albuquerque, New Mexico	LFA–0254	Appeal of an information request denial. *If granted:* Ferenc M. Szasz would receive access to unclassified DOE information about the British mission to Los Alamos.
Dec. 14, 1992	Robertson, Phillips & Knight, Bellevue, Washington	LFA–0253	Appeal of an information request denial. *If granted:* The November 23, 1992 Freedom of Information Request denial would be rescinded, and Robertson, Phillips & Knight would receive access to DOE information.
Dec. 14, 1992	Texaco/Todd's Texaco, Fritch, Texas	RR321–124	Request for modification/rescission in the Texaco refund proceeding. *If granted:* The November 16, 1992 Decision and Order (Case No. RF321–4643 & RF321–19331) issued to Todd's Texaco would be modified regarding the firm's application for refund submitted in the Texaco refund proceeding.
Dec. 15, 1992	Osenbaugh Grass Seeds, Lucas, Iowa	LFA–0255	Appeal of an information request denial. *If granted:* The November 16, 1992 Freedom of Information Request Denial issued by the National Renewable Energy Laboratory (NREL) Area Office would be rescinded, and Osenbaugh Grass Seeds would receive access to a complete copy of NREL's contract with Battelle Memorial Institute and related documents.
Dec. 18, 1992	Seehuus Associates, Prosser, Washington	LFA–0256	Appeal of an information request denial. *If granted:* The December 7, 1992 Freedom of Information Request Denial issued by the Office of the Inspector General would be rescinded, and Seehuus Associates would receive access to the summary results of the IG investigation into Martin Marietta Energy Services leasing practices in the city of Oak Ridge.

REFUND APPLICATIONS RECEIVED
[Week of December 11 to December 18, 1992]

Date received	Name of refund proceeding/ name of refund applicant	Case number
12/14/92	Second Street Canal.	RF346–15
12/15/92	Derby Refining Company.	RF340–178
12/11/92 thru 12/18/92.	Texaco Oil refund applications received.	RF321–19503 thru RF321–19528
12/11/92 thru 12/18/92.	Gulf Oil refund applications received.	RF300–20764 thru RF300–20777
12/11/92 thru 12/18/92.	Atlantic Richfield, applications received.	RF304–13439 thru RF304–13462
12/11/92 thru 12/18/92.	Crude Oil refund applications received.	RF272–93996 thru RF272–94011

[FR Doc. 93–406 Filed 1–7–93; 8:45 am]
BILLING CODE 6450–01–M

Office of Hearings and Appeals

Issuance of Proposed Decisions and Orders During the Week of December 14 Through December 18, 1992

During the week of December 14 Through December 18, 1992, the proposed decisions and orders summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to applications for exception.

Under the procedural regulations that apply to exception proceedings (10 CFR part 205, subpart D), any person who will be aggrieved by the issuance of a proposed decision and order in final form may file a written notice of objection within ten days of service. For purposes of the procedural regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date an aggrieved person receives actual notice, whichever occurs first.

The procedural regulations provide that an aggrieved party who fails to file a Notice of Objection within the time period specified in the regulations will be deemed to consent to the issuance of the proposed decision and order in final form. An aggrieved party who wishes to contest a determination made in a proposed decision and order must also file a detailed statement of objections within 30 days of the date of service of the proposed decision and order. In the statement of objections, the aggrieved party must specify each issue of fact or law that it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these proposed decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, room 1E–234, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, Monday through Friday, between the hours of 1 p.m. and 5 p.m., except federal holidays.

Dated: December 29, 1992.

George B. Breznay,

Director, Office of Hearings and Appeals.

Pioneer International, Inc., Portland, OR, Lee–0036, Reporting Requirements

Pioneer International, Inc., filed an Application for Exception from the Energy Information Administration (EIA) requirement that it file Form EIA–782B, the "Reseller/Retailer's Monthly Petroleum Product Sales Report." In considering the request, the DOE found that the firm was not adversely affected by the reporting requirement in a way that was significantly different from the burden borne by similar reporting firms. Accordingly, on December 17, 1992, the DOE issued a Proposed Decision and Order determining that the exception request should be denied.

Suburban Fuel Company, Alexandria, VA, Lee–0045, Reporting Requirements

Suburban Fuel Company filed an Application for Exception from the provisions of Form EIA–782B, entitled "Resellers/Retailers' Monthly Petroleum Product Sales Report." The exception request, if granted, would permit Suburban Fuel Company to be relieved of the requirement to file Form EIA–782B. On December 17, 1992, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

[FR Doc. 93–407 Filed 1–7–93; 8:45 am]
BILLING CODE 6450–01–M

Implementation of Special Refund Procedures

AGENCY: Office of Hearings and Appeals, Department of Energy.

ACTION: Notice of implementation of special refund procedures.

SUMMARY: The Office of Hearings and Appeals (OHA) of the Department of Energy (DOE) announces the procedures for disbursement of $59,562.31, plus accrued interest, in alleged crude oil overcharges obtained by the DOE under the terms of a Consent Order entered into with E.B. Brooks, Jr., Case No. LEF–0048. The OHA has determined that the funds obtained from Brooks, plus accrued interest, will be distributed in accordance with the DOE's Modified Statement of Restitutionary Policy Concerning Crude Oil Overcharges.

DATE AND ADDRESS: Applications for Refund must be filed in duplicate, addressed to "Subpart V Crude Oil Overcharge Refunds", and sent to: Office of Hearings and Appeals, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

Applications must be postmarked by June 30, 1994.

FOR FURTHER INFORMATION CONTACT: Thomas O. Mann, Deputy Director, Roger Klurfeld, Assistant Director, Office of Hearings and Appeals, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–2094 (Mann); 586–2383 (Klurfeld).

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 205.282(b), notice is hereby given of the issuance of the Decision and Order set out below. The Decision and Order sets forth the procedures that the DOE has formulated to distribute to eligible claimants $59,562.31, plus accrued interest, obtained by the DOE under the terms of a Consent Order entered into with E.B. Brooks, Jr. on April 6, 1988. The funds were paid by Brooks towards the settlement of alleged violations of the DOE price and allocation regulations involving the sale of crude oil during the period September 1, 1973 through December 31, 1976.

The OHA will distribute the Brooks Consent Order fund in accordance with the DOE's Modified Statement of Restitutionary Policy Concerning Crude Oil Overcharges, 51 FR 27899 (August 4, 1986) (the MSRP). Under the MSRP, crude oil overcharge monies are divided between the federal government, the states, and injured purchasers of refined petroleum products. Refunds to the states will be distributed in proportion to each state's consumption of petroleum products during the price control period. Refunds to eligible purchasers will be based on the number of gallons of petroleum products which they purchased and the degree to which they can demonstrate injury.

Applications for Refund must be postmarked by June 30, 1994. Any claimant which has already filed a subpart V crude oil refund application should not file another application, as the prior application will be deemed to be filed in this crude oil refund proceeding. Instructions for the completion of crude oil refund applications are set forth in Decision that immediately follows this notice. Refund claims should be sent to the

address listed at the beginning of this notice.

Unless labelled as "confidential," all submissions must be made available for public inspection between the hours of 1 p.m. and 5 p.m., Monday through Friday, except federal holidays, in the Public Reference Room of the Office of Hearings and Appeals, located in room 1E–234, 1000 Independence Avenue, SW., Washington, DC 20585.

Dated: December 28, 1992.

George B. Breznay,

Director, Office of Hearings and Appeals.

Decision and Order

Name of Firm: E.B. Brooks, Jr.
Date of Filing: August 20, 1992
Case Number: LEF–0048

On August 20, 1992, the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) filed a Petition for the Implementation of Special Refund Procedures with the Office of Hearings and Appeals (OHA), to distribute the funds which E.B. Brooks, Jr. (Brooks) remitted to the DOE pursuant to an April 6, 1988 Consent Order reentered into by Brooks and the DOE. Brooks has remitted $59,562.31 pursuant to the Consent Order, to which $10,112.15 in interest has accrued as of November 30, 1992. In accordance with the procedural regulations codified at 10 CFR part 205, subpart V, the ERA requests in its Petition that the OHA establish special procedures to make refunds in order to remedy the effects of alleged regulatory violations which were resolved by the Consent Order. This Decision and Order establishes the procedures which OHA will employ to distribute these funds.

I. Background

The DOE issued a Remedial Order (RO) to Brooks on July 25, 1977, alleging that Brooks had violated the Federal petroleum price regulations by receiving revenues from the first sales of domestic crude oil in excess of the lawful ceiling price. After Brooks failed to comply with the RO, the ERA issued a Modified Remedial Order (MRO) on April 10, 1985, amending the remedial provisions of the RO to provide for payment of the alleged overcharge amount to the DOE for distribution under subpart V. The MRO was issued as a final Remedial Order by the OHA on October 27, 1987. The DOE and Brooks subsequently entered into the April 6, 1988 Consent Order, whereby Brooks agreed to pay the sum of $50,000, plus interest, to the DOE. To date, Brooks has remitted $59,562.31, to which $10,112.15 in interest has accrued as of November 30, 1992, making available a total of $69,674.46 (the Brooks Consent Order fund) for distribution through subpart V. These funds are being held in an interest-bearing escrow account maintained at the Department of the Treasury pending a determination regarding their proper distribution.

II. Jurisdiction and Authority

The subpart V regulations set forth general guidelines which may be used by the OHA in formulating and implementing a plan of distribution of funds received as a result of an enforcement proceeding. The DOE policy is to use the subpart V process to distribute such funds. For a more detailed discussion of subpart V and the authority of OHA to fashion procedures to distribute refunds, see Petroleum Overcharge Distribution and Restitution Act of 1986, 15 U.S.C. 4501–07, *Office of Enforcement*, 9 DOE ¶82,508 (1981), and *Office of Enforcement*, 8 DOE ¶82,597 (1981).

We have considered the ERA's petition that we implement a subpart V proceeding with respect to the Brooks Consent Order fund and have determined that such a proceeding is appropriate. This Decision and Order sets forth the OHA's plan to distribute this fund.

III. Refund Procedures

On October 8, 1992, OHA issued a Proposed Decision and Order (PD&O) establishing tentative procedures to distribute the Brooks Consent Order fund. That PD&O was published in the **Federal Register**, and a 30-day period was provided for the submission of comments regarding our proposed refund plan. See 57 FR 47634 (October 19, 1992). More than 30 days have elapsed and the OHA has received no comments concerning the proposed procedures for the distribution of the Brooks Consent Order fund. Consequently, the procedures will adopted as proposed.

A. Crude Oil Refund Policy

The funds obtained pursuant to the Brooks Consent Order will be distributed in accordance with the DOE's Modified Statement of Restitutionary Policy in Crude Oil Cases, 51 FR 27899 (August 4, 1986) (the MSRP). The MSRP was issued as a result of a court-approved Settlement Agreement In re: The Department of Energy Stripper Well Exemption Litigation, 653 F. Supp. 108 (D. Kan.), 6 Fed. Energy Guidelines ¶90,509 (1986) (the Stripper Well Settlement Agreement). The MSRP establishes that 40 percent of the crude oil overcharge funds will be remitted to the federal government, another 40 percent to the states, and up to 20 percent may be initially reserved for the payment of claims to injured parties. The MSRP also specifies that any monies remaining after all valid claims by injured purchasers are paid be disbursed to the federal government and the states in equal amounts.

The OHA has utilized the MSRP in all subpart V proceedings involving alleged crude oil violations. See Order Implementing the MSRP, 51 FR 29689 (August 20, 1986). This Order provided a period of 30 days for the filing of comments or objections to our proposed use of the MSRP as the groundwork for evaluating claims in crude oil refund proceedings. Following this period, the OHA issued a Notice evaluating the numerous comments which it received pursuant to the Order Implementing the MSRP. This Notice was published at 52 FR 11737 (April 10, 1987) (the April 10 Notice).

The April 10 Notice contained guidance to assist potential claimants wishing to file refund applications for crude oil monies under the subpart V regulations. Generally, all claimants would be required to (1) document their purchase volumes of petroleum products during the August 19, 1973 through January 27, 1981 crude oil price control period, and (2) prove that they were injured by the alleged crude oil overcharges. We also specified that end-users of petroleum products whose businesses are unrelated to the petroleum industry will be presumed to have been injured by the alleged crude oil overcharges and need not submit any additional proof of injury beyond documentation of their purchase volumes. See *City of Columbus, Georgia*, 16 DOE ¶ 85,550 (1987). Additionally, we stated that crude oil refunds would be calculated on the basis of a per gallon (or "volumetric") refund amount, which is obtained by dividing the crude oil refund pool by the total consumption of petroleum products in the United States during the crude oil price control period. The OHA has adopted the refund procedures outlined in the April 10 Notice in numerous cases. See e.g., *Shell Oil Co.*, 17 DOE ¶ 85,204 (1988) (*Shell*); *Mountain Fuel Supply Co.*, 14 Doe ¶ 85,475 (1986) (*Mountain Fuel*).

B. Refund Claims

We will adopt the DOE's standard crude oil refund procedures to distribute the monies in the Brooks Consent Order fund. We have chosen to initially reserve 20 percent of the fund, plus accrued interest, for direct refunds to claimants in order to ensure that sufficient funds will be available for

injured parties. This reserve figure may later be reduced if circumstances warrant.

The OHA will evaluate crude oil refund claims in a manner similar to that used in subpart V proceedings to evaluate claims based on alleged refined product overcharges. See *Mountain Fuel*, 14 DOE at 88,869. Under these procedures, claimants will be required to document their purchase volumes of petroleum products and prove that they were injured as a result of the alleged violations.

We will adopt a presumption that the crude oil overcharges were absorbed, rather than passed on, by applicants which were (1) end-users of petroleum products, (2) unrelated to the petroleum industry, and (3) not subject to the regulations promulgated under the Emergency Petroleum Allocation Act of 1973 (EPAA), 15 U.S.C. 751–760h. In order to receive a refund, end-user claimants need not submit any evidence of injury beyond documentation of their purchase volumes. See *Shell*, 17 DOE at 88,406.

Petroleum retailer, reseller, and refiner applicants must submit detailed evidence of injury, and they may not rely upon the injury presumptions utilized in some *refined product* refund cases. *Id.* These applicants may, however, use econometric evidence of the type found in the *OHA Report on Stripper Well Overcharges*, 6 Fed. Energy Guidelines ¶ 90,507 (1985). See *also* Petroleum Overcharge Distribution and Restitution Act 3003(b)(2), 15 U.S.C. 4502(b)(2). If a claimant has executed and submitted a valid waiver pursuant to one of the escrows established by the Stripper Well Settlement Agreement, it has waived its rights to file an application for subpart V crude oil refund monies. See *Mid-American Dairymen v. Herrington*, 878 F.2d 1448 (Tempt. Emer. Ct. App.), 3 Fed. Energy Guidelines ¶ 26,617 (1989); *In re: Department of Energy Stripper Well Exemption Litigation*, 707 F. Supp. 1267 (D. Kan.), 3 Fed. Energy Guidelines ¶ 26,613 (1987).

As has been stated in prior Decisions, a crude oil refund applicant will only be required to submit one application for its share of all available crude oil overcharge funds. See, e.g., *A. Tarricone, Inc.*, 15 DOE ¶85,495 (1987). A party that has already submitted a claim in any other crude oil refund proceeding implemented by the DOE need not file another claim. The prior application will be deemed to be filed in all crude oil refund proceedings finalized to date. The DOE has established June 30, 1994 as the current deadline for filing an Application for Refund from the crude oil funds. *Quintana Energy Corp.*, 21 DOE ¶85,032 (1991). It is the policy of the DOE to pay all crude oil refund claims at the rate of $.0008 per gallon. While we anticipate that applicants that filed their claims before June 30, 1988 will receive a supplemental refund payment, we will decide in the future whether claimants that filed later applications should receive additional refunds. See, e.g., *Seneca Oil Co.*, 21 DOE ¶85,327 (1991). Notice of any additional amounts available in the future will be published in the Federal Register.

C. Crude Oil Application Requirements

To apply for a crude oil refund, a claimant should submit an Application for Refund containing all of the following information:

(1) Identifying information including the claimant's name, current business address, business address during the refund period, taxpayer identification number, a statement indicating whether the claimant is a corporation, partnership, sole proprietorship, or other business entity, the name, title, and telephone number of a person to contact for any additional information, and the name and address of the person who should receive any refund check.[1] If the applicant operated under more than one name or under a different name during the price control period, the applicant should specify these names;

(2) If the applicant's firm is owned by another company, or owns other companies, a list of those companies' names, addresses, and descriptions of their relationship to the applicant's firm;

(3) A brief description of the claimant's business and the manner in which it used the petroleum products listed on its application;

(4) A statement identifying the petroleum products which the applicant purchased during the period August 19, 1973 through January 27, 1981, an annual schedule displaying the number of gallons of each petroleum product purchased during this refund period, and the total number of gallons of all petroleum products claimed on the refund application;

(5) An explanation as to how the applicant obtained the above mentioned purchase volumes, and, if estimates were used, a description of its method of estimation;

(6) A statement that neither the claimant, its parent firm, affiliates, subsidiaries, successors, nor assigns has waived any right it may have to receive a crude oil refund (e.g., by having executed and submitted a valid waiver accompanying a claim to any of the escrow accounts established pursuant to the Stripper Well Settlement Agreement);

(7) A statement that the applicant has not filed any other refund application in the subpart V crude oil refund proceeding;

(8) If the applicant is not an end-user, was covered by the DOE price regulations, or is related to the petroleum industry, a showing that the applicant was injured by the alleged crude oil overcharges;

(9) If the applicant is a regulated utility or a cooperative, certifications that it will pass on the entirety of any refund received to its customers, will notify its state utility commission, other regulatory agency, or membership body of the receipt of any refund, and a brief description as to how the refund will be passed along;

(10) The statement listed below signed by the individual applicant or a responsible official of the company filing the refund application:

> I swear (or affirm) that the information contained in this application and its attachments is true and correct to the best of my knowledge and belief. I understand that anyone who is convicted of providing false information to the federal government may be subject to a fine, a jail sentence, or both, pursuant to 18 U.S.C. 1001. I understand that the information contained in this application is subject to public disclosure. I have enclosed a duplicate of this entire application which will be placed in the OHA Public Reference Room.

All applications should be either typed or printed and clearly labeled "Application for Crude Oil Refund." Each applicant must submit an original and one copy of the application. If the applicant believes that any of the information in its application is confidential and does not wish for this information to be publicly disclosed, it must submit an original application, clearly designated "confidential," containing the confidential information, and two copies of the application with

[1] Under the Privacy Act of 1974, the submission of a social security number by an individual applicant is voluntary. An applicant that does not wish to submit a social security number must submit an employer identification number if one exists. This information will be used in processing refund applications, and is requested pursuant to our authority under the Petroleum Overcharge Distribution and Restitution Act of 1986 and the regulations codified at 10 CFR part 205, subpart V. The information may be shared with other Federal agencies for statistical, auditing or archiving purposes, and with law enforcement agencies when they are investigating a potential violation of civil or criminal law. Unless an applicant claims confidentiality, this information will be available to the public in the Public Reference Room of the Office of Hearings and Appeals.

the confidential information deleted. All refund applications should be sent to: Subpart V Crude Oil Overcharge Refunds, Office of Hearings and Appeals, Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585.

The filing deadline is June 30, 1994. Even though an applicant is not required to use any specific form for its crude oil refund application, a suggested form has been prepared by the OHA and may be obtained by sending a written request to the address listed above.

In addition, we are adopting the following procedures, now standard in OHA refund proceedings, relating to refund applications filed on behalf of applicants by "representatives," including refund filing services, consulting firms, accountants, and attorneys. See Texaco Inc., 20 DOE ¶ 85,147 (1990). Each such filing service shall, contemporaneously with its first filing in the crude oil refund proceeding following the issuance of this Decision and Order, submit a statement indicating its qualifications for representing refund applicants and containing a detailed description of the solicitation practices and application procedures that it has used and plans to use.[2] This statement should contain the following information:

(1) A description of the procedures used to solicit refund applications and copies of any solicitation materials mailed to prospective applicants;

(2) A description of how the filing service obtains authorization from its clients to act as their representative, including copies of any type of authorization form signed by refund applicants;

(3) A description of how the filing service obtains and verifies the information contained in refund applications;

(4) A description of the procedures used to forward refunds to its clients;

(5) A description of the procedures used to prevent and check for duplicate filings.

Upon receipt of this information, we may suggest alteration of a filing service's procedures if they do not conform to the procedural requirements of 10 CFR part 205 and this proceeding.

Secondly, we will require strict compliance with the filing requirements as specified in 10 CFR 205.283, particularly the requirement that applications and the accompanying certification statement be signed by the applicant.

Thirdly, we will require from each representative a statement certifying that is maintains a separate escrow account at a bank or other financial institution for the deposit of all refunds received on behalf of applicants, and that its normal business practice is to deposit all subpart V refund checks in that account within two business days of receipt and to disburse refunds to applicants within 30 calendar days thereafter. Unless such certification is received by the OHA, all refund checks approved will be made payable solely to the applicant. Representatives who have not previously submitted an escrow certification form to the OHA may obtain a copy of the appropriate form by contacting: Marcia B. Carlson, Chief, Docket & Publications Division, Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Finally, the OHA reiterates its policy to closely scrutinize applications filed by filing services. Applications submitted by a filing service should contain all of the information indicated in this Decision and Order.

D. Payments to the Federal Government and the States

Under the terms of the MSRP, the remaining eighty percent of the alleged crude oil overcharge amounts subject to this Decision, plus accrued interest, will be disbursed in equal shares to the states and federal government for indirect restitution. Refunds to the states will be in proportion to the consumption of petroleum products in each state during the period of price controls. The share or ration of the funds which each state will receive is contained in Exhibit H of the Stripper Well Settlement Agreement, 6 Fed. Energy Guidelines ¶90.509 at 90,687. When disbursed, these funds will be subject to the same limitations and reporting requirements as all other crude oil monies received by the states under the Stripper Well Settlement Agreement.

It Is Therefore Ordered That:

(1) Applications for Refund from the alleged crude oil overcharges remitted to the Department of Energy by E.B. Brooks, Jr., pursuant to the Consent Order entered into on April 6, 1988, may now be filed.

(2) All crude oil refund applications submitted pursuant to Paragraph (1) above must be postmarked no later than June 30, 1994.

(3) The Director of Special Accounts and Payroll, Office of Departmental Accounting and Financial Systems Development, Controller's Office, Department of Energy, shall transfer $23,824.92, plus accrued interest, from the subaccount denominated "E.B. Brooks, Jr." (Consent Order No. 6A0C00079Z) into the subaccount denominated "Crude Tracking-States," Account No. 999DOE003W.

(4) The Director of Special Accounts and Payroll shall transfer $23,824.92, plus accrued interest, from the subaccount denominated "E.B. Brooks, Jr." into the subaccount denominated "Crude Tracking-Federal," Account No. 999DOE002W.

(5) The Director of Special Accounts and Payroll shall transfer $11,912.47, plus accrued interest, from the subaccount demoninated "E.B. Brooks, Jr." into the subaccount denominated "Crude Tracking-Claimants 4," Account No. 999DOE010Z.

Dated: December 28, 1992.

George B. Breznay,

Director, Office of Hearings and Appeals.

[FR Doc. 93–408 Filed 1–7–93; 8:45 am]

BILLING CODE 6450–01–M

[2] This information with regard to some filing services has already been requested and received by this Office. Such a filing service need not submit this information if it has already done so in the crude oil refund proceeding. A filing service that has submitted this information in another subpart V refund proceeding should provide a copy of the previous submission(s) responsive to items (1)–(5) and provide an update if its response to any of these questions has changed since it first submitted its information. However, in light of the importance of this information, it is prudent for all filing services to review their practices and inform the OHA of any alterations or improvements that may have been made.

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–4553–2]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared December 21, 1992 through December 25, 1992 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 10, 1992 (57 FR 12499).

Draft EISs

ERP No. D–AFS–F70000–MI, Rating EO1, Grand Island National Recreation Area (NRA) Comprehensive Management Plan, Implementation, Hiawatha National Forest, Munising Ranger District, Alger County, MI.

Summary: EPA determined that the preferred alternative did not fully minimize impacts to noise, water quality and terrestrial resources. Other alternatives in the draft EIS satisfy the purpose and need criteria for recreation established by Congress and address potential environmental impacts better than the preferred alternative.

ERP No. D–AFS–J02026–MT, Rating EC2, Beartooth Mountains Oil and Gas Leasing and Development, Approval Implementation, Custer National Forest, Land Management Plan, Beartooth Ranger District, Carbon, Park, Sweetgrass and Stillwater Counties, MT.

Summary: EPA expressed concerns regarding the lack of information regarding monitoring and suggested the use of lease notices to ensure sufficient monitoring. An inventory of sensitive resources (in summary form) was requested.

ERP No. D–UAF–E11029–SC, Rating EC2, Myrtle Beach Air Force Base Disposal and Reuse, Implementation, Horry County, SC.

Summary: EPA expressed environmental concerns and requested additional information due to the uncertainty associated with this proposal. Since the time frame for all selections could be protracted, the additional information may only be available after the record of decision. Depending on the particular alternative and/or mix of options, additional NEPA evaluation may be necessary.

Final EISs

ERP No. F–AFS–J67009–MT, Montanore Mine/Mill Project, Construction and Operation, Permit Approval, section 404 Permit, Special Use Permit, Kootenai National Forest, Lincoln and Sanders Counties, MT.

Summary: EPA expressed environmental objections regarding the proposed action's potential short- and long-term impacts to water quality, fisheries, and aquatic resources. The failure of the final EIS to address issues associated with land application disposal, the tailings impoundment lining, mitigation adequacy, and the avoidance of project impacts may lead to objectionable impacts to outstanding state and national resources and violations of water quality standards. While cooperative efforts between the Forest Service and EPA helped address some of the issues raised during the NEPA process, significant environmental issues remain unresolved.

ERP No. F–UAF–G11021–AR, Eaker Air Force Base Disposal and Reuse, Implementation, Mississippi County, AR.

Summary: EPA had no objections to the proposed action.

ERP No. F–UAF–G11022–LA, England Air Force Base Disposal and Reuse, Implementation, Rapides Parish, LA.

Summary: EPA had no objections to the proposed action.

Dated: January 4, 1993.

William D. Dickerson,

Deputy Director, Office of Federal Activities.

[FR Doc. 93–410 Filed 1–7–93; 8:45 am]

BILLING CODE 6560–50–M

[ER–FRL–4553–1]

Environmental Impact Statements; Availability

RESPONSIBLE AGENCY: Office of Federal Activities, General Information (202) 260–5076 or (202) 260–5075.

Availability of Environmental Impact Statements filed December 28, 1992 through January 1, 1993 pursuant to 40 CFR 1506.9.

EIS No. 920509, DRAFT EIS, SCS, GU, Northern Guam Watershed Protection Plan, Funding and Implementation, Island of Guam, Territory of Guam, GU, Due: February 22, 1993, Contact: Joan Perry (671) 477–5940.

EIS No. 920510, DRAFT SUPPLEMENT, FHW, PR, PR–3 Relocation, PR30 (Humacao South bypass Extension) to PR–15 at Guayama, Funding, Updated Information, PR, Due: February 22, 1993, Contact: Juan O. Gruz (809) 766–5600.

EIS No. 920511, DRAFT EIS, AFS, MT, Upper Camp-Duncie Timber Sale, Harvesting Timber and Road Construction, Implementation, Deerlodge National Forest, Phillipsburg Ranger District, Granite County, MT, Due: March 9, 1993, Contact: Tom Heintz (406) 859–3211.

EIS No. 920512, FINAL EIS, NPS, NV, Great Basin National Park General Management and Development Concept Plans, Implementation, White Pine County, NV, Due: February 8, 1993, Contact: Al Hendricks (702) 234–7331.

Dated: January 5, 1993.

William D. Dickerson,

Deputy Director, Office of Federal Activities.

[FR Doc. 93–411 Filed 1–7–93; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed; New Orleans/ABB Combustion Engineering Terminal Agreement et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224–200711.

Title: New Orleans/ABB Combustion Engineering Terminal Agreement.

Parties: Board of Commissioners of the Port of New Orleans ("Port") ABB Combustion Engineering Systems.

Synopsis: The Agreement concerns the movement of project cargo shipped through the Port's facilities.

Agreement No.: 224–200712.

Title: Tampa Port Authority and The Cargo Trader Leasing Agreement.

Parties: The Tampa Port Authority ("Port") The Cargo Trader ("Cargo Trader")

Synopsis: The Agreement provides for Cargo Trader to lease approximately 1,500 square feet of office space at a monthly rental of $300.00. The term of the leasing arrangement is month-to-month which may be canceled by either party on thirty days advance notice.

Dated: January 4, 1993.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 93–342 Filed 1–7–93; 8:45 am]

BILLING CODE 6730–01–M

Security for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to

Passengers or Other Persons on Voyages pursuant to the provisions of section 2, Public Law 89–777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Nur Touristic GmbH (d/b/a Neckermann Und Reisen), Unicom Management Services (Cyprus) Limited and Fedor Dostoyevskiy Shipping Company Limited, Zimmersmuhlenweg 55, 6370 Oberusl 1, Germany
Vessel: FEDOR DOSTOYEVSKIY
Dated: January 4, 1993.

Joseph C. Polking,
Secretary.

[FR Doc. 93–340 Filed 1–7–93; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Nur Touristic GmbH (d/b/a Neckermann Und Reisen), Zimmersmuhlenweg 55, 6370 Oberusl 1, Germany
Vessel: FEDOR DOSTOYEVSKIY
Dated: January 4, 1992.

Joseph C. Polking,
Secretary.

[FR Doc. 93–341 Filed 1–7–93; 8:45 am]
BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Algemene Maatschappij Voor Nijverheidskrediet N.V., et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 1, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. Algemene Maatschappij Voor Nijverheidskrediet N.V., Antwerp, Kredietbank N.V., Brussels; to engage *de novo* through its subsidiary, Kredietbank Global Management, L.P., Stamford, Connecticut, in the business of investment advisory and portfolio management service pursuant to § 225.25(b)(4) of the Board's Regulation Y.

B. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. First Abilene Bankshares, Inc., Abilene, Texas; to engage *de novo* through its subsidiary, First Financial Investments, Inc., Abilene, Texas, in discount brokerage activities including certain securities, credit and incidental activities pursuant to § 225.25(b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 4, 1993.

Jennifer J. Johnson,
Associate Secretary of the Board.

[FR Doc. 93–417 Filed 1–7–93; 8:45 am]
BILLING CODE 6210–01–F

Beaman Bancshares, Inc., et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than February 1, 1993.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Beaman Bancshares, Inc., Beaman, Iowa; to acquire Beaman Insurance Agency, Inc., Beaman, Iowa, and thereby engage in general insurance activities pursuant to § 225.25(b)(8)(iii) of the Board's Regulation Y.

2. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

3. Old Kent Financial Corporation, Grand Rapids, Michigan; to acquire Gladeshire L.D.H.A., Limited Partnership, Kalamazoo, Michigan, and thereby engage in community development activities by making an equity investment in a low income housing project pursuant to § 225.25(b)(6) of the Board's Regulation Y. **Comments on this application must be received by January 22, 1993.**

Board of Governors of the Federal Reserve System, January 4, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–418 Filed 1–7–93; 8:45 am]

BILLING CODE 6210-01-F

Central Bancompany, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than January 28, 1993.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. Central Bancompany, Inc., Jefferson City, Missouri; to acquire at least 80 percent of the voting shares of First National Bancor, Inc., Lee's Summit, Missouri, and thereby indirectly acquire First National Bank, Lee's Summit, Missouri.

2. Jefferson County Bancshares, Incorporated, Festus, Missouri; to become a bank holding company by acquiring at least 92.5 percent of the voting shares of Eagle Bank & Trust Company of Jefferson County, Hillsboro, Missouri.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. FSB, Inc., Superior, Nebraska; to merge with Tipton Insurance Agency, Inc., Tipton, Kansas, and thereby indirectly acquire The Tipton State Bank, Tipton, Kansas; to acquire Glen Elder Agency, Inc., Glen Elder, Kansas, and thereby indirectly acquire Traders State Bank, Glen Elder, Kansas.

2. Liberty Bancorp, Inc., Oklahoma City, Oklahoma; to acquire up to 9 percent of the voting shares of F and M Bancorporation, Tulsa, Oklahoma, and thereby indirectly acquire The F and M Bank and Trust Co., Tulsa, Oklahoma.

3. One Security of Kansas, Inc., Kansas City, Kansas; to become a bank holding company by acquiring at least 80 percent of the voting shares of One Security, Inc., Kansas City, Kansas, and thereby indirectly acquire Security Bank of Kansas City, Kansas City, Kansas; Mission Bancshares, Inc., Mission, Kansas, and thereby indirectly acquire The Mission Bank, Mission, Kansas; Valley View Bancshares, Inc., Overland Park, Kansas, and thereby indirectly acquire Valley View State Bank, Overland Park, Kansas; and Industrial Bancshares, Inc., Kansas City, Kansas, and thereby indirectly acquire Industrial State Bank, Kansas City, Kansas.

Board of Governors of the Federal Reserve System, January 4, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–419 Filed 1–7–93; 8:45 am]

BILLING CODE 6210-01-F

Huntington Bancshares, Incorporated, et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; and Acquisitions of Nonbanking Companies

The company listed in this notice has applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed company had also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding this application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than January 28, 1993.

A. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Huntington Bancshares, Incorporated, Columbus, Ohio, and Huntington Bancshares West Virginia, Columbus, Ohio; to merge with CB&T Financial Corp., Fairmont, West Virginia, and thereby indirectly acquire Community Bank & Trust, N.A., Fairmont, West Virginia; Community Bank & Trust of Ritchie County, Harrisville, West Virginia; Bank of Hundred, Hundred, West Virginia; and CB&T-Westover Bank, Inc., Westover, West Virginia, and its wholly owned, second-tier bank holding company subsidiary, CB&T Clarksburg Corp., Clarksburg, West Virginia, and thereby indirectly acquire Community Bank & Trust of Harrison County, Clarksburg, West Virginia, and Community Bank & Trust of Randolph County, Elkins, West Virginia.

In connection with this application, Applicants also propose to acquire CB&T Financial Corp., Fairmont, West

Virginia, and CB&T Capital Investment Company, Fairmont, West Virginia, and thereby engage in making or servicing loans pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 4, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-420 Filed 1-7-93; 8:45 am]

BILLING CODE 6210-01-F

The Sakura Bank, Limited, Tokyo, Japan; Application to Engage De Novo in Executing and Clearing Financial Futures Contracts and Options Thereon, and Providing Investment Advice With Respect to the Purchase and Sale of Such Contracts and Options Thereon

The Sakura Bank, Limited, Tokyo, Japan (Applicant), has applied pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8))(BHC Act) and section 225.23(a) of the Board's Regulation Y (12 CFR 225.23(a)) to acquire 60 percent of the outstanding shares of common stock of Dellsher Investment Company, Chicago, Illinois (Company), and through Company to engage *de novo* as a futures commission merchant (FCM) in executing and clearing, on major commodity exchanges, certain financial futures contracts and options thereon, and as an FCM or as a commodity trading advisor (CTA) registered with the Commodity Futures Trading Commission (CFTC) in providing investment advice with respect to the purchase and sale of such contracts and options thereon. These activities would be conducted on a nationwide and worldwide basis.

Applicant proposes to engage *de novo* through Company in the following activities:

(1) As an FCM to execute and clear on the Chicago Board of Trade and the Chicago Mercantile Exchange futures contracts and options on future contracts for foreign currency, government securities, Eurodollars, stock and bond indexes, certificates of deposit, and other money market instruments;

(2) As an FCM to execute and clear futures contracts and options on futures contracts for additional indexes, and to conduct such activities on additional exchanges, after giving notice to and receiving approval from the Federal Reserve Bank of San Francisco (FRBSF) concerning such activities and such exchanges;

(3) As an FCM or a CTA to provide investment advice,consisting primarily of general market information regarding the relationship between the cash and the futures markets, with respect to the purchase and sale of the financial futures contracts and options thereon that have been approved in § 225.25(b)(18) of Regulation Y and the stock and bond index futures and Eurodollar futures, and options thereon, that have been approved by the Board by order, consistent with the terms and conditions of such orders, Regulation Y, and the regulations of the CFTC; and

(4) as an FCM or CTA to provide investment advice as described above with respect to additional indexes, after giving notice to and receiving approval from the FRBSF.

Company also will provide investment advice, as described above, on a separate fee basis, to customers who wish to receive only advisory services.

Section 4(c)(8) of the BHC Act provides that a bank holding company may, with Board approval, engage in any activity "which the Board, after due notice and opportunity for hearing, has determined (by order or regulation) to be so closely related to banking as to be a proper incident thereto." Applicant believes that the proposed activities are "so closely related to banking as to be a proper incident thereto."

Applicant considers the provision by Company to Applicant and its affiliates of the execution and clearance services described above to be permissible under section 4(c)(1)(C) of the BHC Act. The provision of these services to nonaffiliated persons, except with respect to stock and bond indexes and Eurodollars, is authorized by § 225.25(b)(18) of Regulation Y. According to Applicant, the provision of these services to nonaffiliated persons with respect to certain stock and bond indexes that are traded on major commodities exchanges has previously been approved by the Board by order. *See Swiss Bank Corporation*, 77 *Federal Reserve Bulletin* 759 (1991); *J. P. Morgan*, 77 *Federal Reserve Bulletin* 449 (1991); *The Sanwa Bank, Limited*, 77 *Federal Reserve Bulletin* 64 (1991); *Hongkong and Shanghai Banking Corporation*, 76 *Federal Reserve Bulletin* 770 (1990); *Chemical Banking Corporation*, 76 *Federal Reserve Bulletin* 660 (1990); *BankAmerica Corporation*, 75 *Federal Reserve Bulletin* 78 (1989); *The Sumitomo Bank, Limited*, 75 *Federal Reserve Bulletin* 582 (1990); and *The Long-Term Credit Bank of Japan, Limited*, 74 *Federal Reserve Bulletin* 573 (1988). In addition, the execution and clearance for nonaffiliated persons of Eurodollar futures contracts and options thereon on major commodities exchanges also has previously been approved by the Board by order. *See Citicorp*, 76 *Federal Reserve Bulletin* 664 (1990). In providing these services, Applicant has committed to comply with the conditions set forth in § 225.25(b)(18) of Regulation Y with respect to its activities as an FCM thereunder as well as with respect to its activities involving futures contracts on stock and bond indexes and Eurodollars, and options thereon, and with the conditions established by the Board in the above orders.

Applicant considers the provision by Company as an FCM or a CTA to Applicant and its affiliates of the investment advice described above to be permissible under section 4(c)(1)(C) of the BHC Act. The provision of this service to nonaffiliated persons, except with respect to futures contracts on stock and bond indexes and Eurodollars, and options thereon, is authorized by § 225.25(b)(19) of Regulation Y. According to the Applicant, the provision of this service to nonaffiliated persons with respect to futures contracts on stock and bond indexes and Eurodollars, and options thereon, for which Applicant seeks approval has previously been approved by the Board in the above orders. In providing these services, Applicant has committed to comply with the conditions set forth in § 225.25(b)(19) of Regulation Y and with the conditions established by the Board in the above orders.

Applicant takes the position that the proposed activities will benefit the public by enhancing the competitive position of Company and the efficiency of its services in a highly competitive industry. Moreover, Applicant believes that approval of its acquisition of Company will not result in any unsound banking practices or other adverse effects.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than January 22, 1993. Any request for a hearing on this application must, as required by § 262.3(e) of the Board's Rules of Procedures (12 CFR 262.3(e)), be accompanied by a statement of reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal. This application may be inspected at the

offices of the Federal Reserve Bank of San Francisco.

Board of Governors of the Federal Reserve System, January 4, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–421 Filed 1–7–93; 8:45 am]

BILLING CODE 6210–01–F

GENERAL ACCOUNTING OFFICE

Government Auditing Standards Advisory Council Meeting

AGENCY: General Accounting Office.

ACTION: Notice.

SUMMARY: The United States General Accounting Office has scheduled a meeting of the Government Auditing Standards Advisory Council on February 1, 1993, from 8 :30 a.m. until 5 p.m., in room 7313 of the General Accounting Office, 441 G St., NW., Washington, DC.

The agenda for the meeting will consist of a review of the minutes of the December meeting, and discussion of the draft proposed changes to the Government Auditing Standards. Any interested person may attend the meeting as an observer.

FOR FURTHER INFORMATION CONTACT: Marcia B. Buchanan, Project Manager, U.S. General Accounting Office, 441 G St., NW., room 6025, Washington, DC 20548 or call (202) 275–9321.

DATES: February 1, 1993.

ADDRESSES: 441 G St., NW., room 7313, Washington, DC 20548.

Dated: December 21, 1992.

Donald H. Chapin,

Assistant Comptroller General.

[FR Doc. 93–346 Filed 1–7–93; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 92N–0502]

Animal Drug Export; Interceptor® Chewables

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Animal Health, Ciba-Geigy Corp. has filed an application requesting approval for the export of the animal drug Interceptor® Chewables (milbemycin oxime) to Canada.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Gregory S. Gates, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8617.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Ciba-Geigy Animal Health, Ciba-Geigy Corp., P.O. Box 18300, Greensboro, NC 27419–8300, has filed an application requesting approval for the export of the animal drug Interceptor® Chewables (milbemycin oxime) to Canada. The product is intended for use as an anthelmintic in dogs. The application was received and filed in the Center for Veterinary Medicine on December 11, 1992, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by January 18, 1993, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine (21 CFR 5.44).

Dated: January 4, 1993.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 93–315 Filed 1–7–93; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Announcement of Proposed Methodology for Implementation of the Statutory General Funding Preference for Selected Grant Programs Under Titles VII and VIII of the Public Health Service Act for Fiscal Year 1993

AGENCY: Health Resources and Service Administration, HHS.

ACTION: Correction.

SUMMARY: In this notice originally published at 57 FR 60212, on Friday, December 18, 1992, make the following correction:

On page 60213 at the bottom of the second column, the correct phone number for accessing the electronic bulletin board, called the BHPr (Bureau of Health Professions) Bulletin Board, is (301) 443–5913.

Dated: December 31, 1992.

Robert G. Harmon,

Administrator.

[FR Doc. 93–312 Filed 1–7–93; 8:45 am]

BILLING CODE 4160–15–M

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The Public Health Service (PHS) is publishing this notice of petitions received under the National Vaccine Injury Compensation Program ("the Program"), as required by section 2112(b)(2) of the PHS Act, as amended. While the Secretary of Health and Human Services is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Claims Court is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program generally, contact the Clerk, United States Claims Court, 717 Madison Place, NW., Washington, DC 20005, (202) 633–7257. For information on the Public Health Service's role in the Program, contact the Administrator, Vaccine Injury Compensation Program, 6001 Montrose Road, room 702, Rockville, MD 20852, (301) 443–6593.

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation for certain individuals who have been injured by specified childhood vaccines. Subtitle 2 of title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq*, provides that those seeking compensation are to file a petition with the U.S. Claims Court and to serve a copy of the petition on the Secretary of Health and Human Services, who is named as the respondent in each proceeding. The Secretary has delegated his responsibility under the Program to PHS. The Claims Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table set forth at section 2114 of the PHS Act. This Table lists for each covered childhood vaccine the conditions which will lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested after the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that the Secretary publish in the **Federal Register** a notice of each petition filed. Set forth below is a partial list of petitions received by PHS on October 1, 1990.

Section 2112(b)(2) also provides that the special master "shall afford all interested persons an opportunity to submit relevant, written information" relating to the following:

1. The existence of evidence "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition," and

2. Any allegation in a petition that the petitioner either:

(a) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table (see section 2114 of the PHS Act) but which was caused by" one of the vaccines referred to in the Table, or

(b) "Sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine" referred to in the Table.

This notice will also serve as the special master's invitation to all interested persons to submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the U.S. Claims Court at the address listed above (under the heading "For Further Information Contact"), with a copy to PHS addressed to Director, Bureau of Health Professions, 5600 Fishers Lane, room 8–05, Rockville, MD 20857. The Court's caption (Petitioner's Name v. Secretary of Health and Human Services) and the docket number assigned to the petition should be used as the caption for the written submission.

Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

List of Petitions

1. Barbara Simms on behalf of Donald Simms, Mobile, Alabama, Claims Court Number 90–3026 V
2. Frank Aggazio on behalf of Antonio Aggazio, Aspinwall, Pennsylvania, Claims Court Number 90–3027 V
3. Amy Slaughter, Rochester, New York, Claims Court Number 90–3028 V
4. Daniel Salerno, Miami, Florida, Claims Court Number 90–3029 V
5. Constance Harnage, Hawthorne, Nevada, Claims Court Number 90–3030 V
6. Barbara Collins on behalf of Matthew Collins, Pikeville, Kentucky, Claims Court Number 90–3031 V
7. John Wall on behalf of Linda Wall, St. Louis, Missouri, Claims Court Number 90–3032 V
8. Glen Wilkerson, Herkimer, New York, Claims Court Number 90–3033 V
9. Boatmen's National Bank on behalf of Mark Godfrey, St. Louis, Missouri, Claims Court Number 90–3034 V
10. Patricia Lewis on behalf of Jamie Lewis, Crawfordsville, Indiana, Claims Court Number 90–3035 V
11. Kurt Smallcomb on behalf of Kameron Smallcomb, Ukiah, California, Claims Court Number 90–3036 V
12. Robert Wherley on behalf of Dianne Wherley, Minneapolis, Minnesota, Claims Court Number 90–3037 V
13. Lisa Goodrich, Toul-Rosiers AFB, France, Claims Court Number 90–3038 V
14. Earl Houtz on behalf of Angela Houtz, Missoula, Montana, Claims Court Number 90–3039 V
15. Donald Jenkins on behalf of Donald Jenkins, Jr., Brentwood, Tennessee, Claims Court Number 90–3040 V
16. Verlina Hinojosa, Ogden, Utah, Claims Court Number 90–3041 V
17. Albert Wells on behalf of Delia Hostettler, Nashville, Tennessee, Claims Court Number 90–3042 V
18. Valerie Britt, Lawrenceville, Virginia, Claims Court Number 90–3043 V
19. Andrew McMillian, Bridgeport, Connecticut, Claims Court Number 90–3044 V
20. James Hughs on behalf of Cara Hughs, Billings, Montana, Claims Court Number 90–3045 V
21. Jennifer Alcala on behalf of John Alcala, Deceased, Loma Linda, California, Claims Court Number 90–3046 V
22. Ovidio Alaniz on behalf of Omar Alaniz, Chicago, Illinois, Claims Court Number 90–3047 V
23. Karen Bicking, Grand Marais, Minnesota, Claims Court Number 90–3048 V
24. William Angell on behalf of Christine Angell, Aurora, Illinois, Claims Court Number 90–3049 V
25. R. Jay Cummings on behalf of Alexander Cummings, Deceased, Jacksonville, Florida, Claims Court Number 90–3050 V
26. Julie Chapin on behalf of Aaron Chapin, Aberdeen, South Dakota, Claims Court Number 90–3051 V
27. Norman Bell on behalf of Lynn Bell, New Rochelle, New York, Claims Court Number 90–3052 V
28. Lynn Owens on behalf of Dana Owens, Greenville, Texas, Claims Court Number 90–3053 V
29. Michael Juliana on behalf of Kimberly Juliana, Lewisville, Texas, Claims Court Number 90–3054 V
30. Patricia Lankford, Portland, Oregon, Claims Court Number 90–3055 V
31. J. Laurence McCarty on behalf of Laurence J. McCarty, Lexington, Massachusetts, Claims Court Number 90–3056 V
32. Richard Williams on behalf Dennis Williams, Bay Springs, Mississippi, Claims Court Number 90–3057 V
33. John Vedrode on behalf of John W. Vedrode, Midland Texas, Claims Court Number 90–3058 V
34. Robert Longhine on behalf of James Longhine, Perry, New York, Claims Court Number 90–3059 V
35. Michelle Edmondson on behalf of Davis Edmondson, Fruitport, Michigan, Claims Court Number 90–3060 V

36. Robert Lawson on behalf of Rajalyn Lawson, Washington, D.C., Claims Court Number 90–3061 V

37. Mary and Marcel Pincince on behalf of Michelle Pincince, Clearwater, Florida, Claims Court Number 90–3062 V

38. Eva Rodriguez on behalf of Zandra Rodriguez, Fallbrook, California, Claims Court Number 90–3063 V

39. Bobby Pence on behalf of Rebecca Pence, Charleston, South Carolina, Claims Court Number 90–3064 V

40. Theresa Harmon on behalf of Amanda Harmon, Cleveland, Ohio, Claims Court Number 90–3065 V

41. James Seaborne on behalf of Janet Seaborne, Thousand Oaks, California, Claims Court Number 90–3066 V

42. Dwight Jones, McMinnville, Tennessee, Claims Court Number 90–3067 V

43. Karen Machut on behalf of Joseph Machut, Chicago, Illinois, Claims Court Number 90–3068 V

44. Mary Lou Caufield on behalf of Louis Caufield, Philadelphia, Pennsylvania, Claims Court Number 90–3069 V

45. Charles Murray, Lake City, Florida, Claims Court Number 90–3070 V

46. Herman Hillman, Plaucheville, Louisiana, Claims Court Number 90–3071 V

47. Joan Umfress on behalf of Donna Umfress, El Paso, Texas, Claims Court Number 90–3072 V

48. Phillips Gallant on behalf of Ophelia Gallant, Washington, D.C., Claims Court Number 90–3073 V

49. Robert Barton, Chesterfield, Missouri, Claims Court Number 90–3074 V

50. Lawrence Fenn on behalf of Colleen Fenn, Norwich, Connecticut, Claims Court Number 90–3075 V

51. Tammy Moriarty on behalf of Jenny Moriarty, Jordan, Minnesota, Claims Court Number 90–3076 V

52. Timothy Bennett, Newton, North Carolina, Claims Court Number 90–3077 V

53. Mary Ann Roney on behalf of Sharyn Roney, Pittsburgh, Pennsylvania, Claims Court Number 90–3078 V

54. Penelope Vawter on behalf of Ellanore Vawter, Beaver Dam, Wisconsin, Claims Court Number 90–3079 V

55. Cynthia Nadeau on behalf of Gina Nadeau, Panama City, Florida, Claims Court Number 90–3080 V

56. Stanley Warhol on behalf of Theresa Warhol, Farmingdale, New Jersey, Claims Court Number 90–3081 V

57. Susan Sanders on behalf of Stephanie Sanders, Albuquerque, New Mexico, Claims Court Number 90–3082 V

58. Janis Bailey on behalf of Jay Bailey, Sharon, Pennsylvania, Claims Court Number 90–3083 V

59. Joy Broadbrook on behalf of Sherry Grant, Bridgeport, Connecticut, Claims Court Number 90–3084 V

60. Earl Vader on behalf of Eric Vader, Sioux City, South Dakota, Claims Court Number 90–3085 V

61. Sheila Windham, Pontiac, Michigan, Claims Court Number 90–3086 V

62. Cheryl Kupiainen on behalf of April Hall, Nashville, Tennessee, Claims Court Number 90–3087 V

63. Daniel Peterson, Sr., on behalf of Daniel Peterson, Jr., Dubuque, Iowa, Claims Court Number 90–3088 V

64. Roger Madris on behalf of Courtney Madris, White Plains, New York, Claims Court Number 90–3089 V

65. Charlotte May on behalf of Bruce May, Flint, Michigan, Claims Court Number 90–3090 V

66. George Williams on behalf of Katherine Williams, Columbus, Ohio, Claims Court Number 90–3091 V

67. Incoronato Stasi on behalf of Anne Maria Stasi, Glen Cove, New York, Claims Court Number 90–3092 V

68. Bobby L. Mikell on behalf of Robert W. Mikell, Statesboro, Georgia, Claims Court Number 90–3093 V

69. Deanne Whilhite on behalf of Joyzelle Whilhite, Pear Harbor Naval Base, Hawaii, Claims Court Number 90–3094 V

70. Norma Richardson on behalf of Megan Richardson, Columbus, Ohio, Claims Court Number 90–3095 V

71. Mary Vargo, Oregon, Ohio, Claims Court Number 90–3096 V

72. Lee Fisher on behalf of Matthew Fisher, Greenbrae, California, Claims Court Number 90–3097 V

73. David Marling on behalf of Elizabeth Marling, Lake Station, Indiana, Claims Court Number 90–3098 V

74. Louis Dean on behalf of Daniel Dean, Greensboro, North Carolina, Claims Court Number 90–3099 V

75. Amanda Glover, Chillicothe, Ohio, Claims Court Number 90–3100 V

76. Teresa Dvorak on behalf of Michelle Briley, Irving, Texas, Claims Court Number 90–3101 V

77. Katherine Nelson on behalf of Mary Nelson, Colorado Springs, Colorado, Claims Court Number 90–3102 V

78. Larry Grinder on behalf of Jeremy Grinder, Biloxi, Mississippi, Claims Court Number 90–3103 V

79. Barbara Sacco on behalf of Louis Sacco, New Haven, Connecticut, Claims Court Number 90–3104 V

80. Constance Belda, Oregon City, Oregon, Claims Court Number 90–3105 V

81. Deak Sherrell on behalf of Kimberly Sherrell, Merced, California, Claims Court Number 90–3106 V

82. Kecia Butler on behalf of Tyrone Butler, Deceased, Covington, Tennessee, Claims Court Number 90–3107 V

83. Clarence Brown on behalf of Michael Brown, Deceased, Indianapolis, Indiana, Claims Court Number 90–3108 V

84. Jill Litwiller, Manson, Iowa, Claims Court Number 90–3109 V

85. Glade Johnson on behalf of Kendra Johnson, Granger, Utah, Claims Court Number 90–3110 V

86. Joy Broadbrook on behalf of Sherry Grant, Bridgeport, Connecticut, Claims Council Number 90–3111 V

87. Janet Winfield, Baltimore, Maryland, Claims Court Number 90–3112 V

88. Diane Brown on behalf of Steven Brown, Chicago, Illinois, Claims Court Number 90–3113 V

89. Steven Brinkley on behalf of Chad Brinkley, Denver, Colorado, Claims Court Number 90–3114 V

90. Maria Rodriguez on behalf of Katya Pillich, Carolina, Puerto Rico, Claims Court Number 90–3115 V

91. Thou and Ly Do on behalf of Uyen Do, Savannah, Georgia, Claims Court Number 90–3116 V

92. Colin Nelson on behalf of Brett Nelson, Minneapolis, Minnesota, Claims Court Number 90–3117 V

93. Virginia Saltzman on behalf of Corey Saltzman, Deceased, Bozeman, Montana, Claims Court Number 90–3118 V

94. Julia Sing on behalf of John Salmond, Los Gatos, California, Claims Court Number 90–3119 V

95. Richard Myers on behalf of Johnathan Myers, Corvallis, Oregon, Claims Court Number 90–3120 V

96. Robert O'Hara, Jamaica, New York, Claims Court Number 90–3121 V

97. Frances LeFavor, Chicago, Illinois, Claims Court Number 90–3122 V

98. Scott McMillan on behalf of Rachel McMillan, Rochester, New York, Claims Court Number 90–3123 V

99. Jeffrey Agee on behalf of Marshall Agee, Abilene, Texas, Claims Court Number 90–3124 V

100. Carol Tharp on behalf of Jennifer Tharp, Texarkana, Texas, Claims Court Number 90–3125 V

101. David Little on behalf of David Little, II, Winston Salem, North Carolina, Claims Court Number 90–3126 V

102. Pete Ross on behalf of Peter Ross, Hazard, Kentucky, Claims Court Number 90–3127 V

103. Robert Haugh on behalf of Kevin Haugh, Nashville, Tennessee, Claims Court Number 90–3128 V

104. Lorette Kauffman of behalf of Allison Berry, Houston, Texas, Claims Court Number 90–3129 V

105. David Augustine on behalf of Denise Augustine, Milpitas, California, Claims Court Number 90–3130 V

106. Debra Russell, Cut Bank, Montana, Claims Court Number 90–3131 V

107. Bridgette Heller, Evanston, Illinois, Claims Court Number 90–3132 V

108. James Iaculla, Philadelphia, Pennsylvania, Claims Court Number 90–3133 V

109. Doris Powell on behalf of Donny Powell, Shreveport, Louisiana, Claims Court Number 90–3134 V

110. Jacqueline Almeida on behalf of Norman Almeida, Fall River, Massachusetts, Claims Court Number 90–3135 V

111. Kathleen Slattery, Lincoln, Nebraska, Claims Court Number 90–3136 V

112. Oscar Wolf on behalf of Michael Wolf, Deceased, Niagara Falls, New York, Claims Court Number 90–3137 V

113. Oscar Wolf on behalf of Melissa Wolf, Niagara Falls, New York, Claims Court Number 90–3138 V

114. Leslie Reid, Salina, Kansas, Claims Court Number 90–3139 V

115. Robert Dinges on behalf of Christian Dinges, Pittsburgh, Pennsylvania, Claims Court Number 90–3140 V

116. Faith Frey on behalf of Shawn Brunner, Allentown, Pennsylvania, Claims Court Number 90–3141 V

117. Gene Evans on behalf of Tammy Evans, Deceased, Charlotte, North Carolina, Claims Court Number 90–3142 V
118. Lisa Rogers, Salina, Kansas, Claims Court Number 90–3143 V
119. Albert Bauer on behalf of Ernest Bauer, Skokie, Illinois, Claims Court Number 90–3144 V
120. Foster Nelson on behalf of Heather Nelson, Cleveland, Texas, Claims Court Number 90–3145 V
121. Deborah Zingale, Denver, Colorado, Claims Court Number 90–3146 V
122. A.M. Guy on behalf of Cecil Guy, Columbia, Louisiana, Claims Court Number 90–3147 V
123. Sandra Hazeltine on behalf of Nickolas Hazeltine, Penacook, New Hampshire, Claims Court Number 90–3148 V
124. Toni Foster on behalf of Christian Branch, Brooklyn, New York, Claims Court Number 90–3149 V
125. Janet Patterson, East Moline, Illinois, Claims Court Number 90–3150 V
126. Herbert Horil, Chalmette, Louisiana, Claims Court Number 90–3151 V
127. Don Stevenson on behalf of Emily Stevenson, Ogden, Utah, Claims Court Number 90–3152 V
128. Lorraine Gonzales, Detroit, Michigan, Claims Court Number 90–3153 V
129. John Bell, Sr. on behalf of John Bell, Jr., Atlanta, Georgia, Claims Court Number 90–3154 V
130. Thomas Molhook, Bakersfield, California, Claims Court Number 90–3155 V
131. Cheryl Lewis, Devils Lake, North Dakota, Claims Court Number 90–3156 V
132. Jackie Meredith on behalf of Sara Meredith, New Albany, Indiana, Claims Court Number 90–3157 V
133. Carrie Zampino on behalf of Kathleen Zampino, Girard, Pennsylvania, Claims Court Number 90–3158 V
134. Marlene Finley on behalf of Jamie Finley, Dearborn, Michigan, Claims Court Number 90–3159 V
135. Darryl and Tyiese Clark on behalf of Keyonna Clark, La Plata, Maryland, Claims Court Number 90–3160 V
136. Francis Mayer, Port Washington, Wisconsin, Claims Court Number 90–3161 V
137. Jennifer Payne, Albuquerque, New Mexico, Claims Court Number 90–3162 V
138. Sue Patzer on behalf of Joshua Patzer, Vallejo, California, Claims Court Number 90–3163 V
139. Ronald Moline on behalf of Sean Moline, Raytown, Missouri, Claims Court Number 90–3164 V
140. Shirley Rae Weaver Nelson, Ogden, Utah, Claims Court Number 90–3165 V
141. Anna Wilkerson on behalf of Darrell Wilson, Washington, Pennsylvania, Claims Court Number 90–3166 V
142. Bruce Presley on behalf of Bruce Douglas Presley, Ann Arbor, Michigan, Claims Court Number 90–3167 V
143. Marni Etherton on behalf of Kasey Etherton, Gastonia, North Carolina, Claims Court Number 90–3168 V
144. Floyd Gunther on behalf of Floyd Gunther, Jr., Aiken, South Carolina, Claims Court Number 90–3169 V
145. Catherine Heller on behalf of Carolyn Heller, Detroit, Michigan, Claims Court Number 90–3170 V
146. Bernard Kilday on behalf of James Kilday, Arlington, Virginia, Claims Court Number 90–3171 V
147. Irene Russell on behalf of John Russell, Pittsburgh, Pennsylvania, Claims Court Number 90–3172 V
148. Michael Dyer, Battle Creek, Michigan, 73, Claims Court Number 90–3173 V
149. Leslie Hudson on behalf of Jared DeFazio, Delmar, New York, Claims Court Number 90–3174 V
150. Rajendra Desai on behalf of Kiran Desai, Deceased, Evanston, Illinois, Claims Court Number 90–3175 V
151. Annette Spanier on behalf of Jared Spanier, Langdon, North Dakota, Claims Court Number 90–3176 V
152. Jonathan Alberding, Tucson, Arizona, Claims Court Number 90–3177 V
153. Anna Low on behalf of Robert Low, Orange, California, Claims Court Number 90–3178 V
154. Nanelle Racz on behalf of Charles Racz, Key West, Florida, Claims Court Number 90–3179 V
155. Lucille McCauley on behalf of Joseph McCauley, Oklahoma City, Oklahoma, Claims Court Number 90–3180 V
156. Barbara Johnson on behalf of Brandon Johnson, Stone Mountain, Georgia, Claims Court Number 90–3181 V
157. Martha McWilliams, Little Rock, Arkansas, Claims Court Number 90–3182 V
158. Patricia Dyer on behalf of Samurah Sykes, Mt. Pleasant, Pennsylvania, Claims Court Number 90–3183 V
159. Lori Bodga, Chicago, Illinois, Claims Court Number 90–3184 V
160. Cynettie Sanders on behalf of Nartisa Sanders, Warner Robins, Georgia, Claims Court Number 90–3185 V
161. Carolyn Sipes on behalf of Jeremy Sipes, Jackson, Michigan, Claims Court Number 90–3186 V
162. Phyllis Sutton on behalf of Jeffrey Silke, Deceased, Denver, Colorado, Claims Court Number 90–3187 V
163. Richard Martinez on behalf of John-Paolo Martinez, Albuquerque, New Mexico, Claims Court Number 90–3188 V
164. Debrah Reiter, Sioux Falls, South Dakota, Claims Court Number 90–3189 V
165. Steven Haas on behalf of Andrew Haas, King of Prussia, Pennsylvania, Claims Court Number 90–3190 V
166. Nick Parnell on behalf of Christine Parnell, Dallas, Texas, Claims Court Number 90–3191 V
167. Rosemary Kalil on behalf of Anjuli Mendoza, Houston, Texas, Claims Court Number 90–3192 V
168. Robert Adams on behalf of Tina Adams, Great Lakes, Illinois, Claims Court Number 90–3193 V
169. Angela Thompson on behalf of Terrance Thompson, Houston, Texas, Claims Court Number 90–3194 V
170. Dennis Black on behalf of Daniel Black, Rapid City, South Dakota, Claims Court Number 90–3195 V
171. Martin Andrews, Cotonou, DAHOMEY, West Africa, Claims Court Number 90–3196 V and 90–3197 V
172. Robert Jones, Barbourville, Kentucky, Claims Court Number 90–3198 V
173. Janet McCutchan on behalf of Stacey McCutchan, Lafayette, Indiana, Claims Court Number 90–3199 V
174. Alberta Williams on behalf of Billy Rowlett, Jr., Stickney, Illinois, Claims Court Number 90–3200 V
175. Robert Joseph on behalf of Lesley Joseph, Deceased, Evanston, Illinois, Claims Court Number 90–3201 V
176. Clyde Shaw on behalf of Brian Shaw, Seattle, Washington, Claims Court Number 90–3202 V
177. Daniel Eichten on behalf of Debra Eichten, Roseville, Minnesota, Claims Court Number 90–3203 V
178. Muriel Christman on behalf of Cole Christman, Bakersfield, California, Claims Court Number 90–3204 V and 90–3205 V
179. Jacquelyn Peterson on behalf of Matthew Peterson, Poughkeepsie, New York. Claims Court Number 90–3206 V
180. Diane Bradfield on behalf of Mindy Bradfield, Wilmington, Delaware, Claims Court Number 90–3207 V
181. Muriel Ellis, Homer, New York, Claims Court Number 90–3208 V
182. Shirley Shaw on behalf of Shirley Jean Preston, Chester, Pennsylvania, Claims Court Number 90–3209 V
183. Danny Davidson on behalf of Erin Davidson, Arcadia, Louisiana, Claims Court Number 90–3210 V
184. Adrian Diaz, Coral Gables, Florida, Claims Court Number 90–3211 V
185. Jill DeValk on behalf of Matthew DeValk, Kankakee, Illinois, Claims Court Number 90–3212 V
186. Richard Maccabe on behalf of Kenneth Maccabe, Reynoldsburg, Ohio, Claims Court Number 90–3213 V
187. Jack Nichols on behalf of Frederick Nichols, Denver, Colorado, Claims Court Number 90–3214 V
188. Steven Brinkley on behalf of Cecille Brinkley, Deceased, Greeley, Colorado, Claims Court Number 90–3215 V
189. Christopher Sheffield, Chattanooga, Tennessee, Claims Court Number 90–3216 V
190. Joan Arrowood on behalf of Mark Arrowood, Deceased, Doylestown, Pennsylvania, Claims Court Number 90–3217 V
191. Eugene Robinson on behalf of Jesse Robinson, USAF, United Kingdom, Claims Court Number 90–3218 V
192. Patricia Kennedy on behalf of Charles Kennedy, Elizabethtown, Kentucky, Claims Court Number 90–3219 V
193. Gary Sisler on behalf of Carrie Sisler, Hutchinson, Kansas, Claims Court Number 90–3220 V
194. Stephen Paolantonio on behalf of Stephen Eli Paolantonio, Deceased, Bryn Mawr, Pennsylvania, Claims Court Number 90–3221 V
195. Keith Dale Baker, Tahlequah, Oklahoma, Claims Court Number 90–3222 V
196. Patricia Lesniak on behalf of Christopher Lesniak, Wheeling, Illinois, Claims Court Number 90–3223 V
197. Ann Barbour, Burlington, Vermont, Claims Court Number 90–3224 V
198. Robert Siwy, Lackawanna, New York, Claims Court Number 90–3225 V

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Dated: December 31, 1992.
Robert G. Harmon,
Administrator.
[FR Doc. 93–313 Filed 1–7–93; 8:45 am]
BILLING CODE 4160–15–M

National Institutes of Health

National Cancer Institute; Meeting of the Cancer Biology-Immunology Contracts Review Committee (Subcommittee C)

Pursuant to Public Law 92–463, notice is hereby given of a meeting of Subcommittee C, of the Cancer Biology-Immunology Contracts Review Committee, National Cancer Institute, National Institutes of Health, January 27–29, 1993, at the Chevy Chase Holiday Inn, in the Chase Conference Room, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20814. This meeting will be open to the public on January 27 form 8:30 a.m. to 9:30 a.m. to discuss administrative details. Attendance by the public will be limited to space available.

In accordance with provisions set forth in sections 552b(c)(4) and 552(b)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public from 9:30 a.m. on January 27 to adjournment on January 29 for the review, discussion, and evaluation of individual contract proposals. These proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the proposals, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Committee Management Officer, National Cancer Institute, Building 31, room 10A06, National Institutes of Health, Bethesda, Maryland 20892, Tel. 301/496–5708, will provide summaries of the meeting and rosters of committee members upon request.

Dr. Lalita D. Palekar, Scientific Review Administrator, Cancer Biology-Immunology Contracts Review Subcommittee C, 5333 Westbard Avenue, room 805, Bethesda, Maryland 20892, Tel. 301/496–7575, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: December 24, 1992.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 93–428 Filed 1–7–93; 8:45 am]
BILLING CODE 4140–01–M

National Institutes of Health (NIH)

National Institute on Aging; Meeting of the National Advisory Council on Aging

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council on Aging, National Institute on Aging, January 28–29, 1993, to be held at the National Institutes of Health, Building 1, Wilson Hall, Bethesda, Maryland. This meeting will be open to the public on Thursday, January 28, from 8:30 a.m. until 1:30 p.m. for a status report by the Acting Director, NIA; a report on the Geriatrics Program, a report on the Working Group on Program, a report on the Advisory Committee to the Director, and a report on minority activities. The meeting will be open again on Friday, January 29 from 9 a.m. until adjournment for a report on the NIA Intramural Research Program. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the Council will be closed to the public on January 28 from 1:30 p.m. to recess for the review, discussion and evaluation of grant applications.

The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June McCann, Committee Management Officer for the National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, suite 2C218, Bethesda, Maryland 20892 (301/496–9322), will provide a summary of the meeting and a roster of committee members upon request.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health.)

Dated: December 24, 1992.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 93–432 Filed 1–7–93; 8:45 am]
BILLING CODE 4140–01–M

National Institute on Alcohol Abuse and Alcoholism; Meeting of the National Advisory Council on Alcohol Abuse and Alcoholism

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council on Alcohol Abuse and Alcoholism, National Institute on Alcohol Abuse and Alcoholism, February 4 and 5, 1993, Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, MD 20814.

This meeting will be open to the public on February 4 from 9 a.m. to 3 p.m. to discuss administrative details or other issues relating to council activities. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public on February 4 from 3 p.m. to adjournment on February 5 for the review, discussion and evaluation of individual grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

In accordance with the provisions set forth in sec. 552b(c)(9)(B), title 5, U.S.C., the Council meeting will also be closed to the public on February 4 from 3 p.m. to adjournment on February 5 for possible discussion and preparation of comments Council may wish to submit to the Director, NIH, for inclusion in the biennial report to the Congress. Premature disclosure of such information would significantly frustrate implementation of proposed agency actions.

Ms. Diana Widner, NIAAA Committee Management Officer, National Institute on Alcohol Abuse and Alcoholism, Parklawn Building, room 16C–20, 5600 Fishers Lane, Rockville, MD 20857, Telephone: 301/443–4375 will provide a summary of the meeting, roster of council members, and substantive program information upon request.

Dated: December 24, 1992.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 93–429 Filed 1–7–93; 8:45 am]
BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; Meetings: National Advisory Allergy and Infectious Diseases Council; Acquired Immunodeficiency Syndrome Subcommittee; Allergy and Immunology Subcommittee; Microbiology and Infectious Diseases Subcommittee

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Allergy and Infectious Diseases Council, National Institute of Allergy and Infectious Diseases, and its Subcommittees on February 8–10, 1993. Meetings of the NAAIDC Allergy and Immunology Subcommittee and NAAIDC Microbiology and Infectious Diseases Subcommittee will be held at the National Institutes of Health, Building 31C, Bethesda, Maryland 20892. The meeting of the NAADIC Acquired Immunodeficiency Syndrome Subcommittee will be held at the Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

The meeting of the full Council will be open to the public on February 8 in conference room 6 from approximately 1 p.m. until 3:30 p.m. for opening remarks of the Institute Director, discussion of procedural matters, Council business, and a report from the Institute Director which will include a discussion of budgetary matters. The primary program will include a discussion by the Director, Division of Research Grants on issues related to NIAID referred applications on applied clinical research, as well as presentations on Chronic Fatigue Syndrome, Lyme Disease, congressional mandates regarding AIDS Clinical Trial Units, refinements in the select pay process, and an update on large scale vaccine trials.

On February 9 the meetings of the NAAIDC Allergy and Immunology Subcommittee and NAAIDC Microbiology and Infectious Diseases Subcommittee will be open to the public from 8:30 a.m. until recess. Both subcommittees will meet at the National Institutes of Health, Building 31C in conference rooms 9 and 6 respectively. The meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee will be open to the public from 8 a.m. until recess on February 9 and from 8 a.m. until adjournment on February 10. The subcommittee will meet in the Versailles Ballroom, Bethesda Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, the meeting of the NAAIDC Acquired Immunodeficiency Syndrome Subcommittee, NAAIDC Allergy and Immunology Subcommittee and the NAAIDC Microbiology and Infectious Diseases Subcommittee will be closed to the public for approximately three hours for review, evaluation, and discussion of individual grant applications. It is anticipated that this will occur from 8:30 a.m. until approximately 1 p.m. on February 8, in conference rooms 4, 9 and 6 respectively. The meeting of the full Council will be closed from approximately 3:30 p.m. until recess on February 8 for the review, discussion, and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. Patricia Randall, Office of Research Reporting and Public Response, National Institute of Allergy and Infectious Diseases, Building 31, room 7A32, National Institutes of Health, Bethesda, Maryland 20892, telephone 301–496–5717, will provide a summary of the meeting and a roster of the committee members upon request.

Dr. John J. McGowan, Director, Division of Extramural Activities, NIAID, NIH, Solar Building, room 4C07, 6003 Executive Boulevard, Rockville, Maryland 20892, telephone 301–496–7291, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93–855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health.)

Dated: December 24, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–430 Filed 1–7–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its subcommittees, National Institute of Diabetes and Digestive and Kidney Diseases, on February 10–11, 1993, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland. The meeting will be open to the public February 10, from 8:30 a.m. to 12 noon and again on February 11, from 10 a.m. to adjournment to discuss administrative details relating to Council business and special reports. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the subcommittee and full Council meeting will be closed to the public for the review, discussion and evaluation of individual grant applications. The following subcommittees will be closed to the public on February 10, from 1 to 5 p.m.: Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney, Urologic and Hematologic Diseases. The full Council meeting will be closed on February 11, from 8:30 a.m. to 10 a.m.

These deliberations could reveal confidential trade secrets or commercial property, such as patentable materials, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concerning the Council meeting may be obtained from Dr. Walter Stolz, Executive Secretary, National Diabetes and Digestive and Kidney Diseases Advisory Council, NIDDK, Westwood Building, room 657, Bethesda, Maryland 20892, (301) 496–7277.

A summary of the meeting and roster of the members may be obtained from the Committee Management Office, NIDDK, Building 31, room 9A19, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–6917.

(Catalog of Federal Domestic Assistance Program No. 93.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: December 24, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–431 Filed 1–7–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Meeting of the Research Priorities Subcommittee of the National Deafness and Other Communication Disorders Advisory Board

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Research Priorities Subcommittee of the National Deafness and Other Communication Disorders Advisory Board on February 19, 1993. The meeting will take place from 9 a.m. to 11:30 a.m. in Conference Room 7, Building 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892, and will be conducted as a telephone conference with the use of a speaker phone.

The meeting, which will be open to the public from 9 a.m. to 11:10 a.m., is being held to discuss scientific advances in the field of hearing and hearing impairment since the National Strategic Research Plan for that area was developed. Attendance by the public will be limited to the space available.

In accordance with the provisions set forth in sec. 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting will be closed to the public from 11:10 a.m. to adjournment for the discussion and recommendation of individuals to serve as consultants to the Research Priorities Subcommittee. This discussion could reveal personal information concerning these individuals, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of the Subcommittee's meeting and a roster of members may be obtained from Ms. Mirene Boerner, Acting Executive Director, National Deafness and Other Communication Disorders Advisory Board, Building 31, room 3C08, National Institutes of Health, Bethesda, Maryland 20892, 301–402–1129, upon request.

(Catalog of Federal Domestic Assistance Program No. 93.173, Biological Research Related to Deafness and Other Communication Disorders.)

Dated: December 24, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–433 Filed 1–7–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Drug Abuse; Meeting

Pursuant to Public Law 92–463, notice is hereby given of a meeting of an advisory committee of the National Institute on Drug Abuse for January 1993.

The National Advisory Council on Drug Abuse will be performing review of applications for Federal assistance; therefore, portions of this meeting will be closed to the public as determined by the Director, NIH, in accordance with 5 U.S.C. 552b(c)(4) and 552b(c)(6) and section 10(d) of Public Law 92–463.

Summaries of the meetings and rosters of committee members may be obtained from: Ms. Camilla L. Holland, NIDA Committee Management Officer, National Institutes of Health, Parklawn Building, room 10–42, 5600 Fishers Lane, Rockville, MD 20857 (Telephone: 301/443–2755).

Substantive program information may be obtained from the contacts whose names, room numbers, and telephone numbers are listed below.

Committee Name: National Advisory Council on Drug Abuse.

Meeting Date: January 27–28, 1993.

Place: National Institutes of Health, Building 31C, Conference Room 10, 9000 Rockville Pike, Bethesda, Maryland 20892.

Open: January 27, 1993, 9 a.m.–1 p.m., January 28, 1993, 9 a.m.–5 p.m.

Closed: January 27, 1993, 1 p.m.–5 p.m.

Contact: Michael S. Backenheimer, Ph.D, room 10–42, Parklawn Building, Telephone (301) 443–2755.

(Catalog of Federal Domestic Assistance Program Numbers: 93.277, Drug Abuse Research Scientist Development and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs.)

Dated: December 24, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–434 Filed 1–7–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Drug Abuse; Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the review committees of the National Institute on Drug Abuse for February 1993.

These meetings will be open to the public for approximately one-half hour at the beginning of the first day of the meeting for announcements and reports of administrative, legislative, and program development. Attendance by the public will be limited to space available.

As indicated below, in accordance with provisions set forth in section 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, these meetings will be closed to the public for the review, discussion, and evaluation of individual grant applications on the dates indicated below. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of the meetings and rosters of committee members may be obtained from: Ms. Camilla L. Holland, NIDA Committee Management Officer, National Institutes of Health, Parklawn Building, room 10–42, 5600 Fishers Lane, Rockville, MD 20857 (Telephone: 301/443–2755).

Substantive program information may be obtained from the contacts whose names, room numbers, and telephone numbers are listed below.

Committee Name: Biochemistry Research Subcommittee, Drug Abuse Biomedical Research Review Committee.

Meeting Date: February 9–11, 1993.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Open: February 9, 9 a.m. to 9:30 a.m.

Closed: 9:30 a.m., February 9, to adjournment on February 11.

Contact: Rita Liu, Ph.D., room 10–42, Parklawn Building, Telephone (301) 443–2620.

Committee Name: Pharmacology II Research Subcommittee, Drug Abuse Biomedical Research Review Committee.

Meeting Date: February 9–11, 1993.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Open: February 9, 9 a.m. to 9:30 a.m.

Closed: 9:30 a.m., February 9, to adjournment on February 11.

Contact: Gamil Debbas, Ph.D., room 10–42, Parklawn Building, Telephone (301) 443–2620.

Committee Name: Pharmacology I Research Subcommittee, Drug Abuse Biomedical Research Review Committee.

Meeting Date: February 9–12, 1993.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, Maryland 20814.

Open: February 9, 9 a.m. to 9:30 a.m.

Closed: 9:30 a.m., February 9, to adjournment on February 12.

Contact: Syed Husain, Ph.D., room 10–42, Parklawn Building, Telephone (301) 443–2620.

Committee Name: Drug Abuse Clinical and Behavioral Research Review Committee.

Meeting Date: February 9–12. 1993.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland 20814.

Open: February 9, 9 a.m. to 9:30 a.m.

Closed: 9:30 a.m., February 9, to adjournment on February 12.

Contact: Daniel L. Mintz, room 10–22, Parklawn Building, Telephone (301) 443–9042.

Committee Name: Drug Abuse Epidemiology and Prevention Research Review Committee.

Meeting Date: February 9–12, 1993.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland 20814.

Open: February 9, 9 a.m. to 9:30 a.m.

Closed: 9:30 a.m., February 9, to adjournment on February 12.

Contact: Raquel Crider, Ph.D., room 10–22, Parklawn Building, Telephone (301) 443–9042.

(Catalog of Federal Domestic Assistance Program Numbers: 93.277, Drug Abuse Research Scientist Development and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs.)

Dated: December 24, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–436 Filed 1–7–93; 8:45 am]

BILLING CODE 4140–01–M

Meeting on Training Requirements for Dental, Oral and Craniofacial Clinical Trials

Notice is hereby given that the Extramural Program, National Institute of Dental Research, will hold an open meeting on January 27, 1993, from 10 a.m. until 3:30 p.m., at the Holiday Inn, 5520 Wisconsin Avenue, Chevy Chase, Maryland 20815, telephone (301) 656–1500.

The objective of the meeting is to solicit comments from representatives of the academic, industrial and governmental oral health research communities on the types of training needed to develop personnel capable of designing and conducting state-of-the-art clinical trials of methods for the prevention, diagnosis and treatment of dental, oral and craniofacial diseases and disorders. Opportunities for collaboration to provide such training will be discussed.

Further information may be obtained from: Dr. Thomas Valega, Special Assistant for Manpower Development and Training, Extramural Program, NIDR, NIH, Westwood Building, Room 503, Bethesda, Maryland 20892, telephone (301) 496–6324.

Dated: December 28, 1992.

Bernadine Healy,

Director, National Institutes of Health.

[FR Doc. 93–437 Filed 1–7–93; 8:45 am]

BILLING CODE 4140–01–M

Division of Research Grants; Meetings

Pursuant to Public Law 92–463, notice is hereby given of the meetings of the following study sections for January through March 1993, and the individuals from whom summaries of meetings and rosters of committee members may be obtained.

These meetings will be open to the public for approximately one half hour at the beginning of the first session of the first day of the meeting during the discussion of administrative details relating to study section business. Attendance by the public will be limited to space available. These meetings will be closed thereafter in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Office of Committee Management, Division of Research Grants, Westwood Building, National Institutes of Health, Bethesda, Maryland 20892, telephone 301–496–7534 will furnish summaries of the meetings and rosters of committee members. Substantive program information may be obtained from each scientific review administrator, whose telephone number is provided. Since it is necessary to schedule study section meetings months in advance, it is suggested that anyone planning to attend a meeting contact the scientific review administrator to confirm the exact date, time and location. All times are a.m. unless otherwise specified.

Study section	January–March 1993 meetings	Time	Location
Allergy & Immunology, Mr. Howard M. Berman, Tel. 301–496–7380	Feb. 22–24	8:30	Holiday Inn, Chevy Chase, MD.
Bacteriology & Mycology–1, Dr. Timothy J. Henry, Tel. 301–496–7340	Feb. 10–12	8:30	Residence Inn Marriott, Bethesda, MD.
Bacteriology & Mycology–2, Dr. William Branche, Jr., Tel. 301–496–7682	Feb. 24–26	8:30	Holiday Inn, Chevy Chase, MD.
Behavioral Medicine, Ms. Carol Campbell, Tel. 301–496–7109	Feb. 3–5	8:30	Omni Shoreham Hotel, Washington, DC.
Biochemical Endocrinology, Dr. Michael Knecht, Tel. 301–496–7430	Feb. 3–5	8:30	Embassy Suites Hotel, Washington, DC.
Biochemistry, Dr. Adolphus P. Toliver, Tel. 301–496–7516	Feb. 17–19	8:30	The Georgetown Inn, Washington, DC.
Bio-Organic & Natural Products Chemistry, Dr. Harold Radtke, Tel. 301–496–8823.	Feb. 25–27	9	Holiday Inn, Chevy Chase, MD.
Biophysical Chemistry, Dr. John Beisler, Tel. 301–496–7070	Feb. 11–13	8:30	Ramada Renaissance Hotel-Techworld, Washington, DC.
Bio-Psychology, Dr. A. Keith Murray, Tel. 301–496–7058	Feb. 8–10	9	Omni Georgetown Hotel, Washington, DC.
Cardiovascular, Dr. Gordon L. Johnson, Tel. 301–496–7316	Feb. 11–13	8	Holiday Inn, Crowne Plaza, Rockville, MD.
Cardiovascular & Renal, Dr. Anthony Chung, Tel. 301–496–7901	Feb. 8–10	8:30	Holiday Inn, Chevy Chase, MD.
Cellular Biology and Physiology–1, Dr. Gerald Greenhouse, Tel. 301–402–2688	Feb. 3–5	8	American Inn, Bethesda, MD.
Cellular Biology and Physiology–2, Dr. Gerhard Ehrenpeck, Tel. 301–402–2691	Feb. 22–24	8:30	Holiday Inn, Georgetown, DC.
Chemical Pathology, Dr. Edmund Copeland, Tel. 301–496–7078	Jan. 28–30	8	Big Sky Resort, Big Sky, MT.
Diagnostic Radiology, Dr. Catharine Wingate, Tel. 301–496–7650	Feb. 22–24	8:30	ANA Hotel, Washington, DC.
Endocrinology, Dr. Michael Knecht, Tel. 301–496–7430	Feb. 17–19	8:30	Holiday Inn, Bethesda, MD.
Epidemiology & Disease Control–1, Dr. Scott Osborne, Tel. 301–402–1920	Feb. 10–12	8:30	Hyatt Regency Hotel, Bethesda, MD.
Epidemiology & Disease Control–2, Dr. H. M. Stiles, Tel. 301–496–7246	Feb. 9–11	8:30	Hyatt Regency Hotel, Bethesda, MD.
Experimental Cardiovascular Sciences, Dr. Richard Peabody, Tel. 301–496–7940	Feb. 3–5	8	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Experimental Immunology, Dr. Calbert Laing, Tel. 301–496–7238	Feb. 17–19	8:30	The Latham Hotel, Georgetown, DC.
Experimental Therapeutics–1, Dr. Philip Perkins, Tel. 301–496–7839	Feb. 10–12	8:30	Keybridge Marriott Hotel, Arlington, VA.
Experimental Therapeutics–2, Dr. Marcia Litwack, Tel. 301–496–8848	Feb. 24–26	8:30	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Experimental Virology, Dr. Garrett V. Keefer, Tel. 301–496–7474	Feb. 22–24	8:30	NIH, Room 9, Bldg. 31C, Bethesda, MD.
General Medicine A–1, Dr. Harold Davidson, Tel. 301–496–7797	Mar. 1–3	8:30	NIH, Room 10, Bldg. 31C, Bethesda, MD.

Study section	January–March 1993 meetings	Time	Location
General Medicine A–2, Dr. Mushtaq Khan, Tel. 301–496–7140	Feb. 16–18	8:30	One Washington Circle Hotel, Washington, DC.
General Medicine B, Dr. Daniel McDonald, Tel. 301–496–7730	Feb. 15–17	8	Holiday Inn, Chevy Chase, MD.
Genetics, Dr. David Remondini, Tel. 301–496–7271	Feb. 11–13	9	Holiday Inn, Bethesda, MD.
Genome, Dr. Cheryl Corsaro, Tel. 301–496–7896	Mar. 1–3	8:30	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Hearing Research, Dr. Joseph Kimm, Tel. 301–496–7494	Feb. 22–24	8:30	St. James Hotel, Washington, DC.
Hematology-1, Dr. Clark Lum, Tel. 301–496–7506	Feb. 18–20	8	Hyatt Regency Hotel, Bethesda, MD.
Hematology-2, Dr. Jerrold Fried, Tel. 301–496–7506	Feb. 17–19	8:30	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Human Development & Aging-1, Dr. Teresa Levitin, Tel. 301–496–7025	Feb. 16–18	9	Omni Shoreham Hotel, Washington, DC.
Human Development & Aging-2, Dr. Peggy McCardle, Tel. 301–496–7640	Feb. 10–12	8:30	Holiday Inn, Bethesda, MD.
Human Development & Aging-3, Dr. Anita Sostek, Tel. 301–496–8814	Feb. 22–24	9	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Human Embryology & Development-1, Dr. Arthur Hoversland, Tel. 301–496–7597	Feb. 18–19	8	Holiday Inn, Chevy Chase, MD.
Immunobiology, Dr. Bruce Maurer, Tel. 301–496–7780	Feb. 24–26	8:30	Holiday Inn, Chevy Chase, MD.
Immunological Sciences, Dr. Anita Corman Weinblatt, Tel. 301–496–7179	Feb. 17–19	8:30	Holiday Inn, Chevy Chase, MD.
Lung Biology and Pathology, Dr. Anne Clark, Tel. 301–496–4673	Feb. 9–12	7:30 p.m.	Holiday Inn, Chevy Chase, MD.
Mammalian Genetics, Dr. Jerry Roberts, Tel. 301–402–1462	Feb. 18–20	8:30	Holiday Inn, Chevy Chase, MD.
Medical Biochemistry, Dr. Alexander Liacouras, Tel. 301–496–7517	Feb. 15–17	8	St. James Hotel, Washington, DC.
Medicinal Chemistry, Dr. Ronald Dubois, Tel. 301–496–7107	Feb. 24–26	8:30	Hyatt Regency Hotel, Bethesda, MD.
Metabolic Pathology, Dr. Marcelina Powers, Tel. 301–496–5251	Feb. 17–19	8	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Metabolism, Dr. Krish Krishnan, Tel. 301–496–7091	Feb. 17–19	8	Holiday Inn, Georgetown, DC.
Metalloblochemistry, Dr. Edward Zapolski, Tel. 301–496–7733	Feb. 25–27	8:30	Omni Georgetown Hotel, Washington, DC.
Microbial Physiology & Genetics-1, Dr. Martin Slater, Tel. 301–496–7183	Feb. 24–26	8:30	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Microbial Physiology & Genetics-2, Dr. Gerald Liddel, Tel. 301–496–7130	Feb. 17–19	8:30	Holiday Inn, Crowne Plaza, Rockville, MD.
Molecular & Cellular Biophysics, Dr. Nancy Lamontagne, Tel. 301–496–7060	Feb. 11–13	8:30	Embassy Suites, Chevy Chase Pavilion, Washington, DC.
Molecular Biology, Dr. Robert Su, Tel. 301–496–7830	Feb. 11–13	8:30	Holiday Inn, Bethesda, MD.
Molecular Cytology, Dr. Ramesh Nayak, Tel. 301–496–7149	Feb. 4–6	8	Holiday Inn, Chevy Chase, MD.
Neurological Sciences-1, Dr. Andrew Mariani, Tel. 301–496–7279	Feb. 17–19	8	Holiday Inn, Chevy Chase, MD.
Neurological Sciences-2, Dr. Stephen Gobel, Tel. 301–496–8808	Feb. 9–11	8	Holiday Inn, Chevy Chase, MD.
Neurology A, Dr. Joe Marwah, Tel. 301–496–7095	Mar. 1–3	8	Governor's House, Washington, DC.
Neurology B–1, Dr. Samuel Rawlings, Tel. 301–496–7846	Feb. 9–11	8	Governor's House, Washington, DC.
Neurology B–2, Dr. Herman Teitelbaum, Tel. 301–496–7422	Feb. 16–18	8:30	Holiday Inn, Chevy Chase, MD.
Neurology C, Dr. Kenneth Newrock, Tel. 301–496–5591	Feb. 24–27	8:30	Omni Georgetown Hotel, Washington, DC.
Nursing Research, Dr. Gertrude McFarland, Tel. 301–496–0558	Feb. 16–19	8	Holiday Inn, Crowne Plaza, Rockville, MD.
Nutrition, Dr. Sooja Kim, Tel. 301–496–7178	Feb. 10–12	8:30	Residence Inn Marriott, Bethesda, MD.
Oral Biology & Medicine-1, Dr. Larry Pinkus, Tel. 301–496–7818	Feb. 8–10	8:30	St. James Hotel, Washington, DC.
Oral Biology & Medicine-2, Dr. Larry Pinkus, Tel. 301–496–7818	Feb. 1–3	8:30	St. James Hotel, Washington, DC.
Orthopedics & Musculoskeletal, Ms. Ileen Stewart, Tel. 301–496–7581	Feb. 3–5	8:30	Embassy Suites, Chevy Chase Pavilion, Washington, DC.
Pathobiochemistry, Dr. Zakir Bengali, Tel. 301–496–7820	Feb. 24–26	8:30	The Savoy Suites Hotel, Washington, DC.
Pathology A, Dr. Jaswant Bhorjee, Tel. 301–496–7305	Feb. 9–12	7 p.m.	Holiday Inn, Crowne Plaza, Rockville, MD.
Pathology B, Dr. Martin Padarathsingh, Tel. 301–496–7244	Jan. 27–31	7 p.m.	Big Sky Resort, Big Sky, MT.
Pharmacology, Dr. Joseph Kaiser, Tel. 301–496–7408	Feb. 24–26	8:30	American Inn, Bethesda, MD.
Physical Biochemistry, Dr. Gopa Rakhit, Tel. 301–496–7120	Feb. 22–24	8:30	Holiday Inn, Crowne Plaza, Rockville, MD.
Physiological Chemistry, Dr. Jerry Critz, Tel. 301–496–7837	Feb. 18–20	8:30	Holiday Inn, Bethesda, MD.
Physiology, Dr. Michael A. Lang, Tel. 301–496–7878	Feb. 10–12	8:30	Embassy Suites Hotel, Chevy Chase Pavilion, Washington, DC.
Radiation, Dr. Paul Strudler, Tel. 301–496–7073	Feb. 8–10	8:30	ANA Hotel, Washington, DC.
Reproductive Biology, Dr. Abubekar A. Shaikh, Tel. 301–496–8857	Feb. 8–10	8:30	Holiday Inn, Crowne Plaza, Rockville, MD.
Reproductive Endocrinology, Dr. Abubekar A. Shaikh, Tel. 301–496–8857	Feb. 1–3	8	Holiday Inn, Chevy Chase, MD.
Respiratory & Applied Physiology, Dr. Everett Sinnet, Tel. 301–496–7320	Feb. 15–17	8:30	Holiday Inn, Chevy Chase, MD.
Safety & Occupational Health, Dr. Gopal Sharma, Tel. 301–496–6723	Feb. 17–18	8	Holiday Inn, Crowne Plaza, Rockville, MD.
Sensory Disorders & Language, Dr. Jane Hu, Tel. 301–496–7505	Feb. 10–12	8	Holiday Inn, Capitol Hill, Washington, DC.
Social Sciences & Population, Dr. Robert Weller, Tel. 301–496–7906	Feb. 25–27	9	Holiday Inn, Chevy Chase, MD.
Surgery & Bioengineering, Dr. Paul F. Parakkal, Tel. 301–496–7506	Feb. 1–2	8	Holiday Inn, Chevy Chase, MD.
Surgery, Anesthesiology & Trauma, Dr. Keith Kraner, Tel. 301–496–7771	Feb. 17–19	2 p.m.	Holiday Inn, Bethesda, MD.
Toxicology–1, Dr. Alfred Marozzi, Tel. 301–496–7570	Feb. 10–12	8	American Inn, Bethesda, MD.
Toxicology–2, Dr. Alfred Marozzi, Tel. 301–496–7570	Feb. 17–19	8	American Inn, Bethesda, MD.
Tropical Medicine & Parasitology, Dr. Jean Hickman, Tel. 301–496–1190	Feb. 10–12	8:30	Holiday Inn, Bethesda, MD.
Virology, Dr. Rita Anand, Tel. 301–496–7605	Feb. 10–12	8:30	Holiday Inn, Georgetown, DC.
Visual Sciences A, Dr. Anita Suran, Tel. 301–496–7000	Feb. 24–26	8	Holiday Inn, Bethesda, MD.
Visual Sciences B, Dr. Leonard Jakubczak, Tel. 301–496–7251	Feb. 10–12	8:30	Omni Georgetown Hotel, Washington, DC.
Visual Sciences C, Dr. Samuel Rawlings, Tel. 301–496–7795	Feb. 9–12	8:30	The Georgetown Inn, Georgetown, DC.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 24, 1992.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–436 Filed 1–7–93; 8:45 am]

BILLING CODE 4140–10–M

Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Public Health Service (PHS) publishes a list of information collection requests it has submitted to

the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The following requests have been submitted to OMB since the list was last published on Friday, December 18, 1992.

(Call PHS Reports Clearance Officer on 202–690–7100 for copies of requests)

1. Waiting List Community Intervention Project (WLCIP)—New—This controlled field experiment will test the effectiveness of minimal intervention (MI) in changing HIV risk behaviors and motivation to enter treatment among randomly assigned waiting list applicants. MI at three drug programs will include methadone and self help; at another group, counseling to jail inmate applicants. *Respondents:* Individuals or households; *Number of Respondents:* 748; *Number of Responses per Respondent:* 1; *Average Burden per Response:* .56 hours; *Estimated Annual Burden:* 416 hours.

2. Emergency Epidemic Investigations—0920–0008—The Centers for Disease Control (CDC) receives requests from State and local health departments for scientific, medical, and technical assistance in the event of an epidemic or medical emergency. This approval is used so that CDC scientists have a means of collecting data once in the field. *Respondents:* Individuals or households; *Number of Respondents:* 20,000; *Number of Responses per Respondent:* 1; *Average Burden per Response:* .25 hours; *Estimated Annual Burden:* 5,000 hours.

3. National Practitioner Data Bank for Adverse Information on Physicians and other Health Care Practitioners—Regulations and forms (45 CFR Part 60)—0915–0216—This request is for approval of two additional forms for the National Practitioner Data Bank. The first would be used in a biennial survey of entities reporting to and querying the Data Bank to recertify eligibility. The second form can be used by entities to correct information in the Data Bank record. *Respondents:* Individuals or households, State or local governments, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small businesses or organizations.

Title	No. of respondents	No. of responses per respondent	Average burden per response
Currently Approved Collection Burden	25,650	30	.11
Biennial Entity File Verification form	5,650	1	0.25
Entity File Update	1,130	1	0.25

Estimated Total Annual Burden..... 89,170

4. 1993 Teenage Attitudes and Practices Survey II (TAPS II—Field Pretest and Final Survey)—0920–0310—The Teenage Attitudes and Practices Survey II (TAPS II) is a follow-up study to the 1989 Teenage Attitudes and Practices Survey (TAPS). The TAPS II will reinterview the 9,135 teens who responded by telephone to the 1989 TAPS. The objectives are to estimate prevalence of tobacco use among youth, changes in tobacco use status during adolescence, and to measure the predicators of tobacco uptake and cessation among young people. TAPS II will include approximately 6,000 youth to provide current cross-sectional data. *Respondents:* Individuals or households. *Number of Respondents:* 15,135; *Number of Responses per Respondent:* 1; *Average Burden per Response:* .417 hours; *Estimate Annual Burden:* 6,311 hours.

5. National Survey of Family Growth, Cycle V—New—The survey provides data on childbearing, family formation (including adoption), and maternal and child health. The data are used by the Office of Population Affairs, the National Institute of Child Health and Human Development, the Centers for Disease Control, and other agencies, and are disseminated through written reports and public use computer tapes. *Respondents:* Individuals or households; *Number of Respondents:* 4,821; *Number of Responses per Respondent:* 1.840; *Average Burden per Response:* 0.635 hours; *Estimated Annual Burden:* 5,633 hours.

6. Methodology Study for the Institutional Population Component of the National Medical Expenditure Survey (NMES): Round 2—New—This is Round 2 of a methodology study which will assess methods for enhancing the quality of data on medical care and expenditures in the institutional component and for improving the efficiency of data collection. *Respondents:* Individuals or households; businesses or other for-profit. *Number of Respondents:* 840; *Number of Responses per Respondent:* 1.2; *Average Burden per Response:* .99 hours; *Estimated Annual Burden:* 997 hours.

Desk Officer: Shannah Koss.

Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated above at the following address: Human Resources and Housing Branch, New Executive Office Building, room 3002, Washington, DC 20503.

Dated: January 5, 1993.

James Scanlon,

Director, Division of Data Policy, Office of Health Planning and Evaluation.

[FR Doc. 93–451 Filed 1–7–93; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N–92–1917; FR–3350–N–13]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: January 8, 1993.

ADDRESSES: For further information, contact James Forsberg, Department of Housing and Urban Development, room 7262, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–4300; TDD number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: December 29, 1992.

Paul Reitman Bardack,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 93–4 Filed 1–7–93; 8:45 am]

BILLING CODE 4210-35-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–932–4210–06; COC–54517]

Proposed Withdrawal; Opportunity for Public Meeting; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of Agriculture, Forest Service, proposes to withdraw 2,195 acres of National Forest System lands for a period of 10 years to protect Wild and Scenic values in a 23-mile segment of the North Saint Vrain River. This notice will segregate this site from location and entry under the mining laws for a period of 2 years pending final determination on this application. The lands have been and will continue to be open to mineral leasing and Forest Service management.

DATES: Comments or requests for public meeting should be received on or before April 8, 1993.

ADDRESSES: Comments should be addressed to State Director, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215.

FOR FURTHER INFORMATION CONTACT: Robert A. Barbour, BLM Colorado State Office, (303) 239–3708.

SUPPLEMENTARY INFORMATION: The Department of Agriculture filed application on December 28, 1992, to withdraw the following described National Forest System lands from location and entry under the U.S. mining laws (30 U.S.C. ch. 2):

Sixth Principal Meridian

Roosevelt National Forest

T. 3 N., R. 72 W.,
- Sec. 14, lots 10 to 12, inclusive;
- Sec. 17, lots 27 and 28;
- Sec. 18, lots 27 to 30, inclusive;
- Sec. 19, lots 21 to 28, inclusive;
- Sec. 20, lots 1 to 4, inclusive;
- Sec. 21, lots 2 to 7, inclusive;
- Sec. 22, lots 1 to 6, inclusive;
- Sec. 23, lots 1 to 5, inclusive, and lots 7 and 8;
- Sec. 24, lots 4 to 12, inclusive.

T. 3 N., R. 73 W.,
- Sec. 13, S½SE¼;
- Sec. 24, NE¼.

The areas described aggregate approximately 2,195.02 acres of National Forest System lands in Boulder County.

The purpose of this withdrawal is to protect this segment of the North Saint Vrain River which has been determined to be eligible for a suitability evaluation for designation as a Wild and Scenic River.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with this proposal or to request a public meeting may present their views in writing to the Colorado State Director.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with this proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on this proposed action must submit a written request to the Colorado State Director within 90 days of the date of publication of this notice. If the authorized officer determines that a meeting should be held, this meeting will be scheduled and conducted in accordance with Bureau of Land Management Manual, section 2351.16B

This application will be processed in accordance with the regulations set forth in 43 CFR part 2310. For a period of 2 years from the date of publication of this notice in the **Federal Register**, the land will be segregated from operation of the public land laws as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date.

The temporary uses which may be permitted during this segregation period are those which the Forest Service determines will not diminish or change the free-flowing character, water quality, or the scenic, recreational, fish and wildlife, and other values which make the river eligible for designation.

Dated: December 31, 1992.

Andrew J. Senti,

Acting Chief, Branch of Realty Operations.

[FR Doc. 93–347 Filed 1–7–93; 8:45 am]

BILLING CODE 4310-JB-M

Fish and Wildlife Service

Emergency Exemption; Issuance

On December 31, 1992, the U.S. Fish and Wildlife Service (Service) issued a permit (PRT–775005) to Omaha's Henry Doorly Zoo, Omaha, Nebraska to import a pair of Siberian tiger (*Panthera tigris altaica*) cubs. The 30-day public comment period required by section 10(c) of the Endangered Species Act was waived. The Service determined that an emergency affecting the health and life of the tigers existed and that no reasonable alternative was available to the applicant, for the following reasons:

a. The mother of the cubs was a radio-collared animal under study by U.S. and Russian biologists conducting research on this species in the Sikhote-Alin Biosphere Reserve (Reserve) in eastern Russia. The mother was found dead and determined to have been shot by poachers.

b. The cubs were approximately 11–12 weeks of age, which is well before the age of independence/weaning, when they were taken into captivity in an attempt to prevent their deaths.

c. The cubs are currently being held in a field station within the reserve, where they are being maintained in a summer cookhouse.

d. Two of the four cubs taken from the wild have died of complications from diaphragmatic hernias.

e. The Moscow Zoo is in favor of placing the cubs at the Henry Doorly Zoo (zoo) for breeding and expanding the genetic base of the Species Survival Plan for the Siberian tiger population. There is an agreement between the Reserve and the zoo for placement of the tigers at the zoo.

Dated: January 5, 1993.

I. Teiko Saito,

Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 93–423 Filed 1–7–93; 8:45 am]

BILLING CODE 4310-55-M

INTERSTATE COMMERCE COMMISSION

Motor Passenger Carrier or Water Carrier Finance Applications Under 49 U.S.C. 11343–11344

The following applications seek approval to consolidate, purchase, merge, lease operating rights and properties of, or acquire control of motor passenger carriers or water carriers under 49 U.S.C. 11343–11344. The applications are governed by 49 CFR part 1182, as revised in Pur., Merger & Cont.—Motor Passenger & Water Carriers, 5 I.C.C.2d 786 (1989). The findings for these applications are set forth at 49 CFR 1182.18. Persons wishing to oppose an application must follow the rules under 49 CFR part 1182, subpart B. If no one timely opposes the application, this publication automatically will become the final action of the Commission.

MC–F–20231, filed December 10, 1992. Greyhound Lines of Canada Ltd.—Control and Merger—Gray Coach Lines, Inc. and Brewster Transport Company Limited d/b/a Brewster Gray Line & Royal Glacier Tours. Applicant's

representative: Jeremy Kahn, 1726 M Street, NW., suite 702, Washington, DC 20036. Greyhound Lines of Canada Ltd.[1] (Greyhound) (MC–126019), a motor common carrier of passengers, controls through stock ownership Brewster Transport Company Limited d/b/a Brewster Gray Line & Royal Glacier Tours (Brewster) (MC–157275), and Gray Coach Lines, Inc. (Gray) (MC–29861), motor common carriers of passengers. Common Control of Browster was effected in 1982, but, through inadvertence, Greyhound neglected to file for approval or exemption at that time. Greyhound owns all of the stock of Brewster and will acquire all of the capital stock of Gray. Upon approval of the capital stock purchase of Gray, Gray will be merged into Greyhound.

Decided: January 5, 1993.

By the Commission, the Motor Carrier Board.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–400 Filed 1–7–93; 8:45 am]

BILLING CODE 7035–01–M

[Ex Parte No. 347 (Sub-No. 2)]

Rate Guidelines—Non-coal Proceedings

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Proposed guidelines; extension of comment due date.

SUMMARY: By decision served November 17, 1992, (57 FR 54252), the Commission sought public comment by January 15, 1993, on proposed simplified guidelines for determining maximum rail rate reasonableness in proceedings involving relatively low-volume or infrequent shipments. By letters filed December 17 and December 18, 1992, the Association of American Railroads (AAR) and the National Industrial Transportation League (the League), respectively, request a 90-day extension of the January 15, 1993 due date for comments. AAR indicates an extension is reasonable and necessary to evaluate and coordinate the industry's position on the difficult questions posed by the Notice. The League requests the extension so that interested and affected parties can conduct careful and thorough analysis of issues raised by the Notice. The request will be granted.

DATES: Comments must be filed by April 15, 1993.

ADDRESSES: Send an original and 10 copies of comments, referring to Ex Parte No. 347 (Sub-No. 2), to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Jeanne P. Kowolski, (202) 927–6188, [TDD for hearing impaired: (202) 927–5721].

Decided: January 4, 1993

By the Commission, Sidney L. Strickland, Jr., Secretary.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–402 Filed 1–7–93; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 32190]

Central Kansas Railway, Inc.; Acquisition and Operation Exemption; The Atchison, Topeka and Santa Fe Railway Co.

Central Kansas Railway, Inc. (CKR), a noncarrier, has filed a notice of exemption: (1) To acquire and operate approximately 890 miles of rail line owned by The Atchison, Topeka and Santa Fe Railway Company (Santa Fe); and (2) to acquire incidental trackage rights over approximately 70 miles of track owned by Santa Fe, Union Pacific Railroad (UP), Missouri Pacific Railroad Company (MP), Burlington Northern Railroad Company (BN), and St. Louis Southwestern Railway Company (SLSW). CKR will become a class III carrier.[1]

The rail line segments to be acquired consist of 13 rail lines in the States of Kansas and Oklahoma as follows:

(1) Santa Fe's Salina Subdivision rail line between milepost 20+492 feet at Salina, KS, and milepost 102+4751.4 feet in Osborne, KS, including all industry, team, passing, house, and side track, and including all of Santa Fe's yard tracks and side tracks at Salina;

(2) Santa Fe's McPherson Subdivision rail line between milepost 11+1984 feet, west of Marion, KS, and milepost 98+1209.5 feet in Ellinwood, KS, including all industry, team, passing, house, and side tracks, and including all of Santa Fe's yard tracks in Ellinwood, KS, and McPherson, KS;

(3) Santa Fe's Little River Subdivision rail line between milepost 20+2769.6 feet in Lorraine, KS, and milepost 57+2730 feet in Galatia, KS, including all industry, team, passing, house, and side tracks;

(4) Santa Fe's Great Bend Subdivision rail line between milepost 0+0 feet in Great Bend, KS, and milepost 120+1338.7 feet in Scott City, KS, including all industry team, passing, house, and side tracks;

(5) Santa Fe's Garden City Subdivision rail line between milepost 120+169 feet in Scott City, KS, and milepost 125+4687 feet at Shallow Water, KS, including all industry team, passing, house, and side tracks,

(6) Santa Fe's Hutchinson Subdivision rail line between milepost 218.3, east of Monroe St., in Hutchinson, KS, and milepost 315+4230.1 feet in Kinsley, KS, including all industry team, passing, house, and side tracks, and including all of Santa Fe's yard tracks in Great Bend, KS;

(7) Santa Fe's Larned Subdivision rail line between milepost 0+0 feet at Larned, KS and milepost 46+2483.5 feet in Jetmore, KS, including all industry team, passing, house, and side tracks;

(8) Santa Fe's H&S Subdivision rail line between milepost 3+2640 feet, near Darlow, KS, and milepost 59+4005.2 feet in Harper, KS;

(9) Santa Fe's H&S Subdivision rail line between milepost 59+4013.2 feet in Harper, KS, and milepost 128+0 feet in Blackwell, OK, including all industry, team, passing, house, and side tracks;

(10) Santa Fe's H&S Subdivision rail line between milepost X–35+1,848 feet in Blackwell, OK, and milepost X–0+466.3 feet in Wellington, KS, including all industry, team, passing, house, and side tracks;

(11) Santa Fe's Wichita Subdivision rail line between milepost 1.5, west of Seneca St., in Wichita, KS (including the remaining trackage on the Englewood Subdivision in Wichita), and milepost 79+3855 feet in Pratt, KS;

(12) Santa Fe's Englewood Subdivision rail line between milepost 46+0 feet, east of Rago, KS, and milepost 166+2917.7 feet in Englewood, KS, including all industry, team, passing, house, and side tracks; and

(13) Sante Fe's Medicine Lodge Subdivision rail line between milepost 49+1784 feet at O.B. Junction near Belvidere, KS, and milepost 0+1016 feet in Attica, KS, including all industry, team, passing, house, and side tracks, and including the entire spur line located near Sun City, KS.

The incidental trackage rights that CKR will acquire as part of the transaction will be over the following lines in the State of Kansas as follows:

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[1] Applicant Greyhound Lines of Canada Ltd. is not affiliated with Greyhound Lines, Inc. of Dallas, TX, the nationwide passenger carrier in the United States.

[1] This proceeding is related to a petition for exemption filed in Finance Docket No. 32189, The Broe Companies, Inc.—Continuance in Control Exemption—Central Kansas Railway, Inc., in which the Commission in a decision served on December 31, 1992, approved petitioner's continuance in control of CKR when CKR becomes a carrier upon consummation of the transaction described in this notice.

(1) Santa Fe's Hutchinson Subdivision rail line between milepost 218.3 feet, at or near Monroe St., KS, and milepost 213+4333 feet in Hutchinson, KS, including Santa Fe's Hutchinson, KS "Way" Yard Track Nos. 144, 259, 304, 260, 261, 221, 174, 172, 171, 241, 220, 169 and 168;

(2) Santa Fe's H&S Subdivision rail line between milepost 2+2640 feet and milepost 3+2640 feet, north of Darlow, KS;

(3) Santa Fe's Wichita Subdivision rail line between milepost 1.5, west of Seneca St., in Wichita, KS, and Santa Fe's Wichita Subdivision milepost 0+1365 feet, being also Wichita Terminal milepost 213+1378 feet, and further beyond to North Junction Wichita Terminal milepost 211+3610 feet, being also Santa Fe's Arkansas City Subdivision milepost 211+3610 feet, and further beyond to Santa Fe's Arkansas City Subdivision milepost 208+2320 feet, including Santa Fe's Wichita, KS Yard Track Nos. 32, 204, 243, 1, 143, 244, 122, 242, 113, 237, 236, 307, 308, 195, 344 and 124;

(4) Santa Fe's H&S Subdivision and Waynoka Subdivision rail lines between Santa Fe's H&S Subdivision milepost 59+4005.2 feet on the north, and Santa Fe's H&S Subdivision milepost 59+4013.2 feet on the south, and between Waynoka Subdivision milepost 273+0 feet on the east, and Waynoka Subdivision milepost 275+0 feet on the west, including Santa Fe's Harper, KS Yard Track Nos. 1, 11, 12, 14, 31, 32, 33, 37, 43, 45 and 47;

(5) Santa Fe's Medicine Lodge Subdivision rail line between milepost 0+1016 feet and milepost 0+0 feet in Attica, KS, and also Santa Fe's Waynoka Subdivision rail line between milepost 285+4000 feet and 287+1600 feet in Attica, KS, including Santa Fe's Attica, KS Yard Track Nos. 21, 20, 19, 18, 15, and 9;

(6) Santa Fe's H & S and Waynoka Subdivision rail lines in Wellington, KS, between H & S Subdivision X–0+466.3 feet on the south, H & S Subdivision X–0+0 feet on the north, Waynoka Subdivision milepost 238+2331.8 feet on the west, and Waynoka Subdivision milepost 237+1068 feet on the east, including Santa Fe's Wellington, KS Yard Track Nos. 19, 104, 186, 187, 218, 219 and 222;

(7) BN's rail line between milepost 594.1 in Lorraine, KS, and milepost 577.1 in Lyons, KS;

(8) MP's rail line between milepost 487.10 at Newton, KS, and milepost 516.52 at McPherson, KS, including the segment of track extending about 116 feet in a southerly direction from milepost 487.10, and including MP's Siding Track No. 6 at Hesston, KS, and Siding Track No. 1 at Moundridge, KS;

(9) UP's rail line between milepost 164.7 in Abilene, KS, and milepost 184.6 at Salina, KS; and

(10) SLSW's rail line between milepost 246.46 and milepost 243.56 in Hutchinson, KS. Santa Fe will assign to CKR its trackage rights over the UP, MP, BN and SLSW line segments.

The parties intend to consummate the acquisition on or before December 31, 1992.

All comments must be filed with the Commission and served on: Karl Morell, Taylor, Morell & Gitomer, Suite 210, 919 18th St., NW., Washington, DC 20006.

This notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: January 4, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–401 Filed 1–7–93; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Notice of Proposed Settlement Agreement

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that the respective parties named in *United States* v. *Alumax Fabricated Products, Inc. et al*, Civil Action No. CS–91–066–WFN, entered into a proposed Settlement Agreement on December 9, 1992. The Settlement Agreement concerns the Colbert Landfill Superfund Site located in Spokane County, Washington about 2.5 miles from the Town of Colbert, Washington and a half mile east of U.S. Highway No. 2.

The Settlement Agreement requires the defendants to pay to the United States the sum of Seven Hundred and Fifty Thousand Dollars ($750,000) to settle the United States' action which was filed pursuant to sections 107(a) and 113(g) of CERCLA, 42 U.S.C. §§ 9607(a) and 9613(g). This sum constitutes reimbursement of a portion of the United States Environmental Protection Agency's obligated costs in connection with response actions at the Colbert Landfill Superfund Site ("Site") located in Spokane County, Washington.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the Settlement Agreement. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Alumax Fabricated Products, Inc. et al*, DOJ Ref. #90–11–3–411A.

The Settlement Agreement may be examined at the Office of the United States Attorney for the Eastern District of Washington, West 920 Riverside, suite 340, Spokane, Washington, 99201 and at the Region 10 Office of the Environmental Protection Agency, 1200 Sixth Avenue Seattle, Washington, 98101 (Attention: Cynthia Mackey, Assistant Regional Counsel).

The proposed Settlement Agreement may also be examined at the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW., Washington, DC 20004. A copy of the Settlement Agreement may be obtained in person or by mail from the Environmental Enforcement Section Document Center, 601 Pennsylvania Avenue, NW., Box 1097, Washington, DC 20044. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $3.00 (25 cents per page reproduction costs), payable to the "Consent Decree Library." When requesting copies, please refer to *United States* v. *Alumax Fabricated Products, Inc. et al*, DOJ Ref. #90–11–3–411A.

Vicki A. O'Meara,

Acting Assistant Attorney General, Environment and Natural Resources Division.

[FR Doc. 93–348 Filed 1–7–93; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Employment Standards Administration; Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar

character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon and Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume, State, and page number(s). Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Pennsylvania:
PA91–1(Feb. 22, 1991) ..... p. All.
PA91–2(Feb. 22, 1991) ..... p. All.
PA91–24(Feb. 22, 1991) ..... p. All.

Volume III

Hawaii:
HI91–1(Feb. 22, 1991) ..... p. All.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783–3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC This 4th Day of January 1993.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 93–274 Filed 1–7–93; 8:45 am]

BILLING CODE 4510–27–M

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 92–3]

Document Cover Sheet Availability

AGENCY: Copyright Office, Library of Congress.

ACTION: Policy decision: Document Cover Sheet.

SUMMARY: This is to inform the public that the Copyright Office is making available a Document Cover Sheet, which may be submitted to the Office with documents to be recorded under the recording systems specified in the Copyright Act, title 17 of the United States Code. This Document Cover Sheet will expedite the recordation of documents and constitutes the second step in changes in the Copyright Office's document procedures to ensure the more timely recordation of documents.

On a voluntary basis, a Document Cover Sheet, which contains all of the information required by the Office to process a document, may be submitted with the document for recordation. The Office will rely on the information provided on the Document Cover Sheet, and will not examine the document itself except for actual signature (when required) and legibility.

EFFECTIVE DATE: January 8, 1993.

FOR FURTHER INFORMATION CONTACT: Dorothy Schrader, General Counsel, U.S. Copyright Office, Library of Congress Washington, DC 20540. Telephone (202) 707–8380.

SUPPLEMENTARY INFORMATION:

1. Background

The Copyright Office records a wide variety of documents under sections 203, 205, 302(c) and 304(c) of the Copyright Act and section 903(b) of the Semiconductor Chip Act. These sections contain minimal requirements for recordation. For example: The only statutory requirements to record a transfer or other document pertaining to a copyright under 17 U.S.C. 205 are that the document must (1) bear the actual signature of the person(s) who executed it, or (2) be accompanied by a sworn or official certification that it is a true copy of the original signed document, and (3) be accompanied by the recording fee.

On June 17, 1992, 57 FR 27074, the Copyright Office informed the public of new examining practices with respect to recordation of documents pertaining to copyrights. This Office announced that it would examine documents submitted for recordation only for compliance with the requirements of the Copyright

Act and Office regulations. The Office does not examine documents for apparent legal sufficiency. This change in practices was made to accelerate the recordation process in order to provide more timely public access to documents submitted for recordation. This Policy Decision constitutes a second step in changes intended to process documents faster.

2. Document Cover Sheet Policy Decision

In order to shorten the processing time for document recordation, the Copyright Office adopts a Policy Decision encouraging recordation of documents by means of a Document Cover Sheet procedure.

This Notice informs the public of changes in Office procedures for those documents voluntarily submitted with a Document Cover Sheet. Attached as an appendix to this Announcement is a copy of the New Document Cover Sheet with instructions for its completion.

The Document Cover Sheet, when fully completed, will contain all of the information required by the Copyright Office to complete the recordation procedure on a priority basis. The Office will not examine the document itself except for actual signature, when required, and legibility.

The Copyright Office will record the document based on the information contained on the Document Cover Sheet and will not verify the correctness of the information by reference to the document. The person submitting the document bears the responsibility for correctly completing the Document Cover Sheet.

The Document Cover Sheet will be recorded with the document. The Certificate of Recordation of the Office's index record of the recordation will be based on the Document Cover Sheet. An error on a recorded Document Cover Sheet can only be corrected by making a new recordation. This can be done by submitting a corrected Document Cover Sheet, a new document, and a new recording fee. The original, allegedly incorrect recordation will also remain in the records of the Copyright Office. The corrected Document Cover Sheet must be marked clearly at the top of the sheet: "Corrected Document Cover Sheet."

Use of the Document Cover Sheet is voluntary. There are, however, advantages to its use both for the remitter and the Office. Documents submitted with fully completed Document Cover Sheets will be given priority in processing. Use of this Document Cover Sheet procedure by a majority of remitters should result in significant reduction in average processing time for recordation of documents. Documents submitted with incomplete Document Cover Sheets will be processed in the order in which they are received along with documents submitted without a Document Cover Sheet.

The Office suggests that a properly certified copy of the document rather than the original signed document be submitted for recordation in all cases, to avoid the delays associated with returning the original document, if it is submitted for recordation. The Document Cover Sheet itself provides a sworn certification at Space 11, to facilitate submission of copies of documents. Copies of documents on file in a Federal, state or local government office must be accompanied by an official certification by the appropriate Government official.

The Document Cover Sheet procedure places the obligation on the remitter to complete the Document Cover Sheet correctly and in conformity with the accompanying document. The remitter must make certain that the document is legally sufficient to accomplish the purpose for which it is intended. The remitter must ensure that the document satisfies the requirements of the Copyright Office for recordation under the Office regulations applicable to that class of document.

Regulations issued by the Copyright Office under authority of the Copyright Act concerning documents are found in 37 CFR 201.4, 201.10, 201.25, and 201.26. No separate regulation concerning recordation has been issued under the Semiconductor Chip Protection Act. Documents pertaining to masks works are governed by section 903, title 17 U.S.C. They are recorded under the procedure for copyright-related documents, 37 CFR 201.4.

All documents submitted for recordation must be both legible to read and capable of being legibly recorded on microform. The Office will continue to examine for legibility.

In the case of documents submitted with Document Cover Sheets, however, the office will no longer examine a document for compliance with the following regulatory requirements: That transfers and other documents pertaining to copyright submitted under section 205 of the Copyright Act are complete by their own terms; that terminations of transfers submitted under section 304(c) of the Act are complete and exact duplicates of the notice of termination as served and include the actual signature, or a reproduction of the actual signature, and are accompanied by a statement setting forth the date on which the notice was served and the manner of service.

In addition, the Copyright Office will rely solely on the information provided at Space 4 of the Document Cover Sheet concerning completeness of documents. Office regulations at 37 CFR 201.4 continue to require that a transfer or other document pertaining to a copyright must be complete by its own terms to be recordable. A document is complete by its own terms if any schedule, appendix, exhibit, addendum or other material referred to in the document is submitted for recordation with the document, or if the reference is deleted by the parties to the document. If an attachment is completely unavailable for recordation, is not essential to identify the subject matter of the document, and, if it would be impossible or wholly impracticable to have the parties to the document sign or initial a deletion of the reference, the Office regulations permit recordation "as is." Completion of Space 4 to indicate that the document is not complete but should be recorded "as is," is deemed to be a written request for recordation "as is," which satisfies the conditions for such a request in the regulations.

Although the Document Cover Sheet procedure is voluntary at this time, its use is encouraged.

Two copies of a fully completed Document Cover Sheet should accompany each document to be recorded. Submission of two copies facilitates priority processing.

A fully completed Document Cover Sheet is one that contains all of the requested information and required signature(s). The Document Cover Sheet will be recorded with the document and form the basis for the catalog record of the document. The Copyright Office will not examine the document to verify the correctness of the information contained on the Document Cover Sheet, except for the correctness of the number of titles it contains.

Recordation of a document with or without a Document Cover Sheet does not constitute a determination by the Copyright Office of the validity of a document of the effect of that document The determination can only be made by a court of law.

Document Cover Sheets are supplied free of charge by the Copyright Office and may be ordered at anytime by telephoning (202) 707–9100. Orders will be recorded automatically and filled as quickly as possible. Please specify that you need Document Cover Sheets and the number needed. The Office will accept photocopies of the Document Cover Sheet. All Document Cover

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Sheets and attachments should be 8½ x 11 inches in size. The Office prefers that all documents also be the same size to promote uniformity of the microform records. Documents should be typed or printed preferably, but the Office does not make that a requirement for recordation.

Dated: December 14, 1992.

Ralph Oman,

Register of Copyrights.

Approved:

James H. Billington,

The Librarian of Congress.

BILLING CODE 1410-07-M

Document Cover Sheet

BASIC INFORMATION

Read these instructions before completing this form. Make sure all applicable spaces have been filled in before you return this form, or the form cannot be used.

When to Use This Form: Use the Document Cover Sheet when you are submitting a document for recordation in the U.S. Copyright Office.

Mailing Requirements: It is important that you send two copies of the Document Cover Sheet, any additional sheets, the document, and the fee together in the same envelope or package. The Copyright Office cannot process them unless they are received together. Send to: *Documents Unit, LM-462, Cataloging Division, Copyright Office, Library of Congress, Washington, D.C. 20559.*

Two copies of this Document Cover Sheet and any additional sheets you include, which must measure 8 1/2 x 11 inches, should accompany **each document**. Cover sheets should be typed or printed. The cover sheet, when completed, should contain all of the information necessary for the Copyright Office to process the document and ensure that the correct data is recorded promptly. The Copyright Office will process the document on the basis of information contained in the cover sheet without verifying its correctness from the document itself. However, to be recordable, a document must satisfy the recordation requirements of the Copyright Act and Copyright Office regulations.

The person(s) submitting a document with a cover sheet are solely responsible for verifying the correctness of the cover sheet and the sufficiency of the document. Recording a document submitted with or without a cover sheet does not constitute a determination by the Copyright Office of the document's validity or the effect of that document. Only a court of law may make such determinations.

This cover sheet and any additonal sheets will be recorded with the document as part of the official recordation.

PRIVACY ACT ADVISORY STATEMENT
Required by the Privacy Act of 1974 (P.L. 93-579)

The authority for requesting this information is title 17 U.S.C., sec. 205. Furnishing the requested information is voluntary. But if the information is not provided, it may be necessary to delay recordation.

The principal uses of the requested information are the establishment and maintenance of a public record and the evaluation for compliance with legal requirements.

Other routine uses include public inspection and copying, preparation of public indexes, preparation of public catalogs of copyright recordations, and preparation of search reports upon request.

NOTE: No other advisory statement will be given in connection with this application. Please keep this statement and refer to it if we communicate with you regarding this cover sheet.

SPACE-BY-SPACE INSTRUCTIONS

1 SPACE 1: Name of Party or Parties to the Document

Name all of the parties to this document. If additional space is needed, use a white, 8 1/2 x 11 inch sheet of paper to list the parties. The document will be indexed under the names of these parties. For transfers, notices of termination, and other two-party documents, indicate which is assignor, grantor, or party 1 and which is assignee, grantee, or party 2.

2 SPACE 2: Description of Document

Describe the document. This description will be entered in the catalog record of the recordation.

3 SPACE 3: Title(s) of Work(s)

List the titles of all works which are included in the document. Include registration number, names of authors, and other information to identify the work(s) and link them to the original registration. Additional sheets the same size as the cover sheet may be attached, if needed. Indicate that the titles on any addtional sheets are additions to Space 3.

4 SPACE 4: Completeness of Document

All section 205 documents must be complete by their own terms in order to be recordable. Examples of section 205 documents include transfers of copyright ownerships and other documents pertaining to a copyright such as exclusive and non-exclusive licenses, contracts, mortgages, powers of attorney, certificates of change of corporate name or title, wills, and decrees of distribution.

5 SPACE 5: Number of Titles in Document

The number of titles determines the recordation fee. The fee for a document of any length containing one title is $20. Additional titles are $10 for each group of 10 or fewer. The Copyright Office will verify title counts.

6 SPACE 6: Fee

Calculate the fee from the information given in Space 5.

NOTE: The Copyright Office has the authority to adjust fees at 5-year intervals, based on changes in the Consumer Price Index. The next adjustment is due in 1996. Please contact the Copyright Office after July 1995 to determine the actual fee schedule.

7 SPACE 7: Deposit Account

If a Deposit Account is to be charged, give the Deposit Account number.

8 SPACE 8: Date of Execution

Give the date the accompanying document (not this Cover Sheet) was executed and/or became effective.

9 SPACE 9: Affirmation

This space is to be completed by all applicants. The party to the document submitting it for recordation or his/her authorized agent should sign the affirmation and authorization contained in this space. This affirmation and authorization is not a substitute for the certification required for documents containing a photocopy signature. (See Certification, Space 10.)

10 SPACE 10: Certification

Complete this section only if submitting photocopied documents in lieu of a document bearing the actual signature.

Certification: Any transfer of copyright ownership or other document pertaining to a copyright (section 205) may be recorded in the Copyright Office if the document bears the actual signature of the person or persons who executed (signed) the documents. If a photocopy of the original signed document is submitted, it must be accompanied by a sworn or official certification. A sworn certification signed by at least one of the parties to the document or their authorized representative (who is identified as such) at Space 10 will satisfy that requirement.

Copies of documents on file in a Federal, state, or local government office must be accompanied by an official certification.

DOCUMENT COVER SHEET

For Recordation of Documents
UNITED STATES COPYRIGHT OFFICE

DATE OF RECORDATION
(Assigned by Copyright Office)

Month Day Year

Volume _____ Page _____

Volume _____ Page _____

DO NOT WRITE ABOVE THIS LINE.

REMITTANCE _____

FUNDS RECEIVED _____

To the Register of Copyrights:
Please record the accompanying original document or copy thereof.

1 NAME OF THE PARTY OR PARTIES TO THE DOCUMENT, AS THEY APPEAR IN THE DOCUMENT.

Party 1: _____ (assignor, grantor, etc.)
_____ (address)
_____
_____

Party 2: _____ (assignee, grantee, etc.)
_____ (address)
_____
_____

2 DESCRIPTION OF THE DOCUMENT:
Transfer of Copyright
Security Interest
Change of Name of Owner
Termination of Transfer(s) [Section 304]
Shareware
Life, Identity, Death Statement [Section 302]
Transfer of Mask Works
Other _____

3 TITLE(S) OF WORK(S), REGISTRATION NUMBER(S), AUTHOR(S), AND OTHER INFORMATION TO IDENTIFY WORK.

Title	Registration Number	Author

Additional sheet(s) attached?
yes
no
If so, how many? _____

4 Document is complete by its own terms.
Document is not complete. Record "as is."

5 Number of titles in Document: _____

6 Amount of fee enclosed or authorized to be charged to a Deposit Account _____.

7 Account number _____
Account name _____

8 Date of execution and/or effective date of accompanying document _____.
(month) (day) (year)

9 **AFFIRMATION:*** I hereby affirm to the Copyright Office that the information given on this form is a true and correct representation of the accompanying document. This affirmation will not suffice as a certification of a photocopy signature on the document.

_____
Signature

_____
Date

10 **CERTIFICATION:*** Complete this certification if a photocopy of the original signed document is submitted in lieu of a document bearing the actual signature.

I certify under penalty of perjury under the laws of the United States of America that the accompanying document is a true copy of the original document.

_____
Signature

_____
Duly Authorized Agent of:

_____
Date

MAIL RECORDATION TO:

Name▼

Number/Street/Apartment Number▼

City/State/ZIP▼

YOU MUST:
- Complete all necessary spaces
- Sign your cover sheet in space 9

SEND ALL 3 ELEMENTS IN THE SAME PACKAGE
1. Two copies of the Document Cover Sheet
2. Fee in check or money order payable to *Register of Copyrights*
3. Document

MAIL TO
Documents Unit,Cataloging Division, Copyright Office, Library of Congress Washington, D.C. 20559

The Copyright Office has the authority to adjust fees at 5-year intervals, based on changes in the Consumer Price Index. The next adjustment is due in 1996. Please contact the Copyright Office after July 1995 to determine the actual fee schedule.

*Knowingly and willfully falsifying material facts on this form may result in criminal liability. 18 U.S.C.§1001.

December 1992—30,000

☆ U.S. GOVERNMENT PRINTING OFFICE: 1992-342-582/60,032

[FR Doc. 93-318 Filed 1-7-93; 8:45 am]
BILLING CODE 1410-07-C

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Chemistry; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and Time: February 18–19, 1993; 8:30 a.m. to 5 p.m..

Place: Rooms 523, 536, 543, and 1242, National Foundation, 1800 G Street, NW., Washington, DC.

Type of Meeting: Closed.

Contact Persor Dr. Seymour J. Lapporte, Program Director, Division of Chemistry, National Science Foundation, 1800 G St. NW., Washington, DC 20550. Telephone: (202) 357–7503.

Purpose of Meeting: To provide advice and recommendations concerning applications submitted to NSF for financial support.

Agenda: To review and evaluate applications for Postdoctoral Research Fellowships in Chemistry as part of the selection process for awards.

Reason for Closing: The applications being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: January 4, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–392 Filed 1–7–93; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Materials Research; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463 as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Materials Research (DMR).

Date and time: January 26, 1993, 8:30 a.m.–5 p.m.; January 27, 1993, 8:30 a.m.–5 p.m.

Place: NSF Conference & Training Center, 1110 Vermont Avenue, NW, room 500 B, Washington, DC 20550.

Type of meeting: Closed.

Contact person: Dr. John C. Hurt, Program Director, Materials Research Groups, Division of Materials Research, room 408, National Science Foundation, Washington, DC, 20550. Telephone (202) 357–9791.

Purpose of meetings: To provide advice and recommendations concerning support for the Materials Research Groups on Materials Chemistry and Polymers.

Agenda: Examine proposals, reviewers' evaluations, and make recommendations for new and renewal awards for Materials Research Groups in FY 1993 competition.

Reason for closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data such as salaries, and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552 b. (c)(4) and (6) of the Government in the Sunshine Act.

Dated: January 4, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–395 Filed 1–7–93; 8:45 am]

BILLING CODE 7555–01–M

Special Emphasis Panel in Physics; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and time: February 11–12, 1993; 8:30 a.m. to 5 p.m.

Place: Building 203, room 150, Argonne National Laboratory, Argonne, IL 60439.

Type of meeting: Closed.

Contact person: Dr. Harold Britt, Program Director, Nuclear Physics, Rm 341, National Science Foundation, 1800 G St. NW., Washington, DC 20550. Telephone: (202) 357–7993.

Purpose of meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate Accelerator Laboratory Proposals as part of the selection process for awards.

Reason for closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: January 4, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–393 Filed 1–7–93; 8:45 am]

BILLING CODE 7555–01–M

Advisory Panel for Presidential Faculty Fellows; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and Time: February 2–3, 1993; 8:30 a.m. to 5 p.m.

Place: The Latham Hotel, 3000 M Street, NW., Washington, DC.

Type of Meeting: Closed.

Contact Person: Mary Sladek, Program Manager, Division of Graduate Education and Research Development, National Science Foundation (NSF), 1800 G St. NW., rm. 1202, Washington, DC 20550. Telephone: (202) 357–9466.

Purpose of Meeting: To provide advice and recommendations to the Director, NSF, and the President on the selection of Presidential Faculty Fellows recipients.

Agenda. To review and evaluate Presidential Faculty Fellows nominations as part of the selection process for awards.

Reason for Closing: The nominations being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the nominations. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: January 5, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–394 Filed 1–7–93, 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Proposed Generic Communication Mark I and Mark II Steel Containments Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed generic communication: Extension of comment period.

SUMMARY: On November 20, 1992; (57 FR 54860), the NRC published for public comment a proposed generic letter which would recommend actions to be taken by operating plants with Mark I and Mark II steel containments to implement certain inservice inspection procedures that would prevent inadvertent loss of containment integrity and maintain continued conformity with their licensing bases. The comment period for this proposed generic letter was to have expired on December 21, 1992. By letter dated December 17, 1992, the Boiling Water Reactor Owners' Group (BWROG) requested a 60-day extension of the public comment period for the Generic Letter (GL). The reasons for the extension request included the need for: (1) Additional time to understand the potential impact of differences from previously discussed recommended actions, (2) preparing comments, and (3) coordinating this effort with other activities of equal importance. Therefore, the NRC had decided to extend the comment period for an additional 60 days.

DATES: The comment period has been extended and now expires March 9,

1993. Comments received after this date will be considered if it is practical to do so but assurance of consideration cannot be given except for comments received on or before this date.

ADDRESSES: Submit written comments to Chief, Rules and Directives Review Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Written comments may also be delivered to room P–223, Phillips Building, 7920 Norfolk Avenue, Bethesda, Maryland, from 7:30 am to 4:15 pm, federal workdays. copies of written comments received may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ronald Eaton, (301) 504–3041.

Dated at Rockville, Maryland, this 24th day of December 1992.

For the Nuclear Regulatory Commission.

Walter R. Butler,

Project Director, Project Directorate I–3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 93–374 Filed 1–7–93; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

Notice of Request for a Revised Clearance of Standard Form 3102

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (title 44, U.S. Code, chapter 35), this notice announces a request for clearance of a revised information collection. Standard Form 3102, Designation of Beneficiary (FERS), is used by employees and annuitants covered under the Federal Employees Retirement System to designate a beneficiary to receive any lump sum due in the event of his/her death.

Approximately 800 Standard Forms 3102 are completed annually. It takes approximately 15 minutes to complete this form. The annual burden is 200 hours.

For copies of this proposal, contact C. Ronald Trueworthy on (703) 908–8550.

DATES: Comments on this proposal should be received within 30 calendar days from the date of this publication.

ADDRESSES: Send or deliver comments to—

Joseph C. Parker, Chief, FERS Division, Office of Retirement Programs; U.S. Office of Personnel Management, 1900 E Street, NW., room 4429, Washington, DC 20415 and

Joseph Lackey, OPM Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW., room 3002, Washington, DC 20503.

FOR INFORMATION REGARDING ADMINISTRATIVE COORDINATION—CONTACT: Mary Beth Smith-Toomey, Chief, Administrative Management Branch, (202) 606–0623.

U.S. Office of Personnel Management.

Douglas A. Brook,

Acting Director.

[FR Doc. 93–337 Filed 1–7–93; 8:45 am]

BILLING CODE 6325–01–M

Excepted Service

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: This gives notice of positions placed or revoked under Schedules A and B, and positions placed under Schedule C in the excepted service, as required by Civil Service Rule VI, Exceptions from the Competitive Service.

FOR FURTHER INFORMATION CONTACT: Sherry Turpenoff, (202) 606–0950.

SUPPLEMENTARY INFORMATION: The Office of Personnel Management published its last monthly notice updating appointing authorities established or revoked under the Excepted Service provisions of 5 CFR part 213 on September 24, 1992, (57 FR 44218). Individual authorities established or revoked under Schedules A and B and established under Schedule C between August 1 and November 30, 1992, appear in the listing below. Future notices will be published on the fourth Tuesday of each month, or as soon as possible thereafter. A consolidated listing of all authorities as of June 30, 1992, will also be published.

Schedule A

The following exception was revoked:

Department of Defense

Not to exceed 30 positions at grades 6/15 in the Office of Emergency Operations (OEO). No new appointments may be made under this authority after March 31, 1993. Effective August 13, 1992.

The following exception was established:

Department of Transportation

Positions of entry-level air traffic control specialists filled in connection with the testing of alternative methods of training such specialists. These positions require experience or education related to air traffic control that provided knowledges, skills, and abilities comparable to those gained through initial training in the FAA Academy. Appointees under this authority will not participate in such Academy training. This authority will expire on December 31, 1994. Effective September 28, 1992.

Schedule B

No Schedule B authorities were established or revoked during the period August through November 1992.

Schedule C

Agency for International Development

One Public Affairs Specialist to the Chief, Press Relations Division, Office of External Affairs. Effective August 4, 1992.

Two Special Assistants to the Assistant Administrator, Bureau for Private Enterprise. Effective September 18, 1992.

Appalachian Regional Commission

One Senior Policy Advisor to the Federal Co-Chairman. Effective September 3, 1992.

Consumer Product Safety Commission

One Special Assistant (Legal) to a Commissioner. Effective August 28, 1992.

Department of Agriculture

One Staff Assistant to the Assistant Secretary for Congressional Relations, Office of the Secretary. Effective August 4, 1992.

One Regional Director (Levelland, Texas) to the Administrator, Rural Development Administration. Effective August 4, 1992.

One Regional Director (Vicksburg, Mississippi) to the Administrator, Rural Development Administration. Effective August 5, 1992.

One Confidential Assistant to the Director, Public Liaison, Office of Public Affairs, Office of the Secretary. Effective August 5, 1992.

One Confidential Assistant to the Administrator, Food Safety and Inspection Service. Effective August 5, 1992.

One Confidential Assistant to the Executive Assistant to the Secretary of Agriculture. Effective August 18, 1992.

One Confidential Assistant to the Administrator, Agricultural Research Service. Effective September 3, 1992.

One Regional Director (Huntington, West Virginia) to the Administrator,

Rural Development Administration. Effective September 9, 1992.

One Director of Legislative and Public Affairs to the Deputy Administrator, Management and Policy Support, rural Electrification Administration. Effective September 11, 1992.

One Staff Assistant to the Secretary. Effective September 11, 1992.

One Regional Director (Sayre, PA) to the Administrator, Rural Development Administration. Effective September 18, 1992.

One Staff Assistant to the Manager, Federal Crop Insurance Corporation. Effective September 21, 1992.

One Director, Office of Congressional and Public Affairs to the Manager, Federal Crop Insurance Corporation. Effective September 21, 1992.

One Staff Assistant to the Secretary of Agriculture. Effective September 22, 1992.

One Staff Assistant to the Deputy Under Secretary for Small Community and Rural Development. Effective September 28, 1992.

One Staff Assistant to the Manager, Federal Crop Insurance Corporation. Effective September 28, 1992.

One Confidential Assistant to the Director, Intergovernmental Affairs, Office of Public Affairs. Effective October 1, 1992.

One Staff Assistant to the Secretary of Agriculture. November 9, 1992.

One Confidential Assistant to the Executive Assistant to the Secretary. Effective November 12, 1992.

One Confidential Assistant to the Administrator, Agricultural Research Service. November 12, 1992.

Department of Commerce

One Deputy to the Director of Scheduling, Office of the Secretary. Effective August 4, 1992.

One Public Affairs Specialist to the Secretary of Commerce. Effective August 5, 1992.

One Confidential Assistant to the Secretary. Effective August 6, 1992.

One Confidential Assistant to the Deputy Assistant Secretary for Technology and Aerospace Industries, International Trade Administration. Effective August 14, 1992.

One Deputy to the Director, White House Liaison, Office of the Secretary. Effective August 14, 1992.

One Special Assistant to the Under Secretary for Technology, Technology Administration. Effective August 14, 1992.

One Chief Counsel for Technology Administration to the General Counsel. Effective August 14, 1992.

One Confidential Assistant to the Deputy Assistant Secretary for Textiles, Apparel and Consumer Goods, International Trade Administration. Effective August 18, 1992.

One Special Assistant to the Secretary of Commerce. Effective August 19, 1992.

One Confidential Assistant to the Deputy Assistant Secretary and Deputy Commissioner, Patent and Trademark Office. Effective September 21, 1992.

One Confidential Assistant to the Assistant Secretary for Trade Development, International Trade Administration. Effective September 25, 1992.

One Special Assistant to the Director, Minority Business Development Agency. Effective October 6, 1992.

One Congressional Liaison Specialist to the Under Secretary, International Trade Administration. Effective October 15, 1992.

One Special Assistant to the Assistant Secretary for Legislative and Intergovernmental Affairs. Effective October 16, 1992.

One Chauffeur to the Secretary of Commerce. Effective October 21, 1992.

One Chauffeur to the Under Secretary, National Oceanic and Atmospheric Administration. Effective October 22, 1992.

One Special Assistant to the Deputy Assistant Secretary for Intergovernmental Affairs, Office of Legislative and Intergovernmental Affairs. Effective November 5, 1992.

One Special Assistant to the Chief Economist, Economics and Statistics Administration. Effective November 5, 1992.

One Confidential Assistant to the Deputy Assistant Secretary for White House Liaison. Effective November 5, 1992.

One Congressional Liaison Specialist to the Deputy Secretary for Legislative and Intergovernmental Affairs. Effective November 30, 1992.

One Director, Office of Public Affairs to the Under Secretary, International Trade Administration. Effective November 30, 1992.

Department of Defense

One Personal and Confidential Assistant to the Assistant Secretary of Defense. Effective August 6, 1992.

One Special Assistant for Asian Affairs to the Director of Net Assessment, Office of the Under Secretary for Policy. Effective August 6, 1992.

One Private Secretary to the Principal Deputy General Counsel. Effective August 6, 1992.

One Personal and Confidential Assistant to the Assistant Secretary of Defense (International Security Affairs). Effective August 6, 1992.

One Special Assistant to the Under Secretary of Defense (Policy). Effective August 6, 1992.

One Special Assistant (Research) to the Assistant Secretary of Defense for Public Affairs. Effective September 18, 1992.

One Paralegal Specialist to the Chief Judge, U.S. Court of Military Appeals. Effective September 18, 1992.

One Secretary (Office Automation) to the Assistant Secretary of the Army (Manpower and Reserve Affairs). Effective September 18, 1992.

One Special Assistant to the Assistant Secretary of Defense (Legislative Affairs) for Special Operations and Drug Policy. Effective September 28, 1992.

One Staff Assistant to the Assistant to the Vice President for National Security Affairs. Effective October 15, 1992.

Department of Education

One Confidential Assistant to the Assistant Secretary, Office of Intergovernmental and Interagency Affairs. Effective August 4, 1992.

One Confidential Assistant to the Assistant Secretary, Office of Civil Rights. Effective August 14, 1992.

One Confidential Assistant to the Assistant Secretary, Office of Intergovernmental and Interagency Affairs. Effective August 18, 1992.

One Confidential Assistant to the Chief of Staff, Office of the Secretary Effective August 28, 1992.

One Deputy Secretary's Regional Representative—Region I (Boston, MA) to the Director, Regional Liaison Staff, Office of Intergovernmental and Interagency Affairs. Effective September 16, 1992.

One Secretary's Regional Representative, Region X (Seattle, WA) to the Director, Regional Liaison Staff, Office of Intergovernmental and Interagency Affairs. Effective September 25, 1992.

One Special Assistant to the Deputy Assistant Secretary, Office of Higher Education Program. Effective September 25, 1992.

One Confidential Assistant to the Special Advisor to the Secretary on America 2000. Effective September 25, 1992.

One Confidential Assistant to the Assistant Secretary, Office of Intergovernmental and Interagency Affairs. Effective September 25, 1992.

One Deputy Assistant Secretary for Legislative Analysis and Information to the Assistant Secretary, Office of Legislative and Congressional Affairs. Effective September 25, 1992.

One Confidential Assistant to the Deputy Chief of Staff. Effective October 8, 1992.

One Deputy Secretary's Regional Representative, Region VII (Kansas City, MO) to the Secretary's Regional Representative, Office of Intergovernmental and Interagency Affairs. Effective October 9, 1992.

One Special Assistant to the Assistant Secretary, Office of Educational Research and Improvement. Effective October 9, 1992.

One Special Assistant to the Director, Constituent Services Staff, Office of Intergovernmental and Interegency Affairs. Effective October 9, 1992.

One Director, Intergovernmental and Constituent Service to the Deputy Assistant Secretary for Headquarters Operations, Office of Intergovernmental and Interagency Affairs. Effective October 15, 1992.

One Confidential Assistant to the Deputy Chief of Staff, Office of the Secretary. Effective October 16, 1992.

One Congressional Liaison Specialist to the Deputy Assistant Secretary for Congressional Liaison, Office of Legislation and Congressional Affairs. Effective October 21, 1992.

One Director, Administrative Resource Management Service, Office of Human Resources and Administration. Effective October 27, 1992.

One Confidential Assistant to the Deputy Chief of Staff, Office of the Secretary. Effective October 28, 1992.

One Special Assistant to the Administrator for Management Service, Office of Human Resources and Administration. Effective October 30, 1992.

One Director, Secretary's Regional Representatives Services Staff to the Deputy Assistant Secretary for Field Services, Office of Intergovernmental and Interagency Affairs. Effective November 5, 1992.

One Director, Interagency, International and Strategy Service to the Deputy Assistant Secretary for Headquarters Operations, Office of Intergovernmental and Interagency Affairs. Effective November 5, 1992.

Department of Energy

One Staff Assistant to the Principal Deputy Assistant Secretary, Office of Congressional and Intergovernmental Affairs. Effective August 14, 1992.

One Special Assistant to the Director, Office of Technology Utilization, Office of Energy Research. Effective August 31, 1992.

One Staff Assistant to the Director, Office of Technology Utilization, Office of Energy Research. Effective August 31, 1992.

One Special Assistant to the Deputy Secretary of Energy. Effective August 31, 1992.

One Deputy to the Press Secretary/ Principal Deputy Director, Office of Public Affairs. Effective September 28, 1992.

One Congressional Affairs Specialist to the Principal Deputy Assistant Secretary for Congressional and Intergovernmental Affairs. Effective October 9, 1992.

One Staff Assistant to the Deputy Secretary, Office of the Deputy Secretary, Office of the Secretary. Effective October 30, 1992.

One Staff Assistant to the Special Assistant to the Secretary. Effective November 24, 1992.

Department of Health and Human Services

One Special Assistant to the Deputy Assistant Secretary for Population Affairs, Office of the Assistant Secretary for Health, Public Health Service. Effective August 5, 1992.

One Special Assistant to the Commissioner, Social Security Administration. Effective August 25, 1992.

One Confidential Assistant to the Director of Advance, Office of the Secretary. Effective September 18, 1992.

One Special Assistant to the Director, Office of Public Affairs, Administration for Children and Families. Effective September 18, 1992.

One Director, Division of Public Information to the Director, Office of Public Affairs, Administration for Children and Families. Effective September 18, 1992.

One Special Assistant to the Director, Office of Consumer Affairs. Effective September 22, 1992.

One Executive Assistant to the Director, Office of Child Support Enforcement, Administration for Children and Families. Effective September 28, 1992.

One Speechwriter to the Director of Speechwriting, Office of the Assistant Secretary for Public Affairs. Effective October 6, 1992.

One Special Assistant to the Director of Speechwriting. Effective October 9, 1992.

Department of Housing and Urban Development

One Deputy to the Assistant Secretary, Office of Public Affairs. Effective August 11, 1992.

One Assistant to the Secretary for Communication. Effective August 14, 1992.

One Special Assistant to the Deputy Assistant Secretary for Public Affairs. Effective August 18, 1992.

One Executive Assistant to the Secretary. Effective August 18, 1992.

One Staff Assistant to the Deputy Assistant Secretary for Economic Development, Office of the Assistant Secretary for Community Planning and Development. Effective August 18, 1992.

One Special Assistant to the Deputy Assistant Secretary for Operations, Office of Community Planning and Development. Effective September 11, 1992.

One Intergovernmental Relations Officer to the Deputy Assistant Secretary, Office of Intergovernmental Relations. Effective September 21, 1992.

One Senior Intergovernmental Relations to the Deputy Assistant Secretary for Intergovernmental Relations. Effective October 15, 1992.

One Special Assistant to the Assistant Secretary for Community Planning and Development. Effective November 5, 1992.

Department of the Interior

One Special Assistant to the Director, National Park Service. Effective August 5, 1992.

One Special Assistant to the Director, National Park Service. Effective October 21, 1992.

One Special Assistant to the Secretary and Director, Office of Program Analysis. Effective November 27, 1992.

Department of Justice

One Special Assistant to the Associate Deputy Attorney General, Executive Office of Weed and Seed. Effective September 3, 1992.

One Confidential Assistant to the Director, Office of Policy and Communication. Effective October 28, 1992.

One Special Assistant to the Director, Bureau of Justice Statistics, Office of Justice Programs. Effective November 5, 1992.

One Senior Policy Advisory to the Director, Office of Policy Development, Office of Policy and Communications. Effective November 20, 1992.

Department of Labor

One Executive Assistant to the Deputy Assistant Secretary, Veterans Employment and Training Service. Effective August 18, 1992.

One Senior Intergovernmental Officer to the Associate Assistant Secretary for Congressional and Intergovernmental Affairs. Effective September 11, 1992.

One Staff Assistant to the Assistant Secretary for Veterans' Employment and Training. Effective October 27, 1992.

Department of State

One Special Assistant to the Deputy Secretary. Effective September 3, 1992.

One Staff Assistant to the Director, Office of Public Liaison, Bureau of

Public Affairs. Effective September 3, 1992.

One Staff Assistant to the Deputy Secretary. Effective September 3, 1992.

One Executive Secretary to the Permanent Representative, United States Mission, to the Organization of American States, Bureau of Inter-American Affairs. Effective September 14, 1992.

One Secretary (Typing) to the Assistant Secretary, Office of Legislative Affairs. Effective September 15, 1992.

One Secretary (Typing) to the Assistant Secretary, Bureau of Economics and Business Affairs. Effective September 18, 1992.

One Senior Intergovernmental Officer to the Associate Assistant Secretary, Office of Congressional and Intergovernmental Affairs. Effective November 5, 1992.

Department of Transportation

One Staff Assistant to the Assistant Secretary for Governmental Affairs. Effective August 4, 1992.

One Scheduling Assistant to the Deputy Secretary. Effective August 25, 1992.

One Special Assistant to the Assistant Secretary for Policy and International Affairs. Effective August 26, 1992.

One Deputy Scheduler to the Special Assistant for Scheduling and Advance, Office of the Secretary. Effective August 31, 1992.

Department of the Treasury

One Director, Office of Intergovernmental Affairs, to the Deputy Assistant Secretary (Public Liaison), Office of the Assistant Secretary (Public Affairs and Public Liaison). Effective August 10, 1992.

One Public Affairs Assistant to the Deputy Assistant Secretary (Public Liaison), Office of the Assistant Secretary (Public Affairs and Public Liaison). Effective August 10, 1992.

One Staff Assistant to the Treasurer of the United States. Effective August 14, 1992.

One Special Assistant to the Treasurer of the United States. Effective August 19, 1992.

One Travel Assistant to the Deputy Assistant Secretary for Administration, Office of the Assistant Secretary for Management. Effective September 3, 1992.

One Confidential Assistant to the Executive Director, United States Savings Bonds Division. Effective September 8, 1992.

One Confidential Assistant to the Deputy Assistant Secretary for Administration. Effective November 19, 1992.

Department of Veterans Affairs

One Special Assistant to the Secretary of Veterans Affairs. Effective August 14, 1992.

One Special Assistant to the Assistant Secretary for Acquisition and Facilities. Effective September 25, 1992.

Equal Employment Opportunity Commission

One Legislative Affairs Specialist to the Director, Office of Communications and Legislative Affairs, Office of the Chairman. Effective September 17, 1992.

One Executive Assistant to the Director, Office of Communication and Legislative Affairs. Effective October 9, 1992.

Environmental Protection Agency

One Staff Assistant to the Associate Administrator, Office of Congressional and Legislative Affairs. Effective August 4, 1992.

One Program Advisor to the Assistant Administrator, Office of Enforcement. Effective August 11, 1992.

One Program Manager to the Director, Public Liaison Division, Office of Communications, Education and Public Affairs. Effective September 11, 1992.

One Staff Assistant to the Director, Office of Small and Disadvantaged Business Utilization. Effective September 18, 1992.

One Special Assistant to the Assistant Administrator for Administration and Resources Management. Effective September 22, 1992.

Export-Import Bank of the U.S.

One Vice President, Public Affairs and Publications, to the President and Chairman. Effective August 4, 1992.

Federal Maritime Commission

One Counsel to the Commissioner. Effective November 12, 1992.

Federal Trade Commission

One Congressional Liaison Specialist to the Director, Office of Congressional Relations. Effective November 27, 1992.

General Services Administration

One Special Assistant to the Commissioner, Public Building Service. Effective October 6, 1992.

International Trade Commission

One Staff Assistant to a Commissioner. Effective November 19, 1992.

National Labor Relations Board

One Confidential Assistant to the General Counsel. Effective September 10, 1992.

National Transportation Safety Board

One Special Assistant to the Chairman of the National Transportation Safety Board. Effective August 19, 1992.

One Confidential Assistant to the Vice Chairman. Effective September 14, 1992.

One Director, Office of Congressional and Intergovernmental Relations to the Chairman. Effective October 16, 1992.

One Secretary (Typing) to the Chairman, National Transportation Safety Board. Effective October 30, 1992.

Occupational Safety and Health Review Commission

One Confidential Assistant to a Member. Effective September 3, 1992.

One Special Assistant to the Chairman. Effective October 9, 1992.

Office of National Drug Control Policy

One Deputy to the Associate Director for the Bureau of State and Local Affairs. Effective August 25, 1992.

One Confidential Assistant to the Director, Congressional Relations. Effective September 3, 1992.

One Staff Assistant to the Special Assistant to the Director. Effective October 13, 1992.

One Confidential Assistant to the General Counsel. Effective November 20, 1992.

One Special Assistant to the Associate Director. Effective November 20, 1992.

Office of Personnel Management

One Confidential Assistant to the Director, Office of Congressional Relations. Effective September 4, 1992.

Securities and Exchange Commission

One Secretary (Office Automation) to the Director, Division of Market Regulation. Effective September 22, 1992.

Small Business Administration

One Special Assistant to the Administrator. Effective August 11, 1992.

One Special Assistant to the Director, Office of Women's Business Ownership. Effective September 18, 1992.

United States Information Agency

One Special Assistant to the Director, Worldnet Television and Film Service, Bureau of Broadcasting. Effective August 14, 1992.

One Assistant to the Director, Office of Public Liaison. Effective August 19, 1992.

One Confidential Assistant to the Director, Bureau of Broadcasting. Effective August 27, 1992.

One to the Director, Office of Arts America, Bureau of Educational and

Cultural Affairs. Effective October 15, 1992.

United States Tax Court

One Trial Clerk to a Judge. Effective September 4, 1992.

One Secretary (Confidential Assistant) to a Judge. Effective September 22, 1992.

One Trial Clerk to a Judge. Effective October 9, 1992.

One Secretary (Confidential Assistant) to a Judge. Effective November 20, 1992.

United States Trade Representative

One Confidential Assistant to the General Counsel, Office of the United States Trade Representative. Effective October 15, 1992.

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR 1954–1958 Comp., p. 218

Office of Personnel Management.

Douglas A. Brook,

Acting Director.

[FR Doc. 93–338 Filed 1–7–93; 8:45 am]

BILLING CODE 6325–01–M

Historically Black Colleges and Universities (HBCU's) Federal Employment Advisory Group

AGENCY: U.S. Office of Personnel Management.

ACTION: Notice of open meeting.

SUMMARY: According to the provisions of section 10 of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that the Historically Black Colleges and Universities (HBCU's) Federal Employment Advisory Group will meet at the time and place shown below.

DATES: February 2, 1993, 9 a.m.

PLACE: U.S. Office of Personnel Management's Conference Center, room 1350, 1900 E Street, NW., Washington, DC.

AGENDA: The focus of the February 2nd meeting will be the discussion of continued activities to enhance the employment of students and graduates from HBCU's in the Federal Government and future directions for the Advisory Group.

FOR FURTHER INFORMATION CONTACT: Patricia H. Paige, Chief, Recruiting Policy Division, Office of Personnel Management, room 6332, 1900 E Street, NW., Washington, DC 20415.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. If time permits, an opportunity will be provided for members of the public in attendance at the meeting to provide their views. Persons wishing to address the Advisory Group orally at the meeting should submit a written request no later than the close of business on January 19, 1993. The request must include the name and address of the person wishing to appear, the capacity in which the appearance will be made, a short summary of the intended presentation, and the amount of time desired.

U.S. Office of Personnel Management.

Douglas A. Brook,

Acting Director.

[FR Doc. 93–336 Filed 1–7–93; 8:45 am]

BILLING CODE 6325–01–M

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the Railroad Retirement Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) *Collection title:* Application for Survivor Insurance Annuities.

(2) *Form(s) submitted:* AA–17, AA–17b, AA–18, AA–19, AA–19a, AA–19s and AA–20.

(3) OMB Number: 3220–0030.

(4) *Expiration date of current OMB clearance:* Three years from date of OMB approval.

(5) *Type of request:* Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

(6) *Frequency of response:* On Occasion.

(7) *Respondents:* Individuals or households.

(8) *Estimated annual number of respondents:* 10,060.

(9) *Total annual responses:* 10,060.

(10) *Average time per response:* .45258 hours.

(11) *Total annual reporting hours:* 4,553.

(12) *Collection description:* Under section 2(d) of the RRA, monthly survivor annuities are payable to surviving widow(er)s, parents, unmarried children, and, in certain cases, divorced wives (husbands), mothers (fathers), remarried widow(er)s and grandchildren of deceased railroad employees. The collection obtains information needed by the Railroad Retirement Board for determining entitlement to and amount of annuity applied for.

ADDITIONAL INFORMATION OR COMMENTS: Copies of the form and supporting documents can be obtained from Dennis Eagan, the agency clearance officer (312–751–4693). Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street, Chicago, Illinois 60611–2092 and the OMB reviewer, Laura Oliven (202–395–7316), Office of Management and Budget, room 3002, New Executive Office Building, Washington, DC 20503.

Dennis Eagan,

Clearance Officer.

[FR Doc. 93–349 Filed 1–7–93; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–31683; File No. SR–CBOE–92–36]

Self-Regulatory Organizations; Filing and Order Granting Accelerated Approved of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to the Opening of New Series of Index Options

December 31, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 30, 1992, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend Exchange Rule 24.9, "Terms of Index Option Contracts," by adding Interpretation .05, which will allow the Exchange to open for trading additional series of the same class of index options (other than options based on the Standard & Poor's ("S&P") 100 Index) when the current index value of the underlying index moves substantially from the exercise price or prices of the index options previously opened for trading on the Exchange. The text of the proposal is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The CBOE proposes to amend Exchange Rule 24.9, "Terms of Index Option Contracts," by adding Interpretation .05, which will allow the Exchange to open for trading additional series of the same class of index options (other than options based on the S&P 100 Index) when the current index value of the underlying index moves substantially from the exercise price or prices of the index options previously opened for trading on the Exchange. Under the proposal, the exercise price of each series of index options opened for trading must be reasonably related to the current index value of the underlying index to which the options relate at or about the time the series of options is first opened for trading on the Exchange. The proposal applies to all index options traded on the CBOE except for options on the S&P 100 Index.

The CBOE believes that the proposal will provide important benefits to CBOE members and their customers. Specifically, the Exchange believes that the proposed rule change will increase the CBOE's flexibility by permitting the Exchange to open for trading new series of index option as warranted by market conditions and the continuing evolution of index options trading strategies that seek to take advantage of economic opportunities engendered by changes in prices and yields in other markets. The CBOE believes that this, in turn, will better enable the Exchange to respond to the trading needs of its members and their customers. Second, the CBOE believes that the proposal will enhance the Exchange's ability to compete with other options exchanges in seeking to meet their members' trading needs. In this regard, the CBOE notes that the rules of the American Stock Exchange ("Amex") contain a similar provision.[1]

The CBOE believes that the proposal will, in accordance with section 11A(a)(1)(C)(i) of the Act, assure the economically efficient execution of securities transactions and will, in accordance with section 11A(a)(1)(C)(ii) of the Act, promote fair competition among exchange markets. In addition, the CBOE believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and with section 6(b)(5), in particular, in that it is designed to remove impediments to and perfect the mechanism of a free and open market and the national market system.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any inappropriate burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has requested that the proposed rule change be given accelerated effectiveness pursuant to Section 19(b)(2) of the Act.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6(b)(5),[2] in that it is designed to remove impediments to and perfect the mechanism of a free and open market and the national market system. The Commission believes that the proposal will enable the CBOE to respond to changing market conditions and list index options series that provide market participants with an effective means to transfer risk and implement their trading strategies. The Commission believes that the discretion to list additional series of index options will help to ensure the consistent availability of index options series tailored to meet the needs of investors during periods of market volatility. In addition, the Commission notes that the CBOE's proposal is similar to Amex Rule 930C(b), which allows the Amex to list additional series of the same class of index options as the numerical index value of the underlying stock index moves substantially from the initial exercise price or prices.

The Commission believes that the CBOE's proposal strikes a reasonable balance between accommodating the needs of market participants and avoiding the excessive proliferation of options series. In this regard, the proposal provides that the options price of each series of options opened for trading shall be reasonably related to the current value of the underlying index, as discussed below.[3] The proposed rule change also allows the Exchange to open additional series of index options for trading only after a substantial movement in the value of the underlying index.[4]

For stock index options (other than long-term options, *i.e.*, expirations beyond one year), an exercise price of an option series is "reasonably related" to the current index value of the underlying index if it is within no more than the lesser of: (a) 50 points of the current value of the index; or (b) 15% of the current index value. For long-term stock index options (other than reduced value long-term options) an exercise price of an options series is "reasonably related" to the current index value if it is within 25% of the current index value.

The Commission believes that these requirements provide the Exchange with the flexibility to open additional index options series and, at the same time, appropriately limit the number of index options series that may be outstanding at any one time. In addition, the

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[1] See Amex Rule 903C(b), which provides, in part, that the exercise price of each series of stock index options opened for trading on the Amex shall be an integer which is reasonably close to the numerical index value of the underlying stock index group to which such options relate at or about the time such series of options is first opened for trading on the Amex. The Amex rule further provides that additional series of the same class of options may be opened for trading on the Amex as the numerical index value of the underlying stock index group moves substantially from the initial exercise price or prices.

[2] 15 U.S.C. 78f(6)(5) (1982).

[3] See discussion following note 4, *infra*. Not all existing options series listed for trading on the CBOE and Amex, in particular, meet the "reasonably related" standard articulated today. Both exchanges have agreed to delist those series that do not have either put or call open interest and not to list additional month series where open interest exists today. Telephone conversation among Jonathan Kallman, Associate Director, Division of Market Regulation, Commission and Ivers W. Riley, Senior Executive Vice President, Amex and Alger Chapman, Chairman, CBOE (December 23, 1992).

[4] The Commission notes, however, that the Exchange is not obligated to open new series every time the index value changes and, in this regard, in considering whether to open a new series will do so consistent with the maintenance of a fair and orderly market.

Commission notes that although the proposal permits the CBOE to open additional index option series, the CBOE retains the discretion to list fewer series than those allowed under the proposal.[5]

The CBOE has represented that its current system capacity is sufficient to meet the expected demands of the additional strike prices.[6] Nevertheless, the Commission requests that the CBOE monitor the volume of additional series listed as a result of this rule change and the effect of these additional series on the capacity of the CBOE's, Options Price Reporting Authority's and vendors' automated systems.

The Commission finds good cause for approving the CBOE's proposal prior to the thirtieth day after the date of publication of notice of filing thereof in the **Federal Register** in that the proposed rule change is similar to a rule adopted previously by the Amex. The Commission received no comment letters on the Amex's proposal and believes that the CBOE's proposal raises no new regulatory issues. Accordingly, the Commission believes that it is appropriate and consistent with Sections 6(b)(5) and 19(b) of the Act to approve the CBOE's proposal on an accelerated basis.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by January 29, 1993.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[7] that the proposed rule change (SR–CBOE–92–36) is approved

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–331 Filed 1–7–93; 8:45 am]

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[5] See supra note 4.

[6] See Letter from Charles J. Henry, President and Chief Operating Officer, CBOE, to Sharon Lawson, Assistant Director, Exchange and Options Regulation, Division of Market Regulation, SEC, dated December 31, 1992.

[7] 15 U.S.C. 78s(b)(2) (1982).

[Release No. 34–31679; File No. SR–CBOE–92–41]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Board Options Exchange, Inc. Relating to Reduced Transaction Charges for Certain Index Option Spread Transactions

December 31, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 18, 1992, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in items I, II and III below, which Items have been prepared by the CBOE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE has requested an extension through January 31, 1993,[1] of a pilot program[2] which provides a 50% rebate on transaction and trade match fees for "box"[3] trades by public customers in Standard & Poor's 500 Stock Index options ("SPX"), provided the "box" trade totals 500 or more contracts for the four sides of the trade. The text of the proposed rule change is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the CBOE included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The CBOE has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The CBOE has requested an extension through January 31, 1993, of a pilot program which provides a 50% rebate on transaction and trade match fees[4] for "box"[5] trades by public customers in SPX options, provided the "box" trade totals 500 or more contracts for the four sides of the trade (125 contracts per side). The rebate is available to member firms that provide the Exchange's Accounting Department with documents evidencing transactions that meet the standards of the pilot program. At a minimum, the supporting documentation must include the trade date, executing broker acronym, and the contract series, premium and quantity.

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act, in general, and furthers the objectives of section 6(b)(4), in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among CBOE members and other persons using the CBOE's facilities. The Exchange also believes that the proposal is consistent with section

[1] On December 31, 1992, the CBOE amended its proposal to seek an extension of the pilot program through January 31, 1993. See letter from Michael L. Meyer, Schiff Hardin & Waite, to Yvonne Fraticelli, Staff Attorney, Options Branch, Division of Market Regulation, Commission, dated December 31, 1992.

[2] The pilot program was first approved by the Commission on a three-month pilot basis, effective from July 1, 1991, through September 30, 1991. See Securities Exchange Act Release No. 29482 (July 24, 1991), 56 FR 36180. Since then, the pilot has been extended five times: (i) through December 31, 1991; (ii) through March 31, 1992; (iii) through August 31, 1992; (iv) through October 15, 1992; and (v) through December 31, 1992. See Securities Exchange Act Release Nos. 30025 (December 3, 1991), 56 FR 64537; 30288 (January 27, 1992), 57 FR 4226; 30857 (June 24, 1992), 57 FR 29543; 31208 (September 22, 1992), 57 FR 44596; 31428 (November 9, 1992), 57 FR 54431.

[3] The CBOE defines a "box trade" as a four-sided SPX option spread composed of (i) a long call and short put at one strike price and (ii) a short call and long put at a different strike price, where all four positions expire in the same month.

[4] The rebate is $.22 per contract ($.20 transaction fee, plus $.02 trade match fee) on contracts with a premium greater than or equal to $1 and $.12 per contract ($.10 transaction fee, plus $.02 trade match fee) on contracts with a premium less than $1.

[5] See note 3, *supra,* for the CBOE's definition of a "box" trade.

11A(a)(1)(C)(ii) in that it fosters fair competition among exchange markets.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing rule change establishes or changes a due, fee or other charge imposed by the Exchange, it has become effective pursuant to section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b-4 thereunder. The CBOE notes that its proposal is based on a rule adopted by the American Stock Exchange, Inc. ("Amex").[6] At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the CBOE. All submissions should refer to the file number in the caption above and should be submitted by January 29, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

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[6] See Securities Exchange Act Release No. 29822 (October 15, 1991), 56 FR 54594 (order approving File No. SR-Amex-91-23) ("Amex Approval Order"). The CBOE notes that, initially, the Amex reduced customer transaction charges for box spreads from $.40 per contract to $.25 per contract for qualified customer orders of at least 2,000 contracts (500 per side). See Securities Exchange Act Release No. 28183 (July 11, 1990), 55 FR 29128 (order approving File No. SR-Amex-90-12). Subsequently, based upon the CBOE's pilot rebate program, the Amex reduced its fees for box spreads to $.20 per contract for options with premiums priced at $1.00 and above ($.10 per contract for options with premiums below $1.00) for qualified customer orders of at least 500 contracts (125 per side). See Amex Approval Order.

[Release No. 34-31681; File No. SR-MBS-92-02]

Self-Regulatory Organizations; MBS Clearing Corp.; Order Granting Partial Approval of Proposed Rule Change Relating to Major Systems Enhancements

December 31, 1992.

On March 27, 1992, the MBS Clearing Corporation ("MBS") filed a proposed rule change (File No. SR-MBS-92-02) with the Securities and Exchange Commission ("Commission") pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] Notice of the proposal was published in the **Federal Register** on August 29, 1992.[2] No comments were received. Phase I of the proposal[3] was approved on October 23, 1992.[4] Subsequently, MBS submitted amendment numbers 3 and 4 to clarify that the following deliverables are subject to Phase II implementation: (1) Revised netting procedures for certain trades, and (2) revised Settlement Balance Order ("SBO") market differential and cash adjustment procedures.[5] Concurrent with this Order, the Commission is approving by separate order the MBS liquidation procedures.[6] As discussed below, the Commission is approving Phase II of the proposal.

I. Description of the Proposal

A. Revised Netting of SBO Trades

Under current MBS Rules, SBO-destined trades[7] are netted by settlement class[8] in an SBO netting chain[9] to the maximum extent possible to produce SBO trades, without regard to whether the SBO trades will be settled between SBO original contra-side participants.[10] Under the existing netting procedure, MBS: (1) Offsets purchase and sale transactions between the participant and the original contra-side participant to such transactions (netted positions); (2) to the extent that any purchase and sale transactions cannot be so offset, MBS offsets purchase and sale transactions among the participant and any of its original contra-side participants; and (3) to the extent that any purchase and sale transactions still cannot be offset (net

[1] 15 U.S.C. 78S(B)(1) (1988).

[2] Securities Exchange Act Release No. 31058 (August 19, 1992), 57 FR 38697.

[3] As part of Phase I, MBS submitted two amendments. On September 23, 1992, MBS submitted amendment number 1 to SR-MBS-92-02 that reinstated the concept of impending settlement date and impending expiration date that MBS uses in calculating a participant's market margin differential ("MMD") deposit requirement. This concept was deleted in the proposal as originally submitted. Amendment number 2 amended the proposal to state that MBS will implement the enhancements to its operating system in phases and announced the target date of October 23, 1992, as the implementation date for the first phase. In addition, the amendment discussed MBS' fallback procedures. Administrative Bulletin from MBS to all MBS participants (September 29, 1992).

[4] In Phase I, MBS implemented the Comparison and Clearing System ("CCS") for comparing trade input, margining, and comparing clearing information concerning transactions in eligible securities between participants. Some of the operational enhancements to CCS included: (1) Revised account structure, (2) revised procedures regarding "Broker Give-up Trades," (3) revised reporting of settlement information, (4) multiple intra-day batch processing, and (5) revised trade input procedures. In addition, Phase I included various technical changes to MBS rules and reports. Securities Exchange Act Release No. 31352 (October 23, 1992), 57 FR 49728.

[5] On December 9, 1992, MBS submitted amendment number 3, which clarifies that the revised SBO netting procedures, the revised SBO market differential and cash adjustment procedures, the Comparison-Only System and the Limited Purpose Participants Category are part of Phase II.

On December 22, 1992, MBS submitted amendment number 4 which withdrew from the proposed rule filing the proposed Comparison-Only System and Limited Purpose Participants Category. Letter from Jeffrey E. Lewis, Associate Counsel, MBS, to Ester Severson, Jr., Branch Chief, Division of Market Regulation, Commission (December 22, 1992).

[6] Securities Exchange Act Release No. 31680 (December 31, 1992).

[7] MBS, Art. I, Rule 1.

[8] MBS' SBO netting process is one of MBS' basic services. The SBO netting process allows participants to offset or net about 90% of the eligible clearing obligations and related expenses. MBS, Art. II, Rule 5, section 2.

[9] The term "SBO netting chain" refers to a series of purchases and sales of securities in a particular settlement class that have been offset in the SBO netting process. MBS, Art. I, Rule 1.

[10] The term "SBO contra-side participant" means a participant with whom a participant is directed by MBS to effect an SBO trade. MBS, Art. I, Rule 1.

open positions),[11] MBS assigns the participant one or more SBO trades offsetting such net open positions in that particular settlement class. Under MBS' existing rules, the settlement price of each SBO trade is the class average price ("CAP").[12]

Under the proposed rule change, SBO-destined trades are netted by "class" according to essentially the same procedures.[13] The proposal, however, will distinguish the offsetting of purchase and sale transactions between original contra-side participants,[14] which will continue to be called netted positions, and purchase and sale transactions between non-original contra-side participants, which will be called net-out positions.[15] The proposal also will distinguish between SBO trades between original contra-side participants (called "SBOO trades")[16] and SBO trades between non-original contra-side participants (called "SBON trades").[17] These changes will require MBS to change the way it determines the settlement price for SBO trades. Because the parties to SBOO trades are original contra-side participants, MBS will use the firm class average price ("FCAP"),[18] instead of the current CAP, as the settlement price of SBOO trades. The settlement price of SBON trades will be the CAP for all SBO-destined trades in the same class that have been netted to effect the clearance and settlement of SBON trades.[19]

[11] The term "net open positions" refers to any open positions that cannot be offset with other open positions. MBS, Art. I, Rule 1.

[12] Under MBS' current rules, "CAP" means the average price of all SBO-destined trades in a particular settlement class. MBS, Art. I, Rule 1.

[13] Although the proposal replaces the term "settlement class" with "class," this change does not affect the meaning of the term. The term "class" means a class of securities in which all of the securities are of the same product type, have the same coupon rate and maturity date, are issued by the same agency, and are scheduled to settle in the same month. Proposed MBS, Art. 1, Rule 1.

[14] An SBO contra-side participant that is also an original contra-side participant with respect to an SBO trade is an "SBOO contra-side participant." An SBO contra-side participant that is not an original contra-side participant with respect to an SBO trade is an "SBON contra-side participant." Proposed MBS, Art. I, Rule 1.

[15] "Net-out positions" are determined by offsetting purchase and sale SBO-designated trades among non-original contra-side participants within the same class. Proposed MBS, Art. I, Rule 1.

[16] An "SBOO trade" refers to an SBO trade in which both participants are the original parties to the trade. Proposed MBS, Art. I, Rule 1.

[17] An "SBON trade" refers to an SBO trade in which neither of the participants is an original party to the trade. Proposed MBS, Art. I, Rule 1.

[18] The term "FCAP" means the average purchase or sale contract price of a participant's SBO-destined trades with a particular original contra-side participant in a particular class. MBS, Art. I, Rule 1.

[19] The proposal redefines "CAP" to mean the average contract price of all SBO-destined trades in a class that have been netted to produce the SBON trade. Proposed MBS, Art. I, Rule 1.

B. SBO Market Differential and Cash Adjustment

SBO trades are settled in $1 million par value increments with a permitted tolerance of 2% of the par value, which is known as a "variance."[20] MBS currently settles SBO trades at the CAP and makes an adjustment for the difference between the CAP and a participant's buy or sell FCAP, called the "SBO market differential," and for the variance, called the "cash adjustment."[21] For SBO trades involving a broker, MBS also calculates a "broker adjustment" that is included in the SBO cash adjustment to be paid by the delivering and receiving dealers on whose behalf the broker has acted.

Under the proposed rule change, the SBO market differential will be calculated for netted positions, net-out positions and SBON trades. As a result of the changes to the netting of SBO trades, SBOO trades will not be subject to the SBO market differential or the cash adjustment.[22] The market differential for a participant's netted positions and net-out positions in a class is the difference between the participant's FCAP for its purchases and the FCAP for its sales in that class. The market differential for a participant's SBON trades in a class is the difference between the participant's FCAP for its purchase and sale transactions with the original contra-side participant and the CAP for its SBON trades in that class. If a participant has a negative net SBO market differential then MBS requires the participant to pay the net SBO market differential a day before the settlement day ("S–1") and MBS pays any participant with a positive net SBO market differential on settlement day. MBS invests the net SBO market differential it collects and pays those participants that paid the net SBO market differential any interest earned between S–1 and settlement day.

The changes to the SBO market differential will not have any effect on the calculation or the collection of the market margin differential ("MMD") requirements for open commitments and failed trades. MBS has four categories of trades to determine a participant's MMD deposit requirement: "Forward," "impending," "failed" and "aged failed" transactions, and MBS does not allow offset across these categories.[23]

Under the proposed rule change, the cash adjustment is calculated for net-out positions and SBON trades after the SBO trades are settled. The cash adjustment for SBON trades will equal a participant's SBO market differential in the class multiplied by the percentage by which the amortized value of eligible securities delivered or received by the participant on the clearance date[24] is greater or less than the par amount. For a participant with a net-out position in any class, the cash adjustment will be an amount equal to: (1) The amount by which the total cash adjustment payable by the delivering and receiving participants in SBON trades in such class is greater or less than the amount payable by MBS to such participants, which (2) is multiplied by the percentage that such participant's net-out units in the class constitutes the net-out units of all participants in the class.[25] Because dealers will automatically be substituted for brokers in any fully compared broker give-up trade prior to netting, the reference to "broker adjustments" in the current Rules has been deleted from the proposed rules as unnecessary.

II. Discussion

Section 17A of the Act directs the Commission to establish a safe and efficient national clearance and settlement system.[26] In enacting section 17A of the Act, Congress found that new data processing and communication techniques create the opportunity for more efficient, effective, and safe procedures for clearance and settlement.[27] Specifically, sections 17A(b)(3) (A) and (F) of the Act require that a clearing agency be organized and its rules be designed to promote, among other things, the prompt and accurate clearance and settlement of securities transactions and the safeguarding of securities and funds within its custody or control or for which it is responsible.[28] As discussed below, the

[20] Public Securities Association ("PSA"), Uniform Practices for the Clearance and Settlement of Mortgage-Backed Securities and Other Related Securities, Chapters 9 and 10.

[21] MBS, Art. II, Rule 5, Sections 4–5.

[22] SBOO trades are not subject to the cash adjustment because these trades do not create a SBO Market Differential, *i.e.*, FCAP minus FCAP equals zero. Proposed MBS, Art. II, Rule 5 §§ 4–5.

[23] For a more detailed discussion, see Securities Exchange Act Release No. 31352 (October 23, 1992), 57 FR 49728.

[24] The "clearance date" is the date on which the parties to a transaction actually deliver and pay for eligible securities as reported to MBS, which may be a date other than the settlement date. In the case of SBO trades, the settlement date is the settlement date assigned by PSA. MBS, Art. 1, Rule 1.

[25] The term "net-out unit" refers to an SBO-destined purchase transaction and an SBO-destined sale transaction that have been offset through netting. Proposed MBS, Art. I, Rule 1.

[26] 15 U.S.C. 78q–1(a)(2) (1988).

[27] 15 U.S.C. 78q–1(a)(1)(C) (1988).

[28] 15 U.S.C. 78q–1(b)(3) (A) and (F) (1988).

Commission believes that MBS' proposal furthers these goals.

The proposed changes to the netting procedures will allow MBS to use a price for SBOO trades that has some relationship to the actual trade price, FCAP, instead of the CAP. This change will reduce the number of trades that will be subject to the SBO market differential and the cash adjustment without reducing the percentage of trades that are netted. Thus, the Commission believes that the proposal promotes the prompt and accurate clearance and settlement of securities.

Moreover, the Commission believes the proposal reduces the number of trades subject to the SBO market differential and the cash adjustment without creating any additional risk to MBS. The trades that are no longer subject to the SBO market differential and the cash adjustment are trades with original contra-side participants. Any variance would be within the PSA guidelines and thus would place the participant in the same position as if the trade took place outside of MBS. In addition, the use of the FCAP eliminates the need for the SBO margin differential. Thus the proposal furthers the goal of perfecting the mechanics of a national system for prompt and accurate clearance and settlement of securities transactions and promotes the safeguarding of securities and funds within MBS' custody or control.

Because the SBO market differential is a significant safeguard to reduce the risk to MBS in case a participant defaults on its settlement obligations, the Commission believes that MBS should monitor the amount of SBO market differential it collects and assess whether it is sufficient to minimize the risk associated with the participant's default. Thus, MBS has agreed to provide the Commission with data regarding the amount of SBO market differential it has collected each month over the previous six months under the current calculations, the amount of SBO market differential it collects each month for the next six months under the new calculations, and the current and the projected calculations during the testing period.[29]

MBS believes that the extensive testing of its new system and the fallback procedures that are in place should minimize the potential for any interruption to the clearance and settlement of mortgage-back securities. The Commission believes that MBS has acted responsibly in designing and planning for the implementation of the new system, but believes that the current processing system should not be disabled until MBS has sufficient time to assess the performance of the new system and to determine whether the new system can continue to process securities transactions at MBS in an efficient, effective and safe manner. Accordingly, MBS has agreed not to disable the old system without giving the Commission staff prior notice. In addition, MBS has represented to the Commission that it will report any processing delays or other problems during the conversion process and the first four weeks thereafter and, during the first week after the conversion, MBS has agreed to brief the staff of the Division of Market Regulation ("Division") each day and to notify the Division immediately in the event of processing problems.[30]

The Commission believes that the proposed rule change is designed to comply with MBS' obligation to have the capacity to promote prompt and accurate clearance and settlement of securities transactions. MBS has conducted capacity tests and, based on those tests, MBS represents that the new processing system's operating and computer capacity is at least 300% of peak capacity volume during MBS' anticipated hours of operation.[31] MBS will continue to conduct system capacity analysis, taking into account projected growth, new services and enhancements, and will implement additional system upgrades as needed.

III. Conclusion

For the reasons set forth above, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular the requirements of section 17A of the Act.[32]

It is therefore ordered, Pursuant to section 19(b)(2) of the Act,[33] that the above-mentioned proposed rule change (File No. SR–MBS–92–02) be, and hereby is, approved on a partial basis.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[34]

[29] Letter from Jeffrey Lewis, Associate Counsel, MBS, to Ester Saverson, Jr., Branch Chief, Division of Market Regulation, Commission (December 30, 1992).

[30] Letter from Lynn Douglas, Senior Vice President and Chief Operating Officer, MBS, to Ester Saverson, Jr., Branch Chief, Division of Market Regulation, Commission (December 31, 1992).

[31] Letter from Lynn Douglas, Senior Vice President and Chief Operating Officer, MBS, to David Turner, Computer Analyst, Office of Automation and International Markets, Division of Market Regulation, Commission (October 16, 1992).

[32] 15 U.S.C. 78q–1 (1988).

[33] 15 U.S.C. 78s(b) (1988).

[34] 17 CFR 200.30–3(a)(12) (1991).

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 93–328 Filed 1–7–93; 8:45 am]
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[Release No. 34–31680; File No. SR–MBS–92–02]

Self-Regulatory Organizations; MBS Clearing Corp.; Order Approving a Proposed Rule Change Relating to Major Systems Enhancements on a Partial Basis

December 31, 1992.

On March 27, 1992, the MBS Clearing Corporation ("MBS") filed a proposed rule change (File No. SR–MBS–92–02) with the Securities and Exchange Commission ("Commission") pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act").[1] Notice of the proposal was published in the **Federal Register** on August 28, 1992.[2] No comments were received. Subsequently, on September 23, 1992 and September 29, 1992 MBS amended the filing.[3] On October 23, 1992, the Commission approved those aspects of the proposal that addressed, among other things, enhancements to MBS' trade comparison system.[4] This order partially approves those aspects of the proposal that address the legislation of a participant's open commitments.

I. Description

When MBS ceases to act for a participant, MBS rules require MBS to direct the liquidation of all of the defaulting participant's open commitments.[5] Under MBS' current rules, open commitments of the defaulting participant are liquidated by the original contra-side participants that

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] Securities Exchange Act Release No. 31058 (August 19, 1992), 57 FR 38807.

[3] Amendment No. 1 to SR–MBS–92–02 reinstates the concept of impending settlement date and impending expiration date that MBS currently uses in calculating a participant's Market Margin Differential ("MMD") deposit requirement. This concept was deleted in the proposal as originally submitted.

Amendment No. 2 amends the proposal to state that MBS will implement the enhancements to its operating system in phases and announced the target date of October 23, 1992 as the implementation date for the first phase. In addition, the bulletin discusses MBS' fallback procedures. Administrative Bulletin from MBS to all MBS participants (September 29, 1992).

[4] Securities Exchange Act Release No. 31352 (October 23, 1992), 57 FR 49726. More specifically, the Commission approved the first phase ("phase I") of MBS' enhancements to its operating system. In phase I, MBS implemented the Comparison and Clearing System ("CCS"), MBS' system for comparing trade input, margining, and comparing clearing information concerning transactions in eligible securities between participants.

[5] Proposed MBS Rules, Art. III, Rule 3, § 5.

traded with the defaulting participant. Those open commitments may involve four different types of transactions:

(1) Trade-for-trade transactions,
(2) Option transactions,
(3) SBO-destined trades, and
(4) SBO trades.[5]

MBS is proposing changes to its liquidation procedures that will require a participant to liquidate SBO trades when that participant is the contra-side to a defaulting participant's trade, regardless of whether the participant was the original contra-side to the SBO trade. The proposal is designed to:

(1) Reduce MBS' reliance on unwinding transactions when MBS ceases to act for a participant;[7]

(2) Provide a more efficient and timely mechanism to liquidate SBO trades; and

(3) Provide for the payment of any losses incurred by non-original contra-side participants after the orderly liquidation of SBO trades.

A. Current MBS Liquidation Procedures

The current MBS rules require that all open commitments of the defaulting participant be treated as trade-for-trade transactions and thus require the unwinding of SBO trades. In trade-for-trade transactions, SBO-destined transactions, and option transactions[6] the original contra-side participants are responsible for those trades and thus are responsible for the liquidation of the trades after MBS notifies participants that it has ceased to act for a participant.

Because SBO trades are netted and thus may not be matched with the original contra-side, MBS' current rules require the unwinding of all SBO transactions. MBS then matches the defaulting participant's SBO trades with the original contra-side participants. MBS will re-net the remaining SBO trades without the defaulting participant's transactions. MBS will treat the defaulting participant's rematched trades as trade-for-trade transactions and will require the original contra-side participants to the trades to liquidate those transactions.

After MBS ceases to act for a participant, MBS will establish timeframes for the liquidation of those trades depending on the amount and the dollar value of the securities and on market conditions. Within the timeframes set by MBS, the participant must obtain three competitive bids and must either accept the best bid or match it. The participant then must report to MBS the bids obtained, whether it accepted the best bid or matched it, and whether the participant, as a result of the liquidation, has a loss or a gain.

To determine whether the participant has a loss or gain, the participant will subtract the liquidation price from the original price of the trade. If the liquidation results in a loss, the participant will submit a claim to MBS, and, if the liquidation results in a gain, the participant immediately will submit that gain to MBS.

A participant that fails to follow the established timeframes for liquidation will be placed last in MBS' priority scheme for reimbursement. Those participants will rank behind MBS, non-original contra-side participants and original contra-side participants that followed the liquidation timeframes and will receive funds only to the extent that there are excess funds after all claims from a participant with a higher priority are satisfied.

At the time MBS ceases to act for a participant, MBS will liquidate all securities and will draw on any letters of credit deposited by the defaulting participant in MBS' Participants Fund. To pay for any losses suffered by participants as a result of MBS ceasing to act for the defaulting participant, MBS will have at its disposal the cash deposits by the defaulting participant in the participants fund, the funds from the liquidation of securities and from the draw on letters of credit deposited by the defaulting participant in MBS' Participants Fund, and the gains from the liquidation of the defaulting participant's trades.

MBS' rules set the priority for the payment of losses resulting from MBS' decision to cease to act for a participant. First, MBS will pay itself for any money owed MBS by the defaulting participant. if sufficient funds remain, MBS next will pay non-original contra-parties for losses suffered on SBO trades. If sufficient funds are not available to cover the losses incurred by non-original contra-sides, MBS will assess original contra-sides for any deficiency in proportion to the net amounts of their respective purchase and sale transactions with the defaulting participant. Because non-original contra-side participants are not involved in the liquidation of the defaulting participant's trades, losses of non-original contra-sides are limited to interest loss as a result of the failed SBO trades.[9]

Next, to the extent there are sufficient funds available, MBS will pay original contra-sides for any losses incurred.[10] Losses of original contra-side participants may consist of the difference between the original price and the liquidating price of the trades, the interest cost resulting from the failed trades, the lost principal and interest payments, and any brokerage expenses incurred in liquidating the trades. If there are insufficient funds available to pay for all losses incurred by original contra-sides, MBS will distribute any remaining funds to original contra-sides based on the loss realized by each original contra-side participant. If any funds remain after all losses are paid, the remaining funds go to the estate of the defaulting participant.

B. Proposed Changes to MBS Liquidation Procedures

The most significant change under MBS' preposed rule change is that there will be no unwinding of SBO trades. Instead, the defaulting participant's SBO trades will be liquidated by the contra-sides to those SBO trades regardless of whether the contra-side participants were the original or the non-original contra-sides to the trades. For liquidation purposes, the proposal will designate SBO trades as either "SBOO" or "SBON" trades.[11]

Like the current MBS procedures, once MBS decides to cease to act for a participant, the original contra-side participants will liquidate trade-for-trade transactions, option transactions, SBO destined trades and SBOO trades of the defaulting participant. SBON trades, however, will be liquidated by the non-original contra-sides that were matched as a result of the SBO netting process. The proposal will designate contra-side parties to SBON trades of the defaulting participant as agents of MBS at the time MBS decides to cease to act for the participant. In addition, the proposal makes clear that if a SBON contra-side participant, in good faith, follows the liquidation procedures, the participant

[6] Trade-for-trade transactions are trades submitted to MBS for comparison in MBS' comparison and clearing system; SBO-destined trades are trades intended for netting through MBS' multi-party netting system; and SBO (or Settlement Balance Order) trades are trades that have been netted through MBS' multi-party netting system.

[7] MBS uses the term "unwinding" to mean the unnetting of SBO trades.

[8] Upon ceasing to act for a participant, MBS will automatically cancel any "out-of-the-money" option contracts instead of liquidating those option transactions. MBS Rules, Art. III, Rule 3, Section 4.

[9] Interest is calculated per day from the time of the failed trade until the SBO trade is unwound, re-netted and settled.

[10] As discussed earlier, original contra-side participants that fail to follow the established timeframes for liquidation will be last in priority to recover any losses.

[11] As part of the liquidation procedures, MBS is adding definition of SBOO and SBON to its rules. An SBOO trade refers to an SBO trade in which both participants are the original party to the trade, and an SBON trade refers to an SBO trade in which at least one of the participants is not the original party to the trade.

will not incur any liability to original contra-side participants.[12]

The procedures for the liquidation of trades under the proposal will remain the same. As under the current procedures, the contra-side participants must obtain three bids, either accept the best bid or match it, report the result of the liquidation within the timeframe established by MBS, and, if the liquidation results in a gain, submit that gain to MBS. The way to calculate an original contra-side participant's loss from liquidated trades will remain the same. The proposal, however, will require an SBON contra-side participant to use the class average price to determine losses or gains from the liquidation of SBON trades.[13] An SBON contra-side participant will subtract the liquidation price from the class average price to determine if the participant has a loss or a gain.

The priorities for payment of funds from the deposits of the defaulting participant will remain the same. The losses incurred by non-original contra-side participants to an SBO trade, SBON contra-side participants, will be different under the proposal than under the current procedures because these participants will be involved in the liquidation of trades. The losses for SBON participants may consist of the difference between the class average price and the liquidating price of the trades, the interest cost resulting from the failed trade, the lost principal and interest payments, and any brokerage expenses incurred in liquidating the trades. Like the current MBS rules, if sufficient funds are not available to cover the losses incurred by non-original contra-sides, MBS will assess original contra-sides for any deficiency in proportion to the net amounts of their respective purchase and sale transactions with the defaulting participant.

II. Discussion

The Commission believes that MBS' revised liquidation procedures are consistent with the Act and in particular with section 17A of the Act.[14] Sections 17A(b)(3)(A) and (F) of the Act require that a clearing agency be organized and its rules be designed to promote the prompt and accurate clearance and settlement of securities transactions and to assure the safeguarding of securities and funds which are in the custody or control of a clearing agency for which it is responsible.[15] In addition, section 17A(a)(1)(C) of the Act encourages the use of automated techniques in order to achieve safer and more efficient clearance and settlement procedures.[16] As discussed below, the Commission believes that MBS' liquidation procedures further these goals.

The Commission believes that the proposal appropriately will separate the process of liquidating the defaulting participants' securities from the process for allocating losses to participants. By separating the two processes, the proposal creates a more efficient and timely mechanism for liquidating defaulting participants' securities. The proposal shortens the liquidation process and thus reduces the market risk associated with the liquidation process.

MBS' current procedures of unwinding SBO trades and matching the defaulting participant's trades with the original contra-side participants is an inefficient and a time-consuming process. Also, the delays in matching the original parties to SBO trades may cause participants to suffer greater losses in times of market stress and potentially cause greater losses.

The proposal provides for the payment of any losses incurred by non-original contra-side participants after the orderly liquidation of SBO trades. After MBS, non-original contra-side participants are next in line to receive compensation for any losses incurred. Thus the process preserves MBS' loss allocation process in which any losses are ultimately shared by participants that traded with the defaulting participant.

The proposal is consistent with those of other clearing agencies that separate the liquidation process and the loss allocation process to provide for a more efficient and timely liquidation. Like MBS' proposed procedures, other clearing agencies do not unwind netted trades but liquidate the trades of a defaulting participant as soon as practicable. Thus, the Commission believes that MBS' proposed rule change should be approved because it provides for a more efficient clearance and settlement process for a defaulting participant's trades, and it provides for greater safeguarding of funds and securities associated with those trades by reducing market risk, consistent with section 17A of the Act.[17]

III. Conclusion

For the reasons set forth above, the Commission finds that the proposed rule change is consistent with the requirements of the Act and in particular the requirements of section 17A of the Act.[18]

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[19] that the proposed rule change (File No. SR–MBS–92–02) be, and hereby is, approved on a partial basis with respect to its proposed liquidation procedures.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[20]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–333 Filed 1–7–93; 8:45 am]

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[Release No. 34–31678; File No. SR–NASD–91–44]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Notice of Filing of Amendments to Proposed Rule Change Relating to Mandatory Display of Size in Quotations in NASDAQ Securities and Order Granting Accelerated Approval of Proposed Rule Change as Amended

December 31, 1992.

I. Introduction

The National Association of Securities Dealers, Inc. ("NASD" or "Association") submitted on August 22, 1991, and amended on January 31, 1992, April 8, 1992, and December 29, 1992, a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder.[2] The proposal amends Schedule D to the NASD By-Laws[3] and the Rules of Practice and Procedure for the Small Order Execution System ("SOES")[4] to require display of size[5] in quotations for NASDAQ Small-Cap (previously referred to as "regular NASDAQ") securities no less than 500 or 100 shares, depending upon the trading characteristics of the security.[6]

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[12] Proposed MBS Rule, Art. III, Rule 3, § 5(g).

[13] The "class average price" is the average contract price of all SBO-destined trades in the class that has been netted to produce the SBON trade.

[14] 15 U.S.C. 78q–1 (1988).

[15] 15 U.S.C. 78q–1(b)(3)(A) and (F) (1988).

[16] 15 U.S.C. 78q–1(a)(1)(C) (1988).

[17] 15 U.S.C. 78q–1 (1988).

[18] 15 U.S.C. 78q–1 (1988).

[19] 15 U.S.C. 78s(b) (1988).

[20] 17 CFR 200.30–3(a)(12) (1991).

[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1990).

[3] NASD Securities Dealers Manual, Schedule D to the By-Laws, Part VI, section 2, CCH ¶1819.

[4] NASD Securities Dealers Manual, SOES Rules, section a, CCH ¶2451.

[5] That is, the number of shares the market maker is required to buy or sell at the stated quotation.

[6] In other words, a market maker in a regular NASDAQ security that is subject to the 500-share

Notice of the proposed rule change, as originally filed, together with the terms of substance of the proposal was provided by the issuance of a Commission release (Securities Exchange Act Release No. 29859, October 25, 1991) and by publication in the **Federal Register** (56 FR 56258, November 1, 1991). No comments were received in response to the Commission release.

On January 31, 1992, the NASD submitted Amendment No. 1 to the proposed rule change. Amendment No. 1 explains that mandatory display of quotation size will not be applicable to debt securities listed in NASDAQ. Amendment No. 2, filed on April 8, 1992, clarifies that minimum display size for NASDAQ Small-Cap securities shall be 500 shares unless the trading characteristics of the security warrant a display size of 100 shares. Amendment No. 3, filed on December 29, 1992, establishes the criteria that the NASD will use to determine which securities qualify for the 100-share display size.

By this release, the Commission: (i) Solicits comments on Amendments Nos. 1, 2, and 3; and (ii) approves the proposed rule change, as amended, on an accelerated basis. Below is the text of the rule change, as amended by Amendments Nos. 1, 2, and 3. Language added to the original proposal is in italics; proposed deletions are in brackets.

Schedule D—Part VI—Requirements Applicable to Nasdaq Market Makers

* * * * *

Sec. 2 Character of Quotations

(a) Two-Sided Quotations. For each security in which a member is registered as a market maker, the member shall be willing to buy and sell such security for its own account on a continuous basis and shall enter and maintain two-sided quotations in the Nasdaq System, subject to the procedures for excused withdrawal set forth in Section 8 below. Each member registered as a Nasdaq market maker shall display the size for each quotation which size shall be no less than the maximum order size for such security eligible for execution through the Small Order Execution System, as shall be published from time to time by the Association pursuant to paragraph a)7) of the Rules of Practice and Procedure for the Small Order Execution System. Maximum order sizes for Nasdaq/NMS securities shall be 200, 500, or 1,000 shares depending upon trading characteristics of the securities. Maximum order size for Nasdaq *Small-Cap* securities shall be *100 or* 500 shares *depending upon trading characteristics of the securities.* [These sizes may be adjusted on an issue by issue basis, depending upon unique characteristics of the issue as determined by the Association.] *A 500 share display size for Nasdaq Small-Cap securities shall apply to securities with an average daily non-block volume of 1,000 shares or more a day and a bid price of less than $10.00 per share. A 100 share display size for Nasdaq Small-Cap securities shall apply to securities with an average daily non-block volume of less than 1,000 shares a day and a bid price equal to or greater than $10.00 a share. Individual securities may be reclassified from time to time depending upon unique circumstances as determined by the Association. These sizes shall not be applicable to convertible debt securities listed in Nasdaq.*

II. Background

In 1990, the Securities and Exchange Commission ("SEC" or "Commission") approved a rule proposal by the NASD to require market markers that participate in SOES to display size at least equal to the SOES tier size for the security.[7] The proposal made participation in SOES for market makers in National Market System ("NMS") securities mandatory, while SOES participation for NASDAQ Small-Cap securities remained voluntary. The effect of the rule was to require market makers in NASDAQ Small-Cap securities that chose to participate in SOES to display size of at least 500 shares, whereas market makers that did not participate in SOES were only obligated to publish quotation size of at least one round lot, i.e., 100 shares. This dichotomy potentially discouraged NASDAQ market makers from participating in SOES.[8]

The NASD proposed mandatory display of quotation size following the 1987 market break. The Commission staff had recommended that "the NASD and the Commission should reconsider, in light of the market break, the need to require the market makers to include realistic sizes as part of their quotations."[9] In response to this recommendation, and a similar recommendation by the NASD's Quality of Markets Committee,[10] the NASD amended Schedule D to require market makers in NASDAQ securities who are also market makers in SOES to display size in NASDAQ at least equal to the maximum size of an order eligible for automatic execution in SOES.

The instant proposal will extend that requirement to all market makers, whether or not they participate in SOES. More specifically, the proposed changes to Schedule D and the Rules of Practice and Procedure for SOES will set forth the minimum display sizes for both NMS and NASDAQ Small-Cap securities. For NASDAQ Small-Cap stocks, the minimum display size will be 100 or 500 shares;[11] for NMS securities, the minimum display size will continue to be 200, 500, or 1,000 shares, depending upon the trading characteristics of the securities.

III. Commission Findings

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder, and, in particular, with the requirements of

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quote size requirement will have to effect transactions for up to 500 shares at its published bid and ask prices. See Rule 11Ac1–1(c), 17 CFR 240.11Ac1–1 (1992). See also NASD Securities Dealers Manual, Schedule D to the NASD By-Laws, Part VI, Sec. 2(b), CCH ¶ 1819 (1990).

[7] See Securities Exchange Act Release No. 28450 (September 18, 1990), 55 FR 39221 (September 25, 1990).

[8] See letter from Kathryn V. Natale, Assistant Director, Office of National Market System and Over-The-Counter Regulation, Division of Market Regulation, SEC, to Robert E. Aber, Vice President and Deputy General Counsel, NASD, dated May 14, 1990 and response, dated June 6, 1990.

[9] Division of Market Regulation, The October 1987 Market Break xxiv (February 1988). Additionally, the Commission urged, as early as 1980, that market centers, including NASDAQ, display quotations in greater size, thus disclosing a more complete indication of actual buying and selling interest. See Securities Exchange Act Release No. 16590 (February 13, 1980), 45 FR 12391 (February 19, 1980).

[10] NASD, Report of the Special Committee of the Regulatory Review Task Force on the Quality of Markets 28 (July 1988).

[11] Under the rule change, the 100-share display size will be reserved for securities with an average trading price equal to or greater than $10.00 per share, and an average daily volume less than 1,000 shares per day—roughly equivalent to the trading characteristics of the lowest size tier for NMS securities. These criteria are based upon the NASD's concerns with encouraging quality market making without significant disruptions of dealer competition. See letter to Katherine England, Branch Chief, Over-the-Counter Branch, Division of Market Regulation, SEC, from Robert E. Aber, Vice President and Deputy General Counsel, NASD, dated November 19, 1991. The NASD believes that with such securities, a higher mandatory display could discourage market making activity or otherwise adversely affect dealer participation. The NASD estimates that approximately 92 securities—4.6% of NASDAQ Small-Cap issues—will qualify for the 100-share display size. After implementation of the rule change, the NASD will review and analyze the trading characteristics of regular NASDAQ securities semi-annually to determine whether any modifications to the 500-share requirement are appropriate. Modifications to the quotation size criteria must be filed with the Commission pursuant to Section 19(b) of the Act. Changes to the composition of the tiers, *i.e.*, which securities are in the 500-share category and which are in the 100-share category, also must be filed with the Commission.

section 15A(b)(6) of the Act[12] which requires, *inter alia*, that the rules of the Association be designed to: (1) Promote just and equitable principles of trade; (2) facilitate transactions in securities, and remove impediments to and perfect the mechanism of a free and open market and a national market system; and (3) in general, protect investors and the public interest. In addition, the proposed rule change is consistent with section 15A(b)(11),[13] which requires that the Association's rules relating to quotations be designed to produce fair and informative quotations. Indeed, the proposal also furthers Congressional expectations in enacting the Securities Acts Amendments of 1975 which were intended, in part, "to assure the prompt and accurate, reliable and fair * * * publication of [quotation and transaction information] and the fairness and usefulness of the form and content of information with respect to quotation[s] and transactions."[14]

The Commission believes that requiring all NASDAQ Small-Cap market makers to display minimum size in their quotations will eliminate certain inequities under the current display requirements. In the NASDAQ Small-Cap market, the requirement to display a 500-share size currently applies only to market makers that voluntarily participate in SOES. In addition to executing SOES orders at a minimum size of 500 shares, these participating SOES market makers must also honor incoming non-SOES orders at their displayed size of 500 shares because of SEC Rule 11Ac1–1, the "firm quote rule."[15] NASDAQ Small-Cap market makers that participate in SOES, therefore, are disadvantaged by the current rule because they must honor 500-share orders from competing market makers, but may only get executions of 100 shares from those same market makers who do not participate in SOES and who display size of only 100 shares. The Commission believes that extending the minimum display size requirement to all market makers, regardless of whether they participate in SOES, reduces certain inequities among market makers.[16]

The Commission believes that if administered effectively, the proposed rule could will also increase the liquidity and depth of the NASDAQ Small-Cap market. In particular, for those NASDAQ Small-Cap securities that are designated for 500-share minimum display size—approximately 95% of all NASDAQ Small-Cap issues—the rule will assure investors of trade executions up to that size, instead of the current 100-share size. As discussed above, market makers who do not participate in SOES will thus be subject to greater affirmative obligations. Therefore, to the extent that the 500-share size requirement will not require such market makers to effect transactions in 500-share lots, the proposed rule will have the effect of enhancing market liquidity.[17] Moreover, to the extent that NASDAQ Small-Cap market makers not participating in SOES are now subject to the same obligations, vis a vis non-SOES orders, as participating market makers, the rule change may encourage more NASDAQ Small-Cap market makers to participate in SOES.

The Commission believes that display of size in quotations also reflects a more realistic picture of the actual size of executions available and the depth of the market in each security. Display of realistic size enhances investor knowledge and is also beneficial to issuers by publicizing the liquidity and depth of the market for their securities. Increased investor knowledge and market liquidity generally further investor protection, which serves to enhance participation in the market.

The Commission is satisfied that the proposed criteria represent an appropriate balance between the interests of market and investors. The NASD has indicated that it intends to review semi-annually which securities meet its criteria for the 100-share minimum display size, and whether the criteria for this classification of NASDAQ securities are adequate. Any change in the NASD's criteria, of course, will be subject to further Commission review under the Act.

For these reasons, and for the reasons stated above, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of Section 15A and the rules and regulations thereunder.

IV. Accelerated Approval of Rule Change as Amended

By letter dated December 29, 1992, the NASD requests that the Commission approve the rule change as amended by Amendments Nos. 1, 2, and 3, prior to the 30th day after publication of notice of the three amendments in the **Federal Register**. The NASD maintains that such accelerated approval is warranted because investors and the marketplace will benefit from the added liquidity resulting from the mandatory display of quotation size.

The Commission finds good cause for approving the rule change and the three amendments on an accelerated basis. As indicated above, the Commission recognizes that the rule change will provide important benefits to the NASDAQ market in terms of enhanced market liquidity an depth, enhanced investor knowledge, and the elimination of certain inequities among NASDAQ market makers. The NASD, which needs approximately one month to notify its members of their new obligations, is currently prepared to have the rule change become effective on February 1, 1993. The Commission believes that accelerated approval will avoid unnecessary delay in requiring the display of minimum quote size for NASDAQ Small-Cap securities.

Interested persons are invited to submit written data, views, and arguments concerning Amendments Nos. 1, 2, and 3. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted January 29, 1993.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act, that the proposed rule change, SR–NASD–91–

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[12] 15 U.S.C. 78o–3(b)(6) (1988).

[13] 15 U.S.C. 78o–3(b)(11) (1988).

[14] S. Rep. No. 94–75, 94th Cong., 1st Sess. 104, reprinted in 1975 U.S. Code Cong. and Admin. News 179, 282.

[15] See Rule 11Ac1–1(c)(2), 17 CFR 240.11Ac1–1 (1990).

[16] It is important to note that under the rule change, all NASDAQ Small-Cap securities will still be subject to a 500-share SOES maximum order size. Market makers participating in SOES for securities eligible for the 100-share display size will be subject to SOES executions of up to 500 shares, but will only have to honor non-SOES orders of 100 shares.

[17] While this rule change poses a risk that some market makers will withdraw from making markets in some stocks, the Commission believes that on balance, the risk is minimal and is outweighed by the benefits to investors of increased market information and liquidity.

44, be, and hereby is, approved effective February 1, 1993.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.[18]

Margaret H. McFarland,

Deputy Secretary.

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[Release No. 34-31676; File No. SR-NASD-92-57]

Self-Regulatory Organizations; Filing and Immediate Effectiveness of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to the Credit Against the Annual Assessment on Gross Income

December 31, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on December 18, 1992, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The NASD has designated this proposal as one establishing or changing an assessment imposed exclusively on its members under section 19(b)(3)(A)(ii) of the Act, which renders the rule effective upon the Commission's receipt of this filing. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD is amending section 1, Schedule A to the NASD's By-Laws to change the effective period of the credit from calendar year 1992 to calendar year 1993; and hereby advising that the NASD, during 1993, may amend the amount of the credit to members provided under section 1, Schedule A to the NASD's By-Laws, such amendment to be applicable to the entire calendar year 1993.

Below is the text of the proposed rule change. Proposed new language is in italics, proposed deletions are in brackets.

Schedule A

Assessment and fees pursuant to the provisions of Article VI of the By-Laws of the Corporation, shall be determined on the following basis.

Section 1—Assessments

* * * * *

(d) During calendar year January 1, 199[2]*3* through December 31, 199[2]*3* each member shall receive a credit of 59% against the amount of its annual assessment on gross income stated in paragraph (b) above; provided, however that the minimum payment shall be $350.00.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In accordance with the NASD's shift from a fiscal to a calendar budget year in 1991, the NASD determined that member assessments should be based upon gross income reported for the calendar or fiscal year immediately preceding the NASD's calendar budget year. Because assessment invoices are sent to NASD members prior to the receipt of final gross income reports, the invoices will be based upon the most recent gross income reports available. After final gross income reports for 1992 are received from the members, subsequent assessment invoices will be adjusted so that the 1993 assessment is based upon 1992 gross income. The NASD may determine, however, after receipt of final gross income reports for 1992, that it is necessary to amend the amount of the credit set forth in Section 1(d) of Schedule A to the By-Laws which is currently fifty-nine percent (59%). Any amendment to the credit would be applicable to the entire calendar year 1993.

The NASD is also proposing to amend Section 1(d) of Schedule A to change the effective period of the credit from calendar year 1991 to calendar year 1992.

The NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(5) of the Act, which requires that the rules of the Association provide for the equitable allocation of reasonable dues, fees, and other charges among issuers and other persons using any facility or system which the Association operates or controls.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to section 19(b)(3)(A)(ii) of the Act and subparagraph (e) of Rule 19b-4 thereunder in that it establishes or changes an assessment imposed exclusively on the NASD's members.

At any time within 60 days of the filing of a rule change pursuant to Section 19(b)(3)(A) of the Act, the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file

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[18] 17 CFR 200.30-3(a)(12).

number in the caption above and should be submitted by January 29, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–332 Filed 1–7–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–31682; File Nos. SR–OCC–91–12; SR–ICC–92–03]

Self-Regulatory Organizations; The Options Clearing Corp.; The Intermarket Clearing Corp.; Order Approving Proposed Rule Changes Relating to Modification of the Short Option Adjustment

December 31, 1992.

On June 20, 1991, the Options Clearing Corporation ("OCC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR–OCC–91–12) pursuant to section 19(b) of the Securities Exchange Act of 1934 ("Act"),[1] and on May 8, 1992, The Intermarket Clearing Corporation ("ICC") filed with the Commission a similar proposed rule change (File No. SR–ICC–92–03). The proposed rule changes allow OCC and ICC to modify the short option adjustment in their margin calculations. Notice of the proposals appeared in the **Federal Register** on July 25, 1992,[2] and September 22, 1992.[3] The Commission received one letter commenting on OCC's proposal.[4] This order approves the proposals.

I. Description

The proposals will decrease the number of short option positions to which the short option adjustment[5] is applied by allowing OCC and ICC ("the clearing corporations") to pair open net short positions[6] with open net long positions[7] on the same underlying interest on a contract-by-contract basis.[8]

Any short contracts remaining after the pairing in which the additional margin requirement is less than 25% of the applicable margin interval will be subject to the short option adjustment.[9] Consistent with the clearing corporations' current procedures, the short option adjustment, where applied, will increase the clearing member's additional margin deposit for open short positions.[10]

A. OCC and ICC Margin Systems

OCC and ICC use the Theoretical Intermarket Margin System ("TIMS") to project the cost of liquidating a clearing member's option positions assuming a change in the price of the underlying securities equal to the margin interval and set clearing member margin requirements to cover that projected cost. The margin calculation takes into consideration all short option positions and all long option positions over which the clearing corporations are entitled to assert a lien in the event of a clearing member default.

Clearing member daily margin requirements have two components: "Premium margin" and "additional margin."[11] "Premium margin" is designed to mark-to-the-market the option position (i.e., to account for any change in the closing price of the option from the previous day.) "Additional margin" is designed to cover the projected incremental cost of liquidating an option position in the event of an adverse change in the price of the underlying stocks. In general, the clearing corporations calculate "premium margin" and "additional margin" for each class group[12] and sum up the margin requirement for each class group to arrive at the margin requirement for the product group.[13]

The first step in calculating margin is to net offsetting long and short positions in each option series within each class group.[14] Second, premium margin is calculated for the net long or short position in each series of the class group to arrive at a premium margin requirement or credit for the class group.[15] Third, additional margin is determined by comparing the liquidating value of the options positions at several predetermined underlying asset prices. The clearing corporations use options price theory to calculate theoretical liquidating values. Theoretical liquidating values for the class group are calculated: (1) For an upside price, (2) for a downside price, and (3) at intermediate points between the upside price and the downside price.[16] The variation between each of

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[1] 15 U.S.C. 78s(b).

[2] Securities Exchange Act Release No. 29445 (July 17, 1991), 56 FR 34083 [File No. SR–OCC–91–12].

[3] Securities Exchange Act Release No. 31181 (September 14, 1992), 57 FR 43759 [File No. SR–ICC–92–03].

[4] The Commission received a letter from Irvin R. Kessler, Co-Chairman, Kessler Asher Clearing, supporting the proposed modifications to the short option adjustment based on the reasoning that the current short option adjustment imposes a minimum margin requirement for short positions in excess of the risk presented by those positions. Letter from Irvin R. Kessler, Co-Chairman, Kessler Asher Clearing, to Jonathan G. Katz, Secretary, Commission (July 17, 1991).

[5] The short option adjustment is the component of the additional margin calculation that imposes a minimum margin amount of 25% of the applicable margin interval on deep out-of-the-money short options.

[6] The clearing corporations' margin systems are multi-step processes in which the clearing corporations offset gross long positions in the same option series at the first step of the process. See text at Section I.A, *infra*. The terms "net short positions remaining in a class group after offsetting gross long positions against gross short positions within the same series. For definitions of the terms "class group" and "option series", see notes 11 and 13, *infra*.

[7] Proposed rule changes apply to unsegregated long positions, *i.e.*, positions carried in a clearing member's firm, market-maker, or specialist accounts. Long positions carried in customers' and firm non-lien accounts are segregated, and the proposed rule changes do not apply to such positions.

[8] OCC margin requirements apply only to OCC clearing members, *i.e.*, clearing margin. These clearing margin requirements do not involve either: (1) Minimum margin requirements for customer accounts as set forth in Regulation T of the Board of Governors of the Federal Reserve System, 12 CFR part 220, and in Chicago Board Options Exchange Rule 12.3; or (2) minimum net capital requirements for broker-dealers as set forth in Rule 15c3–1 under the Act, 17 CFR 240.15c3–1 (1990).

The ICC margin requirements affected by the proposed rule change refer to margin requirements on options cleared by OCC pursuant to a cross-margining program between OCC and ICC. Securities Exchange Act Release No. 26153 (October 3, 1988), 53 FR 39567.

Commodity options and futures held in cross-margin accounts, market baskets, and index participations would be included in the contract pairing. These products are subject to margin at OCC because of a cross-margining program with a commodity exchange. Securities Exchange Act Release No. 29991 (November 26, 1991). 56 FR 61458.

[9] The "margin interval" is the assumed upward or downward change in price of the underlying securities that OCC and ICC seek to protect against. The "margin interval" is designed to protect against 99% of daily price changes in underlying assets during the previous three months and one year. See OCC Rule 601(b)(8).

[10] Volatile markets may cause deep out-of-the-money (i.e., far below the strike price in the case of a call, or far above the strike price in the case of a put) short positions to become in-the-money and thereby increase risk of those positions. The clearing corporations impose a minimum margin requirement on such positions to help protect against that risk.

[11] The proposed rule changes involve a special adjustment in the calculation of additional margin for deep out-of-the-money short positions and will not affect the way the clearing corporation calculate premium margin.

[12] A "class group" consists of all put and call options relating to the same underlying interest.

[13] The term "product group" means two or more class groups whose underlying assets have been determined by the clearing corporations to exhibit sufficient price correlation to warrant the margining of options thereon on a combined basis. OCC Rule 602A(b)(3). All equity options would form a single "product group." Securities Exchange Act Release NO. 28928 (March 1, 1991), 56 FR 9995.

[14] An option "series" consists of option contracts within the same class with the same exercise price, expiration date, and unit of trading.

[15] In calculating premium margin, OCC uses the previous day's closing asked prices for the option series.

[16] Securities and Exchange Act Release No. 31631 (December 22, 1992), 57 FR 62411 [File Nos. SR–OCC–92–21 and SR–ICC–92–04] (order approving

these liquidating values and the applicable premium margin requirement or credit is determined. The largest variation, whether representing a margin credit or requirement, in the event of a rise in the market value of underlying interest ("upside variation") and the largest variation, whether representing a margin credit or requirement, in the event of a decline in the market value of the underlying interest ("downside variation") are identified. For a product group comprised of only one class group, the additional margin requirement is equal to whichever of the upside variation, the downside variation, or the alternative minimum additional margin requirement [17] represents the largest margin requirement.

For a product group comprised of two or more class groups, TIMS currently calculates additional margin as follows. Any class group upside variation or downside variation that represents a margin credit is reduced by a percentage specified by the clearing corporations.[18] The upside variations in the product group are added together to produce a net upside variation and the downside variations in the product group are added together to produce a net downside variation. The additional margin requirement for the product group is an amount equal to whichever of the total upside variation, the total downside variation, or the alternative minimum additional margin requirement represents the largest margin requirement. Unlike premium margin, which can be either a requirement or a credit, additional margin is always either a margin requirement or zero (i.e., never a margin credit against premium margin requirements). The total margin requirement or credit for the product group is an amount equal to the sum of: (1) The net premium margin requirement (or credit, if applicable) and (2) the additional margin requirement.

For net short positions in deep out-of-the-money options that experience little or no change in value given a change in value of the underlying interest, TIMS will calculate additional margin amounts of zero or close to zero. Volatile markets, however, may cause these positions to become in-the-money or nearly so, creating increased risk to the clearing corporations. The clearing corporations protect against such risk by incorporating into the additional margin calculation of TIMS a margin cushion in the form of the short option adjustment.

B. The Short Option Adjustment

The short option adjustment currently is activated and applied to all net short positions without consideration to spreads between net short and long positions. The clearing corporations, therefore, believe that the short option adjustment may require clearing members to deposit margin in excess of the risk presented by certain net short positions. Under the proposed rule changes, the clearing corporations will pair open net short positions with unsegregated open net long positions on the same underlying interest on a contract-by-contract basis at the class group level. The additional margin requirement for net short contracts having an additional margin requirement of less than 25% of the applicable margin interval will be subject to the short option adjustment (i.e., the additional margin requirement would be increased to 25% of the applicable margin interval).

To illustrate how the modified short option adjustment would be applied, assume a clearing member maintains in its firm account the following net options positions on the same underlying hypothetical equity security.[19] Furthermore, assume that underlying equity's current market value is $115.

Calls	Puts
November 130: 4 short ...	February 110: 1 short.
November 100: 4 short ...	February 100: 1 short.
November 125: 2 long	February 130: 2 long.
November 110: 2 long	February 115: 4 long.
Net 4 short	Net 4 long.

Under the current methodology, TIMS would view all short positions as uncovered and would impose a short option adjustment. Under the proposed methodology, net long calls would be paired against net short calls and net long puts would be paired against net short puts.[20] Four short call contracts would be unpaired since there are four more short call contracts than long call contracts. OCC would review the additional margin calculations made by TIMS, and if TIMS calculates a margin amount of less than 25% of the applicable margin interval, the short option adjustment would be applied to those four short contracts for which TIMS calculates the lowest amounts of additional margin. In the above example, the short option adjustment would be applied to the four short November 130 call contracts since they are the deepest out of the money. No short put contracts would be subject to the modified short option adjustment since all put contracts are paired.

II. Discussion

Section 17A(b)(3)(F) of the Act provides that the rules of a clearing agency must be designed to assure the safeguarding of securities and funds in the custody or control of the clearing agency or for which the clearing agency is responsible.[21] That Section also requires that the rules of a clearing agency be designed to facilitate the prompt and accurate clearance and settlement of securities transactions. Additionally, section 17A(a) of the Act encourages the adoption of safer and more efficient clearance and settlement procedures that are less costly to investors.[22]

The Commission believes that the proposed rule changes will assist the clearing corporations in accurately identifying the risk created by clearing member positions and in setting margin levels to cover that risk without "overmargining." By allowing long contracts to offset the short contracts on the same underlying interest, the clearing corporations will reduce the number of short contracts that are subject to the short option adjustment.

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proposed rule changes relating to the calculation of additional margin).

[17] The alternative minimum additional margin requirement essentially assures that TIMS requires a minimum amount of additional margin even in situations where accounts are fully hedged (i.e., accounts in which the value of the short positions are fully offset by the value of long positions). The alternative minimum additional margin calculation is described in Securities Exchange Act Release No. 29990 (November 28, 1991), 56 FR 61455 [File Nos. SR–OCC–91–16 and SR–ICC–91–01] (order approving proposed rule changes which provide for an alternative minimum additional margin requirement).

[18] This percentage is determined on the basis of studies of the price correlations of the underlying interest in the product group. For example, OCC currently has established the percentage for the stock option product group at 70% and has established percentages that range from 5% to 30% for the various non-equity option product groups.

[19] The example is based on information provided by OCC. Letter from Jean Cawley, Associate Counsel, OCC, to Sonia G. Burnett, Attorney, Division of Market Regulation ("Division"), Commission (July 31, 1991) and telephone conversation between Jean Cawley, Associate Counsel, OCC, Timothy F. Hinkes, Assistant Vice President, Economic Research, OCC, and Jerry W. Carpenter, Branch Chief, Division, Commission (December 30, 1992).

[20] A pair consisting of a net short contract and a net long contract will pose no risk to the clearing corporations if the exercise price of the short position is higher (in the case of a call option) or lower (in the case of a put option) than the exercise price of the long position. Conversely, if the exercise price of the short position is lower (in the case of a call option) or higher (in the case of a put option) the risk to the clearing corporations is the difference between the exercise price of the short and long positions multiplied by the applicable unit of trading ("uneven pairing").

[21] 15 U.S.C. 78q-1(b)(3)(F).

[22] 15 U.S.C. 78q-1(a).

This will eliminate over-collateralizing certain short positions where the risk of such positions is offset by long positions on the same underlying interest.

The pairing of net short contracts with net long contracts should not impose any significant increase in risk because as the risk created by the net short position increases the value of the offsetting long position also increases. The clearing corporations will continue to apply the short option adjustment to truly "naked" deep out-of-the-money options for which TIMS generates additional margin of less than 25% of the applicable margin interval. The clearing corporations' protection with respect to such positions will not be reduced. Thus, the Commission believes that the proposals will allow OCC and ICC to tailor their option methodologies to provide a more accurate measure of the risk presented by clearing member positions.

In some cases, the clearing corporations will pair short contracts with long contracts even if the exercise price of the short contract is lower (in the case of a call) or higher (in the case of a put) than that of the long contract. While this uneven pairing may impose some risk, the Commission is satisfied that the risks is very limited.[23] Moreover OCC has provided examples that show that as of March 12, 1992, had the modified short option adjustments been in effect, the margin required from clearing members would have been reduced by only $450,000, or .015% of the margin controlled by OCC.[24]

In addition, the clearing corporations have represented that their existing back-up systems are capable of identifying any additional risk.[25] OCC and ICC routinely employ Concentration Monitoring ("Con Mon") procedures to identify clearing members that impose high levels of risk relative to their capital base.[26] The Commission believes these procedures enable OCC and ICC to safeguard securities and funds and to promote prompt and efficient clearance and settlement securities transactions consistent with their statutory obligations.

III. Conclusion

For the reasons discussed above, the Commission believes that the modified short option adjustment should not impose any significant increase in risk to the clearing corporations. The Commission believes that the proposals are consistent with the requirements of the Act, particularly with section 17A of the Act, and the rules and regulations thereunder.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act,[27] that the proposed rule changes (File Nos. SR–OCC–91–12 and SR–ICC–92–03) be, and hereby are, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[28]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–327 Filed 1–7–93; 8:45 am]

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[23] As previously noted, if the exercise price of the short contract is lower (in the case of a call option) or higher (in the case of a put option), the risk to the clearing corporation is the difference between the exercise price of the short and long positions multiplied by the applicable unit of trading.

[24] Letter from Jean M. Cawley, Associate Counsel, OCC, to Ester Saverson, Jr., Branch Chief, Commission (March 20, 1992).

[25] *Id.*

[26] Con Mon procedures are designed to quantify the potential risk for each clearing member given "abnormally" large price movements and to relate that risk to the clearing member's financial condition. Based on this analysis, the clearing corporations may require a higher margin deposit from a member that triggers the concentration risk parameters.

[27] 15 U.S.C. 78s(b)(2).

[28] 17 CFR 200.30–3(a)(12).

[Rel. No. IC–19203; 812–8142]

The Alliance Fund, Inc., et al.; Application

December 31, 1992.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company Act of 1940 (the "Act").

APPLICANTS: The Alliance Fund, Inc., Alliance Balanced Fund, Inc., Alliance Bond Fund, Inc., Alliance Global Small Cap Fund, Inc., Alliance Growth and Income Fund, Inc., Alliance International Fund, Inc., Alliance Mortgage Securities Income Fund, Inc., Alliance Mortgage Strategy Trust, Inc., Alliance Multi-Market Strategy Trust, Inc., Alliance New Europe Fund, Inc., Alliance North American Government Income Trust, Inc., Alliance Premier Fund, Inc., Alliance Quasar Fund, Inc., Alliance Growth Short-Term Multi-Market Trust, Inc., and other registered open-end investment companies (a) whose investment adviser is the Adviser (as defined below) or an investment adviser that is under common control with the Adviser, (b) whose principal underwriter is the Distributor (as defined below) or a principal underwriter that is under common control with the Distributor, (c) which hold themselves out to investors as being related for purposes of investment and investor services, and (d) whose shares are divided into up to three classes of securities whose sales load, contingent deferred sales charge ("CDSC"), rate of distribution fees, exchange privileges, conversion feature and differences in voting rights are identical to those applicable to one or more of the Class A, Class B and/or Class C shares as described in the application (the "Funds"); Alliance Capital Management L.P. (the "Adviser"); and Alliance Fund Distributors, Inc. (the "Distributor").

RELEVANT ACT SECTIONS: Order requested pursuant to section 6(c) of the Act to amend a previous order which granted applicants exemptive relief from the provisions of sections 2(a)(32), 2(a)(35), 18(f), 18(g), 18(i), 22(c), and 22(d) of the Act and rule 22c–1 thereunder.

SUMMARY OF APPLICATION: Applicants seek to amend a prior order (the "Prior Order") to permit the Funds and other registered open-end investment companies in the same group of investment companies to issue a third class of securities representing interests in the same portfolio of securities and to assess a CDSC on redemptions of the shares of one of the classes and to waive the CDSC in certain cases.

FILING DATE: The application was filed on November 4, 1992 and amended on December 30, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 25, 1993, and should be accompanied by proof of service on the applicants, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of the date of a hearing may request notification by writing, to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicants, 1345 Avenue of the Americas, New York, New York 10105.

FOR FURTHER INFORMATION CONTACT: James E. Anderson, Staff Attorney, at (202) 272–7027, or C. David Messman, Branch Chief, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the SEC's Public Reference Branch.

Applicants' Representations

1. Each Fund is an open-end management investment company registered under the Act. The Adviser serves as each Fund's investment adviser and the Distributor acts as principal underwriter of the Funds' shares. Each Fund presently offers a class of shares subject to a front-end sales load and a rule 12b–1 plan distribution fee at an annual rate of up to 0.50% of the average daily net asset value of such shares ("Class A Shares") and a class of shares subject to a CDSC and a rule 12b–1 plan distribution fee at an annual rate of up to 1% of the average daily net asset value of such shares ("Class B Shares").[1]

2. Applicants propose to modify their present dual distribution system to establish a triple distribution system (the "Triple Distribution System") to enable the Funds to offer investors the option of purchasing a third class of shares ("Class C Shares"). Class C Shares will be sold subject to a rule 12b–1 plan distribution fee at an annual rate of up to 0.75% and a service fee at an annual rate of up to 0.25%, but without either a front-end sales load or a CDSC. In addition, applicants seek to amend the Prior Order to impose a rule 12b–1 service fee on the Class A Shares and the Class B Shares at an annual rate of up to 0.25%.

3. Under the Triple Distribution System, Class A Shares will be sold at net asset value plus a front-end sales load. As is currently the case, the sales load will be subject to reductions for larger purchases, under a combined purchase privilege, under a right of accumulation, or under a statement of intent. The sales load also will be subject to other reductions permitted by section 22(d) of the Act and set forth in the registration statement of each Fund. Each Fund will pay the Distributor a distribution fee at an annual rate of up to 0.50%, and a service fee at an annual rate of up to 0.25%, of the average daily net asset value of the Class A Shares, rather than the current distribution fee at an annual rate of up to 0.50%.

4. Under the Triple Distribution System, Class B Shares will be sold at net asset value without the imposition of a sales load at the time of purchase. Each Fund will pay the Distributor a distribution fee at an annual rate of up to 0.75%, and a service fee at an annual rate of up to 0.25%, of the average daily net asset value of the Class B Shares, rather than the current payment of a distribution fee at an annual rate of up to 1%. In addition, an investor's proceeds from a redemption of Class B Shares made within a specified period of years of their purchase (typically the length of such period will range from three to six years) generally will be subject to a CDSC. The CDSC is expected to range from 3% to 5% (but can be higher or lower) on shares redeemed during the first year after purchase and to be reduced at a specified rate (usually at a rate of 1%) per year over the applicable CDSC period, so that redemptions of shares held after that period will not be subject to a CDSC.

5. The Funds propose to offer Class C Shares at net asset value per share without the imposition of a sales load at the time of purchase or a CDSC at the time of redemption. Each Fund will pay to the Distributor a distribution fee at an annual rate of up to 0.75%, and a service fee at an annual rate of up to 0.25%, of the average daily net asset value of the Class C Shares. Unlike Class B Shares, Class C Shares will not be subject to a conversion feature; accordingly, such shares will continue to be subject to a distribution fee at a rate that is approximately the same as the rate on the Class B Shares for an indefinite period of time. Proceeds from this fee will be used by the Distributor primarily to pay trail or maintenance sales commissions to financial intermediaries and to the Distributor for other expenses of distribution. Class C Shares of a Fund generally will be exchangeable at net asset value for Class C Shares of other Funds.

6. The three classes will each represent interests in the same portfolio of securities of a Fund and will be identical except that: (a) The distribution fees payable by the Fund to the Distributor will be higher for Class B and Class C than they will be for Class A Shares; (b) the service fees payable by the Fund to Distributor may differ among the Class A, Class B and Class C Shares; (c) the agency costs attributable to each of the Class A, Class B and Class C Shares may differ; (d) each class will bear any other incremental expenses subsequently identified that should be properly allocated to the class which shall be approved by the Commission pursuant to an amended order; (e) the three classes will have different exchange privileges; (f) only Class B Shares will have a conversion feature; and (g) each class will vote separately as a class with respect to the Fund's rule 12b–1 distribution plan and other matters for which separate class voting is appropriate under applicable law, provided that, if the Fund submits to a vote of both the Class A shareholders and the Class B shareholders an amendment to the Fund's rule 12b–1 distribution plan that would materially increase the amount to be paid thereunder with respect to the Class A Shares, the Class A shareholders and the Class B shareholders will vote separately by class.

7. The service fees paid by each Fund will be used by the Distributor for personal services and/or the maintenance of shareholder accounts. Each Fund's distribution plan will provide that the distribution fee paid out of the assets of the Class A, Class B, and Class C Shares will be used in its entirety by the Distributor to defray its expenses in providing distribution-related services (including, in the case of Class B and Class C Shares, commission expenses). Each Fund will accrue and pay the distribution fee at a rate fixed by the Fund's Directors/Trustees (but not in excess of the applicable maximum percentage rate). Such rate is intended to result in payments that will not exceed the amounts actually expended for distribution by the Distributor on behalf of the Fund.

8. Following the implementation of the Triple Distribution System, a Fund may amend its rule 12b–1 distribution plan with respect to a class of shares to structure the rule 12b–1 plan so that it will obligate the Fund to pay the distribution fee attributable to the class to the Distributor as compensation for the Distributor's distribution-related services with respect to the class, and not as reimbursement for specific expenses incurred. The amount of distributed services fees payable by the Fund with respect to a class of shares would not be related directly to the amount of distribution services expenses incurred by the Distributor with respect to such class. Thus, under such a compensation structure, if the Distributor's expenses with respect to its distribution related services with respect to the class were less than the distribution fee, the Distributor would receive the full fee and realize a profit.

9. The Distributor will furnish the Directors/Trustees of each Fund with quarterly and annual statements of distribution revenues and expenditures, in accordance with the requirements of paragraph (b)(3)(ii) of rule 12b–1, to

[1] Applicants offer two classes of shares and impose a CDSC pursuant to the Prior Order, Investment Company Act Release Nos. 17295 (Jan. 8, 1990) (notice) and 17330 (Feb. 2, 1990) (order), as amended, Investment Company Act Release Nos. 18734 (May 27, 1992) (notice) and 18805 (June 23, 1992) (order).

enable the Directors/Trustees to make the findings required by paragraphs (d) and (e) of rule 12b–1. Only distribution expenditures properly attributable to the sale of a particular class will be used to justify the distribution fee charged to that class. Distribution expenses attributable to the sale of each class of shares will be allocated annually to each class based upon the ratio in which the sales of each class bears to the sales of all the shares of the Fund.

10. The decision as to whether a particular distribution expenditure or category of distribution expenditures is properly attributable to the sale of a particular class or to the sale of both classes of shares (and thus allocated to each class of shares in accordance with the method described above) will be subject to the review and approval of the Directors/Trustees. Each Fund's Directors/Trustees have determined all distribution expenditures will continue to be attributable to the sale of each class of shares except (a) commission expenses related to the sale of the Class B Shares and (b) trail or maintenance payments (which will be separately calculated with respect to each class). In the future, however, the Directors/Trustees may determine that a particular distribution expenditure or class of distribution expenditures, in addition to the two categories listed in the immediately preceding sentence, are attributable to the sale of a particular class.

11. All Class B Shares of the Funds, other than those purchased through the reinvestment of dividends and distributions, will automatically convert to Class A Shares in a certain number of years after the end of the calendar month in which the shareholder's order to purchase was accepted, in the circumstances and subject to the qualifications described below. Such number of years, which will be the same with respect to all Class B Shares of a Fund, may be up to eight. The purpose of the conversion feature is to relieve the holders of Class B Shares that have been outstanding for a period of time sufficient for the Distributor to have been compensated for distribution expenses related to such shares from most of the burden of additional distribution expenses.

12. Shares purchased through the reinvestment of dividends and other distributions in respect of Class B Shares will be treated as Class B Shares except that, for purposes of conversion to Class A, all such shares that have not already converted into Class A Shares will be considered held in a separate sub-account. Each time any Class B Shares in the shareholder's account (other than those in the sub-account) convert to Class A, an equal *pro rata* portion of the Class B Shares in the sub-account also will convert to Class A.

13. The Funds have obtained an opinon of counsel that the assessment of the higher distribution fee and transfer agency costs and any other special allocations described above with respect to Class B Shares does not result in any dividends or distributions constituting "preferential dividends" under the Internal Revenue Code of 1986, as amended ("IRC"), and that the conversion of Class B Shares to Class A Shares does not constitute a taxable event under current federal income tax law. The conversion of Class B Shares to Class A Shares may be suspended if such an opinion is no longer available.

14. Currently, Class A Shares of the Funds are exchangeable for the Class A Shares of other Funds, for shares of the other funds in the Adviser's mutual fund complex that are sold subject to a front-end sales load, for money market fund shares, and for shares of Alliance World Income Trust, Inc. ("AWIT"), a non-money-market fund sold without the imposition of a sales load or CDSC but subject to a rule 12b–1 distribution plan. In addition, a holder of shares of any fund in the Adviser's mutual fund complex that is sold subject to a front-end sales load (or a holder of money market fund shares or shares of AWIT acquired through an exchange of such shares) may exchange his or her shares for Class A Shares of a Fund without the payment of any sales or service charge. The Class B shareholders of a Fund have the ability to exchange their Class B Shares for Class B Shares of certain other Funds.

15. It is contemplated that: (a) Class C Shares of a Fund will be exchangeable for Class C Shares of other Funds, for money market fund shares, and shares of AWIT; (b) certain Class B shareholders will have the ability to exchange their shares for Class C Shares without the imposition of a CDSC; and (c) certain Class B or Class C shareholders of a Fund holding shares of that Fund and other mutual funds sponsored by the Adviser with a value equal to the minimum amount at which an investor may purchase Class A shares of a Fund without the imposition of a front-end sales load ("Minimum N.A.V. Purchase Amount") may exchange their Class B or Class C Shares for Class A Shares of the Fund without the payment of a front-end sales charge or CDSC.

16. Except for the differences described above, the Class A, Class B and Class C Shares of a Fund will have identical voting, dividend, liquidation and other rights, preferences, powers, restrictions, limitations, qualifications, designations, and terms and conditions. All expenses incurred by a Fund will be allocated daily among the classes of shares based on the relative percentage of net assets attributable to each class except for any differing expenses of the distribution plan, service fees, and transfer agency costs that will be borne by the classes. Because of the differing expenses that will be borne solely by each of the Class A, Class B, and Class C shares, the net income attributable to and the dividends payable on such shares will differ by class. The net asset value of the Class A Shares initially will be higher than the net asset value of the Class B and Class C Shares, and the net asset value per share of the three classes will continue to diverge over time.

17. Pursuant to the Prior Order, the Applicants assess a CDSC on certain redemptions of Class B Shares of the Funds and waive the CDSC with respect to certain types of redemptions. The Applicants seek to amend the Prior Order to permit the Funds (a) to waive the CDSC on redemptions in connection with the exchange of Class B Shares of each Fund that had been purchased by qualified money purchase pension and profit-sharing plans, including section 401(k) plans ("Qualified Plans"), through the Alliance Premier Retirement Program prior to the creation of the Class C Shares for Class C Shares of the Fund, and (b) to waive the CDSC on redemptions in connection with the exchange of Class B Shares of each Fund that had been purchased by a Qualified Plan for Class A Shares if the aggregate net asset value of shares of all the Funds held by the Qualified Plan reaches the Minimum N.A.V. Purchase Amount level or more on or before December 15 in any year.

18. Currently, the CDSC on Class B Shares is not imposed on redemptions of shares which were purchased more than a specified period of up to six years (the "CDSC Period") prior to their redemption or shares derived from the reinvestment of distributions. Furthermore, no CDSC is imposed on an amount which represents an increase in the value of the shareholder's account resulting from capital appreciation above the amount paid for shares purchased during the CDSC Period. In determining whether a CDSC is applicable, it is assumed, unless the shareholder otherwise specifically directs, that a redemption is made first of any Class A Shares in the shareholder's Fund account, second of shares derived from reinvestment of distributions, third of shares held for a period longer than the CDSC Period,

and fourth of shares held for a period not longer than the CDSC Period.

19. In addition, pursuant to the Prior Order, each Fund has the ability to waive the CDSC on redemptions: (a) Following the death or disability, as defined in section 72(m)(7) of the IRC, of a shareholder; (b) in connection with certain distributions from an individual retirement account, a custodial account maintained pursuant to IRC section 403(b)(7), or a qualified pension or profit-sharing plan ("Retirement Plans"), as described below; (c) of shares purchased by present or former Director/Trustees of the Fund, by the relatives of any such person, by any trust, individual retirement account or retirement plan account for the benefit of any such person or relative, or by the estate of any such person or relative; and (d) in connection with the exchange of Class B Shares of a Fund for Class B Shares of another Fund.

20. If a Fund waives or reduces the CDSC, such waiver or reduction will be uniformly applied to all offerees in the class specified. Also, in waiving or reducing a CDSC, the Funds will comply with the requirements of rule 22d–1 under the Investment Company Act as if such CDSC were a sales load. If the Directors/Trustees of a Fund determine to discontinue the waiver of the CDSC, the disclosure in the Fund's prospectus will be appropriately revised. Also, any Class B Shares purchased prior to the termination of such waiver will be able to have the CDSC waived as provided in the Fund's prospectus at the time of the purchase of such shares. Applicants will comply with Section 26 of the Rules of Fair Practice of the National Association of Securities Dealers.

Applicant's Legal Conclusions

1. Applicants request an exemptive order to the extent that the proposed issuance and sale of Class A, Class B, and Class C Shares representing interests in the Funds might be deemed: (a) To result in the issuance of a "senior security" within the meaning of section 18(g) of the Act and thus be prohibited by section 18(f)(1) of the Act; and (b) to violate the equal voting provisions of section 18(i) of the Act.

2. The proposed Triple Distribution System does not create the potential for the abuses that section 18 was designed to redress. The proposed arrangement will not increase the speculative character of the shares of any Fund. The proposal does not involve borrowing, and all shares will bear, based on the relative net assets of each class, all of the Fund's expenses except the differing rule 12b–1 distribution fees, service fees and transfer agency costs.

3. All classes of shares will be redeemable at all times and no class of shares will have distribution or liquidation preferences with respect to particular assets. No class will have any right to require that lapsed dividends be paid before dividends are declared on the other class, and no class will be protected by any reserve or other account. Since the similarities (and, with respect to the distribution fees, service fees, voting rights, Class B conversion feature, transfer agency costs, and exchange privileges, the dissimilarities) of the Class A, Class B and Class C Shares will be fully disclosed in the Fund's prospectus and statement of additional information, investors will not be given misleading impressions as to the safety or risk of the Class A, Class B and Class C Shares and the Class A, Class B and Class C Shares will not be rendered speculative.

4. The interests of the three classes of shares as to the advisory fees of each Fund are the same and are not in conflict because these fees are used solely to compensate the Adviser for providing management and advisory services that are common to all investors, regardless of the class of shares held. Further, the Directors/Trustees must analyze the reasonableness of the advisory fee, the distribution fee and the service fee under the standards defined by section 36(b) of the Act. Thus, the interests of each class of shareholders will be adequately protected.

5. The proposed allocation of expenses and voting rights relating to the rule 12b–1 distribution plan is equitable and will not discriminate against any group of shareholders. Investors purchasing Class A Shares will bear a proportionately lower share of the Funds' distribution expenses than holders of the Class B and Class C Shares. However, each class will vote separately as a class with respect to the Fund's rule 12b–1 distribution plan, except that, if the Fund submits to a vote of both the Class A shareholders and the Class B shareholders an amendment to the Fund's rule 12b–1 distribution plan that would materially increase the amount to be paid thereunder with respect to the Class A Shares, the Class A shareholders and the Class B shareholders will vote separately by class with regard to such amendment.

Applicants' Conditions

Applicants agree that any order granting the requested relief shall be subject to the following conditions:

1. The Class A, Class B and Class C Shares will represent interests in the same portfolio of investments of a Fund, and be identical in all respects, except as set forth below. The only differences among the Class A, Class B and Class C Shares of a Fund will relate solely to: (a) The impact of the disproportionate distribution fees and service fees allocated to each of the Class A shareholders, Class B shareholders, and Class C shareholders of the Fund, the disproportionate transfer agency costs attributable to each of the Class A, Class B, and Class C Shares of the Fund, and any other incremental expenses subsequently identified that should be properly allocated to one class which shall be approved by the Commission pursuant to an amended order; (b) the fact that each class will vote separately as a class with respect to the Fund's rule 12b–1 distribution plan and other matters for which separate class voting is appropriate under applicable law, provided that, if the Fund submits to a vote of both the Class A shareholders and the Class B shareholders an amendment to the Fund's rule 12b–1 distribution plan that would materially increase the amount to be paid thereunder with respect to the Class A Shares, the Class A shareholders and the Class B shareholders will vote separately by class; (c) the different exchange privileges of the Class A, Class B, and Class C Shares; (d) the fact that only Class B Shares will have a conversion feature; and (e) the designation of each class of shares of the Fund.

2. If a Fund implements any amendment to its rule 12b–1 plan (or, if presented to shareholders, adopts or implements any amendment of a non-rule 12b–1 shareholder services plan) that would increase materially the amount that may be borne by the Class A Shares under the plan, existing Class B Shares will stop converting into Class A unless the Class B shareholders, voting separately as a class, approve the proposal. The Directors/Trustees shall take such action as is necessary to ensure that existing Class B Shares are exchanged or converted into a new class of shares ("New Class A"), identical in all material respects to Class A as it existed prior to implementation of the proposal, no later than such shares previously were scheduled to convert into Class A. If deemed advisable by the Directors/Trustees to implement the foregoing, such action may include the exchange of all existing Class B Shares for a new class ("New Class B"), identical to existing Class B Shares in all material respects except that New

Class B will convert into New Class A. New Class A or New Class B may be formed without further exemptive relief. Exchanges or conversions described in this condition shall be effected in a manner that the Directors/Trustees reasonably believe will not be subject to federal taxation. In accordance with condition 4, any additional cost associated with the creation, exchange, or conversion of New Class A or New Class B shall be borne solely by the Adviser and the Distributor. Class B Shares sold after the implementation of the proposal may convert into Class A Shares subject to the higher maximum payment, provided that the material features of the Class A plan and the relationship of such plan to the Class B Shares are disclosed in an effective registration statement.

3. The Directors/Trustees of each of the Funds, including a majority of the independent Directors/Trustees, shall have approved the Triple Distribution System prior to the implementation of the Triple Distribution System by a particular Fund. The minutes of the meetings of the Directors/Trustees of each of the Funds regarding the deliberations of the Directors/Trustees with respect to the approvals necessary to implement the Triple Distribution System will reflect in detail the reasons for determining that the Triple Distribution System is in the best interests of both the Funds and their respective shareholders.

4. On an ongoing basis, the Directors/Trustees of the Funds, pursuant to their fiduciary responsibilities under the Investment Company Act and otherwise, will monitor each Fund for the existence of any material conflicts among the interests of the three classes of shares. The Directors/Trustees, including a majority of the independent Directors/Trustees, shall take such action as is reasonably necessary to eliminate any such conflicts that may develop. The Adviser and the Distributor will be responsible for reporting any potential or existing conflicts to the Directors/Trustees. If a conflict arises, the Adviser and the Distributor at their own cost will remedy such conflict up to and including establishing a new registered management investment company.

5. The Directors/Trustees of the Funds will receive quarterly and annual statements complying with paragraph (b)(3)(ii) of rule 12b–1, as it may be amended from time to time. In the statements, only distribution expenditures properly attributable to the sale of a particular class will be used to justify the distribution fee charged to that class. Expenditures not related to the sale of a particular class will not be presented to the Directors/Trustees to support the distribution fee attributable to that class. The statements, including the allocations upon which they are based, will be subject to the review and approval of the independent Directors/Trustees in the exercise of their fiduciary duties.

6. Dividends paid by a Fund with respect to its Class A Shares, Class B Shares and Class C Shares, to the extent any dividends are paid, will be calculated in the same manner at the same time on the same day and will be in the same amount, except that distribution fee payments relating to each respective class of shares will be borne exclusively by that class and any incremental transfer agency costs relating to the Class A, Class B or Class C Shares will be borne exclusively by that class.

7. The methodology and procedures for calculating the net asset value and dividends and distributions of the Class A, Class B, and Class C Shares, and the proper allocation of expenses among the classes, have been reviewed by an expert (the "Expert"). The Expert has rendered a report to the Applicants, which has been provided to the staff of the Commission as an exhibit to the application, stating that such methodology and procedures are adequate to ensure that such calculations and allocations will be made in an appropriate manner, subject to the conditions and limitations in that report. On an ongoing basis, the Expert, or an appropriate substitute Expert, will monitor the manner in which the calculations and allocations are being made under the Triple Distribution System and, based upon such review, will render at least annually a report to the Funds that the calculations and allocations are being made properly. The reports of the Expert shall be filed as part of the periodic reports filed with the Commission pursuant to sections 30(a) and 30(b)(1) of the Act. The work papers of the Expert with respect to such reports, following request by the Funds, (which the Funds agree to provide), will be available for inspection by the SEC staff upon the written request to the Funds for such work papers by a senior member of the Division of Investment Management, limited to the Director, an Associate Director, the Chief Accountant, the Chief Financial Analyst, an Assistant Director, and any Regional Administrators or Associate and Assistant Administrators. The initial report of the Expert will be a "Special Purpose" report on the "Design of a System" and the ongoing reports have been and will continue to be "Special Purpose" reports on the "Design of a System and Certain Compliance Tests" as defined and described in SAS No. 44 of the AICPA, as it may be amended from time to time, or in similar auditing standards as may be adopted by the AICPA from time to time.

8. The Applicants have adequate facilities in place to ensure implementation of the methodology and procedures for calculating the new asset value and dividends and distributions of the three classes of shares and the proper allocation of expenses among the three classes of shares. This representation will be concurred with by the Expert in the initial report referred to in condition 7 above, and will be concurred with by the Expert or an appropriate substitute Expert, on an ongoing basis at least annually in the ongoing reports referred to in condition 7 above. The Applicants will take immediate corrective measures if the Expert or appropriate Substitute Expert does not so concur in the ongoing reports.

9. The prospectuses of the Funds relating to the Class A, Class B, and Class C Shares will contain a statement to the effect that a salesperson and any other person may receive different levels of compensation for selling one particular class of shares over another in a Fund.

10. The Distributor will adopt compliance standards as to when Class A, Class B, and Class C Shares may appropriately be sold to particular investors. The Applicants will require all persons selling shares of the Funds to agree to conform to such standards.

11. The conditions pursuant to which the exemptive order is granted and the duties and responsibilities of the Directors/Trustees of the Funds with respect to the Triple Distribution System will be set forth in guidelines which will be furnished to the Directors/Trustees as part of the materials setting forth the duties and responsibilities of the Directors/Trustees.

12. Each Fund will disclose in its prospectus the respective expenses, performance data, distribution arrangements, services, fees, sales loads, deferred sale loads, and exchange privileges applicable to each class of shares offered through the prospectus. Class A, Class B and Class C Shares will be offered and sold through a single prospectus. The shareholder reports of each Fund will disclose the respective expenses and performance data applicable to each class of shares. The shareholder reports will contain, in the statement of assets and liabilities and

statement of operations, information related to the Fund as a whole generally and not on a per class basis. Each Fund's per share data, however, will be prepared on a per class basis with respect to all classes of shares of such Fund. To the extent any advertisement or sales literature describes the expenses or performance data applicable to Class A, Class B, or Class C Shares, it will disclose the expenses and/or performance data applicable to the three classes. The information provided by the Applicants for publication in any newspaper or similar listing of the Funds' net asset values and public offering prices will present separately Class A, Class B, and Class C Shares.

13. The Applicants acknowledge that the grant of the exemptive order requested by the application will not imply SEC approval, authorization or acquiescence in any particular level of payments that the Funds may make pursuant to their rule 12b–1 distribution plans in reliance on the exemptive order.

14. Class B Shares will convert into Class A Shares on the basis of the relative net asset values of the two classes, without the imposition of any sales load, fee or other charge.

Condition Relating to the CDSC

Applicants will comply with the provisions of proposed Rule 6c–10 under the Act, Investment Company Act Release No. 16169 (Nov. 2, 1988), as such rule is currently proposed and as it may be reproposed, adopted, or amended.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–329 Filed 1–7–93; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

[Public Notice 1752]

Shipping Coordinating Committee; Subcommittee on Safety of Life at Sea, Working Group on Ship Design and Equipment; Meeting

The Working Group on Ship Design and Equipment of the Subcommittee on Safety of Life at Sea (SOLAS) will conduct an open meeting on January 29, 1993 at 9:30 a.m. in room 4315 at United States Coast Guard Headquarters, 2100 2d Street SW., Washington, DC.

The purpose of the meeting will be to prepare for the 36th Session of the International Maritime Organization (IMO) Subcommittee on Ship Design and Equipment (DE) scheduled for February 22 to 26, 1993. Items of discussion will include the following: Use on board ships of ozone-depleting substances other than halons; guidelines on standard calculations for anchor positioning systems for mobile offshore drilling units (MODUs); guidelines for dynamic positioning systems for MODUs and ships engaged in similar operations; maneuverability of ships and maneuvering standards; helicopter facilities offshore and on ships; extension of the code on alarms and indicators; ventilation of vehicle decks during loading and unloading; consideration of the introduction of the Harmonized System of Surveys and certification into the MODU Code; revision of the Code of Safety for Dynamically Supported Craft; fuel line failures; reduction of secondary sources of pollution by minimizing the source of general flooding and by improving control of equipment vital to safe operation of the vessel; development of safety standards for combined pusher tug-barges; structural integrity of tankers and bulk carriers; review of existing ships' safety standards; requirements for ships intended for operation in polar waters; guidelines for standardization of the layout of essential instrumentation on the bridge and in the engine room; feasibility study on voyage data recorders; coating requirements for ballast tanks; revision of towing requirements—resolution A.535(XIII); safety of passenger submersibles; introduction of a standard for ship construction into SOLAS 1974; and, the role of the human element in maritime casualties.

The IMO DE Subcommittee works to develop international agreements, guidelines, and standards for machinery, equipment, and systems as these relate to the marine industry. In most cases, these international agreements, guidelines, and standards form the basis for national standards/regulations and class society rules. The U.S. SOLAS Working Group supports the U.S. Representative to the IMO DE Subcommittee in developing the U.S. position on those issues raised at the IMO DE Subcommittee meetings. Because of the impact on domestic regulations through development of these international guidelines, standards, and regulations, the U.S. SOLAS Working Group serves as an excellent forum for the U.S. maritime industry to express their ideas. All shipping companies, shipyards, design firms, naval architects, marine engineers, and consultants are encouraged to send representatives to participate in the development of U.S. positions on those issues affecting your maritime industry and remain abreast of all activities ongoing within IMO DE. Since these meetings are open to the public, anyone may attend up to the seating capacity of the room.

For further information contact LCDR Michael L. Blair at (202) 267–2206, U.S. Coast Guard Headquarters (G–MTH–2), 2100 Second Street SW., Washington, DC 20593–0001.

Dated: January 5, 1993.

Bruce Carter,

Executive Secretary, Shipping Coordinating Committee.

[FR Doc. 93–390 Filed 1–7–93; 8:45 am]

BILLING CODE 4710-07-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–93–1]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before January 28, 1993.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–10), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket

and are available for examination in the Rules Docket (AGC–10), room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Mrs. Jeanne Trapani, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7624.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on December 30, 1992.

Irshad Abdal-Haqq,

Acting Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 23858
Petitioner: Allison Gas Turbine Division, GMC
Sections of the FAR Affected: 14 CFR 34.7 (a) and (b)
Description of Relief Sought: To extend the termination date of Exemption 5383, which expires March 31, 1993, and which allows Allison Gas Turbine Division, GMC (Allison) to produce a very low number of engines that do not meet EPA emission standards, and which allows Allison to produce twelve 501–D22A engines for installation on Lockheed L–100 aircraft to be exported from the United States.

Docket No.: 27051
Petitioner: Coastal Air Service, Inc.
Sections of the FAR Affected: 14 CFR 141.27(c)(2)
Description of Relief Sought: to relieve Coastal Air Service, Inc., from the requirement for a provisional pilot school certificate holder to wait at least 180 days after the certificate expires before reapplying.

Dispositions of Petitions

Docket No.: 26817
Petitioner: Barry F. Clause
Sections of the FAR Affected: 14 CFR 61.101(b)(1)(iii)
Description of Relief Sought/ Disposition: To allow Mr. Clause to operate a UH–12C Hiller helicopter, which has a powerplant of more than 180 horsepower, which only a recreational pilot certificate. *Denial, December 22, 1992, Exemption No. 5580*

Docket No.: 26964
Petitioner: L.R. Services
Sections of the FAR Affected: 14 CFR 135.165 (6) and (7), and 91.511(a)
Description of Relief Sought/ Disposition: A permanent exemption to allow L.R. Services to operate its aircraft in extended overwater operations equipped with one high-frequency communication system. *Partial grant, December 18, 1992, Exemption No. 5579*

[FR Doc. 93–370 Filed 1–7–93; 8:45 am]
BILLING CODE 4910–13–M

[Summary Notice No. PE–93–2]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before January 28, 1993.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC–10), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC–10), room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–3132.

FOR FURTHER INFORMATION CONTACT: Mrs. Jeanne Trapani, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7624.

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on December 30, 1992.

Irshad Abdal-Haqq,

Acting Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No. 22558
Petitioner: Boeing Commercial Airplane Group
Sections of the FAR Affected: 14 CFR 47.69(b)
Description of Relief Sought: To extend the termination date of Exemption No. 3513, which expires May 1, 1993, and which allows operation of aircraft outside the United States using a Dealer's Aircraft Registration Certificate, subject to limits and conditions.

Docket No. 26734
Petitioner: Shannon Engineering, Inc.
Sections of the FAR Affected: 14 CFR 91.9(a) and 91.531(a)(1)
Description of Relief Sought: To amend Condition 3 of Exemption No. 5517, which expires September 30, 1994, to reduce the 500 hours required as pilot in command or copilot of turbojet airplanes in exchange for turbo-powered flight time.

Dispositions of Petitions

Docket No. 17681
Petitioner: Kenmore Air Harbor, Inc.
Sections of the FAR Affected: 14 CFR 135.203(a)(1)
Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 2528, which permits Kenmore Air Harbor, Inc., to conduct operations under visual flight rules (VFR) outside of controlled airspace, overwater, at an altitude below 500 feet. *Grant, December 11, 1992, Exemption No. 2528H*

Docket No. 24671
Petitioner: Bell Helicopter Textron, Inc.
Sections of the FAR Affected: 14 CFR 21.231(a)(3)
Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 5257, which allows Bell Helicopter Textron, Inc., to apply for a delegation option authorization for the type, production, and airworthiness certification of transport category helicopters. *Grant, December 17, 1992, Exemption No. 5257A*

Docket No. 25628
Petitioner: Moody Aviation
Sections of the FAR Affected: 14 CFR part 141, Appendix A

Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 5032, and to amend it to allow Moody Aviation to graduate a part 141 student with a "night flying prohibited" limitation on the private pilot certificate, and to modify Condition 4 to read, "Moody shall amend its Private Pilot Training Course curriculum to delete the night flying requirements." *Grant, December 11, 1992, Exemption No. 5032B*

Docket No. 26359
Petitioner: Federal Express Corporation
Sections of the FAR Affected: 14 CFR 121.623(a)
Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 5264, which expires on December 31, 1992, and to amend the exemption to allow Federal Express Corporation to comply with the alternate airport and fuel requirements for domestic air carriers, and to include McDonnell Douglas MD–11 and Airbus A–300 airplanes. *Grant, December 11, 1992, Exemption No. 5264B*

Docket No. 26859
Petitioner: Precision Airlines, Inc.
Sections of the FAR Affected: 14 CFR 93.123, 93.125, and 93.129
Description of Relief Sought/ Disposition: To allow Precision Airlines, Inc., to conduct additional Separate Access Landing System commuter operations at John F. Kennedy International Airport using short takeoff and landing aircraft and special procedures. *Grant, December 16, 1992, Exemption No. 5577*

Docket No. 26982
Petitioner: Captain David M. Warner
Sections of the FAR Affected: Section 501(b) of the Federal Aviation Act of 1958
Description of Relief Sought/ Disposition: To allow Captain Warner to register a U.S. civil aircraft in his name, even though he is neither a U.S. citizen nor a resident alien who has been lawfully admitted for permanent residence into the United States. *Denial, December 11, 1992, Exemption No. 5575*

Docket No. 27031
Petitioner: Temsco Helicopters, Inc.
Sections of the FAR Affected: 14 CFR 133.19(a)(3) and 133.51
Description of Relief Sought/ Disposition: To allow Temsco to perform certain rotorcraft external-load operations (i.e., logging) in the United States using a Canadian-registered S–61 Sikorsky helicopter. *Grant, December 16, 1992, Exemption No. 5576*

Docket No. 27908
Petitioner: Hartzell Propeller, Inc.
Sections of the FAR Affected: 14 CFR 21.231(a)
Description of Relief Sought/ Disposition: To extend the termination date of Exemption No. 5266, which expires December 31, 1992, and which allows Hartzell Propeller, Inc., to apply for a delegation option authorization for the type, production, and airworthiness certification of propellers manufactured for use on turbopropeller and reciprocating engines of not more than 1,500 brake horsepower. *Grant, December 18, 1992, Exemption No. 5266A*

Docket No. 111CE
Petitioner: Air Tractor, Inc.
Sections of the FAR Affected: 14 CFR 23.49(b)(1)
Description of Relief Sought/ Disposition: To allow certification of the Air Tractor model AT–802A with stall speeds greater than the 61 knot requirement. *Grant, December 11, 1992, Exemption No. 5574*

[FR Doc. 93–371 Filed 1–7–93; 8:45 am]
BILLING CODE 4910–13–M

Intent to Rule on Application to use the revenue from a passenger facility charge (PFC) at Southwest Florida Regional Airport, Fort Myers, FL

AGENCY: Federal Aviation Administration (FAA), DOT.
ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to use the revenue from a PFC at Southwest Florida Regional Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 8, 1993.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Orlando Airports District Office, 9677 Tradeport Drive, suite 130, Orlando, Florida 32827–5397.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Paul Doherty, Executive Director of the Lee County Port Authority at the following address: 16000 Chamberlain Parkway, suite 8671, Fort Myers, Florida 33913–8899.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Lee County Port Authority under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Bart Vernace, Airport Plans & Programs Manager, Orlando Airports District Office, 9677 Tradeport Drive, suite 130, Orlando, Florida 32827–5397, (407) 648–6583. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to use the revenue from a PFC at Southwest Florida Regional Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation regulations (14 CFR part 158).

On December 28, 1992, the FAA determined that the application to use the revenue from a PFC submitted by the Lee County Port Authority was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than April 21, 1993.

The following is a brief overview of the application.

Level of the approved PFC: $3.00
Actual charge effective date: November 1, 1992
Estimated charge expiration date: June 1, 2015
Total estimated PFC revenue: 257,673,262.00
Brief description of proposed projects: Project 1103—Commuter Terminal, Project 1201—Runway 6/24 Extension, Project 1204—Commuter Aircraft Ramp
Class or classes of air carriers which the FAA has approved exemption from collection of PFCs: Air Taxi/ Commercial Operators filing FAA Form 1800—31.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT.**

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Lee County Port Authority.

Issued in Atlanta, Georgia on December 28, 1992.

Stephen A. Brill,
Manager, Airports Division, Southern Region.

[FR Doc. 93–372 Filed 1–7–93; 8:45 am]
BILLING CODE 4910–13–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 5
Friday, January 8, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at 10:05 a.m. on Tuesday, January 5, 1993, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to administrative enforcement proceedings and to the Corporation's corporate activities.

In calling the meeting, the Board determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director Stephen R. Steinbrink (Acting Comptroller of the Currency), concurred in by Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision) and Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Dated: January 5, 1993.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 93-457 Filed 1-6-93; 4:48 pm]

BILLING CODE 6714-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS.

TIME AND DATE: 10:00 a.m., Wednesday, January 13, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: January 5, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board

[FR Doc. 93-458 Filed 1-5-93; 4:51 pm]

BILLING CODE 6210-01-M

NATIONAL CREDIT UNION ADMINISTRATION

Notice of Meetings

TIME AND DATE: 9:30 a.m., Thursday, January 14, 1993.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, NW., Washington, DC 20456.

STATUS: Open.

BOARD BRIEFINGS:

1. Central Liquidity Facility Report and Report on CLF Lending Rate.
2. Insurance Fund Report.
3. Report on Regulatory Review.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Open Meeting.
2. Interest Rate Ceiling on Credit Union Loans.
3. Proposed Charter for Central Brooklyn Federal Credit Union, Brooklyn, New York.
4. Proposed Rule: Amendment to Part 703, NCUA's Rules and Regulations, Investment and Deposit Authority.
5. Final Rule: Amendment to Part 741, NCUA's Rules and Regulations, Requirements for Insurance.
6. Proposed Rule: Amendment to Section 748.1(c), NCUA's Rules and Regulations, Criminal Referral Forms.
7. Appeal by Luke Federal Credit Union of Regional Director's Denial of Field of Membership Expansion.

RECESS: 10:45 a.m.

TIME AND DATE: 11:00 a.m., Thursday, January 14, 1993.

PLACE: Filene Board Room, 7th Floor, 1776 G Street, NW., Washington, DC 20456.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Approval of Minutes of Previous Closed Meeting.
2. Administrative Actions under Section 206 of the FCU Act. Closed pursuant to exemptions (6), (9)(A)(ii), and (9)(B).
3. Request by Credit Union for Waivers from Part 704, NCUA's Rules and Regulations. Closed pursuant to exemption (8).
4. Appeal under Parts 709 and 745, NCUA's Rules and Regulations. Closed pursuant to exemptions (6) and (8).
5. Appeal under Part 709, NCUA's Rules and Regulations. Closed pursuant to exemptions (6), (8), and (9)(B).
6. Personnel Actions. Closed pursuant to exemption (2).

FOR MORE INFORMATION CONTACT: Becky Baker, Secretary of the Board, Telephone (202) 682-9600.

Becky Baker,

Secretary of the Board.

[FR Doc. 93-524 Filed 1-6-93; 12:23 pm]

BILLING CODE 7535-01-M

NUCLEAR REGULATORY COMMISSION

DATE: Weeks of January 11, 18, 25, and February 1, 1993.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of January 11

Monday, January 11

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of January 18—Tentative

Thursday, January 21

11:30 a.m.
Affirmation/Discussion and Vote (Public Meeting) (if needed)

2:00 p.m.
Briefing by NUMARC on Industry Review of NRC Regulations and Regulatory Process (Public Meeting) (Contact: NUMARC—Joe Colvin, 202-872-1280)

Friday, January 22

2:00 p.m.
Briefing on Status of Medical Use Activities (Public Meeting) (Contact: John Greeves, 301-504-3334)

Week of January 25—Tentative

Friday, January 29

10:00 a.m.

Briefing on Implementing Guidance for the Maintenance Rule and Industry Verification and Validation Effort (Public Meeting) (Contact: William Russell, 301–504–1274)

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

2:00 p.m.

Briefing by Agreement States on Their Activities in Medical Use Area (Public Meeting) (Contact: Carlton Kammerer, 301–504–2321)

Week of February 1—Tentative

Wednesday February 3

11:30 a.m.

Affirmation/Discussion and Vote (Public Meeting) (if needed)

Note.—Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has yet been identified as requiring any Commission vote on this date.

TO VERIFY THE STATUS OF MEETING CALL (RECORDING): (301) 504–1292.

CONTACT PERSON FOR MORE INFORMATION: William Hill (301) 504–1661.

Dated: January 6, 1993.

William M. Hill, Jr.,

SECY Tracking Officer, Office of the Secretary.

[FR Doc. 93–482 Filed 1–6–93; 10:48 am]

BILLING CODE 7590–01–M

Corrections

Federal Register

Vol. 58, No. 5

Friday, January 8, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 633

[Docket No. 920778-2263]

RIN 0648-AD63

Pacific Coast Groundfish Fishery

Correction

In rule document 92-27718 beginning on page 54001 in the issue of Monday, November 16, 1992, make the following corrections:

1. On page 54005, in the first column, in the second paragraph, in the first line, "The" should read "Three".

§ 663.35 [Corrected]

2. On page 54009, in the first column, in § 663.35(a)(3), in the seventh line, "my" should read "may".

§ 663.36 [Corrected]

3. On page 54010, in the first column, in § 663.36(a)(2), in the seventh line, "not" should read "no".

BILLING CODE 1505-01-D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 642

[Docket No. 920810-2304]

RIN 0648-AE23

Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic

Correction

In rule document 92-29747 beginning on page 58151 in the issue of Wednesday, December 9, 1992, make the following corrections:

§ 642.7 [Corrected]

1. On page 58154, in the second column, in § 642.7(a), in the first line, "coast" should read "coastal".

§ 642.21 [Corrected]

2. On page 58155, in the first column, in § 642.21(b), in the sixth line, "(25°40.4'N. latitude)" should read "(25°20.4'N. latitude)".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Injury Research Grant Review Committee: Meeting

Correction

In notice document 92-30957 appearing on page 60816 in the issue of Tuesday, December 22, 1992, in the second column, under *Status:*, in the first line, "9 p.m.," should read "9:30 p.m.".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT-070-03-4210-04; M81796]

Realty Action: Exchange, MT

Correction

In notice document 92-30244 beginning on page 59120 in the issue of Monday, December 14, 1992, make the following corrections:

1. On page 59120, in the second column, in the land description for *Gallatin County*, T. 1 S.,R. 2 E., in Sec. 33, "SW¼SE¼" should read "SE¼SE¼".

2. On page 59121, in the first column, in the land description for *Powell County*, under T. 11 N., R. 9 W.,, "Sec. 34: S½, SW¼, NE¼" should read "Sec. 34: S½SW¼, NE¼".

3. On the same page, in the same column, in the same land description, under T. 12 N., R. 10 W., "Sec. 3: W½SW¼SE¼" should read "Sec. 3: W½E½SW¼SE¼".

BILLING CODE 1505-01-D

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Declined General Applications for Federal Assistance

Correction

In notice document 92-29661 beginning on page 58031 in the issue of Tuesday, December 8, 1992, make the following corrections:

1. On page 58031, in the third column, in the fifth paragraph, in the first line, "The Circular" should read "This Circular".

2. On the same page, in the same column, in the same paragraph, in the 14th line, "direction" should read "discretion".

BILLING CODE 1505-01-D

NUCLEAR REGULATORY COMMISSION

Correction

In Sunshine Act meeting notice document 92-30484 appearing on page 59378 in the issue of Tuesday, December 15, 1992, make the following corrections:

1. On page 59378, in the 2nd column, under the heading "Week of December 21-Tentative", the 13th and 14th lines should be removed.

2. On the same page, in the third column, the first through sixth lines should be removed.

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8449]

RIN 1545-AE26

Election, Revocation, Termination, and Tax Effect of Subchapter S Status

Correction

In rule document 92-28193 beginning on page 55445 in the issue of Wednesday, November 25, 1992, make the following correction:

§ 1.1362-0 [Corrected]

On page 55448, in the third column, in § 1.1362-0, in the table of contents entry for § 1.1362-3(c)(6), in the second

line, "includable" should read "includible".

BILLING CODE 1505-01-D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[GL-709-86]
RIN 1545-AM70

Levy and Distraint

Correction

In proposed rule document 92-29633 beginning on page 58760 in the issue of Friday, December 11, 1992, make the following corrections:

§ 301.6331-1 [Corrected]

1. On page 58762, in the 2nd column, in § 301.6331-1(b)(1), in the 11th line, "They" should read "The".

2. On the same page, in the 3rd column, in the same section, in paragraph (b)(1), in the 11th line, "make" should read "made".

§ 301.6331-2 [Corrected]

3. On page 58763, in the second column, in § 301.6331-2(c), in the tenth line, "the" should read "that".

BILLING CODE 1505-01-D

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federal register

Friday
January 8, 1993

Part II

Environmental Protection Agency

40 CFR Part 81
Air Quality Designations and Classifications; Amendments; Final Rule

VOL 58 ISS 5 JA 8 1993 UMI

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[AD-FRL-4158-4]

RIN NO. 2060-AC56

Reclassification of Moderate PM-10 Nonattainment Areas to Serious Areas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Under section 188(b)(1) of the Clean Air Act, EPA is reclassifying as serious four areas in California and one area in Nevada which were initially classified as moderate nonattainment areas for PM-10 (particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers).

EFFECTIVE DATE: This action will become effective on February 8, 1993.

ADDRESSES: The technical reports referenced in today's document can be found in Public Docket No. A-91-53. The docket is located at the U.S. EPA Air Docket, Rm. M-1500, Waterside Mall, LE-131, 401 M St., SW., Washington, DC 20460. The docket may be inspected from 8:30 a.m. to 12 noon and from 1:30 p.m. to 3:30 p.m. on weekdays except for legal holidays, and a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Eric Ginsburg, Air Quality Management Division, Mail Drop 15, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711, (919) 541-0877.

SUPPLEMENTARY INFORMATION:

ELECTRONIC AVAILABILITY: This document is available as an electronic file on *The Federal Bulletin Board* at 9 a.m. the day of publication in the **Federal Register**. By modem dial 202-512-1387 or call 202-512-1530 for disks or paper copies. This file is available in Postscript, Wordperfect 5.1, and ASCII.

I. Background

On the date of enactment of the 1990 Clean Air Act Amendments, PM-10 areas meeting the qualifications of section 107(d)(4)(B) of the Act were designated nonattainment by operation of law [see generally, 42 U.S.C. 7407(d)(4)(B) of the Act; references in this notice to "the Act" or "the Clean Air Act" are to the Clean Air Act, as amended, 42 U.S.C. 7401 et seq.]. These areas included all former Group I areas identified in 52 FR 29383 (August 7, 1987) and clarified in 55 FR 45799 (October 31, 1990), and any other areas violating the PM-10 standards prior to January 1, 1989 (many of these areas were identified by footnote 4 in the October 31, 1990 **Federal Register** document). A **Federal Register** document announcing all of the areas designated nonattainment for PM-10 at enactment and classified as moderate was published in 56 FR 11101 (March 15, 1991). A followup notice correcting some of these areas was published August 8, 1991 (56 FR 37654). These nonattainment designations and moderate area classifications were codified in 40 CFR part 81 in a **Federal Register** document published on November 6, 1991 (56 FR 56694). All of the areas in the Nation not designated nonattainment at enactment were designated unclassifiable [see section 107(d)(4)(B)(iii) of the Act].

Once an area is designated nonattainment, section 188 of the Act outlines the process for classification of the area and establishes the area's attainment date. In accordance with section 188(a) of the Act, at the time of designation, all PM-10 nonattainment areas are initially classified as moderate by operation of law.

A moderate area can subsequently be reclassified as serious either before the applicable moderate area attainment date if EPA determines the area cannot "practicably" attain the PM-10 NAAQS by this attainment date, or following the passage of the applicable moderate area attainment date if EPA determines the area has failed to attain the standard.

Under the plain meaning of the terms of section 188(b)(1) of the Act, EPA has general authority to reclassify at any time before the applicable attainment date any area EPA determines cannot practicably attain the standard by such date. Accordingly, section 188(b)(1) of the Act is a general expression of delegated rulemaking authority. In addition, subparagraphs (A) and (B) of section 188(b)(1) of the Act mandate that EPA reclassify "appropriate" PM-10 nonattainment areas at specified time frames (i.e., by December 31, 1991 for the initial PM-10 nonattainment areas, and within 18 months after the SIP submittal due date for subsequent nonattainment areas). These subparagraphs do not restrict EPA's general authority but simply specify that, at a minimum, it must be exercised at certain times.[1] Any decision by EPA to reclassify an area as serious before the applicable attainment date will be based on facts specific to the nonattainment area at issue, and will only be made after providing notice in the **Federal Register** and an opportunity for public comment on the basis for EPA's proposed decision.

In those cases where EPA determines that an area has failed to attain the NAAQS by the applicable attainment date, the area is reclassified as serious by operation of law [see section 188(b)(2) of the Act]. The EPA must publish a notice in the **Federal Register** of such determinations and consequent reclassifications within 6 months following the applicable attainment date.

In accordance with section 188(b)(1)(A) of the Act, EPA is announcing the reclassification of those initial moderate nonattainment areas which EPA has determined at this time cannot "practicably" attain the PM-10 NAAQS by December 31, 1994, the applicable attainment date [see section 188(c)(1) of the Act]. As explained further below, today's action discharges EPA's statutory obligation under section 188(b)(1)(A) of the Act which required EPA to reclassify appropriate initial moderate PM-10 nonattainment areas as serious by December 31, 1991.

II. Determining That an Area Cannot Practicably Attain

Generally, EPA will rely on information in the State's SIP submittal, such as the control strategy, attainment demonstration, and compliance schedule to determine whether it is practicable to attain the NAAQS in that area by the applicable attainment date. The SIP's which were due on November 15, 1991 for the initial PM-10 moderate nonattainment areas were required to contain, among other requirements, a control strategy based upon the use of reasonably available control measures (RACM) which includes reasonably available control technology (RACT) [see sections 172(c)(1) and 189(a)(1)(C) of the Act].[2] The States were also required to demonstrate that the SIP's provide for timely implementation of RACM and attainment of the NAAQS. The RACM must be implemented in the initial PM-10 nonattainment areas by December 10, 1993, and the areas must attain the standard as expeditiously as practicable, but no later than December 31, 1994, unless an area can demonstrate that attainment by that date

[1] The EPA's interpretation of the reclassification provisions in section 188(b)(1) of the Act was discussed in the proposal for today's final rule and in the "General Preamble to Title I of the Clean Air Act Amendments of 1990," 57 FR 13537-13538 (April 16, 1992).

[2] The RACT is a subset of the overarching RACM requirement (see section 172(c)(1) of the Act). The RACT generally refers to only the technological control measures which apply to large stationary sources. Any reference to RACM herein implicitly includes RACT.

is impracticable [see sections 188(c)(1) and 189(a)(1)(C) of the Act].

There are at least three reasons why an area may not practicably attain the standards by the applicable attainment date. First, implementation of the SIP control strategy, including RACM, may not create sufficient emissions reductions to bring the area into attainment. The State will have demonstrated that an initial PM-10 nonattainment area cannot practicably attain the NAAQS by the applicable attainment date if the implementation of RACM by December 10, 1993 will not achieve sufficient emissions reductions to attain the standards by December 31, 1994. The EPA has interpreted RACM, including RACT, to be those emission-reduction measures which EPA believes are generally reasonable considering technological feasibility and costs of control. The State should prepare a reasoned justification to show that a particular control measure for an existing source is infeasible or otherwise unreasonable and, therefore, would not constitute RACM.[3] Otherwise, the SIP should include implementation of all available emission reduction measures that have not been demonstrated to be unreasonable.

Second, nonanthropogenic sources which cannot reasonably be controlled may contribute significantly to the violation of the PM-10 NAAQS in the area. Moreover, section 188(f) of the Act authorizes the Administrator to waive a specific attainment date for an area where the Administrator determines that nonanthropogenic sources contribute significantly to the violation of the PM-10 standard in the area. Section 188(f) of the Act also provides that the Administrator may, on a case-by-case basis, waive certain requirements applicable to serious areas where the Administrator determines that anthropogenic sources of PM-10 do not contribute significantly to violation of the PM-10 standard in the area.[4] Note that an area is reclassified if EPA determines that it cannot practicably meet the applicable attainment date or that it has failed to meet such date. Thus, reclassification is keyed to a specific date. If that date is waived, the area would not be subject to reclassification because there simply would be no date that the area cannot practicably meet or that the area fails to meet. Thus, while nonanthropogenic sources which cannot be reasonably controlled may be a reason an area cannot practicably attain, if such area qualifies for a waiver of the attainment date under section 188(f) of the Act, it may also be a basis for not reclassifying the area. Note that in today's action, in order not to undermine the waiver provision, EPA has given some consideration to Spokane's potential exclusion from reclassification under section 188(f) of the Act in determining whether it is "appropriate" to reclassify that area at this time.

Third, the area may be significantly impacted by PM-10 emissions emanating from outside the United States. In the latter case, the State may demonstrate that the area qualifies for treatment under section 179B(d) of the Act, which provides that areas which would have attained the NAAQS by the applicable attainment date but for emissions emanating from outside the United States shall not be subject to reclassification requirements under section 188(b)(2) of the Act (see 56 FR 58662). In such cases of international transport, the State will be expected to demonstrate and quantify the international contribution of PM-10 in the affected area. Any State containing an area which may qualify for treatment under this provision still must timely submit a moderate area SIP for such area. In order to have its moderate PM-10 SIP approved under section 179B(a) of the Act in addition to demonstrating that it would have timely attained the PM-10 NAAQS but for international emissions, the State must submit a moderate SIP meeting all requirements applicable to moderate PM-10 nonattainment areas other than the requirement that it demonstrate timely attainment.

The EPA may also consider reclassifying moderate areas for which a SIP has not been submitted whenever it becomes apparent, e.g., because of an extensive delay in submitting the SIP, that the area cannot practicably attain the standards by the end of 1994. The EPA also may determine that an area cannot practicably attain the PM-10 NAAQS by the applicable date when the State submits an incomplete or otherwise inadequate SIP for the area, which would not assure timely attainment and the State does not act expeditiously to correct such deficiencies. The EPA has notified certain States of their failure to submit PM-10 SIP revisions for the initial areas by the November 15, 1991 deadline and has notified some States that their SIP's are incomplete [see, e.g., 57 FR 19906 (May 8, 1992)]. These actions constituted determinations under section 179(a)(1) of the Act and were communicated in letters to affected State Governors. As provided under section 179(a) of the act, States containing areas for which EPA has made such determinations have up to 18 months from EPA's determination to submit the plan or plan revision before EPA is required to impose either the highway funding sanction or the requirement to provide two-to-one new source offsets described in section 179(b) of the Act. The EPA's determination also triggered the requirement for EPA to impose a Federal implementation plan as provided under section 110(c)(1) of the Act. In conjunction with the possible imposition of sanctions, EPA may propose or issue a final determination to reclassify the area as serious. Reclassification of an area as serious does not obviate the legal requirement to implement a moderate area SIP.[5]

III. Determination for Reclassification

As noted, the PM-10 reclassification provisions contain a general delegation of authority to the Administrator indicating that he "may" reclassify as serious "any" moderate nonattainment area that he determines "cannot practicably attain" the PM-10 NAAQS by the applicable statutory deadline [see section 188(b)(1) of the Act]. By its plain terms, this provision confers broad discretionary authority on the Administrator (hereafter referred to as the "discretionary" reclassification authority). As a subset of that broad authority, section 188(b)(1)(A) of the Act mandates that the Administrator propose to reclassify "appropriate" initial moderate nonattainment areas as serious by June 30, 1991 and take final action by December 31, 1991.[6]

As described above, initial moderate area SIP's were due November 15, 1991. Thus, EPA did not have the benefit of these required SIP submittals before developing and issuing the reclassification proposal required under section 188(b)(1)(A) of the Act. In the absence of better information, EPA used surrogate criteria as evidence of an area's ability to timely attain and proposed to reclassify 14 areas relying on that criteria. However, in its proposal, EPA also contemplated that it may get better information about an area's ability to attain in, for example,

[3] See the "General Preamble to Title I of the Clean Air Act Amendments of 1990," 57 FR 13540-13544 and 13560-13561 (April 16, 1992).

[4] The EPA has made available to the public draft guidance on the application of the waiver provisions under section 188(f) of the Act [see 57 FR 31477 (July 16, 1992)] and will finalize that guidance at a later date.

[5] See 56 FR 58658 (November 21, 1991), note 3.

[6] This directive does not restrict EPA's general authority, but simply specifies that it must be exercised, at a minimum, in accordance with certain dates for areas designated nonattainment under section 107(d)(4)(b) of the Act.

the form of the required SIP submittals.[7] Thus, EPA entertained the possibility of receiving information which rebutted the indicators (56 FR 58658; Nov. 21, 1991): Thus, while EPA believes the indicators for assessing an area's ability, or inability, to attain area reasonable, they are rebuttable on a case-by-case basis.

Since this proposal, EPA has received SIP's for some of the 14 areas identified and has received other information bearing on the determination of whether it is appropriate to reclassify such areas at this time. For example, EPA has received SIP submittals and detailed SIP work plans for some of the areas identified in EPA's proposal which purport to provide for timely attainment. As noted, EPA is directed by the statute to make a final decision to reclassify appropriate areas by a date certain and that date has already passed. Due to these time constraints, EPA cannot fully review the SIP's or wait for SIP's which have not yet been submitted. On the other hand, EPA believes this information is relevant and should be given at least some consideration. The EPA has reconciled this dilemma by preliminarily reviewing the SIP submittals and other relevant information (including the public comments submitted in response to EPA's proposal). To the extent such information indicates, contrary to the criteria identified in EPA's proposal, that the area may be able to practicably attain by the end of 1994, EPA is determining that it is not appropriate to reclassify the area at this time and, hence, has declined to take final action on such area in today's rulemaking.

Nevertheless, EPA may conclude at a later date that one of these areas cannot practicably attain. For example, a full review of the required SIP submittal may reveal that the area cannot practicably attain. In addition, the delays in developing and submitting the required November 15, 1991 SIP submittal may become so prolonged that the area cannot practicably attain. In such instances, EPA would exercise its discretionary authority under section 188(b)(1) of the Act to reclassify the area.

Note that EPA's decision not to reclassify these areas at this time does not mean that any SIP relied on in making such determination will be approved. If a SIP purports to demonstrate attainment, that is simply strong evidence contradicting EPA's criteria and militating against reclassifying the area at that time. The EPA may conclude after a full review of the SIP that it has deficiencies that warrant less than full approval. Further, if such deficiency would preclude an area from timely attaining, then EPA may exercise its discretionary authority to reclassify the area. In any case, no binding EPA decision about the approvability of any such SIP will be made until the public has had an opportunity to comment on such decision.

In some instances, EPA's preliminary review of the SIP for an area revealed that the area could not practicably attain by the required date and should be reclassified. These are the areas reclassified in today's action. Specifically, in today's action, EPA is reclassifying five areas (listed in Table 1 and discussed below) which EPA has determined, at this time, cannot practicably attain by December 31, 1994. The EPA has not received public comments or other information during the public comment period in opposition to EPA's decision to reclassify these areas.

Note that, as indicated in EPA's proposal, reclassification of an area in no manner obviates the obligation to submit a moderate area SIP (56 FR 58658; Nov. 21, 1991). Thus, those areas reclassified in today's action must, among other things, submit provisions to assure that reasonably available control measures (including reasonably available control technology) are implemented no later than December 10, 1993 and submit a demonstration that attainment by December 31, 1994 is impracticable.

Two areas identified in EPA's proposal have requested treatment under the International Border provision (see section 179B of the Act). While EPA has not yet received a PM-10 SIP for either of these areas, EPA has significant information suggesting that the areas may qualify for treatment under section 179B of the Act, including an exclusion from reclassification under section 179B(d) of the Act[8]. Because EPA has information indicating that these areas are significantly impacted by emissions emanating from Mexico, but insufficient information to determine whether they would qualify for treatment under section 179B of the Act, EPA is declining to reclassify these areas at this time. This represents, in some fashion, a change in position from EPA's proposal in that EPA believes the information currently available to EPA, standing alone, is a sufficient basis upon which to conclude that these areas should not be reclassified at this time. So as not to undermine section 179B of the Act, EPA believes it is reasonable to conclude that it is not "appropriate" to reclassify these areas at this time where there is some significant evidence suggesting that these areas may qualify for an exclusion from reclassification under that provision.

However, EPA may reclassify these areas using its discretionary reclassification authority should EPA at some time in the future determine, for example, that the areas cannot practicably attain and do not qualify for exclusion from reclassification under section 179B(d) of the Act. For example, prolonged delays in submitting the required SIP for these areas may lead EPA to conclude at some future time that these areas cannot practicably attain by the end of 1994.

In sum, in today's final rulemaking, EPA is reclassifying those areas which EPA has determined at this time cannot practicably attain the PM-10 NAAQS by the applicable statutory attainment date. Today's action wholly discharges EPA's statutory duty to reclassify "appropriate" moderate areas as serious by December 31, 199 [see section 188(b)(1)(A) of the Act]. However, EPA also reserves the right to use its broad discretionary authority under section 188(b)(1) of the Act to reclassify at a later date the nine areas EPA declined to reclassify in today's action. If, at times in the future before the applicable attainment date, EPA determines that such areas cannot practicably attain the PM-10 NAAQS, EPA will take final

[7] The statute does not specify what information EPA must consider in exercising the authority delegated to it by section 188(b)(1) of the Act. Since the statute does not address this precise question, EPA may base a decision that an area cannot practicably attain by the applicable date on any relevant information, which may inlcude SIP submittals, modeling demonstrations, or other reasonable information [*Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 842-845 (1984)].

[8] Section 179B(d) of the Act states that areas demonstrating attainment of the NAAQS but for emissions emanating from outside the United States shall not be subject to section 188(b)(2) of the Act (reclassification for failure to attain). By analogy to this provison and applying rules of statutory construction, EPA will not reclassify before the applicable attainment date areas which can demonstrate attainment of the NAAQS but for emissions emanating from outside the United States [see section 188(b)(1) of the Act]. First, section 179B of the Act evinces a general congressional intent not to penalize areas where emissions emanating from outside the country are the but-for case of the PM-10 attainment problems. Further, if EPA were to reclassify such areas before the applicable attainment date, EPA, in effect, would be reading section 179(d) of the Act out of the statute. Specifically, if EPA proceeded to reclassify before the applicable attainment date those areas qualifying for treatment under section 179B of the Act, an area would never be subject to the provision in section 179B(d) of the Act which prohibits EPA from reclassifying such areas after the applicable attainment date. Canons of statutory construction counsel against interpreting the law such that language is rendered mere surplusage (see 56 FR at 58662; Nov. 21, 1991, note 12).

action to reclassify these areas. Note that the materials in the rulemaking docket for today's action pertaining to the nine areas not reclassified today will remain in force as part of the ongoing rulemaking record for any future decision to reclassify these areas utilizing EPA's discretionary authority.

TABLE 1.—AREAS WHICH EPA IS RECLASSIFYING AT THIS TIME[1]

EPA region	Area of concern	Sources
IX	San Joaquin Valley, CA	FD[2], secondary PM, PB[3]
IX	Owens Valley, CA	FD
IX	South Coast Air Basin, CA	Secondary PM, FD
IX	Coachella Valley, CA	FD
IX	Las Vegas, NV	FD

[1] The full legal descriptions for these areas reclassified in today's document are indicated in the revisions to 40 CFR part 81 at the end of this document.
[2] FD = Fugitive dust.
[3] PB = Prescribed burning.

IV. Areas Which EPA is Reclassifying at This Time

Coachella Valley, California. The EPA is reclassifying the Coachella Valley nonattainment area at this time because the SIP for the area submitted to EPA by the State of California on November 15, 1991 suggests that it is not practicable to provide for attainment of the annual and 24-hour PM-10 NAAQS until December 31, 1995, 1 year after the moderate area attainment date. The PM-10 SIP for the Coachella Valley indicates that 97 percent of the PM-10 emissions are due to fugitive dust sources. The most significant of these sources are construction activities, reentrained dust from paved roads, and windblown dust from agricultural and disturbed lands.

Las Vegas, Nevada. The EPA is reclassifying the Las Vegas nonattainment area due to the fact that the PM-10 SIP submitted to EPA by the State of Nevada on December 6, 1991 suggests that implementation of the control measures contained in the SIP will result in sufficient emissions reductions to attain the annual PM-10 NAAQS by December 31, 1994, but that it will not be practicable to timely attain the 24-hour PM-10 NAAQS. A 1989 valley-wide emissions inventory suggests that a substantial amount of PM-10 emissions are due to fugitive dust sources. Microinventories indicate that significant sources of fugitive dust include construction activities, paved and unpaved roads, and windblown dust from disturbed vacant land including disturbed desert.[9]

Owens Valley, California. The EPA is reclassifying the Owens Valley nonattainment area at this time based upon the fact that the PM-10 SIP submitted to EPA by the State of California on January 9, 1992 suggests that the area cannot practicably attain the PM-10 standards by December 31, 1994. Ambient PM-10 levels in Owens Valley are among the highest in the country. In 1989, for instance, the highest 24-hour PM-10 concentration observed in the area was 1861 micrograms per cubic meter (ug/m^3), in contrast to the NAAQS of 150 ug/m^3. The PM-10 SIP for Owens Valley includes an analysis of wind direction and wind speed on days when PM-10 levels are high, which indicates that the major source causing violations of the PM-10 NAAQS in this area is Owens Dry Lake. Owens Dry Lake covers approximately 110 square miles near the south end of the planning area. Approximately 60 square miles of the lake is dry. The Great Basin Unified Air Pollution Control District is currently developing and evaluating a variety of mitigation measures. The final mitigation program is scheduled for implementation in 1995. The Great Basin Unified Pollution Control District submitted comments to EPA supporting the reclassification of this area.

San Joaquin Valley, California. The EPA is reclassifying the San Joaquin nonattainment area due to the fact that the PM-10 SIP for San Joaquin Valley submitted to EPA by the State of California on December 24, 1991 suggests that the area cannot practicably attain the PM-10 NAAQS by December 31, 1994. Moreover, the area has not projected attainment before the December 31, 2001 serious area attainment date. Violations of the PM-10 NAAQS in the San Joaquin Valley are dominated by two source categories: (1) primary PM-10 sources, including reentrained road dust, construction activities, and farming operations; and (2) secondarily-formed PM-10, including ammonium nitrate and ammonium sulfate. On days when primary PM-10 emissions dominate, fugitive dust emissions account for nearly 80 percent of the PM-10 mass. On days when secondary PM-10 dominates, nitrates and sulfates account for 63 percent of the PM-10 mass. The attainment strategy for the San Joaquin Valley will rely heavily on the control of widespread fugitive dust sources and the control of precursors of PM-10, including nitrogen dioxide, sulfur dioxide, and volatile organic compounds.

South Coast Air Basin, California. The EPA is reclassifying the South Coast Air Basin at this time because the SIP for the South Coast Air Basin projects that it is not practicable to attain the 24-hour PM-10 NAAQS until the year 2000 and attainment of the annual PM-10 NAAQS by the year 2006. These dates are well beyond the December 31, 1994 moderate area attainment date. The basin-wide emissions inventory for the area covers approximately 6600 square miles and indicates that 91 percent of primary PM-10 emissions are due to area sources, primarily reentrained road dust. With projected increases in population (31 percent) and increases in vehicle miles travelled (62 percent), PM-10 emissions associated with reentrained road dust are expected to increase from 663 tons/day in 1987 to 1025 tons/day in 2010. In addition to the widespread sources of primary PM-10 emissions, source

[9] The EPA used the occasion of the publication of the PM-10 reclassification proposal to request public input on issues related to its preliminary efforts to develop a nonbinding policy addressing the section 188(f) of the Act PM-10 waiver provisions (56 FR 56861-56862; Nov. 21, 1991). The Clark County Health District submitted comments setting out some of its suggestions regarding the implementation of 188(f) of the Act. Clark County's comments address EPA's interpretation of anthropogenic and nonanthropogenic under section 188(f) of the Act and do not request that EPA alter its proposed decision to reclassify this area. Moreover, Clark County does substantiate to what extent the October 25, 1989 exceedance example was in fact attributable to nonanthropogenic sources. In any event, the county's comments have no bearing on today's action which, as indicated, ultimately was based on the SIP developed for that area. Finally, EPA recently made a draft of its section 188(f) of the Act policy available to the public and held a public meeting to provide the public with additional opportunity to comment on its contents (57 FR 31477; July 16, 1992). That draft indicates that a decision to reclassify an area as serious will not affect an area's eligibility for a waiver. The EPA will consider the Clark County comments addressing section 188(f) of the Act issues as it revises its draft section 188(f) of the Act policy in light of the various comments received.

contribution estimates indicate that secondarily-formed particles (nitrates and sulfates) can contribute as much as 52 percent of the 24-hour PM-10 mass and as much as 37 percent of the annual PM-10 mass. Therefore, the attainment strategy for the South Coast Air Basin will also rely heavily on the control of important precursors to PM-10 including nitrogen dioxide, sulfur dioxide, and volatile organic hydrocarbons.

V. Areas Which EPA is not Reclassifying at This Time

While EPA is taking final action to reclassify the five areas described above, EPA is not reclassifying the nine areas listed in Table 2 at this time, including those areas which EPA has determined, in its preliminary assessment, to be affected by international transport. Generally, EPA has information for these areas indicating that they may practicably be able to attain the PM-10 NAAQS or may be excluded from reclassification due to international transport [see section 179B(d) of the Act]. Thus, EPA believes it is premature to reclassify these areas at this time. However, as noted, EPA holds open the possibility of reclassifying these areas using its discretionary authority under section 188(b)(1) of the Act. This will permit EPA to undertake a comprehensive review of each area's control strategy. The EPA anticipates that it will take final action on its proposal to reclassify these areas because they cannot practicably attain at the time it takes rulemaking action on each area's SIP. Note also that if a PM-10 SIP control strategy and demonstration have not yet been submitted for an area, EPA may conclude at some future date that the area cannot practicably attain due to protracted delays in making such submittal. A more specific discussion follows below for each of these nine areas, including the significant public comments which EPA has received.

TABLE 2.—AREAS WHICH EPA IS NOT RECLASSIFYING AT THIS TIME [1]

EPA region	Area of concern	Sources
III	Liberty, Lincoln, Port Vue, and Glassport Boroughs and the City of Clairton, PA	Point
V	Oglesby, IL	Point
VIII	Libby, MT	FD [2], RWC [4], PB [3]
VIII	Utah Co., UT	Point [6]
IX	Paul Spur, AZ	Point, FD
IX Nogales, AZ	International [5], FD	
IX	Imperial Valley, CA	FD, International, PB
X Klamath Falls, OR	FD, RWC, PB	
X Spokane, WA	FD, PB, RWC	

[1] The full legal descriptions for those areas which EPA is not reclassifying at this time can be found at 56 FR 56694 (Nov. 6, 1991).
[2] FD = Fugitive dust.
[3] PB = Prescribed burning.
[4] RWC = Residential wood combustion.
[5] International = International transport of PM-10.
[6] Point = Dominant point source impact.

Liberty Borough, Pennsylvania. The EPA has determined that, at this time, it is not appropriate to reclassify the Liberty Borough nonattainment area to serious. This decision is based on comments and information received during the public comment period regarding the ability of Allegheny County to attain and maintain the PM-10 standard by December 31, 1994. The decision is also based on the commitment by the Allegheny County Bureau of Air Pollution Control to submit an applicable implementation plan which demonstrates the attainment of the PM-10 NAAQS by the moderate area attainment date (i.e., December 31, 1994).

The Liberty Borough nonattainment area is comprised of Liberty, Lincoln, Port Vue, Glassport Boroughs, and the City of Clairton in Allegheny County, Pennsylvania (56 FR 56823; Nov. 6, 1991). The area is heavily industrialized with a diverse mix of sources including steel manufacturing, utilities, and industrial boilers. These sources generate both point source PM-10 emissions and fugitive dust. In 1989 and 1990, emissions control measures were implemented in the nonattainment area in addition to those measures which had been installed previously.

However, EPA has not received a PM-10 SIP for the Liberty Borough nonattainment area. On December 16, 1991, the EPA Regional Administrator sent a letter notifying the Governor of Pennsylvania of EPA's determination that the State had failed to submit the PM-10 SIP for Allegheny County by the statutory submittal date of November 15, 1991 (see, e.g., 57 FR 19906, May 8, 1992). This determination started the 18-month timeclock for the imposition of sanctions and the 2-year timeclock for promulgation of a Federal implementation plan.

The EPA did receive a "PM-10 work plan" from the Allegheny County Health Department on March 26, 1992. The work plan commits to attainment of the PM-10 NAAQS by the statutory attainment date of December 31, 1994. It summarizes the procedures to be followed for the development of the SIP submittal, including modeling and monitoring air quality in the area, conducting an emissions inventory, and producing a control strategy. The work plan also establishes a schedule for SIP submittal, indicating that the schedule will be met through a cooperative effort with EPA. The schedule projects that the SIP will be submitted to EPA by June 15, 1993.

The EPA received more detailed comments on its proposal to reclassify the Liberty Borough nonattainment area than on its proposed action on other areas. Rather than discuss those comments and EPA's responses in detail here, EPA has placed a document in the docket accompanying this notice which describes those comments and explains further the rationale for EPA's decision not to reclassify the Liberty Borough nonattainment area as serious at this time.

Comments were received from the local air pollution control agency, the Commonwealth of Pennsylvania, affected industries, local citizens, and public interest groups. Those commenters opposing reclassification based their views on assertions that recent improvements in air quality are the result of locally-instituted controls, that EPA did not adequately consider the air quality impact of those controls in its decision to propose reclassification of this area, and that the PM-10 work plan provides evidence of the State's commitment to, and the practicability of, attaining the PM-10

NAAQS by December 31, 1994. For these reasons, some of the commenters indicated that it would be premature for EPA to reclassify this area. Comments favoring reclassification were based primarily on concerns about poor air quality in the area, on disagreement as to the cause of recently-observed improvements in air quality, on assertions that the State's failure to submit a SIP by the November 15, 1991 due date precludes the area's ability to timely attain the NAAQS, and on the belief that reclassification would best advance the goal of expeditious attainment of the NAAQS.

Briefly, EPA has based its decision on the evidence provided in the Allegheny County Health Department's work plan in support of that area's commitment to attain the NAAQS by December 31, 1994. The EPA has further based its decision on the fact that commenters favoring reclassification have not provided any evidence which rebuts the State's and county's assertions that attainment by December 31, 1994 is practicable. The EPA notes in response to those favoring reclassification that reclassifying the area at this time would result in the requirement that the area implement additional control measures, but would also permit the State to postpone attainment potentially up to the statutory serious area attainment date of December 31, 2001.[10] By not reclassifying the area as serious, EPA intends to enforce the statutory moderate area requirement for the State to adopt a plan which provides for attainment of the NAAQS as expeditiously as practicable, but not later than December 31, 1994. The EPA believes that the principal concerns expressed by the commenters favoring reclassification—the need to promote near-term improvements in air quality—are better served by not taking final action to reclassify an area at this time where there is some reasonable evidence that the area may practicably attain by December 31, 1994.

Spokane, Washington. The EPA is not taking final action to reclassify the Spokane nonattainment area at this time, but will make a final decision at the time the Agency takes rulemaking action on the SIP. This will permit EPA the opportunity to comprehensively review the SIP and to assess the claims that nonattainment in the area is attributable, at least in part, to nonanthropogenic dust storms, and that the area is potentially eligible for a waiver of the December 31, 1994 attainment date under section 188(f) of the Act. The EPA cannot reject or accept these claims at the present time. The Agency is currently reviewing the SIP for Spokane, giving particular consideration to any anthropogenic contributions to emissions that may be reentrained during the area's dust storms. The EPA will determine Spokane's eligibility for a waiver of the moderate area attainment date under section 188(f) of the Act and will make a final decision on reclassification when the Agency has completed its review of the area's SIP.

Comments received from 14 private citizens and government, industry, and environmental groups attribute Spokane's nonattainment status to nonanthropogenic dust storms. One commenter asserted that these dust storms emanate from the approximately 100,000 acres of undeveloped, untilled land southwest of Spokane, and to approximately 500,000 acres of farmland vulnerable to soil erosion due to high winds. According to the Spokane County Conservation District, such soil erosion is especially prevalent after harvest and prior to the emergence of the new crop, stating that it is not possible to prevent windblown dust during this vulnerable period. They add that, when compounded by high winds, preventing this windblown dust is "beyond the realm of legislation or regulation."[11] One conservation farmer indicated, however, that farmers have been working closely with the Soil Conservation Service to mitigate the erosion to their cropland.

In addition to comments regarding nonanthropogenic sources of PM-10 in Spokane County, 3 elected officials in Washington State, the Intermountain Grass Growers Association, 3 Spokane County public agencies, and 1 private corporation contended that the severe duststorms in the Spokane nonattainment area should be treated as "exceptional events," as discussed in 40 CFR part 50, Appendix K, section 2.4. As such, the commenters believe that contributions from these dust storms should be discounted when measuring exceedances of the PM-10 NAAQS. Because the State has measured 7 such occurrences during the 3-year reporting period, there is reason to believe that these events happen with a regularity which would disqualify them from treatment as exceptional events. Again, EPA will make a final determination regarding this claim following a comprehensive review of the SIP submittal. One commenter urged EPA to classify this area as serious, but did not substantively address whether the area cannot practicably attain by the applicable attainment date or the likelihood of the area qualifying for a waiver of its moderate area attainment date under section 188(f) of the Act.

Available information indicates that both Imperial Valley, California, and Nogales, Arizona, may qualify for treatment under the International Transport provision in section 179B of the Act due to particulate matter emanating from Mexico. While the Agency has sufficient data at this time to verify that PM-10 originating in Mexico contributes to nonattainment in these areas, additional monitoring and air quality analysis are necessary to quantify the international contribution so that the SIP's for Nogales and Imperial Valley may accurately discount international transport from their attainment demonstrations, and EPA can correspondingly determine whether the SIP's for the areas would be adequate to attain and maintain the PM-10 NAAQS but for emissions emanating from Mexico (see section 179B of the Act). The following is a more detailed discussion of the areas affected by international transport:

Imperial Valley, California. The EPA is not reclassifying the Imperial Valley nonattainment area at this time. Although the State of California has not yet submitted a PM-10 SIP for Imperial Valley, previous reports indicate that transport from Mexicali, Mexico, may significantly contribute to elevated PM-10 levels in the Valley.[12] As such, the area may qualify for exclusion from reclassification to serious under section 179B(d) of the Act.

On December 16, 1991, the EPA Regional Administrator for Region IX sent a letter to the Governor of California notifying him of the State's failure to submit a SIP for the Imperial Valley. This notification started the 18-month timeclock which will result in the imposition of sanctions if EPA does not receive a SIP [see section 179(a) of the Act]. The Imperial County Air Pollution Control District is currently working with the California Air Resources Board (CARB) to develop a PM-10 SIP for this area. The SIP is scheduled to be submitted to EPA by the

[10] Section 188(b)(2) of the Act requires that such serious nonattainment areas attain the NAAQS as expeditiously as practicable, but not later than December 31, 2001.

[11] Letter from Spokane County Conservation District to Ken Woodard, December 17, 1991.

[12] "Draft Analysis of the Imperial County, California Rural Fugitive Dust Area," prepared by PEI Associates, January 1989; "Example Level One Air Quality Analysis for Particulate Matter State Implementation Plan Revisions (Imperial Valley, California)," State of California Air Resources Board, March 1988; "Draft Program Plan for the Imperial Valley/Mexicali Particulate Matter Sources Apportionment Study," Desert Research Institute, December 20, 1991.

end of 1992. In addition, EPA and CARB will be conducting a PM-10 source apportionment study in the Imperial Valley/Mexicali air basin in cooperation with the Imperial County Air Pollution Control District and the Secretary of Social Development in Mexico. The objectives of the study are to: (1) estimate the spatial and temporal distributions of PM-10 concentrations in the Imperial Valley and Mexicali; (2) apportion PM-10 concentrations to source emissions; and (3) estimate cross-border transport of PM-10. The monitoring portion of the study began on March 10, 1992.

Nogales, Arizona. The EPA is not taking final action to reclassify the Nogales nonattainment area at this time. Despite the fact that the State of Arizona has not yet submitted a PM-10 SIP for Nogales, previous studies by the Arizona Department of Environmental Quality indicate that transport from Nogales, Mexico, may significantly contribute to elevated PM-10 levels in the nonattainment area.[13] As such, the area may qualify for exclusion from reclassification as serious under section 179B(d).

On December 16, 1991, the EPA Regional Administrator for Region IX sent a letter to the Governor of Arizona notifying him of the State's failure to submit a SIP for Nogales. This notification started the 18-month timeclock which will result in the imposition of sanctions if EPA does not receive a SIP [see section 179(a) of the Act]. The Arizona Department of Environmental Quality intends to submit a SIP by the end of 1992. They also planned to initiate a project in the summer of 1992 to provide additional emissions inventory data and source contribution estimates for the Nogales area.

The SIP's submitted for the remaining 5 areas contain control strategy demonstrations purporting to show that the NAAQS will be attained by December 31, 1994. The Agency is reviewing the public comments received for these areas, as well as the SIP control strategies and, as stated previously, will make a determination concerning reclassification upon taking rulemaking action on the SIP's. Further discussion of these areas follows below.

Klamath Falls, Oregon. Based upon EPA's preliminary review of the PM-10 SIP submitted in response to the November 15, 1991 SIP requirement, EPA, at this time, supports the State's determination that the nonattainment area will practicably attain the NAAQS by December 31, 1994. One comment was received from the Oregon Department of Environmental Quality opposing reclassification. The commenter asserted that the PM-10 SIP submittal includes the necessary air pollution control provisions and a demonstration that attainment of the NAAQS by December 31, 1994.

Libby, Montana. Based upon EPA's preliminary review of the area's PM-10 SIP submitted in response to the November 15, 1991 SIP requirement, EPA, at this time, supports Montana's determination that the Libby nonattainment area will practicably attain the NAAQS by December 31, 1994. The Montana Department of Health and Environmental Sciences submitted comments opposing reclassification. The commenter contended that the SIP contains an adequate control strategy, including point source permit modification, and that it would be premature to reclassify at this time.

Oglesby, Illinois. Based upon EPA's preliminary review of the PM-10 SIP for this area, EPA at this time supports the State's determination that the nonattainment area will practicably attain the NAAQS by December 31, 1994. The EPA is currently evaluating the SIP and will make a final determination about reclassifying the area because it cannot practicably attain when EPA takes formal action on the submittal.

Paul Spur, Arizona. Based upon EPA's preliminary review of the SIP submitted for this area, EPA, at this time, supports Arizona's determination that the nonattainment area will practicably attain the NAAQS by December 31, 1994. The Arizona Department of Environmental Quality opposes reclassification based upon EPA's design value criteria [see 56 FR 58658; Nov. 21, 1991] and its belief that EPA should review the SIP before deciding to reclassify the area. One comment received from a private corporation adds that significant improvements to air quality have already been made with the imposition of control measures as indicated by the data from 1988 through the third quarter of 1991. Further control measures, the commenter claims, are outlined in the SIP revision.

Utah County, Utah. Following EPA's preliminary review of the PM-10 SIP submitted for this area in response to the November 15, 1991 SIP requirement, EPA, at this time, supports Utah's determination that the nonattainment area will practicably attain the NAAQS by December 31, 1994. The State of Utah's Department of Environmental Quality opposes reclassification based on its belief that the PM-10 SIP revision provides for emissions reductions sufficient to demonstrate attainment by December 31, 1994. The commenter states that EPA should be fair in giving Utah County the opportunity to show such attainment.

VI. Effect of Reclassification

Additional SIP revisions are required under section 189(b) of the Act for the nonattainment areas that are reclassified to serious. First, regulations requiring the use of best available control measures (BACM), including "the application of best available control technology (BACT) to existing stationary sources," must be adopted and submitted to EPA within 18 months after the area is reclassified to serious [section 189(b)(2) of the Act].[14] The BACM requirement must be implemented within 4 years after the area is reclassified [section 189(b)(1)(B) of the Act]. Second, the State must submit a SIP revision within 4 years after reclassification of the area (within 18 months after reclassification for failure to attain) that includes a demonstration that the plan will attain the PM-10 NAAQS by December 31, 2001 [see sections 188(c)(2), 189(b)(1)(A)(i), and 189(b)(2) of the Act].[15] Third, section 189(b)(3) of the Act provides that "for any Serious Area, the terms 'major source' and 'major stationary source' include any stationary source or group of stationary sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 70 tons per year of PM-10." This provision requires, among other things, smaller new and modified sources (those with the potential to emit 70 tons per year or greater, rather than 100 tons per year or

[13] "Preliminary Investigation of Causes and Extent of the Nogales, Arizona PM-10 Problem," Arizona Department of Environmental Quality, September 1990

[14] As with RACM and RACT, BACT is a subset of the overarching BACM requirement. The BACT generally refers to the technological control measures which apply to large stationary sources. Thus, any reference to BACM herein implicitly includes BACT.

[15] Alternatively, the State must demonstrate that attainment by December 31, 2001, is impracticable, that the plan provides for attainment by the most expeditious alternative date practicable (but no more than 5 years after the serious area attainment date), and that the section 188(e) of the Act requirements for receiving an extension of the attainmet date have been satisfied (i.e., the plan includes the most stringent measures that are included in the implementation plan of any State or are achieved in practice in any State and can feasibly be implemented in the area)[see section 189(b)(1)(A)(ii) of the Act]. Areas that are reclassified under section 188(b)(2) of the Act following failure to attain must submit attainment demonstarations within 18 months after reclassification to serious [see section 189(b)(2) of the Act].

greater) to obtain section 172(c)(5) of the Act construction permits which include requirements to comply with lowest achievable emission rates and to obtain emission offsets [see sections 172(c)(5) and 173 of Act].

Where an area is being reclassified to serious, it may be reasonable for States to consider the relationship of RACM to BACM for the affected sources. The EPA discussed this relationship in the proposal for today's action (see 56 FR 58660-58661; Nov. 21, 1991). The EPA anticipates that BACM for area sources will generally be additive to or not significantly incompatible with RACM for these sources.[16] Therefore, the moderate area SIP's for the areas which EPA is reclassifying should continue to implement the requirements for the application of RACM to appropriate sources. After reclassification to serious, additional regulations which require BACM must be adopted and submitted within 18 months and implemented within 4 years, as stated above.

VII. Miscellaneous

A. Executive Orders

Under Executive Order 12291, EPA has determined that this action is not "major" because reclassification of the areas does not have an annual effect on the economy of $100 million or more, would not cause a major increase in prices, and would not have a significant adverse impact on competition or the ability of United States enterprises to compete with foreign enterprises. This notice and the November 21, 1991 proposal were submitted to the Office of Management and Budget (OMB) as required by Executive Order 12291. Any written comments from OMB and written EPA responses to those comments are included in the docket. Similarly, any written comments from OMB regarding today's final action, and any written responses, have been placed in the docket. This action does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1980 (44 U.S.C. sections 3501 et seq.). A federalism assessment under Executive Order 12612 is not required for this action since this action was directed under section 188(b)(1)(A) of the Act.

B. Regulatory Flexibility Act

Under 5 U.S.C. section 605(b), the Administrator has certified that redesignations do not have a significant economic impact on a substantial number of small entities (see 46 FR 8709). Because the regulatory impact of reclassifications under section 188(b) of the Act is no different substantively from that associated with designations, such actions are also not expected to have significant impacts on small entities.

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: November 18, 1992.

William K. Reilly,
Administrator.

PART 81—[AMENDED]

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7407, 7501-7515, 7601.

2. Section 81.305 is amended by revising the table for California—PM-10, to read as follows:

§ 81.305 California.

* * * * *

CALIFORNIA.—PM–10, Nonattainment Areas

Designated area	Designation		Classification	
	Date	Type	Date	Type
Inyo County				
Owens Valley planning area	11/15/90	Nonattainment	02/08/93	Serious.
Hydrologic Unit #18090103				
San Bernardino, Inyo, and Kern Counties				
Searles Valley planning area	11/15/90	Nonattainment	11/15/90	Moderate.
Hydrologic Unit #18090205				
Mono County				
Mammoth Lake planning area	11/15/90	Nonattainment	11/15/90	Moderate.
Includes the following sections:				
a. Sections 1–12, 17, and 18 of Township T4S, R28E;				
b. Sections 25–36 of Township T3S, R28E;				
c. Sections 25–36 of Township T3S, R27E;				
d. Sections 1–18 of Township T4S, R27E; and				
e. Sections 25 and 36 of Township T3S, R26E				
Fresno, Kern, Kings, Tulare, San Joaquin, Stanislaus, Madera Counties				
San Joaquin Valley planning area	11/15/90	Nonattainment	02/08/93	Serious.
Riverside, Los Angeles, Orange, and San Bernardino Counties				
South Coast Air Basin	11/15/90	Nonattainment	02/08/93	Serious.
Riverside County				
Coachella Valley planning area	11/15/90	Nonattainment	02/08/93	Serious.
Imperial County				
Imperial Valley planning area	11/15/90	Nonattainment	11/15/90	Moderate.
Rest of State	11/15/90	Unclassifiable		

[16] The EPA also discussed the relationship between RACM and BACM in the "General Preamble to Title I of the 1990 Clean Air Act Amendments," 57 FR 13544 (April 16, 1992). Specifically, EPA indicated that it may be reasonable for States containing areas that will be reclassified as serious to consider the compatibility of RACM and RACT with BACM and BACT that ultimately will be implemented under the serious area plans for these areas. The EPA indicated that States containing such areas need not require major changes to control systems for specific stack and process sources in the affected moderate area SIP's where they demonstrate that such changes will be significantly incompatible with the application of BACT-level control systems.

* * * * *

3. Section 81.329 is amended by revising the table for Nevada—PM–10, to read as follows:

§81.329 Nevada.

* * * * *

NEVADA.—PM–10 NONATTAINMENT AREAS

Designated area	Designation		Classification	
	Date	Type	Date	Type
Washoe County				
Reno planning area	11/15/90	Nonattainment	11/15/90	Moderate.
Hydrographic area 87				
Clark County				
Las Vegas planning area	11/15/90	Nonattainment	02/08/93	Serious.
Hydrographic Area 212				
Rest of State	11/15/90	Unclassifiable		

* * * * *

[FR Doc. 93–375 Filed 1–7–93; 8:45 am]

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Friday
January 8, 1993

Part III

Department of Transportation

Research and Special Programs Administration

49 CFR Parts 172 and 173

Elevated Temperature Materials; Revisions and Response to Petitions for Reconsideration; Final Rule

VOL 58 ISS 5 JA 8 1993 UMI

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 172 and 173

[Docket No. HM–198A; Amdt Nos. 172–125 and 173–227]

RIN 2137–AB31

Elevated Temperature Materials; Revisions and Response to Petitions for Reconsideration

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Final rule; revisions and response to petitions for reconsideration.

SUMMARY: In response to petitions for reconsideration, this final rule provides regulatory relief from the final rule for materials posing a hazard due to their being offered for transportation or transported at elevated temperatures. It offers exceptions from packaging requirements for asphalt kettles and authorizes continued use of certain packaging now in service for the transportation of elevated temperature materials. In addition, this final rule contains editorial and technical corrections to the final rule.

EFFECTIVE DATE: January 8, 1993.

FOR FURTHER INFORMATION CONTACT: Beth Romo, Office of Hazardous Materials Standards, (202) 366–4488, James K. O'Steen, or William Gramer, Office of Hazardous Materials Technology, (202) 366–4545, U.S. Department of Transportation, 400 Seventh Street SW., Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Background

On October 2, 1991 (56 FR 49980), the Research and Special Programs Administration (RSPA) published a final rule under Docket HM–198A entitled "Elevated Temperature Materials". Under this final rule, RSPA adopted regulations for materials which pose a hazard due to their being offered for transportation or transported at elevated temperatures. Included were materials in a liquid phase having temperatures at or above 100° C (212° F) and materials in a solid phase having temperatures at or above 240° C (464° F). Also subject to the new regulations, as flammable liquids, were materials in a liquid phase with flash points at or above 37.8° C (100° F) which are intentionally heated and offered for transportation or transported in bulk quantities at or above their flash points. The new regulations imposed hazard communication, classification, and performance packaging requirements on materials in bulk packagings which are intentionally heated before or during transportation. The final rule authorized existing equipment to be used for significant periods of time if in compliance with certain minimum performance standards. Certain exceptions were provided for environmentally-heated materials, materials in non-bulk packagings, solid elevated temperature materials, and molten metals and molten glass transported in rail cars.

RSPA received numerous petitions for reconsideration requesting a delay in the compliance dates contained in the final rule to allow affected entities sufficient time to come into compliance with the new requirements. On December 31, 1991 (56 FR 67542), RSPA published a delay of compliance dates for certain packaging provisions. RSPA also clarified that transition dates provided in § 171.14(b)(3) and (b)(4), as adopted under Docket HM–181 (December 20, 1991; 56 FR 66124) for compliance with new hazard communication and classification requirements, also apply to elevated temperature materials. Therefore, although the Docket HM–198A final rule was effective March 30, 1992, the transitional provisions of § 171.14(b)(3) and (b)(4) allow a delay of compliance dates for classification and hazard communication requirements for elevated temperature materials until October 1, 1993, except for placarding requirements which are not mandatory until October 1, 1994.

II. Petitions for Reconsideration

RSPA received seventeen petitions for reconsideration to the final rule. Each petition requested revisions to the packaging requirements, especially for asphalt and bitumen. All petitions for reconsideration have been considered in preparing this document. Based on the merit of petitions, RSPA is revising certain provisions of the regulations. These revisions are discussed in detail in the section-by-section review.

Except as adopted herein, all petitions for reconsideration received by RSPA regarding issues addressed in the final rule published on October 2, 1991 (Docket HM–198A) are hereby denied. Any subsequent submission regarding issues relating to this rulemaking must be filed as petitions for rulemaking in conformance to 49 CFR 106.31.

These amendments clarify and correct certain provisions of the final rule in response to petitions for reconsideration. These changes impose no new regulatory burden on any person and provide relief from existing requirements; therefore, notice and public comment are unnecessary and good cause exists to make these amendments effective less than 30 days following publication.

III. Regulatory Review Issues

In response to the President's January 28, 1992 announcement of a federal regulatory review, DOT published a notice on February 7, 1992 (57 FR 4744) soliciting public comments on the Department's regulatory programs. RSPA received three comments concerning Docket HM–198A. Two of the comments reiterated earlier petitions requesting revisions to venting requirements and exemption of asphalt and bitumen from the regulations. RSPA's response to these comments is discussed in the section-by-section review. The third comment requested that consistency be maintained between domestic and international provisions. RSPA has and will continue to harmonize regulatory requirements with international requirements as much as possible. International recommendations for the transportation of elevated temperature materials are under consideration by the UN Committee of Experts on the Transport of Dangerous Goods. A U.S. paper patterned after the RSPA's regulations on elevated temperature materials is the basis for UN consideration of international regulations of ETMs.

Section-by-Section Review

The following section-by-section review addresses revisions to the October 2, 1991 final rule.

Section 172.101

Editorial corrections are made to two entries in the Hazardous Materials Table. Because § 173.247 was restructured for consistency with other bulk packaging sections, the entry "Elevated temperature material, solid, n.o.s." is revised to reference the redesignated paragraph. The identification number for the entry "Flammable liquid, elevated temperature material, n.o.s." is revised to read "NA9276". The previous identification number "NA9275" was assigned to regulated medical waste. Because of the earlier hazard communication transition dates required for regulated medical waste, "NA9275" is being continued as the identification number assigned to regulated medical waste.

Section 172.203

Paragraph (g)(3) is revised to correct a section reference.

Section 172.325

The requirement for each bulk package containing an elevated temperature material (ETM) to be marked "HOT" (or "MOLTEN ALUMINUM" or "MOLTEN SULFUR") on each side and each end is revised to require the marking only on two opposing sides. This revision is consistent with additional marking requirements for other materials, such as materials poisonous by inhalation.

A final rule issued October 1, 1992 under Dockets HM–181 and HM–189 added a domestic exception from the Class 9 placarding requirements. Under this exception, placards are not required on bulk packagings containing elevated temperature materials in Class 9 if the package is marked on each side and each end with the appropriate identification number on an orange panel or a white-square-on-point display configuration. The adoption of this domestic exception from Class 9 placarding requirements provides economic and regulatory relief.

In this document, a new paragraph (c) is added to allow the word "HOT" to be displayed in the upper corner of the same white-square-on-point display configuration used for the identification number. The 50 mm (2 inches) minimum height prescribed for the letters in the word "HOT" applies to all bulk packagings, including rail cars, under this provision. However, the 100 mm (3.9 inches) minimum height for rail car markings, as specified in § 172.302, still applies if the word "HOT" is marked on the rail car itself or on a plain white-square-on-point display configuration.

Section 173.247

The format of this section is restructured for consistency with the bulk packaging sections adopted in a final rule issued December 20, 1991 under Docket HM–181. The introductory text clarifies that, on or after October 1, 1993, bulk packagings must meet all requirements in paragraph (g) unless otherwise excepted.

The packaging authorizations in paragraphs (a) and (c) remain unchanged, but the paragraphs are restructured. In paragraph (b), RSPA is providing an exception to permit the use of hat shaped or open channel stiffening rings on carbon steel tanks used to transport ETMs because the elevated temperatures prevent accumulation of moisture which can cause corrosion under the hat shaped or open channel stiffening rings.

Several petitioners requested clarification whether cargo tanks must conform to the current MC 300 series specifications and then, after September 30, 1993, DOT 400 series specifications. Until September 30, 1993, non-specification cargo tanks intended for ETM service may be built either to the accident damage resistance and structural integrity levels of the MC 306, MC 307 or MC 312 series tanks or the DOT 400 series tanks. Tanks built after that date must meet both accident damage resistance and structural integrity requirements specified for DOT 400 series cargo tank motor vehicles. Specification packagings that are being manufactured for the transport of ETMs must be authorized for current construction.

Petitioners also asked RSPA to confirm that self-closing stop valves and gauging devices on packages containing viscous materials such as asphalt and molten sulfur do not have to conform to requirements for MC 300 or DOT 400 series cargo tanks. This is correct for a non-specification packaging built with structural design and accident damage resistance equivalent to specification packaging.

Petitioners stated that most asphalt and bitumen kettles have a capacity between 400 and 600 gallons (2086 and 3129 L). According to petitioners, imposing current closure requirements on these packagings would cause great expense. Petitioners stated that kettles carry smaller quantities of asphalt and bitumen and thus do not pose a significant transportation hazard. RSPA agrees that smaller quantities of asphalt and bitumen pose a lesser potential hazard and, due to a wide usage of this type of packaging in transportation, it is important to recognize the unique characteristics of asphalt and bitumen kettles. Therefore, RSPA is providing specific packaging exceptions for kettles. These exceptions may be broadly categorized as imposing certain minimal requirements on existing kettles and providing incentives for future construction of kettles with high overturn stability.

Paragraph (e) contains new packaging requirements for asphalt and bitumen kettles and provides exceptions for kettles manufactured to certain stability and capacity requirements. A kettle, as defined by the National Roofing Contractors Association (NRCA), is a portable heating apparatus used for melting various bituminous products, such as asphalt, used in the roofing and paving industries. It is designed to be loaded through an opening on its top, which is covered by a metal lid. Burner units are typically fueled by LP gas, kerosene, or diesel fuel. Kettles typically range in capacity for 132 to 5678 L (35 to 1500 gallons) and, depending on the size of the kettle, can have up to three axles. Kettles may be trailer or skid mounted for truck transport to job sites or for use during road and highway construction and repair.

The NRCA also provided an analysis of the center of gravity of a half-filled "typical kettle model" having high overturn stability. Overturn stability can be analytically represented by calculating the ratio of kettle track-width to loaded center of gravity (CG) height. Track-width is the distance measured between the outer edge of the kettle tires. CG height is measured perpendicularly from the road surface. For this model the ratio was 3:4. Because this ratio is simple to calculate and provides an objective way to compare overturn stability of various kettle designs, RSPA is adopting this ratio as a guide for determining exceptions from the packaging requirements of paragraph (g) for kettles. The NRCA petition also stated that "larger kettles" of similar design are even more stable. RSPA agrees that kettles with a high overturn stability have a reduced probability of single vehicle accidents due to overturn and should be excepted from the overturn requirements. In view of this, RSPA encourages future construction of kettles having a ratio of track-width to fully loaded CG height greater than 2:5 and is providing certain exceptions from the requirements in paragraphs (g)(2) and (g)(6).

In paragraph (e)(1), low stability kettles with a ratio of track-width to fully loaded CG height of less than 2:5 must meet all packaging requirements of paragraph (g). This insures that kettles manufactured on or after October 1, 1993 having a higher probability of overturn must meet the overturn protection requirements. Paragraph (e)(1) also explains the method to be used to measure track-width and center of gravity height in order to calculate the roll stability ratio.

In paragraph (e)(2)(i), high stability kettles of less than 2650 L (700 gallons) which have a ratio of track-width to fully loaded CG height of 2:5 or more are excepted from all requirements of paragraph (g)(2), and rollover protection requirements of paragraph (g)(6), provided closures are securely closed during transport and designed to prevent opening and expulsion of the lading in a rollover accident. RSPA is granting this exception to encourage future manufacture of kettles which

have a lower probability of overturn and, therefore, less need for overturn protection and closure requirements. Paragraph (e)(2)(ii) provides larger kettles having a capacity of 2650 L (700 gallons) or more and a ratio of track-width to fully loaded CG height of greater than 2:5 an exception from the requirements for leak tightness in paragraph (g)(2) and the rollover protection requirements of paragraph (g)(6).

Paragraph (f) requires that any bulk packaging intended for ETM service, which is not authorized in paragraphs (a) through (e), meet the packaging requirements of paragraph (g) on or after October 1, 1993. The revised packaging standards for ETMs are contained in paragraph (g).

Petitioners expressed concern over whether pressure or vacuum control devices or vents are required on all ETM packagings. Such devices are required only under certain conditions, as clarified in paragraph (g)(1). When such devices are required, they must be of a self-reclosing nature.

One petitioner asked RSPA to allow tanks with no vents if they are constructed to withstand any vacuum or pressure which might occur under extreme circumstances. The provisions in the final rule for pressure and vacuum control equipment do not require venting if the pressure within the tank increases or decreases less than 10% or if the tank was built to withstand a full vacuum (i.e. 100 kPa, 14.5 psig external pressure). RSPA is reducing the pressure of 14.7 psig to 14.5 psig to conform to the accepted values for an atmosphere of pressure as found in § 171.10.

Paragraphs (g)(1)(i) and (g)(1)(ii) prescribe general requirements and exceptions for pressure and vacuum control equipment. Absolute pressures should be used to calculate changes in order to obtain meaningful differences.

Paragraph (g)(1)(i) is revised to clarify what temperature range must be used to determine eligibility for an exception from installing pressure control equipment on packagings transporting ETMs. The final rule requires that such equipment must "prevent rupture * * * from heating, including fire engulfment"; however, because no specific temperature range would apply in all situations, a specific pressure rise cannot be calculated. Under this exception, packagings containing elevated temperature materials having low vapor pressure at high temperatures (including temperatures encountered in a fire engulfment scenario) may be excepted from pressure control equipment because of the low risk of packaging rupture due to vapor pressure rise of the lading in a fire engulfment scenario. Therefore, a specific temperature range, extending from the lowest designed operating temperature to the temperature encountered in a fire engulfment scenario, is provided to calculate if an exception from pressure control equipment is authorized.

A corresponding revision in paragraph (g)(1)(ii) clarifies the temperature range to be used in determining any exception from installing vacuum control equipment. Again, because no specific temperature range for cooling is required in the final rule, a specific pressure decrease cannot be calculated. Revised paragraph (g)(1)(ii) clarifies that if pressure in a packaging decreases less than 10 percent due to a lading temperature drop from the highest designed operating temperature to the lowest temperature expected during transport, no vacuum control equipment is required. Therefore, the largest pressure change expected during a shipment must be considered before an exception from vacuum control equipment is authorized.

In paragraph (g)(1)(iii), RSPA is authorizing the use of permanent openings and frangible safety vents for transport by highway and safety vents for transport by rail if viscous lading will cause fouling of the reclosing valves. The maximum size allowed for a permanent opening on pressure and vacuum control devices is increased from a diameter of 38 mm (1.5 inches) to a maximum effective area of 22 cm^2 (3.4 in^2). This change is the equivalent of increasing the maximum diameter allowed for a circular permanent opening to 53 cm (2.08 inches) and permits greater flexibility to use opening shapes other than circular openings. This increase is based on the merit of petitions citing the current industry practice of using two-inch nominal pipe (two-inch nominal pipe has a 2.0625-inch diameter) as a means of venting ETM vapors during transport. Further, for bulk packagings transporting asphalt and bitumen, RSPA is authorizing an opening with a maximum effective area of 46 cm^2 (7.4 in^2), which is the equivalent of increasing the maximum diameter allowed for a circular permanent opening to 7.8 cm (3.07 inches), allows an opening with a three-inch nominal pipe diameter (three-inch nominal pipe has a 3.068-inch diameter). This accommodates certain tanks having three-inch nominal pipe vents and provides consistency with the National Fire Protection Association (NFPA) 385 recommendation that "at least 2 inch nominal pipe" be used for venting asphalt and bitumen tanks. A three-inch diameter opening will allow sufficient venting of vapors during transport and will prevent large amounts of ETM from being released suddenly in an overturn. However, RSPA is not adopting the NFPA's open-ended minimum of "at least two inches." If no maximum opening size is specified, potentially large permanent openings would be authorized, conflicting with RSPA's intent to prevent significant release of lading in an overturn.

The provision for installing frangible safety vents instead of permanent openings is based on the merit of a petition from the Sulphur Institute. All pressure and vacuum control devices must prevent release of lading during normal transport conditions due to splashing or surging of the lading.

The final rule required marking the manufacturer's name, date of manufacture, design temperature range, and maximum product weight on each packaging used to transport ETMs and specified the size of the markings to be at least 9.5 mm (0.375 inches). RSPA received several petitions requesting a reduction in the minimum size of the characters to 4.8 mm (3/16 inch) for consistency with the size of characters required on manufacturer identification plates for certain DOT specification packagings. RSPA agrees and is reducing the minimum size requirement to 4.8 mm (3/16 inch).

The requirement to mark "nominal capacity" is removed, and a provision to mark "volumetric capacity" as an alternative to maximum product weight is added. In response to a petition from the Sulphur Institute, paragraph (g)(5) also is revised to provide an alternative marking "load limit" instead of "maximum product weight" for tank cars. "Load limit" means the maximum allowable weight on rail minus the tare weight of the tank car. For example, if the maximum allowable weight on rail is 263,000 pounds and if the tank weighs 63,000 pounds, the load limit is 200,000 pounds.

The exception in paragraph (g)(1)(iii) allowing permanent openings is repeated in paragraph (g)(2). Paragraph (g)(3) is revised for clarification, and paragraph (g)(4) is unchanged. One petitioner questioned whether bottom-fired kettles having a spray wand and similar road oil application equipment used to seal cracks would be considered as sprayers. RSPA considers this equipment to be spraying equipment; therefore, such equipment is excepted from accident damage protection requirements. Paragraph (g)(6) is revised to clarify that spraying equipment and

road oil application equipment are not required to be protected; however, other applicable parts of the packaging must be appropriately protected.

New paragraph (g)(7) is added to clarify that the continued manufacture of packagings listed in paragraphs (a) through (c) is not authorized if construction of those packagings is prohibited elsewhere in the HMR.

Many of the petitioners asked RSPA to extend its grandfathering provisions for continued use of existing equipment from 20 years to up to 40 years, while others asked for unlimited life. Petitioners representing the asphalt industry claimed that, because asphalt is transported short distances only three to six months of the year, the usable life of an asphalt packaging is greater than 20 years.

Asphalt industry petitioners cited an exemplary safety record as the basis for requesting relief from the retrofit and limited grandfathering provisions of the final rule. One petitioner claimed that retrofitting existing asphalt and bitumen packagings to meet accident damage protection requirements would cost as much as $10,000 per unit. Another petitioner stated that of the approximately 10,000 asphalt cargo tanks in service, only a small fraction are built to MC 306 specifications. The majority of these cargo tanks are used to transport previously unregulated asphalt. One petitioner estimated that up to 9,000 tanks would require a partial retrofit to serve out their 20-year lives, presenting serious difficulties for the road construction industry and resulting in higher roadway construction and maintenance costs. Asphalt industry petitioners asked RSPA to allow cargo tanks built prior to March 1993 to be used without retrofit for the duration of their 20-year service lives and, further, to consider extending the service lives for these tanks to up to 40 years.

RSPA believes the petitions are of sufficient merit to allow the continued use of packagings in elevated temperature material service which were manufactured before October 1, 1993, if the packagings meet the general packaging requirements of subparts A and B of part 173. In addition, RSPA is removing the marking and accident damage retrofit requirements for asphalt and bitumen packagings. However, to promote safety, RSPA encourages the cargo tank owners to add accident damage protection whenever practicable, such as when a packaging is undergoing major repair or reconditioning.

Paragraph (h) provides exceptions from certain packaging requirements. The Truck Trailer Manufacturers Association asked whether existing cargo tanks designed for the transportation of molten sulphur, dimethyl-terephthalate and phthalic anhydride may continue in service if in compliance only with the closure requirement by March 30, 1995. This is correct. RSPA realizes that many packagings currently in ETM service will not be authorized for new construction on or after October 1, 1993. However, paragraph (h)(1) is revised to clarify that such packagings may continue in ETM service if the closure requirements of paragraph (g)(2) are met by March 30, 1995, and if the packaging conforms to the general packaging requirements in subparts A and B of part 173.

As mentioned earlier, petitioners stated that most asphalt and bitumen kettles have a capacity between 400 and 600 gallons (1515 and 2270 L). RSPA believes that smaller quantities of asphalt and bitumen pose a lesser potential hazard and, due to a wide usage of this type of packaging in transportation, it is important to recognize the unique characteristics of asphalt and bitumen kettles. Therefore, in this document, RSPA is providing specific packaging exceptions for kettles which will result in economic relief to industry. These exceptions may be broadly categorized as imposing certain minimal requirements on existing kettles and, as discussed earlier, providing incentives for future construction of kettles with high overturn stability.

Paragraph (h)(2) provides exceptions for asphalt or bitumen kettles manufactured before October 1, 1993. Kettles transporting asphalt and bitumen and having less than 2650 L (700 gallons) total capacity are excepted in paragraph (h)(2)(i) from general packaging requirements of this section except for securing closures during transport. Lids, closures, and covers on these packagings must be secured by March 30, 1995 in such a way as to resist opening in the event of overturn. By this date, all other ETM packagings in service before October 1, 1993 must be retrofitted with closures which fully meet the requirements of paragraph (g)(2).

Under paragraph (h)(2)(ii), kettles having a capacity of 2650 L (700 gallons) or greater and in service before October 1, 1993 must meet certain closure requirements in paragraph (g)(2) by October 1, 1995. These packagings may continue in service for as long as they conform to the general packaging requirements in subparts A and B of part 173.

The exceptions in paragraphs (h)(3) and (h)(4) for molten metals and molten glass by rail, and solid elevated temperature materials remain unchanged from the final rule.

49 App. U.S.C. 1804(a)(4) (A) and (B)

In February 28, 1991 final rule (56 FR 8616), RSPA added this new preemption standard to § 107.202 to mirror the statute. Section 105(a)(5) of the HMTA, as amended by the HMTUSA, provides that if DOT issues a regulation concerning any of the covered subjects after the date of enactment of the HMTUSA (November 16, 1990), DOT must determine and publish in the **Federal Register** the effective date of the Federal preemption. That effective date may not be earlier than the 90th day following the date of issuance and not later than two years after the date of issuance.

To the extent that the requirements of Docket HM–198A involve covered subjects, States, political subdivisions, or Indian tribes may only establish, maintain, and enforce laws, regulations, or other requirements concerning such subjects if they are substantively the same as the requirements in Docket HM–198A. In a May 13, 1992 final rule (57 FR 20424), RSPA defined the phrase "substantively the same". RSPA has determined that the effective date of Federal preemption for these requirements will be October 1, 1993.

IV. Regulatory Analyses

A. Executive Order 12291 and DOT Regulatory Policies and Procedures

This final rule has been reviewed under the criteria specified in § 1(b) of Executive Order 12291 and (1) is determined not to be a major rule under Executive Order 12291; (2) does not require a Regulatory Impact Analysis; and (3) is not "significant" under DOT's regulatory policies and procedures (44 FR 11034). This final rule does not impose additional requirements and, in fact, provides regulatory and economic relief in some areas. The net result is that costs imposed under the final rule published in the **Federal Register** on October 2, 1991 (56 FR 49980) are reduced, but without a reduction in safety. The original regulatory evaluation of the final rule has been reexamined but not modified. The changes made under this rule provide relief and will not result in an adverse economic impact on industry.

B. Executive Order 12612

This action has been analyzed in accordance with Executive Order 12612 ("Federalism"). The HMTA contains an

express preemption provisions which RSPA is implementing at the minimum level necessary to achieve the objectives of the statute. Therefore, preparation of a Federalism Assessment is not warranted.

C. Impact on Small Entities

Based on limited information concerning size and nature of entities likely to be affected by this rule, I certify that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

D. Paperwork Reduction Act

This amendment imposes no changes to the information collection and recordkeeping requirements contained in the October 2, 1991 final rule for §§ 172.201 and 172.203, which were approved by the Office of Management and Budget (OMB) under the provisions of 44 U.S.C. chapter 35.

E. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

F. National Environmental Policy Act

This rule has been reviewed under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and does not require an environmental impact statement.

List of Subjects

49 CFR Part 172

Hazardous materials transportation, Hazardous waste, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

In consideration of the foregoing, 49 CFR parts 172 and 173 are amended as follows:

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

1. The authority citation for part 172 continues to read as follows:

Authority: 49 App. U.S.C. 1803, 1804, 1805, and 1808; 49 CFR part 1, unless otherwise noted.

§ 172.101 [Amended]

2. In § 172.101, the Hazardous Materials Table is amended as follows:

a. For the entry, "*Elevated temperature material, solid, n.o.s. (see § 173.247(d)(2))*", in column (2), the reference "*§ 173.247(d)(2)*" is revised to read "*§ 173.247(h)(4)*".

b. For the entry "Flammable liquid, elevated temperature material, n.o.s.", in column (4), the identification number "NA9275" is revised to read "NA9276"

§ 172.203 [Amended]

3. In § 172.203, in paragraph (g)(3), the reference "§ 173.247(d)" is revised to read "§ 173.247(h)(3)".

4. Section 172.325 is revised to read as follows:

§ 172.325 Elevated temperature materials.

(a) Except as provided in paragraph (b) of this section, a bulk packaging containing an elevated temperature material must be marked on two opposing sides with the word "HOT" in black or white Gothic lettering on a contrasting background. The marking must be displayed on the packaging itself or in black lettering on a plain white square-on-point configuration having the same outside dimensions as a placard. (See § 172.302(b) for size of markings on bulk packagings.)

(b) Bulk packagings containing molten aluminum or molten sulfur must be marked "MOLTEN ALUMINUM" or "MOLTEN SULFUR", respectively, in the same manner as prescribed in paragraph (a) of this section.

(c) If the identification number is displayed on a white-square-on-point display configuration, as prescribed in § 172.336(b), the word "HOT" may be displayed in the upper corner of the same white-square-on-point display configuration. The word "HOT" must be in black letters having a height of at least 50 mm (2.0 inches). Except for size, these markings shall be as illustrated for an Elevated temperature material, liquid, n.o.s.:

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

5. The authority citation for part 173 continues to read as follows:

Authority: 49 App. U.S.C. 1803, 1804, 1805, 1806, 1807, 1808, 1817; 49 CFR part 1, unless otherwise noted.

6. Section 173.247 is revised to read as follows:

§ 173.247 Bulk packaging for certain elevated temperature materials (Class 9) and certain flammable elevated temperature materials (Class 3).

When § 172.101 of this subchapter specifies that a hazardous material be packaged under this section, only the following bulk packagings are authorized, subject to the requirements of subparts A and B of part 173 of this subchapter and the special provisions in Column 7 of the § 172.101 Table. On or after October 1, 1993, authorized packagings must meet all requirements in paragraph (g) of this section, unless otherwise excepted.

(a) *Rail cars:* Class DOT 103, 104, 105, 109, 111, 112, 114, 115 tank car tanks; Class DOT 106, 110 multi-unit tank car tanks; AAR Class 203W, 206W, 211W tank car tanks; and non-DOT specification tank car tanks equivalent in structural design and accident damage resistance to specification packagings.

(b) *Cargo tanks:* Specification MC 300, MC 301, MC 302, MC 303, MC 304, MC 305, MC 306, MC 307, MC 310, MC 311, MC 312, MC 330, MC 331 cargo tank motor vehicles; DOT 406, DOT 407, DOT 412 cargo tank motor vehicles; and non-DOT specification cargo tank motor vehicles equivalent in structural design and accident damage resistance to specification packagings. A non-DOT specification cargo tank motor vehicle constructed of carbon steel which is in elevated temperature material service is excepted from § 178.345–7(d)(5) of this subchapter.

(c) *Portable tanks:* Specification 51, 52, 53, 56, 57, 60 portable tanks; IM 101, 102 portable tanks; marine portable tanks conforming to 46 CFR Part 64; and non-specification portable tanks equivalent in structural design and accident damage resistance to specification packagings.

(d) *Crucibles:* Nonspecification crucibles designed and constructed such that the stress in the packaging does not exceed one fourth (0.25) of the ultimate strength of the packaging material at any temperature within the design temperature range. Stress is determined under a load equal to the sum of the static or working pressure in combination with the loads developed from accelerations and decelerations incident to normal transportation. For highway transportation, these forces are assumed to be "1.7g" vertical, "0.75g" longitudinal, and "0.4g" transverse, in reference to the axes of the transport vehicle. Each accelerative or decelerative load may be considered separately.

(e) *Kettles:* A kettle, for the purpose of this section, is a bulk packaging (portable tank or cargo tank) having a capacity not greater than 5678 L (1500 gallons) with an integral heating apparatus used for melting various bituminous products such as asphalt. Kettles used for the transport of asphalt or bitumen are subject to the following requirements:

(1) *Low stability kettles.* Kettles with a ratio of track-width to fully loaded center of gravity (CG) height less than 2.5 must meet all requirements of paragraph (g) of this section (track-width is the distance measured between the outer edge of the kettle tires; CG height is measured perpendicular from the road surface).

(2) *High stability kettles.* (i) Kettles with a total capacity of less than 2650 L (700 gallons) and a ratio of track-width to fully loaded CG height of 2.5 or more are excepted from all requirements of paragraph (g)(2) of this section and the rollover protection requirements of paragraph (g)(6) of this section, if closures meet the requirements of paragraph (e)(2)(iii) of this section.

(ii) Kettles with a total capacity of 2650 L (700 gallons) or more and a ratio of track-width to fully loaded CG height of 2.5 or more are excepted from the "substantially leak tight" requirements of paragraph (g)(2) of this section and the rollover protection requirements of paragraph (g)(6) of this section if closures meet the requirements of paragraph (e)(2)(iii) of this section.

(iii) Closures must be securely closed during transportation. Closures also must be designed to prevent opening and the expulsion of lading in a rollover accident.

(f) *Other bulk packagings:* Bulk packagings, other than those specified in paragraphs (a) through (e) of this section, which are used for the transport of elevated temperature materials, must conform to all requirements of paragraph (g) of this section on or after October 1, 1993.

(g) *General requirements.* Bulk packagings authorized or used for transport of elevated temperature materials must conform to the following requirements:

(1) *Pressure and vacuum control equipment.* When pressure or vacuum control equipment is required on a packaging authorized in this section, such equipment must be of a self-reclosing design, must prevent package rupture or collapse due to pressure, must prevent significant release of lading due to packaging overturn or splashing or surging during normal transport conditions, and may be external to the packaging.

(i) Pressure control equipment is not required if pressure in the packaging would increase less than 10 percent as a result of heating the lading from the lowest design operating temperature to a temperature likely to be encountered if the packaging were engulfed in a fire. When pressure control equipment is required, it must prevent rupture of the packaging from heating, including fire engulfment.

(ii) Vacuum control equipment is not required if the packaging is designed to withstand an external pressure of 100 Kpa (14.5 psig) or if pressure in the packaging would decrease less than 10 percent as a result of the lading cooling from the highest design operating temperature to the lowest temperature incurred in transport. When vacuum control equipment is required, it must prevent collapse of the packaging from a cooling-induced pressure differential.

(iii) When the regulations require a reclosing pressure relief device, the lading must not render the devices inoperable (i.e. from clogging, freezing, or fouling). If the lading affects the proper operation of the device, the packaging must have:

(A) A safety relief device incorporating a frangible disc or a permanent opening, each having a maximum effective area of 22 cm^2 (3.4 $in.^2$), for transportation by highway;

(B) For transportation of asphalt by highway, a safety relief device incorporating a frangible disc or a permanent opening, each having a maximum effective area of 46 cm^2 (7.1 $in.^2$); or

(C) For transportation by rail, a safety relief device incorporating a frangible disc, meeting the requirements of § 179.200–18 of this subchapter.

(iv) Reclosing pressure relief devices, frangible discs or permanent openings must not allow the release of lading during normal transportation conditions (i.e., due to splashing or surging).

(2) *Closures.* All openings, except permanent vent openings authorized in paragraph (g)(1)(iii) of this section, must be securely closed during transportation. Packagings must be substantially leak-tight so as not to allow any more than dripping or trickling of a non-continuous flow when overturned. Closures must be designed and constructed to withstand, without exceeding the yield strength of the packaging, twice the static loading produced by the lading in any packaging orientation and at all operating temperatures.

(3) *Strength.* Each packaging must be designed and constructed to withstand, without exceeding the yield strength of the packaging, twice the static loading produced by the lading in any orientation and at all operating temperatures.

(4) *Compatibility.* The packaging and lading must be compatible over the entire operating temperature range.

(5) *Markings.* In addition to any other markings required by this subchapter, each packaging must be durably marked in a place readily accessible for inspection in characters at least 4.8 mm (3/16 inch) with the manufacturer's name, date of manufacture, design temperature range, and maximum product weight (or "load limit" for tank cars) or volumetric capacity.

(6) *Accident damage protection.* For transportation by highway, external loading and unloading valves and closures must be protected from impact damage resulting from collision or overturn. Spraying equipment and the road oil application portion of a packaging are excepted from this requirement.

(7) *New construction.* Specification packagings that are being manufactured for the transport of elevated temperature materials must be authorized for current construction.

(h) *Exceptions.*

(1) *General.* Packagings manufactured for elevated temperature materials service prior to October 1, 1993, which are not in full compliance with the requirements in paragraph (g) of this section, may continue in service if they meet the applicable requirements of subparts A and B of this part and meet the closure requirements in paragraph (g)(2) of this section by March 30, 1995.

(2) *Kettles.* Kettles in service prior to October 1, 1993, which are used to transport asphalt or bitumen, are excepted from specific provisions of this section as follows:

(i) Kettles with a total capacity of less than 2650 L (700 gallons), which are not in full compliance with the requirements of paragraph (g) of this section, may continue in elevated temperature material service if they meet the applicable requirements of subparts A and B of this part and if, after March 30, 1995, closures are secured during transport to resist opening in an overturn.

(ii) Kettles with a total capacity of 2650 L (700 gallons) or more, which are not in full compliance with the requirements of paragraph (g) of this section, may continue in elevated temperature material service if they meet the applicable requirements of subparts A and B of this part and if, after March 30, 1995, closures are secured during transport to resist opening in an overturn and no opening exceeds 46 cm^2 (7.1 in^2).

(3) *Molten metals and molten glass.* This section does not apply to packagings used for transportation of molten metals and molten glass by rail when movement is restricted to operating speeds less than 15 miles per hour. (See § 172.203(g)(3) of this subchapter for shipping paper requirements.)

(4) *Solid elevated temperature materials.* A material which meets the definition of a solid elevated temperature material is excepted from all requirements of this subchapter except § 172.325 of this subchapter.

Issued in Washington, DC, on January 4, 1993 under authority delegated in 49 CFR part 1.

Douglas B. Ham,

Acting Administrator, Research and Special Programs Administration.

[FR Doc. 93–339 Filed 1–7–93; 8:45 am]

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Part IV

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 1210

Watermelon Research and Promotion Plan; Final Rule

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1210

[AMS-FV-91-275]

RIN 0581-AA32

Watermelon Research and Promotion Plan; Amendments to Procedures for Nominating Producer and Handler Members to the National Watermelon Promotion Board, and Amendments to the Rules and Regulations Issued Thereunder

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action amends the procedures for nominating producer and handler members to the National Watermelon Promotion Board (Board). These amendments: simplify voting procedures used at nomination conventions, set a date by which nominee qualification forms must be received by the Department of Agriculture (Department), and clarify that nominees are responsible for submitting their qualification statements to the Board for forwarding to the Department. Additionally, changes are made to clarify the definition of a handler and to update OMB control numbers.

EFFECTIVE DATE: February 8, 1993.

FOR FURTHER INFORMATION CONTACT: Sonia N. Jimenez, Research and Promotion Branch, F&V, AMS, USDA, Room 2535–South, P.O. Box 96456, Washington, DC 20090–6456; telephone (202) 720–9917.

SUPPLEMENTARY INFORMATION: This final rule is issued under the Watermelon Research and Promotion Plan (7 CFR part 1210), hereinafter referred to as the Plan. The Plan is effective under the Watermelon Research and Promotion Act (7 U.S.C. 4901–4916), hereinafter referred to as the Act.

This rule has been reviewed by the Department in accordance with Departmental Regulation No. 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 1650 of the Act, a person subject to a plan may file a petition with the Secretary stating that such plan, any provision of such plan or any obligation imposed in connection with such plan is not in accordance with law; and requesting a modification of the plan or an exemption from the plan. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which such person is an inhabitant, or has principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided that a complaint is filed within 20 days after the date of entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. The purpose of the RFA is to fit regulatory actions of the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

There are approximately 750 watermelon handlers and 5,000 watermelon producers subject to regulation under the Plan. Small agricultural service firms are defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $3,500,000, and small agricultural producers are defined as those having annual receipts of less than $500,000. The majority of watermelon handlers and producers may be classified as small entities. During 1991, shipments of U.S. watermelons totalled more than 21.5 billion pounds.

This action will not have significant economic impact on small producers or handlers. This action benefits producers and handlers by simplifying the voting procedures employed at nomination conventions. Producers and handlers also benefit from this action through the further clarification of who is a handler for the purposes of paying assessments.

In accordance with the Paperwork Reduction Act (PRA) of 1980 (44 U.S.C. chapter 35) and Office of Management and Budget (OMB) regulations [5 CFR part 1320], the information collection and recordkeeping requirements contained in this action were submitted to the OMB and approved under OMB control numbers 0518–0093 and 0505–0001. These OMB control numbers expire on March 31, 1994.

The Act and Plan provide that handlers are responsible for collecting and submitting both producer and handler assessments to the Board, for reporting their handling of watermelons, and for maintaining records necessary to verify their reportings. This action adds no additional reporting burden.

In the September 15, 1989, issue of the **Federal Register** (54 FR 38202), the Department published an interim final rule with a request for comments establishing the procedures for nominations of producer and handler members to the Board. One comment was received by the November 14, 1989, deadline. The commenter recommended electing both nominees for each available position simultaneously rather than by voting for each nominee separately. The two nominees receiving the greatest number of votes and at least a simple majority of the votes cast would be the two nominees forwarded to the Department for the Secretary of Agriculture's (Secretary) selection for appointment to the Board. Additionally, nominees would no longer be ranked as either the first or second choice of the nominating body.

This comment was deemed to have merit. Therefore, rather than finalizing the September 15, 1989, interim final rule, the Department issued a proposed rule to revise the interim final rule. The proposed rule was published in the January 31, 1992, issue of the **Federal Register** [57 FR 3727]. It included the revision recommended by the commenter as well as additional revisions which were deemed necessary by the Department. The additional revisions included further changes to the nomination procedures, clarification of the definition of a handler, and updated OMB control numbers. Twenty-two comments on the proposal were received from producers, handlers, and one person commenting on behalf of the Board. Two additional comments, one from a dietitian and one from a person representing the National Watermelon Association, were received after the March 2, 1992, deadline. All comments received, including those received late, favored the amendments to the nominating procedures and to the rules and regulations as they were published in the proposed rule. Therefore, these revisions, as described below, are adopted by this final rule.

The nominating procedures as originally set forth in paragraph (f) of § 1210.401 required that the chairperson of each nominating meeting submit the nominee's qualifications statements. Information in such statements is confidential, and having the chairperson responsible for their submission poses a

risk of violating nominee's confidentiality. To better ensure that the confidentiality of information supplied by nominees for Board membership is maintained, paragraph (f) of § 1210.401 is hereby amended to require that each nominee bear the responsibility for completing his or her qualifications statement and forwarding it to the Board's office for submission to the Department. The chairperson will be responsible for submitting the nominating meeting report and for assuring the nominees complete and submit their statements in a timely fashion. This amended paragraph also includes time frames in which qualifications statements and meeting reports must be submitted to the Board and to the Department. The chairperson must submit meeting reports and arrange for the completion and submission of qualifications statements to the Board's office within 14 days of the meeting's completion, but no later than July 8 for appointments to become effective on January 1. The Board's staff must forward such information to the Department within 21 days of the meeting, but no later than July 15 for appointments to become effective on the following January 1.

Paragraph (h) of § 1210.403 is also amended by revising the voting procedure used at nomination meetings. The two nominees receiving the greatest number of votes and at least a simple majority of the votes cast will be the two nominees forwarded to the Department for the Secretary's selection for appointment to the Board. Additionally, nominees would no longer be ranked as either the first or second choice of the nominating body. Revising the nominating procedures in this manner simplifies and shortens the nominating process. It also has the added benefit of encouraging each nominee to submit his or her qualifications statement in a timely fashion since neither nominee would have reason to believe that one has preference over the other in the appointment process. Presently, nominees who are elected as the second choice for a position do not feel they will receive consideration by the Secretary for appointment and, therefore, do not have a great incentive to complete and submit their qualifications statements. Revising the procedures is also expected to reduce the number of disqualifications of nominees who do not complete and submit their qualifications statements.

Section 1201.404 is removed and reserved in order to have all the OMB numbers in one section. Section 1210.540 will contain all the required OMB numbers.

Section 1210.517 of the rules and regulations deals with the definition of a handler for the purpose of payment of assessments to the Board. This action adds a new paragraph (a)(3) to § 1210.517 in order to clarify that a producer who purchases watermelons from one or more producers in any amount and for whatever reason becomes a handler. As a first handler, this producer is therefore responsible for the payment of assessments. This change is necessary to improve operations under the Plan. Therefore, § 1210.517 is revised by redesignating paragraphs (a)(3) through (a)(11) as paragraphs (a)(4) through (a)(12), respectively, and a new paragraph (a)(3) is added to § 1210.517.

Further, the Board recommended inserting the words "/Commission House" after the word "Broker" or "Brokers" each time they occur in existing paragraphs (a)(8) and (a)(9) of § 1210.517 (redesignated paragraphs (a)(9) and (a)(10), respectively). This addition clarifies that commission houses are treated the same as brokers for assessment purposes under the Plan.

Section 1210.540 of the rules and regulations issued under the Plan contains the same OMB control number for information collection referred to in § 1210.404. However, since the initial issuance of section 1210.404, a new nominee background information form has been developed which received OMB approval and assignment of a control number. In addition, the information collection provisions of the Plan have been reapproved and the OMB control number revised. Therefore, section 1210.540 is hereby amended to add the new OMB Control Number 0505–0001 for the nominee background information form and 0581–0093 for other information collections under the Plan.

In addition, editorial changes have been made to the following regulatory text for the purpose of clarity.

Based on the above, the Administrator of the AMS has determined that the issuance of this final rule will not have a significant economic effect on a substantial number of small entities.

After consideration of all relevant material presented, it is found that this regulation, as set forth herein, tends to effectuate the declared policy of the Act.

This final rule will become effective 30 days following the date of publication in the **Federal Register**.

List of Subjects in 7 CFR Part 1210

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Reporting and recordkeeping requirements, Watermelons.

For the reasons set forth in the preamble, part 1210, chapter XI of title 7 is amended to read as follows:

PART 1210—WATERMELON RESEARCH AND PROMOTION PLAN

1. The authority citation for 7 CFR part 1210 continues to read as follows:

Authority: 7 U.S.C. 4901–4916.

2. Section 1210.401 is amended by revising the concluding text of paragraph (f) to read as follows:

§ 1210.401 District conventions.

* * * * *

(f) * * *

This information must be provided by the chairperson to the Board staff in a manner that will ensure receipt, at the address specified in the call for the district convention, within 14 calendar days of the district convention's completion, but not later than July 8 for appointments to become effective on the following January 1. The Board staff must forward such information to the Secretary, in a manner that will ensure receipt, within 21 calendar days of completion of the district convention, but not later than July 15 for appointments to become effective on the following January 1. Further, the chairperson will immediately arrange for completion of qualification statements and other specified information by each nominee, and each nominee shall qualify by forwarding such information to the Board's office within 14 calendar days of completion of the district convention, but not later than July 8 for appointments to become effective on the following January 1. The Board staff must forward the completed qualification statements and other specified information to the Secretary, in a manner that will ensure receipt within 21 calendar days of completion of the district convention, but not later than July 15 for appointments to become effective on the following January 1.

3. Section 1210.403 is amended by revising paragraph (h) to read as follows:

§ 1210.403 Voting procedures.

* * * * *

(h) Two nominees shall be elected for each of the producer and handler positions from each district on the Board. The two nominees for each position shall be elected simultaneously. The convention chairperson will open the floor to the nomination of candidates for possible election as a Board member nominee for

each available position. Each position will be dealt with separately (i.e., candidates for one position will be nominated and then elected before the convention moves on to the next available position). Each eligible voter may vote for two of the nominees on one ballot. The two nominees receiving the greatest number of votes and at least a simple majority of the votes cast will be elected as the district's Board member nominees for the position. No individual elected as a nominee for Board membership may be a candidate on subsequent Board member nominee ballots (i.e., two different producer names and two different handler names must be submitted as nominees for each producer and handler position from each district to the Secretary of Agriculture). There shall be no designation of first and second choice nominees.

§ 1210.404 [Reserved]

4. Section 1210.404 is removed and reserved.

5. Section 1210.517 is amended by redesignating paragraphs (a)(3) through (a)(11) as paragraphs (a)(4) through (a)(12) respectively, adding a new paragraph (a)(3), and revising redesignated paragraphs (a)(9) and (a)(10) to read as follows:

§ 1210.517 Determination of handler.

* * * * *

(a) * * *

(3) Producer purchases watermelons from another producer. The producer purchasing the watermelons is the first handler.

* * * * *

(9) Broker/Commission House receives watermelons from a producer and sells such watermelons in the Broker's/Commission House's name. In this instance, the Broker/Commission House is the first handler, regardless of whether the Broker/ Commission House took title to such watermelons.

(10) Broker/Commission House, without taking title or possession of watermelons, sells such watermelons in the name of the producer. In this instance, the producer is the first handler.

* * * * *

6. Section 1210.540 is revised to read as follows:

§ 1210.540 OMB assigned numbers.

The information collection and recordkeeping requirements contained in this part have been approved by the Office of Management and Budget (OMB) under the provisions of 44 U.S.C. chapter 35 and have been assigned OMB Control Number 0581–0093, except that Board member nominee background information sheets are assigned OMB Control Number 0505–0001.

Dated: December 29, 1992.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 93–200 Filed 1–7–93; 8:45 am]

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Part V

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 1207

Potato Research and Promotion Plan; Final Rule

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1207

[AMS–FV–91–235A]

RIN 0581–AA47

Potato Research and Promotion Plan; Termination of Obsolete Provisions of the Plan and Amendments to the Rules and Regulations Issued Thereunder

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The U.S. Department of Agriculture is adopting with change as a final rule an interim final rule which: Terminated obsolete provisions in the Potato Research and Promotion Plan (Plan) that provided for the one-time refund of assessments and provided the Harmonized Tariff Schedule (HTS) categories, the assessment rates for imported tablestock potatoes, frozen or processed potatoes, and seed potatoes, and the applicable factors for converting processed potatoes to fresh potato weight equivalents.

DATES: This final rule is effective January 8, 1993.

FOR FURTHER INFORMATION CONTACT: Georgia C. Abraham, Research and Promotion Branch, F&V, AMS, USDA, room 2535–So., P.O. Box 96456, Washington, DC 20090–6456; telephone (202) 720–5057.

SUPPLEMENTARY INFORMATION: These amendments to the Plan are issued pursuant to the Potato Research and Promotion Act, as amended on November 28, 1990 (104 Stat. 3865, 7 U.S.C. 2611 *et seq.*), hereinafter referred to as the Act.

This final rule has been reviewed by the U.S. Department of Agriculture (Department) in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any state or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 311 of the Act, a person subject to a plan may file a petition with the Secretary stating that such plan, any provision of such plan or any obligation imposed in connection with such plan is not in accordance with law; and requesting a modification of the plan or an exemption from the plan. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which such person is an inhabitant, or has principal place of business, has jurisdiction to review the Secretary's ruling on the petition, provided that a complaint is filed within 20 days after the date of entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

There are an estimated 2,000 handlers, 6,000 producers, 80 importers of potatoes and potato products for human consumption, and 25 importers of seed potatoes who are subject to the provisions of the Plan. The majority of these persons may be classified as small agricultural producers and small agricultural service firms. Small agricultural producers are defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of potato handlers, producers, and importers may be classified as small entities. During the 1991 crop year, 417.6 million hundredweight of potatoes were produced in the United States. Imports of potatoes for 1991, as reported by the Foreign Agricultural Service, were 6,160,596 hundredweight. Of this total, 4,373,525 hundredweight of tablestock potatoes, 1,787,071 hundredweight of seed potatoes, and 1,628,712 hundredweight of frozen potatoes products were imported from Canada. Potato chip imports from Mexico accounted for 35,935 hundredweight of total potato and potato products imports.

Domestic potato producers are no longer able to apply for and receive refunds of assessments. Importers are subject to the Act's provisions requiring importers to share the cost of the program with domestic potato producers on an equal basis. This burden is not considered significant in light of the benefits all potato producers and importers receive from this program.

In accordance with the Paperwork Reduction Act (PRA) of 1980 (44 U.S.C. chapter 35) and Office of Management and Budget (OMB) regulations (5 CFR part 1320), the information collection and recordkeeping requirements contained in this action were submitted to the OMB and approved under OMB control numbers 0581–0093 and 0505–0001.

The reporting burden for domestic potato producers and importers has decreased since they are no longer required to complete the forms necessary to receive the one-time refund of assessments paid. The reporting burden on importers requires approximately 6 hours per year for each importer of potatoes, potato products, and seed potatoes.

The Plan, as amended in the August 14, 1991, issue of the Federal Register (56 FR 40226), authorizes the National Potato Promotion Board (Board) to collect assessments on potatoes, potato products, and seed potatoes imported into the United States from foreign countries. Importers of such potatoes, potato products, and seed potatoes are required to submit such reports to the Board as it deems necessary to administer the provisions of the Plan. However, no immediate reporting requirements by importers are contemplated at this time since the U.S. Customs Service (Customs Service) of the Department of the Treasury will collect assessments on imported potatoes, potato products, and seed potatoes beginning on November 2, 1992. Importers are required to maintain records, and such records will be subject to inspection. Records are required to be maintained for 2 years beyond the close of the fiscal year in which they were created.

It is estimated that approximately 105 importers are subject to these requirements. Because the assessment is levied at the time of importation or withdrawal for consumption into the United States, there are no added reporting requirements on importers.

An interim final rule was published in the September 2, 1992, issue of the Federal Register (57 FR 40081). The interim final rule: (1) Terminated obsolete provisions in the Potato Research and Promotion Plan (Plan) and the Rules and Regulations issued thereunder that provided for the one-time refund of assessments; and (2) provided the Harmonized Tariff Schedule (HTS) categories, assessment rates for imported tablestock potatoes, for frozen or processed potatoes, and for seed potatoes, and the applicable factors for converting processed potatoes to fresh potato weight equivalents. That action was based on the vote in the referendum conducted from August 19 to September 6, 1991. In the

referendum, domestic potato producers and importers favored levying assessments on imported potatoes, seed potatoes, and frozen or processed potato products and terminating the Plan's refund provisions.

Section 315 of the Act provides the Secretary the authority to terminate provisions of the Plan which do not tend to effectuate the declared policy of the Act. Paragraph (k) of § 1207.328 and § 1207.343 of the Plan and § 1207.514 of the rules and regulations which, respectively, established an escrow account and permitted the one-time refund of assessments if producers and importers did not favor continuance of the amendments as stated in the above paragraph, were rendered obsolete by the results of the referendum conducted in August and September 1991. Therefore, the interim final rule terminated paragraph (k) of § 1207.328 and § 1207.343 of the Plan and § 1207.514 of the rules and regulations.

The interim final rule incorporated the HTS codes of the Customs Service, provided for assessment rates for imports, and added conversion factors by revising § 1207.510. Conversion factors are needed to compute assessment rates for frozen or processed potato products that equal fresh weight equivalents of potatoes.

The interim final rule provided that interested persons could file written comments through October 2, 1992. No written comments were received. However, several interested parties telephoned the Department regarding the assessment of imported, edible potato starch.

In revising § 1207.510, the HTS code, conversion factor, and assessment rate for potato starch were inadvertently omitted. Therefore, paragraph (b) of § 1207.510 is further revised by this final rule to include the HTS code, the conversion factor, and the assessment rate for potato starch. The HTS code for potato starch is 1108.13.000, the conversion factor is .1111, and the assessment rate is 18.0018 cents per hundredweight or 0.3969 cents per kilogram.

In addition, miscellaneous changes are made for clarity in this final rule.

The 1990 amendments to the Act provide that all imported potatoes for human consumption (fresh or processed) and seed potatoes be assessed at rates equivalent to that levied on domestic potato production. In some cases, Customs Service's HTS codes do not differentiate between potatoes and potato products that are intended for human consumption and those intended for non-human consumption. Therefore, the Customs Service will collect assessments on all imported tablestock, processed potato products, and seed potatoes identified by the HTS codes in paragraph (b) of § 1207.510. As previously established in paragraph (b)(2) of § 1207.513 of the rules and regulations, importers may apply to the Board for refund of assessments paid on exempted imported potatoes and processed potato products. As also previously stated in § 1207.501, communications with the Board may be addressed to: The National Potato Promotion Board, 1385 South Colorado Boulevard, Suite 512, Denver, Colorado 80222.

Based on the above, the Administrator of the AMS has determined that the issuance of this final rule will not have a significant economic effect on a substantial number of small entities.

After consideration of all relevant material presented, it is found that the amendments to the rules and regulations, as set forth in the September 2 interim final rule and adopted with change by this final rule, will tend to effectuate the declared policy of the Act. With regard to the termination of provisions in the Plan and the rules and regulations, as set forth in the September 2 interim final rule and finalized by this rule, it is found that these provisions no longer tend to effectuate the declared policy of the Act.

Pursuant to the provisions in 5 U.S.C. 553, it is found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because:

(1) This action is required by the 1990 amendments to the Act and the 1991 amendments to the Plan;

(2) The interim final rule provided a 30-day period to allow interested parties to comment prior to this action;

(3) Section 1207.510(b) became effective November 2, 1992;

(4) Importers are notified of this action through Customs Service's Automated Commercial System's Automated Broker Interface; and

(5) No useful purpose would be served by a delay of the effective date.

List of Subjects in 7 CFR Part 1207

Advertising, Agricultural research, Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 7 CFR part 1207 which was published at 57 FR 40081 on September 2, 1992, is adopted as a final rule with the following changes:

PART 1207—POTATO RESEARCH AND PROMOTION PLAN

1. The authority citation for 7 CFR part 1207 continues to read as follows:

Authority: Potato Research and Promotion Act, as amended, 7 U.S.C. 2611 *et seq.*

2. Section 1207.510 is amended by revising paragraphs (b) (1), (2), and (3) and (c) to read as follows:

§ 1207.510 Levy of assessments.

* * * * *

(b) *Assessments on imports.* (1) An assessment rate of 2 cents per hundredweight shall be levied on all tablestock potatoes imported into the United States for ultimate consumption by humans and all seed potatoes imported into the United States. An assessment rate of 2 cents per hundredweight shall be levied on the fresh weight equivalents of imported frozen or processed potatoes for ultimate consumption by humans. The importer of imported tablestock potatoes, potato products, or seed potatoes shall pay the assessment to the Board through the U.S. Customs Service at the time of entry or withdrawal for consumption of such potatoes and potato products into the United States.

(2) The following conversion factors shall be used to determine the fresh weight equivalents of frozen and processed potato products:

Frozen potato products	.50
Canned potatoes	.636
Potato chips and shoestring potatoes	.245
Dehydrated potato products	.14
Potato starch	.1111

(3) The Harmonized Tariff Schedule (HTS) categories and assessment rates on imported tablestock potatoes and frozen or processed potatoes for ultimate consumption by humans and on imported seed potatoes are as follows:

Tablestock potatoes, frozen or processed potatoes, and seed potatoes	Assessment	
	cents/cwt	cents/kg
0701.10.0020	2.00	0.0441
0701.10.0040	2.00	0.0441
0701.90.1000	2.00	0.0441
0701.90.5010	2.00	0.0441
0701.90.5020	2.00	0.0441
0701.90.5030	2.00	0.0441
0701.90.5040	2.00	0.0441
0710.10.0000	4.00	0.0882
2004.10.4000	4.00	0.0882
2004.10.8020	4.00	0.0882
2004.10.8040	4.00	0.0882
2005.20.6060	3.1446	0.0693
0712.10.0000	14.2857	0.3149
1105.10.0000	14.2857	0.3149
1105.20.0000	14.2857	0.3149
2005.20.6040	14.2857	0.3149
2005.20.2000	8.1633	0.1800
1108.13.0000	18.0018	0.3969

* * * * *

(c) Potatoes and potato products used for nonhuman food purposes, other than seed, are exempt from assessment but are subject to the disposition of exempted potatoes provisions of § 1207.515 of this subpart.

* * * * *

Dated: December 31, 1992.

Jo Ann R. Smith,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93-212 Filed 1-7-93; 8:45 am]

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Part VI

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 1211

Pecan Promotion and Research Plan; Subpart C—Rules of Practice Governing Proceedings on Petitions; Rule

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR PART 1211

[FV-91-277]

RIN 0581-AA50

Pecan Promotion and Research Plan; Subpart C—Rules of Practice Governing Proceedings on Petitions To Modify or To Be Exempted From a Plan

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The U.S. Department of Agriculture is adopting with a minor modification as a final rule an interim final rule which specifies rules of practice governing proceedings on petitions to modify or to be exempted from the Pecan Promotion and Research Plan (Plan). This action is needed to provide persons subject to the Plan with rules of practice for such proceedings.

EFFECTIVE DATE: February 8, 1992.

FOR FURTHER INFORMATION CONTACT: Jim Wendland, Research and Promotion Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2535–S, Washington, DC 20090–6456, telephone (202) 720–9916.

SUPPLEMENTARY INFORMATION: This final rule is issued pursuant to the Pecan Promotion and Research Act of 1990 (7 U.S.C. 6001 *et seq.*), hereinafter referred to as the Act.

This final rule has been reviewed by the U.S. Department of Agriculture (Department) in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order No. 12291 and has been determined to be a "non-major" rule.

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This final rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 1913 of the Act, a person subject to a plan may file a petition with the Secretary stating that such plan, a provision of such plan, or an obligation imposed in connection with such plan is not in accordance with law and requesting a modification of the plan or an exemption from the plan. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the district courts of the United States in any district in which such person resides or carries on business has jurisdiction to review the Secretary's ruling on the petition, if a complaint is filed within 20 days after the date of the entry of a ruling by the Secretary.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

Growers, grower-shellers, and importers of pecans are subject to assessment under the Plan for pecans produced in or imported into the 50 States of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. The Plan provides that first handlers, grower-shellers, and importers are responsible for payment of assessments. Appropriate reporting and recordkeeping requirements are also provided for in the Plan.

The most recent available census of agricultural producers indicates that over 21,000 farms in the United States reported having pecan trees. The majority of these producers are subject to the provisions under the Plan and are classified as small businesses. Producers or growers engaged in the production and sale of pecans are subject to being assessed under the Plan. Small agricultural producers have been defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than $500,000, and small agricultural service firms, which include pecan handlers, shellers, grower-shellers, and importers, have been defined as those having annual receipts of less than $3,500,000. Also, there are approximately 2,000 pecan handlers, 115 shellers, and 25 importers who will be subject to the provisions of the Plan, the majority of whom are also classified as small entities.

Pecan production increased sharply between the early 1970's and the 1980's, with most of the increase in improved varieties. Average production of improved varieties increased from 109 million pounds in 1970–74 to 173 million pounds in 1981–88, a 59 percent increase. For the same periods all pecan production increased from 199 million pounds to 268 million pounds or 33 percent. The industry still has the capacity to produce large crops, such as those in the 1980's. Consequently, the research and promotion program is needed to help to bring demand in line with current production capacity.

During the 1990–91 crop year, 299 million pounds of pecans were produced in the United States, according to the revised final crop figures in USDA's July 1992 report. Pecan imports reported by the Foreign Agricultural Service for 1990–91 reached approximately 66 million pounds (in-shell weight). Approximately 90 percent of these imports were from Mexico and the remaining 10 percent were from Australia.

This action finalizes rules of practice governing proceedings on petitions filed by persons subject to the Plan to modify or be exempted from the Plan or any provision thereof. Section 1913 of the Act provides that any person subject to the Plan may file a written petition with the Secretary stating that the Plan or any provision of the Plan, or any obligation imposed in connection with such Plan, is not in accordance with law. The person may request a modification of the Plan or an exemption from certain provisions or obligations of the Plan. The Act further provides that the petitioner shall be given an opportunity for a hearing on the petition, in accordance with regulations prescribed by the Secretary.

An interim final rule providing procedures whereby a person subject to the Plan may file a petition to modify or to be exempted from the Plan was issued on June 17, 1992, and published in the **Federal Register** (57 FR 27898) on June 23, 1992.

The interim final rule provided that interested persons could file written comments through July 23, 1992. No comments were received.

However, a minor modification is necessary. Section 1211.251(h), the definition of the term "decision" should refer to the judge's "initial decision" rather than the judge's "report to the Secretary." Therefore, this action adopts the June 23 interim final rule with change.

Based on available information, the Administrator of the AMS has determined that the issuance of this rule will not have a significant economic impact on a substantial number of small entities.

It is found that this action will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 1211

Administrative practice and procedure, Advertising, Agricultural research, Imports, Marketing

agreements, Pecans, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 7 CFR part 1211 which was published at 57 FR 27898 on June 23, 1992, is adopted as a final rule with the following change:

PART 1211—PECAN PROMOTION AND RESEARCH PLAN

1. The authority citation for part 1211 continues to read as follows:

Authority: The Pecan Promotion and Research Act of 1990; 7 U.S.C. 6001 *et seq.*

2. Section 1211.251(h) introductory text is revised to read as follows:

§ 1211.251 Definitions.

* * * * *

(h) *Decision* means the judge's initial decision and includes the judge's:

* * * * *

Dated: December 29, 1992.

Daniel Haley,

Administrator.

[FR Doc. 93–199 Filed 1–7–93; 8:45 am]

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Part VII

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 1212

Lime Research, Promotion, and Consumer Information Order; Petition Procedures; Final Rule

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1212

[FV-91-425]

RIN 0581-AA48

Lime Research, Promotion, and Consumer Information Order; Petition Procedures

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The U.S. Department of Agriculture is adopting with a minor modification as a final rule an interim final rule which specifies rules of practice governing proceedings on petitions to modify or to be exempted from the Lime Research, Promotion, and Consumer Information Order (Order). This action is needed to provide persons subject to the Order with rules of practice for such proceedings.

EFFECTIVE DATE: February 8, 1993.

FOR FURTHER INFORMATION CONTACT: Jim Wendland, Research and Promotion Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2535-S, Washington, DC 20090-6456, telephone (202) 720-9916.

SUPPLEMENTARY INFORMATION: This final rule is issued pursuant to the Lime Research, Promotion, and Consumer Information Act of 1990, as enacted by the Food, Agriculture, Conservation and Trade Act of 1990 [Pub. L. 101-624; Title XIX].

This final rule has been reviewed by the U.S. Department of Agriculture (Department) in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order No. 12291 and has been determined to be a "non-major" rule.

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. This final rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 1957 of the Act, a person subject to an order may file a petition with the Secretary stating that such order, a provision of such order, or an obligation imposed in connection with such order is not in accordance with law and requesting a modification of the order or an exemption from the order. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the district courts of the United States in any district in which such person resides or carries on business has jurisdiction to review the Secretary's ruling on the petition, if a complaint is filed within 20 days after the date of the entry of a ruling by the Secretary.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened.

Under section 1957 of the Act, a person subject to an order may file a petition with the Secretary stating that such order, a provision of such order, or an obligation imposed in connection with such order is not in accordance with law and requesting a modification of the order or an exemption from the order. An interim final rule providing procedures whereby a person subject to the Order may file such a petition was issued on May 15, 1992, and published in the **Federal Register** (57 FR 21591) on May 21, 1992.

The interim final rule provided that interested persons could file written comments through June 22, 1992. No comments were received.

However, a minor modification is necessary. Section 1212.251(l), the definition of the term "decision," should refer to the judge's "initial decision" rather than the judge's "report to the Secretary." Therefore, this action adopts the May 21 interim final rule with change.

Based on available information, the Administrator of the AMS has determined that the issuance of this rule will not have a significant economic impact on a substantial number of small entities.

It is found that this action will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 1212

Administrative practice and procedure, Advertising, Agricultural research, Imports, Limes, Marketing agreements, Reporting and recordkeeping requirements.

Accordingly, the interim final rule amending 7 CFR part 1212 which was published at 57 FR 21591 on May 21, 1992, is adopted as a final rule with the following change:

PART 1212—LIME RESEARCH, PROMOTION, AND CONSUMER INFORMATION ORDER

1. The authority citation for part 1212 continues to read as follows:

Authority: The Lime Research, Promotion, and Consumer Information Act of 1990; 7 U.S.C. 6201 *et seq.*

2. Section 1212.251(l) introductory text is revised to read as follows:

§ 1212.251 Definitions.

* * * * *

(l) *Decision* means the judge's initial decision and includes the judge's:

* * * * *

Dated: December 29, 1992.

Kenneth C. Clayton,

Acting Administrator.

[FR Doc. 93-198 Filed 1-7-93; 8:45 am]

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Part VIII

Office of Management and Budget

Budget Rescissions and Deferrals; Notice

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OFFICE OF MANAGEMENT AND BUDGET

Budget Rescissions and Deferrals

December 30, 1992.

The Honorable Thomas S. Foley, Speaker of the House of Representatives, Washington, DC 20515.

Dear Mr. Speaker: In accordance with the Congressional Budget and Impoundment Control Act of 1974, I herewith report three revised and two new deferrals of budget authority, totaling $3.7 billion.

These deferrals affect International Security Assistance programs and the Departments of Agriculture and State. The details of these deferrals are contained in the attached report.

Sincerely,

George Bush,

The White House.

BILLING CODE 3110-01-M

DEFER NO.

D93-1A
D93-8
D93-9

D93-4

D93-7

CONTENTS OF SPECIAL MESSAGE
(in thousands of dollars)

DEFERRAL NO.	ITEM	BUDGET AUTHORITY
	Funds Appropriated to the President:	
	International Security Assistance:	
D93–1A	Economic support fund	1,985,511
D93–8	Foreign military financing grants	1,487,000
D93–9	Foreign military financing program	149,200
	Department of Agriculture:	
	Forest Service:	
D93–4A	Expenses, brush disposal	46,076
	Department of State:	
	Bureau of Refugee Programs:	
D93–7A	United States emergency refugee and migration fund	57,884
	Total, deferrals	3,725,671

Deferral No. D93-1A

Supplemental Report
Report Pursuant to Section 1014(c) of Public Law 93-344

This report updates Deferral No. D93-1, which was transmitted to Congress on October 1, 1992.

This revision increases by $1,492,774,491 the previous deferral of $492,736,396 in the Economic support fund, resulting in a total deferral of $1,985,510,887. The increase results from: (1) a greater-than-anticipated level of unobligated funds being carried over from FY 1992; and (2) the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1993.

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Deferral No. 93–1A

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Funds Appropriated to the President	New budget authority..... * $ 2,689,704,000 (P.L. 102–391)
BUREAU: International Security Assistance	Other budgetary resources.....* $ 534,287,081
Appropriation title and symbol: Economic support fund 1/ 112/31037 *113/41037 11X1037	Total budgetary resources.....* $ 3,223,991,081
	Amount to be deferred: Part of year.....* $ 1,985,510,887 2/ Entire year..... _____
OMB identification code: 11–1037–0–1–152	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act [ ] Other _____
Grant program: [X] Yes [ ] No	
Type of account or fund: [ ] Annual [X] Multi–year: September 30, 1993 *September 30, 1994 (expiration date) [X] No–Year	**Type of budget authority:** [X] Appropriation [ ] Contract authority [ ] Other _____

Coverage:

Appropriation	Account Symbol	OMB Identification Code	Deferred Amount Reported
Economic support fund.....	11X1037	11–1037–0–1–152	* 53,269,987
Economic support fund.....	112/31037	11–1037–0–1–152	462,240,900
Economic support fund.....	113/41037	11–1037–0–1–152	* 1,470,000,000
			* 1,985,510,887

JUSTIFICATION: This account provides economic and counternarcotics assistance to selected countries in support of U.S. efforts to promote stability and U.S. security interests in strategic regions of the world. This account also includes contributions to the International Fund for Ireland. This action defers funds pending review and approval of specific loans and grants to eligible countries. This interagency review process will ensure that each approved transaction is consistent with the foreign and financial policies of the United States and will not exceed the limits of available funds. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

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* Revised from previous report.
1/ This account was the subject of a similar deferral in FY 1992 (D92–1A).
2/ This deferred amount has been reduced to $1,771,082,965 due to subsequent releases.

Deferral No. 93–8

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Funds Appropriated to the President	New budget authority..... $ 3,300,000,000 (P.L. 102–391)
BUREAU: International Security Assistance	Other budgetary resources..... $ _____
Appropriation title and symbol: Foreign military financing grants (FMF) 1/ 1131082	Total budgetary resources..... $ 3,300,000,000
	Amount to be deferred: Part of year..... $ 1,487,000,000
	Entire year..... _____
OMB identification code: 11–1082–0–1–152	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act
Grant program: [X] Yes [ ] No	[ ] Other _____
Type of account or fund: [X] Annual	**Type of budget authority:** [X] Appropriation
[ ] Multi–year: _____ (expiration date)	[ ] Contract authority
[ ] No–Year	[ ] Other _____

JUSTIFICATION: The President is authorized by the Arms Export Control Act to sell or finance by grant, credit, or guarantee articles and defense services to friendly countries to facilitate the common defense. Under Section 2 of the Act, the Secretary of State, under the direction of the President, is responsible for sales made under the Act, including determining whether there shall be a sale to a country and the amount thereof. Executive Order No. 11958 further requires the Secretary of State to obtain the prior concurrence of the Secretaries of Defense and Treasury, respectively, regarding standards and criteria for credit transactions that are based upon national security and financial policies.

These funds have been deferred pending the approval of the Departments of State, Defense, and Treasury for specific programs to eligible countries. Consultation among these Departments will ensure that each approved program is consistent with the foreign, national security, and financial policies of the United States and will not exceed the limits of available funds. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

1/ This account was the subject of a similar deferral in FY 1992 (D92–8).

Deferral No. 93–9

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Funds Appropriated to the President	**New budget authority.....** $ 149,200,000 (P.L. 102–391)
BUREAU: International Security Assistance	**Other budgetary resources.....** $ _____
Appropriation title and symbol: Foreign military financing program 1131085	**Total budgetary resources.....** $ 149,200,000
	Amount to be deferred: **Part of year.....** $ 149,200,000 **Entire year.....** _____
OMB identification code: 11–1085–0–1–152	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act [ ] Other _____
Grant program: [ ] Yes [X] No	
Type of account or fund: [X] Annual [ ] Multi–year: _____ (expiration date) [ ] No–Year	**Type of budget authority:** [X] Appropriation [ ] Contract authority [ ] Other

JUSTIFICATION: The President is authorized by the Arms Export Control Act to sell or finance by credit, loan guarantees, and grants, articles and defense services to friendly countries to facilitate the common defense. Under Section 2 of the Act, the Secretary of State, under the direction of the President, is responsible for sales made under this Act. Executive Order 11958 further requires the Secretary of State to obtain prior concurrence of the Secretaries of Defense and Treasury, respectively, regarding consistency of transactions with national security and financial policies.

As required by the Federal Credit Reform Act of 1990, this account records the subsidy costs associated with the direct loans obligated and loan guarantees for foreign military financing committed in FY 1993 and beyond. The foreign military financing credit program provides loans that finance sales of defense articles, defense services, and design and construction services to foreign countries and international organizations. The subsidy amounts are estimated on a present value basis.

This action defers funds pending review of specific loans to eligible countries by the Departments of State, Treasury, and Defense. The review process will ensure that in each proposed program the proposed recipients are qualified and that the limits of available funds are not exceeded. This action is taken pursuant to the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

Deferral No. D93-4A

Supplemental Report
Report Pursuant to Section 1014(c) of Public Law 93-344

This report updates Deferral No. D93-4, which was transmitted to Congress on October 1, 1992.

This revision increases by $5,835,250 the previous deferral of $40,241,029 in the Department of Agriculture, Forest Service, Expenses, brush disposal account, resulting in a total deferral of $46,076,279. The increase results from a greater-than-anticipated level of unobligated funds being carried over from FY 1992.

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Deferral No. 93–4A

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Department of Agriculture	New budget authority..... $ 27,278,000 (16 U.S.C. 490)
BUREAU: Forest Service	Other budgetary resources.....* $ 87,810,279
Appropriation title and symbol: Expenses, brush disposal 1/ 12X5206	Total budgetary resources.....* $ 115,088,279
	Amount to be deferred: Part of year..... _____ Entire year.....* $ 46,076,279
OMB identification code: 12–9922–0–2–302	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act [ ] Other _____
Grant program: [ ] Yes [X] No	
Type of account or fund: [ ] Annual [ ] Multi–year: _____ (expiration date) [X] No–Year	**Type of budget authority:** [X] Appropriation [ ] Contract authority [ ] Other

JUSTIFICATION: Purchasers of National Forest timber are required to deposit with the Forest Service the established cost for disposing of brush and other debris resulting from timber cutting operations authorized by 16 U.S.C. 490. The deposits becoming available in the current year are estimated, and the related disposal operations are planned for the following year. Efficient program planning and accomplishment is facilitated by operating a stable program well within the funds available in any one year for this purpose. Much of the brush disposal work for which fees are collected cannot be done in the same year because of weather conditions or because harvesting is not completed. The Forest Service is planning for a stable year–to–year program, which will require $69 million in 1993. The current fiscal year reserve is established pursuant to the provisions of the Antideficiency Act (31 U.S.C. 1512) as a reserve for contingencies.

Estimated Program Effect: None

Outlay Effect: None

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* Revised from previous report.
1/ This account was the subject of a similar deferral in FY 1992 (D92–10).

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Deferral No. D93-7A

Supplemental Report
Report Pursuant to Section 1014(c) of Public Law 93-344

This report updates Deferral No. D93-7, which was transmitted to Congress on October 1, 1992.

This revision to a deferral of the Department of State's Emergency refugee and migration assistance fund increases the amount previously reported as deferred from $10,123,000 to $57,884,000. This increase of $47,761,000 reflects the funds made available by the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1993.

Deferral No. 93–7A

DEFERRAL OF BUDGET AUTHORITY
Report Pursuant to Section 1013 of P.L. 93–344

AGENCY: Department of State	**New budget authority**.....* $ 49,261,000 (P.L. 102–391)
BUREAU: Bureau of Refugee Programs	**Other budgetary resources**..... $ 10,126,000
Appropriation title and symbol: United States emergency refugee and migration assistance fund 1/ 11X0040	**Total budgetary resources**.....* $ 59,387,000
	Amount to be deferred: Part of year.....* $ 57,884,000
	Entire year..... _____
OMB identification code: 11–0040–0–1–151	**Legal authority (in addition to sec. 1013):** [X] Antideficiency Act
Grant program: [ ] Yes [X] No	[ ] Other _____
Type of account or fund: [ ] Annual	**Type of budget authority:** [X] Appropriation
[ ] Multi–year: _____ (expiration date)	[ ] Contract authority
[X] No–Year	[ ] Other _____

JUSTIFICATION: Section 501(a) of the Foreign Relations Authorization Act of 1976 (Public Law 94–141) and Section 414(b) (1) of the Refugee Act of 1980 (Public Law 96–212) amended Section 2(c) of the Migration and Refugee Assistance Act of 1962 (22 U.S.C. 2601) by authorizing a fund to enable the President to provide emergency assistance for unexpected urgent refugee and migration needs.

The Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1993 waives the provisions placing a limit on the amounts in the funds. *

Executive Order No. 11922 of June 16, 1976, allocated all funds appropriated to the President for the Emergency Fund to the Secretary of State but reserved for the President the determination of assistance to be furnished and the designation of refugees to be assisted by the Fund.

These funds have been deferred pending Presidential decisions required by Executive Order No. 11922. Funds will be released as the President determines assistance to be furnished and designates refugees to be assisted by the Fund. This deferral action is taken under the provisions of the Antideficiency Act (31 U.S.C. 1512).

Estimated Program Effect: None

Outlay Effect: None

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* Revised from previous report.
1/ This account was the subject of a similar deferral in FY 1992 (D92–6A).

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Part IX

Environmental Protection Agency

40 CFR Parts 85 and 86
Control of Air Pollution From New Motor Vehicles: Emission Regulations for 1994; Proposed Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 85 and 86

[FRL–4551–2]

Control of Air Pollution From New Motor Vehicles and New Motor Vehicle Engines: Gaseous and Particulate Emission Regulations for 1994 and Later Model Year Light-Duty Vehicles and Light-Duty Trucks, and Revised Performance Warranty Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes the addition of "short test" standards and procedures, referred to as the Certification Short Test (CST), to current regulations for certification, audit, and recall of new light-duty vehicles (LDVs) and light-duty trucks (LDTs). Promulgation of the CST is necessary to protect owners of LDVs and LDTs from incurring unnecessary repair expenses on Inspection/Maintenance (I/M) pattern failures, and is required by section 208(a) of the Clean Air Act Amendments of 1990. The intent of the CST is to ensure that properly maintained LDVs and LDTs have no elements of design that would cause pattern failure in an actual I/M program. The Agency is also proposing replacements for all six of the current Clean Air Act section 207(b) procedures, which are used in basic I/M programs for performance warranty purposes. These proposed procedures more precisely define the steps executed by both the I/M emissions analyzer and the emissions inspector, and ensure that vehicles are properly preconditioned during testing. The improvements would serve to reduce the occurrence of I/M failures that would not benefit from repair efforts and to make the performance warranty procedures compatible with computerized emissions analyzers. This proposal also includes several technical amendments to the procedures used to test vehicles and engines for compliance with emission standards.

DATES: Written comments on this NPRM must be submitted on or before March 15, 1993.

EPA will conduct a public hearing on this NPRM on February 12, 1993. Additional information on the submission of comments and the public hearing can be found in **ADDRESSES** and under "Public Participation" in the **SUPPLEMENTARY INFORMATION** section of today's notice.

ADDRESSES: Interested parties may submit written comments (in duplicate if possible) for EPA consideration by addressing them as follows: EPA Air Docket LE–131, Attention: Docket No. A–91–21, U.S. Environmental Protection Agency, room M–1500, 401 M Street, SW., Washington, DC 20460.

The hearing will be held at 9:30 a.m. at the EPA National Vehicle and Fuel Emissions Laboratory, 2565 Plymouth Road, Ann Arbor, Michigan, 48105, telephone (313) 668–4200.

Material relevant to this proposed rulemaking is available for inspection in Docket No. A–91–21, located at the above M Street address on the first floor of Waterside Mall, from 8:30 a.m. to 12 noon and from 1:30 to 3:30 p.m. weekdays. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Lisa M. Snapp, Certification Division, U.S. Environmental Protection Agency, Motor Vehicle Emission Laboratory, 2565 Plymouth Road, Ann Arbor, Michigan 48105. Telephone (313) 668–4282.

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I. Background of Proposed Rule

On November 15, 1990, the Clean Air Act Amendments of 1990 (hereafter referred to as "the 1990 Amendments") were signed into law by the President. Section 208(a) of the Amendments modified section 206(a) of the Clean Air Act (CAA or "the Act") to require the addition of "test procedures capable of determining whether model year 1994 and later model year light-duty vehicles (LDVs) and light-duty trucks (LDTs), when properly maintained and used, will pass the inspection methods and procedures established under 207(b) for that model year, under conditions reasonably likely to be encountered in the conduct of inspection and maintenance (I/M) programs, but which those programs cannot reasonably influence or control." Congress specifically required that the variety of field I/M test conditions to be addressed by the new certification test procedures include ranges of fuel characteristics, ambient temperature, and short waiting periods prior to emission testing. These new test procedures, referred to as the Certification Short Test (CST), will be a necessary step in the certification process for new LDVs and LDTs beginning with the 1994 model year.

The 207(b) procedures referred to in the Amendments form the basis for implementation of the 207(b) or emissions performance warranty. Where a State or local I/M program has adopted one of the 207(b) procedures, failure of the procedure is the first important step towards triggering performance warranty protection for a vehicle

owner.[1] Performance warranty regulations were first promulgated by EPA in 1980 and underwent revision in 1984.[2] Six 207(b) procedures and associated emission standards for hydrocarbons (HC) and carbon monoxide (CO) are currently in force. These procedures and standards may be found in part 85, subpart W, of the Code of Federal Regulations.

The purpose of the performance warranty is to protect individual vehicle owners from incurring repair expenses prompted by failure of an I/M short test due to conditions beyond the owner's control. Through adoption of the performance warranty, Congress recognized that vehicle manufacturers, rather than vehicle owners, might bear responsibility for a given I/M test failure of an in-use vehicle. Vehicle owners, on the other hand, would be liable once the age and mileage limits for a vehicle were surpassed, or for I/M repairs prompted by malmaintenance, misfueling, or tampering. With the manufacturers and vehicle owners each paying for emission repairs for which they were responsible, short tests would be an effective and efficient means to achieve emission reductions from individual vehicles.

This assumption has not been completely borne out by experience, however, since specific groups of vehicles have shown consistent patterns of I/M failure, and neither the emission performance warranty nor vehicle owner action has adequately addressed the failures. For the most part, the Agency has become aware of these "pattern failures" as I/M program officials have sought technical support or assistance in obtaining Federal emission performance warranty coverage for owners of the failed vehicles. Once the existence of pattern failures was recognized, the Agency also undertook analysis of I/M program data to identify vehicle groups with unusually high failure rates, implying some likelihood of additional pattern failure problems. On occasion, the Agency has compiled the available information and has published summaries listing vehicles suspected of pattern failure behavior, describing the causes of the known failures, and recommending approaches for handling the vehicles in I/M programs. In March 1988, for example, the Agency distributed summaries of 38 pattern failure problems, ranging in scope from a few thousand affected vehicles to several million.[3]

Pattern failures arise for a variety of reasons. In some cases, the cause of the pattern failure is the malfunction of a particular component on some or all of the vehicles within an engine family.[4] In other pattern failures, the vehicle performs as designed with no apparent malfunction; instead, the vehicle design is not compatible with the steps of the short test procedure or the conditions under which the test is performed.[5] In either case, the pattern failure vehicles may be errors of commission by the short test. That is, the presence of the short test pattern failure does not guarantee that the same vehicles would also fail a full Federal Test Procedure (FTP). In part this is so because the short test measures emissions on an instantaneous basis, while the FTP is based on emission levels averaged over an extended period. Whether pattern failures arise from malfunctions or incompatibility of a design with the test procedures, however, responsibility for such failures cannot normally be attributed to the vehicle owner.

The Agency recognizes five characteristics of vehicle design that account for the bulk of those pattern failures where incompatibilities exist between the vehicle design and an I/M procedure. First, the fuel control systems on some vehicles are slow to accommodate the abrupt transitions between idle and 2500 rpm modes in the I/M procedures, thereby generating HC or CO emission spikes that are longer than the norm of five to seven seconds or are more gradual in their rate of decline. Such designs may fail I/M tests based on the higher emissions of the spike, when passing levels might have occurred with more extended sampling.

The second important vehicle characteristic is use of air injection or fuel metering timers. These timers have been employed by some manufacturers (notably, Ford Motor Company) to disable secondary air injection during extended idles. The intent was to prevent excess catalyst temperatures in vehicles designed to operate with enriched (usually, open-loop) fuel metering at idle. Most manufacturers significantly alter their fuel metering or air injection strategies following a restart, and some employ fuel metering or air injection timers triggered by any keyoff/restart sequence. Some such strategies increase the chance the vehicle will pass I/M testing; others can lead directly to I/M failure. Pattern failures traced to timers were the major factor behind EPA's 1984 warranty rulemaking cited above.

The third design characteristic is cooldown of the catalyst or oxygen sensor below nominal operating temperatures, particularly during idle operation, when reduced volumes of exhaust gas pass across the sensor or react in the catalyst. During the extended idles that vehicles may occasionally encounter while waiting to be tested in I/M queues, catalyst efficiencies may drop or fuel metering systems may switch to open loop as the vehicle computer detects sluggish oxygen sensor response. Failure of the subsequent I/M test may result.

The fourth characteristic of significance is the strategy for evaporative system purge. Many current vehicles are designed for little or no evaporative purge during idle, in part because the vapor could constitute a significant portion of the fuel flow, affecting idle quality. Such vehicles tend to load the canister while waiting in I/M lanes, only to discharge the vapor during any off-idle modes in the subsequent I/M test. Discharge of canister vapor in this manner can cause fuel enrichment that exceeds the range of authority programmed into a closed-loop fuel control system, resulting in incomplete combustion and, hence, higher instantaneous emissions. Purge failures during 2500 rpm testing may rise dramatically with higher ambient temperatures or with higher fuel volatility.

Finally, there are some vehicles that do not actually fail the numerical standards of the I/M test, but instead fail to properly complete the test procedure. Most significant among these cases are vehicles that require specialized equipment in order to obtain a valid measure of engine speed. Emission analyzers use engine speed to monitor progress and direct the inspector through the modes of the I/M test, to determine the proper point to sample emissions, and to detect certain fault conditions. The I/M test procedures define ranges of acceptable engine speed for idle and off-idle test modes. Until the mid-1980s, most I/M analyzers detected engine speed signals using conventional tachometers, which employ an inductive pickup clamped

[1] A second Federal emissions warranty, the 207(a) or emissions defect warranty, is triggered not by a test failure, but by the discovery of a part that is defective in materials or workmanship. The 207(a) emissions defect warranty is available to all vehicle owners (subject to age, mileage, and maintenance requirements), while the 207(b) performance warranty is only available to vehicle owners that fail a Federally approved 207(b) short test procedure.

[2] 45 FR 34802 (May 22, 1980) and 49 FR 24320 (June 12, 1984).

[3] I/M Pattern Vehicle Summaries, USEPA Office of Mobile Sources, 28 Mar 1988; available in the public docket for review.

[4] See, for example, summary no. 88–04 in *I/M Pattern Vehicle Summaries, op cit.*

[5] See, for example, summary no. 88–25 in *I/M Pattern Vehicle Summaries, op cit.*

around one of the secondary ignition cables. In 1983, one manufacturer introduced an ignition system where the pulse count in the secondary cables was double the count in conventional systems. Later systems deleted the secondary cables entirely or limited access to parts of the ignition system. In response, I/M analyzer manufacturers patched their software and hardware to prevent aborted tests or sampling at incorrect speeds. However, the variety of unconventional ignition systems and the speed with which they were introduced led to a hodgepodge of less-than-comprehensive solutions.

Pattern failures like those described above are problematic for a number of reasons. If the failure is of the type where the vehicle is actually performing as designed, no repair may be available. Owners face increased risk of paying for unnecessary repairs, which may leave emission performance unchanged or even degraded and the owner vulnerable to further I/M failures and unproductive repair visits. Some owners may receive information from the repair sector on how to operate their vehicles during testing to increase the chance of obtaining passing scores, yet program officials may be unable or unwilling to accept such operation as consistent with their I/M program regulations. Determining owner eligibility for emission performance warranty coverage can be more complex. Each of these situations can contribute to frustration for the vehicle owner and a loss of credibility for the I/M program and the vehicle manufacturer.

While resolving the cases of individual owners is of immediate concern to I/M programs and the manufacturers, the long run solution to the pattern failure problem is prevention of future pattern failure groups. Future liability for warranty claims and owner dissatisfaction are incentives for manufacturers to weed out pattern failure designs prior to production. On this basis, one manufacturer has voluntarily added its own I/M simulations to vehicle development testing. Where a manufacturer chooses not to take this approach or where their efforts are not sufficiently comprehensive to identify pattern failure problems, each owner of a pattern failure vehicle must negotiate the repair attempt and warranty claim process individually, where an up-front solution to the problem group as a whole might have been more efficient.

The Agency's Certification, Selective Enforcement Audit (SEA), and Recall programs might seem to be viable mechanisms to address patterns of emission test failure. However, such programs are currently based upon the FTP; they contain no direct simulations of I/M procedures and field test conditions such as extended idles, higher ambient temperatures, and higher fuel volatility.[6] As pointed out above, pattern failure vehicles may be errors of commission by the short tests. Thus, pattern failures that might be of great concern and impact in the field might pass the FTP in current certification, SEA, or recall testing. The current motor vehicle emission control program therefore does not adequately prevent the introduction of pattern failure vehicles.

With this in mind, some I/M programs have previously suggested (and EPA has considered) the addition of I/M short test requirements to the new vehicle certification procedures.[7] With passage of the 1990 Amendments, this approach has become a statutory requirement. The addition of the CST implies a judgment by Congress that manufacturers, not vehicle owners or the I/M programs, must bear the responsibility for addressing conflicts between vehicle designs and federally approved I/M test procedures. Implementing the new CST statutory requirement is the primary purpose of this rule.

The CST is intended to be an indicator of vehicle performance on the 207(b) test procedures in place at the time each model year 1994 and later LDV and LDT is certified. The effectiveness of the indicator test is thus determined to a large extent by the clarity with which the "targets" (i.e., the 207(b) tests) are defined. Absent any action on the part of EPA to change them, the current 207(b) procedures would apply in the 1994 model year. The Agency believes a preferable course is to also amend the 207(b) tests.

Indeed, for at least two reasons, EPA was pursuing 207(b) improvements prior to adoption of the Amendments. First, significant improvements in analyzer technology have taken place since adoption of the original performance warranty tests. Manual analyzers with analog readouts have given way to automated units that place much of the test sequence, sampling algorithm, and pass/fail determination under computer control. These improvements permit EPA to define the 207(b) procedures much more rigorously.

Second, I/M programs now have a decade of experience in testing vehicles equipped with computer-controlled engines and emission control systems. This experience, together with substantial research testing, has shown EPA and the manufacturers that errors of commission on I/M tests can be significantly reduced by changes to the test modes, the emissions sampling algorithm, and improvements in vehicle preconditioning.[8]

Following discussions with I/M programs, vehicle manufacturers, and the analyzer manufacturers, EPA issued a technical report in January 1991 suggesting six alternatives to the current 207(b) procedures.[9] The pass/fail mode types in the six tests were the same as those in the current procedures: Idle, unloaded 2500 rpm, and steady-state loaded. All six procedures included new sampling algorithms and test procedure specifications appropriate for use with computerized emission analyzers and consistent with the objective of reducing errors of commission. All five of the unloaded procedures provided failed vehicles with an immediate "second chance" to pass the I/M test before triggering an I/M repair requirement. The second chance tests incorporated new or extended 2500 rpm vehicle preconditioning modes and improved sampling algorithms.

The Agency determined its strategy for the CST proposal against this backdrop of the statutory CST requirement, experience with the pattern failure problem, and ongoing efforts to improve the existing performance warranty procedures. The Agency has concluded that the intent of Congress is best served by proposing improvements to the 207(b) procedures themselves as part of the CST proposal, though promulgation of the CST alone was specifically required by the Amendments.

Further, the Agency has concluded that the optimum CST would not necessarily require the broad range of testing that the statute could be read to allow. The sheer number of currently

[6] Since model year 1984, both heavy-duty and light-duty trucks have faced a 0.5% CO at idle standard for certification and recall (45 FR 63734, September 25, 1980). This requirement sought emission reductions in localized areas of congested traffic, rather than reduction in I/M pattern failures. The impact of the new CST requirement on the truck idle CO test will be discussed in the issues section to follow.

[7] See, for example, letter to Charles Gray from Richard Joy (Fairbanks North Star Borough) dated May 30, 1986. Available in the public docket for review.

[8] See, for example, EPA technical reports EPA 460/3–88–008, "Variability of I/M Test Scores Over Time," and EPA–AA–TSS–I/M–87–2, "I/M Test Variability." Available in the public docket for review.

[9] Tierney, Eugene J., Herzog, Erik W., and Snapp, Lisa M., "Recommended I/M Short Test Procedures for the 1990's: Six Alternatives," USEPA Office of Air and Radiation, EPA–AA–TSS–I/M–00–3. Available in the public docket for review

approved 207(b) tests, the range of field conditions in the variables called out by Congress, and the diverse vehicle conditions that can trigger pattern failure behavior combine to form a potential complex CST test matrix that could be quite lengthy and expensive. On this basis, the Agency has chosen to propose a CST that (1) includes each of the pass/fail mode types, but not necessarily all six revised I/M tests; (2) targets those pattern failure causes that are of greatest policy concern or largest scope; (3) reduces the complexity of the certification test and the manufacturer data submission requirements, in favor of confirmatory and recall test liability; and (4) still retains the flexibility for future CST revisions to address other pattern failure types or changes to the 207(b) procedures.

Although this proposal includes revisions to the existing 207(b) procedures that will help eliminate many pattern failure problems, additional types of I/M tests may be necessary to address air quality issues in regions where National Ambient Air Quality Standards continue to be exceeded. Thus, in a separate action, the Agency has promulgated a performance standard to establish a minimum emission reduction requirement for areas that must implement enhanced I/M programs under the 1990 Amendments.[10] The Agency's adoption of a stringent performance standard for enhanced I/M will result in the adoption by many States of transient loaded procedures for exhaust testing and functional tests for evaluation of evaporative control systems. Separate EPA rulemakings will incorporate such procedures into regulation as available performance warranty tests and components of the CST. Therefore, transient loaded procedures are not included in today's proposal.

The remainder of this preamble will describe in more detail the proposed 207(b) test procedure revisions and the proposed CST regulations (section II), provide the rationale for the proposed regulations and identify issues for comment from interested parties (section III), and execute certain administrative requirements.

II. Proposed Regulations

A. Performance Warranty Regulations

1. Introduction

This notice proposes six new performance warranty short tests: three idle tests, a pair of unloaded two-speed tests, and a steady-state loaded test. Incorporated in the new procedures is a new "first passing reading" emissions sampling algorithm. The algorithm also requires that preconditioning be performed in a controlled manner. Also proposed are new specifications for the equipment used to perform I/M testing.

The proposed procedures and the associated regulations are intended to eventually replace the current menu of performance warranty procedures available to I/M programs. The advantages of the new procedures for vehicle manufacturers as well as for I/M programs prompt EPA to propose that they be made available to I/M programs with the minimum legal delay, which is thirty days following promulgation of the final rule. Once a program subsequently adopts any of the new procedures, owners of failed vehicles would then be eligible for the performance warranty remedy. As with the existing performance warranty procedures, I/M programs may also choose to employ the procedures on vehicles that have exceeded the age or mileage criteria for performance warranty coverage.

In order to provide for a cost-effective transition to use of the new procedures and for penetration of analyzers meeting the new equipment requirements, the Agency proposes that the existing performance warranty test procedures and the new procedures that are being proposed in this notice be concurrently available to all I/M programs for use on all vehicles through 31 December 1993. In addition, EPA proposes that I/M program areas may continue to use the current performance warranty procedures for model year 1993 and earlier vehicles through 31 December 1995, if approved by the Administrator as part of a State Implementation Plan revision as part of an expeditious transition to more sophisticated inspection equipment or high volume, test-only inspection network. Approval of the request would be based on evidence that earlier adoption of the new procedures or the associated equipment requirements would be impractical or unreasonably costly. An example of such a circumstance might be a program that has recently upgraded its emission analyzers, but not to the extent proposed in this Notice. Of course, the revised 207(b) tests being proposed today would be available for I/M program use thirty days after publication of the final rule.

2. Sequence of the Test Modes

Table 1 provides basic information on the sequence of the test modes in the six new I/M short tests proposed in this notice as well as in the six tests already contained in current regulations. The complete procedures are contained in part 85, subpart W of the proposed regulations.

TABLE 1.—COMPARISON OF I/M TEST PROCEDURES

Test procedure	R/S req'd	First chance				Second chance			
		Mode 1		Mode 2		Mode 1		Mode 2	
		Operation	Type	Operation	Type	Operation	Type	Operation	Type
Original Subpart W Tests:									
Idle	n	(2500 rpm)	p	Idle	s				
Two speed idle*	n	Idle	(s)	2500 rpm	(s)	(Idle)	s		
Loaded*	n	as loaded	(s)	Idle	(s)				
Additions in 1984:									
Engine restart Idle	y	2500 rpm	p	Idle	s				
Engine restart 2500 rpm/Idle.	y	2500 rpm	s	Idle	s				
2500 rpm/Idle	n	2500 rpm	s	Idle	s				
Proposed New Subpart W Tests:									
Idle	n	Idle	s		s	2500 rpm	p	Idle	s
Preconditioned Idle	n	2500 rpm	p	Idle	s	2500 rpm	p	Idle	s

[10] See 57 FR 52950 (November 5, 1992).

TABLE 1.—COMPARISON OF I/M TEST PROCEDURES—Continued

Test procedure	R/S req'd	First chance				Second chance			
		Mode 1		Mode 2		Mode 1		Mode 2	
		Operation	Type	Operation	Type	Operation	Type	Operation	Type
Idle w/Loaded Preconditioning.	n	Idle	s			ss loaded	p	Idle	s
Two Speed	n	Idle	s	2500 rpm	s	2500 rpm	s	Idle	s
Preconditioned Two Speed	n	2500 rpm	s	Idle	s	2500 rpm	(s)	(Idle)	s
Loaded	n	ss loaded	s	Idle	s				

Notes: Abbreviations R/S=restart, ss=steady state, p=preconditioning mode, s=sampling mode.
*At least one of the two optional modes must be selected for this test.
Parentheses indicate optional mode operations (e.g., Idle, 2500 rpm, loaded) or mode types (s).
If sampling is not performed on an optional sampling mode (s), the mode is used for preconditioning.

The table illustrates some of the similarities and differences between the new and old procedures. The proposed tests continue to rely entirely on conventional idle, unloaded 2500 rpm, and steady-state loaded operation, both for preconditioning modes and for sampling (pass/fail) modes. On the other hand, the new tests have a greater emphasis on "second chance" test modes.[11] Each of the five new unloaded procedures includes second-chance modes; in the current procedures, only the Two-Speed Idle Test incorporates second-chance testing. The second chance modes of the proposed procedures are generally of longer duration than the first chance modes (an aspect reflected in the regulations but not in Table 1), and show an increased reliance on preconditioning.

Each of the first chance tests contained within the six proposed procedures has a direct analog in the current procedures. For example, the first-chance portion of the new Preconditioned Idle Test consists of a 2500 rpm preconditioning mode and an idle sampling mode; the same modes are employed in the current Idle Test with optional preconditioning. None of the proposed tests is exclusively a "restart" procedure, that is, one that requires a keyoff/restart step for all vehicles; the two restart procedures from the current regulations have been absorbed as options within the new procedures.[12]

The three proposed idle tests differ only in their use of preconditioning. The proposed "standard" Idle Test retains the simple idle pass/fail mode of its older namesake, but adds a second-chance idle test with three minutes of controlled 2500 rpm preconditioning. The proposed Idle Test with Loaded Preconditioning is very similar to the new Idle Test, but uses 30 seconds of loaded preconditioning in the second-chance test instead of three minutes at 2500 rpm. The third new idle-only test, the Preconditioned Idle Test, is the proposed Idle Test with a short 2500 rpm preconditioning inserted at the beginning.

The proposed unloaded two-speed tests are also closely related. The first chance portion of the Two Speed Test consists of an idle sampling mode followed by a 2500 rpm sampling mode; the Preconditioned Two Speed Test simply reverses the order. Both of these tests employ second chance modes at 2500 rpm and idle.

The sampling modes of the proposed Loaded Test are required modes; in the existing test of the same name, one or the other of the modes could be optional. The existing option to use the loaded mode for preconditioning only has been absorbed in this proposal into the Idle Test with Loaded Preconditioning.

3. Sampling Algorithm

The sampling algorithm is the calculation method used to monitor and control progress through the modes of the test and to determine emission scores and pass/fail status based on the information provided by the optical bench of the emissions analyzer. Elements of the sampling algorithm can include (1) the frequency at which the analog emission signal from the bench is sampled, (2) the method used to "bundle" the sampled values, (3) the criteria for initiating and terminating test modes, (4) the criteria for selecting a score and then determining pass/fail status for each mode based on the standards for each pollutant, (5) the criteria for the detection of fault conditions during both preconditioning and sampling modes, and (6) the decision criteria to be employed when fault conditions are detected.

Because the current performance warranty test procedure regulations were written before the development of low-cost computerized analyzers with digital sampling capabilities, most aspects of the sampling algorithm were left under the inspector's subjective control. For example, the instruction in current regulations to "record exhaust concentrations after stabilized readings are obtained or at the end of 30 seconds, whichever occurs first" was written to accommodate inspectors monitoring emission values on analog gauges.[13]

The Agency developed improved analyzer specifications in 1980, but the improvements were issued as guidance rather than revisions to the performance warranty regulations,[14] and further improvements have since been identified. The Agency proposes at this time to adopt such improvements as part of the regulations for each new proposed performance warranty procedure.

The proposed algorithm samples the stream of emission data from the analyzer's sampling system at a minimum frequency of two hertz; these samples are continuously grouped into five-second running average bundles. Mode initiation occurs for unloaded modes when the inspector prompts the analyzer to begin and the engine speed has been within specified bounds for ten seconds: 700 rpm ± 400 rpm for an idle mode or 2500 rpm ± 300 rpm for a 2500 rpm mode. Vehicle speed criteria are similarly specified for loaded modes: 22 mph to 25 mph for vehicles with up to four cylinders, 29 mph to 32 mph for five and six cylinder vehicles, and 32 mph to 35 mph for vehicles with

[11] Second chance testing is the use of an immediate second I/M test on failed vehicles; second chance test scores supersede first chance scores. The second chance test sequence may include different preconditioning or sampling modes than the first chance test. A second chance test is different than a retest, which is the I/M test performed following a repair attempt. Retests may duplicate the entire initial I/M test procedure (first and second chance).

[12] In order to avoid timer-related pattern failures, EPA has already required a maximum ten-second keyoff and engine restart during second-chance testing of some already-produced vehicles (model 1981–86 Ford products and model year 1984–85 Honda Preludes).

[13] See, for example, 40 CFR 85.2209(b)(4).

[14] 45 FR 34802, *op cit.* and "BAR 90 Analyzer System Specifications," State of California Department of Consumer Affairs, Bureau of Automotive Repair, June 1990. Available in the public docket for review.

seven or more cylinders. The delay in mode initiation provides time for stabilization of emission spikes following mode transitions and for transport of the sample through the exhaust analytical system.

A software timer that monitors the elapsed time in the mode is triggered by mode initiation. Termination of the mode occurs when either the vehicle has passed and a score has been determined, the mode time limit has been reached without the vehicle passing, or a fault condition has occurred.

The software searches throughout the sampling period for a set of passing values and if one is found, the vehicle passes. Thus, rather than selecting scores when the emission readings have either "stabilized" or a specified time has elapsed, the algorithm searches for the "first passing reading" of a five-second bundle in which both the HC and CO values are at or below the standards of 220 parts per million (ppm) HC and 1.2% CO. If the mode reaches a predefined maximum duration without passing, the vehicle fails and the mode terminates. The maximum mode length varies from ninety seconds to three minutes, depending on the type of mode and whether it is part of an initial or second-chance test.

There are also minimum mode durations (generally, 30 seconds). If the pass determination is made, the mode continues until the minimum duration has elapsed. This permits any preconditioning benefits of the mode to be achieved, and also allows the algorithm to report the best passing reading over the length of the mode, rather than always reporting a bundle that is a borderline passing reading (see below). A clean-vehicle "early out" option, however, allows for immediate mode termination if a bundle does not exceed 100 ppm HC and 0.5% CO. Therefore, a very clean vehicle could pass a mode in as little as fifteen seconds (the ten second sampling delay plus one five second bundle). Similarly, a dirty-vehicle early out option is provided for vehicles with no HC exhaust concentration less than 1800 ppm over the course of any sampling mode. This option protects analyzers from excessive HC hangup and contamination of the particulate trap.

Once a pass/fail determination is made, the algorithm must select the simultaneous pair of emission scores that is to be reported; the bundle on which a passing status was assigned will in many cases be just below the standard, which could erroneously indicate that the vehicle is only capable of marginally passing. Therefore, the mode score reporting algorithm instead selects the pair of emission values with the lowest weighted score by continuing to analyze emission values until the mode terminates and reporting that bundle for which the combination of HC + (151 * CO) is a minimum. The weighting factor of 151 is based on the relative magnitude of the two standards and of the two units of measure,[15] and also minimizes the occurrence of non-unique combined values to simplify the score selection process.

A mode can be terminated or prevented from initiating as a result of a fault condition, such as excess exhaust dilution or engine or vehicle speed excursions (including engine stalls). Specifically, a dilution check is continuously performed for each pass/fail mode to guard against leaks in the analyzer sampling train or failure of the inspector to insert the probe to a minimum depth of ten inches. A mode may not initiate or continue if the sum of CO and carbon dioxide (CO_2) concentrations falls below six percent. The test is aborted and the results voided if the dilution check is failed or the vehicle stalls. In addition, vehicle or engine speed must remain within the bounds specified previously; excursions beyond the specified limits for an idle mode result in the mode timer resetting to zero and the mode resuming. Excursions beyond the specified limits for 2500 rpm and loaded modes are limited to two seconds for any single excursion and six seconds total during testing modes, and five seconds for any single excursion and 15 seconds total during preconditioning modes. Exceedances result in the mode timer resetting to zero and the mode resuming.

A maximum time is established for the entire test in order to prevent unlimited mode timer resettings. A test timer is initiated at the start of the first preconditioning or pass/fail mode and runs continuously until the test is completed, voided, or the maximum test duration is reached. The shortest maximum test time is 145 seconds (occurring, for example, in the initial test portion of the Idle Test); the longest maximum test time is 425 seconds (see, for example, the initial test portion of the Two-Speed Idle Test). If the maximum test time is reached before all modes can be completed, the test is terminated and the test is rendered invalid.

[15] HC measured as hexane in parts per million and CO measured in percent concentration.

4. Test Pass/Fail Determination

The pass/fail status of a vehicle for the test as a whole is determined by its pass/fail status on the individual sampling modes of the test. If a second chance test has been performed, the pass/fail determination is made on the basis of its sampling modes; otherwise, the first chance test values are used. Each sampling mode in the applicable first chance or second chance test must have a simultaneous pair of passing HC and CO emission values for the overall test to be passed. Scores are reported for each mode individually as described in the previous section.

5. Equipment Specifications

In addition to the changes in the performnce warranty test procedures, this proposal upgrades equipment specifications to reflect the current capabilities of the analyzer manufacturing industry.[16] The proposed requirements define the physical components of the emissions analyzer more precisely, refine and tighten analyzer accuracy requirements for HC and CO, include specifications for other gases of interest ($C0_2$ and, optionally, nitrogen oxide (NO)), and codify the ranges of ambient conditions under which the analyzer must be able to perform accurately. Furthermore, the proposal defines equipment calibrations and adjustments in more detail.

The current description of the basic components of the emissions analyzer, which merely includes a sample probe, water removal system, and HC and CO analyzers, is expanded to include a CO_2 analyzer, a particulate trap, a sample pump, flow control components, a tachometer, digital displays for HC, CO, and $C0_2$, and a digital display for dynamometer speed and load if testing utilizes loaded operation (see proposed § 85.2225(b)). The revised specifications would require that materials coming in contact with the sample not contaminate or change the character of the gases to be analyzed.

Response time requirements for HC and CO would become more stringent, and the proposal would add response time requirements for the optional NO analyzer. In most cases, accuracy tolerances would be defined for three successive ranges for each of the measured gases, including the new CO_2 channel (see proposed § 85.2225(c)); in current regulations, accuracy is only defined for a single range spanning a small interval below and including the

[16] The proposed specifications are also consistent in all major respects with the BAR 90 specifications employed by the State of California I/M program, *op cit.*

standard. The revised accuracy requirements would be somewhat more stringent at levels near the standards, and would extend to one or two additional ranges exceeding the standards so that the magnitude of the exceedance can more reliably be assessed.

Analyzer noise and repeatability are other aspects that are new in the proposal (see also proposed § 85.2225(c)). The proportion of readings of a midrange calibration gas recorded over a 20 second period that can exceed 150% of the average reading level would be limited to five percent, and the variance of the readings over that period would be restricted to a specified noise limit dependent upon pollutant and range.

The proposed specifications also add ranges for environmental conditions within which the analyzer must meet the accuracy, noise, and repeatability specifications just presented (see proposed § 85.2225(c)). These ranges include ambient temperature (41°F–110°F), humidity (up to at least 80% relative humidity throughout the required temperature range), barometric pressure (the analyzer must compensate for pressure effects for altitudes up to 6000 feet), electromagnetic isolation from interference, and vibration and shock protection. These ranges represent minimum requirements. I/M programs may specify more stringent requirements if local conditions warrant them in order to ensure test accuracy.

Other specifications proposed for adoption that are not included in current regulations are the display refresh rate (twice per second minimum), limitations on interference effects from gases not sampled, a readily visible display of the propane equivalency factor, a provision for lockout of the sampling unit until warm-up requirements are met, a slightly different basis for the determination of equal flow for vehicles with dual exhaust pipes (see proposed § 85.2225(b)), and an analyzer display resolution requirement standardizing emissions reporting at the same level of precision as appears in the accuracy requirements for each channel. In addition, the analyzer must have the hardware and software capable of implementing the sampling algorithm discussed in a previous subsection.

Some improvements to the analyzer calibration requirements are also proposed (see proposed § 85.2233). System checks would lock out the analyzer if HC readings taken through the probe when sampling ambient air exceed 20 ppm. Lockout would also occur if the automatic zero and span checks (newly automated) indicate that drift has caused the signal levels to move beyond the adjustment range of the analyzer. A system leak check, formerly weekly, would now be required on a daily basis. Gas calibration would automatically occur every 72 hours, and would utilize two span points. Failure to pass the calibration would lock the system out from testing.

Additionally, revised dynamometer specifications are proposed based on the specifications currently being applied to loaded-mode testing in the State of Arizona I/M program (see proposed §§ 85.2230 and 85.2233). Different vehicle speeds would be dictated for loaded operation based upon engine size (number of cylinders). The repeatability criterion for power absorption at a constant speed and drift during any single test mode are also proposed to be more adequately defined.

B. Certification Short Test Regulations

1. Overview

The vehicle manufacturer's obligation under this proposal is to design vehicles that pass each of the new performance warranty test procedures described in the previous section, without benefit of the second-chance segments of those procedures, under conditions, reasonably expected to be encountered during in-use testing. The Agency proposes to implement and enforce this obligation by incorporating a new test procedure, the CST, into existing EPA regulations governing new vehicle certification, SEA testing, and emissions recalls. The proposed CST regulations include new test procedures, test conditions, equipment requirements, emission standards, and associated regulations.

The proposed CST procedure is a laboratory simulation of field I/M short test procedures. Vehicle operation during a run of the procedure consists of at most two different first-chance tests from the proposed new performance warranty procedures, in specific combination with modes that simulate vehicle warmup and "wait time" operation in I/M lanes. In order to predict vehicle performance under field I/M conditions, the proposal defines an envelope of vehicle test conditions based on ambient temperature, fuel characteristics, and prior vehicle operation, within which the new CST procedure is to be performed. The Agency's selection of ranges for these parameters reflects the statutory mandate and the current knowledge of pattern failure triggering conditions discussed in section I.

As proposed, neither the vehicle manufacturers nor EPA must perform all possible combinations of the simulated I/M tests and the points in the test envelope. The manufacturer must certify compliance with the complete range of CST tests and conditions, but need only submit data to the Agency on a small subset of those possibilities. The Agency has the authority to perform certification confirmatory tests, SEA tests, and recall tests throughout the range of CST procedures and test conditions, yet it may choose to focus on only one I/M procedure at a specific point in the test envelope.

The Agency is also proposing a second approach to the test envelope that relies on an evaporative canister loading procedure rather than high ambient test temperature and high fuel volatility to generate the high vapor volumes characteristic of purge-related pattern failures. Regulatory language is proposed for the first approach only; however, both approaches are discussed in detail later in this section of the preamble. The Agency solicits comments on both approaches to the test envelope, but proposes to adopt only one approach in the final rule.

The proposed CST equipment requirements, like the CST procedures, are based on the new field I/M requirements proposed in this Notice. Thus, emission scores on the CST procedures are obtained using computerized, nondispersive infrared (NDIR) analyzers measuring undiluted tailpipe exhaust on an instantaneous basis. The analyzers must meet or exceed the new design specifications for I/M analyzers outlined in section II.A. The sampling algorithm proposed for the CST is the algorithm proposed for I/M testing in the field.

The scores obtained for each sampling mode in a run of the CST procedure are compared to CST emission standards to determine the passing or failing status of the vehicle for that mode. Vehicles must pass each individual sampling mode of the procedure to pass the CST as a whole. The CST standards proposed for undeteriorated vehicles (including certification EDVs and SEA test vehicles) are 0.2 percent CO and 50 ppm NC. For deteriorated vehicles (such as recall test vehicles), the proposed standards are identical to the field I/M standards: 1.2 percent CO and 220 ppm NC. Because separate standards are proposed for deteriorated and undeteriorated test vehicles, the evaluation of CST compliance differs from the evaluation of FTP compliance. The CST emission scores for

certification EDVs are not adjusted by a deterioration factor before comparison to the (undeteriorated) emission standard, and thus no CST procedures need be performed on certification durability data vehicles.

The balance of this section clarifies the proposed CST compliance requirement and manufacturer data submission requirements by describing in greater detail the proposed CST test procedures and test condition envelope. Also presented is an alternative approach to the test envelope that employs an evaporative canister loading procedure to replace portions of the observed ranges of field ambient temperature and fuel properties. Comments from interested parties are solicited on all aspects of the proposal.

2. EPA Compliance Testing Pathways

The EPA compliance testing pathways that together make up the proposed CST procedure are illustrated in Figure 1. The procedure consists of three pathways for test preparation, feeding either of two pathways for vehicle testing; thus, there are six overall compliance pathways. The Agency may choose among the six pathways for the purpose of compliance testing to determine if a manufacturer has conformed to the design requirement stated at the beginning of the overview above.

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Figure 1: EPA Compliance Testing Pathways

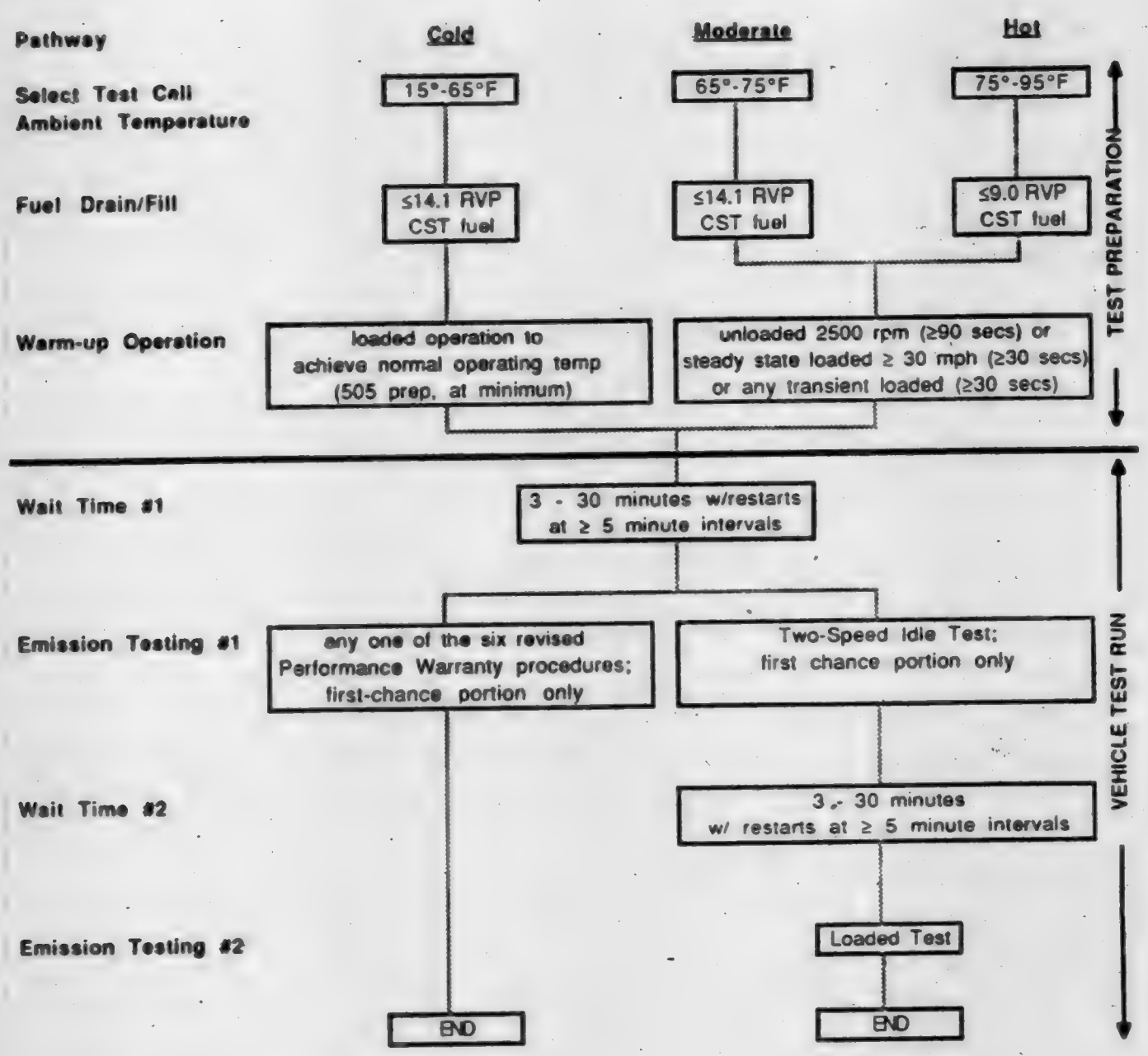

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The proposed range for CST test cell temperature is 15°F to 95°F. The three test preparation pathways are named after three contiguous subsets of this overall range: cold (15°F to 65°F), moderate (65°F to 75°F), and hot (75°F to 95°F) temperature.

The test cell ambient temperature in turn determines the test fuel characteristics. There are two proposed CST test fuels, differing only in their maximum volatility. The fuel for cold and moderate temperature testing may have a Reid vapor pressure (RVP) no higher than 14.1 lbs; the CST fuel for hot temperature testing must be at or below 9.0 RVP. The complete specifications for the two fuels are provided in Table 2 below and in § 86.1413 of the proposed regulations.

TABLE 2.—FUEL SPECIFICATION

Parameter	Specification	
Ambient Test Temperature	≤75°F	76°F–95°F
RVP (psi)	≤14.1	≤9.0
Octane (RON)	≥93	
T90	≥351	
% aromatics	≥38	
% olefins	≤3	
% MTBE	≤0.1	
Wt% sulfur	≥0.06	

No vehicle operation is prescribed or excluded prior to the fuel drain and fill step. Once the vehicle has been refueled, however, EPA must perform operation to warm up the vehicle before entering either of the two vehicle testing pathways. The test cell ambient temperature determines the type of this warm-up operation. In compliance testing along the cold temperature pathway, EPA would perform a transient loaded warm-up cycle of at least 505 seconds duration. Examples of such cycles are the full FTP and its component cycles (the Cold 505 and the LA4) . For either moderate or high temperature testing, EPA would perform, at minimum, unloaded operation at 2500 rpm for 90 seconds, steady-state loaded operation at or above 30 mph for 30 seconds, or any transient loaded operation for 30 seconds.

Normally, EPA would expect to proceed directly into vehicle testing following the warm-up step. If the Agency chooses to perform a loaded warm-up but no loaded short testing, it may be desirable to free up the dynamometer after the warm-up is completed and to perform the emission testing modes elsewhere. In such a case, EPA is proposing to allow up to seven minutes of uncontrolled vehicle operation (including keyoff time) from the close of a loaded warm-up step to the beginning of vehicle testing. The Agency believes that the limited duration of this uncontrolled operation is not likely to significantly affect test results.

As proposed, the vehicle testing portion of the procedure begins with the vehicle at curb idle for between three and thirty minutes. This "wait time" mode simulates the operation of the vehicle once it has been queued for testing at an I/M site. The wait time mode is proposed to include keyoff/restart events at intervals no smaller than five minutes, with no idle interval to be less than three minutes. Thus, the maximum wait time mode of thirty minutes could contain six keyoff/restart events, at maximum.

As shown in Figure 1, the two proposed vehicle testing pathways divide at the first emission testing step. In the first pathway, the wait time mode is followed immediately by the first-chance modes of any single procedure from among the proposed new performance warranty procedures.[17] In the second pathway, the first-chance modes of two specific performance warranty tests—the Two-Speed Idle Test and the Loaded Test—are performed in order, with a second wait time mode in between. This second pathway provides data on each of the sampling mode types (idle, 2500 rpm, steady-state loaded) using one compact sequence.

This proposal does not limit the Agency's authority to perform multiple CSTs in its certification, audit, or enforcement testing programs. A second CST run on the same vehicle might employ a different selection from among the six available pathways, might otherwise set conditions at a different point (temperature, fuel, wait time) in the test envelope, or might focus on a different performance warranty short test. However, the Agency may not bypass the test preparation steps for successive runs of the CST; each run must include the appropriate warm-up operations.

If a manufacturer's EDV fails a run of the CST procedure under this proposal, the Agency will retest the vehicle using the identical CST compliance pathway, including the precise points in the test envelope and the same targeted performance warranty procedure. Vehicles that fail such a retest would then be ineligible for certificates of conformity.

[17] Because the new 207(b) Loaded Test has no second-chance option, all modes of the Loaded Test procedure are considered to be first-chance modes for purposes of the CST.

3. Minimum Certification Data Submittal Requirement

Under this proposal, a vehicle manufacturer must submit emissions data derived from a subset of the CST compliance pathways as a requirement of vehicle certification. The proposed manufacturer minimum testing requirement is illustrated in Figure 2. Once again, there are three test preparation pathways based on the test cell ambient temperature (cold, moderate, hot); however, the manufacturer need only choose one of the three paths for its certification EDV testing. In each case, the warm-up step is optional for the manufacturers during CST certification testing, while it was required for EPA compliance testing. All three paths feed the same actual test sequence, consisting of the first-chance modes of the newly proposed Two-Speed Idle Test and the Loaded Test, each preceded by a wait time mode. Except for the duration of the wait time modes, this is identical to the second EPA compliance testing pathway shown earlier in Figure 1.

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Figure 2: Manufacturer Certification Testing Pathways

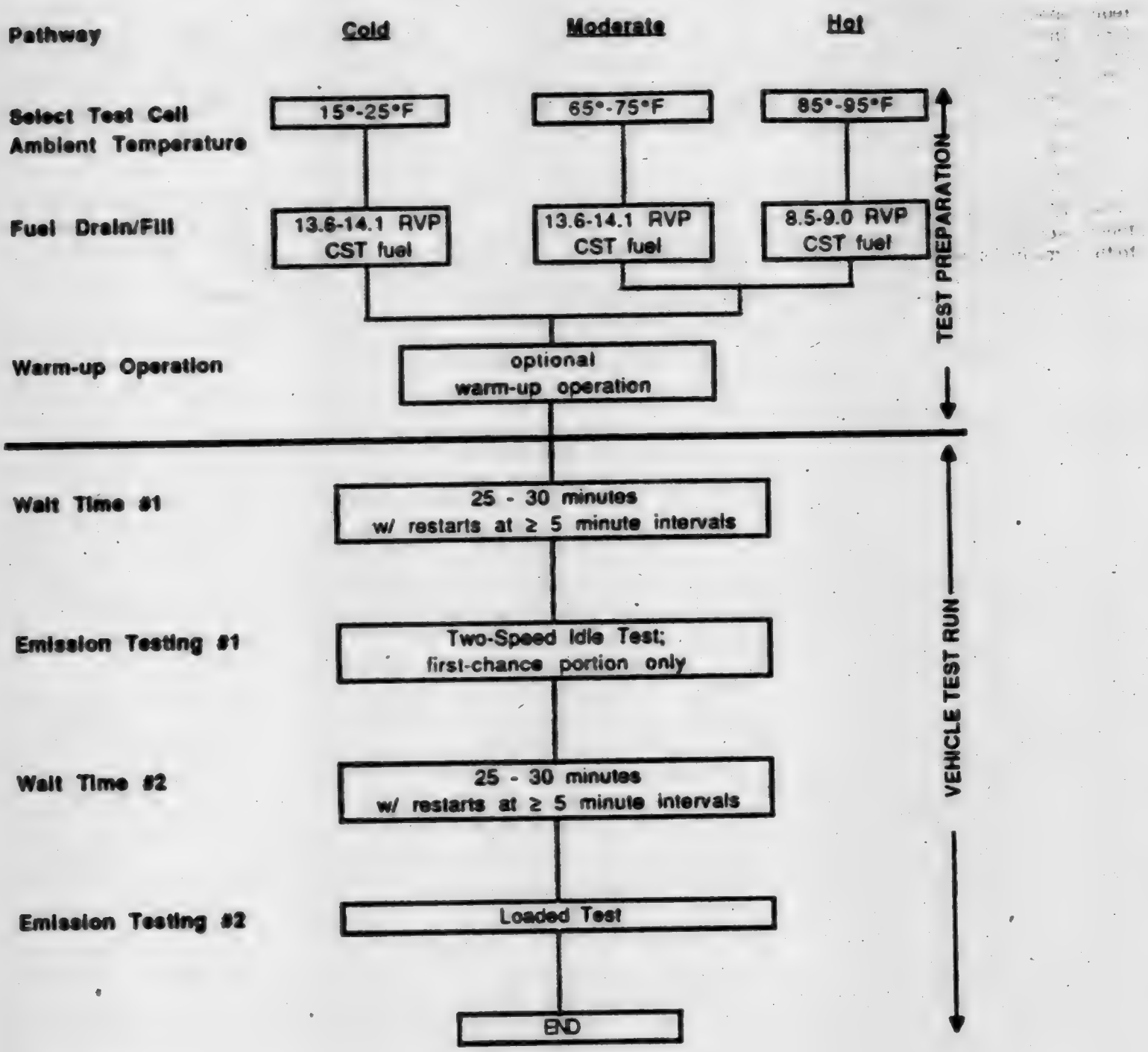

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The ranges for the variables of the test envelope are more restricted for manufacturer certification testing than for EPA testing; the rationale for this approach is presented in section III, as part of the separate discussions on test complexity tradeoffs and the proposed manufacturer data submission requirement. The ambient temperatures for the three options are proposed to fall in bands of width 10°F, centered on 20°F, 70°F, and 90°F, respectively. As proposed, the fuel volatility in the hot temperature test must fall in a 0.5 RVP band that peaks at 9.0 RVP; the volatility of the other two options must fall in a 0.5 RVP band with a maximum of 14.1 RVP. For all three options, the fuel must conform in all other respects to the same fuel specification as for EPA testing. The duration of the wait time modes in each case must be between 25 and 30 minutes. The choice for the number and duration of restart events during the wait time modes is in the manufacturer's hands, being mindful of EPA's right to perform compliance tests across the ranges of these variables.

The aggregate effect of these proposals is to focus the manufacturer's attention on three points in the compliance test envelope: A cold-temperature, high-RVP case; a moderate-temperature, high-RVP case, and a warm-temperature, moderate-RVP case. The manufacturer must pick its certification test condition from among the three.

4. Alternative Approach to the CST Envelope

Figure 3 illustrates an alternative proposal for implementing the CST test condition envelope. In this alternative, only the test preparation pathways, including the test cell ambient temperature options, are different from the proposal outlined earlier in Figures 1 and 2. As mentioned in the overview above, the essential difference between the two approaches to defining the envelope is the use of an evaporative canister loading procedure in place of fuel and temperature factors for generating purge vapor volume. The result is only two test preparation pathways (referred to in Figure 3 as cold temperature and warm temperature) instead of three. In the alternative approach, as with the non-canister procedure discussed previously, each test preparation pathway would be available to both EPA and the manufacturers.

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Figure 3: Alternative EPA and Manufacturer Preparation Pathways

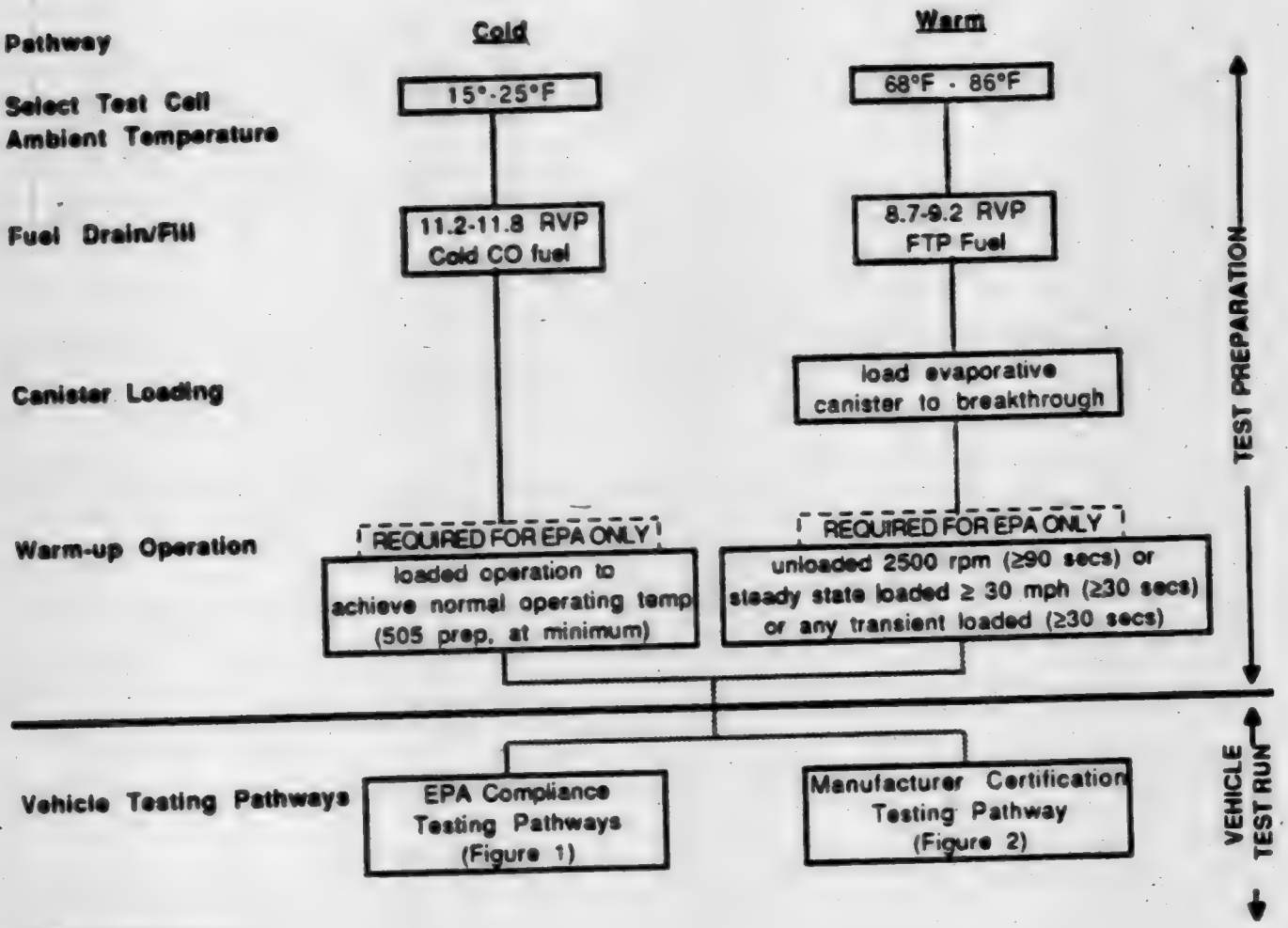

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The ambient temperature ranges and fuel specifications of the cold and warm temperature pathways are deliberately set to coincide with those of the cold CO rule [18] and conventional FTP testing. Thus, as shown in Figure 3, the ambient temperature portion of the test envelope consists of two disjoint ranges that reasonably mirror occurring real-world conditions: 15°F to 25°F for the cold pathway, and 68°F to 86F° for the warm pathway. Associated with these temperature ranges are the complete fuel specifications for cold CO and FTP testing, respectively. Figure 3 includes just the RVP portion of the fuel specifications; the complete specifications for the two fuels are provided in Table 3. As in the basic proposal outlined in Figures 1 and 2, no vehicle operation is specifically prescribed or excluded before the fuel drain and fill step.

TABLE 3—FUEL SPECIFICATION FOR THE ALTERNATIVE ENVELOPE

Parameter	Specification	Specification
Ambient Test Temperature.	15°F–25°F	68°F–86°F
Basis for specification.	Cold CO certification fuel	FTP certification fuel
RVP (psi)	11.5 ± 0.3	8.7–9.2
octane	≥87.5 (RON+MON)/2	≥93 RON
IBP, °F	76–96	75–95
T10, °F	98–118	120–135
T50, °F	179–214	200–230
T90, °F	316–346	300–325
EP, °F	≤413	≤415
Vol % aromatics	28.4 ± 4.0	≤35
Vol % olefins	12.5 ± 5.0	≤10
Wt % sulfur	0.035 ± 0.015	≤0.10
Phosphorus, g/U.S. gal.	≤0.005	≤0.005

As shown in Figure 3, artificial loading of the evaporative canister applies only to vehicles in the warm temperature pathway, since the vapor generation that causes canister loading is more likely to occur in the field under warm than under cold temperature conditions.

The Agency proposes that the canister loading procedures to be promulgated by the Agency in the evaporative emissions rulemaking currently in progress [19] or the similar procedures adopted by CARB for evaporative testing of California vehicles be applicable for this purpose. In both the CST and the evaporative emissions rulemaking, the Agency seeks to put the canister in a worst-case condition. There are no different logistical considerations in the two rules that should dictate different canister loading protocols, while conversely, resources could be saved by using the same procedure for both purposes. For similar reasons, vehicle manufacturers would be expected to likewise seek consistent EPA approaches to its canister loading procedures.

Any level of artificial loading would be permitted in Agency or manufacturer testing, from no loading up to the maximum achievable by the bench procedures permitted in the new EPA and CARB evaporative regulations.

The Agency's rationale for permitting a range of canister loading is twofold. First, EPA proposes that the canister loading portion of the CST be allowed to be completely by-passed if the manufacturer or the Agency has reason to believe that the vehicle system design will not permit any purge during the specific operating modes of I/M testing. Any conclusions regarding the purge behavior of an engine family, however, may be the subject of EPA confirmatory, SEA, and/or recall testing. Second, EPA wishes to preserve the ability to test with a less than fully loaded canister if there is an indication in particular situations that a lesser loading will suffice to conclusively demonstrate a vehicle's CST pass/fail status. This ability is particularly important if the canister loading procedures finalized in the evaporative rulemaking include real time methods such as extended diurnals where resource constraints may be a concern.

The methods for maximizing canister loading currently being considered in the course of the evaporative emissions rulemaking are filling the canister with a fixed volume of vapor (based on the working capacity of the canister) or loading until a specified volume of vapor is measured exiting the canister (breakthrough). In the latter option, the definition of breakthrough depends upon the method by which HC emissions from the canister are measured. If the canister loading is carried out in a sealed enclosure, then breakthrough may be defined as a certain amount of cumulative HC emitted into the enclosure as measured by a flame ionization detector (FID). An equivalent method might be to measure the local concentration of HC at the canister; this case breakthrough would be defined as a specified volume percent increase in the local concentration of hydrocarbons. A third method might be to collect emissions from the vehicle's evaporative system in an additional canister and base the determination of breakthrough on a specified gain in mass of the additional canister.

Following the canister loading step, the vehicle proceeds directly into warm-up operation and then into vehicle testing. The alternative proposal ceases to differ from the basic proposal beginning with the vehicle warm-up step. As before, warm-up is required for EPA testing but is optional for the manufacturers. In this alternative, EPA might choose to employ actual cold CO or FTP testing as the warm-up operation step, then proceeding directly into the CST vehicle testing. These cycles would meet the minimum requirements for warm-up in either the cold or the warm temperature pathway, and the matched fuel specifications would preclude the need for a refueling step. The manufacturers also might choose this warm-up approach, although EPA's right to choose a less stringent warm-up might dictate that, similarly, use of a worst-case warm-up cycle by manufacturers would be more prudent.

5. Equipment Requirements

The CST procedures and test envelope proposed here were conceived so that manufacturer and EPA testing could occur in the same test cells as FTP testing or in the cells that will be necessary for testing under the cold temperature CO and evaporative procedures required by the 1990 Amendments. Thus, the CST will not require the replacement of dynamometers or new equipment for the control of test cell ambient conditions. During loaded warm-up operation modes in the CST, the setting of dynamometer inertia weights and the assignment of power absorption unit (PAU) settings would occur in exactly the same manner as for FTP testing. During the Idle Test with Loaded Preconditioning or the Loaded Test (the only 207(b) procedures to require steady-state loaded operation), the dynamometer would be set to simulate the single-curve dynamometers used for I/M testing in the field, rather than the variable curve units used for conventional certification testing. This is accomplished by decoupling all inertia weights from the dynamometer drive rolls and fixing the variable PAU settings to match the power absorption curve proposed in the new performance warranty procedures for field use.[20,21]

[18] See 57 FR 31888 (July 14, 1992).

[19] See 55 FR 1914 (January 19, 1990).

[20] Because some certification dynamometers employ minimum inertia weights that are not equipped with clutch decoupling systems, the proposed regulations allow for a residual inertia weight of 1000 lbs. The effect of this allowance should be to provide some additional, preconditioning during accelerations and decelerations, but no impact on the steady-state modes themselves. The Agency considers the emission impact of this option to be insignificant.

[21] The power absorption curve, which is the horsepower needed for a vehicle to drive the rolls

Continued

The intent of the proposed regulations is that the CST emission analyzers should employ the same sampling train, NDIR analyzers, sampling algorithms, and repeatability and reliability criteria as the analyzers used for I/M testing in the field. Thus, the proposed CST regulations specify use of emission analyzers that in most significant respects meet the new field analyzer requirements proposed for inclusion in subpart W.

The Agency anticipates that the most straightforward and cost-effective approach will be for both EPA and the vehicle manufacturers to purchase actual I/M analyzers that meet the new subpart W analyzer specification, but have been modified to meet the particular data acquisition and operator interface needs of the individual purchaser. Nevertheless, provision is made for manufacturers to petition for use of equivalent or superior alternatives to the specified hardware and software configurations. However, calculation or interpretation of mean emission scores from bagged emission data (currently permitted for truck idle CO testing) will not be allowed, because it is precisely the sensitivity of pattern failures to instantaneous fluctuations in the emission scores that can lead to pattern failures. Replacement of NDIR HC analyzers with FIDs is also precluded, because of the difficulty in translating FID values into analogous NDIR readings that could be meaningfully compared to NDIR-based pass/fail standards.

A final CST equipment requirement of note is the specification proposed for 40 CFR 86.1437–94 that requires each vehicle to have an engine rpm signal readable via the onboard diagnostics lead, by a conventional inductive tachometer, or by a dedicated in-line lead with a standardized connector. This requirement has been added to the regulations to prevent certification of vehicles that could not complete the 207(b) test procedures in the field due to inaccessible engine speed signals.

C. Selective Enforcement Auditing

Pursuant to CAA section 206(b), the Administrator is authorized to test new motor vehicles in order to determine whether vehicles being manufactured do in fact conform to the regulations with respect to which a certificate of conformity was issued. Therefore, vehicles certified to meet the CST standards are subject to such standards in an SEA.

As with EPA certification confirmatory testing, SEA testing may include any combination of ambient temperatures, test fuel variables, prior vehicle operation, and vehicle wait times as well as any other test variables allowed by the regulations. Thus, SEA testing of a given engine family is not constrained by the particular points in the test envelope or vehicle testing pathways that were employed by the manufacturer for the certification data submission on the family or by EPA in earlier certification confirmatory testing of the family. In furtherance of the underlying purposes of the CST, a pass/fail decision will be based on the CST in its entirety rather than on a per pollutant basis, as would be the case with conventional SEA testing using the FTP. Basing pass/fail decisions on all pollutants simultaneously is consistent with the pass/fail decision methodology used in FTP confirmatory testing and in I/M testing.

Certain technical revisions are proposed to the SEA regulations at part 86, subparts G and K, to incorporate the CST procedures into Selective Enforcement Audits.

D. Imported Motor Vehicle Testing

Certain straightforward revisions are proposed to incorporate the CST procedures into the regulations at part 85, subpart P, that govern the importation of nonconforming motor vehicles and motor vehicle engines.

E. Recall

In addition to promulgating the CST procedures under the amended section 206 of the Clean Air Act, EPA is proposing to use the CST in recall testing, as discussed later in section III.B.12, "Recall Authority". This action subjects the vehicle manufacturers to potential recall liability under section 207(c) in the event, for example, that pattern failure vehicle problems not evident on certification emission data vehicles arise in actual field I/M testing.

For CST recall testing, EPA would target for further scrutiny only those vehicle groups whose field I/M performance indicated a potential pattern failure problem. Any CST recalls would not rely solely on actual field I/M data, but would be confirmed with laboratory testing using the CST. Any CST recall testing conducted in the laboratory would be conducted using only properly used and maintained vehicles and recalls would only be ordered if a substantial number of any class or category of vehicles were found to be failing.

CST recalls would be based on field I/M performance and data from recall testing performed by EPA using the CST procedures. The specific test protocol employed for the recall testing might not be the same as that used by the manufacturer or the Agency during certification of that family. As with SEA testing, recall testing may include any combination of ambient temperatures, test fuel variables, prior vehicle operation, and vehicle wait times as well as any other test variables allowed by the regulations. Thus, recall testing of a given engine family is not constrained by the particular points in the test envelope or vehicle testing pathways that were employed by the manufacturer for the certification data submission on the family or by EPA in earlier certification confirmatory testing of the family. The EPA will exercise reasonable judgment in selecting conditions for recall laboratory testing in order to reflect appropriate in-use conditions. Since recall testing, like I/M testing, occurs on in-use vehicles, the standards employed in recall testing would be those utilized for 207(b) procedures: 220 ppm HC as hexane, and 1.2% CO. Failure to meet the pollutant standard in any mode of the test procedure would be considered to be failure of the CST. However, EPA would not expect to recall vehicles unless it also had an indication that the problem was actually resulting in pattern failures in actual I/M programs.

In addition, the Agency recognizes that I/M test procedures and vehicle designs may interact to create pattern failures. In order to reach an equitable solution to the pattern failure problem, adjustments may need to be made to either the vehicle designs shown to interact poorly with I/M procedures and/or to shortcomings in the procedures themselves. The Agency is prepared to continue to evaluate test procedure shortcomings. The Agency expects that, as in the past, I/M programs will submit information indicating apparent pattern failure designs as well as test procedure shortcomings, and anticipates that manufacturers will similarly keep the Agency informed. The Agency is fully prepared to consider rulemakings to revise test procedures in response to information provided by I/M programs as well as manufacturers outside the context of a particular enforcement action.

F. Previous EPA Proposal for an Alternative Loaded-Mode Test Procedure

This rulemaking action proposes to add a new Loaded Test procedure to the emission performance warranty regulations, in addition to preserving

at various speeds, is horsepower as a cubic function of speed. The specific load-speed relationships for field use are proposed in § 85.2216 and § 85.2219.

the existing Loaded Test (40 CFR 85.2215). The test and chassis dynamometer requirements associated with the loaded-mode portion of this new short test procedure are similar to those proposed in a separate rulemaking by EPA for incorporation into the existing Loaded Test. As a result of this close connection between the two rulemakings, the Agency is taking this opportunity to announce its intention concerning the disposition of the previous, outstanding proposal.

On January 3, 1989, the State of Arizona began loaded-mode testing with somewhat different equipment and procedures than specified in the current Loaded Test requirement. Just prior to that date, on December 23, 1988, EPA published a Notice of Proposed Rulemaking to revise the dynamometer speed/load specifications of the Loaded Test to accommodate Arizona's testing.[22] (Other less significant test procedure changes were also contained in the proposal.) The comment period on the proposed rulemaking was extended several times to allow interested parties an opportunity to comment on new test data from the Arizona inspection and maintenance program. The last comment period closed on February 13, 1990.[23]

The Agency currently intends to take final action on the December 23, 1988 Notice of Proposed Rulemaking at the same time final action is taken on this proposal. EPA is not reopening the comment period on the former action, due to the extensive comment period that has already been provided. The Agency's decision on modifying the existing Loaded Test will be published in the **Federal Register** in conjunction with the final action on today's proposal.

G. Technical Amendments

The technical amendments contained in this rulemaking constitute nonsubstantive changes to subparts B, D, F, and N of part 86 of the regulations. The proposed changes are the only changes proposed to these subparts at this time, and they are unrelated to the proposed changes to I/M regulations or to promulgation of the CST.

One set of proposed amendments concern reducing the frequency of the nitrogen oxides (NO_x) analyzer converter efficiency check applicable to all vehicle classes. The regulations presently state that the NO_x converter efficiency shall be checked at least weekly or after any maintenance which could alter calibration. The amendments propose to change the weekly requirement to a monthly one, because experience has shown that the monthly interval is adequate for the intended purpose of the check. This change applies to testing of light-duty vehicles, light-duty trucks, heavy-duty engines, and motorcycles.

The Agency also proposes to reorganize some of the existing language in § 86.142–90 of subpart B and to clarify and update certain requirements of that section for recording and reporting data during testing of light-duty vehicles and light-duty trucks.

With the exception of the NO_x converter check the amendments would not cause changes to the actual procedure as presently performed, but merely define by regulation what good engineering practice already necessitates. For example, the proposed revisions specify that ambient temperature be recorded throughout testing, rather than merely stating that ambient temperature must be recorded.

III. Rationale and Discussion of Issues

A. Performance Warranty Regulations

The Agency has undertaken revisions to the subpart W procedures at this time for three reasons: to create a more precisely defined benchmark for the CST, to reduce the number of errors of commission in I/M testing, and to legitimize and promote the use of computerized I/M emission analyzers with digital sampling technology. Although the new procedures have direct ancestors in the existing performance warranty tests, they were developed by the Agency to incorporate improvements identified by vehicle manufacturers, analyzer manufacturers, the I/M programs, and EPA's own testing. These improvements, cited in the background and detailed in the previous section, include controlled preconditioning, extended test modes, a computerized sampling algorithm, and broad use of second chance testing.

Each of the new procedures was first presented by the Agency in the January 1991 technical report, "Recommended I/M Short Test Procedures For the 1990's: Six Alternatives."[24] Proposal of the new tests at this time fulfills EPA's commitment in that report to incorporate EPA-recommended improvements into the performance warranty regulations. Release of the technical report corresponded with distribution of a letter by the Motor Vehicle Manufacturers Association (MVMA) encouraging I/M programs to adopt the recommended procedures,[25] and some programs have already taken steps in that direction.

One important consequence of the proposed new mode length criteria and the expanded availability of second-chance testing is that every vehicle that fails one of the procedures must have either undergone minimum levels of preconditioning and sampling or failed due to the "dirty vehicle" early out option. Thus, for example, for the last idle mode to be recorded as a failure under any of the six test procedures, the vehicle must have been exposed to either three minutes at 2500 rpm or 30 seconds of steady-state loaded operation prior to the idle mode. Failures at 2500 rpm will occur only after three minutes at 2500 rpm have elapsed. Loaded-mode failures will have been operated under load for 90 seconds. The objective of these changes is to prevent I/M failures of vehicles that would produce limited benefit from attempts at repair.

The Agency anticipates that many, if not most, vehicles will complete the test at or shortly after the minimum test time as a result of the clean vehicle early out option. This factor should compensate for the longer test times required for the low percentage of failing or borderline vehicles. The applicable cutpoints for this option are designed to reduce test times for very clean vehicles while still providing vehicle owners and program managers with important information on the emission levels of the vehicles.

The Agency recognizes that the new procedures present both advantages and tradeoffs for I/M programs. Performing a preconditioning step prior to the first pass/fail mode, for example, may lower the failure rate on the first chance test but at the cost of a longer test time. The shorter loaded preconditioning times may be preferred to those for unloaded preconditioning, but loaded modes require a dynamometer. Centralized I/M programs in particular may wish to compare the different procedures in light of their lane volume and station capacity concerns. In balance, EPA believes that the increased time devoted to some vehicles on their first I/M visit with some of the new procedures will be more than offset by the reduced need for post-repair retests. Moreover, the benefits to vehicle owners who would have undergone unnecessary and potentially counterproductive repairs must also be considered.

[22] See 53 FR 51956 (December 23, 1988).

[23] See 55 FR 3073 (January 30, 1990).

[24] Tierney, Eugene J., Herzog, Erik W., and Snapp, Lisa M., "Recommended I/M Short Test Procedures for the 1990's: Six Alternatives," USEPA Office of Air and Radiation, EPA–AA–TSS–I/M–90–3. Available in the public docket for review.

[25] Letter regarding vehicle preconditioning prior to I/M testing, from Marcel L. Halberstadt, Motor Vehicle Manufacturers Association, to EPA and State Agency officials (February 12, 1991). Available in the public docket for review.

The Agency expects the proposed revisions to the I/M equipment specifications to be noncontroversial. Such requirements are consistent with the most advanced specifications and, in fact, these units are currently in production. Therefore, the hardware and most software aspects of these analyzers are already in conformance with the proposal.

New software will be necessary to accommodate some aspects of the EPA-proposed sampling algorithm, but the production of new analyzers for I/M programs always necessitates tailoring the software to the test procedures and regulations of the individual program, and the algorithm changes can be incorporated concurrently. The effect of the new analyzer requirements would be to force the eventual retirement of analyzers with lesser capacity and with greater uncertainty in the emission scores produced. As noted in the previous section, the proposal makes allowances for an orderly penetration of analyzers meeting the new specifications.

The action to promulgate revisions to the current performance warranty test procedures is taken under authority of section 207(b) of the Clean Air Act, 42 U.S.C. 7541(b), which provides in pertinent part:

> If the Administrator determines that:
> (i) There are available testing methods and procedures to ascertain whether when in actual use each vehicle complies with (applicable) emission standards;
> (ii) Such methods and procedures are in accordance with good engineering practices; and
> (iii) Such methods and procedures are reasonably capable of being correlated with (certification tests), then he shall establish such methods and procedures by regulation.

The first criterion requires that the methods and procedures be "available," that is, that the procedures are defined with reasonable rigor, can be executed using equipment that can be readily obtained, and can reasonably be employed for the intended purpose of identifying noncomplying vehicles. Given that the procedures and equipment are straightforward improvements on existing performance warranty short tests and equipment and that the necessary equipment is already available in the field, the proposed regulations meet this requirement.

The second criterion requires that the procedures be designed in accordance with good engineering practice, which is satisfied if the tests can be conducted within the reasonable capability of personnel and equipment. Again, this requirement is satisfied, in that the proposals represent improvements to already approved performance warranty procedures. The proposals include no new mode types that might affect the ability of personnel to execute the tests. The proposed sampling algorithm is well within the capabilities of existing analyzers and it removes ambiguity for the inspector in the conduct of the procedures.

The correlation criterion is satisfied because the proposed procedures are in fact modifications of the existing performance warranty tests, which tests have already been held to provide an adequate degree of correlation,[26] and the modifications are specifically designed to reduce errors of commission and therefore improve correlation. The ability of I/M tests to perform their intended function is enhanced.

The Agency finds that the three statutory criteria have been satisfied; accordingly, this notice proposes that the procedures be adopted as performance warranty short tests.

B. Certification Short Test

1. Policy Objectives and Considerations

The Agency considered a number of factors in developing this proposal for the CST. Four policy objectives were established. First among these was the objective that all vehicles should be designed to pass the first-chance portion of the 207(b) performance warranty tests. Second, and by implication from the first, was the objective that the second-chance portions of the 207(b) tests should only be available during field testing, where the intention should be to provide coverage of an anomalous individual vehicle or for the anomalous combination of test variables. The third and fourth policy objectives were based on the strategy of addressing known, significant causes of pattern failures: Purge systems must be controlled during all sampling modes of the 207(b) tests, and feedback or aftertreatment systems must not be rendered inoperative during conditions reasonably likely to be encountered during actual I/M testing.

In addition to the policy objectives, several practical considerations arose, such as the possible need for specialized test cells or test fuels under some proposals, and the duration of any proposed procedure. The Agency considered the burden each option might place on the manufacturers, both in terms of their development testing and their certification data submission requirement. Less burdensome manufacturer data submission requirements were considered, but at the cost of greater EPA reliance on confirmatory testing during certification, or later in-use vulnerability to emission recalls.

The paragraphs that follow analyze EPA's proposal, given the above objectives.

2. Test Complexity Tradeoffs in the Basic Proposal

Under the statute, EPA could have proposed a requirement that manufacturers submit certification data at every point in an array of CST procedures that incorporated all six approved 207(b) field I/M test procedures, each one conducted using a menu of possible fuel characteristics, ambient temperature ranges, and vehicle wait times. Obviously such an approach would be quite complex; for example, the protocol would involve numerous fuel changes, vehicle soaks and emission tests conducted at multiple temperatures, and repeated dynamometer operation to return the vehicle to a baseline condition prior to each emission test. It would also be inefficient, because a manufacturer's own evaluation of its designs would normally be sufficient for it to correctly conclude that the vast majority of the test points in the array would not generate pattern failures of its vehicles.

The Agency has proposed a minimum CST certification data requirement: The manufacturer must submit data from a single procedure (the manufacturer's testing pathway presented earlier in Figure 2), incorporating two performance warranty tests (the proposed new Two-Speed Idle Test and the Loaded Test), at one of three specific points in the total envelope of possible CST test conditions. The set of conditions selected is proposed to be the one that, in the manufacturer's best judgment, represents the worst case, meaning the highest probability that the test vehicle would fail.

These two I/M tests provide data from one compact procedure on all three I/M sampling modes (curb idle, 2500 rpm, and steady-state loaded) included in the six proposed performance warranty tests. The proposed new Two-Speed Idle Test duplicates the 90-second idle mode in the first chance portion of all of the revised performance warranty tests as well as the high-idle sampling modes of the two 2500 rpm pass/fail tests. The order of the proposed Two-Speed Test is also the best for prompting idle-mode pattern failures, because the 2500 rpm mode comes second, and any extra preconditioning effects of that operation will be lost to the idle mode. The presence of the second wait time returns the vehicle to

[26] *Motor Vehicle Manufacturers Association* v. *Ruckleshaus*, 719 F.2d 1159 (D.C. Cir. 1983).

a condition reflecting time in an I/M queue, without the need for refueling or new warmup operation, before the Loaded Test commences.

As mentioned in section II, the ranges for the test envelope are more restricted for the manufacturer data submittal requirement than for EPA testing. The Agency selected the three points from the test envelope to mimic field conditions that are worst-case conditions, in that they are the most likely to (1) elevate canister vapor volumes during I/M testing; (2) trigger the operation of fuel metering and air injection timers, and (3) exacerbate the cooldown of catalysts and oxygen sensors during I/M tests, which were pattern failure triggering conditions identified in section I as being of particular concern.

The Agency only views the above approach as fulfilling the statutory mandate if the Agency has the authority to conduct compliance testing using any approved performance warranty test under any set of conditions that can reasonably be expected to be encountered in actual I/M testing, and not just using the exact procedure and conditions chosen by the manufacturer from among the proposed options. This provides protection against the introduction of pattern failures due either to known or currently unidentified causes.

Thus, the proposal presented in section II of this preamble and in the regulations defines an envelope of test conditions within which EPA may conduct compliance testing. The variables that define the boundaries of the envelope are proposed to be the test cell ambient temperature, the fuel volatility, and the vehicle wait time before entering the formal I/M test procedure. The Agency believes that vehicles designed to pass the I/M tests throughout this envelope will pass I/M tests under the range of conditions likely to be encountered in the field.

Even with this authority, however, the Agency is in no better position than a manufacturer to conduct certification testing using all of the I/M procedures under all possible field conditions. The Agency therefore expects to focus its certification confirmatory test resources on those I/M tests and conditions of concern given factors like the control strategy of a particular engine or the manufacturer's record of pattern failure performance as indicated by in-use data.

Because the certification process typically uses only two emission data vehicles to represent subsequent production for the entire family, the Agency acknowledges that limited certification testing using CST procedures still would not guarantee that manufacturers must design vehicles so as to prevent I/M pattern failures from occurring in the field. The proposal therefore places emphasis on audit and recall testing in lieu of a much more complex marginally more effective certification compliance testing program or manufacturer data submittal requirement. This emphasis is consistent with the Agency's general approach to the Federal motor vehicle emission compliance program, which seeks to minimize the burden of certification data submittals, preserve reasonable manufacturer options, and rely on enforcement testing as an incentive for manufacturer compliance.

As noted in section II, this proposal does not limit the Agency's authority within its certification, audit, or recall programs to perform multiple runs of the CST procedure, employing different combinations of the allowable performance warranty tests and conditions from within the test envelope. Since some vehicles are pattern failures under multiple sets of conditions and procedures while others have patterns of failure only under a single narrow set of conditions, assurance that all appropriate conditions and procedures are considered in the vehicle design can only be accomplished if the EPA is able to test under a variety of combinations. This aspect of the proposal would impose an additional burden only on the Agency, since the manufacturer's obligation is to design its vehicles to pass all of the new performance warranty procedures at any point within the envelope of conditions and perform development tests.

The manufacturer's data submittal requirement, EPA audit testing, and EPA recall testing, are also discussed as individual topics below.

3. Targeting First-Chance-Pass on the CST

The Agency has incorporated second chance testing in the revised performance warranty procedures to address the failure of individual vehicles with essentially clean emissions that fail due to abnormal combinations of test conditions or due to one time anomalies that coincidentally occur during the modes of the I/M test. The second chance to pass should prevent these single vehicles from receiving unnecessary and potentially unproductive repairs.

The Agency contends, however, that manufacturers should design their vehicles to pass the first-chance portion of the revised performance warranty procedures under the range of conditions reasonably likely to be encountered during I/M testing. If the second-chance portion of the test were to become the design target, the I/M testing load would increase as more and more vehicles would require the second chance to pass; ultimately a third chance could eventually be necessary to accommodate abnormal combinations of test conditions or the coincidental failures.

The Agency is therefore proposing that vehicles undergoing certification, SEA, or recall testing be able to pass the first chance portion of the revised performance warranty procedures within the two envelopes of test conditions described in section II. Failing certification vehicles would be denied a certificate of conformity; failing audit or recall vehicles could be subject to enforcement action.

As noted in section II, manufacturers would be provided a repeat test of any CST failure of an emission data vehicle (EDV) on a certification confirmatory test, as a protection against operator error and test-to-test variability. Such a repeat test would be conducted using the same first chance modes and using the same point in the test envelope that were employed when the original EDV failure occurred; this is therefore not the same as a second chance I/M test. Both the original and the retest would have to be failed before a certificate of conformity would be denied. Provision for repeat CST tests during certification is consistent with current practice for failures using other test procedures (e.g., the FTP) during certification.

4. General Aspects of the Two Test-Envelope Approaches

Section II contains both a basic proposal and an alternative proposal for defining the envelope of test conditions applicable during CST testing. Only the basic proposal is reflected in the draft regulations. This section addresses general considerations in the design of the two approaches; more detailed comments on ambient temperature ranges, fuel characteristics, and vehicle wait time follow in the succeeding three subsections.

The Agency believes that both the basic approach and the alternative approach to the test envelope can adequately identify vehicles that will pass the I/M tests under conditions reasonably likely to be encountered in use. Both approaches are predicated on the idea that the envelope can be defined to permit testing for three of the most troublesome pattern failure triggers—evaporative canister purge, fuel metering and air injection timers, and catalyst cooldown. Both approaches

check for the impacts of timers through identical wait time modes that may incorporate keyoff/restart events. Both increase the chance for catalyst cooldown by conducting the wait time in one option at low temperature. The two approaches differ primarily in the methods used to test for evaporative purge failures and in the presumed impact of in-use fuel variables.

The proposed envelope in the basic approach is restricted to continuous ranges of ambient temperatures, fuel characteristics, and vehicle wait times derived from actual in-use data or required by the statute. The bounds on the ambient temperature axis of the envelope are further restricted to the capabilities of test sites projected to be available due to two other CAA-mandated rules—the cold CO rule and the evaporative emissions rule. Certification test fuels, including the cold CO test fuel, would not be acceptable for CST testing under this approach. The basic approach uses real-world fuel volatility (Reid Vapor Pressure, or RVP) and ambient temperatures to generate the fuel vapor necessary to test for purge-related pattern failures.

The hallmark of the alternative approach is the use of a canister loading procedure, rather than high RVP or high ambient temperature, to generate the fuel vapor necessary to test for purge-related failures. The vehicle wait time range is the same as that in the basic approach. The ranges of the other variables are discontinuous. Ambient temperature for cold temperature testing is constrained by the lower bound of the cold CO rule, and for warm temperature testing, by the current range of certification testing with the FTP. The approach presumes use of current certification test fuels, including the cold CO test fuel.

Of the two, the basic approach is therefore a more direct reflection of actual in-use conditions. However, it requires specialized test fuels, and the likely use of specialized hot temperature test cells as well. The alternative approach is simpler because it provides fewer options, and it would promise to place lesser fuel and facility demands on the manufacturers. The tradeoff in the alternative, however, comes in the form of a test that could be more stringent, since the Agency always has the option to perform confirmatory testing with the canister in a breakthrough condition. Artificial loading to breakthrough mirrors the worst case I/M lane scenario, and the EPA thus believes that the alternative approach is as effective as the basic approach in detecting pattern failures caused by canister purge.

The Agency requests comment on the desirability of one approach versus the other, and any environmental, vehicle design or test burden impacts that may be imposed by each approach. This information will aid in the selection of a single approach for the final rule.

Unless a manufacturer has incorporated prohibited defeat devices, the catalysts, purge systems, and other emission control components will not cease to function simply because a test variable falls just beyond the bounds of the test envelope. Thus, in most cases, a vehicle adequately designed to pass each performance warranty test throughout either of the two proposed test envelopes will also pass I/M tests conducted in unusual circumstances outside the envelope. In the field, second chance testing available for the unloaded tests is designed to address those cases of unusual, individual failure.

The Agency recognizes, however, that some pattern failures may theoretically occur that are triggered solely by conditions outside the proposed test envelopes. Such pattern failure types would therefore not be detected by certification, audit, or recall testing with the CST as proposed. The Agency considered establishing manufacturer liability for certification, audit, and recall testing to cover such cases, but including the second-chance portions of the performance warranty procedures when this testing occurred outside the test envelopes proposed today. This would essentially require all vehicle designs to pass the I/M procedures, given second-chance testing, under all combinations of conditions that could ever occur in the field. The Agency concluded that this was an unjustified extension of the legislative mandate to cover reasonable field conditions in the CST, and thus is proposing to limit manufacturer liability for certification, audit, and recall testing to the bounds of the proposed envelopes. If pattern failures do occur under conditions, beyond the limits of the chosen envelope, that come to be recognized as reasonable field conditions, EPA has the authority under the statute to revise the conditions of the CST with a future rulemaking. In the meantime, the performance warranty remedy remains available to individual vehicle owners as a protection against individual I/M failures under any test conditions.

Comments are nevertheless solicited on the approach that would extend manufacturer CST recall liability beyond the envelopes proposed, with or without the addition of second chance testing. EPA is particularly interested in comments pertaining to the ability of the envelopes proposed in section II to prompt manufacturer designs that will eliminate pattern failures both inside and outside the envelopes.

5. Ambient Temperature Conditions

Temperature data compiled in the 1990 Statistical Abstract of the United States [27] served as the basis for determining "reasonably likely to be encountered" ambient temperature conditions for the purposes of this proposal. Based on those data, EPA found that the monthly average of the daily high temperatures and the monthly average of the daily low temperatures for the United States routinely differ by 100 °F in a given year. For example, the 1990 Statistical Abstract reports an average daily minimum in Minneapolis throughout January of 2.4 °F and an average daily maximum in Phoenix throughout July of 105 °F. Both of these cities have centralized I/M programs where conditions in the test bays are essentially outdoor ambient conditions, and both cities maintain testing under these conditions.

These conditions may be considered to reflect the extremes of temperature under which I/M testing may occur. However, the range of conditions that is feasible to replicate in CST testing while maintaining the obvious need for reliable data is somewhat less severe. The Agency examined this question in the light of the cold CO regulations [28] and the proposed evaporative emission regulations [29] which have likewise sought to define, respectively, reasonable lower and upper temperature bounds for compliance testing facilities.

For the above reasons, the Agency is proposing a test cell ambient temperature range of 15 °F to 95 °F. The lower limit of 15 °F is consistent with the requirements of the cold CO regulations; the 95 °F upper limit is consistent with the proposed revisions to the evaporative emission regulations. If the alternative test envelope also proposed in section II is adopted, the cold temperature portion of the disjoint temperature range would be 15 °F to 25 °F, which would again be achieved through the site requirements of the cold CO regulations; the warm temperature portion of the range would

[27] U.S. Bureau of the Census, Statistical Abstract of the United States: 1990 (110th edition.) Washington, DC, 1990.

[28] See 57 FR 31888 (July 17, 1992).

[29] See 55 FR 1914 (January 19, 1990); see also a supplemental workshop notice on the same topic, 55 FR 49914 (December 3, 1990).

be 68 °F to 86 °F, which is simply the range permitted for current FTP testing.

6. Fuel Characteristics

As mentioned previously, EPA is required when designing the CST to consider fuel characteristics as part of the list of conditions "reasonably likely to be encountered" in I/M testing. The Agency has consequently proposed a CST fuel specification in section II of this preamble and in sections 86.1413 and 86.1430(b) of the regulations that addresses a number of fuel variables: fuel volatility (RVP), octane (Research Octane Number, or RON), the 90 percent temperature point on the distillation curve (T_{90}), percent aromatics, percent olefins, percent MTBE, and weight percent sulfur.

The proposed specification was developed in the following manner. The Agency identified fuel characteristics where there was evidence of an impact on tailpipe emissions. Histograms were generated showing the frequency distribution of each fuel variable in in-use fuel samples. Then, 90th percentile values were determined from the histograms in the direction that was judged to be more likely to generate high emissions. Fuels with a given variable at, or worse than, each 90th percentile value would be considered acceptable for use in the CST. Since octane is not known to have a significant impact on tailpipe emissions, the 50th percentile value was used; this value also corresponds to that specified for current certification test fuel. The results were rounded and aggregated into a specification. The specification was then checked for mutual consistency of the variables under scrutiny and adjusted for the impacts of other EPA rulemakings.

As noted in section I, increases in vapor volumes related to increased fuel RVP are a significant contributor to the problem of evaporative purge related pattern failures. For this reason, RVP was a focus of EPA attention when developing the proposed CST fuel specification.

With the exception of RVP, the Agency currently possesses few data on the direct impact of most fuel variables on I/M emissions. However, technical bulletins of the Auto/Oil Air Quality Improvement Research Program (AQIRP) do show significant adverse effects on FTP tailpipe emissions due to high levels of fuel aromatics, T_{90}, and sulfur, and low levels of MTBE and olefins.[30]

The AQIRP Technical Bulletin No. 1 indicated that "the largest single effect" on HC emissions was attributable to reducing T_{90} from 360 °F to 280 °F. This reduction caused a decrease in HC emission levels of nearly 22 percent on average for all fuels tested. In addition, a high T_{90} also increased the relative impact on HC and CO emissions caused by both aromatic and olefin levels.

This study also found that higher levels of aromatics tended to produce higher HC and CO emissions. A reduction in aromatics from 45 percent to 20 percent produced a 6.3 percent reduction in HC emissions and a 13.6 percent drop in CO emissions. As indicated above, the strength of this effect is somewhat dependent on whether T_{90} is high or low.

The effect of olefins on HC emissions was found to be the opposite of that of aromatics. Lowering olefins from 20 percent to 5 percent resulted in a 6.1 percent increase in HC emissions, though it had no statistically significant impact on CO. This study also found that adding MTBE always lowered emissions of both HC and CO. It found that an increase of MTBE from 0 percent to 15 percent resulted in statistically significant decreases in HC emissions of 5.1 percent and in CO of 11.2 percent.

The effects of fuel sulfur content on emissions were presented in the AQIRP Technical Bulletin No. 2, which detailed a statistically significant decrease in HC emissions of 16.1 percent and in CO of 12.9 percent when the sulfur content was lowered from 466 ppm to 49 ppm. This has been shown to be due to sulfur's effect on the conversion efficiency of the vehicle catalyst.

The Agency's source of in-use fuel data was the 1990 MVMA National Fuel Survey.[31] Data on 775 samples were compiled, and separate 90th percentile values were calculated for summer and winter fuels, for each fuel variable cited above. When rounding was taken into account, however, the distinction between the summer and winter values was judged to be insignificant for each variable except RVP, and a single specification for the non-RVP variables was chosen.

For RVP, the maximum CST cold temperature fuel volatility of 14.1 psi was based on the 90th percentile winter fuel RVP, derived from the MVMA National Fuel Survey Data in the manner just described. The fuel RVP for moderate and hot temperature CST testing was derived in a different manner. Beginning in 1992, fuel volatility during May through September will be controlled nationwide by the EPA through the Phase II RVP Control regulations promulgated in June 1990.[32] These regulations specify maximum allowable nationwide summertime commercial gasoline RVP values that vary by state and by month. The regulations were partially superseded by a new volatility control program mandated by the Amendments, but the impacts on this proposal of the differences between the two programs are minor.

Both the Amendments and the Phase II regulations specify a maximum allowable summertime RVP of 9.0 psi, with a more stringent RVP standard of 7.8 psi required for areas that are designated non-attainment for the ozone National Ambient Air Quality Standard (NAAQS). According to the data collected by the 1990 MVMA National Fuel Survey, summertime RVP across the country ranged from a minimum of 6.9 psi to a maximum of 10.7 psi, with a mean of 8.6 psi. Obviously, the 90th percentile of the 1990 fuel survey data will be an inappropriate measure of the fuels reasonably likely to be encountered in I/M testing in 1994, due to implementation of a maximum summer RVP of 9.0 psi in most regions of the United States. On the other hand, not all I/M areas will be implementing the most stringent RVP limits. Consequently, EPA has chosen to specify a maximum of 9.0 psi for the CST hot temperature fuels.

In determining the CST fuel specification, the Agency accounted for the fact that some ozone non-attainment areas will be subject to the reformulated gasoline regulations required by the Amendments, currently undergoing the rulemaking process. These regulations will require reformulated gasoline to be used in gasoline-fueled vehicles in severe and extreme ozone non-attainment areas. Additional ozone non-attainment areas will have the option of joining the reformulated fuels program. However, EPA has identified a significant number of metropolitan areas that conduct I/M testing, yet are not ozone non-attainment areas. The implication is that these regions will continue to perform I/M tests on vehicles in the field using fuels similar to those currently available, since they

[30] Auto/Oil Air Quality Improvement Research Program, Technical Bulletin No. 1: "Initial Mass Exhaust Emissions Results from Reformulated Gasolines," December, 1990, and Auto/Oil Air Quality Improvement Research Program, Technical Bulletin No. 2: "Effects of Fuel Sulfur Levels on Mass Exhaust Emissions," February, 1991.

[31] Motor Vehicle Manufacturers Association of the United States, Inc., "National Fuel Surveys, Gasoline and Diesel Fuel, Summer 1990" and "National Fuel Surveys, Gasoline and Diesel Fuel, Winter 1990." Available in the public docket for review.

[32] See 55 FR 23658 (June 11, 1990).

are unlikely to be affected by the reformulated fuels regulations. With this in mind, EPA has chosen to propose fuel specifications for the CST based on currently available fuels. If it becomes the case in the future that all or a significant majority of I/M areas are using reformulated or otherwise cleaner fuels, or fuel composition in these areas changes considerably, EPA has the option to adjust the CST fuel specifications accordingly. The Agency solicits comment on the proposed fuel specification. In particular, comment is requested on the ease with which this fuel can be blended and its effectiveness at providing in-use I/M emissions information beyond that which could be obtained with standard certification test fuel.

In the alternative approach to the test envelope presented in section II of this preamble, the Agency has proposed use of cold CO fuel for cold temperature CST testing and conventional FTP certification fuel for warm temperature CST testing. The cold CO fuel specification is based on a sales-weighted average of winter fuel samples derived from a joint in-use database of 1990 MVMA Fuel Survey data and Southwest Research Institute data, with tolerances applied to permit production of a practical and cost-effective test fuel.[33] The Agency's intent in the CST under the alternative approach to the test evelope is that CST testing be permitted immediately following cold CO testing, without a fuel change. Thus, the fuel adopted in the cold CO regulation would be incorporated by reference in the CST portion of the regulations.

The Agency recognizes that current certification test fuel is unrepresentative of in-use fuels with respect to RVP, the distillation curve, and several compositional elements. If the alternative CST test envelope were to be adopted and certification fuel consequently used as the warm temperature CST fuel, the canister loading step is intended to supersede any impacts of the difference between certification and in-use fuel RVP on CST test results. The Agency currently possesses insufficient information to confidently predict an adverse impact on CST results at warm temperature from the remaining differences between the certification and in-use fuels. Consequently, the Agency solicits comments from interested parties on the wisdom of incorporating current certification fuel as the warm temperature CST fuel.

7. Vehicle Wait Times and Prior Vehicle Operation

The Agency has selected a range of three to 30 minutes for vehicle wait time. The upper end was determined by the statute, which states that "short (30 minutes or less) waiting periods before tests are conducted" are an in-use condition that is to be included in the conduct of the CST. As a confirmation of the validity of this wait time, the Agency reviewed wait time surveys recently conducted by several I/M programs; these surveys indicated that a 30 minute wait in an I/M lane is not unusual in some programs, particularly at peak periods (e.g., Saturdays near the end of the month).[34]

A long queue in an I/M lane, in which the vehicle idles or undergoes a series of idle and keyoff conditions, can trigger pattern failures related to evaporative canister purge, air injection timers, fuel metering timers, and catalyst cooldown. Thus, in many situations, long wait times are worst case situations. The lower end of three minutes was also selected on the basis of the wait time survey information, which indicated that in some programs wait times are predominantly shorter than five minutes.

The potential for wait times as short as three minutes affected the Agency's proposal for the warm-up step that concludes each vehicle preparation pathway. Current performance warranty regulations require that vehicles be at normal operating temperature entering the I/M test procedures. The regulations do not prescribe a specific type or duration of vehicle operation to achieve this condition. In centralized I/M programs, vehicles are normally presumed to have achieved normal operating temperature as they are driven to the test site shortly before testing. Decentralized programs, on the other hand, may test vehicles that have been soaking for extended periods, and in order to meet the requirements of the performance warranty regulations, inspectors must warm up vehicles prior to the test.

In order for the CST to replicate an I/M test performed in accordance with the performance warranty regulations, the Agency proposes to include a limited amount of warm-up operation immediately before the wait time to bring vehicles to normal operating temperature. The proposal incorporates 90 seconds of 2500 rpm operation or 30 seconds of loaded operation under warm ambient conditions, or transient loaded operation such as a cold 505 cycle under cold ambient temperature conditions. For the cold temperature condition, a longer cycle, such as a cold CO sequence, may be used in place of the cold 505 cycle. Manufacturers may, at their discretion, eliminate the prior operation for development or data submittal testing; the Agency, however, is proposed to be required to perform such operation for confirmatory, SEA, or recall testing.

This notice proposes that the wait time modes may be punctuated with vehicle keyoffs occurring at a maximum rate of one per five minutes, and each stretch at idle during the wait time must exceed three minutes. This reflects the fact that some owners tend to keep their vehicle idling throughout a long wait period in an I/M lane, while others turn their vehicle off, restarting only long enough to creep forward in line. Operator behavior can also depend on the ambient temperature, use of air conditioning, the vehicle's proclivity to overheat or stall, and the length of the queue.

No single type of keyoff behavior, however, can be considered worst case for emission control. Manufacturers have historically employed timers for fuel metering and air injection control of widely varying durations and impacts on instantaneous emission levels. Some vehicles have been designed so that they may not pass unless restarted, because the restart reinitiates injection of secondary air into the exhaust. Others have been designed so that they may not pass if they are restarted, because the restart triggers short durations of open-loop operation with fuel enrichment, coupled with characteristically low catalyst activity at idle. Other designs have required the vehicle to remain off for some number of seconds before air injection timers are reset. However, most vehicle designs are able to provide sufficient catalyst protection and idle quality without such timers, indicating that they are not a necessary component of current vehicle technology.

The objective of the keyoff provision is to protect the consumer from keyoff/restart designs that could result in pattern failures while providing little or no benefit to the manufacturer. Given the range of possible designs, however, it is not possible to specify a single keyoff protocol that would adequately

[33] Motor Vehicle Manufacturers Association of the United States, Inc., "National Fuel Surveys, Gasoline and Diesel Fuel, Winter 1990." Available in the public docket for review.

[34] See, for example, Illinois Environmental Protection Agency I/M Status Report memorandums (September 7, 1989–September 14, 1990); Graphics and data describing customer wait times for the Wisconsin Vehicle Inspection Program from Ed Hammer, Wisconsin Department of Transportation, to Mary Walsh, EPA, Office of Mobile Sources (January 29, 1991). Available in the docket for public review.

protect the consumer. For these reasons, the Agency is not defining a specific set of idle/keyoff actions with a defined wait time for all CST compliance testing, but has instead defined a range of wait times and a varying set of vehicle operations that EPA may employ. The Agency solicits comment on this provision.

The emissions impact of a restart varies depending on the control logic of the vehicle. Some vehicles show increased emissions because they enter timed open-loop operation following a restart; others show cleaner emissions because secondary air is routed to the catalyst for a timed interval following a restart. Clearly, the Agency could be expected to choose the wait time conditions in compliance testing that would be most likely to increase emissions and reveal a pattern failure in the particular design being tested.

8. Manufacturer Certification Data Submittal Requirements

In requiring manufacturers to submit certification CST data at only one point in the test envelope and for only one combination of two performance warranty tests, the Agency has reached two conclusions. The first is that vehicle designs that take into account likely worst-case conditions and eliminate the vehicle-based contributions to pattern failures under those conditions will also eliminate pattern failures under less extreme conditions. Second, if EPA has the authority to perform compliance testing throughout the test envelope, then manufacturers will address all relevant pattern failure types in their development testing and design decisions, not just the ones addressed by the chosen certification test point.

Since the combinations of conditions that are the worst case for a given vehicle design will depend on the pattern failure type that is most likely to occur with that vehicle, the Agency is proposing several combinations from which the manufacturer must choose for data submittal testing. Under the proposal, manufacturers will be required to select the set of conditions for CST testing of their EDVs that represents the worst case from among the three designated points in the test envelope.

For instance, a manufacturer might conclude that a vehicle design was most susceptible to purge-related pattern failures during 2500 rpm operation. These failures will occur more frequently when conditions favor vapor generation and accumulation—that is, high ambient temperature, high volatility fuel, and extended idle times on vehicles designed to purge only during off-idle operation. Since the highest ambient temperatures do not normally occur in conjunction with the highest volatility fuels, two worst-case "reasonably likely" combinations of these variables are possible—moderate ambient temperature with high-RVP fuel and high ambient temperature with low-RVP fuel. In the basic proposal for the test envelope presented in section II, these two combinations are proposed as the "moderate" and "hot" pathways of Figure 2. The moderate temperature option specifies an ambient temperature range of 70°F ± 5°F and a fuel RVP of 13.6 psi to 14.1 psi, while the hot temperature option specifies ambient temperatures of 90°F ± 5°F and a fuel of 8.5 psi to 9.0 psi.

In conjunction with fuel and temperature variables, long idle times contribute to the accumulation of vapor in the canister. Thus, to create the set of worst-case conditions reasonably expected to occur for purge pattern failure vehicles, the maximum wait time allowed by the statute—25–30 minutes—is proposed for manufacturer data submittal testing under warm temperature conditions. As noted previously, the alternative approach to the test envelope targets purge failures by replacing high-RVP fuel or high ambient temperature testing with an artificial canister loading procedure, allowing manufacturer certification testing to take place with normal FTP fuels and temperatures. The remaining purge-related variable, wait time, is again specified to be 25–30 minutes.

A manufacturer may conclude, however, that a certain vehicle design is more prone to pattern failure due to catalytic converter or oxygen sensor cooldown rather than to canister purge. Catalyst cooldown to below light-off temperature is likely to occur when mass flow through the catalyst is low. This is the case on vehicles with small displacement engines during extended idles; the problem is presumably exacerbated by low ambient temperatures. A likely worst case scenario for vehicles sensitive to this problem would be cold ambient temperatures and long I/M lane wait times; thus, the Agency is proposing a cold ambient temperature of 20±5°F, again coupled with the maximum allowable wait time of 25–30 minutes, as the cold temperature CST test option for manufacturers.

A third example illustrating the choice of worst-case conditions by the manufacturer would be pattern failures related to a vehicle restart. Although each of the manufacturer certification data submittal pathways requires use of 25 to 30 minute wait time modes, the manufacturer may select up to six restarts in this period. As pointed out in the above discussion of the CST wait time mode, restarts can either avoid or trigger higher emissions, and thus, the manufacturer may wish to pick the number of restarts and the duration of the keyoff times to reflect a worst-case situation for the given design.

The Agency is not proposing a specific enforcement mechanism for violations of the requirement that the manufacturer select the worst-case scenario from among the prescribed three alternatives. Comments are solicited on the ease with which the selection of the worst-case scenario may be achieved and how this factor may appropriately determine the Agency's enforcement response.

Although the proposed certification data submittal requirement is limited to testing under a single set of conditions as described above, each manufacturer may clearly see advantages in testing under different sets of conditions inside or outside the limits of the proposed test envelope. This additional testing will allow the manufacturer to ensure that the vehicle can pass confirmatory testing under the range of conditions that may be selected by the Agency, and can be as extensive or limited as each manufacturer sees fit.

9. "Inability To Test" Vehicles

The Agency proposes that all vehicles be required to be designed such that they are able to be tested on all six of the revised section 207(b) test procedures. An inability to perform the CST—caused, for instance, by a permanent four-wheel drive configuration that cannot be tested on an I/M dynamometer designed for two-wheel drive vehicles, or by a spark distribution system that will not allow engine speed to be measured in a standardized fashion—is proposed to result in the vehicle failing its certification requirements, and a certificate of conformity would be denied. This requirement is being proposed in order to prevent vehicles that cannot be I/M tested in the conventional manner from being introduced into commerce, thus relieving I/M programs from the responsibility of determining which models require specialized treatment and the form such treatment should take. Special consideration in the form of individualized test procedures or equipment or in the form of waivers of the I/M testing requirement itself would result in longer I/M lane queues and inequitable treatment of vehicles, and is therefore not desirable.

However, the Agency recognizes that vehicles that cannot be tested on certain I/M procedures may continue to enter the marketplace, and it does not wish to deny certification for such vehicles if advance provisions have been made to allow for alternative I/M test procedures. The Agency is proposing to not deny a certificate of conformity as a result of a vehicle's inability to be tested on the standard procedures if the manufacturer has petitioned for and been granted an alternative test procedure as provided in the performance warranty regulations. For example, in the case of permanent four-wheel drive vehicles, such an alternative could be the substitution of unloaded 2500 rpm operation for loaded steady-state operation. Such alternatives, however, must be arranged for each of the six performance warranty procedures on which the vehicle is unable to be tested in order for a certificate of conformity to be granted.

The Agency recognizes that vehicle manufacturers are moving away from vehicle designs that allow use of a conventional induction tachometer to determine engine speed. Such designs have made it difficult for I/M programs to obtain the engine speed readings needed to determine compliance with the rpm requirements of each test mode and thus advance the test through its steps. In order to allow such design innovations to occur while providing for a convenient method to measure engine speed, this proposal includes a requirement for each vehicle to include an electrical lead carrying an accessible engine rpm signal. One option to provide this signal takes advantage of the upcoming requirement that onboard diagnostic (OBD) system[35] be included on model year 1994 and later light-duty vehicles and light-duty trucks. The OBD systems will monitor the functioning of emission control systems and alert the vehicle operator when a fault is detected. Engine speed signals will be available over the standardized OBD connector with a standardized scan tool as part of the fault diagnosis procedure. However, manufacturers may be waived from meeting the full requirements of OBD for model years 1994 and 1995.

Therefore, it is proposed that those vehicles whose engine rpm signals cannot be read by either an OBD readout device or a conventional inductive tachometer be required to have an engine rpm signal available on a dedicated underhood lead with a standardized connector and signal. This would provide I/M programs with a standardized method to obtain the engine rpm signals necessary for performance of the I/M test. Vehicles not furnishing an engine rpm signal through one of these three methods would be considered unable to be tested, and thus would, under this proposal, be denied a certificate of conformity.

The Agency solicits comment on the ability of the alternative test procedure provision to allow design innovations while disallowing testing alternatives for pattern failure issues that would more appropriately be addressed through a design change.

10. Derivation of Standards

A vehicle's ability to pass an emissions test procedure is a function both of the procedure design and the applicable emission standards. For I/M testing in the field, the Agency is proposing improved performance warranty procedures and retention of the current performance warranty emission standards of 1.2 percent CO and 220 ppm HC. The purpose of the CST as prescribed by the Amendments and proposed in this rule is to determine whether properly maintained LDVs and LDTs, when tested in I/M with these standards and procedures, will pass under conditions reasonably likely to be encountered in the field.

An EDV that would fail the CST procedure at the performance warranty cutpoints would be expected to fail at the same cutpoints in actual I/M testing. That design is in all likelihood destined to be a pattern failure, and the statutory purpose of the CST is to prevent the vehicle from being certified. Thus, CST standards at least as stringent as the performance warranty cutpoints are clearly justified.

While the Agency has incorporated several field test conditions into the proposed CST procedure, an additional condition of I/M testing that must be accounted for in the selection of the CST standards is the fact that I/M vehicles are in-use vehicles. They have accumulated age and mileage, and thus, their emission systems are subject to deterioration. Similarly, CST recall test vehicles would be recruited directly from vehicle owners, and thus would be subject to deterioration. Utilizing the I/M cutpoints for CST recall testing is therefore appropriate. However, neither certification EDVs nor selective enforcement audit vehicles represent in-use vehicles. The EDVs are preproduction vehicles, and SEA vehicles are taken directly from the production line. The effects of age and mileage on such vehicles must be simulated.

This is one reason that emission data vehicles that register scores below the performance warranty cutpoints may also become pattern failures in actual I/M testing. Increases in I/M emissions due to deterioration might cause a vehicle to fail at the 207(b) cutpoints, where the undeteriorated vehicle with the pattern problem alone might pass those same cutpoints. The Agency believes the statutory intent would not be achieved, were such vehicles to be certified.

In addition, there may be significant variation within an engine family in the emissions increases caused by a given pattern emissions problem, even if the behavior of a single vehicle is reasonably repeatable. In the field, a 40 percent failure rate is high enough to be considered a serious pattern failure. If such a vehicle passed the CST during certification because the two test cars happened to fall in the 60 percent that could pass the performance warranty standards, yet tighter cutpoints would have flagged the problem, then again the procedure would not have performed its function.

Thus, EPA finds it appropriate to apply tighter standards to CST test results for certification or audit vehicles than are applied to recall test vehicles and to vehicles in actual I/M testing.

In developing this proposal, the Agency considered methods by which the contribution from I/M emissions deterioration might be accounted for. Conventional FTP certification procedures rely on a durability testing program to simulate the emissions effects of accumulated mileage. Under the durability regulations, the actual emission levels of low-mileage EDVs are multiplied by deterioration factors (DFs), and the results are compared to the appropriate emission standards to determine compliance. The DF quantifies the rate of change in the vehicle's emissions for a given pollutant as a function of mileage. The DF is derived through regression of emissions data obtained from a durability data vehicle (DDV) which undergoes emissions testing with the FTP at period mileage intervals. Mileage accumulation on DDVs is accomplished through use of a standardized durability driving cycle.

The Agency considered but rejected the idea of simulating the effects of age and mileage on certification and audit CST test vehicles through a similar process. Unlike the FTP, the CST test envelope includes a broad range of conditions of fuel, ambient temperature, and prior operation of the vehicle. The Agency has no reason to project that the DF that might be obtained from periodic testing of a DDV at one point in the test

[35] See 56 FR 48272 (September 24, 1991).

envelope should be the same as the DF derived from testing at another point. In theory, a large family of DF lines might be the appropriate descriptor of the mileage-related behavior of a vehicle on the CST. It would be unreasonable in the Agency's view to require manufacturers to generate DFs by incorporating the CST procedure in some or all of its permutations into the many periodic test points of a DDV's lifetime. In fact, addition of the CST at a single point in the test envelope over the course of DDV testing would constitute a significant cost, in the likely event that fuel switches and extended wait time modes were required. A far simpler approach has been proposed.

The Agency believes that the baseline performance of current vehicle designs on the performance warranty short tests yields emission scores far below the performance warranty cutpoints. This is so even without the improvements to the procedures proposed in this rule, and without reductions that might occur in pending model years owing to tighter tailpipe requirements like the Tier 1 standards. The current performance warranty standards are designed to capture gross emitters, the dirtiest of I/M vehicles, because these are the ones that will benefit the most from repair. Vehicle performance has also improved overall since the standards were established in 1980.

Supporting this contention is Agency analysis of 436 1983 through 1988 model year in-use vehicles from EPA's Emission Factors (EF).[36] The same database was used to develop the CST standards proposed in this notice. Vehicles in the EF sample receive a battery of the current performance warranty tests; the database provides emission scores for three idle sampling modes (one unpreconditioned, and the other two preconditioned with 30-second 2500 rpm modes) and two 2500 rpm sampling modes (one follows a restart; the other follows an idle mode).

For each vehicle in the EF subsample, the best scores of the three idles and the best scores of the two 2500 rpm modes were determined. Four ranked lists of the entire vehicle sample were created, one each for HC at idle, HC at 2500 rpm, CO at idle, and CO at 2500 rpm. An iterative process was pursued where first a set of possible emission standards was selected, the vehicles that exceeded the standards were identified from the ranked lists, and the proportion of failing vehicles was determined. Excluded from the list of failures were known pattern failures and vehicles with passing counterparts (manufacturer, vehicle type, displacement, fuel metering system, and feedback strategy) elsewhere in the ranked list. The chosen target was a set of emission standards where at least 95 percent of the vehicles in the sample could either pass the standards or had counterparts in the sample that could pass the standards. This target was achieved with the proposed standards of 50 ppm HC and 0.2 percent CO; at those levels, the iteration showed 97 percent compliance for HC and 98 percent compliance for CO.

The ability of current designs to achieve even lower levels was in strong evidence in the EF sample. If the compliance target was lowered to 90 percent, the iteration yielded standards at half the proposed levels. Sixty percent of the vehicles in the sample registered CO emission scores of 0.00% on at least one of the three idle modes in the EF testing protocol; 39 percent registered no detectable HC score on at least one idle mode.

Data from the Nevada I/M program also demonstrate the capability of current designs to routinely achieve I/M scores far below the performance warranty cutpoints.[37] In order to isolate vehicles with a low probability of owner-introduced malfunctions and to mimic the performance of low-mileage EDVs, data for 3278 model year 1989 vehicles, each with less than 10,000 accumulated miles, were analyzed. The average odometer reading for the group was of 6500 miles. The sample showed average HC and CO scores during idle of 23 ppm and 0.04%, respectively. Average scores in the sample were even lower for testing using the 2500 rpm mode. In addition, more than 68% of these vehicles achieved scores of 0.00% CO during idle and 2500 rpm modes, and about 30% achieved scores of 0 ppm HC during both modes.

EPA solicits comment on the level of standards proposed for certification, SEA, and recall testing. The Agency is particularly interested in information supporting claims that the levels of standards proposed would require technology changes on vehicles beyond those that are required to eliminate pattern failure behavior. If other standards are suggested, information supporting the ability of such standards to identify pattern failures is requested.

11. Alternative-Fueled Vehicles

Because no performance warranty regulations exist for dedicated alternative fuel vehicles, EPA is not proposing CST procedures for such vehicles at this time.

12. Recall Authority

The Agency believes that the appropriate response to a widespread failure of the CST standards performed by EPA on in-use vehicles would be to recall the failing vehicles. The CST standards as applied only in certification would partially accomplish Congress' intended goal of reducing the number of vehicles that, by design, both pass the traditional 202(a) standards as measured by the FTP and fail the 207(b) tests. However, to identify pattern failures throughout the range of reasonably likely field conditions, the CST, if performed only in certification, would need to utilize an unduly cumbersome battery of tests in an effort to simulate most of these potential situations arising during I/M testing. The interests of both the industry and the Agency would be served by foregoing this extensive array of certification procedures in favor of a recall program.

In addition, without recall liability, there would be no mechanism for collectively remedying I/M failures that occur in an identifiable class that does not fail the traditional 202 standards as measured by the FTP. If vehicles were not built to meet the CST standards in use and no mechanism existed to remedy widespread nonconformity with these standards in use, Congress' objective in enacting section 206(a)(4)—to eliminate pattern failures and the disaffection with I/M programs such failures breed—would not be achieved.

The Agency believes that section 202(a)(1) authorizes promulgation of the CST standards under that subsection since they are applicable to the emission of any air pollutant from any classes of new motor vehicles which contribute to air pollution which may reasonably be anticipated to endanger public health or welfare.[38] These standards do not increase the stringency of the existing 202(a) standards in the traditional sense of limiting emission levels as measured by the FTP, but rather restrict manufacturer design options in meeting

[36] Memorandum from Roberts French to Robert Maxwell, "Analysis of Potential CST Emission Standards Based on the EF Database," EPA, Office of Mobile Sources (November 22, 1991). Available in the public docket for review.

[37] Memorandum from Roberts French to Robert Maxwell, "Analysis of Low-Mileage I/M Performance of Late Model Vehicles in the Nevada I/M Program," EPA, Office of Mobile Sources (November 22, 1991). Available in the public docket for review.

[38] The Agency is aware of legislative history indicating that the certification short tests are not to be viewed as section 202 standards. See 136 Cong. Rec. H 12897 (daily ed. October 26, 1990) (statement of Rep. Bruce). The Agency does not believe this statement of a single legislator binds the Agency. See. e.g., *Chemical Manufacturers Association* v. *EPA*, 919 F. 2d 158, 164 n. 10 (D.C. Cir. 1990).

such standards by requiring conformance as measured both by the FTP and by I/M-type tests.

The CST standards, by improving public confidence in, and thus the effectiveness of, I/M programs, have the effect of controlling emissions that contribute to air pollution that has long been acknowledged as endangering public health or welfare, and the CST numerical limitations thus provide an air quality benefit in addition to that provided by the other 202(a) standards governing the same pollutants. This benefit will be derived from the increased effectiveness of I/M programs, which programs have been shown to significantly improve air quality.

Specifically, implementation of the CST standards, by improving the ability of vehicles to pass I/M procedures and thus reducing errors of commission in I/M lanes will, in turn, avoid consumer dissatisfaction and skepticism of I/M programs that pattern failures can cause. For any program requiring consumer cooperation to achieve its ends, consumer confidence in the integrity and efficacy of the program is essential, as greater public satisfaction can provide a political climate that will allow states and regions to select the more stringent I/M program options. In addition, consumer acceptance of the validity of a program will reduce the incentives for fraud. Finally, the Agency believes that reducing the number of errors of commission will have the effect of encouraging proper repair of vehicles identified as failures in I/M lanes, by making more accurate the assumption that an I/M failure indicates an FTP failure and that, therefore, a repair is necessary; an increase in the frequency of proper repairs will thereby reduce motor vehicle emissions overall. The CST standards and tests are important to gaining such public confidence and thereby improving the functioning of the state I/M programs.[39]

An additional basis for recalling vehicles that in significant numbers fail the CST during the in-use period arises directly from the statutory structure. Section 206(a)(4) requires that tests capable of determining whether in-use vehicles will pass section 207(b) I/M tests be added to the certification test procedures promulgated and applied under section 206(a). Section 206(a)(1) provides for test procedures that determine whether a vehicle conforms with the standards promulgated under section 202(a).

Section 207(c) authorizes the Administrator to recall vehicles if (s)he finds that a substantial number of any class or category of them fail to conform to section 202(a) standards in use. While pattern failure vehicles do not necessarily violate section 202(a) standards when measured by the FTP, they do by definition fail I/M tests and, in that sense, fail as in-use vehicles 202(a) standards as measured by the CST. As section 202 standards, failure of a significant number of vehicles to comply with these standards during the in-use period could trigger a recall pursuant to section 207(c)(1). In short, by requiring certification to include a new set of tests, Congress specified an additional way to measure compliance with 202(a) standards, and this new means of measuring the 202(a) standards is necessarily available for recall as well.

Recalling vehicles that fail the CST during the in-use period is also consistent with the Congressionally devised relationship between warranty liability and recall liability. Warranty liability under section 207(b) is triggered by failure of a federally approved I/M test during the in-use period. The manufacturer is charged with the task of remedying the nonconformity as measured by the I/M short tests. Therefore, warranty addresses essentially the recall and repair of vehicles on an individual basis. Alternatively, where the Agency discovers a systematic nonconformity in "substantial number(s)," the Agency may charge the manufacturer with the recall and repair of an entire class of vehicles as defined by the Administrator. Recall of vehicles failing the CST would permit vehicles to be identified and remedied as a group rather than on an individual basis. The Agency believes this would improve the cost effectiveness as well as the environmental benefit available from what had been an ad hoc solution to systematic I/M failures.

In conclusion, using the CST in recall testing serves the Congressional purpose of providing incentive to manufacturers to prevent I/M pattern failures from reaching the field by subjecting manufacturers to the significant deterrent effect of the recall remedy. In addition, using the CST in recall testing serves the interests of both the automotive industry and the Agency by avoiding the need to utilize an unduly cumbersome battery of tests at certification. Moreover, since the CST does not increase the stringency of current requirements but simply limits the design options available for vehicle control systems, the Agency does not anticipate that new control hardware will be needed to pass the CST but, rather, only recalibration of existing systems. Thus, it will be feasible to pass the CST at both certification and in use at low cost, thereby improving the ability of I/M programs to prompt proper repairs and their attendant air quality improvements. The legally available option of utilizing the CST in recall thus well serves the public interest and is consistent with Congressional intent by reducing the incidence of pattern failures in use.

13. Truck Idle Carbon Monoxide Procedure

Gasoline-fueled trucks are currently subject to testing for the control of carbon monoxide at vehicle idle under procedures set forth in subpart P of part 86. The applicable standard is contained in part 86, subpart A, § 86.091–9(a)(1)(ii)(B), and is expressed in terms of raw exhaust concentration.

The idle CO regulations were promulgated with the primary intent of reducing or eliminating CO "hot spots" created in areas where traffic is consistently in a stop and go or idle situation. These areas are believed by EPA to pose potential health problems due to the fact that they often occur in populated areas such as busy intersections and parking garages. The idle CO standard and testing procedures also serve the purpose of ensuring that idle CO emissions are not left behind while other gains in emission control are accomplished.

The 0.5 percent idle CO standard applies to both certification (the certification emission values must incorporate a deterioration factor) as well as to in-use testing. Thus, the standard is potentially more stringent than the CO standard for idle pass/fail modes in the CST, although differences in the test procedures that generate emission scores may overshadow the differences in the standards. The Agency is not proposing to delete the current idle CO standard as it applies to LDTs. However, EPA solicits comments on whether the CST proposal, if adopted as proposed here, would make the existing idle CO procedure unnecessary for light-duty trucks. In any case, it is

[39] The EPA does not, however, intend that the proposed certification test be considered to fulfill the requirements of amended section 206(h) of the Act, which requires the Agency to modify certification and production-line tests "to insure that vehicles are tested under circumstances which reflect actual current driving conditions * * *". The legislative history to the provision (as well as the provision's title) indicate that Congress intended for the Agency to amend the existing FTP to better reflect in-use driving conditions. The certification short test proposed today would be used in addition to the FTP. However, by testing in modes not presently used in the FTP, such as an idle mode, the certification short test is consistent with the goals of section 206(h). The Agency plans to develop the section 206(h) FTP amendments in a separate rulemaking.

not the Agency's intention to revisit the applicability of the idle CO procedure to heavy-duty trucks in this rulemaking.

14. Model Year of Applicability

In conformance with the Amendments, this proposal would require compliance with the Certification Short Test for the 1994 model year. However, leadtime constraints suggest that it would be impracticable for many manufacturers to assure compliance with all aspects of this proposal. At this time, most manufacturers have completed design and development work for the 1994 model year; in fact, some have initiated vehicle certification procedures. While manufacturers are generally aware which engine families are pattern failures and could have made compensating design changes, it is unlikely that all such changes would have been made in the absence of a final rule. In addition, lacking specific knowledge of the proposed test procedure, manufacturers could not have been assured that their designs were adequate.

Because of the possibility that compliance may not be feasible for all 1994 model year vehicles, the Agency requests comment on the practicalities of implementing the requirements of the Certification Short Test midway through the model year. Comment is also requested on the legal and practical implications of delaying the model year of applicability.

IV. Economic Impacts

A. Certification Short Test and Performance Warranty Proposals

The Agency's economic analysis of the CST rulemaking takes into account both the promulgation of the CST and the revisions to the 207(b) performance warranty test procedures as proposed. Because the two actions address different causes of the same symptom—vehicles improperly failing I/M tests—most of the costs can be clearly attributed to either the CST or the 207(b) revisions, while the benefits are difficult to separate between the two programs.

In addition, this proposal presents two different approaches to the envelope of CST test conditions (see section II.B). Some costs are equivalent regardless of the approach taken, but others can be separately attributed to one approach. For example, the alternative approach presented in section II.B.4 includes a canister loading procedure in the vehicle preparation pathway, but becomes identical to the basic approach following the loading of the canister. Because the two approaches are expected to be equally effective and accomplish the same result, however, the benefits are expected to be equivalent.

The Agency is also including several amendments of a technical nature in the proposal (see section II.G); the economic impacts of these amendments are also presented below. The detailed analysis of the economic impacts of this rulemaking summarized in this proposal is presented in full in a separate technical memorandum.[40]

This rulemaking is projected by EPA to have a net benefit of approximately $183 million. This projected benefit arises from the aggregate costs and benefits to the three affected parties—the automobile manufacturers, state I/M programs, and individual vehicle owners.

The total annual cost to the automotive industry is estimated to be approximately $3.7 million, or about $0.26 per production vehicle. These costs are incurred as a result of increased vehicle testing for pattern failure characteristics, implementation of minor design changes on vehicles exhibiting such characteristics, and certification of all engine families to the requirements of the CST.

Vehicle testing by manufacturers for pattern failure characteristics is likely to occur at several different points. First, manufacturers will perform development testing on their vehicles prior to conducting the actual certification tests. The Agency assumes that a basic vehicle design has a lifetime of approximately five model years; that is, manufacturers will recertify (usually through carryover) the same basic vehicle for four additional years past its initial certification. Manufacturers will need to verify CST compliance of each new engine family in the year that it is first certified. In the 1994 model year, when the CST first becomes effective, manufacturers will also need to verify CST compliance with the portions of their fleets that are in the middle of their product cycle and would normally have been carryover vehicles. Finally, the implementation of the Tier 1 emission standards on a phase-in basis beginning with the 1994 model year will affect the manufacturers introduction of new designs. Taking all these factors into account, EPA projects that an annual average of 146 engine families will be undergoing CST development testing at manufacturer facilities over the model years 1994 through 1999.

Manufacturers are also likely to verify continued compliance with the CST, at a reduced testing level, after each engine recalibration, which is assumed to take place annually. A similar confirmation of compliance might be desired after each emission-related running change. Finally, manufacturers will be required to perform tests and submit data for the purpose of certification testing.

The Agency has calculated a worst-case cost per CST test of $258 per vehicle and has projected that manufacturers will on average need to run six such tests on two vehicles each in order to verify compliance on an appropriate range within the CST test envelope. On the basis of these projections, the total cost of manufacturer testing is projected to be approximately $1.2 million annually for the entire industry.

In addition to testing impacts, there are associated costs of recalibrating and modifying engine families identified as potential pattern failure problems. The most likely modifications are adjustments to the Electronic Control Module (ECM) in order to address failures caused by inappropriate vehicle timer operation and purge control strategies. Based on historical experience with the frequency with which pattern failures occur, the Agency has estimated that this will involve approximately 15 engine families annually, at an annual cost to the industry of $247,000. Once the manufacturer's primary designs accommodate the CST and original designs do not incorporate the triggering elements, this cost should become negligible.

Manufacturers will also incur two other costs related to the CST requirement. First, there is an associated cost of producing, checking, and reporting to EPA the results of certification testing. The Agency has estimated that these requirements will increase industry costs by approximately $1.7 million annually. Second, some manufacturers and independent contractors will have to purchase one or more exhaust gas analyzer systems compatible with the specifications outlined in this Notice. Based upon an average cost of $10,000 per analyzer and the projected five-year lifetime of such an instrument, the maximum annual expenditure by manufacturers for new analyzers is projected to be approximately $500,000.

Although many state I/M programs already have equipment that is compatible with the proposed new I/M equipment regulations, others will be required to purchase new raw gas analyzers to meet the requirements of

[40] Technical Memorandum, "Economic Impact Analysis of Proposed Certification Short Test Regulations," U.S. Environmental Protection Agency, Certification Division, November 22, 1991. Available in the public docket for review.

the revisions to the 207(b) performance warranty procedures proposed in this Notice. However, the rule contains provisions to accomplish an orderly phase-in of this equipment to coincide with the normal turnover in the existing equipment. The Agency has estimated that these purchases will have an incremental cost over the normal analyzer replacement cost of up to $6.5 million annually.

The calculated benefits of the proposed regulations will be related to a reduction in the number of I/M-related repair attempts and I/M retests. These reductions will be caused both by improvements to the 207(b) performance warranty test procedures to ensure proper operation of the vehicle at the time of emission sampling, and by the addition of the CST to ensure a vehicle design compatible with the 207(b) procedures. The Agency estimates that nearly two million repair attempts will be avoided in this manner, at an average cost per repair visit of $75, for a total savings of $149 million. Most of these benefits will accrue to vehicle owners, although some portion will probably accrue to vehicle manufacturers because of reductions in warranty claims. The Agency currently lacks data that would allow the savings to be accurately divided among the recipients, although the net result remains the same, regardless of the beneficiaries.

State and local I/M programs stand to benefit from this proposal in a labor savings associated with the reduced volume of retests because of fewer errors of commission on the initial tests. The Agency projects that savings to be approximately $9.19 per test, on two million vehicles, or a total of $18.3 million. The combined effects in the proposed performance warranty regulations of the early-out provision for very clean vehicles and the reduced number of retests as a result of the second-chance provision for failing vehicles is a reduction in the mean test time per vehicle of approximately six percent, which will translate into reduced labor costs per test of $0.55, or a total of $26 million as a consequence of the rule.

Other benefits to the I/M programs are likely to result from this proposal; however, they are not quantified in this analysis. Program resources currently expended for identifying and resolving pattern failures will be greatly reduced or eliminated. Improved credibility for the I/M programs should result from greater confidence on the part of the owners and the repair sector in the results of the I/M tests. This improved credibility should translate into a reduced need for enforcement against owners who might seek to avoid I/M testing requirements and a greater focus by repair technicians on finding and remedying real emission-related malperformance.

The Agency notes that promulgation of the CST was mandated by the 1990 Amendments and thus, certain cost impacts of this rule are unavoidable. However, by combining the CST rule with improvements in the performance warranty procedures, EPA believes it has developed a proposal that improves the quality of the CST rule as well as the field procedures, while generating the potential for significant cost savings as well.

B. Technical Amendments

The economic impacts of the proposed technical amendments are expected to be negligible, with the exception of the proposal to change the frequency of the calibration of the NO_x converter from weekly to monthly. The process for this calibration currently takes about 75 minutes per check per converter. Reduction in the frequency of this check will reduce by 36 the number of checks performed on each analyzer in a year. If both manufacturer and EPA sites institute the change for all analyzers, the total savings will be approximately $525,000.

V. Public Participation

A. Comments

EPA welcomes comments on all aspects of this proposed rulemaking. Commenters are especially encouraged to provide suggestions for modification of any aspects of the proposal that they find objectionable. All comments, with the exception of proprietary information, should be directed to the EPA Air Docket LE–131, Attention: Docket No. A–91–21 (see **ADDRESSES** above).

Commenters desiring to submit proprietary information for consideration should clearly distinguish such information from other comments to the greatest possible extent and label it as "Confidential Business Information." Submissions containing such proprietary information should be sent directly to the contact person (see "For Further Information Contact"), and not to the public docket. This will help ensure that proprietary information is not inadvertently placed in the docket. If a commenter wants EPA to use a submission labeled as confidential business information as part of the basis for the final rule, then a nonconfidential version of the document which summarizes the key data or information should be placed in the public docket.

Information covered by a claim of confidentiality will be disclosed by EPA only to the extent allowed and by the procedures set forth in 40 CFR part 2. If no claim of confidentiality accompanies the submission when it is received by EPA, it may be made available to the public without further notice to the commenters.

B. Public Hearing

Any person desiring to testify at the public hearing (see "**DATES**") should notify the contact person listed above of such intent at least 7 days before the hearing date. Persons wishing to testify at the hearing should also provide an estimate of the time required for the presentation of the testimony and notification of any need for audio/visual equipment. It is suggested that sufficient copies of the statement or material to be presented be brought to the hearing for distribution to the audience (suggested number of 200). In addition, a sign-up sheet will be available at the registration table the morning of the hearing for scheduling of the order of testimony.

The official record of the hearing will be kept open for 30 days following the hearing to allow submission of rebuttal and supplementary testimony. All such submittals should be directed to the EPA Air Docket No. A–91–21 (see "**ADDRESSES**").

The hearing will be conducted informally, and technical rules of evidence will not apply. Written transcripts of the hearing will be made and a copy thereof placed in the docket. Anyone desiring to purchase a copy of the transcript should make individual arrangements with the court reporter recording the proceedings.

VI. Administrative Requirements

A. Administrative Designation and Regulatory Impact Analysis

Under Executive Order 12291, EPA has determined that this regulation is minor and does not, therefore, require the preparation of a Regulatory Impact Analysis.

This regulation was submitted to the Office of Management and Budget (OMB), for review as required by Executive Order 12291. The OMB completed its review on December 4, 1992, and returned the proposal to the EPA for reconsideration, asking that the Agency respond in accordance with sections 3(f) and 8(a) of Executive Order 12291. Accordingly, the Agency is publishing this proposal without final agreement with the OMB. OMB's written comments, including its

December 4, 1992 letter to the EPA, and any EPA response to those comments are in the public docket for this rulemaking.

B. Reporting and Recordkeeping Requirements

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 783.17) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC 20460 or by calling (202) 260–2740.

Public reporting burden for this collection of information is estimated to be an increase of 560 hours per response annually, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Chief, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC 20460 and to the Office of Information and Regulatory Affairs; Office of Management and Budget, Washington, DC 20503, and marked "Attention: Desk Officer for EPA." The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Impact on Small Entities

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Flexibility Analysis (RFA).

The Agency has determined that the regulations proposed today will not have a significant impact on a substantial number of small entities. This regulation will affect only manufacturers of motor vehicle engines, a group which does not contain a substantial number of small entities. Further, small motor vehicle manufacturers typically purchase emission control components developed by larger organizations.

Therefore, as required under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., I certify that this regulation does not have a significant impact on a substantial number of small entities.

VII. Statutory Authority

The promulgation of these regulations is authorized by sections 202, 203, 205, 206, 207, 208, 215, 216, and 301(a) of the Clean Air Act as amended by the Clean Air Act Amendments of 1990 [42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7549, 7550, and 7601(a)].

List of Subjects

40 CFR Part 85

Confidential business information, Imports, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements, Research, Warranties.

40 CFR Part 86

Administrative practice and procedure, Air pollution control, Confidential business information, Environmental protection, Gasoline, Imports, Incorporation by reference, Labeling, Motor vehicles, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: December 16, 1992.

William K. Reilly,

Administrator.

APPENDIX TO PREAMBLE.—TABLE OF CHANGES MADE TO VARIOUS SUBPARTS

Section	Change	Reason
1. Authority: Part 85	None.	
2. §85 1502	Redesignate paragraphs (5) through (15) as paragraphs (6) through (16) and add new paragraph (5).	Add definition for CST.
3. §85.1505	Revise paragraphs (a)(2)(ii), (a)(3), (a)(3)(i)(A), (a)(3)(ii)(A), (a)(3)(ii)(B), (a)(3)(v), (a)(3)(vi), (a)(5), (b).	Incorporate CST as condition required for certificate approval for imported vehicles.
4. §85.1507	Revise (a)(5)	Certificate holder must maintain documents demonstrating that each vehicle was CST tested.
5. §85.1508	Revise (a)	Generalize paragraph so as to include CST.
6. §85.1509	Revise (g)(2), (g)(3), (g)(4), (h), (k)(2)	Incorporate CST as a requirement.
7. §85.1513	Revise (e)(1), (e)(2)(i), (e)(3)(ii)(B)	Adds CST as requirement for certificate.
8. Subpart W Table of Contents	Revise	Revise to include CST standards and procedures.
9. §85.2201	Replace paragraph (b) and add new paragraph (c)	Paragraph (b) states that certain test procedures may have calendar and model year applicability limitations; paragraph (c) describes some of those limitations.
10. §85.2203	Redesignate §85.2203–81 as §85.2203, revise paragraph (a), add new paragraph (b).	State standards for light-duty vehicles for different test procedures.
11. §85.2204	Redesignate §85.2204–81 as §85.2204, revise paragraph (a), add new paragraph (b).	State standards for light-duty trucks for different test procedures.
12. §85.2208	Redesignate paragraph (c) as (c)(1), add new paragraph (c)(2).	Limits model year applicability for alternative short test procedures or standards.
13. §85.2209	Rename and redesignate paragraphs (a) and (b) as (b) and (c), add new paragraph (a), revise (c)(6).	Add calendar and model year applicability information for the 2500rpm/idle test.
14. §85.2210	Rename and redesignate paragraphs (a) and (b) as (b) and (c), add new paragraph (a), revise paragraph (c)(7).	Add calendar and model year applicability information for the Engine restart 2500rpm/idle test.
15. §85.2211	Rename and redesignate paragraphs (a) and (b) as (b) and (c), add new paragraph (a).	Add calendar and model year applicability information for the Engine restart idle test.
16. §85.2212	Rename and redesignate paragraphs (a) and (b) as (b) and (c), add new paragraph (a).	Add calendar and model year applicability information for the idle test.
17. §85.2213	§85.2213 is redesignated as §85.2214, and a new §85.2213 is added.	New section called "Idle test-EPA 91" describes new test procedure.
18. §85.2214	Redesignate §85.2214 as §85.2216, and redesignate paragraphs (a) through (c) as (b) through (d), add new paragraph (a), revise paragraphs (c)(4), (c)(5), and (c)(6) of the newly designated §85.2214.	Section renamed "Two speed idle test—EPA 81", add information on applicability.
19. §85.2215	§85.2215 is redesignated as §85.2224 and a new §85.2215 is added.	New section called "Two speed idle test—EPA 91" describes new test procedure.

APPENDIX TO PREAMBLE.—TABLE OF CHANGES MADE TO VARIOUS SUBPARTS—Continued

Section	Change	Reason
20. §85.2216	Redesignate §85.2216 as §85.2229 and redesignate paragraphs (a) through (c) as (b) through (d), add new paragraph (a), and revise paragraphs (c)(6) and (c)(7) of the newly designated §85.2214.	Section renamed "Loaded test—EPA 81", add information on applicability.
21. §85.2217	§85.2217 is redesignated as §85.2232 and a new §85.2217 is added.	New section called "Loaded test—EPA 91" describes new test procedure.
22. §85.2218	§85.2218 is redesignated as §85.2237 and a new §85.2218 is added.	New section called "Preconditioned idle test—EPA 91" describes new test procedure.
23. §85.2219	New section	New section called "Idle test with loaded preconditioning—EPA 91" describes new test procedure.
24. §85.2220	New section	New section called "Preconditioned two speed idle test—EPA 91" describes new test procedure.
25. §85.2224	Redesignate paragraphs (a) through (c) as (b) through (d), add new paragraph (a) to the newly designated §85.2224.	Section renamed "Exhaust analysis system—EPA 81", add information on applicability.
26. §85.2225	New section added	New section called "Steady state exhaust analysis system—EPA 91" describes new test procedure.
27. §85.2229	Redesignate paragraphs (a) through (b) as (b) through (c), add new paragraph (a) to the newly designated §85.2229.	Section renamed "Dynamometer—EPA 81", add information on applicability.
28. §85.2230	New section added	New section called "Steady state test dynamometer—EPA 91" describes dynamometer requirements.
29. §85.2232	Redesignate paragraphs (a) through (e) as (b) through (f), add new paragraph (a), and revise paragraph (f)(1) of the newly designated §85.2232.	Section renamed "Calibrations, adjustments—EPA 81", add information on applicability and gas span check requirements.
30. §85.2233	New section added	New section called "Steady state test equipment calibrations, adjustments—EPA 91" describes required checks and calibration procedures.
31. §85.2237	Renumber §85.2218, rename, redesignate paragraphs (a) through (c) as (b) through (d), add new paragraph (a).	Section renamed "Test report—EPA 81", add information on applicability.
32. §85.2238	New section added	New section called "Test report—EPA 91" describes required contents of test report.
33. Authority: Part 86	None.	
34. §96.094–2	Add definition of Certification Short Test	Add new abbreviations.
35. §86.094–3	Revise paragraph (b)	Include CST emissions standards.
36. §86.094–8	Add new paragraphs (a)(1)(iii) and (a)(3)	Include CST emissions standards.
37. §86.094–9	Add new paragraphs (a)(1)(v) and (a)(3)	Add selection of vehicles for CST exhaust emission compliance testing.
38. §86.094–24	Add new paragraph (b)(1)(xii)	Add selection of vehicles for CST exhaust emission compliance testing.
39. §86.095–24	Add new paragraph (b)(1)(xii)	Include CST emissions standards.
40. §86.096–8	Add new paragraphs (a)(1)(iii) and (a)(3)	Include CST emissions standards.
41. §86.097–9	Add new paragraphs (a)(1)(iv) and (a)(3)	Change the "check the oxides of nitrogen converter efficiency" requirement from weekly to monthly.
42. §86.116–90	Add new paragraph (c)(5), remove and reserve (d)(1) ...	Change the check of oxides of nitrogen analyzer from weekly to monthly.
43. §86.123–78	Revise paragraph (a)	Change some of the information required to be recorded for each test.
44. §86.142–90	Revise paragraphs (d), (e), (f), and (o), replace paragraphs (g), (h), (i), (k), (l), (m), (p), remove and reserve paragraphs (q) and (r).	Add "-fueled" after the word Diesel.
45. Subpart D	Revise heading	Change the check of NOx converter efficiency from weekly to at least monthly.
46. §86.319–79	Revise paragraph (b)	Change the check of NOx converter efficiency from weekly to at least monthly.
47. §86.332–79	Revise paragraph (a), remove and reserve paragraphs (d) and (e).	Change the check of NOx converter efficiency from weekly to at least monthly.
48. §86.516–90	Add new paragraph (c)(3), remove and reserve paragraph (d)(1).	Change the check of NOx converter efficiency from weekly to at least monthly.
49. §86.523–78	Revise paragraph (a)	Include CST as a test procedure.
50. §86.608–80	Revise paragraphs (a), (a)(1), (a)(3)(iii)	Describes calculation and reporting of test results for CST.
51. §86.609–94	Add new section	Incorporate CST into criteria for Selective Enforcement Audit.
52. §86.610–94	New section	Include CST standards.
53. §86.708–94	Add new paragraphs (a)(1)(iii) and (a)(3)	Include CST standards.
54. §86.708–98	Add new paragraphs (a)(1)(iii) and (a)(3)	Include CST standards.
55. §86.709–94	Add new paragraphs (a)(1)(v) and (a)(3)	Include CST standards.
56. §86.709–99	Add new paragraphs (a)(1)(iv) and (a)(3)	Include CST procedures.
57. §86.1008–94	Revise paragraph (a)(2), add paragraphs (a)(4), (a)(6), and (g)(3).	Include CST procedure in description of calculating and reporting.
58. §86.1009–94	Revise paragraphs (a) and (b) redesignate (c)(3) as (c)(4), add paragraph (c)(3).	Incorporate CST into criteria for Selective Enforcement Audits.
59. §86.1010–94	New section	Change check of oxides of nitrogen converter efficiency from weekly to at least monthly.
60. §86.1316–90	Add paragraphs (b)(3), remove and reserve paragraph (c)(1).	

APPENDIX TO PREAMBLE.—TABLE OF CHANGES MADE TO VARIOUS SUBPARTS—Continued

Section	Change	Reason
61. §86.1323–84	Revise paragraph (a)	Change check of oxides of nitrogen converter efficiency from weekly to at least monthly.
62. Subpart O	New subpart	Add new subpart, "Subpart O—Emission Regulations for New Gasoline-Fueled Otto-cycle Light-Duty Vehicles and New Gasoline-Fueled Otto-cycle Light-Duty Trucks; Certification Short Test Procedures".

For the reasons set out in the preamble, parts 85 and 86 of title 40 of the Code of Federal Regulations are proposed to be amended as follows:

PART 85—CONTROL OF AIR POLLUTION FROM MOTOR VEHICLES AND MOTOR VEHICLE ENGINES

1. The authority citation for part 85 continues to read as follows:

Authority: Secs. 202, 203, 205, 206, 207, 208, 212, and 301(a), Clean Air Act as amended; 42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7546, and 7601(a), unless otherwise noted.

Subpart P—[Amended]

2. Section 85.1502 is proposed to be amended by redesignating paragraphs (5) through (15) as paragraphs (6) through (16) and adding a new paragraph (5) to read:

§ 85.1502 Definitions.

* * * * *

(5) *CST.* The Certification Short Test procedure at part 86.

* * * * *

3. Section 85.1505 is proposed to be amended by revising paragraphs (a)(2)(ii), (a)(3) introductory text, (a)(3)(i) introductory text and (A), (a)(3)(ii)(A), (a)(3)(ii)(B), (a)(3)(v), (a)(3)(vi), (a)(5), and (b) to read as follows:

§ 85.1505 Final admission of certified vehicles.

(a) * * *

(2) * * *

(ii) Through an attestation by the certificate holder that the vehicle or engine has been modified in accordance with the provisions of the certificate holder's certificate of conformity and that the certificate holder has conducted an FTP test and, if a vehicle, a CST, at a laboratory within the United States, that demonstrates compliance with Federal emission requirements on every third vehicle or third engine imported under that certificate within 120 days of entry, with sequencing of the tests to be determined by the date of importation of each vehicle or engine. Should the certificate holder have exceeded a threshold of 300 vehicles or engines imported under the certificate without adjustments or other changes in accordance with paragraph (a)(3) of this section, the amount of required FTP and/or CST testing may be reduced to every fifth vehicle or engine. The Administrator may select and prescribe the sequence of the individual test procedures comprising the CST. In order to make a demonstration under paragraph (a)(2)(i) of this section, a certificate holder must have received permission from the Administrator to do so;

(3) The results of every FTP test and CST which the certificate holder conducted on the vehicle or engine. Should a subject vehicle or engine have failed an FTP and/or a CST at any time, the following procedures are applicable:

(i) The certificate holder may either:

(A) Conduct a retest in accordance with the test procedure that the vehicle or engine failed with no adjustment of the vehicle or engine from the previous test (e.g., adjusting the RPM, timing, air-to-fuel ratio, etc.) other than adjustments to adjustable parameters that, upon inspection, were found to be out of tolerance. When such adjustments are made, the parameter may be reset only to the specified (i.e., nominal) value (and not any other value within the tolerance band). If the allowable adjustments above are performed on a vehicle, conduct a retest in accordance with the test procedure that the vehicle did not fail also; or

* * * * *

(ii) * * *

(A) Such retests must be completed no later than five working days subsequent to the first applicable FTP test or CST;

(B) Should the subject vehicle or engine fail the second FTP and/or CST, then the certificate holder must initiate a change in production (a running change) under the provisions of § 86.084–14(c)(13) of this chapter that causes the vehicle to meet Federal emission requirements.

* * * * *

(v) Commencing with the first vehicle or engine receiving the running change, every third vehicle or engine imported under the certificate must be FTP tested and, if a vehicle, CST tested to demonstrate compliance with Federal emission requirements until, as in paragraph (a)(2)(ii) of this section, a threshold of 300 vehicles or engines imported under the certificate is exceeded, at which time the amount of required FTP and/or CST testing may be reduced to every fifth vehicle or engine.

(vi) Reports concerning these running changes shall be made to both the Manufacturers Operations and Certification Divisions of EPA within ten working days of initiation of the running change. The cause of any failure of an FTP and/or a CST shall be identified, if known;

* * * * *

(5) The required CST results and/or the FTP results, adjusted by the deterioration factor, if applicable;

* * * * *

(b) EPA approval for final admission of a vehicle or engine under this section shall be presumed not to have been granted if a vehicle or engine has not been properly modified to be in conformity in all material respects with the description in the application for certification or has not complied with the provisions of paragraph (a)(2) of this section, or if its final FTP results, or in the case of a vehicle, its final CST results, adjusted by the deterioration factor (if applicable) do not comply with applicable emission standards.

* * * * *

4. Section 85.1507 is proposed to be amended by revising paragraph (a)(5) to read as follows:

§ 85.1507 Maintenance of certificate holder's records.

(a) * * *

(5) Documents demonstrating that, where appropriate, each vehicle or engine was emissions tested in accordance with the Federal Test Procedure and, if a vehicle, the CST;

* * * * *

5. Section 85.1508 is proposed to be amended by revising paragraph (a) to read as follows:

§ 85.1508 "In Use" inspections and recall requirements.

(a) Vehicles or engines which have been imported, modified and/or tested by a certificate holder pursuant to § 85.1505 or § 85.1509 may be inspected and emission tested by EPA throughout

the useful lives of the vehicles or engines.

* * * * *

6. Section 85.1509 is proposed to be amended by revising paragraphs (g)(2), (g)(3), (g)(4), (h), and (k)(2) to read as follows:

§ 85.1509 Final admission of modification and test vehicles.

* * * * *

(g) * * *

(2) An attestation by the certificate holder that the vehicle or engine has been modified and/emission tested in accordance with the FTP and, if a vehicle, the CST at a laboratory within the United States. The Administrator may select and prescribe the sequence of any CSTs;

(3) The results of any required FTP and/or CST;

(4) The applicable deterioration factor assigned by EPA;

* * * * *

(h) EPA approval for final admission of a vehicle or engine under this section shall be presumed not to have been granted if its final FTP results and, if a vehicle, its final CST results, adjusted by the deterioration factor, if applicable, do not comply with applicable emission standards.

* * * * *

(k) * * *

(2) Individual vehicles or engines which fail an FTP and/or a CST retest or inspection must be repaired and retested to demonstrate compliance with emission requirements before final admission. If no adjustments are made to the vehicles prior to the subject retest, the certificate holder is only required to retest in accordance with the test procedure(s) that the vehicle failed earlier.

* * * * *

7. Section 85.1513 is proposed to be amended by revising paragraphs (e)(1) introductory text, (e)(2)(i), and (e)(3)(ii)(B) to read as follows:

§ 85.1513 Prohibited acts; penalties.

* * * * *

(e)(1) A certificate holder whose vehicles or engines imported under § 85.1505 or § 85.1509 fail to conform to Federal emission requirements after modification and/or testing under the Federal Test Procedure (FTP) and/or the Certification Short Test (CST) or who fails to comply with applicable provisions of this subpart, may in addition to any other applicable sanctions and penalties be subject to any, or all, of the following sanctions;

* * * * *

(2) * * *

(i) Action or inaction by the certificate holder or the laboratory performing the FTP and/or the CST on behalf of the certificate holder which results in fraudulent, deceitful or grossly inaccurate representation of any fact or condition which affects a vehicle's or engine's eligibility for admission to the U.S. under this subpart;

* * * * *

(3) * * *

(ii) * * *

(B) Demonstrate that the vehicles or engines do in fact comply with applicable regulations in this chapter by retesting such vehicles or engines in accordance with the FTP and, if vehicles, the CST. If no adjustments are made to the vehicles prior to the retest, the certificate holder is only required to retest in accordance with the test procedure(s) that the vehicles failed earlier.

* * * * *

8. The table of contents of subpart W is revised to read as follows:

Subpart W—Emission Control System Performance Warranty Short Tests

Sec.
85.2201 Applicability.
85.2202 General provisions.
85.2203 Short test standards for 1981 and later model year light-duty vehicles.
85.2204 Short test standards for 1981 and later model year light-duty trucks.
85.2205 through § 85.2207 [Reserved]
85.2208 Alternative standards and procedures.
85.2209 2500 rpm/idle test—EPA 81.
85.2210 Engine restart 2500 rpm/idle test—EPA 81.
85.2211 Engine restart idle test—EPA 81.
85.2212 Idle test—EPA 81.
85.2213 Idle test—EPA 91.
85.2214 Two Speed Idle test—EPA 81.
85.2215 Two Speed Idle test—EPA 91.
85.2216 Loaded test—EPA 81.
85.2217 Loaded test—EPA 91.
85.2218 Preconditioned idle test—EPA 91.
85.2219 Idle test with loaded preconditioning—EPA 91.
85.2220 Preconditioned two speed idle test—EPA 91.
85.2221 through § 85.2223 [Reserved].
85.2224 Exhaust analysis system—EPA 81.
85.2225 Steady state test exhaust analysis system—EPA 91.
85.2226 through § 85.2228 [Reserved].
85.2229 Dynamometer—EPA 81.
85.2230 Steady state test dynamometer—EPA 91.
85.2231 [Reserved].
85.2232 Calibrations, adjustments—EPA 81.
85.2233 Steady state test equipment calibrations, adjustments—EPA 91.
85.2234 through § 85.2236 [Reserved].
85.2237 Test report—EPA 81.
85.2238 Test report—EPA 91.

9. Section 85.2201 is proposed to be amended by revising paragraph (b) and adding a new paragraph (c) to read as follows:

§ 85.2201 Applicability.

* * * * *

(b) *Calendar and model year limitations.* Certain test procedures contained in this subpart are subject to calendar and model year limitations. Otherwise, unless specifically indicated, the provisions of this subpart may be used to establish warranty eligibility for any 1981 and later model year light-duty vehicle and light-duty truck when tested during its useful life as prescribed under the Emissions Performance Warranty, in subpart V of this part.

(c) *Special recommendations for Ford Motor Company and Honda Prelude vehicles.* Due to unique emission control systems, 1981 through 1986 model year vehicles manufactured by Ford Motor Company and 1984 through 1985 model year Honda Preludes should be tested with procedures that either incorporate a special engine restart feature or utilize a dynamometer to simulate a road load. The Agency has included short tests with the special engine restart feature in this subpart even though these vehicles are no longer eligible for the Emissions Performance Warranty, to ensure they are properly tested by State or other I/M authorities. Short tests incorporating the restart feature are the Engine Restart 2500 rpm/Idle Test—EPA 81 (§ 85.2210), Engine Restart Idle Test—EPA 81 (§ 85.2211), Idle Test—EPA 91 (§ 85.2213), Two Speed Idle Test—EPA 91 (§ 85.2215), Preconditioned Idle Test—EPA 91 (§ 85.2218). Idle Test with Loaded Preconditioning—EPA 91 (§ 85.2219), and Preconditioned Two Speed Idle Test—EPA 91 (§ 85.2220). Short tests utilizinq a dynamometer are the Loaded Test—EPA 81 (§ 85.2214) and Loaded Test—EPA 91 (§ 85.2217). This recommendation does not apply to tests conducted at altitudes above 4000 feet. Any of the short test procedures may be used for other vehicles which are similarly no longer eligible for performance warranty coverage.

10. Section § 85.2203–81 is proposed to be redesignated as § 85.2203 and revised to read as follows:

§ 85.2203 Short test standards for 1981 and later model year light-duty vehicles.

(a) For light-duty vehicles for which the test procedures described in §§ 85.2209, 85.2210, 85.2211, 85.2212, 85.2214, or 85.2216 are used to establish Emissions Performance Warranty eligibility (i.e., 1981 and later model year light-duty vehicles at low altitude and 1982 and later model year vehicles at high altitude to which high altitude

certification standards of 1.5 g/mile HC and 15 g/mile CO or less apply), short test emissions shall not exceed:

(1) 2500 rpm/idle test—EPA 81, high-speed mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(2) 2500 rpm/idle test—EPA 81, idle mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(3) Engine restart 2500 rpm/idle test—EPA 81, highspeed mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(4) Engine restart 2500 rpm/idle test—EPA 81, idle mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(5) Engine restart idle test—EPA 81.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(6) Idle test—EPA 81.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(7) Two speed idle test—EPA 81, idle mode. The lowest readings from the two idle modes shall be used to determine compliance.

(i) Hydrocarbons: 200 ppm as hexane.

(ii) Carbon monoxide: 1.0%.

(8) Two speed idle test—EPA 81, high-speed mode.

(i) Hydrocarbons: 200 ppm as hexane.

(ii) Carbon monoxide: 1.0%.

(9) Loaded test—EPA 81, idle mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(10) Loaded test—EPA 81, loaded mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(b) For 1981 and later model year light-duty vehicles for which any of the test procedures described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 are utilized to establish Emissions Performance Warranty eligibility (i.e., 1981 and later model year light-duty vehicles at low altitude and 1982 and later model year vehicles at high altitude to which high altitude certification standards of 1.5 g/mile HC and 15 g/mile CO or less apply), short test emissions for all tests and test modes shall not exceed:

(1) Hydrocarbons: 220 ppm as hexane.

(2) Carbon monoxide: 1.2%.

11. Section 85.2204–81 is proposed to be redesignated as § 85.2204 and revised to read as follows:

§ 85.2204 Short test standards for 1981 and later model year light-duty trucks.

(a) For light-duty trucks for which the test procedures described in §§ 85.2209, 85.2210, 85.2211, 85.2212, 85.2214, or 85.2216 are used to establish Emissions Performance Warranty eligibility (i.e., 1981 and later model year light-duty trucks at low altitude and 1982 and later model year trucks at high altitude to which high altitude certification standards of 2.0 g/mile HC and 26 g/mile CO or less apply), short test emissions shall not exceed:

(1) 2500 rpm/idle test—EPA 81, high-speed mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(2) 2500 rpm/idle test—EPA 81, idle mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(3) Engine restart 2500 rpm/idle test—EPA 81, highspeed mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(4) Engine restart 2500 rpm/idle test—EPA 81, idle mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(5) Engine restart idle test—EPA 81.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(6) Idle test—EPA 81.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(7) Two speed idle test—EPA 81, idle mode. The lowest readings from the two idle modes shall be used to determine compliance.

(i) Hydrocarbons: 200 ppm as hexane.

(ii) Carbon monoxide: 1.0%.

(8) Two speed idle test—EPA 81, high-speed mode.

(i) Hydrocarbons: 200 ppm as hexane.

(ii) Carbon monoxide: 1.0%.

(9) Loaded test—EPA 81, idle mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(10) Loaded test—EPA 81, loaded mode.

(i) Hydrocarbons: 220 ppm as hexane.

(ii) Carbon monoxide: 1.2%.

(b) For 1981 and later model year light-duty trucks for which any of the test procedures described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 are utilized to establish Emissions Performance Warranty eligibility (i.e., 1981 and later model year light-duty trucks at low altitude and 1982 and later model year trucks at high altitude to which high altitude certification standards of 2.0 g/mile HC and 26 g/mile CO or less apply), short test emissions for all tests and test modes shall not exceed:

(1) Hydrocarbons: 220 ppm as hexane.

(2) Carbon monoxide: 1.2%.

12. Section 85.2208 is proposed to be amended by redesignating paragraph (c) as (c)(1), and adding a new paragraph (c)(2) to read as follows:

§ 85.2208 Alternative standards and procedures.

* * * * *

(c) (1) * * *

(2) *Model year applicability.* The State or I/M authority allowance for an alternative short test standard or short test procedure as specified in paragraph (c)(1) of this section shall be restricted to 1993 and earlier model year vehicles or engines.

13. The section heading for § 85.2209 is proposed to be revised as set forth below and the section is amended by redesignating paragraphs (a) and (b) as (b) and (c), adding a new paragraph (a), and revising newly designated (c)(6) to read as follows:

§ 85.2209 2500 rpm/idle test—EPA 81.

(a) *General calendar year applicability.* (1) The test procedure described in this section may be used to establish Emissions Performance Warranty eligibility through December 31, 1993, except as allowed in paragraph (a)(2) of this section.

(2) *Special calendar and model year applicability.* (i) For 1993 and earlier model year vehicles or engines, the test procedure described in this section may be used to establish Emissions Performance Warranty eligibility in a State for which the Administrator has approved a State Implementation Plan revision providing for the implementation no later than December 31, 1995 of any test procedure contained in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 as part of an expeditious transition to more sophisticated inspection equipment or a high-volume test only inspection network.

(ii) The extended applicability described in paragraph (a)(2)(i) of this section shall be restricted to 1993 and earlier model year vehicles or engines.

* * * * *

(c) * * *

(6) For vehicles with multiple exhaust pipes, the separate results from each pipe for each mode (as specified in paragraphs (c)(4) and (c)(5) of this section) shall be numerically averaged for each pollutant, unless hardware which is capable of simultaneously sampling multiple exhaust pipes has been used.

* * * * *

14. The section heading for § 85.2210 is proposed to be revised as set forth below and the section is amended by redesignating paragraphs (a) and (b) as (b) and (c), adding a new paragraph (a), and revising newly designated (c)(7) to read as follows:

§ 85.2210 Engine restart 2500 rpm/idle test—EPA 81.

(a) *General calendar year applicability.* (1) The test procedure

described in this section may be used to establish Emissions Performance Warranty eligibility through December 31, 1993, except as allowed in paragraph (a)(2) of this section.

(2) *Special calendar and model year applicability.* (i) For 1993 and earlier model year vehicles or engines, the test procedure described in this section may be used to establish Emissions Performance Warranty eligibility in a State for which the Administrator has approved a State Implementation Plan revision providing for the implementation no later than December 31, 1995 of any test procedure contained in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 as part of an expeditious transition to more sophisticated inspection equipment or a high-volume test only inspection network.

(ii) The extended applicability described in paragraph (a)(2)(i) of this section shall be restricted to 1993 and earlier model year vehicles or engines.

* * * * *

(c) * * *

(7) For vehicles with multiple exhaust pipes, the separate results from each pipe for each mode (as specified in paragraphs (c)(5) and (c)(6) of this section) shall be numerically averaged for each pollutant, unless hardware which is capable of simultaneously sampling multiple exhaust pipes has been used.

* * * * *

15. The section heading for § 85.2211 is proposed to be revised as set forth below and the section is amended by redesignating paragraphs (a) and (b) as (b) and (c), and adding a new paragraph (a) to read as follows:

§ 85.2211 Engine restart idle test—EPA 81.

(a) *General calendar year applicability.* (1) The test procedure described in this section may be used to establish Emissions Performance Warranty eligibility through December 31, 1993, except as allowed in paragraph (a)(2) of this section.

(2) *Special calendar and model year applicability.* (i) For 1993 and earlier model year vehicles or engines, the test procedure described in this section may be used to establish Emissions Performance Warranty eligibility in a State for which the Administrator has approved a State Implementation Plan revision providing for the implementation no later than December 31, 1995 of any test procedure contained in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 as part of an expeditious transition to more sophisticated inspection equipment or a high-volume test only inspection network.

(ii) The extended applicability described in paragraph (a)(2)(i) of this section shall be restricted to 1993 and model year vehicles or engines.

* * * * *

16. The section heading for § 85.2212 is proposed to be revised as set forth below and the section is amended by redesignating paragraphs (a) and (b) as (b) and (c), and adding a new paragraph (a) to read as follows:

§ 85.2212 Idle test—EPA 81.

(a) *General calendar year applicability.* (1) The test procedure described in this section may be used to establish Emissions Performance Warranty eligibility through December 31, 1993, except as allowed in paragraph (a)(2) of this section.

(2) *Special calendar and model year applicability.* (i) For 1993 and earlier model year vehicles or engines, the test procedure described in this section may be used to establish Emissions Performance Warranty eligibility in a State for which the Administrator has approved a State Implementation Plan revision providing for implementation no later than December 31, 1995 of any test procedure contained in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 as part of an expeditious transition to more sophisticated inspection equipment or a high-volume test only inspection network.

(ii) The extended applicability described in paragraph (a)(2)(i) of this section shall be restricted to 1993 and earlier model year vehicles or engines.

* * * * *

16a. The following sections in subpart W are redesignated as set forth in the table below.

Old section	New section
85.2213	85.2214
85.2214	85.2216
85.2215	85.2224
85.2216	85.2229
85.2217	85.2232
85.2218	85.2237

17. A new § 85.2213 is proposed to be added to read as follows:

§ 85.2213 Idle test—EPA 91.

(a) *General requirements*—(1) *Exhaust gas sampling algorithm.* The analysis of exhaust gas concentrations shall begin 10 seconds after the applicable test mode begins. Exhaust gas concentrations shall be analyzed at a minimum rate of two times per second. The measured value for pass/fail determinations shall be a simple running average of the measurements taken over five seconds.

(2) *Pass/fail determination.* A pass or fail determination shall be made for each applicable test mode based on a comparison of the short test standards contained in §§ 85.2203 and 85.2204, and the measured value for HC and CO as described in paragraph (a)(1) of this section. A vehicle shall pass the test mode if any pair of simultaneous measured values for HC and CO are below or equal to the applicable short test standards. A vehicle shall fail the test mode if the values for either HC or CO, or both, in all simultaneous pairs of values are above the applicable standards.

(3) *Void test conditions.* The test shall immediately end and any exhaust gas measurements shall be voided if the measured concentration of CO plus CO_2 falls below six percent or the vehicle's engine stalls at any time during the test sequence.

(4) *Multiple exhaust pipes.* Exhaust gas concentrations from vehicle engines equipped with multiple exhaust pipes shall be sampled simultaneously.

(5) The test shall be immediately terminated upon reaching the overall maximum test time.

(b) *Test sequence.* (1) The test sequence shall consist of a first-chance test and a second-chance test as follows:

(i) The first-chance test, as described under paragraph (c) of this section, shall consist of an idle mode.

(ii) The second-chance test as described under paragraph (d) of this section shall be performed only if the vehicle fails the first-chance test.

(2) The test sequence shall begin only after the following requirements are met:

(i) The vehicle shall be tested in as-received condition with the transmission in neutral or park and all accessories turned off. The engine shall be at normal operating temperature (as indicated by a temperature gauge, temperature lamp, touch test on the radiator hose, or other visual observation for overheating).

(ii) The tachometer shall be attached to the vehicle in accordance with the analyzer manufacturer's instructions.

(iii) The sample probe shall be inserted into the vehicle's tailpipe to a minimum depth of 10 inches. If the vehicle's exhaust system prevents insertion to this depth, a tailpipe extension shall be used.

(iv) The measured concentration of CO plus CO_2 shall be greater than or equal to six percent.

(c) *First-chance test.* The test timer shall start (tt=0) when the conditions specified in paragraph (b)(2) of this section are met. The first-chance test shall have an overall maximum test time

of 145 seconds (tt=145). The first-chance test shall consist of an idle mode only.

(1) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum mode length shall be determined as described under paragraph (c)(2) of this section. The maximum mode length shall be 90 seconds elapsed time (mt=90).

(2) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(i) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(ii) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30), if prior to that time the criteria of paragraph (c)(2)(i) of this section are not satisfied and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(iii) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(iv) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (c)(2)(i), (ii) and (iii) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

(v) *Optional.* The vehicle may fail the first-chance test and the second-chance test shall be omitted if no exhaust gas concentration lower than 1800 ppm HC is found by an elapsed time of 30 seconds (mt=30).

(d) *Second-chance test.* If the vehicle fails the first-chance test, the test timer shall reset to zero (tt=0) and a second-chance test shall be performed. The second-chance test shall have an overall maximum test time of 425 seconds (tt=425). The test shall consist of a preconditioning mode followed immediately by an idle mode.

(1) *Preconditioning mode.* The mode timer shall start (mt=0) when the engine speed is between 2200 and 2800 rpm. The mode shall continue for an elapsed time of 180 seconds (mt=180). If engine speed falls below 2200 rpm or exceeds 2800 rpm for more than five seconds in any one excursion, or 15 seconds over all excursions, the mode timer shall reset to zero and resume timing.

(2) *Idle mode.*—(i) *Ford Motor Company and Honda vehicles.* The engines of 1981–1986 Ford Motor Company vehicles and 1984–1985 Honda Preludes shall be shut off for not more than 10 seconds and restarted. This procedure should not be used for other vehicles. The probe may be removed from the tailpipe or the sample pump turned off if necessary to reduce analyzer fouling during the restart procedure.

(ii) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum idle mode length shall be determined as described in paragraph (d)(2)(iii) of this section. The maximum idle mode length shall be 90 seconds elapsed time (mt=90).

(iii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the idle mode shall be terminated as follows:

(A) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30), if prior to that time the criteria of paragraph (d)(2)(iii)(A) of this section are not satisfied and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), measured values are less than or equal to the applicable short test standards described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (d)(2)(iii)(A), (d)(2)(iii)(B), and (d)(2)(iii)(C) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

18. The newly designated § 85.2214 is proposed to be amended by revising the section heading, redesignating paragraphs (a) through (c) as (b) through (d), adding a new paragraph (a), and revising newly designated paragraphs (c)(4), (c)(5), (c)(6), and (d) to read as follows:

§ 85.2214 Two speed idle test—EPA 81.

(a) *General calendar year applicability.* (1) The test procedure described in this section may be used to establish Emissions Performance Warranty eligibility through December 31, 1993, except as allowed in paragraph (a)(2) of this section.

(2) *Special calendar and model year applicability.* (i) For 1993 and earlier model year vehicles or engines, the test procedure described in this section may be used to establish Emissions Performance Warranty eligibility in a State for which the Administrator has approved a State Implementation Plan revision providing for the implementation no later than December 31, 1995 of any test procedure contained in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 as part of an expeditious transition to more sophisticated inspection equipment or a high-volume test only inspection network.

(ii) The extended applicability described in paragraph (a)(2)(i) of this section shall be restricted to 1993 and earlier model year vehicles or engines.

* * * * *

(c) * * *

(4) The engine speed shall be increased to 2500± 300 rpm, with transmission in neutral. Record exhaust concentrations after stabilized readings are obtained or at the end of 30 seconds, whichever occurs first. Repeat as specified in paragraph (c)(3) of this section for multiple exhaust pipes, if necessary.

(5) The engine speed shall be reduced to free idle with transmission in neutral. Record exhaust concentrations after stabilized readings are obtained or at the end of 30 seconds, whichever occurs first. Repeat as specified in paragraph (c)(3) of this section for multiple exhaust pipes, if necessary.

(6) For vehicles with multiple exhaust pipes, the separate results from each pipe for each mode (as specified in paragraphs (c)(3), (c)(4), and (c)(5) of this section) shall be numerically averaged for each pollutant, unless hardware which is capable of simultaneously sampling multiple tailpipe vehicles has been used.

* * * * *

(d) Exhaust concentration measurements from both the idle mode and the high speed mode are not required. The short test may be used to evaluate emissions from either mode alone or from both modes, the choice

being made by the jurisdiction implementing the inspection program. If exhaust concentrations are not measured on a given mode, the vehicle shall be operated at the specified test condition for 15 to 30 seconds. The final idle mode, paragraph (c)(5) of this section, may be omitted if only high-speed mode exhaust concentrations are to be measured or if the vehicle is below idle standards on the first measurement, paragraph (c)(3) of this section. The high-speed mode may be omitted if only idle mode exhaust concentrations are to be measured and if the vehicle is below idle standards on the first measurement.

19. A new § 85.2215 is added to read as follows:

§ 35.2215 Two speed idle test—EPA 91.

(a) *General requirements.* (1) *Exhaust gas sampling algorithm.* The analysis of exhaust gas concentrations shall begin 10 seconds after the applicable test mode begins. Exhaust gas concentrations shall be analyzed at a rate of two times per second. The measured value for pass/fail determinations shall be a simple running average of the measurements taken over five seconds.

(2) *Pass/fail determination.* A pass or fail determination shall be made for each applicable test mode based on a comparison of the short test standards contained in §§ 85.2203 and 85.2204, and the measured value for HC and CO as described in paragraph (a)(1) of this section. A vehicle shall pass the test mode if any pair of simultaneous values for HC and CO are below or equal to the applicable short test standards. A vehicle shall fail the test mode if the values for either HC or CO, or both, in all simultaneous pairs of values are above the applicable standards.

(3) *Void test conditions.* The test shall immediately end and any exhaust gas measurements shall be voided if the measured concentration of CO plus CO_2 falls below six percent or the vehicle's engine stalls at any time during the test sequence.

(4) *Multiple exhaust pipes.* Exhaust gas concentrations from vehicle engines equipped with multiple exhaust pipes shall be sampled simultaneously.

(5) The test shall be immediately terminated upon reaching the overall maximum test time.

(b) *Test sequence.* (1) The test sequence shall consist of a first-chance test and a second-chance test as follows:

(i) The first-chance test, as described under paragraph (c) of this section, shall consist of an idle mode followed by a high-speed mode.

(ii) The second-chance high-speed mode, as described under paragraph (c) of this section, shall immediately follow the first-chance high-speed mode. It shall be performed only if the vehicle fails the first-chance test. The second-chance idle mode, as described under paragraph (d) of this section, shall follow the second-chance high-speed mode and be performed only if the vehicle fails the idle mode of the first-chance test.

(2) The test sequence shall begin only after the following requirements are met:

(i) The vehicle shall be tested in as-received condition with the transmission in neutral or park and all accessories turned off. The engine shall be at normal operating temperature (as indicated by a temperature gauge, temperature lamp, touch test on the radiator hose, or other visual observation for overheating).

(ii) The tachometer shall be attached to the vehicle in accordance with the analyzer manufacturer's instructions

(iii) The sample probe shall be inserted into the vehicle's tailpipe to a minimum depth of 10 inches. If the vehicle's exhaust system prevents insertion to this depth, a tailpipe extension shall be used.

(iv) The measured concentration of CO plus CO_2 shall be greater than or equal to six percent.

(c) *First-chance test and second-chance high-speed mode.* The test timer shall start (tt=0) when the conditions specified in paragraph (b)(2) of this section are met. The first-chance test and second-chance high-speed mode shall have an overall maximum test time of 425 seconds (tt=425). The first-chance test shall consist of an idle mode followed immediately by a high-speed mode. This is followed immediately by an additional second-chance high-speed mode, if necessary.

(1) *First-chance idle mode.* (i) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum idle mode length shall be determined as described in paragraph (c)(1)(ii) of this section. The maximum idle mode length shall be 90 seconds elapsed time (mt=90).

(ii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode terminated as follows:

(A) The vehicle shall pass the idle mode and the mode shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the idle mode and the mode shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (c)(1)(ii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the idle mode and the mode shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the idle mode and the mode shall be terminated if none of the provisions of paragraphs (c)(1)(ii) (A), (B), and (C) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

(E) *Optional.* The vehicle may fail the first-chance test and the second-chance test shall be omitted if no exhaust gas concentration less than 1800 ppm HC is found by an elapsed time of 30 seconds (mt=30).

(2) *First-chance and second-chance high-speed modes.* This mode includes both the first-chance and second-chance high-speed modes, and follows immediately upon termination of the first-chance idle mode.

(i) The mode timer shall reset (mt=0) when the vehicle engine speed is between 2200 and 2800 rpm. If engine speed falls below 2200 rpm or exceeds 2800 rpm for more than two seconds in one excursion, or more than six seconds over all excursions within 30 seconds of the final measured value used in the pass/fail determination, the measured value shall be invalidated and the mode continued. If any excursion lasts for more than ten seconds, the mode timer shall reset to zero (mt=0) and timing resumed. The minimum high-speed mode length shall be determined as described under paragraphs (c)(2) (ii) and (iii) of this section. The maximum high-speed mode length shall be 180 seconds elapsed time (mt=180).

(ii) *Ford Motor Company and Honda vehicles.* For 1981–1986 model year Ford Motor Company vehicles and 1984–1985 model year Honda Preludes, the pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10) using the following procedure. This procedure should not be used for other vehicles.

(A) A pass or fail determination, as described below, shall be used, for vehicles that passed the idle mode, to determine whether the high-speed test

should be terminated prior to or at the end of an elapsed time of 180 seconds (mt=180).

(*1*) The vehicle shall pass the high-speed mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), the measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(*2*) The vehicle shall pass the high-speed mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (c)(2)(ii)(A)(*1*) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(*3*) The vehicle shall pass the high-speed mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 180 seconds (mt=180), the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(*4*) *Restart.* If at an elapsed time of 90 seconds (mt=90) the measured values are greater than the applicable short test standards as described in paragraph (a)(2) of this section, the vehicle's engine shall be shut off for not more than 10 seconds after returning to idle and then shall be restarted. The probe may be removed from the tailpipe or the sample pump turned off if necessary to reduce analyzer fouling during the restart procedure. The mode timer will stop upon engine shut off (mt=90) and resume upon engine restart. The pass/fail determination shall resume as follows after 100 seconds have elapsed (mt=100).

(*i*) The vehicle shall pass the high-speed mode and the test shall be immediately terminated if, at any point between an elapsed time of 100 seconds (mt=100) and 180 seconds (mt=180), the measured values are less than or equal to the applicable short test standards described in paragraph (a)(2) of this section.

(*ii*) The vehicle shall fail the high-speed mode and the test shall be terminated if paragraph (c)(2)(ii)(A)(*4*)(*i*) of this section is not satisfied by an elapsed time of 180 seconds (mt=180).

(B) A pass or fail determination shall be made for vehicles that failed the idle mode and the high-speed mode terminated at the end of an elapsed time of 180 seconds (mt=180) as follows:

(*1*) The vehicle shall pass the high-speed mode and the mode shall be terminated at an elapsed time of 180 seconds (mt=180) if any measured values of HC and CO exhaust gas concentrations during the high-speed mode are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(*2*) *Restart.* If at an elapsed time of 90 seconds (mt=90) the measured values of HC and CO exhaust gas concentrations during the high-speed mode are greater than the applicable short test standards as described in paragraph (a)(2) of this section, the vehicle's engine shall be shut off for not more than 10 seconds after returning to idle and then shall be restarted. The probe may be removed from the tailpipe or the sample pump turned off if necessary to reduce analyzer fouling during the restart procedure. The mode timer will stop upon engine shut off (mt=90) and resume upon engine restart. The pass/fail determination shall resume as follows after 100 seconds have elapsed (mt=100).

(*i*) The vehicle shall pass the high-speed mode and the mode shall be terminated at an elapsed time of 180 seconds (mt=180) if any measured values of HC and CO exhaust gas concentrations during the high-speed mode are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(*ii*) The vehicle shall fail the high-speed mode and the test shall be terminated if paragraph (c)(2)(ii)(B)(*2*)(*i*) of this section is not satisfied by an elapsed time of 180 seconds (mt=180).

(iii) *All Other Light-Duty Motor Vehicles.* The pass/fail analysis for vehicles not specified in paragraph (c)(2)(ii) of this section shall begin after an elapsed time of 10 seconds (mt=10) using the following procedure.

(A) A pass or fail determination, as described below, shall be used for vehicles that passed the idle mode, to determine whether the high-speed mode should be terminated prior to or at the end of an elapsed time of 180 seconds (mt=180).

(*1*) The vehicle shall pass the high-speed mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), any measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(*2*) The vehicle shall pass the high-speed mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (c)(2)(iii)(A)(*1*) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(*3*) The vehicle shall pass the high-speed mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 180 seconds (mt=180), the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(*4*) The vehicle shall fail the high-speed mode and the test shall be terminated if none of the provisions of paragraphs (c)(2)(iii)(A)(*1*), (*2*), and (*3*) of this section is satisfied by an elapsed time of 180 seconds (mt=180).

(B) A pass or fail determination shall be made for vehicles that failed the idle mode and the high-speed mode terminated at the end of an elapsed time of 180 seconds (mt=180) as follows:

(*1*) The vehicle shall pass the high-speed mode and the mode shall be terminated at an elapsed time of 180 seconds (mt=180) if any measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(*2*) The vehicle shall fail the high-speed mode and the test shall be terminated if paragraph (c)(2)(iii)(B)(*1*) of this section is not satisfied by an elapsed time of 180 seconds (mt=180).

(d) *Second-chance idle mode.* If the vehicle fails the first-chance idle mode and passes the high-speed mode, the test timer shall reset to zero (tt=0) and a second-chance idle mode shall commence. The second-chance idle mode shall have an overall maximum test time of 145 seconds (tt=145). The test shall consist of an idle mode only.

(1) The engines of 1981–1986 Ford Motor Company vehicles and 1984–1985 Honda Preludes shall be shut off for not more than 10 seconds and restarted. The probe may be removed from the tailpipe or the sample pump turned off if necessary to reduce analyzer fouling during the restart procedure. This procedure should not be used for other vehicles.

(2) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If the engine speed exceeds 1100 rpm or falls below 350 rpm the mode timer shall reset to zero and resume timing. The minimum second-chance idle mode length shall be determined as described in paragraph (d)(3) of this section. The maximum second-chance idle mode length shall be 90 seconds elapsed time (mt=90).

(3) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the

second-chance idle mode shall be terminated as follows:

(i) The vehicle shall pass the second-chance idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), any measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(ii) The vehicle shall pass the second-chance idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (d)(3)(i) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(iii) The vehicle shall pass the second-chance idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(iv) The vehicle shall fail the second-chance idle mode and the test shall be terminated if none of the provisions of paragraphs (d)(3)(i), (ii), and (iii) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

20. The newly designated § 85.2216 is proposed to be amended by revising the section heading, by redesignating paragraphs (a) through (c) as (b) through (d), revising newly designated paragraphs (c)(6) and (c)(7), and adding a new paragraph (a) to read as follows:

§ 85.2216 Loaded test—EPA 91.

(a) *General calendar year applicability.* (1) The test procedure described in this section may be used to establish Emissions Performance Warranty eligibility through December 31, 1993, except as allowed in paragraph (a)(2) of this section.

(2) *Special calendar and model year applicability.* (i) For 1993 and earlier model year vehicles or engines, the test procedure described in this section may be used to establish Emissions Performance Warranty eligibility in a State for which the Administrator has approved a State Implementation Plan revision providing for the implementation no later than December 31, 1995 of any test procedure contained in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 as part of an expeditious transition to more sophisticated inspection equipment or a high-volume test only inspection network.

(ii) The extended applicability described in paragraph (a)(2)(i) of this section shall be restricted to 1993 and earlier model year vehicles or engines.

* * * * *

(c) * * *

(6) The vehicle shall be idled with transmission in neutral. Record exhaust concentrations after stabilized readings are obtained or at the end of 30 seconds, whichever occurs first. Repeat as specified in paragraph (c)(5) of this section for multiple exhaust pipes, if necessary.

(7) For vehicles with multiple exhaust pipes, the separate results from each pipe for each mode (as specified in paragraphs (c)(5) and (c)(6) of this section) shall be numerically averaged for each pollutant, unless hardware which is capable of simultaneously sampling multiple tailpipe vehicles has been used.

* * * * *

21. A new § 85.2217 is proposed to be added to read as follows:

§ 85.2217 Loaded test—EPA 91.

(a) *General requirements*—(1) *Exhaust gas sampling algorithm.* The analysis of exhaust gas concentrations shall begin 10 seconds after the applicable test mode begins. Exhaust gas concentrations shall be analyzed at a minimum rate of two times per second. The measured value for pass/fail determinations shall be a simple running average of the measurements taken over five seconds.

(2) *Pass/fail determination.* A pass or fail determination shall be made for each applicable test mode based on a comparison of the short test standards contained in §§ 85.2203 and 85.2204, and the measured value for HC and CO as described in paragraph (a)(1) of this section. A vehicle shall pass the test mode if any pair of simultaneous values for HC and CO are below or equal to the applicable short test standards. A vehicle shall fail the test mode if the values for either HC or CO, or both, in all simultaneous pairs of values are above the applicable standards.

(3) *Void test conditions.* The test shall immediately end and any exhaust gas measurements shall be voided if the measured concentration of CO plus CO_2 falls below six percent or the vehicle's engine stalls at any time during the test sequence.

(4) *Multiple exhaust pipes.* Exhaust gas concentrations from vehicle engines equipped with multiple exhaust pipes shall be sampled simultaneously.

(5) The test shall be immediately terminated upon reaching the overall maximum test time.

(b) *Test sequence.* (1) The test sequence shall consist of a loaded mode using a chassis dynamometer followed immediately by an idle mode as described under paragraphs (c)(1) and (2) of this section.

(2) The test sequence shall begin only after the following requirements are met:

(i) The dynamometer shall be warmed up, in stabilized operating condition, adjusted, and calibrated in accordance with the procedures of § 85.2233. Prior to each test, variable-curve dynamometers shall be checked for proper setting of the road-load indicator or road-load controller.

(ii) The vehicle shall be tested in as-received condition with all accessories turned off. The engine shall be at normal operating temperature (as indicated by a temperature gauge, temperature lamp, touch test on the radiator hose, or other visual observation for overheating).

(iii) The vehicle shall be operated during each mode of the test with the gear selector in the following position:

(A) In drive for automatic transmissions and in second (or third if more appropriate) for manual transmissions for the loaded mode;

(B) In park or neutral for the idle mode.

(iv) The tachometer shall be attached to the vehicle in accordance with the analyzer manufacturer's instructions.

(v) The sample probe shall be inserted into the vehicle's tailpipe to a minimum depth of 10 inches. If the vehicle's exhaust system prevents insertion to this depth, a tailpipe extension shall be used.

(vi) The measured concentration of CO plus CO_2 shall be greater than or equal to six percent.

(c) *Overall test procedure.* The test timer shall start (tt=0) when the conditions specified in paragraph (b)(2) of this section are met and the mode timer initiates as specified in paragraph (c)(1) of this section. The test sequence shall have an overall maximum test time of 240 seconds (tt=240). The test shall be immediately terminated upon reaching the overall maximum test time.

(1) *Loaded mode.* (i)(A) The mode timer shall start (mt=0) when the dynamometer speed is within the limits specified for the vehicle engine size according to the following schedule:

DYNAMOMETER TEST SCHEDULE

Gasoline engine size (cylinders)	Roll speed (mph)	Normal loading (brake horsepower)
4 or less	22–25	2.8–4.1
5–6	29–32	6.6–8.4
7 or more	32–35	8.4–10.8

(B) If the dynamometer speed falls outside the limits for more than five seconds in one excursion, or 15 seconds over all excursions, the mode timer shall reset to zero and resume timing. The minimum mode length shall be determined as described in paragraph (c)(1)(ii) of this section. The maximum mode length shall be 90 seconds elapsed time (mt=90).

(ii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the loaded mode and the mode shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), measured values are less than or equal to the applicable short test standards described in paragraph (a)(2) of this section.

(B) The vehicle shall fail the loaded mode and the mode shall be terminated if paragraph (c)(1)(ii)(A) of this section is not satisfied by an elapsed time of 90 seconds (mat=90).

(C) *Optional.* The vehicle may fail the loaded mode and any subsequent idle mode shall be omitted if no exhaust gas concentration less than 1800 ppm HC is found by an elapsed time of 30 seconds (mt=30).

(2) *Idle mode.* (i) The mode timer shall start (mt=0) when the dynamometer speed is zero and the vehicle engine speed is between 350 and 1100 rpm. If engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum idle mode length shall be determined as described in paragraph (c)(2)(ii) of this section. The maximum idle mode length shall be 90 seconds elapsed time (mt=90).

(ii) the pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (c)(2)(ii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), measured values are less than or equal to the applicable short test standards described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (c)(2)(ii)(A), (c)(2)(ii)(B), and (c)(2)(ii)(C) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

22. A new § 85.2218 is proposed to be added to read as follows:

§ 85.2218 Preconditioned idle test—EPA 91.

(a) *General requirements.*—(1) *Exhaust gas sampling algorithm.* The analysis of exhaust gas concentrations shall begin 10 seconds after the applicable test mode begins. Exhaust gas concentrations shall be analyzed at a minimum rate of two times per second. The measured value for pass/fail determinations shall be a simple running average of the measurements taken over five seconds.

(2) *Pass/fail determination.* A pass or fail determination shall be made for each applicable test mode based on a comparison of the short test standards contained in §§ 85.2203 and 85.2204, and the measured value for HC and CO as described in paragraph (a)(1) of this section. A vehicle shall pass the test mode if any pair of simultaneous values for HC and CO are below or equal to the applicable short test standards. A vehicle shall fail the test mode if the values for either HC or CO, or both, in all simultaneous pairs of values are above the applicable standards.

(3) *Void test conditions.* The test shall immediately end and any exhaust gas measurements shall be voided if the measured concentration of CO plus CO_2 falls below six percent or the vehicle's engine stalls at any time during the test sequence.

(4) *Multiple exhaust pipes.* Exhaust gas concentrations from vehicle engines equipped with multiple exhaust pipes shall be sampled simultaneously.

(5) The test shall be immediately terminated upon reaching the overall maximum test time.

(b) *Test sequence.* (1) The test sequence shall consist of an first-chance test and a second-chance test as follows:

(i) The first-chance test, as described under paragraph (c) of this section, shall consist of a preconditioning mode followed by an idle mode.

(ii) The second-chance test as described under paragraph (d) of this section shall be performed only if the vehicle fails the first-chance test.

(2) The test sequence shall begin only after the following requirements are met:

(i) The vehicle shall be tested in as-received condition with the transmission in neutral or park and all accessories turned off. The engine shall be at normal operating temperature (as indicated by a temperature gauge, temperature lamp, touch test on the radiator hose, or other visual observation for overheating).

(ii) The tachometer shall be attached to the vehicle in accordance with the analyzer manufacturer's instructions.

(iii) The sample probe shall be inserted into the vehicle's tailpipe to a minimum depth of 10 inches. If the vehicle's exhaust system prevents insertion to this depth, a tailpipe extension shall be used.

(iv) The measured concentration of CO plus CO_2 shall be greater than or equal to six percent.

(c) *First-chance test.* The test timer shall start (tt=0) when the conditions specified in paragraph (b)(2) of this section are met. The test shall have an overall maximum test time of 200 seconds (tt=200). The first-chance test shall consist of a preconditioning mode followed immediately by an idle mode.

(1) *Preconditioning mode.* The mode timer shall start (mt=0) when the engine speed is between 2200 and 2800 rpm The mode shall continue for an elapsed time of 30 seconds (mt=30). If engine speed falls below 2200 rpm or exceeds 2800 rpm for more than five seconds in any one excursion, or 15 seconds over all excursions, the mode timer shall reset to zero and resume timing.

(2) *Idle mode.* (i) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum idle mode length shall be determined as described in paragraph (c)(2)(ii) of this section. The maximum idle mode length shall be 90 seconds elapsed time (mt=90).

(ii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds

(mt=30) if, prior to that time, the criteria of paragraph (c)(2)(ii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (c)(2)(ii) (A), (B), and (C) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

(E) *Optional.* The vehicle may fail the first-chance test and the second-chance test shall be omitted if no exhaust gas concentration less than 1800 ppm HC is found at an elapsed time of 30 seconds (mt=30).

(d) *Second-chance test.* If the vehicle fails the first-chance test, the test timer shall reset to zero and a second-chance test shall be performed. The second-chance test shall have an overall maximum test time of 425 seconds. The test shall consist of a preconditioning mode followed immediately by an idle mode.

(1) *Preconditioning mode.* The mode timer shall start (mt=0) when engine speed is between 2200 and 2800 rpm. The mode shall continue for an elapsed time of 180 seconds (mt=180). If the engine speed falls below 2200 rpm or exceeds 2800 rpm for more than five seconds in any one excursion, or 15 seconds over all excursions, the mode timer shall reset to zero and resume timing.

(2) *Idle mode*—(i) *Ford Motor Company and Honda vehicles.* The engines of 1981–1986 Ford Motor Company vehicles and 1984–1985 Honda Preludes shall be shut off for not more than 10 seconds and then shall be restarted. The probe may be removed from the tailpipe or the sample pump turned off if necessary to reduce analyzer fouling during the restart procedure. This procedure should not be used for other vehicles.

(ii) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If the engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum idle mode length shall be determined as described in paragraph (d)(2)(iii) of this section. The maximum idle mode length shall be 90 seconds elapsed time (mt=90).

(iii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (d)(2)(iii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), measured values are less than or equal to the applicable short test standards described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (d)(2)(iii) (A), (B), and (C) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

23. A new § 85.2219 is proposed to be added to read as follows:

§ 85.2219 Idle test with loaded preconditioning—EPA 91.

(a) *General requirements.*—(1) *Exhaust gas sampling algorithm.* The analysis of exhaust gas concentrations shall begin 10 seconds after the applicable test mode begins. Exhaust gas concentrations shall be analyzed at a minimum rate of two times per second. The measured value for pass/fail determinations shall be a simple running average of the measurements taken over five seconds.

(2) *Pass/fail determination.* A pass or fail determination shall be made for each applicable test mode based on a comparison of the short test standards contained in §§ 85.2203 and 85.2204, and the measured value for HC and CO as described in paragraph (a)(1) of this section. A vehicle shall pass the test mode if any pair of simultaneous values for HC and CO are below or equal to the applicable short test standards. A vehicle shall fail the test mode if the values for either HC or CO, or both, in all simultaneous pairs of values are above the applicable standards.

(3) *Void test conditions.* The test shall immediately end and any exhaust gas measurements shall be voided if the measured concentration of CO plus CO_2 falls below six percent or the vehicle's engine stalls at any time during the test sequence.

(4) *Multiple exhaust pipes.* Exhaust gas concentrations from vehicle engines equipped with multiple exhaust pipes shall be sampled simultaneously.

(5) The test shall be immediately terminated upon reaching the overall maximum test time.

(b) *Test sequence.* (1) The test sequence shall consist of a first-chance test and a second-chance test as follows:

(i) The first-chance test, as described under paragraph (c) of this section, shall consist of an idle mode.

(ii) The second-chance test as described under paragraph (d) of this section shall be performed only if the vehicle fails the first-chance test.

(2) The test sequence shall begin only after the following requirements are met:

(i) The dynamometer shall be warmed up, in stabilized operating condition, adjusted, and calibrated in accordance with the procedures of § 85.2233. Prior to each test, variable-curve dynamometers shall be checked for proper setting of the road-load indicator or road-load controller.

(ii) The vehicle shall be tested in as-received condition with all accessories turned off. The engine shall be at normal operating temperature (as indicated by a temperature gauge, temperature lamp, touch test on the radiator hose, or other visual observation for overheating).

(iii) The vehicle shall be operated during each mode of the test with the gear selector in the following position:

(A) In drive for automatic transmissions and in second (or third if more appropriate) for manual transmissions for the loaded preconditioning mode;

(B) In park or neutral for the idle mode.

(iv) The tachometer shall be attached to the vehicle in accordance with the analyzer manufacturer's instructions.

(v) The sample probe shall be inserted into the vehicle's tailpipe to a minimum depth of 10 inches. If the vehicle's exhaust system prevents insertion to this depth, a tailpipe extension shall be used.

(vi) The measured concentration of CO plus CO_2 shall be greater than or equal to six percent.

(c) *First-chance test.* The test timer shall start (tt=0) when the conditions specified in paragraph (b)(2) of this section are met. The test shall have an

overall maximum test time of 155 seconds (tt=155). The first-chance test shall consist of an idle mode only.

(1) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If the engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum mode length shall be determined as described in paragraph (c)(2) of this section. The maximum mode length shall be 90 seconds elapsed time (mt=90).

(2) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(i) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(ii) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (c)(2)(i) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(iii) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(iv) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (c)(2) (i), (ii), and (iii) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

(v) *Optional.* The vehicle may fail the first-chance test and the second-chance test shall be omitted if no exhaust gas concentration less than 1800 ppm HC is found at an elapsed time of 30 seconds (mt=30).

(d) *Second-chance test.* If the vehicle fails the first-chance test, the test timer shall reset to zero (tt=0) and a second-chance test shall be performed. The second-chance test shall have an overall maximum test time of 200 seconds (tt=200). The test shall consist of a preconditioning mode using a chassis dynamometer, followed immediately by an idle mode.

(1) *Preconditioning mode.* (i) The mode timer shall start (mt=0) when the dynamometer speed is within the limits specified for the vehicle engine size in accordance with the following schedule:

DYNAMOMETER TEST SCHEDULE

Gasoline engine size (cylinders)	Roll speed (mph)	Normal loading (brake horsepower)
4 or less	22–25	2.8–4.1
5–6	29–32	6.6–8.4
7 or more	32–35	8.4–10.8

(ii) The mode shall continue for a minimum elapsed time of 30 seconds (mt=30) . If the dynamometer speed falls outside the limits for more than five seconds in one excursion, or 15 seconds over all excursions, the mode timer shall reset to zero and resume timing.

(2) *Idle mode.* (i) The mode timer shall start (mt=0) when the dynamometer speed is zero and the vehicle engine speed is between 350 and 1100 rpm. If the engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum idle mode length shall be determined as described in paragraph (d)(2)(ii) of this section. The maximum idle mode length shall be 90 seconds elapsed time (mt=90).

(ii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (d)(2)(ii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), measured values are less than or equal to the applicable short test standards described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (d)(2)(ii)(A), (B), and (C) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

24. A new § 85.2220 is proposed to be added to read as follows:

§ 85.2220 Preconditioned two speed idle test—EPA 91.

(a) *General requirements*—(1) *Exhaust gas sampling algorithm.* The analysis of exhaust gas concentrations shall begin 10 seconds after the applicable test mode begins. Exhaust gas concentrations shall be analyzed at a minimum rate of two times per second. The measured value for pass/fail determinations shall be a simple running average of the measurements taken over five seconds.

(2) *Pass/fail determination.* A pass or fail determination shall be made for each applicable test mode based on a comparison of the short test standards contained in §§ 85.2203 and 85.2204, and the measured value for HC and CO as described in paragraph (a)(1) of this section. A vehicle shall pass the test mode if any pair of simultaneous values for HC and CO are below or equal to the applicable short test standards. A vehicle shall fail the test mode if the values for either HC or CO, or both, in all simultaneous pairs of values are above the applicable standards.

(3) *Void test conditions.* The test shall immediately end and any exhaust gas measurements shall be voided if the measured concentration of CO plus CO_2 falls below six percent or the vehicle's engine stalls at any time during the test sequence.

(4) *Multiple exhaust pipes.* Exhaust gas concentrations from vehicle engines equipped with multiple exhaust pipes shall be sampled simultaneously.

(5) The test shall be immediately terminated upon reaching the overall maximum test time.

(b) *Test sequence.* (1) The test sequence shall consist of a first-chance test and a second-chance test as follows:

(i) The first-chance test, as described under paragraph (c) of this section, shall consist of a first-chance high-speed mode followed immediately by a first-chance idle mode.

(ii) The second-chance test as described under paragraph (d) of this section shall be performed only if the vehicle fails the first-chance test.

(2) The test sequence shall begin only after the following requirements are met:

(i) The vehicle shall be tested in as-received condition with the transmission in neutral or park and all accessories turned off. The engine shall be at normal operating temperature (as indicated by a temperature gauge, temperature lamp, touch test on the radiator hose, or other visual observation for overheating).

(ii) The tachometer shall be attached to the vehicle in accordance with the analyzer manufacturer's instructions.

(iii) The sample probe shall be inserted into the vehicle's tailpipe to a minimum depth of 10 inches. If the vehicle's exhaust system prevents insertion to this depth, a tailpipe extension shall be used.

(iv) The measured concentration of CO plus CO_2 shall be greater than or equal to six percent.

(c) *First-chance test.* The test timer shall start (tt=0) when the conditions specified in paragraph (b)(2) of this section are met. The test shall have an overall maximum test time of 290 seconds (tt=290). The first-chance test shall consist of a high-speed mode followed immediately by an idle mode.

(1) *First-chance high-speed mode.* (i) The mode timer shall reset (mt=0) when the vehicle engine speed is between 2200 and 2800 rpm. If the engine speed falls below 2200 rpm or exceeds 2800 rpm for more than two seconds in one excursion, or more than six seconds over all excursions within 30 seconds of the final measured value used in the pass/fail determination, the measured value shall be invalidated and the mode continued. If any excursion lasts for more than ten seconds, the mode timer shall reset to zero (mt=0) and timing resumed. The high-speed mode length shall be 90 seconds elapsed time (mt=90).

(ii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the high-speed mode and the mode shall be terminated at an elapsed time of 90 seconds (mt=90) if any measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(B) The vehicle shall fail the high-speed mode and the mode shall be terminated if the requirements of paragraph (c)(1)(ii)(A) of this section are not satisfied by an elapsed time of 90 seconds (mt=90).

(C) *Optional.* The vehicle shall fail the first-chance test and any subsequent test shall be omitted if no exhaust gas concentration lower than 1800 ppm HC is found at an elapsed time of 30 seconds (mt=30).

(2) *First-chance idle mode.* (i) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If the engine speed exceeds 1100 rpm or falls below 350 rpm, the mode timer shall reset to zero and resume timing. The minimum first-chance idle mode length shall be determined as described in paragraph (c)(2)(ii) of this section. The maximum first-chance idle mode length shall be 90 seconds elapsed time (mt=90).

(ii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (c)(2)(ii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the idle mode and the test shall be terminated if none of the provisions of paragraphs (c)(2)(ii) (A), (B), and (C) of this section is satisfied by an elapsed time of 90 seconds (mt=90)

(d) *Second-chance test.* (1) If the vehicle fails either mode of the first-chance test, the test timer shall reset to zero (tt=0) and a second-chance test shall commence. The second-chance test shall be performed based on the first-chance test failure mode or modes as follows:

(i) If the vehicle failed only the first-chance high-speed mode, the second-chance test shall consist of a second-chance high-speed mode as described in paragraph (d)(2) of this section. The overall maximum test time shall be 280 seconds (tt=280).

(ii) If the vehicle failed only the first-chance idle mode, the second-chance test shall consist of a second-chance pre-conditioning mode followed immediately by a second-chance idle mode as described in paragraphs (d) (3) and (4) of this section. The overall maximum test time shall be 425 seconds (tt=425).

(iii) If both the first-chance high-speed mode and first-chance idle mode were failed, the second-chance test shall consist of the second-chance high-speed mode followed immediately by the second-chance idle mode as described in paragraphs (d) (2) and (4) . However, if during this second-chance procedure the vehicle fails the second-chance high-speed mode, then the second-chance idle mode may be eliminated. The overall maximum test time shall be 425 seconds (tt=425).

(2) *Second-chance high-speed mode.* (i) *Ford Motor Company and Honda vehicles.* The engines of 1981–1986 Ford Motor Company vehicles and 1984–1985 Honda Preludes shall be shut off for not more than 10 seconds and then shall be restarted. The probe may be removed from the tailpipe or the sample pump turned off if necessary to reduce analyzer fouling during the restart procedure. This procedure should not be used for other vehicles.

(ii) The mode timer shall reset (mt=0) when the vehicle engine speed is between 2200 and 2800 rpm. If the engine speed falls below 2200 rpm or exceeds 2800 rpm for more than two seconds in one excursion, or more than six seconds over all excursions within 30 seconds of the final measured value used in the pass/fail determination, the measured value shall be invalidated and the mode continued. The minimum second-chance high-speed mode length shall be determined as described in paragraphs (d)(2) (iii) and (iv) of this section. If any excursion lasts for more than ten seconds, the mode timer shall reset to zero (mt=0) and timing resumed. The maximum second-chance high-speed mode length shall be 180 seconds, elapsed time (mt=180).

(iii) In the case where the second-chance high-speed mode is not followed by the second-chance idle mode, the pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the high-speed mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the high-speed mode and the test shall be terminated if at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (d)(2)(iii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the high-speed mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 180 seconds (mt=180), the measured values are less than or equal to the applicable short test standards as

described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the high-speed mode and the test shall be terminated if none of the provisions of paragraphs (d)(2)(iii) (A), (B), and (C) of this section is satisfied by an elapsed time of 180 seconds (mt=180).

(iv) In the case where the second-chance high-speed mode is followed by the second-chance idle mode, the pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the high-speed mode and the mode shall be terminated at the end of an elapsed time of 180 seconds (mt=180) if any measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(B) The vehicle shall fail the high-speed mode and the mode shall be terminated if paragraph (d)(2)(iv)(A) of this section is not satisfied by an elapsed time of 180 seconds (mt=180).

(3) *Second-chance preconditioning mode.* The mode timer shall start (mt=0) when engine speed is between 2200 and 2800 rpm. The mode shall continue for an elapsed time of 180 seconds (mt=180) . If the engine speed falls below 2200 rpm or exceeds 2800 rpm for more than five seconds in any one excursion, or 15 seconds over all excursions, the mode timer shall reset to zero and resume timing.

(4) *Second-chance idle mode.* (i) *Ford Motor Company and Honda vehicles.* The engines of 1981–1986 Ford Motor Company vehicles and 1984–1985 Honda Preludes shall be shut off for not more than 10 seconds and then shall be restarted. The probe may be removed from the tailpipe or the sample pump turned off if necessary to reduce analyzer fouling during the restart procedure. This procedure should not be used for other vehicles.

(ii) The mode timer shall start (mt=0) when the vehicle engine speed is between 350 and 1100 rpm. If the engine speed exceeds 1100 rpm or falls below 350 rpm the mode timer shall reset to zero and resume timing. The minimum second-chance idle mode length shall be determined as described in paragraph (d)(4)(iii) of this section. The maximum second-chance idle mode length shall be 90 seconds elapsed time (mt=90).

(iii) The pass/fail analysis shall begin after an elapsed time of 10 seconds (mt=10). A pass or fail determination shall be made for the vehicle and the mode shall be terminated as follows:

(A) The vehicle shall pass the second-chance idle mode and the test shall be immediately terminated if, prior to an elapsed time of 30 seconds (mt=30), measured values are less than or equal to 100 ppm HC and 0.5 percent CO.

(B) The vehicle shall pass the second-chance idle mode and the test shall be terminated at the end of an elapsed time of 30 seconds (mt=30) if, prior to that time, the criteria of paragraph (d)(4)(iii)(A) of this section are not satisfied, and the measured values are less than or equal to the applicable short test standards as described in paragraph (a)(2) of this section.

(C) The vehicle shall pass the second-chance idle mode and the test shall be immediately terminated if, at any point between an elapsed time of 30 seconds (mt=30) and 90 seconds (mt=90), measured values are less than or equal to the applicable short test standards described in paragraph (a)(2) of this section.

(D) The vehicle shall fail the second-chance idle mode and the test shall be terminated if none of the provisions of paragraphs (d)(4)(iii) (A), (B), and (C) of this section is satisfied by an elapsed time of 90 seconds (mt=90).

25. The newly designated § 85.2224 is proposed to be amended by revising the section heading by redesignating paragraphs (a) through (b) as paragraphs (b) through (c) and adding a new paragraph (a) to read as follows:

§ 85.2224 Exhaust analysis system—EPA 81.

(a) *Applicability.* The requirements of this subsection shall apply to short tests conducted under Emissions Performance Warranty through December 31, 1993. The requirements of § 85.2225 shall apply concurrently until December 31, 1993, except for 1993 and earlier model year vehicles or engines in a state where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 as of a later date (not to exceed December 31, 1995) as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network, after which the requirements of § 85.2225 shall solely be in effect.

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26. A new § 85.2225 is proposed to be added to read as follows:

§ 85.2225 Steady state test exhaust analysis system—EPA 91.

(a) *Applicability.* (1) *General calendar year applicability.* The requirements of this section shall apply to short tests conducted under Emission Performance Warranty. The requirements of § 85.2224 shall apply concurrently through December 31, 1993, except as allowed under paragraph (a)(2) of this section, after which the requirements of this section shall solely be in effect.

(2) *Special calendar and model year applicability.* The requirements of § 85.2224 shall apply concurrently for tests conducted under Emission Performance Warranty on 1993 and earlier model year vehicles or engines in states where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 no later than December 31, 1995, as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network, after which the requirements of this section shall solely be in effect.

(b) *Sampling System—(1) General requirements.* The sampling system for steady state short tests shall, at a minimum, consist of a tailpipe probe, a flexible sample line, a water removal system, particulate trap, sample pump, flow control components, tachometer or dynamometer, analyzers for HC, CO, and CO_2, and digital displays for exhaust concentrations of HC, CO, and CO_2 and engine rpm. Materials that are in contact with the gases sampled shall not contaminate or change the character of the gases to be analyzed, including gases from alcohol fueled vehicles. The probe shall be capable of being inserted to a depth of at least ten inches into the tailpipe of the vehicle being tested, or into an extension boot if one is used. A digital display for dynamometer speed and load shall be included if the test procedures described in § 85.2217 or § 85.2219 are conducted. Minimum specifications for optional NO and O_2 analyzers are also described in this section. The analyzer system shall be able to test, as specified in § 85.2213, § 85.2215, § 85.2217, § 85.2218, § 85.2219, and § 85.2220 all model vehicles in service at the time of sale of the analyzer.

(2) *Temperature Operating Range.* The sampling system and all associated hardware shall be of a design certified to operate within the performance specifications described in paragraph (c) of this section in ambient air temperatures ranging from 41 to 110 degrees Fahrenheit. The analyzer system shall, where necessary, include features to keep the sampling system within the specified range.

(3) *Humidity Operating Range.* The sampling system and all associated hardware shall be of a design certified

to operate within the performance specifications described in paragraph (c) of this section at a minimum of 80 percent relative humidity throughout the required temperature range.

(4) *Barometric Pressure Compensation.* Barometric pressure compensation shall be provided. Compensation shall be made for elevations up to 6000 feet (above mean sea level) . At any given altitude and ambient conditions specified in paragraphs (b) (2) and (3) of this section, errors due to barometric pressure changes of ±2 inches of mercury shall not exceed the accuracy limits specified in paragraph (c) of this section.

(5) *Dual Sample Probe Requirements.* When testing a vehicle with dual exhaust pipes, a dual sample probe of a design certified by the analyzer manufacturer to provide equal flow in each leg shall be used. The equal flow requirement is considered to be met if the flow rate in each leg of the probe has been measured under two sample pump flow rates (the normal rate and a rate equal to the onset of low flow), and if the flow rates in each of the legs are found to be equal to each other (within 15% of the flow rate in the leg having lower flow).

(6) *System Lockout During Warm-up.* Functional operation of the gas sampling unit shall remain disabled through a system lockout until the instrument meets stability and warm-up requirements. The instrument shall be considered "warmed-up" when the zero and span readings for HC, CO, and CO_2 have stabilized, within ±3% of the full range of low scale, for five minutes without adjustment.

(7) *Electromagnetic Isolation and Interference.* Electromagnetic signals found in an automotive service environment shall not cause malfunctions or changes in the accuracy in the electronics of the analyzer system. The instrument design shall ensure that readings do not vary as a result of electromagnetic radiation and induction devices normally found in the automotive service environment, including high energy vehicle ignition systems, radio frequency transmission radiation sources, and building electrical systems.

(8) *Vibration and Shock Protection.* System operation shall be unaffected by the vibration and shock encountered under the normal operating conditions encountered in an automotive service environment.

(9) *Propane Equivalency Factor.* The PEF shall be displayed in a manner that enables it to be viewed conveniently, while permitting it to be altered only by personnel specifically authorized to do so.

(c) *Analyzers*—(1) *Accuracy.* The analyzers shall be of a design certified to meet the following accuracy requirements when calibrated to the span points specified in § 85.2233(e)(2):

Channel	Range	Accuracy	Noise	Repeatability
HC, ppm as hexane	0–400	±12	6	8
	401–1000	±30	10	15
	1001–2000	±80	20	30
CO, %	0–2.00	±0.06	0.02	0.03
	2.01–5.00	±0.15	0.06	0.08
	5.01–9.99	±0.40	0.10	0.15
CO_2, %	0–4.0	±0.6	0.2	0.3
	4.1–14.0	±0.5	0.2	0.3
	14.1–16.0	±0.6	0.2	0.3
NO, ppm	0–1000	±32	16	20
	1001–2000	±60	25	30
	2001–400	±120	50	60

(2) *Minimum Analyzer Display Resolution.* The analyzer electronics shall have sufficient resolution to achieve the following:

HC 1 ppm HC as hexane
CO 0.01% CO
CO_2 0.1% CO_2
NO 1 ppm NO
RPM 1 rpm

(3) *Response Time.* The response time from the probe to the display for HC, CO, and CO_2 analyzers shall not exceed eight seconds to 90% of a step change in input. For NO analyzers, the response time shall not exceed twelve seconds to 90% of a step change in input.

(4) *Display Refresh Rate.* Dynamic information being displayed shall be refreshed at a minimum rate of twice per second.

(5) *Interference Effects.* The interference effects for noninterest gases shall not exceed ±10 ppm for hydrocarbons, ±0.05 percent for carbon monoxide, ±0.20 percent for carbon dioxide, and +20 ppm for oxides of nitrogen.

(6) *Low Flow Indication.* The analyzer shall provide an indication when the sample flow is below the acceptable level. The sampling system shall be equipped with a flow meter (or equivalent) that shall indicate sample flow degradation when meter error exceeds three percent of full scale, or causes system response time to exceed 13 seconds to 90 percent of a step change in input, whichever is less.

(7) *Engine Speed Detection.* The analyzer shall utilize a tachometer capable of detecting engine speed in revolutions per minute (rpm) with a 0.5 second response time and an accuracy of ±3% of the true rpm.

(8) *Test and mode timers.* The analyzer shall be capable of simultaneously determining the amount of time elapsed in a test, and in a mode within that test.

(9) *Sample rate.* The analyzer shall be capable of measuring exhaust concentrations of gases specified in this section at a minimum rate of twice per second.

(d) *Demonstration of conformity.* The analyzer shall be demonstrated to meet the requirements of this section and to be capable of being maintained as required in § 85.2233 to the satisfaction of the inspection program manager, through acceptance testing procedures.

27. The newly designated § 85.2229 is proposed to be amended by revising the section heading, by redesignating paragraphs (a) through (b) as paragraphs (b) through (c) and adding a new paragraph (a) to read as follows:

§ 85.2229 Dynamometer—EPA 81.

(a) *Applicability*—(1) *General calendar year applicability.* The requirements of this section shall apply to short tests conducted under Emission Performance Warranty through December 31, 1993, except as allowed under paragraph (a)(2) of this section. The requirements of § 85.2230 shall apply concurrently.

(2) *Special calendar and model year applicability.* The requirements of this section shall apply to tests conducted under Emission Performance Warranty

on 1993 and earlier model year vehicles or engines in states where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 no later than December 31, 1995, as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network. The requirements of § 85.2230 shall apply concurrently.

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28. A new § 85.2230 is proposed to be added to read as follows:

§ 85.2230 Steady state test dynamometer—EPA 91.

(a) *Applicability*—(1) *General calendar year applicability.* The requirements of this section shall apply to short tests conducted under Emission Performance Warranty. The requirements of § 85.2229 shall apply concurrently through December 31, 1993, except as allowed under paragraph (a)(2) of this section, after which the requirements of this section shall solely be in effect.

(2) *Special calendar and model year applicability.* The requirements of § 85.2229 shall apply concurrently for tests conducted under Emission Performance Warranty on 1993 and earlier model year vehicles or engines in states where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 no later than December 31, 1995, as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network, after which the requirements of this section shall solely be in effect.

(b) The chassis dynamometer for steady state short tests shall provide the following capabilities:

(1) *Power absorption.* The dynamometer shall be capable of applying a load to the vehicle's driving tire surfaces at the horsepower and speed levels specified in paragraph (c).

(2) *Short-term stability.* Power absorption at constant speed shall not drift more than ±0.5 horsepower (hp) during any single test mode.

(3) *Roll weight capacity.* The dynamometer shall be capable of supporting a driving axle weight up to four thousand (4,000) pounds or greater.

(4) *Between roll wheel lifts.* These shall be controllable and capable of lifting a minimum of four thousand (4,000) pounds.

(5) *Roll brakes.* Both rolls shall be locked when the wheel lift is up.

(6) *Speed indications.* The dynamometer speed display shall have a range of 0–60 mph, and a resolution and accuracy of at least 1 mph.

(7) *Safety interlock.* A roll speed sensor and safety interlock circuit shall be provided which prevents the application of the roll brakes and upward lift movement at any roll speed above 0.5 mph.

(c) The dynamometer shall produce the load speed relationships specified in § 85.2216 and § 85.2219.

29. The newly designated § 85.2232 is proposed to be amended by revising the section heading, redesignating paragraphs (a) through (e) as paragraphs (b) through (f), adding a new paragraph (a), and revising paragraph (f)(1) to read as follows:

§ 85.2232 Calibrations, adjustments—EPA 91.

(a) *Applicability*—(1) *General calendar year applicability.* The requirements of this section shall apply to short tests conducted under Emission Performance Warranty through December 31, 1993, except as allowed under paragraph (a)(2) of this section. The requirements of § 85.2233 shall apply concurrently.

(2) *Special calendar and model year applicability.* The requirements of this section shall apply to tests conducted under Emission Performance Warranty on 1993 and earlier model year vehicles or engines in states where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 no later than December 31, 1995, as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network. The requirements of § 85.2233 shall apply concurrently.

* * * * *

(f) * * *

(1) *Gas span check.* Within one week of the test, the analyzers shall have been spanned using calibration gases which met the requirements in paragraph (e)(4) of this section and shall not have been readjusted since to a non-conforming gas. If the analyzer reads the span gas within 2% of the span gas value or within .05% of the CO and 6 ppm HC (use the larger of the two tolerances), then no adjustment of the analyzer is needed. For this check the span gas may be introduced either through the calibration port (if so equipped) or through the probe. This paragraph does not prevent those who wish to always adjust the analyzer to the exact span value from doing so.

* * * * *

30. A new § 85.2233 is proposed to be added to read as follows:

§ 85.2233 Steady state test equipment calibrations, adjustments—EPA 91.

(a) *Applicability*—(1) *General calendar year applicability.* The requirements of this section shall apply to short tests conducted under Emission Performance Warranty. The requirements of § 85.2232 shall apply concurrently through December 31, 1993, except as allowed under paragraph (a)(2) of this section, after which the requirements of this section shall solely be in effect.

(2) *Special calendar and model year applicability.* The requirements of § 85.2232 shall apply concurrently for tests conducted under Emission Performance Warranty on 1993 and earlier model year vehicles or engines in states where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 no later than December 31, 1995, as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network, after which the requirements of this section shall solely be in effect.

(b) Equipment shall be calibrated in accordance with the manufacturers' instructions.

(c) *Prior to each test*—(1) *Hydrocarbon Hang-up Check.* Immediately prior to each test the analyzer shall automatically perform a hydrocarbon hang-up check. If the HC reading, when the probe is sampling ambient air, exceeds 20 ppm, the system shall be purged with clean air or zero gas. If HC hang-up does not drop below 20 ppm within 150 seconds the analyzer shall lock out from testing.

(2) *Automatic, Zero and Span.* The analyzer shall conduct an automatic zero and span check prior to each test. The span check shall include the HC, CO, and CO_2 channels, and the NO and O_2 channels, if present. If zero and/or span drift cause the signal levels to move beyond the adjustment range of the analyzer, it shall lock out from testing.

(3) *Low Flow.* The system shall lock out from testing if sample flow is below the acceptable level as defined in § 85.2225(c)(6)

(d) *Daily Checks.* A system leak check shall be performed within twenty-four hours before the test and may be performed in conjunction with the gas calibration described in paragraph (e)(1)

of this section. If a leak check is not performed within the preceding twenty-four hours, or if the analyzer fails the leak check, the analyzer shall lock out from testing. The leak check shall be a procedure demonstrated to effectively check the sample hose and probe for leaks and shall be performed in accordance with good engineering practices. An error of more than ±3% of the reading using low range span gas shall cause the analyzer to lock out from testing and shall require repair of leaks.

(e) *Every Seventy-Two Hours*—(1) *Gas Calibration.* The analyzer shall automatically require and successfully pass a gas calibration for HC, CO, and CO_2 within seventy-two hours before the test. Gas calibration shall be accomplished by introducing gas that meets the requirements of paragraph (e)(3) of this section into the analyzer through the calibration port. If the analyzer reads the span gas within the allowable tolerance range (i.e., the square root of the sum of the span gas tolerance described in paragraph (e)(3) of this section and the calibration tolerance, which shall be equivalent to the accuracy specifications set forth in § 85.2225(c)(1) at both of the required span points), no adjustment of the analyzer is necessary. The gas calibration procedure shall correct readings that exceed the allowable tolerance range to the center of the allowable tolerance range. The pressure in the sample cell shall be the same with the calibration gas flowing during calibration as with the sample gas flowing during sampling. If the system is not calibrated, or the system fails the calibration check, the analyzer shall lock out from testing.

(2) *Span Points.* A two point gas calibration procedure shall be followed. The span shall be accomplished at one of the following pairs of span points:

(i) 300 ppm propane (HC)
1.0% carbon monoxide (CO)
6.0% carbon dioxide (CO_2)
1000 ppm nitric oxide (if equipped with NO)
1200 ppm propane (HC)
4.0% carbon monoxide (CO)
12.0% carbon dioxide (CO_2)
3000 ppm nitric oxide (if equipped with NO)

(ii) 0 ppm propane
0.0% carbon monoxide
0.0% carbon dioxide
0 ppm nitric oxide (if equipped with NO)
600 ppm propane (HC)
1.6% carbon monoxide (CO)
11.0% carbon dioxide (CO_2)
1200 ppm nitric oxide (if equipped with NO)

(3) *Span Gases.* The span gases used for the gas calibration shall be traceable to National Institute of Standards and Technology (NIST) standards ±2%, and shall be within two percent of the span points specified in paragraph (e)(2) of this section. Zero gases shall conform to the specifications given in § 86.114–79(a)(5) of this chapter.

(f) *Monthly Check.* Within one month preceding each loaded test, the accuracy of the roll speed indicator shall be verified and the dynamometer shall be checked for proper power absorber settings.

(g) *Semi-annual Check.* Within six months preceding each loaded test, the road-load response of the variable-curve dynamometer or the frictional power absorption of the dynamometer shall be checked by a coastdown procedure similar to that described in § 86.138–78. The check shall be done at 30 mph, and a power absorption load setting to generate a total horsepower of 4.1 hp. The actual coastdown time from 45 mph to 15 mph shall be within ±1 second of the time calculated by the following equation:

$$\text{Coast Down Time} = \frac{0.0508^{*}W}{HP}$$

where W is the total inertia weight as represented by the weight of the rollers (excluding free rollers), and any inertia flywheels used, measured in pounds. If the coastdown time is not within the specified tolerance the dynamometer shall be taken out of service and corrective action shall be taken.

(h) *Other Checks.* In addition to the above periodic checks, these shall also be used to verify system performance under the following special circumstances.

(1) *Gas Calibration.* Each time the analyzer electronic or optical systems are repaired or replaced, a gas calibration shall be performed prior to returning the unit to service.

(2) *Leak Checks.* Each time the sample line integrity is broken, a leak check shall be performed prior to testing.

31. The newly designated § 85.2237 is proposed to be amended by revising the section heading, by redesignating paragraphs (a) through (c) as paragraphs (b) through (d) and adding a new paragraph (a) to read as follows:

§ 85.223 Test report—EPA 81.

(a) *Applicability*—(1) *General calendar year applicability.* The requirements of this section shall apply to short tests conducted under Emission Performance Warranty through December 31, 1993, except as allowed under paragraph (a) (2) of this section. The requirements of § 85.2238 shall apply concurrently.

(2) *Special calendar and model year applicability.* The requirements of this section shall apply to tests conducted under Emission Performance Warranty on 1993 and earlier model year vehicles or engines in states where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 no later than December 31, 1995, as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network. The requirements of § 85.2238 shall apply concurrently.

* * * * *

32. A new § 85.2238 is proposed to be added to read as follows:

§ 85.2238 Test report—EPA 91.

(a) Applicability—(1) *General calendar year applicability.* The requirements of this section shall apply to short tests conducted under Emission Performance Warranty. The requirements of § 85.2237 shall apply concurrently through December 31, 1993, except as allowed under paragraph (a) (2) of this section, after which the requirements of this section shall solely be in effect.

(2) *Special calendar and model year applicability.* The requirements of § 85.2237 shall apply concurrently for tests conducted under Emission Performance Warranty on 1993 and earlier model year vehicles or engines in states where the Administrator has approved a SIP revision providing for implementation of test procedures as described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 no later than December 31, 1995, as part of an expeditious transition to more sophisticated testing equipment or a high-volume test only inspection network, after which the requirements of this section shall solely be in effect.

(b) Upon failure of a short test, the vehicle's owner or operator shall be furnished with a test report containing:

(1) Vehicle description, including license plate number, vehicle identification number, weight class, and odometer reading.

(2) Date and time of test.

(3) Name or identification number of the individual performing the test and the location of the test station and lane.

(4) Type of emission test performed.

(5) Applicable emission test standards.

(6) Test results, including exhaust concentrations for each mode measured.

(i) The reported exhaust concentrations shall be that pair of passing exhaust concentrations or, if none are obtained, that pair of failing exhaust concentrations, for which the product of HC+(151*CO) is a minimum.

(ii) If a second-chance test is conducted the reported exhaust concentrations shall be those obtained from the second-chance test.

(7) A statement indicating the availability of warranty coverage as provided in section 207 of the Clean Air Act.

(c) The test report shall certify that the short test was performed in accordance with these regulations and, in the case of service station based programs, it shall be signed by the individual who performed the test.

PART 86—CONTROL OF AIR POLLUTION FROM NEW AND IN-USE MOTOR VEHICLES AND NEW AND IN-USE MOTOR VEHICLE ENGINES: CERTIFICATION AND TEST PROCEDURES

33. The authority citation for part 86 continues to read as follows:

Authority: Secs. 202, 203, 205, 206, 207, 208, 215, 216, 217, 301(a) of the Clean Air Act as amended; 42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7549, 7550, 7552, and 7601; and sec. 9701 of the Independent Offices Appropriations Act (31 U.S.C. 9701).

Subpart A—[Amended]

34. Section 86.094–2 is proposed to be amended by adding the following definition in alphabetical order:

§ 86.094–2 Definitions.

* * * * *

Certification Short Test means the test, for light-duty vehicles and light-duty trucks, performed in accordance with the procedures contained in 40 CFR part 86 subpart 0.

* * * * *

35. Section 86.094–3 is amended by revising paragraph (b) to read as follows:

§ 86.094–3 Abbreviations.

* * * * *

(b) The abbreviations in this section apply to this subpart, and also to subparts B, C, E, F, G, K, M, N, O, and P of this part, and have the following meanings:

ALVW—Adjusted Loaded Vehicle Weight.
CST—Certification Short Test.
OMNMHCE—Organic Material Non-Methane Hydrocarbon Equivalent.
PM—Particulate Matter.
THC—Total Hydrocarbons.

36. Section 86.094–8 is proposed to be amended by adding new paragraphs (a)(1)(iii) and (a)(3) to read as follows:

§ 86.094–8 Emission standards for 1994 and later model year light-duty vehicles.

* * * * *

(a)(1) * * *

(iii) CST emissions from gasoline-fueled Otto-cycle light-duty vehicles measured and calculated in accordance with subpart O of this part shall not exceed:

(A) Hydrocarbons: 50 ppm as hexane.
(B) Carbon monoxide: 0.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(iii) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions

* * * * *

37. Section 86.094–9 is proposed to be amended by adding new paragraphs (a)(1)(v) and (a)(3) to read as follows:

§ 86.094–9 Emission standards for 1994 and later model year light-duty trucks.

(a)(1) * * *

(v) CST emissions from gasoline-fueled Otto-cycle light-duty trucks measured and calculated in accordance with subpart O of this part shall not exceed:

(A) Hydrocarbons: 50 ppm as hexane.
(B) Carbon monoxide: 0.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(v) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

38. Section 86.094–24 is proposed to be amended by adding a new paragraph (b)(1)(xii) to read as follows:

§ 86.094–24 Test vehicles and engines.

* * * * *

(b) * * *

(1) * * *

(xii) For CST exhaust emission compliance for each engine family, the Administrator will select for testing one vehicle from among the vehicles selected in accordance with paragraphs (b)(1) (i) through (iv) of this section. This vehicle shall be tested by the manufacturer in accordance with the test procedures set forth in subpart O of this part.

* * * * *

39. Section § 86.095–24 is proposed to be amended by adding a new paragraph (b)(1)(xii) to read as follows:

§ 86.095–24 Test vehicles and engines.

* * * * *

(b) * * *

(1) * * *

(xii) For CST exhaust emission compliance for each engine family, the Administrator will select for testing one vehicle from among the vehicles selected in accordance with paragraphs (b)(1) (i) through (iv) of this section. This vehicle shall be tested by the manufacturer in accordance with the test procedures set forth in subpart O of this part.

* * * * *

40. Section 86.096–8 is proposed to be amended by adding new paragraphs (a)(1)(iii) and (a)(3) to read as follows:

§ 86.096–8 Emission standards for 1996 and later model year light-duty vehicles.

* * * * *

(a)(1) * * *

(iii) CST emissions from gasoline-fueled Otto-cycle light-duty vehicles measured and calculated in accordance with subpart O of this part shall not exceed:

(A) Hydrocarbons: 50 ppm as hexane.
(B) Carbon monoxide: 0.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(iii) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

41. Section 86.097–9 is proposed to be amended by adding new paragraphs (a)(1)(iv) and (a)(3) to read as follows:

§ 86.097–9 Emission standards for 1997 and later model year light-duty trucks.

(a)(1) * * *

(iv) CST emissions from gasoline-fueled Otto-cycle light-duty trucks measured and calculated in accordance with subpart O of this part shall not exceed:

(A) Hydrocarbons: 50 ppm as hexane.
(B) Carbon monoxide: 0.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(iv) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

Subpart B—[Amended]

42. Section 86.116–90 is proposed to be amended by adding paragraph (c)(5) and removing and reserving paragraph (d)(1) to read as follows:

§ 86.116–90 Calibrations, frequency and overview.

* * * * *

(c) * * *

(5) Check the oxides of nitrogen converter efficiency.

(d) * * *
(1) [Reserved]
* * * * *

43. Section 86.123–78 is proposed to be amended by revising paragraph (a) introductory text to read as follows:

§ 86.123–78 Oxides of nitrogen analyzer calibration.

* * * * *

(a) Prior to introduction into service and at least monthly thereafter the chemiluminescent oxides of nitrogen analyzer shall be checked for NO_2 to NO converter efficiency. Figure B78–9 is a reference for paragraphs (a)(2) through (11) of this section.

* * * * *

44. Section 86.142–90 is proposed to be amended by revising paragraphs (d), (e), (f), (g), (h), (i), (k), (l), (m), (o) and (p), and removing and reserving paragraphs (q) and (r) to read as follows:

§ 86.142–90 Records required.

* * * * *

(d) Test results.
(e) Driver and equipment operator IDs.
(f) Vehicle: ID number, manufacturer, model year, standards, engine family, evaporative emissions family, basic engine description (including displacement, number of cylinders, turbo-/supercharger used, and catalyst usage), fuel system (including number of carburetors, number of carburetor barrels, fuel injection type, and fuel tank(s) capacity and location), engine code, gross vehicle weight rating, inertia weight class, actual curb weight at zero miles, actual road load at 50 mph (80 kph), transmission configuration, axle ratio, car line, system miles, idle rpm, and drive wheel tire pressure, as applicable.
(g) Dynamometer: Dynamometer ID, inertia weight setting, indicated power absorption setting, records to verify compliance with the vehicle speed versus time requirements of the test, and driving distance for each of the three phases of the test, calculated from the measured roll or shaft revolutions.
(h) Gas analyzers: Analyzer bench ID, analyzer ranges, recordings of analyzer output during zero, span, and sample readings.
(i) Recorder charts: Test number, date, vehicle ID, operator ID, and identification of the measurements recorded.
* * * * *
(k) Temperatures: Records to verify compliance with the ambient temperature requirements throughout the test procedure and recordings of vehicle fuel temperature(s) during the diurnal test and of the enclosure temperatures during the diurnal and hot soak tests.
(l) CFV CVS: Total dilute exhaust volume (V_{mix}) for each phase of the exhaust test.
(m) PDP CVS: Test measurements required to calculate the V_{mix}. Total dilute exhaust volume (V_{mix}) for each phase of the exhaust test.
* * * * *
(o) *Additional required records for petroleum-fueled and methanol-fueled diesel vehicles.* (1) Pressure and temperature of the dilute exhaust mixture (and background air if sampled) at the inlet to the gas meter used for particulate sampling.
(2) The temperature of the dilute exhaust mixture inside the dilution tunnel near the inlet of the particulate probe.
(3) The temperature of the gas flowing in the heated sample line before the heated filter, and also before the HFID, and the temperature of the control system of the heated hydrocarbon detector.
(4) Gas meter or flow measurement instrumentation readings at the start of each sample period and at the end of each sample period.
(5) The stabilized pre-test weight and post-test weight of each particulate sample and back-up filter.
(6) Continuous temperature and humidity recording of the ambient air in which the particulate filters were stabilized.
(p) *Additional required records for methanol-fueled vehicles.* (1) Specification of the methanol fuel used during the test.
(2) Volume of sample passed through the methanol sampling system and the volume of deionized water in each impinger.
(3) The methanol concentration in the reference sample and the peak area from the GC analyses of the reference sample.
(4) The peak area of the GC analyses of the test samples (methanol).
(5) Volume of the sample passed through the formaldehyde sampling system, and the volume of DNPH solution in each impinger.
(6) The formaldehyde concentration in the reference sample and the peak area from the HPLC analysis of the reference sample.
(7) The peak area from the HPLC analysis of the test sample (formaldehyde).
(8) The temperature of the sample lines before the HFID and the impingers, and the temperature of the control system of the heated hydrocarbon detector.
(q) [Reserved]
(r) [Reserved]

45. The heading for subpart D is revised to read as follows:

Subpart D—Emission Regulations for New Gasoline-Fueled and Diesel-Fueled Heavy-Duty Engines; Gaseous Exhaust Test Procedures

46. Section 86.319–79 is proposed to be amended by revising paragraph (b) to read as follows:

§ 86.319–79 Analyzer checks and calibrations; frequency and overview.

* * * * *

(b) At least monthly during testing, check the NO_x converter efficiency, as described in § 86.332.

* * * * *

47. Section 86.332–79 is proposed to be amended by revising paragraph (a) and removing and reserving paragraphs (d) and (e) to read as follows:

§ 86.332–79 Oxides of nitrogen analyzer calibration.

(a) At least monthly during testing, perform a converter efficiency check as described in paragraph (b) of this section. Perform a monthly linearity check as described in paragraph (c) of this section.

* * * * *

(d) [Reserved]
(e) [Reserved]

Subpart F—[Amended]

48. Section 86.516–90 of subpart F is proposed to be amended by adding a new paragraph (c)(3) and removing and reserving paragraph (d)(1) to read as follows:

§ 86.516–90. Calibrations, frequency and overview.

* * * * *

(c) * * *
(3) Check the oxides of nitrogen converter efficiency.
(d) * * *
(1) [Reserved]
* * * * *

49. Section 86.523–78 is proposed to be amended by revising paragraph (a) introductory text to read as follows:

§ 86.523–78 Oxides of nitrogen analyzer calibration.

(a) Prior to introduction into service and at least monthly thereafter, if oxides of nitrogen are measured, the chemiluminescent oxides of nitrogen analyzer shall be checked for NO_2 to NO converter efficiency. Figure F78–8 is a reference for paragraphs (a)(1) through (11) of this section.

* * * * *

Subpart G—[Amended]

50. Section 86.608–94 is proposed to be added to read as follows:

§ 86.608–94 Test procedures.

Section 86.608–94 includes text that specifies requirements that differ from § 86.608–90. Where a paragraph in § 86.608–90 is identical and applicable to § 86.608–94, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.608–90." Where a corresponding paragraph of § 86.608–90 is not applicable, this is indicated by the statement "[Reserved]."

(a) The prescribed test procedures are the FTP as described in subpart B of this part, the cold temperature CO test procedure as described in subpart C of this part, and the CST as described in subpart O of this part. For purposes of Selective Enforcement Audit testing, the manufacturer shall not perform any of the test procedures in subpart B of this part relating to evaporative emission testing, except as specified in paragraph (a)(2) of § 86.608–90.

(1) The Administrator may select and prescribe the sequence of any CSTs. Further, the Administrator may, on the basis of a written application by a manufacturer, approve optional test procedures other than those in subparts B, C, and O of this part for any motor vehicle which he determines is not susceptible to satisfactory testing using the procedures in subparts B, C, and O of this part.

(a)(2) through (a)(3) [Reserved]. For guidance see § 86.608–90.

(a)(4) The exceptions to the test procedures in subpart O of this part are applicable to Selective Enforcement Audit testing are listed in paragraphs (a)(4)(i) and (ii) of this section.

(i) The manufacturer need not comply with § 86.1442, since the records required therein are provided under other provisions of subpart G of this part.

(ii) In addition to the requirements of subpart O of this part the manufacturer shall prepare vehicles as in paragraphs (a)(4)(ii) (A) through (C) prior to exhaust emission testing.

(A) The manufacturer shall inspect the fuel system to insure the absence of any leaks of liquid or vapor to the atmosphere by applying a pressure of 14.5±0.5 inches of water to the fuel system, allowing the pressure to stabilize, and isolating the fuel system from the pressure source. pressure must not drop more than 2.0 inches of water in five minutes. If required, the manufacturer shall perform corrective action in accordance with this section and report this action in accordance with § 86.609.

(B) When performing this pressure check, the manufacturer shall exercise care to neither purge nor load the evaporative system.

(C) The manufacturer shall not modify the test vehicle's evaporative emission control system by component addition, deletion, or substitution.

(b) through (i) [Reserved]. For guidance see § 86.608–90.

51. A new § 86.609–94 is proposed to be added to read as follows:

§ 86.609–94 Calculation and reporting of test results.

Section 86.609–94 includes text that specifies requirements that differ from § 86.609–84. Where a paragraph in § 86.609–84 is identical and applicable to § 86.609–94, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.609–84." Where a corresponding paragraph of § 86.609–84 is not applicable, this is indicated by the statement "[Reserved]."

(a) Initial test results are calculated following the Federal Test Procedure and the CST specified in paragraph § 86.608(a). Round the initial test results to the number of decimal places contained in the applicable emission standard expressed to one additional significant figure, in accordance with ASTM E 29–90 ("Standard practice for using significant digits in test data to determine conformance with specifications," American Society for Testing and Materials, 1990). Copies may be obtained from American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103. Copies may be inspected at the EPA Docket Office, Room M–1500, 401 M Street SW., Washington, DC 20460.

(b) Final test results for each test vehicle shall be calculated by summing the initial test results within a specific CST or FTP derived in paragraph (a) of this section for each test vehicle, dividing by the number of times that specific CST or FTP has been conducted on the vehicle, and rounding, in accordance with ASTM E 29–90 (as referenced in paragraph (a) of this section), to the same number of decimal places to the right of the decimal point as the initial test results.

(c) *Final deteriorated test results.* (1) The final deteriorated test results for each light-duty vehicle tested in accordance with subpart B of this part are calculated by multiplying the final test results by the appropriate deterioration factor derived from the certification process for the engine family and model year to which the selected configuration belongs and rounded in accordance with ASTM E 29–90 (as referenced in paragraph (a) of this section) to two significant figures. For the purpose of this paragraph, if a deterioration factor as computed during the certification process is less than one, that deterioration factor shall be one.

(2) There are no deterioration factors for light-duty vehicles tested in accordance with subpart O of this part. Accordingly, for the CST the term "final deteriorated test results" shall mean the final test results derived in paragraph (b) of this section for each test vehicle, rounded to the same number of significant figures contained in the applicable standard in accordance with ASTM E 29–90 (as referenced in paragraph (a) of this section).

(d) [Reserved]. For guidance see § 86.609–84.

52. A new § 86.610–94 is proposed to be added to read as follows:

§ 86.610–94 Compliance with acceptable quality level and passing and failing criteria for Selective Enforcement Audits.

(a) The prescribed acceptable quality level is 40 percent.

(b) A failed vehicle is one whose final deteriorated test results pursuant to paragraph § 86.609(c), for one or more of the applicable exhaust pollutants, exceed the applicable emission standard. For the CST as described in subpart O of this part, a vehicle fail determination is made if the final deteriorated test results for HC and/or CO emissions from any CST exceed the applicable emission standard.

(c) *Pass/fail criteria.*—(1) *FTP criteria.* The manufacturer shall test vehicles comprising the test sample until a pass decision is reached for all pollutants, or a fail decision is reached for one pollutant. A pass decision is reached when the cumulative number of failed vehicles, as defined in paragraph (b) of this section, for each pollutant is less than or equal to the fail decision number appropriate to the cumulative number of vehicles tested. A fail decision is reached when the cumulative number of failed vehicles for one pollutant is greater than or equal to the fail decision number appropriate to the cumulative number of vehicles tested. The pass and fail decision numbers associated with the cumulative number of vehicles tested are determined by use of the Tables in Appendix XI to this part appropriate for the annual projected sales as made by the manufacturer in its report submitted under 40 CFR 600.207–80(a)(2) (the Automobile Fuel Economy Regulations). In the Tables in Appendix XI, sampling plan "stage" refers to the cumulative

number of vehicles tested. Once a pass decision has been made for a particular pollutant, the number of vehicles whose final deteriorated test results exceed the emission standard for that pollutant shall not be considered any further for purposes of the audit.

(2) *CST criteria.* The manufacturer shall test vehicles comprising the test sample until a pass or fail decision is reached for the CST. A pass decision is reached when the cumulative number of failed vehicles, as defined in paragraph (b) of this section, for the CST is less than or equal to the pass decision number appropriate to the cumulative number of vehicles tested. A fail decision is reached when the cumulative number of failed vehicles for the CST is greater than or equal to the fail decision number appropriate to the cumulative number of vehicles tested. The pass and fail decision numbers associated with the cumulative number of vehicles tested are determined by use of the Tables in Appendix XI to this part appropriate for the annual projected sales as made by the manufacturer in its report submitted under 40 CFR 600.207–80(a)(2) (the Automobile Fuel Economy Regulations). In the Tables in Appendix XI, sampling plan "stage" refers to the cumulative number of vehicles tested. Once a pass decision has been made for the CST, the number of vehicles whose final deteriorated test results exceed the emission standard for the CST shall not be considered any further for purposes of the audit.

(d) Passing or failing of an SEA occurs when the decision is made on the last vehicle required to make a decision under paragraph (c) of this section.

(e) The Administrator may terminate testing earlier than required in paragraph (c) of this section.

Subpart H—[Amended]

53. Section 86.708–94 is proposed to be amended by adding new paragraphs (a)(1) (iii) and (a)(3) to read as follows:

§ 686.708–94 In-use emission standards for 1994 and later model year light duty vehicles.

* * * * *

(a)(1) * * *

(iii) CST emissions from gasoline-fueled Otto-cycle light-duty vehicles measured and calculated in accordance with subpart 0 of this part shall not exceed:

(A) Hydrocarbons: 220 ppm as hexane.

(B) Carbon monoxide: 1.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(iii) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

54. Section 86.708–98 is proposed to be amended by adding new paragraphs (a)(1)(iii) and (a)(3) to read as follows:

§ 686.708–98 In-use emission standards for 1998 and later model year light duty vehicles.

* * * * *

(a)(1) * * *

(iii) CST emissions from gasoline-fueled Otto-cycle light-duty vehicles measured and calculated in accordance with subpart 0 of this part shall not exceed:

(A) Hydrocarbons: 220 ppm as hexane.

(B) Carbon monoxide: 1.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(iii) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

55. Section 86.709–94 is proposed to be amended by adding new paragraphs (a)(1)(iv) and (a)(3) to read as follows:

§ 86.709–94 In-use emission standards for 1994 and later model year light-duty trucks.

* * * * *

(a)(1) * * *

(v) CST emissions from gasoline-fueled Otto-cycle light-duty trucks measured and calculated in accordance with subpart O of this part shall not exceed:

(A) Hydrocarbons: 220 ppm as hexane.

(B) Carbon Monoxide: 1.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(v) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

56. Section 86.709–99 is proposed to be amended by adding new paragraphs (a)(1)(iv) and (a)(3) to read as follows:

§ 86.709–99 In-use emission standards for 1999 and later model year light-duty trucks.

* * * * *

(a)(1) * * *

(iv) CST emissions from gasoline-fueled Otto-cycle light-duty trucks measured and calculated in accordance with subpart O of this part shall not exceed:

(A) Hydrocarbons: 220 ppm as hexane.

(B) Carbon monoxide: 1.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(iv) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

Subpart K—[Amended]

57. A new § 86.1008–94 is proposed to be added to read as follows:

§ 86.1008–94 Test procedures.

Section 86.1008–94 includes text that specifies requirements that differ from § 86.1008–90. Where a paragraph in § 86.1008–90 is identical and applicable to § 86.1008–94, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1008–90." Where a corresponding paragraph of § 86.1008–90 is not applicable, this is indicated by the statement "[Reserved]."

(a)(1) For heavy-duty engines, the prescribed test procedure is the Federal Test Procedure as described in subparts N, I, and P of this part.

(2) For light-duty trucks, the prescribed test procedures are the FTP as described in subparts B, C, and P of this part and the CST as described in subpart O of this part. The manufacturer shall not perform the evaporative emission test procedure contained in subpart B. The Administrator may, based on advance application by a manufacturer, approve optional test procedures for use in Selective Enforcement Audit Testing.

(a)(3) [Reserved]. For guidance see § 86.1008–90.

(a)(4) When testing light-duty trucks the following exception to the test procedures in subpart O is applicable:

(i) The manufacturer need not comply with § 86.1442, since the records required therein are provided under other provisions of subpart K of this part.

(ii) In addition to the requirements of subpart O of this part the manufacturer shall prepare vehicles as described in paragraphs (a)(4)(ii) (A) through (C) of this section prior to exhaust emission testing.

(A) The manufacturer shall inspect the fuel system to insure the absence of any leaks of liquid or vapor to the atmosphere by applying a pressure of 14.5 ±0.5 inches of water to the fuel system, allowing the pressure to stabilize, and isolating the fuel system from the pressure source, pressure must not drop more than 2.0 inches of water

(8) Carbon monoxide: 1.2%.

* * * * *

(3) The standards set forth in paragraph (a)(1)(iv) of this section refer to the exhaust emitted during the CST as set forth in subpart O of this part and measured and calculated in accordance with those provisions.

* * * * *

in five minutes. If required, the manufacturer shall perform corrective action in accordance with this section and report this action in accordance with § 86.1009.

(B) When performing this pressure check, the manufacturer shall exercise care to neither purge nor load the evaporative system.

(C) The manufacturer shall not modify the test vehicle's evaporative emission control system by component addition, deletion, or substitution.

(a)(5) [Reserved]. For guidance see § 86.1008–90.

(a)(6) The Administrator may select and prescribe the sequence of any CSTs. Further, the Administrator, may on the basis of a written application by a manufacturer, prescribe minor test procedure variations from those set forth in paragraphs (a)(1) and (a)(2) of this section for any heavy-duty engine or light-duty truck.

(b) through (g)(2) [Reserved]. For guidance see § 86.1008–90.

(g)(3) Light-duty truck manufacturers shall complete emission testing at their facility on a minimum of four vehicles per 24-hour period, including each voided test.

(g)(4) through (i) [Reserved]. For guidance see § 86.1008–90.

58. A new § 86.1009–94 is proposed to be added to read as follows:

§ 86.1009–94 Calculation and reporting of test results.

Section 86.1009–94 includes text that specifies requirements that differ from § 86.1009–84. Where a paragraph in § 86.1009–84 is identical and applicable to § 86.1009–94, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.1009–84." Where a corresponding paragraph of § 86.1009–84 is not applicable, this is indicated by the statement "[Reserved]."

(a) Initial test results are calculated following the FTP and the CST specified in paragraph § 86.1008(a). Round these results to the number of decimal places contained in the applicable emission standard expressed to one additional significant figure, in accordance with ASTM E 29–90 ("Standard practice for using significant digits in test data to determine conformance with specifications," American Society for Testing and Materials, 1990) . Copies may be obtained from American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103. Copies may be inspected at the EPA Docket Office, room M–1500, 401 M Street, SW., Washington, DC 20460.

(b) Final test results are calculated by summing the initial test results within a specific CST or FTP derived in paragraph (a) of this section for each test engine or vehicle, dividing by the number of times that specific CST or FTP has been conducted on the engine or vehicle, and rounding in accordance with ASTM E 29–90 (as referenced in paragraph (a) of this section) to the same number of decimal places contained in the applicable standard expressed to one additional significant figure.

(c) Introductory text through (c)(2) [Reserved]. For guidance see § 86.1009–84.

(c)(3) There are no deterioration factors for light-duty vehicles tested in accordance with subpart O of this part. Accordingly, for the CST the term "final deteriorated test results" shall mean the final test results derived in paragraph (b) of this section for each test vehicle.

(4) The final deteriorated test results are rounded to the same number of significant figures contained in the applicable standard in accordance with ASTM E 29–90 (as referenced in paragraph (a) of this section).

(d) [Reserved]. For guidance see § 86.1009–84.

59. A new § 86.1010–94 is proposed to be added to read as follows:

§ 86.1010–94 Compliance with acceptable quality level and passing and failing criteria for Selective Enforcement Audits.

(a) The prescribed acceptable quality level is 40 percent.

(b) A failed engine or vehicle is one whose final deteriorated test results pursuant to paragraph § 86.1009(c), for one or more of the applicable exhaust pollutants, exceed the applicable emission standard or compliance level. For the CST as described in subpart O of this part, a vehicle fail determination is made if the final deteriorated test results for HC and/or CO emissions from any CST exceed the applicable emission standard.

(c) *Pass/fail criteria*—(1) *FTP criteria.* The manufacturer shall test heavy-duty engines or light-duty trucks comprising the test sample until a pass decision is reached for all pollutants, or a fail decision is reached for one pollutant. A pass decision is reached when the cumulative number of failed engines or vehicles, as defined in paragraph (b) of this section, for each pollutant is less than or equal to the past decision number appropriate to the cumulative number of engines or vehicles tested. A fail decision is reached when the cumulative number of failed engines or vehicles for one or more pollutants is greater than or equal to the fail decision number appropriate to the cumulative number of engines or vehicles tested. The pass and fail decision numbers associated with the cumulative number of engines or vehicles tested are determined by use of the Tables in Appendix X to this part appropriate to the projected sales as made by the heavy-duty engine manufacturer in its Application for Certification or as made by the light-duty truck manufacturer as made in its report submitted under 40 CFR 600.207–80(a)(2) (the Automobile Fuel Economy Regulations). In the Tables in Appendix X to this part, sampling plan "stage" refers to the cumulative number of engines or vehicles tested. Once a pass or fail decision has been made for a particular pollutant, the number of engines or vehicles whose final deteriorated test results exceed the emission standard or compliance level, if applicable, for that pollutant shall not be considered any further for purposes of the audit.

(2) *CST criteria.* The manufacturer shall test vehicles comprising the test sample until a pass or fail decision is reached for the CST. A pass decision is reached when the cumulative number of failed vehicles, as defined in paragraph (b) of this section, for the CST is less than or equal to the pass decision number appropriate to the cumulative number of vehicles tested. A fail decision is reached when the cumulative number of failed vehicles for the CST is greater than or equal to the fail decision number appropriate to the cumulative number of vehicles tested. The pass and fail decision numbers associated with the cumulative number of vehicles tested are determined by use of the Tables in Appendix XI to this part appropriate for the annual projected sales as made the manufacturer in its report submitted under 40 CFR 600.207–80(a)(2) the Automobile Fuel Economy Regulations). In the Tables in Appendix XI, sampling plan "stage" refers to the cumulative number of vehicles tested. Once a pass decision has been made for the CST, the number of vehicles whose final deteriorated test results exceed the emission standard for the CST shall not be considered any further for purposes of the audit.

(d) Passing or failing of an SEA occurs when the decision is made on the last vehicle required to make a decision under paragraph (c) of this section.

(e) The Administrator may terminate testing earlier than required in paragraph (c) of this section.

Subpart N—[Amended]

60. Section 86.1316–90 is proposed to be amended by adding a new paragraph

(b)(3) and removing and reserving paragraph (c)(1) to read as follows:

§ 86.1316–90 Calibrations; frequency and overview.

* * * * *

(b) * * *

(3) Check the oxides of nitrogen converter efficiency.

(c) * * *

(1) [Reserved]

* * * * *

61. Section 86.1323–84 is to be amended by revising paragraph (a) introductory text to read as follows:

§ 86.1323–84 Oxides of nitrogen analyzer calibration.

* * * * *

(a) Prior to introduction into service and at least monthly thereafter, the chemiluminescent oxides of nitrogen analyzer shall be checked for NO_2 to NO converter efficiency. Figure N84–9 is a reference for paragraphs (a) (1) through (11) of this section.

* * * * *

62. A new subpart O is proposed to be added to read as follows:

Subpart O—Emission Regulations for New Gasoline-Fueled OttoCycle Light-Duty Vehicles and New Gasoline-Fueled Otto-Cycle Light-Duty Trucks; Certification Short Test Procedures

Sec.

86.1401–94 Scope; applicability.
86.1402–94 Definitions.
86.1403–94 Abbreviations.
86.1404–94 Section numbering; construction.
86.1405–94 Introduction; structure of subpart.
86.1406–94 Equipment required and specifications; overview.
86.1407–94 [Reserved]
86.1408–94 Dynamometer.
86.1409–94 through § 86.1410–94 [Reserved]
86.1411–94 Exhaust gas analysis system.
86.1412–94 [Reserved]
86.1413–94 Fuel specifications.
86.1414–94 through § 86.1415–94 [Reserved]
86.1416–94 Calibration; frequency and overview.
86.1417–94 through § 86.1421–94 [Reserved]
86 .1422–94 Analyzer calibration.
86.1423–94 through § 86.1425–94 [Reserved]
86.1426–94 Calibration of other equipment.
86.1427–94 Certification Short Test procedure; overview.
86.1428–94 through § 86.1429–94 [Reserved]
86.1430–94 Test sequence; general requirements.
86.1431–94 [Reserved]
86.1432–94 Vehicle preparation.
86.1433–94 through § 86.1436–94 [Reserved]
86.1437–94 Test run—manufacturer.
86.1438–94 Test run—EPA.
86.1439–94 through § 86.1441–94 [Reserved]
86.1442–94 Information required.

Subpart O—Emission Regulations for New Gasoline-Fueled Otto-Cycle Light-Duty Vehicles and New Gasoline-Fueled Otto-Cycle Light-Duty Trucks; Certification Short Test Procedures

86.1401–94 Scope; applicability.

This subpart contains CST procedures for gasoline-fueled Otto-cycle light-duty vehicles, and for gasoline-fueled Otto-cycle light-duty trucks. It applies to 1994 and later model years.

686.1402–94 Definitions.

The definitions in § 86.094–2 of subpart A of this part apply to this subpart.

686.1403–94 Abbreviations.

The abbreviations in § 86.094–3 of subpart A of this part apply to this subpart.

686.1404–94 Section numbering; construction.

(a) The model year of first-chance applicability is indicated by the section number. The two digits following the hyphen designate the first model year for which a section is effective. A section remains effective until superseded.

Example: Section 86.1411–94 applies to the 1994 and subsequent model years until superseded. If § 86.1411–96 is promulgated, it would take effect beginning with the 1996 model year. Section 86.1411–94 would apply to model years 1994 through 1995.

(b) A section reference without a model year suffix refers to the section applicable for the appropriate model year.

(c) All provisions in this subpart apply to gasoline-fueled Otto-cycle light-duty vehicles and to gasoline-fueled Otto-cycle light-duty trucks.

§ 86.1405–94 Introduction; structure of subpart.

(a) This subpart describes equipment and the procedures required to perform the CST on gasoline-fueled Otto-cycle light-duty vehicles and gasoline-fueled Otto-cycle light-duty trucks. Subpart A of this part sets forth the testing requirements, reporting requirements and test intervals necessary to comply with EPA certification procedures, subpart H of this part sets forth the standards for in-use testing, and part 85, subpart W of this chapter sets forth the testing requirements for inspection and maintenance testing (which also may be utilized as part of the CST as defined in this subpart).

(b) Three topics are addressed in this subpart. Sections 86.1406 through 86.1413 set forth specifications and equipment requirements; §§ 86.1416 through 86.1426 discuss calibration methods and frequency; and test procedures and data requirements are listed in §§ 86.1427 through 86.1442.

§ 86.1406–94 Equipment required and specifications; overview.

(a) This subpart contains procedures for performing the CST on gasoline-fueled Otto-cycle light-duty vehicles and gasoline-fueled Otto-cycle light-duty trucks. Equipment required and specifications are as described in paragraphs (a)(1) and (2) of this section.

(1) *Exhaust emission tests.* All vehicles subject to this subpart are tested for exhaust emissions. Necessary equipment and specifications appear in §§ 86.1408 and 86.1411.

(2) *Fuel and analytical tests.* Fuel requirements for the CST are specified in § 86.1413.

(b) [Reserved]

§ 86.1408–94 Dynamometer.

(a) When a CST employs steady-state loaded operation, the dynamometer must be adjusted to the lowest inertial weight setting. When a CST employs transient loaded warm-up operation, the dynamometer shall be adjusted to the setting as described in § 86.129–94.

(b) All other requirements of this section are set forth in paragraphs (b) and (c) of § 85.2230 of this chapter.

§ 86.1411–94 Exhaust gas analysis system.

The requirements of this section are set forth in § 85.2225 (b) and (c) of this chapter, except that the NO and O_2 channels are optional. Other procedures and equipment may be used if shown to yield equivalent or superior results if approved in advance by the Administrator.

§ 86.1413–94 Fuel specifications.

(a) In addition to the Reid Vapor Pressure (RVP) requirements for each testing option as specified in Table O–94–1 of § 86.1430(b), the test fuel to be used for testing options shall conform to the specifications listed in paragraphs (a)(1) through (6) of this section.

(1) MTBE and other oxygenates shall not exceed 0.1% by volume.

(2) The octane content shall not be less than 89 RON.

(3) The distillation temperature corresponding to a 90% distilled volume (T90) shall not be less than 351° F.

(4) The aromatic content shall not be less than 38% by volume.

(5) The olefin content shall not be greater than 3% by volume.

(6) The sulfur content shall not be less than 0.06% by weight.

(b) [Reserved]

§ 86.1416–94 Calibration; frequency and overview.

(a) Calibrations shall be performed as specified in paragraphs (b) through (h) of § 85.2233 of this chapter, with the exception that the calibrations performed at seventy-two hour intervals in § 85.2233(e) of this chapter shall instead be performed prior to each CST.

(b) At least monthly or after any maintenance which could alter calibration, the calibration of the analyzer shall be checked. The analyzer shall be adjusted or repaired as necessary.

(c) Water traps, filters, and conditioning columns shall be checked before each test, and adjusted, repaired or replaced as necessary.

§ 86.1422–94 Analyzer calibration.

(a) Determine that the analyzer has met the acceptance criteria specified in § 85.2225(c) of this chapter in accordance with the specifications and procedures described in the BAR 90 Test Analyzer System Specifications (available from the California Department of Consumer Affairs, Bureau of Automotive Repair, 10240 Systems Parkway, Sacramento, CA 95827), sections 6 and 8 (with the exception of section 6.19, which may be omitted).

(b) *Initial and periodic check.* Prior to its introduction into service and at specified periods thereafter, the analyzer shall receive calibration in accordance with paragraphs (b) through (h) of § 85.2233 of this chapter and with good engineering practice.

§ 86.1426–94 Calibration of other equipment.

Other test equipment used for testing shall be calibrated as often as necessary in accordance with good engineering practice.

§ 86.1427–94 Certification Short Test; overview.

(a) The test procedure described in this subpart is designed to measure raw concentrations of CO (percent) and HC (parts per million) in the exhaust flow under conditions and test modes encountered in the conduct of the Emission Control System Performance Warranty Short Tests, described in part 85, subpart W of this chapter. Emission sampling may occur during idle, 2500 rpm, and loaded modes. Specific conditions defined by this test procedure include fuel characteristics, ambient temperature, and waiting periods prior to being tested.

(b) *Testing by the manufacturer for certification data submittal.* (1) The options provided for testing under this subpart include a cold temperature test with high RVP winter grade fuel, a hot temperature test with a low RVP summer grade fuel, and a moderate temperature test with high RVP fuel, as described in Table O–94–1 of § 86.1430. The manufacturer shall complete testing for the data submittal in accordance with the provisions of § 86.094–23 of subpart A, part 86 under a minimum of one of these scenarios. The scenario selected shall be the one that, in the manufacturer's best judgment, represents the worst case, meaning the highest probability that the test vehicle would fail.

(2) In addition to testing under one of the sets of conditions specified in this subpart, the manufacturer may optionally test under conditions outside the ranges specified in this subpart.

(c) *Testing by the Administrator.* The Administrator reserves the right to conduct testing in accordance with the test procedures described in this subpart and/or the first chance test portions of the test procedures described in part 85, subpart W of this chapter under test conditions within the ranges specified in this subpart. In order for an engine family to be eligible for certification, each of its test vehicles that is subjected to one or more CSTs must obtain a passing result for each combination of fuel, temperature, and test procedure employed in those CSTs, subject to the Administrator's discretion.

(d) *Alternative procedures.* (1) If a vehicle cannot be tested using any of the six test procedures described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, and 85.2220 of this chapter, the manufacturer may request alternative test procedures. The alternative test procedures shall be those which have been approved in advance by the Administrator in accordance with the provisions of § 85.2208 of this chapter.

(2) The emission control information label for any vehicle for which approval has been granted regarding alternative test procedure(s) must note such approval in order for the approval procedures to be effective for that vehicle.

§ 86.1430–94 Certification Short Test sequence; general requirements.

(a) The following sequence lists the major steps encountered during the CST. These steps are described in paragraph (b) of this section and in §§ 86.1432, 86.1437, and 86.1438. Testing conducted for the manufacturer's data submittal shall be in accordance with the provisions of § 86.094–23.

(1) *Test conditions and procedures.* (i) Manufacturer's data submittal. Test conditions shall be selected from Table O–94–1 of paragraph (b) of this section. Further, the vehicle preparation and test run shall be those described in §§ 86.1432 and 86.1437.

(ii) Testing by the Administrator. Test conditions shall be selected from among the set of conditions in Table O–94–2 of paragraph (b) of this section. Further, one or more CST shall be performed in accordance with the provisions of §§ 86.1432 and 86.1438.

(2) Drain and fill, as specified in § 86.1432(b).

(3) Engine start.

(4) *Warm-up operation.* (i) Optionally for the manufacturer's data submittal, warm-up operation is allowed to be performed as specified in § 86.1432(c).

(ii) Testing by the Administrator. Warm-up operation is required to be performed as specified in § 86.1432(c).

(5) *Wait time.* (i) Manufacturer's data submittal. A 25 to 30 minute vehicle wait time of free idle with optional keyoffs and restarts shall be required.

(ii) Testing by the Administrator. A three to 30 minute vehicle wait time of free idle with optional keyoffs and restarts shall be required.

(6) *Test procedure.* (i) For the manufacturer's certification data submittal:

(A) The test procedure begins with the Two Speed Idle Test—EPA 91, which shall be performed as specified in § 85.2215 of this chapter and § 86.1437(g) (first-chance test only), followed by;

(B) A 25 to 30 minute vehicle wait time of free idle with optional keyoffs and restarts, as specified in § 86.1437(h), followed by;

(C) The Loaded Test—EPA 91 as specified in § 85.2217 of this chapter and § 86.1437(i).

(ii) For testing by the Administrator:

(A) The Administrator may select from among the procedures described in paragraph (a)(6)(i) of this section, except that the wait time defined in paragraph (a)(6)(i)(B) of this section shall be three to 30 minutes. Alternatively, the Administrator may select the first-chance test of one or more test procedures described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, or 85.2220 of this chapter. For recall program testing, in-use vehicles will be set to the manufacturer's specifications.

(B) *Multiple CSTs.* If the Administrator elects to conduct more than one CST on a test vehicle in cases other than failure or voiding,

subsequent CSTs shall initiate at the point described in paragraph (a)(1)(ii) of this section. A drain and fill may be performed in accordance with the provisions of § 86.1432(b)

(b) The sets of test conditions identified in this subpart are based on specified ranges of test fuel RVP present in the vehicle fuel tank and ambient temperature during the test. Tables O–94–1 and O–94–2 outline the specific ranges of conditions to be employed in the CST. The manufacturer must run the CST described in this subpart under at least one of the three sets of conditions shown in Table O–94–1 for data submittal under the provisions of § 86.094–23. The set of conditions selected shall be the one that, in the manufacturer's best judgment, represents the worst case, meaning the highest probability that the test vehicle would fail.

TABLE O–94–1.—SETS OF CONDITIONS TO BE EMPLOYED FOR MANUFACTURERS DATA SUBMITTAL IN THE CST

	Option #1	Option #2:	Option #3:
	Cold temperature	Moderate temperature	Warm temperature
Fuel RVP	13.8–14.1 psi	13.8–14.1 psi	8.5–9.0 psi
Ambient temperature	20 °F ± 5 °F	70 °F ± 5 °F	90 °F ± 5°F

TABLE O–94–2.—SETS OF CONDITIONS TO BE EMPLOYED BY THE ADMINISTRATOR IN THE CST

	Option #1	Option #2:	Option #3:
	Cold temperature	Moderate temperature	Warm temperature
Fuel RVP	≤14.1 psi	≤14.1 psi	≤9.0 psi
Ambient temperature	15 °F–65 °F	65 °F–75 °F	78 °F–95 °F

(c) Before the warm-up operation described in § 86.1432(c) may begin, the ambient test cell temperature shall be within the range specified in the selected set of test conditions. If the ambient test cell temperature falls outside the specified range during the warm-up operation or the test run, the CST shall abort.

(d) If the engine stalls at any time during the test run, the CST shall abort unless the stall occurs during the wait times described in paragraphs (b) and (d) of § 86.1437 and paragraph (d)(1)(i) of § 86.1438 and falls within the guidelines for keyoff time as described in these paragraphs.

§ 86.1432–94 Vehicle and equipment preparation.

(a) The test conditions to be employed in the CST procedure shall be selected from the applicable options specified in Table O–94–1 or Table O–94–2 of § 86.1430(b).

(b) The fuel tank(s) shall be filled to approximately the prescribed "tank fuel volume" as defined in § 86.082–2 with the specified test fuel. The temperature of the fuel prior to its delivery to the fuel tank shall be between 45 and 60°F (7.2 and 16°C). If the existing fuel in the fuel tank(s) does not meet the specifications contained in § 86.1413 and § 86.1430(b), the existing fuel must be drained prior to the fuel fill as specified above. Refueling during a CST shall not be performed. Draining and refueling between successive CSTs is allowed and is required prior to any CST for which the specified fuel is different than that existing in the tank(s).

(c) *Warm-up operation.* (1) Optionally for the manufacturer's data submittal, warm-up operation to bring the vehicle to normal operating temperature is allowed in accordance with the procedures described in paragraph (c)(2) of this section.

(2) For testing by the Administrator, warm-up operation to bring the vehicle to normal operating temperature is required. Warm-up operation shall take place in the test cell at the specified ambient temperature for the procedure to be performed.

(i) If option #1 of Table O–94–1 or Table O–94–2 of § 86.1430(b) is selected, warm-up operation shall consist of, at a minimum, loaded operation over the first 505 seconds of the Urban Dynamometer Driving Schedule (in accordance with § 86.115 and Appendix I to this part). If no loaded test procedure is to be performed and loaded warm-up operation occurs, up to seven minutes of uncontrolled vehicle operation shall be allowed from the close of a loaded warm-up operation step until the beginning of the test procedure as described in § 86.1436(d).

(ii) If option #2 or #3 of Table O–94–1 or Table O–94–2 of § 86.1430(b) is selected, warm-up operation shall consist of steady-state loaded operation at a minimum of 30 mph for at least 30 seconds, or unloaded operation at 2500 ±300 rpm for at least 90 seconds, or any transient loaded operation for at least 30 seconds.

(d) *Equipment preparation.* Immediately prior to the wait time portion of the test run described in §§ 86.1437 and 86.1438, or immediately prior to warm-up operation, the steps described in paragraphs (d) (1) through (4) of this section must be performed.

(1) Check the device(s) for removing water from the exhaust sample and the sample filter(s). Remove any water from the water trap(s). Clean and replace the filter(s) as necessary.

(2) Set the zero and span points of the analyzer with the electrical spanning network or with analytical gases.

(3) Attach the tachometer to the vehicle in accordance with the analyzer manufacturer's instructions. The manufacturer must assure, for all test and production vehicles and engines, that the rpm signal is capable of being read by an exhaust gas analyzer via:

(i) A conventional inductive tachometer, or

(ii) The onboard diagnostics (OBD) connector, as described under the provisions of § 86.094–17, or

(iii) A dedicated electrical lead, marked "rpm" and located under the hood, with a female-type, quarter-inch spade terminal. The digital transistor-transistor logic (TTL) signal shall span the 0V–5V range at a rate of one pulse per engine revolution, synchronized to the top dead center position.

(4) The sample probe shall be inserted into the tailpipe to a minimum depth of 10 inches. If the vehicle's exhaust system prevents insertion to this depth, a tailpipe extension shall be used, or the probe may be inserted into the tailpipe

to CVS connector through an aperture provided for this purpose.

§ 86.1437–94 Test run—manufacturer.

(a) This section describes the test run performed by the manufacturer for its data submittal pursuant to obtaining a certificate of conformity under the provisions of § 86.094–23. The test run consists of the wait time and the selected test procedure. The entire test run shall be performed in accordance with the conditions in the option selected from Table O–94–1 of § 86.1430–94.

(b) If the vehicle is not in the test cell with an ambient temperature of the option selected from Table O–94–1 of § 86.1430–94, the vehicle shall be moved to the cell at this time. The vehicle shall be started and allowed to idle freely with the transmission in neutral. The vehicle wait time shall begin when the vehicle engine speed is between 350 and 1100 rpm. Following the first three minutes of idle, this wait time may be interrupted by vehicle keyoffs and restarts occurring no more frequently than every five minutes, with each keyoff having a maximum duration of two minutes. Each period of idle following a restart must be a minimum of three minutes in duration. During each idle period, if the engine speed exceeds 1100 rpm or falls below 350 rpm for more than five seconds in any one excursion the CST shall abort. The total duration of the wait time, including time at idle and time at keyoff, shall be 25 to 30 minutes.

(c) Immediately following the wait time described in paragraph (b) of this section, the first-chance test of the Two Speed Idle Test procedure as specified in § 85.2215(c) of this chapter shall be performed on the test vehicle, with the requirements described in paragraphs (c) (1) through (4) of this section.

(1) The general requirements of § 85.2215(a) (1), (3), and (4) of this chapter shall apply to this test procedure.

(2) For the purposes of this subpart, the maximum mode time for the first-chance high-speed mode of the Two Speed Idle Test (as described in § 85.2215 of this chapter) shall be 90 seconds (mt=90)

(3) A pass or fail determination shall be made as in § 85.2215(a) (2) of this chapter, except that the applicable standards shall be the CST standards contained in § 86.094–8(a) for light-duty vehicles and in § 86.094–9(a) for light-duty trucks.

(4) Paragraphs (c) (1) (ii) (A) and (c) (2) (ii) of § 85.2215 of this chapter shall not apply.

(d) Immediately upon completion of the first-chance test of the Two Speed Idle Test procedure the engine speed shall be reduced to free idle with the transmission in neutral. The vehicle wait time shall begin when the vehicle engine speed is between 350 and 1100 rpm. Following the first three minutes of idle, this wait time may be interrupted by vehicle keyoffs and restarts occurring no more frequently than every five minutes, with each keyoff having a maximum duration of two minutes. Each period of idle following a restart must be a minimum of three minutes in duration. During each idle period, if the engine speed exceeds 1100 rpm or falls below 350 rpm for more than five seconds in any one excursion the test shall abort. The total duration of the wait time, including time at idle and time at keyoff, shall be 25 to 30 minutes.

(e) Immediately following the wait time described in paragraph (d) of this section, the Loaded Test procedure as specified in § 85.2217(b) through (c) of this chapter shall be performed on the test vehicle, with the requirements listed in paragraphs (e) (1) through (3) of this section.

(1) The general requirements of § 85.2217(a) (1), (3), (4), and (5) of this chapter shall apply to this test procedure.

(2) A pass or fail determination shall be made as in § 85.2217(a)(2) of this chapter, except that the applicable standards shall be the CST standards contained in § 86.094–8(a) for light-duty vehicles and in § 86.094–9(a) for light-duty trucks.

(3) Paragraph § 85.2217(c) (2) (ii) (A) of this chapter shall not apply.

§ 86.1438–94 Test run—EPA.

(a) This section describes the test run performed by the Administrator for confirmatory testing pursuant to issuing a certificate of conformity under the provisions of § 86.091–29. The test run consists of the wait time and the selected test procedure. The entire test run shall be performed in accordance with the conditions in the option selected from Table 0–94–2 of § 86.1430–94. The Administrator may also employ this procedure for Selective Enforcement Audit and recall purposes. For recall program testing, in-use vehicles will be set to manufacturer's specifications prior to conduct of the CST. The entire test run shall be performed in accordance with the conditions in the option selected from Table 0–94–2 of § 86.1430–94.

(b) If the vehicle is not in the test cell with an ambient temperature of the option selected from Table 0–94–2 of § 86.1430–94, the vehicle shall be moved to the cell at this time. The vehicle shall be started and allowed to idle freely with the transmission in neutral. The vehicle wait time shall begin when the vehicle engine speed is between 350 and 1100 rpm. Following the first three minutes of idle, this wait time may be interrupted by vehicle keyoffs and restarts occurring no more frequently than every five minutes, with each keyoff having a maximum duration of two minutes. Each period of idle following a restart must be a minimum of three minutes in duration. During each idle period, if the engine speed exceeds 1100 rpm or falls below 350 rpm for more than five seconds in any one excursion the test shall abort. The total duration of the wait time, including time at idle and time at keyoff, shall be three to 30 minutes.

(c) Immediately following the wait time, the selected test procedure shall be performed on the test vehicle, with the requirements described in (c) (1) and (2) of this section.

(1) A test procedure shall be performed in accordance with the conditions prescribed in Table 0–94–2 in § 86.1430(b), and in accordance with one of the test procedures described in paragraphs (c)(1) (i) and (ii) of this section.

(i) If the test procedure described in paragraphs (c) through (e) of § 86.1437 is performed, the allowable wait time described in § 86.1437(d) shall be changed to have a total duration of three to 30 minutes. If the vehicle does not pass the applicable standards during all the applicable modes of the first-chance test portion of the selected test procedure, it fails the CST, and the CST is terminated.

(ii) If the Administrator selects a test procedure from among the six revised tests described in §§ 85.2213, 85.2215, 85.2217, 85.2218, 85.2219, and 85.2220 of this chapter, the portion of the selected procedure designated as "second-chance" shall not apply. For the purposes of this subpart, the maximum mode time for the first-chance portion of the 2500 rpm sequence of the two speed idle test—EPA 91 (§ 85.2215) shall be 90 seconds (mt=90).

(2) A pass or fail determination shall be made as in the first-chance test portion of the selected test procedure described in part 85, subpart W of this chapter, except that the applicable standards shall be, for certification and Selective Enforcement Audit purposes, the CST standards contained in § 86.094–8(a) for light-duty vehicles and in § 86.094–9(a) for light-duty trucks and, for recall purposes, the CST

standards contained in § 86.708(a) for light-duty vehicles and § 86.709(a) for light-duty trucks.

§ 86.1442–94 Information required.

(a) *General data.* The information listed in paragraphs (a) (1) through (12) of this section shall be recorded with respect to each CST.

(1) Test number.

(2) Vehicle description, including vehicle identification number, weight class, engine family code, and odometer reading.

(3) Date and time of day for the test.

(4) Driver and equipment operator IDs.

(5) Vehicle: ID number, manufacturer, model year, standards, engine family, evaporative emissions family, basic engine description (including displacement, number of cylinders, turbo-/supercharger used and catalyst usage), fuel system (including number of carburetors, number of carburetor barrels, fuel injection type and fuel tank(s) capacity and location), engine code, gross vehicle weight rating, inertia weight class and transmission configuration, as applicable.

(6) Gas analyzers: Analyzer bench ID, analyzer ranges, recordings of analyzer output during zero, span, and sample readings.

(7) Recorder charts or computer printouts: Test number, date, vehicle ID, operator ID, and identification of the measurements recorded.

(8) Test cell ambient temperature and, if applicable, barometric pressure and humidity. (A central laboratory barometer may be used, provided that individual test cell barometric pressures are shown to be within ±0.1 percent of the barometric pressure at the central barometer location.)

(9) CST test procedure type(s).

(10) Test fuel specifications, including RVP (psi), T90 (°F), percent volume of aromatics, percent volume of olefins, percent volume of MTBE and other oxygenates, and percent sulfur by weight.

(11) Wait time characteristics, including total time and key-off and restart schedule.

(12) Warm-up operation performed.

(b) *CST emission data,* For each CST, the information listed in paragraphs (b) (1) through (3) of this section shall be recorded with respect to each sampling mode.

(1) The reported exhaust concentrations, i.e. the pair of exhaust concentrations for which the product of HC+(151*CO) is at a minimum.

(2) The test time and mode time at which the reported exhaust concentrations are at a minimum.

(3) Minimum $CO+CO_2$ concentration (if applicable).

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Department of Health and Human Services

Food and Drug Administration

21 CFR Part 878

General and Plastic Surgery Devices; Effective Date of Requirement for Premarket Approval of Silicone Inflatable Breast Prosthesis; Proposed Rule

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 91N-0281]

General and Plastic Surgery Devices; Effective Date of Requirement for Premarket Approval of Silicone Inflatable Breast Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the silicone inflatable breast prosthesis, a medical device. The agency is also summarizing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the approval requirements of the Federal Food, Drug, and Cosmetic Act (the act); and (2) the benefits to the public from the use of the device. In addition, FDA is announcing an opportunity for interested persons to request that the agency change the classification of the device based on new information. This action is a followup to FDA's notice of intent published in the **Federal Register** of January 6, 1989 (54 FR 550).

DATES: Written comments by March 9, 1993; requests for a change in classification by January 25, 1993. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Submit written comments or requests for a change in classification to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas J. Callahan, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301-427-1036.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as "preamendments devices."

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendment device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA until 90 days after FDA's promulgation of a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device is not required to have an approved investigational device exemption (IDE) (21 CFR part 812) until the date identified by FDA in the final rule requiring the submission of a PMA for the device and during the period when a PMA for the device is under FDA review.

Section 515(b)(2)(A) of the act provides that a proceeding for the promulgation of a final rule to require premarket approval shall be initiated by publication in the **Federal Register** of a notice of proposed rulemaking containing: (1) The proposed rule; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that, if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate reclassification of the device under section 513(e) of the act.

Under section 515(b)(3) of the act, FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, promulgate a final rule to require premarket approval or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If the proposed rule to require premarket approval for a preamendments device is made final, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or a notice of completion of a PDP for any such device be filed within 90 days of the date of promulgation of the final rule or 30 months after final classification of the device under section 513 of the act, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)). Adulterated devices, including those that have been distributed but remain unused, are subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334). FDA has in the past requested that manufacturers take action to prevent the further use of devices for which no PMA was filed and may determine that such a request is appropriate for silicone inflatable breast prostheses. In addition, shipment of the device in interstate commerce would be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment would be subject to prosecution under section 303 of the act (21 U.S.C. 333).

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or a notice is required to be filed. The House Report on the amendments states that:

> the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval.

(H. Rept. 853, 94th Cong., 2d sess. 42 (1976)).

On November 28, 1990, the President signed into law the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), which amended the act (21 U.S.C. 301 *et seq.*). The act as amended by the SMDA adds, among other provisions, a new postmarket surveillance section that grants FDA authority to require manufacturers to conduct postmarket surveillance for any device that the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that: (1) Is a permanent implant the failure of which may cause serious adverse health consequences or death; (2) is intended for use in supporting or sustaining human life; or (3) potentially presents a serious risk to human health. In addition, under the new provisions of the act, FDA may, at its discretion, require a manufacturer of any device to conduct postmarket surveillance if FDA determines that postmarket surveillance of the device is necessary to protect the public health or to provide safety or effectiveness data for the device. When reviewing PMA's, PDP's, or a petition to reclassify this device, FDA will also determine whether the silicone inflatable breast prosthesis is a device subject to the mandatory postmarket surveillance provisions of the act as amended by the SMDA, or whether FDA should require postmarket surveillance to protect the public health or provide safety and effectiveness data for the device.

Section 522 of the act as amended by the SMDA grants FDA the authority to require manufacturers of medical devices to conduct postmarket surveillance studies. The intended purpose of section 522 of the act is to create an early warning system that allows for the early identification of potential problems with medical devices within a reasonable time of their first marketing by collecting useful data or other information necessary to protect the public health, and by providing safety and effectiveness information for the devices. The new provision of the act applies to manufacturers and those persons whose devices are cleared for marketing under section 515(e) of the act (21 U.S.C. 360e(e)), or under section 510(k) of the act (21 U.S.C. 360(k)). For the sake of convenience, this notice of proposed rulemaking refers to devices cleared for marketing under section 515(e) of the act. Manufacturers or persons required to conduct postmarket surveillance of a device must submit a protocol for the required surveillance. The agency will supply as much guidance as possible to the manufacturer regarding the content, preparation, and submission of protocols.

The agency is aware that postapproval studies are required in § 814.82 (21 CFR 814.82) of the PMA regulation for certain class III devices. In such cases, the manufacturer will be subject to both the postapproval study requirements under § 814.82 and the postmarket surveillance requirements of section 522 of the act. In some instances, the requirements for postapproval studies may satisfy the postmarket surveillance requirements. Under appropriate circumstances, FDA will allow manufacturers to combine the requirements for postapproval studies with those for postmarket surveillance studies.

A. Classification of the Silicone Inflatable Breast Prosthesis

In the **Federal Register** of June 24, 1988 (53 FR 23856 at 23873), FDA issued a final rule classifying the silicone inflatable breast prosthesis into class III (21 CFR 878.3530). The preamble to the proposal to classify the device (47 FR 2810 at 2819, January 19, 1982) included the recommendation of the General and Plastic Surgery Devices Panel (the Panel), an FDA advisory panel, which met on March 24 and July 6, 1978, regarding the classification of the device. The Panel recommended that the device be placed in class II, but identified certain risks to health presented by the device. FDA disagreed with the Panel's recommendation and proposed that the silicone inflatable breast prosthesis be classified into class III. In the proposal the agency stated that it believed that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard [1] to provide this assurance. The proposal stated that premarket approval is necessary for this device because it presents a potential unreasonable risk of injury due to the possibility of leakage of the contents of the silicone shell and subsequent collapse or deformity of the breast, and contraction of the fibrous tissue capsule that forms around the implanted prosthesis, which can lead to marked asymmetry in breast contour and other potentially painful and disfiguring complications. In support of its proposal to strengthen regulatory surveillance of the device, FDA cited numerous references supporting the proposed classification and identified ongoing scientific debates on the safety of breast prostheses.

The preamble to the final rule classifying the device advised that the earliest date by which PMA's for the device could be required was December 31, 1990, or 90 days after promulgation of a rule requiring premarket approval for the device, whichever occurs later.

In the **Federal Register** of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval of 31 preamendments class III devices assigned a high priority by FDA for the application of premarket approval requirements, including the silicone inflatable breast prosthesis. Among other things, the notice described the factors FDA takes into account in establishing priorities for proceedings under section 515(b) of the act for promulgating final rules requiring that preamendments class III devices have approved PMA's. Using those factors, FDA assigned a high priority to the initiation of a proceeding to require premarket approval for the silicone inflatable breast prosthesis identified in § 878.3530.

Accordingly, FDA is commencing a proceeding under section 515(b) of the act to require that the silicone inflatable breast prosthesis have an approved PMA.

B. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that PMA's or a notice of completion of a PDP be filed with the agency for silicone inflatable breast prostheses within 90 days after promulgation of any final rule based on this proposal. Under § 814.42(a) (21 CFR 814.42(a)), FDA will make a filing decision on a PMA within 45 days of its receipt. FDA will accept a PMA for filing only after making a threshold determination that the PMA is sufficiently complete to permit a substantive review. An applicant whose device was in commercial distribution before May 28, 1976, or has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the silicone inflatable breast prosthesis during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days of the date of filing and a notice of completion of a PDP within 90 days. FDA cautions that, under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the

[1] The SMDA changed the definition of a class II device in section 513(a)(1)(B) from a device for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to one for which special controls are sufficient to provide such assurance.

review period for a PMA unless the agency finds that "the continued availability of the device is necessary for the public health."

FDA intends that the preamble to any final rule based on this proposal will state that, under § 812.2(d) (21 CFR 812.2(d)), the exemptions from the requirements of the IDE regulations in § 812.2 (c)(1) and (c)(2) will cease to apply to clinical investigations of the silicone inflatable breast prosthesis on the date on which a PMA or notice of completion of a PDP is required to be filed. If a PMA or notice of completion of a PDP for the silicone inflatable breast prosthesis is not filed with FDA within 90 days after the date of promulgation of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. A device for which a PMA or notice is not filed may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA cautions therefore, that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period to avoid interrupting investigations.

C. Description of the Device

A silicone inflatable breast prosthesis is a silicone rubber shell made of polysiloxane(s), such as polydimethylsiloxane and polydiphenylsiloxane, that is inflated to the desired size with sterile isotonic saline before or after implantation. The device is intended to be implanted to augment or reconstruct the female breast.

The proposed rule to require premarket approval of silicone inflatable breast prostheses applies only to the silicone inflatable breast prostheses identified above that were being commercially distributed before May 28, 1976, and to devices introduced or proposed for introduction into commercial distribution since that date that are substantially equivalent to the silicone inflatable breast prostheses.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the silicone inflatable breast prosthesis to have an approved PMA or PDP; and (2) the benefits to the public from the use of the device.

E. Degree of Risk

On January 26 and 27, 1983, the Panel met to review and consider all comments that were submitted to FDA on the proposed regulation to classify silicone inflatable breast implants into class III, including comments submitted by the American Society of Plastic and Reconstructive Surgeons (ASPRS) and breast prosthesis manufacturers. The Panel also reviewed additional manufacturing data which had been requested by FDA from all manufacturers of breast prostheses. At the portion of the meeting that was open to the public, FDA presented to the Panel an overview of its reasons for issuing the proposed regulation. Members of ASPRS and representatives of one of the manufacturers, Dow Corning Corp. (Dow Corning), also made presentations. The Panel also met in closed session to review confidential documents on silicone, including data furnished by Dow Corning. During this meeting, the Panel unanimously recommended that FDA classify the silicone inflatable breast prosthesis into class III as proposed.

The Panel met on November 22, 1988, and recommended that, from that date until 1990, FDA and ASPRS conduct a review of all existing national and international registries of breast implants to gather long-term data on all known clinical and preclinical risks related to mammary implants, including carcinogenesis/teratogenesis and immune disorders. Quantitative long-term risk information was not uncovered in this review. (See transcript of the Panel meeting, January 26, 1989.) The Panel also recommended that a national mandatory informed consent program be implemented to educate prospective patients about the risks associated with augmentation mammaplasty. On September 26, 1991, FDA issued a **Federal Register** notice requiring dissemination of information on risks associated with silicone gel-filled and silicone inflatable breast prostheses (56 FR 49098).

Based on all of the Panel's recommendations, FDA has evaluated the risks associated with the implantation of silicone inflatable breast prostheses. Much of the documentation of the risks referred to in paragraphs 1 through 9 below is specific to the silicone inflatable breast prosthesis. Where there is no documentation specific to this device, but there is documentation of risks associated with materials which may be used in the device, or to another similar device, such as another device made from silicone materials, this is so indicated. FDA now believes that the following are significant risks associated with the use of silicone inflatable breast prostheses:

1. Fibrous Capsular Contracture

Fibrous capsular contracture, the formation of a constricting fibrous layer, around the prosthesis, is the most common risk associated with breast augmentation and reconstruction. Capsular contracture may result in excessive breast firmness, discomfort, pain, disfigurement, and displacement of the implant. This condition occurs most commonly within the first few months following surgery (Refs. 1 through 4, 6, and 7). Degrees of capsular contracture have not been quantitatively defined. The rate of clinically significant contracture has been cited as between approximately 3 and 45 percent (Refs. 1, 4, 6, and 7).

Although several etiological factors have been suggested, including hematoma, infection, foreign body reaction, and radiation, no single factor has been demonstrated to be the sole cause of contracture. The etiology of contracture is not understood (Refs. 5, 7 through 10, and 49).

2. Deflation

Deflation of the device results from partial or total loss of the contents due to puncture, rupture or other failure of the shell, or a faulty valve. Deflation results in the loss of shape of the prosthesis, which may cause deformity of the breast and require surgical intervention to correct (Refs. 2, 3, and 11 through 17).

3. Infection

Infection, a risk of any surgical implant procedure, is associated with the use of silicone inflatable breast implants (Refs. 8, 9, and 18 through 20). As in any implantation procedure, compromised device sterility and surgical techniques may be major contributing factors to this risk. Other factors specifically related to breast implants have been identified which may increase the risk of infection associated with this device. Burkhardt et al. have concluded from their studies that *Staphylococcus epidermidis*, which has been cultured from uninfected breast glands, may cause subclinical infections of the periprosthetic area if the ductal system is disrupted during the surgical procedure. It has been suggested that this may also contribute to the early development of capsular contracture (Refs. 7 through 9, 18, and 19).

4. Interference With Early Tumor Detection

Several reports have suggested that the presence of silicone inflatable breast implants may interfere with standard mammography procedures used to screen patients for breast cancer. The presence of the implant can produce a shadow on the radiograph that may reduce visual clarity of a significant portion of the breast (Ref. 21). Furthermore, there is greater reduction of transmission of X-rays through the saline filler than through tissue (Ref. 22). In addition, the presence of the implant compresses overlying breast tissue, particularly fat, creating a denser organ with less radiographic contrast. Compression obliterates the fine trabecular pattern of the breast, making architectural distortions difficult to see in a radiograph (Ref. 23).

The risk of interference with early tumor detection could potentially affect a large number of patients, because most recent predictions indicate that approximately 10 percent of women in the United States will develop breast cancer during their lifetime.

5. Human Carcinogenicity

Carcinogenesis has been widely discussed as a reputed risk secondary to implantation of any material. Evidence from the literature indicates that, in animal studies, different forms of silicone have been associated with various types of cancer (Refs. 28 through 32). Cases of several types of cancer in humans have been reported in association with various forms of implanted silicone (Refs. 24 through 27).

6. Human Teratogenicity

Teratogenesis includes the origin or mode of production of a malformed fetus and the disturbed growth processes involved in the production of a malformed fetus. Studies using silicone fluid in animals have been minimal, and yield contradictory and inconclusive results (Refs. 33 through 35). Prolonged contact with the silicone membrane and its components might present a potential risk of teratogenicity in humans.

7. Adverse Immunological Effects and/or Connective Tissue Disorders

Adverse immunological effects and/or connective tissue disorders may be a serious risk associated with the implantation of a silicone inflatable breast prosthesis. These problems have been discussed related to the use of silicone gel-filled prostheses and silicone injections in augmentation mammaplasty. There are clinical reports of several patients who have undergone augmentation mammaplasty with silicone gel-filled breast prostheses and who have presented with connective tissue disorders (Ref. 36). Because the silicone inflatable breast prosthesis may contain a similar elastomer rubber shell, prolonged contact with this prosthesis presents a potential risk of adverse immunological effects and/or connective tissue disorders in humans.

8. Calcification

Calcification of the fibrous capsule surrounding the implant involves the deposition of mineral salts in the capsule and may compromise interpretation of mammographic films and contribute to diagnostic errors or delays in diagnosis of cancerous lesions. (Refs. 3, 37, and 38).

9. Biological Effects of Silica

Amorphous (fumed) silica is bound to the silicone in the shell and may be fibrogenic. Fumed silica and the silicone shell each elicit cellular responses in rats (Ref. 39). The biological effects of silica present a potential risk.

F. Benefits of the Device

Silicone inflatable breast prostheses are intended to reconstruct or augment the female breast. Whether performed for reconstruction or augmentation purposes, breast implantation is a discretionary elective surgical procedure performed for its psychological benefits.

Reconstructive breast implantation most often follows cancer surgery. In addition to the burden of knowing that they have cancer, it is reported that women facing mastectomy may experience depression that accompanies any degenerative change in body image. Shame and feelings of inadequacy are common, as are anxiety and fear of sexual rejection (Refs. 40 and 41). Reconstruction of the breast may help to alleviate such feelings as well as provide these women with a more hopeful outlook toward their disease (Refs. 41 through 43).

Some studies have shown that women seeking breast enlargement are individuals who feel physically inadequate, with doubts concerning their femininity and desirability (Refs. 44 and 45). Inner concerns about lowered self-esteem and a poor self-concept are expressed as depression, lack of self-confidence, and some degree of sexual inhibition (Refs. 44 and 45).

Changes in outlook, personality, and behavior have been observed following breast augmentation (Refs. 41, 46, and 47). Published studies of augmentation mammaplasty show psychological improvement in the majority of patients (Refs. 16, 40, 41, and 44 through 48). One study, which involved an in-depth psychiatric study of 10 patients and a questionnaire completed by 132 patients, showed enhancement of self-image, improved self-esteem, and a high level of satisfaction with the end result of the implant procedure experienced by all 10 patients evaluated psychiatrically, and by most of the group of 132 patients (Ref. 47).

However, these studies are not totally reliable because they did not use objective and standardized recording/measurement of the psychological benefit of the device. The principal requirements for an acceptable scientific documentation of psychological benefits of the device are provided under the section II of this document.

G. Need for Information for Risk/Benefit Assessment of the Device

As indicated above, there is reasonable knowledge of the risks and benefits associated with the silicone inflatable breast prosthesis. There is, however, insufficient valid scientific data to permit FDA to perform a risk/benefit analysis. Therefore, FDA is now seeking further information on the following safety and effectiveness issues associated with the silicone inflatable breast prosthesis:

(1) Clinical data in the form of valid scientific evidence are needed to show the rate of contracture for any specific silicone inflatable breast prosthesis, i.e., for each substantive external surface modification. In addition, it is not clear how various approaches to the prevention and treatment of capsular contracture may reduce the risks associated with use of this device and, consequently, these approaches should be studied. Such methods have included the use of various implant types, submuscular positioning of the implant, use of manual compression exercises, external capsulotomy, and open capsulotomy or capsulectomy.

(2) The potential long-term adverse effects of silicone inflatable breast implants, such as cancer, adverse immunological effects, connective tissue disorders, calcification, and teratogenicity, are unknown and require study. The agency notes that neither particles, which may be shed from the shell (Refs. 49 and 50), nor the chemical forms of silicone monomers or other additives, which may leach from the shell, have been characterized, and their metabolic fates are not known (Ref. 33). Furthermore, no satisfactory independent study has thoroughly evaluated the chronic long-term

toxicology of cross-linked silicone polymers of different molecular sizes. Because young women are the recipients of a significant percentage of these implants, information regarding the chronic toxic effects or possible teratogenic effects of silicone could be of substantial importance in determining the risk to these patients.

(3) Data demonstrating the effect of the device on the ability of mammograms to detect tumors in the breast are needed. It is predicted that approximately 10 percent of American women will develop breast cancer. Mammography of the breast is one method to detect early tumors. Data are needed that demonstrate whether the presence of a breast prosthesis may interfere with mammographic procedures to screen patients for breast cancer.

(4) Studies demonstrating the incidence and extent of risk of calcification of the fibrous tissue around breast prostheses and its impact on the correct and timely detection of breast tumors by mammography are needed.

(5) Data from both long-term clinical studies and mechanical testing are needed to determine the incidence of deflation and its relationship to the physical characteristics of the device, e.g., tensile strength, valve performance, and compressive cyclic fatigue strength.

(6) Long-term effectiveness data for the device are needed. The incidence of infection, implant failure and attendant causes, as well as the incidence of reoperations required as a result, have not been clearly identified. This information is necessary in order to perform an appropriate risk/benefit analysis.

(7) The presurgical, immediate postsurgical, and long-term psychological benefits of the device after breast reconstruction and augmentation need to be examined and quantified. In order to document the benefits of breast reconstruction and augmentation with silicone inflatable breast prostheses, such factors as patient satisfaction, improved self-image, and improved psychological outlook need to be studied using well-established standardized tests.

FDA believes, therefore, that the silicone inflatable breast prosthesis should undergo premarket approval to determine whether the risks of using the device are adequately balanced by its benefits.

II. PMA Contents

Any PMA for the device must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks and benefits identified above, with results of preclinical and clinical studies, of the device for which premarket approval is sought. In addition, the PMA should include all data and information on: (1) Any risks known to the applicant that have not been identified in this document, (2) the effectiveness of the specific silicone inflatable breast prosthesis that is the subject of the application, and (3) summaries of all existing preclinical and clinical data from investigations on the safety and effectiveness of the device.

Section 515(b) of the act does not require FDA to provide guidance for tests for PMA's prior to issuing a call for PMA's. Nevertheless, FDA is providing the following discussion of tests and test methods in order to assist potential applicants in developing their PMA submissions. This discussion is intended to suggest the content of a PMA and is not intended to bind a PMA applicant or the agency to any specific study or set of studies. FDA is prepared to consider any and all valid scientific evidence in its evaluation of the safety and effectiveness of the silicone inflatable breast prosthesis.

A. Manufacturing Data

The manufacture of the device should be described in detail. Information provided should include, but not necessarily be limited to, chemical formulation and manufacturing procedures, presented as a step-by-step process, from the starting materials to the finished products, including, but not limited to, all nonreactants and reactants (including intermediate precursors) for the outer shell, patch, and injection port materials. A complete master list of common chemical names and alternate names (company, trade, and code) for all nonreactants, reactants (including intermediate precursors), and products should be provided. Chemical characterization of the elastomer intermediates, outer shell, patch, and injection port sufficient to demonstrate control of chemical processing of the device materials should be provided. This should be based on lot-to-lot comparisons of the following information: (1) The molecular weight distribution, expressed as weight average molecular weight, number average molecular weight, peak molecular weight, Z average molecular weight, polydispersity, and viscosity average molecular weight of these precursors; (2) analyses for residual levels of volatile and nonvolatile cyclic compounds; and (3) comparison of viscosity, number average molecular weight, and percent volatiles on a single graph. Information providing documentation establishing the extent of crosslinking in the shell material or silicone-hydride and vinyl content of crosslinked shell material, as well as particle size of the silica if present in the shell, patch, or injection port, should be provided. Copies of the sterility and material qualification standard operating procedures should also be provided.

B. Preclinical Data

All physical and chemical properties of the device should be completely characterized. These should include, but not necessarily be limited to, tensile, fatigue, and shear strengths, elastic modulus, and chemical properties of the finished and sterilized device. Data should also include frequency of device failure, failure mechanism, and specific components that caused failure of the finished and sterilized device. Tests should include the following specific methods or their equivalent: The American Society of Testing and Materials (ASTM) Test Method D412 to measure ultimate elongation and total energy to rupture of shells, patches, and other elastomeric components that comprise a lumen of the finished product; ASTM Test Method D624 to determine tear resistance of patches and other elastomeric components; abrasion resistance test of the shell; finished device fatigue characteristic curve (S/N curve) in the form of applied external pressure (to simulate pressures applied by patient lying on her chest) versus number of cycles to failure performed in air at 1 Hertz; and ASTM Test Method F763 (section 7.2) to test the integrity of adhered or fused joints.

Complete identification and quantification of all chemicals, including residual cyclics and oligomers, extractable from each of the individual structural components (shell and other materials) as they are found in the final sterilized device, should be reported. The solvents used for extraction should have varying polarities and should include, but not be limited to, dichloromethane. The selected solvents and extraction method should be documented to show that they can solubilize potential leachables. Laboratory test methods and animal experiments used in the characterization of the physical, chemical, and mechanical properties of the device should simulate the intended use of the device in humans. Data relevant to the distribution and metabolic fate of silicone used in the manufacturing of the device should be supplied.

Pharmacokinetic/biodegradation studies of all materials contained in the finished device should be reported. Of special concern are questions regarding the ultimate fate, quantities, sites/organs of deposition, routes of excretion, and potential clinical significance of silicone retention and migration.

Toxicological effects (e.g., cytotoxicity, mutagenicity, suppression of the immune system, allergenicity, and reproductive and development organ damage) should be identified. Complete mutagenicity testing of each chemical extracted from the finished, sterilized components of the device should include the following tests: Bacterial mutagenicity, mammalian mutagenicity, deoxyribonucleic acid damage, and cell transformation assay.

Acute, subchronic, and chronic toxicity in vitro and in vivo studies using the chemicals recovered by the above extraction processes should be provided in the evaluation of long-term biocompatibility of the device, including dose response and time to response, as well as histopathological findings in tissues both surrounding implants and distal to implant sites (lymph nodes, liver, kidney, lungs, etc.). Animal studies of chronic toxicity, carcinogenicity, teratogenicity, and reproductive toxicity should be performed in accordance with methods such as those described in "Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food" (Ref. 51). Animal testing of the individual compounds extracted from the final sterilized device should be performed for those that qualify for Concern Level III, as described in Ref. 51. These studies should utilize subcutaneous injection to administer individual compounds to the animals. Appropriately conducted studies have been described in several publications (e.g., "Guidance Document for the Preparation of Investigational Device Exemption Applications for IntraArticular Prosthetic Knee Ligament Devices," 1987). Teratology/reproductive testing of the final sterilized silicone elastomer and extractables from the final sterilized shell should be performed in commonly used species, such as the rabbit.

C. Clinical Data

Valid scientific evidence submitted in a PMA should include information from well-controlled clinical studies, with detailed long-term followup, sufficient to provide reasonable assurance of the safety and effectiveness of the silicone inflatable breast prosthesis. For each clinical investigation of this device, a complete description of all randomization techniques used to minimize potential sources of bias should be given. Such studies should include time course presentations of clinical data demonstrating the presence or absence of fibrous capsular contracture, calcification, infection, or any other adverse health event, including any effects on the immune system, both local to the device and systemic, without regard to the device-relatedness of the event. The diagnostic criteria for each type of immunological and allergic phenomenon should be defined at the beginning of the study and cases should be well documented utilizing these criteria. Data demonstrating the effect of this device on the ability of mammograms to detect tumors in the breast tissue, time course presentations of patient satisfaction with and psychological benefit from the implantation of this device, and the anatomical effect of this device as shown by matched tables of before and after bra and cup sizes should be provided. Full patient accounting, including theoretical followup (the number of patients that would have been examined if all patients were examined according to their followup schedules), time course of revisions, and time course of deaths should be reported. As part of this, each clinical report should clearly state the date that the data base was closed to the addition of new information. A statistical demonstration, based on the number of patients who complete the required study period, should show that the sample size is adequate to provide accurate measures of the safety and effectiveness of this device. The statistical demonstration should identify the effect criteria, statistical error tolerances of α and β, anticipated variances of the response variables, and should provide any assumptions or statistical formulas with copies of any references and all calculations used. Statistical justifications for pooling across several variables such as investigational site, device usage (augmentation versus reconstruction versus revision), type of device, types of device surfaces, device placement, and incision site, should be provided.

Epidemiological studies designed to determine the risk of such occurrences should contain enough subjects to detect a small but significant increase in one or more connective tissue disorders (especially scleroderma) that may be associated with the use of the device.

The agency believes that insufficient time has elapsed to permit a direct evaluation of the risk of cancer posed by the presence of silicone in the human body and that sufficient epidemiological data or experimental animal data are not available to make a reasonable and fair judgment of this risk. Therefore, the agency will require long-term, postapproval followup for any silicone inflatable breast prosthesis permitted to continue in or to enter commercial distribution. Well-designed clinical prospective studies with long-term followup, together with experimental animal studies, will be considered essential in determining the safety and effectiveness of the device. Additional well-designed retrospective and prospective clinical studies to collect long-term data on teratogenic/reproductive effects of the device should be initiated.

FDA recognizes that the implantation of a silicone inflatable breast prosthesis is an elective surgical procedure. FDA understands that evaluation of the degree of benefit involves an assessment of patient satisfaction and psychological well-being, particularly in light of the function of the device. Such evaluation relates to patient expectations and includes subjective factors, which may be transient in nature.

The level of the device's benefit may depend on whether breast implants are used for augmentation mammaplasty, correction of congenital breast anomalies, or reconstruction after tumor ablation. Therefore, the evaluation parameters for this portion of the clinical study should be structured for an objective and standardized recording/measurement of the psychological benefit of the device. The primary requirements for an acceptable scientific documentation of psychological benefits of the device are the use of: (1) Prospective research designs, including presurgical and postsurgical repeated measures; (2) appropriate control/comparison groups; and (3) standardized test instruments rather than informal, nonvalidated questionnaires. FDA also strongly recommends that the following criteria be included in the study: (1) Stratification of data according to augmentation versus reconstruction mammaplasty; (2) quantitative assessment of the level and duration for each of the various parameters evaluated (for example, a numerical score should be assigned to evaluate the level and duration of the preoperative and postoperative satisfaction and psychological improvement of treated compared to untreated control patients); (3) baseline level for each psychological parameter evaluated; (4) correlation of the psychological data with other clinical outcomes of the implant procedure; and (5) adequate followup

time. The benefit assessment (and the entire PMA) must be based on valid scientific evidence as defined in § 860.7(c)(2) (21 CFR 860.7(c)(2)) and well-controlled studies as described in § 860.7(f), in order to provide reasonable assurance of the safety and effectiveness of the silicone inflatable breast prosthesis in reconstruction and augmentation mammaplasty.

Applicants should submit any PMA in accordance with FDA's "Premarket Approval (PMA) Manual," which is available upon request from the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 800–443–2041, or 301–443–6597.

III. Request for Comments

Interested persons may, on or before March 9, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Comments should discuss all aspects of the proposed findings and the recommended PMA contents.

IV. Opportunity To Request a Change in Classification

Before requiring the filing of a PMA or PDP for a device, FDA is required by section 515(b)(2)(A)(iv) of the act to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. (See § 860.132 (21 CFR 860.132).) Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the silicone inflatable breast prosthesis is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by January 25, 1993.

The agency advises that, to assure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). Petitions should be identified by the docket number found in brackets in the heading of this document. Petitions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

If a timely request for a change in the classification of the silicone inflatable breast prosthesis is submitted, the agency will by March 9, 1993, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and § 860.130 (21 CFR 860.130).

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Impact

FDA has examined the economic consequences of this proposed rule in accordance with the criteria in section 1(b) of Executive Order 12291 and finds that this proposal would not be a major rule as specified in the Order. The agency believes that only a small number of firms will be affected by this proposed rule, and the agency certifies under the Regulatory Flexibility Act (Pub. L. 96–354) that the proposed rule will not have a significant economic impact on a substantial number of small entities. An assessment of the economic impact of any final rule based on this proposal has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 878 be amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 878.3530 is amended by revising paragraph (c) to read as follows:

§ 878.3530 Silicone inflatable breast prosthesis.

* * * * *

(c) *Date premarket approval application (PMA) is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), for any silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976, or that has on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to the silicone inflatable breast prosthesis that was in commercial distribution before May 28, 1976. Any other silicone inflatable breast prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed into commercial distribution.

Dated: December 15, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

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Department of Agriculture

Agricultural Marketing Service

7 CFR Part 1209

Mushroom Promotion, Research, and Consumer Information Order; Final Rule

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1209

[FV-91-276]

RIN 0581-AA49

Mushroom Promotion, Research, and Consumer Information Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action establishes a Mushroom Promotion, Research, and Consumer Information Order (Order) which is authorized by the Mushroom Promotion, Research, and Consumer Information Act of 1990. The program will be funded by assessments collected from producers and importers who produce or import, on average, over 500,000 pounds of mushrooms annually that are marketed or imported for fresh use. The program will be administered by a Mushroom Council consisting of at least four but no more than nine producer and importer members. From August 24, 1992, through September 28, 1992, the Department of Agriculture (Department) conducted a referendum among eligible producers and importers to determine whether the Order would go into effect. The Order was approved by a majority of those voting in the referendum with such majority, on average, annually producing and importing more than 50 percent of the mushrooms annually produced and imported by all those voting in the referendum.

DATES: This final rule is effective January 8, 1993.

ADDRESSES: Richard Schultz, Research and Promotion Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, room 2535–S, P.O. Box 96456, Washington, DC 20090–6456.

FOR FURTHER INFORMATION CONTACT: Richard Schultz at the above address or telephone (202) 720–5976.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding: Proposed Rule published in the October 4, 1991, issue of the **Federal Register** (56 FR 50283); Proposed Rule and Meeting Notice published in the January 15, 1992, issue of the **Federal Register** (57 FR 1666); Proposed Rule and Referendum Order published in the June 10, 1992, issue of the **Federal Register** (57 FR 24719); Amendment to Referendum Order published in the August 14, 1992, issue of the **Federal Register** (57 FR 36610); and further Amendment to Referendum Order published in the September 23, 1992, issue of the **Federal Register** (57 FR 43943).

This final rule is issued pursuant to the Mushroom Promotion, Research, and Consumer Information Act of 1990 (Subtitle B of title XIX of the Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. 101–624, November 28, 1990, 7 U.S.C. 6101–6112), as amended, hereinafter referred to as the Act.

This rule has been reviewed by the Department in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This rule has been also reviewed under Executive Order 12778, Civil Justice Reform. It is not intended to have retroactive effect. Section 1930 of the Act provides that nothing in the Act may be construed to preempt or supersede any other program relating to mushroom promotion, research, consumer information, or industry information organized or operated under the laws of the United States or any State.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 1927 of the Act, a person subject to an order may file a petition with the Secretary of Agriculture (Secretary) stating that the Order, a provision of the Order, or an obligation imposed in connection with the Order is not in accordance with law; and requesting a modification of the Order or an exemption from the Order. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary will rule on the petition. The Act provides that the district court of the United States in the district in which such person resides or does business has jurisdiction to review the Secretary's ruling on the petition, if a complaint is filed within 20 days after the date of the entry of a ruling by the Secretary.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this final action on small entities.

The most recent Department estimate of mushroom growers in the United States indicates that there are 390 growers. Between 100 and 150 growers would fall under the definition of producer as defined in the Act and be subject to the provisions of the Order. A majority of these producers are engaged in the production of Agaricus mushrooms, also referred to as button mushrooms. A minority of these producers would be classified as small entities. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms, which include mushroom handlers and importers, have been defined as those having annual receipts of less than $3,500,000. There are approximately 100 handlers, including producers who are also handlers, who would be subject to the provisions of the Order. A majority of these handlers would be classified as small entities. There are no more than 3 importers, out of approximately 30 importers, who would be subject to the provisions of the Order. A majority of these importers would be classified as small entities.

During the period from July 1, 1991, through June 30, 1992, Department statistics indicate that approximately 743 million pounds of mushrooms were produced in the United States. Of this total production, 498 million pounds (67 percent) were for the fresh market and 245 million pounds (33 percent) were for the processed market. During this period, the volume of sales for fresh market Agaricus or button mushrooms totaled 493 million pounds, while the volume of sales for specialty mushrooms totaled approximately 5 million pounds. Virtually all specialty mushrooms, which include Shiitake, Oyster and others, were sold on the fresh market.

During this same period, Department statistics indicate that approximately 4.6 million pounds of fresh mushrooms were imported into the United States. Major exporting countries, as a percentage of total fresh mushroom imports, were Canada (95.2 percent), Japan (1.3 percent), Spain (1.0 percent) and Singapore (0.8 percent). Department statistics for January 1, 1992, through June 30, 1992, indicate that cumulative imports of fresh mushrooms were approximately 2.1 million pounds. Major exporting countries, as a percentage of cumulative fresh mushroom imports, were Canada (95.5 percent), Japan (1.7 percent), Singapore (0.8 percent), and China (0.7 percent).

The Order provides for the payment of assessments by producers and importers who produce or import, on average, over 500,000 pounds of mushrooms annually that are marketed or imported for fresh use. In the first year that the Order is in effect the rate

of assessment cannot exceed one-quarter of one cent per pound of mushrooms. This rate of assessment can be increased incrementally in the second and third year of the Order, but cannot exceed one cent per pound in subsequent years. The rate of assessment would be recommended by the Mushroom Council (Council) and approved by the Secretary. The Order requires an estimated 100 first handlers of fresh mushrooms, a majority of whom would be classified as small entities, to collect and remit such assessments to the Council.

In the first year of the Order, an assessment rate of one-quarter of one cent per pound of fresh mushrooms marketed or imported could result in a total assessment collection of $1.1 million. Beginning in the fourth year of the Order, a maximum assessment rate of one cent per pound of fresh mushrooms marketed or imported could result in a total assessment collection of $4.5 million. The economic impact of a one cent or less assessment per pound of fresh mushrooms on producers and importers will not be significant relative to the potential benefits to be gained from such a program of promotion, research, consumer information, and industry information.

The Order also imposes a reporting and recordkeeping burden on producers, first handlers, and importers. This burden is expected to average approximately seven hours per year and its economic impact will not be significant relative to the potential benefits to be gained from such a program.

Such a program of promotion, research, consumer information, and industry information is expected to benefit producers, handlers, and importers by strengthening the mushroom industry's position in the marketplace; maintaining and expanding existing markets and uses for fresh mushrooms; and developing new markets and uses for fresh mushrooms. The benefits derived from the program are expected to outweigh the costs of the program. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the information collection requirements contained in this action have been approved by the Office of Management and Budget (OMB) and assigned OMB number 0581–0093, except for the Mushroom Council nominee background statement form which is assigned OMB number 0505–0001. This Order sets forth the provisions of a nationwide program for mushroom promotion, research, consumer information, and industry information funded by mushroom producers and importers. Information collection requirements that are included in the Order include:

(1) A requirement that each first handler and importer of fresh mushrooms must file reports at specified intervals. The estimated number of first handlers and importers filing such reports is 103, each submitting a maximum of 12 reports per year, with an estimated average reporting burden of 30 minutes per report. These persons may alternatively prepay assessments annually which would require filing an initial report of anticipated assessments and a final report of actual handling;

(2) An exemption application for persons who produce or import, on average, 500,000 pounds or less of fresh mushrooms annually concerning exemptions from assessments and recordkeeping requirements. The estimated number of persons filing this application is 340, each submitting one application per year, with an estimated average reporting burden of 15 minutes per application;

(3) A referendum ballot which was used in the recent referendum to determine whether eligible voters were in favor of implementing the program. The ballot will also be used periodically hereafter to indicate whether producers and importers favor continuance or amendment of the Order. The estimated number of eligible voters completing this ballot is 153, each submitting one ballot approximately every five years, with an estimated average reporting burden of 6 minutes per ballot.

(4) A nominee background statement form for Mushroom Council membership. The estimated number of individuals completing this form is 18 during the first year of the Order and approximately 6 per year thereafter. Two eligible individuals will be nominated for each open position on the Council, each of these individuals will have an estimated average reporting burden of 6 minutes per form; and

(5) A requirement to maintain records sufficient to verify reports submitted under the Order. The estimated number of persons required to comply with this requirement is 203, each of these persons will have an estimated average recordkeeping burden of 7 minutes per year.

Background

The Act authorizes the Secretary to establish a national mushroom promotion, research, consumer information, and industry information program. This program will be funded by an assessment on producers and importers who produce or import, on average, over 500,000 pounds of mushrooms annually that are marketed or imported for fresh use. The maximum assessment rate cannot be realized until the fourth year of the Order and cannot exceed one cent per pound of mushrooms.

The Act provides for the establishment of such a national program through the issuance of an order by the Secretary. The Act further provides that an order contain certain specified terms and conditions. Such terms and conditions include provisions concerning the establishment of and composition of a Council and the powers and duties of such a Council. Also included under terms and conditions are provisions concerning plans and budgets, contracts and agreements, books and records of the Council, assessments, prohibitions, books and records of first handlers and importers, and other terms and conditions.

The Act provides that the Council will be composed of at least four and not more than nine members. There will be four geographic regions established, representing the geographic distribution of mushroom production throughout the United States, with one member who is a producer nominated and appointed from each region that produces, on average, at least 35,000,000 pounds of mushrooms annually. There will also be a fifth region established, representing importers throughout the United States, with one member who is an importer nominated and appointed from such region importing, on average, at least 35,000,000 pounds of mushrooms annually. Subject to the nine-member limit on the number of Council members, the Secretary will appoint an additional member to the Council from a region for each additional 50,000,000 pounds of production or imports per year, on average, within the region. Should, in the aggregate, regions be entitled to levels of representation that exceed the nine-member limit on the Council, then those regions entitled to representation in excess of the basic quantity use in establishing representation on the Council will have representation allocated among them based on production or importation so that the Council does not exceed its nine-member limit.

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In response to an invitation to submit proposals in the January 30, 1991, issue of the **Federal Register** (56 FR 3425), the Department received one proposal for a Mushroom Promotion, Research, and Consumer Information Order from the American Mushroom Institute (AMI), a national trade association, and several proposed Order provisions from United Foods, Inc. (United), a mushroom producer. The Department reviewed and considered the proposals, and then issued a proposed rule which separately contained the provisions of both proposals, insofar as they were practicable and consistent with the Act, in the October 4, 1991, issue of the **Federal Register** (56 FR 50283).

After reviewing and considering the comments received on the October 4, proposed rule, the Department then issued a proposed rule and meeting notice in the January 15, 1992, issue of the **Federal Register** (57 FR 1666). This rule incorporated the proposed Order provisions submitted by AMI and United into a single proposed Order, addressed comments received by interested persons on the October 4 proposed rule, and announced the holding of a public meeting at the Department of Agriculture in Washington, DC, February 5, 1992.

The Department received 23 comments on the January 15 proposed rule. Comments were received from the AMI; United; the Office for Advocacy of the U.S. Small Business Administration; the American Farm Bureau Federation; the Pennsylvania Farmers' Association; the National Customs Brokers & Forwarders Association of America, Inc.; the Geode Shiitake Producers Association; Kitchen Pride Mushroom Farms; Blue Mountain Mushroom Company, Inc.; Ostroms Farms; Mt. Baker Mushroom Farms; Homestead Mushrooms, Inc.; James H. Paxson & Sons, Inc.; Hastings Mushrooms; Mr. T.H. Bonifocino; Mr. Elmer Blosser; Forest Mushroom Farms; Pictsweet Mushroom Farms; Sun Rise Mushroom Company; B & C Fresh Sales; P. & V. D'Amico Mushrooms; John R. Stinson & Sons, Inc.; Sun Rise Mushroom Co.; and Kubla Khan Food Company.

The comments were discussed in the proposed rule and referendum order which were published in the June 10, 1992, issue of the **Federal Register** (57 FR 24719). The referendum was held from August 24 through September 28. In the referendum, the Order was approved by a majority of the producers and importers voting in the referendum with such majority, on average, annually producing and importing more than 50 percent of the mushrooms annually produced and imported by all those voting in the referendum.

The Order provisions as proposed by the Department and approved in the referendum are summarized as follows:

Sections 1209.1–1209.20 of the Order define certain terms which are used in the Order.

Sections 1209.30–1209.39 of the Order concern the establishment, membership, nominations, appointment, term of office, vacancies, procedure, compensation and reimbursement, powers and duties of the Mushroom Council, which will be the body organized to administer the Order subject to oversight by the Secretary.

Section 1209.40 of the Order authorizes the Council to receive, develop, and evaluate programs, plans, and projects for promotion, research, consumer information, and industry information with respect to fresh mushrooms. The Secretary shall approve such programs, plans or projects prior to their implementation.

Section 1209.50 of the Order authorizes the Council to incur expenses necessary for the performance of its duties and to recommend an annual budget. Section 1209.51 of the Order provides for the collection of assessments. The maximum assessment rate would be one cent per pound of fresh mushrooms produced in or imported into the United States. This section also contains the procedures to be followed by first handlers and importers when remitting assessments; the procedures to be followed by producers and importers seeking exemption from assessments; the establishment of a late payment charge and interest charges for unpaid or late assessments; the collection of assessments through approved third-party organizations; and the prepayment of assessments. Section 1209.52 of the Order authorizes exemption from assessment provided that certain criteria are satisfied. Section 1209.53 of the Order prohibits funds received under this program from influencing governmental action, with specified exceptions.

Sections 1209.60–1209.62 of the Order contain reporting and recordkeeping requirements for persons subject to the Order, and provide that all information obtained by the Council or the Department from books and reports required by the Order will be kept confidential. Sections 1209.70–1209.77 of the Order concern miscellaneous provisions which include the right of the Secretary; procedures for the suspension or termination of the Order; proceedings after the termination of the Order; effect of termination or amendment of the Order; personal liability of Council members; handling of intellectual property arising from funds collected by the Council; amendments to the Order; and separability of Order provisions.

General Findings

The Department conducted a referendum among mushroom producers and importers from August 24, 1992, through September 28, 1992, to determine whether the Order would become effective. The representative period for establishing voter eligibility was from July 1, 1990, through June 30, 1992. Only producers and importers who produced or imported, on average, over 500,000 pounds of mushrooms annually for fresh use during this period were eligible to vote.

It is determined that a majority of those who voted favored the implementation of the Order and that those voters favoring implementation represented a majority of the mushrooms produced and imported by all voters in the referendum. To become effective the Order had to be approved by a majority of producers and importers voting in the referendum, which majority, on average, annually produced and imported into the United States more than 50 percent of the mushrooms annually produced and imported by all those voting in the referendum.

After consideration of all relevant material presented, including the initial proposals, comments received, the referendum results, and other available information, it is found that the Order, and all of the terms and conditions thereof, tends to effectuate the declared policy of the Act.

Additional Findings

Pursuant to 5 U.S.C. 553, it is also found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** because (1) the Act requires implementation of the Order if the Order is approved by the mushroom industry; (2) the industry approved the Order in a recent referendum; (3) the Order cannot be fully implemented until this rule becomes effective and the Mushroom Council is appointed; and (4) no useful purpose would be served by delaying the effective date of this action.

List of Subjects in 7 CFR Part 1209

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements,

Mushrooms, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 1209 is amended as follows:

PART 1209—MUSHROOM PROMOTION, RESEARCH, AND CONSUMER INFORMATION

1. The authority citation for part 1209 continues to read as follows:

Authority: 7 U.S.C. 6101–6112.

2. Subpart A is added to read as follows:

Subpart A—Mushroom Promotion, Research, and Consumer Information Order

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1209.4 Council.
1209.5 Department.
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Promotion, Research, Consumer Information, and Industry Information

1209.40 Programs, plans, and projects.

Expenses and Assessments

1209.50 Budget and expenses.
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1209.70 Right of the Secretary.
1209.71 Suspension or termination.
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PART 1209—MUSHROOM PROMOTION, RESEARCH, AND CONSUMER INFORMATION

Subpart A—Mushroom Promotion, Research, and Consumer Information Order

Definitions

§ 1209.1 Act.

Act means the Mushroom Promotion, Research, and Consumer Information Act of 1990, subtitle B of title XIX of the Food, Agriculture, Conservation, and Trade Act of 1990, Pub. L. 101–624, 7 U.S.C. 6101–6112, and any amendments thereto.

§ 1209.2 Commerce.

Commerce means interstate, foreign, or intrastate commerce.

§ 1209.3 Consumer information.

Consumer information means information and programs that will assist consumers and other persons in making evaluations and decisions regarding the purchase, preparation, and use of mushrooms.

§ 1209.4 Council.

Council means the administrative body referred to as the Mushroom Council established under § 1209.30 of this subpart.

§ 1209.5 Department.

Department means the United States Department of Agriculture.

§ 1209.6 First handler.

First handler means any person who receives or otherwise acquires mushrooms from a producer and prepares for marketing or markets such mushrooms, or who prepares for marketing or markets mushrooms of that person's own production.

§ 1209.7 Fiscal year.

Fiscal year means the 12-month period from January 1 to December 31 each year, or such other period as recommended by the Council and approved by the Secretary.

§ 1209.8 Importer.

Importer means any person who imports, on average, over 500,000 pounds of mushrooms annually from outside the United States.

§ 1209.9 Industry information.

Industry information means information and programs that will lead to the development of new markets and marketing strategies, increased efficiency, and activities to enhance the image of the mushroom industry.

§ 1209.10 Marketing.

(a) *Marketing* means the sale or other disposition of mushrooms in any channel of commerce.

(b) *To market* means to sell or otherwise dispose of mushrooms in any channel of commerce.

§ 1209.11 Mushrooms.

Mushrooms means all varieties of cultivated mushrooms grown within the United States and marketed for the fresh market, or imported into the United States and marketed for the fresh market, except such term shall not include mushrooms that are commercially marinated, canned, frozen, cooked, blanched, dried, packaged in brine, or otherwise processed in such manner as the Council, with the approval of the Secretary, may determine.

§ 1209.12 On average.

On average means a rolling average of production or imports during the last two fiscal years, or such other period as may be determined by the Secretary.

§ 1209.13 Part and subpart.

Part means this mushroom promotion and research order and all rules and regulations and supplemental orders issued thereunder, and the term *subpart* means the mushroom promotion and research order.

§ 1209.14 Person.

Person means any individual, group of individuals, partnership, corporation, association, cooperative, or any other legal entity.

§ 1209.15 Producer.

Producer means any person engaged in the production of mushrooms who owns or shares the ownership and risk of loss of such mushrooms and who produces, on average, over 500,000 pounds of mushrooms per year.

§ 1209.16 Programs, plans, and projects.

Programs, plans, and projects means promotion, research, consumer information, and industry information plans, studies, projects, or programs conducted pursuant to this part.

§ 1209.17 Promotion.

Promotion means any action determined by the Secretary to enhance the image or desirability of mushrooms, including paid advertising.

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§ 1209.18 Region.

Region means one of the described geographic subdivisions of the production areas described in § 1209.30 (b) or as later realigned or reapportioned pursuant thereto, or the import region described in § 1209.30(c).

§ 1209.19 Research.

Research means any type of study to advance the image, desirability, safety, marketability, production, product development, quality, or nutritional value of mushrooms.

§ 1209.20 Secretary.

Secretary means the Secretary of Agriculture of the United States or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in the Secretary's stead.

§ 1209.21 State and United States.

(a) *State* means any of the several States, the District of Columbia, and the Commonwealth of Puerto Rico.

(b) *United States* means collectively the several States of the United States of America, the District of Columbia, and the Commonwealth of Puerto Rico.

Mushroom Council

§ 1209.30 Establishment and membership.

(a) There is hereby established a Mushroom Council of not less than four or more than nine members. The Council shall be composed of producers appointed by the Secretary under § 1209.33, except that, as provided in paragraph (c), importers shall be appointed by the Secretary to the Council under § 1209.33 once imports, on average, reach at least 35,000,000 pounds of mushrooms annually.

(b) For purposes of nominating and appointing producers to the Council, the United States shall be divided into four geographic regions and the number of Council members from each region shall be as follows:

(1) *Region 1:* including Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, Ohio, Kentucky, Indiana, Michigan, Wisconsin, Illinois, Missouri, Iowa, Nebraska, Kansas, Minnesota, North Dakota, South Dakota, Montana, Colorado, and Wyoming—2 Members.

(2) *Region 2:* including Pennsylvania, Delaware, New Jersey, the District of Columbia, West Virginia, Virginia, and Maryland—3 Members.

(3) *Region 3:* including Washington, Oregon, Idaho, Utah, Arizona, California, Nevada, Alaska, and Hawaii—3 Members.

(4) *Region 4:* including New Mexico, Texas, Oklahoma, Arkansas, Louisiana, Alabama, Mississippi, Georgia, Tennessee, North Carolina, South Carolina, Florida, and the Commonwealth of Puerto Rico—1 Member.

(c) Importers shall be represented by a single, separate region, referred to as Region 5, consisting of the United States as defined in § 1209.21(b) when imports, on average, equal or exceed 35,000,000 pounds of mushrooms annually.

(d) At least every five years, and not more than every three years, the Council shall review changes in the geographic distribution of mushroom production volume throughout the United States and import volume, using the average annual mushroom production and imports over the preceding four years, and, based on such review, shall recommend to the Secretary reapportionment of the regions established in paragraph (b), or modification of the number of members from such regions, as determined under the rules established in paragraph (e), or both, as necessary to best reflect the geographic distribution of mushroom production volume in the United States and representation of imports, if applicable.

(e) Subject to the nine-member maximum limitation, the following procedure will be used to determine the number of members for each region to serve on the Council under paragraph (d):

(1) Each region that produces, on average, at least 35,000,000 pounds of mushrooms annually shall be entitled to one representative on the Council.

(2) As provided in paragraph (c), importers shall be represented by a single, separate region, which shall be entitled to one representative, if such region imports, on average, at least 35,000,000 pounds of mushrooms annually.

(3) Each region shall be entitled to representation by an additional Council member for each 50,000,000 pounds of annual production or imports, on average, in excess of the initial 35,000,000 pounds required to qualify the region for representation.

(4) Should, in the aggregate, regions be entitled to levels of representation under paragraphs (e) (1), (2) and (3) that would exceed the nine-member limit on the Council under the Act, the regions shall be entitled to representation on the Council as follows:

(i) Each region first shall be assigned one representative on the Council pursuant to paragraphs (e) (1) and (2).

(ii) Then, each region with 50,000,000 pounds of annual production or imports, on average, in excess of the initial 35,000,000 pounds required to qualify the region for representation shall be assigned one additional representative on the Council, except that if under such assignments all five regions, counting importers as a region, if applicable, would be entitled to additional representatives, that region with the smallest on-average volume, in terms of production or imports, will not be assigned an additional representative.

(iii) After members are assigned to regions under paragraphs (e)(4) (i) and (ii), if less than the entire nine seats on the Council have been assigned to regions, the remaining seats on the Council shall be assigned to each region for each 50,000,000 pound increment of annual production or import volume, on average, in excess of 85,000,000 pounds until all the seats are filled. It for any such 50,000,000 pound increment, more regions are eligible for seats than there are seats available, the seat or seats assigned for such increment shall be assigned to that region or those regions with greater on-average production or import volume than the other regions otherwise eligible at that increment level.

(f) In determining the volume of mushrooms produced in the United States or imported into the United States for purposes of this section, the Council and the Secretary shall:

(1) only consider mushrooms produced or imported by producers and importers, respectively, as those terms are defined in §§ 1209.8 and 1209.15; and

(2) use the information received by the Council under § 1209.60, and data published by the Department.

(g) For purposes of the provisions of this section relating to the appointment of producers and importers to serve on the Council, the term *producer* or *importer* refers to any individual who is a producer or importer, respectively, or if the producer or importer is an entity other than an individual, an individual who is an officer or employee of such producer or importer.

§ 1209.31 Nominations.

All nominations for appointments to the Council under § 1209.33 shall be made as follows:

(a) As soon as practicable after this subpart becomes effective, nominations for appointment to the initial Council shall be obtained from producers by the Secretary. In any subsequent year in which an appointment to the Council is to be made, nominations for positions

whose terms will expire at the end of that year shall be obtained from producers, and as appropriate, importers, and certified by the Council and submitted to the Secretary by August 1 of such year, or such other date as approved by the Secretary.

(b) Nominations shall be made at regional caucuses of producers or importers, or by mail ballot as provided in paragraph (e), in accordance with procedures prescribed in this section.

(c) Except for initial Council members, whose nomination process will be initiated by the Secretary, the Council shall issue a call for nominations by February 1 of each year in which nominations for an appointment to the Council is to be made. The call shall include, at a minimum, the following information:

(1) A list by region of the vacancies for which nominees may be submitted and qualifications as to producers and importers.

(2) The date by which the names of nominees shall be submitted to the Secretary for consideration to be in compliance with paragraph (a) of this section.

(3) A list of those States, by region, entitled to participate in the nomination process.

(4) The date, time, and location of any next scheduled meeting of the Council, and national and State producer or importer associations, if known, and of the regional caucuses, if any.

(d)(1) Except as provided in paragraph (e), nominations for each position shall be made by regional caucus in the region entitled to nominate for such position. Notice of such caucus shall be publicized to all producers or importers within the region, and to the Secretary, at least 30 days prior to the caucus. The notice shall have attached to it the call for nominations from the Council and the Department's equal opportunity policy. Except with respect to nominations for the initial appointments to the Council, the responsibility for convening and publicizing the regional caucus shall be that of the Council.

(2) All producers or importers within the region may participate in the caucus. However, if a producer is engaged in the production of mushrooms in more than one region or is also an importer, such person's participation within a region shall be limited to one vote and shall only reflect the volume of such person's production or imports within the applicable region.

(3) The regional caucus shall conduct the selection process for the nominees in accordance with procedures to be adopted at the caucus subject to the following requirements:

(i) There shall be two individuals nominated for each open position.

(ii) Each nominee shall meet the qualifications set forth in the call.

(iii) If a producer nominee is engaged in the production of mushrooms in more than one region or is also an importer, such individual shall participate within the region that such individual so elects in writing to the Council and such election shall remain controlling until revoked in writing to the Council.

(e) After the regional caucuses for the initial Council, the Council may conduct the selection of nominees by mail ballot in lieu of a regional caucus.

(f) When producers or importers are voting for nominees to the Council, whether through a regional caucus or a mail ballot, the following conditions shall apply:

(1) Voting for any open position shall be on the basis of:

(i) one vote per eligible voter; and

(ii) volume of on-average production or imports of the eligible voter within that region.

(2) Whenever the producers or importers in a region are choosing nominees for one open position on the Council, the proposed nominee with the highest number of votes cast and the proposed nominee with the highest volume of production or importers voted shall be the nominees submitted to the Secretary. If a proposed nominee receives both the highest number of votes cast and the highest volume of production or imports voted, then the proposed nominee with the second highest number of votes cast shall be a nominee submitted to the Secretary along with such proposed nominee receiving both the highest number of votes cast and the highest volume of production or imports voted.

(3) Whenever the producers or importers in a region are choosing nominees for more than one open position on the Council at the same time, the number of the nominations submitted to the Secretary shall equal twice the number of such open positions, and for each open position shall consist of the proposed nominee with the highest number of votes cast and the proposed nominee with the highest volume of production or imports voted with respect to that position, subject to the rule set out in paragraph (f)(2). An individual shall only be nominated for one such open position.

(4) Voters shall certify on their ballots as to their on-average production or import volume within the region involved. Such certification may be subject to verification.

(g)(1) The Secretary may reject any nominee submitted. If there are insufficient nominees from which to appoint members to the Council as a result of the Secretary's rejecting such nominees, additional nominees shall be submitted to the Secretary under the procedures set out in this section.

(2) Whenever producers or importers in a region cannot agree on nominees for an open position on the Council under the preceding provisions of this section, or whenever they fail to nominate individuals for appointment to the Council, the Secretary may appoint members in such manner as the Secretary, by regulation, determines appropriate.

§ 1209.32 Acceptance.

Each individual nominated for membership on the Council shall qualify by filing a written acceptance with the Secretary at the time of nomination.

§ 1209.33 Appointment.

From the nominations made pursuant to § 1209.31, the Secretary shall appoint the members of the Council on the basis of representation provided for in § 1209.30, except that no more than one member may be appointed to the Council from nominations submitted by any one producer or importer.

§ 1209.34 Term of office.

(a) The members of the Council shall serve for terms of three years, except that the members appointed to the initial Council shall serve, proportionately, for terms of one, two, and three years.

(b) Members of the initial Council shall be designated for, and shall serve, terms as follows: One producer member each from regions 1, 2 and 3 shall be appointed for an initial term of one year; one producer member each from regions 1, 2, and 3 shall be appointed for an initial term of two years; and one producer member each from regions 2, 3, and 4 shall be appointed for an initial term of three years. Because current imports of fresh mushrooms are less than 35,000,000 pounds, the minimum established for representation on the Council, importers will not initially have a member appointed to the Council.

(c)(1) Except with respect to terms of office of the initial Council, the term of office for each member of the Council shall begin on January 1 or such other date that may be approved by the Secretary.

(2) The term of office for the initial Council shall begin immediately

following appointment by the Secretary, except that time in the interim period from appointment until the following January 1, or such other date that is the generally applicable beginning date for terms under paragraph (c)(1) approved by the Secretary, shall not count toward the initial term of office.

(d) Council members shall serve during the term of office for which they are appointed and have qualified, and until their successors are appointed and have qualified.

(e)(1) No member shall serve more than two successive three-year terms, except as provided in paragraph (e)(2)(ii).

(2)(i) Those members serving initial terms of two or three years may serve one successive three-year term.

(ii) Those members serving initial terms of one year may serve two successive three-year terms.

§ 1209.35 Vacancies.

(a) To fill any vacancy occasioned by the death, removal, resignation, or disqualification of any member of the Council, the Secretary may appoint a successor from the most recent nominations submitted for open positions on the Council assigned to the region that the vacant position represents, or the Secretary may obtain nominees to fill such vacancy in such manner as the Secretary, by regulation, deems appropriate. Each such successor appointment shall be for the remainder of the term vacated. A vacancy will not be required to be filled if the unexpired term is less than six months.

(b)(1) No successor appointed to a vacated term of office shall serve more than two successive three-year terms on the Council, except as provided in paragraph (b)(2)(ii).

(2)(i) Any successor serving longer than one year may serve one successive three-year term.

(ii) Any successor serving one year or less may serve two successive three-year terms.

(c) If a member of the Council consistently refuses to perform the duties of a member of the Council, or if a member of the Council is known to be engaged in acts of dishonesty or willful misconduct, the Council may recommend to the Secretary that the member be removed from office. If the Secretary finds the recommendation of the Council shows adequate cause, the Secretary shall remove such member from office. Further, without recommendation of the Council, a member may be removed by the Secretary upon showing of adequate cause, including the failure by a member to submit reports or remit assessments required under this part, if the Secretary determines that such member's continued service would be detrimental to the achievement of the purposes of the Act.

§ 1209.36 Procedure.

(a) At a properly convened meeting of the Council, a majority of the members shall constitute a quorum.

(b) Each member of the Council will be entitled to one vote on any matter put to the Council, and the motion will carry if supported by a simple majority of those voting. At assembled meetings of the Council, all votes will be cast in person.

(c) In lieu of voting at a properly convened meeting and, when in the opinion of the chairperson of the Council such action is considered necessary, the Council may take action upon the concurring votes of a majority of its members by mail, telephone, telegraph, or any other means of communication, but any such action shall be confirmed promptly in writing. In that event, all members must be notified and provided the opportunity to vote. Any action so taken shall have the same force and effect as though such action had been taken at a properly convened meeting of the Council. All votes shall be recorded in Council minutes.

(d) Meetings of the Council may be conducted by electronic communications, provided that each member is given prior notice of the meeting and has an opportunity to be present either physically or by electronic connection.

(e) The organization of the Council and the procedures for conducting meetings of the Council shall be in accordance with its bylaws,which shall be established by the Council and approved by the Secretary.

§ 1209.37 Compensation and reimbursement.

The members of the Council shall serve without compensation but shall be reimbursed for necessary and reasonable expenses, including a reasonable per diem allowance, as approved by the Council and the Secretary, incurred by such members in the performance of their responsibilities under this subpart.

§ 1209.38 Powers.

The Council shall have the following powers:

(a) To receive and evaluate or, on its own initiative, develop and budget for proposed programs, plans, or projects to promote the use of mushrooms, as well as proposed programs, plans, or projects for research, consumer information, or industry information, and to make recommendations to the Secretary regarding such proposals;

(b) To administer the provisions of this subpart in accordance with its terms and provisions;

(c) To appoint or employ such individuals as it may deem necessary, define the duties, and determine the compensation of such individuals;

(d) To make rules and regulations to effectuate the terms and provisions of this subpart;

(e) To receive, investigate, and report to the Secretary for action complaints of violations of the provisions of this subpart;

(f) To disseminate information to producers, importers, first handlers, or industry organizations through programs or by direct contact using the public postal system or other systems;

(g) To select committees and subcommittees of Council members, including an executive committee whose powers and membership shall be determined by the Council, subject to the approval of the Secretary, and to adopt such bylaws and other rules for the conduct of its business as it may deem advisable;

(h) To establish committees which may include individuals other than Council members, and pay the necessary and reasonable expenses and fees for the members of such committees;

(i) To recommend to the Secretary amendments to this subpart;

(j) With the approval of the Secretary, to enter into contracts or agreements with national, regional, or State mushroom producer organizations, or other organizations or entities, for the development and conduct of programs, plans, or projects authorized under § 1209.40 and with such producer organizations for other services necessary for the implementation of this subpart, and for the payment of the cost thereof with funds collected and received pursuant to this subpart. The Council shall not contract with any producer or importer for the purpose of mushroom promotion or research. The Council may lease physical facilities from a producer or importer for such promotion or research, if such an arrangement is determined to be cost effective by the Council and approved by the Secretary. Any contract or agreement shall provide that:

(1) the contractor or agreeing party shall develop and submit to the Council a program, plan, or project together with a budget or budgets that shall show the estimated cost to be incurred for such program, plan, or project;

(2) any such program, plan, or project shall become effective upon approval of the Secretary;

(3) the contracting or agreeing party shall keep accurate records of all of its transactions and make periodic reports to the Council of activities conducted, submit accountings for funds received and expended, and make such other reports as the Secretary or the Council may require; and the Secretary may audit the records of the contracting or agreeing party periodically; and

(4) any subcontractor who enters into a contract with a Council contractor and who receives or otherwise uses funds allocated by the Council shall be subject to the same provisions as the contractor;

(k) With the approval of the Secretary, to invest, pending disbursement pursuant to a program, plan, or project, funds collected through assessments provided for in § 1209.51, and any other funds received by the Council in, and only in, obligations of the United States or any agency thereof, in general obligations of any State or any political subdivision thereof, in any interest-bearing account or certificate of deposit of a bank that is a member of the Federal Reserve System, or in obligations fully guaranteed as to principal and interest by the United States;

(l) Such other powers as may be approved by the Secretary; and

(m) To develop and propose to the Secretary voluntary quality and grade standards for mushrooms, if the Council determines that such quality and grade standards would benefit the promotion of mushrooms.

§ 1209.39 Duties.

The Council shall have the following duties:

(a) To meet not less than annually, and to organize and select from among its members a chairperson and such other officers as may be necessary;

(b) To evaluate or develop, and submit to the Secretary for approval, promotion, research, consumer information, and industry information programs, plans, or projects;

(c) To prepare for each fiscal year, and submit to the Secretary for approval at least 60 days prior to the beginning of each fiscal year, a budget of its anticipated expenses and disbursements in the administration of this subpart, as provided in § 2109.50.

(d) To maintain such books and records, which shall be available to the Secretary for inspection and audit, and to prepare and submit such reports from time to time to the Secretary, as the Secretary may prescribe, and to make appropriate accounting with respect to the receipt and disbursement of all funds entrusted to it;

(e) To prepare and make public, at least annually, a report of its activities carried out, and an accounting for funds received and expended;

(f) To cause its financial statements to be prepared in conformity with generally accepted accounting principles and to be audited by an independent certified public accountant in accordance with generally accepted auditing standards at least once each fiscal year and at such other times as the Secretary may request, and submit a copy of each such audit to the Secretary;

(g) To give the Secretary the same notice of meetings of the Council as is given to members in order that the Secretary, or a representative of the Secretary, may attend such meetings;

(h) To submit to the Secretary such information as may be requested pursuant to this subpart;

(i) To keep minutes, books, and records that clearly reflect all the acts and transactions of the Council. Minutes of each Council meeting shall be promptly reported to the Secretary;

(j) To act as intermediary between the Secretary and any producer or importer;

(k) To follow the Department's equal opportunity/civil rights policies; and

(l) To work to achieve an effective, continuous, and coordinated program of promotion, research, consumer information, and industry information designed to strengthen the mushroom industry's position in the marketplace, maintain and expand existing markets and uses for mushrooms, develop new markets and uses for mushrooms, and to carry out programs, plans, and projects designed to provide maximum benefits to the mushroom industry.

Promotion, Research, Consumer Information, and Industry Information

§ 1209.40 Programs, plans, and projects.

(a) The Council shall receive and evaluate, or on its own initiative develop, and submit to the Secretary for approval any program, plan, or project authorized under this subpart. Such programs, plans, or projects shall provide for:

(1) The establishment, issuance, effectuation, and administration of appropriate programs for promotion, research, consumer information, and industry information with respect to mushrooms; and

(2) The establishment and conduct of research with respect to the sale, distribution, marketing, and use of mushrooms and mushroom products, and the creation of new products thereof, to the end that marketing and use of mushrooms may be encouraged, expanded, improved or made more acceptable. However, as prescribed by the Act, nothing in this subpart may be construed to authorize mandatory requirements for quality control, grade standards, supply management programs, or other programs that would control production or otherwise limit the right of individual producers to produce mushrooms.

(b) No program, plan, or project shall be implemented prior to its approval by the Secretary. Once a program, plan, or project is so approved, the Council shall take appropriate steps to implement it.

(c) Each programs, plan, or project implemented under this subpart shall be reviewed or evaluated periodically by the Council to ensure that it contributes to an effective program of promotion, research, consumer information, or industry information. If it is found by the Council that any such program, plan, or project does not contribute to an effective program of promotion, research, consumer information, or industry information, then the Council shall terminate such program, plan, or project.

(d) In carrying out any program, plan, or project, no reference to a brand name, trade name, or State or regional identification of any mushrooms or mushroom product shall be made. In addition, no program, plan, or project shall make use of unfair or deceptive acts or practices with respect to the quality, value, or use of any competing product.

Expenses and Assessments

§ 1209.50 Budget and Expenses.

(a)(1) At least 60 days prior to the beginning of each fiscal year, and as may be necessary thereafter, the Council shall prepare and submit to the Secretary a budget for the fiscal year covering its anticipated expenses and disbursements in administering this subpart. Each such budget shall include:

(i) a statement of objectives and strategy for each program, plan, or project;

(ii) a summary of anticipated revenue, with comparative data for at least one preceding year;

(iii) a summary of proposed expenditures for each program, plan, or project; and

(iv) staff and administrative expense breakdowns, with comparative data for at least one preceding year.

Each budget shall include a rate of assessment for such fiscal year calculated, subject to § 1209.51(b), to provide adequate funds to defray its proposed expenditures and to provide

for a reserve as set forth in paragraph (f). The Council may change such rate at any time, as provided in § 1209.51(b)(5).

(2)(i) Subject to paragraph (a)(2)(ii), any amendment or addition to an approved budget must be approved by the Secretary, including shifting of funds from one program, plan, or project to another.

(ii) Shifts of funds which do not cause an increase in the Council's approved budget and which are consistent with governing bylaws need not have prior approval by the Secretary.

(b) The Council is authorized to incur such expenses, including provision for a reasonable reserve, as the Secretary finds are reasonable and likely to be incurred by the Council for its maintenance and functioning, and to enable it to exercise its powers and perform its duties in accordance with the provisions of this subpart. Such expenses shall be paid from funds received by the Council.

(c) The Council shall not use funds collected or received under this subpart to reimburse, defray, or make payment of expenditures incurred in developing, drafting, studying, lobbying on or promoting the legislation authorizing this subpart. Such prohibition includes reimbursement, defrayment, or payment to mushroom industry associations or organizations, producers or importers, lawyers, law firms, or consultants.

(d) The Council may accept voluntary contributions, but these shall only be used to pay expenses incurred in the conduct of programs, plans, and projects. Such contributions shall be free from any encumbrance by the donor and the Council shall retain complete control of their use. The donor may recommend that the whole or a portion of the contribution be applied to an ongoing program, plan, or project.

(e) The Council shall reimburse the Secretary, from funds received by the Council, for administrative costs incurred by the Secretary in implementing and administering this subpart, except for the salaries of Department employees incurred in conducting referenda.

(f) The Council may establish an operating monetary reserve and may carry over to subsequent fiscal periods excess funds in any reserve so established, except that the funds in the reserve shall not exceed approximately one fiscal year's expenses. Such reserve funds may be used to defray any expenses authorized under this subpart.

(g) With the approval of the Secretary, the Council may borrow money for the payment of administrative expenses, subject to the same fiscal, budget, and audit controls as other funds of the Council.

§ 1209.51 Assessments.

(a) Any first handler initially purchasing, or otherwise placing into the current of commerce, mushrooms produced in the United States shall, in the manner as prescribed by the Council and approved by the Secretary, collect an assessment based upon the number of pounds of mushrooms marketed in the United States for the account of the producer, and remit the assessment to the Council.

(b) The rate of assessment effective during any fiscal year shall be the rate specified in the budget for such fiscal year approved by the Secretary, except that:

(1) The rate of assessment during the first year this subpart is in effect shall be one-quarter of one cent per pound of mushrooms marketed, or the equivalent thereof.

(2) The rate of assessment during the second year this subpart is in effect shall not exceed one-third of one cent per pound of mushrooms marketed, or the equivalent thereof.

(3) The rate of assessment during the third year this subpart is in effect shall not exceed one-half of one cent per pound of mushrooms marketed, or the equivalent thereof.

(4) The rate of assessment during each of the fourth and following years this subpart is in effect shall not exceed one cent per pound of mushrooms marketed, or the equivalent thereof.

(5) The Council may change the rate of assessment for a fiscal year at any time with the approval of the Secretary as necessary to reflect changed circumstances, except that any such changed rate may not exceed the level of assessment specified in paragraphs (b)(1), (2), (3), or (4), whichever is applicable.

(c) Any person marketing mushrooms of that person's own production to consumers in the United States, either directly or through retail or wholesale outlets, shall be considered a first handler and shall remit to the Council an assessment on such mushrooms at the rate per-pound then in effect, and in such form and manner prescribed by the Council.

(d) Only one assessment shall be paid on each unit of mushrooms marketed.

(e)(1) Each importer of mushrooms shall pay an assessment to the Council on mushrooms imported for marketing in the United States, through the U.S. Customs Service or in such other manner as may be established by rules and regulations approved by the Secretary.

(2) The per-pound assessment rate for imported mushrooms shall be the same as the rate provided for mushrooms produced in the United States.

(3) The import assessment shall be uniformly applied to imported mushrooms that are identified by the number, 0709.51.0000, in the Harmonized Tariff Schedule of the United States or any other number used to identify fresh mushrooms.

(4) The assessments due on imported mushrooms shall be paid when the mushrooms are entered or withdrawn for consumption in the United States, or at such other time as may be established by rules and regulations prescribed by the Council and approved by the Secretary and under such procedures as are provided in such rules and regulations.

(5) Only one assessment shall be paid on each unit of mushrooms imported.

(f) The collection of assessments under this section shall commence on all mushrooms marketed in or imported into the United States on or after the date established by the Secretary, and shall continue until terminated by the Secretary. If the Council is not constituted on the date the first assessments are to be collected, the Secretary shall have the authority to receive assessments on behalf of the Council and may hold such assessments until the Council is constituted, then remit such assessments to the Council.

(g)(1) Each person responsible for remitting assessments under paragraphs (a), (c), or (e) shall remit the amounts due from assessments to the Council on a monthly basis no later than the fifteenth day of the month following the month in which the mushrooms were marketed, in such manner as prescribed by the Council.

(2)(i) A late payment charge shall be imposed on any person that fails to remit to the Council the total amount for which the person is liable on or before the payment due date established under this section. The amount of the late payment charge shall be prescribed in rules and regulations as approved by the Secretary.

(ii) An additional charge shall be imposed on any person subject to a late payment charge, in the form of interest on the outstanding portion of any amount for which the person is liable. The rate of interest shall be prescribed in rules and regulations as approved by the Secretary.

(3) Any assessment that is determined to be owing at a date later than the payment due established under this section, due to a person's failure to submit a report to the Council by the payment due date, shall be considered

to have been payable on the payment due date. Under such a situation, paragraphs (g)(2)(i) and (g)(2)(ii) of this section shall be applicable.

(h) The Council, with the approval of the Secretary, may enter into agreements authorizing other organizations to collect assessments in its behalf. Any such organization shall be required to maintain the confidentiality of such information as is required by the Council for collection purposes. Any reimbursement by the Council for such services shall be based on reasonable charges for services rendered.

(i) The Council is hereby authorized to accept advance payment of assessments for the fiscal year by any person, that shall be credited toward any amount for which such person may become liable. The Council shall not be obligated to pay interest on any advance payment.

§ 1209.52 Exemption from assessment.

(a) Persons that produce or import, on average, 500,000 pounds or less of mushrooms annually shall be exempted from assessment.

(b) To claim such exemption, such persons shall apply to the Council, in the form and manner prescribed in the rules and regulations.

(c) Mushrooms produced in the United States that are exported are exempt from assessment and are subject to such safeguards as prescribed in rules and regulations to prevent improper use of this exemption.

(d) Domestic and imported mushrooms used for processing are exempt from assessment and are subject to such safeguards as prescribed in rules and regulations to prevent improper use of this exemption.

§ 1209.53 Influencing governmental action.

No funds received by the Council under this subpart shall in any manner be used for the purpose of influencing legislation or governmental policy or action, except to develop and recommend to the Secretary amendments to this subpart, and to submit to the Secretary proposed voluntary grade and quality standards for mushrooms.

Reports, Books and Records

§ 1209.60 Reports.

(a) Each producer marketing mushrooms of that person's own production directly to consumers, and each first handler responsible for the collection of assessments under § 1209.51(a) shall be required to report monthly to the Council, on a form provided by the Council, such information as may be required under this subpart or any rules and regulations issued thereunder. Such information shall include, but not be limited to, the following:

(1) The first handler's name, address, and telephone number;

(2) Date of report, which is also the date of payment to the Council;

(3) Period covered by the report;

(4) The number of pounds of mushrooms purchased, initially transferred, or that in any other manner are subject to the collection of assessments, and a copy of a certificate of exemption, claiming exemption under § 1209.52 from those who claim such exemptions;

(5) The amount of assessments remitted; and

(6) The basis, if necessary, to show why the remittance is less than the number of pounds of mushrooms determined under paragraph (a)(4) multiplied by the applicable assessment rate.

(b) If determined necessary by the Council and approved by the Secretary, each importer shall file with the Council periodic reports, on a form provided by the Council, containing at least the following information:

(1) The importer's name, address, and telephone number;

(2) The quantity of mushrooms entered or withdrawn for consumption in the United States during the period covered by the report; and

(3) The amount of assessments paid to the U.S. Customs Service at the time of such entry or withdrawal.

(c) The words *final report* shall be shown on the last report at the end of each fiscal year.

§ 1209.61 Books and records.

Each persons who is subject to this subpart shall maintain and make available for inspection by the Council or the Secretary such books and records as are deemed necessary by the Council, with the approval of the Secretary, to carry out the provisions of this subpart and any rules and regulations issued hereunder, including such books and records as are necessary to verify any reports required. Such books and records shall be retained for at least two years beyond the fiscal year of their applicability.

§ 1209.62 Confidential treatment.

All information obtained from books, records, or reports under the Act, this subpart, and the rules and regulations issued thereunder shall be kept confidential by all persons, including all employees and former employees of the Council, all officers and employees and former officers and employees of the Department, and all officers and employees and former officers and employees of contracting and subcontracting agencies or agreeing parties having access to such information. Such information shall not be available to Council members, producers, importers, or first handlers. Only those persons having a specific need for such information to effectively administer the provisions of this subpart shall have access to such information. Only such information so obtained as the Secretary deems relevant shall be disclosed by them, and then only in a suit or administrative hearing brought at the direction, or on the request, of the Secretary, or to which the Secretary or any officer of the United States is a party, and involving this subpart. Nothing in this section shall be deemed to prohibit:

(a) The issuance of general statements based upon the reports of the number of persons subject to this subpart or statistical data collected therefrom, which statements do not identify the information furnished by any person; and

(b) The publication, by direction of the Secretary, of the name of any person who has been adjudged to have violated this subpart, together with a statement of the particular provisions of this subpart violated by such person.

Miscellaneous

§ 1209.70 Right of the Secretary.

All fiscal matters, programs, plans, or projects, rules or regulations, reports, or other substantive actions proposed and prepared by the Council shall be submitted to the Secretary for approval.

§ 1209.71 Suspension or termination.

(a) Whenever the Secretary finds that this subpart or any provision thereof obstructs or does not tend to effectuate the declared policy of the Act, the Secretary shall terminate or suspend the operation of this subpart or such provision thereof.

(b)(1) Five years after the date on which this subpart becomes effective, the Secretary shall conduct a referendum among producers and importers to determine whether they favor continuation, termination, or suspension of this subpart.

(2) Effective beginning three years after the date on which this subpart becomes effective, the Secretary, on request of a representative group comprising 30 percent or more of the number of mushroom producers and importers, may conduct a referendum to determine whether producers and importers favor termination or suspension of this subpart.

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(3) Whenever the Secretary determines that suspension or termination of this subpart is favored by a majority of the mushroom producers and importers voting in a referendum under paragraphs (b) (1) or (2) who, during a representative period determined by the Secretary, have been engaged in producing and importing mushrooms and who, on average, annually produced and imported more than 50 percent of the volume of mushrooms produced and imported by all those producers and importers voting in the referendum, the Secretary shall:

(i) suspend or terminate, as appropriate, collection of assessments within six months after making such determination; and

(ii) suspend or terminate, as appropriate, all activities under this subpart in an orderly manner as soon as practicable.

(4) Referenda conducted under this subsection shall be conducted in such manner as the Secretary may prescribe.

§ 1209.72 Proceedings after termination.

(a) Upon the termination of this subpart, the Council shall recommend not more than five of its members to the Secretary to serve as trustees for the purpose of liquidating the affairs of the Council. Such persons, upon designation by the Secretary, shall become trustees of all the funds and property owned, in the possession of, or under the control of the Council, including any claims unpaid or property not delivered, or any other claim existing at the time of such termination.

(b) The trustees shall: (1) Continue in such capacity until discharged by the Secretary;

(2) Carry out the obligations of the Council under any contract or agreement entered into by it under this subpart;

(3) From time to time account for all receipts and disbursements, and deliver all property on hand, together with all books and records of the Council and of the trustees, to such persons as the Secretary may direct; and

(4) Upon the request of the Secretary, execute such assignments or other instruments necessary or appropriate to vest in such persons full title and right to all of the funds, property, and claims vested in the Council or the trustees under this subpart.

(c) Any person to whom funds, property, or claims have been transferred or delivered under this subpart shall be subject to the same obligations imposed upon the Council and upon the trustees.

(d) Any residual funds not required to defray the necessary expenses of liquidation shall be turned over to the Secretary to be used, to the extent practicable, in the interest of continuing one or more of the promotion, research, consumer information, or industry information programs, plans, or projects authorized under this subpart.

§ 1209.73 Effect of termination or amendment.

Unless otherwise expressly provided by the Secretary, the termination of this subpart or of any rule and regulation issued under this subpart, or the issuance of any amendment to such provisions, shall not:

(a) Affect or waive any right, duty, obligation, or liability that shall have arisen or may hereafter arise in connection with any provision of this subpart or any such rules or regulations;

(b) Release or extinguish any violation of this subpart or any such rules or regulations; or

(c) Affect or impair any rights or remedies of the United States, the Secretary, or any person with respect to any such violation.

§ 1209.74 Personal liability.

No member or employee of the Council shall be held personally responsible, either individually or jointly, in any way whatsoever, to any person for errors in judgment, mistakes, or other acts of either commission or omission of such member or employee under this subpart, except for acts of dishonesty or willful misconduct.

§ 1209.75 Patents, copyrights, inventions, publications, and product formulations.

Any patents, copyrights, inventions, publications, or product formulations developed through the use of funds received by the Council under this subpart shall be the property of the United States Government as represented by the Council and shall, along with any rents, royalties, residual payments, or other income from the rental, sale, leasing, franchising, or other uses of such patents, copyrights, inventions, publications, or product formulations inure to the benefit of the Council and be considered income subject to the same fiscal, budget, and audit controls as other funds of the Council. Upon termination of this subpart, § 1209.72 shall apply to determine disposition of all such property.

§ 1209.76 Amendments.

Amendments to this subpart may be proposed, from time to time, by the Council or by any interested person affected by the provisions of the Act, including the Secretary.

§ 1209.77 Separability.

If any provision of this subpart is declared invalid, or the applicability thereof to any person or circumstances is held invalid, the validity of the remainder of this subpart or the applicability thereof to other persons or circumstances shall not be affected thereby.

Dated: December 31, 1992.

Jo Ann R. Smith,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–211 Filed 1–6–93; 11:04 am]

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Friday
January 8, 1993

Part XII

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 779, 780, 783, and 784
Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Land Use Information; Proposed Rule

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 779, 780, 783, and 784

RIN 1029-AB57

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Land Use Information

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the United States Department of the Interior (DOI) proposes to amend its regulations on Surface mining permit applications—minimum requirements for information on environmental resources; Surface mining permit applications—minimum requirements for reclamation and operation plan; Underground mining permit application—minimum requirements for information on environmental resources; and Underground mining permit application—minimum requirements for reclamation and operation plan. Central to this rulemaking is a proposed rule (Reclamation plan: Land use information) which will simplify and reduce the permit applicant's regulatory reporting burden by eliminating duplicative and/or unnecessary informational requirements.

DATES: *Written comments:* OSM will accept written comments on the proposed rule until 5 p.m. Eastern time on March 9, 1993.

Public hearings: Upon request, OSM will hold public hearings on the proposed rule in Washington, DC; in Denver, Colorado, and in Knoxville, Tennessee on March 4, 1993. Upon request, OSM will also hold public hearings at times and on dates and locations to be announced in the **Federal Register** prior to the hearings. OSM will accept requests for public hearings until 5 p.m. Eastern time on February 8, 1993. Individuals wishing to attend but not testify at any hearing should contact the person identified under "FOR FURTHER INFORMATION CONTACT" beforehand to verify that the hearing will be held.

ADDRESSES: *Written comments:* Hand-deliver to the OSM, Administrative Record, suite 660; 800 North Capitol St., NW., Washington, DC; or mail to the OSM, Administrative Record, 1951 Constitution Avenue, suite 660 NC, NW., Washington, DC 20240.

Public hearings: Department of the Interior Auditorium, 18th and C Streets, NW., Washington, DC; Brooks Towers, 2nd Floor Conference Room, 1020 15th St., Denver, Colorado; and the Hyatt, 500 Hill Avenue, SE., Knoxville, Tennessee. The addresses for any hearings scheduled will be announced prior to the hearings.

Request for public hearings: Submit orally or in writing to the person and address specified under "FOR FURTHER INFORMATION CONTACT."

FOR FURTHER INFORMATION CONTACT: Archana Kohli, 1951 Constitution Avenue, suite 640 NC, Washington, DC. 20240; Telephone: (202) 343-3871 commercial or FTS.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures
II. Background
III. Discussion of Proposed Rule
IV. Procedural Matters

I. Public Comment Procedures

Written Comments

Written comments submitted on the proposed rule should be specific, should be confined to issues pertinent to the proposed rule, and should explain the reason for any recommended change. Where practicable, commenters should submit three copies of their comments. Comments received after the close of the comment period (see "DATES") or delivered to an address other than those listed above (see "ADDRESSES") may not necessarily be considered or included in the Administrative Record for the final rule.

Public Hearings

OSM will hold public hearings on the proposed rule by request only. The addresses for the hearings at three locations are specified previously in this notice (see "DATES" and "ADDRESSES").

Any person interested in participating at a hearing at a particular location should inform Archana Kohli, (see FOR FURTHER INFORMATION CONTACT) either orally or in writing of the desired hearing location by 5 p.m. Eastern time February 8, 1993. If no one has contacted Ms. Kohli to express an interest in participating in a hearing by that date, the hearing will not be held. If only one person expresses an interest, a public meeting rather than a hearing may be held and the results included in the Administrative Record.

If a hearing is held, it will continue until all persons wishing to testify have been heard. To assist the transcriber and ensure an accurate record, OSM requests that persons who testify at a hearing give the transcriber a copy of their testimony to assist OSM in preparing appropriate questions. OSM also requests that persons who plan to testify submit to OSM, at the address previously specified for the submission of written comments, (see ADDRESSES) an advance copy of the testimony.

II. Background

On March 13, 1979, OSM promulgated permanent program rules (44 FR 14902) as required by section 501(b) of the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act), 30 U.S.C. 1201 *et seq.* In the rules, 30 CFR part 779 establishes the minimum permit application requirements for information on existing environmental resources that may be impacted by the conduct and location of proposed surface mining activities. (Part 783 for underground mining) (44 FR 15026).

Thirty CFR part 780 establishes the minimum permit application requirements for surface mining operation and reclamation plans. (Part 784 for underground mining) (44 FR 15047). The information requirements of parts 779/783 and 780/784 accord with the prescriptions of sections 507, 508, 515, and 516 of the Act in two ways: First, the permit application submitted pursuant to these parts must contain sufficient information to meet the public disclosure requirements of the Act. Second, the permit application must also contain sufficient information for the regulatory authority to be able to find in writing on the basis of that information and information otherwise available whether the proposed operation should be permitted. The level of detail and scope of information required in the permit application will vary depending on the needs of the regulatory authority to fulfill its responsibility to make sound approval decisions under section 510(b) of SMCRA and 30 CFR 773.15(c). The required information is intended to assist the regulatory authority in determining whether the applicant can comply with the performance standards for surface and underground mining and whether reclamation of these areas is feasible.

The information requirements of parts 779 and 780 impose a significant reporting burden on permit applicants to obtain, analyze, and present information to both the regulatory authority and the public when seeking to permit a surface coal mining operation. Under the Paperwork Reduction Reauthorization Act of 1986, OSM is responsible for ensuring that its rules do not impose any unnecessary reporting burden on the permit

applicant. (44 U.S.C. 3507(a)(1)(b)). In 1987, OSM established a work group to review the permitting rules and other regulations. One purpose of the review was to determine whether changes to these information requirements could be made to reduce the reporting burden on the permit applicant without compromising their implementation of the purposes and provisions of the Act.

After reviewing the working group's recommendations regarding rule changes, OSM identified four changes which are the subject of this rulemaking. While OSM recognizes its obligation under the Paperwork Reduction Reauthorization Act of 1986 to ensure that public reporting burden be minimized, the office also recognizes the need to maintain a stable regulatory program implementing the purpose and provisions of the Act. On this basis, the balance of the work group's recommended rule changes were rejected because OSM felt the insignificant reduction in reporting burden which they would afford did not justify the potential disruption to the regulatory program which would be caused by such changes.

This rulemaking consolidates two land use information rules, 30 CFR 779.22/783.22 and 30 CFR 780.23/784.15 into proposed 30 CFR 780.23/784.15. OSM also proposes to delete two other rules which provide for the collection of premining environmental resource information, 30 CFR 779.19/783.19 regarding the collection of supplemental information on vegetation, and 30 CFR 779.25(a)(11)/783.25(a)(11) regarding the presentation of premining slopes.

Consistent with its findings when promulgating the 1979 rules, OSM has not identified any differences between surface and underground mines that would appear to necessitate different regulatory provisions under this proposed rulemaking. Therefore, the proposed permitting rule applicable to surface mining activities at 30 CFR 780.23 and the proposed permitting rule applicable to underground mining activities at 30 CFR 784.15 are identical. Likewise the rules for surface mining activities at 30 CFR 779.19, 779.22, and 779.25(a)(11) are identical to the rules for underground mining activities at 30 CFR 783.19, 783.22, and 783.25(a)(11), respectively. Thus, the discussion of changes or deletions to 30 CFR 779.19, 779.22, 779.25(a)(11) and 780.23 will also apply to 30 CFR 783.19, 783.22, 783.25(a)(11) and 784.15.

A. Land Use Information Rules

Section 30 CFR 779.22 identifies the premining land use information required in a permit application. (March 13, 1979, 44 FR 15040).

Section 779.22(a) requires that the application contain a statement of the condition, capability, and productivity of the land within the proposed permit area. Section 779.22(a)(1) requires the application contain a map and a narrative that describes the use of the proposed permit area at the time of filing and the premining land use if its use was changed within five years before the date of application. The map is used to compare premining land uses with proposed postmining land uses. Section 779.22(a)(1) implements section 508(a)(2)(A) of the Act.

Section 779.22(a)(2) requires that the permit application include a narrative of the capability and productivity of the land to support a number of uses to be used in analyzing the land use description contained in § 779.22(a)(1). Environmental information from § 779.22(a)(2) together with land use information from § 779.22(a)(1) provide a foundation for the reclamation plan required by section 30 CFR 780.23 (Reclamation plan: Postmining land uses). Section 779.22(a)(2) and its two subsections, (i) and (ii), implement sections 508(a)(2) (B) and (C) of the Act.

Section 779.22(b) requires a description of premining land use conditions for previously mined areas. These regulations provide that an application for a previously mined area identify the type of mining method used, the coal seams or other mineral strata mined, the extent of coal or minerals removed, the approximate dates of past mining, and the uses of the land preceding mining. Information from this section is used by the regulatory authority both to assess whether the mining operation will be conducted in a manner which mitigates the environmental damage caused by the previous operations and to establish reclamation criteria based on the present condition of the land. This information is not specifically required by the Act.

Section 779.22(c) requires that the application describe the proposed mining area's existing land uses and their classifications under local law. Information from this section is used by the regulatory authority to evaluate the proposed post mining land uses and to assess the compatibility of the proposed land use with the existing land use policies and plans. The information required by this section is essentially the same information required by existing § 780.23(b). Section 779.22(c) implements section 508(a)(3) of the Act.

Section 30 CFR 780.23 establishes the criteria used to approve a postmining land use analysis and plan. Section 780.23 implements section 508(a) (3) and (4) of the Act. (March 13, 1979, 44 FR 15057).

Section 780.23(a) requires that the applicant's reclamation plan describe the proposed postmining land use. Included must be a discussion of the utility and capacity of the reclaimed land to support a variety of alternative uses which must conform to the existing land use policies and plans. Section 780.23(a) implements section 508(a)(3) of the Act.

Section 780.23(a)(1) requires a description of the proposed postmining land use and the method in which the proposed postmining land use is attained. Section 780.23(a)(1) implements section 508(a)(4) of the Act.

Section 780.23(a)(2) requires specific management plans when range and grazing is proposed as a postmining land use. Range or grazing management plans are not specifically required by the Act.

Section 780.23(a)(3) requires information needed to support approval for an alternative postmining land use when requested under § 816.133.

Section 780.23(a)(4) requires that consideration be given to making proposed mining activities consistent with the existing surface owner plans and applicable State and local land use plans and programs. Section 780.23(a)(4) implements section 508(a)(3) of the Act.

Section 780.23(b) provides the reclamation plan include a copy of the comments on the proposed land use by the legal or equitable owner of record of the surface of the proposed permit area and the applicable State and local government agency. Section 780.23(b) implements section 508(a)(3) of the Act.

B. Vegetation Information

Thirty CFR 779.19 authorizes the regulatory authority to require a permit applicant to supplement vegetation information by submitting a map or an aerial photo delineating the existing types of vegetation with a written description of the existing plant communities within the proposed permit area and within any proposed reference area. This data is designed to help the regulatory authority to complete the land use analysis required by existing § 779.22 (Land use information), to assist in evaluating the applicant's ability to meet the performance standards in §§ 816.45–816.46, 816.97, 816.111–816.117 and 816.133 of subchapter K, to establish premining site conditions for wildlife and fish habitat, to establish seed sources used for revegetating the land,

to identify species of vegetation that may contribute to important postmining land use values of the permit area, to quantitatively characterize vegetative communities later used to establish a baseline for comparing premining with postmining success in revegetation, and to help evaluate the present and the potential productivity of the proposed site. (March 13, 1979, 44 FR 15036).

C. Slope Measurement

Thirty CFR 779.25 (Cross sections, maps, and plans) requires slope measurements against which new mining effects can be compared. Section 779.25(a)(11) requires the applicant to include the existing slopes of the proposed mine site. The 1979 preamble indicates that slope can be derived from either a topographic map or from field calculations. (March 13, 1979, 44 FR 15045). These slope measurements are to be used by the regulatory authority to evaluate the applicant's ability to achieve approximate original contour. There is no specific requirement in the Act to provide preexisting slope measurements.

III. Discussion of Proposed Rule

The proposed rulemaking simplifies the current regulations by proposing a single, new rule, 30 CFR 780.23 (Land use information), to replace the two existing land use information rules. Proposed § 780.23 combines sections from existing §§ 780.23 (Reclamation plan: Postmining land use) and 779.22 (Land use information). This rulemaking would delete § 779.22 in its entirety. Paragraphs from existing § 779.22 needed to implement prescriptions of the Act will be relocated to the new § 780.23. The proposed rule also deletes § 779.19 (Vegetation information) and § 779.25(a)(11) (Cross sections, maps, and plans) in their entirety.

A. Land Use Information

Listed below is an outline of the informational requirements that would be incorporated into proposed 30 CFR 780.23 (Reclamation plan: Land use information).

1. Proposed § 780.23(a) would require that the applicant provide a statement of the condition, capability, and the productivity of the land within the proposed permit area as required by section 508(a)(2) of the Act. Proposed § 780.23(a) is existing section 779.22(a).

2. Proposed § 780.23(a)(1) would require that the applicant provide a map and a narrative of the current and historic land uses. This provision implements section 508(a)(2)(A) of the Act. Under existing § 779.22(a)(1), OSM originally set up a specific time frame of five years to indicate how far back the historical land use description must extend. Proposed § 780.23(a)(1) is identical to existing § 779.22(a)(1) with the exception that the latter five year limit is replaced by a historical land use description. The regulatory authority will determine on a case by case basis the length of the period for information on historical land use.

3. Proposed § 780.23(a)(2) would require that the applicant provide a narrative of the land capability and productivity, which analyzes the land use description in conjunction with other environmental resource information. These provisions currently appear as § 779.22(a)(2). No changes have been made to provisions under § 779.22(a)(2) other than their new location in the rules. Proposed § 780.23(a)(2)(i) implements section 508(a)(2)(B) of the Act and proposed § 780.23(a)(2)(ii) implements section 508(a)(2)(C) of the Act.

4. Proposed § 780.23(b) would require a statement on the utility and capacity of the reclaimed land to support a variety of alternative uses. These provisions currently appear in the rules as § 780.23(a). Proposed § 780.23(b) implements section 508(a)(3) of the Act.

5. Proposed § 780.23(b)(1) would require that the applicant discuss how the proposed postmining land use will be achieved. Proposed § 780.23(b)(1) currently appears as § 780.23(a)(1). Proposed § 780.23(b)(1) implements section 508(a)(4) of the Act.

6. Proposed § 780.23(b)(2) would require that the applicant include a detailed description of proposed postmining land uses that are different from the premining land uses. Proposed § 780.23(b)(2) currently appears as § 780.23(a)(3). This section implements sections 508(a)(2)(A) and 508(a)(3) of the Act.

7. Proposed § 780.23(c) would require that the applicant describe comments by the legal or equitable owner of record of the surface of the proposed permit area and the State and local government agencies which would have to initiate, implement, approve, or authorize the proposed use of the land following reclamation. Proposed § 780.23(c) is identical to existing §§ 780.23(a)(4) and (b). Section 508(a)(3) of the Act mandates that the any owners of the surface, State, and local governments or agencies be given the opportunity to comment on the proposed land use and that these comments be incorporated into the permit application. Section 508(a)(8) of the Act requires the reclamation plan include a statement of the consideration which has been given to making the surface mining and reclamation operations consistent with surface owner plans, and applicable State and local land use plans and programs.

1. This rulemaking would delete existing 30 CFR 779.22(b). Section 779.22(b) requires that if specific information about mining activities at previously mined areas is available, such information must be included in the permit application. As will be discussed below, if the information required under this section is even available, it is either provided elsewhere by the applicant in their permit application or available from prior program permitting records and therefore, more accessible to the regulatory authority than to the applicant.

a. Existing § 779.22(b)(1) requires a description of the type of mining method used at the previously mined area. To the extent that information required by 30 CFR 779.25(a)(5) and (8) (Cross sections, maps, and plans) is available to the regulatory authority regarding the previously mined area, the maps and plans would show the type of mining methods used.

b. Existing §§ 779.22(b) (2) and (3) require a statement of the coal seams or other mineral strata mined and the extent of coal or other minerals removed from the previously mined area. This information can easily be calculated by the regulatory authority from other information required to be submitted by the applicant under 30 CFR 779.25(a)(3), (4), (8), and 30 CFR 780.11(a).

c. Existing § 779.22(b)(4) requires a statement of the approximate dates of previous mining. This open-ended informational requirement is unnecessary. The only time that a date is significant for remining purposes is when the applicant intends to reclaim in accordance with the requirements of 30 CFR 816.106. In order to reclaim to such standards, 30 CFR 773.15(c)(12) requires that the applicant must affirmatively establish that the intended site of operations is a previously mined area. Requiring the applicant to submit a statement of this cessation date again under § 779.22(b)(4) serves no useful regulatory purpose.

d. Existing § 779.22(b)(5) requires a statement of the uses of the land preceding previous mining operations. This information will be provided by the applicant under proposed § 780.23(a)(1) (Reclamation plan: Land use information) which requires the submission of a map and a supporting narrative of the historic uses of the land.

2. Existing § 779.22(c) requires a description of the existing land uses and land use classifications under local law

of the proposed permit area and adjacent areas. While OSM considers information required by this provision to be important land use information, existing §§ 780.23(a)(4) and (b) (proposed § 780.23(c)) requires the applicant's submission of essentially the same information.

This rulemaking would also delete existing § 780.23(a)(2) which requires the submission of a detailed management plan where range or grazing was the proposed postmining land use. In 1979, OSM rejected comments to delete this section. At that time, OSM stated its belief that a detailed management plan was necessary to determine the feasibility of a proposed range/grazing post mining land use. (March 13, 1979, 44 FR 15058). Since then, OSM has reconsidered the utility of requiring such detailed plans. For legitimate economic and/or ecological reasons, the actual management plan implemented for a reclaimed area may often vary greatly from the detailed plan submitted under § 780.23(a)(2). The uncertain benefit which may be derived from the submission of these plans does not justify the burden of their preparation. Accordingly, OSM is proposing to delete the requirements of 30 CFR 780.23(a)(2). The provisions of existing § 780.23(a)(1) (proposed § 780.23(b)(1)) should allow for the level of detail necessary to determine the feasibility of the proposed land range/grazing land use.

B. Vegetation Information

Existing § 30 CFR 779.19 (Vegetation information) is proposed for deletion. This section authorizes a regulatory authority to require a map and a description of the plant communities within the proposed permit area and within any proposed reference area. OSM originally envisioned that this detailed information could be helpful in completing the vegetative land use analysis required by § 779.22 (land use information). (March 13, 1979, 44 FR 15037).

In revisiting this issue, OSM has concluded that § 779.19 is redundant. 30 CFR 779.22(a) (proposed §§ 780.23(a) (Reclamation plan: Land use information)), 773.15(c) (Review of permit applications), 780.16 (Fish and Wildlife information), and 780.18(b)(5) (Reclamation plan: General requirements) provide sufficient authority for the regulatory authority to require the level of detailed information necessary to complete the vegetative land use analysis required by § 779.22(a). The regulatory authority may, if needed, craft its own vegetation requirements on a permit by permit basis. In addition, no permit can be approved unless the regulatory authority is satisfied that the approved permit will be sufficient to comply with the revegetation performance standards of 30 CFR 816.111/817.111, and 816.116/817.116 of the rules.

C. Slope Measurement

Existing section 30 CFR 779.25(a)(11) (Cross sections, maps, and plans) requiring slope measurements is proposed to be deleted. OSM recognizes that premining slope measurements are needed to ensure that restored contours meet approximate original contour conditions. The present rule is, however, redundant as it provides no additional information beyond that already available to the regulatory authority under 30 CFR 777.14(a) and OSM's technical information processing system (TIPS). In the 1979 preamble to § 779.25, OSM acknowledged that the required slope measurements could be derived from existing topographic maps or from measurements taken in the fields (March 13, 1979, 44 FR 15045). Since that time, OSM has found most permit applicants would rather derive the required measurements from a topographic map rather than from field measurements. Existing § 777.14(a) requires a permit applicant to submit a topographic map of the permit area which includes U.S. Geological Survey topographic features. Therefore, it makes no difference as to whether the applicant measures the slope from a topographic map in fulfillment of the requirements under § 779.25(a)(11) or the regulatory authority measures the slope from the same or similar topographic map submitted under § 779.14(a) so long as the regulatory authority has adequate information on the slope of the proposed permit area to assure that approximate original contour will be achieved. Subsequent to the 1979 promulgation and issuance of § 779.25(a)(11), OSM has also made available to regulatory authorities the TIPS software and data analysis capabilities which allows both premining slopes and cross sections to be computed.

IV. Procedural Matters

Federal Paperwork Reduction Act

The reductions to the information collection requirements resulting from this proposed rule have been submitted to the Office of Management and Budget for approval as required by 44 U.S.C. 3501 *et seq.*

Executive Order 12291 and Regulatory Flexibility Act

The DOI has determined that this document is not a major rule under the criteria of Executive Order 12291 (February 17, 1981), and that it will not have a significant effect on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The rule does not distinguish between small and large entities. No negative incremental economic effects are anticipated as a result of the rule whose chief purpose is to relieve rather than impose new burden on businesses.

National Environmental Policy Act

OSM prepared a draft environmental assessment (EA), and has made a tentative finding that the proposed rule would not significantly affect the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(C). The draft EA is on file in the OSM Administrative Record at the address specified previously (see "ADDRESSES"). An EA of the final rule will be completed and a final finding made on the significance of any impacts prior to promulgation of the final rule.

Executive Order 12778 on Civil Justice Reform

This proposed rule has been reviewed under the applicable standards of Section 2(b)(2) of Executive Order 12778, Civil Justice Reform (56 Fed. Reg. 55195). In general, the requirements of Section 2(b)(2) of Executive Order 12778 are covered by the preamble discussion of this proposed rule. Additional remarks follow concerning individual elements of the Executive Order:

A. What is the preemptive effect, if any, to be given to the regulation?

To the extent that the proposed rule would relieve, rather than impose, regulatory requirements, the proposed rule would have no preemptive effect.

B. What is the effect on existing Federal law or regulation, if any, including all provisions repealed or modified?

This rule modifies the implementation of SMCRA as described herein, and is not intended to modify the implementation of any other Federal statute. The preceding discussion of this rule specifies the Federal regulatory provisions that are affected by this rule.

C. Does the rule provide a clear and certain legal standard for affected conduct rather than a general standard, while promoting simplification and burden reduction?

The standards established by this rule are as clear and certain as practicable, given the complexity of the topics covered and the mandates of SMCRA.

D. What is the retroactive effect, if any, to be given to the regulation?

This rule is not intended to have retroactive effect.

E. Are administrative proceedings required before parties may file suit in court? Which proceedings apply? Is the exhaustion of administrative remedies required?

No administrative proceedings are required before parties may file suit in court challenging the provisions of this rule under section 526(a) of SMCRA, 30 U.S.C. 1276(a).

Prior to any judicial challenge to the application of the rule, however, administrative procedures must be exhausted. In situations involving OSM application of the rule, applicable administrative procedures may be found at 43 CFR part 4. In situations involving State regulatory authority application of provisions equivalent to those contained in this rule, applicable administrative procedures are set forth in the particular State program.

F. Does the rule define key terms, either explicitly or by reference to other regulations or statutes that explicitly define those items?

Terms which are important to the understanding of this rule are set forth in 30 CFR 700.5 and 701.5.

G. Does the rule address other important issues affecting clarity and general draftsmanship of regulations set forth by the Attorney General, with the concurrence of the Director of the Office of Management and Budget, that are determined to be in accordance with the purposes of the Executive Order?

As of January 8, 1993, the Attorney General and the Director of the Office of Management and Budget have not issued any guidance on this requirement.

Author

The principal author of this rule is Ms. Archana Kohli, Civil Engineer, Division of Technical Services, Office of Surface Mining, 1951 Constitution Avenue, NW., Washington, DC 20240. Ms. Kohli's telephone number is (202) 343–3871 commercial or FTS.

List of Subjects

30 CFR Part 779

Environmental protection, Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 780

Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 783

Environmental protection, Reporting and recordkeeping requirements, Underground mining.

30 CFR Part 784

Reporting and recordkeeping requirements, Underground mining.

Accordingly it is proposed to amend 30 CFR parts 779, 780, 783, and 784 set forth below.

Dated: October 20, 1992.

Richard Roldan,

Deputy Assistant Secretary, Land and Minerals Management.

PART 779—SURFACE MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR INFORMATION ON ENVIRONMENTAL RESOURCES

1. The authority citation for part 779 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*; sec. 115 of Pub. L. 98–146, (30 U.S.C. 1257), and 16 U.S.C. 470 *et seq.*

§ 779.19 [Removed]

2. Section 779.19 is removed.

§ 779.22 [Removed]

3. Section 779.22 is removed.

§ 779.25 [Amended]

4. In section 779.25, paragraph (a)(11) is removed.

PART 780—SURFACE MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENT FOR RECLAMATION AND OPERATION PLAN

5. The authority citation for part 780 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*, as amended; sec. 115 of Pub. L. 98–146, 30 U.S.C. 1257; 16 U.S.C. 470 *et seq.*; and Pub. L. 100–34.

6. Section 780.23 is revised to read as follows:

§ 780.23 Reclamation plan: Land use information.

(a) The plan shall contain a statement of the condition, capability, and productivity of the land within the proposed permit area, including—

(1) A map and supporting narrative of the uses of the land existing at the time of the filing of the application. The historic use of the land shall also be described.

(2) A narrative of land capability and productivity, which analyzes the land-use description under paragraph (a) of this section in conjunction with other environmental resources information. The narrative shall provide analyses of:

(i) The capability of the land before any mining to support a variety of uses, giving consideration to soil and foundation characteristics, topography, vegetative cover and the hydrology of the proposed permit area; and

(ii) The productivity of the proposed permit area before mining, expressed as average yield of food, fiber, forage, or wood products from such lands obtained under high levels of management. The productivity shall be determined by yield data or estimates for similar sites based on current data from the U.S. Department of Agriculture, State agricultural universities or appropriate State natural resource or agricultural agencies.

(b) Each plan shall contain a detailed description of the proposed use, following reclamation, of the land within the proposed permit area including a discussion of the utility and capacity of the reclaimed land to support a variety of alternative uses, and the relationship of the proposed use to existing land use policies and plans. This description shall explain—

(1) How the proposed postmining land use is to be achieved and the necessary support activities which may be needed to achieve the proposed land use; and

(2) Where a land use different from the premining land use is proposed, all materials needed for approval of the alternative use under 30 CFR 816.133.

(c) The consideration which has been given to making all of the proposed surface mining activities consistent with surface owner plans and applicable State and local land use plans and programs. The description shall be accompanied by a copy of the comments concerning the proposed use by the legal or equitable owner of record of the surface of the proposed permit area and the State and local government agencies which would have to initiate, implement, approve, or authorize the proposed use of the land following reclamation.

PART 783—UNDERGROUND MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR INFORMATION ON ENVIRONMENTAL RESOURCES

7. The authority citation for part 783 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*; sec. 115 of Pub. L. 98–146, (30 U.S.C. 1257), and 16 U.S.C. 470 *et seq.*

§ 783.19 [Removed]

8. Section 783.19 is removed.

§ 783.22 [Removed]

9. Section 783.22 is removed.

§ 783.25 [Amended]

10. In § 783.25, paragraph (a)(11) is removed.

PART 784—UNDERGROUND MINING PERMIT APPLICATIONS—MINIMUM REQUIREMENTS FOR RECLAMATION AND OPERATION PLAN

11. The authority citation for part 784 continues to read as follows:

Authority: Pub. L. 95–87, 30 U.S.C. 1201 *et seq.*, as amended; sec. 115 of Pub. L. 98–146, 30 U.S.C. 1257; 16 U.S.C. 470 *et seq.*; and Pub. L. 100–34.

12. Section 784.15 is revised to read as follows:

§ 784.15 Reclamation plan: Land use information.

(a) The plan shall contain a statement of the condition, capability, and productivity of the land within the proposed permit area, including—

(1) A map and supporting narrative of the uses of the land existing at the time of the filing of the application. The historic use of the land shall also be described.

(2) A narrative of land capability and productivity, which analyzes the land-use description under paragraph (a) of this section in conjunction with other environmental resources information. The narrative shall provide analyses of:

(i) The capability of the land before any mining to support a variety of uses, giving consideration to soil and foundation characteristics, topography, vegetative cover and the hydrology of the proposed permit area; and

(ii) The productivity of the proposed permit area before mining, expressed as average yield of food, fiber, forage, or wood products from such lands obtained under high levels of management. The productivity shall be determined by yield data or estimates for similar sites based on current data from the U.S. Department of Agriculture, State agricultural universities or appropriate State natural resources or agricultural agencies.

(b) Each plan shall contain a detailed description of the proposed use, following reclamation, of the land within the proposed permit area including a discussion of the utility and capacity of the reclaimed land to support a variety of alternative uses, and the relationship of the proposed use to existing land use policies and plans. This description shall explain—

(1) How the proposed postmining land use is to be achieved and the necessary support activities which may be needed to achieve the proposed land use; and

(2) Where a land use different from the premining land use is proposed, all materials needed for approval of the alternative use under 30 CFR 817.133.

(c) The consideration which has been given to making all of the proposed surface mining activities consistent with surface owner plans and applicable State and local land use plans and programs. The description shall be accompanied by a copy of the comments concerning the proposed use by the legal or equitable owner of record of the surface of the proposed permit area and the State and local government agencies which would have to initiate, implement, approve, or authorize the proposed use of the land following reclamation.

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Part XIII

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701 and 785

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Definitions; Requirements for Permits and Permit Processing; Final Rule

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701 and 785

RIN 1029–AB45

Surface Coal Mining and Reclamation Operations; Permanent Regulatory Program; Definitions; Requirements for Permits and Permit Processing

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) of the United States Department of the Interior (DOI) is amending its permanent program regulations by revising the definition of "previously mined area" and by clarifying the requirements governing off-site coal preparation plants. OSM is taking this action in response to two U.S. District Court decisions affecting OSM's permanent program regulations. Specifically, OSM is revising the definition of "previously mined area" to include only those lands affected by surface coal mining operations prior to August 3, 1977, the date of enactment of the Surface Mining Control and Reclamation Act (SMCRA), that have not been reclaimed to the performance standards of 30 CFR chapter VII. OSM is also clarifying the extent to which geographic proximity to a mine is an appropriate factor in evaluating whether an off-site coal preparation plant operates in connection with a mine and is thus subject to regulation under SMCRA.

EFFECTIVE DATE: February 8, 1993.

FOR FURTHER INFORMATION CONTACT: Suzanne Hudak, Office of Surface Mining Reclamation and Enforcement, U.S. Department of the Interior, 1951 Constitution Avenue, NW., Washington, DC 20240; Telephone (202) 208–2700 (Commercial) or 268–2700 (FTS).

SUPPLEMENTARY INFORMATION:

I. Background
II. Discussion of Final Rule and Response to Public Comments on Proposed Rule
III. Procedural Matters

I. Background

The Surface Mining Control and Reclamation Act of 1977, 30 U.S.C. 1201 *et seq.* (SMCRA or the Act), sets forth general regulatory requirements governing surface coal mining operations and the surface effects of underground coal mining. OSM has by regulation implemented or clarified many of the general requirements of the Act and set performance standards to be achieved by surface coal mine operations. See 30 CFR chapter VII.

A. Definition of Previously Mined Area

On September 16, 1983, OSM promulgated performance standards at 30 CFR 816.106 and 817.106 (Backfilling and grading: Previously mined areas) for remining operations on previously mined areas, for surface and underground coal mining, respectively (48 FR 41720). These performance standards provide for partial highwall elimination in situations where the previous operator had not reclaimed the remined area to the standards of the Act. Under sections 816.106 and 817.106, such pre-existing highwalls must be eliminated to the maximum extent technically practical using all reasonably available spoil.

The September 1983 rulemaking defined "previously mined area" at 30 CFR 701.5 as "land disturbed or affected by earlier coal mining operations that was not reclaimed in accordance with the requirements of this chapter." This definition, which was challenged as being too broad and contrary to SMCRA, was remanded to the Secretary in In Re: Permanent Surface Mining Regulation Litigation (II), No. 79–1144 Slip Op. at 122, (D.D.C. July 15, 1985).

On May 8, 1987, OSM promulgated a new definition which limited the scope of "previously mined area" to those lands on which there were no surface coal mining operations subject to the standards of the Act (52 FR 17526).

The National Wildlife Federation, Kentucky Resources Council, and other environmental organizations (collectively "NWF") challenged the 1987 definition on the grounds that it improperly expanded the scope of the definition to include lands mined subsequent to SMCRA's enactment (*NWF* v. *Lujan*, Civil Action Nos. 87–1051, 87–1814, and 88–2788 (D.D.C. 1990)). The court remanded the definition of "previously mined area" to the Secretary for revision, finding that a definition using a date other than the date of SMCRA's enactment (August 3, 1977) does not conform to the Act. The court also ruled that the definition must be rewritten to eliminate the possibility that it could be in interpreted to allow a previously mined area that had been fully and satisfactorily reclaimed, to be remined and then reclaimed to the lesser standards applicable to remining operations.

On September 25, 1991, pursuant to the court's ruling in *NWF* v. *Lujan*, OSM proposed a new definition of "previously mined area" at 30 CFR 701.5 to include land affected by surface coal mining operations prior to August 3, 1977, that has not been reclaimed to the performance standards of 30 CFR chapter VII (56 FR 48714). The **Federal Register** notice announced a 30 day comment period ending on October 25, 1991. On October 16, 1991, OSM published a notice in the **Federal Register** extending the comment period on the proposed rule through November 25, 1991 (56 FR 51861).

B. Off-site Coal Preparation Plants: Geographic Proximity; Information Collection Requirements for 30 CFR Part 785

On March 13, 1979, OSM published regulations implementing the permanent regulatory program required by Title V of SMCRA (44 FR 14902 *et seq.*). Permitting requirements and permanent program performance standards for coal processing plants and support facilities not within the permit area for a mine, were codified at 30 CFR 785.21 and 30 CFR Part 827, respectively.

On November 22, 1988, OSM promulgated a final rule amending the language in 30 CFR 785.21 and 827.1 concerning the permit requirements and the scope of the performance standards for off-site coal preparation plants, to clarify that those sections apply only to such facilities that operate "in connection with" a coal mine (53 FR 47384). The preamble to the final rule explained that "the element of geographic proximity, along with the element of functional relationship described in this preamble, are proper factors to consider in evaluating whether an off-site coal preparation plan is subject to regulation under SMCRA."

NWF challenged the regulation, particularly the use of proximity as a factor in determining which off-site coal preparation plants would be subject to SMCRA regulation. The District Court did not object to the language of the regulation, noting that "in connection with" is, "after all, the language of the statute." The court did, however, object to "the Secretary's explanation of his rule" on the grounds that it appeared to make proximity to a mine "the decisive factor in determining whether to regulate an off-site processing plant" and that this appeared "to mean that the Secretary would not regulate off-site plants, except in comparatively rare instances." The court reaffirmed its earlier rulings that: "(1) the Secretary must regulate off-site processing plants; and, (2) the language of the Act clearly indicates that crushing, screening, and sizing coal are covered by SMCRA as processing activities * * *" noting that

"(t)he Court of Appeals has upheld the former ruling, and the latter is now settled law" and that "(t)o that extent, the regulation conflicts with the law." The court remanded the regulation to the Secretary to clarify that proximity may not be the decisive factor in deciding to regulate an off-site processing plant. The court instructed the Secretary to "tailor his action to this Court's and the Court of Appeals' consistent statements that the Act requires regulation of off-site processing and preparation plants." *NWF* v. *Lujan*, 31 E.R.C. 2034 (D.D.C. August 30, 1990), hereafter, "*NWF, Round III.*" The Secretary chose not to prosecute his appeal of that decision.

On March 22, 1991, the U.S. Court of Appeals considered the issue of the effective date of regulation of off-site physical processing facilities, specifically the appeal of an August 1990 district court ruling in *NWF* v. *Lujan*, 733 F.Supp 419 (D.D.C. 1990). In that decision, the district court had ruled that the Secretary may not decline to regulate any off-site crushing, screening, and sizing facilities from the effective date of the Act because the Act requires the Secretary to regulate all of those facilities. The appellate court disagreed stating that "the Act permits, but does not require the Secretary to regulate off-site facilities that crush, screen, and size coal." Thus, the district court "erroneously held that the Secretary violated the Act by declining to regulate all off-site physical processing plants that operated subsequent to enactment of the Act." The appeals court noted that "the fact that the Secretary may regulate these facilities does not mean that he must regulate them" and that "(a)s long as the Secretary gives valid reasons for declining to regulate these facilities, his decision must be upheld." *NWF* v. *Lujan*, 928 F.2d 453 (D.C. Cir. 1991).

On September 25, 1991, OSM proposed to clarify that geographic proximity should not be the decisive factor in determining whether or not an off-site coal preparation plant operates in connection with a mine, and that absent considerations of proximity, such determinations would rely instead on other considerations offered by OSM in earlier preamble discussions. The reader is referred to the September 25, 1991, **Federal Register** notice at 56 FR 48716 for a non-exhaustive listing of applicable preamble citations. The proposed clarification concerned the 1988 final rule preamble language only, and involved no changes to regulatory text. OSM also requested public comment on the effect that the appeals court decision in *NWF* v. *Lujan* had upon the basis of the District Court remand in *NWF, Round III* and the appropriateness of removing geographic proximity as a factor in determining whether or not an offsite coal preparation plant operates in connection with a mine.

OSM also proposed in the September 25, 1991, **Federal Register** notice, to update and amend the information collection requirements pertaining to 30 CFR Part 785—Requirements for Permits for Special Categories of Mining, codified at 30 CFR 785.10.

The comment period on the proposed preamble clarification concerning proximity and the proposed amendment to 30 CFR 785.10 closed on November 25, 1991.

II. Discussion of Final Rule and Response to Public Comments on Proposed Rule

During the comment period, OSM received comments on the proposed rule and clarification from two coal industry trade associations, one environmental group, and one State agency. OSM has reviewed each comment carefully and has considered the commenters' suggestions and remarks in preparing the final rule.

Comments on the previously mined area definition and on the clarification of requirements governing off-site coal preparation plants are analyzed separately in the two sections that follow.

A. Definition of Previously Mined Area and Comments

The September 25, 1991, rulemaking proposal contained a revised definition of "previously mined area" as "land affected by surface coal mining operations prior to August 3, 1977, that has not been reclaimed to the standards of 30 CFR chapter VII." OSM is adopting the revised definition in this final rule.

OSM received two comments on the proposed definition. One commenter objected to the proposed definition on the grounds that it would discourage initiatives by the public and private sectors to promote remining and reclamation of unbonded or underbonded areas that were inadequately reclaimed and/or abandoned between August 3, 1977, and the date(s) of State primacy. The commenter recommended that OSM withdraw the proposed definition and issue a revised definition that defines previously mined areas as abandoned mine lands, regardless of when abandonment occurred, and that any area subject to bond for forfeiture due to inadequate reclamation or abandonment should also be "excluded" from the definition.

OSM recognizes that the definition excludes those areas abandoned after August 3, 1977, from qualifying for the less stringent remining provisions of 30 CFR 816.106 and 817.106 which allow for partial elimination of pre-existing highwalls under certain circumstances. However, the August 3, 1977, cut-off date is consistent with the district court decision in *NWF* v. *Lujan*, which held that using a date other than SMCRA's enactment date to define previously mined areas is contrary to SMCRA.

Another commenter supported the proposed definition insofar as it establishes August 3, 1977, as the cut-off date for defining previously mined areas, but maintained that the proposed definition is otherwise ambiguous in that it could be construed to include areas mined both before and after August 3, 1977. The commenter requested that OSM issue a revised definition to include only those areas where mining occurred and terminated prior to August 3, 1977, and which were left in an unreclaimed status.

OSM disagrees that the definition is ambiguous, and does not accept the commenter's recommended changes. The definition clearly states that only those lands affected by mining prior to August 3, 1977, qualify as previously mined areas, and only when those lands have not been reclaimed to the standards of OSM's regulations at 30 CFR chapter VII. It is thus readily inferred from the definition that a parcel of land reaffected by mining after August 3, 1977, would not qualify as a previously mined area.

The definition achieves its intended effect in that it limits the applicability of 30 CFR 816.106 and 817.106 to those areas mined prior to August 3, 1977, that are either unreclaimed or reclaimed to lesser standards than those prescribed by SMCRA, while also ensuring that areas mined prior to that date that have been fully and satisfactorily reclaimed pursuant to SMCRA's standards will not be redisturbed and then reclaimed under the less stringent requirements of 30 CFR 816.106 and 817.106. Under the definition, unreclaimed or partially reclaimed areas mined prior to August 3, 1977, would continue to qualify for the partial highwall elimination exemption of 30 CFR 816.106 and 817.106, but would be otherwise held to full compliance with the reclamation standards of 30 CFR chapter VII. In such instances, operators would be required to eliminate the highwall to the maximum extent technically practical, and to demonstrate the stability of the remaining highwall remnant. Remining

of such areas is consistent with SMCRA's stated goal at section 102(h) of promoting the reclamation of mined areas left without adequate reclamation prior to SMCRA's enactment and is dually beneficial that it results both in generally improved environmental conditions and enhanced coal recovery.

B. Amendment to Information Collection Requirements at 30 CFR 785.10

Section 785.10 Information Collection

Section 785.10 contains a list of the information collection requirements included in 30 CFR Part 785—Requirements for Permits for Special Categories of Mining, and the Office of Management and Budget (OMB) clearance number indicating OMB approval of the requirements. The rule adopted today updates the data contained in section 785.10 by listing the estimated reporting burden per respondent for complying with the information collection requirements contained in part 785 and the addresses for OSM and OMB where comments on the information collection requirements of part 785 may be sent.

No comments were received on the proposed revisions to section 785.10.

C. Clarification of Preamble to Regulations Governing Off-Site Coal Preparation Plants and Comments

The September 25, 1991, proposed rule included a clarification that geographic proximity should not be the decisive factor in determining whether or not an off-site coal preparation plant operates in connection with a mine and is thus subject to regulation under SMCRA. The proposed clarification was intended to supersede 1988 final rule preamble language, without changing regulatory text. It was required pursuant to the district court's August 30, 1990, ruling in *NWF, Round III* discussed earlier in this preamble. OSM solicited public comment on the proximity issue, specifically on the appropriateness of removing proximity as a factor in regulatory determinations of whether or not a coal preparation plant operates in connection with a mine.

OSM's position on the proximity issue, as clarified today in this final rule, is that surface mining regulatory authorities may consider geographic proximity as a factor in determining whether off-site coal processing facilities operate in connection with a mine as long as proximity is not the decisive factor. To allow proximity to be the decisive factor would render "in connection with" equivalent to "at or near". That is not the Secretary's intent. Instead, the Secretary's intent is to provide regulatory authorities appropriate guidance and discretion in deciding which off-site coal processing plants to regulate. Thus, this clarification supplements the interpretative regulatory guidance contained in the preamble to the November 22, 1988, final rule on off-site coal preparation plants (53 FR 47384) and provides that guidance while preserving discretion.

OSM received three comments on the proposed clarification, one of which included a petition for rulemaking requesting OSM to promulgate rule changes to codify proximity language into OSM's regulations governing off-site coal preparation plants. Although OSM has considered the petition in developing this final rule, OSM is separately publishing its notice of decision on the petition.

One commenter objected to the proposed deletion of proximity as a factor in determining the applicability of SMCRA to off-site coal preparation plants, as exceeding the district court's holding in *NWF, Round III* that proximity could not "serve as the *decisive* factor" in such decisions. The commenter argued that the ruling thus merely required OSM to clarify that geographic proximity to a mine is one of several factors to be weighed by the regulatory authority in determining whether a processing facility operates in connection with a mine. The commenter further maintained that the district court ruling was inconsistent with the 1988 appellate court ruling in *NWF* v. *Hodel*, which the commenter viewed as an endorsement of the use of proximity as a consideration in regulating processing facilities, and was also incorrect in its premise that "the Secretary *must* regulate off-site processing plants." The commenter cited both the 1988 *NWF* v. *Hodel* decision, and the March 1991 ruling in *NWF* v. *Lujan*, to support the view that the Secretary has broad discretion in matters concerning the regulation of off-site coal preparation plants.

OSM has examined the various court decisions cited by the commenter in relation to the proposed clarification on proximity contained in the September 25, 1991, rulemaking proposal. OSM agrees that the 1988 appeals court decision in *NWF* v. *Hodel* can reasonably be construed as an implicit endorsement of the Secretary's discretion in regulating off-site coal preparation plants, and that that discretion was made explicit in *NWF* v. *Lujan* wherein the appellate court said that "the Act permits, but does not require the Secretary to regulate off-site facilities that crush, screen, and size coal." Implicit in that discretion is the power to use proximity as a jurisdictional factor in determining whether off-site processing facilities are subject to regulation under SMCRA and provided "the Secretary gives valid reasons for declining to regulate these facilities." (*NWF* v. *Lujan*, No. 90–5118 (D.C. Cir. 1991)). OSM notes that the court in *NWF* v. *Hodel* acknowledged that, "the legislative history suggests that Congress was specifically concerned about coal processing facilities and stored coal materials, and not necessarily only those within the immediate proximity of an operating surface coal mine." *Id.* at 744. OSM believes that it is not appropriate for proximity to be the decisive jurisdictional factor, but it can be a contributing factor when regulatory authorities exercise their discretion over whether to regulate an off-site plant.

Finally, OSM notes that in rendering its decision in *NWF, Round III*, the court stated that the appellate court in *NWF* v. *Hodel* endorsed the use of proximity only in the context of support facilities such as office buildings, and held that it does not necessarily follow that proximity is an appropriate defining factor for processing plants. The court remanded the matter to the Secretary for clarification "that proximity may not be the decisive factor in deciding to regulate an off-site processing plant." The court based its decision on its earlier rulings that "the Secretary must regulate off-site processing plants" noting that the "Court of Appeals has upheld the former ruling." *NWF, Round III*, 31 E.R.C. 2034, 2050 (D.D.C. August 30, 1990). However, as noted earlier, the appeals court subsequently stated in *NWF* v. *Lujan* that this position was partially rejected in *NWF* v. *Hodel* "in which we held that the Act does not require the Secretary to regulate all coal processing or preparation facilities" and that the District court's holding to the contrary was erroneous. 928 F.2d at 462. The appeals court further held that SMCRA permits but does not require the Secretary to regulate off-site coal processing plants provided the Secretary gives valid reasons for declining to regulate such facilities. This statement demonstrates the Secretary's considerable discretion in this area.

OSM does not believe that the district court's ruling in *NWF, Round III*, compels the Secretary to eliminate geographic proximity to a mine as a factor in regulatory determinations of whether an off-site processing facility operates in connection with a mine, but merely suggests that course of action to

the Secretary as an option for consideration. The court was, however, clearly concerned that proximity should not be decisive or overriding factor in such decisions. Accordingly, OSM reiterates that surface mining regulatory authorities are not precluded from considering the element of geographic proximity in deciding whether an off-site processing or preparation facility operates in connection with a mine provided that proximity is not the decisive factor and that due consideration is also given to other relevant factors such as the processing plant's functional relationship to a mine.

Two commenters objected to OSM's request for public comment on the appropriate use of proximity as a limiting factor in deciding whether a coal preparation plant operates in connection with a mine, maintaining that the March 1991 appeals court decision in *NWF* v. *Lujan* provided no basis for failure to comply with the district court's August 1990 ruling on proximity in *NWF, Round III*. The commenters asserted that the Secretary, having failed to prosecute the proximity issue on appeal, is bound by the district court's decision and that OSM cannot now reimpose proximity as a limiting factor in defining "in connection with."

OSM disagrees with these commenters. The Secretary's obligations with regard to the district court's decision are satisfied by this rulemaking clarifying that proximity cannot be the decisive factor in determining jurisdiction over off-site preparation plants. OSM's failure to appeal the district court's decision does not preclude the Secretary from considering in this rulemaking subsequent statements of the D.C. Circuit Court of Appeals concerning the Secretary's discretion in this area.

One commenter further maintained that OSM had merely solicited public comment on, but not actually proposed proximity, and was thus barred from incorporating such a consideration into this final rule, but must instead reintroduce proximity through a separate rulemaking. The commenter also asserted that sound legal and policy reasons to reject the concept of proximity as a regulatory factor could be found in legal briefs filed by the plaintiffs in *NMF* v. *Lujan*, and in public comments submitted to OSM on the 1988 rulemaking concerning the regulation of off-site coal preparation plants, and incorporated by reference those documents.

OSM has reviewed all relevant material and agrees to some extent with the commenter that, often, sound policy reasons do exist for exercising regulatory jurisdiction, regardless of proximity, over off-site coal preparation plants. However, OSM disagrees that these reasons require OSM to reject proximity entirely as a factor, so long as other factors weigh in factor of declining jurisdiction. The Secretary has discretion to consider all factors, including proximity.

OSM also disagrees with the commenters' objections to OSM's request for public comment concerning the effect of the March 1991 appellate court ruling in *NWF* v. *Lujan*, on the August 1990 district court decision in *NWF, Round III*. In so doing, OSM was not seeking to avoid compliance with the district court's ruling on proximity, but merely to invite meaningful comment on the issue. Nor does OSM agree that a separate rulemaking on proximity is required as the proposed clarification and accompanying preamble discussion contained in the September 25, 1991, rulemaking proposal provided ample opportunity for public comment on the proximity issue.

III Procedural Matters

Effect of the Rule on State Programs

Following promulgation of the final rule, OSM will evaluate permanent State regulatory programs approved under section 503 of SMCRA to determine whether any changes in these programs will be necessary. If OSM determines that certain State program provisions should be amended in order to be made no less effective than the revised Federal rules, the individual States will be notified in accordance with the provisions of 30 CFR 732.17.

Effect of the Rule in Federal Program States and on Indian Lands

The rules under 30 CFR parts 701 and 785 apply through cross-referencing in the following States with Federal programs: California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee and Washington. The Federal programs for these States appear at 30 CFR parts 905, 910, 912, 921, 922, 933, 937, 939, 941, 942 and 947, respectively. The rules also apply through cross-referencing to Indian lands under the Federal program for Indian lands as provided in 30 CFR part 750.

Federal Paperwork Reduction Act

This final rule does not contain any new information collection requirements which require approval by the Office of Management and Budget (OMB) under 44 U.S.C. 3501 *et seq.*

The existing information collection requirements contained in part 785 were previously approved by OMB and assigned clearance number 1029–0040.

OSM is amending the information collection statement located in section 785.10 by listing the estimated reporting burden per respondent for complying with the information collection requirements and also by listing the addresses for OSM and OMB where comments on the information collection requirements contained in part 785 may be sent. The listed burden hours are for existing requirements and should not be mistaken for new requirements.

Executive Order 12291 and Regulatory Flexibility Act

The U.S. Department of the Interior (DOI) has determined that this rule is not a major rule under the criteria of Executive Order 12291 (February 17, 1981) and certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The economic effects of this rule are not estimated to be significant because of the limited number of previously mined sites that will be affected and because the cost of obtaining permits for offsite coal preparation plants will be minor compared to the overall cost of operating such plants. The rule does not distinguish between small and large entities.

National Environmental Policy Act

OSM has prepared an environmental assessment (EA), and has made a finding that this rule will not significantly affect the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C). The environmental assessment and finding of no significant impact are on file in the OSM Administrative Record, Room 660, 800 North Capitol Street, NW., Washington, DC.

Executive Order 12778 on Civil Justice Reform

This rule has been reviewed under the applicable standards of section 2(b)(2) of Executive Order 12778, Civil Justice Reform (56 FR 55195). In general, the requirements of section 2(b)(2) of Executive Order 12778 are covered by the preamble discussion of this rule. Additional remarks follow concerning individual elements of the Executive Order:

A. What is the preemptive effect, if any, to be given to the regulation?

The rule will have the same preemptive effect as other standards adopted pursuant to SMCRA. To retain primacy, States have to adopt and apply standards for their regulatory programs that are no less effective than those set forth in OSM's rules. Any State law that is inconsistent with or that would preclude implementation of this rule would be subject to preemption under SMCRA section 505 and implementing regulations at 30 CFR 730.11. To the extent that the rule would result in preemption of State law, the provisions of SMCRA are intended to preclude inconsistent State laws and regulations. This approach is established in SMCRA, and has been judicially affirmed. See *Hodel* v. *Virginia Surface Mining and Reclamation Ass'n*, 452, U.S. 264 (1981).

B. What is the effect on existing Federal law or regulation, if any, including all provisions repealed or modified?

This rule modifies the implementation of SMCRA as described herein, and is not intended to modify the implementation of any other Federal statute. The preceding discussion of this rule specifies the Federal regulatory provisions that are affected by this rule.

C. Does the rule provide a clear and certain legal standard for affected conduct rather than a general standard, while promoting simplification and burden reduction?

The standards established by this rule are as clear and certain as practicable, given the complexity of the topics covered and the mandates of SMCRA.

D. What is the retroactive effect, if any, to be given to the regulation?

This rule is not intended to have retroactive effect.

E. Are administrative proceedings required before parties may file suit in court? Which proceedings apply? Is the exhaustion of administrative remedies required?

No administrative proceedings are required before parties may file suit in court challenging the provisions of this rule under section 526(a) of SMCRA, 30 U.S.C. 1276(a).

Prior to any judicial challenge to the application of the rule, however, administrative procedures must be exhausted. In situations involving OSM application of the rule, applicable administrative procedures may be found at 43 CFR part 4. In situations involving State regulatory authority application of provisions equivalent to those contained in this rule, applicable administrative procedures are set forth in the particular State programs.

F. Does the rule define key terms, either explicitly or by reference to other regulations or statutes that explicitly define those items.

Terms which are important to the understanding of this rule are set forth in 30 CFR 700.5 and 701.5.

G. Does the rule address other important issues affecting clarity and general draftsmanship of regulations set forth by the Attorney General, with the concurrence of the Director of the Office of Management and Budget, that are determined to be in accordance with the purposes of the Executive Order?

As of January 8, 1993 the Attorney General and the Director of the Office of Management and Budget have not issued any guidance on this requirement.

Author

The principal author of this rule is Suzanne Hudak, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Avenue NW., Washington, DC 20240; Telephone: (202) 208–2700 (Commercial) or (FTS).

List of Subjects

30 CFR Part 701

Law enforcement, Surface mining, Underground mining.

30 CFR Part 785

Reporting and recordkeeping requirements, Surface mining, Underground mining.

Accordingly, 30 CFR parts 701 and 785 are amended as set forth below:

Dated: November 5, 1992.

Richard Roldan,

Deputy Assistant Secretary, Land and Minerals Management.

PART 701—PERMANENT REGULATORY PROGRAM

1. The authority citation for part 701 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100–34.

2. Section 701.5 is amended by revising the definition of "previously mined area" to read as follows:

§ 701.5 Definitions.

* * * * *

Previously mined area means land affected by surface coal mining operations prior to August 3, 1977, that has not been reclaimed to the standards of 30 CFR chapter VII.

* * * * *

PART 785—REQUIREMENTS FOR PERMITS FOR SPECIAL CATEGORIES OF MINING

3. The authority citation for part 785 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100–34.

4. Section 785.10 is revised to read as follows:

§ 785.10 Information collection.

The collections of information contained in 30 CFR 785.13(e), (f), (g), and (h) 785.14, 785.15, 785.16, 785.17(b), 785.18(c), 785.19, 785.20, 785.21 and 785.22 have been approved by the Office of Management and Budget under 44 U.S.C. 3507 and assigned clearance number 1029–0040. The information is being collected to meet the requirements of sections 711 and 515 of Pub. L. 95–87, which require applicants for special types of mining activities to provide descriptions, maps, plans and data of the proposed activity. This information will be used by the regulatory authority in determining if the applicant can meet the applicable performance standards for the special type of mining activities. The obligation to respond is required to obtain a benefit in accordance with Pub. L. 95–87.

Public reporting burden for this information is estimated to average 29 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Information Collection Clearance Officer, Office of Surface Mining, 1951 Constitution Avenue, NW., rm. 640NC, Washington, DC 20240; and to the Office of Management and Budget, Paperwork Reduction Project 1029–0040, Washington, DC 20503.

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Part XIV

Federal Election Commission

11 CFR Part 110

Transfers of Funds From State to Federal Campaigns; Final Rule and Retransmittal of Regulations to Congress

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FEDERAL ELECTION COMMISSION

11 CFR Part 110

[Notice 1993–1]

Transfers of Funds From State to Federal Campaigns

AGENCY: Federal Election Commission.

ACTION: Final rules and retransmittal of regulations to Congress.

SUMMARY: The Commission has revised its regulations regarding the transfer of funds from state to federal campaigns. This revision comes in response to a Petition for Rulemaking filed by Congressman William Thomas. 56 FR 66866 (Dec. 26, 1991). Congressman Thomas' Petition alleges that the current regulations are ineffective, because they fail to prevent the indirect use of impermissible funds in federal elections. The new rule prohibits the transfer of funds from state to federal campaign committees. The Commission originally transmitted this rule to Congress on August 7, 1992. 57 FR 36344 (August 12, 1992). However, Congress adjourned before the expiration of thirty legislative days. Therefore, the Commission is retransmitting the rule in identical form. Further information is provided in the supplementary information which follows.

DATES: Further action, including announcement of an effective date, will be taken after these regulations have been before Congress for 30 legislative days pursuant to 2 U.S.C. 438(d). A document announcing the effective date will be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Ms. Susan E. Propper, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463, (202) 219–3690 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: The Commission is publishing today the text of revisions to its regulations at 11 CFR 110.3 regarding the transfer of funds from state to federal campaigns.

The Commission published a Notice of Proposed Rulemaking ["NPRM"] on April 15, 1992, in which it sought comments on proposed revisions to these regulations. 57 FR 13054 (Apr. 15, 1992). The Commission received thirteen comments in response to the NPRM.

Section 438(d) of title 2, United States Code, requires that any rule of regulation prescribed by the Commission to carry out the provisions of title 2 of the United States Code be transmitted to the Speaker of the House of Representatives and the President of the Senate 30 legislative days before they are finally promulgated.

The Commission originally approved these revisions on August 6, 1992, and transmitted them to Congress on August 7, 1992 for legislative review. 57 FR 36344 (August 12, 1992). However, Congress adjourned before the expiration of thirty legislative days. The Commission retransmitted these revisions to Congress in identical form on January 5, 1993.

After the thirty legislative days have expired, the Commission will publish an effective date for this rule in the **Federal Register**. The Commission plans to include in its announcement of effective date a statement of how the rule will apply to transfers made during the 1994 election cycle. This statement, and the Commission's plans for announcing an effective date, are discussed further below.

Explanation and Justification

The Federal Election Campaign Act, as amended, 2 U.S.C. 431 et. seq. ["FECA" or "the Act"], places certain limitations and prohibitions on the sources and amounts of contributions to federal election campaigns. Section 441a limits the dollar amount of contributions by individuals and multicandidate political committees. Section 441b, in general, prohibits contributions by corporations and labor organizations. The FEC has promulgated regulations to implement these statutory provisions. See 11 CFR parts 110 and 114.

In contrast, many states impose fewer restrictions on contributions to campaigns for state elective offices. Many states allow individuals to make contributions to state candidates that would exceed FECA limits if they were directed to a federal candidate. Many states also allow corporations and labor organizations to make contributions to state candidates, in some cases without any dollar limit. Contributions to state candidates that would be impermissible if given to a federal candidate are often referred to as "soft money" contributions.

In many instances, candidates for federal office who were once candidates for state office have state campaign committees with funds leftover from a state campaign. These candidates often wish to transfer these funds to their federal campaign committees for use in the federal campaign. Until now, the Commission has allowed nonfederal campaign committees to transfer funds to an authorized federal committee of the same candidate, so long as the funds transferred do not contain impermissible or "soft money" contributions. 11 CFR 110.3(c)(6). This policy can be traced to a series of advisory opinions that date back to the Commission's inception. Advisory Opinions 1975–66, 1980–117, 1982–52, 1983–34, 1984–3, 1984–46, 1985–1, 1987–12, 1990–16. See Explanation and Justification of Final Rule, 54 FR 34098, 34104 (Aug. 17, 1989).

On December 5, 1991, Congressman William Thomas filed a Petition for Rulemaking urging the Commission to revise its regulations regarding the transfer of funds from nonfederal campaign committees to federal campaign committees. The Petition alleges that the current regulations are ineffective, because they allow nonfederal committees to use soft money to finance the solicitation of "hard money" contributions that would be permissible under the Act. These permissible contributions can then be transferred to a federal committee for use in the federal campaign. The petition argues that this amounts to an indirect use of impermissible contributions in federal elections.

The Commission published a Notice of Availability on December 26, 1991, which sought public comments on the petition. See 56 FR 66866 (Dec. 26, 1991). The Commission received three comments supporting the petition. An additional comment sought clarification.

On April 15, 1992, the Commission published a Notice of Proposed Rulemaking. 57 FR 13054 (Apr. 15, 1992). The Notice proposed amendments to 11 CFR 110.3(c)(6) that would prohibit the transfer of funds raised using contributions that would be impermissible under the Act. The Notice also contained an alternative proposal, which would reverse the Commission's existing policy and ban all transfers from state campaigns to federal campaigns. The Notice sought comments on whether such a prohibition would be preferable to the proposed rule.

The Commission anticipates that certain practical problems could occur should the proposed rule, rather than the alternative, be implemented. Under the proposed rule, committees must be able to demonstrate that the funds they wish to transfer were raised with funds that are permissible under the Act. Linking specific funds to be transferred to particular fundraising disbursements will be difficult for committees in the best of circumstances. This process would also be difficult for the Commission to monitor and enforce.

The difficulty of this process would often be compounded in several ways.

For example, most state campaigns are subject to less stringent recordkeeping and reporting requirements than those imposed by federal law. In addition, state campaigns often make fundraising disbursements from accounts containing a constantly varying mixture of permissible and impermissible funds. Finally, fundraising activities are often paid for with multiple disbursements over the course of several days.

If fundraising is paid for with multiple disbursements that come from accounts containing a mixture of funds, linking the contributions received to funds disbursed, and then limiting the transfer to those contributions that can be linked to permissible disbursements, would present significant practical difficulties. In addition, the NPRM noted that some campaign committees might choose to set up separate accounts for permissible and impermissible funds in order to simplify the recordkeeping process for future transfers. This practice could raise questions about federal regulation of state campaign activity and about the possible onset of federal candidate status during a state campaign.

It was because of these anticipated difficulties that the Commission included the alternative proposal in the Notice of Proposed Rulemaking. The alternative proposal would prohibit all transfers from state to federal campaign committees. The Notice sought comments on whether this would be preferable to the proposed rule.

The Commission received 13 comments in response to the Notice of Proposed Rulemaking. Most of the commenters endorsed the alternative proposal in some form, and rejected the more limited ban on transfers of contributions raised with soft money. Seven commenters urged the Commission to prohibit all transfers from "commingled" state campaign accounts. Three commenters spoke more generally in support of a prohibition on all transfers from state to federal campaigns. All of the commenters who expressed support for the promulgation of new rules in this area preferred the total ban.

Although the Commission is reluctant to reverse long-standing policy, it is also concerned about the indirect use of impermissible funds in federal elections. This is an area in which the Commission has engaged in closer regulation in recent years. See, e.g., Methods of Allocation Between Federal and Non-Federal Accounts, 55 FR 26058 (June 26, 1990). Consequently, the Commission has decided to promulgate new rules that would more effectively prevent the indirect use of impermissible funds in federal elections.

However, in light of the comments received and the difficulties presented by the proposed rule, the Commission believes that the alternative proposal, a prohibition on all transfers from state to federal campaigns, is the best way to address the concerns raised in the Petition for Rulemaking. Choosing the alternative proposal will avoid the issues raised by a rule that could lead to the segregation of funds in separate state campaign accounts, and will also obviate the need for additional complicated recordkeeping.

The final rule prohibits transfers of cash or other assets from state campaign committees to federal campaign committees. The rule also prohibits transfers from the bank account of a state campaign in order to address those situations where there is no recognized state campaign committee. However, the rule should not be read to proscribe the sale of assets by the state campaign committee to the federal campaign committee, so long as those assets are sold at fair market value. Committees may look to the valuation mechanism contained in 11 CFR 9034.5(c)(1) for guidance in determining fair market value.

Nor should this rule be read to limit the federal campaign committee's right to solicit contributions from those who made contributions to the state campaign. The federal campaign is permitted to solicit contributions from the same contributors. However, if the federal campaign committee intends to use a mailing list compiled by the state campaign, the federal campaign must purchase the list at fair market value. The mailing list is an asset of the state campaign, and any transfer for less than fair market value would violate the rule announced in this Notice.

Effective Date

When the Commission first approved this new rule and transmitted it to Congress in August of 1992, it intended to make the rule effective immediately after the November 3, 1992 general election. The Commission had hoped to have the rule in place at the beginning of the 1994 election cycle.

Since the required thirty legislative days did not elapse before Congressional adjournment, the Commission was unable to make the rule effective immediately after the election. The Commission is now resubmitting the rule for legislative review, and will publish an effective date in the **Federal Register** after it has been before Congress for thirty legislative days. However, the Commission is aware that preparations for the 1994 election campaign may already be underway. In addition, some special elections may be scheduled in early 1993. Therefore, the Commission plans to include in its announcement of effective date a statement of how this rule will apply to transfer made during the 1994 election cycle.

Assuming the thirty legislative days expire before the end of March, 1993, the statement will indicate that this rule prohibits all transfers from state campaigns made in anticipation of any federal election held after April 1, 1993 regardless of when those transfers take place. The statement will also say that, if a committee makes a transfer of funds before the effective date of this rule to finance an election held after April 1, 1993, the committee will be required to return those funds to the state campaign committee within thirty days of this rule's effective date.

However, the statement will also indicate that this rule will not apply to transfers of funds for use in special elections held before April 1, 1993. Transfers for these elections will remain subject to the current regulations at 11 CFR 110.3(c)(6).

Certification of No Effect Pursuant to 5 U.S.C. 605(b) (Regulatory Flexibility Act)

I certify that the attached final rule will not have a significant economic impact on a substantial number of small entities. The basis of this certification is that the rule would bar transfers of funds from a state campaign to a federal campaign for use in federal election activity. This does not impose a significant economic burden, because any small entities affected are already required to comply with the Act's requirements, including those on permissible sources of funds, if they engage in activity designed to influence a federal election.

List of Subjects in 11 CFR Part 110

Campaign funds, Political candidates.

Note: The following amendment is a republication of the regulatory text that appeared at 57 FR 36345, August 12, 1992.

For the reasons set out in the preamble, subchapter A, chapter I of Title 11 of the Code of Federal Regulations is amended as follows:

PART 110—CONTRIBUTION AND EXPENDITURE LIMITATIONS AND PROHIBITIONS

1. The authority citation for part 100 continues to read as follows:

Authority: 2 U.S.C. 431(8), 431(9), 432(c)(2, 437d(a)(8), 438(a)(8), 441a, 441b, 441d, 441e, 441f, 441g and 441h.

2. Section 110.3 is amended by revising the heading of paragraph (c), by removing and reserving paragraph (c)(6), and by adding paragraph (d), to read as follows:

§ 110.3 Contribution limitations for affiliated committees and political party committees; Transfers (2 U.S.C. 441a(a)(5), 441a(a)(4)).

* * * * *

(c) *Permissible transfers.* * * *

* * * * * *

(d) *Transfers from nonfederal to federal campaigns.* Transfers of funds or assets from a candidate's campaign committee or account for a nonfederal election to his or her principal campaign committee or other authorized committee for a federal election are prohibited. However, at the option of the nonfederal committee, the nonfederal committee may refund contributions, and may coordinate arrangements with the candidate's principal campaign committee or other authorized committee for a solicitation by such committee(s) to the same contributors. The full cost of this solicitation shall be paid by the Federal committee.

Dated: January 5, 1993.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. 93–422 Filed 1–7–93; 8:45 am]

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Federal Register

Friday
January 8, 1993

Part XV

The President

Executive Order 12829—National Industrial Security Program

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Title 3—

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Presidential Documents

Title 3—

The President

Executive Order 12829 of January 6, 1993

National Industrial Security Program

This order establishes a National Industrial Security Program to safeguard Federal Government classified information that is released to contractors, licensees, and grantees of the United States Government. To promote our national interests, the United States Government issues contracts, licenses, and grants to nongovernment organizations. When these arrangements require access to classified information, the national security requires that this information be safeguarded in a manner equivalent to its protection within the executive branch of Government. The national security also requires that our industrial security program promote the economic and technological interests of the United States. Redundant, overlapping, or unnecessary requirements impede those interests. Therefore, the National Industrial Security Program shall serve as a single, integrated, cohesive industrial security program to protect classified information and to preserve our Nation's economic and technological interests.

Therefore, by the authority vested in me as President by the Constitution and the laws of the United States of America, including the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011–2286), the National Security Act of 1947, as amended (codified as amended in scattered sections of the United States Code), and the Federal Advisory Committee Act, as amended (5 U.S.C. App. 2), it is hereby ordered as follows:

PART 1. ESTABLISHMENT AND POLICY

Section 101. *Establishment.* (a) There is established a National Industrial Security Program. The purpose of this program is to safeguard classified information that may be released or has been released to current, prospective, or former contractors, licensees, or grantees of United States agencies. For the purposes of this order, the terms "contractor, licensee, or grantee" means current, prospective, or former contractors, licensees, or grantees of United States agencies. The National Industrial Security Program shall be applicable to all executive branch departments and agencies.

(b) The National Industrial Security Program shall provide for the protection of information classified pursuant to Executive Order No. 12356 of April 2, 1982, or its successor, and the Atomic Energy Act of 1954, as amended.

(c) For the purposes of this order, the term "contractor" does not include individuals engaged under personal services contracts.

Sec. 102. *Policy Direction.* (a) The National Security Council shall provide overall policy direction for the National Industrial Security Program.

(b) The Director of the Information Security Oversight Office, established under Executive Order No. 12356 of April 2, 1982, shall be responsible for implementing and monitoring the National Industrial Security Program and shall:

(1) develop, in consultation with the agencies, and promulgate subject to the approval of the National Security Council, directives for the implementation of this order, which shall be binding on the agencies;

(2) oversee agency, contractor, licensee, and grantee actions to ensure compliance with this order and implementing directives;

(3) review all agency implementing regulations, internal rules, or guidelines. The Director shall require any regulation, rule, or guideline to be changed if it is not consistent with this order or implementing directives. Any such decision by the Director may be appealed to the National Security Council. The agency regulation, rule, or guideline shall remain in effect pending a prompt decision on the appeal;

(4) have the authority, pursuant to terms of applicable contracts, licenses, grants, or regulations, to conduct on-site reviews of the implementation of the National Industrial Security Program by each agency, contractor, licensee, and grantee that has access to or stores classified information and to require of each agency, contractor, licensee, and grantee those reports, information, and other cooperation that may be necessary to fulfill the Director's responsibilities. If these reports, inspections, or access to specific classified information, or other forms of cooperation, would pose an exceptional national security risk, the affected agency head or the senior official designated under section 203(a) of this order may request the National Security Council to deny access to the Director. The Director shall not have access pending a prompt decision by the National Security Council;

(5) report any violations of this order or its implementing directives to the head of the agency or to the senior official designated under section 203(a) of this order so that corrective action, if appropriate, may be taken. Any such report pertaining to the implementation of the National Industrial Security Program by a contractor, licensee, or grantee shall be directed to the agency that is exercising operational oversight over the contractor, licensee, or grantee under section 202 of this order;

(6) consider and take action on complaints and suggestions from persons within or outside the Government with respect to the administration of the National Industrial Security Program;

(7) consider, in consultation with the advisory committee established by this order, affected agencies, contractors, licensees, and grantees, and recommend to the President through the National Security Council changes to this order; and

(8) report at least annually to the President through the National Security Council on the implementation of the National Industrial Security Program.

(c) Nothing in this order shall be construed to supersede the authority of the Secretary of Energy or the Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended, or the authority of the Director of Central Intelligence under the National Security Act of 1947, as amended, or Executive Order No. 12333 of December 8, 1981.

Sec. 103. *National Industrial Security Program Policy Advisory Committee.* (a) *Establishment.* There is established the National Industrial Security Program Policy Advisory Committee ("Committee"). The Director of the Information Security Oversight Office shall serve as Chairman of the Committee and appoint the members of the Committee. The members of the Committee shall be the representatives of those departments and agencies most affected by the National Industrial Security Program and nongovernment representatives of contractors, licensees, or grantees involved with classified contracts, licenses, or grants, as determined by the Chairman.

(b) *Functions.* (1) The Committee members shall advise the Chairman of the Committee on all matters concerning the policies of the National Industrial Security Program, including recommended changes to those policies as reflected in this order, its implementing directives, or the operating manual established under this order, and serve as a forum to discuss policy issues in dispute.

(2) The Committee shall meet at the request of the Chairman, but at least twice during the calendar year.

(c) *Administration.* (1) Members of the Committee shall serve without compensation for their work on the Committee. However, nongovernment members may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701–5707).

(2) To the extent permitted by law and subject to the availability of funds, the Administrator of General Services shall provide the Committee with administrative services, facilities, staff, and other support services necessary for the performance of its functions.

(d) *General.* Notwithstanding any other Executive order, the functions of the President under the Federal Advisory Committee Act, as amended, except that of reporting to the Congress, which are applicable to the Committee, shall be performed by the Administrator of General Services in accordance with the guidelines and procedures established by the General Services Administration.

PART 2. OPERATIONS

Sec. 201. *National Industrial Security Program Operating Manual.* (a) The Secretary of Defense, in consultation with all affected agencies and with the concurrence of the Secretary of Energy, the Nuclear Regulatory Commission, and the Director of Central Intelligence, shall issue and maintain a National Industrial Security Program Operating Manual ("Manual"). The Secretary of Energy and the Nuclear Regulatory Commission shall prescribe and issue that portion of the Manual that pertains to information classified under the Atomic Energy Act of 1954, as amended. The Director of Central Intelligence shall prescribe and issue that portion of the Manual that pertains to intelligence sources and methods, including Sensitive Compartmented Information.

(b) The Manual shall prescribe specific requirements, restrictions, and other safeguards that are necessary to preclude unauthorized disclosure and control authorized disclosure of classified information to contractors, licensees, or grantees. The Manual shall apply to the release of classified information during all phases of the contracting process including bidding, negotiation, award, performance, and termination of contracts, the licensing process, or the grant process, with or under the control of departments or agencies.

(c) The Manual shall also prescribe requirements, restrictions, and other safeguards that are necessary to protect special classes of classified information, including Restricted Data, Formerly Restricted Data, intelligence sources and methods information, Sensitive Compartmented Information, and Special Access Program information.

(d) In establishing particular requirements, restrictions, and other safeguards within the Manual, the Secretary of Defense, the Secretary of Energy, the Nuclear Regulatory Commission, and the Director of Central Intelligence shall take into account these factors: (i) the damage to the national security that reasonably could be expected to result from an unauthorized disclosure; (ii) the existing or anticipated threat to the disclosure of information; and (iii) the short- and long-term costs of the requirements, restrictions, and other safeguards.

(e) To the extent that is practicable and reasonable, the requirements, restrictions, and safeguards that the Manual establishes for the protection of classified information by contractors, licensees, and grantees shall be consistent with the requirements, restrictions, and safeguards that directives implementing Executive Order No. 12356 of April 2, 1982, or the Atomic Energy Act of 1954, as amended, establish for the protection of classified information by agencies. Upon request by the Chairman of the Committee, the Secretary of Defense shall provide an explanation and justification for any requirement, restriction, or safeguard that results in a standard for

the protection of classified information by contractors, licensees, and grantees that differs from the standard that applies to agencies.

(f) The Manual shall be issued no later than 1 year from the issuance of this order.

Sec. 202. *Operational Oversight.* (a) The Secretary of Defense shall serve as Executive Agent for inspecting and monitoring the contractors, licensees, and grantees who require or will require access to, or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees. The heads of agencies shall enter into agreements with the Secretary of Defense that establish the terms of the Secretary's responsibilities on behalf of these agency heads.

(b) The Director of Central Intelligence retains authority over access to intelligence sources and methods, including Sensitive Compartmented Information. The Director of Central Intelligence may inspect and monitor contractor, licensee, and grantee programs and facilities that involve access to such information or may enter into written agreements with the Secretary of Defense, as Executive Agent, to inspect and monitor these programs or facilities, in whole or in part, on the Director's behalf.

(c) The Secretary of Energy and the Nuclear Regulatory Commission retain authority over access to information under their respective programs classified under the Atomic Energy Act of 1954, as amended. The Secretary or the Commission may inspect and monitor contractor, licensee, and grantee programs and facilities that involve access to such information or may enter into written agreements with the Secretary of Defense, as Executive Agent, to inspect and monitor these programs or facilities, in whole or in part, on behalf of the Secretary or the Commission, respectively.

(d) The Executive Agent shall have the authority to issue, after consultation with affected agencies, standard forms or other standardization that will promote the implementation of the National Industrial Security Program.

Sec. 203. *Implementation.* (a) The head of each agency that enters into classified contracts, licenses, or grants shall designate a senior agency official to direct and administer the agency's implementation and compliance with the National Industrial Security Program.

(b) Agency implementing regulations, internal rules, or guidelines shall be consistent with this order, its implementing directives, and the Manual. Agencies shall issue these regulations, rules, or guidelines no later than 180 days from the issuance of the Manual. They may incorporate all or portions of the Manual by reference.

(c) Each agency head or the senior official designated under paragraph (a) above shall take appropriate and prompt corrective action whenever a violation of this order, its implementing directives, or the Manual occurs.

(d) The senior agency official designated under paragraph (a) above shall account each year for the costs within the agency associated with the implementation of the National Industrial Security Program. These costs shall be reported to the Director of the Information Security Oversight Office, who shall include them in the reports to the President prescribed by this order.

(e) The Secretary of Defense, with the concurrence of the Administrator of General Services, the Administrator of the National Aeronautics and Space Administration, and such other agency heads or officials who may be responsible, shall amend the Federal Acquisition Regulation to be consistent with the implementation of the National Industrial Security Program.

(f) All contracts, licenses, or grants that involve access to classified information and that are advertised or proposed following the issuance of agency regulations, rules, or guidelines described in paragraph (b) above shall comply with the National Industrial Security Program. To the extent that is feasible, economical, and permitted by law, agencies shall amend, modify, or convert

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preexisting contracts, licenses, or grants, or previously advertised or proposed contracts, licenses, or grants, that involve access to classified information for operation under the National Industrial Security Program. Any direct inspection or monitoring of contractors, licensees, or grantees specified by this order shall be carried out pursuant to the terms of a contract, license, grant, or regulation.

(g) Executive Order No. 10865 of February 20, 1960, as amended by Executive Order No. 10909 of January 17, 1961, and Executive Order No. 11382 of November 27, 1967, is hereby amended as follows:

(1) Section 1(a) and (b) are revoked as of the effective date of this order.

(2) Section 1(c) is renumbered as Section 1 and is amended to read as follows:

> "**Section 1.** When used in this order, the term 'head of a department' means the Secretary of State, the Secretary of Defense, the Secretary of Transportation, the Secretary of Energy, the Nuclear Regulatory Commission, the Administrator of the National Aeronautics and Space Administration, and, in section 4, the Attorney General. The term 'head of a department' also means the head of any department or agency, including but not limited to those referenced above with whom the Department of Defense makes an agreement to extend regulations prescribed by the Secretary of Defense concerning authorizations for access to classified information pursuant to Executive Order No. 12829."

(3) Section 2 is amended by inserting the words "pursuant to Executive Order No. 12829" after the word "information."

(4) Section 3 is amended by inserting the words "pursuant to Executive Order No. 12829" between the words "revoked" and "by" in the second clause of that section.

(5) Section 6 is amended by striking out the words "The Secretary of State, the Secretary of Defense, the Administrator of the National Aeronautics and Space Administration, the Secretary of Transportation, or his representative, or the head of any other department or agency of the United States with which the Department of Defense makes an agreement under section (1)(b)," at the beginning of the first sentence, and inserting in their place "The head of a department of the United States . . . ."

(6) Section 8 is amended by striking out paragraphs (1) through (7) and inserting in their place ". . . the deputy of that department, or the principal assistant to the head of that department, as the case may be."

(h) All delegations, rules, regulations, orders, directives, agreements, contracts, licenses, and grants issued under preexisting authorities, including section 1(a) and (b) of Executive Order No. 10865 of February 20, 1960, as amended, by Executive Order No. 10909 of January 17, 1961, and Executive Order No. 11382 of November 27, 1967, shall remain in full force and effect until amended, modified, or terminated pursuant to authority of this order.

(i) This order shall be effective immediately.

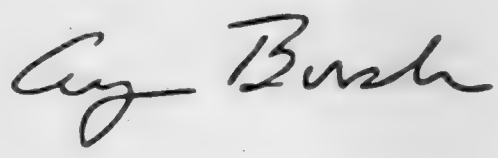

THE WHITE HOUSE,
January 6, 1993.

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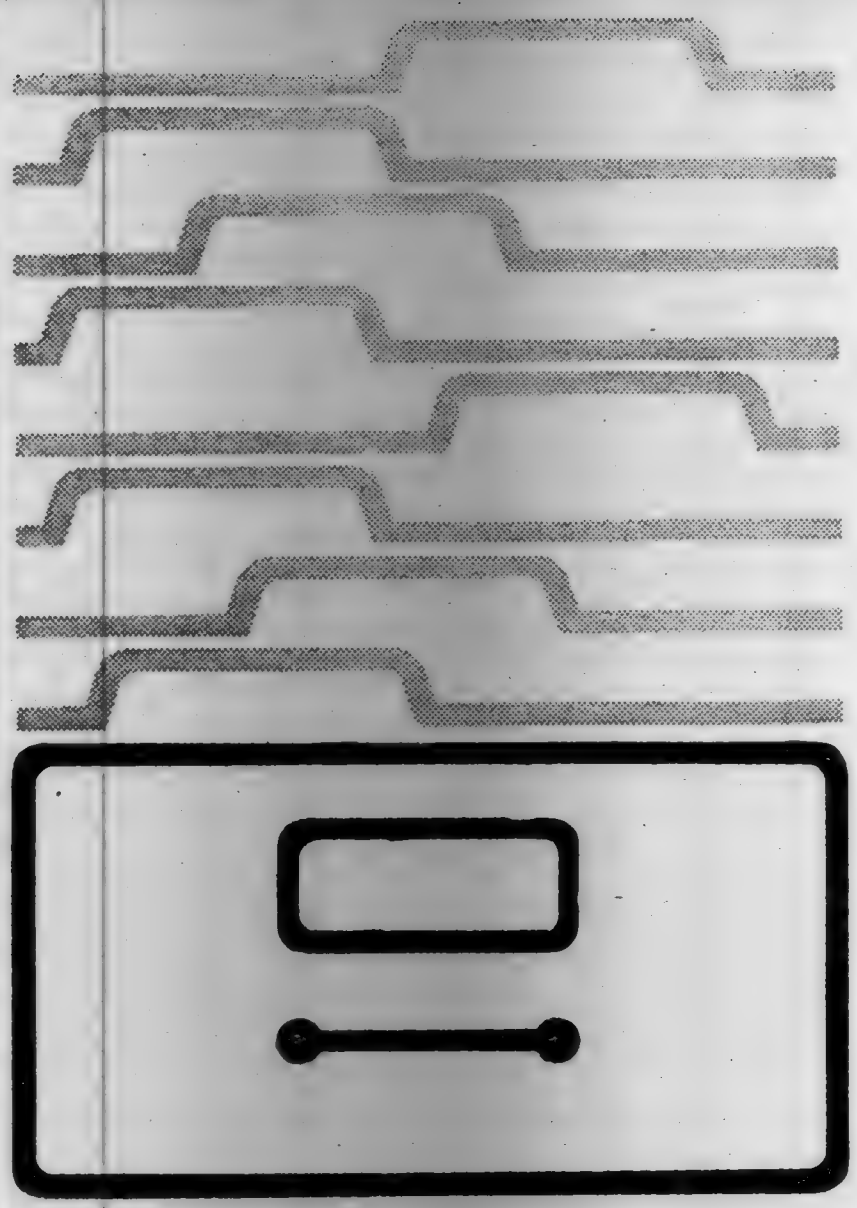

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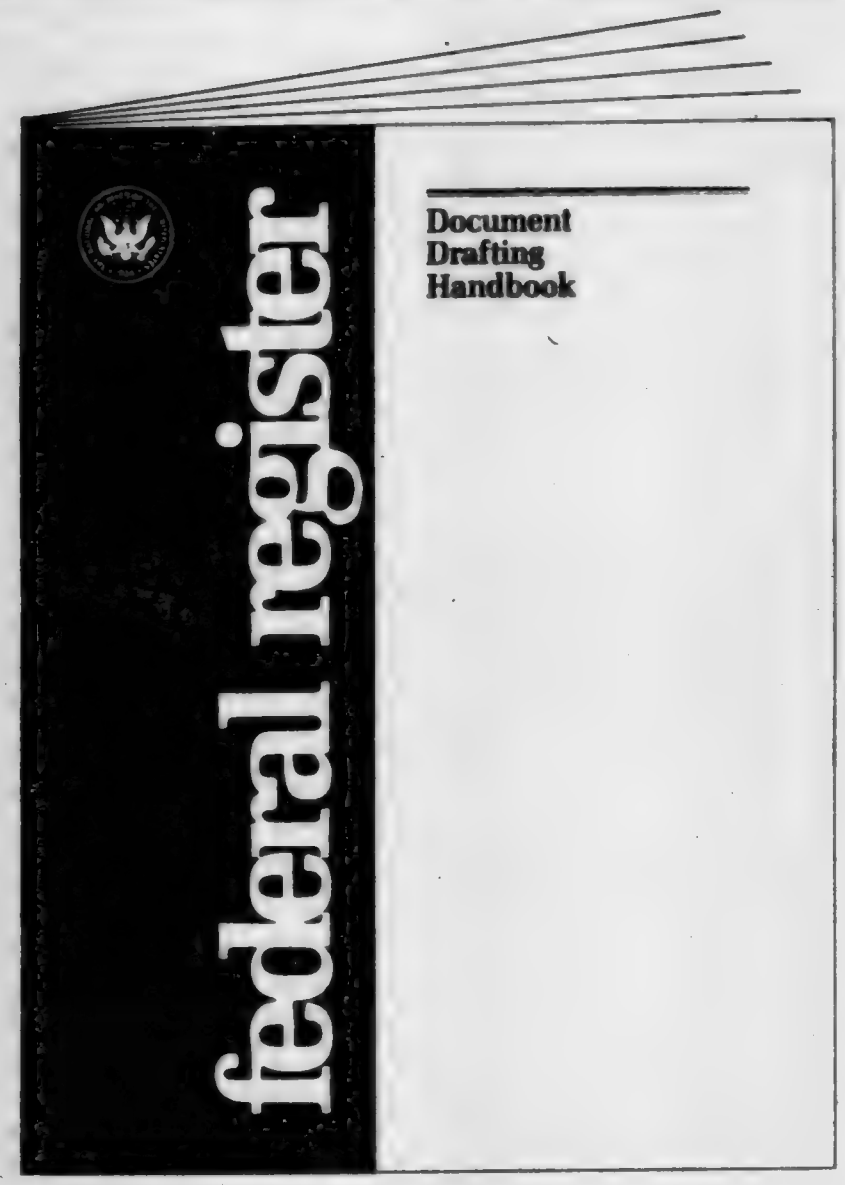

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Title 3—

The President

Memorandum of December 30, 1992

Prescription of the Conditions Under Which Commissioned Officers of the Public Health Service May Be Awarded Military Ribbons, Medals, and Decorations

Memorandum for the Secretary of Defense, the Secretary of Health and Human Services

The authority of the President under section 212(b) of the Public Health Service Act (42 U.S.C. 213(b)) is hereby delegated to the Secretary of Defense. In the exercise of that authority, the Secretary of Defense shall ensure that no military ribbon, medal, or decoration is awarded to an officer of the Public Health Service without the approval of the Secretary of Health and Human Services.

The Secretary of Defense shall ensure the publication of this memorandum in the **Federal Register**.

George Bush

THE WHITE HOUSE,
Washington, December 30, 1992.

[FR Doc. 93–617
Filed 1–7–93; 3:21 pm]
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8 CFR Part

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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 100

[INS No. 1349–92]

RIN 1115–AC95

Statement of Organization; Name Change for Border Patrol Sector Number 3

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This rule amends 8 CFR 100.4 by changing the name of sector headquarters number 3 from "Mayaguez, Puerto Rico" to "Ramey, Puerto Rico". This change is necessary to avoid confusion, since sector number 3 is physically located in Ramey, Puerto Rico.

EFFECTIVE DATE: January 11, 1993.

FOR FURTHER INFORMATION CONTACT: Marion E. Moody, Assistant Chief Patrol Agent, Border Patrol, Immigration and Naturalization Service, 425 I Street, NW., room 7227, Washington, DC 20536, telephone (202) 514–1109.

SUPPLEMENTARY INFORMATION: Originally the Immigration and Naturalization Service intended to install a Sector Headquarters and station in Mayaguez, Puerto Rico, along with maintaining a station in Ramey, Puerto Rico. As a result of budget constraints and lack of suitable space, the Service no longer plans to open a Sector office in Mayaguez. Therefore 8 CFR 100.4 is being amended to change the name of sector headquarters number 3 from "Mayaguez, Puerto Rico" to "Ramey, Puerto Rico", since the sector number 3 headquarters is physically located in Ramey, Puerto Rico.

The Service's implementation of this rule as a final rule is based upon 5 U.S.C. 553(b)(A) as it is a rule of agency organization. The immediate implementation of this final rule is based upon the "good cause" exception found at 5 U.S.C. 553(d) in that the usual notice provisions are unnecessary because the rule will benefit the public by showing the actual city in which the sector headquarters is physically located.

In accordance with 5 U.S.C. 605(b), the Commissioner of the Immigration and Naturalization Service certifies that this rule does not have a significant adverse economic impact on a substantial number of small entities. This rule is not considered to be a major rule within the meaning of section 1(b) of E.O. 12291, nor does this rule have Federalism implications warranting the preparation of a Federalism Assessment in accordance with E.O. 12612.

List of Subjects in 8 CFR Part 100

Authority delegation (Government agencies), Organization and functions (Government agencies).

Accordingly, part 100 of chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 100—STATEMENT OF ORGANIZATION

1. The authority citation for part 100 continues to read as follows:

Authority: 8 U.S.C. 1103; 8 CFR part 2.

§ 100.4 [Amended]

2. In section 100.4, paragraph (d) is amended by changing the name of Sector number 3 from "Mayaguez, Puerto Rico", to "Ramey, Puerto Rico".

Dated: December 9, 1992.

Gene McNary,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 93–461 Filed 1–8–93; 8:45 am]

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FEDERAL HOUSING FINANCE BOARD

12 CFR Part 932

[No. 92–749]

Eligibility of Federal Home Loan Bank Directors

AGENCY: Federal Housing Finance Board.

ACTION: Interim rule.

SUMMARY: The Federal Housing Finance Board (Board) is amending its regulations to revise the dates by which all incumbent directors of the Federal Home Loan Banks (FHLBanks) must submit Personal Certification and Disclosure forms to the Board. The amendments also clarify the date by which nominees for elective director must submit Personal Certification and Disclosure forms to the Board. The amendments also change the date by which the Board must announce the results of the election for FHLBank directors. These date changes are intended to apportion the submission of forms over a longer period in order to enable the Board to devote more time to the review of the forms. The amendments also define more precisely the period during which a director or officer of a member of the FHLBank System who was formerly ineligible to be a FHLBank elective director may once again be eligible to hold that office.

DATES: Interim rule effective on January 11, 1993. Comments must be received on or before March 12, 1993.

ADDRESSES: Comments may be mailed to: Executive Secretariat, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006. Comments will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: Patricia L. Sweeney, Program Analyst, District Banks Directorate, (202) 408–2872; Brandon Straus, Attorney-Advisor, Office of Legal and External Affairs, (202) 408–2589, Federal Housing Finance Board, 1777 F Street, NW., Washington, DC 20006.

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Background

Section 7 of the Federal Home Loan Bank Act (Bank Act), 12 U.S.C. 1421 *et seq.* (Supp. I 1989), vests the management of each FHLBank in a board of elective and appointive directors. *Id.* sec. 1427(a). Bank Act subsection 7(d) authorizes the Board to prescribe rules for the nomination and election of elective FHLBank directors. *Id.* sec. 1427(d). The Board has authority to prescribe rules governing the appointment of appointive FHLBank directors pursuant to its general rulemaking authority in Bank Act subsection 2B(a). See *id.* sec. 1422b(a)(1).

The current Board regulations on appointive director eligibility and elective director eligibility set forth dates by which incumbent directors, nominees for elective director (director nominees), and candidates for appointive director (director candidates) must submit to the Board a certification that they meet certain statutory and regulatory eligibility requirements as well as a statement of disclosure of certain financial relationships. See 12 CFR 932.18(f), 932.21(g). These certifications and disclosures must be made by completing Personal Certification and Disclosure Forms (Forms), denominated A–1, A–2, E–1, or E–2. These forms have been approved by the Office of Management and Budget (OMB) and have been assigned OMB control number 3069–0002. Satisfactory completion of the Forms is a prerequisite for incumbent elective and appointive directors to remain eligible to serve on a FHLBank board. Satisfactory completion of the Forms is also a prerequisite to the ratification of the election of director nominees and the appointment of director candidates by the Board.

Under the current regulations, incumbent appointive directors must submit their Forms annually by November 15, and incumbent elective directors must do by December 1. However, during the months of October through December, the Board also must review Forms submitted by director candidates and director nominees. Director candidates are required to submit their Forms "[p]rior to the initial appointment." *Id.* § 932.18(f). Most director appointments are made near the end of the year because the four year terms of appointive directors expire on December 31. However, some appointments are made other than at year end in order to fill appointive directorships that have been vacated at mid-term.

Director nominees must submit their Forms "[p]rior to each election." *Id.* § 932.21(g). The process of election of director nominees takes place from September 25 to October 25 of each year. *Id.* § 932.14(a), (c). The Board must announce the results of the election by November 15. *Id.* § 932.14(d). As a result of this series of deadlines set forth in the current regulations, the Board is required to review the incoming Forms of approximately 110 incumbent directors while at the same time reviewing Forms from up to sixty director nominees in time for the Board to ratify the election of those nominees by November 15.

II. Analysis of Interim Rule

A New Date For Submission of Personal Certification and Disclosure Forms by Incumbent Directors

In order to allow the Board more time to review the Forms of director candidates and director nominees, which are submitted to the Board in the final months of the calendar year, the Board is amending § 932.18 and § 932.21 of its regulations to provide that incumbent elective and appointive directors must submit Forms E–2 and A–2, respectively, annually by March 1. This change is intended to apportion the submission of Forms over a longer period so that the Board has more time to review individual Forms.

In order to avoid duplicative certification and disclosure requirements for certain new directors, the interim rule creates some exceptions to the requirements for submission of Forms E–2 and A–2. Newly elected elective directors, who were required to submit a Form E–1 in the year in which they were elected, would be exempt from submitting a Form E–2 in the following year. Similarly, appointive directors who submitted a Form A–1 in October, November, or December of the year prior to the year in which their appointment took effect would be exempt from submitting a Form A–2 by March 1 of the following year.

As a consequence of these exceptions, newly elected directors will not be required to submit Forms for up to a fifteen month period: from late October of the year in which they were elected to March 1 of the second year of their terms. In addition, appointive directors who submitted Form A–1 in October, November, or December of the year prior to the year in which their appointment took effect will not be required to submit a Form for up to a seventeen month period: from October 1 of the year prior to the year in which their appointment was effective to March 1 of the second year of their terms.

The Board believes that allowing first-year directors to serve several added months before they are required to meet the certification and disclosure requirements as incumbent directors poses minimal risk to the FHLBanks and the FHLBank System because all incumbent directors are required by regulation to report, on their own initiative, any ineligibility or suspected ineligibility to the Board within thirty days of occurrence. *See id.* §§ 932.18(f)(2), 932.21(g)(2).

B New Dates for Submission of Personal Certification and Disclosure Forms By Elective Director Nominees

The current regulation governing the nomination of director nominees requires each director nominee to complete a "questionnaire" and return it to the Board prior to August 20 in order for the director nominee's name to be placed on the ballot for the next election. *Id.* § 932.13(c)(3). In practice, the Board now requires that director nominees fill out and return to the Board by August 20 that portion of Form E–1 in which director nominees certify that they meet all statutory and regulatory eligibility requirements for election. The Board no longer uses a "questionnaire." Therefore, the interim rule changes the language of § 932.13(c)(3) to reflect this practice.

The current elective director eligibility regulations require that "[p]rior to each election," director nominees must certify in Form E–1 that they meet certain statutory and regulatory eligibility requirements and must disclose to the Board certain financial relationships. See *id.* § 932.21(g)(1), (3). However, it is the current Board practice to wait until after the ballots have been opened to require those director nominees with the highest number of votes for each directorship to complete a Form E–1. The Board must, by regulation, wait until 5 p.m. on October 25 before opening ballots. *Id.* § 932.14(c). The reason for this practice is that the Board wishes to require disclosure of personal financial relationships only by director nominees whose election has some likelihood of being ratified by the Board

The interim rule therefore replaces the phrase "[p]rior to each election" in subparagraphs (g)(1) and (g)(3) of § 932.21 with "[p]rior to the ratification of the election results by the Board." This change is intended to make clear that director nominees are not required to disclose their financial relationships to the Board on Form E–1 until after members cast their ballots and after the results are tabulated. See *id.* § 932 14(c). However, director nominees must submit the completed Form E-l before the Board will ratify their election and declare the election results. The change made by the interim rule is intended to reflect this practice.

The Board recognizes that those director nominees who must fill out Form E–1 prior to ratification of their election by the Board will have filled out the certification section of Form E–1 twice: once by August 20 in order to have his or her name placed on the ballot and again after the election when

disclosing his or her financial relationships. The purpose of requiring director nominees to again certify eligibility after the election is to ensure that director nominees are still eligible to be FHLBank directors at the time the Board ratifies their election. Further, by certifying their eligibility after they are elected, director nominees are exempted from submitting a Form E–2 during the following year.

C. New Date for Declaration of Election Results

The current Board regulation governing the election of FHLBank elective directors provides that the Board will determine and announce the winners of the election by November 15, *Id.* § 932.14(d). However, director nominees are not required to complete Form E–1 until after they have been elected. Therefore, the November 15 date allows only three weeks for director nominees to submit their Forms and for the Board to review the Forms before the election results must be announced. Section 932.14(c) of the interim rule changes the announcement date to December 31. This change is intended to ensure that the Board will have sufficient time to review Forms of director nominees and ratify their election, should director nominees wait until mid- or late December to submit their Forms. The Board does not intend to delay the announcement of election results until December 31, if the Board can ratify the results prior to that date.

D. Clarification of Eligibility Requirement For Elective Directors Whose Institution Fails To Meet Its Capital Requirements

The Board is also amending the regulation governing eligibility of a person who was formerly ineligible to be an elective director due to non-compliance with minimum regulatory capital requirements by the member institution that the person serves as an officer or director. See id. § 932.21(d)(2). The current regulation provides that a "director" who was formerly ineligible is once again eligible in the succeeding calendar year if the member meets the minimum regulatory capital requirements during each phase of the election process for the succeeding calendar year. *Id.*

The interim rule clarifies the regulation by expressly making it applicable to a "person" who was formerly ineligible rather than a "director" who was formerly ineligible. This change is intended to clarify the Board's intent and to reflect current Board practice of applying the regulation not only to incumbent elective directors but also to director nominees and prospective director nominees. This change is also intended to make the regulation's language parallel the language of paragraph (d)(1) of § 932.21, which defines the period during which a "person" who is an officer or director of a member that fails to meet minimum regulatory capital requirements is ineligible to be an elective director. *Id.* § 932.21(d)(1).

The interim rule further amends the regulation governing re-eligibility by rephrasing the time frame during which a member must meet minimum regulatory capital requirements in order for a formerly ineligible person to once again be eligible to be an elective director. The interim rule does not change the time frame, but it defines the time frame in terms of the calendar year rather than in terms of a "phase of the election process."

III. Notice and Public Participation

A. General Notice of Proposed Rulemaking

The Board is requesting public comment on this interim rule, although it is not required by the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, to publish a general notice of proposed rulemaking. Publication of notice of a proposed rulemaking is not required because the Board finds that there is good cause that notice and comment procedure is unnecessary and contrary to the public interest in this instance. See *id.* sec. 553(b)(3)(B). Compliance with the public procedure requirements of APA section 553 is unnecessary because the interim rule makes minor technical amendments to the director eligibility regulations. The amendments do not impose any new substantive requirements on FHLBank directors and therefore do not involve matters of public interest or concern.

Implementation of the interim rule without prior public notice will not create a hardship for those people who are subject to the rule. The deadlines set forth in the new rule will allow incumbent directors an extra three months in which to comply with the certification and disclosure requirements. Director nominees will also have more time to comply with the certification and disclosure requirements because the interim rule makes clear that the deadline for submission of their Forms is no longer prior to the election, but prior to ratification of the election results by the Board, which takes place after the election. Public notice and comment is therefore unnecessary in the promulgation of the interim rule.

Although the content of the interim rule does not involve matters of the public interest, delaying the effect of the interim rule would be contrary to the public interest. The deadline changes in the interim rule allow the Board more time in which to review the Forms of FHLBank directors during the election process. It is in the public interest for the Board to have more time in which to review the qualifications of FHLBank directors because the safe and efficient operation of the FHLBank System is dependent upon the selection of qualified FHLBank directors. Delaying the effect of the interim rule in order to follow the notice and comment procedures would cause the rule to become effective after the deadlines that are changed by the rule have passed. This would deprive the Board of the benefit of the rule in the current election cycle. Therefore, delaying implementation of the interim rule would be contrary to the public interest.

The Board therefore finds good cause that compliance with notice and comment procedures in adoption of this interim rule is unnecessary and contrary to the public interest. Further, the interim rule comes within the exception to the notice and comment requirement for rules of agency procedure, under section 553(b)(3)(A) of the APA. See *id.* section 553(b)(3)(A).

B. Effective Date

The Board finds that section 553(d) of the APA, which generally requires publication of a substantive rule at least thirty days before the rule's effective date, is not applicable to this interim rule. The interim rule makes changes in the Board's procedure for accepting certification and disclosure Forms from FHLBank directors. The interim rule is not a substantive rule because it does not change any of the substantive requirements for director eligibility. Therefore, the requirement of a thirty-day delay in the effective date of a substantive rule does not apply to this interim rule, which is procedural.

The Board also finds that under APA subsection 553(d)(3), there is good cause that the interim rule be effective upon publication for the reasons stated in section III.A.

Although this interim rule is effective immediately, the Board requests public comment. The Board considers comments from the public helpful in formulating clear and effective regulations. Therefore, the Board will consider public comments on this interim rule in developing a final rule.

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IV. Regulatory Flexibility Act

The Board is not required by the Regulatory Flexibility Act (Reg Flex Act), 5 U.S.C. 601 *et seq.*, to prepare a regulatory flexibility analysis for this interim rule. The Reg Flex Act requires that a regulatory flexibility analysis be prepared whenever an agency promulgates a proposed or final rule after being required by the APA to publish a general notice of proposed rulemaking pursuant to section 553 of the APA. See 5 U.S.C. 603(a), 604(a). The Board is not required to publish a general notice of proposed rulemaking for this interim rule because the Board has found good cause that notice and comment is unnecessary and contrary to the public interest in the adoption of this interim rule. See *id.* sec. 553(b)(3)(B). Further, the rule comes within the exception to the notice and comment requirement for rules of agency procedure, under APA subsection 553(b)(3)(A). See *id.* sec. 553(b)(3)(A).

The interim rule does not impose any new reporting requirements. It merely changes the deadlines by which existing requirements must be met. The interim rule therefore will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 12 CFR Part 932

Banks, Banking, Conflicts of interest, Elections, Ethical conduct, Federal home loan banks, Financial disclosure, Reporting and recordkeeping requirements.

Accordingly, chapter IX, title 12, part 932, Code of Federal Regulations, is hereby amended as follows:

PART 932—ORGANIZATION OF THE BANKS

1. The authority citation for part 932 is revised to read as follows:

Authority: 12 U.S.C. 1422a, 1422b, 1426, 1427, 1464; 18 U.S.C. 207; 42 U.S.C. 8101 *et seq.*

2. Section 932.13 is amended by revising the first two sentences of paragraph (c) concluding text to read as follows:

§ 932.13 Designation and nomination of elective directorship.

* * * * *

(c) * * *

With such letter will be sent a list of nominees and a copy of Form E–1. Each nominee must certify to the Board on Form E–1 by August 20 that such nominee meets all applicable eligibility qualifications for his election set forth in section 7 of the Act and this part.

* * *

* * * * *

3. Section 932.14 is amended by revising the first sentence of paragraph (d) to read as follows:

§ 932.14 Election of directors.

* * * * *

(d) By December 31, the Board will declare elected the candidate receiving the highest number of votes cast, and where two or more directorships are to be filled from the ballot, the Board will declare elected each candidate receiving the next succeeding highest number of votes until the number of candidates declared elected equals the number of directorships to be filled. * * *

* * * * *

4. Section 932.18 is amended by revising paragraphs (f)(1) and (f)(3) introductory text to read as follows:

§ 932.18 Appointive director eligibility.

* * * * *

(f) *Certification and reporting.* (1) Prior to the initial appointment, each director candidate for appointive director shall certify in writing to the Board on Form A–1 that he or she meets all applicable eligibility qualifications for his or her appointment set forth in section 7(a) of the Act and this part. By March 1 of each year during the term of the directorship, each appointive director shall certify in writing to the Board on Form A–2 that he or she meets all applicable eligibility qualifications for his or her appointment set forth in section 7(a) of the Act and this part, except that any appointive director who submitted Form A–1 to the Board in October, November, or December of the year prior to the year in which his or her appointment took effect is not required to submit Form A–2 by March 1 of the year in which the appointment took effect.

* * * * *

(3) Prior to the initial appointment, each director candidate for appointive director shall fully disclose in writing to the Board on Form A–1 the financial relationships (as defined in § 931.30 of this chapter) set forth in paragraphs (f)(3) (i), (ii), (iii), and (iv) of this section of such director candidate. By March 1 of each year during the term of directorship, each appointive director shall fully disclose in writing to the Board on Form A–2 the financial relationships (as defined in § 931.30 of this chapter) set forth in paragraphs (f)(3) (i), (ii), (iii), and (iv) of this section of such appointive director, except that any appointive director who submitted a Form A–1 to the Board in October, November, or December of the year prior to the year in which his or her appointment took effect is not required to submit Form A–2 by March 1 of the year in which the appointment took effect.

* * * * *

5. Section 932.21 is amended by revising paragraphs (d)(2), (g)(1), and (g)(3) to read as follows:

§ 932.21 Elective director eligibility.

* * * * *

(d) * * *

(2) A person who is ineligible pursuant to paragraph (d)(1) of this section shall once again be eligible for election in the next succeeding calendar year in which the member(s) he or she serves as an officer or director meet(s) the applicable minimum regulatory capital requirements throughout the entire calendar year. Such compliance with applicable minimum regulatory capital requirements shall not be satisfied by the granting of an exemption or exception to such capital requirements by the appropriate federal regulatory agency.

* * * * *

(g) *Certification and reporting.* (1) Prior to the ratification of the election results by the Board, each director nominee for elective director shall certify in writing to the Board on Form E–1 that he or she meets all applicable eligibility qualifications for his or her election set forth in section 7 of the Act and this part. By March 1 of each year during the term of directorship, each elective director who was not elected in the immediately preceding year shall certify in writing to the Board on Form E–2 that he or she meets all applicable eligibility qualifications for his or her election set forth in section 7 of the Act and this part.

* * * * *

(3) Prior to the ratification of the election results by the Board, each director nominee for elective director shall fully disclose in writing to the Board on Form E–1, and by March 1 of each year thereafter during the term of the directorship each elective director who was not elected in the immediately preceding year shall fully disclose in writing to the Board on Form E–2, any financial relationships (as defined in § 931.30 of this chapter) set forth in § 932.18(f)(3) of this part of such director nominee or elective director.

* * * * *

By the Federal Housing Finance Board

Daniel F. Evans, Jr.,

Chairman.

[FR Doc. 93–537 Filed 1–8–93; 8:45 am]

BILLING CODE 6725–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92–ANE–61; Amendment 39–8445]

Airworthiness Directives; Garrett Engine Division, Allied-Signal Incorporated, Model TFE731–5BR Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule, request for comments.

SUMMARY: This document publishes in the **Federal Register** an amendment adopting Airworthiness Directive (AD) priority letter 92–02–18 that was sent previously to all known U.S. owners and operators of Garrett Engine Division, Allied-Signal Incorporated, Model TFE731–5BR turbofan engines by individual letters. This AD requires discontinuation of inflight operation of certain engines. This amendment is prompted by two reports of inflight shutdowns due to fan gearbox failures. The actions specified by this AD are intended to prevent multiple inflight engine failures.

DATES: Effective February 10, 1993, to all persons except those persons to whom it was made immediately effective by priority letter AD 92–02–18, issued January 14, 1992, which contained the requirements of this amendment.

Comments for inclusion in the Rules Docket must be received on or before February 10, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 92–ANE–61, 12 New England Executive Park, Burlington, Massachusetts 01803–5299.

FOR FURTHER INFORMATION CONTACT: Joseph Costa, Propulsion Branch, ANM–140L, Los Angeles Aircraft Certification Office, Transport Airplane Directorate, Aircraft Certification Service, FAA, 3229 East Spring Street, Long Beach, California, 90806–2425; telephone (310) 988–5246; fax (310) 988–5210.

SUPPLEMENTARY INFORMATION: On January 14, 1992, the FAA issued priority letter AD 92–02–18, applicable to Garrett Engine Division, Allied-Signal Incorporated, Model TFE731 series turbofan engines, which requires discontinuation of inflight operation of certain engines. That action was prompted by reports of two recent inflight engine shutdowns due to fan gearbox failures that occurred within 8 hours time in service following conversion of the engines from Garrett Model TFE731–5AR to Garrett Model TFE731–5BR engines. Preliminary investigation has revealed fatigue cracks originating from the aft damper ring groove of the sun gear. These cracks progressed until the gear cracked along the gear tooth root, which caused a vibration and fragmentation of the sun gear. This condition, if not corrected, could result in multiple inflight engine failures.

Since the unsafe condition described is likely to exist or develop on other engines of the same type design, the FAA issued priority letter AD 92–08–18 to prevent multiple inflight engine failures. The AD requires discontinuation of further flight of certain engines.

Since it was found that immediate corrective action was required, notice and opportunity for prior public comment thereon were impracticable and contrary to the public interest, and good cause existed to make the AD effective immediately by individual letters issued on January 14, 1992, to all known U.S. owners and operators of Garrett Engine Division, Allied-Signal Incorporated, Model TFE731–5BR turbofan engines. These conditions still exist, and the AD is hereby published in the **Federal Register** as an amendment to § 39.13 of part 39 of the Federal Aviation Regulations (FAR) to make it effective as to all persons.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption "**ADDRESSES.**" All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92–ANE–61." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules docket at the location provided under the caption "**ADDRESSES.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

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PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

92–02–18: Garrett Engine Division, Allied-Signal Incorporated: Amendment 39–8445. Docket No. 92–ANE–61.

Applicability: Garrett Engine Division, Allied-Signal Incorporated, Model TFE731–5BR turbofan engines installed on but not limited to Dassault Aviation Model Mystere Falcon 20 and 900 series airplanes.

Compliance: Required prior to further flight, unless accomplished previously.

To prevent multiple inflight engine failures, accomplish the following:

(a) For engines identified on the data plate as Part Number (P/N) 3075330–2 or P/N 3075370–1, discontinue inflight operation.

(b) This AD is an interim directive until approved corrective action is available.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Los Angeles ACO.

(d) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) This amendment becomes effective on February 10, 1993, to all persons except those persons to whom it was made immediately effective by priority letter AD 92–02–18, issued January 14, 1992, which contained the requirements of this amendment.

Issued in Burlington, Massachusetts, on December 16, 1992.

Jay J. Pardee,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 93–476 Filed 1–8–93; 8:45 am]

BILLING CODE 4910–13–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MA–00–01–5383; A–1–FRL–4538–7]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Revised Regulations Controlling Volatile Organic Compound Emissions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving portions of the State Implementation Plan (SIP) revisions submitted by the Commonwealth of Massachusetts which amend its volatile organic compound (VOC) regulations. The intended effect of this action is to approve portions of the Massachusetts revised SIP for ozone. This action is being taken in accordance with section 110 and part D of the Clean Air Act (CAA).

EFFECTIVE DATE: This rule will become effective on February 10, 1993.

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region I, One Congress Street, 10th floor, Boston, MA; Public Information Reference Unit, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460; and Department of Environmental Protection, One Winter Street, 7th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Emanuel Souza, Jr., (617) 565–3248.

SUPPLEMENTARY INFORMATION: On February 3, 1983 (48 FR 5044), June 1, 1987 (52 FR 20422) and May 29, 1990 (55 FR 21755), EPA published Notices of Proposed Rulemakings (NPR) for the Commonwealth of Massachusetts. The February 3, 1983 NPR proposed approval of Massachusetts' 1982 SIP. The June 1, 1987 NPR proposed approval of Massachusetts' generic bubble regulations, 310 CMR 7.18(2)(b) and 310 CMR 7.00: Appendix B. EPA's May 29, 1990 NPR proposed approval of an August 17, 1989 SIP revision of VOC regulations. Massachusetts submitted the formal SIP revisions on August 27, 1982, June 27, 1984, March 6, 1985, April 12, 1985, August 17, 1989 and June 7, 1991. Additionally, the state submitted a letter on December 17, 1991 withdrawing portions of the June 7, 1991 submittal because of typographical errors.

Background

On August 27, 1982, Massachusetts submitted its 1982 SIP to EPA for approval. On February 3, 1983, EPA published an NPR for Massachusetts' 1982 SIP. However, in the final rulemaking notice for Massachusetts' 1982 SIP (48 FR 51480), EPA stated that all the issues regarding the bubble regulations (310 CMR 7.18(2)(b) and 310 CMR 7.00: Appendix B) were not resolved, and that, EPA would take final action on the two bubble regulations at a later date.

On June 27, 1984, March 6, 1985 and April 12, 1985, Massachusetts submitted revisions to its generic bubble regulations, 310 CMR 7.18(2)(b) and 310 CMR 7.00: Appendix B to EPA for approval. On June 1, 1987, EPA published an NPR for Massachusetts' generic bubble regulations. In that notice EPA listed 14 conditions that Massachusetts had to satisfy before EPA would take final action on these regulations.

On May 25, 1988, EPA sent a letter to the Governor of Massachusetts notifying him that the Massachusetts SIP was substantially inadequate to achieve the National Ambient Air Quality Standard (NAAQS) for ozone in the entire State. EPA requested the State to respond to that letter in two phases—the first in the near future and the second following EPA's issuance of a final policy on how the States should correct their SIPs. One of the requirements of the first phase of the State's response was to correct the deficiencies identified by EPA in the existing SIP's VOC regulations.

On June 16, 1988, EPA sent a letter to the Acting Director of the Massachusetts Department of Environmental Protection (DEP) Division of Air Quality Control outlining the corrections that needed to be made to Massachusetts' existing regulations in order to eliminate the identified deficiencies and inconsistencies in the regulations as compared to EPA's national guidance.

The Commonwealth of Massachusetts made changes to its VOC regulations as required by EPA's May 25 and June 16, 1988 letters, and submitted the revised adopted VOC regulations as a formal SIP revision on August 17, 1989.

EPA proposed approval of the August 17, 1989 submittal in two notices. The automobile surface coating regulation was published separately as a proposed partial disapproval and proposed partial approval. This notice was published in the **Federal Register** on October 12, 1990 (55 FR 41553). EPA acted on the automobile surface coating regulation separately because a portion of the submittal, the compliance dates for the

topcoat and final repair applications, had already been disapproved by EPA on September 16, 1988 (53 FR 36011).

The remainder of the regulations submitted on August 17, 1989 were published as a proposed approval. EPA proposed approval of the remaining VOC regulations submitted on August 17, 1989, in an NPR on May 29, 1990 (55 FR 21755). That notice proposed approval of all of Massachusetts' August 17, 1989 submittal with the exception of the automobile surface coating regulation.

On November 15, 1990, the Clean Air Act Amendments of 1990 (CAAA) were enacted. In section 182(a)(2)(A) of the amended Act, Congress codified the requirement that states revise their SIPs for ozone nonattainment areas so that they conform with EPA's preamendment guidance.

On June 7, 1991, Massachusetts submitted revisions to its VOC regulations pursuant to the changes requested in the NPRs published in the **Federal Register**. Today's action approves only certain portions of that submittal. Other portions of the June 7, 1991 submittal dealing with gasoline marketing, solvent metal degreasing and surface coating of miscellaneous parts and products are being proposed for approval in a separate action because EPA never proposed them for public comment.[1] In addition, EPA finally approved as a separate action, revisions to Massachusetts' automobile surface coating regulation in the **Federal Register** on October 8, 1992 (57 FR 46313).

On December 17, 1991 the DEP submitted a letter to EPA withdrawing certain portions of the June 7, 1991 submittal due to typographical errors. This letter does not affect the enforceability or approval of today's action because it affects separable rules that are not the subject of today's action.

EPA is taking final action because this action is consistent with the guidance that existed at the time of the proposal and because it strengthens the SIP. Additionally, these amendments, although submitted in response to the SIP call letter, also fulfill part of the RACT fix-up requirement.

Summary of Amendments Made To Secure Final EPA Approval

EPA's NPR published on June 1, 1987, for Massachusetts' generic bubble regulations, required that 15 issues be addressed prior to final rulemaking. In response to these conditions, Massachusetts' August 17, 1989 SIP revision included an amendment in 310 CMR 7.00: Appendix B: (1)(a)7. stating: "The Department will not issue any new approvals for alternative emission limitations to any facility that did not apply in writing for approval prior to May 25, 1988 until these regulations are amended to be consistent with the National Emissions Trading Policy issued on December 4, 1986 and approved into the SIP by EPA." This amendment to Massachusetts' bubble regulation eliminates the State's authority to issue generic bubbles. Therefore, all issues listed in the June 1, 1987 NPR have been resolved.

EPA's NPR published on May 29, 1990 for its revised VOC regulations required that 10 issues be addressed prior to final rulemaking. In the June 7, 1991 submittal, Massachusetts made the following changes to satisfy the requirements as listed in NPR:

1. Several definitions were revised to correct deficiencies and typographical errors specifically outlined in the NPR.

2. The May 29, 1990 NPR listed corrections Massachusetts needed to make to 310 CMR 7.24, "organic material storage and distribution," 310 CMR 7.18(8), "solvent metal degreasing" and 310 CMR 7.18(11), "miscellaneous metal parts and products regulations." Massachusetts made changes to these regulations and submitted them on June 7, 1991. Revisions to regulation 310 CMR 7.24, portions of 310 CMR 7.18(8) and portions of 310 CMR 7.18(11) are being proposed in another notice since the changes submitted on June 7, 1991 were more significant than those required by EPA in the **Federal Register** on May 29, 1990.

3. Massachusetts made a clarification to 310 CMR 7.18(2)(c). Additionally, EPA listed a requirement in the NPR stating that additional language was needed, which specifically said that sources applying for an alternative RACT would be subject to the underlying SIP until EPA approves an alternative RACT for that source. Massachusetts has explained that no exemption exists in the regulations relieving sources from complying with the SIP, therefore, additional language is not warranted. EPA accepts this explanation and concurs with DEP's response.

4. An addition was made to 310 CMR 7.18(2)(e) to include monitoring requirements for emission capture and control equipment.

5. The definition of halogenated organic compound was not officially removed from the submittal. However, the presence of this definition does not affect the enforceability of 310 CMR 7.18 because no regulations referencing this definition have been submitted as part of the SIP. Therefore, EPA is approving this definition.

6. The typographical error in 310 CMR 7.18(12) was corrected.

7. An addition was made to 310 CMR 7.18(3)(a), (4)(a), (5)(a), (6)(a), (10)(a), (14)(a), (15)(a), (16)(a) and (18)(a) to include the language "before application of air pollution control equipment."

8. A change was made to 310 CMR 7.18(17)(a) to clarify the applicability of the regulation. The State also clarified 310 CMR 7.18(17)(f), so that any RACT determination made pursuant to 310 CMR 7.18(17)(a)–(e) must be approved by EPA.

A more detailed description of these revisions and EPA's rationale for approving them was provided in the NPR and will not be restated here. For additional details of each portion of Massachusetts' regulations, see the Technical Support Document prepared on the revision available at the locations listed in the **ADDRESSES** section of this notice.

Response to Public Comments

EPA received 8 letters of public comment; 7 letters were submitted on NPR published on June 1, 1987 on the proposed approval of the generic bubble rule and 1 letter on the NPR published on May 29, 1990. Consequentially, since Massachusetts has recognized that its generic bubble was not consistent with EPA guidance, Massachusetts has amended its generic bubble regulation so that no additional "bubbles" will be issued. Accordingly, EPA has not prepared a response to the comments submitted on June 1, 1987 because the State revised its regulation to disallow emission trading. Furthermore, the letter submitted on the May 29, 1990 NPR by the MA DEP will be addressed when EPA publishes a final rulemaking notice for those actions proposed on September 22, 1992 (57 FR 43651) since that letter addresses revisions to Massachusetts' regulations which were proposed by EPA on September 22, 1992.

Final Action

EPA is approving the SIP revisions submitted by the Commonwealth of Massachusetts on August 27, 1982, June 27, 1984, March 6, 1985, April 12, 1985, August 17, 1989, and portions of the SIP revision request submitted on June 7, 1991. These revisions amend Massachusetts' VOC regulations. For the reasons described here and in the Technical Support Document, EPA is approving the additions and/or

[1] These revisions were proposed in the **Federal Register** on September 22, 1992 (57 FR 43651).

revisions made to the Massachusetts VOC regulations.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410 (a)(2).

In addition, although portions of these submittals preceded the date of enactment of the CAAA, EPA is approving the submittals as meeting part of the requirements of section 182(a)(2)(A) of the amended Act. Areas designated nonattainment before enactment of the Amendments and which retained that designation and were classified as marginal or above as of enactment are required to meet the RACT fix-up requirement. Under section 182(a)(2)(A), those areas were required by May 15, 1991, to correct RACT as it was required under preamended section 172(b) as that requirement was interpreted in preamendment guidance.[2] The SIP call letters interpreted that guidance and indicated corrections necessary for specific nonattainment areas. The entire state of Massachusetts is classified as a serious, ozone nonattainment area and is, therefore, subject to the RACT fix-up requirement. The portions of Massachusetts' revised regulations that were submitted in response to the SIP call letter, therefore, also fulfill part of the RACT fix-up requirement.

Because EPA proposed approval of this submittal prior to enactment, EPA did not propose approval based on the requirements of new section 182(a)(2)(A). However, EPA believes that the good cause exception to notice-and-comment rulemaking applies and that the Agency, therefore, is not required to repropose approval of the submittal as meeting section 182(a)(2)(A). The Agency's action on a SIP or SIP elements is rulemaking that is subject to the procedural requirements of the Administrative Procedure Act (APA). Section 553(b)(B) of the APA provides that the Agency need not provide notice and an opportunity for comment if the Agency for good cause determines that notice and comment are "impracticable, unnecessary, or contrary to the public interest."

Notice and comment are impracticable and unnecessary in the present circumstance. Section 182(a)(2)(A) does not impose new requirements on the subject nonattainment areas. Rather, section 182(a)(2)(A) codifies the corrections certain nonattainment areas needed to make subject to the EPA SIP call letters issued in 1987 and 1988. Because the Massachusetts SIP submittal meets the SIP call requirements and, therefore, is consistent with the applicable pre-amendment guidance, EPA believes that the submittal also necessarily meets the requirements of section 182(a)(2)(A) of the amended Act. In EPA's earlier proposed approval of the Massachusetts SIP, EPA provided notice and an opportunity for comment on the consistency of the state's rules with EPA's pre-enactment guidance. Since notice and an opportunity for comment have been provided on that set of issues, and section 182(a)(2)(A) does not expand those requirements, it is unnecessary to repeat that process. In addition, it is impracticable for the Agency to take such action because in light of the statutory time constraints on acting on SIPs, such a process would divert valuable agency resources from action on the large number of SIPs addressing new substantive requirements.

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225).

On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and Table 3 revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of two years. EPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any State implementation plan. Each request for revision to the State implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 12, 1993. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

Note: Incorporation by reference of the State Implementation Plan for the Commonwealth of Massachusetts was approved by the Director of the Federal Register on July 1, 1992.

Dated: November 12, 1992.

Julie Belaga,

Regional Administrator, Region I.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Subpart W—Massachusetts

Authority: 42 U.S.C. 7401–7671q.

2. Section 52.1120 is amended by adding paragraph (c)(93) to read as follows:

§52.1120 Identification of plan.

* * * * *

(c) * * *

[2] Among other things, the preamendment guidance consists of the VOC RACT portions of the Post-87 policy, 52 FR 45044 (Nov. 24, 1987); "Issues Relating to VOC Regulation Cutpoints, Deficiencies and Deviations, Clarification to Appendix D of November 24, 1987 Federal Register Notice" (Bluebook) (notice of availability published in the Federal Register on May 25, 1988); and the existing CTGs.

(93) Revisions to the State Implementation Plan submitted by the Massachusetts Department of Environmental Protection on August 27, 1982, June 27, 1984, March 6, 1985, April 12, 1985, August 17, 1989, June 7, 1991 and December 17, 1991.

(i) Incorporation by reference.

(A) Letters from the Massachusetts Department of Environmental Protection dated August 27, 1982, April 12, 1985, August 17, 1989, and June 7, 1991, submitting revisions to the Massachusetts State Implementation Plan.

(B) Amendment to 310 CMR 7.18(2)(b) submitted on August 27, 1982 and effective on September 16, 1982.

(C) Addition of 310 CMR 7.00: Appendix B submitted on April 12, 1985 and effective on September 30, 1984.

(D) Amendments to portions of 310 CMR 7.00 submitted on August 17, 1989 and effective September 15, 1989.

(E) Amendments to portions of 310 CMR 7.00 submitted on June 7, 1991 and effective on April 12, 1991.

(F) Amendments to portions of 310 CMR 7.00 submitted on June 7, 1991 and effective on June 21, 1991.

(ii) Additional materials.

(A) A letter from the Massachusetts Department of Environmental Quality Engineering dated June 27, 1984 submitting 310 CMR 7.00: Appendix B.

(B) A letter from the Massachusetts Department of Environmental Quality Engineering dated March 6, 1985 submitting additional information on 310 CMR 7.00: Appendix B and referencing 310 CMR 7.18(2)(b).

(C) A letter dated December 17, 1991 from the Massachusetts Department of Environmental Protection withdrawing the emission limit for the Primer-surfacer application in 310 CMR 7.18(7)(b) from the June 7, 1991 submittal.

(D) Nonregulatory portions of state submittal.

3. In § 52.1167 Table 52.1167 is amended by adding new entries to existing state citations for "310 CMR 7.00", "310 CMR 7.18(3)", "310 CMR 7.18(4)", "310 CMR 7.18(5)", "310 CMR 7.18(6)","310 CMR 7.18(8)","310 CMR 7.18(9)", "310 CMR 7.18(10)", "310 CMR 7.18(11)", "310 CMR 7.18(12)", "310 CMR 7.18(13)", "310 CMR 7.18(14)", "310 CMR 7.18(15)", "310 CMR 7.18(16)", "310 CMR 7.18(17)", and "310 CMR 7.18(18)"; and by adding new state citations for "310 CMR 7.02(12)", "310 CMR 7.18(1)", "310 CMR 7.18(2)" and "310 CMR 7.00: Appendix B" to read as follows:

§ 52.1167 EPA-approved Massachusetts regulations.

* * * * *

TABLE 52.1167.—EPA-APPROVED RULES AND REGULATIONS

State citation	Title/subject	Date Submitted by State	Date approved by EPA	Federal Register citation	52.1120 (c)	Comments/unapproved sections
•	•	•	•	•	•	•
310 CMR 7.00	Definitions	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Approving the following amended or additional definitions: Application area, asphalt, automobile, bottom filling, bulk terminal, coating line(s), commissioner, condensate, continuous compliance, crude oil, department, end sealing compound, exterior base coat, extreme environmental conditions, flashoff area, freeboard height, freeboard ratio, halogenated organic compound, interior base coat, interior body spray, knife coating, lease custody transfer, light duty truck, manufacturing plant, miscellaneous metal parts and products, overvarnish, paper surface coating, penetrating prime coat, petroleum liquids, prime coat, publication rotogravure printing, quench area, refrigerated chiller, Reid vapor pressure, roll printing, roll coating, single coat, solids, specialty printing, splash filling, standard conditions, submerged filling, three piece can side seam spray, topcoat, transfer efficiency, two piece can exterior end coating, vinyl surface coating, volatile organic compound, waxy, heavy pour crude oil. The definitions of "coating application system" and "bulk plants and terminals" have been deleted.
•	•	•	•	•	•	•
310 CMR 7.02(12)	U Organic Material	August 17, 1989	January 11, 1993	[Insert FR citation from published date].	93	310 CMR 7.02(12) has been recodified and relocated in 310 CMR 7.24, "U Organic Material Storage and Distribution." All subsections and references in 310 CMR 7.02(12) have been recodified accordingly.
•	•	•	•	•	•	•
310 CMR 7.18(1)	U Applicability and Handling Requirements	August 17, 1989	January 11, 1993	[Insert FR citation from published date].	93	Approval of 310 CMR CMR 7.18(1), (a), (c), (d) and (e).

TABLE 52.1167.—EPA-APPROVED RULES AND REGULATIONS—Continued

State citation	Title/subject	Date Submitted by State	Date approved by EPA	Federal Register citation	52.1120 (c)	Comments/unapproved sections
310 CMR 7.18(2)	U Compliance with Emission Limitations	August 27, 1982; August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Approval of 310 CMR 7.18(2), (2)(a), (2)(b), (2)(c) and (2)(e).
310 CMR 7.18(3)	U Metal Furniture Surface Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(3).
310 CMR 7.18(4)	U Metal Can Surface Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(4).
310 CMR 7.18(5)	U Large Appliance Surface Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(5).
310 CMR 7.18(6)	U Magnet Wire Insulation Surface Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(6).
310 CMR 7.18(8)	U Solvent Metal Degreasing	August 17, 1989	January 11, 1993	[Insert FR citation from published date].	93	Approval of 310 CMR 7.18(8), (8)(d), (8)(d)1., (8)(e), (8)(f) and (8)(g).
310 CMR 7.18(9)	U Cutback Asphalt	August 17, 1989	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(9).
310 CMR 7.10	U Metal Coil Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(10).
310 CMR 7.18(11)	U Surface Coating of Miscellaneous Metal Parts and Products	August 17, 1989	January 11, 1993	[Insert FR citation from published date].	93	Approval of 310 CMR 7.18(11), (11)(b), (11)(c), (11)(d) and (11)(e).
310 CMR 7.18(12)	U Graphic Arts	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(12).
310 CMR 7.18(13)	U Dry Cleaning Systems-Perchlor-ethylene	August 17, 1989	January 11, 1993	[Insert FR citation from published date].	93	Approval of 310 CMR 7.18(13), (13)(c), (13)(d) and (13)(e). 310 CMR 7.18(13)(a) 8. has been deleted.
310 CMR 7.18(14)	U Paper Surface Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(14).
310 CMR 7.18(15)	U Fabric Surface Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(15).
310 CMR 7.18(16)	U Vinyl Surface Coating	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(16).

TABLE 52.1167.—EPA-APPROVED RULES AND REGULATIONS—Continued

State citation	Title/subject	Date Submitted by State	Date approved by EPA	Federal Register citation	52.1120 (c)	Comments/Unapproved sections
310 CMR 7.18(17)	U Reasonable Available Control Technology	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Approval of 310 CMR 7.18(17), (17)(a), (17)(b), (17)(c), (17)(d), (17)(e) and (17)(f).
310 CMR 7.18(18)	U Polystyrene Resin Manufacturing Technology	August 17, 1989; June 7, 1991	January 11, 1993	[Insert FR citation from published date].	93	Replacement of 310 CMR 7.18(18).
310 CMR 7.00: Appendix B	Alternative Emission Limitations (Bubble) for Volatile Organic Compounds	April 12, 1985; August 17, 1989	January 11, 1993	[Insert FR citation from published date].	93	Addition of 310 CMR 7.00: Appendix B.

[FR Doc. 93–534 Filed 1–8–93; 8:45 am]

BILLING CODE 6560–50–M

40 CFR Part 272

[FRL–4507–1]

Final Authorization of State Hazardous Waste Management Program: Missouri

AGENCY: Environmental Protection Agency (EPA).

ACTION: Immediate final rule.

SUMMARY: The Resource Conservation and Recovery Act of 1976, as amended (RCRA), provides for the U.S. Environmental Protection Agency (EPA) to grant authorization to State agencies to operate their hazardous waste management programs in lieu of the Federal program. The State of Missouri has applied for authorization of revisions to its previously authorized hazardous waste management program under RCRA. EPA has reviewed Missouri's application and has made a decision, subject to public review and comment, that Missouri's hazardous waste management program revision satisfies all of the requirements necessary to qualify for final authorization. Thus, EPA is approving Missouri's hazardous waste management program revisions.

DATES: Final authorization for the Missouri program revisions shall be effective March 12, 1993, unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. All comments on Missouri's program revision application must be received by the close of business February 10, 1993. The incorporation by reference of certain Missouri statutes and regulations was approved by the Director of the Federal Register as of March 12, 1993, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

ADDRESSES: Copies of Missouri's program revision application are available for inspection and copying during normal business hours at the following addresses: Hazardous Waste Program, Missouri Department of Natural Resources, Jefferson Building, 205 Jefferson Street, Jefferson City, Missouri 65102, Phone: 314–751–3176; U.S. EPA Region VII Library, 726 Minnesota Avenue, Kansas City, Kansas 66101, Phone: 913–551–7241. Written comments should be sent to Gary Bertram, U.S. EPA Region VII, RCRA Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

FOR FURTHER INFORMATION CONTACT: Gary Bertram, U.S. EPA Region VII, RCRA Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101; 913–551–7533.

SUPPLEMENTARY INFORMATION:

A. Background

Authorization Process

Section 3006 of RCRA, 42 U.S.C. 6926 *et seq.*, allows EPA to authorize State hazardous waste management programs to operate in the states in lieu of the Federal hazardous waste program. This is done when a state submits to EPA a request for authorization demonstrating that the state program is equivalent to the Federal program.

In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Pub. L. 98–616, November 8, 1984, hereinafter referred to as "HSWA") allows States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive "interim authorization" for the HSWA requirements under section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements.

Revisions to State hazardous waste programs are necessary whenever Federal or State statutory or regulatory authority is modified or when certain other changes occur. This is because states with final authorization under section 3006(b) of RCRA have continuing obligations to maintain state programs that are equivalent to, consistent with, and no less stringent than the Federal hazardous waste management program. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR parts 260–266 and 124 and 270 that require corresponding changes in the state program in order for the state to maintain its authorization.

EPA Approval of State Programs

EPA codifies its approval of State programs in part 272 of title 40, Code of Federal Regulations (CFR) and incorporates by reference in part 272 the State statutes and regulations that EPA will enforce under section 3008, 3013 and 7003 of RCRA. The purpose of incorporation by reference is to provide clear notice to the public of the scope of the authorized program in each State. Such notice is particularly important in view of the HSWA amendments and the changes in authorized State programs required to reflect these new Federal requirements. By incorporating by reference authorized State programs and by amending the Code of Federal Regulations whenever a new or different

set of requirements is authorized, the status of federally approved requirements in each State will be readily discernible. Thus, EPA is today incorporating by reference the Missouri authorized program in 40 CFR part 272. (See 50 FR 28702, July 15, 1985, for a full discussion of the codification process. For further information, contact EPA Office of Solid Waste, State & Regional Programs Branch, 401 M Street, SW., Washington, DC 20460, Mail Code 5303W.)

The Agency will only incorporate by reference for enforcement purposes those provisions of the Missouri hazardous waste management program for which authorization approval has been granted by EPA. Concerning HSWA, some state requirements may be similar to HSWA requirements that are in effect under Federal statutory authority in that state. However, a state's HSWA-type requirements are not authorized and will not be included in the CFR until the Regional Administrator publishes his final decision to authorize the state for specific HSWA requirements. Until such time, EPA will enforce the HSWA requirements and not the state analogues.

B. Missouri

On November 20, 1985, EPA published a **Federal Register** notice announcing its decision to grant final authorization for the RCRA base program to the State of Missouri (50 FR 47740). EPA's decision to grant authorization for revisions to the Missouri hazardous waste program was published on February 27, 1989 (54 FR 8190).

As noted above, a State with final authorization has a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent that the Federal hazardous waste program. To meet its obligation, Missouri submitted a request for additional program approvals. The Missouri request was submitted to EPA on March 8, 1991. The State is seeking approval of its program revision in accordance with 40 CFR 271.21(b)(3).

EPA has reviewed Missouri's application, and determined that Missouri's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Consequently, EPA is granting final authorization for the additional program modifications to Missouri. Today's decision is being published as an "immediate final" rule in accordance with the provisions of 40 CFR 271.21(b)(3). The public may submit written comments on this immediate final decision until the date noted in the "**DATES**" section of this document. Approval of Missouri's program revision shall become effective 60 days from today unless an adverse written comment pertaining to the State's revision discussed in this notice is received by the end of the comment period. If an adverse comment is received, EPA will publish either (1) a withdrawal of the immediate final decision, or (2) a notice containing a response to comment which either affirms that the immediate final decision takes effect or reverses the decision.

The State has adopted and applied for authorization of the program provisions. For a full discussion of each of the provisions, the reader is referred to the **Federal Register** promulgation of that provision. The provisions are: Radioactive Mixed Waste (July 3, 1986, 51 FR 24504), Standards for Hazardous Waste Storage and Treatment Tank Systems (July 14, 1986), Revised Manual SW–846 (March 16, 1987), Closure/Post-Closure Care for Interim Status Surface Impoundments (March 19, 1987, 52 FR 8704), Definition of Solid Waste (June 5, 1987, 52 FR 21306), Amendments to Part B Information Requirements for Land Disposal Facilities (June 22, 1987, 52 FR 23447), List (Phase 1) of Hazardous Constituents for Ground-Water Monitoring (July 9, 1987, 52 FR 25942), Identification and Listing of Hazardous Waste (July 10, 1987, 52 FR 26012), Liability Requirements for Hazardous Waste Facilities; Corporate Guarantee (November 18, 1987, 52 FR 44314), Hazardous Waste Miscellaneous Units (December 10, 1987, 52 FR 46946), Technical Correction; Identification and Listing of Hazardous Waste (April 22, 1988, 53 FR 13382), Identification and Listing of Hazardous Waste; Treatability Studies Sample Exemption (July 19, 1988, 53 FR 27290), Hazardous Waste Management System; Standards for Hazardous Waste Storage and Treatment Tank Systems (September 2, 1988, 53 FR 34079), Identification and Listing of Hazardous Waste; and Designation, Reportable Quantities, and Notification (September 13, 1988, 53 FR 35412), Statistical Methods for Evaluating Ground-Water Monitoring Data from Hazardous Waste Facilities (October 11, 1988, 53 FR 39720), Identification and Listing of Hazardous Waste; Removal of Iron Dextran from the List of Hazardous Wastes (October 31, 1988, 53 FR 43878), Identification and Listing of Hazardous Waste; Removal of Strontium Sulfide from the List of Hazardous Wastes (October 31, 1988, 53 FR 43881), Hazardous Waste Miscellaneous Units; Standards Applicable to Owners and Operators (January 8, 1989, 54 FR 615), Amendment to Requirements for Hazardous Waste Incinerator Permits (January 30, 1989, 54 FR 4286), and Changes to Interim Status Facilities for Hazardous Waste Management Permits; Modifications of Hazardous Waste Management Permits; Procedures for Post-Closure Permitting (March 7, 1989, 54 FR 9596).

In addition to the seventeen non-HSWA provisions, the State has adopted and requested authorization for the following HSWA provisions: HSWA Codification Rule (With the exception of Delisting and Corrective Action) (July 15, 1985, 50 FR 28702), Burning of Waste Fuel and Used Oil Fuel in Boilers and Industrial Furnaces (November 29, 1985, 50 FR 49164), Listing of Spent Solvents (December 31, 1985, 51 FR 2702), Generators of 100 to 1000 kg Hazardous Waste (March 24, 1986, 51 FR 10146), Codification Rule, Technical Correction (May 28, 1986, 51 FR 19176), Biennial Report; Correction (August 8, 1986, 51 FR 28556), Exports of Hazardous Waste (August 8, 1986, 51 FR 28664), Standards for Generators—Waste Minimization Certifications (October 1, 1986, 51 FR 35190), Listing of EBDC (October 24, 1986, 51 FR 37725), Land Disposal Restrictions (November 7, 1986, 51 FR 40572), HSWA Codification Rule 2 (With the exception of Corrective Action for Injection Wells) (December 1, 1987, 52 FR 45788), and Identification and Listing of Hazardous Waste; Technical Correction (July 19, 1988, 53 FR 27162).

EPA has reviewed the State program in light of current and proposed activities and has determined that authorizing these new provisions will not have a profound effect on the ability of the State to carry out the program.

The State requested authorization for Direct Action Against Insurers (November 8, 1984, HSWA section 3004(t)), however, EPA has determined this to be a non-delegable authority. Reference to this provision remains in the State Authorization Request, however, authorization for the provision is not granted.

The State is not currently requesting Corrective Action authority. Any reference to Corrective Action in the State Authorization Request is not authorized by this notice.

The State will assume lead responsibility for issuing permits for those program areas authorized today. For those HSWA provisions for which the State is not authorized, EPA will retain lead responsibility. For those

permits which will now change to State lead from EPA, EPA will transfer copies of any pending applications, completed permits or pertinent file information to the State within thirty days. EPA will be responsible for enforcing the terms and conditions of federally issued permits while they remain in force. EPA will also be responsible for enforcing the terms and conditions of RCRA permits regarding HSWA provisions that the State does not have the authority to address. The State has agreed to review all State issued permits and to modify or reissue them as necessary to require compliance with the currently approved State law and regulations. When the State reissues federally issued permits as State permits, EPA will rely on the State to enforce them, with the exception of those HSWA provisions not yet authorized.

C. Decision

I conclude that Missouri's application for program revisions meets all of the statutory and regulatory requirements established by RCRA. Accordingly, Missouri is granted final authorization to operate its hazardous waste management program, as revised. Missouri now has responsibility for the permitting of treatment, storage and disposal facilities within its borders and carrying out other aspects of the RCRA program, subject to the limitation of its revised program application and previously approved authorities. Missouri also has primary enforcement responsibilities, although EPA retains the right to conduct inspections under sections 3007, 3013, and 7003 of RCRA.

D. Missouri Authorized Hazardous Waste Program

As noted above, EPA is incorporating by reference for enforcement purposes those provisions of the Missouri hazardous waste management program for which authorization approval has been granted by EPA.

The Missouri authorized hazardous waste program is incorporated by reference in subpart AA to part 272 title 40 of the CFR. The State statutes and regulations are incorporated by reference at § 272.1301(a) and the Memorandum of Agreement, the Attorney General's Statement and the Program Description are referenced at § 272.1301(b), (c) and (d), respectively.

The Agency retains the authority under sections 3008, 3013 and 7003 of RCRA to undertake enforcement actions in authorized states. With respect to such an enforcement action, the Agency will rely on Federal sanctions, Federal inspection authorities and the Federal Administrative Procedure Act rather than the State authorized analogues to these requirements. Therefore, the Agency does not intend to codify for purposes of enforcement such particular, authorized Missouri enforcement authorities. Section 272.1301(a) lists those Missouri authorities that are part of the authorized program but are not codified.

The public also needs to be aware that some provisions of the State's hazardous waste management program are not part of the Federally authorized State program. These non-authorized provisions are not part of the RCRA subtitle C program because they are "broader in scope" than RCRA subtitle C. As a result, State provisions which are "broader in scope" than the Federal program are not incorporated by reference for purposes of enforcement in part 272. Section 272.1301(a) lists for reference and clarity the statutory and regulatory provisions which are "broader in scope" than the Federal program and which are therefore not part of the authorized program being incorporated by reference. "Broader in scope" provisions will not be enforced by EPA; the State, however, will continue to enforce such provisions.

E. HSWA Provisions

As noted above, the Agency is not amending part 272 to include many HSWA requirements and prohibitions that are immediately effective in all States. Section 3006(g) of RCRA provides that any requirement or prohibition of HSWA (including implementing regulations) takes effect in authorized states at the same time that it takes effect in non-authorized states. Thus, EPA has immediate authority to implement a HSWA requirement or prohibition once it is effective. A HSWA requirement or prohibition supersedes any less stringent or inconsistent State provision which may have been previously authorized by EPA. (See 50 FR 28702, July 15, 1985.) Because of the vast number of HSWA statutory and regulatory requirements taking effect over the next few years, EPA expects that many previously authorized and incorporated by reference State provisions will be affected. The States are required to revise their program to adopt the HSWA requirements and prohibitions by the deadlines set forth in 40 CFR 271.21, and then to seek authorization for those revisions pursuant to part 271. EPA expects that the States will be modifying their program substantially and repeatedly. Instead of amending part 272 every time a new HSWA provision takes affect under the authority of RCRA section 3006(g), EPA will wait until the state receives authorization for its analog to the new HSWA provision before amending the state's part 272 incorporation by reference. In the interim, persons wanting to know whether a HSWA requirement or prohibition is in effect should refer to 40 CFR 271.1(j), as amended, which lists each such provision.

The incorporation by reference of State authorized programs in the CFR should substantially enhance the public's ability to discern the current status of the authorized State program and clarify the extent of Federal enforcement authority. This will be particularly true as more State program revisions to adopt HSWA provisions are authorized.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 4 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. This authorization effectively suspends the applicability of certain Federal regulations in favor of Missouri's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

Compliance With Executive Order 12291

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 272

Administrative practice and procedure, Confidential business information, Hazardous waste, Hazardous waste transportation, Incorporation by reference, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements.

Dated: August 31, 1992.

Morris Kay,

Regional Administrator.

For the reasons set forth in the preamble, 40 CFR part 272 is amended as follows:

PART 272—APPROVED STATE HAZARDOUS WASTE MANAGEMENT PROGRAMS

1. The authority citation for part 272 continues to read as follows:

Authority: Secs. 2002(a), 3006, and 7004(b) of the Solid Waste Disposal Act, as amended

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by the Resource Conservation and Recovery Act, as amended, 42 U.S.C. 6912(a), 6926, and 6974(b).

2. Section 272.1 is revised to read as follows:

§ 272.1 Purpose and scope.

This part sets forth the applicable State hazardous waste management programs under section 3006(b) of the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. 6926, and 40 CFR 260.10. "State" is defined in 42 U.S.C. 1004(31) as "any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands."

3. Section 272.2 is added to read as follows:

§ 272.2 Incorporation by reference.

Material listed as incorporated by reference in part 272 was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Material is incorporated as it exists on the date of the approval, and notice of any change in the material will be published in the **Federal Register**. Copies may be obtained or inspected at EPA Waste Management Rules Docket, 401 M Street, SW., Washington, DC 20460 and at the appropriate EPA Regional Office. Copies may be inspected at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. For an informational listing of the State and local requirements incorporated in part 272, see appendix A to this part.

4. Section 272.1301 is amended by revising the introductory text and paragraphs (a), (b) and (c)(2) to read as follows:

§ 272.1301 State-administered program; Final authorization.

Pursuant to section 3006(b) of RCRA, 42 U.S.C. 6926(b), Missouri has final authorization for the following elements as submitted to EPA in Missouri's program application for final authorization which was approved on November 20, 1985. Subsequent program revision applications were approved on February 27, 1989, and March 12, 1992. Copies may be obtained from the Hazardous Waste Program, Missouri Department of Natural Resources, P.O. Box 176, Jefferson City, Missouri 65102.

(a) *State statutes and regulations.* (1) The Missouri statutes and regulations cited in this paragraph are incorporated by reference as part of the hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(i) Missouri Statutory Requirements Applicable to the Hazardous Waste Management Program, 1990.

(ii) Missouri Regulatory Requirements Applicable to the Hazardous Waste Management Program, December 31, 1990.

(2) The following statutes and regulations, although not incorporated by reference for enforcement purposes, are part of the authorized State program. The statutory provisions include: 260.360(4), 260.360(20)–260.377, 260.393–260.394, 260.400, 260.410–260.420, 260.425–260.430. The regulatory provisions include 3.260(1)(A)24–3.260(1)(A)25, 3.260(1)(B)–3.260(1)(D), 4.261(2)(D)3, 5.262(2)(B)2, 5.262(2)(C)2, 5.262(2)(D)1, 6.263(2)(A)10.D–6.263(2)(A)10.I, 6.263(2)(D)3, 7.264(2)(B)1, 7.265(2)(B), 7.266(2)(E)–7.266(2)(E)3, 7.268(2)(A)1, 7.268(2)(A)3, 7.268(2)(E), 7.270(2)(B)12–7.270(2)(B)13, 7.270(2)(B)18, 7.270(2)(C)1.D, 7.270(2)(C)3, 7.270(2)(D)4.

(3) The following statutory and regulatory provisions are broader in scope than the Federal program, and are not part of the authorized State program. The statutory provisions include: 260.360(13), 260.379, 260.380–1.(10), 260.385(1), 260.390(8), 260.391, 260.395–1–260.295–5, 260.395–7.(5)–260.395–7.(6), 260.396, 260.405, 260.423–260.424, 260.431–260.434. The regulatory provisions include: 3.260(1)(A)21, 4.261(2)(A)6–4.261(2)(D)2, 5.262(2)(I), 6.263(2)(A)3–6.263(2)(A)4, 7.264(2)(P), 7.266(2)(C)–7.266(2)(D), 7.266(2)(E)4–7.266(2)(G), 7.270(2)(B)7–7.270(2)(B)8, 7.270(2)(B)10, 7.270(2)(C)1.A, 7.270(2)(H).

(b) *Memorandum of Agreement.* The Memorandum of Agreement between EPA Region VII and the Missouri Department of Natural Resources, signed by the EPA Regional Administrator on August 30, 1988, and the subsequent Agreement signed on August 31, 1992 are referenced as part of the authorized hazardous waste management program under subtitle C of RCRA, 42 U.S.C. 6921 *et seq.*

(c) * * *

(2) "Attorney General's Statement for Final Authorization of Changes to the Federal RCRA Program," signed by the delegated Assistant Attorney General of Missouri on December 1, 1987, and the subsequent Statement signed on February 28, 1992, are referenced as part of the authorized hazardous waste management program under subtitle C of RCRA; 42 U.S.C. 6921 *et seq.*

* * * * *

5. Appendix A to part 272 is added to read as follows:

Appendix A to Part 272

The following is an informational listing of the State and local requirements incorporated in part 272 of the Code of Federal Regulations:

The statutory provisions include: 260.350–260.360(3), 260.360(5)–260.360(12), 260.360(14)–260.360(19), 260.380–1.–260.380–1.(9), 260.380–2., 260.385(2)–260.390(7), 260.390(9), 260.395–6.–260.395–7.(4), 260.395–7.(7)–260.395–18.

The regulatory provisions include: 3.260–3.260(1)(A)20, 3.260(1)(A)22–3.260(1)(A)23, 3.260(2), 4.261–4.261(2)(A)5, 5.262–5.262(2)(B)1., 5.262(2)(B)3.–5.262(2)(C)1., 5.262(2)(C)2.A.–5.262(2)(D), 5.262(2)(D)2.–5.262(2)(H), 6.263–6.263(2)(A)2., 6.263(2)(A)5.–6.263(2)(A)10.C, 6.263(2)(B)–6.263(2)(D)2., 7.264–7.264(2)(A)2., 7.264(2)(B)2.–7.264(2)(O), 7.264(2)(X), 7.265–7.265(2)(A), 7.265(2)(E)–7.265(2)(K), 7.266–7.266(2), 7.268–7.268(2), 7.268(2)(A)., 7.268(2)(A)4.–7.268(2)(C), 7.270–7.270(2)(B)6., 7.270(2)(B)9., 7.270(2)(B)11., 7.270(2)(B)14.–7.270(2)(B)17., 7.270(2)(C)–7.270(2)(C)1., 7.270(2)(C)1.B.–7.270(2)(C)1.C., 7.270(2)(C)2.–7.270(2)(C)2.C., 7.270(2)(C)2.E., 7.270(2)(D)–7.270(2)(D)3., 7.270(2)(E)–7.270(2)(G).

[FR Doc. 93–196 Filed 1–8–93; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 87–6; Notice 5]

RIN 2127–AD64

Federal Motor Vehicle Safety Standards Lamps, Reflective Devices, and Associated Equipment

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This final rule facilitates the introduction of daytime running lamps (DRLs) as an item of optional motor vehicle lighting equipment. The purpose of the rule is to ensure that manufacturers may offer DRLs in all 50 States, and that specifications are adopted so that DRLs do not reduce the current level of highway safety. Any pair of lamps that Standard No. 108 requires on the front of a vehicle (other than parking lamps), or other lamps (except for fog lamps) with lenses marked "DRL", may serve as DRLs by automatically operating during daylight, provided that the minimum candela output of each lamp exceeds 500 at test point H–V, and that the maximum

candela output does not exceed 3,000 at any location (or 7,000 at test point H–V if the lamp is mounted no higher than 864 mm (34 in.), and that steps are taken to prevent their light from masking turn and hazard warning signals.

DATES: Effective date of the final rule is February 10, 1993.

ADDRESSES: Petitions for reconsideration should refer to Docket 87–6; Notice 5, be addressed to the Administrator, and be submitted to: Docket Section, room 5109, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Jere Medlin, Office of Rulemaking, NHTSA, Washington, DC [202–366–5276].

SUPPLEMENTARY INFORMATION: On March 24, 1987, NHTSA opened Docket 87–6, to receive comments on a notice of proposed rulemaking (NPRM) under which Motor Vehicle Safety Standard No. 108 would be amended to permit daytime running lights (DRLs) as optional front lighting equipment on passenger cars, multipurpose passenger vehicles, trucks, and buses (Notice 1). In 1988, NHTSA announced that it was terminating rulemaking on the subject without an amendment (Notice 2), and later that year it denied a petition for reconsideration of the termination (published without docket or notice number, but referred to as Notice 3). The agency reopened rulemaking in 1991, and published a proposal (Notice 4) upon which this final rule is based. The reader is referred to these notices for background information on this topic (52 FR 8316, 53 FR 23673, 53 FR 40921, and 56 FR 38104).

Rulemaking Petition for DRLs

Notice 4 implemented the grant of a petition for rulemaking submitted by General Motors Corporation (GM). The petitioner asked the agency to facilitate the introduction of motor vehicles to be equipped with DRLs. In GM's view, such an amendment "would allow manufacturers to install DRLs on new vehicles without being in violation of the multitude of state laws which currently have the unintended effect of prohibiting them." However, GM did not believe that there is justification for mandating DRLs as standard equipment because there is not yet evidence of a "national safety need" in the United States. Because DRLs are more effective in Northern latitudes where ambient daytime light levels differ from those of the South, they appear to have a greater likelihood of assisting in crash prevention in Alaska or Maine, instead of Florida or Hawaii. Further, as GM had noted in 1987, fuel economy may be reduced by as much as a quarter mile per gallon when some DRLs are used. The petitioner argued that the ability to test DRLs on vehicles in the U.S. could enable it to assess the potential safety benefits of DRLs in this country, and at the same time, their limited use would minimize the penalty of overall fleet fuel economy.

In response to Notice 4, comments were submitted from the following 27 respondents, listed in the order received: John W. Kourik, P.E., Virginia State Police (Virginia), American Motorcycle Association, Department of California Highway Patrol (California), Navistar International, Carter Hart, Ontario Ministry of Transport, Mack Trucks, Inc. (Mack), Hino Motors Inc. (Hino), Saab Cars USA, Inc., Truck-Lite Co. Inc., Volkswagen of America, Inc. (VW), University of Michigan Transport Research Institute, Hella KG, American Honda Motor Co., General Electric Lighting (GE), C.R. Blydenburgh, National Automobile Dealers Association, Volvo Cars of North America, Motor Vehicle Manufacturers Association (MVMA), General Motors Corporation (GM), Advocates for Highway and Auto Safety (Advocates), Chrysler Corporation, American Automobile Association, Ford Motor Company, Insurance Institute for Highway Safety (IIHS), and Ohio Department of Public Safety (Ohio).

Existing State Laws That Could Prohibit DRLs

NHTSA was not aware of any State laws that prohibit DRLs per se. However, GM brought to the agency's attention State laws requiring pre-approval of supplemental lighting devices, and the fact that there is currently no SAE standard for DRLs on which such approval could be based. Further, GM found a variety of State laws that might affect DRLs. 35 States have regulations prohibiting supplemental lighting from projecting light that strikes the roadway at a specified distance in front of the vehicle. In addition, there appeared to be State laws which prohibit the use of lights in tunnels, the use of the parking lamps without headlamps when the car is being driven, and the illumination of fog lamps without the headlamps. GM, which offers DRLs in Canada as mandated by that country's lighting standard, stated that it was impossible to determine whether a particular DRL design that it uses there would be prohibited under this array of State laws. It concluded that DRLs are potentially affected by the laws of 40 to 45 States.

GM also argued that the trend in State lighting laws is towards increasing the daytime conspicuity of vehicles, and that allowing DRLs would be consistent with this trend. Several jurisdictions (Cape Cod and the State of Washington are referenced) now require 24-hour a day headlamp use on some roads. Legislation to mandate DRLs has been introduced in Connecticut. California now specifically regulates DRLs, but only those that are optionally installed. Thus, GM argued that adding a DRL provision to Standard No. 108, thereby preempting under 15 U.S.C. 1392(d) State laws prohibiting DRLs, would not contravene the spirit of Executive Order 12612 (Federalism).

NHTSA reviewed these arguments. It believes that manufacturers who wish to offer this option should not be precluded from doing so, provided that their DRLs do not derogate from existing levels of highway safety. For example, the agency believes that it is necessary to amend Standard No. 108 in a way that ensures the States do not allow DRLs having an intensity that may cause excessive glare. Therefore, NHTSA issued an NPRM to achieve these objectives.

In drafting the proposal, the agency took careful note of the Executive Order on Federalism which seeks to limit preemption of State laws, but recognizes the right of a Federal agency to preempt a State where Congress has provided express preemption authority, such as exists in 15 U.S.C. 1392(d). NHTSA sought to minimize, to the extent consistent with safety, the preemptive effect of the NPRM in accordance with the regulatory philosophy behind the Executive Order. It believed that the Executive Order on Federalism is primarily concerned with Federal preemption of State laws that differ in a fundamental manner from Federal requirements. In this instance, there is no State law that prohibits DRLs per se. Thus, a Federal standard whose effect is to allow DRLs would not be directly preemptive of existing State laws, since there is no existing State law that expressly prohibits DRLs.

The Executive Order requires NHTSA to examine the indirect, as well as the direct, preemptive effect of its regulations as well. NHTSA considered the issue of whether an amendment allowing DRLs would, as a matter of law, preempt State laws that do not deal with DRLs, but whose provisions might be construed to prohibit them. The agency concluded that its preemption authority addresses this possibility as well. Under section 1392(d), NHTSA's safety standards preempt those State standards covering "the same aspect of

performance". This is a broad phrase, and is to be interpreted broadly in the fulfillment of the agency's mission. Therefore, to the extent that any State standard might affect the operation and performance of front lamps used as DRLs, NHTSA considers that, to the same extent, such a State standard may be viewed as covering the same aspect of performance as NHTSA's DRL specifications. For example, if Standard No. 108 allows lamps to be wired to operate automatically as DRLs, and to be specifically marked "DRL", the performance of that lamp is no longer subject to State restrictions on daytime use. As a further example, if the DRL that would be allowed under this rulemaking were provided by a pair of new lamps, and not by the existing lamps required by Standard No. 108, NHTSA believes that such a lamp system would be covered by Standard No. 108, instead of being considered supplementary lighting devices subject to state approval programs for supplemental equipment. Given the apparent trend in the States toward promoting greater daytime conspicuity for motor vehicles, NHTSA argued that preempting the indirect effects of State regulations would be acceptable under the regulatory philosophy of Executive Order 12612.

However, NHTSA did not wish to proceed to a final rule without offering States an opportunity to comment on the safety rationale of statutes and regulations that might be preempted by NHTSA action. For example, comments were invited on the effects that might be attendant to overriding a state prohibition against headlight use in tunnels, or against use of parking lamps alone.

California appeared to be the only state with a DRL law that would be preempted by a Federal specification. Its more stringent regulation establishes a minimum intensity of 500 candela for DRLs, the effect of which is to prohibit the use of parking lamps for this purpose, since the maximum intensity permitted for these lamps is only 250 candela. In its comments, California urged that the States be allowed to continue to regulate DRLs. While NHTSA has decided to adopt its proposal to regulate DRLs, it has, in response to California's comment, adopted a 500 candela minimum in the final rule. The agency notes that this minimum requirement also exists in the Canadian standard for certain non-headlamp DRLs. A proposal to adopt such a minimum appeared in an earlier notice in this series of notices on DRL.

The responses to Notice 4 did not note any State laws that would be inadvertently preempted by Federal DRL requirements. Those states that commented did so in relation to the effects on enforcement of other State laws. The NPRM proposed a maximum DRL mounting height of 83 inches (the maximum permissible for turn signal lamps), far higher than the maximum of 42-inches allowed for auxiliary lamps in Minnesota, Mississippi, and Iowa. The final rule limits DRLs that are not combined with other required lighting equipment to a mounting height of 1.067 m (42 inches) in recognition of the laws of these States.

Virginia requires taillamps to be activated when fog lamps are used, but commented that taillamp use would not be desirable when DRLs are used. California requires that fog lamps be connected to the headlamp circuit. Thus, in California, if DRLs were combined with fog lamps, the headlamps would have to be on. NHTSA has reviewed these comments and understands how the States perceive that a DRL specification might appear to preempt their laws. NHTSA does not believe that having a DRL within a fog lamp actually preempts a State law; however, it might make it more difficult for a State to enforce its law. Thus, to avoid any question of express or implied preemption, NHTSA has decided to exclude fog lamps from use as DRLs.

Front Lamps Likely To Be Used as DRLs

With a few exceptions, the final rule permits the use of any front lamps, whether required by Standard No. 108 or not, as DRLs. For the reasons discussed above, neither parking lamps nor fog lamps may be used as DRLs. On some vehicles, the DRL may be optically combined with a headlamp, i.e., provided by the lower headlamp beam at full or reduced intensity, and, on others, by the upper headlamp beam at a reduced intensity. DRLs may be optically combined with the turn signal lamps and used at the same operational intensity. DRLs may also be provided by a pair of front lamps specifically designed for this purpose.

The NPRM did not address the use of the lower beam headlamps as DRLs, either at full or lower intensity. Both are permitted in Canada. No commenter addressed this issue. There appears to be no reason to prohibit use of the lower beam at full intensity as a DRL. If the lower beam were used for DRLs, one might expect the side and taillamps to be activated when the DRLs are activated just as the side and taillamps are when the lower beam is used for road illumination purposes; in fact, this is a requirement in Canada. However, Canada does not require illumination of the side and taillamps when the lower beam is used at a reduced intensity. NHTSA is concerned about this. The intensity of the lower beam is reduced to about 70 percent of full intensity, creating the possibility that vehicles so equipped will be driven in the DRL mode at night without side and rear marking, instead of with their headlamps at full lower beam intensity. Although the final rule allows use of a lower intensity of a lower beam without activation of side and rear lamps, NHTSA will consider proposing simultaneous activation, or a "DRL on" indicator should accident or complaint records show an emerging problem.

See the further discussion of lower beam photometrics in the section of this notice on "Lamp Intensity."

Appropriate Performance Requirements for DRLs-GM's Recommendation

GM called the agency's attention to three possible models on which to base the agency's DRL requirements. These were the requirements adopted by Canada, those proposed by NHTSA in Notice 1, and those currently under consideration by the SAE in its draft Recommended Practice J2087 Daytime Running Lamps for Use on Motor Vehicles. GM strongly supported adoption of the Canadian requirements because it would facilitate transfer of existing DRL designs in Canada to U.S. production with minimum cost and delay, and that the U.S. standard should harmonize with the Canadian one. With respect to the agency's proposal in Notice 1, GM asked NHTSA to consider the remarks it made in response to it, as the company continued to have reservations about the proposal. Finally it had no fundamental objections to the SAE document and believed that the design criteria contained therein are sufficiently flexible to accommodate many of the DRL designs presently used in Canada.

NHTSA's 1991 NPRM

Notice 4 and this final rule are based upon several considerations. First, some regulation of DRLs is necessary to ensure that they perform in a manner that does not detract from existing levels of highway safety. The two chief goals in this regard are ensuring that the lamps do not create excessive glare, and that their use does not mark the ability of the front turn signal to send its message. To address these issues, the NPRM set forth some very simple proposals. It would establish a maximum candela limitation, a

minimum spacing requirement affecting the distance of a DRL from the turn signal lamp, and a requirement that the lens of any lamp used as a DRL, other than a headlamp, be marked "DRL". It would also specify a range of permissible colors, and that DRLs be provided in pairs, instead of a single lamp. The specific characteristics of a DRL system are discussed below.

A. Number of DRLs

For some years, the single headlamp on a great majority of motorcycles has been wired to light when the ignition is on. This design has provided a DRL for motorcycles. In order to avoid possible misidentification of four-wheeled vehicles as motorcycles, which are much narrower than other vehicles, NHTSA tentatively concluded that the DRL "signature" for vehicles other than motorcycles should be comprised of two symmetrically located lamps. No commenter opposed the proposal, or suggested any benefits accruing from the provisions of a single DRL on 4-wheeled vehicles. Therefore, the DRL system that will be required for vehicles other than motorcycles will consist of a pair of front lamps.

B. Lamp Color

Required lighting equipment under Standard No. 108 may be red, white, or yellow (paragraph S5.1.5) as defined by SAE Standard J578c, February 1977. Standard No. 108 reserves the use of red to rear lighting devices. In addition, red (and blue) are used by States to denote emergency, police, or towing vehicles. NHTSA tentatively concluded in the NPRM that the color of a DRL should be one that the motoring public associates with the front of a vehicle, that is to say, either white or yellow. Thus, if a headlamp or turn signal lamp were used as a DRL, the light from the DRL would be the same color as the light from that lamp. If a front lamp other than one of these were used as a DRL, manufacturers would be required to choose among the following color range: white, white to yellow, white to selective yellow, yellow, or selective yellow, as defined in SAE Standard J587 MAY88.

Comments varied on the proposal. Virginia, Michigan, and GM opted for white, a color associated with the front of motor vehicles, while Ohio and Advocates wanted a color with yellow in it because, in adverse lighting conditions, the amber spectrum is more visible than white. Others, such as Chrysler, supported the NPRM as written. NHTSA has reviewed these comments, and finds no safety disbenefit to allowing any of the colors proposed. Therefore, the color requirements are adopted as proposed.

C. Lamp Intensity

The effectiveness of interior and exterior rear view mirrors is essential for safe vehicle operation in traffic at all times of day. It is important, therefore, to ensure that DRL operation does not interfere with mirror use. NHTSA has completed three research programs to determine acceptable limits of DRL intensity. The most recent, "Evaluation of Glare from Daytime Running Lights", October 1989 (DOT–HS–807–502), is the basis for NHTSA's proposal. (See also "Evaluation of the Conspicuity of Daytime Running Lights", April 1990 (DOT–HS–807–613), and "A Study of Daytime Running Light Design Factors", August 1987 (DOT–HS–807–193). Copies of the three Reports are available in NHTSA's Technical Reference Library.)

The 1989 Report addresses driver perceived glare increases from a succession of increasingly intense DRLs. Separate experiments covered by this Report provided subjective data which indicated that approximately 2,800 candela can be tolerated before the "Just Acceptable" rating on the De Boer glare scale is exceeded. Under Standard No. 108, the maximum allowable intensity of glare test points of a complying lower beam is 2,700 candela. The effect of the proposal was that a lower beam that provides the maximum allowable candela could not function as a DRL. For these reasons, NHTSA tentatively concluded that 2,600 candela appeared to be an appropriate value regardless of how a DRL is provided, and that a maximum for the DRL compatible with the maximum for glare of the U.S. lower beam should be acceptable to U.S. drivers.

Commenters disagreed with NHTSA. Vehicle manufacturers and IIHS urged the agency to allow 7,000 candela at test point H–V as a maximum intensity for two reasons. The simplest DRL is an upper beam headlamp operating at half the voltage with a maximum output at H–V of about 7,000 candela. Canada allows a maximum of 7,000 candela at H–V for a DRL provided by a reduced intensity upper beam headlamp, even though the intensity could be higher elsewhere. Further, Ford, Chrysler, GM, and MVMA questioned the agency's research that led to the proposed limit of 2,600 candela. This limit, nevertheless, was supported by Virginia, Ohio, Advocates, John Kourik, VW, and by GE with respect to certain test points above the horizontal.

There are two kinds of glare: That which discomforts and that which disables. The agency proposed 2,600 candela to limit discomfort from glare from rear view mirrors caused by vehicles with DRLs following closely behind. Canada, however, has adopted a maximum value of 7,000 candela at test point H–V, which was supported by some commenters, and NHTSA reexamined its position on this issue.

In its reexamination, NHTSA proceeded with the assumption that the most likely DRL would be an upper beam headlamp operated at low voltage (the type of DRL found on approximately 53 percent of Canadian DRL-equipped vehicles). The second assumption was that it was unlikely that the greater percentage of DRLs would be mounted at an exterior height near the height of an interior rear view mirror so that they would project light directly upon it. Higher mounted DRLs appeared most likely to be on a comparatively small part of the vehicle population, larger trucks and multipurpose passenger vehicles. The intensity of the upwardly directed light rays of upper beams diminishes rapidly as the angle above the horizontal increases. NHTSA's calculations show, for example, that only 220 to 350 candela would be directed into the rear view mirror of a Honda Civic CRX (mirror height 44 inches) by DRLs of 6,600 candela on a Ford Taurus or Buick Regal (headlamp height 25.5 inches) about one car length (20 feet) behind. The steady intensity of light in the mirrors of cars being followed by cars with DRLs of 7,000 candela at test point H–V would be only about one eighth of the level considered to be discomforting. The driver of a small car would not be exposed to an intensity greater than 2,600 candela unless the mounting height of the DRL of the vehicle behind exceeded 34 inches. This conclusion takes into consideration the imperfectly centered pattern of an actual headlamp (the maximum intensity is not always located at H–V) as well as one half degree upward misaim of the lamp. NHTSA has therefore concluded that DRLs with a maximum intensity of 7,000 at H–V candela may be allowed as long as they are mounted at a height that does not exceed 34 inches, and has so stated in the final rule.

This leaves the question of the appropriate maximum value for DRLs mounted higher than 34 inches. Manufacturers commenting to Notice 4 stated that the proposed 2,600 candela was not practicable. For the reasons set forth below, NHTSA has chosen 3,000 candela as the maximum beam intensity.

The lower limit in Canada for the upper beam operated at low voltage is

2,000 candela. Standard No. 108 establishes a limit of 75,000 candela at test point H–V for the upper beam. Sealed beam headlamps designed to conform to SAE J579c achieve 50,000 to 75,000 candela in NHTSA tests. If a manufacturer were to design an upper beam headlamp to operate as a DRL, it would need to provide an intensity reducing device that achieves only 4 percent of the nominal intensity to give a range. Chrysler of Canada uses similar devices to achieve reduced intensities below 4,500 candela. NHTSA believes that it is possible to adjust these devices to provide lower intensities, and that this is likely to be the most practicable means in the range necessary to minimize discomfort glare, 2,000 to 3,000 candela. If a manufacturer is unable to achieve this limitation by use of upper beam headlamps, it may still use lower beam headlamps, either at full or reduced intensity.

Finally, under the NPRM, DRL photometry would be tested in accordance with SAE J575 DEC88, when a test voltage of 12.8V +/– 20 mV is applied to the input terminals of the DRL lamp switch module or voltage-reducing equipment, whichever is closer to the electrical source on the vehicle. The test distance from the DRL to the photometer would be not less than 18.3 meters (60 feet) if the DRL is optically combined with a headlamp, or 3 meters (10 feet) if the DRL is a lamp, or is optically combined with a lamp other than a headlamp.

GM commented that it did not understand the reference to SAEJ575 and recommended deletion. The final rule clarifies that NHTSA intended to refer only to the photometric test procedures. The NPRM erroneously referenced S5.5.11(b) as the criteria to be met in the photometric test, and the rule corrects that provision so that it refers to S5.5.11(a).

D. Turn Signal Masking Effect

Notice 1 would have prohibited operation of a DRL when a turn signal or hazard warning signal is activated if the distance from the lighted edge of the DRL to the optical axis of the turn signal lamp were less than 4 inches. Notice 4 reproposed this prohibition. However, the spacing requirement would not apply if the turn signal lamp complies with the increased intensity specifications of S5.3.1.7 of Standard No. 108, or if the DRL is deactivated when the turn or hazard warning signal is on.

GM stated that the spacing requirement is an unnecessary impediment to DRLs combined with upper beam headlamps, and is inconsistent with the Canadian standard. It provided data from an SAE Committee test in which observers were asked if they could detect a turn signal of 250 candela located 3/8ths of an inch from a DRL of 5,000 candela at a distance of 500 feet. Although GM stated that performance was acceptable, the data that it submitted indicate that only 46.9 percent of the observers could see the turn signal. This is far below the 80 percent that the SAE considers the minimum acceptable for incorporation into its standards.

Contrary to GM's assertion, NHTSA's proposal and the Canadian requirements for DRL-turn signal spacing are identical. Additionally, the data provided by GM contradicts its assertion that a spacing requirement is unnecessary. After submitting its data, GM supplemented its submission, saying that the data implied that the turn signals would have been more visible at distances less than the test distance of 500 feet, and that turn signal visibility is not necessary beyond 200 feet. Since the stopping distance of trucks from 60 mph is 200 to 300 feet, NHTSA does not consider that 200 feet is an adequate distance. At least one state, Indiana, requires turn signal use for at least 200 feet before turning or changing lanes, unless the speed limit is 50 mph, in which case the distance is 300 feet.

NHTSA conducted its own demonstration for 9 members of the agency staff. The test distance was 300 feet. The test DRL intensities were 2,600, 5,000, and 7,000 candela. The turn signal intensities were 250 and 500 candela. The turn signal/DRL spacings were 2 and 4 inches. At a 2-inch spacing, 70 to 80 percent of the observers could detect turn signals adjacent to a DRL of 2,600 candela. At the higher DRL intensities, only 10 to 25 percent of the observers could detect the turn signals (which were masked almost equally, whether of 250 or 500 candela). However, about 80 to 90 percent of the observers saw the 250 candela turn signal at a 4-inch spacing. This demonstration suggests that spacing is effective, and that an increase in turn signal brightness does not compensate for inadequate spacing. Thus, GM's request for the agency not to adopt a spacing requirement does not appear to be in the interest of safety if DRLs substantially brighter than 2,600 candela are permitted. The alternative of brighter (500 candela) turn signals does not resolve the issue. The only effective alternative to prevent turn signal masking would be to extinguish the DRLs during signaling. Therefore, the final rule adopts the proposed 4-inch minimum spacing requirement, with its exception of temporary DRL deactivation. However, the 4-inch spacing requirement will continue to apply even if a higher candela turn signal is used.

E. Lens Marking

Under Notice 1, there would have been no requirement to identify the lamps used as DRLs. However, in commenting on that proposal, States asked for a lens marking requirement. In their view, State enforcement and vehicle inspection officials would be unable to distinguish between legal and illegal lamps and lamp combinations in the absence of marking. NHTSA tentatively concluded that those arguments had merit, and, further, that resolution of preemption questions would be assisted by a clear designation of the lamps used as DRLs. Under Notice 4, the agency proposed that these lamps would be marked "DRL" in letters not less than 4 mm high. A lamp that optically combines a DRL with a headlamp would be excluded from this requirement.

GM and Ford suggested that the lamps be marked with the SAE identification code, "YZ". To be consistent with the marking procedure specified in the SAE specification on marking of lighting equipment, SAE J759, GM also requested that the size of the lettering be 3 mm. The agency has adopted the latter suggestion in the final rule, but is requiring the "DRL" mark. The SAE specifications and Federal ones differ. To adopt the SAE designation would be inaccurate and confusing because it would signify adoption of the SAE requirements, instead of the different ones that NHTSA is promulgating.

Other Issues on Which Comment Was Requested or Received

The agency proposed that DRLs be activated when the transmission is in any position other than "park" or "neutral", and deactivated when the headlamp control is in the "headlamp on" position. Ford, Mack, Hino, and VW requested that the wording be compatible if not identical to the Canadian requirement. After consideration of the comments, and because the rule does not mandate DRLs, NHTSA has decided to adopt a final rule that is more flexible than either the Canadian requirement or the one that NHTSA originally proposed. It simply requires automatic activation of the system under circumstances to be determined by the vehicle manufacturer, e.g., when the transmission is in any position other than park or neutral, as NHTSA

originally proposed, or operation of the engine without operation of the headlamp switch, the Canadian requirement. The DRL would be deactivated when the headlamp control is in any "on" position, and as otherwise determined by the vehicle manufacturer, such as deactivation of the engine.

Standard No. 108 presently requires the taillamps and side marker lamps to be activated simultaneously with the headlamps. The question arises whether, when a DRL is optically combined with a headlamp, the taillamps and side marker lamps must also be activated when the DRL is. Since there is a fuel economy penalty associated with side and rear lamp use, it is possible that manufacturers combining DRLs with headlamps will not wish to activate simultaneously the side and rear lamps. Further, data exist from some studies conducted on high mounted stop lamps that indicate a negative safety effect can exist on the vehicle's required pair of lower mounted stop lamps when the taillamps are activated. This occurred because the stop lamps were not as readily perceived on some cars when the taillamps were on during the day.

NHTSA requested comments on whether a prohibition against activation of the taillamps and side marker lamps is appropriate when a DRL is optically combined with a headlamp. Notice 4 proposed that the use of side and rear lamps with the DRL be a manufacturer's option. Chrysler and VW concurred with allowance as an option. GM was concerned lest the use become a requirement, a concern also of West Virginia in response to Notice 1. Michigan in its comment to Notice 1, on the other hand, favors simultaneous activation of the taillamps with DRLs so that the rear of the vehicle will be marked in the event that headlamps are not activated during periods in which visibility is reduced. PACCAR recommended that taillamps not be used with DRLs to avoid confusion with stop lamps. After reviewing the comments, the agency finds no compelling reason to prohibit the use of side and rear lamps with DRLs.

NHTSA was also concerned about the possible increases in rear crashes from the effect of daytime taillamp operation upon the efficacy of the stop lamp signal. The presence of the CHMSL ought to provide a distinguishable signal even if the taillamps and other stop lamps are combined in the same lamp housing. However, the NHTSA Report "An Evaluation of Center High Mounted Stoplamps" (DOT–HS–807442) showed that the greatest accident reduction benefit occurred during daylight (a 20 percent reduction, compared with an 8 percent reduction during dusk, nighttime, and dawn). The CHMSL may provide greater benefits when the taillamps are off. Thus, NHTSA requested that commenters address the issue of whether daytime taillamp operation could also lessen the effectiveness of the center stop lamp.

Commenters did not address this issue. NHTSA assumes that because the center highmounted stop lamp is dedicated to a single function, while a stop and taillamp may be combined in a single housing, the center highmounted stop lamp will not be masked by taillamp operation. Beginning September 1, 1993, all new motor vehicles with a GVWR of 10,000 pounds or less will be equipped with the third stop lamp which mitigates against any long term masking problem concerning the other two stop lamps. NHTSA does not believe that larger trucks without the center lamp are likely to be designed so that the rear lamps are activated during DRL operation because of high maintenance costs. For the foregoing reasons, NHTSA has found no safety need to prohibit manufacturers from simultaneous activation of DRLs and taillamps.

The rule indirectly affects States which now have or are considering enacting laws to require operation of the headlamps when the windshield wipers are activated. Some operators of vehicles with DRLs may not, because of the operation of their DRLs, activate the headlamp switch when the wipers are activated. The intent of these laws is to improve vehicle detection in low light levels, an intent that may be fulfilled by DRLs. NHTSA wants to encourage States to allow DRLs as an alternative to headlamps in their wiper use laws. However, this rule does not change normal headlamp functioning. Drivers can still use the master headlamp switch to actuate the headlamps when state laws or driver vision requires it.

Finally, this rule will ensure that DRLs are allowed on vehicles throughout the United States. This will afford an opportunity to evaluate DRL performance under the broad geographic and road conditions that exist throughout the country. However, past DRL studies indicate that unless evaluation studies are carefully controlled, the results are likely to be misleading or inconclusive. NHTSA is interested in evaluating the effectiveness of DRLs in the U.S. and requested that commenters submit suggestions as to how this might best be accomplished.

GM believes that the most effective study can be accomplished through the implementation of a harmonized rule between the U.S. and Canada. In its opinion, this would allow a data base of a large volume of vehicles all meeting the same requirements. However, the suggestion contained no specifics, and no commenter offered more than cursory thoughts on how an evaluation might be done. NHTSA is interested in the ability of manufacturers to identify DRL-equipped vehicles, and suggests that such information be available, at least for make and model of vehicles if it is standard equipment, or by VIN if installed specially, such as on fleet purchases.

GM, Ford, and MVMA stated that the NPRM was not consistent with the goal of international harmonization of regulations within the North American Free Trade Agreement. NHTSA has taken this into account in fashioning the final rule. Harmonization does not require that regulations be identical. The final rule permits a wide range of Canadian DRLs to be used, and establishes a window of harmonization that permits a common design to meet the requirement of both countries.

IIHS commented that DRLs should not be limited to newly manufactured vehicles, and it urged that Standard No. 108 apply to aftermarket DRLs as well. Since the agency is not mandating DRLs, it had given no thought to issues of retrofit, and, in any event, the subject was beyond the scope of the NPRM and not a part of the petition upon which the rulemaking was based.

NHTSA does not believe that the lack of a regulation covering vehicles-in-use that were originally manufactured without DRLs will result in aftermarket DRLs that are contrary to the final rule. State lighting laws for vehicles-in-use are generally identical to Standard No. 108's requirements for new vehicles.

This final rule does not have any retroactive effect. Under 15 U.S.C. 1392(d), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard. 15 U.S.C. 1394 sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

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Shift to Expression of Measurements in Metrics

In implementation of the Department's policy to use the international metric system wherever possible in rulemakings, the values that are adopted are expressed in metrics. This shift will result temporarily in Standard No. 108 using the conventional system of measurement in some sections and the metric system in others. However, eventually, Standard No. 108 will be converted entirely to metric terms, in accordance with a NHTSA timetable.

Rulemaking Analyses

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has considered the economic impacts of this rule and has made a determination that it is not major within the meaning of E.O. 12291 nor significant under Department of Transportation policies and procedures. The rule is not mandatory upon persons otherwise regulated by Standard No. 108, therefore there is no cost impact upon any manufacturer who does not choose to offer a DRL. NHTSA has no information on whether manufacturers other than GM will avail themselves of the option. Because DRL's are not required, any cost from implementing them will be at the manufacturer's choice. There may be a small incremental increase over some standard Canadian DRL models for the purpose of limiting possibly negative safety effects, but NHTSA has not quantified these costs as DRL's are not required. Therefore, preparation of a full regulatory evaluation is not warranted.

National Environmental Policy Act

NHTSA has analyzed this rule for the purposes of the National Environmental Policy Act. It will not have a significant effect upon the environment because there is no requirement that a manufacturer provide DRLs. As noted previously in this notice, there could be a fuel economy penalty of up to one quarter mile per gallon, depending on the type of DRL.

Regulatory Flexibility Act

The agency has also considered the impacts of this rule in relation to the Regulatory Flexibility Act. I certify that this rule will not have a significant economic impact upon a substantial number of small entities, because its adoption will not establish a mandatory requirement on regulated persons. Further, the rule will not affect the price of vehicles purchased by small jurisdictions and organizations. Accordingly, no regulatory flexibility analysis has been prepared.

Executive Order 12612 (Federalism)

This rule has also been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and NHTSA has determined that it does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—[AMENDED]

§ 571.108 [Amended]

In consideration of the foregoing, 49 CFR 571.108, Motor Vehicle Safety Standard No. 108, *Lamps, Reflective Devices, and Associated Equipment* is amended as follows:

1. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

2. Paragraph S5.5.3 is revised to read as follows:

S5.5.3 The taillamps on each vehicle shall be activated when the headlamps are activated in a steady-burning state, but need not be activated if the headlamps are activated at less than full intensity as permitted by paragraph S5.5.11(a).

3. New paragraph S5.5.11 is added to read as follows:

S5.5.11(a) Any pair of lamps on the front of a passenger car, multipurpose passenger vehicle, truck, or bus, whether or not required by this standard, other than parking lamps or fog lamps, may be wired to be automatically activated, as determined by the manufacturer of the vehicle, in a steady burning state as daytime running lamps (DRLs) and to be automatically deactivated when the headlamp control is in any "on" position, and as otherwise determined by the manufacturer of the vehicle, provided that each such lamp:

(1) Has a luminous intensity not less than 500 candela at test point H–V, nor more than 3,000 candela at any location in the beam, when tested in accordance with Section S11 of this standard, unless it is:

(i) A lower beam headlamp intended to operate as a DRL at full voltage, or at a voltage lower than used to operate it as a lower beam headlamp; or

(ii) An upper beam headlamp intended to operate as a DRL, whose luminous intensity at test point H–V is not more than 7,000 candela, and which is mounted not higher than 864 mm above the road surface as measured from the center of the lamp with the vehicle at curb weight;

(2) Is permanently marked "DRL" on its lens in letters not less than 3 mm high, unless it is optically combined with a headlamp;

(3) Is designed to provide the same color as the other lamp in the pair, and that is one of the following colors as defined in SAE Standard J578 MAY88: White, white to yellow, white to selective yellow, selective yellow, or yellow;

(4) If not optically combined with a turn signal lamp, is located so that the distance from the edge of the illuminated surface of its lens to the optical axis (filament center) of the nearest turn signal lamp is not less than 100 mm, unless its luminous intensity as a DRL is not more than 2,600 candela at any location in the beam, or unless it is deactivated when the turn signal lamp is activated; and

(5) If optically combined with a turn signal lamp, is automatically deactivated as a DRL when the turn signal lamp or hazard warning lamp is activated, and automatically reactivated as a DRL when the turn signal lamp or hazard warning lamp is deactivated.

(b) Any pair of lamps that are not required by this standard and are not optically combined with any lamps that are required by this standard, and which are used as DRLs to fulfill the specifications of S5.5.11(a), shall be mounted at the same height, which shall be not more than 1.067 m above the road surface measured from the center of the lamp on the vehicle at curb weight, and shall be symmetrically disposed about the vertical centerline of the vehicle.

4. New paragraph S11 is added to read as follows:

S11. *Photometric Test.* A lamp that is wired in accordance with paragraph S5.5.11 of this standard, shall be tested for compliance with S5.5.11(a)(1) in accordance with the test method specified for photometric testing in SAE Standard J575 DEC88 when a test voltage of 12.8V +/20 mV is applied to the input terminals of the lamp switch module or voltage-reducing equipment, whichever is closer to the electrical source on the vehicle. The test distance from the lamp to the photometer shall be not less than 18.3 m, if the lamp is optically combined with a headlamp, or is a separate lamp, and not less than 3 m, if the lamp is optically combined with a lamp, other than a headlamp, that is required by this standard.

Issued on: January 6, 1993.

Marion C. Blakey,

Administrator.

[FR Doc. 93–531 Filed 1–8–93; 8:45 am]

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Proposed Rules

Federal Register
Vol. 58, No. 6
Monday, January 11, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 410

RIN 3206–AF05

Training

AGENCY: Office of Personnel Management.

ACTION: Proposed rulemaking.

SUMMARY: The Office of Personnel Management (OPM) is proposing to amend its regulations governing the training of Federal employees in areas described in OPM's Memorandum for Heads of Departments and Independent Agencies, January 10, 1992, Subject: Human Resources Development Policy Initiatives. The Policy Initiatives outline a series of actions to strengthen human resources development in the Federal Government. Federal agencies are increasingly dependent on the skills and capabilities of their workforce to enhance productivity and ensure quality service to the American public. The Policy Initiatives provide broad direction and support to agencies in the management of training resources and programs. The proposed regulatory change is seen as a key element in building responsive, cost-effective, and sustained human resource development programs in Federal agencies. Regulations on training needs assessment will require each agency to establish a process that systematically links its training and development plans and resources to the agency's mission, strategic plans, performance goals, and priorities.

DATES: Written comments will be considered if received no later than February 10, 1993.

ADDRESSES: Send or deliver written comments to Dona Wolf, Director, Human Resources Development Group, U.S. Office of Personnel Management, room 5554, 1900 E Street, NW., Washington, DC 20415.

FOR FURTHER INFORMATION CONTACT: Barbara Smith, (202) 376–6804.

SUPPLEMENTARY INFORMATION: The major objective of human resource management in the Federal Government is to attract, develop, and retain a quality, balanced workforce. In its leadership capacity, OPM, in partnership with the agencies, has developed Human Resources Development Policy Initiatives as part of its plan to address this important objective. The initiatives outline critical areas for policy direction and program guidance and focus on a planned, balanced, and continuous approach to the growth and development of Government employees at all levels. In accordance with its authority under 5 U.S.C. 4118, OPM plans to issue regulatory changes as described below.

Training Needs Assessment

OPM proposes to amend its regulations in subpart B of part 410, Determining Training Needs. Needs assessment is the critical first step in a systematic approach for developing plans and programs designed to improve organizational and individual performance. The well-planned and timely assessment of needs ensures that organizational training and development resources are committed to the highest priority needs and provides the most cost effective basis for an agency's expenditure of training dollars.

Through extensive studies, OPM has found that training needs assessment practices vary widely from agency to agency. Some have very sophisticated needs assessment processes, encompassing formal task analyses of key occupations followed by systematic comparisons of employee skill levels to occupational requirements, while other agencies assess needs randomly and haphazardly. Some agencies assess employee needs on an annual basis, while others assess needs only sporadically. The variations and inconsistencies in needs assessment practices are further documented by the Volcker Commission Report, Leadership for America: Rebuilding the Public Service (Washington 1989). The Commission found that at both the career and non-career levels, training is frequently ad hoc and self initiated. Further, the Commission found agencies are not certain what they should train for (short- or long-term), which employees should receive the greatest training emphasis (entry, mid- or senior-level), or when or how often employees need additional education. The Commission also found that career paths are not well planned or designed and, "* * * with a few exceptions, most Federal training is voluntary, individually focused, and job-specific and bears little discernible relation to major agency objectives and missions. Nor is training tied to any performance goals, leaving agencies unable to justify costs in an era of tight budgets."

Based on these findings and the results of its studies on practices in both the private and public sectors, OPM proposes to regulate needs assessment to ensure that agency practices are comprehensive, uniform, and ongoing. The regulations will increase the likelihood that budget and program resources committed to training relate directly to agency mission and performance priorities. Needs assessment based on the identification of agency mission needs and critical occupational and individual performance requirements can help agencies eliminate redundant training efforts, substantially reduce the unnecessary expenditure of training dollars, and assist managers in identifying performance requirements that can best be satisfied by training and other developmental strategies.

The proposed regulations will require agencies to describe desired levels of organizational, occupational, and individual performance. Through its needs assessment process, an agency will determine the difference between actual and desired performance levels. If a gap exists, an agency will identify the underlying cause(s) for the difference. If training is determined to be appropriate, an agency will use information furnished by the needs assessment to identify who needs training and when and how it can best be provided.

The regulations propose a systematic approach to planning career development strategies for Government employees. They focus on the use of training and other development to maintain and improve organizational, occupational, and individual performance. Further, the regulations reflect the importance of a well-trained, fully developed, and balanced workforce in which needs are assessed fairly and equitably for all employees.

To assist agencies in implementing these regulations, OPM will prepare

guidance through the Federal Personnel Manual Chapter 410 (Training) that illustrates performance models, best practices, and useful needs assessment techniques and tools.

Other Development

The proposed regulations provide for consideration of developmental options (e.g., apprenticeships, reassignments, details, rotational assignments, etc.) in determinations covered by subparts B and C of part 410. This reflects OPM's view that these options should be considered in establishing priorities for meeting developmental needs. In some situations, a developmental option could be a more appropriate mechanism for skills development and less costly than formal training.

Training of Persons With Disabilities

The proposed regulations insert a reference to "persons with disabilities" in the sections dealing with "using needs assessment to manage human resources" and "selection and assignments" to ensure that agencies' procedures provide safeguards against unjustified denial of developmental opportunities for persons with disabilities.

E.O. 12291, Federal Regulation

I have determined that this is not a major rule as defined in E.O. 12291, Federal Regulation.

Regulatory Flexibility Act

I certify that these regulations will not have significant economic impact on a substantial number of small entities because they affect only Federal employees and agencies.

List of Subjects in 5 CFR Part 410

Authority delegation, Education, Government employees, Manpower training programs, Personnel Management Office.

Office of Personnel Management.

Douglas A. Brook,

Acting Director.

Accordingly, the Office of Personnel Management proposes to amend 5 CFR part 410 as follows:

PART 410—TRAINING

1. The authority citation for part 410 continues to read as follows:

Authority: 5 U.S.C. 4101, *et seq.*; E.O. 11348, 3 CFR, 1967 Comp., p. 275. § 410.503 also issued under 5 U.S.C. 5364. § 410.506, § 410.511, and § 410.602 also issued under 5 U.S.C. 1104. § 410.902 also issued under 42 U.S.C. 4746.

2. Subpart B, consisting of § § 410.201 and 410.202, is revised to read as follows:

Subpart B—Planning for Human Resource Development

Sec.
410.201 Assessment of needs.
410.202 Using needs assessment to manage human resources and plan human resource development programs.

Subpart B—Planning for Human Resource Development

§ 410.201 Assessment of needs.

(a) *General.* To prepare human resources to accomplish agency goals and program objectives effectively and efficiently, the head of an agency shall establish and maintain a system to assess training and other developmental needs and set priorities for meeting identified needs. Training needs assessment shall be an ongoing activity and incorporated within the agency's overall human resources planning process. Assessing training needs is a collaborative effort requiring the support and involvement of agency management. Agency policies on conducting needs assessment shall be set forth in writing and incorporated into policies established under § 410.301(a) of this part.

(b) *Needs Assessment System.* In conducting the reviews of training needs required by section 4113 of title 5, United States Code, and by Executive Order 11348, an agency shall identify training and other developmental needs using the criteria in paragraphs (c), (d), (e), and (f) of this section.

(1) Organizational assessment will identify broad priorities and objectives established to maintain and improve the performance of the agency and its work units. Organizational assessment ensures that the budget and program resources committed to training and other development will directly support the mission, goals, and performance requirements of the agency.

(2) Occupational assessment will identify short- and long-term job requirements that are essential to achieve operational goals and objectives for each major occupation within the agency including executive, managerial, and supervisory positions.

(3) Individual assessment will identify particular knowledge, skills, and abilities required of employees to perform their jobs. Individual employee needs will be assessed to ensure professional growth and development of employees within career paths, particularly during periods of organizational and technological change to maintain desired levels of performance. At a minimum, needs of individuals will be assessed at critical career stages, including:

(i) Initial entry to the agency;

(ii) Progression from one level of job responsibility to another within a career path, as from entry to journey level to supervisory level; and

(iii) Transition to a new career or job as from one occupation to another, technical expert to team leader, supervisor to manager, and manager to executive.

(d) *Performance Requirements.* Needs assessment will focus on the required or desired performance of the agency, the organizational unit, or the individuals being assessed. Needs assessment will be conducted to determine the difference between required or desired and actual performance levels. The agency will determine if the required or desired level of performance should be attained through training or through other methods, such as modifying systems and procedures, changing working conditions, or improving communications.

(e) *Needs Assessment Planning.* In planning and conducting needs assessments, an agency shall design and develop an assessment plan that:

(1) Identifies the goal, purpose, and level (organizational, occupational, or individual) of the particular assessment;

(2) Uses relevant documents such as productivity reports, work studies, evaluations, trend analyses, and other data sources, including needs assessment instruments, to provide accurate and reliable information on organizational, occupational, and individual performance; and

(3) Incorporates, as needed, other systems to retrieve information on organizational, occupational, and individual performance such as performance appraisal processes, succession planning strategies, and career planning systems.

(f) *Management Involvement.* Managers and supervisors will actively support the agency's needs assessment process. Management actions shall include setting human resources goals, establishing training and other development priorities, making decisions about the investment of resources and assessing the performance of individuals and occupational groups.

(g) *Needs Assessment Implementation and Evaluation.* At least annually, an agency shall:

(1) Analyze findings on new or previously identified needs to:

(i) Assure they are accurate and provide reliable information on the present and projected critical skill

requirements of the organization and individuals; and

(ii) Determine whether the findings are being used effectively by the agency to close identified gaps between desired and actual levels of performance assessed for the organization, occupational groups and individual employees; and

(2) Analyze the effectiveness and efficiency of their documented needs assessment system and procedures to determine:

(i) If they generate relevant information;

(ii) If they are practical to conduct; and

(iii) How needs assessment findings are used by the agency, including how they are used in decisions to allocate agency training resources.

§ 410.202 Using needs assessment to manage human resources and plan human resource development programs.

(a) An agency shall evaluate information derived from organizational, occupational, and individual assessments and use these findings to make decisions on training resource allocations and plan human resources development programs.

(b) Organizational assessment findings shall be used by agency officials as the basis for:

(1) Establishing human resources development goals and priorities;

(2) Integrating human resources development planning with work planning, budgeting, and other personnel management systems;

(3) Making short- and long-term decisions on investment of resources to plan for training and other developmental activities within the agency;

(4) Designing, developing, conducting, and evaluating training, new employee orientation programs, and other development programs and activities for the agency through internal and external resources; and

(5) Assessing agency plans to ensure consistency with the merit system principles set forth in 5 U.S.C. 2301(b)(1) and (2), taking into consideration the need to maintain a diversified workforce in which women, minorities, and persons with disabilities are appropriately represented and developed in the agency.

(c) Occupational assessment findings shall be used as the basis for:

(1) Evaluating workforce trends and occupational forecasts to determine what short- and long-term strategies will be undertaken to attain the future skill requirements;

(2) Developing strategies to address recruiting and retention issues for mission-critical occupations;

(3) Identifying and tracking career paths, where feasible, and the training needs of employees on those paths, including needs for continuing technical/professional development, based on an analysis of the occupation's tasks and an identification of the competencies associated with various stages of advancement in that occupation;

(4) Establishing training and other development programs to meet the knowledge and skill needs of employees in key occupations; and

(5) Ensuring that budget and program resources allocated for mission-related training and other development in key occupations are supportive of organizational or agencywide priorities.

(d) Individual assessment findings shall be used as the basis for:

(1) Developing plans for career and personal growth and to improve individual performance;

(2) Identifying areas where training and other development could improve the performance of an employee rated at a level below "Fully Successful" or enhance the competencies of an employee already performing at a "Fully Successful" or higher level to achieve the highest level of proficiency and to help prepare for future assignments on his/her career path or for occupational change.

(3) Selecting training and other developmental activities for employees; and

(4) Ensuring that resources allocated for individual training and other development are linked to organizational human resources development priorities.

3. Subpart C, consisting of §§ 410.301 through 410.304, is revised to read as follows:

Subpart C—Establishing human resource development programs

Sec.

410.301 Scope and general conduct of programs.
410.302 Selection and assignment of employees for development.
410.303 Utilization of trainees.
410.304 Evaluation of training.

Subpart C—Establishing Human Resource Development Programs

§ 410.301 Scope and general conduct of programs.

(a) The head of an agency shall determine the policies which are to govern the development of the agency's workforce. These policies shall be set forth in writing and include a statement of the broad purposes for which training and other development will be given and of the assignment of responsibilities for seeing that these purposes are achieved.

(b) The head of an agency also shall take such administrative action as is necessary to assure that:

(1) Plans and programs are developed to meet the short- and long-range training and other developmental needs within the agency;

(2) Priorities are established for training and other developmental programs of the agency;

(3) Provision is made for the use of funds and staff hours in accordance with established priorities for training and other developmental programs of the agency;

(4) Employee self-development is fostered through a work environment in which self-development is encouraged, self-study materials are reasonably available, and self-initiated improvement in performance is recognized; and

(5) Information with respect to the general conduct of the training program of the agency is availabled to enable the Office of Personnel Management, the President, and Congress to discharge their respective responsibilities under chapter 41 of title 5, United States Code.

(c) Training programs established by the agencies under chapter 41 of title 5, United States Code, shall to the maximum extent feasible:

(1) Be based on short- or long-range needs, existing or reasonably foreseeable;

(2) Meet as many of these needs as possible, with priorities considered;

(3) Use work assignment flexibility to provide experience to promote employee growth for the purpose of increasing the quality and quantity of work produced; and

(4) Be integrated with other personnel management and operating activities.

(d) As provided in subsection (b) of section 4103 of title 5, United States Code, an agency may train any employee of the agency to prepare the employee for placement in another agency when the following conditions are met:

(1) The head of the agency must determine that the employee will otherwise be separated under conditions which would entitle the employee to severance pay under section 5595 of title 5, United States Code;

(2) Before undertaking any training under this section, the head of the agency shall obtain verification from the Office of Personnel Management that there exists a reasonable expectation of placement in another agency; and

(3) In selecting an employee for training under this section, the head of the agency shall consider:

(i) The extent to which the current skills, knowledge, and abilities of the employee may be used in the new position;

(ii) The employee's capability to learn skills and acquire knowledge and abilities needed in the new position; and

(iii) The benefits to the Government which would result from retaining the employee in the Federal service.

§ 410.302 Selection and assignment of employees for development.

(a)(1) Except as provided by paragraph (a)(2) of this section, an agency must follow its merit promotion procedures when selecting a career or career-conditional employee for training or other development which is:

(i) Part of an authorized training agreement;

(ii) Part of a promotion program; or

(iii) Required before an employee may be considered for a promotion.

(2) Paragraph (a)(1) of this section does not apply if:

(i) The agency's merit promotion procedures have already been applied; or

(ii) The development is associated with an action not covered by or excepted from those procedures.

(b) With respect to selection and assignment of employees to training by, in, or through non-Government facilities, the head of an agency shall provide that each assignment of an employee who is stationed within the continental limits of the United States to training outside these limits be approved by a specifically designated official at the headquarters level of the agency.

(c) The head of an agency shall prescribe such procedures as are necessary to assure that the selection of employees for development is made without regard to race, color, religion, sex, national origin, age, disability, or other factors unrelated to the need for employee development.

§ 410.303 Utilization of trainees.

An agency, in effecting position changes, shall consider significant training and other developmental activities undertaken by employees.

§ 410.304 Evaluation of training.

An agency shall evaluate the results and effects of training programs and other developmental activities in such manner and with such frequency as the agency head considers appropriate.

[FR Doc. 93–397 Filed 1–8–93; 8:45 am]
BILLING CODE 6325–01–M

DEPARTMENT OF AGRICULTURE

Federal Grain Inspection Service

7 CFR Part 68

United States Standards for Rice

AGENCY: Federal Grain Inspection Service, USDA.[1]

ACTION: Proposed rule.

SUMMARY: In compliance with the requirements for periodic review of regulations, the Federal Grain Inspection Service (FGIS) is proposing to revise the United States Standards for Rice. Specifically, FGIS proposes to revise the United States Standards for Rough Rice, Brown Rice for Processing, and Milled Rice by establishing a special grade for aromatic (scented) rice and eliminating the requirement that rough rice or brown rice for processing must contain more than 25 percent of whole kernels in order to be classed as Long grain, Medium grain, Short grain, or Mixed rough rice or brown rice for processing.

DATES: Comments must be submitted on or before April 12, 1993.

ADDRESSES: Written comments must be submitted to George Wollam, FGIS, USDA, Room 0632 South Building, P.O. Box 96454, Washington, DC, 20090–6454; FAX (202) 720–4628. All comments received will be made available for public inspection in Room 0632 USDA South Building, 1400 Independence Avenue SW., Washington, DC, during regular business hours (7 CFR 1.27(b)).

FOR FURTHER INFORMATION CONTACT: George Wollam, address as above, telephone (202) 720–0292.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This proposed rule has been issued in conformance with Executive Order 12291 and Departmental Regulation 1512–1. This action has been classified as nonmajor because it does not meet the criteria for a major regulation established in the Order.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This proposed rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Regulatory Flexibility Act Certification

John C. Foltz, Administrator, FGIS, has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities because those persons who apply the standards and most users of the inspection services do not meet the requirements for small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Further, the standards are applied equally to all entities.

Review of Standards

On January 22, 1992, FGIS published in the **Federal Register** (57 FR 2482) a request for public comment on the review of the United States Standards for Rice. The objective of the review is to ensure that the standards continue to serve the needs of the marketplace to the greatest extent possible. In keeping with this objective, FGIS requested comments on the need for revising various sections of the standards, the potential for improvements, and language clarity. Specifically, FGIS has focused on reviewing the need to:

1. Establish standards for edible brown rice,
2. Establish a special grade for aromatic rice,
3. Increase the limits for broken kernels removed by a 5 plate for U.S. Nos. 1 and 2 milled rice,
4. Eliminate the class Screenings milled rice,
5. Revise the definitions of the classes of rough rice by eliminating the requirement that these classes must contain more than 25 percent whole kernels, and
6. Revise the definitions of the classes Second Head, Screenings, and Brewers milled rice by eliminating the southern production criteria and adopting the western production criteria for rice grown in all areas of production.

Interested parties were invited to participate in the rulemaking process by submitting written comments and/or recommendations on the suggested changes to the official standards. During the 90-day comment period, a total of nine comments were received from private companies, governmental and educational organizations, and groups representing rice growers and millers.

[1] The authority to exercise the functions of the Secretary of Agriculture contained in the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621–1627), concerning inspection and standardization activities related to grain and similar commodities and products thereof has been delegated to the Administrator, Federal Grain Inspection Service (7 U.S.C. 75a; 7 CFR 68.5).

Establishing Standards for Edible Brown Rice

Presently, there are no U.S. standards for edible brown rice; i.e., brown rice that is intended to be consumed without being milled. The current U.S. Standards for Brown Rice for Processing were developed solely for brown rice intended to be processed into milled rice. Most edible brown rice is marketed on private specifications. For this reason, FGIS sought to determine whether there was a need to develop U.S. standards specifically for edible brown rice.

Four groups representing rice growers, millers, and processors commented on the need to establish standards for edible brown rice. It was the view of two of those groups that standards for edible brown rice are not needed. One other group commented that they would not oppose standards for edible brown rice, "but question the industry's desire or need for edible brown rice standards at this time." Only one commenter expressed any support for the establishment of standards provided that "standards do not allow the inclusion of white milled broken rice."

From the comments received, FGIS has determined that a majority of the market would not use U.S. standards for edible brown rice if they were available. Consequently, FGIS will not propose establishing standards for edible brown rice at this time.

Establishing a Special Grade for Aromatic Rice

The amount of aromatic or scented rice produced in the United States has grown steadily in the last decade, as has the demand for relevant standards of quality. In response, FGIS requested comments on the need to establish a special grade for aromatic rice. The present U.S. Standards for Rough Rice, Brown Rice for Processing, and Milled Rice are being applied to aromatic rice. But, the current standards do not provide for grading or otherwise identifying such rice as "Aromatic."

Groups representing rice growers, millers, and processors commented that aromatic rice has the potential to greatly expand both production and consumption beyond current levels. Establishing a special grade for aromatic rice could facilitate this expansion and assist consumers. Therefore, FGIS, is proposing to revise the U.S. Standards for Rough Rice, Brown Rice for Processing, and Milled Rice to establish a special grade for aromatic rice.

Increasing Limits on Broken Kernels Removed by a 5 Plate

A 5 plate is a laminated metal plate with rows of perforated round holes that are 5/64 inch in diameter. "Broken kernels removed by a 5 plate" consist of very small particles of broken rice that become trapped in the plate's holes when a 50 gram sample is poured over the plate. According to the U.S. Standards for Milled Rice, the maximum limit for "broken kernels removed by a 5 plate" in U.S. Nos. 1 and 2 milled rice is 0.04 percent and 0.06 percent, respectively.

FGIS sought comments on whether the limits for "broken kernels removed by a 5 plate" should be increased to 0.1 percent for both U.S. Nos. 1 and 2 milled rice. This action would compensate for the normal variability of the scales used to determine the amount of this material in a sample. The scales used by FGIS to determine the amount of "broken kernels removed by a 5 plate" in a 50 gram sample of milled rice are accurate to plus or minus 0.02 gram. Therefore, the results of any "broken kernels removed by a 5 plate" determination may vary by as much as plus or minus 0.04 percent.

Several of the groups that commented on this suggestion expressed deep concerns about changing the current levels. These commentors felt that allowing a greater amount of small broken kernels in high-quality U.S. rice would reduce the marketability of U.S. Nos. 1 and 2 milled rice. FGIS believes that a slight increase in the limits would not have a noticeable effect on rice quality or appearance. But, FGIS is concerned that any loosening of grade limits may inadvertently harm the United States' reputation for producing and marketing high-quality rice. To avoid any such negative consequences, FGIS plans to investigate other alternatives (e.g., use more accurate scales or increase the sample size to 100 grams), rather than increasing the "broken kernels removed by a 5 plate" limit.

Eliminating the Class Screenings Milled Rice

Broken milled rice, rice that contains less than 25 percent of whole kernels, is currently classed as either Second Heads, Screenings, or Brewers milled rice, depending on the size of the broken kernels. FGIS suggested that consideration be given to eliminating the class Screenings milled rice because there was no known price discount or premium for this class of rice.

Most commenters stated that Screenings milled rice is still a viable and useful classification and that the elimination of it could have a potentially significant negative impact on trade. As a result, FGIS has determined that further review would be necessary before FGIS would propose any change in the classification of broken milled rice.

Revising the Class Definitions for Rough Rice and Brown Rice for Processing

FGIS suggested that the definitions of the classes Long grain, Medium grain, Short grain, and Mixed rough rice may need to be revised by eliminating the requirement that these classes must contain more than 25 percent whole kernels. Rough rice and brown rice for processing that contains less than 25 percent whole kernels cannot be identified by a class name. As a result, this rice cannot be graded. Milled rice, on the other hand, that contains less than 25 percent whole kernels can be identified by class name (e.g., Second Head, Screenings, or Brewers milled rice) and can be graded.

Elimination of the 25 percent whole kernel requirement for classing rough rice and brown rice for processing is supported by rice grower and miller groups who believe that this change will facilitate the marketing of rice and benefit both farmers and rice mills. Therefore, FGIS is proposing to revise the U.S. Standards for Rough Rice and Brown Rice for Processing by eliminating the requirement that rice in the classes Long grain, Medium grain, Short grain, and Mixed rough rice or brown rice for processing must contain more than 25 percent whole kernels.

Eliminating the Southern Production Criteria for Classing Second Head, Screenings, and Brewers Milled Rice

FGIS evaluated the need to revise the definitions of the classes Second Head, Screenings, and Brewers Milled Rice by eliminating the Southern production method and adopting the Western production method for rice grown in all areas. FGIS found that adopting one method for all rice would eliminate buyer confusion and provide nationwide uniformity. Also, sieves (Western production equipment) are less expensive and more portable than sizing plates (Southern production equipment).

Six groups commented on this suggestion. Two private companies and one State governmental organization supported eliminating the Southern production method and using the Western production method for all rice. But, a group that represents rice millers and two groups that represent rice

growers were strongly opposed to adopting the Western production method for rice grown in all areas. They stated that the Western production method would be costly and cumbersome for Southern mills. They also stated that "because of the shape of the kernel, Long grain does not size well on sieves. Therefore, to be tested fairly, a sizing separation using plates is needed." Long grain rice is predominately-grown in the South. There organizations also stated that there is insufficient data to support the elimination of the Southern production method and that another method should be developed that replaces both the Southern and the Western production methods. After due consideration, FGIS has determined that further review would be necessary before FGIS would propose the elimination of either the Southern or Western production methods.

Proposed Action

Based on current market needs, FGIS is proposing to revise:

1. Section 68.202(c)(1) by removing "which contains more than 25 percent of whole kernels and."

2. Section 68.202(c)(2) by removing "which contains more than 25 percent of whole kernels and."

3. Section 68.202(c)(3) by removing "which contains more than 25 percent of whole kernels and."

4. Section 68.202(c)(4) by removing "which contains more than 25 percent of whole kernels and."

5. Section 68.212 by adding a new paragraph (e), that defines aromatic rough rice.

6. Section 68.213 by adding a special grade designation for aromatic rough rice.

7. Section 68.252(d)(1) by removing "more than 25.0 percent of whole kernels of brown rice and."

8. Section 68.252(d)(2) by removing "more than 25.0 percent of whole kernels of brown rice and."

9. Section 68.252(d)(3) by removing "more than 25.0 percent of whole kernels of brown rice and."

10. Section 68.252(d)(4) by removing "more than 25.0 percent of whole kernels of brown rice and."

11. Section 68.263(d)(2) by adding a new paragraph (d), that defines aromatic brown rice for processing.

12. Section 68.264 by adding a special grade designation for aromatic brown rice for processing rice.

13. Section 68.315 by adding a new paragraph (f), that defines aromatic milled rice.

14. Section 68.316 by adding a special grade designation for aromatic milled rice.

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992 memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 7 CFR Part 68

Administrative practice and procedures, Agricultural commodities, Rice.

For reasons set forth in the preamble, 7 CFR part 68 is proposed to be amended as follows:

PART 68—REGULATIONS AND STANDARDS FOR INSPECTION AND CERTIFICATION OF CERTAIN AGRICULTURAL COMMODITIES AND THEIR PRODUCTS

1. The authority citation for part 68 continues to read as follows:

Authority: Secs. 202–208, 60 Stat. 1087, as amended (7 U.S.C. 1621 *et seq.*).

Subpart C—United States Standards for Rough Rice

Subpart D—United States Standards for Brown Rice for Processing

Subpart E—United States Standards for Milled Rice

2. Section 68.202(c) (1) through (4) are revised to read as follows:

§ 68.202 Definition of other terms.

* * * * *

(c) * * *

(1) "Long grain rough rice" shall consist of rough rice which, after milling to a well-milled degree, contains not more than 10.0 percent of whole or broken kernels of medium or short grain rice.

(2) "Medium grain rough rice" shall consist of rough rice which, after milling to a well-milled degree, contains not more than 10.0 percent of whole or large broken kernels of long grain rice or whole kernels of short grain rice.

(3) "Short grain rough rice" shall consist of rough rice which, after milling to a well-milled degree, contains not more than 10.0 percent of whole or large broken kernels of long grain rice or whole kernels of medium grain rice.

(4) "Mixed rough rice" shall consist of rough rice which, after milling to a well-milled degree, contains more than 10.0 percent of "other types" as defined in paragraph (h) of this section.

* * * * *

3. Section 68.212(e) is added after the note to read as follows:

§ 68.212 Special grades and requirements.

* * * * *

(e) *Aromatic rough rice.* Aromatic rough rice shall be special varieties of rice (Oryza sativa L. scented) that have a distinctive and characteristic aroma; e.g., basmati and jasmine rice.

4. Section 68.213 is revised to read as follows:

§ 68.213 Special grade designation.

The grade designation for infested, parboiled, smutty, glutinous, or aromatic rough rice shall include, following the class, the word(s) "Infested," "Parboiled Light," "Parboiled," "Parboiled Dark," "Smutty," "Glutinous," or "Aromatic," as warranted, and all other information prescribed in § 68.211.

5. Section 68.252(d) (1) through (4) are revised to read as follows:

§ 68.252 Definition of other terms.

* * * * *

(d) * * *

(1) "Long grain brown rice for processing" shall consist of brown rice for processing which contains not more than 10.0 percent of whole or broken kernels of medium or short grain rice.

(2) "Medium grain brown rice for processing" shall consist of brown rice for processing which contains not more than 10.0 percent of whole or large broken kernels of long grain rice or whole kernels of short grain rice.

(3) "Short grain brown rice for processing" shall consist of brown rice for processing which contains not more than 10.0 percent of whole or large

broken kernels of long grain rice or whole kernels of medium grain rice.

(4) "Mixed brown rice for processing" shall consist of brown rice for processing which contains more than 10.0 percent of "other types" as defined in paragraph (i) of this section.

* * * * *

6. Section 68.263(d) is added after the note to read as follows:

§ 68.263 Special grades and special grade requirements.

* * * * *

(d) *Aromatic brown rice for processing.* Aromatic brown rice for processing shall be special varieties of rice (Oryza sativa L. scented) that have a distinctive and characteristic aroma; e.g., basmati and jasmine rice.

7. Section 68.264 is revised to read as follows:

§ 68.264 Special grade designation.

The grade designation for parboiled, smutty, glutinous, or aromatic brown rice for processing shall include following the class, the word(s) "Parboiled," "Smutty," "Glutinous," or "Aromatic," as warranted, and all other information prescribed in § 68.262.

8. Section 68.315(f) is added after the note to read as follows:

§ 68.315 Special grades and special grade requirements.

* * * * *

(f) *Aromatic milled rice.* Aromatic milled rice shall be special varieties of rice (Oryza sativa L. scented) that have a distinctive and characteristic aroma; e.g., basmati and jasmine rice.

9. Section 68.316 is revised to read as follows:

§ 68.316 Special grade designation.

The grade designation for coated, granulated brewers, parboiled, undermilled, glutinous, or aromatic milled rice shall include, following the class, the word(s) "Coated," "Granulated," "Parboiled Light," "Parboiled," "Parboiled Dark," "Undermilled," "Glutinous," or "Aromatic," as warranted, and all other information prescribed in § 68.314.

Dated: December 14, 1992.

John C. Foltz,

Administrator.

[FR Doc. 93–399 Filed 1–8–93; 8:45 am]

BILLING CODE 3410–EN–M

Commodity Credit Corporation

7 CFR Part 1446

RIN 0560–AC89

Peanuts

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Proposed Rule.

SUMMARY: This proposed rule would amend regulations with respect to the "disaster transfer" of peanuts for pricing purposes from an additional loan pool to a quota loan pool. The proposed change would exclude any peanut poundage quota transferred to a farm under the "fall transfer" provision from the poundage quota available to that farm to effect a transfer under the "disaster transfer" provision. This change is needed to prevent the possibility of increased cost to the peanut program and related increases in the public debt. This action is necessary to provide applicable rules for 1993 through 1995 crops of peanuts with respect to transfer restrictions.

DATES: Comments must be received on or before February 10, 1993 in order to be assured of consideration.

ADDRESSES: Send comments to the Director, Tobacco and Peanuts Division, Agricultural Stabilization and Conservation Service (ASCS), United States Department of Agriculture (USDA), P.O. Box 2415, Washington, DC 20013–2415, or deliver to room 5750, South Building, 14th Street and Independence Avenue, SW., Washington, DC. All written comments received in response to this request will be made available for public inspection in room 5750, South Building, USDA, between the hours of 8:15 a.m. and 4:45 p.m., on regular workdays.

FOR FURTHER INFORMATION CONTACT: Jack S. Forlines, Deputy Director, Tobacco and Peanuts Division, ASCS, USDA, P.O. Box 2415, Washington, DC 20013–2415, telephone 202–720–0156.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

This proposed rule has been reviewed under USDA procedures established in accordance with Executive Order 12291 and has been classified not major because it does not meet any of the three criteria identified under the Executive Order. This action will not have an annual effect on the economy of $100 million or more, nor will it result in major increases in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographical regions. Furthermore, it will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Federal Assistance Program

The title and number of the Federal assistance program, as found in the Catalog of Federal Domestic Assistance, to which this proposed rule applies are: Commodity Loans and Purchases—10.051.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this proposed rule since the Commodity Credit Corporation (CCC) and ASCS are not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Executive Order 12372

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Paperwork Reduction Act

The information collection requirements contained in the regulations in 7 CFR part 1446 for the peanut price support program were approved by the Office of Management and Budget (OMB), as required by 44 U.S.C. chapter 35, and assigned OMB control numbers 0560–0006, 0560–0014, and 0560–0033. This proposed rule does not change the information collection as approved by OMB. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, room 404W, Washington, DC 20250; and to the Office of Management and Budget, Paperwork Reduction Project (OMB #0506–0006), Washington, DC 20503.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

USDA is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, USDA actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy for

the public to understand, use or comply with. In short, USDA is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. USDA applies this principle to the full extent possible, consistent with law.

USDA has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, USDA believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, USDA specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this Notice.

Background

Under section 358–1(b)(8)(D) of the Agricultural Adjustment Act of 1938, as amended, any increase in the farm poundage quota for a farm for a marketing year may be used during the marketing year for the transfer of additional peanuts produced on the farm to the quota loan pool for pricing purposes on such basis as the Secretary of Agriculture shall by regulation prescribe. Such transfers for pricing purposes are commonly known as "disaster transfers."

Section 1446.307 of the peanut regulations provides the conditions for approving a "disaster transfer" of Segregation 2 and Segregation 3 peanuts from an additional loan to a quota loan. Generally, such transfer may be approved to the extent the effective farm poundage quota exceeds the sum of the amount of peanuts retained on the farm for seed or other uses and the production of Segregation 1 peanuts on the farm.

The purpose of the disaster transfer is to prevent an economic disaster to the producer who has a poundage quota and plants peanuts with the expectation of marketing the peanuts as quota peanuts but, because of conditions beyond the producer's control, is prevented from marketing some of the peanuts as quota peanuts because the peanuts are graded as Segregation 2 or Segregation 3 peanuts that are ineligible for marketing as quota peanuts. The current difference between an additional loan and a quota loan is more than $500 per ton of peanuts.

Under the "fall transfer" provision of 7 CFR part 729, peanut poundage quota may be transferred to a farm by lease, owner, or operator to the extent needed to market the entire production of peanuts on the farm as quota peanuts. If the harvest of peanuts has not been completed, the quantity of peanut poundage quota that may be transferred is determined on the basis of estimated production. When peanuts are graded as Segregation 2 or Segregation 3 after a fall transfer of poundage quota has been approved, the poundage quota that has been transferred to the farm may be used to effect a disaster transfer with resulting loss to CCC. Generally, § 1446.307 of the peanut regulations permits the transfer of Segregation 2 or 3 peanuts from an additional loan to a quota loan for pricing purposes, since Segregation 2 and Segregation 3 peanuts are not eligible for a quota loan at time of marketing. Under current rules, such transfers are allowed to the extent the effective farm poundage quota exceeds the sum of peanuts retained on the farm for seed or other uses and the production of Segregation 1 peanuts on the farm, unless the producer has been indemnified for such peanuts by the Federal Crop Insurance Corporation. Except for offsets from any pool profits otherwise earned by the producer, "disaster transfers" result in a loss to CCC of $350 to $550 per ton for each ton transferred.

Permitting disaster transfers without adjustment for fall transfers provided greater flexibility to farmers and has been permitted before for that reason, subject to additional review. However, while that flexibility has value, it appears on further review that the value of that flexibility may not overweigh the potential of increased program cost and that the issue should be the subject of further comment. Accordingly, in order to allow for minimizing the potential cost of the peanut program, this proposed rule would amend § 1446.307 to limit a disaster transfer to the amount by which the poundage quota, that was in effect on the farm before the "fall transfer" of quota, is greater than the sum of peanuts retained on the farm for seed or other purposes and the production of Segregation 1 peanuts on the farm. In the event the farm has Segregation 2 or Segregation 3 peanuts, however, it may be that the farm will qualify as having undermarketings which can be carried forward.

List of Subjects in 7 CFR Part 1446

Loan programs—Agriculture, Peanuts, Price support programs, Reporting and recordkeeping requirements, Warehouses.

Accordingly, it is proposed that 7 CFR part 1446 be amended as follows:

PART 1446—PEANUTS

1. The authority citation for 7 CFR part 1446 continues to read as follows:

Authority: 7 U.S.C. 1359a, 1375, 1421 *et seq.*; 15 U.S.C. 714b and 714c.

2. In § 1446.307, paragraph (b) is revised to read as follows:

§ 1446.307 Disaster transfer of Segregation 2 or Segregation 3 peanuts from additional loan to quota loan.

* * * * *

(b) *Limitation of amount eligible for transfer.* The amount of such transfer made in accordance with this section may not exceed the effective farm poundage quota minus the sum of:

(1) Peanuts retained on the farm for seed or other uses,

(2) Production of Segregation 1 peanuts on the farm, and

(3) Amount of peanuts equal to the amount of quota transferred to the farm through a fall transfer pursuant to part 729 of this title.

* * * * *

Signed at Washington, DC, on January 5, 1993.

John A. Stevenson,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 93–450 Filed 1–8–93; 8:45 am]

BILLING CODE 3410–05–M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 40, 50, 70, 72

RIN 3150–AE16

Self-Guarantee as an Additional Financial Assurance Mechanism

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission is proposing to amend its regulations for decommissioning licensed facilities to allow certain non-electric utility licensees to use self-guarantee as a means of financial assurance. The proposed rule would reduce the cost burden of financial assurance while providing NRC with sufficient assurance that decommissioning costs will be funded. This proposed rule responds to a petition for rulemaking (PRM–30–59) from General Electric Company and Westinghouse Electric Corporation.

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DATES: Comment period expires March 29, 1993. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, 20555, Attention: Docketing and Service Branch.

Deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

Copies of the regulatory analysis and comments received may be examined at: The NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Clark Prichard, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–3734.

SUPPLEMENTARY INFORMATION:

Background

On September 25, 1991 (56 FR 48445), the NRC published a notice of receipt of a petition for rulemaking from the General Electric Company (GE) and the Westinghouse Electric Corporation (Westinghouse). The petitioners requested that the NRC amend its decommissioning regulations contained in 10 CFR parts 30, 40, 50, 70, and 72 to provide a means for self-guarantee of decommissioning funding costs by certain NRC licensees who meet stringent financial standards and related reporting and oversight requirements. The petitioners proposed that electric utility reactor licensees under 10 CFR part 50 not be affected by the proposals in the petition.

On June 27, 1988 (53 FR 24018), the NRC published a final rule that established general requirements for decommissioning nuclear facilities. These requirements provide assurance that licensed facilities will be decommissioned in a safe and timely manner and that adequate funds will be available for decommissioning. Under the present decommissioning regulations, licensees are permitted to provide financial assurance for decommissioning funding through prepayment, insurance, a surety bond, a letter of credit, a parent company guarantee, or for electric utilities, the establishment of an external sinking fund.

In 1990, GE and Westinghouse requested exemptions from the financial assurance requirements for decommissioning. The requested exemptions would have permitted GE and Westinghouse to demonstrate financial assurance for decommissioning by submitting a self-guarantee that otherwise met or exceeded the criteria for qualifying parent company guarantees under appendix A to 10 CFR part 30. The Commission denied the requests for exemption. Later in 1990, GE and Westinghouse each submitted a petition for reconsideration of their requests for exemption. These requests for reconsideration were also denied. However, in informing GE and Westinghouse of the denial, the Commission indicated a willingness to consider a petition for rulemaking from GE and Westinghouse.

The GE/Westinghouse petition was docketed on July 11, 1991 (PRM–30–59). The petition requested that parts 30, 40, 50, 70, and 72 be amended to allow corporate self-guarantee as an additional method of complying with financial assurance for decommissioning requirements in those parts. The petition proposed criteria for corporate self-guarantee which would assure that only very strong financial entities could qualify. The financial criteria which were proposed are:

(1) Tangible net worth of at least $1 billion.

(2) Tangible net worth at least 10 times the current decommissioning cost estimate, or the current amount required if certification is used.

(3) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the current decommissioning cost estimate, or the current amount required if certification is used.

(4) A current bond rating of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

A number of procedural requirements were also proposed:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company will provide the Commission with copies of all reports filed with the Securities and Exchange Commission under section 13 of the Securities Exchange Act of 1934.

(3) The company's independent certified public accountant must compare the data used by the company in the financial test with the company's independently audited yearend financial statements.

(4) The company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

(5) The company must notify NRC within 90 days of any matters coming to the attention of the auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

The self-guarantee would be available only for an applicant or licensee having no parent company holding majority control of its voting stock.

Basis for Petition

The petitioners believed that they have been adversely and unreasonably affected by limitations in the current decommissioning regulations. Companies such as the petitioners are unable to guarantee decommissioning funding if they themselves are the licensee. However, relatively weaker financial institutions, such as banks, insurance companies, and savings and loans, are permitted to guarantee decommissioning funding for licensees without providing any evidence of financial strength.

Furthermore, licensees without the financial strength of the petitioners may provide qualifying parent company guarantees solely because these parent companies are legal entities distinct from the subsidiary licensees whose decommissioning funding they guarantee.

The petitioners asserted that the lack of an internal decommissioning funding method imposes unwarranted compliance costs upon them. The current regulations compel the petitioners to either restructure their licensed activities into less financially secure subsidiaries for which they could then provide a parent company guarantee, or to purchase outside financial assurance.

Public Comments

The Commission received five comment letters in response to the publication of the notice of receipt of the petition. Most of the letters supported a revision of the Commission's regulations to allow self guarantee. Three large materials licensees supported self guarantee, although they favored less stringent financial criteria for self guarantee so that a wider range of licensees could qualify to use self guarantee. One large materials licensee prefers that the tangible net worth requirement should be ten times the estimated decommissioning costs, or in the case of licensees with multiple facilities requiring decommissioning, $500 million to $1 billion depending on the number of such facilities. Another large materials licensee suggests that NRC use the same financial requirements now applicable to parent company

guarantees. It does not see any need to make the tangible net worth criterion any higher than $50 million. The minimum bond rating requirement should be BBB or Baa, the lowest rating still considered investment grade. Also, in their opinion, the financial ratio tests in appendix A to 10 CFR part 30 should be retained as an alternative to the bond rating criterion. Finally, this commenter does not believe that the more restrictive tangible net worth/decommissioning cost ratio proposed in the petition is justified. Another large materials licensee asserts that there is no rational basis for establishing criteria for a company self-guarantee which differ significantly from existing criteria for the parent company guarantee. In either instance, the adequacy of the financial assurance requirement provided is based on the value of the assets securing the decommissioning obligation. According to this commenter, if the assets are held in two separate pools, each technically owned by a different but related company, the level of financial security provided does not increase in any significant measure. In virtually all instances where the parent guarantee is utilized, the subsidiaries are wholly or substantially owned by the parent such that the financial and other elements of the two entities are substantially the same. As an alternative, this commenter recommends that the NRC adopt the petitioners' proposal, modified by reducing the minimum tangible net worth requirement to at most $100 million, and requiring a bond rating not lower than BBB or Baa.

An electric utility licensee opposes the petition's exclusion of the electric utility reactor licensees under 10 CFR part 50. Its position is that decommissioning regulations should apply to all licensees equally and that compliance alternatives contingent on licensee financial status and size should also be available to utilities.

A commenter opposed self-guarantee, citing the potential for takeover and breakup of large corporations. This would mean that a company initially allowed to use a self guarantee by meeting the criteria, subsequently could be substantially weakened through restructuring. The ability of the restructured company to meet decommissioning costs could be in doubt.

Response to Comments

Several commenters favored the self guarantee concept but argued for less stringent financial criteria. The Commission is interested in alternative financial criteria which would permit more licensees to use the proposed self-guarantee, yet would maintain a high level of financial assurance. The Commission is asking for public comments on a possible alternative to the proposed financial criteria (see Alternative Criteria).

Regarding the comment concerning the exclusion of electric utilities from the scope of the proposed self-guarantee, the Commission allows electric utilities to accumulate decommissioning funds in an external sinking fund. Unlike other licensees subject to financial assurance requirements, electric utilities do not have to provide financial assurance "up front." Thus, electric utilities already are permitted a cost-reducing financial assurance mechanism.

In response to the comment that self-guarantee should not be allowed because of the potential for takeover and breakup of large companies, the Commission believes that the requirements for annual re-certification, combined with timely bond rating reviews, will be adequate to maintain the level of financial assurance of the proposed self-guarantee.

Basis for the Commission's Decision

The Commission has carefully reviewed the arguments in the petition, as well as the public comments. For the reasons outlined below, it has decided to initiate this rulemaking, which, if promulgated as final, would grant the petition.

Stringent Financial Criteria

The financial criteria proposed for self-guarantee are exceptionally stringent. The Commission is confident that licensees able to meet the financial criteria provide the necessary reasonable assurance that funding will be available to meet decommissioning costs. The regulatory analysis estimates that only approximately 20 present NRC licensees could meet the criteria.

The criterion for tangible net worth, $1 billion, far exceeds that required for the NRC parent company guarantee ($10 million). In addition to the $1 billion tangible net worth requirement, the proposed rule would require that a licensee must have tangible net worth at least ten times the total current decommissioning cost estimate for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor, or the current amount required if certification is used. To assure that assets are within reach of the Commission's authority, 90 percent of total assets or at least ten times total decommissioning cost estimates for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor, or the current amount if certification is used, would need to be in the United States.

In addition to tangible net worth criteria, the financial criteria include a bond rating of A or above. This bond rating is above that required to classify debt securities as "investment grade." The principal debt rating services, Moodys and Standard and Poors, classify bonds with a rating of Baa and BBB respectively, as "investment grade as opposed to bonds with a lesser rating which are classified as "speculative grade." Bond ratings are reviewed often, and changed in response to changes in the issuer's financial condition. A bond rating of A or better assures that the financial strength of a licensee offering a self-guarantee has been independently reviewed and affirmed. It provides an excellent guide to the ability of a company to meet its obligations. According to Moodys, default rates associated with companies whose bonds are rated A or above in 1 of 3 years prior to default are 0.13 percent annually.[1]

There could be concern that a self-guaranteeing licensee's financial condition could deteriorate over time, jeopardizing decommissioning funding. The proposed rule has the following safeguards against this possibility: (1) A licensee using self-guarantee would need to be re-certified each year as meeting the financial criteria, (2) Copies of all current financial reports filed with the Securities and Exchange Commission would also need to be provided to the Commission, (3) The company would need to notify NRC within 90 days of any matters which could prevent the company from any longer passing the financial criteria, and (4) The company would need to notify NRC within 20 days if its bonds are no longer rated A or better.

Cost Savings

The objective of this proposed rule is to reduce the licensee's cost burden without adverse effects on public health and safety. The draft regulatory analysis developed for this proposed rule estimates that annual total cost savings would be approximately $600,000 for all licensees using the self-guarantee. This estimate is based on rather conservative assumptions (i.e., $750,000 total decommissioning cost per license); the actual cost savings may be considerably greater. Both the petition for rulemaking

[1] Corporate Bond Defaults and Default Rates, Moody's Special Report, January 1991, p. 32.

and several public comment letters assert much greater cost savings.

The cost savings would result from the elimination of the cost of third party financial assurance for licensees qualifying to use the proposed self-guarantee. Annual fees for letters of credit, surety bonds, and other forms of third party financial assurance typically are approximately 1.5 percent of the amount of financial assurance provided.

Comparison With Parent Guarantee

The NRC currently allows licensees to comply with his financial assurance regulations by means of a parent company guarantee. The parent company of a licensee, if it meets the financial criteria in 10 CFR part 30, appendix A, may guarantee that funds will be available to decommission the facility of its subsidiary licensee. The parent company guarantee allowed in NRC regulations does not provide a greater degree of financial assurance than self-guarantee for a company meeting the criteria proposed here. Under current regulations, there is no explicit regulatory requirement that licensees using the parent company guarantee: (1) Be wholly independent of the parent company who provides the guarantee and (2) demonstrate financial qualifications in itself that are comparable to those required of a parent company guarantor under current regulations or those proposed for self-guarantee in the petition.

A company which meets the financial criteria for the proposed rule could readily pass the financial test in 10 CFR part 30, appendix A, and would thus be eligible to provide a parent company guarantee for a subsidiary. It is anomalous for NRC regulations to permit a large, financially strong company to provide a parent company guarantee, but not allow that same company to provide a self-guarantee. Moreover, a large, financially strong company could carry out a corporate restructuring to create a licensee subsidiary which could then be covered by a parent company guarantee.

EPA Precedent

The Environmental Protection Agency (EPA) allows self-guarantee as a mechanism for meeting its financial assurance regulations for hazardous waste facilities (40 CFR parts 264 and 265). The objective of EPA and NRC financial assurance regulations is the same; to ensure that adequate funds are available to safely decommission facilities. EPA has about 10 years of experience with self-guarantee to date (the final rule was promulgated on April 7, 1982, 47 FR 15033), and self-guarantee has been an effective financial assurance mechanism.

Alternative Criteria

The Commission notes that a majority of commenters on the petition questioned the need for the financial criteria for self-guarantee to be as stringent as proposed here. Allowing less stringent criteria would permit additional licensees to use self-guarantee and thus reduce the costs of complying with the Commission's regulations. The draft regulatory analysis indicates that one approach which could widen the range of eligible licensees would be to delete the $1 billion tangible net worth criterion. A company's tangible net worth is an important factor comprising its bond rating, and the rating itself, combined with the other criteria, may be a sufficient indicator of financial stability. Since all firms qualifying would need an A or better bond rating, this alternative may not be riskier in terms of financial assurance than the proposed rule. The draft regulatory analysis examines the effects of deleting the $1 billion tangible net worth requirement from the financial criteria in the proposed rule, all other criteria remaining constant. The conclusion is that this alternative, if adopted, would allow an additional 7 firms, holding 11 licenses, to use the proposed self-guarantee. The Commission is especially interested in public comments on this alternative financial criteria—the criteria in this proposed rule without the $1 billion tangible net worth requirement.

Administrative Conforming Changes

Sections 30.8(b), 40.8(b) and 50.8(b) are being revised to list all the regulatory provisions of these parts that contain information collections.

Environmental Impact: Categorical Exclusion

The NRC has determined that this proposed regulation is the type of action described as a categorical exclusion in 10 CFR 51.22(c)(10)(i). Therefore, neither an environmental impact statement nor an environmental assessment has been prepared for this proposed regulation.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

The public reporting burden for this collection of information is estimated to average 19 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB–7714), U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–3019, (3150–0017, –0020, –0011, –0009, –0132), Office of Management and Budget, Washington, DC 20503.

Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The draft analysis is available for inspection in the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Single copies of the draft analysis may be obtained from Clark W. Prichard, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC, 20555 telephone (301) 492–3734.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** hearing.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that, if promulgated, this proposed rule will not have a significant economic impact upon a substantial number of small entities. The proposed rule would affect only entities with a tangible net worth of $1 billion. The licensees affected by this proposed rule do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards of the NRC applicable to a small business (56 FR 56671; November 6, 1991).

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule, because these amendments do not involve any

provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 30

Byproduct material, Civil penalty, Government contracts, Intergovernmental relations, Isotopes, Nuclear material, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalty, Government contracts, Hazardous materials-transport, Nuclear materials, Reporting and recordkeeping requirements, Source material, Uranium.

10 CFR Part 50

Antitrust, Classified information, Criminal penalty, Fire protection, Incorporation by reference, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

10 CFR Part 70

Criminal penalty, Hazardous materials-transportation, Material control and accounting, Nuclear materials, Packaging and containers, Penalty, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 72

Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 30, 40, 50, 70, and 72.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 continues to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.10, 30.34 (b), (c), (f), (g) and (i), 30.41 (a) and (c), and 30.53 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); § 30.10 is issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 30.6, 30.9, 30.34(g), 30.36, 30.50, 30.51, 30.52, 30.55, and 30.56 (b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

2. In § 30.8 paragraph (b) is revised to read as follows:

§ 30.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 30.15, 30.19, 30.20, 30.32, 30.34, 30.35, 30.36, 30.37, 30.38, 30.50, 30.51, 30.55, 30.56, and appendix A and B.

* * * * *

3. In § 30.35, the introductory text of paragraph (f)(2) is revised to read as follows:

§ 30.35 Financial assurance and recordkeeping for decommissioning.

* * * * *

(f) * * *

(1) * * *

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A of this part. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix B of this part. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

4. A new appendix B is added to part 30 to read as follows:

Appendix B to Part 30—Criteria Relating to Use of Financial Tests and Self Guarantees for Providing Reasonable Assurance of Funds for Decommissioning

I. Introduction

An applicant or licensee may provide reasonable assurance of the availability of funds for decommissioning based on furnishing its own guarantee that funds will be available for decommissioning costs and on a demonstration that the company passes the financial test of section II of this appendix. The terms of the self-guarantee are in section III of this appendix. This appendix establishes criteria for passing the financial test for the self guarantee and establishes the terms for a self-guarantee.

II. Financial Test

A. To pass the financial test, a company must meet all of the following criteria:

(1) Tangible net worth of at least $1 billion.

(2) Tangible net worth at least 10 times the total current decommissioning cost estimate for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor, or the current amount required if certification is used.

(3) Assets located in the United States amounting to at least 90 percent of total assets or at least 10 times the total current decommissioning cost estimate for all decommissioning activities for which the company is responsible as self-guaranteeing licensee and as parent-guarantor, or the current amount required if certification is used.

(4) A current rating for its most recent bond issuance of AAA, AA, or A as issued by Standard and Poors (S&P), or Aaa, Aa, or A as issued by Moodys.

B. To pass the financial test, a company must meet all of the following additional requirements:

(1) The company must have at least one class of equity securities registered under the Securities Exchange Act of 1934.

(2) The company's independent certified public accountant must have compared the data used by the company in the financial test which is derived from the independently audited, yearend financial statements for the latest fiscal year, with the amounts in such financial statement. In connection with that procedure, the licensee shall inform NRC within 90 days of any matters coming to the attention of the

auditor that cause the auditor to believe that the data specified in the financial test should be adjusted and that the company no longer passes the test.

(3) After the initial financial test, the company must repeat passage of the test within 90 days after the close of each succeeding fiscal year.

III. Company Self-Guarantee

The terms of a self-guarantee which an applicant or licensee furnishes must provide that:

A. The guarantee will remain in force unless the licensee sends notice of cancellation by certified mail to the Commission. Cancellation may not occur, however, during the 120 days beginning on the date of receipt of the notice of cancellation by the Commission, as evidenced by the return receipt.

B. The licensee will provide alternative financial assurance as specified in the Commission's regulations within 90 days following receipt by the Commission of a notice of cancellation of the guarantee.

C. The guarantee and financial test provisions must remain in effect until the Commission has terminated the license or until another financial assurance method acceptable to the Commission has been put in effect by the licensee.

D. The licensee will promptly forward to the Commission and the licensee's independent auditor all reports covering the latest fiscal year filed by the licensee with the Securities and Exchange Commission pursuant to the requirements of section 13 of the Securities and Exchange Act of 1934.

E. If, at any time, the licensee's most recent bond issuance ceases to be rated in any category of "A" or above by either Standard and Poors or Moodys, the licensee will provide notice in writing of such fact to the Commission within 20 days after publication of the change by the rating service.

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

5. The authority citation for part 40 continues to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022).

Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 40.3, 40.25(d) (1)–(3), 40.35 (a)–(d) and (f), 40.41 (b) and (c), 40.46, 40.51 (a) and (c), and 40.63 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); § 40.10 is issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 40.5, 40.9, 40.25 (c), (d) (3) and (4), 40.26(c)(2), 40.35(e), 40.42, 40.60 40.61, 40.62, 40.64, and 40.65 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

6. In § 40.8 paragraph (b) is revised to read as follows:

§ 40.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 40.25, 40.26, 40.31, 40.35, 40.36, 40.42, 40.43, 40.44, 40.60, 40.61, 40.64, 40.65, and appendix A.

7. In § 40.36 the introductory text of paragraph (e)(2) is revised to read as follows:

§ 40.36 Financial assurance and recordkeeping for decommissioning.

* * * * *

(e) * * *

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A of 10 CFR part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix B of 10 CFR part 30. A guarantee by the applicant or licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

8. The authority citation for part 50 continues to read as follows:

Authority: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 1244, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88, Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 936, 955, as amended (42 U.S.C. 2131, 2235); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97–415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Sections 50.80–50.81 also issued under sec. 184, 68 stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); § § 50.5, 50.46 (a) and (b), and 50.54(c) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); § § 50.5, 50.7(a), 50.10 (a)–(c), 50.34 (a) and (e), 50.44 (a)–(c), 50.46 (a) and (b), 50.47(b), 50.48 (a), (c), (d), and (e), 50.49(a), 50.54 (a), (i), (i)(1), (l)–(n), (p), (q), (t), (v), and (y), 50.55(f), 50.55a (a), (c)–(e), (g), and (h), 50.59(c), 50.60(a), 50.62(b), 50.64(b), 50.65, and 50.80 (a) and (b) are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and § § 50.9, 50.49 (d), (h), and (j), 50.54 (w), (z), (bb), (cc), and (dd), 50.55(e), 50.59(b), 50.61(b), 50.62(b), 50.70(a), 50.71(a)–(c) and (e), 50.72(a), 50.73 (a) and (b), 50.74, 50.78, and 50.90 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

9. In § 50.8 paragraph (b) is revised to read as follows:

§ 50.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in § § 50.30, 50.33, 50.33a, 50.34, 50.34a, 50.35, 50.36, 50.36a, 50.48, 50.49, 50.54, 50.55, 50.55a, 50.59, 50.60, 50.61, 50.63, 50.64, 50.65, 50.71, 50.72, 50.75, 50.80, 50.82,

50.90, 50.91, and appendices A, B, E, G, H, I, J, K, M, N, O, Q, and R.

10. In § 50.75 the introductory text of paragraph (e)(1)(iii) and paragraph (e)(2)(iii) are revised to read as follows:

§ 50.75 Reporting and recordkeeping for decommissioning planning.

* * * * *

(e) * * *

(1) * * *

(iii) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

(2) * * *

(iii) A surety method, insurance, or other guarantee method. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A of 10 CFR part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix B of 10 CFR part 30. A guarantee by the applicant or the licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company.

* * * * *

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

11. The authority citation for part 70 continues to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 97–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.62 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 70.3, 70.10, 70.19(c), 70.21(c), 70.22 (a), (b), (d)–(k), 70.24 (a) and (b), 70.32 (a) (3), (5), (6), (d), and (i), 70.36, 70.39 (b) and (c), 70.41(a), 70.42 (a) and (c), 70.56, 70.57 (b), (c), and (d), 70.58 (a)–(g)(3) and (h)–(j) are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 70.7, 70.10, 70.20a (a) and (d), 70.20b (c) and (e), 70.21(c), 70.24(b), 70.32 (a), (b), (c), (d), (e), and (g), 70.36, 70.51 (c)–(g), 70.56, 70.57 (b) and (d), and 70.58 (a)–(g)(3) and (h)–(j) are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 70.5, 70.9, 70.20b (d) and (e), 70.38, 70.50, 70.51 (b) and (i), 70.52, 70.53, 70.54, 70.55, 70.58 (g)(4), (k), and (l), 70.59 and 70.60 (b) and (c) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

12. In § 70.25, the introductory text of paragraph (f)(2) is revised to read as follows:

§ 70.25 Financial assurance and recordkeeping for decommissioning.

* * * * *

(f) * * *

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A of 10 CFR part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix B of 10 CFR part 30. A guarantee by the applicant or the licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock of the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

13. The authority citation for part 72 continues to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 102, Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332); Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148 (c), (d), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168 (c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2244 (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and sec. 218(a), 96 Stat. 2252 (42 U.S.C. 10198).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 72.6, 72.12, 72.22, 72.24, 72.26, 72.28(d), 72.30, 72.32, 72.44 (a), (b) (1), (4), (5), (c), (d) (1), (2), (e), (f), 72.48(a), 72.50(a), 72.52(b), 72.72 (b), (c), 72.74 (a), (b), 72.76, 72.78, 72.104, 72.106, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.140 (b), (c), 72.148, 72.154, 72.156, 72.160, 72.166, 72.168, 72.170, 72.172, 72.176, 72.180, 72.184, 72.186 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); §§ 72.10 (a), (e), 72.12, 72.22, 72.24, 72.26, 72.28, 72.30, 72.32, 72.44 (a), (b), (1), (4), (5), (c), (d) (1), (2), (e), (f), 72.48 (a), 72.50(a), 72.52(b), 72.90 (a)–(d), (f), 72.92, 72.94, 72.98, 72.100, 72.102 (c), (d), (f), 72.104, 72.106, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.140 (b), (c), 72.142, 72.144, 72.146, 72.148, 72.150, 72.152, 72.154, 72.156, 72.158, 72.160, 72.162, 72.164, 72.166, 72.168, 72.170, 72.172, 72.176, 72.180, 72.182, 72.184, 72.186, 72.190, 72.192, 72.194 are issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 72.10(e), 72.11, 72.16, 72.22, 72.24, 72.26, 72.28, 72.30, 72.32, 72.44 (b)(3), (c)(5), (d)(3), (e), (f), 72.48 (b), (c), 72.50(b), 72.54 (a), (b), (c), 72.56, 72.70, 72.72, 72.74 (a), (b), 72.76(a), 72.78(a), 72.80, 72.82, 72.92(b), 72.94(b), 72.140 (b), (c), (d), 72.144(a), 72.146, 72.148, 72.150, 72.152, 72.154 (a), (b), 72.156, 72.160, 72.162, 72.168, 72.170, 72.172, 72.174, 72.176, 72.180,

72.184, 72.186, 72.192, 72.212(b), 72.216, 72.218, 72.230, 72.234 (e) and (g) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

14. In § 72.30 the introductory text of paragraph (c)(2) is revised to read as follows:

§ 72.30 Decommissioning Planning including financing and recordkeeping.

* * * * *

(c) * * *

(2) A surety method, insurance, or other guarantee method. These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, letter of credit, or line of credit. A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A of 10 CFR part 30. A parent company guarantee may not be used in combination with other financial methods to satisfy the requirements of this section. A guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix B of 10 CFR part 30. A guarantee by the applicant or the licensee may not be used in combination with any other financial methods to satisfy the requirements of this section or in any situation where the applicant or licensee has a parent company holding majority control of the voting stock for the company. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

* * * * *

Dated at Rockville, Maryland, this 5th day of January, 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93–473 Filed 1–8–93; 8:45 am]

BILLING CODE 7590–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[CO–76–90]

RIN 1545–AP19

Regulations Under Section 108 of the Internal Revenue Code; Discharge of Indebtedness; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed regulations that provide rules for determining whether stock issued for indebtedness is nominal or token under section 108(e)(8)(A) and rules for applying the proportionality test of section 108(e)(8)(B).

DATES: The public hearing originally scheduled for Tuesday, January 12, 1993, beginning at 10 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), 202–622–7190, (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 108(e)(8) of the Internal Revenue Code of 1986. A notice of public hearing appearing in the **Federal Register** for Monday, November 30, 1992 (57 FR 56534), announced that the public hearing on proposed regulations under section 108(e)(8) of the Internal Revenue Code of 1986 would be held on Tuesday, January 12, 1993, beginning at 1 p.m., in the IRS Commissioner's Conference Room, room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

The public hearing scheduled for Tuesday, January 12, 1993, has been cancelled.

Cynthia E. Grigsby,

Alternate Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 93–646 Filed 1–7–93; 2:33 am]

BILLING CODE 4830–01–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

[CC Docket No. 90–337, Phase II; FCC 92–496]

International Accounting Rates: In the Matter of Regulation of

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: On November 5, 1992, the Commission adopted a Second Further Notice of Proposed Rulemaking in Phase II of the Regulation of International Accounting Rates proceeding seeking comment on whether conditioning section 214 authorizations or modifying its nondiscriminatory accounting rate, equal division of tolls or proportionate return requirements might be an appropriate means of achieving lower accounting rates as facilities-based competition is introduced in foreign countries.

DATES: Comments on the Second Further Notice of Proposed Rulemaking are due February 5, 1993; Reply Comments are due March 8, 1993.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Teresa Marrero, Attorney, Common Carrier Bureau, (202) 632–3214.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Further Notice of Proposed Rulemaking adopted November 5, 1992, and released November 27, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the Federal Communications Commission Reference Center, Room 239, 1919 M Street, NW., Washington, DC. The complete text of this decision also may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1114 21st Street, NW., Washington, DC 20036.

Paperwork Reduction Act

The proposals will not create any undue burden on the public.

Initial Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act of 1980, the FCC's initial analysis is as follows:

Need and Purpose of This Action

The proceeding is initiated to obtain comment regarding possible modification of the Commission's nondiscriminatory accounting rate, equal division of tolls or proportionate return traffic requirements, and/or conditioning of section 214 authorizations, where facilities-based competition for international services is available in foreign countries. The Commission seeks recommendations on the most appropriate methods of implementing any such modifications that might be adopted.

Summary of Second Further Notice of Proposed Rulemaking

The Second Further Notice of Proposed Rulemaking requests comment on whether allowing some flexibility in our nondiscriminatory accounting rate, division of tolls, or proportionate return policy might be an appropriate means of achieving lower accounting rates as facilities-based competition is introduced in foreign countries. Specifically, the Commission invites

suggestions on what modifications to its International Settlements Policy (ISP) might best achieve this goal. It also requests comment on whether conditioning Section 214 authorizations where a competitive environment exists in a foreign country might help to reduce accounting rates, and, if so, how this goal might be achieved.

Public Benefits

The Commission is open to the possibility that, where there is a competitive market in a foreign country, its ISP requirements may be relaxed in an effort to facilitate lower accounting rates and ultimately lower outpayments to foreign correspondents, which could ultimately result in lower collection rates for U.S. consumers.

Ordering Clauses

Accordingly, *It is Ordered* that notice is hereby given of the proposed regulatory action described above, and that comment is sought on these proposals.

For further information on this item contact Teresa Marrero, Attorney, Common Carrier Bureau, (202) 632–3214.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–447 Filed 1–8–93; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 76

[MM Docket No. 92–264, FCC 92–542]

Cable Television Services; Implementation of the Cable Television Act, Horizontal and Vertical Ownership Limits, Cross-Ownership Limitations and Anti-Trafficking Provisions

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission, by this Notice of Proposed Rule Making and Notice of Inquiry (Notice), seeks to implement sections 11 and 13 of the Cable Television Consumer Protection and Competition Act of 1992 (1992 Cable Act). In this Notice, the Commission solicits comment on the interpretation and implementation of the cross-ownership and anti-trafficking provisions of the 1992 Cable Act. The Commission also solicits comment on the adoption of limits on horizontal concentration and vertical integration in the cable industry. The action is taken in order to comply with the 1992 Cable Act.

DATES: Comments are due by February 9, 1993, and reply comments are due by March 3, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jacqueline Chorney, Mass Media Bureau, Policy and Rules Division (202) 632–7792.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making and Notice of Inquiry in MM Docket No. 92–264, FCC 92–542, adopted December 10, 1992, released December 28, 1992. The complete text of this document is available for inspection and copying during normal business hours in the FCC Reference Center, 1919 M Street, NW., room 239, Washington, DC, and also may be purchased from the Commission's copy contractor, Downtown Copy Center, at (202) 452–1422, 1990 M Street, NW., room 640, Washington DC 20554.

Synopsis of the Notice of Proposed Rule Making

1. The Commission, in accordance with the 1992 Cable Act, considers the interpretation and implementation of the cross-ownership and anti-trafficking provisions of the 1992 Cable Act. The Commission also considers adoption of limits on horizontal concentration and vertical integration in the cable industry.

2. Section 13 of the 1992 Cable Act adds a new section 617 to the Communications Act of 1934, as amended, which establishes a three-year holding requirement for cable systems. Section 11 of the Cable Act of 1992 establishes several restrictions on the ownership and sale of cable systems. First it modifies section 613(a) of the Communications Act of 1934, as amended, to prohibit the common ownership of a cable system and a multichannel multipoint distribution service ("MMDS") or a cable system and a satellite master antenna television service ("SMATV"), apart from the franchised cable service, within a franchise area. Section 11 of the new Act also amends section 613 of the Communications Act of 1934 by adding a new subsection (f)(1), which requires the Commission to conduct a proceeding:

(1) To prescribe reasonable limits on the number of cable subscribers a person can reach through cable systems owned by such person ("subscriber limits");

(2) To prescribe reasonable limits on the number of cable channels that can be occupied by a video programmer in which a cable operator has an ownership interest ("channel occupancy limits"); and

(3) To consider the necessity and appropriateness of imposing limitations on the degree to which "multichannel video programming distributors" may participate in the creation or production of video programming.

3. The MMDS and SMATV cross-ownership restrictions and the anti-trafficking rule contain no specific effective date and, therefore, became effective on December 4, 1992 (the effective date of the 1992 Cable Act). However, the provision of the anti-trafficking rule which establishes a 120-day limit on the amount of time that a franchise authority has to disapprove a request to transfer a cable system, will not become effective until the Commission adopts regulations regarding the information required in connection with such requests. In this proceeding, the Commission seeks to identify the proper interpretation of the anti-trafficking rule and to establish an appropriate system of implementation.

4. The 1992 Cable Act and its legislative history demonstrate Congress' concern regarding horizontal concentration and vertical integration in the cable television industry. Congress, through the vertical and horizontal limits required by section 11 of the 1992 Cable Act, sought to prevent large, vertically integrated cable systems from creating barriers to entry of new programmers and from causing a reduction in the number of media voices available to consumers through cable television. In addition, the 1992 Cable ACt indicates Congress' conclusion that increasing vertical integration provides cable operators with both the incentive and the ability to favor their affiliated programmers over other programming services, and that vertically integrated program suppliers have the incentive and ability to favor their affiliated cable operators over other cable operators and programming distributors using alternative technologies. In establishing the subscriber limits and channel occupancy restrictions required by the 1992 Cable Act, the Commission must balance these concerns expressed by Congress with the efficiencies and benefits to be gained by increased concentration and integration.

Sales of Cable Systems

5. Section 13 of the 1992 Cable Act establishes a three-year holding period for cable systems. Under the cable anti-trafficking rule, with certain exceptions, "no cable operator may sell or otherwise transfer ownership in a cable system within a 36-month period following

either the acquisition or initial construction of such system by such operator." For purposes of this provision, multiple system transfers which provide for the subsequent transfer of one or more such systems shall be considered part of the initial transaction.

6. Jurisdiction and Enforcement. Because local franchising authorities are responsible for awarding cable franchises, and for approving sales and transfer of such franchises, the Commission tentatively concludes that local franchising authorities can most efficiently monitor and enforce compliance with the anti-trafficking restriction. The Commission proposes to require cable operators seeking to transfer ownership in cable system to certify to the franchise authority that the proposed transfer satisfies the three-year holding requirement or is exempt under one of the exceptions contained in the rule. If the terms of the franchise agreement do not require approval of the franchise authority for transfer or assignment of a cable system, the cable operator should nonetheless certify to the franchising authority that such transfer is not in violation of the three-year holding requirement. Operators making such a certification will be presumed to be in compliance with the anti-trafficking rule unless the local franchise authority finds to the contrary. Alternatively, a cable operator may seek a waiver of the anti-trafficking rule from the Commission in appropriate circumstances. Commenters are asked to address whether these procedures are suitable for enforcing the anti-trafficking rule. The Commission also invites comment regarding how these procedures could best be crafted.

7. Transfer of Ownership. The Commission seeks comment on the appropriate interpretation of "transfer of ownership in a cable system" for purposes of applying the three-year holding period. The Commission also asks commenters to identify the types of transactions Congress sought to include within the anti-trafficking rule. In commenting on this matter, parties are asked to consider existing Commission rules restricting the transfer of broadcast licenses and construction permits. Specifically, note the Commission's one-year holding requirement applicable to broadcast licenses obtained through the comparative hearing process or pursuant to the Minority Ownership Policy. See 47 CFR 73.3597(a)(4). Pursuant to section 310(d) of the Communications Act of 1934, this one-year holding requirement does not apply to transfers to ownership interests which do not result in a transfer of control or assignment of license. Commenting parties are asked to address whether "transfer of ownership in a cable system" should be defined by references to the broadcast transfer of control standards implemented pursuant to section 310(d) of the Communications Act of 1934.

8. The Commission tentatively concludes that its broadcast transfer of control standards are appropriate to implement the cable anti-trafficking rule. Commenters are asked to indicate whether those standards will provide cable operators and franchise authorities with sufficient guidance regarding application of the anti-trafficking restriction, and encompass the types of transfers that Congress intended to restrict. Alternatively, it may be preferable to establish a fixed transfer of ownership threshold encompassing only changes in who controls 50% or more of the outstanding equity in a cable system. The Commission invites commenters to indicate whether this definition would be consistent with the objectives of the anti-trafficking rule or whether a standard based on some lesser percentage of ownership (e.g., 25%, 30%, 40%) would be more appropriate. Finally, the attribution criteria contained in § 73.3555 (Notes) of the Commission's Rules could also be used to define ownership interests subject to the anti-trafficking rule. The Commission invites comment regarding which of these standards would be most appropriate in implementing the cable anti-trafficking provision in accordance with Congressional intent.

9. The Commission also invites comment regarding what, if any, procedures should be established for resolution of complaints arising from determinations under this provision. Commenters should indicate whether the Commission or the federal or state courts should resolve complaints involving the application of the anti-trafficking rule to a particular transaction. Preliminarily, the Commission believes that such complaints should be resolved at the local level, either according to relevant procedures contained in the franchise agreement or by commencement of an action in the state or federal courts. Alternatively, commenters are asked to indicate whether the Commission should establish specific procedures to be followed in resolving disputes regarding application of the anti-trafficking rule to ensure consistency in the interpretation of the rule and to allow for participation by all interested parties. If such procedures are appropriate, commenters should indicate whether the provisions of § 76.7 of the Commission's Rules (the special relief rules), or some modified form of these procedures, would be acceptable. Commenters should also address what, if any, sanctions would be appropriate for transfers in violation of the anti-trafficking rule. The Commission notes that although some sanctions such as forfeiture may be applicable (via section 503 of the Communications Act), the Commission does not interpret the anti-trafficking provision as necessarily requiring reversal of transfers of ownership based on good faith interpretation of the rule, where such transfers are subsequently found to violate the rule.

10. Regarding computation of the three-year holding period, commenters are requested to specify what dates should be used when calculating the period between initial construction and transfer or assignment of a cable system. Commenters should also specify what dates should apply when calculating the period between initial acquisition of a cable system and transfer of assignment of such system. The Commission further seeks comment regarding the appropriate treatment of multiple system owner (MSO) transfers under this provision. Commenters should indicate what procedures the Commission should establish for determining compliance with the anti-trafficking provision for transfers or assignments of MSOs.

11. Exceptions. The Cable Act of 1992 establishes three exceptions to the anti-trafficking restriction. The Commission seeks to clarify implementation of these exceptions, and asks commenters to indicate what types of transactions are contemplated by each exception. The first exception excludes any transfer or assignment of a cable system, which is not subject to Federal income tax liability. The Commission tentatively finds that this exemption applies to (a) transactions involving tax certificates issued by the Commission pursuant to section 1071 of the Internal Revenue Code ("Code"), which allows deferral of gains taxes for businesses acquired by minorities, (b) so-called "tax free" exchanges of assets under section 1031 of the Code, and (c) "tax free" reorganizations under section 368 of the Code. The Commission invites comment regarding whether the payment of cash or other taxable consideration, to equalize the value of assets in like system exchanges, should render such a transaction ineligible for this exception. Commenters are requested to address these tentative conclusions and to identify any other transactions that may qualify for this exception.

12. The second exception excludes any sale required by operation of any law, or by any act of any Federal agency, any state or political subdivision thereof, or any franchising authority. The Commission believes that this exception was intended primarily to enable franchise authorities or other government entities to require the transfer of a cable system that is in violation of its franchise agreement or that is otherwise providing inadequate service. This exception may also be interpreted to include transfers of cable systems in the context of bankruptcy proceedings or other types of receivership. The Commission seeks comment on these interpretations and on any other types of transactions that may be contemplated by this exception. The Commission further asks commenters to indicate whether sales of municipally operated cable systems were also intended to be exempt from the anti-trafficking rule pursuant to this exception.

13. Third, the 1992 Cable Act exempts any sale, assignment or transfer to one or more purchasers, assignees or transferees controlled by, controlling, or under common control with the seller, assignor or transferor. The Commission believes that this exception was intended to apply to *pro forma* transfers as defined in § 73.3540(f) of the Commission's Rules. The Commission asks commenters to indicate what other inter-company transfers should be included within this exception. The Commission does not interpret this provision as requiring a new three-year holding period to commence following each transfer to an affiliate entity. The Commission also tentatively concludes that the acquisition date following a transfer between affiliated entities should relate back to the original date such system was constructed or acquired by the affiliated transferor.

14. Finally, the Commission initially finds that cable operators seeking to transfer ownership of a cable system prior to the expiration of the statutory three-year holding period should submit to the franchise authority all information necessary to support a certification that the proposed transfer satisfies one of the stated exceptions. Commenters are asked to indicate what types of information should be required in order to establish eligibility under each of these exceptions.

15. Waivers. The 1992 Cable Act empowers the Commission, consistent with the public interest, to waive the three-year holding requirement. In connection with the general waive authority granted by this provision, comment is solicited on whether to establish specific waiver criteria and, if specific waiver criteria are adopted, what types of showing should be required. The 1992 Cable Act directs the Commission to use its waiver authority to permit "appropriate transfers in cases of default, foreclosure, or other financial distress," but it does not define the term "financial distress." The Commission invites comment on whether criteria contained in § 73.3597(a)(4) of the Commission's Rules should be used to define "financial distress" or whether some other standard would be more appropriate in this context.

16. If approval of the franchise authority is required in connection with the transfer of a cable system, the 1992 Cable Act provides that the Commission shall not waive such requirements unless the franchise authority has approved the proposed transfer. The Commission proposes that in such circumstances, waivers may nonetheless be granted prior to franchise authority consideration, provided such waivers are contingent upon ultimate approval by the franchising authority. The Commission seeks comment on whether such conditional waivers would be appropriate under the 1992 Cable Act and on whether franchise authority approval should create a presumption that the Commission will grant a waiver authorizing a particular transfer.

17. Limitation on Duration of Franchise Authority Power to Disapprove Transfers. Subsection (e) of the anti-trafficking rule limits the amount of time that a franchising authority has to disapprove a transfer of a cable system and also indicates that the Commission will establish regulations indicating the information that will be required in connection with such a request for transfer. The Commission seeks comment regarding what type of informational requirements to establish in connection with transfer requests. The Commission seeks to establish a minimum standard for such informational requirements and allow franchise authorities to request any additional information that may be necessary to evaluate a particular transfer.

MMDS/SMATV Cross-Ownership Prohibition

18. Section 11 of the 1992 Cable Act amends section 613(a) of the Communications Act of 1934 to add a prohibition against common ownership of a cable system and either an MMDS or a SMATV service in its franchise area. The provision is intended to address Congress' concern that common ownership of different means of video distribution may reduce service competition.

19. The Commission has already adopted regulations implementing a cable/MMDS cross-ownership prohibition in a recently concluded rulemaking initiated to facilitate the provision of "wireless cable" service to the public.[1] The recently adopted rules "prohibit, directly or indirectly, ownership interests in, control of, or leasing of * * * MMDS * * * by cable television companies in geographic areas which overlap the * * * MMDS protected service areas * * * for cable franchise areas lacking two or more competing cable television companies." The Commission's Rules include the attribution rules and definitions of "control," "areas" and "overlap" necessary to effectuate this prohibition. 47 CFR 21.912. The Commission's Rules also provide for limited exceptions to the general prohibition which the Commission has already determined will be in the public interest, i.e., a rural exception (47 CFR 21.912(d)(1) and a local programming exception (47 CFR 21.912(e)).

20. The Commission believes these recently adopted rules are consistent with and effectively implement the cross-ownership prohibitions of the 1992 Cable Act as regards the MMDS service and that the same rules and their implementing criteria are appropriate for the cross-ownership prohibitions as they relate to SMATV.[2] Commenters are invited to address these tentative conclusions.

21. The 1992 Cable Act provides for the grandfathering of existing cross-ownership situations that existed on October 5, 1992. Note that the current Commission Rules grandfathered those cable/MMDS cross-ownership interests that existed on their effective date. In view of the Commission's tentative position that the exiting Rules fulfill the 1992 Cable Act's mandate with respect to MMDS, the Commission proposes to continue to grandfather only those cable/MMDS cross-ownership interests. No additional cable/MMDS cross-ownership relationships would be grandfathered pursuant to the terms of

[1] Report and Order in Gen. Docket Nos. 90–54 and 80–113, 55 FR 46006, October 31, 1990; Order on Reconsideration in Gen. Docket Nos. 90–54 and 80–113, 56 FR 57596, November 13, 1991; Second Report and Order in Gen. Docket No. 90–54, 56 FR 57808, November 4, 1991.

[2] The Commission has not determined whether, and to what extent, the existing cable/MMDS cross-ownership rules and the 1992 Cable Act cross-ownership restriction apply to Local Multipoint Distribution Service ("LMDS"). This issue is addressed more fully and comments are requested in the Notice of Proposed Rulemaking in CC Docket 92–297, released December 10, 1992.

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the 1992 Cable Act in any event. Cable/SMATV cross-ownership interests will be grandfathered as of October 5, 1992. Furthermore, the 1992 Cable Act permits the Commission to waive the statutory prohibition against cable/MMDS and cable/SMATV cross-ownership to the extent that it is determined that cross-ownership is needed to ensure that all significant portions of a franchise area are able to obtain video programming. Comment is requested on whether the existing public interest waiver standard for cable/MMDS situations is sufficient or whether additional rules or criteria for such waivers in the context of this proceeding should be established. If the Commission adopts such criteria, what types of information would be needed to indicate that cross-owned systems serving the same franchise area provide the only means to distribute multichannel video program service to the public? Finally, the Commission notes that the rules and procedures specified in § 76.7 are applicable for the filing of most requests for waiver of the cable television rules. Should waivers of these cross-ownership rules also be subject to these provisions? Are there any modifications needed to implement these specific cross-ownership waiver requests?

22. With respect to enforcement of the cross-ownership provision, the Commission believes it appropriate to establish procedures for consideration of complaints. The Commission seeks comment regarding what procedures should be adopted to allow participation by all interested parties, and on whether to apply the provisions of § 76.7 of the Commission's Rules (the special relief rules), or some modified form of these procedures, in such cases. Alternatively, cable operators could be required to provide information regarding ownership of MMDS services or SMATV systems in filings required of cable systems, such as the annual Form 325 or on CARS license applications. The Commission asks commenters to consider whether this type of reporting requirement is necessary. In this regard, commenters are asked to suggest the sort of specific information that would be useful.

Subscriber Limits

23. In order to enhance competition, section 11 of the 1992 Cable Act requires the Commission within one year to conduct a proceeding intended to "prescribe reasonable limits on the number of cable subscribers a person is authorized to reach through cable systems owned by such person or in which such person has an attributable interest."

24. Commenters are asked to consider, in commenting on Section 11, the public interest objectives delineated in the 1992 Cable Act:

(A) To ensure that no cable operator or group of cable operators can unfairly impede the flow of video programming from the programmer to the consumer;

(B) To ensure that cable operators do not favor affiliated video programmers in determining carriage and do not unreasonably restrict the flow of video programming of unaffiliated video programmers to other video distributors;

(C) To take account of the market structure, ownership patterns, and other relationships of the cable industry, including the market power of the local franchise, joint ownership of cable systems and video programmers, and the various types of non-equity controlling interests;

(D) To take into account any efficiencies and other benefits that might be through increased ownership or control;

(E) To ensure that such rules and regulations reflect the dynamic nature of the communications marketplace;

(F) To impose limitations that will not prevent cable operators from serving previously unserved rural areas; and

(G) To impose limitations that will not impair the development of diverse and high quality programming.

25. In prescribing subscriber limits, the Commission must, as a preliminary matter, determine the markets in which such subscriber limits should be established. Horizontal concentration may be measured on a local, regional or national basis. The Commission asks commenters to indicate whether regional concentration in any market is sufficient to allow MSOs to exercise undue market power in competing for program acquisition or advertising. Commenters should also describe any efficiencies, economies of scale, and other benefits which result from regional and national concentration. Commenters are asked to indicate whether both regional and national subscriber limits are necessary or appropriate to execute the objectives of the 1992 Cable Act. Commenters are also asked to indicate whether it would be appropriate in calculating compliance with the national subscriber limits to subtract the number of subscribers reached or homes passed by cable systems in areas where effective competition is established.

26. Under the 1992 Cable Act, the Commission may prescribe subscriber limits either as a share of cable subscribers or as a share of homes passed. Commenters should address which of these measures should be used to implement the subscriber limits established in this proceeding. The Commission recognizes that subscriber-based measures have traditionally been used for purposes of analysis. Nonetheless, the Commission believes that homes passed may be a more appropriate and practical measure for this purpose, since it encompasses all television households for which a particular cable operator provides access to cable programming. For this reason and to provide consistency in the interpretation of our rules, the Commission proposes to use a homes passed measure to implement the cable subscriber limits established in this proceeding and seeks comment on this proposal.

27. Commenters are also asked to indicate what percentage of homes passed nationally would constitute a reasonable limit on horizontal concentration. In this regard, commenters should indicate at what percentage of homes passed a single MSO could preclude the success of a new cable service. Are there recent examples of this type of conduct? How many subscribers must be cleared nationally to launch and sustain a new cable programming service? Does the number of subscribers needed vary depending on the type of programming involved? Is it relevant that the Commission's broadcast multiple ownership rules limit the audience reach of television stations in which a person can hold an attributable interest to 25% of television households nationwide? It should also be noted that Commission Rules also provide for increased ownership of broadcast stations representing up to 30% of the television households nationwide if the additional stations are minority owned. The Commission seeks comment on whether to adopt a similar provision in the cable context. The Commission also notes that, under its rules, national television networks are also permitted to own cable systems which reach 10% of the homes passed nationally. Should this figure, which takes into consideration the national audience reach and ability to control programming associated with a broadcast network, serve as a guide in crafting national ownership limits for cable systems? Finally, commenters are asked to indicate whether divestiture should be required for any MSO which exceeds the limit ultimately adopted on the number of homes passed nationally.

28. The attribution criteria contained in § 73.3555 of the Commission's Rules may be useful for determining

ownership in connection with the subscriber limits ultimately established. It should be noted, however, that these attribution criteria were intended to include ownership thresholds which may impart the ability either to influence or control management or programming decisions of a broadcast licensee, and consequently these criteria may not be appropriate to address the concerns at issue in this proceeding. The Commission seeks comment regarding whether these attribution criteria (or a modified version thereof) are appropriate for implementing cable subscriber limits or whether some other attribution criteria would be more suitable. Commenters should also indicate if there are other types of ownership interests, such as non-equity interests, that should be cognizable for purposes of determining ownership under this provision.

29. Jurisdiction and Enforcement. The Commission tentatively concludes that reporting requirements may be unnecessary in connection with enforcing the subscriber limits ultimately adopted. In the alternative, the Commission believes that a system of certification may be an appropriate means of enforcing the subscriber limits imposed. The Commission may, for example, require cable operators upon transfer or assignment of a cable system to certify that such transfer will not result in ownership of cable systems exceeding the subscriber limits established by the Commission. Comment is invited on whether such a certification should be made to the local franchise authority having jurisdiction over the cable system being acquired, or to the Commission. If a system of certification is appropriate, comment is requested on whether all cable systems should be required to make the requisite certification or only the five or ten largest cable systems. The Commission also requests comment on whether such a certification is necessary at all, or whether, in the alternative, the Commission should enforce the subscriber limits on a complaint only basis. Commenters should also indicate if there are other more appropriate procedures to enforce the subscriber limits. The Commission further seeks comment on whether waivers or exceptions to the subscriber limits should be obtainable in appropriate circumstances.

30. The Commission, in compliance with the legislative history of the 1992 Cable Act, proposes to institute a review of the subscriber limits every five years to ensure that they continue to accurately reflect the objectives of the legislation and are reasonable under the prevailing market conditions. Commenters are asked to indicate whether such review procedures are adequate to ensure that subscriber limits continue to serve the objectives for which they were established.

Channel Occupancy Limits

31. Section 11 of the 1992 Cable Act requires the Commission within one year to "prescribe reasonable limits on the number of channels on a cable system that can be occupied by a video programmer in which a cable operator has an attributable interest."

32. Although the 1992 Cable Act does not indicate the ownership standard that should be applied in connection with channel occupancy limits, the Senate Report indicates that the Committee intended for the Commission to use the attribution criteria set forth in § 73.3555, or such other criteria as the Commission may deem appropriate in implementing channel occupancy limits. Comment is requested on whether the attribution criteria contained in § 73.3555 of the Commission's Rules, which are designed to identify ownership interests that afford influence or control over station operations or programming, are appropriate for this purpose. Should any modifications be made for purposes of determining ownership affiliations between cable operators and program services? In the event that the Commission increases the attribution threshold or otherwise modifies the attribution criteria as proposed in MM Docket No. 92–51, 7 FCC Rcd 2654 (1992), commenters should indicate whether the Commission should similarly modify those criteria for purposes of the cable ownership rules. Commenters are asked to address how application of these attribution rules would affect investment by cable operators in new cable programming services. Parties also are asked to indicate whether higher attribution thresholds are warranted in connection with this restriction in order to provide cable operators with the flexibility to continue investing in new cable programming services.

33. The Commission seeks comment on the procedures that should be used in calculating the cable channel occupancy limits ultimately adopted. The 1992 Cable Act and its legislative history are unclear on this issue. The Senate Report suggests that the Commission may establish such limits based on the number of activated channels, less the number of over-the-air broadcast channels, public, educational, governmental and leased access channels carried. Under this approach, using a hypothetical 20% channel occupancy limit, a system with 54 channels, 14 of which are over-the-air channels, would have a channel occupancy limit of 8 channels for MSO affiliated programming. Parties are requested to comment on whether these procedures for calculating channel capacity are appropriate and reasonably serve the objectives of the legislation.

34. In addressing this issue, commenters should consider that one of the objectives of vertical ownership limits was to ensure that unaffiliated cable programmers have a reasonable opportunity to gain access to vertically integrated cable systems. In this regard, the Commission questions whether it is appropriate to subtract the over-the-air broadcast channels, and public, educational, governmental and leased access channels in calculating a system's channel capacity. Broadcast channels contain programming that is competitive with cable programming, and leased access channels provide alternative outlets for unaffiliated video programmers. In addition, the commercial and educational broadcast channels are subject to must-carry requirements, pursuant to section 4 of the 1992 Cable Act. To the extent that carriage of these signals is mandatory, the Commission questions whether it is appropriate for such channels to be subtracted from the total number of channels in calculating channel occupancy limits. Comments are invited to address how such a procedure would serve the statutory objectives of increasing diversity and expanding the number of cable choices available to consumers. The Commission further seeks comment regarding how pay channels, such as HBO, Showtime and pay-per-view channels, should be treated for purposes of calculating the channel occupancy limits, since not all subscribers receive these channels. In addition, what provisions should be made for "multiplexing" of pay channels, where the same programming is shown on several different channels at different times? Commenters should also indicate whether channel occupancy limits apply only to vertically integrated national programming networks, or whether such limits should also apply to vertically integrated regional programming networks.

35. It is unclear from the statutory language and the legislative history how Congress intended such channel occupancy limits to be applied. For example, it is unclear whether such limits were meant to apply only to video programmers affiliated with the particular cable operator or whether

such limits were intended to apply to any cable affiliated video programmer. It is similarly unclear if the latter interpretation is used, whether the channel occupancy limit should be applied so that a total of eight channels could be occupied by all vertically integrated programming combined or whether such a limit should be applied so that the programming of each MSO could occupy up to the maximum of eight channels on such a system. The Senate Report could be read to suggest that the channel occupancy limits should apply to the number of channels that any cable operator can devote to any vertically integrated programming, regardless of whether a programmer is affiliated with that particular cable operator. Commenters are asked to indicate how the channel occupancy limits we ultimately adopt should be applied to most effectively address Congress' concerns.

36. Given the uncertainty surrounding the application of the channel occupancy limits, the Commission believes that the more reasoned approach is to apply such limits only to video programmers affiliated with the particular cable operator. The Commission notes that such an interpretation would be consistent with Congress' objectives of increasing diversity and expanding the number of voices available to consumers. Moreover, such an interpretation addresses Congress' goal of reducing the ability and the incentive of cable operators to favor their own affiliated video programmers. Commenters are asked to indicate whether this proposal is appropriate. In considering this issue, commenters should consider whether vertically integrated programing has an adverse effect on diversity.

37. The Commission also seeks comment on how to determine what constitutes a reasonable channel occupancy limit. What criteria should be used to establish such limits? Are there other regulatory analogies that would be useful in determining what percentage of a cable system's channels should be occupied by vertically integrated program services? In addressing this issue, commenters are asked to consider the vertical relationships and ownership patterns that were reported in appendix G to the 1990 Cable Report. Commenters are asked to provide relevant information, such as the average number of channels occupied by vertically integrated program services. Commenters are also requested to address how the availability of leased access channels should affect the establishment of channel occupancy limits. Commenters are asked to indicate the degree to which vertical integration threatens the ability of rival programming services to obtain cable carriage. It is the Commission's intention to establish a channel occupancy limit that maximizes the number of voices that are available to cable viewers without impairing the ability or incentive of cable operators to invest in new and existing programming services. In this regard, the Commission notes that MSO investment has been essential to the development and continuation of many of the most popular and innovative programming services.

38. The Commission tentatively concludes that it should establish a percentage limit on the number of channels that can be occupied by vertically integrated programming services. Commenters are asked to indicate what percentage of cable channels would be most appropriate to prevent competitive abuses without discouraging investment relationships between cable operators and program services. In suggesting the appropriate percentage limit, commenters are asked to consider the other structural and behavioral restrictions included in sections 12 and 19 of the 1992 Cable Act. Moreover, commenters should consider the must-carry and leased access requirements applicable to cable systems in commenting on this issue.

39. The Commission also seeks comment on what effect emerging technologies such as digital signal compression and fiber optic cable should have on the channel occupancy limits. The Commission proposes to establish a threshold beyond which the channel occupancy limits would not be applicable, and asks commenters to indicate the appropriate number of channels for establishing such a threshold. The Commission suggests that the channel occupancy limits would apply only for channels up to this threshold, with no limits applicable for channels in excess of the threshold.

40. Finally, the Commission seeks comment on whether channel occupancy limits should be phased out in communities where effective competition has developed. Once effective competition has been established and a cable operator no longer occupies a program access bottleneck position, channel occupancy limits may no longer be necessary or desirable. With such developments, the incentive and ability of a cable system to favor its own programming over unaffiliated programming is diminished, and alternative outlets for programming should be available to the public. In seeking comment on this issue, we ask whether phasing out channel occupancy limits under these conditions is consistent with Congressional intent. In addition, we ask whether channel occupancy limits should be lifted for any cable system that meets the effective competition criteria, or whether only certain of those criteria would justify removing the limits.

41. Jurisdiction and Enforcement. The Commission proposes that the local franchise authorities have primary responsibility for enforcement of the channel occupancy limits, as they are most familiar with the channel capacity and programming services carried on the systems within their jurisdiction. Because the Commission seeks to minimize the burden imposed on local franchise authorities and cable operators by these restrictions, it is proposed that such channel occupancy limits should be enforced by certification. Accordingly, cable operators would be required to certify annually to the franchise authority that they are in compliance with the channel occupancy limits ultimately adopted. In order to ensure continuous compliance, cable operators would be obligated to notify the franchise authority within 30 days of any changes during the course of the year which would affect compliance with the channel occupancy restrictions. In addition, a franchise authority would be entitled to request any additional information it determined was reasonably necessary to establish the accuracy of a system's certification, if such certification was challenged. The Commission also proposes to grandfather any existing vertical relationships which exceed the channel occupancy limits at the time such limits are adopted. Comment is invited on this proposal and on whether these procedures are appropriate to ensure compliance with the channel occupancy limits.

Participation in Program Production

42. Section 11 of the 1992 Cable Act also requires the Commission to consider the necessity and appropriateness of imposing limits on the degree to which multichannel video programming distributors ("multichannel distributors") may engage in the creation or production of video programming. As previously stated in this Notice, the 1992 Cable Act mandates that the Commission establish certain structural limits on the development of horizontal and vertical integration in the cable industry. In addition to the structural limits addressed in this proceeding, the 1992 Cable Act establishes certain behavioral restrictions which prohibit

anticompetitive conduct by cable operators in the acquisition of programming. In view of the structural and behavioral restrictions already required under the 1992 Cable Act, the Commission seeks comment on whether additional restrictions on the ability of multichannel distributors to engage in the creation or production of video programming are warranted. The Commission believes that at the present time the objectives of such a restriction may be fully addressed by the other provisions of section 11, section 12, and section 19 of the 1992 Cable Act. Commenters who believe that further restrictions are warranted should indicate what, if any, additional benefits would be achieved by imposing such additional restrictions and what effect they would have on the growth and development of new programming services.

Administrative Matters

Initial Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980, the Commission finds:

43. Reason for the Action: The purpose of this Notice is to establish rules and regulations in accordance with the Cable Television Consumer Protection and Competition Act of 1992 relating to the development of horizontal and vertical ownership limits and implementation of cross-ownership and anti-trafficking provisions.

44. Objective of This Action: The 1992 Cable Act and the subsequent actions to implement it are intended to encourage competition in the cable industry and prevent the exercise of undue market power by horizontally or vertically integrated cable systems. This action is meant to clarify and the interpretation and implementation of sections 11 and 13 of the 1992 Cable Act. This proceeding will codify the statutory anti-trafficking restriction and the cross-ownership restriction. This proceeding will also establish subscriber limits and channel occupancy limits required by the 1992 Cable Act.

45. Legal Basis: Authority for the actions proposed in this Notice may be found in sections 4 and 303, 613, and 617 of the Communications Act of 1934, as amended, 47 U.S.C. 154 and 303, 533 and 537.

46. Reporting, Recordkeeping, and Other Compliance Requirements Inherent in the Proposed Rule: This Notice proposes to implement new certification and filing requirements applicable to cable systems, in order to ensure compliance with the proposed rules.

47. Federal Rules Which Overlap, Duplicate, or Conflict With the Proposed Rule: None.

48. Description, Potential Impact and Number of Small Entities Involved: Approximately 11,000 existing cable systems of all sizes may be affected by the proposals contained in the Notice. In addition, an unknown number of video programming sources may be affected.

49. Any Significant Alternatives Minimizing the Impact of Small Entities and Consistent With the Stated Objectives: The purpose of this Notice is to seek comment on issues including alternatives that would minimize the impact on small entities.

50. As required by section 603 of the Regulatory Flexibility Act, the FCC has prepared an initial regulatory flexibility analysis (IRFA) of the expected impact of these proposed policies and rules on small entities. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Notice of Proposed Rule Making and Notice of Inquiry, but they must have a separate and distinct heading designating them as responses to the regulatory flexibility analysis. The Secretary shall cause a copy of this Notice of Proposed Rule Making and Notice of Inquiry, including the initial regulatory flexibility analysis, to be sent to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164, 5 U.S.C. section 601 *et seq.* (1981).

Ex Parte

51. This is a non-restricted notice and comment rule making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's Rules. See generally 47 CFR 1.1202, 1.1203, and 1.1206(a).

Comments

52. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before February 9, 1993, and reply comments on or before March 3, 1993. To file formally in this proceeding, you must file an original plus four copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, room 239, Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

Ordering Clauses

53. Authority for this Notice of Proposed Rule Making is contained in sections 4(i) and (j), 303, 613 and 617 of the Communications Act of 1934, as amended.

List of Subjects in 47 CFR Part 76

Cable television.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–448 Filed 1–8–93; 8:45 am]

BILLING CODE 6712–01–M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1312

[Ex Parte No. MC–211]

Revision of Tariff Regulations—Indexes

AGENCY: Interstate Commerce Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Commission is considering whether there is a need to reimpose requirements for tariff indexes, and if so, what kinds of indexes should be required. Because many tariffs now on file contain thousands of pages but no indexes, the rates applicable to particular shipments can be difficult to determine. Indexes may improve the public's ability to determine the rates which are contained in the tariffs and which are therefore applicable by law.

DATES: Comments are due on March 8, 1993.

ADDRESSES: Send comments (an original and 10 copies) referring to Ex Parte No. MC–211 to: Interstate Commerce Commission, Office of the Secretary, Case Control Branch, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Larry Herzig, (202) 927–5180. (TDD for hearing impaired (202) 927–5721).

SUPPLEMENTARY INFORMATION: In Revision of Tariff Regulations, All Carriers, 1 I.C.C.2d 404 (1984), the Commission adopted new tariff

publishing rules. In so doing, the Commission decided to remove the rule requiring indexing. First, the Commission believed that carriers would continue to publish indexes if they were necessary for marketing reasons. Second, a high volume of change in tariff matter would make indexes difficult to maintain. Finally, the requiring of indexes seemed unnecessary and burdensome because if indexes were useful competition would force carriers to provide them. It now appears that indexes may be important and useful but that carriers are not providing them. The purpose of this proceeding, initiated in part because of a request from Congress that we do so,[1] is to determine if there is a need for reimposing requirements for tariff indexes, and if so, what kinds of indexes we should require.

The primary purpose behind tariffs is to inform all interested parties of the services, practices and rates offered to the public by common carriers. A secondary purpose is to protect shippers by insuring that any rates and related provisions negotiated with carriers are honored. In order to implement these purposes, a shipper must be able to locate a given rate in a carrier's tariff, not only the rate covering the shipper's own traffic but also the rates and provisions covering a competitor's traffic. It would appear to be an undue burden on tariff users for carriers to construct tariffs without affording users the means for determining where they can obtain all information required to be on file under the statute and our regulations.

Our files indicate that many carriers have not found it in their interest to publish and maintain indexes in their tariffs. Moreover, there are tariffs on file with this Commission which contain well over 100,000 pages, without indexes, which are not arranged in any logical order. Needless to say, it is very difficult to locate provisions contained in these tariff publications. While maintaining comprehensive indexes may indeed be a burden on carriers, the present circumstances suggest that reimposing the indexing requirement would be in the public interest.

While indexes may well be necessary for commodity rate tariffs and tariffs naming specific discounts, they would appear not to be necessary for other types of tariffs which are arranged in a manner which allows a tariff user to easily find information. For example, in certain class rate tariffs the origin and destination points are listed alphabetically or geographically. Also, the classification assigning class ratings to all commodities has an index. Historically, the Commission's tariff publishing regulations indexes only for commodity rate tariffs, because discounts were not a usual form of tariff publication. At the time discounts were beginning to proliferate, the Commission removed the requirement for indexes.

After receipt of comments, we may propose regulations which would require that tariffs contain indexes when they are arranged in a manner which does not allow a tariff user to find information quickly, accurately, and completely. In the past our regulations have required every filed common carrier tariff to contain indexes of contents, commodities, origin points, and destination points. It has now become apparent that some sort of index may also be needed for tariffs which contain service, practices, or rate information which is applicable only to individual customers or accounts. Further, it may be appropriate to require that all carriers file an index listing the tariffs they have filed with the Commission and which also lists the rate bureau tariffs that the carriers participate in.

However, before we make proposals we would like to consider the views of all parties which may be interested in this issue. Comments concerning the need to reimpose a requirement of indexing, as well as the types of indexes which are needed in today's competitive environment are solicited.

Regulatory Flexibility

Because this not a notice of proposed rulemaking within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we need not make, at this time, the small business impact examination required by that Act. Nevertheless, we welcome any comments regarding the small entities considerations embodied in that Act. If we decide to issue a notice of proposed rulemaking, we will conduct an appropriate Regulatory Flexibility Act examination at that time.

Environmental Statement

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Authority: 49 U.S.C. 10761(a) and 10762.

List of Subjects in 49 CFR Part 1312

Motor carriers, Moving of household goods, Pipelines.

Decided: December 23, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary

[FR Doc. 93–488 Filed 1–8–93; 8:45 am]

BILLING CODE 7035–01–M

[1] Senate Report No. 102–351, dated July 30 1992, and accompanying the U.S. Department of Transportation and Related Agencies Appropriations Bill, 1993

Notices

Federal Register
Vol. 58, No. 6
Monday, January 11, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF COMMERCE

Bureau of Export Administration

[Docket No. 921246–2346]

Foreign Availability Assessment: Advanced High Speed Modems

AGENCY: Office of Foreign Availability, Bureau of Export Administration, Commerce.

ACTION: Notice of Initiation of an Assessment and Request for Comments.

SUMMARY: The Office of Foreign Availability (OFA) is providing notice that it has initiated an assessment of foreign availability of advanced high speed modems operating above the current control level of 9,600 bits per second to both noncontrolled and controlled countries. OFA will assess foreign availability under part 791 of the Export Administration Regulations (EAR). OFA is seeking public comments on the foreign availability of these items worldwide.

DATES: The period for submission of information will close on February 10, 1993.

ADDRESSES: Submit information relating to this foreign availability assessment to: Steven C. Goldman, Office of Foreign Availability, Bureau of Export Administration, U.S. Department of Commerce, room 1087, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230.

The public record concerning this notice will be maintained in the Bureau of Export Administration's Freedom of Information Record Inspection Facility, room 4518, U.S. Department of Commerce, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Laure Ferguson, Office of Foreign Availability, Department of Commerce, Washington, DC 20230, Telephone: (202) 482–5953.

SUPPLEMENTARY INFORMATION: Although the Export Administration Act (EAA) expired on September 30, 1990, the President, invoking the International Emergency Economic Powers Act, continued in effect the powers of the EAA and the Export Administration Regulations (EAR), to the extent permitted by law, in the Executive Order 12730 of September 30, 1990.

Part 791 of the EAR (15 CFR 730 *et seq.*) establishes the procedures and criteria for determining the foreign availability of goods and technology whose export is controlled and controlled destinations. This equipment is controlled for national security reasons.

On December 7, 1992, OFA initiated a foreign availability assessment pursuant to § 791.4 of the EAR relating to the decontrol of advanced high speed modems using the "bandwidth of one voice channel" with a "data signalling rate" exceeding the current control parameter of 9,600 bits per second to both noncontrolled for national security reasons under paragraph (c)(1) Export Control Classification Number (ECCN) 5A02A of the Commerce Control List (CCL) (15 CFR 799.1, Supp. 1): "Telecommunications transmission equipment".

By May 7, 1993, the Department intends to submit for publication in the **Federal Register** its determination of the foreign availability of the item.

To assist OFA in assessing such foreign availability, any person may submit relevant information to OFA at the above address.

The following information would be especially useful:

—Product names and model designations of the U.S. and non-U.S. items;
—Names and locations of non-U.S. sources;
—Key performance elements, attributes, and characteristics of the items on which quality comparisons may be made;
—Non-U.S. sources' production quantities and/or sales of any allegedly comparable item;
—An estimate of market demand and the potential economic impact of the control on the U.S. item;
—Extent to which any allegedly comparable item is based on U.S. technology;
—Product names, model designations, and value of U.S. controlled parts and components incorporated in any allegedly comparable item; and
—Information supporting the proposition that the foreign item is in fact available to the country or countries for which foreign availability is alleged.

Evidence supporting such relevant information may include, but is not limited to: Foreign manufacturers' catalogs, brochures, or operations or maintenance manuals; articles from reputable trade publications; photographs; and depositions based upon eyewitness accounts. Supplement No. 1 to Part 791 of the EAR provides additional examples of evidence that would be helpful to the investigation.

OFA will also accept comments or information accompanied by a request that part or all of the material be treated confidentially because of its proprietary nature or for any other reason. The information for which confidential treatment is requested should be submitted to OFA separately from any non-confidential information. The top of each page should be marked with the term "Confidential Information." Confidential submissions must include a statement from the submitter that the material is commercial or financial information which the submitter does not customarily release to the public. If OFA will not accept the submission in confidence, it will return it. A non-confidential summary must accompany any submission of confidential information. OFA will make the summary available for public inspection.

Regardless of whether the submitter has requested confidential treatment, OFA will maintain the confidentiality of any information exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). This may include communications from agencies of the United States Government and foreign governments which are exempt from disclosure under the Freedom of Information Act.

All other information received in response to this notice will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires written comments. Oral comments must be followed by written memoranda, which also will be a matter of public

record and will be available for public review and copying.

The public record of information received in response to this notice will be maintained in the Bureau of Export Administration's Freedom of Information Records Inspection Facility, room 4525, Department of Commerce, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in part 4 of title 15 of the Code of Federal Regulations.

Information about the inspection and copying of records at the facility may be obtained from Margaret Cornejo, Bureau of Export Administration, Freedom of Information Officer, at the above address or by calling (202) 482–5653.

Due to the strict statutory time limitations in which Commerce must make its determination, the period for submission of relevant information will close on February 10, 1993. The Department will consider all information received before the close of the comment period in developing the assessment. Information received after the end of the period will be considered if possible, but its consideration cannot be assured.

Accordingly, the Department encourages persons who wish to provide information related to this foreign availability submission to do so at the earliest possible time to permit the Department the fullest consideration of the information.

Dated: January 5, 1993.

James M. LeMunyon,

Acting Assistant Secretary for Export Administration.

[FR Doc. 93–468 Filed 1–8–93; 8:45 am]

BILLING CODE 3510–DT–M

Foreign-Trade Zones Board

[Order No. 624]

Approval for Processing Activity (Auto Audio Components) Within Foreign-Trade Zone 64; Jacksonville, FL

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u) (the Act), and the Foreign-Trade Zones (FTZ) Board Regulations (15 CFR part 400), the Foreign-Trade Zones Board (the Board) adopts the following order:

Whereas, § 400.28(a)(2) of the Board's regulations, requires approval of the Board prior to commencement of new manufacturing/processing activity within existing zone facilities;

Whereas, Trade Zone Operations, Inc., operator of FTZ 64, Jacksonville, Florida, has requested authority under § 400.32(b)(1) of the Board's regulations on behalf of General Motors Corporation, Chevrolet Motor Division, to use zone procedures for the installation of foreign auto audio components into automobiles assembled abroad for GM (filed 10/29/92, A(32b1)–6–92; Doc. 39–92, assigned 12/22/92);

Whereas, Pursuant to § 400.32(b)(1), the Commerce Department's Assistant Secretary for Import Administration has authority to act for the Board in making such decisions on new manufacturing/processing activity under certain circumstances, including situations where the proposed activity is the same in terms of products involved, to activity recently approved by the Board under similar circumstances (§ 400.32(b)(1)(i)); and,

Whereas, the FTZ Staff has reviewed the proposal, taking into account the criteria of § 400.31, and the Executive Secretary has recommended approval;

Now, therefore, the Assistant Secretary for Import Administration, Acting for the Board pursuant to § 400.32(b)(1), concurs in the recommendation and hereby approves the request subject to the Act and the Board's Regulations (as revised, 56 FR 50790–50808, 10/8/91), including § 400.28.

Signed at Washington, DC, this 30th day of December, 1992, pursuant to Order of the Board.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates, Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–544 Filed 1–8–93; 8:45 am]

BILLING CODE 3510–DS–M

[Docket A(28a3)–2–92]

Foreign-Trade Subzone 29C, General Electric Company, Louisville, KY; Compressors for Refrigerators and Room Air Conditioners

The Foreign-Trade Zones Board (the Board) has been notified pursuant to § 400.28(a)(3) of the Board's regulations by the General Electric Company (GE), operator of Foreign-Trade Subzone 29C, Louisville, Kentucky, with additional information as to the use of zone procedures for foreign-sourced compressors used in the manufacture of refrigerators and room air conditioners at the GE home appliance manufacturing plant in Louisville, Kentucky.

The Board authorized subzone status for the GE plant in December 1985 (Board Order 321, 50 FR 52180, 12/27/85). Manufacturing authority involves the production of large home appliances including refrigerators, dishwashers, dryers, electric ranges, and room air conditioners for the U.S. market and for export using certain materials and components sourced from abroad.

The original application listed certain components sourced from abroad to be admitted to the subzone in foreign status. While compressors are among the items sourced abroad, they were now included in that list. GE has not notified the Board that it wishes to admit the compressors (HTSUS #8414.30, duty rate: 3.4%) sourced abroad into the subzone in foreign status. The manufacturing activity otherwise remains unchanged.

Zone procedures would exempt GE from Customs duty payments on the foreign components used in production for export. On domestic sales, the firm would be able to choose the duty rate for finished refrigerators and air conditioners (2.9% and 2.2%) to apply to the foreign-origin compressors (duty rate 3.4%).

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is February 10, 1993. A copy of the request will be available for public inspection at the following location: Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, room 3716, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230.

Dated: December 31, 1992.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–547 Filed 1–8–93; 8:45 am]

BILLING CODE 3510–DS–M

[Docket No. 38–92]

Foreign-Trade Zone 84; Harris County, TX; Application for Expansion (Houston Port of Entry), Zone Site #11—Oiltanking of Houston, Inc., Houston, TX

An application has been submitted to the Foreign-Trade Zones Board (the Board) by the Port of Houston Authority, grantee of FTZ 84, requesting authority to expand Zone Site 11 at the liquid bulk storage facilities of Oiltanking of Houston, Inc. (Oiltanking) (formerly Oiltanking of Texas, Inc.)

located in Houston, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally filed on December 22, 1992.

The FTZ Board approved FTZ 84 in 1983 (Board Order 214, 48 FR 34792, 8/1/83), and the zone project currently includes 12 sites in Harris County, Texas. Zone Site 11 (50 acres) covers a portion of the Oiltanking facility. It was authorized by the Board for the storage of liquid bulk products in 1988 (Board Order 409, 53 FR 53042, 12/30/88). The facility is located at 15602 Jacintoport Blvd. in Houston, Texas.

The application requests authority to expand Site 11 to cover the entire Oiltanking facility (269 Acres). The expansion would include new storage facilities constructed since 1988, adding 6 million barrels of liquid bulk storage capacity to the 3.1 million barrels at existing site 11. All limitations (e.g., no blending, processing) stated in Board Order 409 authorizing the original site would apply to the expanded site.

In accordance with the Board's regulations, a member of the FTZ Staff has been designated examiner to investigate the application and report to the Board.

Public comment is invited from interested parties. Submissions (original and 3 copies) shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is March 12, 1993. Rebuttal comments in response to material submitted during the subsequent 15-day period is March 29, 1993.

A copy of the application will be available for public inspection at each of the following locations:

U.S. Department of Commerce District Office, #1 Allen Center, 500 Dallas, Suite #1160, Houston, Texas 77002.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 3716, 14th & Constitution Avenue, NW., Washington, DC 20230.

Dated: December 30, 1992.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–546 Filed 1–8–93; 8:45 am]

BILLING CODE 3510–DS–M

[Order No. 620]

Expansion of Foreign-Trade Zone 94 Laredo, TX

Pursuant to its authority under the Foreign-Trade Zones (FTZ) Act of June 18, 1934, as amended (19 U.S.C. 81a–81u) (the Act), and the FTZ Board Regulations (15 CFR part 400), the FTZ Board (the Board) adopts the following Resolution and Order:

Whereas, an application from the City of Laredo, Texas, grantee of Foreign-Trade Zone No. 94, for authority (subject to an activation limit) to expand its general-purpose zone to include a site at the International Commerce Center in Laredo, Texas, within the Laredo Customs port of entry, was filed by the Board on November 6, 1991, and notice inviting public comment was given in the **Federal Register** on December 2, 1991 (Docket 77–91, 56 FR 61228);

Whereas, an examiners committee has investigated the application in accordance with the Board's regulations and recommends approval;

Whereas, the expansion is necessary to improve and expand zone services in the Laredo area; and,

Whereas, The Board has found that the requirements of the Act and the Board's regulations are satisfied, and that approval, subject to an activation limit, is in the public interest;

Now, Therefore, the Board hereby orders: That the grantee is authorized to expand its zone in accordance with the application filed on November 6, 1991, subject to the Act and the Board's regulations (as revised, 56 FR 50790–50808, 10–8–91) including § 400.28, and subject to the condition that further Board approval is required prior to activation at the International Commerce Center site beyond 1,500 acres.

Signed at Washington, DC, this 29th day of December, 1992.

Alan M. Dunn,

Assistant Secretary of Commerce for Import Administration, Chairman, Committee of Alternates Foreign-Trade Zones Board.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 93–545 Filed 1–8–93; 8:45 am]

BILLING CODE 3510–DS–M

International Trade Administration

[A–351–813]

Preliminary Determination of Sales at Less Than Fair Value: Certain Alloy and Carbon Hot-Rolled Bars, Rods, and Semifinished Products of Special Bar Quality Engineered Steel From Brazil

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 11, 1993.

FOR FURTHER INFORMATION CONTACT: Cherrie L. Rusnak or Linda L. Pasden, Office of Agreements Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone: (202) 482–3793.

PRELIMINARY DETERMINATION: We preliminarily determine that certain alloy and carbon hot-rolled bars, rods, and semifinished products of special bar quality engineered steel from Brazil are being, or are likely to be, sold in the United States at less than fair value, as provided in section 733 of the Tariff Act of 1930, as amended (the Act). The estimated margins are shown in the "Suspension of Liquidation" section of this notice.

Case History

Since the initiation of this investigation on June 29, 1992 (57 FR 29703, July 6, 1992), the following events have occurred.

On July 24, 1992, the U.S. International Trade Commission (ITC) issued an affirmative preliminary injury determination.

On August 14, 1992, the Department presented questionnaires to Industries Villares, S.A. and its related companies (Villares) with regard to finished bars and rods, and to Aco Minas Gerais S.A. (ACOMINAS) with regard to semifinished products. These companies accounted for the overwhelming majority of imports of the subject merchandise from Brazil during the period of investigation. Responses to the questionnaires were originally due on August 27, 1992 and September 14, 1992. At Villares' request, the Department granted extensions until September 3, 1992 for section A and September 28, 1992 for sections B and C of its response. At the request of ACOMINAS, the Department granted extensions until September 1, 1992 for section A and September 28, 1992 for sections B and C of its response. Villares and ACOMINAS submitted their questionnaire responses on the deadlines specified.

On September 21, 1992 and September 22, 1992, petitioners provided comments on the section A responses of ACOMINAS and Villares, respectively. Petitioners requested, on October 6, 1992, a postponement of the preliminary determination from November 16, 1992 until January 5, 1993. The postponement was granted on October 15, 1992 (57 FR 48356, October 23, 1992). On October 7, 1992, petitioners alleged that ACOMINAS and Villares sold the subject merchandise in the home market below its cost of

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production (COP). Petitioners submitted comments on the sections B and C responses of both ACOMINAS and Villares on October 15, 1992. Additional comments were provided by petitioners on October 19, 1992 regarding ACOMINAS' sections B and C responses. We issued a supplemental questionnaire and the constructed value questionnaire to ACOMINAS on October 22, 1992. Villares was issued a supplemental questionnaire and a constructed value questionnaire on October 23, 1992. The supplemental questionnaire responses were received from ACOMINAS and Villares on November 5, 1992 and November 13, 1992, respectively.

On October 30, 1992, a COP questionnaire was presented to Villares. ACOMINAS, on November 9, 1992, requested an extension of time to respond to the constructed value questionnaire until December 4, 1992. The Department issued revised model match instructions on November 13, 1992, concerning changes in the methodology used by the Department to compensate for the effects of hyperinflation. Also on November 13, 1992, Villares requested an extension until December 7, 1992, for submission of the revised product concordance, U.S. sales listing, and constructed value/COP information. On November 17, 1992, the Department granted both ACOMINAS' and Villares' requests for extension and issued a second supplemental questionnaire to ACOMINAS.

A COP questionnaire was presented to ACOMINAS on November 18, 1992, which was due and received on December 18, 1992. Also on November 18, 1992, ACOMINAS requested an extension for submission of the second supplemental questionnaire response until November 24, 1992, and requested an additional extension of time until December 4, 1992, to prepare the constructed value response and to prepare a new product concordance in accordance with the Department's November 13, 1992 revised model match instructions. The Department granted this request on November 20, 1992.

On December 2, 1992, the Department met with counsel for ACOMINAS to allow them to explain several discrepancies the Department found in the home market sales, U.S. sales, and differences-in-merchandise databases submitted on November 25, 1992. During this meeting, counsel stated that the product concordance, which was due to the Department on December 4, 1992, had not been done in accordance with the Department's November 13, 1992 revised model match instructions. They stated that ACOMINAS would be revising the concordance and submitting a new one along with the cost of production data on December 18, 1992. However, a request for extension was never received from ACOMINAS regarding the product concordance. Upon receipt of the December 4, 1992 submission, the Department confirmed that the product concordance was not completed in accordance with the instructions issued on November 13, 1992.

On December 2, 1992, the Department issued a second deficiency letter to Villares. The response was due, and was subsequently received, on December 7, 1992. On December 3, 1992, ACOMINAS submitted revised total home market sales volume and value information. Petitioners filed comments regarding legal and factual issues pertinent to the Department's preliminary determination on December 7, 1992.

On December 15, 1992, Villares submitted comments on the Department's change in its methodology concerning difference in merchandise adjustments for price-to-price comparisons. On December 16, 1992, Villares submitted revisions to its U.S. sales listing and cost of production information. Villares submitted further revisions on December 18, 1992 to both the cost of production and constructed value databases. On December 22, 1992, Villares again submitted revised calculations to both the cost of production and the constructed value databases, along with printouts and a revised computer tape.

On December 18, 1992, petitioners submitted comments regarding the constructed value responses filed by ACOMINAS and Villares on December 4, and December 7, 1992, respectively. On this same date, ACOMINAS submitted its cost of production response along with a revised product concordance. ACOMINAS filed, on December 22, 1992, a list of corrections to its December 4, 1992 constructed value information, and to the December 18, 1992 cost of production and product concordance.

Scope of Investigation

The products covered in this investigation are:

- Hot-finished alloy and carbon bars and rods of special bar quality engineered steel.
- Semifinished products of special bar quality engineered steel.

The term "hot-finished alloy and carbon bars and rods of special bar quality engineered steel" covers certain hot-finished carbon and alloy steel (other than stainless steel, high-speed steel, silico-manganese steel, and tool steel) bars and rods, other than forged, which have a uniform solid cross-section along their whole length and are in the shape of circles, segments of circles, ovals, rectangles, triangles, or other convex polygons, and do not conform to the definitions for semifinished steel, flat-rolled products, hot-rolled bars and rods in irregularly wound coils, reinforcing bars and rods, and wire. The subject bars and rods are of special bar quality engineered steel that is described in Society of Automotive Engineers (SAE) J403, J404, J411, J1081, J1249, J1268, and modifications thereof, whether they be domestic or foreign, of other than merchant quality grades M 1000 through M 1044, not containing by weight 0.03 percent or more of lead or 0.05 percent or more of bismuth, as classifiable under the following subheadings of the Harmonized Tariff Schedule of the United States (HTS): 7214.30.0000, 7214.40.0010, 7214.40.0030, 7214.40.0050, 7214.50.0010, 7214.50.0030, 7214.50.0050, 7214.60.0010, 7214.60.0030, 7214.60.0050, 7228.30.8005, and 7228.30.8050.

The term "semifinished products of special bar quality engineered steel" covers certain alloy steel ingots (other than stainless steel, high-speed steel, silico-manganese steel, tool steel, and high-nickel alloy steel), and semifinished products of carbon and alloy steel (other than stainless steel, high-speed steel, silico-manganese steel, tool steel, and high-nickel alloy steel) of circular or rectangular (including square) cross-section with a width measuring less than four times the thickness, of special bar quality engineered steel that is described in Society of Automotive Engineers (SAE) J403, J404, J411, J1081, J1249, J1268, and modifications thereof, whether they be domestic or foreign, not containing by weight 0.03 percent or more of lead or 0.05 percent or more of bismuth, as classifiable under the following subheadings of the Harmonized Tariff Schedule of the United States (HTS): 7207.11.0000, 7207.12.0010, 7207.19.0030, 7207.20.0025, 7207.20.0075, 7224.10.0075, 7224.90.0045, and 7224.90.0065.

Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

Class or Kind of Merchandise

When the Department initiated this investigation on June 29, 1992 (57 FR

29703), we provisionally accepted petitioners' claim that the subject merchandise comprised one class or kind. However, we also noted our reservations regarding petitioners' claim, and allowed for a 14-day period during which interested parties were requested to comment on the scope of this proceeding. The Department summarized its concerns regarding the class or kind issue in more detail in a memorandum to the file dated July 17, 1992.

During the comment period, the Department received comments from petitioners and respondents and from one importer of the subject merchandise. Department staff also toured petitioners' steelmaking facilities on July 28, 1992, to gain more detailed knowledge about the production process and channels of trade of the subject merchandise.

In considering whether the merchandise subject to investigation comprised one or several classes or kinds of merchandise, the Department applied the criteria used to evaluate class or kind of merchandise established in *Diversified Products* versus *United States*, 6 CIT 155 (1983), and incorporated into our examination an analysis of the comments received and of the information collected during the steel plant tours. Based on our examination, we determined in a decision memorandum of August 12, 1992, that the subject merchandise of this investigation constitutes two distinct classes or kinds: Alloy and carbon hot-rolled bars and rods of special bar quality engineered steel, and semifinished products of special bar quality engineered steel.

In our August 12 decision memorandum, we noted that there are distinct differences in physical characteristics between semifinished products and hot-rolled bars and rods of special bar quality engineered steel. We explained that semifinished products have a larger grain structure, a rough appearance, and relatively inexact tolerances, while hot-rolled bars and rods have smaller grains and a much smoother surface condition with few or no surface imperfections, and tolerances that are significantly more exacting than those for semifinished products. We also noted that semifinished products and hot-rolled bars and rods of special bar quality engineered steel have different ultimate uses, in that semifinished products are usually further hot-rolled by steel companies (although they are forged in a minority of instances), while hot-rolled bars and rods have numerous ultimate uses, including machining, forging, and hot- and cold-forming. We concluded that the expectations of the ultimate purchasers of semifinished products and hot-rolled bars and rods of special bar quality engineered steel are different. Specifically, consumers of hot-rolled bars and rods expect a product which meets relatively exacting tolerances, while consumers of semifinished products do not require such exacting specifications. We observed that semifinished products and hot-rolled bars and rods of special bar quality engineered steel have different channels of trade, as most semifinished products are consumed internally by steelmakers and generally cannot be used by outside customers, while hot-rolled bars and rods are normally sold to outside customers who perform various operations on the product. Finally, we noted that semifinished products and hot-rolled bars and rods of special bar quality engineered steel are advertised differently, as semifinished products are not generally sold to outside customers and therefore are not generally advertised, while hot-rolled bars and rods generally are sold and advertised to producers of end-user products.

Period of Investigation

The period of investigation (POI) is January 1, 1992 through June 30, 1992.

Use of Best Information Available

ACOMINAS

As stated above, the product concordance submitted by ACOMINAS on December 4, 1992 was not done in accordance with the Department's revised model match instructions issued on November 13, 1992. A request for extension to revise and resubmit this information was never received from ACOMINAS. However, this respondent did in fact file a revised product concordance on December 18, 1992 and, on December 22, 1992, submitted corrections to be made to the concordance.

In its December 23, 1992 submission, ACOMINAS argued that the Department should use home market prices or constructed value as the basis for foreign market value in its preliminary determination. Respondent further argued that the Department had sufficient time to incorporate the December 18, 1992 cost of production data into its preliminary determination. However, no mention was made of the new product concordance which was also submitted on December 18, 1992.

ACOMINAS is incorrect in its claim that the Department had sufficient time to use the information submitted on December 18, 1992 in making its preliminary determination. Because respondent did not submit a complete and accurate response in a timely manner, the Department was, in fact, unable to perform a complete and accurate analysis of ACOMINAS' selling practices in time for its preliminary determination. The best information rule prevents a respondent from controlling the results of the investigation by providing partial information or by delaying or otherwise hindering the investigation. The Department is not required to use selected portions of an incomplete response, and is thus justified in relying on information supplied by petitioners as the "best information otherwise available." *Pistachio Group of the Ass'n of Food Indus.* v. *United States*, 11 CIT 668, 679, 671 F. Supp. 31, 40 (1987).

However, because ACOMINAS has submitted a revised product concordance on the record which will be reviewed for possible consideration for use in the final determination, and has been cooperative throughout this proceeding, we used the average margin (of the 1992 sales) alleged in the petition for semifinished products, which is 19.67%, as best information available for the preliminary determination.

Villares

The Department reviewed the cost of production and constructed value information submitted by Villares on December 7, 1992 and found several fundamental flaws which the Department was unable to correct.

For example, Villares' submitted material costs, which are a significant component of the cost of manufacture for special bar quality engineered steel, were based on standard yield rates, i.e., the theoretical quantity of consumption of each type of material for each stage of production, instead of actual usage. In addition, respondent computed average acquisition "at sight" prices for each raw material type by reducing the gross unit price recorded on invoices by an imputed financing amount, claiming that the gross unit prices are inclusive of financing charges for extended payment terms. However, no documentation was submitted to support this claim, and it does not appear that Villares' normal accounting system adjusts for payment terms. In addition, adjusting for payment terms appears to double count the benefit received from delayed payment since the Department already reduces COP and constructed value by short term interest income (see Memorandum to Marie E. Parker, Office of Accounting, dated December 28, 1992). The

computer tapes submitted by Villares reflected only the "at sight" figures, and not the gross unit prices. Therefore, the Department was itself unable to revise the computer program to reflect gross unit input prices.

Because all of the pertinent information was not provided on the computer tapes (i.e., the gross prices for raw material inputs), because certain requested data were not provided at all (i.e., actual yields), and because there were various incorrect calculations, the Department determined that this information could not be used to reflect accurately the production costs for the POI. See *Rhone Poulenc, Inc.* v. *United States*, 13 CIT 218, 710 F.Supp. 341, (1989). Therefore, in accordance with section 353.37(a)(1) of the Department's regulations, we have resorted to the best information available for the preliminary determination.

However, because a deficiency letter has not yet been issued regarding the COP and constructed value data and, like ACOMINAS, Villares has been cooperative throughout this proceeding, we used the average margin (of the 1992 sales) alleged in the petition for finished bars and rods, which was 57.00%, as the best information available for the preliminary determination (see § 353.37(b)).

Verification

As provided in section 776(b) of the Act, we will verify the information used in making our final determination.

Suspension of Liquidation

In accordance with section 733(d)(1) of the Act, we are directing the Customs Service to suspend liquidation of all entries of certain alloy and carbon hot-rolled bars, rods, and semifinished products of special quality engineered steel from Brazil that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. The Customs Service shall require a cash deposit or posting of a bond equal to the estimated preliminary dumping margins, as shown below. This suspension of liquidation will remain in effect until further notice. The average dumping margins are as follows:

Producer/manufacturer/exporter	Weighted-average margin percentage
Semifinished products	
Aco Minas Gerais S.A.	19.67
All others	19.67
Finished bars and rods	
Industrias Villares S.A. and its related companies	57.00
All others	57.00

ITC Notification

In accordance with section 733(f) of the Act, we have notified the ITC of our determination. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threatening material injury to, the U.S. industry.

Public Comment

In accordance with 19 CFR 353.38, case briefs or other written comments, in at least ten copies, must be submitted to the Assistant Secretary for Import Administration no later than March 3, 1993. Rebuttal briefs must be submitted no later than March 8, 1993. In accordance with 19 CFR 353.38(b), we will hold a public hearing, if requested, to afford interested parties an opportunity to comment on arguments raised in case or rebuttal briefs. Tentatively, the hearing will be held on March 10, 1993, at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Parties should confirm by telephone the time, date, and place of the hearing 48 hours before the scheduled date.

Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Import Administration, U.S. Department of Commerce, room B–099, within ten days of the publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. In accordance with 19 CFR 353.38(b), oral presentations will be limited to issues raised in the briefs.

This determination is published pursuant to section 733(f) of the Act and 19 CFR 353.15(a)(4).

Dated: January 5, 1992.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 93–542 Filed 1–8–93; 8:45 am]

BILLING CODE 3510–DS–M

Special Export Permit Determination: Certain Machining Center Frames and Machining Centers

AGENCY: Import Administration/ International Trade Administration, Commerce.

ACTION: Notice of determination denying authorization of special export permits for certain machining center frames and machining centers.

SUMMARY: The Department of Commerce ("Department") hereby denies a request for special export permits for 400–450 machining center frames for 1992 and 1993, and 50 machining centers for July–December 1992, under Paragraph 9 of the Understanding Between the Coordination Council for North American Affairs and the American Institute in Taiwan Concerning Trade in Certain Machine Tools.

FOR FURTHER INFORMATION CONTACT: Joseph A. Spetrini, Import Administration, U.S. Department of Commerce, room 3069A, 14th Street & Constitution Avenue, NW., Washington, DC 20230 (202) 482–2104.

SUPPLEMENTARY INFORMATION: Pargraph 9 of the Understanding Between the Coordination Council for North American Affairs (CCNAA) and the American Institute in Taiwan (AIT) Concerning Trade in Certain Machine Tools (Understanding) provides for the authorization of special export permits. Such permits allow the importation of machine tools from the territory represented by CCNAA to the territory represented by AIT in excess of the applicable export limit provided for in the Understanding when we determine that: (a) Approval would serve a unique national security need; (b) approval would directly lead to an increase in U.S. machine tool manufacturing capacity; and/or (c) comparable tools are not available from U.S. manufacturers or suppliers. Special export permits are authorized for a limited time period and for a specified number of machines, on a product-by-product basis.

On June 26, 1992, Hurco Companies, Inc. (Hurco) submitted a special export permit authorization request for 400–450 cast iron frames for machining centers for 1992 and 1993, and 50 machining centers without numerical controls for July–December 1992 under Paragraph 9 of the Understanding. The requested products are considered to be substantially complete machine tools subject to the quantitative export limits of the Understanding.

On July 2, 1992, the Department published a notice which announced Hurco's request in the **Federal Register** and provided an opportunity for public comments (57 FR 29628). Initial comments were to be submitted no later than July 6, 1992, with replies to those comments due no later than July 10, 1992. A public record of these comments is on file in the Central Records Unit, room B–099, Import Administration, U.S. Department of Commerce, at the above address.

The Department received a total of 35 comments to the **Federal Register** notice. Included in these comments were three submissions (Met-Coil Systems Corporation, The National Acme Company, and Deputy Assistant Secretary of Defense David Berteau) supporting Hurco's request, and rebuttal comments by Hurco. The two companies that supported Hurco's request did not address the criteria specifically, but rather submitted brief, general statements of support. The remaining 31 comments objected to Hurco's request.

Analysis

The Department analyzed Hurco's request, and the comments received, in the context of the criteria for authorizing special export permits outlined above. Each criterion is addressed below.

Unique National Security Need

In its request, Hurco notes that it is a "leader in research and development of critical computer numerical control and software technology" and that special permits are needed to save highly skilled employment, production capability, and ensure continued development of essential technology. David Berteau, Principal Deputy Assistant Secretary of Defense, writes in a letter that "Hurco is a leader in open architecture control and software technology and has extensively participated in the National Center for Manufacturing Sciences (NCMS) sponsorship of the development of this technology. The Department believes such (favorable) consideration will enhance, rather than impair, the domestic machine tool industrial base, with commensurate benefits for national security."

Most comments received, however, question whether Hurco's contribution with regard to controls and software is in fact unique and whether it serves a unique national security need. Several parties note that the open architecture concept is not new or unique to any one supplier. Three companies (Bridgeport Machines, Anilam Electronics Corporation, and Fadal Engineering Co. Inc.) stated that they have introduced PC-based open architecture control systems. They also note that other U.S. companies (e.g., Thermwood Corporation and Automation Intelligence) also manufacture PC-based open architecture machine tool controls. Cincinnati Milacron and Giddings & Lewis claim to have added open architecture features to their own control systems. Giddings & Lewis further notes that Hurco "controls and software technology are not used on the advanced CNC machine tools and flexible manufacturing systems used to manufacture today's advanced weapon systems. Over the years, Giddings & Lewis has been and will continue to be a leading supplier of advanced controls and software technology needed to make sophisticated weapon systems." Giddings & Lewis also noted that several firms other than Hurco (including Giddings & Lewis, Allen-Bradley, Cincinnati Milacron and Automation Intelligence) have also been participating in the Next Generation Control project sponsored by NCMS.

Although Hurco states its position as that of a leader in research and development of critical computer numerical control and software technology, no evidence was provided by any party that Hurco has made a unique contribution to machine tool control and/or software development. Hence, we have no basis to believe that Hurco's control is more open or more technologically advanced than other systems produced domestically.

As a result, the Department determines that this criterion has not been met. Information on the record indicates that several U.S. companies have made significant advances in both PC-based and other forms of open architecture control and software technology and are producing machine tool computer numerical controls (CNC) using this technology, and no other information on the record demonstrates that authorizing Hurco's request would serve a unique national security need.

Increase in U.S. Machine Tool Manufacturing Capacity

Hurco states that it has requested special export permits to maintain its domestic supply base of over 1,600 U.S. suppliers and purchases of over $3 million. Approval of this request, Hurco argues, would allow it to "maintain viable manufacturing operations in the United States and continue the important research and development in critical CNC and software technology." Hurco argues that the effect of cast iron imports on the domestic industry would be minimal.

Various parties state that granting this request will have a negative effect on U.S. machine tool manufacturing capacity. The Association of Manufacturing Technology (AMT) notes that granting this request would result in "decreased (domestic) manufacturing capacity." Several domestic machine tool producers claim that granting this request would result in their losing market share to Hurco. Haas Automation Inc. states "an open exception to the Hurco Companies will allow them to flood the market with cheap iron from Taiwan harming the companies who actually build equipment in the USA." Fadal writes that "granting this request will do nothing for national security and will have a negative effect on U.S. machine tool manufacturing capacity * * * Hurco has targeted Fadal" and "the impact of your granting this request will be born[e] primarily by Fadal. We sincerely doubt that Hurco's imported machine tools will displace many other imports." Bridgeport indicates that if this request is approved, "Bridgeport Machines would find itself in the unfortunate position of losing market share [to Hurco]." Another company states that "Hurco cannot contend that these licenses will ultimately expand U.S. manufacturing capacity * * * Even in their own statement, Hurco claims to be an 'assembler' of machine tools. 'Assembly' is not, of course, manufacturing."

Haas argues that approval of Hurco's request would adversely affect the U.S. machine tool supplier base. "If our company is harmed, so to[o] will all of our suppliers including the foundries who provide us with our American made parts." Cast-Fab Technologies, Inc., a major U.S. foundry, notes that granting Hurco's request would undermine the investments and quality improvements made by U.S. machine tool suppliers.

In discussing the impact approval would have on U.S. capacity, Hurco argues that some other domestic firms import complete machining centers. However, Hurco overstates the extent to which this practice is occurring. Hurco fails to mention that Fadal and Haas—two of Hurco's major domestic competitors—produce machining centers and controls exclusively in the United States. One company cited by Hurco imports only one model from an overseas subsidiary, producing all other machining center models and controls in the United States. In any event, these imports are from non-VRA countries and thus are not relevant to a determination under the Understanding.

Mr. Berteau of the Department of Defense suggests that favorable consideration of Hurco's current request would be similar to that received by Hurco prior to 1991 under the original machine tool agreement with CCNAA. However, the original VRA negotiated with CCNAA in 1986 contained a transitional provision to facilitate transfer of input sourcing and machine tool manufacturing from Taiwan to the United States and non-VRA countries, which the current Understanding does not contain. We note that after an

extended transition period toward domestic sourcing, Hurco advised the Department that this process would be complete in 1991. On March 25, 1991, Hurco wrote to the Department as follows: "We ask the Department to assist Hurco Companies in completing its transition to domestic sourcing and machining of certain castings for machining centers by authorizing the Taiwan authorities to issue special licenses for the export to Hurco Companies of 14 substantially complete machining centers * * * These machines are ready for shipment and are intended to tide us over until we receive the [domestic] castings we have ordered. After the export of the 14 substantially complete machining centers under special licenses, Hurco will satisfy the Criteria for Substantially Complete Machining Centers for all subsequent imports from Taiwan of machining center components or obtain regular export licenses." The Department granted this request. Since mid-1991, Hurco has been sourcing and machining certain castings domestically. Approving Hurco's request thus would amount to facilitating a reversal of the changes Hurco made to comply with the machine tool program's overall objectives. Hurco has failed to demonstrate how returning to importing such components from Taiwan would benefit domestic manufacturing capacity.

In summary, there is no evidence on the record to indicate that approval of this request would lead to an increase in U.S. machine tool manufacturing capacity. Hurco is requesting permission to import all major castings from Taiwan, with all machining of these castings performed in Taiwan. Hurco is currently sourcing and machining certain castings in the United States, and assembling them at its Indianapolis facility. Approval would allow Hurco to import substantially complete machining centers, not individual castings, and thus would not lead to increased U.S. machine tool manufacturing capacity. Since the record does not indicate that an increase in machine tool manufacturing capacity would occur if Hurco's request was authorized, this criterion has not been met.

Comparable Tools Are Not Available From U.S. Manufacturers or Suppliers

Hurco does not claim that there is a shortage of machining centers or castings in the United States or that its machines are unique. Rather, Hurco states that it needs a single castings source and that it cannot "mix and match" castings from different foundries since "multiple suppliers of machined cast iron components has deteriorated our ability to compete."

Various parties argue that there is no shortage of the machining centers Hurco sells. One company refers to its low capacity utilization rates. Haas states "there is not a shortage of machine tools in the U.S. at this time. We feel that there is a considerable excess in capacity in our industry." Several parties also note that there is no shortage of high-quality U.S. castings. In fact, Giddings & Lewis offered to supply Hurco with castings from its Wisconsin foundry. The American Foundrymen's Society offered to work with Hurco "to identify foundries that are very capable of supplying their machine bases in a timely manner and at the desired quality level."

While Hurco states that it cannot "mix and match" castings from multiple sources, domestic machine tool builders routinely do just that. Hurco's desire for a single casting source does not form the basis for concluding that the requested products are unavailable from U.S. machine tool manufacturers and suppliers. Satisfying this criterion entails a demonstration that domestic suppliers cannot provide or produce the requested products. There is no information on the record that such a situation exists.

In fact, the preponderance of the information submitted to the Department establishes that the machining centers and castings Hurco wishes to import in excess of the Understanding's limits are available from domestic sources. Therefore, we determine that Hurco has failed to meet the criterion that comparable products are not available from U.S. manufacturers or suppliers.

Conclusion

The Department has determined that authorization of special export permits for Hurco would not serve a unique national security need. While Hurco and Defense claim that Hurco is a leader in open architecture control systems, other U.S. companies produce open architecture PC-based controls. The record does not contain any information indicating that Hurco's control is more open or technologically advanced than those produced by others. Further, Hurco has not indicated how approval of permits would lead directly to an increase in U.S. machine tool manufacturing capacity; in fact, others in the industry claim that approval would work to the detriment of the industry as a whole. Finally, the record demonstrates that there is no shortage of domestic machining centers and that domestic sources are available for the castings Hurco seeks authorization to import from Taiwan.

Because Hurco has not demonstrated that its request for special export permits satisfies the criteria for the authorization of such permits, the Department denies its request in its entirety.

Alan M. Dunn,

Assistant Secretary for Import Administration.

[FR Doc. 93–543 Filed 1–8–93; 8:45 am]

BILLING CODE 3510-06-M

National Telecommunications and Information Administration

National Endowment for Children's Educational Television, Advisory Council on Children's Educational Television; Open Meeting

AGENCY: National Telecommunications and Information Administration (NTIA), DOC.

ACTION: Notice is hereby given of the second meeting of the Advisory Council on Children's Educational Television, created pursuant to the National Endowment for Children's Educational Television Act of 1990.

SUMMARY: Congress established the National Endowment for Children's Educational Television under the direction of the Secretary of Commerce. Authority to administer this program is further delegated to the National Telecommunications and Information Administration. Congress mandated creation of the Advisory Council to advise on the making of contracts and grants to aid in the creation and production of television programming specifically directed toward the development of fundamental intellectual skills.

AUTHORITY: Public Law 101–437, 104 Stat. 997, approved October 18, 1990, codified at 47 U.S.C. 394.

DATES: The meeting will be held on Wednesday, January 27, 1993, from 10 a.m. to 4:30 p.m.

ADDRESSES: The meeting will take place in room 6800 of the Herbert C. Hoover Commerce Building, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Dr. Heather Birnie; Acting Director, National Endowment for Children's Educational Television (NECET); National Telecommunications and Information Administration (NTIA); U.S. Department of Commerce, room

4625, 14th Street and Constitution Avenue, NW.; Washington, DC 20230. Telephone: 202/482–5802.

SUPPLEMENTARY INFORMATION: The Council was chartered on September 13, 1991 pursuant to 47 U.S.C. 394 to advise the Secretary of Commerce on matters related to the making of contracts and grants that would enhance the education of children through the creation and production of television programming specifically directed toward the development of fundamental intellectual skills.

AGENDA.

1. Opening Introductions and Remarks by participants from the National Telecommunications and Information Administration (NTIA) and the National Endowment for Children's Educational Television (NECET).
2. Discussion of Draft NECET Notice of Availability of Funds, the public announcement of the availability of funding for the creation and production of children's educational television programming.
3. Future Meeting Dates and Agenda Items.
4. Other Items for Discussion.

PUBLIC PARTICIPATION: The meeting will be open to the public, with limited seating available on a first-come, first-served basis.

Gregory F. Chapados,

Assistant Secretary for Communications and Information.

[FR Doc. 93–480 Filed 1–8–93, 8:45 am]

BILLING CODE 3510–60–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Announcing Settlement on Import Limits and a Guaranteed Access Level for Certain Wool Textile Products Produced or Manufactured in the Dominican Republic

January 5, 1993.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing a limit and announcing a guaranteed access level.

EFFECTIVE DATE: January 12, 1993.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

In a Memorandum of Understanding (MOU) dated December 22, 1992, between the Governments of the United States and the Dominican Republic agreement was reached agreement to establish a limit for wool textile products in Category 443 for the periods September 30, 1992 through January 31, 1993, February 1, 1993 through December 31, 1993, and January 1, 1994 through December 31, 1994.

Also, the two governments agreed to establish a guaranteed access level (GAL) for Category 443 for the periods February 1, 1993 through December 31, 1993, and January 1, 1994 through December 31, 1994.

Beginning on January 15, 1993, the U.S. Customs Service will start signing the first section of the form ITA–370P for shipments of U.S. formed and cut parts in Category 443 that are destined for the Dominican Republic and subject to the GAL established for Category 443 for the period beginning on February 1, 1993 and extending through December 31, 1993. These products are governed by Harmonized Tariff item number 9802.00.8010 and chapter 61 Statistical Note 5 and chapter 62 Statistical Note 3 of the Harmonized Tariff Schedule. Interested parties should be aware that shipments of cut parts in Category 443 must be accompanied by a form ITA–370P, signed by a U.S. Customs officer, prior to export from the United States for assembly in the Dominican Republic in order to qualify for entry under the Special Access Program.

In the letter published below, the Chairman of CITA directs the Commissioner of Customs to establish a limit for Category 443 for the period beginning on September 30, 1992 and extending through January 31, 1993 and to begin signing the first section of form ITA–370P.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 56 FR 60101, published on November 27, 1991; and 57 FR 54976, published on November 23, 1992). Also see 57 FR 47328, published on October 15, 1992.

Requirements for participation in the Special Access Program are available in **Federal Register** notices 51 FR 21208, published on June 11, 1986; 52 FR 6594, published on March 4, 1987; 52 FR 26057, published on July 10, 1987; and 54 FR 50425, published on December 6, 1989.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU, but are designed to assist only in the implementation of certain of its provisions.

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 5, 1993.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854), and the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as further extended on July 31, 1991; pursuant to the Memorandum of Understanding (MOU) dated December 22, 1992 between the Governments of the United States and the Dominican Republic; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 12, 1993, entry into the United States for consumption and withdrawal from warehouse for consumption of wool textile products in Category 443, produced or manufactured in the Dominican Republic and exported during the four-month period beginning on September 30, 1992 and extending through January 31, 1993, in excess of 49,352 numbers [1].

The limit set forth above is subject to adjustment in the future pursuant to the provisions of the MOU dated December 22, 1992 between the Governments of the United States and the Dominican Republic.

For the import period September 30, 1992 through October 31, 1992, you are directed to charge 14,992 numbers to the limit established in this directive for Category 443.

Beginning on January 15, 1993, the U.S. Customs Service is directed to start signing the first section of the form ITA–370P for shipments of U.S. formed and cut parts in Category 443 that are destined for the Dominican Republic and re-exported to the United States on and after February 1, 1993.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

[1] The limit has not been adjusted to account for any imports exported after September 29, 1992.

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Sincerely,
J Hayden Boyd,
Acting Chairman, Committee for the Implementation of Textile Agreements.
[FR Doc. 93–467 Filed 1–8–93; 8:45 am]
BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

Department of the Army

Board of Visitors, United States Military Academy; Open Meeting

In accordance with section 10(a) (20) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following meeting:

Name of Committee: Board of Visitors, United States Military Academy
Date of Meetings: 24 February 1993
Place of Meeting: Washington, DC
Start Time of Meeting: 8 a.m.
Proposed Agenda: Election of officers; selection of Executive Committee; scheduling of meetings for remainder of year; and identification of areas of interest for 1993.

All proceedings are open. For further information contact Lieutenant Colonel Stephen R. Furr, United States Military Academy, West Point, New York 10996–5000, (914) 938–5870.

Kenneth L. Denton,
Army Federal Register Liaison Officer.
[FR Doc. 93–466 Filed 1–8–93; 8:45 am]
BILLING CODE 3710–08–M

Intent To Grant an Exclusive License to Elan Pharmaceutical Research Corp.

AGENCY: Office of the Army Judge Advocate General, DOD.
ACTION: Notice of intent.

In compliance with 37 CFR 404 *et seq.*, the Department of the Army hereby gives notice of its intent to grant to Elan Pharmaceutical Research Corporation, a corporation having its principal place of business at 1300 Gould Drive, Gainesville, GA 30504, an exclusive license under U.S. Patent Application SN 07/779/744, entitled "Composition and Method for Therapy and Prevention of Cancer, AIDS, and Anemia." Anyone wishing to object to the grant of this license has 60 days from the date of this notice to file written objections along with supporting evidence, if any.

EFFECTIVE DATE: This grant of exclusive license becomes effective on the 61st day after the publishing date in the **Federal Register** unless otherwise rescinded or changed.

ADDRESSES: Send or objectives to Intellectual Property Law Division, Office of the Judge Advocate General, ATTN: JALSIP (Earl T. Reichert), 901 North Stuart Street, Arlington, VA 22203–1837.

FOR FURTHER INFORMATION CONTACT: Earl T. Reichert, (703) 696–8113.

Kenneth L. Denton,
Army Federal Register Liaison Office.
[FR Doc. 93–464 Filed 1–8–93; 8:45 am]
BILLING CODE 3710–08–M

Imposition of Secrecy Orders on Patent Applications Under Secrecy Act

AGENCY: Office of the Army Judge Advocate General, DOD.
ACTION: Notice of proposed action.

SUMMARY: Section 181 of title 35 U.S. Code provides that the Commissioner of Patents, upon being notified by an interested agency that the publication of an invention by the grant of a patent on a pending patent application might, or would, be detrimental to the national security, shall order that the invention be kept secret and shall withhold the issuance of a patent for such period as the national interest requires by the issuance of Secrecy Orders.

By Chapter of 28 September 1953, the Secretaries of the Army, Navy and Air Force delegated to the Armed Services Patent Advisory Board (ASPAB), a joint agency of the three military departments, the authority to recommend the imposition of such Security Orders.

In 1985, ASPAB began recommending the imposition of Secrecy Orders on unclassified patent applications which may be export controlled based on the guidelines contained in the Military Critical Technologies List (MCTL).

A report issued by the Advisory Panel on the National Defense Authorition Act in July 1992, and a report issued in August 1992 by the Advisory Commission on Patent Law Reform, have both questioned the practice of using the MCTL to implement unilateral export controls in a manner inconsistent with criteria established for export of technical data by the Departments of State and Commerce.

At a meeting on 26 October 1992 ASPAB adopted the following motion:

Members of ASPAB will discontinue the use of the MCTL or export control regulations as a basis to impose or renew secrecy orders on U.S. patent applications. They will rely primarily on classification guides in determining whether publication or disclosure by the grant of a patent on an invention contained in a U.S. patent application would be detrimental to the national security.

ADDRESSES: Forward written comments within 30 days to: ASPAB, U.S. Army Intellectual Property Law Division, 901 North Stuart Street, suite 400, Arlington, VA 22203–1837.

FOR FURTHER INFORMATION CONTACT: Mr. Earl T. Reichert, (703) 696–8113.

Kenneth L. Denton,
Army Federal Register Liaison Officer.
[FR Doc. 93–465 Filed 1–8–93; 8:45 am]
BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Educational Research Grant Program: Improved Assessments of K–12 Student Performance and State Systemic Educational Reforms

AGENCY: Department of Education.
ACTION: Withdrawal of notices of proposed priorities.

SUMMARY: The Secretary withdraws notices of proposed priorities for Educational Research Grant Program: Improved Assessments of K–12 Student Performance published on August 3, 1992 (57 FR 34170) and Educational Research Grant Program: State Systemic Educational Reforms published on August 11, 1992 (57 FR 35956). The Secretary withdraws these proposed priorities because no funds are available for fiscal year 1993 to support awards under these priorities.

FOR FURTHER INFORMATION CONTACT: Dr. Joseph Conaty, U.S. Department of Education, Office of Educational Research and Development, 555 New Jersey Avenue, NW., room 610, Washington, DC 20208–5573. Telephone: (202) 219–2079. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

Dated: December 31, 1992.

Lamar Alexander,
Secretary of Education.
(Catalog of Federal Domestic Assistance Number 84.117, Educational Research Grant Program)
[FR Doc. 93–460 Filed 1–8–93; 8:45 am]
BILLING CODE 4000–01–M

National Assessment Governing Board; Meetings

AGENCY: National Assessment Governing Board; Education.
ACTION: Notice of closed meetings.

SUMMARY: This notice sets forth the schedule and proposed agenda of forthcoming meetings of the Achievement Levels Committee,

Executive Committee, and the full National Assessment Governing Board. This notice also describes the functions of the Board. Notice of these meetings is required under section 10(a)(2) of the Federal Advisory Committee Act.

Date: January 12, January 13, and January 14, 1993.

Time: January 12, 1993—Achievement Levels Committee, noon to 4 p.m. (closed);

January 13, 1993—Executive Committee, 3 p.m. to 4:30 p.m. (closed);

January 14, 1993—Full Board, 1 p.m. to 3 p.m. (closed).

LOCATION: January 12, Phoenix Park Hotel, Washington, DC; January 13 and 14, teleconferences, National Assessment Governing Board, 800 North Capitol Street, NW., Suite 825, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mary Ann Wilmer, Operations Officer, National Assessment Governing Board, Suite 825, 800 North Capitol Street, NW., Washington, DC, 20002–4233, Telephone: (202) 357–6938.

SUPPLEMENTARY INFORMATION: The National Assessment Governing Board was established under section 406(i) of the General Education Provisions Act (GEPA) as amended by section 3403 of the National Assessment of Educational Progress Improvement Act (NAEP Improvement Act), Title III–C of the Augustus F. Hawkins—Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988 (Pub. L. 100–297), (20 U.S.C. 1221e–1).

The Board is established to formulate policy guidelines for the National Assessment of Educational Progress. The Board is responsible for selecting subject areas to be assessed, developing assessment objectives, identifying appropriate achievement goals for each grade and subject tested, and establishing standards and procedures for interstate and national comparisons.

On January 12, 1993, the Achievement Levels Committee of the National Assessment Governing Board will meet from noon until 4 p.m. This meeting will be closed to the public to permit the Committee to review preliminary, unreleased data from the 1992 reading assessment. Upon the completion of the review of this data, the Committee will formulate a recommendation for action by the Executive Committee.

On January 13 at 3 p.m., a joint teleconference of the Achievement Levels Committee and the Executive Committee will be held in closed session. During the joint meeting, the Executive Committee will review the recommendations from the Achievement Levels Committee regarding the setting of "cut scores" for the 1992 reading assessment. The Executive Committee will discuss these recommendations and, if appropriate, formulate a final recommendation for action by the full Board. Discussions during these two meetings will include references to specific items from the assessment, the disclosure of which would significantly frustrate implementation of the NAEP.

The results of the assessment must be presented in closed session because reference may be made to data which may be incorrect, incomplete, or misinterpreted. Premature disclosure of this data might significantly frustrate implementation of a proposed agency action. Such matters are protected by exemption 9(B) of section 552b(c) of title 5 U.S.C.

The full Board will convene via telephone conference in closed session from 1 p.m. to 3 p.m. on January 14, 1993, to review the recommendation from the joint Achievement Levels and Executive Committee meeting, and to take final action on the achievement levels for the 1992 reading assessment. The meeting will be closed to the public because the Board's deliberations will involve the review of preliminary unreleased data from the 1992 reading assessment. The discussion will include references to specific items from the assessment, the disclosure of which would significantly frustrate implementation of the NAEP. The results of the assessment must be presented in closed session because reference may be made to data which may be incorrect, incomplete, or misinterpreted. Premature disclosure of these data might significantly frustrate implementation of a proposed agency action. Such matters are protected by exemption 9(B) of section 552b(c) of title 5 U.S.C.

The public is being given less than fifteen days notice of this meeting since the committees' schedules and project timeliness did not allow the meeting to be set earlier.

A summary of the activities at the closed portion of the meeting and related matters, which are informative to the pubic consistent with the policy of 5 U.S.C. will be available to the public within fourteen days after the meeting.

Records are kept of all Board proceedings and are available for public inspection at the U.S. Department of Education, National Assessment Governing Board, suite 825, 800 North Capitol Street, NW., Washington, DC, from 8:30 a.m. to 5 p.m.

Roy Truby,

Executive Director, National Assessment Governing Board.

[FR Doc. 93–589 Filed 1–8–93; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Secretary of Energy Advisory Board Task Force on Radioactive Waste Management; Opportunity to Review and Comment on Draft Task Force Report

Pursuant to the Charter of the Secretary of Energy Advisory Board, notice is hereby given of the opportunity to review and comment on the draft report of the Secretary of Energy Advisory Board Task Force on Radioactive Waste Management. The draft report contains the Task Force's recommendations to the Secretary of Energy on measures the Department of Energy might take to strengthen public trust and confidence in its radioactive waste management activities.

The draft report will be available for review and copying in the Public Reading Room, 1E–190 Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m. Monday through Friday, except Federal Holidays. Single copies of the report will be available upon request by calling (202) 586–7092.

Persons wishing to submit written comment on the report should forward them to the individual listed below by Thursday, March 11, 1993, in order to receive full consideration.

Contact: Dr. Daniel Metlay, Designated Federal Officer, Secretary of Energy Advisory Board, AC–1, 1000 Independence Avenue, SW., Washington DC., 20585, (202) 586–7092.

Issued: Washington, DC, on: January 6, 1993.

Marcia L. Morris,

Deputy Advisory Committee Management Officer.

[FR Doc. 93–548 Filed 1–8–93; 8:45 am]

BILLING CODE 6450–01–M

Office of Energy Research

Energy Research Financial Assistance Program Notice 93–06: Mid-Latitude Atmospheric Ozone/UV–B Survey: Trends, Distributions, and Chemical Determinants

AGENCY: Department of Energy (DOE).

ACTION: Notice inviting grant applications.

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SUMMARY: The Office of Health and Environmental Research (OHER) of the Department of Energy (DOE) hereby announces its interest in receiving applications to support DOE's evaluation of atmospheric ozone trends and distributions, the chemical determinants of atmospheric ozone concentrations, and the resulting perturbations of surface UV–B fluxes. The research activities conducted under this solicitation will focus specifically on mid-latitude phenomena, and will include analysis of ozone in the remote free troposphere as well as in the stratosphere. The remote free troposphere is defined for this program as that portion of the troposphere that exists above the planetary boundary layer and at extended distances from concentrated anthropogenic pollution sources, such as urban areas and industrial complexes.

DATES: Formal applications submitted in response to this notice must be received by the Acquisition and Assistance Management Division by 4:30 p.m., March 2, 1993, to be accepted for a merit review in April 1993 and to permit timely coordination for award in fiscal year 1993.

ADDRESSES: The application kit and guide for the ER Special Research Grant Program is available from the U.S. Department of Energy, Office of Health and Environmental Research, Environmental Sciences Division, ER–74, Washington, DC 20585. Telephone requests may be made by calling (301) 903–4208. Formal applications referencing Program Notice 93–06 should be forwarded to: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER–64, Washington, DC 20585, ATTN: Program Notice 93–06. The following address must be used when submitting applications by U.S. Postal Service Express, any commercial mail delivery service, or when hand carried by the applicant: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER–64, 19901 Germantown Road, Germantown, MD 20874.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Riches, Office of Health and Environmental Research, Environmental Sciences Division, ER–74, Washington, DC 20585, (301) 903–3264 or by OMNET at M. RICHES.

SUPPLEMENTARY INFORMATION: This solicitation is funded under the Ozone Project of the DOE Atmospheric Chemistry Program (ACP). (Supporting documentation for the Ozone Project is available in the draft report entitled Overview of the ACP's Ozone Project, December 1992, and is available upon request from the office listed in "**ADDRESSES**" section of this notice.) The research is divided into two components, the first addressing ozone and UV–B trends, and the second dealing with reaction chemistry. Applications directed towards the first research component must address one or more of the following general questions:

(1) How reliable are the data currently used to evaluate vertical ozone distributions, ozone column loadings, and their trends?

(a) What are the errors associated with existing instrumentation, especially those involving altitude dependencies, chemical interferents, data-reduction algorithms, and physical interferents (e.g. clouds and aerosols)?

(b) What are the probable errors associated with measurement procedures and their changes?

(c) What are the statistical (sampling) errors associated with the sparse existing data set?

(2) How can the existing ozone data base be applied, possibly in conjunction with concurrent data bases for other atmospheric properties, to maximize reliable information regarding distributions, column loadings, and trends?

(3) What modifications to existing techniques and procedures can be made to increase the value of future data regarding ozone distributions and trends?

(4) How reliable are the data currently used to evaluate surface-level UV–B fluxes and their trends?

(a) What are the errors associated with existing instrumentation, especially those involving physical and chemical interferents, sensitivity drift, and wavelength resolution?

(b) What are the probable errors associated with procedural activities?

(c) What are the statistical (sampling) errors associated with the sparse existing data set?

(5) How can this existing UV–B data base be applied, possibly in conjunction with concurrent observations of other atmospheric properties, to maximize reliable information regarding surface fluxes and their trends?

(6) What modifications to existing techniques and procedures can be made to increase the value of future data regarding UV–B surface fluxes and trends?

Although individual research applications are expected to deal with subsets of these questions, the goal is that the funded applications will provide a complete as possible evaluation of all primary surface UV–B and ozone measurement methods, including surface-based and satellite remote sensing, balloon platforms, and rocket-based measurement systems. Total ozone column measurements, as well as ozone profiling measurements will be included. The application of combined data sets (e.g. for co-existing pollutants, clouds, etc.) for interpretive analyses is encouraged.

The second component of this research addresses sensitivities and uncertainties associated with chemical-kinetics parameterizations currently being used for simulating ozone formation/destruction chemistry in global models. In essence this component is intended to examine existing kinetics parameterizations under various temperature, pressure, pollutant-mix, and radiative conditions to evaluate:

- Sensitivities of predicted ozone concentrations (or reaction rates) to rate-coefficient values for each of the reactions simulated in a chosen parameterization;
- Sensitivities of predicted ozone concentrations (or reaction rates) to temperature, pressure, pollutant-mix, and radiative conditions;
- Uncertainties associated with the values of these parameters; and
- The collective uncertainty in ozone concentration (or reaction rate) corresponding to these individual sensitivity/uncertainty values.

This second research component is not intended to involve the use of multidimensional transport models. It focuses, rather, on the reaction-kinetics components of these models, which can be executed essentially as zero-dimensional, time-variant simulations, using state-of-the-art sensitivity analysis techniques. Applications addressing this component should explicitly state the scientific approach to be followed, including the reaction-kinetics parameterizations to be investigated, parameters and parameter ranges to be scrutinized, the statistical basis for the parametric experiment design, the sensitivity-analysis technique to be applied, and the techniques to be used for aggregating individual uncertainties to obtain composite values.

It is anticipated that three to five grants will be awarded for a 3-year period during FY 1993. Contingent upon availability of appropriated funds, approximately $1M per year is expected.

Information about submission of applications, eligibility, limitations, evaluation and selection processes, and other policies and procedures may be found in the ER Special Research Grant

Application Kit and Guide and 10 CFR Part 605.

The Catalog of Federal Domestic Assistance Number for this program is 81.049.

Issued in Washington, DC, on December 30, 1992.

D.D. Mayhew,

Director, Office of Management, Office of Energy Research.

[FR Doc. 93–549 Filed 1–8–93; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Project Nos. 10395, 10646, 11053 Kentucky]

The City of Augusta, et al.; Availability of Environmental Assessment

January 5, 1993

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the competing applications for major license for the proposed Meldahl Hydroelectric Project located on the Ohio River in Bracken County, near the City of Augusta, Kentucky, and has prepared a Comparative Environmental Assessment (CEA) for the proposed project. In the CEA, the Commission's staff has analyzed the potential environmental impacts of the proposed project and has concluded that approval of the proposed project, with appropriate mitigative measures, would not constitute a major Federal action significantly affecting the quality of the human enviroment.

Copies of the CEA are available for review in the Public Reference Branch, room 3308, of the Commission's offices at 941 North Capitol Street, NE., Washington, DC 20426.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–504 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM–3–9–20–000]

Algonquin Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

January 5, 1993

Take notice that Algonquin Gas Transmission Company ("Algonquin") on December 30, 1992, tendered for filing proposed changes in its FERC Gas Tariff, Third Revised Volume No. 1, as set forth in the following revised tariff sheets:

Proposed to be effective December 1, 1992
1 Rev 12 Rev Sheet No. 41
1 Rev 12 Rev Sheet No. 42

Algonquin states that the revised tariff sheets flow through rate changes in Texas Eastern Transmission Corporation's ("Texas Eastern's") Rate Schedules SS–2 and SS–3, which underlie Algonquin's Rate Schedule STB and SS–III, respectively. Pursuant to section 10 of Rate Schedule STB and section 9 of Rate Schedule SS–III in Algonquin's FERC Gas Tariff, Third Revised Volume No. 1, Algonquin is hereby filing the above sheets to track the latest changes filed by Texas Eastern on October 28, 1992.

Algonquin further states that Texas Eastern made its October 28 filing to comply with the terms and conditions of the Commission approved Stipulation and Agreement ("S&A") in Docket No. RP88–067 Phase II (PCB's). The Commission found the tariff sheets to be in satisfactory compliance with the S&A and approved them on December 16, 1992.

Algonquin notes that copies of this filing were served upon each affected party and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with sections 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–507 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–58–000]

ANR Pipeline Co.; Proposed Changes in FERC Gas Tariff

January 5, 1993

Take notice that ANR Pipeline Company ("ANR"), on December 30, 1992 tendered for filing as part of its First Revised Volume No. 1–A of its FERC Gas Tariff, six copies of First Revised Sheet Nos. 67 and 68.

ANR states that the referenced tariff sheets are being submitted to reflect a change in ANR's Order No. 497 Electronic Bulletin Board access procedures. ANR has requested that the Commission accept the tendered tariff sheets to become effective January 4, 1993.

ANR states that all of its Volume No. 1–A customers and interested State Commission have been apprised of this filing.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Commission, 825 N. Capitol Street, NE., Washington, DC 20426 by January 12, 1993, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure 18 CFR 385.211 and 385.214. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–508 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TQ93–3–21–000; TM93–8–21–000]

Columbia Gas Transmission Corp.; Proposed Changes in FERC Gas Tariff

January 5, 1993.

Take notice that Columbia Gas Transmission Corporation (Columbia) on December 31, 1992, tendered for filing the following proposed changes to its FERC Gas Tariff, First Revised Volume No. 1 to be effective February 1, 1993.

Thirty-first Revised Sheet No. 26
Twenty-fourth Revised Sheet No. 26.1
Twenty-ninth Revised Sheet No. 26A
Twenty-fourth Revised Sheet No. 26A.1
Twenty-fifth Revised Sheet No. 26B
Twentieth Revised Sheet No. 26B.1
Twenty-seventh Revised Sheet No. 26C
Fourteenth Revised Sheet No. 26C.1
Twenty-first Revised Sheet No. 26D
Twenty-eight Revised Sheet No. 163

Columbia states the sales rates set forth on Twenty-fourth Revised Sheet No. 26.1 reflect a decrease of 13.16¢ per Dth in the commodity rate and an overall increase of $0.485 per Dth in the total demand rate when compared with the total CDS rates filed in Columbia's January 1, 1993 Interim PGA which was

filed on December 30, 1992 in Docket No. TF93–3–21. The transportation rates set forth on Fourteenth Revised Sheet No. 26C.1 and Twenty-first Revised Sheet No. 26D reflect a decrease of 0.38¢ per Dth in the Fuel Change component.

Columbia states that copies of the filing were served upon Columbia's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, Union Center Plaza Building, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of Columbia's filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–509 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM93–3–33–000]

El Paso Natural Gas Co.; Tariff Filing

January 5, 1993

Take notice that on December 31, 1992 El Paso Natural Gas Company ("El Paso"), gave notice, pursuant to part 154 of the Federal Energy Regulatory Commission ("Commission") Regulations under the Natural Gas Act, of a revision to El Paso's Throughput Surcharge subject to section 22, Take-or-Pay Buyout and Buydown Cost Recovery, contained in the General Terms and Conditions of El Paso's First Revised Volume No. 1–A Tariff. El Paso requests that the tendered tariff sheets be accepted for filing and permitted to become effective February 1, 1993.

El Paso states that on July 31, 1992 at Docket No. RP92–214–000, El Paso filed a general rate case to become effective September 1, 1992. In the filing, El Paso included an illustrative Thoughput Surcharge rate of $0.0450 per dth based upon buyout and buydown cost recovery filings made up to such filing date and an annual throughput underlying El Paso's proposed rates of 1,107,542,022 per dth.

El Paso states that on August 31, 1992 at Docket No. TM93–1–33–000, El Paso filed, among other things, a revision to its Throughput Surcharge effective October 1, 1992. In such filing El Paso revised the Throughput Surcharge to $0.0349 per dth and stated that it had used throughput levels for purposes of the filing based upon the throughput levels underlying its currently effective rates at Docket No. RP91–188–000. Additionally, El Paso stated in such filing that it would file, with appropriate notice as required by the Commission's Regulations, a Throughput Surcharge rate to reflect the throughput levels underlying the rates at Docket No. RP92–214–000 to be effective upon the date such rates are placed into effect. By order issued September 30, 1992 at Docket No. TM93–1–33–000, the Commission accepted El Paso's proposed Throughput Surcharge of $0.0349 per dth effective October 1, 1992, which rate is currently in effect.

El Paso further states that the tendered tariff sheets, when accepted by the Commission and permitted to become effective, serve to update the Throughput Surcharge based on the throughput levels underlying El Paso's proposed rates at Docket No. RP92–214–000 which, upon motion, will become effective February 1, 1993.

El Paso states that copies of the filing are being served upon all of El Paso's interstate pipeline transportation and sales customers and all interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–510 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–57–000]

El Paso Natural Gas Co.; Tariff Filing

January 5, 1993

Take notice that on December 30, 1992, El Paso Natural Gas Company ("El Paso") tendered for filing, pursuant to part 154 of the Federal Energy Regulatory Commission's ("Commission") Regulations Under the Natural Gas Act certain tariff sheets which reflect revisions to the existing creditworthiness provisions contained its First Revised Volume No. 1–A Tariff and add a creditworthiness provision to its Second Revised Volume No. 1 Tariff.

El Paso states that by order issued July 2, 1992 at Docket No. RP92–185–000, the Commission, among other things, rejected certain tariff sheets containing creditworthiness provisions without prejudice to El Paso refiling them consistent with the Commission's discussion in the text of the order. El Paso and El Paso Electric Company filed requests for rehearing of the July 2, 1992 order.

El Paso states that on December 3, 1992 at Docket Nos. RP92–185–000, 001 and 002, the Commission issued an order which, among other things, granted in part and denied in part requests for rehearing and directed El Paso to refile certain currently effective tariff sheets containing creditworthiness provisions. Said order also permitted El Paso to refile, as its option, certain modified tariff sheets consistent with Commission precedent and El Paso's explanation of certain terms and conditions set forth in its request for rehearing.

El Paso states that as to the revisions directed by the Commission, it is refiling its creditworthiness provisions to clarify that El Paso will not suspend service to a bankrupt customer in a manner that is inconsistent with the Federal Bankruptcy Code. El Paso is also providing appropriate clarification within certain sections of the same creditworthiness provisions of the tendered tariff sheets based on El Paso's explanation set forth in its request for rehearing. In addition, El Paso is tendering for its Volume No. 1 Tariff a revised tariff sheet, which adds a new Section 6.5, Creditworthiness, and incorporates the revisions described therein.

El Paso has requested that the tariff sheets be accepted for filing and permitted to become effective February 1, 1993, which is not less than thirty (30) days after the date of filing.

El Paso states that copies of the filing are being served upon all of El Paso's interstate pipeline transportation and

sales customers and all interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–511 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TQ93–3–34–000]

Florida Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

January 5, 1993.

Take notice that on December 30, 1992 Florida Gas Transmission Company (FGT) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets to be effective February 1, 1993:

Thirty-Sixth Revised Sheet No. 8
Seventh Revised Sheet No. 222
Eighth Revised Sheet No. 223
Eighth Revised Sheet No. 228

FGT states that Thirty-Sixth Revised Sheet No. 8 is being filed in accordance with § 154.308 of the Commission's Regulations and pursuant to Section 15 of FGT's FERC Gas Tariff, Second Revised Volume No. 1 to reflect a decrease in FGT's jurisdictional rates due to a decrease in its average cost of gas purchased from that reflected in its Quarterly PGA filing, Docket No. TQ93–2–34–000, effective November 1, 1992.

FGT further states that its projected purchase cost of gas for the period February, 1993 through April, 1993, shown in detail on Schedule Q1, represents a decrease from $3.0677/MMBtu saturated, as reflected in FGT's Quarterly PGA filing in Docket No. TQ93–2–34–000, effective November 1, 1992 to $2.8014/MMBtu saturated in the instant filing.

FGT is required to update its Index of Entitlements concurrently with its Quarterly PGA filing pursuant to Section 9 of the General Terms and Conditions of its Tariff and has included such changes in Seventh Revised Sheet No. 222, and Eighth Revised Sheet Nos. 223 and 228.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 in accordance with §§ 385.211 and 385.214 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene.

Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–512 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–62–000]

Equitrans, Inc.; Notice of Proposed Changes in FERC Gas Tariff

January 5, 1993

Take notice that on December 31, 1992, Equitrans, Inc. ("Equitrans") tendered for filing proposed changes in its FERC Gas Tariff reflecting a rat change from currently effective rates and other changes in its tariff. The proposed changes would increase revenues from jurisdictional services by $5,178,837 based on costs for the twelve (12) month period ending August 31, 1992, as adjusted. Equitrans states that this rate increases is necessitated by increases in costs necessary to operate and maintain its pipeline.

Equitrans submits primary tariff sheets which it proposes to implement in coordination with its restructuring compliance filing in Docket No. RS92–15, and its certificate application filing in Docket No. CP93–44–000. The rates, terms and conditions reflected in the primary sheets reflect various new or expanded services including no-notice transportation service and open access firm and interruptible storage service, which are required by Order No. 636. In addition, Equitrans proposes to apply the cost allocation and rate design principles directed by Order No. 636, including the adoption of straight fixed-variable rate design, removal of costs related to Equitrans' merchant function from the cost of service, and the reallocation of storage costs among services.

In accordance with Order No. 636, Equitrans proposes to recover $40,629,504 in transition costs related to stranded production and gathering facilities and products extraction. Equitrans proposes to amortize these costs over a four-year period and to collect these costs through a demand surcharge applied to all Part 284 transportation.

Equitrans is requesting that the primary tariff sheets under which open access storage service will be rendered be made effective on April 1, 1992, the beginning of the traditional storage injection season, and that the balance of the primary tariff sheets become effective on July 1, 1993, the date that Equitrans contemplates its Order No. 636 Compliance Filing will become effective. Equitrans requests whatever waivers may be necessary for the Commission to make the tariff sheets effective on the dates requested subject to refund.

Equitrans states that copies of the filing were served upon Equitrans jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capital Street, Washington, DC 20426 in accordance with Rule 211 and 214 of the commission's Rules of Practice and Procedures. All such petitions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining appropriate action, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filings are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–502 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. TM93–9–4–000 and RP91–164–008]

Granite State Gas Transmission, Inc.; Notice of Proposed Changes in Rates and Tariff Provisions

January 5, 1993.

Take notice that on December 29, 1992, Granite State Gas Transmission, Inc. (Granite State), 300 Friberg Parkway, Westborough, Massachusetts 01581 filed the revised tariff sheets listed below in its FERC Gas Tariff, First

Revised Volume No. 2, containing changes in rates and tariff provisions for effectiveness on the dates indicated:

Proposed Effective Date: July 1, 1992

Second Revised Sheet No. 5
Second Revised Sheet No. 15
Second Revised Sheet No. 25
Second Revised Sheet No. 26
Second Revised Sheet No. 36

Proposed Effective Date: January 1, 1993

Third Revised Sheet No. 8
Fourth Revised Sheet No. 18
Sixth Revised Sheet No. 28
Fourth Revised Sheet No. 39
Second Revised Sheet No. 39A
Third Revised Sheet No. 62
Third Revised Sheet No. 63
Third Revised Sheet No. 72
Third Revised Sheet No. 73

According to Granite State, all of the above listed revised tariff sheets reflect either rate changes or changes in the tariff provisions in its Rate Schedules T–1 through T–6 pursuant to which Granite State provides transportation services for its affiliated distribution company customers, Bay State Gas Company and Northern Utilities, Inc. Granite State further states that Tennessee Gas Pipeline Company (Tennessee) provides the transportation services for Granite State's account and Granite State's transportation rate schedules are modelled on Tennessee's underlying rate schedules. It is further stated that Granite State is authorized to track changes in Tennessee's underlying rate schedules.

According to Granite State, the revised tariff sheets listed above for effectiveness on July 1, 1992 reflect a change in the Fuel Use percentages in its Rate Schedules T–1 through T–4 to track changes in the Fuel Use percentages which Tennessee filed in the underlying rate schedules as part of its compliance filing in Docket Nos. RP86–119 and RP88–229, *et al.*, for effectiveness on July 1, 1992.

Granite State further states that the revised tariff sheets listed above for effectiveness on January 1, 1993 reflect: (1) Tracking Tennessee's filings in the underlying rate schedules to include the demand charge component of the interim Gas Research Institute (GRI) funding unit for 1993 approved by the Commission in Docket No. RP92–133–000 (Phase I) and (2) compliance with the requirements of Granite State's rate settlement in Docket No. RP91–164–000, approved by the Commission on June 29, 1992. According to Granite State, the demand component of the interim GRI funding unit is applicable to its firm Rate Schedules T–4, T–5 and T–6. It is further stated that the rate revisions in compliance with the settlement in Docket No. RP91–164–000 establish lower "Seller's System Charges" in all of Granite State's transportation rate schedules as prescribed for the Phase 2 rate period.

Granite State further states that copies of its filing were served upon its customers and the regulatory commissions of the states of Maine, Massachusetts and New Hampshire.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–513 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–59–000]

High Island Offshore System; Proposed Changes in FERC Gas Tariff

January 5, 1993

Take notice that on December 31, 1992, High Island Offshore System ("HIOS") filed, pursuant to section 4 of the Natural Gas Act, for a general increase in its transportation rates, proposing an effective date of February 1, 1993.

According to the filing, HIOS attributes the need for an increase in rates to increases in operating and maintenance expenses and other increases in its cost of service as well as declining levels of firm service contracts and transportation volumes on its system. HIOS states that the increase reflects the inclusion of the ACA charge as an operating and maintenance expense in lieu of such charge's past recovery as a rate surcharge.

HIOS states that, based upon volumes transported during the base period, as adjusted, the proposed rates will result in an increase in annual revenues to HIOS of approximately $11.5 million when compared to the annual revenues generated by currently effective rates in effect subject to refund in Docket No. RP92–50. However, HIOS also states that the proposed rates reflect a decrease of approximately $2.8 million in HIOS' cost of service underlying its currently effective rates being collected subject to refund in Docket No. RP92–50.

HIOS requests the removal of the 100% load factor rate design condition for designing its rate, which was imposed in Docket Nos. CP75–104, *et al.*

HIOS also requests removal of the biennial rate filing requirement that was imposed in Docket Nos. CP75–104, *et al.*

HIOS states that copies of the filing have been served on all affected shippers.

Any person desiring to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 and Rule 214 of the Commission's Rules of Practice and Procedures, 18 CFR 385.211 and 385.214. All protests and motions to intervene should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–514 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TQ93–5–25–000]

Mississippi River Transmission Corp.; Notice of Rate Change Filing

January 5, 1993

Take notice that on December 30, 1992, Mississippi River Transmission Corporation (MRT) tendered for filing Fifth Revised Eighty-Third Revised Sheet No. 4 and Fifth Revised Forty-Second Revised Sheet No. 4.1 to its FERC Gas Tariff, Second Revised Volume No. 1 to be effective January 1, 1993. MRT states that the purpose of the instant filing is to reflect an out-of-cycle purchase gas cost adjustment (PGA).

MRT states that Fifth Revised Eighty-Third Revised Sheet No. 4 and Fifth Revised Forty-Second Revised Sheet No. 4.1 reflect a decrease of 17.79 cents per MMBtu in the commodity cost of purchased gas from PGA rates filed on November 30, 1992 to be effective

December 1, 1992, in Docket No. TQ93–4–25–000. MRT also states that since the November 30, 1992 filing date, MRT has experienced changes in purchase and transportation costs for its system supply that could not have been reflected in that filing under current Commission regulations. MRT states that the revised tariff sheets also contain the 1993 GAs Research Institute (GRI) surcharges previously submitted by MRT in Docket No. TM93–4–25–000.

MRT states that a copy of this filing has been served on all of MRT's jurisdictional sales customers and to the State Commissions of Arkansas, Illinois and Missouri.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 92–503 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–98–000]

Gas Company of New Mexico, A Division of Public Service Company of New Mexico; Application for a Presidential Permit for the Construction, Operation and Maintenance and Connection at the United States/Mexico International Boundary of Facilities for the Export of Natural Gas

January 5, 1993.

Take notice that on December 7, 1992, Gas Company of New Mexico, a Division of Public Service Company of New Mexico (GCNM), Alvarado Square, Albuquerque, New Mexico 87158, filed an application pursuant to section 3 of the Natural Gas Act (NGA), as amended, 15 U.S.C. 717(b); Sections 153.1 *et seq.* and 153.10 *et seq.* of the Commission's Regulations, 18 CFR 153.1 and 153.10, Executive Order Nos. 10485 and 12038, and the Secretary of Energy's Delegation Order No. 0204–112, for a Presidential Permit authorizing construction of certain facilities at the international border with Mexico. GCNM requests authority to construct, connect, operate and maintain facilities for the purpose of exporting natural gas to Mexico, all as more fully set forth in the application on file with the Commission and open to public inspection.

GCNM indicates that it has contemporaneously filed an application with the Department of Energy's Office of Fossil Energy (DOE/FE) requesting authority to export natural gas to Mexico. GCNM states that the proposed facilities will be constructed under an agreement with Petroleos Mexicanos, S.A. (PEMEX), or its designee. GCNM states that the proposed facilities will permit the interconnection of GCNM's distribution facilities with the transmission system of PEMEX or PEMEX's designee at a point on the international boundary at the Santa Teresa Port of Entry. GCNM further states that Commission approval of the proposed construction will not involve a major federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4332(2)(c). GCNM also states that it includes a detailed Environmental Assessment which elaborates on the proposed construction and operation of the proposed facilities.

GCNM states that it plans to extend additional natural gas service into the region northwest and west of Sunland Park by constructing two pipelines and a Meter Station. One pipeline, the Chamberino-Foamex Gas Line, will interconnect with the El Paso Natural Gas California Main Line (EPNG) near Chamberino, NM, and transport gas from EPNG to the Foamex Regulator Station located at the Rail-Air Industrial Park. This pipeline will be approximately 17.5 miles long, and 8-inches in diameter. This pipeline will provide additional capacity to the Rail-Air Industrial Park and to the distribution trunk line between the industrial Park and Sunland Park, NM. The second pipeline, the Foamex-Santa Teresa Gas Line, and the Meter Station will be constructed to supply gas to customers in the Santa Teresa International Center area. This pipeline will be an 8-inch diameter underground gas transmission pipe approximately 1800 feet-long.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 26, 1993, file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–505 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TA93–1–59–000]

Northern Natural Gas Co., Notice of Purchased Gas Cost Annual Filing

January 5, 1993.

Take notice that on December 31, 1992 Northern Natural Gas Company, (Northern), tendered for filing, as part of Northern's F.E.R.C. Gas Tariff its 1993 Annual PGA Filing, pursuant to Section 154.305 of the Commission's Regulations and as required by Commission Order Nos. 483 and 483–A. This filing is substantially different than previous Annual PGA filings as a result of the Commission's Order Approving Settlement with Modifications issued June 26, 1992. In Docket Nos. RP88–259 and RP89–1227, et. al., approving the New Service Settlement (Settlement). Northern states that in accordance with the Settlement, this Annual PGA filing reflects fourteen months of data (August 1991 through October 1992).

In the Settlement, Northern unbundled its sales from its throughput capacity and provided that it will establish its monthly commodity price by means of a Monthly Declared Price (MDP) which includes the R, N, and C structure similar to what was in effect in the Interim Gas Inventory Charge mechanism. However, effective November 1, 1992, Northern's MDP is determined in conjunction with a marker price.

On December 2, 1992 the Commission issued an Order in TA92–1–59–002, 003, 005 relating to the 1992 Annual PGA filing. In that Order, the Commission required Northern to refile, within 60 days, certain revisions to correct the carrying charge calculations. Northern states that its instant filing does not incorporate the effect of those required change, if any. However, when Northern files its compliance with the December 2, 1992 Order, Northern

expounds that it will also refile, if necessary, any schedules within its 1993 Annual PGA filing.

Northern states that within its 1993 Annual PGA filing:

(1) Northern is not proposing to change its currently effective Canadian-As-Billed (CAB) demand charge of $0.139, which was approved by the Commission on October 29, 1992.

(2) Northern will use the flex PGA process and the Marker Price structure to establish rates for 1993 pursuant to the terms of the New Service Settlement.

(3) No adjustment is made for the Reconciliation Adjustment (Surcharge). In the Compliance filing for New Services and Docket No. RP92–228, Northern received approval of the Reconciliation Adjustment and simultaneously filed to defer the increase effective January 1, 1993.

(4) Northern's actual gas purchase costs for each assessment interval of the Purchased Gas Assessment Test were less than 103% of the computed projected purchased gas costs.

Any person desiring to be heard or to protest said filing should file a petition to Intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. In accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such petitions or protests should be filed on or before January 21, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–515 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–117–000]

San Diego Gas and Electric Co.; Application for a Presidential Permit and Section 3 Authorization to Construct and Operate an Export Point at the United States/Mexican Border, and Also for a Blanket Certificate

January 5, 1993

Take notice that on December 16, 1992, San Diego Gas and Electric Company (SDG&E), Post Office Box 1831, San Diego, California 92112, filed in Docket No. CP93–117–000 for (1) an application pursuant to section 3 of the Natural Gas Act and under part 153 of the Commission's Regulations for approval to construct, connect, operate, and maintain certain pipeline and metering facilities in San Diego County, California, in the vicinity of the International Boundary between the United States and the Republic of Mexico, and (2) an application for a blanket certificate for certain transportation, sales, and assignments pursuant to part 284 of the Commission's Regulations.

Section 3 and Presidential Permit

In particular SDG&E proposes to construct an operate the following facilities (the Otay Mesa Extension):

(1) 2.1 miles of 36-inch diameter pipeline extending from SDG&E's existing local distribution system in San Diego County, California to the International Boundary and;

(2) A metering station near the International Boundary.

The proposed facilities would have a capacity of 500 MMcf per day. SDG&E estimates that the facilities will cost about $3,640,000 and will be financed with internally generated funds and/or new debt or equity.

SDG&E states that the Otay Mesa Extension will be used to provide, in conjunction with Southern California Gas Company (SoCal), a transportation service from receipt points on the SoCal system to the border under § 284.224 of the Commission's Regulations. A connecting pipeline, will be built on the Mexican side of the border and be operated by Petroleos Mexicanos. SDG&E states, this will link its facilities with a power plant at Rosarito, Baja California.

Blanket Certificate

SDG&E states that it is exempt from the Commission's jurisdiction under section 1(c) of the Natural Gas Act. It proposes to transport certain volumes of natural gas produced outside of California to a point at the International Boundary between the United States and the Republic of Mexico. SDG&E seeks a blanket certificate under § 284.224 of the Commissions Regulations to perform such transportation. SDG&E further states that it may from time to time engage in other sales, transportation, or exchanges authorized by the blanket certificate that it seeks.

SDG&E states that it and SoCal will offer the transportation service on an open access basis. The rates for that service will be on file with, and approved by, the California Public Utilities Commission. Shippers will be required to obtain the proper export authorization from the Department of Energy, Office of Fossil Energy.

SDG&E and SoCal have jointly filed a related Joint Petition for Declaratory Order which is being noticed separately.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 26, 1993, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 or 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All Protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants party to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 3, 7, and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion to intervene is timely filed or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Linwood A Watson, Jr.,

Acting Secretary.

[FR Doc. 93–506 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–138–000]

Sea Robin Pipeline Co.; Notice of Application

January 5, 1993.

Take notice that on December 30, 1992, Sea Robin Pipeline Company (Sea Robin), P.O. Box 2563, Birmingham, Alabama 35202–2563, filed in Docket No. CP93–138–000 an application pursuant to Section 7(b) of the Natural

Gas Act for permission and approval to abandon a transportation service it performs for Tennessee Gas Pipeline Company (Tennessee), all as more fully set forth in the application on file with the Commission and open to public inspection.

Sea Robin proposes to abandon a transportation service performed for Tennessee under a September 29, 1971, agreement, as amended, on file as Sea Robin's Rate Schedule X–4.[1] Sea Robin states that it is authorized to transport up to 10,050 Mcf of gas per day from various locations offshore Louisiana to an interconnection with Columbia Gulf Transmission Company at the terminus of Sea Robin's pipeline near Erath, Vermilion Parish, Louisiana. Sea Robin advises that, although the primary term of the agreement expired on March 12, 1992, the agreement has continued in effect under the provisions of an evergreen clause. Further, Sea Robin advises that it is willing to waive the six month notice provision otherwise required for cancellation of the agreement. Sea Robin proposes that the abandonment authorization become effective December 31, 1992, stating that Tennessee has requested the abandonment of service under the X–4 Rate Schedule in order that replacement service may be implemented under new agreements with Sea Robin for IT and FT service under Sea Robin's part 284 tariff.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 26, 1993, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Sea Robin to appear or be represented at the hearing.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–500 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[1] See 51 FPC 645, and 52 FERC ¶ 62,157.

[Docket No. CP93–119–000]

Southern California Gas Co. and San Diego Gas and Electric Co.; Notice of Joint Petition for Declaratory Order

January 5, 1993.

Take notice that on December 16, 1992, Southern California Gas Company (SoCalGas), 555 West Fifth Street, Los Angeles, California 90013–7011 and San Diego Gas and Electric Company (SDG&E), P.O. Box 1831, San Diego, California 92112 filed a joint petition pursuant to Rule 207 of the Commission's Rules of Practice and Procedure (18 CFR 385.207). They are requesting that the Commission issue an order declaring that certain facilities to be built by SoCalGas and SDG&E are not subject to the Commission's jurisdiction under the Natural Gas Act, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

SoCalGas and SDG&E state that SDG&E is concurrently seeking in Docket No. CP93–117–000 authorization under Section 3 of the Natural Gas Act and a Presidential Permit to construct and operate facilities in San Diego County, California to export up to 500 MMcf per day of gas to the Republic of Mexico and SDG&E is also seeking a blanket certificate under § 284.224 of the Commission's Regulations. In addition to SDG&E's export facilities SoCalGas and SDG&E state in this docket (Docket No. CP93–119–000) that the gas to be transported to Mexico will flow primarily through existing facilities. However both SoCalGas and SDG&E are building facilities upstream of the proposed export point.

SoCalGas and SDG&E state that the new facilities will become integral parts of their distribution systems serving both native-load customers and the new export point. Thus they say the facilities should remain under the jurisdiction of the California Public Utilities Commission (CPUC) and should not be regulated by the Commission. SoCalGas and SDG&E seek a declaratory order from the Commission affirming their view of the jurisdictionality of the new facilities.

SoCalGas and SDG&E state that the transportation services through the facilities described in this docket will be authorized under § 284.224 of the Commission's Regulations. SoCalGas was issued a Blanket Certificate in 41 FERC ¶ 61,173. SDG&E is requesting a Blanket Certificate in Docket No. CP93–117–000.

Any person desiring to be heard or to make any protest with reference to said petition should on or before January 26, 1993, file with the Federal Energy Regulatory Commission, Washington DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–516 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–54–000]

Texas Eastern Transmission Corp.; Notice of Proposed Changes in FERC Gas Tariff

January 5, 1993.

Take notice that Texas Eastern Transmission Corporation ("Texas Eastern") on December 30, 1992, resubmitted for filing as part of its Gas Tariff, Fifth Revised Volume No. 1, six copies of the following tariff sheets:

Proposed to be Effective November 1, 1992

Sub Revised Twenty-sixth Revised Sheet No. 51
Sub Revised Sixteenth Revised Sheet No. 51B
Sub Revised Sixteenth Revised Sheet No. 51D

Proposed to be Effective December 1, 1992

Sub Twenty-eighth Revised Sheet No. 51
Sub Eighteenth Revised Sheet No. 51B
Sub Eighteenth Revised Sheet No. 51D

Proposed to be Effective January 1, 1993

Sub Twenty-ninth Revised Sheet No. 51

Texas Eastern states that this resubmission is made pursuant to the Commission's November 30, 1992 Letter Order entitled "Letter Order Pursuant to § 375.307 (b)(1) and (b)(2), OPPR Allocation and Rate Design Branch, Texas Eastern Transmission Corporation, Docket No. GT93–6–000." In its November 30, 1992 Letter Order the Commission rejected the tariff sheets listed above on grounds that Texas Eastern had failed to file the appropriate supporting schedules required by § 154.63(3)(b) of the Commission's regulations. The Commission's rejection was without prejudice to refiling the sheets in accordance with the requirements of the Commission's regulations.

Texas Eastern states that the tariff sheets rejected by the Commission were filed in accordance with prior orders of the Commission approving the CD–1 Adjustment Program service in Docket No. CP88–180. In particular, in such orders the Commission approved initial rates for the CD–1 Adjustment Program service which included an incremental demand surcharge to cover the cost of constructing the facilities to provide the service. Texas Eastern asserts that the resubmitted tariff sheets reflect such approved surcharge, pursuant to the Commission's June 21, 1991 order in Docket No. CP88–180–009. Accordingly, there is no rate change involved. Rather, the tariff sheets implement the Commission's orders by applying the incremental demand surcharge to the firm transportation service to which customers have converted as certificated by the Commission in Docket No. CP88–180. In light of the foregoing, Texas Eastern believes that good cause exists to permit the attached tariff sheets to become effective on November 1, 1992 and December 1, 1992 as set forth above. The surcharge effective December 1, 1992 reflects adjustments for PCB related costs and was approved pursuant to the Commission's order dated December 16, 1992 in Docket No. RP88–067–061 Phase II (PCBs). In this connection, Texas Eastern is filing contemporaneously herewith a protective request for Rehearing with respect to the November 30, 1992 order.

In addition, Texas Eastern states that on December 1, 1992, in Docket No. TM93–3–17–000, Texas Eastern filed as a part of its FERC Gas Tariff, Fifth Revised Volume No. 1, Twenty-ninth Revised Sheet No. 51 as one of the tariff sheets necessary to reflect an interim funding mechanism for the Gas Research Institute ("GRI") in Section 25 of the General Terms and Conditions ("GRI Filing"). The tariff sheets were submitted pursuant to the Commission's orders approving an interim GRI funding mechanism for 1993. Gas Reserach Institute, Order on Proposed Funding Mechanism, 60 F.E.R.C. Paragraph 61,203 (August 28, 1992), Order Denying Rehearing, issued October 28, 1992.

Texas Eastern asserts that in conjunction with the current filing, it submitted Sub Twenty-ninth Revised Sheet No. 51, which reflects the incremental demand surcharge for the CD–1 Adjustment Program service as approved in Docket No. CP88–180, to replace the Twenty-ninth Revised Sheet No. 51 included in the GRI Filing.

The proposed effective dates of the tariff sheets are November 1, 1992, December 1, 1992, and January 1, 1993, as indicated.

Texas Eastern states that copies of the filing were served on Texas Eastern's jurisdictional customers and interested state commissions. Copies of this filing have also been served on all parties on the service list in Docket No. CP88–180.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–517 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM93–3–18–000]

Texas Gas Transmission Corp.; Notice of Proposed Changes in FERC Gas Tariff

January 5, 1993.

Take notice that on December 31, 1992, Texas Gas Transmission Corporation (Texas Gas) tendered for filing the revised tariff sheets contained in appendix A to the filing.

Texas Gas states that the proposed tariff sheets reflect changes to its Base Tariff Rates pursuant to the Transportation Cost Adjustment provisions contained in section 32 of its FERC Gas Tariff Original Volume No. 1 and section 27 of its FERC Gas Tariff First Revised Volume No. 2–A, and are proposed to be effective February 1, 1993.

Texas Gas states that copies of the filing were served on Texas Gas' jurisdictional sales customers, all parties on the Commission's official restricted service list in the consolidated proceedings, and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such protests or motions should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–516 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–55–000]

Trailblazer Pipeline Co.; Notice of Proposed Changes in FERC Gas Tariff

January 5, 1993

Take notice that on December 30, 1992, Trailblazer Pipeline Company (Trailblazer) tendered for filing as part of its FERC Gas Tariff, the tariff sheets listed in appendices A and B, attached to the filing, to become effective February 1, 1993. Trailblazer states that this filing is a general rate case submitted principally to comply with the terms of Trailblazer's last settlement at Docket No. RP84–94.

Trailblazer states that the filing reflects a base period encompassing the twelve months ended August 31, 1992, adjusted for known and measurable changes anticipated to occur during the nine month period ended May 31, 1993 Trailblazer notes that its filing also reflects a straight fixed-variable rate design, an equity return allowance of 15%, a higher depreciation rate, and reduced operation and maintenance expenses when compared to the level

established in Trailblazer's last rate case settlement at Docket No. RP84–94.

Trailblazer states that copies of the filing were served upon all of Trailblazer's jurisdictional customers and interested state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–519 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–56–000]

Transwestern Pipeline Co.; Notice of Proposed Changes in FERC Gas Tariff

January 5, 1993

Take notice that, on December 30, 1992, Transwestern Pipeline Company (Transwestern) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Primary Tariff Sheets

Effective April 1, 1993:

100th Revised Sheet No. 5
Original Sheet No. 5E(v)
65th Revised Sheet No. 6
10th Revised Sheet No. 6C
1st Revised Sheet No. 6D
7th Revised Sheet No. 87
13th Revised Sheet No. 89
2nd Revised Sheet No. 89A
10th Revised Sheet No. 90
3rd Revised Sheet No. 92

Alternate Tariff Sheets

Effective April 1, 1993:

Alternate 100th Revised Sheet No. 5
6th Revised Sheet No. 5A
2nd Revised Sheet No. 5A.01
2nd Revised Sheet No. 5A.02
2nd Revised Sheet No. 5A.03
2nd Revised Sheet No. 5A.04
1st Revised Sheet No. 5A.05
4th Revised Sheet No. 5B
Alternate 10th Revised Sheet No. 90A

The above referenced tariff sheets are being filed by Transwestern to modify its take-or-pay, buy-out and buy-down mechanism ("Transition Cost Recovery" or "TCR" mechanism) in order to recover certain take-or-pay settlement, buy-out, buy-down, and contract reformation costs ("Transition Costs") which amounts it paid subsequent to the implementation date of its Gas Inventory Charge ("GIC"), October 1, 1989, and which do not qualify under the Litigation Exception provision of its tariff.

Transwestern has paid an additional $5,454,449.38 in Transition Costs ("TCR Amount Eleven") and is revising certain tariff sheets and requesting authority to begin recovery of such amounts under the tariff sheets.

Under the tariff sheets, Transwestern proposes to absorb twenty-five percent (25%) of the additional Transition Costs it has incurred and to recover the remaining seventy-five percent (75%) through an exit point, volumetric surcharge which includes a reconciliation or "true-up" mechanism that complies with Order Nos. 528–A and 528–B.

Transwestern respectfully requests that the Commission grant any and all waivers of its rules, regulations, and orders as may be necessary so as to permit the above listed tariff sheets to become effective April 1, 1993.

Transwestern states that copies of the filing have been mailed to each of its jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.214 and 385.211). All such petitions or protests must be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–520 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–61–000]

U–T Offshore System; Notice of Proposed Changes in FERC Gas Tariff

January 5, 1993.

Take notice that on December 31, 1992, U–T Offshore System ("U–TOS") filed, pursuant to section 4 of the Natural Gas Act, for a general increase in its transportation rates, proposing an effective date of February 1, 1993.

According to the filing, U–TOS attributes the need for an increase in rates to increases in operating and maintenance expenses and other increases in its cost of service (including its negative salvage rate) as well as declining levels of firm service contracts and transportation volumes on its system. U–TOS states that the increase reflects the inclusion of the ACA charge as an operating and maintenance expense in lieu of such charge's past recovery as a rate surcharge.

U–TOS states that, based upon volumes transported during the base period, as adjusted, the proposed rates will result in an increase in annual revenues to U–TOS of approximately $1.8 million when compared to the annual revenues generated by currently effective rates in effect subject to refund in Docket No. RP92–47.

U–TOS requests the removal of the 100% load factor rate design condition for designing its rate, which was imposed in Docket Nos. CP76–118, *et al.*

U–TOS also requests removal of the biennial rate filing requirement that was imposed in Docket Nos. CP76–118, *et al.*

U–TOS states that copies of the filing have been served on all affected shippers.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 12, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make Protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–501 Filed 1–8–93; 8:45 am]

BILLING CODE 6717–01–M

Western Area Power Administration

Transition from Guidelines and Acceptance Criteria to Integrated Resource Planning

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of Transition to Integrated Resource Planning.

SUMMARY: In recognition of the intent of Congress in superseding title II of the Hoover Power Plant Act of 1984 through enactment of the Energy Policy Act of 1992, and in anticipation of the Western Area Power Administration's (Western) development of the Energy Planning and Management Program (Program), Western will no longer require customer compliance with the Guidelines and Acceptance Criteria for Customer Conservation and Renewable Energy Programs in order to facilitate the preparation of integrated resource plans by Western's long-term firm power customers.

FOR FURTHER INFORMATION CONTACT:

Robert C. Fullerton, Western Area Power Administration, P.O. Box 3402, Golden, CO 80401–3398. (303) 231–1679.

James D. Davies, Billings Area Office, Western Area Power Administration, P.O. Box 35800, Billings, MT 59107–5800. (406) 657–6532.

Stephen A. Fausett, Loveland Area Office, Western Area Power Administration, P.O. Box 3700, Loveland, CO 80539–3003. (303) 490–7201.

Thomas A. Hine, Phoenix Area Office, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457. (602) 352–2453.

David G. Coleman, Sacramento Area Office, Western Area Power Administration, 1825 Bell Street, Suite 105, Sacramento, CA 95825–1097. (916) 649–4418.

Lloyd Greiner, Salt Lake City Area Office, Western Area Power Administration, P.O. Box 11606, Salt Lake City, UT 84147–0606. (801) 524–6372.

SUPPLEMENTARY INFORMATION: On October 24, 1992, the Energy Policy Act of 1992 became law. Section 114 of that legislation requires the preparation of integrated resource plans by the long-term firm power customers of Western. Section 114 also supersedes title II of the Hoover Plant of 1984 in its entirety. The Hoover Power Plant Act of 1984 was the statutory basis for Western's Guidelines and Acceptance Criteria for Customer Conservation and Renewable Energy Programs, 50 FR 33892 (August 21, 1985). To replace the Guidelines and Acceptance Criteria, Western is developing a Program that includes a requirement for all Western firm power customers to prepare an integrated resource plan consistent with the provisions of the Energy Policy Act. In recognition of the action of Congress, Western will no longer require customer compliance with the existing Guidelines and Acceptance Criteria so that customers can begin to focus their resources on the transition to preparation of quality integrated resource plans.

Issued in Golden, Colorado, December 29, 1992.

William H. Clagett,

Administrator.

[FR Doc. 93–550 Filed 1–6–93; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[WH–FRL–4553–8]

State and Local Assistance; Grants for State Water Pollution Control Revolving Funds (Title VI) Under the Clean Water Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of allotment.

SUMMARY: The Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1993, (the Act) provides $1,927,500,000 to capitalize State Revolving Fund (SRF) programs authorized by title VI of the Clean Water Act (CWA). This notice sets forth the State allotments for fiscal year 1993 for their SRF programs. It also provides notice that one-half of one percentum of the appropriation, $9,637,500, is reserved for grants to Indian Tribes and Alaska Native Villages to construct sewage treatment facilities.

FOR FURTHER INFORMATION CONTACT: Mr. Leonard B. Fitch, Program Management Branch, Municipal Support Division, Office of Wastewater Enforcement and Compliance, (202) 260–5858.

SUPPLEMENTARY INFORMATION: Public Law 102–389, the Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1993, provides $1,927,500,000 to capitalize SRF programs authorized by title VI of the CWA. Section 604(a) of the CWA requires that funds appropriated for title VI for fiscal years 1987–1990 be allotted in accordance with the table in section 205(c)(3) of the CWA. Congress has given the Agency no instruction regarding the allotment of fiscal year 1993 funds. In the absence of Congressional action, the Agency will allot the fiscal year 1993 funds in accordance with the table in section 205(c)(3) except as described below.

Indian Tribes Adjustment

The Act authorizes the Administrator to reserve up to one half on one percentum of fiscal year 1993 title VI funds for making grants to Indian Tribes and Alaska Native Villages for construction of wastewater treatment facilities. The full amount is hereby reserved to be administered under the Indian Set-Aside Program authorized by section 518(c) of the CWA. These funds will be allotted to the Indian Tribes and Alaska Native Villages based on the 1990 Indian Set-Aside Project Priority List published in the **Federal Register** December 21, 1990. Projects were ranked on this Priority List based on water quality and public health criteria.

Trust Territory Adjustment

In Public Law 99–658, Congress approved a Compact of Free Association for the Trust Territories' members. Two entities, the Federated States of Micronesia and the Republic of the Marshall Islands have implemented Compacts and are no longer eligible for grants under title VI. At the effective date of this allotment the Republic of Palau has yet to implement a Compact of Free Association, and, under Public Law 99–239, section 105(h)(2), remains eligible for title VI grants. Funds that otherwise would have been allotted to the Federated States of Micronesia and the Republic of the Marshall Islands are redistributed to the States and Territories by proportionally increasing their respective shares of the appropriation as shown in the column titled "Allotment Formula After Trust Territory Adjustments." The actual allotments resulting from the adjusted allotment shares are shown in the column titled "fiscal year 1993 State Allotment." The table at the end of this notice lists the amount of funding made available to each State. These funds are available for obligation until September 30, 1994. Grants from the allotments may be awarded as of the date that the funds were issued to the Regional Administrators by the Comptroller of EPA.

Dated: January 4, 1993.

William K. Reilly,

Administrator.

State	Allotment formula	Allotment formula after trust terr. adjustments	FY 1993 state allotment
Alabama	0.011309	0.011320	$21,709,300
Alaska	0.006053	0.006059	11,619,800
Arizona	0.006831	0.006837	13,113,100
Arkansas	0.006616	0.006622	12,700,400
California	0.072333	0.072400	138,853,800
Colorado	0.008090	0.008098	15,529,900
Connecticut	0.012380	0.012402	23,784,400
Delaware	0.004965	0.004970	9,531,000
District of Columbia	0.004965	0.004970	9,531,000
Florida	0.034139	0.034171	65,534,700
Georgia	0.017100	0.017116	32,825,900
Hawaii	0.007833	0.007840	15,038,800
Idaho	0.004965	0.004970	9,531,000
Illinois	0.045741	0.045783	87,806,400
Indiana	0.024374	0.024397	46,789,400
Iowa	0.013688	0.013701	26,276,100
Kansas	0.009129	0.009137	17,524,400
Kentucky	0.012872	0.012884	24,709,700
Louisiana	0.011118	0.011128	21,342,600
Maine	0.007829	0.007836	15,028,900
Maryland	0.024461	0.024484	46,956,400
Massachusetts	0.034338	0.034370	65,916,700
Michigan	0.043487	0.043527	83,479,600
Minnesota	0.018589	0.018606	35,684,300
Mississippi	0.009112	0.009120	17,491,800
Missouri	0.028037	0.028063	53,821,100
Montana	0.004965	0.004970	9,531,000
Nebraska	0.005173	0.005178	9,930,300
Nevada	0.004965	0.004970	9,531,000
New Hampshire	0.010107	0.010116	19,401,800
New Jersey	0.041329	0.041367	79,337,000
New Mexico	0.004965	0.004970	9,531,000
New York	0.111632	0.111736	214,293,900
North Carolina	0.018253	0.018270	35,039,300
North Dakota	0.004965	0.004970	9,531,000
Ohio	0.056936	0.056989	109,296,800
Oklahoma	0.008171	0.008179	15,685,400
Oregon	0.011425	0.011436	21,931,900
Pennsylvania	0.040062	0.040099	76,904,800
Rhode Island	0.006791	0.006797	13,036,300
South Carolina	0.010361	0.010371	19,889,400
South Dakota	0.004965	0.004970	9,531,000
Tennessee	0.014692	0.014706	28,203,400
Texas	0.046226	0.046269	88,737,500
Utah	0.005329	0.005334	10,229,800
Vermont	0.004965	0.004970	9,531,000
Virginia	0.020698	0.020717	39,732,800
Washington	0.017588	0.017604	33,762,700
West Virginia	0.015766	0.015781	30,265,100
Wisconsin	0.027342	0.027367	52,486,900
Wyoming	0.004965	0.004970	9,531,000
American Samoa	0.000908	0.000909	1,743,000
Guam	0.000657	0.000658	1,261,200
Northern Marianas	0.000422	0.000422	810,200
Puerto Rico	0.013191	0.013203	25,322,000
Pacific Trust Terr	0.001295	0.001367	704,500
Virgin Islands	0.000527	0.000527	1,011,700
Subtotal	1.000000	1.000000	$1,917,862,500
Indian Set-Aside	.....	.....	$9,637,500
Total	.....	.....	$1,927,500,000

[FR Doc. 93–525 Filed 1–8–93; 8:45 a.m.]

BILLING CODE 6560–50–M

[FRL–4554–1]

Public Meeting of the Phosphoric Acid Production Waste Dialogue Committee

AGENCY: Environmental Protection Agency.

ACTION: Federal Advisory Committee meeting.

SUMMARY: As required by the Federal Advisory Committee Act, we are giving notice of the January meeting of the Phosphoric Acid Waste Dialogue Committee. The meeting is open to the public without advance registration.

The purpose of the meetings is to continue to review information on the issue of pollution prevention in the production of phosphoric acid.

DATES: The Committee meeting will be held on January 29, 1993 from 8:30 a.m. to 4 p.m.

ADDRESSES: The meeting will be held at the Marriott Airport Hotel, 7499 Augusta National Drive, Orlando, Florida.

FOR FURTHER INFORMATION CONTACT:

Persons needing further information on the technical or scientific matters related to phosphoric acid wastes should contact Dr. Daniel R. Bushman, Office of Pollution Prevention and Toxics, Economics, Exposure and Technology Division, TS 779, Environmental Protection Agency, Washington, DC 20460; phone (202) 260–6700. Persons needing further information on the committee's procedural and logistical matters should call Deborah Dalton, Consensus and Dispute Resolution Program, (202) 260–5495, or the Committee's facilitator, Greg Bourne, Southeast Negotiation Network, Georgia Institute of Technology, Atlanta, GA (404) 853–9846.

Dated: January 5, 1993.

Deborah Dalton,

Designated Federal Official, Office of Regulatory Management and Evaluation, Office of Policy, Planning and Evaluation.

[FR Doc. 93–523 Filed 1–8–93; 8:45 am]

BILLING CODE 6560–50–M

[FRL–4553–6]

Proposed Administrative Settlement Under Section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act; Hooper Sands, South Berwick, ME

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of proposed administrative settlement and request for public comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing to enter into an administrative settlement to address claims under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9601. Notice is being published to inform the public of the proposed settlement and of the opportunity to comment. The settlement is intended to resolve the liability under CERCLA of the United States Department of the Navy for unrecovered costs incurred by EPA in conducting response actions at or in connection with the Hooper Sands Superfund Site in South Berwick, Maine through and including May 12, 1992.

DATES: Comments must be provided on or before February 10, 1993.

ADDRESSES: Comments should be addressed to the Docket Clerk, U.S. Environmental Protection Agency, Region I, JFK Federal Building—RCG, Boston, Massachusetts 02203, and should refer to: In the Matter of Hooper Sands Superfund Site, South Berwick, Maine, U.S. EPA Docket No. I–92–1082.

FOR FURTHER INFORMATION CONTACT: Kathleen Woodward, U.S. Environmental Protection Agency, Office of Regional Counsel, RCV, J.F.K. Federal Building, Boston, Massachusetts 02203, (617) 565–3687.

SUPPLEMENTARY INFORMATION: In accordance with section 122(i)(1) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9622(i)(1), notice is hereby given of a proposed administrative settlement concerning the Hooper Sands Superfund Site in South Berwick, ME. The settlement was approved by EPA Region I on December 4, 1992, subject to review by the public pursuant to this Notice. The United States Department of the Navy, the Settling Party, has executed a signature page committing it to participate in the settlement. Under the proposed settlement, the Settling Party is required to pay $728,209.81 to the Hazardous Substances Superfund. EPA believes the settlement is fair and in the public interest.

EPA is entering into this agreement under the authority of section 122(h) of CERCLA. Section 122(h) of CERCLA provides EPA with authority to consider, compromise, and settle a claim under section 107 of CERCLA for costs incurred by the United States if the claim has not been referred to the U.S. Department of Justice for further action. The U.S. Department of Justice approved this settlement in writing on November 17, 1992.

EPA will receive written comments relating to this settlement for thirty (30) days from the date of publication of this Notice.

A copy of the proposed administrative settlement may be obtained in person or by mail from the Docket Clerk, U.S. Environmental Protection Agency, Office of Regional Counsel, JFK Federal Building—RCG, Boston, Massachusetts 02203, (617) 565–3351.

The Agency's response to any comments received will be available for public inspection with the Docket Clerk, U.S. Environmental Protection Agency, Region I, JFK Federal Building—RCG, Boston, Massachusetts 02203 (U.S. EPA Docket No. I–92–1082).

Dated: December 4, 1992.

Paul Keough,

Acting Regional Administrator.

[FR Doc. 93–526 Filed 1–8–93; 8:45 am]

BILLING CODE 6560–50–M

[FRL–4553–5]

Proposed Administrative Settlement Under Section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act; L.E. MacNair Building Superfund Site, Houlton, ME

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of proposed adminisrative settlement and request for public comment.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing to enter into an administrative settlement to address claims under the Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9601. Notice is being published to inform the public of the proposed settlement and of the opportunity to comment. The settlement is intended to resolve the liability under CERCLA of Bangor and Aroostook Railroad Company, G. Milton Carter, G.M. Nicholas Carter, L.E. MacNair Creditor Trust (David Edgar and John Rogers, Trustees; AFCO Credit Corporation, Bemis Company, and Stanford Holdings, Ltd., Beneficiaries), and Maine Potato Growers, Inc. for costs incurred by EPA in conducting response actions at the L.E. MacNair Building Superfund Site in Houlton, Maine.

DATES: Comments must be provided on or before February 10, 1993.

ADDRESSES: Comments should be addressed to the Docket Clerk, U.S. Environmental Protection Agency, Region I, JFK Federal Building—RCG, Boston, Massachusetts 02203, and should refer to: In the matter of L.E. MacNair Building Superfund Site, Houlton, ME, U.S. EPA Docket No. I–92–1100.

FOR FURTHER INFORMATION CONTACT: Andrew Raubvogel, U.S. Environmental Protection Agency, Office of Regional Counsel, RCV, J.F.K. Federal Building, Boston, Massachusetts 02203, (617) 565–3169.

SUPPLEMENTARY INFORMATION: In accordance with section 122(i)(1) of the

Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), 42 U.S.C. 9622(i)(1), notice is hereby given of a proposed administrative settlement concerning the L.E. MacNair Building Superfund Site in Houlton, ME. The settlement was approved by EPA Region I on December 16, 1992 subject to review by the public pursuant to this Notice. Bangor and Aroostook Railroad Company, G. Milton Carter, G.M. Nicholas Carter, the L.E. MacNair Creditor Trust (David Edgar and John Rogers, Trustees; AFCO Credit Corporation, Bemis Company, and Stanford Holdings, Ltd., Beneficiaries), and Maine Potato Growers, Inc., the Settling Parties, have executed signature pages committing it to participate in the settlement. Under the proposed settlement, the Settling Parties are required to pay $875,000 to the Hazardous Substances Superfund. EPA believes the settlement is fair and in the public interest.

EPA is entering into this agreement under the authority of section 122(h) of CERCLA. Section 122(h) of CERCLA provides EPA with authority to consider, compromise, and settle a claim under section 107 of CERCLA for costs incurred by the United States if the claim has not been referred to the U.S. Department of Justice for further action. The U.S. Department of Justice approved this settlement in writing on December 16, 1992.

EPA will receive written comments relating to this settlement for thirty (30) days from the date of publication of this Notice.

A copy of the proposed administrative settlement may be obtained in person or by mail from Andrew Raubvogel, U.S. Environmental Protection Agency, Office of Regional Counsel, JFK Federal Building—RCV, Boston, Massachusetts 02203, (617) 565–3169.

The Agency's response to any comments received will be available for public inspection with the Docket Clerk, U.S. Environmental Protection Agency, Region I, JFK Federal Building—RCG, Boston, Massachusetts (U.S. EPA Docket No. I–92–1100).

Dated: December 16, 1992.

Paul G. Keough,

Acting Regional Administrator.

[FR Doc. 93–527 Filed 1–8–93; 8:45 am]

BILLING CODE 6560-50-M

Proposed Administrative Settlement Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, as Amended by the Superfund Amendments and Reauthorization Act

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended by the Superfund Amendments and Reauthorization Act ("CERCLA"), notice is hereby given that a proposed administrative cost recovery settlement concerning the Route 52 Site in Bluefield, West Virginia was issued by the Agency on September 24, 1992. The settlement resolves an EPA claim under Section 107 of CERCLA against Joy Technologies Inc. The settlement requires Joy Technologies Inc. to pay $200,000.000 to the Hazardous Substances Superfund.

For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency's response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, Region III, Regional Docket Clerk (3RC00), 841 Chestnut Building, Philadelphia, PA, 19107.

DATES: Comments must be submitted on or before February 10, 1993.

ADDRESSES: The proposed settlement and additional background information relating to the settlement are available for public inspection at U.S. EPA, Region III, 841 Chestnut Building, Philadelphia, PA, 19107. A copy of the proposed settlement may be obtained from Suzanne Canning (3RC00), Regional Docket Clerk, U.S. EPA, Region III, 841 Chestnut Building, Philadelphia, PA, 19107. Comments should reference the Route 52 Site, Bluefield, WVA and EPA Docket No. III–92–09–DC, and should be addressed to Suzanne Canning (3RC00), Regional Docket Clerk, at the above address.

FOR FURTHER INFORMATION CONTACT: Heather Torres (3RC21), Associate Regional Counsel, U.S. EPA, Region III, 841 Chestnut Building, Philadelphia, PA, 19107, (215) 597–0376.

December 10, 1992.

Alvin R. Morris,

Acting Regional Administrator, United States Environmental Protection Agency, Region III.

[FR Doc. 93–528 Filed 1–8–93; 8:45 am]

BILLING CODE 6560-50-M

ENVIRONMENTAL PROTECTION AGENCY

DEPARTMENT OF DEFENSE

Army Corps of Engineers

[FRL–4553–9]

Basis for the Advanced Identification of Wetlands in New Jersey's Hackensack Meadowlands

AGENCY: United States Environmental Protection Agency, United States Army Corps of Engineers, DOD.

ACTION: Notice of completion.

SUMMARY: The United States Environmental Protection Agency (EPA), Region II office, and the United States Army Corps of Engineers (USACE), New York District office, have completed the "Basis for the Advanced Identification of Wetlands in New Jersey's Hackensack Meadowlands". The report may be acquired at the EPA Region II office, 26 Federal Plaza, New York, New York, or the Hackensack Meadowlands Development Commission offices, One DeKorte Park Plaza, Lyndhurst, New Jersey; or may be received upon request to EPA Region II, Marine and Wetlands Protection Branch, 26 Federal Plaza, New York, NY 10278, (212) 264–5170.

FOR FURTHER INFORMATION CONTACT: Mr. Mario Del Vicario, Chief, Marine and Wetlands Protection Branch, U.S. Environmental Protection Agency Region II, 26 Federal Plaza, New York, NY 10278, (212) 264–5170.

SUPPLEMENTARY INFORMATION: The New Jersey Department of Environmental Protection and Energy (NJDEPE), Bureau of Revenue, Maps and Publications Section will serve as a repository for the "Basis for the Advanced Identification of Wetlands in New Jersey's Hackensack Meadowlands". Copies are available for purchase by contacting NJDEPE, Bureau of Revenue, Maps and Publications Section, CN 402, Trenton, New Jersey 08625, (609) 777–1038 or 1039. The cost is $2.00 per figure and approximately $1.25 for the text. Pre-payment to the Treasurer, State of New Jersey, Bureau of Revenue, CN 402, Trenton, NJ 08625 is required.

For the Environmental Protection Agency.

Dated: December 7, 1992.

Constantine Sidamon-Eristoff,

Regional Administrator.

For the Army Corps of Engineers.

Dated: December 9, 1992.

Thomas A. York,

District Engineer.

[FR Doc. 93–533 Filed 1–8–93; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License; Reissuance

Notice is hereby given that the following ocean freight forwarder license has been reissued by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, 46 CFR Part 510.

License No.	Name/address	Date reissued
2477–R	MDR Enterprises, Inc., 7377 Pacific Street, #219, Omaha, NE 68114.	October 21, 1992.

Bryant L. VanBrakle,
Director, Bureau of Tariffs, Certification and Licensing.

[FR Doc. 93–491 Filed 1–8–93; 8:45 am]
BILLING CODE 6730–01–M

Ocean Freight Forwarder License; Revocations

Notice is hereby given that the following ocean freight licenses have been revoked by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, 46 CFR part 510.

License No:	311.
Name:	John V. Carr & Son, Ltd.
Address:	1600 West Lafayette, Detroit, MI 48216.
Date Revoked:	September 1, 1992.
Reason:	Surrendered license voluntarily.
License Number:	2269.
Name:	Customs Clearance & Dispatch, Inc.
Address:	6300 NW 74th Ave., Miami, FL 33166.
Date Revoked:	September 19, 1992.
Reason:	Failed to furnish a valid surety bond.
License Number:	2706.
Name:	B.V.T. America, Inc.
Address:	55 Armstrong Road, Des Moines, IL 60018.
Date Revoked:	November 12, 1992.
Reason:	Surrendered license voluntarily.
License Number:	266.
Name:	E.A. Jasper, Inc.
Address:	711 Brush Ave., Bronx, NY 10465.
Date Revoked:	December 2, 1992.
Reason:	Failed to furnish a valid surety bond.
License Number:	3481.
Name:	Jinco, Inc.
Address:	1101 Ellis Drive, Bensenville, IL 60106.
Date Revoked:	December 2, 1992.
Reason:	Failed to furnish a valid surety bond.
License Number:	2493–R.
Name:	Universal Transportation Systems, Ltd.
Address:	1695 Woodward, Ste. 200, Bloomfield Hills, MI 48302.
Date Revoked:	December 3, 1992.
Reason:	Surrendered license voluntarily.
License Number:	1309.
Name:	Taub & Carmel, Inc.
Address:	33 Rector Street, New York, NY 10006.
Date Revoked:	December 9, 1992.
Reason:	Failed to furnish a valid surety bond.
License Number:	2238.
Name:	Genuine International Freight Forwarders, Inc.
Address:	183 Milkweed Ct., Three Bridges, NJ 08887.
Date Revoked:	December 12, 1992.
Reason:	Failed to furnish a valid surety bond.
License Number:	3547.
Name:	BMA International Traders and Forwarders. Inc.
Address:	250 South Maple Ave., #B, So. San Francisco, CA 94080.
Date Revoked:	December 20, 1992.
Reason:	Failed to furnish a valid surety bond.

Bryant L. VanBrakle,
Director, Bureau of Tariffs, Certification and Licensing.

[FR Doc. 93–490 Filed 1–8–93; 8:45 am]
BILLING CODE 6730–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Proposed Aquatic Nuisance Species Program

AGENCY: U.S. Fish and Wildlife Service, Interior.

ACTION: Notice of extension of comment period.

SUMMARY: The due date for comments on the proposed Aquatic Nuisance Species Program (Program) and draft environmental assessment is extended to February 3, 1993. The notice announcing the availability of these documents was published on November 18, 1992 (57 FR 54408).

DATES: Comments must be submitted to the address in **ADDRESSES** by February 3, 1993.

ADDRESSES: Requests for copies of and comments about the proposed Aquatic Nuisance Species Program or draft environmental assessment should be sent to Robert A. Peoples, U.S. Fish and Wildlife Service (820 ARLSQ), Department of the Interior, 1849 C Street, NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Robert A. Peoples at (703) 358–1718.

SUPPLEMENTARY INFORMATION: The proposed Program was prepared by the Aquatic Nuisance Species Task Force in accordance with section 1202 of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (Pub. L. 101–646, 16 U.S.C. 4701 *et seq.*). Comments received will be considered in completing the final Program that will become the basis for Federal participation in cooperative responses to aquatic nuisance species.

The November 18, 1992, notice and the six public meetings announced at that time and held in December 1992 have generated substantial interest in the proposed Program among diverse interests. To provide adequate time for interested parties to review and comment on the proposed Program, the comment period is extended 30 days to February 3, 1993.

Dated: January 4, 1993.

Gary Edwards,
Co-Chair, Aquatic Nuisance Species Task Force.

[FR Doc. 93–494 Filed 1–8–93; 8:45 am]
BILLING CODE 4310–55–M

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 731–TA–632–635 (Preliminary)]

Certain Cordage Products From Costa Rica, Korea, Mexico, and Portugal; Withdrawal of Petition in Antidumping Investigations

AGENCY: International Trade Commission.

ACTION: Notice of withdrawal of petition in antidumping investigations.

SUMMARY: On January 4, 1993, the U.S. Department of Commerce and the U.S. International Trade Commission received a letter from petitioner in the subject investigations (the Cordage Institute, Hingham, MA) withdrawing its petition. Commerce has not initiated investigations as provided in section 732(c) of the Tariff Act of 1930 (19 U.S.C. 1673a(c)). Accordingly, the

Commission gives notice that its antidumping investigations concerning certain cordage products from Costa Rica, Korea, Mexico, and Portugal (investigations Nos. 731–TA–632–635 (Preliminary)) are discontinued.

EFFECTIVE DATE: January 4, 1993.

FOR FURTHER INFORMATION CONTACT: Robert Carpenter (202–205–3172), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

By order of the Commission.

Issued: January 6, 1993.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–492 Filed 1–8–93; 8:45 am]

BILLING CODE 7020–02–M

INTERSTATE COMMERCE COMMISSION

Intent to Engage in Compensated Intercorporate Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).

A.1. Parent corporation and address of principal office: Kraft General Foods, Inc., Three Lakes Drive, Northfield, IL 60093–2758.

2. Wholly owned subsidiaries which will participate in the operations, and State(s) of incorporation:

a. Tombstone Pizza Corporation, a Delaware corporation.

b. National Dairy Products Corp., a Delaware corporation.

B.1. Parent Corporation: Louis Dreyfus Energy Corp., 10 Westport Road, P.O. Box 810, Wilton, CT 06897–0810.

2. Wholly owned subsidiaries which will participate in the operations, and states of incorporation: Louis Dreyfus Energy Heating Oil Inc., a Delaware corporation and Louis Dreyfus Energy Heating Oil Company of Delaware, a Delaware corporation.

C.1. The parent corporation is Ryder System, Inc. a Florida corporation. Its address is 3600 NW. 82d Avenue, Miami, FL 33166.

2. The names of all wholly owned subsidiaries which will participate in the operations, and the state of incorporation, are as follows:

Aeronautical Improvements Corporation	Florida.
Airplane Things, Inc	Texas.
APS Technical Specialities, Inc	California.
ATE Management & Service Company, Inc	Delaware.
ATE Management of Duluth, Inc	Minnesota.
Automotive Rail Handling, Inc	Michigan.
Aviall Far East, Inc	Florida.
Aviation Sales Company, Inc	Florida.
Aviation Sales Leasing Company, Inc	Florida.
B&C, Inc	Michigan.
Blazer Truck Lines, Inc	Michigan.
F. J. Boutell Driveaway Co., Inc	Michigan.
Cape Area Transportation System, Inc	Massachusetts.
Carrier Support, Inc	Delaware.
Central Virginia Transit Management Company, Inc	Virginia.
Commercial Carriers, Inc	Michigan.
Complete Auto Transit, Inc	Michigan.
Consolidated Convoy Company	Oregon.
Convoy Company	Oregon.
E/H Service Corporation	Wisconsin.
Far East Freight, Inc	Florida.
Fleet Carrier Corporation	New York.
Fleet Carrier Dealers Service, Inc	Michigan.
H.N.S. Management Company, Inc	Connecticut.
Inventory Locator Service, Inc	Tennessee.
Jackson Public Transportation Company, Inc	Mississippi.
Janesville Auto Transport Company	Delaware.
M&G Convoy, Inc	New York.
Managed Logistics System, Inc	Delaware.
Merrimack Valley Area Transportation Co., Corp	Massachusetts.
Metro Service Corp	Wisconsin.
Mid-South Transportation Management, Inc	Tennessee.
Murry Recon, Inc	New York.
National Trucking Company	Delaware.
Network Sales, Inc	Tennessee.
Network Vehicle Central, Inc	Florida.
9755 S.W. 67 Avenue, Inc	Florida.
Old Dominion Transit Management Company	Virginia.
OSHCO, Inc	Florida.
Parking Management of Southwest Virginia, Inc	Virginia.
Port Terminal Transport, Inc	California.
QAT, Inc	Florida.
RMX, Inc	Delaware.
RSI Acquisition Corp	Delaware.
RSI Aviation, Inc	Florida.
RSI Purchase Corp	Delaware.

Ryder Airline, Inc	Delaware.
Ryder Airline Services, Inc	Delaware.
Ryder Automotive Carrier Group, Inc	Florida.
Ryder Automotive Operations, Inc	Florida.
Ryder Aviall, Inc	Florida.
Ryder Aviation Sales International, Inc	Florida.
Ryder Capital Corp., Inc	Florida.
RYDERCORP	Delaware.
RYDERCORP, Inc	Tennessee.
Ryder Dedicated Capacity, Inc	Delaware.
Ryder Distribution Resources, Inc	Florida.
Ryder Driver Leasing, Inc	Florida.
Ryder Energy Distribution Corporation	Nevada.
Ryder Equity, Inc	Florida.
Ryder Finance, Inc	Virginia.
Ryder Freight Broker, Inc	Oregon.
Ryder Move Management, Inc	Delaware.
Ryder Realty, Inc	Florida.
Ryder Relocation Services, Inc	Florida.
Ryder Services Corporation	Missouri.
Ryder St. Louis Redevelopment Corporation	Rhode Island.
Ryder Student Assistance Fund, Inc	Florida.
Ryder Student Transportation Services, Inc	Florida.
Ryder Support, Inc	Florida.
Ryder Truck Rental, Inc	Delaware.
Ryder Truck Rental—One Way, Inc	Florida.
Ryder Truckstops, Inc	Florida.
South Florida Mortgage Group, Inc	Virginia.
Southwestern Virginia Transit Management Co., Inc	Delaware.
Summit Industries, Inc	Washington.
Terminal Service Co	California.
Transit Contractors, Inc	Texas.
Transit Management Company of Laredo	Virginia.
Transit Management of Alexandria, Inc	North Carolina.
Transit Management of Charlotte, Inc	Connecticut.
Transit Management of Connecticut, Inc	Illinois.
Transit Management of Danville, Inc	Illinois.
Transit Management of Decatur, Inc	North Carolina.
Transit Management of Durham, Inc	Montana.
Transit Management of Great Falls, Inc	Ohio.
Transit Management of Hamilton, Inc	New York.
Transit Management of Jamestown, Inc	Michigan.
Transit Management of Monroe County, Inc	Missouri.
Transit Management of St. Joseph, Inc	South Carolina.
Transit Management of Spartanburg, Inc	Arizona.
Transit Management of Tucson, Inc	Nevada.
Transit Management of Washoe, Inc	Wisconsin.
Transit Management of Waukesha, Inc	Delaware.
Transport Support, Inc	Tennessee.
Transportation Management of Tennessee, Inc	Florida.
Westside Corporate Center, Inc	

Sidney L. Strickland, Jr.,
Secretary.

[FR Doc. 93–489 Filed 1–8–93; 8:45 am]
BILLING CODE 7035–01–M

[No. 40888]

Reconsideration of Special Tariff Authorities Authorizing the Publication of Customer Account Codes in Tariffs

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposal to reconsider outstanding Special Tariff Authorities.

SUMMARY: The Commission plans to reconsider all outstanding Special Tariff Authorities that allow carriers to publish tariff rates for shippers identified only through the means of account codes listed in the tariffs. Questions have been raised regarding whether the publication of rates in this manner complies with the rate disclosure requirements of the Interstate Commerce Act, and Congress has requested the Commission to initiate a proceeding to reconsider the matter. After consideration of the comments received and the issues involved, the Commission expects to determine whether the Special Tariff Authorities should be continued, modified or revoked.

DATES: Comments are due on March 8, 1993.

ADDRESSES: Send comments (an original and 10 copies) referring to Docket No. 40888 to: Interstate Commerce Commission, Office of the Secretary, Case Control Branch, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: James W. Greene (202) 927–5597, or Ronald A. Hall (202) 927–5595, [TDD for hearing impaired (202) 927–5721].

SUPPLEMENTARY INFORMATION: On January 30, 1985, the Commission approved a motor carrier's request to restrict the application of tariff rates to specific customers by the use of unique customer code numbers.[1] The reason advanced by the carrier in support of its request was primarily to facilitate the computerization of rating and billing processes. Subsequently, numerous similar authorizations were granted to other motor and water carriers, and, on

[1] Special Tariff Authority No. 84–9406.

April 29, 1986, the Commission's Suspension/Special Permission Board, acting on its own motion, granted a Special Tariff Authority [2] which allowed all motor carriers and freight forwarders to make use of shipper account codes in tariffs filed by them or on their behalf. (A complete listing of all outstanding Special Tariff Authorities allowing the publication of shipper codes is contained in appendix A.)

The Commission again addressed the issue of customer account codes in Pet. for Declar. Order-Discounts and Customer Acct. Codes, 8 I.C.C.2d 47 (1991). In that proceeding, the Commission declined to find customer account code tariffs unlawful, per se, but indicated its willingness to consider such tariffs on a case-by-case basis. As the Commission there stated (8 I.C.C.2d at 54):

> If a tariff lacks any of the essential information concerning the commodities, service points, and rate information, it is not the use of a customer code that would invalidate the tariff. Conversely, mere use of shipper codes does not mean necessarily that the tariff lacks any necessary information. [footnote omitted]

Based on Congress' request that we do so,[3] we are instituting this proceeding to reconsider whether the Special Tariff Authorities that allow carriers to publish tariff rates for shippers identified only through the means of account codes should be continued, modified, or revoked.

Comments are invited from interested parties regarding the lawfulness of publishing rates through the use of shipper account codes that are not explained in the rates tariff or in a governing tariff. Comments are also invited as to whether the Commission should continue or revoke the existing Special Tariff Authorities, the likely impact of such action, and any modifications the Commission should consider with respect to such Authorities. We are well aware that shipper codes may be used in connection with other methods of tariff publication which are alleged to fail the disclosure requirements such as the range and trigger tariff provisions being considered in Docket Nom. 40887, Range Tariffs of All Motor Common Carriers—Show Cause Proceeding, show cause order served concurrenfly with the notice here. Parties are requested to limit their comments in this proceeding to the question of whether a tariff that in all other respects satisfies disclosure requirements should be deemed to be invalid simply because it is published utilizing undisclosed shipper codes.

Decided: December 23, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

Outstanding Special Tariff Authorities Authorizing the Publication of Customer Account Codes in Tariffs

84–9406	85–2105	86–314	86–531
85–144	85–2106	86–316	86–535
85–547	85–2107	86–325	86–547
85–1455	85–2108	86–340	86–558
85–1507	85–2115	86–344	86–563
85–1508	85–2125	86–351	86–591
85–1594	85–2132	86–398	86–603
85–1619	85–2136	86–404	86–607
85–1620	85–2155	86–440	86–638
85–1648	85–2156	86–448	86–639
85–1685	85–2160	86–470	87–196
85–1666	85–2164	86–479	88–26
85–1668	85–2192	86–482	88–43
85–1671	85–2195	86–483	88–48
85–1672	85–2196	86–487	88–60
85–1677	85–2206	86–492	89–30
85–1683	85–2209		
85–1695	85–2232		
85–1703	85–2257		
85–1715	85–2261		
85–1725	85–2264		
85–1730	85–2275		
85–1731	85–2282		
85–1773	85–2318		
85–1777	85–2344		
85–1779	85–2345		
85–1780	85–2350		
85–1805	85–2352		
85–1808	85–2353		
85–1809	85–2358		
85–1823	85–2362		
85–1834	85–2398		
85–1857	85–2399		
85–1860	85–2413		
85–1866	85–2424		
85–1873	85–2429		
85–1876	85–2438		
85–1879	85–2439		
85–1888	85–2458		
85–1895	85–2460		
85–1927	85–2461		
85–1928	85–2488		
85–1929	85–2509		
85–1935	85–2538		
85–1937	85–2544		
85–1943	85–2576		
85–1952	85–2577		
85–1957	85–2578		
85–1960	85–2600		
85–1969	85–2663		
85–1986	85–2690		
85–1988	85–2715		
85–1989	86–1		
85–1990	86–35		
85–2004	86–41		
85–2016	86–48		
85–2033	86–78		
85–2039	86–129		
85–2040	86–132		
85–2042	86–152		
85–2047	86–155		
85–2056	86–195		
85–2067	86–247		
85–2093	86–265		
85–2103	86–275		
85–2104	86–294		

[2] Special Tariff Authority 86–639, amended April 29, 1986, to provide for numerical and/or alphabetical codes.

[3] Senate Report No. 102–351, dated July 30, 1992, and accompanying the U.S. Department of Transportation and Related Agencies Appropriations Bill, 1993.

[FR Doc. 93–487 Filed 1–8–93; 8:45 am]

BILLING CODE 7035–01–M

[No. 40887]

Range Tariffs of All Motor Common Carriers—Show Cause Proceeding

In Docket Nos. 40843 ("Ranges of Rates") [1] and ("Ranges of Discounts") [2] we ordered certain tariff publishing agents and motor common carriers to show cause why we should not order particular "range" tariffs canceled for failure to comply with the rate disclosure requirements of 49 U.S.C. 10762. We are now requiring all publishers and motor common carrier users of range tariffs likewise to demonstrate why their tariffs should not be ordered canceled. Because the proceeding will be of interest to many shippers, we are also inviting the public to comment. A consolidated decision will then be issued for the three proceedings.

We decided to institute this industry-wide proceeding principally [3] because the comments received in the two pending show cause proceedings do not persuade us at this point that the range tariffs which they address meet the disclosure requirements of the Interstate Commerce Act (Act). Range tariffs are clearly useful to certain segments of the

[1] Docket No. 40843, Tariffs of Certain Motor Common Carriers Containing "Ranges of Rates"—Show Cause Proceeding (not printed), show cause order served August 20, 1992.

[2] Docket No. 40840, Tariffs of Certain Motor Common Carriers Containing "Ranges of Discounts"—Show Cause Proceeding (not printed), served September 8, 1992.

[3] A second consideration was that a number of comments state that almost all motor common carriers now use similar range tariffs, and that it is unfair and ineffectual to single out individual, mostly small carriers for show cause proceedings. We agree. Third, the Senate Committee on Appropriations has instructed us "to initiate, as soon as possible, an industrywide proceeding to eliminate motor tariff filings that fail to explicitly state actual rates applied by carriers or that use so-called 'range' or 'write-in' provisions." *See* Senate Report No. 102–351, dated July 30, 1992, and accompanying the U.S. Department of Transportation and Related Agencies Appropriations Bill, 1993.

industry and may also further certain goals of the national transportation policy. However, Congress has not repealed the rate-filing requirement or the antidiscrimination requirement [4] of the Act. Therefore, our primary focus must be on whether such tariffs disclose their rates sufficiently to satisfy the mandates of sections 10761(a) and 10762, as elucidated in *Regular Common Carrier Conference* v. *United States*, 793 F.2d 376 (D.C. Cir. 1986). Comments are requested to address this issue in particular.

Additional information is contained in the Commission's decision. To obtain a copy of the full decision, write to, call, or pick up in person from: Office of the Secretary, room 2215, Interstate Commerce Commission, Washington, DC 20423. Telephone: (202) 927–7428. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Comments are due March 8, 1993. Send comments (an original and 10 copies) referring to Docket No. 40887 to: Interstate Commerce Commission, Office of the Secretary, Case Control Branch, Washington, DC 20423.

Decided: December 23, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–486 Filed 1–8–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–290 (Sub-No. 119X)]

Norfolk and Western Railway Co.; Abandonment Exemption; Delphos, OH

Norfolk and Western Railway Company (NW) has filed a notice of exemption under 49 CFR part 1152 subpart F—Exempt Abandonments to abandon its 0.54-mile line of railroad between mileposts AY–0.00 and AY–0.14 and between AY–1.36 and AY–1.76 at Delphos, OH, in Allen and Putnam Counties, OH.

NW has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; and (3) no formal complaint filed by a user of rail service on the line (or a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period. NW also certified that it has complied with the requirements at 49 CFR 1105.7 and 1105.8, 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies).

As a condition to the use of this exemption, any employee affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expressions of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on February 10, 1993, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking statements under 49 CFR 1152.29 must be filed by January 21, 1993.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by February 1, 1993, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: F. Blair Wimbush, Norfolk Southern Corporation, Three Commercial Place, Norfolk, VA 23510–2191.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

Applicant has filed an environmental report which addresses the abandonment's effect, if any, on the environmental or historic resources.

The Section of Energy and Environment (SEE) will issue an environmental assessment (EA) by January 16, 1993. Interested persons may obtain a copy of the EA from SEE by writing to it (room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief, SEE at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: December 28, 1992.

By the Commission, Julia Farr, Acting Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–485 Filed 1–8–93; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Manufacturer of Controlled Substances; Application

Pursuant to § 1301.43(a) of title 21 of the Code of Federal Regulations (CFR), this is notice that on December 1, 1992, Johnson Matthey Inc., Custom Pharmaceuticals Department, 2002 Nolte Drive, West Deptford, New Jersey 08066, requested by application to the Drug Enforcement Administration (DEA) for registration as a bulk manufacturer of the basic classes of controlled substances listed below:

Drug	Schedule
Methylphenidate (1724)	II
Alfentanil (9737)	II
Sufentanil (9740)	II
Fentanyl (9801)	II

Any other such applicant and any person who is presently registered with DEA to manufacture such substances may file comments or objections to the issuance of the above application and may also file a written request for a hearing thereon in accordance with 21 CFR 1301.54 and in the form prescribed by 21 CFR 1316.47.

Any such comments, objections, or requests for a hearing may be addressed to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, United States Department of Justice, Washington, DC 20537, Attention: DEA Federal Register Representative (CCR) and must be filed no later than 30 days from publication.

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[4] 49 U.S.C. 10741; see also the policy expressed in 10101(a)(1)(D) that rates be reasonable and "without unreasonable discrimination".

[1] A stay will be routinely issued by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Section of Energy and Environment in its independent investigation) cannot be made prior to the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible in order to permit this Commission to review and act on the request before the effective date of this exemption.

[2] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[3] The Commission will accept a late-filed trail use statement as long as it retains jurisdiction to do so.

Dated: December 28, 1992.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. 93–493 Filed 1–8–93; 8:45 am]

BILLING CODE 4410–09–M

Office of Justice Programs; Office for Victims of Crime

Children's Justice Act Discretionary Grant Program for Native Americans and Application Kit for Fiscal Year 1993

AGENCY: Office of Justice Programs, Office for Victims of Crime, Justice.

ACTION: Public announcement of the availability of Fiscal Year 1993 grant funds and Application Kit for the Children's Justice Act Discretionary Grant Program for Native Americans.

SUMMARY: The Office for Victims of Crime (OVC) is publishing this announcement of the availability of Fiscal Year 1993 grant funds and the Application Kit for the Children's Justice Act Grant Program for Native Americans (CJA). The purpose of this grant program is to develop model projects in Native American communities for the purpose of improving the investigation, prosecution and handling of cases of child sexual abuse and serious child physical abuse in a manner that increases support for and reduces trauma to child victims.

DATES: The Application Kit specifies the due date for applications. All applications responding to the announcement must be received by OVC by the close of business on the specified due date indicated in the Application Kit. Applications received after the deadline will not be considered.

ADDRESSES: Office for Victims of Crime, Federal Crime Victims Division, 633 Indiana Avenue, NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Cathy Sanders or Bill Brantley, Federal Crime Victims Division, Office for Victims of Crime, at the above address. Telephone (202) 514-6445 for further information and to obtain a copy of the Application Kit.

SUPPLEMENTARY INFORMATION: Pursuant to section 1402(g) of the Victims of Crime Act (VOCA) of 1984, Public Law 98–473, as amended, 42 U.S.C. 10601(g), the Attorney General, acting through the Director of OVC, is authorized to make grants for the purpose of assisting Indian tribes in developing, establishing and operating programs designed to improve the handling, investigation and prosecution of child abuse cases, especially child sexual abuse cases.

The goal of this program is to strengthen existing Native American CJA programs and/or develop new programs that improve the handling of child physical and sexual abuse cases during the investigation, prosecution, and treatment phases. The objectives are to make systemic improvements and to develop effective programs that address serious child abuse cases. Once projects are in place, they will serve as models for other tribes seeking to make similar improvements. Each program must address coordination with Federal and State authorities as well as coordination within the tribe.

The program focuses on handling serious cases of child abuse that would be handled in criminal court from the initial report and the first stages of intervention and investigation through the resolution of the case, in a manner that increases support for the child victim and lessens the trauma. Desired results are improved investigative and prosecutorial practices, better case coordination, and improved services for child victims and their families.

The Office for Victims of Crime published a Notice in the **Federal Register** (57 FR 52639, November 4, 1992) announcing the FY 1993 Discretionary Program Plan. The Grant Application Kit for the Children's Justice Act Discretionary Grant Program for Native Americans expands upon information provided in the program plan and defines specific application requirements and deadlines.

John E. Dawson,

Acting Deputy Director, Office for Victims of Crime.

Olga R. Trujillo,

Acting General Counsel.

[FR Doc. 93–442 Filed 1–8–93; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Labor Advisory Committee for Trade Negotiations and Trade Policy; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463 as amended), notice is hereby given of a meeting of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

Date, time and place: February 10, 1993, 10 am–12 noon, Rm. S–4215 A&B, Department of Labor Building, 200 Constitution Ave., NW., Washington, DC 20210.

Purpose: to discuss trade negotiations and trade policy of the United States.

This meeting will be closed under the authority of section 10(d) of the Federal Advisory Committee Act and 5 U.S.C. 552(c)(1). The Committee will hear and discuss sensitive and confidential matters concerning U.S. trade negotiations and trade policy.

For further information, contact: Fernand Lavallee, Director, Trade Advisory Group, Phone: (202) 523–2752.

Signed at Washington, DC, this 6th day of January, 1993.

Shellyn G. McCaffrey,

Deputy Under Secretary International Affairs.

[FR Doc. 93–535 Filed 1–8–93; 8:45 am]

BILLING CODE 4510–28–M

Pension and Welfare Benefits Administration

[Prohibited Transaction Exemption 93–2; Exemption Application Nos. D–8243 and D–8323]

Class Exemption for the Receipt of Certain Services by Individuals for Whose Benefit Individual Retirement Accounts or Retirement Plans for Self-Employed Individuals Have Been Established or Maintained

AGENCY: Pension and Welfare Benefits Administration, U.S. Department of Labor.

ACTION: Grant of class exemption.

SUMMARY: This document contains a final exemption from certain prohibited transaction restrictions of the Internal Revenue Code of 1986 (the Code). The exemption permits the receipt of services at reduced or no cost by an individual for whose benefit an individual retirement account (IRA), or, if self-employed, a Keogh Plan, is established or maintained, or by members of his or her family, from a bank, provided the conditions of the exemption are met. The exemption affects certain individuals with a beneficial interest in the IRAs or Keogh Plans who receive such services, as well as the banks that provide the services.

EFFECTIVE DATE: May 11, 1993.

FOR FURTHER INFORMATION CONTACT: Allison K. Padams, Office of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor, (202) 523–8971 (this is not a toll-free number); or Susan E. Rees, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, (202) 523–9141 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On February 28, 1991, the Department of

Labor (the Department) published a notice in the **Federal Register** (56 FR 8365) of the pendency of a proposed class exemption from the sanctions resulting from the application of sections 4975(a) and (b), 4975(c)(3) and 408(e)(2) of the Code by reason of section 4975(c)(1)(D), (E) and (F) of the Code.[1] The Department proposed the class exemption in response to applications filed on behalf of the American Bankers Association (the ABA) on November 14, 1989 and the Consumer Bankers Association on February 20, 1990. The applications were filed under section 4975(c)(2) of the Code, and in accordance with the procedure set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975).

The notice of pendency gave interested persons an opportunity to comment on the proposal. Twenty-three public comments were received pursuant to the provisions of section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1. Upon consideration of all the comments received, the Department has determined to grant the proposed class exemption subject to certain modifications. These modifications and the major comments are discussed below.

Discussion of Comments Received

1. Scope

The proposed exemption limited relief to transactions involving IRAs and Keogh Plans which are not "employee benefit plans" covered by title I of ERISA.[2] The ABA and a number of other commenters urged the Department to expand the exemption to provide relief for transactions involving simplified employee pensions (SEPs) as defined under section 408(k) of the Code. According to the comments, SEP arrangements are, for all practical purposes, no different than other IRAs covered by the proposed exemption. On the basis of the comments received, the Department has decided that it may be appropriate to provide administrative relief from sections 406(a)(1)(D) and 406(b) of the Employee Retirement Income Security Act of 1974 (ERISA) for transactions involving SEPs.

However, the Department did not propose relief from section 406(b) of ERISA at the time the class exemption was proposed, and pursuant to the requirements of section 408(a) of ERISA, the Department is required to offer interested persons an opportunity to present their views and an opportunity for a hearing before granting an exemption from section 406(b). Therefore, in order not to delay the exemption from section 4975(c)(1) (D), (E) and (F) of the Code for transactions involving IRA and Keogh Plans not covered by title I of ERISA, the Department has decided to grant the exemption described herein, and to simultaneously publish elsewhere in this issue of the **Federal Register**, a notice of proposed class exemption from sections 406(a)(1)(D) and 406(b) of ERISA for transactions involving the receipt of services at reduced or no cost by a participant covered under a SEP.

Other commenters requested that relief be extended to include all IRAs and Keogh Plans covered by title I of ERISA. As noted above, the extension of relief to all title I IRAs and Keogh Plans is beyond the scope of this proceeding. Moreover, the Department does not agree that, on the basis of current information, an exemption should be proposed to extend relief to IRAs and Keogh Plans covered by title I other than SEPs. Accordingly, the Department has not made the requested modification.

Finally, the ABA urged the Department to modify the final exemption to provide relief from all of section 4975(c)(1) of the Code in order to avoid uncertainty as to the scope and effect of the exemption. The Department is not persuaded that additional relief is necessary for the transactions covered by the exemption. Consequently, the exemption has not been revised in this regard.

2. Conditions

Section II(b) of the proposed exemption conditioned relief on the services being of the type which the bank itself could offer consistent with applicable federal and state banking law. Two commenters suggested that the Department modify this condition to permit banks to offer services provided by affiliates of the bank which are not of the type that the bank itself could provide to customers directly (e.g., brokerage services). Other commenters requested that the Department broaden section II(b) to include services provided by third parties. The Department is not persuaded by the commenters that such an expansion of the exemption would be appropriate. The Department, however, recognizes that banks typically contract with third parties to provide customers with products of a de minimis value such as checkbooks which are directly related to the provision of customary banking services. The Department believes that the provision of such incidental products is consistent with the safeguards embodied in the exemption. To clarify this matter, the final exemption includes a new section III(g) which defines the term "services".

Under section II(c) of the proposed exemption, the services were required to be provided by the bank in the ordinary course of the bank's business to customers who do not qualify for reduced or no cost banking services. Two commenters urged the Department to modify section II(c) to allow banks to offer some services exclusively to relationship banking customers (e.g., consolidated account summaries or special teller lines). The commenters noted that these banking services are part of established and legitimate business practices. The Department finds merit in these comments. However, the Department believes that the limitation on relationship banking services to services that the bank provides to relationship banking customers who do not maintain IRAs or Keogh Plans with the bank is an important safeguard under the exemption. Accordingly, section II(c) has been revised to require that the reduced or no cost banking services must be offered by the bank to customers other than those who qualify for such services by reason of IRAs and Keogh Plans maintained with the bank. In this regard, the Department notes that this condition would preclude the provision of services that specifically relate to the establishment or maintenance of IRAs or Keogh Plans.

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[1] Section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) generally transferred the authority of the Secretary of the Treasury to issue administrative exemptions under section 4975(c)(2) of the Code to the Secretary of Labor.

[2] 29 CFR 2510.3–2(d) explains that IRAs described in section 408(a) of the Code will not be considered pension plans subject to title I of ERISA, provided that: (1) No contributions to the plan are made by the employer or employee association; (2) participation is completely voluntary for employees or members; (3) the sole involvement of the employer or employee organization is without endorsement to permit the sponsor to publicize the program, to collect contributions on behalf of the sponsor through payroll deductions or dues checkoffs and to remit them to the sponsor; and (4) the employer or employee organization receives no consideration in the form of cash or otherwise other than reasonable compensation for services actually rendered in connection with payroll deductions or dues checkoffs.

29 CFR 2510.3–3(b) explains that for purposes of title I of ERISA, "employee benefit plan" shall not include a Keogh Plan under which no employees are covered under the plan. In this regard, 29 CFR 2510.3–3(c) states that for purposes of the above referenced section: (1) An individual and his or her spouse shall not be deemed to be employees with respect to a trade or business, whether incorporated or unincorporated, which is wholly owned by the individual and his or her spouse; and (2) a partner in a partnership and his or her spouse shall not be deemed to be employees with respect to the partnership.

Another commenter requested that the final exemption clarify that services provided in the ordinary course of an affiliate's business are also covered by the exemption. The Department wishes to note that relief is available under the exemption for services provided by an affiliate of the bank if such services are of the type that the bank itself could offer consistent with applicable banking law and are offered by the bank on a regular basis to customers who do not maintain IRAs and Keogh Plans with the bank. To the extent that the commenter is requesting additional relief, the Department does not believe that it is appropriate to further revise this condition.

Section II(d) of the proposal required that, for the purpose of determining eligibility to receive services at reduced or no cost, the deposit balance in the IRA or Keogh Plan be treated in the same manner as account balances of the same dollar amount, other than those in IRAs or Keogh Plans, which are maintained by customers of the bank. A number of commenters suggested that this condition was inconsistent with the current practice of the banking industry because the economics of banking require price discrimination by account type. The commenters urged the Department to modify this condition to permit banks to establish different minimum balances for each type of account according to the bank's own rate of return earned on each type of account. The Department recognizes that the exemption as proposed may be inconsistent with the existing practices of some banks, and, therefore, may discourage banks from including IRA and Keogh Plans in their relationship banking programs. However, the Department is concerned that a relationship banking program which establishes a different dollar threshold amount for each type of account in order to qualify for reduced or no cost services could have an adverse impact on IRA and Keogh Plan investments. In light of this concern, but in recognition that many financial institutions do not treat all banking balances as fungible, the Department has determined to revise section II(d) to provide that a relationship banking program would comply with this condition if the deposit balance requirement for IRAs and Keogh Plans is equal to the lowest balance required for any type of account which is counted by the bank in determining eligibility to receive reduced or no cost services. For example, if a bank establishes a relationship banking program under which a customer will be eligible for reduced or no cost services if he maintains a savings account balance of $1,000 or a Certificate of Deposit (CDs) balance of $5,000, section II(d) would be satisfied if the minimum balance required for IRAs or Keogh Plans to receive services under this program is $1,000 regardless of whether a savings account or CD investment is selected for the IRA or Keogh Plan.

In this regard, the Department notes that relief would not be available under the exemption for programs that determine eligibility on the basis of an aggregate balance of different types of account balances, unless the dollar amount of the IRA or Keogh Plan balance is weighted in the same manner as the dollar amount in the type of account with the lowest minimum balance eligible to participate in the program. For example, section II(d) will not be satisfied if a bank offers a package of services under a program which: (1) Requires customers to maintain an aggregate balance of $10,000 or more; (2) counts only those accounts with a minimum balance of $1000; and (3) counts, for purposes of aggregation, CDs and checking account balances on a dollar for dollar basis, and passbook accounts, IRAs and Keogh Plans on the basis of 50 cents for each dollar in such accounts. This type of program does not satisfy section II(d) because the IRA and Keogh Plan balances are not weighted in the same manner as the balances of either CDs or checking accounts.

The Department further notes that, under the rule contained in section II(d), if banks offer different packages of services depending on the amount of the customers' balances, the IRA or Keogh Plan customer must be eligible to receive the same services that non-IRA and non-Keogh Plan customers are eligible to receive under the particular relationship banking package. For example, if a bank establishes a multi-level relationship banking program, under which a Level I customer is eligible for reduced or no cost services if he maintains a savings account balance of $1,000 or a CD balance of $5,000, the minimum balance required under section II(d) for IRAs or Keogh Plans would be $1,000, and the IRA or Keogh Plan customer must be eligible to receive the same Level I services as non-IRA and non-Keogh Plan customers. Similarly, if a Level II customer is eligible to receive additional services if he maintains a savings account balance of $5,000 or a CD balance of $10,000 the minimum balance required for the IRA or Keogh Plan would be $5,000, and the IRA or Keogh Plan customer must be eligible to receive the same Level II services as non-IRA and non-Keogh Plan customers.

The Department also notes that relationship banking programs which treat all banking balances as fungible would continue to satisfy section II(d) as revised.

Under section II(e) of the proposal, the receipt of services would have been covered if the rate of return on the IRA or Keogh Plan investment was no less favorable than the rate of return on an identical investment that could have been made at the same time by a customer of the bank who is not eligible for (or who does not receive) reduced or no cost services. Several commenters urged the Department to delete section II(e). Other commenters requested that the Department clarify that section II(e) only requires that the rate of return earned on an IRA or Keogh Plan investment of a relationship banking customer be identical to that of an IRA or Keogh Plan investment of a non-relationship banking customer. In this regard, the Department wishes to note that section II(e) of the proposal was not limited by its terms to a comparison of IRA and Keogh Plan investments by relationship banking customers with IRA and Keogh Plan investments by non-relationship banking customers. The Department believes that a separate condition which requires that identical investments be offered to non-plan customers assures that the IRAs and Keogh Plans are afforded the same investment opportunities which are available to other customers of the bank who do not receive reduced or no cost services. Therefore, the Department cannot conclude that deletion or modification of this section is warranted.

Two commenters requested that the Department substitute the word "similar" for the word "identical" with respect to this condition. Since the adoption of this suggestion would necessitate a subjective determination, the Department does not believe that it would be appropriate to revise section II(e) in this regard.

Two commenters urged the Department to limit section II(e) to those investments made at the same branch of a bank because banks often offer different rates of return at different branches of the bank according to the market conditions of that geographic area. The Department sees merit in these comments and has limited this section to each branch of the bank.

Finally, in response to several comments, the Department notes that section II(e) does not preclude a bank from offering a more favorable rate of return on an IRA or Keogh Plan

investment which is otherwise identical to an investment available to other customers of such bank, regardless of participation in the relationship banking program.

3. Effective Date

As proposed, the final exemption would be effective as of the date of publication in the **Federal Register**. The ABA requested that the final exemption provide three types of transitional relief: (1) A delayed effective date of 120 days; (2) the exemption of binding arrangements; and (3) the exemption of binding investments. The ABA stated that banks will need 120 days to make the transition from Announcement 90–1[3] since it contains conditions which are different than those in the proposed exemption. The Department concurs with this comment and believes that a delayed effective date of 120 days is a reasonable period of time for banks to accomplish this transition.[4]

The second type of transitional relief requested is the exemption of binding arrangements involving reduced or no cost services entered into prior to the effective date of the exemption which comply with Announcement 90–1. Lastly, the ABA requested that the Department modify the exemption to permit banks to consider, for relationship banking purposes, binding IRA and Keogh Plan investments made prior to the exemption's effective date that complied with that Announcement. The ABA argued that these arrangements and investments may not meet the conditions of the final exemption, and that banks would be required to disregard them.

The Department is not persuaded by the commenter's argument regarding the provision of additional transitional relief. Under Announcement 90–1, the Service stated that the Announcement would be effective until the Department's final determination regarding the exemption. In this regard, the Department notes that banks were fully aware of the temporary nature of the Announcement, and had the opportunity to develop or alter their relationship banking packages accordingly. In addition, the Department believes that the safeguards contained in the final exemption would be diminished if the exemption were to provide relief for these binding arrangements and investments. Accordingly, the Department believes that a delayed effective date of 120 days adequately addresses the commenter's concerns regarding the need for transitional relief. This effective date provides sufficient time for banks to conform their relationship banking programs and policies to the conditions of the final exemption.

4. Definitions

The term bank is defined under the proposal as a bank described in section 408(n) of the Code. One commenter requested that the Department modify the definition of bank to include institutions which qualify as trustees of IRAs under section 408(a)(2) of the Code. Another commenter urged the Department to include bank affiliates which offer IRAs to customers. In the absence of any showing regarding how the safeguards contained in the exemption would apply to financial institutions described in Code section 408(a)(2) or bank affiliates, the Department is unable to conclude that such modification is warranted.

The proposed exemption defined the term deposit balance as having the same meaning as the term deposits which is contained in section 408(b)(4) of ERISA and defined under 29 CFR 2550.408b–4(c)(3). Thus, deposit balance includes any account upon which a reasonable rate of interest is paid, including a certificate of deposit issued by a bank or similar financial institution. The ABA urged the Department to broaden the definition of deposit balance to encompass all investments made by IRAs and Keogh Plans including those available only to IRAs and Keogh Plans. One of the Department's concerns in developing this exemption was to assure that the rate of return earned on an IRA or Keogh Plan investment is not sacrificed in favor of a customer's receipt of reduced or no cost services. In light of the Department's discussion above regarding the requirement under section II(e) that identical investments be offered to plan and non-plan customers, the Department does not believe that further relief is warranted.

One commenter was concerned about the Department's decision to include brothers, sisters and spouses of brothers or sisters within the definition of "member of his or her family." In this regard, the Department notes that this definition does not preclude a bank from limiting the number of family members entitled to receive relationship banking services under its program. Two other commenters urged the Department to expand this definition to include "domestic partners." The Department has determined not to make this revision because the scope of the term "domestic partners" has not been sufficiently defined.

Miscellaneous

1. Two commenters sought clarification from the Department regarding who is eligible to receive relationship banking services under the exemption. In response to the comments the Department has added language to the exemption to clarify that relief is limited under the exemption to the receipt of services by the individual covered under the IRA or Keogh Plan and his or her beneficiaries who are members of the family within the meaning of section III(f) of the final exemption.

2. Two commenters raised the question whether banks can include services which are available to all customers at no cost in their relationship banking programs. The Department notes that the exemption does not preclude banks from offering free services to customers participating in a relationship banking program.

3. A commenter requested that the Department clarify that, for purposes of the exemption, the term "service" includes the provision of life insurance by a credit union to its members. The Department directs the commenter to the Grant of Class Exemption for Certain Transactions Involving Persons for Whose Benefit an Individual Retirement Account or Retirement Plan for Self-Employed Individuals is Established which the Department is also publishing in today's **Federal Register**.

4. Certain commenters expressed concern whether banks may include credit based products as a method of qualifying for a bank's relationship banking program. In this regard, the Department notes that the preamble to the proposed exemption, in explaining the application of section II(d), contained an example of a relationship banking program which included loan balances in determining eligibility to receive services at reduced or no cost.[5]

5. In response to one commenter, the Department notes that the exemption does not require banks to include either or both IRAs and Keogh Plans in their relationship banking programs.

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[3] The Service issued a nonenforcement policy which provides that the Service will not raise issues concerning the tax effects resulting from possible prohibited transactions arising from certain cash, property or services offered by financial institutions to individuals for whom the financial institution maintains certain IRAs and Keogh Plans. See Announcement 90–1, 1990–2 I.R.B. 31, (January 1, 1990).

[4] In this regard, the Department has consulted with the Service regarding the application of Announcement 90–1. The Service has indicated that the Announcement will continue to be in effect during this 120 day period.

[5] See 56 FR 6367.

General Information

The attention of interested persons is directed to the following:

(1) In accordance with section 4975(c)(2) of the Code, and based upon the entire record, the Department finds that the exemption is administratively feasible, in the interests of the IRAs and Keogh Plans and of their participants and beneficiaries and protective of the rights of participants and beneficiaries of such plans.

(2) The exemption is supplemental to, and not in derogation of the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(3) The exemption is applicable to a transaction only if the conditions specified in the exemption are met.

Exemption

Accordingly, the following exemption is granted under the authority of section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975).

Section I: Covered Transaction

Effective May 11, 1993, the sanctions resulting from the application of section 4975 of the Code, including the loss of exemption of an individual retirement account (IRA) pursuant to section 408(e)(2)(A) of the Code, by reason of section 4975(c)(1) (D), (E) and (F) of the Code, shall not apply to the receipt of services at reduced or no cost by an individual for whose benefit an IRA or, if self-employed, a Keogh Plan, is established or maintained, or by members of his or her family, from a bank pursuant to an arrangement in which the deposit balance in the IRA or Keogh Plan is taken into account for purposes of determining eligibility to receive such services, provided that each condition of section II of this exemption is satisfied.

Section II: Conditions

(a) The IRA or Keogh Plan, the deposit balance of which is taken into account for purposes of determining eligibility to receive services at reduced or no cost, is established and maintained for the exclusive benefit of the participant covered under the IRA or Keogh Plan, his or her spouse or their beneficiaries.

(b) The services must be of the type that the bank itself could offer consistent with applicable federal and state banking law.

(c) The services are provided by the bank (or an affiliate of the bank) in the ordinary course of the bank's business to customers who qualify for reduced or no cost banking services but do not maintain IRAs or Keogh Plans with the bank.

(d) For the purpose of determining eligibility to receive services at reduced or no cost, the deposit balance required by the bank for the IRA or Keogh Plan is equal to the lowest balance required for any other type of account which the bank includes to determine eligibility to receive reduced or no cost services.

(e) The rate of return on the IRA or Keogh Plan investment is no less favorable than the rate of return on an identical investment that could have been made at the same time at the same branch of the bank by a customer of the bank who is not eligible for (or who does not receive) reduced or no cost services.

Section III: Definitions

The following definitions apply to this exemption:

(a) The term bank means a bank described in section 408(n) of the Code.

(b) The term IRA means an individual retirement account described in Code section 408(a). For purposes of this exemption, the term IRA shall not include an IRA which is an employee benefit plan covered by title I of ERISA.

(c) The term Keogh Plan means a pension, profit sharing, or stock bonus plan qualified under Code section 401(a) and exempt from taxation under Code section 501(a) under which some or all of the participants are employees described in section 401(c) of the Code. For purposes of this exemption, the term Keogh Plan shall not include a Keogh Plan which is an employee benefit plan covered by title I of ERISA.

(d) The term deposit balance means deposits as that term is defined under 29 CFR 2550.408b–4(c)(3).

(e) An affiliate of a bank includes any person directly or indirectly controlling, controlled by, or under common control with the bank. The term control means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(f) The term members of his or her family refers to beneficiaries of the individual for whose benefit the IRA or Keogh Plan is established or maintained, who would be members of the family as that term is defined in Code section 4975(e)(6), or a brother, a sister, or spouse of a brother or a sister.

(g) The term service includes incidental products of a *de minimis* value provided by third persons, pursuant to an arrangement with the bank, which are directly related to the provision of banking services covered by the exemption.

Signed at Washington, DC, this 5th day of January 1993.

Alan D. Lebowitz,

Deputy Assistant Secretary of Program Operations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 93–539 Filed 1–8–93; 8:45 am]

BILLING CODE 4510–29–M

[Application Number D–9124]

Proposed Amendment to Prohibited Transaction Exemption 93–2 (PTE 93–2) for the Receipt of Certain Services by Individuals for Whose Benefit Individual Retirement Accounts or Retirement Plans for Self-Employed Individuals Have Been Established or Maintained

AGENCY: Pension and Welfare Benefits Administration, U.S. Department of Labor.

ACTION: Notice of Proposed Amendment to PTE 93–2.

SUMMARY: This document contains a notice of pendency before the Department of Labor of a proposed amendment to PTE 93–2. PTE 93–2 is a class exemption that permits the receipt of services at reduced or no cost by an individual for whose benefit an individual retirement account (IRA) or, if self-employed, a Keough Plan, is established or maintained, or by members of his or her family, from a bank, provided the conditions of the exemption are met. The proposed amendment, if adopted, would affect individuals with a beneficial interest in the IRAs who receive such services as well as the banks that provide such services.

DATES: If adopted, the proposed amendment would be effective as of May 11, 1993, the effective date of PTE 93–2. Written comments and requests for a public hearing should be received by the Department on or before February 25, 1993.

ADDRESSES: All written comments and requests for a public hearing (preferably three copies) should be addressed to the U.S. Department of Labor, Office of Exemption Determinations, Pension and Welfare Benefits Administration, room N–5649, 200 Constitution Avenue, NW., Washington, DC 20210, (ATTN: D–9124).

FOR FURTHER INFORMATION CONTACT: Ms. Allison K. Padams, Office of Exemption Determinations, Pension and Welfare Benefits Administration, U.S.

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Department of Labor, (202) 523–8971 (this is not a toll-free number); or Ms. Susan E. Rees, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, (202) 523–9141 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Notice is hereby given of the pendency before the Department of a proposed amendment to PTE 93–2. The amendment would provide relief from the restrictions of sections 406(a)(1)(D) and 406 (b) of the Employee Retirement Income Security Act of 1974 the (ERISA) and the sanctions resulting from the application of sections 4975(a) and (b), 4975(c)(3) and 408(e)(2) of the Internal Revenue Code of 1986 (the Code) by reason of section 4975(c)(1) (D), (E) and (F) of the Code.

By notice appearing elsewhere in this issue of the **Federal Register**, the Department has granted PTE 93–2 to permit the receipt of services at reduced or no cost by an individual for whose benefit an IRA or Keough Plan is established or maintained, or by members of his or her family, from a bank pursuant to an arrangement in which the deposit balance in the IRA or Keough Plan is taken into account for purposes of determining eligibility to receive such services, provided that the conditions of the exemption are met.[1] PTE 93–2 provides an exemption from the sanctions resulting from the application of sections 4975(a) and (b), 4975(c)(3) and 408(e)(2) of the Code by reason of section 4975(c)(1) (D), (E) and (F) of the Code.[2]

In response to the proposed exemption for the receipt of relationship banking services,[3] a number of commenters (the Commenters) urged the Department to expand the exemption to provide relief for transactions involving individuals for whose benefit a simplified employee plan (SEP), as defined under section 408(k) of the Code, is established or maintained. Since the Department did not previously propose relief from sections 406(a)(1)(D) and 406(b), it would not be appropriate to grant such relief as part of the final exemption because the proposed exemption did not offer interested persons an opportunity to present their views with respect to the Department's contemplated action. Because the Department was desirous of not delaying the grant of relief from section 4975(c)(1)(D), (E), and (F) of the Code for transactions involving IRAs and Keogh Plans not covered by title I of ERISA, the Department decided to adopt PTE 93–2, and to propose an amendment which would extend the relief provided pursuant to PTE 93–2 to individuals for whose benefit SEPs have been established or maintained. The Department is proposing this relief on its own motion, pursuant to section 408(a) of ERISA and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (55 FR 32836, August 10, 1990).

According to the Commenters, SEP arrangements are, for all practical purposes, no different than other IRAs covered by PTE 93–2, and the banking industry makes no distinction between a SEP-IRA and any other IRA. In this regard, the Commenters indicated that a SEP is an IRA which is funded by employer contributions. Once an employer makes the required contributions to a participant's SEP, the employer's role with respect to the SEP is limited. A participant owns and controls his SEP like any other IRA. Thus, participants generally are free to transfer the employer contributions to other IRAs or withdraw them at any time.

Based on the arguments presented by the Commenters and the additional protections already embodied in PTE 93–2, it appears to the Department that the safeguards of PTE 93–2 would not be diminished by the proposed amendment. However, the Department is of the view that the exemption should not be available to SEP arrangements which restrict the participant's ability to transfer assets from the SEP to an IRA maintained at a financial institution of the participant's choice. Therefore, the Department has decided to propose relief for SEPs that provide participants with the unrestricted authority to transfer the assets to IRAs sponsored by different financial institutions. In this regard, the Department requests that interested persons, in addition to other comments, describe how a relationship banking program would operate with respect to SEPs, and whether additional safeguards are necessary in order to protect the interests of the participants and beneficiaries of SEPs.

The Department notes that the exemption will not be available for the receipt of services by third persons other than those described in the exemption. Thus, for example, no relief would be available under the exemption for the receipt of services by the employer establishing or maintaining the SEP on behalf of its employees.

Notice to Interested Persons

Because many participants in SEPs and financial institutions sponsoring SEPs could conceivably be considered interested persons, the only practical form of notice is publication in the **Federal Register**.

General Information

The attention of interested persons is directed to the following:

(1) Before an exemption may be granted under section 408(a) of ERISA and section 4975(c)(2) of the Code, the Department must find that the exemption is administratively feasible, in the interests of the IRAs and their participants and beneficiaries and protective of the rights of participants and beneficiaries of such plans.

(2) The proposed amendment, if granted, will be supplemental to, and not in derogation of, any other provisions of ERISA and the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(3) If granted, the proposed amendment will be applicable to a transaction only if the conditions specified in the class exemption are met.

Written Comments and Hearing Request

All interested persons are invited to submit written comments or requests for a public hearing on the proposed exemption to the address and within the time period set forth above. All comments will be made a part of the record. Comments and requests for a hearing should state the reasons for the writer's interest in the proposed exemption. Comments received will be available for public inspection with the

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[1] PTE 93–2 applies only to IRAs described in section 408(a) of the Code which are not "employee benefit plans" covered by title I of ERISA.

29 CFR 2510.3–2(d) explains that IRAs described in section 408(a) of the Code will not be considered pension plans subject to title I of ERISA, provided that: (1) No contributions to the plan are made by the employer of employee association; (2) participation is completely voluntary for employees or members; (3) the sole involvement of the employer or employee organization is without endorsement to permit the sponsor to publicize the program, to collect contributions on behalf of the sponsor through payroll deductions or dues checkoffs and to remit them to the sponsor; and (4) the employer or employee organization receives no consideration in the form of cash or otherwise other than reasonable compensation for services actually rendered in connection with payroll deductions or dues checkoffs.

[2] Section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) generally transferred the authority of the Secretary of the Treasury to issue administrative exemptions under section 4975(c)(2) of the Code to the Secretary of Labor.

[3] See Proposed Class Exemption for the Receipt of Certain Services by Individuals Establishing or Maintaining Individual Retirement Accounts or Retirement Plans for Self-Employed Individuals (58 FR 8365, February 28, 1993).

referenced application at the above address.

Proposed Amendment

Under section 408(a) of ERISA and section 4975(c)(2) of the Code and in accordance with the procedures set forth in 29 CFR Part 250, Subpart B (55 FR 32836, August 10, 1990), the Department proposes to amend PTE 93–2 as set forth below:

(1) Section I is amended to read: "Effective May 11, 1993, the restrictions of sections 406(a)(1)(D) and 406(b) of ERISA and the sanctions resulting from the application of section 4975 of the Code, including the loss of exemption of an IRA pursuant to section 408(e)(2)(A) of the Code, by reason of section 4975(c)(1) (D), (E) and (F) of the Code, shall not apply to the receipt of services at reduced or no cost by an individual for whose benefit an IRA or Keogh Plan is established or maintained, or by members of his or her family, from a bank, pursuant to an arrangement in which the deposit balance in the IRA or Keogh Plan is taken into account for purposes of determining eligibility to receive such services, provided that each condition of section II of this exemption is satisfied."

(2) Section III(b) is amended to read: The term IRA means an individual retirement account described in Code section 408(a). For purposes of this exemption, the term IRA shall not include an IRA which is an employee benefit plan covered by title I or ERISA, except for a Simplified Employee Pension (SEP) described in section 408(k) of the Code which provides participants with the unrestricted authority to transfer their SEP balances to IRAs sponsored by different financial institutions.

Signed at Washington, DC, this 5th day of January, 1993.

Alan D. Lebowitz,

Deputy Assistant Secretary for Program Operations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 93–540 Filed 1–8–93; 8:45 am]

BILLING CODE 4510–29–M

[Prohibited Transaction Exemption 93–1; Application Number D–4064]

Class Exemption for Certain Transactions by Individuals for Whose Benefit Individual Retirement Accounts or Retirement Plans for Self-Employed Individuals Have Been Established or Maintained

AGENCY: Pension and Welfare Benefits Administration, U.S. Department of Labor.

ACTION: Grant of class exemption.

SUMMARY: This document contains a final exemption from certain prohibited transaction restrictions of the Internal Revenue Code of 1986 (the Code). The class exemption permits the receipt of certain cash, premiums or other consideration paid to an individual in connection with a transaction involving an individual retirement account (IRA) or a retirement plan for a self-employed individual (Keogh Plan), provided that the conditions of the exemption are met. The exemption affects individuals with a beneficial interest in the IRAs or Keogh Plans who receive such premiums or gifts, as well as the financial institutions which provide the payments.

EFFECTIVE DATE: January 1, 1975.

FOR FURTHER INFORMATION CONTACT: Allison K. Padams, Office of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor, (202) 523–8971 (this is not a toll-free number; or Susan E. Rees, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, (202) 523–9141 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On February 1, 1983, the Department of Labor (the Department) and the Internal Revenue Service (the Service) published a notice of proposed class exemption (48 FR 4592) from the sanctions resulting from the application of sections 4975 (a) and (b), 4975(c)(3) and 408(e)(2) of the Code by reason of section 4975(c)(1) of the Code.[1] The transactions involve the payment of cash, premiums and other consideration to individuals in connection with establishment of, or contribution to an IRA or Keogh Plan by organizations authorized to sponsor IRAs or Keogh Plans. Because of the apparent prevalence of this type of transaction, the Department and the Service proposed the class exemption on their own motion pursuant to section 4975(c)(2) of the Code, and in accordance with the procedures set forth in Rev. Proc. 75–26 (1975–1 C.B. 722) and ERISA Procedure 75–1 (40 FR 18471, April 28, 1975).

The notice of pendency invited interested persons to submit written comments or request that a public hearing be held on the proposed exemption. Over twenty public comments and requests for a public hearing with regard to the proposed class exemption were received pursuant to section 4975(c)(2) of the Code and in accordance with the procedures set forth in Rev. Proc. 75–26 and in ERISA Procedure 75–1. Notice of a public hearing was published on July 1, 1983 (48 FR 30510), and the public hearing was held on August 17, 1983. To date, the Department has not granted relief for the transactions described in the proposed exemption.

Recently, it came to the attention of the Department that many financial institutions may no longer offer premiums as incentives for their customers to establish IRAs or Keogh Plans with their particular institutions. Rather, it appeared that financial institutions were offering banking services at reduced or no cost as an inducement to customers to begin or expand banking relationships. Consequently, the Department published a notice in the **Federal Register** (56 FR 8368, February 28, 1990) in which it requested comments from interested persons regarding the disposition of the proposed class exemption (the Notice to Solicit Comments).[2]

The Notice to Solicit Comments gave interested persons an opportunity to submit written comments to be considered by the Department in deciding whether or not to provide exemptive relief for the receipt of cash, premiums, or other consideration by an individual in connection with the establishment of, or contribution to, an IRA or Keogh Plan. Specifically, the Department requested that interested persons provide current information on the extent of the need for exemptive relief for transactions of this type and the standards and safeguards upon which exemptive relief should be conditioned. Ten comments were received pursuant to the Notice to Solicit Comments.

Upon consideration of the entire record in this matter, including all the comments received and testimony offered at the public hearing, the Department has determined to grant the proposed class exemption subject to certain modifications.

Description of the Proposal

The 1983 Proposal provided retroactive and prospective relief from the sanctions resulting from the

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[1] Section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) generally transferred the authority of the Secretary of the Treasury to issue administrative exemptions under section 4975(c)(2) of the Code of the Secretary of Labor.

[2] By notice appearing elsewhere in this issue of the **Federal Register**, the Department has granted a conditional class exemption which permits the receipt of certain services at reduced or no cost by an individual, for whose benefit an IRA or Keogh Plan is established or maintained, from a bank.

application of 4975 of the Code, including the loss of exemption of an IRA pursuant to section 408(e)(2)(A) of the Code, by reason of section 4975(c)(1) of the Code, for the payment of cash, property or other consideration by an organization authorized to sponsor IRAs or Keogh Plans, to an individual establishing or contributing to an IRA or Keogh Plan or to members of his or her family as defined by section 4975(e)(6) of the Code.

The proposal contained specific conditions designed to insure that the transactions did not conflict with the basic purpose of such plans which is to provide retirement savings for participants and their beneficiaries. Thus, the IRA or Keogh Plan must be established solely to benefit the person receiving the cash, property or other consideration, his or her spouse, and their beneficiaries. The fair market value of the property or other consideration which may be measured by its cost to the financial institution, or the cash received, must not exceed $10 for a deposit of less than $5,000 and $20 for a deposit of $5,000 or more. The conditions of the proposed exemption did not specifically limit the form the premium or other consideration may take.

The Department also noted in the preamble to the proposal that the exemption would not be available for transactions involving IRAs or Keogh Plans which are subject to title I of ERISA.[3] Nor would the exemption be available to exempt the receipt of cash, property or other consideration by third persons other than those described in the exemption.

[3] 29 CFR 2510.3–2(d) explains that IRAs described in section 408(a) of the Code will not be considered pension plans subject to title I of ERISA, provided that: (1) No contributions to the plan are made by the employer or employee-association; (2) participation is completely voluntary for employees or members; (3) the sole involvement of the employer or employee organization is without endorsement to permit the sponsor to publicize the program, to collect contributions on behalf of the sponsor through payroll deductions or dues checkoffs and to remit them to the sponsor; and (4) the employer or employee organization receives no consideration in the form of cash or otherwise other than reasonable compensation for services actually rendered in connection with payroll deductions or dues checkoffs.

29 CFR 2510.3–3(b) explains that for purposes of title I of ERISA, "employee benefit plan" shall not include a Keogh Plan under which no employees are covered under the plan. In this regard, 29 CFR 2510.3–3(c) states that for purposes of the above referenced section: (1) An individual and his or her spouse shall not be deemed to be employees with respect to a trade or business, whether incorporated or unincorporated, which is wholly owned by the individual and his or her spouse; and (2) a partner in a partnership and his or her spouse shall not be deemed to be employees with respect to the partnership.

The Department proposed the class exemption based upon its understanding that it was common practice for financial institutions to offer premiums in connection with the establishment of, or the additional contribution to, an IRA or Keogh Plan. The Department also recognized that the apparent prevalence of this type of transaction could result in adverse consequences to a large number of individuals establishing IRAs and Keogh Plans.

Discussion of the Comments

I. Major Issues Raised in Response to the 1983 Notice of Proposed Exemption and Public Hearing

Several commenters suggested that no exemption was necessary because the transactions described in the proposed exemption are not prohibited transactions under section 4975(c)(1) of the Code. In this regard, section 4975(c)(1) of the Code prohibits, in relevant part, the transfer to, or use by or for the benefit of, a disqualified person of the income or assets of a plan (4975(c)(1)(D)); an act by a disqualified person who is a fiduciary whereby he deals with the income or assets of a plan in his own interest or for his own account (4975(c)(1)(E)); and the receipt of any consideration for his own personal account by any disqualified person who is a fiduciary from any party dealing with the plan in connection with a transaction involving the income or assets of plan (4975(c)(1)(F)). The Department disagrees with these comments. The term "disqualified person", as defined in Code section 4975(e)(2), includes a fiduciary and a person providing services to the plan. Persons who exercise discretionary authority or control over the assets of a plan, including IRAs and Keogh Plans, are fiduciaries subject to the restrictions imposed by section 4975(c)(1) of the Code.[4] Thus the receipt of cash, premiums or other consideration by such individuals in connection with the investment of his or her IRA or Keogh Plan assets is a transaction prohibited under section 4975(c)(1) of the Code.[5] In the absence of an exemption, the individual who receives such cash, premiums or other consideration and the plan involved may be subject to the sanctions applied under section 408(e)(2) and 4975(c)(1) of the Code. To clarify the Department's position, the final exemption now specifies the subsections of section 4975(c)(1) from which relief is provided.

A number of commenters expressed concern that the exemption would discourage financial institutions from providing IRA and Keogh Plan participants with customary financial services, such as free checking accounts and free check-cashing privileges which have traditionally been based on account balances maintained by a customer at the financial institution. It was represented that these services, unlike such premiums as toasters and radios, cannot readily be valued because their cost varies greatly among institutions and recipients. In this regard, the Department notes that a separate exemption for the receipt of certain services buy individuals covered under individual retirement accounts or retirement plans for self-employed individuals is published in today's **Federal Register**. Consequently, the Department has determined not to revise the subject exemption in this regard.

Several commenters recommended that institutions be permitted to pay premiums with respect to an IRA or Keogh Plan on an annual or more frequent basis without regard to whether additional contributions have been made. The Department is not persuaded by the commenters that such an expansion would be appropriate. Another commenter urged the Department to permit the payment of premiums with respect to each contribution made to an IRA or Keogh Plan. The commenters suggested that failure to allow such payments may result in IRA and Keogh Plan assets being transferred to another financial institution solely to obtain additional premiums. The Department generally believes that most plan participants are more concerned with their future retirement income and the terms and conditions of the various investment options offered at particular financial institutions than with the *de minimis* premiums permitted by this exemption. Nevertheless, the Department recognizes that some IRA and Keogh funds may be transferred from institution to institution in order to receive a premium. Accordingly, the Department has determined to modify the final exemption to permit the payment of cash, premiums or other consideration in connection with the making of additional contributions to an established IRA or Keogh Plan, including the transfer of assets from another plan.

A number of commenters urged the Department to delete or modify the $10 and $20 limits under the proposed

[4] See section 4975(e)(3) of the Code.

[5] See Advisory Opinion 89–12A (July 14, 1989)

exemption. Several commenters suggested that the exemption permit market forces to establish the dollar limitations. Another commenter suggested a "rule of reasonableness" or a maximum limit set as a percentage of the total IRA (or Keogh Plan) investment. The Department believes that deleting or increasing the dollar limits, or substituting a maximum limit set as a percentage of total plan investment, could have an adverse impact on IRAs and Keogh Plans by creating an incentive for individuals to make IRA or Keogh Plan investments at a particular financial institution for reasons unrelated to the purposes for which such plans are established, i.e. to provide retirement income. Regarding the other suggested modifications to the dollar limits, the Department does not believe it would be appropriate to revise these limits in this regard since adoption of these suggestions would necessitate a subjective determination of the appropriate limit.

A number of commenters suggested that the relief provided by the class exemption should be given retroactive application without any dollar limitation on the amount of the premiums and that the dollar limitations should only apply prospectively. The Department is not persuaded by the commenters' arguments regarding additional retroactive relief. In this regard, the Department notes that financial institutions were aware of the dollar limitations found in the Notice of Proposed Exemption,[6] and had the opportunity to alter their banking programs accordingly. Additionally, the Department wishes to note that on January 8, 1990, the Service issued an IRA nonenforcement policy (the IRA Nonenforcement Policy),[7] which provides that the Service will not raise issues concerning the tax effects resulting from possible prohibited transactions arising from certain cash, property or services offered by financial institutions described in section 408(n) of the Code to individuals for whom the financial institution maintains certain IRAs and Keogh Plans. The IRA Nonenforcement Policy applies to the cash, property or other consideration described in the 1983 Proposal.

Several commenters urged the Department to clarify that the exemption provides relief for the provision by a credit union of life insurance coverage to members who maintain or establish IRAs and Keogh Plans at such credit union.[8] According to the commenters, it is a long established and customary practice for a credit union to provide life insurance, in an amount equal to the balance of the savings of its members, including IRA and Keogh Plan accounts. Each credit union determines the maximum level of insurance coverage that it will furnish its members. One commenter stated that 99% of all credit unions currently limit life insurance coverage to $5,000 per member. The insurance is provided by credit unions through the purchase of group term life insurance policies with coverages in an amount equal to each member's total account balance up to the maximum amount established by the particular credit union.

According to the commenters, in calculating the dollar amount of insurance coverage, a credit union generally considers the relevant accounts maintained by an individual in the order in which they are established. Since the value of the insurance attributable to the IRA or Keogh Plan balance may differ from member to member depending upon the number of other accounts maintained by the member, the maximum level of coverage selected by the credit union, and the order in which each account is opened, the commenter argued that it would be difficult for the financial institutions to comply with the dollar limitations with regard to these insurance programs. Additionally, because the nature of life insurance contemplates that coverage be maintained from year to year, it would raise administrative problems for the financial institutions, and prove disadvantageous to members, if additional contributions were required in order to maintain insurance coverage from year to year. On the basis of these comments, the Department has determined that it would be appropriate to modify the final exemption to permit the provision of group term life insurance by a financial institution.

Accordingly, we have revised the exemption to provide additional relief for the provision of life insurance subject to a requirement limiting the amount of coverage that may be provided. Thus, under the final exemption, where a financial institution takes into account an IRA or Keogh Plan balance in determining eligibility for life insurance, the amount of insurance that is attributable on a dollar for dollar basis to the IRA or Keogh Plan deposit balance may not exceed $5,000.

II. Major Issues Raised in Response to the 1991 Notice to Solicit Comments

Nine commenters urged the Department to finalize the proposed exemption. These commenters indicated that financial institutions may still offer premiums to attract customers. One commenter requested that the Department withdraw the proposed exemption.

Several of these commenters requested that the Department increase the dollar limitations on the value of the cash, premiums or other consideration to account for inflation. The Department is not persuaded by the comments submitted in favor for this modification. The Department continues to believe that the value of the cash, premiums or other consideration allowed under the exemption must be *de minimis* to assure that such transactions do not conflict with the basic purpose of IRAs and Keogh Plans which is to provide retirement savings for participants and their beneficiaries.

III. Miscellaneous

For purposes of clarification, the Department has defined the terms "IRA" and "Keogh Plan" under the final exemption. In addition, the definition of "members of his or her family" has been modified to make it consistent with the definition contained in the class exemption for the receipt of certain services at reduced or no cost by an individual for whose benefit an IRA or a Keogh is established and maintained from a bank which is published in this issue of the **Federal Register**.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 4975(c)(2) of the Code does not relieve a fiduciary or other disqualified person from certain other provisions of the Code. These provisions include any prohibited transaction provisions in section 4975(c)(1) to which the exemption does not expressly apply; nor does the exemption affect the requirement of section 408(a) of the Code that an IRA must operate for the exclusive benefit of the individual for whose benefit the IRA is maintained and his or her beneficiaries, or the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of

[6] See 48 FR 4592, at 4593.

[7] Announcement 90–1, 1990–2 I.R.B. 31 (January 8, 1990).

[8] The Credit Union National Association Inc., (CUNA) was among the commenters who raised this issue. Additionally, CUNA provided comments on the proposed exemption for the receipt of certain services by individuals establishing or maintaining Individual Retirement Accounts or Retirement Plans for Self-Employed Individuals (56 FR 8365, February 28, 1991), and filed an individual exemption request to permit credit unions to provide members with such life insurance coverage.

the employer maintaining the plan and their beneficiaries.

(2) This exemption is supplemental to, and not in derogation of, any other provisions of the Code, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

(3) The class exemption is applicable to a particular transaction only if the transaction satisfies the conditions specified in the class exemption.

(4) In accordance with section 4975(c)(2) of the Code and the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975), and based upon the entire record, the Department has made the following determinations:

(i) The exemption is administratively feasible;

(ii) It is in the interest of the individuals for whose benefit the IRA and Keogh Plans are maintained; and

(iii) It is protective of the rights of those individuals and their beneficiaries.

Exemption

Accordingly, the following exemption is granted under the authority of section 4975(c)(2) of the Code, and in accordance with the procedures set forth in ERISA Procedure 75–1.

I. Effective January 1, 1975, the sanctions resulting from the application of section 4975 of the Code, including the loss of exemption of an IRA pursuant to section 408(e)(2)(A) of the Code, by reason of section 4975(c)(1)(D), (E) and (F) of the Code, shall not apply to the payment of cash, property, or other consideration by an organization authorized to sponsor IRAs or Keogh Plans, to an individual for whose benefit an IRA or Keogh Plan is established or maintained, or to members of his or her family provided that:

(a) The IRA or Keogh Plan in connection with which cash, property or other consideration is given, is established solely to benefit the participant, his or her spouse and their beneficiaries;

(b) The cash, property or other consideration is given only in connection with the establishment of the IRA or Keogh Plan or the making of an additional contribution, including the transfer of assets from another plan, to an existing IRA or Keogh Plan.

(c) During any taxable year, the total of the fair market value of the property or other consideration to the sponsor of the IRA or Keogh Plan, and the cash received is not more than:

(1) $10 for deposits to the IRA or Keogh Plan of less than $5,000; and

(2) $20 for deposits to the IRA or Keogh Plan of $5,000 or more.

(d) In any case where the consideration provided by a financial institution to an individual for whose benefit an IRA or Keogh Plan is established or maintained, is group term life insurance, the limitations set forth in conditions (b) and (c) shall not apply to the provision of such insurance if, during any taxable year, no more than $5,000 of the face value of the insurance is attributable on a dollar for dollar basis to the assets of the IRA or Keogh Plan.

II. Definitions

(a) The term "taxable year" means the taxable year of the individual. In determining the taxable year for payments in connection with transfers of assets from previously established plans, the calendar year in which the transfer is received by the organization is deemed to be the taxable year of the individual.

(b) The "fair market value of the cash, property or other consideration" given may be measured by the cost to the financial institution.

(c) The term "members of his or her family" refers to beneficiaries of the individual for whose benefit the IRA or Keogh Plan is established or maintained, who would be members of the family as that term is defined in Code section 4975(e)(6), or a brother, a sister, or spouse of a brother or a sister.

(d) The term "IRA" means an individual retirement account described in Code section 408(a). For purposes of this exemption, the term IRA shall not include an IRA which is an employee benefit plan covered by title I of ERISA.

(e) The term "Keogh Plan" means a pension, profit sharing or stock bonus plan qualified under Code section 401(a) and exemption from taxation under Code section 501(a) under which some or all of the participants are employees described in section 401(c) of the Code. For purposes of this exemption the term Keogh Plan shall not include a Keogh Plan which is an employee benefit plan covered by title I or ERISA.

Signed at Washington, DC, this 5th day of January 1993.

Alan D. Lebowitz,

Deputy Assistant Secretary for Program Operations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 93–541 Filed 1–8–93; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL ADVISORY COUNCIL ON THE PUBLIC SERVICE

NACPS to Hold Public Hearing, Friday, February 5, 1993

SUMMARY: The National Advisory Council on the Public Service will hold a public hearing on the Federal government as an employer. The hearing is scheduled for Friday, February 5, 1993, in the hearing room of the Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland from 9:30 a.m. to 12 noon.

Invited witnesses will give testimony to the Council on such issues as recruiting and retention, model human resources programs, career development programs, women in the Federal workforce and family-friendly policies.

The hearing will be open to the public. Time will be allotted to those persons wishing to make comment to the Council concerning the Federal Employment. Any person or organization wishing to reserve time to make public comment during the hearing should pre-register by calling the Council at 202–724–0796 before February 1. Those persons who do not pre-register to make comments cannot be guaranteed an opportunity to do so. The Council also welcomes written comments on Federal workforce issues, which should be sent to the Council office at 420 National Press Building, 529 14th Street, NW., Washington, DC 20045.

For more information and for media coverage, contact Rhea Farberman at 202–724–0796.

Issued January 6, 1993.

Jean M. Curtis,

Executive Director, National Advisory Council on the Public Service.

[FR Doc. 93–462 Filed 1–8–93; 8:45 am]

BILLING CODE 75-25-01

NATIONAL COMMISSION ON AMERICAN INDIAN, ALASKA NATIVE, AND NATIVE HAWAIIAN HOUSING

Meeting

AGENCY: The National Commission on American Indian, Alaska Native, and Native Hawaiian Housing.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Commission on American Indian, Alaska Native, and Native Hawaiian Housing announces the forthcoming meeting of the Commission.

DATES: January 26, 1993, 9 a.m. to 5 p.m.

ADDRESSES: Holiday Inn Downtown, The Governor's House, 17th & Rhode Island, NW., Washington, DC., (202) 296–2100.

FOR FURTHER INFORMATION CONTACT: Lois V. Toliver, Administrative Officer, (202) 275–0045.

SUPPLEMENTARY INFORMATION:

Type of Meeting: Open.

Agenda: Call to Order, Roll Call, Chairman's Message, Update of Commission Activities, Committee Reports, Commission Strategy Session.

Lois V. Toliver,

Administrative Officer.

[FR Doc. 93–444 Filed 1–8–93; 8:45 am]

BILLING CODE 6820–07–M

NATIONAL COMMISSION ON MANUFACTURED HOUSING

Meeting

AGENCY: National Commission on Manufactured Housing.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 101–625, as amended, the National Commission on Manufactured Housing announces a forthcoming meeting of the Commission.

DATES: January 7, 1993, 9 a.m.–5 p.m.; January 8, 1993, 9 a.m.–5 p.m.

ADDRESSES: Hyatt Regency, 400 New Jersey Avenue, Washington, DC 20001, Bryce Room.

FOR FURTHER INFORMATION CONTACT: Carmelita R. Pratt, Administrative Officer, The National Commission on Manufactured Housing, (GSA) 7th & D Street, SW., #7109, Washington, DC 20407 (202) 708–5702.

TYPE OF MEETING: Open.

Due to scheduling difficulties, this notice could not be published 15 days prior to this meeting as required by Federal Advisory Committee Act.

Carelita R. Pratt,

Administrative Officer.

[FR Doc. 93–455 Filed 1–8–93; 8:45 am]

BILLING CODE 6820–EA–M

NUCLEAR REGULATORY COMMISSION

Abnormal Occurrences for Third Quarter CY 1992; Dissemination of Information

Section 208 of the Energy Reorganization Act of 1974, as amended, requires the NRC to disseminate information on abnormal occurrences (i.e., unscheduled incidents or events that the Commission determines are significant from the standpoint of public health and safety). During the third quarter of CY 1992, the following incidents at NRC licensees were determined to be abnormal occurrences (AOs) and are described below, together with the remedial actions taken. The events are also being included in NUREG–0090, Vol. 15, No. 3 ("Report to Congress on Abnormal Occurrences: July—September 1992"). This report will be available at the NRC's Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC 20555 about three weeks after the publication date of this **Federal Register** Notice.

Other NRC Licensees

(Industrial Radiographers, Medical Institutions, Industrial Users, etc.)

92–9 Medical Therapy Misadministration at Cooper Hospital/University Medical Center in Camden, New Jersey

One of the AO reporting guidelines notes that a therapeutic misadministration affecting two or more patients at the same facility can be considered an abnormal occurrence.

Date and Place—November 11, 1991 to January 7, 1992; Cooper Hospital/University Medical Center; Camden, New Jersey.

Nature and Probable Consequences—On January 27, 1992, the NRC Region I office was notified by telephone that five therapeutic misadministrations involving Iridium-192 (Ir-192) wire occurred at Cooper Hospital/University Medical Center at Camden, New Jersey from November 11, 1991 to January 7, 1992. The licensee had discovered the error on January 24, 1992, after the review of patient charts in preparation for the Quality Management Program submittal. The error caused a 12.2 percent underdosing of the patients.

Four patients received external beam therapy (Linear Accelerator) in addition to the radiation received from the Ir-192 implants. Patient A was to receive 1043 rads from an Ir-192 intracavitary bronchial implant for the treatment of lung cancer and received 916 rads on November 11, 1991. Patient A later received 5576 rads from external beam therapy. Patient B was to receive 1266 rads to the head and neck from an Ir-192 interstitial implant for the treatment of cancer and received 1112 rads on November 12, 1992. Patient B later received 4600 rads from external beam therapy. Patient C was to receive 2150 rads from an Ir-192 interstitial implant for the treatment of breast cancer and received 1888 rads on December 2, 1991. Patient C later received 5940 rads from external beam therapy. Patient D was to receive 2000 rads to the tongue for the treatment of cancer from an Ir-192 interstitial implant and received 1756 rads on January 7, 1992. Patient D later received 5940 rads from external beam therapy. The licensee has determined that the above patient's treatment were not compromised by the small decrease in the total dose received when the external beam therapy treatment is factored into the assessment.

One patient did not receive external beam therapy. On November 21, 1991, Patient E was prescribed to receive 4628 rads to the pelvis for the treatment of cancer from an Ir-192 interstitial implant and received 4063 rads. Patient E's attending physician had originally calculated a desired dose between 4000 and 4500 rads and wanted to include hyperthermia treatment. Hyperthermia treatment required insertion of interstitial microwave antennae so that heat treatment was terminated within one hour before the implants were inserted and was initiated within one hour after the implants were removed. The attending physician was informed by the licensee's's staff that the implants would have to be removed at unreasonable times in order to fall within the attending physician's desired dose range. The attending physician then agreed to give 4628 rads so that the second hyperthermia treatment could be given at a more reasonable time. Since the actual delivered dose fell within the attending physician's initial range, the licensee does not foresee any adverse effects for Patient E.

Cause or Causes—It was determined that the cause of the misadministration was an input error into the treatment planning computer. Specifically, the source calibration factor was in non-Systeme Internationale (SI) units (non-metric), however, the computer was set to receive the data in SI units and the setting was not changed.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective action was to include the calibration factor that is used during treatments in their records for Implant Source Inventory—Source Type Characteristics so that the licensee can verify that the proper factors are used.

NRC—An NRC Region I inspector conducted an inspection of the incident on August 5, 1992, to determine the circumstances associated with the misadministration. The inspector's findings were in agreement with the licensee concerning the cause of the misadministration. The inspector

determined that the licensee's corrective actions were adequate to prevent recurrence. Inspection findings regarding the misadministration are documented in Inspection Field Notes approved September 9, 1992.

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92–10 Extremity Overexposure of a Radiographer at MQS Inspection, Inc., Field Site in Trenton, Michigan

One of the AO reporting guidelines notes that an exposure of the feet, ankles, hands, or forearms of any individual to 375 rem or more of radiation can be considered an abnormal occurrence.

Date and Place—July 6, 1992; a temporary radiography field site in Trenton, Michigan.

Nature and Probable Consequences—On July 6, 1992, a licensee radiographer was assigned to radiograph various pipes at a construction site. Radiography is a non-destructive testing technique which uses a sealed radiation source to make X-ray-like images of heavy metal objects.

The configuration of this job required that the radiography exposure device (camera) be suspended 20 feet above the floor. The radiation source is exposed using a remote cable to make the film image and then is retracted into the shielded camera. After an exposure, the radiographer used an aerial platform to reach the camera. He performed a radiation survey as he approached to assure that the source was in the shield. The radiographer was wearing his audible alarm radiation measuring device, but it was turned off.

The radiographer then moved the camera to reach the camera port to lock the radiation source inside. When he removed the tube which guides the source, he discovered the radiation source was exposed about 4 inches outside the camera. The source had apparently shifted into the unshielded position when the radiographer moved the camera to lock it. The source was locked into place in its exposed condition. The radiographer immediately returned to ground level, but later returned to the camera to unlock it so that the radiation source would be retracted into its shield.

The incident was subsequently reenacted by the licensee's Radiation Safety Officer and NRC inspectors to evaluate the radiation exposure received by the radiographer. The calculation by the Radiation Safety Officer, based on a series of reenactments, indicated a minimum 440 rem exposure to the individual's hand. NRC inspectors estimated that the dose was about 880 rem. The radiation measuring device worn by the worker indicated a whole body radiation exposure of about 250 millirem.

The worker's hand was evaluated and monitored by medical radiation specialists at an area medical center. No short-term physical changes to the skin of the hand were observed.

The NRC limit was extremity exposures is 18.75 rem in a calendar quarter. Therefore, the reenactment showed that the exposure received was substantially over the limit. The whole body radiation exposure was within the NRC limit of 3 rem in a calendar quarter.

Cause or Causes—The overexposure occurred as a result of the failure of the radiographer to use an audible alarm exposure measuring device as required by NRC regulations. The locking mechanism allowed the source to be locked in place while it was still exposed.

The radiographer was wearing an audible alarm device required by the NRC for radiography work, but the device was turned off. The device had been turned off to conserve battery power while the radiographer was doing paperwork, but had not been turned back on for the remainder of the day. Use of an operable alarm device could have avoided or minimized the overexposure.

Actions Taken to Prevent Recurrence

Licensee—The licensee alerted its staff to the potential problem with the locking mechanism of this type of radiography camera. It also provided additional training on the use of the required audible alarm radiation devices and included verifying that the devices are turned on during routine internal audits of radiography activities. The radiographer was restricted indefinitely from further work with radioactive materials.

NRC—The NRC Region III conducted a special inspection of the licensee's activities on July 8–10, 1992. The inspection identified three violations of NRC requirements associated with the overexposure incident: (1) The extremity exposure in excess of the 18.75 rem limit for a calendar quarter; (2) failure of the radiographer to wear an operable audible radiation monitoring device; and (3) failure to perform an adequate radiation survey of the radiography camera in that the radiographer did not survey the full circumference of the camera. The first two violations were classified as a Severity Level I problem, and the third as a Level IV violation (on a scale in which Severity Levels I through V are the most and least significant, respectively). On October 9, 1992, a $5,000 fine was proposed for the first two violations. No fine was proposed for the third violation. On November 2, 1992, the licensee paid the civil penalty

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92–11 Medical Therapy Misadministration at the Medical Center of Delaware, Incorporated, in Wilmington, Delaware

One of the AO reporting guidelines notes that a therapeutic exposure to a part of the body not scheduled to received radiation can be considered an abnormal occurrence.

Date and Place—August 11, 1992; The Medical Center of Delaware, Incorporated; Wilmington, Delaware.

Nature and Probable Consequence—On August 12, 1992, the NRC Region I office was notified by telephone by the licensee's radiation safety office that a therapeutic misadministration involving a cobalt-60 teletherapy unit occurred on August 11, 1992.

The physician's written directive called for 3015 rads in 15 fractions to be delivered to the central area of the pelvic region with the teletherapy machine set up in a fixed modality. During the 14th fraction, the radiation therapy technologist (RTT) did not ensure that the teletherapy machine was set in the fixed modality and started the treatment. The previous patient had received treatment in the rotational modality and the setting of the machine was not changed. The patient received a total of 160 rads to the pelvic treatment area instead of the prescribed 200 rads. In addition, the licensee estimates that the patient received an estimated dose of 80 to 110 rads to the left side of the pelvis outside of the treatment area and between 60 to 70 rads to the right side of the pelvis outside of the treatment area. The licensee has determined that the patient will not suffer any adverse effects in the areas that received an unintended radiation dose. The licensee will increase the prescribed dose for the 15th fraction to make up for the underdosing during the 14th fraction.

Cause or Causes—It was determined that the cause of the misadministration was the failure of the licensee to follow the department's Quality Management (QM) Program. The licensee's QM Program calls for two RTTs to be present when a patient is being set up to ensure that the setup is done properly. The first RTT did not ensure that the setup was done correctly and the second RTT was out of the department getting another patient.

Actions Taken to Prevent Recurrence

Licensee—The licensee's corrective action was to provide a training session to all RTTs on the requirements of the Quality Management Program.

NRC—An NRC Region I inspector conducted an inspection on November 19, 1992, to determine the circumstances associated with the misadministration. The inspection findings are still under review by the NRC, and enforcement action is under consideration.

* * * * *

Dated at Rockville, MD this 5th day of January, 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93–474 Filed 1–8–93; 8:45 am]

BILLING CODE 7590–01–M

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the Office of Management and Budget review of information collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. Type of submission, new, revision, or extension: Extension.

2. The title of the information collection: 10 CFR part 33—Specific Domestic Licenses of Broad Scope for Byproduct Material.

3. The form number if applicable: Not applicable.

4. How often the collection is required: New applications may be submitted at any time. Renewal applications are submitted every five years.

5. Who will be required or asked to report: Persons applying for or holding an NRC license for broad scope use of radioactive byproduct material. Applicants and licensees are primarily medical institutions, colleges, universities, government agencies, and large private companies engaged in broad educational, research, and development activities.

6. An estimate of the number of responses: 120.

7. An estimate of the total number of hours needed to complete the requirement or request: Twenty hours per submittal. The total industry burden is 2,400 hours.

8. An indication of whether section 3504(h), Public Law 96–511 applies: Not applicable.

9. Abstract: 10 CFR part 33 specifies requirements for applying for and being granted licenses authorizing broad scope use of radioactive byproduct material. The information submitted is reviewed by NRC to determine whether the applicant has adequate equipment, facilities, procedures, training, and experience to safely use radioactive material.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

Comments and questions may be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs (3150–0015), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments may also be communicated by telephone at (202) 395–3084.

The NRC Clearance officer is Brenda Jo. Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 30th day of December 1992.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 93–472 Filed 1–8–93; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF MANAGEMENT AND BUDGET

[Issuance of Policy Letter 92–5]

Office of Federal Procurement Policy; Past Performance Information

AGENCY: Executive Office of the President, Office of Management and Budget, Office of Federal Procurement Policy (OFPP).

ACTION: Final Issuance of OFPP Policy Letter 92–5.

SUMMARY: Policy Letter 92–5 establishes policies that require Executive agencies to prepare evaluations of contractor performance on all contracts over $100,000 and to specify past performance as an evaluation factor in solicitations for offers for all competitively negotiated contracts expected to exceed $100,000. The Policy Letter also provides requirements to help assure that confidentiality and fairness concerns are addressed in the collection and use of past performance information (PPI).

FOR FURTHER INFORMATION CONTACT: Charles W. Clark, OFPP, Office of Management and Budget, Washington, DC 20503, (202) 395–6805.

SUPPLEMENTARY INFORMATION: A draft of Policy Letter 92–5 was published in the **Federal Register** for review and public comment on December 6, 1991 (56 FR 63988). Comments were received in response to the **Federal Register** notice from 23 Government and 22 private organizations. All comments were reviewed and, where warranted, changes have been made in the final Policy Letter. The main issues and concerns raised during the comment period are summarized below:

1. *Purpose.* Comments from one Federal agency recommended that the Policy Letter be expanded to include the use of past performance information for "general procurement management purposes." Comments from several private organizations requested that the Policy Letter be limited to addressing the use of Past Performance Information (PPI) in responsibility determinations and sources selections. This latter recommendation was accepted. If agencies continue to believe after the issuance of this Policy Letter that further policy guidance is needed on PPI, OFPP will consider supplementing the Policy Letter.

2. *Definitions.* A definition of "contractor" was added at the request of several private organizations, and an expanded definition of PPI has been provided. The definition of PPI was taken, in part, from Defense Logistic Agency (DLA) Solicitation No. DLA 200–91–R–0068, March 29, 1991. DLA's actions under this solicitation were protested to the General Accounting Office (GAO). The Comptroller General upheld DLA's actions in *CORVAC, Inc.*, B–244766, 91–2, CPD, ¶ 454. This decision and the DLA solicitation provide useful background information on the use of past performance.

3. *Distinction Between Responsibility Determinations and Evaluation Factors.* Several Federal agencies recommended that the Policy Letter made a clear distinction between using PPI for responsibility determinations versus as a source selection factor. The Policy Letter provides that PPI is to be considered (a) in responsibility determinations pursuant to Federal Acquisition Regulation (FAR) 9.1; and (b) in source selections for competitively negotiated contracts expected to exceed $100,000 (except where the contracting officer determines that such use is not appropriate). CORVAC, referenced in Paragraph 2 above, and the cases cited therein

discuss the distinction between "technical acceptability" (as an evaluation factor) and "responsibility."

4. *PPI Systems.* Many Federal agencies commented that the provisions in the draft Policy Letter that would have required agencies to establish "formal systems" for compiling and using PPI were unnecessary and impractical. The provision was generally interpreted as requiring agencies to fund the establishment of automated systems and central data banks. The agencies indicated in their comments that they did not have funds for this purpose. While automated systems may be appropriate for major contracting centers or in some agencies, the Policy Letter has been changed to only require that PPI be used and that existing systems be reviewed to determine if they can be consolidated. Agency procedures for obtaining and using PPI (including systems, if any) must still comply with the fairness and openness provisions of Paragraph 7. of the Policy Letter.

5. *Government/Industry Data Exchange Program (GIDEP).* Two agencies stated that it was not necessary to issue the Policy Letter as it duplicated OFPP Policy Letter 91–3, Reporting Nonforming Products, April 15, 1991 (56 FR 15108). Policy Letters 91–3 and 92–5 are not duplicative. Policy Letter 91–3 requires agencies to exchange information about nonconforming products through GIDEP. Policy Letter 92–5 requires contracting officers to (a) evaluate a contractor's performance on contracts over $100,000, and (b) use past performance information in making responsibility determinations and, where feasible, as a source evaluation factor in competitively negotiated procurements over $100,000. GIDEP helps eliminate instances where agencies or contractors acquire products and materials previously identified as nonconforming by other agencies. The use of PPI helps eliminate instances where agencies might, unknowingly, hire a contractor with a poor performance record.

6. *De Facto Suspensions or Debarments.* Some agencies said that the compilation and use of past performance information would lead to the de facto suspension or debarment of contractors. Policy Letter 92–5 specifies, in Paragraph 4., that the Policy Letter is not intended to supplant contracting officials' judgments in initiating or conducting debarment and suspension proceedings under FAR 9.4. Even though PPI may be used in debarment or suspension proceedings, the Policy Letter does not waive or change any of the due process requirements presently provided with suspension and debarment proceedings. To the contrary, the contractor notification and other provisions contained in Paragraph 7, as well as other parts of the Policy Letter, should help prevent de facto suspensions and debarments.

7. *Specification of Evaluation Factors.* Several private organizations suggested that OFPP specify in the Policy Letter the specific performance evaluation factors and subfactors that agencies would be required to consider in evaluating contractors. Several Federal agencies recommended that OFPP not define rating factors. Rating factors have not been defined as evaluations will vary depending upon the nature of the contract and the circumstances surrounding the contractor's performance. Evaluation factors under fixed price supply contracts will be different, for example, than factors under a cost-type service contract. Instead of listing the evaluation factors, the Policy Letter specifies in Paragraph 6.c. that past performance should be used as an evaluation factor in solicitations for competitively negotiated contracts. It is within the agency's discretion to determine what aspects of performance are important for a particular contract and the relative weight that these factors will be given.

8. *Confidentiality of PPI.* The most frequent comment received on the proposed Policy Letter was that OFPP should make a determination in the Policy Letter that past performance information should not be released to any private party without a contractor's consent. Several private organizations as well as Government agencies asked OFPP to make a determination in the Policy Letter that past performance information is not susceptible to being released under a Freedom of Information Act (FOIA) request. Agencies and private sector individuals alike view past performance information as "privileged" or "pre-decisional," and therefore not subject to FOIA requests. OFPP cannot make a general determination that PPI is exempt from FOIA inquiries. Each FOIA inquiry must be evaluated on its own merits and considerations must be given to the nature of the information to be released as well as the purpose for which the information is currently being used.

9. *Newly Established Firm.* Several commentors requested that OFPP define newly established firm in the Policy Letter. This suggestion was not adopted, as there are no criteria that would be generally applicable. In some fields, for example, a newly established firm may have been in existence for three years and completed very little business. In other situations, a new firm could have been in business for only one year and completed several contracts. The intent of the Policy Letter with respect to newly established firms is to specifically state that a firm cannot be prohibited from competing for a Government contract policy because of a lack of performance history, particularly if the firm is adequately funded and has experienced, reputable key personnel. However, if past performance is specified in the solicitation for offers as an award factor, a firm with a proven performance history generally would be preferred over a firm without a performance history, if all other factors were equal.

10. *Review Process.* Many Federal agencies stated that the requirement in the Policy Letter to provide copies of contractor evaluations to the contractors would lead to disputes and lengthen the contracting process. These agencies indicated that if performance evaluations were shared with contractors, the evaluators would not be candid and the evaluations would be bland and not very meaningful. OFPP believes that this is a problem with the evaluators and not with the requirement to share evaluations. Candid discussions between Government contracting officials and contractors will serve to improve both contractor performance and administration of the contracts by Government contracting officials. There is no requirement in the Policy Letter that contracting officials obtain the concurrence or approval of the contractor regarding the content of the evaluation. The ultimate content of the evaluation lies within the discretion of the contracting agency and normally would not be subject to dispute, unless the evaluation were to form the basis for a contract claim as defined by the Contract Disputes Act and FAR implementing regulations.

11. *Evaluation of Subcontractor Performance.* Several private concerns stated that a contractor's performance is often related to subcontractor performance and the prime contractor should not receive a poor performance evaluation because of the failure of a subcontractor to perform. Provisions to this effect were not included in the Policy Letter. The Government lacks privity of contract with the subcontractor. Moreover, the Government generally looks to the prime contractor to assure that subcontractors perform. A prime contractor's ability to select subcontractors that perform is indicative of the contractors' management ability.

12. *Relationship to OFPP Policy Letter 91–2, Service Contracting.* Two private organizations requested that the relationship be clarified between this Policy Letter (Policy Letter 92–5) and Policy Letter 91–2 (56 FR 15116, April 15, 1991). "Performance-based contracting" as defined in Policy Letter 91–2 means, "structuring all aspects of an acquisition around the purpose of the work to be performed as opposed to either the manner by which the work is to be performed or broad and imprecise statements of work." One of the purposes of performance-based contracting is to permit the quantitative and qualitative measurement of the tasks performed under a contract. Policy Letter 92–5 compliments this purpose by requiring that written evaluations be made of a contractor's performance and that PPI be used in source selections. A major difference between the policy letters is that 91–2 pertains only to service contracting while 92–5 covers contracts for both services and supplies.

13. *General.* Other comments accommodated in the Policy Letter include:

—Deletion of the word "transparency." A number of commentors said they did not understand the meaning of the word. Accordingly, "transparency" has been replaced by "public notice" in Paragraph 7.a.(2) of the Policy Letter.

—Deletion of the reference to "routine reference checks." These words were deleted from Paragraph 7.a.(4) in response to comments that stated that PPI should not be provided to third parties without the contractor's consent.

—Lengthening the time (from three years to six years) that PPI should be retained without being disposed of or updated. Several commentors noted that some contracts run longer than three years, and the retention period should exceed the length of the contract.

—Clarifying that PPI is not limited to prior performance on Government contracts but also includes work performed for private firms. This clarification was made in Paragraph 7.a.(7).

Allan V. Burman,

Administrator.

Policy Letter No. 92–5

To The Heads of Executive Departments and Establishments

Subject: Past Performance Information

1. *Purpose.* This Policy Letter establishes requirements for evaluating contractor performance and for using past performance information in the contractor selection process. The Policy Letter is intended to further the exercise of good business judgment and improve contractor performance.

2. *Authority.* The Policy Letter is issued pursuant to Section 6(a) of the Office of Federal Procurement Policy (OFPP) Act, as amended, 41 U.S.C. 405.

3. *Definitions.*

a. *Executive Agency.* Means an Executive department, and an independent establishment within the meaning of 5 U.S.C. 101, 102, 103(1) and 104(1), respectively.

b. *Contractor.* A contractor is an entity, or in a large company a specific division or unit, identified by a Contractor Establishment Code pursuant to the Federal Acquisition Regulation (FAR) 4.6.

c. *Past Performance Information.* Past performance information is relevant information regarding a contractor's actions under previously awarded contracts. It includes the contractor's record of conforming to specifications and to standards of good workmanship; the contractor's record of containing and forecasting costs on any previously performed cost reimbursable contracts; the contractor's adherence to contract schedules, including the administrative aspects of performance; the contractor's history for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the contractor's business-like concern for the interest of the customer.

d. *Past Performance Information System.* A past performance information system is an ongoing effort to collect and record past performance information for subsequent use in determining contractor eligibility and selection.

4. *Scope.* This Policy Letter pertains to past performance information as defined above. The Policy Letter does not pertain to procedures used by agencies in assessing performance for purposes of determining fees under award or incentive fee contracts. Similarly, the Policy Letter is not intended to supplant contracting officials' judgments in initiating or conducting debarment and suspension proceedings under Federal Acquisition Regulation (FAR) 9.4. The Policy Letter is applicable to direct Federal procurements, it is not applicable to procurements under grants or cooperative agreements or to procurements made by Government contractors.

5. *Background.* A contractor's past performance record is a key indicator for predicting future performance. A satisfactory performance record is a prerequisite to being determined a "responsible source" pursuant to 41 U.S.C. 403. In addition, FAR 15.605 requires that quality be addressed in every source selection and recognizes past performance as a factor in assessing quality. Several agencies have established policies and procedures for collecting, recording and using past performance information. These practices are extremely important to both the Government and to contractors, and requirements are necessary to help ensure their integrity and fairness. This Policy Letter provides such requirements.

6. *Policy.* It is the policy of the Federal Government that Executive agencies shall:

a. Prepare evaluations of contractors' performance on all new contracts over $100,000. Evaluations shall be made during contract performance, as required for contract administration purposes, and at the time the work under the contract is completed.

b. Use past performance information in making responsibility determinations in both sealed bid and competitively negotiated procurements. Performance information is one factor, among many, that must be considered in making such a determination (see FAR 9.1).

c. Specify past performance as an evaluation factor in solicitations for offers for all competitively negotiated contracts expected to exceed $100,000 except where the contracting office determines that such action is not appropriate. Such determinations shall be in writing and included in the contract file. As an evaluation factor, past performance should be used to assess the relative capabilities of competing offerors and to help assure greatest value source selections.

d. Allow newly established firms to compete for contracts even though they lack a history of past performance.

7. *Responsibilities.*

a. *Heads of Executive Agencies.* In implementing the policies in Paragraph 6, above, Executive agencies shall comply with the following:

(1) *Agency Regulations.* Heads of departments and agencies are responsible for taking all necessary actions to assure effective implementation of these policies, such as disseminating this Letter to appropriate program and other staff, developing implementation strategies and initiating staff training. Since these policies must be implemented in the FAR, agencies should not duplicate the development of implementing procurement regulations being undertaken by the Federal Acquisition Regulatory Councils. However, implementation of these policies in the FAR must be accomplished within the time period specified in Paragraph 8 below, with inclusion in agency solicitations and resulting contracts, as appropriate, to occur immediately thereafter.

(2) *Public Notice.* Regulations developed to implement provisions of this Policy Letter must conform to the publication requirements of Section 22 of the Office of Federal Procurement Policy Act (41 U.S.C. 418(b)) and FAR, Part 1.5.

(3) *Notification to Contractors.* Contractor evaluations shall be provided to the contractor at the time they are completed. Contractors shall be given a minimum of 30 days to discuss any evaluation with the contracting officer or if the contracting officer does the evaluation with the head of the contracting activity. While the ultimate conclusion and content of an evaluation is a decision of the contracting agency, the contractor may submit rebutting statements or additional information at any time. Copies of any such statements shall be appended to the evaluation and included in the contract file.

(4) *Confidentiality of Information.* Upon request, past performance information should be made available to other Federal

procurement activities. However, past performance information about a contractor shall not be provided, without the contractor's consent, to any private party, except where the agency determines that such information must be released pursuant to a Freedom of Information Act request. Additionally, because of the sensitive nature of contractor histories, appropriate management and technical controls should be made a part of any automated system used for tracking contractor performance to assure that only authorized personnel have access to the data.

(5) *Permanency of Information.* Performance information should not be considered a permanent indicator of a contractor's capability. The age and relevancy of the information should be considered at the time it is used. It should not be maintained for more than 6 years without being disposed of or updated.

(6) *Preservation of Contracting Officer's Judgment.* Information about a contractor's performance shall not be used to supplant the judgment of contracting officers in their selection of contractors. Past performance information is, in part, subjective and must be interpreted and considered by the contracting officer within the context of all other available data.

(7) *Obtaining Past Performance Information.* Data on a contractor's performance may be obtained from a variety of sources. Information on prior agency contracts should be available from within the agency. Information on contracts outside the agency may be obtained from past performance assessments made by other contracting activities including private firms. The methods used to obtain past performance information should be tailored to focus on information that demonstrates the quality of performance relative to the size, content, and complexity of the requirements for the instant procurement.

(8) *Using Past Performance Information.* Past performance information should be used to assess risk. Each performance evaluation and risk assessment should consider the number and severity of a contractor's problems, the effectiveness of corrective actions taken, and the contractor's overall work record. The assessment of performance risk should consider the relative merits of the contractor's prior experience and performance as compared to that of other competing offerors.

(9) *Review of Existing Systems.* Existing past performance information systems shall be reviewed to determine if multiple systems can be consolidated, and to ensure compliance with this Policy Letter. Agencies considering the establishment of a past performance information system shall first consider the use of an existing system.

(a) *Special Requirements for Architect/Engineer (A/E) and Construction Contracts.* Agencies shall evaluate construction contractor performance in accordance with FAR 36.201 and A/E contractor performance in accordance with FAR 36.604. Rather than establishing independent systems for maintaining performance evaluation forms—Standard Forms 1420 (Construction Contracts) and 1421 (Architect Engineer Contracts)—agencies are encouraged to use the following existing systems operated by the Corps of Engineers:

—The Construction Contract Appraisal Support System (CCASS) which contains over 15,000 performance appraisals covering approximately 7000 construction firms.

—The A/E Contract Administration Support System (ACASS) which contains 18,000 performance appraisals covering approximately 4,000 A/E firms.

The present point of contact for ACASS is Ms. Judy McGinnis, (503) 326–4910, and for CCAS, Ms. Kem Morrow at the same telephone number.

8. *Federal Acquisition Regulatory Councils.* Pursuant to Subsection 6(a) of the Office of Federal Procurement Policy Act, as amended, (41 U.S.C. 401 *et seq.*), the Federal Acquisition Regulatory Councils shall ensure that the policies established herein are incorporated in the FAR within 210 days from the date this Policy Letter is published in final form in the **Federal Register**. Promulgation of final FAR regulations within that 210 day period shall be considered issuance in a "timely manner" as prescribed in 41 U.S.C. 405(b)."

9. *Effective Date.* This Policy Letter is effective upon issuance.

10. *Information.* Questions or inquiries about this Policy Letter should be directed to Charles W. Clark, Office of Federal Procurement Policy, 725 17th Street, NW., Washington, DC 20503, telephone (202) 395–6803.

Allan V. Burman,

Administrator.

[FR Doc. 93–443 Filed 1–8–93; 8:45 am]

BILLING CODE 3110–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–31684; File No. SR–NASD–92–35]

Self-Regulatory Organizations; Filing of Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to Margin Requirements

January 4, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on August 20, 1992,[1] the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") a proposed rule change. The NASD subsequently filed on December 4, 1992, Amendment No. 1 to the filing which replaced in its entirety the original filing. The proposal as amended is described in Items I, II, and III below, which have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] Simultaneously with the filing of this proposed rule change, the NASD withdrew its filing SR–NASD–88–50, which was originally proposed to conform the NASD's margin rules with those of the New York Stock Exchange ("NYSE"). *See* discussion *infra* at Item II.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD is herewith filing a proposed rule change to amend Appendix A of Article III, Section 30 of the Rules of Fair Practice by replacing in its entirety the current Appendix A. A summary discussion of the proposed rule change follows. Interested persons may obtain a copy of the complete rule filing and/or the text of the proposed rule change by request to the Office of General Counsel, National Association of Securities Dealers, Inc., 1735 K Street, NW., Washington, DC 20006.

Description of Proposed Rule Change

Section 1

The NASD is proposing to amend section 1 of appendix A to provide that members of the NASD designated to another self-regulatory organization ("SRO") for oversight of the member's compliance with applicable securities laws, rules and regulations, and SRO rules under SEC Rule 17d–2 are exempt from the provisions of appendix A. Under the current provisions of section 1, members of any other national securities exchange are exempt from appendix A. The proposed amendment to section 1 will permit the designated examining authority to apply its own margin rules rather than the rules of another self-regulatory organization, significantly simplifying examinations.

Section 2

Proposed new section 2 consists of definitions relating to options transactions substantially the same as NYSE Rule 700. The definitions will apply to the margin requirements for options transactions set forth in proposed subsection 3(f)(2). NYSE Rule 431(f)(2) (the NYSE's options margin rules) references the definitions in NYSE Rule 700 (part of the NYSE's general options rules). There are no comparable definitions in current Section 4. Current section 2 relating to initial margin requirements will be replaced by proposed Subsection 3(b).

Section 3

Unless stated below, the language of the proposed new section 3 is the same as NYSE Rule 431 in all material respects. Current section 3 is being replaced by proposed subsection 3(f)(1)

with respect to valuation of securities; however, the provision in current Section 3 permitting the NASD to require additional margin in the event of undue concentration is not being replaced. The following describes the provisions of proposed new section 3, and, where applicable, those current provisions of Schedule A which will be replaced:

Subsection 3(a)

Proposed subsections 3(a) (1) through (8) are definitions of general applicability to the new margin rule. There are no comparable definitions in current Section 4.

Subsection 3(b) and 3(c)

Proposed new subsections 3(b) and 3(c) establish initial and maintenance margin requirements and replace section 2, and subsections 4(a) (1) through (3) and 4(a) (5) of current appendix A. Proposed new subsection 3(c) (5) establishes margins for American Stock Exchange ("AMEX") Emerging Company Marketplace securities as approved by the SEC in SR–NASD–92–10.[2]

Subsection 3(d)

Proposed new subsection 3(d) requires members to establish procedures for evaluating customer credit and imposing higher margin than required by the other provisions of proposed section 3. Current subsection 4(b)(3) permits the NASD to require 100% margin for certain securities in certain circumstances; otherwise, there is no comparable provision in Section 4.

Subsection 3(e)(1)

Proposed new subsection 3(e)(1) sets margins at 10% of current market value for convertible securities carried long offset against a short position in the resulting security, and 5% of current market value for long securities when the same security is carried long and short in the same account. Current subsections 4(b) (1) and (2) require 10% in each case.

Subsection 3(e)(2)(A)

Proposed new subsection 3(e)(2)(A) requires margins on obligations of the United States ranging from 1% to 6%, based on times to maturity ranging from less than 1 year to 20 years or more, respectively. Current subsection 4(8)(i) imposes margins ranging from ½% to 3% for maturities of less than 1 year up to 10 years, respectively, and current Subsection 4(7) requires margin at 5% for maturities greater than 10 years.

Subsection 3(e)(2)(B)

Proposed new subsection 3(e)(2)(B) sets margins for "all other exempted securities" other than obligations of the United States at the greater of 15% of the current market value or 7% of the principal amount of the obligation. Current Subsection 4(6) requires 25% and 15% respectively, whichever is lower.

Subsection 3(e)(2)(C)

Proposed new subsection 3(e)(2)(C) sets margins for "nonconvertible corporate debt securities" at the greater of 20% of the current market value or 7% of the principal amount, except for certain mortgage related securities for which the margin is 5% of the current market value. There is no comparable provision in section 4 currently. However, subsection 4(a) requires margin of 25% of the market value of all securities long in the account, and subsection 4(a)(8)(ii) permits the Association to establish lower requirements upon application.

Subsection 3(e)(2)(D)

Proposed new subsection 3(e)(2)(D) permits members to clear and carry "basket transactions" for members who are market makers at margin rates satisfactory to the parties, provided the margin is adequate to cover all real and potential risks. This Subsection also permits the carrying member to take a charge to net worth when computing net capital for any margin deficiency in the account. This provision differs slightly from the NYSE's rule because the NYSE requires the computation of net capital under this Rule 325, while the NASD's proposed rule specifies the computation of net capital under SEC Rule 15c3–1. This provision replaces current section 12.

Subsection 3(e)(2)(E)(i)

Proposed new subsection 3(e)(2)(E)(i) permits members to use accrued interest as an offset against maintenance margin requirements. This provision will replace current Section 15 which limits the crediting of accrued interest to interest in government securities.

Subsection 3(e)(2)(E)(ii)

Proposed new subsection 3(e)(2)(E)(ii) provides that the NASD may permit lower margin requirements upon written application. This provision will replace current Subsection 4(a)(8)(ii).

Subsection 3(e)(2)(F)

Proposed new subsection 3(e)(2)(F) provides that in cash transactions with customers for issued exempted securities in a cash account, full payment must be made promptly; otherwise, a deposit shall be required as if it were a margin transaction. Transactions with members or non-member broker/dealers in issued exempted securities however, do not require margin. This provision replaces current Subsection 6(a).

Subsection 3(e)(3)

Proposed new subsection 3(e)(3) permits accounts in which a partner or stockholder of the carrying organization has an interest, to maintain margin according to section 3 for all other participants in the account with respect to such interest as if such interest were in a separate account. There is no comparable provision in current appendix A.

Subsection 3(e)(4)

Proposed new subsection 3(e)(4) exempts international arbitrage accounts of non-member foreign broker/dealers from the requirements of appendix A; however, any deficiency between equity and required margin under appendix A must be charged against the member's net capital. There is no comparable provision in current appendix A.

Subsection 3(e)(5)

Proposed new subsection 3(e)(5) permits a member to carry the account of a market maker or specialist on the margin provided for under the rule, or, as an option, on a margin basis satisfactory to both parties, provided the carrying member takes a deduction against net capital for any deficit below the required margin. This provision, along with proposed subsection 3(e)(2)(D) and 3(e)(6), replaces current Section 12.

Subsection 3(e)(6)

Proposed new subsection 3(e)(6) permits a member to carry the proprietary account of another broker/dealer on a margin basis satisfactory to the parties and in compliance with Federal Reserve Board Regulation T. The provision also permits the member to take a deduction against net capital rather than require margin from the broker/dealer, provided, the account is not in deficit on equity positions. This provision, along with proposed new subsection 3(e)(2)(D) and 3(e)(5) replaces current Section 12.

Subsection 3(e)(7)

Proposed new subsection 3(e)(7) permits members to establish "non-purpose credit" accounts for customers. The term "non-purpose credit" is defined by reference to § 220.2(u) of

[2] Securities Exchange Act Release No. 30703 (May 14, 1992), 57 FR 21684 (May 21, 1992).

Regulation T. There is no comparable provision in current appendix A.

Subsection 3(e)(8)

Proposed new subsection 3(e)(8) establishes margin requirements for "shelf registered," "control" and "restricted" securities. There is no comparable provision in current appendix A.

Subsection 3(f)(1)

Proposed new subsection 3(f)(1) provides that active securities are to be valued at current market prices, and other securities are to be valued after considering liquidation value, price volatility and market liquidity. This provision replaces current section 3.

Subsection 3(f)(2)(D)(i) through 3(f)(2)(K)

Proposed new subsections 3(f)(2)(D)(i) through 3(f)(2)(K) establish margin requirements for options. These provisions typically require margin in excess of 100% of the current market value of any short option. These provisions replace current subsection 4(a)(4), 4(a)(8)(vi) and section 7.

Subsection 3(f)(3)

Proposed new subsection 3(f)(3) provides that the margin required for securities "when issued" is the same as if the security were issued. This provision replaces current section 5.

Subsections 3(f)(4) and 3(f)(5)

Proposed new subsections 3(f)(4) and 3(f)(5) permit the consolidation of any guaranteed account with another account, or the consolidation of any two accounts of a customer, for margin purposes, provided the guarantee or consolidation is agreed to in writing. These provisions replace current sections 8 and 9

Subsections 3(f)(6) and 3(f)(7)

Proposed subsections 3(f)(6) and 3(f)(7) provide that members should collect required margin as quickly as possible and not permit customers routinely to meet Regulation T margin calls through the liquidation of account positions. These provisions replace current sections 10 and 13.

Subsection 3(f)(8)

Proposed new subsection 3(f)(8) provides that the Association may establish higher margin requirements than otherwise required by proposed new section 3. Current subsection 4(b)(3) is comparable to this provision. Proposed new subsection 3(f)(8) also establishes margin requirements for "day traders."

Subsection 3(f)(9)

Proposed new subsection 3(f)(9) provides that members may not permit customers to "free ride" by effecting transactions in cash accounts where the cost of the security is met by the sale of the same securities. There is no comparable provision in current section 4.

Other Changes

Current sections 11 and 14, relating to recordkeeping requirements and the definition of "margin account," respectively, are being eliminated as redundant of other provisions. Recordkeeping requirements are adequately covered by the current SEC rules and the proposed new NASD rules adequately define the terms necessary for interpretation of the rule.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The NASD is proposing to amend Article III, Section 30, Schedule A of the Rules of Fair Practice to closely conform the NASD's margin rules to those of the NYSE by deleting the current provisions of appendix A and replacing them with rule language substantially identical to the NYSE margin rules.

In November 1988 the NASD filed a proposed rule change, SR-NASD-88-50 ("88-50"), with the SEC to amend appendix A to Article III, section 30 of the Rules of Fair Practice ("Appendix A") in order to make it consistent with the then-recently approved amendments to the NYSE's margin rules (NYSE Rule 431). While the proposed rule change was pending at the SEC, the NYSE again amended its margin rules. The NASD determined to further amend appendix A to closely conform the provisions of appendix A to the amended NYSE margin rules.[3]

Currently, sections 2 and 4 of appendix A provide for initial and minimum margin to be deposited and maintained under rules and formulas which are similar to those of the NYSE, but which differ in several respects. For instance, current section 4 does not require members to evaluate the credit of customers or to establish higher margin requirements for securities or customers based on such evaluation. In addition, current Section 4 permits lower margins to be maintained on U.S. Government securities. Finally, current section 4 does not permit members to establish "non-purpose credit" accounts for customers, does not establish margin requirements for shelf registered, control or restricted securities, or for "day traders." Each of these differences, as well as the others, are addressed in the proposed amendment to appendix A by conforming the NASD's margin rules to those of the NYSE.

The NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act[4] in that making the NASD's margin rules consistent with those of the NYSE will foster coordination in regulating, clearing, settling and facilitating transactions in securities by providing for a single uniform margin scheme and reducing confusion among customers dealing with NYSE and non-NYSE-member firms.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement of Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such

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[3] In addition, on April 1, 1992, the Executive Committee of the NASD Board of Governors approved an amendment to the current Appendix A to provide margin rules for securities which are listed on "incubator" or "emerging company" exchanges such as the AMEX's Emerging Company Marketplace. SR-NASD-92-10 was filed with the SEC on April 2, 1992, and approved by the SEC on May 14, 1992. The proposed amendments to Appendix A include the provisions approved by the SEC in SR-NASD-92-10.

[4] 15 U.S.C. 78o-3 (1988).

longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by [insert date 21 days from the date of publication].

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–495 Filed 1–8–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–31688; File No. SR–NYSE–92–31]

Self-Regulatory Organizations; Filing of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to Organizations Controlled or Guaranteed by Members or Member Organizations

January 5, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 16, 1992, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The changes consist of the amendment of Rule 321 ("Formation of Corporate Affiliates"), rescission of Rules 322 ("Guaranteed Corporate Subsidiaries") and 324 ("Formation of Associated Partnerships"); adoption of new Rule 322 ("Guarantees by, or Flow Through Benefits for Members or Member Organizations"); and amendments to Rules 113 ("Specialists' Public Customers"), 122 ("Orders With More Than One Broker"), 342 ("Offices—Approval, Supervision and Control"), 346 ("Limitations—Employment and Association with Members and Member Organizations"), 416 ("Questionnaires and Reports") and 476 ("Disciplinary Proceedings Involving Charges Against Members, Member Organizations, Allied Members, Approved Persons, or Employees").

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

Current NYSE Rules 321, 322 and 324 prescribe the requirements which must be followed by a member or member organization in order to obtain Exchange approval to form and operate any entity (corporate affiliate, guaranteed subsidiary or associated partnership) which they will control that is engaged in a securities or kindred business.

The rules were originally adopted in the late 1960s in a very different environment, *e.g.*, before public ownership of securities firms and the advent of sophisticated corporate structures, diversification of product and business lines and the internationalization of our business. Rule 321 was intended to protect member organizations' capital by segregating out what were then deemed more risky or speculative activities such as underwriting, advisory, and securities brokerage dealings on a principal basis. Under this Rule, member organizations are required, among other things, to own 40 percent of the total capitalization, own all of the voting stock and are prohibited from guaranteeing the liabilities and obligations of these corporate affiliates. Directors and key officers of the entity must be associated with the member organization and together with registered representatives must be approved by the Exchange.

Corporate entities controlled by member organizations formed to do what were considered more traditional brokerage activities (foreign and domestic) are required to be wholly-owned and guaranteed subsidiaries under Rule 322. Such entities and their associated persons are subject to the Constitution and Rules of the Exchange to the same extent as are member organizations. Such entities may engage in an agency business only (may not transact business on a principal basis). Entities formed under Rule 324 are subject to virtually the same provisions as entities formed under Rule 322 except that Rule 324 applies to associated partnerships. Broker-dealers required to be formed under these Rules 321, 322 and 324 must introduce customer accounts to their parent member organizations as they are not permitted to carry customer accounts on their books.

The original concept of these rules and many of their restrictive requirements are outdated and no longer serve a valid regulatory purpose. The rules' requirements inhibit member organizations management of their assets, organizational structure and business activities and impose significant impediments to their pursuit of legitimate business activities. In addition, the existing rules, by their terms, apply only to direct subsidiaries. Member organizations having a holding company structure have been able to avoid the rules' restrictions. According to the NYSE, member organizations, however, should not be forced to choose between forming a holding company and incurring the attendant expenses or refraining from engaging in legitimate business activities.

The proposed rule changes will allow member organizations the flexibility to structure their affiliates in a manner that would permit diversification and keep

pace with the competitive environment within the industry, while also maintaining appropriate regulatory safeguards.

Proposed amended Rule 321 will require prior written approval whenever a member or member organization controls another person, within the meaning of Rule 2,[1] who is engaged as a broker or dealer in securities. In addition, the proposed rule change deletes many provisions relating to capitalization, structure (*e.g.*, classes of stock; fixed interest by members and allied members) and content and submission of documents (*e.g.*, charter, certificate of incorporation and bylaws) by affiliates which are outdated and/or are not currently required of member organizations. Current Rules 322 and 324 are proposed to be rescinded in view of proposed amendments to Rule 321 and proposed adoption of new Rule 322.

With intent to protect members and member organizations' financial integrity and provide the Exchange with the means to monitor impact upon capital, proposed new Rule 322 will require prior written notice whenever a member or member organization guarantees or assumes or endorses the obligations and/or liabilities of another person. The written notice must include a statement with respect to financial and operational impact upon the member or member organization. Further, members and member organizations will be required to provide the Exchange with access to books and records whenever requested. Broker-dealers subject to Rule 322 will have to file FOCUS reports and non-broker-dealers would submit other financial statements specified by the Exchange.

In order to effect these proposed rule changes, and to provide for consistency in the rules, changes are necessary to other rules (Rules 113 "Specialists' Public Customers," 122 "Orders With More Than One Broker" and 416 "Questionnaires and Reports") that also apply to affiliates of members and member organizations. Further, amendments to Rule 342 will define the term foreign branch office and provide that all foreign branch office personnel of member organizations will be subject to the Exchange Constitution and Rules to the same extent as personnel of member organizations. Amended Rule 342 also provides that a foreign branch office shall continue to be treated as any other branch of the member organization for regulatory purposes and that all obligations and liabilities shall continue to be assumed or guaranteed by the parent member or member organization. Proposed amendments to Rule 476 clarify and codify the Exchange's authority to impose sanctions against all persons subject to Exchange jurisdiction (including affiliates) upon a finding of guilt in a proceeding under Rule 476.

(b) Statutory Basis

The proposed rule changes are consistent with the requirements of the Act and the rules and regulations thereunder applicable to the Exchange in that they are designed, in accordance with section 6(b)(1) of the Act, to enhance the Exchange's capacity to carry out the purposes of the Act and to compel and enforce compliance by its members and member organizations and their associated persons with the provisions of the Act, the rules and regulations thereunder and the rules of the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the publication of this notice in the **Federal Register** or within such other period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies, of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR–NYSE–92–31 and should be submitted by February 1, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–484 Filed 1–8–93; 8:45 am]

BILLING CODE 8010–01–M

[1] Rule 2 defines "control," in pertinent part, as the power to direct or cause direction of the management or policies of a person. There is a presumption of control where a person (i) has the right to vote 25% or more of the voting securities, or (ii) is entitled to 25% or more of the net profits.

Self-Regulatory Organizations; Midwest Stock Exchange, Inc.; Application for Unlisted Trading Privileges in one Over-the-Counter Issue and to Withdraw Unlisted Trading Privileges in an Over-the-Counter Issue

January 4, 1993.

On December 22, 1992, the Midwest Stock Exchange, Inc. ("MSE") submitted an application for unlisted trading privileges ("UTP") pursuant to section 12(f)(1)(C) of the Securities Exchange Act of 1934 ("Act") in the following over-the-counter ("OTC") security, *i.e.*, a security not registered under Section 12(b) of the Act.

File No.	Symbol	Issuer
7–9868	MTCEF	MTC Electronic Technologies Co. LTD. Common Stock No par value

The above-referenced issue is being applied for as a replacement for the following security, which forms a portion of the Exchange's program in which OTC securities are being traded pursuant to the granting of UTP.

The MSE also applied to withdraw UTP pursuant to section 12(f)(4) of the Act for the following issue:

File No.	Symbol	Issuer
7–9869	FOFF	50-Off Stores, Inc. Common Stock. $.01 par value.

Withdrawal of the Common Stock of 50-Off Stores, Inc. is requested due to lack of trading activity.

Comments

Interested persons are invited to submit, on or before January 25, 1993, written comments, data, views and arguments concerning this application. Persons desiring to make written comments should file three copies with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

Commentators are asked to address whether they believe the requested grant of UTP as well as the withdrawal of UTP would be consistent with section 12(f)(2), which requires that, in considering an application for extension or withdrawal of UTP in an OTC security, the Commission consider, among other matters, the public trading activity in such security, the character of such trading, the impact of such extension on the existing markets for such security, and the desirability of removing impediments to and the progress that has been made toward the development of a national market system.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–496 Filed 1–8–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Midwest Stock Exchange, Inc.; Application for Unlisted Trading Privileges in one Over-the-Counter Issue and to Withdraw Unlisted Trading Privileges in an Over-the-Counter Issue

January 4, 1993.

On November 17, 1992, the Midwest Stock Exchange, Inc. ("MSE") submitted an application for unlisted trading privileges ("UTP") pursuant to section 12(f)(1)(C) of the Securities Exchange Act of 1934 ("Act") in the following over-the-counter ("OTC") security, *i.e.*, a security not registered under section 12(b) of the Act.

File No.	Symbol	Issuer
7–9866	NNCXF	Newbridge Network Corporation.
		Common stock No par value

The above-referenced issue is being applied for as a replacement for the following security, which forms a portion of the Exchange's program in which OTC securities are being traded pursuant to the granting of UTP.

The MSE also applied to withdraw UTP pursuant to section 12(f)(4) of the Act for the following issue:

File No.	Symbol	Issuer
7–9867	CUSA	Compusa Inc. Common stock No par value

A replacement issue is being requested as the common stock of Compusa Inc. has been listed on the NYSE, rendering it ineligible for the OTC/UTP program.

Comments

Interested persons are invited to submit, on or before January 25, 1993, written comments, data, views and arguments concerning this application. Persons desiring to make written comments should file three copies with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549.

Commentators are asked to address whether they believe the requested grant of UTP as well as the withdrawal of UTP would be consistent with section 12(f)(2), which requires that, in considering an application for extension or withdrawal of UTP in an OTC security, the Commission consider, among other matters, the public trading activity in such security, the character of such trading, the impact of such extension on the existing markets for such security, and the desirability of removing impediments to and the progress that has been made toward the development of a national market system.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–497 Filed 1–8–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Midwest Stock Exchange, Inc.; Application for Unlisted Trading Privileges in Seven Over-the-Counter Issues and to Withdraw Unlisted Trading Privileges in Seven Over-the-Counter Issues

January 4, 1993.

On December 22, 1992, the Midwest Stock Exchange, Inc. ("MSE") submitted an application for unlisted trading privileges ("UTP") pursuant to section 12(f)(1)(C) of the Securities Exchange Act of 1934 ("Act") in the following over-the-counter ("OTC") securities, *i.e.*, securities not registered under section 12(b) of the Act.

File No.	Symbol	Issuer
7–9870	APBI	Applied Bioscience, International, Inc., Common Stock, $.01 par value.
7–9871	BSTN	Boston Tecnology, Inc., Common Stock, $.001 par value.
7–9872	LGNT	Legent Corp., Common Stock, $.01 par value.
7–9873	CGNE	Calgene, Inc., Common Stock, $.001 par value.
7–9874	CLCDF	Clearly Canadian Beverage Corp., Common Stock, No par value.
7–9875	TKOS	Tokos Medical Corp. (Delaware), Common Stock, $.001 par value.
7–9876	TOPP	Topps Co., Inc. (THE), Common Stock, $.01 par value.

The above-referenced issues are being applied for as replacements for the following securities, which form a portion of the Exchange's program in which OTC securities are being traded pursuant to the granting of UTP.

The MSE also applied to withdraw UTP pursuant to section 12(f)(4) of the Act for the following issues:

File No.	Symbol	Issuer
7–9877	BELL	Bell Bancorp, Inc., Common Stock, $.01 par value.
7–9878	CDIC	Cardinal Distribution, Inc., Common Stock, No par value.
7–9879	DBRL	Dibrell Brothers, Inc., Common Stock, $1.00 par value.
7–9880	IRIC	Information Resources, Inc., Common Stock, $.01 par value.
7–9881	MAFB	MAF Bancorp, Inc., Common Stock, $.01 par value.

File No.	Symbol	Issuer
7–9882	NSBI	N.S. Bancorp, Inc., Common Stock, $.01 par value.
7–9883	SPBC	St. Paul Bancorp, Inc., Common Stock, $.01 par value.

Replacement issues are being requested due to a lack of trading activity in these issues.

Comments

Interested perrsons are invited to submit, on or before January 25, 1993, written comments, data, view and arguments concerning this application. Persons desiring to make written comments should file three copies with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

Commentators are asked to address whether they believe the requested grant of UTP as well as the withdrawal of UTP would be consistent with section 12(f)(2), which requires that, in considering an application for extension or withdrawal of UTP in an OTC security, the Commission consider, among other matters, the public trading activity in such security, the character of such trading, the impact of such extension on the existing markets for such security, and the desirability of removing impediments to and the progress that has been made toward the development of a national market system.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–498 Filed 1–8–93; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF STATE

[Public Notice 1751]

Advisory Committee on International Communications and Information Policy; Subcommittee on Industrialized Country Policy; Meeting

The Department of State announces that the Subcommittee on Industrialized Country Policy of the Committee on International Communications and Information Policy will hold an open meeting on Tuesday, January 26, 1993, from 10 a.m.–12 noon in Room 6909, Department of State, 2201 "C" Street, NW., Washington, DC 20520.

At the meeting, there will be a report from the U.S. Delegation to the Committee for Information, Computer and Communications Policy (ICCP) of the Organization for Economic Cooperation and Development (OECD) on issues currently before the ICCP and its various working parties and experts groups. Also, ideas will be solicited to propose to the OECD for inclusion in the ICCP's 1994 work program to be determined at its next meeting in March, 1993.

Ms. Cathy Slesinger and Mr. Kenneth Leeson, co-chairs of the Subcommittee, will chair the meeting. Mr. Richard C. Beaird, Deputy U.S. Coordinator and Deputy Director, Bureau of International Communications and Information Policy, U.S. Department of State, and Chairman of the ICCP, will participate in the meeting.

Members of the general public may attend the meeting and join in the discussion, subject to the instructions of the co-chairs. Admittance of public members will be limited to seating available. In that regard, entrance to the Department of State building is controlled and individual passes are required for each attendee. Entry will be facilitated if arrangements are made in advance of the meeting.

Prior to the meeting, persons who plan to attend should so advise the office of Mr. Timothy C. Finton, Department of State, Washington, DC.; telephone (202) 647–5220. They must provide Mr. Finton with their name, title, company name, social security number, and date of birth. All attendees must use the "C" Street entrance to the building.

Dated: December 24, 1992.

Timothy C. Finton,

Chairman, U.S. Delegation to the ICCP.

[FR Doc. 93–446 Filed 1–8–93; 8:45 am]

BILLING CODE 4710–46–M

THRIFT DEPOSITOR PROTECTION OVERSIGHT BOARD

Region 1 Advisory Board

AGENCY: Thrift Depositor Protection Oversight Board.

ACTION: Change of meeting date and location.

SUMMARY: This is to announce a change in date and location for the Region 1 Advisory Board meeting scheduled for January 21 as published in the **Federal Register**, December 24, 1992, page 61468. The new meeting date is January 19 at the Sheraton River House in Miami.

DATES: January 19, 9 a.m. to 12:30 p.m.

ADDRESSES: Sheraton River House, Miami International Airport, 3900 Northwest 21st Street, Miami, Florida.

FOR FURTHER INFORMATION CONTACT: Jill Nevius, Committee Management Officer, Thrift Depositor Protection Oversight Board, 1777 F Street, NW., Washington, DC 20232, 202/786–9675.

Dated: December 5, 1993.

Jill Nevius,

Committee Management Officer.

[FR Doc. 93–445 Filed 1–8–93; 8:45 am]

BILLING CODE 2222–01–M

DEPARTMENT OF THE TREASURY

Office of the Secretary

[Department Circular—Public Debt Series—No. 2–93]

Treasury Notes of January 15, 2000, Series E–2000 (CUSIP No. 912827 J3 7)

Washington, January 6, 1993.

1. Invitation for Tenders

1.1 The Secretary of the Treasury, under the authority of chapter 31 of title 31, United States Code, invites tenders for United States securities, as described above and in the offering announcement, hereafter referred to as Notes. The Notes will be sold at auction, and bidding will be on a yield basis. Payment will be required at the price equivalent of the yield of each accepted bid. The interest rate on the Notes and the price equivalent of each accepted bid will be determined in the manner described below. Additional amounts of the Notes may be issued to Federal Reserve Banks for their own account in exchange for maturing Treasury securities. Additional amounts of the Notes may also be issued at the average price to Federal Reserve Banks, as agents for foreign and international monetary authorities.

2. Description of Securities

2.1. The issue date and maturity date of the Notes are stated in the offering announcement. The Notes will accrue interest from the issue date. Interest will be payable on a semiannual basis as described in the offering announcement through the date that the principal becomes payable. The Notes will not be subject to call for redemption prior to maturity. In the event any payment date is a Saturday, Sunday, or other nonbusiness day, the amount due will be payable (without additional interest) on the next business day.

2.2. The Notes will be issued only in book-entry form in the minimum and multiple amounts stated in the offering announcement. They will not be issued in registered definitive or in bearer form.

2.3. The Department of the Treasury's general regulations governing United States securities, i.e., Department of the Treasury Circular No. 300, current revision (31 CFR part 306), as to the extent applicable to marketable securities issued in book-entry form, and the regulations governing book-entry Treasury Bonds, Notes, and Bills, as adopted and published as a final rule to govern securities held in the TREASURY DIRECT Book-Entry Securities System in Department of the Treasury Circular, Public Debt Series, No. 2–86 (31 CFR part 357), apply to the Notes offered in this circular.

3. Sales Procedures

3.1. Tenders will be received at Federal Reserve Banks and Branches and at the Bureau of the Public Debt, Washington, DC 20239–1500. The closing times for the receipt of noncompetitive and competitive tenders are specified in the offering announcement. Noncompetitive tenders will be considered timely if postmarked (U.S. Postal Service cancellation date) no later than the day prior to the auction and received no later than close of business on the issue day.

3.2. The par amount of Notes bid for must be stated on each tender. The minimum bid is stated in the offering announcement, and larger bids must be in multiples of that amount.

3.3. Competitive bids must also show the yield desired, expressed in terms of an annual yield with two decimals, e.g., 7.10%. Fractions may not be used. A single bidder, as defined in Treasury's single bidder guidelines contained in Attachment A to this circular, may submit bids at more than one yield. However, at any one yield, the Treasury will not recognize any amount tendered by a single bidder in excess of 35 percent of the public offering amount. A competitive bid by a single bidder at any one yield in excess of 35 percent of the public offering will be reduced to that amount.

3.4. Noncompetitive tenders do not specify a yield. A single bidder should not submit a noncompetitive tender for more than $5,000,000. A noncompetitive bid by a single bidder in excess of $5,000,000 will be reduced to that amount. A bidder, whether bidding directly or through a depository institution or a government securities broker/dealer, may not submit a noncompetitive bid for its own account in the same auction in which it is submitting a competitive bid for its own account. A bidder may not submit a noncompetitive bid if the bidder holds a position, in the Notes being auctioned, in "when-issued" trading, or in futures or forward contracts. A noncompetitive bidder may not enter into any agreement to purchase or sell or otherwise dispose of the security being auctioned, nor may it commit to sell the security prior to the designated closing time for receipt of competitive bids.

3.5. The following institutions may submit tenders for accounts of customers: depository institutions, as described in section 19(b)(1)(A), excluding those institutions described in subparagraph (vii), of the Federal Reserve Act (12 U.S.C. 461(b)(1)(A)); and government securities broker/dealers that are registered with the Securities and Exchange Commission or noticed as government securities broker/dealers pursuant to Section 15C(a)(1) of the Securities Exchange Act of 1934. Others are permitted to submit tenders only for their own account. A submitted, if bidding competitively for customers, must include a customer list with the tender giving, for each customer, the name of the customer and the amount bid. A separate tender and customer list should be submitted for each competitive yield. For noncompetitive bids, the customer list must provide, for each customer, the name of the customer and the amount bid. For mailed tenders, the customer list must be submitted with the tender. For other than mailed tenders, the customer list should accompany the tender. If the customer list is not submitted with the tender, information for the list must be complete and available for review by the deadline for submission of noncompetitive tenders. The customer list should be received by the Federal Reserve Bank on auction day. All competitive and noncompetitive bids submitted on behalf of trust estates must provide, for each trust estate, the name or title of the trustee(s), a reference to the document creating the trust with the date of execution, and the employer identification number of the trust. Customer bids may not be aggregated on the customer list. The customer list must include customers and customers of those customers, where applicable.

3.6. A competitive single bidder must report its net long position if the total of all its bids for the security being offered and its net position in the security equals or exceeds $2 billion, with the position to be determined as of one half-hour prior to the closing time for the receipt of competitive tenders. A net long position includes positions, in the security being auctioned, in "when-issued" trading, and in futures and forward contracts. Bidders who meet this reporting requirement and are customers of a depository institution or a government securities broker/dealer must report their positions through the institution submitting the bid on their behalf.

3.7. Tenders from bidders who are making payment by charge to a funds account at a Federal Reserve Bank and tenders from bidders who have an approved autocharge agreement on file at a Federal Reserve Bank will be received without deposit. In addition, tenders from States, and their political subdivisions or instrumentalities; public pension and retirement and other public funds; international organizations in which the United States holds membership; foreign central banks and foreign states; and Federal Reserve Banks will be received without deposit. Tenders from all others, including tenders submitted for Notes to be maintained on the book-entry records of the Department of the Treasury, must be accompanied by full payment for the amount of Notes applied for, or by a guarantee from a commercial bank or a primary dealer of 5 percent of the par amount applied for.

3.8. After the deadline for receipt of competitive tenders, there will be a public announcement of the amount and yield range of accepted bids. Subject to the reservations expressed in section 4, noncompetitive bids will be accepted in full, and then competitive bids will be accepted, starting with those at the lowest yields, through successively higher yields to the extent required to attain the amount offered. Bids at the highest accepted yield will be prorated if necessary. After the determination is made as to which bids are accepted, an interest rate will be established, at a ⅛ of one percent increment, which results in an equivalent average accepted price close to 100.000 and a lowest accepted price above the original issue discount limit. That stated rate of interest will be paid on all of the Notes. Based on such interest rate, the price on each competitive tender allotted will be determined and each successful competitive bidder will be required to pay the price equivalent to the yield bid. Those submitting noncompetitive bids will pay the price equivalent to the weighted average yield of accepted competitive bids. Price calculations will be carried to three decimal places on the basis of price per hundred, e.g., 99.923, and the determinations of the Secretary of the Treasury shall be final. If the amount of noncompetitive bids received would absorb all or most of the offering, competitive bids will be accepted in an amount sufficient to provide a fair determination of the yield. Bids received from Federal Reserve Banks

will be accepted at the price equivalent to the weighted average yield of accepted competitive bids.

3.9. No single bidder will be awarded securities in an amount exceeding 35 percent of the public offering. The determination of the maximum award to a single bidder will take into account the bidder's net long position, if the bidder has been obliged to report its position per the requirements outlined in section 3.6.

3.10. Notice of awards will be provided by a Federal Reserve Bank or Branch or the Bureau of the Public Debt to bidders who have submitted accepted competitive bids, whether for their own account or for the account of customers. Those submitting non-competitive bids will be notified only if the bid is not accepted in full, or when the price at the average yield is over par. No later than 12:00 noon local time on the day following the auction, the appropriate Federal Reserve Bank will notify each depository institution that has entered into an autocharge agreement with a bidder as to the amount to be charged to the institution's funds account at the Federal Reserve Bank on the issue date. Any customer that is awarded $500 million or more of securities must furnish, no later than 10 a.m. local time on the day following the auction, written confirmation of its bid to the Federal Reserve Bank or Branch where the bid was submitted. A depository institution or government securities broker/dealer submitting a bid for a customer is responsible for notifying its customer of this requirement if the customer is awarded $500 million or more of securities as a result of bids submitted by the depository institution or government securities broker/dealer.

4. Reservations

4.1. The Secretary of the Treasury expressly reserves the right to accept or reject any or all bids in whole or in part, to allot more or less than the amount of Notes specified in the offering announcement, and to make different percentage allotments to various classes of applicants when the Secretary considers it in the public interest. The Secretary's action under this section is final.

5. Payment and Delivery

5.1. Settlement for the Notes allotted must be made timely at the Federal Reserve Bank or Branch or at the Bureau of the Public Debt, wherever the tender was submitted. Settlement on Notes allotted will be made by a charge to a funds account or pursuant to an approved autocharge agreement, as provided in section 3.7. Settlement on Notes allotted to institutional investors and to others whose tenders are accompanied by a guarantee as provided in section 3.7. must be made or completed on or before the issue date. Payment in full must accompany tenders submitted by all other investors. Payment must be in cash; in other funds immediately available to the Treasury; in Treasury notes or bonds maturing on or before the settlement date but which are not overdue as defined in the general regulations governing United States securities; or by check drawn to the order of the institution to which the tender was submitted, which must be received from institutional investors by the time stated in the offering announcement. When payment has been submitted with the tender and the purchase price of the Notes allotted is over par, settlement for the premium must be completed timely, as specified above. When payment has been submitted with the tender and the purchase price is under par, the discount will be remitted to the bidder.

5.2. In every case where full payment has not been completed on time, an amount of up to 5 percent of the par amount of Notes allotted may, at the discretion of the Secretary of the Treasury, be forfeited to the United States.

5.3. Registered definitive securities tendered in payment for the Notes allotted and to be held in TREASURY DIRECT are not required to be assigned if the inscription on the registered definitive security is identical to the registration of the Note being purchased. In any such case, the tender form used to place the Notes allotted in TREASURY DIRECT must be completed to show all the information required thereon, or the TREASURY DIRECT account number previously obtained.

6. General Provisions

6.1. As fiscal agents of the United States, Federal Reserve Banks are authorized, as directed by the Secretary of the Treasury, to receive tenders, to make allotments, to issue such notices as may be necessary, to receive payment for, and to issue, maintain, service, and make payment on the Notes.

6.2. The Secretary of the Treasury may at any time supplement or amend provisions of this circular if such supplements or amendments do not adversely affect existing rights of holders of the Notes. Public announcement of such changes will be promptly provided.

6.3. The Notes issued under this circular shall be obligations of the United States, and, therefore, the faith of the United States Government is pledged to pay, in legal tender, principal and interest on the Notes.

6.4. Attachment A and the offering announcement are incorporated as part of this circular.

Gerald Murphy,

Fiscal Assistant Secretary.

Attachment A—Treasury's Single Bidder Guidelines for Noncompetitive Bidding in All Treasury Security Auctions

The investor categories listed below define what constitutes a single noncompetitive bidder.

(1) *Bank Holding Companies and Subsidiaries*—

A bank holding company (includes the company and/or one or more of its subsidiaries, whether or not organized as separate entities under applicable law).

(2) *Banks and Branches*—

A parent bank (includes the parent and/or one or more of its branches, whether or not organized as separate entities under applicable law).

(3) *Thrift Institutions and Branches*—

A thrift institution, such as a savings and loan association, credit union, savings banks, or other similar entity (includes the principal or parent office and/or one or more of its branches, whether or not organized as separate entities under applicable law).

(4) *Corporations and Subsidiaries*—

A corporation (includes the corporation and/or one or more of its majority-owned subsidiaries, i.e., any subsidiary more than 50 percent of whose stock is owned by the parent corporation or by any other of its majority-owned subsidiaries).

(5) *Familes*—

A married person (includes his or her spouse, and any unmarried adult children, having a common address and/or household).

Note: A minor child, as defined by the law of domicile, is not permitted to submit tenders individually, or jointly with an adult bidder. (A minor's parent acting as natural guardian is not recognized as a separate bidder.)

(6) *Partnerships*—

Each partnership (includes a partnership or individual partner(s), acting together or separately, who own the majority or controlling interest in other partnerships, corporations, or associations).

(7) *Guardians, Custodians, or other Fiduciaries*—

A guardian, custodian, or similar fiduciary, identified by (a) the name or title of the fiduciary, (b) reference to the document, court order, or other authority under which the fiduciary is acting, and (c) the taxpayer identifying number assigned to the estate.

(8) *Trusts*—

A trust estate, which is identified by (a) the name or title of the trustee, (b) a reference to the document creating the trust, e.g., a trust indenture, with date of execution, or a will, (c) the IRS employer identification number (not social security account number).

(9) *Political Subdivisions*—

(a) A state government (any of the 50 states and the District of Columbia).

(b) A unit of local government (any county, city, municipality, or township, or other unit

of general government, as defined by the Bureau of the Census for statistical purposes, and includes any trust, investment, or other funds thereof).

(c) A commonwealth, territory, or possession.

(10) *Mutual Funds*—

A mutual fund (includes all funds that comprise it, whether or not separately administered).

(11) *Money Market Funds*—

A money market fund (includes all funds that have a common management).

(12) *Investment Agents/Money Managers*—

An individual, firm, or association that undertakes to service, invest, and/or manage funds for others.

(13) *Pension Funds*—

A pension fund (includes all funds that comprise it, whether or not separately administered).

Notes: The definitions do not reflect all bidder situations. "Single bidder" is not necessarily synonymous with "single entity".

Questions concerning the guidelines should be directed to the Office of Financing, Bureau of the Public Debt, Washington, DC 20239 (telephone 202/219–3350).

Auction of 7-Year Notes Totaling $9,750 Million

The Treasury will auction $9,750 million of 7-year notes to refund $6,195 million of 7-year notes maturing January 15, 1993, and to raise about $3,550 million new cash. The $6.195 million of maturing 7-year notes are those held by the public, including $528 million currently held by Federal Reserve Banks as agents for foreign and international monetary authorities.

The $9,750 million is being offered to the public, and any amounts tendered by Federal Reserve Banks as agents for foreign and international monetary authorities will be added to that amount. Tenders for such accounts will be accepted at the average price of accepted competitive tenders.

In addition to the public holdings, Federal Reserve Banks for their own accounts hold $320 million of the maturing securities that may be refunded by issuing additional amounts of the new notes at the average price of accepted competitive tenders.

Details about the new security are given in the attached highlights of the offering and in the official offering circular.

Attachment

Highlights of Treasury Offering to the Public of 7-Year Notes To Be Issued January 15, 1993

January 6, 1993

Amount Offered:	
To the public	$9,750 million
Description of Security:	
Term and type of security.	7-year notes.
Series and CUSIP designation	E–2000 (CUSIP No. 912827 J3 7).
Maturity date	January 15, 2000.
Interest rate	To be determined based on the average of accepted bids.
Investment yield	To be determined at auction.
Premium or discount.	To be determined after auction.
Interest payment dates.	July 15 and January 15.
Minimum denomination available.	$1,000.
Terms of Sale:	
Method of sale	Yield auction.
Competitive tenders.	Must be expressed as an annual yield, with two decimals, e.g., 7.10%.
Noncompetitive tenders.	Accepted in full at the average price up to $5,000,000.
Accrued interest payable by investor.	None.
Key Dates:	
Receipt of tenders.	Wednesday, January 13, 1993.
(a) noncompetitive.	Prior to 12:00 noon, EST.
(b) competitive	Prior to 1:00 p.m., EST.
Settlement (final payment due from institutions):	
(a) funds immediately available to the Treasury.	Friday, January 15, 1993.
(b) readily-collectible check.	Wednesday, January 13, 1993.

[FR Doc. 93–578 Filed 1–7–93; 8:45 am]

BILLING CODE 4810–40–M

Public Information Collection Requirements Submitted to OMB for Review

Date: January 5, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Financial Management Service

OMB Number: New
Form Number: None
Type of Review: New collection
Title: Green Book Survey
Description: The data collected will be used to determine the effectiveness of the Green Book and identify areas which need improvement.
Respondents: Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents: 9,000
Estimated Burden Hours Per Response: 15 minutes
Frequency of Response: Other (One-time survey)
Estimated Total Reporting Burden: 2,250 hours
Clearance Officer: Jacqueline R. Perry (301) 344–8577, Financial Management Service, 3361–L 75th Avenue, Landover, MD 20785
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–529 Filed 1–8–93; 8:45 am]

BILLING CODE 4810–35–M

Public Information Collection Requirements Submitted to OMB for Review

Date: January 5, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171, Treasury Annex, 1500 Pennsylvania, NW., Washington, DC 20220.

Department Offices

OMB Number: 1505–0118
Form Number: TD F 90–22.39
Type of Review: Extension
Title: Travel to Cuba, U.S. Department of the Treasury, Office of Foreign Assets Control, Declaration
Description: Declarations to be completed by persons traveling from the U.S. to Cuba will provide the U.S. Government information to be used in administering and enforcing economic sanctions imposed against Cuba pursuant to 31 CFR part 515
Respondents: Individual or households, Businesses or other for-profit, Federal agencies or employees, Non-profit institutions, Small business or organizations
Estimated Number of Respondents: 26,000

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Estimated Burden Hours Per Response: 5 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 2,166 hours
Clearance Officer: Lois K. Holland (202) 622–1563, Departmental Offices, Room 3171, Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503

Lois K. Holland,
Departmental Reports Management Officer.
[FR Doc. 93–530 Filed 1–8–93; 8:45 am]
BILLING CODE 4810–25–M

Customs Service

[T.D. 93–4]

Revocation of Individual Broker License No. 4063; Kenneth A. Anderson, Jr.

AGENCY: U.S. Customs Service, Department of the Treasury.
ACTION: General notice.

SUMMARY: Notice is hereby given that the Secretary of the Treasury, pursuant to section 641, Tariff Act of 1930, as amended (19 U.S.C. 1641), and part 111.74 of the Customs Regulations, as amended (19 CFR 111.74), revoked the individual broker license no. 4063 issued to Kenneth A. Anderson, Jr. This action having been upheld by the United States Court of International Trade (Court No. 90–11–00617); and, under appeal, by the Court of Appeals for the Federal Circuit (Appeal No. 92–1444) is effective as of November 28, 1992.

Dated: January 5, 1993.

Thomas P. Banner,
Acting Deputy Director, Office of Trade Operations.
[FR Doc. 93–469 Filed 1–8–93; 8:45 am]
BILLING CODE 4820–02–M

Office of Thrift Supervision

[AC–1: OTS No. 3404]

First Federal Savings Bank of Maryville, Maryville, TN; Approval of Conversion Application

Notice is hereby given that on December 28, 1992, the Deputy Assistant Director, Corporate Activities Division, Office of Thrift Supervision, or her designee, acting pursuant to delegated authority, approved the application of First Federal Savings Bank of Maryville, Maryville, Tennessee for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Information Services Division, Office of Thrift Supervision, 1776 G Street, NW., Washington, DC 20552, and the Central Regional Office, Office of Thrift Supervision, 111 East Wacker Drive, Suite 800, Chicago, Illinois 60601.

Dated: January 6, 1993.

By the Office of Thrift Supervision.

Nadine Y. Washington,
Corporate Secretary.
[FR Doc. 92–552 Filed 1–8–92; 8:45 am]
BILLING CODE 6720–01–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 6
Monday, January 11, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice

(January 6, 1993)

The following notice of meeting is published pursuant to Section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C. 552b:

DATE AND TIME: January 13, 1993, 10 a.m.

PLACE: 825 North Capitol Street NE., Room 9306, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

*Note.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Lois D. Cashell, Secretary, Telephone (202) 208–0400. For a recording listing items stricken from or added to the meeting, call (202) 208–1627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the Reference and Information Center.

Consent Agenda—Hydro, 971st Meeting—January 13, 1993, Regular Meeting (10:00 a.m.)

CAH–1.
Project No. 8835–017, Dewey B. Smith
CAH–2.
Project No. 2614–018, City of Hamilton, Ohio
CAH–3.
Project Nos. 1953–006 and 008, Consolidated Water Power Company
CAH–4.
Project No. 1957–004, Wisconsin Public Service Corporation
CAH–5.
Project No. 11080–001, Eagle Mountain Energy Company
CAH–6.
Omitted
CAH–7.
Project No. 1417–042, Central Nebraska Public Power and Irrigation District
Project No. 1835–080, Nebraska Public Power District
CAH–8.
Project No. 7270–012, Northern Wasco County People's Utility District
CAH–9.
Project Nos. 2110–002, 2192–005, 2256–002 and 2590–002, Consolidated Water Power Company
CAH–10.
Project No. 2523–002, Wisconsin Electric Power Company
CAH–11.
Project Nos. 9885–027, 032 and 033, Marysville Hydro Partners

Consent Electric Agenda

CAE–1.
Docket No. ER92–533–000, Louisville Gas and Electric Company
CAE–2.
Docket No. EL92–24–001, The Algoma Group v. Wisconsin Public Service Corporation
CAE–3.
Docket No. RM92–3–000, Annual Update of Commission Filing Fees
CAE–4.
Docket No. EL92–22–000, City of Lebanon, Ohio v. Cincinnati Gas & Electric Company
CAE–5.
Docket No. EL92–42–000, UNITIL Power Corporation v. Public Service Company of New Hampshire and Northeast Utilities
CAE–6.
Omitted
CAE–7.
Docket No. EL91–36–000, Northeast Utilities Service Company
CAE–8.
Docket No. ER92–809–001, Illinois Power Company
CAE–9.
Docket No. EC88–2–009, Utah Power & Light Company, PacifiCorp, and PC/UP&L Merging Corporation

Consent Miscellaneous

CAM–1.
Docket No. RM93–6–000, Repeal of Certain Standards of Conduct Provisions in Part 3c
CAM–2.
(A) Docket No. RO86–13–000, Merit Petroleum, Inc.
(B) Docket No. RO87–6–000, Petrade International, Inc.
(C) Docket No. RO88–11–000, Port Petroleum, Inc., Morris M. James, T. Michael Howell, and C. Geogory Crafts
(D) Docket No. RO88–1–000, Leonard O. Rice d/b/a Rice Oil Company and Rice-Lindquist, Inc.

Consent Oil and Gas Agenda

CAG–1.
Omitted
CAG–2.
Docket Nos. TM93–2–24–000, 001 and 002, Equitrans, Inc.
CAG–3.
Docket Nos. RP93–31–000 and CP88–328–000, Transcontinental Gas Pipe Line Corporation
CAG–4.
Omitted
CAG–5.
Docket No. TA92–1–28–008, Panhandle Eastern Pipe Line Company
CAG–6.
Docket Nos. RP92–215–000 and 001, Columbia Gas Transmission Corporation
CAG–7.
Docket Nos. RP88–228–039, 040, CP87–115–008, 009, RP88–249–009, 010, RP86–119–027, 030, RP92–206–001, RP88–191–030, RP89–30–006, RP90–122–009, RP91–167–008, RP89–29–013, RP89–149–009, RP89–242–008, CP89–470–006, TA84–2–9–022, TA85–1–9–014, TA89–1–9–004, TA90–1–9–008, TA91–1–9–006, RP91–16–004, 005, CP87–103–011, CP91–3135–005, RP91–210–013 and RP92–220–003, Tennessee Gas Pipeline Company
CAG–8.
Docket No. RP92–132–008, Tennessee Gas Pipeline Company
CAG–9.
Docket No. RP92–132–009, Tennessee Gas Pipeline Company
CAG–10.
Docket No. RP92–165–007, Trunkline Gas Company
CAG–11.
Docket Nos. RP93–4–001 and RS92–43–001, Mississippi River Transmission Corporation
CAG–12.
Docket No. RP89–185–007, Panhandle Eastern Pipe Line Company
CAG–13.
Docket Nos. RP87–30–000 (Phase II) and RP90–69–000 (Phase A), Colorado Interstate Gas Company
CAG–14.
Docket No. RP91–143–000, Great Lakes Gas Transmission Limited Partnership
CAG–15.
Docket No. RM87–17–004, Natural Gas Data Collection System
CAG–16.
Omitted
CAG–17.
Docket No. GP91–8–001, Jack J. Grynberg, Individually and as General Partner for the Greater Green River Basin Drilling Program: 72–73 v. Rocky Mountain Natural Gas Company, a division of KN Energy, Inc.
Docket No. GP91–10–001, Rocky Mountain Natural Gas Company v. Jack J. Grynberg, Individually and as General Partner for the Greater Green River Basin Drilling Program: 72–73
CAG–18.
Docket No. GP89–54–000, Amoco Production Company
CAG–19.

Docket No. RS92–87–002, Transwestern Pipeline Company

CAG–20.
Docket Nos. RP93–5–002 and RS92–69–001, Northwest Pipeline Corporation

CAG–21.
Docket Nos. RS92–60–005 and RP92–214–003, El Paso Natural Gas Company

CAG–22.
Docket Nos. CP93–57–000, RS92–82–000 and CP92–189–001, Superior Offshore Pipeline Company
Docket No. CP93–47–000, United Gas Pipe Line Company
Docket No. CP76–304–000, Transcontinental Gas Pipe Line Corporation

CAG–23.
Docket No. CP92–504–001, Arkla Energy Resources, a Division of Arkla, Inc. and Arkla Energy Resources Company

CAG–24.
Docket No. CP92–498–001, Trunkline Gas Company

CAG–25.
Docket No. CP90–2155–001, Southern Natural Gas Company

CAG–26.
Docket No. CP90–1249–001, Colorado Interstate Gas Company

CAG–27.
Docket No. CP92–441–001, National Fuel Gas Supply Corporation and Tennessee Gas Pipeline Company

CAG–28.
Omitted

CAG–29.
Docket No. CP92–472–001, Equitrans, Inc.

CAG–30.
Omitted

CAG–31.
(A) Docket Nos. CP89–800–000 and 001, Panhandle Eastern Pipe Line Company
(B) Docket No. CP92–190–000, Panhandle Eastern Pipe Line Company
Docket No. CP92–203–000, KN Wattenburgh Transmission Limited Liability Company
Docket No. CP92–208–000, KN Front Range Gathering Company

CAG–32.
Omitted

CAG–33.
Omitted

CAG–34.
Docket No. CP92–351–000, Williams Natural Gas Company
Docket No. CP92–416–000, Trident NGL, Inc. and Oryx Energy Company

CAG–35.
Docket No. CP89–2165–002, Algonquin Gas Transmission Company

CAG–36.
Docket No. RM90–7–003, Revisions to Regulations Governing Transportation under Section 311 of the Natural Gas Policy Act of 1978 and Blanket Transportation Certificates
Docket Nos. CP93–11–000 and CP93–83–000, El Paso Natural Gas Company

CAG–37.
Docket Nos. CP92–44–000 and 001, El Paso Natural Gas Company

CAG–38.
Docket No. CP92–273–000, West Texas Gas, Inc.

CAG–39.
Docket No. CP92–592–000, United Gas Pipe Line Company

CAG–40.
Docket No. CP91–2904–000, Mississippi River Transmission Corporation

CAG–41.
Docket Nos. RP88–259–060, 059, CP89–1227–000, RP90–124–000, RP90–161–000, RP92–228–000 and RP92–1–008, Northern Natural Gas Company

CAG–42.
Docket Nos. RP91–187–007, CP91–2448–000 and FA91–23–001, Florida Gas Transmission Company

Hydro Agenda

H–1.
Reserved

Electric Agenda

E–1.
Docket No. ER92–280–000, Public Service Electric and Gas Company. Order on transmission rate filing.

E–2.
Docket Nos. ER92–317–001 and ER92–456–001, Public Service Company of Colorado. Order on rehearing regarding transmission rate filing.

E–3.
Docket Nos. EC92–21–000 and ER92–806–000, Entergy Services, Inc. and Gulf States Utilities Company. Order on rate filing and request for merger authorization.

E–4.
Omitted

Miscellaneous Agenda

M–1.
Reserved

Oil and Gas Agenda

I. Pipeline Rate Matters

PR–1.
(A) Docket No. RP91–143–005, Great Lakes Gas Transmission Limited Partnership. Order on rehearing.
(B) Docket Nos. RP89–186–008 and RP90–20–005, Great Lakes Gas Transmission Limited Partnership. Order on rehearing.

II. Restructuring Matters

RS–1.
Docket No. RS92–11–000, Texas Eastern Transmission Corporation. Order on Order No. 636 compliance filing.

III. Pipeline Certificate Matters

PC–1.
Docket Nos. CP92–184–000 and 001, Texas Eastern Transmission Corporation
Docket Nos. CP92–185–000 and 001, Algonquin Gas Transmission Company. Application to construct facilities and to provide firm transportation for six shippers.

PC–2.
Docket Nos. CP91–732–003 and CP88–332–024, Indicated Shippers v. El Paso Natural Gas Company. Order on rehearing.

PC–3.
Docket No. CP80–34–009, Panhandle Eastern Pipe Line Company
Docket No. CP80–35–009, Colorado Interstate Gas Company. Application to amend existing exchange/transportation/sales agreement.

PC–4.
Docket Nos. CP92–182–000, 001 and 002, Florida Gas Transmission Company
Docket No. CP92–415–000, Transcontinental Gas Pipe Line Corporation and Florida Gas Transmission Company. Application to construct Phase III facilities and application for expansion of Mobile Bay facilities.

Linwood A. Watson, Jr.,
Acting Secretary.

[FR Doc. 93–677 Filed 1–7–93; 2:50 pm]
BILLING CODE 6717–01–M

Federal Register

Monday
January 11, 1993

Part II

Environmental Protection Agency

40 CFR Part 72, et al.
Acid Rain Program; Final Rule

VOL 58 ISS 6 JA 11 1993 UMI

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 72, 73, 75, 77 and 78
[FRL–4543–5]

Acid Rain Program: General Provisions and Permits, Allowance System, Continuous Emissions Monitoring, Excess Emissions and Administrative Appeals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Title IV of the Clean Air Act (the Act), as amended November 15, 1990, requires the Environmental Protection Agency (EPA or Agency) to establish an Acid Rain Program to reduce the adverse effects of acidic deposition. To implement this statutory mandate, the Acid Rain Program requirements will be codified in seven regulations. This action delineates all or portions of five final regulations that were initially proposed December 3, 1991: General Provisions and Permits; the Allowance System; Continuous Emissions Monitoring; Excess Emissions Penalties; and Administrative Appeals. (The administrative appeals procedures were originally proposed as a subpart of the permits rule; EPA has decided to remove it from part 72 and place it in a separate part 78.)

In addition to the final rules, this action includes a brief overview of the acid rain problem, summaries of major provisions of the proposed rules, the public's comments on these proposals, and summaries of the major changes that have been made in this final rule.

DATES: These rules become effective February 10, 1993. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of February 10, 1993.

FOR FURTHER INFORMATION CONTACT: Brian McLean, Director, Acid Rain Division (6204J), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. (617) 674–7377.

SUPPLEMENTARY INFORMATION:

I. General Background

The burning of fossil fuels, particularly coal and oil, releases emissions of sulfur dioxide (SO_2) and nitrogen oxides (NO_x) into the atmosphere. Once in the air, SO_2 and NO_x may undergo various chemical reactions, resulting in transformation of the emissions into sulfates, nitrates, sulfuric acid and nitric acid. These compounds can fall to earth near the emission sources of SO_2 and NO_x or be transported hundreds of miles. Referred to as acidic deposition or acid rain, these compounds can be either dry (gases, aerosols, and particles) or wet (precipitation such as rain, fog, or snow). SO_2, and NO_x emissions and their byproducts damage ecosystems and man-made materials, are suspected of posing a threat to human health at current levels, and reduce visibility.

Of the approximately 23 million tons of SO_2 and 19 million tons of NO_x emitted annually from all sources in the United States in 1985, about 16 million tons of SO_2 and 7 million tons of NO_x were emitted by electric utilities. Title IV of the Act requires EPA to establish an Acid Rain Program and a national emissions cap of 8.95 million tons per year on electric utility SO_2 emissions to be implemented in two phases. Phase I (beginning in 1995) requires the 110 highest-emitting utility plants to meet an intermediate SO_2 emissions limitation. By the year 2000 (in which Phase II begins) virtually all other utility units with output capacity greater than 25 megawatts and all new utility units will be required to meet emissions limitations as well. Total annual SO_2 emissions will be reduced by 10 million tons below 1980 levels beginning in the year 2000, a reduction of total SO_2 emissions of approximately 40%. Title IV also requires that certain coal-fired electric utility boilers reduce their emissions of NO_x through installation of low NO_x burner technologies at the same time they are required to comply with the SO_2 limitations. However, these rules do not address the NO_x reduction provisions of the Act.

The centerpiece of the Acid Rain Program is a unique trading system in which allowances (each authorizing the emission of up to one ton of SO_2) are bought and sold at prices determined in a free market. Existing utility sources are allocated allowances based on their historic fuel use and the emissions limitations specified in the Act. Utility units are required to limit SO_2 emissions to the number of allowances they hold, but since allowances are fully transferrable, utilities may meet their emissions control requirements in the most cost-effective manner possible. For instance, a utility may decide to (1) switch to a lower sulfur fuel, (2) install flue gas desulfurization equipment (scrubbers) and bank unused allowances or sell them to other utilities/individuals, (3) forego emissions reductions and buy additional allowances (if necessary) or (4) implement energy efficiency measures at the plant or by encouraging customers to undertake them. Other options and combinations of options are possible, providing an unusually high degree of flexibility for affected sources to comply with the law. The procedures for transferring and tracking allowances are codified in 40 CFR part 73.

In order to operate, each affected source must apply for a permit in which the source certifies that it will hold a sufficient number of allowances to cover its SO_2 emissions, and specifies the source's planned method of compliance. The permit regulation is codified in 40 CFR part 72.

In order to ensure that source compliance results in achieving nationally mandated reductions in SO_2 and NO_x emissions, each affected source must install a system to continuously monitor the emissions and to collect, record, and report emissions data. The continuous emissions monitoring rule is codified in 40 CFR part 75.

If an affected unit exceeds its emissions limitation for either SO_2 or NO_x, the Act requires the affected source to pay penalties and, for SO_2, to submit a plan detailing how the excess SO_2 emissions will be offset and when. These requirements act as a strong incentive for compliance with the mandated emissions reductions of the Acid Rain Program. Excess emissions penalty requirements are codified in 40 CFR part 77.

Finally, should there be disputes over decisions by the Administrator regarding any aspect of the Acid Rain Program, administrative appeals procedures are defined in 40 CFR part 78.

II. Acid Rain Rulemaking Overview

Prior to the publication of the proposed acid rain regulations, EPA solicited comments and ideas from many individuals and organizations that would be affected by such rules. The Acid Rain Advisory Committee (ARAC) was formed for that purpose, and included 44 members representing various stakeholder groups, including utilities, emissions control equipment vendors, State Public Utility Commissioners, academicians, coal companies, State air pollution control agencies, labor, and environmental groups. In addition to the Committee members, hundreds of people attended the six ARAC public meetings and participated in varying degrees in the discussions. Input from these stakeholders and others was extremely helpful in drafting the proposed acid rain rules.

To date, the Agency has proposed three rulemaking packages pursuant to title IV of the Act and finalized one. The first, proposed on May 23, 1991 and finalized December 17, 1991, was

subpart E of 40 CFR part 73 which governs the auction and sale of allowances under the Acid Rain Program. Recently, on July 7, 1992, subparts B and G of 40 CFR part 73 were proposed for public comment. These subparts address the allocation of allowances to electric utilities and small diesel refineries.

The most extensive of the acid rain proposals (hereafter referred to as the "core rules") were proposed in the Federal Register on December 3, 1991. That proposal addressed the acid rain permitting procedures for electric utilities, including administrative appeals (part 72); the operation of the allowance system, including the conservation and renewable energy reserve (subparts A, C, D, and F of part 73); installation and operation of continuous emission monitors (part 75); and penalty procedures if emissions exceed allowances held or emissions limitations (part 77). The core rules are finalized in today's rulemaking.

Between January 6 and 10, 1992, EPA conducted public hearings in Washington, DC, Chicago, and San Francisco on the core rules. Testimony was given by 33 individuals, representing industry, State regulatory organizations, and environmental groups. A full record of both written and oral comment is available in the EPA docket on this rulemaking.

During the public comment period, which closed on February 12, 1992, the Agency received 3249 letters, documents, and telephone communications from a wide variety of interested parties. The general public submitted 2576 letters; private industry, 434; local governments, 131; state agencies and governors, 42; Congress, 32; and environmental groups, 31. These communications contained over 7800 individual comments focused on over 850 major and minor issues. Approximately 80% of the comments were focused on 14 major issue areas. These issue areas are addressed in the preamble that follows, along with other issues that received fewer comments but are judged by the Agency to be of sufficient importance to discuss here. All public comments and the Agency's response to each are available at the docket established for this rule at EPA Headquarters, Air Docket, room M–1500, 1st floor, 401 M Street, SW., Washington, DC, 20460, between the hours of 8:30 a.m. and noon, and 1:30 p.m. to 3:30 p.m., Monday through Friday.

Structural Changes to Today's Rules

Although the final rules published in today's notice remain consistent in content and relatively similar in form with those proposed in December 1991, some structural changes have been made to improve the cogency and general readability of the rules. In drafting the final rules, EPA has endeavored to simplify and streamline the text wherever possible; sections have been relocated to improve the flow of information, redundancies eliminated, and many sections rewritten to enhance clarity. Major changes are noted below. More specific structural changes that are unique to each rule are addressed in the preamble section for that rule.

Definitions and Abbreviations

The proposed rules included definitions and abbreviations sections and other general provisions within the body of each part. This resulted in both redundancies and inconsistencies across rules. In response to public comment on this issue, the Agency has placed all definitions, abbreviations, State and Federal authorities, and other general provisions for parts 72–78 in subpart A of part 72.

EPA has also revised a number of term definitions to improve clarity; others whose meanings were analogous to common English usage have been deleted. Some definitions have been removed because they explain terms that were more appropriately delineated in substantive portions of the rules. Composite term definitions that incorporate expressions defined separately have been eliminated, as well as definitions of terms no longer used in the rules.

All of these steps are intended to ease the task of referencing and understanding terms for the reader and ensure that term definitions are now consistent across all rules. Changes made to individual terms based on public comment on the term itself, on issues that impact the term, or new terms and definitions suggested by the public, are discussed in the appropriate section of the preamble.

Opt-ins Provisions

The proposed core rules contained various provisions concerning opt-in sources under section 410 of the Act. Because the Agency is still developing regulations on opt-ins, virtually all provisions and references to opt-ins have been removed in the final rule. These matters will be addressed in upcoming rulemakings.

Appeals Procedures

The proposed core rules included an appeals section in part 72 that applied only to permits. Public comment was specifically solicited to determine if a broader appeals process located in a separate part would enhance the Acid Rain Program core regulations. In response to comments affirming the idea of both a separate and broadened rule to address appeals issues, part 72, subpart H, has been revised and relocated to part 78. This rule now addresses administrative appeals procedures for the entire Acid Rain Program.

Forms

In the proposed core rules, EPA introduced the concept of using standard forms to submit required applications and to report data and information for all parts of the Acid Rain Program. EPA proposed a number of forms for the regulated community to use in submittals regarding allowance transactions, compliance plans, and continuous emission monitors. The primary rationale for including these forms in the proposal was to solicit public comment on the overall forms approach to information transfer and to gather opinion on specific data elements requested on the forms. During the public comment period, EPA also held a special public meeting regarding these forms to obtain additional feedback.

The Agency received many public comments supporting the concept of standard form utilization; none received were opposed to the recommendation. Commenters indicated that the forms and instructions were generally sound as proposed, but numerous specific recommendations were offered suggesting how forms and instructions could be improved to eliminate redundancy and increase clarity and consistency. Some commenters stated that improved versions of the forms could be developed as experience is gained through their use. Other commenters questioned the need and usefulness of some data elements, and pointed out that some of the information requests by EPA were "nice-to-know" information or data that the Agency already had in its possession. Comments about data elements were carefully considered as the final substantive sections of today's rule were developed, and are discussed throughout the preamble, as appropriate.

As in December's proposed rule, EPA will itemize in the final rule each of the information and data elements that must be submitted by the owners and operators of an affected source to a permitting authority. While specific forms are not part of the rule, form content will continue to be governed by the rule, which enumerates information requirements.

Commenters and EPA agreed that forms should be removed from the final rule. Not doing so would mean even simple revisions to forms would require rule changes. Since many of these forms will be used throughout the life of the program (and some not utilized until Phase II), the opportunity to easily incorporate the experiences of Phase I permit issuances could significantly benefit implementation of the Acid Rain Program in Phase II. Commenters also stressed that future developments in the field of electronic reporting would more easily be incorporated into the program if forms were not made a part of the rulemaking.

No later than the effective date of this rule, EPA will direct mail packages of standard forms to the owners of all Phase I sources. These packages, with instructions, contain permit forms, monitoring plan forms, and certificates of representation. The certificates of representation will be sent to owners of Phase II sources in the event they wish to certify their representative now. Owners and operators are encouraged to certify as soon as possible in order to fully participate in allowance activities such as auction and sale (see the Discussion of Changes to part 73 for further discussion). The form for an application for a Phase I extension will be sent to those owners who have indicated interest in this compliance option. Any other interested party may obtain the packages of forms and instructions by calling the Acid Rain Hotline.

The preamble that follows outlines the major changes that the proposed rules have undergone since their publication in December 1991 and discusses public comment.

III. Changes to Part 72—Permits

A. Structural Changes

(1) Introduction

EPA received a large number of public comments regarding part 72. The general thrust of many of these was that the proposed rule needed to be simpler and more coherent. In response to these suggestions, EPA has made many revisions to part 72 that are designed to enhance readability and understanding. Because a substantial number of the changes made to this rule are structural and not substantive, the preamble addressing part 72 is divided into two sections, the first summarizing structural changes (streamlining efforts, relocations of sections, deletions, etc.) and the second addressing substantive revisions made to the rule.

(2) General Provisions

The general provisions section in proposed subpart A of part 72, which formerly applied only to the permits rule, has been modified and now applies, for the most part, to the entire Acid Rain Program. Provisions regarding Acid Rain Program definitions, measurements, abbreviations and acronyms, federal authority, state authority, applicability, standard requirements, availability of information, and computation of time that were located in various places in the proposed rule have been consolidated and are now included under this subpart. This modification promotes consistency among the parts of the rule and eliminates unwarranted redundancies.

(3) Definitions

Definitions for the Acid Rain Program have been combined into a single definitions section (§ 72.2) for 40 CFR parts 72, 73, 75, 77, and 78. Some definitions have also been revised to enhance the clarity of the regulatory text. Terms whose definitions did not differ from common English usage (e.g., "calendar year") have been deleted. Conversely, some terms whose definitions include a common meaning but that possess specific connotations regarding the Acid Rain Program have been clarified or removed from the definitions section when the textual context of the rule suffices in conveying the meaning of the term.

A number of definitions have also been eliminated or streamlined because they articulated substantive requirements that were more appropriately denoted in pertinent sections of the rules. Definitions redundant with substantive provisions of the rules have been deleted. The following table lists terms removed from the proposed rules glossary and, where applicable, their location within the text of the final rules.

Acid rain compliance option.	part 72, subpart D
Acid Rain permit application.	part 72, subpart C
Administrative permit amendment.	part 72, subpart H
Alternate authorized account representative.	§ 73.33(d)
Alternate designated representative.	§ 72.22
Applicable requirement of the Act.	Title V, § 70.2
Approved compliance plan.	part 72, subpart D
Automatic permit amendment.	part 72, subpart H
Complete permit application.	§ 72.50
Continuous	§ 72.2 (definitions of CEMS & COMS)
Control unit	Streamlined definition, see also § 72.42
Designated representative.	Streamlined definition, see also § 72.20
Determination of completeness.	§§ 72.61 and 72.72(b)(1)
Dual span system	part 75
Energy conservation measure.	§§ 72.43 and 73.81
Fast track modification.	part 72, subpart H
First-in, first-out accounting basis.	§ 73.35(c)(2)
Load management	§ 73.81(b)(4)
Monitor data availability.	part 75
Non-utility unit	section 402(25) of the Act
Path continuous emission monitoring system.	part 75
Permit modification	part 72, subpart H
Phase I extension unit.	part 72, subpart D
Proposed compliance plan.	part 72, subpart D
Ranking application	§ 72.42
Reduced utilization through energy conservation.	§ 72.43
Reduced utilization through improved unit efficiency.	§ 72.43
Renewable energy generation.	§ 73.81(c)
Renewable energy input.	§ 73.82(a) (12) and (13)
Repowering extension period.	§ 73.44
Sulfur-free generator	§ 72.2 (definition of sulfur-free generation)
Transferee account	part 73, subpart D
Transferror account	part 73, subpart D
Transferror unit account.	part 73, subpart D
Uncontrolled emissions rate.	§ 72.42 and part 75
Use allowances	§ 73.35

The definitions portion of the final rules no longer includes separate definitions for terms that are composites of separately defined terms. For example, the proposed definition for "existing affected unit" was deleted from the final rule since the terms "existing unit" and "affected unit" are defined separately.

One commenter asked that the rules include all statutory definitions applicable to the Program. Although sources should continue to refer to those definitions, § 72.2 lists statutory definitions only for those statutory terms utilized within the rules.

Some rule and terminology revisions have necessitated the redefinition of certain terms. For example, the term "Phase I affected unit" has been revised to read "Phase I unit" throughout the

rules since all Phase I units are affected units.

(4) Deletions and Relocations

A number of the provisions proposed in this subpart have been deleted or moved to other sections. For example, the provisions of the prohibitions (§ 72.8 in the proposed rule) and signatory requirements (§ 72.9 in the proposed rule) sections are, for the most part, now located in § 72.9 (standard requirements), § 72.20 (authorization and responsibilities of the designated representative), and § 72.21 (submissions) of this rule.

(a) Common stacks. Section 72.50 of the proposed rule described special provisions for units with common stacks. Because common stacks are also addressed in part 75 of this chapter, this section was deleted from part 72; requirements that are not redundant have been incorporated into the common stack provisions of part 75. The portion of the preamble covering part 75 discusses public comment on and changes made to the common stack provisions of that rule.

(b) Appendices A & B. Part 72 as proposed contained two lists of affected units: Proposed Appendix A (which listed all Phase I units, had a blank column for their Phase I allocations, and stated the units' 1988 and 1989 SO_2 emissions) and proposed Appendix B (which catalogued Phase II units and allocations). Both have been removed from the rule.

Proposed Appendix A was removed because the list of Phase I units and their allocations has now been promulgated in Table 1 of § 73.10(a) of this chapter with some corrections. In addition, some commenters objected to the figures for 1988 and 1989 SO_2 emissions. Those figures are needed only for those Phase I units involved in a Phase I extension plan and, under the final rule, must be submitted as part of the early ranking application or Phase I extension plan. Comments concerning 1988 and 1989 SO_2 emissions are addressed in section B(5)(c)(ii) of the part 72 preamble, and any remaining comments on proposed Appendix A will be addressed in the rulemaking on subpart B of part 73 of this chapter.

Proposed Appendix B was removed from the final rule because a large number of requests for revisions to proposed Appendix B were received. A more comprehensive and accurate list of existing Phase II units and allocations was proposed, and will be finalized, in Table 2 of subpart B of part 73. All comments on the inclusion or exclusion of specific units in proposed Appendix B will be considered in that rulemaking. See 57 FR 29940, 29965–30024, July 7, 1992.

It should be noted that the final rule contains new appendices that are unrelated to proposed Appendices A and B. Final Appendix A contains the methodology for annualizing emissions limitations. Final Appendix B contains the methodology for converting SO_2 emissions limitations to lb/mmBtu. Final Appendix C contains the methodology for calculating annual tonnage of SO_2 emissions. The methodologies in these final appendices are from the NADB Version 2.1 Technical Support Document.

(c) Reproposals. EPA has determined that further consideration is needed in order to properly draft some provisions originally proposed in the applicability portion of the rule. These provisions concern cogeneration units, new independent power production facilities, and qualifying facilities. The reproposals were included in the proposed rules for allowance allocations and reserves (parts 72 and 73). See 57 FR 29940, 29944–47 July 7, 1992.

The reproposed provisions will be incorporated into this part when promulgated in final form. Public comments received in response to the December 3, 1991 proposal will be addressed in the final rulemaking for these provisions.

(d) Addresses. Addresses for submissions to the Acid Rain Program have been eliminated from the rule so that changes to the addresses will not require a rule change. Appropriate addresses for submissions will be communicated in guidance, forms packages, or separate Federal Register notices as the need arises. EPA headquarters and regional addresses are listed and updated in 40 CFR 1.7.

(5) Combined Subparts and Sections

EPA has removed two subparts of proposed part 72. As mentioned in the overview, subpart H (appeals) has been removed and is now part 78. In addition, the provisions of proposed subparts F and G have, in large part, been combined in the final rule in subpart F. This should not be interpreted as a substantive change since both proposed subparts addressed essentially the same subject, i.e., federal permit issuance procedures in Phase I. All procedures for issuance or denial of a Phase I Acid Rain permit are now located in subpart F of the final rules. Some of the few requirements that were not redundant have been moved to other sections in subpart A or subpart C of the final rule.

Proposed subpart I has been renamed subpart G, but still governs implementation of Phase II of the Acid Rain Program. Subpart G sets out criteria for State operating permit program approval under title V of the Act, which augment or replace criteria set forth at 40 CFR part 70.

Proposed subpart J is now subpart H. In addition to clarifying and streamlining changes, two major substantive changes have been made to proposed subpart J. First, the Agency has eliminated proposed Option 1 under the fast-track modification procedure from the final rule. Second, the Agency has eliminated the requirement that notice be given to interested persons of all administrative amendments that occur under the Acid Rain Program.

Proposed subpart K, renamed subpart I in the final rule, still describes compliance certifications that a designated representative must submit for each affected unit. Because EPA believes that compliance certifications are critical to the smooth operation of the Acid Rain Program, this subpart was reorganized to promote clarity, while some certifications have been eliminated or made more specific. Comments concerning certifications for underutilization, Phase I extensions, and repowering and any major changes to provisions for such certifications are addressed in the respective portions of this preamble dealing with those compliance options.

B. Major Issues

(1) Exemptions (Subpart D)

(a) New units exemption. The proposed rule asked for comment on the possibility of providing an exemption from the Acid Rain Program for small new units. Many commenters requested that the Agency provide some kind of *de minimis* exemption for new units from permitting and all other requirements of title IV. Suggestions included size cutoffs ranging from 5 to 25 MWe, emission tonnage cutoffs such as those for Prevention of Significant Deterioration programs, and exemptions based on boiler or engine type. These recommendations relied heavily on the argument that monitoring costs would be overly burdensome to small utilities and small communities, that emissions from such units are very small and have negligible, if any, effect on the environment, and that the burden on sources and the Agency of permitting all such units would outweigh the benefit of such permitting.

Response: Although the Act does not explicitly provide for a *de minimis* exemption for new units, the Agency agrees with the commenters that such an exemption is appropriate. The

Agency believes that provision of a limited exemption is within its discretion in administering the Act. See *Alabama Power Co.* v. *Costle*, 636 F. 2d 323, 360–61 (D.C. Cir. 1979). Accordingly, EPA has included a provision allowing permitting authorities to grant a *de minimis* exemption in the new § 72.7 of the rule. The Agency reserves the right to reconsider this provision in future years, however, if the total emissions from all exempt units is significantly higher than projected. The rule provides an exemption from most title IV requirements (including the requirement to monitor emissions, hold allowances to cover emissions, and have an Acid Rain permit) for all new utility units that serve one or more generators, the nameplate capacities of which total 25 MWe or less, and that use fuels with a sulfur content less than or equal to 0.05% by weight.

The exemption for these units is based on the Agency's belief that emissions from such units will be *de minimis*. The vast majority of units of 25 MWe or less that use clean fuels are peaking diesel and dual-fuel (natural gas/diesel fuel) internal combustion engines or peaking combustion turbines (primarily natural gas). These units combust low sulfur fuels, such as natural gas and diesel fuel. In the near future, diesel fuel sulfur content requirements for motor vehicles will be reduced to 0.05% sulfur by weight, in accordance with the Act. This fuel will also be available for diesel-fired units and, indeed, may be the only fuel available to them in the future. The sulfur content of natural gas is significantly less than that of diesel fuel. Based on utility projections provided to the Department of Energy and EPA, approximately 170 new units under 25 MWe (including 22 combustion turbines and 148 diesel- or distillate-fired or dual fuel units) are expected to come on line between 1990 and 2000. All of these will likely be peaking units. Based on average heat input for units of this size and type in the NADB and AP42 emission factors, the projected new units will have total annual emissions in the year 2000 of approximately 4 tons of SO_2 and 800 tons of NO_x for the gas-fired units and 134 tons of SO_2 and 1,134 tons of NO_x for the diesel- or distillate-fired units. Because of the higher cost per MWe of operating a unit of this size and type rather than a larger unit burning less expensive fuels, it is extremely unlikely that these units will operate more hours than units of similar size and type have historically. Consequently, EPA has determined that the total SO_2 and NO_x emissions from new units under the exemption will be *de minimis*. EPA made this determination in light of the national cap of 8.95 million tons of SO_2 and the fact that these units have no NO_x limits under title IV and will provide information about their NO_x emission under title I.

This exemption will be of primary benefit to the small peaking diesel and dual fuel units that are operated by many small communities and will also apply to small combustion turbines of the same size, which also have extremely low emission levels. EPA rejected the option of exempting units by engine type, rather than by size and fuel, because a unit may switch to higher sulfur fuels. In addition, larger units will not necessarily have low emission levels. EPA also rejected the idea of exempting units on a case-by-case basis using predicted emissions because of the greater confusion, uncertainty, and regulatory burden that could result.

Although the statutory exemption for existing units that serve only generators with nameplate capacities of 25 MWe or less does not sum the nameplate capacities of all the generators served by the unit and require the total to be 25 MWe or less, the exemption for new units does sum in this manner. The Agency believes that since the new units exemption is based on a determination that emissions from exempt units are *de minimis*, a stricter standard is justified to ensure that the emissions reductions foregone are truly *de minimis*. Also, many of the units are reciprocating engines rather than boilers and therefore do not serve multiple generators. The Agency does not want to encourage future use of multiple generators with such units as a means of avoiding the requirements of title IV and therefore has applied the exemption based on the capacity of individual generators.

To obtain an exemption for a unit, the designated representative must submit a petition stating that the unit meets the criteria for the exemption, that the sulfur content of the fuel deliveries will be tested and information on the sulfur content of the fuel will be kept on site, and that the unit will comply with all requirements of the Acid Rain Program if operations change so that it no longer meets the exemption criteria. In addition, the designated representative must agree to surrender any allowances that the unit would otherwise be allocated under the Act for any years for which the unit will be exempted. Using the same procedures as those for issuing an Acid Rain permit, the permitting authority will then issue a written exemption delineating the exemption and the requirements applicable to the unit. The permitting authority's actions on exemptions are subject to the same right of appeal as actions on permit applications.

Because the Acid Rain Program is based on the calendar year (e.g., the program limits total annual emissions to allowances held at the end of the year), the exemption is effective on a calendar year basis. The exemption takes effect on January 1 of the year after the exemption is approved. An exempt new unit will not have to submit any further information or compliance certifications so long as it meets the exemption criteria. However, the unit must comply with any requirements of the Acid Rain Program that relate to the period during which the unit was not exempted. The exemption will have to be renewed every 5 years, as is an Acid Rain permit. This approach of requiring a renewal submission every 5 years and no annual certifications reduces the burden on the unit and the permitting authority while preserving the permitting authority's ability to keep track of the unit's compliance status.

The exemption will apply unless and until operations at the unit change so that the requirements are no longer met. Should the unit no longer qualify for the exemption, the owners and operators must comply with all requirements of the Acid Rain Program, including the requirement to submit a permit application. Monitoring requirements will take effect as for new units, except that the date on which the unit no longer qualifes for the exemption will be treated as the date of commencement of commercial operation. Although the permitting authority may not be able to issue an Acid Rain permit for such units by the time the unit is required to begin accounting for emissions, the permit application, once deemed complete, will be binding until issuance of a permit.

(b) Retired Units Exemption. The proposed permit rule did not discuss units that retire prior to their compliance deadline. Commenters, however, requested that the Agency provide relief from monitoring and permitting requirements for units that will be retired before the date that they must comply with Acid Rain Program requirements.

Response: The Agency agrees that full permitting is not necessary for retired units under certain circumstances. The Agency has therefore added a new § 72.8, which provides an exemption from some Phase II permitting requirements for any unit that retires

before the issuance, or the renewal, of a Phase II permit. The designated representatives of units that are affected during Phase I and that retire before issuance of a Phase I permit are not exempted from the requirement to submit a Phase I permit application for the unit. A Phase I permit is necessary because, if the unit is underutilized as compared to its baseline (e.g., by being shut down), it must meet the requirement of this part that the underutilization be accounted for. Moreover, a reduced utilization plan may have to be submitted for the unit.

The owners and operators of a unit retired under this section must appoint a designated representative. A designated representative is necessary not only because a petition for an exemption must be submitted, but also because allowances will continue to be allocated to the unit's account in accordance with 40 CFR part 73.

To obtain an exemption, the designated representative must submit a petition by not later than the deadline for submission of a Phase II permit application or, if the unit already has a Phase II permit, for reapplication for an Acid Rain permit. The petition must contain a statement that the unit is or will be retired and a requirement that the designated representative will submit a permit application for the unit before it may recommence operation. As suggested by a commenter, the application deadline is 24 months before the unit recommences operation. This deadline was chosen because it is consistent with the statutory deadline for new units to submit permit applications.

The permitting authority will act on the petition and issue a written exemption for the retired unit using the same procedures as those for issuing an Acid Rain permit. As with the new units exemption, the retired units exemption takes effect January 1 of the year after the exemption is approved. The unit must comply with all requirements of the Acid Rain Program related to the period before it was exempted. No annual submissions or certifications are required so long as the unit qualifies for the exemption, but the exemption will have to be renewed every 5 years. Both the retired units and new units exemptions will be handled by the States, upon approval of their operating permit programs under subpart G of this part and part 70 of this chapter. The costs of issuance and administration of the exemptions are indirect costs of the operating permit program.

This section addresses exemptions from permitting requirements only and does not specify the conditions under which a retired unit may be exempt from monitoring requirements. Those conditions are discussed in the portion of the preamble covering part 75 of this chapter.

(2) Definitions (Subpart A)

(a) *Fuels terminology.* Several comments were submitted concerning the categorization of units by fuel type. Because of the crosscutting nature of these issues, they deserve discussion here.

As many of the commenters noted, the fuels terminology used in the Act and the rules (e.g., "coal-fired", "gas-fired", and "oil-fired", "fossil fuel", "fossil fuel-fired", "coal", "coal-derived", "natural gas", and "fuel oil") affect the applicability of a wide range of Acid Rain Program requirements to affected units. For example, the repowering extension provisions in part 72 of the rules, and the NO_x requirements in section 407 of the Act, apply to "coal-fired" boilers only. Monitoring requirements can also vary depending on whether a unit is classified as "coal-fired", "gas-fired", or "oil-fired." Other provisions, such as a unit's baseline and allowance allocations, are dependent on the "fossil fuel" consumed.

Coal-derived fuel. Numerous commenters asked that the definition of "coal-fired" be revised by deleting the reference to "coal-derived" fuel. They noted that the reference would result in oil- or gas-fired units that burn any amount of coal-derived gas or liquid fuel being treated as "coal-fired" for purposes of the monitoring requirements of the Acid Rain Program. Several commenters noted that coal gas, although not in widespread use, "should burn cleanly" and should be treated as natural gas or methane. Others noted that coal gases and coal liquids are likely to be used in the future as supplemental fuels for gas- and oil-fired units that consume no solid coal. They argue that the regulation of such units as "coal-fired" would inadvertently inhibit advances in important coal-derived fuels technology.

The statute does not define "coal" or "coal-fired", although both terms are used throughout title IV (e.g., definition of "repowering", NO_x applicability). The legislative history, however, makes clear that "coal" fuel includes coal-derived fuels such as washed coal, liquified or gasified coal, and other conversions of coal. For example, the original Administration bill limited repowering to units burning "pulverized coal" (i.e., the conventional method of burning coal). This wording was changed to the more general term "coal-fired", thus implicitly expanding the universe of units potentially eligible for repowering extensions. As evidenced, for example, in the Senate and House committee reports accompanying S. 1630 and H.R. 3030 (Senate Rep. No. 101–228 at 292–93 (1989) and House Rep. No. 101–490 at 363 (1990)), Congress was aware that coal-firing options included a variety of coal-derived fuels.

Although some of the coal derivatives mentioned in the comments are expected to be cleaner than pulverized coal, it is unclear whether the developing technologies will become so standardized as to guarantee the removal of all sulfur components from these new fuel forms. Thus, whether a particular unit burning gasified or liquified coal will or will not emit substantial amounts of SO_2 or NO_x can only be determined with certainty by rigorous continuous emissions monitoring. Sources relying on such fuel in the future will be able to avail themselves of the authority in the Act and the rules to petition for approval of an alternative monitoring system. The state of the technology is not, however, so well established or uniform as to warrant a broad reclassification of such fuels and consequent exceptions to, for example, the monitoring requirements of the Acid Rain Program.

This rule, therefore, preserves the "coal-derived" reference in the definition of "coal-fired." In addition, the terms "coal" and "coal-derived" are defined to add clarity to the rule. The definition of "coal" is based on the definition in 40 CFR 60.41(f), the new source performance standards for coal-fired utility boilers. (The NSPS definition has been revised slightly to cite the correct ASTM and the incorporation by reference section.) The term "coal-derived" is defined in accordance with the legislative history references to include solid coal derivatives, liquified coal, gasified coal, and several other known coal derivatives.

The definition for the term "coal-fired" has also been revised to reflect the different characterizations that will apply under different parts of the Acid Rain Program. Thus, while for purposes of the part 75 monitoring requirements, any unit that burns any amount of coal or coal-derived fuel is "coal-fired", the classification for purposes of other parts of the Acid Rain Program is limited to units burning coal or coal-derived fuel as the primary fuel.

Gas- and oil-fired. One commenter asked that the rules address whether a "gas-fired" unit forced to convert to fuel oil due to a catastrophic interruption or

gas curtailment would be unavoidably held in violation of the monitoring requirements of the rule. The commenter suggested EPA adopt a five-year averaging approach for reclassification to avoid such forced non-compliance. EPA does not believe a specific rule provision is the best way to address such incidents. EPA has adopted an approach based on both the average and the annual figures over three years. In addition, the Agency has ample enforcement discretion in addressing violations caused by catastrophic events beyond the control of a unit.

Several commenters asked that the term "natural gas" (used in the definition of "gas-fired") be defined and that it include: Propane, landfill gas, digester gas, and methane; biomass; and coal-gasification. The final rules include a definition for "natural gas." The Agency, however, rejects the broad interpretation suggested by the commenters since it would not be consistent with the general scientific understanding of the term, nor with the Acid Rain Program's limited applicability to fossil fuel-fired units. The definition of "natural gas" does not, therefore, include landfill gas, digester gas, biomass, or gasified coal.

However, the definition of "gas-fired" was revised to include coal-derived gaseous fuel with a sulfur content no greater than that of natural gas, along with natural gas. Further, the definitions of both "gas-fired" and "oil-fired" have been revised so as not to preclude the use of non-fossil gas and liquid fuels as supplemental fuels for gas-fired and oil-fired units. These changes will allow essentially sulfur-free fuels, such as natural gas, landfill methane, or synthetic propane, but will exclude solid fuels such as wood or municipal waste since such fuels could not be monitored using the excepted methods of appendix D of part 75.

One commenter asked that the words "if any" be added at the end of the definitions for "gas-fired" and "oil-fired", to indicate that units do not have to burn more than one type of fuel. EPA agrees that the change would clarify the definition, and have revised the definitions accordingly.

The rules also include new definitions for "fossil fuel-fired", "fuel oil", "diesel fuel", "primary fuel" or "primary fuel supply".

In addition to the new fuels definitions, the final rules clarify the fuels treatment in the applicability and other provisions of each part of the rule, particularly in so far as a unit might be reclassified due to changes in fuel usage. For example, an existing unit's allowance allocations, based on historical data, will not change if the unit changes from coal-fired to gas-fired; a new unit could not avoid becoming affected by burning something other than a fossil fuel when commencing operation and subsequently switching to a fossil fuel; and the continued availability of a monitoring exception can change should a gas-fired unit begin combusting coal. For greater detail concerning fuel classifications, see the applicable portions of the preamble below.

(b) Utility units. The proposed applicability section identified affected units by referring to units as existing units or new units, or by describing the specific circumstances under which various units serve generators. Several commenters suggested changes to these terms to clarify that only utility units rather than all units are subject to the requirements of the Acid Rain Program.

Response: The term "utility" as defined in the Act specifies that only those units that currently produce, or at various times in the past produced, electricity for sale are utility units. Because the definitions of the terms "existing" and "new" used in the proposal and in the Act both include reference to serving a generator that produces electricity for sale, any unit that is not a utility unit would by definition be excluded by the proposed language. The requested clarification is, therefore, not a substantive change. The rule now includes the term "utility" in conjunction with the terms "existing" and "new" to clarify this point for the reader.

The proposal repeated the statutory definition of the term "utility unit" with a few minor changes. Paragraph (B) of the statutory definition was repeated in the proposal as follows:

> "* * * a unit that was in commercial operation during 1985, but did not, during 1985, serve a generator that produced electricity for sale, shall not be a utility unit for purposes of the Acid Rain Program."

Commenters pointed out that this paragraph of the proposed definition needed clarification because the statutory language, read literally, describes a situation that on its face seems impossible. Since, under section 402(22) of the Act, "commence commercial operation" means "to have begun to generate electricity for sale," it is difficult to see how a unit that did not generate any electricity for sale in 1985 could be considered in commercial operation.

Response: EPA agrees and this paragraph of the definition has, therefore, been clarified in the definitions in today's rule and in the applicability section at § 72.6(b)(3). The Agency has interpreted this latter provision to mean that units that served self-generators in 1985 (i.e., did not generate electricity for sale) are not utility units as long as they continue to serve self-generators (i.e., do not currently generate electricity for sale). Thus, for example, an industrial boiler transmitting steam to a generator to produce electricity for public sale is a utility unit.

(c) Combined Cycle Units. The proposed rules requested comment on the treatment of existing combined cycle units. The proposal included combined cycle units without auxiliary firing in the definition of "simple combustion turbine," causing these units, if they commenced commercial operation before November 15, 1990, to be exempt from the requirements of the Acid Rain Program. Combined cycle units with auxiliary firing were not exempted from the Acid Rain Program in the proposal. Some commenters disagreed with the Agency's position and requested that combined cycle units with auxiliary firing also be exempted, based on the sulfur content of the fuel used. Other commenters supported the Agency's decision.

Response: The Agency has retained the proposed definition of "simple combustion turbine" because it is based on equipment configuration rather than operations. The complex array of operating scenarios under which combined cycle units operate and the relative ease with which operations can be adjusted would make a definition based on operations complex and difficult to implement. This rule, therefore, provides that existing combined cycle turbines that did not use auxiliary firing for commercial power generation in the baseline period (1985–1987) will be treated as simple combustion turbines and are exempt from the requirements of the Acid Rain Program under § 72.6 of the final rule. However, if such a unit after November 15, 1990, utilized firing, EPA will treat that unit as a new unit, subject to the Acid Rain Program. Such a unit will receive no allowances.

(d) Owner or operator. The definition of "owner or operator" has been revised to delete the words "designated representative." The proposed rule interpreted the statutory authorities, responsibilities, and duties of the designated representative as establishing a specific category of the "operator" role. *See* 56 FR 63009 (December 3, 1991). EPA solicited comment on an alternative reading of the statutory language that would

exclude "designated representative" from the definition of "owner or operator" in all cases. *See id.*

The Agency today reaffirms, with some refinements, the statutory interpretation set forth in the preamble. In most cases, the responsibilities of a designated representative will be narrower than those of an operator. Accordingly, based upon comments of the Department of Energy and others, EPA has determined that it would be inappropriate to broadly sweep all designated representatives into the definition of "owner or operator" as provided in the rulemaking proposal.

In some cases, however, the scope of the designated representative's responsibilities, as provided in the final regulations, would in fact be coextensive with those of an operator, and in those cases he or she would still be an operator. As discussed below, one such case is where there is a common designated representative for multiple sources lacking a common owner and operator and participating in a substitution plan. Thus, the definition has been revised to more accurately reflect the varied nature of the role of designated representatives under the Acid Rain Program by effectively providing that a designated representative is an operator only when his or her duties and responsibilities bring him or her within the ambit of that term.

(3) Designated Representative

Title IV of the Clean Air Act requires the owners and operators of each affected source to appoint a designated representative to act as a liaison between the source and EPA on matters concerning the Acid Rain Program.

(a) Designated representative requirements. (i) Universal requirement. In the proposal, EPA required that all sources have a designated representative. Several commenters suggested that EPA eliminate the requirement to have a designated representative where there is only one owner/operator at a source. The commenters argue that a designated representative is not needed in those situations and that the certification requirements are unnecessary and burdensome where there is a single owner/operator.

Response: The Agency disagrees. The designated representative is needed to simplify the Agency's administration of the Acid Rain Program and to ensure the accountability of an owner or operator for actions governed by the program by, *inter alia*, reducing the likelihood of inconsistent submissions by a source. In addition, requiring the source to interact with the Agency exclusively through one designated representative will permit the regulated community to exercise the flexibility in compliance provided under the Acid Rain Program while being assured that EPA will only act on a submission (e.g., an allowance transfer) that is authorized by the source. Thus, no matter how many owners or operators there are at a source, having a single designated representative will benefit both the regulated community and the Agency.

The Agency agrees, however, that one of the certification requirements in the proposed rules was unnecessarily burdensome on sources with single owners and operators. For sources with a single owner and operator, the Agency has eliminated the requirement that the designated representative send written notice of the agreement under which he or she is selected to that owner and operator, who undoubtedly already knows of the agreement. In the final rules, this requirement only applies to sources with multiple owners and operators.

(ii) Designation by source or unit. Several commenters objected to EPA's proposal requiring that each source have only one designated representative. These commenters argued that the language in sections 408(a) and 402(26) of the Act specify that designated representatives should be appointed by unit. The commenters also claimed that units, not sources are accountable for allowance transactions, compliance plans, monitoring reports, and excess emission penalties.

Response: The Agency agrees that most compliance requirements under the Acid Rain Program are imposed on a unit, rather than a source, basis. Nonetheless, the Agency believes that it is appropriate to require one designated representative per source. While units at a source may have some different owners and operators, there is generally one operator who coordinates operations of all the units and whose decisions concerning one unit may have consequences for the operation of other units. The requirement of a single designated representative per source reflects this operating reality. If units at a source were to have different designated representatives, the designated representative of a unit that was out of compliance might claim that the violation was caused by actions at another unit, whose separate designated representative might dispute the claim. The Agency does not believe that it should become involved in these kinds of disputes among units when it assesses compliance with the Acid Rain Program. Therefore, the Agency is requiring that only one designated representative be certified per source. Under this approach, the designated representative will resolve such disputes and will balance the needs of all of the units at the source in order to facilitate compliance by all units whenever possible. This also minimizes the possibility of inconsistent submissions concerning the different units at the source.

(iii) Daily notice requirement. Some commenters objected to the requirement that the designated representative give daily notice for two weeks by publication in a journal of national and general circulation of the agreement by the owners and operators appointing him or her, particularly where there is only a single owner or operator.

Response: Despite these comments, the Agency believes that this requirement is necessary to ensure that all persons that might consider themselves to be owners and operators of a source have the opportunity to learn of the selection of the designated representative. Without public notice, only those persons whom the designated representative believes are owners or operators will get notice of the selection, i.e., through written notice by the designated representative. In order to reduce the potential cost of providing public notice, the Agency modified the rule to require notice for 7 days in a newspaper of general circulation in the area where the source is located or in a State publication designed to give general notice. The provisions concerning the type of publications to be used parallel certain public notice requirements in 40 CFR part 70. The Agency believes that, in light of the significant financial consequences potentially at stake in the selection of a designated representative, this requirement is not unduly burdensome.

(b) Designated representative's responsibilities. Several commenters suggested that EPA allow sources to delegate responsibility for non-allowance related submissions to a responsible official of the company, rather than requiring the designated representative to make all submissions under the Acid Rain Program. The commenters argued that this would provide them with more flexibility and would ensure the integrity of the submissions, by allowing the source to delegate responsibility to someone with personal knowledge about the particular information.

Response: The Agency has attempted to provide sources with maximum flexibility in the Acid Rain Program while ensuring accountability, but does

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not agree that submissions may be made by someone other than the designated representative without adversely affecting the integrity of the program. Under section 402(26) of the Act, the designated representative represents the owners and operators in matters under the Acid Rain Program concerning the source, and, as discussed above, there are important reasons for limiting each source to a single representative. Interposing another person between him or her and the Agency would dilute his or her responsibility and in effect create multiple designated representatives for a source. Further, by leaving the responsibility to make submissions with the designated representative, the final rule has the salutary effect of making it clear that the designated representative should be aware of all submissions and, before submitting them, should inquire of persons with personal knowledge of the information in those submissions. Within these parameters the designated representative has flexibility to delegate duties (such as the preparation of submissions). However, under the final rule, the designated representative retains responsibility under the program for, and must sign and certify, all submissions.

(c) Minority ownership issues. (i) Unanimous agreement on selection of designated representative. The Agency received numerous comments on whether the designated representative should be selected by unanimous agreement of all of the owners and operators. Opponents of that approach claim that requiring unanimous consent would result in EPA improperly interfering in existing commercial relationships and contracts. These commenters believe that existing contractual agreements provide the means of resolving potential disagreements among multiple owners of a unit and that it would be counter-productive to require unanimous consent because it would embroil EPA in commercial disputes and, contrary to EPA policy, would supersede existing agreements in some cases.

Other commenters claim that requiring unanimous agreement is necessary to protect minority owners from "tyranny of the majority." Minority owners are concerned that they will be frozen out of the choice of the designated representative, who will then have control over allowances that belong in part to the minority owners and who will exercise this control in a manner adverse to the interests of the minority owners. Minority owners are also concerned that the designated representative will be chosen over their objections and that the actions of the designated representative, over which they have no control, will result in noncompliance for which the minority owners will be liable.

Response: The Agency does not believe that it should require the designated representative to be certified by unanimous consent. Title IV does not explicitly authorize EPA to impose such a requirement. EPA does not believe that it should alter existing commercial arrangements absent express authorization from Congress to do so. (Some existing agreements among source owners, of course, may require unanimous consent). EPA's position is consistent with the approach taken in the Sanford amendment, which included what became sections 402(26) (designated representative definition) and 408(i) of the Act and which was aimed at "ensur[ing] that the existing relationship between the various parties with legal interests in an affected unit are [sic] preserved." (136 Cong. Rec. S3378, daily ed., March 28, 1990 (Senator Sanford)). In addition, requiring unanimous consent of all owners could give leverage to dissidents, allowing them to force majority owners into unreasonable concessions (which may or may not be related to the Acid Rain Program) simply to remove the objections.

(ii) Unanimous agreement on allowance decisions. Several of the commenters who supported unanimous consent in choosing the designated representative recommended that, at a minimum, EPA require that co-owners of a unit explicitly discuss and decide how to hold, use, and distribute allowances or apportion liabilities that might be incurred by the source. These commenters claimed that existing agreements, negotiated before allowances were created, do not confer adequate authority on the designated representative to handle allowances. These commenters assert that the Sanford amendment was designed to protect minority owners and that, under it, only a unanimous, new agreement, negotiated expressly to reallocate allowances, should be allowed to override the provision in section 408(i) that allowances otherwise be held and distributed in accordance with the ownership interests in the unit.

Response: The Agency agrees that section 408(i) was introduced to provide protection for minority owners without burdening EPA "with the responsibility of using scarce resources to rigorously examine the relationship between various parties whenever there are multiple holders in a unit." (136 Cong. Rec. S3379, daily ed., March 28, 1990 (Senator Sanford)). Since the section 408(i) protections are to be applied by the parties and, if necessary, the courts, the Agency has decided not to go beyond the specific requirements of section 408(i). Instead, the final rules incorporate the statutory language requiring allowances to be distributed in proportion to legal, equitable, leasehold, or contractual reservation or entitlement in the absence of a contract expressly providing for a different distribution. EPA will leave it to the parties involved to apply this provision and determine whether and under what circumstances a unanimous, new agreement is appropriate. The Agency believes that this approach gives minority owners the protection that they were granted in the Act, while preventing EPA from becoming embroiled in ownership disputes.

(iii) Limiting designated representative's discretion. Several commenters also suggested limiting the discretion of the designated representative in certain matters in order to protect minority owner interests. For example, commenters suggested that EPA: Require an agency relationship to be established between the designated representative and all co-owners; limit the ability of the designated representative to use allowances belonging to the joint owners or to sell allowances without express authorization from co-owners; require co-owners to enter into agreements concerning the holding and distribution of allowances; and take a more active role in oversight of the actions of the designated representative.

Response: The Agency has rejected these suggestions because they would require EPA to review and alter existing commercial arrangements, and oversee new arrangements, in the utility industry, a role for which EPA has neither the necessary expertise nor express statutory authority. The Agency's approach concerning section 408(i) of the Act preserves the minority owner protection granted under the Act.

(iv) Freezing allowance accounts. EPA asked for comment on whether it should freeze allowance accounts in the event of a dispute over the actions of the designated representative. Numerous commenters objected to EPA's proposal not to freeze allowances, claiming that a freeze would better protect against the trading of co-owner's allowances without their express authorization and would further ensure compliance. Other commenters supported EPA's proposed approach of not freezing allowances because it avoids having EPA become embroiled in private disputes among joint owners. These commenters believe that aggrieved multiple owners have

adequate protection through their commercial agreements and through the courts.

Response: The Agency has decided not to include in the final rule any provision requiring the freezing of allowance accounts in the event of an allowance dispute. The Agency believes that such a provision would undermine the functioning of the allowance market, which depends on the ability of third parties to rely on the full effectiveness of the recordation of an allowance transfer.

Freezing accounts automatically whenever any owner or operator claimed there was an allowance dispute would be extremely disruptive to the allowance market. Allowance trading could be disrupted frequently and at any time. Any majority or minority owner or operator could use such "claims" to force unable concessions. Providing for routine freezing of accounts where a claimed dispute seems meritorious would require EPA to evaluate the merits of disputes. Such routine evaluation of disputes is beyond the expertise of the Agency.

However, in § 72.4 of the final rule, the Agency reserves the right to take action (e.g., with regard to the Allowance Tracking System) in extraordinary circumstances that require action to ensure the orderly and competitive functioning of the allowance system. In addition, of course, parties may obtain injunctive relief, where appropriate, from the courts.

(v) Liability of owners and operators. Many commenters objected to provisions in the proposed rule that imposed liability on all owners and operators of a source or unit for violations of title IV of the Act and the regulations. The commenters pointed to language in the proposal concerning joint and several liability for owners and operators for violations of title IV requirements. They argued that the Act does not give the Agency authority to impose joint and several liability. In addition, commenters also objected to the preamble discussion of shared liability as an attempt to impose joint and several liability without authority.

In particular, the commenters argued that under title IV, liability for violations could only arise for persons who exercised operational control over the affected source or unit. Many utility units subject to Acid Rain Program requirements are owned by several entities, some of which possess minority ownership interests in the unit or source. They argue that existing contractual arrangements often cede responsibility for operational control, including compliance with environmental laws, to the majority owners. Due to these pre-existing contractual arrangements, commenters contend they lack any operational control sufficient to exert any influence on compliance with title IV requirements. In addition, commenters claimed the Agency unlawfully relied on section 408(i) of the Act to impose responsibility for compliance with title IV requirements on minority owners. These commenters suggested that EPA should amend the proposal to exempt minority owners from liability.

Response: The Agency does not agree that the final rule should exempt minority owners from liability but does agree that all provisions in the proposal that expressly establish joint and several liability on the owners and operators of an affected source or affected unit should be removed. The question of the liability of a specific owner and operator is best left to case-by-case determination in the context of enforcement against specific violations, rather than being resolved in the abstract in a rulemaking.

On one hand, various sections of title IV impose obligations on owners and operators without distinguishing between majority and minority owners or owners that are not operators. (See sections 408(h), 409(f), 411, and 412(e) of the Act). Moreover, by virtue of an ownership interest in a business or property, an owner may exercise influence over operation of a facility and help foster compliance with environmental laws. This may be true even if the owner cannot exercise unilateral authority or significant control over operations. It is important to encourage oversight of activities at one's business or property and discourage tacit approval or willful ignorance of illegal activities that threaten the environment.

On the other hand, the Agency does not blindly enforce against all parties regardless of their level of awareness, control, and responsibility for violations of the Act. EPA focuses enforcement efforts on those parties most truly culpable for violations. EPA and the courts look to the culpability of parties in determining liability and assessing civil penalties.

The Agency, therefore, has removed from the final rule language that expressly imposes joint and several liability on all owners and operators and is leaving the question of liability to case-by-case determination in proceedings before the Agency and, ultimately, the courts.

(vi) Liability of designated representative. Several commenters expressed concern that a designated representative would be liable, under the proposal, for violations by owners and operators.

Response: As a general matter, EPA expects that its civil and administrative enforcement actions under the Acid Rain Program usually will focus on the owners and operators of affected units that do not adhere to emission limitation requirements under the program (sections 404 and 405 of the Act). Designated representatives also have responsibilities under the Act and would be liable for violations of those responsibilities. The Act, at section 402(26), defines the designated representative as a responsible person authorized by the owner or operator to represent the owner or operator as to certain matters, including, for example, holding and transfer of allowances (section 403) and submission of and compliance with permits and compliance plans and related documents (sections 408(c)(1) and 408 (h)(1)).

It is EPA's statutory interpretation that a designated representative is not liable for acts or omissions that are not within the scope of his responsibility as designated representative. Under the Act, owners and operators shall be fully liable for the emission limitations (sections 404(a) and 405(a)) and monitoring requirements (section 412) for an affected unit and are responsible for operating the unit in compliance with those requirements. A designated representative would not be subject to liability for a unit's noncompliance with those requirements, except to the extent that the designated representative is an owner, an operator, or has control over the operation of the affected unit, or has been authorized by the owner or operator to ensure compliance with those provisions. Accordingly, where a particular violation resulted from acts or omissions that are within the scope of the designated representative's responsibilities, he will be subject to liability for that violation.

(4) Phase I Substitution Plans (Subpart D)

Section 72.41 of this regulation implements section 404 (b) and (c) of the Act, which give the designated representative the option of submitting a substitution plan. Under a substitution plan, the designated representative of a Phase I unit identifies affected units (i.e., Phase II units) that would not otherwise be subject to Phase I requirements and requests that they become Phase I units subject to these requirements. Since the substitution units will then receive allowances in Phase I, this approach may enable the

designated representative to achieve compliance with the sulfur dioxide emissions limitations required during Phase I in a more cost-effective manner.

(a) Common owner or operator. Section 404(b) of the Act allows the owner or operator of a Phase I unit to designate, as a substitution unit, a unit "under the control of such owner or operator." In interpreting this statutory language, the proposed rule stated that a designated representative is an operator and that a common designated representative for all units in a substitution plan would, therefore, fulfill the statutory requirement that the original Phase I unit and the substitution unit be under the control of the same owner or operator. The proposed rule also required that the units have the same designated representative regardless of any other common control.

Many commenters supported the proposed interpretation of the substitution provision and commended the Agency for providing flexibility. Some of these commenters also asked for clarification that a common designated representative would not be required if the units in a substitution plan had another owner or operator in common.

A few commenters disagreed with the Agency's interpretation. They felt that substitution plans should be limited to one operating company. They argued that Congress intended Phase I reductions to be achieved in the geographical areas of the country where the environmental effects of acid rain are most extreme (i.e., the eastern U.S. where most Phase I units are located).

Response: The Agency has upheld the proposed interpretation of the statute on legal and policy grounds. In general, a designated representative is not considered to be an operator. However, in some cases, his or her duties and level of responsibility can be equivalent to that of an operator. For example, in cases where the designated representative represents multiple sources without a common owner or operator that are participating in a Phase I substitution plan, the designated representative is responsible for coordination among the sources for purposes of submitting permit applications and compliance plans. In that case, the designated representative's responsibilities would be broad enough to bring him or her within the definition of operator because he or she would be responsible not only for determining that the compliance plans for the multiple units accurately reflect the provisions in the substitution plan, but also that the units comply with the substitution plan. See section 404(b) of the Act. The regulations provide (§ 72.41(b)(1)(i)) that the owners and operators of the units must act through a common owner, operator or designated representative. These types of important coordination activities and responsibilities make it appropriate to deem the designated representatives who perform them the equivalent of an "operator," and assure that the statutory concern regarding accountability will be met. See 56 FR 63015 (December 15, 1991). Accordingly, the statutory requirement in section 404(b) that a substitution plan involve a common owner or operator is satisfied.

Moreover, this approach offers utilities, particularly small utilities, flexibility to pursue least cost compliance. Small utilities would effectively be denied the flexibility available to larger utilities under the substitution provisions if participation were limited to a single operating company. A small operating company is less likely to have its own Phase II unit to designate as a substitution unit.

Although most Phase I units are located in the eastern U.S., Congress did not explicitly target a geographical area in identifying Phase I units, but instead used size and emissions rate as the criteria for identifying Phase I units. The Acid Rain Program clearly calls for nationwide reductions of sulfur dioxide without explicit requirements that the reductions be restricted to a specific geographical area. See 136 Cong. Record S17244, daily ed., October 26, 1990 and S16979, daily ed., October 27, 1990.

This rule also clarifies that units with different designated representatives will be acceptable in a single substitution plan, provided that they have another owner or operator in common. This approach is consistent with the Act, which does not require more than a common owner or operator. The rule clarifies that if an owner, operator, or designated representative is changed after a substitution plan is approved, the requirement to have a common owner or operator must continue to be met. If it is not, the substitution plan must be terminated beginning January 1 of the calendar year during which the change was made.

(b) "Unnecessary" substitutions. The proposed rule required calculations in a proposed substitution plan showing that the SO_2 emissions reductions obtained by all units in the plan would be greater than or equal to the SO_2 emissions reductions that would have been obtained by all such units without the plan. On its face, the proposed rule allowed calculations showing, under the plan, the substitution unit using all its allocated allowances and making no reductions and the original unit making 100% of expected reductions. The rule did not explicitly state whether such a situation, where no real substitution of emissions reductions was proposed, would be acceptable. Several commenters recommended that the Agency clarify that it will accept a substitution plan under which no transfer of reductions is proposed.

Response: The Agency has clarified in § 72.41(c) (3) and (4) of this rule to require that the total number of allowances allocated under a substitution plan not exceed the maximum amount allowed to be allocated to the substitution units under the rule; the allowances do not have to be allocated to or used at the original Phase I unit. This means that a substitution plan can be used solely for the purpose of making a Phase II unit subject to Phase I requirements. The Agency has taken this position because the alternative, i.e., allowing only those substitution plans that project a transfer of reduction obligations to the substitution unit, could be circumvented by the submission of plans projecting that one ton of SO_2 reductions be transferred. Since there is no obligation under the Act to actually carry out the projected transfer of emissions reduction obligations once the allowances are allocated under the plan and since the same total number of allowances will be allocated under a plan whether the transfer was to be one ton, 5000 tons, or zero tons, the Agency sees no reason to implement the substitution provisions in a manner that would require artificial projections and would lead to more burdensome paperwork requirements.

(c) Substitution plan allowance calculation. The proposal calculated the allowances allocated under each substitution plan based on the substitution unit's baseline multiplied by the lesser of the unit's 1985 actual SO_2 emissions rate, its 1985 allowable SO_2 emissions rate, or its most stringent federally enforceable allowable emissions rate at the time of application. Commenters presented opposing views on this requirement. Several commenters suggested that the Agency has no authority to limit substitution allowances to current federally enforceable emissions rates and that Congress was concerned about reducing emissions from 1980 or 1985 levels and not from current levels. Other commenters suggested that the Agency use current utilization at substitution units rather than their historical baseline in the calculation of

allowances. They argued that using this methodology would provide substitution units with allowances to account for growth at those units since 1985 and that credit for growth is justified.

Other commenters argued the opposite extreme, saying that any reduction required by law, State or Federal, should be considered a reduction that would have occurred in the absence of a substitution plan.

Response: The manner in which allowances for a substitution plan are calculated has been revised. Consideration of the most stringent federally enforceable emissions rate at the time of application has been eliminated in today's rulemaking. Only 1985 emissions rates will be included in the calculation.

The Agency's position on this issue hinges on interpretation of the requirement in section 404(b)(5) of the Act that emissions reductions under the plan be no less than without the plan. Section 404(b)(3) requires a proposed substitution plan to include the 1985 actual or allowable SO_2 emissions rate and makes no mention of the current allowable rate or current utilization. The Agency believes that this language in section 404(b)(3) strongly implies that the allowances allocated under a substitution plan are to be based upon the substitution unit's baseline multiplied by the lesser of its 1985 actual or allowable SO_2 emissions rate. This interpretation assumes that the reductions contemplated under the substitution plan are to be measured from 1985 levels and is generally consistent with the approach in sections 404 and 405 of achieving emissions reductions, by allocating allowances, from 1985–1987 levels. Any reductions in emissions rate made at a substitution unit since 1985 will not have resulted from title IV and will, thus, not be counted as reductions that would have occurred without the plan. The elimmation of current allowable rates from the calculation of substitution allowances is also responsive to the many commenters who were strongly opposed to EPA's proposal to annualize current allowable emissions rates using the procedures by which 1985 allowable rates were annualized for NADB.

Moreover, consistent with this interpretation, the 1985, not the current, utilization level of a substitution unit will be used in the calculation of allowances. Applying the concept of a 1985 starting point for both factors (emissions rate and utilization level) used to calculate reductions is internally consistent and follows the language of section 404(b)(3) of the Act. The Agency finds that the use of current data for utilization would not provide the overall reductions contemplated by the Act because it would provide allowances for growth at Phase II units. Finally, the use of well-established 1985–87 data not only provides more certainty that reductions will actually be achieved, but also facilitates implementation of the provision.

(d) Demonstration requirements. The proposal specifies procedures for demonstrating that a substitution plan meets the requirement of section 404(b)(5) of the Act that the plan "achieve the same or greater emissions reductions than would have been achieved by the original affected unit and the substitute unit or units without such substitution." The proposed procedures required the calculation of projected annual emissions reductions from each unit in the plan and the comparison of these reductions to those that would be achieved without the plan. Some commenters pointed out that the total number of allowances allocated under a substitution plan determines whether the total emissions reductions achieved under the plan will be adequate and that the distribution of the requested allowances among the original and substitution units is, thus, incidental.

The commenters suggested that the Agency should simply require calculation of the total allowances available under the plan and eliminate the requirement to calculate reductions to be obtained by each unit.

Response: The Agency agrees that calculation of the unit-by-unit reductions is unnecessary and has streamlined the procedures for demonstrating the section 404(b)(5) requirement accordingly. The rule limits the total number of substitution allowances allocated under the plan to the maximum number calculated to be available under the plan, i.e., an amount equal to the total tonnage the substitution units could have emitted if they were not under the plan and so did not have to make any emission reductions. This requirement fulfills the demonstration requirement because total reductions for the original and substitution units will equal what total reductions would be without the plan: 100% of expected reductions by the original unit and no reductions by the substitution unit under title IV. The rule then provides the designated representative the option to choose to have some or all of these allowances redistributed from the substitution units to the original Phase I units in the plan. If no redistribution is chosen, the designated representatives must simply indicate this in the application. The streamlined approach to this demonstration greatly reduces the burden of preparing a substitution plan. Allowances, of course, may always be transferred after they are allocated under the plan.

To further simplify the substitution plan, the Agency does not require that the original Phase I unit report its baseline, its 1985 actual and allowable SO_2 emissions rates, and its allowance allocation. This information has already been collected and appears in NADB and Table 1 of § 73.10(a). The Agency, therefore, has no need to require the source to report it. Further, although required to be reported under section 404(b)(4) of the Act, the substitution unit's proposed emissions rate under the plan is not required in the rule. Similarly, the substitution unit's projected emissions without the plan—a figure that is not mentioned in section 404(b)(3)—is no longer required. Because allocation of allowances under the plan is based on historical data, proposed or projected rates are not needed.

(e) NO_x applicability. The proposed rule stated that each substitution unit is affected for NO_x on the date that it becomes affected for SO_2. The final rule states only that each substitution unit will be affected for NO_x and defers specification of the deadlines and conditions to the future rulemaking on NO_x regulations to implement section 407 of the Act. Because substitution plans provide a lot of flexibility for sources to bring Phase II units into the program during Phase I, the implications for NO_x emissions could be significant. For this reason and because many related issues concerning NO_x requirements have not been finalized, the details of NO_x applicability for substitution units have been deferred.

(f) Termination of plans. Under the proposal, substitution plans may be terminated through an administrative permit amendment, provided that the designated representative surrenders the allowances allocated under the substitution plan for the years of the termination. The final rule clarifies this provision to specify that notification to terminate a substitution plan must be submitted to the Administrator by at least 60 days before the allowance transfer deadline applicable to the first year for which the termination is to be in effect. This should allow the revision of the permit and the deduction of allowances to take place by the allowance transfer deadline. The Agency believes that retroactive terminations limited in this way should

be allowed in order to maximize flexibility in compliance.

(5) Phase I extension plans (subpart D). Section 72.42 of this regulation implements section 404(d) of the Act. A Phase I extension plan allows the designated representatives of units that commit to install technologies achieving 90% reduction of sulfur dioxide to obtain a two-year extension of the deadline for meeting Phase I emissions reduction requirements by applying for additional allowances from a special allowance reserve. The designated representatives of units that will transfer their emissions reduction obligations to the units installing control technologies may also request reserve allowances.

(a) Early ranking procedure. Prior to the proposal, the Agency determined, in consultation with the regulated community, that the 3.5 million allowance reserve for Phase I extensions was likely to be oversubscribed. Because the Act specifies that the Administrator must act on each application in the "order of receipt," some applicants would, therefore, not receive reserve allowances. The appropriate method for distribution of Phase I extension reserve allowances thus became one of the most controversial issues encountered in this rulemaking. Faced with the prospect of a drawn out debate, the regulated community advised EPA that certainty regarding the chances of receiving Phase I extension reserve allowances at the earliest possible date was important. For this reason, the Agency proposed an early ranking procedure to determine the order of receipt of Phase I extension applications prior to submission of a Phase I permit application. A telephone queuing procedure was proposed as the method for ranking these applications.

The Agency received extensive comment on this issue from the regulated community, high sulfur coal interests, low sulfur coal interests, equipment vendors, Congressmen and Senators, and a few environmental groups. Almost all commenters urged the Agency to abandon telephone queuing. Even those commenters who disagreed on what the alternative should be agreed on this point. The most frequently cited reasons for eliminating telephone queuing were cost to industry and the Agency and concerns about the security of the queuing system.

On one hand, commenters who favored a pro rata distribution of Phase I extension reserve allowances to all qualified applicants, argued that telephone queuing or any other first-come, first-served procedure fails to implement the intent of the Phase I extension provision. They argued that the provision was meant to buffer the economic impact of title IV on those utilities and States that are most dependent on high sulfur coal. The intent, they claimed, was to encourage the installation of control technology. A pro rata approach would ensure that all qualified utilities would receive at least some share of the reserve allowances and would, thus, allow more of them to proceed with the installation of controls.

On the other hand, low sulfur coal interests argued that the language of section 404(d) of the Act does not allow for pro rata distribution and supported the Agency's proposal to act on applications one at a time on a first-come, first-served basis until the allowances run out. These commenters did not argue, however, that the proposed telephone queuing procedure was the best way to implement their recommended approach. Some of the first-come, first-served supporters suggested a lottery drawing instead, pointing out that the effect would be the same as that of a telephone queue, at much less cost to sources and the Agency and with fewer security concerns. Some commenters who supported a pro rata approach also indicated that a lottery drawing would be satisfactory if the Agency decided against pro rata.

Response: The Agency has considered all of these comments carefully and has determined that a lottery drawing is consistent with the statutory language and will be the least burdensome and most expeditious method to provide an early ranking of Phase I extension applications. A lottery is also the only approach that commenters from both points of view seemed willing to accept. This was an important factor in the Agency's decision since litigation on this provision would only delay the certainty that is so important to the regulated community.

The rule specifies that the Administrator will begin receiving early ranking applications on the 40th day after promulgation of this rule. Forty days have been provided so that sources will have adequate time to obtain and read the rule and to appoint a designated representative. All early ranking applications received on the same day will be deemed to be received simultaneously. If the applications received on any one day result in the reserve to be oversubscribed, a public lottery drawing will be held to determine the order in which to act on each application received on each such day. About two weeks will elapse between the time that the source is notified of the lottery and the day on which the lottery is to be held so that applicants will have the opportunity to negotiate among themselves or to drop their applications if desired.

The conditions on the rank order, once it is determined, remain the same as those proposed. Several commenters did, however, ask for clarification that an application would not lose its place in the rank order if the information originally submitted requires adjustments. Only complete early ranking applications will be given a rank order. An application that contains all of the requested information is considered complete and is not rendered incomplete by the need to correct later any of the information. Once a complete application is given a rank order, adjustments can be made without changing the rank order of the application. The addition of new control units will not, however, be considered an adjustment. Similarly, the inclusion or exclusion of transfer units will be allowed as an adjustment but the total number of Phase I extension allowances requested will not be increased. The addition of new control units or additional requested allowances to an existing application would have the same effect as permitting submission of a new application ahead of other existing applications. Allowing such changes to existing applications would therefore contradict the requirement that applications be considered in order of receipt.

Allowances will be awarded to each unit based on the information in the early ranking application. The allowances will not actually be allocated (i.e., they will not appear in each unit's subaccount) until a full permit application containing a Phase I extension plan has been acted upon by the Administrator and each unit's permit has been issued.

It must be noted that one utility has filed suit against the Agency seeking court intervention requiring EPA to rank its request for allowances based on the March 1991 submission date of the request. *Monongahela Power Co., et al.* v. *Reilly,* Civ. No. 91–137–C (N.D. W.Va). While the case remains unresolved, the possibility exists that EPA may, at some later date, be required to revise the ranking procedures.

(b) Qualifying Phase I technology contract. The proposal required a fully executed contract for construction of qualifying Phase I technology contingent only on the receipt of Phase I extension reserve allowances.

Several commenters found the proposed rule language specifying requirements for the qualifying Phase I technology contract to be unduly

restrictive. Commenters pointed out that section 404(d)(2)(B) of the Act states that the contract "may be contingent upon the Administrator approving the proposal" and does not restrict the contract to a single contingency. Many commenters also suggested that the proposed requirement for a single contract for qualifying Phase I technology does not reflect the complexities of such agreements.

Response: The rule language has been modified to reflect more closely the statutory language. Other contingencies are, thus, permissible. However, the contract must be a binding agreement between the parties for installation of equipment capable of at least 90% reduction of SO_2.

The rule language has also been modified to, consistent with the language in section 404(d)(2)(B), allow for multiple contracts. The rule still requires contracts covering activities up to and including construction of the main scrubber module or, in the case of precombustion or combustion technologies, construction of the primary components of the removal system.

In addition, the rule specifies that submission of full contracts for qualifying Phase I technology with the early ranking application and with the Phase I extension plan will not be required. Instead, a source may submit, for each contract, a letter agreement that includes: (1) Identification of the qualifying Phase I technology to which the contract applies, (2) the parties to the contract, (3) the date each party executed the contract, (4) identification of the units to which the contract applies, (5) a list identifying each provision of the contract, (6) any dates to which the parties agreed, (7) the total dollar amount of the contract, and (8) the signature of each party and the date that each party signed. The listed information is needed to review the Phase I extension and early ranking applications. Condensing this information into a brief, but binding summary will streamline EPA's review and will reduce significantly the volume of documentation required to be submitted by each applicant.

The rule also specifies that a copy of the actual contract must be kept on file, and must be sent to the Administrator upon request. This requirement is necessary because section 404(d)(2)(B) of the Act requires that each extension proposal provide a copy of an executed contract for the design engineering, and construction of the qualifying Phase I technology. Since all permit applications are placed in a public docket, the statutory provision has the effect of requiring the contract to be available to the public. The opportunity for public examination of the contract must, therefore, be preserved. Elimination of the requirement to submit the entire contract reduces the paperwork burden on the source and on EPA while maintaining the opportunity for public review.

(c) *Calculation of reserve allowances. (i) General concept.* The proposal asked for comment on the Agency's interpretation of the procedures for allowance awards to each unit under a Phase I extension plan. The proposal provides that each control unit may receive reserve allowances based on the lesser of the unit's average annual emissions for 1988 and 1989 or the unit's projected uncontrolled emissions for 1995 and 1996 regardless of when during the extension period the control technology is actually installed. The Agency asked for comment on an alternative interpretation whereby the control unit would receive allowances based on uncontrolled emissions only if the control technology was not yet installed. Under this scenario, the control unit would still get reserve allowances, but the number would be based on the difference between their basic allowances and the number of tons they would emit with the controls installed.

Most commenters supported the proposed interpretation, although some commenters preferred the alternative interpretation because it ties reserve allowances more closely to the actual operations at a unit. Many commenters also requested that the final rule clarify that reserve allowances for transfer units are to be calculated using the same principles as applied to control units.

Response: The rule maintains the interpretation for calculating reserve allowances that was proposed. The Agency believes that the intent of the Phase I extension provision was to allow qualifying utilities to operate, during the extension period, as they would have been able to operate without title IV and to bank that amount of allowances if they installed control technology prior to January 1, 1997. See 136 Cong. Record, S2532, daily ed., (March 9, 1990) (Senator Bond). Under this interpretation, all units receiving the extension are treated in the same manner throughout the extension period, regardless of whether they install controls earlier than required by the Act.

The rule also clarifies that reserve allowances for transfer units are calculated using the same principles as applied to control units. This means that transfer units also receive reserve allowances based on the lesser of their average annual emissions for 1988 and 1989 or their projected uncontrolled emissions, i.e., what emissions would have resulted from operation of the unit in the absence of title IV.

(ii) 1988 and 1989 average annual emissions. The proposal specified the 1988 and 1989 emissions to be used for each unit in the calculation of Phase I extension allowances in proposed Appendices A and B. These figures were based on data reported on EIA Form 767 filed in those years. The EIA data was analyzed by EPA using the methodology in the NADB Version 2.1 Technical Support Document, Appendix D at 2.

Some commenters disagreed with the figures published in the proposal.

Response: The Agency has removed proposed Appendices A and B, with the 1988 and 1989 sulfur dioxide emissions data, from the rule. Individual figures therefore can be revised without revising the rule. EPA, in reviewing Phase I extension applications, will generally rely on the designated representative's certification that the data is correct. If a dispute over the data arises during the permit issuance process, EPA will rely on whatever data EIA reports to EPA for the unit in question and will convert this data to an annual tonnage figure using the methodology in the document cited above, which methodology is now contained in the final Appendix C of this part.

The proposal also stated that allowances for control and transfer units would be limited not only to the average annual emissions for 1988 and 1989, but also to the most stringent federally enforceable allowable emissions limitation for those years. Thus, if a unit had been out of compliance in those years, it would not receive reserve allowances for the emissions above the compliance level. Commenters on this issue questioned both the Agency's authority to impose this restriction and the procedures that were proposed for the annualization of allowable emissions rates. Commenters from the regulated community argue that the Agency has no authority to consider allowable emissions in this context since section 404(d)(4) specifically provides for consideration of average annual emissions and makes no mention of allowable emissions. This contrasts with other sections of the Act (e.g., section 409(c)) that expressly refer to allowable emissions. Commenters also claim that the Agency lacks authority to use the annualization procedures specified in the Act for allowable 1985 emissions rates for the annualization of other emissions rates.

Response: Because section 404(d)(4) expressly limits reserve allowances by only the average annual emissions for 1988 and 1989, the requirement to limit reserve allowances to 1988 and 1989 allowable rates has been eliminated altogether.

(iii) Projected emissions for 1995 through 1999. The proposed rule specified that projected emissions for 1995 through 1999 at control and transfer units be based on projected annual utilization as reported on EIA Form 767 and projected emissions rate for each year. This emission rate could not exceed the most stringent federally enforceable allowable emissions rate in lbs/mmBtu.

Commenters objected to the use of the EIA form as a source of projected utilization data, both because it does not provide annual projections for the appropriate years and because using previously reported projections does not provide sources enough flexibility. Commenters suggested that EPA simply require "good faith" utilization projections and asked EPA to clarify that because these projections are used to calculate Phase I extension reserve allowances, they would not need to be revised once the Phase I extension plan had been approved and the allowances allocated.

Some commenters objected to restricting projected rates to the most stringent federally enforceable allowable emissions rate. In addition, although neither the proposed rule nor the proposed preamble explicitly stated that the most stringent federally enforceable rate used for comparison to the projected rate would be annualized, some commenters felt that annualization was implied. They disagreed with the requirement to express an allowable rate in annualized form rather than in the format in which it is enforced.

Response: The Agency agrees with the majority of commenters that the use of EIA Form 767 as a source for projected utilization figures is not workable. The final rule simply requires projected annual utilization for 1995 through 1999. EPA intends that these projections be good faith projections. In addition, as commenters suggested, these projections need not be revised once the Phase I extension plan is approved.

The final rule similarly requires projected uncontrolled or controlled emission rates for 1995 through 1999 (as applicable), and EPA intends that they be good faith projections. EPA maintains that any projected emissions rate that exceeds the unit's most stringent federally enforceable emissions rate promulgated as of the filing of the Phase I extension plan will, on its face, not be good faith. As with the 1988 and 1989 actual emissions, EPA will generally rely on the certification of the designated representative. Should a dispute arise during the permit issuance process, EPA will convert the unit's most stringent federally enforceable emissions rate at the time of application to lbs/mmBtu using the conversion methodology in the NADB Version 2.1, Technical Support Document, Appendix D at 2. This methodology is now set forth in the Appendix B of the final rule. If there are two or more applicable federally enforceable rates, the rates will be converted to lbs/mmBtu, but not annualized, and the lowest rate will be compared with the projected emission rate.

(d) NO_x applicability. The proposal stated that control units must comply with nitrogen oxides reduction requirements on the date that the unit shuts down to install the control equipment and that transfer units are subject to nitrogen oxides reduction requirements on January 1, 1995.

Many commenters pointed out that the proposal seems inconsistent with section 407(a) of the Act, providing that a Phase I extension unit is subject to NO_x requirements when it must meet SO_2 reduction requirements, and section 404(d)(1), postponing SO_2 reduction requirements for such units for two years.

Response: The Agency agrees. The rule states that both control and transfer units are subject to nitrogen oxides requirements on January 1, 1997 in accordance with section 407 of the Act and regulations implementing section 407.

The only caveat to this provision is that transfer units not transferring the total number of emissions possible (i.e., the lesser of average annual emissions for 1988–1989 or projected uncontrolled emissions during the extension) to a control unit will not be exempt from nitrogen oxides requirements during those years that the transfer is partial, unless the transfer unit is the last unit allocated allowances under the Phase I extension plan. If the designated representative is not requesting the full amount of reserve allowances for which a transfer unit might be eligible, then the unit is subject at least in part to the SO_2 reduction requirements under title IV (section 407(a)) and so is subject to applicable nitrogen oxides emissions limitations on January 1, 1995. This interpretation was necessary to prevent gaming whereby numerous transfer units would be attached to each control unit, only requesting a few reserve allowances for each and thereby making them all exempt from nitrogen oxides requirements. The Agency does not believe such widespread exemption from nitrogen oxides reductions was contemplated under this provision and has, therefore, explicitly prevented it. However, if a transfer unit is the last unit allocated allowances under a Phase I extension plan and cannot receive all of the allowances for which it is eligible, e.g., because the Phase I extension reserve is depleted, the unit will be exempt from nitrogen oxides requirements until 1997. In the latter case, the partial transfer is unavoidable and so should not disadvantage the transfer unit.

(e) Demonstration of 90% removal efficiency. The proposal required control units to demonstrate 90% removal efficiency for qualifying Phase I Technology on an average annual basis beginning upon commencement of operation of the technology. A requirement to perform a 30-day start-up test was also proposed.

The Agency received many comments on this provision. Many commenters claimed that the average annual demonstration was unnecessary since under section 404(d)(7) of the Act, control units must not exceed the projected tonnage emissions of sulfur dioxide in their permit application. Many commenters also suggested that the demonstration not be required beginning upon commencement of operation of the qualifying Phase I technology. They suggest that since, with the 2-year extension, the deadline for operation of the technology is January 1, 1997, the requirement to demonstrate 90% removal should not begin until that date. In addition, commenters argued that if 90% removal is to be determined on an annual average basis, as proposed, a start-up test that can be repeated until the end of the calendar year is meaningless and redundant.

Response: Section 404(d)(2)(E) states that the control unit must project the number of allowances expected to be necessary for annual operation after the qualifying Phase I technology has been installed. However, the requirement not to exceed projected tonnage emissions does not ensure that 90% control will be achieved since the limitation could be met by reducing load or by using a lower sulfur fuel. Because the statutory definition of qualifying phase I technology requires that the technology achieves 90 percent reduction and because this requirement is a condition for awarding reserve allowances that provide a substantial economic benefit at the expense of other units, the

Agency does not agree with the commenters who suggested that the provisions based on section 404(d)(7) of the Act provide adequate demonstration and that the proposed additional demonstration be removed. The Agency does agree that the requirement to demonstrate 90% removal should not begin until January 1, 1997 and has revised the rule accordingly.

The proposed demonstration has also been revised to eliminate the requirement to perform a 30-day start-up test. The Agency agrees with commenters that both tests are not necessary. The rule does, however, require the designated representative to submit, for informational purposes, a copy of the start-up test results upon which the vendor is released from liability for providing a technology through which 90% sulfur dioxide reduction is achievable.

(f) Failure to meet 90% removal efficiency. The proposal specified that Phase I extension reserve allowances would be allocated conditionally until 90% removal was demonstrated. Following the demonstration each year, that year's reserve allowances would be allocated. Failure to achieve 90% removal efficiency would result in the allocation of fewer reserve allowances than had been set aside for that unit. This failure to receive reserve allowances would be in addition to any allowances that the Agency would deduct, under section 404(d)(7) of the Act, for failure to meet the projected tonnage limit specified in the permit.

Several commenters argued that the Administrator does not have the authority to withhold reserve allowances in this manner and that if the Agency chooses to keep the 90% removal demonstration, reserve allowances should not be affected by failure to meet the requirement. In addition, several commenters have argued that the "conditional" allocation and subsequent removal of some reserve allowances for failure to meet the demonstration requirements would unreasonably limit the utility's ability to realize the economic incentives that reserve allowances were meant to provide.

Response: Section 404(d)(6) of the Act authorizes the Administrator to allocate reserve allowances to each control unit with qualifying Phase I technology (i.e., technology that achieves 90% reduction) for the years in which the technology is required. The Act does not specify the timing of this allocation. The Agency, therefore, has the discretion to withhold allocation until all requirements are met, e.g., until the technology achieves 90% reduction. However, the Agency has revised the proposal so that reserve allowances will be allocated when the Phase I extension plan is approved, but the failure to demonstrate 90% removal efficiency in a particular year will result in an appropriate deduction of allowances after the end of the year. The Agency has made this revision to provide those utilities granted a Phase I extension with more flexibility. However, if the Agency could not require such a deduction after the end of each year, the Agency believes that the statute would require the alternative approach of delaying allocation of reserve allowances each year until the annual 90% removal requirement had been demonstrated.

(g) Reallocation of returned allowances. The proposal did not explicitly address the issue of reserve allowances that might be returned to the Administrator. Several commenters asked the Agency for clarification on how these allowances would be used.

Response: The final rule specifies that any reserve allowances made available at any time will be allocated in rank order to the next application that still meets the requirements for a Phase I extension.

(6) Phase I Reduced Utilization Plans and Underutilization Requirements

The reduced utilization provisions arise from a statutory requirement in section 408(c)(1)(B) of the Act. This paragraph prevents a Phase I unit from circumventing its emissions reduction requirements by shifting load to units that are not subject Phase I requirements. The statute requires an up-front plan when a unit is planning to shift its load in order to reduce its emissions.

Section 72.43 of the final rule outlines the requirements of a reduced utilization plan and describes the circumstances that dictate its submittal. Subpart I delineates the procedures that are required by all Phase I units at the end of each year in Phase I. Specifically, § 72.91 contains formulas that each Phase I unit must use to (i) calculate its "adjusted utilization" to determine whether it was underutilized and (ii) calculate the extent to which it accounted for underutilization through a reduced utilization plan. A unit is underutilized if its "adjusted utilization" is greater than zero. Section 72.92 contains a sequence of accounting steps that are mandatory for any unit that cannot fully account for underutilization through a plan. These steps involve a series of formulas used to determine the number of allowances, if any, that must be surrendered as a result of a shift in load that resulted in increased emissions at a unit not subject to an emissions limitation in Phase I.

As a result of public comment, changes were made to the proposed regulations. While the intent of this section remains basically the same, the Agency believes that the changes more effectively carry out this intent.

(a) Reduced utilization planning requirement. The Agency does not believe that section 408(i) of the Act requires a unit to file a reduced utilization plan in all circumstances involving underutilization and load shifting. As discussed in the preamble of the proposal, this interpretation of section 408(c)(1)(B) is contingent on the Agency's ability to require a unit to surrender allowances under section 403(d) to account for the emissions resulting from certain load shifting. In the absence of the ability to require such surrender, the Agency believes that the statute would require application of section 408(c)(1)(B) to virtually all cases of underutilization in order to ensure that the emissions reductions mandated by the statute are achieved. See Senate Rep. No. 101–228 at 334 (1989). The Agency continues to reject this latter interpretation of section 408(c)(1)(B) of the Act.

Commenters presented different scenarios in which they argued that it was unclear whether the planning requirement applied. The majority of them involved utilities that were planning to comply by a means other than reducing utilization. As a result of this alternative method, the utilities' Phase I units would be underutilized.

Response: Section 408(c)(1)(B) requires an up-front plan where the owner or operator proposes to meet the requirements of that section by reducing utilization of the unit as compared with its baseline or by shutting down the unit. In applying this section, the Agency is distinguishing between knowing that incidental underutilization may happen and making it happen for the purpose of compliance. Under the Agency's interpretation, it is only those utilities that underutilize for the purpose of compliance that are obligated to file a reduced utilization plan, provided that all other underutilization is subject to the allowance surrender requirement.

(b) Economic dispatching. Of particular concern to the commenters was the uncertainty as to whether underutilization caused by economic dispatching will require a reduced utilization plan. Under the proposal, if a utility did not fall under one of the listed safe harbors (which could cover a utility that carried out economic

dispatching) and had factored in the value of allowances avoided, saved, or banked into its economic dispatching. EPA could deem the utility to be in violation of the planning requirement. The use of a dispatch order based only on operating costs, and not the cost of emitting SO_2, could exempt a unit from the section 408(c)(1)(B) planning requirement. However, this approach would defeat the purpose of title IV, which is to create an allowance market that assigns SO_2 emissions a value and thereby enables utilities to consider the value of allowances needed or saved, along with other operating costs, in making dispatching decisions.

Response: EPA has therefore modified its approach by explicitly including economic dispatching as a safe harbor from the planning requirement. This safe harbor applies whether the unit obtains compensating generation from within or outside the unit's dispatch system. It also applies where underutilization is caused by an order of a utility regulatory authority issued to achieve economic dispatching. In addition, the Agency has eliminated regulatory language suggesting that consideration of the value of allowances in dispatching indicates that there was an unlawful failure to plan. There will be no retrospective determination of violation of the planning requirement under § 72.43 if a unit is underutilized due to economic dispatch and surrenders allowances as prescribed in § 72.92.

(c) Indicators. The Agency received comments addressing the indicators that should be considered to determine on a case-by-case basis the applicability of the planning requirement in section 408(c)(1)(B).

Response: The Agency has clarified that these indicators will be used when a utility is not operating under a reduced utilization plan and cannot fully account for its underutilization under any of the safe harbors. In that situation, the Agency will consider the indicators and any relevant evidence and determine on a case-by-case basis whether there was a planning violation. In addition, as discussed, the indicators have been modified, consistent with the Agency's approach concerning economic dispatch.

(d) Nitrogen oxides requirements. Under the proposal, compensating units would not be subject to nitrogen oxide requirements of section 407 of the Act. EPA received comments both supporting an interpretation of section 408(c)(1)(B) that would result in only SO_2 requirements applying to compensating units, not NO_x requirements, and supporting an interpretation under which both SO_2 and NO_x requirements would apply. The comments reiterated the arguments set forth in the preamble on the proposal.

Response: Like the proposed rule, the final rule provides that designated compensating units that would not otherwise be subject to Phase I of the Acid Rain Program are not subject to the Phase I NO_x limitations. As the Agency stated in the preamble to the proposed rule, EPA considered two opposing views on this issue, and noted that textual arguments can be made from the statutory language to support either view. (For a discussion of these opposing views, see the preamble to the proposed rule at 56 FR 63022–63023 December 3, 1991). After considering the comments on this issue, EPA has determined to adopt in its final rule the interpretation that EPA proposed, because the Agency has concluded that this interpretation best implements Congressional intent. *See Chevron, U.S.A.* v. *Natural Resources Defense Council,* 467 U.S. 837, 843, 865 (1984).

EPA reached this conclusion based on its belief that, in enacting the reduced utilization provision of section 408(c)(1)(B), Congress was concerned with compliance with SO_2 emission tonnage limitations in Phase I. In enacting section 408(c)(1)(B), Congress was not addressing compliance with NO_x emission rate limitations. This is shown by the phrase in section 408(c)(1)(B) expressly providing that an otherwise unaffected compensating unit is to be deemed an affected unit under section 404, but omitting any mention of section 407.

Moreover, the legislative history is clear that Congress' concern in enacting section 408(c)(1)(B) was to prevent circumvention of SO_2 emission tonnage limitations. S. Rep. No. 228, 101st Cong., 1st Sess. 334 (1989). Section 408(c)(1)(B) does not refer to just any utilization reduction at a unit, which could also apply to the NO_x provisions of section 407, but only to a unit's utilization reduction *as* compared with its *baseline.* Reducing utilization below the baseline level is germane only to compliance with the SO_2 tonnage limitations and allowances. It is not a method of compliance with the NO_x limitations of section 407, which are emission rate limitations.

With regard to the SO_2 requirements, the baseline is the utilization level that the statute multiplies by 2.5 lbs/mmBtu to determine the SO_2 allowance allocations. Thus, a unit could seek to comply with Phase I SO_2 requirements by keeping its emission rate above 2.5 lbs/mmBtu and reducing its utilization *below its baseline.*

The baseline utilization level has no such significance for compliance with the NO_x rate limitations of section 407, since a unit's emission rate is independent of whether it operates at, above, or below its baseline utilization level. Furthermore, utilization reductions below baseline are not relevant with respect to compliance with the Btu-weighted average annual emission rate under a section 407(e) Phase I NO_x averaging plan. Nor are such reductions relevant with respect to the calculation of penalties under section 411 for the number of tons emitted in excess of a unit's NO_x emissions limitation requirement. Both of those provisions are concerned with the total amount of tons emitted during the past year, based on a unit's actual utilization during that year.

In summary, Congress' use of the baseline as the utilization reduction trigger for section 408(c)(1)(B) indicates that the provision is aimed only at utilization reductions for compliance with the SO_2 tonnage limitations, and consequently, that the NO_x requirements do not apply to compensating units.

(e) Sulfur-free generators. (i) Conversion of Kwh to mmBtus. In the proposal, EPA requested comment on how to convert kilowatt hours of sulfur-free generation into mmBtu. The conversion factor is used to calculate the amount of sulfur-free generation that accounts for underutilization (which is in mmBtus) at the Phase I unit. Several commenters suggested using 10,000 Btu/kwh as an average heat rate.

Response: Given the wide range of variation in heat rates among Phase I units, EPA rejects this approach as being unacceptably inaccurate. The more accurate method, which the Agency has adopted, is to use the heat rate of the unit reducing utilization. The same conversion method is used to convert Kwh savings from energy conservation to mmBtus and to determine how much load is shifted to a reducing unit by a compensating unit.

(ii) Benchmark year. Under the proposal, in order to receive credit for sulfur-free generation, the designated representative of the reducing unit had to demonstrate an increase in generation at that generator as compared to the previous year. The Agency received comments requesting a change in the benchmark year used to demonstrate that increase. All commenters objected to comparing the current year's generation with the previous year's generation. The commenters recommended using 1985–87 average

generation for comparison in a manner analogous to the use of baselines under title IV.

Response: The Agency agrees that the recommended approach is reasonable, considering that there is no intent under section 408(c)(1)(B) to penalize utilities that have shifted to sulfur-free generation since 1987. Therefore, under the final rule, a Phase I unit will not have to surrender allowances to the extent that it can demonstrate an increase in generation at a sulfur-free generator above the 1985–87 average generation and above any sales growth in the Phase I unit's dispatch system. Sales growth in the Phase I unit's dispatch system is used as a proxy for sales growth in the sulfur-free unit's system, which data may not be available.

(f) Energy Conservation. (i) Verification of energy conservation and improved unit efficiency measures. The proposal outlined a procedure under which a utility using energy conservation or improved unit efficiency measures would verify actual reductions for three quarters of a year. An estimate of fourth quarter savings would be added to the actual reductions to determine the amount to be claimed in the annual compliance certification report. Within 90 days of the end of the year, a verification of the fourth quarter savings was to be submitted. This approach required separate verification of the first three quarters and the last quarter. Moreover, commenters asserted that the proposed rule may not provide sufficient time for accurate verification. In addition, EPA received comment on the lack of rigor in, and consistency among, States' verification methods of verifying savings from energy conservation.

Response: In light of these comments and in order to be consistent with the 6-month verification period allowed in connection with applications for allowances in the Energy Conservation and Renewable Energy Reserve under part 73, the Agency has made some changes to the verification procedure. To promote accurate and economical verification, utilities using energy conservation and improved unit efficiency will make a good faith estimate of savings for the entire year in the annual compliance certification report. A confirmation report showing verified annual savings is not due to EPA until July 1 of the following year. Further, because of inconsistencies among States' verification methods, savings from energy conservation must be verified in accordance with requirements in the final part 73 (concerning verification for purposes of obtaining allowances from the Energy Conservation and Renewable Energy Reserve), which have been strengthened in light of this problem. See the portion of the preamble addressing part 73 for further discussion of this issue.

(ii) Return of allowances. The proposal required deduction of allowances where heat input savings resulting from the use of energy conservation or improved unit efficiency measures were overestimated for the fourth quarter. Commenters requested that EPA return allowances surrendered when the annual compliance certification report underestimated energy conservation savings under a reduced utilization plan. Commenters argued that deducting allowances for overestimates while not returning allowances for underestimates was unfair and would inevitably lead to consistent overestimation of conservation savings.

Response: The Agency has provided in the final rule for the return of allowances in the case of underestimated energy savings for the year as well as allowance deduction for overestimates. The final rule contains a procedure for determining whether differences between the estimated and verified savings result in the deduction or return of allowances and in a change in the compliance status of the unit (e.g., excess emissions) for the year for which savings were estimated.

(g) Definition of "dispatch system". Utility system is defined as a unit's utility operating company as listed in the NADB. In the proposed reduced utilization provisions, utility system was used as the universe of units for establishing parameters such as system-wide sales decline, the Phase I aggregate utilization test (i.e., the calculation of the net utilization of a group of Phase I units), and savings from energy conservation and improved unit efficiency measures. Commenters opposed the proposed definition of utility system, claiming that it does not consider the manner by which sources are centrally dispatched. Some comments suggested broadening the definition to include holding company, while others suggested a definition as broad as power pool.

Response: The Agency has adopted a new term, "dispatch system", and defined it in § 72.2 to include, at the discretion of the designated representative with certain conditions, an operating company, holding company, or power pool if they are centrally dispatched. Although the Agency is adopting this broad definition, this flexibility brings many complications. It must be understood that for verification purposes and to prevent double counting, all units within a given dispatch system must all apply the same definition of dispatch system and use consistent data for purposes of compliance with reduced utilization and allowance surrender requirements. If a group of units wants to adopt a definition of dispatch system that is broader than utility system, the designated representatives of those units that will be in the dispatch system must jointly submit an identification of that dispatch system, listing all units that agree to be treated as such a group. In addition, a dispatch system may be required at the end of the year to submit a report with certain dispatch system data. In order to ensure the use of consistent values, all the designated representatives of units in a dispatch system must certify together that the data is accurate and that their submissions for their respective units will be consistent with this data.

The Agency reserves the right to reject a unit's designation of a dispatch system broader than the utility system if the submissions of all units claimed to be in that dispatch system are not consistent. For example, if two designated representatives of units in the same dispatch system submit annual compliance certification reports with different values for dispatch system sales decline, all annual compliance certification reports received from any unit in that system will be rejected. At that time, each designated representative will be required to resubmit the annual compliance certification report with its dispatch system defined as the utility system. The Agency is adopting this approach because the most effective way of ensuring consistent submissions by all units in a dispatch system is to put the burden of ensuring consistency on those units.

Consistent with the approach of increasing flexibility by basing the reduced utilization provisions on the "dispatch system," the Agency has determined that a unit with multiple owners that is dispatched into more than one system should also have more flexibility. Each Unit has one utility system, i.e., the system of the utility that operates the unit, and without further flexibility, only that system (or a dispatch system of which the utility system is a part) could be considered for purposes of applying the reduced utilization provisions. Under the final rule, the designated representative of a multi-owned unit may petition the Administrator to apportion the unit so that an owner's portion of the unit is treated as part of the dispatch system

into which it is dispatched. An owner's portion of the unit is its percentage ownership interest in the capacity of the unit. The apportionment is only for purposes of calculating a unit's adjusted utilization and the number of allowances that must be surrendered. The designated representative of the unit remains responsible for surrendering allowances for the entire unit, and the deduction of allowances is still from the Allowance Tracking System account of the unit.

If the petition is approved, an owner's portion of the unit will be treated as a separate unit from the rest of the original unit solely for such calculations. Adjusted utilization will be calculated separately under § 72.91 for the owner's portion and for the remaining portion of the original unit. Most of the data used in the calculation will be apportioned based on ownership in the unit's capacity. Plan reductions will be treated in a manner determined by the Administrator on a case-by-case basis. This is because the specific facts of each case may affect how such plan reductions should be handled.

Similarly, where the petition is approved, the allowance surrender formula in § 72.92 will be applied treating the owner's portion of the unit as a separate unit from the rest of the original unit. The designated representatives of the unit and of all dispatch systems that include any portion of the unit must submit all reports required under §§ 72.91 and 72.92 and demonstrate that they are using properly apportioned data that does not result in any undercounting or double-counting. Where the designated representatives fail to meet their burden, the Administrator may require them to resubmit all reports and return to treating the entire unit as a single unit.

(h) Annual compliance certification report. (i) Basic approach of allowance surrender formulas. Under the proposal, generation compensating for underutilization of a Phase I unit was segregated according to whether the generation could be attributed to a known unit in order to determine how many allowances the Phase I unit should surrender. To the extent load was shifted to other Phase I units in the same utility system, no allowances would be surrendered for the unit's share of such a shift. If load were shifted to undesignated but known non-Phase I units, that utilization would be multiplied by the weighted emission rates of those known units. The product would be used to determine the number of allowances to be surrendered for those shifts. If the load was shifted to unknown non-Phase I units, the Agency proposed the use of a proxy for establishing an emissions rate, i.e., a current weighted average emissions rate for all non-Phase I units in the NERC region in which the Phase I unit was located. The Agency believed this to be a reasonable approach, considering that the NERC region was the most probable universe of sources from which compensating generation would be obtained.

Much of the public comment addressed issues concerning the allowance surrender formula and stated that the formula was confusing and unworkable as proposed.

Response: In light of these public comments, the Agency has determined that the basic approach in the proposal should be modified. Under the proposal, multiple Phase I units could claim compensating generation from a low-emitting, off system, non-designated unit. There would be no means of requiring all these units to agree on how to divide up such generation or of preventing double counting of such generation.

The final rule distinguishes compensating generation within a defined dispatch system from that provided from outside the dispatch system. Of course, a unit may adopt an expansive definition of its dispatch system. For a unit to be credited for compensating generation from a specific unit or sulfur-free generator (whether from within or outside the dispatch system), the compensating unit or sulfur-free generator must be designated. Otherwise, the unit surrenders allowances based on an appropriate weighted average emission rate. The total amount of underutilization for the dispatch system will be multiplied by an emissions rate that is the weighted average of the current dispatch system emissions rate and the 1985 NERC region emissions rate. These emissions rates are averages based on the emissions rates of Phase II units in the dispatch system and of non-foreign and non-Phase I units in the NERC region respectively. This is explained in detail below. The result is the number of allowances to be surrendered, reflecting certain adjustments for other Phase I units, dispatch system sales decline, and foreign sources.

(ii) Verification of compensating generation. Under the proposal, increased generation at designated compensating units in a utility system was counted in the Phase I aggregate utilization test for calculating the net underutilization of Phase I units in the system. Phase I units with underutilization would surrender allowances for their share of the net underutilization for the system. Under that approach, however, if there were more than one underutilization Phase I unit in the utility system, all such units would be credited with a portion of the generation at any designated compensating unit within that system. The Phase I unit that designated it would still surrender allowances based on its share of the net underutilization for the utility system. It was therefore necessary to devise a method whereby the Phase I unit designating a compensating unit would receive credit for all of the increase in generation at that compensating unit.

In the final rule, the designated representatives of the Phase I unit reducing its utilization and the compensating unit must certify that the amount of generation (in Kwhs) to be credited (after conversion to mmBtus based on the reducing unit's heat rate) to the reducing unit will be reflected (after conversion based on the compensating unit's heat rate) in calculating the utilization of the compensating unit. By adjusting each unit's utilization before determining net underutilization of the dispatch system, the designated compensating generation is attributed to the unit that designated it. This also prevents double counting of the compensating generation.

Compensating generation from sulfur-free generators designated by the reducing unit requires a different approach because these generators are not regulated under the Acid Rain Program. If a sulfur-free generator is in the same dispatch system as the reducing unit, then the reducing unit must demonstrate an increase in generation at that generator above any increase that resulted from sales growth in the dispatch system. This method essentially attributes all increases at the sulfur-free generator to the Phase I unit that designated it. If a Phase I unit has designated a sulfur-free generator outside of its dispatch system, the Phase I unit must, in addition, provide documentation showing that an amount of electrical energy at least equal to the amount of claimed compensating generation was actually purchased by the unit's dispatch system from the sulfur-free generator.

If the sulfur-free generator is providing compensating generation for more than one Phase I unit, inside or outside of the dispatch system, it is the responsibility of those Phase I units to claim in total only the amount of the increased generation at that sulfur-free generator and apportion that amount among themselves.

(iii) NERC-wide generation and emissions data. Under the proposal, NERC-wide information would have been used to calculate two factors in the allowance surrender formulas. First, the formulas used, as a proxy emissions rate, a current NERC-wide average emissions rate calculated using the annual average emissions rate for all non-Phase I units within a given NERC region. In addition, in response to industry input in the proposed rulemaking, it was agreed that there should be no allowance surrender to the extent that Phase I units might have compensated for a portion of the underutilization. In order to approximate this portion, a unit would establish what percent of its compensating generation came from unknown sources and what percent of total current NERC generation was produced by Phase I units. Multiplying the two percentages would approximate the fraction of emissions that should not be subject to allowance surrender. EPA requested comment on the feasibility of compiling this NERC-wide data for a given calendar year by the allowance transfer deadline for that year.

Several commenters stated that current, annual NERC-wide data could not be compiled within that time frame. Because of this problem, some commenters suggested that NERC-wide data for other periods (e.g., September 1–August 31 of the prior calendar year) be used.

Response: EPA now recognizes that, whatever period is used, it would be unduly burdensome to require that each unit calculate NERC-wide data on its own. Moreover, such an approach could well result in utilities within a given NERC region arriving at different calculations and data. To facilitate consistency within each NERC region, information for each region could be compiled by one impartial source. EPA considered acting as the clearing house for these yearly calculations. However, this approach was rejected as a result of experience gained in establishing baselines for the NADB. It has taken several years to resolve disputes over the data and publish final data.

In the final rule, the Agency has taken an approach that solves the timing, burden, and consistency problems. EPA has included in the rule the NERC-wide non-foreign and non-Phase I emissions rate and percent of non-foreign and non-Phase I generation for each NERC region for 1985, which are derived from the extensively reviewed, final data in the NADB. This NERC-wide data will be used to approximate the emissions resulting from, and therefore to determine the number of allowances surrendered for, compensating generation by units outside of the dispatch system. The methodology used to calculate these values is available in the docket.

(iv) Sulfur-free generators. Commenters requested that EPA expand the Phase I aggregate utilization test under the proposal to include non-designated sulfur-free generators in calculating net underutilization for the utility system.

Response: The Agency agrees in principle that there should be no allowance surrender to the extent that a unit can demonstrate that compensating generation was provided by a sulfur-free generator. Including sulfur-free generators when determining the net underutilization for the dispatch system would require a showing that such generators increased their generation above average annual 1985–1987 generation and after accounting for system-wide growth. In addition, designated representatives would be required to agree, before submitting their annual reports, on how to divide sulfur-free generation into designated and undesignated categories. These demonstrations would essentially duplicate those required at the end of the year where a plan is submitted. The burden of completing and submitting a plan designating a sulfur-free generator is minimal, and the plan can be submitted or activated any time at least 90 or 60 days respectively before the allowance transfer deadline. Therefore, to avoid unnecessary complexity in the rule and the implementation of the rule, the Agency requires in the final rule that to receive credit for increased generation at sulfur-free generators, a unit must designate the generators in the reduced utilization plan.

(v) Forced outages. The Agency wishes to clarify the confusion arising as a result of a typographical error in proposed § 72.409. Subsection (e) of proposed § 72.409 should have read, "To the extent the demonstrations required by paragraphs *(a)(1)–(2)* of this section do not account for the entire amount of unplanned underutilization," allowances must be surrendered consistent with the allowance surrender formula (emphasis added). Shifts in generation due to forced outage—like generation shifts resulting from economic dispatch—may result in increased SO_2 emissions at units not subject to the Acid Rain emissions limitations during Phase I and therefore must be subject to allowance surrender. This correction is reflected in the final rule.

Under the proposal, units would be required to submit information about every forced outage. This information included, but was not limited to, the cause of the outage, what steps were being taken to rectify the situation, and the extent of the underutilization that was attributable to that outage. Commenters claimed that the reporting requirements in the event of a forced outage were too burdensome.

Response: EPA is under a statutory obligation to require a Phase I unit to file a reduced utilization plan when the unit is shut down for purposes of compliance and so is underutilized. The Agency maintains that the reporting requirements in the event of a forced outage are necessary to prevent the circumvention of the section 408(c)(1)(B) planning requirement. For this reason, the information required under the rule to be reported concerning a forced outage is the same as in the proposed rule.

However, the Agency has modified the reporting requirements so that they apply to a smaller universe of forced outages. A given outage will trigger the reporting requirement only if the outage will be identified in the annual compliance certification report as a justification for unaccounted-for underutilization or if the outage is continuing and is expected to last longer than 4 months. This approach will reduce the reporting burden and provide information necessary to identify instances of potential circumvention. In all cases, underutilization resulting from a forced outage will be compensated for by allowance surrender according to the formulas in § 74.92.

(vi) Treatment of foreign generation. The preamble of the proposal stated that underutilization resulting in generation being shifted to foreign sources would be excluded from allowance surrender. However, the allowance surrender formulas did not actually deduct load from foreign sources in calculating emissions for which surrender was required. Therefore, in the proposal, the practical result would have been allowance surrender for these shifts.

The Agency requested comment on the treatment of foreign generation. Several commenters claimed that the intent of title IV is to regulate sources within the United States. Therefore, Phase I units that shift generation to foreign sources are allegedly under no obligation to surrender allowances for those shifts.

Response: The Agency believes that there should be no allowance surrender for shifts to foreign sources (i.e., Canadian sources), but for reasons different from those suggested in public comment. As a result of the U.S.-Canada

Air Quality Agreement, Canadian sources will be subject to an annual national sulfur dioxide emissions cap. If a Canadian source chooses to increase its output in order to sell to the U.S., it will have to account for those emissions in Canada. The resulting costs will presumably be reflected in the price the U.S. utility pays for the Canadian generation. Requiring allowance surrender by the U.S. utility would result in double counting of the costs of emitting SO_2 in Canada. Consequently, the final rule does not require allowance surrender for such shifts.

(7) Phase II Repowering Extensions

Repowering is the only optional compliance method available for compliance with sulfur dioxide emissions limitations during Phase II of the Acid Rain Program. A repowering extension provides a qualifying utility the extra allowances needed to cover its emissions during the time required to install a qualified repowering technology. Congress created this extension to encourage certain types of new, innovative clean coal technologies.

In § 72.44 of the final rule, the Agency has clarified certain provisions and some inconsistencies between the proposed rule and preamble. While many comments were received concerning the repowering extension, they addressed the same issues and presented many of the arguments discussed in the proposal. As a result, the Agency made few substantive changes to the original proposal.

(a) Definitions. (i) "Qualifying repowering technology". According to the proposal, a "qualifying repowering technology" must involve boiler replacement. While most commenters addressed this issue, they presented the same arguments as those discussed in the preamble of the proposed rule.

Response: EPA still maintains that the statute clearly mandates boiler replacement as a prerequisite for approval as a qualifying technology. The Agency reiterates that the failure to qualify for a repowering extension does not preclude a utility from employing a clean coal technology or other method of complying with Phase II emissions limitations.

(ii) "Replacement." In the proposal, the Agency stated that it would determine whether a technology involved boiler replacement on a case-by-case basis, using the test in 40 CFR 60.15 for "reconstruction" as general guidance. EPA requested comment on this approach. Several commenters objected to the proposed 40 CFR 60.15 test—which requires that new components cost over 50 percent of total cost to construct a comparable new facility—as too strict for innovative technologies. Other commenters claimed that the 40 CFR 60.15 test is not strict enough because it would not require 100% boiler replacement.

Commenters from environmental groups and one utility agreed with the Agency's proposed definition. They argue that the broader the definition of repowering, the greater the number of allocated bonus allowances breaking the 8.95 million ton cap during 2000–2010 and the larger the ratchet reducing non-repowering units' allowance allocations in Phase II.

Response: The Agency continues to believe that a case-by-case approach is warranted by the complex and intensely factual nature of the determination of whether a technology involves boiler replacement. Moreover, the 40 CFR 60.15 test strikes a balance between an overly broad interpretation that would increase overall emissions and an overly narrow interpretation that would limit the incentives under section 409 of the Act for innovative technology, and the test will therefore be used as guidance.

(b) Treatment of failed projects. The proposal mirrored section 409(b)(2) of the Act, which provides that if the repowering technology has been properly constructed and tested on such unit but fails to meet emission reduction limitations and is economically or technologically infeasible, the unit will continue to receive its extension allowances. This would permit the unit to be retrofitted or repowered with another control technology. Once the extension ended on December 31, 2003, the repowered unit would be limited to the standard Phase II allowance allocation. The Agency requested comment on the treatment of repowering projects that fail before they are completed and tested and whether and under what conditions a unit that did not complete construction should continue to get extension allowances.

Those commenters who maintained that a unit need not complete construction in order to continue to get such allowances suggested that, based on legislative history, EPA has the discretion to grant utilities extension allowances when a technology falls, or a utility decides to terminate the project, before construction and testing is completed. Commenters argued that EPA should use this discretion to allow utilities to continue to receive extension allowances when there has been a good faith effort to try to complete a project. Otherwise, these utilities would be forced to spend large sums of money to finish the project, which is doomed to failure, in order to receive the allowances.

Response: The Agency believes that "proper" construction and testing to determine if a project has failed does not necessarily require "completion" of construction. Thus, consistent with the legislative history, EPA has discretion to make case-by-case judgments of whether there was proper construction and testing of a given project. However, because repowering extensions will break the Phase II emissions cap, the Agency is under a statutory mandate to be frugal in granting the full repowering extension where the repowered unit is not completed. The final rule provides that to be considered properly constructed and tested, the project must be constructed at least to the extent to permit direct testing of the multiple combustion emissions from the operation of the repowering technology at nameplate capacity.

(c) Treatment of unused allowances. While section 409(c)(1) of the Act states that allowances are not transferable to any other source, this does not preclude a unit from transferring unused allowances to another unit at the same source. However, several commenters believe that a unit granted repowering extension allowances cannot transfer those allowances to any other units and should be required to return any unused extension allowances.

Response: Extension allowances are transferable between units at the same source. Nothing bars a transferee from transferring any allowances, freed up by that transfer, to other units at any source. Because there is no express statutory authority for EPA to require the surrender of unused allowances and any surrender requirement could be so easily circumvented, the Agency has rejected the commenters' approach.

However, the Agency has clarified the meaning of the bar on transferring allowances to other sources. The final rule bars the transfer of the extension allowances to any Allowance Tracking System account other than unit accounts of other units at the same source. Since allowances cannot be used for compliance unless they are recorded in the Allowance Tracking System, the bar on transfers should focus on transfers among Allowance Tracking System accounts. The language in the final rule will prevent direct use of the extension allowances by units at other sources.

(d) Repowering application deadlines. Section 403(a) of the Act requires the Agency to issue final Phase II allowance allocations (reflecting repowering extension allowances) by June 1, 1998. Under section 408(d), the Phase II

permit application, including the repowering extension, must be submitted by January 1, 1996 and the Phase II permit must be issued by no later than December 31, 1997. Under section 409(a), the owner or operator of an existing unit must demonstrate by December 31, 1997 that it meets the requirements for a repowering extension. Reflecting these constraints, EPA proposed a January 1, 1996 deadline for submitting the repowering extension plan. If conditional approval was sought, the approved plan could be activated any time on or before December 31, 1997. Further, the proposal sets a June 1, 1997 deadline for submitting the petition for approval of a repowering technology in order to allow the Agency 6 months to review and act on the petition before the December 31, 1997 deadline for action on the permit application. The Agency requested comment on the proposed deadlines. Several commenters claimed that certain non-statutory deadlines in the proposal were not justified.

Response: The Agency maintains that the proposed deadlines are consistent with the statute and necessary for the smooth and timely implementation of the repowering extension. In particular, if the repowering technology petition were not submitted until the end of 1997, the statutory deadline for permit issuance would be missed. For these reasons and the reasons stated in the preamble for the proposal, the deadlines are retained in the final rule.

(8) Acid Rain Permit Application and Acid Rain Permit (Subparts C and E)

Under section 408 of the Act, the designated representative of each affected source must submit a permit application, including a compliance plan that sets forth the methods to be used to comply with the requirements of the Acid Rain Program. The permitting authority reviews such applications, approves or disapproves the compliance plans, and issues or denies permits.

a. Permit application information available from other data sources. In the preamble to the proposed rule, EPA requested comments on whether the Agency should request information that could be obtained from other data sources. Commenters agreed that EPA should require all the information needed to issue the permit to be submitted on one permit application form, rather than attempting to obtain this information from other data sources.

Response: The Agency therefore will require all needed information to be submitted by the applicant. The Agency has, however, attempted to simplify and clarify the information requirements for the permit application. The final rule asks only for the information that is needed to write the permit; the Agency will not ask for extraneous information. The Agency believes that having clear and simplified permit application requirements will facilitate compliance by all affected units.

b. Data no longer required in permit application. (i) Project annual utilization. Several commenters objected to the requirement to provide projected annual utilization, as reported on EIA form 767, for units covered by the permit application. They pointed out that EIA form 767 data will not be available at the time the permit applications are due and will not provide all of the required projections. Furthermore, commenters questioned what EPA would do with the information.

Response: The Agency has reconsidered the need for this information and decided that there was no statutory basis for requiring that these projections be met. The Agency has therefore deleted this requirement as being unnecessary and burdensome on the regulated community.

(ii) Most stringent federally enforceable emissions limitation. Several commenters objected to the fact that EPA was requiring the most stringent federally enforceable emissions limitations to be annualized (in accordance with a formula used in the NADB) and provided on the permit application. Commenters claimed that this was an inappropriate use of annualization factors.

Response: The Agency has reconsidered this information requirement and determined that it is not necessary. While under the proposal the information was necessary for substitution plans and Phase I extensions plans, the Agency has decided not to use the information in the case of substitution plans and has limited its use in Phase I extension plans. The reasons for the changes are discussed in the preamble sections of these plans. There is no need to require this information for all units. Further, while holding allowances under the Acid Rain Program does not exempt a unit from the requirement to comply with any other applicable limitation under the Act, the Agency believes that the Acid Rain permit application is not the appropriate place to record other limitations. Operating permits issued under title V will address the requirements of other programs.

(iii) Monitoring information. The Agency received several comments on the proposed requirement to submit certain monitoring information with the permit application, including the monitoring plan and the monitoring certification. Some commenters supported this provision, arguing for concurrent review of the application and the monitoring plan. Others argued that no formal approval of the monitoring plan should be required and that the timing of submitting monitoring plans nine months before monitor certification is due would be burdensome on sources.

One commenter was also concerned that if monitoring plans and monitor certifications became part of the permit, the permit would need frequent revisions as changes to the monitoring plan were made and as monitoring recertification became necessary. Instead, the commenter recommended that EPA allow the source to certify that it will comply with the monitor certification requirements in part 75.

Response: In the final rules, the Agency is not requiring that any monitoring information be submitted with the permit application. This decision is motivated principally by the timing of the permit application and monitoring requirements. In Phase I, permit applications are due February 15, 1993 (see section 408(c) of the Act), while monitors need not be certified until November 15, 1993 (section 412(b)). The Agency believes that it would be unnecessarily burdensome on sources to require monitoring submissions to be made so long before monitor certification is required. The timing problem is reversed in Phase II, where monitors must be certified by January 1, 1995 (section 412(c)) but permit applications are not due until January 1, 1996 (section 408(d)(2)). For the same reasons, the Agency has also deleted the requirement that monitoring plans and monitor certifications be a part of the permit. Instead, each Acid Rain permit will contain a standard requirement that the source must comply with part 75 (see § 72.9(b)(1)). Thus, a violation of any requirement in part 75 will be a violation of the permit (see the portion of the preamble for part 75).

(c) Conditional approval of compliance plans. (i) Enforceable milestones. Section 72.40(c) (proposed § 72.32(g)) allows sources to obtain conditional approval for compliance options. Thus, when the source submits its application, it may submit one or more compliance options for conditional approval. These compliance options will go through public notice and comment with the proposed permit. They will be approved conditionally, and the source may activate the options

by notifying the Agency. The activation of a conditionally approved compliance option is an administrative amendment.

One commenter objected that the provision that compliance options are not effective until activated by the designated representative could be used to evade the Act's requirement for enforceable compliance schedules for sources that employ certain optional methods of compliance. The commenter stated that a source that intended to rely on an optional method of compliance could identify the proposed method as conditionally approved and thereby prevent enforcement of interim milestones in its approved compliance schedule for that option by failing to activate the option until after the milestones have passed.

Response: The Agency believes that such a situation is not likely to occur. However, the Agency does not want to allow conditional approval to be used as a vehicle to escape from otherwise enforceable requirements. The Agency therefore has included a provision in the final rule that states that compliance options with enforceable interim milestones must be activated prior to the interim steps set forth in the compliance option or else not activated at all.

(ii) Notification of activation. Another commenter stated that EPA should not require notification of activation of a conditionally approved compliance option since the option has already been reviewed and approved by the Agency.

Response: The Agency disagrees. EPA needs notification of activation of the conditionally approved compliance option in order to modify the allowance allocations based on the compliance option. For example, the source may have a conditionally approved substitution plan; upon activation, the Phase II substitution unit becomes a Phase I unit eligible for allowances. Unless EPA receives notice, it cannot allocate allowances to the unit. In fact, because of the need to amend the unit's permit and allocate allowances, the final rule clarifies that conditionally approved substitution or reduced utilization plans must be activated no later than 60 days before the allowance transfer deadline applicable to the year in which the plan is to take effect. However, the notice does not give the Agency the opportunity to revisit the merits of the previously approved compliance option.

The need for notification is amplified where the conditionally approved compliance option involves two or more units that have different designated representatives. Under such circumstances, the compliance option cannot be implemented unless all the designated representatives agree to the activation. The prior notification requirement ensures that all the designated representatives will be aware of, and act in accordance with, the activation. Moreover, the final rule clarifies that all designated representatives of units involved in the compliance option must sign the activation notice.

(d) Interaction between permit and compliance plan. In the proposal, EPA asked for comment on whether compliance plans should be included in the permit (and possibly renamed "alternative operating scenarios") or should remain separate documents that are incorporated in the permit by reference to the compliance plan. There was no consensus among the commenters who addressed this issue, and none addressed the renaming issue. All of the commenters, however, were concerned with ensuring that sources have the maximum flexibility possible to make minor operational changes without being subject to a time consuming permit revision procedure.

Response: On reconsideration, the Agency believes that there is no practical or legal difference between including the compliance plan in the permit and treating the compliance plan as a separate document incorporated by reference in the permit. The Agency is adopting the approach of treating the compliance plan as part of the permit in order to make it clear that the plan, like the other permit provisions, is binding. Since the Act uses the term "compliance plan" and no commenters expressed any interest in changing the term used in the regulations, the final rule continues to use the statutory term.

(e) Permit shield. The permit shield provisions in proposed § 72.53(b) were supported by some commenters and opposed by others. Supporters stated that the permit shield would provide affected sources with certainty that compliance with the terms of the permit would shield the source from enforcement action. Opponents objected that the proposed shield was too narrow because the shield would not apply unless the permit conditions were clearly in compliance with title IV and the Acid Rain Program.

Response: EPA has retained in its final rule language similar to that in the proposed permit shield. The language in the proposal and in the final rule is very similar to the language in section 408(h)(2) of the Act, which provides that compliance with a permit issued under title V *which complies with this title* for sources subject to this title shall be deemed in compliance with the requirement to operate in compliance with an operating permit.

However, the Agency modified the language in the permit shield to clarify it and make it consistent with provisions, originally in the proposal and retained in the final rule, concerning the liability of the owners and operators of units involved in multi-unit compliance options or units with a common stack. Under these provisions, the owners and operators of one such unit are liable for violations of the plan by the other units. The permit shield in the final rule specifically refers to these provisions in order to clarify that such owners and operators continue to bear such potential liability. As discussed above, EPA's enforcement efforts will focus on the truly culpable parties.

(9) Federal Permit Issuance Procedures (Subpart F)

Under section 408 of the Act, EPA is the permitting authority in Phase I and, for geographic areas not covered by an approved State operating permit program, in Phase II. As the permitting authority, EPA is responsible for review of permit applications and issuance of permits. Section 408 requires EPA to develop regulations to establish permit issuance procedures.

(a) Denial of permit application. The Agency deleted proposed § 72.61(c)–(e) although these provisions do not appear elsewhere in the rules. These provisions concerned the denial of Acid Rain permit applications and Acid Rain permits and the procedure for correcting denied applications.

Response: The Agency believes that these sections are unnecessary and merely add confusion to the permit issuance process. The proposed and final rules already provide that if an application is incomplete, the Agency will issue a notice of incompleteness. Further, under these rules, the Agency may request supplemental information even where the application is complete. Moreover, where the permit application fails to meet the requirements of the Act, the Agency may issue a draft permit (called a "proposed" permit in the proposal) that disapproves compliance options requested in the permit application or may deny a draft permit. The Agency will provide a statement of basis explaining its action. In all of these circumstances, the designated representative may make necessary changes to the permit application. Thus, the Agency deleted the provisions in the proposal addressing denial and correction of permit applications and denial of permits because the provisions

duplicated, and to some extent contradicted, procedures already provided in the rule.

(b) EPA approval/denial time frame. One commenter objected to proposed § 72.70(b)(3), which stated that even though an application was deemed complete, the 6-month period for EPA action on the application would not begin to run where the designated representative subsequently failed to submit any requested supplemental information in a timely manner. The commenter stated that this provision is inconsistent with section 408(c)(2) of the statute, which requires EPA to act on compliance plans within 6 months and with proposed § 72.72(b)(2)(ii), which states that failure to provide supplemental information shall result in a denial of the permit.

Response: The Agency agrees that proposed § 72.72(b)(3) was inconsistent with the Act and has therefore deleted the provision. Under the final rules, where an applicant fails to submit supplemental information in a timely manner, the portion of the permit for which the information was necessary may be denied.

(c) Criteria for completeness. Several commenters requested that EPA clearly state the criteria it will use to determine whether a permit application is complete.

Response: The Agency reviewed proposed § 72.72(b)(3), which simply repeated or cross-referenced the requirements for permit applications. In the interests of clarity, the Agency has deleted this section and amended § 72.31 to set forth the information required in a "complete" permit application. The Agency believes that the information requirements set forth at § 72.31 are clear and straightforward and that sources will not have difficulty understanding and complying with the requirement to submit a complete application. In addition, the Agency will publish standard application forms that the sources can use. These forms, if filled out completely, will help ensure that the source submits a complete application.

(d) Proposed permits binding on a source. One commenter objected to proposed § 72.73(e), which makes proposed permits (called "draft" permits in the final rule to be consistent with the part 70 regulations under title V) binding on the source until a final permitting decision is issued. The commenter argued that "it would be extraordinarily unfair to impose on any source the terms of a mere proposed permitting decision that has not been subjected to proper procedures to ensure consistency with the Act." The commenter also stated that there is no statutory support for making the proposed permit binding on the source.

Response: The Agency agrees. Upon reconsideration of this issue, the Agency believes that a draft permit (formerly called a "proposed permit") should not be binding on the source since such a permit has not yet gone through notice and comment procedures giving the applicant and other parties the opportunity to address its consistency with the Act and with Agency policy. The Agency, therefore, has eliminated the requirement that the draft permit be binding on the source in lieu of a permit until the permit is issued. Instead, a complete permit application and compliance plan will be binding on the source until a permit is issued, as provided in section 408(c)(1)(A) and (d)(3) of the Act.

(e) Public comment period. (i) Permits and monitoring plan. EPA received several comments on the public comment provisions of its proposal. Several commenters supported the public comment provisions as proposed, but recommended that EPA allow comments on monitoring plans during permit review to minimize the possibility of redundant public comment periods.

Response: The Agency agrees that redundant public comment periods are a waste of time and resources for the Agency, the public, and the affected source. However, as discussed above, the final rules eliminate the requirement for a monitoring plan as part of the permit because of timing differences between permitting and monitor certification. Thus, in general, there will be no reason to make comment on the monitoring plan in the context of permit review.

(ii) Need for public comment. One commenter suggested that EPA eliminate the requirement for a public comment period for Acid Rain permits. The commenter states that utilities will either purchase allowances, add controls, or switch fuels and that since the Act gives sources the choice of which option to pursue, there is no need for public comment.

Response: The Agency disagrees. Section 408(a) of the statute mandates that title IV be implemented by permits issued in accordance with title V, as modified by title IV. A fundamental requirement of title V (set forth in section 502(b)(6)) is provision of an opportunity for the public to comment on the proposed permit. Furthermore, title IV gives sources the opportunity to request certain optional methods of compliance, such as substitution, Phase I extension, repowering extension, and reduced utilization plans. Before the Agency approves these optional methods of compliance, the public should have an opportunity to comment on the source's proposal and whether it meets the requirements of the Act. In addition, the comment period gives the source an opportunity to object to the draft permit that EPA proposes to issue in final.

(f) Fast-track modifications. (i) General. The Agency received numerous comments supporting the fast-track modification approach. Commenters supported promulgating Option 1, Option 2, or both. Several of the commenters who supported both options, however, stated that if EPA were to promulgate only one, it should promulgate Option 2. Several commenters who supported Option 1 also requested clarification from EPA on what it meant by "significant objections" to a fast-track modification that would require the source to shift to the regular modification procedure. The Agency received comments from environmental groups stating that they need at least 30 days to comment adequately on permit conditions.

Response: The Agency considered all of these comments and determined that Option 2 best addresses the concerns of the commenters. Option 1 provides only 15 days for public comment while Option 2 provides 30 days. The Agency believes that it is critical that interested persons be given an opportunity to comment adequately on significant changes in permit conditions. Option 1 does not allow adequate opportunity for comment. In addition, the Agency believes that proposed Option 1 could prove to be less expeditious than Option 2. Option 1 requires that the permit modification procedures be followed if significant objections are received during the 15-day comment period. Thus, to effect the change, two different permit revision procedures might have to be implemented. Under Option 2, there is a 30-day opportunity for comment. The Agency then has 30 days to review and act on the application and all comments. In many cases, Option 2 will prove to be more expeditious. For these reasons, the Agency has decided to promulgate only Option 2 in its final rule and clarify that fast-track procedures may be used, for any of the listed revisions, at the option of the designated representative submitting the permit revision.

(ii) Notice to interested persons. Numerous commenters also stated that, as proposed, only people who commented on the proposed permit would receive written notice of a fast-track modification. These commenters

objected to this limitation, stating that any person who asked to be put on a mailing list should receive notice of any fast-track modifications. One commenter pointed out that this limitation was inconsistent with proposed § 72.77 (public comments), which allows interested persons to put their names on a mailing list at any time and to receive notice of future actions affecting that permit.

Response: The Agency agrees with these commenters and has clarified in the final rule that written notice must be given to any interested person. Under § 72.2, an interested person is someone who either comments on the draft permit, testifies at a public hearing on a draft permit, or requests to have his or her name put on a mailing list to receive notice of any future actions on that permit.

(g) Minor permit modifications. In the proposal, the Agency asked for comment on whether some of the changes to the permit that were proposed as modifications or fast-track modifications could be accomplished using the minor permit modification (originally referred to as "minor permit amendment") procedure proposed in part 70 of this chapter. The Agency received several comments on this issue. One commenter agreed with EPA that the fast-track modification will be expeditious enough for approval of a new compliance option. Several other commenters stated that permit revisions should not be required for replacement of equipment but implied that if a revision were required, the minor permit modification would be appropriate.

Response: The Agency is not requiring notification or a permit revision for changes to equipment. In fact, permits will not include detailed information about how the source is going to operate or comply unless the source applies for an optional method of compliance. For example, if a source initially chooses to comply by switching to low sulfur coal but decides in 1997 to install a scrubber, neither the initial compliance decision nor the change will be included in the permit. This is because these approaches do not require approval of an option compliance method but rather require only that the source undertake to hold sufficient allowances to cover its emissions. Thus, the minor permit modification procedure is not needed for these types of changes. Moreover, since no commenters recommended that changes now covered by fast-track modifications be accomplished using the minor permit modification procedure, the Agency has decided not to promulgate a minor permit modification for changes to Acid Rain permits. The Agency believes that this revision procedure is unnecessary for the Acid Rain Program because the program requires notification only of changes in compliance options and of certain relatively minor permit changes, which can be accomplished through fast-track modifications and administrative amendments respectively.

(h) Administrative amendments. Generally, commenters supported the Agency's proposed administrative permit amendment provisions. These commenters believed that the changes included in this section could be accomplished without public notice and comment.

Response: The Agency agrees and has eliminated the requirement in the proposed rule that notice be given to interested persons of every administrative amendment to the permit. The Agency believes that interested persons should have access to current information about changes in permits and permit conditions. However, the Agency does not believe that the burden of providing notice is justified in this case because administrative permit amendments are relatively minor or noncontroversial and become effective without any opportunity for public comment. One example of such an administrative amendment is the adoption of or a change in a reduced utilization plan that does not involve designation of a compensating unit (e.g., a plan relying on energy conservation or sulfur-free generation). The Agency notes that the permits will be publicly available at EPA Headquarters and the Regional Office in the region where the source is located. In Phase II, permits will also be available at the office of the State permitting authority.

(10) State Permit Program Approval Criteria (Subpart G)

Under section 408(d) of the Act, each State must submit, for EPA's approval, a permit program, in accordance with title V, under which the State will issue Acid Rain permits for Phase II. The permit program must meet certain criteria in order to be approved by EPA. If the State program is approved by July 1, 1996, EPA will cease issuing Phase II Acid Rain permits. Under title V, State permit programs must also meet criteria concerning, and provide for, issuance of operating permits implementing other requirements of the Act in addition to those under title IV. The permit programs must be submitted by November 15, 1993.

(a) Complexity of acid rain program requirements. Some commenters were concerned about the complexity of the proposed Acid Rain regulations and the effect that complexity would have on States' ability to develop their permit programs under title V by the statutory deadline of November 15, 1993. One commenter suggested that EPA review separately State submissions under title V and title IV and give States longer to develop and submit their title IV permit programs.

Response: EPA believes that adoption of the commenter's suggestion is not warranted at this time. Both section 408(a) and section 502(a) of the Act require that title IV be implemented through title V, as modified by title IV. Thus, the Acid Rain Program will be an integral part of a State's title V operating permit program. Furthermore, the Agency believes that State regulations needed to implement the Acid Rain Program will not be particularly complex since many of the more complex aspects of the program (e.g., allowance allocations) will be implemented by EPA. The Acid Rain portion of the title V operating permit will be considerably less complex than the portion implementing the State implementation plan (SIP) and other requirements of the Act.

(b) Interference with allowance market. The Agency received numerous comments on proposed § 72.202(a), which bars a State operating permit program from interfering with the allowance market. The majority of the commenters supported § 72.202(a) as proposed, saying that State interference with the allowance program would frustrate a crucial objective of title IV: The achievement of nationwide emissions reductions at the least cost to utilities. However, a significant minority of the commenters opposed this section, claiming that it would limit a State's ability to protect legitimate interests, such as limiting the total deposition within the State and protecting national parks and forests.

Response: The Agency has retained this provision in its final rules. The Agency believes that these restrictions on State action are necessary to ensure that a national allowance market has an opportunity to develop and that sources are allowed to comply with the Acid Rain Program in the most cost-effective manner possible. The Agency realizes that States have a legitimate interest in protecting ambient air quality and that they therefore may want to limit emissions by restricting allowance trading. Nonetheless, the Acid Rain Program is a national program designed to reduce substantially total national

loadings of acid deposition precursors. The national transfer of allowances was clearly contemplated by the drafters of the Act. Geographical limitations on allowance transfers were included in early Senate and House versions of the bill, but later rejected in favor of national transfers. Congress was aware that failure of a nation-wide allowance market would create significant problems for new power plants (particularly those constructed by independent power producers) that are not allocated allowances by EPA but must purchase enough to cover their emissions. Report of the Committee on Energy and Commerce, House Report No. 490, at 366–67 (1990). In fact, prior versions of the bill that became the Clean Air Act Amendments of 1990 divided the country into two regions and permitted allowance transfers only within those regions. That restriction was removed in the final bill. See, e.g., *id.* at 372. Moreover, the active trading of allowances will enable utilities to adopt the least-cost approach to achieve their required SO_2 emissions reductions. The allowance market would likely fail if State or local permitting authorities had the ability to restrict the transfer of allowances.

Furthermore, under the Act, States have authority to protect local air quality concerns through requiring compliance with the SIP and with applicable National Ambient Air Quality Standards, rather than through restrictions on allowance trading. Section 403(f) provides that compliance with the Acid Rain Program will not excuse compliance with other applicable Clean Air Act requirements. The Agency realizes that a SIP will not allow a State to influence compliance decisions of utilities in neighboring States, which may have less stringent emissions requirements in their SIPs, and that emissions may travel across State lines and affect air quality or acid deposition in other States. Nonetheless, States had limited authority to influence compliance decisions of sources in neighboring States prior to enactment of the 1990 Amendments to the Clean Air Act, and the Agency does not believe title IV was intended to expand such authority. If Congress had intended to expand States' authority in this regard, it would have expressly said so.

(c) EPA intervention in appeals. Section 72 .202(i)(3) of the proposed rule required that the Administrator be given authority to intervene as a matter of right in any State administrative or judicial permit appeals involving an Acid Rain permit provision. This provision was proposed in order to ensure national consistency in State interpretations of Acid Rain permit requirements. One commenter considered this provision too intrusive on the rights of States to administer a delegated title V program.

Response: The Agency agrees only in part. For the rest of the title V program, EPA's oversight role through review and possible veto of permits will suffice. However, national consistency is needed in the Acid Rain Program more than in the rest of the title V program in order to ensure that a national allowance market has an opportunity to develop. To ensure that States do not adopt inconsistent interpretations of Acid Rain provisions that would adversely affect the allowance market, the Agency must have the opportunity to participate in State proceedings affecting Acid Rain permits. When there is an administrative appeal of an Acid Rain portion of a title V permit, there is a chance for inconsistent interpretations of Acid Rain provisions. The Agency needs to be assured that it will have an opportunity, before such interpretations are adopted, to present its interpretation of the Acid Rain Program in any State administrative appeal of an Acid Rain permit. However, by intervening in the State administrative proceeding, EPA may participate as a party in any subsequent State judicial appeal. In the unlikely case that EPA has no involvement until the judicial appeal, the Agency believes the courts will likely permit its participation as an *amicus*. Thus, the final rule requires a right of intervention only in State administrative appeals.

(11) Compliance Certifications (Subpart I)

Proposed subpart K, renamed subpart I in the final rule, described the compliance certifications that the designated representative would need to submit for each affected unit.

These compliance certifications included: Quarterly reports concerning emissions data and quality assurance information and the unit's compliance status with regard to deadlines and increments of progress; and annual reports concerning the requirement to hold allowances not less than total annual emissions, to submit a reduced utilization plan and surrender allowances for underutilization of Phase I units, and to meet nitrogen oxides emissions limitations. In addition, there were a number of periodic certifications required under the various compliance options.

Simplification and Reduction of Burden

A number of commenters found the subpart to be confusing in general and claimed that there was a need to reduce the regulatory burden imposed by the certification requirements.

Response: The Agency has endeavored to simplify and clarify the certification requirements and reduce the regulatory burden, while recognizing that compliance certification plays an important role in the Acid Rain Program. First, the annual requirements that all units certify to their total tons of emissions for the year and the total number of allowances held in the unit's compliance subaccount as of the allowance transfer deadline have been deleted. The Agency will already get quarterly emissions data from the units and will keep track, on an ongoing basis, of the allowances in each unit's account. There is no need to require submissions duplicating this data.

Also removed are the requirements to file quarterly certifications of each unit's compliance status with regard to scheduled deadlines or increments of progress (proposed § 72.401), periodic certifications to change certain deadlines under specified compliance options or to give notice of the failure to meet certain deadlines and reporting or submission requirements (proposed § 72.403), and certifications of any nonscheduled event that affects compliance (proposed § 72.403).

Annual Compliance Certifications and Other Submissions

In contrast to the proposal, the final rule requires each unit to provide annual and quarterly compliance certifications limited to certain key aspects of the Acid Rain Program. The annual compliance certification report must include certifications concerning the requirements to meet Acid Rain emissions limitations, maintain an up-to-date monitoring plan, and monitor and account for all emissions. Any changes in the facts that form the basis for monitor certification or for using excepted or alternative monitoring methods must be certified. In addition, quarterly submissions of monitoring data are still required under 40 CFR part 75. These submissions must be accompanied by a certification that the data was obtained or derived as required under part 75. (See § 75.64(c)). These certification requirements are consistent with the certification requirements under part 70 of this chapter.

Finally, some reports related to specific compliance options are retained in the final rule. Submissions concerning reduced utilization and the surrender of allowances are required. (The comments addressing those submissions are addressed above in the portion of the preamble on reduced

utilization). Only those periodic reports that the Agency found to be necessary to administer Phase I extension plans and repowering extension plans are still required. Some new information for which a periodic report is no longer required still requires a permit revision (e.g., to change the date of commencement of operation of qualified Phase I technology). See § 72.83 (administrative permit amendment).

The Agency believes that reducing the number, and clarifying the information requirements, of reports and certifications in this way will reduce the regulatory burden while meeting the statutory compliance certification and reporting requirements of title V that are applicable to title IV. Section 504(c) of the Act and the part 70 regulations implementing title V require compliance certifications at least annually that contain statements of the methods of determining compliance, such as monitoring, recordkeeping, and reporting requirements and test methods. See 40 CFR 70.5(c)(a). However, under the Acid Rain Program, unlike other programs under the Act, the Agency already receives a large volume of highly reliable data on unit operation, emissions, and monitor calibration. Consequently, the scope of compliance certification needed under the Acid Rain Program is less than under other programs under the Act and can be limited to what is set forth in the final rule.

IV. Discussion of Changes to Part 73—Allowance System

There are three main structural changes to part 73. First, the definitions are being moved to part 72. All definitions for the Acid Rain Program will be in part 72. Second, in subpart D, § 73.52 Submission of Transfers was merged with § 73.50 Scope of Transfers. Finally, also in subpart D, § 73.55 Non-Recordation of Transfers was merged with § 73.53 Notification. In addition, §§ 73.3 (Definitions) and 73.4 (Deadlines), which were previously published with subpart E—"Auctions, Direct Sales, and Independent Power Producers Written Guarantee", on December 17, 1991, pages 65592–65607, are recodified at §§ 72.2 and 72.12, respectively. This recodification is being performed in order to locate all the definitions for the Acid Rain Program in one place, solely for the ease and convenience of the reader. In addition, the definitions that are being recodified were already subject to notice and comment under subpart E of this part. Any changes made to the definitions were made to reconcile all the provisions of the Acid Rain Program and are not for the most part substantive changes. To the extent that there are any substantive changes, these changes were made in response to public comment on the definitions under other proposed subparts of the Acid Rain Program rules (since in many cases the same definitions appeared in various different subparts of the rules). Thus, EPA finds that for all these reasons, additional public notice and comment on this recodification is impracticable, unnecessary, and contrary to the public interest, pursuant to 5 U.S.C. 553(b)(B), 42 U.S.C. 7607(d)(1).

This section of the preamble discusses the four issues that were of most interest to the public, a number of additional significant issues, and any changes made to the rule as a result of comments on these issues. The section also clarifies the procedure EPA will use to return proceeds from the auction and direct sale to each unit. Other issues and comments are addressed in the Response to Comments Document.

On July 7, 1992, EPA proposed the Phase I allowance allocations; Phase I Extension Reserve, and establishment of the Special Allowance Reserve (57 FR 29939). To facilitate trading and Phase I compliance planning, as well as the first auction of allowances from the Special Allowance Reserve, EPA is choosing to finalize the Phase I allocations and reserves today, rather than promulgate them with the rest of the Phase II allocation rules. Only one comments was received on the Phase I allocations, and EPA has modified the allocations for the Sunbury plant in response to that comment. Five comments were made regarding the calculation of the Phase I Extension Reserve. Four of the comments supported EPA's calculation methodology and one requested a modification. EPA has chosen to maintain its calculation methodology and discusses the requested method in the docket. No comments were received on the establishment of the Special Allowance Reserve for the Phase I period, so the proposed language has been adopted.

A. Allowance Transfer Deadline

The "allowance transfer deadline" is the last day on which allowance transfers may be submitted to EPA for recordation in a compliance subaccount for use in meeting a unit's SO_2 emissions limitation requirements for the year. EPA proposed to establish January 30 of the calendar year following the year for which compliance is being established as the "allowance transfer deadline."

EPA received a total of 122 comments on the issue of the allowance transfer deadline. The majority of commenters requested a 45-day (or February 14) allowance transfer deadline. A significant number of commenters supported at least the proposed January 30 deadline, a few commenters requested a 60-day (or March 1) deadline, and some commenters supported a December 31 deadline. Those supporting a December 31 allowance transfer deadline claim that an allowance transfer deadline after December 31 establishes a bad precedent for a market-based program. They believe that companies should be able to plan for the transfers needed for compliance well in advance of December 31, and thus should not need an extended deadline. They also believe that companies should maintain prudent contingency reserves to allow them to meet the requirements on December 31. In addition, the commenters are concerned that such an extension or "book closing period" is inconsistent with the intent of the Act and its enforcement and compliance provisions. Finally, they believe a January 30 deadline makes it difficult to complete the steps required for development of excess emission offset plans, due by March 1, on a timely basis.

Other commenters felt that the proposed 30-day, or January 30, transfer deadline is appropriate. They argue that 30 days are needed to provide units with sufficient time to transact and submit allowance transfers. They also comment that the January 30 deadline affords units one month from the submission of transfers to complete and submit excess emissions offset plans, if necessary, and EPA one month to record final transfers and resolve any associated errors.

The commenters supporting a 45-day, or February 14, allowance transfer deadline state that such a deadline is in line with Congress' intent and has no effect on the emission reduction goals of the program. In addition, they argue an extra 15 days will result in fewer transfer errors, and reduce the likelihood that any utility will actually be out of compliance and have to file an excess emission offset plan. Commenters supporting a longer transfer deadline also claim that EPA should not need 30 days after the transfer deadline for recording allowance transfers and handling claims of error, especially with an electronic Allowance Tracking System. They argue that additional time for compliance procedures is important for small utilities that do not have the staff or

expertise to promptly complete their compliance certification reports and locate allowances, if needed. A number of utilities commented that extending the transfer deadline by 15 days still leaves them enough time to prepare and submit their excess emission offset plan by the statutory deadline of March 1. Finally, they claim that allowing more time to negotiate allowance transactions for compliance helps minimize the overall compliance costs of the program.

A number of commenters favored a January 30 or February 14 allowance transfer deadline for its accommodation of utilities in power pools or those seeking to create allowance pools. For such power and allowance pools, they argue an extended allowance transfer deadline would enable member units to arrange for allowances to be transferred after the designated representatives have fully collected and assessed the final emissions data for the year on a system-wide or pool basis. At that point, since compliance is determined on a unit-by-unit basis rather than on an aggregate basis, surplus allowances from certain units could be transferred during the extended allowance transfer period to any units in the pool that needed them. These commenters assert that a December 31 transfer deadline, coinciding with the calendar year compliance requirements mandated by the Act, could inhibit the creation and operation of such power and allowance pools.

Several commenters suggest a 60-day, or March 1, allowance transfer deadline. They claim that such a deadline is in the interest of a viable and flexible emission trading system, and that it provides adequate time for the staffs of small utilities to comply with the complex rules.

Response: As stated in the preamble to the proposed rule, EPA believes the additional flexibility of an extended allowance transfer period is important to the Acid Rain program and is also consistent with Congressional intent.

The final rule, in § 73.35(a), sets January 30 as the date of the allowance transfer deadline. EPA continues to believe that a January 30 deadline provides units with ample time to transact and submit allowance transfers, and in the case of units with excess emissions, to submit offset plans within 60 days after the end of the year.

Through continuous emissions monitoring under part 75, units will be able to estimate their emissions during the year and determine their exact annual emissions within hours of year-end. This capability will allow allowance or power pools as well as individual units plenty of time to transact and transfer allowances before January 30.

A February 14 allowance transfer deadline would compress the amount of time for both EPA and the authorized account representatives to complete several time-consuming activities which must occur before March 1. First, EPA will have to record transfers and notify the authorized account representatives as to whether the trades are recorded. If a large volume of transfers are submitted at once, there may be a delay between submission and recordation for any given transfer. Second, the authorized account representatives will need to determine the accuracy of any recordations and, if necessary, to submit error claims to EPA. Finally, EPA will have to resolve each error claim. EPA believes that the period from February 15 to March 1 does not offer sufficient time to carry out these activities reliably, especially in Phase II of the Acid Rain program when the number of affected units will increase to over 2,000.

Extending the allowance transfer deadline to March 1, as several commenters suggested, would leave no time for these activities and is therefore not a viable option.

Because of all the activities that must take place between the January 30 allowance transfer deadline and the March 1 deadline for submission of excess emissions penalties and offset plans, EPA strongly encourages utilities to submit allowance transfers before the January 30 deadline. Designated representatives should try to submit compliance-related transfers prior to the allowance transfer deadline because if an error is made on the transfer form, there would still be time to resubmit the transfer before the January 30 deadline. Under the final rule, resubmission of the transfer after January 30 would be too late to use these allowances for compliance purposes in the previous calendar year. An additional incentive to submit transfers early is that it provides more time to file a claim of error regarding an allowance transfer and to have the claim resolved (see next section). Resolution of a claim of error could be of critical importance if the trade's outcome determined whether the unit was in compliance.

B. Serialization

In § 73.34(d) EPA proposed to assign a unique identification number to each allowance. Most commenters supported EPA's proposal because it provides a method for establishing a cost basis for allowances and, therefore, greater flexibility for tax and compliance planning purposes. A few commenters, however, disagreed with the need for serialization, except to indicate the compliance use date for each allowance. One commenter argued that the compliance use date was necessary to establish the cost basis for an allowance, but that the assignment of a unique number would destroy the fungibility of allowances. Another said that EPA's assignment of a unique number was unnecessary because a utility would probably assign its own unique numbers that are consistent with its internal accounting system. A third commenter argued that the administrative burden of assigning a unique identification number to each allowance outweighed any possible benefits. Still another commenter claimed that only an identifier of the year for which the allowances are valid and the attachment of a transaction number when allowances are transferred are necessary for tracking purposes.

One commenter recommended that, in addition to the compliance use date, an allowance's unique identification number include a means of identifying the source of the allowance's original allocation. This would enable utilities and their regulators to distinguish between allocated and acquired allowances for tax and accounting purposes.

Response: EPA continues to believe that the assignment of unique serial numbers to allowances will provide significant flexibility to the market's participants in their financial, tax, and compliance planning efforts. Furthermore, because such numbers would be useful to most companies for their internal recordkeeping purposes, EPA decided that the aggregate benefit of providing a standard numbering system outweighs the administrative cost to EPA of generating and tracking the identification numbers.

In response to the comments, EPA will assign a unique number to each allowance that will include the compliance use date and that will enable utilities to differentiate between allocated and purchased allowances. EPA is including the compliance use date as part of the unique number to further enhance the establishment of a cost basis for each allowance. EPA agrees that it will be useful to readily identify compliance dates and to distinguish allocated from acquired allowances using serial numbers since it is important to utilities and regulators for establishing a cost basis for allowances.

EPA is not providing, by regulation, the exact format of the serial numbers for the allowance system. In implementing the system, EPA will

limit the use of source codes to those cases where such identification is necessary.

C. Verification of Energy Savings

Section 404(f)(2)(B)(ii) of the Act requires an applicant to the Conservation and Renewable Energy Reserve (CRER) to quantify its estimates of avoided emissions according to regulations promulgated by the Administrator. EPA proposed to defer conservation verification to State regulators in cases where the State has regulatory oversight. EPA's rationale for this approach was that regulatory scrutiny for conservation savings applied for under the Reserve is likely to be fairly rigorous because utilities applying for the program must be subject under the Act to "net income neutrality" ratemaking structures. EPA also reasoned that with the complexity and multitude of verification methods for energy savings, verification guidelines must be flexible enough to allow States to develop procedures that best suit the circumstances of their utilities. In cases of non-State-regulated utilities, EPA proposed to require the use of an EPA Conservation Verification Protocol (CVP), to be published at a later date.

Some commenters questioned EPA's approach for deferring verification of energy savings to States. It was noted that some methods of net income neutrality rate-making do not link the revenues awarded to the utility with the amount of verified energy savings. For example, ratemaking structures that decouple a utility's revenues from sales volumes do not require verification of savings from conservation programs. Several commenters also noted that State verification methods vary widely in their accuracy and rigor. For example, some States base their verification of savings solely on engineering estimates, which may be grossly inaccurate.

Commenters gave a number of suggestions for revising the criteria for deferring conservation verification to States, including (1) requiring all applicants to the Reserve to use the CVP or some other verification standards that EPA would promulgate, which might include region-specific engineering estimates for conservation measures; (2) having EPA adopt State estimates of energy savings only in cases in which the State requires "measured" energy savings, i.e., savings that are verified in statistically valid studies using billing data or data collected by electricity end-use sub-meters; and (3) having EPA defer to States only if the State uses evaluation of energy savings to determine performance-based financial awards for energy conservation programs and these performance based awards are subject to adjustment to reflect periodic evaluation of energy savings.

Response: EPA has decided to adopt this last approach with one modification. Section 73.82(c) of today's rule allows States to perform verification of energy savings if they use evaluation of energy savings to determine *any* type of performance based rate adjustment, rather than just performance based *financial awards*, as suggested by the commenter. EPA believes that allowing this broader category of performance based mechanisms is more consistent with today's definition of net income neutrality, which allows both performance-based financial awards (i.e., "shared savings mechanisms") and "lost revenue adjustment mechanisms." For both of these types of mechanisms, regulators must evaluate energy savings achieved by utility conservation programs in order to determine the proper adjustment to a utility's rates necessary to recover lost revenues or to provide a financial award.

EPA has adopted this approach for several reasons. First, the Agency believes it is representative of EPA's original rationale of deferring to State regulators where verification is likely to be fairly rigorous. The Agency believes that there is an incentive for rigorous verification when evaluation of energy savings is used to determine how much of the ratepayer's money will go towards conservation incentives. In contrast, without this tie to performance based rate adjustments, States might have an incentive to overestimate savings to obtain the largest number of Reserve allowances.

Second, although the use of engineering estimates would still be allowed, the requirement to periodically modify performance-based rate adjustments through the evaluation of energy savings would help ensure that the State is committed to good evaluation practices. EPA notes that evaluation of energy savings is a new and rapidly evolving field and that States often begin their evaluation programs solely with engineering estimates. Most evaluation experts agree, however, that while engineering estimates are useful, they should be supplemented with a statistically valid measurement of the change in energy use resulting from installation of conservation measures.

Finally, EPA believes that this approach is more consistent with the fundamental approach of the Acid Rain program, which encourages flexibility but insists upon appropriate measurement standards. Thus, while today's regulations provide a minimum standard for deferring conservation verification to States, EPA is not prescribing verification methods or procedures. States will still have the flexibility to design their own verification approaches. Because of the diversity of evaluation methodologies and the ongoing evaluation activities of States, EPA believes that this approach will be more effective than mandating specific methods or requiring universal use of the CVP.

EPA also notes that it has modified the proposed verification requirement for applicants that do not qualify to have verification performed by their State commissions. The proposal required such applicants to use the CVP. The final rule requires applicants to demonstrate to the satisfaction of the Administrator that energy savings have been secured and allows applicants to do so through use of the CVP.

D. Appropriate Biomass Categories

EPA proposed to allow the biomass component of municipal solid waste (MSW) to be considered as biomass resources for purposes of the Reserve. The Agency noted in the proposal that inclusion of MSW was consistent with the definition of biomass in the Public Utility Regulatory Policies Act of 1978 (PURPA). EPA also proposed to limit the total number of allowances that may be allocated in connection with any one of the four categories of renewable resources—biomass, solar, geothermal, and wind—to no more than 10% of the Reserve, or 30,000 allowances. This reflected EPA's concern that biomass, which, in the aggregate, represents more than 90% of the combustible MSW stream, could absorb a disproportionate share of the Reserve.

Twenty-five commenters opposed EPA's proposal to allow the biomass components of MSW to be considered a biomass resource for purposes of the Reserve. One set of commenters stated that the goals of PURPA and the Clean Air Act are entirely different; PURPA was intended to stimulate energy production, while the Clean Air Act was designed to promote clean air. Moreover, these commenters argued the CRER was created to accelerate the development of conservation measures and renewable energy technologies that meet two standards: (1) They enhance the goals of the Act to improve air quality, and (2) they are in greatest need of an additional Federal incentive. The commenters argued that while incineration of MSW may be a suitable

method of solid waste disposal in some cases, it does not meet these two standards.

Fifteen additional commenters noted that MSW waste-to-energy projects are not environmentally benign or beneficial, and they emit a number of pollutants including SO_2, NO_x, particulates, and a variety of toxics. Commenters also contended that MSW waste-to-energy generation is a well developed technology that does not need additional incentives. Finally, several commenters argued that the additional incentive for incineration of MSW provided by Reserve allowances could disadvantage more environmentally beneficial solid waste disposal options such as source reduction and recycling.

Only one commenter unequivocally supported EPA's proposal to allow the biomass components of MSW to be considered a biomass resource for purposes of the Reserve. The commenter argued that all renewable technologies covered by PURPA should be considered qualified renewable energy technologies for purposes of the CRER.

One additional commenter argued that before receiving allowances from the CRER, waste-to-energy projects should obtain certification from the Department of Energy (DOE) that the project was operating in full compliance with an approved integrated solid waste management plan. The commenter stated that this plan should include recycling to the maximum extent practicable.

Response: EPA, having considered these comments, finds that there is no policy or statutory basis for excluding the biomass component of MSW as a biomass resource for purposes of the Reserve. While commenters are correct in noting that MSW waste-to-energy (WTE) projects emit a number of pollutants, EPA has already promulgated regulatory standards that mandate, reductions in these emissions to acceptable levels (*FR* Vol. 56, No. 28, February 11, 1991, p. 5488). Moreover, WTE plants often yield certain environmental benefits in addressing solid waste management concerns. In any event, the Act does not contemplate an environmental ranking of renewable energy technologies.

EPA agrees with the comment that WTE technology is both mature and geographically dispersed. The number of WTE projects has grown substantially in recent years—65 WTE projects began operation in the years between 1980 and 1989, and 75 additional projects are planned or have recently begun operations. However, the exclusion of a particular renewable technology from access to the Reserve merely because it is highly cost-effective would be totally inconsistent with the thrust of the emissions allowances system, which uses a flexible market-based system rather than a command-and-control approach precisely because the former can elicit the most cost-effective responses to meet environmental objectives and energy needs. Finally, Congress explicitly considered the definition of "qualified renewable energy" in the Act and, while explicitly excluding hydropower, did not exclude WTE biomass. Thus, on legal as well as policy grounds, it would be inappropriate for the Agency to impose such a restriction. Accordingly, after considering the comments received, the Agency has determined that MSW will remain on the list of qualified renewable energy technologies in Appendix (A)(3) of today's rule.

The proposed rule assured that no single technology would absorb a disproportionate share of the Reserve by limiting to 30,000 the amount of allowances that can be allocated from the Reserve. This same limitation is included in the final rule.

E. Other Changes to Part 73

(1) Allowance Accounts

In § 73.31(a) of the proposed rule, EPA specified that the allowance account for an existing affected unit would be established in the Allowance Tracking System no later than January 30, 1993. Accounts for new units would be established upon receipt of a valid certification of representation for a new unit pursuant to part 72.

Upon review, EPA is eliminating the specification that EPA establish Allowance Tracking System accounts by no later than January 30, 1993. Because EPA imposed this specification upon itself and it was not a statutory requirement, EPA believes its inclusion is unnecessary.

(2) Freezing of Accounts

In § 73.50(a)(4) EPA proposed to prohibit, or give the Administrator the discretion to prohibit, EPA from executing any transfers of allowances from a compliance subaccount if the unit had excess emissions in the previous calendar year and the Administrator had not yet deducted allowances or approved the unit's offset plan. In such cases, EPA would have allowed a transfer if the number of allowances in the compliance subaccount equaled or exceeded the sum of the number of allowances subject to the transfer and the unit's excess emissions in the previous year.

Several commenters questioned the purpose of giving EPA authority to "freeze" an affected unit's subaccounts in the ATS under these conditions. Specifically, they requested EPA to delete these proposed provisions (§ 73.50(a) and § 73.55(b)).

Response: On reexamining this issue, EPA has decided to delete these provisions and has revised the rule accordingly. EPA reasons that even if a unit's offset plan to cover its excess emissions in the previous year has not yet been approved and allowances have not yet been deducted for excess emissions, EPA should allow transfers of allowances out of the current year's compliance account. Once the offset plan is approved, EPA could deduct allowances from the current compliance subaccount as the plan requests. If a unit fails to abide by its offset requirements and lacks sufficient allowances in its current compliance subaccount to cover its excess emissions, EPA has the authority in accordance with § 77.4 to automatically deduct allowances from the current compliance subaccount whenever more allowances are recorded in the compliance subaccount. The only situation in which allowances would be unavailable to EPA would be if the unit transferred all allowances from its account and ceased operation, which could be done before an offset plan is even submitted to EPA. In such a case, EPA could pursue enforcement actions. Therefore, EPA agrees that the proposed provisions concerning freezing an affected unit's subaccount are duplicative and unnecessary.

The final rule contains language under the general requirements of part 72, subpart A that allows EPA to take action to protect the orderly and competitive functioning of the allowance system. This is to ensure that EPA is able to protect the allowance system and participants from fraud or misrepresentation.

(3) Account Error and Dispute Resolution

As proposed in § 73.37, EPA required that all claims of error be submitted within 20 business days following the date of submission of the recordation notice or within 10 business days of the date of EPA's notification of the recordation. Only one additional appeal to the Administrator's decision of the submitted claim would be considered. No appeals provision was made for EPA's corrections and the Administrator's discretion to waive deadlines.

Commenters requested that such appeals procedures be extended to

apply also to corrections made at EPA's own discretion and the Administrator's right to waive deadlines. Other commenters supported having a more formal administrative appeals procedure, similar to the one proposed in part 72, to cover any action by the Administrator under part 73.

Response: EPA reviewed its proposed claim of error procedures to ensure that adequate response time for account holders is provided consistently throughout the compliance period. EPA is modifying the claim of error process so that only properly documented claims submitted within 15 business days following the date mark of notification of the transfer's recordation will be considered, subject to the waiver of deadlines process § 73.37.

As defined in § 73.37, a properly submitted claim consists of (1) a description and complete documentation of an error allegedly made by EPA, (2) a proposed correction, and (3) certification by the authorized account representative. Any appeal of the decision made by the Administrator in response to the submitted claim of error will be handled through the administrative appeals procedure contained in part 78. The deadline and process will not be altered for claims submitted near or after the Allowance Transfer Deadline. This means that unless EPA uses its discretion to waive the deadlines, EPA would have 20 business days to respond in writing to a claim of error received on the allowance transfer deadline. Thus, the designated representative might not know the outcome of the claim until after March 1. This could present a problem to the designated representative where the outcome of this claim of error is of critical importance in determining whether the unit was in compliance. However, if EPA made an error in recordation that appeared to put the unit out of compliance, EPA will correct the error and acknowledge that the unit was in compliance.

Based on supporting comments received, EPA is extending the claim of error process to cover EPA corrections, and the administrative appeals process described in part 78 will extend to appeals of the Administrator's discretion to waive deadlines contained in § 73.37(f).

In addition to the claim of error process for allowance transfers, the administrative appeals procedure in part 78 can be applied to any decision or action by the Administrator under part 73.

(4) Authorized Account Representative Notification of Submissions

In part 72, EPA proposed that the designated representative provide each owner and operator with a copy of any Acid Rain program submission. EPA did not propose in part 73 that the authorized account representative notify all persons who have an ownership interest in the account of any Acid Rain Program submissions. This meant that non-unit account holders may be unaware of submissions made by their authorized account representative.

One commenter suggested that where the designated representative is engaging in a transfer that violates the binding agreement to represent the owners, EPA should temporarily halt the transfer for a period of time sufficient to obtain a temporary injunction pending resolution of the conflict.

Response: Under part 72 the designated representative is required to notify all owners and operators of any Acid Rain program submissions. In addition, § 73.33(b) of the final rule requires the authorized account representative to notify all persons who have an ownership interest with respect to the allowances held in the account of any part 73 or part 78 Acid Rain Program submissions by the date of the submission.

EPA is requiring such notification for all account holders for two reasons. First, where a transfer violates the binding agreement, requiring the notification will give an owner or a person with an ownership interest at least the period of time that it takes EPA to process and record the transfer to obtain a temporary injunction from a court. Second, because in some cases utilities will set up non-unit accounts to pool allowances, EPA believes this notification requirement is necessary to ensure that the owners and operators of the units in the allowance pool are notified. EPA is limiting this notification requirement to part 73 and part 78 submissions because the other parts are not relevant to non-unit accounts.

(5) Allowance Deductions for Units Sharing a Common Stack

In § 73.35(f) of the proposed rule, EPA planned to aggregate the allowances in the compliance subaccounts for all units governed by a common stack plan for purposes of deducting allowances to meet SO_2 emissions limitation requirements. Following the deductions, EPA would return any remaining aggregated allowances to each unit's account on a per capita basis.

EPA received one comment supporting the proposal. However, the commenter noted that the importance of this aggregation will be less if EPA proceeds with its non-unit account proposal.

Response: EPA reviewed and decided to modify the manner in which allowances are deducted for units sharing a common stack. Instead of aggregating allowances, § 73.35(e) of the final rule allows the designated representative to identify the percentage of allowances to be deducted from each unit's compliance subaccount. In the absence of such an identification, EPA will deduct an equal percentage from each unit's compliance subaccount. Of course, the designated representative still has the option to identify, by serial number, the specific allowances to be deducted. These specific allowances would be deducted first; then, if more allowances need to be deducted, the percentage would be applied.

EPA is making this change to conform to the unit-by-unit allocation and compliance provisions of the Act and the Acid Rain program. By aggregating the allowances as in the proposal, if one unit is in violation for excess emissions, then all are. However, this rule enables compliance and excess emissions violations to be determined on a unit-by-unit basis by applying a percentage for allowances to be deducted from each unit's compliance subaccount. Also, since EPA is proceeding with the non-unit account proposal, EPA agrees with the commenter that aggregating allowances is less important.

(6) Transfer Recordation—Non-recordation of Transfers

Four commenters requested EPA consider the date of recordation of a transfer to be the date it was originally received by EPA. They also requested that any subsequent claim procedures to correct the recordation of a transfer not affect the original date of recordation, which would be the original date of its receipt by EPA.

Response: Although EPA understands the commenters' concern that the original date of submission be acknowledged, EPA does not believe the date of recordation will have substantial impact on the effectiveness of any transfer agreements. The buyer and seller can arrange the date their agreement takes effect for legal purposes separately from the actual date of transfer of allowances by EPA. Therefore, EPA has not changed the rule, and the date of recordation will be the date EPA enters the information into the Allowance Tracking System. Any incomplete or inaccurate transfer forms

will be returned to the senders and will not be recorded. Resubmitted transfers will be treated as if they are a new transfer and the date of recordation will be the date EPA enters the information into the ATS. The original date of submission is not considered to be the date of recordation because resubmitted transfers are considered to be new transfers.

(7) Collection of Market Information

EPA proposed not to collect price and other terms of allowance transactions, and the rule is not changed from the proposal, despite some comments expressing concern on this issue.

Response: While EPA is not collecting information on price and other terms of allowance transfers, EPA is providing some market information by publishing the results of the annual auction and sale and by making the information contained in each allowance account available, in summary form, for public review. EPA recognizes that there are concerns about the availability of market information on allowances. EPA continues to believe that market information on allowances will be available through other public and private channels such as the Federal Energy Regulatory Commission (FERC) and futures exchanges. However, to address these concerns EPA will evaluate the allowance market and the availability of market information prior to Phase II to determine what action, if any, may be needed.

(8) Least Cost Planning

(a) Section 404(f)(2)(B)(iii)(II) of the Act requires qualified energy conservation measures or qualified renewable energy generation to be consistent with the applicant's least cost plan. Although this requirement was included in § 73.82(a)(5) of the proposal, it was inadvertently omitted from § 73.81(c)(2) of the proposal, which listed the requirements for approval of qualified renewable energy technologies not already listed in Appendix (B)(1) of the rule. Section 73.81(c)(2)(i) of today's rule has been corrected to include this requirement.

(b) One commenter questioned the relevance of the proposed rule's least cost planning requirement for independent power producers (IPPs) that make use of renewable energy. Generally, these units sell wholesale power to other utilities and are not subject to least cost planning requirements. The commenter suggested that it would be more meaningful to require these types of applicants to demonstrate that the renewable energy generation was *purchased* pursuant to the *purchasing* utility's least cost plan, which should be approved or accepted by the appropriate regulatory authority.

Response: EPA agrees with the commenter and has adopted the suggested change in § 73.82(a)(8). The Agency believes that this approach is more consistent with the actual operation of IPPs and with the intent of the Act.

(c) EPA proposed that if an applicant to the Reserve is not subject to the ratemaking jurisdiction of a State regulatory authority, its least cost plan must be approved and certified by the entity with rate-making authority for the applicant. The Agency also proposed that applicants not subject to the rate-making jurisdiction of an entity with ratemaking authority must apply to the Administrator for approval of the plan. Five commenters suggested that the rule language be clarified to specify that public power utilities not subject to State ratemaking authority have their plans approved by the appropriate local ratemaking authorities. In addition, several commenters noted that *all* utilities are subject to the rate-making jurisdiction of an entity with rate-making authority. These commenters suggested that EPA clarify that a least cost plan could be approved by any entity with rate-making authority.

Response: EPA agrees with the commenters' suggestion and has revised language in § 73.82(a)(6) and § 73.82(a)(7) of the final regulations to clarify that the least cost plan may be approved by any entity that regulates the rates of the applicant.

(d) EPA also received comments urging the Agency to revise the proposed rule so that the definition of an "approved" least cost energy plan includes least cost plans that are "accepted" by the State regulatory authority. The commenters suggest the change because some State regulatory authorities are unwilling to approve a utility's least cost plan out of concern that such approval will tie the hands of future State regulatory bodies. However, these State authorities will *accept* a least cost plan if it complies with the State regulatory authority's requirements.

One commenter also suggested that where States implement ratemaking and planning processes that are consistent with least cost planning principles, they should not need to have a formal "plan."

Response: The final rule contains two changes regarding the requirements for regulatory oversight of a utility's least cost plan. The first, in § 73.82(a)(6) and § 73.82(a)(7), would allow a commission to "accept" a least cost plan in addition to "approving" a least cost plan. The second change, in § 73.82(a)(4), would allow a utility to meet the least cost planning requirement if it has a least cost plan *or* a "least cost planning process."

(e) One commenter questioned EPA's requirement that least cost plans be subject to public notice and comment. The commenter stated that EPA should allow States to use alternative public participation procedures such as collaborative processes that allow public participation from interested groups.

Response: Section 73.82(a)(4) of the rule has been revised to require public notice and comment on a least cost plan *or* a comparable public participation process.

(9) Net Income Neutrality

EPA received comments on several issues related to the net income neutrality provision. The Agency has addressed these comments in consultation with the Department of Energy (DOE), which is responsible for certifying that an applicant's State regulatory authority has implemented provisions that meet net income neutrality requirements.

(a) Six commenters stated that the definition of and the requirements for net income neutrality should state explicitly that they only apply to investor-owned utilities (IOU). The commenters noted that public power utilities are non-profit and do not have "net income."

Response: EPA and DOE agree with the commenters and have added language to § 73.82(a)(9) of today's regulations that specifies that this requirement only applies to IOUs.

(b) One commenter argued that the three compliance approaches for net income neutrality specified in § 73.82(a)(9) do not, in and of themselves, constitute net income neutrality.

Response: EPA and DOE believe that the mere existence of one of these three mechanisms does not necessarily meet the net income neutrality requirement and that the specifics of each rate-making mechanism must be reviewed by the Secretary of Energy before a determination of net income neutrality can be made. Accordingly, § 73.82(a)(9)(ii) of today's regulations clarify this point.

(c) Three commenters stated that the proposal's definition of net income neutrality implies that utilities must use a "rate basing" accounting mechanism for recovering the costs of conservation programs. The commenters contend that the term "net income on book value"

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used in the definition suggests that conservation expenditures must be treated as a capital expense that should be included in the utility's ratebase. These commenters noted that many utilities use an "expensing" mechanism to recover conservation expenditures, a mechanism that does not add to utility book value.

Response: It was not the intent of the proposal to prescribe the type of cost recovery mechanisms that may be used for conservation expenditures. EPA and DOE believe that the choice of cost recovery mechanisms should be left to the discretion of utilities and their economic regulators. Therefore, the term "book value" has been deleted from the definition of net income neutrality in § 72.2 of today's regulations.

(d) Five commenters argued that the definition of net income neutrality should not imply that ratemaking procedures should *guarantee* that utility incomes will be no lower if investments in conservation are made. Rather, ratemaking procedures should provide the *opportunity* for utilities to earn a net income comparable to that which it would have achieved without the conservation programs. The commenters noted that under some shared savings incentive mechanisms the return received by some utilities depends upon the verified performance of their conservation investments.

Response: EPA and DOE agree that providing an opportunity for net income neutrality is consistent with the intent of the net income neutrality requirement. These regulations modify the definition of net income neutrality in § 72.2 to include State ratemaking approaches that provide for this opportunity based on performance-based results of conservation programs.

(10) Qualified Conservation Measures

(a) Three commenters stated that EPA should clarify or delete the requirement that there be no net increase in sulfur dioxide from qualified conservation measures. For example, one commenter noted the difficulty of determining the exact type and amount of fuel that might be avoided by the marginal energy savings of a particular conservation measure.

Response: EPA notes that it was not the intent of the proposed regulations to require such a detailed evaluation of the emissions impacts of given conservation measures. Rather, the requirement was directed towards measures that increase energy efficiency by utilizing industrial waste gases containing sulfur. EPA believes that where utilization of these waste gases does not lead to a net increase in sulfur dioxide (i.e., cases where the gas is already being flared), these measures should be considered qualified energy conservation measures. The Agency has modified language in § 73.81(a) and § 73.81(b) of the regulations to better reflect the intent of this provision.

(b) EPA received a comment that supported EPA's criteria for approving qualifying DSM measures not explicitly listed in the appendix to the regulations. However, the commenter explained that requiring specific approval of qualified conservation measures by the applicable State regulatory authority or by the Administrator may stifle flexibility to install innovative measures.

Response: The final rule, therefore, states in § 73.81(a)(2) that EPA will deem as qualified each conservation measure installed pursuant to a conservation *program* and approved by the relevant authority, as long as it meets the criteria listed in § 73.81(a) and is not an excluded measure under § 73.81(b).

(11) Applicability for CRER

(a) EPA proposed that an applicant would be eligible to apply to the Reserve if "any subsidiary of the applicant" owns or operates an affected unit. One commenter argued that eligibility should also extend to any subsidiary of the applicant's *holding company* that owns or operates an affected unit, either in whole or in part.

Response: EPA agrees that this change reflects the language and intent of the Act, and § 73.82(a)(2) of today's regulations reflect this change.

(b) EPA also proposed that an applicant would be eligible to apply for the CRER if it is a utility or an industrial customer that purchases power from an affected unit under a "life-of-the-unit" firm power contract.

Response: The Agency now believes, however, that it would be contrary to the intent of the Act to allow industrial customers that purchase power from affected units to qualify for the Reserve. Section 404(f)(2)(A) clearly requires that an applicant to the Reserve be an "electric utility", which is defined in section 404(f)(1)(C) as any person, State agency, or Federal agency, which sells electric energy. Since industrial customers with a life-of-the-unit contract *buy* electricity, rather than *sell* electricity, they would generally not meet the definition of an electric utility. Consequently, § 73.82(a)(2) of these regulations deletes industrial customers from the language describing the types of eligible applicants to the Reserve.

(12) Application Requirements

(a) EPA proposed that applicants to the Reserve must pay in whole or in part for qualified conservation measures or qualified renewable energy generation, either directly or through payment to another person. The Agency also proposed that the applicant must specify the amount spent on the conservation measure or renewable energy generation. One commenter argued that in the case of renewable energy generation produced by independent power producers, these expenditures are proprietary information that should not be disclosed.

Response: EPA now believes that information on expenditures of both renewable energy generation and qualified conservation measures are unnecessary. Rather, EPA will require in § 73.82(a)(3) that applicants to the Reserve certify that they have paid for the qualified conservation measures or qualified renewable energy generation.

(b) EPA proposed to allocate allowances from the Reserve for qualified renewable energy generation purchased or generated by an applicant. One commenter stated that EPA should allocate allowances for qualified renewable energy generation only to utilities purchasing such generation, rather than to the generating utilities. The commenter argued that such a policy would provide the strongest incentive for the development of renewable energy.

Response: EPA believes that the commenter's suggestion would be contrary to section 404(f)(2)(F) of the Act, which clearly provides for allocation of Reserve allowances to *both* purchasers and generators of qualified renewable energy generation. However, EPA has added language to § 73.84(g) of these regulations that would prevent the generator and the purchaser of the same renewable energy generation from receiving allowances from the Reserve based on the same kilowatthours of electricity generation and the same avoided emissions. These regulations provide that these applications would be processed and approved in order of the date of receipt. If applications based on the same renewable electric generation are received on the same date, allowances awarded will be divided evenly between all the relevant applicants unless the Administrator is otherwise directed by all applicants. EPA strongly encourages qualified generators and purchasers of the same electricity generated by qualified renewable energy technologies to coordinate their applications to the

Reserve to avoid confusion over allowance awards.

(c) EPA proposed that applications to the CRER be submitted to the Administrator beginning on January 1, 1993. Eleven commenters suggested that EPA delay this date to allow time for more accurate verification of conservation savings. Commenters had a variety of suggestions for how long to delay the application date, ranging from three to twenty months. Three commenters supported the January 1 date or suggested minor modifications.

A number of commenters argued that since the allowances from the Reserve are allocated on a first-come-first-served basis, there will be pressure to send in applications to the Administrator before complete and accurate verification of conservation savings can be fully assured. Commenters noted that verification of conservation savings is time consuming, particularly verification of savings resulting from complex conservation programs. The commenters also noted that a January 1 application date leaves too little time for verification of savings by State regulatory authorities.

Several commenters argued that an early application deadline penalizes utilities that use more rigorous (and time consuming) verification methods such as metering, bill analysis, and statistical models. Utilities that use simpler and potentially less accurate engineering estimates would be able to apply for allowances sooner. Several commenters also noted that an earlier application date would give an unfair advantage to publicly owned utilities, which are not required to go through state review and verification processes before submitting their applications to EPA.

Response: EPA believes that delaying the application date will encourage good verification of energy savings. The Agency recognizes that evaluation of energy savings requires time for data collection and analysis. Although States are not required to file their applications on the application date, there would be an advantage to filing earlier because allowances are awarded from the Reserve on a first-come-first-served basis. Moreover, because EPA is not mandating a single verification methodology, there could be an unfair advantage for utilities in States that allow verification methodologies that take less time to implement.

The Agency believes that a delay of the application date by six months would provide a reasonable amount of time for States and utilities to complete verification of energy savings. Therefore, § 73.82(g) of these regulations allow utilities to submit applications beginning July 1, 1993, and on July 1 of each subsequent year for the savings achieved in the previous year. (For example, an applicant could apply for savings achieved in 1993 on July 1, 1994.)

Because these rules delay the annual application date by six months to allow more time for verification of savings, EPA believes it is now more likely that the Reserve will become oversubscribed by more than one applicant on a single day than was anticipated under the proposal. (EPA does not anticipate that an oversubscription will occur during the first several years of applications.) A January 1 application date would have led to a more gradual stream of applications over the first part of the year as utilities and their State commissions completed verification of the previous year's energy savings at different times.

Accordingly, § 73.84(f)(1) of the final rule provides that in the event that the Reserve becomes oversubscribed by more than one applicant on a single day, the allowances remaining in the Reserve will be distributed on a pro rata basis. EPA believes that this method for allocating allowances is administratively simple and is appropriate for the Reserve. EPA also considered other methods, such as a lottery, for allocating allowances from the Reserve when it is oversubscribed. However, unlike the Phase I extension provision where 100 percent of the incentive allowances are expected to be claimed on the first day of application, EPA expects that a relatively small portion of the Reserve allowances will remain when it becomes oversubscribed. Thus, because of the relatively few allowances at stake, EPA does not believe that the extra administrative burden of a public lottery would be merited.

F. Return of Auction and Direct Sale Proceeds Under Subpart E

Under subpart E, which was previously published as 40 CFR part 73, in 56 FR 65592–65607, December 17, 1991, EPA must return the proceeds from the auction and direct sale within 90-days of the conclusion of the auction or sale. EPA is planning to return the proceeds by sending a proceeds check to the designated representative for each unit. Until the unit has filed a certificate of representation for the designated representative under subpart B of part 72, EPA will not know the person to whom the proceeds check must be sent. Therefore, EPA will hold the proceeds check until a certificate of representation is filed with EPA. Because EPA will be selling allowances in the advance auction that are taken from Phase II units, and because EPA cannot pay any interest on the proceeds, Phase II units are encouraged to submit a certification of representation for the designated representative before the first auction in March 1993.

V. Discussion of Changes to Part 75—Continuous Emissions Monitoring

This part of this final rule explains the major changes made to part 75, the proposed Continuous Emissions Monitoring (CEM) rule, in response to public comment.

Some structural changes are incorporated into the final CEM rule. First, many of the general provisions contained in subpart A of the proposed CEM rule, such as definitions and abbreviations, have been consolidated for the Acid Rain Program in subpart A of part 72. Second, the proposed rule had only two subparts (A—General and B—Standards); the final rule recognizes that many of the provisions can be grouped functionally into several subparts: subpart B—Monitoring Provisions, incorporates §§ 75.11–75.16 from the proposed rule; subpart C—Operation and Maintenance Requirements, incorporates §§ 75.18–75.20, as well as the procedures for proposing alternatives to the ASTM methods that were originally contained in § 75.21 in the proposed rule; subpart D—Missing Data Substitution Provisions, consolidates the missing data procedures that were located throughout the monitoring provisions, §§ 75.12–75.16 in the proposed rule; subpart E—Alternative Monitoring Systems, incorporates the provisions originally contained in § 75.21 in the proposal; subpart F—Recordkeeping Requirements, incorporates the provisions originally contained in § 75.22; and subpart G—Reporting Requirements, contains the provisions in § 75.23.

While the Appendices have not been reformatted, two new appendices have been added: A new Appendix E (Optional NO_x Emissions Estimation Protocol for Gas- and Oil-Fired Peaking Units), as well as Appendix G (Optional determination of CO_2 Emissions). These appendices were created for this final rule, in response to comments. As a result, the old Appendix E from the proposed rule (Conversion Procedures) has been moved in the final rule to Appendix F.

In the final rule the term "designated representative" now often appears in places where the term "owner or operator" appeared in the proposed rule. As the official responsible for

meeting the reporting requirements under the Acid Rain Program, the designated representative represents the owner and operator when reporting is required. The term "owner or operator" is used in the final rule when action is specifically required at the source.

Overall, the proposed CEM rule received more than 2,700 comments, or approximately 35 percent of the total number of comments received on the proposed core rulemaking package. Approximately 70 percent of the comments received on the proposed CEM rule fell into eight major issue categories: certification and recertification, relative accuracy and Relative Accuracy Test Audits, bias test and bias adjustment factor, flow monitoring, alternative monitoring systems, missing data procedure, exceptions to monitoring with CEMS, and Quality Assurance/Quality Control issues (including calibration testing). Responses to public comment on these major CEM rule issues are discussed below.

A. Certification and Recertification Issues

There were numerous comments related to the certification and recertification of CEM systems. The comments fell into roughly two broad comment categories: notification and Administrator response requirements, and recertification. The EPA's intent is to foster a cooperative environment where the sources seek to initiate, and work through, the process of certification as soon as possible with the appropriate certifying Authorities. The EPA believes that this cooperative effort involving frequent and open communication between sources seeking certification and the certifying authorities will facilitate the start up of the program.

(1) Notification Requirements and Administrator Response

Issues: A number of commenters indicated that the time needed for the Administrator to respond to a certification request coupled with a 30 day notification-of-testing requirement along with, at a minimum, a 7 day certification test would force sources to initiate a CEM certification almost 6 months in advance of the deadline by which the Act states a CEM must be certified. Commenters also indicated that it was unclear as to the procedures a source could follow if, during the course of a certification test, a unit was determined to be failing that test or what to do in the event certification test dates need to be adjusted after notifying the appropriate authorities. Furthermore, commenters had concerns with the requirements placed on new units that would be coming online in the future.

Response: EPA has clarified in the accompanying rule when a new unit would need to be certified. This requirement is based upon an analysis of the intent of the Act to account for all emissions from affected sources in a two phased approach and with the recognition that not all affected sources will be operating prior to January 1, 1995. Furthermore, this rule takes into account the comment that some types of units that will be affected can be brought online and turned over to the dispatcher in a relatively short period of time and that units typically need to burn some fuel prior to a time when a CEM system can be in and certified.

EPA analyzed the reporting, notification, and approval procedures, time frames, and burdens on the sources and governmental resources in response to the comments received. EPA has modified the certification forms and process to include more interaction between sources and agencies, however the overall time that this rule is reserving for notification of testing and review of completed certification submittals has been *reduced* relative to the statutorily mandated deadlines for units to have certified CEM systems operational. EPA analysis indicates that the new procedures and forms will require 45 days to properly review at a minimum and should, therefore, be submitted at least that far in advance of the commencement of certification testing. However, EPA believes that (and actively encourages) the cooperative procedures developed will actually be initiated far in advance of 45 days and proceed in a series of logically derived steps that will culminate in a fully successful certification.

This cooperative, multi-step process also leads the agency to believe that monitors can be provisionally certified upon the successful completion of certification testing and that if a unit is determined to be failing a certification test that a new series of tests can be commenced immediately as part of the certification effort. The Administrator will still need to reserve the full 120 days from receipt of a complete certification request to perform analysis of test results before a final notice of certification can be served to a particular CEM system; however, all data collected from a provisionally certified system that is subsequently fully certified is valid data and provisional certification meets the requirements of the Act with respect to the dates by which units must install and operate CEMS, quality assure the data and keep records and reports.

For this reason, EPA has determined that the certification testing must be completed and the system(s) must have initiated full, quality assured operation by the statutory deadlines. However, the unit may submit its certification request complete with the required test reports up to 30 days thereafter. This change accommodates the time normally necessary to prepare those reports and the request. The Administrator's review will take place within 120 days of receipt of the complete package. Additionally, if a future audit of the system (a certification report) uncovers a discrepancy or poor performance that requires recertification of the CEMS, the emissions will be determined using the appropriate missing data procedures, prospectively, upon receipt by the owner or operator of the Agency's determination until the recertification testing is successfully completed.

EPA believes that these modifications fully address the commenters concerns while addressing the legislative mandates and insuring the integrity of a CEM system certification.

(2) Recertification

Issues: A number of issues were raised by commenters related to recertification. Among the issues raised was that it was unclear as to what actually triggered the need for a recertification, the time needed to notify of recertification testing, approval time needed, recertification time-frames in the event of an emergency, and the types and numbers of tests required for recertification.

Response: EPA has further clarified the sentence in the proposal that indicated when recertification becomes necessary. Essentially any change, other than routine maintenance or quality assurance activities, that affects the monitors measuring systems or analysis systems in such a way that measurements or calculations have changed, or potentially could have changed significantly, triggers a recertification. The EPA continues to feel that the nature of Title IV and its reliance on strict accountability of all emissions necessitates a reliance on certified measurement devices and calculation methodologies, hence, forcing the agency to require recertification whenever either or both of these items are significantly modified in any particular CEM system.

EPA is persuaded by public comment and analysis that the notification of recertification testing dates should be shortened to 7 business days prior to the commencement of a scheduled

recertification testing period and that in the event of emergency testing (e.g. testing due to significant repairs after a lightning strike or tornado damage to a CEM) notification should be made to the appropriate authorities no later than 2 working days following the emergency and indicating when testing is expected to be completed. EPA believes that this compromise addresses the commenters concerns about monitor availability and the long lead times that would put data obtained during this time into an uncertain state as to acceptability while also preserving the needs of the regulating authorities to be aware and available for a cooperative effort to recertify as quickly as possible while preserving the intent of the Act to account for all emissions.

B. Relative Accuracy and RATA Testing

(1) Relative Accuracy Standards for SO_2 and NO_x

(a) Normal emitters. The proposed rule required SO_2 monitors and NO_x monitoring systems to meet a 10 percent relative accuracy (RA) standard in Phases I and II of the Acid Rain Program. Some commenters argued that the 10 percent standard was, at best, premature and, at worst, too stringent, and that it would result in high failure rates due to the variability of the reference method, leading to wasted resources for retesting. They proposed that the standard should be set initially at 15 percent. Other commenters indicated that the standards were either achievable or not sufficiently stringent.

Response: The EPA analyzed data from relative accuracy test audits (RATAs), conducted during 1984–1990 at non-low-emitting subpart Da units. ("Subpart Da" units refer to electric utility fossil fuel steam generators, covered under 40 CFR part 60, subpart Da of the New Source Performance Standards (NSPS).) This analysis indicates that SO_2 CEMS, measured in ppm, achieved the 10 percent standard in 89 percent of the RATAs, even though meeting a 10 percent relative accuracy standard was not required. Extensive field tests at one unit confirmed these results. In relative accuracy testing performed over a 9 week period, the installed SO_2 CEMS, measuring in ppm, passed the 10 percent RA standard in 98.2 percent of the RATAs constructed from 176 runs conducted at the test site. These results were obtained by moving a 12-run window through the 176 runs and applying the test procedures prescribed in the proposed regulations. For each incrementing of the window, relative accuracy results were computed, producing a total of 165 RATA tests for the entire data stream. This procedure revealed that 95.8 percent of the RATAs achieved RA ≤7.5 percent, and 82.4 percent of the RATAs achieved RA ≤5 percent. Comparable results for the NO_x CEMS measured in lbs/MMBtu were 100 percent achieving RA ≤10 percent; 97.6 percent achieving RA ≤7.5 percent; and 86.7 percent achieving RA ≤5 percent. EPA believes that these test results support the proposed 10 percent RA standards for both SO_2 and NO_x, which are retained in the final rule.

(b) Low emitters. For SO_2 concentrations less than or equal to 250.0 ppm, the proposed rule allowed use of an alternative accuracy standard: The mean of the CEMS measurements had to be within ±15.0 ppm of the reference method mean. Commenters pointed out that low emitting units should have the option of using either the normal relative accuracy standard or the alternative standard. They also noted that the low emitter accuracy provision should be added to the "out-of-control" provisions in appendix B.

Response: EPA agrees. For units whose monitor measurements of SO_2 during the RATA are close to 250.0 ppm, the ±15 ppm specification could represent a more stringent standard than the 10 percent RA specification. This is not intended. Therefore, the final rule clarifies that either the low SO_2 emitter accuracy standard or the normal SO_2 RA standard can be used. As the commenters recommended, the low SO_2 emitter accuracy standard has been added to the "out-of-control" provisions in appendix B.

The proposed rule also allowed use of an alternative accuracy standard for NO_x emissions less than or equal to 0.50 lb/MMBtu: The monitoring system mean had to be within ±0.05 lb/MMBtu of the reference method mean. A number of commenters noted that the low NO_x emitter threshold of 0.50 lb/MMBtu must be in error, because it is the same level as the statute's presumptive NO_x limit for wall-fired boilers and is higher than the 0.45 lb/MMBtu limit for T-fired units. The proposed low NO_x emitter threshold would, in effect, define all units affected by the NO_x emission limits as low NO_x emitters.

Response: Clearly, this was in error. In the final rule the low NO_x emitter accuracy standard is revised as follows: For units emitting less than or equal to 0.20 lb/MMBtu NO_x, the NO_x monitoring system mean must be within ±0.02 lb/MMBtu of the reference method mean value. This is analogous to the low-emitter accuracy standard for SO_2. Similarly, the low NO_x emitter accuracy standard has been added to the "out-of-control" provisions in appendix B.

(2) SO_2 and NO_x RATA Frequency

For SO_2 and NO_x CEMS, the proposed role required semiannual RATAs, except when an SO_2 monitor or NO_x monitoring system achieves a RA of less than or equal to 7.5 percent. In such cases, the proposal extended the time period for the next RATA to 12 months instead of six. Many commenters supported the proposed RATA frequency incentive system, which linked decreased RATA frequency to superior RA test results. These commenters suggested expanding the incentive system to include low emitters. There were, however, a number of commenters who categorically opposed requiring a RATA more often than annually, whether there was an incentive system or not. They maintained that more frequent RATAs would not improve the accuracy of CEMS data and would be unnecessarily costly. Still other commenters proposed basing RATA frequency on results of daily calibration error tests rather than on RATA results.

Other commenters supported requiring quarterly RATAs until test results justified less frequent RATAs. One group maintained that RATA tests were snapshots and that a series of tests, over four quarters, showing consistent or steadily improving results was a better indicator of CEMS performance than one RATA per year. This commenter supported a phased approach that would require quarterly RATAs for all Phase I affected units with less frequent testing in Phase II, pending Phase I results. This commenter also recommended adoption of an incentive-based system that would credit and debit allowances, based on a unit's performance compared to the best performers in the industry.

Response: Alter considering the range of comments, EPA has decided to retain the RATA frequency and incentive system as proposed and to provide an analogous incentive system for low-emitters. Extending the incentive system to units where SO_2 concentrations are low should stimulate improved RA, while reducing the frequency, and hence cost, of performing RATAs at these units. As designed, the low SO_2 emitter incentive system should yield the same proportion of less frequent RATAs as the incentive system for normal SO_2 emitters. If a unit's mean SO_2 concentration is less than or equal to 250.0 ppm and within ±8.0 ppm of the reference method mean, the next required RATA test would be required in 12 months rather than six.

The Agency decided not to base the RATA frequency on the daily calibration error test results, as suggested, because calibration error tests do not test CEMS for many potential sources of error, making them an inappropriate basis for determining RATA frequency. EPA also rejected the suggestion of universal or phased-in quarterly RATAs, as imposing a greater financial and regulatory burden on industry than necessary, without significantly improving the accuracy of the emissions data. Finally, the allowance-based incentive system proposed by one commenter appears to be a promising approach but would be too complex and difficult to implement, particularly considering the time requirements imposed by statutory deadlines.

(3) Combined SO_2-Flow

The proposed rule stipulated that, starting on January 1, 2000, the combined SO_2-flow monitoring systems would have to meet a 10 percent RA standard. Many commenters criticized this proposed combined relative accuracy test. These commenters stated that because each monitor is required to also pass QA/QC tests individually, the combined RA is merely a mathematical exercise, which, judging from existing data, is technically insupportable and likely to yield erratic and meaningless results. These commenters also maintained that the combined RA test was redundant, unnecessary, and could lead to expensive and needless re-testing. Others argued that the 10 percent combined RA standard may not be achievable in light of measurement errors associated with reference method procedures and that any future combined SO_2/flow RA standard should not be less than 20 percent. One commenter stated that the proposed 7-day certification test for the combined SO_2/flow system would be costly and impossible to pass. Several other commenters recommended that EPA defer promulgating a combined SO_2/flow RA standard until more data was obtained.

However, supporters of the combined RA test were numerous. These commenters maintained that the combined standard would result in more accurate data. Among their proposals were starting the requirement in 1995 rather than in 2000, requiring a combined SO_2/flow RA standard more stringent than 10 percent in Phase I so that the allowance system would not be compromised, requiring a lb/hr RA for SO_2 and a lb/MMBtu RA standard for NO_x, rather than individual monitor RA's, and establishing an alternative combined standard for low emitters.

Response: EPA believes that both individual SO_2 and flow monitor measurements and combined lb/hr SO_2 values derived from those measurements should meet explicit and verifiable accuracy standards. Flow monitor data should meet accuracy standards because, in addition to lb/hr calculations, it is used: (1) In calculating heat input (for reduced utilization), (2) for missing data procedures, and (3) for calculating NO_x penalties. SO_2 monitor data should meet accuracy standards because, in addition to lb/hr calculations, it is used for missing data procedures. The lb/hr values should meet accuracy standards because they are the ultimate measure of environmental impact and the basis for determining compliance with allowances held.

At the same time, EPA agrees with comments noting that there is currently insufficient data to establish a definitive combined SO_2/flow relative accuracy standard. Therefore, EPA is deferring promulgation of a specific combined relative accuracy standard in the final rule, while reserving a section in part 75 for future promulgation of this standard once sufficient data has been accumulated. EPA believes that a combined SO_2/flow RA requirement is an important additional indicator of system performance.

Twenty percent relative accuracy is widely acknowledged as an achievable baseline standard for combined relative accuracy performance, that is in keeping with the combined standard established in EPA's Performance Specification 6 (Appendix B, 40 CFR part 60). Preliminary test data from state programs employing Performance Specification 6 indicate that combined relative accuracies below 10 percent are routinely achieved. In addition, simulation analysis shows that units whose flow and pollutant concentration monitors individually achieve relative accuracies of 10 percent or better almost invariably will meet a relative accuracy standard of 15 percent on the combined test. The EPA is fully committed to promulgating a combined standard once sufficient data has been obtained and evaluated under Phase I of the Acid Rain Program.

(4) Bypass Flues and Peaking Units

The proposed rule would have subjected CEMS on bypass flues and peaking units to the same RATA frequency (quarterly, semiannual or annual) as those on normal stacks and baseload units. Several commenters argued that CEMS on bypass stacks should only have to perform annual RATAs. These commenters also suggested defining RATA testing frequency in terms of unit operating hours, rather than calendar time, and postponing RATAs until the bypass stack was next called into regular operation. Another commenter stated that the final rule should not require a unit to be operated or a pollution control system to be bypassed just to conduct a RATA, since this would result in unnecessary emissions and loss of allowances and might cause a unit to violate its operating permit.

The same commenters and several others noted that it would be very expensive and create needless pollution to run low capacity factor "peaking" units just to conduct RATA tests. These commenters recommended basing a peaking unit's RATA frequency on unit operating hours and performing RATAs on peaking units every two operating years.

Response: EPA agrees that it is not desirable to require a pollution control system to be bypassed solely to perform a RATA. However, the statute requires monitoring of emissions from all affected units and enforcement of performance standards that guarantee accurate emissions measurement.

To reduce the overall time required to perform RATAs on monitors at peaking units and bypass stacks, the final rule requires only a one-level RATA to be performed on flow monitors on peaking units and bypass flues instead of the usual 3-level RATA. EPA believes that it should be possible to schedule RATAs during the normal operation of peaking units and bypass stacks through careful advanced planning.

C. Bias Test and Bias Adjustment Factor

Accuracy in emissions measurements is essential to the complete accounting of all SO_2 and NO_x emissions reductions, stipulated in the Clean Air Act Amendments, and to the effective functioning of SO_2 allowance trading. Consequently, the acid rain regulations proposed that each CEMS satisfy two complementary statistical tests for accuracy both at initial certification and during periodic quality assurance performance evaluations: (1) A relative accuracy test to ensure that all sources of monitor error (both random and non-random) fall below a specified percentage of the average reference method measurements; (2) a bias test to determine if a monitor is measuring consistently low. These two tests are applied to emissions data obtained during the relative accuracy test audit (RATA), a field test procedure that compares at least nine monitor

measurements to contemporaneous measurements by an EPA specified monitoring reference method.

To determine whether a CEMS is measuring consistently low, the bias test relies on the well-established t-test at 95-percent confidence level, applied here to low bias only. The t-test, specified in these regulations, is constructed to ensure that there is at most a 2.5 percent probability of mistakenly detecting low bias during the RATA test.

When low bias is detected, operators have two options: they can remedy the causes of the low bias by fixing a faulty monitor, correcting installation problems, or improving operator practices that may be contributing to the consistently low measurements. Alternatively, they can elect to apply a bias adjustment factor to subsequent emissions measurements reported to EPA. The bias adjustment factor is a multiplier, calculated from RATA data, whose magnitude is directly proportional to the degree of low bias detected during the RATA performance test.

(1) Bias Test

(a) Overview. The EPA received comments both supporting and criticizing the proposed bias test. Numerous commenters supported the proposed bias test as an essential element of a monitoring program. Many others proposed dropping the bias test, arguing that daily quality control procedures offered sufficient safeguards against monitor bias. Still others supported a t-test for bias, but advocated that it be based on data from the daily calibration error test rather than from the RATA test. Some of the commenters, who either opposed the bias test entirely or proposed basing it on calibration data, also advocated applying the RATA-based bias test only at initial monitor certification. Subsequently, they would rely exclusively on quality control procedures or the calibration-based bias test to prevent low bias. Another proposal, by the commenters advocating the calibration-based bias test, was to drop all bias testing requirements when relative accuracy test results fell below some threshold value.

Response: After carefully evaluating each commenter's proposal, data provided by the commenters, data independently collected by EPA, and statistical theory, EPA has decided to retain the proposed t-test for bias and the bias adjustment factor. The EPA's analysis of the specific comments on the bias test is summarized below.

(b) Long-term validity of bias test. Some commenters challenged the ability of a t-test, based on a 4–8 hour RATA, to determine whether a CEMS was producing consistently low measurements (i.e., bias) over the long run. They maintained that a bias test, based on RATA data, was only a snapshot that would produce inconsistent results if performed on the same monitor on successive days. To support their argument, they provided bias test results from two plants.

Response: The EPA found one of the commenter's data sets inadequate. EPA believes that the data was not sufficiently extensive to support the commenter's argument, since it consisted only of a total of six RATAs: Two successive RATAs conducted on August 18–19, 1987, May 26–27, 1988, and September 20, 22, 1988. Further, there was insufficient documentation to determine whether the variability in the test results was due to the test procedure or factors that may have introduced bias into the system. To analyze the long-term variability of bias test results, the factors subject to variation must be strictly controlled or, at least, documented. If factors such as monitor location, operating procedures, and unusual interventions (e.g., lightning strikes) vary from test to test, then variations in test results may not reflect variability inherent in the statistical test but variability in the monitoring environment that may have produced systematic error reflected in the bias test results. Without additional documentation it is not possible to determine whether changes may have occurred that could have introduced bias into the system.

The second set of bias test results cited by the commenter contradicts the commenter's contention: the same flow monitor consistently failed the bias test in RATAs performed on four successive days. While the commenter argues that the test results show that the bias adjustment factor is "unstable," the results clearly do not support the commenter's position on the variability of bias test results.

The t-test is a well established and widely accepted statistical procedure for detecting bias. As noted above, the statistical premises underlying the form of the t-test specified in the regulations limit the likelihood of mistakenly detecting low bias to no more than a 2.5 percent probability. Thus, a high degree of assurance is built into the test itself that, over the long run, this statistical test will detect bias that is actually present in the system, not "random measurement error" as the commenter claims.

In the preamble to the proposed rule, it was noted that EPA collected and analyzed data from RATAs performed between 1984 and 1990 primarily at units subject to Subpart Da requirements and found that 70 percent of the SO_2 RATAs, measured in ppm, passed the proposed t-test for bias. These results were obtained from RATAs performed at a time when CEMS technology and operational experience were in an earlier stage of development than they are today.

An extended field test at one unit also reflected consistency in the bias test results. Following the calculation procedures prescribed in the proposed regulations and moving a 12-run window through a 176-run data stream, 165 RATAs were produced for the 9-week testing period. The bias test pass rate was 73.3 percent for the SO_2 CEMS, measured in ppm, and 99.4 percent for the NO_x CEMS, measured in lbs/MMBtu. Bias test failures were clustered, not randomly distributed, along the data stream, providing a further indication that the t-test was detecting actual systematic error, not random measurement error. It is also noteworthy that 98.2 percent of the SO_2 CEMS and 100 percent of the NO_x CEMS passed the 10 percent relative accuracy test.

In the preamble to the proposed rule, EPA noted that "it can be assumed that subsequent improvements in monitor technology will yield even better performance on the bias test." RATA data, submitted to EPA for a new CEMS technology, based on ultraviolet/differential optical absorption spectroscopy, convincingly supports this prediction and displays consistency in the bias test results. Of the 16 RATAs performed on this monitoring system, 87.5 percent passed the bias test, while achieving an average relative accuracy of 6.9 percent.

Thus, EPA believes that both statistical theory and field test results show that the bias test is a sound and effective statistical procedure for detecting consistent measurement error in the long-term operation of a CEMS.

It should be noted, however, that EPA is sympathetic to the commenter's concern that data used in the bias test be "sufficiently representative of long-term monitor performance." From a strictly statistical standpoint, the larger the sample size, i.e., the longer and more frequent the RATA, the more representative the RATA will be of long-term monitor performance. For this reason, EPA considered requiring quarterly RATAs in all cases. However, the agency chose to balance statistical considerations against the burden

imposed on the regulated community. The agency believes the 9-run RATA supports statistically credible results at the least cost to society.

(c) Impact of reference method variability on the bias determination. Some commentators argued that inherent variability in the reference method performance could inappropriately cause CEMS to fail the bias test even when the CEM measurements were not biased relative to the true emissions concentration. They argued that the variability among reference monitors should be accounted for by adjusting the t-test. The potential for a CEMS to fail the bias test by being compared to a certified reference monitor was investigated in the above referenced field study. In this study, RM measurements were taken simultaneously by four laboratory test teams, and compared with an operating plant CEM. The field results demonstrated that the low bias test results were consistent, regardless of the particular reference monitor chosen. Further, the variation associated with RM-to-RM comparisons exhibited good reproducibility, suggesting that laboratory variability did not inappropriately influence the bias determination. This result is encouraging, and strongly supports the choice of the RMs and its use. However, detailed review of the RM data produced some troublesome results that warrant concern. While the variance across RMs relative to the mean difference in RM readings was low, bias could be calculated between the different reference monitors (in as many as 50% of the comparisons). Concern has been expressed that the high frequency of bias in comparisons among reference monitors occurred despite the reproducibility of results among reference monitors noted above because of low variance in reference method test data. Additionally, some commenters expressed concern that bias was triggered at lower emissions levels (below 200 ppm).

While the Agency currently supports the bias test, the data suggest that further study is appropriate. The Agency, in consultation with the Department of Energy, will initiate additional field studies as soon as possible to determine whether there are statistically significant variances in the reference monitors. These field studies will attempt, among other things, to distinguish between the variability in the reference monitor reading attributable to measurement error and the variability due to the choice of reference moritor among those certified by the agency. The studies will also assess whether any adjustments indicated are technically unnecessary or infeasible to properly determine bias. Finally, the field studies will also investigate possible differences in bias test failure rates by emissions concentration levels. The Agency will initiate the field studies as soon as possible to determine whether the bias test should be adjusted to compensate for statistical variances in the reference method. These studies will be completed by October 31, 1993. Within 90 days of the completion of the studies, the Administrator shall publish by notice of proposed rulemaking in the **Federal Register** his determination of whether there should be an adjustment of the bias test. The rulemaking shall be completed within 9 months thereafter. EPA will also adjust the t-test used to certify alternative monitoring systems if a bias t-test adjustment is made.

(d) Statistically significant vs. practically significant measurement differences. Some commenters argued that the paired t-test may identify measurement differences between the CEMS and reference method that are statistically significant but that are not necessarily practically significant.

Response: The fact that the bias adjustment factor is directly proportional to the magnitude of the measurement differences ensures that sources will not be unfairly penalized for differences that are not practically significant. If, as the commenter contends, the measurement differences are not practically significant, then it follows directly from the commenter's argument that the bias adjustment factor will not be practically significant, and, consequently, the adjustment of subsequent measurements will also not be significant.

(e) Bias test results for volumetric flow monitors. Several comments specifically questioned the application of the bias test to flow monitors. They maintained that the proposed bias test was beyond the current capabilities of volumetric flow monitors. They noted that less than 30 percent of the RATAs in EPA's pre-proposal flow monitor database passed the bias test.

Response: A number of utilities have subsequently provided EPA with field test results from 56 additional flow monitor RATAs, bringing the total number of RATAs in the database up to 73 from the original 17. In evaluating the tests included in this database, several considerations are relevant. The flow monitors in this database were not long-standing installations, but were still in a shake-down phase where various utilities were evaluating competing brands in anticipation of purchasing one of them. Thus, several competing flow monitors were installed on a single stack and put through their paces under extreme testing conditions, without the benefit of installation fine-tuning that would accompany an actual installation. Shake-down testing of this kind produces poorer test results than can be expected when the selected monitor is finally installed and many of the problems that emerged during shake-down are corrected. Furthermore, because gas stratification is so important in measuring volumetric flow and each site has a unique stratification profile, flow monitor performance tends to be very installation specific. As a result, it is not uncommon that one monitoring technology performs well at one unit, while a different technology is better suited for another unit.

With this in mind, it is noteworthy that at each utility unit where multiple brands of flow monitors were tested, at least one flow monitor model had a bias test pass rate of better than 80 percent. In fact, at four of the five utilities testing multiple brands of flow monitors, at least one monitor model had a 100 percent pass rate on the bias test. Excluding one manufacturer's monitor that appears to have had recurring difficulty eliminating low bias, 65.1 percent of the remaining 43 RATAs passed the bias test.

These test results provide additional support for EPA's conclusion that the bias test performance standard is within the technical capabilities of current flow monitoring technology.

(f) Exemption from bias test. Some commenters proposed retaining the bias test but exempting units that achieve excellent results on the relative accuracy test.

Response: EPA does not support this suggested exemption. Under the proposed regulations, units were already rewarded for excellent relative accuracy results by being allowed to perform less frequent RATAs. Because bias represents systematic rather than random error, it is correctable and, therefore, should be eliminated to ensure that the monitoring program provides the level of accuracy required for compliance with the emissions standards mandated by the Clean Air Act Amendments and for effective functioning of the allowance trading program.

Furthermore, waiving the test for low bias could have serious environmental consequences even when relative accuracy is very low. As its name implies, relative accuracy reveals the proportional relationship between inaccuracy in the CEMS and the average emissions level of the unit being tested.

For high emitters, e.g., units whose mean SO_2 emissions concentration could measure as high as 3000 ppm, the absolute magnitude of the inaccuracy may be environmentally significant, even though its relative size (i.e., the relative accuracy) is small. Thus, excellent relative accuracy can obscure the presence of environmentally consequential and operationally correctable inaccuracy that only the bias test will reveal.

(g) Daily calibration error test and periodic quality control (QC) instead of the bias test. One commenter called for replacing the proposed bias test with "the daily calibration error test and periodic QC."

Response: EPA supports the use of the calibration error test and periodic QC as important components of a comprehensive quality assurance/quality control (QA/QC) program. However, by themselves QA/QC procedures and calibration testing can neither detect nor eliminate many important sources of bias. For example, calibration testing is unlikely to detect bias attributable to incorrect calibration gas values, uncorrected sensitivity to pressure and temperature, non-representative sampling, interferences from flue gas constituents, or scrubbing by precipitates on the particulate filter. Without a means to detect these sources of bias, QA/QC procedures would be blind to their presence and would be unlikely to correct the problem. Only the RATA-based bias test, which compares the installed CEMS to an independent reference monitoring method under actual operating conditions, can detect all major sources of systematic measurement error that constitutes bias. If the calibration and QA/QC procedures proposed by the commenter are conscientiously implemented in concert with periodic RATA-based bias and relative accuracy tests, monitor accuracy as required by the Clean Air Act Amendments should be achieved.

(h) Calibration-based bias test and adjustment factor. As an alternative to the RATA-based bias test, some commenters proposed retaining the one-tail t-test but applying it to data obtained from the daily calibration test instead of data from the periodic RATA. They supported their proposal by noting that the pass-fail rates on the two tests are comparable. In addition, they noted that the bias adjustment resulting from their alternative bias test was substantially lower on average than that adjustment factor derived from the RATA-based test.

Response: The suggested calibration-based bias test is flawed on engineering and statistical grounds. Two problems with a cal-gas based bias test from an engineering standpoint are its lack of an independent test procedure and failure to detect all sources of bias. First, to objectively quantify CEMS accuracy requires an independent test. That is, the standard against which the CEMS is checked should share no components in common with the CEMS. For the RATA test, where the reference method shares no components with the installed CEMS, this condition holds. In contrast, the calibration test is not an independent test, since the same CEMS used to perform emissions measurements is also used to measure calibration gas concentration. Second, the cal-based bias test is capable of detecting only a few of the potential sources of CEMS bias. The cal-based test should be able to detect bias caused by electronic/optical drift, improper interfacing of the analyzer and the data acquisition system, and loss of gas by absorption or adsorption. It may be able to detect bias caused by system leaks and plugging and by improper microprocessor corrections. However, it is unlikely to be able to detect bias caused by incorrect calibration gas values, uncorrected sensitivity to pressure and temperature, non-representative sampling, interferences from flue gas constituents, or scrubbing by precipitates on the particulate filter. In essence, the cal-based bias test simply detects consistent daily electronic/optical drift and operator introduced error, not full system bias.

From a statistical perspective, there are several serious drawbacks to use of the cal-gas based bias test. First, because the calibration procedure adjusts the CEMS based on the previous day's drift, the test procedure itself introduces time dependencies into the data, possibly limiting the applicability of the t-test. This contrasts with the RATA-based bias test. While the process being measured may display time dependencies, the RATA-based test procedure is unlikely to introduce time dependencies into the data.

Second, if the calibration procedure is not completely automated and an operator adjusts the CEMS each time a calibration is performed, it is difficult to determine whether the t-test is picking up bias in the installed CEMS or systematic error introduced by the operator's role in the test procedure. Unlike the RATA-based bias test, where the test protocol and reliance on an independent reference method minimize the chance of systematic error being introduced by the tester, there are no such inherent procedural safeguards in the cal-gas bias test. An operator's intervention in the calibration test also raises the possibility of obscuring of bias through over-adjustments of the daily measurements on which the bias test depends. For example, if an operator repeatedly over-adjusts up one day and over-compensates low the next day, the presence of bias is likely to be hidden by the oscillating over-adjustments.

Besides these problems with the cal-based bias test, the commenter's observation that the cal-based test's pass/fail rate is close to the pass/fail rate on the RATA-based bias test is irrelevant. The two tests are measuring two different phenomenon, which are not necessarily correlated. Any closeness of pass/fail rates is therefore likely to be purely coincidental.

(i) Performing RATA-based bias test only at initial certification. Some commenters proposed that the RATA-based bias test only be performed at initial certification of the CEMS. Some of these commenters proposed using a bias test based on daily calibration data after certification; others proposed using the calibration error test and routine quality control procedures to prevent bias.

Response: While it is particularly important to perform the RATA-based bias test at initial certification of the monitor, when many installation-related sources of bias can be detected and overcome, periodic RATA-based bias testing is equally important after installation, because it represents the only reliable way to detect and correct bias that can arise once the CEMS begins operation. Routine occurrence (like precipitate buildup on the probe) and unpredictable events (like lightning strikes) can cause installation and operating conditions to change over time, and these changes can cause monitor bias which could go undetected without periodic RATA-based bias testing. As explained above, neither calibration error testing nor bias testing based on calibration data can detect many of the major sources of bias that arise during initial installation or extended operation. EPA believes that periodic RATA-based bias testing is the most reliable way to determine whether bias has developed in the monitoring system.

(2) Bias Adjustment Factor: Comments and Responses

Comments for and against the proposed bias adjustment factor were about evenly divided. Many commenters supported the adjustment as an important element in an effective, yet flexible, monitoring program. Many others recommended dropping the bias adjustment factor and emphatically

stated that bias test failure should not result in the monitor being designated "out of control," as was once contemplated, but not subsequently proposed, as an alternative to the bias adjustment. A number of commenters proposed variations on how the adjustment should be computed and when it should be applied.

(a) Technical justifiability of the adjustment factor. Some commenters contended that the bias adjustment, based on the RATA test, is technically insupportable. In part, their position rests on the argument, summarized above, that the RATA-based t-test itself is not an appropriate measure of bias. Furthermore, the commenters maintained that an adjustment factor derived from a nine-run RATA "would result in an artificial inflation of reported emissions that would remove SO_2 allowances from the marketplace."

Response: It should be noted that the adjustment factor is a regulatory mechanism intended to add flexibility to the performance testing program. The adjustment factor gives units an alternative to eliminating the sources of bias, while minimizing the likelihood that emissions measurements will be under-reported. When low bias is detected by the t-test, a source can choose either to find the cause of the problem and fix it or to adjust subsequent emissions measurements by a factor commensurate with the extent of bias detected at the time of the RATA. Deriving the bias adjustment factor directly from the RATA results means that there is no "artificial inflation," over-compensation, or conservativeness involved, because it reflects conditions exactly as they are at the time of the RATA.

EPA's analysis indicates that the average bias adjustment factor is likely to be below 5 percent. In the SO_2 lbs/MMBtu RATA database, the average bias adjustment factor was 4.4 percent for RATAs that met the RA≤10 percent relative accuracy requirement but failed the bias test. For these RATAs the adjustments ranged from 0.89 percent to 6.99 percent. Thus, the bias adjustment factor would appear to provide utilities with a reasonable and practical alternative to repair a low biased CEMS.

(b) Bias adjustment factor for high bias as well as low bias. Some commenters proposed that the bias adjustment factor should not only be applicable to monitors that measure consistently low (i.e., low biased CEMS), but also to those that measure consistently high (i.e., high biased CEMS).

Response: EPA believes this modification is neither necessary nor desirable. As proposed in the regulations, the bias adjustment factor provides an incentive for eliminating low bias, comparable to the financial incentive that the allowance market gives to eliminating high bias. In tandem, these twin incentives will provide a self-enforcing mechanism, virtually free of regulatory intervention, for minimizing monitor bias—both high and low. An adjustment for high bias would remove the self-enforcing market incentive for eliminating high bias and require the imposition of a more burdensome administrative procedure for controlling high bias. There is also no environmental justification for an adjustment factor for high bias.

(c) Bias adjustment for flow monitors. A number of flow monitor vendors expressed concern that bias test results and the corresponding bias adjustment are likely to vary substantially at the three different load levels required for the flow monitor RATA test. It was feared that requiring a bias adjustment factor to be derived only at the normal load level might inadvertently distort monitor accuracy at other load levels.

Response: The bias adjustment factor specified in the proposed regulations is not a mechanism for calibrating the flow monitor to the reference method over the load range. Such a calibration procedure can be incorporated into a manufacturer's proprietary instrumentation, for example, by means of a regression curve, as suggested by one vendor. Rather, the bias adjustment factor is simply a regulatory mechanism, giving sources an alternative to eliminating the causes of bias, while minimizing the likelihood that flow measurements will be under-reported. EPA requires the flow monitor bias test to be computed only on the RATA data collected at the normal operating level. However, if the bias test is failed at normal load, the bias adjustment to be applied to subsequent data are the largest of the adjustments derived from the low, normal, and high-load RATAs. This should avert under-reporting of flow measurements, in light of the commenters' contention that the magnitude of the bias adjustment factor may not be uniform across load levels. In addition, during Phase I of the Acid Rain Program, EPA will analyze data from the low- and high-load RATA tests to see if bias test results at these loads would have diverged substantially from those obtained at the currently required normal load level and will continue to evaluate the bias test requirements for flow monitors.

The extensive analysis of comments on bias described here has led EPA to conclude that the RATA-based bias test and the bias adjustment factor are sound and essential elements in a performance testing program for assuring the accuracy of CEMS. Unlike other alternatives proposed, the RATA-based bias test provides a procedure for detecting systematic error that tests the full system against an independent reference method monitoring system under actual operating conditions. In tandem with the bias adjustment factor, this procedure represents a cost effective and self-enforcing mechanism for eliminating systematic error from monitoring systems.

D. Flow Monitors

Commenters raised seven major issues related to flow monitoring. Three pertained to the RATA (relative accuracy test audit) for flow monitors: Proposed changes to the relative accuracy standard; the requirement that RATAs be performed at three load levels; and the required frequency of RATAs. In addition, commenters charged that there was not a "level playing field" for all flow monitor technologies, asserting that the proposed calibration test for flow monitors was discriminatory against specific technologies. Commenters also questioned the need for an orientation sensitivity test. There were also comments on the proposed definition of "span" for flow monitors. Finally, there was a comment on the petition process for alternative monitoring locations for flow monitors.

(1) Relative Accuracy Standards

The proposed rule required that flow monitors meet a 15 percent relative accuracy (RA) standard through December 31, 1999 and a 10 percent RA standard thereafter. Because the mathematical structure of the RA statistic makes it very difficult to achieve the 10 percent RA standard when the flow rate is low, the proposed rule would have allowed flow monitors to be within ±1 foot per second (fps) of the reference value, rather than achieving 10 percent RA, when the flow rate was less than or equal to 10 fps.

EPA received many comments regarding the proposed flow monitor RA standards. Some commenters maintained that the proposed flow monitor RA standards were too stringent and could not be supported with EPA's limited database. Some of these commenters also claimed that the proposed RA standards were beyond the capabilities of current flow monitoring technology. Several commenters suggested extending the 15 percent RA standard through Phase II; two other

commenters proposed a 20 percent RA standard throughout Phases I and II.

However, other commenters stated that the proposed flow monitor RA standards were not stringent enough. They asserted that a 10 percent standard for Phase I was clearly achievable based on the evidence cited in the preamble to the proposed rule. One commenter stated that a 15 percent RA standard was very liberal, while another claimed that the flow monitor Phase I RA standard could be tightened to better than 5 percent.

Response: Eighty-two percent of the 73 RATAs now in the EPA database pass a 15 percent RA standard, and 70 percent pass a 10 percent standard. The EPA believes that these test results justify retention of the proposed RA standards in the final rule, except the low flow standard, which is discussed below.

Some commenters urged EPA to change the low flow accuracy standard from ±1 fps to ±2 fps and to clarify that a unit with low flow conditions may apply either the low flow accuracy test or the standard RA test.

Response: Upon further consideration of the measurement capabilities of flow monitors, EPA has decided to accept the commenters' suggestion to change the low flow accuracy standard to ±2 fps for flows less than or equal to 10 fps. The final rule will also make it clear that in low flow situations, units can satisfy their relative accuracy requirements by achieving either the ±2 fps specification or the applicable RA standard. The EPA believes that this change better accommodates the low flow thresholds of current flow monitoring technologies and should prevent unwarranted RATA failures.

(2) Three-Level Relative Accuracy Test

The proposed regulations would have required the operator to perform separate relative accuracy tests on flow monitors at low, normal, and high flow rates or at low, normal, and high unit operating levels. The three-level relative accuracy tests were to be conducted at the initial certification of the flow monitor and annually thereafter as part of the quality assurance performance requirements for flow monitors.

Two commenters supported the concept of an annual 3-level audit for flow monitors. Others suggested that the 3-level flow monitor RATA not be performed annually, but only (1) at certification and (2) when a change in stack/duct configuration necessitated recertification of the monitor. To support their position, these commenters cited the additional testing costs of multiple RATAs, the small likelihood that the flow profile would change absent stack/duct changes, and the potential interference of the multi-level requirement with the economic dispatch of electricity.

Response: EPA's analysis shows that numerous conditions may arise after siting, installation, and certification of a flow monitor to change a flow profile. These include: in-leakages or out-leakages in ducts or stacks, complete or partial disintegration of dampers or straightening vanes, stack or duct blockages due to caking, and changes in fan performance. These changes can occur without necessarily triggering recertification, yet can affect flow monitor performance. The EPA believes that only the annual 3-level audit can determine whether monitor performance has been significantly adversely affected by such changes since certification.

While EPA expects that the cost of 3-level relative accuracy tests will be somewhat higher than a 1-level test, the marginal cost of performing the two additional RATAs should be modest if all three tests are performed consecutively. This will ensure that two major costs will remain one-time expenditures for all three RATAs: the cost to transport the test team to the site and the cost of setting up and breaking down the test equipment. Annual RATA tests can be planned months in advance and scheduled to integrate into economic electric dispatch. Thus, EPA anticipates that utilities should be able to maintain adequate electrical generation in the affected area during the 3-level testing through planned dispatching arrangements.

Based on this assessment, the final rule retains the annual 3-level flow monitor RATA requirement. However, it broadens and increases the flexibility in defining each of the 3 test levels and clarifies the RATA testing requirements for flow monitors installed on common stacks.

(3) RATA Frequency

The proposed rule specified quarterly, semiannual and/or annual RATA frequency, depending on whether the flow monitor performed a daily electronic drift test or a calibration error test and on the relative accuracy level achieved. Monitors that performed a daily drift test, instead of a daily calibration error test, and obtained relative accuracy results greater than 10 percent were required to perform quarterly RATAs.

(a) Quarterly RATAs. Some commenters stated that quarterly RATAs were unreasonable and excessive for any flow monitor that is checked daily. Other commenters favored the calibration error test over the electronic drift test, arguing that the calibration error test was more meaningful. One commenter recommended dropping the electronic drift test option entirely. Nevertheless, most commenters supported the proposal to reduce RATA frequency for flow monitors achieving superior relative accuracy and stated that the proposed reduced frequency reward system would provide an incentive to maintain and improve CEMS performance. In contrast, one commenter opposed reducing RATA frequency to less than quarterly and suggested an incentive-based system that would credit and debit allowances by indexing the relative accuracy standard to the best industry performers.

Response: After carefully considering the range of comments on RATA frequency and criticisms of the electronic drift test, EPA has decided to delete the proposed requirement of quarterly RATAs and the option of performing an electronic drift test in place of the calibration error test. At the same time, as discussed in section 4 below, the final rule expands the allowable procedures that can be followed in performing calibration tests on flow monitors. Field studies and equipment specifications show that all major flow monitor technologies should now be able to perform the calibration tests as specified in the final rule. The EPA believes that the elimination of the electronic drift test and the addition of expanded calibration test procedures should assure daily indication of proper operation of all flow monitors as intended in the proposed regulations. Therefore, because of the deletion of the less credible electronic drift test, which needed quarterly RATA frequency, EPA believes semi-annual RATA frequency is now sufficient.

EPA rejected the proposal to credit and debit allowances. Although the proposal has merit in encouraging better RATA performance, EPA believes it would be administratively complex and difficult to implement.

(b) Frequency incentive under low flow conditions. Other comments on RATA frequency pertained specifically to low flow situations. Commenters argued that under low flow conditions the RATA frequency incentive system was inapplicable because of technological limits on achievable accuracy when flow rates drop below 10 fps. The commenters proposed that under low flow conditions, regardless of the accuracy achieved, RATAs should be performed on the least frequent basis

required for that type of flow monitor, i.e., annually for those performing a calibration error test and semiannually for those performing an electronic drift test.

Response: EPA believes that the proposed reduced RATA frequency incentive system is practical at low flow rates because of the new low flow accuracy standard of ±2 fps, described above. Consequently, EPA is extending the RATA frequency incentive system to low flow rate conditions. Under such conditions, flow monitors will qualify for reduced RATA frequency when the flow monitor mean is within ±1.5 fps of the reference method mean. Thus, if a flow monitor meets this standard and corresponding incentive thresholds on the other levels of the 3-level RATA, it may perform its next RATA in 12 months rather than six months. Manufacturer specifications for many flow monitors indicate that they are capable of meeting the 1.5 fps standard.

EPA believes that extending the incentive system to low flow conditions will provide the same incentive for improved accuracy under low flow conditions as under normal flow conditions. It should also reduce the required frequency, and hence the cost, of performing RATAs.

(4) Level Playing Field

At the time the proposed rule was drafted only ultrasonic flow monitors were known to be performing calibration error tests on the entire flow monitoring system— from sampling point through and including the data acquisition and handling system. Thus, in the proposed regulations, only ultrasonic monitors were required to perform the calibration error test, while non-ultrasonic monitors could either perform this test or conduct an electronic drift test. However, if they chose the latter, which only checks the stability of the monitor's electronics, not the full system, they were required to perform more frequent RATAs. In addition, the preamble requested comments on a proposal for a modified calibration test procedure for differential pressure monitors, which would be allowed to test from a point outside the stack, rather than from the probe tip, through the data acquisition and handling system.

The proposed flow monitor calibration error test was seen as discriminatory by several commenters, particularly vendors of thermal and differential pressure flow monitors. These vendors stated that the proposed requirements were detrimental to their competitive positions and could drive them out of the market unless the calibration error test were changed. Several ultrasonic and thermal flow monitor vendors supported the calibration error test as proposed. Differential pressure flow monitor vendors supported the modified calibration error test procedure, performed from a point outside the stack, rather than from the probe tip, provided that the probe is regularly backpurged.

Response: The final rule delineates two acceptable procedures that can be used in performing the calibration error test on any flow monitor: (1) A system check from and including the transducer/transceiver through and including the data acquisition and handling system in combination with daily or more frequent backpurge/probe/transceiver cleaning, or (2) a full system test from and including the sampling point, through and including the data acquisition and handling system. Whichever of these procedures is employed, all monitors are also required to perform an interference check no less frequently than every 24 hours. The interference check is a means to detect and correct plugging, fouling, and malfunctions that could interfere with the calibration test. Field studies and equipment specifications show that each of the three main types of flow monitors (thermal, differential pressure, and ultrasonic) are capable of performing the calibration error test, promulgated in today's rule.

(5) Orientation Sensitivity Test

To ensure that flow monitors would be properly oriented in the gas stream, the proposed regulations included an orientation sensitivity test. Several commenters stated that the orientation sensitivity test was unnecessary and difficult to perform for multi-port or array-type systems. These commenters also suggested that the periodic RATA would detect flow monitor orientation problems.

Response: EPA agrees with the commenters that proper orientation of a flow monitor would be ensured by periodic RATAs. Performing an orientation sensitivity test on installed multi-port or array-type flow monitors may be problematic because of the size and complexity of the installation. Out of these considerations, the orientation sensitivity test requirement has been deleted from the final rule.

(6) Instrument Span

Commenters urged EPA to delete or modify the proposed requirement that the span of the flow monitor be set so that average measured monthly volumetric flow fell between 40–75 percent of span. They maintained that the proposed span requirement might not serve the purpose of ensuring more accurate measurements at the predominant flow rates, because a unit might spend half its time at full load (e.g., during the day) and half of its time at low load (e.g., at night) and thereby meet the monthly average 40–75 percent requirement, while rarely ever actually measuring at 40–75 percent of span. One commenter suggested that EPA change the span requirement to an annual average.

Response: EPA agrees that diurnal changes in load and flow rates commonly occur, making it possible for a flow monitor to meet the proposed monthly average 40–75 percent of span requirement, but only infrequently actually measure flow rates at 40–75 percent of span. The purpose of the proposed span requirement was to (a) ensure that flow monitors would measure the predominant flow rates in the middle third of the monitor's span, (b) minimize full-scale exceedances, and (c) prevent artificially high spans that might diminish the monitor's accuracy at low flow rates.

To meet these goals and, at the same time, be responsive to public comment, the final rule drops the proposed requirement that average monthly volumetric flow fall within 40–75 percent of span. Instead, the final rule defines a "maximum potential flow" value, which is derived from the cross sectional area of the stack or duct where the monitor is located, the maximum heat input of all units feeding into that stack or duct, and the amount of combustion air. This value equals the maximum flow possible for a given stack or duct configuration, assuming all units feeding into the stack or duct are operating at their maximum heat input. The 7-day calibration error test, performed at initial certification, and the daily calibration error test calibrate the monitor on reference values set at 0–20 percent and 50–70 percent of the span. In addition, the final rule requires the span of a flow monitor to be set at 125 percent of the maximum potential flow value. This requirement should prevent full-scale exceedances.

E. Alternative Monitoring Systems

Section 412(a) of the Clean Air Act Amendments of 1990 requires that alternative monitoring systems provide information with "the same precision, reliability, accessibility, and timeliness as that provided by CEMS." The proposed regulations designated certified CEMS as the benchmark for evaluating an alternative's performance. Thus, to demonstrate equivalent

precision, an alternative was required to pass three statistical tests evaluating the CEMS and alternative method in terms of their respective systematic error, random error, and correlation. To meet the reliability criterion, the alternative was required to match a certified CEMS in terms of annual availability and ability to achieve performance specifications and quality assurance requirements. Finally, to meet the accessibility and timeliness criteria, an alternative had to match the CEMS' ability to record requisite emissions data on an hourly basis and report results within 24 hours.

(1) Overview

There were three major lines of comments on the alternative monitoring system requirements. One commenter strongly supported the proposed requirements for alternative monitoring systems as a way to ensure strict adherence to requirements of the Clean Air Act Amendments. Another commenter thought the requirements needed to be strengthened by not only stipulating that alternative monitoring systems provide information equivalent to CEMS, but also that the alternatives meet the same certification and performance test requirements as a CEMS (e.g., in terms of relative accuracy). A third set of commenters criticized the applicability of the statistical tests for precision, the stringency of these tests, the requirement that the alternative be compared to a CEMS, and the timeliness requirement. Another commenter objected to subjecting an alternative monitoring procedure to all of the Appendix B "Quality Assurance and Quality Control Procedures," noting that "meeting this criterion may be impossible."

Response: EPA agrees with the first commenter's position and notes that the second commenter's concerns were accommodated in the proposed regulations. An approved alternative monitoring would be subject to all the relevant Part 75 requirements as a CEMS, including initial certification and periodic performance testing requirements. As stated in the proposed regulations, alternative monitoring systems must satisfy all "the applicable requirements of appendix B" unless the owner or operator can demonstrate to the agency's satisfaction that meeting the requirements is physically or technologically impossible and can document equivalent or superior performance on comparable quality assurance and quality control performance standards. The agency believes that these provisions will ensure equivalency with a certified CEMS while leaving room for new technologies that may employ innovative monitoring methods.

The remainder of this section on alternative monitoring systems presents the agency's response to the concerns raised by the third group of commenters.

(2) Applicability of Statistical Tests

Some commenters argued that the three proposed statistical tests for precision were often inappropriate, because they depended on statistical assumptions that were often not met, namely, that the data are normally distributed and independent over time.

(a) Normality assumption. One commenter cited several studies that found emissions data to be lognormally distributed rather than normally distributed and to exhibit time dependency (also called autocorrelation). To support their argument, the commenter presented 22 paired hourly data points obtained simultaneously at the same monitoring location by two separate test teams, using EPA designated Reference Method 6 for measuring SO_2 concentration. The commenters' analysis found that the data did not support the assumptions of normality and statistical independence.

Response: The EPA's own statistical analysis, conducted to evaluate these comments, contradicts the claim that emissions data are frequently not normally distributed. To evaluate normality, EPA applied two standard tests (Shapiro-Wilk test and Kolmogorov test) in conjunction with visual inspections of Quantile-Quantile plots and histograms of the data. These were applied to the commenter's two data sets and 13 other emissions data sets, containing from 62 to 16,081 data points. All the data sets, except the data from the commenter's Test Team B, were found to be normally distributed as evidenced by their yielding extreme values of the test statistics, unimodal symmetric histograms, and straight diagonal Quantile-Quantile plots.

The disparity in the distributional form of Test Team A's and B's data may indicate a problem in one or both team's implementation of Method 6. Two test teams carrying out exactly the same reference method procedure concurrently at the same location will obtain different measurement values, but they should not obtain data with different distributions, unless the testing procedure was inconsistently applied or some other unrecognized problem occurred.

While EPA's analysis does not support the commenter's contention about the distributional form of emissions data, the regulations have nevertheless been modified to accommodate the possible situation, highlighted by the commenter, where emissions data are lognormally distributed. If such a case does arise, the regulations now allow using a logarithmic transformation to normalize the data before the three statistical tests are applied.

(b) Independence assumption. The commenter also notes that the validity of the statistical tests that are applied to alternative monitoring systems depends on the data being statistically independent over time. The commenter maintains that the assumption of independence is often violated.

Response: EPA finds that the commenter's point merits attention. When data are not independent over time, its variance tends to be understated by standard statistical procedures. An underestimated variance could distort the results obtained on some of the proposed statistical tests. An accepted and theoretically substantiated way to compensate for variance underestimation is to multiply the variance by an inflation factor derived from an autocorrelation analysis of the data. This autocorrelation-adjusted variance is then used in statistical tests that are premised on data independence. The EPA has augmented the statistical tests for alternative monitoring systems with a procedure for computing the variance inflation factor. The final rule identifies the conditions under which the factor would be applied.

(3) Stringency of Statistical Tests

Besides maintaining that the statistical tests were inappropriate, the commenter also argued that they were so stringent that "no alternative monitoring system will likely ever be certified." This claim rests mainly on two arguments.

(a) Argument 1: Two reference methods fail the test. The commenter applied the three proposed statistical tests to the paired data from the concurrently run Reference Methods 6 discussed above. The side-by-side reference methods failed the tests, leading the commenter to conclude that "If two identical, concurrently run Reference Methods * * * cannot pass the alternatives testing, it is highly unlikely that any alternative system evaluated against a Reference Method (or certified monitor) would ever pass."

Response: EPA discounts the credibility of the commenter's analysis, because the underlying data are suspect and the sample size too limited. As

noted earlier, concurrent measurements by two duplicate reference methods at the same test location should not produce data with different statistical distributions: Test Team A's data was normally distributed, while Test Team B's was non-normal. This disparity suggests a flaw in one or both of the test team's implementation of the reference method. Drawing conclusions from such data are questionable, particularly when the conclusions are premised on statistical procedures that require the two data sets to be normally distributed. In addition, EPA believes that the sample size of 22 points is too small to support the commenter's conclusion.

(b) Argument 2: The bias test is so sensitive to "incredibly small" measurement differences between two data sets that it is impossible to pass the t-test. The commenter maintains that the t-test is not practically useful because it detects statistically significant differences that are not practically significant.

Response: EPA believes that inconsistencies in the underlying premises render this argument unconvincing. On the one hand, the commenter asserts that the t-test cannot be applied to the cited Reference Method 6 data, because the paired differences are not normally distributed. Then, ignoring this very stricture, the commenter assumes normality and extrapolates the t-test results from the cited 22 hours of data to 720 hours of hypothesized data, concluding that a mere 2 ppm measurement difference would have caused failure on the t-test at the larger sample size. If absence of normality made it inappropriate to apply the t-test to the 22 hours of actual data, as the commenter claims, then extrapolating these t-test results to 720 hours of hypothetical data seems even more questionable.

To further evaluate the commenter's concerns about the stringency of the alternative monitoring statistical tests, EPA analyzed 30–60 days of hourly field test data from four CEMS installed on a common duct at a coal-fired utility that was assessing various brands of monitors as part of their procurement process. While the CEMS were not certified and this was not a controlled experiment that ensured uniformity in the operation of the four CEMS, the data was adequate to assess the stringency of the three alternative monitoring system statistical tests in a situation where no deliberate attempt was being made to meet the test criteria. Forty-one separate data subsets, containing 30 or more successive days of paired hourly CEMS–CEMS measurements were extracted from the field data. Of these, 26 passed the bias test and 20 passed all three statistical tests simultaneously. Had this been a controlled experiment, it could be expected that the pass rate would have been even higher. In any case, the analysis demonstrates that the three tests are not impossibly stringent, as the commenter claims.

While EPA's analysis does not corroborate the commenter's claim that the proposed standards are unattainable, the data screening and adjustment procedures, discussed in the preceding section should ensure that the statistical tests are fully applicable even when the data are not independent over time. Together with the issues discussed above, these additions to the final rule should address the commenter's concerns about the achievability of the alternative monitoring system requirements. Moreover, EPA believes that by clearly articulating the standards that will be used in evaluating proposed alternatives and by basing these standards on objective and widely accepted statistical tests, the proposed alternative monitoring system requirements should reduce the uncertainty that might otherwise impede technological development.

(4) Testing Against a Reference Method Instead of a CEMS

Several commenters objected to having to install a certified CEMS in order to perform the tests needed to gain approval for an alternative method. They pointed out that there were sites where an alternative was being requested because it was not possible to install a CEMS. They proposed that alternative methods be certified by testing them against EPA Reference Methods.

Response: The Clean Air Act Amendments specifically stipulate that alternative monitoring systems provide information with the same precision, reliability, accessibility, and timeliness as that provided by CEMS. The EPA interprets this as requiring comparison to an actual CEMS. Nevertheless, since the CEMS must be certified prior to and during operation by comparison to the Reference Method, EPA agrees with the commenters that a reference method may be used whenever they are operated to provide the same hourly data that would form the basis of the CEMS to alternative comparison on which the criteria are based. Specifically, the reference method would have to produce 720 hourly emission rates. However, many EPA approved reference methods, like the manual wet chemistry Method 6 for SO_2, are completely unsuitable for the round-the-clock testing required to demonstrate long-term operational equivalency to a CEMS. Often labor intensive, the reference methods were designed to provide a measurement standard for short-term performance tests like the Relative Accuracy Test Audit. EPA believes they are not practical for long-term equivalency testing. Nevertheless, today's final rule allows for the generation of the required hourly emission rate data through the use of reference method testing as well as an actual CEMS to be compared with an alternative monitoring system as specified in the rule.

(5) Timeliness Requirements

Arguing that it is "legally unnecessary and unreasonable as a practical matter," one commenter objected to defining timeliness as the ability to provide hourly data and issue a record of the data for the previous day within 24 hours.

Response: EPA disagrees with the commenter. The market-based regulatory process demands an unprecedented degree of accuracy in the emissions totals that are used to calculate allowances. The more aggregated the measurements, the less verification is possible, and the less will be the assurance of accurate allocation of allowances. Both CEMS and approved alternative monitoring systems must be able to provide data in hourly increments and report data within 24 hours if the Acid Rain Program is to implement effective quality assurance and control procedures, validate emissions data, and correct problems before the end of year allowance/emissions reconciliation. The timeliness requirements are also necessary for the proper functioning of the missing data procedure, which depends on hourly values to ensure that substituted values are derived from verifiable, quality assured historical data. EPA believes that the requirements are practically justified and technologically feasible, as discussed above. In addition, the requirements are not unduly burdensome for the regulated community, being equivalent to those mandated by the Clean Air Act Amendments for CEMS.

F. Missing Data Procedure

Section 412(d) of the Clean Air Act requires EPA to prescribe a method for calculating emissions when valid data are not being supplied by a unit's continuous emissions monitoring system (CEMS) or by an approved alternative monitoring system. To meet this requirement, the proposed regulations established a missing data

substitution procedure, designed to achieve five major goals:

- To encourage the use of CEMS as the primary method for determining emissions and, at the same time, foster effective operations and maintenance programs by putting in place strong incentives for minimizing monitor downtime and maximizing data capture rates.
- To replace missing values with modest estimates when monitor availability has been good and missing data periods have been short.
- To replace missing values with more conservative estimates when monitor availability has been poor and missing data periods have been long.
- To establish a procedure that is automatic in its execution, relying only on the CEMS-generated emissions database, thereby minimizing the need for enforcement actions and supporting the smooth and unambiguous operation of the program.
- To establish a procedure that is readily implementable by all affected units and not administratively burdensome for units or EPA.

The missing data procedure, established to achieve these goals, is a multi-tiered computational routine for deriving a substitution value from the values previously recorded by the monitor. The procedure is based on the premise that the longer the gap in recorded data and/or the lower the annual monitor availability, the more conservative the value to be substituted. In concert, two trigger conditions determine the conservativeness of the substituted value. The first trigger condition is annualized availability, i.e., the percentage of the immediately preceding 8760 unit operating hours in which valid, quality assured data was obtained. (Note that for the purposes of the missing data procedure, there are 8760 hours in a year, 2160 hours in a quarter, and 720 hours in a month.) The annualized availability determines the calculation tier that applies: Monitors whose annualized availability has been good (i.e., 95 percent or better) would employ the calculation options on the top tier where the resulting substitution values are likely to be least conservative. On the other hand, monitors whose annualized availability has been poor (i.e., below 90 percent) would use the calculation options on the lowest tier where the resulting substitution values would be most conservative.

Within each of these tiers, the second trigger condition, the length of the current outage, determines the elements of the calculation routine that will be combined to derive the substitution value. The calculation routine consists of three elements: A calculation method, e.g., average, percentile, or maximum value; a lookback period, e.g., the preceding 720 monitor operating hours or the hour before and the hour after the outage; and an indicator, known as a "bin," of whether the substituted value will be chosen from a pre-defined subset or from all of the values that were recorded during the lookback period. Longer outages trigger combinations of calculation elements that are likely to yield conservative substitution values to ensure that actual emissions will not be underestimated. Thus, a short outage (e.g., 4 hours) might trigger a calculation routine employing the average (method) of the monitored values in the hour before and hour after the outage (lookback), using all the recorded data (i.e., no bins are used). On the other hand, a long outage (e.g., 30 hours) might trigger the maximum (method) of the monitored values in the preceding 720 hours (lookback) for the subset of the previously recorded values falling within the same load range as occurred when the monitor was "down" (i.e., bins are employed).

Tables 1 and 2 summarize the missing data procedure for SO_2, NO_x, and flow as modified in the final rule. The crossed out entries in these tables show elements of the proposed procedure that were changed in response to public comments that EPA received. For example, Table 1 shows that the proposed sulfur content bins have been deleted from the missing data procedure for SO_2 CEMS in response to many comments indicating that the requirement would be very burdensome on affected units. It may be helpful to refer to these tables when reading the following detailed discussion of the public comments and the changes produced in response to them.

EPA received more than 400 comments on various aspects of the proposed missing data procedure. To help evaluate these comments and verify earlier analyses, EPA developed a sophisticated computer simulation model for testing the likely impact of variations of the trigger conditions and calculation routines in the missing data procedure. The model was applied to historic SO_2 and NO_x emissions data from units both with and without emissions controls. Each individual data set contained approximately 10,000 hourly emissions measurements. Sensitivity analysis was performed using both "worst case" and "most likely" scenarios for outage occurrences.

(Note: EPA has requested that Table 1 be printed as shown below. Crossed out entries in this table represent items, originally in the proposed regulations, that were changed in the final version of the regulations.)

TABLE 1.—MISSING DATA PROCEDURE FOR SO_2 CEMS

Trigger conditions		Calculation routines		
Annualized availability (percent)	Duration (N) of outage (hours)	Method	Lookback period	Bins[1]?
95% or more	N≤24	Average	HB/HA	No.
	N>24	Max of Average	HB/HA	No.
		Max of 90th percentile	720 operating hours	~~Yes.~~ No.
90% or more, but below 95%	N≤~~6~~ 8	Average	HB/HA	No.
	~~6<N≤24~~	Max of ~~Average~~	~~HB/HA~~	~~No.~~
		~~Max of 90th percentile~~	~~720 operating hours~~	~~Yes.~~
	N>~~24~~ 8	Max of Average	HB/HA	No.
		Max of ~~90th~~ 95th percentile ..	~~8760~~ 720 operating hours	~~Yes.~~ No.
Below 90%	N>0	~~Max of Average~~	~~HB/HA~~	~~No.~~
		~~Max of 90th percentile~~ Maximum[2].	~~8760~~ 720 operating hours	~~Yes.~~ No.

HB/HA=hour before and hour after the outage.
[1] For SO_2 CEMS, the bins were defined on sulfur content ranges.

[2] Where unit with add-on emission controls can demonstrate that the controls are operating properly, as provided in §75.34, the unit may, upon approval, use the maximum controlled emission rate from the previous 720 operating hours.

(Note: EPA has requested that Table 2 be printed as shown below. Crossed out entries in this table represent items, originally in the proposed regulations, that were changed in the final version of the regulations.)

TABLE 2.—MISSING DATA PROCEDURE FOR NO_x and Flow CEMS

Trigger conditions		Calculation routines		
Annualized availability (percent)	Duration (N) of outage (hours)	Method	Lookback period	Bins [1] 7
95% or more	N≤24	Average	~~HB/HA~~ 2160 operating hours	Yes.
	N>24	Max of Average	HB/HA	No.
		Max of 90th percentile	~~720~~ 2160 operating hours	Yes.
90% or more, but below 95%	N≤8 8	Average	~~HB/HA~~ 2160 operating hours	No.
				Yes.
	~~8<N≤24~~	~~Max of Average~~	~~HB/HA~~	No.
		Max of ~~90th~~ percentile	~~720 operating hours~~	~~Yes.~~
	N>24 8	Max of Average	HB/HA	No.
		Max of ~~90th~~ 95th percentile	~~8760~~ 2160 operating hours	Yes.
Below 90%	N>0	~~Max of Average~~	~~HB/HA~~	~~No.~~
		Max of ~~90th percentile~~ Maximum.	~~8760~~ 2160 operating hours	Yes.

HB/HA=hour before and hour after the outage.
[1] For NO_x and Flow CEMS, the bins were defined on load ranges.

The major issues, raised by commenters and analyzed by EPA, were the following:

(1) Underlying Concepts

In general, commenters supported the basic underlying concept, on the one hand, of substituting an *interpolated* value derived from the average of the hour before and hour after when outages were short and annualized availability was above some threshold and, on the other hand, substituting a more conservative *historical* value when outages were longer or annualized availability dropped below some threshold. It should be noted, however, EPA does not agree with those commenters who seem to view interpolated values, like the average of the hour before and the hour after, as comparable to CEMS data. Interpolated values provide a satisfactory substitute for CEMS data only when outages are relatively short in duration and infrequent in occurrence. More extensive use of interpolated values increases the likelihood of incorrectly estimating emissions for individual monitors. To function effectively, the allowance trading component of the Acid Rain Program requires a complete and accurate accounting of emissions. It cannot rely on interpolated values for such an accounting. The EPA believes that high monitor availability, made possible by a missing data procedure that discourages outages, is the only effective guarantee that emissions will not be underestimated, as required by section 412(d) of the Clean Air Act.

(2) Trigger Conditions

(a) Annualized availability. A number of commenters expressed concern about the ability of CEMS to attain availabilities of 95 percent or more, particularly with monitors that would have to be retrofitted to meet the requirements of the Acid Rain Program. It was asserted that unsatisfactory results were experienced in Pennsylvania, where the average annualized availability for monitors retrofitted to meet the requirements of the State Implementation Plan was below 95 percent in the early phase of the program.

Response: A study of 186 retrofitted monitors during 1988–90 did not lend support to the commenters' concern. The study showed that approximately 75 percent of monitors at existing units, including units that will be covered under Phase I of the Acid Rain Program, have consistently attained availabilities above 95 percent. In addition, the most recent data on CEMS availability, obtained from the Commonwealth of Pennsylvania, indicates that, on average, annualized availability was 96 percent. This leads EPA to conclude that 95 percent availability is readily achievable, even by retrofitted monitors that are required to meet strict quality assurance and data validation standards in order to qualify as "available". It is also important to note that a monitor could be inoperative for a full 18 days each year and still have an annualized availability of more than 95 percent. The EPA believes that 18 days is more than enough time to accommodate both routine and unexpected outages for a properly maintained and operated CEMS.

Another commenter proposed indexing the top tier annualized availability trigger to the performance of the best monitors. It was argued that this would create an incentive for continuing improvement in monitor availability across the whole regulated community.

Response: While EPA encourages continuing improvement in availability, the agency believes the indexing approach might introduce an element of uncertainty into the emissions monitoring program that could be reflected, in turn, in the allowance market. The indexing approach would also present serious administrative difficulties both for EPA and sources. Therefore, EPA rejected this proposal.

Still another commenter argued that the bottom tier should be deleted and the second tier's trigger conditions and calculation routines should apply when annualized availability drops below 95 percent.

Response: EPA did not accept this proposal for several reasons. First, it would encourage the proliferation of short outages (6 hours or less, using the structure in the proposed missing data procedure), because values derived using the average of the hour before and the hour after an outage could be substituted for these short outages no matter how low the monitors annualized availability dropped. This would reduce confidence in the monitor's emissions accounting. Furthermore, the proposed change would remove virtually all incentives to repair a monitor with poor annualized availability. Accordingly, the Agency did not accept this commenter's proposal, instead preserving the

proposed separate lower tier, which is triggered by annualized availabilities below 90 percent and where conservative values are always substituted for missing data.

In summary, the final rule retains the three-tier structure of the earlier proposal, with the top tier still triggered by annualized availabilities 95 percent or better, and the bottom tier triggered by annualized availabilities below 90 percent.

(b) Duration of outages. Commenters made several proposals for modifying the length of outages that trigger various calculation routines. A number of commenters argued that the most conservative calculation routines should not be triggered by outages exceeding 24 hours but by outages exceeding 48 hours. The commenters maintained that a 48-hour trigger condition would provide a more reasonable length of time to repair monitors rendered inoperative by freak events beyond the operator's control.

Response: EPA rejected this proposal on three grounds. First, moving to a 48-hour trigger condition would remove an important incentive for quickly repairing monitors, even when the cause of the failure is easily fixed. Second, the commenters' proposal would mean that the calculation method based on averaging measurements taken the hour before and the hour after an outage would be used for outages as long as 48 hours. Using the hour before and the hour after approach on such long periods of missing data are likely to produce appreciable underestimations of emissions. Third, the argument for changing the trigger condition cutoff to 48 hours to allow more time for repairs was based on anecdotal evidence of repairs requiring more than 24 hours and did not convincingly demonstrate that 24 hours was insufficient for most repairs. The commenter's rationale could just as easily have been used for lengthening the cutoff to any duration longer than 24 hours.

Many commenters requested that the average hour-before/hour-after calculation procedure apply for outages longer than 6 hours when annualized availabilities ranged from 90 percent up to 95 percent (i.e., on the middle availability tier). Some proposed moving the trigger condition up to 8 hours; others proposed 12 and 24 hours. They argued that more repairs could be completed in 8, 12, or 24 hours than in 6.

Response: After weighing the possibility that extending the use of the average of the hour before and the hour after might reduce the incentive for quick repairs and increase the variability of substitution values produced by the missing data procedure, the agency has decided to adopt the proposal to extend the trigger condition from 6 to 8 hours in the final rule. The EPA believes that this change should allow more time for monitor repairs without significantly impairing the accuracy and consistency of emissions accounting. Along with this modification, only one trigger condition ($N>8$) will now apply to outages longer than 8 hours in the middle availability tier, whereas two trigger conditions ($6<N\leq24$ and $N>24$) applied to outages longer than 6 hours in the original proposed regulations. Together, these modifications simplify and support a truly graduated system of increasing incentives for improvements in annualized availability.

(3) Calculation Routines

(a) Calculation method. Commenters expressed strong views on the appropriate calculation method to employ in the missing data procedure. A diverse array of commenters argued that only by substituting the maximum previously recorded value could EPA effectively meet the requirement in section 412(d) of the Clean Air Act, stipulating that a unit should be considered as operating "in an uncontrolled manner" during periods when "the owner or operator cannot provide information, satisfactory to the Administrator, on emissions during that period." These commenters considered the maximum value as the only effective deterrent to deliberate shutdowns of CEMS during periods of high emissions.

Many commenters supported using a percentile of previously recorded values to calculate substitution values. Most thought the 90th percentile provided an adequate incentive for high CEMS availability without producing an undue overestimation of emissions and a concomitant inappropriate loss of allowances. Some proposed using the 70th percentile when annualized availability exceeded 90 percent.

The proposed rule requested comment on the advisability of using the average of the five highest previously recorded values as a calculation method. Almost all commenters rejected this proposal.

Response: EPA has incorporated into the revised missing data procedure calculation methods that it believes reflect a reasonable compromise of the extremes proposed by the commenters. The final rule contains a balanced, graduated approach with the substitution of progressively more conservative values for periods of missing data. Those monitors attaining the target annualized availability of 95 percent or better will substitute the 90th percentile value during outages exceeding 24 hours. Monitors whose annualized availability falls in the middle tier (from 90 percent up to 95 percent) will substitute the slightly higher 95th percentile value during outages exceeding 8 hours. Finally, monitors whose poor annualized availabilities place them on the third tier (below 90 percent annualized availability) will substitute the maximum recorded value for any outage. This should provide a substantial incentive to improve monitor availability. Combined with the use of uniform and shortened lookback periods, described below, this graduated approach will result in a more consistent incentive to maintain high operating availabilities than the proposed procedures.

(b) Lookback period. In the proposed rule, percentile calculations were performed on either 30 or 365 operating days of previously recorded data. Commenters objected to the 365-day lookback period, particularly for SO_2 concentration CEMS. They were concerned that a unit that reduced its SO_2 emissions could still be "stuck" with outdated high substitution values for a full year. This could prove particularly troublesome in the initial year of allowance accounting when substituted values might be derived from periods prior to the required implementation of SO_2 emissions reductions.

Response: The final rule drops the 365-day lookback period and adopts a 30-day lookback (i.e., 720 monitor operating hours) for all percentile and maximum value calculations employed in the missing data procedure for SO_2 CEMS. Moving to a single 30-day lookback addresses the commenters' concerns without reducing the incentive for increased monitor availability. One commenter noted and EPA's analysis indicates that the 90th percentile of 365 days of data did not yield consistently higher substitution values than the 90th percentile of 30 days of data. Shortening the lookback period from 365 to 30 days also substantially reduces data storage requirements for the missing data procedure.

On the same grounds, a single 90-day lookback (i.e., 2160 monitor operating hours) will be employed for NO_x and flow CEMS, instead of the 30- and 365-day lookback periods originally proposed. A 90-day lookback, rather than a 30-day lookback, is required for NO_x and flow, in order to increase the likelihood that appropriate load "bins" will contain at least some previously

recorded CEMS values. As explained below, "bins" are retained in the missing data procedure for NO_x and flow CEMS, but dropped for SO_2 CEMS.

(c) Bins. Many commenters objected to the expense of the proposed requirement for fuel sampling and analysis, which were needed in order to use SO_2 bins in the missing data procedure. Other commenters noted that it is inappropriate to mix coal sampling and CEMS data because coal sampling data are less precise and reliable. Data provided by one utility showed a daily variability of −10 percent to +45 percent in the difference between the SO_2 values derived from coal sampling and the SO_2 CEMS measurements.

Response: Based on this data, EPA agrees that it is inappropriate to compare coal sulfur content with CEMS values, either by correlation with contemporaneous CEMS readings or by direct substitution. Therefore, the final rule drops the fuel sulfur "bins" requirement from the missing data procedure for SO_2 CEMS. That is, SO_2 concentration will not need to be correlated with fuel sulfur content when performing percentile calculations of SO_2 substitution values. An added benefit of removing the fuel sulfur bin requirement is that the cost of implementing the missing data procedure for SO_2 CEMS will be reduced substantially, because utilities will not be required to perform coal sampling and analysis in order to implement the missing data procedure.

The Agency also considered dropping the load "bins" requirement from the missing data procedures for NO_x and flow CEMS. However, many commenters supported the use of load ranges when calculating substitution values for NO_x and flow, arguing that this would produce more accurate substitution values. Commenters who opposed the NO_x/load or flow/load correlations, embodied in "bins," cited either the unnecessary complexity of correlating operating data and monitor data, or the more accurate correlations that could be obtained using regression analysis.

Response: Using a uniform 90-day lookback in the missing data procedure for NO_x and flow CEMS and a smaller number of uniformly sized bins should reduce the complexity noted by some commenters. Although the regression analysis could provide satisfactory correlations, the method would require site-by-site analysis of extensive amounts of flow and load data. EPA believes that this approach would impose too great an administrative burden both on the industry and EPA. Thus, EPA has decided to retain the load bins for NO_x and flow CEMS and adopt a uniform 90-day lookback period in the NO_x and flow missing data procedures.

(4) Other Missing Data Issues

(a) Definition of missing data. The Agency reiterates that data from a certified backup monitor or an approved alternative monitoring system is not considered to be "missing." When such methods are operating in accordance with the regulations, data are considered to be "available," as required under section 412(d) of the Act. Correspondingly, when quality assured hourly data are not available from the certified CEMS or from one of these methods, then the missing data procedure must be used.

(b) Alternative missing data procedures. Several commenters requested that an administrative mechanism be established to allow sources to employ alternative missing data procedures in place of those specified in the regulations.

Response: The proposed regulations included provisions that would allow units with emissions controls that are independent of the combustion process (e.g., scrubbers) to use parametric substitution methods for missing data, instead of the standard missing data procedure. However, this "alternative" procedure is applicable only under clearly prescribed circumstances: it was designed to address anomalies that could result if the standard missing data procedure were applied to one specific class of units, those with independent emissions controls. In this case, the standard missing data procedure could seriously overestimate emissions. If the CEMS failed to report an hourly value but the emissions control equipment was functioning properly, the standard missing data procedure could substitute an inappropriately high uncontrolled emissions value, seriously overestimating emissions. The option of using a parametric substitution method at these units provides a greater level of consistency in emissions accounting between controlled and uncontrolled units.

The final rule includes distinct missing data procedures for oil- and gas-fired peaking units that qualify for exceptions to the SO_2 CEMS requirements, as described in Appendix D of the regulations. These procedures are adaptations of the standard missing data procedure, tailored to the specific characteristics of the excepted monitoring method.

EPA does not consider alternative missing data procedures to be justified for types of units other than those discussed above. The EPA is particularly concerned that a multiplicity of alternative missing data procedures could seriously jeopardize the national consistency of emissions accounting.

(c) Maximum controlled emission rate. Several commenters requested that EPA allow an affected unit equipped with add-on emission controls to substitute something more reasonable than the maximum recorded value, which may have occurred when the add-on emission controls were not functioning properly, if the owner or operator can show that the add-on emission controls were in fact operating properly during the current monitor outage.

Response: EPA agrees, and has modified the final rule to allow for a petition to the Administrator; specifically, if the owner or operator can demonstrate that (1) the affected unit's monitor data availability is below 90% availability and (2) the add-on emission controls were operating properly for the time period (or data gap) during which the affected unit experienced the monitor outage that would result in the substitution of an uncontrolled maximum value under the standard missing data procedures, then the owner or operator may submit the list of the average hourly values for the previous 720 quality-assured monitor operating hours, highlighting both the maximum recorded value and the value corresponding to the maximum controlled emission rate. The Administrator will automatically approve the use of the maximum controlled emission rate, if the petition adequately demonstrates that all of these requirements have been met.

G. Calibration Testing

Comments on the proposed calibration testing requirements for pollutant concentration monitors touched upon four major issues: terminology, the definition of instrument span, test specifications, and test procedures. Calibration issues related to flow monitors were discussed in the section on flow monitors above.

(1) Terminology

In the proposed rule the term "calibration error test" was used to refer to three separate calibration testing requirements, i.e., those required daily, quarterly, and at initial certification. The use of a single name created confusion because the purposes and procedures of the tests differed. The EPA received many comments that lack of clarity in the terminology caused uncertainty about the intent, timing, and

procedures of the tests. Commenters also noted that the proposed 7-day calibration error test at initial certification was really a hybrid of two tests: (1) A linearity check to ensure that CEMS responses were within tight tolerances of the calibration gases and that deviations remained relatively linear over the entire measurement range; and (2) a drift test to detect and limit day-to-day drift in the calibration curve of the monitoring instrument and to keep the instrument within range of high- and zero-level calibration gases. Commenters suggested that not only were the hybrid requirements confusing, but that using the tight standards of a linearity check in a calibration drift test could render the hybrid test needlessly difficult to pass without achieving the implicit goals of the calibration procedure. It was also noted that the linearity component of the hybrid test was equivalent to the proposed quarterly 3-point calibration error test and the drift test component was equivalent to the proposed daily calibration error test.

Response: In the final rule the calibration procedure performed at initial certification is disaggregated into its two component tests: a linearity check performed for one day only and a 7-day calibration error test. The term "daily calibration error" test has not been changed in the final rule.

The linearity check is a 3-point test in which the permissible deviation of the CEMS response from the calibration gases is defined as a percent of the "tag" value of the gases. The "tag" value is the vender certified concentration specified on the label of a cylinder of calibration gas. What was referred to as the "quarterly calibration error test" in the proposed rule is now called a "quarterly linearity check" to indicate that it is the same test as the linearity check performed at initial certification.

The daily calibration error test, specified in today's regulations, is a 2-point drift test, comparable to the calibration drift test required under NSPS (40 CFR 60, Appendix B) except that it requires using Protocol 1 calibration gases. Unlike the daily calibration error test in the proposed regulations, the permissible day-to-day drift in the CEMS measurements is now defined as a percent of the span of the instrument rather than as a percent of the calibration gas value. The 7-day calibration error test performed during certification is the same 2-point drift test as the daily calibration error test.

(2) Instrument Span

The proposed regulations stipulated that the CEMS span should be set to ensure that the average concentration would fall between 40 and 75 percent of the span of the instrument. Whenever the monthly average emissions concentration fell outside these boundaries, the operator was required to adjust the span to bring it back into compliance. The regulations also stated that "full-scale exceedances shall not occur."

A majority of commenters stated that the 40–75 percent span requirement would be too difficult to maintain and that the proposed monthly adjustments of span were not practical. They suggested that the boundaries on monthly concentration be expanded from 40–75 percent to 10–90 percent or that the span requirement be completely redefined to be compatible with definition of span under subpart Da of the New Source Performance Standards (NSPS).

Response: EPA continues to believe that the best way to define span for the purposes of the Acid Rain Program is to base it on boundaries that ensure that the predominant monitor readings fall in the middle third of the span, as was done in the proposed rule. However, in light of many negative comments and in order to make the calibration procedures under the Acid Rain Program as compatible as possible with current practices under subpart Da of NSPS, EPA has modified the span requirements in the final rule.

Under the final rule, every unit is required to set the span of its SO_2 and NO_x pollutant concentration CEMS at 125 percent of the "maximum *potential* concentration." For SO_2 CEMS, a unit's maximum potential concentration is determined by the specific characteristics of the fuel that the unit is capable of burning. In particular, the maximum potential concentration is calculated from the maximum percentage sulfur content and the gross calorific value of the fuel, using a conversion factor that assumes complete combustion (see Equation 1.2.1.a in Appendix A to part 75). The monitor range defined on the maximum potential concentration is known as the "high-scale" of the monitor.

For SO_2 CEMS on units with emission control equipment, the monitor must not only be capable of meeting the above requirements, it must also be able to perform and pass the calibration tests using low, mid, and high calibration gases whose concentrations are defined by the unit's "maximum *expected* concentration." For these units, the "maximum *expected* concentration" is the maximum concentration that would occur if the unit's control equipment is operating at its fractional design removal efficiency. It is calculated by multiplying the maximum potential concentration by one minus the design removal efficiency. The monitor range is set at 125 percent of the maximum expected concentration and is known as the "low-scale" of the monitor.

The operator of any unit may also elect to establish "maximum expected concentration" levels in order to determine additional sets of low, mid, and high SO_2 calibration gas concentrations to be used in calibrating on spans other than the one defined on the "maximum potential concentration." This option should accommodate situations, identified by commenters, where the most prevalent emission concentrations fall into one or more discrete bands, not necessarily in the center of the span range established using the maximum potential concentration. This rule allows sources, under such circumstances, to employ multi-span monitors, each span being calibrated on its own set of calibration gases.

As in NSPS, the span of NO_x and diluent gas CEMS is explicitly specified in the final rule: For boilers without emissions controls, the maximum potential concentration for NO_x pollutant concentration is assigned a value of 1,600 ppm at coal-fired units and 480 ppm at oil-fired and gas-fired units. For boilers with emissions controls, the maximum expected concentration is assigned a value of 800 ppm at coal-fired units and 400 ppm at oil-fired and gas-fired units. For other units electing to set a low-scale for their NO_x pollutant concentration monitor, the maximum expected concentration is assigned a value of 320 ppm at coal-fired units and 160 ppm at oil-fired and gas-fired units. The span of the diluent gas monitor would be set at 25 percent O_2 or CO_2, as applicable. Based on NSPS experience, this approach to defining the span of NO_x and diluent gas CEMS is effective without being either restrictive or burdensome.

Operators at all units are required to perform the quarterly and initial certification linearity checks on the high-scale of their instruments. In addition, operators of units with emission controls and other units that choose to use additional spans must also perform the quarterly and initial linearity checks on the low-scale of their instruments. Finally, operators need only perform the daily calibration error test on the monitor ranges that were actually used for one hour or more since the previous daily calibration error test.

This new approach for defining the span of CEMS responds to commenters' concern that the earlier 40–75 percent

approach in the proposed regulations would inevitably lead to violations of the stricture that "full-scale exceedances shall not occur." The EPA believes that under the new requirement full-scale exceedances should not occur. At the same time, the agency encourages operators to set the span of their instruments, where practicable, so that the majority of readings occur within 25–75 percent of the instrument span.

The modified approach to defining the span of CEMS closely resembles that used in NSPS, although it cannot exactly coincide due to differing program standards and emissions characteristics of the regulated units. Coordination of the definitions of span should reduce needless disparities in requirements on units affected by both NSPS and the Acid Rain Program. It should also facilitate implementation, since CEMS operators will find the new requirements to be familiar.

At the same time, the new approach addresses the commenters' two major concerns regarding the originally proposed method for defining span. It eliminates the uncertainty engendered by basing span adjustments on the previous month's average emissions concentration, and it prevents full-scale exceedances.

(3) Performance Specifications

The proposed rule required that pollutant concentration monitors be calibrated to within a performance specification of ±2.5 percent of the gas concentration when measuring calibration gases whose concentration was above 250 ppm and to within a performance specification of the greater of ±5.0 percent or ±8 ppm when measuring calibration gases whose concentration was 250 ppm or lower. For diluent gas monitors the specification was set at ±0.5 percent of the calibration gas. In all three calibration tests—daily, quarterly, and initial certification—the specification applied to the monitor's measurement of a reference Protocol 1 gas. On the daily and quarterly calibration tests, the monitor would be considered "out of control" if the percentage deviation of the monitor measurement from the "tag" value of the calibration was more than twice the performance specification. However, on the initial certification test, if the percentage deviation simply exceeded the performance specification, the monitor would fail and have to repeat the 7-day calibration error test.

A majority of commenters stated that it would be practically impossible to meet the specifications when using low-level concentration gases having concentrations between zero and 20 percent of the instrument span. Commenters suggested that the specification should not be applied to the "tag" value of the calibration gas, but to the full span of the instrument.

Response: EPA is making two substantive modifications of the proposed regulations to respond to the commenters' concerns. First, the definitions of the low- and mid-level concentration gases used in the linearity checks performed during initial certification and quarterly thereafter have been changed in the final rule. The low-level concentration is now designated as 20–30 percent of span instead of 0–20 percent of span; mid-level will be 50–60 percent, not 40–60 percent; and high-level will remain at 80–100 percent. Separate sets of calibration gases are determined separately for the high- and low-scale of the monitor, based on their respective span values. The revised concentration ranges are consistent with requirements under NSPS, which defines the concentration levels in this manner. As a result of these modifications and the change in the definition of the span of the instrument, the low-level gas, which was of greatest concern to commenters, is likely to be of higher concentration than it would have been under the proposed requirements. Therefore, monitors will more easily meet the linearity check performance specifications at the low calibration gas concentration. In addition, if the CEMS response is within ±5 percent of the calibration gas value, the specification will be considered to be met.

Second, in the daily calibration error test, the specification for the SO_2 and NO_x pollutant concentration monitors will be applied to the span of the instrument and not the "tag value" of the calibration gas, as had originally been proposed. At both the zero-level (0–20 percent) and high-level (80–100 percent) calibration gas, the pollutant concentration monitor's response will be required not to deviate from the calibration gas by more than twice the specification times the span of the instrument. For SO_2 and NO_x CEMS this means that the monitor and the calibration gas must not differ by more than 5 percent of the instrument span (either the high-scale or low-scale span, as applicable). For diluent gas, the monitor response and the calibration gas must not differ by not more than 1 percent CO_2 or O_2. In Pennsylvania, where similar standards have been in place, the failure rate on comparable daily calibration tests over several years has been below 1.5 percent.

Though EPA is making these changes in response to comments, the agency is concerned that basing the calibration specification on the span of the instrument may allow a large and potentially detrimental margin of error when calibrating on zero-level concentration gases. Therefore, the agency will continue to analyze the daily calibration error test data obtained under the Acid Rain Program and evaluate the effectiveness of the calibration error test.

In the linearity checks, both at initial certification and during the quarterly calibration audits, the performance specification will continue to be applied to the calibration gas value. This approach is necessary to ensure the accuracy of the monitoring program and is consistent with standard practice for linearity tests. Data from periodic cylinder gas audits performed under NSPS and under Pennsylvania's State Implementation Plan indicate that the required performance specifications for linearity checks are attainable.

(4) Test Procedures

(a) For initial certification. As part of the initial certification requirements, the proposed rule required the calibration error test to be performed once a day for seven consecutive days with the unit operating at 50 percent or more of maximum load. Each day, a three-point test, using low-, mid-, and high-level gases, was to be performed with the monitor being challenged 3 times at each concentration. Comments on this test requirement focused on three main issues: Many commenters felt the requirement to operate at 50 percent or more of maximum load was unnecessarily burdensome and could force some units to operate above their planned dispatch levels. Others objected to having to challenge the monitor three times at each gas concentration, saying that so much time would be spent on calibration that the monitor's ability to measure actual emissions would be impaired. Still others thought that a 7-day, 3-point test was redundant and unnecessary.

Response: In agreement with the commenters' concerns, the final rule drops the load stipulation for the calibration tests performed at initial certification. However, the unit is required to be operating during the period of testing, because calibration of the instrument is affected by temperature, pressure, and moisture conditions of the sampled gas as encountered under actual operating conditions. The final rule retains the requirement to challenge a monitor three times at each concentration level.

Under the final regulations a 3-point linearity check must be performed only for one day during certification. In this test three gas concentrations are needed to ensure linearity over the range of monitor measurements. The 7-day test is now a 2-point calibration error test. It is the same as the daily calibration error test that will be performed once the certified monitor begins operation.

The EPA believes that comprehensive and thorough calibration testing at certification is particularly important, because it will allow detection and correction of problems before the monitor becomes operational under the Acid Rain Program. Meticulous testing at certification can pay large rewards over the life of the monitoring program, enabling units to eliminate problems early that would have been much more costly and disruptive to correct later.

(b) Quarterly assessment. The proposed regulations required a three-point calibration error test to be performed each calendar quarter. Using low, mid, and high concentration gases, the monitor would be challenged three times at each concentration. Dual range monitors would perform a separate 3-point test at each range. Commenters expressed some confusion about the purpose and requirements of this test.

Response: The final rule retains the quarterly assessment essentially as originally proposed. As noted above, to help clarify the nature and purpose of the quarterly assessment, its name has been changed to "linearity check" instead of "three-point calibration error test." The quarterly test is intended to serve as a periodic "spot check" to ensure that CEMS measurements do not deviate from the "tag" value of each of the three calibration gases by more than ±5.0 percent. In addition, as a linearity check, it will ensure that deviations from the calibration gas values are relatively uniform over the full measurement range of the monitor.

(c) Daily assessments. The proposed rule required calibration error tests to be performed at least once every 24 hours using a low and high concentration reference gas. When performing this test, the operator was to make no adjustments for low-level concentration measurements before completing the high-level calibration checks. Commenters expressed concern that this requirement would prevent an operator from correcting the drift at the high-level gas (known as span drift) by the drift measured at the zero-level gas (known as zero drift). Another major concern focused on the ability of a CEMS to meet a performance specification based on the "tag value" of the low concentration gas.

Response: This test remains as proposed, except that the performance specification will be applied to the span of the instrument instead of to the reference gas values, as discussed in detail above under "Performance Specifications." This change should address the concern about the achievability of the performance specification. The final regulations retain the restrictions on adjustments for drift. However, the agency notes that an operator may computationally correct span drift for zero-drift, but only after both zero- and span-drift have been documented. This is comparable to the requirements under Performance Specification 2 (40 CFR part 60, Appendix B).

Exceptions to CEMS Requirement

EPA received more than 1,000 comments on proposed exceptions to monitoring requirements for SO_2, NO_x, and opacity, as well as on a general exception to the Acid Rain Program's emission reduction, permitting, and monitoring requirements for clean, small new units.

(1) For SO_2 CEMS

In the proposed regulations, exceptions from the CEMS requirements for SO_2 were proposed for two categories of units: Oil-fired units, in general, and combined gas/oil-fired units that derived 90 percent or more of their heat input during the year from natural gas. In the following discussion, the latter units will be referred to as "90-percent gas-fired units."

The first exception would allow oil-fired units to monitor their oil flow rate using a fuel flow meter, analyze the sulfur content of either continuous drip or "flow proportional" samples of the oil, and, then, calculate hourly SO_2 emissions from the corresponding hourly flow rate and sulfur content measurements. "Flow proportional" sampling refers to an automated process whose frequency of sampling is not tied to the time elapsed but rather is proportional to the amount of fluid passing the monitoring location. For example, samples might be taken every ten barrels or every 100 gallons or every 50 pounds of fluid. Under this proposed exception, hourly SO_2 emissions had to be reported within 24 hours of their occurrence.

The exception for 90 percent gas-fired units was similar. However, these units were required only to take daily manual grab samples of the oil, calculate daily SO_2 emissions, and report results within 24 hours. By implication, units burning natural gas exclusively were completely exempted from the SO_2 CEMS requirements.

Some commenters supported the proposed SO_2 monitoring exceptions; some recommended a longer turnaround time for oil analysis; and some proposed a less frequent sampling requirement for oil-fired units. One organization opposed less frequent oil sampling. Others supported allowing a fuel flow meter combined with a diluent monitor to be used in place of a volumetric flow monitor.

Response: The two exceptions included in the proposed regulations are retained in the final rule. In addition, based on the public comments that were received and an analysis of SO_2 emissions data in the National Utility Reference File (NURF) emission inventory, EPA is extending the exception for 90 percent gas fired units to all oil-fired units and lengthening the required turnaround time for oil sample analysis under this exception from 24 hours to thirty days. No other changes to the originally proposed exceptions from SO_2 monitoring have been made. In general, the exceptions granted to gas- and oil-fired units were based on substantial evidence showing that the excepted monitoring methods performed extremely well for these types of fuels with respect to the statutory criteria for equivalency to CEMS, as specified in section 412(a) of the Act. EPA believes that these exceptions are within its discretion in administering the Act. *See Alabama Power Co.* v. *Costle*, 636 F. 2d 323,360–61 (D.C. Cir. 1979). Details of EPA's position are given below.

(a) Exception for oil-fired units. As noted in the preceding paragraph, today's rule provides an exception in Appendix D of Part 75 for monitoring SO_2 emissions at oil-fired units based on the performance of the excepted monitoring methods. The first excepted method relies on automatic fuel sampling, whose sampling frequency is proportional to the fuel flow, with a minimum of one sample drawn each hour. In addition, the "continuous" and flow-proportional oil samples are required to be aggregated and analyzed for sulfur content on a daily basis, using American Society for Testing and Materials (ASTM) standard laboratory procedures. Finally, the rule requires that oil flow meters be calibrated annually.

Since SO_2 emissions from this class of unit can be significant, the rules have designed the method to ensure accurate information, representative of each hour of unit operation, thus ensuring equivalence to CEMS. The method has three main features: accurate metering

of oil flow, as-fired oil sampling (i.e., actual fuel samples taken in proportion to fuel consumption as measured by the fuel flow meters), and accurate accepted procedures specified by ASTM for analyzing the sulfur content and density of the oil samples.

As is explained further below, the evidence available indicates that the oil sampling and analysis method compares favorably to the statutory criteria for "sameness" in section 412(a) of the Act: (1) It is as precise as CEMS; (2) it is no less reliable than CEMS; (3) the information generated from the method—calculations of actual hourly emissions based on representative samples and measurements—is as accessible and useful as that reported by CEMS; and (4) it compares acceptably to the CEMS requirements with regard to the timeliness of measurements and data verification. In short, the only relevant distinction between the CEMS requirements and the flow-proportion continuous oil sampling and analysis method approved today is the measurement method.

The following is an elaboration of EPA's response to two aspects of this exception that attracted specific public comments:

(i) Accuracy of fuel-flow metering. The final rule preserves the proposed fuel flow meter accuracy specification of ±2 percent. The EPA clarifies that this specification is ±2 percent of the maximum flow that can be measured by the meter, known as the "upper range value". Several commenters asked that EPA set a more relaxed accuracy limit. This proposal may have been prompted by confusion over whether the accuracy specification was to be applied to the actual flow or the upper range value. The EPA evaluated this request and decided not to alter the accuracy requirement, based on two considerations: First, information available to EPA indicates that the ±2 percent accuracy specification is achievable by commonly-used types of flow meters, including coriolis-type mass flow meters, positive displacement flow meters, and square-orifice differential-pressure flow meters, and some other less expensive flow meters. Second, the ±2 percent accuracy limit is necessary given the variations in accuracy inherent in the ASTM fuel sample analysis methods. Maintaining the ±2 percent accuracy limit is particularly important, because the final rule adds flexibility by allowing the use of numerous applicable ASTM analytical methods.

(ii) As-fired oil sampling. The CEMS requirements call for continuous measurements of emissions (i.e., hourly averages based on measurements taken at fifteen minute intervals with no fewer than 2 measurements in any hour) followed by data verification within 24 hours. The excepted method for oil-fired units requires automatic sampling on an hourly (or more frequent) basis in proportion to the rate of oil flow. In the oil fuel sampling and analysis method, fuel sample grabs are taken in proportion to the fuel used, with sample grabs required at least once each hour, and sample analyses required each day. This provides samples that are truly representative of each hour of unit operation. Thus, both methods result in measured hourly values.

Commenters suggested a number of ways that the frequency of oil sampling could be reduced, including procedures that account for changes in the sulfur content upon the arrival of each new oil delivery. EPA rejected these suggestions because they would have resulted in less frequent sampling, which would have increased the potential to underestimate the sulfur content of the oil combusted by this category of unit, and would not have assured that the reported emissions represented the actual emissions for the reported point in time.

(b) Exception for oil-fired and gas-fired units. The final rule retains the previously proposed excepted method for calculating SO_2 emissions at gas-fired units that burn natural gas for no less than 90 percent of their total heat input during the year and burn oil—including diesel oil—as their backup fuel for the remaining heat input. *See* 56 FR at 63089. In addition, as noted above, the final rule extends this exception as an option to oil-fired units. These units are not required to use this excepted method for SO_2 monitoring. Rather, they may install a CEMS or employ the continuous oil fuel sampling method described above and in appendix D of part 75.

(i) De minimis exemption from SO_2 monitoring when units burn 100 percent natural gas. Gas-fired units would only be required to monitor SO_2, when they are actually burning oil. This is appropriate due to the *de minimis* nature of the SO_2 emissions from refined natural gas fuel. See discussion of *de minimis* exceptions in the preamble to part 72, Permits. Specifically, units that exclusively use natural gas emit only a small amount of SO_2 each year. Based on the typical amount of sulfur found in natural gas, as measured by ASTM analysis methods, a typical exclusively gas-fired unit emits less than 100 kg of SO_2 annually while combusting natural gas. See discussion of *de minimis* exceptions in the preamble to part 72, Permits.

While emissions are also relatively small from gas-fired units that use oil, including diesel, as a back-up fuel for no more than 10 percent of their heat input, the emissions are not completely negligible. According to the National Allowances Database, there are 525 existing 90-percent gas-fired units. This category of unit emitted 7,600 tons of SO_2 in 1985, yielding per unit average emissions of less than 15 tons annually. Six of the 525 units emitted more than 100 tons in 1985, the cut-off under title V of the Act for "major" sources. Thus, the final regulations stipulate that when a 90-percent gas-fired unit combusts oil, it is required to use an in-line oil flow meter to continuously monitor the amount of oil consumed and to use the highest sulfur value from a series of daily fuel samples in calculating the SO_2 mass emissions in units of pounds per hour.

(ii) Comparison of the excepted method to CEMS. As with the excepted continuous fuel sampling method, this exception for 90 percent gas-fired and oil-fired units compares well to CEMS with regard to precision, reliability, and accessibility. The method differs from the flow-proportional "continuous" oil fuel sampling method—and thus from CEMS—only with regard to the measurement method. As was discussed above, the CEMS and the flow-proportional continuous oil fuel sampling method call for continuous measurements of emissions. In contrast, the alternate excepted method for 90 percent gas-fired and oil-fired units requires daily manual oil samples. Furthermore, SO_2 emissions are required to be calculated using the highest measured fuel sulfur content, recorded in the previous 30 daily samples.

EPA believes that differences between this method and CEMS with regard to measurement and verification frequency are not critical to the exception's methodology. Specifically, as discussed in greater detail below, the measurement frequency, applicable to CEMS, is not needed in the case of gas-fired units and oil-fired units in order to generate representative calculations of a unit's actual SO_2 emissions on an hour by hour basis.

Measurement frequency. EPA considered several factors in concluding that the specified measurement frequency is sufficiently timely for gas-fired units and oil-fired units. First, due to the homogeneity of this particular fuel source, the sulfur content of the daily oil-fuel supply used by these categories of units is unlikely to vary

significantly during a day. Oil fuel typically has a highly homogeneous sulfur content as compared to coal and coal-derived fuels. Moreover, even day-to-day variation in sulfur content will be very limited, since the two source categories which will use this method typically purchase and consume batches of oil fuel infrequently. In addition, fuel usage at gas- and oil-fired units can be measured accurately, and virtually instantaneously, using a flow meter.

Finally, the approved daily sampling method requires that SO_2 emissions be calculated using the highest measured sulfur content of the previous 30 daily samples. This prevents any possible underestimation in the unlikely event that a daily sample had a lower sulfur content than the average for the entire day. It is, thus, highly improbable that any emissions would not be accounted for using this method.

Verification frequency. Although the "timeliness" criterion in section 412(a) of the Act does not unequivocally mandate exactly the same turn-around time in measurement verifications for CEMS and excepted methods that involve collection of actual measurement samples, EPA believes that the verification frequency for any monitoring method should be as short as is practical. This is important in order to provide up-to-date emissions information to the allowance market and to meet regulatory deadlines for quarterly emissions reports and the end-of-year allowance/emissions reconciliation. Nevertheless, as numerous commenters pointed out, a "next day" turn-around requirement would be particularly impractical for units covered by this exception. They are frequently located in remote areas and, due to their size and the infrequency of their burning oil, they typically must send their oil samples to outside commercial laboratories for analysis. Many commenters suggested that seven days would be the minimum reasonable amount of time to send out oil samples for analysis and receive results while others suggested a 15 or 30 day turnaround. Concern was expressed that it would be administratively impractical to conduct a 24 or even 7 day turnaround thus making this option unattractive to most, if not all, of the oil fired units for which this option is intended. As proposed, those selecting this option would be driven to inefficiently analyzing single or small batch samples. Concern was also expressed that this approach could inadvertently encourage the development of on-site, less accurate, lab analysis. Thus, EPA does not consider a seven day turnaround practical for small or remotely located units. Further, in situations where the information is needed more quickly for end of year true-up or enforcement purposes, the sample(s) could be analyzed more quickly on a case by case, as needed, basis. Thus, EPA has decided to promulgate a 30 day turnaround period.

(iii) Other considerations. EPA's analysis also indicates that this exception represents an appropriate way to reduce the particularly disproportionate financial burden that requiring SO_2 CEMS would impose on oil-fired units. Total emissions from all oil-fired units represent approximately 4 percent of the SO_2 emissions from all affected units. Nevertheless, monitoring costs under the Acid Rain Program for small oil-fired units can range as high as $490–$49,000 per ton of SO_2 emitted. The proposed exception will provide a viable, more cost effective option for such sources.

Another concern, raised by commenters, was that units qualifying for this exception might subsequently change their proportion of oil usage, thereby increasing the level of emissions not being monitored by CEMS. To address this concern, the definition of "gas-fired" has been revised in the final rule to include a cap on the amount of oil that qualifying units could use in any one-year or 3-year period. Further, by extending the option to all oil-fired units, the decision to install an SO_2 CEM system will not be capacity factor driven. The result is a simplified set of requirements that provide additional operational flexibility to units that experience atypical increases in utilization in any given year.

(c) Other suggested methods for calculating SO_2 emissions considered. Commenters proposed several other methods for determining SO_2 emissions. EPA rejected these approaches because they represented clear departures from the statutory criteria for evaluating alternative monitoring methods and because of concerns about their administration and enforceability.

Permit limit proxy. One proposal for oil-fired units was to always use the "maximum permitted" oil sulfur content as a default sulfur value for units with such permit limitations. The EPA rejected the proposal because a fuel's permitted sulfur content bears no relationship to physical measurement and verification procedures, based on actual operations, that are implicit in the word "monitoring," as mandated in the Act.

"F-factor"/fuel flow method. Other commenters proposed allowing a diluent monitor, an "F-factor," and a fuel flow meter to be used as an alternative to a CEMS volumetric flow monitor. (An "F-factor" is a fuel-specific constant that relates the heat content of a fuel and the amount of gases given off upon combustion. It is used to convert diluent gas concentration and pollutant concentration into a value of pounds of pollutant per million British thermal units of heat input.) In a four-day experiment performed by one commenter, the method appears to have produced measurements that track those generated by a combined SO_2, CEMS and volumetric flow monitor. However, EPA does not believe that four consecutive days of data are sufficient to support a conclusive equivalency determination at this time. To be approved, this method would have to meet the criteria for alternative methods in a thirty-day trial as required by the provisions of § 75.40 of the rule. If approved, this alternative method would be promulgated as an excepted monitoring method in appendix I and would apply categorically to oil-fired and gas-fired boilers.

Coal fuel sampling: EPA also considered coal fuel sampling as a method of monitoring SO_2 emissions. As with other methods suggested, EPA evaluated the method's ability to obtain accurate and representative samples and evaluated the practicality of using the method to obtain samples, determine the amount of fuel used, and calculate emissions for any given hour. Whereas flow-proportional continuous oil fuel sampling yields extremely accurate information on which to base actual emissions calculations, such accuracy cannot be consistently achieved by coal fuel sampling. Oil fuels have highly homogeneous sulfur content as compared to coal and coal-derived fuels. Comparisons of oil fuel sampling to CEMS have shown variations in contemporaneous readings of 0 to ±5 percent on an hourly basis. Similar comparisons of coal sampling to CEMS have shown variations in contemporaneous readings ranging from ±10 to ±45 percent on a daily basis, with significantly greater variations on an hourly basis.

These results are not unexpected since the physical composition of coal makes it extremely difficult to specify and use a standardized process for taking representative fuel samples. Because coal characteristically can contain large, but irregular, concentrations of impurities, the sulfur content of coal can vary greatly within a single shipment. Consequently, two adjoining chunks of coal may differ dramatically from each other. EPA does not consider that units performing coal

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fuel sampling and analysis qualify for an exception to the CEMS monitoring requirements for SO_2.

(2) For NO_x CEMS

The proposed regulations included no exceptions to the NO_x CEMS requirements.

Through the public comment process, EPA received numerous proposals for exemptions from the NO_x monitoring requirements. The comments focused primarily on the category of affected units that are not coal-fired and are not, therefore subject to NO_x emission limitations under section 407 of the Acid Rain Program. Some commenters asked that such units be exempt from the title IV NO_x emissions monitoring obligations in their entirety. Others recommended an alternative method for infrequently operated (i.e., "peaking") units, such as diesel- and dual-fuel reciprocating internal combustion engine units, combustion turbines, and other oil- and gas-fired units with a capacity factor below some stipulated level.

Response: EPA disagrees with those proposing a total exemption from NO_x monitoring requirements for units that do not have a NO_x emission reduction obligation under section 407 of the Act. Section 412 of the Act clearly requires *all* units with emissions limitations under title IV, not just those with NO_x limitations, to monitor NO_x emissions. This information is important to Acid Rain Program implementation, particularly with regard to the various studies and reports mandated by the Act, which specifically identifies NO_x as a key acidic deposition precursor pollutant.

EPA agrees, however, that it is appropriate to craft a limited exception to the NO_x CEMS requirements, applicable only to gas- and oil-fired "peaking" units having a capacity of 10 percent or less over the previous three years. See discussion of *de minimis* exceptions in the preamble to part 72, Permits. These two categories of peaking units have extremely low emissions both collectively and individually. Total NO_x emissions from this category of unit is estimated at 40,000 tons per year. At the same time, the cost of monitoring NO_x emissions using CEMS could be several hundred dollars per ton of NO_x monitored. In addition, a large number of sources that fall into these two categories are located in small municipalities, where the cost of installing, operating, and maintaining CEMS would be particularly burdensome.

EPA believes that these considerations, and the fact that these categories of units are not subject to NO_x emission reduction requirements under title IV, are pertinent. The EPA believes that exceptions to monitoring requirements are appropriate to consider in cases where insignificant annual emissions are involved and the statutory objectives can be met. Specifically, the primary concern underlying the statutory emphasis on CEMS as the mandated monitoring method is the need for precise, reliable and timely information indicating the exact emissions of each unit *in order to determine whether a source or unit has met its emissions limitations.* (emphasis added). S. Rep. No. 427, 101st Cong., 1st Sess. 336–337 (1989). In short, given the absence of a compliance obligation for these two categories of units, and the high costs of installing and operating CEMS at the units, a reliable exception method would seem justified.

(a) Approved method. The final regulations allow gas- and oil-fired "peaking" units to account for their NO_x emissions using site-specific NO_x emission factor correlations at various unit loads. The term "peaking unit" is typically used by industry to describe a unit that is operated at a capacity factor of 10 percent or less. See, for example, the Electrical Power Research Institute's *Technical Assessment Guidelines* (1991), which classifies units on the basis of load. The term "capacity factor" refers to the ratio of the unit's actual electrical or steam output (in MWehr) to the output if the unit ran continuously for 8760 hours a year at the unit's rated nameplate capacity. A capacity factor of 10 percent would be typical of a unit that operates 400 hours a year. A "low capacity factor" unit typically refers to a unit that is operated at a capacity factor of 30 percent or less. The term encompasses both "intermediate load" and "peaking" units. A "high capacity factor" or "base loaded" unit refers to units operated at a capacity factor of 50 to 70 percent.

Any unit using this method will be required to develop a historical record of NO_x emissions at various loads to establish the correlations. The site-specific derivation of correlations, based on historical emissions data, is necessary, because NO_x formation is uniquely dependent on the particular operating characteristics and equipment used at a unit. Once the correlations are derived, they are applied to the unit's actual load data in order to calculate the unit's NO_x emissions for the year. In addition, periodic NO_x emissions stack testing is required to verify the continued representativeness of the correlations. The EPA believes these procedures will ensure that the correlations produce sufficiently representative data on actual emissions for this limited class of units. This approach is consistent with the recommendations of many of the commenters who identified the need for an exception to NO_x CEMS for gas- and oil-fired peaking units.

It is important to note that the approved emissions/load exception does not meet the criteria for an alternative monitoring system, as specified in section 412(a) of the Act. As such, it is only approved for use in a very limited class of units. To date, no continuous alternative NO_x monitoring system has been field tested alongside a certified NO_x CEMS and shown to meet the equivalency criteria specified in the Act. Thus, there is no exception to NO_x CEMS requirements beyond the exception for oil- and gas-fired "peaking" units.

Some commenters expressed concern that a unit, once qualified for an exception to the NO_x CEMS requirement, could then change from a low capacity factor to a high capacity factor unit, or change its fuel usage and thereby undermine the representativeness of the emissions/load correlations. To prevent this, the final rule includes a definition for "peaking unit" that links the continued availability of the NO_x monitoring exception to a unit's mode of operation during the previous three years. It provides additional operational flexibility in the case of atypical end-of-year increased utilization, while setting limits on a source's ability to qualify for an exception to the NO_x CEMS requirements. The regulations also include procedures for determining if units with fewer than three years of operating experience qualify as peaking units. If a unit's utilization changes so that it is no longer a "peaking" unit, it would become subject to the CEMS monitoring requirements in the following calendar year. Similarly, if a unit changes its fuel usage and thereby changes its emission characteristics, the owner or operator would be required to revise the unit's correlations or install a CEMS for NO_x by the end of the following calendar year.

(b) Other methods considered for NO_x exceptions: AP–42. A number of commenters promoted an approach, similar to the emissions/load correlation approach approved today, but based on the EPA-developed emission estimation factor known as AP–42. Despite superficial similarities, that approach would rely on emission factors derived from industry-wide average (i.e., generic) estimates of emissions for different fuel and boiler types. The EPA

rejects such an approach, because its estimates are not based on the actual historical operating experience of the units to which the estimates would be applied. Generic estimation would be especially detrimental in calculating NO_x emissions, because of wide variations in emissions formation characteristics from unit to unit.

The unit-specific NO_x emissions/load correlation approach approved today provides a more representative calculation of the actual emissions at a particular unit than the generic AP–42 emission estimation factors. This is especially true for combustion turbines and diesel and dual-fuel reciprocating internal combustion engines, which tend to have relatively steady and predictable NO_x emissions.

(c) Other capacity factor cut-offs. As discussed above, the exception to the NO_x CEMS requirement applies to "peaking units," defined as units with a capacity factor of 10 percent or less over the previous three years and 20 percent or less in each of those years. The EPA received proposals for NO_x CEMS exceptions based on other capacity factor cut-offs. Some commenters suggested that oil- and/or gas-fired units with a capacity factor of 30 percent or less should be able to determine NO_x emissions by an excepted method. The EPA has rejected this suggestion since it considers the NO_x emissions from existing units operating at a capacity factor between the approved 10 percent cut-off and the proposed 30 percent cut-off to be not *de minimis*, either individually or as a group. Such units can emit more NO_x than many coal-fired units affected in Phase I of the program. According to the NURF database, the entire category of 30 percent or less, gas- and oil-fired units emitted approximately 400,000 tons of NO_x in 1985.

(3) For Opacity Monitoring

The proposed rule contained two classes of exemptions to the part 75 requirement that affected units install continuous opacity monitors. Gas-fired units that derived no less than 90 percent of their total annual heat input from natural gas were exempt as were wet scrubbed units. These and all other affected units would still be required to meet any other applicable federal, state, and local opacity monitoring requirements.

Some commenters suggested that the opacity monitoring requirements under the Acid Rain Program should not go beyond other existing federal, state, and local requirements.

Response: EPA cannot adopt this proposal, since section 412 of the Clean Air Act Amendments requires the installation of continuous opacity monitors at all affected units. There appear to be a substantial number of affected units combusting residual oil which exhibit significant opacity levels, yet are not subject to opacity monitoring requirements in every state. The opacity data, obtained under part 75 of these regulations, is to be sent to state and local air control agencies.

However, the Agency is using its discretionary authority to provide class exemptions for units that do not have significant opacity levels and for units that may not be able to provide meaningful opacity information. Thus, in the interest of meshing the Acid Rain Program opacity monitoring requirements with those of pre-existing federal, State, and local air quality programs, the final rule exempts gas-fired units that combust natural gas for no less than 90 percent of their total heat input during the previous three calendar years and diesel and dual-fuel reciprocating internal combustion engine units. As noted in the preamble to the proposed rule, gas-fired units have very low opacity levels, and extremely few of them (less than 5 percent of the 90-percent gas-fired units in the National Allowances Database) are required to monitor for opacity under other federal, State, or local regulations. Likewise, states such as Indiana, Iowa, and Kansas with many diesel and dual-fuel reciprocating internal combustion engines do not require the monitoring of opacity because of low opacity levels (e.g. below 10 percent opacity, even during startup). Nevertheless, where such requirements exist, this exception for title IV purposes has no effect on a unit's obligation to comply with other provisions of the Act. *See Alabama Power Co.* v. *Costle*, 636 F. 2d 323, 360–61 (D.C. Cir. 1979).

One commenter remarked that many wet scrubbed units successfully monitor for opacity under state programs and suggested that it would be appropriate for EPA to require opacity monitors on wet scrubbed units.

Response: EPA acknowledges that it is sometimes possible to monitor opacity in the stack or at the inlet of wet scrubbed units, depending on site-specific conditions such as the temperature of the flue gas. Therefore, under the final rule, only wet scrubbed units where condensed water is present are exempted from opacity monitoring for acid rain purposes. Nevertheless, if the State, local, and other federal programs require monitoring of opacity, then compliance with those regulations is still required.

Another commenter expressed concern that the opacity monitoring requirements might be avoided by units whose classification changes from "gas-fired" to "oil-fired," due to their using a higher proportion of oil for their heat input.

Response: The Agency has revised its definition of a "gas-fired" unit to allow units to use a three year period in calculating the proportion of their heat input derived from natural gas. This will reduce the likelihood of a unit's being accidentally reclassified without significantly changing the characteristics of its emissions. However, if a unit should still exceed the specified proportion of oil in its fuel blend and thereby change its emission characteristics, the owner or operator is required to install and certify a continuous opacity monitor within 365 days of the occurrence of the change in classification.

(4) For Clean, Small New Units

In the proposed rule, EPA requested comment on whether exceptions to some or all of the Acid Rain Program requirements should be extended to small new units, based on the relative insignificance of their total emissions. Existing units of less than 25MWe capacity are exempt from the title IV by virtue of the statutory definition for "existing unit," but there is no explicit exemption for small new units. Specifically, EPA asked whether small generators that only incidentally supply power to the grid should be subject to the full range of Acid Rain Program requirements. The overwhelming majority of those who commented on the issue believed that some form of relief would be appropriate for small new units with low emissions. Various demarcations were suggested by the commenters for defining the categories of units that would qualify for such an exception. They include: A size cutoff in MWe, with commenters suggesting sizes ranging from 5 to 25 MWe; a tonnage emissions cutoff such as that used in EPA's Prevention of Significant Deterioration air pollution control programs; and exceptions based on boiler or engine type. Two related concerns, particularly noted by the commenters, were the relatively high, per-unit cost of monitoring extremely small sources (i.e., those emitting in the range of one-ton of SO_2 per year), and the unusual burden these costs would impose on small generators and small communities. Commenters also drew attention to the heavy burden, both to sources and to EPA, that would result from having to issue acid rain permits to all such units.

Response: As is discussed more fully in the preamble to part 72, the Agency agrees with the commenters that a conditional *de minimis* exception to the emissions reduction, permitting, and monitoring requirements of the Acid Rain Program is appropriate for small, new, "clean" units. Specifically, units having a nameplate capacity of 25 MWe or less and combusting fuels with a sulfur content not greater than .05 percent by weight would be conditionally excepted from all Acid Rain Program emission reduction, permitting and monitoring requirements, subject to a continuing requirement to certify their eligibility for this exception. EPA's analysis indicates that the sulfur content standard of this exception would be met by units combusting natural gas and by units combusting diesel fuel refined to meet requirements in the Clean Air Act Amendments for on-road vehicles. Those units that do not meet the nameplate capacity and fuel sulfur content criteria will be required to meet all title IV Acid Rain Program requirements. Moreover, EPA will reconsider the exception if significant increases in emissions from this category are found to occur in the future. EPA believes that this exception, and the safeguards associated with it, are in keeping with the Administrator's authority to grant *de minimis* exceptions.

VI. Discussion of Changes to Part 77—Excess Emissions

Part 77 sets forth the requirements for units that have sulfur dioxide or nitrogen oxide emissions in excess of their emissions limitations. Units with excess emissions of sulfur dioxide must submit offset plans providing for the deduction of allowances equal to the tonnage of excess emissions and must pay $2,000 (as adjusted by the Consumer Price Index) per ton of excess emissions. Units with excess emissions of nitrogen oxides also must pay a $2,000 per ton penalty. In addition, interest is owed for late penalty payments.

A. Restructuring Changes

In response to general comments encouraging streamlining of the rules, portions of part 77 have been reorganized and simplified. First, like all the definitions of terms in other parts of the rule, definitions from part 77 have been consolidated in § 72.2. Further, provisions that were redundant with generally applicable provisions in part 72 were deleted. These include applicability, federal and state authority, signatory requirements, and recordkeeping. The substance of these provisions (including the reservation of federal authority) was not altered by this organizational change. Finally, Appendix A was deleted. It duplicated certain provisions already in the rule and provided information, showing the calculation of the excess emission penalty, that is more appropriately left for guidance materials.

B. Response to Comment

(1) Offset Plans for Excess Emissions of Sulfur Dioxide

Section 77.2 of the proposed rule required that each offset plan contain specific, detailed information about every unit with excess emissions. For example, the proposed rule required that the plan explain how and why excess emissions occurred at the unit, what corrective actions had been taken, and the schedule and increments of progress for offsetting the emissions in the future. A unit wishing to use a new compliance option to obtain allowances for offsetting had to include the planning requirements for that option in the offset plan.

The Agency received numerous comments on this section of the rule. In general, the commenters thought the offset planning process was unnecessarily lengthy, burdensome, and complicated. Moreover, they strongly supported eliminating most of the offset information and scheduling requirements, especially for cases where an offset plan simply calls for deduction of allowances from the excess emitting unit's account in the year after the excess emissions occurred. In addition, a few commenters questioned the Agency's authority to impose certain information requirements.

Response: Section 411 of the Act requires the owners and operators of a unit with excess emissions to submit "a proposed plan to achieve the required offsets," which plan the Administrator will approve "as submitted, modified, or conditioned." This provision gives EPA the discretion to require information deemed necessary to review offset plans and to determine what conditions to require. Further, Congress intended that offset plans could be broader than simply a statement of when allowances would be deducted. See 136 Cong. Rec. S16969, 16982, daily ed., October 27, 1990 (stating that the offset plan should show how source will reduce its emissions to achieve the requirements of title IV, including a plan to achieve required offsets). Nevertheless, in light of the comments supporting an easing of the regulatory burden, the Agency has reconsidered its approach for carrying out section 411 and has simplified the requirements for offset plans.

Information requirements have been tailored to fit the type of offset plan that is submitted and the compliance status of the unit involved. In general, if a plan specifies an immediate deduction of allowances to offset excess emissions, no additional information is required. Only if the unit has had excess emissions for two years in a row must the plan include information on how the excess emissions occurred and what measures are being taken to prevent excess emissions in the future. If a plan specifies a deduction of allowances at a date after the year following the year in which excess emissions occurred, the plan must in addition demonstrate that deducting the allowances earlier would interfere with electric reliability. However, compliance options are no longer tied to offset plans and are submitted separately as permit revisions.

There are several reasons for these changes. First, the Agency believes that by simplifying the proposed rule, it can ease the regulatory burden on sources and on the Agency without any adverse environmental impact. The Agency believes that in most cases an offset plan that simply requires immediate surrender of allowances to offset excess emissions will be sufficient. Such a plan, coupled with the automatic penalty of $2,000 per ton of excess emissions and the enforcement remedies under other sections of the Act, provides a strong incentive for owners and operators to be in compliance. However, a more detailed plan, including compliance schedules, may be needed in unusual cases, e.g., to ensure immediate and appropriate steps are taken to bring a unit with recurring and egregious violations back into compliance. The Agency believes that, in cases of repeated excess emissions, information on the cause of the excess emissions and measures to prevent future excess emissions will assist in determining whether a more detailed offset plan is necessary. The Agency has reserved the authority to require detailed schedules of compliance on a case-by-case basis and intends to use this authority only in extraordinary cases.

Second, even though some of the upfront information requirements have been deleted, the Agency's ability to obtain information about the unit has not been compromised. The Administrator still retains the discretion to ask for supplemental information under this part and also has the broad

authority to demand information under sections 114 and 307 of the Act.

Finally, while a compliance option (such as substitution or reduced utilization) may no longer be approved as part of the offset plan, units retain the flexibility that they had, under the proposal, to use compliance options to accomplish the offsets. Under the final rule, a unit may still use the permit revision procedures in part 72 to obtain approval for a compliance option. Depending on whether the unit obtains approval for an offset plan with delayed deductions of offset allowances, newly available allowances under an approved compliance option can be used directly to make offsets or to replenish the unit's account after offset allowances have already been deducted. Under this approach, a compliance option is approved under the same procedures in part 72 regardless of whether the unit involved had excess emissions in the prior year. Of course, the choice of a compliance option will not alter or stay the requirements of the offset plan.

(2) Administrator's Action on Proposed Offset Plans

The proposed rule required each proposed offset plan, regardless of how simple or complex it was, to undergo the same approval process. This process included a public notice and public comment period and was to be completed within six months of the proposed offset plan's submission. Several commenters questioned the Agency's authority to provide public notice and comment and recommended shortening the approval process for at least the simplest kinds of offset plans. The six-month approval process was viewed as serving only to delay expeditious compliance with the offset requirements.

Response: The Agency believes that it has the same authority to provide for notice and comment for an offset plan, which conditions a permit, as it has with regard to the permit itself. Nonetheless, in light of these comments and the simplified approach the Agency has taken to offset planning, the Agency has decided to shorten the process for approving most offset plans.

Accordingly, the Agency has divided offset plans into two categories: Those that specify deducting allowances immediately and those that specify deducting allowances at a later date. In the latter case, the offset plan will still go through the up-to-six-month approval process described in § 77.4 of the final rule. This is essentially the same process that was laid out in the proposal. When a unit wants allowances deducted later in the year or in a subsequent year, the public should have the opportunity to comment, e.g., on why allowances are not being immediately deducted or whether a more detailed plan is appropriate.

The Agency will generally deal with the first category of offset plans in a much simpler way. If a proposed offset plan specifies deducting allowances immediately and the allowances are in the unit's account, the plan may be approved without further review as an automatic amendment to the permit. The Agency believes that, in general, a public notice and comment period in such a case would serve no purpose. In requiring the soonest possible deduction of allowances, the offset plan already meets the requirement, under section 411(b) of the Act, that allowances be deducted from those allocated for the source. Notice and comment would only delay the offsetting of emissions that would otherwise occur soon after submission of the proposed offset plan. However, in those exceptional cases where, despite the submission of a plan calling for immediate deductions, the Agency determines that a more detailed offset plan with compliance schedules is necessary, the public should have an opportunity to comment on the schedules. Therefore, the six-month approval process will apply.

(3) Interest on Penalties for Excess Emissions

The proposal required the owners and operators to pay interest on the automatic $2,000 penalty for each ton of excess emissions if the penalty payment was late. The Agency received numerous comments concerning the interest requirement. In general, commenters questioned whether the Agency had the authority to collect interest on the penalties. Furthermore, they strongly argued that at a minimum, if a penalty payment was late, interest should accrue from the due date of the penalty, not January 1.

Response: The Agency clearly has the authority to collect interest on penalties. That authority comes from the Debt Collection Act, 31 U.S.C. 3717, which allows the head of an executive agency to charge a minimum annual rate of interest on an outstanding debt on a United States government claim. However, the Debt Collection Act provides that interest accrues from the date on which notice of the amount due is first mailed to the debtor. Therefore, the Agency has revised the rule to require that, for any penalty payment not made in full within 60 days of the end of the year in which excess emissions occurred, interest accrues from the date on which a demand notice from the Agency is mailed. Consistent with the Debt Collection Act, interest will not be charged if the claim is paid within 30 days after the date that notice of the amount due is mailed to the debtor.

VII. Discussion of Changes to Part 78—Administrative Appeals

Proposed subpart H of part 72 (renamed part 78) provided the procedures for administrative appeals of certain decisions of the Administrator under the Acid Rain Program. The basic approach to administrative appeals taken in the final part 78 rule is the same as that in the proposal, with a few changes. References in the proposal to the Administrator have been changed to refer, in the final rule, to the Environmental Appeals Board. In the past, appeals to the Administrator were delegated to the Chief Judicial Officer or decided by the Administrator. On February 13, 1992, the Agency established the Environmental Appeals Board of three members who will take over the appellate functions formerly exercised by the Chief Judicial Officer and the Administrator. (See 57 FR 5320, February 13, 1992.)

Further, references to "submit" or "submissions" have been changed to refer to "file" or "filing." This reflects the fact that, for purposes of applying the filing deadlines set forth in part 78, the date of receipt by the Administrator, Environmental Appeals Board, Presiding Officer, or Hearing Clerk (as appropriate), not of sending, is determinative. Also, as part of an effort to streamline the role, some provisions (e.g., proposed §§ 72.101(c)(2) and (d)) were deleted as unnecessary or redundant in light of the broad authority of the Presiding Officer under other provisions.

A. Expansion of Appeals to Allowance Rule Decisions

Proposed part 72, subpart H applied only to the Administrator's decisions concerning Acid Rain permits but the Agency stated in the preamble to the proposal that it was considering whether the appeals procedure should cover other decisions under the Acid Rain Program. The Agency received numerous comments requesting that the appeals procedures be expanded to cover other decisions. In particular, commenters noted the account error and dispute resolution process, proposed in § 73.37, applicable to allowance transfers recorded by the Administrator in the Allowance Tracking System. While the commenters generally supported that process, several commenters suggested that the appeals

procedure in part 72, subpart H be expanded to cover decisions of the Administrator under part 73, as a supplement to the account error and dispute resolution process.

Response: The Agency agrees that the administrative appeals procedure should be available for decisions of the Administrator under part 73. The final rules therefore include a provision allowing appeals regarding various decisions on the transfer, allocation, sale, return, or deduction of allowances by the Administrator. The administrative appeals procedure may not, however, be used to challenge provisions or requirements promulgated in regulations, including part 73.

Like the account error and dispute resolution procedure, only the authorized account representative of the account involved may appeal decisions under part 73 (e. g., allowance allocations under compliance options). This minimizes interference with the operation of the Allowance Tracking System and the allowance market. However, decisions under part 72 affecting allowances (e.g., decisions on compliance options resulting in allowance allocations) may be appealable by other interested persons.

B. Expansion to Monitoring Rule Decisions

Many commenters also supported using the administrative appeals procedure for decisions of the Administrator under part 75 because of the critical role that monitoring plays in the Acid Rain Program.

Response: The Agency agrees and the final rules allow monitoring decisions of the Administrator to be appealed under part 78, including the following: (1) The decision on petition for approval of an alternative monitoring system; (2) the approval or disapproval of a monitor certification or recertification: (3) finalization of annual emissions data, including retroactive adjustments based on audits; (4) the determination of the percentage emissions reduction achieved by Phase I extension technology; and (5) the determination on the acceptability of parametric missing data procedures. The Agency is providing for appeal of these decisions because they involve judgement and discretion on the part of the Administrator, rather than a blanket application of the regulations in part 75. These administrative appeals procedures may not be used to challenge the part 75 regulations.

C. Other Related Changes

Consistent with the expansion of the scope of the administrative appeals procedures in the final rule, the final rule applies these procedures to various decisions (in addition to the issuance or denial of permits) under the permits rule, including the issuance or denial of written exemptions for new and retired units, the determination of the incompleteness of an Acid Rain permit application, and the deduction or return of allowances under the compliance options. The procedures also now apply to the approval or disapproval of excess emissions offset plans and related allowance deductions under part 77.

Moreover, the significantly broader scope of Agency decisions subject to administrative appeal is likely to impose a much heavier burden on the Environmental Appeals Board and the Administrative Law Judges in terms of the number and complexity of the cases. Consequently, certain provisions of the proposal have been changed in order to ease that burden and ensure sufficient time for reasoned decision-making. In particular, under the final rule, the Presiding Officer in an evidentiary proceeding must issue a proposed decision "within a reasonable time" after completion of the hearing, rather than within 90 days as required in the proposal. Similarly, rulings on motions must be made within a reasonable time, rather than within 60 days.

Finally, the expansion of the appeals procedures means that they may apply to decisions on matters concerning which there was no opportunity to file comments or claims of error before the appeal. For the latter decisions, the final rule places the burden of going forward on the Administrator. Except for such cases, the petitioner has the burden of going forward. In all cases, the petitioner or, where the issuance or denial of an Acid Rain permit and a written exemption is involved, the prospective permittee has the burden of persuasion. This is consistent with the discussion of burden of proof in the portion of the preamble for the proposed rule addressing appeals.

VIII. Impact Analyses

A. Executive Order 12291

Under Executive Order 12291, the Administrator must judge whether a regulation is "major" and therefore subject to the requirement to conduct a Regulatory Impact Analysis (RIA). This rule package is "major" as defined in 1(b) of E.O. 12291 because the annual effect on the economy will be greater than $100 million. While the annual effect on the economy will be greater than $100 million, EPA does not anticipate major increases in prices, costs, or other significant adverse effects on competition, investment, productivity, or innovation or on the ability of United States enterprises to compete with foreign enterprises in domestic or foreign markets due to the proposed regulations.

Title IV, on its own without any implementing regulations, mandates extensive emission reductions and imposes continuous emission monitoring requirements on all sources. The reductions basically impose a reduction in emissions equal to the limit of allocated "basic" allowances. Such a program costs much more than the program assuming allowance trading, which provides for flexible, cost-effective compliance, the permits program, which provides for special compliance options such as the Phase I technology reserve program, and the monitoring program, which allows sources to implement alternative monitoring systems if they are demonstrated to match or exceed CEM systems.

A high base case and a low base case scenario were used in the analysis. These two cases were used by EPA to estimate the impacts of the legislation during the debate in Congress.

EPA's RIA evaluates the effects of a set of three regulations termed the "implementation regulations." These regulations are the General Provisions and Permits regulation; the Allowance System regulation, including tracking, transfers, auctions and sales, and conservation and renewable energy; and the Continuous Emissions Monitoring regulation. Collectively, this set of implementation regulations establishes and implements the core of the acid rain program. NO_x control costs were not included in this analysis.

EPA estimated the costs of achieving the reductions in SO_2 emissions under the statute and the implementation regulations for the time period from 1993 through 2010. While the total costs will be much lower in Phase I than Phase II, this analysis annualized the costs over the entire 18-year period. The statute without the implementation regulations (absent regulations case) imposes substantial costs, with the total annualized costs ranging from $1.6 to $2.5 billion per year. The costs of the implementation regulations (regulatory case), with total annualized costs ranging from $0.9 to $1.5 billion, are substantially less than the costs of the statute absent the implementation regulations. Thus, to achieve the mandated SO_2 emission reductions, the implementation regulations result in annual cost savings of between $0.7 and $1 billion compared to the statute absent the regulations.

While these costs are large in absolute terms, they are relatively small compared to the $200 billion average annual costs of generating electricity. The annualized costs of the implementation regulations are estimated to increase the annual costs of generating electricity by 0.5 to 1.2 percent.

For permitting under the regulatory case, program participants will incur administrative costs to obtain permits. The administrative cost for affected sources to obtain permits is estimated to be $0.5 million per year for Phase I (1995–1999) and $5.4 million per year for Phase II (2000–2010). Under the absent regulations case, no permitting would take place, so there would be no costs associated with permits.

In the regulatory case, EPA estimates that the total impact for participants in the allowance trading market will range between $15 and $30 million per year. This estimate includes market evaluation and transactions costs. These costs are based on the assumption that transactions costs will average 1.5 percent of the value of trades, which is assumed to range between $1 and $2 billion annually. In the absent regulations case, no trading would occur, so there would be no transaction costs in that case.

Although the auction and direct sale regulations are not included in this rulemaking, the costs are presented here for completeness. The total estimated annual costs to auction participants are minor, ranging from $13,600 to $81,300. The estimated total costs for direct sale applicants is $13,500 over 2 years. Assuming all IPP guarantee applications occur in the first year, the total cost to IPP guarantee applicants is estimated to be $225,000.

The conservation and renewable energy reserve is an optional program intended to provide additional incentive for utilities to conduct conservation programs. Affected sources that choose to participate in this program are likely to do so because it is economically beneficial. Under the regulatory case, the cost to affected sources that choose to participate associated with obtaining allowances from the conservation and renewable energy reserve is estimated to be $100,000 to $200,000 per year. These costs include the burden to assemble and submit an application to EPA each year in order to receive allowances from the reserve. Under the absent regulations case, no conservation and renewable energy reserve would be established.

For monitoring, the costs to the regulated community under the absent regulations case include costs associated with the installation and maintenance of continuous emissions monitors (CEMs), continuous opacity monitors (COMs), and flow monitoring systems, if they do not already have one in place. No alternative monitoring methods would be allowed and no data reporting costs would be incurred. In this case the estimated cost to the regulated community is $195 million annually.

The analysis considered five monitoring options under the regulatory case. All five options include operation and maintenance requirements. Option 1 presents the most stringent regulatory case and has an estimated annualized cost to electric utilities of $239 million dollars. Option 2 some monitoring exceptions and is estimated to cost $211 million annually. Option 3 exempts retiring plants from all monitoring requirements and has an estimated annualized cost of $234 million. Option 4 requires the use of standardized data reporting and recordkeeping requirements and is estimated to cost $235 million annually. Finally, EPA's proposed option, Option 5 has an estimated annualized cost of $184 million.

Both the absent regulation and regulatory cases will yield environmental benefits due to the 10 million ton reduction in SO_2 below 1980 levels. The reductions will result in less acid rain and sulfate exposure, and better visibility and local air quality. The implementation regulations are expected to generate additional long run benefits by creating incentives for the development of improved pollution control technology.

The analysis is contained in the Regulatory Impact Analysis (RIA) of the Acid Rain Regulations, July 1992, EPA, Office of Atmospheric and Indoor Air Programs.

This rule and RIA were submitted to the Office of Management and Budget (OMB) for review prior to publication as required by E.O. 12291.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires each Federal agency to perform a Regulatory Flexibility Analysis for all rules that are likely to have a "significant impact on a substantial number of small entities."

For the purposes of this analysis, EPA used the Small Business Administration definition that a small electric power utility is one that generates a total of less than 4 billion kilowatt-hours per year. Not all small utilities are affected by the acid rain Title of the Act. Utilities will be unaffected if all of their units are: (1) Exempt (e.g., units use non-fossil sources of energy or simple gas turbines), or (2) below statutory minimums for electric generating capacity (e.g., generate less than 25 megawatts).

To examine the effects on small entities, EPA constructed six model small utilities of varying fuel type and size to represent most of the small utility population. Costs of SO_2 reductions are the incremental costs of acid rain controls, relative to the pre-statute case, under the absent regulations and regulatory cases. The implementation regulations lead to cost savings (or no change) relative to the absent regulations case for four of the six model utilities. However, even after the reductions in cost provided by the implementation regulations, the impacts on some small coal- and oil-fired utilities are expected to be significant. In the worst case, the regulatory cost to these utilities could represent between 6 to 7 percent of the average value of electricity produced in the year 2000. About 36, or one-third, of the 105 affected small utilities could face impacts of up to this magnitude. The other two-thirds have regulatory impacts that are comparable to or less than the impacts on all utilities as a group.

EPA's analysis concludes that virtually all of the impacts on small entities are caused by statutory provisions of the Act. Although EPA's regulations are intended to mitigate some of the burden on small businesses, the statutory provisions restrict the amount of relief that can be given. The implementation regulations are likely to result in substantial reductions in the costs imposed by the statute on small entities. As a percentage of the costs under the absent regulations case, the savings provided by the regulations may be similar to the savings for larger utilities. In addition, the rules provide an exemption from all title IV requirements for all new utility units that serve one or more generators, the nameplate capacities of which total 25 MWe or less, and that use fuels with a sulfur content less than or equal to .05% by weight. The rules also provide an exception from the NO_x monitoring requirements for gas-fired units with capacity factors of 10% or less. Therefore, by implementing these regulations, EPA has provided all the relief available under the statute to help the most affected small utilities. Based on this analysis and pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this attached rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. These requirements are not effective until OMB approves them and a technical amendment to that effect is published in the **Federal Register**.

The total public reporting burden for these regulations is estimated to range between 41,000 and 45,000 hours in 1993; 38,000 and 42,000 hours in 1994; and 64,000 and 67,000 hours in the first nine months of 1995. In order to obtain a permit, the public reporting burden to develop a permit application and compliance plan including certification of a designated representative is estimated to average a total of 370 hours per application. For tracking and transferring allowances, the public reporting burden to complete and submit an allowance tracking system new account application (if necessary) and an allowance transfer form is estimated to average 30 hours and 2 hours respectively. The burden for assembling and submitting an application to obtain allowances from the conservation and renewable energy reserve is estimated to average 80 hours per application. Finally, to meet the emissions monitoring requirements, the public reporting burden is estimated to average 40 hours per report per plant for preparing and submitting quarterly emissions data reports, and 20 hours per plant for submitting a one-time monitoring plan. These burden estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information.

Send comments regarding these burden estimates or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch; U.S. Environmental Protection Agency; 401 M St., SW. (PM–223Y); Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 726 Jackson Place NW, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

IX. Supporting Information

List of Subjects

40 CFR Parts 72 and 75

Air pollution control, Compliance plans, Continuous emissions monitors, Electric utilities, Incorporation by reference, Nitrogen oxides, Permits, Reporting and recordkeeping requirements, and Sulfur dioxide.

40 CFR Parts 73, 77, and 78

Air pollution control, Compliance plans, Continuous emissions monitors, Electric utilities, Nitrogen oxides, Permits, Reporting and recordkeeping requirements, Sulphur dioxide.

Dated: October 26, 1992.

William K. Reilly,

Administrator, U.S. Environmental Protection Agency.

For the reasons set forth in the preamble chapter I of title 40 of the Code of Federal Regulations is amended as follows:

1. Title 40 is amended by adding part 72 to read as follows:

PART 72—PERMITS REGULATION

Subpart A—Acid Rain Program General Provisions

Sec.
72.1 Purpose and scope.
72.2 Definitions.
72.3 Measurements, abbreviations, and acronyms.
72.4 Federal authority.
72.5 State authority.
72.6 Applicability.
72.7 New units exemption.
72.8 Retired units exemption.
72.9 Standard Requirements.
72.10 Availability of information.
72.11 Computation of time.
72.12 Administrative Appeals.
72.13 Incorporation by Reference.

Subpart B—Designated Representative

72.20 Authorization and responsibilities of the designated representative.
72.21 Submissions.
72.22 Alternate designated representative.
72.23 Changing the designated representative, alternate designated representative; changes in the owners and operators.
72.24 Certificate of representation.
72.25 Objections.

Subpart C—Acid Rain Applications

72.30 Requirement to apply.
72.31 Information requirements for Acid Rain permit applications.
72.32 Permit application shield and binding effect of permit application.
72.33 Identification of Dispatch System.

Subpart D—Acid Rain Compliance Plan and Compliance Options

72.40 General.
72.41 Phase I substitution plans.
72.42 Phase I extension plans.
72.43 Phase I reduced utilization plans.
72.44 Phase II repowering extensions.

Subpart E—Acid Rain Permit Contents

72.50 General.
72.51 Permit shield.

Subpart F—Federal Acid Rain Permit Issuance Procedures

72.60 General.
72.61 Completeness.
72.62 Draft permit.
72.63 Administrative record.
72.64 Statement of basis.
72.65 Public notice of opportunities for public comment.
72.66 Public comments.
72.67 Opportunity for public hearing.
72.68 Response to comments.
72.69 Issuance and effective date of acid rain permits.

Subpart G—Acid Rain Phase II Implementation

72.70 Relationship to title V operating permit program.
72.71 Approval of state programs—general.
72.72 State permit program approval criteria.
72.73 State issuance of Phase II permits.
72.74 Federal issuance of Phase II permits.

Subpart H—Permit Revisions

72.80 General.
72.81 Permit modifications.
72.82 Fast-track modifications.
72.83 Administrative permit amendment.
72.84 Automatic permit amendment.
72.85 Permit reopenings.

Subpart I—Compliance Certification

72.90 Annual compliance certification report.
72.91 Phase I unit adjusted utilization.
72.92 Phase I unit allowance surrender.
72.93 Units with Phase I extension plans.
72.94 Units with repowering extension plans.
72.95 Allowance deduction formula.
72.96 Administrator's action on compliance certifications.

Appendix A to Part 72—Methodology for Annualization of Emissions Limits

Appendix B to Part 72—Methodology for Conversion of Emissions Limits

Appendix C to Part 72—Actual 1985 Yearly SO_2 Emissions Calculations

Authority: 42 U.S.C. 7651, *et seq.*

Subpart A—Acid Rain Program General Provisions

§ 72.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to establish certain general provisions and the operating permit program requirements for affected sources and affected units under the Acid Rain Program, pursuant to title IV of the Clean Air Act, 42 U.S.C. 7401, et seq., as amended by Public Law 101–549 (November 15, 1990).

(b) *Scope.* The regulations under this part set forth certain generally applicable provisions under the Acid Rain Program. The regulations also set forth requirements for obtaining three types of Acid Rain permits, during Phases I and II, for which an affected source may apply: Acid Rain permits

issued by the United States Environmental Protection Agency during Phase I; the Acid Rain portion of an operating permit issued by a State permitting authority during Phase II; and the Acid Rain portion of an operating permit issued by EPA when it is the permitting authority during Phase II. The requirements under this part supplement, and in some cases modify, the requirements under part 70 of this chapter and other regulations implementing title V for approving and implementing State operating permit programs and for federal issuance of operating permits under title V, as such requirements apply to affected sources under the Acid Rain Program.

§ 72.2 Definitions.

The terms used in this part, in parts 73, 75, 77 and 78 of this chapter, and in regulations implementing sections 407 and 410 of the Act, shall have the meanings set forth in the Act, including sections 302 and 402 of the Act, and in this section, as follows:

Account number means the identification number given by the Administrator to each Allowance Tracking System account pursuant to § 73.31(d) of this chapter.

Acid Rain compliance option means one of the methods of compliance used by an affected unit under the Acid Rain Program as described in a compliance plan submitted and approved in accordance with subpart D of this part or regulations implementing section 407 of the Act.

Acid Rain emissions limitation means:

(1) For the purposes of sulfur dioxide emissions:

(i) The tonnage equivalent of the allowances authorized to be allocated to an affected unit for use in a calendar year under section 404 (a)(1) and (a)(3) of the Act, or the basic Phase II allowance allocations authorized to be allocated to an affected unit for use in a calendar year;

(ii) As adjusted:

(A) By allowances allocated by the Administrator pursuant to section 403, section 405 (a)(2), (a)(3), (b)(2), (c)(4), (d)(3), and (h)(2), and section 406 of the Act;

(B) By allowances allocated by the Administrator pursuant to subpart D of this part; and thereafter

(C) By allowance transfers to or from the compliance subaccount for that unit that were recorded or properly submitted for recordation by the allowance transfer deadline as provided in § 73.35 of this chapter, after deductions and other adjustments are made pursuant to § 73.34(c) of this chapter; and

(2) For purposes of nitrogen oxides emissions, the applicable limitation established by regulations promulgated by the Administrator pursuant to section 407 of the Act, as modified by an Acid Rain permit application submitted to the permitting authority, and an Acid Rain permit issued by the permitting authority, in accordance with regulations implementing section 407 of the Act.

Acid Rain emissions reduction requirement means a requirement under the Acid Rain Program to reduce the emissions of sulfur dioxide or nitrogen oxides from a unit to a specified level or by a specified percentage.

Acid Rain permit or permit means the legally binding written document, or portion of such document, issued by a permitting authority under this part (following an opportunity for appeal pursuant to part 78 of this chapter or any State administrative appeals procedure), including any permit revisions, specifying the Acid Rain Program requirements applicable to an affected source, to each affected unit at an affected source, and to the owners and operators and the designated representative of the affected source or the affected unit.

Acid Rain Program means the national sulfur dioxide and nitrogen oxides air pollution control and emissions reduction program established in accordance with title IV of the Act, this part and parts 73, 75, 77, and 78 of this chapter, and regulations implementing sections 407 and 410 of the Act.

Act means the Clean Air Act, 42 U.S.C. § 7401, et seq. as amended by Public Law No. 101–549 (November 15, 1990).

Actual SO_2 emissions rate means the annual average sulfur dioxide emissions rate for the unit (expressed in lb/mmBtu), for the specified calendar year; *provided* that, if the unit is listed in the NADB, the "1985 actual SO_2 emissions rate" for the unit shall be the rate specified by the Administrator in the NADB under the data field "SO2RTE."

Add-on control means a pollution reduction control technology that operates independent of the combustion process.

Additional advance auction means the auction of advance allowances that were offered the previous year for sale in an advance sale.

Administrator means the Administrator of the United States Environmental Protection Agency or the Administrator's duly authorized representative.

Advance allowance means an allowance that may be used for purposes of compliance with a unit's Acid Rain sulfur dioxide emissions limitation requirements beginning no earlier than seven years following the year in which the allowance is first offered for sale.

Advance auction means an auction of advance allowances.

Advance sale means a sale of advance allowances.

Affected source means a source that includes one or more affected units.

Affected unit means a unit that is subject to any Acid Rain emissions reduction requirement or Acid Rain emissions limitation.

Affiliate shall have the meaning set forth in section 2(a)(11) of the Public Utility Holding Company Act of 1935, 15 U.S.C. 79b(a)(11), as of November 15, 1990.

Allocate or allocation means the initial crediting of an allowance by the Administrator to an Allowance Tracking System unit account or general account.

Allowable SO_2 emissions rate means the most stringent federally enforceable emissions limitation for sulfur dioxide (in lb/mmBtu) applicable to the unit for the specified calendar year, or for such subsequent year as determined by the Administrator where such a limitation does not exist for the specified year; *provided* that, if the unit is listed in the NADB, the "1985 allowable SO_2 emissions rate" for the unit shall be the rate specified by the Administrator in the NADB under the data field "1985 annualized boiler SO_2 emission limit."

Allowance means an authorization by the Administrator under the Acid Rain Program to emit up to one ton of sulfur dioxide during or after a specified calendar year.

Allowance deduction, or deduct when referring to allowances, means the permanent withdrawal of allowances by the Administrator from an Allowance Tracking System compliance subaccount to account for the number of the tons of SO_2 emissions from an affected unit for the calendar year, for tonnage emissions estimates calculated for periods of missing data as provided in part 75 of this chapter, or for any other allowance surrender obligations of the Acid Rain Program.

Allowances held or hold allowances means the allowances recorded by the Administrator, or submitted to the Administrator for recordation in accordance with § 73.50 of this chapter, in an Allowance Tracking System account.

Allowance reserve means any bank of allowances established by the Administrator in the Allowance

Tracking System pursuant to sections 404(a)(2) (Phase I extension reserve), 404(g) (energy conservation and renewable energy reserve), or 416(b) (special allowance reserve) of the Act, and implemented in accordance with part 73, subpart B of this chapter.

Allowance Tracking or ATS means the Acid Rain Program system by which the Administrator allocates, records, deducts, and tracks allowances.

Allowance Tracking System account means an account in the Allowance Tracking System established by the Administrator for purposes of allocating, holding, transferring, and using allowances.

Allowance transfer deadline means midnight of January 30 or, if January 30 is not a business day, midnight of the first business day thereafter and is the deadline by which allowances may be submitted for recordation in an affected unit's compliance subaccount for the purposes of meeting the unit's Acid Rain emissions limitation requirements for sulfur dioxide for the previous calendar year.

Alternative monitoring system means a system or a component of a system designed to provide direct or indirect data of mass emissions per time period, pollutant concentrations, or volumetric flow, that is demonstrated to the Administrator as having the same precision, reliability, accessibility, and timeliness as the data provided by a certified CEMS or certified CEMS component in accordance with part 75 of this chapter.

As-fired means the taking of a fuel sample just prior to its introduction into the unit for combustion.

Auction subaccount means a subaccount in the Special Allowance Reserve, as specified in section 416(b) of the Act, which contains allowances to be sold at auction in the amount of 150,000 per year from calendar year 1995 through 1999, inclusive, and 200,000 per year for each year begnning in calendar year 2000, subject to the adjustments noted in the regulations in part 73, subpart E of this chapter.

Authorized account representative means a responsible natural person who is authorized, in accordance with part 73 of this chapter, to transfer and otherwise dispose of allowances held in an Allowance Tracking System general account; or, in the case of a unit account, the designated representative of the owners and operators of the affected unit.

Automated data acquisition and handling system means that component of the CEMS, COMS, or other emissions monitoring system approved by the Administrator for use in the Acid Rain Program, designed to interpret and convert individual output signals from pollutant concentration monitors, flow monitors, diluent gas monitors, opacity monitors, and other component parts of the monitoring system to produce a continuous record of the measured parameters in the measurement units required by part 75 of this chapter.

Award means the conditional set-aside by the Administrator, based on the submission of an early ranking application pursuant to subpart D of this part, of an allowance from the Phase I extension reserve, for possible future allocation to a Phase I extension applicant's Allowance Tracking System unit account.

Baseline means the annual average quantity of fossil fuel consumed by a unit, measured in millions of British Thermal Units (expressed in mmBtu) for calendar years 1985 through 1987; *provided* that in the event that a unit is listed in the NADB, the baseline will be calculated for each unit-generator pair that includes the unit, and the unit's baseline will be the sum of such unit-generator baselines. The unit-generator baseline will be as provided in the NADB under the data field "BASE8587", as adjusted by the outage hours listed in the NADB under the data field "OUTAGEHR" in accordance with the following equation:

$$\text{Baseline}=\text{BASE8587}\times\{26280/(26280-\text{OUTAGEHR})\}\times\{36/(36-\text{months not on line})\}\times 10^{6}$$

"Months not on line" is the number of months during January 1985 through December 1987 prior to the commencement of firing for units that commenced firing in that period, i.e., the number of months, in that period, prior to the on-line month listed under the data field "BLRMNONL" and the on-line year listed in the data field "BLRYRONL" in the NADB.

Basic Phase II allowance allocations means:

(1) For calendar years 2000 through 2009 inclusive, allocations of allowances made by the Administrator pursuant to section 403 and section 405 (b)(1), (3), and (4); (c)(1), (2), (3), and (5); (d)(1), (2), (4), and (5); (e); (f); (g)(1), (2), (3), (4), and (5); (h)(1); (i); and (j).

(2) For each calendar year beginning in 2010, allocations of allowances made by the Administrator pursuant to section 403 and section 405 (b)(1), (3), and (4); (c)(1), (2), (3), and (5); (d)(1), (2), (4), and (5); (e); (f); (g)(1), (2), (3), (4), and (5); (h)(1) and (3); (i); and (j).

Bias means systematic error, resulting in measurements that will be either consistently low or high relative to the reference value.

Boiler means an enclosed fossil or other fuel-fired combustion device used to produce heat and to transfer heat to recirculating water, steam, or any other medium.

By-pass stack means any duct, stack, or conduit through which emissions from an affected unit may or do pass to the atmosphere, which either augments or substitutes for the principal stack exhaust system or ductwork during any portion of the unit's operation.

Calibration error means the difference between:

(1) The response of gaseous monitor to a calibration gas and the known concentration of the calibration gas;

(2) The response of a flow monitor to a reference signal and the known value of the reference signal; or

(3) The response of a continuous opacity monitoring system to an attenuation filter and the known value of the filter after a stated period of operation during which no unscheduled maintenance, repair, or adjustment took place.

Calibration gas means:

(1) A standard reference material;

(2) A NIST/EPA-approved certified reference material;

(3) A Protocol 1 gas; or

(4) Zero ambient air material.

Capacity factor means the ratio of a unit's actual annual electric output (expressed in Mwe hr) and the unit's nameplate capacity times 8,760 hours.

CEMS precision or précision as applied to the monitoring requirements of part 75 of this chapter, means the closeness of a measurement to the actual measured value expressed as the uncertainty associated with repeated measurements of the same sample or of different samples from the same process (e.g., the random error associated with simultaneous measurements of a process made by more than one instrument). A measurement technique is determined to have increasing "precision" as the variation among the repeated measurements decreases.

Centroidal area means a representational concentric area that is geometrically similar to the stack or duct cross section, and is not greater than 1 percent of the stack or duct cross-sectional area.

Certificate of representation means the completed and signed submission required by § 72.20, for certifying the appointment of a designated representative for an affected source or a group of identified affected sources authorized to represent the owners and operators of such source(s) and of the affected units at such source(s) with regard to matters under the Acid Rain Program.

Certifying official, for purposes of part 73 of this chapter, means:

(1) For a corporation, a president, secretary, treasurer, or vice-president of the corporation in charge of a principal business function, or any other person who performs similar policy or decision-making functions for the corporation;

(2) For partnership or sole proprietorship, a general partner or the proprietor, respectively; and

(3) For a local government entity or State, federal, or other public agency, either a principal executive officer or ranking elected official.

Coal means all solid fuels classified as anthracite, bituminous, subbituminous, or lignite by the American Society for Testing and Materials Designation ASTM D388–92 "Standard Classification of Coals by Rank" (as incorporated by reference in § 72.13).

Coal-derived fuel means any fuel, whether in a solid, liquid, or gaseous state, produced by the mechanical, thermal, or chemical processing of coal (e.g., pulverized coal, coal refuse, liquified or gasified coal, washed coal, chemically cleaned coal, coal-oil mixtures, and coke).

Coal-fired means the combustion of fuel consisting of coal or any coal-derived fuel (except a coal-derived gaseous fuel with a sulfur content no greater than natural gas), alone or in combination with any other fuel, where:

(1) For purposes of the requirements of part 75 of this chapter, a unit is "coal-fired" independent of the percentage of coal or coal-derived fuel consumed in any calendar year (expressed in mmBtu); and

(2) For all other purposes under the Acid Rain Program (including for calculating allowance allocations pursuant to part 73 of this chapter and applicability of the requirements of section 407 of the Act), a unit is "coal-fired" if it uses coal or coal-derived fuel as its primary fuel (expressed in mmBtu); *provided* that, if the unit is listed in the NADB, the primary fuel is the fuel listed in the NADB under the data field "PRIMEFUEL".

Cogeneration unit means a unit that has equipment used to produce electric energy and forms of useful thermal energy (such as heat or steam) for industrial, commercial, heating or cooling purposes, through the sequential use of energy.

Commence commercial operation means to have begun to generate electricity for sale, including the sale of test generation.

Commence construction means that an owner or operator has either undertaken a continuous program of construction or has entered into a contractual obligation to undertake and complete, within a reasonable time, a continuous program of construction.

Commence operation means to have begun any mechanical, chemical, or electronic process, including start-up of an emissions control technology or emissions monitor or of a unit's combustion chamber.

Common stack means the exhaust of emissions from two or more units through a single flue.

Compensating unit means a unit that is not otherwise subject to Acid Rain emissions limitation or Acid Rain emissions reduction requirements during Phase I and that is designated as a Phase I unit in a reduced utilization plan under § 72.43; *provided* that a unit that is not an affected unit under the Acid Rain Program shall not be a compensating unit.

Compliance certification means a submission to the Administrator or permitting authority, as appropriate, that is required by this part, by part 73, 75, 77, or 78, or by regulations implementing sections 407 or 410 of the Act to report an affected source or an affected unit's compliance or non-compliance with a provision of the Acid Rain Program and that is signed and verified by the designated representative in accordance with subparts B and I of this part and the Acid Rain Program regulations generally.

Compliance plan, for purposes of the Acid Rain Program, means the document submitted for an affected source in accordance with subpart C of this part, specifying the method(s) (including one or more Acid Rain compliance options under subpart D or regulations implementing section 407 of the Act) by which each affected unit at the source will meet the applicable Acid Rain emissions limitation and Acid Rain emissions reduction requirements.

Compliance subaccount means the subaccount in an affected unit's Allowance Tracking System account, established pursuant to § 73.31 (a) or (b) of this chapter, in which are held, from the date that allowances for the current calendar year are recorded under § 73.34(a) until December 31, allowances available for use by the unit in the current calendar year and, after December 31 until the date that deductions are made under § 73.35(b), allowances available for use by the unit in the preceding calendar year, for the purpose of meeting the unit's Acid Rain emissions limitation for sulfur dioxide.

Compliance use date means the first calendar year for which an allowance may be used for purposes of meeting a unit's Acid Rain emissions limitation for sulfur dioxide.

Conservation Verification Protocol means a methodology developed by the Administrator for calculating the kilowatt hour savings from energy conservation measures and improved unit efficiency measures for the purposes of title IV of the Act.

Construction means fabrication, erection, or installation of a unit or any portion of a unit.

Consumer Price Index or CPI means, for purposes of the Acid Rain Program, the U.S. Department of Labor, Bureau of Labor Statistics unadjusted Consumer Price Index for All Urban Consumers for the U.S. city average, for All Items on the latest reference base, or if such index is no longer published, such other index as the Administrator in his or her discretion determines meets the requirements of the Clean Air Act Amendments of 1990.

(1) *CPI (1990)* means the CPI for all urban consumers for the month of August 1989. The "CPI (1990)" is 124.6 (with 1982–1984=100). Beginning in the month for which a new reference base is established, "CPI (1990)" will be the CPI value for August 1989 on the new reference base.

(2) *CPI (year)* means the CPI for all urban consumers for the month of August of the previous year.

Continuous emission monitoring system or CEMS means the equipment required by part 75 of this chapter used to sample, analyze, measure, and provide, by readings taken at least once every 15 minutes, a permanent record of emissions, expressed in pounds per hour (lb/hr) for sulfur dioxide and in pounds per million British thermal units (lb/mmBtu) for nitrogen oxides. The following systems are component parts included in a continuous emission monitoring system:

(1) Sulfur dioxide pollutant concentration monitor;

(2) Flow monitor;

(3) Nitrogen oxides pollutant concentration monitors;

(4) Diluent gas monitor (oxygen or carbon dioxide);

(5) A continuous moisture monitor when such monitoring is required by part 75 of this chapter; and

(6) A data acquisition and handling system.

Continuous opacity monitoring system or COMS means the equipment required by part 75 of this chapter to sample, measure, analyze, and provide, with readings taken at least once every 6 minutes, a permanent record of opacity or transmittance. The following systems are component parts included

in a continuous opacity monitoring system:

(1) Opacity monitor; and

(2) A data acquisition and handling system.

Control unit means a unit employing a qualifying Phase I technology in accordance with a Phase I extension plan under § 72.42.

Current year subaccount means the subaccount in an Allowance Tracking System general account, established pursuant to § 73.31(c) of this chapter, in which are held allowances that may be transferred to a unit's compliance subaccount for use by the unit for the purpose of meeting its Acid Rain sulfur dioxide emissions limitation.

Customer means a purchaser of electricity not for purposes of transmission or resale.

Decisional body means any EPA employee who is or may reasonably be expected to act in a decision-making role in a proceeding under part 78 of this chapter, including the Administrator, a member of the Environmental Appeals Board, and a Presiding Officer, and any staff of any such person who are participating in the decisional process.

Demand-side measure means a measure:

(1) To improve the efficiency of consumption of electricity from a utility by customers of the utility; or

(2) To reduce the amount of consumption of electricity from a utility by customers of the utility without increasing the use by the customer of fuel other than: Biomass (i.e., combustible energy-producing materials from biological sources, which include wood, plant residues, biological wastes, landfill gas, energy crops, and eligible components of municipal solid waste), solar, geothermal, or wind resources; or industrial waste gases where the party making the submission involved certifies that there is no net increase in sulfur dioxide emissions from the use of such gases. "Demand-side measure" includes the measures listed in part 73, Appendix A, section 1 of this chapter.

Designated representative means a responsible natural person authorized by the owners and operators of an affected source and of all affected units at the source, as evidenced by a certificate of representation submitted in accordance with subpart B of this part, to represent and legally bind each owner and operator, as a matter of federal law, in matters pertaining to the Acid Rain Program. Whenever the term "responsible official" is used in part 70 of this chapter, in any other regulations implementing title V of the Act, or in a State operating permit program, it shall be deemed to refer to the "designated representative" with regard to all matters under the Acid Rain Program.

Diesel fuel means a low sulfur fuel oil of grades 1–D or 2–D, as defined by the American Society for Testing and Materials ASTM D975–91, "Standard Specification for Diesel Fuel Oils" (as incorporated by reference in § 72.13).

Diesel reciprocating engine unit means an internal combustion engine that combusts only diesel fuel and that thereby generates electricity through the operation of pistons, rather than by heating steam or water.

Diluent gas means a major gaseous constituent in a gaseous pollutant mixture, which in the case of emissions from fossil fuel-fired units are carbon dioxide and oxygen.

Diluent gas monitor means that component of the continuous emission monitoring system that measures the diluent gas concentration in a unit's flue gas.

Direct Sale Subaccount means a subaccount in the Special Allowance Reserve, as specified in section 416(b) of the Act, which contains Phase II allowances to be sold in the amount of 25,000 per year, from calendar year 1993 to 1999, inclusive, and of 50,000 per year for each year beginning in calendar year 2000, subject to the adjustments noted in the regulations at part 73, subpart E of this chapter.

Dispatch means the assignment within a dispatch system of generating levels to specific units and generators to effect the reliable and economical supply of electricity, as customer demand rises or falls, and includes:

(1) The operation of high-voltage lines, substations, and related equipment; and

(2) The scheduling of generation for the purpose of supplying electricity to other utilities over interconnecting transmission lines.

Dispatch system means either:

(1) A specified unit and generator or specified group of units, and portions of units, and generators that are interconnected and centrally dispatched, *provided* that the requirements of § 72.33 are met; or

(2) In the event the requirements specified in paragraph (1) of this definition are not met, the unit and generator or group of units and generators that make up one utility system.

Draft Acid Rain permit or draft permit means the version of the Acid Rain permit, or the Acid Rain portion of an operating permit, that a permitting authority offers for public comment.

Dual-fuel reciprocating engine unit means an internal combustion engine that combusts any combination of natural gas and diesel fuel and that thereby generates electricity through the operation of pistons, rather than by heating steam or water.

Emissions means air pollutants exhausted from a unit or source into the atmosphere, as measured, recorded, and reported to the Administrator by the designated representative and as determined by the Administrator, in accordance with the emissions monitoring requirements of part 75 of this chapter.

Environmental Appeals Board means the three-member board established pursuant to § 1.25(e) of this chapter and authorized to hear appeals pursuant to part 78 of this chapter.

EPA means the United States Environmental Protection Agency.

EPA trial staff means an employee of EPA, whether temporary or permanent, who has been designated by the Administrator to investigate, litigate, and present evidence, arguments, and positions of EPA in any evidentiary hearing under part 78 of this chapter. Any EPA or permitting authority employee, consultant, or contractor who is called as a witness in the evidentiary hearing by EPA trial staff shall be deemed to be "EPA trial staff".

Equivalent diameter means a value, calculated using the equation in paragraph 2.1 of Method 1 in part 60, Appendix A of this chapter, and used to determine the upstream and downstream distances for locating CEMS or CEMS components in flues or stacks with rectangular cross sections.

Ex parte communication means any communication, written or oral, relating to the merits of an adjudicatory proceeding under part 78 of this chapter, that was not originally included or stated in the administrative record, in a pleading, or in an evidentiary hearing or oral argument under part 78 of this chapter, between the decisional body and any interested person outside EPA or any EPA trial staff. Ex parte communication shall not include:

(1) Communication between EPA employees other than between EPA trial staff and a member of the decisional body; or

(2) Communication between the decisional body and interested persons outside the Agency, or EPA trial staff, where all parties to the proceeding have received prior written notice of the proposed communication and are given an opportunity to be present and to participate therein.

Excess emissions means:

(1) Any tonnage of sulfur dioxide emitted by an affected unit during a

calendar year that exceeds the Acid Rain emissions limitation for sulfur dioxide for the unit; and

(2) Any tonnage of nitrogen oxide emitted by an affected unit during a calendar year that exceeds the annual tonnage equivalent of the Acid Rain emissions limitation for nitrogen oxides applicable to the affected unit taking into account the unit's heat input for the year.

Existing unit means a unit (including a unit subject to section 111 of the Act) that commenced commercial operation before November 15, 1990 and that on that date served a generator with a nameplate capacity of greater than 25 MWe. "Existing unit" does not include simple combustion turbines or any unit that on November 15, 1990 served only generators with a nameplate capacity of 25 MWe or less. Any "existing unit" that is modified, reconstructed, or repowered after November 15, 1990 shall continue to be an "existing unit."

Facility means any institutional, commercial, or industrial structure, installation, plant, source, or building.

File means to send or transmit a document, information, or correspondence to the official custody of the person specified to take possession in accordance with the applicable regulation. Compliance with any "filing" deadline shall be determined by the date that person receives the document, information, or correspondence.

Flow meter accuracy means the closeness of the measurement made by a flow meter to the reference value of the fuel flow being measured, expressed as the difference between the measurement and the reference value.

Flow monitor means a component of the continuous emission monitoring system that measures the volumetric flow of exhaust gas.

Flue means a conduit or duct through which gases or other matter are exhausted to the atmosphere.

Forced outage means the removal of a unit from service due to an unplanned component failure or other unplanned condition that requires such removal immediately or within 7 days from the onset of the unplanned component failure or condition. For purposes of §§ 72.43, 72.91, and 72.92, "forced outage" also includes a partial reduction in the heat input or electrical output due to an unplanned component failure or other unplanned condition that requires such reduction immediately or within 7 days from the onset of the unplanned component failure or condition.

Fossil fuel means natural gas, petroleum, coal, or any form of solid, liquid, or gaseous fuel derived from such material.

Fossil fuel-fired means the combustion of fossil fuel or any derivative of fossil fuel, alone or in combination with any other fuel, independent of the percentage of fossil fuel consumed in any calendar year (expressed in mmBtu).

Fuel oil means any petroleum-based fuel (including diesel fuel or petroleum derivatives such as oil tar) as defined by the American Society for Testing and Materials in ASTM D396–90a, "Standard Specification for Fuel Oils" (incorporated by reference in § 72.13), and any recycled or blended petroleum products or petroleum by-products used as a fuel whether in a liquid, solid or gaseous state; *provided* that for purposes of the monitoring requirements of part 75 of this chapter, "fuel oil" shall be limited to the petroleum-based fuels for which applicable ASTM methods are specified in Appendices D, E, or F of part 75 of this chapter.

Fuel supply agreement means a legally binding agreement between a new IPP or a firm associated with a new IPP and a fuel supplier that establishes the terms and conditions under which the fuel supplier commits to provide fuel to be delivered to the new IPP.

Future year subaccount means a subaccount in an Allowance Tracking System account, established by the Administrator pursuant to § 73.31 of this chapter, in which allowances are held for one of the 30 years following the later of 1995 or a current calendar year following 1995.

Gas-fired means the combustion of: Natural gas, or a coal-derived gaseous fuel with a sulfur content no greater than natural gas, for at least 90 percent of the average annual heat input during the previous three calendar years and for at least 85 percent of the annual heat input in each of those calendar years; and any fuel other than coal or any other coal-derived fuel for the remaining heat input, if any; *provided* that for purposes of the monitoring exceptions of part 75 of this chapter, the supplemental fuel used in addition to natural gas, if any, shall be limited to gaseous fuels containing no more sulfur than natural gas or, as specified in the monitoring exceptions, fuel oil.

General account means an Allowance Tracking System account that is not a unit account.

Generator means a device that produces electricity and was or would have been required to be reported as a generating unit pursuant to the United States Department of Energy Form 860 (1990 edition).

Hearing clerk means an EPA employee designated by the Administrator to establish a repository for all books, records, documents, and other materials relating to proceedings under part 78 of this chapter.

Heat input means the product (expressed in mmBtu/time) of the gross calorific value of the fuel (expressed in Btu/lb) and the fuel feed rate into the combustion device (expressed in mass of fuel/time) and does not include the heat derived from preheated combustion air, recirculated flue gases, or exhaust from other sources.

Hybrid generation facility means a plant that generates electrical energy derived from a combination of qualified renewable energy (wind, solar, biomass, or geothermal) and one or more other energy resources.

Independent auditor means a professional engineer who is not an employee or agent of the source being audited.

Interested person means any person who submitted written comments or testified at a public hearing on the draft permit or other matter subject to notice and comment under the Acid Rain Program or any person who submitted his or her name to the Administrator or the permitting authority, as appropriate, to be placed on a list of persons interested in such matter. The Administrator or the permitting authority may update the list of interested persons from time to time by requesting additional written indication of continued interest from the persons listed and may delete from the list the name of any person failing to respond as requested.

Investor-owned utility means a utility that is organized as a tax-paying for-profit business.

Kilowatthour saved or *savings* means the net savings in electricity use (expressed in Kwh) that result directly from a utility's energy conservation measures or programs.

Least-cost plan or *least-cost planning process* means an energy conservation and electric power planning methodology meeting the requirements of § 73.82(a)(4) of this chapter.

Life-of-the-unit, firm power contractual arrangement means a unit participation power sales agreement under which a utility or industrial customer reserves, or is entitled to receive, a specified amount or percentage of nameplate capacity and associated energy generated by any specified generating unit and pays its proportional amount of such unit's total costs, pursuant to a contract:

(1) For the life of the unit;

(2) For a cumulative term of no less than 30 years, including contracts that permit an election for early termination; or

(3) For a period equal to or greater than 25 years or 70 percent of the economic useful life of the unit determined as of the time the unit was built, with option rights to purchase or release some portion of the nameplate capacity and associated energy generated by the unit at the end of the period.

Mail or serve by mail means to submit or serve by means other than personal service.

Maximum potential NO_x emission rate means the emission rate of nitrogen oxides (in lb/mmBtu) calculated in accordance with section 3 of appendix F of part 75 of this chapter, using the maximum potential nitrogen oxides concentration and either the minimum oxygen concentration (in % O_2) or the maximum carbon dioxide concentration (in % CO_2) as defined in section 2 of appendix A of part 77 of this chapter.

Missing data period means the total number of consecutive hours during which any component part of a certified CEMS or approved alternative monitoring system is not providing quality-assured data, regardless of the reason.

Monitor accuracy means the closeness of the measurement made by a CEMS or by one of its component parts to the reference value of the emissions or volumetric flow being measured, expressed as the difference between the measurement and the reference value.

Monitor operating hour means any hour or portion thereof over which a CEMS, COMS, or other monitoring system approved by the Administrator under part 75 of this chapter is operating regardless of the number of measurements (i.e., data points) collected during the hour.

Most stringent federally enforceable emissions limitation means the most stringent emissions limitation for a given pollutant applicable to the unit, which has been approved by the Administrator under the Act, whether in a State implementation plan approved pursuant to title I of the Act, a new source performance standard, or otherwise. To determine the most stringent emissions limitation for sulfur dioxide, each limitation shall be converted to lbs/mmBtu, using the appropriate conversion factors in appendix B of this part; *provided* that for determining the most stringent emissions limitation for sulfur dioxide for 1985, each limitation shall also be annualized, using the appropriate annualization factors in appendix A of this part.

Multi-header generator means a generator served by ductwork from more than one unit.

Multi-header unit means a unit with ductwork serving more than one generator.

Nameplate capacity means the maximum electrical generating output (expressed in MWe) that a generator can sustain over a specified period of time when not restricted by seasonal or other deratings, as listed in the NADB under the data field "NAMECAP" if the generator is listed in the NADB or as measured in accordance with the United States Department of Energy standards if the generator is not listed in the NADB.

National Allowance Data Base or *NADB* means the data base established by the Administrator under section 402(4)(C) of the Act.

Natural gas means a naturally occurring fluid mixture of hydrocarbons containing little or no sulfur (e.g., methane, ethane, or propane), produced in geological formations beneath the Earth's surface, and maintaining a gaseous state at standard atmospheric temperature and pressure conditions under ordinary conditions.

NERC region means the North American Electric Reliability Council region or, if any, subregion.

Net income neutrality means, in the case of energy conservation measures undertaken by an investor-owned utility whose rates are regulated by a State utility regulatory authority, rates and charges established by the State utility regulatory authority that ensure that the net income earned by the utility on its State-jurisdictional equity investment will be *no lower* as a consequence of its expenditures on cost-effective qualified energy conservation measures and any associated lost sales than it would have been had the utility not made such expenditures, or that the State utility regulatory authority has implemented a ratemaking approach designed to meet this objective.

New independent power production facility or *new IPP* means a unit that:

(1) Commences commercial operation on or after November 15, 1990;

(2) Is nonrecourse project-financed, as defined in 10 CFR part 715;

(3) Sells 80% of electricity generated at wholesale; and

(4) Does not sell electricity to any affiliate or, if it does, demonstrates it cannot obtain the required allowances from such an affiliate.

New unit means a unit that commences commercial operation on or after November 15, 1990, including any such unit that serves a generator with a nameplate capacity of 25 MWe or less or that is a simple combustion turbine.

Ninetieth (90th) percentile means a value that would divide an ordered set of increasing values so that at least 90 percent are less than or equal to the value and at least 10 percent are greater than or equal to the value.

Ninety-fifth (95th) percentile means a value that would divide an ordered set of increasing values so that at least 95 percent of the set are less than or equal to the value and at least 5 percent are greater than or equal to the value.

NIST/EPA-approved certified reference material or NIST/EPA-approved CRM means a calibration gas mixture that has been approved by EPA and the National Institutes of Standards and Technologies (NIST) as having specific known chemical or physical property values certified by a technically valid procedure as evidenced by a certificate or other documentation issued by a certifying standard-setting body.

Offset plan means a plan pursuant to part 77 of this chapter for offsetting excess emissions of sulfur dioxide that have occurred at an affected unit in any calendar year.

Oil-fired means the combustion of: fuel oil for more than 10 percent of the average annual heat input during the previous three calendar years or for more than 15 percent of the annual heat input in any one of those calendar years; and any solid, liquid, or gaseous fuel, other than coal or any other coal-derived fuel (except a coal-derived gaseous fuel with a sulfur content no greater than natural gas), for the remaining heat input, if any; *provided* that for purposes of the monitoring exceptions of part 75 of this chapter, the supplemental fuel used in addition to fuel oil, if any, shall be limited to gaseous fuels, other than a coal-derived fuel.

Opacity means the degree to which emissions reduce the transmission of light and obscure the view of an object in the background.

Operating permit means a permit issued under part 70 of this chapter and any other regulations implementing title V of the Act.

Out-of-control period means any period:

(1) Beginning with the hour corresponding to the completion of a daily calibration error, linearity check, or quality assurance audit that indicates that the instrument is not measuring and recording within the applicable performance specifications; and

(2) Ending with the hour corresponding to the completion of an additional calibration error, linearity

check, or quality assurance audit following corrective action that demonstrates that the instrument is measuring and recording within the applicable performance specifications.

Oversubscription payment deadline means 30 calendar days prior to the allowance transfer deadline.

Owner means any of the following persons:

(1) Any holder of any portion of the legal or equitable title in an affected unit; or

(2) Any holder of a leasehold interest in an affected unit; or

(3) Any purchaser of power from an affected unit under a life-of-the-unit, firm power contractual arrangement as that term is defined herein and used in section 408(i) of the Act. However, unless expressly provided for in a leasehold agreement, owner shall not include a passive lessor, or a person who has an equitable interest through such lessor, whose rental payments are not based, either directly or indirectly, upon the revenues or income from the affected unit; or

(4) With respect to any Allowance Tracking System general account, any person identified in the submission required by § 73.31(c) of this chapter that is subject to the binding agreement for the authorized account representative to represent that person's ownership interest with respect to allowances.

Owner or operator means any person who is an owner or who operates, controls, or supervises an affected unit or affected source and shall include, but not be limited to, any holding company, utility system, or plant manager of an affected unit or affected source.

Peaking unit means a unit that has:

(1) an average capacity factor of no more than 10 percent during the previous 3 calendar years and

(2) a capacity factor of no more than 20 percent in each of those calendar years.

Permit revision means a permit modification, fast track modification, administrative permit amendment, or automatic permit amendment, as provided in subpart H of this part.

Permitting authority means either

(1) the Administrator in the case of issuance and administration of Acid Rain permits or

(2) the State air pollution control agency, local agency, other State agency, or other agency authorized by the Administrator to issue proposed Acid Rain permits under subpart G of this part and the other regulations promulgated pursuant to titles IV and V of the Act.

Person includes an individual, corporation, partnership, association, State, municipality, political subdivision of a State, any agency, department, or instrumentality of the United States, and any officer, agent, or employee thereof.

Phase I means the Acid Rain Program period beginning January 1, 1995 and ending December 31, 1999.

Phase I unit means any affected unit that is subject to an Acid Rain emissions reduction requirement or Acid Rain emissions limitation beginning in Phase I.

Phase II means the Acid Rain Program period beginning January 1, 2000, and continuing into the future thereafter.

Phase II unit means any affected unit that is subject to an Acid Rain emissions reduction requirement or Acid Rain emissions limitation during Phase II only.

Pollutant concentration monitor means that component of the continuous emission monitoring system that measures the concentration of a pollutant in a unit's flue gas.

Power distribution system means the portion of an electricity grid owned or operated by a utility that is dedicated to delivering electric energy to customers.

Power sales agreement is a legally-binding agreement between a new IPP or a firm associated with a new IPP and a regulated electric utility that establishes the terms and conditions for the sale of power from the new IPP to the utility.

Presiding Officer means an Administrative Law Judge appointed under 5 U.S.C. 3105 and designated to preside at a hearing in an appeal under part 78 of this chapter or an EPA lawyer designated to preside at any such hearing under § 78.6(b)(3)(ii) of this chapter.

Primary fuel or primary fuel supply means the main fuel type (expressed in mmBtu) consumed by an affected unit for the applicable calendar year.

Proposed Acid Rain permit or proposed permit means, in the case of a State operating permit program, the version of an Acid Rain permit that the permitting authority submits to the Administrator after the public comment period, but prior to completion of the EPA permit review period, as provided for in part 70 of this chapter.

Protocol 1 gas means a calibration gas mixture prepared and analyzed according to the "Procedure for NBS-Traceable Certification of Compressed Gas Working Standards Used for Calibration and Audit of Continuous Emission Monitors ("Revised Traceability Protocol No. 1")," Quality Assurance Handbook for Air Pollution Measurement Systems, Volume III, Stationary Source Specific Methods, Section 3.04, EPA–600/4–77–027b, June 1987 (set forth in Appendix H of part 75 of this chapter).

Qualifying Phase I technology means a technological system of continuous emission reduction that is demonstrated to achieve a ninety (90) percent (or greater) reduction in emissions of sulfur dioxide from the emissions that would have resulted from the use of fossil fuels that were not subject to treatment prior to combustion, as provided in § 72.42.

Qualifying repowering technology means:

(1) Replacement of an existing coal-fired boiler with one of the following clean coal technologies: atmospheric or pressurized fluidized bed combustion, integrated gasification combined cycle, magnetohydrodynamics, direct and indirect coal-fired turbines, integrated gasification fuel cells, or as determined by the Administrator, in consultation with the Secretary of Energy, a derivative of one or more of these technologies, and any other technology capable of controlling multiple combustion emissions simultaneously with improved boiler or generation efficiency and with significantly greater waste reduction relative to the performance of technology in widespread commercial use as of the date of enactment of the Clean Air Act Amendments of 1990; or

(2) Any oil- or gas-fired unit that has been awarded clean coal technology demonstration funding as of January 1, 1991, by the Department of Energy.

Quality assured monitor operating hour means any hour over which a certified CEMS, COMS, or other monitoring system approved by the Administrator under part 75 of this chapter, is operating: in accordance with § 75.10(e) and (f); and within the performance specifications set forth in part 75, Appendix A of this chapter and the quality control/quality assurance procedures set forth in part 75, appendix B of this chapter, without unscheduled maintenance, repair, or adjustment.

Receive or receipt of means the date the Administrator or a permitting authority comes into possession of information or correspondence (whether sent in writing or by authorized electronic transmission), as indicated in an official correspondence log, or by a notation made on the information or correspondence, by the Administrator or the permitting authority in the regular course of business.

Recordation, record, or recorded means, with regard to allowances, the transfer of allowances by the

Administrator from one Allowance Tracking System account or subaccount to another.

Reduced utilization means a reduction, during any calendar year in Phase I, in the heat input (expressed in mmBtu for the calendar year) at a Phase I unit below the unit's baseline, where such reduction subjects the unit to the requirement to file a reduced utilization plan under § 72.43.

Reference method means any direct test method of sampling and analyzing for an air pollutant as specified in part 60, Appendix A of this chapter.

Reference value or reference signal means the known concentration of a calibration gas, the known value of an electronic calibration signal, or the known value of any other measurement standard approved by the Administrator, assumed to be the true value for the pollutant or diluent concentration or volumetric flow being measured.

Relative accuracy means a statistic designed to provide a measure of the systematic and random errors associated with data from continuous emission monitoring systems, and is expressed as the absolute mean difference between the pollutant concentration or volumetric flow measured by the pollutant concentration or flow monitor and the value determined by the applicable reference method(s) plus the 2.5 percent error confidence coefficient of a series of tests divided by the mean of the reference method tests in accordance with part 75 of this chapter.

Schedule of compliance means an enforceable sequence of actions, measures, or operations designed to achieve or maintain compliance, or correct non-compliance, with an applicable requirement of the Acid Rain Program, including any applicable Acid Rain permit requirement.

Secretary of Energy means the Secretary of the United States Department of Energy or the Secretary's duly authorized representative.

Serial number means, when referring to allowances, the unique identification number assigned to each allowance by the Administrator, pursuant to § 73.34(d) of this chapter.

Simple combustion turbine means a unit that is a rotary engine driven by a gas under pressure that is created by the combustion of any fuel. This term includes combined cycle units without auxiliary firing but excludes such units with auxiliary firing.

Site lease, as used in part 73, subpart E of this chapter, means a legally-binding agreement signed between a new IPP or a firm associated with a new IPP and a site owner that establishes the terms and conditions under which the new IPP or the firm associated with the new IPP has the binding right to utilize a specific site for the purposes of operating or constructing the new IPP.

Source means any governmental, institutional, commercial, or industrial structure, installation, plant, building, or facility that emits or has the potential to emit any regulated air pollutant under the Act. For purposes of section 502(c) of the Act, a "source", including a "source" with multiple units, shall be considered a single "facility."

Span means the range of values that a monitor component is required to be capable of measuring under part 75 of this chapter.

Spot allowance means an allowance that may be used for purposes of compliance with a unit's Acid Rain sulfur dioxide emissions limitation requirements beginning in the year in which the allowance is offered for sale.

Spot Auction means an auction of a spot allowance.

Spot Sale means a sale of a spot allowance.

Stack means a structure that includes one or more flues and the housing for the flues.

Standard conditions means 68 °F at 1 atm (29.92 in. of mercury).

Standard reference material or *SRM* means a calibration gas mixture issued and certified by NIST as having specific known chemical or physical property values.

State means one of the 48 contiguous States and the District of Columbia and includes any non-federal authorities, including local agencies, interstate associations, and State-wide agencies with approved State operating permit programs. The term "State" shall have its conventional meaning where such meaning is clear from the context.

State operating permit program means an operating permit program that the Administrator has approved as meeting the requirements of titles IV and V of the Act, part 70 of this chapter, and this part, including subpart G of this part.

Stationary gas turbine means a turbine that combusts natural gas, coal-derived gaseous fuel with a sulfur content no greater than natural gas, or fuel oil in order to heat inlet combustion air and thereby turn a turbine, in addition to or instead of producing steam or heating water, and that is not self propelled.

Steam sales agreement is a legally-binding agreement between a new IPP or a firm associated with a new IPP and an industrial or commercial establishment requiring steam that sets the terms and conditions under which the new IPP will provide steam to the establishment.

Submit or serve means to send or transmit a document, information, or correspondence to the person specified in accordance with the applicable regulation:

(1) In person;

(2) By United States Postal Service certified mail with the official postmark or, if service is by the Administrator or the permitting authority, by any other mail service by the United States Postal Service; or

(3) By other means with an equivalent time and date mark used in the regular course of business to indicate the date of dispatch or transmission and a record of prompt delivery. Compliance with any "submission", "service", or "mailing" deadline shall be determined by the date of dispatch, transmission, or mailing and not the date of receipt.

Substitute data means emissions or volumetric flow data provided to assure 100 percent recording and reporting of emissions when all or part of the continuous emission monitoring system is not functional or is operating outside applicable performance specifications.

Substitution unit means an affected unit, other than a unit under section 410 of the Act, that is designated as a Phase I unit in a substitution plan under § 72.41.

Sulfur-free generation means: the generation of electricity by a process that does not have any emissions of sulfur dioxide, including hydroelectric, nuclear, solar and wind generation. A "sulfur-free generator" is a generator that produces such "sulfur-free generation."

Supply-side measure means a measure to improve the efficiency of the generation, transmission, or distribution of electricity, implemented by a utility in connection with its operations or facilities to provide electricity to its customers, and includes the measures set forth in part 73, Appendix A, section 2 of this chapter.

Ton or tonnage means any "short ton" (i.e., 2,000 pounds). For the purpose of determining compliance with the Acid Rain emissions limitations and reduction requirements, total tons for a year shall be calculated as the sum of all recorded hourly emissions (or the tonnage equivalent of the recorded hourly emissions rates) in accordance with part 75 of this chapter, with any remaining fraction of a ton equal to or greater than 0.50 ton deemed to equal one ton and any fraction of a ton less than 0.50 ton deemed not to equal any ton.

Transfer unit means a Phase I unit that transfers all or part of its Phase I

emission reduction obligations to a control unit designated pursuant to a Phase I extension plan under § 72.42.

Underutilization means a reduction, during any calendar year in Phase I, of the heat input (expressed in mmBtu for the calendar year) at a Phase I unit below the unit's baseline.

Unit means a fossil fuel-fired combustion device.

Unit account means an Allowance Tracking System account, established by the Administrator for an affected unit pursuant to § 73.31 (a) or (b) of this chapter.

Unit load means the total (i.e., gross) output of a unit or source in any calendar year (or other specified time period) produced by combusting a given heat input of fuel, expressed in terms of:

(1) The total electrical generation (MWe) for use within the plant and for sale; or

(2) In the case of a unit or source that uses part of its heat input for purposes other than electrical generation, the total steam pressure (psia) produced by the unit or source.

Unit operating hours means, when referring to the availability of a monitoring system, the number of hours (or fraction of an hour) that a unit combusts any fuel; and, in the case of a COMS availability, includes the number of hours (or fraction of an hour) after combustion has ceased when fans are operating.

Utility means any person that sells electricity.

Utility competitive bid solicitation is a public request from a regulated utility for offers to the utility for meeting future generating needs. A new IPP may be regarded as having been "selected" in such solicitation pursuant to section 405(g)(6)(A)(iv) of the Act if the utility has named the IPP as a project with which it intends to negotiate a power sales agreement.

Utility regulatory authority means an authority, board, commission, or other entity (limited to the local-, State-, or federal-level, whenever so specified) responsible for overseeing the business operations of utilities located within its jurisdiction, including, but not limited to, utility rates and charges to customers.

Utility system means all interconnected units and generators controlled by the same utility operating company, as reported in the NADB under the data field "UTILNAME".

Utility unit means a unit owned or operated by a utility:

(1) That serves a generator in any State that produces electricity for sale, or

(2) That during 1985, served a generator in any State that produced electricity for sale.

(3) Notwithstanding paragraphs (1) and (2) of this definition, a unit that was in operation during 1985, but did not serve a generator that produced electricity for sale during 1985, and did not commence commercial operation on or after November 15, 1990 is not a utility unit for purposes of the Acid Rain Program.

(4) Notwithstanding paragraphs (1) and (2) of this definition, a unit that cogenerates steam and electricity is not a utility unit for purposes of the Acid Rain Program, unless the unit is constructed for the purpose of supplying, or commences construction after November 15, 1990 and supplies, more than one-third of its potential electrical output capacity and more than 25 MWe output to any power distribution system for sale.

Utilization means the heat input (expressed in mmBtu/time) for a unit.

Volumetric flow means the rate of movement of a specified volume of gas past a cross-sectional area (e.g., cubic feet per hour).

Zero ambient air material means a gas that consists of ambient air and that is vendor-certified to contain: traceable concentrations respectively of SO_2, NO_x, and THC below 0.1 ppm; a concentration of CO below 1 ppm; and a concentration of CO_2 below 400 ppm.

§ 72.3 Measurements, abbreviations, and acronyms.

Measurements, abbreviations, and acronyms used in this part are defined as follows:

acfh—actual cubic feet per hour.
atm—atmosphere.
bbl—barrel.
Btu—British thermal unit.
°C—degree Celsius (centigrade).
cfm—cubic feet per minute.
cm—centimeter.
dcf—dry cubic feet.
DOE—Department of Energy.
dscf—dry cubic feet at standard conditions.
dscfh—dry cubic feet per hour at standard conditions.
EIA—Energy Information Administration.
eq—equivalent.
°F—degree Fahrenheit.
fps—feet per second.
gal—gallon.
hr—hour.
in—inch.
°K—degree Kelvin.
Kwh—kilowatt hour.
lb—pounds.
m—meter.
mmBtu—million Btu.
min—minute.
mol. wt.—molecular weight.
MWe—megawatt electrical.
MWge—gross megawatt electrical.
ppm—parts per million.
psi—pounds per square inch.
°R—degree Rankine.
scf—cubic feet at standard conditions.
scfh—cubic feet per hour at standard conditions.
sec—second.
std—at standard conditions.
CO_2—carbon dioxide.
NO_x—nitrogen oxides.
O_2—oxygen.
THC—total hydrocarbon content.
SO_2—sulfur dioxide.

§ 72.4 Federal authority.

(a) The Administrator reserves all authority under sections 112(r)(9), 113, 114, 120, 301, 303, 304, 306, and 307(a) of the Act, including, but not limited to, the authority to:

(1) Secure information needed for the purpose of developing, revising, or implementing, or of determining whether any person is in violation of, any standard, method, requirement, or prohibition of the Act, this part, parts 73, 75, 77, and 78 of this chapter, and regulations implementing sections 407 and 410 of the Act;

(2) Make inspections, conduct tests, examine records, and require an owner or operator of an affected unit to submit information reasonably required for the purpose of developing, revising, or implementing, or of determining whether any person is in violation of, any standard, method, requirement, or prohibition of the Act, this part, parts 73, 75, 77, and 78 of this chapter, and regulations implementing sections 407 and 410 of the Act; and

(3) Issue orders, call witnesses, and compel the production of documents.

(b) The Administrator reserves the right under title IV of the Act to take any action necessary to protect the orderly and competitive functioning of the allowance system, including actions to prevent fraud and misrepresentation.

§ 72.5 State authority.

Consistent with section 116 of the Act, the provisions of the Acid Rain Program shall not be construed in any manner to preclude any State from adopting and enforcing any other air quality requirement (including any continuous emissions monitoring) that is not less stringent than, and does not alter, any requirement applicable to an affected unit or affected source under the Acid Rain Program; *provided* that such State requirement, if articulated in an operating permit, is in a portion of the operating permit separate from the

portion containing the Acid Rain Program requirements.

§ 72.6 Applicability.

(a) Each of the following units shall be an affected unit, and any source that includes such a unit shall be an affected source, subject to the requirements of the Acid Rain Program:

(1) A unit listed in Table 1 of § 73.10(a) of this chapter.

(2) An existing unit that is identified as qualifying for an allowance allocation under regulations implementing sections 403 and 405 of the Act and any other existing utility unit, except a unit under paragraph (b) of this section.

(3) A utility unit, except a unit under paragraph (b) of this section, that:

(i) Is a new unit; or

(ii) Did not serve a generator with a nameplate capacity greater than 25 MWe on November 15, 1990 but serves such a generator after November 15, 1990.

(b) The following types of units are not affected units subject to the requirements of the Acid Rain Program:

(1) A simple combustion turbine that commenced operation before November 15, 1990.

(2) Any unit that commenced commercial operation before November 15, 1990 and that did not, as of November 15, 1990, and does not currently, serve a generator with a nameplate capacity of greater than 25 MWe.

(3) Any unit that, during 1985, did not serve a generator that produced electricity for sale and that did not, as of November 15, 1990, and does not currently, serve a generator that produces electricity for sale.

(4) [Reserved: cogeneration units].

(5) [Reserved: qualifying facilities].

(6) [Reserved: new independent power production facilities].

(7) [Reserved: solid waste incinerators].

(8) A non-utility unit.

§ 72.7 New units exemption.

(a) *Applicability.* This section applies to any new utility unit that serves one or more generators with total nameplate capacity of 25 MWe or less and burns only fuels with a sulfur content of 0.05 percent or less by weight, as determined in accordance with paragraph (d)(2) of this section.

(b) *Petition for Written Exemption.* The designated representative, authorized in accordance with subpart B of this part, of a source that includes a unit under paragraph (a) of this section may petition the permitting authority for a written exemption, or to renew a written exemption, for the unit from certain requirements of the Acid Rain Program. The petition shall include the following elements in a format prescribed by the Administrator:

(1) Identification of the unit.

(2) The nameplate capacity of each generator served by the unit.

(3) A list of all fuels currently burned by the unit and their percentage sulfur content by weight, determined in accordance with paragraph (a) of this section.

(4) A list of all fuels that are expected to be burned by the unit and their sulfur content by weight.

(5) The special provisions in paragraph (d) of this section.

(c) *Permitting Authority's Action.*

(1)(i) The permitting authority shall issue, for any unit meeting the requirements of paragraphs (a) and (b) of this section, a written exemption from the requirements of the Acid Rain Program except for the requirements specified in this section and §§ 72.1 through 72.6 and §§ 72.10 through 72.13; *provided* that no unit shall be exempted unless allowances, equal in number to, and with the same or earlier compliance use date as, all of those allocated under subpart B of part 73 of this chapter for any year for which the unit will be exempted, are deducted from the unit's Allowance Tracking System account.

(ii) The exemption shall take effect on January 1 of the year immediately following the earlier of the date on which the written exemption is issued subject to administrative appeal under part 78 of this chapter or is issued as a final agency action subject to judicial review, in accordance with paragraph (c)(2) of this section; *provided* that the owners and operators, and, to the extent applicable, the designated representative, shall comply with the requirements of the Acid Rain Program concerning all years for which the unit was not exempted, even if such requirements arise, or must be complied with, after the exemption takes effect. The exemption shall not be a defense against any violation of such requirements of the Acid Rain Program whether the violation occurs before or after the exemption takes effect.

(2) In considering and issuing or denying a written exemption under paragraph (c)(1) of this section, the permitting authority shall apply the procedures in subparts F and G of this part and part 70 of this chapter, as applicable, by:

(i) Treating the petition as an Acid Rain permit application under such provisions;

(ii) Issuing or denying a draft written exemption that is treated as the issuance or denial of a draft permit under such provisions; and

(iii) Where the Administrator is the permitting authority, issuing or denying a written exemption that is treated as the issuance or denial of a permit under subpart F of this part or, where a State is the permitting authority, issuing or denying a proposed written exemption that is treated as the issuance or denial of a proposed permit under subpart G of this part and part 70 of this chapter; *provided* that no provision under subparts F and G of this part and part 70 of this chapter concerning the content, effective date, or term of an Acid Rain permit shall apply to the written exemption or proposed written exemption under this section.

(3) A written exemption issued under this section shall have a term of 5 years from its effective date, except as provided in paragraph (d)(4) of this section.

(d) *Special Provisions.* (1) The owners and operators of each unit exempted under this section shall surrender allowances equal in number to, and with the same or an earlier compliance use date as, all of those allocated to the unit under subpart B of part 73 of this chapter for any year for which the unit is exempted and shall waive the right to receive any allowances to be allocated under subpart B of part 73 of this chapter for any year for which the unit is exempted.

(2) The owners and operators of each unit exempted under this section shall determine the sulfur content by weight of its fuel as follows:

(i) For petroleum or petroleum products that the unit burns starting on the first day on which the exemption takes effect until the exemption terminates, a sample of each delivery of such fuel shall be tested using ASTM methods ASTM D4057–88 and ASTM D129–91, ASTM D2622–92, or ASTM D4294–90 (all methods incorporated by reference under § 72.13 of this part.)

(ii) For natural gas that the unit burns starting on the first day on which the exemption takes effect until the exemption terminates, the sulfur content shall be assumed to be 0.05 per cent or less by weight.

(iii) For gaseous fuel (other than natural gas) that the unit burns starting on the first day on which the exemption takes effect until the exemption terminates, a sample of each delivery of such fuel shall be tested using ASTM methods ASTM D1072–90 and ASTM D1265–92 (incorporated by reference under § 72.13 of this part); *provided* that if the gaseous fuel is delivered by pipeline to the unit, a sample of the fuel shall be tested, at least once every

quarter in which the unit operates during any year for which the exemption is in effect, using ASTM method ASTM D1072–90 (incorporated by reference under § 72.13 of this part).

(3) The owners and operators of each unit exempted under this section shall retain at the source that includes the unit, the records of the results of the tests performed under paragraph (d)(2)(i) and (iii) of this section and a copy of the purchase agreements for the fuel under paragraph (d)(2) of this section, stating the sulfur content of such fuel. Such records and documents shall be retained for 5 years from the date they are created.

(4) On the earlier of the date the written exemption expires, the date a unit exempted under this section burns any fuel with a sulfur content in excess of 0.05 percent by weight (as determined in accordance with paragraph (d)(2) of this section), or 24 months prior to the date the unit first serves one or more generators with total nameplate capacity in excess of 25 MWe, the unit shall no longer be exempted under this section and shall be subject to all requirements of the Acid Rain Program, except that:

(i) Notwithstanding § 72.30 (b) and (c), the designated representative of the source that includes the unit shall submit a complete Acid Rain permit application on the later of January 1, 1998 or the date the unit is no longer exempted under this section.

(ii) For purposes of applying monitoring requirements under part 75 of this chapter, the unit shall be treated as a new unit that commenced commercial operation on the date the unit no longer meets the requirements of paragraph (a) of this section.

§ 72.8 Retired units exemption.

(a) *Applicability.* This section applies to any affected unit that is retired prior to the issuance (including renewal) of a Phase II Acid Rain permit for the unit as a final agency action.

(b) *Petition for Written Exemption.* (1) The designated representative, authorized in accordance with subpart B of this part, of a source that includes a unit under paragraph (a) of this section may petition the permitting authority for a written exemption, or to renew a written exemption, for the unit from certain requirements of this part.

(2) A petition under this section shall be submitted on or before:

(i) The deadline for submitting an Acid Rain permit application for Phase II; or

(ii) If the unit has a Phase II Acid Rain permit, the deadline for reapplying for such permit.

(3) The petition under this section shall include the following elements in a format prescribed by the Administrator:

(i) Identification of the unit.

(ii) The applicable deadline under paragraph (b)(2) of this section.

(iii) The actual or expected date of retirement of the unit.

(iv) The following statement: "I certify that this unit ['is' or 'will be', as applicable] permanently retired on the date specified in this petition and will not emit any sulfur dioxide or nitrogen oxides after such date."

(v) A description of any actions that have been or will be taken and provide the basis for the certification in paragraph (b)(3)(iv) of this section.

(iv) The special provisions in paragraph (d) of this section.

(c) *Permitting Authority's Action.* (1)(i) The permitting authority shall issue, for any unit meeting the requirements of paragraphs (a) and (b) of this section, a written exemption from the requirements of this part except for the requirements specified in this section and §§ 72.1 through 72.6 and §§ 72.10 through 72.13.

(ii) The exemption shall take effect on January 1 of the year following the earlier of the date on which the written exemption is issued subject to administrative appeal under part 78 of this chapter or is issued as a final agency action subject to judicial review, in accordance with paragraph (c)(2) of this section; *provided* that the owners and operators, and, to the extent applicable, the designated representative, shall comply with the requirements of this part concerning all years for which the unit was not exempted, even if such requirements arise or must be complied with after the exemption takes effect. The exemption shall not be a defense against any violation of such requirements of the Acid Rain Program whether the violation occurs before or after the exemption takes effect.

(2) In considering and issuing or denying a written exemption under paragraph (c)(1) of this section, the permitting authority shall apply the procedures in subparts F and G of this part and part 70 of this chapter, as applicable, by:

(i) Treating the petition as an Acid Rain permit application under such provisions;

(ii) Issuing or denying a draft written exemption that is treated as the issuance or denial of a proposed permit under such provisions; and

(iii) Where the Administrator is the permitting authority, issuing or denying a written exemption that is treated as a permit under subpart F of this part or, where a State is the permitting authority, issuing or denying a proposed written exemption that is treated as a proposed permit under subpart G of this part and part 70 of this chapter; *provided* that no provision under subparts F and G of this part and part 70 of this chapter concerning, the content, effective date, or term of an Acid Rain permit shall apply to the written exemption or proposed written exemption under this section.

(3) A written exemption issued under this section shall have a term of 5 years, except as provided in paragraph (d)(3) of this section.

(d) *Special Provisions.* (1) A unit exempted under this section shall not emit any sulfur dioxide and nitrogen dioxide starting on the date it is exempted.

(2) The owners and operators of a unit exempted under this section shall comply with monitoring requirements in accordance with part 75 of this chapter and will be allocated allowances in accordance with part 73 of this chapter.

(3) A unit exempted under this section shall not resume operation unless the designated representative of the source that includes the unit submits an Acid Rain permit application for the unit not less than 24 months prior to the later of January 1, 2000 or the date the unit is to resume operation. On the earlier of the date the written exemption expires or the date an Acid Rain permit application is submitted or is required to be submitted under this paragraph, the unit shall no longer be exempted under this section and shall be subject to all requirements of this part.

§ 72.9 Standard requirements.

(a) *Permit Requirements.* (1) The designated representative of each affected source and each affected unit at the source shall:

(i) Submit a complete Acid Rain permit application (including a compliance plan) under this part in accordance with the deadlines specified in § 72.30;

(ii) Submit in a timely manner a complete reduced utilization plan if required under § 72.43; and

(iii) Submit in a timely manner any supplemental information that the permitting authority determines is necessary in order to review an Acid Rain permit application and issue or deny an Acid Rain permit.

(2) The owners and operators of each affected source and each affected unit at the source shall:

(i) Operate the unit in compliance with a complete Acid Rain permit application or a superseding Acid Rain permit issued by the permitting authority; and

(ii) Have an Acid Rain Permit.

(b) *Monitoring Requirements.* (1) The owners and operators and, to the extent applicable, designated representative of each affected source and each affected unit at the source shall comply with the monitoring requirements as provided in part 75 of this chapter and section 407 of the Act and regulations implementing section 407 of the Act.

(2) The emissions measurements recorded and reported in accordance with part 75 of this chapter and section 407 of the Act and regulations implementing section 407 of the Act shall be used to determine compliance by the unit with the Acid Rain emissions limitations and emissions reduction requirements for sulfur dioxide and nitrogen oxides under the Acid Rain Program.

(3) The requirements of part 75 of this chapter and regulations implementing section 407 of the Act shall not affect the responsibility of the owners and operators to monitor emissions of other pollutants or other emissions characteristics at the unit under other applicable requirements of the Act and other provisions of the operating permit for the source.

(c) *Sulfur Dioxide Requirements.* (1) The owners and operators of each source and each affected unit at the source shall:

(i) Hold allowances, as of the allowance transfer deadline, in the unit's compliance subaccount (after deductions under § 73.34(c) of this chapter) not less than the total annual emissions of sulfur dioxide for the previous calendar year from the unit; and

(ii) Comply with the applicable Acid Rain emissions limitation for sulfur dioxide.

(2) Each ton of sulfur dioxide emitted in excess of the Acid Rain emissions limitations for sulfur dioxide shall constitute a separate violation of the Act.

(3) An affected unit shall be subject to the requirements under paragraph (c)(1) of this section as follows:

(i) Starting January 1, 1995, an affected unit under § 72.6(a)(1);

(ii) Starting on or after January 1, 1995 in accordance with §§ 72.41 and 72.43, an affected unit under § 72.6(a) (2) or (3) that is a substitution or compensating unit;

(iii) Starting January 1, 2000, an affected unit under § 72.6(a)(2) that is not a substitution or compensating unit; or

(iv) Starting on the later of January 1, 2000 or the deadline for monitor certification under part 75 of this chapter, an affected unit under § 72.6(a)(3) that is not a substitution or compensating unit.

(4) Allowances shall be held in, deducted from, or transferred among Allowance Tracking System accounts in accordance with the Acid Rain Program.

(5) An allowance shall not be deducted, in order to comply with the requirements under paragraph (c)(1)(i) of this section, prior to the calendar year for which the allowance was allocated.

(6) An allowance allocated by the Administrator under the Acid Rain Program is a limited authorization to emit sulfur dioxide in accordance with the Acid Rain Program. No provision of the Acid Rain Program, the Acid Rain permit application, the Acid Rain permit, or the written exemption under §§ 72.7 and 72.8 and no provision of law shall be construed to limit the authority of the United States to terminate or limit such authorization.

(7) An allowance allocated by the Administrator under the Acid Rain Program does not constitute a property right.

(d) *Nitrogen Oxides Requirements.* The owners and operators of the source and each affected unit at the source shall comply with the applicable Acid Rain emissions limitation for nitrogen oxides.

(e) *Excess Emissions Requirements.* (1) The designated representative of an affected unit that has excess emissions in any calendar year shall submit a proposed offset plan, as required under part 77 of this chapter.

(2) The owners and operators of an affected unit that has excess emissions in any calendar year shall:

(i) Pay without demand the penalty required, and pay upon demand the interest on that penalty, as required by part 77 of this chapter; and

(ii) Comply with the terms of an approved offset plan, as required by part 77 of this chapter.

(f) *Recordkeeping and Reporting Requirements.* (1) Unless otherwise provided, the owners and operators of the source and each affected unit at the source shall keep on site at the source each of the following documents for a period of 5 years from the date the document is created. This period may be extended for cause, at any time prior to the end of 5 years, in writing by the Administrator or permitting authority.

(i) The certificate of representation for the designated representative for the source and each affected unit at the source and all documents that demonstrate the truth of the statements in the certificate of representation, in accordance with § 72.24; *provided* that the certificate and documents shall be retained on site at the source beyond such 5-year period until such documents are superseded because of the submission of a new certificate of representation changing the designated representative.

(ii) All emissions monitoring information, in accordance with part 75 of this chapter.

(iii) Copies of all reports, compliance certifications, and other submissions and all records made or required under the Acid Rain Program.

(iv) Copies of all documents used to complete an Acid Rain permit application and any other submission under the Acid Rain Program or to demonstrate compliance with the requirements of the Acid Rain Program.

(2) The designated representative of an affected source and each affected unit at the source shall submit the reports and compliance certifications required under the Acid Rain Program, including those under subpart I of this part and part 75 of this chapter.

(g) *Liability.* (1) Any person who knowingly violates any requirement or prohibition of the Acid Rain Program, a complete Acid Rain permit application, an Acid Rain permit, or a written exemption under § 72.7 or § 72.8, including any requirement for the payment of any penalty owed to the United States, shall be subject to enforcement pursuant to section 113(c) of the Act.

(2) Any person who knowingly makes a false, material statement in any record, submission, or report under the Acid Rain Program shall be subject to criminal enforcement pursuant to section 113(c) of the Act and 18 U.S.C. 1001.

(3) No permit revision shall excuse any violation of the requirements of the Acid Rain Program that occurs prior to the date that the revision takes effect.

(4) Each affected source and each affected unit shall meet the requirements of the Acid Rain Program.

(5) Any provision of the Acid Rain Program that applies to an affected source (including a provision applicable to the designated representative of an affected source) shall also apply to the owners and operators of such source and of the affected units at the source.

(6) Any provision of the Acid Rain Program that applies to an affected unit (including a provision applicable to the designated representative of an affected unit) shall also apply to the owners and operators of such unit. Except as

provided under § 72.41 (substitution plans), § 72.42 (Phase I extension plans), § 72.43 (reduced utilization plans), § 72.44 (Phase II repowering extension plans), and section 407 of the Act and regulations implementing section 407 of the Act, and except with regard to the requirements applicable to units with a common stack under part 75 of this chapter (including §§ 75.16, 75.17, and 75.18), the owners and operators and the designated representative of one affected unit shall not be liable for any violation by any other affected unit of which they are not owners or operators or the designated representative and that is located at a source of which they are not owners or operators or the designated representative.

(7) Each violation of a provision of this part, parts 73, 75, 77, and 78 of this chapter, and regulations implementing sections 407 and 410 of the Act by an affected source or affected unit, or by an owner or operator or designated representative of such source or unit, shall be a separate violation of the Act.

(h) *Effect on Other Authorities.* No provision of the Acid Rain Program, an Acid Rain permit application, an Acid Rain permit, or a written exemption under § § 72.7 or 72.8 shall be construed as:

(1) Except as expressly provided in title IV of the Act, exempting or excluding the owners and operators and, to the extent applicable, the designated representative of an affected source or affected unit from compliance with any other provision of the Act, including the provisions of title I of the Act relating to applicable National Ambient Air Quality Standards or State Implementation Plans.

(2) Limiting the number of allowances a unit can hold; *provided*, that the number of allowances held by the unit shall not affect the source's obligation to comply with any other provisions of the Act.

(3) Requiring a change of any kind in any State law regulating electric utility rates and charges, affecting any State law regarding such State regulation, or limiting such State regulation, including any prudence review requirements under such State law.

(4) Modifying the Federal Power Act or affecting the authority of the Federal Energy Regulatory Commission under the Federal Power Act.

(5) Interfering with or impairing any program for competitive bidding for power supply in a State in which such program is established.

§ 72.10 Availability of information.

The availability to the public of information provided to, or otherwise obtained by, the Administrator under the Acid Rain Program shall be governed by part 2 of this chapter.

§ 72.11 Computation of time.

(a) Unless otherwise stated, any time period scheduled, under the Acid Rain Program, to begin on the occurrence of an act or event shall begin on the day the act or event occurs.

(b) Unless otherwise stated, any time period scheduled, under the Acid Rain Program, to begin before the occurrence of an act or event shall be computed so that the period ends on the day before the act or event occurs.

(c) Unless otherwise stated, if the final day of any time period, under the Acid Rain Program, falls on a weekend or a federal holiday, the time period shall be extended to the next business day.

(d) Whenever a party or interested person has the right, or is required, to act under the Acid Rain Program within a prescribed time period after service of notice or other document upon him or her by mail, 3 days shall be added to the prescribed time.

§ 72.12 Administrative Appeals.

The procedures for appeals of decisions of the Administrator under this part are contained in part 78 of this chapter.

§ 72.13 Incorporation by reference.

The materials listed in this section are incorporated by reference in the corresponding sections noted. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they existed on the date of approval, and a notice of any change in these materials will be published in the **Federal Register**. The materials are available for purchase at the corresponding address noted below and are available for inspection at the Office of the Federal Register, 800 N. Capitol Street, NW., Washington, DC, at the Public Information Reference Unit of the U.S. EPA, 401 M Street SW, Washington, DC and at the Library (MD–35), U.S. EPA, Research Triangle Park, North Carolina.

(a) The following materials are available for purchase from the following addresses: American Society for Testing and Material (ASTM), 1916 Race Street, Philadelphia, Pennsylvania 19103; and the University Microfilms International 300 North Zeeb Road, Ann Arbor, Michigan 48106.

(1) ASTM D129–91, Standard Test Method for Sulfur in Petroleum Products (General Bomb Method), for § 72.7 of this chapter.

(2) ASTM D388–92, Standard Classification of Coals by Rank for § 72.2 of this chapter.

(3) ASTM D396–90a, Standard Specification for Fuel Oils, for § 72.2 of this chapter.

(4) ASTM D975–91, Standard Specification for Diesel Fuel Oils, for § 72.2 of this chapter.

(5) ASTMD1072–90, Standard Test Method for Total Sulfur in Fuel Gases, for § 72.7 of this chapter.

(6) ASTMD1265–92, Standard Practice for Sampling Liquified Petroleum (LP) Gases (Manual Method), for § 72.7 of this chapter.

(7) ASTM D2622–92, Standard Test Method for Sulfur in Petroleum Products by X-Ray Spectrometry, for § 72.7 of this chapter.

(8) ASTM D 4057–88, Standard Practice for Manual Sampling of Petroleum and Petroleum Products, for § 72.7 of this chapter.

(9) ASTM D4294–90, Standard Test Method for Sulfur in Petroleum Products by Energy-Dispersive X-Ray Fluorescence Spectroscopy, for § 72.7 of this chapter.

Subpart B—Designated Representative

§ 72.20 Authorization and responsibilities of the designated representative.

(a) Except as provided under § 72.22, each affected source, including all affected units at the source, shall have one and only one designated representative, with regard to all matters under the Acid Rain Program concerning the source or any affected unit at the source.

(b) Upon receipt by the Administrator of a complete certificate of representation, the designated representative of the source shall represent and, by his or her actions, inactions, or submissions, legally bind each owner and operator of the affected source represented and each affected unit at the source in all matters pertaining to the Acid Rain Program, not withstanding any agreement between the designated representative and such owners and operators. The owners and operators shall be bound by any order issued to the designated representative by the Administrator, the permitting authority, or a court.

(c) The designated representative shall be selected and act in accordance with the certifications set forth in § 72.24(a) (4), (5), (7), and (9).

(d) No Acid Rain permit shall be issued to an affected source, nor shall any allowance transfer be recorded for an Allowance Tracking System account of an affected unit at a source, until the Administrator has received a complete

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certificate of representation for the designated representative of the source and the affected units at the source.

§ 72.21 Submissions.

(a) Each submission under the Acid Rain Program shall be submitted, signed, and certified by the designated representative for all sources on behalf of which the submission is made.

(b) In each submission under the Acid Rain Program, the designated representative shall certify, by his or her signature:

(1) The following statement, which shall be included verbatim in such submission: "I am authorized to make this submission on behalf of the owners and operators of the affected source or affected units for which the submission is made."

(2) The following statement, which shall be included verbatim in such submission: "I certify under penalty of law that I have personally examined, and am familiar with, the statements and information submitted in this document and all its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the statements and information are to the best of my knowledge and belief true, accurate, and complete. I am aware that there are significant penalties for submitting false statements and information or omitting required statements and information, including the possibility of fine or imprisonment."

(c) The Administrator and the permitting authority shall accept or act on a submission made on behalf of owners or operators of an affected source and an affected unit only if the submission has been made, signed, and certified in accordance with paragraphs (a) and (b) of this section.

(d) (1) The designated representative of a source shall serve notice on each owner and operator of the source and of an affected unit at the source:

(i) By the date of submission, of any Acid Rain Program submissions by the designated representative and

(ii) Within 10 business days of receipt of a determination, of any written determination by the Administrator or the permitting authority,

(iii) Provided that the submission or determination covers the source or the unit.

(2) The designated representative of a source shall provide each owner and operator of an affected unit at the source a copy of any submission or determination under paragraph (d)(1) of this section, unless the owner or operator expressly waives the right to receive such a copy.

(e) The provisions of this section shall apply to a submission made under parts 73, 75, 77, and 78 of this chapter and under regulations implementing sections 407 and 410 of the Act only if it is made or signed, or required to be made or signed in accordance with parts 73, 75, 77, and 78 of this chapter and regulations implementing sections 407 and 410 of the Act, by:

(i) The designated representative; or

(ii) The authorized account representative or alternate authorized account representative of a unit account.

§ 72.22 Alternate designated representative.

(a) The certificate of representation may designate one and only one alternate designated representative, who may act on behalf of the designated representative. The agreement by which the alternate designated representative is selected shall include a procedure for the owners and operators of the source and affected units at the source to authorize the alternate designated representative to act in lieu of the designated representative.

(b) Upon receipt by the Administrator of a complete certificate of representation that meets the requirements of § 72.24 (including those applicable to the alternate designated representative), any action, representation, or failure to act by the alternate designated representative shall be deemed to be an action, representation, or failure to act by the designated representative.

(c) In the event of a conflict, any action taken by the designated representative shall take precedence over any action taken by the alternate designated representative if, in the Administrator's judgement, the actions are concurrent and conflicting.

(d) Except in this section, § 72.23, and § 72.24, whenever the term "designated representative" is used under the Acid Rain Program, the term shall be construed to include the alternate designated representative.

§ 72.23 Changing the designated representative, alternate designated representative; changes in the owners and operators.

(a) *Changing the designated representative.* The designated representative may be changed at any time upon receipt by the Administrator of a superseding complete certificate of representation. Notwithstanding any such change, all submissions, actions, and inactions by the previous designated representative prior to the time and date when the Administrator receives the superseding certificate of representation shall be binding on the new designated representative and on the owners and operators of the source represented and the affected units at the source.

(b) *Changing the alternate designated representative.* The alternate designated representative may be changed at any time upon receipt by the Administrator of a superseding complete certificate of representation. Notwithstanding any such change, all submissions, actions, and inactions by the previous alternate designated representative prior to the time and date when the Administrator receives the superseding certificate of representation shall be binding on the new alternate designated representative and on the owners and operators of the source represented and the affected units at the source.

(c) *Changes in the owners and operators.* (1) In the event a new owner or operator of an affected source or an affected unit is not included in the list of owners and operators submitted in the certificate of representation, such new owner or operator shall be deemed to be subject to and bound by the certificate of representation, the submissions, actions, and inactions of the designated representative and any alternative designated representative of the source or unit, and the decisions, actions, and inactions of the Administrator and permitting authority, as if the new owner or operator were included in such list.

(2) Within 30 days following any change in the owners and operators of an affected unit, including the addition of a new owner or operator, the designated representative or any alternative designated representative shall submit a revision to the certificate of representation amending the list of owners and operators to include the change.

§ 72.24 Certificate of representation.

(a) A complete certificate of representation for a designated representative or an alternate designated representative shall include the following elements in a format prescribed by the Administrator:

(1) Identification of the affected source and each affected unit at the source for which the certificate of representation is submitted.

(2) The name, address, and telephone and facsimile numbers of the designated representative and any alternate designated representative.

(3) A list of the owners and operators of the affected source and of each affected unit at the source and all State or local utility regulatory authorities with jurisdiction over each owner.

(4) The following statement: "I certify that I was selected as the 'designated representative' or 'alternate designated representative,' as applicable, by an agreement binding on the owners and operators of the affected source and each affected unit at the source."

(5) The following statement: "I certify that I have given notice of the agreement, selecting me as the 'designated representative' or 'alternate designated representative,' as applicable for the affected source and each affected unit at the source identified in this certificate of representation, daily for a period of one week in a newspaper of general circulation in the area where the source is located or in a State publication designed to give general public notice."

(6) The following statement: "I certify that I have all necessary authority to carry out my duties and responsibilities under the Acid Rain Program on behalf of the owners and operators of the affected source and of each affected unit at the source and that each such owner and operator shall be fully bound by my actions, inactions, or submissions."

(7) The following statement: "I certify that I shall abide by any fiduciary responsibilities imposed by the agreement by which I was selected as 'designated representative' or 'alternate designated representative', as applicable."

(8) The following statement: "I certify that the owners and operators of the affected source and of each affected unit at the source shall be bound by any order issued to me by the Administrator, the permitting authority, or a court regarding the source or unit."

(9) The following statement: "Where there are multiple holders of a legal or equitable title to, or a leasehold interest in, an affected unit, or where a utility or industrial customer purchases power from an affected unit under life-of-the-unit, firm power contractual arrangements, I certify that:

(i) "I have given a written notice of my selection as the 'designated representative' or 'alternate designated representative', as applicable, and of the agreement by which I was selected to each owner and operator of the affected source and of each affected unit at the source; and

(ii) "Allowances and proceeds of transactions involving allowances will be deemed to be held or distributed in proportion to each holder's legal, equitable, leasehold, or contractual reservation or entitlement or, if such multiple holders have expressly provided for a different distribution of allowances by contract, that allowances and the proceeds of transactions involving allowances will be deemed to be held or distributed in accordance with the contract."

(10) If there is an alternate designated representative, the following statement: "The agreement by which I was selected as the alternate designated representative includes a procedure for the owners and operators of the source and affected units at the source to authorize the alternate designated representative to act in lieu of the designated representative."

(11) The signature of the designated representative and any alternate designated representative and the date signed.

(b) Unless otherwise required by the Administrator or the permitting authority, documents of agreement or notice referred to in the certificate of representation shall not be submitted to the Administrator or the permitting authority. Neither the Administrator nor the permitting authority shall be under any obligation to review or evaluate the sufficiency of such documents, if submitted.

§ 72.25 Objections.

(a) Once a complete certificate of representation has been submitted in accordance with § 72.24, the Administrator will rely on the certificate of representation unless and until a superseding complete certificate is submitted to the Administrator.

(b) Except as provided in § 72.23, no objection or other communication submitted to the Administrator or the permitting authority concerning the authorization, or any submission, action or inaction, of the designated representative shall affect any submission, action, or inaction of the designated representative, or the finality of any decision by the Administrator or permitting authority, under the Acid Rain Program. In the event of such communication, the Administrator and the permitting authority are not required to stay any allowance transfer, any submission, or the effect of any action or inaction under the Acid Rain Program.

(c) Neither the Administrator nor any permitting authority will adjudicate any private legal dispute concerning the authorization or any submission, action, or inaction of any designated representative, including private legal disputes concerning the proceeds of allowance transfers.

Subpart C—Acid Rain Permit Applications

§ 72.30 Requirement to apply.

(a) *Duty to apply.* The designated representative of any source with an affected unit shall submit a complete Acid Rain permit application by the applicable deadline in paragraphs (b) and (c) of this section, and the owners and operators of such source and any affected unit at the source shall not operate the source or unit without a permit that states its Acid Rain program requirements.

(b) *Deadlines.* (1) *Phase I.* (i) The designated representative shall submit a complete Acid Rain permit application governing an affected unit during Phase I to the Administrator on or before February 15, 1993 for:

(A) Any source with such a unit under § 72.6(a)(1); and

(B) Any source with such a unit under § 72.6(a) (2) or (3) that is designated a substitution or compensating unit in a substitution plan or reduced utilization plan submitted to the Administrator for approval or conditional approval.

(ii) Notwithstanding paragraph (b)(1)(i) of this section, if a unit at a source not previously permitted is designated a substitution or compensating unit in a submission requesting revision of an existing Acid Rain permit, the designated representative of the unit shall submit a complete Acid Rain permit application on the date that the submission requesting the revision is made.

(2) *Phase II.* For any source with an existing unit under § 72.6(a)(2), the designated representative shall submit a complete Acid Rain permit application governing such unit during Phase II to the permitting authority on or before January 1, 1996.

(ii) For any source with a new unit under § 72.6(a)(3)(i), the designated representative shall submit a complete Acid Rain permit application governing such unit to the permitting authority at least 24 months before the later of January 1, 2000 or the date on which the unit commences operation.

(iii) For any source with a unit under § 72.6(a)(3)(ii), the designated representative shall submit a complete Acid Rain permit application governing such unit to the permitting authority at least 24 months before the later of January 1,2000 or the date on which the unit begins to serve a generator with a nameplate capacity greater than 25 MWe.

(3) *Acid Rain Compliance Option Deadlines.* The deadlines for applying for approval of any Acid Rain compliance options shall be the

deadlines specified in the relevant section of subpart D of this part and in section 407 of the Act and regulations implementing section 407 of the Act.

(c) *Duty to Reapply.* The designated representative shall submit a complete Acid Rain permit application for each source with an affected unit at least 6 months prior to the expiration of an existing Acid Rain permit governing the unit during Phase II or such longer time as may be approved under part 70 of this chapter that ensures that the term of the existing permit will not expire before the effective date of the permit for which the application is submitted.

(d) The original and three copies of all permit applications for Phase I and where the Administrator is the permitting authority, for Phase II, shall be submitted to the EPA Regional Office for the Region where the affected source is located. The original and three copies of all permit applications for Phase II, where the Administrator is not the permitting authority, shall be submitted to the State permitting authority for the State where the affected source is located.

§ 72.31 Information requirements for Acid Rain permit applications.

A complete Acid Rain permit application shall include following elements in a format prescribed by the Administrator:

(a) Identification of the affected source for which the permit application is submitted;

(b) Identification of each Phase I unit at the source for which the permit application is submitted for Phase I or each Phase II unit at the source for which the permit application is submitted for Phase II;

(c) A complete compliance plan for each unit, in accordance with subpart D of this part;

(d) The standard requirements under § 72.9; and

(e) If the Acid Rain permit application is for Phase II and the unit is a new unit, the date that the unit has commenced or will commence operation and the deadline for monitor certification.

§ 72.32 Permit application shield and binding effect of permit application.

(a) Once a designated representative submits a timely and complete Acid Rain permit application, the owners and operators of the affected source and the affected units covered by the permit application shall be deemed in compliance with the requirement to have an Acid Rain permit under § 72.9(a)(2) and § 72.30(a); *provided* that any delay in issuing an Acid Rain permit is not caused by the failure of the designated representative to submit in a complete and timely fashion supplemental information, as required by the permitting authority, necessary to issue a permit.

(b) Prior to the earlier of the date on which an Acid Rain permit is issued subject to administrative appeal under part 78 of this chapter or is issued as a final agency action subject to judicial review, an affected unit governed by and operated in accordance with the terms and requirements of a timely and complete Acid Rain permit application shall be deemed to be operating in compliance with the Acid Rain Program.

(c) A complete Acid Rain permit application shall be binding on the owners and operators and the designated representative of the affected source and the affected units covered by the permit application and shall be enforceable as an Acid Rain permit from the date of submission of the permit application until the issuance or denial of an Acid Rain permit covering the units and subject to administrative appeal, where the Administrator is the permitting authority, or the issuance or denial of such permit as a final agency action subject to judicial review, where the State is the permitting authority.

§ 72.33 Identification of dispatch system.

(a) Every Phase I unit shall be treated as part of a dispatch system for purposes of § 72.92 in accordance with this section.

(b)(1) The designated representatives of all affected units in a group of all units and generators that are interconnected and centrally dispatched and that are included in the same utility system, holding company, or power pool, may jointly submit to the Administrator a complete identification of dispatch system.

(2) Except as provided in paragraphs (d) and (f) of this section, each Phase I unit may be listed in only one identification of dispatch system.

(3) Any identification of dispatch system must be filed by January 30 of the first year for which the identification is to be in effect.

(c) A complete identification of dispatch system shall include the following elements in a format prescribed by the Administrator:

(1) The name of the dispatch system.

(2) The list of all units and sulfur-free generators in the dispatch system.

(3) The first calendar year for which the identification is to be in effect.

(4) The following statement: "I certify that the units listed herein are and will continue to be interconnected and centrally dispatched, and will be treated as a dispatch system under § 72.92, during the period that this identification of dispatch system is in effect. During such period, all information concerning these units and contained in any submissions under § 72.92 by me and the other designated representatives of these units shall be consistent and shall conform with the data in the dispatch system data reports under § 72.92(b)(2). I understand that if this requirement is not met, then the Administrator will reject all such submissions and treat each unit's utility system as its dispatch system. In such an event, I will make the submissions required under § 72.92 (including a dispatch system data report), treating as the dispatch system the utility system of each unit that I represent."

(5) The signatures of the designated representative for each affected unit in the dispatch system.

(d) In order to change a unit's current dispatch system, complete identifications of dispatch system shall be submitted for the unit's current dispatch system and the unit's new dispatch system, reflecting the change.

(e)(1) Any Phase I unit that is not listed in a complete identification of dispatch shall treat its utility system as its dispatch system.

(2) During the period that the identification of dispatch system is in effect, all information that concerns the units in a given dispatch system and that is contained in any submissions under § 72.92 by designated representatives of these units shall be consistent and shall conform with the data in the dispatch system data reports under § 72.92(b)(2). If this requirement is not met, the Administrator will reject all such submissions, and the designated representatives shall make the submissions under § 72.92 (including the dispatch system data report) treating the utility system of each unit as its dispatch system.

(f)(1) Notwithstanding paragraph (e)(1) of this section or any submission of an identification of dispatch system under paragraphs (b), (c), or (d) of this section, the designated representative of a Phase I unit with two or more owners may petition the Administrator to treat, as the dispatch system for an owner's portion of the unit, the dispatch system of another unit. For purposes of paragraphs (f)(1) through (6) of this section, the owner's portion of the unit shall equal the percentage of that owner's ownership interest in the capacity of the unit.

(2) The petition shall be submitted by January 30 of the first year for which the dispatch system proposed in the petition will take effect, if approved.

The petition shall include the following elements:

(i) The owner's portion of the unit and the other owners' portion(s) of the unit and a demonstration that the sum of all owners' portions of the unit equals 100 percent;

(ii) Documentation demonstrating that the owner's portion specified in the petition equals its ownership interest in the capacity of the unit;

(iii) The name of the proposed dispatch system and documentation demonstrating that the owner's portion of the unit, along with the other units in the proposed dispatch system, are a group of all units and generators that are interconnected and centrally dispatched and that are included in the same utility system, holding company, or power pool.

(iv) The following statement, signed by the designated representatives of all units in the proposed dispatch system: "I certify that the units in the dispatch system proposed in this petition are and will continue to be interconnected and centrally dispatched, and will be treated as a dispatch system under § 72.92, during the period that this petition, as approved, is in effect."

(v) The following statement, signed by the designated representatives of all units in all dispatch systems that will include any portion of the unit if the petition is approved: "During the period that this petition, if approved, is in effect, all information that concerns the units in any dispatch system including any portion of the unit apportioned under the petition and that is contained in any submissions under §§ 72.91 and 72.92 by me and the other designated representatives of these units shall be consistent and shall conform to the data in the dispatch system data reports under § 72.92(b)(2). I am aware of, and will comply with, the requirements imposed under 40 CFR 72.33(f) (4) and (5)."

(3) The Administrator will approve in whole, in part, or with changes or conditions, or deny the petition within 90 days of receipt of the petition. The Administrator will treat the petition, as changed or conditioned upon approval, as amending any identification of dispatch system that is submitted prior to the approval and includes any portion of the unit for which the petition is approved.

(4) The designated representative for the unit for which a petition is approved and the designated representatives of all other units included in all dispatch systems that include any portion of the unit shall submit all annual compliance certification reports, dispatch system data reports, and other reports required under §§ 72.91 and 72.92 treating, as a separate unit, each portion of the unit for which a petition is approved under paragraph (f)(3) of this section and the remaining portion of the unit. The reports shall include all required calculations and demonstrations, treating each such portion of the unit as a separate unit; provided that plan reductions shall be treated in a manner to be determined by the Administrator on a case-by-case basis. The designated representatives shall demonstrate that the data in all the reports under §§ 72.91 and 72.92 has been properly attributed to or apportioned among the owners' portions of the unit and the dispatch systems and that there is no undercounting or double-counting with regard to such data.

(5) In the event that the designated representatives fail to make all the proper attributions, apportionments, calculations, and demonstrations, the Administrator may require that:

(i) All portions of the unit be treated as part of the dispatch system of the unit in accordance with paragraph (e)(1) of this paragraph and any identification of dispatch system submitted under paragraph (b) of this section; and

(ii) The designated representatives make all submissions under §§ 72.91 and 72.92 (including the dispatch system data report) in accordance with paragraph (e)(1) of this paragraph and any identification of dispatch system submitted under paragraph (b) of this section.

(6) Except as expressly provided in paragraphs (f) (1) through (5) of this section or the Administrator's approval of the petition, all provisions of the Acid Rain Program applicable to an affected source or an affected unit shall apply to the entire unit regardless of whether a petition has been submitted or approved, or reports have been submitted, under such paragraphs. Approval of a petition under such paragraphs shall not constitute a determination of the percentage ownership in a unit under any other provision of the Acid Rain Program.

Subpart D—Acid Rain Compliance Plan and Compliance Options

§ 72.40 General.

(a) For each affected unit included in an Acid Rain permit application, a complete compliance plan shall:

(1) For sulfur dioxide emissions, certify that, as of the allowance transfer deadline, the designated representative will hold allowances in the unit's compliance subaccount (after deductions under § 73.34(c) of this chapter) not less than the total annual emissions of sulfur dioxide from the unit. The compliance plan may also specify, in accordance with this subpart, one or more of the Acid Rain compliance options.

(2) For nitrogen oxides emissions, certify that the unit will comply with the applicable limitation established by regulations implementing section 407 of the Act or shall specify one or more Acid Rain compliance options, in accordance with section 407 of the Act and regulations implementing section 407.

(b) *Multi-unit compliance options.* (1) A plan for a compliance option, under § 72.41, 72.42, 72.43, or 72.44 of this part or section 407 of the Act and regulations implementing section 407, that includes units at more than one affected source shall be complete only if:

(i) Such plan is signed and certified by the designated representative for each source with an affected unit governed by such plan; and

(ii) A complete permit application is submitted covering each unit governed by such plan.

(2) A permitting authority's approval of a plan under paragraph (b)(1) of this section that includes units in more than one State shall be final only after every permitting authority with jurisdiction over any such unit has approved the plan with the same modifications or conditions, if any.

(c) *Conditional Approval.* In the compliance plan, the designated representative of an affected unit may propose, in accordance with this subpart, any Acid Rain compliance option for conditional approval, except a Phase I extension plan; *provided* that an Acid Rain compliance option under section 407 of the Act may be conditionally proposed only to the extent provided in regulations implementing section 407 of the Act.

(1) To activate a conditionally-approved Acid Rain compliance option, the designated representative shall notify the permitting authority in writing that the conditionally-approved compliance option will actually be pursued beginning January 1 of a specified year. If the conditionally approved compliance option includes a plan described in paragraph (b)(1) of this section, the designated representative of each source governed by the plan shall sign and certify the notification. Such notification shall be subject to the limitations on activation under subpart D of this part and regulations implementing section 407 of the Act.

(2) The notification under paragraph (c)(1) of this section shall specify the

first calendar year and the last calendar year for which the conditionally approved Acid Rain compliance option is to be activated. A conditionally approved compliance option shall be activated, if at all, before the date of any enforceable milestone applicable to the compliance option. The date of activation of the compliance option shall not be a defense against failure to meet the requirements applicable to that compliance option during each calendar year for which the compliance option is activated.

(3) Upon submission of a notification meeting the requirements of paragraphs (c) (1) and (2) of this section, the conditionally-approved Acid Rain compliance option becomes binding on the owners and operators and the designated representative of any unit governed by the conditionally-approved compliance option.

(4) A notification meeting the requirements of paragraphs (c) (1) and (2) of this section will revise the unit's permit in accordance with § 72.83 (administrative permit amendment).

(d) *Termination of Compliance Option.* (1) The designated representative for a unit may terminate an Acid Rain compliance option by notifying the permitting authority in writing that an approved compliance option will be terminated beginning January 1 of a specified year. If the compliance option includes a plan described in paragraph (b)(1) of this section, the designated representative for each source governed by the plan shall sign and certify the notification. Such notification shall be subject to the limitations on termination under subpart D of this part and regulations implementing section 407 of the Act.

(2) The notification under paragraph (d)(1) of this section shall specify the calendar year for which the termination will take effect.

(3) Upon submission of a notification meeting the requirements of paragraphs (d) (1) and (2) of this section, the termination becomes binding on the owners and operators and the designated representative of any unit governed by the Acid Rain compliance option to be terminated.

(4) A notification meeting the requirements of paragraphs (d) (1) and (2) of this section will revise the unit's permit in accordance with § 72.83 (administrative permit amendment).

§ 72.41 Phase I substitution plans.

(a) *Applicability.* This section shall apply during Phase I to the designated representative of:

(1) Any unit listed in Table 1 of § 73.10(a) of this chapter; and

(2) Any other existing utility unit that is an affected unit under this part, provided that this section shall not apply to a unit under section 410 of the Act.

(b)(1) The designated representative may include, in the Acid Rain permit application for a unit under paragraph (a)(1) of this section, a substitution plan under which one or more units under paragraph (a)(2) of this section are designated as substitution units, provided that:

(i) Any unit under paragraph (a)(2) of this section has the same owner or operator (which includes, for purposes of this section, a designated representative) as the unit under paragraph (a)(1) of this section; and

(ii) In accordance with paragraph (c)(3) of this section, the emissions reductions achieved under the plan shall be the same or greater than would have been achieved by all units governed by the plan without such plan.

(2) The designated representative of each source with a unit designated as a substitution unit in any plan submitted under paragraph (b)(1) of this section shall incorporate in the permit application each such plan.

(3) The designated representative may submit a substitution plan not later than 90 days, or a notification to activate a conditionally approved plan in accordance with § 72.40(c) not later than 60 days, before the allowance transfer deadline applicable to the first year for which the plan is to take effect.

(c) *Contents of a Substitution Plan.* A complete substitution plan shall include the following elements in a format prescribed by the Administrator:

(1) Identification of each unit under paragraph (a)(1) of this section and each substitution unit to be governed by the substitution plan. A unit shall not be a substitution unit in more than one substitution plan.

(2) Except where the designated representative requests conditional approval of the plan, the first calendar year and, if known, the last calendar year in which the substitution plan is to be in effect. Unless the designated representative specifies an earlier calendar year, the last calendar year will be deemed to be 1999.

(3) Calculations to demonstrate that the total emissions reductions achieved under the substitution plan will be equal to or greater than the total emissions reductions that would have been achieved without the plan, as follows:

(i) for each substitution unit:

(A) the unit's baseline.

(B) the lesser of the unit's 1985 actual SO_2 emissions rate or 1985 allowable SO_2 emissions rate.

(C) the product of the baseline in paragraph (c)(3)(i)(A) of this section and the emissions rate in paragraph (c)(3)(i)(B) of this section, divided by 2000 lbs/ton.

(ii) The sum of the amounts in paragraph (c)(3)(i)(C) of this section for all substitution units to be governed by the plan. This sum is the total number of allowances available each year under the substitution plan.

(4) Distribution of substitution allowances.

(i) A statement that the allowances in paragraph (c)(3)(ii) of this section are not to be distributed to any units under paragraph (a)(1) of this section that are to be governed by the plan; or

(ii) A list showing any annual distribution of the allowances in paragraph (c)(3)(ii) of this section from a substitution unit to the unit under paragraph (a)(1) of this section to be governed by the plan. The total number of such allowances allocated among such units each year may not exceed the number calculated under paragraph (c)(3)(ii) of this section.

(5) The special provisions in paragraph (e) of this section.

(d) *Administrator's Action.* (1) If the Administrator approves a substitution plan, he or she will allocate allowances to the Allowance Tracking System accounts of the units under paragraph (a)(1) of this section and substitution units, as provided in the approved plan, upon issuance of an Acid Rain permit containing the plan, except that if the substitution plan is conditionally approved, the allowances will be allocated upon revision of the permit to activate the plan.

(2) In no event shall allowances be allocated, under paragraph (d)(1) of this section, for any year in excess of the amount in paragraph (c)(3)(ii) of this section, as adjusted by the Administrator in approving the plan.

(e) *Special Provisions.*

(1) *Emissions Limitations.* (i) Each substitution unit governed by an approved substitution plan shall become a Phase I unit from January 1 of the year for which the plan takes effect until January 1 of the year for which the plan is no longer in effect or is terminated.

(ii) Each unit under paragraph (a)(1) of this section, and each substitution unit, governed by an approved substitution plan shall be subject to the Acid Rain emissions limitations for nitrogen oxides in accordance with section 407 of the Act and regulations implementing section 407 of the Act.

(2) *Liability.* The owners and operators of a unit governed by an approved substitution plan shall be liable for any violation of the plan or this section at that unit or any other unit that is the first unit's substitution unit or for which the first unit is a substitution unit under the plan, including liability for fulfilling the obligations specified in part 77 of this chapter and section 411 of the Act.

(3) *Termination.* (i) A substitution plan shall be in effect only in Phase I for the calendar years specified in the plan or until the calendar year for which a termination of the plan takes effect, provided that no substitution plan shall be terminated, and no unit shall be de-designated as a substitution unit, before the end of Phase I if the substitution unit serves as a control unit under a Phase I extension plan.

(ii) To terminate a substitution plan for a given calendar year prior to the last year for which the plan was approved:

(A) A notification to terminate in accordance with § 72.40(d) shall be submitted no later than 60 days before the allowance transfer deadline applicable to the given year; and

(B) In the notification to terminate, the designated representative of each unit governed by the plan shall state that he or she surrenders for deduction from the unit's Allowance Tracking System account allowances equal in number to, and with the same or an earlier compliance use date as, those allocated under paragraph (d)(1) of this section for all calendar years for which the plan is to be terminated. The designated representative may identify the serial numbers of the allowances to be deducted. In the absence of such identification, allowances will be deducted on a first-in, first-out basis under § 73.35(c)(2) of this chapter.

(iii) If the requirements of paragraph (e)(2)(ii) of this section are met and upon revision of the permit to terminate the substitution plan, the Administrator will deduct the allowances specified in paragraph (e)(2)(ii)(B) of this section. No substitution plan shall be terminated, and no unit shall be de-designated as a Phase I unit, unless such deduction is made.

(iv) Change of owner or operator. If there is a change in the owners or operators (which includes for purposes of this section the designated representative) of any unit governed by an approved substitution plan and the requirement under paragraph (b)(1)(i) of this section is no longer met, then the designated representatives of the units governed by the plan shall terminate the plan as of January 1 of the calendar year during which the change was made. if the designated representatives fail to terminate the plan, the Administrator, on his own motion, shall terminate the plan and deduct the allowances required to be surrendered under paragraph (e)(2)(ii) of this section.

§ 72.42 Phase I extension plans.

(a) *Applicability.* (1) This section shall apply to any designated representative seeking a 2-year extension of the deadline for meeting Phase I sulfur dioxide emissions reduction requirements at any of the following types of units by applying for allowances from the Phase I extension reserve:

(i) a unit listed in Table 1 of § 73.10(a) of this chapter;

(ii) a unit designated as a substitution unit in accordance with § 72.41; or

(iii) a unit designated as a compensating unit in accordance with § 72.43, except a compensating unit that is a new unit.

(2) A unit for which a Phase I extension is sought shall be either:

(i) A control unit, which shall be a unit under paragraph (a)(1) of this section and at which qualifying Phase I technology shall commence operation on or after November 15, 1990 but not later than December 31, 1996; or

(ii) A transfer unit, which shall be a unit under paragraph (a)(1)(i) of this section and whose Phase I emissions reduction obligation shall be transferred in whole or in part to one or more control units.

(3) A Phase I extension does not exempt the owner or operator for any unit governed by the Phase I extension plan from the requirement to comply with such unit's Acid Rain emissions limitations for sulfur dioxide.

(b) To apply for a Phase I extension:

(1) The designated representative for each source with a control unit may submit an early ranking application for a Phase I extension plan in person, beginning on the 40th day after publication of this subpart in the **Federal Register**, between the hours of 9 a.m. and 5 p.m. Eastern Standard Time at Acid Rain Division, Attn: Early Ranking, U.S. Environmental Protection Agency, 501 3rd Street NW., 4th floor, Washington, DC; or send the application by regular mail, certified mail, or overnight delivery service to Acid Rain Division, Attn: Early Ranking, U.S. Environmental Protection Agency, 6204 J, 401 M Street, SW., Washington, DC 20460.

(2) By February 15, 1993: (i) The designated representative for each source with a control unit shall submit a Phase I extension plan as a part of the Acid Rain permit application for the source, and

(ii) The designated representative for each source with a unit designated as a transfer unit in any plan submitted under paragraph (b)(2)(i) of this section shall incorporate in the Acid Rain permit application each such plan.

(c) *Contents of Early Ranking Application.* A complete early ranking application shall include the following elements in a format prescribed by the Administrator:

(1) Identification of each control unit. All control units in an application must be located at the same source. If the control unit is not a unit under paragraph (a)(1)(i) of this section, a substitution plan or a reduced utilization plan governing the unit shall be submitted by the deadline for submitting a Phase I permit application.

(2) Identification of each transfer unit. A unit shall not be a transfer unit in more than one early ranking application.

(3) For each control and transfer unit, the total tonnage of sulfur dioxide emitted in 1988 plus the total tonnage of sulfur dioxide emitted in 1989, divided by 2. The 1988 and 1989 tonnage figures shall be consistent with the data filed on EIA form 767 for those years and the conversion methodology specified in Appendix B of this part.

(4) For each control and transfer unit:

(i) The projected annual utilization (in mmBtu) for 1995 multiplied by the projected uncontrolled emissions rate (i.e., the emissions rate in the absence of title IV of the Act) for 1995 (in lbs/mmBtu), divided by 2000 lbs/ton.

(ii) The projected annual utilization (in mmBtu) for 1996 multiplied by the projected uncontrolled emissions rate (i.e., the emissions rate in the absence of title IV of the Act) for 1996 (in lbs/mmBtu), divided by 2000 lbs/ton.

(5) For each control and transfer unit, the number of Phase I extension reserve allowances requested for 1995 and for 1996, not to exceed the difference between:

(i) The lesser of the value for the unit under paragraph (c)(3) of this section and the value for the unit for that year under paragraph (c)(4) of this section, and

(ii) Each unit's baseline multiplied by 2.5 lb/mmBtu, divided by 2000 lbs/ton.

(6) Documentation that the annual emissions reduction obligations transferred from all transfer units to all control units do not exceed those authorized under this section, as follows:

(i) For each control unit, the difference, calculated separately for 1995 and 1996, between:

(A) The control unit's allowance allocation in Table 1 of § 73.10(2) of this chapter, the allocation under § 72.41 if the control unit is a substitution unit, or the allocation under § 72.43 if the control unit is a compensating unit; and

(B) The projected emissions resulting from 90% control after installing the qualifying Phase I technology, i.e., 10% of the projected uncontrolled emissions for the control unit for the year in accordance with paragraph (c)(4) of this section.

(ii) The sum, by year, of the results under paragraph (c)(6)(i) of this section for all control units.

(iii) The sum, by year, of Phase I extension reserve allowances requested for all transfer units.

(iv) A showing that, for each year, the sum under paragraph (c)(6)(ii) of this section is greater than or equal to the sum under paragraph (c)(6)(iii) of this section.

(7) For each control and transfer unit, the projected controlled emissions for 1997, for 1998, and for 1999 calculated as follows:

Projected annual utilization (in mmBtu) multiplied by the projected controlled emission rate (in lbs/mmBtu), divided by 2000 lbs/ton.[1]

(8) For each control unit, the number of Phase I extension reserve allowances requested for 1997, for 1998, and for 1999, calculated as follows:

The unit's baseline multiplied by 1.2 lbs/mmBtu and divided by 2000 lbs/ton, minus the projected controlled emissions (in tons/yr) under paragraph (c)(7) of this section for the given year.

(9) The total of Phase I extension reserve allowances requested for all units in the plan for 1995 through 1999.

(10) With regard to each executed contract for the design engineering and construction of qualifying Phase I technology at each control unit governed by the early ranking application, either a copy of the contract or a certification that the contract is on site at the source and will be submitted to the Administrator upon written request. The contract or contracts may be contingent on the Administrator approving the Phase I extension plan.

(11) For each contract for which a certification is submitted under paragraph (c)(10) of this section, a binding letter agreement, signed and dated by each party and specifying:

(i) The type of qualifying Phase I technology to which the contract applies;

(ii) The parties to the contract;

(iii) The date each party executed the contracts;

(iv) The unit to which the contract applies;

(v) A brief list identifying each provision of the contract;

(vi) Any dates to which the parties agree, including construction completion date; and

(vii) The total dollar amount of the contract.

(12) A vendor certification of the sulfur dioxide removal efficiency guaranteed to be achievable by the qualifying Phase I technology for the type and range of fossil fuels (before any treatment prior to combustion) that will be used at the control unit; *provided* that a vendor certification shall not be a defense against a control unit's failure to achieve 90% control of sulfur dioxide.

(13) The date (not later than December 31, 1996) on which the owners and operators plan to commence operation of the qualifying Phase I technology.

(14) The special provisions of paragraph (f) of this section.

(d) *Contents of Phase I Extension Plan.* A complete Phase I extension plan shall include the following elements in a format prescribed by the Administrator:

(1) Identification of each unit in the plan.

(2)(i) A statement that the elements in the Phase I extension plan are identical to those in the previously submitted early ranking application for the plan and that such early ranking application is incorporated by reference; or

(ii) All elements that are different from those in the previously submitted early ranking application for the plan and a statement that the early ranking application is incorporated by reference as modified by the newly submitted elements; *provided* that the Phase I extension plan shall not add any new control units or increase the total Phase I extension allowances requested; or

(iii) All elements required for an early ranking application and a statement that no early ranking application for the plan was submitted.

(e) *Administrator's Action.* (1) *Early ranking applications.* (i) The Administrator may approve in whole or in part or with changes or conditions, as appropriate, or disapprove an early ranking application.

(ii) The Administrator will act on each early ranking application in the order of receipt.

(ii) The Administrator will determine the order of receipt by the following procedures:

(A) Hand-delivered submissions and mailed submissions will be deemed to have been received on the date they are received by the Administrator; *provided* that all submissions received by the Administrator prior to the 40th day after publication of this subpart in the **Federal Register** will be deemed received on the 40th day.

(B) All submissions received by the Administrator on the same day will be deemed to have been received simultaneously.

(C) The order of receipt of all submissions received simultaneously will be determined by a public lottery if allocation of Phase I extension reserve allowances to each of the simultaneous submissions would result in oversubscription of the Phase I extension reserve.

(iv) Based on the allowances requested under paragraph (c)(9) of this section, as adjusted by the Administrator in approving the early ranking application, the Administrator will award Phase I extension reserve allowances for each complete early ranking application to the extent that allowances that have not been awarded remain in the Phase I extension reserve at the time the Administrator acts on the application. The allowances will be awarded in accordance with the procedures set forth the allocation of reserve allowances in paragraph (e)(3) of this section.

(v) The Administrator's action on an early ranking application shall be conditional on the Administrator's action on a timely and complete Acid Rain permit application that includes a complete Phase I extension plan and, where the plan includes a unit under paragraph (a)(1) (ii) and (iii) of this section, a complete substitution plan or reduced utilization plan, as appropriate.

(vi) Not later than 15 days after receipt of each early ranking application, the Administrator will notify, in writing, the designated representative of each application of the date that the early ranking application was received and one of the following:

(A) The award of allowances if the application was complete and the Phase I extension reserve as not oversubscribed;

(B) A determination that the application was incomplete and is disapproved; or

(C) If the Phase I extension reserve was oversubscribed, a list of the applications received on that date, the number of Phase I extension allowances requested in each application, and the

[1] In the case of a transfer unit that shares a common stack with a unit not listed in Table 1 of § 73.10(a) of this chapter and whose emissions of sulfur dioxide are not monitored separately or apportioned in accordance with part 75 of this chapter, the projected figures for the transfer unit under paragraph (c)(7) of this section must be for the units combined.

date, time, and location of a lottery to determine the order of receipt for all applications received on that date.

(vii) The date of a lottery for all applications received on a given day will not be earlier than 15 days after the Administrator notifies each designated representative whose applications were received on that date.

(viii) Any early ranking application may be withdrawn from the lottery if a letter signed by the designated representative of each unit governed by the application and requesting withdrawal is received by the Administrator before the lottery takes place.

(2) *Phase I extension plans.* (i) The Administrator will act on each Phase I extension plan in the order that the early ranking application for that plan was received or, if no early ranking application was received, in the order that the Phase I extension plan was received, as determined under paragraph (e)(1)(iii) of this section.

(ii) Based on the allowances requested under paragraph (c)(9) of this section, as adjusted under paragraph (d) of this section and by the Administrator in approving the Phase I extension plan, the Administrator will allocate Phase I extension reserve allowances to the Allowance Tracking System account of each control and transfer unit upon issuance of an Acid Rain permit containing the approved Phase I extension plan. The allowances will be allocated using the procedures set forth in paragraph (e)(3) of this section.

(iii) The Administrator will not approve a Phase I extension plan, even if it meets the requirements of this section, unless unallocated allowances remain in the Phase I extension reserve at the time the Administrator acts on the plan.

(3) *Allowance Allocations.* In addition to any allowances allocated in accordance with Table 1 of § 73.10(a) of this chapter and other approved compliance options, the Administrator will allocate Phase I extension reserve allowances to each eligible unit in a Phase I extension plan in the following order.

(i) For 1995, to each control unit in the order in which it is listed in the plan and then to each transfer unit in the order in which it is listed.

(ii) For 1996, to each control unit in the order in which it is listed in the plan and then to each transfer unit in the order in which it is listed.

(iii) For 1997, to each control unit in the order in which it is listed in the plan, then likewise for 1998, and then likewise for 1999.

(iv) The Administrator will allocate any Phase I extension reserve allowances returned to the Administrator to the next Phase I extension plan, in the rank order established under paragraph (e)(1)(iii) of this section, that continues to meet the requirements of this section and this part.

(f) *Special Provisions.* (1) *Emissions Limitations.*

(i) *Sulfur Dioxide.*

(A) If a control or transfer unit governed by an approved Phase I extension plan emits in 1997, 1998, or 1999 sulfur dioxide in excess of the projected controlled emissions for the unit specified for the year under paragraph (c)(7) of this section as adjusted under paragraph (d) of this section and by the Administrator in approving the Phase I extension plan, the Administrator will deduct allowances equal to such exceedence from the unit's annual allowance allocation in the following calendar year.[2]

(B) Failure to demonstrate at least a 90% reduction of sulfur dioxide in 1997, 1998, or 1999 in accordance with part 75 of this chapter at a control unit governed by an approved Phase I extension plan shall be a violation of this section. In the event of any such violation, in addition to any other liability under the Act, the Administrator will deduct allowances from the control unit's compliance subaccount for the year of the violation. The deduction will be calculated as follows:

Allowances deducted=(1−(percent reduction achieved÷90%))×Phase I extension reserve allowances received

where:

"Percent reduction achieved" is the percent reduction determined in accordance with part 75 of this chapter.

"Phase I extension reserve allowances received" is the number of Phase I extension reserve allowances allocated for the year under paragraph (e)(2)(ii) of this section.

(ii) *Nitrogen Oxides.*

(A) Beginning on January 1, 1997, each control and transfer unit shall be subject to the Acid Rain emissions limitations for nitrogen oxides.

(B) Notwithstanding paragraph (f)(1)(ii)(A) of this section, a transfer unit shall be subject to the Acid Rain emissions limitations for nitrogen oxides, under section 407 of the Act and regulations implementing section 407 of the Act, beginning on January 1 of any year for which a transfer unit is allocated fewer Phase I extension reserve allowances than the maximum amount that the designated representative could have requested in accordance with paragraph (c)(5) of this section (as adjusted under paragraph (d) of this section and by the Administrator in approving the Phase I extension plan) unless the transfer unit is the last unit allocated Phase I extension reserve allowances under the plan.

(2) *Monitoring Requirements.* Each control unit shall comply with the special monitoring requirements for Phase I extension plans in accordance with part 75 of this chapter.

(3) *Reporting Requirements.* Each control and transfer unit shall comply with the special reporting requirements for Phase I extension plans in accordance with § 72.93.

(4) *Liability.* The owners and operators of a control or transfer unit governed by an approved Phase I extension plan shall be liable for any violation of the plan or this section at that or any other unit governed by the plan, including liability for fulfilling the obligations specified in part 77 of this chapter and section 411 of the Act.

(5) *Termination.* A Phase I extension plan shall be in effect only in Phase I, and no Phase I extension plan shall be terminated before the end of Phase I. The designated representative may, however, withdraw a Phase I extension plan at any time prior to issuance of the Phase I Acid Rain permit that includes the Phase I extension plan, as adjusted.

§ 72.43 Phase I reduced utilization plans.

(a) *Applicability.* This section shall apply to:

(1) The designated representative of any Phase I unit, including:

(i) Any unit listed in Table 1 of § 73.10(a) of this chapter; and

(ii) Any other unit that becomes a Phase I unit (including any unit designated as a compensating unit under this section or a substitution unit under § 72.41).

(b)(1) The designated representative shall include in the Acid Rain permit application for a Phase I unit a reduced utilization plan, meeting the requirements of this section, when the owners and operators of the unit plan to:

(i) Reduce utilization of the unit below the unit's baseline to achieve compliance, in whole or in part, with the unit's Phase I Acid Rain emissions limitations for sulfur dioxide; and

[2] In the case of a transfer unit that shares a common stack with a unit not listed in Table 1 of § 73.10(a) of this chapter where the units are not monitored separately or apportioned in accordance with part 75 of this chapter, the combined emissions of both units will be deemed to be the transfer unit's emissions for purposes of applying paragraph (f)(1)(i) of this section.

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(ii) Accomplish such reduced utilization through one or more of the following:

(A) Shifting generation of the unit to a compensating unit that would not otherwise be a Phase I unit or to a sulfur-free generator; or

(B) Using one or more energy conservation measures or improved unit efficiency measures.

(2)(i) Energy conservation measures shall be either demand-side measures implemented after December 31, 1987 in the residence or facility of a customer to whom the unit's utility system sells electricity or supply-side measures implemented after December 31, 1987 in facilities of the unit's utility system.

(ii) The utility system shall pay in whole or in part for the energy conservation measures either directly or, in the case of demand-side measures, through payment to another person who purchases the measure.

(iii) Energy conservation measures shall not include:

(A) Conservation programs that are exclusively informational or educational in nature;

(B) Load management measures that lead to reduction of electric energy demands during a utility's peak generating period, unless kilowatt hour savings can be verified under § 72.92; or

(C) Utilization of industrial waste gases, unless the designated representative certifies that there is no net increase in sulfur dioxide emissions from such utilization.

(iv) For calendar years when the unit's utility system is a subsidiary of a holding company and the unit's dispatch system is or includes all units that are interconnected and centrally dispatched and included in that holding company, then:

(A) Energy conservation measures shall be either demand-side measures implemented in the residence or facility of a customer to whom any utility system in the holding company sells electricity or supply-side measures implemented in facilities of any utility system in the holding company. Such utility system shall pay in whole or in part for the measures either directly or, in the case of demand-side measures, through payment to another person who purchases the measures.

(B) The limitations in paragraph (b)(2)(iii) of this section shall apply.

(3)(i) Improved unit efficiency measures shall be implemented in the unit. Such measures shall include supply-side measures listed in Appendix A, section 2.1 of part 73 of this chapter.

(ii) The utility system shall pay in whole or in part for the improved unit efficiency measures.

(4) The requirement to submit a reduced utilization plan shall apply in the event that the owners and operators of a Phase I unit decide, at any time during any Phase I calendar year, to rely on the method of compliance in paragraph (b)(1) of this section. In that case, the designated representative shall submit a reduced utilization plan not later than 90 days, or a notification to activate a conditionally approved plan in accordance with § 72.40(c) not later than 60 days, before the allowance transfer deadline applicable to the first year for which the plan is to take effect.

(5) The designated representative of each source with a unit designated as a compensating unit in any plan submitted under paragraphs (b) (1) or (4) of this section shall incorporate by reference in the permit application each such plan.

(c) *Contents of Reduced Utilization Plan.* A complete reduced utilization plan shall include the following elements in a format prescribed by the Administrator:

(1) Identification of each Phase I unit for which the owners and operators plan reduced utilization.

(2) Except where the designated representative requests conditional approval of the plan, the first calendar year and, if known, the last calendar year in which the reduced utilization plan is to be in effect. Unless the designated representative specifies an earlier calendar year, the last calendar year shall be deemed to be 1999.

(3) A statement whether the plan designates a compensating unit or relies on sulfur-free generation, any energy conservation measure, or any improved unit efficiency measure to account for any amount of reduced utilization.

(4) If the plan designates a compensating unit, or relies on sulfur-free generation, to account for any amount of reduced utilization:

(i) Identification of the compensating unit or sulfur-free generator.

(ii) For each compensating unit, the allowance allocation calculated as the compensating unit's baseline multiplied by the lesser of the compensating unit's 1985 actual SO_2 emissions rate or 1985 allowable SO_2 emissions rate, divided by 2000 lbs/ton. If the compensating unit is a new unit, it shall be deemed to have a baseline of zero and shall be allocated no allowances.

(iii) For each sulfur-free generator, identification of any other Phase I units that designate the same sulfur-free generator in another plan submitted under paragraphs (b) (1) or (4) of this section.

(iv) For each compensating unit or sulfur-free generator not in the dispatch system of the unit reducing utilization under the plan, the system directives or power purchase agreements or other contractual agreements governing the purchase of the electrical energy that is generated by the compensating unit or sulfur-free generator and on which the plan relies to accomplish reduced utilization.

(5) The special provisions in paragraph (f) of this section.

(d) *Administrator's Action.* If the Administrator approves the reduced utilization plan, he or she will allocate allowances, as provided in the approved plan, to the Allowance Tracking System accounts for any designated compensating unit upon issuance of an Acid Rain permit containing the plan, except that, if the plan is conditionally approved, the allowances will be allocated upon revision of the permit to activate the plan.

(e) *Failure to Submit a Plan.* (1) The designated representative of a Phase I unit will be deemed not to violate, during a Phase I calendar year, the requirement to submit a reduced utilization plan under paragraph (b) (1) or (4) of this section:

(i) If a unit's adjusted utilization under § 72.91(a) for the year is less than or equal to zero.

(ii) If the unit's adjusted utilization under § 72.91(a) for the year is greater than zero, to the extent that the designated representative complies with the allowance surrender and other requirements of § 72.91 and § 72.92 of this chapter and demonstrates one or more of the following:

(A) The adjusted utilization was offset by adjusted utilization at other Phase I units in the unit's dispatch system;

(B) The adjusted utilization was caused by a dispatch-system-wide sales decline; *provided* that to the extent the percentage of adjusted utilization exceeds the percentage of dispatch-system-wide sales decline, the presumption of this paragraph will be rebuttable and will not apply to the extent the Administrator finds, based on clear and convincing evidence, that the dispatch-system-wide sales decline was not the cause;

(C) The adjusted utilization was caused by a forced outage at the unit; or

(D) The adjusted utilization was caused by economic dispatching that reflected changes in the unit's dispatch order in the dispatch system resulting from increases in the relative cost of generation at the unit (including increases due to the installation of

pollution control equipment or other equipment changes at the unit, the value of allowances saved or avoided, or changes in fuel supply) or by an order of a utility regulatory authority, with rate jurisdiction over an owner of the unit, issued for the purpose of achieving such economic dispatching.

(2) If a Phase I unit's adjusted utilization under § 72.91(a) for a Phase I calendar year is greater than zero and to the extent the demonstrations (if any) made in accordance with paragraph (e)(1) of this section fail to account for any of the adjusted utilization, the Administrator shall determine on a case-by-case basis whether the designated representative of the unit violated the requirement to submit a reduced utilization plan under paragraph (b) (1) or (4) of this section.

(i) Where measures (e.g., the use of low-sulfur coal) were taken at the unit to reduce its emissions rate for the year to 2.5 lbs/mmBtu or less, this will be considered an indicator that the adjusted utilization was not due to a failure to plan.

(ii) Where the adjusted utilization was due to a permanent shutdown of the unit or the owners and operators of the unit did not pursue methods of compliance sufficient to ensure compliance without reduced utilization, this will be considered an indicator of a failure to plan.

(3) Notwithstanding any demonstration or determination under paragraphs (e) (1) and (2) of this section, the designated representative of any Phase I unit shall surrender allowances in accordance with subpart I of this part.

(f) *Special Provisions.* (1) *Emissions Limitations.* (i) Any compensating unit designated under an approved reduced utilization plan shall become a Phase I unit from January 1 of the calendar year in which the plan takes effect until January 1 of the year for which the plan is no longer in effect or is terminated, except that such unit shall not become subject to the Acid Rain emissions limitations for nitrogen oxides in Phase I under section 407 of the Act and regulations implementing section 407 of the Act.

(ii) The designated representative of any Phase I unit (including a unit governed by a reduced utilization plan relying on energy conservation, improved unit efficiency, sulfur-free generation, or a compensating unit) shall surrender allowances, and the Administrator will deduct or return allowances, in accordance with subpart I of this part.

(2) *Reporting Requirements.* The designated representative of any Phase I unit (including a unit governed by a reduced utilization plan relying on energy conservation, improved unit efficiency, sulfur-free generation, or a compensating unit) shall comply with the special reporting requirements under §§ 72.91 and 72.92.

(3) *Liability.* The owners and operators of a unit governed by an approved reduced utilization plan shall be liable for any violation of the plan or this section at that or any other unit governed by the plan, including liability for fulfilling the obligations specified in part 77 of this chapter and section 411 of the Act.

(4) *Termination.* (i) A reduced utilization plan shall be in effect only in Phase I for the calendar years specified in the plan or until the calendar year for which a termination of the plan takes effect; *provided* that no reduced utilization plan that designates a compensating unit that serves as a control unit under a Phase I extension plan shall be terminated, and no such unit shall be de-designated as a compensating unit, before the end of Phase I.

(ii) To terminate a reduced utilization plan for a given calendar year prior to its last year for which the plan was approved:

(A) A notification to terminate in accordance with § 72.40(d) shall be submitted no later than 60 days before the allowance transfer deadline applicable to the given year; and

(B) In the notification to terminate, the designated representative of any compensating unit governed by the plan shall state that he or she surrenders for deduction from the unit's Allowance Tracking System account allowances equal in number to, and with the same or an earlier compliance use date as, those allocated under paragraph (d) of this section to each compensating unit for the calendar years for which the plan is to be terminated. The designated representative may identify the serial numbers of the allowances to be deducted. In the absence of such identification, allowances will be deducted on a first-in, first-out basis under § 73.35(c)(2) of this chapter.

(iii) If the requirements of paragraph (f)(3)(ii) are met and upon revision of the permit to terminate the reduced utilization plan, the Administrator will deduct the allowances specified in paragraph (f)(3)(ii)(B) of this section. No reduced utilization plan shall be terminated, and no unit shall be de-designated as Phase I unit, unless such deduction is made.

§ 72.44 Phase II repowering extensions.

(a) *Applicability.* (1) This section shall apply to the designated representative of:

(i) Any existing affected unit that is a coal-fired unit and has a 1985 actual SO_2 emissions rate equal to or greater than 1.2 lbs/mmBtu.

(ii) Any new unit that will be a replacement unit, as provided in paragraph (b)(2) of this section, for a unit meeting the requirements of paragraph (a)(1)(i) of this section.

(iii) Any oil and/or gas-fired unit that has been awarded clean coal technology demonstration funding as of January 1, 1991 by the Secretary of Energy.

(2) A repowering extension does not exempt the owner or operator for any unit governed by the repowering plan from the requirement to comply with such unit's Acid Rain emissions limitations for sulfur dioxide.

(b) The designated representative of any unit meeting the requirements of paragraph (a)(1)(i) of this section may include in the unit's Phase II Acid Rain permit application a repowering extension plan that includes a demonstration that:

(1) The unit will be repowered with a qualifying repowering technology in order to comply with the Phase II emissions limitations for sulfur dioxide; or

(2) The unit will be replaced by a new utility unit that has the same designated representative and that is located at a different site using a qualified repowering technology and the existing unit will be permanently retired from service on or before the date on which the new utility unit commences commercial operation.

(c) In order to apply for a repowering extension, the designated representative of a unit under paragraph (a) of this section shall:

(1) Submit to the permitting authority, by January 1, 1996, a complete repowering extension plan;

(2) Submit to the Administrator, before June 1, 1997, a complete petition for approval of repowering technology; and

(3) If the repowering extension plan is submitted for conditional approval, submit by December 31, 1997, a notification to activate the plan in accordance with § 72.40(c).

(d) *Contents and Review of Petition for Approval of Repowering Technology* (1) A complete petition for approval of repowering technology shall include the following elements, in a format prescribed by the Administrator, concerning the technology to be used in a plan under paragraph (b) of this section and may follow the repowering

technology demonstration protocol issued by the Administrator:

(i) Identification and description of the technology

(ii) Vendor certification of the guaranteed performance characteristics of the technology, including:

(A) Percent removal and emission rate of each pollutant being controlled;

(B) Overall generation efficiency; and

(C) Information on the state, chemical constituents, and quantities of solid waste generated (including information on land-use requirements for disposal) and on the availability of a market to which any by-products may be sold.

(iii) If the repowering technology is not listed in the definition of a qualified repowering technology in § 72.2, a vendor certification of the guaranteed performance characteristics that demonstrate that the technology meets the criteria specified for non-listed technologies in § 72.2; *provided* that the existence of such guarantee shall not be a defense against the failure to meet the criteria for non-listed technologies.

(2) The Administrator may request any supplemental information that is deemed necessary to review the petition for approval of repowering technology.

(3) The Administrator shall review the petition for approval of repowering technology and, in consultation with the Secretary of Energy, shall make a conditional determination of whether the technology described in the petition is a qualifying repowering technology.

(4) Based on the petition for approval of repowering technology and the information provided under paragraph (d)(2) of this section and § 72.94(a), the Administrator will make a final determination of whether the technology described in the petition is a qualifying repowering technology.

(e) *Contents of Repowering Extension Plan.* A complete repowering extension plan shall include the following elements in a format prescribed by the Administrator:

(1) Identification of the existing unit governed by the plan.

(2) The unit's federally-approved State Implementation Plan sulfur dioxide emissions limitation.

(3) The unit's 1995 actual SO_2 emissions rate.

(4) A schedule for construction, installation, and commencement of operation of the repowering technology approved or submitted for approval under paragraph (d) of this section, with dates for the following milestones:

(i) Completion of design engineering;

(ii) For a plan under paragraph (b)(1) of this section, removal of the existing unit from operation to install the qualified repowering technology;

(iii) Commencement of construction;

(iv) Completion of construction;

(v) Start-up testing;

(vi) For a plan under paragraph (b)(2) of this section, shutdown of the existing unit; and

(vii) Commencement of commercial operation of the repowering technology.

(5) For a plan under paragraph (b)(2) of this section:

(i) Identification of the new unit. A new unit shall not be included in more than one repowering extension plan.

(ii) Certification that the new unit will replace the existing unit.

(iii) Certification that the new unit has the same designated representative as the existing unit.

(iv) Certification that the existing unit will be permanently retired from service on or before the date the new unit commences commercial operation.

(6) The special provisions of paragraph (h) of this section.

(f) *Permitting Authority's Action on Repowering Extension Plan.* (1) The permitting authority shall not approve a repowering extension plan until the Administrator makes a conditional determination that the technology is a qualified repowering technology, unless the permitting authority conditionally approves such plan subject to the conditional determination of the Administrator.

(2) *Permit Issuance.* (i) Upon a conditional determination by the Administrator that the technology to be used in the repowering extension plan is a qualified repowering technology and a determination by the permitting authority that such plan meets the requirements of this section, the permitting authority shall issue the Acid Rain portion of the operating permit including:

(A) The approved repowering extension plan; and

(B) A schedule of compliance with enforceable milestones for construction, installation, and commencement of operation of the repowering technology and other requirements necessary to ensure that Phase II emission reduction requirements under this section will be met.

(ii) Except as otherwise provided in paragraph (g) of this section, the repowering extension shall be in effect starting January 1, 2000 and ending on the day before the date (specified in the Acid Rain permit) on which the existing unit will be removed from operation to install the qualifying repowering technology or will be permanently removed from service for replacement by a new unit with such technology; *provided* that the repowering extension shall end no later than December 31, 2003.

(iii) The portion of the operating permit specifying the repowering extension and other requirements under paragraph (f)(2)(i) of this section shall be subject to the Administrator's final determination, under paragraph (d)(4) of this section, that the technology to be used in the repowering extension plan is a qualifying repowering technology.

(3) *Allowance Allocation.* The Administrator will allocate allowances after issuance of an operating permit containing the repowering extension plan (or, if the plan is conditionally approved, after the revision of the Acid Rain permit under § 72.40(c)) and of the Administrator's final determination, under paragraph (d)(4) of this section, that the technology to be used in such plan is a qualifying repowering technology. Allowances will be allocated (including a pro rata allocation for any fraction of a year), as follows:

(i) To the existing unit under the approved plan, in accordance with section 409(c)(1) of the Act and part 73 of this chapter during the repowering extension under paragraph (f)(2)(ii) of this section; and

(ii) To the existing unit under the approved plan under paragraph (b)(1) of this section or, in lieu of any further allocations to the existing unit, to the new unit under the approved plan under paragraph (b)(2) of this section, in accordance with section 409(c) (2) through (4) of the Act and part 73 of this chapter after the repowering extension under paragraph (f)(2)(ii) of this section ends.

(g) *Failed Repowering Projects.* (1)(i) If, at any time before the end of the repowering extension under paragraph (f)(2)(ii) of this section, the designated representative of a unit governed by an approved repowering extension plan notifies the Administrator in writing that the owners and operators have decided to terminate efforts to properly design, construct, and test the repowering technology specified in the plan before completion of construction or start-up testing and demonstrates, in a proposed permit revision, to the Administrator's satisfaction that such efforts were in good faith, the unit shall not be deemed in violation of the Act because of such a termination. Where the preceding requirements of this paragraph are met, the permitting authority shall revise the operating permit in accordance with this paragraph and paragraph (g)(1)(ii) of this section and § 72.81 (permit modification).

(ii) Regardless of whether notification under paragraph (g)(1)(i) of this section

is given, the repowering extension will end beginning on the earlier of the date of such notification or the date by which the designated representative was required to give such notification under § 72.94(d). The Administrator will deduct allowances (including a pro rata deduction for any fraction of a year) from the Allowance Tracking System account of the existing unit to the extent necessary to ensure that, beginning the day after the extension ends, allowances are allocated in accordance with section 409(c) (2) through (4) of the Act and part 73 of this chapter.

(2) If the designated representative of a unit governed by an approved repowering extension plan demonstrates to the satisfaction of the Administrator, in a proposed permit revision, that the repowering technology specified in the plan was properly constructed and tested on such unit but was unable to achieve the emissions reduction limitations specified in the plan and that it is economically or technologically infeasible to modify the technology to achieve such limits, the unit shall not be deemed in violation of the Act because of such failure to achieve the emissions reduction limitations. In order to be properly constructed and tested, the repowering technology shall be constructed at least to the extent necessary for direct testing of the multiple combustion emissions (including sulfur dioxide and nitrogen oxides) from such unit while operating the technology at nameplate capacity. Where the preceding requirements of this paragraph are met:

(i) The permitting authority shall revise the Acid Rain portion of the operating permit in accordance with paragraphs (g)(2) (ii) and (iii) and § 72.81 (permit modification).

(ii) The existing unit may be retrofitted or repowered with another clean coal or other available control technology.

(iii) The repowering extension will continue in effect until the earlier of the date the existing unit commences commercial operation with such control technology or December 21, 2003. The Administrator will allocate or deduct allowances as necessary to ensure that allowances are allocated in accordance with paragraph (f)(3) of this section applying the repowering extension under this paragraph.

(h) *Special Provisions.* (1) *Emissions Limitations.* (i) *Sulfur Dioxide.* Allowances allocated during the repowering extension under paragraphs (f)(3) and (g)(2)(iii) of this section to a unit governed by an approved repowering extension plan shall not be transferred to any Allowance Tracking System account other than the unit accounts of other units at the same source as that unit.

(ii) *Nitrogen Oxides.* Any existing unit governed by an approved repowering extension plan shall be subject to the Acid Rain emissions limitations for nitrogen oxides in accordance with section 407 of the Act and regulations implementing section 407 of the Act beginning on the date that the unit is removed from operation to install the repowering technology or is permanently removed from service.

(iii) No existing unit governed by an approved repowering extension plan shall be eligible for a waiver under section 111(j) of the Act.

(iv) No new unit governed by an approved repowering extension plan shall receive an exemption from the requirements imposed under section 111 of the Act.

(2) *Reporting Requirements.* Each unit governed by an approved repowering extension plan shall comply with the special reporting requirements of § 72.94.

(3) *Liability.* (i) The owners and operators of a unit governed by an approved repowering plan shall be liable for any violation of the plan or this section at that or any other unit governed by the plan, including liability for fulfilling the obligations specified in part 77 of this chapter an section 411 of the Act.

(ii) The units governed by the plan under paragraph (b)(2) of this section shall continue to have a common designated representative until the existing unit is permanently retired under the plan.

(4) *Terminations.* Except as provided in paragraph (g) of this section, a repowering extension plan shall not be terminated after December 31, 1999.

Subpart E—Acid Rain Permit Contents

§ 72.50 General.

(a) Each Acid Rain permit (including any draft or proposed Acid Rain permit) will contain the following elements in a format prescribed by the Administrator:

(1) All elements required for a complete Acid Rain permit application under § 72.31 of this part, as approved or adjusted by the permitting authority;

(2) The applicable Acid Rain emissions limitation for sulfur dioxide; and

(3) The applicable Acid Rain emissions limitation for nitrogen oxides.

(b) Each Acid Rain permit is deemed to incorporate the definitions of terms under § 72.2 of this part.

§ 72.51 Permit shield.

Each affected unit operated in accordance with the Acid Rain permit that governs the unit and that was issued in compliance with title IV of the Act, as provided in this part and parts 73, 75, 77, and 78 of this chapter, and the regulations implementing section 407 of the Act, shall be deemed to be operating in compliance with the Acid Rain Program, except as provided in § 72.9(g)(6) of this part.

Subpart F—Federal Acid Rain Permit Issuance Procedures

§ 72.60 General.

(a) *Scope.* This subpart contains the procedures for federal issuance of Acid Rain permits for Phase I of the Acid Rain Program and Phase II for sources in States or geographic areas where the Administrator is the permitting authority as provided under regulations implementing title V of the Act. The procedures in this subpart do not apply to the issuance of Acid Rain permits by State permitting authorities with operating permit programs approved under part 70 of this chapter, except as expressly provided in subpart G of this part.

(b) *Permit Decision Deadlines.* The Administrator will issue or deny an Acid Rain permit under § 72.69(a) within 6 months of receipt of a complete Acid Rain permit application submitted for a unit, in accordance with § 72.21, at the U.S. EPA Regional Office for the Region in which the source is located.

§ 72.61 Completeness.

(a) *Determination of Completeness.* The Administrator will determine whether the Acid Rain permit application is complete within 30 days of receipt by the U.S. EPA Regional Office for the Region in which the source is located. The permit application shall be deemed to be complete if the Administrator fails to notify the designated representative to the contrary within 30 days of receipt.

(b) *Supplemental Information.* (1) Regardless of whether the Acid Rain permit application is complete under paragraph (a) of this section, the Administrator may require submission of any additional information that the Administrator determines to be necessary in order to review the Acid Rain permit application and issue an Acid Rain permit.

(2)(i) The designated representative shall submit the information required under paragraph (b)(1) of this section within 30 days after he or she is notified of the requirement for supplemental information unless the Administrator

allows for additional time to collect and submit the information.

(ii) If the designated representative fails to submit the supplemental information within the required time period, the Administrator may disapprove that portion of the Acid Rain permit application for the review of which the information was necessary and may deny the source an Acid Rain permit.

§ 72.62 Draft permit.

(a) After the Administrator receives a complete Acid Rain permit application and any supplemental information, the Administrator will issue a draft permit that incorporates in whole, in part, or with changes or conditions as appropriate, the permit application or deny the source a draft permit.

(b) The draft permit will be based on the information submitted by the designated representative of the affected source and other relevant information.

(c) The Administrator will serve a copy of the draft permit and the statement of basis on the designated representative of the affected source.

(d) The Administrator will provide a 30-day period for public comment, and opportunity to request a public hearing, on the draft permit or denial of a draft permit, in accordance with the public notice required under § 72.65(a)(1)(i) of this part.

§ 72.63 Administrative record.

(a) *Contents of the Administrative Record.* The Administrator will prepare an administrative record for an Acid Rain permit or denial of an Acid Rain permit. The administrative record will contain:

(1) The permit application and any supporting or supplemental data submitted by the designated representative;

(2) The draft permit;

(3) The statement of basis;

(4) Copies of any documents cited in the statement of basis and any other documents relied on by the Administrator in issuing or denying the draft permit (including any records of discussions or conferences with owners, operators, or the designated representative of affected units at the source or interested persons regarding the draft permit), or, for any such documents that are readily available, a statement of their location;

(5) Copies of all written public comments submitted on the draft permit or denial of a draft permit;

(6) The record of any public hearing on the draft permit or denial of a draft permit;

(7) The Acid Rain permit; and

(8) Any response to public comments submitted on the draft permit or denial of a draft permit and copies of any documents cited in the response and any other documents relied on by the Administrator to issue or deny the Acid Rain permit, or, for any such documents that are readily available, a statement of their location.

(b) [Reserved]

§ 72.64 Statement of basis.

(a) The statement of basis will briefly set forth significant factual, legal, and policy considerations on which the Administrator relied in issuing or denying the draft permit.

(b) The statement of basis will include:

(1) The reasons, and supporting authority, for approval or disapproval of any compliance options requested in the permit application, including references to applicable statutory or regulatory provisions and to the administrative record; and

(2) The name, address, and telephone, and facsimile numbers of the EPA office processing the issuance or denial of the draft permit.

§ 72.65 Public notice of opportunities of public comment.

(a)(1) The Administrator will give public notice of the following:

(i) The draft permit or denial of a draft permit and the opportunity for public review and comment and to request a public hearing; and

(ii) Date, time, location, and procedures for any scheduled hearing on the draft permit or denial of a draft permit.

(2) Any public notice given under this section may be for the issuance or denial of one or more draft permits.

(b) *Methods.* The Administrator will give the public notice required by this section by:

(1) Serving written notice on the following persons (except where such person has waived his or her right to receive such notice):

(i) The designated representative;

(ii) The State or local air pollution agency and any State or local utility regulatory authority with jurisdiction over the owners of any source or any unit covered by the Acid Rain permit application;

(iii) The State or local air pollution agency for any contiguous State whose air quality may be affected by, or for any State located within a 50-mile radius of, any source covered by the Acid Rain permit application; and

(iv) Any interested person.

(2) Giving notice by publication in the Federal Register and in a newspaper of general circulation in the area where the source covered by the Acid Rain permit application is located or in a State publication designed to give general public notice.

(c) *Contents.* All public notices issued under this section will contain the following information:

(1) Identification of the EPA office processing the issuance or denial of the draft permit for which the notice is being given.

(2) Identification of the designated representative for the affected source.

(3) Identification of each unit covered by the Acid Rain permit application and the draft permit.

(4) Any compliance options proposed for approval in the draft permit or for disapproval and the total allowances (including any under the compliance options) allocated to each unit if the Acid Rain permit application is approved.

(5) The address and office hours of a public location where the administrative record is available for public inspection and a statement that all information submitted by the designated representative and not protected as confidential under section 114(c) of the Act is available for public inspection as part of the administrative record.

(6) For public notice under paragraph (a)(1)(i) of this section, a brief description of the public comment procedures, including:

(i) A 30-day period for public comment beginning the date of publication of the notice or, in the case of an extension or reopening of the public comment period, such period as the Administrator deems appropriate;

(ii) The address where public comments should be sent;

(iii) Required formats and contents for public comment;

(iv) An opportunity to request a public hearing to occur not earlier than 15 days after public notice is given and the location, date, time, and procedures of any scheduled public hearing; and

(v) Any other means by which the public may participate.

(d) *Extensions and Reopenings of the Public Comment Period.* On the Administrator's own motion or on the request of any person, the Administrator may, at his or her discretion, extend or reopen the public comment period where he or she finds that doing so will contribute to the decision-making process by clarifying one or more significant issues affecting the draft permit or denial of a draft permit. Notice of any such extension or reopening shall be given under paragraph (a)(1)(i) of this section.

§ 72.66 Public comments.

(a) *General.* During the public comment period, any person may submit written comments on the draft permit or the denial of a draft permit.

(b) *Form.* (1) Comments shall be submitted in duplicate.

(2) The submission shall clearly indicate the draft permit issuance or denial to which the comments apply.

(3) The submission shall clearly indicate the name of the person commenting, his or her interest in the matter, and his or her affiliation, if any, to owners and operators of any unit covered by the Acid Rain permit application.

(c) *Contents.* Timely comments on any aspect of the draft permit or denial or a draft permit will be considered unless they concern:

(1) Any standard requirement under § 72.9;

(2) Issues that are not relevant, such as:

(i) The environmental effects of acid rain, acid deposition, sulfur dioxide, or nitrogen oxides generally; and

(ii) Permit issuance procedures, or actions on other permit applications, that are not relevant to the draft permit issuance or denial in question.

(d) Persons who do not wish to raise issues concerning the issuance or denial of the draft permit, but who wish to be notified of any subsequent actions concerning such matter may so indicate in writing during the public comment period or at any other time. The Administrator will place their names on a list of interested persons.

§ 72.67 Opportunity for public hearing.

(a) During the public comment period, any person may request a public hearing. A request for a public hearing shall be made in writing and shall state the issues proposed to be raised in the hearing.

(b) On the Administrator's own motion or on the request of any person, the Administrator may, at his or her discretion, hold a pubic hearing whenever the Administrator finds that such a hearing will contribute to the decision-making process by clarifying one or more significant issues affecting the draft permit or denial of a draft permit. Public hearings will not be held on issues under § 72.66(c) (1) and (2).

(c) During a public hearing under this section, any person may submit oral or written comments concerning the draft permit or denial of a draft permit. The Administrator may set reasonable limits on the time allowed for oral statements and will require the submission of a written summary of each oral statement.

(d) The Administrator will assure that a record is made of the hearing.

§ 72.68 Response to comments.

(a) The Administrator will consider comments on the draft permit or denial of a draft permit that are received during the public comment period and any public hearing. The Administrator is not required to consider comments otherwise received.

(b) In issuing or denying an Acid Rain permit, the Administrator will:

(1) Identify any permit provision or portion of the statement of basis that has been changed and the reasons for the change; and

(2) Briefly describe and respond to relevant comments under paragraph (a) of this section.

§ 72.69 Issuance and effective date of Acid Rain permits.

(a) After the close of the public comment period, the Administrator will issue or deny an Acid Rain permit. The Administrator will serve a copy of any Acid Rain permit and the response to comments on the designated representative for the source covered by the issuance or denial and serve written notice of the issuance or denial on any persons who are entitled to written notice under § 72.65(b)(1) (ii), (iii), and (iv) of this part. The Administrator will also give notice in the **Federal Register**.

(b)(1) The term of every Acid Rain permit shall be 5 years commencing on its effective date.

(2) Every Acid Rain permit for Phase I shall take effect on January 1, 1995.

Subpart G—Acid Rain Phase II Implementation

§ 72.70 Relationship to title V operating permit program.

(a) *Scope.* This subpart sets forth criteria for approval of State operating permit programs and the requirements with which State permitting authorities with approved programs shall comply, and with which the Administrator will comply in the absence of an approved State program, to issue Phase II Acid Rain permits.

(b) *Relationship to Operating Permit Program.* Each State permitting authority with an affected source shall act in accordance with this part and part 70, and part 78 of this chapter for the purpose of incorporating Acid Rain Program requirements into each affected source's operating permit or for issuing written exemptions under §§ 72.7 and 72.8. To the extent that any requirements of this part and part 78 of this chapter are inconsistent with the requirements of part 70 of this chapter, this part and part 78 of this chapter shall take precedence and shall govern the issuance, denial, revision, reopening, renewal, and appeal of the Acid Rain portion of an operating permit. For purposes of applying this subpart, the provisions of this subpart and of part 70 applicable to Acid Rain permit applications and draft, proposed, and final Acid Rain permits shall also apply to petitions for exemption and draft, proposed, and final written exemptions respectively for new or retired units to the extent consistent with §§ 72.7 and 72.8 of this chapter.

§ 72.71 Approval of state programs—general.

(a) Each State shall submit, to the Administrator for approval, a proposed operating permit program meeting the requirements of this subpart and part 70 of this chapter.

(b) The Administrator will act on State submissions of an operating permit program in accordance with the schedule and procedures set forth in § 70.4(e) of this chapter. The Administrator will approve State programs that conform to the applicable requirements of this subpart and § 70.4(b) of this chapter.

(c)(1) After approval of a State operating permit program, the Administrator will suspend, in accordance with this part and part 70 of this chapter, federal issuance of Acid Rain permits for Phase II for sources and units subject to the State program.

(2) The Administrator will issue all Acid Rain permits for Phase I. However, the Administrator reserves the right to delegate the remaining administration of Acid Rain permits for Phase I to approved State operating permit programs.

§ 72.72 State permit program approval criteria.

A State operating permit program shall meet the following criteria concerning the Acid Rain Program. Any aspect of the State program or any implementation of the State program that is inconsistent with these criteria shall be grounds for disapproval or withdrawal of approval of the State program by the Administrator:

(a) *Non-Interference with Acid Rain Program.* The State operating permit program shall not include or implement any measures that would interfere with the Acid Rain Program. In particular, the State program shall not restrict or interfere with allowance trading and shall not interfere with the Administrator's decision on an offset plan. Aspects and implementation of the State program that would constitute interference with the Acid Rain

Program, and are thus prohibited, include but are not limited to:

(1) Prohibitions, inconsistent with the Acid Rain Program, on the acquisition or transfer of allowances by an affected unit under the jurisdiction of the State permitting authority;

(2) Restrictions, inconsistent with the Acid Rain Program, on an affected unit's ability to sell or otherwise obligate its allowances;

(3) Requirements that an affected unit maintain a balance of allowances in excess of the level determined to be prudent by any utility regulatory authority with jurisdiction over the owners of the affected unit;

(4) Failing to notify the Administrator of any State administrative or judicial appeals of, or decisions covering, Acid Rain permit provisions that might affect Acid Rain Program requirements;

(5) Issuing an order, inconsistent with the Acid Rain Program, interpreting Acid Rain Program requirements as not applicable to an affected source or an affected unit in whole or in part or otherwise adjusting the requirements;

(6) Withholding approval of any compliance option that meets the requirements of the Acid Rain Program; or

(7) Any other aspect of implementation that the Administrator determines would hinder the operation of the Acid Rain Program.

(b) The State operating permit program shall require the following:

(1) *Acid Rain Permit Issuance.* Issuance or denial of Acid Rain permits shall follow the procedures under this part and part 70 of this chapter including:

(i) *Permit Application.* (A) *Requirement to Comply.* The owners and operators and the designated representative for each affected source under jurisdiction of the State permitting authority shall be required to comply with subparts B, C, and D of this part.

(B) *Effect of an Acid Rain Permit Application.* A complete Acid Rain permit application shall be binding on the owners and operators and the designated representative of the affected source, all affected units at the source, and any other unit governed by the permit application and shall be enforceable as an Acid Rain permit, from the date of submission of the permit application until the issuance or denial of the Acid Rain permit under paragraph (b)(1)(vii) of this section.

(C) *Submission to the Administrator.* The State permitting authority shall submit a written notice of application completeness to the Administrator within 10 working days following a determination by the State permitting authority that the Acid Rain permit application is complete.

(ii) *Draft Permit.* (A) The State permitting authority shall prepare the draft Acid Rain permit in accordance with subpart E of this part or deny a draft Acid Rain permit.

(B) The State permitting authority shall prepare a statement of basis in accordance with the requirements for a statement of basis under § 72.64 of this part.

(iii) *Notice to Administrator.* The State permitting authority shall submit a copy of the draft Acid Rain permit and the statement of basis to the Administrator and all other relevant portions of the operating permit that may affect the draft Acid Rain permit. This submission requirement will not be waived.

(iv) *Public Notice and Comment Period.* Public notice of the issuance or denial of the draft Acid Rain permit and the opportunity to comment and request a public hearing shall be given by publication in a newspaper of general circulation in the area where the source is located or in a State publication designed to give general public notice. A notice shall be served on those persons required to receive notice under §§ 70.7(h) and 70.8(b) of this chapter.

(v) *Proposed Permit.* Following the public notice and comment period on a draft Acid Rain permit, the permitting authority shall incorporate all changes necessary and issue a proposed Acid Rain permit in accordance with subpart E of this part or deny a proposed Acid Rain permit.

(vi) *Submittal to Administrator.* (A) The State permitting authority shall submit the proposed Acid Rain permit or denial of a proposed Acid Rain permit to the Administrator in accordance with § 70.8(a) of this chapter, the provisions of which shall be treated as applying to the issuance or denial of a proposed Acid Rain permit.

(B) The Administrator will review the proposed Acid Rain permit or denial of a proposed Acid Rain permit in accordance with § 70.8(c) of this chapter, the provisions of which shall be treated as applying to the issuance or denial of a proposed Acid Rain permit.

(vii) *Acid Rain Permit Issuance.* Following the Administrator's review of the proposed Acid Rain permit or denial of a proposed Acid Rain permit, the State permitting authority shall or, under § 70.8(c) of this chapter (treated as applying to the issuance or denial of an Acid Rain permit), the Administrator will, incorporate any required changes and issue or deny the Acid Rain permit in accordance with subpart E of this part.

(viii) *Effective Date of Acid Rain Permit.* Each source's Acid Rain permit issued by a State permitting authority under this section shall be effective for a period of 5 years.

(ix) *New Owners.* An Acid Rain permit shall be binding on any new owner or operator or designated representative of any source or unit governed by the permit.

(x) Each Acid Rain permit (including a draft or proposed permit) shall contain all applicable Acid Rain requirements, shall be a complete and segregable portion of the operating permit, and shall not incorporate information contained in any other documents, other than documents that are readily available.

(xi) Invalidation of the Acid Rain portion of an operating permit shall not affect the continuing validity of the rest of the operating permit, nor shall invalidation of any other portion of the operating permit affect the continuing validity of the Acid Rain portion of the permit.

(xii) No Acid Rain permit (including a draft or proposed permit) shall be issued unless the Administrator has received a certificate of representation for the designated representative of the source in accordance with subpart B of this part.

(xiii) Notwithstanding any State law providing that a permit must be issued by default after a specified time, no Acid Rain permit shall be issued until the Administrator and other States have had an opportunity to review a proposed Acid Rain permit as provided in this section and § 70.8(b) of this chapter.

(xiv) Except as provided in § 72.73(b), the State permitting authority shall issue or deny an Acid Rain permit within 18 months of receiving a complete Acid Rain permit application submitted for an affected unit in accordance with § 72.21 or such lesser time approved under part 70 of this chapter.

(2) *Permit Revisions.* In acting on any Acid Rain permit revision, the State permitting authority shall follow the provisions and procedures set forth at subpart H of this part.

(3) *Permit Renewal.* The renewal of an Acid Rain permit for an affected source shall be subject to all the requirements of this subpart pertaining to the issuance of permits.

(4) *Acid Rain Program Forms.* In developing the Acid Rain portion of the operating permit, the permitting authority shall use the applicable forms or other formats prescribed by the

Administrator under the Acid Rain Program; *provided* that the Administrator may waive this requirement in whole or in part.

(5) *Acid Rain Appeal Procedures.* (i) Appeals of the Acid Rain portion of an operating permit issued by the State permitting authority that do not challenge or involve decisions or actions of the Administrator under this part, parts 73, 75, 77 and 78 of this chapter, and sections 407 and 410 of the Act and regulations implementing sections 407 and 410 shall be conducted according to procedures established by the State under § 70.4(b)(3)(x) of this chapter. Appeals of the Acid Rain portion of such a permit that challenge or involve such decisions or actions of the Administrator shall follow the procedures under part 78 of this chapter and section 307 of the Act. Such decisions or actions include, but are not limited to, allowance allocations, determinations concerning alternative monitoring systems, and determinations of whether a technology is a qualifying repowering technology.

(ii) Under no circumstances shall a State administrative appeal or judicial appeal of the Acid Rain portion of an operating permit be allowed more than 90 days (or such shorter period as provided by the applicable State appeals procedures) following respectively issuance of the Acid Rain portion that is subject to administrative appeal or issuance of the final agency action subject to judicial appeal.

(iii) The State permitting authority shall serve written notice on the Administrator of any State administrative or judicial appeal concerning as Acid Rain provision of any operating permit or denial of an Acid Rain portion of any operating permit within 30 days of the filing of the appeal.

(iv) Any State administrative permit appeals procedures shall ensure that the Administrator may intervene as a matter of right in any permit appeal involving an Acid Rain permit provision or denial of an Acid Rain permit.

(v) The State permitting authority shall serve written notice on the Administrator of any determination or order in a State administrative or judicial proceeding that interprets, modifies, voids, or otherwise relates to any portion of an Acid Rain permit. Following any such determination or order, the Administrator will have an opportunity to review and veto the Acid Rain permit or revoke the permit for cause in accordance with § 70.8 of this chapter.

(vi) A failure of the State permitting authority to issue an Acid Rain permit in accordance with § 72.73(b)(1)(i) shall be ground for filing an appeal.

(vii) No appeal concerning an Acid Rain requirement shall result in a stay of any provision of the Acid Rain permit for which a stay is barred under part 78 of this chapter.

(6) *Cooperation with Utility Regulatory Authority.* In considering any Acid Rain permit application, the State permitting authority shall ensure coordination with any utility regulatory authority with jurisdiction over the owners of the affected unit.

(7) *New Units and Retired Units Exemptions.* The State permitting authority shall act in accordance with §§ 72.7 and 72.8 on any petition for exemption of a new unit or retired unit from requirements of the Acid Rain Program.

(8) *State Permit Evaluation.* The State permitting authority shall periodically evaluate the extent to which its operating permit program meets the Acid Rain Program requirements and supports a cost-effective implementation of the program. The permit fee rates set by the State permitting authority shall be adequate to cover such evaluation.

§ 72.73 State issuance of Phase II permits.

(a) *State Permit Issuance.* (1) A State with an operating permit program that has been approved by the Administrator under this part and part 70 of this chapter on or before July 1, 1996, shall be responsible for issuing Acid Rain permits for Phase II to all affected sources in that State.

(2) A State that has obtained interim operating permit program approval (as defined in § 70.4(d) of this chapter) on or before July 1, 1996 shall be responsible for issuing Acid Rain permits for Phase II to all affected sources in that State.

(3) A State that has obtained partial operating permit program approval (as defined in § 70.4(c) of this chapter) on or before July 1, 1996 shall be responsible for issuing Acid Rain permits for Phase II to all affected sources in the geographic area to which the partial approval applies.

(4) The State permitting authority shall comply with the procedures for issuance, revision, renewal, and appeal of Acid Rain permits under this subpart.

(b) *Permit Issuance Deadline.* (1)(i) On or before December 31, 1997, a State with an approved operating permit program shall issue an Acid Rain permit for Phase II to each affected source in the geographic area for which the program is approved as set forth in paragraph (a) of this section; *provided* that the designated representative of the source submitted a timely and complete Acid Rain permit application in accordance with § 72.21 of this part and meets the requirements of this subpart and part 70 of this chapter.

(ii) Each Acid Rain permit issued in accordance with this section shall have a term of 5 years commencing on its effective date. Each Acid Rain permit issued in accordance with paragraph (b)(1)(i) of this section shall take effect by the later of January 1, 2000, or, where the permit governs a unit under § 72.6(a)(3) of this part, the deadline for monitor certification under part 75 of this chapter.

(2) *Nitrogen Oxides.* Not later than January 1, 1999, the State permitting authority shall reopen the Acid Rain permit to add the Acid Rain Program nitrogen oxides requirements; *provided* that the designated representative of the affected source submitted a timely and complete Acid Rain permit application for nitrogen oxides in accordance with § 72.21. Such reopening shall not affect the term of the Acid Rain portion of an operating permit.

§ 72.74 Federal issuance of Phase II permits.

(a) The Administrator will be responsible for issuing Acid Rain permits for Phase II for any affected sources in a geographic area (including a State) that does not have an operating permit program with full, partial, or interim approval by the Administrator on or before July 1, 1996, under part 70 of this chapter. After approval of a State program, the Administrator will suspend, in accordance with this part and part 70 of this chapter, federal issuance of such permits for sources in the geographic area covered by the State program and the State shall be responsible for issuing such permits in accordance with § 72.73 of this part.

(b) *Permit Issuance Deadline.* (1)(i) On or before January 1, 1998, the Administrator will issue an Acid Rain permit for Phase II governing Acid Rain Program sulfur dioxide requirements to each affected source in a geographic area that, on July 1, 1996, did not have an approved operating permit program under part 70 of this chapter; *provided* that the designated representative for the source submitted a timely and complete Acid Rain permit application in accordance with § 72.21 of this part. The failure by the Administrator to issue a permit in accordance with this paragraph shall be grounds for the filing of an appeal under part 78 of this chapter.

(ii) Notwithstanding paragraph (b)(1)(i) of this section, the Administrator may delegate to any State

that obtains operating permit program approval after July 1, 1996, responsibility for permit review and implementation.

(iii) Each Acid Rain permit issued in accordance with this section shall have a term of 5 years commencing on its effective date. Each Acid Rain permit issued in accordance with paragraph (b)(1) shall take effect by the later of January 1, 2000 or, where a permit governs a under § 72.6(a)(3) of this part, the deadline for monitor certification under part 75 of this chapter.

(2) *Nitrogen Oxides.* Not later than 6 months following submission by the designated representative of a timely and complete Acid Rain permit application for nitrogen oxides, the Administrator shall reopen the Acid Rain permit for Phase II to add the Acid Rain Program nitrogen oxides requirements. Such reopening shall not affect the term of the Acid Rain permit.

(c) *Permit Issuance.* The Administrator will issue Acid Rain permits for Phase II in accordance with subparts E and F of this part and the regulations implementing title V of the Act.

Subpart H—Permit Revisions

§ 72.80 General.

(a) This subpart shall govern revisions to any Acid Rain permit issued by the Administrator and to the Acid Rain portion of any operating permit issued by a State with an approved operating permit program under part 70 of this chapter.

(b) The provisions of this subpart shall supersede the operating permit revision procedures specified in part 70 of this chapter with regard to revision of any Acid Rain Program permit provision.

(c) A permit revision may be submitted for approval at any time. No permit revision shall affect the term of the Acid Rain permit to be revised. No permit revision shall excuse any violation of an Acid Rain Program requirement that occurred prior to the effective date of the revision.

(d) The terms of the Acid Rain permit shall apply while the permit revision is pending.

(e) Any determination or interpretation by a State (including a State court) modifying or voiding any Acid Rain permit provision shall be subject to review by the Administrator in accordance with § 70.8(c) of this chapter as applied to permit modifications, unless the determination or interpretation is an administrative amendment approved in accordance with § 72.83 of this part.

(f) The standard requirements of § 72.9 of this part shall not be modified or voided by a permit revision.

(g) Any permit revision involving incorporation of a compliance option that was not submitted for approval and comment during the permit issuance process, or involving a change in a compliance option that was previously submitted, shall meet the requirements for applying for such compliance option under subpart D and section 407 of the Act and regulations implementing section 407 of the Act.

(h) For permit revisions not described in §§ 72.81 and 72.82 of this part, the permitting authority may, in its discretion, determine which of these sections is applicable.

§ 72.81 Permit modifications.

(a) Permit revisions that shall follow the permit modification procedures are:

(1) Relaxation of an excess emission offset requirement after approval of the offset plan by the Administrator;

(2) Incorporation of a final nitrogen oxides alternative emission limitation following a demonstration period;

(3) Determinations concerning failed repowering projects under § 72.44(g)(1)(i) and (2) of this part.

(b) The following permit revisions shall follow, at the option of the designated representative submitting the permit revision, either the permit modification procedures or the fast-track modification procedures under § 72.82 of this part:

(1) Consistent with paragraph (a) of this section, incorporation of a compliance option that the designated representative did not submit for approval and comment during the permit issuance process; except that incorporation of a reduced utilization plan that was not submitted during the permit issuance process, that does not designate a compensating unit, and that meets the requirements of § 72.43 of this part, may use the administrative permit amendment procedures under § 72.83 of this part;

(2) Changes in a substitution plan or reduced utilization plan that result in the addition of a new substitution unit or a new compensating unit under the plan;

(3) Addition of a nitrogen oxides averaging plan to a permit; and

(4) Changes in a Phase I extension plan, repowering plan, nitrogen oxides averaging plan, or nitrogen oxides compliance deadline extension.

(c)(1) Permit modifications shall follow the permit issuance requirements of:

(i) Subparts E, F, and G of this part, where the Administrator is the permitting authority; or

(ii) Subpart G of this part and § 70.7(e)(4)(ii) of this chapter, where the State is the permitting authority.

(2) For purposes of applying paragraph (c)(1) of this section, a permit modification shall be treated as an Acid Rain permit application, to the extent consistent with this subpart.

§ 72.82 Fast-track modifications.

The following procedures shall apply to all fast-track modifications.

(a) The designated representative shall serve a copy of the fast-track modification on the Administrator, the permitting authority, and any person entitled to a written notice under § 72.65(b)(1) (ii), (iii) and (iv) of this part. Within 5 business days of serving such copies, the designated representative shall also give public notice by publication in a newspaper of general circulation in the area where the source is located or in a State publication designed to give general public notice.

(b) The public shall have a period of 30 days, commencing on the date of publication of the notice, to comment on the fast-track modification. Comments shall be submitted in writing to the permitting authority and to the designated representative.

(c) The designated representative shall submit the fast-track modification to the permitting authority on or before commencement of the public comment period.

(d) Within 30 days of the close of the public comment period, the permitting authority shall consider the fast-track modification and the comments received and approve, in whole or in part or with changes or conditions as appropriate, or disapprove the modification. A fast-track modification shall be effective immediately upon issuance, in accordance with § 70.7(a)(1)(v) of this chapter as applied to significant permit modifications.

§ 72.83 Administrative permit amendment.

(a) Acid Rain permit revisions that shall follow the administrative permit amendment procedures are:

(1) Activation of a compliance option conditionally approved by the permitting authority; *provided* that all requirements for activation under subpart D of this part are met;

(2) Changes in the designated representative or alternative designated representative; *provided* that a new certificate of representation is submitted;

(3) Correction of typographical errors;

(4) Changes in names, addresses, or telephone or facsimile numbers;

(5) Changes in the owners or operators; *provided* that a new

certificate of representation is submitted within 30 days;

(6) Termination of a compliance option in the permit; *provided* that all requirements for termination under subpart D of this part shall be met and this procedure shall not be used to terminate a repowering plan after December 31, 1999 or a Phase I extension plan;

(7) Changes in a substitution or reduced utilization plan that do not result in the addition of a new substitution unit or a new compensating unit under the plan;

(8) Changes in the date, specified in a unit's Acid Rain permit, of commencement of operation of qualifying Phase I technology, *provided* that they are in accordance with § 72.42 of this part;

(9) Changes in the date, specified in a new unit's Acid Rain permit, of commencement of operation or the deadline for monitor certification, *provided* that they are in accordance with § 72.9 of this part;

(10) The addition of or change in a nitrogen oxides alternative emissions limitation demonstration period, *provided* that the requirements of regulations implementing section 407 of the Act are met; and

(11) Incorporation of changes that the Administrator has determined to be similar to those in paragraphs (a) (1) through (10) of this section.

(b) Administrative amendments shall follow the procedures set forth at § 70.7(d)(3) of this chapter. Where the State is the permitting authority, the permitting authority shall submit the revised portion of the permit to the Administrator within 10 working days after the date of final action on the request for an administrative amendment.

§ 72.84 Automatic permit amendment.

The following permit revisions shall be deemed to amend automatically, and become a part of the affected unit's Acid Rain permit by operation of law without any further review:

(a) Upon recordation by the Administrator under part 73 of this chapter, all allowance allocations to, transfers to, and deductions from an affected unit's Allowance Tracking System account; and

(b) Incorporation of an offset plan that has been approved by the Administrator under part 77 of this chapter.

§ 72.85 Permit reopenings.

(a) As provided in § 70.7(f) of this chapter, the permitting authority shall reopen an Acid Rain permit for cause, including whenever additional requirements become applicable to any affected unit governed by the permit.

(b) In reopening an Acid Rain permit for cause, the permitting authority shall issue a draft permit changing the provisions, or adding the requirements, for which the reopening was necessary. The draft permit shall be subject to the requirements of subparts E, F, and G of this part.

(c) As provided in §§ 72.73(b)(2) and 72.74(b)(2) of this part, the permitting authority shall reopen an Acid Rain permit to incorporate nitrogen oxides requirements, consistent with section 407 of the Act and regulations implementing section 407 of the Act.

(d) Any reopening of an Acid Rain permit shall not affect the term of the permit.

Subpart I—Compliance Certification

§ 72.90 Annual compliance certification report.

(a) *Applicability and Deadline.* For each calendar year in which a unit is subject to the Acid Rain emissions limitations, the designated representative of the source at which the unit is located shall submit to the Administrator, within 60 days after the end of the calendar year, an annual compliance certification report for the unit.

(b) *Contents of Report.* The designated representative shall include in the annual compliance certification report under paragraph (a) of this section the following elements, in a format prescribed by the Administrator, concerning the unit and the calendar year covered by the report:

(1) Identification of the unit;

(2) For all Phase I units, the information in accordance with §§ 72.91(a) and 72.92(a) of this part;

(3) If the unit is governed by an approved Phase I extension plan, then the information in accordance with § 72.93 of this part;

(4) At the designated representative's option, the total number of allowances to be deducted for the year, using the formula in § 72.95 of this part, and the serial numbers of the allowances that are to be deducted;

(5) At the designated representative's option, for units that share a common stack and whose emissions of sulfur dioxide are not monitored separately or apportioned in accordance with part 75 of this chapter, the percentage of the total number of allowances under paragraph (b)(4) of this section for all such units that is to be deducted from each unit's compliance subaccount; and

(6) The compliance certification under paragraph (c) of this section.

(c) *Annual Compliance Certification.* In the annual compliance certification report under paragraph (a) of this section, the designated representative shall certify, based on reasonable inquiry of those persons with primary responsibility for operating the source and the affected units at the source in compliance with the Acid Rain Program, whether each affected unit for which the compliance certification is submitted was operated during the calendar year covered by the report in compliance with the requirements of the Acid Rain Program applicable to the unit, including:

(1) Whether the unit was operated in compliance with the applicable Acid Rain emissions limitations, including whether the unit held allowances, as of the allowance transfer deadline, in its compliance subaccount (after accounting for any allowance deductions under § 73.34(c) of this chapter) not less than the unit's total sulfur dioxide emissions during the calendar year covered by the annual report;

(2) Whether the monitoring plan that governs the unit has been maintained to reflect the actual operation and monitoring of the unit and contains all information necessary to attribute monitored emissions to the unit;

(3) Whether all the emissions from the unit, or a group of units (including the unit) using a common stack, were monitored or accounted for through the missing data procedures and reported in the quarterly monitoring reports;

(4) Whether the facts that form the basis for certification of each monitor at the unit or a group of units (including the unit) using a common stack or for using an Acid Rain Program excepted monitoring method or approved alternative monitoring method, if any, has changed; and

(5) If a change is required to be reported under paragraph (c)(4) of this section, specify the nature of the change, the reason for the change, when the change occurred, and how the unit's compliance status was determined subsequent to the change, including what method was used to determine emissions when a change mandated the need for monitor recertification.

§ 72.91 Phase I unit adjusted utilization.

(a) *Annual Compliance Certification Report.* The designated representative for each Phase I unit shall include in the annual compliance certification report the unit's adjusted utilization for the

calendar year covered by the report, calculated as follows:

Adjusted utilization-baseline–actual utilization–plan reductions+compensating generation provided to other units

where:

(1) "Baseline" is as defined in § 72.2 of this part.

(2) "Actual utilization" is the actual annual heat input (in mmBtu) of the unit for the calendar year determined in accordance with part 75 of this chapter.

(3) "Plan reductions" are the reductions in actual utilization, for the calendar year, below the baseline that are accounted for by an approved reduced utilization plan. The designated representative for the unit shall calculate the "plan reductions" (in mmBtu) using the following formula and converting all values in Kwh to mmBtu using the actual annual average heat rate (Btu/Kwh) of the unit (determined in accordance with part 75 of this chapter) before the employment of any improved unit efficiency measures under an approved plan:

Plan reductions=reduction from energy conservation+reduction from improved unit efficiency improvements+shifts to designated sulfur-free generators+shifts to designated compensating units

where:

(i) "Reduction from energy conservation" is a good faith estimate of the expected kilowatt hour savings during the calendar year from all conservation measures under the reduced utilization plan and the corresponding reduction in heat input (in mmBtu) resulting from those savings. The verified amount of such reduction shall be submitted in accordance with paragraph (b) of this section.

(ii) "Reduction from improved unit efficiency" is a good faith estimate of the expected improvement in heat rate during the calendar year and the corresponding reduction in heat input (in mmBtu) at the Phase I unit as a result of all improved unit efficiency measures under the reduced utilization plan. The verified amount of such reduction shall be submitted in accordance with paragraph (b) of this section.

(iii) "Shifts to sulfur-free generators" is the reduction in utilization (in mmBtu), for the calendar year, that is accounted for by all sulfur-free generators designated under the reduced utilization plan and documented under paragraph (a)(6) of this section. This term equals the sum, for all such generators, of the "shift to sulfur-free generator" calculated for each generator using the following formula:

Shift to sulfur-free generator–actual sulfur-free utilization–[(average 1985–87 sulfur-free annual utilization) (1+percentage change in dispatch system sales)]

where:

(A) "Actual sulfur-free utilization" is the actual annual generation (in Kwh) of the designated sulfur-free generator for the calendar year converted to mmBtus.

(B) "Average 1985–87 sulfur-free utilization" is the sum of annual generation (in Kwh) for 1985, 1986, and 1987 for the designated sulfur-free generator, divided by three and converted to mmBtus.

(C) "Percentage change in dispatch system sales" is calculated as follows:

$$\text{Percentage change in dispatch system sales} = [S_c - (\sum_{y=1985}^{1987} S_y \div 3)] \div [\sum_{y=1985}^{1987} S_y \div 3]$$

where:

S=dispatch system sales (in Kwh)
c=calendar year
y=1985, 1986, or 1987

If the result of the formula for percentage change in dispatch system sales is less than or equal to zero, then percentage change in dispatch system sales shall be treated as zero only for purposes of paragraph (a)(3)(iii) of this section.

(D) If the result of the formula for "shift to sulfur-free generator" is less than or equal to zero, then "shift to sulfur-free generator" is zero.

(iv) "Shifts to designated compensating units" is the reduction in utilization (mmBtu) that is accounted for by increased generation at compensating units designated under the reduced utilization plan. This term equals the heat rate (Btu/Kwh) of the unit reducing utilization multiplied by the sum, for all such compensating units, of the "generation shifted to designated compensating unit" for each compensating unit. "Generation shifted to designated compensating unit" shall equal the amount of compensating generation (in Kwh) that the designated representatives of the unit reducing utilization and the compensating unit have certified (in their respective annual compliance certification reports) as the amount that will be converted to mmBtus and subtracted, in accordance with paragraph (a)(4) of this section, from the adjusted utilization for the compensating unit.

(4) "Designated compensating generation provided to other units" is the total amount of utilization necessary to provide the generation that was shifted to the unit as a designated compensating unit under any other reduced utilization plans. This term equals the heat rate of such unit multiplied by the sum of the portion of each "generation shifted to designated compensating units" that is attributed to the unit in the annual compliance certification reports submitted by the Phase I units under such other plans and that is certified under paragraph (a)(3)(iv) of this section. If the unit filing the report is not a designated compensating unit under any other plans, this term is zero.

(5) Notwithstanding paragraphs (a)(3)(i) and (iii) of this section, where two or more Phase I units include in "plan reductions", in their annual compliance certification reports for the calendar year, estimated kilowatt hour savings from the same specific conservation measures or increased utilization of the same sulfur-free generator:

(i) The designated representatives of all such units shall submit with their annual reports a certification signed by all such designated representatives. The certification shall apportion the total kilowatt hour savings or increased utilization among such units.

(ii) Each designated representative shall include in its annual report only its share of the total savings or total increased utilization, in accordance with the certification under paragraph (a)(5)(i) of this section.

(6) Where a unit includes in "plan reductions" under paragraph (a)(3) of this section the increase in utilization of a sulfur-free generator that is not in the unit's dispatch system, the designated representative of the unit shall submit, with its annual compliance certification report, documentation demonstrating that an amount of electrical energy at least equal to the portion of the "shift to sulfur-free generators" attributed to the sulfur-free generator in the annual report was actually purchased by the unit's dispatch system from the sulfur-free generator.

(b) *Confirmation Report.* (1) If a unit's annual compliance certification report

estimates any expected kilowatt hour savings or improvement in heat rate from energy conservation or improved unit efficiency measures under a reduced utilization plan, the designated representative shall submit, by July 1 of the year in which the annual report was submitted, a confirmation report. The Administrator may grant, for good cause shown, an extension of the time to file the confirmation report. The confirmation report shall include the following elements in a format prescribed by the Administrator:

(i) The verified kilowatt hour savings from each such energy conservation measure and the verified corresponding reduction in the unit's heat input resulting from each measure during the calendar year covered by the annual report. For purposes of this paragraph (b), all values in Kwh shall be converted to mmBtu using the actual annual heat rate (Btu/Kwh) of the unit (determined in accordance with part 75 of this chapter) before the employment of any improved unit measures under an approved reduced utilization plan.

(ii) The verified reduction in the heat rate achieved by each improved unit efficiency measure and the verified corresponding reduction in the unit's heat input resulting from such measure.

(iii) For all figures under paragraphs (b)(1) (i) and (ii) of this section:

(A) Documentation (which may follow the EPA Conservation Verification Protocol) verifying specified figures to the satisfaction of the Administrator; or

(B) Certification, by a State utility regulatory authority that has ratemaking jurisdiction over the utility system that paid for the measures in accordance with § 72.43(b)(2) of this part and over rates reflecting any of the amount paid for such measures and that meets the criteria in § 73.82(c)(1) (i) and (ii) of this chapter, that such authority verified specified figures related to demand-side measures; and

(C) Certification, by a utility regulatory authority that has ratemaking jurisdiction over the utility system that paid for the measures in accordance with § 72.43(b)(2) of this part and over rates reflecting any of the amount paid for such measures, that such authority verified specified figures related to supply-side measures.

(2) Notwithstanding paragraph (b)(1)(i) of this section, where two or more Phase I units include in the confirmation report the verified kilowatt hour savings from the same specific conservation measures:

(i) The designated representatives of all such units shall submit with their confirmation reports a certification signed by all such designated representatives. The certification shall apportion the total kilowatt hour savings among such units.

(ii) Each designated representative shall include in its confirmation report only its share of the total savings in accordance with the certification under paragraph (b)(2)(i) of this section.

(3) If the total, included in the confirmation report, of the amounts of verified reduction in the unit's heat input from energy conservation and unit efficiency measures equals the total estimated in the unit's annual compliance certification report from such measures for the calendar year, then the designated representatives shall include in the confirmation report a statement indicating that is true.

(4) If the total, included in the confirmation report, of the amounts of verified reduction in the units's heat input from energy conservation and improved unit efficiency measures is greater than the total estimated in the unit's annual compliance certification report from such measures for the calendar year, then the designated representative shall include in the confirmation report the number of allowances to be credited to the unit's compliance subaccount calculated using the following formula:

Allowances credited=(verified heat input reduction-estimated hear input reduction) × emissions rate ÷ 2000 lbs/ton

where:

(i) "Verified heat input reduction" is the total of the amounts of verified reduction in the units' heat input (in mmBtu) from energy conservation and improved unit efficiency measures included in the confirmation report.

(ii) "Estimated heat input reduction" is the total of the amounts of reduction in the unit's heat input (in mmBtu) accounted for by energy conservation and improved efficiency measures as estimated in the unit's annual compliance certification report for the calendar year.

(iii) "Emissions rate" is the "emissions rate" under § 72.92(c)(2)(v) of this part.

(5) If the total, included in the confirmation report, of the amounts of verified reduction in the unit's heat input from energy conservation and improved unit efficiency measures is less than the total estimated in the unit's annual compliance certification report for such measures for the calendar year, then the designated representative shall include in the confirmation report the number of allowances to be deducted from the unit's compliance subaccount, which equals the absolute value of the result of the formula for allowances credited under paragraph (b)(4) of this section.

(6) Unless paragraph (b)(3) of this section applies, the designated representative shall include in the confirmation report the adjusted amount of allowances that would have held in the unit's compliance subaccount if the deductions made under § 73.35(b) of this chapter had been based on the verified, rather than the estimated, reduction in the unit's heat input from energy conservation and improved efficiency measures, calculated as follows:

Adjusted amount of allowances=allowances held after deduction–excess emissions + allowances credited–allowances deducted

where:

(i) "*Allowances held after deductions*" is the amount of allowances held in the unit's compliance subaccount after deductions were made under § 73.35(b) of this chapter based on the annual compliance certification report.

(ii) "*Excess emission*" is the amount (if any) of excess emissions determined under § 73.35(b) for the calendar year based on the annual compliance certification report.

(iii) "*Allowances credited*" is the amount of allowances calculated under paragraph (b)(4) of this section.

(iv) "*Allowances deducted*" is the amount of allowances calculated under paragraph (b)(5) of this section.

(v) If the result of the formula for "adjusted amount of allowances" is negative, the absolute value of the result constitutes excess emissions of sulfur dioxide. If the result is positive, there are no excess emissions of sulfur dioxide.

(7) If the amount of excess emissions of sulfur dioxide calculated under paragraph (b)(6) of this section differs from the amount of excess emissions of sulfur dioxide determined under § 73.35(b) of this chapter based on the annual compliance certification report, then the designated representative shall include in the confirmation report a demonstration of: the number of allowances that should be deducted to offset any increase in excess emissions or returned to account for any decrease in excess emissions; and the amount of the excess emissions penalty (excluding interest) that should be paid or returned to account for the change in excess emissions. The Administrator will deduct immediately from the unit's compliance subaccount the amount of allowances that he or she determines is

necessary to offset any increase in excess emissions or will return immediately to the unit's compliance subaccount the amount of allowances that he or she determines is necessary to account for any decrease in excess emissions. The designated representative may identify the serial numbers of the allowances to be deducted or returned. In the absence of such identification, the deduction will be on a first-in, first-out basis under § 73.35(c)(2) of this chapter and the return will be at the Administrator's discretion.

(8) If the designated representative of a unit fails to submit on a timely basis a confirmation report (in accordance with paragraph (b) of this section) with regard to the estimate of expected kilowatt hour savings or improvement in heat rate from any energy conservation or improved unit efficiency measure under the reduced utilization plan, then the Administrator will reject such estimate and correct it to equal zero in the unit's annual compliance certification report that includes that estimate. The Administrator will deduct immediately, on a first-in, first-out basis under § 73.35(c)(2) of this chapter, the amount of allowances that he or she determines is necessary to offset any increase in excess emissions of sulfur dioxide that results from the correction and require the owners and operators to pay an excess emission penalty in accordance with part 77 of this chapter.

§ 72.92 Phase I unit allowance surrender.

(a) *Annual Compliance Certification Report.* If a Phase I unit's adjusted utilization for the calendar year under § 72.91(a) is greater than zero, then the designated representative shall include in the annual compliance certification report the following elements:

(1) The number of allowances that shall be surrendered for adjusted utilization using the formula in paragraph (c) of this section and the calculations that were performed to obtain that number.

(2) Identification of the amounts of adjusted utilization that were caused by a dispatch-system-wide decline in sales, a forced outage at the unit, or economic dispatching in accordance with § 72.43(e)(1).

(3) If the unit experienced a forced outage during the year that is used to account for any adjusted utilization of the unit under paragraph (a)(2) of this section or if the unit is currently experiencing a forced outage that is expected to last longer than 4 months:

(i) A statement specifying the event that caused the forced outage;

(ii) The amount of adjusted utilization attributable to the forced outage (in mmBtu and Kwh), if any;

(iii) The duration or expected duration of the forced outage;

(iv) If the unit has not been returned to normal service, the expected date on which the unit will be returned to normal service; and

(v) A demonstration of the measures taken by the owners and operators to restore the unit to normal service as expeditiously as practicable, including any measures taken to prevent any similar forced outage in the future.

(b) *Other Submissions.*

(1) If a Phase I unit experienced a force outage during the calendar year that will cause the unit to shut down permanently and shift generation to any unit that would not otherwise be affected during Phase I, the designated representative shall submit to the Administrator within 60 days of the determination to shut down the unit permanently:

(i) A reduced utilization plan that designates one or more compensating units to which the unit will shift generation; or

(ii) A certification, from an independent auditor or a utility regulatory authority with ratemaking jurisdiction over any owner of the unit and over rates reflecting any capital or operating costs of the unit, that it is not possible to restore the unit to service at a reasonable cost.

(2)(i) If any Phase I unit in a dispatch system is governed during the calendar year by an approved reduced utilization plan relying on sulfur-free generation, then the designated representatives of all affected units in such dispatch system shall jointly submit, within 60 days of the end of the calendar year, a dispatch system data report that includes the following elements in a format prescribed by the Administrator:

(A) The name of the dispatch system as reported under § 72.33;

(B) The calculation of "percentage change in dispatch system sales" under § 72.91(a)(3)(iii)(C);

(C) A certification that each designated representative will use this figure, as appropriate, in its annual compliance certification report and will submit upon request the data supporting the calculation; and

(D) The signatures of all the designated representatives.

(ii) If any Phase I unit in a dispatch system has adjusted utilization greater than zero for the calendar year, then the designated representatives of all Phase I units in such dispatch system shall jointly submit, within 60 days of the end of the calendar year, a dispatch system data report that includes the following elements in a format prescribed by the Administrator:

(A) The name of the dispatch system as reported under § 72.33;

(B) The calculation of "percentage change in dispatch system sales" under § 72.91(a)(3)(iii)(C);

(C) The calculation of "dispatch system adjusted utilization" under paragraph (c)(2)(i) of this section;

(D) The calculation of "dispatch system aggregate baseline" under paragraph (c)(2)(ii) of this section;

(E) The calculation of "fraction of generation within dispatch system" under paragraph (c)(2)(v)(A) of this section;

(F) The calculation of "dispatch system emissions rate" under paragraph (c)(2)(v)(C) of this section;

(G) A certification that each designated representative will use these figures, as appropriate, in its annual compliance certification report and will submit upon request the data supporting these calculations; and

(H) The signatures of all the designated representatives.

(c) *Allowance Surrender Formula.* (1) As provided under the allowance surrender formula in paragraph (c)(2) of this section:

(i) Allowances are not surrendered for deduction for the portion of adjusted utilization accounted for by:

(A) Shifts in generation from the unit to other Phase I units;

(B) A dispatch-system-wide sales decline;

(C) Plan reductions under a reduced utilization plan as calculated under § 72.91; and

(D) Foreign generation.

(ii) Allowances are surrendered for deduction for the portion of adjusted utilization that is not accounted for under paragraph (c)(1)(i) of this section.

(2) The designated representative shall surrender for deduction the number of allowances calculated using the following formula:

Allowances surrendered = [dispatch system adjusted utilization + (dispatch system aggregate baseline × percentage change in dispatch system sales)] × unit's share × emissions rate ÷ 2000 lbs/ton.

If the result of the formula for "allowances surrendered" is less than or equal to zero, then no allowances are surrendered.

(i) *Calculating Dispatch System Adjusted Utilization.* "Dispatch system adjusted utilization" (in mmBtu) is the sum of the adjusted utilization under § 72.91(a) for all Phase I units in the dispatch system. If "dispatch system adjusted utilization" is less than or

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equal to zero, then no allowances are surrendered by any unit in that dispatch system.

(ii) *Calculating Dispatch System Aggregate Baseline.* "Dispatch system aggregate baseline" is the sum of the baselines (as defined in § 72.2 of this chapter) for all Phase I units in the dispatch system.

(iii) *Calculating Percentage Change in Dispatch System Sales.* "Percentage change in dispatch system sales" is the "percentage change in dispatch system sales" under § 72.91 (a)(3)(iii)(C); *provided* that if result of the formula in § 72.91(a)(3)(iii)(C) is greater than or equal to zero, the value shall be treated as zero only for purposes of paragraph (c)(2) of this section.

(iv) *Calculating Unit's Share.* "Unit's share" is the unit's adjusted utilization divided by the sum of the adjusted utilization for all Phase I units within the dispatch system that have adjusted utilization of greater than zero and is calculated as follows:

$$Unit's\ share = \frac{U_{unit}}{\sum_{i=1}^{m} U_i}$$

where:

(A) U_{unit} = the unit's adjusted utilization for the calendar year;

(B) U_i = the adjusted utilization of a Phase I unit in the dispatch system for the calendar year; and

(C) m = all Phase I units in the dispatch system having an adjusted utilization greater than 0 for the calendar year.

(v) *Calculating Emissions Rate.* "Emissions rate" (in lbs./mmBtu) is the weighted average emissions rate for sulfur dioxide of all units, within and outside the dispatch system, that contributed to the dispatch system's electrical output for the year, calculated as follows:

Emissions rate = [fraction of generation within dispatch system × dispatch system emissions rate] + [fraction of generation outside dispatch system × fraction of non-Phase I and non-foreign generation in NERC region × NERC region average emissions rate]

where:

(A) "Fraction of generation within dispatch system" is the fraction of the dispatch system's total sales accounted for by generation from units within the dispatch system. This term equals the total generation (in Kwh) by all units and generators within the dispatch system for the calendar year divided by the total sales (in Kwh) by the dispatch system for the calendar year.

(B) "Fraction of generation outside dispatch system" = 1 – fraction of generation within dispatch system.

(C) "Dispatch system emissions rate" is the weighted average rate (in lbs/mmBtu) for the dispatch system calculated as follows:

$$\text{Dispatch system emissions rate} = \sum_{i=1}^{k} g_i r_i \div \sum_{i=1}^{k} g_i$$

where:

g_i = a Phase II unit's utilization for the calendar year

r_i = a Phase II unit's emission rate, determined in accordance with part 75 of this chapter, for the calendar year

k = number of Phase II units in the dispatch system

(D) "Fraction of non-Phase I and non-foreign generation in NERC region" is the portion of the NERC region's total sales generated by units other than Phase I units or foreign sources in the unit's NERC region in 1985, as set forth in Table 1 of this section.

(E) "NERC region average emissions rate" is the weighted average emissions rate (in lbs/mmBtu) for the unit's NERC region in 1985, as set forth in Table 1 of this section.

TABLE 1.—NERC REGION GENERATION AND EMISSIONS RATE IN 1985

NERC region	Fraction of non-phase I and non-foreign generation in NERC region	NERC weighted average emissions rate (lb/mmBtu)
WSCC	1.000	0.466
SPP	0.940	0.647
SERC	0.662	1.315
NPCC	0.864	1.058
MAPP	0.946	1.171
MAIN	0.577	1.495
MAAC	0.683	1.599
ERCOT	1.000	0.491
ECAR	0.541	1.564

§ 72.93 Units with Phase I extension plans.

Annual Compliance Certification Report. The designated representative for a control unit governed by a Phase I extension plan shall include in the unit's annual compliance certification report for calendar year 1997, the start-up test results upon which the vendor is released from liability under the vendor certification of guaranteed sulfur dioxide removal efficiency under § 72.42(c)(12).

§ 72.94 Units with repowering extension plans.

(a) *Design and Engineering and Contract Requirements.* No later than January 1, 2000, the designated representative of a unit governed by an approved repowering plan shall submit to the Administrator and the permitting authority:

(1) Satisfactory documentation of a preliminary design and engineering effort.

(2) A binding letter agreement for the executed and binding contract (or for each in a series of executed and binding contracts) for the majority of the equipment to repower the unit using the technology conditionally approved by the Administrator under § 72.44(d)(3).

(3) The letter agreement under paragraph (a)(2) of this section shall be signed and dated by each party and specify:

(i) The parties to the contract;

(ii) The date each party executed the contract;

(iii) The unit to which the contract applies;

(iv) A brief list identifying each provision of the contract;

(v) Any dates to which the parties agree, including construction completion date;

(vi) The total dollar amount of the contract; and

(vii) A statement that a copy of the contract is on site at the source and will be submitted upon written request of the Administrator or the permitting authority.

(b) *Removal From Operation to Repower.* The designated representative of a unit governed by an approved repowering plan shall notify the Administrator in writing at least 60 days in advance of the date on which the existing unit is to be removed from operation so that the qualified repowering technology can be installed, or is to be replaced by another unit with the qualified repowering technology, in accordance with the plan.

(c) *Commencement of Operation.* Not later than 60 days after the units repowered under an approved repowering plan commences operation at full load, the designated representative of the unit shall submit a report comparing the actual hourly emissions and percent removal of each pollutant controlled at the unit to the actual hourly emissions and percent removal at the existing unit under the plan prior to repowering, determined in accordance with part 75 of this chapter.

(d) *Decision to Terminate.* If at any time before the end of the repowering extension the owners and operators decide to terminate good faith efforts to design, construct, and test the qualified repowering technology on the unit to be repowered under an approved repowering plan, then the designated

representative shall submit a notice to the Administrator by the earlier of the end of the repowering extension or a date within 30 days of such decision, stating the date on which the decision was made.

§ 72.95 Allowance deduction formula.

The following formula shall be used to determine the total number of allowances to be deducted for the calendar year from the allowances held in an affected unit's compliance subaccount as of the allowance transfer deadline applicable to that year:

Total allowances deducted=Tons emitted + Allowances surrendered for underutilization+Allowances deducted for Phase I extensions

where:

(a) "Tons emitted" is the total tons of sulfur dioxide emitted by the unit during the calendar year, as reported in accordance with part 75 of this chapter.

(b) "Allowances surrendered for underutilization" is the total number of allowances calculated in accordance with § 72.92 (a) and (c).

(c) "Allowances deducted for Phase I extensions" is the total number of allowances calculated in accordance with § 72.42(f)(1)(i).

§ 72.96 Administrator's action on compliance certifications.

(a) The Administrator may review, and conduct independent audits concerning, any compliance certification and any other submission under the Acid Rain Program and make appropriate adjustments of the information in the compliance certifications and other submissions.

(b) The Administrator may deduct allowances from or return allowances to a unit's Allowance Tracking System account in accordance with part 73 of this chapter based on the information in the compliance certifications and other submissions, as adjusted.

Appendix A to Part 72—Methodology for Annualization of Emissions Limits

For the purposes of the Acid Rain Program, 1985 emissions limits must be expressed in pounds of SO_2 per million British Thermal Unit of heat input (lb/mmBtu) and expressed on an annual basis.

Annualization factors are used to develop annual equivalent SO_2 limits as required by § 402(18) of the CAA. Many emission limits are enforced on a shorter term basis (or averaging period) than annually. Because of the variability of sulfur in coal and, in some cases, scrubber performance, meeting a particular limit with an averaging period of less than a year and at a specified statutory emissions level would require a lower annual average SO_2 emission rate (or annual equivalent SO_2 limit) than would the shorter term statutory limit. EPA has selected a compliance level of one exceedance per 10 years. For example, an SO_2 emission limit of 1.2 lbs/MMBtu, enforced for a scrubbed unit over a 7-day averaging period, would result in an annualized SO_2 emission limit of 1.16 lbs/MMBtu. In general, the shorter the averaging period, the lower the annual equivalent would be. Thus, the annualization of limits is established by multiplying each federally enforceable limit by an annualization factor that is determined by the averaging period and whether or not it's a scrubbed unit.

TABLE A–1.—SO_2 EMISSION AVERAGING PERIODS AND ANNUALIZATION FACTORS

Definition	Annualization factor	
	Scrubbed unscrubbed	
	Unit	Unit
Oil/gas unit	1.00	1.00
<=1 day	0.93	0.89
1 week	0.97	0.92
30 days	1.00	0.96
90 days	1.00	1.00
1 year	1.00	1.00
Not specified	0.93	0.89
At all times	0.93	0.89
Coal unit: No Federal limit or limit unknown	1.00	1.00

Appendix B to Part 72—Methodology for Conversion of Emissions Limits

For the purposes of the Acid Rain Program, all emissions limits must be expressed in pounds of SO_2 per million British Thermal Unit of heat input (lb/mmBtu).

The factor for converting pounds of sulfur to pounds of SO_2 is based on the molecular weights of sulfur (32) and SO_2 (64). Limits expressed as percentage of sulfur or parts per million (ppm) depend on the energy content of the fuel and thus may vary, depending on several factors such as fuel heat content and atmospheric conditions. Generic conversions for these limits are based on the assumed average energy contents listed in Table A–2. In addition, limits in ppm vary with boiler operation (e.g., load and excess air); generic conversions for these limits assume, conservatively, very low excess air. The remaining factors are based on site-specific heat rates and capacities to develop conversions for Btu per hour. Standard conversion factors for residual oil are 42 gal/bbl and 7.88 lbs/gal.

TABLE B–1.—CONVERSION FACTORS

[Emission limits converted to lbs SO_2/MMBtu by multiplying as below]

Unit measurement	Plant fuel type			
	Bituminous coal	Subbituminous coal	Lignite coal	Oil
Lbs sulfur/MMBtu	2.0	2.0	2.0	2.0
% sulfur in fuel	1.66	2.22	2.86	1.07
Ppm SO_2	0.00287	0.00384	.....	0.00167
Ppm sulfur in fuel	.....	.....	.....	0.00334
Tons SO_2/hour	2,000,000/(HEATRATE*SUMNDCAP*capacity factor) [1]			
Lbs SO_2/hour	1,000/(HEATRATE*SUMNDCAP*capacity factor) [1]			

[1] In these cases, if the limit was specified as the "site" limit, the summer net dependable capability for the entire plant is used; otherwise, the summer net dependable capability for the unit is used. For units listed in the NADB, "HEATRATE" shall be that listed in the NADB under that field and "SUMNDCAP" shall be that listed in the NADB under that field. For units not listed in the NADB, "HEATRATE" is the generator net full load heat rate reported on Form EIA–860 and "SUMNDCAP" is the summer net dependable capability of the generator (in MWe) as reported on Form EIA–860.

TABLE B–2.—ASSUMED AVERAGE ENERGY CONTENTS

Fuel type	Average heat content
Bituminous Coal	24 MMBtu/ton.
Subbituminous Coal	18 MMBtu/ton.
Lignite Coal	14 MMBtu/ton.
Residual Oil	6.2 MMBtu/bbl.

Appendix C to Part 72—Actual 1985 Yearly SO_2 Emissions Calculation

The equation used to calculate the yearly SO_2 emissions (SO2) is as follows:

SO2 = (coal SO_2 emissions) + (oil SO_2 emissions) (in tons)

If gas is the only fuel, gas emissions are defaulted to 0.

Each fuel type SO_2 emissions is calculated on a yearly basis, using the equation:

fuel SO_2 emissions (in tons) = (yrly wtd. av. fuel sulfur %) × (AP–42 fact.) × (1–scrb. effic. %/100) × (units conver. fact.) × (yearly fuel burned)

For coal, the yearly fuel burned is in tons/yr and the AP–42 factor (which accounts for the ash retention of sulfur in coal), in lbs SO_2 ton coal, is by coal type:

Coal type	AP–42 factor
Bituminous, anthracite	39 lbs/ton
Subbituminous	35
Lignite	30

For oil, the yearly fuel burned is in gal/yr. If it is in bbl/yr, convert using 42 gal/bbl oil. The AP–42 factor (which accounts for the oil density), in lbs SO_2/thousand gal oil, is by oil type:

Oil type	AP–42 factor
Distillate (light)	142 lbs/1,000 gal
Residual (heavy)	157

For all fuel, the units conversion factor is 1 ton/2000 lbs.

2. The authority citation for part 73 continues to read as follows:

Authority: 42 U.S.C. 7651.

3. Part 73 is amended by revising subpart A and by adding subparts B through D to read as follows:

PART 73—ALLOWANCE SYSTEM

Subpart A—Background and Summary

Sec.
73.1 Purpose and scope.
73.2 Applicability.
73.3 General.

Subpart B—Allowance Allocations

73.10 Initial allocations for Phase I.
73.25 Phase I extension reserve.
73.27 Special allowance reserve.

Subpart C—Allowance Tracking System

73.30 Allowance tracking system accounts.
73.31 Establishment of accounts.
73.32 Allowance account contents.
73.33 Authorized account representative.
73.34 Recordation in accounts.
73.35 Compliance.
73.36 Banking.
73.37 Account error and dispute resolution.
73.38 Closing of accounts.

Subpart D—Allowance Transfers

73.50 Scope and submission of transfers.
73.51 Prohibition.
73.52 EPA recordation.
73.53 Notification.

Subpart A—Background and Summary

§ 73.1 Purpose and scope.

The purpose of this Part is to establish the requirements and procedures for the following:

(a) The allocation of sulfur dioxide emissions allowances;

(b) The tracking, holding, and transfer of allowances;

(c) The deduction of allowances for purposes of compliance and for purposes of offsetting excess emissions pursuant to parts 72 and 77 of this chapter;

(d) The sale of allowances through EPA-sponsored auctions and a direct sale, including the independent power producers written guarantee program; and

(e) The application for, and distribution of, allowances from the Conservation and Renewable Energy Reserve.

§ 73.2 Applicability.

The following parties shall be subject to the provisions of this Part:

(a) Owners, operators, and designated representatives of affected sources and affected units pursuant to § 72.6 of this chapter;

(b) Any new independent power producer as defined in section 416 of the Act and § 72.2 of this chapter, except as provided in section 405(g)(6) of the Act;

(c) Any owner of an affected unit who may apply to receive allowances under the Energy Conservation and Renewable Energy Reserve Program established in accordance with section 404(f) of the Act;

(d) Any small diesel refinery as defined in § 72.2 of this chapter, and

(e) Any other person, as defined in § 72.2 of this chapter, who chooses to purchase, hold, or transfer allowances as provided in section 403(b) of the Act.

§ 73.3 General.

Part 72 of this chapter, including §§ 72.2 (definitions), 72.3 (measurements, abbreviations, and acronyms), 72.4 (Federal authority), 72.5 (State authority), 72.6 (applicability), 72.7 (new units exemption), 72.8 (retired unit exemption), 72.9 (standard requirements), 72.10 (availability of information), and 72.11 (computation of time) of part 72, subpart A of this chapter, shall apply to this part. The procedures for appeals of decisions of the Administrator under this part are contained in part 78 of this chapter. Sections 73.3 (Definitions) and 73.4 (Deadlines), which were previously published with subpart E of this part—"Auctions, Direct Sales, and Independent Power Producers Written Guarantee", are codified at §§ 72.2 and 72.12 of this chapter, respectively.

Subpart B—Allowance Allocations

§ 73.10 Initial allocations for Phase I.

(a) *Phase I Allowances.* The Administrator will allocate allowances to the unit account for each unit listed in Table 1 of this section in the amount listed in Column A to be held in each future year subaccount for the years 1995 through 1999.

TABLE 1.—PROPOSED PHASE I ALLOWANCE ALLOCATIONS

State name	Plant name	Boiler	Column A final phase 1 allocation	Column B auction and sales reserve
Alabama	Colbert	1	13213	357
		2	14907	403
		3	14995	405
		4	15005	405
		5	36202	978
	E.C. Gaston	1	17624	476
		2	18052	488
		3	17828	482

TABLE 1.—PROPOSED PHASE I ALLOWANCE ALLOCATIONS—Continued

State name	Plant name	Boiler	Column A final phase 1 allocation	Column B auction and sales reserve
		4	18773	507
		5	58265	1575
Florida	Big Bend	BB01	27662	748
		BB02	26367	713
		BB03	26036	704
	Crist	6	18695	505
		7	30846	834
Georgia	Bowen	1BLR	54639	1482
		2BLR	53329	1441
		3BLR	69862	1888
		4BLR	69852	1888
	Hammond	1	8549	231
		2	8977	243
		3	8676	234
		4	36650	990
	Jack McDonough	MB1	19386	524
		MB2	20058	542
	Wansley	1	68908	1862
		2	63708	1722
	Yates	Y1BR	7020	190
		Y2BR	6855	185
		Y3BR	6767	183
		Y4BR	8676	234
		Y5BR	9162	248
		Y6BR	24108	652
		Y7BR	20915	565
Illinois	Baldwin	1	46052	1245
		2	48695	1316
		3	46644	1261
	Coffeen	01	12925	349
		02	39102	1057
	Grand Tower	09	6479	175
	Hennepin	2	20182	545
	Joppa Steam	1	12259	331
		2	10487	283
		3	11947	323
		4	11061	299
		5	11119	301
		6	10341	279
	Kincaid	1	34585	934
		2	37063	1002
	Meredosia	05	15227	411
	Vermilion	2	9735	263
Indiana	Bailly	7	12256	331
		8	17134	463
	Breed	1	20280	548
	Cayuga	1	36581	989
		2	37415	1011
	Clifty Creek	1	19620	530
		2	19289	521
		3	19873	537
		4	19552	528
		5	18851	509
		6	19844	536
	Elmer W. Stout	50	4253	115
		60	5229	141
		70	25883	699
	F.B. Culley	2	4703	127
		3	18603	503
	Frank E. Ratts	1SG1	9131	247
		2SG1	9296	251
	Gibson	1	44288	1197
		2	44956	1215
		3	45033	1217
		4	44200	1195
	H.T. Pritchard	6	6325	171
	Michigan City	12	25553	691
	Petersburg	1	18011	487
		2	35496	959
	R. Gallagher	1	7115	192
		2	7980	216
		3	7159	193
		4	8386	227
	Tanners Creek	U4	27209	735
	Wabash River	1	4385	118
		2	3135	85
		3	4111	111
		5	4023	109
		6	13462	364

TABLE 1.—PROPOSED PHASE I ALLOWANCE ALLOCATIONS—Continued

State name	Plant name	Boiler	Column A final phase 1 allocation	Column B auction and sales reserve
Iowa	Warrick	4	29577	799
	Burlington	1	10428	282
	Des Moines	11	2259	61
	George Neal	1	2571	69
	Milton L. Kapp	2	13437	363
	Prairie Creek	4	7965	215
	Riverside	9	3885	105
Kansas	Quindaro	2	4109	111
Kentucky	Coleman	C1	10954	296
		C2	12502	338
		C3	12015	325
	Cooper	1	7254	196
		2	14917	403
	E.W. Brown	1	6923	187
		2	10623	287
		3	25413	687
	Elmer Smith	1	6348	172
		2	14031	379
	Ghent	1	27662	748
	Green River	5	7614	206
	H.L. Spurlock	1	22181	599
	HMP&L Station 2	H1	12989	351
		H2	11986	324
	Paradise	3	57613	1557
	Shawnee	10	9902	268
Maryland	C.P. Crane	1	10058	272
		2	8987	243
	Chalk Point	1	21333	577
		2	23690	640
	Morgantown	1	34332	928
		2	37467	1013
Michigan	J.H. Campbell	1	18773	507
		2	22453	607
Minnesota	High Bridge	6	4158	112
Mississippi	Jack Watson	4	17439	471
		5	35734	966
Missouri	Asbury	1	15764	426
	James River	5	4722	128
	LaBadie	1	39055	1055
		2	36718	992
		3	39249	1061
		4	34994	946
	Montrose	1	7196	194
		2	7984	216
		3	9824	266
	New Madrid	1	27497	743
		2	31625	855
	Sibley	3	15170	410
	Sioux	1	21976	594
		2	23067	623
	Thomas Hill	MB1	9980	270
		MB2	18889	510
New Hampshire	Merrimack	1	9922	268
		2	21421	579
New Jersey	B.L. England	1	8822	238
		2	11412	308
New York	Dunkirk	3	12268	332
		4	13690	370
	Greenidge	6	7342	198
	Milliken	1	10876	294
		2	12083	327
	Northport	1	19289	521
		2	23476	634
		3	25783	697
	Port Jefferson	3	10194	276
		4	12006	324
Ohio	Ashtabula	7	18351	496
	Avon Lake	11	12771	345
		12	33413	903
	Cardinal	1	37568	1015
		2	42006	1135
	Conesville	1	4615	125
		2	5360	145
		3	6029	163
		4	53463	1445
	Eastlake	1	8551	231
		2	9471	256
		3	10984	297
		4	15906	430

TABLE 1.—PROPOSED PHASE I ALLOWANCE ALLOCATIONS—Continued

State name	Plant name	Boiler	Column A final phase 1 allocation	Column B auction and sales reserve
		5	37349	1009
	Edgewater	13	5536	150
	Gen. J.M. Gavin	1	86690	2343
		2	88312	2387
	Kyger Creek	1	18773	507
		2	18072	488
		3	17439	471
		4	18218	492
		5	18247	493
	Miami Fort	5–1	417	11
		5–2	417	11
		6	12475	337
		7	42216	1141
	Muskingum River	1	16312	441
		2	15533	420
		3	15293	413
		4	12914	349
		5	44364	1199
	Niles	1	7608	206
		2	9975	270
	Picway	9	5404	146
	R.E. Burger	5	3371	91
		6	3371	91
		7	11818	319
		8	13626	368
	W.H. Sammis	5	26496	716
		6	43773	1183
		7	47360	1280
	Walter C. Beckjord	5	9811	265
		6	25235	682
Pennsylvania	Armstrong	1	14031	379
		2	15024	406
	Brunner Island	1	27030	730
		2	30282	818
		3	52404	1416
	Cheswick	1	38139	1031
	Conemaugh	1	58217	1573
		2	64701	1749
	Hatfield's Ferry	1	36835	995
		2	36338	982
		3	39210	1060
	Martins Creek	1	12327	333
		2	12483	337
	Portland	1	5784	156
		2	9961	269
	Shawville	1	10048	272
		2	10048	272
		3	13846	374
		4	13700	370
	Sunbury	3	8530	230
		4	11149	301
Tennessee	Allen	1	14917	403
		2	16329	441
		3	15258	412
	Cumberland	1	84419	2281
		2	92344	2496
	Gallatin	1	17400	470
		2	16855	455
		3	19493	527
		4	20701	559
	Johnsonville	1	7585	205
		10	7351	199
		2	7828	212
		3	8189	221
		4	7780	210
		5	8023	217
		6	7682	208
		7	8744	236
		8	8471	229
		9	6894	186
West Virginia	Albright	3	11684	316
	Fort Martin	1	40496	1094
		2	40116	1084
	Harrison	1	47341	1279
		2	44936	1214
		3	40406	1092
	Kammer	1	18247	493
		2	18948	512
		3	16932	458

TABLE 1.—PROPOSED PHASE I ALLOWANCE ALLOCATIONS—Continued

State name	Plant name	Boiler	Column A final phase 1 allocation	Column B auction and sales reserve
Wisconsin	Mitchell	1	42823	1157
		2	44312	1198
	M.T. Storm	1	42570	1150
		2	34644	936
		3	41314	1116
	Edgewater	4	24099	651
	Genoa	1	22103	597
	Nelson Dewey	1	5852	158
		2	6504	176
	North Oak Creek	1	5083	137
		2	5005	135
		3	5229	141
		4	6154	166
	Pulliam	8	7312	198
	South Oak Creek	5	9416	254
		6	11723	317
		7	15754	426
		8	15375	415

(b) [Reserved]

§ 73.25 Phase I extension reserve.

The Administrator will initially allocate 3.5 million allowances to the Phase I Extension Reserve account of the Allowance Tracking System. Allowances from this Reserve will be allocated to units under § 72.42 of this chapter. Allowances remaining in the Phase I Extension Reserve account following allocation of all extension allowances under § 72.42 of this chapter will remain in the Reserve.

§ 73.27 Special allowance reserve.

(a) *Establishment of Reserve.* (1) The Administrator will allocate 150,000 allowances annually for calendar years 1995 through 1999 to the Auction Subaccount of the Special Allowance Reserve.

(b) *Distribution of Proceeds.* Monetary proceeds from the auctions and sales of allowances from the Special Allowance Reserve (under subpart E of this part) for use in calendar years 1995 through 1999 will be distributed to the designated representative of the unit according to the following equation:

unit proceeds=(Column B of Table 1 of section 73.10/150,000) × total proceeds

(c) *Reallocation of Allowances.* Allowances remaining in the Special Allowance Reserve following the annual auctions and sales (under subpart E of this part) for use in calendar years 1995 through 1999 will be reallocated to the unit's Allowance Tracking System Account according to the following equation:

unit allowances = (Column B of Table 1 of section 73.10/150,000) × Allowances remaining

(d) *Calculation Rounding.* All proceeds under this section shall be distributed as whole dollars. All calculations for such allowances shall be rounded down for decimals less than .5 and up for decimals of .5 or greater.

(e) *Achieving Exact Totals.* (1) If the sum of the proceeds to be distributed under paragraph (b) of this section exceeds the total proceeds or the allowances to be reallocated under paragraph (c) of this section exceeds the allowances remaining, then the Administrator will withdraw one dollar or allowance from each unit, beginning with the unit receiving the largest number of dollars or allowances, in descending order, until the distribution balances with the proceeds and the reallocated allowances balance with the remaining allowances.

(2) If the sum of the proceeds to be distributed under paragraph (b) of this section is less than the total proceeds or the allowances to be reallocated under paragraph (c) of this section is less than the allowances remaining, then EPA will distribute one dollar or allowance for each unit, beginning with the unit receiving the largest number of dollars or allowances, in descending order, until the distribution balances with the proceeds and the reallocated allowances balance with the remaining allowances.

Subpart C—Allowance Tracking System

§ 73.30 Allowance tracking system accounts.

(a) *Nature and function of unit accounts.* The Administrator will establish accounts for all affected units pursuant to § 73.31 (a) and (b). All allocations of allowances pursuant to subparts B, E, and F of this part and part 72 of this chapter, transfers of allowances made pursuant to subparts C and D, and deductions of allowances made for purposes of offsetting emissions pursuant to § 73.35 (b) and (d) and parts 72, 75, and 77 of this chapter will be reordered in the unit's Allowance Tracking System account.

(b) *Nature and function of general accounts.* Transfers of allowances held for any person other than an affected unit, made pursuant to subparts C, D, E, F, and G of this part will be recorded in that person's Allowance Tracking System account established pursuant to § 73.31(c).

§ 73.31 Establishment of accounts.

(a) *Existing affected units.* The Administrator will establish an Allowance Tracking System account and allocate allowances for each unit that is, or will become, an existing affected unit pursuant to sections 404(a) or 405 of the Act and § 72.6 of this chapter.

(b) *New units.* Upon receipt of a complete certificate of representation for the designated representative for a new unit pursuant to part 72, subpart B of this chapter, the Administrator will establish an Allowance Tracking System account for the unit.

(c) *General accounts.* (1) Any person may apply to open an Allowance Tracking System account for the purpose of holding and transferring allowances. Such application shall be submitted to the Administrator in a format to be specified by the Administrator by means of the General Allowance Account Information Form, or by providing the following information in a similar format:

(i) Name and title of the authorized account representative and alternate

authorized account representative (if any) pursuant to § 73.33;

(ii) Mailing address, telephone number and facsimile transmission number (if any) of the authorized account representative and alternate authorized account representative (if any);

(iii) Organization or company name (if applicable) and type of organization (if applicable);

(iv) A list of all persons subject to a binding agreement for the authorized account representative to represent their ownership interest with respect to the allowances held in the general account and which shall be amended and resubmitted within 30 days following any transaction giving rise to any change of the list of persons subject to the binding agreement;

(v) A certification statement by the authorized account representative and alternate authorized account representative (if any) that reads "I certify that I was selected under the terms of an agreement that is binding on all persons who have an ownership interest with respect to allowances held in the Allowance Tracking System account. I certify that I have all necessary authority to carry out my duties and responsibilities on behalf of the persons with an ownership interest and that they shall be fully bound by my actions, inactions, or submissions under 40 CFR part 73. I shall abide by any fiduciary responsibilities assigned pursuant to the binding agreement. I am authorized to make this submission on behalf of the persons with an ownership interest for whom this submission is made. I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the information is to the best of my knowledge and belief true, accurate, and complete. I am aware that there are significant penalties for submitting false material information, or omitting material information, including the possibility of fine or imprisonment for violations.";

(vi) The signature of the authorized account representative and the alternate authorized account representative (if any); and

(vii) The date of the signature of the authorized account representative and the alternate authorized account representative (if any).

(2) Upon receipt of such complete application, the Administrator will establish an Allowance Tracking System account for the person or persons identified in the application.

(3) No allowance transfers will be recorded for a general account until the Administrator has established the new account.

(d) *Account identification.* The Administrator will assign a unique identifying number to each account established pursuant to this section.

§ 73.32 Allowance account contents.

Each allowance account will include, at a minimum, the following:

(a) The name, address, telephone number and facsimile transmission number, if any, of the authorized account representative; and

(1) In the case of a unit account, a list of all persons identified as owners of record of the unit in § 72.25(a)(3) of this chapter, or

(2) In the case of a general account, a list of all persons subject to the binding agreement for the authorized account representative to represent their ownership interest with respect to allowances, as identified in accordance with § 73.31(c);

(b) A list of transfers of allowances to, and from, the account, including the identity of the transferror and transferee accounts;

(c) In the case of a unit account for an existing affected unit, beginning in 1995, a compliance subaccount;

(d) In the case of a unit account for a new unit, a compliance subaccount;

(e) In the case of a general account, a current year subaccount;

(f) Future year subaccounts for each of the 30 calendar years following the later of 1995 or the current calendar year;

(g) In the case of a unit account, the current total of sulfur dioxide emissions in tons for the current calendar year as reported to date pursuant to part 75 of this chapter.

§ 73.33 Authorized account representative.

(a) Following the establishment of an Allowance Tracking System account, all matters pertaining to the account, including, but not limited to, the deduction and transfer of allowances in the account, shall be undertaken only by the authorized account representative.

(b) *Authorized account representative identification.* The Administrator will assign a unique identifying number to each authorized account representative or alternate authorized account representative identified pursuant to § 73.31(c).

(c) *Notification of parties subject to the binding agreement.* The authorized account representative for a general account shall notify, in writing, all persons who have an ownership interest with respect to the allowances held in the account of any Acid Rain Program submission required by this part or in a procedure under part 78 of this chapter, by the date of submission. Each person who has an ownership interest with respect to the allowances held in the account may expressly waive his or her right to receive such notification.

(d) *General account alternate authorized account representative.* Any application for opening a general account may designate one alternate authorized account representative to act on behalf of the certifying authorized account representative, in the event the authorized account representative is absent or otherwise not available to perform actions and duties under this part. The alternate shall be a natural person and shall be authorized, provided that the conditions and procedures specified in § 73.31(c)(1) are met.

(1) The alternate authorized account representative may be changed at any time by the authorized account representative upon receipt by the Administrator of a new complete application as required in § 73.31(c);

(2) The alternate authorized account representative shall be subject to the provisions of this part applicable to authorized account representatives;

(3) Whenever the term "authorized account representative" is used in this part it shall be construed to include the alternate authorized account representative, unless such a construction would be illogical from the context; and

(4) Any action, representation or failure to act by the alternate authorized account representative when acting in that capacity shall be deemed to be an action of the authorized account representative, with all the rights, duties, and responsibilities pertaining thereto.

(e) *Changes to the general account authorized account representative.* An authorized account representative for a general account may be succeeded by any person who submits an application pursuant to § 73.31(c). The actions of an authorized account representative for a general account shall be binding on any successor.

(f) *Objections to the authorized account representative.* Except for a certification pursuant to paragraph (e) of this section, no objection or other communication submitted to the Administrator concerning any submission to the Administrator by the authorized account representative shall affect the recordation of transfers submitted by the authorized account representative pursuant to subpart D of

this part. Neither the United States, the Administrator, nor any permitting authority will adjudicate any dispute between and among persons concerning any submission to the Administrator by the authorized account representative; any actions of the authorized account representative; or any other matter arising directly or indirectly from the certification, actions or representations of the authorized account representative.

§ 73.34 Recordation in accounts.

(a) *Recordation in compliance subaccounts.* At the beginning of 1995 and, in the case of each year thereafter, after the Administrator has made all deductions from an affected unit's compliance subaccount pursuant to § 73.35(b), the Administrator will record in the compliance subaccount the allowances held in the future year subaccount for the year corresponding to the current calendar year. The future year subaccount for the new 30th year will be established at the same time and include the allowances allocated for the unit for that year pursuant to subpart B of this part.

(b) *Recordation in current year subaccounts.* At the beginning of 1995 and each year thereafter, the Administrator will record in the current year subaccount the allowances held in the future year subaccount for the year corresponding to the current calendar year.

(c) *Recordation in subaccounts.* Allowances in each compliance, current year, and future year subaccounts will reflect:

(1) All allowances allocated or deducted for the unit for the year pursuant to subpart B of this part;

(2) All allowances allocated or deducted pursuant to § 72.41, § 72.42, § 72.43, and § 72.44 of this chapter;

(3) All allowances allocated pursuant to subparts F and G of this part;

(4) All allowances recorded as a result of purchases or returns from the annual auctions or direct sale pursuant to subpart E of this part;

(5) All allowances recorded or deducted as a result of allowance transfers recorded pursuant to subpart D of this part; and

(6) All allowances deducted or returned pursuant to § 73.35(d), §§ 72.91 and 72.92, and part 77 of this chapter.

(d) *Serial numbers for allocated allowances.* Upon the allocation of allowances to an account, including allowances contained in reserves as provided in subpart B of this part, the Administrator will assign each allowance a unique identification number that will include digits identifying the allowance's compliance use date.

§ 73.35 Compliance.

(a) *Allowance transfer deadline.* No allowance shall be deducted for purposes of compliance with an affected unit's sulfur dioxide Acid Rain emissions limitation requirements pursuant to title IV of the Act and paragraph (b) of this section unless:

(1) The compliance use date of the allowance is no later than the year in which the unit's SO_2 emissions occurred; and

(2) Such allowance is recorded in the compliance subaccount, or its transfer to the unit's compliance subaccount is submitted correctly pursuant to subpart D for recordation in the compliance subaccount for the unit by not later than the allowance transfer deadline of January 30 of the calendar year following the year for which compliance is being established in accordance with the requirements of subpart D of this part.

(b) *Deductions for compliance.* (1) Except as provided in paragraph (d) of this section, following the recordation of transfers submitted correctly pursuant to subpart D for recordation in the compliance subaccount pursuant to paragraph (a) of this section and subpart D of this part, the Administrator will deduct allowances from each affected unit's compliance subaccount in accordance with the allowance deduction formula in § 72.95 of this chapter and any correction made under § 72.96 of this chapter.

(2) The Administrator will make deductions until either the number of allowances deducted is equal to the amount calculated in accordance with § 72.95 of this chapter, as modified under § 72.96 of this chapter or until no more allowances remain in the compliance subaccount.

(c)(1) *Identification of allowances by serial number.* By no later than sixty days after the end of the calendar year, the authorized account representative for each unit account may identify by serial number the allowances to be deducted from the compliance subaccount for purposes of compliance with the unit's sulfur dioxide emissions limitation requirements. Such identification shall be made pursuant to part 72 of this chapter.

(2) *First-in, first-out.* In the absence of an identification or in the case of a partial identification of allowances by serial number, as provided for in paragraph (b)(1) or (d) of this section, the Administrator will deduct allowances on a first-in, first-out (FIFO) accounting basis beginning with those allowances with the earliest compliance use date originally allocated for the unit and recorded in its compliance subaccount. Following the deduction of all originally allocated allowances from the compliance subaccount, the Administrator will deduct those allowances that were transferred and recorded in the unit's compliance subaccount pursuant to subpart D of this part, beginning with those with the earliest date of recordation.

(d) *Deductions for excess emissions.* Pursuant to § 77.4 of this chapter, and following the process of recordation set forth in § 73.34(a) of this part, the Administrator will deduct allowances for each unit with excess emissions for the preceding calendar year in an amount equal to the unit's excess emissions tonnage.

(e) *Deductions for units sharing a common emission stack.* In the case of units sharing a common emission stack and have emissions that are not individually monitored pursuant to part 75 of this chapter, the authorized account representative may identify the percentage of allowances to be deducted from each unit's compliance subaccount. Such identification shall be made pursuant to part 72, subpart I of this chapter. In the absence of an identification, the Administrator will deduct an equal percentage of allowances from each unit's compliance subaccount.

§ 73.36 Banking.

(a) *Unit accounts.* Any allowance in a compliance subaccount not deducted pursuant to § 73.35 will remain in the compliance subaccount.

(b) *General accounts.* In the case of a general account, any allowances in the current year subaccount at the end of the current calendar year will remain in the current year subaccount.

§ 73.37 Account error and dispute resolution.

(a) *Claim of error.* The authorized account representative may notify the Administrator of any claim that the Administrator made an error in recording transfer information that was submitted correctly pursuant to subpart D of this part, provided that such claim of error notification is submitted to the Administrator by no later than 15 business days following the date mark of the notification by the Administrator pursuant to actions taken under § 73.37(d) or § 73.53. Such claim of error notification shall be in writing and shall include:

(1) A description of the error alleged to have been made by the Administrator;

(2) A proposed correction of the alleged error;

(3) Any supporting documentation or other information concerning the alleged error and proposed correction; and

(4) Certification by the signature of and the date of the signature of the authorized account representative.

The Administrator will not act on claim of error notifications received after the stated deadlines (except as provided under paragraph (f) of this section, or that do not contend that the Administrator made an error in recordation.

(b) *EPA action.* The Administrator, at the Administrator's sole discretion based on documentation provided, will determine what changes, if any, will be made to the accounts subject to the alleged error. Not later than 20 business days after receipt of a claim of error notification pursuant to paragraph (a) of this section, the Administrator will submit to the authorized account representative a written response stating:

(1) The determination made and any action taken by, the Administrator; and

(2) The reasons for such action.

(c) *Administrative Appeals Procedure.* Following the Administrator's action pursuant to paragraph (b) of this section, the authorized account representative may appeal the Administrator's action through the administrative appeals procedure pursuant to part 78 of this chapter.

(d) *EPA corrections.* The Administrator may, without prior notice of a claim of error and in the Administrator's sole discretion, correct any errors in any account on his or her own motion. The Administrator will notify the authorized account representative by no later than 20 business days following any such corrections.

(e) *Excess Emissions Requirements.* The filing of a claim of error notification pursuant to paragraph (a) of this section, or the pendency of the Administrator's action pursuant to paragraph (b) of this section, shall not affect a unit's obligations under part 77 of this chapter.

(f) *Waiver of Deadline.* The Administrator may, in his or her discretion, accept claim of error submissions made following the deadlines imposed in this section upon a demonstration by the authorized account representative of good cause for the delay. The finding of whether good cause exists shall be in the sole discretion of the Administrator. Appeals of a decision by the Administrator under this paragraph will be addressed pursuant to the administrative appeals process in part 78 of this chapter.

§ 73.38 Closing of accounts.

(a) *General Account.* The authorized account representative of a general account may instruct the Administrator to close the general account by submitting an allowance transfer, pursuant to § 73.50 and § 73.52, requesting the transfer of all allowances held in the account to one or more other accounts in the Allowance Tracking System, and by submitting in writing, with the signature of the authorized account representative, a request to delete the general account from the Allowance Tracking System.

(b) *Inactive accounts.* If a general account shows no activity for a period of a year or more and does not contain any allowances in its subaccounts, the Administrator will notify the account's authorized account representative that the account will be closed and eliminated from the Allowance Tracking System following 20 business days from the date the notice is sent. The account will be closed following the 20-day period, unless the Administrator receives and records a request for the transfer of allowances into the account pursuant to § 73.52 before the end of the 20-day period, or the authorized account representative submits, in writing, demonstration of good cause as to why the inactive account should not be closed. The finding of whether good cause exists shall be in the sole discretion of the Administrator.

Subpart D—Allowance Transfers

§ 73.50 Scope and submission of transfers.

(a) *Scope of transfers.* Except as provided in § 73.51 and § 73.52, the Administrator will record transfers of an allowance to and from Allowance Tracking System accounts, including, but not limited to, transfers of an allowance to and from contemporaneous future year subaccounts, and transfers of an allowance to and from compliance subaccounts and current year subaccounts, and transfers of all allowances allocated for a unit for each calendar year, in perpetuity.

(b) *Submission of transfers.* (1) Authorized account representatives seeking recordation of an allowance transfer shall request such transfer by submitting to the Administrator, in a format to be specified by the Administrator, an Allowance Transfer Form. To be considered correctly submitted the request for transfer shall include:

(i) The numbers identifying both the transferror and transferee accounts;

(ii) A specification by serial number of each allowance to be transferred, or correct indication on the allowance transfer where a request involves the transfer of the unit's allowances in perpetuity;

(ii) Signatures of the authorized account representatives of both the transferror and transferee accounts;

(iv) The dates of the signatures of the authorized account representatives;

(v) The numbers identifying the authorized account representatives for both the transferror and transferee account; and

(vi) Where the transferee account has not been established, information as required pursuant to § 73.31 (b) or (c).

(2) Transfers of allowances to or from compliance subaccounts submitted for recordation following the allowance transfer deadline will not be recorded until after completion of the process of recordation set forth in § 73.34(a).

§ 73.51 Prohibition.

Except as provided in § 73.34(a), the Administrator will not record a transfer of allowances from a future year subaccount to a subaccount for an earlier year.

§ 73.52 EPA recordation.

(a) *General recordation.* Except as provided in § 73.50, § 73.51, and this paragraph (a), the Administrator will record an allowance transfer by no later than five business days following receipt of an allowance transfer request pursuant to § 73.50, by moving each allowance from the transferror account to the transferee account as specified by the request pursuant to § 73.50, provided that:

(1) The information submitted pursuant to § 73.50 is complete;

(2) The transferror account includes each allowance identified by serial number in the allowance transfer request submitted pursuant to § 73.50, except when a request for transfer of the unit's allowances in perpetuity is indicated correctly on the allowance transfer submission;

(3) If the allowances identified by serial number specified pursuant to § 73.50(b)(1)(ii) are subject to the limitation on transfer imposed pursuant to § 72.44(h)(i), of this chapter, the transfer is in accordance with such limitation; and

(4) The transfer meets all applicable requirements of this subpart.

(b) Where an allowance transfer submitted for recordation fails to meet the requirements of this subpart, the Administrator will not record such transfer.

§ 73.53 Notification.

(a) *Notification of recordation.* The Administrator will notify each party to an allowance transfer within five business days following the recordation of the transfer. Notice will be given in writing or in a format to be specified by the Administrator, to the authorized account representatives of both the transferror and transferee accounts.

(b) *Notification of non-recordation.* By no later than five business days following receipt of an allowance transfer request by the Administrator, the Administrator will notify, in writing or in a format to be specified by the Administrator, the authorized account representatives of the accounts subject to the allowance transfer request submitted for recordation of:

(1) A decision not to record the transfer, and

(2) The reasons for such non-recordation.

(c) Nothing in this section shall preclude the submission of an allowance transfer request for recordation following notification of non-recordation.

Subpart E—[Amended]

4. Section 73.72 Direct sales.

* * * * *

(c) *Price.* Allowances in the direct sale will be sold at $1,500 per allowance, adjusted by the Consumer Price Index (CPI). The following formula will be used each year to calculate the price:

$$\$1{,}500 \times \left(1 + \frac{\text{CPI (year)} - \text{CPI (1990)}}{\text{CPI (1990)}} \right)$$

* * * * *

5. Part 73 is amended by adding subpart F to read as follows:

Subpart F—Energy Conservation and Renewable Energy Reserve

73.80 Operation of allowance reserve program for conservation and renewable energy.
73.81 Qualified conservation measures and renewable energy generation.
73.82 Application for allowances from reserve program.
73.83 Secretary of Energy's action on net income neutrality applications.
73.84 Administrator's action on applications.
73.85 Administrator review of the reserve program.
73.86 State regulatory autonomy.

Appendix A to Subpart F—List of Qualified Energy Conservation Measures

Subpart F—Energy Conservation and Renewable Energy Reserve

§ 73.80 Operation of allowance reserve program for conservation and renewable energy.

(a) *General.* The Administrator will allocate allowances from the Conservation and Renewable Energy Reserve (the "Reserve") established under subpart B based on verified kilowatt hours saved through the use of one or more qualified energy conservation measures or based on kilowatt hours generated by qualified renewable energy generation. Allowances will be allocated to applicants that meet the requirements of this subpart according to the formulas specified in § 73.82(d), and in the order in which applications are received, except where provided for in § 73.84 and § 73.85, until a total of 300,000 allowances have been allocated.

(b) *Period of applicability.* Allowances will be allocated under this subpart for qualified energy conservation measures or renewable energy generation sources that are operational on or after January 1, 1993, and before the date on which any unit owned or operated by the applicant becomes a Phase I unit or a Phase II unit.

(c) *Termination of the Reserve.* The Administrator will reallocate any allowances remaining in the Reserve after January 2, 2010 to the affected units from whom allowances were withheld by the Administrator, in accordance with section 404(g), for purposes of establishing the Reserve. Each unit's allocation under this paragraph will be calculated as follows:

$$\frac{\text{Remaining allowances in the Reserve} \times \text{Unit's allowances withheld}}{\text{Total amount in Reserve}}$$

(Allowances will be rounded to the nearest allowance)

§ 73.81 Qualified conservation measures and renewable energy generation.

(a) *Qualified energy conservation measures.* A qualified energy conservation measure is a demand-side measure not operational until the period of applicability, implemented in the residence or facility of a customer to whom the utility sells electricity, that:

(1) Is specified in appendix A(1) of this subpart; or

(2) In the case of a device or material that is not included in appendix A(1) of this subpart,

(i) Is a cost-effective demand-side measure consistent with an applicable least-cost plan or least-cost planning process that increases the efficiency of the customer's use of electricity (as measured in accordance with § 73.82(c)) without increasing the use by the customer of any fuel other than qualified renewable energy, industrial waste heat, or, pursuant to paragraph (b)(5) of this section, industrial waste gases;

(ii) Is implemented pursuant to a conservation program approved by the utility regulatory authority, which certifies that it meets the requirements of paragraph (a)(2)(i) of this section and is not excluded by paragraph (b) of this section; and

(iii) Is reported by the applicant in its application to the Reserve.

(b) *Non-qualified energy conservation measures.* The following energy conservation measures shall not qualify for Allowance Reserve allocations:

(1) Demand-side measures that were operational before January 1, 1992;

(2) Supply-side measures;

(3) Conservation programs that are exclusively informational or educational in nature;

(4) Load management measures that lead to economic reduction of electric energy demand during a utility's peak generating periods, unless kilowatt hour savings can be verified by the utility pursuant to § 73.82(c); or

(5) Utilization of industrial waste gases, unless the applicant has certified that there is no net increase in sulfur dioxide emissions from such utilization.

(c) *Qualified renewable energy generation.* Qualified renewable energy generation is electrical energy generation, not operational until the period of applicability, that:

(1) Is specified in appendix A(3) of this subpart; or

(2) In the case of renewable energy generation that is not included in appendix A(3) of this subpart is:

(i) Consistent with a least cost plan or a least cost planning process and derived from biomass (*i.e.*, combustible energy-producing materials from biological sources which include wood,

plant residues, biological wastes, landfill gas, energy crops, and eligible components of municipal solid waste), solar, geothermal, or wind resources;

(ii) Implemented pursuant to approval by the utility regulatory authority, which certifies that it meets the requirements of paragraphs (c)(2)(i) and (c)(2)(ii) of this section and is not excluded by paragraph (d) of this section; and

(iii) Is reported by the applicant in its application to the Reserve.

(d) *Non-qualified renewable energy generation.* The following renewable energy generation shall not qualify for Allowance Reserve allocations:

(1) Renewable energy generation that was operational before January 1, 1992;

(2) Measures that reduce electricity demand for a utility's customers without providing electric generation directly for sale to customers; and

(3) Measures that appear on the list of qualified energy conservation measures in Appendix A(1) of this subpart.

§ 73.82 Application for allowances form reserve program.

(a) *Application Requirements.* Each application for Conservation and Renewable Energy Reserve allowances, shall:

(1) Certify that the applicant is a utility;

(2) Demonstrate that the applicant, any subsidiary of the applicant, or any subsidiary of the applicant's holding company, is an owner or operator, in whole or in part, of at least one Phase I or Phase II unit by including in the application the name and Allowance Tracking System account number of a Phase I or Phase II unit which it owns or operates and for which it is listed as an owner or operator on the certificate of representation submitted by the designated representative for the unit pursuant to § 72.20 of this chapter;

(3) Through certification, demonstrate that the applicant is paying in whole or in part for one or more qualified energy conservation measures or qualified renewable energy generation (that became operational during the period of applicability) either directly or through payment to another person that purchases the qualified energy conservation measure or qualified renewable energy generation;

(4) Demonstrate that the applicant is subject to a least cost plan or a least cost planning process that:

(i) provides an opportunity for public notice and comment or other public participation processes;

(ii) evaluates the full range of existing and incremental resources in order to meet expected future demand at lowest system cost;

(iii) treats demand-side resources and supply-side resources on a consistent and integrated basis;

(iv) takes into account necessary features for system operation such as diversity, reliability, dispatchability, and other factors of risk;

(v) may take into account other factors, including the social and environmental costs and benefits of resource investments; and

(vi) is being implemented by the applicant to the maximum extent practicable.

(5) Demonstrate that the qualified energy conservation measure adopted or qualified renewable energy generated, or both, are consistent with the least cost plan or least cost planning process;

(6) If the applicant is subject to the rate-making jurisdiction of a State or local utility regulatory authority, its least cost plan or least cost planning process has been approved or accepted by the utility regulatory authority in the State or locality in which the qualified conservation measure(s) are adopted or in which the qualified renewable energy generation is utilized, and such State or local utility regulatory authority certifies that the least-cost plan or least-cost planning process meets the requirements of paragraph (a)(4) of this section;

(7) If the applicant is not subject to the rate-making jurisdiction of a State or local regulatory authority, its least cost plan or least cost planning process has been approved or has been accepted by the utility regulatory authority with rate-making jurisdiction over the applicant, and such utility regulatory authority certifies that the least cost plan or least cost planning process meets the requirements of paragraph (a)(4) of this section;

(8) If the applicant is an independent power production facility that sells qualified renewable energy generation to another utility, the applicant has enclosed documentation that such qualified renewable energy generation was purchased pursuant to the purchasing utility's least cost plan or least cost planning process, which has been approved or accepted by the purchasing utility's utility regulatory authority.

(9)(i) If the applicant is an investor-owner utility subject to the ratemaking jurisdiction of a State utility regulatory authority and is submitting an application on the basis of one or more qualified energy conservation measures, such State utility regulatory authority has established a procedure for determining rates and charges ensuring net income neutrality, as defined in § 72.2 of this chapter, including a provision that the utility's net income is compensated in full (considering factors such as risk) for lost sales attributable to the utility's conservation programs, which may include:

(A) General ratemaking for formulas that decouple utility profits from actual utility sales;

(B) Specific rate adjustment formulas that allow a utility to recover in its retail rates the full costs of conservation measures plus any associated net revenues lost as a result of reduced sales resulting from conservation initiatives; or

(C) Conservation incentive mechanisms designed to provide positive financial rewards to a utility to encourage implementation of cost-effective measures;

(ii) Provided that the existence of any one of the categories of ratemaking or rate adjustment formulas or conservation incentive mechanisms specified in paragraph (a)(9)(i) of this section shall not necessarily constitute fulfillment of the net income neutrality requirement unless, pursuant to § 73.83, the Secretary of Energy has certified the establishment of such net income neutrality;

(10) Demonstrate that the applicant has implemented the qualified energy conservation measures or used the qualified renewable energy generation specified in the application during the period of applicability;

(11) Demonstrate the extent to which installation of the qualified conservation measure(s) has achieved actual energy savings, by stating, on the basis of the performance of the measure(s) following installation:

(i) The amount of kilowatt hour savings resulting from the measure(s) in the given year(s);

(ii) Pursuant to paragraph (c) of this section, the methodology used to calculate the kilowatt hour savings; and

(iii) The name, address, and phone number of the person who performed the calculation of kilowatt hour savings;

(12) Report the type and amount of yearly qualified renewable energy generation, by stating (and submitting documentation, including copies of plant operation records, supporting such statements) the kilowatt hours of qualified renewable energy generated during a previous calendar year or years; and

(13) Report the extent to which qualified renewable energy generation was produced in combination with other energy sources (hereafter "hybrid generation") by stating (and submitting documentation, including copies of plant operation records, supporting such statements) the heat input and heat

rate of the non-qualified renewable generation, the total annual kilowatt hours generated, and the kilowatt hours that can be attributed to qualified renewable energy generation;

(14) Demonstrate the extent to which the implementation of qualified energy conservation measures or the use of qualified renewable energy generation has resulted in avoided tons of sulfur dioxide emissions by the utility during the period of applicability, pursuant to paragraph (d) of this section.

(b) *Application to the Secretary of Energy.* For purposes of paragraph (a)(9) of this section, the applicant shall fulfill the following requirements:

(1) If a utility applying for allowances from the Reserve has not received certification of net income neutrality from the Secretary of Energy or such certification is no longer applicable, the applicant shall submit to the Secretary of Energy:

(i) A copy of the relevant State utility regulatory authority's final order or decision setting forth the approved ratemaking mechanisms that ensure that a utility's net income will be at least as high upon implementation of energy conservation measures as such net income would have been if the energy conservation measures has not been implemented;

(ii) A description of how the State utility regulatory authority's order or decision meets the definition of net income neutrality as defined in § 72.2; and

(iii) Any additional information necessary for Secretary of Energy to certify that the State regulatory authority has established rates and charges that ensure net income neutrality.

(2) If a utility applying for allowances from the Reserve has already received certification of net income neutrality from the Secretary of Energy in connection with a previous application for allowances, and the ratemaking methods or procedures that ensure net income neutrality have not been altered, the applicant shall certify that the ratemaking methods and procedures that led to the original certification are still in place.

(c) *Verification of energy savings methodology.* For the purposes of paragraph (a)(11) of this section:

(1) Applicants subject to the ratemaking jurisdiction of a State utility regulatory authority shall use the energy conservation verification methodology approved by such authority in support of energy conservation applications under this subpart and part 72 of this chapter, provided that

(i) The authority in question uses this methodology to determine the applicant's entitlement to performance-based rate adjustments, which permit a utility's rates to be adjusted for additional kilowatt hours saved due to the utility's energy conservation programs;

(ii) Such performance based rate adjustments are subject to modification either prospectively or retrospectively to reflect periodic evaluations of energy savings secured by the applicant; and

(iii) The applicant has provided the Administrator with a description of the State utility regulatory authority's verification methodology and documentation that the requirements of this paragraph (c) have been met.

(2) All other applicants, including applicants whose rates are not subject to the ratemaking jurisdiction of a State utility regulatory authority shall demonstrate to the satisfaction of the Administrator through submission of documentation that savings have been achieved and may use the EPA Conservation Verification Protocol.

(3) All records of verification of energy savings shall be kept on file by the applicant for a period of 3 years. The Administrator may extend this period for cause at any time prior to the end of 3 years by notifying the applicant in writing.

(4) The Administrator reserves the right to conduct independent reviews, analyses, or audits to ascertain that the verification is valid and correct. If the Administrator determines that the verification is not valid or correct, the Administrator may revise the allocation of allowances to an applicant or require the surrender of allowances from the applicant's Allowance Tracking System account.

(d) *Calculation of allowances to be allocated.*

(1) In the case of an application submitted on the basis of qualified energy conservation measures, the sulfur dioxide emissions tonnage deemed avoided for any calendar year shall be equal to the product of:

$$\frac{(A)\times(B)}{2000\ \text{lbs./ton}}$$

(Rounded to the nearest ton)

Where:

(A)=the kilowatt hours that were not, but would otherwise have been, supplied by the utility during such year in the absence of such qualified energy conservation measures.

(B)=0.004 lbs. of sulfur dioxide per kilowatt hour.

(2) In the case of an application submitted on the basis of qualified renewable energy generation, the sulfur dioxide emissions tonnage deemed avoided for any calendar year shall be equal to the product of:

$$\frac{(A)\times(B)}{2000\ \text{lbs./ton}}$$

(Rounded to the nearest ton)

Where:

(A)=the actual kilowatt hours of qualified renewable energy generated or purchased by the applicant (based on the qualified renewable energy generation portion for hybrid generation).

(B)=0.004 lbs. of sulfur dioxide per kilowatt hour.

(e) *Certification by Applicant's Certifying Official.*

(1) Certification of all application requirements, including the net income neutrality requirements, shall be made by a certifying official of the applicant upon such official's verification of all information and documentation submitted.

(2) The applicant shall submit a certification statement signed by the applicant's certifying official that reads "I certify under penalty of law that I have personally examined and am familiar with the information submitted in this document and all its attachments. Based on my inquiry of those individuals with primary responsibility for obtaining the information, I certify that the information is to the best of my knowledge and belief true, accurate, and complete. I am aware that there are significant penalties for submitting false material information, or omitting material information, including the possibility of fine or imprisonment for violations."

(f) *Certification by State Utility Regulatory Authority.* Applicants subject to the ratemaking jurisdiction of a State utility regulatory authority shall include in their applications a certification by the State utility regulatory authority's certifying official that it has reviewed the application, including supporting documentation, and finds it to be accurate, complete, and consistent with all applicable requirements of this subpart.

(g) *Time period to apply.* (1) Beginning no earlier than July 1, 1993, and no earlier than July 1 of each subsequent year, applicants may apply to the Administrator for allowances from the Reserve for emissions avoided in a previous year or years by use of qualified energy conservation measures or qualified renewable energy generation that became operational during the period of applicability; and

(2) Beginning no earlier than January 1, 1993, any applicant may apply to the Secretary of Energy for the Secretary's certification of net income neutrality where the application is based on the use of one or more qualified energy conservation measures.

(3) Applications will be received by the Administrator and the Secretary of Energy until January 2, 2010, pursuant to § 73.80(c), or until no allowances remain in the Reserve.

(h) *Submittal location.* Applicants shall submit one copy of the completed Reserve application, not including the net income neutrality application, via registered mail to the Administrator at an address to be specified in later guidance. Applicants shall submit 10 copies of the net income neutrality application via registered mail to the Department of Energy at the following address: Department of Energy, Office of Conservation and Renewable Energy, Mail Stop CE–10, Room 6c–036, 1000 Independence Avenue, SW., Washington, DC 20585, Attn: Net Income Neutrality Certification.

§ 73.83 Secretary of Energy's action on net income neutrality applications.

(a) *First come, first served.* The Secretary of Energy will process and certify net income neutrality applications on a "first-come, first served" basis, according to the order, by date and time, in which they are received from either the applicant or, in the case of an application submitted to the Administrator and then forwarded to the Secretary, from the Administrator.

(b) *Deficient applications.* If the Secretary of Energy determines that the net income neutrality certification application does not meet the requirements of § 73.82 (a)(9) and (b), the Secretary will notify the applicant and the Administrator in writing of the deficiency. The applicant may then supply additional information or a new revised application as necessary for the Secretary to make a determination that the applicant meets the requirements of § 73.28(a)(9) and (b). Additional information or revised applications will be processed according to the date of receipt of such information or revisions.

(c) *Notification of approval.* The Secretary of Energy will review the net income neutrality application to determine whether it meets the requirements of § 73.82 (a)(9) and (b) and will certify this finding in writing to the applicant and to the Administrator within 60 calendar days of receipt of the net income neutrality application or a revised application, except that the Secretary may specify a later date for certification.

§ 73.84 Administrator's action on applications.

(a) *First come, first served.* The Administrator will process and approve Allowance Reserve applications, in whole or in part, on a "first-come, first-served" basis as established by the order of date of receipt, provided that the Administrator shall not allocate more than a total of 30,000 allowances in connection with applications based on any one of the four categories of qualified renewable energy generation enumerated in § 73.81(c)(2)(i) and Appendix A(3.1–3.4).

(b) *Deficient applications.* An application is deficient and will be returned by the Administrator if it fails to meet the requirements set forth in this subpart, including those set forth in § 73.82. A revised application that is submitted after being returned for failure to meet the requirements of this subpart will be processed according to the date of receipt of the revised application.

(c) *Notification of approval.* Applications that the Administrator determines to be complete and correct will be conditionally approved, subject to notification to EPA of a net income neutrality certification from the Department of Energy, within 120 calendar days of receipt. Allowances from the Reserve will be awarded subject to the Department of Energy certification, or, if a DOE certification has already been issued to the applicant, allocated to applicants from such applications depending on the availability of allowances in the Reserve. In the event the initial application approval is conditioned upon the Secretary of Energy's certification, final approval will be granted upon notification of certification by the Secretary of Energy pursuant to § 73.83. The Administrator will notify applicants of final approval in writing.

(d) *Allocation of allowances.* Beginning in 1995, the Administrator will allocate allowances from the Reserve for each approved application into the applicant's account or accounts in the Allowance Tracking System. If the applicant does not have an account in the Allowance Tracking System, or wishes to open a new account for the allowances from the Reserve, an application pursuant to § 73.31(c) must accompany the application for Reserve allowances.

(e) *Partial fulfillment of requests.* (1) In the event that the allowances available in the Reserve are less than the number that could otherwise be allocated to an approved applicant's account under the application as approved, the applicant will receive the allowances remaining in the Reserve.

(2) In the event that a subaccount is established by EPA, pursuant to § 73.85, and the applicant is making a request for allowances not included in the subaccount, the Allowance Reserve allocations for the approved applicant will be made, in addition to any that may be allocated pursuant to paragraph (f)(3) of this section, from any allowances remaining in the Reserve that are not contained in the subaccount.

(f) *Oversubscription of the Reserve.*

(1) In the event that the Reserve becomes oversubscribed by more than one applicant on a single day, the allowances remaining in the Reserve will be distributed on a pro rata basis to applicants meeting the requirements of § 73.82.

(2) If Reserve applications are received by the Administrator after all allowances from the Reserve have been allocated, the Administrator will so notify the applicant within 5 business days after receipt of the application.

(3) In the event that applications meeting the requirements pursuant to § 73.82 are received by the Administrator prior to February 1, 1998, and

(i) All remaining allowances in the Reserve have been placed in a subaccount pursuant to § 73.85; and

(ii) The applicant is not eligible for an allocation of allowances from the subaccount; the application will be placed on a waiting list in order of receipt.

(iii) The Administrator will notify the applicant of such action within 5 business days after receipt of the application.

(4) If any allowances are returned to the Reserve after February 1, 1998 pursuant to § 73.85(c), the Administrator will review the wait-listed applications in order of receipt and allocate any remaining allowances to the approved applicants in the order of their receipt until no more allowances remain in the Reserve.

(g) *Applications for allowances based on the same avoided emissions from the same energy conservation measures or renewable energy generation.*

(1) The Administrator will not award allowances to more than one applicant for the same avoided emissions from the same energy conservation measure or the same qualified renewable energy generation, and will process and act on such duplicative applications on a "first-come, first-serve" basis as determined by the order of date of receipt.

(2) Any allowances awarded pursuant to two or more applications received on the same date based on the same avoided emissions from the same energy conservation measure or the same renewable electric generation will be divided equally between all such applicants unless the Administrator is otherwise directed by all such applicants.

§ 73.85 Administrator review of the reserve program.

(a) *Administrator review of the Reserve and creation of a subaccount.* In the event that an allocation of allowances from the Reserve pursuant to a pending application would bring the total number of allowances allocated to a number greater than 240,000, the Administrator will review the distribution of all allowances allocated as follows:

(1) If at least 60,000 allowances have been allocated from the Reserve for *each* of

(i) Qualified energy conservation measures, and

(ii) Qualified renewable energy generation, allocations of allowances will continue pursuant to § 73.82, until no more allowances remain in the Reserve.

(2) If fewer than 60,000 allowances have been allocated for either qualified energy conservation measures or qualified renewable energy generation, the Administrator will establish a subaccount for the allocation of allowances for applications based on the category for which fewer than 60,000 allowances have been allocated. The subaccount will contain allowances equal to 60,000 less the number of allowances previously allocated for such category.

(b) *Allocation of allowances from the subaccount.* The Administrator will allocate allowances from the subaccount established pursuant to paragraph (a) of this section to approved and DOE certified applicants that fulfill the requirements of this subpart, including § 73.82 and § 73.83, on a "first-come, first-served basis", pursuant to § 73.84(a), until the subaccount is depleted or closed pursuant to paragraph (c) of this section.

(c) *Closure of the subaccount.* Unless all allowances in the subaccount have been previously allocated, the Administrator will terminate the subaccount not later than February 1, 1998 and return any allowances remaining in the subaccount to the general account of the Reserve. After all Reserve allocations have been made to applicants with approved and DOE certified applications subject to § 73.84(f)(3), the Administrator will allocate any remaining allowances to any applicants that meet the requirements of this subpart, including § 73.82 and § 73.83, on a "first-come, first-served" basis, pursuant to § 73.84.

§ 73.86 State regulatory autonomy.

Nothing in this Subpart shall preclude a state or state regulatory authority from providing additional incentives to utilities to encourage investment in any conservation measures or renewable energy generation.

Appendix A to Subpart F—List of Qualified Energy Conservation Measures, Qualified Renewable Generation, and Measures Applicable for Reduced Utilization

1. Demand-side Measures Applicable for the Conservation and Renewable Energy Reserve Program or Reduced Utilization

The following listed measures are approved as "qualified energy conservation measures" for purposes of the Conservation and Renewable Energy Reserve Program or reduced utilization qualified energy conservation plans under § 72.43 of this chapter. Measures not appearing on the list may also be qualified conservation measures if they meet the requirements specified in § 73.81(a) of this part.

1.1 Residential

1.1.1 Space Conditioning

- Electric furnace improvements (intermittent ignition, automatic vent dampers, and heating element change-outs)
- Air conditioner (central and room) upgrades/replacements
- Heat pump (ground source, solar assisted, and conventional) upgrades/replacements
- Cycling of air conditioners and heat pumps
- Natural ventilation
- Heat recovery ventilation
- Clock thermostats
- Setback thermostats
- Geothermal steam direct use
- Improved equipment controls
- Solar assisted space conditioning (ventilation, air-conditioning, and desiccant cooling)
- Passive solar designs
- Air conditioner and heat pump clean and tune-up
- Heat pipes
- Whole house fans
- High efficiency fans and motors
- Hydronic pump insulation
- Register relocation
- Register size and blade configuration
- Return air location
- Duct sizing
- Duct insulation
- Duct sealing
- Duct cleaning
- Shade tree planting

1.1.2 Water Heating

- Electric water heater upgrades/replacements
- Electric water heater tank wraps/blankets
- Low-flow showerheads and fittings
- Solar heating and pre-heat units
- Geothermal heating and pre-heat units
- Heat traps
- Water heater heat pumps
- Recirculation pumps
- Setback thermostats
- Water heater cycling control
- Solar heating for swimming pools
- Pipe wrap insulation

1.1.3 Lighting

- Lamp replacement
- Dimmers
- Motion detectors and occupancy sensors
- Photovoltaic lighting
- Fixture replacement
- Outdoor lighting controls

1.1.4 Building Envelope

- Attic, basement, ceiling, and wall insulation
- Passive solar building systems
- Exterior roof insulation
- Exterior wall insulation
- Exterior wall insulation bordering unheated space (e.g., a garage)
- Knee wall insulation in attic
- Floor insulation
- Perimeter insulation
- Storm windows/doors
- Caulking/weatherstripping
- Multi-glazed inserts for sliding glass doors
- Sliding door replacements
- Installation of French doors
- Hollow core door replacement
- Radiant barriers
- Window vent conversions
- Window replacement
- Window shade screens
- Low-e windows
- Window reduction
- Attic ventilation
- Whole house fan
- Passive solar design

1.1.5 Other Appliances

- Refrigerator replacements
- Freezer replacements
- Oven/range replacements
- Dishwasher replacements
- Clothes washer replacements
- Clothes dryer replacements
- Customer located power generation based on photovoltaic, solar thermal, biomass, wind or geothermal resources
- Swimming pool pump replacements
- Gasket replacements
- Maintenance/coil cleaning

1.2 Commercial

1.2.1 Heating/Ventilation/Air Conditioning (HVAC)

- Heat pump replacement
- Fan motor efficiency
- Resizing of chillers
- Heat pipe retrofits in air conditioning units
- Dehumidifiers
- Steam trap insulation
- Radiator thermostatic valves
- Variable speed drive on fan motor
- Solar assisted HVAC including ventilation, chillers, heat pumps, and desiccants
- HVAC piping insulation
- HVAC ductwork insulation
- Boiler insulation
- Automatic night setback
- Automatic economizer cooling
- Outside air control

- Hot and cold deck automatic reset
- Reheat system primary air optimization
- Process heat recovery
- Deadband thermostat
- Timeclocks on circulating pumps
- Chiller system
- Increase condensing unit efficiency
- Separate make-up air for exhaust hoods
- Variable air volume system
- Direct tower cooling (chiller strainer cycle)
- Multiple chiller control
- Radiant heating
- Evaporative roof surface cooling
- Cooling tower flow control
- Ceiling fans
- Evaporative cooling
- Direct expansion cooling system
- Heat recovery ventilation (water and air-source)
- Set-back controls for heating/cooling
- Make-up air control
- Manual fan switches
- Energy saving exhaust hood
- Night flushing
- Spot radiant heating
- Terminal regulated air volume control scheme
- Variable speed motors for HVAC system
- Waterside economizers
- Airside economizer
- Gray water systems
- Well water for cooling

1.2.2 Building envelope
- Insulation
- Wall insulation
- Floor/slab insulation
- Roof insulation
- Window and door upgrades, replacements, and films (to reduce solar heat gains)
- Passive solar design
- Earth berming
- Shading devices and tree planting
- High reflectivity roof coating
- Evaporative cooling
- Infiltration reduction
- Weatherstripping
- Caulking
- Low-e windows
- Multi-glazed windows
- Replace glazing with insulated walls
- Thermal break window frames
- Tinted glazing
- Vapor barrier
- Vestibule entry

1.2.3 Lighting
- Electronic ballast replacements
- Delamping
- Reflectors
- Occupancy sensors
- Daylighting with controls
- Photovoltaic lighting
- Efficient exterior lighting
- Manual selective switching
- Efficient exit signs
- Daylighting construction
- Cathode cutout ballasts
- High intensity discharge luminaries
- Outdoor light timeclock and photocell

1.2.4 Refrigeration
- Refrigerator replacement
- Freezer replacement
- Optimize heat gains to refrigerated space
- Optimize defrost control
- Refrigeration pressure optimization control
- High efficiency compressors
- Anti-condensate heater control
- Floating head pressure
- Hot gas defrost
- Parallel unequal compressors
- Variable speed compressors
- Water cooler controls
- Waste heat utilization
- Air doors on refrigeration equipment

1.2.5 Water Heating
- Electric water heating upgrades/replacements
- Electric water heater wraps/blankets
- Pipe insulation
- Solar heating and/or pre-heat units
- Geothermal heating and/or pre-heat units
- Circulating pump control
- Point-of-use water heater
- Heat recovery domestic water heater (DWH) system
- Chemical dishwashing system
- End-use reduction using low-flow fittings

1.2.6 Other end-uses and miscellaneous
- Energy management control systems for building operations
- Customer located power based on photovoltaic, solar thermal, biomass, wind, and geothermal resources
- Energy efficient office equipment
- Customer-owned transformer upgrades and proper sizing

1.3 Industrial

1.3.1 Motors
- Retire inefficient motors and replace with energy efficient motors, including the use of electronic adjustable speed or variable frequency drives
- Rebuild motors to operate more efficiently through greater contamination protection and improved magnetic materials
- Install self-starters
- Replace improperly sized motors

1.3.2 Lighting
- Electronic ballast replacement/improvement
- Electromagnetic ballast upgrade
- Installation of reflectors
- Substitution of lamps with built-in automatic cathode cut-out switches
- Modify ballast circuits with additional impedance devices
- Metal halide and high pressure sodium lamp retrofits
- High pressure sodium retrofits
- Daylighting with controls
- Occupancy sensors
- Delamping
- Photovoltaic lighting
- Two step and dimmable high intensity discharge ballast

1.3.3 Heating/Ventilation/Air Conditioning (HVAC)
- Heat pump replacement/upgrade
- Furnace upgrade/replacement
- Fan motor efficiency
- Resizing of chillers
- Heat pipe retrofits on air conditioners
- Variable speed drive on fan motor
- Solar assisted HVAC including ventilation, chillers, heat pumps and desiccants

1.3.4 Industrial Processes
- Upgrades in heat transfer equipment
- Insulation and burner upgrades for industrial furnaces/ovens/boilers to reduce electricity loads on motors and fans
- Insulation and redesign of piping
- Upgrades/retrofits in condenser/evaporation equipment
- Process air and water filtration for improved efficiency
- Upgrades of catalytic combustors
- Solar process heat
- Customer located power based on photovoltaic, solar thermal, biomass, wind, and geothermal resources
- Power factor controllers
- Utilization of waste gas fuels
- Steam line and steam trap repairs/upgrades
- Compressed air system improvements/repairs
- Industrial process heat pump
- Optimization of equipment lubrication or maintenance
- Resizing of process equipment for optimal energy efficiency
- Use of unique thermodynamic power cycles

1.3.5 Building Envelope
- Insulation of ceiling, walls, and ducts
- Window and door replacement/upgrade, including thermal energy barriers
- Caulking/weatherstripping

1.3.6 Water Heating
- Electric water heater upgrades/replacements
- Electric water heater wraps/blankets
- Pipe insulation
- Low-flow showerheads and fittings
- Solar heating and pre-heat units
- Geothermal heating and pre-heat units

1.3.7 Other End-uses and miscellaneous
- Refrigeration system retrofit/replacement
- Energy management control systems and end use metering
- Customer-owned transformer retrofits/replacements and proper sizing

1.4 Agricultural

1.4.1 Space Conditioning
- Building envelope measures
- Efficient HVAC equipment
- Heat pipe retrofit on air conditioners
- System and control measures
- Solar assisted HVAC including ventilation, chillers, heat pumps, and desiccants
- Air-source and geothermal heat pumps replacement/upgrades

1.4.2 Water heating
- Upgrades/replacements
- Water heater wraps/blankets
- Pipe insulation
- Low-flow showerheads and fittings
- Solart heating and/or pre-hear units
- Geothermal heating and/or pre-heat units

1.4.3 Lighting
- Electronic ballast replacements
- Delamping
- Reflectors
- Occupancy sensors
- Daylighting with controls
- Photovoltaic lighting
- Outdoor lighting controls

1.4.4 Pumping/Irrigation
- Pump upgrades/retrofits
- Computerized pump control systems
- Irrigation load management strategies
- Irrigation pumping plants
- Computer irrigation control
- Surge irrigation
- Computerized scheduling of irrigation

- Drip irrigation systems

1.4.5 Motors

- Retire inefficient motors and replace with energy efficient motors, including the use of electronic adjustable speed and variable frequency drives
- Rebuild motors to operate more efficiently through greater contamination protection and improved magnetic materials
- Install self-starters
- Replace improperly sized motors

11.4.6 Other end uses

- Ventilation fans
- Cooling and refrigeration system upgrades
- Grain drying using unheated air
- Grain drying using low temperature electric
- Customer-owned transformer retrofits/replacements and proper sizing
- Programmable controllers for electrical farm equipment
- Controlled livestock ventilation
- Water heating for production agriculture
- Milk cooler heat exchangers
- Direct expansion/ice bank milk cooling
- Low energy precision application systems
- Heat pump crop drying

1.5 Government Services Sector

1.5.1 Streetlighting

- Replace incandescent and mercury vapor lamps with high pressure sodium and metal halide

1.5.2 Other

- Energy efficiency improvements in motors, pumps, and controls for water supply and waste water treatment
- District heating and cooling measures derived for cogeneration that result in electricity savings

2. Supply-side Measures Applicable for Reduced Utilization

Supply-side measures that may be approved for purposes of reduced utilization plans under § 72.43 include the following:

2.1 Generation efficiency

- Heat rate improvement programs
- Availability improvement programs
- Coal cleaning measures that improve boiler efficiency
- Turbine improvements
- Boiler improvements
- Control improvements, including artificial intelligence and expert systems
- Distributed control—local (real-time) versus central (delayed)
- Equipment monitoring
- Performance monitoring
- Preventive maintenance
- Additional or improved heat recovery
- Sliding/variable pressure operations
- Adjustable speed drives
- Improved personnel training to improve man/machine interface

2.2 Transmission and distribution efficiency

- High efficiency transformer switchouts using amorphous core and silicon steel technologies
- Low-loss windings
- Innovative cable insulation
- Reactive power dispatch optimization
- Power factor control
- Primary feeder reconfiguration
- Primary distribution voltage upgrades
- High efficiency substation transformers
- Controllable series capacitors
- Real-time distribution data acquisition analysis and control systems
- Conservation voltage regulation

3. Renewable Energy Generation Measures Applicable for the Conservation and Renewable Energy Reserve Program

The following listed measures are approved as "qualified renewable energy generation" for purposes of the Conservation and Renewable Energy Reserve Program. Measures not appearing on the list may also be qualified renewable energy generation measures if they meet the requirements specified in § 73.81.

3.1 Biomass resources

- Combustible energy-producing materials from biological sources which include: wood, plant residues, biological wastes, landfill gas, energy crops, and eligible components of municipal solid waste.

3.2 Solar resources

- Solar thermal systems and the non-fossil fuel portion of solar thermal hybrid systems
- Grid and non-grid connected photovoltaic systems, including systems added for voltage or capacity augmentation of a distribution grid.

3.4 Geothermal resources

- Hydrothermal or geopressurized resources used for dry steam, flash steam, or binary cycle generation of electricity.

3.5 Wind resources

- Grid-connected and non-grid-connected wind farms
- Individual wind-driven electrical generating turbines

(The information requirements in this subpart have been approved by the Office of Management and Budget under the control number 2060–0221.)

6. Title 40 is amended by adding part 75 to read as follows:

PART 75—CONTINUOUS EMISSION MONITORING

Subpart A—General

Sec.

75.1 Purpose and scope.
75.2 Applicability.
75.3 General Acid Rain Program provisions.
75.4 Compliance dates.
75.5 Prohibitions.
75.6 Incorporation by reference.
75.7 EPA Study.
75.8 [reserved].

Subpart B—Monitoring Provisions

75.10 General operating requirements.
75.11 Specific provisions for monitoring SO_2 emissions (SO_2 and flow monitors).
75.12 Specific provisions for monitoring NO_x emissions (NO_x and diluent gas monitors).
75.13 Specific provisions for monitoring CO_2 emissions.
75.14 Specific provisions for monitoring opacity.
75.15 Specific provisions for monitoring SO_2 emissions removal by qualifying Phase I technology.
75.16 Specific provisions for monitoring emissions from common, by-pass, and multiple stacks for SO_2 emissions and heat input determinations.
75.17 Specific provisions for monitoring emissions from common, by-pass, and multiple stacks for NO_x emission rate.
75.18 Specific provisions for monitoring emissions from common and by-pass stacks for opacity.

Subpart C—Operation and Maintenance Requirements

75.20 Certification and recertification procedures.
75.21 Quality assurance and quality control requirements.
75.22 Reference test methods.
75.23 Alternatives to ASTM methods.
75.24 Out-of-control periods.

Subpart D—Missing Data Substitution Procedures

75.30 General provisions.
75.31 Initial missing data procedures.
75.32 Determination of monitor data availability for standard missing data procedures.
75.33 Standard missing data procedures.
75.34 Units with add-on emission controls.

Subpart E—Alternative Monitoring Systems

75.40 General demonstration requirements.
75.41 Precision criteria.
75.42 Reliability criteria.
75.43 Accessibility criteria.
75.44 Timeliness criteria.
75.45 Daily quality assurance criteria.
75.46 Missing data substitution criteria.
75.47 Criteria for a class of affected units.
75.48 Petition for an alternative monitoring system.

Subpart F—Recordkeeping Requirements

75.50 General recordkeeping provisions.
75.51 General recordkeeping provisions for specific situations.
75.52 Certification, quality assurance and quality control record provisions.
75.53 Monitoring plan.

Subpart G—Reporting Requirements

75.60 General provisions.
75.61 Notification of certification and recertification test dates.
75.62 Monitoring plan.
75.63 Certification or recertification applications.
75.64 Quarterly reports.
75.65 Opacity reports.
75.66 Petitions to the Administrator.
75.67 Retired units petitions.
Appendix A to Part 75—Specifications and Test Procedures
Appendix B to Part 75—Quality Assurance and Quality Control Procedures
Appendix C to Part 75—Missing Data Statistical Estimation Procedures
Appendix D to Part 75—Optional SO_2 Emissions Data Protocol for Gas-Fired Units and Oil-Fired Units
Appendix E to Part 75—Optional NO_x Emissions Estimation Protocol for Gas-Fired Peaking Units and Oil-Fired Peaking Units
Appendix F to Part 75—Conversion Procedures

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Appendix G to Part 75—Determination of CO_2 Emissions
Appendix H to Part 75—Revised Traceability Protocol No. 1
Appendix I to Part 75—Optional F-factor/Fuel Flow Method [reserved]

Authority: 42 U.S.C. 7651k and note.

Subpart A—General

§ 75.1 Purpose and scope.

(a) *Purpose.* The purpose of this part is to establish requirements for the monitoring, recordkeeping, and reporting of sulfur dioxide, nitrogen oxides, and carbon dioxide emissions, volumetric flow, and opacity data from affected units under the Acid Rain Program pursuant to Sections 412 and 821 of the Clean Air Act, 42 U.S.C. 7401–7671q as amended by Public Law 101–549 [November 15, 1990] [the Act].

(b) *Scope.* The regulations established under this part include general requirements for the installation, certification, operation, and maintenance of continuous emission or opacity monitoring systems and specific requirements for the monitoring of SO_2 emissions, volumetric flow, NO_x emissions, opacity, CO_2 emissions and SO_2 emissions removal by qualifying Phase I technologies. Specifications for the installation and performance of continuous emission monitoring systems, certification tests and procedures, and quality assurance tests and procedures are included in Appendices A and B to this part. Criteria for alternative monitoring systems and provisions to account for missing data from certified continuous emission monitoring systems or approved alternative monitoring systems are also included in the regulation.

Statistical estimation procedures for missing data are included in appendix C to this part. Optional protocols for estimating SO_2 mass emissions from gas-fired or oil-fired units and NO_x emissions from gas-fired peaking or oil-fired peaking units are included in appendices D and E, respectively, to this part. Requirements for recording and recordkeeping of monitoring data and for quarterly electronic reporting also are specified. Procedures for conversion of monitoring data into units of the standard are included in appendix F to this part. Procedures for the monitoring and calculation of CO_2 emissions are included in appendix C of this part.

§ 75.2 Applicability.

(a) Except as provided in paragraph (b) of this section, the provisions of this part apply to each affected unit subject to Acid Rain emission limitations or reduction requirements for SO_2 or NO_x.

(b) The provisions of this part do not apply to:

(1) A new unit for which a written exemption has been issued under § 72.7 of this chapter (any new unit that serves one or more generators with total nameplate capacity of 25 MWe or less and burns only fuels with a sulfur content of 0.05 percent or less by weight may apply to the Administrator for an exemption); or

(2) An existing utility unit which serves a generator with nameplate capacity not greater than 25 MWe; or

(3) an existing simple combustion turbine; or

(4) An affected unit for which a written exemption has been issued under § 72.8 and an exception granted under § 75.67.

§ 75.3 General Acid Rain Program provisions.

The provisions of part 72, including the following, shall apply to this part:

(a) § 72.2 (Definitions);
(b) § 72.3 (Measurements, Abbreviations, and Acronyms);
(c) § 72.4 (Federal Authority);
(d) § 72.5 (State Authority);
(e) § 72.6 (Applicability);
(f) § 72.7 (New Unit Exemption);
(g) § 72.8 (Retired Units Exemption);
(h) § 72.9 (Standard Requirements);
(i) § 72.10 (Availability of Information); and
(j) § 72.11 (Computation of Time).

In addition, the procedures for appeals of decisions of the Administrator under this part are contained in part 78 of this chapter.

§ 75.4 Compliance dates.

(a) The provisions of this part apply to each existing Phase I and Phase II unit on February 10, 1993. For substitution or compensating units that are so designated under the acid rain permit which governs the unit and contains the approved substitution or reduced utilization plan, pursuant to § 72.41 or § 72.43 of this chapter, the provisions of this part become applicable upon the issuance date of the acid rain permit. In accordance with § 75.20, the owner or operator of each existing affected unit shall ensure that all certification tests for the required continuous emission monitoring systems and continuous opacity monitoring systems are completed not later than the following dates (except as provided in paragraphs (d) and (e) of this section):

(1) For Phase I unit, November 15, 1993.

(2) For a substitution or a compensating unit that is designated under an approved substitution plan or reduced utilization plan pursuant to § 72.41 or § 72.43 of this chapter, the later of the following dates:

(i) November 15, 1993; or

(ii) not later than 90 days after the issuance date (or date of approval of permit revision) of the acid rain permit which governs the unit and contains the approved substitution or reduced utilization plan.

(3) For a Phase II unit, January 1, 1995.

(b) In accordance with § 75.20, the owner or operator of each new affected unit shall ensure that all certification tests for the required continuous emission monitoring systems and continuous opacity monitoring systems are completed on or before the later of the following dates:

(1) January 1, 1995; or

(2) Not later than 90 days after the date the unit commences commercial operation, not to exceed the date the unit is declared commercial in accordance with DOE Form EIA–860 instructions (i.e., the date the unit is turned over to the dispatcher).

(c) In accordance with § 75.20, the owner or operator of an existing unit that did not serve a generator with a nameplate capacity greater than 25 MWe on November 15, 1990, but serves such a generator after November 15, 1990, shall ensure that all certification tests for the required continuous emission monitoring systems and continuous opacity monitoring systems are completed on or before the later of the following dates:

(1) January 1, 1995; or

(2) Not later than 90 days after the date the unit begins to serve a generator with a nameplate capacity greater than 25 MWe.

(d) In accordance with § 75.20, the owner or operator of an existing unit that is shut down and is not yet operating by the applicable dates listed in paragraph (a) of this section, shall ensure that all certification tests for the required continuous emission monitoring systems and continuous opacity monitoring systems are completed not later than 90 days after the date that the unit recommences commercial operation of the affected unit, not to exceed the date the unit is declared commercial in accordance with DOE Form EIA–860 instructions (i.e., the date the unit is turned over to the dispatcher).

(e) In accordance with § 75.20, the owner or operator of a unit with a qualifying Phase I technology which requires the use of an inlet SO_2-diluent continuous emission monitoring system for the purpose of monitoring SO_2 emissions removal from January 1, 1997

through December 31, 1999 shall ensure that all certification tests for the inlet and outlet SO_2-diluent continuous emission monitoring systems are completed no later than January 1, 1997.

§ 75.5 Prohibitions.

(a) A violation of any applicable regulation in this part by the owners or operators or the designated representative of an affected source or an affected unit is a violation of the Act.

(b) No owner or operator of an affected unit shall operate the unit without complying with the requirements of §§ 75.2 through 75.67 and appendices A through G of this part.

(c) No owner or operator of an affected unit shall use any alternative monitoring system, alternative reference method, or any other alternative for the required continuous emission monitoring system without having obtained the Administrator's prior written approval in accordance with §§ 75.23, 75.48 and 75.66.

(d) No owner or operator of an affected unit shall operate the unit so as to discharge, or allow to be discharged, emissions of SO_2, NO_x, or CO_2 to the atmosphere without accounting for all such emissions in accordance with the provisions of §§ 75.10 through 75.18.

(e) No owner or operator of an affected unit shall disrupt the continuous emission monitoring system, any portion thereof, or any other approved emission monitoring method, and thereby avoid monitoring and recording SO_2, NO_x, or CO_2 emissions discharged to the atmosphere, except for periods when maintenance is performed pursuant to § 75.21 and appendix B of this part.

§ 75.6 Incorporation by reference.

The materials listed in this section are incorporated by reference in the corresponding sections noted. These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. These materials are incorporated as they existed on the date of approval, and a notice of any change in these materials will be published in the Federal Register. The materials are available for purchase at the corresponding address noted below and are available for inspection at the Office of the Federal Register, 800 N. Capitol Street, NW., Washington, DC, at the Public Information Reference Unit of the U.S. EPA, 401 M Street, SW., Washington, DC and at the Library (MD–35), U.S. EPA, Research Triangle Park, North Carolina.

(a) The following materials are available for purchase from the following addresses: American Society for Testing and Material (ASTM), 1916 Race Street, Philadelphia, Pennsylvania 19103; and the University Microfilms International 300 North Zeeb Road, Ann Arbor, Michigan 48106.

(1) ASTM D129–91, Standard Test Method for Sulfur in Petroleum Products (General Bomb Method), for appendices A and D of this part.

(2) ASTM D240–87 (Reapproved 1991), Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter, for appendices A, D, E and F of this part.

(3) ASTM D287–82 (Reapproved 1987), Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method), for appendix D of this part.

(4) ASTM D388–92, Standard Classification of Coals by Rank, incorporation by reference for appendix F of this part.

(5) ASTM D941–88, Standard Test Method for Density and Relative Density (Specific Gravity) of Liquids by Lipkin Bicapillary Pycnometer, for appendix D of this part.

(6) ASTM D1072–90, Standard Test Method for Total Sulfur in Fuel Gases, for appendix D of this part.

(7) ASTM D1217–91, Standard Test Method for Density and Relative Density (Specific Gravity) of Liquids by Bingham Pycnometer, for appendix D of this part.

(8) ASTM D1250–80 (Reapproved 1990), Standard Guide for Petroleum Measurement Tables, for appendix D of this part.

(9) ASTM D1298–85 (Reapproved 1990), Standard Practice for Density, Relative Density (Specific Gravity) or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method, for appendix D of this part.

(10) ASTM D1480–91, Standard Test Method for Density and Relative Density (Specific Gravity) of Viscous Materials by Bingham Pycnometer, for appendix D of this part.

(11) ASTM D1481–91, Standard Test Method for Density and Relative Density (Specific Gravity) of Viscous Materials by Lipkin Bicapillary Pycnometer, for appendix D of this part.

(12) ASTM D1552–90, Standard Test Method for Sulfur in Petroleum Products (High Temperature Method), for appendices A and D of the part.

(13) ASTM D1826–88, Standard Test Method for Calorific (Heating) Value of Gases in Natural Gas Range by Continuous Recording Calorimeter, for appendices E and F of this part.

(14) ASTM D1945–91, Standard Test Method for Analysis of Natural Gas by Gas Chromatography, for appendices F and G of this part.

(15) ASTM D1946–90, Standard Practice for Analysis of Reformed Gas by Gas Chromatography, for appendices F and G of this part.

(16) ASTM D2013–86, Standard Method of Preparing Coal Samples for Analysis, for appendix F of this part.

(17) ASTM D2015–91, Standard Test Method for Gross Calorific Value of Coal and Coke by the Adiabatic Bomb Calorimeter, for appendices, A, D, E and F of this part.

(18) ASTM D2234–89, Standard Test Methods for Collection of a Gross Sample of Coal, for appendix F of this part.

(19) ASTM D2382–88, Standard Test Method for Heat of Combustion of Hydrocarbon Fuels by Bomb Calorimeter (High-Precision Method), for appendices D, E and F of this part.

(20) ASTM D2502–87, Standard Test Method for Estimation of Molecular Weight (Relative Molecular Mass) of Petroleum Oils from Viscosity Measurements, for appendix G of this part.

(21) ASTM D2503–82 (Reapproved 1987), Standard Test Method for Molecular Weight (Relative Molecular Mass) of Hydrocarbons by Thermoelectric Measurement of Vapor Pressure, for appendix G of this part.

(22) ASTM D2622–92, Standard Test Method for Sulfur in Petroleum Products by X-Ray Spectrometry, for appendices A and D of this part.

(23) ASTM D3174–89, Standard Test Method for Ash in the Analysis Sample of Coal and Coke From Coal, for appendix G of this part.

(24) ASTM D3176–89, Standard Practice for Ultimate Analysis of Coal and Coke, for appendices A and F of this part.

(25) ASTM D3177–89, Standard Test Methods for Total Sulfur in the Analysis Sample of Coal and Coke, for appendix A of this part.

(26) ASTM D3178–89, Standard Test Methods for Carbon and Hydrogen in the Analysis Sample of Coal and Coke, for appendix G of this part.

(27) ASTM D3238–90, Standard Test Method for Calculation of Carbon Distribution and Structural Group Analysis of Petroleum Oils by the n–d–M Method, for appendix G of this part.

(28) ASTM D4052–91, Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter, for appendix D of this part.

(29) ASTM D4057–88, Standard Practice for Manual Sampling of

Petroleum and Petroleum Products, for appendix D of this part.

(30) ASTM D4177–82 (Reapproved 1990), Standard Practice for Automatic Sampling of Petroleum and Petroleum Products, for appendix D of this part.

(31) ASTM D4239–85, Standard Test Methods for Sulfur in the Analysis Sample of Coal and Coke Using High Temperature Tube Furnace Combustion Methods, for appendix A of this part.

(32) ASTM D4294–90, Standard Test Method for Sulfur in Petroleum Products by Energy-Dispersive X-Ray Fluorescence Spectroscopy, for appendices A and D of this part.

(b) The following materials are available for purchase from the American Society of Mechanical Engineers (ASME), 22 Law Drive, Box 2350, Fairfield, NJ 07007–2350.

(1) ASME MFC–3M–1989 with September 1990 Errata, Measurement of Fluid Flow in Pipes Using Orifice, Nozzle, and Venturi, for § 75.20 and appendices D and E of this part.

(2) ASME MFC–4M–1986 (Reaffirmed 1990), Measurement of Gas Flow by Turbine Meters, for § 75.20 and appendix E of this part.

(3) ASME MFC–5M–1985, Measurement of Liquid Flow in Closed Conduits Using Transit-Time Ultrasonic Flowmeters, for § 75.20 and appendices D and E of this part.

(4) ASME MFC–6M–1987 with June 1987 Errata, Measurement of Fluid Flow in Pipes Using Vortex Flow Meters, for § 75.20 and appendices D and E of this part.

(5) ASME MFC–7M–1987 (Reaffirmed 1992), Measurement of Gas Flow by Means of Critical Flow Venturi Nozzles, for § 75.20 and appendix E of this part.

(6) ASME MFC–9M–1988 with December 1989 Errata, Measurement of Liquid Flow in Closed Conduits by Weighing Method, for § 75.20 and appendices D and E of this part.

(7) ASME Power Test Code 4.1–1964 (Reaffirmed 1991), Steam Generating Units, for appendix E of this part.

(8) ASME Performance Test Code 17–1973 (Reaffirmed 1991), Reciprocating Internal Combustion Engines, for appendix E of this part.

(9) ASME Performance Test Code 22–1985, Gas Turbine Power Plants, for appendix E of this part.

§ 75.7 EPA Study.

The Agency will initiate rulemaking to adjust the equations in the bias test by an amount sufficient to compensate for reference monitor variance based on a study, which EPA shall complete by October 31, 1993, unless the Administrator determines that adjustments are technically unnecessary or infeasible to properly determine bias.

§ 75.8 [Reserved]

Subpart B—Monitoring Provisions

§ 75.10 General operating requirements.

(a) *Primary Measurement Requirement.* The owner or operator shall measure opacity, and all SO_2, NO_x, and CO_2 emissions for each affected unit as follows:

(1) The owner or operator shall install, certify, operate, and maintain, in accordance with all the requirements of this part, a SO_2 continuous emission monitoring system (consisting of an SO_2 pollutant concentration monitor and a flow monitor) with the automated data acquisition and handling system for measuring and recording SO_2 concentration (in ppm), volumetric gas flow (in scfh), and SO_2 mass emissions (in lb/hr) discharged to the atmosphere, except as provided in §§ 75.11 and 75.16 and subpart E;

(2) The owner or operator shall install, certify, operate, and maintain, in accordance with all the requirements of this part, a NO_x continuous emission monitoring system (consisting of a NO_x pollutant concentration monitor and an O_2 or CO_2 diluent gas monitor) with the automated data acquisition and handling system for measuring and recording NO_x concentration (in ppm) and NO_x emission rate (in lb/mmbtu) discharged to the atmosphere, except as provided in §§ 75.12 and 75.17 and subpart E;

(3) The owner or operator shall determine CO_2 emissions by using one of the following options:

(i) The owner or operator shall install, certify, operate, and maintain, in accordance with all the requirements of this part, a CO_2 continuous emission monitoring system (consisting of a CO_2 pollutant concentration monitor and a flow monitor) with the automated data acquisition and handling system for measuring and recording CO_2 concentration (in ppm or percent, volumetric gas flow (in scfh), and CO_2 mass emissions (in tons/hr) discharged to the atmosphere;

(ii) The owner or operator shall determine CO_2 emissions based on the measured carbon content of the fuel and the procedures in Appendix G of this part to estimate CO_2 emissions (in ton/day) discharged to the atmosphere; or

(iii) The owner or operator shall install, certify, operate, and maintain, in accordance with all the requirements of this part, an O_2 concentration monitor in order to determine CO_2 emissions using the procedures in appendix F of this part to measure CO_2 emissions (in tons/hr) and to estimate CO_2 emissions (in ton/day) discharged to the atmosphere; and

(4) The owner or operator shall install, certify, operate, and maintain, in accordance with all the requirements in this part, a continuous opacity monitoring system with the automated data acquisition and handling system for measuring and recording the opacity of emissions (in percent opacity) discharged to the atmosphere, except as provided in §§ 75.14 and 75.18.

(b) *Primary Equipment Performance Requirements.* The owner or operator shall ensure that each continuous emission monitoring system required by this part meets the equipment, installation, and performance specifications in Appendix A to this part; and is maintained according to the quality assurance and quality control procedures in Appendix B to this part; and shall record SO_2 and NO_x emissions in the appropriate units of measurement (i.e., lb/hr for SO_2 and lb/mmBtu for NO_x).

(c) *Heat Input Measurement Requirement.* The owner or operator shall determine and record the heat input to each affected unit for every hour or part of an hour any fuel is combusted following the procedures in Appendix F to this part.

(d) *Primary Equipment Hourly Operating Requirements.* The owner or operator shall ensure that all continuous emission or opacity monitoring systems required by this part are in operation at all times that the affected unit combusts any fuel and that the following requirements are met:

(1) The owner or operator shall ensure that each continuous emission monitoring system and component thereof is capable of completing a minimum of one cycle of operation (sampling, analyzing, and data recording) for each successive 15-min interval. The owner or operator shall reduce all SO_2 concentrations, volumetric flow, SO_2 mass emissions, SO_2 emission rate in lb/mmBtu (if applicable), CO_2 concentration, O_2 concentration, CO_2 mass emissions (if applicable), NO_x concentration, and NO_x emission rate data to 1-hr averages. The owner or operator shall compute these averages from four or more data points equally spaced over each 1-hr period, except during periods when calibration, quality assurance, or maintenance activities pursuant to § 75.21 and appendix B of this part are being performed. During these periods, a valid hour shall consist of at least two data points separated by a minimum of 15 minutes. For combined monitoring systems (NO_x-diluent and SO_2-diluent), the hourly average emission rate is valid

only if the hourly average concentration from each of the component monitors is valid.

(2) The owner or operator shall ensure that each continuous opacity monitoring system is capable of completing a minimum of one cycle of sampling and analyzing for each successive 10-sec period and one cycle of data recording for each successive 6-min period. The owner or operator shall reduce all opacity data to 6-min averages calculated from 36 or more data points equally spaced over each 6-min period, except where the applicable State implementation plan (pursuant to part 51, Appendix M of this chapter) or operating permit requires a different averaging period, in which case the State requirement shall satisfy this Acid Rain Program requirement.

(3) Failure of an SO_2 pollutant concentration monitor, flow monitor, or NO_x continuous emission monitoring system to acquire the minimum number of data points comprising a valid hour, as specified in paragraph (d) of this section shall result in the loss of such component data for the entire hour. The owner or operator shall estimate and record emission or flow data for the missing hour by means of the automated data acquisition and handling system, in accordance with the applicable procedure for missing data substitution in subpart D of this part.

(e) Optional Backup Monitor Requirements. If the owner or operator chooses to certify two or more continuous emission monitors or NO_x continuous emission monitoring systems that are each capable of monitoring a specific affected unit, or group of units using a common stack, then the owner or operator shall designate one such monitor or monitoring system as the primary monitor or monitoring system, and shall record this information in the monitoring plan, as provided for in § 75.53. The owner or operator shall designate the other certified monitor(s) or monitoring system(s) as the backup monitor(s) or monitoring system(s) in the monitoring plan. When the certified primary monitor or certified primary monitoring system is operating and not out-of-control as defined in § 75.24, only data from the certified primary monitor or certified primary monitoring system shall be reported as valid, quality-assured data. Thus, data from the certified backup monitor or certified backup monitoring system may be reported as valid, quality-assured data only when the backup is operating and not out-of-control as defined in § 75.24 *and* when the certified primary monitor or certified primary monitoring system is not operating (or is operating but out-of-control). A particular monitor may be designated both as a certified primary monitor for one unit and as a certified backup monitor for another unit.

(f) Minimum Measurement Capability Requirement. The owner or operator shall ensure that each continuous emission or opacity monitoring system and component thereof is capable of accurately measuring, recording, and reporting data, and shall not incur a full scale exceedance.

(g) Minimum Recording and Reporting Requirements. The owner or operator shall record and the designated representative shall report the hourly, daily, quarterly, and annual information collected under the requirements of this part as specified in subparts F and G of this part.

§ 75.11 Specific provisions for monitoring SO_2 emissions (SO_2 and flow monitors).

(a) *Coal-fired units.* The owner or operator shall meet the general operating requirements in § 75.10 for an SO_2 continuous emission monitoring system for each affected coal-fired unit, except as provided in § 75.16 and in subpart E of this part.

(b) *Moisture correction.* Where SO_2 concentration is measured on a dry basis, the owner or operator shall either:

(1) Install, operate, and maintain a continuous moisture monitor for measuring and recording the moisture content of the flue gases; or

(2) Determine the moisture content of the flue gases continuously (or on an hourly basis) and correct the measured hourly volumetric flow rates for moisture when calculating SO_2 mass emissions (in lb/hr) using the procedures in appendix F of this part.

(c) *Unit with no appropriate location for a flow monitor.* Where no location exists that satisfies the minimum physical siting criteria in appendix A to this part for installation of a flow monitor in either the stack or the ducts serving an affected unit or installation of a flow monitor in either the stack or ducts is demonstrated to the satisfaction of the Administrator to be technically infeasible, the owner or operator must either:

(1) Petition the Administrator for an alternative flow monitor location or alternative method for monitoring volumetric flow; or

(2) Construct a new stack or modify existing ductwork to accommodate the installation of a flow monitor, and petition the Administrator for an extension to the required certification date given in § 75.4 of this part. Phase I affected units may be granted an extension to January 1, 1995, for the submission of the certification application for the purpose of constructing a new stack or making substantial modifications to ductwork for installation of a flow monitor.

(d) *Gas-fired units and oil-fired units.* The owner or operator of an affected gas-fired or oil-fired unit shall measure and record SO_2 emissions using one of the following methods:

(1) Meet the general operating requirements in § 75.10 of this part for an SO_2 continuous emission monitoring system. When the owner or operator uses an SO_2 continuous emission monitoring system to monitor SO_2 mass emissions from an affected unit, the owner or operator shall comply with applicable monitoring provisions in paragraph (a) of this section; or

(2) Provide other information satisfactory to the Administrator using the procedure specified in appendix D to this part for estimating hourly SO_2 mass emissions.

(e) *Other units.* The owner or operator of an affected unit that combusts wood, refuse, or other material in addition to oil or gas shall comply with the monitoring provisions for coal-fired units specified in paragraph (a) of this section.

§ 75.12 Specific provisions for monitoring NO_x emissions (NO_x and diluent gas monitors).

(a) *Coal-fired units, gas-fired nonpeaking units or oil-fired nonpeaking units.* The owner or operator shall meet the general operating requirements in § 75.10 of this part for a NO_x continuous emission monitoring system for each affected coal-fired unit, gas-fired nonpeaking unit, or oil-fired nonpeaking unit, except as provided in paragraph (c) of this section, § 75.17, and in subpart E of this part. The diluent gas monitor in the NO_x continuous emission monitoring system may measure either O_2 or CO_2 concentration in the flue gases.

(b) *Determination of NO_x emission rate.* The owner or operator shall calculate hourly, quarterly, and annual NO_x emission rates (in lb/mmBtu) by combining the NO_x concentration (in ppm) and diluent concentration (in percent O_2 or CO_2) measurements according to the procedures in appendix F of this part.

(c) *Gas-fired peaking units or oil-fired peaking units.* The owner or operator of an affected gas-fired peaking unit or oil-fired peaking unit shall comply with the following:

(1) If a unit's operations in the previous three calendar years are no more than a capacity fact or of 20 percent in each calendar year and no

more than an average capacity factor of 10 percent, then the owner or operator shall measure and record NO_x emissions using one of the following methods:

(i) Meet the general operating requirements in § 75.10 of this part for a NO_x continuous emission monitoring system; or

(ii) Provide information satisfactory to the Administrator using the procedure specified in appendix E of this part for estimating hourly NO_x emission rate.

(2) If a unit's operations in the previous three calendar years exceed a capacity factor of 20 percent in any calendar year or exceed an average capacity factor of 10 percent, the owner or operator shall install, certify, and operate a NO_x continuous emission monitoring system by December 31 of the following calendar year.

(3) When the owner or operator of an affected gas-fired peaking unit or oil-fired peaking unit uses a NO_x continuous emission monitoring system to monitor the NO_x emission rate from the unit, the owner or operator shall comply with the applicable monitoring provisions in paragraph (a) of this section.

(d) *Other units.* The owner or operator of an affected unit that combusts wood, refuse, or other material in addition to oil or gas shall comply with the monitoring provisions specified in paragraph (a) of this section.

§ 75.13 Specific provisions for monitoring CO_2 emissions.

(a) *CO_2 continuous emission monitoring system.* If the owner or operator chooses to use the continuous emission monitoring method, then the owner or operator shall meet the general operating requirements in § 75.10 of this part for a CO_2 continuous emission monitoring system for each affected unit. The owner or operator shall comply with the applicable provisions specified in § 75.11 (a) through (e) or § 75.16 of this part, except that the phrase "SO_2 continuous emission monitoring system" is replaced with "CO_2 continuous emission monitoring system," the term "SO_2 concentration" is replaced with "CO_2 concentration", and the phrase "SO_2 mass emissions" is replaced with "CO_2 mass emissions."

(b) *Determination of CO_2 emissions using Appendix G of this part.* If the owner or operator chooses to use the appendix G method, then the owner or operator may provide information satisfactory to the Administrator for estimating daily CO_2 mass emissions based on the measured carbon content of the fuel and the amount of fuel combusted. For units with wet flue gas desulfurization systems or other add-on emissions controls generating CO_2, the owner or operator shall use the procedures in appendix G to this part to estimate both combustion-related emissions based on the measured carbon content of the fuel and the amount of fuel combusted and sorbent-related emissions based on the amount of sorbent injected. The owner or operator shall calculate daily, quarterly, and annual CO_2 mass emissions (in tons) in accordance with the procedures in appendix G to this part.

(c) *Determination of CO_2 mass emissions using appendix F of this part.* If the owner or operator chooses to use the appendix F method, then the owner or operator may estimate hourly CO_2 mass emissions based on continuous O_2 concentration monitoring, fuel F and F_c factors, and where O_2 concentration is measured on a dry basis, hourly corrections for the moisture content of the flue gases, using the methods and procedures specified in appendix F to this part. For units using a common stack the owner or operator may use the provisions of § 75.16 of this part, except that the phrase "SO_2 continuous emission monitoring system" is replaced with "CO_2 continuous emission monitoring system," the term "SO_2 concentration" is replaced with "CO_2 concentration", and the phrase "SO_2 mass emissions" is replaced with "CO_2 mass emissions."

§ 75.14 Specific provisions for monitoring opacity.

(a) *Coal-fired units and oil-fired units.* The owner or operator shall meet the general operating provisions in § 75.10 of this part for a continuous opacity monitoring system for each affected coal-fired or oil-fired unit, except as provided in paragraphs (b), (c), and (d) of this section and in § 75.18. Each continuous opacity monitoring system shall meet the design, installation, equipment, and performance specifications in Performance Specification 1 in appendix B to part 60 of this chapter. Any continuous opacity monitoring system previously certified to meet Performance Specification 1 shall be deemed certified for the purposes of this part.

(b) *Unit with wet flue gas pollution control system.* If the owner or operator can demonstrate that condensed water is present in the exhaust flue gas stream and would impede the accuracy of opacity measurements, then the owner or operator of an affected unit equipped with a wet flue gas pollution control system for SO_2 emissions or particulates is exempt from the opacity monitoring requirements of this part.

(c) *Gas-fired units.* The owner or operator of an affected gas-fired unit is exempt from the opacity monitoring requirements of this part. Whenever a unit previously categorized as a gas-fired unit is recategorized as another type of unit by changing its fuel mix, the owner or operator shall install, operate, and certify a continuous opacity monitoring system as required by paragraph (a) of this section by December 31 of the following calendar year.

(d) *Diesel-fired units and dual-fuel reciprocating engines units.* The owner or operator of an affected diesel-fired unit or a dual-fuel reciprocating engine unit is exempt from the opacity monitoring requirements of this part.

§ 75.15 Specific provisions for monitoring SO_2 emissions removal by qualifying Phase I technology.

(a) *Additional monitoring provisions.* In addition to the SO_2 monitoring requirements in § 75.11 or § 75.16, for the purposes of adequately monitoring SO_2 emissions removal by qualifying Phase I technology operated pursuant to § 72.42 of this chapter, the owner or operator shall, except where specified below, use both an inlet SO_2-diluent continuous emission monitoring and an outlet SO_2-diluent continuous emission monitoring system, consisting of an SO_2 pollutant concentration monitor and a diluent CO_2 or O_2 monitor. (The outlet SO_2-diluent continuous emission monitoring system may consist of the same SO_2 pollutant concentration monitor that is required under § 75.11 or § 75.16 for the measurement of SO_2 emissions discharged to the atmosphere and the diluent monitor used as part of the NO_x continuous emission monitoring system that is required under § 75.12 or § 75.17 for the measurement of NO_x emissions discharged into the atmosphere.) During the period when required to measure emissions removal efficiency, from January 1, 1997 through December 31, 1991, the owner or operator shall meet the general operating requirements in § 75.10 of this part for both the inlet and the outlet SO_2-diluent continuous emission monitoring systems, and in addition, the owner or operator shall comply with the monitoring provisions in this section. On January 1, 2000, the owner or operator may cease operating and/or reporting on the inlet SO_2-diluent continuous emission monitoring system results for the purposes of the Acid Rain Program.

(1) *Pre-combustion technology.* The owner or operator of an affected unit for which a precombustion technology has been employed for the purpose of

meeting qualifying Phase I technology requirements shall use Reference Method 19 in appendix A to part 60 of this chapter to estimate, daily, the percentage SO_2 removal efficiency from such technology.

(2) *Combustion technology.* The owner or operator of an affected unit for which a combustion technology has been installed and operated for the purpose of meeting qualifying Phase I technology requirements shall use the coal sampling and analysis procedures in appendix F to this part and Equation 5 in paragraph (b) of this section to estimate the percentage SO_2 removal efficiency from such technology.

(3) *Post-combustion technology.* The owner or operator of an affected unit for which a post-combustion technology has been installed and operated for the purpose of meeting qualifying Phase I technology requirements shall install, certify, operate, and maintain both an inlet and an outlet SO_2-diluent continuous emission monitoring system.

(i) Both inlet and outlet SO_2-diluent continuous emission monitoring systems shall consist of an SO_2 pollutant concentration monitor and a diluent gas monitor for measuring the O_2 or CO_2 concentrations in the flue gas and shall measure and record average hourly SO_2 emission rates (in lb/mmBtu).

(ii) The SO_2-diluent continuous emission monitoring systems for measuring and recording the SO_2 emissions removal by a qualifying Phase I technology shall meet all the requirements of this part during the period when required to measure emissions removal, from January 1, 1997 through December 31, 1999, and shall meet the certification deadline specified in § 75.4.

(iii) The SO_2 pollutant concentration monitors and the diluent gas monitors at the inlet the outlet of the SO_2 emission controls shall meet all requirements specified in appendices A and B to this part.

(b) *Demonstration of SO^2 emissions removal efficiency.* The owner or operator shall demonstrate the average annual percentage SO_2 emissions removal efficiency of the installed technology or combination of technologies during the period when required to measure emissions removal, from January 1, 1997 through December 31, 1999, according to the following procedures:

(1) Calculate the average annual SO_2 emissions removal efficiency using Equations 1–7 as follows:

$$\%R = 100\{1.0-(1.0-\%R_f/100)\,(1.0-\%R_s/100)\,(1.0-\%R_c/100)\}$$ (*Eq.*1)

where,

%R = Overall percentage SO_2 emissions removal efficiency.

$\%R_f$ = Percentage SO_2 emissions removal efficiency from fuel pretreatment, calculated from Equation 19–22 in Reference Method 19 in Appendix A to part 60 of this chapter.

$\%R_c$ = Percentage SO_2 emissions removal of combustion emission controls, calculated from Equation 5.

$\%R_s$ = Percentage SO_2 removal efficiency of post-combustion emission controls, calculated from Equation 2.

$$\%R_s = 100\left[1.0-\frac{E_o}{E_i}\right]$$

(Eq.2)

where,

E_o=Average hourly SO_2 emission rate in lb/mmBtu, measured at the outlet of the post-combustion emission controls during the calendar year, calculated from Equation 3.

E_i=Average hourly SO_2 emission rate in lb/mmBtu, measured at the inlet to the post-combustion emission controls during the calendar year, calculated from Equation 4.

$$E_o = \frac{\sum_{j=1}^{n} E_{hoj}}{n}$$

(Eq. 3)

where,

E_{hoj}=Each hourly SO_2 emission rate in lb/mmBtu, measured by the continuous emission monitoring system at the outlet to the post-combustion emission controls.

n=Total unit operating hours during which the SO_2 continuous emission monitoring system at the outlet of the emission controls collected quality-assured data.

$$E_i = \frac{\sum_{j=1}^{m} E_{hij}}{m}$$

(Eq. 4)

where,

E_{hij}=Each hourly SO_2 emission rate in lb/mmBtu, measured by the continuous emission monitoring system at the inlet to the post-combustion emission controls.

m=Total unit operating hours during which the SO_2 continuous emission monitoring system at the inlet to the emission controls collected quality-assured data.

$$\%R_c = 100\left[1.0-\frac{E_{co}}{E_{ci}}\right]$$

(Eq. 5)

where,

E_{co}=Average hourly SO_2 emission rate in lb/mmBtu, measured at the outlet of the combustion emission controls during the calendar year, calculated from Equation 6.

E_{ci}=Average hourly SO_2 emission rate in lb/mmBtu, determined by coal sampling and analysis according to the methods and procedures in Appendix G, Section 2.5.4 of this part, calculated from Equation 7.

$$E_{co} = \frac{\sum_{j=1}^{q} E_{ocj}}{q}$$

(Eq. 6)

where,

E_{ocj}=Each hourly SO_2 emission rate in lb/mmBtu, measured by the continuous emission monitoring system at the outlet to the combustion controls.

q=Total unit operating hours for which the outlet SO_2 continuous emission monitoring system collected quality-assured data during the calendar year.

$$E_{ci} = \frac{\sum_{j=1}^{p} E_{icj}}{p}$$

(Eq. 7)

where,

E_{icj}=Each average hourly SO_2 emission rate in lb/mmBtu, determined by the coal sampling and analysis methods and procedures in Appendix G, Section 2.5.4 of this part and calculated using Appendix A, Method 19 of part 60 of this chapter, performed once a day.

p=Total unit operation hours during which coal sampling and analysis is performed to determine SO_2 emissions at the inlet to the combustion controls.

(2) The owner or operator shall include all periods when fuel is being combusted in determining total unit operating hours for the purpose of calculating the average SO_2 emissions removal efficiency during the calendar year.

(3) The owner or operator shall use only quality-assured SO_2 emissions data in the calculation of SO_2 emissions removal efficiency.

(4) Compliance with the 90-percent SO_2 emissions removal efficiency requirement under this part is

determined annually beginning January 1, 1997 through December 31, 1999.

§ 75.16 Special provisions for monitoring emissions from common by-pass, and multiple stacks for SO_2 emissions and heat input determinations.

(a) *Phase I common stack procedures.* During Phase I of the Acid Rain Program, the following procedures shall be used when more than one unit utilize a common stack:

(1) *Unit utilizing common stack with other Phase I units(s).* When a Phase I affected unit uses a common stack with one or more other Phase I affected units, but no other units, the owner or operator shall either:

(i) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the duct to the common stack from each affected unit; or

(ii) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the common stack; and

(A) Combine emissions for the affected units for compliance purposes; or

(B) Develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning SO_2 mass emissions measured in the common stack to each of the Phase I affected units. The Administrator may approve such demonstrated substitute methods for apportioning SO_2 mass emissions measured in a common stack whenever the demonstration ensures complete and accurate accounting of all emissions regulated under this part.

(2) *Unit utilizing common stack with non-Phase I unit(s).* When one or more Phase I affected units uses a common stack with one or more Phase II or nonaffected units, the owner or operator shall either:

(i) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the duct to the common stack from each Phase I unit; or

(ii) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the common stack; and

(A) Designate the Phase II units as substitution units according to the procedure in part 72 of this chapter and the nonaffected units as opt-in units in accordance with the regulations implementing section 410 of the Act and combine emissions for compliance purposes; or

(B) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the duct from each Phase II or nonaffected unit; determine SO_2 mass emissions from the affected units as the difference between SO_2 mass emissions measured in the common stack and SO_2 mass emissions measured in the ducts of the Phase II and/or nonaffected units; and combine emissions for the Phase I affected units for compliance purposes; or

(C) Develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning SO_2 mass emissions measured in the common stack to each of the units using the common stack. The Administrator may approve such demonstrated substitute methods for apportioning SO_2 concentration measured in a common stack whenever the demonstration ensures complete and accurate accounting of all emissions regulated under this part.

(b) *Phase II common stack procedures.* During Phase II of the Acid Rain Program, the following procedures shall be used when more than one unit use a common stack:

(1) *Unit utilizing common stack with other affected units(s).* When a Phase I or Phase II affected unit utilizes a common stack with one or more other Phase I or Phase II affected units, but no nonaffected units, the owner or operator shall either:

(i) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the duct to the common stack from each affected unit; or

(ii) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the common stack; and

(A) Combine emissions for the affected units for compliance purposes; or

(B) Develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning SO_2 mass emissions measured in the common stack to each of the Phase I and Phase II affected units. The Administrator may approve such demonstrated substitute methods for apportioning SO_2 mass emissions measured in a common stack whenever the demonstration ensures complete and accurate accounting of all emissions regulated under this part.

(2) *Unit utilizing common stack with nonaffected unit(s).* When one or more Phase I or Phase II affected units utilizes a common stack with one or more nonaffected units, the owner or operator shall either:

(i) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the duct to the common stack from Phase I and Phase II unit; or

(ii) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the common stack; and

(A) Designate the nonaffected units as opt-in units in accordance with the regulations implementing section 410 of the Act and combine emissions for compliance purposes; or

(B) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in the duct from each nonaffected unit; determine SO_2 mass emissions from the affected units as the difference between SO_2 mass emissions measured in the common stack and SO_2 mass emissions measured in the ducts of the nonaffected units; and combine emissions for the Phase I and Phase II affected units for compliance purposes; or

(C) Develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning SO_2 mass emissions measured in the common stack to each of the units using the common stack. The Administrator may approve such demonstrated substitute methods for apportioning SO_2 concentration measured in a common stack whenever the demonstration ensures complete and accurate accounting of all emissions regulated under this part.

(c) *Unit with by-pass stack.* When any portion of the flue gases from an affected unit can be routed so as to avoid the installed SO_2 continuous emission monitoring system, the owner or operator shall install, certify, operate, and maintain an SO_2 continuous emission monitoring system on the by-pass flue, duct, or stack gas stream.

(d) *Unit with multiple stacks.* When the flue gases from an affected unit utilize two or more ducts feeding into two or more stacks (that may include flue gases from other affected or nonaffected units), the owner or operator shall either:

(1) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in each duct feeding into the stacks and determine SO_2 mass emissions from each affected unit as the sum of the SO_2 mass emissions measured in the ducts; or

(2) Install, certify, operate, and maintain an SO_2 continuous emission monitoring system in each stack and develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning measured SO_2 mass emissions to each affected unit. The Administrator may approve such demonstrated substitute methods for

apportioning measured SO_2 mass emissions from multiple stacks whenever the demonstration ensures complete and accurate accounting of all emissions regulated by this part.

(e) *Heat Input.* The owner or operator of an affected unit using a common stack with a diluent monitor and a flow monitor may choose to determine the heat input for the affected unit, wherever flow and diluent monitor measurements are used to determine the heat input, using the procedures specified in paragraphs (a) through (d) of this section, except that the terms "SO_2 mass emissions" or "emissions" are replaced with the term "heat input" and the phrase "SO_2 continuous emission monitoring system" is replaced with the phrase "a diluent monitor and a flow monitor".

§ 75.17 Specific provisions for monitoring emissions from common, by-pass, and multiple stacks for NO_x emission rate.

(a) *Unit utilizing common stack with other affected unit(s).* When an affected unit utilizes a common stack with one or more affected units, but no nonaffected units, the owner or operator shall either:

(1) Install, certify, operate, and maintain a NO_x continuous emission monitoring system in the duct to the common stack from each affected unit; or

(2) Install, certify, operate, and maintain a NO_x continuous emission monitoring system in the common stack and follow the appropriate procedure in paragraphs (a)(2) (i) through (iii) of this section, depending on whether or not the units are required to comply with a NO_x emission limitation (in lb/mmBtu, annual average basis) pursuant to section 407(b) of the Act (referred to hereafter as "NO_x emission limitation").

(i) When each of the affected units has a NO_x emission limitation, the designated representative shall submit a compliance plan to the Administrator that indicates:

(A) Each unit will comply with the most stringent NO_x emission limitation of any unit utilizing the common stack; or

(B) Each unit will comply with the applicable NO_x emission limitation by averaging its emissions with the other unit(s) utilizing the common stack.

(ii) When none of the affected units has a NO_x emission limitation, the owner or operator and the designated representative have no additional obligations pursuant to section 407 of the Act and may record and report a combined NO_x emission rate (in lb/mmBtu) for the affected units utilizing the common stack.

(iii) When at least one of the affected units has a NO_x emission limitation and at least one of the affected units does not have a NO_x emission limitation, the owner or operator shall either:

(a) Install, certify, operate, and maintain NO_x and diluent monitors in the ducts from the affected units; or

(B) Develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning the combined NO_x emission rate (in lb/mmBtu) measured in the common stack on each of the units. The Administrator may approve such demonstrated substitute methods for apportioning NO_x emission rate measured in a common stack whenever the demonstration ensures complete and accurate estimation of all emissions regulated under this part.

(b) *Unit utilizing common stack with nonaffected units(s).* When one or more affected units utilizes a common stack with one or more nonaffected units, the owner or operator shall either:

(1) Install, certify, operate, and maintain a NO_x continuous emission monitoring system in the duct from each affected unit; or

(2) Develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning the combined NO_x emission rate (in lb/mmBtu) measured in the common stack for each of the units. The Administrator may approve such demonstrated substitute methods for apportioning NO_x emission rate measured in a common stack whenever the demonstration ensures complete and accurate estimation of all emissions regulated under this part.

(c) *Unit with by-pass stack.* When any portion of the flue gases from an affected unit can be routed so as to by-pass the installed NO_x continuous emission monitoring system, the owner or operator shall install, certify, operate, and maintain a NO_x continuous emission monitoring system on the by-pass flue, duct, or stack gas stream.

(d) *Unit with multiple stacks.* When the flue gases from an affected unit utilize two or more ducts feeding into two or more stacks (that may include flue gases from other affected or nonaffected units), the owner or operator shall either:

(1) Install, certify, operate, and maintain a NO_x continuous emission monitoring system in each duct feeding into the stacks and determine the NO_x emission rate for the unit as the Btu-weighted sum of the NO_x emission rates measured in the ducts using the heat input estimation procedures in appendix F to this part; or

(2) Install, certify, operate, and maintain a NO_x continuous emission monitoring system in each stack and develop, demonstrate, and provide information satisfactory to the Administrator on methods for apportioning measured NO_x emission rates to each affected unit. The Administrator may approve such demonstrated substitute methods for apportioning measured NO_x emission rates from multiple stacks whenever the demonstration ensures complete and accurate accounting of all emissions regulated by this part.

§ 75.18 Specific provisions for monitoring emissions from common and by-pass stacks for opacity.

(a) *Unit using common stack.* When an affected unit utilizes a common stack with other affected units or nonaffected units, the owner or operator shall comply with the applicable monitoring provision in this paragraph, as determined by existing Federal, State, or local opacity regulations.

(1) Where another regulation requires the installation of a continuous opacity monitoring system upon each affected unit, the owner or operator shall install, certify, operate, and maintain a continuous opacity monitoring system meeting Performance Specification 1 in appendix B to part 60 of this chapter (referred to hereafter as a "certified continuous opacity monitoring system") upon each unit.

(2) Where another regulation does not require the installation of a continuous opacity monitoring system upon each affected unit, and where the affected source is not subject to any existing Federal, State, or local opacity regulations, the owner or operator shall install, certify, operate, and maintain a certified continuous opacity monitoring system upon each common stack for the combined effluent.

(b) *Unit with by-pass stack.* Where any portion of the flue gases from an affected unit can be routed so as to by-pass the installed continuous opacity monitoring system, the owner or operator shall install, certify, operate, and maintain a continuous opacity monitoring system on the by-pass flue, duct, or stack gas stream.

Subpart C—Operation and Maintenance Requirements

§ 75.20 Certification and recertification procedures.

(a) *Initial certification approval process.* The owner or operator shall ensure that each continuous emission or opacity monitoring system required by this part, the automated data acquisition and handling system, and, where

applicable, the CO_2 continuous emission monitoring system meets the certification requirements of this section by the deadlines specified in § 75.4 of this part and prior to use in the Acid Rain Program.

(1) *Notificaiton of certification test dates or certification retesting dates.* The owner or operator or designated representative shall submit a written notice of the dates of certification testing at least 45 calendar days prior to the first day of certification testing, as specified in §§ 75.60 and 75.61.

(i) Except as provided in paragraph (a)(1)(ii) of this section, the owner or operator or designated representative shall also submit notification (or provide notification by telephone) at least 7 business days in advance of any proposed adjustments to the certification test dates.

(ii) The owner or operator may elect to repeat a certification test immediately, without advance notification, whenever the owner or operator has determined during the certification testing that a continuous emission or opacity monitoring system or component thereof has failed the test.

(2) *Certification Application.* The designated representative shall apply for certification of each continuous emission or opacity monitoring system used under the Acid Rain Program. The designated representative shall submit the certification application in accordance with § 75.60 and each complete certification application shall include the information specified in § 75.63 of this part.

(3) *Provisional approval of certification applications.* Upon the successful completion of the required certification procedures for each continuous emission or opacity monitoring system or component thereof and subsequent submittal of a complete certification application in accordance with § 75.63, each continuous emission or opacity monitoring system or component thereof shall be deemed provisionally certified for use under the Acid Rain Program for a period not to exceed 120 days following receipt by the Administrator of the complete certification application. Data measured and recorded by a provisionally certified continuous emission or opacity monitoring system or component thereof, in accordance with the requirements of appendix B of this part, will be considered valid quality-assured data (retroactive to the date and time of completion of the certification tests), provided that the Administrator does not invalidate the provisional certification by issuing a notice of disapproval within 120 days of receipt of the complete certification application.

(4) *Certification application formal approval process.* The Administrator will issue a written notice of certification application status to the owner or operator within 120 days of receipt of the complete certification application. In the event the Administrator does not issue a written notice of certification application status within 120 days of receipt, each continuous emission or opacity monitoring system which meets the performance requirements of this part and is included in the certification application will be deemed certified for use under the Acid Rain Program.

(i) *Approval notice.* If the certification application is complete and shows that each continuous emission or opacity monitoring system meets the performance requirements of this part, then the Administrator will issue a written notice of approval of the certification application within 120 days of receipt.

(ii) *Incomplete application notice.* If the certification application is not complete, then the Administrator will issue a written notice of insufficiency. The 120-day review period shall not begin prior to receipt of a complete application.

(iii) *Disapproval notice.* If the certification application is complete but shows that any continuous emission or opacity monitoring system or component thereof does not meet the performance requirements of this part, the Administrator shall issue a written notice of disapproval of the certification application within 120 days of receipt. By issuing the notice of disapproval, the provisional certification is invalidated by the Administrator, and the data measured and recorded by each uncertified continuous emission or opacity monitoring system or component thereof shall not be considered valid quality-assured data from the date and time of completion of the invalid certification tests until the date and time that the owner or operator completes subsequently approved initial certification tests. The owner or operator shall follow the loss of certification procedures in paragraph (a)(5) of this section to replace all of the invalid data for each continuous emission or opacity monitoring system or component which was disapproved.

(iv) *Audit decertifications.* Whenever an audit of a continuous emission or opacity monitoring system or component thereof or of the certification application reveals that any continuous emission or opacity monitoring system or component does not meet the performance requirements of this part (after the initial 120-day certification application review period), the Administrator may issue a notice of disapproval of the certification status of such system or component. By issuing the notice of disapproval, the certification status is invalidated, prospectively, by the Administrator, and the data measured and recorded by each continuous emission or opacity monitoring system from the date of the notification of the invalid certification status until the date and time that the owner or operator completes subsequently approved initial certification tests shall not be considered valid quality-assured data. The owner or operator shall follow the loss of certification procedures in paragraph (a)(5) of this section to replace, prospectively, all of the invalid data for each continuous emission or opacity monitoring system or component which was disapproved.

(5) *Loss of Certification Procedures.* When the Administrator issues a notice of disapproval of a certification application or a notice of disapproval of certification status, then for the period of invalid data (as specified in paragraph (a)(4) of this section), the owner or operator shall:

(i) Use the maximum potential concentration of SO_2 or NO_x, or the maximum potential velocity, as defined in section 2.1 of appendix A of this part, or the minimum O_2 concentration or maximum CO_2 concentration used to determine the maximum potential concentration of SO_2 in section 2.1.1.1 of appendix A of this part to report SO_2 concentration, NO_x concentration, calculate and report volumetric flow rate, or O_2 or CO_2 concentration data until such time, date, and hour as the continuous emission monitoring system or component thereof can be adjusted, repaired, or replaced and certification tests successfully completed (a subsequently approved initial certification); and

(ii) Ensure that the owner or operator or designated representative submits a notification of certification test dates and a new certification application according to the procedures in paragraphs (a)(1)(ii) and (a)(2) of this section, where the notification shall be provided no later than 2 business days prior to retesting for certification.

(b) *Recertification approval process.* Whenever the owner or operator makes a replacement, modification, or change in the certified continuous emission monitoring system or continuous opacity monitoring system, including the automated data acquisition and

handling system, that significantly affects the ability of the system to measure or record the SO_2 concentration, volumetric gas flow, SO_2 mass emissions, NO_x emission rate, CO_2 concentration, or opacity, the owner or operator shall recertify the continuous emission monitoring system, continuous opacity monitoring system, or component according to the procedures in this paragraph. Replacement of the analytical method, including the analyzer; change in location or orientation of the sampling probe or site; rebuilding of equipment; and analytical modifications to computer algorithms in software systems require recertification. Furthermore, whenever the owner or operator makes a replacement, modification, or change to the flue gas handling system that significantly affects the ability of the CEM or COM or component thereof to measure or record SO_2, NO_x, CO_2, or opacity emissions, the owner or operator shall recertify the CEM or COM or component according to the procedures in this paragraph. Recertification is not required in cases where all of the following conditions have been met: a continuous emission monitoring system has previously been certified with the same sampling location; all components of the continuous emissions monitoring system have previously been certified; and component monitors that have changed location (i.e., certified portable monitors) pass a linearity check (for pollutant concentration monitors) or a calibration error test (for flow monitors) prior to their use for monitoring of emissions or flow.

However, changes resulting from routine or normal corrective maintenance and/or quality assurance activities do not require recertification, nor do software modifications in the automated data acquisition and handling system, where the modification is only for the purpose of generating additional or modified reports for the State Implementation Plan or for reporting requirements under subpart G of this part.

(1) *Notification of recertification test dates.* For a recertification test, the owner or operator or designated representative shall submit the notification in accordance with the provisions in paragraph (a)(1) of this section except when recertification testing results from an emergency situation, in which case, the owner or operator or designated representative may submit notice (or provide notification by telephone) no later than 2 business days following the emergency, identifying when the testing has been or will be completed.

(2) *Recertification application.* The designated representative shall apply for recertification of a continuous emission or opacity monitoring system used under the Acid Rain Program according to the procedures in paragraph (a)(2) of this section.

(3) *Approval/disapproval of request for recertification.* The Administrator will grant provisional approval according to the procedure in paragraph (a)(3) of this section and will issue a written notice of approval or disapproval according to the procedures in paragraphs (a)(4) and (a)(5) of this section, the period for provisional certification shall not exceed 60 days following receipt of the complete recertification application by the Administrator, because the Administrator will issue a written notice of approval or disapproval within 60 days of receipt.

(c) *Certification procedures.* Prior to the deadline in § 75.4 of this part, the owner or operator shall conduct certification tests and in accordance with § 75.63, the designated representative shall submit an application to demonstrate that the continuous emission or opacity monitoring system and components meet the specifications in appendix A to this part. The owner or operator shall compare reference method values with output from the automated data acquisition and handling system that is part of the continuous emission monitoring system being tested. Except as specified in paragraphs (d) and (e) of this section, the owner or operator shall perform the following tests for certification or recertification of continuous emission or opacity monitoring systems or components according to the requirements of appendix A to this part:

(1) For each SO_2 pollutant concentration monitor and NO_x continuous emission monitoring system:

(i) A 7-day calibration error test, where, for the NO_x continuous emission monitoring system, this test is performed separately on the NO_x pollutant concentration monitor and the diluent gas monitor;

(ii) A linearity check, where, for the NO_x continuous emission monitoring system, this check is performed separately on the NO_x pollutant concentration monitor and the diluent gas monitor;

(iii) A relative accuracy test audit;

(iv) A bias test; and

(v) A cycle time/response time test.

(2) For each flow monitor:

(i) A 7-day calibration error test;

(ii) Relative accuracy test audits at three flue gas velocities;

(iii) A bias test (at normal operating load); and

(3) The relative accuracy test audits for the SO_2 pollution concentration monitor and the flow monitor shall be performed contemporaneously.

(4) A CO_2 diluent gas monitor certified for use in a NO_x continuous emission monitoring system shall be deemed certified for the purposes of § 75.10(a)(3).

(5) For each CO_2 pollutant concentration monitor which is not certified as part of a NO_x continuous emission monitoring system and for each SO_2-diluent continuous emission monitoring system:

(i) A 7-day calibration error test, where, for the SO_2-diluent system, this test is performed separately on each component monitor;

(ii) A linearity check, where, for the SO_2 diluent system, this check is performed separately on each component monitor;

(iii) A relatively accuracy test audit; and

(6) The owner or operator shall ensure that certification or recertification of a continuous opacity monitor for use under the Acid Rain Program is conducted according to one of the following procedures:

(i) Performance of the following tests for certification or recertification, according to the requirements of Performance Specification 1 in appendix B to part 60 of this chapter.

(ii) A continuous opacity monitoring system tested and certified previously under State or other federal requirements to meet the requirements of Performance Specification 1 shall be deemed certified for the purposes of this part.

(7) For the automated data acquisition and handling system, tests designed to verify:

(i) Proper computation of hourly averages for pollutant concentrations, flow rate, pollutant emission rates, and pollutant mass emissions; and

(ii) Proper computation and application of the missing data substitution procedures in subpart D of this part and the bias adjustment factors in Section 7 of appendix A to this part.

(8) When the optional SO_2 mass emissions estimation procedure in appendix D to this part or the optional NO_x emissions estimation protocol in appendix E of this part is used, the owner or operator shall provide data from a calibration test for each fuel flowmeter according to the appropriate calibration procedures among the following ASME methods: ASME MFC–

3M–1989 with September 1990 Errata, "Measurement of Fluid Flow in Pipes Using Orifice, Nozzle, and Venturi", ASME MFC–4M–1986 (Reaffirmed 1990) "Measurement of Gas Flow by Turbine Meters", ASME MFC–5M–1985 "Measurement of Liquid Flow in Closed Conduits Using Transit-Time Ultrasonic Flowmeters", ASME MFC–6M–1987 with June 1987 Errata, "Measurement of Fluid Flow in Pipes Using Vortex Flow Meters", ASME MFC–7M–1987 (Reaffirmed 1992), "Measurement of Gas Flow by Means of Critical Flow Venturi Nozzles", or ASME MFC–9M–1988 with December 1989 Errata, "Measurement of Liquid Flow in Closed Conduits by Weighing Method", as required by appendices D and E of this part (all methods incorporated by reference under § 75.6 of this part).

(9) The owner or operator shall provide, or cause to be provided, adequate facilities for certification or recertification testing that include:

(i) Sampling ports adequate for test methods applicable to such facility, including:

(A) Volumetric flow rates, pollutant concentration, and pollutant emission rates can be accurately determined by applicable test methods and procedures; and

(B) A stack or duct free of cyclonic flow during performance tests, as demonstrated by applicable test methods and procedures.

(ii) Basic facilities (i.e. electricity) for sampling and testing equipment.

(d) *Certification/recertification procedures for optional backup or portable continuous emission monitoring systems.* The owner or operator of an optional backup or an optional portable continuous emission monitoring system shall comply with all the requirements for initial certification and recertification according to the procedures specified in paragraphs (a) and (c) of this section for each backup or portable continuous emission monitoring system, except as follows: the owner or operator of a backup or portable continuous emission monitoring system may omit the 7-day calibration error test for certification or recertification of an SO_2 pollutant concentration monitor, flow monitor, NO_x pollutant concentration monitor, or diluent gas monitor, provided the backup or portable system is not used for reporting on affected unit(s) for more than 720 hours in any calendar year. Prior to each use for recording and reporting emissions, the owner or operator shall ensure that the certified backup or portable continuous emission monitoring system passes a linearity check (for pollutant concentration monitors) or a calibration error test (for flow monitors). The owner or operator shall comply with all the requirements for recertification of the backup or portable continuous emission monitoring system according to the procedures specified in paragraph (b) of this section (except that the 7-day calibration error test may be omitted) once every other year. However, when a backup or portable system is used for reporting more than 720 hours in one calendar year, it becomes a primary continuous emission monitoring system; then the owner or operator must ensure that the monitor or continuous emission monitoring system, previously considered as backup or portable, has passed all required certification tests, including the 7-day calibration error test, before valid data may be reported for more than 720 hours from any affected unit in a calendar year. Nevertheless, a portable monitor that qualifies as a reference monitor pursuant to the requirements of 40 CFR part 60, appendix A, need not be recertified prior to its use pursuant to paragraph (d) of this section.

(e) *Certification/recertification procedures for either peaking unit or by-pass stack/duct continuous emission monitoring systems.* The owner or operator of either a peaking unit or by-pass stack/duct continuous emission monitoring system shall comply with all the requirements for certification or recertification according to the procedures specified in paragraphs (a), (b), and (c) of this section, except as follows: the owner or operator need only perform one Nine-run relative accuracy test audit for certification or recertification of a flow monitor installed on the by-pass stack/duct or on the stack/duct used only by affected peaking unit(s). The relative accuracy test audit shall be performed during normal operation of the peaking unit(s) or the by-pass stack/duct.

(f) *Certification/recertification procedures for alternative monitoring systems.* The designated representative representing the owner or operator of each alternative monitoring system approved by the Administrator as equivalent to or better than a continuous emission monitoring system according to the criteria in subpart E of this part shall apply for certification to the Administrator prior to use of the system under the Acid Rain Program, and shall apply for recertification to the Administrator following a replacement, modification, or change according to the procedures in paragraph (c) of this section. The owner or operator of an alternative monitoring system shall comply with the notification and application requirements for certification or recertification according to the procedures specified in paragraphs (a) and (b) of this section.

(1) The Administrator will publish each request for initial certification of an alternative monitoring system in the **Federal Register** and, following a public comment period of 60 days, will issue a notice of approval or disapproval.

(2) No alternative monitoring system shall be authorized by the Administrator in a permit issued pursuant to part 72 of this chapter unless approved by the Administrator in accordance with this part.

(g) *Certification procedures for approved exceptions to CEMS.* The owner or operator of a gas-fired unit, oil-fired unit, or diesel-fired unit shall ensure that any measurement method used in lieu of a CEMS meets the general operating requirements of this part and of appendices D and E to this part, and the designated representative shall submit a certification application by the deadlines specified in § 75.4 of this part and prior to use in the Acid Rain Program.

§ 75.21 Quality assurance and quality control requirements.

(a) *Continuous emission monitoring systems.* The owner or operator of an affected unit shall operate, calibrate, and maintain each continuous emission monitoring system used under the Acid Rain Program according to the quality assurance and quality control procedures in appendix B of this part.

(b) *Continuous opacity monitoring systems.* The owner or operator of an affected unit shall operate, calibrate, and maintain each continuous opacity monitoring system used under the Acid Rain Program according to the procedures specified for State Implementation Plans, pursuant to part 51, appendix M of this chapter.

(c) *Calibration gases.* The owner or operator shall ensure that all calibration gases used to quality assure the operation of the instrumentation required by this part shall meet the definition in § 72.2 of this chapter.

§ 75.22 Reference test methods.

(a) The owner or operator shall use the following methods included in appendix A to part 60 of this chapter to conduct monitoring system tests for certification or recertification of continuous emission monitoring systems and quality assurance and quality control procedures.

(1) Methods 1, or 1A are the reference methods for selection of sampling site and sample traverses.

(2) Methods 2, 2A, 2C, or 2D are the reference methods for determination of volumetric flow.

(3) Methods 3, 3A, or 3B are the reference methods for the determination of the dry molecular weight O_2 and CO_2 concentrations in the emissions.

(4) Method 4 is the reference method for the determination of moisture in the stack.

(5) Methods 6, 6A, 6B or 6C, and 7, 7A, 7C, 7D or 7E, as applicable, are the reference methods for determining SO_2 and NO_x pollutant concentrations. (Methods 6A and 6B may also be used to determine SO_2 emission rate in lb/mmBtu.)

(6) Method 20 is the reference method for determining NO_x and diluent emissions from stationary gas turbines.

§ 75.23 Alternatives to ASTM methods.

(a) The designated representative of a unit may petition the Administrator for an alternative to any ASTM method prescribed in this part.

(b) The designated representative shall include the following information in the petition for use of an alternative method:

(1) A description of why the prescribed ASTM method is not being used or cannot be used;

(2) A description and diagram(s) of all equipment and procedures in the proposed alternative method;

(3) Data demonstrating that the proposed alternative method produces data of equal or greater precision and accuracy to that from the prescribed ASTM method(s).

§ 75.24 Out-of-control periods.

(a) If an out-of-control period occurs to a monitor or continuous emission monitoring system, the owner or operator shall take corrective action and repeat the tests applicable to the "out-of-control parameter" as described in appendix B of this part.

(1) For daily calibration error tests, an out-of-control period occurs when the calibration error of a pollutant concentration monitor exceeds 5.0 percent based upon the span value, the calibration error of a diluent gas monitor exceeds 1.0 percent O_2 or CO_2, or the calibration error of a flow monitor exceeds 6.0 percent based upon the span value, which is twice the applicable specification in Appendix A to this part.

(2) For quarterly linearity checks, an out-of-control period occurs when the error in linearity at any of three gas concentrations (low, mid-range, and high) exceeds the applicable specification in appendix A to this part.

(3) For relative accuracy test audits, an out-of-control period occurs when the relative accuracy exceeds the applicable specification in Appendix A to this part.

(b) When a monitor or continuous emission monitoring system is out-of-control, any data recorded by the monitor or monitoring system are not quality-assured and shall not be used in calculating monitor data availabilities pursuant to § 75.32 of this part.

(c) When a monitor or continuous emission monitoring system is out-of-control, the owner or operator shall take one of the following actions until the monitor or monitoring system has successfully met the relevant criteria in appendices A and B of this part as demonstrated by subsequent tests:

(1) Apply the procedures for missing data substitution to emissions from affected unit(s); or

(2) Use a certified backup or certified portable monitor or monitoring system or a reference method for measuring and recording emissions from the affected unit(s); or

(3) Adjust the gas discharge paths from the affected unit(s) with emissions normally observed by the out-of-control monitor or monitoring system so that all exhaust gases are monitored by a certified monitor or monitoring system meeting the requirements of appendices A and B of this part.

(d) When the bias test indicates a monitor or monitoring system is biased low (i.e., the arithmetic mean of the differences between the reference method value and the monitor or monitoring system measurements in a relative accuracy test audit exceed the bias statistic in section 7 of appendix A to this part), the owner or operator shall adjust the monitor or continuous emission monitoring system to eliminate the cause of bias such that it passes the bias test or calculate and use the bias adjustment factor as specified in section 2.3.3 of appendix B to this part and in accordance with § 75.7.

(e) The owner or operator shall determine if a continuous opacity monitoring system is out-of-control and shall take appropriate corrective actions according to the procedures specified for State Implementation Plans, pursuant to 40 CFR part 51, appendix M. When repeated out-of-control periods occur to a continuous opacity monitoring system, causing the monitor data availability of the system to fall below 90.0 percent, the owner or operator shall either:

(1) Use a certified backup continuous opacity monitoring system for measuring and recording opacity from the affected unit(s); or

(2) Use the procedures in Method 9 in appendix A to part 60 of this chapter to measure the opacity of emissions discharged to the atmosphere from the affected unit(s).

Subpart D—Missing Data Substitution Procedures

§ 75.30 General provisions.

(a) Except as provided in § 75.34 of this subpart, the owner or operator shall provide substitute data for each affected unit according to the missing data procedures in this subpart whenever the unit combusts any fuel and:

(1) A valid hour of SO_2 concentration data (in ppm) has not been measured and recorded for an affected unit by a certified SO_2 pollutant concentration monitor, or by an approved alternative monitoring method under subpart E of this part; or

(2) A valid hour of flow data (in scfh) has not been measured and recorded for an affected unit from a certified flow monitor, or by an approved alternative monitoring system under subpart E of this part; or

(3) A valid hour of NO_x emission rate data (in lb/mmBtu) has not been measured and recorded for an affected unit by a certified NO_x continuous emission monitoring system, or by an approved alternative monitoring system under subpart E of this part.

(b) However, the owner or operator shall have no need to provide substitute data according to the missing data procedures in this subpart if the owner or operator uses SO_2 concentration, flow, or NO_x emission rate data recorded from a certified backup or certified portable continuous emission monitor or a reference method when the certified primary monitor is down or out-of-control, provided that the backup or portable monitor has been certified according to the procedures in § 75.20 of this part prior to the missing data period, and provided that the backup or portable monitor passes a linearity check (for pollutant concentration monitors) or a calibration error test (for flow monitors) prior to each period of use of the certified backup monitor or certified portable monitor for recording and reporting emissions. Such use of certified portable monitor, certified backup monitor, or reference method is optional and at the discretion of the owner or operator.

(c) When the certified primary monitor is down or out-of-control, then data recorded for an affected unit from a certified backup or certified portable continuous emission monitor are used, as if such data were from the certified primary monitor, to calculate monitor data availability in § 75.32, and to provide the quality-assured data used in

the missing data procedures in §§ 75.31 and 75.33, such as the "hour after" value.

§ 75.31 Initial missing data procedures.

(a) During the first 720 quality-assured monitor operating hours following initial certification (i.e., beginning from the date and time of completion of successful certification tests), of the SO_2 pollutant concentration monitor and during the first 2,160 quality-assured monitor operating hours following initial certification of the flow monitor and NO_x continuous emission monitoring system(s), the owner or operator shall provide substitute data required under this subpart according to the procedures in paragraphs (b) and (c) of this section.

(b) *SO_2 concentration data.* For each hour of missing SO_2 concentration data, the owner or operator shall calculate the substitute data as follows:

(1) Whenever prior quality assured data exist, the owner or operator shall substitute, by means of the data acquisition and handling system, the average of the hourly SO_2 concentrations recorded for an affected unit by a certified monitor for the unit operating hour immediately before and the unit operating hour immediately after the missing data period for each hour of missing data (henceforth referred to as "the hour before and after").

(2) Whenever no prior quality-assured SO_2 concentration data exist, the owner or operator shall substitute the maximum potential concentration for SO_2, as specified in section 2.1 of appendix A, for each hour of missing data.

(c) *Volumetric flow and NO_x emission rate data.* For each hour of missing volumetric flow or NO_x emission rate data:

(1) Whenever prior quality-assured data exist in the load range corresponding to the operating load at the time the missing data period occurred, the owner or operator shall substitute, by means of the automated data acquisition and handling system, the average hourly flow rate (or NO_x emission rate) recorded for the affected unit by a certified flow monitor (or a certified NO_x continuous emission monitoring system). The flow rate (or NO_x emission rate) shall be calculated from the corresponding load range as determined using the procedure in appendix C of this part.

(2) Whenever no prior quality-assured flow or NO_x emission rate data exist for the corresponding load range, the owner and operator shall substitute the average hourly flow rate or the average hourly NO_x emission rate at the next higher level load range for which quality-assured data is available, for each hour of missing data.

(3) Whenever no prior quality-assured flow or NO_x emission rate data exist for any load range, the owner or operator shall use the maximum potential velocity to calculate and substitute the maximum flow rate or shall substitute the maximum potential NO_x emission rate, as specified in section 2.1 of appendix A, for each hour of missing data.

§ 75.32 Determination of monitor data availability for standard missing data procedures.

(a) Following initial certification, upon completion of the first 720 quality-assured monitor operating hours of the SO_2 pollutant concentration monitor or the first 2,160 quality-assured monitor operating hours of the flow monitor or NO_x continuous emission monitoring system, the owner or operator shall calculate and record, by means of the automated data acquisition and handling system, the percent monitor data availability for the SO_2 pollutant concentration monitor, the flow monitor, and the NO_x continuous emission monitoring system as follows:

(1) Prior to completion of 8,760 unit operating hours following initial certification, the owner or operator shall, for the purpose of applying the standard missing data procedures of § 75.33, use Equation 8 to calculate, hourly, percent monitor data availability.

$$\text{Percent monitor data availability} = \frac{\text{Total unit operating hours for which quality-assured data were recorded since certification}}{\text{Total unit operating hours since certification}} \times 100 \quad \text{(Eq. 8)}$$

(2) Upon completion of 8,760 unit operating hours following initial certification and thereafter, the owner or operator shall, for the purpose of applying the standard missing data procedures of § 75.33, use Equation 9 to calculate, hourly, percent monitor data availability.

$$\text{Percent monitor data availability} = \frac{\text{Total unit operating hours for which quality-assured data were recorded during previous 8,760 unit operating hours}}{8{,}760} \times 100 \quad \text{(Eq. 9)}$$

(3) The owner or operator shall include all unit operating hours, and all monitor operating hours for which quality-assured data were recorded by a certified primary monitor, a certified backup monitor, a certified portable monitor, and a reference method for that unit, and from an approved alternative monitoring system under subpart E of this part when calculating percent monitor data availability using Equation 8 or 9.

(b) Although the monitor data availability need not be recorded during the missing data period, then the owner or operator shall record the percent monitor data availability at the end of each missing data period, (and thereafter, continue to record monitor data availability hourly, pursuant to § 75.50).

§ 75.33 Standard missing data procedures.

(a) Following initial certification and upon completion of the first 720 quality-assured monitor operating hours of the SO_2 pollutant concentration monitor or the first 2,160 quality-assured monitor operating hours of the flow monitor or NO_x continuous emission monitoring

system, the owner or operator shall provide substitute data required under this subpart according to the procedures in paragraphs (b) and (c) of this section and depicted in Table 1 (SO_2) and Table 2 (NO_x, flow).

TABLE 1.—MISSING DATA PROCEDURE FOR SO_2 CEMS

Trigger conditions		Calculation routines	
Availability (percent)	Duration (N) of outage (hours)	Method	Lookback period
95 or more	N≤24	Average	HB/HA.
	N>24	Max. of average	HB/HA.
		Max. of 90th percentile	720 operating hours*.
90 or more, but below 95	N≤8	Average	HB/HA.
	N>8	Max. of average	HB/HA.
		Max. of 95th percentile	720 operating hours*.
Below 90	N >0	Maximum value[1]	720 operating hours*.

HB/HA=hour before and hour after the outage.
*=Quality-assured, monitor operating hours.
[1]Where unit with add-on emission controls can demonstrate that the controls are operating properly, as provided in §75.34, the unit may, upon approval, use the maximum controlled emission rate from the previous 720 operating hours.

TABLE 2.—MISSING DATA PROCEDURE FOR NO_x AND FLOW CEMS

Trigger conditions		Calculation routines		
Availability (percent)	Duration (N) of outage (hours)	Method	Lookback period	Load ranges
95 or more	N ≤ 24	Average	2160 operating hours*	Yes.
	N > 24	Max of average	HB/HA	No.
		Max of 90th percentile	2160 operating hours*	Yes.
90 or more, but below 95	N ≤ 8	Average	2160 operating hours*	Yes.
	N > 8	Max of Average	HB/HA	No.
		Max of 95th percentile	2160 operating hours*	Yes.
Below 90	N > 0	Maximum Value[1]	2160 operating hours*	Yes.

HB/HA = hour before and hour after the outage.
* = Quality-assured, monitor operating hours.
[1]Where unit with add-on emission controls can demonstrate that the controls are operating properly, as provided in §75.34, the unit may, upon approval, use the maximum controlled emission rate from the previous 720 operating hours.

(b) *SO_2 concentration data.* For each hour of missing SO_2 concentration data,

(1) Whenever the monitor data availability is equal to or greater than 95.0 percent, the owner or operator shall calculate substitute data by means of the automated data acquisition and handling system for each hour of each missing data period according to the following procedures:

(i) For a missing data period less than or equal to 24 hours, substitute the average of the hourly SO_2 concentrations recorded by an SO_2 pollutant concentration monitor for the hour before and the hour after the missing data period.

(ii) For a missing data period greater than 24 hours, substitute the greater of:

(A) The 90th percentile hourly SO_2 concentration recorded by an SO_2 pollutant concentration monitor during the previous 720 quality-assured monitor operating hours; or

(B) The average of the hourly SO_2 concentrations recorded by an SO_2 pollutant concentration monitor for the hour before and the hour after the missing data period.

(2) Whenever the monitor data availability is at least 90.0 percent but less than 95.0 percent, the owner or operator shall calculate substitute data by means of the automated data acquisition and handling system for each hour of each missing data period according to the following procedures:

(i) For a missing data period of less than or equal to 8 hours, substitute the average of the hourly SO_2 concentrations recorded by an SO_2 pollutant concentration monitor for the hour before and the hour after the missing data period.

(ii) For a missing data period of more than 8 hours, substitute the greater of:

(A) the 95th percentile hourly SO_2 concentration recorded by an SO_2 pollutant concentration monitor during the previous 720 quality-assured monitor operating hours; or

(B) The average of the hourly SO_2 concentrations recorded by an SO_2 pollutant concentration monitor for the hour before and the hour after the missing data period.

(3) Whenever the monitor data availability is less than 90.0 percent, the owner or operator shall substitute for each hour of each missing data period the maximum hourly SO_2 concentration recorded by an SO_2 pollutant concentration monitor during the previous 720 quality-assured monitor operating hours.

(c) *Volumetric flow and NO_x emission rate data.* For each hour of missing volumetric flow or NO_x emission rate data,

(1) Whenever the monitor or continuous emission monitoring system data availability is equal to or greater than 95.0 percent, the owner or operator shall calculate substitute data by means of the automated data acquisition and handling system for each hour of each missing data period according to the following procedures:

(i) For a missing data period less than or equal to 24 hours, substitute the average hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system during the previous 2,160 quality-assured monitor operating hours at the corresponding unit load range recorded for each missing hour, as determined using the procedure in Appendix C to this part.

(ii) For a missing data period greater than 24 hours, substitute the greater of:

(A) The 90th percentile hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system at the corresponding

unit load range recorded for each missing hour during the previous 2,160 quality-assured monitor operating hours, as determined using the procedure in appendix C to this part; or

(B) The average of the hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system for the hour before and the hour after the missing data period.

(2) Whenever the monitor or continuous emission monitoring system data availability is at least 90.0 percent but less than 95.0 percent, the owner or operator shall calculate substitute data by means of the automated data acquisition and handling system for each hour of each missing data period according to the following procedures:

(i) For a missing data period of less than or equal to 8 hours, substitute the average hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system at the corresponding unit load range recorded for the missing hour during the previous 2,160 quality-assured monitor operating hours, as determined using the procedure in appendix C to this part.

(ii) For a missing data period greater than 8 hours, substitute the greater of:

(A) The 95th percentile hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system at the corresponding unit load range recorded for the missing hour during the previous 2,160 quality-assured monitor operating hours, as determined using the procedure in appendix C to this part; or

(B) The average of the hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system for the hour before and the hour after the missing data period.

(3) Whenever the monitor or continuous emission monitoring system data availability is at least 90.0 percent but less than 95.0 percent, the owner or operator shall calculate substitute data by means of the automated data acquisition and handling system for each hour of each missing data period according to the following procedures:

(i) For a missing data period of less than or equal to 8 hours, substitute the average hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system at the corresponding unit load range recorded for the missing hour during the previous 2,160 quality-assured monitor operating hours, as determined using the procedure in appendix C to this part.

(ii) For a missing data period greater than 8 hours, substitute the greater of:

(A) The 95th percentile hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system at the corresponding unit load range recorded for the missing hour during the previous 2,160 quality-assured monitor operating hours, as determined using the procedure in appendix C to this part; or

(B) The average of the hourly flow or NO_x emission rate recorded by a flow monitor or NO_x continuous emission monitoring system for the hour before and the hour after the missing data period.

(4) Whenever the monitor data availability is less than 90.0 percent, the owner or operator shall calculate substitute data by means of the automated data acquisition and handling system for each hour of each missing data period by substituting the maximum hourly flow or NO_x emission rate recorded by the flow monitor or NO_x continuous emission monitoring system at the corresponding unit load range recorded for the missing hour during the previous 2,160 quality-assured monitor operating hours, as determined using the procedure in Section 2 of Appendix C to this part.

(5) Whenever no prior quality-assured flow or NO_x emission rate data exist for the corresponding load range, the owner or operator shall substitute the maximum hourly flow rate or the maximum hourly NO_x emission rate at the next higher level load range for which quality-assured data is available for each hour of missing data.

§ 75.34 Units with add-on emission controls.

(a) The owner or operator of an affected unit equipped with add-on SO_2 and/or NO_x emission controls may choose one of the following options:

(1) The owner or operator may use the missing data routine as specified for all affected units in §§ 75.31 through 75.33. In addition, the owner or operator may petition the Administrator to replace the maximum recorded value in the last 720 quality-assured monitor operating hours with a value corresponding to the maximum controlled emission rate (an emission rate recorded when the add-on emission controls were operating) recorded during the last 720 quality-assured monitor operating hours. The owner or operator must demonstrate that the following conditions are met: the monitor data availability, calculated in accordance with § 75.32, for the affected unit is below 90 percent and parametric monitors can establish that the add-on emission controls were operating properly during the time period under petition.

(2) The owner or operator may petition the Administrator under § 75.66 for approval of site-specific parametric monitoring procedure(s) for calculating substitute data for missing SO_2 pollutant concentration and NO_x emission rate data in accordance with the requirements of this section and of appendix C to this part.

(b) For an affected unit equipped with add-on SO_2 emission controls, the owner or operator may petition the Administrator to approve a parametric monitoring procedure, as described in appendix C of this part, for calculating substitute SO_2 concentration data for missing data periods. The owner or operator shall use the procedures in § 75.31, 75.33, or § 75.34(a) of this part for providing substitute data for missing SO_2 concentration data unless a parametric monitoring procedure has been approved by the Administrator.

(1) Where the monitoring data availability is 90.0 percent or more for an outlet SO_2 pollutant concentration monitor, the owner or operator may calculate substitute data using an approved parametric monitoring procedure.

(2) Where the monitor data availability for an outlet SO_2 pollutant concentration monitor is less than 90.0 percent, the owner or operator shall calculate substitute data using the procedures in § 75.33(b)(3) or § 75.34(a) of this part, even if the Administrator has approved a parametric monitoring procedure.

(c) For an affected unit with NO_x add-on emission controls, the owner or operator may petition the Administrator to approve a parametric monitoring procedure, as described in Appendix C of this part, in order to calculate substitute NO_x emission rate data for missing data periods. The owner or operator shall use the procedures in §§ 75.31 or 75.33 of this part for providing substitute data for missing NO_x emission rate data prior to receiving the Administrator's approval for a parametric monitoring procedure.

(1) Where monitor data availability for a NO_x continuous emission monitoring system is 90.0 percent or more, the owner or operator may calculate substitute data using an approved parametric monitoring procedure.

(2) Where monitor data availability for a NO_x continuous emission monitoring system is less than 90.0 percent, the owner or operator shall calculate substitute data using the procedure in § 75.33(c)(3) or petition in accordance with § 75.34(a)(1) of this part, even if the

Administrator has approved a parametric monitoring procedure.

(d) The owner or operator shall provide information as described in subparts F and G of this part to verify the proper operation of the SO_2 or NO_x emission controls during all periods of missing data. Whenever such data are not provided or proper operation of the SO_2 or NO_x emission controls has not been maintained, the owner or operator shall substitute the maximum potential concentration for NO_x, as defined in section 2.1 of Appendix A, and the minimum O_2 concentration or maximum O_2 concentration used to determine the maximum potential concentration of SO_2 in section 2.1.1.1 of appendix A in calculations of NO_x emission rate or the maximum hourly SO_2 concentration recorded by the inlet monitor during the previous 720 quality assured monitor operating hours for each hour of missing data until parametric data demonstrating proper operation of the SO_2 or NO_x emission controls are available.

Subpart E—Alternative Monitoring Systems

§ 75.40 General demonstration requirements.

(a) The owner or operator of an affected unit, or the owner or operator of an affected unit and representing a class of affected units which meet the criteria specified in § 75.47, required to install a continuous emission monitoring system may apply to the Administrator for approval of an alternative monitoring system (or system component) to determine average hourly emission data for SO_2, NO_x, and/or volumetric flow by demonstrating that the alternative monitoring system has the same or better precision, reliability, accessibility, and timeliness as that provided by the continuous emission monitoring system.

(b) The requirements of this subpart shall be met by the alternative monitoring system when compared to a contemporaneously operating, fully certified continuous emission monitoring system or a contemporaneously operating reference method, where the appropriate reference methods are listed in § 75.22.

§ 75.41 Precision criteria.

(a) *Data collection and analysis.* To demonstrate precision equal to or better than the continuous emission monitoring system, the owner or operator shall conduct an F-test, a correlation analysis, and a t-test for bias as described in this section. The t-test shall be performed only on sample data at the normal operating level and primary fuel supply, whereas the F-test and the correlation analysis must be performed on each of the data sets required under paragraphs (a)(4) and (a)(5) of this section. The owner or operator shall collect and analyze data according to the following requirements:

(1) Data from the alternative monitoring system and the continuous emission monitoring system shall be collected and paired in a manner that ensures each pair of values applies to hourly average emissions during the same hour.

(2) An alternative monitoring system that directly measures emissions shall have probes or other measuring devices in locations that are in proximity to the continuous emission monitoring system and shall provide data on the same parameters as those measured by the continuous emission monitoring system. Data from the alternative monitoring system shall meet the statistical tests for precision in paragraph (c) of this section and the t-test for bias in appendix A of this part.

(3) An alternative monitoring system that indirectly quantifies emission values by measuring inputs, operating characteristics, or outputs and then applying a regression or another quantitative technique to estimate emissions, shall meet the statistical tests for precision in paragraph (c) of this section and the t-test for bias in Appendix A of this part.

(4) For flow monitor alternatives, the alternative monitoring system must provide sample data for each of three different exhaust gas velocities while the unit or units, if more than one unit exhausts into the stack or duct, is burning its primary fuel at:

(i) A frequently used low operating level, selected within the range between the minimum safe and stable operating level and 50 percent of the maximum operating level,

(ii) A frequently used high operating level, selected within the range between 80 percent of the maximum operating level and the maximum operating level, and

(iii) The normal operating level, or an evenly spaced intermediary level between low and high levels used if the normal operating level is within a specified range, (10.0 percent of the maximum operating level) of either (a)(4) (i) or (ii) of this section.

(5) For pollutant concentration monitor alternatives, the alternative monitoring system shall provide sample data for the primary fuel supply and for all alternative fuel supplies that have significantly different sulfur content.

(6) For the normal unit operating level and primary fuel supply, paired hourly sample data shall be provided for at least 90.0 percent of the hours during 720 unit operating hours. For each of the remaining two operating levels for flow monitor alternatives, and for each alternative fuel supply for pollutant concentration monitor alternatives, paired hourly sample data shall be provided for at least 24 successive unit operating hours.

(7) The owner or operator shall not use missing data substitution procedures to provide sample data.

(8) If the collected data meet the requirements of the F-test, the correlation test, and the t-test at one or more, but not all, of the operating levels or fuel supplies, the owner or operator may elect to continue collecting the paired data for up to 1,440 additional operating hours and repeat the statistical tests using the data for the entire 30- to 90-day period.

(9) The owner or operator shall provide two separate time series data plots for the data at each operating level or fuel supply described in paragraphs (a)(4) and (a)(5) of this section. Each data plot shall have a horizontal axis that represents the clock hour and calendar date of the readings and shall contain a separate data point for every hour for the duration of the performance evaluation. The data plots shall show the following:

(i) Percentage difference versus time where the vertical axis represents the percentage difference between each paired hourly reading generated by the continuous emission monitoring system and the alternative emission monitoring system as calculated using the following equation:

$$\Delta e = \frac{e_p - e_v}{e_v} \times 100\%$$

(Eq.10)

where,

Δe=Percentage difference between the readings generated by the alternative monitoring system and the continuous emission monitoring system.

e_p=Measured value from the alternative monitoring system.

e_v=Measured value from the continuous emission monitoring system.

(ii) Alternative monitoring system readings and continuous emissions monitoring system readings versus time where the vertical axis represents

hourly pollutant concentrations or volumetric flow, as appropriate, and two different symbols are used to represent the readings from the alternative monitoring system and the continuous emission monitoring system, respectively.

(b) *Data screening and calculation adjustments.* In preperation for conducting the statistical tests, described in paragraph (c) of this section, the owner or operator may screen the data for lognormality and time dependency autocorrelation. If either is detected, the owner or operator shall make the following calculation adjustments:

(1) *Lognormality.* The owner or operator shall conduct any screening and adjustment for lognormality according to the following procedures.

(i) Apply the log transformation to each measured value of either the certified continuous emissions monitoring system or certified flow monitor, using the following equation:

$l_v = \ln e_v$

where,

e_v=Hourly value generated by the certified continuous emissions monitoring system or certified flow monitoring system

l_v=Hourly lognormalized data values for the certified monitoring system

and to each measured value, e_p, of the proposed alternative monitoring system, using the following equation to obtain the lognormalized data values, l_p:

$l_p = \ln e_p$

where,

e_p=Hourly value generated by the proposed alternative monitoring system.

l_p=Hourly lognormalized data values for the proposed alternative monitoring system.

(ii) Separately test each set of transformed data, l_v and l_p, for normality, using the following:

(A) Shapiro-Wilk test;

(B) Histogram of the transformed data; and

(C) Quantile-Quantile plot of the transformed data.

(iii) The transformed data in a data set will be considered normally distributed if all of the following conditions are satisfied:

(A) The Shapiro-Wilk test statistic, W, is greater than or equal to 0.75 or is not statistically significant at α=0.05.

(B) The histogram of the data is unimodal and symmetric.

(C) The Quantile-Quantile plot is a diagonal straight line.

(iv) If both of the transformed data sets, l_v and l_p, meet the conditions for normality, specified in paragraphs (b)(1)(iii) (A) through (C) of this section, the owner or operator may use the transformed data, l_v and l_p, in place of the original measured data values in the statistical tests for alternative monitoring systems as described in paragraph (c) of this section and in appendix A of this part.

(v) If the transformed data are used in the statistical tests in paragraph (c) of this section and in appendix A of this part, the owner or operator shall provide the following:

(A) Copy of the original measured values and the corresponding transformed data in printed and electronic format.

(B) Printed copy of the test results and plots described in paregraphs (b)(1) (i) through (iii) of this section.

(2) *Time dependency (autocorrelation).* The screening and adjustment for time dependency are conducted according to the following procedures:

(i) Calculate the degree of autocorrelation of the data on their LAG1 values, where the degree of autocorrelation is represented by the Pearson autocorrelation coefficient, ρ, computed from an AR(1) autoregression model, such that where,

$$\rho = \frac{COV(x_i', x_i'')}{S_{x_i'} S_{x_i''}}$$

(Eq. 13)

X'_i=The original data value at i.

X''_i=The LAG1 data value at hour i.

$COV(X'_i, X''_i)$=The autocovariance of X'_i and defined by,

$$COV(x_i', x_i'') = \frac{\sum_{i=1}^{n} (x_i' - \bar{x}')(x_i'' - \bar{x}'')}{(n-1)}$$

(Eq. 14)

n=The total number of observations in which both the original value, X'_i, and the lagged value, X''_i, are available in the data set.

S'_{x_i}=The standard deviation of the original data values, X'_i defined by,

$$S_{x_i'} = \sqrt{\frac{\sum_{i=1}^{n} (x_i' - \bar{x}')^2}{n-1}}$$

(Eq. 15)

S''_{x_i}=The standard deviation of the LAG1 data values, X''_i, defined by

$$S_{x_i''} = \sqrt{\frac{\sum_{i=1}^{n} (x_i'' - \bar{x}'')^2}{n-1}}$$

(Eq. 16)

$\bar{X}'$=The mean of the original data values, X'_i defined by

$$\bar{x}' = \frac{\sum_{i=1}^{n} x_i'}{n}$$

(Eq. 17)

$\bar{X}''$=The mean of the LAG1 data values, X''_i, defined by

$$\bar{x}'' = \frac{\sum_{i=1}^{n} x_i''}{n}$$

(Eq. 18)

(ii) The data in a data set will be considered autocorrelated if the autocorrelation coefficient, ρ, is significant at the 5 percent significance level. To determine if this condition is satisfied, calculate Z using the following equation:

$$Z = 0.5\left[\ln\left(\frac{1+\rho}{1-\rho}\right)\right]\sqrt{n-3}$$

(Eq. 19)

If $Z > 1.96$, then the autocorrelation coefficient, ρ, is significant at the 5 percent significance level ($\alpha = 0.05$).

(iii) If the data in a data set satisfy the conditions for autocorrelation, specified in paragraph (b)(2)(ii) of this section, the variance of the data, S^2, may be adjusted using the following equation:

$S^2_{adj} = VIF \times S^2$

(Eq. 20)

where,

S^2=The original, unadjusted variance of the data set.

VIF=The variance inflation factor, defined by

$$VIF = \frac{1}{\left[1 - \frac{2\rho}{(n-1)(1-\rho)} + \frac{2\rho(1-\rho^n)}{n(n-1)(1-\rho)^2}\right]}$$

(Eq. 21)

S^2_{adj}=The autocorrelation-adjusted variance for the data set.

(iv) The procedures described in paragraphs (b)(2)(i)–(iii) of this section may be separately applied to the following data sets in order to derive distinct autocorrelation coefficients and variance inflation factors for each data set:

(A) The set of measured hourly values, e_v, generated by the certified continuous emissions monitoring system or certified flow monitoring system.

(B) The set of hourly values, e_p, generated by the proposed alternative monitoring system.

(C) The set of hourly differences, $e_v - e_p$, between the hourly values, e_v, generated by the certified continuous emissions monitoring system or certified flow monitoring system and the hourly values, e_p, generated by the proposed alternative monitoring system.

(v) For any data set, listed in paragraph (b)(2)(iv) of this section, that satisfies the conditions for autocorrelation specified in paragraph (b)(2)(ii) of this section, the owner or operator may adjust the variance of that data set, using Equation 20 of this section.

(A) The adjusted variance may be used in place of the corresponding original variance in the F-test Equation 23 of this section.

(B) In place of the standard error of the mean,

$$\frac{S_d}{\sqrt{n}},$$

in the bias test Equation A–9 of Appendix A the following adjusted standard error of the mean may be used:

$$\left(\frac{S_d}{\sqrt{n}}\right)_{adj} = \left[\sqrt{\left(\frac{1+\rho}{1-\rho}\right) - \left(\frac{2\rho(1-\rho^n)}{n(1-\rho)^2}\right)}\right] \times \sqrt{VIF} \times \left(\frac{S_d}{\sqrt{n}}\right) \qquad \text{(Eq. 22)}$$

where,

$\left(\frac{S_d}{\sqrt{n}}\right)_{adj}$ = The autocorrelation-adjusted standard error of the mean.

(vi) For each data set in which a variance adjustment is used, the owner or operator shall provide the following:

(A) All values in the data set in printed and electronic format.

(B) Values of the autocorrelation coefficient, its level of significance, the variance inflation factor, and the unadjusted original and adjusted values found in Equations 20 and 22 of this section.

(C) Equation and related statistics of the AR(1) autoregression model of the data set.

(D) Printed documentation of the intermediate calculations used to derive the autocorrelation coefficient and the Variance Inflation Factor.

(c) *Statistical Tests.* The owner or operator shall perform the F-test and correlation analysis as described in this paragraph and the t-test for bias described in Appendix A of this part to demonstrate the precision of the alternative monitoring system.

(1) *F-test.* The owner or operator shall conduct the F-test according to the following procedures.

(i) Calculate the variance of the certified continuous emission monitoring system or certified flow monitor as applicable, S_v^2, and the proposed method, S_p^2, using the following equation.

$$S^2 = \frac{\sum_{i=1}^{n} (e_i - e_m)^2}{n-1} \qquad \text{(Eq. 23)}$$

where,

e_i = Measured values of either the certified continuous emission monitoring system or certified flow monitor, as applicable, or proposed method.

e_m = Mean of either the certified continuous emission monitoring system or certified flow monitor, as applicable, or proposed method values.

n = Total number of paired samples.

(ii) Determine if the variance of the proposed method is significantly different from that of the certified continuous emission monitoring system or certified flow monitor, as applicable, by calculating the F-value using the following equation.

$$F = \frac{S_p^2}{S_v^2} \qquad \text{(Eq. 24)}$$

Compare the experimental F-value with the critical value of F at the 95-percent confidence level with n-1 degrees of freedom. The critical value is obtained from a table for F-distribution. If the calculated F-value is greater than the critical value, the proposed method is unacceptable.

(2) *Correlation analysis.* The owner or operator shall conduct the correlation analysis according to the following procedures.

(i) Plot each of the paired emissions readings as a separate point on a graph where the vertical axis represents the value (pollutant concentration or volumetric flow, as appropriate) generated by the alternative monitoring system and the horizontal axis represents the value (pollutant concentration or volumetric flow, as appropriate) generated by the continuous emission monitoring system. On the graph, draw a horizontal line representing the mean value, e_p, for the

alternative monitoring system and a vertical line representing the mean value, e_v, for the continuous emission monitoring system where,

$$\overline{e_p} = \frac{\sum e_p}{n}$$

(Eq. 25)

$$\overline{e_v} = \frac{\sum e_v}{n}$$

(Eq. 26)

where,

e_p=Hourly value generated by the alternative monitoring system.

e_v=Hourly value generated by the continuous emission monitoring system.

n=Total number of hours for which data were generated for the tests.

A separate graph shall be produced for the data generated at each of the operating levels or fuel supplies described in paragraphs (a)(4) and (a)(5) of this section.

(ii) Use the following equation to calculate the coefficient of correlation, r, between the emissions data from the alternative monitoring system and the continuous emission monitoring system using all hourly data for which paired values were available from both monitoring systems.

$$r = \frac{\sum e_p e_v - (\sum e_p)(\sum e_v)/n}{\left(\sum e_p^2 - (\sum e_p)^2/n\right)\left[\sum e_p^2 - (\sum e_v)^2/n\right]^{1/2}} \qquad \text{(Eq. 27)}$$

(Eq. 27)

(iii) If the calculated r-value is less than 0.8, the proposed method is unacceptable.

§ 75.42 Reliability criteria.

To demonstrate reliability equal to or better than the continuous emission monitoring system, the owner or operator shall demonstrate that the alternative monitoring system is capable of providing valid 1-hr averages for 95.0 percent or more of unit operating hours over a 1-yr period and that the system meets the applicable requirements of Appendix B of this part.

§ 75.43 Accessibility criteria.

To demonstrate accessibility equal to or better than the continuous emission monitoring system, the owner or operator shall provide reports and onsite records of emission data to demonstrate that the alternative monitoring system provides data meeting the requirements of subparts F and G of this part.

§ 75.44 Timeliness criteria.

To demonstrate timeliness equal to or better than the continuous emission monitoring system, the owner or operator shall demonstrate that the alternative monitoring system can meet the requirements of subparts F and G of this part; can provide a continuous, quality-assured, permanent record of certified emissions data on an hourly basis; and can issue a record of data for the previous day within 24 hours.

§ 75.45 Daily quality assurance criteria.

The owner or operator shall either demonstrate that daily tests equivalent to those specified in Appendix B of this part can be performed on the alternative monitoring system or demonstrate and document that such tests are unnecessary for providing quality-assured data.

§ 75.46 Missing data substitution criteria.

The owner or operator shall demonstrate that all missing data can be accounted for in a manner consistent with the applicable missing data procedures in subpart D of this part.

§ 75.47 Criteria for a class of affected units.

(a) The owner or operator of an affected unit may represent a class of affected units for the purpose of applying to the Administrator for a class-approved alternative monitoring system.

(b) The owner or operator of an affected unit representing a class of affected units shall provide the following information:

(1) A description of the affected unit and how it appropriately represents the class of affected units;

(2) A description of the class of affected units, including data describing all the affected units which will comprise the class; and

(3) A demonstration that the magnitude of emissions of all units which will comprise the class of affected units are *de minimis*.

(c) If the Administrator determines that the emissions from all affected units which will comprise the class of units are *de minimis*, then the Administrator shall publish notice in the **Federal Register**, providing a 30-day period for public comment, prior to granting a class-approved alternative monitoring system.

§ 75.48 Petition for an alternative monitoring system.

(a) The designated representative shall submit the following information in the application for certification or recertification of an alternative monitoring system.

(1) Source identification information.

(2) A description of the alternative monitoring system.

(3) Data, calculations, and results of the statistical tests, specified in § 75.41(c) of this part, including:

(i) Date and hour.

(ii) Hourly test data for the alternative monitoring system at each required operating level and fuel type.

(iii) Hourly test data for the continuous emissions monitoring system at each required operating level and fuel type.

(iv) Arithmetic mean of the alternative monitoring system measurement values, as specified in Equation 24 in § 75.41(c) of this part, of the continuous emission monitoring system values, as specified on Equation 25 in § 75.41(c) of this part, and of their differences.

(v) Standard deviation of the difference, as specified in Equation A–8 in Appendix A to this part.

(vi) Confidence coefficient, as specified in Equation A–9 in Appendix A to this part.

(vii) The bias test results as specified in § 7.6.4 in Appendix A to this part.

(viii) Variance of the measured values for the alternative monitoring system and of the measured values for the continuous emissions monitoring system, as specified in Equation 22 in § 75.41(c) of this part.

(ix) F-statistic, as specified in Equation 23 in § 75.41(c) of this part.

(x) Critical value of F at the 95-percent confidence level with n-1 degrees of freedom.

(xi) Coefficient of correlation, r, as specified in Equation 26 in § 75.41(c) of this part.

(4) Data plots, specified in §§ 75.41(a)(9) and 75.41(c)(2)(i) of this part.

(5) Results of monitor reliability analysis.

(6) Results of monitor accessibility analysis.

(7) Results of monitor timeliness analysis.

(8) A detailed description of the process used to collect data, including location and method of ensuring an accurate assessment of operating hourly conditions on a real-time basis.

(9) A detailed description of the operation, maintenance, and quality assurance procedures for the alternative monitoring system as required in Appendix B of this part.

(10) A description of methods used to calculate heat input or diluent gas concentration, if applicable.

(11) Results of tests and measurements (including the results of all reference method field test sheets, charts, laboratory analyses, example calculations, or other data as appropriate) necessary to substantiate that the alternative monitoring system is equivalent in performance to an appropriate, certified operating continuous emission monitoring system.

Subpart F—Recordkeeping Requirements

§ 75.50 General recordkeeping provisions.

(a) *Recordkeeping requirements for affected sources.* The owner or operator of any affected source subject to the requirements of this part shall maintain for each affected unit [or for each group of affected or nonaffected units utilizing a common stack and common monitoring systems pursuant to § 75.16–§ 75.18 of this part (referred to hereafter as "each affected unit")] a file of all measurements, data, reports, and other information required by this part at the source in a form suitable for inspection for at least three (3) years from the date of each record. This file shall contain the following information:

(1) The data and information required in paragraphs (b) through (f) of this section;

(2) The component data and information used to calculate values required in paragraphs (b) through (f) of this section;

(3) The current monitoring plan as specified in § 75.53 of this part; and

(4) The quality control plan as described in Appendix B to this part.

(b) *Operating parameter record provisions.* The owner or operator shall record hourly the following information on unit operating time, heat input, and load for each affected unit, including individual affected units utilizing a common stack except as provided in paragraph (b)(6) of this section for gas-fired units.

(1) Date and hour;

(2) Unit operating time (rounded to nearest hour);

(3) Total integrated hourly gross unit load (rounded to nearest MW_{ge}) (or steam load in lb/hr at stated temperature and pressure, rounded to the nearest lb/hr, if elected in the monitoring plan);

(4) Operating load range corresponding to total integrated gross load of 1–10, except for units using a common stack, which may use the number of unit load ranges up to 20, specified in the monitoring plan for the common stack;

(5) Total heat input (mmBtu, rounded to the nearest tenth); and

(6) For gas-fired units, the owner or operator may record total heat input (mmBtu, rounded to the nearest tenth) daily.

(c) *SO_2 emission record provisions.* The owner or operator shall record hourly the information required by this paragraph for each affected unit or group of units using a common stack and common monitoring systems, except a gas-fired or oil-fired unit for which the owner or operator is using the optional protocol in Appendix D to this part for estimating SO_2 mass emissions:

(1) For SO_2 concentration, as measured and reported from the certified primary monitor, certified back-up or certified portable monitor, or other approved method of emissions determination:

(i) Monitor-channel identification code as provided for in § 75.53;

(ii) Date and hour;

(iii) Average hourly SO_2 concentration (ppm, rounded to the nearest tenth),

(iv) Average hourly SO_2 concentration (ppm, rounded to the nearest tenth) adjusted for bias, if bias adjustment factor is required as provided for in § 75.24(d) of this part;

(v) Percent monitor data availability (recorded to the nearest tenth of a percent) calculated pursuant to § 75.32 of this part; and

(vi) Method of determination for average hourly SO_2 concentration using Codes 1–12 in Table 3 of this section.

(2) For flow as measured and reported from the certified primary monitor, certified back-up or certified portable monitor or other approved method of emissions determination:

(i) Monitor-channel identification code as provided for in § 75.53;

(ii) Date and hour;

(iii) Average hourly volumetric flow rate (in scfh, rounded to the nearest thousand);

(iv) Average hourly volumetric flow rate (in scfh, rounded to the nearest thousand) adjusted for bias, if bias adjustment factor required as provided for in § 75.24(d) of this part;

(v) Average hourly moisture content of flue gases (volume fraction) where SO_2 concentration is measured on dry basis;

(vi) Percent monitor data availability, (recorded to the nearest tenth of a percent), calculated pursuant to § 75.32 of this part; and

(vii) Method of determination for average hourly flow rate using Codes 1–12 in Table 3.

(3) For SO_2 mass emissions as measured and reported from the certified primary monitoring system, certified back-up or certified portable monitoring systems, or other approved method of emissions determination:

(i) Date and hour;

(ii) Average hourly SO_2 mass emission (lb/hr, rounded to the nearest tenth);

(iii) Average hourly SO_2 mass emissions (lb/hr, rounded to the nearest tenth) adjusted for bias, if bias adjustment factor required, as provided for in § 75.24(d); and

(iv) Unique three-digit code identifying emissions formula used to derive hourly SO_2 mass emissions from SO_2 concentration and flow data in paragraphs (c)(1) and (c)(2) of this section as provided for in § 75.53.

TABLE 3.—CODES FOR METHOD OF EMISSIONS AND FLOW DETERMINATION

Code	Hourly emissions/flow measurement or estimation method
1	Certified primary emission/flow monitoring system.
2	Certified back-up or certified portable emission/flow monitoring system.
3	Approved alternative monitoring system.
4	Reference Method: SO_2: Method 6, 6A, 6B, or 6C. Flow: Method 2, 2A, 2C, or 2D. NO_x: Method 7, 7A, 7C, 7D, or 7E.
5	For units with add-on SO_2 and/or NO_x emission controls: SO_2 concentration or NO_x emission rate estimate from Agency preapproved parametric monitoring method.
6	Average of the hourly SO_2 concentrations, flow, or NO_x emission rate for the hour before and the hour following a missing data period.
7	Average hourly SO_2 concentration, flow rate, or NO_x emission rate using initial missing data procedures.
8	90th percentile hourly SO_2 concentration, flow rate, or NO_x emission rate.
9	95th percentile hourly SO_2 concentration, flow rate, or NO_x emission rate.
10	Maximum hourly SO_2 concentration, flow rate, or NO_x emission rate.
11	Average hourly flow rate or NO_x emission rate in corresponding load range.

TABLE 3.—CODES FOR METHOD OF EMISSIONS AND FLOW DETERMINATION—Continued

Code	Hourly emissions/flow measurement or estimation method
12	Maximum potential concentration of SO_2 maximum potential flow rate, or NO_x emission rate corresponding to maximum potential concentration of NO_x and minimum O_2 or maximum CO_2 concentration, as determined using section 2.1 of Appendix A of this part.
13	Other data (specify method).

(d) *NO_x emission record provisions.* The owner or operator shall record hourly the information required by this paragraph for each affected unit, except for a gas-fired peaking unit or oil-fired peaking unit for which the owner or operator is using the option protocol in Appendix E to this part for estimating NO_x emission rate. For each NO_x emission rate as measured and reported from the certified primary monitor, certified back-up or certified portable monitor, or other approved method of emissions determination:

(1) Monitor-channel identification code as provided for in § 75.53;

(2) Date and hour;

(3) Average hourly NO_x concentration (ppm, rounded to the nearest tenth);

(4) Average hourly diluent gas concentration (percent O_2 or percent CO_2, rounded to the nearest tenth);

(5) Average hourly NO_x emission rate (lb/mmBtu, rounded to nearest hundredth);

(6) Average hourly NO_x emission rate (lb/mmBtu, rounded to nearest hundredth) adjusted for bias, if bias adjustment factor is required as provided for in § 75.24(d) of this part;

(7) Percent monitoring system data availability, (recorded to the nearest tenth of a percent), calculated pursuant to § 75.32 of this part;

(8) Method of determination for average hourly NO_x emission rate using Codes 1–12 in Table 3; and

(9) Unique three-digit code identifying emissions formula used to derive average hourly NO_x emission rate, as provided for in § 75.53.

(e) *CO_2 emission record provisions.* The owner or operator shall record or calculate CO_2 emissions for each affected unit using one of the following methods specified in this section:

(1) If the owner or operator chooses to use a CO_2 continuous emission monitoring system (or an O_2 continuous emission monitor and flow monitor as specified in Appendix F), then the owner or operator shall record hourly the following information for CO_2 mass emissions, as measured and reported from the certified primary monitor, certified back-up or certified portable monitor, or other approved method of emissions determination:

(i) Monitor-channel identification code as provided for in § 75.53;

(ii) Date and hour;

(iii) Average hourly CO_2 (or O_2) concentration (in percent, rounded to the nearest tenth);

(iv) Average hourly volumetric flow rate (scfh, rounded to the nearest scf);

(v) Average hourly CO_2 mass emissions (tons/hr, rounded to the nearest tenth);

(vi) Percent monitor data availability (recorded to the nearest tenth of a percent); calculated pursuant to § 75.32 of this part;

(vii) Method of determination for average hourly CO_2 mass emissions using Codes 1–12 in Table 3; and

(viii) Unique three-digit emissions formula used to derive average hourly CO_2 mass emissions, as provided for in § 75.53.

(2) As an alternative to § 75.50(e)(1), the owner or operator may use the procedures in § 75.13 and in Appendix G to this part, and shall record daily the following information for CO_2 mass emissions:

(i) Date;

(ii) Average daily combustion-formed CO_2 mass emissions (tons/day, rounded to the nearest tenth);

(iii) For coal-fired units, flag indicating whether optional procedure to adjust combustion-formed CO_2 mass emissions for carbon retained in flyash has been used and, if so, the adjustment;

(iv) For a unit with a wet flue gas desulfurization system or other controls generating CO_2, average daily sorbent-related CO_2 mass emissions (tons/day, rounded to the nearest tenth); and

(v) For a unit with a wet flue gas desulfurization system or other controls generating CO_2, average total daily CO_2 mass emissions (tons/day, rounded to the nearest tenth) as sum of combustion-formed emissions and sorbent-related emissions.

(f) *Opacity record provisions.* The owner or operator shall record every six minutes (or other averaging period specified by the State or local air pollution control agency) the information required by this paragraph for each affected unit, except as provided for in § 75.14 (b), (c), and (d). The owner or operator shall also keep records of all incidents of opacity monitor downtime during unit operation, including reason(s) for the monitor outage(s) and any corrective action(s) taken for opacity, as measured and reported by the continuous opacity monitoring system:

(1) Monitor-channel identification code;

(2) Date, hour, and minute;

(3) Average opacity of emissions (in percent opacity);

(4) If the average opacity of emissions exceeds the applicable standard, then a code indicating such an exceedance has occurred; and

(5) Percent monitor data availability, recorded to the nearest tenth of a percent, calculated pursuant to § 75.32 of this part.

§ 75.51 General recordkeeping provisions for specific situations.

(a) *Specific SO_2 emission record provisions for units with qualifying Phase I technology.* In addition to the SO_2 emissions information required in § 75.50(c) of this part, from January 1, 1997, through December 31, 1999, the owner or operator shall record the applicable information in this paragraph for each affected unit on which SO_2 emission controls have been installed and operated for the purpose of meeting qualifying Phase I technology requirements pursuant to § 72.42 of this chapter and § 75.15.

(1) For units with post-combustion emission controls:

(i) Monitor-channel identification codes for each inlet and outlet SO_2-diluent continuous emission monitoring system;

(ii) Date and hour;

(iii) Average hourly inlet SO_2 emission rate (lb/mmBtu, rounded to nearest hundredth);

(iv) Average hourly inlet SO_2 concentration (ppm, rounded to the nearest tenth) adjusted for bias, if bias adjustment factor required (see § 75.24(d) of this part);

(v) Average hourly outlet SO_2 emission rate (lb/mmBtu, rounded to nearest hundredth);

(vi) Average hourly outlet SO_2 concentration (ppm, rounded to the nearest tenth) adjusted for bias, if bias adjustment factor required (see § 75.24(d) of this part);

(vii) Percent data availability for both inlet and outlet SO_2-diluent continuous emission monitoring systems (recorded to the nearest tenth of a percent), calculated pursuant to Equation 8 of § 75.32 (for the first 8,760 unit operating hours following initial certification) and Equation 9 of § 75.32, thereafter; and

(viii) Emissions formula used to derive average hourly SO_2 mass emissions for each affected unit or group of units using a common stack.

(2) For units with combustion and/or pre-combustion emission controls:

(i) Monitor-channel identification codes for each outlet SO_2 continuous emission monitoring system;

(ii) Date and hour;

(iii) Average hourly outlet SO_2 emission rate (lb/mmBtu, rounded to nearest hundredth);

(iv) For units with combustion controls, average daily inlet SO_2 emission rate (lb/mmBtu, rounded to nearest hundredth), determined by coal sampling and analysis procedures in Appendix F to this part; and

(v) For units with pre-combustion controls (i.e., fuel pretreatment), fuel analysis demonstrating the weight, sulfur content, and gross calorific value of the product and raw fuel lots.

(b) *Specific parametric data record provisions for calculating substitute emissions data for units with add-on emission controls.* In addition to the SO_2 and NO_x emission data to be recorded under § 75.50, the owner or operator of an affected unit with add-on emission controls where the owner or operator is using the approved site-specific parametric monitoring procedures for calculation of substitute data in accordance with § 75.34, then the owner or operator shall also record for each hour during each missing data period the applicable information in this paragraph (b):

(1) For units with add-on SO_2 emission controls, for each hour of missing SO_2 concentration or volumetric flow data:

(i) The information required in § 75.50(b) of this part for SO_2 concentration and volumetric flow if either one of these monitors is still operating;

(ii) Date and hour;

(iii) Number of operating scrubber modules;

(iv) Feedrate of makeup slurry to each operating scrubber module (gal/min);

(v) Average pressure differential across each operating scrubber module (inches of water column);

(vi) For a unit with a wet flue gas desulfurization system, an inline measure of absorber pH for each operating scrubber module;

(vii) For a unit with a dry flue gas desulfurization system, the inlet and outlet temperatures across each operating scrubber module;

(vii) The slurry feed rate (gal/min) to the atomizer nozzle; and

(ix) Method of determination of SO_2 concentration and volumetric flow, using Codes 1–12 in Table 3 of § 75.50 of this part.

(2) For units with add-on NO_x emission controls, for each hour of missing NO_x emission rate data:

(i) Date and hour;

(ii) Inlet air flow rate (acfh, rounded to the nearest thousand);

(iii) Excess O_2 concentration of flue gas at stack outlet (rounded to nearest tenth of a percent);

(iv) CO concentration of flue gas at stack outlet (ppm, rounded to the nearest tenth);

(v) Temperature of flue gas at furnace exit or economizer outlet duct (°F); and

(vi) Other parameters specific to NO_x emission controls (e.g., average hourly reagent feedrate).

(c) *Specific SO_2 Emission Record Provisions for Gas-Fired or Oil-Fired Units Using Optional Protocol in Appendix D to This Part.* In lieu of recording the information in § 75.50(c) of this section, the owner or operator shall record the applicable information in this paragraph for each affected gas-fired or oil-fired unit for which the owner or operator is using the optional protocol in Appendix D to this part for estimating SO_2 mass emissions.

(1) When the unit is combusting oil:

(i) Date and hour;

(ii) Average hourly flow rate of oil with the units in which oil flow is recorded, (gal/hr, lb/hr, or bbl/hr, rounded to the nearest tenth);

(iii) Sulfur content of daily oil sample, rounded to nearest tenth of a percent;

(iv) Method of oil sampling (flow proportional, continuous drip, or manual);

(v) Mass of oil combusted each hour (lb/hr, rounded to the nearest tenth); and

(vi) Average hourly SO_2 mass emissions (lb/hr, rounded to the nearest tenth).

(2) for gas-fired units or oil-fired units using the optional protocol in Appendix D of this part of daily manual oil sampling, when the unit is combusting oil, the highest sulfur content recorded from the most recent 30 daily oil samples rounded to nearest tenth of a percent.

(3) When the unit is combusting natural gas,

(i) Date and hour; and

(ii) Daily heat input from natural gas according to procedures in Appendix F to this part (mmBtu, rounded to the nearest tenth).

(iii) Sulfur content or SO_2 emission rate, in one of the following formats, in accordance with the appropriate procedure from Appendix D of this part:

(A) Sulfur content of daily gas sample, (rounded to the nearest 0.1 grains/100 scf) and the volume of gas combusted per day, in 100 scf; or

(B) SO_2 emission rate from NADB (in lb/mmBtu).

(d) *Specific NO_x Emission Record Provisions for Gas-Fired Peaking Units or Oil-Fired Peaking Units Using Optional Protocol in Appendix E of This Part.* In lieu of recording the information in paragraph § 75.50(d), the owner or operator shall record the applicable information in this paragraph for each affected gas-fired peaking unit or oil-fired peaking unit for which the owner or operator is using the optional protocol in Appendix E to this part for estimating NO_x emission rate.

(1) When the unit is combusting oil,

(i) Date and hour;

(ii) Average daily fuel flow of oil with the units in which oil flow is recorded (gal/day or bbl/day);

(iii) NO_x emission rate F-factor for oil combusted according to procedure in Appendix E to this part; and

(iv) Average daily NO_x emission rate (lb/mmBtu, rounded to nearest tenth).

(2) When the unit is combusting natural gas,

(i) Date and hour;

(ii) Average daily fuel flow of natural gas (million cubic ft);

(iii) NO_x emission rate F-factor for gas combusted according to procedure in Appendix E to this part; and

(iv) Average daily NO_x emission rate (lb/mmBtu, rounded to nearest tenth).

§ 75.52 Certification, quality assurance and quality control record provisions.

(a) The owner or operator shall record the applicable information in this section for each certified monitor or certified monitoring system (including certified backup or certified portable monitors) measuring and recording emissions or flow from an affected unit.

(1) For each SO_2 or NO_x pollutant concentration monitor, flow monitor, CO_2 monitor, or diluent gas monitor, the owner or operator shall record the following for all daily and 7-day calibration error tests, including any follow-up tests after corrective action:

(i) Monitor channel identification code;

(ii) Instrument span;

(iii) Date and hour;

(iv) Reference value, (i.e., calibration gas concentration or reference signal value, in ppm or other appropriate units);

(v) Observed value (monitor response during calibration, in ppm or other appropriate units);

(vi) Percent calibration error (rounded to nearest tenth of a percent);

(vii) Number of out-of-control hours, if any, following test; and

(viii) Description of any adjustments, corrective actions, or maintenance following test.

(2) For each flow monitor, the owner or operator shall record the following for all daily interference checks, including any follow-up tests after corrective action:

(i) Code indicating whether monitor passes or fails the interference check;

(ii) Number of out-of-control hours, if any, following test; and

(iii) Description of any adjustments, corrective actions, or maintenance following test.

(3) For each SO_2 or NO_x pollutant concentration monitor, CO_2 monitor, or diluent gas monitor, the owner or operator shall record the following for the initial and all subsequent linearity check(s), including any follow-up tests after corrective action:

(i) Monitor channel identification code;

(ii) Instrument span;

(iii) Date and hour;

(iv) Reference value (i.e., reference gas concentration, in ppm or other appropriate units);

(v) Observed value (average monitor response at each reference gas concentration, in ppm or other appropriate units);

(vi) Percent error at each of three reference gas concentrations (rounded to nearest tenth of a percent);

(vii) Number of out-of-control hours, if any, following test; and

(viii) Description of any adjustments, corrective action, or maintenance following test.

(4) For each flow monitor, where applicable, the owner or operator shall record the following for all quarterly leak checks, including any follow-up tests after corrective action:

(i) Code indicating whether monitor passes or fails the quarterly leak check;

(ii) Number of out-of-control hours, if any, following test; and

(iii) Description of any adjustments, corrective actions, or maintenance following test.

(5) For each SO_2 pollutant concentration monitor, flow monitor, CO_2 pollutant concentration monitor; NO_x continuous emission monitoring system, SO_2-diluent continuous emission monitoring system; and approved alternative monitoring system, the owner or operator shall record the following information for the initial and all subsequent relative accuracy tests and test audits:

(i) Date and hour;

(ii) Reference method(s) used;

(iii) Individual test run data from the relative accuracy test audit for the SO_2 concentration monitor, flow monitor, CO_2 pollutant concentration monitor, NO_x continuous emission monitoring system, SO_2-diluent continuous emission monitoring system, or approved alternative monitoring systems, including:

(A) Date, hour, and minute of beginning of test run,

(B) Date, hour, and minute of end of test run,

(C) Monitor-channel identification code,

(D) Run number,

(E) Run data for monitor;

(F) Run data for reference method; and

(G) Flag value (0 or 1) indicating whether run has been used in calculating relative accuracy and bias values.

(iv) Calculations and tabulated results, as follows:

(A) Arithmetic mean of the monitoring system measurement values, reference method values, and of their differences, as specified in Equation A–7 in appendix A to this part.

(B) Standard deviation, as specified in Equation A–8 in appendix A to this part.

(C) Confidence coefficient, as specified in Equation A–9 in appendix A to this part.

(D) Relative accuracy test results, as specified in Equation A–10 in appendix A to this part. (For the 3-level flow monitor test only, relative accuracy test results should be recorded at each of three gas velocities. Each of these three gas velocities shall be expressed as a total integrated gross unit load, rounded to the nearest MWe.)

(E) Bias test results as specified in section 7.6.4 in appendix A to this part.

(F) Bias adjustment factor from Equations A–11 and A–12 in appendix A to this part for any monitoring system or component that failed the bias test and 1.0 for any monitoring system or component that passed the bias test. (For flow monitors only, bias adjustment factors should be recorded at each of three gas velocities).

(G) Number of out-of-control hours, if any, following test.

(H) Description of any adjustment, corrective action, or maintenance following test.

(6) F-factor value(s) used to convert NO_x pollutant concentration and diluent gas (O_2 or CO_2) concentration measurements into NO_x emission rates (in lb/mmBtu), heat input or CO_2 emissions.

(7) Results of all trial runs and certification tests and quality assurance activities and measurements (including all reference method field test sheets, charts, records of combined system responses, laboratory analyses, and example calculations) necessary to substantiate compliance with all relevant appendices in this part.

§ 75.53 Monitoring plan.

(a) General provisions. The owner or operator of an affected unit shall prepare and maintain a monitoring plan. Except as provided in paragraphs (c) and (d) of this section, a monitoring plan shall contain sufficient information on the continuous emission or opacity monitoring systems and the use of data derived from these systems to demonstrate that all unit SO_2 emissions, NO_x emissions, CO_2 emissions when monitored continuously, and opacity are monitored and reported by continuous emission or opacity monitoring systems.

(b) Whenever the owner or operator makes a replacement, modification, or change, either in the certified continuous emission monitoring system or continuous opacity monitoring system, including the automated data acquisition and handling system or in the flue gas handling system, that requires recertification, then the owner or operator shall update the monitoring plan.

(c) Contents of the monitoring plan. Each monitoring plan shall contain the following:

(1) Precertification information, including the identification of the test strategy and protocol for the relative accuracy test audit and other relevant test information; and

(2) Unit table. A table identifying all units, using ORISPL numbers developed by the Department of Energy and used in the National Allowance Database, for all affected units involved in the monitoring plan with the following information for each unit:

(i) Short name;

(ii) Classification of unit as one of the following: Phase I affected (including substitution units), Phase II affected, new, or nonaffected;

(iii) Type of boiler (or boilers for a group of units using a common stack);

(iv) Type of fuel(s) fired, by boiler, and if more than one fuel, the fuel classification of the boiler;

(v) Type(s) of emission controls for SO_2, NO_x, and particulates installed or to be installed, including specifications of whether such controls are pre-combustion, post-combustion, or integral to the combustion process; and

(vi) Identification of all units using a common stack.

(3) Description of monitor site location. Description of site locations for each monitoring component in the continuous emission or opacity monitoring systems, including schematic diagrams and engineering drawings specified in paragraphs (c)(7) and (c)(8) of this section, and any other documentation that demonstrate each monitor location meets the appropriate siting criteria.

(4) Monitoring component table. Identification and description of each monitoring component (including each monitor and its identifiable components such as analyzer and/or probe) in the

continuous emission monitoring systems (i.e., SO_2 pollutant concentration monitor, flow monitor, moisture monitor; NO_x pollutant concentration monitor and diluent gas monitor) and the continuous opacity monitoring system, including:

(i) Manufacturer model number and serial number;

(ii) Monitor-channel identification code assigned by the utility to each monitor or identifiable monitoring component (such as the analyzer and/or probe). The code shall use a six-digit format, unique to each monitoring component, where the first three digits indicate the number of the component and the second three digits indicate the "channel" the particular parameter that the monitor measures;

(iii) Actual or projected installation date (month and year); and

(iv) A brief description of the component type or method of operation, such as in situ pollutant concentration monitor or thermal flow monitor.

(v) A brief description of the flow monitor that is sufficiently detailed to allow a determination of whether the applicable interference check design specification meets the requirements specified in Appendix A of this part.

(vi) A designation of the component as a primary or backup component, as provided for in § 75.10(g).

(5) Data acquisition and handling system table. Identification and description of all major hardware and software components of the automated data acquisition and handling system, including:

(i) For hardware components, the manufacturer, model number, and actual or projected installation date;

(ii) For software components, identification of the provider, whether the software is a custom, turn-key, or commercially available product, and a brief description of features;

(iii) A data flow diagram denoting the complete information handling path from output signals of continuous emission monitoring system components to final reports;

(iv) A copy of the test results verifying the accuracy of the automated data acquisition and handling system (once such results are available).

(6) Emissions formula table. A table giving explicit formulas for each reported unit emission parameter, using monitor-channel identification codes to link continuous emission monitoring system observations with reported concentrations, mass emissions, or emission rates, according to the conversions listed in appendix F to this part. The formulas must contain all constants and factors required to derive mass emissions or emission rates from monitor-channel code observations, and each emissions formula is identified with a unique three digit code.

(7) Schematic stack diagrams. A schematic diagram identifying entire gas handling system from boiler to stack for all affected units, using identification numbers for units, monitors, and stacks corresponding to the identification numbers provided in paragraphs (c)(2), (c)(4), (c)(5), and (c)(6) of this section. Comprehensive and/or separate schematic diagrams shall be used to describe groups of units using a common stack.

(8) Stack and duct engineering diagrams. Stack and duct engineering diagrams showing the dimensions, and also showing location of fans, turning vanes, air preheaters, monitors, probes, reference method sampling ports and other equipment which affects the monitoring system location, performance or quality control checks.

(9) Inside crosssectional area (ft^2) at flue exit.

(10) Contents of monitoring plan for specific situations. The following information shall be included in the monitoring plan for gas-fired or oil-fired units:

(i) For each gas-fired unit or oil-fired unit for which the owner or operator uses the optional protocol in Appendix D of this part for estimating SO_2 mass emissions or Appendix E of this part for estimating NO_x emission rate (using a fuel flow meter), the designated representative shall include in the monitoring plan a description of the fuel flowmeter and data demonstrating its flow meter accuracy.

(ii) For each gas-fired peaking unit and oil-fired peaking unit for which the owner or operator uses the optional procedures in Appendix E to this part for estimating NO_x emission rate, the designated representative shall include in the monitoring plan:

(A) The NO_x emission rate F-factor for each fuel combusted by the unit; and

(B) All baseline and periodic NO_x emissions test data and results used to determine the NO_x emission rate F-factor for each fuel.

Subpart G—Reporting Requirements

§ 75.60 General provisions.

(a) The designated representative for any affected unit subject to the requirements of this part shall comply with all reporting requirements in this section and with the signatory requirements of § 72.21 of this chapter for all submissions.

(b) Submissions. The designated representative shall submit all reports and petitions (except as provided in § 75.61) as follows:

(1) All certification or recertification notifications, certification or recertification applications, monitoring plans, petitions for alternative monitoring systems, notifications, electronic quarterly reports, and other communications required by this subpart shall be submitted to the Administrator.

(2) Copies of certification or recertification notifications, certification or recertification applications and monitoring plans shall be submitted to the appropriate Regional Office of the U.S. Environmental Protection Agency and appropriate State or local air pollution control agency.

§ 75.61 Notification of certification and recertification test dates.

(a) *Submission.* The owner or operator or designated representative for an affected unit shall submit written notification of certification tests, recertification tests, and revised test dates for continuous emission monitoring systems, as specified in § 75.20 of this part. Certification test notifications shall be submitted not later than 45 days prior to the first day of certification or recertification testing, except as provided in § 75.20(a)(1)(ii) of this part. Recertification test notifications shall be provided as soon as practicable but not later than the second business day following the identified need for recertification.

(1) The owner or operator or designated representative shall notify the Administrator, the appropriate EPA Regional Office, and the applicable State air pollution control agency at least 7 business days in advance of any proposed adjustments to the certification testing dates.

(2) The owner or operator or designated representative shall submit notification of certification tests and recertification tests for continuous opacity monitoring systems, as specified in § 75.20(c)(6) of this part to the State or local air pollution control agency.

(3) If notification substantially similar to that required in this section is required by any other State or local agency, the owner or operator or designated representative may send the Administrator a copy of that notification to satisfy this requirement, provided the ORISPL unit identification number(s) is denoted.

(b) [Reserved]

§ 75.62 Monitoring plan.

(a) *Submission.* The designated representative for an affected unit shall submit the monitoring plan to the

Administrator no later than 45 days prior to the certification test.

(b) *Contents.* Monitoring plans shall contain the information specified in § 75.53 of this part.

§ 75.63 Certification or recertification application.

(a) *Submission.* The designated representative for an affected unit shall submit the request to the Administrator within 30 days after completing the certification test.

(b) *Contents.* Each application for certification or recertification shall contain the following information:

(1) A copy of the monitoring plan (or any modifications to the monitoring plan) for the unit or units if not previously submitted.

(2) The results of the test(s) required by § 75.20 of this part, including the type of test conducted, testing date, and including the results of any failed tests that had been repeated pursuant to the requirements in § 75.20.

(3) Results of the tests for verification of the accuracy of emissions and volumetric flow calculations performed by the automated data acquisition and handling system, including a summary of equations used to convert component data to units of the standard and to calculate substitute data for missing data periods, including sample calculations.

(c) *Electronic format.* Each certification application shall be submitted in a format to be specified by the Administrator.

§ 75.64 Quarterly reports.

(a) *Submission.* The designated representative for an affected unit shall electronically report the data and information in paragraphs (a), (b), and (c) of this section to the Administrator quarterly, beginning with the data from the later of: The last (partial) calendar quarter of 1993 (where the calendar quarter data begins at November 15, 1993); or the calendar quarter corresponding to the relevant deadline for certification in § 75.4 of this part. For any provisionally-certified monitoring system, some or all of the quarterly data may be invalidated, if the Administrator subsequently issues a notice of disapproval within 120 days of receipt of the complete certification application for the monitoring system. Each electronic report must be submitted to the Administrator within 30 days following the end of each calendar quarter and shall include for each affected unit (or group of units using a common stack):

(1) The information and hourly data required in §§ 75.50–75.52 of this part, excluding the descriptions of adjustments, corrective action, and maintenance and excluding any information which is incompatible with electronic reporting (e.g., field data sheets, lab analyses, quality control plan, etc.).

(2) Tons (rounded to the nearest tenth) of SO_2 emitted during the quarter and cumulative SO_2 emissions for calendar year.

(3) Average NO_x emission rate (lb/mmBtu, rounded to the nearest hundredth) during the quarter and cumulative NO_x emission rate for calendar year.

(4) Tons of CO_2 emitted during quarter and cumulative CO_2 emissions for calendar year.

(5) Total heat input (mmBtu) and integrated gross unit load (MWge) for quarter and cumulative heat input and integrated gross unit load for calendar year.

(6) If the affected unit is using a qualifying Phase I technology, then the quarterly report shall include the information required in paragraph (e) of this section.

(b) The designated representative shall affirm that the monitor-channel identification codes and formulas in the quarterly electronic reports, submitted to the Administrator pursuant to § 75.53 of this part, represent current operating conditions.

(c) *Compliance certification.* The designated representative shall submit a certification in support of each quarterly emissions monitoring report based on reasonable inquiry of those persons with primary responsibility for ensuring that all of the unit's emissions are correctly and fully monitored. The certification shall indicate whether the monitoring data submitted were recorded in accordance with the applicable requirements of this part including the quality control and quality assurance procedures and specifications of this part and its appendices, and any such requirements, procedures and specifications of an applicable excepted or approved alternative monitoring method. In the event of any missing data periods, the certification must describe the measures taken to cure the causes for the missing data periods.

(d) *Electronic format.* Each quarterly report shall be submitted in a format to be specified by the Administrator.

(e) *Phase I qualifying technology reports.* In addition to reporting the information in paragraphs (a), (b), and (c) of this section, the designated representative for an affected unit on which SO_2 emission controls have been installed and operated for the purpose of meeting qualifying Phase I technology requirements pursuant to § 72.42 of this chapter shall also submit reports documenting the measured percent SO_2 emissions removal to the Administrator on a quarterly basis, beginning the first quarter of 1997 and continuing through the fourth quarter of 1999. Each report shall include the following information:

(1) For the first report only, a copy of the start up acceptance test result upon which the designated representative accepted the systems potential to meet the ninety percent reduction requirement.

(2) All measurements and calculations necessary to substantiate that the qualifying technology achieves the overall percent reduction in SO_2 emissions.

§ 75.65 Opacity reports.

The designated representative shall report excess emissions of opacity to the applicable State or local air pollution control agency, in a format specified by the applicable State or local air pollution control agency.

§ 75.66 Petitions to the Administrator.

(a) *Alternative flow monitor location demonstration reports.* In cases where no location exists for installation of a flow monitor in either the stack or the ducts serving an affected unit that satisfies the minimum physical siting criteria in Appendix A to this part or where installation of a flow monitor in either the stack or duct is demonstrated to the satisfaction of the Administrator to be technically infeasible, the designated representative for the affected unit may petition the Administrator for an alternative monitoring location or alternative method for monitoring volumetric flow. The demonstration report shall, at a minimum, contain the following information.

(1) Identification of the affected unit(s).

(2) Description of why the minimum siting criteria cannot be met within the existing ductwork or stack(s). This description shall include diagrams of the existing ductwork or stack, as well as documentation of any attempts to locate a flow monitor.

(3) Description of proposed alternative monitoring location or alternative method for monitoring flow.

(b) *Alternative ASTM method demonstration reports.* The designated representative for an affected unit may apply to the Administrator for an alternative to any ASTM method prescribed in this part. The designated representative shall include the following information in an application:

(1) A description of why the prescribed ASTM method is not being used;

(2) A description and diagram(s) of all equipment and procedures in the proposed alternative method;

(3) Data demonstrating that the proposed alternative method produces data of equal or greater precision and accuracy to that from the prescribed ASTM method(s).

(c) *Alternative monitoring system petitions.* The designated representative for an affected unit may submit a petition to the Administrator for approval and certification of an alternative monitoring system or component according to the procedure in subpart E of this part. Each petition shall contain the information and data specified in subpart E, including the information specified in § 75.48, in a format to be specified by the Administrator.

(d) *Parametric monitoring procedure petitions.* The designated representative for an affected unit may submit a petition to the Administrator, where each petition shall contain the information specified in § 75.51(b) for use of a parametric monitoring method.

(e) *Missing Data Petitions for units with add-on emission controls.* The designated representative for an affected unit may submit a petition to the Administrator, which the Administrator will automatically approve if the petition adequately demonstrates that all the requirements in § 75.34 are satisfied, where each petition shall contain the information listed below for the time period (or data gap) during which the affected unit experienced the monitor outage that would result in the substitution of an uncontrolled maximum value under the standard missing data procedures contained in subpart D of this part:

(1) Data demonstrating that the affected unit's monitor data availability for the time period under petition was less than 90%,

(2) Data demonstrating that the add-on emission controls were operating properly during time period under petition, and

(3) A list of the average hourly values for the previous 720 quality-assured monitor operating hours, highlighting both the maximum recorded value and the value corresponding to the maximum controlled emission rate.

(f) *Any other petitions to the Administrator.* The designated representative for an affected unit shall include sufficient information for the evaluation of any other petition submitted to the Administrator under this part.

§ 75.67 Retired units petitions.

For units that will be permanently retired prior to January 1, 1995, an exemption from the requirements of this part, including the requirement to install and certify a continuous emissions monitoring system, may be obtained from the Administrator if the designated representative submits a complete petition, as required in § 72.8, to the Administrator prior to the deadline in § 75.4 by which the continuous emission or opacity monitoring systems must complete the required certification tests.

Appendix A to Part 75—Specifications and Test Procedures

1. Installation and Measurement Location

1.1 Pollutant Concentration and CO_2 or O_2 Monitors

Following the procedures in section 3.1 of Performance Specification 2 in Appendix B to part 60 of this chapter, install the pollutant concentration monitor or monitoring system at a location where the pollutant concentration and emission rate measurements are directly representative of the total emissions from the affected unit. Select a representative measurement point or path for the monitor probe(s) (or for the path from the transmitter to the receiver) such that the SO_2 pollutant concentration monitor or NO_x continuous emission monitoring system (NO_x pollutant concentration monitor and diluent gas monitor) will pass the relative accuracy test (see section 6).

It is recommended that monitor measurements be made at locations where the exhaust gas temperature is above the dew-point temperature. If the cause of failure to meet the relative accuracy tests is determined to be the measurement location, relocate the monitor probe(s).

1.1.1 Point Pollutant Concentration and CO_2 or O_2 Monitors

Locate the measurement point (1) within the centroidal area of the stack or duct cross section, or (2) no less than 1.0 meter from the stack or duct wall.

1.1.2 Path Pollutant Concentration and CO_2 or O_2 Gas Monitors

Locate the measurement path (1) totally within the inner area bounded by a line 1.0 meter from the stack or duct will, or (2) such that at least 70.0 percent of the path is within the inner 50.0 percent of the stack or duct cross-sectional area, or (3) such that the path is centrally located within any part of the centroidal area.

1.2 Flow Monitors

Install the flow monitor in a location that provides representative volumetric flow over all operating conditions. Such a location is one that provides an average velocity of the flue gas flow over the stack or duct cross section, provides a representative SO_2 emission rate (in lb/hr), and is representative of the pollutant concentration monitor location. Where the moisture content of the flue gas affects volumetric flow measurements, use the procedures in both Reference Methods 1 and 4 of Appendix A to part 60 of this chapter to establish a proper location for the flow monitor. EPA recommends (but does not require) performing a flow profile study following the procedures in 40 CFR part 60, Appendix A, Text Method, 1, section 2.5 for each of the three operating or load levels indicated in section 6.5.2 of this appendix to determine the acceptability of the potential flow monitor location and to determine the number and location of flow sampling points required to obtain a representative flow value. The procedure in 40 CFR part 60, Appendix A, Test Method 1, section 2.5 may be used even if the flow measurement location is greater than or equal to 2 equivalent stack or duct diameters downstream or greater than or equal to ½ duct diameter upstream from a flow disturbance. If a flow profile study shows that cyclonic (or swirling) or stratified flow conditions exist at the potential flow monitor location that are likely to prevent the monitor from meeting the performance specifications of this part, then EPA recommends either (1) selecting another location where there is no cyclonic (or swirling) or stratified flow condition, or (2) eliminating the cyclonic (or swirling) or stratified flow condition by straightening the flow, e.g., by installing straightening vanes. EPA also recommends selecting flow monitor locations to minimize the effects of condensation, coating, erosion, or other conditions that could adversely affect flow monitor performance.

1.2.1 Acceptability of Monitor Location

The installation of a flow monitor is acceptable if (1) the location satisfies the minimum siting criteria of Method 1 in Appendix A to part 60 of this chapter (i.e., the location is greater than or equal to eight stack or duct diameters downstream and two diameters upstream from a flow disturbance; or, if necessary, two stack or duct diameters downstream and one-half stack or duct diameter upstream from a flow disturbance), (2) the results of a flow profile study, if performed, are acceptable (i.e., there are no cyclonic (or swirling) or stratified flow conditions), and (3) the flow monitor satisfies the performance specifications of this part. If the flow monitor is installed in a location that does not satisfy these physical criteria, but nevertheless the monitor achieves the performance specifications of this part, then the Administrator may certify the location as acceptable.

1.2.2 Alternative Monitoring Location

Whenever the flow monitor is installed in a location that is grater than or equal to two stack or duct diameters downstream and greater or equal to one-half diameter upstream from a flow disturbance, and/or in a location that is acceptable based on a flow profile study, but nevertheless the monitor does not achieve the performance specifications of this part, perform another flow profile study (the procedures described in section 2.5 of Method 1 in Appendix A to part 60 of this chapter may be used) to select an alternative flow monitoring installation site.

Whenever the owner or operator successfully demonstrates that modifications

to the exhaust duct or stack (such as installation of straightening vanes, modifications of ductwork, and the like) are necessary for the flow monitor to meet the performance specifications, the Administrator may approve an interim alternative flow monitoring methodology and an extension to the required certification date for the flow monitor.

Where no location exists that satisfies the physical siting criteria in section 1.2.1, where the results of flow profile studies performed at two or more alternative flow monitor locations are unacceptable, and where installation of a flow monitor in either the stack or the ducts is demonstrated to be technically infeasible, the owner or operator may petition the Administrator for an alternative method for monitoring flow.

2. Equipment Specifications

2.1 Instrument Span

In implementing sections 2.1.1 through 2.1.4 of this appendix, to the extent practicable, measure at a range such that the majority of readings obtained during normal operation are between 25 and 75 percent of full-scale range of the instrument.

2.1.1 SO_2 Pollutant Concentration Monitors

Determine, as indicated below, a span value for pollutant concentration monitors so that it includes all expected concentrations.

2.1.1.1 Maximum Potential Concentration

The monitor must be capable of accurately measuring up to 125 percent of the maximum potential concentration as calculated using Equation A–1a or A–1b. Calculate the maximum potential concentration by using Equation A–1a or A–1b and the maximum percent sulfur and minimum gross calorific value (GCV) for the highest sulfur fuel to be burned. Base the maximum percent sulfur and minimum GCV on the results of all available fuel sampling and analysis data from the previous 12 months (where such data exists) using ASTM Methods ASTM D3177–89, "Standard Test Methods for Total Sulfur in the Analysis Sample of Coal and Coke," ASTM D4239–85, "Standard Test Methods for Sulfur in the Analysis Sample of Coal and Coke Using High Temperature Tube Furnace Combustion Methods," ASTM D4294–90, "Standard Test Method for Sulfur in Petroleum Products by Energy-Dispersive X-Ray Fluorescence Spectroscopy," ASTM D1552–90, "Standard Test Method for Sulfur in Petroleum Products (High Temperature Method)," ASTM D129–91, 'Standard Test Method for Sulfur in Petroleum Products (General Bomb Method),' or ASTM D2622–92, "Standard Test Method for Sulfur in Petroleum Products by X-Ray Spectrometry" for sulfur content of solid or liquid fuels, or ASTM D3176–89, "Standard Practice for Ultimate Analysis of Coal and Coke", ASTM D240–87 (Reapproved 1991), "Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter" or ASTM D2015–91, "Standard Test Method for Gross Calorific Value of Coal and Coke by the Adiabatic Bomb Calorimeter" for GCV (incorporated by reference under § 75.6). Then, multiply the maximum potential concentration by 125 percent, and round up the resultant concentration to the nearest multiple of 100 ppm to determine the span value. Select the full-scale range of the instrument to be consistent with section 2.1 of this appendix, and to be greater than or equal to the span value. The span value will be used to determine the concentrations of the calibration gases. The selected monitor range based on 125 percent of the maximum potential concentration will henceforth be referred to as the "high-scale" of the SO_2 pollutant concentration monitor.

$$MPC = 11.32 \times 10^6 \left(\frac{\%S}{GCV}\right)\left(\frac{20.9-\%O_{2w}}{20.9}\right) \qquad \text{(Eq. A–1a)}$$

or

$$MPC = 66.93 \times 10^6 \left(\frac{\%S}{GCV}\right)\left(\frac{\%CO_{2w}}{100}\right) \qquad \text{(Eq. A–1b)}$$

where,

MPC=Maximum potential concentration (ppm, wet basis). To convert to dry basis, divide the MPC by 0.9.)

%S=Maximum sulfur content of fuel to be fired, wet basis, weight percent, as determined by ASTM D3177–89, ASTM D4239–85, ASTM D4294–90, ASTM D1552–90, ASTM D129–91, or ASTM D2622–92 for solid or liquid fuels (incorporated by reference under § 75.6).

GCV=Minimum gross calorific value of the fuel lot consistent with the sulfur analysis (Btu/lb), as determined using ASTM D3176–89, ASTM D240–87 (Reapproved 1991), or ASTM D2015–91 (incorporated by reference under § 75.6).

$\%O_{2w}$=Minimum oxygen concentration, percent wet basis, under normal operating conditions.

$\%CO_{2w}$=Maximum carbon dioxide concentration, percent wet basis, under normal operating conditions.

11.32×10^6=Oxygen-based conversion factor in (Btu/lb)(ppm)/%.

66.93×10^6=Carbon dioxide-based conversion factor in (Btu/lb)(ppm)/%

Note: All percent values to be inserted in the equations of this section are to be expressed as a percentage, not a fractional value, e.g., 3, not .03.

2.1.1.2 Maximum Expected Concentration

If the majority of SO_2 concentration values are predicted to be less than 25 percent of the full-scale range of the instrument based upon 125 percent of the maximum potential concentration, (e.g., at the outlet of an SO_2 emission control) use an additional (lower) monitor range. (For this second range, use Equation A–2 to calculate the maximum expected concentration (MEC). Multiply the maximum expected concentration by 125 percent, and round up the resultant concentration to the nearest multiple of 10 ppm to determine the span value. For this lower range, select the full-scale range of the instrument to be consistent with section 2.1 of this appendix, and to be greater than or equal to the lower range span value. Units using a lower range must also be capable of accurately measuring the anticipated actual concentrations up to and including 125 percent of the maximum potential concentration. The span value of this additional range will also be used to determine concentrations of the calibration gases for this additional range. The selected monitor range based on 125 percent of the maximum expected concentration will henceforth be referred to as the "low-scale" of SO_2 pollutant concentration monitors.

MEC=MPC[(100–RE)/100] (Eq. A–2)

where,

MEC=Maximum expected concentration (ppm).

MPC=Maximum potential concentration (ppm), as determined by Eq. A–1a or A–1b.

RE=Design removal efficiency of control equipment (%).

2.1.1.3 Auto-ranging Monitors

For monitors that can continuously and automatically adjust their range of measurement, the monitor must be capable at any time of accurately measuring up to 125

percent of the maximum potential concentration, as calculated using Equation A–1a or A–1b. Define the span value(s) for an auto-ranging monitor as 125 percent of the maximum potential concentration and 125 percent of the maximum expected concentration if a second span is determined to be necessary under section 2.1.1.2 of this appendix. Determine concentrations of the calibration gases based upon the span value(s).

2.1.1.4 Adjustment of Span

Whenever the SO_2 concentration exceeds the maximum potential concentration and the monitor can measure and record these values accurately, they may be reported for use in the Acid Rain Program. If the concentration exceeds the monitor's ability to measure and record values accurately, adjust the full-scale range setting to prevent future exceedances. Whenever the fuel supply or emission controls change such that the maximum expected or potential concentration may change significantly, adjust the range setting to assure the continued proper operation of the monitoring system. Whenever the range setting is adjusted, multiply the new range setting by 80 percent, and round up the resultant concentration to the nearest multiple of 100 ppm (or 10 ppm, if appropriate) to determine the new span value. Record the new span value and report the new span value as part of the results of the daily calibration error test required by Appendix B of this part. Whenever the span value is adjusted, use calibration gas concentrations based on the new span value.

2.1.2 NO_x Pollutant Concentration Monitors

Determine, as indicated below, a span value for the NO_x pollutant concentration monitor so that all expected NO_x concentrations can be determined and recorded accurately including both the maximum expected and potential concentration.

2.1.2.1 Maximum Potential Concentration

Use 800 ppm for coal-fired and 400 ppm for oil- or gas-fired units as the maximum potential concentration of NO_x. Select the full-scale range of the instrument to be consistent with section 2.1 of this appendix, and to be greater than or equal to the span value of 125 percent of the maximum potential concentration. If the maximum potential concentration is expected to be higher than the values stated above due to unit type (e.g. cyclone burner), or if it is determined through testing of the unit that the maximum potential concentration exceeds the above values, do one of the following: (1) Use a maximum potential concentration of 1600 ppm for coal-fired or 480 ppm for oil- or gas-fired units and set a span value of 125 percent of the maximum potential concentration (yielding a span value of 2000 ppm or 600 ppm); or (2) determine the maximum potential concentration based upon testing results and set the span value equal to 125 percent of the maximum potential concentration, rounding up to the nearest multiple of 100 ppm. The concentration of calibration gases is calculated as a percentage of the span value. The selected monitor range based on 125 percent of the maximum potential concentration will henceforth be referred to as the "high-scale" of the NO_x pollutant concentration monitor.

2.1.2.2 Maximum Expected Concentration

If the majority of NO_x concentrations are expected to be less than 25 percent of the full-scale range of the instrument based upon 125 percent of the maximum potential concentration, (e.g., at the outlet of a NO_x add-on emission control) use an additional "low-scale" monitor range. Use 320 ppm for coal-fired and 160 ppm for oil- or gas-fired units as the maximum expected concentration of NO_x. Calculate the span value of this second range by multiplying the maximum expected concentration by 125 percent (yielding 400 ppm or 200 ppm as the span value). If the efficiency of removal of an emission control is such that the maximum expected concentration, as determined by Equation A–2, differs by more than ±50 ppm from the values above, instead use the maximum expected concentration determined by Equation A–2. Calculate the span by multiplying the maximum expected concentration by 125 percent and round up the resultant concentration to the nearest multiple of 10 ppm. Select the full-scale range of the instrument to be consistent with section 2.1 of this appendix, and to be greater or equal to the lower range span value. The selected monitor range based on 125 percent of the maximum expected concentration will henceforth be referred to as the "low-scale" of NO_x pollutant concentration monitors. The span value of this additional range will also be used to determine the concentrations of the calibration gases for this additional range. NO_x pollutant concentration monitors on affected units with NO_x emission controls, or on other units with dual-span monitors, must also be capable of accurately measuring up to 125 percent of the maximum potential concentration. For dual-span NO_x pollutant concentration monitors, determine the concentration of calibration gases based on both span values.

2.1.2.3 Auto-ranging monitors

For monitors that can continuously and automatically adjust their range of measurement, the monitor must be capable at any time of accurately measuring up to 125 percent of the maximum potential concentration as defined in section 2.1.2.1 of this appendix. Define the span value(s) for an auto-ranging monitor as 125 percent of the maximum potential concentration and 125 percent of the maximum expected concentration if a second span is determined to be necessary under section 2.1.2.2 of this appendix. Determine concentrations of the calibration gases based upon the span value(s).

2.1.2.4 Adjustment of Span

Whenever the actual NO_x concentration exceeds the monitor's ability to measure and record values accurately, adjust the full-scale range setting to prevent future exceedances. Whenever the fuel supply, emission controls, or other process parameters change such that the maximum expected concentration or the maximum potential concentration may change significantly, adjust the NO_x pollutant concentration monitor range to assure the continued accuracy of the monitoring system. Whenever the range setting is adjusted, multiply the new range setting by 80 percent, and round up the resultant concentration to the nearest multiple of 100 ppm (or 10 ppm, if appropriate) to determine the new span value. Record the new span value, and report the new span value as part of the results of the daily calibration error test required by Appendix B of this part. Whenever the span value is adjusted, use calibration gas concentrations based on the new span value.

2.1.3 CO_2 and O_2 Monitors

Define the "high scale" span value as 20 percent O_2 or 20 percent CO_2. All O_2 and CO_2 analyzers must have "high-scale" measurement capability. Select the full-scale range of the instrument to be consistent with section 2.1 of this appendix, and to be greater than or equal to the span value. If the O_2 or CO_2 concentrations are expected to be consistently low, a "low scale" measurement range may be used for increased accuracy, provided that it is consistent with section 2.1 of this appendix. Multiply the "low-scale" range setting by 80 percent to determine the lower range span value, and determine the concentration of calibration gases based on both span values.

2.1.4 Flow Monitors

Select the full-scale range of the flow monitor so that it is consistent with section 2.1 of this appendix, and can accurately measure all potential volumetric flow rates at the flow monitor installation site. For this purpose, determine the span value of the flow monitor by multiplying the maximum potential velocity from previous tests or calculations by 125 percent, or using the following procedure. Calculate the maximum potential velocity (MPV) using Equation A–3a or A–3b. Multiply the MPV by 125 percent, and round up to the nearest multiple of 100 fpm to calculate the span value.

$$MPV = \left(\frac{F_d\ H_f}{A}\right)\left(\frac{20.9}{20.9 - \%O_{2d}}\right)\left[\frac{100}{(100 - \%H_2O)}\right]$$

or

$$MPV = \left(\frac{F_c\ H_f}{A}\right)\left(\frac{100}{\%CO_{2d}}\right)\left[\frac{100}{(100-\%H_2O)}\right] \text{(Eq. A-3b)}$$

where:

MPV=maximum potential velocity (fpm, standard wet basis),

F_d=dry-basis F factor (dscf/mmBtu) from Table 1, Appendix F of this part,

F_c=carbon-based F factor (scfCO_2/mmBtu) from Table 1, Appendix F of this part,

H_f=maximum heat input (mmBtu/minute) for all units, combined, exhausting to the stack or duct where the flow monitor is located,

A=inside cross sectional area (ft^2) of the flue at the flow monitor location,

$\%O_{2d}$=maximum oxygen concentration, percent dry basis, under normal operating conditions,

$\%CO_{2d}$=minimum carbon dioxide concentration, percent dry basis, under normal operating conditions,

$\%H_2O$=maximum percent flue gas moisture content under normal operating conditions.

If the volumetric flow rate exceeds the flow monitor's ability to accurately measure and record values, adjust the full-scale range setting to prevent future exceedances. If the fuel supply, process parameters or other conditions change such that the maximum potential velocity may change significantly, adjust the range to assure the continued accuracy of the flow monitor. Whenever the range setting is adjusted, multiply the new range setting by 80 percent, and round up the resultant value to the nearest multiple of 100 fmp to determine the new span value. Record the new span value and report the new span value and reference values as parts of the results of the calibration error test required by Appendix B of this part. Whenever the span value is adjusted, use reference values for the calibration error test based on the new span value.

2.2 Design for Quality Control Testing

2.2.1 Pollutant Concentration and CO_2 or O_2 Monitors

Design and equip each pollutant concentration and CO_2 or O_2 monitor with a calibration gas injection port that allows a check of the entire measurement system when calibration gases are introduced. For extractive and dilution type monitors, all monitoring components exposed to the sample gas, (e.g., sample lines, filters, scrubbers, conditioners, and as much of the probe as practicable) are included in the measurement system. For in situ type monitors, the calibration must check against the injected gas for the performance of all active electronic and optical components (e.g. transmitter, receiver, analyzer).

Design and equip each pollutant concentration or CO_2 or O_2 monitor to allow daily determinations of calibration error (positive or negative) at the zero- and high-level concentrations specified in Section 5.2 of this Appendix.

2.2.2 Flow Monitors

Design all flow monitors to meet the applicable performance specifications.

2.2.2.1 Calibration Error Test

Design and equip each flow monitor to allow for a daily calibration error test consisting of at least two reference values: (1) Zero to 20 percent of span or an equivalent reference value (e.g., pressure pulse or electronic signal) and (2) 50 to 70 percent of span. Flow monitor response, both before and after any adjustment, must be capable of being recorded by the data acquisition and handling system. Design each flow monitor to allow a daily calibration error test of (1) the entire flow monitoring system, from and including the probe tip (or equivalent) through and including the data acquisition and handling system, or (2) the flow monitoring system from and including the transducer through and including the data acquisition and handling system.

2.2.2.2 Interference Check

Design and equip each flow monitor with a means to ensure that the moisture expected to occur at the monitoring location does not interfere with the proper functioning of the flow monitoring system. Design and equip each flow monitor with a means to detect, on at least a daily basis, pluggage of each sample line and sensing port, and malfunction of each resistance temperature detector (RTD), transceiver or equivalent.

Design and equip each differential pressure flow monitor to provide (1) an automatic, periodic back purging (simultaneously on both sides of the probe) or equivalent method of sufficient force and frequency to keep the probe and lines sufficiently free of obstructions on at least a daily basis to prevent velocity sensing interference, and (2) a means for detecting leaks in the system on at least a quarterly basis (manual check is acceptable).

Design and equip each thermal flow monitor with a means to ensure on at least a daily basis that the probe remains sufficiently clean to prevent velocity sensing interference.

Design and equip each ultrasonic flow monitor with a means to ensure on at least a daily basis that the transceivers remain sufficiently clean (e.g., backpurging system) to prevent velocity sensing interference.

3. Performance Specifications

3.1 Calibration Error

The initial calibration error performance specification of SO_2 and NO_x pollutant concentration monitors shall not deviate from the reference value of the calibration gas by more than 2.5 percent based upon the span of the instrument, as calculated using Eq. A–5 of this appendix. Alternatively, where the span value is less than 200 ppm, calibration error test results are also acceptable if the absolute value of the difference between the monitor response value and the reference value, $|R-A|$ in Equation A–5 of this appendix, is less than or equal to 5 ppm. The calibration error of CO_2 or O_2 monitors shall not deviate from the reference value of the zero- or high-level calibration gas by more than 0.5 percent O_2 or CO_2 as calculated using the term $|R-A|$ in the numerator of Eq. A–5 of this appendix. The calibration error of flow monitors shall not exceed 3.0 percent based upon the span of the instrument as calculated using Eq. A–6 of this appendix.

3.2 Linearity Check

For SO_2 and NO_x pollutant concentration monitors, the error in linearity for each calibration gas concentration (low-, mid-, and high-levels) shall not exceed or deviate from the reference value by more than 5.0 percent (as calculated using Equation A–4 of this appendix). Linearity check results are also acceptable if the absolute value of the difference between the average of the monitor response values and the average of the reference values, $|R-A|$ in Equation A–4 of this appendix, is less than or equal to 5 ppm. For CO_2 or O_2 monitors:

(1) The error in linearity for each calibration gas concentration (low-, mid-, and high-levels) shall not exceed or deviate from the reference value by more than 5.0 percent as calculated using Equation A–4 of this appendix; or

(2) The absolute value of the difference between the average of the monitor response values and the average of the reference values, $|R-A|$ in Equation A–4 of this appendix, shall be less than or equal to 0.5 percent CO_2 or O_2, whichever is less restictive.

3.3 Relative Accuracy

3.3.1 Relative Accuracy for SO_2

The relative accuracy for SO_2 pollutant concentration monitors and for SO_2-diluent continuous emission monitoring systems used by units with a qualifying Phase I technology for the period during which the units are required to monitor SO_2 emission removal efficiency, from January 1, 1997 through December 31, 1999, shall not exceed 10.0 percent except as provided below in this section.

For affected units where the average of the monitor measurements of SO_2 concentration during the relative accuracy test audit is less than or equal to 250.0 ppm (or for SO_2-diluent monitors, less than or equal to 0.5 lb/mmBTU), the mean value of the monitor

measurements shall not exceed ±15.0 ppm of the reference method mean value (or, for SO_2-diluent monitors, not to exceed ±0.03 lb/mmBTU for the period during which the units are required to monitor SO_2 emission removal efficiency, from January 1, 1997 through December 31, 1999) wherever the relative accuracy specification of 10.0 percent is not achieved.

3.3.2 Relative Accuracy for NO_x

The relative accuracy for NO_x continuous emission monitoring systems shall not exceed 10.0 percent.

For affected units where the average of the monitoring system measurements of NO_x emission rate during the relative accuracy test audit is less than or equal to 0.20 lb/mmBtu, the mean value of the NO_x continuous emission monitoring system measurements shall not exceed ±0.02 lb/mmBtu of the reference method mean value wherever the relative accuracy specification of 10.0 percent is not achieved.

3.3.3 Relative Accuracy for CO_2 Pollutant Concentration Monitors

The relative accuracy for CO_2 monitors shall not exceed 10 percent. The relative accuracy test results are also acceptable if the mean difference of the CO_2 monitor measurements and the corresponding reference method measurement, calculated using Equation A–7 of this appendix, is within ±1.0 percent CO_2 .

3.3.4 Relative Accuracy for Flow

Except as provided below in this section, the relative accuracy for flow monitors, where volumetric gas flow is measured in scfh, shall not exceed 15.0 percent through December 31, 1999. Beginning on January 1, 2000, (except as provided below in this section) the relative accuracy of flow monitors shall not exceed 10.0 percent.

For affected units where the average of the flow monitor measurements of gas velocity during one or more operating levels of the relative accuracy test audit is less than or equal to 10.0 fps, the mean value of the flow monitor velocity measurements shall not exceed ±2.0 fps of the reference method mean value in fps wherever the relative accuracy specification above is not achieved.

3.3.5 Combined SO_2/Flow Monitoring System [Reserved]

3.4 Bias

3.4.1 SO_2 Pollutant Concentration Monitors and NO_x Continuous Emission Monitoring Systems.

SO_2 pollutant concentration monitors and NO_x continuous emission monitoring systems shall not be biased low as determined by the test procedure in section 7.6 of this appendix. The bias specification applies to all SO_2 pollutant concentration monitors, including those measuring an average SO_2 concentration of 250.0 ppm or less, and to all NO_x continuous emission monitoring systems, including those measuring an average NO_x emission rate of 0.20 lb/mmBtu or less

3.4.2 Flow Monitors

Flow monitors shall not be biased low as determined by the test procedure in section 7.6 of this appendix. The bias specification applies to all flow monitors including those measuring an average gas velocity of 10.0 fps or less.

3.5 Cycle Time/Response Time

The cycle time/response time for pollutant concentration monitors, and continuous emission monitoring systems shall not exceed 15 min.

4. Data Acquisition and Handling Systems

Automated data acquisition and handling systems shall: (1) Read and record the full range of pollutant concentrations and volumetric flow from zero through span; and (2) provide a continuous, permanent record of all measurements and required information as an ASCII flat file capable of transmission via an IBM-compatible personal computer diskette or other electronic media. These systems also shall have the capability of interpreting and converting the individual output signals from an SO_2 pollutant concentration monitor, a flow monitor, and a NO_x continuous emissions monitoring system to produce a continuous readout of pollutant mass emission rates in the units of the standard. Where CO_2 emissions are measured with a continuous emission monitoring system, the data acquisition and handling system shall also produce a readout of CO_2 mass emissions in tons.

Data acquisition and handling systems shall also compute and record monitor calibration error; any bias adjustments to pollutant concentration, flow rate, or NO_x emission rate data; and all missing data procedure statistics specified in subpart D of this part.

5. Calibration Gas

5.1 Reference Gases

For the purposes of part 75, calibration gases include the following.

5.1.1 Standard Reference Materials

These calibration gases may be obtained from the National Institute of Standards and Technology (NIST) at the following address: Quince Orchard and Cloppers Road, Gaithersburg, Maryland 20899.

5.1.2 NIST/EPA-Approved Certified Reference Materials

A current list of certified reference material cylinder gases and certified reference material vendors is available from the Quality Assurance Division (MD 77), Environmental Monitoring System Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

5.1.3 EPA Traceability Protocol 1 Gases

Protocol 1 gases must be vendor-certified to be within 2.0 percent of the concentration specified on the cylinder label (tag value).

5.2 Concentrations

Four concentration levels are required as follows.

5.2.1 Zero-level Concentration

0 to 20 percent of span, including span for high scale or both low- and high-scale for SO_2 and NO_x pollutant concentration monitors, as appropriate.

5.2.2 Low-level Concentration

20 to 30 percent of span, including span for high scale or both low- and high-scale for SO_2 and NO_x pollutant concentration monitors, as appropriate.

5.2.3 Mid-level Concentration

50 to 60 percent of span, including span for high scale or both low- and high-scale for SO_2 and NO_x pollutant concentration monitors, as appropriate.

5.2.4 High-level Concentration

80 to 100 percent of span, including span for high scale or both low- and high-scale for SO_2 and NO_x pollutant concentration monitors, as appropriate.

6. Certification Tests and Procedures

6.1 Pretest Preparation

Install the components of the continuous emission monitoring system (i.e., pollutant concentration monitors, CO_2 or O_2 monitor, and flow monitor) as specified in sections 1, 2, and 3 of this appendix, and prepare each system component and the combined system for operation in accordance with the manufacturer's written instructions. Operate the unit(s) during each period when measurements are made. Units may be tested on non-consecutive days.

6.2 Linearity Check

Measure the linearity of each pollutant concentration monitor and CO_2 or O_2 monitor according to the following procedures.

Challenge each pollutant concentration or CO_2 or O_2 monitor with NIST/EPA-approved certified reference material, standard reference material, or Protocol 1 calibration gases certified to be within 2 percent of the concentration specified on the label at the low-, mid-, or high-range concentrations specified in section 5.2 of this appendix. For units using emission controls and other units using a maximum expected concentration value to determine calibration gases, perform a linearity check on both the low- and high-scales.

Introduce the calibration gas at the gas injection port, as specified in section 2.2.1 of this appendix. Operate each monitor at its normal operating temperature and conditions. For extractive and dilution type monitors, pass the calibration gas through all filters, scrubbers, conditioners, and other monitor components used during normal sampling and through as much of the sampling probe as is practical. For in situ type monitors, perform calibration checking all active electronic and optical components, including the transmitter, receiver, and analyzer.

Repeat the procedure for SO_2 and NO_x pollutant concentration monitors using the low-scale for units equipped with emission controls with dual span monitors. Challenge the monitor three times with each reference gas. Do not use the same gas twice in succession. Record the monitor response from the data acquisition and handling system (see example data sheet in Figure 1). For each concentration, use the average of the responses to determine the error in linearity using Equation A–4 in this appendix.

Linearity checks are acceptable for monitor or monitoring system certification if none of

the test results exceed the applicable performance specifications in section 3.2 of this appendix.

6.3 7-Day Calibration Error Test

6.3.1 7-day Calibration Error Test for Pollutant Concentration Monitors and CO_2 and O_2 Monitors

Measure the calibration error of each pollutant concentration monitor and CO_2 or O_2 monitor once each day for 7 consecutive operating days according to the following procedures. (In the event that extended unit outages occur after the commencement of the test, the 7 consecutive operating days need not be 7 consecutive calendar days.) Units using dual span monitors must perform the calibration error test on both high- and low-scales of the pollutant concentration monitor.

Do not make manual adjustments to the monitor settings during the 7-day test. If automatic adjustments are made, conduct the calibration error test in a way that the magnitude of the adjustments can be determined and recorded.

The calibration error tests should, to the extent practicable, be approximately 24 hours apart, (unless the 7-day test is performed over non-consecutive days). Perform calibration error tests at two concentrations: (1) Zero-level and (2) high-level, as specified in section 5.2 of this appendix. In addition, repeat the procedure for SO_2 and NO_x pollutant concentration monitors using the low-scale for units equipped with emission controls or other units with dual span monitors. Use only NIST/EPA-approved certified reference material, standard reference material or Protocol 1 calibration gases certified by the vendor to be within 2 percent of the label value.

Introduce the calibration gas at the gas injection port, as specified in section 2.2.1 of this appendix. Operate each monitor in its normal sampling mode. For extractive and dilution type monitors, pass the audit gas through all filters, scrubbers, conditioners, and other monitor components used during normal sampling and through as much of the sampling probe as is practical. For in situ type monitors, perform calibration checking all active electronic and optical components, including the transmitter, receiver, and analyzer. Challenge the pollutant concentration monitors and CO_2 or O_2 monitors once with each gas. Record the monitor response from the data acquisition and handling system. Using Equation A–5 of this appendix, determine the calibration error at each concentration once each day (at 24-hour intervals) for 7 consecutive days according to the procedures given in this section.

Calibration error tests are acceptable for monitor or monitoring system certification if none of these daily calibration error test results exceed the applicable performance specifications in section 3.1 of this appendix.

6.3.2 7-Day Calibration Error Test for Flow Monitors

Measure the calibration error of each flow monitor according to the following procedures.

Introduce the reference signal corresponding to the values specified in section 2.2.2.1 of this appendix to the probe tip (or equivalent), or to the transducer. During the 7-day certification test period, conduct the calibration error test once each day while the unit is operating (as close to 24-hour intervals as practicable). In the event that extended unit outages occur after the commencement of the test, the 7 consecutive operating days need not be 7 consecutive calendar days. Record the flow monitor responses by means of the data acquisition and handling system. Calculate the calibration error using Equation A–6 of this appendix.

Do not perform any corrective maintenance, repair, replacement or manual adjustment upon the flow monitor during the 7-day certification test period other than that required in the monitor operation and maintenance manual. If the flow monitor operates within the calibration error performance specification, (i.e., less than or equal to 3 percent error each day and does not require corrective maintenance, repair, replacement or manual adjustment during the 7-day test period) the flow monitor passes the calibration error test portion of the certification test. Wherever automatic adjustments are made, record the magnitude of the adjustments. Record all maintenance and required adjustments. Record output readings from the data acquisition and handling system before and after all adjustments.

6.4 Cycle Time/Response Time Test

Perform cycle time/response time tests for each pollutant concentration monitor, and continuous emission monitoring system according to the following procedures. Use a low-level and a high-level calibration gas (as defined in section 5.2 of this appendix) alternately. While the monitor or monitoring system is measuring and recording the concentration or emission rate, inject either a low-level concentration or a high-level concentration calibration gas into the injection port. Continue injecting the gas until a stable response is reached. Record the amount of time required for the monitor or monitoring system to complete 95.0 percent of the concentration or emission rate stepchange using data acquisition and handling system output. Then repeat the procedure with the other gas. For monitors or monitoring systems that perform a series of operations (such as purge, sample, and analyze), time the injections of the calibration gases so they will produce the longest possible response time. (Note: for the NO_x continuous emission monitoring system test and SO_2-diluent continuous emission monitoring system test, it will be necessary to simultaneously inject calibration gases into the pollutant and diluent monitors, in order to measure the step change in the lb/mmBtu emission rate.)

Cycle time/response time test results are acceptable for monitoring or monitoring system certification if none of the response times exceed 15 min.

6.5 Relative Accuracy and Bias Tests

Perform relative accuracy test audits for each CO_2 and SO_2 pollutant concentration monitor, each SO_2-diluent continuous emission monitoring system (lb/mmBtu) used by units with a qualifying Phase I technology for the period during which the units are required to monitor SO_2 emission removal efficiency, from January 1, 1997 through December 31, 1999, flow monitor, and NO_x continuous emission monitoring system. Record monitor or monitoring system output from the data acquisition and handling system. Perform concurrent relative accuracy test audits for each SO_2 pollutant concentration monitor and flow monitor, at least once a year (see section 2.3.1 of Appendix B of this part), during the flow monitor test at the normal operating level specified in section 6.5.2 of this appendix. Concurrent relative accuracy test audits may be performed by conducting simultaneous SO_2 and flow relative accuracy test audit runs, or by alternating an SO_2 relative accuracy test audit run with a flow relative accuracy test audit run until all relative accuracy test audit runs are completed. Where two or more probes are in the same proximity, care should be taken to prevent probes from interfering with each other's sampling. For each SO_2 pollutant concentration monitor, each flow monitor, and each NO_x continuous emission monitoring system, calculate bias, as well as relative accuracy, with data from the relative accuracy test audits.

Complete each relative accuracy test audit within a 7-day period while the unit (or units, if more than one unit exhausts into the flue) is combusting its primary fuel. When relative accuracy test audits are performed on continuous emission monitoring systems or component(s) on bypass stacks/ducts, use the fuel normally combusted by the unit (or units, if more than one unit exhausts into the flue) when emissions exhaust through the bypass stack/ducts. Do not perform corrective maintenance, repairs, replacements or adjustments during the relative accuracy test audit other than as required in the operation and maintenance manual.

6.5.1 SO_2 and CO_2 Pollutant Concentration Monitors and SO_2 and NO_x Continuous Emission Monitoring Systems

Perform relative accuracy test audits for each SO_2 or CO_2 pollutant concentration monitor or NO_x continuous emission monitoring system or SO_2-diluent continuous emission monitoring system (lb/mmBtu) used by units with a qualifying Phase I technology for the period during which the units are required to monitor SO_2 emission removal efficiency, from January 1, 1997 through December 31, 1999, at a normal operating level for the unit (or combined units, if common stack).

6.5.2 Flow Monitors

Except for flow monitors on bypass stacks/ducts and peaking units, perform relative accuracy test audits for each flow monitor at three different exhaust gas velocities, expressed in terms of percent of flow monitor span, or different operating or load levels. For a common stack/duct, the three different exhaust gas velocities may be obtained from frequently used unit/load combinations for units exhausting to the common stack. Select the operating levels as follows: (1) A frequently used low operating level selected

within the range between the minimum safe and stable operating level and 50% load, (2) a frequently used high operating level selected within the range between 80 percent of the maximum operating level and the maximum operating level, and (3) the normal operating level. If the normal operating level is within a specified range, [10.0 percent of the maximum operating level] of either (1) or (2) above, use a level that is evenly spaced between the low and high operating levels used. The maximum operating level shall be equal to the nameplate capacity less any physical or regulatory limitations or other deratings. Calculate flow monitor relative accuracy at each of the three operating levels. If a flow monitor fails the relative accuracy test on any of the three levels of a three-level relative accuracy test audit, the three-level relative accuracy test audit must be repeated. For flow monitors on bypass stacks/ducts and peaking units, the flow monitor relative accuracy test audit is required only at the normal operating level.

6.5.3 CO_2 Pollutant Concentration Monitors

Perform relative accuracy test audits for each CO_2 monitor (measuring in percent CO_2) at a normal operating level for the unit (or combined units, if common stack).

6.5.4 Calculations

Using the data from the relative accuracy test audits, calculate relative accuracy and bias in accordance with the procedures and equations specified in section 7 of this appendix.

6.5.5 Reference Method Measurement Location

Select a location for reference method measurements that is (1) accessible; (2) in the same proximity as the monitor or monitoring system location; and (3) meets the requirements of Performance Specification 2 in Appendix B to part 60 of this chapter for SO_2 and NO_x continuous emission monitoring systems, or Method 1 (or 1A) in Appendix A to part 60 of this chapter for volumetric flow, except as otherwise indicated in this section.

6.5.6 Reference Method Traverse Point Selection

Select traverse points that (1) ensure acquisition of representative samples of pollutant and diluent concentrations, moisture content, temperature, and flue gas flow rate over the flue cross section; and (2) meet the requirements of Performance Specification 2 in Appendix B to part 60 of this chapter (for SO_2 and NO_x), Method 1 (or 1A) (for volumetric flow), Method 3 (for O_2 CO_2 and dry molecular weight), and Method 4 (for moisture determination) in Appendix A to part 60 of this chapter.

6.5.7 Sampling Strategy

Conduct the reference method tests so they will yield results representative of the pollutant concentration, emission rate, moisture, temperature, and flue gas flow rate from the unit and can be correlated with the pollutant concentration monitor, CO_2 or O_2 monitor, flow monitor, and SO_2 or NO_x continuous emission monitoring system measurements. Conduct the diluent (O_2 or CO_2) measurements and any moisture measurements that may be needed simultaneously with the pollutant concentration and flue gas flow rate measurements. To properly correlate individual SO_2 and CO_2 pollutant concentration monitor data, SO_2 or NO_x continuous emission monitoring system data (in lb/mmBtu), and volumetric flow rate data with the reference method data, mark the beginning and end of each reference method test run (including the exact time of day) on the individual chart recorder(s) or other permanent recording device(s).

6.5.8 Correlation of Reference Method and Continuous Emission Monitoring System

Confirm that the monitor or monitoring system and reference method test results are on consistent moisture, pressure, temperature, and diluent concentration basis (e.g., since the flow monitor measures flow rate on a wet basis, Method 2 test results must also be on a wet basis). Compare flow-monitor and reference method results on a scfh basis. Also, consider the response times of the pollutant concentration monitor, the continuous emission monitoring system, and the flow monitoring system to ensure comparison of simultaneous measurements.

For each relative accuracy test audit run, compare the measurements obtained from the monitor or continuous emission monitoring system (in ppm, percent CO_2, lb/mmBtu, or other units) against the corresponding reference method values. Tabulate the paired data in a table such as the one shown in Figure 2.

6.5.9 Number of Reference Method Tests

Perform a minimum of nine sets of paired monitor (or monitoring system) and reference method test data for every required (i.e., certification, semiannual, or annual) relative accuracy or bias test audit. For the certification and annual quality assurance relative accuracy test audits for flow monitors, perform a minimum of nine sets at each of the three operating levels specified in section 6.5.2 of this appendix. Conduct each set within a period of 30 to 60 minutes.

Note: The tester may choose to perform more than nine sets of reference method tests. If this option is chosen, the tester may reject a maximum of three sets of the test results as long as the total number of test results used to determine the relative accuracy or bias is greater than or equal to nine. Report all data, including the rejected data, and reference method test results.

6.5.10 Reference Methods

The following methods from Appendix A to part 60 of this chapter or their approved alternatives are the reference methods for performing relative accuracy test audits: Method 1 or 1A for siting; Method 2 (or 2A, 2C, or 2D) for velocity; Methods 3, 3A, or 3B for O_2 or CO_2; Method 4 for moisture; Methods 6, 6A, or 6C for SO_2; Methods 7, 7A, 7C, 7D, 7E for NO_x; and Method 20 for determination of NO_x, SO_2, and O_2 or CO_2 from stationary gas turbines.

7. Calculations

7.1 Linearity Check

Analyze the linearity data for pollutant concentration and CO_2 or O_2 monitors as follows. Calculate the percentage error in linearity based upon the reference value at the low-level, mid-level, and high-level concentrations specified in section 6.2 of this appendix. Perform this calculation once during the certification test. Use the following equation to calculate the error in linearity for each reference value.

$$LE = \frac{|R-A|}{R} \times 100$$

(Eq. A–4)

where,

LE=Percentage Linearity error, based upon the reference value.

R=Reference value of Low-, mid-, or high-level calibration gas introduced into the monitoring system.

A=Average of the monitoring system responses.

7.2 Calibration Error

7.2.1 Pollutant Concentration and Diluent Monitors

For each reference value, calculate the percentage calibration error based upon instrument span for daily calibration error tests using the following equation:

$$CE = \frac{|R-A|}{S} \times 100$$

(Eq. A–5)

where,

CE=Percentage Calibration error based upon span of the instrument.

R=Reference value of zero- or high-level calibration gas introduced into the monitoring system.

A=Actual monitoring system response to the calibration gas.

S=Span of the instrument, as specified in Section 2 of this appendix.

7.2.2 Flow Monitor Calibration Error

For each reference value, calculate the percentage calibration error based upon span using the following equation:

$$CE = \frac{|R-A|}{S} \times 100$$

(Eq. A–6)

where,

CE=Calibration error;

R=Low or high level reference value specified in section 2.2.2.1 of this appendix;

A=Actual flow monitor response to the reference value; and

S=Flow monitor span.

Whenever the flow rate exceeds the monitor's ability to measure and record values accurately, adjust the span to prevent future exceedances. If process parameters change or other changes are made such that the expected flue gas velocity may change significantly, adjust the span to assure the continued accuracy of the monitoring system.

7.3 Relative Accuracy for SO_2 and CO_2 Pollutant Concentration Monitors, SO_2 Continuous Emission Monitoring Systems, and Flow Monitors

Analyze the relative accuracy test audit data from the reference method tests for SO_2 and CO_2 pollutant concentration monitors, SO_2-diluent continuous emission monitoring systems (lb/mmBtu) used by units with a qualifying Phase I technology for the period during which the units are required to monitor SO_2 emission removal efficiency, from January 1, 1997 through December 31, 1999, and flow monitors using the following procedures. Summarize the results on a data sheet. An example is shown in Figure 2. Calculate the mean of the monitor or monitoring system measurement values. Calculate the mean of the reference method values. Using data from the automated data acquisition and handling system, calculate the arithmetic differences between the reference method and monitor measurement data sets. Then calculate the arithmetic mean of the difference, the standard deviation, the confidence coefficient, and the monitor or monitoring system relative accuracy using the following procedures and equations.

7.3.1 Arithmetic Mean

Calculate the arithmetic mean of the differences, $\bar{d}$, of a data set as follows.

$$\bar{d} = \frac{1}{n}\sum_{i=1}^{n} d_i$$

(Eq. A–7)

where,

n=Number of data points.

$\sum_{i=1}^{n} d_i$=Algebraic sum of the individual differences d_i.

d_i=The difference between a reference method value and the corresponding continuous emission monitoring system value ($RM_i - CEM_i$) at a given point in time i.

When calculating the arithmetic mean of the difference of a flow monitor data set, be sure to correct the monitor measurements for moisture if applicable.

7.3.2 Standard Deviation

Calculate the standard deviation, S_d, of a data set as follows:

$$S_d = \sqrt{\frac{\sum_{i=1}^{n} d_i^2 - \left[\frac{\left(\sum_{i=1}^{n} d_i\right)^2}{n}\right]}{n-1}}$$

(Eq. A–8)

7.3.3 Confidence Coefficient

Calculate the confidence coefficient (one-tailed), cc, of a data set as follows.

$$cc = t_{0.025}\frac{S_d}{\sqrt{n}}$$

(eq. A–9)

where,

$t_{0.025}$=t value (see Table 7–1).

TABLE 7–1 T-VALUES

n-1	$t_{0.025}$	n-1	$t_{0.025}$	n-1	$t_{0.025}$
1	12.706	12	2.179	23	2.069
2	4.303	13	2.160	24	2.064
3	3.182	14	2.145	25	2.060
4	2.776	15	2.131	26	2.056
5	2.571	16	2.120	27	2.052
6	2.447	17	2.110	28	2.048
7	2.365	18	2.101	29	2.045
8	2.306	19	2.093	30	2.042
9	2.262	20	2.086	40	2.021
10	2.228	21	2.080	60	2.000
11	2.201	22	2.074	>60	1.980

7.3.4 Relative Accuracy

Calculate the relative accuracy of a data set using the following equation.

$$RA = \frac{|\bar{d}| + |cc|}{\overline{RM}} \times 100$$

(Eq. A–10)

where,

RM=Arithmetic mean of the reference method values.

|d|=The absolute value of the mean difference between the reference method values and the corresponding continuous emission monitoring system values.

|cc|=The absolute value of the confidence coefficient.

7.4 Relative Accuracy for NO_x Continuous Emission Monitoring Systems

Analyze the relative accuracy test audit data from the reference method tests for NO_x continuous emissions monitoring system as follows.

7.4.1 Data Preparation

If C_{NO_x}, the NO_x concentration, is in ppm, multiply it by 1.194×10^{-7} (lb/dscf)/ppm to convert it to units of lb/dscf. If C_{NO_x} is in mg/dscm, multiply it by 6.24×10^{-8} (lb/dscf)/(mg/dscm) to convert it to lb/dscf. Then, use the diluent (O_2 or CO_2) reference method results for the run and the appropriate F or F_c factor from Table 1 in Appendix F of this part to convert C_{NO_x} from lb/dscf to lb/mmBtu units. Use the equations and procedure in section 3 of Appendix F to this part, as appropriate.

7.4.2 NO_x Emission Rate (Monitoring System)

For each test run in a data set, calculate the average NO_x emission rate (in lb/mmBtu), by means of the data acquisition and handling system, during the time period of the test run. Tabulate the results as shown in example Figure 4.

7.4.3 Relative Accuracy

Use the equations and procedures in section 7.3 above to calculate the relative accuracy for the NO_x continuous emission monitoring system. In using Equation A–7, "d" is, for each run, the difference between the NO_x emission rate values (in lb/mmBtu) obtained from the reference method data and the NO_x continuous emission monitoring system.

7.5 Relative Accuracy for Combined SO_2/Flow [Reserved]

7.6 Bias Test and Adjustment Factor

Test the relative accuracy test audit data sets for SO_2 pollutant concentration monitors, flow monitors, and NO_x continuous emission monitoring systems for bias using the procedures outlined below.

7.6.1 Arithmetic Mean

Calculate the arithmetic mean of the difference, $\bar{d}$, of the data set using Equation A–7 of this appendix. To calculate bias for an SO_2 pollutant concentration monitor, "d" is, for each paired data point, the difference between the SO_2 concentration value (in ppm) obtained from the reference method and the monitor. To calculate bias for a flow monitor, "d" is, for each paired data point, the difference between the flow rate values (in scfh) obtained from the reference method and the monitor. To calculate bias for a NO_x continuous emission monitoring system, "d" is, for each paired data point, the difference between the NO_x emission rate values (in lb/mmBtu) obtained from the reference method and the monitoring system.

7.6.2 Standard Deviation

Calculate the standard deviation, S_d, of the data set using Equation A–8.

7.6.3 Confidence Coefficient

Calculate the confidence coefficient, cc, of the data set using Equation A–9.

7.6.4 Bias Test

If the mean difference, $\bar{d}$, is greater than the absolute value of the confidence coefficient, |cc|, the monitor or monitoring system has failed to meet the bias test requirement. For flow monitor bias tests, if the mean difference, $\bar{d}$, is greater than |cc| at the normal operating level (or equally spaced intermediary level), the monitor has failed to meet the bias test requirement. For flow monitors, apply the bias test at normal operating level (or an evenly spaced intermediary level).

7.6.5 Bias Adjustment

If the monitor or monitoring system fails to meet the bias test requirement, adjust the value obtained from the monitor using the following equation:

$CEM_i^{Adjusted} = CEM_i^{Monitor} \times BAF$

(Eq. A–11)

where,

$CEM_i^{Monitor}$=Data (measurements) provided by the monitor at time i.

$CEM_i^{Adjusted}$=Data value, adjusted for bias, at time i.

BAF=Bias adjustment factor, defined by

$$BAF = 1 + \frac{|\bar{d}|}{CEM}$$

(Eq. A–12)

where,

$\bar{d}$=Arithmetic mean of the difference obtained during the failed bias test using Equation A–7.

CEM=Mean of the data values provided by the monitor during the failed bias test.

If the bias test is failed by a flow monitor on a 3-level relative accuracy test audit, calculate the bias adjustment factor for each of the three operating levels. Apply the largest of the three bias adjustment factors to subsequent flow monitor data using Equation A–11.

Apply this adjustment prospectively to all monitor or monitoring system data from the date and time of the failed bias test until the date and time of a relative accuracy test audit that does not show bias. Use the adjusted values in computing substitution values in the missing data procedure, as specified in subpart D of this part, and in reporting the emitted tons of SO_2 and CO_2 and the average NO_x emission rate during the quarter and calendar year, as specified in subpart G of this part.

FIGURE 1.—LINEARITY ERROR DETERMINATION

Day	Date and time	Reference value	Monitor value	Difference	Percent of reference value
Low-level					
Mid-level					
High-level					

FIGURE 2.—RELATIVE ACCURACY DETERMINATION (POLLUTANT CONCENTRATION MONITORS)

Run No.	Date and time	SO_2 (ppm[c])			Date and time	CO_2 (Pollutant) (ppm[c])		
		RM[a]	M[b]	Diff		RM[a]	M[b]	Diff
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
Arithmetic Mean Difference (Eq. A–7).								
Confidence Coefficient (Eq. A–9).								
Relative Accuracy (Eq. A–10).								

[a] RM means "reference method data."
[b] M means "monitor data."
[c] Make sure that RM and M data are on a consistent basis, either wet or dry.

FIGURE 3.—RELATIVE ACCURACY DETERMINATION (FLOW MONITORS)

Run No.	Date and time	Flow rate (Low) (scf/hr) *			Date and time	Flow rate (Normal) (scf/hr) *			Date and time	Flow rate (High) (scf/hr) *		
		RM	M	Diff		RM	M	Diff		RM	M	Diff
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
Arithmetic Mean Difference (eq. A–7). Confidence Coefficient (eq. A–9). Relative Accuracy (eq. A–10).												

* Make sure that RM and M data are on a consistent moisture basis.

FIGURE 4:—RELATIVE ACCURACY DETERMINATION (NO_x/diluent combined system)

Run No.	Date and time	Reference method data		NO_x system (lb/mmBtu)		
		NO_x ( )*	O_2/CO_2%	RM	M	Difference
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
Arithmetic Mean Difference (eq. A–7).						

FIGURE 4:—RELATIVE ACCURACY DETERMINATION (NO_x/diluent combined system)—Continued

Run No.	Date and time	Reference method data		NO_x system (lb/mmBtu)		
		NO_x ( )*	O_2/CO_2%	RM	M	Difference
Confidence Coefficient (eq. A–9).						
Relative Accuracy (eq. A–10).						

*Specify units: ppm, lb/dscf,ng/dscm.

Appendix B to Part 75—Quality Assurance and Quality Control Procedures

1. Quality Control Program

Develop and implement a quality control program for the continuous emission monitoring systems and their components. As a minimum, include in each quality control program a written plan that describes in detail complete, step-by-step procedures and operations for each of the following activities.

1.1 Calibration Error Test and Linearity Check Procedures

Identify calibration error test and linearity check procedures specific to the continuous emission monitoring system that may require variance from the procedures in Appendix A to this part (e.g., how gases are to be injected, adjustments of flow rates and pressures, introduction of reference values, length of time for injection of calibration gases, steps for obtaining calibration error or error in linearity, determination of interferences, and when calibration adjustments should be made).

1.2 Calibration and Linearity Adjustments

Explain how each component of the continuous emission monitoring system will be adjusted to provide correct responses to calibration gases, reference values, and/or indications of interference both initially and after repairs or corrective action. Identify equations, conversion factors, assumed moisture content, and other factors affecting calibration of each continuous emission monitoring system.

1.3 Preventive Maintenance

Keep a written record of procedures, including those specified by the manufacturers, needed to maintain the continuous emission monitoring system in proper operating condition and a schedule for those procedures. Include provisions for maintaining an inventory of spare parts.

1.4 Audit Procedures

Keep a written record of procedures and details peculiar to the installed continuous emission monitoring system that are to be used for relative accuracy test audits, such as sampling and analysis methods.

1.5 Recordkeeping and Reporting

Keep a written record describing procedures that will be used to implement the recordkeeping and reporting requirements in subparts F and G of this part.

2. Frequency of Testing

A summary chart showing each quality assurance test and the frequency at which each test is required is located at the end of this appendix in Figure 1.

2.1 Daily Assessments

For each monitor or continuous emission monitoring system, perform the following assessments during each day in which the unit combusts any fuel (hereafter referred to as a "unit operating day"), or for a monitor or continuous emission monitoring system on a bypass stack/duct, during each day that emissions pass through the by-pass stack or duct. These requirements are effective as of the date when the monitor or continuous emission monitoring system completes certification testing.

2.1.1 Calibration Error Test for Pollutant Concentration and CO_2 or O_2 Monitors

Test, record, and compute the calibration error of each SO_2 or NO_x pollutant concentration and CO_2 or O_2 monitor at least once on each unit operating day, or for monitors or monitoring systems on bypass ducts/stacks, on each day that emissions pass through the by-pass stack or duct. Conduct calibration error checks, to the extent practicable, approximately 24 hours apart. Perform the daily calibration error test according to the procedure in Appendix A, section 6.3.1 of this part.

For units with add-on emission controls and dual span or auto-ranging monitors, and other units that use maximum expected concentration value to determine calibration gas values, perform the daily calibration error test on each scale that has been used since the previous calibration error test. For example, if the emissions concentration has not exceeded the low-scale span value, (based on the maximum expected concentration) since the calibration test during the previous calendar day, the calibration error test may be performed on the low-scale only. If, however, the emissions concentration has exceeded the low-scale span value for one hour or longer since the previous calibration error test, perform the calibration error on both the low- and high-scales.

2.1.2 Calibration Error Test for Flow Monitors

Test, compute, and record the calibration error of each flow monitor at least once on each unit operating day, or for monitors or monitoring systems on bypass ducts/stacks, on each day that emissions pass through the by-pass stack or duct. Introduce the reference values (specified in section 2.2.2.1 of Appendix A to this part) to the probe tip (or equivalent) or to the transducer. Record flow monitor output from the data acquisition and handling system before and after any adjustments to the flow monitor. Keep a record of all maintenance and adjustments. Calculate the calibration error using Equation A–6 in Appendix A of this part.

2.1.3 Interference Check

Perform the daily flow monitor interference checks specified in section 2.2.2.2 of Appendix A to this part at least once per operating day (when the unit(s) operate for any part of the day).

2.1.4 Recalibration

Adjust the calibration, at a minimum, whenever the daily calibration error exceeds the limits of the applicable performance specification for the pollutant concentration monitor, CO_2, or O_2 monitor, or flow monitor in Appendix A of this part. Repeat the calibration error test procedure following the adjustment or repair to demonstrate that the corrective actions were effective.

2.1.5 Out-of-Control Period

An out-of-control period occurs when the calibration error of an SO_2 or NO_x pollutant concentration monitor exceeds 5.0 percent based upon the span value (or exceeds 10 ppm, for span values <200 ppm), when the calibration error of a diluent gas monitor exceeds 1.0 percent O_2 or CO_2, or when the calibration error of a flow monitor exceeds 6.0 percent based upon the span value, which is twice the applicable specification of Appendix A of this part. The out-of-control period begins with the hour of completion of the failed calibration error test and ends with the hour of completion following an effective recalibration. Whenever the failed calibration, corrective action, and effective recalibration occur within the same hour, the hour is not out of control if 2 or more valid readings are obtained during that hour as required by § 75.10 of this part. A NO_x continuous emission monitoring system is considered out-of-control if either component monitor exceeds twice the applicable specification in Appendix A of this part.

An out-of-control period also occurs whenever interference of a flow monitor is identified. The out-of-control period begins with the hour of completion of the failed interference check and ends with the hour of completion of an interference check that is passed.

2.1.6 Data Recording

Record and tabulate all calibration error test data according to month, day, clock-hour, and magnitude in either ppm, percent volume, or scfh. Program monitors that automatically adjust data to the corrected

calibration values (e.g., microprocessor control) to record either: (1) The unadjusted concentration or flow rate measured in the calibration error test prior to resetting the calibration, or (2) the magnitude of any adjustment. Record the following applicable flow monitor interference check data: (1) Sample line/sensing port pluggage, and (2) malfunction of each RTD, transceiver, or equivalent.

2.2 Quarterly Assessments

For each monitor or continuous emission monitoring system, perform the following assessments during each calendar quarter in which the unit combusts any fuel (hereafter referred to as a "unit operating quarter"), or for monitors or monitoring systems on bypass ducts/stacks, during each calendar quarter that emissions pass through the by-pass stack or duct (hereafter referred to as a "bypass operating quarter"). This requirement is effective as of the calendar quarter following the calendar quarter in which the monitor or continuous emission monitoring system is provisionally certified.

2.2.1 Linearity Check

Perform a linearity check for each SO_2 and NO_x pollutant concentration monitor and each CO_2 or O_2 monitor at least once during each unit operating quarter or each bypass operating quarter, in accordance with the procedures in Appendix A, section 6.2 of this part. For units using emission controls and other units using a low-scale span value to determine calibration gases, perform a linearity check on both the low- and high-scales. For the linearity check, use calibration gas cylinders that are different cylinders from the ones used in the daily calibration error tests. Conduct the linearity checks no less than 2 months apart.

2.2.2 Leak Check

For differential pressure flow monitors, perform a leak check of all sample lines (a manual check is acceptable) at least once during each unit operating quarter or each bypass operating quarter. Conduct the leak checks no less than 2 months apart.

2.2.3 Out-of-Control Period

An out-of-control period occurs when the error in linearity at any of the three concentrations (six for dual range monitors) in the quarterly linearity check exceeds the applicable specification in Appendix A, section 3.2 of this part. The out-of-control period begins with the hour of the failed linearity check and ends with the hour of a satisfactory linearity check following corrective action and/or monitor repair. For the NO_x continuous emission monitoring system, the system is considered out-of-control if either of the component monitors exceed the applicable specification in Appendix A, section 3.2 of this part. An out-of-control period occurs when a flow monitor sample line leak is detected. The out-of-control period begins with the hour of the failed leak check and ends with the hour of a satisfactory leak check following corrective action.

2.3 Semiannual and Annual Assessments

For each monitor or continuous emission monitoring system, perform the following assessments once semiannually or once annually after the calendar quarter in which the monitor or monitoring system was last tested, as specified below for the type of test and the performance achieved. For monitors or continuous emission monitoring systems on bypass ducts/stacks, the assessments are to be performed once every two successive bypass operating quarters or once every four successive operating quarters after the calendar quarter in which the monitor or monitoring system was last tested, as specified below for the type of test and the performance achieved. This requirement is effective as of the calendar quarter or bypass operating quarter following the calendar quarter in which the monitor or continuous emission monitoring system is provisionally certified. A summary chart showing the frequency with which a relative accuracy test audit must be performed, depending on the accuracy achieved, is located at the end of this appendix in Figure 2.

2.3.1 Relative Accuracy Test Audit

Perform relative accuracy test audits semiannually and no less than 4 months apart for each SO_2 or CO_2 pollutant concentration monitor, flow monitor, NO_x continuous emission monitoring system, for SO_2-diluent continuous emission monitoring systems used by units with a Phase I Qualifying technology for the period during which the units are required to monitor SO_2 emission removal efficiency, from January 1, 1997 through December 31, 1999, in accordance with the procedures in section 6.5 of Appendix A of this part. For monitors on bypass stacks/ducts, perform relative accuracy test audits once every two successive bypass operating quarters in accordance with the procedures in section 6.5 of Appendix A of this part. Successive audits shall be no less than 4 months apart. The audit frequency may be reduced, as specified below for monitors or monitoring systems which qualify for less frequent testing.

For flow monitors, one-level and three-level relative accuracy test audits shall be performed alternately (when a flow RATA is conducted semiannually), such that the three-level relative accuracy test audit is performed at least once annually. The three-level audit shall be performed at the three different operating or load levels specified in Appendix A, section 6.5.2 of this part, and the one-level audit shall be performed at the normal operating or load level. Relative accuracy test audits need only be performed once every two successive unit or bypass operating quarters at the normal operating or load level for monitors and continuous emission monitoring systems on peaking units and bypass stacks/ducts.

Relative accuracy test audits may be performed on an annual basis rather than on a semiannual basis under any of the following conditions (or for monitors on peaking units and bypass ducts/stacks, once every four successive unit or bypass operating quarters): (1) The relative accuracy during the previous audit for an SO_2 or CO_2 pollutant concentration monitor, or NO_x or SO_2 continuous emissions monitoring system is 7.5 percent or less; (2) prior to January 1, 2000, the relative accuracy during the previous audit for a flow monitor is 10.0 percent or less at each operating level tested; (3) on and after January 1, 2000, the relative accuracy during the previous audit for a flow monitor is 7.5 percent or less at each operating level tested; (4) on low flow (≤10.0 fps) stacks/ducts, when the monitor mean, calculated using Equation A–7 in Appendix A of this part is within ±1.5 fps of the reference method mean or achieves a relative accuracy of 7.5 percent (10 percent if prior to January 1, 2000) or less during the previous audit; (5) on low SO_2 emitting units (SO_2 concentrations ≤250.0 ppm), when the monitor mean is within ±8.0 ppm (or equivalent in lb/mmBTU for SO_2-diluent monitors) of the reference method mean or achieves a relative accuracy of 7.5 percent or less (or equivalent lb/mmBTU value for SO_2-diluent monitors) during the previous audit; or (6) on low NO_x emitting units (NO_x emission rate ≤0.20 lb/mmbtu), when the NO_x continuous emission monitoring system achieves a relative accuracy of 7.5 percent or less.

A maximum of two relative accuracy test audit trials may be performed for the purpose of achieving the results required to qualify for less frequent relative accuracy test audits. Whenever two trials are performed, the results of the second (later) trial must be used in calculating both the relative accuracy and bias.

2.3.2 Out-of-Control Period

An out-of-control period occurs under any of the following conditions: (1) The relative accuracy of an SO_2 pollutant concentration monitor or a NO_x or SO_2 continuous emission monitoring system exceeds 10.0 percent; (2) prior to January 1, 2000, the relative accuracy of a flow monitor exceeds 15.0 percent; (3) on and after January 1, 2000, the relative accuracy of a flow monitor exceeds 10.0 percent; (4) for low flow situations (≤10.0 fps), the flow monitor mean value (if applicable) exceeds±2.0 fps of the reference method mean whenever the relative accuracy is greater than 15.0 percent for Phase I or 10 percent for Phase II; (5) for low SO_2 emitter situations, the monitor mean values exceeds ±15.0 ppm of the reference method mean whenever the relative accuracy is greater than 10.0 percent; or (6) for low NO_x emitting units (NO_x emission rate ≤0.2 lb/mmbtu), the NO_x continuous emission monitoring system mean values exceed ±0.02 lb/mmBtu of the reference method mean whenever the relative accuracy is greater than 10.0 percent. For SO_2, NO_x emission rate, and flow relative accuracy test audits performed at only one level, the out-of-control period begins with the hour of completion of the failed relative accuracy test audit and ends with the hour of completion of a satisfactory relative accuracy test audit. For a flow relative accuracy test audit at 3 operating levels, the out-of-control period begins with the hour of completion of the first failed relative accuracy test audit at any of the three operating levels, and ends with the hour of completion of a satisfactory three-level relative accuracy test audit.

Failure of the bias test does not result in the system or monitor being out-of-control.

the bias adjustment factor given in Equations A–11 and A–12 of Appendix A to this part to adjust the monitored data.

2.4 Other Audits

Affected units may be subject to relative accuracy test audits at any time. If a monitor or continuous emission monitoring system fails the relative accuracy test during the audit, the monitor or continuous emission monitoring system shall be considered to be out-of-control beginning with the date and time of completion of the audit, and continuing until a successful audit test is completed following corrective action. If a monitor or monitoring system fails the bias test during an audit, use the bias adjustment factor given by Equations A–11 and A–12 in Appendix A to this part to adjust the monitored data. Apply this adjustment factor from the date and time of completion of the audit until the date and time of completion of a relative accuracy test audit that does not show bias.

FIGURE 1.—QUALITY ASSURANCE TEST REQUIREMENTS

Test	QA test frequency requirements		
	Daily*	Quarterly*	Semiannual*
Calibration Error (2 pt.).	√		
Interference (flow).	√	√	
Linearity (3 pt.).		√	

FIGURE 1.—QUALITY ASSURANCE TEST REQUIREMENTS—Continued

Test	QA test frequency requirements		
	Daily*	Quarterly*	Semiannual*
RATA (SO_2, NO_x, CO_2)[1].			√
RATA (flow, alternating 1-load and 3-load)[2].			√

*For monitors on bypass stack/duct, bypass operating days or quarters, only.
[1]Conduct annually, if monitor meets accuracy requirements to qualify for less frequent testing.
[2]Conduct 3-load RATAs annually, if requirements to qualify for less frequent testing are met.

FIGURE 2.—RELATIVE ACCURACY TEST FREQUENCY INCENTIVE SYSTEM

RATA	Semiannually*	Annual*
SO_2	RA ≤ 10%	RA ≤ 7.7% or ± 8ppm**
NO_x	RA ≤ 10%	RA ≤ 7.5%
Flow (Phase I)[3]	RA ≤ 15%	RA ≤ 10% or ± 1.5 fps**
Flow (Phase II)[3]	RA ≤ 10%	RA ≤ 7.5% or ± 1.5 fps**

*For monitors on bypass stack/duct, bypass operating quarters, only.
**The difference between monitor and reference method mean values; low emitters or low flow, only.
[3]Conduct 3-load RATAs annually, if requirements to qualify for less frequent testing are met.

Appendix C to Part 75—Missing Data Estimation Procedures

1. Parametric Monitoring Procedure for Missing SO_2 Concentration or NO_x Emission Rate Data

1.1 Applicability

The owner or operator of any affected unit equipped with post-combustion SO_2 or NO_x emission controls and SO_2 pollutant concentration monitors and/or NO_x continuous emission monitoring systems at the inlet and outlet of the emission control system may apply to the Administrator for approval and certification of a parametric, empirical, or process simulation method or model for calculating substitute data for missing data periods. Such methods may be used to parametrically estimate the removal efficiency of the SO_2 of postcombustion NO_x emission controls which, with the monitored inlet concentration or emission rate data, may be used to estimate the average concentration of SO_2 emissions or average emission rate of NO_x discharged to the atmosphere. After approval by the Administrator, such method or model may be used to for filling in missing SO_2 concentration or NO_x emission rate data when data from the outlet SO_2 pollutant concentration monitor or outlet NO_x continuous emission monitoring system have been reported with an annual monitor data availability of 90.0 percent or more.

Base the empirical and process simulation methods or models on the fundamental chemistry and engineering principles involved in the treatment of pollutant gas. On a case-by-case basis, the Administrator may pre-certify commercially available process simulation methods and models.

1.2 Demonstration Requirements

Continuously monitor, determine, and record hourly averages for the parameters specified below, at a minimum. The affected facility shall supply additional parametric information where appropriate. At least 4 evenly spaced data points are required for a valid hourly average, except during periods of calibration, maintenance, or quality assurance activities, during which 2 data points per hour are sufficient. The Administrator will review all applications on a case-by-case basis.

1.2.1 Parameters for Wet Flue Gas Desulfurization System

1.2.1.1 Number of scrubber modules in operation.

1.2.1.2 Total slurry rate to each scrubber module (gal per min).

1.2.1.3 In-line absorber pH of each scrubber module.

1.2.1.4 Pressure differential across each scrubber module (inches of water column).

1.2.1.5 Unit load (MWe).

1.2.1.6 Inlet and outlet SO_2 concentration as determined by the monitor or missing data substitution procedures.

1.2.1.7 Percent solids in slurry for each scrubber module.

1.2.1.8 Any other parameters necessary to verify scrubber removal efficiency, if the Administrator determines the parameters above are not sufficient.

1.2.2 Parameters for Dry Flue Gas Desulfurization System

1.2.2.1 Number of scrubber modules in operation.

1.2.2.2 Atomizer slurry flow rate to each scrubber module (gal per min).

1.2.2.3 Inlet and outlet temperature for each scrubber module (°F).

1.2.2.4 Pressure differential across each scrubber module (inches of water column).

1.2.2.5 Unit load (MWe).

1.2.2.6 Inlet and outlet SO_2 concentration as determined by the monitor or missing data substitution procedures.

1.2.2.7 Any other parameters necessary to verify scrubber removal efficiency, if the Administrator determines the parameters above are not sufficient.

1.2.3 Parameters for Other Flue Gas Desulfurization Systems

If SO_2 control technologies other than wet or dry lime or limestone scrubbing are selected for flue gas desulfurization, a corresponding empirical correlation or process simulation parametric method using appropriate parameters may be developed by the owner or operator of the affected unit, and then reviewed and approved or modified by the Administrator on a case-by-case basis.

1.2.4 Parameters for Post-Combustion NO_x Emission Controls

1.2.4.1 Inlet air flow rate to the unit (boiler) (mcf/hr).

1.2.4.2 Excess oxygen concentration of flue gas at stack outlet (percent).

1.2.4.3 Carbon monoxide concentration of flue gas at stack outlet (ppm).

1.2.4.4 Temperature of flue gas at outlet of the unit (°F).

1.2.4.5 Inlet and outlet NO_x emission rate as determined by the NO_x continuous emission monitoring system or missing data substitution procedures.

1.2.4.6 Any other parameters specific to the emission reduction process necessary to verify the NO_x control removal efficiency, (e.g., reagent feedrate in gal/mi).

emission monitoring system or missing data substitution procedures.

1.2.4.6 Any other parameters specific to the emission reduction process necessary to verify the NO_x control removal efficiency, (e.g., reagent feedrate in gal/mi).

1.3 Correlation of Emissions With Parameters

Establish a method for correlating hourly averages of the parameters identified above with the percent removal efficiency of the SO_2 or post-combustion NO_x emission controls under varying unit operating loads. Equations 1–7 in § 75.15 of this part may be used to estimate the percent removal efficiency of the SO_2 emission controls.

Each parametric data substitution procedure should develop a data correlation procedure to verify the performance of the SO_2 emission controls or post-combustion NO_x emission controls, along with the SO_2 pollutant concentration monitor and NO_x continuous emission monitoring system values for varying unit load ranges.

For NO_x emission rate data, and wherever the performance of the emission controls varies with the load, use the load range procedure provided in section 2.2 of this appendix.

1.4 Calculations

1.4.1 Use the following equation to calculate substitute data for filling in missing (outlet) SO_2 pollutant concentration monitor data.

$M_o = L_c (1–E)$
(Eq. C–1)

where,
M_o = Substitute data for outlet SO_2 concentration, ppm.
L_c = Recorded inlet SO_2 concentration, ppm.
E = Removal efficiency of SO_2 emission controls as determined by the correlation procedure described in section 1.2 of this appendix.

1.4.2 Use the following equation to calculate substitute data for filling in missing (outlet) NO_x emission rate data.

$M_o = L_c (1–E)$
(Eq. C–2)

where,
M_o = Substitute data for outlet NO_x emission rate, lb/mmBtu.
L_c = Recorded inlet NO_x emission rate, lb/mmBtu.
E = Removal efficiency of post-combustion NO_x emission controls determined by the correlation procedure described in section 1.2 of this appendix.

1.5 Missing Data

1.5.1 If both the inlet and the outlet SO_2 pollutant concentration monitors are unavailable simultaneously, use the maximum inlet SO_2 concentration recorded by the inlet SO_2 pollutant concentration monitor during the previous 720 quality assured monitor operating hours to substitute for the inlet SO_2 concentration in Equation C–1 of this appendix.

1.5.2 If both the inlet and outlet NO_x continuous emission monitoring systems are unavailable simultaneously, use the maximum inlet NO_x emission rate for the corresponding unit load recorded by the NO_x continuous emission monitoring system at the inlet during the previous 2160 quality assured monitor operating hours to substitute for the inlet NO_x emission rate in Equation C–2 of this Appendix.

1.6 Application

Apply to the Administrator for approval and certification of the parametric substitution procedure for filling in missing SO_2 concentration or NO_x emission rate data using the established criteria and information identified above. DO not use this procedure until approved by the Administrator.

2. Load-Based Procedure for Missing Flow Rate and NO_x Emission Rate Data

2.1 Applicability

This procedure is applicable for data from all affected units for use in accordance with the provisions of this part to provide substitute data for volumetric flow (scfh) and NO_x emission rate (in lb/mmBtu).

2.2 Procedure

2.2.1 For a single unit, establish 10 operating load ranges defined in terms of percent of the maximum integrated hourly gross load of the unit, in gross megawatts (MWge), (that is, load resulting from all combustion of fuel, including internal usage and generation for sale) as shown in Table C–1. For units sharing a common stack monitored with a single flow monitor, the load ranges for flow may be broken down into 20 equally-sized operating load ranges in increments of 5 percent of the combined maximum integrated hourly gross load of all units utilizing the common stack. For a cogenerating unit or other unit that does not produce electricity only from heat input, use the hourly gross steam load of the unit, in pounds of steam per hour at the measured temperature (°F) and pressure (psia) instead of MWge. Indicate a change in the number of load ranges or the units of loads to be used in the precertification section of the monitoring plan.

TABLE C–1.—DEFINITION OF OPERATING LOAN RANGES FOR LOAD-BASED SUBSTITUTION DATA PROCEDURES

Operating load range	Percent of maximum integrated hourly gross load (%)
1	0–10
2	>10–20
3	>20–30
4	>30–40
5	>40–50
6	>50–60
7	>60–70
8	>70–80
9	>80–90
10	>90–100

2.2.2 Beginning with the first hour of unit operation after installation and certification of the flow monitor or the NO_x continuous emission monitoring system, for each hour of unit operation record a number, 1 through 10, (or 1 through 20 for flow at common stacks) that identifies the operating load range corresponding to the integrated hourly gross load of the unit(s) recorded for each unit operating hour.

2.2.3 Beginning with the first hour of unit operation after installation and certification of the flow monitor or the NO_x continuous emission monitoring system and continuing thereafter, calculate and record the following information for each unit operating hour within each identified load range during the shorter of: (1) the previous 2,160 quality assured monitor operating hours (on a rolling basis), or (2) all previous quality assured monitor operating hours.

2.2.3.1 A running average of the hourly flow rates reported by a flow monitor, in scfh, for all unit operating hours.

2.2.3.2 The 90th percentile value of hourly flow rates, in scfh.

2.2.3.3 The 95th percentile value of hourly flow rates, in scfh.

2.2.3.4 The maximum value of hourly flow rates, in scfh.

2.2.3.5 A running average of the hourly NO_x emission rate, in lb/mmBtu, reported by a NO_x continuous emission monitoring system for all unit operating hours.

2.2.3.6 The 90th percentile value of hourly NO_x emission rates, in lb/mmBtu.

2.2.3.7 The 95th percentile value of hourly NO_x emission rates, in lb/mmBtu.

2.2.3.8 The maximum value of hourly NO_x emission rates, in lb/mmBtu.

2.2.4 Calculate all monitor or continuous emission monitoring system data averages, maximum values, and percentile values determined by this procedure using bias adjusted values in the load ranges.

2.2.5 When a bias adjustment is necessary for the flow monitor and/or the NO_x continuous emission monitoring system, apply the adjustment factor to all monitor or continuous emission monitoring system data averages, maximum values, and percentile values determined by the procedure.

2.2.6 Use the calculated monitor or monitoring system data averages, maximum values, and percentile values to substitute for missing flow rate and NO_x emission rate data according to the procedures in subpart D of this part.

Appendix D to part 75—Optional SO_2 Emissions Data Protocol for Gas-Fired and Oil-Fired Units

1. Applicability

1.1 This procedure may be used in lieu of continuous SO_2 pollutant concentration and flow monitors for the purpose of determining hourly SO_2 emissions from: (1) Gas-fired units as defined in § 72.2 of this chapter; or (2) oil-fired units as defined in § 72.2 of this chapter. This optional SO_2 emissions data protocol contains two methods for conducting oil sampling and analysis in Section 2.2 of this appendix; the procedures for flow proportional oil sampling and the procedures for manual daily oil sampling may be used for any gas-fired unit or oil-fired unit.

1.2 This procedure may also be certified by the Administrator and used in lieu of continuous SO_2 pollutant concentration and flow monitors for the purpose of determining hourly SO_2 emissions from new gas-fired units or new oil-fired units provided that the new gas-fired unit or oil-fired unit is

designed to combust only oil, natural gas, or a coal-derived gaseous fuel with a sulfur content no greater than natural gas.

1.3 Apply to the Administrator for certification using this method in lieu of continuous SO_2 pollutant concentration and flow monitors no later than the deadlines for the certification of continuous emission monitoring system specified in § 75.4 of this part. Whenever the monitoring method is to be changed, reapply to the Administrator for certification of the new monitoring method.

1.4 Do not use the methods specified in this appendix for accounting for SO_2 emissions prior to obtaining certification from the Administrator.

2. Procedure

2.1 Flowmeter Measurements

When the unit is combusting oil, measure and record the flow of oil consumed on an hourly basis. Measure the flow of oil with an in-line fuel flowmeter and automatically record the data. Measure the flow of all oil entering and being combusted by the unit. Any pipe returning fuel to a pipe that provides oil to the unit (e.g. a pipe recirculating oil to the storage tank) requires an in-line fuel flowmeter.

2.1.1 Design and equip each fuel flowmeter used to meet the requirements of this protocol to demonstrate a flowmeter accuracy of 2.0 percent of the upper range value (i.e. maximum calibrated oil flow rate) as measured under laboratory conditions by the manufacturer or by the owner or operator. Use the procedures in the following ASME codes for flow measurement for use in the laboratory, as appropriate to the type of flow meter: ASME MFC–3M–1989 with September 1990 Errata (Measurement of Fluid Flow in Pipes Using Orifice, Nozzle, and Venturi), ASME MFC–5M–1985 (Measurement of Liquid Flow in Closed Conduits Using Transit-Time Ultrasonic Flowmeters), ASME MFC–6M–1987 with June 1987 Errata (Measurement of Fluid Flow in Pipes Using Vortex Flow Meters), or ASME MFC–9M–1988 with December 1989 Errata (Measurement of Liquid Flow in Closed Conduits by Weighing Method) for all other flow meter types (incorporated by reference under § 75.6 of this part). If the flow meter accuracy exceeds 2 percent of the upper range value, the flow meter does not qualify for certification.

2.1.2 Recalibrate each fuel flowmeter to a flowmeter accuracy of 2.0 percent of the upper range value at least annually, or more frequently if required by manufacturer specifications using the same ASME procedures required for initial calibration and certification, to meet the requirements of this protocol.

2.1.3 Alternatively, the fuel flowmeter used for the purposes of this part may be recalibrated to a flowmeter accuracy of 2.0 percent of the upper range value at least annually by comparing the measured flow of a flow meter to the measured flow from another flow meter which has been calibrated or recalibrated during the previous 365 days using the procedures in ASME MFC–9M–1988 with December 1989 Errata, "Measurement of Liquid Flow in Closed Conduits by Weighing Method", or which has been recalibrated by the manufacturer. Perform the comparison over a period of no more than seven consecutive unit operating days. Compare the average of three fuel flow readings for each meter at each of three different flow levels, corresponding to the three operating levels listed in § 6.5.2 of Appendix A of this part. Calculate the flowmeter accuracy using [Equation A–7 in Appendix A of this part, substituting the measured flow from the flow meter that is calibrated by the weighing method for the reference value.] Or the following equation:

$$ACC = \frac{|R-A|}{URV} \times 100$$

(Eq. D–1)

where,

ACC = Flow meter accuracy as a percentage of the upper range value.

R = Average of the three low-, mid-, or high-level flow measurements of the reference flow meter.

A = Average of the three measurements of the flow meter being tested.

URV = Upper range value of fuel flow meter being tested (i.e. maximum measurable flow).

If the flow meter accuracy exceeds 2% of the upper range value, either recalibrate the flow meter until the accuracy is within the performance specification, or replace the flow meter with another one that is within the performance specification.

2.2 Oil Sampling and Analysis

Perform sampling and analysis of as-fired oil to determine the percentage of sulfur by weight in the oil.

2.2.1 Perform oil sampling every day the unit is combusting oil. Use either the flow proportional method described in section 2.2.2 of this appendix or the daily manual method described in section 2.2.3 of this appendix for gas-fired units and oil-fired units.

2.2.2 Conduct flow proportional oil sampling or continuous drip oil sampling in accordance with ASTM D4177–82 (Reapproved 1990), "Standard Practice for Automatic Sampling of Petroleum and Petroleum Products" (incorporated by reference under § 75.6 of this part), every day the unit is combusting oil. Extract oil at least once every hour and blend into a daily composite sample. The sample compositing period may not exceed 24 hr.

2.2.3 For a gas-fired unit or oil-fired unit, representative as-fired oil samples may be taken manually every 24 hr according to ASTM D4057–88, "Standard Practice for Manual Sampling of Petroleum and Petroleum Products" (incorporated by reference under § 75.6 of this part), provided that the highest fuel sulfur content recorded at that unit from the most recent 30 daily samples is used for the purposes of calculating SO_2 emissions under Section 3 of this appendix.

Note: For units with pressurized fuel flow lines such as some diesel and dual-fuel reciprocating internal combustion engine units, a manual sample may be taken from the point closest to the unit where it is safe to take a sample (including back to the oil tank), rather than just prior to entry to the boiler or combustion chamber.

2.2.4 Split and label each daily oil sample. Maintain a portion (at least 200 cc) of each daily sample throughout the calendar year and in all cases for not less than 90 calendar days after the end of the calendar year allowance accounting period. Analyze oil samples for percent sulfur content by weight in accordance with ASTM D129–91, "Standard Test Method for Sulfur in Petroleum Products (General Bomb Method)," ASTM D1552–90, "Standard Test Method for Sulfur in Petroleum Products (High Temperature Method)," ASTM D2622–92, "Standard Test Method for Sulfur in Petroleum Products by X-Ray Spectrometry," or ASTM D4294–90, "Standard Test Method for Sulfur in Petroleum Products by Energy-Dispersive X-Ray Fluorescence Spectroscopy" (incorporated by reference under § 75.6).

2.2.5 Where the flowmeter records volumetric flow rather than mass flow, analyze daily oil samples to determine the density or specific gravity of the oil. Determine the density or specific gravity of the oil sample in accordance with ASTM D941–88, "Standard Test Method for Density and Relative Density (Specific Gravity) of Liquids by Lipkin Bicapillary Pycnometer," ASTM D1217–91, "Standard Test Method for Density and Relative Density (Specific Gravity) of Liquids by Bingham Pycnometer," ASTM D1481–91, "Standard Test Method for Density and Relative Density (Specific Gravity) of Viscous Materials by Lipkin Bicapillary," ASTM D1480–91, "Standard Test Method for Density and Relative Density (Specific Gravity) of Viscous Materials by Bingham Pycnometer," ASTM D1298–85 (Reapproved 1990), "Standard Practice for Density, Relative Density (Specific Gravity) or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method," or ASTM D4052–91, "Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter" (incorporated by reference under § 75.6).

2.2.6 Analyze daily oil samples to determine the heat content of the fuel. Determine oil heat content in accordance with ASTM D240–87 (1Reapproved 1991), "Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter," ASTM D1382–88, "Standard Test Method for Heat or Combustion of Hydrocarbon Fuels by Bomb Calorimeter (High-Precision Method)", or ASTM D2015–91, "Standard Test Method for Gross Calorific Value of Coal and Coke by the Adiabatic Bomb Calorimeter" (incorporated by reference under § 75.6).

2.2.7 Results from the daily oil sample analysis must be available no later than thirty calendar days after the same is composited or taken. However, during an audit, the Administrator may require the results of the analysis in less than thirty calendar days.

2.3 Missing Data Procedures.

When data from the procedures of this part are not available, provide substitute data using the following procedures.

2.3.1 When sulfur content data from the analysis of a daily oil sample are missing or

invalid, substitute the highest measured sulfur content and oil density (if using a volumetric flowmeter) recorded during the previous 30 days when the unit burned oil.

2.3.2 When data from the fuel flowmeter are missing, substitute for each hour in the missing data period the average hourly oil flow rate measured and recorded by the fuel flowmeter at the closet unit load (in MWe) greater than the load recorded for the missing data period for which oil flow rate data are available during the previous 720 hours during which the unit combusted oil. If no oil flow rate data are available at a load greater than the load recorded during the missing data period, substitute the maximum flow rate that the flowmeter can measure.

2.4 . For each hour that natural gas is combusted by the unit, account for the daily SO_2 emissions, either by (1) measuring the sulfur content of the gas using ASTM D1072–90, "Standard Test Method for Total Sulfur in Fuel Gases" (incorporated by reference under § 75.6 of this part) and the fuel usage in 100 scf or (2) using the SO_2 emission rates listed in NADB for that unit and the daily heat input from natural gas, as determined using the procedures in Appendix F of this part.

3. Calculations

Where the flowmeter records mass flow, use the calculation procedures in section 3.1, and where the flowmeter records volumetric flow, use the calculation procedures in section 3.2.

3.1 SO_2 Calculation Using Mass Flow

3.1.1 Use the following equation to calculate SO_2 mass emissions per hour (in lb/hr).

$M_{so2}=2.0\times M_{oil}\times \%S_{oil}/100.0$
(Eq. D–1)

where,
M_{so2}=Hourly mass of SO_2 emitted, lb/hr.
M_{oil}=Mass of oil consumed per hr, lb/hr.
$\%S_{oil}$=Percentage of sulfur by weight measured in the sample.
2.0=Ratio of lb SO_2/lb S.

3.1.2 Record the SO_2 mass emissions for each hour. Calculate and record total quarterly and annual SO_2 mass emissions by summing hourly SO_2 mass emissions for each hour during that quarter or year when the unit combusted any oil.

3.2 SO_2 Calculation Using Volumetric Flow

3.2.1 Where the flowmeter records volumetric flow rather than mass flow, calculate and record the oil mass for each hourly period using hourly oil flow measurements and the density or specific gravity of the daily oil sample.

3.2.2 Convert density, specific gravity, or API gravity of the oil sample to density of the oil sample at the sampling location's temperature using ASTM D1250–80 (Reapproved 1990), "Standard Guide for Petroleum Measurement Tables" (incorporated by reference under § 75.6 of this part).

3.2.3 Where density of the oil is determined by the applicable ASTM procedures from section 2.2.5 of this appendix, use the following equation to calculate the mass of oil consumed (in lb/hr).

$M_{oil}=V_{oil}\times D_{oil}$
(Eq. D–2)

where,
M_{oil}=Mass of oil consumed per hr, lb/hr.
V_{oil}=Volume of oil consumed per hr, measured in scf, gal, barrels, or m^3.
D_{oil}=Density of oil, measured in lb/scf, lb/gal, lb/barrel, or lb/m^3.

3.2.4 Calculate the hourly heat input to the unit from oil (mmBtu) by multiplying the heat content of the daily oil sample by the hourly oil mass.

Appendix E to Part 75—Optional NO_x Emissions Estimation Protocol for Gas-Fired Peaking Units and Oil-Fired Peaking Units

1. Applicability.

1.1 Existing Unit

This NO_x emissions estimation procedure may be used in lieu of a continuous NO_x emission monitoring system (lb/mmBtu) for determining the average NO_x emission rate and hourly NO_x emission rate from gas-fired peaking units and oil-fired peaking units when these units are (1) operated with a capacity factor of 10 percent or less on the average during the previous three calendar years and (2) operated at a capacity factor of 20 percent or less in each of those three previous calendar years. If for any year a unit's operations exceed a capacity factor of 20 percent, or if a unit's operations exceed an average capacity factor of 10 percent over the most recent three calendar years, install and certify a continuous NO_x emission monitoring system no later than December 31 of the following calendar year.

1.2 New Unit

For a new gas-fired peaking unit or a new oil-fired peaking unit commencing commercial operation after November 15, 1990 where the projected capacity factor is 10 percent or less when averaged over 3 consecutive calendar years, this procedure may be certified and used in lieu of a continuous NO_x emission monitoring system. If the new gas-fired peaking unit or the new oil-fired peaking unit operating rate is greater than 20 percent in any one calendar year or greater than 10 percent on the average for any 3 consecutive calendar years, install and certify a continuous NO_x emission monitoring system on or before December 31 of the following calendar year.

1.3 Certification

1.3.1 Apply to the Administrator for certification of this optional method no later than the deadlines for the installation of continuous emission monitoring systems specified in § 75.4 of this part.

1.3.2 Do not use this optional method to record or report NO_x emissions prior to obtaining certification from the Administrator.

2. Procedure

2.1 Initial Performance Testing

Use the following procedures for measuring NO_x emission rates at different load levels; measuring unit efficiency and heat input; and plotting the correlation between operating load and NO_x emission rate or unit efficiency, in order to determine the performance and emission rate of the unit(s) prior to certification of this optional method.

2.1.1 Load Selection

Establish five approximately equally spaced operating load points, ranging from the maximum operating load to the minimum operating load. Use the unit's nameplate capacity as the maximum operating load. Select the minimum operating load from the operating history of the unit during the most recent two years. For new gas-fired peaking units or new oil-fired peaking units, select the minimum operating load from the expected minimum load to be dispatched to the unit in the first three calendar years of operation.

2.1.2 NO_x and O_2 Concentration Measurements

Use the following procedures to measure NO_x and O_2 concentration in order to determine NO_x emission rate.

2.1.2.1 Except for stationary gas turbines, measure the NO_x and O_2 concentration at 3 excess oxygen levels at each load point for each fuel or each combination of fuels to be combusted using the methods specified below in section 2.1.2.2 or 2.1.2.3 of this appendix. Establish the three excess oxygen levels as the minimum, normal, and maximum levels. Select the minimum, normal, and maximum levels at each load point according to the operating history of the unit during the most recent two years. For new gas-fired peaking units or new oil-fired peaking units, select the minimum, normal, and maximum levels at each load point per manufacturer's recommendations. For stationary gas turbines, measure the NO_x and O_2 concentration at the normal oxygen level at each load, and again at another oxygen level if the temperature of the (combustion) air at the air intake varies by more than 4°F from the average test conditions at that load.

2.1.2.2 Measure the NO_x and O_2 concentrations according to Appendix A, Method 20 of part 60 of this chapter for stationary gas turbines. Measure the NO_x and O_2 concentrations according to Method 20 for diesel or dual fuel fuel reciprocating engines, but modify Method 20 with respect to the selection of a sampling site to be as close as practical to the exhaust of the engine.

2.1.2.3 Measure the NO_x and O_2 concentrations according to Appendix A, Methods 7E of 3A of part 60 of this chapter for all other gas-fired peaking units or oil-fired peaking units.

2.1.2.4 Allow the unit to stabilize for a minimum of one hour prior to commencing NO_x, O_2, and unit efficiency measurements. Repeat the NO_x measurement two times (i.e., for a total of three times) and obtain an arithmetic average of the NO_x measurements for each of the three oxygen levels. Record the oxygen level for a period of at least 20 minutes at 5 minute intervals and report the average of all readings as the excess oxygen level for this period.

2.1.3 Heat Input

Measure the total heat input of fuel flow or a combination of fuel flows as follows:

2.1.3.1 Calibrate in-line flow meters using the procedures and specifications contained in the following ASME codes for flow measurement for use in the laboratory, as appropriate to the type of flow meter: ASME MFC–3M–1989 with September 1990 Errata (Measurement of Fluid Flow in Pipes Using Orifice, Nozzle, and Venturi), ASME MFC–4M–1986 (Reaffirmed 1990) (Measurement of Gas Flow by Turbine Meters, ASME MFC–5M–1985 (Measurement of Liquid Flow in Closed Conduits Using Transit-Time Ultrasonic Flowmeters), ASME MFC–6M–1987 with June 1987 Errata (Measurement of Fluid Flow in Pipes Using Vortex Flow Meters), ASME MFC–7N–1987 (Reaffirmed 1992) (Measurement of Gas Flow by Means of Critical Flow Venturi Nozzles), ASME MFC–9M–1988 with December 1989 Errata (Measurement of Liquid Flow in Closed Conduits by Weighing Method for other flow meter types for liquids) (incorporated by reference under § 75.6 of this part), or any other standard method approved by the Administrator. Measure the total consumption of the fuels with in-line flow meters for a period of 15 minutes. Correct any gaseous fuel flow rate measured at actual temperature and pressure to standard conditions.

2.1.3.2 For liquid fuels, analyze daily fuel samples to determine the heat content of the fuel. Determine heat content in accordance with ASTM D240–87 (Reapproved 1991) "Standard Test Method for Heat of Combustion of Liquid Hydrocarbon Fuels by Bomb Calorimeter," ASTM D2382–88, "Standard Test Method for Heat of Combustion of Hydrocarbon Fuels by Bomb Calorimeter (High-Precision Method)" or ASTM D2015–91, "Standard Test Method for Gross Calorific Value of Coal and Coke by the Adiabatic Bomb Calorimeter" (incorporated by reference under § 75.6 of this part). Measure the heat content of gaseous fuels according to ASTM D1826–88, "Standard Test Method for Calorific (Heating) Value of Gases in Natural Gas Range by Continuous Recording Calorimeter". Calculate the total heat input using Equation E–1 of this appendix. Record the total heat input of fuel flow or a combination of fuel flows for each excess oxygen level at each load point.

2.1.4 Unit Efficiency

Use the following procedures to measure unit efficiency.

2.1.4.1 Measure the unit efficiency of the stationary gas turbine, the diesel, or the dual fuel-reciprocating engine at the same excess oxygen levels as established in section 2.1.2.1 of this appendix at each load point for each fuel or combination of fuels to be combusted according to one of the following methods. Use the same method for subsequent periodic retesting of the initial unit efficiency correlations.

2.1.4.2 Measure the fuel consumption, the total heat input of fuel flow or combination of fuel flows to the stationary gas turbine, and the electric energy output of the stationary gas turbine for a period of 15 minutes using the procedures specified in the ASME Performance Test Code (PTC) 22–1985, Gas Turbine Power Plants (incorporated by reference under § 75.6 of this part). Correct any gaseous fuel flow rate measured at actual temperature and pressure to standard conditions (68°F and 29.92 inches of mercury). Measure the fuel consumption, the total heat input of fuel flow or combination of fuel flows, and the electric energy output of the diesel or dual-fuel reciprocating engine for a period of 15 minutes using the procedures specified in the ASME Performance Test Code 17–1973 (Reaffirmed 1991), Reciprocating Internal-Combustion Engines (incorporated by reference under § 75.6 of this part). Compute the unit efficiency of the reciprocating engines using Equation E–2 of this appendix.

2.1.4.3 Measure the unit efficiency of all other oil- or gas-fired units at the same excess oxygen levels as established in section 2.1.2 of this appendix using the Heat Loss Method contained in the ASME Power Test Code 4.1–1964 (Reaffirmed 1991), Steam Generating Units (incorporated by reference under § 75.6 of this part). Compute the unit efficiency of the gas-fired peaking unit or oil-fired peaking unit using Equation E–2 of this appendix.

2.1.4.4 Allow the unit to stabilize for a minimum of one hour prior to commencing NO_x, O_2, and unit efficiency measurements. Repeat the NO_x measurement two times (i.e. for a total of three times) and obtain an arithmetic average of the NO_x measurements for each of the three oxygen levels. Record the oxygen level for a period of at least 20 minutes at 5 minute intervals and report the average of all readings as the excess oxygen level for this period.

2.1.5 Tabulation of Results

Tabulate the results of each baseline correlation test for each fuel or combination of fuels, listing: time of test, duration, operating loads, F-factors, excess oxygen levels, NO_x concentrations (ppm) on a dry basis (at actual excess oxygen level), and unit efficiency. Convert the NO_x concentrations (ppm) to NO_x emission rates (to the nearest 0.01 lb/mmBtu) according to the equation E–3 or E–4, as appropriate, of this appendix.

2.1.6 Plotting of Results

Plot the tabulated results as an x-y graph for each fuel or combination of fuel to be combusted according to the following procedures.

2.1.6.1 Plot the operating load as the independent (or x) variable and the NO_x emission rates (lb/mmBtu) as the dependent (or y) variable, where three values corresponding to the three excess oxygen levels are established according to section 2.1.2.1 of this appendix for each load point. Construct the graph by drawing four straight line segments between the five load points by connecting the highest NO_x concentration at each load point.

2.1.6.2 Plot the operating load as the independent (or x) variable and the unit efficiency as the dependent (or y) variable, where three values corresponding to the three excess oxygen levels are established according to section 2.1.2.1 of this appendix for each load point. Construct the graph by drawing four straight line segments between the five load points by connecting the unit efficiency corresponding to the nominal oxygen level at each load point.

2.2 Periodic NO_x Emission Rate Testing

Retest the NO_x emission rate of the gas-fired peaking unit or the oil-fired peaking unit prior to the earlier of 3,000 unit operating hours or the 5-year anniversary and renewal of its operating permit under part 72 of this chapter.

2.3 Other Quality Assurance/Quality Control-Related NO_x Emission Rate Testing

When the operating levels of certain parameters exceed the limits specified below, retest the NO_x emission rate to re-verify the gas-fired peaking unit's or the oil-fired peaking unit's NO_x emission rate.

2.3.1 For a stationary gas turbine, redetermine the NO_x emission rate-load correlation for each fuel and combination of fuels after exceeding the manufacturer's recommended range of the following operating parameters: positioning of inlet guide vanes (i.e., degrees of rotation of inlet guide vanes), amount of air bypass used for turbine blade cooling, flow rate of steam or water injection used for NO_x emission control, exhaust temperature, compression ratio, ambient air temperature and pressure, inlet oxygen temperature and press (if stored oxygen or on-site oxygen plant is used), unit efficiency (or unit heat rate), and any other parameters specified by the unit manufacturer.

2.3.2 For a diesel or a dual-fuel reciprocating engine, redetermine the NO_x emission rate-load correlation for each fuel or combination of fuels after exceeding the manufacturer's recommended range of the following operating parameters: air intake manifold temperature, air intake manifold pressure, exhaust temperature, compression ratio, piston speed, brake mean effective pressure, supercharging, turbocharging, unit efficiency (or unit heat rate), and any other parameters specified by the unit manufacturer.

2.3.3 For all other gas-fired peaking units and oil-fired peaking units, redetermine the NO_x emission rate load correlation for each fuel and combination of fuels if any of the following occurs:

2.3.3.1 The heat input rate (mmBtu/hr) at either the maximum or the minimum operating load varies by more than 10 percent from the heat input rate at the maximum or the minimum operating load during the previous NO_x emission rate test; or

2.3.3.2 The excess oxygen level at either the maximum or the minimum operating load varies by more than 2 percentage points O_2 from the level during the maximum or minimum operating load during the previous NO_x emission rate test; or

2.3.3.3 The unit efficiency at nominal excess O_2 at either the maximum or the minimum operating load varies by more than 3 percentage points from the unit efficiency during the maximum operating load of the previous unit efficiency test, as defined using Equation E–2 of this appendix.

2.4 Procedures for Determining Hourly NO_x Emission Rate

2.4.1 Record the time (hr. and min.) and electric energy output (MWh) at the beginning of each time period, with each time period as close to one hour in duration as practical. Calculate the average operating load using equation E–8 of this appendix.

Record this average operating load to the nearest 0.1 MW as the reading for the beginning of the time period, time t. Record the next average operating load to the nearest 0.1 MW as the reading for the end of the first time period, time t+1, and so on.

2.4.2 Read the NO_x emission rate (lb/mmBtu) corresponding to the appropriate operating load, linearly interpolating to the nearest 0.1 MW and 0.01 lb/mmBtu, using the tabulated results of the baseline NO_x correlation appropriate to the fuel or fuel combination being combusted. Record the NO_x emission rate (to the nearest 0.01 lb/mmBtu) at the beginning of each time period.

2.5 Missing Data

Provide substitute data for each unit electing to use this alternative procedure whenever a valid quality-assured hour of NO_x emission rate data has not been obtained according to the procedures and specifications of section 2.4 of this appendix. For all missing data, substitute the highest NO_x emission rate tabulated during the most recent set of baseline correlation tests for any fuel or combination of fuels at the observed operating load. Maintain a record indicating which data are substitute data and the reasons for the failure to provide a valid quality-assured hour of NO_x emission rate data according to the procedures and specifications of section 2.4 of this appendix.

3. Calculations

3.1 Heat Input

Calculate the total heat input by summing over the product of fuel consumption and the measured heat control of each fuel, as in the following equation:

$$H_T = \sum_{f=1}^{n} \sum_{t=1}^{T} 10^{-6} Q_{ft} H_f t$$

(Eq. E–1)

where

H_T=total heat input of fuel flow or a combination of fuel flows over a total time of T hours, mmBtu;

10^{-6}=conversion of Btu to mmBtu;

H_f=heat content of each fuel, Btu/scf, Btu/lb, or other appropriate units;

Q_{ft}=flow rate measured for each fuel at time t (and corrected to 68°F and 29.92 inches of mercury if fuel is gaseous), scfh, lb/hr, or other appropriate units;

n=total number of fuels to be combusted;

T=total number of hours during which heat input is computed.

3.2 Unit Efficiency

Compute unit efficiency according to the following equation:

$$\eta = \frac{(100)\ (3412)\ E}{H\ 10^6}$$

(Eq. E–2)

where,

η=unit efficiency, percent;

100=factor to convert to percentage;

10^6=conversion of mmBtu to Btu;

E=total electric energy output (kilowatt-hour) for a specified interval of time, kWh;

3412=factor to convert kwh to Btu;

H=total heat input of fuel flow for the same specified interval of time as in E, mmBtu.

3.3 F-factors

Compute the F-factors for each fuel or combination of fuels to be combusted according to Appendix A, Method 19, sections 3.2.1–3.2.4 and section 3.3 of part 60 of this chapter. For a combination of fuels, use Eq. F–8 in Appendix F of this part, using the F-factors computed above for each fuel.

3.4 NO_x Emission Rate

3.4.1 Conversion from Concentration to Emission Rate

Convert the NO_x concentrations (ppm) to NO_x emission rates (to the nearest 0.01 lb/mmBtu) according to the appropriate one of the following equations:

$$E = K\ C_d\ F_d\ \frac{20.9}{20.9 - \%O2}$$

(Eq. E–3)

where,

E=NO_x emission rate, lb/mmBtu;

K=1.19×10^{-7} (lb/dscf)/ppm NO_x

C_d=NO_x concentration measured, dry basis, ppm;

F_d=dry basis F-factor computed in Section 3.3 of this appendix, dscf/mmBtu;

20.9=percentage of air that is oxygen, percent;

$\%O_2$=O_2 concentration measured, dry basis, %.

or

$$E = K\ C_w\ F_d\ \frac{20.9}{[(20.9/100)\ (100 - \%H_2O)\ - \%O_{2w}]}$$

(Eq. E–4)

where,

E=NO_x emission rate, lb/mmBtu;

K=1.19×10^{-7} (lb/dscf)/ppm NO_x

C_w=NO_x concentration measured, wet basis, ppm;

F_d=dry basis F-factor computed in Section 3.3 of this appendix, dscf/mmBtu;

20.9=percentage of air that is oxygen, percent;

$\%H_2O$=moisture content of sample gas as measured by Appendix A, Method 4, of part 60 of this chapter, percent.

$\%O_{2w}$=O_2 concentration measured, wet basis, %.

3.4.2 Quarterly Average NO_x Emission Rate

Report the quarterly average emission rate (lb/mmBtu) as required in subpart G of this part. Calculate the quarterly average NO_x emission rate according to the following equation:

$$E_q = \sum_{i=1}^{n} \frac{E_i}{n}$$ (Eq. E-5)

where,

E_q=NO_x emission rate averaged over a quarter, lb/mmBtu;

E_i=hourly NO_x emission rate, lb/mmBtu;

n=number of hourly rates available in the preceding quarter.

3.4.3 Annual Average NO_x Emission Rate

Report the quarterly average emission rate (lb/mmBtu) as required in subpart G of this part. Calculate the annual average NO_x emission rate according to the following:

$$E_a = \sum_{i=1}^{n} \frac{E_i}{n}$$ (Eq. E-6)

where,

E_a=NO_x emission rate averaged over the previous calendar year, lb/mmBtu;

E_i=hourly NO_x emission rate, lb/mmBtu;

n=number of hourly NO_x emission rates available in the preceding calendar year.

3.4.4 Cumulative NO_x Emission

Report the cumulative NO_x emissions (tons) as required in subpart G of this part. Calculate the cumulative NO_x emission rate according to the following equation:

$$E_{total} = \frac{E_a H_a}{2000}$$ (Eq. E-7)

where,

E_{total}=cumulative NO_x emissions in the previous calendar year, tons;

E_a=NO_x emission rate averaged over the previous calendar year, lb/mmBtu;

H_a=total heat input in the previous calendar year, mmBtu.

3.5 Average Operating Load

Calculate the average operating load as follows:

$$P = \frac{E_{t+1} - E_t}{T}$$ (Eq. E-8)

where,

P=average operating load (electric), MWe;

E_t=electric energy output (megawatt-hour) reading at the beginning of the time period, time t, MWh;

E_{t+1}=electric energy output (megawatt-hour) reading at the end of the time period, time t+1, MWh;

T=the duration of the time period from t to t+1, calculated by taking the difference between t+1 and t, hr.

4. Quality Assurance/Quality Control Plan

Include a section on the NO_x emission rate determination as part of the monitoring quality assurance/quality control plan required under § 75.21 and Appendix B of this part for each gas-fired peaking unit and each oil-fired peaking unit. In this section present information including, but not limited to, the following: (1) A copy of all data and results from the initial NO_x emission rate and unit efficiency testing, including the values of quality assurance parameters specified in Section 2.3 of this appendix; (2) a copy of all data and results from the most recent NO_x emission rate load correlation and unit efficiency testing; (3) a copy of the unit manufacturer's recommended range of quality assurance- and quality control-related operating parameters.

4.1 Submit a copy of the unit manufacturer's recommended range of operating parameter values, and the range of operating parameter values recorded during the previous NO_x emission rate test and unit efficiency test that determined the unit's NO_x emission rate, along with the unit's monitoring plan.

4.2 Keep records of these operating parameters for each hour of operation in order to demonstrate that a unit is remaining within the manufacturer's recommended operating range.

Appendix F to Part 75—Conversion Procedures

1. Applicability

Use the procedures in this appendix to convert measured data from a monitor or continuous emission monitoring system into the appropriate units of the standard.

2. Procedures for SO_2 emissions

Use the following procedures to compute hourly, quarterly, and annual SO_2 mass emissions (in lb/hr). Use the procedures in Method 19 in Appendix A to part 60 of this chapter to compute hourly SO_2 emission rates (in lb/mmBtu) for qualifying Phase I technologies.

2.1 When measurements of SO_2 concentration and flow rate are on a wet basis, use the following equation to compute hourly SO_2 mass emissions (in lb/hr).

$E_h = K C_{hw} Q_{hs}$

(Eq. F–1)

where,

E_h=Hourly SO_2 mass emissions, lb/hr.

$K=1.660\times10^{-7}$ for SO_2, (lb/scf)/ppm.

C_{hw}=Hourly average SO_2 concentration, stack moisture basis, ppm.

Q_{hs}=Hourly average volumetric flow rate, stack moisture basis, scfh.

2.2 When measurements by the SO_2 pollutant concentration monitor are on a dry basis and the flow rate monitor measurements are on a wet basis, use the following equation to compute hourly SO_2 mass emissions (in lb/hr).

$$E_h = K C_{hw} Q_{hs} \frac{(100-\%H_2O)}{100}$$

(Eq. F–2)

where,

E_h=Hourly SO_2 mass emissions, lb/hr.

$K=1.660\times10^{-7}$ for SO_2, (lb/scf)/ppm.

C_{hw}=Hourly average SO_2 concentration, ppm (dry).

Q_{hs}=Hourly average volumetric flow rate, scfh as measured (wet).

$\%H_2O$=Hourly average stack moisture content, percent by volume.

2.3 Use the following equations to calculate total SO_2 mass emissions for each calendar quarter (Eq. F–3) and for each calendar year (Eq. F–4) in tons.

$$E_q = \frac{\sum_{h=1}^{n} E_h}{2000}$$

(Eq. F–3)

where,

E_q=Quarterly total SO_2 mass emissions, tons.

E_h=Hourly SO_2 mass emissions, lb/hr.

n=Number of hourly SO_2 emissions values during calendar quarter.

2000=Conversion of 2000 lb per ton.

$$E_a = \sum_{q=1}^{4} E_q$$

(Eq. F–4)

where,

E_a=Annual total SO_2 mass emissions, tons.

E_q=Quarterly SO_2 mass emissions, tons.

q=Quarters for which E_q are available during calendar year.

2.4 Round all SO_2 mass emissions to the number of decimal places identified in § 75.50(c) of this part (in lb/hr).

3. Procedures for NO_x Emission Rate

Use the following procedures to convert continuous emission monitoring system measurements of NO_x concentration (ppm) and diluent concentration (percentage) into NO_x emission rates (in lb/mmBtu). Perform measurements of NO_x and diluent (O_2 or CO_2) concentrations on the same moisture (wet or dry) basis.

3.1 When the NO_x continuous emission monitoring system uses O_2 as the diluent, and measurements are performed on a dry basis, use the following conversion procedure:

$$E = K C_h F \frac{20.9}{20.9 - \%O_2}$$

(Eq. F–5)

where,

K, E, C_h, F, and $\%O_2$ are defined in section 3.3 of this appendix. When measurements are performed on a wet basis, use the equations in Method 19 in Appendix A of part 60 of this chapter.

3.2 When the NO_x continuous emission monitoring system uses CO_2 as the diluent, use the following conversion procedure:

$$E = K C_h F_c \frac{100}{\%CO_2}$$

(Eq. F–6)

where,

K, E, C_h, F_c, and $\%CO_2$ are defined in section 3.3 of this appendix.

3.3 Use the definitions listed below to derive values for the parameters in Equations F–5 and F–6 of this appendix.

3.3.1 $K=1.19\times10^{-7}$ (lb/dscf)/ppm NO_x.

3.3.2 E=pollutant emissions, lb/mmBtu.

3.3.3 C_h=hourly average pollutant concentration, ppm.

3.3.4 $\%O_2$, $\%CO_2$=oxygen or carbon dioxide volume (expressed as percent O_2 or CO_2).

3.3.5 F, F_c=a factor representing a ratio of the volume of dry flue gases generated to the caloric value of the fuel combusted (F), and a factor representing a ratio of the volume of CO_2 generated to the calorific value of the fuel combusted (F_c), respectively. Table 1 lists the values of F and F_c for different fuels.

TABLE 1.—F- AND F_c-FACTORS [1]

Fuel	F-factor (dscf/mmBtu)	F_c-factor (scf CO_2/mmBtu)
Coal (as defined by ASTM D388–92):		
Anthracite	10,100	1,970
Bituminous and subbituminous	9,780	1,800
Lignite	9,860	1,910
Oil	9,190	1,420
Gas:		
Natural gas	8,710	1,040
Propane	8,710	1,190
Butane	8,710	1,250
Wood:		
Bark	9,600	1,920
Wood residue	9,240	1,830

[1] Determined at standard conditions: 20 °C (68 °F) and 29.92 inches of mercury.

3.3.6 Equations F–7a and F–7b may be used in lieu of the F or F_c factors specified in Section 3.3.5 of this appendix to calculate an F factor (dscf/mmBtu) on a dry basis or an F_c factor (scf CO_2/mmBtu) on either a dry or wet basis.

(Calculate all F- and F_c factors at standard conditions of 20 °C (68 °F) and 29.92 inches of mercury.)

$$F = \frac{3.64(\%H) + 1.53(\%C) + 0.57(\%S) + 0.14(\%N) - 0.46(\%O)}{GCV} \times 10^6$$

(Eq. F–7a)

$$F_c = \frac{321 \times 10^3 (\%C)}{GCV}$$

(Eq. F–7b)

3.3.6.1 H, C, S, N, and O are content by weight of hydrogen, carbon, sulfur, nitrogen, and oxygen (expressed as percent), respectively, as determined on the same basis as the gross calorific value (GCV) by ultimate analysis of the fuel combusted using ASTM D3176–89, "Standard Practice for Ultimate Analysis of Coal and Coke" (solid fuels), or computed from results using ASTM D1945–91, "Standard Test Method for Analysis of Natural Gas by Gas Chromatography" or ASTM D1946–90, "Standard Practice for Analysis of Reformed Gas by Gas Chromatography" (gaseous fuels) as applicable. (These three methods are incorporated by reference under § 75.6 of this part.)

3.3.6.2 GCV is the gross calorific value (Btu/lb) of the fuel combusted determined by ASTM D2015–91, "Standard Test Method for Gross Calorific Value of Coal and Coke by the Adiabatic Bomb Calorimeter" for solid and liquid fuels, and ASTM D1826–88, "Standard Test Method for Calorific (Heating) Value of Gases in Natural Gas Range by Continuous Recording Calorimeter" for gaseous fuels, as applicable. (These two methods are incorporated by reference under § 75.6 of this part).

3.3.6.3 For affected units that combust a combination of fossil (coal, oil and gas) and nonfossil (e.g., bark, wood, residue, or refuse) fuels, the F or F_c value is subject to the Administrator's approval.

3.3.6.4 For affected units that combust combinations of fossil fuels or fossil fuels and wood residue, prorate the F or F_c factors determined by Section 3.3.5 of this appendix in accordance with the applicable formula as follows:

$$F = \sum_{i=1}^{n} X_i F_i \qquad F_c = \sum_{i=1}^{n} X_i (F_c)_i$$

(Eq. F–8)

where,

X_i = Fraction of total heat input derived from each type of fuel (e.g., natural gas, bituminous coal, wood).

F_i or $(F_c)_i$ = Applicable F or F_c factor for each fuel type determined in accordance with Section 3.3.5 of this appendix.

n = Number of fuels being combusted in combination.

3.4 Use the following equations to calculate the average NO_x emission rate for each calendar quarter (Eq. F–9) and the annual average emission rate for each calendar year (Eq. F–10) in lb/mmBtu.

$$E_q = \sum_{i=1}^{n} \frac{E_i}{n}$$

(Eq. F–9)

where,

E_q = Quarterly average NO_x emission rate, lb/mmBtu.

E_i = Hourly average No_x emission rate, lb/mmBtu.

n = Number of hourly rates during calendar quarter.

$$E_a = \sum_{i=1}^{m} \frac{E_i}{m}$$

(Eq. F–10)

where,

E_a = Annual average No_x emission rate, lb/mmBtu.

E_i = Average hourly NO_x emission rate, lb/mmBtu.

m = Number of hours for which E_i is available in preceding calendar year.

3.5 Round all NO_x emission rates to the nearest 0.01 lb/mmBtu.

4. Procedures for CO_2 Mass Emissions

Use the following procedures to convert continuous emission monitoring system measurements of CO_2 concentration (percentage) and volumetric flow rate (scfh) into CO_2 mass emissions (in tons/day) when the owner or operator uses a CO_2 continuous emission monitoring system (consisting of a CO_2 diluent gas monitor and a flow monitor) to monitor CO_2 emissions from an affected unit.

4.1 When CO_2 concentration is measured on a wet basis, use the following equation to calculate hourly CO_2 mass emissions rates (in tons/hr).

$E_h = K C_h Q_h$

(Eq. F–11)

where,

E_h = Hourly CO_2 mass emissions, tons/hr.

$K = 5.7 \times 10^{-7}$ for CO_2, (tons/scf) /$\%CO_2$.

C_h = Hourly average CO_2 concentration, stack moisture basis, $\%CO_2$.

Q_h = Hourly average volumetric flow rate, stack moisture basis, scfh.

4.2 When CO_2 concentration is measured on a dry basis, use Equation F–2 to calculate the hourly CO_2 mass emissions (in tons/hr) with a K-value of 5.7×10^{-7} (tons/scf)$\%CO_2$, where E_h = hourly CO_2 mass emissions, tons/hr and C_{wp} = hourly average CO_2 concentration in flue; dry basis, $\%CO_2$.

4.3 Use the following equations to calculate total CO_2 mass emissions for each calendar quarter (Equation F–12 and for each calendar year (Equation F–13).

$$E_{CO_{2q}} = \sum_{i=1}^{H_R} E_{h_i}$$

(Eq. F–12)

where,

E_{co2q} = Quarterly total CO_2 mass emissions, tons.

E_{hi} = Hourly CO_2 mass emissions (tons/hr).

H_R = Number of hourly CO_2 mass emissions available during calendar quarter.

$$E_{CO_{2a}} = \sum_{q=1}^{4} E_{CO_{2q}}$$

(Eq. F–13)

where,

E_{co2a}=Annual total CO_2 mass emissions, tons.

E_{co2q}=Quarterly total CO_2 mass emissions, tons.

q=Quarters for which E_{co2q} are available during calendar year.

4.3.1 Whenever a valid hour of CO_2 concentration data has not been obtained and recorded, substitute for each hour in each missing data period the average of the recorded CO_2 concentration for the hour immediately before and the hour immediately following the missing data period.

4.3.2 Whenever a valid hour of volumetric flow rate data has not been obtained and recorded, use the procedure specified in subpart D of this part to provide substitute data.

4.3.3 Whenever CO_2 mass emissions data have not been measured and recorded for a period of 72 consecutive unit operating hours or for at least 90 percent of the total unit operating hours during the calendar quarter, use the appropriate procedures in Appendix G to this part to estimate CO_2 mass emissions from the affected unit.

4.4 For an affected unit, when the owner or operator is continuously monitoring O_2 concentration (in percent by volume) of flue gases using a diluent O_2 monitor, use the equations and procedures in section 4.4.1–4.4.3 of this appendix to determine hourly CO_2 mass emissions (in tons).

4.4.1 Use appropriate F and F_c factors from section 3.3.5 of this appendix in the following equation to determine hourly average CO_2 concentration of flue gases (in percent by volume).

$$CO_{2h} = 100 \frac{F_c}{F} \frac{20.9 - O_{2h}}{20.9}$$

(Eq. F–14)

Where,

CO_{2h}=Hourly average CO_2 concentration, percent by volume, dry basis.

F, F_c=F-factor or carbon-based F_c-factor from Section 3.3.5 of this appendix.
20.9=percentage of O_2 in ambient air.
O_{2d}=Hourly average O_2 concentration, percent by volume, dry basis.Q02

4.4.2 Determine CO_2 mass emissions (in tons) from hourly average CO_2 concentration (percent by volume) using Equation F–11 and the procedures in Sections 4.1 and 4.2 of this appendix.

4.4.3 Whenever a valid hour of O_2 concentration data has not been obtained and recorded, use the procedures in Sections 4.3.1–4.3.3 of this appendix to provide substitute data for each hour of each missing data period except that the phrase "CO_2 concentration" is replaced with "O_2 concentration."

5. Procedures for Heat Input

Use the following procedures to compute heat input to an affected unit (in mmBtu/hr or mmBtu/day).

5.1 Calculate and record heat input to an affected unit on an hourly basis, except as provided below for natural gas, or for units using a common stack, the owner or operator may choose to use the provisions specified in § 75.16(e) in conjunction with the procedures provided below to apportion heat input among each unit using the common stack.

5.2 For an affected unit that has a flow monitor (or approved alternate monitoring system under subpart E of this part for measuring volumetric flow rate) and a diluent gas (O_2 or CO_2) monitor, use the recorded data from these monitors and one of the following equations to calculate hourly heat input (in mmBtu/hr).

5.2.1 When measurements of CO_2 concentration are on a wet basis, use the following equation:

$$HI = Q_w \frac{1}{F_c} \frac{\%CO_{2w}}{100}$$

(Eq. F–15)
where,
HI=Hourly heat input, mmBtu/hr.
Q_w=Hourly average volumetric flow rate, wet basis, scfh.
F_c=Carbon-based F-factor, listed in Section 3.3.5 of this appendix for each fuel, scf/mmBtu.
$\%CO_{2w}$=Hourly concentration of CO_2, percent CO_2 wet basis.

5.2.2 When measurements of CO_2 concentrations are on a dry basis, use the following equation:

$$HI = Q_h \left[\frac{(100-\%H_2O)}{100F_c}\right]\left(\frac{\%CO_{2d}}{100}\right)$$

(Eq. F–16)
where
HI=Hourly heat input, mmBtu/hr.
Q_h=Hourly average volumetric flow rate, wet basis, scfh.
F_c=Carbon-based F-Factor, listed above in Section 3.3.5 of this appendix for each fuel, scf/mmBtu.
$\%CO_{2d}$=Hourly concentration of CO_2, $\%CO_2$ dry basis.
$\%H_2O$=Moisture content of gas in the stack, percent.

5.2.3 When measurements of O_2 concentration are on a wet basis, use the following equation:

$$HI = Q_w \frac{1}{F} \frac{[(20.9/100)(100 - \%H_2O) - \%O_{2w}]}{20.9}$$

(Eq. F–17)
where
HI=Hourly heat input, mmBtu/hr.
Q_w=Hourly average volumetric flow rate, wet basis, scfh.
F=Dry basis F-Factor, listed above in Section 3.3.5 of this appendix for each fuel, dscf/mmBtu.
$\%O_{2w}$=Hourly concentration of O_2, percent O_2 wet basis.
$\%H_2O$=Hourly average stack moisture content, percent by volume.

5.2.4 When measurements of O_2 concentration are on a dry basis, use the following equation:

$$HI = Q_w \left[\frac{(100 - \%H_2O)}{100F}\right]\left[\frac{(20.9 - \%O_{2d})}{20.9}\right]$$

(Eq. F–18)
where,
HI=Hourly heat input, mmBtu/hr.
Q_w=Hourly average volumetric flow, wet basis, scfh.
F=Dry basis F-factor, listed above in Section 3.3.5 of this appendix for each fuel, dscf/mmBtu.
$\%H_2O$=Moisture content of the stack gas, percent.
$\%O_{2d}$=Hourly concentration of O_2, percent O_2 dry basis.

5.3 Whenever a valid hour of flow data has not been obtained and recorded, use the procedures specified in subpart D of this part to provide substitute data.

5.4 Whenever a valid hour of diluent (O_2 or CO_2) concentration data has not been obtained and recorded, substitute for each hour in each missing data period the average of the recorded diluent gas (O_2 or CO_2) percentage concentration for the hour immediately before and the hour immediately following the missing data period.

5.5 For a gas-fired or oil-fired unit that does not have a flow monitor and is using the procedures specified in appendix D to this part to monitor SO_2 emissions or for any affected unit using a common stack for which the owner or operator chooses to determine heat input by fuel sampling and analysis, use the following procedures to calculate hourly (or, when combusting natural gas, daily) heat input in mmBtu/hr or mmBtu/day.

5.5.1 When the unit is combusting oil, use the following equation to calculate hourly heat input.

$$HI_o = M_o \frac{GCV_o}{10^6}$$

(Eq. F–19)
where,
HI_o=Hourly heat input from oil, mmBtu/hr.
M_o=Mass of oil consumed per hour, as determined using procedures in appendix D of this part, in lb, tons, or kg.
GCV_o=Gross calorific value of oil, as measured daily by ASTM D240–87 (Reapproved 1991), ASTM D2015–91, or ASTM D2382–88, Btu/unit mass (incorporated by reference under § 75.6 of this part).
10^6=Conversion of Btu to mmBtu.

5.5.2 When the unit is combusting natural gas, use the following equation to calculate heat input from natural gas for each 24-hour period.

$HI_g = Q_g\ GCV_g$
(Eq. F–20)
where,
HI_g=Daily heat input from natural gas, mmBtu/day.
Q_g=Flow or amount of natural gas combusted during 24-hour period, million cubic feet.
GCV_g=Gross calorific value of natural gas, as verified by the contractual supplier using ASTM D1826–88, Btu/cubic foot (incorporated by reference under § 75.6 of this part).

5.5.3 When the unit is combusting coal, use the procedures, methods, and equations in sections 5.5.3.1–5.5.3.3 of this appendix to determine the heat input from coal for each 24-hour period. (All ASTM methods are incorporated by reference under § 75.6 of this part.)

5.5.3.1 Perform coal sampling daily according to section 5.3.2.2 in Method 19 in Appendix A to part 60 of this chapter and use ASTM Method D2234–89, "Standard Test Methods for Collection of a Gross Sample of Coal," (incorporated by reference under § 75.6 of this part) Type I, Conditions A, B, or C and systematic spacing for sampling.

5.5.3.2 Use ASTM D2013–86, "Standard Method of Preparing Coal Samples for Analysis," for preparation of a daily coal sample and analyze each daily coal sample for gross calorific value using ASTM D2015–91, "Standard Test Method for Gross Calorific Value of Coal and Coke by the Adiabatic Bomb Calorimeter." (Both ASTM methods are incorporated by reference under § 75.6 of this part.)

On-line coal analysis may also be used if the on-line analytical instrument has been demonstrated to be equivalent to the applicable ASTM methods.

5.5.3.3 Calculate the heat input from coal using the following equation:

$$HI_c = M_c \frac{GCV_c}{500}$$

(Eq. F–21)

where,

Hl_c=Daily heat input from coal, mmBtu/day.

M_c=Mass of coal consumed per day, as measured and recorded in company records, tons.

GCV_c=Gross calorific value of coal sample, as measured by ASTM D3176–89, or D2015–91, Btu/lb.

500=Conversion of Btu/lb to mmBtu/ton.

6. Procedure for Converting Volumetric Flow to STP

Use the following equation to convert volumetric flow at actual temperature and pressure to standard temperature and pressure.

$$F_{STP}=F_{Actual}(T_{Std}/T_{Stack})(P_{Stack}/P_{Std})$$

(Eq. F–22)

where,

F_{STP}=Flue gas volumetric flow rate at standard temperature and pressure, scfh.

F_{Actual}=Flue gas volumetric flow rate at actual temperature and pressure, acfh.

T_{Std}=Standard temperature=68 degrees F.

T_{Stack}=Flue gas temperature at flow monitor location, degrees F.

P_{Stack}=The absolute flue gas pressure=barometric pressure at the flow monitor location + flue gas static pressure, inches of Hg.

P_{Std}=Standard pressure=29.92 inches of Hg.

Appendix G to Part 75—Determination of CO_2 Emissions

1. Applicability

The procedures in this appendix may be used to estimate CO_2 mass emissions discharged to the atmosphere (in tons/day) as the sum of CO_2 emissions from combustion and, if applicable, CO_2 emissions from sorbent used in a wet flue gas desulfurization control system, fluidized bed boiler, or other emission controls.

2. Procedures for Estimating CO_2 Emissions From Combustion

Use the following procedures to estimate daily CO_2 mass emissions from the combustion of fossil fuels. The optional procedure in section 2.3 of this appendix may also be used for an affected gas-fired unit. For an affected unit that combusts any nonfossil fuels (e.g., bark, wood, residue, or refuse), either use a CO_2 continuous emission monitoring system or apply to the Administrator for approval of a unit-specific method for determining CO_2 emissions.

2.1 Use the following equation to calculate daily CO_2 mass emissions (in tons/day) from the combustion of fossil fuels.

$$W_{CO_2}=\frac{(MW_c+MW_{O_2})\times W_c}{2{,}000\ MW_C}$$

(Eq. G–1)

Where,

W_{co2} = CO_2 emitted from combustion, tons/day.

MW_c = Molecular weight of carbon (12.0).

W_{o2} = Molecular weight of oxygen (32.0)

W_c = Carbon burned, lb/day, determined using average weekly fuel analysis by ASTM D3178–89 for coal; or determined by the percentage of carbon in oil from the ultimate analysis of oil, or computed based upon ASTM D3238–90 and either ASTM D2502–87 or ASTM D2503–82 (Reapproved 1987) for oil; or computed based on ASTM D1945–91 or ASTM D1946–90 for gas; and weekly fuel feed rates from company records for all fuels (these six methods are incorporated by reference under § 75.6 of this chapter).

2.2 For an affected coal-fired unit, the estimate of daily CO_2 mass emissions given by Equation G–1 may be adjusted to account for carbon retained in the ash using the procedures in either section 2.21–2.23 or Section 2.24 of the appendix.

2.2.1 Determine the ash content of the weekly sample of coal using ASTM D3174–89 "Standard Test Method for Ash in the Analysis Sample of Coal and Coke From Coal" (incorporated by reference under § 75.6 of this part).

2.2.2 Sample and analyze the carbon content of the fly-ash according to ASTM D3178–89, "Standard Test Methods for Carbon and Hydrogen in the Analysis Sample of Coal and Coke" (incorporated by reference under § 75.6 of this part).

2.2.3 Discount the estimate of daily CO_2 mass emissions from the combustion of coal given by Equation G–1 by the percent carbon retained in the ash using the following equation:

$$W_{NCO2}=W_{CO2}-\left(\frac{MW_{CO2}}{MW_c}\right)\left(\frac{A\%}{100}\right)\left(\frac{C\%}{100}\right)W_{COAL}$$

(Eq. G-2)

where,

W_{NCO2} = Net CO_2 mess emissions discharged to the atmosphere, tons/day.

W_{CO2} = Daily CO_2 mass emissions calculated by Equation G–1, tons/day.

MW_{CO2} = Molecular weight of carbon dioxide (44.0).

MW_c = Molecular weight of carbon (12.0).

A% = Ash content of the coal sample, percent by weight.

C% = Carbon content of ash, percent by weight.

W_{COAL} = Feed rate of coal from company records, tons/day.

2.2.4 The daily CO_2 mass emissions from combusting coal may be adjusted to account for carbon retained in the ash using the following equation:

$$W_{NCO2}=.99\ W_{CO2}$$

(Eq. G–3)

where,

W_{NCO2} = Net CO_2 mass emissions from the combustion of coal discharged to the atmosphere, tons/day.

.99 = Average fraction of coal converted into CO_2 upon combustion.

W_{CO2} = Daily CO_2 mass emissions from the combustion of coal calculated by Equation G–1 tons/day.

2.3 In lieu of using the procedures, methods, and equations in Section 2.1 of this appendix, the owner or operator of an affected gas-fired unit may use the following equation and records of daily gas-fired unit may use the following equation and records of daily heat input to estimate daily CO_2 mass emissions (in tons).

$$W_{CO_2}=\left(\frac{F_c\times H\times U_f\times MW_{CO_2}}{2000}\right)$$

(Eq.G–4)

where,

W_{CO2} emitted from combustion, tons/day.

F_c = Carbon-based F-factor, 1,040 scf/mmBtu for natural gas; 1,420 scf/mm/btu for crude, residual, or distillate oil.

H = Daily heat input in mmBtu, as reported in company records.

U_f = 1/385 scf CO_2/lb-mole at 14.7 psia and 68 °F.

3. Procedures for Estimating CO_2 Emissions From Sorbent

When the affected unit has a wet flue gas desulfurization system, is a fluidized bed boiler, or uses other emission controls with sorbent injection, use either a CO_2 continuous emission monitoring system (consisting of a CO_2 diluent gas monitor and a flow monitor) or use the procedures, methods, and equations in sections 3.1–3.2 of this appendix to determine daily CO_2 mass emissions from the sorbent (in tons).

3.1 When limestone is the sorbent material, use the equations and procedures in either section 3.1.1 or 3.1.2 of this appendix.

3.1.1 Use the following equation to estimate daily CO_2 mass emissions from sorbent (in tons).

$$SE_{CO_2}=W_{CaCO_3}\ F_s\ \frac{MW_{CO_2}}{MW_{CaCO_3}}$$

(Eq. G–5)

where,

SE_{CO2}=CO_2 emitted from sorbent, tons/day.

W_{CaCO3}=$CaCO_3$ used, tons/day.

F_s=1.00, the calcium to sulfur stoichiometric ratio.

MW_{CO2}=Molecular weight of carbon dioxide (44).

MW_{CaCO3}=Molecular weight of calcium carbonate (100).

3.1.2 In lieu of using Equation G–5, any owner or operator who operates and maintains a certified SO_2 continuous emission monitoring system (consisting of an SO_2 pollutant concentration monitor and an O_2 or CO_2 diluent gas monitor), for measuring and recording SO_2 emission rate (in lb/mmBtu) at the outlet to the emission controls and who uses the applicable procedures, methods, and equations in § 75.15 of this part to estimate the SO_2 emissions removal efficiency of the emission controls, may use the following equation to estimate daily CO_2 mass emissions from sorbent (in tons).

$$SE_{CO_2} = F_s \frac{W_{SO_2}}{2000} \frac{MW_{CO_2}}{MW_{SO_2}}$$

(Eq. G–6)

where,

SE=CO_2 emitted from sorbent, tons/day.

MW_{CO2}=Molecular weight of carbon dioxide (44).

MW_{SO2}=Molecular weight of sulfur dioxide (64).

W_{SO2}=Sulfur dioxide removed, lb/day, based on applicable procedures, methods, and equations in § 75.15 of this part.

F_s=1.0, the calcium to sulfur stoichiometric ratio.

3.2 When a sorbent material other than limestone is used, modify the equations, methods, and procedures in Section 3.1 of this appendix as follows to estimate daily CO_2 mass emissions from sorbent (in tons).

3.2.1 Determine a site-specific value for F_s, defined as the ratio of the number of moles of CO_2 released upon capture of one mole of SO_2, using methods and procedures satisfactory to the Administrator. Use this value of F_s (instead of 1.0) in either Equation G–5 or Equation G–6.

3.2.2 When using Equation G–5, replace MW_{CaCO3}, the molecular weight of calcium carbonate, with the molecular weight of the sorbent material that participates in the reaction to capture SO_2 and that releases CO_2, and replace W_{CaCO3}, the amount of calcium carbonate used (in tons/day), with the amount of sorbent material used (in tons/day).

4. Procedures for Estimating Total CO_2 Emissions

When the affected unit has a wet flue gas desulfurization system, is a fluidized bed boiler, or uses other emission controls with sorbent injection, use the following equation to obtain total daily CO_2 mass emissions (in tons) as the sum of combustion-related emissions and sorbent-related emissions.

$W_t = W_{CO2} + SE_{CO2}$

(Eq. G–7)

where,

W_t=Estimated total CO_2 mass emissions, tons/day.

W_{CO2}=CO_2 emitted from fuel combustion, tons/day.

SE_{CO2}=CO_2 emitted from sorbent, tons/day.

Appendix H to Part 75—Revised Traceability Protocol No. 1

This appendix consists of section 3.0.4 of the Quality Assurance Handbook for Air Pollution Measurement Systems, Vol. 3, U.S. Environmental Protection Agency (revised 6/9/87). The Quality Assurance Handbook may be obtained from the Methods Research and Development Division, MD 78–A, Atmospheric Research Exposure and Assessment Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711.

3.0.4. Procedure for NBS-Traceable Certification of Compressed Gas Working Standards Used for Calibration and Audit of Continuous Source Emission Monitors (Revised Traceability Protocol No. 1)

Contents

Subsection	Title
3.0.4.0	General Information
3.0.4.1	*Procedure G1:* Assay and Certification of a Compressed Gas Standard Without Dilution
3.0.4.2	References

4.0 General Information

4.0.1 Purpose and Scope of the Procedure

Section 3.0.4 describes a procedure for assaying the concentration of gaseous pollutant concentration standards and certifying that the assay concentrations are traceable to an authoritative reference concentration standard. This procedure is recommended for certifying the local working concentration standards required by the pollutant monitoring regulations of 40 CFR Part 60[1,2] for the calibration and audit of continuous source emission monitors. The procedure covers certification of compressed gas (cylinder) standards for CO, CO_2, NO, NO_2, and SO_2 (Procedure G1).

4.0.2 Reference Standards

Part 60 of the monitoring regulations [1,2] require that working standards used for calibration and audit of continuous source emission monitors be traceable to either a National Bureau of Standards (NBS) gaseous Standard Reference Material (SRM or a NBS/EPA-approved Certified reference material (CRM) [3]. Accordingly, the reference standard used for assaying and certifying a working standard for these purposes must be an SRM, a CRM, or a suitable intermediate standard (see the next paragraph). SRM cylinder gas standards available from NBS are listed in Table 7.2 at the end of subsection 4.0. A current list of CRM cylinder gases and CRM vendors is available from the Quality Assurance Division (MD–77), Environmental Monitoring Systems Laboratory, U.S. EPA, Research Triangle Park, NC 27711.

The EPA regulations define a "traceable" standard as one which"... has been compared and certified, either directly or via not more than one intermediate standard, to a primary standard such as a . . . NBS [gaseous] SRM or . . . CRM"[4,5]. Certification of a working standard directly to an SRM or CRM primary standard is, of course, preferred and recommended because of the lower error. However, an intermediate reference standard is permitted, if necessary. In particular, a *Gas Manufacturer's Intermediate Standard* (see subsection 4.0.2.1) that has been referenced directly to an SRM or a CRM according to Procedure G1 is an acceptable intermediate standard and could be used as the reference standard on that basis. However, purchasers of commercial gas standards referenced to an intermediate standard such as a GMIS should be aware that, according to the above definition, such a standard would have to be used directly for calibration or audit. Since a second intermediate standard is not permitted, such a standard could not be used as a reference standard to certify other standards.

4.0.2.1 *Gas Manufacturer's Intermediate Standard (GMIS).* A GMIS is a compressed (cylinder) gas standard that has been assayed with direct reference to an SRM or CRM and certified according to Procedure G1, and also meets the following requirements:

1. A candidate GMIS must be assayed a minimum of three (3) times, uniformly spaced over a three (3) month period.

2. Each of the three (or more) assays must be within 1.0 percent of the mean of the three (or more) assays.

3. The difference between the last assay and the first assay must not exceed 1.5 percent of the mean of the three (or more) assays.

4. The GMIS must be recertified every three months, and the reassay must be within 1.5 percent of the previous certified assay. The recertified concentration of the GMIS is the mean of the previous certified concentration and the reassay concentration.

4.0.2.2 *Recertification of Reference Standards.* Recertification requirements for SRMs and CRMs are specified by NBS and NBS/EPA, respectively. See 4.0.2.1 for GMIS recertification requirements.

4.0.3 Using the Procedure

The assay/certification procedure described here is carefully designed to minimize both systematic and random errors in the assay process. Therefore, the procedure should be carried out as closely as possible to the way it is described. Similarly, the assay apparatus has been specifically designed to minimize errors and should be configured as closely as possible to the design specified. Good laboratory practice should be observed in the selection of inert materials (e.g. Teflon, stainless steel, or glass, if possible) and clean, non-contaminating components for use in portions of the apparatus in contact with the candidate or reference gas concentrations.

4.0.4 Certification Documentation

Each assay/certification must be documented in a written certification report signed by the analyst and containing at least the following information:

1. Identification number (cylinder number).

2. Certified concentration of the standard, in ppm or mole percent.

3. Balance gas in the standard mixture.

4. Cylinder pressure at certification.

5. Date of the assay/certification.

6. Certification expiration date (see 4.0.6.3).

7. Identification of the reference standard used: SRM number, cylinder number, and concentration for an SRM; cylinder number and concentration for a CRM or GMIS.

8. Statement that the assay/certification was performed according to this section 3.0.4.

9. Identification of the laboratory where the standard was certified and the analyst who performed the certification.

10. Identification of the gas analyzer used for the certification, including the make, model, serial number, the measurement principle, and the date of the last multipoint calibration.

11. All analyzer readings used during the assay/certification and the calculations used to obtain the reported certified value.

12. Chronological record of all certifications for the standard.

Certification concentrations should be reported to 3 significant digits. Certification documentation should be maintained for at least 3 years.

4.0.5 Certification Label

A label or tag bearing the information described in items 1 through 9 of subsection 4.0.4 must be attached to each certified gas cylinder.

4.0.6 Assay/Certification of Compressed Gas (Cylinder) Standards

4.0.6.1 *Aging of newly-prepared gas standards.* Freshly prepared gas standard concentrations and newly filled gas cylinders must be aged before being assayed and certified. SO_2 concentrations contained in steel cylinders must be aged at least 15 days; other standards must be aged at least 4 days.

4.0.6.2 *Stability test for reactive gas standards.* Reactive gas standards, including nitric oxide (NO), nitrogen dioxide (NO_2), sulfur dioxide (SO_2), and carbon monoxide (CO), that have not been previously certified must be tested for stability as follows: Reassay the concentration at least 7 days after the first assay and compare the two assays. If the second assay differs from the first assay by 1.5% or less, the cylinder may be considered stable, and the mean of the two assays should be reported as the certified concentration. Otherwise, age the cylinder for a week or more and repeat the test, using the second and third assays as if they were the first and second assays. Cylinders that are not stable may not be sold and/or used for calibration or audit purposes.

4.0.6.3 *Recertification of compressed gas standards.* Compressed gas standards must be recertified according to this section 3.0.4 within the time limits specified in Table 7.1[3,6,7]. The reassay concentration must be within 5% of the previous certified concentration. If not, the cylinder must be retested for stability (subsection 4.0.6.2). The certified concentration of a recertified standard should be reported as the mean of all assays, unless a clear trend or substantial change suggests that previous assays are no longer valid.

TABLE 7.1.—RECERTIFICATION LIMITS FOR COMPRESSED GAS STANDARDS

Pollutant	Balance gas	Concentration range	Maximum months until recertification for cylinder material	
			Al or SS	Other
Carbon monoxide	N_2 or air	≥ 5 ppm	18	6
Nitric oxide	N_2	≥ 10 ppm	18	6
Sulfur dioxide	N_2	≥ 10 ppm	18	6
Nitrogen dioxide	N_2 or air	≥ 10 ppm	6	6
Carbon dioxide	N_2 or air	≥ 300 ppm	18	18
Oxygen	N_2	≥ 2 percent	18	18
Sulfur dioxide and carbon dioxide	N_2	≥ 200 ppm SO_2, 10 percent CO_2	18	6
Propane	N_2 or air	≥ 5 ppm	18	6
Others not specifically listed			6	6

4.0.6.4 *Minimum cylinder pressure.* No compressed gas cylinder standard should be used when its gas pressure is below 700 kPa (100 psi), as indicated by the cylinder pressure gauge.

4.0.6.5 *Assay/certification of multi-component compressed gas standards.* Procedure G1 may be used to assay and certify individual components of multi-component gas standards, provided that none of the components other than the component being assayed cause a detectable response on the analyzer.

4.0.7 Analyzer Calibration

4.0.7.1 *Basic analyzer calibration requirements.* The assay procedure described in this section 3.0.4 employs a direct ratio referencing technique that inherently corrects for minor analyzer calibration variations (drift) and DOES NOT depend on the absolute accuracy of the analyzer calibration. What is required of the analyzer is as follows: 1) it must have a *linear* response to the pollutant of interest (see subsection 4.0.7.5), 2) it must have good resolution and low noise, 3) its response calibration must be reasonably stable during the assay/certification process, and 4) all assay concentration measurements must fall within the calibrated response range of the analyzer.

4.0.7.2 *Analyzer multipoint calibration.* The gas analyzer used for the assay/certification must have had a multipoint calibration within 3 months of its use when used with this procedure. This calibration is *not* used to quantitatively interpret analyzer readings during the assay/certification of the candidate gas because a more accurate, direct ratio comparison of the candidate concentration to the reference standard concentration is used. However, this multipoint calibration is necessary to establish the calibrated range of the analyzer and its response linearity.

The multipoint calibration should consist of analyzer responses to at least 5 concentrations, including zero, approximately evenly spaced over the concentration range. Analyzer response units may be volts, millivolts, percent of scale, or other measurable analyzer response units. The upper range limit of the calibrated range is determined by the highest calibration point used. If the analyzer has a choice of concentration ranges, the optimum range for the procedure should be selected and calibrated. Plot the calibration points and compute the linear regression slope and intercept. See subsection 4.0.7.5 for linearity requirements and the use of a mathematical transformation, if needed. The intercept should be less than 1 percent of the upper concentration range limit, and the correlation coefficient (r) should be at least 0.999.

4.0.7.3 *Zero and span check and adjustment.* On each day that the analyzer will be used for assay/certification, its response calibration must be checked with a zero and at least one span concentration near the upper concentration range limit. If necessary, the zero and span controls of the analyzer should be adjusted so that the analyzer's response (i.e. calibration slope) is within about ±5 percent of the response indicated by the most recent multipoint calibration. If a zero or span adjustment is made, allow the analyzer to stabilize for at least an hour or more before beginning the assay procedure, since some analyzers drift for a period of time following zero or span adjustment. If the analyzer is not in continuous operation, turn it on and allow it to stabilize for at least 12 hours before the zero and span check.

4.0.7.4 *Pollutant standard for multipoint calibration and zero and span adjustment.* The pollutant standard or standards used for multipoint calibration or zero and span checks or adjustments must be obtained from a compressed gas standard certified traceable to an NBS SRM or a NBS/EPA CRM according to Procedure G1 of this section 3.0.4. This standard need not be the same as the reference standard used in the assay/certification. The zero gas must meet the requirements in subsection 4.0.8.

4.0.7.5 *Linearity of analyzer response.* The direct ratio assay technique used in Procedure G1 requires that the analyzer have a linear response to concentration. Linearity is determined by comparing the quantitative difference between a smoothly-drawn calibration curve based on all calibration points and a straight line drawn between zero and an upper reference point (see Figure 1). This difference is measured in concentration units, parallel to the concentration axis, from a point on the calibration curve to the corresponding point for the same response on the straight line.

For the general linearity requirement, the straight line is drawn between zero and the highest calibration point (Figure 1a). Linearity is then acceptable when no point on the smooth calibration curve deviates from the straight line by more than 1.5

percent of the value of the highest calibration concentration. An alternative linearity requirement is defined on the basis of the actual reference and candidate concentrations to be used for the assay. In this case, the reference and candidate concentrations are plotted on the calibration curve, and the straight line is drawn from zero to the reference concentration and extrapolated, if necessary, beyond the candidate concentration (Figure 1b). The deviation of the smooth calibration curve from the straight line at the candidate concentration point then must not exceed 0.8 percent of the value of the reference concentration. This latter specification may allow the use of an analyzer having greater nonlinearity when the reference and candidate concentrations are nearly the same.

For analyzers having an inherently non-linear response, the response can usually be linearized with a simple mathematical transformation of the response values, such as R′=square root(R) or R′=log(R), where R′ is the transformed response value and R is the actual analyzer response value. Using the transformed response values, the multipoint calibration should meet one of the above linearity requirements as well as the requirements for intercept and correlation coefficient given in subsection 4.0.7.2.

4.0.8 Zero Gas

Zero gas used for dilution of any candidate or reference standard should be clean, dry, zero-grade air or nitrogen containing a concentration of the pollutant of interest equivalent to less than 0.5 percent of the analyzer's upper range limit concentration. The zero gas also should contain no contaminant that causes a detectable response on the analyzer or that suppresses or enhances the analyzer's response to the pollutant. The oxygen content of zero air should be the same as that of ambient air.

4.0.9 Accuracy Assessment of Commercially Available Standards

Periodically, the USEPA will assess the accuracy of commercially available compressed gas standards that have been assayed and certified according to this section 3.0.4. Accuracy will be assessed by EPA audit analysis of representative actual commercial standards obtained via an anonymous agent. The accuracy audit results, identifying the actual gas manufacturers or vendors, will be published as public information.

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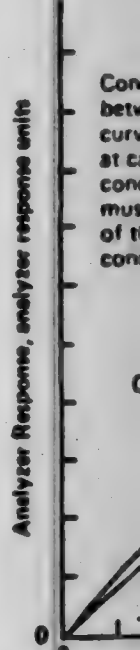

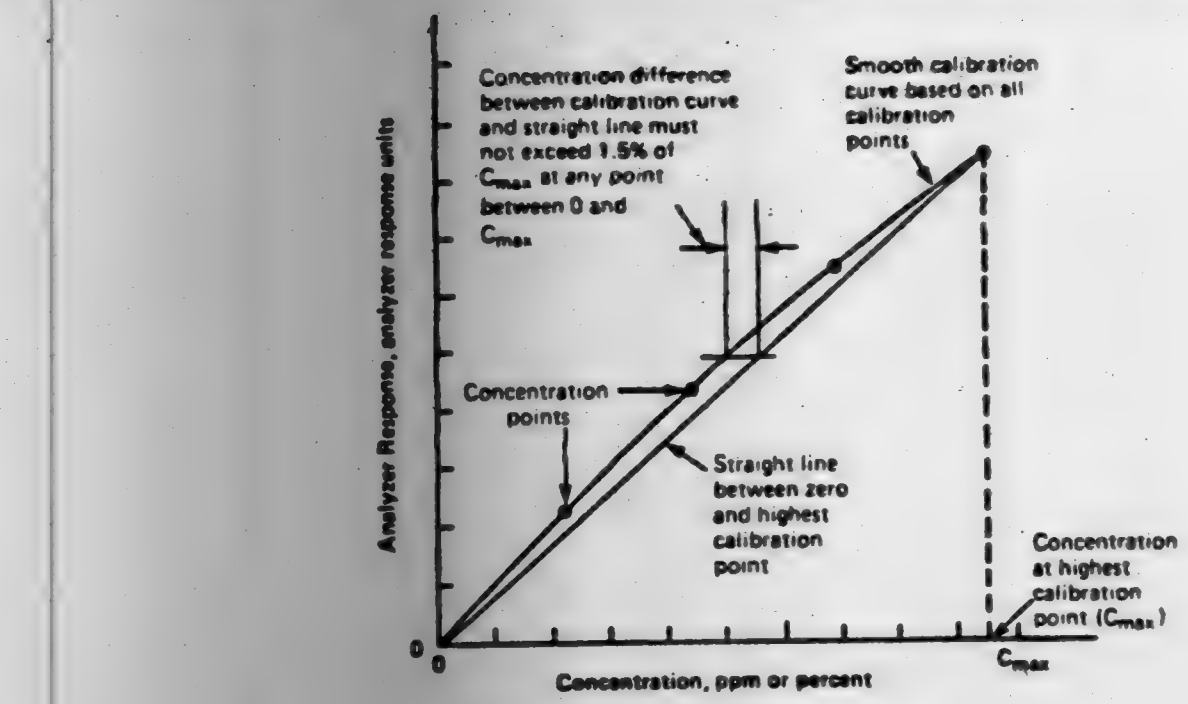

a) General linearity requirement

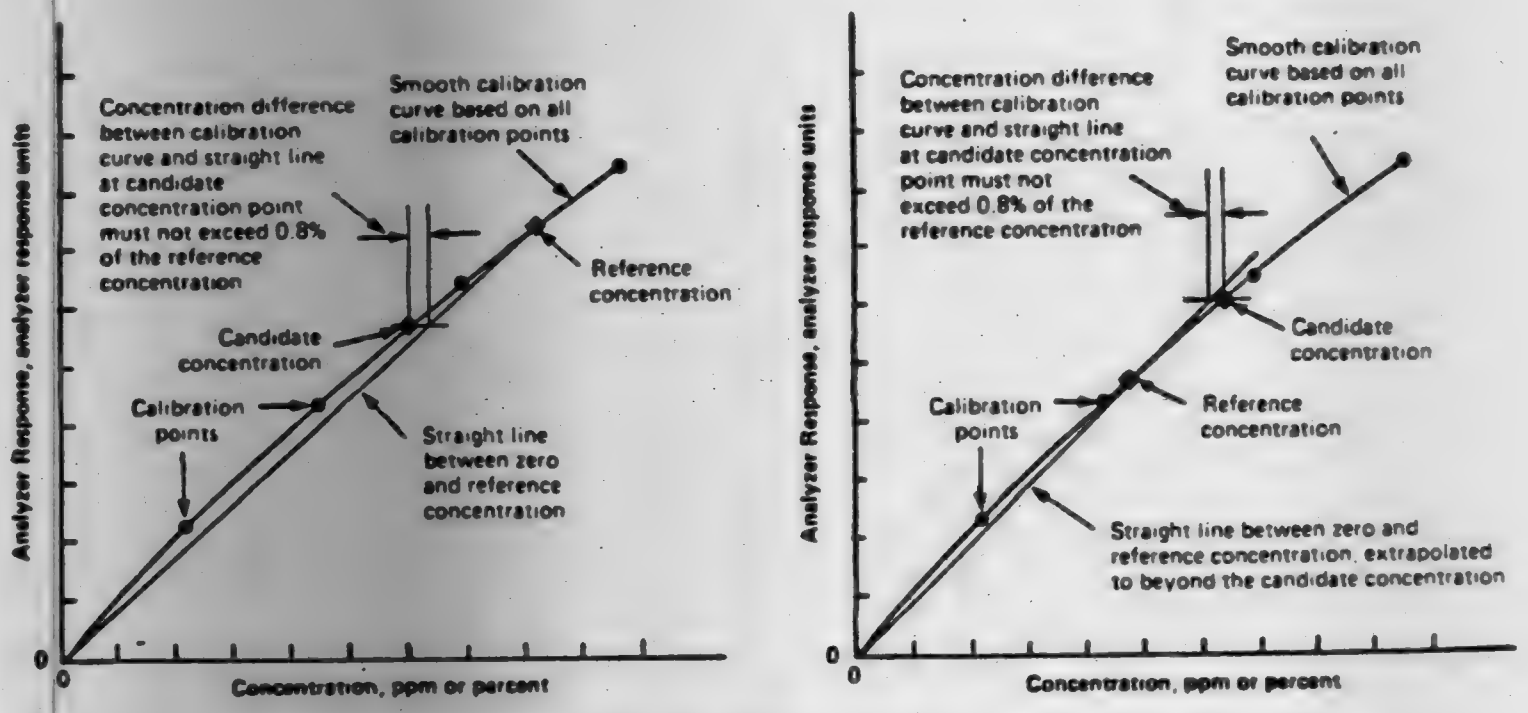

b) Alternative linearity requirement

Figure 1. Illustration of linearity requirements.

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TABLE 7.2.—NBS SRM REFERENCE GASES

SRM No.	Type	Nominal concentration
2627	NO/N_2	5 ppm.
2628	NO/N_2	10 ppm.
2629	NO/N_2	20 ppm.
1683b	NO/N_2	50 ppm.
1684b	NO/N_2	100 ppm.
1685b	NO/N_2	250 ppm.
1686b	NO/N_2	500 ppm.
1687b	NO/N_2	1000 ppm.
2630	NO/N_2	1500 ppm.
2631	NO/N_2	3000 ppm.
2653	$NO/_2Air$	250 ppm.
2654	$NO/_2Air$	500 ppm.
2655	$NO/_2Air$	1000 ppm.
2656	$NO/_2Air$	2500 ppm.
2612a	CO/Air	10 ppm.
2613a	CO/Air	20 ppm.
2614a	CO/Air	45 ppm.
1677c	CO/N_2	10 ppm.
2635	CO/N_2	25 ppm.
1678c	CO/N_2	50 ppm.
1679c	CO/N_2	100 ppm.
2636	CO/N_2	250 ppm.
1680c	CO/N_2	500 ppm.
1681c	CO/N_2	1000 ppm.
2637	CO/N_2	2500 ppm.
2638	CO/N_2	5000 ppm.
2639	CO/N_2	1 percent.
2640	CO/N_2	2 percent.
2641	CO/N_2	4 percent.
2642	CO/N_2	8 percent.
2657	O_2/N_2	2 percent.
2658	O_2/N_2	10 percent.
2659	O_2/N_2	21 percent.
1693	SO_2/N_2	50 ppm.
1694	SO_2/N_2	100 ppm.
1661a	SO_2/N_2	500 ppm.
1662a	SO_2/N_2	1000 ppm.
1663a	SO_2/N_2	1500 ppm.
1664a	SO_2/N_2	2500 ppm.
1696	SO_2/N_2	3500 ppm.
1670	CO_2/Air	330 ppm.
1671	CO_2/Air	340 ppm.
1672	CO_2/Air	350 ppm.
2632	CO_2/N_2	300 ppm.
2633	CO_2/N_2	400 ppm.
2634	CO_2/N_2	800 ppm.
2619a	CO_2/N_2	0.5 percent.
2720a	CO_2/N_2	1.0 percent.

TABLE 7.2.—NBS SRM REFERENCE GASES—Continued

SRM No.	Type	Nominal concentration
2621a	CO_2/N_2	1.5 percent.
2622a	CO_2/N_2	2.0 percent.
2623a	CO_2/N_2	2.5 percent.
2624a	CO_2/N_2	3.0 percent.
2625a	CO_2/N_2	3.5 percent.
2626a	CO_2/N_2	4.0 percent.
1674b	CO_2/N_2	7.0 percent.
1675b	CO_2/N_2	14.0 percent.
1665b	C_3H_8/Air	3 ppm.
1666b	C_3H_8/Air	10 ppm.
1667b	C_3H_8/Air	50 ppm.
1668b	C_3H_8/Air	100 ppm.
1669b	C_3H_8/Air	500 ppm.
2643	C_3H_8/N_2	100 ppm.
2644	C_3H_8/N_2	250 ppm.
2645	C_3H_8/N_2	500 ppm.
2646	C_3H_8/N_2	1000 ppm.
2647	C_3H_8/N_2	2500 ppm.
2648	C_3H_8/N_2	5000 ppm.
2649	C_3H_8/N_2	1 percent.
2650	C_3H_8/N_2	2 percent.

NBS–SRM cylinders contain approximately 670 liters of gas at STP.

For availability, contact: Office of Standard Reference Materials, Chemistry Building, Room B311, NBS, Gaithersburg, Maryland 20899, (301) 975–6776. (FTS 879–6776).

4.1 *Procedure G1:* Assay and Certification of a Compressed Gas Standard Without Dilution

4.1.1 Applicability

This procedure may be used to assay the concentration of a candidate compressed gas (cylinder) pollutant standard, based on the concentration of a compressed gas (cylinder) reference standard of the same pollutant compound, and certify that the assayed concentration thus established for the candidate standard is traceable to the reference standard. The procedure employs a pollutant gas analyzer to compare the candidate and reference gas concentrations by direct measurement—without dilution of either gas—to minimize assay error.

4.1.2 Limitations

1. The concentration of the candidate gas standard must be between 0.3. and 1.3 times the concentration of the reference gas standard.

2. The analyzer must have a calibrated range capable of directly measuring both the candidate and the reference gas concentrations.

3. The analyzer's response (or transformed response) must be linear with respect to concentration.

4. The balance gas in both the candidate and reference standards must be identical, unless it can be shown that the analyzer is insensitive to any difference in the balance gases.

5. A source of clean, dry zero gas is required.

4.1.3 Assay Apparatus

Figure G1 illustrates the relatively simple assay apparatus. The configuration is designed to allow convenient routing of the zero gas and undiluted samples of the reference gas and candidate gases, in turn, to the analyzer for measurement, as selected by three-way valves V1 and V2. Pressure regulators and needle valves (V3 and V4) control the individual gas flows. The pollutant concentrations are delivered to the analyzer via a vented tee, which discharges excess flow and insures that the assay concentrations sampled by the analyzer are always at a fixed (atmospheric) pressure. A small, uncalibrated rotameter monitors the vent flow to verify that the total gas flow rate exceeds the sample flow rate demand of the analyzer so that no room air is admitted through the vent. Valves V1 and V2 could be replaced by a single four-way valve (with 3 inputs and 1 output) or by manually moving the output connection to each of the gases as needed. See also subsection 4.0.3.

BILLING CODE 6560-50-M

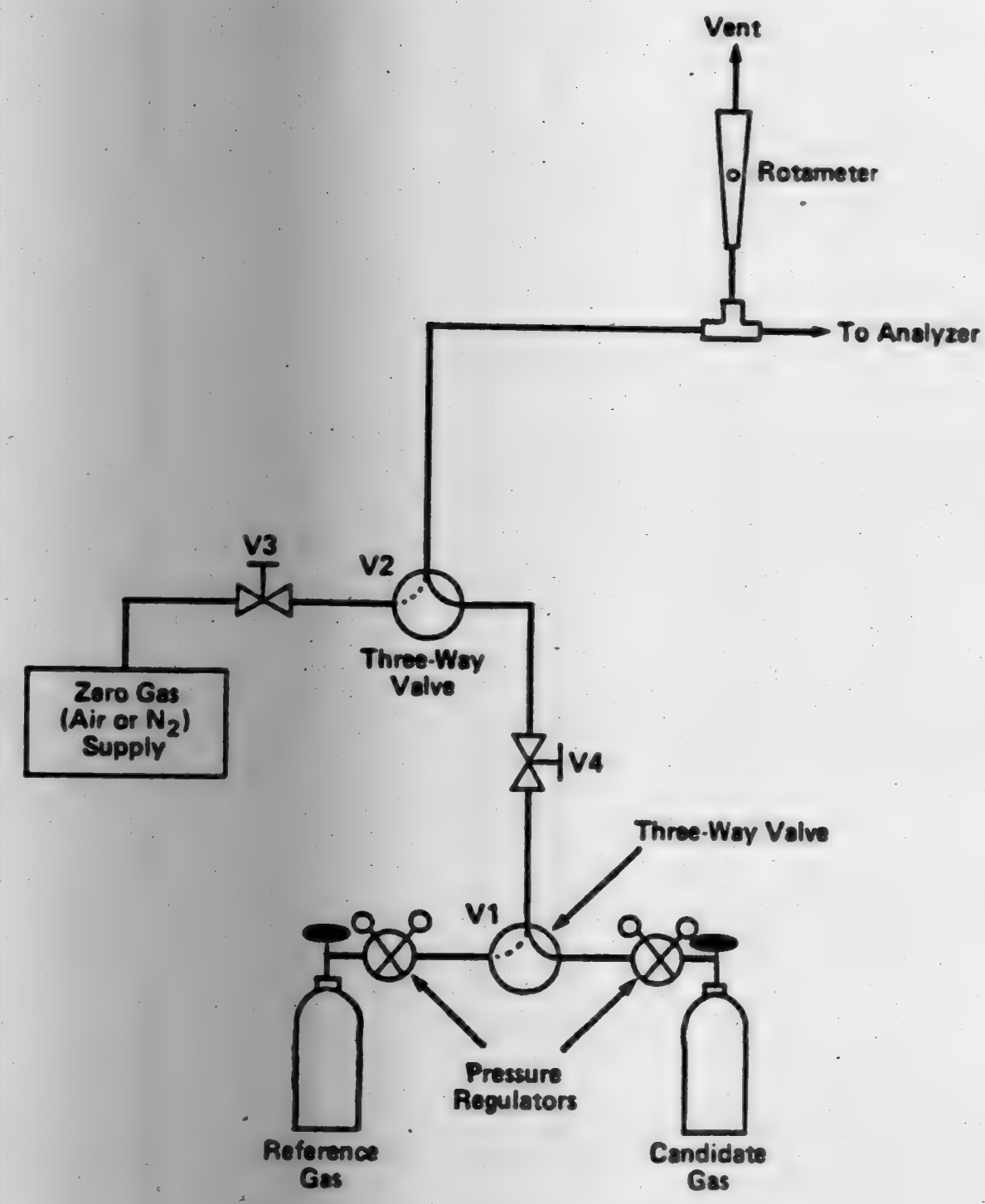

Figure G1. Suggested assay apparatus for Procedure G1.

BILLING CODE 6560-50-C

4.1.4 Analyzer

See subsection 4.0.7.1. The pollutant gas analyzer must have a linear response function and a calibrated range capable of measuring the full concentration of both the candidate and the reference gas standards directly, without dilution. It must have good resolution (readability), good precision, a stable response, and low output signal noise. In addition, the analyzer must have good specificity for the pollutant of interest so that it has no detectable response to any contaminant that may be contained in either the candidate or reference gas. If the candidate and reference gases contain dissimilar balance gases (air versus nitrogen or different proportions of oxygen in the balance air, for example), the analyzer must be proven to be insensitive to the different balance gases. This may be accomplished by showing no difference in analyzer response when measuring pollutant concentrations diluted with identical flow rates of the two balance gases.

The analyzer should be connected to a suitable, precision chart recorder or other data acquisition device to facilitate graphical observation and documentation of the analyzer responses obtained during the assay.

4.1.5 Analyzer Calibration

4.1.5.1 *Multipoint calibration.* See subsections 4.0.7.2 and 4.0.7.4.

4.1.5.2 *Calibration range.* The calibrated range of the analyzer must include both the candidate and reference gas concentrations, such that the higher concentration does not exceed 97 percent of the upper range limit, and the lower concentration is not below 25 percent of the upper range limit (assuming a lower range limit of zero). Within these limits, select a calibrated analyzer range that will produce the highest analyzer responses.

4.1.5.3 *Linearity.* The direct ratio assay technique used in this procedure requires that the analyzer have a linear response to concentration (see subsection 4.0.7.5). High-concentration-range analyzers of the type that are required for this procedure may not be inherently linear, but they usually have a predictable, non-linear response characteristic that can be mathematically transformed to produce a sufficiently linear response characteristic suitable for use in this procedure. Any such response transformation should be verified by using it for the multipoint calibration. Caution should be exercised in using a transformed response curve because physical zero or span adjustments to the analyzer may produce unexpected effects on the transformed characteristic.

4.1.5.4 *Zero and span adjustment.* See subsections 4.0.7.3 and 4.0.7.4. Prior to carrying out the assay/certification procedure, check the calibration of the analyzer and, if necessary, adjust the analyzer's zero and span controls to reestablish the response characteristic determined at the most recent multipoint calibration. Allow the analyzer to stabilize for an hour or more after any zero or span adjustment. If there is any doubt that a transformed response characteristic is still linear following a zero or span adjustment, verify linearity with a multipoint calibration (subsection 4.0.7.2) using at least 3 known pollutant concentrations, including zero.

4.1.6 Assay Gases

4.1.6.1 *Candidate gas standard.* See subsections 4.0.6 and 4.1.2.

4.1.6.2 *Reference gas standard.* See subsections 4.0.2, 4.1.2, and 4.0.6.4. Select a reference standard such that the concentration of the candidate gas is not more than 30 percent above nor less than 70 percent below the concentration of the standard.

4.1.6.3 *Zero gas.* See subsection 4.0.6. The zero gas should match the balance gas used in the cylinder concentrations.

4.1.7 Assay Procedure

1. Verify that the assay apparatus is properly configured, as described in subsection 4.1.3 and shown in Figure G1.

2. Verify that the linearity of the analyzer has been checked within the last 3 months (see subsections 4.0.7.2, 4.0.7.5, and 4.1.4), that the zero and span are adjusted correctly (subsection 4.0.7.3), that the candidate and reference gas concentrations are within 25 and 97 percent of the upper range limit of the calibrated measurement range of the analyzer, and that the analyzer is operating stably.

3. Adjust the flow rates of the three gases (reference, candidate, and zero) to approximately the same value that will provide enough flow for the analyzer and sufficient excess to assure that no ambient air will be drawn into the vent.

4. Conduct a triad of measurements with the analyzer. Each triad consists of a measurement of the zero gas concentration, a measurement of the reference gas concentration, and a measurement of the candidate gas concentration. Use valves V1 and V2 to select each of the three concentrations for measurement. For each measurement, allow ample time for the analyzer to achieve a stable response reading. Record the stable analyzer response for each measurement, using the same response units (volt, millivolts, percent of scale, etc.) used for the multipoint calibration and any transformation of the response readings necessary for linearity. Do not translate the response readings to concentration values via the calibration curve (see the footnote following Equation G1). Do not make any zero, span, or other physical adjustments to the analyzer during the triad of measurements.

5. Conduct at least 2 additional measurement triads, similar to step 4 above. However, for these subsequent triads, change the order of the three measurements (e.g. measure reference gas, zero gas, candidate gas for the second triad and zero gas, candidate gas, reference gas for the third triad, etc.).

6. If any one or more of the measurements of a triad is invalid or abnormal for any reason, discard all three measurements of the triad and repeat the triad.

7. For each triad of measurements, calculate the assay concentration of the candidate gas as follows:

$$C_c = C_r \frac{R_c - R_z}{R_r - R_z}$$

Equation G1

where:

C_c=Assay concentration of the candidate gas standard, ppm or percent;

C_r=Concentration of the reference gas standard, ppm or percent;

R_c=Stable response reading of the analyzer for the candidate gas, analyzer response units;*

R_z=Stable response reading of the analyzer for the zero gas, analyzer response units;*

R_r=Stable response reading of the analyzer for the reference gas, analyzer response units.*

*Analyzer response units are the units used to express the *direct* response readings of the analyzer, such as volts, millivolts, percent of scale, etc. DO NOT convert these direct response readings to concentration units with the multipoint calibration curve or otherwise adjust these readings except for transformation necessary to achieve response linearity.

8. Calculate the mean of the 3 (or more) valid assays. Calculate the percent difference of each assay from the mean. If any one of the assay values differs from the mean by more than 1.5%, discard that assay value and conduct another triad of measurements to obtain another assay value. When at least 3 assay values all agree within 1.5% of their mean, report the mean value as the certified concentration of the candidate gas standard. For newly-prepared reactive standards, a reassay at least 7 days later is required to check the stability of the standard; see subsection 4.0.6.2.

4.1.8 Stability Test for Newly-Prepared Standards

See subsections 4.0.6.1 and 4.0.6.2.

4.1.9 Certification Documentation

See subsections 4.0.4 and 4.0.5.

4.1.10 Recertification Requirements

See subsections 4.0.6.3 and 4.0.6.4.

4.2 References

1. *Code of Federal Regulations*, Title 40, part 60, "Standards of Performance for New Stationary Sources," Appendix A, Method 20 (1982).

2. Standards of Performance for New Stationary Sources; Quality Assurance Requirements for Gaseous Continuous Emission Monitoring Systems Used for Compliance Determination, promulgated in the **Federal Register**, June 4, 1987, pp. 21003–21010.

3. "A Procedure for Establishing Traceability of Gas Mixtures to Certain National Bureau of Standards Standard Reference Materials. EPA–600/7–81–010. Joint publication by NBS and EPA, May 1981. Available from the U.S. Environmental Protection Agency, Environmental Monitoring Systems Laboratory (MD–77), Research Triangle Park, NC 27711.

4. *Code of Federal Regulation*, Title 40, part 50, "National Ambient Air Quality Measurement Methodology".

5. *Code of Federal Regulations*, Title 40, part 58, "Ambient Air Quality Surveillance," Appendixes A and B.

6. Shores, R.C. and F. Smith, "Stability Evaluation of Sulfur Dioxide, Nitric Oxide, and Carbon Monoxide Gases in Cylinders. NTIS No. PB 85–122646. Available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

7. Method 6A and 6B, "Determination of Sulfur Dioxide, Moisture, and Carbon Dioxide Emissions from Fossil Fuel Combustion Sources," *Quality Assurance Handbook for Air Pollution Measurement Systems*, Volume III, Section 3.13.8, July 1986. Available from the U.S. Environmental Protection Agency, Center for Environmental Research Information, Cincinnati, OH 45268.

8. "List of Designated Reference and Equivalent Methods." Current edition available from the U.S. Environmental Protection Agency, Environmental Monitoring Systems Laboratory, Quality Assurance Division (MD–77), Research Triangle Park, NC 27711.

Appendix I of Part 75

[This appendix is reserved.]

7. Title 40 is amended by adding part 77 to read as follows:

PART 77—EXCESS EMISSIONS

Sec.

77.1 Purpose and scope.
77.2 General.
77.3 Offset plans for excess emissions of sulfur dioxide.
77.4 Administrator's action on proposed offset plans.
77.5 Deduction of allowances to offset excess emissions of sulfur dioxide.
77.6 Penalties for excess emissions of sulfur dioxide and nitrogen oxides.

Authority: 42 U.S.C. 7651j.

PART 77—EXCESS EMISSIONS

§ 77.1 Purpose and scope.

(a) This part sets forth the excess emissions offset planning and offset penalty requirements under section 411 of the Clean Air Act, 42 U.S.C. 7401, et seq., as amended by Public Law 101–549 (November 15, 1990). These requirements shall apply to the owners and operators and, to the extent applicable, the designated representative of each affected unit and affected source under the Acid Rain Program.

(b) Nothing in this part shall limit or otherwise affect the application of sections 112(r)(9), 113, 114, 120, 303, 304, or 306 of the Act, as amended. Any allowance deduction, excess emission penalty, or interest required under this part shall not affect the liability of the affected unit's and affected source's owners and operators for any additional fine, penalty, or assessment, or their obligation to comply with any other remedy, for the same violation, as ordered under the Act.

§ 77.2 General.

Part 72 of this chapter, including §§ 72.2 (definitions), 72.3 (measurements, abbreviations, and acronyms), 72.4 (federal authority), 72.5 (State authority), 72.6 (applicability), 72.7 (new units exemption), 72.8 (retired units exemption), 72.9 (standard requirements), 72.10 (availability of information), and 72.11 (computation of time), shall apply to this part. The procedures for appeals of decisions of the Administrator under this part are contained in part 78 of this chapter.

§ 77.3 Offset plans for excess emissions of sulfur dioxide.

(a) *Applicability.* The owners and operators of any affected unit that has excess emissions of sulfur dioxide in any calendar year shall be liable to offset the amount of such excess emissions by an equal amount of allowances from the unit's Allowance Tracking System account.

(b) *Deadline.* Not later than 60 days after the end of any calendar year during which an affected unit had excess emissions of sulfur dioxide (except for any increase in excess emissions under § 72.91(b) of this chapter), the designated representative for the unit shall submit to the Administrator a complete proposed offset plan to offset those emissions. Each day after the 60-day deadline that the designated representative fails to submit a complete proposed offset plan shall be a separate violation of this part.

(c) *Number of Plans.* The designated representative shall submit a proposed offset plan for each affected unit with excess emissions of sulfur dioxide.

(d) *Contents of Plan.* A complete proposed offset plan shall include the following elements in a format prescribed by the Administrator for the unit and for the calendar year for which the plan is submitted:

(1) Identification of the unit.

(2) If the unit had excess emissions for the calendar year prior to the year for which the plan is submitted, an explanation of how and why the excess emissions occurred for the year for which the plan is submitted and a description of any measures that were or will be taken to prevent excess emissions in the future.

(3) The amount of excess emissions of sulfur dioxide (in tons/year) for the year for which the plan is submitted and the number of allowances required to be deducted from the unit's Allowance Tracking System account to offset the excess emissions.

(4) At the designated representative's option, the serial numbers of the allowances that are to be deducted from the unit's Allowance Tracking System account.

(5) Whether the allowances are to be deducted immediately from the unit's account or, if not, the date on which they are to be deducted.

(6) If the proposed offset plan does not propose a deduction of the amount of allowances under paragraph (d)(3) of this section from the compliance subaccount during the year after the year for which the plan is submitted, a demonstration that such a deduction will interfere with electric reliability.

§ 77.4 Administrator's action on proposed offset plans.

(a) *Determination of Completeness.* The Administrator will determine whether the proposed offset plan is complete within 30 days of receipt by the Administrator. The offset plan shall be deemed complete if the Administrator fails to notify the designated representative to the contrary within 30 days of receipt or when the Administrator approves the offset plan and deducts allowances in accordance with paragraph (b)(1) of this section.

(b) *Review of proposed offset plans.* (1) If the designated representative submits a complete proposed offset plan for immediate deduction, from the unit's compliance subaccount, of all allowances required to offset excess emissions of sulfur dioxide, the Administrator will approve the proposed offset plan without further review and will serve written notice of any approval on the designated representative and on any persons entitled to written notice under paragraphs (g)(2)(i) (B), (C) and (D) of this section. The Administrator will also give notice of any approval in the **Federal Register**. The plan will be incorporated into the unit's Acid Rain permit in accordance with § 72.84 (automatic permit amendment) and will not be subject to the requirements of paragraphs (d) through (k) of this section.

(2) Notwithstanding paragraph (b)(1) of this section, the Administrator may, in his or her discretion, require that the proposed offset plan under paragraph (b)(1) of this section be reviewed under paragraphs (c) through (k) of this section. The Administrator may exercise such discretion where he or she determines that review of the plan is necessary to ensure compliance with the

emissions limitation and reduction goals or other purposes of title IV of the Act.

(3) If the designated representative submits a complete proposed offset plan that does not meet the requirements of paragraph (b)(1) of this section, the Administrator will review the plan under paragraphs (c) through (k) of this section.

(c) *Supplemental Information.* (1)(i) Regardless of whether the proposed offset plan is complete under paragraph (a) of this section, the Administrator may require submission of any additional information that the Administrator determines is necessary to approve an offset plan.

(ii) Such supplemental information may include, but is not limited to:

(A) A description of the measures that are proposed to be taken to ensure that the unit will have sufficient allowances to offset the excess emissions and to prevent excess emissions in future years;

(B) A schedule of compliance with appropriate increments of progress for the proposed measures; and

(C) A schedule for the submission of progress reports, and supporting documentation, describing actions taken and actions remaining to be taken under the schedule of compliance and any proposed adjustments to the schedule of compliance.

(2)(i) The designated representative shall submit the information required under paragraph (c)(1) of this section within 30 days after he or she is notified of the requirement for supplemental information unless the Administrator allows for additional time to collect and submit the information.

(ii) If the designated representative fails to submit the supplemental information within the required time period, the Administrator may disapprove the proposed offset plan.

(d) *Draft Offset Plan.* (1) After the Administrator receives a complete proposed offset plan and any supplemental information, the Administrator will prepare a draft offset plan that incorporates in whole, in part, or with changes or conditions as appropriate, the proposed offset plan or disapprove a draft offset plan for the affected unit. Regardless of whether the Administrator required the submission of the information set forth in paragraph (c)(1)(ii) of this section, the draft offset plan may include, among other requirements and conditions as determined to be appropriate by the Administrator, the submission of schedules of compliance, progress reports, and monitoring and other information.

(2) The draft offset plan will be based on the information submitted by the designated representative for the affected unit and other relevant information.

(3) The Administrator will serve a copy of the draft offset plan and the statement of basis on the designated representative of the affected unit.

(4) The Administrator will provide a 30-day period for public comment, and opportunity to request a public hearing, on the draft offset plan or disapproval of a draft offset plan in accordance with the public notice required under paragraph (g)(1)(i)(A) of this section.

(e) *Offset Plan Administrative Record.* (1) The Administrator will prepare an administrative record for an offset plan or disapproval of an offset plan. The administrative record will contain:

(i) The proposed offset plan and any supporting or supplemental information submitted by the designated representative;

(ii) The draft offset plan;

(iii) The statement of basis;

(iv) Copies of all documents relied on by the Administrator in approving or disapproving the draft offset plan (including any records of discussions or conferences with owners, operators or the designated representative of the unit or interested persons regarding the draft offset plan) or, for any such documents that are readily available, a statement of their location;

(v) Copies of all written public comments submitted on the draft offset plan or disapproval of a draft offset plan;

(vi) The record of any public hearing on the draft offset plan or disapproval of a draft offset plan;

(vii) The offset plan approved by the Administrator; and

(viii) Any response to public comments submitted on the draft offset plan or disapproval of a draft offset plan, including any documents cited in the response and any other documents relied on by the Administrator or, for any such documents that are readily available, a statement of their location.

(2) The Administrator will approve or disapprove an offset plan within 6 months of receipt of a complete proposed offset plan.

(f) *Statement of Basis.* (1) The statement of basis will briefly set forth significant factual, legal, and policy considerations on which the Administrator relied in approving or disapproving the draft offset plan.

(2) The statement of basis will include:

(i) The reasons, and supporting authority, for approval or disapproval of any proposed offset plan that does not require deduction of allowances during the year after the year for which the plan is submitted, including references to applicable statutory or regulatory provisions and to the administrative record; and

(ii) The name, address, and telephone and facsimile number of the EPA office processing the approval or disapproval of the offset plan.

(g) *Opportunities for Public Comment on Draft Offset Plans.*

(1) *Generally.* (i) The Administrator will give public notice of the following:

(A) The draft offset plan or disapproval of a draft offset plan and the opportunity for public comment and to request a public hearing; and

(B) Date, time, location, and procedures for any scheduled hearing on the draft offset plan or the disapproval of a draft offset plan.

(ii) Any public notice given under this section may be for the approval or disapproval of one or more draft offset plans.

(2) *Methods.* The Administrator will give the public notice required by this section by:

(i) Serving written notice on the following persons (except to the extent any such person has waived his or her right to receive such notice):

(A) The designated representative;

(B) The State or local air pollution agency and any utility regulatory authority with jurisdiction over the owners of the unit covered by the proposed offset plan;

(C) The State or local air pollution agency for any contiguous State whose air quality may be affected by, or for any State located within a 50-mile radius of, the unit covered by the proposed offset plan; and

(D) Any interested person.

(ii) Giving notice by publication in the **Federal Register** and in a newspaper of general circulation in the area where the unit is located or in a State publication designed to give general public notice.

(3) *Contents.* All public notices issued under this part will contain the following information:

(i) Identification of the EPA office processing the approval or disapproval of the draft offset plan for which the notice is being given.

(ii) Identification of the designated representative for the affected unit.

(iii) Identification of each affected unit covered by the proposed offset plan.

(iv) The amount of excess emissions that must be offset and the date on which the allowances are proposed to be deducted.

(v) The address and office hours of a public location where the

administrative record is available for public inspection and a statement that all information submitted by the designated representative and not protected as confidential pursuant to section 114(c) of the Act is available for public inspections as part of the administrative record.

(vi) For public notice under paragraph (g)(1)(i)(A) of this section, a brief description of the public comment procedures, including:

(A) A 30-day public comment period beginning the date of publication of the notice or, in the case of an extension or reopening of the public comment period, such period as the Administrator deems appropriate;

(B) The address where public comments should be sent;

(C) Required formats and contents for public comment;

(D) An opportunity to request a public hearing to occur not earlier than 15 days after public notice is given and the location, date, time, and procedures of any scheduled public hearing; and

(E) Any other means by which the public may participate.

(4) *Extensions and Reopenings of the Public Comment Period.* On the Administrator's own motion, or on the request for any person, the Administrator may, at his or her discretion, extend or reopen the public comment period where he or she finds that doing so will contribute to the decision-making process by clarifying one or more significant issues affecting the draft offset plan or disapproval of a draft offset plan. Notice of any such extension or reopening will be given under paragraph (g)(1)(i)(A) of this section.

(h) *Public comments.* (1) General. During the public comment period, any person may submit written comments on the draft offset plan or disapproval of a draft offset plan.

(2) Form. (i) Comments shall be submitted in duplicate.

(ii) The submission shall clearly indicate the draft offset plan approval or disapproval to which the comments apply.

(iii) The submission shall clearly indicate the name of the commenter, his or her interest, and his or her affiliation, if any, to owners and operators of any unit covered by the proposed offset plan.

(3) Contents. Timely comments on any aspect of a draft offset plan or disapproval of a draft offset plan will be considered unless they concern issues that are not relevant, such as:

(i) The environmental effects of acid rain, acid deposition, sulfur dioxide, or nitrogen oxides generally; and

(ii) Offset plan approval procedures or actions on other proposed offset plans that are not relevant to approval or disapproval of the draft offset plan in question.

(4) Persons who do not wish to raise issues on the draft offset plan or denial of a draft offset plan, but who wish to be notified of any subsequent actions concerning such matter, may so indicate during the public comment period or at any other time. The Administrator will place their names on a list of interested persons.

(i) *Opportunity for Public Hearing.* (1) During the public comment period, any person may request a public hearing. A request for a public hearing shall be made in writing and shall state the issues proposed to be raised in the hearing.

(2) On the Administrator's own motion or on the request of any person, the Administrator may, at his or her discretion, hold a public hearing whenever the Administrator finds that such a hearing will contribute to the decision-making process by clarifying one or more significant issues affecting the draft offset plan or disapproval of a draft offset plan. Public hearings will not be held on issues under paragraphs (h)(3) (i) and (ii) of this section.

(3) During a public hearing under this section, any person may submit oral or written comments concerning the draft offset plan or disapproval of a draft offset plan. The Administrator may set reasonable limits on the time allowed for oral statements and will require the submission of written summaries of each oral statement.

(4) The Administrator will assure that a record is made of the hearing.

(j) *Response to Comments.* (1) The Administrator will consider comments on the draft offset plan or disapproval of a draft offset plan received during the public comment period and any public hearing. The Administrator is not required to consider comments otherwise received.

(2) In approving or disapproving an offset plan, the Administrator will:

(i) Identify any draft offset plan provision or portion of the statement of basis that has been changed and the reasons for the change; and

(ii) Briefly describe and respond to relevant comments under paragraph (j)(1) of this section.

(k) *Approval and Effective Date of Excess Emissions Offset Plans.* (1) After the close of the public comment period, the Administrator will approve an offset plan requiring allowance deductions in an amount equal to the unit's tons of excess emissions or disapprove an offset plan. The Administrator will serve a copy of any approved offset plan and the response to comment on the designated representative for the affected unit involved and serve written notice of the approval or disapproval of the offset plan on any persons who are entitled to written notice under paragraphs (g)(2)(i) (B), (C), and (D) of this section. The Administrator will also give notice in the **Federal Register**.

(2) The Administrator will approve an offset plan requiring deduction from the unit's compliance subaccount, by December 31 of the year after the year for which the report is submitted, of all allowances necessary to offset the excess emissions except to the extent the designated representative of the unit demonstrates that such a deduction will interfere with electric reliability.

(3) Upon approval of the offset plan by the Administrator, the offset plan will be incorporated into the Acid Rain permit in accordance with § 72.84 (automatic permit amendment) and shall supersede any inconsistent provision of the permit.

§ 77.5 Deduction of allowances to offset excess emissions of sulfur dioxide.

(a) The Administrator will deduct allowances to offset excess emissions in accordance with the offset plan approved under § 77.4(b) (1) or (k) or in accordance with § 72.91(b) of this chapter.

(b) The designated representative shall hold enough allowances in the appropriate compliance subaccount to cover the deductions to be made in accordance with paragraph (a) or paragraph (c) of this section.

(c) If the designated representative does not submit a timely and complete proposed offset plan, or if the Administrator disapproves a proposed offset plan under § 77.4 (c) or (k), the Administrator will immediately deduct allowances, from the unit's compliance subaccount on a first-in, first-out basis in accordance with § 73.35(c)(2) of this chapter, equal to the amount of the unit's excess emissions of sulfur dioxide.

(d) If a compliance subaccount does not contain adequate allowances to offset the excess emissions, the Administrator will deduct the required allowances whenever allowances are recorded to that account.

§ 77.6 Penalties for excess emissions of sulfur dioxide and nitrogen oxides.

(a) If excess emissions of sulfur dioxide or nitrogen oxides occur at an affected unit during any year, the owners and operators of the affected unit shall pay, without demand, an excess emissions penalty, as calculated

under paragraph (b) of this section. Such payment shall be submitted to the Administrator no later than 60 days after the end of any year during which excess emissions occurred at an affected unit or, for any increase in excess emissions of sulfur dioxide determined after adjustments made under § 72.91(b) of this chapter, by July 31 of the year in which the adjustments are made. Each day after the applicable deadline that the payment is not submitted shall be a separate violation of this part.

(b) *Penalty Formula.* (1) The following formulas shall be used to determine the excess emissions penalty:

Penalty for excess emissions of sulfur dioxide=$2000/ton × annual adjustment factor × tons of excess emissions of sulfur dioxide.

Penalty for excess emissions of nitrogen oxides=$2000/ton × annual adjustment factor × tons of excess emissions of nitrogen oxides.

(i) The annual adjustment factor will be calculated as follows:

Annual adjustment factor=1+{[CPI(year)–CPI(1990)]/CPI(1990)}

where:

(A) "CPI(year)" is the Consumer Price Index as defined in § 72.2 of this chapter and "year" is the year in which the unit had excess emissions.

(B) "CPI(1990)" is the Consumer Price Index for 1990, as defined in § 72.2 of this chapter.

(ii) The Administrator will publish the annual adjustment factor in the **Federal Register** by October 15 of each year beginning in 1995.

(2) The penalty may be rounded to the nearest dollar after completing the calculation in paragraph (b)(1)(i) of this section.

(3) The penalty for excess emissions of sulfur dioxide shall be paid separately from the payment for excess emissions of nitrogen oxides. Each payment shall be accompanied by a document, in a format prescribed by the Administrator, indicating the unit for which the payment is made, whether the payment is for excess emissions of sulfur dioxide or nitrogen oxides, the number of tons of excess emissions, the penalty amount, and the check or money order number of the payment.

(c) If an excess emissions penalty due under this part is not paid on or before the applicable deadline under paragraph (a) of this section, the penalty shall be subject to interest charges in accordance with the Debt Collection Act (31 U.S.C. 3717). Interest shall begin to accrue on the date on which the Administrator mails, to the designated representative of the unit with excess emissions, a demand notice for the payment.

(d)(1) Except for wire transfers made in accordance with paragraph (d)(2) of this section, payments of penalties shall be made by money order, cashier's check, certified check, or U.S. Treasury check made payable to the "U.S. EPA."

(2) Payments made under paragraph (c)(1) of this section shall be mailed to the following address, unless the Administrator has notified the designated representative of a different address: U.S. EPA: Headquarters Accounting Operations Branch, Acid Rain Excess Emissions Penalties, P.O. Box 952491, St. Louis, MO 63195–2491.

(3) Payments of penalties of $25,000 or more may be made by wire transfer to the U.S. Treasury at the Federal Reserve Bank of New York.

(e) If the Administrator determines that overpayment has been made, he or she will refund the overpayment without interest, as promptly as administratively possible.

(f) Excess emissions in any year resulting directly from an order issued in that year under section 110(f) of the Act shall not be subject to the penalty payment requirements of this section; *provided* that the designated representative of any unit subject to such order shall advise the Administrator within 30 days of issuance of the order that the order will result in such excess emissions.

8. Title 40 is amended by adding part 78 to read as follows:

PART 78—APPEAL PROCEDURES FOR ACID RAIN PROGRAM

Sec.

78.1 Purpose and scope.
78.2 General.
78.3 Petition for administrative review and request for evidentiary hearing.
78.4 Filings.
78.5 Limitation on filing or presenting new evidence and raising new issues.
78.6 Action on petition for administrative review.
78.7 Stays of contested Acid Rain requirements pending appeal.
78.8 Consolidation and severance of appeals proceedings.
78.9 Notice of the filing of petition for administrative review.
78.10 Ex *parte* communications during pendency of a hearing.
78.11 Intervenors.
78.12 Standard of review.
78.13 Scheduling orders and pre-hearing conferences.
78.14 Evidentiary hearing procedure.
78.15 Motions in evidentiary hearings.
78.16 Record of appeal proceeding.
78.17 Proposed findings and conclusions and supporting brief.
78.18 Proposed decision.
78.19 Interlocutory appeal.
78.20 Appeal of decision of Administrator or proposed decision to the Environmental Appeals Board.

Authority: 42 U.S.C. 7601 and 7651, et. seq.

PART 78—APPEAL PROCEDURES FOR ACID RAIN PROGRAM

§ 78.1 Purpose and scope.

(a) This part shall govern appeals of any decision of the Administrator under the Acid Rain Program that, in the absence of an administrative appeal, will be final agency action; *provided* that matters listed in § 78.3(d) and interim decisions, such as draft Acid Rain permits or proposed alternative monitoring systems, may not be appealed.

(b) The decisions of the Administrator that may be appealed include but are not limited to:

(1) Under part 72 of this chapter;

(i) The determination of incompleteness of an Acid Rain permit application;

(ii) The issuance or denial of an Acid Rain permit and approval or disapproval of a compliance option by the Administrator;

(iii) The approval or disapproval of an early ranking application for Phase I extension under § 72.42 of this chapter;

(iv) The final determination of whether a technology is a qualified repowering technology under § 72.44 of this chapter;

(v) The issuance or denial of a written exemption for new units or retired units under §§ 72.7 and 72.8 of this chapter;

(vi) The approval or disapproval of a permit revision;

(vii) The decision on the deduction or return of allowances under §§ 72.41, 72.42, 72.43, 72.44, 72.91(b), and 72.92 (a) and (c) of this chapter; and

(viii) The failure to issue an Acid Rain permit in accordance with the deadline under § 72.74(b) of this chapter.

(2) Under part 73 of this chapter,

(i) The decision on a claim of error in a transfer recordation;

(ii) The decision on the allocation of allowances from the Conservation and Renewal Energy Reserve;

(iii) The decision on the allocation of allowances under regulations implementing sections 404(e), 405(g)(4), 405(i)(2), and 410(h) of the Act;

(iv) The decision on the allocation of allowances under part 73, subpart F of this chapter;

(v) The decision on the sale or return of allowances and transfer of proceeds under part 73, subpart E; and

(vi) The decision on the deduction of allowances under § 73.35(b) of this chapter.

(3) Under part 75 of this chapter,

(i) The decision on a petition for approval of an alternative monitoring system;

(ii) The approval or disapproval of a monitoring system certification or recertification;

(iii) The finalization of annual emissions data, including retroactive adjustment based on audit;

(iv) The determination of the percentage of emissions reduction achieved by qualifying Phase I technology; and

(v) The determination on the acceptability of parametric missing data procedures for a unit equipped with add-on controls for sulfur dioxide and nitrogen oxides in accordance with part 75 of this chapter.

(4) Under part 77 of this chapter, the determination of incompleteness of an offset plan and the approval or disapproval of an offset plan under § 77.4 of this chapter and the deduction of allowances under § 77.5(c) of this chapter.

(c) In order to appeal a decision under paragraph (a) of this section, a person shall file a petition for administrative review with the Environmental Appeals Board under § 78.3. The Environmental Appeals Board will, consistent with § 78.6, either:

(1) Issue an order deciding the appeal; or

(2) Where there is a disputed issue of fact material to the contested portions of the decision, refer the proceeding to the Chief Administrative Law Judge, who will designate an Administrative Law Judge to conduct an evidentiary hearing to decide the disputed issue of fact. If the proposed decision is contested or the Environmental Appeals Board decides to review the proposed decision, the Environmental Appeals Board will issue an order deciding the appeal.

(d) Questions arising at any stage of a proceeding that are not addressed in this part will be resolved at the discretion of the Environmental Appeals Board or the Presiding Officer.

§ 78.2 General.

Part 72 of this chapter, including sections 72.2 (definitions), 72.3 (measurements, abbreviations, and acronyms), 72.4 (federal authority), 72.5 (State authority), 72.6 (applicability), 72.7 (new units exemption), 72.8 (retired units exemption), 72.9 (standard requirements), 72.10 (availability of information), and 72.11 (computation of time), shall apply to this part.

§ 78.3 Petition for administrative review and request for evidentiary hearing.

(a)(1) The following persons may petition for administrative review of a decision of the Administrator that is made under parts 72, 75, and 77 of this chapter and that is appealable under § 78.1(a) of this part:

(i) The designated representative for the unit covered by the decision;

(ii) The authorized account representative for an account covered by the decision; and

(iii) Any interested person.

(2) The following persons may petition for administrative review of a decision of the Administrator that is made under part 73 of this chapter and that is appealable under § 78.1(a):

(i) The authorized account representative for any Allowance Tracking System account covered by the decision; and

(ii) With regard to the decision on the allocation of allowances from the Conservation and Renewable Energy Reserve, the certifying official whose application is covered by the decision.

(b)(1) Within 60 days following issuance of a decision under § 78.1 of this part by the Administrator, any person under paragraph (a) of this section may file a petition with the Environmental Appeals Board for administrative review of the decision. If no petition for administrative review of a decision under § 78.1 of this part is filed within such period, the decision shall become final agency action.

(2) The petition may include a request for an evidentiary hearing to resolve any disputed issue of material fact concerning the decision.

(3) At the same time that the petition for administrative review is filed, the petitioner shall:

(i) Serve a copy of the petition on the designated representative or authorized account representative under paragraph (a)(1) and (2) of this section (unless the designated representative or authorized account representative is the petitioner) and the Administrator; and

(ii) Mail a notice of the petition to the persons entitled to written notice under § 72.65(b)(1)(ii), (iii), and (iv) of this chapter.

(c) The petition for administrative review under this part shall state with specificity:

(1) Each material factual and legal issue alleged to be in dispute and any such factual issue for which an evidentiary hearing is sought;

(2) A clear and concise statement of the nature and scope of the interest of the petitioner;

(3) A clear and concise brief in support of the petition, explaining why the factual or legal issues are material and, if an evidentiary hearing is requested, why direct and cross-examination of witnesses is necessary to resolve such factual issues;

(4) If an evidentiary hearing is requested, the time estimated to be necessary for an evidentiary hearing;

(5) If an evidentiary hearing is requested, a certified statement that, in the event of an evidentiary hearing, and without cost or expense to any other party, any of the following persons shall be available to appear and testify:

(i) The petitioner; and

(ii) Any officer, director, employee, consultant, or agent of the petitioner.

(6) Specific references to the contested portions of the decision;

(7) Any revised or alternative action of the Administrator sought by the petitioner as necessary to implement the requirements, purposes, or policies of title IV of the Act; and

(8) Identification of any portion of the decision that the petitioner believes should be stayed pending resolution of the appeal.

(d) In no event shall a petition for administrative review be filed, or review be available under this part, with regard to:

(1) A decision under part 73 of this chapter to which the claim of error procedure applies, but for which no claim of error notification was submitted, under part 73 of this chapter;

(2) Any provision or requirement of parts 72, 73, 75, or 77 of this chapter and regulations implementing sections 407 and 410 of the Act, including any standard requirement under § 72.9 of this chapter and any emissions monitoring or reporting requirements under part 75 of this chapter;

(3) The reliance by the Administrator on a certificate of representation submitted by a designated representative or a certification statement submitted by an authorized account representative under the Acid Rain Program; and

(4) Actions of the Administrator under sections 112(r), 113, 114, 120, 301, and 303 of the Act.

§ 78.4 Filings.

(a) All original filings made under this part shall be signed by the person making the filing or by an attorney or authorized representative. Any filings on behalf of owners and operators of an affected unit or affected source shall be signed by the designated representative. Any filings on behalf of persons with an interest in allowances in a general account shall be signed by the authorized account representative. The name, address, telephone number, and

facsimile number of the person making the filing shall be provided with the filing.

(b)(1) All data and information referred to, or in any way relied upon, in any filings made under this part shall be included in full and may not be incorporated by reference, unless the data or information is contained in the administrative record for the decision being appealed.

(2) Notwithstanding paragraph (b)(1) of this section, State or federal statutes, regulations, and judicial decisions published in a national reporter system, officially issued EPA documents of general applicability, and any other publicly and generally available reference material may be incorporated by reference. Any person incorporating such materials by reference shall provide copies of the materials as instructed by the Environmental Appeals Board or the Presiding Officer.

(3) If any part of any filing is in a foreign language, it shall be accompanied by an English translation verified by the person making the translation, under oath, to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. Translations filed of material originally produced in a foreign language shall be accompanied by copies of the original material.

(4) Where relevant data or information is contained in a document also containing irrelevant matter, either the irrelevant matter shall be deleted or an index to the relevant portions of the document shall be included in the document.

(c)(1) Failure to comply with the requirements of this section or any other requirement in this part may result in the noncomplying portions of the filing being excluded from consideration. If the Environmental Appeals Board or the Presiding Officer determines on motion by any party or *sua sponte* that a filing fails to meet any requirement of this part, the Environmental Appeals Board or Presiding Officer may return the filing, together with a reference to the applicable requirements on which the determination is based. A person whose filing has been rejected has 7 days, from the date the returned filing is mailed, to correct the filing in conformance with this part and refile it, unless the Environmental Appeals Board or Presiding Officer authorizes a longer time based on good cause shown.

(2) The making of a filing shall not mean or imply that the filing, in fact, meets all applicable requirements, that the filing contains reasonable grounds for the action requested, or that the action requested is in accordance with law.

(d) An original and two copies of any written filing under this part shall be filed with the Environmental Appeals Board unless a proceeding is pending before a Presiding Officer, in which case they shall be filed with the Hearing Clerk (except as provided under § 78.19(d)) of this part.

(e)(1) The party making any filing in a proceeding under this part shall also serve a copy of the filing on each party to the proceeding, or, with regard to a petition for administrative review, on the persons specified in § 78.3(b)(3) of this part.

(2) Every filing made under this part shall be accompanied by a certificate of service citing the date, place, time, and manner of service and the names of the persons served.

(f) The Hearing Clerk will maintain and furnish, to any person upon request, the official service list containing the name, service address, telephone, and facsimile numbers of each party to a proceeding under this part and his or her attorney or duly authorized representative.

(g) Affidavits filed under this part shall be made on personal knowledge and belief, set forth only those facts that are admissible into evidence under § 78.5 of this part, and show affirmatively that the affiant is competent to testify to the matters stated therein.

§ 78.5 Limitation on filing or presenting new evidence and raising new issues.

(a) Where there was an opportunity for public comment, or to submit a claim of error notification, prior to the decision that is subject to appeal, no evidence shall be filed or presented, and no issues raised, in a proceeding under this part that were not filed, presented, or raised during the public comment period, absent a showing of good cause explaining the party's failure to do so during the public comment period or in the claim of error notification. Good cause shall include any instance where the party seeking to file or present new evidence or raise a new issue shows that the evidence could not have reasonably been ascertained, filed, or presented, the issue could not have reasonably been ascertained or raised, or that the materiality of the new evidence or issue could not have reasonably been anticipated, prior to the close of the public comment period or the period for submitting a claim of error notification.

(b) If an evidentiary hearing is granted, no evidence shall be filed or presented on questions of law or policy or on matters not subject to challenge in the evidentiary hearing.

§ 78.6 Action on petition for administrative review.

(a) If no evidentiary hearing concerning the petition for review is requested or is to be held, the Environmental Appeals Board will issue an order under § 78.20(c) of this part.

(b)(1) The Environmental Appeals Board may grant a request for an evidentiary hearing, or schedule an evidentiary hearing *sua sponte*, if the Environmental Appeals Board finds that there are disputed issues of fact material to contested portions of the decision and determines, in its discretion, that an opportunity for direct- and cross-examination of witnesses may be necessary in order to resolve these factual issues.

(2) To the extent the Environmental Appeals Board grants a request for an evidentiary hearing, in whole or in part, it will:

(i) Identify the portions of the decision that have been contested, and the disputed factual issues that have been raised by the petitioner with regard to which the evidentiary hearing has been granted; and

(ii) Refer the disputed factual issues to the Chief Administrative Law Judge for decision and, in its discretion, may also refer all or a portion of the remaining legal, policy, or factual issues to the Chief Administrative Law Judge for decision.

(3)(i) After issues are referred to the Chief Administrative Law Judge, he or she will designate an Administrative Law Judge as Presiding Officer to conduct the evidentiary hearing.

(ii) Notwithstanding paragraph (b)(3)(i) of this section, if all parties waive in writing their right to have an Administrative Law Judge designated as the Presiding Officer, the Administrator may designate a lawyer permanently or temporarily employed by EPA and without any prior connection with the proceeding to serve as Presiding Officer.

§ 78.7 Stays of contested Acid Rain requirements pending appeal.

(a) A contested decision of the Administrator may be stayed, in whole or in part consistent with paragraph (b) of this section, by the Environmental Appeals Board or the Presiding Officer upon request of a party during a proceeding under this part only to the extent necessary to prevent irreparable injury pending final agency action.

(b) The following requirements shall in no event be stayed due to any appeal of a decision of the Administrator and shall be fully effective and enforceable:

(1) The allowance allocations for any year during which the appeal proceeding is pending or is being conducted;

(2) Any standard requirements under § 72.9 of this chapter;

(3) The emissions monitoring and reporting requirements applicable to the affected units at an affected source under part 75 of this chapter;

(4) Uncontested provisions of the decision; and

(5) The terms of a certificate of representation submitted by a designated representative under part 72, subpart B of this chapter or a certification statement submitted by an authorized account representative under part 73, subpart C of this chapter.

(c) The permit shield under § 72.51 of this chapter shall continue to be in effect.

(d) The Environmental Appeals Board or Presiding Officer shall specify which provisions of the decision shall be stayed.

§ 78.8 Consolidation and severance of appeals proceedings.

(a) The Environmental Appeals Board or Presiding Officer has the discretion to consolidate, in whole or in part, two or more proceedings under this part whenever it appears that a joint proceeding on any or all of the matters at issue in the proceedings will be in the interest of justice, will expedite or simplify consideration of the issues, and will not prejudice any party. Consolidation of proceedings under this paragraph (a) will not affect the right of any party to raise issues that might have been raised had there been no consolidation.

(b) The Environmental Appeals Board or Presiding Officer has the discretion to sever issues or parties from a proceeding under this part whenever it appears that separate proceedings will be in the interest of justice, will expedite or simplify consideration of the issues, and will not prejudice any party.

§ 78.9 Notice of the filing of petition for administrative review.

The Administrator will publish in the **Federal Register** a notice stating that a petition for administrative review of a decision of the Administrator has been filed and specifying any request in the petition for an evidentiary hearing.

§ 78.10 Ex parte communications during pendency of a hearing.

(a)(1) No party or interested person outside EPA, representative of a party or interested person, or member of the EPA trial staff shall make, or knowingly cause to be made, to any member of the decisional body an *ex parte* communication on the merits of a proceeding under this part.

(2) No member of the decisional body shall make, or knowingly cause to be made, to any party or interested person outside EPA, representative of a party or interested person, or member of the EPA trial staff, an *ex parte* communication on the merits of any proceeding under this part.

(3) A member of the decisional body who receives, makes, or knowingly causes to be made an *ex parte* communication prohibited by this paragraph shall file with the Environmental Appeals Board (or, if the proceeding is pending before an Administrative Law Judge, with the Hearing Clerk) for inclusion in the record of the proceeding under this part any such written *ex parte* communication and memoranda stating the substance of any such oral *ex parte* communication.

(b) Whenever any member of the decisional body receives an *ex parte* communication made, or knowingly caused to be made by a party or representative of a party to a proceeding under this part, the person presiding over the proceedings then in progress may, to the extent consistent with justice, require the party to show good cause why its claim or interest in the proceedings should not be dismissed, denied, disregarded, or otherwise adversely affected on account of these *ex parte* communications.

(c) The prohibitions of paragraph (a) of this section shall begin to apply upon publication by the Administrator of the notice of the filing of a petition under § 78.9 of this part. This prohibition terminates on the date of final agency action.

§ 78.11 Intervenors.

(a) Within 30 days after notice is given under § 78.9 of this part that the petition for administrative review has been filed, any person listed in § 78.3(a) of this part may file a motion for leave to intervene in the proceeding. A motion for leave to intervene under this section shall set forth the grounds for the proposed intervention and may respond to the petition for administrative review. Late motions to intervene may be granted only for good cause shown.

(b) The Environmental Appeals Board of Presiding Officer will grant a motion to intervene only upon an express finding that:

(1) The motion to intervene raises matters relevant to the factual or legal issues to be reviewed;

(2) The intervenor consented to be bound by all stipulations previously entered into by the existing parties, and all orders previously issued, in the proceeding; and

(3) The intervention will promote the interests of justice and will not cause undue delay or prejudice to the rights of the existing parties.

§ 78.12 Standard of review.

(a) On appeal of a decision of the Administrator prior to which there was an opportunity for public comment, or to submit a claim of error notification:

(1) Except as provided under paragraph (a)(2) of this section, the petitioner shall have the burden of going forward and of persuasion to show that a finding of fact or conclusion of law underlying the decision is clearly erroneous or that an exercise of discretion or policy determination underlying the decision is arbitrary and capricious or otherwise warrants review.

(2) The owners and operators of the source or unit involved shall have the burden of persuasion that an Acid Rain permit or a written exemption under §§ 72.7 or 72.8 of this chapter was properly issued or should be issued.

(b) On appeal of a decision of the Administrator not covered by paragraph (a) of this section, the Administrator shall have the burden of going forward to show the rational basis for the decision. The petitioner shall have the burden of persuasion to show that a finding of fact or conclusion of law underlying the decision is clearly erroneous or that an exercise of discretion or policy determination underlying the decision is arbitrary and capricious or otherwise warrants review.

§ 78.13 Scheduling orders and pre-hearing conferences.

(a) If a request for an evidentiary hearing is granted, the Presiding Officer will issue an order scheduling the following:

(1) The filing by each party of a narrative statement of position on each factual issue in controversy.

(2) The identification of any witness that a party expects to call and of any written testimony, documents, papers, exhibits, or other materials that a party expects to introduce into evidence. At the request of the Presiding Officer, the party shall include a brief narrative summary of any witness' expected testimony and of any such materials.

(3) The filing of written testimony, in accordance with § 78.14(b) of this part, and other evidence in support of a narrative statement.

(4) The filing of any motions by any party, including motions for the

production of documentation, data, or other information material to the disputed facts to be addressed at the hearing.

(b) The Presiding Officer may also, on motion or *sua sponte*, schedule one or more pre-hearing conferences on the record to address any of the following:

(1) Simplification, clarification, amplification, or limitation of the issues.

(2) Admissions and stipulations of facts and determinations of the genuineness of documents.

(3) Objections to the introduction into evidence at the hearing of any written testimony or other submissions proposed by a party; *provided* that at any time before the end of the hearing, any party may make, and the Presiding Officer may consider and rule upon, a motion to strike testimony or other evidence (other than evidence included in the administrative record (if any) under § 72.63 of this chapter) on the grounds of relevance, competency, or materiality.

(4) Taking official notice of any matters.

(5) Grouping of parties with substantially similar interests to eliminate redundant evidence, motions, objections, and briefs.

(6) Such other matters that may expedite the hearing or aid in the disposition of matters in dispute.

(c) The Presiding Officer will issue an order (which may be in the form of a transcript) reciting the actions taken at any pre-hearing conferences, setting the schedule for any hearing, and stating any areas of factual and legal agreement and disagreement and the methods and procedures to be used in developing any evidence.

§ 78.14 Evidentiary hearing procedure.

(a) If a request for an evidentiary hearing is granted, the Presiding Officer will conduct a fair and impartial hearing on the record, take action to avoid unnecessary delay in the disposition of the proceedings, and maintain order. For theses purposes, the Presiding Officer may:

(1) Administer oaths and affirmations.

(2) Regulate the course of the hearings and prehearing conferences and govern the conduct of participants.

(3) Examine witnesses.

(4) Identify and refer issues for interlocutory decision under § 78.19 of this part.

(5) Rule on, admit, exclude, or limit evidence.

(6) Establish the time for filing motions, testimony and other written evidence, and briefs and making other filings.

(7) Rule on motions and other pending procedural matters, including but not limited to motions for summary disposition in accordance with § 78.15 of this part.

(8) Order that the hearing be conducted in stages whenever the number of parties is large or the issues are numerous and complex.

(9) Allow direct and cross-examination of witnesses only to the extent the Presiding Officer determines that such direct and cross-examination may be necessary to resolve disputed issues of material fact; *provided* that no direct or cross-examination shall be allowed on questions of law or policy or regarding matters that are not subject to challenge in the evidentiary hearing.

(10) Limit public access to the hearing where necessary to protect confidential business information. The Presiding Officer will provide written notice of the hearing to the parties, and where the hearing will be open to the public, notice in the **Federal Register** no later than 15 days prior to commencement of the hearings.

(11) Take any other action not inconsistent with the provisions of this part for the maintenance of order at the hearing and for the expeditious, fair and impartial conduct of the proceeding.

(b) All direct and rebuttal testimony at an evidentiary hearing shall be filed in written form, unless, upon motion and good cause shown, the Presiding Officer, in his or her discretion, determines that oral presentation of such evidence on any particular factual issue will materially assist in the efficient resolution of the issue.

(c)(1) The Presiding Officer will admit all evidence that is not irrelevant, immaterial, unduly repetitious, or otherwise unreliable or of little probative value. Evidence relating to settlement that would be excluded in the federal courts under Rule 408 of the Federal Rules of Evidence shall not be admissible.

(2) Whenever any evidence or testimony is excluded by the Presiding Officer as inadmissible, all such evidence will remain a part of the record as an offer of proof. The party seeking the admission of oral testimony may make an offer of proof by means of a brief statement on the record describing the testimony excluded.

(3) When two or more parties have substantially similar interests and positions, the Presiding Officer may limit the number of attorneys or authorized representatives who will be permitted to examine witnesses and to make and argue motions and objections on behalf of those parties.

(4) Rulings of the Presiding Officer on the admissibility of evidence or testimony, the propriety of direct and cross-examination, and other procedural matters will appear in the record of the hearing and control further proceedings unless reversed by the Presiding Officer or as a result of an interlocutory appeal taken under § 78.19 of this part.

(5) All objections shall be made promptly or be deemed waived; *provided* that parties shall be presumed to have taken exception to an adverse ruling. No objection shall be deemed waived by further participation in the hearing.

§ 78.15 Motions in evidentiary hearings.

(a) Any party may make a motion to the Presiding Officer on any matter relating to the evidentiary hearing in accordance with the scheduling orders issued under § 78.13 of this part. All motions shall be in writing and served as provided in § 78.4 of this part, except those made on the record during an oral hearing before the Presiding Officer.

(b) Any party may make a motion for a summary disposition in its favor on any factual issue on the basis that there is no genuine issue of material fact. When a motion for summary disposition is made and supported, any party opposing the motion may not rest upon mere allegations or denials, but must show, by affidavit or by other materials subject to consideration by the Presiding Officer, that there is a genuine issue of material fact.

(c) Within 10 days after a motion made on the record or service of any written motion, any party may file a response to the motion. The time for response may be shortened or extended by the Presiding Officer for good cause shown.

(d) The Presiding Officer may schedule an oral argument and call for the filing of briefs on any motion. The Presiding Officer will rule on the motion within a reasonable time after the date that responses to the motion may be filed under paragraph (c) of this section and that any oral argument or filing of briefs is completed.

(e) If all factual issues are decided by summary disposition prior to the hearing, no hearing will be held and the Presiding Officer will issue a proposed decision under § 78.18 of this part. If a summary disposition is denied or if partial summary disposition is granted, the hearing shall proceed on the remaining issues.

§ 78.16 Record of appeal proceeding.

(a) The proposed decision issued by the Presiding Officer, transcripts of oral hearings or oral arguments, written

direct and rebuttal testimony, and any other written materials of any kind filed in the proceeding will be part of the record and will be available to the public in the office of the Hearing Clerk, subject to the requirements of part 2 of this chapter.

(b) Hearings and oral arguments shall be recorded as specified by the Presiding Officer, and thereupon transcribed. After the hearing or oral argument, the reporter will certify and file with the Hearing Clerk.

(1) The original transcript; and

(2) Any exhibits received or offered into evidence at the hearing.

(c) The Hearing Clerk will promptly give written notice to the parties when any transcript is available. Any party that desires a copy of the transcript may obtain a copy upon payment of costs.

(d) The Presiding Officer will allow witnesses, parties, and their counsel or representatives:

(1) Up to 7 days from issuance of the notice under paragraph (c) of this section in order to file written proposed corrections of the transcript necessary to correct errors made in the transcribing; and

(2) Up to 7 days from the submission of the corrections in order to file objections to the proposed corrections.

(e) The Presiding Officer will determine which, if any, corrections should be made to the transcript and incorporate them into the record.

§ 78.17 Proposed findings and conclusions and supporting brief.

Within 45 days after issuance of a notice under § 78.16(c) of this part that the complete transcript of the evidentiary hearing is available, any party may file with the Hearing Clerk proposed findings and conclusions on the issues referred to the Presiding Officer and a brief in support thereof. Briefs shall contain appropriate references to the record. The Presiding Officer, for good cause shown, may shorten or extend the time for filing and may allow reply briefs.

§ 78.18 Proposed decision.

(a) The Presiding Officer will review and evaluate the record, including the proposed findings and conclusions and any briefs filed by the parties, and issue a proposed decision on the factual, policy, and legal issues referred by the Environmental Appeals Board for decision under § 78.6(b)(2)(ii) of this part, accompanied by findings of fact and proposed conclusions of law, as appropriate, within a reasonable time after the evidentiary hearing is completed. The Hearing Clerk will promptly serve copies of the proposed decision on all parties and on the Environmental Appeals Board.

(b) The proposed decision of the Presiding Officer shall become the final agency action under section 307 of the Act 30 days after service unless within that time:

(1) A party files objections with the Environmental Appeals Board pursuant to § 78.20(a) of this part, or

(2) The Environmental Appeals Board *sua sponte* files a notice that it will review the decision under § 78.20(b) of this part.

§ 78.19 Interlocutory appeal.

(a) Interlocutory appeal from orders or rulings of the Presiding Officer made during the course of a proceeding may be taken if the Presiding Officer certifies those orders or rulings to the Environmental Appeals Board for interlocutory appeal on the record. Any requests to the Presiding Officer to certify an interlocutory appeal shall be filed within 10 days of notice of the order or ruling and shall state briefly the grounds for the request.

(b)(1) Within 15 days of the filing of any request for interlocutory appeal, the Presiding Officer may certify an order or ruling for interlocutory appeal to the Environmental Appeals Board if:

(i) The order or ruling involves an important question on which there is substantial ground for difference of opinion, and

(ii) Either:

(A) An immediate appeal of the order or ruling will materially advance the ultimate completion of the proceeding, or

(B) A review after the proceeding is completed will be inadequate or ineffective.

(2) If the Presiding Officer takes no action within 15 days of the filing of a request for interlocutory appeal, the request shall be automatically dismissed without prejudice.

(c) If the Presiding Officer grants certification, the Environmental Appeals Board may accept or decline the interlocutory appeal within 30 days of certification. If the Environmental Appeals Board decides that certification was improperly granted, it will decline to hear the interlocutory appeal. If the Environmental Appeals Board takes no action within 30 days of certification, the interlocutory appeal shall be automatically dismissed without prejudice.

(d) If the Presiding Officer declines to certify an order or ruling for an interlocutory appeal, the order or ruling may be reviewed by the Environmental Appeals Board only upon an appeal of the proposed decision following completion of the proceedings before the Presiding Officer, except when the Environmental Appeals Board determines, upon motion of a party and in exceptional circumstances, that to delay review would not be in the public interest. Such motion shall be filed with Environmental Appeals Board within 5 days after the earlier of automatic dismissal of the request for interlocutory appeal or receipt by the party of notification that the Presiding Officer declines to certify an order or ruling for interlocutory appeal.

(e) The failure of a party to request an interlocutory appeal shall not prevent an appeal of an order or ruling as part of an appeal of a proposed decision under § 78.20 of this part.

§ 78.20 Appeal of decision of Administrator or proposed decision to the Environmental Appeals Board.

(a) Within 30 days after the issuance of a proposed decision by a Presiding Officer under this part, any party may appeal any matter set forth in the proposed decision, or any other order or ruling made during the proceeding to which the party objected during the proceeding before the Presiding Officer, by filing an objection with the Environmental Appeals Board. On appeal of an order, ruling, or proposed decision of a Presiding Officer:

(1) The party filing the objection shall have the burden of going forward to show that the order, ruling, or proposed decision is based on a finding of fact or conclusion of law that is clearly erroneous; or a policy determination or exercise of discretion that is arbitrary and capricious or otherwise warrants review; and

(2) The petitioner or the owners and operators shall have the burden of persuasion, as set forth in § 78.12(a) (1) and (2) of this part.

(b) Within 30 days after issuance of a proposed decision of a Presiding Officer, the Environmental Appeals Board may issue *sua sponte* in its discretion a notice of intent to review such proposed decision. The Environmental Appeals Board will serve such notice upon all parties to the proceeding.

(c) Within a reasonable time following the filing of a petition for administrative review of a decision of the Administrator under § 78.3 of this part, or, if any issues raised by such petition are referred to the Presiding Officer, the filing of objections under paragraph (a) of this section or the issuance of a notice of intent to review under paragraph (b) of this section, the Environmental Appeals Board will issue an order affirming, reversing, modifying, or

remanding the decision or proposed decision, as appropriate. Prior to issuing this order, the Environmental Appeals Board may provide an opportunity for parties to file additional briefs.

(d) If the Environmental Appeals Board issues an order affirming, reversing, or modifying the decision of the Administrator, then the decision as supplemented or changed by the order, shall be final agency action.

(e) If the Environmental Appeals Board issues an order affirming, reversing, or modifying the proposed decision, the proposed decision, as supplemented or changed by the order, shall be final agency action.

(f) If the Environmental Appeals Board issues an order remanding the proceeding, then final agency action occurs upon completion of the remanded proceeding, including any appeals to the Environmental Appeals Board in the remanded proceeding.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[AMS–FRL–4550–7]

Criteria and Procedures for Determining Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Funded or Approved Under Title 23 U.S.C. or the Federal Transit Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: EPA proposes criteria and procedures for determining that transportation plans, programs, and projects which are funded or approved under title 23 U.S.C. or the Federal Transit Act conform with State or Federal air quality implementation plans. This action is required under section 176(c)(4) of the Clean Air Act Amendments of 1990.

Conformity to an implementation plan is defined in the Clean Air Act as conformity to an implementation plan's purpose of eliminating or reducing the severity and number of violations of the national ambient air quality standards and achieving expeditious attainment of such standards. Federal activities may not cause or contribute to new violations of air quality standards, exacerbate existing violations, or interfere with the timely attainment or interim emission reductions towards attainment. This proposal would establish the process by which the Federal Highway Administration and the Federal Transit Administration of the United States Department of Transportation and metropolitan planning organizations determine conformity of highway and transit projects.

DATES: Written comments on this notice will be accepted for 60 days until March 12, 1993. EPA will conduct three public hearings on this proposal beginning at 10:30 a.m. on January 29, 1993 in Washington, DC; February 5, 1993 in California; and February 10, 1993 in Missouri. The hearings will continue throughout the day until all testimony has been presented.

ADDRESSES: Interested parties may submit written comments (in duplicate, if possible) to: Air Docket Section (LE–131), U.S. Environmental Protection Agency, Attention: Docket No. A–92–21, 401 M Street, SW., Washington, DC 20460. (Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.)

Public hearings will be held in Washington, DC, at the Ramada Renaissance Techworld, 999 9th St. NW.; in Los Angeles, California at the Sheraton Grand Hotel, 333 South Figueroa; and in St. Louis, Missouri at the Stouffer Concourse Hotel, 9801 Natural Bridge Road.

Materials relevant to this proposal have been placed in Public Docket A–92–21 by EPA. The docket is located at the above address in room M–1500 Waterside Mall (ground floor) and may be inspected from 8:30 a.m. to 12 p.m. and from 1:30 p.m. to 3:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Kathryn Sargeant, Emission Control Strategies Branch, Emission Planning and Strategies Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105. Telephone: (313) 668–4441.

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I. Authority

Authority for the actions proposed in this notice is granted to EPA and DOT by section 176(c) of the Clean Air Act as amended (42 U.S.C. 7521(a)).

II. Background of Proposed Rule

A. Overview of the Transportation Planning Process

The joint Federal Highway Administration (FHWA)/Federal Transit Administration (FTA) urban transportation planning regulations codified at 23 CFR 450 require all urban areas with a population of more than 50,000 to have a continuous, cooperative, and comprehensive (3C) transportation planning process. The 3C planning process forms the basis for all local and State decisions involving Federal highway and transit assistance in urban areas. The planning process is generally carried out by State governments, metropolitan planning organizations (MPOs), and transit operators. The designation and membership of MPOs are decided by the units of local government and the State governor.

The urban transportation planning process requires each urbanized area to develop a transportation plan and a transportation improvement program (TIP). The MPO must approve the plan, and the MPO and the State governor must approve the TIP in order to receive Federal funds for transportation projects.

The transportation plan is a long-range plan describing policies, strategies, and facilities to accommodate current and future travel demands and to make more efficient use of the existing transportation system. It identifies facilities which should function as an integrated metropolitan transportation system, giving emphasis to those facilities that serve important national and regional transportation functions.

The TIP is a more specific program of transportation projects that are consistent with the transportation plan. The TIP includes a priority list of projects and project segments to be carried out within each three-year period after the initial adoption of the TIP. The TIP is developed by the MPO, in cooperation with the State and affected transit operators, and must be updated at least once every two years.

In addition to the transportation plans and TIPs, each State must annually prepare and submit to DOT a statewide program of projects which the State proposes for Federal assistance. FHWA and FTA generally require that the projects for urbanized areas be drawn from each area's TIP.

The approval actions taken by FHWA and FTA are on the statewide TIPs.

Prior to taking these actions on the metropolitan portion(s) of the statewide TIP, FHWA and FTA must find that (1) the metropolitan TIP is based on a 3C planning process carried on cooperatively by the States and local communities in accordance with the provisions of 23 U.S.C. 134 and 135 and the Federal Transit Act; and (2) in nonattainment areas, the metropolitan TIP conforms with the implementation plan and priority has been given to transportation control measures contained in the implementation plan in accordance with procedures in this conformity regulation.

Before a federally assisted transportation project is actually implemented, it must go through project development/analysis of alternatives and final design phases. The project development/analysis of alternatives phase gathers more detailed information on the impacts of several potential project alternatives. The environmental, social, and economic impacts of the alternatives are analyzed, and the environmental assessments and impact statements required by the National Environmental Policy Act (NEPA) are prepared. After the public has had an opportunity for review and comment, a final NEPA document is prepared. Although NEPA requires the consideration of reasonable alternatives which would avoid or minimize adverse environmental impacts, NEPA does not require the preferred alternative to be chosen solely on the basis of environmental impacts. The final environmental document must be approved by FHWA or FTA.

Once the environmental process is completed, the final design is developed, construction plans, specifications, and estimates are developed, cost estimates are refined, and rights-of-way are acquired. The project may then proceed to construction.

B. Overview of the Air Quality Planning Process

The Clean Air Act (CAA) as amended in 1990 (Pub. L. 101–549; 42 U.S.C. 7401, et seq.) requires each State to submit to EPA a State implementation plan (SIP). The SIP is an air quality management plan which contains rules and regulations for air pollution sources under State control and a demonstration that the State will attain the national ambient air quality standards (NAAQS) by the dates set forth in the CAA.

State air quality agencies have the primary responsibility for preparing the SIP. However, State and local air quality and transportation agencies must work together to develop SIP strategies for transportation that are realistic, fundable, and effective in reducing emissions. The State SIP development process involves public hearings, and the SIP must be supported by adequate State legislation before the governor submits it to EPA.

Under section 107(d) of the CAA, all areas of the country are designated attainment, nonattainment, or unclassifiable with respect to the NAAQS. SIPs for most nonattainment areas must contain an inventory of current NAAQS pollutant emissions, as well as air quality modeling which demonstrates that given certain assumptions about population growth, economic growth, and growth in vehicle miles traveled (VMT), the SIP's control measures will result by a certain date in a level of emissions which is in attainment with the NAAQS. The attainment demonstration establishes a level of allowable emissions, which EPA calls an emissions budget. Attainment demonstrations for areas designated nonattainment for particulate matter less than ten microns in diameter (PM_{10}) are already due to EPA, and carbon monoxide (CO) nonattainment areas which are classified as serious or moderate with design value above 12.7 parts per million must submit attainment demonstrations by November 15, 1992. Ozone nonattainment areas which are classified as serious, severe, or extreme must submit attainment demonstrations by November 15, 1994. Moderate ozone nonattainment areas must submit such demonstrations by November 15, 1993, unless they are using regional airshed modeling, in which case they have until November 15, 1994.

In addition to the attainment demonstration, SIPs for most ozone nonattainment areas must demonstrate reasonable further progress (RFP) toward attainment for certain milestone years. Moderate, serious, severe, and extreme ozone areas must demonstrate in the SIP that emissions of volatile organic compounds (VOC) will be reduced by 15% from 1990 baseline emissions by 1996. (Certain adjustments and exclusions apply.) Serious, severe, and extreme ozone areas must also demonstrate that in milestone years occurring every three years from 1996 until the attainment date, VOC will be reduced from baseline emissions by an average of three percent per year. (Nitrogen oxides emissions reductions may in some cases substitute for all or a part of the required VOC emissions reductions.) PM_{10} nonattainment areas must also submit SIPs with quantitative emission reduction milestones which must be achieved every three years. The RFP requirements in effect create an emissions budget for each milestone year, in addition to the budget that applies for the attainment year.

If a State fails to make an SIP submission, if an SIP submission is disapproved by EPA, or if a requirement in an approved SIP is not being implemented, EPA may (and in some cases must) apply highway funding sanctions. These highway sanctions would prohibit DOT from approving projects or awarding grants in the affected nonattainment area, unless the project or grant was to improve a demonstrated safety problem, was one of several exempt types listed in the CAA, or was found to reduce air pollution problems by the EPA Administrator. Within two years after an EPA finding of State failure or SIP disapproval, EPA would be required to promulgate a Federal implementation plan (FIP) which would correct the SIP's deficiencies.

EPA's document "State Implementation Plans; General Preamble for the Implementation of title I of the Clean Air Act Amendments of 1990" (57 FR 13498, April 16, 1992) provides more information on the SIP process and the 1990 CAA requirements.

C. History of Conformity

Conformity provisions first appeared in the Clean Air Act Amendments of 1977 (Pub. L. 95–95). Although these provisions did not define conformity, they provided that no Federal department "shall (1) engage in, (2) support in any way or provide financial assistance for, (3) license or permit, or (4) approve any activity which does not conform to a plan [State implementation plan] after it has been approved or promulgated." Assurance of conformity was an affirmative responsibility of the head of each Federal agency. In addition, no MPO could approve any transportation project, program, or plan which did not conform to a State or Federal implementation plan.

Following enactment of the 1977 Amendments, the Department of Transportation (DOT) consulted with EPA to develop conformity procedures for programs administered by FHWA and the Urban Mass Transportation Administration (now FTA). The June 1978 Memorandum of Understanding Regarding Integration of Transportation and Air Quality Planning provided EPA an opportunity to jointly review and comment on the conformity of transportation plans and TIPs.

In April 1980, EPA published an advance notice of proposed rulemaking on conformity (45 FR 21590, April 1,

1980). EPA maintained that the Congressional intent of CAA section 176(c) was to prevent Federal actions from causing a delay in the attainment or maintenance of the NAAQS. However, no further rulemaking action was taken.

In June 1980 EPA and DOT jointly issued a guidance document entitled "Procedures for Conformance of Transportation Plans, Programs and Projects with Clean Air Act State Implementation Plans." This guidance established that in nonattainment and maintenance areas (areas experiencing NAAQS violations and required to develop air quality maintenance plans under 40 CFR part 51, subpart D), conformity determinations must be documented as a necessary element of all certifications, TIP reviews, and EIS findings. It was necessary to make certifications that the planning process had been conducted according to the 3C process and consistent with Clean Air Act requirements.

Transportation plans and programs were considered to conform with the SIP if they did not adversely affect the transportation control measures (TCMs) in the SIP, and if they contributed to reasonable progress in implementing those TCMs. A transportation project would conform if it were a TCM from the SIP, came from a conforming TIP, or did not adversely affect the TCMs in the SIP.

Subsequently, DOT developed and issued an interim final rule (46 FR 8426, January 26, 1981) based upon the joint guidance. DOT established this rule to meet its obligations under section 176(c) of the CAA, and the rule was put into effect immediately upon publication. It amended 23 CFR part 770 (FHWA Air Quality Guidelines) and added 49 CFR part 623 (UMTA Air Quality Conformity and Priority Procedures).

The rule used the joint guidance's definition of conformity, interpreting conformity in the context of TCMs rather than emissions budgets or air quality analysis. Compliance with the conformity requirements was to be demonstrated as part of the planning and NEPA processes.

D. Conformity Under the Clean Air Act Amendments of 1990

The Clean Air Act Amendments of 1990 expand the scope and content of the conformity provisions by defining conformity to an implementation plan to mean conformity to the plan's purpose of eliminating or reducing the severity and number of violations of the national ambient air quality standards and achieving expeditious attainment of such standards; and that such activities will not (i) cause or contribute to any new violation of any standards in any area; (ii) increase the frequency or severity of any existing violation of any standard in any area; or (iii) delay timely attainment of any standard or any required interim emission reductions or other milestones in any area.

In addition to this general definition which applies to all Federal actions, transportation plans, programs, and projects funded under title 23 U.S.C. or the Federal Transit Act (hereinafter "transportation plans, programs, and projects") must be found to conform before they can be approved at the local level by the MPO. Transportation plans, programs, and projects also must be found to conform at the Federal level by DOT before they can be approved, accepted, or funded.

Section 176(c)(2) of the 1990 Amendments requires the expected emissions from transportation plans and TIPs to be consistent with the implementation plan's motor vehicle emission estimates and required emissions reductions. A transportation project would conform if it came from a conforming plan and TIP, or if it was demonstrated that the projected emissions from the project, when considered together with the emissions projected for the conforming transportation plan and TIP, were consistent with the emission reduction projections and schedules in the implementation plan. Finally, TIPs must provide for the timely implementation of TCMs consistent with schedules included in the implementation plan.

The Clean Air Act Amendments of 1990 therefore emphasize reconciling the estimates of emissions from transportation plans and programs with the implementation plan, rather than simply providing for the implementation of TCMs. This integration of transportation and air quality planning is intended to protect the integrity of the implementation plan by ensuring that its growth projections are not exceeded without additional measures to counterbalance the excess growth, that progress targets are achieved, and that air quality maintenance efforts are not undermined.

Once specific emissions reduction schedules are established in the implementation plan as required by sections 182 and 187 of the 1990 Amendments, conformity requires that the emissions expected from plans and TIPs be consistent with those emissions reductions in the implementation plan. Until that time, the 1990 Amendments together with the rule proposed today establish interim requirements for transportation plans and TIPs to provide for the expeditious implementation of TCMs in the applicable implementation plan, to contribute to VOC and CO emissions reductions, and to avoid any increase in PM_{10} or NO_x emissions relative to 1990 emission levels of these pollutants. In carbon monoxide (CO) nonattainment areas, transportation projects must also eliminate or reduce the severity and number of violations of the CO standards in the area substantially affected by the project.

According to section 176(c)(4), EPA must promulgate criteria and procedures for determining conformity and must require each State to submit an implementation plan revision that includes such criteria and procedures. The criteria and procedures which EPA promulgates will apply as Federal law to both Federal and local (MPO) conformity determinations. The implementation plan revisions will make conformity criteria and procedures State requirements as well. States may elect to incorporate more stringent conformity criteria and procedures in their implementation plans than are contained in the Federal rule.

Section 176(c) of the CAA applies to all departments, agencies, and instrumentalities of the Federal government. This proposal applies only to the conformity of transportation plans, programs, and projects developed, funded, or approved under title 23 U.S.C. or the Federal Transit Act. Criteria and procedures for determining the conformity of all other Federal actions, including highway and transit projects which require funding or approval from a Federal agency other than FHWA or FTA, will be promulgated in a forthcoming rule.

E. Interim EPA/DOT Conformity Guidance

On June 7, 1991, EPA and DOT jointly issued guidance for determining conformity of transportation plans, programs, and projects during the period before the final rule is promulgated. This guidance is based on the interim conformity requirements in § 176(c)(3) of the CAA.

According to the interim guidance, a transportation plan or TIP conforms if it supports the implementation plan's purpose of achieving the NAAQS; has no goals, directives, recommendations, or projects which will have adverse impacts on the implementation plan; provides for the expeditious implementation of TCMs in the implementation plan; contributes to ozone and CO emission reductions; and

does not increase the frequency or severity of existing violations of the NAAQS for which the area is designated nonattainment.

Transportation projects conform if they come from a conforming plan and TIP and, in CO nonattainment areas, if they eliminate or reduce the number and severity of CO violations. Projects which are not from a TIP (e.g., projects outside metropolitan areas but still in nonattainment areas, and projects whose design concept and scope have changed significantly since TIP adoption) conform if they do not interfere with TCMs, if they contribute to regional emissions reductions, and in CO nonattainment areas, if they reduce local CO violations.

F. Public Consultation in the Development of This Proposal

Because the Clean Air Act Amendments of 1990 significantly broadened the scope of transportation conformity, EPA involved potentially affected parties early in its process of developing conformity criteria and procedures. EPA, FHWA, and FTA jointly funded a grant to the National Association of Regional Councils (NARC), in part to establish a technical review panel which would provide a framework for education of the affected State and local agencies and coordination of their comments to EPA. The technical review panel for conformity is comprised of representatives from the affected government entities, including representatives from NARC (which represents MPOs), the American Association of State Highway and Transportation Officials, the American Public Transit Association, the State and Territorial Air Pollution Program Administrators, and the Association of Local Air Pollution Control Officials. EPA staff have by invitation attended several panel meetings.

EPA circulated concept papers to the conformity technical review panel and other interested parties, including representatives of the environmental community and the development community. EPA also hosted a roundtable discussion in Ann Arbor, Michigan in October 1991. EPA received a substantial number of comments, which are available in the docket. The agency welcomes comments from all interested parties on the contents of this specific proposal.

III. Applicability Issues

A. Geographic Applicability

EPA has heard a wide range of opinion on the legal and public policy issues associated with whether conformity must apply in areas which have been designated as attainment or unclassifiable areas continuously since initial designation, as opposed to areas that were one designated as nonattainment areas and have since been redesignated to attainment. Some MPOs in such attainment areas believe that Congress did not intend such areas to be brought under the conformity requirements; they are also concerned that the regulatory burden associated with analyzing transportation-related emissions is not justified in areas without air quality problems. Small MPOs in particular have limited staff, planning resources, and air quality modeling experience. However, some members of the environmental community are concerned that rapidly growing attainment areas that have never before been designated nonattainment may begin violating the NAAQS unless the long-range transportation and air quality planning associated with conformity is performed.

The CAA as amended in 1990 now defines conformity in section 176(c)(1)(B)(i) as meaning, among other things, that activities will not "cause or contribute to any new violation of any standard in any area." This language can be taken to imply applicability of conformity requirements to all attainment and nonattainment areas. However, some ambiguity is introduced by the section's placement within part D of the CAA, entitled "Plan Requirements for Nonattainment Areas," and by other details of the phrasing of the conformity requirement.

After extensive review of the statutory provisions and the legislative history on this issue, EPA has concluded that a reasonable, and therefore permissible, reading of section 176(c) is that it applies only to nonattainment areas and those attainment areas subject to the maintenance plans required by section 175A of the CAA, as described below. Because the statutory language itself is ambiguous, there is no clear indication on the face of section 176(c) as to where the provision should apply. EPA has therefore looked to the statute as a whole to determine the appropriate application of the provision.

EPA believes that an important piece of evidence is the placement of section 176(c) within part D of the CAA, entitled "Plan Requirements for Nonattainment Areas," and specifically within subpart 1, entitled "Nonattainment Areas in General." EPA believes that all provisions within these parts should apply only in nonattainment areas, unless the overall weight of the evidence in a given section indicates some other legislative intent. As described here, EPA can find no such intent in section 176 to apply the conformity requirement to the full universe of attainment areas.

Certain participants in the discussion on this issue have indicated that section 176(c)(1)(B)(i), which requires that Federal activities not lead to any new violation of any standard in any area, must be interpreted as applying to all areas, including all attainment areas. However, the provision can be read, within the context of EPA's interpretation of section 176(c), as applying only to all areas subject to the provision—that is, all nonattainment and (for the reasons discussed further below) maintenance areas.

Despite extensive legislative history on section 176(c), no mention is made of the areas subject to the provision. Because of the significant burden that imposing conformity requirements will have, especially on smaller areas outside large urban centers, EPA believes that Congress would have discussed the provision's applicability to all attainment areas if it intended the provision to apply there despite its location within part D.

In contrast, EPA believes that both the statutory language itself and the legislative history support application of the conformity requirement to those attainment areas subject to maintenance plans under section 175A of the CAA. Section 176(c)(4)(B)(iii) explicitly requires EPA's conformity procedures to address how conformity determinations will be made with respect to maintenance plans. Further in describing section 176(c), one of the lead sponsors of the 1990 CAA Amendments stated that "to the extent that the transportation plan includes a period that extends beyond the attainment deadline for an area, section 176(c)(1)(B)(i) also requires that mobile sources not cause violations of a NAAQS during the maintenance period" (136 Congressional Record, S16073, October 27, 1990). In addition, the Senate Committee Report indicates that "[t]he conformity determination applies to each pollutant for which an attainment or maintenance plan is required" (Senate Report 101–228, page 29). These pieces of statutory and legislative evidence lead EPA to conclude that under a reasonable, and therefore permissible, reading of section 176(c), conformity should apply in all areas subject to maintenance plans, despite the general limitation of conformity requirements to designated nonattainment areas.

Application of conformity to only nonattainment areas and maintenance areas was the approach historically taken by EPA and DOT with respect to transportation activities. EPA does not see any reason to alter this approach in light of the 1990 CAA Amendments. It is true that EPA has in the past indicated that section 176(c) might apply to attainment areas with respect to other types of Federal activities (45 FR 21590, April 1, 1980, Advance Notice of Proposed Rulemaking on section 176(c) in general). However, EPA never took any formal rulemaking action based on such a legal interpretation of section 176(c). As explained above, based on section 176(c) as amended, EPA believes that it would be reasonable to interpret section 176(c) so that conformity applies only in nonattainment and maintenance areas.

EPA believes that the section 176(c) and legislative references to "maintenance plans" and the legislative reference to "maintenance periods" refer to the maintenance plans and maintenance periods described in CAA section 175A, the preceding section of the CAA. That section refers to maintenance plans required for redesignation under the CAA as amended in 1990, and the maintenance period to be provided by such plans. Thus, under the interpretation EPA is proposing to adopt today, the conformity requirements would apply, with respect to a particular pollutant, only to (1) those areas designated nonattainment for that pollutant and (2) those areas that, while designated attainment for that pollutant, are subject to a maintenance plan required by section 175A because they had been redesignated from nonattainment to attainment under the 1990 amendments.

EPA believes therefore that maintenance areas include all areas designated nonattainment pursuant to the 1990 CAA Amendments and subsequently redesignated to attainment subject to the requirement to develop a maintenance plan under section 175A of the amended CAA. EPA proposes that all of these areas be subject to the requirements of section 176(c).

Furthermore, conformity applies pollutant-by-pollutant; for example, an area designated nonattainment only for ozone must consider ozone impacts in its conformity reviews. EPA notes that presently there are relatively few maintenance areas for the criteria pollutants for which conformity does apply.

B. Non-Federal Projects

This proposal would apply only to those projects which receive Federal funds or approval under title 23 U.S.C. or the Federal Transit Act. EPA is proposing that non-federal highway and transit projects—those which receive no Federal funding and require no Federal approvals or actions—are not subject to conformity. However, the emissions analyses required for conformity determinations on transportation plans and TIPs would be required to account for the impacts of all regionally significant non-federal projects.

In the event of a nonconformity determination, only Federally assisted or approved projects would be delayed. However, State and local officials are encouraged to review and revise the total mix of projects in order to bring the area into conformity.

The CAA is ambiguous regarding the applicability of conformity to non-federal projects. Section 176(c)(2)(C) of the CAA says that "transportation projects" must be found to conform if they are adopted or approved by an MPO or any recipient of funds designated under title 23 U.S.C. or the Federal Transit Act. This could be read to apply conformity to any transportation project approved by a recipient of DOT funds, regardless of the project's actual source of funding. Under this interpretation, all projects by State Departments of Transportation would require conformity determinations, because the State Departments of Transportation receive some DOT funds. An alternative reading is that "transportation project," which is not defined anywhere in the CAA, means a Federally funded or approved project, and the "any recipient of funds" provision is included to cover Federal projects which will be built outside the jurisdiction of any MPO. The title of section 176, "Limitations on Certain Federal Assistance," suggests that Congress intended only Federally approved or assisted projects to be affected by the provisions of section 176(c). None of the legislative history clearly indicates that non-federal projects were meant to be subject to conformity, but none of it clearly contradicts such applicability.

EPA concludes that the better reading of the ambiguous statutory language is that section 176(c) only covers projects supported in some way or approved by FHWA or FTA. This conclusion is bolstered by the reference to title 23 or Urban Mass Transportation Act funds in defining the project sponsors whose projects will be subject to the conformity requirement, which indicates that the requirement should apply only to those of their projects which are funded through such sources; applicability to projects which are approved by FHWA or FTA, even if they are not FHWA/FTA funded, follows from the general requirement for Federal actions (including approvals) to conform to the applicable implementation plan. Further, the requirement to find transportation projects in conformity is located in section 176(c)(2)(C) following the introductory words "in particular" at the end of the first paragraph of section 176(c)(2). Those words indicate that all that follows merely expands on and clarifies the preceding text. The preceding sentence in the body of section 176(c)(2) restates the obligation of Federal agencies to make conformity findings, and thus clearly applies only to Federally supported or approved projects.

In addition, the introductory paragraph of section 176(c) clearly imposes the requirements of the provision only on Federal agencies and MPOs, which are entities created by Federal law to distribute Federal monies to Federally funded transportation projects. Finally, the one piece of legislative history that appears to speak most directly to this point states that the law "clarifies what is meant by requiring that activities assisted, supported or licensed by Federal agencies 'conform to' a [SIP]" (Senate Report 101–228, page 28). These indications, coupled with the title of section 176(c) applying only to Federal assistance, lead EPA to conclude that the term "project" in section 176(c) only refers to federally supported or approved projects.

In the past, EPA has interpreted the ambiguous general language in the initial paragraph of section 176(c) as it appeared in the 1977 CAA Amendments as covering all projects approved by MPOs, whether or not they were Federally funded or approved. See, for example, Arizona Federal Implementation Plan, 56 FR 5458, 5474 (February 11, 1991). However, detailed language was added to section 176(c) in the 1990 CAA Amendments which required EPA to reanalyze this issue. Although EPA concluded that the ambiguity should be resolved in favor of covering all projects under the introductory paragraph of section 176(c) as it stood alone in 1977, EPA's review of the new detailed language added in 1990 lead EPA to conclude the opposite. As described above, on reading the section as a whole, EPA believes that section 176(c) in its entirety applies only to federally supported or approved projects.

EPA believes that applying conformity only to federally funded or approved projects will not significantly

reduce the protection of air quality, and thus is consistent with the purpose of the CAA as a whole. State governments have the power to regulate non-federal projects. Further, many regionally important highways will require Federal approvals for connections to interstate highways or under other statutes, for example, wetlands protection permits under the Clean Water Act. Finally, as explained in the next paragraph, the transportation plan and TIP will be required to compensate for any adverse impact of regional emissions from non-federal projects.

The collective impact of non-federal projects will eventually affect the conformity of transportation plans and TIPs, because Federal and non-federal projects share the "budget" of motor vehicle emissions which meets implementation plan emission reduction milestones and demonstrates attainment. Therefore, there is a practical need for transportation and air quality planners to consider the emissions impacts of regionally significant non-federal projects in making conformity determinations. As a result, EPA would require regionally significant non-federal projects to be addressed in the regional air quality analyses of plans and TIPs, although these non-federal projects would not require project-level conformity determinations.

Although it would still be possible for non-federal project sponsors to add or modify projects without additional analysis after the plan has been found to conform, the next plan would have to offset any emissions increases above the implementation plan's emissions budgets. States which are concerned about the impact of non-federal projects may, of course, extend conformity criteria and procedures to them, with no formal involvement of DOT.

C. Regional Significance

EPA's proposal would require the impacts of "regionally significant" projects to be considered in the regional emissions analyses for plans and TIPs. EPA's use of the term "regionally significant" is intended to limit emissions analysis to those projects which would have significant impacts on regional travel, emissions, and air quality. EPA believes that the emissions and air quality impacts of regionally insignificant projects can be considered de minimis in relation to the plan and TIP regional emissions analysis.

EPA is proposing that a "regionally significant" transportation facility is a facility with an arterial or higher functional classification, or any other facility regardless of functional classification that serves regional travel needs and would normally be included in the modeling for the transportation network. Regional travel needs would include, for example, access to major activity centers in the region, to transportation terminals, and to and from the area outside the region.

EPA considered several options for defining "regionally significant," including a definition only according to functional level or a quantifiable threshold such as average daily traffic. Definition solely by functional level would pose difficulties because regional significance does not correspond exactly with functional level. Some collectors could be considered regionally significant, but defining all collectors as regionally significant would increase required analysis resources to impracticable levels. (Collectors are surface streets providing land access and traffic circulation service within residential, commercial, and industrial areas.)

Definition according to a quantifiable threshold would eliminate ambiguity. However, although transportation professionals have an intuitive understanding of which facilities are regionally significant, the choice of an appropriate threshold is not obvious. Definition according to a precise threshold could prevent transportation and air quality professionals from using their best judgment in cases where a facility is clearly significant or insignificant.

The proposed definition refers to functional classification, the intuitive understanding of regional significance, and professional judgment. Therefore, EPA believes it is the most likely to include truly significant facilities and exclude insignificant facilities.

IV. Actions Covered by This Rule

This rule addresses only transportation plans, programs, and projects which are developed, funded, accepted or approved under title 23 U.S.C. or the Federal Transit Act. For such highway (FHWA) and transit (FTA) projects which also require action by other Federal agencies (e.g., wetlands permits), the other Federal agencies will not be required to do a separate air analysis. Those Federal agencies may adopt the air analysis of the lead agency, or agency with primary responsibility, in order to make a conformity determination of their own.

Highway and transit projects which need approval from other Federal agencies but which are not funded or approved by FHWA or FTA are not covered by this rule, but they will be addressed in a forthcoming proposed rule. That proposed rule will provide that satisfaction of the criteria and procedures in today's rule would be sufficient for the highway and transit aspects of such other projects also.

This rule would require DOT and the MPO to make conformity determinations in order to adopt, accept, or approve a transportation plan or TIP developed pursuant to 23 U.S.C. 134 or the Federal Transit Act.

The conformity of existing transportation plans would have to be determined within eighteen months of the date of publication of the final rule. After eighteen months, the conformity status of the existing or previous transportation plan would automatically lapse.

This rule would also require conformity determinations for highway or transit projects which are proposed to receive funding assistance and approval through the Federal-Aid Highway program or the Federal mass transit program, or which require FHWA or FTA approval for some aspect of the project. For such projects, conformity determinations would be made by DOT, based on information provided by the project sponsor.

Certain highway and transit projects which by their nature are neutral in terms of emissions impacts would be exempt from conformity determinations, including most safety projects and operating assistance to transit agencies. However, implementation of these projects must not interfere with the timely implementation of TCMs. These neutral projects are listed in § 51.373 of the proposed rule.

As defined in this proposal, the term "transit project" would specifically not encompass operational actions such as route changes, service schedule adjustments, or fare changes.

Conformity determinations on such activities would be cumbersome, and they are associated with Federal action only indirectly through general operating assistance. FTA is specifically prohibited from becoming involved in these types of local decisions (49 U.S.C. app. 1608(d)). EPA believes that FHWA and FTA do not have sufficient control over the use of general operating funds to justify conformity findings with respect to each individual use of such funds. However, conformity determinations for plans, TIPs, and some projects would be required to consider the most recent and planned transit routes, fares, tolls, and other highway and transit system operational policies as background assumptions.

EPA is aware that in some areas transit routes and policies play an important role in total regional emission

levels, and some people believe that proposed changes in transit routes and fares should be subject to conformity review. EPA believes such an approach would not be feasible if applied to all types of changes to transit system operational policies. However, EPA invites comment on what type of limited application of conformity might be appropriate.

Although changes in road or bridge tolls which do not require Federal approval could significantly affect travel on the transportation network, the agencies adjusting road or bridge tolls should have flexibility, and conformity determinations on such activities would be cumbersome. Again, the link to Federal support of such activities does not appear sufficient to justify application of § 176(c). Such changes would in any case have to be considered in background modeling assumptions.

Pre-existing projects which received final NEPA approval (a categorical exclusion, Finding of No Significant Impact, or a record of decision on a Final Environmental Impact Statement) and a final conformity determination by FHWA or FTA prior to the effective date of the final rule would need no further conformity determinations unless there were a significant change in design concept and scope or a supplemental environmental document for air quality purposes were required. Otherwise, such pre-existing projects which are subject to this rule could not be implemented without a new conformity determination consistent with the requirements of the final rule.

V. Implementation Plan Revision

Section 176(c)(4)(C) of the CAA requires each State to submit an implementation plan revision which includes criteria and procedures for assessing conformity. The CAA directs EPA to require submittal of these implementation plan revisions by November 15, 1992, which is twelve months after the final rule was to have been promulgated. Because the promulgation of the final rule has been delayed and will not even be effective by November 15, 1992, and because the implementation plan revisions cannot reasonably be prepared without the final rule, it is not possible for EPA to require States to submit implementation plan revisions by that date. Therefore, EPA is proposing that the plan revisions be submitted within twelve months of promulgation of the final rule. EPA believes it is appropriate to give the States a year to develop and submit implementation plan revisions, as Congress anticipated. The direct requirements of the final rule will apply as a matter of Federal law to Federal agencies and MPOs, and will not depend upon the completion or approval of the State plan revision. Therefore, EPA believes it is reasonable to allow the States twelve months to submit their plan revisions, as the CAA originally intended.

EPA requests comment on the acceptable forms which the criteria and procedures may take, for example, a State statute or a State agency rule binding on MPOs. EPA notes that the CAA requires the criteria and procedures to be legally enforceable, and a public hearing must be held prior to their adoption by the State.

A State may include procedures in its conformity plan revision which are more stringent than those in the final Federal rule. For example, a State may choose to apply conformity statewide, in all its attainment areas as well as nonattainment areas. The Ozone Transport Commission may also recommend to EPA the application of conformity throughout the transport region, under § 184(c) of the CAA. To apply conformity in attainment areas, States would need State authorizing legislation and would have to develop appropriate criteria and procedures. The criteria and procedures in this rule were designed for nonattainment areas.

VI. Interagency Consultation and Public Participation

A. Interagency Consultation

This rule proposes that the implementation plan revision addressing conformity shall include well-defined interagency consultation procedures. Specifically, development of the implementation plan, the transportation plan, and the TIP would require consultation between representatives of the MPOs; State and local air quality planning agencies; State and local transportation agencies; other organizations with responsibilities for developing, submitting, or implementing provisions of an implementation plan required by the CAA; and local or regional offices of the EPA, FHWA, and FTA.

EPA believes that the consultation process will be most successful if it accommodates the structure of involved organizations and addresses existing relationships. By proposing that the States develop the details of their own consultation procedures, EPA is allowing States the flexibility to tailor the consultation process so it can be most effective in each State. To ensure that the procedures are thorough and well-considered, EPA has included in the proposed rule a list of issues which States must address through the design and operation of the consultation process.

EPA is proposing interagency consultation during the development of implementation plans as well as during the development of transportation plans and TIPs because it believes the early and continuous involvement of air quality and transportation agencies is crucial. For example, consultation during the development of motor vehicle emissions budgets is necessary to insure that the budgets are reasonable and to allow the transportation community to begin adjusting its planning. In addition, transportation and air quality planning documents use interdependent assumptions and analyses. Delaying consultation until planning documents are already developed does not allow enough opportunity for meaningful exchange or settlement of disputes. Furthermore, if consultation on a conformity determination were not begun until the draft conformity determination was released, the conformity finding could be delayed and transportation activities could be disrupted pending resolution of any disagreement over the basis for the final conformity determination.

Although it is not feasible to require EPA concurrence on conformity determinations themselves, EPA recognizes the importance of reaching agreement on the methodology of the analyses supporting conformity determinations. Therefore, EPA invites comment on whether to adopt this proposal's approach of simply requiring consultation with EPA on the choice of the models and associated methodologies to be used in hot-spot analyses and regional air quality modeling, or whether EPA concurrence with these decisions should be required.

EPA invites comment on what if any consequences the implementation plan should impose if the implementation plan's consultation process is not observed by the MPO or State and local air quality agencies. The proposed rule does not specifically address this question.

Today's proposal requires that the implementation plan revision establishing consultation procedures address the process for obtaining comment on draft documents prior to adoption. EPA expects that memoranda of understanding will be developed between DOT and EPA and/or the State air quality agencies which will address how comments on proposed conformity determinations will be handled. However, EPA requests comment on whether this rule should specifically require DOT to explicitly consider

EPA's (or the State air quality agencies') comments on proposed conformity determinations and notify EPA (or State agencies) of the disposition of its comments before taking final action on the conformity determination. This would be consistent with DOT's interim final rule on conformity (46 FR 8426, January 26, 1981).

B. Public Participation

EPA would also require the conformity implementation plan revision to include procedures which would provide a reasonable opportunity for public review and comment on conformity determinations and their supporting materials prior to formal action on a conformity determination, where otherwise required by law.

Public consultation procedures for the development of plans and TIPs (which will include the conformity determination) are being developed by DOT in response to requirements in the Intermodal Surface Transportation Efficiency Act (ISTEA) (Pub. L. 102–240). Therefore, EPA is not proposing specific public consultation procedures in this rule. However, States may need to adopt public consultation procedures in their implementation plan revisions before DOT publishes the ISTEA requirements.

VII. Description of the Proposal

A. Frequency of Conformity Determinations

EPA is proposing that events which would fundamentally affect the basis of a conformity determination—specifically, changes to transportation plans, TIPs, or air quality implementation plans—would automatically trigger a requirement for a new conformity determination. However, in no case could more than three years elapse between determinations on transportation plans and TIPs. If conformity were not redetermined according to these requirements, the conformity status of the plan and TIP would automatically lapse, and projects could not be approved.

The three-year timeframe is the least frequent allowed by the CAA. However, EPA believes it will adequately ensure that if triggering events are infrequent, conformity determinations would still be periodically updated to reflect the current transportation system and the most recent model revisions and planning assumptions.

EPA believes conformity determinations should be made frequently enough to ensure that the conformity process is meaningful. At the same time, EPA believes it is important to limit the number of triggers for conformity determinations in order to preserve the stability of the transportation planning process.

EPA is proposing that all amendments to transportation plans and TIPs involving non-exempt projects would require conformity determinations for the plans and TIPs. Plans and TIPs are the focus of regional emissions analyses, so any changes to these documents must be analyzed for their impact on transportation-related emissions in the aggregate before one can be assured of continued conformity.

A new transportation plan or plan revision would also require a new conformity determination for the TIP, because the TIP's conformity is determined in the context of the areawide transportation system. Changes to the plan, which describes the predicted areawide transportation system, could change the conformity status of a TIP. A new regional emissions analysis would not necessarily be required of the TIP's conformity redetermination if it could be qualitatively demonstrated that the plan's changes would not affect the analyses in the previous TIP conformity determination. Because plan revisions can be anticipated, EPA expects that MPOs will be able to coordinate plan revisions and new TIPs so that only one conformity determination on a TIP would be necessary. EPA's proposal allows a reasonable interval of six months after a plan is amended or a new plan is adopted during which the TIP could be revised and a new conformity determination made by the MPO and DOT.

EPA is proposing that certain other events would trigger a new conformity determination on the transportation plan within eighteen months. EPA believes eighteen months allows timely consideration of new information without disrupting or unreasonably compressing the transportation planning cycle. The triggers would not apply to TIPs because new TIPs or TIP amendments, which require conformity determinations, would already be occurring every one or two years. The triggering events include publication of the final rule and an implementation plan revision which changes a transportation-related emissions budget or which adds, changes or deletes TCMs.

Publication of the final rule on transportation conformity would trigger a conformity determination for the plan, in order to ensure that the plan conforms according to the final criteria and procedures. Otherwise, it is possible that a plan found to conform immediately before the publication of the final rule would remain in effect for up to three years without its conformity being redetermined according to the requirements of the final rule.

Another proposed trigger is EPA approval of an implementation plan revision which changes a transportation-related emissions budget or which adds or deletes TCMs. Because conformity exists in reference to the implementation plan, any changes to the implementation plan's emissions budget or TCMs necessitate a new determination. If the transportation plan must be revised to conform with the implementation plan revision, EPA believes eighteen months from the implementation plan approval would allow a reasonable period of time for the revision and the new emissions analysis. If the existing emissions analysis for the current transportation plan demonstrates that the current plan is consistent with the new implementation plan budget, a conformity finding can be made for the current plan. The transportation plan would not need to be revised and a new regional emissions analysis would not be necessary. However, such an action would not renew the life of the plan for three years; emissions analysis must occur at least every three years.

EPA requests comment on whether the triggering event should be EPA approval of the implementation plan revision, or the governor's submission of the implementation plan revision to EPA. This proposal would make the trigger EPA approval, because EPA believes transportation plans should not be required to conform to an implementation plan which does not have the force of Federal law and which may still need revisions to make it approvable under the CAA. Section 176(c)(1) specifically requires conformity to "an implementation plan" after it has been approved. However, because the implementation plan revision has undergone a public consultation process prior to its submission to EPA, the content of the revision is known before EPA approval. Therefore, it would be possible to use the implementation plan revision as the basis for conformity determinations even before EPA approval. There may be advantages to avoiding the delay associated with EPA processing of the implementation plan revision, particularly for additional TCMs which are already adopted or committed to by local agencies. However, more caution may be appropriate for revisions to emissions budgets and deletion or substitution of TCMs.

EPA is not proposing that other changes which could affect conformity determinations, such as the publication of new emissions models or the adoption of changes in planning assumptions, would necessarily trigger conformity determinations for the transportation plan. These changes would be incorporated as other triggers occur or at the time of the next periodic conformity determination, which will occur at intervals of no more than three years. Although ideally new conformity determinations would be made whenever new information becomes available, the stability of the transportation planning process requires that triggers for determinations be limited and predictable. Changes in emissions models or planning assumptions may occur too frequently to justify triggering a new determination.

B. Content of Transportation Plans

EPA is proposing requirements for how specifically projects must be defined in the transportation plan in order for their emissions to be estimated sufficiently for a conformity demonstration. EPA believes that transportation plans should be sufficiently specific to allow meaningful regional emissions estimates. However, the specificity necessary to quantify regional emissions depends on the sensitivity of an area's modeling capabilities. EPA is proposing two-tiered specificity requirements in order to accommodate the differing capabilities and resources of MPOs.

EPA is proposing the most specificity for plans in serious, severe, and extreme ozone areas and serious CO areas. After January 1, 1995, the proposed rule would require plans in these areas (hereinafter referred to as specific plans) to be specific enough to be analyzed using state-of-the-art travel demand network models. Because these areas have the worst air quality, they have the most need for accurate regional analyses.

In other areas, EPA would require that the transportation system envisioned for the future specifically enough to allow emissions from the plan to be quantified. Because they may not have network models, these areas would not require transportation plans which are as highly specific as those EPA is proposing for the serious and above areas. However, areas which have already been developing specific plans would be required to continue doing so.

EPA is proposing to allow areas which are "bumped up" to a serious classification two years to meet the more rigorous plan content requirements. This will allow these areas time to specify their networks and perform the other research and data collection activities necessary to develop network models and specific plans.

The proposed requirements would supplement other regulations governing the format or content of transportation plans. Furthermore, the degree of specificity required in the plan would not preclude the consideration of alternatives in the NEPA process or other project development studies. If the NEPA process were to result in a project with a design concept and scope significantly different from that in the plan or TIP, the project could still be found to conform under the proposed conformity criteria and procedures for projects which are not from a conforming plan and TIP.

C. Fiscal Constraints on Plans and TIPs

ISTEA requires that the transportation plan include a financial plan that demonstrates how the transportation plan can be implemented, indicates resources from public and private sources that are reasonably expected to be available throughout the plan's timeframe, and recommends any innovative financing. ISTEA also requires that prior to a project's inclusion in a TIP, full funding must be reasonably anticipated to be available within the time period contemplated for completion of the project. EPA anticipates that DOT will issue a rule or interpretation to more specifically implement these provisions.

EPA believes these ISTEA requirements will adequately ensure that the transportation activities analyzed for conformity can realistically be built, and therefore is proposing that plans and TIPs comply with the ISTEA requirements.

D. Summary of Proposed Criteria and Procedures

1. Pollutants and Types of Analyses

Because the definition of conformity in CAA section 176(c)(1)(B) refers to an activity's impact on the NAAQS, EPA would require conformity determinations to include analyses of local CO concentrations ("hot spots") in CO nonattainment and maintenance areas; analyses of PM_{10} hot spots in PM_{10} nonattainment and maintenance areas; regional analyses of CO in CO nonattainment and maintenance areas; regional analyses of ozone precursors (volatile organic compounds and nitrogen oxides) in ozone nonattainment and maintenance areas; regional analyses of nitrogen oxide (NO_x) in NO_2 nonattainment and maintenance areas; and regional analyses of PM_{10} and PM_{10} precursors such as VOC and NO_x if the applicable implementation plan identifies transportation-related precursor emissions within the area as a significant contributor to the PM_{10} nonattainment problem) in PM_{10} nonattainment and maintenance areas. Projects also would be required to be designed and funded to comply with PM_{10} control measures for control of fugitive dust from construction activities and any other transportation-related PM_{10} control measures in the applicable PM_{10} implementation plan. EPA would not require analyses of local ozone or NO_2 concentrations or precursor emissions because they are regional-scale pollutants.

Based on available emissions information, EPA believes highway and transit motor vehicles are not significant sources of lead or sulfur dioxide. Therefore, transportation plans, TIPs, and projects are presumed to conform to the applicable implementation plans for these pollutants.

If a fully approved implementation plan demonstrates that a constraint on regional PM_{10}, PM_{10} precursors, or CO emissions is not necessary to ensure attainment, those regional emissions tests would not apply for conformity. This would be the case if historical PM_{10} or CO violations were attributable to sources other than motor vehicles, or if CO violations can and will be solved by localized small-scale actions only.

2. Difference in Criteria and Procedures by Period of Time

The criteria and procedures for determining conformity would vary according to the period of time in which the determination is made. There are three periods of time outlined in this rule: the interim period (Phase I and Phase II), the control strategy period, and the maintenance period. A given area may be in different periods with respect to different pollutants.

Phase I of the interim period, which lasts until the effective date of the final rule, is governed directly by the provisions of the CAA. The EPA/DOT interim conformity guidance of June 7, 1991 is available as an informal joint interpretation of the statute with respect to those provisions. Phase II of the interim period would begin on the effective date of the final rule and would last until EPA approves or promulgates implementation plan revisions with reasonable further progress and attainment demonstrations. (Note: Phase II will terminate on different dates for different areas.) Approval of these

implementation plan revisions would begin the control strategy period, which would continue until the area is redesignated as an attainment area. After an area is redesignated to attainment, it would be considered in the maintenance period. Although the CAA requires no further planning actions or changes in control strategies after a certain number of years as a maintenance area (a maximum of twenty), there is no explicit end of the maintenance period.

The control strategy period and the maintenance period would have the same criteria and procedures for determining conformity. However, the interim period would have different criteria and procedures for regional analysis and project-level analysis from those that apply during the control strategy and maintenance periods.

EPA is proposing interim period criteria and procedures because the emissions budget test required in section 176(c)(2)(A) of the CAA cannot be applied until emissions budgets are established in the implementation plan. The CAA acknowledges the need for an interim period and establishes interim requirements in section 176(c)(3). Although the interim period discussed in the CAA lasts until the conformity plan revisions are approved, EPA is proposing that the interim requirements be extended until the control strategy plan revisions are approved, because it would be impossible to apply the emissions budget test prior to such approval. The interim criteria proposed today differ somewhat from those in the joint EPA/DOT June 7, 1991, guidance, particularly in the treatment of non-federal projects.

The statutory interim period criterion requiring regional analysis, which is in section 176(c)(3)(A)(iii) of the CAA, applies only to ozone and CO areas. EPA is now also proposing a requirement for regional analysis of PM_{10} and NO_x, with a somewhat different criterion, to ensure that there is no increase in the frequency or severity of existing violations and to ensure timely attainment of the standards for these pollutants during the interim period, as required by section 176(c)(1)(B).

3. Overview of Criteria by Type of Action

All actions. Conformity determinations for all actions would be required to use the most recent planning assumptions, as required by section 176(c)(1) of the CAA, and the most recent motor vehicle emission estimation model.

Plans and TIPs. Conformity demonstrations for plans and TIPs would be required to include regional emissions analyses or tests and demonstrate timely implementation of TCMs in applicable implementation plans. Regional analyses would be required for plans and TIPs because these documents address the areawide transportation system.

In the control strategy and maintenance periods, regional emissions from plans and TIPs would need to be consistent with the implementation plan's emissions budgets. This criterion is required by section 176(c)(2)(A) of the CAA. In the interim period, regional analysis would need to demonstrate that each plan and TIP contributes to reductions in emissions of volatile organic compounds (an ozone precursor) and CO. In PM_{10} and NO_2 nonattainment areas, regional analysis would also need to demonstrate that PM_{10} and NO_x emissions would not be increased from 1990 levels. Regional analysis in the interim period is required by sections 176(c)(1)(B) and 176(c)(3)(A)(iii) of the CAA.

Regional analysis requirements for TIPs would differ according to the specificity of the area's transportation plan. In some circumstances in areas with specific plans, the regional emissions criteria could be satisfied without a new regional emissions analysis, as described further below.

In all periods, plans and TIPs would be required to provide for the timely implementation of TCMs consistent with the schedules included in the air quality implementation plan. Provision for the implementation of TCMs in the implementation plan is required for plans and TIPs in the interim period by section 176(c)(3)(A)(ii) of the CAA, and for TIPs in all other periods by section 176(c)(2)(B). EPA is proposing that plans must also satisfy this requirement during the control strategy and maintenance periods in order to ensure conformity to the purpose of the implementation plan (see section 176(c)(1)(A)). During the control strategy period, requiring the plans to provide for the timely implementation of TCMs would also prevent delay in the timely attainment of any milestones, as required by section 176(c)(1)(B)(iii) of the CAA.

Projects which are from a conforming plan and conforming TIP. In areas with a specific plan, a regionally significant project would be considered to be "from a conforming plan" if the project were specifically identified in the currently conforming plan. A project which is not regionally significant in an area with a specific plan, and any type of project in an area without a specific plan, would be considered to come from a conforming plan if it were identified in the plan, or if it were consistent with the policies and purpose of the plan and would not interfere with other projects specifically included in the plan. The content requirements for transportation plans do not require these types of projects to be specifically identified in the transportation plan, although they may be.

A project of any type would be considered to be from a conforming TIP only if the project were specifically included in the currently conforming TIP, if the project's design concept and scope were adequate at the time of the TIP conformity determination to determine its contribution to the TIP's regional emissions, and if the project's design concept and scope had not changed significantly from those described in the TIP.

In areas other than CO and PM_{10} nonattainment and maintenance areas, projects would require no further analysis if it could be demonstrated that they were from a conforming plan and TIP. They would not require regional analysis because it would already have been performed for the conformity determinations on the plan and TIP. Section 176(c)(2)(C) of the CAA provides for this approach.

In CO and PM_{10} nonattainment and maintenance areas, conformity determinations for projects which are from a conforming plan and TIP would also need to be analyzed for their impacts on local CO and PM_{10} concentrations. During all periods, a finding would need to be made by the MPO and DOT that a project would not cause or contribute to any new localized CO or PM_{10} violation or worsen existing CO or PM_{10} violations, in order to satisfy the requirements of CAA section 176(c)(1)(B). During the interim period in CO nonattainment areas, projects would also need to eliminate or reduce the severity and number of localized CO violations. This is required in section 176(c)(3)(B)(ii) of the CAA.

All projects would have to be designed and funded to comply with PM_{10} control measures in the implementation plan, as required independently by the implementation plan.

Projects which are not from a conforming plan and conforming TIP. Projects which are not from a conforming plan and TIP would be those projects not identified in a conforming TIP, projects whose design concept and scope are significantly different than those described in the TIP

or were inadequate to determine emissions at the time of the TIP conformity determination, and in areas with specific plans, those regionally significant projects which are not specifically included in the plan.

Demonstrations of conformity for these projects would need to include regional analyses, analyses of local impacts in CO and PM_{10} nonattainment and maintenance areas, and an examination of the impacts on timely implementation of TCMs. These projects would be required to comply with PM_{10} control measures in the implementation plan, and there would need to be a conforming plan and TIP in place.

Case-by-case approval for projects which are not from a conforming plan and TIP is provided for in section 176(c)(2)(D) of the CAA. These projects would require a regional analysis which considers emissions from the project together with emissions from the plan and TIP. The analysis would have to demonstrate that if the project were added to the plan and TIP, the plan and TIP would still conform. This regional analysis could be performed at the time of the plan or TIP conformity demonstrations if so desired.

In CO and PM_{10} nonattainment and maintenance areas, the local impacts of all projects would need to be considered. Therefore, the proposed requirements for projects not from a conforming plan and TIP are the same as those discussed for projects which are from a conforming plan and TIP.

In any area, projects which are not from a conforming plan and TIP could not conform if they would interfere with the implementation of any TCM in the implementation plan.

E. Discussion of Criteria and Procedures

1. Latest Planning Assumptions

Conformity determinations for all actions would need to be based upon the estimates of current and future population, employment, travel, and congestion which have been most recently developed by the MPO or other agency authorized to make such estimates and approved by the MPO. In addition, the most recent road and bridge tolls, transit routes, fares, and other transit system operational policies would have to be considered in conformity determinations. Authorization to make estimates may be a matter of State law, and the implementation plan revision establishing conformity procedures should document the agency authorized to make the estimates.

Although revisions to planning assumptions would not trigger a conformity determination, the transportation and air quality modeling required for future conformity determinations would need to reflect the revised assumptions.

When a conformity determination is based on a previous analysis and no new transportation or air quality modeling is otherwise required (as may occur for TIPs which are from a specific plan), EPA would not require new modeling solely to incorporate revised assumptions.

2. Latest Emissions Model

EPA is proposing a grace period after the release of a new motor vehicle emissions model in order to allow planners time to install it and understand its changes. EPA and DOT would consult to determine the length of the grace period, which would be a minimum of three months and a maximum of two years. In this way, EPA and DOT could allow a longer grace period within the two-year limit when it might be necessary for States to revise their implementation plans to establish new emissions budgets consistent with the new models, or when transportation plans must be revised very substantially.

EPA believes that this grace period is consistent with the four-part test for grandfathering established in *Sierra Club* v. *EPA*, 719 F.2d 436 (D.C. Cir. 1983). These tests include whether the new rule represents an abrupt departure from previously established practice, the extent to which a party relied on the previous rule, the degree of burden which application of the new rule would impose on the party, and the statutory interest in applying the new rule immediately. In this case, use of a new emissions model is clearly an abrupt departure from use of the prior emissions model. Ongoing planning using the prior model would clearly have relied on the existence of and ability to use the old model. Furthermore, it would impose a significant burden on planners to stop in midstream and immediately redo ongoing planning using the new model. These factors taken together appear to outweigh any statutory interest in requiring use of the new emissions model effective immediately upon release.

EPA believes that the appropriate amount of time for planners to incorporate use of the new emissions model will vary according to the circumstances of the individual situation, and is thus providing for a variable grace period keyed to the needs of the situation. For instance, if the new model produces emissions estimates which are significantly higher than had been expected using the previous model, States may wish to revise their attainment demonstration to allow an increased motor vehicle emissions budget. EPA believes that while States are making this decision, consistency with the implementation plan's emissions budget should be demonstrated using the previous model, which was also used to develop the implementation plan. Such a grace period would last no more than two years and would allow States time to reconcile the emissions budget with the new model without disrupting ongoing transportation activities.

States may also wish to revise the implementation plan's motor vehicle emissions budget if the new model produces emissions estimates which are significantly lower than had been expected. In this case, the State may wish to allocate the budget windfall to stationary sources. A grace period would prevent new transportation activities from consuming the budget windfall before the State had made its allocation decisions.

3. Timely Implementation of TCMs

In order for a TCM to be considered to be implemented "consistent with schedules included in the applicable implementation plan," as required by section 176(c)(2)(B) of the CAA, the TCM would have to be planned and programmed consistently with both the definition and schedule included in the implementation plan. That is, the TCM's physical arrangement, legal provisions, pricing policies, and other action items would have to be consistent with those described for the TCM in the implementation plan. However, the TCM would not be required to demonstrate that it has achieved the predicted effect on emissions or personal behavior in order to be considered consistent with the implementation plan, unless the implementation plan explicitly provided such a requirement.

EPA believes that the requirement for timely implementation in section 176(c)(2)(B) applies only to those TCMs which are eligible for funding under title 23 U.S.C. or the Federal Transit Act. The plan and TIP must avoid interfering with non-federally funded TCMs, however, and in this sense provide for their implementation to the extent of the plan and TIP's authority.

TCMs which are being implemented consistent with the schedules in the implementation plan could be provided for in any manner, including funding solely by State, local, or private sources. If the TIP does not include projects

which are non-federally funded, the conformity determination can be made if there is material accompanying the TIP which provides documentation that those TCMs which are eligible but not proposed for Federal funding are being implemented consistent with the schedules in the implementation plan.

EPA considered several mechanisms by which a plan and TIP could provide for the expeditious implementation of TCMs which have been delayed and are therefore currently planned and programmed on a schedule which is not consistent with the schedule in the implementation plan. The central issues involve how much effort should be required to close the schedule gap, and how to prevent further delays from occurring.

One means of providing for the expeditious implementation of TCMs involves the use of Federal funds. For example, EPA considered requiring TCMs which are eligible for Federal funding and are behind the schedule in the implementation plan to receive maximum priority in Federal funding. However, DOT reports that a requirement for Federal funds to be set aside for TCMs is not statutorily permissible under title 23 U.S.C. and the Federal Transit Act. At the same time, EPA believes that simply requiring Federally fundable TCMs which are behind schedule to be included in the next plan and TIP would not be sufficient, because this approach would not address the sources of the delays in implementation.

Therefore, EPA is proposing that if TCMs which are in the implementation plan and eligible for Federal funding are behind schedule, the TIP may be found to conform only if past obstacles to implementation have been identified and are being overcome, and if State and local agencies with influence over approvals or funding are giving TCMs maximum priority. This approach accommodates unforeseen obstacles to implementation, but prevents a positive conformity determination until all possible actions to overcome the obstacles are being pursued.

In addition, if Federal funds have been programmed for a TCM but the funds have not been obligated and the TCM is behind schedule, this proposal would not allow those funds to be reallocated to any TIP projects which are not TCMs. If there were no other TCMs in the TIP, those funds could be reallocated to projects which are eligible for Federal funding under ISTEA's Congestion Mitigation and Air Quality Improvement Program (CMAQ). Under ISTEA, no CMAQ funds may be provided for a project which will result in the construction of new capacity available to single occupant vehicles, unless the project consists of a high occupancy vehicle facility available to single occupant vehicles only at other than peak travel times.

EPA believes it is unreasonable to find a plan or TIP in nonconformity (and therefore withhold Federal funds for all TIP projects) until TCM implementation is returned to its schedule. Such an approach does not allow for uncontrollable delays in TCM implementation. However, EPA requests comment on whether the rule should require that when a TCM falls behind the schedule in the implementation plan, the State must submit an implementation plan revision with a new schedule for implementation of the TCM and the required demonstration that adequate legal authority and resources exist to carry it out.

Although today's proposal would not prohibit a finding of conformity simply because a TCM is behind schedule, the regional emissions analysis would not be permitted to assume emissions reduction credit from a TCM which is behind schedule until its implementation is assured. This would prevent conformity findings from being based on unrealistic assumptions, and it would provide an incentive to implement the TCM which is behind schedule or some other TCM with similar emissions reduction potential.

EPA's proposal would not allow TCMs to be approved or funded in the absence of a conforming plan and TIP. The effects of TCMs must be analyzed in the context of the entire transportation system, because the effects of TCMs may depend on how they are incorporated in that overall scheme.

Definition of a TCM. As defined in this proposal, "transportation control measures" would include those transportation measures specifically identified and committed to in the applicable implementation plan. In order to ensure that all such TCMs can be clearly identified by all affected units of government and other interested parties, States are encouraged to specifically designate such measures as TCMs in their implementation plans.

In order to facilitate early agreement on the responsibilities of the transportation community, EPA would require the interagency consultation process to develop a list of TCMs in the implementation plan. EPA believes that TCMs need to be clearly and specifically defined in order for the transportation community to effectively provide for their timely implementation. Therefore, EPA believes TCMs in the implementation plan must be specific in terms of scale, location, and the process of implementation, enforcement, monitoring, and maintenance. The CAA requires States to hold public hearings before they may adopt an implementation plan. Because of the conformity implications associated with including TCMs in the implementation plan, EPA believes it is especially important for the public to be made aware of the TCMs in the implementation plan.

4. Projects From a Conforming Plan and Program

Section 176(c)(2)(C) of the CAA allows projects which come from a conforming plan and TIP to be found to conform without further regional analysis. Federal projects which are not demonstrated to come from a conforming plan and TIP would require regional analysis consistent with the requirements of section 176(c)(2)(D). EPA believes that the proposed interpretation of "from a conforming plan and TIP" would ensure that those projects which have already been considered in the plan and TIP's regional analysis would be exempted from further regional analysis.

5. Localized CO or PM_{10} Violations

EPA is proposing to require quantitative hot-spot analyses only when qualitative demonstrations cannot clearly demonstrate that the project would not cause or contribute to a new localized CO or PM_{10} violation or increase the frequency or severity of an existing violation. Not every project needs quantitative modeling to determine its impacts on localized concentrations, and allowing qualitative analyses in some circumstances would allow conservation of analysis resources. Because any possibility of a new or worsened violation would require a quantitative analysis, allowing the option for qualitative analysis would not diminish air quality protection.

A seemingly new violation could be considered to be a relocation and reduction of an existing violation only if it were in the area substantially affected by the project and if the predicted design value for the site would be less than the design value without the project—that is, if there would be a net air quality benefit. (The design value is the standardized representation of the current ambient pollution level.)

EPA firmly believes that some reasonable allowance of this sort is necessary to accommodate projects which may move a hot spot a short distance, but which improve air quality

overall. EPA is aware of concerns that this allowance may be vague due to the lack of definition of "area substantially affected by the project." If that area is too large, it would not be appropriate to consider a violation a relocation of an existing one. However, EPA believes that the size of the area cannot be established upfront for all situations, as it will depend heavily upon local circumstance and meteorology. Consequently, EPA believes that this must be determined on a case-by-case basis in the context of the conformity determination. EPA requests comment on other approaches or definitions which also provide a reasonable interpretation of "new" violations.

This criterion could be satisfied for a project from a conforming transportation plan or TIP regardless of any impact which the project may have on actual or potential regional-scale emissions, provided all other applicable criteria are satisfied.

EPA and DOT plan to develop guidance on methods for modeling PM_{10} hot spots.

Construction-related activities. EPA believes that conformity should address long-term emissions from the transportation system, and that conformity should not prevent project implementation because of temporary emissions increases. In addition, the NEPA process provides the most appropriate forum to analyze construction-related emissions impacts and to establish mitigation measures.

Analyses and findings regarding localized CO and PM_{10} concentration impacts would not have to include construction-related activities which cause temporary and self-correcting increases in local concentrations. Temporary and self-correcting increases are defined as those which occur only during the construction phase and last five years or less at any individual site. Each site which is affected by construction-related activities would be considered separately, using established "Guideline" methods.

Although construction-related fugitive dust contributes to PM_{10} nonattainment in many areas, the extent of the problem is not well known. Nonattainment areas differ greatly in their potential for hot spots, and within an area there may be variations according to the season and the site. Areas with dust problems have been crafting strategies to demonstrate attainment utilizing available emissions estimation techniques and modeling, but there are continuing efforts to better quantify construction dust emissions and control measure effectiveness. EPA requests comment on what evidence must be developed and considered when determining that no new violations will be caused or existing violations worsened. The interagency consultation process would have to address what procedures are appropriate.

PM_{10} hot spots from bus terminals and transfer points. Although EPA expects that typically-sized diesel bus terminals and transfer points will not cause or contribute to new PM_{10} violations, EPA believes it is practical to require a determination to that effect. EPA requests comment on allowing DOT to make a categorical determination based on appropriate modeling of various terminal sizes and configurations if it believes this would make the planning process more certain and efficient. The modeled scenarios used to make the categorical determinations would need to be derived in consultation with EPA, and more refined analysis would be necessary for projects which do not meet the parameters of the modeled scenario.

Other PM_{10} hot spots. Generally, EPA believes that direct vehicle PM_{10} emissions are capable of causing violations only in situations of unusually heavy diesel truck/bus traffic and limited dispersion, such as street canyons. FHWA and FTA projects may affect the density of diesel vehicle traffic on such streets. EPA requests comment on requiring quantitative analyses in order to satisfy this hot-spot criterion only for sites at which violations have been verified by monitoring and others which have essentially identical dispersion conditions and diesel vehicle traffic (including sites near one at which a violation has been monitored).

Increased diesel transit bus service at sites with known violations may be a concern. However, the only relevant Federally-supported activity which is subject to conformity is the purchase of new buses for a major expansion of the fleet. EPA believes that new bus purchases are not causally related to the worsening of PM_{10} hot spots. EPA therefore proposes that conformity determinations for new bus purchases would not be required to address localized PM_{10} violations. In addition, because of the more stringent PM_{10} standard now in effect for urban buses, which is being phased in from 1991 to 1994, all current and future bus purchases will put significantly cleaner vehicles on city streets.

6. Consistency With Emissions Budgets

Emissions budgets. The implementation plan's demonstration of reasonable further progress and attainment will be based on certain projected motor vehicle emission levels for future years. These motor vehicle emissions will be the emissions budget for later conformity determinations. Thus, the budget will be defined for a number of future dates, depending on the reasonable further progress and attainment showings required for the area.

States will need to make sure that the motor vehicle emissions budget is stated clearly and unambiguously in the implementation plan to facilitate future conformity determinations. EPA would allow an area to have a single areawide budget for each criteria pollutant or precursor for which it is in nonattainment. However, because photochemical grid models estimate vehicle emissions for many small grid squares, States would also have the option to specify subregional emissions budgets. Thus, the implementation plan could either establish a budget using the sum of vehicle emissions from all grids in the area, or it could divide the area into major subareas and establish a budget for each. Subregional budgets would provide additional assurance that through future conformity determinations transportation plans and programs will produce emission patterns that will achieve attainment.

In some nonattainment areas the implementation plan's attainment demonstration may show that motor vehicle emissions are not an important part of the nonattainment problem. This is most likely with PM_{10} violations near industrial sources. In such a situation, the implementation plan may establish no budget for motor vehicles and explicitly provide that no regional emissions tests are needed for conformity determinations. EPA will closely scrutinize such claims before approving the implementation plan.

Need for analysis of long-term regional emissions. Because emissions budgets will address a timeframe which is longer than any single TIP, demonstration of the TIP's consistency with the implementation plan's budget should be done in the context of the long-term transportation system. Therefore, EPA's proposal would require regional analyses of TIPs to include all expected regionally significant projects in the timeframe of the plan, regardless of their funding source.

In some areas, plans will describe future actions specifically enough to allow comprehensive regional analysis with network models. In these areas, as described below, EPA would require the TIP's conformity determination to use the plan's regional analysis. In areas without specific plans, the plan's

regional analysis will most likely rely on demographically-based projections and adjustments to current VMT and emissions (based on planned TCMs and any regionally significant projects that are identified). These regional analyses would not define projects and estimate emissions with sufficient detail to ensure that any TIP derived from the plan is consistent with the emissions budget. In addition, there would be much flexibility to place newly conceived projects in the TIP which were not identified in the plan. Therefore, EPA would also require a regional analysis of the TIP in areas without specific plans.

TIPs from specific plans. Under this proposal, a TIP which is from a specific plan could demonstrate consistency with the emissions budget without additional regional analysis. EPA believes that if the TIP is financially feasible and consistent with the plan, it is appropriate to rely on the regional analysis which has been performed for the plan.

For the TIP to be considered financially feasible, the TIP would have to be consistent with the Federal funding which may be reasonably expected for the timeframe of the TIP. Necessary State/local matching funds would also have to be consistent with the revenue sources expected over the same period.

For the TIP to be considered consistent with the plan, the following conditions would have to be satisfied: (1) The TIP would have to contain all regionally significant projects which must be started in the TIP's timeframe in order to achieve the highway and transit system envisioned by the plan in its horizon years; (2) all TIP projects which add or modify regionally significant highway or transit facilities would have to be part of the specific highway or transit system envisioned in the plan's horizon years; and (3) there could be no regionally significant TIP projects which have a design concept or scope different from those in the plan.

The tests for financial feasibility and consistency with the plan would help ensure that the projects assumed in the plan will be built, and that the TIP includes no projects different from those assumed in the plan's analysis.

If the TIP is not financially feasible, EPA would require the TIP to be amended until feasibility can be demonstrated.

If the TIP's consistency with the plan cannot be demonstrated, EPA is proposing that either the TIP or the plan must be amended. Thus, if the TIP includes projects which are not from the plan or if the TIP does not include projects necessary for the plan's envisioned network, either the plan would need to be amended and reanalyzed for conformity, or the TIP would need to be amended to be consistent with the current plan. If the plan is amended to be consistent with the proposed TIP, and the plan is found to conform after a new regional analysis, no further analysis of the TIP would be required.

EPA would require the plan and/or TIP to be amended to be consistent before a conformity determination can be made for the TIP so that the plan's regional analysis can be the basis for TIP and project conformity determinations in the future. Because the conformity of each future TIP will depend on its relationship to the plan, additions or deletions to the envisioned transportation network must be reflected in the plan.

EPA requests comment on whether there should be a distinction in the regional emissions analysis requirements between specific plans and non-specific plans, because metropolitan planning under ISTEA will require future transportation plans to define project design concept and scope sufficient to determine conformity.

Projects not from a conforming plan and conforming TIP. In areas without specific plans, EPA would require all projects not from a conforming plan and TIP to be regionally analyzed. The regional analysis would have to estimate the emissions expected from the transportation network if the proposed project, the currently conforming plan and TIP, and all other regionally significant projects expected in the nonattainment or maintenance area are implemented. The analysis would also have to account for the emissions of previously approved projects which were not from a plan and TIP. This approach is consistent with section 176(c)(2)(D) of the CAA.

In areas with specific plans, EPA is proposing that projects could be found to conform without additional regional analysis if they are consistent with the plan, even if they are not specifically included in the latest conforming TIP. A demonstration of consistency would require that regionally significant projects are part of the specific system envisioned in the plan's horizon years which has been analyzed for emissions, even though the projects are not formally included in both the plan and TIP. A demonstration of consistency with the plan would also have to show that allocating funds to the project would not delay the implementation of those projects in the transportation plan or TIP which are necessary to achieve the highway and transit system envisioned by the plan.

If a project is not consistent with a specific plan, EPA would require additional regional analysis as described for projects which are not from a conforming plan and TIP in areas without specific plans.

EPA anticipates that projects not from a conforming plan and TIP will be either newly conceived projects not expected when the TIP was prepared, or projects which are in the nonattainment or maintenance area but outside the metropolitan planning area. When the projects which are not from a plan and TIP are known at the time of the plan and TIP conformity determination, as in the latter case, only one regional analysis may be necessary. In that case, the plan or TIP's regional analysis would include those projects which are not from a TIP, and the analysis would have to demonstrate that the plan or TIP together with the extra projects is consistent with the emissions budget.

Special provisions for areas not required to demonstrate reasonable further progress and attainment. Nonattainment areas which are not required to demonstrate reasonable further progress and attainment may not have an emissions budget. Therefore, EPA is proposing special provisions for rural ozone nonattainment areas, marginal ozone areas, submarginal ozone areas, transitional ozone areas, incomplete data ozone areas, moderate CO areas with a design value of 12.7 ppm or less, and not classified CO areas. In addition, maintenance areas may not have a motor vehicle emissions budget in the applicable maintenance plan if that plan was approved under the provisions of the 1977 CAA, rather than the new provisions of the 1990 CAA.

During the control strategy and maintenance periods, these areas would continue under the interim requirement to contribute to emissions reductions, unless they choose to submit an implementation plan revision with an attainment demonstration and emissions budget. If an area establishes an emissions budget, it would have to demonstrate that plans, TIPS, and projects not from a plan and TIP are consistent with the emissions budget.

The interim requirement to contribute to emissions reductions may be stricter than an emissions budget test. For example, an attainment demonstration may show that an area could have some emissions increases and still meet its attainment deadline.

7. Eliminate or Reduce the Severity and Number of Localized CO Violations

During the interim period, all projects in CO nonattainment areas would have to demonstrate that they would eliminate or reduce the severity and number of localized CO violations in the area substantially affected by the project. The number of violations resulting from the project's implementation would have to be less than the number of violations predicted without the project. The predicted design value for the site after the project's implementation would have to be less than the design value without the project.

As described above, EPA is proposing to require quantitative hot-spot analyses only when qualitative demonstrations cannot clearly indicate that the project would eliminate or reduce the severity and number of localized CO violations.

This interim requirement for CO nonattainment areas is established in section 176(c)(3)(B)(ii) of the CAA. EPA is proposing this requirement only in the context of localized CO violations, because regional violations are addressed by the requirement to contribute to reductions in CO emissions, as discussed below. This criterion could be satisfied for a project from a conforming transportation plan or TIP regardless of any impact which the project may have on actual or potential regional-scale emissions, provided all other applicable criteria were satisfied.

8. Contribute to Emission Reductions in Ozone and CO Areas

Overview. EPA is proposing that during the interim period, plans, TIPs, and projects not from a conforming plan and TIP would have to contribute to reductions in ozone precursor emissions (VOC) in ozone nonattainment areas and in CO emissions in CO nonattainment areas. A regional analysis would have to demonstrate that emissions from the transportation system if the proposed action(s) were implemented would be less than the emissions from the transportation system without the proposed action(s).

The regional analysis would establish a "Baseline" and "Action" scenario and analyze emissions from each scenario for certain future years. The analysis years would depend on the action being proposed, but would always include the attainment year. For each analysis year, the emissions predicted from the "Action" scenario would have to be less than those predicted from the "Baseline" scenario.

Although EPA is not proposing to require NO_x reductions in ozone areas during the interim period, States may require such reductions in their implementation plan revisions which establish the criteria and procedures for determining conformity.

Rationale. Section 176(c) (3) (A)(iii) of the CAA establishes the interim requirement for regional analysis in ozone and CO areas, which will eventually be replaced by a requirement for emissions budget tests during the control strategy and maintenance periods. The CAA requires plans and TIPs to "contribute to annual emissions reductions consistent with sections 182(b)(1) and 187 (a)(7)," which require reasonable further progress and attainment demonstrations.

However, the implementation plan revisions including these demonstrations will not exist during the interim period. Thus, the exact percentage reduction required from mobile sources will not be known. Therefore, reductions consistent with the reasonable further progress and attainment demonstrations could mean either the entire fifteen percent reduction by 1996 required for moderate and above ozone nonattainment areas for reasonable further progress, and arbitrary annual percentage reduction, or any nonzero reduction.

EPA does not believe that Congress intended the entire fifteen percent emission reduction to be achieved in motor vehicle emissions. Such an extreme measure would have been clearly stated. Sections 182(b)(1) and 187(a)(7) refer only to reasonable further progress, not the fifteen percent requirement; there is not a fixed percentage required for CO areas to demonstrate reasonable further progress.

In addition, EPA does not believe it is appropriate to require specific annual emissions reductions before they have been established in the reasonable further progress and attainment demonstrations. EPA believes the States should be allowed to decide how much reduction to require from motor vehicles and how much to require from stationary sources. Furthermore, until the implementation plan's emissions inventories are submitted, it will not be possible to determine the baseline from which emissions must be reduced. Therefore, EPA is interpreting the CAA's interim requirement to mean that plans, TIPs, and projects not from a conforming plan and TIP must contribute to emission reductions by any amount.

EPA believes that this interpretation is consistent with the statutory requirement. Section 176(c)(3)(A)(iii) requires contributions to annual emissions reductions consistent with sections 182(b)(1) and 187(a)(7). Section 187(a)(7) does not require any specific numerical amount of emission reduction, merely requiring such annual emission reduction as is necessary to demonstrate attainment. Section 182(b)(1) actually imposes two separate requirements. It first requires VOC reductions of 15% over six years, and then in a separate sentence requires such annual reductions as necessary to provide for attainment. EPA believes that the proper interpretation of § 176(c)(3)(A)(iii) is that by its own terms it refers only to the annual emission reductions in the second sentence of § 182(b)(1). Thus, areas are not constrained by any predefined percentage reduction for purposes of demonstrating conformity. Areas must simply demonstrate that activities contribute to annual emission reductions, which they may do by simply producing some positive emission reductions.

There is some reference in the legislative history that appears to indicate that Congress intended to impose a 15% reduction requirement on conformity demonstrations (136 Congressional Record, S16972, October 27, 1990). However, this legislative language simply misinterprets the clear reference in the statutory language to the annual emission reduction requirements in sections 182(b)(1) and 187(a)(7), rather than the 15% over six years requirement in section 182(b)(1). EPA agrees with the legislators that mobile source emissions should not be allowed to increase during the development of implementation plan emission budgets, but EPA believes that this requirement is met by showing some positive emission reduction.

A concern has been expressed that there may be long delays in establishing emission reduction targets for conformity purposes. These delays could occur because of delays in submitting emission budgets, because of the time which can elapse between adoption of budgets and formal revision of the implementation plan by EPA, or for other reasons. Because emission reduction targets are a key aspect of the conformity requirements, EPA is requesting comment on ways to alleviate the potential problems associated with delays. One specific suggestion which has been offered would place a cap on CO and ozone precursors during the interim period which is equal to the 1990 base year inventory of these pollutants, and no credit would be given for reductions in emissions from tailpipe standards. EPA notes that in the General Preamble for the Implementation of title 1 of the

Clean Air Act Amendments of 1990 (57 FR 13498, April 16, 1992), EPA rejected such an approach in the context of CAA section 182(d)(1)(A), which requires TCMs to offset growth in emissions from growth in VMT in severe and extreme ozone nonattainment areas and serious CO nonattainment areas. EPA believes this approach would have drastic implications. Since VMT is growing at rates as high as four percent per year in some cities, draconian measures such as mandatory no-drive restrictions would be necessary to achieve reductions from 1990 emission levels without credit for tailpipe standards. However, EPA is interested in other more workable approaches to handle the potential problems with delayed emissions budgets.

"Baseline" and "Action" scenarios. The regional emissions analysis would have to demonstrate that the emissions from the transportation system in the milestone and attainment years, if it included the proposed action and all other expected regionally significant projects (the "Action" scenario), would be less than the emissions from the current transportation system in the milestone and attainment years (the "Baseline" scenario). This "Baseline"/"Action" comparison would be required only during the interim period, except in areas which are not required to demonstrate reasonable further progress and attainment, as described above.

The "Baseline" scenario would include all in-place regionally significant highway and transit facilities, services, and activities; all ongoing travel demand management or transportation system management activities; and completion of all regionally significant projects in the nonattainment area that are currently under construction, undergoing right-of-way acquisition, come from the first three years of a previously conforming plan and/or TIP, or have completed the NEPA process (regardless of funding source).

If no major steps to advance a project have occurred within three years after completion of the NEPA process, 23 CFR 771.129 requires a written re-evaluation of the final NEPA document. If the written reevaluation requires a new NEPA document for design concept and scope or air quality reasons, a new conformity determination would be required for the project. This would deter an area from artificially inflating the "Baseline" scenario by including projects which are not actually being built.

The "Action" scenario is the future transportation situation that will result from the implementation of the action (i.e., plan, TIP, or project not from a plan and TIP) and other planned highway and transit projects, regardless of funding source. This would include all facilities, services, and activities in the "Baseline" scenario (unless the "Action" scenario specifies the deletion of some "Baseline" facilities, services, or activities); the completion of all TCMs and regionally significant facilities, services, and activities associated with the proposed action which will be operational by the analysis year; and the completion of expected regionally significant non-FHWA/FTA highway and transit projects that have clear funding sources and commitments leading to their implementation and completion by the analysis year. Although these non-FHWA/FTA projects may not be included in the plan or TIP, the "Action" scenario must account for all regionally significant projects in the aggregate in order to give a realistic approximation of the regional emissions burden.

Because the "Action" scenario would include non-FHWA/FTA projects, EPA would also allow the "Action" scenario to include non-FHWA/FTA TCMs which have been fully adopted and/or funded since the last conformity determination on the action. The "Action" scenario could also include the incremental effects of any non-FHWA/FTA TCMs which have been modified since the last conformity determination on the action to be more stringent or effective. These TCMs would not have to be identified in the implementation plan, but they would have to be fully adopted and/or funded in order to receive emissions reduction credit.

9. No Increase in Emission in PM_{10} and NO_2 Areas

EPA is proposing that emissions in PM_{10} and NO_2 nonattainment areas could not increase above 1990 levels during the interim period. EPA is proposing this requirement, rather than the "Baseline"/"Action" comparison proposed for ozone and CO areas, because the CAA does not include specific interim requirements for contributions to regional emission reductions in PM_{10} and NO_2 nonattainment areas. Furthermore, EPA believes that requiring a build/no-build comparison in PM_{10} and NO_x areas could have undesirable consequences which were unanticipated by Congress. A ceiling on NO_x and PM_{10} emissions at their 1990 level is proposed because the definition of conformity prohibits any increase in the frequency or severity of existing violations.

EPA believes it is reasonable to assume that when Congress was addressing ozone and CO, it established a build/no-build test under the then-accepted belief that a well-designed "build" scenario could reduce emissions without reducing VMT itself. In fact, the available emissions models of that time indicated that congestion relief measures can reduce ozone and CO emissions in any area by improving speeds. EPA notes that Congress reserved its VMT-oriented TCM requirements for only the areas with the very worst air quality. (See, for example, sections 182(d)(1)(A) and 187(b)(2).) This indicates that Congress expected most areas affected by conformity to have some tolerance for VMT growth.

There is no indication that Congress was aware that in many cases, NO_x emissions and PM_{10} emissions (depending on roadway type and classification and surface particulate loadings) increase with improved traffic flow and increased speeds. Also, there is no indication that Congress considered the potential for increased PM_{10} emissions from increased use of diesel transit buses. Both of these effects may make it difficult for a "build" scenario to demonstrate emissions reductions, other than by reducing VMT itself below what would otherwise occur. EPA does not believe Congress intended difficult VMT reductions in the interim period. Because EPA is not certain what degree of VMT reduction might be needed to pass a build/no-build comparison, and because the CAA Amendments do not appear to require it, EPA is not proposing a build/no-build comparison during the interim period in PM_{10} and NO_x nonattainment areas.

Instead, EPA believes that preventing emissions from increasing above 1990 levels would be sufficient to prevent the exacerbation of existing violations during the interim period. This will allow speed increases and associated increases in emissions, if these are offset by fleet turnover and other elements of the plan or program, such as paving or cleaning roads. Because PM_{10} and NO_x modeling for plans and TIPs is less common than VOC and CO modeling, EPA is not certain of the emissions impact and compliance difficulty of this approach as compared to a build/no-build approach. EPA therefore invites comment on whether the proposed approach is appropriate and feasible.

EPA believes 1990 is the most reasonable year to use as a baseline because it is the year the CAA amendments were enacted. Although there has been some decrease in NO_x emissions due to fleet turnover since

1990, this decrease is less than that in CO and VOC emissions. Therefore, there is a more limited opportunity for transportation actions to claim NO_x reductions from fleet turnover since 1990 in order to allow increased NO_x emissions from future development activities.

However, EPA notes that there is no requirement for a 1990 inventory in PM_{10} and NO_2 nonattainment areas. EPA invites comment on allowing other years to be used as the baseline, such as the year(s) of the ambient data upon which the designation was based (or, for PM_{10} nonattainment areas, upon which the moderate or serious classification was based).

F. Procedures for Estimating Emissions and Ambient Concentrations

1. Regional Emissions Analysis

Serious CO and serious, severe, and extreme ozone areas. After January 1, 1995, this proposal would require these areas to use network-based transportation demand models or models relating travel demand and transportation system performance to land-use patterns, population demographics, employment, transportation infrastructure, and transportation policies. The proposal includes detailed procedural requirements, and additional useful guidance on modeling practices may be found in EPA's section 187 VMT Forecasting and Tracking Guidance (March 1992) and the forthcoming National Association of Regional Councils' "Manual of MPO Modeling Practice."

Areas which are not serious CO or serious, severe, or extreme ozone. Unless these areas have been using network models, these areas could estimate regional emissions using methods which do not explicitly or comprehensively account for the influence of land use and transportation infrastructure on vehicle miles traveled (VMT) and traffic speeds and congestion. Such methods could extrapolate historical VMT or project future VMT by considering growth in population and historical growth trends for VMT per person. These methods would also adjust this extrapolated VMT in consideration of future economic activity, transit alternatives and other TCMs, specific major highway changes, and transportation system policies which make the demographically-based extrapolation alone inappropriate. Population growth has the largest influence on regional motor vehicle emissions and should be a sufficient predictor.

Rationale. EPA believes the proposed network modeling procedures reflect the current consensus in the transportation and air quality planning professions on minimum acceptable modeling practices. EPA welcomes comments on the proposed procedures and is monitoring developments from the National Association of Regional Councils' MPO Modeling Practices project.

EPA is reserving the most rigorous requirements for those areas which have the most extensive air quality planning needs and which are already encouraged to develop network models by other sections of the CAA. EPA is not proposing to require network models in all areas because it would be impractical for these areas to obtain the necessary financial and technical resources before their attainment date, which is 1996 at the latest. Areas which are currently using network models would be required to continue using them for conformity analyses. In addition, the new planning requirements associated with ISTEA are expected to encourage more areas to develop network models.

EPA requests comment on whether serious PM_{10} nonattainment areas should be required to use network models and develop specific transportation plans. Specifically, EPA requests comment on whether the air quality benefits from using network models to perform conformity analyses justify the financial investment which would be required.

Transportation control measures. Areas will need to project the effect of TCMs as part of performing the regional emissions analysis. The changes in travel time of day, mode choice, trip length, trip frequency, and travel speed will result in creditable emissions reductions. For the purposes of plan and TIP conformity, areas must assume a prospective level of TCM effectiveness which is consistent with the implementation plan. Those TCMs which are in place must be modeled consistent with the available information on the degree of compliance with the measures.

Construction-related activities. EPA believes that temporary emissions increases of VOC and CO due to construction-related traffic congestion will not cause violations at the regional level. These emissions changes are small increases due to traffic speed changes and are not associated with VMT growth, which is the primary concern with regional violations. Also, the NEPA process considers the construction-related impacts of projects and is intended to ensure that appropriate mitigation measures are considered. Therefore, EPA believes that emissions increases from construction-related congestion are not significant at the regional level, and such increases will not cause any new regional-scale violations or exacerbate existing ones.

However, construction activity can be a significant direct source of fugitive PM_{10} due to the disturbance of ground cover and the movement of construction vehicles on unpaved areas. In addition, construction vehicles can carry soil onto paved roads, where it can be re-entrained into ambient air by other passing vehicles.

EPA is proposing to require regional PM_{10} emissions analyses to consider construction-related fugitive PM_{10} in those areas with implementation plans which identify it as a contributor to the nonattainment problem. The regional analysis would have to account for the level of construction activity, the fugitive PM_{10} control measures in the implementation plan, and the dust-producing capacity of the proposed activities. Those areas with implementation plans which do not identify construction-related fugitive PM_{10} as a contributor to the nonattainment problem do not have to consider it in their regional emissions analysis.

2. Hot-spot Analysis

If consideration of local factors clearly demonstrates that the hot-spot criteria are satisfied, EPA would not require quantitative modeling. EPA believes that quantitative modeling is not necessary to demonstrate satisfaction of the hot-spot criteria in every case, since the range of FHWA and FTA projects includes many which could not reasonably be argued to have any significant CO emissions effect. However, at this time EPA cannot propose cutoffs on project size, geography, or other characteristics above which modeling is always required. Therefore, EPA requests comment on whether and how to more clearly define when quantitative modeling is and is not required. EPA also invites comment on specific procedures or evidence which should be considered for qualitative hot-spot analysis.

CO hot-spot modeling. EPA is proposing that when quantitative modeling is required, the choice of a hot-spot model and associated methods and assumptions must be the subject of interagency consultation. However, EPA would require quantitative CO hot-spot analyses to be based on the applicable air quality models, data bases, and other requirements specified in the most recent version of the "Guideline on Air

Quality Models (Revised)" (EPA publication no. 450/2–78–027R), including all Supplements finally published in the **Federal Register** by the date of this final rule, in those locations, areas, or categories of sites which the implementation plan identifies as sites of current violation or possible current violation, and at other sites if the use of the "Guideline" models is practicable and reasonable given the potential for violations. The "Guideline on Air Quality Models" is used in the implementation plan's attainment demonstration, and EPA believes it is advisable to use consistent modeling techniques at sites which are the same as or similar to those sites addressed in the attainment demonstration. Other quantitative models could be used at such sites only if after the interagency consultation process and with the approval of the EPA Regional Administrator, it is determined that "Guideline" models are not practicable or not reasonable.

At sites which are not identified as violations and at which the use of "Guideline" models is not practicable or reasonable, EPA would allow other quantitative methods to be used if they represent reasonable and common professional practice. Where "Guideline" and non-"Guideline" models are both available, "Guideline" models would have to be given the greatest consideration. EPA is proposing this flexibility because it is not clear that sites which are not identified as current violations or possible current violations need the same modeling techniques as those used in the implementation plan.

G. Exempt Projects

EPA is proposing that certain highway and transit projects would not require a conformity determination and could proceed toward implementation even without a conforming transportation plan and TIP because of the nature of such projects and their inherent lack of impact on air emissions. Alabama Power v. EPA, 636 F.2d 323, 360, D.C. Cir. 1979, gives EPA the authority to create such de minimis exemptions. Examples of such projects include various safety projects; certain mass transit projects, such as rehabilitation of transit vehicles and construction of small passenger shelters; continuation of ride-sharing and vanpooling promotional activities; bicycle and pedestrian facilities; landscaping; and sign removal. Any specific project in these categories may be made non-exempt if the MPO and other agencies in the interagency consultation process concur that it has potentially adverse emissions impacts.

By exempting these projects with neutral air quality impacts, EPA would minimize the resource use and project delays which could be associated with the conformity process. EPA also believes that areas without a currently conforming plan and TIP should be permitted to implement projects with neutral air quality impact. Although no conformity determination would be required of exempt projects, States and MPOs should ensure that exempt projects would not interfere with TCM implementation. If TCM implementation is delayed because of exempt projects, future TIPs and plans may not be able to receive a conformity finding.

EPA also proposes that certain projects be exempt from regional emissions analyses. These projects, which EPA believes have no regional emissions impacts, would include intersection channelization and signalization projects; interchange reconfiguration projects; changes in vertical and horizontal alignment; truck size and weight inspection stations; and bus transfer terminals.

These projects would require analysis of local impacts for project-level conformity determinations, but could be excluded from regional analyses of plans, TIPs, and projects which are not from a conforming plan and TIP. EPA believes that exempting these projects from regional analyses would simplify regional analysis and minimize the burden of conformity. Because these projects have no impact on regional emissions, they cannot cause an emissions budget to be exceeded, and they therefore satisfy the requirements of CAA section 176(c)(2)(D). Therefore, these projects could proceed even in the absence of a conforming plan and TIP.

However, this provision would not waive any planning requirements established by ISTEA.

VIII. Environmental and Health Benefits

This rule will help ensure that the implementation plan achieves its goal of attaining air quality standards. The environmental and health benefits of attaining the national ambient air quality standards are attributable to the strategies contained in the implementation plan rather than to this rule directly.

IX. Economic Impact

The primary impact of this rule involves the increased requirements for MPOs to perform regional transportation and emissions modeling and document the regional air quality impacts of transportation plans and programs. Because conformity requirements have existed in some form since 1977, the framework for consultation and TCM tracking has already been established.

The impact of today's proposed conformity requirements on MPOs may vary widely depending on the pollutant for which an area is in nonattainment, the classification of the nonattainment area, the population of the area, and the technical capabilities already developed in the area.

The approximately 25 MPOs which will be subject to the most stringent modeling requirements—which are also among the largest MPOs—have been spending during Phase I of the interim period approximately $150,000 for a conformity determination on the transportation plan and TIP. Costs for smaller MPOs in nonattainment areas which are not classified as serious or above have ranged from $10,000 to $60,000.

These estimates do not necessarily reflect the costs which will result from today's proposed rule. On one hand, these may be overestimates of the costs, because determinations will probably become less expensive as the MPOs gain experience. For example, for future determinations it may be possible to perform the modeling with fewer runs. On the other hand, these estimates do not reflect the more specific requirements of today's rule and may therefore underestimate the cost of determinations in the control strategy period. EPA is continuing to research the costs of conformity to MPOs.

Estimates of conformity costs among the larger MPOs vary from as low as $50,000 to as high as $725,000 (for a TIP, a plan, and TIP amendments associated with the plan), which illustrates the difficulty of estimating the costs specifically associated with conformity's increased requirements. Because ISTEA and other CAA provisions also indirectly require increased modeling, it is difficult to separate the costs attributable to the conformity requirements. For example, ISTEA assigns more responsibility to the MPOs and shifts the planning focus to intermodalism and congestion management. This will require more sophisticated transportation modeling. The VMT tracking and forecasting requirements in sections 182 and 187 of the CAA will also promote the use of transportation demand network models in some nonattainment areas.

In addition, although the conformity requirements may prompt additional data collection and model development, these costs cannot be solely attributed to

conformity. It is an ongoing responsibility of MPOs to review and upgrade their analysis capabilities to reflect the most recent understanding of travel demand and transportation forecasting. Resource constraints during the 1980's prevented many MPOs from updating their analysis procedures, so conformity is in many cases simply raising the priority of modeling improvements.

Metropolitan planning is eligible for funds under ISTEA. In addition, EPA has attempted to minimize the costs of conformity in several ways. First, EPA is proposing flexible methodological requirements for regional analyses in areas which don't use network models, in order to accommodate the varying technical capabilities of MPOs. In addition, by designating projects which are exempt from conformity determinations or regional analyses, EPA is allowing project sponsors to conserve their analysis resources. Finally, EPA has attempted to minimize the frequency of conformity redeterminations by limiting the number of triggers and by allowing grace periods before the use of new emissions models and following an area's reclassification.

X. Public Participation

A. Comments and the Public Docket

EPA and DOT welcome comments on all aspects of this proposed rulemaking. All comments should be directed to the EPA Air Docket Section, Docket No. A–92–21 (see "ADDRESSES"). As noted above in section II. D., EPA is currently drafting an NPRM proposing criteria and procedures for determining conformity of general Federal actions (general conformity rule). If EPA determines it is appropriate, EPA may reopen the public comment period on this rule to coincide with the public comment period on the general conformity rule.

B. Public Hearing

Anyone who wants to present testimony about this proposal at the public hearing (see "DATES") should, if possible, notify the contact person (see "FOR FURTHER INFORMATION CONTACT") at least seven days prior to the day of the hearing. The contact person should be given an estimate of the time required for the presentation of testimony and notification of any need for audio/visual equipment. A sign-up sheet will be available at the registration table the morning of the hearing for scheduling those who have not notified the contact earlier. This testimony will be scheduled on a first-come, first-serve basis to follow the previously scheduled testimony.

EPA requests that approximately 50 copies of the statement or material to be presented be brought to the hearing for distribution to the audience. In addition, EPA would find it helpful to receive an advance copy of any statement or material to be presented at the hearing at least one week before the scheduled hearing date. This is to give EPA staff adequate time to review such material before the hearing. Such advance copies should be submitted to the contact person listed.

The official records of the hearing will be kept open until the close of the comment period to allow submission of rebuttal and supplementary testimony. All such submittals should be directed to the Air Docket, Docket No. A–92–21 (see "ADDRESSES").

Dick Wilson is hereby designated Presiding Officer of the hearing. The hearing will be conducted informally, and technical rules of evidence will not apply. A written transcript of the hearing will be placed in the above docket for review. Anyone desiring to purchase a copy of the transcript should make individual arrangements with the court reporter recording the proceeding.

As noted above in section II. D., EPA is currently drafting an NPRM proposing criteria and procedures for determining conformity of general Federal actions (general conformity rule). If EPA determines it is appropriate, EPA may hold additional public hearings concurrently or consecutively with the public hearings on the general conformity rule.

XI. Administrative Requirements

A. Administrative Designation

Under Executive Order 12291, EPA and DOT must judge whether a regulation is a "major" rule and, therefore, subject to the requirement that a Regulatory Impact Analysis (RIA) be prepared. Since EPA has determined that this regulation is not major, an RIA has not been prepared.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rulemaking.

B. Reporting and Recordkeeping Requirements

This rule does not contain any information collection requirements which require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Flexibility Analysis (RFA).

EPA has determined that the regulations proposed today will not have a significant impact on a substantial number of small entities. This regulation will affect Federal agencies and metropolitan planning organizations, which by definition are designated only for metropolitan areas with a population of at least 50,000.

Therefore, as required under § 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., I certify that this regulation does not have a significant impact on a substantial number of small entities.

List of Subjects in 40 CFR Part 51

Administrative practice and procedures, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: December 22, 1992.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, title 40, chapter I, part 51 of the Code of Federal Regulations is proposed to be amended as follows.

PART 51—[AMENDED]

1. The authority citation for part 51 continues to read as follows:

Authority: 42 U.S.C. 7401(b)(1); 7407(d), 7410(k)(1), 7470–79, 7501–7508, and 7601(a)

2. Part 51 is amended by adding a new subpart T to read as follows:

Subpart T—Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Developed, Funded or Approved Under Title 23 U.S.C. or the Federal Transit Act

Sec.

51.390 Purpose.
51.391 Definitions.
51.392 Applicability.
51.393 Implementation plan revision.
51.394 Priority.
51.395 Frequency of conformity determinations.
51.396 Consultation.
51.397 Content of transportation plans.
51.398 Relationship of plan and TIP conformity with the NEPA process.
51.399 Fiscal constraints for transportation plans and TIPs.

Sec.
51.400 Criteria and procedures for determining conformity of transportation plans, programs, and projects.
51.401 Procedures for determining regional transportation-related emissions.
51.402 Procedures for determining localized CO and PM_{10} concentrations.
51.403 Exempt projects.
51.404 Projects exempt from regional emissions analyses.
51.405 Special provisions for nonattainment areas which are not required to demonstrate reasonable further progress and attainment.

Subpart T—Conformity to State or Federal Implementation Plans of Transportation Plans, Programs, and Projects Developed, Funded or Approved Under Title 23 U.S.C. or the Federal Transit Act

§ 51.390 Purpose.

The purpose of this subpart is to implement section 176(c) of the Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et seq.*), and the related requirements of 23 U.S.C. 109(j), with respect to the conformity of transportation plans, programs, and projects which are developed, funded, or approved by the United States Department of Transportation (DOT), and by metropolitan planning organizations (MPOs) or other recipients of funds under title 23 U.S.C. or the Federal Transit Act (49 U.S.C. 1601 *et seq.*). This subpart sets forth policy, criteria, and procedures for demonstrating and assuring conformity of such activities to an applicable implementation plan developed pursuant to section 110 and part D of the CAA.

§ 51.391 Definitions.

Terms used but not defined in this subpart shall have the meaning given them by the CAA, titles 23 and 49 U.S.C., other Environmental Protection Agency (EPA) regulations, or other DOT regulations, in that order of priority.

Applicable implementation plan is defined in section 302(q) of the CAA and means the portion (or portions) of the implementation plan, or most recent revision thereof, which has been approved under section 110, or promulgated under section 110(c), or promulgated or approved pursuant to regulations promulgated under section 301(d) and which implements the relevant requirements of the CAA.

CAA means the Clean Air Act, as amended.

Cause or contribute to a new violation for a project means to cause or contribute to a new violation of a standard at a location or over a region which would otherwise not be in violation of the standard during the future period in question, if the project were not implemented.

Control strategy implementation plan is the applicable implementation plan which contains specific strategies for controlling the emissions of and reducing ambient levels of pollutants in order to satisfy CAA requirements for demonstrations of reasonable further progress and attainment.

Control strategy period with respect to particulate matter less than 10 microns in diameter (PM_{10}), carbon monoxide (CO), nitrogen dioxide (NO_2), and/or ozone precursors (volatile organic compounds and oxides of nitrogen), means that period of time after EPA approves control strategy implementation plans containing strategies for controlling PM_{10}, NO_2, CO, and/or ozone, as appropriate. This period ends when a State submits and EPA approves a request under section 107(d) of the CAA for redesignation to an attainment area.

Design concept means the type of facility identified by the project, e.g., freeway, expressway, arterial highway, grade-separated highway, reserved right-of-way rail transit, mixed-traffic rail transit, exclusive busway, etc.

Design scope means the design aspects which will affect the proposed facility's impact on regional emissions, usually as they relate to vehicle or person carrying capacity and control, e.g., number of lanes to be constructed or added, length of project, signalization, access control including approximate number and location of interchanges, preferential treatment for high-occupancy vehicles, etc.

DOT means the United States Department of Transportation.

Emissions budget is that portion of the total allowable emissions defined in the applicable implementation plan for the purpose of meeting reasonable further progress milestones or attainment or maintenance demonstrations, for any criteria pollutant or its precursors, allocated by the applicable implementation plan to highway and transit vehicles.

EPA means the Environmental Protection Agency.

FHWA means the Federal Highway Administration of DOT.

FHWA/FTA project, for the purpose of this subpart, is any highway or transit project which is proposed to receive funding assistance and approval through the Federal-Aid Highway program or the Federal mass transit program, or requires Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) approval for some aspect of the project, such as connection to an interstate highway or deviation from applicable design standards on the interstate system.

FTA means the Federal Transit Administration of DOT.

Highway project is an undertaking to implement or modify a highway facility or highway-related program. Such an undertaking consists of all required phases necessary for implementation. For analytical purposes, it must be defined sufficiently to:

(1) Connect logical termini and be of sufficient length to address environmental matters on a board scope;

(2) Have independent utility or significance, i.e., be usable and be a reasonable expenditure even if no additional transportation improvements in the area are made; and

(3) Not restrict consideration of alternatives for other reasonably foreseeable transportation improvements.

Horizon year is a year for which the transportation plan describes the envisioned transportation system according to § 51.397 of this subpart.

Hot-spot analysis is an estimation of likely future localized CO and PM_{10} pollutant concentrations and a comparison of those concentrations to the national ambient air quality standards. Pollutant concentrations to be estimated should be based on the total emissions burden which may result from the implementation of a single, specific project, summed together with future background concentrations (to include emissions from facilities or actions which have completed environmental review) expected in the area. The total concentration must be estimated and analyzed at appropriate receptor locations in the area substantially affected by the project.

Incomplete data area means any ozone nonattainment area which EPA has classified, in 40 CFR part 81, as an incomplete data area.

Increase the frequency or severity means to cause a location or region to exceed a standard more often or to cause a violation at a greater concentration than previously existed and/or would otherwise exist during the future period in question, if the project were not implemented.

ISTEA means the Intermodal Surface Transportation Efficiency Act of 1991.

Maintenance area means any geographic region of the United States designated nonattainment pursuant to the CAA Amendments of 1990 and subsequently redesignated to attainment subject to the requirement to develop a maintenance plan under section 175A of the CAA Amendments.

Metropolitan planning organization (MPO) is that organization designated as being responsible, together with the State, for conducting the continuing, cooperative, and comprehensive planning process under 23 U.S.C. 134 and 49 U.S.C. 1607. It is the forum for cooperative transportation decision-making.

Milestone has the meaning given in section 182(g)(1) of the CAA.

National ambient air quality standards (NAAQS) are those standards established pursuant to section 109 of the CAA.

NEPA means the National Environmental Policy Act.

NEPA process completion, for the purposes of this regulation, with respect to FHWA or FTA, means the point at which there is a specific action to make a determination that a project is categorically excluded, to make a Finding of No Significant Impact, or to issue a record of decision on a Final Environmental Impact Statement under NEPA. Other recipients of funds under title 23 U.S.C. or the Federal Transit Act must establish and document project-level conformity in an environmental document submitted to FHWA or FTA prior to Federal completion of the NEPA process.

Nonattainment area means any geographic region of the United States which has been designated as nonattainment under section 107 of the CAA for any pollutant for which a national ambient air quality standard exists.

Non-federal TCM is any transportation control measure implemented by a State or local transportation agency which utilizes no Federal funding and requires no Federal approval.

Not classified area means any carbon monoxide nonattainment area which EPA has not classified.

Phase II of the interim period with respect to a pollutant or pollutant precursor means that period of time after the effective date of this rule, lasting until the relevant control strategy implementation plans are approved or promulgated by EPA.

Project means a highway project or transit project.

Regional-scale with respect to an actual or potential carbon monoxide, ozone, nitrogen dioxide, or particulate matter (less than 10 microns in diameter) national ambient air quality standard violation refers to a violation which occurs on a wide geographic scale due to emissions over a wide area, possibly over an extended period of time. This is in contrast to a hot-spot violation which occurs near a specific source and is predominantly due to recent emissions from that source being added to background concentrations.

Regionally significant, in the case of transportation facilities, means any facility with an arterial or higher functional classification, plus any other facility that serves regional travel needs (such as access to and from the area outside of the region, to major activity centers in the region, or to transportation terminals) and would normally be included in the modeling for the transportation network.

Rural area means any geographic region of the United States which has a population of less than 50,000 and which is not located within a Metropolitan Statistical Area or Consolidated Metropolitan Statistical Area as defined by the United States Census Bureau.

Standard means a national ambient air quality standard.

Submarginal area means any ozone nonattainment area which EPA has classified as submarginal in 40 CFR Part 81.

Transit is mass transportation by bus, rail, or other conveyance which provides general or special service to the public on a regular and continuing basis. It does not include school buses or charter or sightseeing services.

Transit project is an undertaking to implement or modify a transit facility or transit-related program; purchase transit vehicles or equipment; or provide financial assistance for transit operations. It would not include actions that are solely within the jurisdiction of local transit agencies, such as routes, schedules, or fares. It may consist of several phases. For analytical purposes, it must be defined inclusively enough to:

(1) Connect logical termini and be of sufficient length to address environmental matters on a broad scope;

(2) Have independent utility or independent significance, i.e., be a reasonable expenditure even if no additional transportation improvements in the area are made; and

(3) Not restrict consideration of alternatives for other reasonably foreseeable transportation improvements.

Transitional area means any ozone nonattainment area which EPA has classified as transitional in 40 CFR part 81.

Transportation control measure (TCM) is any measure that is specifically identified and committed to in the applicable implementation plan that is either one of the types listed in section 108 of the CAA, or any other measure for the purpose of reducing emissions or concentrations of air pollutants from transportation sources by reducing vehicle use or changing traffic flow or congestion conditions. Notwithstanding the above, vehicle technology-based, fuel-based, and maintenance-based measures which control the emissions from vehicles under fixed traffic conditions are not TCMs for the purposes of this regulation.

Transportation improvement program (TIP) is a program of transportation projects drawn from or consistent with the transportation plan and developed pursuant to title 23 U.S.C. and the Federal Transit Act.

Transportation plan is the long-range plan which identifies facilities that should function as an integrated metropolitan transportation system and is developed pursuant to title 23 U.S.C. and the Federal Transit Act. It gives emphasis to those facilities that serve important national and regional transportation functions, and includes a financial plan that demonstrates how the transportation plan can be implemented.

Transportation project is a highway project or a transit project.

§ 51.392 Applicability.

(a) *Action applicability.* Except as provided for in paragraph (c) of this section or § 51.403 of this subpart, conformity determinations are required for:

(1) The adoption, acceptance, or approval of transportation plans developed pursuant to 23 U.S.C. 134 or the Federal Transit Act by an MPO or DOT;

(2) The adoption, acceptance, or approval of TIPs developed pursuant to 23 U.S.C. 134 or the Federal Transit Act by an MPO or DOT; and

(3) The approval, funding, or implementation of FHWA/FTA projects.

(b) *Geographic applicability.* The provisions of this subpart shall apply in all nonattainment and maintenance areas for transportation-related criteria pollutants. The transportation-related criteria pollutants are ozone, carbon monoxide, nitrogen dioxide, and particles with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM_{10}). The provisions apply with respect to emissions of the criteria pollutants themselves and to emissions of precursor pollutants, i.e., volatile organic compounds and nitrogen oxides in ozone areas, nitrogen oxides in nitrogen dioxide areas, and volatile organic compounds, nitrogen oxides, and PM_{10} in PM_{10} areas.

(c) *Limitations.* Projects subject to this regulation for which the NEPA process and a conformity determination have

been completed by FHWA or FTA may proceed toward implementation without further conformity determinations. All phases of such projects which were considered in that action are also included, if those phases were for the purpose of funding, final design, right-of-way acquisition, construction, or any combination of these phases. However, any significant change in design concept and scope or a supplemental environmental document for air quality purposes shall also trigger a requirement for a new conformity determination of the project.

§ 51.393 Implementation plan revision.

States must submit to the EPA and DOT a revision to their implementation plan which contains criteria and procedures for DOT, MPOs and other State or local agencies to assess the conformity of transportation plans, programs, and projects, consistent with these regulations. This revision is to be submitted within 12 months of the promulgation of this rule. EPA will provide DOT with a 30-day comment period before taking action to approve or disapprove the submission.

§ 51.394 Priority.

When assisting or approving any action with air quality-related consequences, FHWA and FTA shall give priority to the implementation of those transportation portions of an applicable implementation plan prepared to attain and maintain the NAAQS. This priority shall be consistent with statutory requirements for allocation of funds among States or other jurisdictions. Where other important factors are a consideration, transportation measures which are not included in the applicable implementation plan can be funded or implemented; however, transportation measures in the applicable implementation plan must retain a high priority and funding decisions must promote their timely implementation to the extent that funds are available.

§ 51.395 Frequency of conformity determinations.

(a) *Transportation plans.* (1) Each new transportation plan must be found to conform based on the requirements of this rule and the applicable implementation plan prior to the transportation plan's adoption by the MPO.

(2) All transportation plan revisions must be found to conform based on the requirements of this rule and the applicable implementation plan, unless the revision merely adds or deletes exempt projects listed in § 51.403 of this subpart. The conformity determination must be based on the transportation plan and the revision taken as a whole.

(3) Conformity must be redetermined within 18 months of the following:

(i) [Insert date of publication of the final rule in the **Federal Register**];

(ii) Any implementation plan submitted by a State which meets the completeness criteria, is approved by EPA, and which:

(A) Establishes or revises a transportation-related emissions budget (as required by CAA sections 175A(a), 182(b)(1), 182(c)(2)(A), 182(c)(2)(B), 187(a)(7), 189(a)(1)(B), and 189(b)(1)(A); and sections 192(a) and 192(b), for nitrogen dioxide); or

(B) Adds, deletes, or changes TCMs; and

(iii) Any implementation plan promulgated by EPA which establishes or revises a transportation-related emissions budget or adds, deletes, or changes TCMs.

(4) In any case, conformity determinations must be made no less frequently than every three years.

(b) *Transportation improvement programs.* (1) A new TIP must be found to conform based on the requirements of this subpart and the applicable implementation plan prior to the TIP's approval.

(2) A TIP amendment requires a new conformity determination for the entire TIP prior to its approval, unless the amendment merely adds or deletes exempt projects listed in § 51.403 of this subpart.

(3) Conformity must be redetermined by the MPO and DOT within six months of the MPO's adoption of a new or revised transportation plan, unless the new or revised plan merely adds or deletes exempt projects listed in § 51.403 of this subpart.

(4) In any case, conformity determinations must be made no less frequently than every three years.

(c) *Projects.* FHWA/FTA projects must be found to conform prior to their approval.

§ 51.396 Consultation.

The implementation plan revision required under § 51.393 of this subpart shall include consultation procedures to be undertaken by MPOs, State departments of transportation, and DOT with State and local air quality agencies before making conformity determinations, and shall also include consultation procedures for ensuring an opportunity for public participation and review of draft transportation plans and TIPs prior to final action.

(a) *Interagency consultation procedures.* States shall provide in the implementation plan well-defined procedures whereby representatives of the MPOs; State and local air quality planning agencies; State and local transportation agencies; and other organizations with responsibilities for developing, submitting, or implementing provisions of an implementation plan required by the CAA consult with each other and with local or regional offices of EPA, FHWA, and FTA on the development of the implementation plan, the transportation plan, and the TIP. Interagency consultation procedures shall include, at a minimum:

(1) The roles and responsibilities assigned to each agency at each stage in the implementation plan development process and the transportation planning process, including technical meetings;

(2) The organizational level of regular consultation;

(3) A process for circulating (or providing ready access to) draft documents and supporting materials for comment prior to formal adoption or publication;

(4) The frequency of, or process for convening, consultation meetings and responsibilities for agenda formation;

(5) A process for escalating disagreements to higher organizational levels for settlement;

(6) The development of a list of the TCMs in the applicable implementation plan;

(7) A process involving the MPO, State and local air quality planning agencies, State and local transportation agencies, EPA, and DOT for evaluating and choosing a model (or models) and associated methods and assumptions to be used in hot-spot analyses and regional air quality modeling;

(8) A process involving the MPO, State and local air quality planning agencies, and State and local transportation agencies for evaluating events which will trigger new conformity determinations in addition to those triggering events established in § 51.395 of this subpart;

(9) A process involving the MPO, State and local air quality planning and transportation agencies, EPA, and DOT for evaluating whether projects otherwise exempted from meeting the requirements of this subpart (see §§ 51.403 and 51.404 of this subpart) should be treated as non-exempt in cases where potential adverse emissions impacts may exist for any reason;

(10) Where the metropolitan planning area does not include the entire nonattainment or maintenance area, a process involving the MPO and the State department of transportation for cooperative planning and analysis for

purposes of determining conformity of all projects outside the metropolitan area and within the nonattainment or maintenance area; and

(11) A process for consulting on the design, schedule, and funding of research and data collection efforts and regional air quality model development by the MPO (e.g., household/travel transportation surveys).

(b) *Public consultation procedures.* (1) Affected agencies making conformity determinations on plans, programs, and projects shall provide a reasonable opportunity for public review and comment prior to taking formal action on a conformity determination for all plans and TIPs, and on conformity determinations for projects where otherwise required by law.

(i) The agency shall publish the proposed procedures to be used for this requirement and allow 45 days for written public comment.

(ii) An agency which revises these procedures, as determined when the need arises by the agencies involved in the process, shall publish the new procedures and allow 45 days for written public comment.

(2) The MPO shall prepare a summary and analysis of written and oral comments before taking final action on conformity determinations subject to paragraph (b)(1) of this section.

(3) If the transportation plan or TIP to be submitted to DOT is significantly different than the one which was made available for public comment by the MPO and raises new material issues which interested parties could not reasonably have foreseen from the MPO notifications, then an additional opportunity for public comment on the revised plan or TIP must be provided.

(4) New public consultation procedures for plans and TIPs are being developed by DOT in response to requirements in the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA). When a DOT regulation on this subject is published in final form, its provisions will govern and the public consultation requirements contained in paragraph (b) of this section will cease to apply.

§ 51.397 Content of transportation plans.

(a) *Transportation plans adopted after January 1, 1995 in serious, severe, or extreme ozone nonattainment areas and in serious carbon monoxide nonattainment areas.* The transportation plan must specifically describe the transportation system envisioned for certain future years which shall be called horizon years.

(1) The agency or organization developing the transportation plan may choose any years to be horizon years, subject to the following restrictions:

(i) Horizon years may be no more than 10 years apart;

(ii) The first horizon year may be no more than 10 years from the base year used to validate the transportation demand planning model;

(iii) If the attainment year is in the time span of the plan, the attainment year must be a horizon year;

(iv) The last horizon year must be the last year of the plan's forecast period.

(2) For these horizon years:

(i) The plan shall quantify and document the demographic and employment factors influencing expected transportation demand, including land use forecasts, in accordance with implementation plan provisions and § 51.396 of this subpart;

(ii) The highway and transit system shall also be described in terms of the regionally significant additions or modifications to the existing transportation network which the plan envisions to be operational in the horizon years. Additions and modifications to the highway network shall be sufficiently identified to indicate intersections with existing regionally significant facilities, and to determine their effect on route options between transportation analysis zones. Each added or modified highway segment shall also be sufficiently identified in terms of its design concept and design scope to allow modeling of travel times under various traffic volumes, consistent with the modeling methods for area-wide transportation analysis in use by the MPO. Transit facilities, equipment, and services envisioned for the future shall be identified in terms of design concept, design scope, and operating policies sufficiently to allow modeling of their user volumes. The description of additions and modifications to the transportation network shall also be sufficiently specific to show that there is a reasonable relationship between expected land use and the envisioned transportation system; and

(iii) Other future transportation policies, requirements, services, and activities, including intermodal activities, shall be described.

(b) *Moderate areas reclassified to serious.* Ozone or CO nonattainment areas which are reclassified from moderate to serious must meet the requirements of paragraph (a) of this section within two years from the date of reclassification.

(c) *Transportation plans for other areas.* Transportation plans for other areas must meet the requirements of paragraph (a) of this section at least to the extent it has been the previous practice of the MPO to prepare plans which meet those requirements. Otherwise, transportation plans must describe the transportation system envisioned for the future specifically enough to allow determination of conformity according to the criteria and procedures of § 51.400 of this subpart.

(d) *Savings.* The requirements of this section supplement other requirements of applicable law or regulation governing the format or content of transportation plans.

§ 51.398 Relationship of plan and TIP conformity with the NEPA process.

The degree of specificity required in the transportation plan and the specific travel network assumed for air quality modeling do not preclude the consideration of alternatives in the NEPA process or other project development studies. Should the NEPA process result in a project with design concept and scope significantly different from that in the plan or TIP, the project must meet the criteria in § 51.400 of this subpart for projects not from a TIP before NEPA process completion.

§ 51.399 Fiscal constraints for transportation plans and TIPs.

(a) *Transportation plans.* The ISTEA requires that the transportation plan include a financial plan that demonstrates how the transportation plan can be implemented, indicates resources from public and private sources that are reasonably expected to be available throughout the plan's timeframe, and recommends any innovative financing techniques to finance needed projects and programs, including such techniques as value capture, tolls, and congestion pricing.

(b) *TIPs.* The ISTEA requires that full funding must be reasonably anticipated to be available for a project, or an identified phase of a project, within the time period contemplated for completion of the project prior to its inclusion in a TIP. The ISTEA also requires a financial plan that demonstrates how the TIP can be implemented, indicates resources from public and private sources that are reasonably expected to be made available for its implementation, and recommends any innovative financing techniques to finance needed projects and programs.

§ 51.400 Criteria and procedures for determining conformity of transportation plans, programs, and projects.

Transportation plans, programs, and projects must satisfy the following criteria and procedures in order to be

found to conform to the applicable implementation plan(s) for ozone, carbon monoxide (CO), nitrogen dioxide (NO_2), and particulate matter less than 10 microns in diameter (PM_{10}). The criteria for making conformity determinations may differ for plans, TIPs, and projects, for the time period in which the conformity determination is to be made, and for the relevant pollutant. An action may be found to conform to the purpose of the applicable implementation plan when the criteria in Table 1 are satisfied for the type of activity in the relevant time period, and when all applicable conformity requirements of implementation plans and of court orders for the area which pertain specifically to conformity determination requirements are fully satisfied. The procedures which correspond to each criterion in Table 1 are described in paragraphs (a) through (q) of this section.

TABLE 1.—CONFORMITY CRITERIA

Action	Criteria
Phase II of the Interim Period	
Transportation Plan	a,b,c(1),j,o.
TIP	a,b,c(2),m,p.
Project (From a conforming plan and TIP).	a,b,d,e,f,g,k.
Project (Not from a conforming plan and TIP).	a,b,c(3),d,f,g,k,n,q.
Control Strategy and Maintenance Periods	
Transportation Plan	a,b,c(1),h.
TIP	a,b,c(2),l.
Project (From a conforming plan and TIP).	a,b,d,e,f,g.
Project (Not from a conforming plan and TIP).	a,b,c(3),d,f,g,j.

(a) The conformity determination must be based on the latest planning assumptions.
(b) The conformity determination must be based on the latest emission estimation model available.
(c) The transportation plan, TIP, or project which is not from a conforming plan and TIP must provide for the timely implementation of TCMs from the applicable implementation plan.
(d) There must be a currently conforming transportation plan and currently conforming TIP at the time of project approval.
(e) The project must come from a conforming plan and program.
(f) The project must not cause or contribute to any new localized CO or PM_{10} violations or increase the frequency or severity of any existing CO or PM_{10} violations in CO and PM_{10} nonattainment and maintenance areas.
(g) The project must comply with PM_{10} control measures in the applicable implementation plan.
(h) The transportation plan must be consistent with the motor vehicle emissions budget(s) in the applicable implementation plan.
(i) The TIP must be consistent with the motor vehicle emissions budget(s) in the applicable implementation plan.
(j) Highway and transit projects which are not from a conforming plan and conforming TIP must be consistent with the motor vehicle emissions budget(s) in the applicable implementation plan.
(k) The project must eliminate or reduce the severity and number of localized CO violations in CO nonattainment areas.
(l) The transportation plan must contribute to emissions reductions in ozone and CO nonattainment areas.
(m) The TIP must contribute to emissions reductions in ozone and CO nonattainment areas.
(n) The project which is not from a conforming plan and TIP must contribute to emissions reductions in ozone and CO nonattainment areas.
(o) The transportation plan must not increase emissions in PM_{10} and NO_2 nonattainment areas.
(p) The TIP must not increase emissions in PM_{10} and NO_2 nonattainment areas.
(q) The project which is not from a conforming plan and TIP must not increase emissions in PM_{10} and NO_2 nonattainment areas.

(a) *The conformity determination must be based on the latest planning assumptions.* This criterion applies during all periods. It is satisfied if the conformity determination, with respect to all other applicable criteria in this section, is based upon the most recent planning assumptions in force at the time of the conformity determination. Assumptions must be derived from the estimates of current and future population, employment, travel, and congestion most recently developed by the MPO or other agency authorized to make such estimates and approved by the MPO. Conformity determinations must also include reasonable assumptions about transit service and increases in transit fares and road and bridge tolls over time.

(b) *The conformity determination must be based on the latest emission estimation model available.* This criterion applies during all periods. It is satisfied if the most current version of the motor vehicle emissions model specified by EPA for use in the preparation or revision of implementation plans in that State or area is used for the conformity analysis. EPA will consult with DOT to establish a grace period following the specification of any new model; any analysis begun during the grace period may use the previous version of the model. The grace period will be no less than three months and no more than 24 months after notice of availability is published in the **Federal Register**, depending on the degree of change in the model and the scope of re-planning likely to be necessary by MPOs in order to assure conformity. If the grace period will be longer than three months, EPA will announce the appropriate grace period in the **Federal Register**.

(c) *The transportation plan, TIP, or project which is not from a conforming plan and TIP must provide for the timely implementation of TCMs from the applicable implementation plan.* This criterion applies during all periods.

(1) For transportation plans, this criterion is satisfied if:

(i) The transportation plan, in describing the envisioned future transportation system, provides for the timely completion or implementation of all TCMs in the applicable implementation plan which are eligible for funding under title 23 U.S.C. or the Federal Transit Act, consistent with schedules included in the applicable implementation plan; and

(ii) Nothing in the transportation plan interferes with the implementation of any TCM in the applicable implementation plan.

(2) For TIPs, this criterion is satisfied if:

(i) An examination of the specific steps and funding source(s) needed to fully implement each TCM indicates that TCMs which are eligible for funding under title 23 U.S.C. or the Federal Transit Act are on or ahead of the schedule established in the applicable implementation plan, or, if such TCMs are behind the schedule established in the applicable implementation plan, the MPO and DOT have determined that past obstacles to implementation of the TCMs have been identified and have been or are being overcome, and that all State and local agencies with influence over approvals or funding for TCMs are giving maximum priority to approval or funding of TCMs over other projects within their control, including projects in locations outside the nonattainment or maintenance area.

(ii) If TCMs in the applicable implementation plan have previously been programmed for Federal funding but the funds have not been obligated and the TCMs are behind the schedule in the implementation plan, then the TIP cannot be found to conform if the funds intended for those TCMs are reallocated to projects in the TIP other than TCMs. If there are no other TCMs in the TIP, the funds may be reallocated to projects which are eligible for Federal funding under ISTEA's Congestion Mitigation and Air Quality Improvement Program.

(iii) Nothing in the TIP may interfere with the implementation of any TCM in the applicable implementation plan.

(3) For transportation projects which are not from a conforming transportation plan and TIP, this criterion is satisfied if the project does not interfere with the implementation of any TCM in the applicable implementation plan.

(d) *There must be a currently conforming transportation plan and currently conforming TIP at the time of project approval.* This criterion applies during all periods. It is satisfied if the current transportation plan and TIP have been found to conform to the applicable implementation plan by the MPO and DOT according to the procedures of this subpart. Only one conforming transportation plan may exist in an area at any time; conformity determinations of previous transportation plans expire once the current plan is found to conform by DOT.

(e) *The project must come from a conforming plan and program.* This

criterion applies during all periods. It is satisfied if there is a conforming transportation plan and program in place at the time of the conformity determination for the project.

(1) A project is considered to be from a conforming plan if:

(i) For projects which are required to be identified in the plan in order to satisfy § 51.397 of this subpart, the project is specifically included in the plan; or

(ii) For projects which are not required to be specifically identified in the plan, the project is identified in the plan, or is consistent with the policies and purpose of the plan and will not interfere with other projects specifically included in the plan.

(2) A project is considered to be from a conforming program if the project is included in the conforming TIP and the design concept and scope of the project were adequate at the time of the TIP conformity determination to determine its contribution to the TIP's regional emissions and have not changed significantly from those which were described in the TIP, or in a manner which would significantly impact use of the facility. Otherwise, the project must satisfy all criteria in Table 1 for a project not from a TIP.

(f) *The project must not cause or contribute to any new localized CO or PM_{10} violations or increase the frequency or severity of any existing CO or PM_{10} violations in CO and PM_{10} nonattainment and maintenance areas.* This criterion applies during all periods. It is satisfied if either:

(1) Consideration of local factors clearly demonstrates that new violations will not be created and the severity or number of existing violations will not be increased; or

(2) Hot-spot analysis demonstrates that no new local violations will be created and the severity or number of existing violations will not be increased as a result of the project.

(i) The model used shall be one selected as a result of consultation under § 51.396(a)(7) of this subpart.

(ii) Hot-spot analysis shall be performed according to the requirements of § 51.402 of this subpart.

(g) *The project must comply with PM_{10} control measures in the applicable implementation plan.* This criterion applies during all periods. It is satisfied if control measures (for the purpose of limiting PM_{10} emissions from the construction activities and/or normal use and operation associated with the project) contained in the applicable implementation plan are included in the plans, specifications, and estimates package for the project.

(h) *The transportation plan must be consistent with the motor vehicle emissions budget(s) in the applicable implementation plan.* This criterion applies during the control strategy and maintenance periods, except as provided in § 51.405 of this subpart. The total emissions of ozone precursors (VOC and NO_x), CO, or PM_{10} (and its precursors if the applicable implementation plan identifies transportation-related precursor emissions within the nonattainment area as a significant contributor to the PM_{10} nonattainment problem and establishes a budget for such emissions) expected from the transportation system as a result of implementing the new projects and activities contained in the plan or expected in the area must be estimated. This criterion is satisfied if the emissions are demonstrated to be less than or equal to each of the motor vehicle emissions budgets established in the applicable implementation plan for the milestone and attainment years. This demonstration requires that a regional emissions analysis be performed as follows:

(1) The emissions analysis methodology shall meet the requirements of § 51.401 of this subpart.

(2) The emissions analysis shall include all projects contained in the plan and all other regionally significant highway and transit projects expected in the nonattainment or maintenance area. The emissions analysis may not include for emissions reduction credit any TCMs which have been delayed beyond the scheduled date(s) until such time as implementation has been assured. TCMs which require a State or local regulation in order to be implemented and which are not specifically identified in the applicable implementation plan may not be included in the emissions analysis unless the regulation is already adopted by the enforcing jurisdiction.

(3) For areas with a transportation plan that meets the content requirements of § 51.397(a) of this subpart, the emissions analysis shall be performed for each horizon year. Emissions in milestone years which are between the horizon years may be determined by interpolation.

(4) For areas with a transportation plan that does not meet the content requirements of § 51.397(a) of this subpart, the emissions analysis shall be performed for years in the time span of the transportation plan provided they are not more than ten years apart and provided the analysis is performed for the last year of the plan's forecast period. If the attainment year is in the time span of the plan, the emissions analysis must also be performed for the attainment year. Emissions in milestone years which are between these analysis years may be determined by interpolation.

(i) *The TIP must be consistent with the motor vehicle emissions budget(s) in the applicable implementation plan.* This criterion applies during the control strategy and maintenance periods, except as provided in § 51.405 of this subpart. The total emissions of ozone precursors (VOC and NO_x), CO, or PM_{10} (and its precursors if the applicable implementation plan identifies transportation-related precursor emissions within the nonattainment area as a significant contributor to the PM_{10} nonattainment problem and establishes a budget for such emissions) expected from the transportation system in general as a result of implementing the projects in the TIP and other expected projects must be estimated for the milestone and attainment years. Those estimates must be less than or equal to each of the motor vehicle emissions budgets for the milestone and attainment years in order for the TIP to conform.

(1) For areas with a conforming transportation plan that fully meets the content requirements of § 51.397(a) of this subpart, this criterion may be satisfied without additional regional analysis if:

(i) Each program year of the TIP is consistent with the Federal funding which may be reasonably expected for that year, and required State/local matching funds and funds for State/local funding-only projects are consistent with the revenue sources expected over the same period; and

(ii) The TIP is consistent with the transportation plan such that the regional emissions analysis already performed for the plan applies to the TIP also. This requires a demonstration that:

(A) The TIP contains all projects which must be started in the TIP's timeframe in order to achieve the highway and transit system envisioned by the plan in each of its horizon years;

(B) All TIP projects which add or modify regionally significant highway or transit facilities are part of the specific highway or transit system envisioned in the transportation plan's horizon years; and

(C) The design concept and scope of each regionally significant project in the TIP is not significantly different from that described in the transportation plan.

(iii) If the requirements in paragraphs (i)(1)(i) and (i)(1)(ii) of this section are not met, then:

(A) The TIP may be modified to meet those requirements; otherwise.

(B) The transportation plan must be revised so that the requirements in paragraphs (i)(1)(i) and (i)(1)(ii) of this section are met. Once the revised plan has been found to conform, this criterion is met for the TIP with no additional analysis except a demonstration that the TIP meets the requirements of (i)(1)(i) and (ii) of this section.

(2) For areas with a transportation plan that does not meet the content requirements of § 51.397(a) of this subpart, a regional emissions analysis must be performed for the TIP. This criterion may be satisfied if:

(i) The analysis methodology meets the requirements of § 51.401(b) of this subpart;

(ii) The analysis estimates emissions from the transportation system, including all projects contained in the proposed TIP, and all other regionally significant projects expected in the nonattainment or maintenance area in the timeframe of the transportation plan. The emissions analysis may not include for emissions reduction credit any TCMs which have been delayed beyond the scheduled date(s) established until such time as implementation has been assured. TCMs which require a State or local regulation in order to be implemented and which are not specifically identified in the applicable implementation plan may not be included in the emissions analysis unless the regulation is already adopted by the enforcing jurisdiction; and

(iii) The emissions analysis is performed for the last year of the plan's forecast period and any other years in the time span of the transportation plan which are not more than ten years apart. If the attainment year is in the time span of the plan, the emissions analysis must also be performed for the attainment year. Emissions in milestone years which are between these analysis years may be determined by interpolation.

(j) *Highway and transit projects which are not from a conforming plan and a conforming TIP must be consistent with the motor vehicle emissions budget(s) in the applicable implementation plan.* This criterion applies during the control strategy and maintenance periods, except as provided in § 51.405 of this subpart. It is satisfied if emissions from the implementation of the project, when added to the emissions from the projects in the conforming transportation plan and TIP and all other regionally significant projects expected in the area, do not exceed the motor vehicle emissions budget in the applicable implementation plan in the milestone or the attainment years.

(1) For areas with a conforming transportation plan that meets the content requirements of § 51.397(a) of this subpart:

(i) This criterion may be satisfied without additional regional analysis if the project is included in the conforming transportation plan, even if it is not specifically included in the latest conforming TIP. This requires a demonstration that:

(A) Allocating funds to the project will not delay the implementation of projects in the transportation plan or TIP which are necessary to achieve the highway and transit system envisioned by the plan in each of its horizon years;

(B) The project is not regionally significant or is part of the specific highway or transit system envisioned in the transportation plan's horizon years; and

(C) The design concept and scope of the project is not significantly different from that described in the transportation plan.

(ii) If the requirements of paragraph (j)(1)(i) of this section are not met, a regional emissions analysis must be performed as follows:

(A) The analysis methodology shall meet the requirements of § 51.401 of this subpart;

(B) The analysis shall estimate emissions from the transportation system, including the proposed project and all other regionally significant projects expected in the nonattainment or maintenance area in the timeframe of the transportation plan. The analysis must include emissions from all previously approved projects which were not from a plan and TIP. The emissions analysis may not include the emissions reduction credit any TCMs which have been delayed beyond the scheduled date(s) established until such time as implementation has been assured. TCMs which require a State or local regulation in order to be implemented and which are not specifically identified in the applicable implementation plan may not be included in the emissions analysis unless the regulation is already adopted by the enforcing jurisdiction; and

(C) The emissions analysis shall be performed for each horizon year. Emissions in milestone years which are between the horizon years may be determined by interpolation.

(2) For areas with a transportation plan that does not meet the content requirements of § 51.397(a) of this subpart, a regional emissions analysis must be performed for the project together with the conforming TIP and all other regionally significant projects expected in the nonattainment or maintenance area. This criterion may be satisfied if:

(i) The analysis methodology meets the requirements of § 51.401(b) of this subpart;

(ii) The analysis estimates emissions from the transportation system, including the proposed project, and all other regionally significant projects expected in the nonattainment or maintenance area in the timeframe of the transportation plan. The emissions analysis may not include for emissions reduction credit any TCMs which have been delayed beyond the scheduled date(s) established until such time as implementation is assured. TCMs which require a State or local regulation in order to be implemented and which are not specifically identified in the applicable implementation plan may not be included in the emissions analysis unless the regulation is already adopted by the enforcing jurisdiction; and

(iii) The emissions analysis is performed for the last year of the plan's forecast period and any other years in the time span of the transportation plan which are not more than ten years apart. If the attainment year is in the time span of the plan, the emissions analysis must also be performed for the attainment year. Emissions in milestone years which are between these analysis years may be determined by interpolation.

(k) *The project must eliminate or reduce the severity and number of localized CO violations in CO nonattainment areas.* This criterion applies during Phase II of the interim period only. It is satisfied with respect to existing localized CO violations if either:

(1) Consideration of local factors clearly indicates that existing CO violations will be eliminated or reduced in severity and number; or

(2) Hot-spot analysis indicates that existing CO violations will be eliminated or reduced in severity and number as a result of the project.

(i) The model used shall be one selected as a result of consultation under § 51.396(a)(7) of this subpart.

(ii) CO hot-spot analysis shall be performed according to the requirements of § 51.402 of this subpart.

(l) *The transportation plan must contribute to emissions reductions in ozone and CO nonattainment areas.* This criterion applies during Phase II of the interim period only, except as otherwise provided in § 51.405 of this subpart. It applies to the net effect on emissions of all projects contained in a new or revised transportation plan. This

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criterion may be satisfied if the regional emissions analysis is performed as follows:

(1) Determine the analysis years for which emissions are to be estimated. The first analysis year shall be no later than the first milestone year (1995 in CO nonattainment areas and 1996 in ozone nonattainment areas). The second analysis year shall be either the attainment year for the area, or if the attainment year is the same as the first analysis year or earlier, the second analysis year shall be at least five years beyond the first analysis year.

(2) Define the "Baseline" scenario for each of the plan's horizon years to be the future transportation system that would result from current programs, composed of the following (except that projects listed in § 51.403 of this subpart need not be explicitly considered):

(i) All in-place regionally significant highway and transit facilities, services and activities;

(ii) All ongoing travel demand management or transportation system management activities; and

(iii) Completion of all regionally significant projects, regardless of funding source, which are currently under construction or are undergoing right-of-way acquisition; come from the first three years of the previously conforming plan and/or TIP; or have completed the NEPA process.

(3) Define the "Action" scenario for each of the plan's horizon years as the transportation system that will result in that year from the implementation of the proposed transportation plan, TIPs adopted under it, and other expected regionally significant projects in the nonattainment area. It will include the following (except that projects listed in § 51.403 of this subpart need not be explicitly considered):

(i) All facilities, services, and activities in the "Baseline" scenario;

(ii) Completion of all TCMs and regionally significant facilities, services, and activities specifically identified in the proposed plan which will be operational or in effect in the horizon year, except that regulatory TCMs may not be assumed to begin at a future time unless the regulation is already adopted by the enforcing jurisdiction or the TCM is identified in the applicable implementation plan;

(iii) All non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which have been fully adopted and/or funded by the enforcing jurisdiction or sponsoring agency since the last conformity determination on the transportation plan;

(iv) The incremental effects of any non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which were adopted and/or funded prior to the date of the last conformity determination on the transportation plan, but which have been modified since then to be more stringent or effective;

(v) Completion of all expected regionally significant highway and transit projects which are not from a conforming plan and TIP; and

(vi) Completion of all expected regionally significant non-FHWA/FTA highway and transit projects that have clear funding sources and commitments leading toward their implementation and completion by the horizon year.

(4) Estimate the emissions predicted to result in each analysis year from travel on the transportation systems defined by the "Baseline" and "Action" scenarios and determine the difference in regional VOC emissions (for all ozone nonattainment areas) and CO emissions (for CO nonattainment areas) between the two scenarios. The analysis must be performed for each of the plan's horizon years according to the requirements of § 51.401 of this subpart. The analysis must address the periods between the analysis years and the periods between 1990, the first milestone year (1996 for ozone and 1995 for CO), and the first of the analysis years. Emissions in milestone years which are between the analysis years may be determined by interpolation. The regional analysis must show that the "Action" scenario contributes to a reduction in emissions from the 1990 emissions by any nonzero amount.

(5) This criterion is met if the regional VOC emissions (for ozone nonattainment areas) and CO emissions (for CO nonattainment areas) predicted in the "Action" scenario are less than the emissions predicted from the "Baseline" scenario in each analysis year, and if this can reasonably be expected to be true in the periods between the first milestone year and the analysis years.

(m) *The TIP must contribute to emissions reductions in ozone and CO nonattainment areas.* This criterion applies during Phase II of the interim period only, except as otherwise provided in § 51.405 of this subpart. It applies to the net effect on emissions of all projects contained in a new or revised TIP. This criterion may be satisfied if a regional emissions impact analysis is performed as follows:

(1) Determine the analysis years for which emissions are to be estimated. The first analysis year shall be no later than the first milestone year (1995 in CO nonattainment areas and 1996 in ozone nonattainment areas). The second analysis year shall be either the attainment year for the area, or if the attainment year is the same as the first analysis year or earlier, the second analysis year shall be at least five years beyond the first analysis year.

(2) Define the "Baseline" scenario as the future transportation system that would result from current programs, composed of the following (except that projects listed in § 51.403 of this subpart need not be explicitly considered):

(i) All in-place regionally significant highway and transit facilities, services and activities;

(ii) All ongoing travel demand management or transportation system management activities; and

(iii) Completion of all regionally significant projects, regardless of funding source, which are currently under construction or are undergoing right-of-way acquisition; come from the first three years of the previously conforming TIP; or have completed the NEPA process.

(3) Define the "Action" scenario as the future transportation system that will result from the implementation of the proposed TIP and other expected regionally significant projects in the nonattainment area. It will include the following (except that projects listed in § 51.403 of this subpart need not be explicitly considered):

(i) All facilities, services, and activities in the "Baseline" scenario;

(ii) Completion of all TCMs and regionally significant facilities, services, and activities included in the proposed TIP, except that regulatory TCMs may not be assumed to begin at a future time unless the regulation is already adopted by the enforcing jurisdiction or the TCM is contained in the applicable implementation plan;

(iii) All non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which have been fully adopted and/or funded by the enforcing jurisdiction or sponsoring agency since the last conformity determination on the TIP;

(iv) The incremental effects of any non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which were adopted and/or funded prior to the date of the last conformity determination on the TIP, but which have been modified since then to be more stringent or effective;

(v) Completion of all expected regionally significant highway and transit projects which are not from a conforming plan and TIP; and

(vi) Completion of all expected regionally significant non-FHWA/FTA highway and transit projects that have clear funding sources and commitments leading toward their implementation and completion by the horizon year.

(4) Estimate the emissions predicted to result in each analysis year from travel on the transportation systems defined by the "Baseline" and "Action" scenarios, and determine the difference in regional VOC emissions (for all ozone nonattainment areas) and CO emissions (for CO nonattainment areas) between the two scenarios. The analysis shall consider the period between 1990 and the analysis years and shall meet the requirements of § 51.401 of this subpart.

(5) This criterion is met if the regional VOC emissions (for ozone nonattainment areas) and CO emissions (for CO nonattainment areas) predicted in the "Action" scenario are less than the emissions predicted from the "Baseline" scenario in each analysis year, and if this can reasonably be expected to be true in the period between the analysis years. The regional analysis must show that the "Action" scenario contributes to a reduction in emissions from the 1990 emissions by any nonzero amount.

(n) *The transportation project which is not from a conforming plan and TIP must contribute to emissions reductions in ozone and CO nonattainment areas.* This criterion applies during Phase II of the interim period only, except as otherwise provided in § 51.405 of this subpart. This criterion is satisfied if a regional emissions impact analysis is performed which meets the requirements of paragraph (1) of this section and which includes the plan and project in the "Action" scenario. If the project which is not from a conforming plan and TIP is a modification of a project currently in the plan or TIP, the "Baseline" scenario must include the project with its original design concept and scope, and the "Action" scenario must include the project with its new design concept and scope.

(o) *The transportation plan must not increase emissions in PM_{10} and NO_2 nonattainment areas.* This criterion is satisfied if it is demonstrated that when the projects in the transportation plan and TIP and all other regionally significant projects expected in the area are implemented, the transportation system's total highway and transit emissions of PM_{10} in a PM_{10} nonattainment area (and transportation-related precursors of PM_{10} in nonattainment areas for which the Administrator has made a finding or approved a finding in the applicable implementation plan that such precursor emissions from within the nonattainment area are a significant contributor to the PM_{10} nonattainment problem) and of NO_x in an NO_2 nonattainment area will not be greater than 1990 levels. This criterion applies only during Phase II of the interim period. This criterion may be satisfied if the regional emissions analysis is performed as follows:

(1) Determine the 1990 regional emissions of PM_{10} (for PM_{10} nonattainment areas) and NO_x (for NO_2 nonattainment areas) from highway and transit sources.

(2) Determine the analysis years for which emissions are to be estimated. The first analysis year shall be no later than the first milestone year (1995 in NO_2 nonattainment areas and 1996 in PM_{10} nonattainment areas). The second analysis year shall be either the attainment year for the area, or if the attainment year is the same as the first analysis year or earlier, the second analysis year shall be at least five years beyond the first analysis year.

(3) Define the "Action" scenario in each of the analysis years as the transportation situation that will result in that year from the implementation of the proposed transportation plan and TIPs adopted under it. It will include the following (except that projects listed in § 51.403 and § 51.404 of this subpart need not be explicitly considered):

(i) All in-place regionally significant highway and transit facilities, services and activities;

(ii) All ongoing travel demand management or transportation system management activities;

(iii) Completion of all regionally significant projects, regardless of funding source, which are currently under construction or are undergoing right-of-way acquisition; come from the first three years of the previously conforming plan and/or TIP; or have completed the NEPA process;

(iv) Completion of all TCMs and regionally significant facilities, services, and activities included in the proposed plan which will be operational or in effect in the horizon years, except that regulatory TCMs may not be assumed to begin at a future time unless the regulation is already adopted by the enforcing jurisdiction or the TCM is identified in the applicable implementation plan;

(v) All non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which have been fully adopted and/or funded by the enforcing jurisdiction or sponsoring agency since the last conformity determination on the transportation plan;

(vi) The incremental effects of any non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which were adopted and/or funded prior to the date of the last conformity determination on the transportation plan, but which have been modified since then to be more stringent or effective; and

(vii) Completion of all expected regionally significant non-FHWA/FTA highway and transit projects that have clear funding sources and commitments leading toward their implementation and completion by the horizon year.

(4) Estimate the emissions predicated to result in the attainment year from travel on the transportation systems defined the "Action" scenario.

(5) This criterion is met if the emissions from the "Action" scenario in the attainment year are no greater than 1990 emissions of PM_{10} (for PM_{10} nonattainment areas) or NO_x (for NO_2 nonattainment areas) from highway and transit sources.

(p) *The TIP must not increase emissions in PM_{10} and NO_2 nonattainment areas.* This criterion is satisfied if it is demonstrated that when the projects in the transportation plan and TIP and all other regionally significant projects expected in the area are implemented, the transportation system's total highway and transit emissions of PM_{10} in a PM_{10} nonattainment area (and transportation-related precursors of PM_{10} in nonattainment areas for which the Administrator has made a finding or approved a finding in the applicable implementation plan that such precursor emissions from within the nonattainment area a significant contributor to the PM_{10} nonattainment problem) and of NO_x in an NO_2 nonattainment area will not be greater than 1990 levels. This criterion applies only during Phase II of the interim period. This criterion may be satisfied if a regional emissions impact analysis is performed as follows:

(1) Determine the 1990 regional emissions of PM_{10} (for PM_{10} nonattainment areas) and NO_x (for NO_2 nonattainment areas) from highway and transit sources.

(2) Determine the analysis years for which emissions are to be estimated. The first analysis year shall be no later than the first milestone year (1995 in NO_2 nonattainment areas and 1996 in PM_{10} nonattainment areas). The second analysis year shall be either the attainment year for the area, or if the attainment year is the same as the first analysis year or earlier, the second

analysis year shall be at least five years beyond the first analysis year.

(3) Define the "Action" scenario in each of the analysis years as the transportation situation that will result in that year from the implementation of the proposed transportation plan and TIPs adopted under it. It will include the following (except that projects listed in § 51.403 and § 51.404 of this subpart need not be explicitly considered):

(i) All in-place regionally significant highway and tranist facilities, services and activities;

(ii) All ongoing travel demand management or transportation system management activities;

(iii) Completion of all regionally significant projects, regardless of funding source, which are currently under construction or are undergoing right-of-way acquisition; come from the first three years of the previously conforming TIP; or have completed the NEPA process;

(iv) Completion of all TCMs and facilities, services, and activities included in the plan and the proposed TIP, except that regulatory TCMs may not be assumed to begin at a future time unless the regulation is already adopted by the enforcing jurisdiction or the TCM is identified in the applicable implementation plan;

(v) All non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which have been fully adopted and/or funded by the enforcing jurisdiction or sponsoring agency since the last conformity determination on the TIP;

(vi) The incremental effects of any non-federal TCMs known to the MPO, but not included in the applicable implementation plan, which were adopted and/or funded prior to the date of the last conformity determination on the TIP, but which have been modified since then to be more stringent or effective; and

(vii) Completion of all regionally significant non-FHWA/FTA projects that have clear funding sources and commitments leading toward their implementation and completion by the analysis year.

(4) Estimate the emissions predicted to result in the attainment year from travel on the transportation systems defined by the "Action" scenario. If the attainment year and the analysis year do not coincide, the regional emissions analysis must be performed for the first analysis year after the attainment year. The attainment year may then be considered by interpolating between 1990 and the analysis year. The regional emissions analysis shall meet the requirements of § 51.401 of this subpart.

(5) This criterion is met if the emissions from the "Action" scenario in the attainment year are less than 1990 emissions of PM_{10} (for PM_{10} nonattainment areas) or NO_x (for NO_2 nonattainment areas) from highway and transit sources.

(q) *The transportation project which is not from a conforming plan and TIP must not increase emissions in PM_{10} and NO_2 nonattainment areas.* This criterion is met if a regional emissions impact analysis is performed which meets the requirements of paragraph (o) of this section and which includes the plan and project in the "Action" scenario. If the project which is not from a conforming plan and TIP is a modification of a project currently in the plan or TIP, the "Baseline" scenario must include the project with its original design concept and scope, and the "Action" scenario must include the project with its new design concept and scope.

§ 51.401 Procedures for determining regional transportation-related emissions.

(a) *Serious, severe, and extreme ozone nonattainment areas and serious carbon monoxide areas after January 1, 1995.* Estimates of regional transportation-related emissions used to support conformity determinations must be made according to procedures which meet the requirements in paragraphs (a)(1) through (5) of this section.

(1) A network-based transportation demand model or models relating travel demand and transportation system performance to land-use patterns, population demographics, employment, transportation infrastructure, and transportation policies must be used to estimate travel within the metropolitan planning area of the nonattainment area. Such a model shall possess the following attributes:

(i) The modeling methods and the functional relationships used in the model(s) shall in all respects be in accordance with acceptable professional practice, and reasonable for purposes of emission estimation;

(ii) The network-based model(s) must be validated against ground counts for a base year that is not more than 10 years prior to the date of the conformity determination. Land use, population, and other inputs must be based on the best available information and appropriate to the validation base year;

(iii) For peak-hour or peak-period traffic assignments, a capacity sensitive assignment methodology must be used;

(iv) Zone-to-zone travel times used to distribute trips between origin and destination pairs must be in reasonable agreement with the travel times which result from the process of assignment of trips to network links. Where use of transit currently is anticipated to be a significant factor in satisfying transportation demand, these times should also be used for modeling mode splits;

(v) Free-flow speeds on network links shall be based on empirical observations;

(vi) Peak and off-peak travel demand and travel times must be provided;

(vii) The model(s) must utilize and document a logical correspondence between the assumed scenario of land development and use and the future transportation system for which emissions are being estimated, but reliance on a formal land-use model is not specifically required;

(viii) A dependence of trip generation on the accessibility of destinations via the transportation system is not specifically required, unless the network model is capable of such determinations and the necessary information is available;

(ix) A dependence of regional economic and population growth on the accessibility of destinations via the transportation system is not specifically required, unless the network model is capable of such determinations and the necessary information is available; and

(x) Consideration of emissions increases from construction-related congestion is not specifically required.

(2) Highway Performance Monitoring System (HPMS) estimates of vehicle miles traveled shall be considered the primary measure of vehicle miles traveled within the portion of the nonattainment area and for the functional classes of roadways included in HPMS, for urban areas which are sampled on a separate urban area basis. A factor (or factors) shall be developed to reconcile and calibrate the network-based model estimates of vehicle miles traveled in the base year of its validation to the HPMS estimates for the same period, and these factors shall be applied to model estimates of future vehicle miles traveled. In this factoring process, consideration will be given to differences in the facility coverage of the HPMS and the modeled network description. Departure from these procedures is permitted with the concurrence of DOT and EPA.

(3) Reasonable methods shall be used to estimate nonattainment area vehicle travel on off-network roadways within the urban transportation planning area, and on roadways outside the urban transportation planning area.

(4) Reasonable methods in accordance with good practice must be used to estimate traffic speeds and delays in a

manner that is sensitive to the estimated volume of travel on each roadway segment represented in the network model.

(5) Ambient temperatures shall be consistent with those used to establish the emissions budget in the applicable implementation plan. Factors other than temperatures, for example the fraction of travel in a hot stabilized engine mode, may be modified after interagency consultation according to § 51.396 of this subpart if the newer estimates incorporate additional or more geographically specific information or represent a logically estimated trend in such factors beyond the period considered in the applicable implementation plan.

(b) *Other situations.* (1) Procedures which satisfy some or all of the requirements of paragraph (a) of this section shall be used in all areas not subject to paragraph (a) of this section in which those procedures have been the previous practice of the MPO.

(2) Regional emissions may be estimated by methods which do not explicitly or comprehensively account for the influence of land use and transportation infrastructure on vehicle miles traveled and traffic speeds and congestion. Such methods may extrapolate historical VMT or may project future VMT by considering growth in population and historical growth trends for vehicle miles travelled per person. These methods must also consider future economic activity, transit alternatives, and transportation system policies.

(c) *PM_{10} from construction-related fugitive dust.* (1) For areas in which the implementation plan does not identify construction-related fugitive PM_{10} as a contributor to the nonattainment problem, the fugitive PM_{10} emissions associated with highway and transit project construction are not required to be considered in the regional emissions analysis.

(2) In PM_{10} nonattainment and maintenance areas with implementation plans which identify construction-related fugitive PM_{10} as a contributor to the nonattainment problem, the regional PM_{10} emissions analysis shall consider construction-related fugitive PM_{10} and shall account for the level of construction activity, the fugitive PM_{10} control measures in the applicable implementation plan, and the dust-producing capacity of the proposed activities.

§ 51.402 Procedures for determining localized CO and PM_{10} concentrations.

(a) CO hot-spot analyses must be based on the applicable air quality models, data bases, and other requirements specified in the most recent version of the "Guideline on Air Quality Models (Revised)" (EPA publication No. 450/2–78–027R), including Supplements, which is hereby incorporated by reference as it exists on the date of approval (a notice of any change will be published in the **Federal Register**), in the following cases unless, after the interagency consultation process described in § 51.396(a) and with the approval of the EPA Regional Administrator, it is determined to be inappropriate:

(1) In locations, areas, or categories of sites which are identified in the SIP as sites of current violation or possible current violation; and

(2) Where use of the "Guideline" models is practicable and reasonable given the potential for violations.

(b) In cases other than those described in paragraphs (a)(1) and (a)(2) of this section, other quantitative methods may be used if they represent reasonable and common professional practice. Where both "Guideline" and non-"Guideline" models are available, "Guideline" models must be given the greatest consideration.

(c) CO hot-spot analyses must include the entire project, and may be performed only after the major design features which will significantly impact CO concentrations which have been identified. The background concentration must reflect emissions from all existing facilities and emissions expected from future projects which have completed environmental review.

(d) Hot-spot analysis assumptions must be consistent with those in the regional emissions analysis for those inputs which are required for both analyses.

(e) PM_{10} or CO mitigation or control measures shall be assumed in the hot-spot analysis only where there is a commitment in the NEPA document to incorporate such measures into the design and funding of the project.

(f) CO and PM_{10} hot-spot analyses are not required to consider construction-related activities which cause temporary and self-correcting increases in emissions. Each site which is affected by construction-related activities shall be considered separately, using established "Guideline" methods. Temporary and self-correcting increases are defined as those which occur only during the construction phase and last five years or less at any individual site.

§ 51.403 Exempt projects.

Notwithstanding the other requirements of this subpart, highway and transit projects of the types listed in Table 2 are exempt from the requirement that a conformity determination be made. Such projects may proceed toward implementation even in the absence of a conforming transportation plan and TIP. A particular action of the type listed in Table 2 is not exempt if the MPO in consultation with other agencies (see § 51.396(a)(8) of this subpart), the EPA, and the FHWA (in the case of a highway project) or the FTA (in the case of a transit project) concur that it has potentially adverse emissions impacts for any reason. States and MPOs must ensure that exempt projects do not interfere with TCM implementation.

Table 2.—Exempt Projects

Safety

Railroad/highway crossing
Hazard elimination program
Safer non-Federal-aid system roads
Shoulder improvements
Increasing sight distance
Safety improvement program
Traffic control devices and operating assistance other than signalization projects
Railroad/highway crossing warning devices
Guardrails, median barriers, crash cushions
Pavement resurfacing and/or rehabilitation
Pavement marking demonstration
Emergency relief (23 U.S.C. 125)
Fencing
Skid treatments
Safety roadside rest areas
Adding medians
Truck climbing lanes outside the urbanized area
Lighting improvements
Widening narrow pavements or reconstructing bridges (less than one travel lane)

Mass Transit

Operating assistance to transit agencies
Purchase of support vehicles
Rehabilitation of transit vehicles
Purchase of office, shop, and operating equipment for existing facilities
Purchase of operating equipment for vehicles (e.g., radios, fareboxes, lifts, etc.)
Construction or renovation of power, signal, and communications systems
Construction of small passenger shelters and information kiosks
Reconstruction or renovation of transit buildings and structures (e.g., rail or bus buildings, storage and maintenance facilities, stations, terminals, and ancillary structures)
Rehabilitation or reconstruction of track structures, track, and trackbed in existing rights-of-way

Purchase of new buses and rail cars to replace existing vehicles or for minor expansions of the fleet
Construction of new bus or rail storage/maintenance facilities categorically excluded in 23 CFR 771

Air Quality

Continuation of ride-sharing and van-pooling promotion activities at current levels
Bicycle and pedestrian facilities

Other

Engineering to assess social, economic, and environmental effects of the proposed action or alternatives to that action
Noise attenuation
Advance land acquisitions (23 CFR 712 or 23 CFR 771)
Acquisition of scenic easements
Plantings, landscaping, etc.
Sign removal

§ 51.404 Projects exempt from regional emissions analyses.

Notwithstanding the other requirements of this subpart, highway and transit projects of the types listed in Table 3 are exempt from regional CO or VOC emissions analysis requirements. The local effects of these projects with respect to CO or PM_{10} concentrations must be considered to determine if a hot-spot analysis is required prior to making a project-level conformity determination. These projects may then proceed to the project development process even in the absence of a conforming plan and TIP. A particular action of the type listed in Table 3 is not exempt from regional emissions analysis if the MPO in consultation with other agencies (see § 51.396(a)(8) of this subpart), the EPA, and the FHWA (in the case of a highway project) or the FTA (in the case of a transit project) concur that it has potential regional impacts for any reason.

Table 3.—Projects Exempt From Regional Emissions Analyses

Intersection channelization projects
Intersection signalization projects
Interchange reconfiguration projects
Changes in vertical and horizontal alignment
Truck size and weight inspection stations
Bus transfer terminals

§ 51.405 Special provisions for nonattainment areas which are not required to demonstrate reasonable further progress and attainment.

(a) *Application.* This section applies in the following areas:

(1) Rural ozone nonattainment areas;
(2) Marginal ozone areas;
(3) Submarginal ozone areas;
(4) Transitional ozone areas;
(5) Incomplete data ozone areas;
(6) Moderate CO areas with a design value of 12.7 ppm or less; and
(7) Not classified CO areas.

(b) *Default conformity procedures.* The criteria and procedures in § 51.400(l)–(n) of this subpart will remain in effect throughout the control strategy period for transportation plans, TIPs, and projects (not from a conforming plan and TIP) in lieu of the procedures in § 51.400(h)–(j) of this subpart, except as otherwise provided in paragraph (c) of this section.

(c) *Optional conformity procedures.* The State or MPO may voluntarily develop an attainment demonstration and corresponding motor vehicle emissions budget like those required in areas with high nonattainment classifications. In this case, the State must submit an implementation plan revision which contains that budget and attainment demonstration. Once EPA has approved this implementation plan revision, the procedures in § 51.400(h)–(j) of this subpart apply in lieu of the procedures in § 51.400(l)–(n) of this subpart.

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Part IV

Department of Commerce

Economic Development Administration

Economic Development Assistance Programs; Appropriations, 1993; Notice of Funds Availability

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DEPARTMENT OF COMMERCE

Economic Development Administration

[Docket No. 921116-2316]

Economic Development Assistance Programs as Described in Public Law 102-395, Departments of Commerce, Justice, State, the Judiciary, and Related Agencies Appropriations, 1993; Availability of Funds

AGENCY: Economic Development Administration (EDA), Department of Commerce (DoC).

ACTION: Notice.

SUMMARY: The Economic Development Administration (EDA) announces its policies and application procedures for funds available in fiscal year 1993 to support projects designed to alleviate conditions of substantial and persistent unemployment and underemployment in economically distressed areas and regions of the Nation and to address economic dislocations resulting from sudden, severe job losses. The purpose of this announcement is to communicate to potential applicants for EDA funds the policies and procedures that will be used to administer the Agency's programs during fiscal year 1993.

I. General Policies

According to existing statutory criteria, areas containing approximately 90 percent of the U.S. population are eligible for EDA assistance which, in fiscal year 1993, totals approximately $217 million. Priority consideration for funding will be given only to those proposals having the greatest potential to benefit areas experiencing or threatened with substantial economic distress. EDA is particularly interested in projects located in authorized and designated enterprise zones. Distress may exist in a variety of forms, including exceptionally high levels of unemployment, extremely low income levels, large concentrations of low income families, low labor force participation rates, significant decline in per capita employment, substantial loss of population because of the lack of employment opportunities, unusually large numbers (or high rates) of business failures, farm foreclosures, sudden major layoffs or plant closures, and drastically reduced tax bases.

Potential applicants are responsible for demonstrating to EDA, through the provision of statistics and other appropriate information, the nature and level of the distress their efforts are intended to alleviate. In the absence of evidence of exceptionally high levels of distress, EDA funding is unlikely. In considering proposals to benefit severely distressed areas, EDA will give special consideration to those that address the needs of rural communities, particularly aid directed toward the economic diversification of such areas.

During FY 1993, EDA will place a special emphasis upon assisting projects that focus on exports, entrepreneurship, and technology initiatives including innovation, transfer, and commercialization to alleviate conditions of substantial and persistent unemployment and underemployment in economically distressed areas and regions, through the provision of grants for Public Works and Development Facilities, Technical Assistance, Economic Development Planning, and Economic Adjustment Assistance.

EDA recognizes that small communities experience impediments to economic development other than the traditional inadequacies of existing water, sewer and roadway systems; therefore, in fiscal year 1993, EDA will give consideration to projects that will assist an area to overcome a special development or infrastructure problem that is preventing employment growth and economic development from taking place. Such projects may involve, but are not limited to, activities designed to enhance the expansion of the service sector of the economy when that sector is deemed more growth oriented than the traditional industrial sector, or innovative projects designed for the development of publicly-owned telecommunications infrastructure when it can be demonstrated that such a project is needed to foster productivity or enhance economic growth within an EDA-designated area. Such proposals must be appropriately scaled and provide substantial and direct benefit to the local economy or otherwise enhance the economic prosperity of the area. EDA will consider providing assistance to demonstration type projects that are especially creative from an economic development standpoint and that leverage a substantial amount of nonfederal resources.

EDA expects substantial state and local support for proposed projects. Proposals that do not provide evidence of strong state and local leadership and financing are less likely to receive EDA assistance.

In the case of projects involving construction, EDA expects construction to be initiated and completed in a timely manner. Applicants are expected to anticipate predictable delays such as those caused by normal weather conditions, permits and approvals, legal complications, community disputes, land acquisition, etc., and account for them in developing project schedules. Projects which are likely to encounter significant delays will receive low funding priority. Projects that experience unreasonable delays following EDA approval may be terminated and the funds deobligated. These policies are consistent with EDA's objective of supporting activities that can begin to benefit local economies as soon as possible, thereby meeting the pressing development needs identified by project applicants. EDA expects those responsible for developing and managing projects to maximize the impact of the public funds by preparing and implementing projects as thoroughly and expeditiously as possible.

EDA funding will not be used directly or indirectly to assist employers who transfer one or more jobs from one commuting area to another. EDA nonrelocation requirements (13 CFR 309.3) apply to all grants involving construction, rehabilitation or repair under titles I, IV, IX, and section 301(f) of the Public Works and Economic Development Act of 1965 (Pub. L. 89-136, 42 U.S.C. 3121-3246h), as amended (including grants for Revolving Loan Funds, under title IX).

No award of Federal funds shall be made to an applicant who has an outstanding delinquent Federal debt until either:

1. The delinquent account is paid in full;
2. A negotiated repayment schedule is established and at least one payment is received, or
3. Other arrangements satisfactory to DoC are made.

Applicants may be subject to a pre-award accounting system survey by the Department of Commerce's Office of Inspector General, and fund recipients may be subject to audits or other inspections by the same office.

Applicants eligible for assistance because of membership in an economic development district must be active participants in the district's economic development planning process. EDA will evaluate applications for conformance with published statutory, regulatory, and policy requirements. Applications proposed for funding under these programs are subject to the requirements of Executive Order 12372, "Intergovernmental Review of Federal Programs."

An invitation to submit an application does not assure EDA funding. Factors that will be considered in evaluating proposals include if and to what extent the project meets the selection criteria.

Unsuccessful applicants will be notified of the status of their applications when the appropriate program funds have been awarded.

Processing time for proposals will depend upon the completeness of the information and supporting documents provided in the application at the time of submission. Proposals that require additional information from applicants or other sources will be returned to correct deficiencies and the official application receipt dates will be adjusted accordingly.

EDA will not approve projects that involve actual or potential conflict-of-interest situations. If EDA identifies or suspects a possible conflict-of-interest situation, or an appearance of such, application processing and/or grant award may be suspended and the burden will be on the applicant/grantee to take appropriate steps to eliminate the perception of a conflict of interest before application processing of the grant is resumed.

Recipients must agree that no funds made available by EDA shall be used, directly or indirectly, for paying attorneys' or consultants' fees in connection with securing awards made by the Government, such as, for example, preparation of the application. However, attorneys' and consultants' fees incurred for meeting award requirements, such as conducting a title search or preparing plans and specifications, may be eligible project costs and may be paid out of funds made available by EDA, if such costs are otherwise eligible.

Public Law 101–510, enacted November 5, 1990, section 1405, amending subchapter IV of chapter 15, title 31, United States Code, prescribes the rules for determining the availability of appropriations. Accordingly, grant funds obligated for a project will expire in five years from the fiscal year of the grant award.

Applicants must submit a completed Form CD–511, "Certifications Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying."

Recipients shall require applicants/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the award to submit, if applicable, a completed Form CD–512, "Certifications Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions and Lobbying" and disclosure form, SF–LLL, "Disclosure of Lobbying Activities." Form CD–512 is intended for the use of recipients and should not be transmitted to the Department. SF–LLL submitted by any tier recipient or subrecipient should be submitted to the Department in accordance with the instructions contained in the award document.

Prospective participants (as defined at 15 CFR part 26, section 105) are subject to 15 CFR part 26, "Nonprocurement Debarment and Suspension" and the related section of the certification form.

Grantees (as defined at 15 CFR part 26, section 605) are subject to 15 CFR part 26, subpart F, "Governmentwide Requirements for Drug-Free Workplace (Grants)" and the related section of the certification form.

Persons (as defined at 15 CFR part 28, section 105) are subject to the lobbying provisions of 31 U.S.C. 1352, "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," and the lobbying section of the certification form which applies to applications/bids for grants, cooperative agreements, and contracts for more than $100,000, and loans and loan guarantees for more than $150,000, or the single family maximum mortgage limit for affected programs, whichever is greater. Any applicant that has paid or will pay for lobbying using any funds must submit an SF–LLL, "Disclosure of Lobbying Activities," as required under 15 CFR part 28, appendix B.

Applicants should be aware that a false statement on the application is grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001.

All nonprofit and for-profit applicants are subject to a name check review process. Name checks are intended to reveal if any key individuals associated with the applicant have been convicted of, or are presently facing, criminal charges such as fraud, theft, perjury, or other matters which significantly reflect on the applicant's management, honesty or financial integrity.

Recipients and subrecipients are subject to all Federal laws and Federal and Departmental policies, regulations, and procedures applicable to Federal financial assistance awards.

Unsatisfactory performance under prior Federal awards may result in an application not being considered for funding.

If an application is selected for funding, EDA has no obligation to provide any additional future funding in connection with an award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of the EDA.

Applicants should be aware that if they incur any costs prior to an award being made they do so solely at their own risk of not being reimbursed by the Government. Notwithstanding any verbal assurance that might have been received, there is no obligation on the part of EDA to cover pre-award costs.

The following material describes other policies and procedures associated with each of EDA's programs.

II. Program: Public Works and Development Facilities Assistance

(Catalog of Federal Domestic Assistance: 11.300 Economic Development Grants and Loans for Public Works and Development Facilities. 11.304 Economic Development Public Works Impact Program (PWIP))

Summary

Funds available under the Public Works and Development Facilities Program are used to finance projects that contribute to the economic development of distressed areas. Grants are authorized by titles I and IV of the Public Works and Economic Development Act of 1965, as amended (PWEDA), 42 U.S.C. 3131 and 42 U.S.C. 3171(a) (3).

Eligibility

Eligible applicants under this program include any state, or political subdivision thereof, Indian tribe, the Federated States of Micronesia, the Republic of the Marshall Islands, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Commonwealth of the Northern Mariana Islands, or private or public nonprofit organization or association representing any redevelopment area or part thereof, if the project is located within an EDA-designated redevelopment area.

Redevelopment areas, other than those designated under the Public Works Impact Program, must have a current EDA-approved Overall Economic Development Program (OEDP). Political entities claiming eligibility under OEDPs developed by multicounty economic development organizations are expected to continue to participate actively in the organization. Further information on eligibility is available from EDA's regional offices. Nonprofit applicants are urged to seek the cooperation and support of units of local government and, when deemed appropriate by EDA, to have the local government serve as co-applicant for EDA assistance. This serves the purpose of ensuring the financial stability and continuity of the project, in the event that the nonprofit entity finds itself in a position of not having the financial resources to properly and efficiently administer,

operate, and maintain the EDA-assisted facility consistent with the provisions of 13 CFR 314–Property Management Standards.

Program Objective

The purpose of the Public Works Program is to assist communities with the funding of public works and development facilities that contribute to the creation or retention of private sector jobs and to the alleviation of unemployment and underemployment. Such assistance is designed to help communities achieve lasting improvement by stabilizing and diversifying local economies, and improving local living conditions and the economic development of the area. EDA emphasizes the alleviation of unemployment and underemployment among residents of the project area as a primary focus of this program. In view of the current rural distress, applications from rural communities will be reviewed with particular interest.

Funding Availability

Funds in the amount of $147.435 million are available for this program.

Funding Instrument

EDA may provide direct grants not to exceed 50 percent of the estimated cost of the project. However, under certain circumstances supplementary grants to augment the direct grant may be provided up to a maximum of 80 percent of the eligible project costs. But in no event shall the Federal participation exceed 80 percent of the aggregate cost of any such project, except in the case of a grant to an Indian Tribe, where EDA may waive the non-Federal share. Applicants are required to provide the local share from acceptable sources including, but not limited to cash, local government general obligation or revenue bonds, Community Development Block Grant (CDBG) entitlement funds or balance of state awards, Farmers Home Administration loans, and other public and private financing, including donations.

The local share need not be in hand at the time of application, however, the applicant must satisfy EDA that the funds will be available to provide the nonfederal share of the project.

The local share must not be encumbered in any way that would preclude its use consistent with the requirements of the grant. Priority will be given to applications which maximize the local share's percentage of the project cost. Supplementary grant assistance to finance over 50 percent of the project costs will be approved by EDA only for proposals in areas of high distress. Decisions on such supplementary grant assistance will be based on the nature of the project, the amount of fair user charges or other revenues the project may reasonably be expected to generate, and the relative needs of the area (see 13 CFR 305.5).

Selection Criteria

For both regular public works projects and Public Works Impact Program (PWIP) projects, priority consideration will be given to those which are the most competitive based upon the project selection criteria set forth below, that best meet the needs of eligible areas, and that are located in areas of severe economic distress.

A. Public Works Projects

Factors that will be taken into account in considering projects eligible under section 101(a)(1)(A)–(C) of PWEDA, 42 U.S.C. 3131(a)(1)(A)–(C), include if and to what extent the project:

1. Improves opportunities for the successful establishment or expansion of industrial or commercial facilities in the area where such project will be located.

2. Assists in creating or retaining private sector jobs in the near term and assists in the creation of additional long-term employment opportunities, provided the jobs are not transferred from any other area of the United States, and will result in a low cost-per-job in relation to total EDA cost.

3. Benefits the long-term unemployed and members of low-income families who are residents of the area to be served by the project.

4. Fulfills a pressing need of the area, or part thereof, in which it will be located.

5. Is consistent with the EDA approved Overall Economic Development Program (OEDP) for the area in which it is, or will be, located, and has broad community support.

6. Is supported by significant private sector investment.

7. Promotes exports, entrepreneurship, or technology initiatives including innovation, transfer and commercialization.

8. Has evidence of adequate local share of funds.

9. Supports developments taking place in designated enterprise zones, particularly in rural areas.

10. Demonstrates that necessary permits, land acquisitions, or options on land and rights-of-way have been obtained and that all other legal requirements of the application process have been satisfied.

11. Maximizes the amount of local, state or other Federal funding that is available.

12. Gives evidence of the ability to begin and complete construction in a timely manner in accordance with a schedule to be agreed upon by EDA and the applicant and included in the grant award. EDA discourages the start of construction prior to grant award and cautions that financial hardship may be experienced by applicants whose projects are not approved. EDA will require all applicants that request approval to proceed with construction prior to grant award to acknowledge that they are proceeding at their own risk and without recourse to EDA if the grant is not awarded or EDA requirements are not met. EDA also requires that compliance with environmental regulations be completed before construction begins. EDA's regional office must have time to complete its "Finding of No Significant Impact," and clearances must be obtained from appropriate state and Federal agencies. Furthermore, EDA may view the start of construction prior to grant award as an indication that the grant funds are not essential for the successful implementation of the project.

13. If located in an Economic Development Center (i.e., Growth Center) that has a stable economy with little distress, must include an employment plan that explains how new employment opportunities for residents of nearby highly distressed redevelopment areas will be provided.

B. Public Works Impact Program

Factors that will be considered in the evaluation of projects under the Public Works Impact Program (PWIP) authorized by section 101(a)(1)(D) of PWEDA, 42 U.S.C. 3131(a)(1)(D), include if and to what extent the project:

1. Directly assists in creating immediate useful work (i.e., construction jobs) for the unemployed and underemployed residents in the project area;

2. Improves the economic or community environment in areas of severe economic distress;

3. Includes a specific plan (i.e., PWIP Employment Strategy) for hiring the unemployed and underemployed persons from the project area to work on the construction of the project; EDA will evaluate all plans to ensure that they contain a logical explanation of how the employment objectives will be met;

4. Assists in providing long-term employment opportunities or other economic benefits for the unemployed and underemployed in the project area;

5. Primarily benefits low-income families by providing essential community services, or satisfying a pressing public need;

6. In addition to the requirement for regular public works projects, as contained in paragraph A, can begin construction quickly (normally within 120 days after acceptance of the grant by the applicant);

7. Has substantial labor intensity, where labor intensity is the proportion of labor costs to the total project costs; and

8. Promotes exports, entrepreneurship or technology initiatives including innovation, transfer, and commercialization.

C. Industrial Park Projects

Applications proposing projects that will primarily serve an industrial park or site will be evaluated on such additional factors as:

1. A detailed analysis of existing industrial park capacity and utilization; occupancy rates for existing developed industrial parks currently available within a 25-mile radius of the project site. For cities with populations over 50,000, the prescribed area may be determined by an analysis of industrial sites within an established industrial area, which may be less than a 25-mile radius. Contact the economic development representative (EDR) for the area or the appropriate EDA regional office for guidance.

2. Commitments in writing from identified tenants to expand existing operations or to locate in the industrial park or site. Commitments must include a description of the industry, the number of jobs created or saved, an implementation schedule, and the relationship of the commitment to the requested grant assistance.

3. The existence of a documented marketing strategy and demonstrated financial ability to market space in the industrial park or site. Strong emphasis will be placed upon this requirement.

Construction Project Implementation

As indicated in the first section of this Notice, EDA expects construction projects to be initiated and completed in a timely manner and in accordance with the schedule agreed upon in the grant documentation. The recipient will be responsible for promptly notifying EDA of any events that prevent adherence to the approved schedule. The recipient must provide an explanation of why the events were beyond its ability to predict or control and obtain EDA's approval of changes in the schedule prior to proceeding with project implementation. EDA expects recipients to anticipate predictable delays (such as those caused by land acquisition problems, local financing requirements, normal weather conditions in the area, acquisition of state permits and approvals, and known public objections to the project), and to take them into account in preparing the project schedule. Recipients who fail to comply with project schedules are subject to grant suspension or termination.

Under most circumstances, EDA will not provide additional funds to finance cost overruns that occur during project implementation.

Proposal Submission Procedures

To establish the merits of project proposals, interested parties should first contact the economic development representative for the area (see listing in section X). The economic development representative for the area will provide a preapplication form (ED–101P, OMB Control No. 0610–0011) and arrange for conferences to discuss the proposal. EDA will screen proposals before inviting the submission of an application. As previously mentioned, an invitation does not assure EDA funding. Proposals will be evaluated based upon:

1. Conformance with statutory and other legal requirements and with the selection criteria mentioned above;

2. The merits of the proposal in addressing the economic development needs of the eligible area; and

3. The availability of program funds.

Processing time for project proposals depends upon the completeness of information and supporting documents provided in the preapplication form at the time of submission. Project proposals that require additional information from applicants or other sources will be returned to correct deficiencies and the official application receipt dates will be adjusted accordingly.

Application Procedures

Following a review of project proposals, EDA will invite entities whose projects are selected for consideration to submit applications. The application will include a form ED–101A, as approved by the Office of Management and Budget Control No. 0610–0011. The demand for public works assistance is expected to exceed available funding. Therefore, to avoid having incomplete proposals delay other more timely grant awards, a 120-day time restriction will apply to invited applications for resolving application deficiencies. Applications that cannot be recommended for approval within 120 days of receipt in a regional office because of unresolved issues will be returned to the applicants. Such applications may be reconsidered at a future date, but must compete with other proposals at that time.

Previous Applications

Project applications invited, but not funded in FY 1992, remain eligible for funding consideration. Applications received prior to the date of this Notice will be processed and evaluated in accordance with the project selection criteria published for FY 1992 and current legal requirements. Those applications received on or after the date of this Notice must be consistent with the project selection criteria and requirements published in this Notice. Applicants whose projects were invited but not submitted to EDA in FY 1992 should contact the appropriate EDA regional office regarding forms to be used for FY 1993.

Further Information

For further information contact the appropriate EDA regional office or economic development representative for your area (see section X of this Notice).

III. Program: Local Technical Assistance

(Catalog of Federal Domestic Assistance: 11.303 Economic Development—Technical Assistance)

Summary

Funds under the Local Technical Assistance Program are awarded to eligible applicants to help assure the successful initiation and implementation of area, state, and regional development efforts designed to alleviate economic distress. This program is authorized under section 301(a) of the Public Works and Economic Development Act of 1965, as amended, 42 U.S.C. 3151(a).

Eligibility

Eligible applicants for Local Technical Assistance grants or cooperative agreements include public or private nonprofit national, state, area, district, or local organizations; public and private colleges and universities; Indian tribes, local governments, and state agencies. In certain circumstances, applications may be considered from other applicants such as private individuals, partnerships, firms, and corporations.

Program Objective

The Local Technical Assistance Program is designed to help alleviate or prevent conditions of excessive

unemployment or underemployment and problems of economically distressed populations in rural and urban areas.

Funding Availability

Funds in the amount of $600,000 are available for the Local Technical Assistance Program. (Note: EDA generally will limit its funding for a proposed Local Technical Assistance project to $25,000.)

Funding Instrument

EDA will provide grants and cooperative agreements not to exceed 75 percent of the proposed project costs. Applicants are expected to provide the remaining share, preferably in cash. The Assistant Secretary may waive all or part of the 25 percent share of technical assistance grants, if he/she determines that the nonfederal share is not reasonably available because of the critical nature of the situation requiring technical assistance or for other good cause.

Project Duration

Assistance will be for the period of time required to complete the scope of the work. This typically does not exceed twelve months.

Selection Criteria

Preference will be given to Local Technical Assistance proposals which:

1. Show that the proposed project will lead to the near-term (between one and five years) generation or retention of private sector jobs.
2. Support the efforts of state and local organizations and institutions, including nonprofit development groups, to undertake and promote effective economic development programs targeted to people and areas in distress.
3. Stimulate significant private and nonfederal public investment for economic development purposes.
4. Benefit severely distressed areas, particularly rural counties and communities.
5. Demonstrate innovative approaches to stimulating economic development in depressed areas. EDA is particularly interested in receiving innovative proposals in the following areas:
   a. Export development as an economic development strategy;
   b. Assistance to business in uses of technology initiatives including innovation, transfer, and commercialization;
   c. Minority business development in distressed areas;
   d. Tourism;
   e. Rural enterprise zones;
   f. Linkages in economic development and environmental goals; and
   g. Entrepreneurship.
6. Are consistent with the EDA approved Overall Economic Development Program (OEDP) for the area in which the projects are located and have been recommended by the OEDP Committee (if appropriate to the nature of the project).
7. Present an appropriate and clear project design.
8. Are proposed by organizations with the capacity, qualifications and staff necessary to undertake the intended activities.
9. Present a reasonable, itemized budget for the proposed activities.

Pre-Application Procedures

Parties seeking support for Local Technical Assistance projects should contact the economic development representative (EDR) for information before preparing a proposal. (See EDR listing in section X of this announcement.)

EDA will evaluate all proposals as they are received and invite applications for those which best satisfy the selection criteria. An invitation does not, however, assure EDA funding.

Potential applicants should submit one original and two copies of a brief and concise proposal.

Proposal Submission Procedures

Potential applicants must submit to the appropriate EDR proposals that include:

1. A cover page giving a short descriptive project title, the name and address of the applicant organization, the name and telephone number of the project director, the project duration, the amount of EDA funds requested, and the program (Local Technical Assistance) that would provide the funds;
2. A brief description of the project;
3. A brief explanation of why the project is needed and its objectives;
4. A work plan showing different phases of the project and their timing;
5. A detailed budget showing cost breakdowns, with EDA-funded and non-EDA-funded costs presented in separate columns and with the EDA-funded costs equaling to the total shown on the cover page.

Application Procedures

The appropriate EDA regional office will invite entities whose proposals for Local Technical Assistance projects are selected for further consideration to submit application packages. The application will include a Standard Form–424 (OMB Control No. 038–0043).

Further Information

For further information about Local Technical Assistance projects contact the appropriate EDR. (See EDR listing in section X of this announcement.)

IV. Program: National Technical Assistance

(Catalog of Federal Domestic Assistance: 11.303 Economic Development—Technical Assistance)

Summary

Funds under the National Technical Assistance Program are awarded to eligible applicants who will offer assistance to local, regional and state organizations, and/or conduct demonstrations of and disseminate information about innovative development techniques designed to alleviate economic distress. This program is authorized under section 301(a) of the Public Works and Economic Development Act of 1965, as amended, 42 U.S.C. 3151(a).

Eligibility

Eligible applicants for National Technical Assistance grants or cooperative agreements include public or private nonprofit national, state, area, district, or local organizations; public and private colleges and universities; Indian tribes, local governments, and state agencies. In certain circumstances, applications may be considered from other eligible applicants such as private individuals, partnerships, firms, and corporations.

Program Objective

The National Technical Assistance Program is designed to help alleviate or prevent conditions of excessive unemployment or underemployment and problems of economically distressed populations.

Funding Availability

Funds in the amount of $830,000 are available for the National Technical Assistance Program.

Funding Instrument

EDA will provide grants and cooperative agreements not to exceed 75 percent of proposed project costs. Applicants are expected to provide the remaining share. In cases where EDA issues a Solicitation of Applications, an applicant's share may not be required. The Assistant Secretary may waive all or part of the 25 percent nonfederal share of technical assistance grants, if he/she determines that the nonfederal share is not reasonably available because of the critical nature of the

situation requiring technical assistance or for other good cause.

Project Duration

Assistance will be for the period of time required to complete the scope of the work. Generally, this will not exceed fifteen months.

Selection Criteria

Preference will be given to those Technical Assistance proposals which:

1. Do not depend upon further EDA or other Federal funding assistance to achieve results.
2. Support the capability of state and local organizations and institutions, including nonprofit development groups, to undertake and promote effective economic development programs targeted to people and areas in distress.
3. Stimulate significant private and nonfederal public investment for economic development purposes.
4. Benefit severely distressed areas.
5. Demonstrate innovative approaches to stimulating economic development in depressed areas. EDA is particularly interested in receiving innovative proposals in the following areas:
   a. Assistance to business in implementing technology initiatives including innovations, transfer, and commercialization;
   b. Exports;
   c. Entrepreneurship;
   d. Tourism;
   e. Rural enterprise zones; and
   f. Linkages in economic development and environmental goals.
6. Present an appropriate and clear project design.
7. Are proposed by organizations with the capacity, qualifications, and staff necessary to undertake the intended activities.
8. Present a reasonable, itemized budget for the proposed activities.

Pre-Application Procedure

Potential applicants should submit one original and two copies of a brief and concise proposal which should not exceed 20 pages. Vita and capability information may be appended.

Proposals should include:

1. A cover page giving a short descriptive project title, the name and address of the performing organization, the name and telephone number of the project director, the project duration, the amount of EDA funds requested, and the program (National Technical Assistance) that would provide the funds;
2. A brief scope-and-objectives section indicating why the project is needed, giving its objectives, and providing a capsule description of the project;
3. A more detailed description of the project and its methodology;
4. A work plan showing different phases of the project and their timing;
5. A detailed budget showing cost breakdowns, with EDA-funded and non-EDA-funded costs presented in separate columns and with the EDA-funded costs adding to the total shown on the cover page;
6. Résumés for the project director and principal staff; and
7. A corporate or institutional capability statement, where appropriate.

Proposals should be submitted to the Director, Technical Assistance and Research Division, Economic Development Administration, room 7315, U.S. Department of Commerce, Washington, DC 20230.

Application Procedures

The Technical Assistance and Research Division will invite entities whose proposals for National Technical Assistance projects are selected for further consideration to submit application packages. Such invitation, however, does not assure EDA funding. The application will include a Standard Form-424 (OMB Control No. 038–0043).

Eligibility for Specific Solicitations

EDA may, during the course of the year, identify additional specific economic development technical assistance activities. Organizations and individuals interested in being invited to respond to Solicitations of Applications (SOAs) to conduct such work should submit information on their capabilities and experience to the Director, Technical Assistance and Research Division, Economic Development Administration, room 7315, U.S. Department of Commerce, Washington, DC 20230.

Further Information

For further information about National Technical Assistance projects contact the National Technical Assistance Coordinator, telephone (202) 482–2127.

V. Program: University Center Technical Assistance Projects

(Catalog of Federal Domestic Assistance: 11.303 Economic Development—Technical Assistance)

Summary

Funds for basic university center projects are used as seed money to help selected colleges and universities mobilize their own and other resources to assist in the economic development of distressed areas. The efforts of university centers should focus on helping public bodies, nonprofit organizations and businesses plan and implement activities designed to generate jobs and income. In addition, funds may be used for projects which promote the goals of the University Center Program in other ways that demonstrate innovative economic development. Support for these types of projects is authorized under section 301(a) of the Public Works and Economic Development Act of 1965, as amended, 42 U.S.C. 3151(a).

Eligibility

Eligible applicants for university center grants and cooperative agreements are public and private colleges and universities, associations representing such institutions, and other organizations with expertise in University Center Program issues.

Program Objective

The objective of these projects is to enable colleges and universities to contribute to overall economic development by using their resources to provide technical assistance that will alleviate or prevent conditions of excessive unemployment or underemployment and problems of distressed populations in individual states or substate areas.

Funding Availability

Funds in the amount of $7.570 million are available for university center projects. It is expected that continuation grants for existing centers will use all of this amount.

Funding Instrument

EDA will provide grants or cooperative agreements not to exceed 75 percent of the proposed project costs.

Project Duration

Grants will be for a one-year period.

Selection Criteria

University center proposals (for both continuation and initial grants) must present a clear description of the economy of the proposed service area, its economic development needs, and the activities to be carried out with the requested funding. The work program for the university center must be structured under the following categories:

1. Providing technical assistance (which must be the major emphasis of the program),
2. Conducting applied research, and
3. Disseminating results of university center activities.

For this program, EDA defines technical assistance as any activity

undertaken in response to a direct request for help from a client outside the sponsoring institution, and applied research is defined as any activity undertaken by the university center at its own initiative.

Each proposal must contain quantitative and qualitative evaluation criteria for each activity listed under the above three work program categories. These criteria, when accepted by EDA, will be used to judge the performance of the university center.

Each university center that received funding in fiscal year 1992 was required to provide these evaluation criteria for its work program. EDA will give significant weight in assessing the overall performance of a university center to the degree that the university center met these quantitative and qualitative evaluation criteria.

If one or more university centers fails to qualify for a fiscal year 1993 continuation grant, EDA will hold an open competition for those funds in the appropriate regional office. In judging proposals for initial grants under an open competition, EDA will consider the:

1. Quality of the proposed work program;
2. Degree to which the work program is focused on providing technical assistance to organizations outside the sponsoring institution (i.e., on providing technical assistance);
3. Presence of a methodology for recognizing/rewarding the participation of faculty and students in the work program;
4. Presence of a five-year financial plan for the university center;
5. Commitment, as evidenced by financial support and other resources, of the university leadership at the highest levels to the mission and purpose of the university center;
6. Capacity of the institution and the university center to provide the proposed technical and other types of assistance to jurisdictions and organizations within the service area;
7. Degree to which the proposal complements and supports the local, regional or state economic development strategies in the service area;
8. Extent to which the center proposes to target its assistance to the economically-distressed sections of its proposed service area; and
9. Presence of other technical assistance providers in the proposed service area including Small and Minority Business Development Centers (SBDCs and MBDCs) and Trade Adjustment Assistance Centers.

Institutions seeking continuation or initial grants under this program should realize that EDA will not award university center funds to provide small business counseling or management assistance in areas serviced by an SBDC or an MBDC.

All applicants should realize that EDA limits the indirect cost rate that may be charged to grants under this program to 20 percent of total direct costs or the institution's negotiated indirect cost rate, whichever is less. Institutions with indirect cost rates above 20 percent may not use the amount above the 20 percent level as part of the nonfederal share.

Proposals for other projects that meet the goals of the University Center Program will be judged on similar factors. These include the potential impact of the project on distressed areas, the quality of the proposed work program, and the qualifications of the applicant to carry it out.

Depending on the availability of funds, EDA may hold a competition for short-term (one to three years) incentive grants. This competition will be open to all currently and previously funded centers, except those whose funding was discontinued because of poor performance.

Funding Policy

Public Law 102–395, the Department of Commerce fiscal year 1993 Appropriations Act, provides $7.570 million for this program, a $154,000 reduction from the fiscal year 1992 amount. The accompanying Conference Report directs EDA to award these funds to university centers that received funding in fiscal year 1992 and to make any adjustments in individual funding levels equitably among all of the university centers.

A successful applicant under any such open competition will be eligible for funding under the program for a five year period, subject to the continued availability of program funds and an annual determination by EDA of satisfactory performance by the university center. Any institution receiving an initial university center grant in fiscal year 1993 will be required to provide a nonfederal share equal to 25 percent of the total project costs for the first year. If funding is available, for the second through the fifth years, the institution should increase its nonfederal share to equal the university center grant.

Proposal Submission Procedures for Continuation Grants

Each existing university center will be notified by the appropriate regional office of its eligibility for continuation funding. At that time, university centers eligible for continuation funding will be notified of the amount of the required nonfederal share and provided with additional program guidance.

Proposal Submission Procedures for Basic Grants

Institutions seeking funding for a university center should submit a proposal describing the activities to be carried out with the grant funds to the appropriate EDA regional office or to the EDR for the area. (See EDA regional office and EDR list in Section X of this announcement.)

Further Information

For further information about University Center Technical Assistance projects contact the appropriate EDR or regional office (listing in Section X of this announcement) or the University Center Coordinator, Technical Assistance and Research Division, Economic Development Administration, room 7315, U.S. Department of Commerce, Washington, DC 20230; telephone (202) 482–2127.

VI. Program: Planning Assistance for Economic Development Districts, Indian Tribes, and Redevelopment Areas

(Catalog of Federal Domestic Assistance: 11.302 Economic Development—Support for Planning Organizations)

Summary

Funds under the District, Indian, and Area Planning Program are awarded to defray administrative expenses in support of the economic development planning efforts of economic development districts (Districts), redevelopment areas (Areas) and Indian tribes. This program is authorized under section 301(b) of the Public Works and Economic Development Act of 1965, as amended, 42 U.S.C. 3151(b).

Eligibility

Eligible applicants are economic development districts, redevelopment areas, organizations representing redevelopment areas (or parts of such Areas), Indian tribes, organizations representing multiple Indian tribes, the Federated States of Micronesia, the Republic of the Marshall Islands, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Program Objective

The primary objective of planning assistance for administrative expenses under section 301(b) is to support the formulation and implementation of

economic development programs designed to create or retain full-time permanent jobs and income, particularly for the unemployed and underemployed in the most distressed areas served by the applicant. Planning activities supported by these program funds must be part of a process involving significant leadership by public officials and private citizens.

Funding Availability

Funds in the amount of $20.254 million are available in two categories: Districts/Areas (Category A)—$17.353 million; and Indian tribes (Category B)—$2.901 million.

Funding Instrument

Grant assistance can be provided for up to 75 percent of project costs for Category A grants with the applicant required to provide the remaining share from local (non-federal) sources. Category B grant assistance may be provided for up to 100 percent of project costs.

Project Duration

Assistance will normally be for a period of twelve months.

Selection Criteria

EDA will consider the following factors, among other things, in evaluating proposals:

1. The responsiveness of the proposed work program to the program regulations contained in 13 CFR 307.22;
2. The economic distress of the area served by the applicant;
3. Provision of an institutional capability statement, defining management and staff capacity and qualifications in economic program/policy development and operations;
4. Past performance of any currently funded grantee (including information in scheduled progress reports);
5. The local leaders' involvement in the applicants' economic development activities;
6. The amount of local participation provided as matching dollars to the Federal funds; and
7. Priority consideration will be given to currently funded grantees.

Proposal Submission Procedures

Application procedures may be obtained from EDA's regional offices for the following:

a. Currently funded planning grantees;

b. Proposals from applicants not currently funded under Categories A or B, that would fit into either of those categories; and

c. Special economic development activities that benefit one or more 301(b) grantees and cannot be financed with other resources.

Eligible applicants under both Categories A and B should submit proposals which include:

1. A letter signed by the chief elected official (Chairman of the Board, Tribal Chairman) or another authorized official of the applicant stating the organization's desire to receive funds to carry out the types of planning and administrative activities eligible under the 301(b) program.
2. Significant, verifiable information on the level of economic distress in the area, including unemployment and income data. Any major changes in distress levels during the past year should be described.
3. A work program outlining the specific development activities that will be carried out under the grant and explaining how they relate to the problems identified in the area QEDP, annual report, or other documents.

New applicants should submit one copy of the proposal to the appropriate economic development representative, and an original and one copy to the appropriate EDA regional office. Addresses of the EDA regional offices and listing of the economic development representatives are found in section X of this Notice.

Formal Application Procedures

EDA regional offices will contact currently funded grantees to inform them of the procedures for submitting applications for continuation funding.

Following review of the proposals submitted, EDA will invite those selected for funding consideration to submit formal applications. Funding levels will be determined by the economic distress and need of the area served by the applicants, past performance of previously funded grantees, and availability of program funds. The application will include an SF–424, as approved by the Office of Management and Budget Control No. 0348–0043.

Further Information

For further information contact the appropriate economic development representative, EDA regional office (see section X of this Notice), or the Director, Planning Division, Economic Development Administration, room 7321, U.S. Department of Commerce, Washington, DC 20230; telephone (202) 482–3027.

VII. Program: Planning Assistance for States and Urban Areas

(Catalog of Federal Domestic Assistance: 11.305 Economic Development—State and Urban Area Economic Development Planning)

Summary

Funds under the State and Urban Planning Program are awarded to defray administrative expenses in support of economic development planning efforts of eligible applicants. This program is authorized under section 302(a) of the Public Works and Economic Development Act of 1965, as amended, 42 U.S.C. 3151a.

Eligibility

Eligible applicants under this program are the governors of states, the chief executive officers of cities and counties, and substate planning and development organizations (including redevelopment areas and economic development districts).

Program Objective

The primary objective of planning assistance under section 302(a) is to support significant economic development planning and implementation initiatives of eligible applicants, particularly those experiencing severe economic distress.

Assistance must be part of a continuous process involving significant local leadership from public officials and private citizens and should include efforts to reduce unemployment and increase incomes. These efforts should be systematic and coordinated, when applicable, with planning organizations, and should strengthen the planning capabilities of applicants.

Planning program funds will not be used to provide support to activities that can be funded under the EDA Technical Assistance programs.

Activities eligible for support include economic analysis, definition of development goals, determination of project opportunities, development of economic development policies, processes and procedures, and formulation and implementation of a development program.

EDA is interested in proposals for planning activities designed to address problems of economically distressed segments of the population. Funding priority will be given to proposals promoting exports, entrepreneurship, and technology initiatives including innovation, transfer and commercialization, or that reduce barriers to the development of new businesses. In the case of proposals from states, EDA is particularly interested in innovative approaches to planning and implementing economic development initiatives, as well as efforts that lend themselves to replication in other areas.

Funding Availability

Funds in the amount of $4.516 million are available for providing grant assistance under this program.

Funding Instrument

Grant assistance may be provided for up to 75 percent of project costs. Applicants will be required to provide the remaining share, preferably in cash. Applications for grants exceeding $200,000 will be given low funding priority. EDA will consider proposals for smaller grants to support the aforementioned appropriate activities.

Project Duration

Assistance will be for the period of time required to complete the work. This period is normally 12 to 18 months. If Congress makes funds available for this program in subsequent years, grantees may submit applications for appropriate projects for up to a total of three awards.

Selection Criteria

The content of the proposal and the economic distress of the area will be the principal factors considered in evaluating proposals from eligible entities. In assessing the distress factor, priority consideration will be given to proposals from states and urban areas experiencing substantial economic distress. In the case of urban areas, high priority will be given to those with unemployment rates two or more percentage points higher than the U.S. average and per capita income levels 80 percent or less of the U.S. average. For states, high priority will be given to those that meet both of the above criteria, as well as those that meet one of the above criteria and have distress equal to or greater than the national level for the other criterion. The most recent per capita income and 24-month average unemployment data available will be used to measure economic distress.

Proposals from states or urban areas which do not exhibit significant distress on the basis of unemployment or income data will not be considered unless other acceptable evidence of substantial distress is provided by the applicant (e.g., large numbers of agricultural and business failures, large numbers of low income families, drastically reduced tax bases, etc.).

Proposals from states and urban areas which are both below the U.S. national unemployment rate and above the national per capita income are unlikely to be funded.

Proposals will be judged on the basis of:

1. Appropriateness of the work program to the section 302(a) program objectives;
2. The economic distress of the area served by the applicant;
3. Extent to which the proposed planning activities are expected to impact upon the service area's economic development needs, and the extent to which the proposal addresses the problems of the unemployed and underemployed of the area, including the farm families, minorities, workers displaced by plant closings, etc.;
4. Past performance of currently or formerly funded grantees, if applicable;
5. The amount of local participation provided as matching dollars to the Federal funds;
6. The proximity of the performing office to the chief executive (i.e., likelihood that the activities will have a significant influence on the policy and decision making process); and
7. Other characteristics, such as involvement of the private sector in the proposed activities, and particularly for states, the innovativeness of the proposed approach and replicability of the process or results.

Proposal Submission Procedures

Potential applicants should submit proposals that include:

1. A letter, signed by the chief executive of the applicant organization, indicating a desire to receive funds to carry out the planning activities outlined in the proposal; where the funded planning program will be placed in the organization, including the name and title of the person to be responsible for program implementation; the amount and for what period funding is being requested; and the anticipated funding arrangement if the planning activity is to continue beyond the period of EDA support.
2. Significant, verifiable information on the level of economic distress in the area, including unemployment and income data. Any major changes in distress levels during the past year should be described.
3. Information indicating the applicant's commitment to the proposed work program as demonstrated by amount of local funding and the degree of interest displayed by the chief executive.
4. A time chart showing all major work program elements, projected element start and completion dates, and the related financial expenditures programmed for each work element.
5. A work program of no more than 10 pages which outlines the specific planning activities that will be carried out under the grant and specifies which activities will be handled by in-house staff, consultants, etc. The work program should also explain the need for the proposed activities, expected impacts and their timing, target population(s), and involvement of the private sector in the proposed activities.

Current grantees seeking additional funding under this announcement should comply with the instructions of this notice and include a 3–5 page progress report for the current grant.

One copy of the proposal should be sent to the appropriate economic development representative, and an original and one copy to the appropriate EDA regional office. The EDA regional office or the name, address and telephone number of the economic development representative for the applicant's area can be found in section IX of this Notice.

Formal Application Procedures

EDA will evaluate proposals using the selection criteria cited above. Once the merits of the proposal are established, EDA will initiate discussions with the prospective applicant to clarify and improve elements of the proposal, if necessary, and will invite those whose proposals are selected for funding consideration to submit formal applications, which will include an SF–424 (OMB Control No. 0348–0043) and other application materials. It should be noted that an invitation to submit a proposal does not assure EDA funding. Proposals and applications will be processed as they are received. Applications received after FY 1993 funds are exhausted may be retained by EDA for consideration for funding the following fiscal year, assuming funds are available.

Further Information

For further information contact the appropriate economic development representative, EDA regional office (see section X of this Notice), or the Director, Planning Division, Economic Development Administration, room 7321, U.S. Department of Commerce, Washington, DC 20230; telephone (202) 482–3027.

VIII. Program: Economic Adjustment Assistance (Title IX)

(Catalog of Federal Domestic Assistance No: 11.307 Special Economic Development and Adjustment Assistance Program—Long-Term Economic Deterioration (LTED) and Sudden and Severe Economic Dislocation (SSED))

Summary

Funds under the Economic Adjustment Program are used to assist areas experiencing long-term economic

deterioration (LTED) and areas threatened or impacted by sudden and severe economic dislocation (SSED). This program is authorized under title IX of the Public Works and Economic Development Act of 1965, as amended, 42 U.S.C. 3241–3245.

Program Objective

The LTED Program assists eligible applicants to develop or implement strategies designed to halt and reverse the long-term decline of their economies. The most common type of activity funded under the LTED Program is Revolving Loan Funds (RLFs), although other types of eligible title IX activities may be funded.

The SSED Program assists eligible applicants to respond to actual or threatened major job losses (dislocations) and other severe economic adjustment problems. It is designed to help communities prevent a sudden, major job loss; to reestablish employment opportunities and facilitate community adjustment as quickly as possible after one occurs; or to meet special needs resulting from severe changes in economic conditions. SSED assistance is intended to respond to permanent rather than temporary job losses. Assistance may be in the form of a grant to develop a strategy to respond to the dislocation (Strategy Grant) or a grant to implement an EDA approved strategy (Implementation Grant).

In light of the current high level of economic distress in rural areas, EDA is particularly interested in title IX projects designed to mitigate serious rural economic adjustment problems. EDA is also interested in proposals to help severely distressed areas with large minority populations.

Funding Availability

Funds in the amount of $22.075 million are available for the Economic Adjustment Program in FY 1993. Of that amount, $11.038 million will be available for the SSED Program and $11.037 million will be available for the LTED Program.

Funding Instrument

Title IX funds are awarded through grants not to exceed 75 percent of the project cost. Acceptable sources of the local share include, but are not limited to, local government general revenue funds; Community Development Block Grant (CDBG) entitlement funds or balance of state awards; and other public and private donations. The Assistant Secretary may waive all or part of the 25 percent nonfederal share of economic adjustment assistance grants, if he/she determines that the nonfederal share is not reasonably available because of the critical nature of the situation requiring economic adjustment assistance or for other good cause. The full amount of the local share need not be in hand at the time of application; however, the applicant must have a firm commitment from identified source(s), and the funds must be readily available. The local share must not be encumbered in any way that would preclude its use as required by the grant agreement. The local share for the RLF Program must be in cash, and while the local share for the SSED Program may be cash or in-kind, priority consideration will be given to proposals with a cash local share.

Eligible Applicants

Eligible applicants within areas meeting the EDA eligibility criteria described below include a redevelopment area or economic development district established under title IV of this Act, 42 U.S.C. 3161; an Indian tribe; a state; a city or other political subdivision of a state, or a consortium of such political subdivisions; a Community Development Corporation defined in the Community Economic Development Act, 42 U.S.C. 9802; a nonprofit organization determined by EDA to be the representative of a redevelopment area; the Federated States of Micronesia, the Republic of the Marshall Islands, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Eligible Areas

A. LTED

In order to receive priority consideration for funding under the LTED/RLF Program, an area must be experiencing at least one of three economic problems: Very high unemployment; low per capita income; or chronic distress (i.e., failure to keep pace with national economic growth trends over the last five years). Priority will be given to those areas with two or more of these indicators. Eligibility is determined statistically. Further information is available from EDA's regional offices or the economic development representative for your area (see Section X of this Notice).

B. SSED

In order to receive priority consideration for funding under the SSED Program, an area must show actual or threatened permanent job losses that exceed the following threshold criteria, unless otherwise determined by the Assistant Secretary:

1. For areas not in Metropolitan Statistical Areas:

a. If the unemployment rate of the Labor Market Area exceeds the national average, the dislocation must amount to the lesser of two (2.0) percent of the employed population, or 500 direct jobs.

b. If the unemployment rate of the Labor Market Area is equal to or less than the national average, the dislocation must amount to the lesser of four (4.0) percent of the employed population, or 1,000 direct jobs.

2. For areas within Metropolitan Statistical Areas:

a. If the unemployment rate of the Metropolitan Statistical Area exceeds the national average, the dislocation must amount to the lesser of one-half (0.5) percent of the employed population, or 4,000 direct jobs.

b. If the unemployment rate of the Metropolitan Statistical Area is equal to or less than the national average, the dislocation must amount to the lesser of one (1.0) percent of the employed population or 8,000 direct jobs.

In addition, fifty (50) percent of the job loss threshold must result from the action of a single employer, or eighty (80) percent of the job loss threshold must occur in a single standard industry classification (i.e., two digit SIC code).

In the case of a Presidentially declared natural disaster, the area eligibility criteria are waived. In other similarly exceptional circumstances, the criteria may be partially waived at the discretion of the Assistant Secretary.

Actual dislocations must have occurred within one year and threatened dislocations must be anticipated to occur within two years of the date EDA is contacted.

Selection Criteria

Proposals will be evaluated based on conformance with statutory and regulatory requirements, the economic adjustment needs of the area, the merits of the proposed project in addressing those needs and the potential applicant's ability to manage the grant effectively.

A. LTED/RLF Selection Criteria

Key factors in EDA's selection of proposed LTED/RLF projects include:

1. Economic and Financial Needs of the Project Area:

a. Areas with the highest levels of economic distress (high unemployment, low per capita income, vacant plants, deteriorating infrastructure, and declining farm economy, etc.) will receive priority consideration.

b. Need for RLF financing will be evaluated based on the local capital market and the applicant's analysis of it,

and how clearly this analysis defines the financial problems to be addressed by the RLF project.

c. Applicant's need for grant funds to carry out the project will be based on an assessment of its financial resources.

2. Objectives and Benefits of Proposed Projects:

Priority will be given to projects that:

a. Stimulate private sector employment. The number and types of jobs to be created/retained will be key factors in project selection along with the job/cost ratio established for the RLF portfolio as a whole.

b. Target assistance to meet program objectives and to support specific economic adjustment activities planned or underway in the area, particularly those identified in the OEDP, title IX strategy, or other plans developed to deal with specific economic adjustment problems affecting the area. This may include target areas, industries, types of employers or other criteria that maximize the impact of assistance on specific needs within the area.

c. Leverage higher ratios of private investment than the required minimum ratio of two private sector investment dollars to one RLF dollar.

Note: The local share or other funds provided by the RLF to finance loans cannot be counted as leveraged dollars.

d. Promote exports, entrepreneurship, and technology initiatives including innovation, transfer and commercialization.

e. Direct new job opportunities to the long-term unemployed and underemployed.

f. Provide technical and management assistance for RLF borrowers, in addition to loan funds.

g. Use creative financing techniques to overcome specific gaps in the local capital market.

h. Make loans on a timely basis. The implementation schedule for RLF projects will normally require that RLF loans in the initial round be closed (and all EDA funds disbursed) within three years of grant approval with no less than 50 percent disbursed within eighteen months and 80 percent within two years.

i. Include a larger local share than the required 25 percent or secure commitments for future funding from other private or nonfederal public sources.

j. Coordinate activities with other economic development organizations, loan programs, employment training programs and private lenders in the area.

k. Are established to fill capital gaps as opposed to providing subsidized credit (i.e., below market interest rates).

3. Effective Management of the RLF:

EDA will also evaluate proposed projects to determine that the RLF will be properly managed. Key factors include:

a. A strong and effective Loan Administration Board with broad community representation, including appropriate public and private sector representation.

b. Staff capacity in program and policy development, finance, law, marketing, credit analysis, loan packaging, processing, and servicing.

c. Efficient procedures for loan selection, approval, and servicing which emphasize the economic development potential of loans as well as sound management and financing practices.

d. A strategy for relending loan repayments which will ensure that the RLF revolves continuously and thus fulfills its purpose of creating jobs and stimulating economic activity on an ongoing basis.

e. Adequate resources to cover administrative costs of the RLF.

f. The potential applicant's experience and capacity for administering economic and business loan programs. If the potential applicant has designated another organization to administer the project, EDA will evaluate the experience and capacity of that organization, rather than the potential applicant.

Nongovernmental (excluding economic development districts) organizations seeking funds must be sponsored by the local or state government having jurisdiction over the project area, and the sponsor must be willing to assume responsibility for operating the RLF should the nongovernmental entity no longer be able to administer the project.

B. SSED Evaluation Criteria

Key factors in EDA's selection of proposed SSED projects include:

1. The severity of the dislocation as measured by, but not limited to, the following factors:

a. The degree to which the number of dislocated workers exceeds the eligibility threshold.

b. The proportion of the total job loss represented by a single employer.

c. The proportion of employment in a single standard industry classification represented by the firm(s) closing.

d. The applicant's need for grant funds to carry out the project based on an assessment of its financial resources.

2. The objectives and benefits of proposed activities as measured by the extent to which:

a. For Implementation Grants:

(1) Job creation or retention and restoration of the community's economic base in the near term are emphasized versus more long-term, general economic development. Projects likely to encounter delays, particularly in initiating or completing construction, will normally not be given favorable consideration.

(2) The jobs to be created or retained are permanent, will directly benefit the dislocated workers or will directly facilitate community adjustment, and are new employment opportunities and not transferred from one area of the United States to another.

(3) The response to the problem is timely.

(4) EDA assistance will be complemented by, or will complement, appropriate state and local efforts; for example, training and job placement services, other Federal investments, and private sector support.

(5) The adjustment strategy and implementation activities proposed demonstrate an appropriately creative approach to addressing the dislocation.

(6) The cost per job created or retained is minimized.

(7) In the case of a Revolving Loan Fund, the recycled loan proceeds generate economic development benefits.

(8) The local share exceeds the required 25 percent.

b. For Strategy Grants:

(1) The applicant has demonstrated the capacity to manage the planning process and subsequent implementation activities.

(2) The proposed scope of work is responsive to the problem.

(3) The focus of the planning effort is on the generation of practical and implementable solutions.

(4) The local share exceeds the required 25 percent.

Project Implementation

As indicated in the first section of this Notice, EDA expects all grant-funded projects to be initiated and completed in a timely manner in accordance with the schedule agreed upon in the grant documentation. The recipient will be responsible for promptly notifying EDA of any events that prevent adherence to the approved schedule. The grantee must also provide an explanation of why the events were beyond its ability to predict or control and obtain EDA approval of changes in the schedule prior to proceeding with project implementation.

EDA expects grantees to anticipate predictable delays (such as those caused by land acquisition problems, local financing requirements, acquisition of state permits and approvals, normal weather conditions in area, and public

objections to the project), and take them into account in preparing the project schedule. Grantees who fail to comply with project schedules may be subject to grant suspension or termination.

Proposal Submission Procedures

Interested parties should contact the economic development representative for the area or the appropriate EDA regional office (see section X of this Notice) for a proposal package. Project proposals, submitted by eligible entities, will be evaluated by EDA staff on the basis of:

1. Conformance with the evaluation criteria mentioned above and statutory, regulatory and policy requirements.
2. The availability of funds.

Application Procedures

Following a review of project proposals, EDA will invite those projects selected for funding consideration to submit applications. It should be noted that an invitation to apply does not assure funding. The application will include an ED–540, as approved by the Office of Management and Budget Control No. 0610–0058.

Further Information

For further information, contact the appropriate economic development representative, EDA regional office (see section X of this Notice), or the Director, Economic Adjustment Division, Economic Development Administration, room 7327, U.S. Department of Commerce, Washington, DC 20230; telephone (202) 482–2659.

IX. Program: Trade Adjustment Assistance

(Catalog of Federal Domestic Assistance: 11.313 Economic Development—Trade Adjustment Assistance)

Summary

Funds under the Trade Adjustment Assistance Program are awarded to a network of Trade Adjustment Assistance Centers, located around the Nation, which provide technical assistance to certified firms adversely affected by increased imports. Funds are also awarded under this program to organizations representing trade-injured industries. This program is authorized under the Trade Act of 1974, title II, Public Law 93–618, as amended, 88 Stat. 1978, 19 U.S.C. 2101–2487.

Funding Availability

Funds in the amount of $13.220 million are available for trade adjustment assistance to firms. These funds will be provided to the nationwide network of twelve (12) Trade Adjustment Assistance Centers (TAACs) through cooperative agreements which will utilize all of the available funds for trade adjustment assistance.

Therefore, no new centers will be funded in FY 1993. Funds in the amount of $500,000 are available for industry technical assistance.

Program Objective

The Trade Adjustment Assistance Program is designed to provide technical assistance to certified firms and industries hurt by the impact of increased imports. The TAACs help firms submit certification petitions to the Trade Adjustment Assistance Division (TAAD) of EDA, and if the firm is certified, provides technical assistance. A firm should work closely with the appropriate TAAC in petitioning for certification. Certified firms should also work closely with the appropriate TAAC in diagnosing their problems and developing an adjustment proposal, and in applying for technical assistance.

An industry association or other organization interested in receiving an industry assistance cooperative agreement must meet with a TAAD representative to discuss the industry's problems, opportunities, and assistance needs.

Criteria for Selecting Industry Assistance Proposals

Industry associations and other organizations seeking trade adjustment industry assistance must demonstrate that the industry is injured by foreign trade and that the activities to be funded will yield some short-term actions that the industry itself (and individual firms) can and will take toward the restoration of the industry's international competitiveness.

The emphasis is on practical results that can be implemented in the near term, and long-term research and development activities are given low priority. It is also expected that the industry will continue activities on its own without the need for continued Federal assistance.

Application Procedures

Industry associations or other organizations seeking industry assistance must submit an application identified as Standard Form 424 (OMB Control No. 0348–0043), if encouraged to do so as a result of the meeting with a TAAD representative.

Acceptable industry assistance applications will be processed as funds are available; normally one to three months is required for final decision on application.

Formula and Matching Requirements

Generally, a minimum of 50 percent share is required for industry assistance cooperative agreements.

Length and Time Phasing of Assistance

Industry assistance cooperative agreements are generally for a 12-month period, but may be longer for tasks requiring more time to complete.

Further Information

For further information, contact the Director, Trade Adjustment Assistance Division, Economic Development Administration, room 7023, U.S. Department of Commerce, Washington, DC 20230; telephone (202) 482–3373.

X. EDA Regional Offices and Economic Development Representatives

The EDA regional offices, states covered, and the economic development representatives (EDRs) are listed below.

EDRs	States covered
ATLANTA REGIONAL OFFICE	
401 West Peachtree Street, NW., suite 1820, Atlanta, Georgia 30308–3510, Telephone: (404) 730–3002	
Burnette, F. Wayne, Aronov Building, room 134, 474 South Court Street, Montgomery, AL 36104, Telephone: (205) 223–7008.	Alabama.
Day, William J. Jr., Federal Building, room 423, 80 North Hughey Avenue, Orlando, FL 32801, Telephone: (407) 648–6572.	Florida.
Smith, Lola B., 401 West Peachtree Street, NW., suite 1820, Atlanta, GA 30308–3510, Telephone: (404) 730–3000.	Georgia.
Hunter, Bobby D., 771 Corporate Drive, suite 200, Lexington, KY 40503–5477, Telephone: (606) 233–2596	Kentucky.

EDRs	States covered
Ainsworth, Bob, 221 Federal Building, 100 West Capital Street, Jackson, MS 39269, Telephone: (601) 965–4342.	Mississippi.
Jones, Dale L., P.O. Box 2522, Raleigh, NC 27601, Telephone: (919) 856–4570	North Carolina.
Dixon, Patricia M., Strom Thurmond Federal Building, 1835 Assembly Street, room 840, Columbia, SC 29201, Telephone: (803) 765–5676.	South Carolina.
Parks, Mitchell S., 261 Cumberland Bend Drive, Nashville, TN 37228, Telephone: (615) 736–5911	Tennessee.
AUSTIN REGIONAL OFFICE	
Suite 201, Grant Building, 611 East Sixth Street, Austin, Texas 78701–3748, Telephone: (512) 482–5461	
Spearman, Sam, room 2509, Federal Building, 700 West Capitol, Little Rock, AR 72201, Telephone: (501) 324–5637.	Arkansas.
Davidson, Pamela, 412 North Fourth Street, room 104, Baton Rouge, LA 70802–5523, Telephone: (504) 389–0227.	Louisiana.
Swearingen, James, P.O. Box 2662, Santa Fe, NM 87501, Telephone: (505) 988–6557	New Mexico.
Waters, Alvin X. Jr., 5500 North Western, suite 148, Oklahoma City, OK 73118–4011, Telephone: (405) 231–4197.	Oklahoma.
Ramirez, Roy, suite 201, Grant Building, 611 East Sixth Street, Austin, TX 78701–3748, Telephone: (512) 482–5118.	Texas (south).
Jacob, Lawrence, suite 201, Grant Building, 611 East Sixth Street, Austin, TX 78701–3748, Telephone: (512) 482–5119.	Texas (north).
CHICAGO REGIONAL OFFICE	
111 North Canal Street, suite 855, Chicago, IL 60606–7204, Telephone: (312) 353–7706	
Casals, Alfred L., 509 West Capitol, suite 204, Springfield, IL 62704, Telephone: (217) 492–4224	Illinois.
Henderson, Richard L., Federal Building Courthouse, room 402, 46 East Ohio Street, Indianapolis, IN 46204, Telephone: (317) 226–6104.	Indiana.
Collison, James L., 100 North Warren Avenue, room 1018, Saginaw, MI 48606–0867, Telephone: (517) 758–4097.	Michigan.
Arnold, John B. III, 104 Federal Building, 515 West First Street, Duluth, MN 55802, Telephone: (218) 720–5326.	Minnesota.
Hickey, Robert P., Federal Building, room 607, 200 North High Street, Columbus, Ohio 43214, Telephone: (614) 469–7314.	Ohio.
Price, Jack D., 505 South Dewey Street, room 202, Eau Claire, WI 54701, Telephone: (715) 834–4079	Wisconsin.
DENVER REGIONAL OFFICE	
1244 Speer Boulevard, room 670, Denver, Colorado 80204, Telephone: (303) 844–4714	
Zender, John, 1244 Speer Boulevard, room 632, Denver, CO 80204, Telephone: (303) 844–4902	Colorado, Kansas.
Cecil, Robert, Federal Building, room 593A, 210 Walnut Street, Des Moines, IA 50309, Telephone: (515) 284–4746.	Iowa.
Koch, Forrest E., Robert A. Young Building, room 8.308H, 1222 Spruce Street, St. Louis, MO 63103, Telephone: (314) 539–2321.	Missouri.
Rogers, John C., Federal Building, room 196, Drawer 10074, Helena, MT 59626, Telephone: (406) 449–5074	Montana.
Albertson, Warren A., Federal Building, room 219, Pierre, SD 57501, Telephone: (605) 224–8280	Nebraska, South Dakota.
Grant, Cornelius P., P.O. Box 1911, Bismarck, ND 58501, Telephone: (701) 250–4321	North Dakota.
Ockey, Jack, Federal Building, room 2414, 125 South State Street, Salt Lake City, UT 84138, Telephone: (801) 524–5119.	Utah, Wyoming.
PHILADELPHIA REGIONAL OFFICE	
Curtis Center, Independence Square West, suite 140 South, Philadelphia, PA 19106, Telephone: (215) 597–4603	
Hammarlund, C.N. Jr., Federal Office Building, room 453, 450 Main Street, Hartford, CT 06103, Telephone: (203) 240–3258.	Connecticut, Rhode Island.
Flynn, Patricia A., 2568 Riva Road, 2nd Floor, Annapolis, MD 21401, Telephone: (410) 962–2513	Delaware, Maryland, District of Columbia.
Blitz, Sandford, Federal Building, room 410D, 40 Western Avenue, Augusta, ME 04330, Telephone: (207) 622–8271.	Maine.
Fitzhenry, William A., Boston Federal Office Building, 10 Causeway Street, room 420 (Box 2), Boston, MA 02222–1036, Telephone: (617) 565–7235.	Massachusetts.
Potter, Rita, V., 143 North Main Street, suite 209, Concord, NH 03301, Telephone: (603) 225–1624	New Hampshire, Vermont.
Rossignol, Clifford J., 44 South Clinton Avenue, room 703, Trenton, NJ 08609, Telephone: (609) 989–2192	New Jersey.
Marshall, Harold J. II, 620 Erie Boulevard West, suite 104, Syracuse, NY 13204, Telephone: (315) 423–5203	New York.
Pecone, Anthony M., 1933A New Berwick Highway, Bloomsburg, PA 17815, Telephone: (717) 389–7560	Pennsylvania.
Cruz, Ernesto L., Federal Office Building, room 620, 150 Carlos Chardon Avenue, Hato Rey, PR 00918–1738, Telephone: (809) 766–5187.	Puerto Rico, Virgin Islands.
Noyes, Neal E., P.O. Box 10229, Richmond, VA 23240, Telephone: (804) 771–2061	Virginia.
Davis, R. Byron, Rose City Press Building, 550 Eagan Street, room 305, Charleston, WV 25301, Telephone: (304) 347–5252.	West Virginia.

EDRs	States covered
SEATTLE REGIONAL OFFICE	
Jackson Federal Building, room 1856, 915 Second Avenue, Seattle, Washington 98174, Telephone: (206) 553–0596	
Richert, Bernhard E. Jr., 605 West 4th Avenue, room G–80, Anchorage, AK 99501–7594, Telephone: (907) 271–2272.	Alaska.
Perot, C. Antony, Federal Building, room 3406, 230 North First Avenue, Phoenix, AZ 85025, Telephone: (602) 379–3750.	Arizona, Nevada (except Elko, Eureka and White Pine Counties).
Sosson, Deena R., 1345 J Street, suite B, Sacramento, CA 95814, Telephone: (916) 551–1541	California (northern).
Lewis, William J., 1345 J Street, suite , Sacramento, CA 95814, Telephone: (916) 551–2160	California (central).
Oaks, Charles W., 11000 Wilshire Boulevard, room 11105, Los Angeles, CA 90024, Telephone: (310) 575–7286	California (southern).
McChesney, Frank, P.O. Box 50264, Federal Building, room 4106, Honolulu, HI 96850, Telephone: (808) 541–3391.	Hawaii, Guam, American Samoa, Marshall Islands, Micronesia, Northern Marianas.
Ames, Aldred F., room 441, 304 North 8th Street, Boise, ID 83702, Telephone: (208) 334–1521	Idaho, Nevada (counties of Elko, Eureka & White Pine).
Berblinger, Anne S., One World Trade Center, 121 S.W. Salmon Street, suite 244, Portland, OR 97204, Telephone: (503) 326–3078.	Oregon.
Busch, Jay M., Jackson Federal Building, 915 Second Avenue, room 1856, Seattle, WA 98174, Telephone: (206) 553–4740.	Washington.

Dated: January 5, 1993.

L. Joyce Hampers,

Assistant Secretary for Economic Development.

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Part V

Department of Agriculture

Agricultural Marketing Service

7 CFR Part 52

U.S. Standards for Grades of Frozen Cauliflower; Proposed Rule

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DEPARTMENT OF AGRICULTURE

Agriculture Marketing Service

7 CFR Part 52

[FV-91-329]

United States Standards for Grades of Frozen Cauliflower

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The purpose of this proposed rule is to revise the current voluntary U.S. Standards for Grades of Frozen Cauliflower. The proposed rule was developed by the U.S. Department of Agriculture (USDA) at the request of the American Frozen Food Institute (AFFI) and the National Food Processors Association (NFPA). Its effect would be to improve the standards by: Bringing the standards in line with current marketing practices and innovations in processing techniques; providing for the "individual attributes" procedure for product grading with sample sizes, acceptable quality levels (AQL's), tolerances and acceptance numbers (number of allowable defects) being published in the standards; replacing dual grade nomenclature with single letter grade designations, such as "U.S. Grade A" or U.S. Fancy," with "U.S. Grade A;" and providing a uniform format consistent with other recently revised U.S. grade standards by adopting definitions for terms and replacing textual descriptions with easy-to-read tables. This proposed rule also includes conforming and editorial changes.

DATES: Comments must be received on or before March 12, 1993.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in duplicate to the Office of the Branch Chief, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, room 0709, South Building, Washington, DC 20090–6456. Comments should make reference to the date and page number of this issue of the Federal Register and will be made available for public inspection in the Office of the Branch Chief during regular business hours.

FOR FURTHER INFORMATION CONTACT: Randle A. Macon, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, room 0709, South Building, Washington, DC 20090–6456, Telephone: (202) 720–6247.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under USDA procedures, Executive Order 12291 and Departmental Regulation 1512–1 and has been designated as a "nonmajor" rule. It will not result in an annual effect on the economy of $100 million or more. There will be no major increase in cost or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions. It will not result in significant effects on competition, employment, investments, productivity, innovations, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This proposed rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

Agencies are required to periodically review existing regulations. An objective of the regulatory review is to ensure that the grade standards are serving their intended purpose, the language is clear, and the standards are consistent with AMS policy and authority.

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy for the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992 memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal.

Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this Notice.

The Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act, Pub. L. 96–354 (5 U.S.C. 601 *et seq.*). The proposed changes reflect current marketing practices. The use of these standards is voluntary. A small entity may avoid incurring any economic impact by not employing the standards.

In 1988, the Western Technical Advisory Committee of the American Frozen Food Institute (AFFI), requested that the USDA prepare a draft revision of the U.S. grade standards for frozen cauliflower. This draft was to allow for the use of mechanical trimming devices in cauliflower processing by de-emphasizing the importance of uniform shape and symmetry of cauliflower clusters. Mechanical trimmers now perform processing operations previously done by hand. The mechanical trimming devices produce clusters which are less uniform in size, shape, and symmetry and remove, partially or completely, the bud portion of the unit. Shapes are "cosmetic" in nature and do not significantly affect the eating quality or nutritional value of frozen cauliflower.

It was also requested that the draft revision of the standards incorporate a grading system to make a better determination of quality. The grading system would assign individual tolerances to each individual quality factor. The system of grading, referred to as "individual attributes," would provide statistically derived acceptable quality levels (AQL's) based on the tolerances in the current grade standards. The USDA prepared a market survey, incorporating the requested changes and several other minor editorial changes.

USDA staff discussed this draft with the AFFI Western Technical Advisory Committee in January 1989. At that meeting, the USDA asked if other styles should be incorporated in the proposed standards. The Committee preferred to limit the styles as defined in the draft. No further comments were received. USDA then prepared another draft incorporating several minor editorial changes and submitted it to the AFFI

Western Technical Advisory Committee in February 1990. No comments were received.

In 1992, the USDA Grade Standards Review Subcommittee of the National Food Processors Association (NFPA), requested that the USDA prepare a draft revision of the U.S. grade standards for frozen cauliflower. It also requested that the draft revision of the standards incorporate the "individual attributes" grading system. The USDA prepared a draft revision and discussed it with the NFPA USDA Grade Standards Review Subcommittee in May 1992. The subcommittee recommended minor editorial changes for the draft standard.

The proposed standards would incorporate the recommended changes and USDA's policy of replacing dual grade nomenclature with single letter grade designations. Under the proposal, "U.S. Grade A" (or "U.S. Fancy") and "U.S. Grade B" (or "U.S. Extra Standard") would simply become "U.S. Grade A," and "U.S. Grade B."

In addition to these substantive changes, this proposed rulemaking would modify the standards so as to present them in a simplified easy-to-use format. Consistent with recent revisions of other U.S. grade standards, definitions of terms and easy-to-read tables would replace the textual descriptions. These changes are intended to facilitate better understanding and more uniform application of the grade standards.

List of Subjects in 7 CFR Part 52

Food grades and standards, Food labeling, Frozen foods, Fruit juices, Fruits, Reporting and recordkeeping requirements, Vegetables.

For the reasons set forth in the preamble, the U.S. Department of Agriculture proposes to amend 7 CFR part 52 as follows:

PART 52—PROCESSED FRUITS AND VEGETABLES, PROCESSED PRODUCTS THEREOF, AND CERTAIN OTHER PROCESSED FOOD PRODUCTS

1. The authority for part 52 continues to read as follows:

Authority: 7 U.S.C. 1622, 1624.

2. The Subpart—United States Standards for Grades of Frozen Cauliflower is revised to read as follows:

Subpart—United States Standards for Grades of Frozen Cauliflower

Sec.
52.721 Product description.
52.722 Styles.
52.723 Requirements for style.
52.724 Definitions of terms.
52.725 Grades.
52.726 Factors of quality.
52.727 Requirements for classified quality factors.
52.728 Sample size.
52.729 Acceptable criteria.

§ 52.721 Product description.

Frozen cauliflower is prepared from fresh flower heads of the cauliflower plant *(Brassica oleracea botrytis)* by trimming, washing, and blanching and is frozen and maintained at temperatures necessary for preservation of the product.

§ 52.722 Styles.

(a) *Clusters* mean individual segments of trimmed and cored cauliflower heads, which measure not less than 20 mm (0.75 in) in the greatest dimension across the top of the unit.

(b) *Clusters for limited use* mean individual segments of trimmed and cored cauliflower heads, which measure from 6 mm (0.25 in) to less than 20 mm (0.75 in) in the greatest dimension across the top of the unit.

§ 52.723 Requirements for style.

TABLE I.—AQL'S AND TOLERANCES (TOL.) FOR STYLE DEFECTS IN CLUSTERS, BASED ON 100 UNITS OF PRODUCTS FOR 13 SAMPLE UNITS, 100×13=1300 UNITS

	Clusters style	AQL	Tol.
Style defects	Each unit, less than 20 mm (0.75 in)	18.3	20.0

TABLE II.—ACCEPTANCE NUMBERS FOR STYLE DEFECTS IN CLUSTERS

Units of product	300	600	1300	2100	2900
Style defects [units less than 20 mm(0.75 in)]	66	125	261	414	585

TABLE III.—AQL'S AND TOLERANCES (TOL.) FOR STYLE DEFECTS IN CLUSTERS FOR LIMITED USE, 300 GRAMS OF PRODUCT FOR 13 SAMPLE UNITS, 300×13=3900 GRAMS

	Clusters for limited use style	AQL	Tol.
Style defects	20 mm (0.75 in) or greater	19.0	20.0
Style defects	Less than 6 mm (0.25 in)	9.2	10.0

TABLE IV.—ACCEPTANCE NUMBER FOR STYLE DEFECTS IN CLUSTERS FOR LIMITED USE

Grams of product	900	1800	3900	6300	8700
Style defects (grams) [units 20 mm (0.75 in) or greater]	190	369	781	1248	1713
Style defects (grams) [units less than 6 mm (0.25 in)]	98	187	390	619	847

§ 52.724 Definition of terms.

(a) *Acceptable quality level* (AQL) means the maximum percent of defective units or the maximum number of defects per hundred units of product that, for the purpose of acceptance sampling, can be considered satisfactory as a process average.

(b) *Blemished* means the cluster is affected or damaged by pathological injury, insect injury, discoloration or any other injury, which singly or in combination, affects the appearance or eating quality of the unit.

(1) *Minor* means a unit with a dark blemish exceeding the area of a circle 4 mm (0.16 in) in diameter but not exceeding 6 mm (0.25 in) or a light blemish exceeding the area of a circle 6 mm (0.25 in) in diameter.

(2) *Major* means a unit with a dark blemish exceeding the area of a circle 6 mm (0.25 in) in diameter.

(c) *Character* means the extent of firmness and compactness of the cluster and its degree of freedom from fuzzy, mushy, ricey and soft units.

(1) *Fuzzy character* means a cluster with elongated individual floral stems (petioles) that results in a fuzzy appearance.

(2) *Mushy character* means a cluster that is excessively soft or flabby and the flesh yields readily when handled.

(3) *Ricey character* means a cluster with elongated branches that result in a loose or granular appearance.

(4) *Soft character* means a cluster that is limp but not flabby.

(d) *Color defect* means that after cooking, the cluster possesses a color darker than light cream. The individual units may possess a characteristic green or bluish tint on the branches.

(e) *Core material* means the loose or attached center portion of the cauliflower head which is tough or fibrous.

(f) *Defect* means any nonconformance of a unit(s) of product from a specified requirement of a single quality characteristic.

(g) *Fragments* mean a stem or other cauliflower material without head material (exclusive of core material, loose leaves, and small pieces).

(h) *Loose leaves* mean leaf material, exclusive of small tender leaves, that is detached from the stem.

(i) *Mechanical damage* means that the appearance of the unit is seriously affected by excessive or insufficient trimming, or the unit is crushed or broken to the extent that the appearance is materially affected.

(j) *Normal flavor and order* means that the cauliflower, before or after cooking, has a flavor and odor that is normal and is free from objectionable flavors and odors.

(k) *Sample unit* means the amount of product specified to be used for grading. It may be:

(1) The entire contents of a container;

(2) A portion of the contents of a container;

(3) A combination of the contents of two or more containers.

(l) *Tolerance* (TOL.) means the maximum percent defective allowed, for each quality factor for a specific sample size, per defect.

(m) *Unit* means one cluster or piece of cauliflower.

§ 52.725 Grades.

(a) *U.S. Grade A* is the quality of frozen cauliflower that:

(1) Meets the following prerequisites in which the cauliflower:

(i) Has similar varietal characteristics; and

(ii) Has a normal flavor and odor.

(2) Is within the limits for defects as specified in Tables VI and VIII, as applicable for the style in § 52.727.

(b) *U.S. Grade B* is the quality of frozen cauliflower that:

(1) Meets the following prerequisites in which the cauliflower:

(i) Has similar varietal characteristics; and

(ii) Has a normal flavor and odor.

(2) Is within the limits for defects as specified in Tables VI and VIII, as applicable for the style in § 52.727.

(c) *Substandard* is the quality of frozen cauliflower that fails to meet the requirements of U.S. Grade B.

§ 52.726 Factors of quality.

The grade of frozen cauliflower is based on meeting the requirements for the following factors:

(a) Prerequisites;

(1) Varietal characteristics; and

(2) Flavor and odor.

(b) Classified quality factors;

(1) Blemished;

(2) Fuzzy character;

(3) Mushy character;

(4) Ricey character;

(5) Soft character;

(6) Color defects;

(7) Core material;

(8) Fragments;

(9) Loose leaves; and

(10) Mechanical damage.

§ 52.727 Requirements for classified quality factors.

TABLE V.—AQL'S AND TOLERANCES (TOL.) FOR DEFECTS IN CLUSTERS STYLE BASED ON 100 UNITS OF PRODUCT FOR 13 SAMPLE UNITS, 100×13=1300 UNITS

Defects	Grade A		Grade B	
	AQL	Tol.	AQL	Tol.
Blemished (major)	4.1	5.0	8.7	10.0
Total blemished (major & minor)	8.7	10.0	13.5	15.0
Fuzzy character	1.47	2.0	6.8	8.0
Mushy character	0.651	1.0	3.2	4.0
Ricey character	5.9	7.0	12.4	14.0
Soft character	8.7	10.0	12.5	14.0
Color defect	2.32	3.0	8.7	10.0
Core material	2.32	3.0	4.1	5.0
Fragments	6.8	8.0	13.5	15.0
Loose leaves	2.32	3.0	6.8	8.0
Mechanical damage	6.8	8.0	13.5	15.0

TABLE VI.—ACCEPTANCE NUMBERS FOR CLUSTERS STYLE

Units of product	Grade A					Grade B				
	300	600	1300	2100	2900	300	600	1300	2100	2900
Blemished (major)	18	33	65	101	137	34	64	130	205	276
Total blemished (major & minor)	34	64	130	205	278	50	94	195	309	421
Fuzzy character	8	14	26	40	53	28	51	104	162	220
Mushy character	4	7	13	20	26	15	26	52	80	108
Ricey character	24	45	91	142	192	46	87	180	286	389
Soft character	34	64	130	205	278	47	88	182	287	392
Color defect	11	20	39	60	81	34	64	130	205	276
Core material	11	20	39	60	81	18	33	65	101	137

TABLE VI.—ACCEPTANCE NUMBERS FOR CLUSTERS STYLE—Continued

Units of product	Grade A					Grade B				
	300	600	1300	2100	2900	300	600	1300	2100	2900
Fragments	28	51	104	162	220	50	94	195	309	421
Loose leaves (No. of leaves)	11	20	39	60	81	28	51	104	162	220
Mechanical damage	28	51	104	162	220	50	94	195	309	421

TABLE VII.—AQL'S AND TOLERANCES (TOL.) FOR DEFECTS IN CLUSTERS FOR LIMITED USE STYLE BASED ON 300 GRAMS OF PRODUCT FOR 13 SAMPLE UNITS, 300×13=3900 GRAMS

Defects	Grade A		Grade B	
	AQL	Tol.	AQL	Tol.
Blemished (major)	4.5	5.0	9.2	10.0
Total blemished (major & minor)	92	10.0	14.1	15.0
Fuzzy character	1.67	2.0	7.3	8.0
Mushy character	0.774	1.0	3.5	4.0
Ricey character	6.3	7.0	13.1	14.0
Soft character	9.2	10.0	13.1	14.0
Color defect	4.5	5.0	9.2	10.0
Core material	2.6	3.0	4.5	5.0
Fragments	14.1	15.0	24.9	26.0
Loose leaves	2.6	3.0	7.3	8.0
Mechanical damage	7.3	8.0	14.1	15.0

TABLE VIII.—ACCEPTANCE NUMBERS FOR DEFECTS IN CLUSTERS FOR LIMITED USE STYLE

Grams of product	Grade A					Grade B				
	900	1800	3900	6300	8700	900	1800	3900	6300	8700
Blemished (Grams) (Major)	51	96	197	311	424	98	187	390	619	847
Total blemished (grams) (major & minor)	98	187	390	619	847	144	278	586	934	1280
Fuzzy character (grams)	21	39	78	122	165	79	150	312	495	677
Mushy character (grams)	11	20	39	60	81	41	76	156	245	333
Ricey character (grams)	69	131	271	430	587	134	259	546	869	1192
Soft character (grams)	98	187	390	619	847	134	259	546	869	1192
Color defect (grams)	51	96	197	311	424	98	187	390	619	847
Core material (grams)	31	58	118	185	251	51	96	197	311	424
Fragments (grams)	144	278	586	934	1280	245	478	1015	1625	2233
Loose leaves (No. of leaves)	31	58	118	185	251	79	150	312	495	677
Mechanical damage (grams)	79	150	312	495	677	144	278	586	934	1280

§ 52.728 Sample size.

The sample size used to determine whether the requirements of these standards are met shall be as specified in the sampling plans and procedures in the "Regulations Governing Inspection and Certification of Processed Fruits and Vegetables, Processed Products Thereof, and Certain Other Processed Products" (7 CFR 52.1 through 52.83).

§ 52.729 Acceptance criteria.

(a) *Style.* A lot of frozen cauliflower clusters, is considered as meeting the requirements for style if the acceptance numbers in Table II or IV in § 52.723, as applicable, are not exceeded.

(b) *Quality Factors.* A lot of frozen cauliflower is considered as meeting the requirements for quality if:

(1) The prerequisites specified in § 52.726 are met; and

(2) The Acceptance Numbers in Table VI or VIII in § 52.727, as applicable, are not exceeded.

(c) *Single Sample Unit.* Each unofficial sample unit submitted for quality evaluation will be treated individually and is considered as meeting requirements for quality and style if:

(1) The prerequisites specified in § 52.726 are met; and

(2) The Acceptable Quality Levels (AQL's) in Tables I, III, V & VII in §§ 52.723 and 52.727, as applicable, are not exceeded.

Dated: December 31, 1992.

Daniel Haley,

Administrator

[FR Doc. 93–521 Filed 1–8–93; 8:45 am]

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Part VI

Department of Labor

Office of the Secretary

29 CFR Part 18

Use of Settlement Judges in Proceedings Before the Office of Administrative Law Judges; Proposed Rule

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DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 18

RIN 1290–AA12

Use of Settlement Judges in Proceedings Before the Office of Administrative Law Judges

AGENCY: Office of the Secretary, Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: The purpose of this proposal is to permit the appointment of settlement judges in proceedings before the Office of Administrative Law Judges. The procedure would use informal conferences to encourage claim settlement without adjudication. This is a voluntary procedure intended to reduce the costs to parties of filing and defending complaints and to expedite the resolution of complaints pursuant to Executive Order No. 12778 (Oct. 23, 1991) and the Department of Labor's Alternative Dispute Resolution Interim Policy, 57 FR 7292 (1992).

DATES: Comments must be received on or before February 25, 1993.

ADDRESSES: Submit comments to John M. Vittone, Deputy Chief Administrative Law Judge, room 4150, Office of Administrative Law Judges, 800 K Street, NW., suite 400, Washington, DC 20001–8002.

FOR FURTHER INFORMATION CONTACT: John M. Vittone, Deputy Chief Administrative Law Judge, Office of Administrative Law Judges. Telephone: (202) 633–0341.

SUPPLEMENTARY INFORMATION: In furtherance of its Alternative Dispute Resolution Interim Policy, 57 FR 7292 (1992), the Department is studying and implementing alternative dispute resolution methods appropriate to agency adjudications. This rule proposes use of settlement judges in certain proceedings before the Office of Administrative Law Judges. It is modeled on Recommendation 88–5 of the Administrative Conference of the United States, 1 CFR 305.88–5, and the settlement judge procedures of other agencies. See 18 CFR 385.603 (FERC); 24 CFR 104.620 (HUD); 29 CFR 2200.101 (OSHRC); 47 CFR 1.244 (FCC); 48 CFR 6302.30 (DOT). The procedure supplements rather than supplants settlement techniques traditionally used by administrative law judges. See, e.g., 29 CFR 18.8 (discussion of negotiation, compromise or settlement at prehearing conferences); 29 CFR 18.9 (deferment of hearing for settlement negotiations by the parties). It is expected that the Office of Administrative Law Judges would train a group of judges in mediation techniques. This group would be the pool from which settlement judges would be chosen.

The regulation permits appointment of a settlement judge by the Chief Administrative Law Judge upon motion by the parties or the presiding judge. Any party could veto use of the procedure. The settlement judge would be an active or retired administrative law judge other than the presiding judge. The settlement judge would direct settlement negotiations, assess the relative merits of the case for the parties, and consult with the parties either jointly or individually. The duration of the procedure would be limited because it is meant to quicken rather than delay dispute resolution, and because an exigent hearing motivates serious negotiation. The settlement judge would be prohibited from discussing any aspect of the case with the presiding judge. Any statements or conduct by the parties or the settlement judge at settlement negotiations would not be admissible in later proceedings before the Department.

Settlement judges would not be available in Black Lung or Longshore cases. The Benefits Review Board has found that the Black Lung Benefits Reform Act prohibits settlements. *See Gerzarowski* v. *Lehigh Valley Anthracite, Inc.*, 12 BLR 1–62 (1988); *Ladigan* v. *Central Industries, Inc.*, 7 BLR 1–192 (1984). Even without the prohibition, settlement judge procedures are not appropriate where entitlement to a benefit is an all-or-nothing question, as in Black Lung cases, since a settlement judge could do nothing except convince one party to concede.

Longshore cases are often settled; but neither the Department nor the public would benefit from a formal settlement judge procedure. The Longshore bar is comfortable with techniques used by the Office of Administrative Law Judges for many years, such as early prehearing exchanges, calendar calls in which settlement possibilities are discussed; and opportunities for discussion immediately prior to a hearing. See Notice of *Amendment to Interim ADR Policy*, 57 FR 28701, 28702–3 (June 26, 1992). See also Joseph & Gilbert, Breaking the Settlement Ice: The Use of Settlement Judges in Administrative Proceedings 2 Administrative L.J. 571, 594–595 (1989/1990) (indicating that if large numbers of cases are currently settled without the use of settlement judges, imposing the procedure is not advised).

Procedural Matters

This is not a major rule as defined by Executive Order 12291. The Agency Head has certified that this rule, if promulgated, will not have a significant economic impact upon a substantial number of small entities as defined in the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The rule does not contain any information collection or recordkeeping requirements as defined in the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

List of Subjects in 29 CFR Part 18

Administrative practice and procedure.

Accordingly, part 18 of title 29 of the Code of Federal Regulations is proposed to be amended as follows:

PART 18—RULES OF PRACTICE AND PROCEDURE FOR ADMINISTRATIVE HEARINGS BEFORE THE OFFICE OF ADMINISTRATIVE LAW JUDGES

1. The authority citation for part 18 is revised to read:

Authority: 5 U.S.C. 301; 5 U.S.C. 551–553; 5 U.S.C. 581; E.O. 12778; 57 Fed. Reg. 7292.

2. Section 18.9 is amended by revising the section heading and by adding new paragraph (e) to read as follows:

§ 18.9 Consent order or settlement; settlement judge procedure.

* * * * *

(e)(1) *Settlement judge procedure; purpose.* This paragraph establishes a voluntary process whereby the parties may use a settlement judge to mediate settlement negotiations. A settlement judge is an active or retired administrative law judge who convenes and presides over settlement conferences and negotiations, confers with the parties both jointly and individually, and seeks voluntary resolution of issues. Unlike a presiding judge, a settlement judge does not render a formal judgment or decision in the case; his or her role is solely to facilitate fair and equitable solutions and to provide an assessment of the relative merits of the respective positions of the parties.

(2) *How initiated.* A settlement judge may be appointed by the Chief Administrative Law Judge upon a request by a party or the presiding administrative law judge. The Chief Administrative Law Judge has sole discretion to decide whether to appoint a settlement judge, except that a settlement judge shall not be appointed where—

(i) A party objects to referral of the matter to a settlement judge;

(ii) Such appointment is inconsistent with a statute, executive order, or regulation;

(iii) The proceeding arises pursuant to the Longshore and Harbor Workers' Compensation Act, 33 U.S.C. 901 et seq., and associated acts such as the District of Columbia Workmen's Compensation Act, 36 DC Code 501 et seq.; or

(iv) The proceeding arises pursuant to Title IV of the Federal Mine Safety and Health Act, 30 U.S.C. 901 et seq., also known as the Black Lung Benefits Act.

(3) *Selection of settlement judge.* The selection of a settlement judge is at the sole discretion of the Chief Administrative Law Judge, provided that the individual selected

(i) Is an active or retired administrative law judge, and

(ii) Is not the administrative law judge assigned to hear and decide the case. The settlement judge shall not be appointed to hear and decide the case.

(4) *Duration of proceeding.* Unless the Chief Administrative Law Judge directs otherwise, settlement negotiations under this section shall not exceed thirty days from the date of appointment of the settlement judge, except that with the consent of the parties, the settlement judge may request an extension from the Chief Administrative Law Judge. The negotiations will be terminated immediately if a party unambiguously indicates that it no longer wishes to participate, or if in the judgment of the settlement judge, further negotiations would be fruitless.

(5) *General powers of the settlement judge.* The settlement judge has the power to convene settlement conferences; to require that parties, or representatives of the parties having the authority to settle, participate in conferences; and to impose other reasonable requirements of the parties to expedite an amicable resolution of the case, provided that all such powers shall terminate immediately if negotiations are terminated pursuant to paragraph (e)(4).

(6) *Suspension of discovery.* Requests for suspension of discovery during the settlement negotiations shall be directed to the presiding administrative law judge who shall have sole discretion in granting or denying such requests.

(7) *Settlement conference.* In general the settlement judge should communicate with the parties by telephone conference call. The settlement judge may, however, schedule a personal conference with the parties where:

(i) A conference may be scheduled in a place and on a day that the settlement judge is scheduled to preside in other proceedings;

(ii) The offices of the attorneys or other representatives of the parties, and the settlement judge, are in the same metropolitan area; or

(iii) The settlement judge, with the concurrence of the Chief Administrative Law Judge, determines that a personal meeting is necessary for a resolution of substantial issues, and represents a prudent use of resources.

(8) *Confidentiality of settlement discussions.* All discussions between the parties and the settlement judge shall be off-the-record. No evidence regarding statements or conduct in the proceedings under this section is admissible in the instant proceeding or any subsequent administrative proceeding, except by stipulation of the parties. Documents disclosed in the settlement process may not be used in litigation unless obtained through appropriate discovery or subpoena. The settlement judge shall not discuss any aspect of the case with any administrative law judge or other person, nor be subpoenaed or called as a witness in any hearing of the case or any subsequent administrative proceedings with respect to any statement or conduct during the settlement discussions.

(9) *Contents of consent order or settlement agreement.* Any agreement disposing of all or part of the proceeding shall be written and signed by all parties. Such agreement shall conform to the requirements of paragraph (b) of this section.

(10) *Report of the settlement.* The parties shall report to the presiding judge in writing within seven working days of the termination of negotiations. The report shall include a copy of the settlement agreement and/or proposed consent order.

(11) *Review of agreement by presiding judge.* A settlement agreement arrived at with the help of a settlement judge shall be treated by the presiding judge as would be any other settlement agreement.

(12) *Non-reviewable decisions.* Decisions concerning whether a settlement judge should be appointed, the selection of a particular settlement judge, or the termination of proceedings under this section, are not subject to review by Department officials.

Signed at Washington, DC this 5th day of January, 1993.

Lynn Martin,

Secretary of Labor.

[FR Doc. 93–536 Filed 1–8–93; 8:45 am]

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3 (1991 Compilation and Parts 100 and 101)	(869–017–00002–7)	17.00	[1] Jan. 1, 1992
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[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period Jan. 1, 1987 to Dec. 31, 1991. The CFR volume issued January 1, 1987, should be retained.

[5] No amendments to this volume were promulgated during the period Apr. 1, 1990 to Mar. 31, 1991. The CFR volume issued April 1, 1990, should be retained.

[6] No amendments to this volume were promulgated during the period Apr. 1, 1991 to Mar. 30, 1992. The CFR volume issued April 1, 1991, should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 1989 to June 30, 1992. The CFR volume issued July 1, 1989, should be retained.

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[9] No amendments to this volume were promulgated during the period October 1, 1991 to September 30, 1992. The CFR volume issued October 1, 1991, should be retained.

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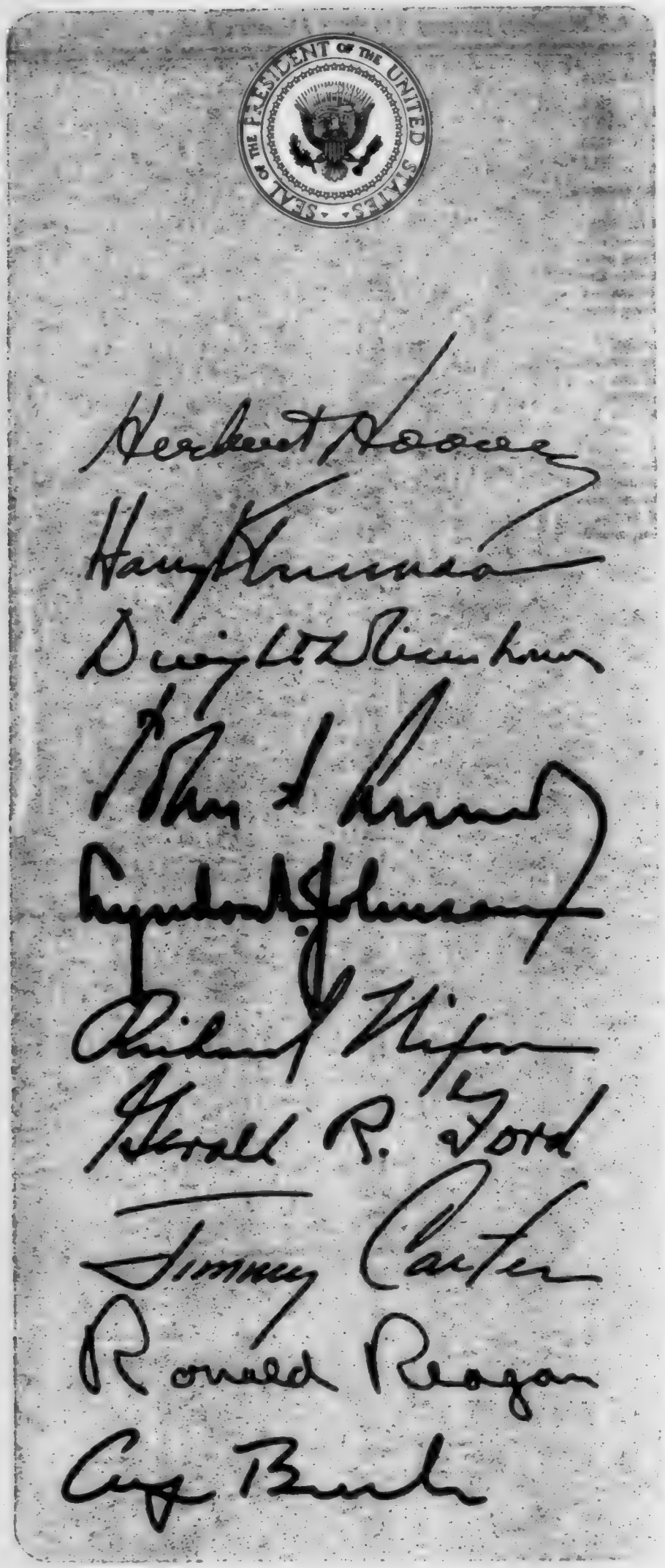

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 0

RIN 3150–AE47

Conduct of Employees; Conforming Amendments

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission ("NRC" or "Commission") is amending its regulations governing the conduct of NRC employees. This amendment removes provisions which have been superseded by recently issued Office of Government Ethics (OGE) regulations, which take effect on February 3, 1993.

EFFECTIVE DATE: February 3, 1993.

FOR FURTHER INFORMATION CONTACT: L. Michael Rafky, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: 301–504–1606.

SUPPLEMENTARY INFORMATION:

Background

On August 7, 1992 (57 FR 35006), the Office of Government Ethics published its final rule establishing government-wide standards of conduct for executive branch employees. These regulations, which are codified at 5 CFR part 2635, take effect on February 3, 1993, and will supplant Nuclear Regulatory Commission standards of conduct regulations. Section 2635.105 of that final rule permits individual agencies to issue jointly with OGE supplemental regulations to address particular agency needs.

The purpose of this rule is to abrogate those portions of the NRC's standard of conduct regulations, codified at 10 CFR part 0, which will be superseded by the government-wide regulations. The NRC has retained those provisions which will likely be subjects of supplemental regulations or relate to procedural issues to be addressed in forthcoming internal NRC Management Directives.

Because the NRC is required to delete superseded provisions of 10 CFR part 0 with no discretion in the matter, the NRC finds, pursuant to 5 U.S.C. 553(b)(B), that there is good cause not to seek public comment on this rule, as such comment is unnecessary. The rule will become effective on February 3, 1993, the date the OGE regulations take effect. The NRC also finds that good cause exists to waive the 30-day deferred effective date provisions of the Administrative Procedure Act (5 U.S.C. 553(d)(3)). Delaying the effective date of this rule would be contrary to the public interest because it would be confusing for regulations which have been superseded to remain in effect beyond February 3, 1993.

Environmental Impact: Categorical Exclusion

The NRC has determined that this final rule is the type of action described in categorical exclusion 10 CFR 51.22(c)(1). Therefore, neither an environmental assessment nor an environmental impact statement has been prepared for the final regulation.

Paperwork Reduction Act Statement

This final rule contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

Regulatory Analysis

The Nuclear Regulatory Commission is eliminating regulations that have been superseded by the Office of Government Ethics' government-wide standards of conduct regulations. This rule has no significant impact on health, safety or the environment. There is no substantial cost to licensees, the NRC, or other Federal agencies.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this final rule and that a backfit analysis is not required for this final rule, because these supplemental regulations do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects in 10 CFR Part 0

Conflict of interest, Criminal penalty.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR part 0.

PART 0—CONDUCT OF EMPLOYEES

1. The authority citation for part 0 continues to read as follows:

Authority: Secs. 25, 161, 68 Stat. 925, 948, as amended (42 U.S.C. 2035, 2201); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841); E.O. 11222, 30 FR 6469, 3 CFR 1964–1965 COMP., p. 306; 5 CFR 735.104.

Sections 0.735–21 and 0.735–29 also issued under 5 U.S.C. 552, 553. Section 0.735–26 also issued under secs. 501, 502, Public Law 95–521, 92 Stat. 1864, 1867, as amended by secs. 1, 2, Public Law 96–28, 93 Stat. 76, 77 (18 U.S.C. 207).

§§ 0.735–1—0.735–2 [Removed]

2. Sections 0.735–1 and 0.735–2 are removed.

3. Section 0.735–3 is revised to read as follows:

§ 0.735–3 Responsibilities and authorities.

The General Counsel: (a) is the Designated Agency Ethics Official for NRC.

(b) Serves as NRC's designee to the Office of Government Ethics on matters covered by this part.

(c) Designates deputy counselors.

(d) Coordinates counseling services, and assures that counseling and interpretations on questions of conflicts of interest and other matters covered by the part are available to deputy counselors.

§§ 0.735–4—0.735–6 [Removed]

4. Sections 0.735–4 through 0.735–6 are removed.

5. Section 0.735–8 is revised to read as follows:

§ 0.735–8 Information collection requirements: OMB approval.

This part contains no information collection requirements and therefore is not subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

§ 0.735–20 [Removed]

6. Section 0.735–20 is removed.

7. In § 0.735–21 paragraph (d) is revised to read as follows:

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§ 0.735–21 Acts affecting a personal financial interest (based on 18 U.S.C. 208.

* * * * *

(d) *Special exemption for special Government employees.* Federal Personnel Manual Chapter 735, Appendix C provides that a special Government employee should in general be disqualified from participating as such in a matter of any type the outcome of which will have a direct and predictable effect upon the financial interests covered by 18 U.S.C. 208. However, that chapter states that the power of exemption may be exercised in this situation "if the special Government employee renders advice of a general nature from which no preference or advantage over others might be gained by any particular person or organization." It is the policy of the Nuclear Regulatory Commission in conformity with the foregoing, to exercise the power of exemption pursuant to 18 U.S.C. 208(b) in such situations. The authority to grant such an exemption is delegated to the NRC official responsible for appointment or designation of the particular consultant or advisor.

8. Section 0.735–23 is revised to read as follows:

§ 0.735–23 Activities of officers and employees in claims against and other matters affecting the Government (based on 18 U.S.C. 205).

(a)(1) Nothing in 18 U.S.C. 205 prevents a special Government employee from acting as agent or attorney for another person in the performance of work under a grant by, or a contract with or for the benefit of, the United States if the Executive Director for Operations certifies in writing that the national interest so requires. Such certification shall be submitted for publication in the **Federal Register.**

(2) The special Government employee shall immediately notify the NRC when so designated to act as agent or attorney by his private employer.

§§ 0.735–24—0.735–25 [Removed]

9. Sections 0.735–24 and 0.735–25 are removed.

10. Section 0.735–26 is revised to read as follows:

§ 0.735–26 Disqualification of former officers and employees in matters connected with former duties or official responsibilities; disqualification of partners of current officers and employees (based on 18 U.S.C. 207).

The prohibitions of 18 U.S.C. 207 shall not apply—

(a) With respect to the making of communications solely for the purpose of furnishing scientific or technological information if the following procedures are observed:

(1) The former employee proposing to make the communication solely for the purpose of furnishing scientific or technological information receives prior written authorization from the Executive Director for Operations. The individual shall provide to the Executive Director for Operations a written statement that indicates he or she is a former employee subject to post-employment restrictions under this section, that briefly summarizes the content of the proposed communication, that describes his or her involvement, if any, as an NRC employee on the matter to be discussed, and that certifies the communication he or she desires to make is solely for the purpose of furnishing scientific or technological information; and

(2) The Executive Director for Operations before deciding whether to authorize the communication shall consult with the counselor or deputy counselor. The primary factor to be considered by the Executive Director for Operations is whether receipt of the scientific or technological information would further the agency's mission.

(b) If the Commission, in consultation with the Director of the Office of Government Ethics, makes a certification published in the **Federal Register** that the former employee has outstanding qualifications in a scientific, technological, or other technical discipline, and is acting with respect to a particular matter which requires such qualifications, and that the national interest would be served by the participation of the former officer or employee. The Commission under this provision may authorize communications that are not limited to transmission of scientific or technological information.

§§ 0.735–27—0.735–28a [Removed]

11. Sections 0.735–27 through 0.735–28a are removed.

Subpart C (§ 0.735–30)—[Removed]

12. Part 0 is amended by removing subpart C (§ 0.735–30).

§ 0.735–40 [Amended]

13. Section 0.735–40 is amended by removing paragraphs (e), (g) and (h), and redesignating paragraph (f) as paragraph (e).

§§ 0.735–41—0.735–49a [Removed]

14. Sections 0.735–41 through 0.735–49a are removed.

Subpart E (§§ 0.735–50—0.735–55)—[Removed]

15. Part 0 is amended by removing subpart E (§§ 0.735–50—0.735–55).

Dated at Rockville, Maryland this 28th day of December, 1992.

For the Nuclear Regulatory Commission,

James M. Taylor,

Executive Director for Operations.

[FR Doc. 93–373 Filed 1–11–93; 8:45 am]

BILLING CODE 7590–01–M

DEPARTMENT OF TRANSPORTATION

Office of Commercial Space Transportation

14 CFR Parts 413, 415

RIN 2105–AB96

Commercial Space Transportation; Removal of User Fees

AGENCY: Office of Commercial Space Transportation, DOT.

ACTION: Final rule.

SUMMARY: Pursuant to the National Aeronautics and Space Administration Authorization Act, Fiscal Year 1993, the Department of Transportation (the Department) is removing from the Commercial Space Transportation Licensing Regulations the requirement for the payment of user fees by license applicants and licensees.

EFFECTIVE DATE: This rule becomes effective January 12, 1993.

FOR FURTHER INFORMATION CONTACT: Elaine Orfanos David, Office of the Assistant General Counsel for Regulation and Enforcement, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–9305.

SUPPLEMENTARY INFORMATION:

Background

The Department of Transportation (the Department) is authorized to license and regulate commercial space launch activities pursuant to the Commercial Space Launch Act of 1984, as amended (CSLA) (49 U.S.C. app. 2601–2623). The Secretary's responsibilities under the CSLA are implemented by the Department's Office of Commercial Space Transportation (OCST).

OCST's appropriations for fiscal year 1991 reflected Congressional sentiment that "a viable user fee structure should be established" for its regulatory activities, and the Department of Transportation and Related Agencies Appropriations Act (DOT

Appropriations Act) 1991 (Pub. L. 101–516) provided that "there may be credited up to $300,000 to this account funds received from user fees." In a final rule published in the Federal Register on August 19, 1991 (56 FR 41062–41068), OCST established fees for the submission of a license application and the conduct of any launch pursuant to a license. The regulations assessing such fees were issued pursuant to the general statutory authority for the establishment of federal user fee programs, the Independent Offices Appropriations Act of 1952, as amended (IOAA) (31 U.S.C. 9701). Instructions for the payment of user fees were published in the Federal Register on October 31, 1991 (56 FR 56111–56112).

Allowance of a credit to OCST's appropriations of up to $300,000 received from user fees established for regulatory services was continued in the DOT Appropriations Act, 1992 (Pub. L. 102–143) and the DOT Appropriations Act, 1993 (Pub. L. 102–388). However, the National Aeronautics and Space Administration Authorization Act, Fiscal Year 1993 (NASA FY93 Authorization Act) (Pub. L. 102–588), amended the CSLA by authorizing fiscal year 1993 appropriations and prohibiting the collection of user fees for any regulatory or other services conducted pursuant to the CSLA, unless specifically authorized by the CSLA. At present, no such authorization is provided by the CSLA.

The NASA FY93 Authorization Act was signed into law by the President on November 4, 1992, and the prohibition against collection of user fees became effect on that date. Accordingly, OCST is removing from the regulations any reference to the collection of user fees, i.e., license application or launch fees.

Because the statutory prohibition against OCST's collection of user fees makes notice and an opportunity for public comment impracticable and unnecessary, the Department has determined that good cause exists to issue this regulation as a final rule.

Rulemaking Analyses and Notices

A. Executive Order No. 12291

Executive Order (E.O.) No. 12291 requires that regulations be classified as major or nonmajor for purposes of review by the Office of Management and Budget (OMB). According to E.O. 12291, major rules are regulations that are likely to result in:

(1) An annual effect on the economy of $100 million or more; or

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

OCST has determined that this rule removing the user fee regulations is non-major under E.O. 12291 because it would not result in an annual effect on the economy of $100 million or more. In Fiscal Year 1992, the only full fiscal year in which OCST collected user fees, a total of $203,175 was received. This figure reflects six license applications received by OCST and seven licensed launches (six orbital and one suborbital). Based upon the number of licensed launches currently listed on the Department's U.S. Commercial Space Transportation Manifest through Fiscal Year 1995, it does not appear that revenues resulting from user fees in any fiscal year would approach $100 million. Eliminating the imposition of user fees will relieve an economic burden on the commercial space launch industry and will not result in a major increase in costs or prices referenced in (2) above, or any of the significant adverse effects referenced in (3) above.

B. Department Regulatory Policies and Procedures

This regulation has been reviewed and determined not to be significant under the Department's Regulatory Policies and Procedures, dated February 26, 1979.

C. Regulatory Flexibility Act

This regulation will have minimal economic impact and therefore does not require a Regulatory Flexibility Analysis. Accordingly, I hereby certify that this regulation will not have a significant economic impact on a substantial number of small entities.

D. Federalism Implications

This regulation will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this regulation does not have federalism implications warranting the preparation of a Federalism Assessment.

E. Paperwork Reduction Act

There are no reporting or recordkeeping provisions included in this rule that require approval from the Office of Management and Budget under section 3504(h) of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

List of Subjects in 14 CFR Parts 413 and 415

Administrative practice and procedure, Space transportation and exploration, Launch operations, Launch vehicles, User fees.

For the reasons set forth in the preamble, title 14 of the Code of Federal Regulations is amended as follows:

PART 413—APPLICATIONS

1. The authority citation for part 413 is revised to read as follows:

Authority: 49 U.S.C. app. 2601 note.

2. In § 413.5, paragraph (d) is removed.

PART 415—LAUNCH LICENSES

3. The authority citation for part 415 is revised to read as follows:

Authority: 49 U.S.C. app. 2601 note.

§ 415.4 [Removed]

4. Section 415.4 is removed.

§ 415.9 [Removed]

5. In § 415.9, paragraph (e) is removed.

Issued in Washington, DC, this 6th day of January, 1993.

Donald R. Trilling,

Acting Director, Office of Commercial Space Transportation.

[FR Doc. 93–567 Filed 1–11–93; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[T.D. 8467]

RIN 1545–AM72

Effect of Honoring Levy

AGENCY: Internal Revenue Service, Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations regarding the consequences of honoring an Internal Revenue Service levy. These regulations are necessary to reflect changes to the tax law by the Technical and Miscellaneous Revenue Act of 1988 (TAMRA). TAMRA amended section 6332(e) of the Internal Revenue Code, to provide that any

person who surrenders property to the Internal Revenue Service pursuant to a levy, is discharged from any obligation or liability to the delinquent taxpayer or to any other person arising from the surrender of such property. Before section 6332(e) was amended by TAMRA, a person who surrendered levied upon property was discharged from liability to the taxpayer, but not to a third party. The final regulations provide that if a taxpayer has an apparent interest in property in the possession of someone else, and if the possessor makes a good faith determination that the property has been levied upon by the Internal Revenue Service, the possessor is relieved of liability to a third party that has an interest in the property, even if it is subsequently determined that the property is not properly subject to levy.

DATES: These final regulations are effective on January 11, 1993. However, persons surrendering property to the Internal Revenue Service may rely on the regulations with respect to levies issued after November 10, 1988.

FOR FURTHER INFORMATION CONTACT: Susan B. Watson 202–622–3640 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations amending the Procedure and Administration Regulations (26 CFR part 301) under section 6332 of the Internal Revenue Code (Code). These final regulations reflect the amendment of section 6332 by sections 1015(t)(1) (A) and (B) of the Technical and Miscellaneous Revenue Act of 1988 (TAMRA) (Pub. L. 100–647).

The Internal Revenue Service published a notice of proposed rulemaking in the **Federal Register** on October 16, 1991 (56 FR 51855) providing proposed rules under section 6332 of the Code. Several parties submitted written comments concerning the regulations. Some of the issues raised in the public comments either had been considered prior to publication of the proposed regulations or fell outside the scope of the regulations. The following is a description of the provisions of the final regulations and a discussion of some of the comments received by the Internal Revenue Service with respect to the proposed regulations.

Explanation of Provisions

As amended by sections 1015(t)(1) (A) and (B) of TAMRA, section 6332(e) of the Code provides that any person who surrenders levied upon property in that person's possession to the Internal Revenue Service, is discharged from any obligation or liability to the delinquent taxpayer, and also to any other person. Prior to the amendment, the Code provided no such protection from liability to third parties. Accordingly, the regulations under section 6332 of the Code in existence at the time TAMRA was enacted provide that any person who mistakenly surrenders to the Internal Revenue Service property or rights to property not properly subject to levy is not relieved from liability to a third party who owns the property. Under those regulations, a person in possession of property that ostensibly belonged to a taxpayer frequently was faced with competing claims of ownership in the property and had to make a determination, at his or her peril, whether the property was properly subject to levy under the provisions of the Code and the provisions of state law.

The final regulations conform the existing regulations under section 6332 of the Code to the changes in the statutory language by providing that if a taxpayer has an apparent interest in property in the possession of someone else, a possessor who makes a good faith determination that such property has been levied upon by the Internal Revenue Service and who surrenders such property to the Internal Revenue Service in response to the levy is relieved of any liability or obligation to a third party who has an interest in the property, even if it is subsequently determined that the property was not properly subject to levy. If, however, a person surrenders property in which the taxpayer has no apparent interest and that property is not properly subject to levy, the person is not relieved of liability to a third party that owns the property. These new rules do not provide relief from liability to the taxpayer because such relief is unnecessary. (If, despite an apparent interest in levied upon property, the taxpayer in fact does not own the property, the taxpayer has no property rights that could be violated.) In addition, the relief provision does not apply to deposits a bank improperly surrenders before the end of the 21 day holding period mandated by section 6332(c).

The final regulations also clarify that the owners of surrendered property may seek to have the property returned through the administrative relief provided in section 6343(b) of the Code, or may bring suit to recover the property under section 7426 of the Code. The final regulations set forth examples illustrating the effect of honoring a levy.

Section 6332 of the Code was further amended by the deletion of language providing that an insuring organization that satisfies a levy with respect to a life insurance or endowment contract is discharged from any obligation or liability to any beneficiary of such contract. This language was superfluous in light of the more general protection from liability to third parties now provided with the enactment of TAMRA sections 1015(t)(1) (A) and (B). The final regulations remove the corresponding language in the existing regulations to conform to the statutory amendment.

Several written comments were received and considered. First, one of the commenters expressed general concern about the proposed retroactive effective date of the regulations. This concern, however, seems misplaced. These regulations benefit levied upon parties because they interpret a statutory amendment that provides a federal defense to wrongful turnover of property rather than forcing reliance on state law. At the same time, these regulations do not unfairly disadvantage taxpayers whose property has been erroneously levied upon. Therefore, although the effective date has been revised to be January 11, 1993, persons surrendering property they possess to the Internal Revenue Service prior to January 11, 1993, may rely on the regulations with respect to levies issued after November 10, 1988.

One of the commenters suggested that in paragraph (c)(1) of the regulations, the phrase "pursuant to section 6331 and regulations thereunder" be added for clarification after the phrase "levy has been made." However, the same language is present in the existing regulations and has not been a source of confusion. Accordingly, this comment has not been adopted.

Another commenter expressed concern that the regulations might be interpreted as creating a new federal cause of action. The new provision, however, does not give rise to a federal cause of action. To the contrary, the statutory change codified the result reached in *United States* v. *National Bank of Commerce*, 472 U.S. 713 (1985), and created a federal defense for a levied upon party who turns over property to the Internal Revenue Service pursuant to a levy. No changes were made to the final regulations as a result of this comment.

One of the commenters recommended that the regulations allow a levied upon party to make a good faith determination of the taxpayer's apparent interest in the property based solely upon the books and records in possession of the levied upon party.

Conversely, the same commenter suggested that the regulations provide that the levied upon party would be relieved of liability to the Internal Revenue Service if the party's books and records supported an erroneous determination that the taxpayer did not have an apparent interest in the property.

Neither of these comments was adopted. Apparent interest is an objective test. If an apparent interest exists, the possessor must act in good faith in determining whether the property in question has been levied upon by the Internal Revenue Service. The determination of whether these two requirements for relief from liability are met depends on the relevant facts and circumstances. For example, a bank generally may rely on its books and records to determine if the taxpayer has an apparent interest in an account and in making a good faith determination that the account has been levied upon by the Internal Revenue Service. Additionally, the issue of relief from liability to the Internal Revenue Service is beyond the scope of these regulations.

One commenter suggested that the regulations provide that a bank would be relieved of liability only if the bank notified all persons with an apparent interest in the property within 10 days of receipt of the levy. If a person so notified failed to respond by the 21st day, the bank would be automatically relieved of liability to that third party. This comment was not adopted for two reasons. First, it would impose an undesirable administrative burden on banks and other taxpayers. Second, the information obtained by this process might be inaccurate.

Finally, one commenter suggested eliminating the requirement that a person in possession of property make a good faith determination that the property has been properly levied upon by the Internal Revenue Service. In the commenter's opinion, the good faith requirement is burdensome and beyond the scope of the amendment. The proposed regulations were revised in response to this comment. As indicated above, the good faith determination a possessor of property must make is not that the property is properly subject to levy but rather that the property has been levied upon by the Internal Revenue Service.

Special Analyses

It has been determined that these regulations are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these final regulations, and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these final regulations is Susan B. Watson, Office of the Assistant Chief Counsel (General Litigation), Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulations on matters of both substance and style.

List of Subjects in 26 CFR Part 301

Administrative practice and procedure, Alimony, Bankruptcy, Child support, Continental shelf, Courts, Crime, Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Investigations, Law enforcement, Oil pollution, Penalties, Pensions, Reporting and recordkeeping requirements, Statistics, Taxes.

Final Amendments to the Regulations

Accordingly, 26 CFR part 301 is amended as follows:

PART 301—[AMENDED]

Paragraph 1. The authority citation for part 301 continues to read in part:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Section 301.6332–1(c) is revised to read as follows:

§ 301.6332–1 Surrender of property subject to levy.

* * * * *

(c) *Effect of honoring levy*—(1) *In general.* Any person in possession of, or obligated with respect to, property or rights to property subject to levy and upon which a levy has been made who, upon demand by the district director, surrenders the property or rights to property, or discharges the obligation, to the district director, or who pays a liability described in paragraph (b)(1) of this section, is discharged from any obligation or liability to the delinquent taxpayer and any other person with respect to the property or rights to property arising from the surrender or payment.

(2) *Exception for certain incorrectly surrendered property.* Any person who surrenders to the Internal Revenue Service property or rights to property not properly subject to levy in which the delinquent taxpayer has no apparent interest is not relieved of liability to a third party who has an interest in the property. However, if the delinquent taxpayer has an apparent interest in property or rights to property, a person who makes a good faith determination that such property or rights to property in his or her possession has been levied upon by the Internal Revenue Service and who surrenders the property to the United States in response to the levy is relived of liability to a third party who has an interest in the property or rights to property, even if it is subsequently determined that the property was not properly subject to levy.

(3) *Remedy.* In situations described in paragraphs (c)(1) and (c)(2) of this section, taxpayers and third parties who have an interest in property surrendered in response to a levy may secure from the Internal Revenue Service the administrative relief provided for in section 6343(b) or may bring suit to recover the property under section 7426.

(4) *Examples.* The provisions of this paragraph (c) may be illustrated by the following examples:

Example 1. M Bank is served with a notice of levy for an unpaid tax liability due from A in the amount of $2,000. M Bank holds $2,000 in a checking account in the names of A or B or C. Although all of the deposits into the account were made by B and C, A has an unrestricted right to withdraw the funds from the account. M Bank surrenders the entire account to the district director at the end of the holding period provided in section 6332(c). Under paragraph (c)(1) of this section, M Bank is not liable to B or C for any amount, even if B or C prove that the funds in the account did not belong to A, because A's unrestricted right to withdraw the funds is an interest which in subject to levy. B or C may, however, seek the return of the funds from the United States as provided in sections 6343(b) and 7426 of the Internal Revenue Code.

Example 2. A is indebted to B for $400. Unbeknownst to A, B has assigned his right to receive payment to C. A is served with a notice of levy for an unpaid tax liability due from B for $400. A, acting with no knowledge of the assignment to C, surrenders $400 to the district director. A is discharged from his obligation to pay B, the taxpayer. Under paragraph (c)(2) of this section, because B had an apparent interest in the funds that A owed to B, and because A determined in good faith that those funds had been levied upon, A is also discharged from any liability to C, even though the money is not properly subject to levy. C may, however, seek return of the payment from the United States as provided in sections 6343(b) and 7426 of the Internal Revenue Code.

Example 3. M Bank is served with a notice of levy for an unpaid tax liability due from "John H. Smith, Sr." in the amount of $5,000.

M Bank fails to read the notice of levy carefully. When searching its records, M Bank finds the name of "John H. Smith, Jr." and looks no further. M Bank surrenders $5,000 from John H. Smith, Jr.'s checking account to the district director. M Bank is not discharged from liability under section 6332(e) of the Internal Revenue Code because the delinquent taxpayer (John H. Smith, Sr.) had no apparent interest in the account of John H. Smith, Jr. (Generally, John H. Smith Jr. may seek return of the payment from the United States as provided in sections 6343 and 7426 of the Internal Revenue Code.)

Example 4. M Bank is served with a notice of levy for an unpaid tax liability due from "Robert A. Jones" in the amount of $5,000. M Bank searches its records and identifies four separate accounts of $1,000 each in the name of "Robert A. Jones." All four accounts list different addresses and social security identification numbers. M Bank surrenders all four accounts totalling $4,000 in response to the levy. M Bank could not in good faith have determined that all four accounts were levied upon. Therefore, M Bank is not discharged from liability to any person other than the taxpayer whose account was levied upon.

(5) *Effective date.* Paragraph (c) of this section is effective January 11, 1993. However, persons surrendering property to the Internal Revenue Service may rely on the regulations with respect to levies issued after November 10, 1988.

Shirley D. Peterson,

Commissioner of Internal Revenue.

Approved: December 15, 1992.

Alan J. Wilensky,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 93-439 Filed 1-11-93; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 901

Alabama Abandoned Mine Land Reclamation Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of a proposed amendment to the Alabama Abandoned Mine Land Reclamation (AMLR) Plan (hereinafter referred to as the Alabama Plan) under the Surface Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1231 *et seq.*, as amended. The amendment would revise Alabama's procedures for ranking and selecting AMLR projects and is intended to meet the requirements of the applicable provisions of SMCRA, as amended, and enacted on November 5, 1990.

EFFECTIVE DATE: January 12, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Jesse Jackson, Jr., Director Birmingham Field Office, Office of Surface Mining Reclamation and Enforcement, 135 Gemini Circle, suite 215, Birmingham, Alabama 35209. Telephone: (205) 290-7282.

SUPPLEMENTARY INFORMATION:

I. Background on the Alabama Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision.
VI. Procedural Determinations.

I. Background on the Alabama Program

The Secretary of the Interior approved the Alabama AMLR Plan on May 20, 1982. Information pertinent to the general background, revisions, and amendments to the initial plan submission, as well as the Secretary's findings and the disposition of comments can be found in the May 20, 1982, **Federal Register** (47 FR 22062). Actions taken subsequent to the approval of the Alabama AMLR Plan are identified at 30 CFR 901.20 and 901.25.

II. Submission of Amendment

By letter dated June 26, 1992, Alabama submitted a reclamation plan amendment to OSM on its own initiative (Administrative Record No. AL-0484). The amendment consists of revised narratives to modify one section of the approved Alabama Plan pursuant to the provisions of 30 CFR 884.13. By letter dated October 8, 1992, Alabama submitted additional revisions to the proposed amendment (Administrative Record No. AL-0493). The June and October revisions are intended to replace Alabama's current ranking and selection procedures.

OSM announced receipt of the proposed amendment in the August 19, 1992 **Federal Register** (57 FR 37497) and in the same notice opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on September 18, 1992.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment submitted on June 26, 1992, and revised on October 8, 1992. Any revisions not specifically addressed below are found to be no less stringent than SMCRA and no less effective than the Federal rules.

Procedures for Ranking and Selecting AMLR Projects

1. Section I—Introduction

Alabama is proposing to follow a systematic, objective procedure for the ranking and selection of projects for inclusion in AML construction grants. Currently eligible for reclamation are those sites mined for coal or affected by such mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977. Additional sites will become eligible upon enactment by the State Legislature of a bill that will extend the cut-off date to November 5, 1990. Section 404 of SMCRA describes those lands and waters eligible for reclamation. The Director finds that the proposed amendment at Section I is consistent with the provisions of section 404 of SMCRA.

2. Section II.A—Site Identification

During each fiscal year, Alabama is proposing to identify the AML sites that need to be reclaimed. Information regarding site-specific AML problems will be analyzed and a list prepared identifying potential projects with the highest priority AML problems.

The Federal regulations at 30 CFR 884.13(c) require that the State provide a description of policies and procedures it will follow in conducting the reclamation program including criteria for the ranking and selection of projects. The Director finds the proposed amendment at Section II.A to be consistent with the Federal regulations at 30 CFR 884.13(c).

3. Section II.B—Preliminary Site Evaluation

Alabama is proposing that the identified sites be evaluated and assessed according to the following criteria: (1) Compliance with Public Law 95-87—The project must meet the eligibility requirements specified in the public law or be rejected. If a project is rejected, a statement explaining the reason for the rejection will be filed. (2) Feasibility—Alabama will make certain determinations concerning the availability of proven technology, physical resources, and funding to accomplish the required work. Alabama will also determine if the project is to be designated a Research and Demonstration Project to develop new technology. (3) Purpose of Project—Reclamation projects will be prioritized as follows: Priority 1—Extreme Danger to Public; Priority 2—Adverse Effect on Public; Priority 3—Restoration of

Environment; Priority 4—Research and Demonstration; Priority 5—Protection and Enhancement of Public Facilities; Priority 6—Development of Public Lands; Priority 7—Extreme Danger to Public (Non-coal); Priority 8—Adverse Effect on Public (Non-coal); Priority 9—Restoration of Environment (Non-coal); and Priority 10—Construction of Public Facilities (Non-coal).

Section 403(a) of SMCRA defines the priorities for the expenditures of moneys on eligible lands and waters which were mined for coal or affected by such mining. Sections 411 (c) and (e) of SMCRA define the priorities for non-coal sites. The Director finds the proposed amendment at Section II.B to be consistent with the provisions of sections 403(a) and 411 (c) and (e) of SMCRA.

4. Section II.C—Tentative Project Selection

Alabama is proposing that after all listed projects have been visited by the AML Field Supervisor and Branch Chief of Planning and Maintenance, those projects meeting the above specified criteria and being the most urgent and deserving will be identified and recommended.

The Federal regulations at 30 CFR 884.13(c) require that the State submit a description of the policies and procedures it will follow in conducting the reclamation program. The Director finds the proposed amendment at Section II.C to be consistent with the Federal regulations at 30 CFR 884.13(c).

5. Section II.D—Intensive Site Evaluation

Alabama is proposing that authorized projects be investigated on a site-by-site basis by a qualified, interdisciplinary team consisting of planners, foresters, biologists, and engineers. All project planning will be done in accordance with the National Environmental Policy Act of 1969 and related environmental laws, regulations and executive orders. Investigators will furnish locational data, document mining history, establish the need of the project, and assess certain site parameters as they exist due to past mining and how they will likely be affected by the proposed reclamation. Those parameters include: Hazards to public health, safety and general welfare; cultural and/or historic resources; water quality; wetlands; floodplains; fish and wildlife (including threatened or endangered species); prime or unique farmland; recreational resources; air quality; socioeconomic factors; and cumulative impacts. The investigative team will also recommend preferred reclamation alternatives and estimate costs necessary to alleviate public health and safety hazards and achieve environmental stability. The U.S. Department of Interior, Bureau of Mines, may be consulted regarding the newest reclamation technology applicable to abandoned coal mine lands. A list of projects, ranked in order of preference to be included in the next construction grant application, will be submitted for review by the AML Chief Planner.

The Federal regulations at 30 CFR 884.13(c) require that the State provide a description of the policies and procedures it will follow in conducting the reclamation program. The Director finds the proposed amendment at Section II.D to be consistent with the Federal regulations at 30 CFR 884.13(c).

6. Section II.E—Final Project Selection

Alabama is proposing that a project selection committee discuss and compare the merits of each project recommended for inclusion in the next construction grant. The committee will consist of the AML Field Supervisor, Branch Chief of Planning and Maintenance, AML Chief Planner, State Programs Deputy Administrator and State Programs Administrator. Review factors include but are not limited to: Degree or magnitude of hazard, number of persons and acreage affected, cost versus funding, community support, future mining potential, and acceptability of any additional adverse impacts to people or the environment. The committee will prepare a final list of projects.

The Federal regulations at 30 CFR 884.13(c) require that the State provide a description of the policies and procedures it will follow in conducting the reclamation program. The Director finds the proposed amendment at Section II.E to be consistent with the Federal regulations at 30 CFR 884.13(c).

7. Section II.F—Consultation

Alabama is proposing that review comments be solicited and documented for each project from various Federal and State agencies and other parties as appropriate. All comments received from the agencies or parties will be considered during project planning and construction for the mitigation of environmental impacts, and documented in the grant application.

The Federal regulations at 30 CFR 884.13 (c)(3) and (c)(7) require that the State provide procedures for public participation and involvement in the State reclamation program. The Director finds the proposed amendment at Section II.F consistent with the Federal regulations at 30 CFR 884.13 (c)(3) and (c)(7).

8. Section II.G—Public Participation

Alabama is proposing that copies of the project proposals be placed in appropriate locations for public review for a two week period. The public will be afforded the opportunity to submit written comments and request a public meeting. Legal notices will be placed in local newspapers with general circulation in the areas in which the project is located. Public comments will be considered for inclusion in the grant application following completion of the public review period.

The Federal regulations at 30 CFR 884.13(c)(7) require that the State provide procedures for public participation and involvement in the State reclamation program. The Director finds the proposed amendment at Section II.G consistent with the Federal regulations at 30 CFR 884.13(c)(7).

IV. Summary and Disposition of Comments

Public Comments

The public comment period and opportunity to request a public hearing announced in the August 19, 1992, **Federal Register** (57 FR 37497) ended on September 18, 1992. No public comments were received and a public hearing was not held as no one requested an opportunity to provide testimony.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Alabama program.

The Department of Labor, Mine Safety and Health Administration, the Department of Agriculture, Soil Conservation Service and Forest Service, and the Alabama Historical Commission concurred without comment.

The Department of the Army, Army Corps of Engineers (Corps), commented that the State should: (1) Specify the technical criteria that will be used to identify and select the abandoned mine sites for reclamation; (b) initiate consultation with the Corps early in the screening process; and (c) consider the impacts of abandoned mine sites on Corps projects and coordinate reclamation plans with the Corps. In response, the Director notes that: (a) The identification and selection process Alabama sets forth in Sections II.A–E provides an adequate framework for the

evaluation process and is consistent with the corresponding Federal regulations at 30 CFR 884.13(c), as discussed in Findings 2 through 6; (b) the consultation procedure Alabama proposes in Section II.F is consistent with the corresponding Federal regulations at 30 CFR 884.13 (c)(3) and (c)(7) as discussed in Finding 7; and (c) the screening procedure Alabama proposes in Sections II.A–F is consistent with the corresponding Federal requirements at 30 CFR 884.13(c) as discussed in Findings 2 through 7. The Director further notes that Alabama has been provided with a copy of the Corps' comments for the State's consideration.

The Department of Interior, Fish and Wildlife Service (FWS), commented that it would like Alabama to address endangered and threatened species as a separate priority, or, less preferably, to specifically address them under Priority 3. The FWS provided a list of those Federally protected and candidate species present in the drainages of Alabama's coal fields. The Director notes that in Section II.B.3, Alabama specifically mentions threatened and endangered species under Priority 3. As discussed in Finding 3, Alabama's proposed rule is consistent with the corresponding rule at section 403(a) of SMCRA. The Director further notes that Alabama has been provided with a copy of the FWS's comments for the State's consideration.

The Department of the Interior, Bureau of Mines (Bureau), commented that Alabama should provide for consultation with the Bureau on newest technology applicable to abandoned coal mine lands. The Director notes that in Section II.D, Alabama has added a provision providing for consultation with the Bureau. As discussed in Finding 5, Alabama's proposed rule is consistent with the corresponding Federal regulations at 30 CFR 884.13(c). Further, as discussed in Finding 7, Alabama's procedure for consultation in Section II.F is consistent with the corresponding Federal requirements at 30 CFR 884.13(c)(7). The Director further notes that Alabama has been provided with a copy of the Bureau's comments for the State's consideration.

V. Director's Decision

Based on the above findings, the Director is approving the program amendment submitted by Alabama on June 26, 1992, and revised on October 8, 1992.

The Federal regulations at 30 CFR part 901 codifying decisions concerning the Alabama program are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage states to bring their programs in conformity with the Federal standards without delay. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no provisions in these categories. The EPA did, however, respond with no comment.

VI. Procedural Determinations

Executive Order 12291

On March 30, 1992, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or disapproval of State and Tribal abandoned mine land reclamation plans and revisions thereof. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State and Tribal abandoned mine land reclamation plans and revisions thereof since each such plan is drafted and adopted by a specific State or Tribe, not by OSM. Decisions on proposed State and Tribal abandoned mine land reclamation plans and revisions thereof submitted by a State or Tribe are based on a determination of whether the submittal meets the requirements of Title IV of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1231–1243) and the Federal regulations at 30 CFR parts 884 and 888.

National Environmental Policy Act

No environmental impact statement is required for this rule since agency decisions on proposed State and Tribal abandoned mine land reclamation plans and revisions thereof are categorically excluded from compliance with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State (or Tribal) submittal which is the subject of this rule is based upon Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements established by SMCRA or previously promulgated by OSM will be implemented by the State (or Tribe). In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions in the analyses for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 901

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 30, 1992.

Alfred E. Whitehouse,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 901—ALABAMA

1. The authority citation for part 901 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In § 901.25, a new paragraph (c) is added to read as follows:

§ 901.25 Amendment to approved Alabama Abandoned Mine Land Reclamation Plan.

* * * * *

(c) The Alabama amendment revising the ranking and selection procedures for abandoned mine land reclamation projects submitted on June 26, 1992,

and revised on October 8, 1992, is approved effective January 12, 1993.

[FR Doc. 93-593 Filed 1-11-93; 8:45 am]
BILLING CODE 4310-05-M

30 CFR Part 917

Kentucky Regulatory Program; General Provisions for Permits

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval, with one exception, of a proposed program amendment to the Kentucky regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment consists of proposed modifications to Kentucky Administrative Regulations (KAR) at 405 KAR 8:010 regarding general provisions for permits and new permit application forms, procedures for incidental boundary revisions, and the establishment of a new category of revisions for operator changes.

EFFECTIVE DATE: January 12, 1993.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503, Telephone (606) 233-2896.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision.
VI. Procedural Determinations.

I. Background on the Kentucky Program

The Secretary of the Interior conditionally approved the Kentucky program on May 18, 1982. Information pertinent to the general background and revisions to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404-21435).

Subsequent actions concerning the conditions of approval and proposed amendments are identified at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

II. Submission of Amendments

By letter dated June 28, 1991 (Administrative Record Number KY-1059), Kentucky submitted a proposed program amendment modifying 19 regulations and incorporating two Technical Reclamation Memorandum (No. 19 and No. 20).

OSM announced receipt of the proposed amendment in the July 22, 1991, **Federal Register** (56 FR 33398), and in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on August 21, 1991.

By letter dated November 11, 1991 (Administrative Record Number KY-1079), Kentucky submitted a proposed program amendment which modified that portion of the June 28, 1991, submission involving 405 KAR 8:010. This latest amendment identified and incorporated permit application forms that had been revised primarily to capture information required by Kentucky's approved ownership and control regulations (56 FR 47907, September 23, 1991).

OSM announced receipt of the November 11, 1991, submission in the December 13, 1991, **Federal Register** (56 FR 65031) and in the same notice, reopened the comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on January 13, 1992.

By letter dated March 31, 1992 (Administrative Record Number KY-1123), Kentucky submitted a proposed program amendment which replaced those portion of the two earlier amendments (KY-1059 and KY-1079) amending 405 KAR 8:010 relating to general permitting provisions, operator change revisions, and incidental boundary revisions.

OSM announced receipt of the March 31, 1992, submission in the May 21, 1992, **Federal Register** (57 FR 21636) and in the same notice, reopened the comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on June 5, 1992.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17 are the Director's findings concerning the proposed amendment to the Kentucky program.

Revisions not specifically discussed below concern nonsubstantive wording changes, or revised cross-references and paragraph notations to reflect organizational changes resulting from this amendment.

A. Revisions to Kentucky's Regulations That Are Not Substantively Identical to the Corresponding Federal Regulations

1. 405 KAR 8:010 Section 12(1)(a)

Kentucky proposes to revise this rule to provide that applications for transfer, assignment, or sale of permit rights shall be made available for public inspection and copying, at reasonable times, in accordance with Kentucky open records statutes, KRS 61.870 to 61.884. This revision was submitted in response to, and fully satisfies, a required amendment set forth at 30 CFR 917.16(d)(3). Therefore, the Director finds the proposal to be no less effective than the counterpart Federal rule set forth at 30 CFR 773.13(d).

2. 405 KAR 8:010 Section 14(8)

Kentucky proposes to revise this rule by adding a requirement that where a permit applicant has entered into a payment schedule approved by OSM, the permit may be issued only if it includes a condition that the permittee comply with the approved payment schedule. The Federal rule at 30 CFR 773.15(c)(7) requires that no permit application shall be approved unless the regulatory authority finds that the applicant has paid all reclamation fees from previous and existing operations. However, 30 CFR 773.15(b)(2) allows for the issuance of a conditional permit where a violation is in the process of being corrected, i.e., the applicant has entered into a payment schedule with OSM for the payment of outstanding reclamation fees. Therefore, the Director finds that the proposed rule is no less effective than 30 CFR 773.15(b)(2) since the issuance of the permit is conditioned upon the permittee's compliance with the OSM-approved payment schedule.

B. Revisions to Kentucky's Regulations With No Corresponding Federal Regulations

1. 405 KAR 8:010 Necessity and Function

Kentucky proposes to revise this section, which summarizes the coverage of this particular regulation, by including references to permit amendments, administrative and judicial review, and procedures relating to improvidently issued permits. While there is no corresponding Federal regulation, the Director finds that the proposal adds clarity and specificity to this regulation, does not adversely impact any Federal requirements, and

is, therefore, not inconsistent with SMCRA or the Federal rules.

2. 405 KAR 8:010 Section 5(1)(c)

Kentucky proposes to add this rule which lists and incorporates into the rules fourteen (14) forms required to be submitted by applicants in connection with various aspects of the permitting process. While there is no direct Federal counterpart, the Director finds that this addition does not adversely impact any Federal requirement, and is, therefore, not inconsistent with SMCRA or the Federal rules. Should there be any conflict between the contents of the forms and the requirements of Kentucky's approved regulations, then the approved regulations shall prevail.

3. 405 KAR 8:010 Section 5(1)(d)

Kentucky proposes to add this rule which identifies the times and locations where the forms listed in section 5(1)(c) can be reviewed or obtained. While there is no direct Federal counterpart, the Director finds that the proposal does not adversely impact any Federal requirement, and is, therefore, not inconsistent with SMCRA or the Federal rules.

4. 405 KAR 8:010 Section 20(2)(a) and Section 20(3)(a)

Kentucky proposes to revise these rules by providing exceptions to the category of (1) major permit revisions for incidental boundary revisions (IBRs) and operator change revisions, and (2) minor permit revisions for operator change revisions, which are considered separately in proposed new rules at section 20(3)(f)[IBRs] and section 20(6) [Operator change revisions]. The Director finds that the exceptions proposed in sections 20(2)(a) and 20(3)(a), when read together with proposed new section 20(3)(f) and section 20(6), are not inconsistent with any Federal requirement since 30 CFR 774.13(b)(2) does not require that IBRs or operator changes be considered significant (major) revisions.

5. 405 KAR 8:010 Section 20(2)(a)10

Kentucky proposes to revise its listing of examples of major revisions by deleting incidental boundary revisions that include new areas from which coal will be removed. The revised rule specifies that these revisions shall be limited to ten (10) percent of the permit area acreage or five (5) acres, whichever is less. There is no Federal counterpart to this provision. The Director finds that the proposed deletion will not render Kentucky's program less effective than SMCRA or the Federal regulations.

6. 405 KAR 8:010 Section 20(3)(d)(23)

Kentucky proposes to delete this rule which classifies proposals to cut berms as a minor field revision. The deletion of this rule is consistent with the Director's findings at 55 FR 46054 (November 1, 1990), in which he determined that "(A)llowing the practice of cutting berms to relieve impounded water would render the Kentucky regulations less effective than the Federal regulations at 30 CFR 816/817.46(b)(2) in that it would also allow the permittee to remove ponded water from the permit area without first passing it through a siltation structure".

7. 405 KAR 8:010 Section 23(3)(f)1–10

Kentucky proposes to add a new paragraph (f) which sets forth the following 10 conditions which incidental boundary revisions must meet in order to be deemed minor revisions.

(1) Do not exceed ten (10) percent of the relevant surface or underground acreage in the original or amended permit area;

(2) Are contiguous to the current permit area;

(3) Are within the same watershed as the current permit area;

(4) Are required for an orderly continuation of the mining operation;

(5) Involve mining of the same coal seam or seams as in the current permit;

(6) Involve only lands for which the hydrologic and geologic data and the probable hydrologic consequences determination in the current permit are applicable;

(7) Do not involve properties on which mining is prohibited under KRS 350.085 and 405 KAR 24:040 (Areas unsuitable for mining), unless appropriate waivers have been obtained, or which have been designated as unsuitable for mining under 405 KAR 24.030 (Lands unsuitable for surface mining operations), or any properties eligible for listing on the National Register of Historic Places;

(8) Do not involve any of the categories of mining in 405 KAR 7:060 (Experimental mining practices) and 405 KAR 8:050 (Special categories of mining) unless the current permit already includes the relevant category;

(9) Do not constitute a change in the current method of mining; and

(10) Will be reclaimed in conformity with the current reclamation plan.

This proposal implements changes to Kentucky's Surface Mining Law (KRS Chapter 350), contained in Senate Bill 256 and House Bill 519 [identical bills], which were approved by OSM on February 6, 1991 [56 FR 4721, Finding 7(a)]. As pointed out by the Director in that approval, neither SMCRA nor the Federal regulations provide guidance on what is an incidental boundary revision. Therefore, within reason, the scale and extent of such revisions are left to the discretion of the State regulatory authority. Because the State criteria give reasonable meaning to the term "incidental boundary revision" in that such revisions would result in only minor or insignificant changes to the permit area, the Director finds that the proposal is not inconsistent with section 511(a)(3) of SMCRA or with 30 CFR 774.13(d).

8. 405 KAR 8:010 Section 20(5)

Kentucky proposes to add new section 20(5) which sets forth the following size limitations for incidental boundary revisions.

(1) For surface mining activities, the revisions shall not exceed ten (10) percent of the acreage in the original or amended permit, and shall not exceed twenty (20) acres.

(2) For underground mining activities, surface operations and underground workings shall be considered separately, as follows:

(a) For surface operations, the revision shall not exceed the greater of two (2) acres or ten (10) percent of the surface operations acreage in the original or amended permit area, and shall not exceed twenty (20) acres.

(b) For underground workings, the revision shall not exceed ten (10) percent of the acreage of the underground workings in the original or amended permit area, and shall not exceed twenty (20) acres.

(3) Cumulative incidental acreage added by successive incidental boundary revisions shall not exceed the limitations in this subsection. Acreage added by revisions prior to a permit amendment shall not be counted toward cumulative acreage after the amendment.

For the reasons set forth in finding B.7. of this preamble, the Director has determined that the proposal, which implements revisions to Kentucky's Surface Mining Law previously approved by OSM (56 FR 4721, February 6, 1991), is not inconsistent with SMCRA or with the Federal Regulations.

9. 405 KAR 8:010 Section 20(6)

Kentucky proposes to add new section 20(6), consisting of paragraphs (a) through (h), which establishes a new category of permit revision for operator changes that do not constitute a transfer, assignment or sale of permit rights. The proposal sets forth the application

procedures and the information required to be included in the application for approval of the operator change. In addition, the proposal sets forth requirements for advertisement of receipt of the application, procedures for public comment, criteria for approval of the application, and notification requirements upon approval or denial of the application.

Although Kentucky provides in proposed paragraph (a) that these procedures apply to all operator changes that do not constitute a transfer, assignment or sale of permit rights, OSM, in adopting the Federal definition of "transfer, assignment or sales of rights", stated that "* * * these terms will include any change in ownership or in the person actually exercising the right to mine. For example, these terms would include all subcontractors who actually perform the mining who were not listed in the original application * * *" (44 FR 15106, March 13, 1979). Therefore, Kentucky's proposed procedures and requirements for operator change revisions must meet the Federal regulatory requirements for a transfer, assignment or sale of permit rights as set forth at 30 CFR 774.17.

Kentucky's proposed paragraphs (6)(a) and (b) are substantively identical to the general application and approval requirements of 30 CFR 774.17 (a) and (b)(1). Therefore, the Director finds that these proposals are no less effective than their Federal counterparts.

Proposed paragraphs (6)(c) 1, 2, 3, and 4, which set forth information to include in the application for approval of the operator change, are substantively identical to the application information requirements of 30 CFR 774.17(b)(1) except for that portion of subparagraph 4 which provides that abated violation information shall not be required. The corresponding Federal rule at 30 CFR 774.17(b)(1)(iii) provides that the application shall include the legal, financial, compliance, and related information required by 30 CFR part 778 for the applicant for approval of the transfer, assignment or sale of permit rights. Paragraph (c) of 30 CFR 778.14 provides that each application shall contain a list of all violation notices received by the applicant during the 3-year period preceding the application date for any violation of a provision of the Act, or of any law, rule or regulation of the United States, or of any State law, rule or regulation enacted pursuant to Federal law, rule or regulation pertaining to air or water environmental protection incurred in connection with any surface coal mining operation. This Federal requirement is derived from section 510(c) of SMCRA, which, unlike paragraphs (a) and (b) of the same section, applies only to new permit applications. Therefore, Kentucky's proposed rule, which would not require the submission of information concerning abated violations, is no less stringent than SMCRA. Furthermore, the information submitted under 30 CFR 778.14 is used only to determine whether, as required by 30 CFR 774.17(d)(1), the applicant (proposed operator) is eligible to receive a permit in accordance with 30 CFR 773.15(b) and (c). Nothing in 30 CFR 773.15(b) and (c) requires the consideration of abated violations. Instead these paragraphs only address unabated violations and pattern of violation determinations. Therefore, the Director finds that the exclusion for abated violation information proposed by Kentucky in paragraph (c)4 is not inconsistent with the requirements of SMCRA and the Federal regulations, and the proposed rule at 405 KAR 8:010 section 20(6)(c), in total, is no less effective than its Federal counterpart.

In paragraph (6)(d), Kentucky proposes to require that the application be verified under oath by the permittee and the proposed operator in the manner required by 405 KAR 8:010 section 7. While there is no direct Federal counterpart, the Director finds that the proposal is not inconsistent with the permit application requirements of SMCRA and the Federal regulations since it would not adversely impact any Federal requirement.

The requirements for advertisement of the application for operator change contained in proposed paragraph (6)(e) are substantively identical to the Federal requirements set forth at 30 CFR 774.17(b)(2). Therefore, the Director finds that the proposal is no less effective than its Federal counterpart.

The provisions of proposed paragraph (6)(f) for filing comments regarding the proposed change in operators are substantively identical to the requirements contained in 30 CFR 774.17(c). Therefore, the Director finds that the proposal is no less effective than its Federal counterpart.

The criteria for approval of the application for operator change set forth in proposed paragraph (6)(g) are substantively identical to the Federal provisions found at 30 CFR 774.17(d). Therefore, the Director finds that the proposal is no less effective than its Federal counterpart.

The notification requirements contained in proposed paragraph (6)(h) are similar to those found in the Federal regulations at 30 CFR 774.17(e)(1). However, the proposal does not include notification of OSM, which is part of the Federal rule, nor does the State rule include a counterpart to 30 CFR 774.17(e)(2), which requires that the regulatory authority be notified when the approved change is consummated. Although Kentucky does effectively notify OSM by means of the information which is input into the Applicant/Violator System (AVS), the proposed rule must specifically set forth the notification requirement consistent with the Federal rule. Therefore, the Director is requiring Kentucky to amend its program to specifically include a requirement that OSM be notified of the decision to approve or deny the application for a change in operator and that the regulatory authority be notified when the change takes place.

10. 405 KAR 8:010 Section 20(7)

Kentucky proposes to revise this rule by providing an exception to the basic application fee for operator change revisions. This change is consistent with the authority granted to the State by 30 CFR 777.17, which governs permit fees.

IV. Summary and Disposition of Comments

Public Comments

The public comment period and opportunity to request a public hearing was announced in the July 22, 1991, **Federal Register** (56 FR 33398). The comment period closed on August 21, 1991. No one requested an opportunity to testify at the scheduled public hearing so no hearing was held. On August 22, 1991, the Kentucky Resources Council (KRC) filed comments in response to the proposed rule. A discussion of those comments is included in the summary below. KRC filed additional comments on January 13, 1992, in response to the **Federal Register** notice (56 FR 65031, December 13, 1991) announcing receipt of Kentucky's revised program amendment which was filed on November 11, 1991. These additional comments are included in the summary below. Finally, the KRC filed comments on May 18, 1992 and June 8, 1992, in response to the **Federal Register** notice (57 FR 21636, May 21, 1992) announcing receipt of Kentucky's March 31, 1992, revised program amendment and those comments are also included in the summary which follows. No one requested an opportunity to testify at the scheduled public hearings announced in the December 13, 1991, and the May 21, 1992, **Federal Register** notices so no hearings were held.

405 KAR 8:010 Section 8(2)

The KRC commented that this section must be modified to require that public notice shall not be initiated until the cabinet has determined that an application is administratively complete. While this section is not being revised as part of the program amendment submitted by Kentucky, the Director agrees with KRC and previously published a required amendment (55 FR 53490, December 31, 1990) at 30 CFR 917.16(d)(2) advising Kentucky to amend its program to require that public notice shall not be initiated until the cabinet has determined that an application is administratively complete. OSM is currently pursuing resolution of this issue with Kentucky.

405 KAR 8:010 Section 13(4)(a)

The KRC commented that this section, as well as section 25(2)(a)2, which authorize a presumption of correction of violation rule, are inconsistent with SMCRA. While these sections are not being revised as part of the program amendment submitted by Kentucky, the Director has previously deferred action on these sections and advised Kentucky that the presumption provisions can not be enforced by the State (56 FR 47907, September 23, 1991). That action by the Director is still in effect.

405 KAR 8:010 Section 13(4)(c)

The KRC commented that this section remains inconsistent with the Secretary's regulations in assuring that those operators who have a demonstrated pattern of willful violations of SMCRA, including both federal *and* other-state violations, will be barred from obtaining a permit in Kentucky. The Director agrees with KRC's comments, and previously published a required amendment (56 FR 47907, September 23, 1991) at 30 CFR 917.16(e) advising Kentucky to amend its program to include violations of Federal regulatory programs and other State regulatory programs, not just violations of KRS chapter 350 and regulations adopted pursuant thereto. OSM is pursuing resolution of that required amendment with Kentucky.

405 KAR 8:010 Section 20(5)

The KRC stated its belief that the scope of allowable incidental boundary revisions far exceeds the intent of Congress in creating the exemption from the obligation to obtain a new permit for addition of areas beyond permitted boundaries. The Director previously considered similar comments from KRC in connection with proposed changes to Kentucky's Revised Statutes regarding incidental boundary revisions (56 FR 4721, February 6, 1991). As the Director pointed out at that time, the legislative history on this subject is extremely sparse. When Congressional intent is unclear or unknown, great deference is given to the agency interpretation of a statute. As long as an agency's interpretation is reasonable, that interpretation is upheld. The size limitations of incidental boundary revisions proposed by Kentucky in this program amendment are consistent with the statutory limitations approved by the Director in the final rule published on February 6, 1992. Therefore, Kentucky will not be required to make any changes.

405 KAR 8:010 Section 20(6)(b)

In Kentucky's original submission dated June 28, 1991, the State proposed to add a rule which stated a permittee shall not allow an operator to conduct operations on the permit area unless the operator has been approved in the permit. In the resubmission dated November 11, 1991, Kentucky deleted this proposed rule and KRC has objected to the deletion. Since Kentucky removed this proposed rule prior to a final decision by the Director, it has never been part of the State's approved program. In addition, there is no equivalent Federal rule. However, it is clear from the rules proposed by Kentucky in section 20(6) that an applicant must file for, and receive cabinet approval of, any change in operator.

405 KAR 8:010 Section 20(6)(c)4

The KRC expressed concern with the exemption granted by this rule to the reporting by the proposed operator of abated violation information required by 405 KAR 8:030/8:040 section 3(3). However, as discussed in Finding B.9 herein, the Director has determined that the exemption provided by section 20(6)(c)4 is not inconsistent with either the State rule at 405 KAR 8:030/8:040 section 3(3), section 510(c) of SMCRA or the Federal rule at 30 CFR 774.17.

405 KAR 8:010 Section 20(6)(f)

The KRC indicated that the public comment period of fifteen (15) days proposed by this rule was too compressed to allow for meaningful public input and should be expanded to a thirty (30) day comment period. KRC's position is based upon its characterization of an operator change revision as a significant revision subject to a thirty (30) day comment period pursuant to 30 CFR 773.13(b)(2). However, there is nothing in the Federal rules at 30 CFR 773.13(b)(2) or 30 CFR 774.17 that suggests that operator changes must be considered significant revisions. Like, the Federal rules at 30 CFR 774.17 governing applications for the transfer, assignment or sale of permit rights, Kentucky has established public notice requirements that fall between those for major (significant) revisions and minor revisions. The Director feels that Kentucky has reasonably exercised the authority granted under 30 CFR 774.13(b)(2) in establishing the requirement for public comment periods. As pointed out in the preamble to 30 CFR 774.13(b)(2) (48 FR 44377, September 28, 1983), the section "* * * provides flexibility to the regulatory authority to establish guidelines suitable to the operation of individual State programs." The 15-day period is consistent with the existing provisions in Kentucky's program dealing with the comment period regarding applications for transfer, assignment or sale of permit rights as set forth at 405 KAR 8:010 section 22(3). The Director finds that the proposed rule is reasonable and consistent with Federal requirements. No further action by the State will be required.

405 KAR 8:010 Section 20(6)(h)

The KRC has expressed its objection to the proposed rule which provides that the cabinet will approve or disapprove a request for an operator change within fifteen (15) days of "receipt of a complete application". KRC reiterates its position that this type of revision constitutes a major revision and that a 15-day comment period is too compressed and "becomes even more meaningless when the agency intends to render a decision at the same time that the comment period ends." The Director notes that the proposed rule actually provides for approval or disapproval of the application within 15 days after the close of the comment period. Furthermore, as discussed in his response to the preceding comment, the Director does not agree with KRC that an operator change revision constitutes a significant revision.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Kentucky program. The Bureau of Land Management, Soil Conservation Service, Mine Safety and Health Administration, Fish and Wildlife Service, Environmental Protection Agency, Bureau of Mines, Forest Service, Tennessee Valley Authority, and the Kentucky Heritage Council

acknowledged receipt of the proposed amendment and offered no comments.

V. Director's Decision

Based on the above findings, the Director is approving, with the exception noted in Finding B.9, the program amendment relating to 405 KAR 8:010, as submitted by Kentucky on June 28, 1991, and as modified and resubmitted on November 11, 1991, and March 31, 1992.

The Federal regulations at 30 CFR 917 codifying decisions concerning the Kentucky program are being amended to implement this decision. The Director is approving these proposed rules with the understanding that they be promulgated in a form identical to that submitted to OSM and reviewed by the public. Any differences between these rules and the State's final promulgated rules will be processed as a separate amendment subject to public review at a later date. This final rule is being made effective immediately to expedite the State program amendment process and to encourage the State to conform its program with the Federal standards without delay. Consistency of State and Federal standards is required by SMCRA.

Environmental Protection Agency (EPA) Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment that relates to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no provisions in these categories and that EPA's concurrence is not required.

VI. Procedural Determinations

Executive Order No. 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the review required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102 (2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based on counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 25, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 917—KENTUCKY

1. The authority citation for part 917 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. 30 CFR 917.15, is amended by adding a new paragraph (oo) to read as following:

§ 917.15 Approval of regulatory program amendments.

* * * * *

(oo) The amendment to the Kentucky Administrative Regulations (KAR) at 405 KAR 8:010, relating to General Provisions of Permits, as submitted to OSM on June 28, 1991, and revised on November 11, 1991, and March 31, 1992, is approved, with the exception noted herein, effective January 12, 1993. The approved amendment consists of modifications to the following sections of 405 KAR 8:010:

Section 5(1)(c)—General format and content of applications.
Section 5(1)(d)—General format and content of applications.
Section 12(1)(a)—Public availability of information in permit applications on file with the cabinet.
Section 14(8)—Criteria for application approval or denial.
Section 20(2)(a)—Permit revisions: Major revisions.
Section 20(2)(a)10—Permit revisions: Major revisions.
Section 20(3)(a)—Permit revisions: Minor revisions.
Section 20(3)(d)23—Permit revisions: Minor field revisions.
Section 20(3)(f)—Permit revisions: Minor revisions; Incidental boundary revisions.
Section 20(5)—Permit revisions: Incidental boundary revisions; size limitations.
Section 20(6)—Permit revisions: Operator change revisions. Except to the extent that subparagraph (h) fails to provide for notification of OSM of the cabinet's decision on the application, and notification of the cabinet when the change takes place.
Section 20(7)—Permit revisions: Fees.

3. In 30 CFR 917.16, paragraph (d)(3) is removed and reserved. In addition, new paragraph (h) is added, to read as follows:

§ 917.16 Required program amendments.

* * * * *

(h) By June 14, 1993, Kentucky shall amend its rules at 405 KAR 8:010 section 20(6)(h) by including OSM as one of the parties to be notified of the cabinet's decision to approve or deny the application for an operator change and to require that the regulatory authority be notified when the approved change is consummated.

[FR Doc. 93-594 Filed 1-11-93; 8:45 am]
BILLING CODE 4310-05-M

30 CFR Part 935

Ohio Regulatory Program; Revision of Administrative Rule

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of proposed Program Amendment Number 59 to the Ohio permanent regulatory program (hereinafter referred to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment was initiated by Ohio and is intended to make the Ohio program as effective as the corresponding Federal regulations. The amendment concerns the permitting of coal preparation plants or support facilities operated in connection with a coal mine but not located within the permit area for a specific mine.

EFFECTIVE DATE: January 12, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Richard J. Seibel, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, 2242 South Hamilton Road, room 202, Columbus, Ohio 43232; (614) 866-0578.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision.
VI. Procedural Determinations.

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the general background of the Ohio program submission, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program, can be found in the August 10, 1982 **Federal Register** (47 FR 34688). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Submission of Amendment

By letter dated June 30, 1992 (Administrative Record No. OH-1730), the Ohio Department of Natural Resources, Division of Reclamation (Ohio), submitted proposed Program Amendment Number 59 to revise the Ohio program at Ohio Administrative Code (OAC) 1501:13-13-06.

OSM announced receipt of proposed Program Amendment Number 59 in the August 18, 1992, **Federal Register** (57 FR 37138), and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on September 17, 1992. The public hearing scheduled for September 14, 1992, was not held as no one requested an opportunity to testify.

On September 30, 1992, representatives of OSM and Ohio met and discussed the amendment (Ohio Administrative Record No. OH-1787). By letter dated October 21, 1992 (Ohio Administrative Record No. OH-1789), Ohio submitted clarifying information in support of its proposed amendment.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment.

Ohio is proposing to add the phrase "in connection with a coal mine but" to paragraph (A) of OAC 1501:13-13-06. Revised paragraph (A) would read:

(A) Applicability. Each person who operates a coal preparation plant or support facility *in connection with a coal mine* but not located within the permit area for a specific mine shall obtain a permit in accordance with paragraph (I) of rule 1501:13-4-12 of the Administrative Code, obtain a bond in accordance with these rules and operate the plant or support facility in accordance with these rules (emphasis added).

The corresponding Federal rules at 30 CFR 785.21 require that persons operating or who intend to operate a coal preparation plant in connection with a coal mine but outside the permit area must obtain a permit from the regulatory authority. However, unlike the proposed State rule, the Federal counterpart does not require the permitting of support facilities operated in connection with a coal mine but outside the permit area for a specific mine.

Ohio's definition of support facilities at OAC 1501:13-1-02 paragraph (PPPPP) includes activities which are normally associated with coal preparation plants such as coal crushing and sizing. These activities are contemplated within the Federal definition of coal preparation plant at 30 CFR 701.5. Ohio's definition of support facilities is restricted to facilities "resulting from or incident to coal mining and reclamation operations." Further, Ohio clarifies in this definition that the phrase "resulting from or incident to" connotes an element of proximity to the coal mining and reclamation operations. There appears to be an inconsistency with Ohio's definition of support facilities since it includes certain coal preparation activities and the element of proximity as a decisive factor in regulating coal preparation plant activities. As the District Court noted, the Court of Appeals in *NWF* v. *Hodel*, 839 F.2d 694, 745 (DC Cir. 1988) "endorsed the use of proximity to define in part the idea of 'resulting from or incident to' only in the context of support facilities * * * It does not necessarily follow at all that proximity is an appropriate defining factor for processing plants." *NWF* v. *Lujan*, 31 Env't Rep. Cas. 2034, 2050 (D.D.C. 1990). The District Court remanded the regulation, ordering the Secretary "to clarify that proximity may not be the decisive factor in deciding to regulate an off-site processing plant." *Id.* Ohio's proposed wording, therefore, appears not to be consistent with the phrase "in connection with a coal mine" and with the Court's finding. By letter dated October 21, 1992 (Ohio Administrative Record No. OH-1789), Ohio submitted a clarification of this inconsistency. Ohio stated that proposed OAC 1501:13-13-06 applies only to coal preparation plants and support facilities not located at or near the mine site or not within the permit area and that Ohio's determination to regulate will not be based on proximity. Ohio further stated that the phrase "in connection with a coal mine" takes precedence over the proximity language in the State definition of "support facilities." The "in connection with" language proposed by Ohio in Program Amendment Number 59 expresses the intent of Ohio to not use proximity as a factor when regulating off-site coal

preparation plants and support facilities. Therefore, the "in connection with" wording is controlling in this instance over the element of proximity to the mine site and the Director finds that the proposed rule is consistent with the District Court's opinion and no less effective than the Federal regulations at 30 CFR 785.21.

IV. Summary and Disposition of Comments

Public Comments

The public comment period and opportunity to request a public hearing in the August 18, 1992, **Federal Register** closed on September 17, 1992. Comments were received from the Ohio Historic Preservation Office (OHPO). The OHPO supported the proposed amendment. No one requested an opportunity to testify at the scheduled public hearing so no hearing was held.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Ohio program. The U.S. Department of Agriculture, Soil Conservation Service, and the U.S. Army Corps of Engineers responded that they had no comments. The U.S. Department of Labor, Mine Safety and Health Administration, commented that the proposed amendment did not conflict with MSHA's regulations.

The comments submitted by the Environmental Protection Agency (EPA) are discussed below under "EPA Concurrence."

V. Director's Decision

Based on the above findings, the Director is approving Ohio Program Amendment Number 59, as submitted by Ohio on June 30, 1992, and clarified by letter dated October 21, 1992.

The Federal regulations at 30 CFR part 935 codifying decisions concerning the Ohio program are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to conform their programs with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no such provisions and that EPA concurrence is, therefore, unnecessary. However, by letter dated September 22, 1992 (Administrative Record Number OH–1778), EPA submitted its concurrence with the following comment. The EPA concluded that the proposed amendment to Ohio's program demonstrates the legal authority, administrative capability, and the technical conformity with controlling National Pollutant Discharge Elimination System regulations necessary to maintain water quality standards promulgated under the authority of the Clean Water Act (CWA), as amended (33 U.S.C. 1251 *et seq.*) The EPA noted that the activities listed in the proposed amendment that are connected with coal preparation plants are all activities which may require permits to be issued pursuant to the CWA. The Director acknowledges EPA's comments but notes that neither the cited Ohio regulation nor the Federal counterpart can be construed as superseding, amending or repealing the CWA because such activities are prohibited by section 702 of SMCRA. Furthermore, the Director is approving Ohio's proposed amendment to the extent that it does not supersede applicable CWA requirements.

VI. Procedural Determinations

Executive Order No. 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paper Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 19, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 935—OHIO

1. The authority citation for part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In Section 935.15, a new paragraph (iii) is added to read as follows:

§ 935.15 Approval of regulatory program amendments.

* * * * *

(iii) The following amendment to the Ohio regulatory program, as submitted to OSM on June 30, 1992, and clarified on October 21, 1992, is approved, effective January 12, 1993: Amendment Number 59 which consists of revisions to the Ohio Administrative Code (OAC) at 1501:13–13–06(A) concerning the permitting of coal preparation plants or support facilities operated in connection with a coal mine but not located within the permit area for a specific mine.

[FR Doc. 93–595 Filed 1–11–93; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AE61

Regional Office Committees on Waivers and Compromises

AGENCY: Department of Veterans Affairs.

ACTION: Final regulations.

SUMMARY: In order to comply with legislative changes to 38 U.S.C. 5302 (formerly 3102), the Department of Veterans Affairs (VA) has amended current VA regulations which establish the standards by which Committees on Waivers and Compromises consider requests for waiver of collection of all benefit and home loan program debts.

EFFECTIVE DATE: January 12, 1993.

FOR FURTHER INFORMATION CONTACT: Peter Mulhern, Debt Management Policy Division (047G7), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233–3405.

SUPPLEMENTARY INFORMATION: On pages 15046 through 15047 of the **Federal Register** of April 24, 1992, VA published proposed regulations to amend the standards by which Committees on Waivers and Compromises consider requests for waiver of collection of all benefit and home loan program debts. No comments were received from the general public. However, the U.S. Court of Veterans Appeals, in the case of *Farless* v. *Derwinski* (U.S. Vet. App. No. 90–1372), noted a discrepancy between the language of 38 U.S.C. 5302(c) and the language found in section 1.965(b).

As we stated in the preamble to the publication of the proposed regulations, 38 CFR 1.963, 1.964, and 1.965 establish the standards by which our Regional Office Committees on Waivers and Compromises consider waiver requests on all benefit and home loan program debts. This authority comes directly from section 5302 of title 38 of the U.S. Code. Congress enacted (Public Law 101–237, "The Veterans Benefits Amendment Act of 1989" (December 18, 1989), which revised Section 5302(c). Prior to this legislative change, Section 5302(c) stated that the authority to waive recovery of any payment or the collection of any indebtedness may not be exercised if there existed an indication of fraud, misrepresentation, material fault, or lack of good faith on the part of the person or persons having an interest in obtaining a waiver. Public Law 101–237 removed material fault and lack of good faith as absolute bars to waiver and replaced them with bad faith. As a result of this legislative change, we revised the three regulations to comply with these new standards.

In the *Farless* case, the U.S. Court of Veterans Appeals noted that 38 U.S.C. 5302(c) states that an indebtedness may not be waived where there exists an "indication of" fraud, misrepresentation, or bad faith. The Court then found an inconsistency in the corresponding regulation, 38 CFR 1.965(b), because it does not contain the phrase, "indication of". In publishing our proposed revision of 38 CFR 1.963, 1.964, and 1.965, we applied the phrase "indication of" to our revision of sections 1.963 and 1.964. However, since our revision of section 1.965 was limited to a revision of its subsection (b)(2), we failed to incorporate the exact statutory language into the initial portion of subsection (b). In order to avoid any questions concerning this inconsistency, we have amended the language of section 1.965(b) to include the phrase "indication of".

The Secretary hereby certifies that these final rules will not, if promulgated, have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. Pursuant to 5 U.S.C. 605(b), these rules are therefore exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604. The reason for this certification is that these rules primarily affect only individuals indebted to the U.S. Government as a result of participation in benefit programs administered by the Department of Veterans Affairs.

These final rules have also been reviewed under E.O. 12291 and have been determined to be nonmajor because they will not have a $100 million annual effect on the economy and will not have any adverse economic impact on or increase costs to consumers, individual industries, Federal, State, and local government agencies or geographic regions.

There is no Catalog of Federal Domestic Assistance number.

List of Subjects in 38 CFR Part 1

Claims, Administrative practice and procedures, Veterans.

Approved: December 1, 1992.

Anthony J. Principi,

Acting Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 1 is amended as set forth below.

PART 1—GENERAL PROVISIONS

1. The authority citation for §§ 1.955 through 1.970 is revised to read as follows:

Authority: 38 U.S.C. 3720 and 5302; 5 U.S.C. 5584.

2. In § 1.963, paragraph (a) and the authority citation at the end of the section are revised to read as follows:

§ 1.963 Waiver-other than loan guaranty.

(a) *General.* Recovery of overpayments of any benefits made under laws administered by the VA shall be waived if there is no indication of fraud, misrepresentation, or bad faith on the part of the person or persons having an interest in obtaining the waiver and recovery of the indebtedness from the payee who received such benefits would be against equity and good conscience.

* * * * *

(Authority: 38 U.S.C. 5302 (a) & (c)).

3. In § 1.964, paragraph (a) and the authority citation at the end of the section are revised to read as follows:

§ 1.964 Waiver-loan guaranty.

(a) *General.* Any indebtedness of a veteran or the indebtedness of the spouse shall be waived only when the following factors are determined to exist:

(1) Following default there was a loss of the property which constituted security for the loan guaranteed, insured or made under chapter 37 of title 38 United States Code;

(2) There is no indication of fraud, misrepresentation, or bad faith on the

part of the person or persons having an interest in obtaining the waiver; and

(3) Collection of such indebtedness would be against equity and good conscience.

* * * * *

(Authority: 38 U.S.C. 5302 (b) and (c)).

4. In § 1.965, the introductory text of paragraph b and paragraph (b)(2) are revised, and an authority citation is added at the end of the section to read as follows:

§ 1.965 Application of standard.

* * * * *

(b) In applying this single standard for all areas of indebtedness, the following elements will be considered, any indication of which, if found, will preclude the granting of waiver:

* * * * *

(2) *Bad Faith.* This term generally describes unfair or deceptive dealing by one who seeks to gain thereby at another's expense. Thus, a debtor's conduct in connection with a debt arising from participation in a VA benefits/services program exhibits bad faith if such conduct, although not undertaken with actual fraudulent intent, if undertaken with intent to seek an unfair advantage, with knowledge of the likely consequences, and results in a loss to the government.

* * * * *

(Authority: 38 U.S.C. 5302(c)).

[FR Doc. 93–561 Filed 1–11–93; 8:45 am]
BILLING CODE 8320–01–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[IL 40–1–5436; FRL–4541–1]

Approval and Promulgation of Implementation plans; Illinois

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Final rule.

SUMMARY: USEPA is taking action to approve a revision to parts 218 and 219 of title 35 of the Illinois Administrative Code (35 IAC) as revisions to the State Implementation Plan (SIP) for ozone. USEPA's action is based upon a revision request which was submitted by the State to satisfy the requirements of section 182(b)(3) of the Clean Air Act as amended in 1990 (CAA), which requires all ozone nonattainment areas classified as moderate or worse to require specified gasoline dispensing facilities to install and operate State II vapor recovery equipment. In Illinois, subject areas include the Chicago ozone nonattainment area (Cook, DuPage, Kane, Lake, McHenry, Will Counties and Aux Sable and Goose Lake Townships in Grundy County and Oswego Township in Kendall County) and the Illinois portion of the East St. Louis ozone nonattainment area (Madison, Monroe, and St. Clair Counties). USEPA's action is being taken with no prior proposal.

DATES: This action will be effective March 15, 1993 unless notice is received within 30 days of publication that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the **Federal Register.**

ADDRESSES: Copies of the requested SIP revision, technical support documents and public comments received are available at the following address:

U.S. Environmental Protection Agency, Region 5, Air and Radiation Division, Regulation Development Branch, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Comments on this rulemaking should be addressed to:

J. Elmer Bortzer, Chief, Regulation Development Section, Regulation Development Branch (5AR–18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Francisco J. Acevedo, Environmental Engineer, Regulation Development Section, Regulation Development Branch (5AR–18J), United States Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604. (312)886–6061.

Anyone wishing to come to Region 5 offices should contact Francisco J. Acevedo first.

SUPPLEMENTARY INFORMATION:

I. Background/Summary of State Submittal

On September 30, 1992, the Illinois Environmental Protection Agency (IEPA) submitted to USEPA Stage II Vapor Recovery Rules: Amendments to 35 ILL. ADM. CODE PARTS 215, 218 AND 219 (R91–30). The rules were adopted by the Illinois Pollution Control Board (IPCB) on August 13, 1992. The rules became effective on August 24, 1992. The State submitted these rules to satisfy the section 182(b)(3) requirements of the CAA which is applicable to the Chicago and East St. Louis ozone nonattainment areas. The information presented below summarizes the requested SIP revision and USEPA's action on it. A more detailed analysis of the State's submittal is contained in a technical support document dated September 3, 1992, which is available from the Region 5 office listed above.

Illinois' regulations specify that Stage II vapor recovery systems are required at gasoline dispensing facilities that dispense more than 10,000 gallons per month. Private fueling facilities such as government and company fleet fueling facilities as well as retailers are subject to the Stage II requirements. The regulations specify the use of California Air Resource Board certified Stage II systems, which have been demonstrated to achieve at least 95 percent control of Volatile Organic Compound (VOC) emissions. The rules also mandate the proper installation and operation of such systems, to be achieved by requiring the installed systems to be tested for proper installation and requiring the State to perform all necessary enforcement.

The rules mandate Stage II vapor recovery systems to be implemented pursuant to the following phase-in schedule:

(1) Facilities that commenced construction after November 1, 1990, must comply by May 1, 1993;

(2) Facilities that commenced construction before November 1, 1990, and dispense an average monthly volume of more than 100,000 gallons of motor fuel per month, must comply by November 1, 1993; and

(3) All other facilities must comply by November 1, 1994.

II. Review Criteria

USEPA reviewed the submittal against the requirements of section 182(b)(3) of the CAA, as interpreted in the General Preamble for the Implementation of title I of the Clean Air Act Amendments of 1990 (57 FR 13498, 13513 (April 16, 1992)), and two USEPA documents entitled Technical Guidance—Stage II Vapor Recovery Systems for Control of Vehicle Refueling Emissions at Gasoline Dispensing Facilities (Technical Guidance) and the Enforcement Guidance for Stage II Vehicle Refueling Control Programs (Enforcement Guidance). Specifically seven general criteria need to be met for a Stage II vapor recovery regulation to be acceptable. The regulation must fulfill the following requirements:

(1) Installation of Stage II Controls and Determination of Regulated Facilities. Facilities that dispense more than 10,000 gallons per month must install and operate Stage II controls. For gasoline dispensing facilities that are owned and operated by an independent

small business marketer, the State may establish a cut-point as high as 50,000 gallons per month. In the General Preamble, USEPA indicated that the suggested method for calculating the gallons per month dispensed by affected facilities is determined by calculating the average volume of product dispensed per month for the 2-year period prior to the adoption of the rule by the State. (See General Preamble, 57 FR at 13514.) The Enforcement Guidance suggests that if sufficient data is not available for a full 2-year period, then the actual months of operation during that 2-year period should be used to calculate the facility's average gallons per month. (See Enforcement Guidance, Sec. 3.2.)

(2) Establishment of a Time Schedule for Installation of Stage II Control Equipment. Section 182(b)(3)(B) of the CAA establishes three standard deadlines for the installation and application of Stage II controls, after adoption by the State of the Stage II requirements. The phase-in schedule given in the CAA is the following:

(a) 6 months after adoption for all facilities commencing construction after November 15, 1990;

(b) 1 year for all facilities which dispense 100,000 gallons or more of gasoline per month; and

(c) 2 years for all other facilities required to be regulated.

(3) System Certification. An approved system should be tested and certified so as to meet a minimum requirement of 95 percent emission reduction efficiency. USEPA believes that this efficiency rate has been demonstrated to be feasible. As stated in the General Preamble, the States may achieve this by utilizing one of the following three alternatives: (a) A method tested and approved by California Air Resources Board (CARB) past, current or future recognized test methods, or (b) an equivalent testing program adopted by the State, conducted by the Program Oversight Agency (POA) or by a third party recognized by the POA, and submitted and approved by USEPA for incorporation in the SIP, or (c) a system approved by CARB. (See Enforcement Guidance, Sec. 4.2.)

(4) Facility Verification of the Proper Installation and Function of Stage II Vapor Control Systems. The General Preamble indicates in order for the State Stage II requirement to be enforceable, the State must require the regulated facility to verify proper installation and function of the Stage II equipment. The Enforcement Guidance specifies performing a Liquid Blockage Test which determines if there is an unacceptable low point in the piping, and a Leak Test which measures the vapor tightness of the Stage II system. The Enforcement Guidance also states that a facility should recertify the functions of the Stage II equipment at least every 5 years, or upon major facility modification (75 percent or more equipment change), whichever comes first. (See April 16, 1992 (57 FR 13514) **Federal Register**, and; Enforcement Guidance, Sec. 8.2.)

(5) Recordkeeping and Reporting. In the Enforcement Guidance, USEPA identifies various records that the State should require facilities to keep and to make available upon request. USEPA believes that these documents must be available in order to make the Stage II requirement enforceable. These documents include: (a) A license/permit to install and operate the Stage II system; (b) verification of passing functional tests after installation of equipment; this includes the Liquid Blockage Test, Leak Test, all shutoff/flow prohibiting device testing; (c) general station file containing initial station information such as motor vehicle fuel throughput information; (d) equipment maintenance and compliance file log containing verification that proper maintenance has been conducted in accordance with manufacturer's specifications and requirements; (e) training certification files. (See Enforcement Guidance, Sec. 8.0.)

(6) Periodic Inspection of Regulated Facility. The State POA should conduct a minimum of 1 compliance inspection per facility per year with mandatory follow-up at stations with violations. USEPA believes such inspections are necessary to ensure that facilities are complying with the Stage II requirements. This is necessary not only for enforcement action but to notify sources that are violating the Stage II requirements so they can make the necessary adjustments to come into compliance. The compliance inspection should consist of a visual inspection of the required paperwork, and Stage II equipment. In addition to the visual inspection, a functional inspection to determine if the facility's Stage II equipment is functioning properly must also be performed. (See Enforcement Guidance, Sec. 5.2(d).)

(7) Requirement to ensure regulated facility compliance with program requirements through enforcement mechanisms, and a penalty schedule that establishes appropriate penalties for facilities violating the Stage II requirements. (See Enforcement Guidance, Sec. 5.2(e).)

III. Results of USEPA Review

USEPA reviewed the Illinois submittal to determine if criteria for approval have been met. The results of USEPA's review are as follows:

(1) Installation of Stage II Controls and Determination of Regulated Facilities

Illinois' submittal mandates the requirement of Stage II vapor recovery systems on any gasoline dispensing facility that dispenses a monthly average volume of 10,000 gallons or more. The submittal also includes a requirement that affected facilities be identified by calculating the average volume of product dispensed per month for the 2 year period prior to adoption of the rule by the State. USEPA finds this acceptable because it directly addresses the Federal requirement.

(2) Establishment of a Time Schedule for Installation of Stage II Control Equipment

The time schedule stated in the Illinois rule mandates installation of the Stage II control equipment by (1) May 1, 1993, for facilities that started construction after November 1, 1990; (2) November 1, 1993, for facilities which started construction before November 1, 1990, and dispense more than 100,000 gallons of motor fuel per month; and, (3) November 1, 1994, for facilities which have started construction before November 1, 1990 and dispense less than 100,000 gallons of motor fuel per month. Under section 812(b)(3) (B) and (C), the state must establish a two year time table for source implementation of Stage II. The Act provides that this time table must run from the date of adoption of the Stage II rules and then defines adoption to mean the date the State adopts the requirements for installation and operation of the Stage II equipment. Although Illinois adopted its Stage II regulations on August 13, 1991, USEPA believes that it can interpret the adoption date to be November 1, 1992 under the limited circumstances presented in this submittal.

USEPA is proposing to approve the submitted time table running from November 1, 1992 for three reasons. First, USEPA recognizes that the date selected by Illinois precedes the date by which the State was required to submit the Stage II regulations to USEPA. Thus Illinois could have waited to adopt the Stage II regulations on November 1, 1992, and still have met the November 15, 1992 submittal date. Second, the time table initiation date established by the State—November 1, 1992—began shortly after adoption of the regulation. Third, the State would have a limited

ability to remedy this deficiency. To the extent the State could amend the implementation date, many sources within the State would not have the lead time intended by the statute to install and operate the system. If the State chose to withdraw and readopt their Stage II requirement, potentially the time table could run from a date later than November 15, 1992; this would further delay implementation of Stage II. Finally, the Illinois rule otherwise fulfills the Stage II requirements and USEPA believes it will provide substantial air quality benefits to the regulated areas. Therefore, USEPA believes it is in the public interest to approve and make enforceable this requirement at the earliest time feasible. In the limited circumstances described above, USEPA believes that it is not inconsistent to interpret the adoption date to be November 1, 1992.

(3) System Certification

The adopted rules mandate that all Stage II vapor control systems used be certified by CARB to meet 95 percent emission reduction efficiency. Use of CARB-certified systems is acceptable to USEPA. USEPA has specified in its guidance documents that it believes that CARB approved Stage II systems meet the CAA requirement with no additional efficiency testing required. Therefore, USEPA believes the specified system certification in the Illinois submittal is acceptable.

(4) Installation of Stage II Vapor Control Systems

The Illinois rule mandates that proper tests be performed to verify proper installation and function of the Stage II systems, and requires systems to be retested after major facility modification. USEPA believes the testing procedures specified help make the rule enforceable and, therefore, are consistent with the CAA requirements.

(5) Recordkeeping and Reporting

Illinois is exempting any facility subject to Stage II requirement from the air pollution control permit requirement applicable to regulated sources under the SIP. The exemption is allowed provided that the affected facilities provide a registration of their Stage II equipment. The Illinois rule requires that registration material be kept on site. It also requires that, at a minimum, the registration information includes: the facility name and address, signature of owner or operator, the CARB Executive Order Number for the Stage II system used, number of nozzles used, the monthly average volume of gasoline dispensed, and the location (including contact person's name, address, and telephone number) of other records and reports required by the rule. Other records and reports required by the rule to be kept on file by the owner or operator and which need to be made available to the POA upon request include: Proof that a certified Stage II system has been installed and tested to verify its performance according to its specifications; records that show that proper maintenance has been conducted according to manufacturer specifications; records that show time periods and duration of all malfunctions of the Stage II system; motor vehicle fuel throughput information for each calendar month of the previous year; and proof of employee training certiftcation. After discussions between IEPA and USEPA regarding the recordkeeping requirements, the above format was agreed to by USEPA as meeting Stage II Enforcement Guidance requirements.

(6) Periodic Inspection Requirements

The IEPA has committed to adhere to Enforcement Guidance that specifies annual inspections for the facilities or the development of an inspection schedule approved by USEPA through IEPA's inspection program plan.

(7) Regulated Facility Compliance with Program Requirements

The Illinois Environmental Protection Act (Act), section 42(a), states that any person that violates any provision of this Act or any regulation adopted by the IPCB, or any permit or term or condition thereof, or that violates any determination or order of the IPCB pursuant to this Act, shall be liable to a civil penalty not to exceed $50,000 for the violation and an additional $10,000 for each day for which the violation continues. In that this submittal is a regulation adopted by the IPCB, a violation of which subjects the violator to penalties under section 42(a), the submittal is consistent with the policy established by USEPA in its Enforcement Guidance.

IV. Rulemaking Action

USEPA approves 35 Ill. Adm. Code §§ 218.586(a)–(h) and 219.586(a)–(h) as a revision to the Illinois ozone SIP because the submittal meets all the criteria required for approvability as cited above. The Stage II vapor recovery SIP revision for the Chicago and East St. Louis ozone nonattainment areas will be complete following today's action.

USEPA is publishing this action without prior proposal because the USEPA views this as a noncontroversial revision and anticipates no adverse comments. This action will be effective March 15, 1993 unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted. If such notice is received, this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective March 15, 1993.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements. USEPA has submitted a request for a permanent waiver for Table 2 and Table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on USEPA's request.

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989, (54 FR 214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of 2 years.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et. seq., USEPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, USEPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic

reasonableness of state action. The CAA forbids USEPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (S. Ct. 1976); 42 U.S.C. 7410(a)(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 15, 1993. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note—Incorporation by reference of the State Implementation Plan for the State of Illinois was approved by the Director of the Federal Register on July 1, 1982.

Dated: November 18, 1992.

Valdas V. Adamkus,

Regional Administrator.

For the reasons set out in the preamble, part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

1. The authority citation for part 52 continues to read as follows:

Authority: 7401–7671q.

Subpart O—Illinois

2. Section 52.720 is amended by adding paragraph (c)(93) to read as follows:

§ 52.720 Identification of plan.

* * * * *

(c) * * *

(93) On September 30, 1992, the State submitted rules regulating volatile organic compound emissions from gasoline dispensing facilities' motor vehicle fuel operations.

(i) Incorporation by reference.

(A) Illinois Administrative Code, title 35 Environmental Protection, subtitle B: Air Pollution, chapter I: Pollution Control Board part 218: Organic Material Emission Standards and Limitations for the Chicago Area; subpart Y: Gasoline Distribution; § 218.583 Gasoline Dispensing Facilities—Storage Tank Filling Operations, amended at 16 Illinois Register 13864 effective August 24, 1992, and; § 218.586 Gasoline Dispensing Facilities—Motor Vehicle Fueling Operations, added at 16 Illinois Register 13864, effective August 24, 1992.

(B) Illinois Administrative Code, title 35 Environmental Protection, subtitle B: Air Pollution, Chapter I: Pollution Control Board, part 219: Organic Material Emission Standards and limitations for the East St. Louis Area; Subpart Y: Gasoline Distribution; § 219.583 Gasoline Dispensing Facilities—Storage Tank Filling Operations, amended at 16 Illinois Register 13883, effective August 24, 1992. Section 219.586 Gasoline Dispensing Facilities—Motor Vehicle Fueling Operations, added at 16 Illinois Register 13883, effective August 24, 1992.

(ii) Additional materials.

(A) Stage II Vapor Recovery SIP Program Description dated September 29, 1992.

3. Section 52.726 is amended by adding paragraph (f) to read as follows:

§ 52.726 Control Strategy: Ozone.

* * * * *

(f) On September 30, 1992, the State submitted rules regulating volatile organic compound emissions from gasoline dispensing facilities' motor vehicle fuel operations (Stage II vapor recovery rules) in the Chicago and East St. Louis Ozone nonattainment areas. The Illinois Environmental Protection Agency Bureau of Air must as part of the program conduct inspections of facilities subject to this rule to ensure compliance with the applicable rules. These inspections will be conducted on an annual basis or an alternative schedule as approved in the USEPA Fiscal Year Inspection Program Plan.

[FR Doc. 93–479 Filed 1–11–93; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 52

[IL 37–1–5397; FRL–4529–6]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Final rule.

SUMMARY: The USEPA is approving a request by the State of Illinois to revise its State Implementation Plan to provide for the regulation of fine particulate matter, known as PM–10. The revision establishes a PM–10 air quality standard, revises particulate matter episode rules, and revises two rules pertaining to particulate matter emissions from iron and steelmaking facilities. The purpose of the SIP revision is to satisfy Federal requirements under the Clean Air Act (Act), as amended, for an approvable PM–10 SIP in Illinois.

DATES: This action will be effective March 15, 1993, unless notice is received within 30 days that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the **Federal Register.**

ADDRESSES: Copies of the SIP revision request and USEPA's analysis are available for inspection at the following address: (It is recommended that you telephone Gustavo Felix at (312) 353–6009, before visiting the Region V Office.) U.S. Environmental Protection Agency, Region V, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Written comments should be sent to: J. Elmer Bortzer, Chief, Regulation Development Section, Regulation Development Branch (5AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

A copy of today's revision to the Illinois SIP is available for inspection at: U.S. Environmental Protection Agency, Public Information Reference Unit, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Gustavo Felix, Regulation Development Branch, Regulation Development Section (5AR–18J), U.S. Environmental Protection Agency, Region V, Chicago, Illinois 60604, (312) 353–6009.

SUPPLEMENTARY INFORMATION:

I. Summary of State Submittal

The SIP revision approved today, among other things, replaces Illinois' TSP air quality standards with PM–10 air quality standards. On July 1, 1987, USEPA revised the National Ambient Air Quality Standard for particulate matter, replacing total suspended particulate (TSP) as the indicator with a new indicator that included only those particles with an aerodynamic diameter less than or equal to a nominal 10 microns (PM–10). The 24-hour PM–10 standard is set at 150 micrograms per cubic meter ($\mu g/m_3$) and the annual PM–10 standard at 50 $\mu g/m_3$. See 52 FR 24634.

Today's action will also revise the State's emergency episode rules to incorporate various alert levels for PM–10. Episodes are periods of extremely high concentrations of specific air contaminants. These regulations set forth what steps are taken during such periods to prevent the occurrence of significant public harm.

Finally, the SIP revision imposes opacity limits on fugitive PM-10 emissions from Blast Furnace Cast Houses, and a water quality standard on quench water used for coke oven quenching.

The revision which is the subject of today's approval action is necessary in order to satisfy, as a preliminary matter, the Federal requirements under the (Act), as amended in 1990, for approvable PM–10 SIPs for Illinois.[1] The Act requires each state to adopt a SIP that provides for attainment and maintenance of the Federal air quality standards. 42 U.S.C. 7410. Upon enactment of the Act Amendments of 1990, areas meeting the qualifications of section 107(d)(4)(B) of the Act were designated nonattainment for PM–10 by operation of law. Additionally, in accordance with section 188(a), all PM–10 areas designated nonattainment at enactment were classified as moderate by operation of law. A **Federal Register** notice announcing all of the initial areas designated nonattainment for PM–10 and classified as moderate at enactment was published in 56 FR 11101 (March 15, 1991).[2] Four Illinois areas were initially designated nonattainment and classified as moderate for PM–10 in the March 15, 1991 notice. These areas are located in portions of Cook County, LaSalle County, and Madison County. Section 189(a)(2) of the amended Act required each state to submit to USEPA, no later than November 15, 1991, a SIP adopting certain specified rules for all areas initially designated nonattainment upon enactment. Since Illinois is among those states with areas initially designated nonattainment for PM–10, it was required to submit a plan by November 15, 1991 for these areas which meets the applicable requirements of the amended Act. By adopting the regulations for PM–10 described above, this revision amends previously identified deficiencies in the State's particulate matter regulations and, consequently, is an integral step in the process of ensuring the submittal of fully-adopted and technically and administratively complete PM–10 SIPs for the State of Illinois.

In an effort to meet the requirements of the Act, as amended, the Illinois Environmental Protection Agency (IEPA) submitted to USEPA, on April 30, 1992, a requested revision of its SIP which amends the following rules:

(1) 35 Ill. Adm. Code 243, Air Quality Standards and Measurement Methods: Section 243.108 Incorporations by Reference; section 243.120 PM–10; section 243.121 Repealed; section 243 appendix A, B, and C.

(2) 35 Ill. Adm. Code 244, Episodes: Section 244.101 Definitions; section 244.106 Monitoring; section 244.107 Determination of Areas Affected; section 244.121 Local Agency Responsibilities; section 244.161 Advisory Alert and Emergency Levels; section 244.162 Criteria for Declaring an Advisory; section 244.163 Criteria for Declaring a Yellow Alert; section 244.166 Criteria for Terminating Advisory, Alert and Emergency; section 244.167 Episode Stage Notification; section 244.168 Contents of Episode Stage Notification; section 244.169 Actions During Episode Stages Adopted; section 244 appendix A, B, C and D.

(3) 35 Ill. Adm. Code 212, Visible and Particulate Matter Emissions: Section 212.113 Incorporations by Reference; section 212.424 Fugitive Particulate Matter Control for the Portland Cement Manufacturing Plant and Associated Quarry Operations located in LaSalle County, South of the Illinois River; section 212.443(h) Coke Plants, Quenching; section 212.445 Blast Furnace Cast Houses.

Illinois is federally mandated by the Act to submit an implementation plan, which provides for the adoption and enforcement of rules which are structured to achieve and maintain the new federal standards. See section 110(a). By virtue of Illinois' adoption of the amended provision in (1), above, State has adopted the federal PM–10 standard constituting it as an integral part of the Illinois PM–10 SIP.

The Act further provides that a SIP must contain provisions for immediate emission reductions in the event of emergency air pollution episodes. See section 110(G). The amended provisions in (2), above, serve to address the new Federal standards and to satisfy this requirement of the Act.

The amended provisions identified in (3), above, address previously identified deficiencies in Illinois' regulations pertaining to control of fugitive particulate matter emissions from certain iron & steel operations, and acceptable concentration of total dissolved solids in water used for coke oven quenching. The amendments are necessary to complete the inclusion of approvable PM–10 regulations into Illinois' SIP. In addition, minor editorial changes were made to clarify section references contained in section 212.424

The Illinois Pollution Control Board (IPCB), Illinois' Board granted authority by State law to adopt environmental regulations, went to First Notice with a proposed revision on December 19, 1991. The USEPA provided formal comments on this regulatory proposal on March 2, 1992. On March 11, 1992, the IPCB went to Second Notice on the proposal. The proposed revision, considered here today, was formally adopted when the IPCB went to Final Order on April 9, 1992.

What follows is a summary of the State's submittal and USEPA's analysis of it. The State's submittal and USEPA's detailed evaluation is available for inspection at the Region 5 Office listed above.

II. USEPA's Analysis of State Submittal

A. The revision is intended to regulate particulate matter with an aerodynamic diameter less than or equal to a nominal 10 microns, which is known as PM–10. The revision replaces the total suspended particulate (TSP) air quality standards with PM–10 air quality standards. The revision sets a 24-hour PM–10 standard of 150 $\mu g/m^3$, with no more than one exceedance allowed per year. It sets out an annual PM–10 standard at a level of 50 $\mu g/m^3$, in the form of an annual arithmetic mean.

B. The revision also affects the requirements with respect to episodes. Episodes are periods of extremely high concentrations of specific air contaminants. These regulations set forth the steps which must be taken during such periods to prevent the occurrence of significant harm. The regulations adopt Advisory, Yellow Alert, Red Alert, and Emergency Alert levels for PM–10.

In addition to the change from TSP levels to PM–10 levels, those parts of the revision affecting episodes make the following changes:

1. Section 244.107, removes an ambiguity in the current regulations governing episodes with regard to whether or not emission reductions can be required in Illinois, based on out-of-state episode levels caused by Illinois' sources. The amended regulations now state that emission reductions can be required in Illinois, based on out-of-

[1] The 1990 Amendments to the Act made significant changes to the air quality planning requirements for areas that do not meet (or that significantly contribute to ambient air quality in a nearby area that does not meet) the PM–10 national ambient air quality standards (see Pub. L. 101–549, 104 Stat. 2399). References herein are to the Clean Air Act, as amended, 42 U.S.C. sections 7401 *et seq.*

[2] A subsequent notice correcting certain information in the March 15, 1991, notice was published in 56 FR 37654 (August 8, 1991).

state episode levels caused by Illinois' sources.

2. Since the IEPA will now be "advising" when elevated pollutant levels actually occur rather than "watching" to see if they occur, all references to "watch" are deleted and pollutant-specific notification provisions of section 244.168 is to include advisories as well as alerts and emergencies.

3. Under the revision, episode notification is made to the IEPA, rather than to IEPA's Emergency Action Center.

4. A change is made in the ozone advisory level from a 2-hour ozone concentration in the former rules to a 1-hour ozone concentration of 0.12 parts per million in the revision.

Several other changes in the episode portion of the revision that are nonsubstantive to the rules are explained in the Second Notice and Final Order, and are not addressed here.

C. This revision also includes two rules which control particulate emissions for certain iron and steel sources. The two rules are 212.443 Coke Plants and 212.445 Blast Furnace Cast Houses.

The first rule, a coke oven quenching rule, which earlier had been conditionally approved by USEPA (46 FR 44182) is being revised to make it fully approvable. This rule will require that quench water used for coke oven quench towers not exceed a concentration of 1200 mg/1 for total dissolved solids, averaged weekly. Also, baffles, used in the quench towers, are now required to cover 95% of the cross sectional area of the exhaust vent or stack.

The second rule, a blast furnace cast house rule, which was earlier disapproved by USEPA (46 FR 44185) is also being revised to make it fully approvable. This revised rule will impose a 20% opacity on fugitive particulate matter coming from Blast Furnace Cast Houses, and a 10% opacity on emissions coming from control equipment used for the tap hole, trough, iron or slag runners, or iron or slag spouts. Method 9 of 40 CFR part 60, appendix A will be used to enforce the opacity limits.

III. USEPA's Rulemaking Action

For the reasons above, USEPA approves the incorporation of the revisions and additions to the following state rules into the Illinois SIP: Sections 212.113, 212.424, 212.443, 212.445, appendices A, B, and C and Illustrations A, B, and C to part 212; sections 243.108, 243.120, 243.121, appendices A, B, and C to part 243; 244.101, 244.106, 244.107, 244.121, 244.161, 244.162, 244.163, 244.166, 244.167, 244.168, 244.169, and appendices A, B, C, and D to part 244.

Because USEPA considers today's action noncontroversial and routine, we are approving it today without prior proposal. The action will become effective on March 15, 1993. However, if we receive notice by February 11, 1993 that someone wishes to submit critical comments, then USEPA will publish: (1) A notice that withdraws the action, and (2) a notice that begins a new rulemaking by proposing the action and establishing a comment period.

This action has been classified as a Table 2 action by the Regional Administrator under the procedures published in the Federal Register on January 19, 1989, (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for a period of 2 years. USEPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions. The OMB has agreed to continue the temporary waiver until such time as it rules on USEPA's request.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors, and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et. seq., USEPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, USEPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, part D of the Act do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the federal SIP-approve does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-State relationship under the Act, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of State action. The Act forbids USEPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *U.S.E.P.A.*, 427 U.S. 246, 255–66 (S. Ct. 1976); 42 U.S.C. 7410(a)(2).

This rulemaking does not propose to approve any of the part D SIPs required for the Illinois nonattainment areas. It proposes to approve a set of rules that supplements the part D nonattainment SIPs required for the Lake Calumet and Granite City nonattainment areas. The USEPA has reviewed this request for revision of Illinois' federally approved State Implementation Plan for conformance with the provisions of the Act Amendments, enacted on November 15, 1990. The USEPA has determined that this action conforms with those requirements.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 15, 1993. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Incorporation by reference, Ozone, Particulate matter.

Note: Incorporation by reference of the State Implementation Plan for the State of Illinois was approved by the Director of the Federal Register on July 1, 1982.

Dated: June 30, 1992.

Valdas V. Adamkus,

Regional Administrator.

For the reasons stated in the preamble 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671(q).

Subpart O—Illinois

2. Section 52.720 is amended by adding paragraph (c)(92) to read as follows:

§ 52.720 Identification of plan.

* * * * *

(c) * * *

(92) On June 4, 1992, the State submitted particulate matter regulations adopted as part of Pollution Control Board Proceeding R91–35. These

regulations concern particulate matter ambient limits and episode regulations.

(i) Incorporation by reference. Illinois Administrative Code, Title 35: Environmental Protection, Subtitle B: Air Pollution, Chapter I: Pollution Control Board

(A) Part 212 Visible and Particulate Matter Emissions: Section 212.113 Incorporations by Reference; section 212.424 Fugitive Particulate Matter Control for the Portland Cement Manufacturing Plant and Associated Quarry Operations located in LaSalle County, South of the Illinois River; section 212.443 Coke Plants; section 212.445 Blast Furnace Cast Houses; adopted at 16 Illinois Register 8204, effective May 15, 1992.

(B) Part 243 Air Quality Standards: Section 243.108 Incorporations by Reference; section 243.120 PM_{-10}; section 243.121 Repealed; adopted at 16 Illinois Register 8185, effective May 15, 1992.

(C) Part 244 Episodes: Section 244.101 Definitions; section 244.106 Monitoring; section 244.107 Determination of Areas Affected; section 244.121 Local Agency Responsibilities; section 244.161 Advisory Alert and Emergency Levels; section 244.162 Criteria for Declaring and Advisory; section 244.163 Criteria for Declaring a Yellow Alert; section 244.166 Criteria for Terminating Advisory, Alert and Emergency; section 244.167 Episode Stage Notification; section 244.168 Contents of Episode Stage Notification; section 244.169 Actions During Episode Stages Adopted; section 244 appendix D; adopted at 16 Illinois Register 8191, effective May 15, 1992.

[FR Doc. 93–481 Filed 1–11–93; 8:45 am]
BILLING CODE 6560–50–M

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40 CFR Part 52

[KS–2–1–5640; FRL–4552–3]

Approval and Promulgation of Implementation Plans; State of Kansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Kansas Department of Health and Environment (KDHE) has submitted a revision to its State Implementation Plan (SIP), which revises the state prevention of significant deterioration (PSD) regulation to incorporate by reference the EPA revisions to 40 CFR 52.21 at 53 FR 40656 pertaining to PSD nitrogen oxide (NO_x) increments. The state also revised its miscellaneous metal parts surface coating rule and updated its continuous emission monitoring rule. EPA is taking final action to approve these revisions to the Kansas SIP. The effect of this action is to update and strengthen the Kansas SIP.

EFFECTIVE DATE: This action will be effective March 15, 1993 unless notice is received by February 11, 1993 that adverse or critical comments will be submitted. If the effective date is delayed, timely notice will be published in the **Federal Register.**

ADDRESSES: Copies of the documents relevant to this action are available for public inspection during normal business hours at the: Environmental Protection Agency, Air Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101; Kansas Department of Health and Environment, Bureau of Air Quality and Radiation, Forbes Field, Building 740, Topeka, Kansas 66620; and the Public Information Reference Unit, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Wayne A. Kaiser at (913) 551–7603.

SUPPLEMENTARY INFORMATION: On October 17, 1988, EPA revised the PSD regulations at 40 CFR 52.21 (53 FR 40656) for NO_x. These regulations establish the maximum increase in ambient nitrogen dioxide concentrations allowed in an area above the baseline concentration; these maximum allowable increase are called increments. The effect of these regulations is to require all applicants for major new stationary sources and major modification emitting nitrogen oxides to account for and, if necessary, restrict emissions so as not to cause or contribute to exceedances of the increment.

On September 29, 1992, the KDHE submitted revisions to its PSD rule, K.A.R. 28–19–17, which incorporates by reference the revisions to 40 CFR 52.21, effective October 17, 1988. The state rule became effective June 8, 1992.

The state also provided a demonstration that it meets the conditions for approval of adoption of the NO_x increment program as detailed in the EPA guidance memorandum on the subject dated August 17, 1990.

The EPA memorandum above described specific conditions for EPA approval of a state's adoption of the NO_x increment rule. Those conditions pertained to regulatory language, increment consumption analysis, increment consumption for the transition period, and legal authority. EPA has evaluated the state's submittal in accordance with the August 17, 1990, guidance and finds that the state submittal is acceptable.

The state also revised rule K.A.R. 28–19–17 by replacing the existing 40 CFR 52.21 language with adoption by reference to the appropriate sections of 40 CFR 52.21 and, where appropriate, updated references to the federal rules. In so doing, the state adopted by reference two provisions which had previously been retained by EPA in 40 CFR 52.884. EPA previously retained the authority for the provisions of 52.21(v), innovative control technology (49 FR 48185), in 40 CFR 52.884(a)(2), but the state will now have that authority in its adoption by reference of 52.21(v) in rule 28–19–17q. Thus, 40 CFR 52.884(a)(2) is being deleted.

Also, EPA previously retained the authority to issue PSD permits to marine terminal facilities in 40 CFR 52.884(a)(3) (49 FR 48185) because of a pending court decision and because the state's definition of "building, structure, facility or installation" did not exclude vessels. Since the state's definition is now consistent with 52.21(b)(6), 40 CFR 52.884(a)(3) is being deleted, thus giving the state authority to act on PSD permits for marine terminals with vessel emissions.

The state also revised rule K.A.R. 28–19–19, continuous emission monitoring (CEM), to update the reference to 40 CFR part 60, appendix A, Method 19, as in effect July 1, 1989.

Finally, the state revised rule K.A.R. 28–19–73, surface coating of miscellaneous metal parts and products, and metal furniture. This rule generally requires a volatile organic compound (VOC) content of 3.5 pounds per gallon for surface coatings for applications subject to the rule. In this revision, the state adopted the reasonably available control technology (RACT) limit by allowing a VOC content of 4.3 pounds per gallon for coatings applied to the interior of metal pails and drums. This determination was made on the basis of the unavailability of lower VOC coatings that can withstand the harsh, toxic, and corrosive nature of many of the chemicals that are shipped in these containers. Only three sources are subject to this rule.

The 4.3 pound limit is consistent with the maintenance plan approved by EPA for the Kansas City metropolitan area. Because the 3.5 pound limit has not been achieved by sources subject to the limit, the emission inventory includes a 4.3 pound actual emission rate for the three sources subject to the rule. Since the plan's control strategy is based on 4.3 pounds, and the new allowable limit merely reflects that rate, EPA has concluded that no adjustments to the

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maintenance plan are necessary as a result of this revision.

The state provided adequate opportunity for public notice and comment consistent with the requirements of 40 CFR 52.102 prior to rule adoption. These rule revisions were adopted by the Secretary of the KDHE on April 3, 1992, and became effective on June 8, 1992.

EPA Action

EPA is taking final action to approve certain rule revisions to the Kansas SIP. This includes revisions to rule K.A.R. 28–19–17, which adopts by reference the PSD NO_x requirements of 40 CFR 52.21 at 53 FR 40656; to K.A.R. 28–19–19, the CEM rule; and to K.A.R. 28–19–73, a surface coating rule.

EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. This action will be effective March 15, 1993 unless, within 30 days of its publication, notice is received that adverse or critical comments will be submitted.

If such notice is received this action will be withdrawn before the effective date by publishing two subsequent notices. One notice will withdraw the final action, and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period. If no such comments are received, the public is advised that this action will be effective March 15, 1993.

Nothing in this action should be construed as permitting, or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors, and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities (5 U.S.C. 603 and 604). Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under section 110 and subchapter I, Part D of the CAA do not create any new requirements, but simply approve requirements that the state is already imposing. Therefore, because the federal SIP approval does not impose any new requirements, EPA certifies that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal/state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds (*Union Electric Co.* v. *U.S. E.P.A.*, 427 U.S. 246, 256–66 (1976); 42 U.S.C. 7410(a)(2)).

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the **Federal Register** on January 19, 1989 (54 FR 2214–2225). EPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions from the requirements of Section 3 of Executive Order 12291. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 15, 1993. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of Kansas was approved by the Director of the Federal Register on July 1, 1982.

Dated: December 7, 1992.

Morris Kay,

Regional Administrator.

40 CFR part 52, subpart R is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

Subpart R—Kansas

2. Section 52.870 is amended by adding paragraph (c)(27) to read as follows:

§ 52.870 Identification of plan.

* * * * *

(c) * * *

(27) On September 15, 1992, the Secretary of KDHE submitted rule revisions to K.A.R. 28–19–17, the PSD rule; to K.A.R. 28–19–19, the CEM rule; and to K.A.R. 28–19–73, a surface coating rule. These rule revisions were adopted by KDHE on April 3, 1992.

(i) Incorporation by reference.

(A) Revised regulations K.A.R. 28–19–17 through 28–19–171, K.A.R. 28–19–19 and K.A.R. 28–19–73, and new regulations K.A.R. 28–19–17m through 28–19–17q, effective June 8, 1992.

(ii) Additional material.

(A) Letter and attachment from KDHE dated September 15, 1992 pertaining to PSD NO_x requirements.

* * * * *

§ 52.884 [Amended]

3. Section 52.884 is amended by removing paragraphs (a)(2) and (a)(3).

[FR Doc. 93–477 Filed 1–11–93; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 81

[AL–34–1–5601; FRL–4554–3]

Designation of Areas for Air Quality Planning Purposes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On April 8, 1992, the Alabama Department of Environmental Management (ADEM) submitted a request for redesignation to attainment for sulfur dioxide (SO_2) in Colbert and Lauderdale Counties, Alabama. The redesignation request included five years of quality assured monitoring data which showed no exceedances of the National Ambient Air Quality Standards (NAAQS) for SO_2. The State has also implemented controls to reduce emissions to the level indicated by dispersion modeling. EPA is redesignating Colbert County, Alabama, and Lauderdale County, Alabama to attainment for sulfur dioxide (SO_2).

DATES: This action will be effective March 15, 1993 unless notice is received within 30 days that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Copies of the material submitted by Alabama may be examined during normal business hours at the following locations.

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460

Region IV Air Programs Branch, Environmental Protection Agency, 345 Courtland Street, Atlanta, Georgia 30365

Air Division, Alabama Department of Environmental Management, 1751 Congressman W.L. Dickinson Drive, Montgomery, Alabama 36109.

FOR FURTHER INFORMATION CONTACT: Scott Miller of the Region IV Air Programs Branch at 404–347–2864 and at the above address.

SUPPLEMENTARY INFORMATION: In a **Federal Register** notice published March 3, 1978, Lauderdale and Colbert Counties, Alabama, were designated as nonattainment for SO_2. On April 8, 1992, the Air Division of ADEM submitted a request for Colbert and Lauderdale Counties to be redesignated to attainment for SO_2.

This request was based on five years (1987–1991) of quality assured monitoring data obtained from the four ambient monitors located in both counties which showed that Colbert County and Lauderdale County had not violated the National Ambient Air Quality Standard (NAAQS) for SO_2. The State has also implemented controls to reduce emissions to the level indicated by dispersion modeling. The State of Alabama has met all of the Clean Air Act Amendments of 1990 (CAAA) requirements for redesignation pursuant to § 107(d)(3)(E).

§ 107(d)(3)(E)(i) The Administrator has determined that the area has attained the National Ambient Air Quality Standard

Alabama submitted air quality data showing that Lauderdale and Colbert Counties have attained the sulfur dioxide NAAQS for the five year period, 1987–1991. During that period there were no exceedances, and hence, no violations of the sulfur dioxide standard.

§ 107(d)(3)(E)(ii) The Administrator has fully approved the applicable implementation plan for the area under Section 110(k).

The Alabama SO_2 SIP is fully approved and meets all requirements under section 110(k) which are applicable to the Colbert and Lauderdale County areas. Under section 110(k)(5) of the CAAA, whenever the Administrator finds that a SIP is substantially inadequate to attain or maintain the relevant NAAQS, the Administrator shall require the state to revise the plan as necessary to correct such inadequacies. A source specific SIP revision was published in the **Federal Register** at 55 FR 2235 on January 23, 1990. The notice revised Plant Colbert's operating permit to reduce allowable SO_2 emissions from 4.0 lbs SO_2 emitted/mmBTU to 2.2 lbs SO_2 emitted/mmBTU.

§ 107(d)(3)(E)(iii) The Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable implementation plan and applicable Federal air pollutant control regulations and other permanent and enforceable reductions.

TVA Plant Colbert comprises the only significant source of SO_2 emissions in Lauderdale and Colbert Counties. Therefore, all SO_2 emission reductions came from this source. TVA Plant Colbert's new allowable emission rate of 2.2 lbs SO_2 emitted/mmBTU was made permanent and federally enforceable through a source specific SIP revision published January 23, 1990 at 55 FR 2235. The revision was made to ensure that no emission limit reflects credit for the use of any stack height greater than Good Engineering Practice (GEP). Dispersion modeling was required for all sources including Plant Colbert that were identified as utilizing stack heights or dispersion techniques prohibited by the GEP regulations. Dispersion modeling results for Plant Colbert showed that it would be necessary to revise the allowable SO_2 emission rate from 4.0 lbs SO_2 emitted/mmBTU to 2.2 lbs SO_2 emitted/mmBTU. This reduction of credit for stack heights in excess of GEP ensures protection of the NAAQS at ground level as well as decreasing interstate impacts from SO_2 transport. Therefore, permanent enforceable SO_2 emissions reductions have been made through State and Federal programs.

§ 107(d)(3)(E)(iv) The Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A.

ADEM submitted a maintenance plan pursuant to section 175A. However, since Colbert and Lauderdale Counties are secondary nonattainment for SO_2, this maintenance plan is not required by EPA for redesignation.

§ 107(d)(3)(E)(v) The State containing such area has met all requirements applicable to the area under section 110 and part D.

The State has complied with all requirements for section 110 of the Act and part D. In addition, a PSD program exists and will apply in Lauderdale and Colbert Counties upon redesignation to attainment. Therefore, the State has complied with all requirements of section 110 and Part D of the Act. Therefore, all of the requirements of section 107(d)(3)(E) have been satisfied.

Additional information is provided in a Technical Support Document which contains a detailed review of the material submitted. This is available at the EPA address given previously.

Final Action

EPA is approving the redesignation of Colbert and Lauderdale Counties, Alabama, to attainment for SO_2. This action is being taken without prior proposal because the changes are noncontroversial and EPA anticipates no significant comments on them. The public should be advised that this action will be effective 60 days from the date of this **Federal Register** notice. However, if notice is received within 30 days that someone wishes to submit adverse or critical comments, this action will be withdrawn and two subsequent notices will be published before the effective date. One notice will withdraw the final action and another will begin a new rulemaking by announcing a proposal of the action and establishing a comment period.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq., EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

Redesignation of an area to attainment under section 107(d)(3)(E) of the CAA does not impose any new requirements on small entities. Redesignation is an action that affects the status of a geographical area and does not impose any regulatory requirements on sources. The Administrator certifies that the approval of the redesignation request will not affect a substantial number of small entities.

This action has been classified as a table 2 action by the Regional Administrator under the procedures published in the **Federal Register** on January 6, 1989, (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget waived table 2 and table 3 SIP revisions (54 FR 2222) from the requirements of section 3 of Executive Order 12291 for two years.

EPA has submitted a request for a permanent waiver for table 2 and table 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

Under section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate by March 15, 1993. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

Nothing in this action shall be construed as permitting or allowing or establishing a precedent for any future request for a redesignation of any nonattainment area. Each request for redesignation of any nonattainment area shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: December 15, 1992.

Patrick M. Tobin,

Acting Regional Administrator.

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

40 CFR part 81, subpart C, is amended as follows:

1. The authority citation for part 81 continues to read as follows:

Authority: 42 U.S.C. 7407, 7501–7515. 7601.

2. Section 81.301 is amended by revising the table for "Alabama—SO_2" to read as follows:

§ 81.301 Alabama.

* * * * *

ALABAMA—SULFUR DIOXIDE

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
Statewide	.....	.....	.....	X

[FR Doc. 93–643 Filed 1–11–93; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[FAR Case 91–50]

48 CFR Part 31

Federal Acquisition Regulation; Nonmanufacturer Rule; Technical Correction

AGENCIES: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Technical correction to FAC 90–16.

SUMMARY: The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council are correcting the interim rule published on December 21, 1992, at 57 FR 60580 concerning FAR case 91–50, Nonmanufacturer Rule. The "**DATES**" and "**ADDRESSES**" captions are corrected by adding the "*Comment Date*" and address to read as follows:

DATES: * * *.

Comment Date: Comments should be submitted to the FAR Secretariat at the address shown below on or before February 19, 1993, to be considered in the formulation of a final rule.

ADDRESSES: Interested parties should submit written comments to: General Services Administration, FAR Secretariat (VRS), 18th & F Streets, NW., room 4037, Washington, DC 20405.

Please cite FAC 90–16, FAR case 91–50 in all correspondence related to this case.

FOR FURTHER INFORMATION CONTACT: Mr. Jack O'Neill, Office of Federal Acquisition Policy, GS Building, Washington, DC 20405, (202) 501–3856.

Dated: December 28, 1992.

Edward C. Loeb,

Acting Director, Office of Federal Acquisition Policy.

[FR Doc. 93–600 Filed 1–11–93; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 541

[Docket No. T84–01; Notice 29]

RIN 2127–AE64

Final Listing of High Theft Lines for 1993 Model Year; Motor Vehicle Theft Prevention Standard

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule; technical amendment.

SUMMARY: The purpose of this final rule is: To report the results of this agency's actions for determining which car lines are subject to the marking requirements of the motor vehicle theft prevention standard for the 1993 model year; and publish a list of those car lines. NHTSA has previously published lists of the car lines that were selected as high theft car lines for prior model years, beginning with the 1987 model year. The list in this document includes all of the car lines in the previous lists. In addition, this listing shows the four car lines that have standard equipment anti-theft devices and have been granted exemptions from the requirements of the theft prevention standard beginning with the 1993 model year. Two more car lines have been exempted in part and are required to have only their engines and transmissions marked.

This final listing for the 1993 model year is intended to inform the public, particularly law enforcement groups, of the car lines that are subject to the marking requirements of the theft prevention standard for the 1993 model year.

EFFECTIVE DATE: This listing applies to the 1993 model year. The amendment made by this document is effective January 12, 1993.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara A. Gray, Office of Market Incentives, NHTSA, 400 Seventh Street,

SW., Washington, DC 20590. Ms. Gray's telephone number is (202) 366–1740.

SUPPLEMENTARY INFORMATION: The Federal Motor Vehicle Theft Prevention Standard, 49 CFR part 541, sets forth requirements for inscribing or affixing identification numbers onto covered original equipment major parts, and the replacement parts for those original equipment parts, on all vehicles in lines selected as high theft lines.

Section 603(a)(2) of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 2023(a)(2)) (hereinafter "the Cost Savings Act") specifies that NHTSA shall select the high theft lines, with the agreement of the manufacturer, if possible. Section 603(d) of the Cost Savings Act (15 U.S.C. 2023(d)) provides that once a line has been designated as a high theft line, it remains subject to the theft prevention standard unless that line is exempted under section 605 of the Cost Savings Act (15 U.S.C. 2025). Section 605 provides that a manufacturer may petition to have a high theft line exempted from the requirements of part 541, if the line is equipped as standard equipment with an antitheft device. The exemption is granted if NHTSA determines that the antitheft device is likely to be as effective as compliance with part 541 in reducing and deterring motor vehicle thefts.

The agency annually publishes the names of the lines which were previously listed as high theft lines and of the lines which are being listed for the first time and will be subject to the theft prevention standard beginning with the next model year. This notice is intended to inform the public, particularly law enforcement groups, of the high theft car lines for the 1993 model year. It also identifies those car lines that are exempted from the theft prevention standard for the 1993 model year because of standard equipment antitheft devices.

For the 1993 model year, the agency selected no new car line, in accordance with procedures published in 49 CFR part 542, as likely to be a high theft line. The list of high theft car lines includes all those lines that were selected as high theft lines and listed for prior model years.

The list of exempted lines includes six high theft car lines exempted by the agency, beginning in MY 1993, from the parts marking requirements of part 541. Four of these car lines are exempted in full from part 541, and two are exempted in part, with the manufacturer required to mark only the engines and transmissions of these vehicles. The four car lines exempted in full are the Nissan Infiniti J30, the Mercedes-Benz 124, the Mercedes-Benz 129, and the Mitsubishi Diamante. The two car lines exempted in part are the General Motors Buick LeSabre, and the General Motors Oldsmobile 88 Royale (formerly named the Oldsmobile Delta 88). One car line, the General Motors Cadillac Fleetwood, previously exempted in part from parts marking, has been renamed for the 1993 model year as the Cadillac Sixty Special. The updated list reflects this name change.

Notice and Comment; Effective Date

The car lines listed as being subject to the standard have previously been selected as high theft lines in accordance with the procedures of 49 CFR part 542 and section 603 of the Cost Savings Act. Under these procedures, manufacturers evaluate new car lines to conclude whether those new lines are likely to be high theft lines. Manufacturers submit these evaluations and conclusions to the agency, which makes an independent evaluation, and, on a preliminary basis, determines whether the new line should be subject to parts marking. NHTSA informs the manufacturer in writing of its evaluations and determinations, together with the factual information considered by the agency in making them. The manufacturer may request the agency to reconsider these preliminary determinations. Within 60 days of the receipt of the request, NHTSA makes its final determination. NHTSA informs the manufacturer by letter of these determinations and its response to the request for reconsideration. If there is no request for reconsideration, the agency's determination becomes final 45 days after sending the letter with the preliminary determination. Each of the new car lines on the high theft list is the subject of a prior final determination.

Similarly, the car lines listed as being exempt from the standard have previously been exempted in accordance with the procedures of 49 CFR part 543 and section 605 of the Cost Savings Act.

Therefore, NHTSA finds for good cause that notice and opportunity for comment on these listings are unnecessary. Further, public comment on the listings of selections and exemptions is not contemplated by title VI, and is unnecessary since the selections and exemptions have previously been made in accordance with the statutory criteria and procedure.

For the same reasons, since this revised listing only informs the public of previous agency actions, and does not impose any additional obligations on any party, NHTSA finds for good cause that the amendment made by this notice should be effective as soon as it is published in the Federal Register.

This final rule does not have any retroactive effect and it does not preempt any State law. Section 610 of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. 2030) provides that judicial review of this rule may be obtained pursuant to section 504 of the Cost Savings Act (15 U.S.C. 2004). The Cost Savings Act does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Regulatory Impacts

NHTSA has determined that this rule listing the car lines that are high theft and are subject to the requirements of the vehicle theft prevention standard and the car lines that are exempt from the standard is neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of Department of Transportation regulatory policies and procedures. As noted above, the selections have previously been made in accordance with the provisions of the Cost Savings Act, and the manufacturers of the selected lines have already been informed that those lines are subject to the requirements of part 541 for the 1993 model year. Further, this listing does not actually exempt lines from the requirements of part 541; it only informs the general public of all such previously granted exemptions. Since the only purpose of this final listing is to inform the public of prior agency action for the 1993 model year, a full regulatory evaluation has not been prepared.

The agency has also considered the effects of this listing under the Regulatory Flexibility Act. I hereby certify that this rule will not have a significant economic impact on a substantial number of small entities. As noted above, the effect of this notice is simply to inform the public of those lines that are subject to the requirements of part 541 for the 1993 model year. The agency believes that listing of this information will not have any economic impact on small entities.

In accordance with the National Environmental Policy Act of 1969, the agency has considered the environmental impacts of this rule, and determined that it will not have any significant impact on the quality of the human environment.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that

the proposed rulemaking does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 49 CFR Part 541

Administrative practice and procedure, Labeling, Motor vehicles, Reporting and recordkeeping requirements.

PART 541—[AMENDED]

In consideration of the foregoing, 49 CFR part 541 is amended as follows:

1. The authority citation for part 541 continues to read as follows:

Authority: 15 U.S.C. 2021–2024 and 2026; delegation of authority at 49 CFR 1.50.

2. In part 541, appendix A, appendix A–I and appendix A–II are revised to read as follows:

Appendix A—Lines Subject to the Requirements of This Standard

Manufacturer and Subject Lines

Alfa Romeo:
- Milano 141
- Fiat 144

BMW:
- 3—Car Line
- 5—Car Line
- 6—Car Line

Chrysler:
- Chrysler Executive Sedan/Limousine
- Chrysler Fifth Avenue/Newport
- Chrysler Laser
- Chrysler LeBaron/Town & Country
- Chrysler LeBaron GTS
- Chrysler's TC
- Chrysler New Yorker Fifth Avenue
- Dodge Aries
- Dodge Daytona
- Dodge Diplomat
- Dodge Lancer
- Dodge 600
- Dodge Stealth
- Eagle Talon
- Plymouth Caravelle
- Plymouth Laser
- Plymouth Gran Fury
- Plymouth Reliant

Consulier:
- Consulier GTP

Ferrari:
- Mondial 8
- 308
- 328

Ford:
- Ford Mustang
- Ford Thunderbird
- Ford Probe
- Mercury Capri
- Mercury Cougar
- Lincoln Continental
- Lincoln Mark
- Lincoln Town Car
- Merkur Scorpio
- Merkur XR4Ti

General Motors:
- Buick Electra
- Buick Reatta
- Buick Regal
- Buick Riviera
- Cadillac Eldorado
- Cadillac Seville
- Chevrolet Nova
- Chevrolet Lumina
- Oldsmobile Cutlass Supreme
- Oldsmobile Toronado
- Pontiac Fiero
- Pontiac Grand Prix
- Geo Prizm
- Geo Storm
- Saturn Sports Coupe

Isuzu:
- Impulse
- Stylus

Jaguar:
- XJ
- XJ–6
- XJ–40

Lotus:
- Elan

Maserati:
- Biturbo
- Quattroporte
- 228

Mazda:
- GLC
- 626
- MX–6
- MX–5 Miata
- MX–3

Mercedes-Benz:
- 190 D
- 190 E
- 250D–T
- 260 E
- 300 SEL
- 380 SEC/500 SEC
- 380 SEL/500 SEL
- 380 SL
- 420 SEL
- 560 SEL
- 560 SEC
- 560 SL

Mitsubishi:
- Cordia
- Tredia
- Eclipse

Peugeot:
- 405

Porsche:
- 924S

Reliant:
- SS1

Saab:
- 900

Subaru:
- XT
- SVX

Toyota:
- Camry
- Celica
- Corolla/Corolla Sport
- MR2
- Starlet

Volkswagen:
- Audi Quattro
- Volkswagen Cabriolet
- Volkswagen Rabbit
- Volkswagen Scirocco
- Volkswagen Corrado

Appendix A–I—High-Theft Lines with Antitheft Devices That Are Exempted From the Requirements of This Standard Pursuant to 49 CFR Part 543

Manufacturer and Exempted Lines

Austin Rover:
- Sterling

BMW:
- 7—Car line
- 8—Car line

Chrysler:
- Chrysler Conquest
- Imperial

General Motors:
- Cadillac Allante
- Chevrolet Corvette

Honda:
- Acura NS–X
- Acura Legend
- Acura Vigor

Isuzu:
- Impulse (MY's 1987–1991)

Mazda:
- 929
- RX–7

Mercedes-Benz:
- 124 Car line,[1] consisting of the following models: 300 E, 400 E, 500 E, 300 D, 300 TE, 300 CE
- 129 Car line,[1] consisting of the following models: 300 SL, 500 SL, 600 SL.

Mitsubishi:
- Galant
- Starion
- Diamante[1]

Nissan:
- Maxima
- 300 ZX
- Infiniti M30
- Infiniti Q45
- Infiniti J30[1]

Porsche:
- 911
- 928
- 968

Saab:
- 9000

Toyota:
- Supra
- Cressida
- Lexus LS400
- Lexus ES250
- Lexus SC300
- Lexus SC400

Volkswagen:
- Audi 5000S

[1] Beginning from Model Year 1993, these lines are exempted from the requirements of part 541, pursuant to 49 CFR part 543.

Audi 100
Audi 200
Volvo:
480ES

Appendix A–II—High Theft Lines With Antitheft Devices That Are Exempted in Part From the Parts-Marking Requirements of This Standard Pursuant to 49 CFR Part 543

MANUFACTURER—GENERAL MOTORS

Exempted lines	Parts marked
Chevrolet Camaro	Engine, transmission.
Pontiac Firebird	Engine, transmission.
Cadillac DeVille	Engine, transmission.
Cadillac Sixty Special	Engine, transmission.
Oldsmobile 98	Engine, transmission.
Buick Park Avenue	Engine, transmission.
Pontiac Bonneville	Engine, transmission.
Buick LeSabre[1]	Engine, transmission.
Oldsmobile 88 Royale[1]	Engine, transmission.

[1]Beginning from Model Year 1993, these lines are exempted in part from the requirements of part 541, pursuant to 49 CFR part 543.

Issued on: January 6, 1993.

Marion C. Blakey,

Administrator.

[FR Doc. 93–574 Filed 1–11–93; 8:45 am]

BILLING CODE 4910–59–M

49 CFR Part 571

[Docket No. 92–46; Notice 2]

RIN 2127–AE57

Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices, and Associated Equipment

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This notice amends Safety Standard No. 108 to reduce the thickness of the bulb ring on the Type HB2 standardized replaceable light source for headlamps from a minimum of .5 to .45 mm, in order to harmonize with corresponding European requirements.

DATES: The rule is effective on February 11, 1993.

FOR FURTHER INFORMATION CONTACT: Jere Medlin, Office of Rulemaking (202–366–5276).

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking on this subject was published in the **Federal Register** on September 2, 1992, and an opportunity afforded for comment (57 FR 40165). As the notice stated, T.A. Pickett, Technical Advisor SC34B—U.S. National Committee of the International Electrotechnical Committee, has petitioned for rulemaking to amend Standard No. 108 to harmonize a dimension of the Type HB2 replaceable light source for headlamps to accord with a recent change to its European counterpart, the H4. The agency granted the petition.

Figures 23–4 and 23–5 of Standard No. 108 specify dimensions for Type HB2. The Table for Dimensional Requirements specifies a minimum value of .5 mm for Dimension S, the thickness of the bulb ring. According to the petitioner, "this change * * * was approved via voting on document 34B (Central Office) 649 * * * issued by the International Electrotechnical Commission (IEC) as a Draft International Standard [and] will be published in the standard IEC 61." The minimum thickness would be reduced to .45 mm. The purpose of the change "is to permit utilization of commercially available sheet metal stock."

In the agency's opinion, this change will not affect bulb or headlamp performance. The performance of the bulb is related to the dimensions measured from the reference axis which is the front surface of the bulb ring. The thickness of the metal is not relevant in locating the reference axis of the bulb. Bulbs are secured to the headlamp with snap rings, or threaded attachment rings. The details of attachment connectors are not specified either in Standard No. 108, or in the European standards. A change of this nature would further implement the Administration's goal of international harmonization of safety standards.

Comments were received from Phillips, Koito, Chrysler Corporation, and the Secretary of the IEC Subcommittee 34B. All concurred in the proposed change. Phillips and Koito recommended maintaining the other dimensions of Figures 23–4 and 23–5; NHTSA agrees. In Chrysler's view, the change will offer greater flexibility in the application of replaceable bulb headlamp sources without compromising photometric performance. The Secretary of the IEC Subcommittee pointed out that an incorrect version of Figure 23–5 had been published with the notice. A corrected Figure 23–5 is published with the final rule.

This final rule will not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard. Section 105 of the Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Effective Date

Because the amendment relieves a restriction, and imposes no additional burden on any party, it is hereby found that good cause is shown for an effective date earlier than 180 days after issuance of the final rule, and the final rule is effective 30 days after its publication in the **Federal Register**.

Rulemaking Analyses

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has considered the impacts of this rulemaking action and has determined that it is neither major within the meaning of Executive Order 12291 "Federal Regulation", nor significant under Department of Transportation regulatory policies and procedures. It does not involve a matter of substantial public interest. The rulemaking would not have an effect upon the economy in excess of $100 million a year. The impacts of the slight dimensional change adopted are so minimal that preparation of a full evaluation is not required.

Regulatory Flexibility Act

The agency has also considered the effects of this rulemaking action in relation to the Regulatory Flexibility Act. I certify that this rulemaking action will not have a significant economic effect upon a substantial number of small entities. Motor vehicle headlamp and light source manufacturers are generally not small businesses within the meaning of the Regulatory Flexibility Act. Further, small organizations and governmental jurisdictions would not be significantly affected as the price of new motor vehicles will not be impacted. Accordingly, no Regulatory Flexibility Analysis has been prepared.

Executive Order 12612 (Federalism)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 on "Federalism." It has been determined that the rulemaking action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

National Environmental Policy Act

NHTSA has analyzed this rulemaking action for purposes of the National Environmental Policy Act. The rulemaking action will not have a significant effect upon the environment. There is no environmental impact associated with reducing a minimum dimension. The rulemaking action will not have an effect upon fuel consumption.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

In consideration of the foregoing, 49 CFR part 571 is amended as follows:

1. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.108 [Amended]

2. In § 571.108 Figures 23–4 and 23–5 are revised as follows:

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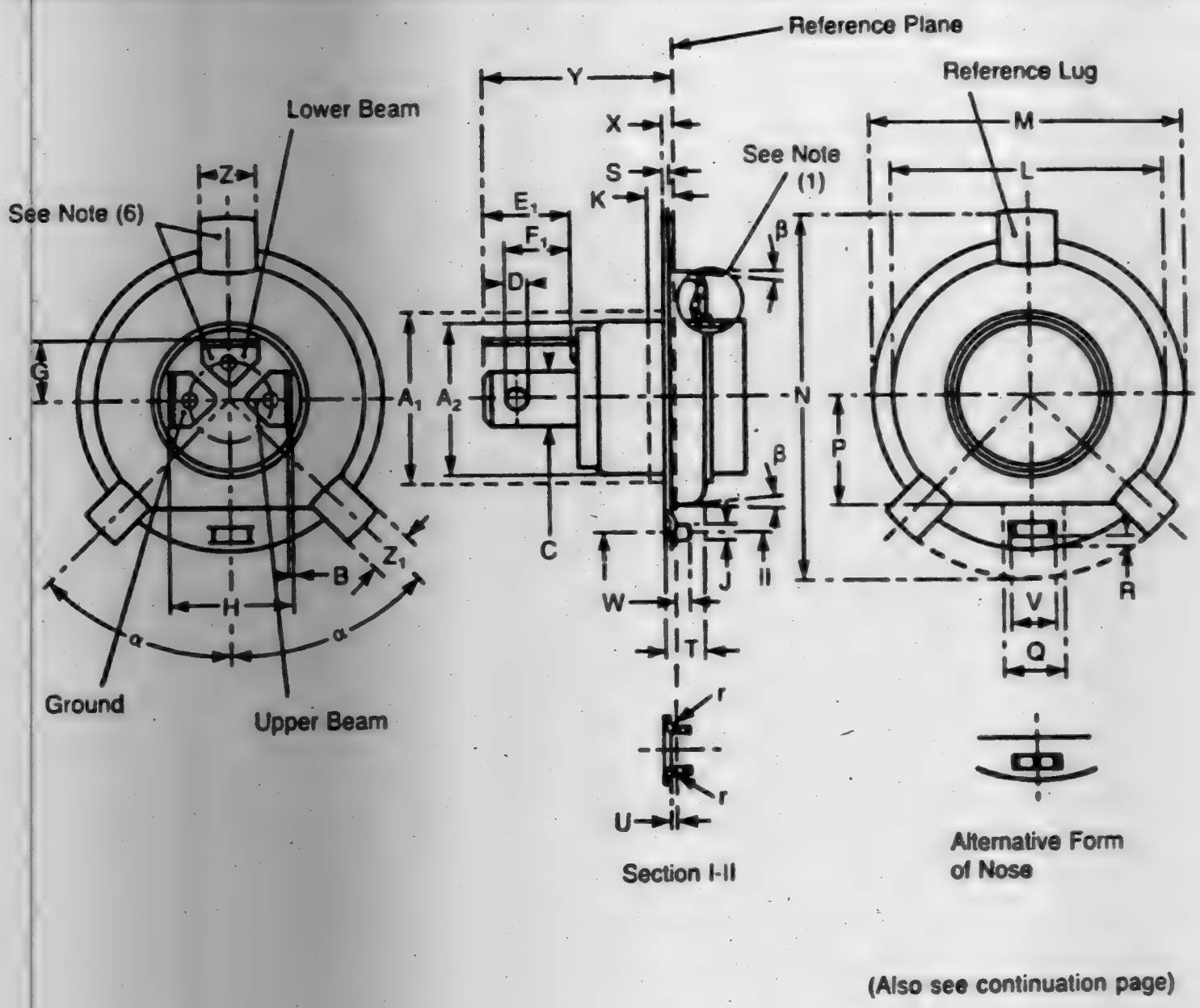

(Also see continuation page)

Figure 23-4. Type HB-2 Replaceable Light Source — Assembled Base P43t-38 on Finished Light Source — Dimensional Specifications

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FIGURE 23–5.—(CONTINUED) TYPE HB–2 REPLACEABLE LIGHT SOURCE—ASSEMBLED BASE P43T–38 ON FINISHED LIGHT SOURCE—DIMENSIONAL SPECIFICATIONS

Dimension	Min.	Max.	Dimension	Min.	Max.
A_1[8]	25.0	25.0	Q[2,7]	8.5	—
A_2[10]	Nominal	22.0	R	1.3	1.7
B	0.7	0.8	S	0.45	—
C	7.7	8.1	T	5.0	8.0
D	3.0	3.3	U	(9)	(9)
E_1	11.8	13.6	V[2,5]	6.3	6.5
F_1	8.8	10.3	W	1.8	2.2
G	8.5	9.0	X	1.1	1.3
H	17.0	17.9	Y	—	32.0
J	1.9	2.1	Z	7.9	8.0
K[10]	2.0	2.0	Z_1	5.8	6.2
L[2,4]	37.8	38.0	r	(9)	(9)
M[3]	42.9	43.0	α	44°	46°
N	51.6	52.0	β	—	5°
P[2,7]	15.3	15.5			

Dimensions in millimeters. The drawing is intended only to indicate the dimensions essential for interchangeability.
[1] The form of this part of the ring is optional and may be flat or recessed. However, the form shall be such that it will not cause any abnormal glare from the lower beam filament when the light source is in its normal operating position in the vehicle.
[2] This dimension is measured at the reference plane.
[3] Dimension M is the diameter on which the light source is centered when checking its dimensional characteristics.
[4] The maximum allowable eccentricity of cylinder L with respect to the circle of diameter M is 0.05 mm.
[5] The maximum allowable displacement of the center of the nose from the line running through the centers of the reference lug and the circle of diameter M is 0.05 mm. The sides of the nose shall not bend outwards.
[6] [Reserved]
[7] Dimension Q denotes the minimum width over which both the minimum and maximum limits of dimension P shall be measured. Outside dimension Q, the maximum limit for dimension P shall not be exceeded.
[8] The means of securing the ring in the headlamp shall not encroach on this cylindrical zone, which extends over the full length of the shell shown on this side of the ring.
[9] The radius r shall be equal to or smaller than dimension U.
[10] Beyond distance K, in the direction of the contact tabs, both the minimum and the maximum limits of dimension A_2 shall be measured.

Issued on January 6, 1993.

Marion C. Blakey,

Administrator.

[FR Doc. 93–575 Filed 1–11–93; 8:45 am]

BILLING CODE 4910–59–M

49 CFR Parts 564 and 571

[Docket No. 85–15; Notice 12]

RIN 2127–AE07

Replaceable Light Source Dimensional Information Federal Motor Vehicle Safety Standards; Lamps, Reflective Devices and Associated Equipment

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This notice adopts a rule that requires the manufacturers of replaceable light sources for headlamps to file dimensional information with NHTSA in a public docket pursuant to a new regulation, Replaceable Light Source Information. The replaceable light sources must be designed to meet certain performance requirements of S7.7 of Standard No. 108, and replaceable bulb headlamps equipped with such bulbs must meet the requirements of S7.5 that presently apply to replaceable bulb headlighting systems. The intended benefit of the changes is to afford manufacturers greater opportunities for design freedom and innovation, and to relieve them of the burden of petitioning for amendments to Standard No. 108 if they develop new frontal lighting systems. In a parallel change to Standard No. 108, the notice also adopts an amendment which ensures that replaceable light sources covered in the new regulations and intended for replacement purposes, have the dimensions and performance of the original replaceable light source. Finally, in continuing implementation of headlighting reform, the lower beam headlighting requirements of Standard No. 108 are amended by adding minimum photometric values at test points above the horizontal. The purpose of this addition is to maintain the ability of headlighting systems to illuminate overhead traffic signs.

DATES: The effective date of the final rule is February 11, 1993. Mandatory compliance with the added photometric values is not required until September 1, 1994. Petitions for reconsideration of either final rule must be filed not later than February 11, 1993.

ADDRESSES: Petitions for reconsideration should be addressed to the Administrator, refer to Docket No. 85–15, Notice 12, and be submitted to: Docket Section, room 5109, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are from 9:30 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Kenneth O. Hardie, Office of Rulemaking, NHTSA (202–366–6987).

SUPPLEMENTARY INFORMATION: On October 18, 1991, NHTSA published a supplementary notice of proposed rulemaking (SNPRM) to revise NHTSA's May 1989 notice of proposed rulemaking (NPRM) (54 FR 20084) that manufacturers of replaceable light sources for headlamps be required to file dimensional information with NHTSA in a public docket pursuant to a new regulation, part 564 Replaceable Light Source Information (56 FR 52242). Under the SNPRM, the new light sources would have to be designed to meet certain performance requirements of S7.6 (now S7.7) of Federal Motor Vehicle Safety Standard No. 108, Lamps, Reflective Devices, and Associated Equipment, and replaceable bulb headlamps equipped with part 564 light sources would have to meet the requirements of S7.5 that presently apply to replaceable bulb headlight systems. The SNPRM also revised NHTSA's May 1989 proposal to ensure that part 564 replaceable light sources intended for replacement purposes would have the dimensions and performance of the original replaceable light source. Finally, the SNPRM proposed to amend the headlighting requirements of Standard No. 108 by adding minimum photometric values at two zones and two test points above the horizontal.

Comments on the SNPRM were submitted by General Motors Corporation (GM), General Electric Corporation (GE), Motor Vehicle Manufacturers Association (MVMA), Ford Motor Company, Chrysler Corporation, Volkswagen of America, Volvo Cars of North America, American Honda Motor Co., Suzuki Motor Corp., GTE Sylvania, the States of Connecticut, Delaware, Illinois, Iowa, Maine, Maryland, Michigan, New York, North Carolina, Oregon, South Carolina, Virginia, Washington, and Wisconsin, Valeo, Stanley, Koito Manufacturing Co.

Ltd., American Association of State Highway and Transportation Officials, national Committee on Uniform Traffic Control Devices, Mitsubishi Motors Corporation, Western Star Trucks, Federal Highway Administration, Donald Vierimäa, and Advocates for Auto & Highway Safety.

Additional Types of Replaceable Light Sources

NHTSA's desire to make Standard No. 108 more performance oriented led it to the tentative conclusion that future designs of replaceable light sources should no longer be specified in Standard No. 108. To ensure that replaceable light sources manufactured for replacement are interchangeable with those used as original equipment, and that photometric performance equivalent to the original is provided, NHTSA issued the NPRM, proposing new part 564, Replaceable Bulb Dimensional Information, and appropriate amendments to Standard No. 108. Part 564 would require manufacturers of replaceable bulbs, used as original equipment in the headlighting systems, to submit to the agency certain dimensional information as specified in the regulation, such as filament position dimensions and tolerances, dimensions pertaining to the filament capsule and its supports, and bulb base interchangeability dimensions and tolerances. The agency has established similar information dockets relative to tire rim combinations (Standard No. 109), and vehicle identification number (49 CFR part 565), and has found that they have worked well to date.

The NPRM was generally supported as adequate for reducing the existing regulatory burden and for assuring that future light sources would meet the needs of vehicle manufacturers and their customers. The reader is referred to the SNPRM for a discussion on the issues raised by the commenters regarding the NPRM.

In revising proposed part 564 for the SNPRM, NHTSA modified its terms to enhance fairness and enforceability. The SNPRM was supported, and is adopted exactly as proposed.

Under part 564, manufacturers will submit information before, and not after, a new light source enters production; specifically, at least 60 days in advance. The Administrator will review the submission promptly, and provide a response within 30 days. This will allow completion of the review process before manufacture begins, instead of after production has begun, and should result in less disruption of the manufacturing process if the submission is found unacceptable by NHTSA. After information has been accepted for filing, no changes in it will be permitted.

In commenting on the SNPRM, GE expressed concern that relaxing the regulation on replaceable light sources could lead to a proliferation of unique bulbs designed for use on only a single car line, resulting in consumer confusion and a reduction in the number of outlets in which replacements might be available. However, vehicle manufacturers have told NHTSA that the development of new light sources is very capital intensive. NHTSA believes that this fact will limit the number of truly new light sources that will be submitted for incorporation in part 564. The most likely immediate scenario for part 564 is the addition of European light sources (other than H–4) to the docket that are not presently covered by the HB Types currently allowed.

In addition, part 564 covers only filament-type light sources. Since the trend in headlighting technology is towards non-filament light sources, such as high intensity discharge (HID) systems, there is further reason to believe that the number of additions to part 564 will be limited. The advantages in reduced energy consumption, cost savings, and styling freedom that HID technology offers practically ensures its widespread introduction over the next decade.

GE also expressed concern that part 564 would allow approval of supposedly new light sources which, in fact, were only slightly changed versions of existing light sources, thus leading to proliferation. NHTSA believes that § 564.5(c) addresses GE's concern. This section states that NHTSA will not accept any submission if the light source is interchangeable with any light source permitted at the time of the submission, or if it is a modification of any such light source.

Finally, GE recommended that recognized industry group, such as SAE, scrutinize and resolve the types of concerns raised in its comments. NHTSA has no objection to scrutiny of new light sources by industry organizations before the information is submitted to part 564. However, should such a group be established, it would exist outside of the framework of Standard No. 108 and part 564. There would be no legal requirement for manufacturers to submit information to the group for review, or to be bound by its conclusions, if negative.

Further, although NHTSA intends part 564 as a regulatory substitute for aspects of Standard No. 108, its adoption does not affect the right of any person to petition for rulemaking to amend Standard No. 108 to adopt new filament-type light sources. However, the petitioner would be expected to justify why it is seeking rulemaking rather than simply filing information in part 564.

Chrysler Corporation recommended that part 564 include information only on light sources actually intended for use as original equipment. It argued that other wise NHTSA might unnecessarily be burdened with many new designs or types of light sources that may never be used in production. NHTSA disagrees that submission of information could ever constitute a "burden", and believes that, because of the competitive nature of the lighting industry, new light source designs will not be submitted unless they are intended for use as original equipment in production motor vehicles. Nor would NHTSA wish to retard innovation in roadworthy concept motor vehicles if they complied with all Federal motor vehicle safety standards except a docket submission on a new headlamp light source. Although the "Scope", Applicability", and "Reporting Requirements" section make clear that the intent of the regulation is to cover equipment that is about to be used, or is being used, as original equipment, NHTSA does not intend to make actual production a condition of acceptance.

Performance of Replaceable Light Sources Other Than Type HB

In developing the SNPRM, NHTSA tentatively concluded that additional replaceable light sources ought not to be allowed, even if information relating to them met the requirements of part 564, unless the light sources met current performance requirements for the HB Types, and unless headlamps equipped with them performed with equivalence to those equipped with single and dual filament HB Type light sources. Thus, the SNPRM departed from the NPRM in proposing appropriate amendments to Standard No. 108 which, in effect, would incorporate part 564 by reference.

Specifically, after NHTSA had accepted information for filing in part 564, Standard No. 108 would require the light source to be designed to conform to that information, and to be tested in the same manner as the current HB Type replaceable light sources. Standard No. 108 would also require that headlamps equipped with single and dual filament part 564 light sources meet the same performance requirements as headlamps equipped with single and dual filament HB Type light sources.

Because of the equivalence of performance that would be required of all replaceable light sources, NHTSA proposed to amend the definition of "standardized replaceable light source" to drop the word "standardized", and to amend it to substitute "replaceable light source". A "replaceable light source" would be one designed to conform to S7.7 (S7.6 at the time of the SNPRM). S7.7 would drop the word "Standardized" from its title and contain two groups of replaceable light sources: those designed to conform to subparagraphs (a) through (e) (Types HB1 through HB5), and those designed to conform to new subparagraph (g) (i.e., in accordance with their dimensional and performance specifications on file in part 564). New subparagraphs (f) and (h) would contain certification and marking requirements appropriate for subparagraphs (a) through (e), and subparagraph (g) light sources respectively.

Current subparagraphs (f) through (i) contain testing requirements for the HB Types that appear adaptable for other kinds of replaceable light sources. These would be amended as appropriate. These were proposed as new subparagraphs (i) through (k). Proposed new subparagraph (i) combined old subparagraphs (f) and (g) since subparagraph (f) was only one sentence long. Additionally, old subparagraph (j) would become the final sentence to subparagraph (a) since subparagraph (j) references Figure 3 and subparagraph (a) is the only place in S7.7 concerned with Figure 3.

The NPRM also proposed that S7.5 Replaceable Bulb Headlamp System be amended where appropriate. By adding the word "replaceable" before "light source" whenever it appears in S7.5, NHTSA meant to ensure in the simplest manner possible that both groups of light sources under the umbrella definition of "replaceable light source" would be included. The effect of this would be to require that headlamps meet applicable photometrics regardless of whether the light source was designed to meet HB specifications or those on file in part 564. However, new dual filament bulbs would be restricted to headlamp systems providing photometrics of Figure 17 (Type HB2), and could not be used in systems providing the photometrics associated with systems using Type HB1 or Type HB5 photometrics. NHTSA asked for comments on this point.

Illumination of Overhead Signs

AS NHTSA noted in the NPRM, an important aspect of NHTSA's original vehicle-based illumination performance proposal of 1989 was the specific need to provide illumination for overhead signs. The present requirements of Standard No. 108 for headlighting photometry on the lower beam do not require any light above the horizontal (though imposing a maximum limit to prevent glare). Because of the trend towards retroreflective highway regulatory and informational signs rather than self-illuminated ones, the absence of such a requirement in Standard No. 108 has caused concern to the Federal Highway Administration (FHWA), NHTSA's companion agency in DOT. Energy and maintenance costs for self-illuminated signs constitute such a large burden for the States that they are increasingly choosing to install retroreflective signs when they install new signs or refurbish old ones.

Given the desirability for drivers to have headlighting above the horizontal, the question is presented of the quantum of light that would maintain the present level of motor vehicle safety. NHTSA proposed to add minimum photometric values to the headlamp lower beam at two zones and two test points above the horizontal. The first zone is located from 8L to 8R and H to 4U, with a minimum of 64 candela. The second zone is located from 4L to 4R and H to 2U, with a minimum of 135 candela. At test point 0.5U between 1R and 3R, where a maximum of 2,700 candela exists, NHTSA proposed a minimum of 1,000 candela. At test point 1.5 between 1R and 5R a maximum of 1,400 candela is specified. NHTSA proposed a minimum candela of 450.

The commenters on the various subjects discussed above raised five issues of significance that the agency addresses below.

1. Whether the NPRM Addresses a Safety Issue

Ford stated that it did not recognize a need at all to address lower beam illumination above the horizontal, while GM, recognizing a need to aid in reading signs, did not believe that there was a demonstrated need for the values that NHTSA proposed, and that those values went beyond the illumination levels necessary for safety. GM is willing to accept the two zones of 64 and 135 candela, but recommended that the proposed minimum values of 1,000 and 450 be reduced to 500 and 200 respectively.

NHTSA believes that the rulemaking does address a safety issue. There are an increasing number of automobiles, both foreign and domestic, that are equipped with headlamps whose lower beams feature a sharp cut-off that results in substantially less light being projected upwards. Such lamps are to be found on vehicles with elliptical headlamp reflectors. While most headlamps currently used by U.S. manufacturers are not designed to provide the cut-off, future U.S. lamps could incorporate this feature. The result is a deterioration in the driver's ability to read reflective signs located above the height of headlamps. With the general aging of the driving population that is presently occurring (the increase in drivers over 40 years of age), and the financial ability of that age group to purchase vehicles with these typically more expensive elliptical reflector headlighting systems, there appears to be an increase in risk to motorists driving at night. As NHTSA has noted before, there is a trend towards retroreflective signs instead of those that are self-illuminated. Further, the presence of some light on the lower beam is required to allow sufficient time to detect, read, understand, and react to the message on the sign. Many commenters, including Chrysler and several States, agree with NHTSA.

2. The Minimum Reasonable and Practicable Level of Light

The issue here concerns the appropriateness of the values proposed for the two zones, and for the two test points.

GM, Ford, Chrysler, Volvo, and Volkswagen supported the proposed zonal values of 64 and 135 candela, as did other commenters with the exception of Koito, which recommended 32 and 67 candela. Koito claimed that it is difficult to design headlamps to those values. Ford, however, commented that if NHTSA intended that these values be based on the values recommended to the GTB, those values converted to candela should be used, and that, on this basis, the second zone should be 125 candela, rather than 135.

NHTSA believes that Ford has based its calculations on a test voltage of 12V, instead of the U.S. test voltage at 12.8V. When the U.S. test voltage is used, the candela is not 125, but 151. Thus, the 135 candela proposed is less than the 125 European candela, and should be acceptable to the GTB. Given the fact that the proposed values of 64 and 135 candela were acceptable to virtually all commenters, NHTSA is adopting the values proposed.

NHTSA's proposed test point minima of 1,000 and 450 candela did not find the same support. Chrysler recommended their elimination from the final rule, while GM and Ford recommended that reduced values of 500 candela and 200 candela be adopted. The primary reason for this

recommendation is the possibility that more light would be added to the left of the line, above the horizontal, resulting in an increase in glare. A secondary reason is that some current production headlamps do not meet the proposed values, and would have to be redesigned, resulting in substantial expenses for retooling of molds. GM advanced the argument that the 500 and 200 candela values come closer to meeting the harmonized values recommended at present by the SAE Beam Pattern Task Force.

The question to be answered then is whether the lower values recommended by Ford and GM adequately address the safety need for illumination above the horizontal. The values that NHTSA proposed were based upon light intensity levels recommended in SAE Technical Paper 870238, "The Potential Impact of Automotive Headlight Changes on the Visibility of Reflectorized Highway Signs" (1987) by John B. Arens, an employee of the Federal Highway Administration, SAE 870238 states that the generally accepted distances for the detection and legibility of overhead signs on limited access roads, required to initiate proper motorist reactions, are 1,200 and 900 feet respectively. Based upon this, and utilizing a 3.4 candela per meter per meter legend luminance as the minimally acceptable sign brightness, Arens determined the minimum intensity for two existing "maximum" points in the upper right quadrant for lower beam photometry. Arens concluded that these two minimum intensities, approximately equal to one-third of the existing maximum, should be required, rather than the implied zero that now exists. Thus, at test point 0.5U between 1R and 3R, a maximum of 2,700 candela exists. Arens recommended a minimum of 1,000 candela for that test point. At test point 1.5U between 1R and 5R, a maximum of 1,400 candela is specified. Arens believed the minimum candela that Standard No. 108 should specify for that test point ought to be 450 candela. The Arens values represent the ideal amount of headlamp luminous intensity necessary to obtain a near-zero risk to the motorist for visibility of overhead signage at night. However GM and Ford commented that the Arens intensity levels are not practicable for some of their lamps, and would require costly design and tooling changes to realize small increases in photometric intensity without a commensurate safety benefit. NHTSA has concluded that it may adopt the values suggested by GM and Ford without compromising its original intent, because the light provided will be sufficient to illuminate overhead traffic signs.

Ford asked that the agency also consider the effects of the ambient illumination provided by a sign's surroundings, the illumination from headlamps reflected upwards from the roadway, and the effect of illumination from other drivers on the roadway, and the agency has done so. Considering the discussion above, the variables suggested by Ford, and the costs of conformance that might be caused by adoption of the higher values originally proposed, NHTSA is adopting test point candela values of 500 and 200.

Ford also recommended that the sweep at 1.5U between 1R and 5R extend only to 3R at both test points. The originally proposed 5R would result in a projection of light 70 feet to the right of the driver, while the value of 3R would result in a projection of light 42 feet to the right. This is sufficient for purposes of illumination, and NHTSA is adopting the limit suggested by Ford.

Under the proposal, new dual filament bulbs would have been restricted to headlamp systems providing photometrics of Figure 17 (Type HB2). Several commenters recommended that these bulbs be allowed as well to meet the less stringent requirements of Table 1 of SAE Standard J579 DEC84, and the more stringent ones of Figures 15 and 15A. As this suggestion would relieve a design restriction, NHTSA has adopted it.

3. Test Burden

Under the proposal, testing for the two zones would occur throughout the entire region. Citing the burden that this would cause, GM and Ford recommended that measurements be made only at discrete points corresponding to the four corners of the zones. NHTSA concurs, but believes that sufficient illumination can be assured with measurements at only five of the eight corner test points: 4U–8L, 4U–8R, and H–8L for the 64 candela zone, and 2U–4L, and H–4L for the 135 candela zone. This results in eliminating test point H–8R for the 64 candela zone, and H–4R and 2U–4R for the 135 candela zone. The proximity of the line points (1.5U, 1–3R, and 0.5U, 1–3R) will cause sufficient light at the right corners of the zones that there is little need to test at the remaining three test points H–8R, H–4R, and 2U–4R.

4. Replacement Headlamps

A number of commenters wanted to know if the new photometric requirements will apply to replacement headlamps produced after the effective date for use on vehicles produced before the effective date.

As NHTSA explains below, all motor vehicles manufactured on and after September 1, 1994, must be equipped with headlamps incorporating the upper illumination improvements. This means that headlamps produced after September 1, 1994, and which are replacement headlamps only for vehicles produced before September 1, 1994, are not required to meet the new photometric requirements. On the other hand, headlamps manufactured on and after September 1, 1994, which could be used as replacement headlamps for vehicles produced both before and after September 1, 1994, must comply with the new photometric requirements.

5. Leadtime

NHTSA proposed an effective date of October 1, 1992, which was slightly less than one year after publication of the SNPRM. Most commenters recommended that NHTSA provide at least 2 years of leadtime following issuance of the final rule. It appears that some manufacturers must modify headlamp designs on some vehicles, and that to require an effective date of only one year after issuance of the rule might be insufficient leadtime for them. Accordingly, the agency is adopting an effective date of September 1, 1994, for the new photometric requirements.

NHTSA is amending Standard No. 108 in a manner that allows a manufacturer from now until September 1, 1994, the option of equipping motor vehicles with headlamp systems meeting the current photometrics or the photometrics with the new test points and zones. This is accomplished by the addition of four new Figures to the standard. The options that are allowed are design conformance to Table 1 of SAE Standard J579 DEC84 or new Figure 27, Table 2 of SAE Standard J579 DEC84 or new Figure 28, Figure 15 or new Figure 15A, and Figure 17 or new Figure 17A. The headlamp system on a motor vehicle manufactured on and after September 1, 1994, would have to be designed to conform to one of four options: Figure 15A, Figure 17A, Figure 27, or Figure 28. Appropriate amendments are made throughout the text of S7, and in S10. Figure 26 is revised to reference the new Figures. S9, the bulb deflection test procedures is revised to reference dimensions in part 564 for determining dimension "A" of Figure 8.

This final rule does not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety

standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard. Section 105 of the Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Effective Dates

The effective date of the final rule is February 11, 1993. Because of the necessity for new replaceable light sources covered by part 564 to conform to the requirements of Standard No. 108, it is hereby found for good cause shown that an effective date for the amendments to Standard No. 108 that is earlier than 180 days after their issuance is in the public interest. However, because of the need to afford some headlamp manufacturers sufficient leadtime to conform with the additional photometric requirements, mandatory compliance with Figures 15A, 17A, 27, and 28 is not required until September 1, 1994.

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has considered the economic impacts of this rule and has made a determination that it is neither major within the meaning of E.O. 12291 nor significant under Department of Transportation policies and procedures. Implementation of this rule will eliminate the burden on manufacturers who would otherwise have to petition for rulemaking amendments to use new headlamp bulbs. The imposition of test points to maintain sign illumination is expected to cause little quantifiable burden, e.g., testing for the five new test points during the normal course of testing for photometric performance. For those lamp manufacturers who have chosen to produce lamps which do not provide current levels of sign illumination, an unquantifiable but probably low level of cost would be imposed for the updating of photometric prescriptions, should those lamps still be placed on new vehicles two years hence. Thus, headlamp costs should not be significantly affected. Since the rule does not have any significant cost or other impacts, preparation of a full regulatory evaluation is not warranted.

National Environmental Policy Act

NHTSA has analyzed this rule for the purposes of the National Environmental Policy Act. It is not anticipated that the rule will have a significant effect upon the environment. The design and composition of headlamps or light sources will not change from those presently in production.

Regulatory Flexibility Act

The agency has also considered the impacts of this rule in relation to the Regulatory Flexibility Act. I certify that this rule will not have a significant economic impact upon a substantial number of small entities. Accordingly, no regulatory flexibility analysis has been prepared. Manufacturers of motor vehicles, headlamps, and light sources, those affected by the rule, are generally not small businesses within the meaning of the Regulatory Flexibility Act. Further, small organizations and governmental jurisdictions will be significantly affected only if the price of new vehicles, headlamps, and light sources is more than minimally impacted. This will not occur since, as noted above, the agency believes that almost all current headlamps and light sources are designed to meet the proposed photometric requirements.

Executive Order 12612 (Federalism)

This rule has also been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and NHTSA has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Paperwork Reduction Act

The reporting and recordkeeping requirement associated with this rule has been approved by the Office of Management and Budget in accordance with 44 U.S.C. chapter 35. The OMB control number is 2127–0563.

List of Subjects

49 CFR Part 564

Motor vehicle safety, Motor vehicles.

49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 564—[ADDED]

1. In consideration of the foregoing, a new part 564 is added to read as follows:

PART 564—REPLACEABLE LIGHT SOURCE INFORMATION

Sec.
564.1 Scope.
564.2 Purpose.
564.3 Applicability.
564.4 Definitions.
564.5 Reporting requirements.
Appendix A—Information To Be Submitted for Replaceable Light Sources

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 564.1 Scope.

This part requires manufacturers of original equipment replaceable light sources used in motor vehicle headlighting systems to submit dimensional, electrical specification, and marking/designation information as specified in this part.

§ 564.2 Purpose.

The purpose of this part is to ensure the availability to replacement light source manufacturers of the manufacturing specifications of original equipment light sources and thus ensure also that replacement light sources are interchangeable with original equipment light sources and provide equivalent performance, and that redesigned or newly developed light sources are designated as distinct and different and noninterchangeable with previously existing light sources.

§ 564.3 Applicability.

This part applies to manufacturers of replaceable light sources that are used as original equipment in motor vehicle headlighting systems.

§ 564.4 Definitions.

All terms defined in the Act and the regulations and standards issued under its authority are used as defined therein.

§ 564.5 Reporting requirements.

(a) Each manufacturer of a replaceable light source used as original equipment in a headlighting system on a motor vehicle, other than a replaceable light source meeting the requirements of subparagraphs (a) through (e) of paragraph S7.7 of § 571.108 of this chapter, shall furnish the information specified in appendix A of this part to: Administrator, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Attn: Replaceable Light Source Docket.

(b) The manufacturer shall submit the information specified in appendix A of this part not later than 60 days before it intends to begin the manufacture of the replaceable light source to which the information applies. Each submission shall consist of one original set of information and 10 legible reproduced copies, all on 8½ by 11-inch paper.

(c) The Administrator shall promptly review each submission, and inform the manufacturer not later than 30 days after its receipt whether the submission has been accepted. The Administrator shall not accept any submission that does not contain all the information specified in Appendix A of this part, or if the information indicates that it is interchangeable with any light source for which information has been filed, or with any standardized replaceable light source specified in section 571.108 of this title.

(d) Information submitted under this section is made available by NHTSA for public inspection not later than the date on which a vehicle equipped with a new or revised replaceable light source is offered for sale.

Appendix A—Information To Be Submitted for Replaceable Light Sources

I. Filament Position Dimensions and Tolerances Using Either Direct Filament Dimensions or the Three Dimensional Filament Tolerance Box

A. Lower beam filament dimensions or filament tolerance box dimensions and relation of these to the bulb base reference plane and centerline.

1. Axial location of the filament centerline or the filament tolerance box relative to the bulb base reference plane.

2. Vertical location of the filament centerline or the filament tolerance box relative to the bulb base centerline.

3. Transverse location of the filament centerline or the filament tolerance box relative to the bulb base centerline.

4. Filament tolerance box dimensions, if used.

B. Upper beam filament dimensions or the filament tolerance box dimensions, and relation of these to the bulb base reference plane and centerline.

1. Axial location of the filament centerline or the filament tolerance box relative to the bulb base reference plane.

2. Vertical location of the filament centerline or the filament tolerance box relative to the bulb base centerline.

3. Transverse location of the filament centerline or the filament tolerance box relative to the bulb base centerline.

4. Filament tolerance box dimensions, if used.

C. If the replaceable light source has both a lower beam and an upper beam filament, the dimensional relationship between the two filament centerlines or the filament tolerance boxes may be provided instead of referencing the upper beam filament centerline or filament tolerance box to the bulb base centerline or reference plane.

II. Dimensions Pertaining to Filament Capsule and Capsule Supports

A. Maximum length from bulb base reference plane to tip of filament capsule.

B. Maximum radial distances from bulb base centerline to periphery of filament capsule and/or supports.

C. Location of black cap relative to low beam filament centerline, filament tolerance box or other to-be-specified reference.

D. Size, length, shape, or other pertinent features and dimensions for providing undistorted walls for the filament capsule.

III. Bulb Base Interchangeability Dimensions and Tolerance

A. Angular locations, diameters, key/keyway sizes, and any other interchangeability dimensions for indexing the bulb base in the bulb holder.

B. Diameter, width, depth, and surface finish of seal groove, surface, or other pertinent sealing features.

C. Diameter of the bulb base at the interface of the base and its perpendicular reference surface.

D. Dimensions of features related to retention of the bulb base in the bulb holder such as tabs, keys, keyways, surfaces, etc.

IV. Bulb Holder Interchangeability Dimensions and Tolerance

A. Mating angular locations, diameters, key/keyway sizes, and any other interchangeability dimensions for indexing the bulb base in the bulb holder.

B. Mating diameter, width, depth, and surface finish of seal groove, surface, or other pertinent sealing features.

C. Mating diameter of the bulb holder at the interface of the bulb base aperture and its perpendicular reference surface.

D. Mating dimensions of features related to retention of the bulb base in the bulb holder such as tabs, keys, keyways, surfaces, etc.

V. Wiring Harness Connector to Bulb Base Interchangeability Dimensions and Tolerances

A. Maximum depth of harness connector insertion into bulb base.

B. Location of electrical pins in bulb base.

C. Dimensions of electrical pins in bulb base—length, diameter, width, thickness and etc.

D. Fit of harness connector into bulb base providing all necessary dimensions, key/keyway controls, and dimensions, tapers etc.

E. Dimensions and location of locking features for wiring harness connector to bulb base.

F. Identification of upper beam, lower beam, and common terminals.

VI. Seal Specifications (if replaceable light source is intended to be of a sealed base design)

A. Type.

B. Material.

C. Dimensions.

VII. Electrical Specifications for Each Filament at 12.8 Volts

A. Maximum power (in watts).

B. Luminous Flux with tolerance (in lumens) with black cap if so equipped, measured in accordance with the document: Illuminating Engineering Society of North America, LM–45; IES Approved Method for Electrical and Photometric Measurements of General Service Incandescent Filament Lamps (April 1980).

VIII. Bulb Markings/Designation—ANSI Number, ECE Identifier, Manufacturer's Part Number, Individually or in Any Combination

IX. All Other Dimensions or Performance Specifications Necessary for Interchangeability Purposes Not Listed Above

PART 571—[AMENDED]

2. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.108 [Amended]

3. In § 571.108 Motor Vehicle Safety Standard No. 108, Lamps Reflective Devices and Associated Equipment, section S4, the definition of *Replaceable bulb headlamp* is amended by removing the word "standardized".

4. In section S4, the definition of *Standardized replaceable light source* is removed and a new definition *Replaceable light source* is added in alphabetical order to read:

Replaceable light source means an assembly of a capsule, base, and terminals that is designed to conform to the requirements of paragraph S7.7 of this standard.

5 and 6. Paragraph S7.1 is revised to read: S7.1 Each passenger car, multipurpose passenger vehicle, truck, and bus shall be equipped with a headlighting system designed to conform to the requirements of S7.3, S7.4, S7.5, or S7.6, except that Tables 1 and 2 of SAE J579 DEC84 and Figures 15 and 17 shall not apply to any such vehicle manufactured on and after September 1, 1994, and Figures 27, 28, 15A and 17A shall apply in lieu thereof.

7. Paragraph S7.2(d) is added to read: (d) Unless stated otherwise, a tolerance of +/– ¼ degree is permitted during photometric performance tests for any headlamp or beam contributor, and the test points 10U–90U shall be measured from the normally exposed surface of the lens face. The term 'aiming plane' means 'aiming reference plane' or an appropriate vertical plane defined by the manufacturer as required in S7.7.1.

8. Paragraph S7.3.2(a)(3) is revised to read: (3) In paragraphs 4.5.2 and 5.1.6, the words "either Table 2 of SAE J579 DEC84 or Figure 28 of Motor Vehicle Safety Standard No. 108" are substituted for "Table 3".

9. Paragraph S7.3.3(a) is revised to read: (a) the requirements of paragraphs S7.3.2 (a) through (c), except that the substitutions for Table 3 in paragraph S7.3.2(a)(3) are either Table 1 of SAE J579 DEC84 or Figure 27.

10. Paragraph S7.3.4 is revised to read: S7.3.4 *Type C Headlighting*

System. A type C headlighting system consists of two Type 1C1 and two Type 2C1 headlamps and associated hardware, which are designed to conform to the requirements of paragraph S7.3.2 (a) through (d), except that the substitutions for Table 3 in paragraph S7.3.2(a)(3) are either Table 2 of SAE J579 DEC84 or Figure 28.

11. Paragraph S7.3.5(a) is revised to read: (a) A Type D headlighting system consisted of two Type 2D1 headlamps and associated hardware, which are designed to conform to the requirements of paragraph S7.3.2 (a) through (c), except that the substitutions for Table 3 in paragraph S7.3.2(a)(3) are either Table 1 of SAE J579 DEC84 or Figure 27.

12. Paragraph S7.3.6(a) is revised to read: (a) A Type E headlighting system consists of two Type 2E1 headlamps and associated hardware, which are designed to conform to the requirements of paragraph S7.3.2 (a) through (c), except that the substitutions for Table 3 in paragraph S7.3.2(a)(3) are either Table 1 of SAE J579 DEC84 or Figure 27.

13. Paragraphs S7.3.7(b), S7.4(a)(1) (i) and (ii), S7.4(a)(3), S7.5(e)(3) (i) and (ii), and S10 (a) and (b) are amended by adding the words "or Figure 15A" after the words "Figure 15".

14. In paragraph S7.36(b), the last sentence is revised to read: "In paragraph 4.5.2, the words 'either Table 2 of SAE J579 DEC84, or Figure 28' are substituted for the words 'Table 3'".

15. Paragraph S7.3.9(a) is revised to read: (a) Paragraphs S7.3.8 (a) through (d) except that in paragraph S7.3.8(b), the substitutes for Table 3 are Table 1 of SAE J579 DEC84 or Figure 27.

16. Paragraph S7.4(a)(1)(iii) is revised to read: (iii) Table 2 of SAE Standard J579 DEC84 or Figure 28.

17. Paragraphs S7.4(a)(2)(i), S7.5(e)(2)(i) (A) and (B), and S7.5(e)(2)(ii) (A) and (B) are amended by adding the words "or Figure 17A" after the words "Figure 17".

18. Paragraph S7.4(a)(2)(ii) is amended by adding the words "or Figure 27" after the words "Table 1 of SAE J579 DEC84".

19. Paragraph S7.4(d) is removed, and paragraphs S7.4(e), (f), (g), (h), and (i) are redesignated (d), (e), (f), (g), and (h) respectively.

20. In paragraph S7.5(b), the phrase "paragraphs (c) through (e) of this section" is revised to read "subparagraphs (c) through (e) of this paragraph".

21. Paragraph S7.5(c) is revised to read: (c) The test requirements of sections 4.1, 4.1.4, and performance requirements of section 5.1.4 of SAE J1383 APR85, using the photometric requirements specified in subparagraphs (d) and (e) of this paragraph.

22. Paragraph S7.5(d) is revised to read: (d) For a headlamp equipped with dual filament replaceable light sources, the following requirements apply:

23. Paragraphs S7.5(d)(2), and S7.5(e)(1) are amended by adding the word "replaceable" between the words "two" and "light."

24. Paragraph S7.5(d)(2)(i)(A)(*1*) is revised to read: (*1*) The lower beam requirements of Table 1 of SAE Standard J579 DEC84 if the light sources in the headlamp system are Type HB1, or Type HB5, or any combination of the two; or the lower beam requirements of Table 1 of SAE Standard J579 DEC84 or Figure 27 if the light sources in the headlamp system are any combination of dual filament replaceable light sources other than Type HB2.

25. Paragraph S7.5(d)(2)(i)(A)(*2*) is revised to read: (*2*) The lower beam requirements of Figure 17 or Figure 17A, if the light sources are Type HB2, or any dual filament replaceable light source other than Type HB1 and Type HB5; or

26. Paragraph S7.5(d)(2)(i)(B) is revised to read: (B) By both light sources in the headlamp, designed to conform to the lower beam requirements specified above.

27. Paragraph S7.5(d)(2)(ii)(A)(*2*) is revised to read: (*2*) the upper beam requirements of Figure 17 or Figure 17A, if the light sources are Type HB2, or any dual filament replaceable light source other than Type HB1 and Type HB5; or

28. Paragraph S7.5(d)(2)(ii)(B) is revised to read: (B) By both light sources in the headlamp, designed to conform to the upper beam requirements specified above.

29. Paragraph S7.5(d)(3) is amended by adding the word "replaceable" between the words "single" and "light."

30. Paragraph S7.5(d)(3)(i)(A) is revised to read: (A) The lower beam requirements of Table 1 of SAE Standard J579 DEC84 if the light sources in the headlamp system are Type HB1 or Type HB5 or any combination of the two; or the lower beam requirements of Table 1 of SAE Standard J579 DEC84 or Figure 27 if the light sources in the headlamp system are any combination of dual filament light sources other than Type HB2; or

31. Paragraph S7.5(d)(3)(i)(B) is revised to read: (B) The lower beam requirements of Figure 15 or Figure 15A, if the light sources are Type HB2, or dual filament light sources other than Type HB1 and Type HB5. The lens of each such headlamp shall be marked with the letter "L".

32. Paragraph S7.5(d)(3)(ii)(A) is revised to read: (A) The upper beam requirements of Table 1 of SAE Standard J579 DEC84 if the light sources in the headlamp system are Type HB1 or Type HB5 or any combination of the two; or the upper beam requirements of Table 1 of SAE Standard J579 DEC84 or Figure 27 if the light sources are any combination of dual filament light sources other than Type HB2; or

33. Paragraph S7.5(d)(3)(ii)(B) is revised to read: (B) The upper beam requirements of Figure 15 or Figure 15A, if the light sources are Type HB2, or dual filament light sources other then Type HB1 and Type HB5. The lens of each such headlamp shall be marked with the letter "U".

34. Paragraph S7.5(e) is amended by adding the word "replaceable" between the words "of" and "light".

35. Paragraph S7.5(e)(2) is revised to read: (2) The lower and upper beams of a headlamp system consisting of two lamps, each containing a combination of two replaceable light sources (other than those combinations specified in subparagraph (d) of this paragraph) shall be provided only as follows:

36. Paragraph S7.5(e)(3) is revised to read: (3) The lower and upper beams of a headlamp system consisting of four lamps, using any combination of replaceable light sources except those specified in subparagraph (d) of this paragraph, each lamp containing only a single replaceable light source, shall be provided only as follows:

37. In paragraph S7.5(f), the phrase "paragraphs (d) and (e) of this section" is revised to read "subparagraphs (d) and (e) of this paragraph".

38. Paragraph S7.5(g) is revised to read: (g) The lens of each replaceable bulb headlamp shall bear permanent marking in front of each replaceable light source with which it is equipped that states the HB Type, if the light source is designed to conform to subparagraphs (a) through (e) of paragraph S7.7, or the bulb marking/designation provided in compliance with Section VIII of appendix A of part 564, if the light source is designed to conform to subparagraph (g) of paragraph S7.7. No marking need be provided if the only replaceable light source in the headlamp is Type HB1.

39. Paragraph S7.7 is amended by removing the words "Standardized" and "standardized."

40. Paragraph S7.7(a) is amended by adding the following sentence at the end thereof: (a) * * * A general tolerance shall apply to Figure 3 as follows: +/− 0.004 in. (0.10 mm) to all linear dimensions and 1 degree 00 minutes to all angular dimensions except for

referenced dimensions and unless otherwise specified.

41. Paragraphs S7.7 (f), (g), (h), (i), (j), and (k) are removed, and new paragraphs S7.7 (f), (g), (h), (i), (j) and (k) are added to read:

(f) Each replaceable light source designed to conform to subparagraphs (a) through (e) of this paragraph shall be marked with the symbol DOT and with a name or trademark in accordance with S7.2. In addition, the base of each such light source shall be marked with its HB Type designation.

(g) Any other replaceable light source shall be designed to conform to the dimensions and electrical specifications furnished with respect to it pursuant to part 564 of this chapter.

(h) Each replaceable light source designed to conform to subparagraph (g) of this paragraph, shall be marked with the bulb marking designation specified for such light source in compliance with Section VIII of Appendix A of part 564 of this chapter, with the symbol DOT, and with a name or trademark in accordance with S7.2.

(i) The filament of a replaceable light source shall be seasoned before measurement of maximum power and luminous flux. Such measurement shall be made with the direct current test voltage regulated within one quarter of one percent. The test voltage shall be design voltage, 12.8v. The measurement of luminous flux shall be in accordance with the Illuminating Engineering Society of North America, LM–45; IES Approved Method for Electrical and Photometric Measurements of General Service Incandescent Filament Lamps (April 1980), shall be made with the black cap installed on Type HB1, Type HB2, Type HB4, and Type HB5, and on any other replaceable light source so designed, and shall be made with the electrical conductor and light source base shrouded with an opaque white colored cover, except for the portion normally located within the interior of the lamp housing. The measurement of luminous flux for the Types HB3 and HB4 shall be with the base covered with a white cover shown in Figures 19–1 and 20–1. The white covers are used to eliminate the likelihood of incorrect lumen measurement that will occur should the reflectance of the light source base and electrical connector be low.

(j) The capsule, lead wires and/or terminals, and seal on each Type HB1, Type HB3, Type HB4, and Type HB5 light source, and on any other replaceable light source which uses a seal, shall be installed in a pressure chamber as shown in Figure 25 so as to provide an airtight seal. The diameter of the aperture in Figure 25 on a replaceable light source designed to conform to subparagraph (e) of this paragraph shall be that figure furnished for such light source in compliance with section IV.8 of appendix A of part 564 of this chapter. An airtight seal exists when no air bubbles appear on the low pressure (connector) side after the light source has been immersed in water for one minute while inserted in a cylindrical aperture specified for the light source, and subjected to an air pressure of 70kPa (10 P.S.I.G.) on the glass capsule side.

(k) After the force deflection test conducted in accordance with S9, the permanent deflection of the glass envelope shall not exceed 0.005 in. (0.13 mm) in the direction of the applied force.

42. Paragraph S9 is retitled *"Deflection test for replaceable light sources"*, and is amended by adding the following sentence at the end thereof: S9. * * * Distance 'A' for replaceable light sources designed to conform to paragraph S7.7(g) shall be the dimension listed for its type as specified in part 564 of this chapter, appendix A, section I.A.I if the light source has a lower beam filament, or as specified in section I.B.I if the light source has only an upper beam filament.

43. Figure 26 is revised as indicated below.

44. Figures 15A, 17A, 27, and 28 are added as set forth below.

Issued on: January 6, 1993.

Marion C. Blakey,

Administrator.

BILLING CODE 4910-59-M

FIGURE 15A

PHOTOMETRIC TEST POINT VALUES

UPPER BEAM			LOWER BEAM		
Test Points (degrees)	cd max.	cd min.	Test Points (degrees)	cd max.	cd min.
2U-V	—	1,500	10U-90U	125	—
1U-3L and 3R	—	5,000	4U-8L and 8R	—	64
H-V	70,000	40,000	2U-4L	—	135
H-3L and 3R	—	15,000	1-1/2U-1R to 3R	—	200
H-6L and 6R	—	5,000	1-1/2U-1R to R	1,400	—
H-9L and 9R	—	3,000	1U-1-1/2L to L	700	—
H-12L and 12R	—	1,500	1/2U-1-1/2L to L	1,000	—
1-1/2D-V	—	5,000	1/2U-1R to 3R	2,700	500
1-1/2D-9L and 9R	—	2,000	H-4L	—	135
2-1/2D-V	—	2,500	H-8L	—	64
2-1/2D-12L and 12R	—	1,000	1/2D-1-1/2L to L	3,000	—
4D-V	5,000	—	1/2D-1-1/2R	20,000	10,000
			1D-6L	—	1,000
			1-1/2D-2R	—	15,000
			1-1/2D-9L and 9R	—	1,000
			2D-15L and 15R	—	850
			4D-4R	12,500	—
			4D-V	7,000	—
			H-V	5,000	—

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FIGURE 17A

PHOTOMETRIC TEST POINT VALUES

2-LAMP SYSTEM

UPPER BEAM			LOWER BEAM		
Test Points (degrees)	cd max.	cd min.	Test Points (degrees)	cd max.	cd min.
2U-V	—	1,500	10U-90U	125	—
1U-3L and 3R	—	5,000	4U-8L and 8R	—	64
H-V	75,000	40,000	2U-4L	—	135
H-3L and 3R	—	15,000	1-1/2U-1R to 3R	—	200
H-6L AND 6R	—	5,000	1-1/2U-1R to R	1,400	—
H-9L and 9L	—	3,000	1U-1-1/2L to L	700	—
H-12L and 12R	—	1,500	1/2U-1-1/2L to L	1,000	—
1-1/2D-V	—	5,000	1/2U-1R to 3R	2,700	500
1-1/2D-9L and 9R	—	2,000	H-4L	—	135
2-1/2D-V	—	2,500	H-8L	—	64
2-1/2D-12L and 12R	—	1,000	1/2D-1-1/2L to L	3,000	—
4D-V	12,000	—	1/2D-1-1/2R	20,000	10,000
			1D-6L	—	1,000
			1-1/2D-2R	—	15,000
			1-1/2D-9L and 9R	—	1,000
			2D-15L and 15R	—	850
			4D-4R	12,500	—

FIGURE 26 TABLE OF PHOTOMETRIC REQUIREMENTS [1. Four-Headlamp Systems (4)] [2 Two-Headlamp Systems (2)]					
LIGHT SOURCE TYPE	HB1	HB2	HB3	HB4	HB5
HB1	Fig. 27 (2 or 4)	Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)	Fig. 27 (2 or 4)
HB2		Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)
HB3			Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)
HB4				Fig. 15(4) Fig. 17(2)	Fig. 15(4) Fig. 17(2)
HB5					Fig. 27 (2 or 4)

FIGURE 27

PHOTOMETRIC TEST POINT VALUES

UPPER BEAM			LOWER BEAM		
Test Points (degrees)	cd. max.	cd. min.	Test Points (degrees)	cd. max.	cd. min.
2U-V	—	1,000	10U-90U	125	—
1U-3L and 3R	—	2,000	4U-8L and 8R	—	64
H-V	75,000	20,000	2U-4L	—	135
H-3L and 3R	—	10,000	1-1/2U-1R to 3R	—	200
H-6L and 6R	—	3,250	1-1/2U-1R to R	1,400	—
H-9L and 9R	—	1,500	1U-1-1/2L to L	700	—
H-12L and 12R	—	750	1/2U-1-1/2L to L	1,000	—
1-1/2D-V	—	5,000	1/2U-1R to 3R	2,700	500
1-1/2D-9L and 9R	—	1,500	H-4L	—	135
2-1/2D-V	—	2,500	H-8L	—	64
2-1/2D-12L and 12R	—	750	1/2D-1-1/2L to L	2,500	—
4D-V	5,000	—	1/2D-1-1/2R	20,000	8,000
			1D-6L	—	750
			1-1/2D-2R	—	15,000
			1-1/2D-9L and 9R	—	750
			2D-15L and 15R	—	700
			4D-4R	12,500	—

FIGURE 28

PHOTOMETRIC TEST POINT VALUES

	UPPER BEAM			
Headlamp Type	1A1, 1C1, 1G1		2A1, 2C1, 2G1	
Test Points (degrees)	cd. max.	cd. min.	cd. max.	cd. min.
2U-V	—	750	—	750
1U-3L and 3R	—	3,000	—	2,000
H-V	60,000	18,000	15,000	7,000
H-3L and 3R	—	12,000	—	3,000
H-6L and 6R	—	3,000		2,000
H-9L and 9R	—	2,000	—	1,000
H-12L and 12R	—	750	—	750
1-1/2D-V	—	3,000	—	2,000
1-1/2D-9L and 9R	—	1,250	—	750
2-1/2D-V	—	1,500	—	1,000
2-1/2D-12L and 12R	—	600	—	400
4D-V	5,000	—	2,500	—

	LOWER BEAM	
Headlamp Type	2A1, 2C1, 2G1	
Test Points (degrees)	cd. max.	cd. min.
10U-90U	125	—
4U-8L and 8R	—	64
2U-4L	—	135
1-1/2U-1R to 3R	—	200
1-1/2U-1R to R	1,400	—
1U-1-1/2L to L	700	—
1/2U-1-1/2L to L	1,000	—
1/2U-1R to 3R	2,700	500
H-4L	—	135
H-8L	—	64
1/2D-1-1/2L to L	2,500	—
1/2D-1-1/2R	20,000	8,000
1D-6L	—	750
1-1/2D-2R	—	15,000
1-1/2D-9L and 9R	—	750
2D-15L and 15R	—	700
4D-4R	12,500	—

[FR Doc. 93-631 Filed 1-11-93; 8:45 am]
BILLING CODE 4910-59-C

Proposed Rules

Federal Register
Vol. 58, No. 7
Tuesday, January 12, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

7 CFR Part 723

RIN 0560–AC81

National Marketing Quotas for Fire-cured (Type 21), Fire-cured (Types 22 & 23), Dark air-cured (Types 35 & 36), Virginia Sun-cured (Type 37), Cigar-filler (Type 46) and Cigar-filler and Cigar-binder (Types 42–44 & 53–55) Tobaccos

AGENCY: Agricultural Stabilization and Conservation Service (USDA).

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture (the Secretary) is required by the Agricultural Adjustment Act of 1938 (the Act), as amended, to proclaim by March 1, 1993, national marketing quotas for cigar-filler (type 46) and cigar-filler and binder (types 42–44 & 53–55) tobaccos for the 1993–94, 1994–95, and 1995–96 marketing years (MY's) and to determine and announce the amounts of the national marketing quotas for fire-cured (type 21), fire-cured (types 22 & 23), dark air-cured (types 35 & 36), Virginia sun-cured (type 37), and cigar-filler (type 46) cigar-filler and cigar-binder (types 42–44 & 53–55) kinds of tobacco for the 1993–94 marketing year. The public is invited to submit written comments, views, and recommendations concerning the determination of the national marketing quotas for such kinds of tobacco, the conduct of the referenda, and other related matters which are discussed in this proposed rule.

DATES: Comments must be received on or before February 5, 1993, in order to be assured consideration.

ADDRESSES: Send comments to the Deputy Administrator, Policy Analysis, Agricultural Stabilization and Conservation Service (ASCS), United States Department of Agriculture (USDA), room 3090, South Building, P.O. Box 2415, Washington, DC 20013–2415. All written submissions will be made available for public inspection from 8:15 a.m. to 4:45 p.m., Monday through Friday, except holidays, in room 3739, South Building, 14th and Independence Avenue, SW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Robert L. Tarczy, Agricultural Economist, Tobacco and Peanuts Analysis Division, ASCS, room 3739, South Building, P.O. Box 2415, Washington, DC 20013–2415, 202–720–8839. The Preliminary Regulatory Impact Analysis describing the options considered in developing this proposed rule and the impact of implementing each option is available on request from Robert L. Tarczy.

SUPPLEMENTARY INFORMATION:

Executive Order 12291 and Departmental Regulation 1512–1

This proposed rule has been reviewed under USDA procedures established to implement Executive Order 12291 and Departmental Regulation 1512–1 and has been classified "not major." The matters under consideration will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) Major increases in costs for consumers, individual industries, Federal, State or local government agencies or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, the environment, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Executive Order 12778

This proposed rule has been reviewed in accordance with Executive Order 12778, Civil Justice Reform. The provisions of the proposed rule do not preempt State laws, are not retroactive, and do not involve administrative appeals.

Federal Assistance Program

The title and number of the Federal Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this notice applies are: Commodity Loans and Purchases—10.051.

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this proposed rule since ASCS is not required by 5 U.S.C. 553 or any provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

Executive Order 12372

This activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Paperwork Reduction Act Requirements

The amendments to 7 CFR part 723 set forth in this proposed rule do not contain any new or revised information collection requirements that require clearance through the Office of Management and Budget under the provisions of 44 U.S.C. chapter 35. The information collection requirements contained in the current regulations at 7 CFR part 723 have been approved through August 31, 1995, by the Office of Management and Budget under the provisions of 44 U.S.C. Chapter 35, and assigned OMB No. 0560–0058. Public reporting burden for these collections is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of the information collection requirements, including suggestions for reducing the burden, to the Department of Agriculture, Clearance Officer, OIRM, room 404–W, Washington, DC 20250; and to the Office of Management and Budget, Paperwork Reduction Project (OMB No. 0560–0058), Washington, DC 20503.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

USDA is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, USDA actively seeks to promulgate regulations that promote economic growth, create jobs, are

minimally burdensome and are easy for the public to understand, use or comply with. In short, USDA is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. USDA applies this principle to the full extent possible, consistent with law.

USDA has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, USDA believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, USDA specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this rule.

Statutory Background

Section 312(b) of the Act provides that the Secretary shall determine and announce, no later than March 1, 1993, with respect to kinds of tobacco specified in this proposed rule, the amount of the national marketing quota which will be in effect for MY 1993 in terms of the total quantity of tobacco which may be marketed that will allow a supply of each kind of tobacco equal to the reserve supply level.

Section 312(c) of the Act provides that the Secretary is required to conduct, within 30 days after proclamation of national marketing quotas for cigar-filler (type 46) and cigar-filler and cigar-binder (types 42–44 & 53–55) tobaccos, referenda of farmers engaged in the 1992 production of each kind of tobacco (1988 in the case of cigar-filler (type 46)) to determine whether they favor or oppose marketing quotas for MY's 1993, 1994, and 1995. Producers of cigar-filler (type 46) tobacco disapproved marketing quotas for the 1992–94 years in March of 1992 (57 FR 47448). However, since that disapproval was the first such disapproval since 1952, marketing quotas must be proclaimed for the 1993–95 period. For cigar-filler and binder (types 42–44 & 53–55) tobacco, MY 1992 is the last year of the three consecutive MY's for which marketing quotas previously proclaimed will be in effect.

If more than one-third of the farmers voting in a referendum for a kind of tobacco oppose the quotas, the results shall be proclaimed by the Secretary and the national marketing quotas so proclaimed shall not become effective, but the results shall in no way affect or limit the subsequent proclamation and submission to a referendum of national marketing quota as otherwise authorized in section 312.

Section 313(g) of the Act authorizes the Secretary to convert the national marketing quota into a national acreage allotment by dividing the national marketing quota by the national average yield for the 5 years immediately preceding the year in which the national marketing quota is proclaimed. In addition, the Secretary is authorized to apportion, through county committees, the national acreage allotment to tobacco producing farms, less a reserve not to exceed 1 percent thereof for new farms, to make corrections and adjust inequities in old farm allotments, through the national factor. The national factor is determined by dividing the preliminary quota (the sum of quotas for old farms) into the quota determined for the MY in question (less the reserve).

Procedures will continue unchanged for (1) converting marketing quotas into acreage allotments; (2) apportioning allotments among old farms; 3) apportioning reserves for use in (a) establishing allotments for new farms, and (b) making corrections and adjusting inequities in old farm allotments; and (4) holding referenda.

Proposed Rule

This rule proposes to amend 7 CFR part 723, subpart A to include 1993-crop national marketing quotas for fire-cured (type 21), fire-cured (types 22 & 23), dark air-cured (types 35 & 36), Virginia sun-cured (type 37), cigar-filler (type 46), and cigar-filler and cigar-binder (types 42–44 & 53–55) tobaccos. These six kinds of tobacco account for about 3 percent of total U.S. tobacco production. Accordingly, comments are requested concerning the establishment of the national marketing quotas for the following:

(1) Fire-Cured (Type 21) Tobacco

The 1993-crop national marketing quota for fire-cured (type 21) tobacco will range from 2.5 to 3.0 million pounds. This range reflects the assumption that the national acreage factor will range from 0.9 to 1.00.

(2) Fire-Cured (Types 22 & 23) Tobacco

The 1993-crop national marketing quota for fire-cured (types 22 & 23) tobacco will range from 32 to 38 million pounds. This range reflects the assumption that the national acreage factor will range from 0.95 to 1.05.

(3) Dark Air-Cured (Types 35 & 36) Tobacco

The 1993-crop national marketing quota for dark air-cured (types 35 & 36) tobacco will range from 9.5 to 12 million pounds. This range reflects the assumption that the national acreage factor will range from 0.90 to 1.00.

(4) Virginia Sun-Cured (Type 37) Tobacco

The 1993-crop national marketing quota for Virginia sun-cured (type 37) tobacco will range from 140,000 to 157,000 pounds. This range reflects the assumption that the national acreage factor will range from 0.90 to 1.00.

(5) Cigar-Filler (Type 46) Tobacco

The 1993-crop national marketing quota for cigar-filler (type 46) tobacco will be zero.

Accordingly, the national acreage factor will be zero.

(6) Cigar-Filler and Cigar-Binder (Types 42–44 & 53–55) Tobaccos

The 1993-crop national marketing quota for cigar-filler and cigar-binder (types 42–44 & 53–55) tobaccos will range from 19 to 21 million pounds. This range reflects the assumption that the national acreage factor will range from 0.90 to 1.00.

List of Subjects in 7 CFR Part 723

Acreage allotments, Marketing quotas, Penalties, Reporting and recordkeeping requirements, Tobacco.

Accordingly, it is proposed that 7 CFR part 723, subpart A be amended as follows:

PART 723—TOBACCO

1. The authority citation for 7 CFR part 723 continues to read as follows:

Authority: 7 U.S.C. 1301, 1311–1314, 1314–1, 1314c, 1314d, 1314f, 1314h, 1315, 1316, 1363, 1372–75, 1377–1379, 1421, 1445–1, and 1445–2.

2. Sections 723.107–112, 723.118–119, and 723.121 are added and reserved and §§ 723.113–117, and 723.120 are added to read as follows:

§ 723.107–112 [Reserved]

§ 723.113 Fire-cured (type 21) tobacco.

The 1993-crop national marketing quota will range from 2.5 to 3.0 million pounds.

§ 723.114 Fire-cured (types 22 & 23) tobaccos.

The 1993-crop national marketing quota will range from 32 to 38 million pounds.

§ 723.115 Dark air-cured (types 35 & 36) tobacco.

The 1993-crop national marketing quota will range from 9.5 to 12 million pounds.

§ 723.116 Sun-cured (type 37) tobacco.

The 1993-crop national marketing quota will range from 140,000 to 157,000 pounds.

§ 723.117 Cigar-filler and cigar-binder (types 42–44 & 53–55) tobacco.

The 1993-crop national marketing quota will range from 19 to 21 million pounds.

§ 723.118–119 [Reserved]

§ 723.120 Cigar-filler (type 46) tobacco.

The 1993-crop national marketing quota will be 0.0.

§ 723.121 [Reserved]

Signed at Washington, DC, January 6, 1993.

John A. Stevenson,

Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 93–571 Filed 1–11–93; 8:45 am]

BILLING CODE 3410–05–M

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7 CFR Part 781

RIN 0560–AD06

Amendment to the Regulations For the Agricultural Foreign Investment Disclosure Act of 1978 Regarding Land Used For Forestry Production.

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Notice of proposed rulemaking.

SUMMARY: The purpose of this proposed rule is to amend, for clarification, the definition of agricultural land as it pertains to the reporting requirements for the disclosure of foreign investment in land used for forestry production under the authority of the Agricultural Foreign Investment Disclosure Act of 1978 (The Act). The Department has reviewed the regulations pertaining to the Act and has determined to clarify a possible ambiguity concerning the fact that its interpretation of land used for forestry production is not presently in the definition of agricultural land. The primary impact of this action will be to provide for public comments with an opportunity to clarify and publish a revised definition of agricultural land as it relates to land used for forestry production. This action will reduce confusion regarding the reporting of foreign investment in agricultural land.

DATES: Comments must be received on or before February 11, 1993 in order to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice of proposed rulemaking. Comments should be addressed to William A. Brown, Emergency Operations and Livestock Programs Division, Agricultural Stabilization and Conservation Service (ASCS), United States Department of Agriculture (USDA), room 4095 South Building, P.O. Box 2415, Washington, DC 20013–2415. All written submissions made pursuant to this rule will be made available for public inspection in room 4089 South Building, USDA, between the hours of 8:15 a.m. and 4:45 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: William A. Brown, Emergency Operations and Livestock Programs Division, ASCS, USDA, room 4095 South Building, P.O. Box 2415, Washington, DC 20013–2415, telephone 202–720–6833.

SUPPLEMENTARY INFORMATION:

Background

The present definition of agricultural land at 7 CFR 781.2(b) includes "forestry" production. ASCS has interpreted that term based on the definition of forest land used by USDA's Forest Service definition in An Analysis of Land Base Situation in the United States: 1989–2040, General Technical Report RM–181. This proposed rule incorporates the Forest Service's definition of forest land as part of the definition of agricultural land as it pertains to land used for forestry production.

The definition of land used for forestry production covers all stages of growing trees, with a minimum of 10 percent stockage by trees of any size, to qualify for reporting purposes as it pertains to AFIDA.

This proposed rule also amends the definition of agricultural land by referring to the 1987 edition of the Standard Industrial Classification Manual instead of the 1972 edition.

It is intended that this proposed rule will provide the public with a better understanding of the term agricultural land as it pertains to land used for forestry production.

Written comments are solicited regarding the above-mentioned definition of land used for forestry production as part of the definition of agricultural land in the disclosure of foreign investment under the Act.

This proposed rule has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Departmental Regulation No. 1512–1 and has been designated as "non-major." It has been determined that this rule will not result in:

(1) An annual effect on the economy of $100 million or more:

(2) A major increase in costs or prices for consumers, individual industries, Federal, State or local governments or geographical regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed rule has been reviewed in accordance with Executive Order 12778, Civil Justice Reform. The provisions of the proposed rule do not preempt State laws, are not retroactive, and do not involve administrative appeals.

The program is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

This proposed rule has also been reviewed with regard to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354). Pursuant to that review, Keith Bjerke, Administrator, ASCS, has certified that this proposed rule does not have a significant economic impact on a substantial number of small entities because the rule merely requires reports to be filed by foreign persons owning U.S. agricultural land. The proposed rule would only impact a small percent of foreign investors owning land used for forestry production allowing clearer and less burdensome reporting regulations to be followed in the reporting process.

This proposed rule contains no information collection or recordkeeping requirements that require clearance by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.).

It has been determined by an environmental evaluation that this action will not have a significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

USDA is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal

discretion permits, USDA actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use or comply with. In short, USDA is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in the President's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. USDA applies this principle to the full extent possible, consistent with law.

USDA has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, USDA believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, USDA specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternatives that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 7 CFR Part 781

Administrative practice and procedure, Agriculture, Foreign investment in the United States, Penalties, Reporting and recordkeeping requirements.

Accordingly, it is proposed that 7 CFR part 781 be amended as follows:

PART 781—DISCLOSURE OF FOREIGN INVESTMENT IN AGRICULTURAL LAND

1. The authority citation for 7 CFR part 781 continues to read as follows:

Authority: Sec. 1–10, 92 Stat. 1266 (7 U.S.C. 3501 et seq.).

2. § 781.2(b) is revised to read as follows:

§ 781.2 Definitions.

* * * * *

(b) *Agricultural land.* Agricultural land means land in the United States used for forestry production and land in the United States currently used for, or, if currently idle, land last used within the past five years, for farming, ranching, or timber production, except land not exceeding ten acres in the aggregate if the annual gross receipts from the sale of the farm, ranch, or timber products produced thereon do not exceed $1,000. Farming, ranching, or timber production includes, but is not limited to activities set forth in the Standard Industrial Classification Manual (1987). Division A, exclusive of industry numbers 0711–0783, 0851, and 0912–0919 which cover animal trapping, game management, hunting carried on as a business enterprise, trapping carried on as a business enterprise and wildlife management. Land used for forestry production means land at least 10 percent stocked by forest trees of any size, including land that formerly had such tree cover and that will be naturally or artificially regenerated. Land used for forestry production includes transition zones, such as areas between heavily forested and nonforested lands that are at least 10 percent stocked with forest trees, and forest areas adjacent to urban and built-up lands. Also included are pinyon-juniper and chaparral areas in the West, and afforested areas. The minimum area for classification of land used for forestry production is 10 acres. Roadside, streamside, and shelterbelt strips of timber must have a minimum crown width of 120 feet to qualify as land used for forestry production. Unimproved roads and trails, streams, and clearings in forest areas are classified as land used for forestry production if less than 120 feet in width.

* * * * *

Signed at Washington, DC on January 5, 1993.

John A. Stevenson,

Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 93–568 Filed 1–11–93; 8:45 am]

BILLING CODE 3410-05-M

FARM CREDIT ADMINISTRATION

12 CFR Part 620

RIN 3052–AB40

Disclosure to Shareholders

AGENCY: Farm Credit Administration.

ACTION: Proposed rule.

SUMMARY: The Farm Credit Administration (FCA) proposes to amend § 620.2(b)(3), which requires, in part, that quarterly reports filed with the FCA under part 620 be certified by each member of the board of directors (board) of filing Farm Credit System (FCS) institutions. Under the proposed regulations, at least one of the following directors of the board of a filing institution would be required to certify quarterly reports on behalf of the entire board: (1) The chairperson of the board; (2) the chairperson of the audit committee; or (3) a director designated by the chairperson of the board. Other board members of the institution would no longer be required to sign quarterly reports, unless such directors elect otherwise.

DATES: Written comments must be received on or before February 11, 1993.

ADDRESSES: Comments must be submitted in writing (in triplicate) to Patricia W. DiMuzio, Division Director, Regulation Development Division, Office of Examination, Farm Credit Administration, McLean, Virginia 22102–5090. Copies of all communications received will be available for examination by interested parties in the Regulation Development Division, Farm Credit Administration.

FOR FURTHER INFORMATION CONTACT:

Tong-Ching Chang, Staff Accountant, Technical and Operations Division, Office of Examination, Farm Credit Administration, McLean, Virginia 22102–5090, (703) 883–4483, TDD (703) 883–4444,

or

William L. Larsen, Senior Attorney, Regulatory Operations Division, Office of General Counsel, Farm Credit Administration, McLean, Virginia 22102–5090, (703) 883–4020, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: In connection with amendments to part 620, Disclosure to Shareholders, undertaken to implement the 1987 amendments (Pub. L. 100–233) to the Farm Credit Act of 1971 (1971 Act), 12 U.S.C. 2001 *et seq.*, the FCA amended § 620.2(b)(3) to require each member of the board of an FCS institution to certify quarterly reports filed with the FCA within 45 days after the end of each reporting quarter. See 56 FR 29412 (June 27, 1991). After the amended regulations became effective on September 10, 1991, the FCA received letters from several FCS institutions indicating that requiring directors to certify quarterly reports is burdensome and creates a logistical problem for their quarterly report filings. The institutions stated that, due to the frequency and timing of their board meetings and the geographic dispersion of board members, directors cannot certify quarterly reports in time to file the reports by the due dates required by the regulations.

To address these logistical and timing problems in certification of quarterly reports, the FCA proposes to revise § 620.2(b)(3) expanding the options available to institutions for compliance with quarterly report director certification requirements. The proposed amendment would require quarterly reports filed with the FCA to be certified by, at a minimum, one of the

following directors on behalf of the entire board of the filing institution: (1) The chairperson of the board; (2) the chairperson of the audit committee; or (3) a board member designated by the chairperson of the board. Other directors of the filing institution would no longer be required to sign quarterly reports filed with the FCA.

Under proposed § 620.2(b)(3)(i), individual directors may continue to certify quarterly reports if they so choose, or, by formal board action, they may delegate the obligation of certifying quarterly reports to one or more directors. After formal board action authorizing the designation, the designated signing director(s) may certify quarterly reports on behalf of the nonsigning members of the board. This could eliminate the need for each director to certify quarterly reports.

The FCA continues to believe that a requirement for directors' certification of quarterly reports is appropriate because it provides a mechanism to ensure that board members are regularly involved in their institution's operations and are monitoring its performance. Certification helps ensure that directors maintain the level of awareness of the institution's activities and financial condition needed to carry out the board members' fiduciary responsibility as directors. While the board may delegate day-to-day operations to management, it remains responsible for ensuring that the institution operates within the board's prescribed policies, in compliance with applicable laws and regulations, and in a safe and sound manner. The delegation does not relieve directors of the need to be informed about their institution's activities and financial condition.

Since directors are accountable, to the best of their knowledge and belief, for the institution's affairs, whether directors certify the institution's periodic reports or not does not affect directors' responsibility as it exists under applicable laws and regulations. Accordingly, the boards of FCS institutions should have policies in place to ensure timely review by all directors prior to filing periodic reports. Within this framework of director responsibility, the proposed rule should alleviate the regulatory burden of FCS institutions and their directors without compromising the regulatory concern regarding directors' accountability embodied in the requirement of § 620.2(b)(3).

List of Subjects in 12 CFR Part 620

Accounting, Agriculture, Banks, Banking, Organization and functions (Government agencies), Credit, Reporting and recordkeeping requirements, Rural areas.

For the reasons stated in the preamble, part 620 of chapter VI, title 12 of the Code of Federal Regulations is proposed to be amended to read as follows:

PART 620—DISCLOSURE TO SHAREHOLDERS

1. The authority citation for part 620 is revised to read as follows:

Authority: Secs. 5.17, 5.19, 8.11 of the Farm Credit Act; 12 U.S.C. 2252, 2254, 2279aa-11; sec. 424 of Pub. L. 100-233, 101 Stat. 1568, 1656.

Subpart A—General

2. Section 620.2 is amended by revising paragraph (b)(3) to read as follows:

§ 620.2 Preparing and filing the reports.

* * * * *

(b) * * *

(3)(i) For each quarterly report filed under this section, each member of the board or, at a minimum, one of the following board members formally designated by action of the board to certify quarterly reports on behalf of individual board members: The chairperson of the board; the chairperson of the audit committee; or a board member designated by the chairperson of the board.

(ii) For all other reports, each member of the board.

* * * * *

Dated: January 6, 1993.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 93-553 Filed 1-11-93; 8:45 am]

BILLING CODE 6705-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 91-NM-121-AD]

Airworthiness Directives; Fokker Model F28 Mark 1000, 2000, 3000, and 4000 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to all Fokker F28 Mark 1000, 2000, 3000, and 4000 series airplanes, that currently requires supplemental structural inspections to detect fatigue cracks, and repair or replacement, as necessary, to ensure continued airworthiness. This action would continue to require the same inspections, but would add or revise certain significant structural items for which inspection is necessary. This proposal is prompted by a structural re-evaluation by the manufacturer which identified additional structural elements where fatigue damage is likely to occur. The actions specified by the proposed AD are intended to prevent reduced structural integrity of these airplanes.

DATES: Comments must be received by March 9, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 91-NM-121-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Fokker Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Quam, Aerospace Engineer, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (206) 227-2145; fax (206) 227-1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact

concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 91–NM–121–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 91–NM–121–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On December 19, 1989, the FAA issued AD 89–07–16 R1, Amendment 39–6444 (55 FR 266, January 4, 1990), which is applicable to all Fokker Model F28 Mark 1000, 2000, 3000, and 4000 series airplanes. That AD requires operators to incorporate into their FAA-approved Maintenance Inspection Program the items defined in the Fokker Structural Integrity Program (SIP) Document No. 28438, Part I, including revisions up through November 1, 1988. That action was prompted by a structural re-evaluation conducted by the manufacturer, which identified certain significant structural components where fatigue damage is likely to occur. The requirements of that AD are intended to prevent reduced structural integrity of these airplanes.

Since the issuance of that AD, Fokker has issued SIP Document No. 28438, Part I, including revisions up through October 15, 1992, to add or revise various items for inspection, repair, or replacement. These additional or revised items were included as a result of (1) fatigue analysis and tests, (2) service experience, (3) follow-up action to an AD that required a one-time inspection and report of findings to the manufacturer, and (4) in some cases, an interim repair. The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, classified the revised SIP document as mandatory and issued Netherlands Airworthiness Directive BLA No. 82–026 in order to assure the continued airworthiness of these airplanes in the Netherlands.

This airplane model is manufactured in Netherlands and is type certificated for operation in the United States under the provisions of Section 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would supersede AD 89–07–16 R1 to require incorporation of the latest revisions of Fokker SIP Document No. 28438, Part I, revised up through October 15, 1992, into the FAA-approved maintenance program. The continuing inspections, repair, and replacement would be required to be accomplished in accordance with this latest revision of the service document.

This proposal also revises the existing AD to allow repairs to be accomplished in accordance with other data meeting the certification basis of the airplane which is approved by the FAA or by the RLD.

The FAA estimates that 40 airplanes of U.S. registry would be affected by this proposed AD. Implementation of the inspections, repairs, or replacements specified in the revisions to the SIP document into an operator's maintenance program is estimated to require approximately 605 work hours (including removal, inspection, and installation work hours) per airplane per year, at an average labor rate of $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $1,331,000, or $33,275 per airplane, for the first year and annually thereafter. This total cost figure assumes that no operator has yet accomplished the proposed requirements of this AD action.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES".

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–6444 (55 FR 266, January 4, 1990), and by adding a new airworthiness directive (AD), to read as follows:

Fokker: Docket 91–NM–121–AD. Supersedes AD 89–07–16 R1, Amendment 39–6444.

Applicability: All Model F28 Mark 1000, 2000, 3000 and 4000 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced structural integrity of these airplanes, accomplish the following:

(a) Within six months after February 5, 1990 (the effective date of Amendment 39–6444, AD 89–07–16 R1), incorporate into the FAA-approved maintenance program the inspections, inspection intervals, repairs, or replacements defined in the Fokker Structural Inspection Program (SIP) Document No. 28438, Part I, including revisions up through November 1, 1988; and inspect, repair, and replace, as applicable. The non-destructive inspection techniques referenced in this document provide acceptable methods for accomplishing the inspections required by this AD. Inspection results, where a crack is detected, must be reported to Fokker, in accordance with the instructions of the SIP document. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(b) Within six months after the effective date of this AD, replace the revision of the FAA-approved maintenance program required by paragraph (a) of this AD with the inspections, inspection intervals, repairs, or replacements defined in the Fokker SIP Document No. 28438, Part I, including revisions up through October 15, 1992; and inspect and repair, or replace, as applicable. The non-destructive inspection techniques referenced in this document provide acceptable methods for accomplishing the inspections required by this AD. Inspection results, where a crack is detected, must be reported to Fokker, in accordance with the instructions of the SIP document. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.) and have been assigned OMB Control Number 2120–0056.

(c) Cracked structure detected during the inspections required by paragraph (a) or (b) of this AD must be repaired or replaced, prior to further flight, in accordance with the instructions in Fokker SIP Document No. 28438, Part I, including revisions up through November 1, 1988 (for airplanes inspected in accordance with paragraph (a) of this AD); or Fokker SIP Document No. 28438, Part I, including revisions up through October 15, 1992 (for airplanes inspected in accordance with paragraph (b) of this AD); or in accordance with other data meeting the certification basis of the airplane which is approved by the FAA or by the Rijksluchtvaartdienst (RLD).

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(e) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on January 6, 1993.

N.B. Martensen,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–588 Filed 1–11–93; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 71

[Airspace Docket No. 91–ASW–24]

Proposed Revision of Transition Area: Las Cruces, NM

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking.

SUMMARY: This notice revises an earlier proposal to revise the transition area located at Las Cruces, NM. That proposal was necessary due to the development of a new standard instrument approach procedure (SIAP), based on a new instrument landing system (ILS), to Runway 30. Since the notice of proposed rulemaking (NPRM) was published in the **Federal Register**, the criteria used for the development of transition areas has changed. The intended effect of this supplemental NPRM is to allow for comments on the revised description of the Las Cruces transition area, which has been developed in accordance with this new criteria to provide adequate controlled airspace for aircraft executing the new ILS Runway 30 SIAP.

DATES: Comments must be received on or before March 5, 1993.

ADDRESSES: Send comments on the proposal in triplicate to Manager, System Management Branch, Air Traffic Division, Southwest Region, Docket No. 91–ASW–24, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530.

The official docket may be examined in the office of the Assistant Chief Counsel, Southwest Region, Federal Aviation Administration, 4400 Blue Mound Road, Forth Worth, TX, between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the System Management Branch, Southwest Region, Federal Aviation Administration, 440 Blue Mound Road, Fort Worth, TX.

FOR FURTHER INFORMATION CONTACT: Alvin E. DeVane, System Management Branch, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530; telephone: (817) 624–5535.

SUPPLEMENTARY INFORMATION:

History

On October 23, 1991, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the transition area located at Las Cruces, NM (56 FR 54811). Interested persons were invited to participate in this rulemaking proceeding by submitting written commets on the proposal to the FAA. The only comment received was from the State of New Mexico, Aviation Division and it favored the proposal. Delays in delivery of the ILS equipment for the SIAP resulted in the NPRM being put on hold until the proposal would be more timely. Since the NPRM was published in the **Federal Register**, the criteria used in the development of transition areas has changed. The new criteria became effective on October 15, 1992. Changes include mileage being expressed in terms of nautical miles rather than statute miles and measurements described to a tenth of a nautical mile rather than to a half of a statute mile. This supplemental NPRM describes the Las Cruces transition area utilizing this new criteria. Changes from the original NPRM include the transition area radius being decreased from 10.5 statute miles to 6.8 nautical miles. This decrease in the transition area radius necessitates the description of extensions for the existing nondirectional radio beacon (NDB) runway 8 SIAP and the NDB–A SIAP. Additionally, the Las Cruces International Airport coordinates in the earlier proposal were based on North American Datum 27; however, these coordinates have been updated to North American Datum 83.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit, with those comments, a self-addressed, stamped, postcard containing the following statement: "Comments to Airspace Docket No. 91–ASW–24." The postcard will be date/time stamped and returned to the commenter. All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this

notice may be changed in the light of comments received. All comments submitted will be available for examination in the office of the Assistant Chief Counsel, 4400 Blue Mound Road, Fort Worth, TX, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Supplemental Notice of Proposed Rulemaking (SNPRM)

Any person may obtain a copy of this SNPRM by submitting a request to the Manager, System Management Branch, Department of Transportation, Federal Aviation Administration, Fort Worth, TX 76193–0530. Communications must identify the notice number of this SNPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise the transition area located at Las Cruces, NM. This proposal is necessary due to the development of a new SIAP based on a new ILS to Runway 30. Since the NPRM was published in the **Federal Register**, the criteria used for the development of transition areas has changed. This SNPRM allows for comments on the revised description of the Las Cruces transition area, which has been developed in accordance with this new criteria, and whose coordinates are based on North American Datum 83. Transition areas are published in Section 71.181 of FAA Order 7400.7A dated November 2, 1992, and effective November 27, 1992, which is incorporated by reference in 14 CFR 71.1. The transition area listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations that needs frequent and routine amendments to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Incorporation by reference, Transition areas.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.7A, Compilation of Regulations, dated November 2, 1992, and effective November 27, 1992, is amended as follows:

Section 71.181 Designation of Transition Areas

* * * * *

ASW NM TA Las Cruces, NM [Revised]

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Las Cruces International Airport (latitude 32°17′22″N., longitude 106°55′19″W.) and within 1.4 miles each side of the ILS localizer southeast course extending from the 6.8-miles radius to 12.3 miles southeast of the airport, and within 8 miles west and 4 miles east of the 179° bearing from the Las Cruces RBN (latitude 32°16′56″N., longitude 106°55′25″W.) extending from 6.8-mile radius to 16 miles south of the RBN, and within 2.5 miles each side of the 101° bearing from the Las Cruces RBN extending from the 6.8–miles radius to 7.5 miles west of the RBN.

* * * * *

Issued in Fort Worth, TX on December 31, 1992.

Larry L. Craig,

Manager, Air Traffic Division, Southwest Region.

[FR Doc. 93–623 Filed 01–11–93; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[EE–62–92]

RIN 1545–AR09

Nondiscrimination Requirements for Qualified Plans

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed amendments to the final regulations under section 401(a)(4) of the Internal Revenue Code of 1986. They interpret the section 401(a)(4) requirement that contributions or benefits provided under a tax-qualified retirement plan not discriminate in favor of highly compensated employees. This section and the minimum coverage requirements of section 410(b) form a coordinated nondiscrimination rule that prohibits a tax-qualified retirement plan from being designed or operated in favor of highly compensated employees.

The proposed regulations reflect changes made by the Tax Reform Act of 1986 and by the Technical and Miscellaneous Revenue Act of 1988. The regulations provide the guidance necessary to comply with the law and affect sponsors of, and participants in, tax-qualified retirement plans.

DATES: Written comments must be received by March 15, 1993. Requests to speak (with outlines of oral comments) at a public hearing scheduled for Friday, April 23, 1993, at 10 a.m., and continuing, if necessary, on Monday, April 26, 1993, at 10 a.m., must be received by Friday, April 2, 1993.

ADDRESSES: Please send comments, requests to appear at the public hearing, and outlines of oral comments to be presented at the public hearing to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attn: CC:CORP:T:R (EE–62–92), room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the hearing, Mike Slaughter, Regulations Unit, Assistant Chief Counsel (Corporate), at (202) 622–7190 (not a toll-free number). Concerning the proposed regulations, David Munroe, Patricia McDermott, or Marjorie Hoffman at (202) 622–4606 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On May 14, 1990, the Internal Revenue Service published in the

Federal Register proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 401(a)(4) of the Internal Revenue Code of 1986 (Code) (55 FR 19897). The May 1990 proposed regulations were supplemented and modified by proposed regulations published in the Federal Register on September 14, 1990 (55 FR 37888), and December 3, 1990 (55 FR 49906).

Written comments were received from the public on the proposed regulations, and a public hearing was held on September 26, 27, and 28, 1990. After consideration of the written comments received and the statements made at the public hearing, the proposed regulations under section 401(a)(4) were adopted as modified by final regulations (T.D. 8360) published in the Federal Register on September 19, 1991 (56 FR 47524).

On August 10, 1992, the Internal Revenue Service published in the Federal Register (57 FR 35536) proposed regulations to extend the effective date of the final regulations under section 401(a)(4) and related regulations, generally to plan years beginning on or after January 1, 1994. The purpose of this extension was to provide additional time for employers and practitioners to review the September 1991 final regulations and to provide the Treasury and the Service with comments and suggestions with regard to the regulations. In addition, the extension was to provide the Treasury and the Service with time to consider those comments and to propose modifications to simplify the final regulations and otherwise facilitate compliance with the nondiscrimination requirements.

Coordination With Other Regulations

The regulations under section 401(a)(4) were developed in conjunction with regulations under related statutory nondiscrimination provisions governing tax-qualified retirement plans, principally sections 401(a)(17), 401(a)(26), 401(*l*), 410(b), and 414(s). Together, these regulations provide coordinated and comprehensive guidance on those statutory provisions.

This coordinated approach to the nondiscrimination requirements was initially adopted in developing the May 1990 proposed regulations and is intended to provide taxpayers with an integrated framework for applying the nondiscrimination provisions of the Code. In addition, this approach made it possible to simplify many of the related nondiscrimination rules. For example, the development of the rules under section 401(a)(4) permitted substantial simplification of the minimum participation rules previously proposed under section 401(a)(26) (finalized as T.D. 8375 on December 4, 1991, 56 FR 63410). Similarly, this approach permitted simplification of the early termination restrictions contained in final regulations under section 1.401–4 and of previously-published proposed regulations under the permitted disparity rules of section 401(*l*), the minimum coverage rules of section 410(b), and the definition of compensation under section 414(s).

Obsolescence of Prior Revenue Rulings

Prior to the development of a comprehensive set of nondiscrimination regulations, the nondiscrimination requirements were set forth in a variety of regulations, revenue rulings, and other administrative guidance published over the years. The development of a comprehensive set of nondiscrimination regulations achieves additional simplification by consolidating the nondiscrimination requirements into one set of documents, thereby allowing the obsolescence of much of the prior guidance. An announcement is being issued simultaneously with these regulations identifying the guidance that the Treasury and the Service propose to obsolete when these regulations are effective. That announcement also solicits comments on the proposal.

Explanation of Provisions

1. Development of Regulations

A number of significant comments have been made by employers, practitioners, and other interested parties since publication of the September 1991 regulations. After considering these comments, the Treasury and the Service published several proposals to modify the September 1991 regulations and requested comments on the proposals in order to assist in the development of these proposed amendments to the regulations. Announcement 92–81, 1992–22 I.R.B. 56, contained a proposed revenue procedure reducing the frequency of testing where appropriate and describing the quality of data that may be used to substantiate compliance with the nondiscrimination regulations. Notices 92–31 and 92–32, 1992–29 I.R.B. 6 and 9, respectively, proposed changes designed to increase the number of plans that can use the regulatory safe harbors to demonstrate nondiscrimination in the amount of benefits. Finally, Notice 92–37, 1992–36 I.R.B. 16, proposed changes designed to simplify the general testing alternative for determining whether the amount of benefits provided under a defined benefit plan is nondiscriminatory and to enhance the predictability of that test.

In general, the proposals described in Notices 92–31, 92–32, and 92–37 have been incorporated in these proposed regulations, after taking into consideration public comments. However, certain of the proposals described in those notices are not included in these proposed regulations. In particular, the safe harbor for PIA offset plans described in Notice 92–32 and the expansion of the imputed compensation rules described in Notices 92–31 and 92–37 primarily involve the regulations under sections 401(*l*) and 414(s), respectively, and will be reflected in forthcoming modifications to those regulations. Similarly, after taking into account comments, the proposals in Announcement 92–81 will be issued in a final revenue procedure.

Significant comments also have been received on the September 1991 regulations under the related statutory provisions including, for example, the regulations under section 410(b). These comments will be taken into account in forthcoming modifications to those regulations.

As part of an ongoing effort to reduce taxpayer burden, the Treasury and the Service have also reviewed the September 1991 regulations generally to identify those areas where the regulations could be simplified or clarified. Accordingly, these proposed regulations contain a number of changes that eliminate detailed rules and increase flexibility, while retaining the basic nondiscrimination requirements of the regulations.

2. Overview of Regulations and Summary of Significant Modifications to Final Regulations

Section 401(a)(4) provides generally that a plan is a qualified plan only if the contributions or the benefits provided under the plan do not discriminate in favor of highly compensated employees. As under the final regulations, the rules in these proposed regulations are the exclusive rules for determining whether this requirement is met. A plan, therefore, will satisfy section 401(a)(4) only if it complies both in form and in operation with the rules in these regulations.

In general, these proposed regulations retain the structure of the September 1991 regulations. Section 1.401(a)(4)-1 of the regulations set forth the three general requirements a plan must meet to satisfy section 401(a)(4) and provides rules on how these requirements are applied. This section also provides that most collectively bargained plans (including governmental collectively

bargained plans) automatically satisfy the requirements of section 401(a)(4).

The first general requirement under section 401(a)(4) is that either the contributions or the benefits provided under a plan must be nondiscriminatory in amount. A plan generally is permitted under the regulations to satisfy this requirement on the basis of either contributions or benefits, regardless of whether the plan is a defined contribution plan or a defined benefit plan.

The second general requirement is that the benefits, rights, and features provided under the plan must be made available to employees in the plan in a nondiscriminatory manner. The benefits, rights, and features subject to this requirement are optional forms of benefit (such as retirement annuities and single sum payments), ancillary benefits (such as disability benefits), and other rights and features (such as plan loans and investment options).

The third general requirement is that the effect of plan amendments (including grants of past service credit) and plan terminations must be nondiscriminatory.

3. Nondiscrimination in Amount of Contributions or Benefits

The regulations retain two basic testing alternatives for determining nondiscrimination in amounts. Safe-harbor testing, which focuses primarily on the provisions of the plan, provides designed-based or simplified testing methods for plans with essentially uniform benefits. General testing provides a more flexible approach, permitting plans with greater diversity in contributions or benefits to demonstrate that, despite this diversity, the benefits under the plan do not result in discrimination in operation.

a. Changes Affecting Both Safe Harbor and General Testing

The proposed regulations include a number of broad modifications that affect both the safe-harbor and general testing approaches. The most significant of these changes include the incorporation of the proposals set forth in Notices 92–31 and 92–37 regarding service crediting. In response to comments, the regulations amplify and provide examples illustrating these service-crediting proposals.

In general, these proposed regulations modify the final regulations to allow defined benefit plans to recognize service with another employer or during a leave of absence in a wide range of circumstances provided certain basic facts and circumstances standards are met. These standards are (i) that all similarly-situated employees are treated in the same manner, (ii) that there is a legitimate business purpose for crediting the service, and (iii) that the crediting of the service does not discriminate significantly in favor of highly compensated employees. Consistent with this approach, the regulations provide that employees receiving ongoing service credit in these circumstances will be treated as active employees and not former employees for purposes of nondiscriminatory amounts testing. To the extent that the analysis contained in Rev. Rul. 73–238, 1973–1 C.B. 143, conflicts with the provisions of these regulations that permit the imputation of service, the revenue ruling will be modified. In connection with the expansion of the service-crediting provisions, the proposed regulations also expand the circumstances in which benefits under a defined benefit plan are determined without regard to offsets of benefits under other plans. These include defined benefit plans that offset benefits by benefits previously accrued under another qualified defined benefit plan, a defined contribution plan, or a foreign plan for which there is a reasonable expectation that the benefits will be paid. In general, the rules for service crediting and offsets are contained in § 1.401(a)(4)-11. The regulations also add a grandfather rule for service credited prior to the effective date of the regulations under a plan provision adopted and in effect as of February 11, 1993.

The proposed regulations liberalize the fresh-start rules in § 1.401(a)(4)-13, which permit benefits before a particular date to be disregarded for testing purposes, by incorporating the proposals set forth in Notices 92–31 and 92–37. Thus, the proposed regulations permit plans to disregard certain increases in benefits that results from increases in compensation after a fresh start. In contrast, the September 1991 regulations provide this option only when the fresh start precedes the effective date of the regulations. In addition, the rules have been modified to allow a fresh start to be limited solely to a group of employees acquired in a merger or acquisition. Finally, in the case of a safe harbor plan or an acquired group of employees, the rules have been expanded to allow a fresh start on any date within a plan year (rather than only on the last day of a plan year).

The proposed regulations preserve the general requirement that compensation be determined by averaging over a period of at least three consecutive years. However, the regulations make a number of changes to increase flexibility in defining average annual compensation. These include permitting the use of nonconsecutive years in determining average compensation under any plan that does not use permitted disparity, permitting a plan to determine average compensation by taking into account less than ten years of compensation history, and liberalizing the rules permitting certain periods to be disregarded in determining average compensation.

In addition, the proposed regulations clarify a number of other issues that have arisen since the publication of the September 1991 regulations and that affect both safe-harbor testing and general testing. For example, additional guidance is provided on testing early retirement window benefits, including a special rule that allows a plan that provides an early retirement window benefit to avoid demonstrating that it would satisfy the average benefits percentage test if the plan would not need to satisfy that test in the absence of the window benefit. In addition, the regulations confirm that qualified disability benefits are not taken into account in determining whether the amount of benefits provided under a plan is nondiscriminatory. However, the regulations include an optional rule permitting certain qualified disability benefits to be treated as accrued benefits for testing purposes, and thus to be counted in the nondiscriminatory amount tests, if the disabled employee returns to service with the employer. Finally, the definition of uniform normal retirement age has been amended to clarify that a plan may treat social security retirement age as the normal retirement age for purposes of the nondiscriminatory amount tests if all employees in the plan (or, if applicable, the component plan) have the same social security retirement age.

b. Cashanges Affecting Safe-Harbor Testing

Sections 1.401(a)(4)–2 and 1.401(a)(4)–3 of the proposed regulations, which provide rules for testing nondiscrimination in the amount of contributions or benefits, respectively, contain several safe-harbor testing alternatives that are design-based or rely on simplified testing. In addition to the changes noted above, other proposed modifications would increase the number of plans that satisfy the safe harbors. These include the elimination of the uniform vesting and service-crediting requirements and a provision permitting the use of a safe harbor by a plan that has nonuniform benefits solely because it provides lower benefits to highly compensated employees than to

other employees. The latter change, in conjunction with the restructuring rules of § 1.401(a)(4)–9, accommodates situations in which certain employees (e.g., transferred employees) are receiving compensation adjustments based on their compensation with the employer or another employer, but not service credits. Such a plan will remain in the safe harbor if it satisfies section 410(b) after treating as not benefiting under the plan any nonhighly compensated employees receiving only these compensation adjustments.

c. Changes Affecting General Testing

Both §§ 1.401(a)(4)–2 and 1.401(a)(4)–3 of the proposed regulations retain the general-test approach to demonstrating nondiscrimination in the amount of contributions or benefits. In general, this approach focuses on the actual allocation or accrual rates provided to employees in the plan and compares the rates in determining whether the plan discriminates in favor of highly compensated employees.

In addition to the changes noted above (relating to service crediting, fresh starts, and determination of average annual compensation), these proposed regulations include the additional revisions to this testing approach proposed in Notice 92–37. Thus, the proposed regulations add a facts-and-circumstances safety valve for an otherwise nondiscriminatory defined benefit plan that fails the general test by a relatively small margin, expand access to grouping alternatives for accrual and allocation rates, and enlarge the bands for grouping most valuable accrual rates.

In addition to the proposals made in Notice 92–37, these proposed regulations contain a number of other modifications that are designed to increase flexibility in the general test. For example, the proposed regulations eliminate the detailed, step-by-step procedures prescribed by the September 1991 regulations for determining accrual rates. Under the proposed regulations, plans are no longer limited to using those procedures, and may instead be tested using any reasonable method consistent with basic principles described in the regulations. These principles are generally the same as the basic principles underlying the methods for determining accrual rates in the September 1991 regulations. In connection with these changes, references to the annual method, accrued-to-date method, and projected method of determining accrual rates have been replaced by references to the "measured period", which can be any of three alternative periods corresponding to the three alternative methods. In addition, the proposed regulations allow certain defined benefit plans to recognize the section 415 limitations in testing.

Because the changes to the general test both increase flexibility and substantially reduce the sensitivity of the general test to relatively minor differences in accrual rates, it also has been possible to simplify the general test by eliminating certain potential adjustments in the determination of accrual rates, such as the floor on most valuable accrual rates and the disability adjustment factor. In addition, because the general test and the safe harbors have been made more flexible and accessible, the need for the alternative general test, which tests only most valuable accrual rates, has been greatly reduced, and therefore the alternative test has been eliminated.

4. Nondiscrimination in Availability of Benefits, Rights, and Features

In general, § 401(a)(4)-4 of the proposed regulations retains the requirement that optional forms of benefit, ancillary benefits, and other rights and features be currently available to a group of employees that satisfies the nondiscriminatory classification requirement of section 410(b) without regard to the average benefit percentage test. In addition, the group of employees to whom these benefits, rights, and features are effectively available must not substantially favor highly compensated employees.

The September 1991 regulations contain a special merger and acquisition rule under which optional forms of benefit and other rights and features resulting from such a transaction may be treated as satisfying the nondiscrimination requirements on an ongoing basis. The proposed regulations liberalize this rule in three ways. First, the rule is extended to ancillary benefits. Second, the rule is simplified by providing that the nondiscrimination requirements must be met only once, on any date selected by the employer that is after the transaction and within the section 410(b)(6)(C) transition period. Third, the rule is extended to benefits that have been amended in certain circumstances.

The September 1991 regulation also contain a grandfather rule that deems optional forms of benefit or other rights and features eliminated for prospective accruals to satisfy the nondiscrimination requirements permanently provided that they do so as of the date of elimination. The proposed regulations expand this rule to cover certain ancillary benefits. In addition, the rule would treat a benefit, right, or feature as prospectively eliminated for this purpose even if the benefits to which it relates include compensation adjustment after a fresh start and would extend the special rule for plan loans in the September 1991 regulations to all benefits, rights, and features that are not section 411(d)(6)-protected benefits.

Other modifications to § 1.401(a)(4)–4 include relief relating to qualified participants under the section 401(a)(28)(B) investment diversification requirements for employee stock ownership plans (ESOPs), unpredictable contingent event benefits, and benefits, rights and features available solely to employees with accrued benefits below a threshold specified in the plan. The proposed regulations also clarify that a plan's vesting and service-crediting provisions are not tested under section 1.401(a)(4)–4, but rather under the vesting and service-crediting rules of § 1.401(a)–11.

5. Nondiscrimination Testing of Plan Amendments and Plan Termination

Section 1.401(a)(4)–5 of the proposed regulations retains the facts-and-circumstances testing of the effect of plan amendments and retains the basic pre-termination restrictions. However, the proposed regulations clarify that the nondiscrimination analysis for plan amendments focuses on whether the timing of a plan amendment or series of amendments discriminates significantly in favor of highly compensated employees or highly compensated former employees. The provisions regarding pre-termination restrictions on payments to certain highly compensated employees have been modified to eliminate the specific requirements for determining the plan's funded status for this purpose, and clarified in certain respects, e.g., to reflect the fact that the restrictions need only be applied to the 25 employees with the largest amount of compensation as determined on an employer-wide, rather than a plan-by-plan, basis.

6. Employee Contributions in Defined Benefit Plans

Section 1.401(a)(4)–6 of the proposed regulations retains rules for defined benefit plans that include employee contributions. In general, benefits from employer contributions must be tested separately from those derived from employee contributions. In order to facilitate nondiscrimination testing, the proposed regulations preserve the simplified alternatives to the section 411(c) method for determining the portion of the benefit derived from

employer contributions. The proposed regulations also revise the testing process for a plan with step-rate employee contributions by permitting separate adjustments to the base and the excess benefit rates under the plan, thereby allowing the plan to satisfy section 401(l) and, thus, a safe harbor.

7. Imputation of Permitted Disparity

Section 1.401(a)(4)–7 retains the rules for taking permitted disparity into account in general testing. Proposed modifications to § 1.401(a)(4)–7 allow a defined benefit plan to impute less than the full permitted disparity and clarify that disparity cannot be imputed for employees with negative accrual rate. The elimination of the required step-by-step procedure for determining accrual rates in § 1.401(a)(4)–3 has led to the elimination of certain related rules from § 1.401(a)(4)–7. However, the principles underlying those rules have been retained and, hence, the amount of permitted disparity that can be imputed under the proposed regulations will generally be the same as determined under the September 1991 regulations.

8. Cross-Testing

Several revisions simplify the rules in § 1.401(a)(4)–8 for cross-testing defined benefit plans on a contributions basis and defined contribution plans on a benefits basis. These revisions include the replacement of the special rules for employees beyond testing age with a basic rule protecting a defined contribution plan from failing the nondiscriminatory amount requirement on a cross-tested basis merely because contributions continue to be made after normal retirement age at the same rate. In addition, the safe harbor testing rules for target benefit plans have been modified to eliminate the requirement that the stated benefit formula follow the fresh-start rules in § 1.401(a)(4)–13. Furthermore, the follow-offset plan rules have been modified to allow use of ESOPs as offset plans (to the extent permitted under ERISA).

The September 1991 regulations in §§ 1.401(a)(4)–8 and 1.401(a)(4)–13 also provide safe harbor testing rules for cash balance plans. These rules generated significant comment, which the Treasury and the Service are continuing to review. Consequently, amendments to the safe harbor testing rules for cash balance plans are not provided at this time.

9. Plan Aggregation and Disaggregation

Section 1.401(a)(4)–9 generally retains the plan aggregation and disaggregation provisions. However, a number of relatively minor simplifying and clarifying revisions have been made.

10. Nondiscrimination Testing of Former Employees

These proposed regulations continue to provide for separate testing of former employees in § 1.401(a)(4)–10. However, they significantly simplify this testing by eliminating the objective standards prescribed by the September 1991 regulations. Under the modified rules, the amount of contributions or benefits and the availability of benefits, rights, and features provided to former employees will be nondiscriminatory if all of the relevant facts and circumstances show that the plan does not discriminate significantly in favor of highly compensated former employees. As noted above, the definition of employee has been changed in a manner consistent with other proposed modifications to treat individuals receiving allocations or accruals based on ongoing compensation or service credits as employees and not former employees.

11. Additional Rules

The additional rules in § 1.401(a)(4)–11, including the ability to make a retroactive correction to a plan, have been retained. In addition to expanding the rules on vesting and service crediting, as described above, the proposed regulations add provisions relating to the treatment of employee payments to a defined benefit plan to repay a prior distribution (in order to restore the employee's prior accrued benefit) or to make up missed employee contributions.

12. Definitions

As in the September 1991 regulations, § 1.401(a)(4)–12 of the proposed regulations contains a number of important definitions used in applying the rules contained in the regulations. However, there have been some modifications to these definitions in connection with other changes to the regulation. For example, in certain circumstances, the definition of uniform normal retirement age permits the use of a service definition other than an anniversary of commencement of participation.

13. Proposed Effective Dates

The regulations would be generally effective for plan years beginning on or after January 1, 1994, or, in the case of governmental plans and plans maintained by tax-exempt organizations, for plan years beginning on or after January 1, 1996. For plan years beginning on or after the first day of the first plan year to which the amendments made by section 1112(a) of TRA '86 apply to a plan and before the applicable regulatory effective date, § 1.4019(a)(4)–13 provides that a plan must be operated in accordance with a reasonable, good faith interpretation of the requirements of section 401(a)(4), taking into account pre-existing guidance and the amendments made by TRA '86 to related Code provisions, such as sections 401(*l*), 401(a)(17), and 401(b). Whether compliance is reasonable and in good faith will generally be determined on the basis of all relevant facts and circumstances, including the extent to which the employer has consistently resolved unclear issues in its favor. Reasonable, good faith compliance will be deemed to exist, however, if a plan is operated in accordance with the 1990 proposed regulations, the September 1991 regulations, or these proposed regulations.

In Notice 92–36, 1992–35 I.R.B. 12, the Service provided transition relief and extended the date by which plan amendments to comply with TRA '86 must be made generally until the close of the first plan year for which these regulations are effective. This extended amendment date and related transition relief, combined with the reasonable, good faith compliance standard contained in these regulations, is designed to ensure that plan sponsors have a reasonable period in which to amend qualified plans.

Governmental Plans

The proposed regulations retain the special transition rule for governmental plans. Thus, section 401(a)(4) is deemed satisfied in the case of governmental plans described in section 414(d) for plan years beginning before 1996. Some commentators have suggested that governmental plans should not be subject to nondiscrimination testing. However, in the absence of statutory provisions excepting governmental plans from these requirements, the regulations recognize their applicability. Nevertheless, the Treasury and the Service recognize that governmental plans may have certain unique features relating to the sponsoring employer's status as a governmental entity. Comments have been received on such features, and additional comments are specifically requested from governmental employers regarding appropriate modifications to the regulations to take into account the operation of governmental plans.

Plans Maintained by More Than One Employer

Multiple employer plans must satisfy section 401(a)(4) on an employer-by-employer basis rather than on the basis of participating employers in the aggregate. Any non-collectively bargained portion of a multiemployer plan is tested as a multiple employer plan. The consequences of failure to satisfy section 401(a)(4) with respect to any component of this testing process may affect the plan for all participating employers. The regulations do not provide an exception to this rule. However, where a multiemployer plan or a multiple employer plan fails to satisfy section 401(a)(4), the Commissioner could, in a proper case, treat the plan as satisfying section 401(a)(4) for innocent employers by requiring corrective and remedial action with respect to the plan. Such remedial action could include allowing the withdrawal of an offending employer, allowing a disqualifying defect to be cured within a reasonable period of time after the plan administrator has or should have knowledge of the disqualifying event or was otherwise notified by the Service of the disqualifying defect, or requiring plan amendments to prevent future disqualifying events.

Effect on Other Laws

Compliance with the provisions of this regulation does not ensure compliance with other applicable Federal laws, including, but not limited to, the provisions of Title I of the Employee Retirement Income Security Act of 1974, which are administered by the Secretary of Labor pursuant to Reorganization Plan Number 4 of 1978. Employers should note that plan amendments pursuant to this regulation may necessitate reporting and disclosure under that Act, including requirements relating to summary plan description and summaries of material modifications.

Additional Authority

The regulations provide that the Commissioner may, in revenue rulings, notices, and other guidance of general applicability, provide any additional rules that may be necessary or appropriate in applying the nondiscrimination requirements of section 401(a)(4).

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Requests to Appear at the Public Hearing

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted timely (preferably a signed original and eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying in their entirety. Because the Treasury Department expects to issue final regulations on this matter as soon as possible, a public hearing will be held at 10 a.m. on April 23, 1993, and continuing, if necessary, on April 26, 1993, in the I.R.S. Auditorium, Seventh Floor, 7400 Corridor, Internal Revenue Service, 1111 Constitution Ave., NW., Washington, DC. Comments must be received by March 15, 1993. Requests to speak (with outlines of oral comments) must be received by April 2, 1993. See notice of hearing published elsewhere in this issue of the **Federal Register**.

Drafting Information

The principal authors of these proposed regulations are Nancy J. Marks, David Munroe, Marjorie Hoffman, and Patricia McDermott of the Office of the Associate Chief Counsel (Employee Benefits and Exempt Organizations), Internal Revenue Service. However, personnel from other offices of the Service and Treasury Department participated in their development.

List of Subjects in 26 CFR 1.401–0 Through 1.419A–2T

Bonds, Employee benefit plans, Income taxes, Pensions, Reporting and recordkeeping requirements, Securities, Trusts and trustees.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805 * * *

Paragraph 2. Sections 1.401(a)(4)–0 through 1.401(a)(4)–8(c)(2)(iii) and §§ 1.401(a)(4)–8(d) through 1.401(a)(4)–13(e)(2) are revised and § 1.401(a)(4)–8(c)(2)(iv) is added to read as follows:

§ 1.401(a)(4)–0 Table of contents.

This section contains a listing of the major headings of §§ 1.401(a)(4)–1 through 1.401(a)(4)–13.

§ 1.401(a)(4)–1 Nondiscrimination Requirements of Section 401(a)(4)

(a) In general.
(b) Requirements a plan must satisfy.
  (1) In general.
  (2) Nondiscriminatory amount of contributions or benefits.
  (3) Nondiscriminatory availability of benefits, rights, and features.
  (4) Nondiscriminatory effect of plan amendments and terminations.
(c) Application of requirements.
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§ 1.401(a)(4)–2 Nondiscrimination in Amount of Employer Contributions Under a Defined Contribution Plan

(a) Introduction.
  (1) Overview.
  (2) Alternative methods of satisfying nondiscriminatory amount requirement.
(b) Safe harbors.
  (1) In general.
  (2) Safe harbor for plans with uniform allocation formula.
  (3) Safe harbor for plans with uniform points allocation formula.
  (4) Use of safe harbors not precluded by certain plan provisions.
(c) General test for nondiscrimination in amount of contributions.
  (1) General rule.
  (2) Determination of allocation rates.
  (3) Satisfaction of section 410(b) by a rate group.
  (4) Examples.

§ 1.401(a)(4)–3 Nondiscrimination in Amount of Employer-Provided Benefits Under a Defined Benefit Plan

(a) Introduction.
  (1) Overview.
  (2) Alternative methods of satisfying nondiscriminatory amount requirement.
(b) Safe harbors.
  (1) In general.

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(2) Uniformity requirements.
(3) Safe harbor for unit credit plans.
(4) Safe harbor for plans using fractional accrual rule.
(5) Safe harbor for insurance contract plans.
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(c) General test for nondiscrimination in amount of benefits.
(1) General rule.
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(3) Certain violations disregarded.
(4) Examples.
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(1) Definitions.
(2) Rules of application.
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(4) Early retirement window benefits.
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(8) Adjustment for certain QPSA charges.
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§ 1.401(a)(4)–4 Nondiscriminatory Availability of Benefits, Rights, and Features

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§ 1.401(a)(4)–9 Plan Aggregation and Restructuring

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(b) Application of nondiscrimination requirements to DB/DC plans.
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(2) Special rules for demonstrating nondiscrimination in amount of contributions or benefits.
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(2) Identification of component plans.
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§ 1.401(a)(4)–10 Testing of Former Employees

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§ 1.401(a)(4)–11 Additional Rules

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§ 1.401(a)(4)–1 Nondiscrimination requirements of section 401(a)(4).

(a) *In general.* Section 401(a)(4) provides that a plan is a qualified plan only if the contributions or the benefits provided under the plan do not discriminate in favor of HCEs. Whether a plan satisfies this requirement depends on the form of the plan and on its effect in operation. In making this determination, intent is irrelevant. This section sets forth the exclusive rules for determining whether a plan satisfies section 401(a)(4). A plan that complies in form and operation with the rules in this section therefore satisfies section 401(a)(4).

(b) *Requirements a plan must satisfy*—(1) *In general.* In order to satisfy section 401(a)(4), a plan must satisfy each of the requirements of this paragraph (b).

(2) *Nondiscriminatory amount of contributions or benefits*—(i) *General rule.* Either the contributions or the benefits provided under the plan must be nondiscriminatory in amount. It need not be shown that both the contributions and the benefits provided are nondiscriminatory in amount, but only that either the contributions alone or the benefits alone are nondiscriminatory in amount.

(ii) *Defined contribution plans*—(A) *General rule.* A defined contribution plan satisfies this paragraph (b)(2) if the contributions allocated under the plan (including forfeitures) are nondiscriminatory in amount under § 1.401(a)(4)–2. Alternatively, a defined contribution plan (other than an ESOP) satisfies this paragraph (b)(2) if the equivalent benefits provided under the plan are nondiscriminatory in amount under § 1.401(a)(4)–8(b). Section 1.401(a)(4)–8(b) includes a safe-harbor testing method for contributions provided under a target benefit plan.

(B) *Section 401(k) plans and section 401(m) plans.* A section 401(k) plan is deemed to satisfy this paragraph (b)(2) because § 1.401(b)–9 defines a section 401(k) plan as a plan consisting of elective contributions under a qualified cash or deferred arrangement (i.e., one that satisfies section 401(k)(3), the nondiscriminatory amount requirement applicable to qualified cash or deferred arrangements). A section 401(m) plan satisfies this paragraph (b)(2) only if the plan satisfies § 1.401(m)–1(b) and 1.401(m)–2. Contributions under a nonqualified cash or deferred arrangement, elective contributions described in § 1.401(k)–1(b)(4)(iv) that fail to satisfy the allocation and compensation requirements of § 1.401(k)–1(b)(4)(i), matching contributions that fail to satisfy § 1.401(m)–1(b)(4)(ii)(A), and qualified nonelective contributions treated as elective or matching contributions for certain purposes under §§ 1.401(k)–1(b)(5) and 1.401(m)–1(b)(5), respectively, are not subject to the special rule in this paragraph (b)(2)(ii)(B), because they are not treated as part of a section 401(k) plan or section 401(m) plan as those terms are defined in § 1.410(b)–9. The contributions described in the preceding sentence must satisfy paragraph (b)(2)(ii)(A) of this section.

(iii) *Defined benefit plans.* A defined benefit plan satisfies this paragraph (b)(2) if the benefits provided under the plan are nondiscriminatory in amount under § 1.401(a)(4)–3. Alternatively, a defined benefit plan satisfies this paragraph (b)(2) if the equivalent allocations provided under the plan are nondiscriminatory in amount under § 1.401(a)(4)–8(c). Section 1.401(a)(4)–8(c) includes a safe-harbor testing method for benefits provided under a cash balance plan. In addition, § 1.401(a)(4)–8(d) provides a safe-harbor testing method for benefits provided under a defined benefit plan that is part of a floor-offset arrangement.

(3) *Nondiscriminatory availability of benefits, rights, and features.* All benefits, rights, and features provided under the plan must be made available in the plan in a nondiscriminatory manner. Rules for determining whether this requirement is satisfied are set forth in § 1.401(a)(4)–4.

(4) *Nondiscriminatory effect of plan amendments and terminations.* The timing of plan amendments must not have the effect of discriminating significantly in favor of HCEs. Rules for determining whether this requirement is satisfied are set forth in § 1.401(a)(4)–5(a). Section § 1.401(a)(4)–5(b) provides additional requirements regarding plan terminations.

(c) *Application of requirements*—(1) *In general.* The requirements of paragraph (b) of this section must be applied in accordance with the rules set forth in this paragraph (c).

(2) *Interpretation.* The provisions of §§ 1.401(a)(4)–1 through 1.401(a)(4)–13 must be interpreted in a reasonable manner consistent with the purpose of preventing discrimination in favor of HCEs.

(3) *Plan-year basis of testing.* The requirements of paragraph (b) of this section are generally applied on the basis of the plan year and on the basis of the terms of the plan in effect during the plan year. Thus, unless otherwise provided, the compensation, contributions, benefit accruals, and other items used to apply these requirements must be determined with respect to the plan year being tested. However, § 1.401(a)(4)–11(g) provides rules allowing a plan to be amended retroactively after the close of the plan year to satisfy certain requirements under paragraph (b) of this section.

(4) *Application of section 410(b) rules*—(i) *Relationship between sections 401(a)(4) and 410(b).* To be a qualified plan, a plan must satisfy both sections 410(b) and 401(a)(4). Section 410(b) requires that a plan benefit a nondiscriminatory group of employees, and section 401(a)(4) requires that the contributions or benefits provided to employees benefiting under the plan not discriminate in favor of HCEs. Consistent with this requirement, the definition of a plan subject to testing under section 401(a)(4) is the same as the definition of a plan subject to testing under section 410(b), i.e., the plan determined after applying the mandatory disaggregation rules of § 1.410(b)–7(c) and the permissive aggregation rules of § 1.410(b)–7(d). In addition, whichever testing option is used for the plan year under § 1.410(b)–8(a) (e.g, quarterly testing) must also be used for purposes of determining whether the plan satisfies section 401(a)(4) for the plan year.

(ii) *Special rules for certain aggregated plans.* Special rules are set forth in § 1.401(a)(4)–9(b) for applying the nondiscriminatory amount and availability requirements of paragraphs (b)(2) and (b)(3) of this section to a plan that includes one or more defined benefit plans and one or more defined contribution plans that have been permissively aggregated under § 1.410(b)–7(d).

(iii) *Restructuring.* In certain circumstances, a plan may be restructured on the basis of employee groups and treated as comprising two or more plans, each of which is treated as a separate plan that must independently satisfy sections 401(a)(4) and 410(b). Rules relating to restructuring plans for purposes of applying the requirements of paragraph (b) of this section are set forth in § 1.401(a)(4)–9(c).

(iv) *References to section 410(b).* Except as otherwise specifically provided, references to satisfying section 410(b) in §§ 1.401(a)(4)–1 through 1.401(a)(4)–13 mean satisfying § 1.410(b)–2 (taking into account any special rules available in satisfying that section, other than the permissive aggregation rules of § 1.410(b)–7(d)). In the case of a plan described in section 410(c)(1) that has not made the election described in section 410(d) and is not subject to section 403(b)(12)(A)(i), references in §§ 1.410(a)(4)–1 through 1.401(a)(4)–13 to satisfying section 410(b) mean satisfying section 410(c)(2).

(5) *Collectively-bargained plans.* The requirements of paragraph (b) of this section are treated as satisfied by a collectively-bargained plan that automatically satisfies section 410(b) under § 1.410(b)–2(b)(7).

(6) *Former employees.* In applying the nondiscriminatory amount and availability requirements of paragraphs (b)(2) and (b)(3) of this section, former employees are tested separately from active employees, unless otherwise provided. Rules for applying paragraphs (b)(2) and (b)(3) of this section to former employees are set forth in § 1.401(a)(4)–10.

(7) *Employee-provided contributions and benefits.* In applying the nondiscriminatory amount requirement of paragraph (b)(2) of this section, employee-provided contributions and benefits are tested separately from employer-provided contributions and benefits, unless otherwise provided. Rules for determining the amount of employer-provided benefits under a defined benefit plan that includes employee contributions not allocated to separate accounts are set forth in § 1.401(a)(4)–6(b), and rules for applying paragraph (b)(2) of this section to employee contributions under such a plan are set forth in § 1.401(a)(4)–6(c). See paragraph (b)(2)(ii)(B) of this section for rules applicable to employee contributions allocated to separate accounts.

(8) *Allocation of earnings.* Notwithstanding any other provision in §§ 1.401(a)(4)–1 through 1.401(a)(4)–13, a defined contribution plan does not satisfy paragraph (b)(2) of this section if the manner in which income, expenses, gains, or losses are allocated to accounts under the plan discriminates in favor of HCEs or former HCEs.

(9) *Rollovers, transfers, and buybacks.* In applying the requirements of paragraph (b) of this section, rollover (including direct rollover) contributions described in section 402(c), 402(e)(6), 403(a)(4), 403(a)(5), or 408(d)(3), elective transfers described in § 1.411(d)–4, Q&A–3(b), transfers of assets and liabilities described in section 414(*l*), and employee buybacks are treated in accordance with the rules set forth in § 1.401(a)(4)–11(b).

(10) *Vesting.* A plan does not satisfy the nondiscriminatory amount requirement of paragraph (b)(2) of this section unless it satisfies § 1.401(a)(4)–11(c) with respect to the manner in which employees vest in their accrued benefits.

(11) *Crediting service.* A plan does not satisfy paragraphs (b)(2) and (b)(3) of this section unless it satisfies § 1.401(a)(4)–11(d) with respect to the manner in which employee's service is credited under the plan. Service other than actual service with the employer may not be taken into account in determining whether the plan satisfies paragraphs (b)(2) and (b)(3) of this section except as provided in § 1.401(a)(4)–11(d).

(12) *Governmental plans.* The rules of this section apply to a governmental plan within the meaning of section 414(d), except as provided in §§ 1.401(a)(4)–11(f) and 1.401(a)(4)–13(b).

(13) *Employee stock ownership plans.* [Reserved]

(14) *Section 401(h) benefits.* In applying the requirements of paragraph (b) of this section, the portion of a plan providing benefits described in section 401(h) is tested separately from the portion of the same plan providing retirement benefits, and thus is not required to satisfy this section. Rules applicable to section 401(h) benefits are set forth in § 1.401–14(b)(2).

(15) *Definitions.* In applying the requirements of this section, the definitions in § 1.401(a)(4)–12 govern.

(16) *Effective dates and fresh-start rules.* In applying the requirements of this section, the effective dates set forth in § 1.401(a)(4)–13 govern. Section 1.401(a)(4)–13 also provides certain transition and fresh-start rules that apply for purposes of this section.

(d) *Additional rules.* The Commissioner may, in revenue rulings, notices, and other guidance of general applicability, published in the Internal Revenue Bulletin, provide any additional rules that may be necessary or appropriate in applying the nondiscrimination requirements of section 401(a)(4). See § 601.601(d)(2)(ii)(*b*) of this chapter.

§ 1.401(a)(4)–2 Nondiscrimination in amount of employer contributions under a defined contribution plan.

(a) *Introduction*—(1) *Overview.* This section provides rules for determining whether the employer contributions allocated under a defined contribution plan are nondiscriminatory in amount as required by § 1.401(a)(4)–1(b)(2)(ii)(A). Certain defined contribution plans that provide uniform allocations are permitted to satisfy this requirement by meeting one of the safe harbors in paragraph (b) of this section. Plans that do not provide uniform allocations may satisfy this requirement by satisfying the general test in paragraph (c) of this section. See § 1.401(a)(4)–(b)(2)(ii)(B) for the exclusive tests applicable to section 401(k) plans and section 401(m) plans.

(2) *Alternative methods of satisfying nondiscriminatory amount requirement.* A defined contribution plan is permitted to satisfy paragraph (b)(2) or (c) of this section on a restructured basis pursuant to § 1.401(a)(4)–9(c). Alternatively, a defined contribution plan (other than an ESOP) is permitted to satisfy the nondiscriminatory amount requirement of § 1.401(a)(4)–1(b)(2)(ii)(A) on the basis of equivalent benefits pursuant to § 1.401(a)(4)–8(b).

(b) *SAFE harbors*—(1) *In general.* The employer contributions allocated under a defined contribution plan are nondiscriminatory in amount for a plan year if the plan satisfies either of the safe harbors in paragraph (b)(2) or (b)(3) of this section. Paragraph (b)(4) of this section provides exceptions for certain plan provisions that do not cause a plan to fail to satisfy this paragraph (b).

(2) *Safe harbor for plans with uniform allocation formula*—(i) *General rule.* A defined contribution plan satisfies the safe harbor in this paragraph (b)(2) for a plan year if the plan allocates all amounts taken into account under paragraph (c)(2)(ii) of this section for the plan year under an allocation formula that allocates to each employee the same percentage of plan year compensation, the same dollar amount, or the same dollar amount for each uniform unit of service (not to exceed one week) performed by the employee during the plan year.

(ii) *Permitted disparity.* If a plan satisfies section 401(*l*) in form, differences in employees' allocations under the plan attributable to uniform disparities permitted under § 1.401(*l*)–2 (including differences in disparities that

are deemed uniform under § 1.401(*l*)–2(c)(2)) do not cause the plan to fail to satisfy this paragraph (b)(2).

(3) *Safe harbor for plans with uniform points allocation formula*—(i) *General rule.* A defined contribution plan (other than an ESOP) satisfies the safe harbor in this paragraph (b)(3) for a plan year if its satisfies both of the following requirements:

(A) The plan must allocate amounts under a uniform points allocation formula. A uniform points allocation formula defines each employee's allocation for the plan year as the product of the total of all amounts taken into account under paragraph (c)(2)(ii) of this section and a fraction, the numerator of which is the employee's points for the plan year and the denominator of which is the sum of the points of all employees in the plan for the plan year. For this purpose, an employee's points for a plan year equal the sum of the employee's points for age, service, and units of plan year compensation for the plan year. Under a uniform points allocation formula, each employee must receive the same number of points for each year of age, the same number of points for each year of service, and the same number of points for each unit of plan year compensation. The unit of plan year compensation used in the allocation formula must be a single dollar amount for all employees that does not exceed $200. A uniform points allocation formula need not grant points for both age and service, but it must grant points for at least one of them. If the allocation formula grants points for years of service, the plan is permitted to limit the number of years of service taken into account to a single maximum number of years of service. In all cases, a uniform points allocation formula must grant points for plan year compensation.

(B) For the plan year, the average of the allocation rates for the HCEs in the plan must not exceed the average of the allocation rates for the NHCEs in the plan. For this purpose, allocation rates are determined in accordance with paragraph (c)(2) of this section, without imputing permitted disparity and without grouping allocation rates under paragraph (c)(2)(iv) and (v) of this section.

(ii) *Example.* The following example illustrates the safe harbor in this paragraph (b)(3):

Example. (a) Plan A has a single allocation formula that applies to all employees, under which each employee's allocation for the plan year equals the product of the total of all amounts taken into account for all employees for the plan year under paragraph (c)(2)(ii) of this section and a fraction, the numerator of which is the employee's points for the plan year and the denominator of which is the sum of the points of all employees for the plan year. Plan A grants each employee 10 points for each year of service and one point for each $100 of plan year compensation. For the 1994 plan year, the total allocations are $81,200, and the total points for all employees are 8,120. Each employee's allocation for the 1994 plan year is set forth in the table below.

Employee	Years of service	Plan year compensation	Points	Amount of allocation	Allocation rate (percent)
H1	20	$200,000	2,200	$22,000	11.0
H2	10	200,000	2,100	21,000	10.5
H3	30	100,000	1,300	13,000	13.0
H4	3	100,000	1,030	10,300	10.3
N1	10	40,000	500	5,000	12.5
N2	5	35,000	400	4,000	11.4
N3	3	30,000	330	3,300	11.0
N4	1	25,000	260	2,600	10.4
Total	.....	.....	8,120	$81,200	.....

(b) Under these facts, for the 1994 plan year, Plan A allocates amounts under a uniform points allocation formula within the meaning of paragraph (b)(3)(i)(A) of this section.

(c) For the 1994 plan year, the average allocation rate for the HCEs (H1 through H4) is 11.2 percent, and the average allocation rate for NHCEs (N1 through N4) is 11.3 percent. Because the average of the allocation rates for the HCEs does not exceed the average of the allocation rates for the NHCEs, Plan A satisfies paragraph (b)(3)(i)(B) of this section and, thus, the safe harbor in this paragraph (b)(3) for the 1994 plan year.

(4) *Use of safe harbors not precluded by certain plan provisions*—(i) *In general.* A plan does not fail to satisfy this paragraph (b) merely because the plan contains one or more of the provisions described in this paragraph (b)(4). Unless otherwise provided, any such provision must apply uniformly to all employees.

(ii) *Entry dates.* the plan provides one or more entry dates during the plan year as permitted by section 410(a)(4).

(iii) *Certain conditions on allocations.* The plan provides that an employee's allocation for the plan year is conditioned on the employee's employment on the last day of the plan year or on the employee's completion of a minimum number of hours of service during the plan year (not to exceed 1,000). Such a provision may include an exception from this condition for all employees who terminate employment during the plan year or only for those employees who terminate employment during the plan year on account of one or more of the following circumstances: retirement, disability, death, or military service.

(iv) *Certain limits on allocations.* The plan limits allocations otherwise provided under the allocation formula to a maximum dollar amount or a maximum percentage of plan year compensation, limits the dollar amount of plan year compensation taken into account in determining the amount of allocations, or applies the restrictions of section 409(n) or the limits of section 415.

(v) *Lower allocations for HCEs.* The allocations provided to one or more HCEs under the plan are less than the allocations that would otherwise be provided to those employees if the plan satisfied this paragraph (b) (without regard to this paragraph (b)(4)(v)).

(vi) *Multiple formulas*—(A) *General rule.* The plan provides that an employee's allocation under the plan is the greater of the allocations determined under two or more formulas, or is the sum of the allocations determined under two or more formulas. This paragraph (b)(4)(vi) does not apply to a plan unless each of the formulas under the plan satisfies the requirements of paragraph (b)(4)(vi)(B) through (D) of this section.

(B) *Sole formulas.* The formulas must be the only formulas under the plan.

(C) *Separate testing.* Each of the formulas must separately satisfy this paragraph (b). A formula that is available solely to some or all NHCEs is deemed to satisfy this paragraph (b)(4)(vi)(C).

(B) *Availability*—(1) *General rule.* All of the formulas must be available on the same terms to all employees.

(2) *Formulas for NHCEs.* A formula does not fail to be available on the same terms to all employees merely because the formula is not available to any NCEs, but is available to some or all NHCEs on the same terms as all of the other formulas in the plan.

(3) *Top-heavy formulas.* In the case of a plan that provides the greater of the allocations under two or more formulas, one of which is a top-heavy formula, the top-heavy formula does not fail to be available on the same terms to all employees merely because it is available solely to all non-key employees on the same terms as all the other formulas under the plan. Furthermore, the top-heavy formula does not fail to be available on the same terms as the other formulas under the plan merely because it is conditioned on the plan's being top-heavy within the meaning of section 416(g). Finally, the top-heavy formula does not fail to be available on the same terms as the other formulas under the plan merely because it is available to all employees described in § 1.461–1, Q&A M–10 (i.e., all non-key employees who have not separated from service as of the last day of the plan year). The preceding sentence does not apply, however, unless the plan would satisfy section 410(b) if all employees whose only allocations under the plan are provided under the top-heavy formula were treated as not currently benefiting under the plan. For purposes of this paragraph (b)(4)(vi)(D)(*3*), a top-heavy formula is a formula that provides the minimum benefit described in section 416(c)(2) (taking into account, if applicable, the modification in section 416(h)(2)(A)(ii)(II)).

(E) *Provisions may be applied more than once.* The provisions of this paragraph (b)(4)(vi) may be applied more than once. For example, a plan satisfies this paragraph (b) if an employee's allocation under the plan is the greater of the allocations under two or more formulas, and one or more of those formulas is the sum of the allocations under two or more other formulas, provided that each of the formulas under the plan satisfies the requirements of paragraph (b)(4)(vi)(B) through (D) of this section.

(F) *Examples.* The following examples illustrate the rules in this paragraph (b)(4)(vi):

Example 1. Under Plan A, each employee's allocation equals the sum of the allocations determined under two formulas. The first formula provides an allocation of five percent of plan year compensation. The second formula provides an allocation of $100. Plan A satisfies this paragraph (b)(4)(vi).

Example 2. Under Plan B, each employee's allocation equals the greater of the allocations determined under two formulas. The first formula provides an allocation of seven percent of plan year compensation and is available to all employees who complete at least 1,000 hours of service during the plan year and who have not separated from service as of the last day of the plan year. The second formula is a to-heavy formula that provides an allocation of three percent of plan year compensation and this available to all employees described in § 1.416–1, Q&A M–10. Plan B does not satisfy the general rule in paragraph (b)(4)(vi)(D)(*1*) of this section because the formulas are not available on the same terms to all employees (i.e., an employee is required to complete 1,000 hours of service during the plan year to receive an allocation under the first formula, but not under the second formula). Nonetheless, because he second formula is a top-heavy formula, the special availability rules for top-heavy formulas in paragraph (b)(4)(vi)(D)(*3*) of this section apply. Thus, the second formula does not fail to be available on the same terms as the first formula merely because the second formula is available to all employees described in § 1.416–1, Q&A M–10, as long as the plan would satisfy section 410(b) if all employees whose only allocation under the plan is provided under the second formula were treated as not currently benefiting under the plan. This is true even if the plan conditions the availability of the second formula on the plan's being top-heavy for the plan year.

Example 3. The facts are the same as in *Example 2*, except that the first formula is available to all employees who have not separated from service as of the last day of the plan year, regardless of whether they complete at least 1,000 hours of service during the plan year. Plan B still does not satisfy the general rule in paragraph (b)(4)(vi)(D)(*1*) of this section because the two formulas are not available on the same terms to all employees (i.e., the second formula is only available to all non-key employees). Nonetheless, because the second formula is a top-heavy formula, the special availability rules for top-heavy formulas in paragraph (b)(4)(vi)(D)(*3*) of this section apply. Thus, the second formula does not fail to be available on the same terms as the first formula merely because the second formula is available solely to all non-key employees.

(c) *General test for nondiscrimination in amount of contributions*—(1) *General rule.* The employer contributions allocated under a defined contribution plan are nondiscriminatory in amount for a plan year if each rate group under the plan satisfies section 410(b). For purposes of the paragraph (c), a rate group exists a plan for each HCE and consists of the HCE and all other employees in the plan (both HCEs and NHCEs) who have an allocation rate greater than or equal to the HCE's allocation rate. Thus, an employee is in the rate group for each HCE who has an allocation rate less than or equal to the employee's allocation rate.

(2) *Determination of allocation rates*—(i) *General rule.* The allocation rate of an employee for a plan year equals the sum of the allocations to the employee's account for the plan year, expressed either as percentage of plan year compensation or as a dollar amount.

(ii) *Allocations taken into account.* The amount taken into account in determining allocation rates for a plan year include all employer contributions and forfeitures that are allocated or treated as allocated to the amount of an employee under the plan for the Plan year, other than amounts described in paragraph (c)(2)(iii) of this section. For this purpose, employer contributions include annual additions described in § 1.415–6(b)(2)(i) (regarding amounts arising from certain transactions between the plan and the employer). In the case of a defined contribution plan subject to section 412, an employer contribution is taken into account in the plan year for which it is required to be contributed and allocated to employees' accounts under the plan, even if all or part of the required contribution is not actually made.

(iii) *Allocations not taken into account.* Allocations of income, expenses, gains, and losses attributable to the balance in an employee's account are not taken into account in determining allocation rates.

(iv) *Imputation of permitted disparity.* The disparity permitted under section 401(*l*) may be imputed in accordance with the rules of § 401(a)(4)–7.

(v) *Group of allocation rates*—(A) *General rule.* An employer may treat all employees who have allocation rates within a specified range above and below a midpoint rate chosen by the employer as having an allocation rate equal to the midpoint rate within that range. Allocation rates within a given range may not be grouped under this paragraph (c)(2)(v) if the allocation rates of HCEs within the rang generally are significantly higher than the allocation rates of NHCEs in the range. The specified ranges within which all employees are treated as having the same allocation rate may not overlap and may be no larger than provided in paragraph (c)(2)(v)(B) of this section. Allocation rates of employees that are not within any of these specified ranges are determined without regard to this paragraph (c)(2)(v).

(B) *Size of specified ranges.* The lowest and highest allocation rates in the range must be within five percent (not five percentage points) of the midpoint rate. If allocation rates are determined as a percentage of plan year

compensation, the lowest and highest allocation rates need not be within five percent of the midpoint rate, if they are no more than one quarter of a percentage point above or below the midpoint rate.

(vi) *Consistency requirement.* Allocation rates must be determined in a consistent manner for all employees for the plan year.

(3) *Satisfaction of section 410(b) by a rate group*—(i) *General rule.* For purposes of determining whether a rate group satisfies section 410(b), the rate group is treated as if it were a separate plan that benefits only the employees included in the rate group for the plan year. Thus, for example, under § 1.401(a)(4)–1(c)(4)(iv), the ratio percentage of the rate group is determined taking into account all nonexcludable employees regardless of whether they benefit under the plan. Paragraph (c)(3) (ii) and (iii) of this section provide additional special rules for determining whether a rate group satisfies section 410(b).

(ii) *Application of nondiscriminatory classification test.* A rate group satisfies the nondiscriminatory classification test of § 410(b)–4 (including the reasonable classification requirement of § 1.410(b)–4(b)) if and only if the ratio percentage of the rate group is greater than or equal to the lesser of—

(A) The midpoint between the safe and the unsafe harbor percentages applicable to the plan; and

(B) The ratio percentage of the plan.

(iii) *Application of average benefit percentage test.* A rate group satisfies the average benefit percentage test of § 1.410(b)–5 (without regard to § 1.410(b)–5(f)). In the case of a plan that relies on § 1.410(b)–5(f) to satisfy the average benefit percentage test, each rate group under the plan satisfies the average benefit percentage test (if applicable) only if the rate group separately satisfies § 1.410(b)–5(f).

(4) *Examples.* The following examples illustrate the general test in this paragraph (c):

Example 1. Employer X maintains two defined contribution plans, Plan A and Plan B, that are aggregated and treated as a single plan for purposes of sections 410(b) and 401(a)(4) pursuant to § 1.410(b)–7(d). For the 1994 plan year, Employee M has plan year compensation of $10,000 and receives an allocation of $200 under Plan A and an allocation of $800 under Plan B. Employee M's allocation rate under the aggregated plan for the 1994 plan year is 10 percent (i.e., $1,000 divided by $10,000).

Example 2. The employees in Plan C have the following allocation rates (expressed as a percentage of plan year compensation): 2.75 percent, 2.80 percent, 2.85 percent, 3.25 percent, 6.65 percent, 7.33 percent, 7.34 percent, and 7.35 percent. Because the first four rates are within a range of no more than one quarter of a percentage point above and below 3.0 percent (a midpoint rate chosen by the employer), under paragraph (c)(2)(v) of this section the employer may treat the employees who have those rates as having an allocation rate of 3.0 percent (provided that the allocation rates of HCEs within the range generally are not significantly higher than the allocation rates of NHCEs within the range). Because the last four rates are within a range of no more than five percent above and below 7.0 percent (a midpoint rate chosen by the employer), the employer may treat the employees who have those rates as having an allocation rate of 7.0 percent (provided that the allocation rates of HCEs within the range generally are not significantly higher than the allocation rates of NHCEs within the range).

Example 3. (a) Employer Y has only six nonexcludable employees, all of whom benefit under Plan D. The HCEs are H1 and H2, and the NHCEs are N1 through N4. For the 1994 plan year, H1 and N1 through N4 have an allocation rate of 5.0 percent of plan year compensation. For the same plan year, H2 has an allocation rate of 7.5 percent of plan year compensation.

(b) There are two rate groups under Plan D. Rate group 1 consists of H1 and all those employees who have an allocation rate greater than or equal to H1's allocation rate (5.0 percent). Thus, rate group 1 consists of H1, H2, and N1 through N4. Rate group 2 consists only of H2 because no other employee has an allocation rate greater than or equal to H2's allocation rate (7.5 percent).

(c) The ratio percentage for rate group 2 is zero percent—i.e., zero percent (the percentage of all nonhighly compensated nonexcludable employees who are in the rate group) divided by 50 percent (the percentage of all highly compensated nonexcludable employees who are in the rate group). Therefore rate group 2 does not satisfy the ratio percentage test under § 1.410(b)–2(b)(2). Rate group 2 also does not satisfy the nondiscriminatory classification test of § 1.410(b)–4 (as modified by paragraph (c)(3) of this section). Rate group 2 therefore does not satisfy section 410(b) and, as a result, Plan D does not satisfy the general test in paragraph (c)(1) of this section. This is true regardless of whether rate group 1 satisfies § 1.410(b)–2(b)(2).

Example 4. (a) The facts are the same as in *Example 3*, except that N4 has an allocation rate of 8.0 percent.

(b) There are two rate groups in Plan D. Rate group 1 consists of H1 and all those employees who have an allocation rate greater than or equal to H1's allocation rate (5.0 percent). Thus, rate group 1 consists of H1, H2 and N1 through N4. Rate group 2 consists of H2, and all those employees who have an allocation rate greater than or equal to H2's allocation rate (7.5 percent). Thus, rate group 2 consists of H2 and N4.

(c) Rate group 1 satisfies the ratio percentage test under § 1.410(b)–2(b)(2) because the ratio percentage of the rate group is 100 percent—i.e., 100 percent (the percentage of all nonhighly compensated nonexcludable employees who are in the rate group) divided by 100 percent (the percentage of all highly compensated nonexcludable employees who are in the rate group).

(d) Rate group 2 does not satisfy the ratio percentage test of § 1.410(b)–2(b)(2) because the ratio percentage of the rate group is 50 percent—i.e., 25 percent (the percentage of all nonhighly compensated nonexcludable employees who are in the rate group) divided by 50 percent (the percentage of all highly compensated nonexcludable employees who are in the rate group).

(e) However, rate group 2 does satisfy the nondiscriminatory classification test of § 1.410(b)–4 because the ratio percentage of the rate group (50 percent) is greater than the safe harbor percentage applicable to the plan under § 1.410(b)–4(c)(4) (45.5 percent).

(f) If rate group 2 satisfies the average benefit percentage test of § 1.410(b)–5, then rate group 2 satisfies section 410(b). In that case, Plan D satisfies the general test in paragraph (c)(1) of this section, because each rate group under the plan satisfies section 410(b).

Example 5. (a) Plan E satisfies section 410(b) by satisfying the nondiscriminatory classification test of § 1.410(b)–4 and the average benefit percentage test of § 1.410(b)–5 (without regard to § 1.410(b)–5(f)). See § 1.410(b)–2(b)(3). Plan E uses the facts-and-circumstances requirements of § 1.410(b)–4(c)(3) to satisfy the nondiscriminatory classification test of § 1.410(b)–4. The safe and unsafe harbor percentages applicable to the plan under § 1.410(b)–4(c)(4) are 29 and 20 percent, respectively. Plan E has a ratio percentage of 22 percent.

(b) Rate group 1 under Plan E has a ratio percentage of 23 percent. Under paragraph (c)(3)(ii) of this section, the rate group satisfies the nondiscriminatory classification requirement of § 1.410(b)–4, because the ratio percentage of the rate group (23 percent) is greater than the lesser of—

(1) The ratio percentage for the plan as a whole (22 percent); and

(2) The midpoint between the safe and unsafe harbor percentages (24.5 percent).

(c) Under paragraph (c)(3)(iii) of this section, the rate group satisfies section 410(b) because the plan satisfies the average benefit percentage test of § 1.410(b)–5.

§ 1.401(a)(4)–3 Nondiscrimination in amount of employer-provided benefits under a defined benefit plan.

(a) *Introduction*—(1) *Overview.* This section provides rules for determining whether the employer-provided benefits under a defined benefit plan are nondiscriminatory in amount as required by § 1.401(a)(4)–1(b)(2)(iii). Certain defined benefit plans that provide uniform benefits are permitted to satisfy this requirement by meeting one of the safe harbors in paragraph (b) of this section. Plans that do not provide uniform benefits may satisfy this requirement by satisfying the general test in paragraph (c) of this section. Paragraph (d) of this section provides rules for determining the individual

benefit accrual rates needed for the general test. Paragraph (e) of this section provides rules for determining compensation for purposes of applying the requirements of this section. Paragraph (f) of this section provides additional rules that apply generally for purposes of both the safe harbors in paragraph (b) of this section and the general test in paragraph (c) of this section. See § 1.401(a)(4)–6 for rules for determining the amount of employer-provided benefits under a contributory DB plan, and for determining whether the employee-provided benefits under such a plan are nondiscriminatory in amount.

(2) *Alternative methods of satisfying nondiscriminatory amount requirement.* A defined benefit plan is permitted to satisfy paragraph (b) or (c) of this section on a restructured basis pursuant to § 1.401(a)(4)–9(c). Alternatively, a defined benefit plan is permitted to satisfy the nondiscriminatory amount requirement of § 1.401(a)(4)–1(b)(2)(iii) on the basis of equivalent allocations pursuant to § 1.401(a)(4)–8(c). In addition, a defined benefit plan that is part of a floor-offset arrangement is permitted to satisfy this section pursuant to § 1.401(a)(4)–8(d).

(b) *Safe harbors*—(1) *In general.* The employer-provided benefits under a defined benefit plan are nondiscriminatory in amount for a plan year if the plan satisfies each of the uniformity requirements of paragraph (b)(2) of this section and any one of the safe harbors in paragraphs (b)(3) (unit credit plans), (b)(4) (fractional accrual plans) and (b)(5) (insurance contract plans) of this section. Paragraph (b)(6) of this section provides exceptions for certain plan provisions that do not cause a plan to fail to satisfy this paragraph (b). Paragraph (f) of this section provides additional rules that apply in determining whether a plan satisfies this paragraph (b).

(2) *Uniformity requirements*—(i) *Uniform normal retirement benefit.* The same benefit formula must apply to all employees. The benefit formula must provide all employees with an annual benefit payable in the same form commencing at the same uniform normal retirement age. The annual benefit must be the same percentage of average annual compensation or the same dollar amount for all employees who will have the same number of years of service at normal retirement age. (See § 1.401(a)(4)–11(d)(3) for limits on service that may be taken into account as years of service.) The annual benefit must equal the employee's accrued benefit at normal retirement age (within the meaning of section 411(a)(7)(A)(i) and must be the normal retirement benefit under the plan (within the meaning of section 411(a)(9)).

(ii) *Uniform post-normal retirement benefit.* With respect to an employee with a given number of years of service at any age after normal retirement age, the annual benefit commencing at that employee's age must be the same percentage of average annual compensation or the same dollar amount that would be payable commencing at normal retirement age to an employee who had that same number of years of service at normal retirement age.

(iii) *Uniform subsidies.* Each subsidized optional form of benefit available under the plan must be currently available (within the meaning of § 1.401(a)(4)–4(b)(2)) to substantially all employees. Whether an optional form of benefit is considered subsidized for this purpose may be determined using any reasonable actuarial assumptions.

(iv) *No employee contributions.* The plan must not be a contributory DB plan.

(v) *Period of accrual.* Each employee's benefit must be accrued over the same years of service that are taken into account in applying the benefit formula under the plan to that employee. For this purpose, any year in which the employee benefits under the plan (within the meaning of § 1.410(b)–3(a)) is included as a year of service in which a benefit accrues. Thus, for example, a plan does not satisfy the safe harbor in paragraph (b)(4) of this section unless the plan uses the same years of service to determine both the normal retirement benefit under the plan's benefit formula and the fraction by which an employee's fractional rule benefit is multiplied to derive the employee's accrued benefit as of any play year.

(vi) *Examples.* The following examples illustrate the rules in this paragraph (b)(2):

Example 1. Plan A provides a normal retirement benefit equal to two percent of average annual compensation times each year of service commencing at age 65 for all employees. Plan A provides that employees of Division S receive their benefit in the form of a straight life annuity and that employees of Division T receive their benefit in the form of a life annuity with an automatic cost-of living increase. Plan A does not provide a uniform normal retirement benefit within the meaning of paragraph (b)(2)(i) of this section because the annual benefit is not payable in the same form to all employees.

Example 2. Plan B provides a normal retirement benefit equal to 1.5 percent of average annual compensation times each year of service at normal retirement age for all employees. The normal retirement age under the plan is the earlier of age 65 or the age at which the employee completes 10 years of service, but in no event earlier than age 62. Plan B does not provide a uniform normal retirement benefit within the meaning of paragraph (b)(2)(i) of this section because the same uniform normal retirement age does not apply to all employees.

Example 3. Plan C is an accumulation plan under which the benefit for each year of service equals one percent of plan year compensation payable in the same form to all employees commencing at the same uniform normal retirement age. Under paragraph (e)(2) of this section, an accumulation plan may substitute plan year compensation for average annual compensation. Plan C provides a uniform normal retirement benefit within the meaning of paragraph (b)(2)(i) of this section, because all employees with the same number of years of service at normal retirement age will receive an annual benefit that is treated as the same percentage of average annual compensation.

Example 4. The facts are the same as in *Example 3*, except that the benefit for each year of service equals one percent of plan year compensation increased by reference to the increase in the cost of living from the year of service to normal retirement age. Plan C does not provide a uniform normal retirement benefit, because the annual benefit defined by the benefit formula can vary for employees with the same number of years of service at normal retirement age, depending on the age at which those years of service were credited to the employee under the plan.

Example 5. Plan D provides a normal retirement benefit of 50 percent of average annual compensation at normal retirement age (age 65) for employees with 30 years of service at normal retirement age. Plan D provides that, in the case of an employee with less than 30 years of service at normal retirement age, the normal retirement benefit is reduced on a pro rata basis for each year of service less than 30. However, if an employee with less than 30 years of service at normal retirement age continues to work past normal retirement age, Plan D provides that the additional years of service worked past normal retirement age are taken into account for purposes of the 30 years of service requirement. Thus, an employee who has 26 years of service at age 65 but who does not retire until age 69 with 30 years of service will receive a benefit of 50 percent of average annual compensation. Plan D provides uniform post-normal retirement benefits within the meaning of paragraph (b)(2)(ii) of this section.

Example 6. (a) Plan E is amended on February 14, 1994, to provide an early retirement window benefit that consists of an unreduced early retirement benefit to employees who terminate employment after attainment of age 55 with 10 years of service and between June 1, 1994, and November 30, 1994. The early retirement window benefit is a single subsidized optional form of benefit. Paragraph (b)(2)(iii) of this section requires that the subsidized optional form of benefit be currently available (within the meaning of § 1.401(a)(4)–4(b)(2)) to substantially all employees. Section 1.401(a)(4)–

4(b)(2)(ii)(A)(*2*) provides that age and service requirements are not disregarded in determining the current availability of an optional form of benefit if those requirements must be satisfied within a specified period of time. Thus, the early retirement window benefit is not currently available to an employee unless the employee will satisfy the eligibility requirements for the early retirement window benefit by the close of the early retirement window benefit period. Plan E will fail to satisfy paragraph (b)(2)(iii) of this section unless substantially all of the employees satisfy the eligibility requirements for the early retirement window benefit by November 30, 1994. However, see § 1.401(a)(4)–9(c)(6), *Example 2*, for an example of how a plan with an early retirement window benefit may be restructured into two component plans, each of which satisfies the safe harbors of this paragraph (b).

(b) A similar analysis would apply if, instead of an unreduced early retirement benefit, the early retirement window benefit consisted of a special schedule of early retirement factors, defined by starting with the plan's usual schedule and then treating each employee eligible for the early retirement window benefit as being five years older than the employee actually is, but not older than the employee's normal retirement age.

Example 7. Plan F generally provides a normal retirement benefit of 1.5 percent of an employee's average annual compensation multiplied by the employee's years of service with the employer. For employees transferred outside of the group of employees covered by the plan, the plan's benefit formula takes into account only years of service prior to the transfer, but determines average annual compensation taking into account section 414(s) compensation both before and after the transfer. Plan F does not satisfy the requirements of paragraph (b)(2)(v) of this section with respect to transferred employees, because their benefits are accrued over years of service (i.e., after transfer) that are not taken into account in applying the plan's benefit formula to them. However, see *Example 2* of paragraph (b)(6)(xi)(B) of this section for an example of how a plan that continues to take transferred employees' section 414(s) compensation into account after their transfer may still satisfy this paragraph (b).

(3) *Safe harbor for unit credit plans*—(i) *General rule.* A plan satisfies the safe harbor in this paragraph (b)(3) for a plan year if it satisfies both of the following requirements:

(A) The plan must satisfy the 133⅓% percent accrual rule of section 411(b)(1)(B).

(B) Each employee's accrued benefit under the plan as of any plan year must be determined by applying the plan's benefit formula to the employee's years of service and (if applicable) average annual compensation, both determined as of that plan year.

(ii) *Example.* The following example illustrates the rules in this paragraph (b)(3):

Example. Plan A provides that the accrued benefit of each employee as of any plan year equals the employee's average annual compensation times a percentage that depends on the employee's years of service determined as of that plan year. The percentage is two percent for each of the first 10 years of service, plus 1.5 percent for each of the next 10 years of service, plus two percent for all additional years of service. Plan A satisfies this paragraph (b)(3).

(4) *Safe harbor for plans using fractional accrual rule*—(i) *General rule.* A plan satisfies the safe harbor in this paragraph (b)(4) for a plan if it satisfies each of the following requirements:

(A) The plan must satisfy the fractional accrual rule of section 411(b)(1)(C).

(B) Each employee's accrued benefit under the plan as of any plan year before the employee reaches normal retirement age must be determined by multiplying the employee's fractional rule benefit (within the meaning of § 1.411(b)–1(b)(3)(ii)(A)) by a fraction, the numerator of which is the employee's years of service determined as of the plan year, and the denominator of which is the employee's projected years of service as of normal retirement age.

(C) The plan must satisfy one of the following requirements:

(*1*) Under the plan, it must be impossible for any employee to accrue in a plan year a portion of the normal retirement benefit described in paragraph (b)(2)(i) of this section that is more than one third larger than the portion of the same benefit accrued in that or any other plan year by any other employee, when each portion of the benefit is expressed as a percentage of each employee's average annual compensation or as a dollar amount. In making this determination, actual and potential employees in the plan with any amount of service at normal retirement must be taken into account (other than employees with more than 33 years of service at normal retirement age). In addition, in the case of a plan that satisfies section 401(*l*) in form, an employee is treated as accruing benefits at a rate equal to the excess benefit percentage in the case of a defined benefit excess plan or at a rate equal to the gross benefit percentage in the case of an offset plan.

(*2*) The normal retirement benefit under the plan must be a flat benefit that requires a minimum of 25 years of service at normal retirement age for an employee to receive the unreduced flat benefit, determined without regard to section 415. For this purpose, a flat benefit is a benefit that is the same percentage of average annual compensation or the same dollar amount for all employees who have a minimum number of years of service at normal retirement age (e.g., 50 percent of average annual compensation), with a pro rata reduction in the flat benefit for employees who have less than the minimum number of years of service at normal retirement age. An employee is permitted to accrue the maximum benefit permitted under section 415 over a period of less than 25 years, provided that the flat benefit under the plan, determined without regard to section 415, can accrue over no less than 25 years.

(*3*) The plan must satisfy the requirements of paragraph (b)(4)(i)(C)(*2*) of this section (other than the requirement that the minimum number of years of service for receiving the unreduced flat benefit is at least 25 years), and, for the plan year, the average of the normal accrual rates for all nonhighly compensated nonexcludable employees must be at least 70 percent of the average of the normal accrual rates for all highly compensated nonexcludable employees. The averages in the preceding sentence are determined taking into account all nonexcludable employees (regardless of whether they benefit under the plan). In addition, contributions and benefits under other plans of the employer are disregarded. For purposes of this paragraph (b)(4)(i)(C)(*3*), normal accrual rates are determined under paragraph (d) of this section.

(ii) *Examples.* The following examples illustrate the rules in this paragraph (b)(4). In each example, it is assumed that the plan has never permitted employee contributions.

Example 1. Plan A provides a normal retirement benefit equal to 1.6 percent of average annual compensation times each year of service up to 25. Plan A further provides that an employee's accrued benefit as of any plan year equals the employee's fractional rule benefit multiplied by a fraction, the numerator of which is the employee's years of service as of the plan year, and the denominator of which is the employee's projected years of service as of normal retirement age. The greatest benefit that an employee could accrue in any plan year is 1.6 percent of average annual compensation (this is the case for an employee with 25 or fewer years of projected service at normal retirement age). Among potential employees with 33 or fewer years of projected service at normal retirement age, the lowest benefit that an employee could accrue in any plan year is 1.212 percent of average annual compensation (this is the case for an employee with 33 years of projected service at normal retirement age). Plan A satisfies paragraph (b)(4)(i)(C)(*1*) of this section because 1.6 percent is not more than one third larger than 1.212 percent.

Example 2. Plan B provides a normal retirement benefit equal to 1.0 percent of average annual compensation up to the integration level, and 1.6 percent of average annual compensation above the integration level, times each year of service up to 35. Plan B further provides that an employee's accrued benefit as of any plan year equals the employee's fractional rule benefit multiplied by a fraction, the numerator of which is the employee's years of service as of the plan year and the denominator of which is the employee's projected years of service as of normal retirement age. For purposes of satisfying the one third larger rule in paragraph (b)(4)(i)(C)(*1*) of this section, because Plan B satisfies section 401(*l*) in form, all employees with less than 35 projected years of service are assumed to accrue benefits at the rate of 1.6 percent of average annual compensation (the excess benefit percentage under the plan). Plan B satisfies paragraph (b)(4)(i)(C) of this section because all employees with 33 or fewer years of projected service at normal retirement age accrue in each plan year a benefit of 1.6 percent of average annual compensation.

Example 3. Plan C provides a normal retirement benefit equal to four percent of average annual compensation times each year of service up to 10 and one percent of average annual compensation times each year of service in excess of 10 and not in excess of 30. Plan C further provides that an employee's accrued benefit as of any plan year equals the employee's fractional rule benefit multiplied by a fraction, the numerator of which is the employee's years of service as of the plan year, and the denominator of which is the employee's projected years of service as of normal retirement age. The greatest benefit that an employee could accrue in any plan year is four percent of average annual compensation (this is the case for an employee with 10 or fewer years of projected service at normal retirement age). Among employees with 33 or fewer years of projected service at normal retirement age, the lowest benefit that an employee could accrue in a plan year is 1.82 percent of average annual compensation (this is the case of an employee with 33 years of projected service at normal retirement age). Plan C fails to satisfy this paragraph (b)(4) because four percent is more than one third larger than 1.82 percent. See also § 1.401(a)(4)–9(c)(6), *Example 3.*

Example 4. Plan D provides a normal retirement benefit 100 percent of average annual compensation, reduced by four percentage points for each year of service below 25 the employee has at normal retirement age. Plan D further provides that an employee's accrued benefit as of any plan year is equal to the employee's fractional rule benefit multiplied by a fraction, the numerator of which is the employee's years of service as of the plan year, and the denominator of which is the employee's projected years of service at normal retirement age. In the case of an employee who has five years of service as of the current plan year, and who is projected to have 10 years of service at normal retirement age, the employee's fractional rule benefit would be 40 percent of average annual compensation, and the employee's accrued benefit as of the current plan year would be 20 percent of average annual compensation (the fractional rule benefit multiplied by a fraction of five years over 10 years). Plan D satisfies this paragraph (b)(4).

Example 5. The facts are the same as in *Example 4*, except that the normal retirement benefit is 125 percent of average annual compensation, reduced by five percentage points for each year of service below 25 that the employee has at normal retirement age. Plan D satisfies this paragraph (b)(4), even though an employee may accrue the maximum benefit allowed under section 415 (i.e., 100 percent of the participant's average compensation for the high three years of service) in less than 25 years.

Example 6. The facts are the same as in *Example 1*, except that the plan determines each employee's accrued benefit by multiplying the employee's projected normal retirement benefit (rater than the fractional rule benefit) by the fraction described in *example 1*. In determining an employee's projected normal retirement benefit, the plan defines each employee's average annual compensation as the average annual compensation the employee would have at normal retirement age if the employee's annual section 414(s) compensation in future plan years equaled the employee's plan year compensation for the prior plan year. Under these facts, Plan A does not satisfy paragraph (b)(4)(i)(B) of this section because the employee's accrued benefit is determined on the basis of a projected normal retirement benefit that is not the same as the employee's fractional rule benefit determined in accordance with § 1.411(b)–1(b)(3)(ii)(A).

Example 7. Plan E provides a normal retirement benefit of 50 percent of average annual compensation, with a pro rata reduction for employees with less than 30 years of service at normal retirement age. Plan E further provides that an employee's accrued benefit as of any plan year is equal to the employee's fractional rule benefit multiplied by a fraction, the numerator of which is the employee's years of service as of the plan year, and the denominator of which is the employee's projected years of service at normal retirement age. For purposes of determining this fraction, the plan limits the years of service taken into account for an employee to the number of years the employee has participated in the plan. However, all years of service (including years of service before the employee commenced participation in the plan) are taken into account in determining an employee's normal retirement benefit under the plan's benefit formula. Plan E fails to satisfy this paragraph (b)(4) because the years of service over which benefits accrue differ from the years of service used in applying the benefit formula under the plan. See paragraph (b)(2)(v) of this section.

Example 8. (a) Plan F provides a normal retirement benefit equal to 2.0 percent of average annual compensation, plus 0.65 percent of average annual compensation above covered compensation, for each year of service up to 25. Plan F further provides that an employee's accrued benefit as of any plan year equals the sum of—

(1) The employee's fractional rule benefit (determined as if the normal retirement benefit under the plan equaled 2.0 percent of average annual compensation for each year of service up to 25) multiplied by a fraction, the numerator of which is the employee' years of service as of the plan year and the denominator of which is the employee's projected years of service as of normal retirement age; plus

(2) 0.65 percent of the employee's average annual compensation above covered compensation multiplied by the employee's years of service (up to 25) as of the current plan year.

(b) Although Plan F satisfies the fractional accrual rule of section 411(b)(1)(C), the plan fails to satisfy this paragraph (b)(4) because the plan does not determine employees' accrued benefits in accordance with paragraph (b)(4)(i)(B) of this section.

(5) *Safe harbor for insurance contract plans.* A plan satisfies the safe harbor in this paragraph (b)(5) if it satisfies each of the following requirements:

(i) The plan must satisfy the accrual rule of section 411(b)(1)(F).

(ii) The plan must be an insurance contract plan within the meaning of section 412(i).

(iii) The benefit formula under the plan must be one that would satisfy the requirements of paragraph (b)(4) of this section if the stated normal retirement benefit under the formula accrued ratably over each employee's period of plan participation through normal retirement age in accordance with paragraph (b)(4)(i)(B) of this section. Thus, the benefit formula may not recognize years of service before an employee commenced participation in the plan because, otherwise, the definition of years of service for determining the normal retirement benefit would differ from the definition of years of service for determining the accrued benefit under paragraph (b)(4)(i)(B) of this section. See paragraph (b)(4)(ii), *Example 7*, of this section. Notwithstanding the foregoing, an insurance contract plan adopted and in effect on September 19, 1991, may continue to recognize years of service prior to an employee's participation in the plan for an employee who is a participant in the plan on that date to the extent provided by the benefit formula in the plan on such date.

(iv) The scheduled premium payments under an individual or group insurance contract used to fund an employee's normal retirement benefit must be level annual payments to normal retirement age. Thus, payments may not be scheduled to cease before normal retirement age.

(v) The premium payments for an employee who continues benefiting after normal retirement age must be

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equal to the amount necessary to fund additional benefits that accrue under the plan's benefit formula for the plan year.

(vi) Experience gains, dividends, forfeitures, and similar items must be used solely to reduce future premiums.

(vii) All benefits must be funded through contracts of the same series. Among other requirements, contracts of the same series must have cash values based on the same terms (including interest and mortality assumptions) and the same conversion rights. A plan does not fail to satisfy this requirement, however, if any change in the contract series or insurer applies on the same terms to all employees. But see § 1.401(a)(4)–5(a)(4), *Example 12* (change in insurer considered a plan amendment subject to § 1.401(a)(4)–5(a)).

(viii) If permitted disparity is taken into account, the normal retirement benefit stated under the plan's benefit formula must satisfy § 1.401(*l*)–3. For this purpose, the 0.75-percent factor in the maximum excess or offset allowance in § 1.401(*l*)–3(b)(2)(i) or (b)(3)(i), respectively, adjusted in accordance with § 1.401(*l*)–3(d)(9) and (e), is reduced by multiplying the factor by 0.80.

(6) *Use of safe harbors not precluded by certain plan provisions*—(i) *In general.* A plan does not fail to satisfy this paragraph (b) merely because the plan contains one or more of the provisions described in this paragraph (b)(6). Unless otherwise provided, any such provision must apply uniformly to all employees.

(ii) *Section 401(l) permitted disparity.* The plan takes permitted disparity into account in a manner that satisfies section 401(*l*) in form. Thus, differences in employees' benefits under the plan attributable to uniform disparities permitted under § 1.401(*l*)–3 (including differences in disparities that are deemed uniform under § 1.401(*l*)–3(c)(2)) do not cause a plan to fail to satisfy this paragraph (b).

(iii) *Different entry dates.* The plan provides one or more entry dates during the plan year as permitted by section 410(a)(4).

(iv) *Certain conditions on accruals.* The plan provides that an employee's accrual for the plan year is less than a full accrual (including a zero accrual) because of a plan provision permitted by the year-of-participation rules of section 411(b)(4).

(v) *Certain limits on accruals.* The plan limits benefits otherwise provided under the benefit formula or accrual method to a maximum dollar amount or to a maximum percentage of average annual compensation (e g., by limiting service taken into account in the benefit formula) or in accordance with section 401(a)(5)(D), applies the limits of section 415, or limits the dollar amount of compensation taken into account in determining benefits.

(vi) *Dollar accrual per uniform unit of service.* The plan determines accruals based on the same dollar amount for each uniform unit of service (not to exceed one week) performed by each employee with the same number of years of service under the plan during the plan year. The preceding sentence applies solely for purposes of the unit credit safe harbor in paragraph (b)(3) of this section.

(vii) *Prior benefits accrued under a different formula.* The plan determines benefits for years of service after a fresh-start date for all employees under a benefit formula and accrual method that differ from the benefit formula and accrual method previously used to determine benefit accruals for employees in a fresh-start group for years of service before the fresh-start date. This paragraph (b)(6)(vii) applies solely to plans that satisfy § 1.401(a)(4)–13(c) with respect to the fresh start.

(viii) *Employee contributions.* The plan is a contributory DB plan that would satisfy the requirements of paragraph (b) of this section if the plan's benefit formula provided benefits at employees' employer-provided benefit rates determined under § 1.401(a)(4)–6(b). This paragraph (b)(6)(viii) does not apply to a plan tested under paragraph (b)(4) or (b)(5) of this section unless the plan satisfies one of the methods in § 1.401(a)(4)–6(b)(4) through (b)(6). A minimum benefit added to the plan solely to satisfy § 1.401(a)(4)–6(b)(3) is not taken into account in determining whether this paragraph (b)(6)(viii) is satisfied.

(ix) *Certain subsidized optional forms.* The plan provides a subsidized optional form of benefit that is available to fewer than substantially all employees because the optional form of benefit has been eliminated prospectively as provided in § 1.401(a)(4)–4(b)(3).

(x) *Lower benefits for HCEs*—(A) *General rule.* The benefits (including any subsidized optional form of benefit) provided to one or more HCEs under the plan are inherently less valuable to those HCEs (determined by applying the principles of § 1.401(a)(4)–4(d)(4)) than the benefits that would otherwise be provided to those HCEs if the plan satisfied this paragraph (b) (determined without regard to this paragraph (b)(6)(x)). These inherently less valuable benefits are deemed to satisfy this paragraph (b).

(B) *Examples.* The following examples illustrate the rules in this paragraph (b)(6)(x):

Example 1. Plan A would satisfy this paragraph (b) (determined without regard to this paragraph (b)(6)(x)), except for the fact that it fails to satisfy the requirement of paragraph (b)(2)(iii) of this section (i.e., a subsidized optional form must be available to substantially all employees on similar terms). Each subsidized optional form in the plan is available to all the NHCEs on similar terms, but one of the subsidized optional forms of benefit is not available to any of the HCEs. Plan A satisfies this paragraph (b), because Plan A is a safe harbor plan with respect to the NHCEs and provides inherently less valuable benefits to the HCEs.

Example 2. (a) Plan B would satisfy this paragraph (b) (determined without regard to this paragraph (b)(6)(x)), except for the fact that some employees are not being credited with years of service under the plan, but are continuing to accrue benefits as a result of compensation increases. These are employees who have been transferred from the employer that sponsors Plan B to another member of the controlled group whose employees are not covered by Plan B. For these employees, Plan B fails to satisfy the requirement of paragraph (b)(2)(v) of this section, (i.e., each employee's benefit must accrue over the same years of service used in applying the benefit formula).

(b) Plan B is restructured into two component plans under the provisions of § 1.401(a)(4)–9(c). One component plan (Component Plan B1) consists of all NHCEs who are not being credited with years of service under the plan's benefit formula but are continuing to accrue benefits as a result of compensation increases, and the other component plan (Component Plan B2) consists of the balance of the employees.

(c) Component Plan B1 satisfies this section and section 410(b), because it benefits only NHCEs.

(d) Component Plan B2 is treated as satisfying this paragraph (b), because Plan B would satisfy this paragraph (b) (determined without regard to this paragraph (b)(6)(x)) with respect to the employees in Component Plan B2 but for the fact that it provides inherently less valuable benefits to some HCEs in that component plan (i.e., the employees who are credited only with compensation increases rather than both years of service and compensation increases).

(e) Under § 1.401(a)(4)–9(c), if Component Plan B2 satisfies section 410(b), then Plan B satisfies this section.

(xi) *Multiple formulas*—(A) *General rule.* The plan provides that an employee's benefit under the plan is the greater of the benefits determined under two or more formulas, or is the sum of the benefits determined under two or more formulas. This paragraph (b)(6)(xi) does not apply to a plan unless each of the formulas under the plan satisfies the requirements of paragraph (b)(6)(xi)(B) through (D) of this section.

(B) *Sole formulas.* The formulas must be the only formulas under the plan.

(C) *Separate testing.* Each of the formulas must separately satisfy the uniformity requirements of paragraph (b)(2) of this section and also separately satisfy one of the safe harbors in paragraphs (b)(3) through (b)(5) of this section. A formula that is available solely to some or all NHCEs is deemed to satisfy this paragraph (b)(6)(xi)(C).

(D) *Availability—(1) General rule.* All of the formulas must be available on the same terms to all employees.

(*2*) *Formulas for NHCEs.* A formula does not fail to be available on the same terms to all employees merely because the formula is not available to any HCEs, but is available to some or all NHCEs on the same terms as all of the other formulas in the plan.

(*3*) *Top-heavy formulas.* Rules parallel to those in § 1.401(a)(4)–2(b)(4)(vi)(D)(*3*) apply in the case of a plan that provides the greater of the benefits under two or more formulas, one of which is a top-heavy formula. For purposes of this paragraph (b)(6)(xi)(D)(*3*), a top-heavy formula is a formula that provides a benefit equal to the minimum benefit described in section 416(c)(1) (taking into account, if applicable, the modification in section 416(h)(2)(A)(ii)(I)).

(E) *Provisions may be applied more than once.* The provisions of this paragraph (b)(6)(xi) may be applied more than once. See § 1.401(a)(4)–2(b)(4)(vi)(E) for an example of the application of these provisions more than once.

(F) *Examples.* The following examples illustrate the rules in this paragraph (b)(6)(xi):

Example 1. Under Plan A, each employee's benefit equals the sum of the benefits determined under two formulas. The first formula provides one percent of average annual compensation per year of service. The second formula provides $10 per year of service. Plan A is eligible to apply the rules in this paragraph (b)(6)(xi).

Example 2. Under Plan B, each employee's benefit equals the greater of the benefits determined under two formulas. The first formula provides $15 per year of service and is available to all employees who complete at least 500 hours of service during the plan year. The second formula provides 1.5 percent of average annual compensation per year of service and is available to all employees who complete at least 1,000 hours of service during the plan year. Plan B does not satisfy this paragraph (b)(6)(xi) because the two formulas are not available on the same terms to all employees.

Example 3. Under Plan C, each employees's benefit equals the greater of the benefits determined under two formulas. The first formula provides $15 per year of service and is available to all employees who complete at least 1,000 hours of service during the plan year. The second formula provides the minimum benefit described in section 416(c)(1) and is available to all non-key employees who complete at least 1,000 hours of service during the plan year. Plan C does not satisfy the general rule in paragraph (b)(6)(xi)(D)(*1*) of this section because the two formulas are not available on the same terms to all employees (i.e., the second formula is only available to all non-key employees). Nonetheless, because the second formula is a top-heavy formula, the special availability rules for top-heavy formulas in paragraph (b)(6)(xi)(D)(*3*) of this section apply. Thus, the second formula does not fail to be available on the same terms as the first formula merely because the second formula is available solely to all non-key employees on the same terms. This is true even if the plan conditions the availability of the second formula on the plan's being top-heavy for the plan year.

Example 4. Under Plan D, each employee's benefit equals the greater of the benefits determined under two formulas. The first formula is available to all employees and provides a benefit equal to 1.5 percent of average annual compensation per year of service. The second formula is only available to NHCEs and provides a benefit equal to two percent of average annual compensation per year of service, minus two percent of the primary insurance amount per year of service. The amount of the offset is not limited to the maximum permitted offset under § 1.401(*l*)–3(b). Under paragraph (b)(6)(xi)(D)(*2*) of this section, both formulas are treated as available to all employees on the same terms. Furthermore, even though the second formula does not satisfy any of the safe harbors in this paragraph (b), the formula is deemed to satisfy the separate testing requirement under paragraph (b)(6)(xi)(C) of this section, because the formula is available solely to some or all NHCEs.

Example 5. Plan E provides a benefit of one percent of average annual compensation per year of service to all employees. In 1994, the plan is amended to provide a benefit of two percent of average annual compensation per year of service after 1993, while continuing to provide a benefit of one percent of average annual compensation per year of service for all years of service before 1994. Thus, the plan's amended benefit formula provides a benefit equal to the sum of the benefits determined under two benefit formulas: one percent of average annual compensation per year of service, plus one percent of average annual compensation per year of service after 1993. Plan E satisfies this paragraph (b)(6)(xi).

Example 6. The facts are the same as in *Example 5*, except that the plan amendment in 1994 decreases the benefit to 0.75 percent of average annual compensation per year of service after 1993, while retaining the one-percent formula for all years of service before 1994. Thus, the plan's amended benefit formula provides a benefit equal to the sum of the benefits determined under two benefit formulas: 0.75 percent of average annual compensation per year of service, plus 0.25 percent of average annual compensation per year of service before 1994. Under these facts, the second formula does not separately satisfy any of the safe harbors in this paragraph (b) because the definition of years of service for purposes of applying the benefit formula (years of service before 1994) differs from the definition of years of service over which the resulting benefit is accrued (all years of service). See paragraph (b)(2)(v) of this section. But see paragraph (b)(6)(vii) of this section and § 1.401(a)(4)–13 which provide rules under which Plan E, as amended, may be able to satisfy this paragraph (b).

Example 7. Plan F provides a benefit to all employees of one percent of average annual compensation per year of service. Employee M was hired as the president of the employer in December 1994 and was not a HCE under section 414(q) during the 1994 calendar plan year. In 1994, Plan F is amended to provide a benefit that is the greater of the benefit determined under the pre-existing formula in the plan and a new formula that is available solely to some NHCEs (including Employee M). The new formula does not satisfy the uniformity requirements of paragraph (b)(2) of this section, because it provides a different benefit for some NHCEs than for other NHCEs. As a result of this change, Employee M receives a higher accrual in 1994 than the NHCEs who are not eligible for the new formula. In 1995, when Employee M first becomes a HCE, the second formula no longer applies to Employee M. It would be inconsistent with the purpose of preventing discrimination in favor of HCEs for Plan F to use the special rule for a formula that is available solely to some or all NHCEs to satisfy the separate testing requirement of paragraph (b)(6)(xi)(C) of this section for the 1994 calendar plan year. See § 1.401(a)(4)–1(c)(2).

(c) *General test for nondiscrimination in amount of benefits—(1) General rule.* The employer-provided benefits under a defined benefit plan are nondiscriminatory in amount for a plan year if each rate group under the plan satisfies section 410(b). For purposes of this paragraph (c)(1), a rate group exists under a plan for each HCE and consists of the HCE and all other employees (both HCEs and NHCEs) who have a normal accrual rate greater than or equal to the HCE's normal accrual rate, and who also have a most valuable accrual rate greater than or equal to the HCE's most valuable accrual rate. Thus, an employee is in the rate group for each HCE who has a normal accrual rate less than or equal to the employee's normal accrual rate, and who also has a most valuable accrual rate less than or equal to the employee's most valuable accrual rate.

(*2*) *Satisfaction of section 410(b) by a rate group.* For purposes of determining whether a rate group satisfies section 410(b), the same rules apply as in § 1.401(a)(4)–2(c)(3). See paragraph (c)(4) of this section and § 1.401(a)(4)–2(c)(4), *Example 3* through *Example 5* for examples of this rule.

(3) *Certain violations disregarded.* A plan is deemed to satisfy paragraph (c)(1) of this section if the plan would satisfy that paragraph by treating as not benefiting no more than five percent of the HCEs in the plan, and the Commissioner determines that, on the basis of all of the relevant facts and circumstances, the plan does not discriminate with respect to the amount of employer-provided benefits. Among the relevant factors that the Commissioner may consider in making this determination are—

(i) The extent to which the plan has failed the test in paragraph (c)(1) of this section;

(ii) The extent to which the failure is for reasons other than the design of the plan;

(iii) Whether the HCEs causing the failure are five-percent owners or are among the highest paid nonexcludable employees;

(iv) Whether the failure is attributable to an event that is not expected to recur (e.g., a plant closing); and

(v) The extent to which the failure is attributable to benefits accrued under a prior benefit structure or to benefits accrued when a participant was not a HCE.

(4) *Examples.* The following examples illustrate the rules in this paragraph (c):

Example 1. (a) Employer X has 1100 nonexcludable employees, N1 through N1000, who are NHCEs, and H1 through H100, who are HCEs. Employer X maintains Plan A, a defined benefit plan that benefits all of these nonexcludable employees. The normal and most valuable accrual rates (determined as a percentage of average annual compensation) for the employees in Plan A for the 1994 plan year are listed in the following table.

Employee	Normal accrual rate	Most valuable accrual rate
N1 through N100	1.0	1.4
N101 through N500 ..	1.5	3.0
N501 through N750 ..	2.0	2.65
N751 through N1000	2.3	2.8
H1 through H50	1.5	2.0
H51 through H100	2.0	2.65

(b) There are 100 rate groups in Plan A because there are 100 HCEs in Plan A.

(c) Rate group 1 consists of H1 and all those employees who have a normal accrual rate greater than or equal to H1's normal accrual rate (1.5 percent) and who also have a most valuable accrual rate greater than or equal to H1's most valuable accrual rate (2.0 percent). Thus, rate group 1 consists of H1 through H100 and N101 through N1000.

(d) Rate group 1 satisfies the ratio percentage test of § 1.410(b)–2(b)(2) because the ratio percentage of the rate group is 90 percent, i.e., 90 percent (the percentage of all nonhighly compensated nonexcludable employees who are in the rate group) divided by 100 percent (the percentage of all highly compensated nonexcludable employees who are in the rate group).

(e) Because H1 through H50 have the same normal accrual rates and the same most valuable accrual rates, the rate group with respect to each of them is identical. Thus, because rate group 1 satisfies section 410(b), rate groups 2 through 50 also satisfy section 410(b).

(f) Rate group 51 consists of H51 and all those employees who have a normal accrual rate greater than or equal to H51's normal accrual rate (2.0 percent) and who also have a most valuable accrual rate greater than or equal to H51's most valuable accrual rate (2.65 percent). Thus, rate group 51 consists of H51 through H100 and N501 through N1000. (Even though N101 through N500 have a most valuable accrual rate (3.0 percent) greater than H51's most valuable accrual rate (2.65 percent), they are not included in this rate group because their normal accrual rate (1.5 percent) is less than H51's normal accrual rate (2.0 percent).)

(g) Rate group 51 satisfies the ratio percentage test of § 1.410(b)–2(b)(2) because the ratio percentage of the rate group is 100 percent, i.e., 50 percent (the percentage of all nonhighly compensated nonexcludable employees who are in the rate group) divided by 50 percent (the percentage of all highly compensated nonexcludable employees who are in the rate group).

(h) Because H51 through H100 have the same normal accrual rates and the same most valuable accrual rates, the rate group with respect to each of them is identical. Thus, because rate group 51 satisfies section 410(b), rate groups 52 through 100 also satisfy section 410(b).

(i) The employer-provided benefits under Plan A are nondiscriminatory in amount because each rate group under the plan satisfies section 410(b).

Example 2. The facts are the same as in *Example 1*, except that H96 has a most valuable accrual rate of 3.5. Each of the rate groups is the same as in *Example 1*, except that rate group 96 consists solely of H96 because no other employee has a most valuable accrual rate greater than 3.5. Because the plan would satisfy the test in paragraph (c)(1) of this section by treating H96 (who constitutes less than five percent of the HCEs in the plan) as not benefiting, the Commissioner may determine under paragraph (c)(3) of this section that, on the basis of all of the relevant facts and circumstances, the plan does not discriminate with respect to the amount of benefits.

(d) *Determination of accrual rates*—(1) *Definitions*—(i) *Normal accrual rate.* The normal accrual rate for an employee for a plan year is the increase in the employee's accrued benefit (within the meaning of section 411(a)(7)(A)(i)) during the measurement period, divided by the employee's testing service during the measurement period, and expressed either as a dollar amount or as a percentage of the employee's average annual compensation.

(ii) *Most valuable accrual rate.* The most valuable accrual rate for an employee for a plan year is the increase in the employee's most valuable optional form of payment of the accrued benefit during the measurement period, divided by the employee's testing service during the measurement period, and expressed either as a dollar amount or as a percentage of the employee's average annual compensation. The employee's most valuable optional form of payment of the accrued benefit is determined by calculating for the employee the normalized QJSA associated with the accrued benefit that is potentially payable in the current or any future plan year at any age under the plan and selecting the largest (per year of testing service). If the plan provides a QSUPP, the most valuable accrual rate also takes into account the QSUPP payable in conjunction with the QJSA at each age under the plan. Thus, the most valuable accrual rate reflects the value of all benefits accrued or treated as accrued under section 411(d)(6) that are payable in any form and at any time under the plan, including early retirement benefits, retirement-type subsidies, early retirement window benefits, and QSUPPs. In addition, the most valuable accrual rate must take into account any such benefits that are available during a plan year, even if the benefits cease to be available before the end of the current or any future plan year.

(iii) *Measurement period.* The measurement period can be—

(A) The current plan year;

(B) The current plan year and all prior years; or

(C) The current plan year and all prior and future years.

(iv) *Testing service*—(A) *General rule.* "Testing service" means an employee's years of service as defined in the plan for purposes of applying the benefit formula under the plan, subject to the requirements of paragraph (d)(1)(iv)(B) of this section. Alternatively, testing service means service determined for all employees in a reasonable manner that satisfies the requirements of paragraph (d)(1)(iv)(B) of this section. For example, the number of plan years that an employee has benefited under the plan within the meaning of § 1.410(b)–3(a) is an acceptable definition of testing service because it determines service in a reasonable manner and satisfies paragraph (d)(1)(iv)(B) of this section. See also § 1.401(a)(4)–11(d)(3) (additional limits on service that may be taken into account as testing service).

(B) *Requirements for testing service*—(*1*) *Employees not credited with years of service under the benefit formula.* An employee must be credited with testing service for any year in which the

employee benefits under the plan (within the meaning of § 1.410(b)–3(a)), unless that year is part of a period of service that may not be taken into account under § 1.401(a)(4)–11(d)(3). The rule applies even if the employee does not receive service credit under the benefit formula for that year (e.g., because of a service cap in the benefit formula or because of a transfer out of the group of employees covered by the plan).

(2) *Current year testing service.* In the case of a measurement period that is the current plan year, testing service for the plan year equals one (1).

(2) *Rules of application*—(i) *Consistency requirement.* Both normal and most valuable accrual rates must be determined in a consistent manner for all employees for the plan year. Thus, for example, the same measurement periods must be used, and the rules of this paragraph (d)(2) and any available options described in paragraph (d)(3) of this section must be applied consistently. If plan benefits are not expressed as straight life annuities beginning at employees' testing ages, they must be normalized.

(ii) *Determining plan benefits, service and compensation*—(A) *In general.* Potential plan benefits, testing service, and average annual compensation must be determined in a reasonable manner, reflecting actual or projected service and compensation only through the end of the measurement period. The determination of potential plan benefits is not reasonable if it incorporates an assumption that, in future years, an employee's compensation will increase or the employee will terminate employment before the employee's testing age (other than the assumptions under paragraph (d)(1)(ii) of this section that the employee's service will end in connection with the payment of each potential QJSA in future years).

(B) *Section 415 limits.* For purposes of determining accrual rates under this paragraph (d), plan benefits are generally determined without regard to whether those benefits are permitted to be paid under section 415. However, plan provisions implementing the limits of section 415 may be taken into account in applying this paragraph (d) if the plan does not provide for benefit increases resulting from section 415(d)(1) adjustments for former employees who were employees in a plan year in which such plan provisions were taken into account in applying this paragraph (d). If the limits of section 415 are taken into account under this paragraph (d)(2)(ii)(B) as of the end of the measurement period, they must also be taken into account as of the beginning of the measurement period. If the limits of section 415 are not taken into account in testing the plan for the current plan year, but were taken into account in testing the plan for the preceding plan year, any resulting increase in the accrued benefits taken into account in testing the plan is treated as an increase in accrued benefits during the current plan year.

(iii) *Requirements for measurement period that includes future years*—(A) *Discriminatory pattern of accruals.* A measurement period that includes future years (as described in paragraph (d)(1)(iii)(C) of this section) may not be used if the pattern of accruals under the plan discriminates in favor of HCEs (i.e., if projected benefits for HCEs are relatively frontloaded when compared to the degree of frontloading or backloading for NHCEs). This determination is made based on all relevant facts and circumstances.

(B) *Future-period limitation.* Future years beginning after an employee's attainment of the employee's testing age (or after the employee's assumed termination in the case of most valuable accrual rates) may not be included in the measurement period.

(3) *Optional rules*—(i) *Imputation of permitted disparity.* The disparity permitted under section 401 (*l*) may be imputed in accordance with the rules of § 1.401(a)(4)–7.

(ii) *Grouping of accrual rates*—(A) *General rule.* An employer may treat all employees who have accrual rates within a specified range above and below midpoint rate chosen by the employer as having an accrual rate equal to the midpoint rate within that range. Accrual rates within a given range may not be grouped under this paragraph (d)(3)(ii) if the accrual rates of HCEs within the range generally are significantly higher than the accrual rates of NHCEs in the range. The specified ranges within which all employees are treated as having the same accrual rate may not overlap and may be no larger than provided in paragraph (d)(3)(ii)(B) of this section. Accrual rates of employees that are not within any of these specified ranges are determined without regard to this paragraph (d)(3)(ii).

(B) *Size of specified ranges.* In the case of normal accrual rates, the lowest and highest accrual rates in the range must be within five percent (not five percentage points) of the midpoint rate. In the case of most valuable accrual rates, the lowest and highest accrual rates in the range must be within 15 percent (not 15 percentage points) of the midpoint rate. If accrual rates are determined as a percentage of average annual compensation, the lowest and highest accrual rates need not be within five percent (or 15 percent) of the midpoint rate, if they are no more than one twentieth of a percentage point above or below the midpoint rate.

(iii) *Fresh-start alternative*—(A) *General rule.* Notwithstanding the definition of measurement period provided in paragraph (d)(1)(iii) of this section, measurement period for a fresh-start group is permitted to be limited to the period beginning after the fresh-start date with respect to the group if the plan makes a fresh start that satisfies § 1.401(a)(4)–13(c) (without regard to § 1.401(a)(4)–13(c)(2)(i) and (ii)). If the measurement period is so limited or the measurement period is the plan year (whether or not so limited), any compensation adjustments during the measurement period to the frozen accrued benefit as of the fresh-start date that are permitted under the rules of § 1.401(a)(4)–13(d) may be disregarded in determining the increase in accrued benefits during the measurement period, but only if—

(*1*) The Plan makes a fresh start as of the fresh-start date that satisfies § 1.401(a)(4)–13(c) (without regard to § 1.401(a)(4)–13(c)(2)(ii) in conjunction with a bona fide amendment to the benefit formula or accrual method under the plan; and

(*2*) The Amendment provides for adjustments to employees' frozen accrued benefits as of the fresh-start date in accordance with the rules of § 1.401(a)(4)–13(d).

(B) *Application of consistency requirements.* Limiting the application of the fresh-start alternative in this paragraph (d)(3)(iii) to a fresh-start group that consists of fewer than all employees does not violate the consistency requirement of paragraph (d)(2)(i) of this section.

(4) *Examples.* The following examples illustrate the following rules in this paragraph (d):

Example 1. The employees in Plan A have the following normal accrual rates (expressed as percentage of average annual compensation): 0.8 percent, 0.83 percent, 0.9 percent, 1.9 percent, 2.0 percent, and 2.1 percent. Because the first three rates are within a range of no more than one twentieth of a percentage point above or below 0.85 percent (a midpoint rate chosen by the employer), the employer may treat the employees who have those rates as having an accrual rate of 0.85 percent (provided that the accrual rates of HCEs within the range are not significantly higher than the accrual rates for NHCEs within the range). Because the last three rates are within a range of no more than five percent above or below 2.0 percent (a midpoint rate chosen by the employer), the employer may treat the employees who have

those rates as having an accrual rate of 2.0 percent (provided that the accrual rates of HCEs within the range are not significantly higher than the accrual rates for HCEs within the range).

Example 2. Employer X maintains a plan under which headquarters employees accrue a benefit of 1.25 percent of average compensation for the first 10 years of service and 0.75 percent of average compensation for subsequent years of service, while all other employees accrue a benefit of one percent of compensation for all years of service. Assume that the group of headquarters employees does not satisfy section 410(b). Under these facts, the pattern of accruals under the plan discriminates in favor of HCEs, and, therefore, under paragraph (d)(2)(iii)(A) of this section, the measurement period for determining accrual rates under the plan may not include future service.

(e) *Compensation rules*—(1) *In general.* This paragraph (e) provides rules for determining average annual compensation. Safe harbor plans that satisfy paragraph (b) of this section must determine benefits either as a dollar amount unrelated to employees' compensation or as a percentage of each employee's average annual compensation. In contrast, plans that must satisfy the general test of paragraph (c) of this section are not required under this section to determine benefits under any particular definition of compensation or in any particular manner, but the accrual rates used in testing these plans must be expressed either as a dollar amount or determined as a percentage of each employee's average annual compensation.

(2) *Average annual compensation*—(i) *General rule.* An employee's average annual compensation is the average of the employee's annual section 414(s) compensation determined over the averaging period in the employee's compensation history during which the average of the employee's annual section 414(s) compensation is the highest. For this purpose, an averaging period must consist of three or more consecutive 12-month periods, but need not be longer than the employee's period of employment. An employee's compensation history may begin at any time, but must be continuous, be no shorter than the averaging period, and end in the current plan year.

(ii) *Certain permitted modifications to average annual compensation*—(A) *Use of plan year compensation.* If the measurement period for determination of accrual rates is the current plan year, or the plan is an accumulation plan that satisfies paragraph (b) of this section, then plan year compensation may be substituted for average annual compensation.

(B) *Drop-out years.* The following types of 12-month periods in an employee's compensation history may be disregarded in determining the employee's average annual compensation (including for purposes of the requirement to average section 414(s) compensation over consecutive 12-month periods), but only if the plan disregards those periods in determining benefits—

(*1*) The 12-month period in which the employee terminates employment; or

(*2*) All 12-month periods in which the individual performs no services or performs services for less than one half of the time that an employee working on a full-time basis would perform the same services during that 12-month period.

(C) *Drop-out months within 12-month periods.* If a plan determines an employee's average annual compensation using 12-month periods that do not end on a fixed date (e.g., average annual compensation as of a date is defined as the average of the employee's section 414(s) compensation for the 60 consecutive months within the compensation history in which the average is highest), then, for purposes of determining a 12-month period, those months in which the employee performs no services or performs services for less than one half of the time that a full-time employee would normally perform the same services may be disregarded (including for purposes of the requirement to average section 414(s) compensation over consecutive 12-month periods). This rule does not apply unless the plan disregards those months in determining benefits.

(D) *Exception from consecutive-period requirement for certain plans.* The requirement that the periods taken into account under paragraph (e)(2)(i) of this section be consecutive does not apply in the case of a plan that is not a section 401(*l*) plan, provided that it does not take permitted disparity into account under § 1.401(a)(4)–7. This paragraph (e)(2)(ii)(D) applies only if the plan does not take into account whether 12-month periods of compensation are consecutive in determining average compensation for purposes of calculating benefits.

(iii) *Consistency requirements.* Average annual compensation must be determined in a consistent manner for all employees.

(3) *Examples.* The following examples illustrate the rules in this paragraph (e):

Example 1. Plan A is a defined benefit plan. Plan A determines benefits on the basis of the average of each employee's annual compensation for the five consecutive plan years (or the employee's period of employment, if shorter) during the compensation history in which the average of the employee's annual compensation is the highest. The compensation history used for this purpose is the last 10 plan years, plus the current plan year. In determining compensation for each plan year in the compensation history, Plan A defines compensation using a single definition that satisfies section 414(s) as a safe harbor definition under § 1.414(s)-1(c). Plan A determines benefits on the basis of average annual compensation.

Example 2. Plan B is a defined benefit plan. Plan B determines benefits on the basis of the average of each employee's compensation for the five consecutive 12-month periods ending on the employee's termination date (or the employee's period of employment, if shorter). In determining the average, Plan B disregards all months in which the employee performs services for less than one half of the time that a full-time employee would normally perform services. Plan B defines compensation for each 12-month period using a single definition that satisfies § 1.414(s)-1. Plan B determines benefits on the basis of average annual compensation.

Example 3. (a) The facts are the same as in *Example 1*, except that, for plan years prior to 1994, the compensation for a plan year was determined under a rate of pay definition of compensation that satisfies section 414(s), while, for plan years after 1993, the compensation for a plan year is determined using a definition that satisfies section 414(a) as a safe harbor definition under § 1.414(a)-1(c).

(b) The underlying definition of compensation for each plan year in the employee's compensation history is section 414(s) compensation, because for each plan year the definition satisfies the requirements for section 414(s) compensation under § 1.401(a)(4)-12. Therefore, Plan A determines benefits on the basis of average annual compensation, even though the underlying definition used to measure the amount of compensation for each plan year in an employee's compensation history is not the same for all plan years.

Example 4. The facts are the same as in *Example 1*, except that Plan A determines benefits on the basis of the average of the employee's annual section 414(s) compensation for the five consecutive 12-month periods ending on June 30 during the employee's compensation history in which the average is highest. An employee's compensation history begins when the employee commences participation in the plan and ends in the current plan year. In the case of an employee with less than five consecutive years of plan participation as of June 30, the compensation history is extended prior to the employee's commencement of participation to include the five consecutive 12-month periods ending on June 30 of the current plan year (or the employee's total period of employment, if shorter). Plan A determines benefits on the basis of average annual compensation.

Example 5. The facts are the same as in *Example 4*, except that Plan A determines benefits on the basis of the average of each employee's compensation for the employee's

entire compensation history. Plan A determines benefits on the basis of average annual compensation.

(f) *Special rules*—(1) *In general.* The special rules in this paragraph (f) apply for purposes of applying the provisions of this section to a defined benefit plan. Any special rule provided in this paragraph (f) that is optional must, if used, apply uniformly to all employees.

(2) *Certain qualified disability benefits.* In general, qualified disability benefits (within the meaning of section 411(a)(9)) are not taken into account under this section. However, a qualified disability benefit that results from the crediting of compensation or service for a period of disability in the same manner as actual compensation or service is credited under a plan's benefit formula is permitted to be taken into account under this section as an accrued benefit upon the employee's return to service with the employer following the period of disability, provided that the qualified disability benefit is then treated in the same manner as an accrued benefit for all purposes under the plan.

(3) *Accruals after normal retirement age*—(i) *General rule.* An employee's accruals for any plan year after the plan year in which the employee attains normal retirement age are taken into account for purposes of this section. However, any plan provision that provides for increases in an employee's accrued benefit solely because the employee has delayed commencing benefits beyond the normal retirement age applicable to the employee under the plan may be disregarded, but only if—

(A) the same uniform normal retirement age applies to all employees; and

(B) The percentage factor used to increase the employee's accrued benefit is no greater than the largest percentage factor that could be applied to increase actuarially the employee's accrued benefit using any standard mortality table and any standard interest rate.

(ii) *Examples.* The following examples illustrate the rules of this paragraph (f)(3). In each example, it is assumed that the plan satisfies the requirements of paragraph (f)(3)(i) (A) and (B) of this section.

Example 1. Plan A provides a benefit of two percent of average annual compensation per year of service for all employees. In addition, Plan A provides an actuarial increase in an employee's accrued benefit of six percent for each year that an employee defers commencement of benefits beyond normal retirement age. For employees who continue in service beyond normal retirement age, the employee's two-percent accrual for the current plan year is offset by the six-percent actuarial increase, as permitted under section 411(b)(1)(H)(iii)(II). For purposes of this section, the actuarial increase (and hence the offset) may be disregarded, and thus all employees may be treated as if they were accruing at the rate of two percent of average annual compensation per year.

Example 2. The facts are the same as in *Example 1*, except that the employee's two-percent accrual for the current plan year is not offset by the six-percent actuarial increase. The employer may disregard the actuarial increase and thus may treat all employees as if they were accruing at the rate of two percent of average annual compensation per year.

(4) *Early retirement window benefits*—(i) *General rule.* In applying the requirements of this section, all early retirement benefits, retirement-type subsidies, QSUPPs, and other optional forms of benefit under a plan, and changes in the plan's benefit formula, are taken into account regardless of whether they are permanent features of the plan or are offered only to employees whose employment terminates within a limited period of time. Additional rules and examples relevant to the testing of early retirement window benefits are found in *Example 6* of paragraph (b)(2)(vi) of this section; *Example 2* of paragraph (c)(2) of § 1.401(a)(4)–4; paragraphs (d)(3) and (e)(1)(iii) of § 1.401(a)(4)–4; *Example 3* of paragraph (c)(4)(i) and *Example 2* of paragraph (c)(6) of § 1.401(a)(4)–(9); and the definition of benefit formula in § 1.401(a)(4)–12.

(ii) *Special rules*—(A) *Year in which early retirement window benefit taken into account.* Notwithstanding paragraph (f)(4)(i) of this section, an early retirement window benefit is disregarded for purposes of determining whether a plan satisfies this section with respect to an employee for all plan years other than the first year in which the benefit is currently available (within the meaning of § 1.401(a)(4)–4(b)(2)) to the employee. For purposes of this paragraph (f)(4), in determining the plan year in which the benefit is currently available, an early retirement window benefit that consists of a temporary change in the plan's benefit formula is treated as an optional form of benefit.

(B) *Treatment of early retirement window benefit that consists of temporary change in benefit formula.* An early retirement window benefit is disregarded for purposes of determining an employee's normal accrual rate, even if the early retirement window benefit consists of a temporary change in a plan's benefit formula. However, if an early retirement window benefit consists of a temporary change in a plan's benefit formula, the plan does not satisfy paragraph (b) of this section during the period for which the change is effective unless the plan satisfies paragraph (b) of this section both reflecting the temporary change in the benefit formula and disregarding that change.

(C) *Effect of early retirement window benefit on most valuable accrual rate.* In determining an employee's most valuable optional form of payment of the accrued benefit (which is used in determining the employee's most valuable accrual rate under paragraphs (d)(1)(ii) and (f)(4)(i) of this section), an early retirement window benefit that is currently available to the employee (within the meaning of paragraph (f)(4)(ii)(A) of this section) and that is not disregarded for a plan year under paragraph (f)(4)(ii)(A) of this section is taken into account in that plan year with respect to the employee's accrued benefit as of the earliest of the employee's date of termination, the close of the early retirement window, or the last day of that plan year.

(D) *Effect of early retirement window benefit on average benefit percentage test.* Notwithstanding paragraph (c)(2) of this section, a rate group under a plan that provides an early retirement window benefit is deemed to satisfy the average benefit percentage test of § 1.410(b)–5 if—

(*1*) All rate groups under the plan would satisfy the ratio percentage test of § 1.410(b)-2(b)(2) if the early retirement window benefit were disregarded; and

(*2*) The group of employees to whom the early retirement window benefit is currently available (within the meaning of paragraph (f)(4)(ii)(A) of this section) satisfies section 410(b) without regard to the average benefit percentage test of § 1.410(b)–5.

(iii) *Early retirement window benefit defined.* For purposes of this paragraph (f)(4), an early retirement window benefit is an early retirement benefit, retirement-type subsidy, QSUPP, or other optional form of benefit under a plan that is available, or a change in the plan's benefit formula that is applicable, only to employees who terminate employment within a limited period specified by the plan (not to exceed one year) under circumstances specified by the plan. A benefit does not fail to be described in the preceding sentence merely because the plan contains provisions under which certain employees may receive the benefit even though, for bona fide business reasons, they terminate employment within a reasonable period after the end of the limited period. An amendment to an early retirement window benefit that

merely extends the periods in the preceding sentences is not treated as a separate early retirement window benefit, provided that the periods, as extended, satisfy the preceding sentences. However, any other amendment to an early retirement window benefit creates a separate early retirement window benefit.

(iv) *Examples.* The following examples illustrate the rules of this paragraph (f)(4):

Example 1. (a) Plan A provides a benefit of one percent of average annual compensation per year of service and satisfies the requirements of paragraph (b)(2) of this section. Thus, the plan provides the same benefit to all employees with the same years of service under the Plan. Plan A is amended to treat all employees with ten or more years of service who terminate employment after attainment of age 55 and between March 1, 1999, and November 30, 1999, as if they had an additional five years of service under the benefit formula. However, in order to ensure the orderly implementation of the early retirement window, the plan amendment provides that designated employees in the human resources department who would otherwise be eligible for the early retirement window benefit are only eligible to be treated as having the additional five years of service if they terminate between December 1, 1999, and February 28, 2000.

(b) The additional benefits provided under this amendment are tested as benefits provided to employees rather than former employees. The effect of this amendment is temporarily to change the benefit formula for employees who are eligible for the early retirement window benefit because the amendment changes (albeit temporarily) the amount of the benefit payable to those employees at normal retirement age. See the definition of benefit formula in § 1.401(a)(4)–12. Assume that the additional years of service credited to employees eligible for the window benefit do not represent past service (within the meaning of § 1.401(a)(4)–11(d)(3)(i)(B)) or pre-participation or imputed service (within the meaning of § 1.401(a)(4)–11(d)(i)(C)) and thus may not be taken into account as years of service. See § 1.401(a)(4)–11(d)(3)(i)(A) (regarding years of service that may be taken into account under § 1.401(a)(4)–1(b)(2)). Thus, the window-eligible employees are entitled to a larger benefit (as a percentage of average annual compensation) than other employees with the same number of years of service, and the plan does not satisfy the uniform normal retirement benefit requirement of paragraph (b)(2)(i) of this section.

(c) Plan A is restructured under the provisions of § 1.401(a)(4)–8(c) into two component plans: Component Plan A1, consisting of all employees who are not eligible for the early retirement window benefit and all of their accruals and benefits, rights and features, and Component Plan A2, consisting of all employees who are eligible for the early retirement window benefit and all of their accruals and benefits, rights and features under the plan.

(d) Component Plan A1 still satisfies paragraph (b) of this section, because there has been no change for the employees in that component plan. Similarly, Component Plan A2 satisfies paragraph (b) of this section disregarding the change in the benefit formula.

(e) Because the early retirement window benefit consists of a temporary change in the benefit formula, paragraph (f)(4)(ii)(B) of this section requires that the plan satisfy the requirements of paragraph (b) of this section reflecting the change in order to remain a safe harbor plan. After reflecting the change, Component Plan A2 still provides the same benefit (albeit higher than under the regular benefit formula) to all employees with the same years of service that may be taken into account in testing the plan, and thus the benefit formula (as temporarily amended) satisfies the requirements of paragraph (b)(2)(i) and (ii) of this section.

(f) Since Component Plan A2 also satisfies all of the other requirements of paragraph (b)(2) of this section and the safe harbor of paragraph (b)(3) of this section reflecting the change in the benefit formula, Component Plan A2 satisfies this paragraph (b) both reflecting and disregarding the change in the benefit formula. Thus, Component Plan A2 satisfies paragraph (b) of this section.

Example 2. The facts are the same as in *Example 1*, except that the plan's benefit formula used the maximum amount of permitted disparity under section 401(*l*) prior to the amendment. The analysis is the same as in paragraphs (a) through the first sentence of paragraph (e) of *Example 1*. In order to satisfy the requirements of paragraph (b)(2) of this section, a plan that uses permitted disparity must satisfy the requirements of section 401 (*l*) after reflecting the change in the benefit formula. Because, as stated in *Example 1*, the additional five years of service may not be taken into account for purposes of satisfying paragraph (b) of this section, the disparity that results from crediting that service exceeds the maximum permitted disparity under section 401(*l*). Thus, the plan does not satisfy the requirements of paragraph (b) of this section.

Example 3. The facts are the same as in *Example 1*, except that Plan A is tested under the general test in paragraph (c) of this section. The early retirement window benefit is disregarded for purposes of determining the normal accrual rates, but is taken into account in 1999 for purposes of determining the most valuable accrual rates, of employees who were eligible for the early retirement window benefit (regardless of whether they elected to receive it). As stated in *Example 1*, the additional five years of service do not represent past service, pre-participation service, or imputed service, and thus under § 1.401(a)(4)–11(d)(3)(i)(A) may not be taken into account as testing service.

(5) *Unpredictable contingent event benefits*—(i) *General rule.* In general, an unpredictable contingent event benefit (within the meaning of section 412(*l*)(7)(B)(ii)) is not taken into account under this section until the occurrence of the contingent event. Thus, the special rule in § 1.401(a)(4)–4(d)(7) (treating the contingent event as having occurred) does not apply for purposes of this section. In the case of an unpredictable contingent event that is expected to result in the termination from employment of certain employees within a period of time consistent with the rules for defining an early retirement window benefit in paragraph (f)(4)(iii) of this section, the unpredictable contingent event benefit available to those employees is permitted to be treated as an early retirement window benefit, thus permitting the rules of paragraph (f)(4) of this section to be applied to it. See § 1.401(a)(4)–4(d)(7) for an additional rule relevant to the testing of unpredictable contingent event benefits.

(ii) *Example.* The following example illustrates the rules of this paragraph (f)(5):

Example. (a) Employer X operates various manufacturing plants and maintains Plan A, a defined benefit plan that covers all of its nonexcludable employees. Plan A provides an early retirement benefit under which employees who retire after age 55 but before normal retirement age and who have at least 10 years of service receive a benefit equal to their normal retirement benefit reduced by four percent per year for each year prior to normal retirement age. Plan A also provides a plant-closing benefit under which employees who satisfy the conditions for receiving the early retirement benefit and who work at a plant where operations have ceased and whose employment has been terminated will receive or unreduced normal retirement benefit. The plant-closing benefit is an unpredictable contingent event benefit.

(b) During the 1997 plan year, Employer X had no plant closings. Therefore, the plant-closing benefit is not taken into account for the 1997 plan year in determining accrual rates or in applying the safe harbors in paragraph (b) of this section.

(c) During the 1998 plan year, Employer X begins to close one plant. Employees M through Z, who are employees at the plant that is closing, are expected to terminate employment with Employer X during the plan year and will satisfy the conditions for the plant-closing benefit. Therefore, in testing Plan A under this section for the 1998 plan year, the availability of the plant-closing benefit to Employees M through Z must be taken into account in determining their accrual rates or in determining whether the plan satisfies one of the safe harbors under paragraph (b) of this section.

(d) Because the employees eligible for the unpredictable contingent event benefit are expected to terminate employment with Employer X during a period consistent with the rules for defining an early retirement window benefit, in testing Plan A under this section for the 1998 plan year, the special rules in paragraph (f)(4)(ii) of this section may be applied. Thus, for example, normal accrual rates may be determined without reference to the unpredictable contingent event benefit.

(e) Despite the closing of the plant, Employee Q remains an employee into the 1999 plan year. Under paragraph (f)(4)(ii)(A) of this section, the availability of the plant-closing benefit to Employee Q may be disregarded in the 1999 plan year.

(6) *Determination of benefits on other than plan-year basis.* For purposes of this section, accruals are generally determined based on the plan year. Nevertheless, an employer may determine accruals on the basis of any period ending within the plan year as long as the period is at least 12 months in duration. For example, accruals for all employees may be determined based on accrual computation periods ending within the plan year.

(7) *Adjustments for certain plan distributions.* For purposes of this section, an employee's accrued benefit includes the actuarial equivalent of prior distributions of accrued benefits from the plan to the employee if the years of service taken into account in determining the accrued benefits that were distributed continue to be taken into account under the plan for purposes of determining the employee's current accrued benefit. For purposes of this paragraph (f)(7), actuarial equivalence must be determined in a uniform manner for all employees using reasonable actuarial assumptions. A standard interest rate and a standard mortality table are among the assumptions considered reasonable for this purpose. Thus, for example, if an employee has commenced receipt of benefits in accordance with the minimum distribution requirements of section 401(a)(9), and the plan reduces the employee's accrued benefit to take into account the amount of the distributions, the employee's accrued benefit for purposes of this section is restored to the value it would have had if the distributions had not occurred.

(8) *Adjustment for certain OPSA charges.* For purposes of this section, an employee's accrued benefit includes the cost of a qualified preretirement survivor annuity (QPSA) that reduces the employee's accrued benefit otherwise determined under the plan, as permitted under § 1.401(a)–20, Q&A–21. Thus, an employee's accrued benefit for purposes of this section is determined as if the cost of the QPSA had not been charged against the accrued benefit. This paragraph (f)(8) applies only if the QPSA charges apply uniformly to all employees.

(9) *Disregard of certain offsets*—(i) *General rule.* For purposes of this section, an employee's accrued benefit under a plan includes that portion of the benefit that is offset under an offset provision described in § 1.401(a)(4)–11(d)(3)(i)(D). The rule in the preceding sentence applies only to the extent that the benefit by which the benefit under the plan being tested is offset is attributable to periods for which the plan being tested credits pre-participation service (within the meaning of § 1.401(a)(4)–11(d)(3)(ii)(A)) that satisfies § 1.401(a)(4)–11(d)(3)(iii) or past service (within the meaning of § 1.401(a)(4)–11(d)(3)(i)(B)), and only if—

(A) The benefit under the plan being tested is offset by either—

(*1*) Benefits under a qualified defined benefit plan or defined contribution plan (whether or not terminated); or

(*2*) Benefits under a foreign plan that are reasonably expected to be paid; and,

(B) If any portion of the benefit that is offset is nonforfeitable (within the meaning of section 411), that portion is offset by a benefit (or portion of a benefit) that is also nonforfeitable (or vested, in the case of a foreign plan).

(ii) *Examples.* The following examples illustrate the rules in this paragraph (f)(9):

Example 1. (a) Employer X maintains two qualified defined benefit plans, Plan A and Plan B. Plan B provides that, whenever an employee transfers to Plan B from Plan A, the service that was credited under Plan A is credited in determining benefits under Plan B. The Plan A service credited under Plan B is pre-participation service that satisfies § 1.401(a)(4)–11(d)(3)(iii). Plan B offsets the benefits determined under Plan B by the employee's vested benefits under Plan A. Plan A does not credit additional benefit service or accrual service after employees transfer to Plan B.

(b) The Plan B provision providing for an offset of benefits under Plan A satisfies § 1.401(a)(4)–11(d)(3)(i)(D). This is because the provision applies to similarly-situated employees and the benefits under Plan A that are offset against the Plan B benefits are attributable to pre-participation service taken into account under Plan B.

(c) This paragraph (f)(9) applies in determining the benefits that are taken into account under this section for employees in Plan B who are transferred from Plan A. This is because the offset provision is described in § 1.401(a)(4)–11(d)(3)(i)(D), the benefits under the other plan by which the benefits under the plan being tested are offset are attributable solely to pre-participation service that satisfies § 1.401(a)(4)–11(d)(3)(iii), and the benefits are offset solely by vested benefits under another qualified plan. Thus, for example, the accrual rates of employees in Plan B are determined as if there were no offset, i.e., by adding back the benefits that are offset to the net benefits under Plan B.

(d) The result would be the same even if Plan A continued to recognize compensation paid after the transfer in the determination of benefits under Plan A. However, if Plan A continued to credit benefit or accrual service after the transfer, then, to the extent that Plan B's offset of benefits under Plan A increased as a result, the additional benefits offset under Plan B would not be added back in determining the benefits under Plan B that are taken into account under this section.

Example 2. The facts are the same as in *Example 1*, except that Plan A is not a plan described in paragraph (f)(9)(i)(A) of this section. None of the benefits under Plan B that are offset by benefits under Plan A may be added back in determining the benefits under Plan B that are taken into account under this section. Thus, benefits under plan B are tested on a net basis.

§ 1.401(a)(4)–4 Nondiscriminatory availability of benefits, rights, and features.

(a) *Introduction.* This section provides rules for determining whether the benefits, rights, and features provided under a plan (i.e., all optional forms of benefit, ancillary benefits, and other rights and features available to any employee under the plan) are made available in a discriminatory manner. Benefits, rights, and features provides under a plan are made available to employees in a nondiscriminatory manner only if each benefit, right, or feature satisfies the current availability requirement of paragraph (b) of this section and the effective availability requirement of paragraph (c) of this section. Paragraph (d) of this section provides special rules for applying these requirements. Paragraph (e) of this section defines optional form of benefit, ancillary benefit, and other right or feature.

(b) *Current availability*—(1) *General rule.* The current availability requirement of this paragraph (b) is satisfied if the group of employees to whom a benefit, right, or feature is currently available during the plan year satisfies section 410(b) (without regard to the average benefit percentage test of § 1.410(b)–5). In determining whether the group of employees satisfies section 410(b), an employee is treated as benefiting only if the benefit, right, or feature is currently available to the employee.

(2) *Determination of current availability*)—(i) *General rule.* Whether a benefit, right, or feature that is subject to specified eligibility conditions is currently available to an employee generally is determined based on the current facts and circumstances with respect to the employee (e.g., current compensation, accrued benefit, position, or net worth).

(ii) *Certain conditions disregarded*—(A) *Certain age and service conditions*—(*1*) *General rule.* Notwithstanding paragraph (b)(2)(i) of this section, any specified age or service condition with respect to an optional form of benefit or a social security supplement is disregarded in determining whether the

optional form of benefit or the social security supplement is currently available to an employee. Thus, for example, an optional form of benefit that is available to all employees who terminate employment on or after age 55 with at least 10 years of service is treated as currently available to an employee, without regard to the employee's current age or years of service, and without regard to whether the employee could potentially meet the age and service conditions prior to attain the plan's normal retirement age.

(2) *Time-limited age or service conditions not disregarded.* Notwithstanding paragraph (b)(2)(ii)(A)(*1*) of this section, an age or service condition is not disregarded in determining the current availability of an optional form of benefit or social security supplement if the condition must be satisfied within a limited period of time. However, in determining the current availability of an optional form of benefit or a social security supplement subject to such an age or service condition, the age and service of employees may be projected to the last date by which the age condition or service condition must be satisfied in order to be eligible for the optional form of benefit or social security supplement under the plan. Thus, for example, an optional form of benefit that is available only to employees who terminate employment between July 1, 1995, and December 31, 1995, after attainment of age 55 with at least 10 years of service is treated as currently available to an employee only if the employee could satisfy those age and service conditions by December 31, 1995.

(B) *Certain other conditions.* Specified conditions on the availability of a benefit, right, or feature requiring termination of employment, death, satisfaction of a specified health condition (or failure to meet such condition), disability, hardship, marital status, default on a plan loan secured by a participant's account balance, execution of a covenant not to compete, application for benefits or similar ministerial or mechanical acts, election of a benefit form, execution of a waiver of rights under the Age Discrimination in Employment Act, or absence from service, are disregarded in determining the employees to whom the benefit, right, or feature is currently available.

(C) *Certain conditions relating to mandatory cash-outs.* In the case of a plan that provides for mandatory cash-outs of all terminated employees who have a vested accrued benefit with an actuarial present value less than or equal to a specified dollar amount (not to exceed $3,500) as permitted by sections 411(a)(11) and 417(e), the implicit condition on any benefit, right, or feature (other than the mandatory cash-out) that requires the employee to have a vested accrued benefit with an actuarial present value in excess of the specified dollar amount is disregarded in determining the employees to whom the benefit, right, or feature is currently available.

(D) *Other dollar limits.* A condition that the amount of an employee's vested accrued benefit or the actuarial present value of that benefit be less than or equal to a specified dollar amount is disregarded in determining the employees to whom the benefit, right, or feature is currently available.

(E) *Certain conditions on plan loans.* In the case of an employee's right to a loan from the plan, the condition that an employee must have an account balance sufficient to be eligible to receive a minimum loan amount specified in the plan (not to exceed $1,000) is disregarded in determining the employees to whom the right is currently available.

(3) *Benefits, rights, and features that are eliminated prospectively*—(i) *Special testing rule.* Notwithstanding paragraph (b)(1) of this section, a benefit, right, or feature that is eliminated with respect to benefits accrued after the later of the eliminating amendment's adoption or effective date (the "elimination date"), but is retained with respect to benefits accrued as of the elimination date, and that satisfies this paragraph (b) as of the elimination date, is treated as satisfying this paragraph (b) for all subsequent periods. This rule does not apply if the terms of the benefit, right, or feature (including the employees to whom it is available) are changed after the elimination date.

(ii) *Elimination of a benefit, right, or feature*—(A) *General rule.* For purposes of this paragraph (b)(3), a benefit, right, or feature provided to an employee is eliminated with respect to benefits accrued after the elimination date if the amount or value of the benefit, right, or feature depends solely on the amount of the employee's accrued benefit (within the meaning of section 411(a)(7)) as of the elimination date, including subsequent income, expenses, gains, and losses with respect to that benefit in the case of a defined contribution plan.

(B) *Special rule for benefits, rights, and features that are not section 411(d)(6)-protected benefits.* Notwithstanding paragraph (b)(3)(ii)(A) of this section, in the case of a benefit, right, or feature under a defined contribution plan that is not a section 411(d)(6)-protected benefit (within the meaning of § 1.411(d)–4, Q&A-1), e.g., the availability of plan loans, for purposes of this paragraph (b)(3)(ii) each employee's accrued benefit as of the elimination date may be treated, on a uniform basis, as consisting exclusively of the dollar amount of the employee's account balance as of the elimination date.

(C) *Special rule for benefits, rights, and features that depend on adjusted accrued benefits.* For purposes of this paragraph (b)(3), a benefit, right or feature provided to an employee under a plan that has made a fresh start does not fail to be eliminated as of an elimination date that is the fresh-start date merely because it depends solely on the amount of the employee's adjusted accrued benefit (within the meaning of § 1.401(a)(4)–13(d)(8)).

(c) *Effective availability*—(1) *General rule.* Based on all of the facts and circumstances, the group of employees to whom a benefit, right, or feature is effectively available must not substantially favor HCEs.

(2) *Examples.* The following examples illustrate the rules of this paragraph (c):

Example 1. Employer X maintains Plan A, a defined benefit plan that covers both of its highly compensated nonexcludable employees and nine of its 12 nonhighly compensated nonexcludable employees. Plan A provides for a normal retirement benefit payable as an annuity and based on a normal retirement age of 65, and an early retirement benefit payable upon termination in the form of an annuity to employees who terminate from service with the employer on or after age 55 with 30 or more years of service. Both HCEs of Employer X currently meet the age and service requirement, or will have 30 years of service by the time they reach age 55. All but two of the nine NHCEs of Employer X who are covered by Plan A were hired on or after age 35 and, thus, cannot qualify for the early retirement benefit. Even though the group of employees to whom the early retirement benefit is currently available satisfies the ratio percentage test of § 1.410(b)–2(b)(2) when age and service are disregarded pursuant to paragraph (b)(2)(ii)(A) of this section, absent other facts, the group of employees to whom the early retirement benefit is effectively available substantially favors HCEs.

Example 2. Employer Y maintains Plan B, a defined benefit plan that provides for a normal retirement benefit payable as an annuity and based on a normal retirement age of 65. By a plan amendment first adopted and effective December 1, 1996, Employer Y amends Plan B to provide an early retirement benefit that is available only to employees who terminate employment by December 15, 1998, and who are at least age 55 with 30 or more years of service. Assume that all employees were hired prior to attaining age 25 and that the group of employees who have, or will have, attained age 55 with 30 years of service by December 15, 1998, satisfies the ratio percentage test of § 1.410(b)–2(b)(2). Assume, further, that the

employer takes no steps to inform all eligible employees of the early retirement option on a timely basis and that the only employees who terminate from employment with the employer during the two-week period in which the early retirement benefit is available are HCEs. Under these facts, the group of employees to whom this early retirement window benefit is effectively available substantially favors HCEs.

Example 3. Employer Z amends Plan C on June 30, 1999, to provide for a single sum optional form of benefit for employees who terminate from employment with Employer Z after June 30, 1999, and before January 1, 2000. The availability of this single sum optional form of benefit is conditioned on the employee's having a particular disability at the time of termination of employment. The only employee of the employer who meets this disability requirement at the time of the amendment and thereafter through December 31, 1999, is a HCE. Under paragraph (b)(2)(ii)(B) of this section, the disability condition is disregarded in determining the current availability of the single sum optional form of benefit. Nevertheless, under these facts, the group of employees to whom the single sum optional form of benefit is effectively available substantially favors HCEs.

(d) *Special rules*—(1) *Mergers and acquisitions*—(i) *Special testing rule.* A benefit, right, or feature available under a plan solely to an acquired group of employees is treated as satisfying paragraphs (b) and (c) of this section during the period that each of the following requirements is satisfied:

(A) The benefit, right, or feature must satisfy paragraphs (b) and (c) of this section (determined without regard to the special rule in section 410(b)(6)(C)) on the date that is the latest date of hire or transfer into an acquired trade or business for an employee to be included in the acquired group of employees. This determination is made with reference to the plan of the current employer and its nonexcludable employees.

(B) The benefit, right, or feature must be available under the plan of the current employer after the transaction on the same terms as it was available under the plan of the prior employer before the transaction. This requirement is not violated merely because of a change made to the benefit, right, or feature that is permitted by section 411(d)(6), provided that—

(*1*) The change is a replacement of the benefit, right, or feature with another benefit, right, or feature that is available to the same employees as the original benefit, right, or feature, and the original benefit, right, or feature is of inherently equal or greater value (within the meaning of paragraph (d)(4)(i)(A) of this section) than the benefit, right, or feature that replaces it; or

(*2*) The change is made before January 12, 1993.

(ii) *Scope of special testing rule.* This paragraph (d)(1) applies only to benefits, rights, and features with respect to benefits accruing under the plan of the current employer, and not to benefits, rights, and features with respect to benefits accrued under the plan of the prior employer (unless, pursuant to the transaction, the plan of the prior employer becomes the plan of the current employer, or the assets and liabilities with respect to the acquired group of employees under the plan of the prior employer are transferred to the plan of the current employer in a plan merger, consolidation, or other transfer described in section 414(*l*)).

(iii) *Example.* The following examples illustrates the rules of this paragraph (d)(1):

Example. Employer X maintains Plan A, a defined benefit plan with a single sum optional form of benefit for all employees. Employer Y acquires Employer X and merges Plan A into Plan B, a defined benefit plan maintained by Employer Y that does not otherwise provide a single sum optional form of benefit. Employer Y continues to provide the single sum optional form of benefit under Plan B on the same terms as it was offered under Plan A to all employees who were acquired in the transaction with Employer X (and to no other employees). The optional form of benefit satisfies paragraphs (b) and (c) of this section immediately following the transaction (determined without taking into account section 410(b)(6)(C)) when tested with reference to Plan B and Employer Y's nonexcludable employees. Under these facts, Plan B is treated as satisfying this section with respect to the single sum optional form of benefit for the plan year of the transaction and all subsequent plan years.

(2) *Frozen participants.* A plan must satisfy the nondiscriminatory availability requirement of this section not only with respect to benefits, rights, and features provided to employees who are currently benefiting under the plan, but also separately with respect to benefits, rights, and features provided to nonexcludable employees with accrued benefits who are not currently benefiting under the plan ("frozen participants"). Thus, each benefit, right, and feature available to any frozen participant under the plan is separately subject to the requirements of this section. A plan satisfies paragraphs (b) and (c) of this section with respect to a benefit, right, or feature available to any frozen participant under the plan only if one or more of the following requirements is satisfied:

(i) The benefit, right, or feature must be one that would satisfy paragraphs (b) and (c) of this section if it were not available to any employee currently benefiting under the plan.

(ii) The benefit, right, or feature must be one that would satisfy paragraphs (b) and (c) of this section if all frozen participants were treated as employees currently benefiting under the plan.

(iii) No change in the availability of the benefit, right, or feature may have been made that is first effective in the current plan year with respect to a frozen participant.

(iv) Any change in the availability of the benefit, right, or feature that is first effective in the current plan year with respect to a frozen participant must be made in a nondiscriminatory manner. Thus, any expansion in the availability of the benefit, right, or feature to any highly compensated frozen participant must be applied on a consistent basis to all nonhighly compensated frozen participants. Similarly, any contraction in the availability of the benefit, right, or feature that affects any nonhighly compensated frozen participant must be applied on a consistent basis to all highly compensated frozen participants.

(3) *Early retirement window benefits.* If a benefit, right, or feature meets the definition of an early retirement window benefit in § 1.401(a)(4)–3(f)(4)(iii) (or would meet that definition if the definition applied to all benefits, rights, and features), the benefit, right, or feature is disregarded for purposes of applying this section with respect to an employee for all plan years other than the first plan year in which the benefit is currently available to the employee.

(4) *Permissive aggregation of certain benefits, rights, or features*—(i) *General rule.* An optional form of benefit, ancillary benefit, or other right or feature may be aggregated with another optional form of benefit, ancillary benefit, or other right or feature, respectively, and the two may be treated as a single optional form of benefit, ancillary benefit, or other right or feature, if both of the following requirements are satisfied:

(A) One of the two optional forms of benefit, ancillary benefit, or other rights or features must in all cases be of inherently equal or greater value than the other. For this purpose, one benefit, right, or feature is of inherently equal or greater value than another benefit, right, or feature only if, at any time and under any conditions, it is impossible for any employee to receive a smaller amount or a less valuable right under the first benefit, right, or feature than under the second benefit, right, or feature.

(B) The optional form of benefit, ancillary benefit, or other right or feature of inherently equal or greater value must separately satisfy paragraphs

(b) and (c) of this section (without regard to this paragraph (d)(4)).

(ii) *Aggregation may be applied more than once.* The aggregation rule in this paragraph (d)(4) may be applied more than once. Thus, for example, an optional form of benefit may be aggregated with another optional form of benefit that itself constitutes two separate optional forms of benefit that are aggregated and treated as a single optional form of benefit under this paragraph (d)(4).

(iii) *Examples.* The following examples illustrate the rules in this paragraph (d)(4):

Example 1. Plan A is a defined benefit plan that provides a single sum optional form of benefit to all employees. The single sum optional form of benefit is available on the same terms to all employees, except that, for employees in Division S, a five-percent discount factor is applied and, for employees of Division T, a seven-percent discount factor is applied. Under paragraph (e)(1) of this section, the single sum optional form of benefit constitutes two separate optional forms of benefit. Assume that the single sum optional form of benefit available to employees of Division S separately satisfies paragraphs (b) and (c) of this section without taking into account this paragraph (d)(4). Because a lower discount factor is applied in determining the single sum optional form of benefit available to employees of Division S than is applied in determining the single sum optional form of benefit available to employees of Division T, the first single sum optional form of benefit is of inherently greater value than the second single sum optional form of benefit. Under these facts, these two single sum optional forms of benefit may be aggregated and treated as a single optional form of benefit for purposes of this section.

Example 2. The facts are the same as in *Example 1*, except that, in order to receive the single sum optional form of benefit, employees of Division S (but no employees of Division T) must have completed at least 20 years of service. The single sum optional form of benefit available to employees of Division S is not of inherently equal or greater value than the single sum optional form of benefit available to employees of Division T, because an employee of Division S who terminates employment with less than 20 years of service would receive a smaller single sum amount (i.e., zero) than a similarly-situated employee of Division T who terminates employment with less than 20 years of service. Under these facts, the two single sum optional forms of benefit may not be aggregated and treated as a single optional form of benefit for purposes of this section.

(5) *Certain spousal benefits.* In the case of a plan that includes two or more plans that have been permissively aggregated under § 1.410(b)–7(d), the aggregated plan satisfies this section with respect to the availability of any nonsubsidized qualified joint and survivor annuities, qualified preretirement survivor annuities, or spousal death benefits described in section 401(a)(11), if each plan that is part of the aggregated plan satisfies section 401(a)(11). Whether a benefit is considered subsidized for this purpose may be determined using any reasonable actuarial assumptions. For purposes of this paragraph (d)(5), a qualified joint and survivor annuity, qualified preretirement survivor annuity, or spousal death benefit is deemed to be nonsubsidized if it is provided under a defined contribution plan.

(6) *Special ESOP rules.* An ESOP does not fail to satisfy paragraphs (b) and (c) of this section merely because it makes an investment diversification right or feature or a distribution option available solely to all qualified participants (within the meaning of section 401(a)(28)(B)(iii), or merely because the restrictions of section 499(n) apply to certain individuals.

(7) *Special testing rule for unpredictable contingent event benefits.* A benefit, right, or feature that is contingent on the occurrence of an unpredictable contingent event (within the meaning of section 412(l)(7)(B)(ii) is tested under this section as if the event had occurred. Thus, the current availability of a benefit that becomes an optional form of benefit upon the occurrence of an unpredictable contingent event is tested by deeming the event to have occurred and by disregarding age and service conditions on the eligibility for that benefit to the extent permitted for optional forms of benefit under paragraph (b)(2) of this section.

(e) *Definitions*—(1) *Optional form of benefit*—(i) *General rule.* The term "optional form of benefit" means a distribution alternative (including the normal form of benefit) that is available under a plan with respect to benefits described in section 411(d)(6)(A) or a distribution alternative that is an early retirement benefit or retirement-type subsidy described in section 411(d)(6)(B)(i), including a QSUPP. Except as provided in paragraph (e)(1)(ii) of this section, different optional forms of benefit exist if a distribution alternative is not payable on substantially the same terms as another distribution alternative. The relevant terms include all terms affecting the value of the optional form, such as the method of benefit calculation and the actuarial assumptions used to determine the amount distributed. Thus, different optional forms of benefit may result from differences in terms relating to the payment schedule, timing, commencement, medium of distribution (e.g., in cash or in kind), election rights, or the portion of the benefit to which the distribution alternative applies.

Exceptions—(A) *Differences in benefit formula or accrual method.* A distribution alternative available under a defined benefit plan does not fail to be a single optional form of benefit merely because the benefit formulas, accrual methods, or other factors (including service-computation methods and definitions of compensation) underlying, or the manner in which employees vest in, the accrued benefit that is paid in the form of the distribution alternative are different for different employees to whom the distribution alternative is available. Notwithstanding the foregoing, differences in the normal retirement ages of employees (other than differences that do not prevent a plan from having a single uniform normal retirement age) or in the form in which the accrued benefit of employees is payable at normal retirement age under a plan are taken into account in determining whether a distribution alternative constitutes one or more optional forms of benefit.

(B) *Differences in allocation formula.* A distribution alternative available under a defined contribution plan does not fail to be a single optional form of benefit merely because the allocation formula or other factors (including service-computation methods, definitions of compensation, and the manner in which amounts described in § 1.401(a)(4)–2(c)(2)(iii) are allocated) underlying, or the manner in which employees vest in, the accrued benefit that is paid in the form of the distribution alternative are different for different employees to whom the distribution alternative is available.

(C) *Distributions subject to section 417(e).* A distribution alternative available under a defined benefit plan does not fail to be a single optional form of benefit merely because, in determining the amount of a distribution, the plan applies a lower interest rate to determine the distribution for employees with a vested accrued benefit having an actuarial present value not in excess of $25,000, as required by section 417(e)(3) and § 1.417(e)–1.

(iii) *Examples.* The following examples illustrate the rules in this paragraph (e)(1):

Example 1. Plan A is a defined benefit plan that benefits all employees of Divisions S and T. The plan offers a qualified joint and 50-percent survivor annuity at normal retirement age, calculated by multiplying an employee's single life annuity payment by a

factor. For an employee of Division S whose benefit commences at age 65, the plan provides a factor of 0.90, but for a similarly-situated employee of Division T the plan provides a factor of 0.85. The qualified joint and survivor annuity is not available to employees of Division S and T on substantially the same terms, and thus it constitutes two separate optional forms of benefit.

Example 2. Plan B is a defined benefit plan that benefits all employees of Divisions U and V. The plan offers a single sum distribution alternative available on the same terms and determined using the same actuarial assumptions, to all employees. However, different benefit formulas apply to employees of each division. Under the exception provided in paragraph (e)(1)(ii)(A) of this section, the single sum optional form of benefit available to employees of Division U is not a separate optional form of benefit from the single sum optional form of benefit available to employees of Division V.

Example 3. Defined benefit Plan C provides an early retirement benefit based on a schedule of early retirement factors that is a single optional form of benefit. Plan C is amended to provide an early retirement window benefit that consists of a temporary change in the plan's benefit formula (e.g., the addition of five years of service to an employee's actual service under the benefit formula) applicable in determining the benefits for certain employees who terminate employment within a limited period of time. Under the exception provided in paragraph (e)(1)(ii)(A) of this section, the early retirement optional form of benefit available to window-eligible employees is not a separate optional form of benefit from the early retirement optional form of benefit available to the other employees.

(2) *Ancillary benefit.* The term "ancillary benefit" means social security supplements (other than QSUPPs), disability benefits not in excess of a qualified disability benefit described in section 411(a)(9), ancillary life insurance and health insurance benefits, death benefits under a defined contribution plan, preretirement death benefits under a defined benefit plan, shut-down benefit not protected under section 411(d)(6), and other similar benefits. Different ancillary benefit exist if an ancillary benefits is not available on substantially the same terms as another ancillary benefit. Principles similar to those in paragraph (e)(1)(ii) of this section apply in making this determination.

(3) *Other right or feature*—(i) *General rule.* The term "other right or feature" generally means any right or feature applicable to employees under the plan. Different rights or features exist if a right or feature is not available on substantially the same terms as another right or feature.

(ii) *Exceptions to definition of other right or feature.* Notwithstanding paragraph (e)(3)(i) of this section, a right or feature is not considered an "other right or feature" if it—

(A) Is an optional form of benefit or an ancillary benefit under the plan;

(B) Is one of the terms that are taken into account in determining whether separate optional forms or ancillary benefits exist, or that would be taken into account but for paragraph (e)(1)(ii) of this section (e.g., benefit formulas or the manner in which benefits vest); or

(C) Cannot reasonably be expected to be of meaningful value to an employee (e.g., administrative details).

(iii) *Examples.* Other rights and features include, but are not limited to—

(A) Plan loan provisions (other than those relating to a distribution of an employee's accrued benefit upon default under a loan);

(B) The right to direct investments;

(C) The right to a particular form of investment, including, for example, a particular class or type of employer securities (taking into account, in determining whether different forms of investment exist, any differences in conversion, dividend, voting, liquidation preference, or other rights conferred under the security);

(D) The right to make each rate of elective contributions described in § 1.401(k)–1(g)(3) (determining the rate based on the plan's definition of the compensation out of which the elective contributions are made (regardless of whether that definition satisfies section 414(s)), but also treating different rates as existing if they are based on definitions of compensation or other requirements or formulas that are not substantially the same);

(E) The right to make after-tax employee contributions to a defined benefit plan that are not allocated to separate accounts;

(F) The right to make each rate of after-tax employee contributions described in § 1.401(m)–1(f)(6) (determining the rate based on the plan's definition of the compensation out of which the after-tax employee contributions are made (regardless of whether that definition satisfies section 414(s)), but also treating different rates as existing if they are based on definitions of compensation or other requirements or formulas that are not substantially the same);

(G) The right to each rate of allocation of matching contributions described in § 1.401(m)–1(f)(12) (determining the rate using the amount of matching, elective and after-tax employee contributions determined after any corrections under §§ 1.401(k)–1(f)(i), 1.401(m)–1(e)(1)(i), and 1.401(m)–2(c), but also treating different rates as existing if they are based on definitions of compensation or other requirements or formulas that are not substantially the same);

(H) The right to purchase additional retirement or ancillary benefits under the plan; and

(I) The right to make rollover contributions and transfers to and from the plan.

§ 1.401(a)(4)–5 Plan amendments and plan terminations.

(1) *Introduction*—(1) *Overview.* This paragraph (a) provides rules for determining whether the timing of a plan amendment or series of amendments has the effect of discriminating significantly in favor of HCEs or former HCEs. For purposes of this section, a plan amendment includes, for example, the establishment or termination of the plan, and any change in the benefits, rights, or features, benefit formulas, or allocation formulas under the plan. Paragraph (b) of this section sets forth additional requirements that must be satisfied in the case of a plan termination.

(2) *Facts-and-circumstances determination.* Whether the timing of a plan amendment or series of plan amendments has the effect of discriminating significantly in favor of HCEs or former HCEs is determined at the time the plan amendment first becomes effective for purposes of section 401(a), based on all relevant facts and circumstances. These include for example, the relative numbers of current and former HCEs and NHCEs affected by the plan amendment, the relative length of service of current and former HCEs and NHCEs, the length of time the plan or plan provision being amended has been in effect, and the turnover of employees prior to the plan amendment. In addition, the relevant facts and circumstances include the relative accrued benefits of current and former HCEs and NHCEs before and after the plan amendment and any additional benefits provided to current and former HCEs and NHCEs under other plans (including plans of other employers, if relevant). In the case of a plan amendment that provides additional benefits based on an employee's service prior to the amendment, the relevant facts and circumstances also include the benefits that employees and former employees who do not benefit under the amendment would have received had the plan, as amended, been in effect throughout the period on which the additional benefits are based.

(3) *Safe harbor for certain grants of benefits for past periods.* The timing of a plan amendment that credits (or increases benefits attributable to) years

of service for a period in the past is deemed not to have the effect of discriminating significantly in favor of HCEs or former HECs if the period for which the service credit (or benefit increase) is granted does not exceed the five years immediately preceding the year in which the amendment first becomes effective, the service credit (or benefit increase) is granted on a reasonably uniform basis to all employees, benefits attributable to the period are determined by applying the current plan formula, and the service credited is service (including pre-participation or imputed service) with the employer or a previous employer that may be taken into account under § 1.401(a)(4)–11(d)(3) (without regard to § 1.401(a)(4)–11(d)(3)(i)(B)). However, this safe harbor is not available if the plan amendment granting the service credit (or increasing benefits) is part of a pattern of amendments that has the effect of discriminating significantly in favor of HCEs or former HCEs.

(4) *Examples.* The following examples illustrate the rules in this paragraph (a):

Example 1. Plan A is a defined benefit plan that covered both HCEs and NHCEs for most of its existence. The employer decides to wind up its business. In the process of ceasing operations, but at a time when the plan covers only HCEs, Plan A is amended to increase benefits and thereafter is terminated. The timing of this plan amendment has the effect of discriminating significantly in favor of HCEs.

Example 2. Plan B is a defined benefit plan that provides a social security supplement that is not a QSUPP. After substantially all of the HCEs of the employer have benefited from the supplement, but before a substantial number of NHCEs have become eligible for the supplement, Plan B is amended to reduce significantly the amount of the supplement. The timing of this plan amendment has the effect of discriminating significantly in favor of HCEs.

Example 3. Plan C is a defined benefit plan that contains an ancillary life insurance benefit available to all employees. The plan is amended to eliminate this benefit at a time when life insurance payments have been made only to beneficiaries of HCEs. Because all employees received the benefit of life insurance coverage before Plan C was amended, the timing of this plan amendment does not have the effect of discriminating significantly in favor of HCEs or former HCEs.

Example 4. Plan D provides for a benefit of one percent of average annual compensation per year of service. Ten years after Plan D is adopted, it is amended to provide a benefit of two percent of average annual compensation per year of service, including years of service prior to the amendment. The amendment is effective only for employees currently employed at the time of the amendment. The ratio of HCEs to former HCEs is significantly higher than the ratio of NHCEs to former NHCEs. In the absence of any additional factors, the timing of this plan amendment has the effect of discriminating significantly in favor of HCEs.

Example 5. The facts are the same as in *Example 4*, except that, in addition, the years of prior service are equivalent between HCEs and NHCEs who are current employees, and the group of current employees with prior service would satisfy the nondiscriminatory classification test of § 1.410(b)–4 in the current and all prior plan years for which past service credit is granted. The timing of this plan amendment does not have the effect of discriminating significantly in favor of HCEs or former HCEs.

Example 6. Employer V maintains Plan E, an accumulation plan. In 1993, Employer V amends Plan E to provide that the compensation used to determine an employee's benefit for all preceding plan years shall not be less than the employee's average annual compensation as of the close of the 1993 plan year. The years of service and percentage increases in compensation for HCEs are reasonably comparable to those of NHCEs. In addition, the ratio of HCEs to former HCEs is reasonably comparable to the ratio of NHCEs to former NHCEs. The timing of this plan amendment does not have the effect of discriminating significantly in favor of HCEs or former HCEs.

Example 7. Employer W currently has six nonexcludable employees, two of whom, H1 and H2, are HCEs, and the remaining four of whom, N1 through N4, are NHCEs. The ratio of HCEs to former HCEs is significantly higher than the ratio of NHCEs to former NHCEs. Employer W establishes Plan F, a defined benefit plan providing a benefit of one percent of average annual compensation per year of service, including years of service prior to the establishment of the plan. H1 and H2 each have 15 years of prior service, N1 has nine years of past service, N2 has five years, N3 has three years, and N4 has one year. The timing of this plan establishment has the effect of discriminating significantly in favor of HCEs.

Example 8. Assume the same facts as in *Example 7*, except that N1 through N4 were hired in the current year, and Employer W never employed any NHCEs prior to the current year. Thus, no NHCEs would have received additional benefits had Plan F been in existence during the preceding 15 years. The timing of this plan establishment does not have the effect of discriminating significantly in favor of HCEs or former HCEs.

Example 9. The facts are the same as in *Example 7*, except that Plan F limits the grant of past service credit to five years, and the grant of past service otherwise satisfies the safe harbor in paragraph (a)(3) of this section. The timing of this plan establishment is deemed not to have the effect of discriminating significantly in favor of HCEs or former HCEs.

Example 10. The facts are the same as in *Example 9*, except that, five years after the establishment of Plan F, Employer W amends the plan to provide a benefit equal to two percent of average annual compensation per year of service, taking into account all years of service since the establishment of the plan. The ratio of HCEs to former HCEs who terminated employment during the five-year period since the establishment of the plan is significantly higher than the ratio of NHCEs to former NHCEs who terminated employment during the five-year period since the establishment of the plan. Although the amendment described in this example might separately satisfy the safe harbor in paragraph (a)(4) of this section, the safe harbor is not available with respect to the amendment because, under these facts, the amendment is part of a pattern of amendments that has the effect of discriminating significantly in favor of HCEs.

Example 11. Employer Y maintains Plan G, a defined benefit plan, covering all its employees. In 1995, Employer Y acquires Division S from Employer Z. Some of the employees of Division S had been covered under a defined benefit plan maintained by Employer Z. Soon after the acquisition, Employer Y amends Plan G to cover all employees of Division S and to credit those who were in Division S's defined benefit plan with years of service for years of employment with Employer Z. Because the timing of the plan amendment was determined by the timing of the transaction, the timing of this plan amendment does not have the effect of discriminating significantly in favor of HCEs or former HCEs.

Example 12. Plan H is an insurance contract plan within the meaning of section 412(i). For all plan years before 1999, Plan H purchases insurance contracts from Insurance Company J. In 1999, Plan H shifts future purchases of insurance contracts to Insurance Company K. The shift in insurance companies is a plan amendment subject to this paragraph (a).

(b) *Pre-termination restrictions*—(1) *Required provisions in defined benefit plans.* A defined benefit plan has the effect of discriminating significantly in favor of HCEs or former HCEs unless it incorporates provisions restricting benefits and distributions as described in paragraph (b) (2) and (3) of this section at the time the plan is established or, if later, as of the first plan year to which §§ 1.401(a)(4)–1 through 1.401(a)(4)–13 apply to the plan under § 1.401(a)(4)–13 (a) or (b). This paragraph (b) does not apply if the Commissioner determines that such provisions are not necessary to prevent the prohibited discrimination that may occur in the event of an early termination of the plan. The restrictions in this paragraph (b) apply to a plan within the meaning of § 1.410(b)–7(b) (i.e., a section 414(*l*) plan). Any plan containing a provision described in this paragraph (b) satisfies section 411(d)(2) and does not fail to satisfy section 411 (a) or (d)(3) merely because of the provision.

(2) *Restriction of benefits upon plan termination.* A plan must provide that, in the event of plan termination, the benefit of any HCE (and any former HCE) is limited to a benefit that is

nondiscriminatory under section 401(a)(4).

(3) *Restrictions on distributions*—(i) *General rule.* A plan must provide that, in any year, the payment of benefits to or on behalf of a restricted employee shall not exceed an amount equal to the payments that would be made to or on behalf of the restricted employee in that year under—

(A) A straight life annuity that is the actuarial equivalent of the accrued benefit and other benefits to which the restricted employee is entitled under the plan (other than a social security supplement); and

(B) The amount of the payments that the restricted employee is entitled to receive under a social security supplement, if any.

(ii) *"Restricted employee" defined.* For purposes of this paragraph (b), the term "restricted employee" generally means any HCE or former HCE. However, an HCE or former HCE need not be treated as a restricted employee in the current year if the HCE or former HCE is not one of the 25 (or a larger number chosen by the employer) nonexcludable employees and former employees of the employer with the largest amount of compensation in the current or any prior year. Plan provisions defining or altering this group can be amended at any time without violating section 411(d)(6).

(iii) *"Benefit" defined.* For purposes of this paragraph (b), the term "benefit" includes, among other benefits, loans in excess of the amounts set forth in section 72(p)(2)(A), any periodic income, any withdrawal values payable to a living employee or former employee, and any death benefits not provided for by insurance on the employee's or former employee's life.

(iv) *Nonapplicability in certain cases.* The restrictions in this paragraph (b)(3) do not apply, however, if any one of the following requirements is satisfied:

(A) After payment to or on behalf of the restricted employee of all benefits payable to or on behalf of that restricted employee under the plan, the value of plan assets must equal or exceed 110 percent of the value of current liabilities, as defined in section 412(*l*)(7).

(B) The value of the benefits payable to or on behalf of the restricted employee must be less than one percent of the value of current liabilities before distribution.

(C) The value of the benefits payable to or on behalf of the restricted employee must not exceed the amount described in section 411(a)(11)(A) (restrictions on certain mandatory distributions).

(v) *Determination of current liabilities.* For purposes of this paragraph (b), any reasonable and consistent method may be used for determining the value of current liabilities and the value of plan assets.

(4) *Operational restrictions on certain money purchase pension plans.* A money purchase pension plan that has an a accumulated funding deficiency, within the meaning of section 412(a), must comply in operation with the restrictions on benefits and distributions as described in paragraphs (b)(2) and (b)(3) of this section. Such a plan does not fail to satisfy section 411(d)(6) merely because of restrictions imposed by the requirements of this paragraph (b)(4).

§ 1.401(a)(4)–6 Contributory defined benefit plans.

(a) *Introduction.* This section provides rules necessary for determining whether a contributory DB plan satisfies the nondiscriminatory amount requirement of § 1.40(a)(4)–1(b)(2). Paragraph (b) of this section provides rules for determining the amount of benefits derived from employer contributions (employer-provided benefits) under a contributory DB plan for purposes of determining whether the plan satisfies § 1.40(a)(4)–1(b)(2) with respect to such amounts. Paragraph (c) of this section provides the exclusive rules for determining whether a contributory DB plan satisfies § 1.40(a)(4)–1(b)(2) with respect to the amount of benefits derived from employee contributions not allocated to separate accounts (employee-provided benefits). See § 1.40(a)(4)–1(b)(2)(ii)(B) for the exclusive tests applicable to employee contributions allocated to separate accounts under a section 401(m) plan.

(b) *Determination of employer-provided benefit*—(1) *General rule.* An employee's employer-provided benefit under a contributory DB plan for purposes of section 401(a)(4) equals the difference between the employee's total benefit and the employee's employee-provided benefit under the plan. The rules of section 411(c) generally must be used to determine the employee's employer-provided benefit for this purpose. However, paragraphs (b)(2) through (b)(6) of this section provide alternative methods for determining the employee's employer-provided benefit.

(2) *Composition-of-workforce method*—(i) *General rule.* A contributory DB plan that satisfies paragraph (b)(2)(ii)(A) and (B) of this section may determine employee's employer-provided benefit rates under the rules of paragraph (b)(2)(iii) of this section.

(ii) *Eligibility requirements*—(A) *Uniform rate of employee contributions.* A contributory DB plan satisfies this paragraph (b)(2)(ii)(A) if all employees make employee contributions at the same rate, expressed as a percentage of plan year compensation (the "employee contribution rate"). A plan does not fail to satisfy this paragraph (b)(2)(ii)(A) merely because it eliminates employee contributions for all employees with plan year compensation below a specified "contribution breakpoint" that is either a stated dollar amount or a stated percentage of covered compensation (within the meaning of § 1.401(*l*)–1(c)(7); or merely because all employees make employee contributions at the same rate (expressed as a percentage of plan year compensation) with respect to plan year compensation up to the contribution breakpoint ("base employee contribution rate") and at a higher rate (expressed as a percentage of plan year compensation) that is the same for all employees with respect to plan year compensation above the contribution breakpoint ("excess employee contribution rate").

(B) *Demographic requirements*—(*1*) *In geneal.* A contributory DB plan satisfies this paragraph (b)(2)(ii)(B) if it satisfies either of the demographic tests in paragraph (b)(2)(ii)(B)(*2*) or (*3*) of this section.

(*2*) *Minimum percentage test.* This test is satisfied only if more than 40 percent of the NHCEs in the plan have attained ages at least equal to the plan's target age, and more than 20 percent of the NHCEs in the plan have attained ages at least equal to the average attained age of the HCEs in the plan. For this purpose, a plan's target age is the lower of age 50 or the average attained age of the HCEs in the plan minus X years, where X equals 20 minus the product of five times the employee contribution rate under the plan. In no case, however, may X years be fewer than zero (0) years. Thus, for example, if the average attained age of the HCEs in the plan is 53 and the employee contribution rate is two percent of plan year compensation, the plan's target age is 43 years (i.e., 53–(20–(5×2))).

(*3*) *Ratio test.* This test is satisfied only if the percentage of all nonhighly compensated nonexcludable employees, who are in the plan and who have attained ages at least equal to the average attained age of the HCEs in the plan, is at least 70 percent of the percentage of all highly compensated nonexcludable employees, who are in the plan and who have attained ages at least equal to the average attained aged of the HCEs in the plan. Attained ages

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must be determined as of the beginning of the plan year. In lieu of determining the actual distribution of the attained ages of the HCEs, an employer may assume that 50 percent of all HCEs have attained ages at least equal to the average attained age of the HCEs.

(iii) *Determination of employer-provided benefit*—(A) *Safe harbor plans other than section 401(l) plans.* For purposes of applying the exception to the safe harbor in § 1.401(a)(4)–3(b)(6)(viii) with respect to employer-provided benefits under a plan other than a section 401(*l*) plan, the employee's entire accrued benefit is treated as employer-provided

(B) *Section 401(l) plans*—(*1*) *General rule.* For purposes of applying the exception to the safe harbor in § 1.401(a)(4)–3(b)(6)(viii) with respect to employer-provided benefits under a section 401(*l*) plan, an employee's base benefit percentage and excess benefit percentage are reduced, or an employee's gross benefit percentage is reduced, by subtracting the product of the employee contribution rate and the factor determined under paragraph (b)(2)(iv) of this section from the respective percentage for the plan year. For this purpose, the employee contribution rate is the highest rate of employee contributions applicable to any potential level of plan year compensation for the plan year under the plan.

(*2*) *Excess plans with varying contribution rates.* In the case of a defined benefit excess plan described in the second sentence of paragraph (b)(2)(ii)(A) of this section, solely for purposes of reducing an employee's base benefit percentage as required under paragraph (b)(2)(iii)(B)(*1*) of this section, it may be assumed that the employee's contribution rate equals the weighted average of the base employee contribution rate and the excess employee contribution rate. In determining this weighted average, the weight of the base employee contribution rate is equal to a fraction, the numerator of which is the lesser of the integration level and the contribution breakpoint and the denominator of which is the integration level. The weight of the excess employee contribution rate is equal to difference between one and the weight of the base employee contribution rate.

(*3*) *Offset plans with varying contribution rates.* In the case of an offset plan described in the second sentence of paragraph (b)(2)(ii)(A) of this section, an equivalent adjustment to the alternative method in paragraph (b)(2)(iii)(B)(*2*) of this section may be made to the offset percentage.

(C) *Employer-provided benefits under the general test.* For purposes of applying the general test § 1.401(a)(4)–3(c) with respect to employer-provided benefits, an employee's normal and most valuable accrual rates otherwise determined under § 1.401(a)(4)–3(d) (without applying any of the options under § 1.401(a)(4)–3(d)(3) other than the fresh-start alternative of § 1.401(a)(4)–3(d)(3)(iii) are each reduced by subtracting the product of the employee's contribution (expressed as a percentage of plan year compensation) and the factor determined under paragraph (b)(2)(iv) of this section from the respect accrual rates. A plan may then apply thee optional rules in § 1.401(a)(4)–3(d)(3) (i) and (ii) to this resulting accrual rate.

(D) *Additional limitation.* A plan may not use the composition-of-workforce method provided in this paragraph (b)(2) to determine an employee's base benefit percentage, excess benefit percentage gross benefit percentage, offset percentage or accrual rates unless employee contributions have been made at the same rate (or rates) throughout the period after the fresh-start date or throughout the measurement period used to determine accrual rates.

(iv) *Determination of plan factor.* The factor for a plan is determined under the following table based on the average entry age of the employees in the plan and on whether the plan determines benefits based on average compensation. For this purpose, average entry age equals the average attained age of all employees in the plan, minus the average years of participation of all employees in the plan. A plan is treated as determining benefits based on average compensation if it determines benefits based on compensation average over a specified period not exceeding five consecutive years (or the employee's entire period of employment with the employer, if shorter).

TABLE OF FACTORS

Average entry age	Factors	
	Average compensation benefit formula	Other formulas
Less than 30	0.5	0.75
30 to 40	0.4	0.6
Over 40	0.2	0.3

(v) *Examples.* The following examples illustrate the rules of this paragraph (b)(2):

Example 1. Plan A is a contributory DB plan that is a defined benefit excess plan providing a benefit equal to 2.0 percent of employees' average annual compensation at or below covered compensation, plus 2.5 percent of average annual compensation above covered compensation times years of service up to 35. Under the plan, average annual compensation is determined using a five-consecutive-year period for purposes of § 1.401(a)(4)–3(e)(2). The plan requires employee contributions at a rate of four percent of plan year compensation for all employees. Assume that the plan satisfies the demographic requirements of paragraph (b)(2)(ii)(B) of this section. Under these facts, the plan satisfies the eligibility requirements of paragraph (b)(2)(ii) of this section. Assume, further, that the average attained age for all employees in the plan is 55, and that the average years of participation of all employees in the plan is 10. The average entry age for the plan is therefore 45, and, accordingly, the appreprate factor under the table is 0.2. Thus, in applying the safe harbor requirements of § 1.401(a)(4)–3(b) to this plan for the plan year (including the requirements of § 1.401(*l*)–3), the employee's base benefit percentage and excess benefit percentage are each reduced by 0.8 percent (4 percent × 0.2) and equal 1.2 percent and 1.7 percent, respectively.

Example 2. The facts are the same as in *Example 1*, except that the employee contribution rate is two percent of plan year compensation up to the covered compensation level, and four percent for plan year compensation at or above that contribution breakpoint. The employer elects to apply the alternative method in paragraph (b)(2)(iii)(B)(*2*) of this section to determine the reduction in the base benefit percentage. Because the contribution breakpoint is equal to the integration level, the weight of the employee contribution rate below the contribution breakpoint is 100 percent, and the weight of the employee contribution rate above the contribution breakpoint is zero. Thus, the weighted average of employee contribution rates is two percent. Under the alternative method in paragraph (b)(2)(iii)(B)(*2*) of this section, the reduction in the employee's base benefit percentage is 0.4. In applying the safe harbor requirements of § 1.401(a)(4)–3(b) to this plan (including the requirements of § 1.401(*l*)–3), the employee's base benefit percentage is 1.6 percent, and the employee's excess benefit percentage is 1.7.

Example 3. The facts are the same as in *Example 1*, except that the employee contribution rate is two percent of plan year compensation up to 50 percent of the covered compensation level, and four percent for plan year compensation at or above that contribution breakpoint. Because the contribution breakpoint is equal to 50 percent of the integration level, the weight of the employee contribution rate below the contribution breakpoint is 50 percent, and the weight of the employee contribution rate above the contribution breakpoint is 50 percent. Thus, the weighted average of employee contribution rates is three percent. Under the alternative method in paragraph (b)(2)(iii)(B)(*2*) of this section, the reduction in the employee's base benefit percentage is 0.6. In applying the safe harbor requirements of § 1.401(a)(4)–3(b) to this plan (including the requirements of § 1.401(*l*)–3), the

employee's base benefit percentage is 1.4 percent, and the employee's excess benefit percentage is 1.7.

Example 4. The facts are the same as in *Example 1*, except that the plan is tested using the general test in § 1.401(a)(4)–3(c). Assume Employee M benefits under Plan A and has a normal accrual rate for the plan year (calculated with respect to Employee M's total accrued benefit) of 2.2 percent of average annual compensation. In applying the general test in § 1.401(a)(4)–3(c) with respect to employer-provided benefits, this rate is reduced by 0.8 to yield a normal accrual rate of 1.4 percent. This rate may then be adjusted using either of the optional rules in § 1.401(a)(4)–3(d)(3)(i) or (ii).

(3) *Minimum-benefit method*—(i) *Application of uniform factors.* A contributory DB plan that satisfies the uniform rate requirement of paragraph (b)(2)(ii)(A) of this section and the minimum benefit requirement of paragraph (b)(3)(ii) of this section may apply the adjustments provided in paragraph (b)(2)(iii) of this section as if the average entry age of employees in the plan were within the range of 30 to 40, without regard to the actual demographics of the employees in the plan.

(ii) *Minimum benefit requirement.* This requirement is satisfied if the plan provides that, in plan years beginning on or after the effective date of these regulations, as set forth in § 1.401(a)(4)–13(a) and (b), each employee will accrue a benefit that equals or exceeds the sum of—

(A) The accrued benefit derived from employee contributions made for plan years beginning on or after the effective date of these regulations, determined in accordance with section 411(c); and

(B) Fifty percent of the total benefit accrued in plan years beginning on or after the effective date of these regulations, as determined under the plan benefit formula without regard to that portion of the formula designed to satisfy the minimum benefit requirement of this paragraph (b)(3)(ii).

(iii) *Example.* The following example illustrates the minimum-benefit method of this paragraph (b)(3):

Example. Plan A is contributory DB plan. For the plan year beginning in 1994, Employee M participates in Plan A and accrues a benefit under the terms of the plan (without regard to the minimum benefit requirement of paragraph (b)(3)(ii) of this section) of $3,000. The portion of Employee M's benefit accrual for the plan year beginning in 1994 derived from employee contributions is $2,000, determined by applying the rules of section 411(c) of such contributions. The requirement of paragraph (b)(3)(ii) of this section is not satisfied for the plan year beginning in 1994 unless the plan provides that Employee M's benefit accrual for the plan year beginning in 1994 is equal to $3,500 ($2,000 + (50 percent x $3,000)).

(4) *Grandfather rule for plans in existence on May 14, 1990.* A contributory DB plan that satisfies paragraph (c)(4) of this section may determine an employee's employer-provided benefit by subtracting from the employee's total benefit the employee-provided benefits determined using any reasonable method set forth in the plan, provided that it is the same method used in determining whether the plan satisfies paragraph (c)(4)(iv) of this section.

(5) *Government-plan method.* A contributory DB plan that is established and maintained for its employees by the government of any state or political subdivision or by any agency or instrumentality thereof may treat an employee's total benefit as entirely employer-provided.

(6) *Cessation of employee contributions.* If a contributory DB plan provides that no employee contributions may be made to the plan after the last day of the first plan year beginning on or after the effective date of these regulations, as set forth in § 1.401(a)(4)–13(a) and (b), the plan may treat an employee's total benefit as entirely employer-provided.

(c) *Rules applicable in determining whether employee-provided benefits are nondiscriminatory in amount*—(1) *In general.* A contributory DB plan satisfies § 1.401(a)(4)–1(b)(2) with respect to the amount of employee-provided benefits for a plan only if the plan satisfies the requirements of paragraph (c)(2), (c)(3), or (c)(4) of this section for the plan year. This requirement applies regardless of the method used to determine the amount of employer-provided benefits under paragraph (b) of this section.

(2) *Same rate of contributions.* This requirement is satisfied for a plan year if the employee contribution rate (within the meaning of paragraph (b)(2)(ii)(A) of this section) is the same for all employees for the plan year.

Total-benefits method. This requirement is satisfied for a plan year if—

(i) The total benefit (i.e., the sum of employer-provided and employee-provided benefits) under the plan would satisfy § 1.401(a)(4)–3 if all benefits were treated as employer-provided benefits; and

(ii) The plan's contribution requirements satisfy paragraph (b)(2)(ii)(A) of this section.

(4) *Grandfather rule for plans in existence on May 14, 1990.* This requirement is satisfied for a plan year if all the following requirements are met:

(i) On May 14, 1990, the plan required employee contributions at a greater rate (expressed as a percentage of compensation) at higher levels of compensation that at lower levels of compensation.

(ii) The required rate of employee contributions is not increased after May 14, 1990, although the level of compensation at which employee contributions are required may be increased or decreased.

(iii) All employees are permitted to make employee contributions under the plan at a uniform rate with respect to all compensation, beginning no later than the last day of the first plan year to which these regulations apply, as set forth in § 1.401(a)(4)–13 (a) and (b).

(iv) The benefits provided on account of employee contributions at lower levels of compensation are comparable to those provided on account of employee contributions at higher levels of compensation.

§ 1.401(a)(4)–7 Imputation of permitted disparity.

(a) *Introduction.* In determining whether a plan satisfies section 401(a)(4) with respect to the amount of contributions or benefits, section 401(a)(5)(C) allows the disparities permitted under section 401(*l*) to be taken into account. For purposes of satisfying the safe harbors of §§ 1.401(a)(4)–2(b)(2) and 1.401(a)(4)–3(b), permitted disparity may be taken into account only by satisfying section 401(*l*) in form in accordance with § 1.401(*l*)–2 or 1.401(*l*)–3, respectively. For purposes of the general tests of §§ 1.401(a)(4)–2(c) and 1.401(a)(4)–3(c), permitted disparity may be taken into account only in accordance with the rules of this section. In general, this section allows permitted disparity to be arithmetically imputed with respect to employer-provided contributions or benefits by determining an adjustment allocation or accrual rate that appropriately accounts for the permitted disparity with respect to each employee. Paragraph (b) of this section provides rules for imputing permitted disparity with respect to employer-provided contributions by adjusting each employee's unadjusted allocation rate. Paragraph (c) of this section provides rules for imputing permitted disparity with respect to employer-provided benefits by adjusting each employee's unadjusted accrual rate. Paragraph (d) of this section provides rules of general application.

(b) *Adjusting allocation rates*—(1) *In general.* The rules in this paragraph (b) produce an adjusted allocation rate for each employee by determining the excess contribution percentage under the hypothetical formula that would

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yield the allocation actually received by the employee, if the plan took into account the full disparity permitted under section 401(*l*)(2) and used the taxable wage base as the integration level. This adjusted allocation rate is used to determine whether the amount of contributions under the plan satisfies the general test of § 1.401(a)(4)–2(c) and to apply the average benefit percentage test on the basis of contributions under § 1.410(b)–5(d)(5) or ~~(e)~~(2). Paragraphs (b)(2) and (b)(3) of this section apply to employees whose plan year compensation does not exceed and does exceed, respectively, the taxable wage base, and paragraph (b)(4) of this section provides definitions.

(2) *Employees whose plan year compensation does not exceed taxable wage base.* If an employee's plan year compensation does not exceed the taxable wage base, the employee's adjusted allocation rate is the lesser of the A rate and the B rate determined under the formulas below, where the permitted disparity rate and the unadjusted allocation rate are determined under paragraph (b)(4)(ii) and (iv) of this section, respectively.

A Rate=2xunadjusted allocation rate
B Rate=unadjusted allocation rate+permitted disparity rate

(3) *Employees whose plan year compensation exceeds taxable wage base.* If an employee's plan year compensation exceeds the taxable wage base, the employee's adjusted allocation rate is the lesser of the C rate and the D rate determined under the formulas below, where allocations and the permitted disparity rate are determined under paragraph (b)(4)(i) and (ii) of this section, respectively.

$$\text{C Rate} = \frac{\text{allocations}}{\text{plan year compensation}-\text{½ taxable wage base}}$$

$$\text{D Rate} = \frac{\text{allocations}+(\text{permitted disparity rate} \times \text{taxable wage base})}{\text{plan year compensation}}$$

(4) *Definitions.* In applying this paragraph (b), the following definitions govern—

(i) *Allocations.* "Allocations" means the amount determined by multiplying the employee's plan year compensation by the employee's unadjusted allocation rate.

(ii) *Permitted disparity rate*—(A) *General rule.* "Permitted disparity rate" means the rate in effect as of the beginning of the plan year under section 401(*l*)(2)(A)(ii) (e.g., 5.7 percent for plan years beginning in 1990).

(B) *Cumulative permitted disparity limit.* Notwithstanding paragraph (b)(4)(ii)(A) of this section, the permitted disparity rate is zero for an employee who has benefited under a defined benefit plan taken into account under § 1.401(*l*)–5(a)(3) for a plan year that begins on or after one year from the first day of the first plan year to which these regulations apply, as set forth in § 1.401(a)(4)–13(a) and (b), if imputing permitted disparity would result in a cumulative disparity fraction for the employee, as defined in § 1.401(*l*)–5(c)(2), that exceeds 35. See § 1.401(*l*)–5(c)(1) for special rules for determining whether an employee has benefited under a defined benefit plan for this purpose.

(iii) *Taxable wage base.* "Taxable wage base" means the taxable wage base, as defined in § 1.401(*l*)–1(c)(32), in effect as of the beginning of the plan year.

(iv) *Unadjusted allocation rate.* "Unadjusted allocation rate" means the employee's allocation rate determined under § 1.401(a)(4)–2(c)(2)(i) for the plan year (expressed as a percentage of plan year compensation), without imputing permitted disparity under this section.

(5) *Example.* The following example illustrates the rules in this paragraph (b):

Example. (a) Employees M and N participate in a defined contribution plan maintained by Employer X. Employee M has plan year compensation of $30,000 in the 1990 plan year and has an unadjusted allocation rate of five percent. Employee N has plan year compensation of $100,000 in the 1990 plan year and has an unadjusted allocation rate of eight percent. The taxable wage base in 1990 is $51,300.

(b) Because Employee M's plan year compensation does not exceed the taxable wage base, Employee M's A rate is 10 percent (2 × 5 percent), and Employee M's B rate is 10.7 percent (5 percent + 5.7 percent). Thus, Employee M's adjusted allocation rate is 10 percent, the lesser of the A rate and the B rate.

(c) Employee N's allocations are $8,000 (8 percent × $100,000). Because Employee N's plan year compensation exceeds the taxable wage base, Employee N's C rate is 10.76 percent ($8,000 divided by ($100,000 – (½ × $51,300))), and Employee N's D rate is 10.92 percent (($8,000 + (5.7 percent × $51,300)) divided by $100,000). Thus, Employee N's adjusted allocation rate is 10.76 percent, the lesser of the C rate and the D rate.

(c) *Adjusting accrual rates*—(1) *In general.* The rules in this paragraph (c) produce an adjusted accrual rate for each employee by determining the excess benefit percentage under the hypothetical plan formula that would yield the employer-provided accrual actually received by the employee, if the plan took into account the full permitted disparity under section 401(*l*)(3)(A) in each of the first 35 years of an employee's testing service under the plan and used the employee's covered compensation as the integration level. This adjusted accrual rate is used to determine whether the amount of employer-provided benefits under the plan satisfies the alternative safe harbor for flat benefit plans under § 1.401(a)(4)–3(b)(4)(i)(C)(3) or the general test of § 1.401(a)(4)–3(c), and to apply the average benefit percentage test on the basis of benefits under § 1.410(b)–5(d)(6) or (e)(2). Paragraphs (c)(2) and (c)(3) of this section apply to employees whose average annual compensation does not exceed and does exceed, respectively, covered compensation, and paragraph (c)(4) of this section provides definitions. Paragraph (c)(5) of this section provides a special rule for employees with negative unadjusted accrual rates.

(2) *Employees whose average annual compensation does not exceed covered compensation.* If an employee's average annual compensation does not exceed the employee's covered compensation, the employee's adjusted accrual rate is the lesser of the A rate and the B rate determined under the formulas below, where the permitted disparity factor and the unadjusted accrual rate are determined under paragraph (c)(4)(iii) and (v) of this section, respectively.

A Rate = 2x unadjusted accrual rate
B Rate = unadjusted accrual rate + permitted disparity factor

(3) *Employees whose average annual compensation exceeds covered compensation.* If an employee's average annual compensation exceeds the employee's covered compensation, the employee's adjusted accrual rate is the lesser of the C rate and D rate determined under the formulas below, where the employer-provided accrual and the permitted disparity factor are determined under paragraph (c)(4) (ii) and (iii) of his section, respectively.

$$\text{C Rate} = \frac{\text{employer-provided accrual}}{\text{Average annual compensation} - \text{½ covered compensation}}$$

$$\text{D Rate} = \frac{\text{Employer-provided accrual} + (\text{permitted disparity factor} \times \text{covered compensation})}{\text{average annual compensation}}$$

(4) *Definitions.* For purposes of this paragraph (c), the following definitions apply.

(i) *Covered compensation.* "Covered compensation" means covered compensation as defined in § 1.401(*l*)–1(c)(7). Notwithstanding § 1.401(*l*)–1(c)(7)(iii), an employee's covered compensation must be automatically adjusted each plan year for purposes of applying this paragraph (c).

(ii) *Employer-provided accrual.* "Employer-provided accrual" means the amount determined by multiplying the employee's average annual compensation by the employee's unadjusted accrual rate.

(iii) *Permitted disparity factor*—(A) *General rule.* "Permitted disparity factor" for an employee means the sum of the employee's annual permitted disparity factors determined under paragraph (c)(4)(iii)(B) of this section for each of the years in the measurement period used for determining the employee's accrual rate in § 1.401(a)(4)–3(d)(1), divided by the employee's testing service during that measurement period.

(B) *Annual permitted disparity factor*—(*1*) *Definition.* An employee's annual permitted disparity factor is generally 0.75 percent adjusted, pursuant to § 1.401(*l*)–3(e), using as the age at which benefits commence the lesser of age 65 or the employee's testing age. No adjustments are made in the annual permitted disparity factor unless and employee's testing age is different from the employee's social security retirement age. An annual permitted disparity factor that is less than the annual permitted disparity factor described in the first sentence of this paragraph (c)(4)(iii)(B)(*1*) may be used if it is a uniform percentage of that factor (e.g., 50 percent of the annual permitted disparity factor) or a fixed percentage (e.g., 0.65 percent) for all employees.

(*2*) *Annual permitted disparity factor after 35 years.* For purposes of determining the sum described in paragraph (c)(4)(iii)(A) of this section, the annual permitted disparity factor for each of the employee's first 35 years of testing service is the amount described in paragraph (c)(4)(iii)(B)(*1*) of this section, and the annual permitted disparity factor in any subsequent year equals zero. This rule applies regardless of whether the end of the measurement period extends beyond an employee's first 35 years of testing service. Thus, for example, if the measurement period is the current plan year and the employee completed 35 years of testing service prior to the beginning of the current plan year, under this paragraph (c)(4)(iii)(B)(*2*) the annual permitted disparity factor in the current plan year (and hence the sum of the annual permitted disparity factors for each year in the measurement period) is zero.

(3) *Cumulative permitted disparity limit.* The 35 years used in paragraph (c)(4)(iii)(B)(*2*) of this section must be reduced by the employee's cumulative disparity fraction, as defined in § 1.401(*l*)–5(c)(2), but determined solely with respect to the employee's total years of service under all plans taken into account under § 1.401(*l*)–5(a)(3) during the measurement period, other than the plan being tested.

(iv) *Social security retirement age.* "Social security retirement age" means social security retirement age as defined in section 415(b)(8).

(v) *Unadjusted accrual rate.* "Unadjusted accrual rate" means the normal or most valuable accrual rate, whichever is being determined for the employee under § 1.401(a)(4)–3(d), expressed as a percentage of average annual compensation, without imputing permitted disparity under this section.

(5) *Employees with negative unadjusted accrual rates.* Notwithstanding the formulas in paragraph (c)(2) and (c)(3) of this section, if an employee's unadjusted accrual rate is less than zero, the employee's adjusted accrual rate is deemed to be the employee's unadjusted accrual rate.

(6) *Example.* The following example illustrates the rules in this paragraph (c):

Example. (a) Employees M and N participate in a defined benefit plan that uses a normal retirement age of 65. The plan is being tested for the plan year under § 1.401(a)(4)–3(c), using unadjusted accrual rates determined using a plan year measurement period under § 1.401(a)(4)–3(d)(1)(iii)(A). Employee M has an unadjusted normal accrual rate of 1.48 percent, average annual compensation of $21,000, and an employer-provided accrual of $311 (1.48 percent × $21,000). Employee N has an unadjusted normal accrual rate of 1.7 percent, average annual compensation of $106,000, and an employer-provided accrual of $1,802 (1.7 percent × $106,000). The covered compensation of both Employees M and N is $25,000, and social security retirement age for both employees is 65. Neither employee has testing service of more than 35 years and neither has ever participated in another plan.

(b) Because Employee M's average annual compensation does not exceed covered compensation, Employee M's A rate is 2.96 percent (2.0 × 1.48 percent), and Employee M's B rate is 2.23 percent (1.48 percent + 0.75 percent). Thus, Employee M's adjusted accrual rate is 2.23 percent, the lesser of the A rate and the B rate.

(c) Because Employee N's average annual compensation exceeds covered compensation, Employee N's C rate is 1.93 percent ($1,802/($106,000–(0.5 × $25,000))), and Employee N's D rate is 1.88 percent (($1,802 + (0.75 percent × $25,000))/$106,000). Thus, Employee N's adjusted accrual rate is 1.88 percent, the lesser of the C rate and the D rate.

(d) *Rules of general application*—(1) *Eligible plans.* The rules in this section may be used only for those plans to which the permitted disparity rules of section 401(*l*) are available. See § 1.401(*l*)–1(a)(3).

(2) *Exceptions from consistency requirements.* A plan does not fail to satisfy the consistency requirements of § 1.401(a)(4)–2(c)(2)(vi) or § 1.401(a)(4)–3(d)(2)(i) merely because the plan does not impute disparity for some employees to the extent required to comply with paragraph (d)(3) of this section, or because the plan does not impute disparity for any employees (including self-employed individuals within the meaning of section 401(c)(1)) who are not covered by any of the taxes under section 3111(a), section 3221, or section 1401.

(3) *Overall permitted disparity.* The annual overall permitted disparity limits of § 1.401(*l*)–5(b) apply to the employer-provided contributions and benefits for an employee under all plans taken into account under § 1.401(*l*)–5(a)(3). Thus, if an employee who benefits under the plan for the current plan year also benefits under a section 401(*l*) plan for the plan year ending with or within the current plan year, permitted disparity may not be imputed for that employee for the plan year. See § 1.401(*l*)–5(b)(9), *Example 4*. Similarly, if an employee who benefits under the plan for the current plan year also benefits under another plan of the employer for the plan year ending with or within the current plan year, disparity may be imputed for that employee under only one of the plans.

§ 1.401(a)(4)–8 Cross-testing.

(a) *Introduction.* This section provides rules for testing defined benefit plans on the basis of equivalent employer-provided contributions and defined contribution plans on the basis of equivalent employer-provided benefits under § 1.401(a)(4)–1(b)(2). Paragraphs (b)(1) and (c)(1) of this section provide general tests for nondiscrimination based on individual equivalent accrual or allocation rates determined under paragraphs (b)(2) and (c)(2) of this section, respectively. Paragraphs (b)(3), (c)(3), and (d) of this section provide additional safe-harbor testing methods for target benefit plans, cash balance plans, and defined benefit plans that are part of floor-offset arrangements, respectively, that generally may be satisfied on a design basis.

(b) *Nondiscrimination in amount of benefits provided under a defined*

contribution plan—(1) *General rule.* Equivalent benefits under a defined contribution plan (other than an ESOP) are nondiscriminatory in amount for a plan year if the plan would satisfy § 1.401(a)(4)–2(c)(1) for the plan year if an equivalent accrual rate, as determined under paragraph (b)(2) of this section, were substituted for each employee's allocation rate in the determination of rate groups. A plan does not fail to satisfy this paragraph (b)(1) merely because allocations are made at the same rate for employees who are older than their testing age (determined without regard to the current-age rule in paragraph (4) of the definition of testing age in § 1.401(a)(4)–12) as they are made for employees who are at that age.

(2) *Determination of equivalent accrual rates*—(i) *Basic definition.* An employee's equivalent accrual rate for a plan year is the annual benefit that is the result of normalizing the increase in the employee's account balance during the measurement period, divided by the number of years in which the employee benefited under the plan during the measurement period, and expressed either as a dollar amount or as a percentage of the employee's average annual compensation. A measurement period that includes future years may not be used for this purpose.

(ii) *Rules of application*—(A) *Determination of account balance.* The increase in the account balance during the measurement period taken into account under paragraph (b)(2)(i) of this section does not include income, expenses, gains, or losses allocated during the measurement period that are attributable to the account balance as of the beginning of the measurement period, but does include any additional amounts that would have been included in the increase in the account balance but for the fact that they were previously distributed (including a reasonable adjustment for interest). For this purpose, an employer may disregard distributions made to a NHCE as well as distributions made to any employee in plan years beginning before a selected date no later than January 1, 1986.

(B) *Normalization.* The account balances determined under paragraph (b)(2)(ii)(A) of this section are normalized by treating them as single-sum benefits that are immediately and unconditionally payable to the employee. A standard interest rate, and a straight life annuity factor that is based on the same or a different standard interest rate and on a standard mortality table, must be used in normalizing these benefits. In addition, no mortality may be assumed prior to the employee's testing age.

(iii) *Options.* Any of the optional rules in § 1.401(a)(4)–3(d)(3) (e.g., imputation of permitted disparity) may be applied in determining an employee's equivalent accrual rate by substituting the employee's equivalent accrual rate (determined without regard to the option) for the employee's normal accrual rate (i.e., not most valuable accrual rate) in that section where appropriate. For this purpose, however, the last sentence of the fresh-start alternative in § 1.401(a)(4)–3(d)(3)(iii)(A) (dealing with compensation adjustments to the frozen accrued benefit) is not applicable. No other options are available in determining an employee's equivalent accrual rate except those (e.g., selection of alternative measurement periods) specifically provided in this paragraph (b)(2). Thus, for example, none of the optional special rules in § 1.401(a)(4)–3(f) (e.g., determination of benefits on other than a plan year basis under § 1.401(a)(4)–3(f)(6)) is available.

(iv) *Consistency rule.* Equivalent accrual rates must be determined in a consistent manner for all employees for the plan year. Thus, for example, the same measurement periods and standard interest rates must be used, and any available options must be applied consistently if at all.

(3) *Safe-harbor testing method for target benefit plans*—(i) *General rule.* A target benefit plan is a money purchase pension plan under which contributions to an employee's account are determined by reference to the amounts necessary to fund the employee's stated benefit under the plan. Whether a target benefit plan satisfies section 401(a)(4) with respect to an equivalent amount of benefits is generally determined under paragraphs (b)(1) and (b)(2) of this section. A target benefit plan is deemed to satisfy section 401(a)(4) with respect to an equivalent amount of benefits, however, if each of the following requirements is satisfied:

(A) *Stated benefit formula.* Each employee's stated benefit must be determined as the straight life annuity commencing at the employee's normal retirement age under a formula that would satisfy the requirements of § 1.401(a)(4)–3(b)(4)(i)(C) (*1*) or (*2*), and that would satisfy each of the uniformity requirements in § 1.401(a)(4)–3(b)(2) (taking into account the relevant exceptions provided in § 1.401(a)(4)–3(b)(6)), if the plan were a defined benefit plan with the same benefit formula. In determining whether these requirements are satisfied, the rules of § 1.401(a)(4)–3(f) do not apply, and, in addition, except as provided in paragraph (b)(3)(vii) of this section, an employee's stated benefit at normal retirement age under the stated benefit formula is deemed to accrue ratably over the period ending with the plan year in which the employee is projected to reach normal retirement age and beginning with the latest of: the first plan year in which the employee benefited under the plan, the first plan year taken into account in the stated benefit formula, and any plan year immediately following a plan year in which the plan did not satisfy this paragraph (b)(3). Thus, except as provided in paragraph (b)(3)(vii) of this section, under § 1.401(a)(4)–3(b)(2)(v) an employee's stated benefit may not take into account service in years prior to the first plan year that the employee benefited under the plan, and an employee's stated benefit may not take into account service in plan years prior to the current plan year unless the plan satisfied this paragraph (b)(3) in all of those prior plan years.

(B) *Employer and employee contributions.* Employer contributions with respect to each employee must be based exclusively on the employee's stated benefit using the method provided in paragraph (b)(3)(iv) of this section, and forfeitures and any other amounts under the plan taken into account under § 1.401(a)(4)–2(c)(2)(ii) (other than employer contributions) are used exclusively to reduce employer contributions. Employee contributions (if any) may not be used to fund the stated benefit.

(C) *Permitted disparity.* If permitted disparity is taken into account, the stated benefit formula must satisfy § 1.401(*l*)–3. For this purpose, the 0.75-percent factor in the maximum excess or offset allowance in § 1.401(*l*)–3(d)(9) (and, if the employee's normal retirement age is not the employee's social security retirement age, § 1.401(*l*)–3(e)), is further reduced by multiplying the factor by 0.80.

(ii) *Changes in stated benefit formula.* A plan does not fail to satisfy paragraph (b)(3)(i) of this section merely because the plan determines each employee's stated benefit in the current plan year under a stated benefit formula that differs from the stated benefit formula used to determine the employee's stated benefit in prior plan years.

(iii) *Stated benefits after normal retirement age.* A target benefit plan may limit increases in the stated benefit after normal retirement age consistent with the requirements applicable to defined benefit plans under section 411(b)(1)(H) (without regard to section 411(b)(1)(H)(iii)), provided that the

limitation applies on the same terms to all employees. Thus, post-normal retirement benefits required under § 1.401(a)(4)–3(b)(2)(ii) must be provided under the stated benefit formula, subject to any uniformly applicable service cap under the formula.

(iv) *Method for determining required employer contributions*—(A) *General rule.* An employer's required contribution to the account of an employee for a plan year is determined based on the employee's stated benefit and the amount of the employee's theoretical reserve as of the date the employer's required contribution is determined for the plan year (the "determination date"). Paragraph (b)(3)(iv)(B) of this section provides rules for determining an employee's theoretical reserve. Paragraph (b)(3)(iv)(C) and (d) of this section provides rules for determining an employer's required contributions.

(B) *Theoretical reserve*—(1) *Initial theoretical reserve.* An employee's theoretical reserve as of the determination date for the first plan year in which the employee benefits under the plan, the first plan year taken into account under the stated benefit formula (if that is the current plan year), of the first plan year immediately following any plan year in which the plan did not satisfy this paragraph (b)(3), is zero.

(2) *Theoretical reserve in subsequent plan years.* An employee's theoretical reserve as of the determination date for a plan year (other than a plan year described in paragraph (b)(3)(iv)(B)(*1*) of this section) is the employee's theoretical reserve as of the determination date for the prior plan year, plus the employer's required contribution for the prior plan year (as limited by section 415, but without regard to the additional contributions described in paragraph (b)(3)(v) of this section) both increased by interest from the determination date for the prior plan year through the determination date for the current plan year, but not beyond the determination date for the plan year that includes the employee's normal retirement date. (Thus, an employee's theoretical reserve as of the determination date for a plan year does not include the amount of the employer's required contribution for the plan year.) The interest rate for determining employer contributions that was in effect on the determination date in the prior plan year must be applied to determine the required interest adjustment for this period. For plan years beginning after the effective date applicable to the plan under § 1.401(a)(4)–13 (a) or (b), a standard interest rate must be used, and may not be changed except on the determination date for a plan year.

(C) *Required contributions for employees under normal retirement age.* The required employer contributions with respect to an employee whose attained age is less than the employee's normal retirement age must be determined for each plan year as follows:

(*1*) Determine the employee's fractional rule benefit (within the meaning of § 1.411(b)–1(b)(3)(ii)(A)) under the plan's stated benefit formula as if the plan were a defined benefit plan with the same formula.

(*2*) Determine the actuarial present value of the fractional rule benefit determined in paragraph (b)(3)(iv)(C)(*1*) of this section as of the determination date for the current plan year, using a standard interest rate and a standard mortality table that are set forth in the plan and that are the same for all employees, and assuming no mortality before the employee's normal retirement age.

(*3*) Determine the excess, if any, of the amount determined in paragraph (b)(3)(iv)(C)(*2*) of this section over the employee's theoretical reserve for the current plan year determined under paragraph (b)(3)(iv)(B) of this section.

(*4*) Determine the required employer contribution for the current plan year by amortizing on a level annual basis, using the same interest rate used for paragraph (b)(3)(iv)(C)(*2*) of this section, the result in paragraph (b)(3)(iv)(C)(*3*) of this section over the period beginning with the determination date for the current plan year and ending with the determination date for the plan year in which the employee is projected to reach normal retirement age.

(D) *Required contributions for employees over normal retirement age.* The required employer contributions with respect to an employee whose attained age equals or exceeds the employee's normal retirement age is the excess, if any, of the actuarial present value, as of the determination date for the current plan year, of the employee's stated benefit for the current plan year (determined using an immediate straight life annuity factor based on a standard interest rate and a standard mortality table, for an employee whose attained age equals the employee's normal retirement age) over the employee's theoretical reserve as of the determination date.

(v) *Effect of section 415 and 416 requirements.* A target benefit plan does not fail to satisfy this paragraph (b)(3) merely because required contributions under the plan are limited by section 415 in a plan year, or merely because additional contributions are made consistent with the requirements of section 416(c)(2) (regardless of whether the plan is top-heavy).

(vi) *Certain conditions on allocations.* A target benefit plan does not fail to satisfy this paragraph (b)(3) merely because required contributions under the plan are subject to the conditions on allocations permitted under § 1.401(a)(4)–2(b)(4)(iii).

(vii) *Special rules for target benefit plans qualified under prior law*—(A) *Service taken into account prior to satisfaction of this paragraph.* For purposes of determining whether the stated benefit formula satisfies paragraph (b)(3)(i)(A) of this section (e.g., whether the period over which an employee's stated benefit is deemed to accrue is the same as the period taken into account under the stated benefit formula as required by paragraph (b)(3)(i)(A) of this section), a target benefit plan that was adopted and in effected on September 19, 1991, is deemed to have satisfied this paragraph (b)(3), and an employee is treated as benefiting under the plan, in any year prior to the effective date applicable to the plan under § 1.401(a)(4)–13 (a) or (b) that was taken into account in the stated benefit formula under the plan on September 19, 1991, if the plan satisfied the applicable nondiscrimination requirements for target benefit plans for that prior year.

(B) *Initial theoretical reserve.* Notwithstanding paragraph (b)(3)(iv)(B)(*1*) of this section, a target benefit plan under which the stated benefit formula takes into account service for an employee for plan years prior to the first plan in which the plan satisfied this paragraph (b)(3), as permitted under paragraph (b)(3)(vii)(A) of this section, must determine an initial theoretical reserve for the employee as of the determination date for the last plan year beginning before such plan year under the rules of § 1.401(a)(4)–13(e).

(C) *Satisfaction of prior law.* In determining whether a plan satisfied the applicable nondiscrimination requirements for target benefit plans for any period prior to the effective date applicable to the plan under § 1.401(a)(4)–13 (a) or (b), no amendments after September 19, 1991, other than amendments necessary to satisfy section 401(l), are taken into account.

(viii) *Examples.* The following examples illustrate the rules in this paragraph (b)(3):

Example 1. (a) Employer X maintains a target benefit plan with a calendar plan year

that bases contributions on a stated benefit equal to 40 percent of each employee's average annual compensation, reduced pro rata for years of participation less than 25, payable annually as a straight life annuity commencing at normal retirement age. The UP–84 mortality table and an interest rate of 7.5 percent are used to calculate the contributions necessary to fund the stated benefit. Required contributions are determined on the last day of each plan year. The normal retirement age under the plan is 65. Employee M is 39 years old in 1994, has participated in the plan for six years, and has average annual compensation equal to $60,000 for the 1994 plan year. Assume that Employee M's theoretical reserve as of the last day of the 1993 plan year is $13,909, determined under § 1.401(a)(4)–13(e), and that required employer contributions for 1993 were determined using an interest rate of six percent.

(b) Under these facts, Employer X's 1994 required contribution to fund Employee M's stated benefit is $1,318, calculated as follows:

(1) Employee M's fractional rule benefit is $24,000 (40 percent of Employee M's average annual compensation of $60,000).

(2) The actuarial present value of Employee M's fractional rule benefit as of the last day of the 1994 plan year is $30,960 (Employee M's fractional rule benefit of $24,000 multiplied by 1.290, the actuarial present value factor for an annual straight life annuity commencing at age 65 applicable to a 39-year old employee, determined using the stated interest rate of 7.5 percent and the UP–84 mortality table, and assuming no mortality before normal retirement age).

(3) The actuarial present value of Employee M's fractional rule benefit ($30,960) is reduced by Employee M's theoretical reserve as of the last day of the 1994 plan year. The theoretical reserve on that day is $14,744–the $13,909 theoretical reserve as of the last day of the 1993 plan year, increased by interest for one year at the rate of six percent. Because the required contribution for the 1993 plan year is taken into account under § 1.401(a)(4)–13(e)(2) in determining the theoretical reserve as of the last day of the 1993 plan year, it is not added to the theoretical reserve again in this paragraph (b)(3) of this *Example 1*. The resulting difference is $16,216 ($30,960–$14,744).

(4) The $16,216 excess of the actuarial present value of Employee M's fractional rule benefit over Employee M's theoretical reserve is multiplied by 0.0813, the amortization factor applicable to a 39-year old employee determined using the stated interest rate of 7.5 percent. The product of $1,318 is the amount of the required employer contribution for Employee M for the 1994 plan year.

Example 2. (a) The facts are the same as in *Example 1*, except that as of January 1, 1995, the plan's stated benefit formula is amended to provide for a stated benefit equal to 45 percent of average annual compensation, reduced pro rata for years of participation less than 25, payable annually as a straight life annuity commencing at normal retirement age. For the 1995 plan year, Employee M's average annual compensation continues to be $60,000. The mortality table used for the calculation of the employer's required contributions remains the same as in the prior plan year, but the plan's stated interest rate is changed to 8.0 percent effective as of December 31, 1995.

(b) Under these facts, Employer X's required contribution for Employee M is $1,290, calculated as follows:

(1) Employee M's fractional rule benefit is $27,000 (45 percent of $60,000).

(2) The actuarial present value of Employee M's fractional rule benefit as of the last day of the 1995 plan year is $32,319 ($27,000 multiplied by 1.197, the actuarial present value factor for an annuity commencing at age 65 applicable to a 40-year old employee, determined using the stated interest rate of 8.0 percent and the UP–84 mortality table, and assuming no mortality before normal retirement age).

(3) The actuarial present value of Employee M's fractional rule benefit ($32,319) is reduced by Employee M's theoretical reserve as of the last day of the 1995 plan year. The theoretical reserve as of that day is $17,267—the $14,744 theoretical reserve as of the last day of the 1994 plan year plus the $1,318 required contribution for the 1994 plan year, both increased by interest for one year at the rate of 7.5 percent. The resulting difference is $15,052 ($31,319–$17,267).

(4) The result in paragraph (b)(3) of this *Example 2* is multiplied by 0.0857, the amortization factor applicable to a 40-year old employee determined using the stated interest rate of 8.0 percent. The product, $1,290, is the amount of the required employer contribution for Employee M for the 1995 plan year.

(c) *Nondiscrimination in amount of contributions under a defined benefit plan*—(1) *General rule.* Equivalent allocations under a defined benefit plan are nondiscriminatory in amount for a plan year if the plan would satisfy § 1.401(a)(4)–3(c)(1) (taking into account § 1.401(a)(4)–3(c)(3)) for the plan year if an equivalent normal and most valuable allocation rate, as determined under paragraph (c)(2) of this section, were substituted for each employee's normal and most valuable accrual rate, respectively, in the determination of rate groups.

(2) *Determination of equivalent allocation rates*—(i) *Basic definitions.* An employee's equivalent normal and most valuable allocation rates for a plan year are, respectively, the actuarial present value of the increase over the plan year in the benefit that would be taken into account in determining the employee's normal and most valuable accrual rates for the plan year, expressed either as a dollar amount or as a percentage of the employee's plan year compensation. In the case of a contributory DB plan, the rules in § 1.401(a)(4)–6(b)(1), (b)(5), or (b)(6) must be used to determine the amount of each employee's employer-provided benefit that would be taken into account for this purpose.

(ii) *Rules for determining actuarial present value.* The actuarial present value of the increase in an employee's benefit must be determined using a standard interest rate and a standard mortality table, and no mortality may be assumed prior to the employee's testing age.

(iii) *Options.* The optional rules in § 1.401(a)(4)–2(c)(2)(iv) (imputation of permitted disparity) and (v) (grouping of rates) may be applied to determine an employee's equivalent normal and most valuable allocation rates by substituting those rates (determined without regard to the option) for the employee's allocation rate in that section where appropriate. In addition, the limitations under section 415 may be taken into account under § 1.401(a)(4)–3(d)(2)(ii)(B), and qualified disability benefits may be taken into account as accrued benefits under § 1.401(a)(4)–3(f)(2), in determining the increase in an employee's accrued benefit during a plan year for purposes of paragraph (c)(2)(i) of this section, if those rules would otherwise be available. No other options are available in determining an employee's equivalent normal and most valuable allocations rate except those (e.g., selection of alternative standard interest rates) specifically provided in this paragraph (c)(2). Thus, while all of the mandatory rules in § 1.401(a)(4)–3(d) and (f) for determining the amount of benefits used to determine an employee's normal and most valuable accrual rates (e.g., the treatment of early retirement window benefits in § 1.401(a)(4)–3(f)(4)) are applicable in determining an employee's equivalent normal and most valuable allocation rates, none of the optional rules under § 1.401(a)(4)–3 is available (except the options relating to the section 415 limits and qualified disability benefits noted above).

(iv) *Consistency rule.* Equivalent allocation rates must be determined in a consistent manner for all employees for the plan year. Thus, for example, the same standard interest rates must be used, and any available options must be applied consistently if at all.

* * * * *

(d) *Safe-harbor testing method for defined benefit plans that are part of a floor-offset arrangement*—(1) *General rule.* A defined benefit plan that is part of a floor-offset arrangement is deemed to satisfy the nondiscriminatory amount requirement of § 1.401(a)(4)–1(b)(2) if all of the following requirements are satisfied:

(i) Under the floor-offset arrangement, the accrued benefit (as defined in

section 411(a)(7)(A)(i)) that would otherwise be provided to an employee under the defined benefit plan must be reduced solely by the actuarial equivalent of all or part of the employee's account balance attributable to employer contributions under a defined contribution plan maintained by the same employer (plus the actuarial equivalent of all or part of any prior distributions from that portion of the account balance). If any portion of the benefit that is being offset is nonforfeitable, that portion may be offset only by a benefit (or portion of a benefit) that is also nonforfeitable. In determining the actuarial equivalent of amounts provided under the defined contribution plan, an interest rate no higher than the highest standard interest rate must be used, and no mortality may be assumed in determining the actuarial equivalent of any prior distributions from the defined contribution plan or for periods prior to the benefit commencement date under the defined benefit plan.

(ii) The defined benefit plan may not be a contributory DB plan (unless it satisfies § 1.401(a)(4)–6(b)(6)), and benefits under the defined benefit plan may not be reduced by any portion of the employee's account balance under the defined contribution plan (or prior distributions from that account) that are attributable to employee contributions.

(iii) The defined benefit plan and the defined contribution plan must benefit the same employees.

(iv) The offset under the defined benefit plan must be applied to all employees on the same terms.

(v) All employees must have available to them under the defined contribution plan the same investment options and the same options with respect to the timing of preretirement distributions.

(vi) The defined benefit plan must satisfy the uniformity requirements of § 1.401(a)(4)–3(b)(2) and the unit credit safe harbor in § 1.401(a)(4)–3(b)(3) without taking into account the offset described in paragraph (d)(1)(i) of this section (i.e., on a gross-benefit basis), and the defined contribution plan must satisfy any of the tests in § 1.401(a)(4)–2(b) or (c). Alternatively, the defined benefit plan must satisfy any of the tests in § 1.401(a)(4)–3(b) or (c) without taking into account the offset described in paragraph (d)(1)(i) of this section, and the defined contribution plan must satisfy the uniform allocation safe harbor in § 1.401(a)(4)–2(b)(2).

(vii) The defined contribution plan may not be a section 401(k) plan or a section 401(m) plan.

(2) *Application of safe-harbor testing method to qualified offset arrangements.* A defined benefit plan that is part of a qualified offset arrangement as defined in section 1116(f)(5) of the Tax Reform Act of 1986, Pub. L. No. 99–514, is deemed to satisfy the requirements of paragraph (d)(1) (vi) and (vii) of this section, if the only defined contribution plans included in the qualified offset arrangement are section 401(k) plans, section 401(m) plans, or both, and the defined benefit plan would satisfy the requirements of paragraph (d)(1)(vi) of this section assuming the elective contributions for each employee under the defined contribution plan were the same (either as a dollar amount or as a percentage of compensation) for all plan years since the establishment of the plan.

§ 1.401(a)(4)–9 Plan aggregation and restructuring.

(a) *Introduction.* Two or more plans that are permissively aggregated and treated as a single plan under §§ 1.410(b)–7(d) must also be treated as a single plan for purposes of section 401(a)(4). See § 1.401(a)(4)–12 (definition of plan). An aggregated plan is generally tested under the same rules applicable to single plans. Paragraph (b) of this section, however, provides special rules for determining whether a plan that consists of one or more defined contribution plans and one or more defined benefits plans (a DB/DC plan) satisfies section 401(a)(4) with respect to the amount of employer-provided benefits and the availability of benefits, rights, and features. Paragraph (c) of this section provides rules allowing a plan to be treated as consisting of separate component plans and allowing the component plans to be tested separately under section 401(a)(4).

(b) *Application of nondiscrimination requirements to DB/DC plans*—(1) *General rule.* Except as provided in paragraphs (b)(2) and (b)(3) of this section, whether a DB/DC plan satisfies section 401(a)(4) is determined using the same rules applicable to a single plan.

(2) *Special rules for demonstrating nondiscrimination in amount of contributions or benefits*—(i) *Application of general tests.* A DB/DC plan satisfies section 401(a)(4) with respect to the amount of contributions or benefits for a plan year if it would satisfy § 1.401(a)(4)–3(c)(1) (without regard to the special rule in § 1.401(a)(4)–3(c)(3)) for the plan year if an employee's aggregate normal and most valuable allocation rates, as determined under paragraph (b)(2)(ii)(A) of this section, or an employee's aggregate normal and most valuable accrual rates, as determined under paragraph (b)(2)(ii)(B) of this section, where substituted for each employee's normal and most valuable accrual rates, respectively, in the determination of rate groups.

(ii) *Determination of aggregate rates*—(A) *Aggregate allocation rates.* An employee's aggregate normal and most valuable allocation rates are determined by treating all defined contribution plans that are part of the DB/DC plan as a single plan, and all defined benefit plans that are part of the DB/DC plan as a separate single plan; and determining an allocation rate and equivalent normal and most valuable allocation rates for the employee under each plan under §§ 1.401(a)(4)–2(c)(2) and 1.401(a)(4)–8(c)(2), respectively. The employee's aggregate normal allocation rate is the sum of the employee's allocation rate and equivalent normal allocation rate determined in this manner, and the employee's aggregate most valuable allocation rate is the sum of the employee's allocation rate and equivalent most valuable allocation rate determined in this manner.

(B) *Aggregate accrual rates.* An employee's aggregate normal and most valuable accrual rates are determined by treating all defined contribution plans that are part of the DB/DC plan as a single plan, and all defined benefit plans that are part of the DB/DC plan as a separate single plan; and determining an equivalent accrual rate and normal and most valuable accrual rates for the employee under each plan under §§ 1.401(a)(4)–8(b)(2) and 1.401(a)(4)–3(d), respectively. The employee's aggregate normal accrual rate is the sum of the employee's equivalent accrual rate and the normal accrual rate determined in this manner, and the employee's aggregate most valuable accrual rate is the sum of the employee's equivalent accrual rate and most valuable accrual rate determined in this matter.

(iii) *Options applied on an aggregate basis.* The optional rules in § 1.401(a)(4)–2(c)(2)(iv) (imputation of permitted disparity) and (v) (grouping of rates) may not be used to determine an employee's allocation or equivalent allocation rate, but may be applied to determine an employee's aggregate normal and most valuable allocation rates by substituting those rates (determined without regard to the option) for the employee's allocation rate in that section where appropriate. The optional rules in § 1.401(a)(4)–3(d)(3) (e.g., imputation of permitted disparity) may not be used to determine an employee's accrual or equivalent accrual rate, but may be applied to

determine an employee's aggregate normal and most valuable accrual rate by substituting those rates (determined without regard to the option) for the employee's normal and most valuable accrual rates, respectively, in that section where appropriate.

(iv) *Consistency rule*—(A) *General rule.* Aggregate normal and most valuable allocation rates and aggregate normal and most valuable accrual rates must be determined in a consistent manner for all employees for the plan year. Thus, for example, the same measurement periods and interest rates must be used, and any available options must be applied consistently, if at all, for the entire DB/DC plan. Consequently, options that are not permitted to be used under § 1.401(a)(4)–8 in cross-testing a defined contribution plan or a defined benefit plan (such as measurement periods that include future periods, non-standard interest rates, the option to disregard compensation adjustments described in § 1.401(a)(4)–13(d), or the option to disregard plan provisions providing for actuarial increases after normal retirement age under § 1.401(a)(4)–3(f)(3)) may not be used in testing a DB/DC plan on either a benefits or contributions basis, because their use would inevitably result in inconsistent determinations under the defined contribution and defined benefit portions of the plan.

(B) *Exception for section 415 alternative.* A DB/DC plan does not fail to satisfy the consistency rule in paragraph (b)(2)(iv)(A) of this section merely because the limitations under section 415 are not taken into account, or may not be taken into account, under § 1.401(a)(4)–3(d)(2)(ii)(B) in determining employees' accrual or equivalent allocation rates under the defined benefit portion of the plan, even though those limitations are applied in determining employees' allocation and equivalent accrual rates under the defined contribution portion of the plan.

(3) *Special rules for demonstrating nondiscrimination in availability of certain benefits, rights, and features*—(i) *Current availability.* A DB/DC plan is deemed to satisfy § 1.401(a)(4)–4(b)(1) with respect to the current availability of a benefit, right, or feature other than a single sum benefit, loan, ancillary benefit, or benefit commencement date (including the availability of in-service withdrawals), that is provided under only one type of plan (defined benefit or defined contribution) included in the DB/DC plan, if the benefit, right, or feature is currently available to all NHCEs in all plans of the same type as the plan under which is provided.

(ii) *Effective availability.* The fact that it may be difficult or impossible to provide a benefit, right, or feature described in paragraph (b)(3)(i) of this section under a plan of a different type than the plan or plans under which it is provided is one of the factors taken into account in determining whether the plan satisfies the effective availability requirement of § 1.401(a)(4)–4(c)(1).

(c) *Plan restructuring*—(1) *General rule.* A plan may be treated, in accordance with this paragraph (c), as consisting of two or more component plans for purposes of determining whether the plan satisfies section 401(a)(4). If each of the component plans of a plan satisfies all of the requirements of sections 401(a)(4) and 410(b) as if it were a separate plan, then the plan is treated as satisfying section 401(a)(4).

(2) *Identification of component plans.* A plan may be restructured into component plans, each consisting of all the allocations, accruals, and other benefits, rights, and features provided to a selected group of employees. The employer may select the group of employees used for this purpose in any manner, and the composition of the groups may be changed from plan year to plan year. Every employee must be included in one and only one component plan under the same plan for a plan year.

(3) *Satisfaction of section 401(a)(4) by a component plan*—(i) *General rule.* The rules applicable in determining whether a component plan satisfies section 401(a)(4) are the same as those applicable to a plan. Thus, for this purpose, any reference to a "plan" in section 401(a)(4) and the regulations thereunder (other than this paragraph (c)) is interpreted as a reference to a "component plan." As is true for a plan, whether a component plan satisfies the uniformity and other requirements applicable to safe harbor plans under §§ 1.401(a)(4)–2(b) and 1.401(a)(4)–3(b) is determined on a design basis. Thus, for example, plan provisions are not disregarded merely because they do not currently apply to employees in the component plan if they will apply to those employees as a result of the mere passage of time.

(ii) *Certain testing rules involving averaging.* The safe harbor in § 1.401(a)(4)–2(b)(3) for plans with uniform points allocation formulas are not available in testing (and thus cannot be satisfied by) contributions under a component plan. See §§ 1.401(k)–1(b)(3)(iii) and 1.401(m)–1(b)(3)(iii) for rules regarding the inapplicability of restructuring to section 401(k) plans and section 401(m) plans.

(4) *Satisfaction of section 410(b) by a component plan*—(i) *General rule.* The rules applicable in determining whether a component plan satisfies section 410(b) are generally the same as those applicable to a plan. However, a component plan is deemed to satisfy the average benefit percentage test of § 1.410(b)–5 if the plan of which it is a part satisfies § 1.410(b)–5 (without regard to § 1.410(b)–5(f)). In the case of a component plan that is part of a plan that relies on § 1.410(b)–5(f) to satisfy the average benefit percentage test, the component plan is deemed to satisfy the average benefit percentage test only if the component plan separately satisfies § 1.410(b)–5(f)). In addition, all component plans of a plan are deemed to satisfy the average benefit percentage test if the plan makes an early retirement window benefit (within the meaning of § 1.401(a)(4)–3(f)(4)(iii)) currently available (within the meaning of § 1.401(a)(4)–3(f)(4)(ii)(A)) to a group of employees that satisfies section 410(b) (without regard to the average benefit percentage test), and if it would not be necessary for the plan or any rate group or component plan of the plan to satisfy that test in order for the plan to satisfy sections 401(a)(4) and 410(b) in the absence of the early retirement window benefit.

(ii) *Relationship to satisfaction of section 410(b) by the plan.* Satisfaction of section 410(b) by a component plan is relevant solely for purposes of determining whether the plan of which it is a part satisfies section 401(a)(4), and not for purposes of determining whether the plan satisfies section 410(b) itself. The plan must still independently satisfy section 410(b) in order to be a qualified plan. Similarly, satisfaction of section 410(b) by a plan is relevant solely for purposes of determining whether the plan, and not the component plan, satisfies section 410(b). Thus, for example, a component plan that does not satisfy the ratio percentage test of § 1.410(b)–2(b)(2) must still satisfy the average benefit test of § 1.410(b)–2(b)(3), even though the plan of which it is a part satisfies the ratio percentage test.

(5) *Effect of restructuring under other sections.* The restructuring rules provided in this paragraph (c) apply solely for purposes of sections 401(a)(4) and 410(*l*), and those portions of sections 410(b), 414(s), and any other provisions that are specifically applicable in determining whether the requirements of section 410(a)(4) are satisfied. Thus, for example, a component plan is not treated as a separate plan under section 401(a)(26).

(6) *Examples.* The following examples illustrate the rules in this paragraph (c):

Example 1. Employer X maintains a defined benefit plan. The plan provides a normal retirement benefit equal to 1.0 percent of average annual compensation times years of service to employees at Plant S, and 1.5 percent of average annual compensation times years of service to employees at Plant T. Under paragraph (c)(2) of this section, the plan may be treated as consisting of two component defined benefit plans, one providing retirement benefits equal to 1.0 percent of average annual compensation times years of service to the employees at Plant S, and another providing benefits equal to 1.5 percent of average annual compensation times years of service to employees at Plant T. If each component plan satisfies sections 401(a)(4) and 410(b) as if it were a separate plan under the rules of this paragraph (c), then the entire plan satisfies section 401(a)(4).

Example 2. (a) Employer Y maintains Plan A, a defined benefit plan, for its Employees M, N, O, P, Q, and R. Plan A provides benefits under a uniform formula that satisfies the requirements of § 1.401(a)(4)–3(b)(2) and (b)(3) before it is amended on February 14, 1994. The amendment provides an early retirement window benefit that is a subsidized optional form of benefit under § 1.401(a)(4)–3(b)(2)(iii) and that is available on the same terms to all employees who satisfy the eligibility requirements for the window. The early retirement window benefit is available only to employees who retire between June 1, 1994, and November 30, 1994.

(b) Assume that Employees M, N, and O will be eligible to receive the window benefit by the end of the window period and Employees P, Q, and R will not. Because substantially all employees will not satisfy the eligibility requirements for the early retirement window benefit by the close of the early retirement window benefit period, Plan A fails to satisfy the uniform subsidies requirement of § 1.401(a)(4)–3(b)(2)(iii). See § 1.401(a)(4)–3(b)(2)(vi), *Example 6.*

(c) Under paragraph (c)(2) of this section, Employees M, N, O, P, Q, and R may be grouped into two component plans, one consisting of Employees M, N, and O and all their accruals and other benefits, rights, and features under the plan (including the early retirement window benefit), and another consisting of Employees P, Q, and R, and all their accruals and other benefits, rights, and features under the plan. Each of the component plans identified in this manner satisfies the uniform subsidies requirement of § 1.401(a)(4)–3(b)(2)(iii), and thus satisfies § 1.401(a)(4)–3(b). If each of these component plans also satisfies section 410(b) (including, if applicable, the reasonable classification requirement of § 1.410(b)–4(b)) as if it were a separate plan under the rules of this paragraph (c), then the entire plan satisfies section 401(a)(4).

Example 3. (a) Employer Z maintains Plan B, a defined benefit plan with a benefit formula that provides two percent of average annual compensation for each year of service up to 20 to each employee. Assume that Plan B would satisfy the fractional accrual rule safe harbor in § 1.401(a)(4)–3(b)(4), except that some employees accrue a portion of their normal retirement benefit in the current plan year that is more than one third larger than the portion of the same benefit accrued by other employees for the current plan year, and the plan therefore fails to satisfy the one-third-larger-requirement of § 1.401(a)(4)–3(b)(4)(i)(C)(*1*).

(b) Employer Z restructures Plan B into two plans, one covering employees with 30 years or less of service at normal retirement age, and the other covering all other employees. Each component plan would separately satisfy the one-third-larger requirement of § 1.401(a)(4)–3(b)(4)(i)(C)(*1*) if the only employees taken into account were those employees included in the component plan in the current plan year. Under paragraph (c)(3)(i) of this section and § 1.401(a)(4)–3(b)(4)(i)(C)(*1*), however, the component plans do not satisfy the one-third-larger requirement because the safe harbor determination is made taking into account the effect of the plan benefit formula on any potential employee in the component plan (other than employees with more than 33 years of service at normal retirement age), and not just those employees included in the component plan in the current plan year.

§ 1.401(a)(4)–10 Testing of former employees.

(a) *Introduction.* This section provides rules for determining whether a plan satisfies the nondiscriminatory amount and nondiscriminatory availability requirements of § 1.401(a)(4)–1(b)(2) and (3), respectively, with respect to former employees. Generally, this section is relevant only in the case of benefits provided through an amendment to the plan effective in the current plan year. See the definitions of employee and former employee in § 1.401(a)(4)–12.

(b) *Nondiscrimation in amount of contributions or benefits*—(1) *General rule.* A plan satisfies § 1.401(a)(4)–1(b)(2) with respect to the amount of contributions or benefits provided to former employees if, under all of the facts and circumstances, the amount of contributions or benefits provided to former employees does not discriminate significantly in favor of former HCEs. For this purpose, contributions or benefits provided to former employees includes all contributions or benefits provided to former employees or, at the employer's option, only those contributions or benefits arising out of the amendment providing the contributions or benefits. A plan under which no former employee currently benefits (within the meaning of § 1.410(b)–3(b)) is deemed to satisfy this paragraph (b).

(2) *Permitted disparity.* Section 401(*l*) and § 1.401(a)(4)–7 generally apply to benefits provided to former employees in the same manner as those provisions apply to employees. Thus, for example, for purposes of determining a former employee's cumulative permitted disparity limit, the sum of the former employee's total annual disparity fractions (within the meaning of § 1.401(*l*)–5) as an employee continues to be taken into account. However, the permitted disparity rate applicable to a former employee is determined under § 1.401(*l*)–3(e) as of the age the former employee commenced receipt of benefits, not as of the date the employee receives the accrual for the current plan year.

(3) *Examples.* The following examples illustrate the rules in this paragraph (b):

Example 1. Employer X maintains a section 401(*l*) plan, Plan A, that uses maximum permitted disparity. Plan A is amended to increase the benefits of all former employees in pay status. The percentage increase for each former employee is reasonably comparable to the adjustment in social security benefits under section 215(i)(2)(A) of the Social Security Act since the former employee commenced receipt of benefits. Plan A does not fail to satisfy this paragraph (b) merely because of the amendment.

Example 2. The facts are the same as in *Example 1*, except that the amendment provides an across-the-board 20 percent increase in benefits for all former employees in pay status. The cost of living has increased at an average rate of three percent in the two years preceding the amendment, and some HCEs have retired and become former HCEs during that period. Because this amendment increases the disparity in the plan formula beyond the maximum permitted disparity adjusted for any reasonable approximation of the increase in the cost of living since the HCEs retired, Plan A discriminates significantly in favor of former HCEs, and thus does not satisfy this paragraph (b).

Example 3. The facts are the same as in *Example 1*, except that Plan A is only amended to increase the benefits of former employees in pay status who terminated employment with Employer X after attaining early retirement age. The determination of whether the amendment causes Plan A to fail to satisfy this paragraph (b) must take into account the relative numbers of former HCEs and former NHCEs who have terminated employment with Employer X after attaining early retirement age.

(c) *Nondiscrimination in availability of benefits, rights, or features.* A plan satisfies section 401(a)(4) with respect to the availability of benefits, rights, and features provided to former employees if any change in the availability of any benefit, right, or feature to any former employee is applied in a manner that, under all of the facts and circumstances, does not discriminate significantly in favor of former HCEs. For purposes of demonstrating that a plan satisfies section 401(a)(4) with respect to the availability of loans provided to former employees, an employer may treat

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former employees who are parties in interest within the meaning of section 3(14) of the Employee Retirement Income Security Act of 1974 as employees.

§ 1.401(a)(4)–11 Additional rules.

(a) *Introduction.* This section provides additional rules for determining whether a plan satisfies section 401(a)(4). Paragraph (b) of this section provides rules for the treatment of the portion of an employee's accrued benefit or account balance that is attributable to rollovers, transfers between plans, and employee buybacks. Paragraph (c) of this section provides rules regarding vesting. Paragraph (d) of this section provides rules regarding service crediting. Paragraph (e) of this section, regarding family aggregation, and paragraph (f) of this section, regarding governmental plans, are reserved. Paragraph (g) of this section provides rules regarding the extent to which retroactive amendments may be made for purposes of section 401(a).

(b) *Rollovers, transfers, and buybacks*—(1) *Rollovers and elective transfers.* The portion of an employee's accrued benefit or account balance under a plan that is attributable to rollover (including direct rollover) contributions to the plan that are described in section 402(c), 402(e)(6), 403(a)(4), 403(a)(5), or 408(d)(3), or elective transfers to the plan that are described in § 1.411(d)–4, Q&A–3(b), is not taken into account in determining whether the plan satisfies the nondiscriminatory amount requirement of § 1.401(a)(4)–1(b)(2).

(2) *Other transfers.* [Reserved]

(3) *Employee buybacks*—(i) *Rehired employee buyback of previous service.* An employee's repayment to a plan of a prior distribution from the plan (including reasonable interest from the time of the distribution) that results in the restoration of the employee's accrued benefit under the plan (or the service associated with that accrued benefit) that would otherwise be disregarded in determining the employee's accrued benefit in accordance with section 411 on account of the distribution is not treated as an employee contribution for purposes of §§ 1.401(a)(4)–1 through 1.401(a)(4)–13.

(ii) *Make-up of missed employee contributions.* If a contributory DB plan gives all employees who did not make employee contributions for a prior period the right to make the missed contributions at a later date (including reasonable interest from the time of the missed contributions) and, once the contributions have been made, determines benefits under the plan by treating the employee contributions (excluding the interest) as if they were actually made during that prior period, then those contributions must satisfy § 1.401(a)(4)–6(c) as if they were employee contributions actually made during that prior period. Thus, for example § 1.401(a)(4)–6(c)(2) is not satisfied for the current plan year if the employee contribution rate (within the meaning of § 1.401(a)(4)–6(b)(2)(ii)(A) but determined without regard to the interest) for the employees making up missed contributions is different than the employee contribution rate applicable to other employees during the prior period. The rule in this paragraph (b)(3)(ii) may be extended to employees who did not make employee contributions for a period of service that is or would otherwise have been credited under the plan and that preceded their participation in the plan.

(c) *Vesting*—(1) *General rule.* A plan satisfies this paragraph (c) if the manner in which employees vest in their accrued benefits under the plan does not discriminate in favor of HCEs. Whether the manner in which employees vest in their accrued benefits under a plan discriminates in favor of HCEs is determined under this paragraph (c) based on all of the relevant facts and circumstances, taking into account any relevant provisions of sections 401(a)(5)(E), 411(a)(10), 411(d)(1), 411(d)(2), 411(d)(3), 411(e), and 420(c)(2), and taking into account any plan provisions that affect the nonforfeitability of employees' accrued benefits (e.g., plan provisions regarding suspension of benefits permitted under section 411(a)(3)(B)), other than the method of crediting years of service for purposes of applying the vesting schedule provided in the plan.

(2) *Deemed equivalence of statutory vesting schedules.* For purposes of this paragraph (c), the manner in which employees vest in their accrued benefits under the vesting schedules in section 411(a)(2) (A) and (B) are treated as equivalent to one another, and the manner in which employees vest in their accrued benefits under the vesting schedules in section 416(b)(1) (A) and (B) are treated as equivalent to one another.

(3) *Safe harbor for vesting schedules.* The manner in which employees vest in their accrued benefits under a plan does not discriminate in favor of HCEs if each combination of plan provisions that affect the nonforfeitability of any employee's accrued benefit would satisfy the nondiscriminatory availability requirements of § 1.401(a)(4)–4 if that combination were another right or feature.

(4) *Examples.* The following examples illustrate the rules in this paragraph (c):

Example 1. Plan A provides the six-year graded vesting schedule described in section 416(b)(1)(B). In 1996, Plan A is amended to provide the five-year vesting schedule described in section 411(a)(2)(A). To comply with section 411(a)(10)(B), the plan amendment also provides that all employees with at least three years of service may elect to retain the prior vesting schedule. The manner in which employees vest in their accrued benefits under Plan A does not discriminate in favor of HCEs merely because the prior vesting schedule continues to apply to the accrued benefits of electing employees, even if, at the time of the election or in future years, the prior vesting schedule applies only to a group of employees that does not satisfy section 410(b).

Example 2. The facts are the same as in *Example 1*, except that, for administrative convenience in complying with section 411(a)(10)(B), the plan amendment automatically provides all employees employed on the date of the amendment with the higher of the nonforfeitable percentages determined under either schedule. The manner in which employees vest in their accrued benefits under Plan A does not discriminate in favor of HCEs merely because, for administrative convenience in complying with section 411(a)(10), the amendment exceeds the requirements of section 411(a)(10). The result would be the same if the plan amendment automatically provided the higher of the nonforfeitable percentages only to those employees with at least three years of service.

Example 3. (a) Employer Y maintains Plan B covering all of its employees. On January 1, 1996, Employer Y sells Division M to Employer Z, and all the employees in Division M become employees of Employer Z. Employer Y obtains a determination letter that the resulting cessation of participation by these employees in Plan B constitutes a partial termination. Therefore, in order to satisfy section 411(d)(3), Plan B fully vests the accrued benefit of each of the employees of Division M whose participation in Plan B ceased as a result of the sale on January 1, 1996.

(b) The manner in which employees vest in their accrued benefits under Plan B does not discriminate in favor of HCEs merely because, in order to satisfy section 411(d)(3), the accrued benefits of all employees affected by the partial termination become fully vested. This is true even if the affected group of employees does not satisfy section 410(b).

Example 4. (a) The facts are the same as in *Example 3*, except that Employer Y does not obtain a determination letter that the sale of Division M to Employer Z will cause a partial termination. Instead, based on its reasonable belief that the sale will cause a partial termination, and in order to ensure that Plan B will satisfy section 411(d)(3), Employer Y amends Plan B to vest fully the accrued benefit on January 1, 1996 of each of the employees it reasonably believes to be an affected employee.

(b) The manner in which employees vest in their accrued benefits under Plan B does not discriminate in favor of HCEs merely

because, based on Employer Y's reasonable belief that the sale will cause a partial termination, Plan B is amended to vest fully the accrued benefits of each of the employees it reasonably believes to be an affected employee.

(d) *Service-crediting rules*—(1) *Overview*—(i) *In general.* A plan does not satisfy this paragraph (d) with respect to the manner in which service is credited under the plan unless the plan satisfies paragraph (d)(2) of this section. Paragraph (d)(3) of this section provides rules for determining whether service other than actual service with the employer may be taken into account in determining whether a plan satisfies § 1.401(a)(4)–1(b)(2) or (b)(3). The rules of this paragraph (d) apply separately to service credited under a plan for each different purpose under the plan, including, but not limited to: application of the benefit formula (benefit service), application of the accrual method (accrual service), application of the vesting schedule (vesting service), entitlement to benefits, rights and features (entitlement service), and application of the requirements for eligibility to participate in the plan (eligibility service).

(ii) *Special rule for pre-effective date service.* A plan is deemed to satisfy this paragraph (d) with respect to service credited for periods prior to the effective date applicable to the plan under § 1.401(a)(4)–13 (a) or (b) under a plan provision adopted and in effect as of February 11, 1993 (and any such service may be taken into account for purposes of satisfying § 1.401(a)(4)–1 (b)(2) or (b)(3)), if the plan satisfied the applicable nondiscrimination requirements with respect to the services that were in effect for all relevant periods prior to the applicable effective date.

(2) *Manner of crediting service*—(i) *General rule.* A plan satisfies this paragraph (d)(2) if, on the basis of all of the relevant facts and circumstances, the manner in which employees' service is credited for all purposes under the plan does not discriminate in favor of NCEs.

(ii) *Equivalent service-crediting methods.* For purposes of this paragraph (d)(2), a service-crediting method used for a specified purpose that is based on hours of service, as provided in 29 CFR 2530.200b–2, and a service-crediting method used for the same purpose that is based on one of the equivalences set forth in 29 CFR 2530.200b–3, are treated as equivalent if the service-crediting methods are otherwise the same.

(iii) *Safe harbor for service-crediting.* The manner in which service is credited under a plan for a specified purpose satisfies this paragraph (d)(2) if each combination of service-crediting provisions applied for that purpose would satisfy the nondiscriminatory availability requirements of § 1.401(a)(4)–4 if that combination were another right or feature.

(iv) *Examples.* The following examples illustrate the rules in this paragraph (d)(2):

Example 1. (a) Plan A covers both salaried employees and hourly employees. All of the HCEs in Plan A are salaried employees. For administrative convenience, salaried employees in Plan A (none of whom are part-time) have their years of service calculated in accordance with the elapsed time provisions in § 1.410(a)–7. Hourly employees in Plan A (most of whom are schedule to work 2,000 hours in a year) have their hours of service calculated in accordance with 29 CFR 2530.200b–2 and are credited with a year of service for each plan year in which they complete 1,000 hours of service.

(b) Plan A does not fail to satisfy this paragraph (d)(2) merely because different service-crediting provisions are applied to salaried and hourly employees for administrative convenience. The service-crediting provisions for hourly employees in Plan A are reasonably comparable to the service-crediting provisions for salaried employees. This is because the amount of service credited to hourly employees who complete fewer than 1,000 hours of service before termination of employment (i.e., quit, retirement, discharge, or death) during the plan year (and are treated less favorably than the salaried employees with the same period of employment during the plan year) is balanced by the amount of service credited to hourly employees who complete more than 1,000 hours of service before termination of employment during the plan year (who are treated more favorably than the salaried employees with the same period of employment during the plan year).

Example 2. (a) The facts are the same as in *Example 1*, except Plan A requires hourly employees to complete 2,000 hours of service in order to be credited with a full year of service, with a pro rata reduction for hourly employees who complete fewer than 2,000 hours of service.

(b) Plan A does not fail to satisfy this paragraph (d)(2) merely because different service-crediting provisions are applied to salaried and hourly employees for administrative convenience. The service-crediting provisions for hourly employees in Plan A are reasonably comparable to the service-crediting provisions for salaried employees. This is because the amount of service credited to hourly employees whose employment terminates (i.e., quit, retire, are discharged, or die) during the plan year is reasonably comparable to the amount of service credited to salaried employees whose employment is terminated during the plan year with the same period of employment during the plan year.

(3) *Service-crediting period*—(i) *Limitation on service taken into account*—(A) *General rule.* Except as otherwise provided in this paragraph (d)(3), service for periods in which an employee does not perform services as an employee of the employer or in which the employee did not participate in the plan may not be taken into account in determining whether the plan satisfies § 1.401(a)(4)–1 (b)(2) and (b)(3). In addition, in determining whether a plan satisfies § 1.401(a)(4)–1 (b)(2) and (b)(3), no more than one year of service may be taken into account with respect to any 12-consecutive-month period (with adjustments for shorter periods, if appropriate) unless the additional service is required to be credited under section 410 or 411, whichever is applicable.

(B) *Past service.* Notwithstanding paragraph (d)(3)(i)(A) of this section, service for periods in which an employee did not participate in a plan, but in which the employee would have participated in the plan but for the fact that the plan (or the plan amendment extending coverage to the employee) was not in existence during that period, may be taken into account in determining whether the plan satisfies § 1.401(a)(4)–1 (b)(2) and (b)(3). This is because service for such periods generally would have been credited for the employee but for the timing of the plan establishment or amendment, and the timing of the plan establishment or amendment must satisfy § 1.401(a)(4)–5(a).

(C) *Pre-participation and imputed service.* Notwithstanding paragraph (d)(3)(i)(A) of this section, to the extent that a plan treats pre-participation service and imputed service as actual service with the employer, such service may be taken into account in determining whether the plan satisfies § 1.401(a)(4)–1 (b)(2) and (b)(3) if the service satisfies each of the requirements in paragraph (d)(3)(iii) of this section and, in the case of imputed service, applies the additional rules in paragraph (d)(3)(iv) of this section.

(D) *Additional limitations on service-crediting in the case of certain offsets.* Notwithstanding paragraph (d)(3)(i) (B) and (C) of this section, if a plan credits benefit service or accrual service under paragraph (d)(3)(i) (B) or (C) of this section for a period before an employee becomes a participant in the plan, but offsets the benefits determined under the plan by benefits under another plan (whether or not qualified or terminated) that are attributable to the same period for which that service is credited, then that service may not be taken into account for purposes of determining whether the first plan satisfies § 1.401(a)(4)–1 (b)(2) or (b)(3) unless the offset provision applies on the same basis to all similarly-situated employees

(within the meaning of paragraph (d)(3)(iii)(A) of this section).

(ii) *Definitions*—(A) *Pre-participation service.* For purposes of this section, pre-participation service includes all years of service credited under a plan for years of service with the employee or a prior employer for periods before the employee commenced or recommenced participation in the plan (other than the service described in paragraph (d)(3)(i)(B) of this section).

(B) *Imputed service.* For purposes of this section, imputed service includes any service credited for periods after an employee has commenced participation in a plan while the employee is not performing services as an employee for the employer (including a period in which the employee performs services for another employer, e.g., a joint venture), or while the employee has a reduced work schedule and would not otherwise be credited with service at the level being credited under the general terms of the plan.

(iii) *Requirements for pre-participation and imputed service*—(A) *Provision applied to all similarly-situated employees*—(1) *General rule.* A plan provision crediting pre-participation service or imputed service to any HCE must apply on the same terms to all similarly-situated NHCEs. Whether two employees are similarly situated for this purpose must be determined based on reasonable business criteria, generally taking into account only the circumstances resulting in the employees being covered under the plan or being granted imputed service and on the situation of the employees (e.g., the plan in which the employees benefit or the employer by which they are employed) during the period for which the pre-participation service or imputed service is credited. For example, employees who enter a plan as a result of a particular merger and who participated in the same plan of a prior employer are generally similarly situated. As another example, employees who are transferred to different joint ventures or different spun-off divisions are generally not similarly situated.

(2) *Examples.* The following examples illustrate the rules in this paragraph (d)(3)(iii)(A):

Example 1. Employer X maintains defined benefit Plans A and B and defined contribution Plan C. Plan A covers all employees who work at the headquarters of Employer X. Plan B covers some employees in Division M of Employer X, and Plan C covers the other employees of Division M. Plans B and C have not been aggregated for purposes of satisfying section 401(a)(4) or 410(b) for the period for which service is being credited. Plan A provides that, whenever an employee covered by Plan B transfers from Division M to the headquarters, the employee's service credited under Plan B is credited under Plan A, and the employee's benefit under Plan A is offset by the employee's benefit under Plan B. However, Plan A provides for no similar recognition of service or offset for employees covered by Plan C who transfer from Division M to the headquarters. Plan A does not fail to satisfy this paragraph (d)(3)(iii)(A) merely because it credits service for employees transferring from Plan B but not from Plan C, because it is reasonable to treat employees participating in different plans that have not been aggregated as not being similarly situated.

Example 2. The facts are the same as in *Example 1*, except that Employer X acquires two trades or businesses from different employers. Employees of the acquired trades or businesses become employees of Division M and become covered by Plan B. In addition, Plan B is amended to credit service with one of the trades or businesses but not the other. Plan B does not fail to satisfy this paragraph (d)(3)(iii)(A) merely because it credits service for one acquired trade or business but not another, because it is reasonable to treat employees of one acquired trade or business as not similarly situated to employees of another acquired trade or business.

(B) *Legitimate business reason*—(1) *General rule.* There must be a legitimate business reason, based on all the relevant facts and circumstances, for a plan to credit imputed service or for a plan to credit pre-participation service for a period of service with another employer.

(2) *Relevant facts and circumstances when crediting service with another employer.* The following are examples of relevant facts and circumstances for determining whether a legitimate business reason exists for a plan to credit pre-participation or imputed service for a period of service with another employer as service with the employer: whether one employer has a significant ownership, control, or similar interest in, or relationship with, the other employer (though not enough to cause the two employers to be treated as a single employer under section 414); whether the two employers share interrelated business operations; whether the employers maintain the same multiple-employer plan; whether the employers share similar attributes, such as operation in the same industry or the same geographic area; and whether the employees are an acquired group of employees or the employees became employed by the other employer in a transaction between the two employers that was a stock or asset acquisition, merger, or other similar transaction involving a change in the employer of the employees of a trade or business. Other factors may also be relevant for this purpose, such as the plan's treatment of service with other employers with which the employer has a similar relationship and the type of service being credited (e.g., vesting service as compared to benefit service or accrual service). A legitimate business reason is deemed to exist for a plan to credit military service as service with the employer.

(3) *Examples.* The following examples illustrate the rules in this paragraph (d)(3)(iii)(b):

Example 1. Twenty unrelated employers jointly sponsor a multiple-employer plan that covers all employees of the employers. From time to time, employees transfer employment among the employers. There is a legitimate business reason for a disaggregated portion of the plan that benefits the employees of one of the employers to treat service with any of the other employers as service with the employer.

Example 2. Employer X owns 20 percent of the outstanding stock of Employer Y. From time to time, employees transfer from Employer X to Employer Y at the request of Employer X. Employer X maintains defined benefit Plan A. Plan A provides that years of service include an employee's years of service with Employer Y. There is a legitimate business reason for Plan A to credit service with Employer Y because Employer X, through its 20-percent ownership interest, benefits from the service that the transferred employees provide to Employer Y.

Example 3. Employer Z manufacturers widgets and belongs to the National Widget Manufacturers' Association. From time to time, Employer Z hires employees from other widget manufacturers. Employer Z maintains a defined benefit plan, Plan B, which credits pre-participation service for periods of service with all other members of the Association located in the western half of the United States as service with Employer Z. There is a legitimate business reason for Plan B to treat service with other members of the Association as service with Employer Z.

(C) *No significant discrimination*—(1) *General rule.* Based on all of the relevant facts and circumstances, a plan provision crediting pre-participation or imputed service must not be design or in operation discriminate significantly in favor of HCEs.

(2) *Relevant facts and circumstances.* The following are examples of relevant facts and circumstances for determining whether a plan provision crediting pre-participation or imputed service discriminates significantly in favor of HCEs: whether the service credit does not duplicate benefits but merely makes an employee whole (i.e., prevents the employee from being disadvantaged with respect to benefit by a change in job or employer or provides the employee with the benefits comparable to those of other employees); the degree

of business ties between the current employer and the prior employer, such as the degree of ownership interest or other affiliation; the degree of excess coverage under section 401(b) of NHCEs for the plan crediting the service, taking into account employees who are credited with pre-participation service; whether the other employer maintains a qualified plan for its employees; the existence of reciprocal service under other plans of the employer or the prior employer; the circumstances underlying the employee's transfer into the group of employees covered by the plan; the type of service being credited; and the relative number of employees other than five-percent owners or the most highly-paid HCEs of the employer who are being credited with pre-participation or imputed service. The relative number referred to in the last factor is determined taking into account all employees who have been over time, or are reasonably expected to be in the future, credited with such service.

(3) *Examples.* The following examples illustrate the rules in this paragraph (d)(3)(iii)(C). It is assumed that facts not described in an example do not, in the aggregate, suggest that the relevant plan provision either does or does not discriminate significantly in favor of HCEs.

Example 1. (a) Employer W maintains defined benefit Plans A and B. Plan A covers all employees who work at the headquarters of Employer W. Plan B covers all employees of Division M of Employer W. Plan A provides that, whenever an employee transfers from division M to the headquarters, the employee's service credited under Plan B is credited under Plan A, and the employee's benefit under Plan A is offset by the employee's benefit under Plan B. Employees, including a meaningful number of NHCEs, are periodically transferred from Division M to the headquarters of Employer W for bona fide business reasons.

(b) The Plan A provision crediting service under Plan B does not discriminate significantly in favor of HCEs. The provision is designed only to prevent employees from being disadvantaged by being transferred from Division M to the headquarters, and a meaningful number of NHCEs can be expected to benefit from it.

Example 2. (a) The facts are the same as in *Example 1*, except that the only employees transferred from Division M to the headquarters of Employer W are HCEs (but not the most highly-paid HCEs of Employer W).

(b) Employer W determines that Plan A would have satisfied sections 401(a)(4) and 410(b) for the period for which the transferred employees are being credited with preparticipation service had the employees participated in Plan A during that period. This determination is based on test results under sections 401(a)(4) and 410(b) for the current year, taking into account significant demographic changes over this period.

(c) The Plan A provision crediting service under Plan B does not significantly discriminate in favor of HCEs in the current year. This conclusion is based on the fact that the circumstances underlying the transfers indicate that they were made for bona fide business reasons, that Plan A would have satisfied sections 401(a)(4) and 410(b) had the transferred employees participated in Plan A during the period for which the pre-participation service is credited, and that the transferred employees are not the most highly-paid HCEs of Employer W.

Example 3. (a) The facts are the same as in *Example 1*, except that the only employee who is transferred from Division M to the headquarters of Employer W is Employee P, who is among the most highly-paid HCEs of Employer W. Plan A provides an unreduced early retirement benefit at age 55 for employees with 20 years of service, but Plan B's early retirement benefits are not subsidized. Employee P is transferred to the headquarters with 20 years of service credited under Plan B and shortly before attainment of age 55. Employee P is expected to retire upon reaching age 55.

(b) The Plan A provision crediting service under Plan B discriminates significantly in favor of HCEs in the year of the transfer. This is because the circumstances underlying this transfer (i.e., its occurrence shortly before Employee P's expected retirement and the fact that the transfer significantly increased Employee P's early retirement benefits) indicate the Employee P was transferred to the headquarters primarily to obtain the higher pension benefits provided under Plan A.

(c) Because of this conclusion, the pre-participation service credited to Employee P cannot be taken into account in determining whether Plan A satisfies § 1.401(a)(4)–1(b)(2) and (b)(3). Thus, if Plan A credits the service, it cannot be a safe harbor plan because the benefit formula will take into account service that may not be taken into account under this paragraph (d)(3). In addition, Employee P's accrual rates under the general test in § 1.401(a)(4)–3(c) are likely to be higher than those of other employees because, while the pre-participation service may be used to determine Employee P's benefits under Plan A, the service must be disregarded in determining Employee P's testing service. Also, if Employee P's pre-participation service is used in determining Employee P's entitlement to a benefit, right, or feature under Plan A, the fact that the service must be disregarded in determining Employee P's entitlement service for purposes of § 1.401(a)(4)–4 may cause the benefit, right, or feature to be treated as a separate benefit, right, or feature that is currently available only to Employee P.

Example 4. (a) Employer X manufactures widgets and belongs to the National Widget Manufacturers' Association. Each member of the Association maintains a defined benefit plan that credits pre-participation service for periods of service with other members and offsets benefits under the plan by benefits under the plans of the other members. Employer X maintains defined benefit Plan C. Employer X periodically hires employees from other widget manufacturers who are not among its most highly-paid HCEs. In 1997, however, the only employee hired by Employer X from another member of the Association is Employee Q, who is among Employer X's most highly-paid HCEs. Employee Q receives pre-participation service credit in accordance with the terms of Plan C. Some of the plans maintained by other members of the Association credited pre-participation service to NHCEs for the same period for which the pre-participation service is credited to Employee Q.

(b) The provision of Plan C crediting pre-participation service with other members of the Association does not discriminate significantly in 1997, despite the fact that the only employee who received pre-participation service credit under the provision in that year was among the most highly-paid HCEs of Employer X. This conclusion is based on the relative number of employees other than Employer X's most highly-paid HCEs who have been credited in the past, or are reasonably expected to be credited in the future, with pre-participation service for periods of service with other members of the Association, and the fact that other employees who are NHCEs are being credited with pre-participation service under a reciprocal agreement.

Example 5. Employer Y owns 79 percent of the outstanding stock of Employer Z. From time to time, employees transfer from Employer Y to Employer Z at the request of Employer Y. The only employees who have ever been transferred are HCEs. Employer Y maintains a defined benefit plan, Plan D, which credits employees transferred to Employer Z with imputed benefit and accrual service while employed by Employer Z. Employer Z maintains no qualified plan. Plan D would fail either section 401(a)(4) or section 410(b) in the current plan year if the portion of Plan D covering the transferred employees were treated as maintained by Employer Z. The Plan D provision crediting imputed benefit and accrual service to employees transferred to Employer Z significantly discriminates in favor of HCEs in the current plan year.

Example 6. The facts are the same as in *Example 5*, except that Plan D credits the individuals who transfer to Employer Z only with imputed vesting and entitlement service. The Plan D provision crediting imputed vesting and entitlement service to individuals transferred to Employer Z does not significantly discriminate in favor of HCEs in the current plan year, because there is less potential for discrimination when the only types of service being imputed are vesting and entitlement service.

(iv) *Additional rules for imputed service*—(A) *Legitimate business reasons for crediting imputed service*—(1) *General rule.* A legitimate business reason does not exist for a plan to impute service after an individual has permanently ceased to perform services as an employee (within the meaning of § 1.410(b)–9) for the employer maintaining the plan, i.e., is not expected to resume performing services

as an employee for the employer. The preceeding sentence does not apply in the case of an individual who is not performing services for the employer because of disability or is performing services for another employer under an arrangement (such as a transfer of the employee to another employer) that provides some ongoing business benefit to the original employer. The first sentence in this paragraph (d)(3)(iv)(A)(*1*) also does not apply in the case of vesting and entitlement service if the employee is performing services for another employer that is being treated under the plan as actual service with the original employer.

(*2*) *Certain presumptions applicable.* Whether an individual has permanently ceased to perform services as an employee for an employer is determined taking into account all of the relevant facts and circumstances. There is a rebuttable presumption for a period of up to two years that an individual who has ceased to perform services as an employee for an employer is nonetheless expected to resume performing services as an employee for the employer, if the employer continues to treat the individual as an employee for significant purposes unrelated to the plan. After two years, there is a rebuttable presumption that an individual who has ceased to perform services as an employee for the employer is not expected to resume performing services as an employee for the employer. The fact that an individual is absent to perform jury duty or military service automatically rebuts the latter presumption. Other evidence, such as the employer's layoff policy, the terms of an employment contract, or specific leave to pursue a degree requiring more than two years of study, may also rebut this presumption.

(*3*) *Imputed service for part-time employees.* Rules similar to the rules in paragraph (d)(3)(iv)(A) (*1*) and (*2*) of this section apply in the case of an employee whose work hours are temporarily reduced and who therefore would normally be credited with service at a reduced rate, but who continues to be credited with service at the same rate as before the reduction (e.g., an employee who continues to be credited with service as if the employee were a full-time employee during a temporary change from a full-time to a part-time work schedule).

(B) *Additional factors for determining whether a provision crediting imputed service discriminates significantly.* In addition to the factors described in paragraph (d)(3)(iii)(C)(*2*) of this section, relevant facts and circumstances for determining whether a plan provision crediting imputed service during a leave of absence or a period of reduced services discriminates significantly include any terms that restrict the ability of employees to take leaves of absence or work temporarily on a part-time basis, respectively.

(v) *Satisfaction of other service-crediting rules.* A plan does not fail to satisfy this paragraph (d)(3) merely because it credits service to the extent necessary to satisfy the service-crediting rules in section 410(a), 411(a), 413, or 414(a), § 1.410(a)–7 (elapsed-time method of service-crediting) or 29 CFR 2530.200b–2 (regarding hours of service to be credited), whichever is applicable, or 29 CFR § 2530.204–2(d) (regarding double portion of service and compensation).

(e) *Family aggregation rules.* [Reserved]

(f) *Governmental plans.* [Reserved]

(g) *Retroactive correction*—(1) *In general.* This paragraph (g) provides rules for retroactively amending a plan after the close of the plan year for purposes of satisfying section 401(a) for the plan year. These rules apply in addition to the rules of section 401(b). Paragraph (g)(2) of this section describes the scope of the retroactive amendments that are permitted to be made. Paragraph (g)(3) of this section specifies the conditions under which a retroactive amendment may be made. Paragraph (g)(4) of this section provides a rule prohibiting retroactive amendments that benefit terminated nonvested employees from being taken into account for certain purposes. Paragraph (g)(5) of this section discusses the effect of the retroactive amendments permitted under this paragraph (g) under provisions other than section 401(a).

(2) *Scope of retroactive amendments*—(i) *Minimum coverage and nondiscrimination in amount of contributions or benefits.* For purposes of satisfying the minimum coverage requirements of section 410(b) or the nondiscriminatory amount requirement of § 1.401(a)(4)–1(b)(2), a plan may be retroactively amended to increase accruals or allocations for employees who benefited under the plan during the preceding plan year, or to grant accruals or allocations to individuals who did not benefit under the plan during the preceding plan year.

(ii) *Nondiscriminatory availability of benefits, rights, and features.* A plan may not be retroactively amended to make available to an employee a benefit, right, or feature under the plan that previously was not available to the employee solely to satisfy the nondiscriminatory availability requirements of § 1.401(a)(4)–(4). A plan may, however, be retroactively amended to make available to an employee a benefit, right, or feature that is directly related to a retroactive increase under paragraph (g)(2)(i) of this paragraph in the amount of an employee's accrual or allocation (including a grant of accruals or allocations to an employee who otherwise would not be treated as benefiting under the plan).

(iii) *Nondiscriminatory effect of plan amendments and terminations.* A plan may be retroactively amended to correct a discriminatory plan amendment so that the plan satisfies § 1.401(a)(4)–5(a). A plan may not, however, be retroactively amended to correct for a failure to incorporate the pre-termination restrictions of § 1.401(a)(4)–5(b).

(iv) *Special rules for section 401(k) and 401(m) plans.* Neither a section 401(k) plan nor a section 401(m) plan may be retroactively amended under this paragraph (g) to extend eligibility under the plan to an employee for purposes of § 1.410(b)–3(a)(2)(i) or 1.401(k)–1(b)(1)(i).

(3) *Conditions for retroactive correction*—(i) *In general.* A retroactive amendment is not permitted under this paragraph (g) unless it satisfies each of the requirements of paragraph (g)(3)(ii) through (v) of this section.

(ii) *Benefits not reduced.* The retroactive amendment may not result in a reduction of an employee's benefits (including any benefit, right, or feature) determined based on the terms of the plan in effect immediately before the amendment.

(iii) *Amendment effective for all purposes.* For purposes of determining an employee's rights and benefits under the plan, the retroactive amendment must be effective as if the amendment had been made on the first day of the preceding plan year. Thus, increases in an employee's allocations or accruals, along with the associated benefits, rights, and features, must be increased to the level at which they would have been had the amendment been in effect for the entire preceding plan year.

(iv) *Time when amendment must be adopted and put into effect*—(A) *General rule.* Any retroactive amendment intended to apply to the preceding plan year must be adopted and implemented before the 15th day of the 10th month after the close of the plan year in order to be taken into account for the preceding plan year.

(B) *Determination letter requested by employer or plan administrator.* If, on or before the end of the period set forth in paragraph (g)(3)(iv)(A) of this section, the employer or plan administrator files a request pursuant to § 601.201(o) of this

chapter (Statement of Procedural Rules) for a determination letter on the amendment, the initial or continuing qualification of the plan, or the trust that is part of the plan, the period set forth in paragraph (g)(3)(iv)(A) of this section is extended in the same manner as provided for an extension of the remedial amendment period under § 1.401(b)–1(d)(3).

(v) *Retroactive amendment must separately satisfy sections 401(a)(4) and 410(b).*—(A) *General rule.* Except as provided in paragraph (g)(3)(v)(B) of this section, the additional allocations or accruals resulting from the retroactive amendment of a plan must separately satisfy section 401(a)(4) for the preceding plan year and must benefit a group of employees that separately satisfies section 410(b) for the preceding plan year (determined by applying the same rules as are applied in determining whether a component plan separately satisfies section 410(b) under § 1.401(a)(4)–9(c)(1)(i)). Thus, for example, in applying the rules of this paragraph (g)(3)(v), an employer may not aggregate the additional accruals or allocations resulting from the retroactive amendment with the other accruals or allocations already provided under the terms of the plan as in effect during the plan year without regard to the retroactive amendment.

(B) *Retroactive amendment to conform to safe harbor.* The requirements of paragraph (g)(3)(v)(A) of this section need not be met if the retroactive amendment is for purposes of conforming the plan to one of the safe harbors in § 1.401(a)(4)–2(b) or 1.401(a)(4)–3(b) (including for purposes of applying the requirements of those safe harbors under the optional testing methods in § 1.401(a)(4)–8(b)(3) or (c)(3)), or ensuring that the plan continues to meet one of those safe harbors.

(4) *Retroactive amendments affecting terminated nonvested employees.* A retroactive amendment is not taken into account in determining whether a plan satisfies section 401(a)(4) or 410(b) to the extent the amendment affects nonvested employees whose employment with the employer terminated on or before the close of the preceding year, and who therefore would not have received any economic benefit from the amendment if it had been made in the prior year.

(5) *Effect under other statutory requirements.* A retroactive amendment under this paragraph (g) is effective only for purposes of section 401(a). Thus, for example, the retroactive amendment is effective not only for purposes of sections 401(a)(4) and 410(b), but also for purposes of determining whether the plan satisfies sections 401(*l*) and 401(a)(26) for the preceding plan year. By contrast, the amendment is not given retroactive effect for purposes of section 404 (deductions for employer contributions) or section 412 (minimum funding standards).

(6) *Examples.* The following examples illustrate the rules in this paragraph (g):

Example 1. Employer U maintains a calendar year defined benefit plan that in 1994 is tested using the safe harbor for flat benefit plans in § 1.401(a)(4)–3(b)(4). In 1996, Employer U is concerned that the plan will not satisfy the demographic requirement in § 1.401(a)(4)–3(b)(4)(i)(c)(3) for the 1995 plan year because the average of the normal accrual rates for all NHCEs is less than 70 percent of the average of the normal accrual rates for all HCEs. Provided the retroactive amendment would otherwise satisfy this paragraph (g), Employer U may retroactively amend the plan to increase the number of NHCEs so that the amended plan satisfies the safe harbor for the 1995 plan year. The retroactive amendment need not satisfy paragraph (g)(3)(v)(A) of this section because Employer U is retroactively amending the plan to conform to a safe harbor in § 1.401(a)(4)–3(b). See paragraph (g)(3)(v)(B) of this section.

Example 2. Employer V maintains a calendar year defined contribution plan covering all the employees in Division M and Division N. Under the plan, only employees in Division M have the right to direct the investments in their account. For plan years prior to 1996, the plan met the current availability requirement of § 1.401(a)(4)–4(b) because the employees in Division M were a group of employees that satisfied the nondiscriminatory classification test of § 1.410(b)–4. Because of attrition in the employee population in Division M in 1996, the group of employees to whom the right to direct investments is available no longer meets the nondiscriminatory classification test of § 1.410(b)–4. Thus, the right to direct investments under the plan fails the current availability requirement of § 1.401(a)(4)–4(b) for 1996. In 1997, Employer U cannot retroactively amend the plan to make the right to direct investments available for 1996 to a group of employees that would satisfy the current availability requirement of § 1.401(a)(4)–4(b).

Example 3. The facts are the same as in *Example 2.* In 1997, Employer V may amend the plan to benefit the employees in Division O as well as Divisions M and N so that the plan will meet the minimum coverage requirements of section 410(b) for 1996. In increasing plan coverage, the right to direct investments may also be made available to the employees in Division O for 1996.

Example 4. Employer W maintains a defined benefit plan that covers all employees and that offsets an employee's benefit by the employee's projected primary insurance amount. The plan is not eligible to use the safe harbors under § 1.401(a)(4)–3(b) because the plan does not satisfy section 401(*l*). Under the plan, the accrual rates for all HCEs (determined under the general test of § 1.401(a)(4)–3(c)) for 1998 are less than 1.5 percent of average annual compensation, and the accrual rates for all NHCEs (determined under the general test of § 1.401(a)(4)–3(c)) for 1998 are two percent of average annual compensation. Employer W may not retroactively increase HCEs' benefits under the plan so that their accrual rates equal those of the NHCEs, because such a retroactive amendment would not separately satisfy sections 410(b) and 401(a)(4) if it were treated as a separate plan. This is the case even if, after taking the amendment into account, the plan would satisfy sections 410(b) and 401(a)(4) for the 1998 plan year.

Example 5. Employer X maintains two plans—Plan A and Plan B. Plan A satisfies the ratio percentage test of § 1.410(b)–2(b)(2), but Plan B does not. Thus, in order to satisfy section 410(b), Plan B must satisfy the average benefits test of § 1.410(b)–2(b)(3). The average benefit percentage of Plan B is 60 percent. Employer X may increase the accruals under either Plan A or Plan B so that the average benefit percentage meets the 70 percent requirement of the average benefits test.

Example 6. Employer Y maintains Plan C, which does not satisfy section 401(a)(4) in a plan year. Under the terms of paragraph (g)(2) of this section, Employer Y amends Plan C to increase the benefits of certain employees retroactively. In designing the amendment, Employer Y identifies those employees who have terminated without vested benefits during the period after the end of the prior plan year and before the adoption date of the amendment, and the amendment provides increases in benefits primarily to those employees. It would be inconsistent with the purpose of preventing discrimination in favor of HCEs for Plan C to treat the amendment as retroactively effective under this paragraph (g). See § 1.401(a)(4)–1(c)(2).

Example 7. Employer Z maintains both a section 401(k) plan and a section 401(m) plan that provides matching contributions at a rate of 50 percent with respect to elective contributions under the section 401(k) plan. In plan year 1995, the section 401(k) plan fails to satisfy the actual deferral percentage test of section 401(k)(3). In order to satisfy section 401(k)(3), Employer G makes corrective distributions to HCEs H1 through H10 of their excess contributions as provided under § 1.401(k)–1(f). The matching contributions that H1 through H10 had received on account of their excess contributions are not forfeited, however. Thus, the effective rate of matching contributions provided to H1 through H10 is increased as a result of the corrective distributions. See § 1.401(a)(4)–4(e)(3)(iii)(G). Since no NHCE in the section 401(m) plan is provided with an equivalent rate of matching contributions, the rate of matching contributions provided to H1 through H10 does not satisfy the nondiscriminatory availability requirement of § 1.401(a)(4)–4 in plan year 1995. This violation may not be corrected under this paragraph (g).

§ 1.401(a)(4)–12 Definitions.

Unless otherwise provided, the definitions in this section govern in applying the provisions of §§ 1.401(a)(4)–1 through 1.401(a)(4)–13.

Accumulation plan. "Accumulation plan" means a defined benefit plan under which the benefit of every employee for each plan year is separately determined, using plan year compensation (if benefits are determined as a percentage of compensation rather than as a dollar amount) separately calculated for the plan year, and each employee's total accrued benefit as of the end of a plan year is the sum of the separately determined benefit for that plan year and the total accrued benefit as of the end of the preceding plan year.

Acquired group of employees. "Acquired group of employees" means employees of a prior employer who become employed by the employer in a transaction between the employer and the prior employer that is a stock or asset acquisition, merger, or other similar transaction involving a change in the employer of the employees of a trade or business, plus employees hired by or transferred into the acquired trade or business on or before a date selected by the employer that is within the transition period defined in section 410(b)(6)(C)(ii). In addition, in the case of a transaction prior to the effective date of these regulations, the date by which employees must be hired by or transferred into the acquired trade or business in order to be included in the acquired group of employees may be any date prior to February 11, 1993, without regard to whether it is later than the end of the transition period defined in section 410(b)(6)(C)(ii).

Actuarial equivalent. An amount or benefit is the "actuarial equivalent" of, or is "actuarially equivalent" to, another amount or benefit at a given time if the actuarial present value of the two amounts of benefits (calculated using the same actuarial assumptions) at that time is the same.

Actuarial present value. "Actuarial present value" means the value as of a specified date of an amount or series of amounts due thereafter, where each amount is—

(1) Multiplied by the probability that the condition or conditions on which payment of the amount is contingent will be satisfied; and

(2) Discounted according to an assumed rate of interest to reflect the time value of money.

Ancillary benefit. "Ancillary benefit" is defined in § 1.401(a)(4)–4(e)(2).

Average annual compensation. "Average annual compensation" is defined in § 1.401(a)(4)–3(e)(2).

Base benefit percentage. "Base benefit percentage" is defined in § 1.401(l)–1(c)(3).

Benefit formula. "Benefit formula" means the formula a defined benefit plan applies to determine the accrued benefit (within the meaning of section 411(a)(7)(A)(i)) in the form of an annual benefit commencing at normal retirement age of an employee who continues in service until normal retirement age. Thus, for example, the benefit formula does not include the accrual method the plan applies (in conjunction with the benefit formula) to determine the accrued benefit of an employee who terminates employment before normal retirement age. For purposes of this definition, a change in plan provisions that applies only to contain employees who terminate within a limited period of time (e.g., an early retirement window benefit) is treated as a change in the plan's benefit formula for the employees to whom the change is potentially applicable during the period that the change is potentially applicable to them. The preceding sentence applies only to the extent that the change in plan provisions would result in a change in the benefit formula if it were permanent and applied without regard to when the employees' employment was terminated.

Benefit, right, or feature. "Benefit, right, or feature" means an optional form of benefit, an ancillary benefit, or an other right or feature within the meaning of § 1.401(a)(4)–4(e).

Contributory DB plan. "Contributory DB plan" means a defined benefit plan that includes employee contributions not allocated to separate accounts.

Defined benefit excess plan. "Defined benefit excess plan" is defined in § 1.401(l)–1(c)(16)(i).

Defined benefit plan. "Defined benefit plan" is defined in § 1.410(b)–9.

Defined contribution plan. "Defined contribution plan" is defined in § 1.410.(b)–9.

Determination date. "Determination date" is defined in § 1.401(a)(4)–8(b)(3)(iv)(A).

Employee. With respect to a plan for a given plan year, "employee" means an employee (within the meaning § 1.410.(b)–9) who benefits as an employee under the plan for the plan year (within the meaning of § 1.410.(b)–3(a)). An individual must be treated as an employee with respect to allocations under a defined contribution plan and with respect to increases in accrued benefits (within the meaning of section 411(a)(7)) under a defined benefit plan that are based on ongoing service or compensation (including imputed service or compensation) credits.

Employer. "Employer" is defined in § 1.410(b)–9.

ESOP. "ESOP" is denied in § 1.410(b)–9.

Excess benefit percentage. "Excess benefit percentage" is defined in § 1.401(*l*)–1(c)(14).

Former employee. With respect to a plan for a given plan year, "former employee" means a former employee (within the meaning of § 1.410(b)–9) who is not treated as excludable under § 1.410(b)–6(h), or an employee (within the meaning of § 1.410(b)–9) who benefits under the plan for the plan year (within the meaning of § 1.410(b)–3), except to the extent that the individual is treated as an employee with respect to the plan for the plan year under the definition of employee in this section.

Former HCE. "Former HCE" means a former employee who is a highly compensated former employee within the meaning of section 414(q)(9).

Former NHCE. "Former NHCE" means a former employee who is not a former HCE.

Fresh-start date. "Fresh-start date" is defined in § 1.401(a)(4)–13(c)(5)(iii).

Fresh-start group. "Fresh-start group" is defined in § 1.401(a)(4)–13(c)(5)(ii).

Gross benefit percentage. "Gross benefit percentage" is defined in § 1.401(*l*)–1(c)(18).

HCE. "HCE" means an employee who is a highly compensated employee within the meaning of section 414(q).

Integration level. "Integration level" is defined in § 1.401(*l*)–1(c)(20).

Measurement period. "Measurement period" is defined in § 1.401(a)(4)–3(d)(1)(iii).

NHCE. "NHCE" means an employee who is not a HCE.

Nonexcludable employee. "Nonexcludable employee" means an employee within the meaning of § 1.410(b)–9, other than an excludable employee with respect to the plan as determined under § 1.410(b)–6.

Normalize. With respect to a benefit payable to an employee in a particular form, "normalize" means to convert the benefit to an actuarially equivalent straight life annuity commencing at the employee's testing age. The actuarial assumptions used in normalizing a benefit must be reasonable and must be applied on a gender-neutral basis. A standard interest rate and a standard mortality table are among the assumptions considered reasonable for this purpose.

Offset plan. "Offset plan" is defined in § 1.401(l)–1(c)(24).

Optional form of benefit. "Optional form of benefit" is defined in § 1.401(a)(4)–4(e)(1).

Other right or feature. "Other right or feature" is defined in § 1.401(a)(4)–4(e)(3).

Plan. "Plan" means a plan within the meaning of § 1.410(b)–7(a) and (b), after application of the mandatory disaggregation rules of § 1.410(b)–7(c) and the permissive aggregation rules of § 1.410(b)–7(d).

Plan year. "Plan year" is defined in § 1.410(b)–9.

Plan year compensation—(1) *In general.* "Plan year compensation" means section 414(s) compensation for the plan year determined by measuring section 414(s) compensation during one of the periods described in paragraphs (2) through (4) of the definition. Whichever period is selected must be applied uniformly to determine the plan year compensation of every employee.

(2) *Plan year.* This period consists of the plan year.

(3) *Twelve-month period ending in the plan year.* This period consists of a specified 12-month period ending with or within the plan year, such as the calendar year or the period for determining benefit accruals described in § 1.401(a)(4)–3(f)(6).

(4) *Period of plan participation during the plan year.* This period consists of the portion of the plan year during which the employee is a participant in the plan. This period may be used to determine plan year compensation for the plan year in which participation begins, the plan year in which participation ends, or both. This period may be used to determine plan year compensation when substituted for average annual compensation § 1.401(a)(4)–3(e)(2)(ii)(A) only if the plan year is also the period for determining benefit accruals under the plan rather than another period as permitted under § 1.401(a)(4)–3(f)(6). Further, selection of this period must be made on a reasonably consistent basis from plan year to plan year in a manner that does not discriminate in favor of HCEs.

(5) *Special rule for new employees.* Notwithstanding the uniformity requirement of paragraph (1) of this definition, if employees' plan year compensation for a plan year is determined based on a 12-month period ending within the plan year under paragraph (3) of this definition, then the plan year compensation of any employees whose date of hire was less than 12 months before the end of that 12-month period must be determined uniformly based either on the plan year or on the employees' periods of participation during the plan year, as provided in paragraphs (2) and (4), respectively, of this definition.

QJSA. "QJSA" means a qualified joint and survivor annuity as defined in section 417(b).

QSUPP—(1) *In general.* "QSUPP" or "qualified social security supplement" means a social security supplement that meets each of the requirements in paragraphs (2) through (6) of this definition.

(2) *Accrual*—(i) *General rule.* The amount of the social security supplement payable at any age for which the employee is eligible for the social security supplement must be equal to the lesser of—

(A) The employee's old-age insurance benefit, unreduced on account of age, under title II of the Social Security Act; and

(B) The accrued social security supplement, determined under one of the methods in paragraph (2)(ii) through (iv) of this definition.

(ii) *Section 401(l) plans.* In the case of a section 401(*l*) plan that is a defined benefit excess plan, each employee's accrued social security supplement equals the employee's average annual compensation up to the integration level, multiplied by the disparity provided by the plan for the employee's years of service used in determining the employee's accrued benefit under the plan. In the case of a section 401(l) plan that is an offset plan, each employee's accrued social security supplement equals the dollar amount of the offset accrued for the employee under the plan.

(iii) *PIA Offset plan.* In the case of a PIA offset plan, each employee's accrued social security supplement equals the dollar amount of the offset accrued for the employee under the plan. For this purpose, a PIA offset plan is a plan that reduces an employee's benefit by an offset based on a stated percentage of the employee's primary insurance amount under the Social Security Act.

(iv) *Other plans.* In the case of any other plan, each employee's social security supplement accrues ratably over the period beginning with the later of the employee's commencement of participation in the plan or the effective date of the social security supplement and ending with the earliest age at which the social security supplement is payable to the employee. The effective date of the social security supplement is the later of the effective date of the amendment adding the social security supplement or the effective date of the amendment modifying an existing social security supplement to comply with the requirements of this definition. If, by the end of the first plan year to which these regulations apply, as set forth in § 1.401(a)(4)–13 (a) and (b), an amendment is made to a social security supplement in existence on September 19, 1991, the employer may treat the accrued portion of the social security supplement, as determined under the plan without regard to amendments made after September 19, 1991, as included in the employee's accrued social security supplement, provided that the remainder of the social security supplement is accrued under the otherwise-applicable method.

(3) *Vesting.* The plan must provide that an employee's right to the accrued social security supplement becomes nonforfeitable within the meaning of section 411 as if it were an early retirement benefit.

(4) *Eligibility.* The plan must impose the same eligibility conditions on receipt of the social security supplement as on receipt of the early retirement benefit in conjunction with which the social security supplement is payable. Furthermore, if the service required for an employee to become eligible for the social security supplement exceeds 15 years, then the ratio percentage of the group of employees who actually satisfy the eligibility conditions on receipt of the QSUPP in the current plan year must equal or exceed the unsafe harbor percentage applicable to the plan under § 1.410(b)–4(c)(4)(ii).

(5) *QJSA.* At each age, the most valuable QSUPP commencing at that age must be payable in conjunction with the QJSA commencing at that age. In addition, the plan must provide that, in the case of social security supplement payable in conjunction with a QJSA, the social security supplement will be paid after the employee's death on the same terms as the QJSA, but in no event for a period longer than the period for which the social security supplement would have been paid to the employee had the employee not died. For example, if the QJSA is in the form of a joint annuity with a 50-percent survivor's benefit, the social security supplement must provide a 50-percent survivor's benefit. When section 417(c) requires the determination of a QJSA for purposes of determining a qualified pre-retirement survivor's annuity as defined in section 417(c) ("QPSA"), the social security supplement payable in conjunction with that QJSA must be paid in conjunction with the QPSA.

(6) *Protection.* The plan must specifically provide that the social security supplement is treated as an early retirement benefit that is protected under section 411(d)(6) (other than for purposes of sections 401(a)(11) and 417). Thus, the accrued social security supplement must continue to be payable notwithstanding subsequent amendment of the plan (including the plan's termination), and an employee

may meet the eligibility requirements for the social security supplement after plan termination.

Qualified plan. "Qualified plan" means a plan that satisfies section 401(a). For this purpose, a qualified plan includes an annuity plan described in section 403(a).

Rate group. "Rate group" is defined in § 1.401(a)(4)–2(c)(1) or is defined in § 1.401(a)(4)–3(c)(1).

Ratio percentage. "Ratio percentage" is defined in § 1.401(b)–9.

Section 401(a)(17) employee. "Section 401(a)(17) employee" is defined in § 1.401(a)(17)–1(e)(2)(ii).

Section 401(k) plan. "Section 401(k) plan" is defined in § 1.410(b)–9.

Section 401(l) plan. "Section 401(l) plan" is defined in § 1.401(b)–9.

Section 401(m) plan. "Section 401(m) plan" is defined in § 1.410(b)–9.

Section 414(s) compensation—(1) *General rule.* When used with reference to compensation for a plan year, 12-month period, or other specified period, "section 414(s) compensation" means compensation measured using an underlying definition that satisfies section 414(s) for the applicable plan year. Whether an underlying definition of compensation satisfies section 414(s) is determined on a year-by-year basis, based on the provisions of section 414(s) in effect for the applicable plan year and, if relevant, the employer's HCEs and NHCEs for that plan year. See 1.414(s)–1(i) for transition rules for plan years beginning before the effective date applicable to the plan under § 1.401(a)(4)–13 (a) or (b). For a plan year or 12-month period beginning before January 1, 1988, any underlying definition of compensation may be used to measure the amount of employees' compensation for purposes of this definition, provided that the definition was nondiscriminatory based on the facts and circumstances in existence for that plan year or for the plan year in which that 12-month period ends.

(2) *Determination period for section 414(s) nondiscrimination requirement*—(i) *General rule.* If an underlying definition of compensation must satisfy the nondiscrimination requirement in § 1.414(s)–1(d)(3) in order to satisfy section 414(s) for a plan year, any one of the following determination periods may be used to satisfy the nondiscrimination requirement—

(A) The plan year;

(B) The calendar year ending in the plan year; or

(C) The 12-month period ending in the plan year that is used to determine the underlying definition of compensation.

(ii) *Exception for partial plan year compensation.* Notwithstanding the general rule in paragraph (2)(i) of this definition, if the period for measuring the underlying compensation is the portion of the plan year during which each employee is a participant in the plan (as provided in paragraph (4) of the definition of plan year compensation in this section), that period must be used as the determination period.

(3) *Plans using permitted disparity.* In the case of a section 401(*l*) plan or a plan that imputes permitted disparity in accordance with § 1.401(a)(4)–7, an underlying definition of compensation is not section 414(s) compensation if the definition results in significant under-inclusion of compensation for employees.

Social security supplement. "Social security supplement" is defined in § 1.411(a)–7(c)(4)(ii).

Standard interest rate. "Standard interest rate" means an interest rate that is neither less than 7.5 percent nor greater than 8.5 percent, compounded annually. The Commissioner may, in revenue rulings, notices, and other guidance of general applicability, change the definition of standard interest rate.

Standard mortality table. "Standard mortality table" means one of the following tables: the UP–1984 Mortality Table (Unisex); the 1983 Group Annuity Mortality Table (1983 GAM) (Female); the 1983 Group Annuity Mortality Table (1983 GAM) (Male); the 1983 Individual Annuity Mortality Table (1983 IAM) (Female); the 1983 Individual Annuity Mortality Table (1983 IAM) (Male); the 1971 Group Annuity Mortality Table (1971 GAM) (Female); the 1971 Group Annuity Mortality Table (1971 GAM) (Male); the 1971 Individual Annuity Mortality Table (1971 IAM) (Female); or the 1971 Individual Annuity Mortality Table (1971 IAM) (Male). These standard mortality tables are available from the Society of Actuaries, 475 N. Martingale Road, Suite 800, Schaumberg, Illinois 60173. The Commissioner may, in revenue rulings, notices, and other guidance of general applicability, change the definition of standard mortality table. See § 601.601(d)(2)(ii)(*b*) of this Chapter.

Straight life annuity. "Straight life annuity" means an annuity payable in equal installments for the life of the employee that terminates upon the employee's death.

Testing age. With respect to an employee, "testing age" means the age determined for the employee under the following rules:

(1) If the plan provides the same uniform normal retirement age for all employees, the employee's testing age is the employee's normal retirement age under the plan.

(2) If a plan provides different uniform normal retirement ages for different employees or different groups of employees, the employee's testing age is the employee's latest normal retirement age under any uniform normal retirement age under the plan, regardless of whether that particular uniform normal retirement age actually applies to the employee under the plan.

(3) If the plan does not provide a uniform normal retirement age, the employee's testing age is 65.

(4) If an employee is beyond the testing age otherwise determined for the employee under paragraphs (1) through (3) of this definition, the employee's testing age is the employee's current age. The rule in the preceding sentence does not apply in the case of a defined benefit plan that fails to satisfy the requirements of § 1.401(a)(4)–3(f)(3)(i) (permitting certain increases in benefits that commence after normal retirement age to be disregarded).

Testing service. "Testing service" is defined in § 1.401(a)(4)–3(d)(1)(iv).

Uniform normal retirement age—(1) *General rule.* "Uniform normal retirement age" means a single normal retirement age under the plan that does not exceed the maximum age in paragraph (3) of this definition and that is the same for all of the employees in a given group.

(2) *Stated anniversary date*—(i) *General rule.* A group of employees does not fail to have a uniform normal retirement age merely because the plan provides that the normal retirement age of all employees in the group is the later of a stated age (not exceeding the maximum age in paragraph (3) of this definition) or a stated anniversary no later than the fifth anniversary of the time each employee commenced participation in the plan. For employees who commenced participation in the plan before the first plan year beginning on or after January 1, 1988, the stated anniversary date may be later than the anniversary described in the preceding sentence if it is no later than the earlier of the tenth anniversary of the date the employee commenced participation in the plan (or such earlier anniversary selected by the employer, if less than 10) or the fifth anniversary of the first day of the first plan year beginning on or after January 1, 1988.

(ii) *Use of service other than anniversary of commencement of participation.* In lieu of using a stated anniversary date as permitted under paragraph (2)(i) of this definition, a plan may use a stated number of years of

service measured on another basis, provided that the determination is made on a basis that satisfies section 411(a)(8) and that the stated number of years of service does not exceed the number of anniversaries permitted under paragraph (2)(i) of this definition. For example, a uniform normal retirement age could be based on the earlier of the fifth anniversary of the commencement of participation and the completion of five years of vesting service.

(3) *Maximum age.* The maximum age is generally 65. However, if all employees have the same social security retirement age (within the meaning of section 415(b)(8)), the maximum age is the employees' social security retirement age. Thus, for example, a component plan has a uniform normal retirement age of 67 if it defines normal retirement age as social security retirement age and all employees in the component plan have a social security retirement age of 67.

Year of service. "Year of service" means a year of service as defined in the plan for a specific purpose, including the method of crediting service for that purpose under the plan.

§ 1.401(a)(4)–13 Effective dates and fresh-start rules.

(a) *General effective dates*—(1) *In general.* Except as otherwise provided in this section, §§ 1.401(a)(4)–1 through 1.401(a)(4)–13 apply to plan years beginning on or after January 1, 1994.

(2) *Plans of tax-exempt organizations.* In the case of plans maintained by organizations exempt from income taxation under section 501(a), including plans subject to section 403(b)(12)(A)(i) (nonelective plans), §§ 1.401(a)(4)–1 through 1.401(a)(4)–13 apply to plan years beginning on or after January 1, 1996.

(3) *Compliance during transition period.* For plan years beginning before the effective date of these regulations, as set forth in paragraph (a) (1) and (2) of this section, and on or after the first day of the first plan year to which the amendments made to section 410(b) by section 1112(a) of the Tax Reform Act of 1986 ("TRA '86") apply, a plan must be operated in accordance with a reasonable, good faith interpretation of section 401(a)(4), taking into account pre-existing guidance and the amendments made by TRA '86 to related provisions of the Code (including, for example, sections 401(*l*), 401(a)(17), and 410(b)). Whether a plan is operated in accordance with a reasonable, good faith interpretation of section 401(a)(4) will generally be determined on the basis of all relevant facts and circumstances, including the extent to which an employer has resolved unclear issues in its favor. A plan will be deemed to be operated in accordance with a reasonable, good faith interpretation of section 401(a)(4) if it is operated in accordance with the terms of §§ 1.401(a)(4)–1 through 1.401(a)(4)–13.

(b) *Effective date for governmental plans.* In the case of governmental plans described in section 414(d), including plans subject to section 403(b)(12)(A)(i) (nonelective plans), §§ 1.401(a)(4)–1 through 1.401(a)(4)–13 apply to plan years beginning on or after the later of January 1, 1996, or 90 days after the opening of the first legislative session beginning on or after January 1, 1996, of the governing body with authority to amend the plan, if that body does not meet continuously. Such plans are deemed to satisfy section 401(a)(4) for plan years before that effective date. For purposes of this paragraph (b), the term "governing body with authority to amend the plan" means the legislature, board, commission, council, or other governing body with authority to amend the plan.

(c) *Fresh-start rules for defined benefit plans*—(1) *Introduction.* This paragraph (c) provides rules that must be satisfied in order to use the fresh-start testing options for defined benefit plans in § 1.401(a)(4)–3 (b)(6)(vii) and (d)(3)(iii), relating to the safe harbors and the general test, respectively. Those fresh-start options are designed to allow a plan to be tested without regard to benefits accrued before a selected fresh-start date. To the extent provided in paragraph (d) of this section, those options also may be used to disregard certain increases in benefits attributable to compensation increases after a fresh-start date. While this paragraph (c) generally requires a plan to be amended to freeze employees' accrued benefits as of a fresh-start date and to provide any additional accrued benefits after the fresh-start date solely in accordance with certain specified formulas, certain of these requirements do not apply to a plan that is tested under the general test of § 1.401(a)(4)–3(c). See § 1.401(a)(4)–3 (b)(6)(vii) and (d)(3)(iii).

(2) *General rule.* A defined benefit plan satisfies this paragraph (c) if—

(i) Accrued benefits of employees in the fresh-start group are frozen as of the fresh-start date in accordance with paragraph (c)(3) of this section;

(ii) Accrued benefits after the fresh-start date for employees in the fresh-start group are determined under one of the fresh-start formulas in paragraph (c)(4) of this section; and

(iii) Paragraph (c)(5) of this section is satisfied.

(3) *Definition of frozen*—(i) *General rule.* An employee's accrued benefit under a plan is frozen as of the fresh-start date if it is determined as if the employee terminated employment with the employer as of the fresh-start date (or the date the employee actually terminated employment with the employer, if earlier), and without regard to any amendment to the plan adopted after that date, other than amendments recognized as effective as of or before that date under section 401(b) or § 1.401(a)(4)–11(g). The assumption that an employee has terminated employment applies solely for purposes of this paragraph (c)(3). Thus, for example, the fresh start has no effect on the service taken into account for purposes of determining vesting and eligibility for benefits, rights, and features under the plan.

(ii) *Permitted compensation adjustments.* An employee's accrued benefit under a plan that satisfies paragraph (d) of this section does not fail to be frozen as of the fresh-start date merely because the plan makes the adjustments described in paragraph (d)(7) and (8) of this section with regard to the fresh-start date. In addition, if the frozen accrued benefit of an employee under the plan includes top-heavy minimum benefits, an employee's accrued benefit under a plan does not fail to be frozen as of the fresh-start date merely because the plan increases the frozen accrued benefit of each employee in the fresh-start group solely to the extent necessary to comply with the average compensation requirement of section 416(c)(1)(D)(i).

(iii) *Permitted changes in optional forms.* An employee's accrued benefit under a plan does not fail to be frozen as of the fresh-start date merely because the plan provides a new optional form of benefit with respect to the frozen accrued benefit, if—

(A) The optional form is provided with respect to each employee's entire accrued benefit (i.e., accrued both before and after the fresh-start date);

(B) The plan provided meaningful coverage as of the fresh-start date, as described in paragraph (d)(4) of this section; and

(C) The plan provides meaningful current benefit accruals as described in paragraph (d)(6) of this section.

(4) *Fresh-start formulas*—(i) *Formula without wear-away.* An employee's accrued benefit under the plan is equal to the sum of—

(A) The employee's frozen accrued benefit; and

(B) The employee's accrued benefit determined under the formula applicable to benefit accruals in the

current plan year ("current formula") as applied to the employee's years of service after the fresh-start date.

(ii) *Formula with wear-away.* An employee's accrued benefit under the plan is equal to the greater of—

(A) The employee's frozen accrued benefit; or

(B) The employee's accrued benefit determined under the current formula as applied to the employee's total years of service (before and after the fresh-start date) taken into account under the current formula.

(iii) *Formula with extended wear-away.* An employee's accrued benefit under the plan is equal to the greater of—

(A) The amount determined under paragraph (c)(4)(i) of this section; or

(B) The amount determined under paragraph (c)(4)(ii)(B) of this section.

(5) *Rules of application*—(i) *Consistency requirement.* This paragraph (c)(5) is not satisfied unless the fresh-start rules in this paragraph (c) (and paragraph (d) of this section, if applicable) are applied consistently to all employees in the fresh-start group. Thus, for example, the same fresh-start date and fresh-start formula (within the meaning of paragraph (c)(4) of this section) must apply to all employees in the fresh-start group. Similarly, if a plan makes a fresh start for all employees with accrued benefits on the fresh-start date and, for a later plan year, is aggregated for purposes of section 401(a)(4) with another plan that did not make the same fresh start, the aggregated plan must make a new fresh start in order to use the fresh-start rules for that later plan year or any subsequent plan year.

(ii) *Definition of fresh-start group.* Generally, the fresh-start group with respect to a fresh start consists of all employees who have accrued benefits as of the fresh-start date and have at least one hour of service with the employer after that date. However, a fresh-start group with respect to a fresh start may consist exclusively of all employees who have accrued benefits as of the fresh-start date, have at least one hour of service with the employer after that date, and are—

(A) Section 401(a)(17) employees; or

(B) Members of an acquired group of employees (provided the fresh-start date is the date determined under paragraph (c)(5)(iii)(B) of this section).

(iii) *Definition of fresh-start date.* Generally, the fresh-start date is the last day of a plan year. However, a plan may use a fresh-start date other than the last day of the plan year if—

(A) The plan satisfied the safe harbor rules of § 1.401(a)(4)-3(b) for the period from the beginning of the plan year through the fresh-start date; or

(B) The fresh-start group is an acquired group of employees, and the fresh-start date is the latest date of hire or transfer into an acquired trade or business selected by the employer for any employees to be included in the acquired group of employees.

(6) *Examples.* The following examples illustrate the rules in this paragraph (c):

Example 1. (a) Employer X maintains a defined benefit plan with a calendar plan year. The plan formula provides an employee with a normal retirement benefit at age 65 of one percent of average annual compensation up to covered compensation, multiplied by the employee's years of service for Employer X, plus 1.5 percent of average annual compensation in excess of covered compensation, multiplied by the employee's years of service for Employer X up to 40.

(b) For plan years beginning after 1994, Employer X amends the plan formula to provide a normal retirement benefit of 0.75 percent of average annual compensation up to covered compensation multiplied by the employee's total years of service for Employer X up to 35, plus 1.4 percent of average annual compensation in excess of covered compensation multiplied by the employee's years of service for Employer X up to 35. For plan years after 1994, each employee's accrued benefit is determined under the fresh-start formula in paragraph (c)(4)(iii) of this section (formula with extended wear-away), using December 31, 1994, as the fresh-start date.

(c) As of December 31, 1994, Employee M has 10 years of service for Employer X, has average annual compensation of $38,000, and has covered compensation of $30,000. Employee M's accrued benefit as of December 31, 1994, is therefore $4,200 ((1 percent×$30,000×10 years)+(1.5 percent×$8,000×10 years)). As of December 31, 1995, Employee M has 11 years of service for Employer X, has average annual compensation of $40,000, and has covered compensation of $32,000. Employee M's accrued benefit as of December 31, 1995, is $4,552, the greater of—

(1) $4,552, the sum of Employee M's accrued benefit frozen as of December 31, 1994, ($4,200) and the amended formula applied to Employee M's years of service after 1994 ((0.75 percent×$32,000×1 year)+(1.4 percent×$8,000×1 year), or $352); or

(2) $3,872, the amended formula applied to Employee M's total years of service ((0.75 percent×$32,000×11years)+(1.4 percent×$8,000×11 years)).

Example 2. (a) Employer Y maintains a defined benefit plan, Plan A, that has a calendar plan year. For the 1995 plan year, Plan A satisfies the requirements for a safe harbor plan in § 1.401(a)(4)–3(b). Employer Y selects a date in 1995 for all the employees, freezes the employees' accrued benefits as of that date under the rules of paragraph (c)(3) of this section, and, in accordance with the rules of this paragraph (c), amends Plan A to determine benefits for all employees after that date using the formula with wear-away described in paragraph (c)(4)(ii) of this section. The new benefit formula would satisfy the requirements for a safe harbor plan in § 1.401(a)(4)–3(b) if all accrued benefits were determined under it.

(b) Because Plan A satisfied the requirements for a safe harbor plan for the period from the beginning of the plan year through the selected date, paragraph (c)(5)(iii)(A) of this section permits the selected date to be a fresh-start date, even if it is not the last day of the plan year. Thus, Plan A satisfies the requirements in this paragraph (c) for a fresh start as of the fresh-start date.

(c) Under § 1.401(a)(4)–3(b)(6)(vii), a plan does not fail to satisfy the requirements of § 1.40(a)(4)–3(b), merely because of benefits accrued under a different formula prior to a fresh-start date. Thus, Plan A still satisfies the safe harbor requirements of § 1.401(a)(4)–3(b) after the amendment to the benefit formula. Because Plan A satisfied the requirements for a safe harbor plan for the period from the beginning of the plan year, taking the amendment into account, Employer Y may select any date within the plan year (which may be the same date as the first fresh-start date) and apply the fresh-start rules in this paragraph (c) a second time as of that date.

(d) *Compensation adjustments to frozen accrued benefits*—(1) *Introduction.* In addition to the fresh-start rules in paragraph (c) of this section, this paragraph (d) sets forth requirements that must be satisfied in order for a plan to disregard increases in benefits accrued as of a fresh-start date that are attributable to increases in employees' compensation after the fresh-start date.

(2) *In general.* In the case of a defined benefit plan that is tested under the safe harbors in § 1.401(a)(4)–3(b) or § 1.401(a)(4)–8(c)(3), an employee's adjusted accrued benefit (determined under the rules in paragraph (d)(8) of this section) may be substituted for the employee's frozen accrued benefit in applying the formulas in paragraph (c)(4) of this section (or paragraph (f)(2) of this section, if applicable) if paragraphs (d)(3) through (d)(7) of this section are satisfied. Thus, for example, in determining whether such a plan satisfies § 1.401(a)(4)–3(b), any compensation adjustments to the employee's frozen accrued benefit described in paragraph (d)(8) of this section are disregarded. Similarly, in the case of a defined benefit plan tested under the general test in § 1.401(a)(4)–3(c), the compensation adjustments described in paragraph (d)(8) of this section may be disregarded under the rules of § 1.401(a)(4)–3(d)(3)(iii) if paragraphs (d)(3) through (d)(7) of this section are satisfied. Of course, any increases in accrued benefits exceeding these adjustments must be taken into

account under the general test, and a plan providing such excess increases generally will fail to satisfy the safe harbor requirements of § 1.401(a)(4)–3(b). Where paragraphs (d)(3) through (d)(7) of this section are satisfied with respect to a plan as of the fresh-start date, but one or more of those paragraphs fail to be satisfied for a later plan year, further compensation adjustments described in paragraph (d)(8) of this section may not be disregarded in testing the plan under § 1.401(a)(4)–3.

(3) *Plan requirements*—(i) *Pre-fresh-start date.* As of the fresh-start date, the plan must have contained a benefit formula under which benefits of each employee in the fresh-start group that are accrued as of the fresh-start date and are attributable to service before the fresh-start date would be affected by the employee's compensation after the fresh-start date. A plan satisfies this requirement, for example, if it based benefits on an employee's highest average pay over a fixed period of years or on an a employee's average pay over the employee's entire career with the employer. A plan does not satisfy this paragraph (d)(3)(i) if the Commissioner determines, based on all of the relevant facts and circumstances, that the plan provision described in the first sentence of this paragraph (d)(3) was added primarily in order to provide additional benefits to HCEs that are disregarded under the special testing rules described in this paragraph (d).

(ii) *Post-fresh-start date.* The plan by its terms must provide that the accrued benefits of each employee in the fresh-start group after the fresh-start date be at least equal to the employee's adjusted accrued benefit (i.e., the frozen accrued benefit as of the fresh-start date, adjusted as provided under paragraph (d)(7) of this section, plus the compensation adjustments described in paragraph (d)(8) of this section).

(4) *Meaningful coverage as of fresh-start date.* The plan must provide meaningful coverage as of the fresh-start date. A plan provided meaningful coverage as of the fresh-start date if the group of employees with accrued benefits under the plan as of the fresh-start date satisfied the minimum coverage requirements of section 410(b) as in effect on that date (determined without regard to section 410(b)(6)(C). In order to satisfy the requirement in the preceding sentence, an employer may amend the plan to grant past service credit under the formula in effect as of the fresh-start date to NHCEs, if the amount of past service granted them is reasonably comparable, on average, to the amount of past service HCEs have under the plan. Any benefit increase that results from the grant of past service credit to a NHCE under this paragraph (d)(4) is included in the employee's frozen accrued benefit.

(5) *Meaningful ongoing coverage*—(i) *General rule.* The fresh-start group must have satisfied the minimum coverage requirements of section 410(b) for all plan years from the first plan year beginning after the fresh-start date through the current plan year. Thus, if a fresh-start group fails to satisfy the minimum coverage requirements of section 410(b) for any plan year, this paragraph (d)(5) is not satisfied for that plan year or any subsequent plan year; however, such a failure is not taken into account in determining whether this paragraph (d)(5) is satisfied for any previous plan year.

(ii) *Alternative rules.* Notwithstanding paragraph (d)(5)(i) of this section, a fresh-start group is deemed to satisfy this paragraph (d)(5) for all plan years following the fresh-start date if any one of the following requirements is satisfied.

(A) *Section 410(b) coverage for first five years beginning after the fresh-start date.* The fresh-start group must have satisfied the minimum coverage requirements of section 410(b) for the first five plan years beginning after the fresh-start date.

(B) *Ratio percentage coverage as of fresh-start date.* The fresh-start group must have satisfied the ratio percentage test of § 1.410(b)–2(b)(2) as of the fresh-start date.

(C) *Fresh start for acquired group of employees.* The fresh-start group must consist of an acquired group of employees that satisfied the minimum coverage requirements of section 410(b) (determined without regard to section 410(b)(6)(C)) as of the fresh-start date.

(D) *Fresh start before applicable effective date.* The fresh-start date with respect to the fresh-start group must have been on or before the effective date applicable to the plan under paragraph (a) or (b) of this section.

(6) *Meaningful current benefit accruals.* The benefit formula and accrual method under the plan that apply to the fresh-start group must provide benefit accruals in the current plan year (other than increases in benefits accrued as of the fresh-start date) at a rate that is meaningful in comparison to the rate at which benefits accrued for the fresh-start group in plan years beginning before the fresh-start date. Whether this requirement is satisfied with respect to a fresh-start group that is an acquired group of employees may be determined taking into account the rate at which benefits are provided to other employees in the plan.

(7) *Minimum benefit adjustment*—(i) *In general.* In the case of a section 401(*l*) plan or a plan that imputes disparity under § 1.401(a)(4)–7, the plan must make the minimum benefit adjustment described in paragraph (d)(7) (ii) or (iii) of this section.

(ii) *Excess or offset plans.* In the case of a plan that is a defined benefit excess plan as of the fresh-start date, each employee's frozen accrued benefit is adjusted so that the base benefit percentage is not less than 50 percent of the excess benefit percentage. In the case of a plan that is a PIA offset plan (as defined in paragraph (2)(iii) of the definition of QSUPP in § 1.401(a)(4)–12) as of the fresh-start date, each employees' offset as applied to determine the frozen accrued benefit is adjusted so that it does not exceed 50 percent of the benefit determined without applying the offset.

(iii) *Other plans.* In the case of a plan that is not described in paragraph (d)(7)(ii) of this section, each employee's frozen accrued benefit is adjusted in a manner that is economically equivalent to the adjustment required under that paragraph, taking into account the plan's benefit formula, accrual rate, and relevant employee factors, such as period of service.

(8) *Adjusted accrued benefit*—(i) *General rule.* The term "adjusted accrued benefit" means an employee's frozen accrued benefit that is adjusted as provided in paragraph (d)(7) of this section and then multiplied by a fraction (not less than one), the numerator of which is the employee's compensation for the current plan year and the denominator of which is the employee's compensation as of the fresh-start date determined under the same definition. For purposes of this adjustment, the compensation definition must be either the same compensation definition and formula used to determine the frozen accrued benefit or average annual compensation (without regard to § 1.401(a)(4)–3(e)(2)(ii)(A) (use of plan year compensation)).

(ii) *Alternative formula for pre-effective-date fresh starts.* In the case of a fresh-start date before the effective date that applies to the plan under paragraph (a) or (b) of this section, the adjusted accrued benefit may be determined by multiplying the frozen accrued benefit by a fraction (not less than one) determined under this paragraph (d)(8)(ii). The numerator of the fraction is the employee's average annual compensation for the current plan year. The denominator of the fraction is the employee's

"reconstructed average annual compensation" as of the fresh-start date. An employee's reconstructed average annual compensation is determined by—

(A) Selecting a single plan year beginning after the fresh-start date but beginning not later than the last day of the first plan year to which these regulations apply under paragraph (a) or (b) of this section;

(B) Determining the employee's average annual compensation for the selected plan year under the same method used to determine the employee's average annual compensation for the current plan year under this paragraph (d)(8)(ii); and

(C) Multiplying the employee's average annual compensation for the selected plan year by a fraction, the numerator of which is the employee's compensation as of the fresh-start date determined under the same compensation definition and formula used to determine the employee's frozen accrued benefit and the denominator of which is the employee's compensation for the selected plan year determined under the compensation definition and formula used to determine the employee's frozen accrued benefit.

(iii) *Effect of section 401(a)(17).* In determining the numerators and the denominators of the fractions described in this paragraph (d)(8), the annual compensation limit under section 401(a)(17) generally applies. See, however, § 1.401(a)(17)–1(e)(4) for special rules applicable to section 401(a)(17) employees.

(iv) *Option to make less than the full permitted adjustment.* A plan may limit the increase in an employee's frozen accrued benefit for the current and all future years to a percentage (not more than 100 percent) of the increase otherwise provided under this paragraph (d)(8). Furthermore, the plan may, at any time, terminate all future adjustments permitted under this paragraph (d).

(9) *Example.* The following example illustrates the rules of this paragraph (d).

Example. (a) Employer X maintains a defined benefit plan that is an excess plan with a calendar plan year. For plan years before 1989, the plan is integrated with benefits provided under the Social Security Act, providing each employee with a normal retirement benefit equal to one percent of the employee's average annual compensation in excess of the employee's covered compensation, multiplied by the employee's years of service for Employer X. The benefit formula thus provides no benefit with respect to average annual compensation up to covered compensation.

(b) As of December 31, 1988, Employee M has 10 years of service for Employer X and has covered compensation of $25,000 and average annual compensation of $20,000. Employee M's average annual compensation has never exceeded $20,000. Therefore, as of December 31, 1988, Employee M's accrued benefit under the plan is zero.

(c) Effective with the 1989 plan year, the plan is amended to provide each employee with a normal retirement benefit of 0.6 percent of average annual compensation up to covered compensation plus 1.2 percent of average annual compensation in excess of covered compensation, multiplied by the employee's years of service up to 35. The plan also provides that, for plan years after 1988, each employee's accrued benefit is determined under the formula in paragraph (c)(4)(i) of this section (formula without wear-away) and, in applying the fresh-start formula, each employee's frozen accrued benefit under paragraph (c)(4)(i) of this section will be adjusted under this paragraph (d), using the same compensation definition and formula used to determine the frozen accrued benefit under paragraph (d)(8)(i) of this section.

(d) The plan uses the permitted disparity of section 401(*l*) and thus must also make the minimum benefit adjustment under paragraph (d)(7) of this section. Because the excess benefit percentage under the plan for years before 1989 was one percent, the plan must provide a base benefit percentage for those years of at least 0.5 percent. After the minimum benefit adjustment, Employee M's accrued benefit as of December 31, 1988, is $1,000 (0.5 percent × $20,000 × 10 years).

(e) As of December 31, 1992, Employee M has 14 years of service and has covered compensation of $30,000 and average annual compensation of $35,000. Employee M's adjusted accrued benefit as of December 31, 1992, is $1,750 ($1,000 × $35,000/$20,000), and Employee M's accrued benefit as of December 31, 1992, is $2,710 (the sum of $1,750 plus $960 ((0.6 percent × $30,000 × 4 years) plus (1.2 percent × $5,000 × 4 years))).

(e) *Determination of initial theoretical reserve for target benefit plans)*—(1) *General rule.* In the case of a target benefit plan the stated benefit formula under which takes into account service for years in which the plan did not satisfy § 1.401(a)(4)–8(b)(3), as permitted under § 1.401(a)(4)–8(b)(3)(vii), the theoretical reserve as of the determination date for the last plan year beginning before the first day of the first plan satisfies § 1.401(a)(4)–8(b)(3) of an employee who was a participant in the plan on that determination date, is determined as follows:

(i) Determine the actuarial present value, as of that determination date, of the stated benefit that the employee is projected to have at the employee's normal retirement age, using the actuarial assumptions, the provisions of the plan, and the employee's compensation as of that determination date. For an employee who attained age equals or exceeds the employee's normal retirement age, determine the actuarial present value of the employee's stated benefit at the employee's current age, but using an immediate straight life annuity factor for an employee whose attained age equals the employee's normal retirement age.

(ii) Calculate the actuarial present value of future required employer contributions (without regard to limitations under section 415 or additional contributions described in § 1.40(a)(4)–8(b)(3)(v)) as of that determination date (i.e., the actuarial present value of the level contributions due for each plan year through the end of the plan year in which the employee attains normal retirement age). This calculation is made assuming that the required contribution in each future year will be equal to the required contribution for the plan year that includes that determination date, and applying the interest rate that was used in determining that required contribution.

(iii) Determine the excess, if any, of the amount determined in paragraph (e)(1)(i) of this section over the amount determined in paragraph (e)(1)(ii) of this section. This excess is the employee's theoretical reserve on that determination date.

(2) *Example.* The following example illustrates the determination of an employee's theoretical reserve.

Example. (a) A target benefit plan was adopted and in effect before September 9, 1991, and satisfied the requirements of Rev. Rul. 76–464, 1976–2 C.B. 115, with respect to all years credited under the stated benefit formula through 1993. The plan provides a stated benefit equal to 40 percent of compensation, payable annually as a straight life annuity beginning at normal retirement age. Normal retirement age under the plan is 65. The stated interest rate under the plan is six percent. The determination date for required contributions under the plan is the last day of the plan year. Employee M is 38 years old on the determination date for the 1993 plan year, has participated in the plan for five years, and has compensation equal to $60,000 in 1993. The amount of employer contribution to Employee M's account for 1993 was $2,468.

(b) Under these facts, Employee M's theoretical reserve is equal to $13,909, calculated as follows:

(1) The actuarial present value of Employee M's stated benefit is calculated using the actuarial assumptions, provisions of the plan and Employee M's compensation as of the determination date for the 1993 plan year. This amount is equal to $46,512, Employee M's stated benefit of $24,000 ($60,000 multiplied by 40 percent), multiplied by 1.938, the actuarial present value factor applicable to a participant who is 38 years old using a stated interest rate of six percent.

(2) The actuarial present value of future employer contributions is calculated assuming that the required contribution in each future year will be equal to the required contribution for the 1993 plan year and assuming the same interest rate as was used in determining that contribution. This amount is equal to $32,603, which is equal to the amount of the level annual employer contribution ($2,468) multiplied by a factor of 13.2105 (the temporary annuity factor for a period of 27 years, assuming the six percent interest rate that was used to determine the required employer contribution).

(3) Employee M's theoretical reserve is $13,909, the excess of the amount determined in paragraph (b)(2) of this *Example* over the amount determined in paragraph (b)(3) of this *Example*.

* * * * *

Shirley D. Peterson,

Commissioner of Internal Revenue.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Indiana Regulatory Program Amendment

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing receipt of a proposed amendment submitted by Indiana as a modification to the State's regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA).

The amendment (Program Amendment 92–8) submitted consists of proposed changes to the Indiana Surface Mining Rules concerning ownership and control. The amendment would define what constitutes ownership and control of a surface mining operation; establish actions to be taken to identify and correct improvidently issued permits; and resolve outstanding violations. The amendment is intended to revise the Indiana program to be consistent with the corresponding Federal regulations.

This notice sets forth the times and locations that the Indiana program and the proposed amendment to that program will be available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed for a public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on February 11, 1993; if requested, a public hearing on the proposed amendment is scheduled for 1 p.m. on February 8, 1993; and, requests to present oral testimony at the hearing must be received on or before 4 p.m. on a January 27, 1993.

ADDRESSES: Written comments and requests to testify at the hearing should be directed to Mr. Roger W. Calhoun, Director, Indianapolis Field Office, at the address listed below. If a hearing is requested, it will be held at the same address.

Copies of the Indiana program, the amendment, a listing of any scheduled public meetings, and all written comments received in response to this notice will be available for public review at the following locations, during normal business hours, Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Indianapolis Field Office, Minton-Capehart Federal Building, 575 North Pennsylvania Street, room 301, Indianapolis, IN 46204. Telephone: (317) 226–6166.

Indiana Department of Natural Resources, 402 West Washington Street, room 295, Indianapolis, IN 46204. Telephone: (317) 232–1547.

Each requester may receive, free of charge, one copy of the proposed amendment by contacting the OSM Indianapolis Field Office.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Telephone (317) 226–6166.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982, **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.10, 914.15, and 914.16.

II. Discussion of the Proposed Amendment

By letter dated May 11, 1989 (Administrative Record No. IND–0644), OSM informed Indiana of changes to the Federal regulations concerning ownership and control which may necessitate changes in the Indiana program.

By letter dated May 11, 1992, (Administrative Record No. IND–1080), the Indiana Department of Natural Resources (IDNR) submitted a proposed amendment to the Indiana program at 310 Indiana Administrative Code (IAC) 12–0.5, 12–3, and 12–6.

By letter dated August 26, 1992, OSM requested that Indiana correct and/or clarify certain provisions in the proposed amendment (Administrative Record No. IND–1137).

By letter dated November 13, 1992, Indiana submitted a revised amendment (Program Amendment 92–8) and requested that the amendment submitted on May 11, 1992 (Program Amendment 92–3), be withdrawn (Administrative Record No. IND–1167). OSM prepared a National Notice of Withdrawal on November 18, 1992.

The proposed amendment includes changes to the following Indiana rules:

Rule Number and Subject (Intended Action):	
310 IAC 12–0.5–72.5.	Definition of "MSHA." (New).
310 IAC 12–0.5–80.5.	Definition of "owned or controlled". (New).
310 IAC 12–3–19.	(Repeal).
310 IAC 12–3–19.1.	Surface mining permit applications; identification of interests. (Replace; new).
310 IAC 12–3–20.	Surface mining permit applications; compliance information. (Amend).
310 IAC 12–3–111.	Review, public participation, and approval or disapproval of permit applications; permit terms and conditions; review of permit applications. (Amend).
310 IAC 12–3–112.	Review, public participation, and approval or disapproval of permit applications; permit terms and conditions; permit approval or denial. (Amend).
310 IAC 12–3–119.5.	Administrative and judicial review of improvidently issued permits; general procedures. (New).
310 IAC 12–3–119.6.	Administrative and judicial review of decisions by the director on permit applications; judicial review; improvidently issued permits; rescission procedures. (New).
310 IAC 12–6–5	State enforcement; cessation orders. (Amend).

The full text of the proposed program amendment submitted by Indiana is available for public inspection at the addresses listed above. The Director now seeks public comment on whether the proposed amendment is no less effective than the Federal regulations. If approved, the amendment will become part of the Indiana program.

III. Public Comment Procedures

In accordance with provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by Indiana satisfies the requirements of 30 CFR 732.15 for the approval of State program amendments. If the amendment is deemed adequate, it will become part of the Indiana program.

Written Comments

Written comments should be specific, pertain only to issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under "DATES" or at locations other than the Indianapolis Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "FOR FURTHER INFORMATION CONTACT" by the close of business on January 27, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons schedule to comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons who desire to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the Indianapolis Field Office by contacting the person listed under "FOR FURTHER INFORMATION CONTACT." All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed above under "ADDRESSES". A summary of the meeting will be included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.13 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(c) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 25, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 93–592 Filed 1–11–93; 8:45 am]

BILLING CODE 4310–05–M

FEDERAL COMMUNICATIONS COMMISSIONS

47 CFR Parts 1, 73, 76 AND 100

[MM Docket No. 92–261, FCC 92–539]

Revision of Broadcast and Cable Television EEO Rules and Policies

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This Notice of Proposed Rule Making in MM Docket No. 92–261 seeks comment on proposed new rules and amendments to existing broadcast and cable EEO rules as mandated by the equal employment opportunity (EEO) provisions of section 22 of the Cable Television Consumer Protection and Competition Act of 1992. Specifically, the Act requires a mid-term review of broadcast television stations as well as the collection of more specific employment data from cable operators, expands the number of job categories from nine to 15, and includes within the scope of these rules DBS and MMDS systems. The intended effect of this

notice of proposed rule making is to implement the equal employment opportunity provisions of the Cable Television Consumer Protection and Competition Act of 1992.

DATES: Initial comments due February 16, 1993; reply comments due March 4, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Lisa M. Higginbotham, Mass Media Bureau, Enforcement Division. (202) 632–7069.

SUPPLEMENTARY INFORMATION: The following collection of information contained in these proposed rules has been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act. Copies of the submission may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1990 M Street, NW, suite 640, Washington, DC 20036. Persons wishing to comment on this information should direct their comments to Jonas Neihardt, (202) 395–4814, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503. A copy of any comments should also be sent to the Federal Communications Commission, Office of Managing Director, Washington, DC 20554. For further information contact Judy Boley, Federal Communications Commission, (202) 632–7513.

OMB Number: 3060–0095
Title: Annual Employment Report—Cable Television
Form: FCC 395–A
Action: Revised Collection
Respondents: Businesses or other for-profit, small businesses or organizations
Frequency of Response: Annually
Estimated Annual Response: 2,450 cable units/MMDS/DBS file complete FCC 395–A, 2.5 hours per response; 405 cable units/MMDS/DBS file one-time certification, 0.25 hours; 490 cable units/MMDS/DBS complete supplemental investigation sheet, 2.5 hours; 7,451 hours total.
Needs and Uses: FCC 395–A is a data collection device used to assess a cable entity's equal employment policies and practices in accordance with public and federal objectives.

This is a synopsis of the Commission's notice of proposed rule making in MM Docket No. 92–261, adopted December 10, 1992, and released January 5, 1993.

The complete text of this notice of proposed rule making, which was adopted in MM Docket No. 92–261, is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street, NW, Washington, DC, and also may be purchased from the Commission's copy contractor, Downtown Copy Center, at (202) 452–1422, 1990 M Street, NW., suite 640, Washington, DC 20036.

Synopsis of Notice of Proposed Rule Making

1. To implement the equal employment opportunity provisions of section 22 of the Cable Television Consumer Protection and Competition Act of 1992, the Commission adopted a notice of proposed rule making. The Commission sought comment on its initial view that the criteria to be used for the mid-term review should consist only of a statistical comparison of a television station's employment profile as reflected in the first two annual employment reports filed after grant of license renewal with the relevant labor force of the MSA or county in which the station is located. The Commission's internal processing guidelines would then be applied to the results of the comparison. As the Commission noted, the Act's language conceivably could be read to require a review of a station's EEO efforts. However, the Commission determined that the Conference Report, with its more specific language, should be followed.

2. The Commission sought comment on its proposal to conduct mid-term reviews approximately two and one half years following grant of renewal of license and to send the results of such review only to those licensees whose employment profiles evidenced a need for improvement. As the Commission observed, the Act's language is unclear as to who should receive a review letter. However, the Conference Report suggests that only licensees with deficient "employment practices" need to receive a letter.

3. The Commission sought comment on its tentative conclusion that an EEO program that failed to receive a deficiency letter would not be treated as being in compliance with the EEO Rule at renewal time merely because no mid-term letter was sent. The Commission noted that the Act was silent on the issue of what impact the mid-term review would have on subsequent renewal while the Conference Report suggested Congress' intent that the review should not be used as a sanction. The Commission concluded that because the mid-term review, under its proposal, would consist of an analysis that is only one aspect of the EEO efforts-based renewal evaluation, the mid-term review would not establish compliance with the EEO Rule at renewal time.

4. In accordance with the Act, the Commission proposed to amend the cable annual employment report (Form 395–A) to collect employment data for full and part-time employees separately as well as by job title. In addition, the Commission proposed to collect recruitment, promotion and employment information for the additional six new upper-level job categories. The Commission believed that its proposed amendment to its form would fulfill Congress' intent to provide an additional method of ensuring accuracy while improving the ability to monitor industry employment trends. Comment is sought on these proposals.

5. As the Commission explained, the Act adds the following six upper-level job categories: Corporate officers; general manager, chief engineer; comptroller; general sales manager; and production manager. Thus, cable operators are now required to report employment data for 15 job categories, including 10 upper-level job categories. In accordance with the Act's mandate, the Commission proposed to adopt rules defining the six new upper-level job categories "so as to ensure that only employees who are principal decisionmakers and who have supervisory authority are reported." The Commission sought comment on the proposed definitions as well as suggestions for any pre-existing sources for defining these new categories. In addition, the Commission proposed adopting its current definitions for the nine other job categories.

6. The Commission also sought comment on whether the Act requires it to provide statistical information as it currently does for the nine current job categories. In addition, it sought comment on its initial conclusion that Congress did not intend it to engage in a competency-based analysis which it currently does not employ.

7. The Commission noted that the Act increases the penalty for noncompliance with the cable EEO requirements from $220 to $500. Accordingly, the Commission stated that the higher forfeiture amounts would be applied to future cable EEO actions, as appropriate.

8. Finally, the Commission sought comment on its proposal to amend its rules to include "any multichannel video programming distributor" within the scope of the cable EEO rules. It proposed to adopt the Act's definition of this term which would require the Commission to apply its cable EEO regulations to DBS and MMDS systems.

Initial Regulatory Flexibility Analysis

As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected impact on small entities of the proposals suggested in the notice of proposed rule making. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the notice of proposed rule making, but they must have a separate and distinct heading designating them as responses to the Initial Regulatory Flexibility Analysis. The Secretary shall send a copy of the notice of proposed rule making, including the Initial Regulatory Flexibility Analysis to the Chief Counsel for Advocacy of the Small Business Administration in accordance with paragraph 603(a) of the Regulatory Flexibility Act, Public Law No. 96–354, 94 Stat. 1164, 5 U.S.C. 601, *et seq.* (1980).

I. Reason for action: This action is taken to implement the equal employment opportunity provisions of the Cable Television Consumer Protection and Competition Act of 1992.

II. Objectives: The legislation and this subsequent Commission action establish guidelines for the regulation of equal employment opportunity policy and practices in the cable and broadcast television industries. This proceeding is intended to institute a national policy to encourage employment opportunities for women and minorities and to ensure non-discrimination in the cable and broadcast television industries.

III. Legal basis: Action as proposed for this rule making is contained in section 4(i), (j) and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), (j) and 303 and section 22 of the Cable Television Consumer Protection and Competition Act of 1992, Pub. L. No. 102–385, 106 Stat. 1460 (1992).

IV. Reporting, recordkeeping and other compliance requirements: Cable entities will be required to submit additional documentation as part of the Commission's investigation responsibilities as mandated by the Cable Act. The documentation requirement will be new only for licensees and permitters of DBS, MMDS and other systems which fall within the Act's definition of "multichannel video programming distributor."

V. Federal rules which overlap, duplicate or conflict with this rule: None.

VI. Description, potential impact and number of small entities affected: In order to implement the equal employment opportunity provisions of the Cable Act of 1992, the Commission has proposed to modify some rules and add new rules. The Cable Act of 1992's definition of systems subject to the EEO provisions differs in some respect from our current requirements. If we adopt the Cable Act's definition of a cable system as we have proposed, we believe the following additional entities will be affected. Licensees and permittees of direct broadcast satellite systems (DBS) and multichannel, multipoint distribution service (MMDS) could now come under the scope of our cable EEO regulations.

VII. Any significant alternatives minimizing impact on small entities and consistent with stated objective. None.

List of Subjects

47 CFR Part 1

Reporting and recordkeeping requirements.

47 CFR Part 73

Television broadcasting.

47 CFR Part 76

Equal employment opportunity, Reporting and recordkeeping requirements.

47 CFR Part 100

Equal employment opportunity.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–614 Filed 1–11–93; 8:45 am]

BILLING CODE 6712–01–M

Notices

Federal Register
Vol. 58, No. 7
Tuesday, January 12, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

National Conservation Review Group; Meeting

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The National Conservation Review Group will meet to consider recommendations from State and County Conservation Review Groups with respect to the operational features of the Agricultural Conservation Program (ACP), the Emergency Conservation Program (ECP), the Forestry Incentive Program (FIP) and the Water Bank Program (WBP). Comments and suggestions will be received from the public concerning these conservation and environmental programs administered by the Agricultural Stabilization and Conservation Service (ASCS).

DATES: Meeting Date: February 17, 1993.

ADDRESSES: Meeting Location: The meeting is scheduled to be held in the Palladian Room of the OMNI Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Grady Bilberry, Chief, Conservation and Environmental Activities Branch, Conservation and Environmental Protection Division, ASCS, U.S. Department of Agriculture, P.O. Box 2415, room 4723, South Building, Washington, DC 20013–2415, 202–720–7333.

SUPPLEMENTARY INFORMATION: The National Conservation Review Group meeting is scheduled to be held from 9 a.m. to 1 p.m. on February 17, 1993, in the Palladian Room of the OMNI Shoreham Hotel, 2500 Calvert Street, NW.,Washington, DC. Meeting sessions will be open to the public.

The agenda will include consideration of State and County Review Group recommendations for changes in the administrative procedures and policy guidelines of the ACP, ECP, FIP, and WBP. An opportunity will be provided for the public to present comments at the meeting on these conservation and environmental programs administered by ASCS.

Because of time constraints and anticipated participation from interested individuals and groups, comments will be limited to not more than 5 minutes. Individuals or groups interested in making recommendations may also make them in writing and submit them to the Chief, Conservation and Environmental Activities Branch, Conservation and Environmental Protection Division, ASCS, U.S. Department of Agriculture, P.O. Box 2415, room 4723–S, Washington, DC 20013–2415. The meeting may also include discussion of current procedures, criteria, and guidelines relevant to the implementation of these programs.

Because of limited space, persons desiring to attend the meeting should call Mr. Grady Bilberry at 202–720–7333 to make reservations.

Signed at Washington, DC, on January 5, 1993.

John A. Stevenson,

Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 93–570 Filed 1–11–93; 8:45 am]

BILLING CODE 3410–05–M

Forest Service

Advisory Council Meeting; Allegheny Wild and Scenic River, Allegheny National Forest, Pennsylvania

AGENCY: Forest Service, USDA.

ACTION: Meeting notice.

SUMMARY: The Allegheny National Wild and Scenic River Advisory Councils will meet on January 27 at 7 p.m. at the Five Forks Restaurant, Tionesta Pennsylvania. This meeting will be a joint meeting of both the Northern and Southern Councils for the purpose of providing training and orientation for Advisory Council members. No other business will be conducted at this initial meeting of the councils.

The meeting is open to interested members of the public. A sign language interpreter will be provided if requested by January 20, 1993.

FOR FURTHER INFORMATION CONTRACT: Lionel Lemery, Wild and Scenic River Coordinator, Allegheny National Forest, 222 Liberty Street, Warren, Pennsylvania 16365, 814/723–5150 (voice).

Dated: January 6, 1993.

Ernest F. Rozelle,

Acting Forest Supervisor.

[FR Doc. 93–585 Filed 1–11–93; 8:45 am]

BILLING CODE 3410–11–M

Soil Conservation Service

Mud Creek Watershed Water Quality Plan; Barry, Eaton and Ionia Counties, MI

AGENCY: Soil Conservation Service, U.S. Department of Agriculture.

ACTION: Notice of finding of no significant impact.

SUMMARY: Pursuant to section 102(2) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR part 1500); and the Soil Conservation Service Guidelines (7 CFR part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for Mud Creek Watershed; Barry, Eaton and Ionia Counties, Michigan.

FOR FURTHER INFORMATION CONTACT: Mr. Homer R. Hilner, State Conservationist, Soil Conservation Service, room 101, 1405 South Harrison Road, East Lansing, Michigan 48823–5202, telephone (517) 337–6701, Ext. 1200.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action indicates that the project will not cause significant local, regional or national impacts on the environment. A contact has been made with the State Historic Preservation Officer and concludes that it will have no effect on any cultural resources either eligible for or listed on the National Register of Historic Places. The State Archaeologist will be contacted if any land disturbance associated with this project encounter archaeological sites, features or

materials. As a result of these findings, Mr. Homer R. Hilner, State Conservationist, has determined that the preparation and review of an Environmental Impact Statement are not needed for this project.

The project purposes are to improve water quality, restore recreational uses, enhance fish habitat and protect and restore wetlands of Mud Creek Watershed and Thornapple Lake. The planned works of improvement include: Conservation tillage, no-till, cover crops, pasture and hayland planting, water and sediment control basins, diversion, grade stabilization structures, grassed waterways, fencing, critical area seeding, streambank stabilization, livestock watering systems, filter strips, wetland improvements, windbreaks and vegetative barriers.

The Notice of a Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, state and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. Homer R. Hilner.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register**.

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904—Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with state and local officials.)

Dated: December 17, 1992.

Homer R. Hilner,

State Conservationists.

[FR Doc. 93–610 Filed 1–11–93; 8:45 am]

BILLING CODE 3410–16–M

ARMS CONTROL AND DISARMAMENT AGENCY

Government Sponsored Chemical Weapons Convention (CWC) Seminars for the Chemical and Related Industry

AGENCY: United States Arms Control and Disarmament Agency (ACDA).

ACTION: ACDA will sponsor seminars to explain the CWC and its significance for U.S. industry.

SUMMARY: The recently completed Chemical Weapons Convention (CWC) will directly affect private sector chemical producers, consumers and processors. The CWC imposes requirements on relevant industrial facilities.

Depending on the specific chemical, the CWC requires:

- Detailed reports of the quantities produced, processed, or consumed in your facilities;
- Detailed production plans and site (plant) information;
- Short-notice on-site inspections of industry facilities and records by international inspection teams.

The key issues for U.S. chemical and related industry managers:

- Compliance with CWC Requirements;
- Protection of confidential/proprietary business information;
- Controlling adverse publicity/ controversy;
- Prevention of unnecessary costs/ production disruptions;
- Inspection readiness;
- Schedule of implementation.

The U.S. Arms Control and Disarmament Agency is sponsoring regional one-day seminars to explain the CWC and its significance for U.S. industry. You are invited to attend one of the following:

Washington, DC.....February 11, 1993.
Newark, NJ.....February 25, 1993.
Houston, TX.....March 9, 1993.
Los Angeles, CA.....March 25, 1993.
Chicago, IL.....March 31, 1993.

FOR FURTHER INFORMATION CONTACT: For registration materials and more information on how the CWC affects your company, contact: Gordon Burck, Deputy Director, Chemical and Biological Arms Control Institute, 2111 Eisenhower Avenue, suite 301, Alexandria, VA 22314–4679. Telephone: (800) 528–1041 or (703) 739–1033. Fax: (703) 739–1525.

Cathleen Lawrence,

Administrative Director.

[FR Doc. 93–562 Filed 1–11–93; 8:45 am]

BILLING CODE 6820–32–M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Malcolm Baldrige National Quality Award's Board of Overseers

AGENCY: National Institute of Standards and Technology, DOC.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2, notice is hereby given that there will be a meeting of the Board of Overseers of the Malcolm Baldrige National Quality Award on Wednesday, February 10, 1993, from 8:30 a.m. to 5 p.m. The Board of Overseers consists of six members prominent in the field of quality management and appointed by the Secretary of Commerce, assembled to advise the Secretary of Commerce on the conduct of the Baldrige Award. The purpose of the meeting on February 10, 1993, will be for the Board of Overseers to receive and then discuss reports from the National Institute of Standards and Technology (NIST) and the Panel of Judges of the Malcolm Baldrige National Quality Award. These reports will cover the following topics: Introductions and overview of the Award process; update on the 1992 and 1993 Awards; roundtable discussions with the Panel of Judges of the Malcolm Baldrige National Quality Award and the Board of Overseers.

DATES: The meeting will convene February 10, 1993, at 8:30 a.m., and adjourn at 5 p.m. on February 10, 1993.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Administration Building Conference Room (seating capacity 36, includes 24 participants), Gaithersburg, Maryland 20899.

FOR FURTHER INFORMATION CONTACT: Dr. Curt W. Reimann, Director for Quality Programs, National Institute of Standards and Technology, Gaithersburg, Maryland 20899, telephone number (301) 975–2036.

Dated: January 6, 1993.

John Lyons,

Director.

[FR Doc. 93–664 Filed 1–11–93; 8:45 am]

BILLING CODE 3510–13–M

Malcolm Baldrige National Quality Award's Panel of Judges

AGENCY: National Institute of Standards and Technology, DOC.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2, notice is hereby given that there will be a meeting of the Panel of Judges of the Malcolm Baldrige National Quality Award on Tuesday, February 9, 1993, and on Wednesday, February 10, 1993. The Panel of Judges is composed of nine members prominent in the field of quality management and appointed by the Director of the National Institute of Standards and Technology.

The meeting will be composed of two parts. On February 9, the Panel of Judges will meet to review the Award processes (first stage, consensus, site visit, and final selection); hold final discussions on the 1992 Award cycle;

prepare for the Panel's meeting on February 10 with the Board of Overseers of the Malcolm Baldrige National Quality Award on the 1993 Award status and plans; and discuss future plans for the Award program. This meeting will include a working lunch. On February 10, there will be a combined meeting of the members of the Panel of Judges and the Board of Overseers to review the Award process, discuss the 1992 and 1993 Awards, and outline plans and issues for the 1993 and 1994 Award process.

DATES: The meeting will convene on February 9, 1993, at 8:30 a.m. and adjourn at 5 p.m. on February 10, 1993.

ADDRESSES: The meeting will be held at the National Institute of Standards and Technology, Administration Building Conference Room (seating capacity 36, including 18 participants on February 9, and 24 participants on February 10, 1993), Gaithersburg, Maryland 20899.

FOR FURTHER INFORMATION CONTACT: Dr. Curt W. Reimann, Director for Quality Programs, National Institute of Standards and Technology, Gaithersburg, Maryland 20899, telephone number (301) 975–2036.

Dated: January 6, 1993.

John Lyons,

Director.

[FR Doc. 93–663 Filed 1–11–93; 8:45 am]

BILLING CODE 3510–13–M

[Docket No. 921237–2337]

Standard on Safe Entry and Cleaning of Petroleum Storage Tanks: Announcement of Intent To Revise Under American National Standards Institute Procedures and Request for Review

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice of intent to revise standard and request for comments and participation in the standardization process.

SUMMARY: The American Petroleum Institute (API), with the assistance of other interested organizations, proposes to revise API Publication 2015, "Safe Entry and Cleaning of Petroleum Storage Tanks." The purpose of this notice is to increase public participation in that revision by announcing the intent to revise the standard, by inviting review of the existing standard and requesting participation in the standardization process. The publication of this notice by the National Institute of Standards and Technology (NIST) on behalf of API is being undertaken as a public service. NIST does not necessarily endorse, approve, or recommend the standard referenced in this notice.

DATES: Comments must be submitted on or before March 15, 1993.

ADDRESSES: Interested persons may contact: M.H. Matheson, Manufacturing, Distribution and Marketing, American Petroleum Institute, 1220 L Street, NW., Washington, DC 20005. (202) 682–8189.

FOR FURTHER INFORMATION CONTACT: M.H. Matheson, at (202) 682–8189.

SUPPLEMENTARY INFORMATION:

Background

API develops and publishes voluntary standards for petroleum processing equipment and operations. These standards are used by companies and by governmental agencies, which may incorporate them by reference into their regulations.

API publication 2015, "Safe Entry and Cleaning of Petroleum Storage Tanks," presents precautions and procedures considered essential for preventing fires, accidents, injuries, and illness while petroleum storage tanks are prepared for entry and while the tanks are actually entered, worked on or in and cleaned.

Request for Comments

Send all inquiries to M. H. Matheson, Manufacturing, Distribution and Marketing, American Petroleum Institute, 1220 L Street, NW., Washington, DC 20005. Interested persons are urged to submit any information or recommendations pertaining to the revision of Publication 2015 for consideration immediately. Interested persons may also request copies of the current edition for review.

Dated: January 6, 1993.

John W. Lyons,

Director.

[FR Doc. 93–622 Filed 1–11–93; 8:45 am]

BILLING CODE 3510–13–M

National Oceanic and Atomospheric Administration

Coastal Zone Management; Federal Consistency Appeal by Claire Pappas From an Objection by the New York State Department of State

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice of decision.

On October 26, 1992, the Secretary of Commerce (Secretary) issued a decision in the consistency appeal of Claire Pappas (Appellant). The Appellant had applied to the U.S. Army Corps of Engineers (Corps) for a permit to construct a wood deck structure for dining over a canal as an addition to her seafood restaurant in Hemstead, New York. In conjunction with the Federal permit application, the Appellant submitted to the Corps for review by the New York State Department of State (State), the State of New York's coastal management agency, under section 307(c)(3)(A) of the Coastal Zone Management Act of 1972, as amended (CZMA), 16 U.S.C. 1456(c)(3)(A), a certification that the proposed activity is consistent with the State's federally-approved Coastal Management Program (CMP).

On February 15, 1990, the State objected to the Appellant's consistency certification for the proposed project on the ground that the proposed project is not in accordance with the State's CMP policies and objectives of facilitating the siting of water dependent uses and facilities on or adjacent to coastal waters. Under CZMA section 307(c)(3)(A) and 15 CFR 930.131, the State's consistency objection precludes the Corps from issuing a permit for the activity unless the Secretary finds that the activity is either consistent with the objectives or purposes of the CZMA (Ground I) or necessary in the interest of national security (Ground II). The Appellant based her appeal on Ground I.

Upon consideration of the information submitted by the Appellant, the State and interested Federal agencies, the Secretary made the following findings pursuant to 15 CFR 930.121(d): the alternative proposed by the State of adding additional space to the Appellant's existing restaurant structure was a reasonable, available alternative that would be consistent with the State's CMP. Accordingly, the proposed project is not consistent with the objectives or purposes of the CZMA. Because the Appellant's proposed project failed to satisfy all of the requirements of Ground I, the Secretary did not override the State's objection to the Appellant's consistency certification. Consequently, the proposed project may not be permitted by Federal agencies. Copies of the decision may be obtained from the contact person listed below.

FOR ADDITIONAL INFORMATION CONTACT: Glenn E. Tallia, Attorney-Adviser, Office of the Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1825 Connecticut Avenue, NW., suite 603, Washington, DC 20235, (202) 606–4200.

Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance.

Dated: January 4, 1993.

Thomas A. Campbell,

General Counsel.

[FR Doc. 93–662 Filed 1–11–93; 8:45 am]

BILLING CODE 3510–08–M

Endangered Species

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Receipt of application for permit.

Notice is hereby given that Dr. David Wm. Owens, Professor, Department of Biology, Texas A&M University, College Station, TX 77843–3258, has applied in due form for a Permit (P531) to take endangered species for scientific purposes as authorized by the Endangered Species Act of 1973 (16 U.S.C. 1531–1543) and NMFS regulations governing endangered fish and wildlife permits (50 CFR Parts 217–222).

The applicant proposes to capture up to 179 Olive ridley turtles (*Lepidochelys olivacea*) in order to study the reproductive, migratory and feeding biology of the species. Other species which would be observed only for feeding studies include up to 10 each of loggerhead turtles, (*Caretta caretta*), black turtles, (*Chelonia agassizi*) and leatherback turtles, (*Dermochelys coriacea*). Turtles would be captured by hand from a small boat, transported to a research vessel and brought onboard for tests. Turtles will be examined to determine blood chemistry, reproductive state, mating and migratory behavior, and to determine feeding preferences. Examination methods include blood sampling, use of ultrasound and stomach lavage. The primary field work would take place in April 1993, with satellite tracking continuing for up to 2 years. Field work would take place off the Pacific coasts of Costa Rica and Panama.

Written data or views, or requests for a public hearing on this application should be submitted to the NMFS, U.S. Department of Commerce, 1335 East-West Highway, Silver Spring, Maryland 20910, within 30 days of the publication of this notice. Those individuals requesting a hearing should set forth the specific reasons why a hearing on this particular application would be appropriate. The holding of such a hearing is at the discretion of the Assistant Administrator for Fisheries. All statements and opinions contained in this application are summaries of those of the applicant and do not necessarily reflect the views of NMFS. Documents submitted in connection with the above application are available for review by interested persons in the following offices:

Office of Protected Resources, NMFS, NOAA, 1335 East-West Highway, SSMC #1, room 8268, Silver Spring, Maryland 20910, TEL: 301/713–2319;

Director, Southwest Region, NOAA, NMFS, 501 W. Ocean Blvd., Suite 4200, Long Beach, California 90802, TEL: 310/980–4001.

Dated: December 31, 1992.

Michael F. Tillman,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 93–558 Filed 1–11–93; 8:45 am]

BILLING CODE 3510–22–M

Mid-Atlantic Fishery Management Council; Public Hearing

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of public hearing; request for comments.

SUMMARY: The Mid-Atlantic Fishery Management Council (Council) will hold a public hearing on a resubmitted portion of Amendment 2 to the Summer Flounder Fishery Management Plan (FMP). The purpose of the hearing is to obtain public comments on management provisions that will be resubmitted to NMFS to replace provisions disapproved by the Regional Director. NMFS rejected vessel data collection until NMFS can implement a single coastwide mandatory vessel reporting system. NMFS plans to implement that system on January 1, 1994, and with that implementation, compliance with the Paperwork Reduction Act will not be a question.

DATES: The hearing will be held at 7 p.m., January 19, 1993. Written comments on the proposed revisions must be submitted by 4:30 p.m., January 15, 1993.

ADDRESSES: Send written comments to Mr. John C. Bryson, room 2115, Federal Building, 300 South New Street, Dover, DE 19901–6790 (Phone 302–674–2331) (FAX 301–674–5399). A public hearing will be held at 7:00 p.m., January 19, 1993, at the Dunes Manor Hotel, 28th Street & the Ocean, Ocean City, MD 21842 (Phone 301–289–1100).

FOR FURTHER INFORMATION CONTACT: Mr. John C. Bryson, (Phone 302–674–2331) (FAX 302–674–5399).

SUPPLEMENTARY INFORMATION: The Council is proposing to resubmit section 9.1.3.1 of Amendment 2 to the FMP, revised to read as follows (added language italicized; bracketed language added for clarity):

9.1.3.1 Domestic and foreign fishermen

Section 303(a)(5) of the MFCMA [Magnuson Fishery Conservation and Management Act] requires at least information regarding the type and quantity of fishing gear used, catch by species in numbers of fish or weight thereof, areas in which fishing was engaged in, time of fishing, and number of hauls must be submitted to the Secretary [of Commerce]. In order to achieve the objectives of this FMP and to manage the fishery for the maximum benefit of the U.S., it is necessary that, at a minimum, the Secretary collect on a continuing basis and make available to the Councils: (1) summer flounder catch, effort, and ex-vessel value and the catch and ex-vessel value of those species caught in conjunction with summer flounder for the commercial fishery provided in a form that analysis can be performed at the trip, water area, gear, month, year, principal (normal) landing port, landing port for trip, and State levels of aggregation; (2) catch and effort for the recreational fishery; (3) biological (e.g., length, weight, age, and sex) samples from both the commercial and recreational fisheries; and (4) annual and fully comparable NMFS bottom trawl surveys for analyses of both CPUE [catch per unit of effort] and age/size frequency. The Secretary may implement necessary data collection procedures through amendments to the regulations. It is mandatory that these data be collected for the entire management unit, including North Carolina, on a compatible and comparable basis.

Commercial logbooks must be submitted on a monthly basis by Federal moratorium permit holders in order to monitor the fishery.

Operators of party and charter boats with Federal permits issued pursuant to this FMP must submit logbooks monthly showing at least name and permit number of the vessel; total amount in pounds and numbers of each species taken; date(s) fished; number of trips; duration of trip; locality fished; crew size; landing port; number of anglers carried on each trip; and discard rate.

States are encouraged to implement equivalent fishery data collection systems for the development of a coordinated statistics gathering effort.

Implementation of the vessel reporting shall begin no later than January 1, 1994.

Foreign fishermen are subject to the reporting and recordkeeping requirements in 50 CFR [part] 611.

To be consistent with these revisions, the proposed regulations would be changed in § 625.6 Recordkeeping and reporting requirements.

These revisions do not change the environmental, economic, or regulatory impacts of Amendment 2, so the Environmental Impact Statement and Regulatory Impact Review are not being revised.

Dated: January 6, 1993

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93-560 Filed 1-11-93; 8:45 am]

BILLING CODE 3510-22-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Application of Import Restraint Limits for Certain Wool Textile Products Produced or Manufactured in the Former Czech and Slovak Republic

January 6, 1993.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs to apply limits.

EFFECTIVE DATE: January 1, 1993

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-5850. For information on embargoes and quota re-openings, call (202) 482-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3; 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Government of the United States has decided to apply the limits on various wool textile products established in the Memorandum of Understanding (MOU) between the Governments of the United States and the Former Czech and Slovak Federal Republic dated September 17, 1991, to the Czech Republic and Slovak Republic on a cumulative basis.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 56 FR 60101, published on November 27, 1991). Also see 57 FR 20810, published on May 15, 1992. Information regarding the 1993 CORRELATION will be published in the **Federal Register** at a later date.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the MOU, but are designed to assist only in the implementation of certain of its provisions.

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 6, 1993.

Commissioner of Customs,
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on May 11, 1992, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of wool textile products in Categories 410, 433, 435 and 443, produced or manufactured in the Czech and Slovak Federal Republic and exported during the twelve-month period beginning on June 1, 1992 and extending through May 31, 1993. You are directed to no longer charge imports of textile products, produced or manufactured in the Czech and Slovak Federal Republic.

Under the terms of Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1984); pursuant to the Bilateral Textile Agreement, effected by exchange of notes dated June 25 and July 22, 1986, as amended and extended by a Memorandum of Understanding dated September 17, 1991, between the Governments of the United States and the Czech and Slovak Federal Republic; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 1, 1993, entry into the United States for consumption and withdrawal from warehouse for consumption of wool textile products in the following categories, produced or manufactured in the Czech Republic and Slovak Republic, cumulatively, and exported during the twelve-month period which began on June 1, 1992 and extends through May 31, 1993, in excess of the following levels of restraint:

Category	Twelve-month restraint limit [1]
410	1,616,000 square meters.
433	16,665 dozen.
435	20,200 dozen.
443	161,600 numbers.

[1] The limits have not been adjusted to account for any imports exported after May 31, 1992.

Imports charged to these category limits for the restraint period June 1, 1991 through May 31, 1992 for goods exported from the former Czech and Slovak Federal Republic shall be charged against those levels of restraint to the extent of any unfilled balances. In the event the limits established for that period have been exhausted by previous entries, such goods shall be subject to the levels set forth in this directive.

Imports charged to these category limits for the restraint period June 1, 1992 through May 31, 1993 for goods exported from the former Czech and Slovak Federal Republic shall be applied to the limits established in this directive for the Czech Republic and Slovak Republic.

The limits set forth above are subject to adjustment in the future pursuant to the provisions of the MOU between the Governments of the United States and the former Czech and Slovak Federal Republic.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 93-596 Filed 1-11-93; 8:45 am]

BILLING CODE 3510-DR-F

DEPARTMENT OF DEFENSE

Department of the Army

Privacy Act of 1974; Adding Systems of Records

AGENCY: Department of the Army, DOD.

ACTION: Adding systems of records.

SUMMARY: The Department of the Army is adding two systems of records to its existing inventory of records system subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective February 11, 1993, unless comments are received which result in a contrary determination.

ADDRESSES: U.S. Army Information Systems Command, ATTN: ASOP-MP, Fort Huachuca, AZ 85613-5000.

FOR FURTHER INFORMATION CONTACT: Ms. Patricia A. Turner at (602) 538-6856 or DSN 879-6856.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974 have been published in the **Federal Register** and are available from the address above.

New system reports, as required by 5 U.S.C. 552(r) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, were submitted on December 23, 1992, to the Committee on Governmental Operations of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget (OMB) pursuant to paragraph 4b of Appendix I to OMB Circular No. A-130, "Federal Agency Responsibilities for Maintaining Records About Individuals," dated

December 12, 1985 (50 FR 52730, Dec 24, 1985).

Dated: December 30, 1992.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

A0027–1kDAJA

SYSTEM NAME:

Judge Advocate General Professional Conduct Files.

SYSTEM LOCATION:

Primary location: Department of the Army Standards of Conduct Office, ATTN: DAJA-SC (Room 2D439), The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310–2200.

Decentralized segments: Staff Judge Advocate, HQ Forces Command, Fort McPherson, GA 30330-6000;

Staff Judge Advocate, HQ, Training and Doctrine Command, Fort Monroe, VA 23651-5000;

Judge Advocate, HQ, U.S. Army Europe and 7th Army, ATTN: AEAJA, Unit 29351, Heidelberg, APO AE 09014-0100;

Staff Judge Advocate, HQ United Nations Command/U.S. Forces Korea/ Eighth U.S. Army, ATTN: FKJA, Seoul, Republic of Korea, APO AP 96205-0009;

Staff Judge Advocate, HQ, U.S. Army Pacific, Building T102, Stop 111, Ft. Shafter, HI 96858-5100;

Staff Judge Advocate, U.S. Army Materiel Command, ATTN: AMCCC, 5001 Eisenhower Avenue, Alexandria, VA 22333-0001;

Staff Judge Advocate, HQ, U.S. Army Health Services Command, ATTN: HSJA, Fort Sam Houston, TX 78234-6000;

Command Legal Counsel, HQ, U.S. Army Recruiting Command, ATTN: RCLC, Fort Knox, KY 40121-2726;

Staff Judge Advocate, HQ, U.S. Army Criminal Investigation Command, ATTN: CIJA-ZA, Nassif Building, 5611 Columbia Pike, Falls Church, VA 22041-5015;

Legal Advisor, U.S. Army Strategic Defense Command, P.O. Box 15280, Arlington, VA 22215-0280;

Command Judge Advocate, Military Traffic Management Command, ATTN: MTJA, Nassif Building, 5611 Columbia Pike, Room 405, Falls Church, VA 22041-5050;

Staff Judge Advocate, HQ, U.S. Army Information Systems Command, ATTN: ASJA, Fort Huachuca, AZ 85613-5000;

Staff Judge Advocate, HQ, U.S. Army Intelligence and Security Command, ATTN: IASJA, Ft. Belvior, VA 22212-5000;

Staff Judge Advocate, HQ, U.S. Army Military District of Washington, ATTN: ANJA, Fort McNair, DC 20319-5050;

Staff Judge Advocate, U.S. Army Special Operations Command, ATTN: AOJA, Fort Bragg, NC 28307-5200;

Staff Judge Advocate, HQ, U.S. Army South, Ft. Clayton, Panama, APO AA 34004-5000;

Staff Judge Advocate, U.S. Military Academy, ATTN: MAJA, West Point, NY 10996-1781;

Commandant, The Judge Advocate General's School, Army, ATTN: JAGS, 600 Massie Road, Charlottesville, VA 22903-1781;

Commander, U.S. Army Claims Service, ATTN: JACS, Building 4411, Llewellyn Avenue, Ft. Meade, MD 20755-5360;

The Assistant Judge Advocate General, ATTN: DAJA-ZB (Room 2E444), The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310-2200;

Commander, U.S. Army Legal Services Agency, ATTN: JALS, Nassif Building, 5611 Columbia Pike, Falls Church, VA 22041-5013;

Chief, U.S. Army Trial Defense Service, ATTN: JALS-TD, Nassif Building, 5611 Columbia Pike, Falls Church, VA 22041-5013;

Chief, Defense Appellate Division, ATTN: JALS-GA, Nassif Building, 5611 Columbia Pike, Falls Church, VA 22041-5013;

Chief, Government Appellate Division, ATTN; JALS-TD, Nassif Building, 5611 Columbia Pike, Falls Church, VA 22041-5013;

Director, Guard and Reserve Affairs Department, The Judge Advocate General's School, Army, ATTN: JAGS-GRA, 600 Massie Road, Charlottesville, VA 22903-1781;

Assistant Judge Advocate General for Civil Law and Litigation, ATTN: DAJA-ZC (Room 2E432), The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310-2200;

Assistant Judge Advocate General for Military Law and Operations, ATTN: DAJA-ZD (Room 2E432), The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310-2200;

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Judge Advocates, civilian attorneys of the Judge Advocate Legal Service, and civilian attorneys subject to the disciplinary authority of the Judge Advocate General who have been the subject of a complaint related to their professional conduct.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include, but are not limited to complaints with substantiating documents, tasking memoranda, preliminary screening reports (containing sensitive personal information, witness statements, and screening officer's findings/ recommendations), supervisory judge advocate recommendations/actions, staff memoranda to the Judge Advocate General's Corps leadership, Professional Responsibility Committee opinions, memoranda related to disciplinary actions and responses from subjects, and correspondence with governmental agencies and professional licensing authorities. All records associated with professional responsibility inquires under the provisions of Chapter 7, Army Regulation 27–1, Judge Advocate Legal Services.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3037(c); RCM 109, Manual for Courts-Martial, 1984; Chapter 302, Army Regulation 690–300, Position Management; Chapter 7, Army Regulation 27–1, Judge Advocate Legal Service.

PURPOSE(S):

To assist the Judge Advocate General in the evaluation, management, administration, and regulation of the delivery of legal services by offices and personnel under his jurisdiction.

To record the disposition of ethics complaints and to document ethics violations and corrective action taken.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Information concerning substantiated misconduct may be released to (a) professional licensing authorities (e.g. state and local bar associations) and to (b) current and potential governmental employers during authorized background checks to assist their efforts to protect the public by maintaining the integrity of the legal profession.

The "Blanket Routine Uses" set forth at the beginning of the Army's compilation of systems of records notices apply to this record system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS:

STORAGE:

Paper records in file folders and on computers.

RETRIEVABILITY:

By subject's name.

SAFEGUARDS:

Records are maintained in locked offices and/or in locked file cabinets in secured building or on military installations protected by police patrols. All information is maintained in secured areas accessible only to

designated individuals having official need therefor in the performance of official duties. Computer stored information is password protected.

RETENTION AND DISPOSAL:

Cases resolved at the Office of the Judge Advocate General after a preliminary screening inquiry will be maintained as permanent files. The files will be maintained in the Standards of Conduct Office for ten years, at which time they will be reviewed and transferred for permanent retention to the Washington National Records Center.

Cases resolved at other offices, after a preliminary screening inquiry, will ordinarily be destroyed after ten years. The files will be maintained in the Standards of Conduct Office. Review of the record will determine whether to destroy the file or to transfer to the Washington National Records Center for permanent retention. In cases where the files are destroyed, data will be extracted for statistical purposes prior to destroying the files.

Cases resolved at other offices, where allegations were found not credible and no preliminary screening inquiry was conducted, will be maintained in the office where action was taken for a period of three years, at which time the data will be extracted for statistical purposes and then destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

Department of the Army Standards of Conduct Office, ATTN: DAJA-SC (Room 2D439), The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310–2200.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Department of the Army Standards of Conduct Office, ATTN: DAJA-SC (Room 2D439), The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310–2200.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves should address written inquiries to the Department of the Army Standards of Conduct Office, ATTN: DAJA-SC (Room 2D439), The Judge Advocate General, 2200 Army Pentagon, Washington, DC 20310–2200.

CONTESTING RECORD PROCEDURES:

The Army's rules for access to records and for contesting contents and appealing initial determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is received from individuals and from federal, state, and local authorities (e.g. preliminary screening report, other Army records, state bar records, law enforcement records, educational institution records, etc.).

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

A0600–85fDAPE

SYSTEM NAME:

ADAPCP Clinical Certification Program Application File.

SYSTEM LOCATION:

U.S. Army Medical Department Center and School, Academy of Health Sciences, Medical Field Service School, ATTN: HSHA-MB, (Certification Program Office), Fort Sam Houston, Texas 78234–6100.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Department of Army Civilian Psychologists, Social Workers, Drug and Alcohol Program Specialists, Social Services Representatives/Assistants, Psychology Technicians, and enlisted military counselors (Behavioral Science Specialists) employed or assigned to the ADAPCP Community Counseling Centers or Residential Treatment Facilities who provide counseling services to ADAPCP clients.

CATEGORIES OF RECORDS IN THE SYSTEM:

Copies of the Candidate Application Portfolio with education and employment history and related documents that include Social Security Numbers, are required for each certification candidate. A Competency Assessment Form Rating containing a recommendation and documentation of successful completion of the 1-year internship requirement; a signed Privacy Act Statement, a signed copy of the ADAPCP Clinical Code of Ethics; and a signed copy of the Sobriety Statement are included in the application portfolio. Copies of course certificates and/or official college transcripts are also required in the candidate's file. Certification examination results and correspondence pertaining to the application status, certification renewal and Board decisions are also maintained in the candidate's file.

Roster of all certified personnel; examination failures; inactive certified personnel; and other program status information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013.

PURPOSE(S):

To receive, evaluate, and maintain applications for ADAPCP Clinical Certification Staff; process information routinely used to verify and ensure accuracy of education and employment or assignment records; document successful completion of a 1-year clinical internship requirement; ensure incumbents are minimally qualified within 3 years of employment or assignment to provide quality care to ADAPCP clients; and provide statistical information for program analysis.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of system of records notices.

To qualified personnel conducting scientific research, management, or financial audits or program evaluations. All personal identifiers are removed from data.

In response to a court order based on the showing of good cause in which the need for disclosure and the public's interest is necessary to support clinical competence.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS:

STORAGE:

Information is stored on a personal computer and in locked file cabinets.

RETRIEVABILITY:

Retrieved by the surname, applicant file number, and social security number.

SAFEGUARDS:

All information is maintained in secured areas accessible only to designated individuals having official need therefor in the performance of official duties.

RETENTION AND DISPOSAL:

Information will be maintained during the tenure of the person and five years beyond the date of departure from the program. Persons who transfer to another ADAPCP organization constitutes a file transfer also.

SYSTEM MANAGER(S) AND ADDRESS:

U.S. Army Medical Department Center and School, Academy of Health Sciences, Medical Field Service School, Behavioral Sciences Division, ATTN: HSHA-MB (Certification Program Office), Fort Sam Houston, TX 78234–6100.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the Commander, U.S. Army Medical Center and School, ATTN: HSHA-MB (Certification Program), Fort Sam Houston, TX 78234–6100.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of record should address written inquiries to Commander, U.S. Army Medical Center and School, ATTN: HSHA-MB (Certification Program), Fort Sam Houston, TX 78234–6100.

CONTESTING RECORD PROCEDURES:

The Department of the Army rules for accessing records and for contesting contents and appealing initial Army determinations are published in Army Regulation 340–21; 32 CFR part 505; or may obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individuals employed by or assigned to the Army Alcohol and Drug Abuse Prevention and Control Program who submit requested information to apply for ADAPCP Clinical Certification as a condition of continuing employment or otherwise.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 93–618 Filed 01–11–93; 8:45 am]

BILLING CODE 3810–01–F

Defense Logistics Agency

Privacy Act of 1974; Add a System of Records.

AGENCY: Defense Logistics Agency, DOD.

ACTION: Add a system of records.

SUMMARY: The Defense Logistics Agency proposes to add a new record system to its inventory of systems of records notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

DATES: This action will be effective without further notice on February 11, 1993, unless comments are received that would result in a contrary determination.

ADDRESSES: Send comments to the Privacy Act Officer, Administrative Management Branch, Planning and Resource Management Division, Defense Logistics Agency, Room 5A120, Cameron Station, Alexandria, VA 22304–6100.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Salus at (703) 617–7583.

SUPPLEMENTARY INFORMATION: The Defense Logistics Agency record system notices subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed new system report, as required by 5 U.S.C. 552a(r) of the Privacy Act was submitted on December 23, 1992, to the Committee on Government Operations of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Office of Management and Budget (OMB) pursuant to paragraph 4b of Appendix I to OMB Circular No. A–130, "Federal Agency Responsibilities for Maintaining Records About Individuals," dated December 12, 1985 (50 FR 52730, December 4, 1985).

Dated: December 30, 1992.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

S200.50 DLA-M

SYSTEM NAME:

Individual Weight Management File.

SYSTEM LOCATION:

Records are maintained by the heads of the DLA Primary Level Field Activities (PLFA's). Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

For members assigned to Headquarters DLA, records are maintained by DASC-DW, Cameron Station, Alexandria, VA 22304–6130.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military active duty and reserve personnel assigned to DLA.

CATEGORIES OF RECORDS IN THE SYSTEM:

Member's name, Social Security Number, weight management record, and physical readiness data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 302(b)(1), Delegation of authority; 10 U.S.C. 136, Assistant Secretaries of Defense; and DoD Directive 1308.1, Physical Fitness and Weight Control Programs.

PURPOSE(S):

The system will be used to record the weight and physical readiness of military members assigned to DLA. It will also be used to monitor the progress of those entered into the weight management program.

Records may be used by member's service for remedial, corrective, or administrative separation actions.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS:

STORAGE:

Records are stored in paper and computerized form.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Records are maintained in areas accessible only to DLA personnel who must access the records to perform their duties. The computer files are password protected with access restricted to authorized users.

Access to paper and computerized files is restricted to member's commander, the weight control officer, medical personnel, the director of the military personnel function at the activity where assigned, and the military personnel function of the member's service.

RETENTION AND DISPOSAL:

Records are retained until the member departs, at which time the member collects the record for forwarding to his or her next duty assignment.

SYSTEM MANAGER(S) AND ADDRESS:

The Staff Director, Office of Military Personnel, DLA-M, Cameron Station, Alexandria, VA 22304–6100, and the heads of the DLA Primary Level Field Activities. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to or visit the system manager of the particular DLA activity involved. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

Individuals assigned to HQ DLA may address inquiries to or visit DASC-DW, Cameron Station, Alexandria, VA 22304–6100. For personal visits, individuals must present proper identification.

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to or visit the system manager of the particular DLA activity

involved. Official mailing addresses are published as an appendix to DLA's compilation of systems of records notices.

Individuals assigned to HQ DLA may address written inquiries to or visit DASC-DW, Cameron Station, Alexandria, VA 22304–6100. For present proper identification.

CONTESTING RECORD PROCEDURES:

The DLA rules for contesting contents and appealing initial agency determinations are contained in DLA Regulation 5400.21; 32 CFR part 323; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is taken from the record subject, individual weigh-ins, medical personnel, and medical records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 93–619 Filed 01–11–93; 8:45 am]

BILLING CODE 3810–01–F

DELAWARE RIVER BASIN COMMISSION

Commission Meeting and Public Hearing

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday, January 20, 1993. The hearing will be part of the Commission's business meeting which is open to the public and scheduled to begin at 1 p.m. in the Goddard Conference Room of the Commission's offices at 25 State Police Drive, West Trenton, New Jersey.

An informal conference session among the Commissioners and staff will be open for public observation at 10 a.m. at the same location and will include reports on the status of the Upper Delaware ice jam project and Water Quality Advisory Committee deliberations and discussion of ground and surface water permit renewal issues.

The subjects of the hearing will be as follows:

Applications for Approval of the Following Projects Pursuant to Article 10.3, Article 11 and/or Section 3.8 of the Compact

1. Holdover Project: Circuit Foil USA D–92–21

An application for approval of a proposed industrial wastewater treatment plant (IWTP) to treat approximately 48,000 gallons per day (gpd) of process wastewater generated by the applicant's metallic copper foil manufacturing operation. The existing IWTP (0.3 mgd) which currently discharges to an unnamed tributary of Mile Hollow Brook, will no longer be used by Circuit Foil USA, and the new IWTP will discharge to Crosswicks Creek. The proposed IWTP will provide an 80 percent reduction in the volume of waste water discharged due to process water recovery and recycle. The IWTP will be located just west of Route 130 and approximately 2000 feet northeast of the City of Bordentown's corporate limits, in the Township of Bordentown, Burlington County, New Jersey.

2. City of New Castle D–78–71 CP RENEWAL–2

An application for the renewal of a ground water withdrawal project to supply up to 48 million gallons (mg)/30 days of water to the applicant's distribution system from Well Nos. 1–4. Commission approval on August 5, 1987 was limited to five years. The applicant requests that the total withdrawal from all wells remain limited to 48 mg/30 days. The project is located in the City of New Castle, New Castle County, Delaware.

3. Schuylkill Haven Bleach and Dye Works, Inc. D–81–30 RENEWAL–2

An application for the renewal of a ground water withdrawal project to supply up to 7.2 mg/30 days of water to the applicant's industrial facility from Well Nos. 1, 2 and 3. Commission approval on February 24, 1988 was limited to five years and will expire unless renewed. The applicant requests that the total withdrawal from all wells remain limited to 7.2 mg/30 days. The project is located in Schuylkill Haven Borough, Schuylkill County, Pennsylvania.

4. Evesham Municipal Utilities Authority D–82–39 CP RENEWAL

An application for the renewal of a ground water withdrawal project to supply up to 136 mg/30 days of water to the applicant's distribution system from Well Nos. 4–11. Commission approval on June 27, 1984 was limited to five years. The total withdrawal from all wells has been decreased from 146 mg/30 days to 136 mg/30 days. The project is located in Evesham Township, Burlington County, New Jersey.

5. Borough of Catasauqua D–87–60 CP RENEWAL

An application for the renewal of a ground water withdrawal project to supply up to 23.7 mg/30 days of water to the applicant's distribution system from Well No. 5. Commission approval on January 13, 1988 was limited to five years and will expire unless renewed. The applicant requests that the total withdrawal from all wells remain limited to 40 mg/30 days. The project is located in North Catasauqua Borough, Northampton County, Pennsylvania.

6. Gloucester County Utility Authority D–90–74 CP

A regional wastewater treatment plant modification project to expand the treatment capacity from 20.1 mgd to 24.1 mgd to meet projected flows for the design year 2000. The treatment plant will continue to discharge secondary treated effluent to the Delaware River in Water Quality Zone 4. The plant site is located on the west side of Mantua Creek about 500 feet north of Broad Street, in West Deptford Township, Gloucester County, New Jersey.

7. Womelsdorg-Robesonia Joint Authority D–92–35 CP (R)

A request for a revision of approved Docket No. D–92–35 CP to amend decision "s". The revised decision would impose a ban on new service connections in Millcreek Township until the adoption of a water conservation ordinance by Millcreek Township, Berks County, Pennsylvania.

8. Lehigh County Authority D–92–40 CP

An application for approval of withdrawal of 0.15 mgd of water from the applicant's Main System Reservoir, located on Trout Creek in Heidelburg Township, Lehigh County. The project withdrawal will serve a section of the applicant's water distribution system located in Washington Township. A small section, however, will continue to be served by the Borough of Slatington from which the applicant will purchase 20,000 gpd of water. The project is located entirely within Lehigh County, Pennsylvania.

9. Upper Merion Municipal Utility Authority D–92–51 CP

A sewage treatment plant (STP) expansion project that will increase the existing 5.0 mgd capacity STP to treat an average of 6.0 mgd of wastewater generated in the applicant's Upper Merion Township service area. The STP will provide secondary treatment with a trickling filter/solids contact process. The STP is located near the confluence of Trout Run with the Schuylkill River and will continue to discharge to Trout Run via the existing outfall structure all within Upper Merion Township, Montgomery County, Pennsylvania.

10. Grand View Hospital D–92–63 CP

An application for approval of a ground water withdrawal project to supply up to 3.6 mp/30 days of water to the Grand View Hospital from new Well Nos. 4 and 5 and existing Well Nos. 1, 2 and 3, and to limit the withdrawal from all wells to 3.6 mg/30 days. The project is located in West Rockhill Township, Bucks County in the Southeastern Pennsylvania Ground Water Protected Area.

Documents relating to these items may be examined at the Commission's offices. Preliminary dockets are available in single copies upon request. Please contact George C. Elias concerning docket-related questions. Persons wishing to testify at this hearing are requested to register with the Secretary prior to the hearing.

Dated: January 5, 1993.

Susan M. Weisman,

Secretary.

[FR Doc. 93–599 Filed 1–11–93; 8:45 am]

BILLING CODE 6360–01–M

DEPARTMENT OF EDUCATION

Advisory Committee on Student Financial Assistance; Meeting

AGENCY: Advisory Committee on Student Financial Assistance, Education.

ACTION: Notice of partially closed meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming partially closed meeting of the Advisory Committee on Student Financial Assistance. This notice also describes the functions of the Committee. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public.

DATES AND TIMES: January 25, 1993, beginning at 9 a.m. and ending at 5 p.m.; and January 26, 1993, beginning at 8:30 a.m. and ending at 12 noon, but closed from 9:30 a.m. to 10:30 a.m..

ADDRESSES: Wyndham Bristol Hotel, Potomac Rooms I and II, 2430 Pennsylvania Avenue, NW., Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: Dr. Brian K. Fitzgerald, Staff Director, Advisory Committee on Student Financial Assistance, room 4600, ROB–3, 7th & D Streets, SW., Washington, DC 20202–7582 (202) 708–7439.

SUPPLEMENTARY INFORMATION: The Advisory Committee on Student Financial Assistance is established under section 491 of the Higher Education Act of 1965 as amended by Public Law 100–50 (20 U.S.C. 1098). The Advisory Committee is established to provide advice and counsel to the Congress and the Secretary of Education on student financial aid matters, including providing technical expertise with regard to systems of need analysis and application forms, making recommendations that will result in the maintenance of access to postsecondary education for low- and middle-income students, conducting a study of institutional lending in the Stafford Student Loan Program, and assisting with activities related to reauthorization of the Higher Education Act of 1965. As a result of the passage of the Higher Education Amendments of 1992, the Congress also has directed the Advisory Committee to assist with a series of special assessments and conduct an in-depth study of student loan simplification.

The Advisory Committee will meet in Washington, D.C. on January 25, 1993, from 9 a.m. to 5 p.m., and on January 26, from 8:30 a.m. to 12 noon. The meeting will be closed to the public from 9:30 a.m. to 10:30 a.m. to elect a new chairman and discuss other personnel matters. The ensuing discussions will relate to internal personnel rules and practices and will disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy if conducted in open session, and such matters are protected by exemptions (2) and (6) of section 552(b)(c) of 5 U.S.C. The meeting will be closed under the authority of section 10(d) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C., appendix 2) and under exemptions (2) and (6) of Section 552(b)(c) of the Government in the Sunshine Act (Pub. L. 94–409).

A summary of the activities at the closed session and related matters which are informative to the public consistent with the policy of 5 U.S.C. 552(b) will be available to the public within fourteen days of the meeting.

The proposed agenda includes (a) a discussion of the loan simplification study; (b) updates on the National Student Loan Data Base and Loan Standardization Progress; (c) a discussion on the early eligibility research update; (d) the delivery system and direct lending pilot program updates; and (e) an Advisory Committee regulatory update and planning session for the upcoming year's agenda.

Records are kept of all Committee proceedings, and are available for public inspection at the Office of the Advisory Committee on Student Financial Assistance, room 4600, 7th and D Streets, SW., Washington, DC from the hours of 9 a.m. to 5:30 p.m., weekdays, except Federal holidays.

Dated: January 7, 1993.

Dr. Brian K. Fitzgerald,

Staff Director, Advisory Committee on Student Financial Assistance.

[FR Doc. 93–644 Filed 1–11–93; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Bonneville Power Administration

South Fork Tolt River Hydroelectric Project; Record of Decision

AGENCY: Bonneville Power Administration (BPA), DOE.

ACTION: Record of decision for a billing credit to Seattle City Light for the proposed South Fork Tolt River Hydroelectric Project.

SUMMARY: BPA has decided to grant a Billing Credit [1] to Seattle City Light (SCL), a Department of the City of Seattle, with headquarters in Seattle, Washington, for the power output from the proposed South Fork Tolt River Hydroelectric Project (South Fork Tolt Project, Project). The proposed Project, with an installed capacity of 15 megawatts that would produce 6.55 average megawatts of firm energy per year, is one small renewable resource available to BPA through its Billing Credits pilot program. The Billing Credit will result in a reduction of the Administrator's obligation to acquire resources by accommodating a small percentage of SCL's projected load growth, thus reducing the net requirements for supply of electric power to SCL by BPA. By granting the Billing Credit to SCL, BPA assures the development of this resource.

To make this decision, BPA used information in the South Fork Tolt River Final Environmental Impact Statement (EIS) (adopted portions of the Federal Energy Regulatory Commission (FERC) Final EIS, Snohomish River Basin, Washington, Seven Hydroelectric Projects, Docket No. EL85–19–101, for application for FERC license to construct, operate, and maintain the project) and Attachment. BPA's review and analysis of the adequacy of the portions of the 1987 FERC Final EIS relating to the proposed South Fork Tolt River Hydroelectric Project as well as all other documents pertaining to the South Fork Tolt proposed project was included in an Attachment to the South Fork Tolt River Hydroelectric Project EIS issued by BPA in April 1992 (DOE/EIS–0184).

BPA has determined that granting a billing credit to SCL is consistent with the Billing Credits policy and with the Northwest Power Planning Council's Power Plan. The proposed project will meet all requirements of the FERC license and other Federal, State, and local requirements.

[1] One method that BPA uses to acquire energy resources is Billing Credits. With this innovative mechanism, authorized by the Northwest Power Act, BPA provides a credit to an eligible customer (utility, certain industries, and others) for load reduction actions and energy resource developments. Under BPA's 1990 Resource Program, BPA is seeking to test the Billing Credits Policy by acquiring up to 50 average megawatts; a solicitation for proposals was issued on July 9, 1990.

A complete description of the Billing Credits Policy is presented in an Environmental Assessment (EA) (DOE/EA–0180, June 1982), which has been made available to the public. The Billing Credits Policy provides for site-specific National Environmental Policy Act (NEPA) review for each proposal after it is received (Billing Credit EA, page 5–2).

Mitigation plans and other environmental agreements are in place or will be completed prior to construction for protection of fish and wildlife, water quality, wild and scenic river values, flooding, cultural resources, and the FERC permit requirements. The implementation of these plans and agreements are the practical means of avoiding or minimizing environmental harm from the above mentioned billing credit.

ADDRESSES: Copies of the South Fork Tolt River Hydroelectric Project EIS and Attachment, April 1992, (DOE/EIS–0184), the comments we have received on this issue, this Record of Decision, and the 1990 Resource Program, are available from BPA's Public Involvement Office, P.O. Box 12999, Portland, Oregon 97212.

FOR FURTHER INFORMATION CONTACT:

Mr. Charles Alton, Environmental Coordinator for Energy Resources, Bonneville Power Administration, P.O. Box 3621–RAE, Portland, Oregon 97208; telephone (503) 230–5878. For further information on DOE NEPA activities contact Carol M. Borgstrom, Director, Office of NEPA Oversight, EH–25, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington DC, 20585; telephone (202) 586–4000 or (800) 472–2756. For copies of the documents listed above, you may also contact BPA's Public Involvement Office at (503) 230–3478. Oregon callers may use (800) 622–4519. Information may also be obtained from:

Mr. George Bell, Lower Columbia Area Manager, suite 243, 1500 NE. Irving Street, Portland, OR 97232, (503) 230–4551.

Mr. Robert N. Laffel, Eugene District Manager, room 206, 211 East Seventh Avenue, Eugene, OR 97410, (503) 465–6592.

Mr. Wayne R. Lee, Upper Columbia Area Manager, room 561, West 920 Riverside Avenue, Spokane, WA 99201, (509) 353–2515.

Mr. George E. Eskridge, Montana District Manager, 800 Kensington, Missoula, MT 59801, (406) 329–3060.

Mr. Ronald K. Rodewald, Wenatchee District Manager, room 307, 301 Yakima Street, Wenatchee, WA 98801, (509) 662–4377, extension 379.

Mr. Terence G. Esvelt, Puget Sound Area Manager, suite 400, 201 Queen Anne Avenue North, Seattle, WA 98109–1030, (206) 553–4130.

Mr. Thomas V. Wagenhoffer, Snake River Area Manager, 101 West Poplar, Walla Walla, WA 99362, (509) 522–6226.

Ms. C. Clark Leone, Idaho Falls District Manager, 1527 Hollipark Drive, Idaho Falls, ID 83401, (208) 523–02706.

Mr. Thomas H. Blankenship, Boise District Manager, room 494, 550 West Fort Street, Boise, ID 83724, (208) 334–9137.

SUPPLEMENTARY INFORMATION:

I. Background

BPA is a Federal power marketing agency with statutory responsibilities to supply electrical power to its utility, industrial, and other customers in the Pacific Northwest. According to BPA's current load/resource balance study, the demand for energy now exceeds supply by about 400 aMW. The load/resource balance forcast projects a deficit of 1,500 to 2,600 aMW by the year 2000. The underlying need for action is to satisfy BPA's customers' demand for electrical energy.

Consistent with the 1991 Northwest Conservation and Electric Power Plan (Power Plan) and the 1980 Northwest Electric Power Planning and Conservation Act (Power 2Act) (Pub. L. 96–501 6.(h)(1)(B)), BPA has initiated a dynamic resource acquisition effort to acquire new resources. BPA is using three acquisition methods: Billing credits, competitive acquisition, and contingency options to acquire energy for the region. BPA can provide a billing credit to an eligible customer (utility, industries, and others) for load reduction actions and resource developments.

The proposed South Fork Tolt Project of SCL is one small renewable resource available to BPA through its Billing Credits pilot program. Power generated by the Project would be used by SCL to accommodate a small percentage of its projected load growth. By granting a Billing Credit to SCL, BPA reduces its firm load obligation to SCL by 6.55 average firm megawatts.

The proposed project has undergone extensive environmental reviews at both the State and Federal levels. SCL completed a Washington State Environmental Policy Act (SEPA) Final Environmental Impact Statement in 1980 after holding a public information meeting and receiving public comments on the SEPA Draft EIS. In 1984, the FERC completed a National Environmental Policy Act (NEPA) Environmental Assessment and, on March 29, issued license No. 2959 to SCL for a duration of 40 years beginning the first day of the month in which the license was issued. The license established minimum stream flow requirements and required SCL to consult with the Fish and Wildlife Service, National Marine Fisheries Services, Washington Department of Fisheries, Washington Department of Wildlife, and the Tulalip Tribes (Agencies) to determine instream flows needed to ensure the protection and enhancement of fishery and wildlife resources, and to submit the recommended flow regime to FERC for approval.

As a result of concerns expressed by the Agencies regarding long-term conditions for flow and habitat restoration and SCL application for a rehearing relative to instream flow conditions, FERC issued a stay order on July 5, 1984 pending further environmental review. In June 1987, FERC completed further environmental review of the proposed South Fork Tolt Project as part of a FERC Final EIS that evaluated the individual and cumulative impacts of seven proposed small hydroelectric projects in the Snohomish River basin (FERC Final EIS, Snohomish River Basin, Washington, Seven Hydroelectric Projects, Docket No. EL85–19–101). Action on the proposed South Fork Tolt Project was deferred pending the resolution agreement between SCL and the Agencies regarding instream flows and habitat restoration. The South Fork Tolt River Settlement Agreement was signed in October of 1988. FERC lifted the stay order on July 20, 1989 and incorporated the provisions of the Settlement Agreement into the Project license. The license is for forty years from this date.

BPA distributed the South Fork Tolt River Hydroelectric Project EIS and Final Attachment to the public for a 30-day review in July 1992 and the Environmental Protection Agency Notice of Availability was published in the **Federal Register** on September 18, 1992.

Notice of this Record of Decision will be distributed to the interested and affected public, as well as through a subsequent **Federal Register** Notice.

II. Alternatives

A. No Action

Under this alternative, BPA would not grant a billing credit for the proposed action, foregoing the opportunity to reduce BPA's projected energy deficit by approximately 6.5 firm megawatts annually. SCL would not build the project without the billing credit and the environmental impacts of the proposed action would not occur. This is the environmental preferable alternative due to no impacts, but this alternative has not been selected because it would not meet BPA's energy needs.

B. Other Actions

Applicants for billing credits develop each potentially qualifying action independently and submit them to BPA separately. Therefore, collective consideration of all potential actions is not practical. However, implementing the proposed action will not foreclose future consideration of other potential BPA energy resource actions by means of the Billing Credit Program and other resource acquisitions mechanisms. In fact, because this proposed action would merely reduce, not eliminate, the need for power, other resources, independent of the proposed action, will likely be considered, pursuant to NEPA, regardless of whether a billing credit is granted for the proposed action. Resource types potentially available to meet future load growth include:

—Conservation (commercial, residential, and industrial sectors);
—Renewables (hydropower, geothermal, biomass, wind, and solar power);
—Cogeneration;
—Combustion turbines;
—Nuclear power; and
—Coal.

To comparatively evaluate these resource types, BPA is currently preparing an environmental impact statement (EIS) on its resource programs (Resource Programs Draft EIS, April 1992).

Generally, every two years BPA prepares a Resource Program that communicates how it proposes to meet its expected load obligations. For each Resource Program, alternatives are examined which are composed of different combinations of energy resource types from BPA's resource stack (the resource stack is the list of resources, ordered generally by cost, forecast to be available to meet electric power needs). BPA's planning model relies on this resource stack in simulating resource acquisitions and serves as a basis for BPA's resource planning decisions.

In developing a Resource Program, BPA prepares load forecasts jointly with the Northwest Power Planning Council. A range of forecasts are prepared to reflect uncertainties about future load growth. Next, a range of load/resource balances are prepared by comparing the capability of the existing Federal system resources to the range of projected Federal system loads over the next 20 years. In a parallel process, BPA and the Council develop new resource supply forecasts to plan acquisition of cost-effective resources as needed to meet load growth and to facilitate program design. Pursuant to this formula, resources other than the proposed action will undoubtedly be examined and evaluated in the future for their eligibility and capability to satisfy BPA's future needs.

III. Decision Factors and Issues

A. 1990 Resource Program and BPA Billing Credits Policy Considerations

The 1990 Resource Program identified actions BPA would take to develop new resources to meet the power requirements of its customers. One of these resource actions was to acquire 50 aMW from a billing credit acquisition process. A solicitation for billing credit proposals was issued on July 9, 1990. Other actions to acquire new resources included conservation acquisition, competitive bid from "all sources," hydro efficiency improvements, geothermal pilot project, and a Resource Contingency Plan.

As outlined in the 1990 Resource Program, the primary reasons why BPA has selected this combination of resource actions are: manages risk appropriately; provides flexibility and diversity; reflects existing and potential capability to develop new resources; and maintains budget and rate impacts within bounds.

The August 30, 1984, Billing Credits Policy as amended interpreted the applicable provisions of the Power Act, prescribed criteria for customer and resource eligibility for Billing Credits, established general procedures for BPA's evaluation and approval of Billing Credit applications, and prescribed how Billing Credits would be granted and considered. The South Fork Tolt Project is consistent with this policy.

In January 1992, BPA issued a draft 1992 Resource Program. This program recommended the development of new resources in addition to those outlined in the 1990 Resource Program.

B. Environmental Permits, Licenses, Consultations, and Mitigation Agreements

BPA reviewed the status of all Project permits and licenses (including environmental mitigation requirements of the FERC permit), consultations by SCL to satisfy areawide, state, and local environmental plans and programs, and environmental mitigation plans to assure that all environmental requirements are addressed. Development of the proposed South Fork Tolt Project would be consistent with environmental policies established by NEPA (FERC 1987), by the Washington SEPA (SCL 1980), and by the 1980 Power Act, and would be consistent with the requirements of the 1991 Power Plan (NPPC 1991) as indicated in the South Fork Tolt River Hydroelectric Project Attachment adopted by DOE July 1992.

1. Endangered and Threatened Species and Critical Habitat

Of the threatened and endangered plant and animal species in the Snohomish River Basin listed in the FERC Final EIS (1987), only the bald eagle and fringed pinesap were listed as being potentially impacted by the Project. Based on an SCL wintering bald eagle survey, a response letter from the U.S. Fish and Wildlife Service, requirements for enhancement of anadromous fish addressed by paragraph 3.1.1 of the Settlement Agreement, and subsequent commitment that any impact will be mitigated, adequate protection of bald eagles for the South Fork Tolt Project has been effected.

The 1987 FERC Final EIS and surveys of mature forests in 1991 indicated no significant habitat for threatened or endangered plants, including the fringed pinesap, exists in the construction area. SCL has indicated their intent to follow through with all recommendations of the FERC Final EIS and incorporate specific considerations in the SCL construction plans and procedures as appropriate. Therefore, adequate protection of endangered or threatened flora is achieved.

The spotted owl, listed by Washington State as a threatened species and so treated in the 1987 FERC Final EIS, is now federally listed as endangered. Based on post-1987 work, most recently a site survey in January 1992, there are no old-growth stands and too few old-growth trees in the Project area for use by species requiring large contiguous areas of old-growth for nesting. No impact on the spotted owl is expected from the Project.

2. Fish and Wildlife Conservation

Based on the 1988 FERC license, the Northwest Power Planning Council does not consider the South Fork Tolt Project to be subject to the Council's protected area rule for two reasons. The Project license preceded the designation of the area as protected in the August 1986 Council Power Plan and the Project is at an existing hydro facility which renders it exempt from the ruling.

SCL and the Tolt River Fisheries Advisory Committee (TFAC), which includes representatives from the National Marine Fisheries Service, U.S. Fish and Wildlife Service, the Tulalip Tribes, and Washington Departments of Fisheries and Wildlife, developed the South Fork Tolt Settlement Agreement

to establish minimum stream flows required to ensure protection and enhancement of fishery and wildlife resources as required by the FERC license The Settlement Agreement was signed in 1988.

The FERC affirmed the Settlement Agreement flow rates, ramping rates, survey activities, and requirements for an Erosion and Sediment Control Plan (ESCP).

The ESCP will define procedures for control of erosion during construction and addresses secondary environmental concerns including dust control, hazardous and non-hazardous materials handling and disposal, and machine wash-down. When the TFAC review of the draft ESCP is completed in late December 1992, any needed changes will be made and the ESCP submitted to FERC.

3. Cultural Resources

No adverse impacts to cultural resources were identified in the adopted portions of the FERC Final EIS (2.3.7) or by the Tribes since that time.

4. State, Area-wide, and Local Plan and Program Consistency

The FERC Final EIS identified permits or procedures associated with siting of the South Fork Tolt Project. Most of the permits have been addressed by SCL. Several additional permits (Puget Sound Air Pollution Control Agency (PSAPCA) Air Quality, Washington Department of Ecology Coastal Zone Program) not indicated in the FERC Final EIS are now identified by and will be completed by SCL prior to construction.

5. Coastal Management Program Consistency

The South Fork Tolt Project requires review and permitting for compliance with the Coastal Zone Management Program. King County's Shoreline Substantial Development Permit (SSDP) is the lead document in this process. Washington Department of Ecology will issue its Coastal Zone Certification based on the findings of the King County SSDP. SCL is currently working with King County on a Memorandum of Agreement that will indicate what is needed to complete requirements for a shoreline permit.

6. Floodplains

DOE finds there is no practicable alternative to locating parts of the proposed project (return flow conduit and energy dissipation structure) within the floodplains, consistent with the policy set forth in Executive Order 11988. Erosion and sediment control procedures mandated by the Settlement Agreement will address landslides in the construction areas. No other proposed construction should impact the floodplain.

7 Wetlands

There would be no significant impact to wetlands. The new penstock would cross the South Fork Tolt River and a number of creeks, and the energy dissipation structure would be located along the edge of the South Fork Tolt River. The South Fork Tolt River Hydroelectric Project Attachment discusses potential environmental impacts and mitigation measures in sections 3.1.3 and 3.1.4. The impacts and mitigation measures are consistent with those identified in the FERC Final EIS (4.2.1.1.4, Adopted Portions, 3.2.4).

There are no wetlands located near the new transmission line between Kelly Road and the new Puget Power substation would cross Harris Creek and Stossel Creek. Stossel Creek is a designated wetland. This area will not be disturbed because SCL intends to span the wetlands.

8. Recreation Resources

Recreational resources will not be adversely affected by the South Fork Tolt Project, since areas within the hydrographic boundary of the watershed area and water diversion areas will continue to be closed to the public. SCL consulted with the U.S. Forest Service, National Park Service, Washington State Parks and Recreation Commission, Washington Department of Wildlife, King County Parks Division, and Weyerhaeuser in developing an alternative mitigation plan for recreation. The proposed mitigation recreational plan includes:

1. SCL will provide financial support of $220,000 for development of the 175-acre Moss Lake wetlands, located about 3 miles west of the existing South Fork Tolt dam, in conjunction with King County Parks.

2. SCL will provide financial support of $110,000 for development of a trailhead and parking lot on the Middle Fork of the Snoqualmie River. The trailhead will eventually provide access to a 35-mile USFS trail system.

A Memorandum of Agreement (MOA) for mitigating recreational activities must be signed by SCL, King County Parks, and USFS and submitted to FERC upon completion. The completed MOA should provide adequate mitigation for loss of recreational resources of the South Fork Tolt Project.

9. Global Warming

The South Fork Tolt Project will utilize only non-fossil fuel sources in the generation of electricity and would not contribute to global warming.

10. Permit for Structures on Navigable Waters

The U.S. Army Corps of Engineers (ACOE 1991) considers the South Fork Tolt River non-navigable. Permits required under section 10 of the Rivers and Harbors Act, 33 U.S.C. 403, do not apply.

11. Permit for Discharges Into the Waters of the United States

The permit process under Section 404 of the Clean Water Act, 33 U.S.C., is likely to be required for the South Fork Tolt Project. The project developer is expected to obtain the 404 Permit, if required, upon completion of the project final design. Should a 404 Permit be required, the Washington Department of Ecology, Shorelines and Coastal Zone Management office states that the licensee should pay strict attention to the prerequisite permits for the 404 Permit process (WDOE 1992). Review for the 404 Permit by the Corps of Engineers requires that the Shoreline Substantial Development Permit, the WDOE Coastal Zone Management Certification, and the 401 Clean Water Certification all be previously prepared. WDOE states that typical times to obtain the Shoreline Permit is 9 months to 2 years depending on the need for public participation. WDOE also states that a Coastal Zone Management Permit takes only several days since WDOE used the county process as the basis of their decision making. The 401 certification was obtained in January 1983; however, SCL applied in September 1992 for an updated permit.

12. Permit for Right-of-Way on Public Lands

The South Fork Tolt Project includes use of State Forest lands at river crossings. A Lease of State Lands Permit is identified in the FERC Final EIS (Table 4–4) with the Washington Department of Natural Resources as the responsible agency. Obtaining this permit is not expected to be difficult.

13. Energy Conservation at Federal Facilities

The South Fork Tolt Project includes no Federal facilities or buildings.

14. Pollution Control

SCL has identified current procedures to be used during the Project construction to achieve compliance with Federal, state, and local regulations and ordinances relating to procurement of goods and services from EPA listed facilities, clean air standards, water

quality standards, solid waste disposal, hazardous waste handling and disposal, drinking water standards, noise abatement, pesticide control, asbestos, Toxic Substance Control Act, 1980 Comprehensive Environmental Response Compensation and Liability Act, and radon (SCL 1992).

IV. Monitoring and Enforcement

The project developer has or will have mitigation agreements including an Erosion and Sediment Control Plan (ESCP), recreation mitigation agreements, and South Fork Tolt Settlement Agreement to ensure protection and enhancement of fishery and wildlife resources.

Issued in Portland, Oregon, on December 17, 1992.

John S. Robertson,

Deputy Administrator.

[FR Doc. 93–551 Filed 1–11–93; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket No. JD93–02317T Texas–93]

State of Texas; NGPA Notice of Determination by Jurisdictional Agency Designating Tight Formation

January 6, 1993.

Take notice that on December 28, 1992, the Railroad Commission of Texas (Texas) submitted the above-referenced notice of determination pursuant to § 271.703(c)(3) of the Commission's regulations, that the Second Escondido Formation underlying a portion of Webb County, Texas, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978. The designated area is within Railroad Commission District 4 and includes the following surveys:

Survey	Abstract
A.B.&M.	A–402
A.B.&M.	A–406
I.&G.N. R.R.	A–428
J.B. Owens	A–2748
J.B. Owens	A–2749
I.G. Gomez	A–3096
M. Riojas	A–2660

The notice of determination also contains Texas' findings that the referenced portion of the Second Escondido Formation meets the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–656 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TM93–3–48–000]

ANR Pipeline Company; Proposed Changes in FERC Gas Tariff

January 6, 1993.

Take notice that ANR Pipeline Company ("ANR"), on December 31, 1992 tendered for filing as part of its First Revised Volume Nos. 1 and 1–A and Original Volume Nos. 2 and 3 of its FERC Gas Tariff, the tariff sheets listed on Attachment A to the filing.

ANR states that the referenced tariff sheets are being submitted as part of ANR's Fourth Annual Reconciliation of buyout buydown costs being recovered by means of Volumetric Buyout Buydown Surcharges and Fixed Monthly Charges contained in Docket Nos. RP91–33, *et al.*, RP91–192, RP92–4, RP92–199 and RP93–29. ANR has requested that the Commission accept the tendered tariff sheets to become effective February 1, 1993.

ANR states that a copy of this filing, or such applicable parts, has been mailed to all of its Volume Nos. 1, 1–A, 2 and 3 customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Commission, 825 N. Capitol Street, NE., Washington, DC 20426 by January 13, 1993, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene . Copies of this application are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–653 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RS92–14–000]

CNG Transmission Corporation; Notice of Conference

January 6, 1993.

Take notice that a conference will be held in this proceeding on Friday, January 15, 1993, at 10 a.m., at the offices of Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC. The purpose of the conference is to discuss CNG's compliance filing under Order Nos. 636 and 636–A and the comments on that filing. All parties and the Commission Staff are invited to attend. For additional information, contact William J. Collins at (202) 208–0248.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–657 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–185–003]

El Paso Natural Gas Co.; Notice of Compliance Filing

January 6, 1993.

Take notice that on December 30, 1992, El Paso Natural Gas Company ("El Paso") filed pursuant to part 154 of the Federal Energy Regulatory Commission ("Commission") Regulations Under the Natural Gas Act, and in compliance with the Commission's order issued December 3, 1992 at Docket Nos. RP92–185–000, 001 and 002 certain tariff sheets to its FERC Gas Tariff, First Revised Volume No. 1–A to become effective February 1, 1993.

El Paso states that ordering paragraph (E) of the Commission's December 3, 1992 order directed El Paso to file, within thirty (30) days of the date of the order, revised tariff sheets incorporating the revisions required by the order. The revisions address primarily the administration of volume imbalances on El Paso's system, such as, cash-out, netting and penalties.

El Paso respectfully requested that the Commission grant such waivers of its applicable rules and regulations as may be necessary to permit the tendered tariff sheets to become effective on February 1, 1993, which is at least thirty (30) days following the date of the filing. El Paso requested that the tariff sheets become effective on the first day of the month inasmuch as business accounting is affected by the revisions proposed. El Paso also states that such action will provide for a clear distinction between old and new imbalances at the beginning of a business month, and ease the administrative burden for El Paso, its customers, and Shippers.

El Paso states that copies of the filing were served upon all parties of record at Docket No. RP92–185–000 and all interested state regulatory commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure 18 CFR 385.211. All such protests should be filed on or before January 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of the filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–647 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TQ93–4–46–000]

Kentucky West Virginia Gas Company; Proposed Change in FERC Gas Tariff

January 6, 1993.

Take notice that Kentucky West Virginia Gas Company (Kentucky West) on January 4, 1993, tendered for filing with the Federal Energy Regulatory Commission (Commission) a Quarterly PGA filing, which includes Forty-Fifth Revised Sheet No. 41 to its FERC Gas Tariff, Second Revised Volume No. 1, to become effective February 1, 1993. The revised tariff sheet reflects a current decrease of $0.3190 per Dth in the average cost of purchased gas resulting in a Weighted Average Cost of Gas of $1.9784 per Dth.

Kentucky West states that effective February 1, 1993, pursuant to its obligations under various gas purchase contracts, it has specified a total price of $1.9850 per Dth, inclusive of all taxes and any other production-related cost add-ons, that it would pay under these contracts.

Kentucky West states that, by its filing, or any request or statement made therein, it does not waive any rights to collect amounts, nor the right to collect carrying charges applicable thereto, to which it is entitled pursuant to the mandate of the United States Court of Appeals for the Fifth Circuit issued on March 6, 1986, in *Kentucky West Virginia Gas Co.* v. *FERC*, 780 F.2d 1231 (5th Cir. 1986), or to which it is or becomes entitled pursuant to any other judicial and/or administrative decisions.

Kentucky West states that a copy of its filing has been served upon each of its jurisdictional customers and interested state commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–652 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–60–000]

National Fuel Gas Supply Corporation; Petition To Waive Tariff Provision

January 6, 1993.

Take notice that on December 31, 1992 National Fuel Gas Supply Corporation ("National") filed a Petition For Waiver of a provision of Rate Schedule IT.

The proposed effective date of the waiver is January 31, 1993.

National requests a waiver of Subsection 4.5 of National's IT Rate Schedule as necessary to prevent automatic reductions of IT Shippers' Maximum Daily Transportation Quantities ("MDTQ"), until the effective date of tariff sheets approved by the Commission as a compliance filing by National under Order No. 636, or until such earlier time as the Commission may order. National proposes an effective date of January 31, 1993 for this waiver, to prevent the automatic reductions from taking effect.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20428, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure 18 CFR 385.211 and 395.214. All such motions or protests should be filed on or before January 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–651 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TQ93–2–86–000]

Pacific Gas Transmission Company; Change in Sales Rates Pursuant to Purchased Gas Adjustment

January 6, 1993.

Take notice that on December 31, 1992, Pacific Gas Transmission Company (PGT) submitted for filing pursuant to Part 154 of the Federal Energy Regulatory Commission's (Commission) regulations a proposed change in rates applicable to service rendered under Rate Schedule PL–1, affected by and subject to Paragraph 21, "Purchased Gas Cost Adjustment" (PGA) of the General Terms and Conditions of its FERC Gas Tariff, Second Revised Volume No. 1. Such rates are proposed to become effective February 1, 1993.

PGT states that copies of the filing is being served upon all affected jurisdictional sales customers and interested state commissions.

Any person desiring to be heard or protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before January 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–654 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TA93–1–28–000 and TM93–3–28–000]

Panhandle Eastern Pipe Line Co.; Proposed Changes in FERC Gas Tariff

January 6, 1993.

Take notice that Panhandle Eastern Pipe Line Company (Panhandle) on December 31, 1992, tendered for filing the following revised tariff sheets listed to its FERC Gas Tariff, Original Volume No. 1:

Ninety-Fifth Revised Sheet No. 3–A
Ninth Revised Sheet No. 3–A.1
Seventy-Second Revised No. 3–B
Nineteenth Revised Sheet No. 3–B.1

The proposed effective date of these tariff sheets is March 1, 1993.

Panhandle propose that the revised tariff sheets filed herewith reflect a commodity rate decrease of (59.38¢) per Dt. This decrease includes:

(1) A (59.44¢) per Dt. decrease in the projected purchased gas cost component computed in accordance with § 18.2 of the General Terms and Conditions of Panhandle's tariff; and

(2) A (2.52¢) per Dt. decrease in the surcharge to recover the Current Deferred Account Balance at October 31, 1992 and related carrying charges pursuant to § 18.3 of the General Terms and Conditions of Panhandle's tariff; and

(3) A 2.58¢ per Dt. increase pursuant to section 27 of the General Terms and Conditions of Panhandle's tariff (Transportation Cost Adjustment).

Panhandle further states that the revised tariff sheets filed herewith also reflect the following changes to Panhandle's demand rates:

(1) A ($3.25) per Dt. decrease in the surcharge to recover the Current Deferred Balance at October 31, 1992 and related carrying charges pursuant to § 18.4 of the General Terms and Conditions of Panhandle's tariff; and

(2) An increase of $0.21 pursuant to section 27 of the General Terms and Conditions to Panhandle's tariff (Transportation Cost Adjustment).

Panhandle states these changes are being made in accordance with § 154.305 (Annual PGA Filing) of the Commission's Regulations and pursuant to section 18 (Purchased Gas Cost Rate Adjustment) and section 27 (Transportation Cost Adjustment) of Panhandle's FERC Gas Tariff, Original Volume No. 1. Panhandle has included in this filing projected gas purchase volumes from its suppliers for the three (3) month period commencing March 1, 1993, as detailed in Schedule A1.

Panhandle states that copies of its filing have been served on all jurisdictional sales customers and applicable state regulatory agencies.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with such motions §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 22, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–650 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. TA93–1–17–001 and TQ93–3–17–000]

Texas Eastern Transmission Corp.; Notice of Proposed Changes in FERC Gas Tariff

January 6, 1993.

Take notice that Texas Eastern Transmission Corporation (Texas Eastern) on December 31, 1992 tendered for filing as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, six copies each of the tariff sheets listed on Appendices A and B of the filing.

The proposed effective date of the tariff sheets listed on Appendices A and B of the filing is February 1, 1993.

Texas Eastern states that the commodity current adjustment proposed herein is an increase of $0.5326/dth compared to Texas Eastern's last scheduled PGA filing in Docket No. TQ93–2–17 (the November, 1992 Quarterly). The commodity surcharge resulting from this reduced annual sales volume projection is $2.0156/dth. Texas Eastern included alternate tariff sheets which employ the 11¢ commodity surcharge originally set forth in the December 2 Filing.

Texas Eastern states that the commodity current adjustment proposed herein is an increase of $0.5326/dth compared to Texas Eastern's last scheduled PGA filing in Docket No. TQ93–2–17 (the November, 1992 Quarterly). The commodity surcharge resulting from this reduced annual sales volume projection is $2.0156/dth. Texas Eastern included alternate tariff sheets which employ the 11¢ commodity surcharge originally set forth in the December 2 Filing.

Texas Eastern states that copies of the filing were served upon Texas Eastern's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–649 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. TQ93–2–52–000 and 001]

Western Gas Interstate Company; Notice of Proposed Changes in FERC Gas Tariff

January 6, 1993.

Take notice that on December 31, 1992, Western Gas Interstate Company ("Western"), pursuant to section 4 of the Natural Gas Act, the Commission's regulations thereunder and Western's FERC Gas Tariff, tendered for filing proposed changes to its FERC Gas Tariff, Second Revised Volume No. 1. The proposed effective date for the tariff sheet is February 1, 1993.

Western states that, its filing proposes changes to its rates in accordancce with the terms of the Purchased Gas Adjustment Clause of its FERC Gas Tariff.

Western further states that the Tariff sheet proposed to become effective February 1, 1993 is to provide for: (1) A decrease in purchased gas cost under Western's Rate Schedule CD–N of $0.4781 per MMBTU; and (2) a decrease in purchased gas cost under Western's Rate Schedule CD–S of $0.2567 per MMBTU.

Finally, Western states that copies of the filing were served upon Western's transmission system customers and interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a motion

to intervene with the Federal Energy Regulatory Commission, 825 North Capitol Street, NW., Washington, DC 20426, in accordance with §§ 385.211 and 385.214 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–655 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. TQ93–2–49–000 and TM93–4–49–000]

Williston Basin Interstate Pipeline Co.; Notice of Purchased Gas Adjustment Filing

January 6, 1993.

Take notice that on December 31, 1992, Williston Basin Interstate Pipeline Company (Williston Basin), 200 North Third Street, suite 300, Bismarck, North Dakota 58501, tendered for filing as part of its FERC Gas Tariff the following revised tariff sheets:

First Revised Volume No. 1

Forty-seventh Revised Sheet No. 10

Original Volume No. 1–A

Thirty-ninth Revised Sheet No. 11
Forty-fourth Revised Sheet No. 12
Twenty-fourth Revised Sheet No. 97A

Original Volume No. 1–B

Thirty-fifth Revised Sheet No. 10
Thirty-fifth Revised Sheet No. 11

Original Volume No. 2

Forty-sixth Revised Sheet No. 10
Forty-first Revised Sheet No. 11B

The proposed effective date of the tariff sheets is February 1, 1993.

Williston Basin states that Forty-seventh Revised Sheet No. 10 (First Revised Volume No. 1) reflects a decrease in the Current Gas Cost Adjustment applicable to Rate Schedules G–1, SGS–1 and E–1 of 9.055 cents per dkt as compared to that contained in the Company's September 30, 1992 filing in Docket Nos. TQ93–1–49–000 and TM93–2–49–000 which became effective November 1, 1992.

Williston Basin further states that Thirty-ninth Revised Sheet No. 11, Forty-fourth Revised Sheet No. 12 and Twenty-fourth Revised Sheet No. 97A (Original Volume No. 1–A), Thirty-fifth Revised Sheet Nos. 10 and 11 (Original Volume No. 1–B), Forty-sixth Revised Sheet No. 10 and Forty-first Revised Sheet No. 11B (Original Volume No. 2) reflect revisions to the fuel reimbursement charge and percentage components of the Company's relevant gathering, transportation and storage rates as compared to that contained in the Company's September 30, 1992 filing in Docket Nos. TQ93–1–49–000 and TM93–2–49–000.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before January 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party to the proceeding must file a motion to intervene. Copies of the filing are on file with the Commission and are available for public inspection.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 93–648 Filed 1–11–93; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–4553–7]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected cost and burden; where appropriate, it includes the actual data collection instrument.

DATES: Comments must be submitted on or before February 11, 1993.

FOR FURTHER INFORMATION OR TO OBTAIN A COPY OF THIS ICR, CONTACT: Ms. Sandy Farmer at EPA, (202) 260–2740.

SUPPLEMENTARY INFORMATION:

Office of Air and Radiation

Title: New Source Performance Standards (NSPS) for Bulk Gasoline Terminals (Subpart XX)–Information Requirements (EPA ICR No. 0664.04; OMB No. 2060–0006). This is a request for renewal of a currently approved information collection.

Abstract: Owners and operators of all bulk gasoline terminals with a daily throughput greater than 75,500 liters per day that commenced construction or modification after December 17, 1980, are required to notify EPA or the State regulatory authority of construction, modifications, startups, shutdowns, and malfunctions, and the date and results of the initial performance test. Each owner/operator must record the identification number of each gasoline tank truck loaded, and must record any leak detected during monthly inspections. The notifications and reports enable EPA or the delegated authority to determine that best demonstrated technology is installed and properly operated and maintained and to schedule inspections.

Burden Statement: The public reporting burden for this collection of information is estimated to average 16 hours per response for reporting, and 285 hours per recordkeeper annually. This estimate includes the time needed to review instructions, search existing data sources, gather the data needed and review the collection of information.

Respondents: Owners and operators of bulk gasoline terminals.

Estimated Number. of Respondents: 3.

Estimated Number of Responses Per Respondent: 5.

Estimated Number of Recordkeepers: 45.

Estimated Total Annual Burden on Respondents: 13,091 hours.

Frequency of Collection: On occasion.

Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to:

Ms. Sandy Farmer, U.S. Environmental Protection Agency,Information Policy Branch (PM–223Y), 401 M Street, SW.,Washington, DC, 20460.

and

Mr. Chris Wolz, Office of Management and Budget, Office of Information and Regulatory Affairs, 725 17th Street, NW.,Washington, DC, 20503.

Dated: January 6, 1993.

Paul Lapsley,

Director, Regulatory Management Division.

[FR Doc. 93–642 Filed 1–11–93; 8:45 am]

BILLING CODE 6560–50–F

[OPPTS-40024; FRL-4181-5]

Conditional Exemptions From TSCA Section 4 Test Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is granting conditional exemptions from Toxic Substances Control Act (TSCA) section 4 Test Rule requirements to certain manufacturers of chemicals substances subject to these rules.

DATES: These conditional exemptions are effective on January 12, 1993.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS-799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551.

SUPPLEMENTARY INFORMATION: This notice grants conditional exemptions from TSCA section 4 test rule requirements to all manufacturers of the chemical substances identified below who submitted exemption applications in accordance with 40 CFR 790.80. In each case, EPA has received a letter of intent to conduct the testing from which exemption is sought. Accordingly, the Agency has conditionally approved these exemption applications because the conditions set out in 40 CFR 790.87 have been met. All conditional exemptions thus granted are contingent upon successful completion of testing and submission of data by the test sponsors according to the requirements of the applicable test rule.

If the test requirements are not met and EPA terminates a conditional exemption under 40 CFR 790.93, the Agency will notify each holder of an affected conditional exemption by certified mail or **Federal Register** notice.

This conditional approval applies to all manufacturers who submitted exemption applications for testing of chemical substances named in the final test rules listed below as of the date of this notice. Any application received after that date will be addressed separately.

Chemicals	CAS No.	CFR citation	Company
C9 aromatic hydrocarbon 1,2,4-trimethylbenzene	95-63-6	799.2175	BYK-Chemie USA. The Glidden Company.
cresols, *o*-cresol, *p*-cresol	95-48-7 106-44-5	799.1250	The Glidden Company. The Proctor and Gamble Company.
cumene	98-82-8	799.1285	BYK-Chemie USA. The Glidden Company.
diethylene glycol butyl ether	112-34-5	799.1560	The Glidden Company.
diethylenetriamine	111-40-0	799.1575	CBI.
2-ethylhexanoic acid	149-57-5	799.1650	The Glidden Company.
fluoroalkenes vinylidene fluoride	75-38-7	799.1700	Ausimont U.S.A., Inc.
isopropanol	67-63-0	799.2325	The Glidden Company.
2-mercaptobenzothiazole	149-30-4	799.2475	Prochimie International, Inc.
methyl ethyl ketoxime	96-29-7	799.2700	The Glidden Company. Troy Corporation Inc. Dura Chemical Corporation Ltd.
oleylamine 9-octadecenylamine	112-90-3	799.3175	CBI.
tetrabromobisphenol A	79-94-7	799.4000	Plaskon Electronic Materials, Inc.

As provided in 40 CFR 790.80, processors are not required to apply for an exemption or conduct testing unless EPA so specifies in a test rule or in a special **Federal Register** notice.

Authority: 15 U.S.C. 2601,2603.

Dated: January 5, 1993.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

[FR Doc. 93-641 Filed 1-11-93; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed; Port of Houston/Fairway Terminal Corp., et al.

The Federal Maritime Commission hereby gives notice that the following agreement(s) has been filed with the Commission pursuant to section 15 of the Shipping Act, 1916, and section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments and protests are found in § 560.602 and/or 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the agreement at the address shown below.

Agreement No.: 224-200714.

Title: Port of Houston/Fairway Terminal Corporation Assessment Agreement.

Parties: The Port of Houston Authority ("Port") Fairway Terminal Corporation ("Fairway").

Filing Agent: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas.

Synopsis: The Agreement establishes a facility assignment between the Port and Fairway, whereby Fairway will perform freight handling services at the Port's Barbours Cut Transit Shed Number One Section B (West to Pole Number Seven), for loading cargo onto, or unloading cargo from railroad cars and motor vehicles, allocating space within the facility to accommodate cargo of ships assigned to berth and the facility by Port, and such other

incidental services necessary to expedite the movement of cargo between vessels and land carriers. The term of the Agreement is for two years.

Agreement No.: 224–200717.

Title: Port of Houston/Strachan Shipping Company Guarantee Assignment Agreement.

Parties: The Port of Houston Authority ("Port") Strachan Shipping Company ("Strachan").

Filing Agent: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas.

Synopsis: The Agreement establishes a facility assignment between the Port and Strachan, whereby Strachan will perform freight handling services at the Port's Open & Shed Areas Number 24E through 26, for loading cargo onto, or unloading cargo from railroad cars and motor vehicles, allocating space within the facility to accommodate cargo of ships assigned to berth and the facility by Port, and such other incidental services necessary to expedite the movement of cargo between vessels and land carriers. The term of the Agreement is for two years.

Agreement No.: 224–200722.

Title: Port of Houston/Shippers Stevedoring Company Guarantee Assignment Agreement.

Parties: The Port of Houston Authority ("Port") Shippers Stevedoring Company ("Shippers").

Filing Agent: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas.

Synopsis: The Agreement establishes freight handling services to be performed by Shippers at the Port's Open & Shed Areas Number 31. Shippers will load cargo onto, or unload cargo from railroad cars and motor vehicles, allocate space within the facility to accommodate cargo of ships assigned to berth and the facility by Port, and such other incidental services necessary to expedite the movement of cargo between vessels and land carriers. The term of the Agreement is for two years.

Agreement No.: 224–200723.

Title: Port of Houston/Shippers Stevedoring Company Assessment Assignment Agreement.

Parties: The Port of Houston Authority ("Port") Shippers Stevedoring Company ("Shippers").

Filing Agent: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas.

Synopsis: The Agreement establishes freight handling services to be performed by Shippers at the Port's Barbours Cut Transit Sheds Number Two Section A (East). Shippers will load cargo onto, or unload cargo from railroad cars and motor vehicles, allocate space within the facility to accommodate cargo of ships assigned to berth and the facility by Port, and such other incidental services necessary to expedite the movement of cargo between vessels and land carriers. The term of the Agreement is for two years.

Agreement No.: 224–200724.

Title: Port of Houston/Fairway Terminal Corporation Guarantee Assignment Agreement.

Parties: The Port of Houston Authority ("Port") Fairway Terminal Corporation ("Fairway").

Filing Agent: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas.

Synopsis: The Agreement establishes freight handling services to be performed by Fairway at the Port's Open & Shed Areas Number 27 through 29, for the loading of cargo onto, or the unloading of cargo from railroad cars and motor vehicles, to allocate space within the facility to accommodate cargo of ships assigned to berth and the facility by Port, and such other incidental services necessary to expedite the movement of cargo between vessels and land carriers. The term of the Agreement is for two years.

By Order of the Federal Maritime Commission.

Dated: January 6, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 93–584 Filed 1–11–93; 8:45 am]

BILLING CODE 6730–01–M

Notice of Agreement(s) Filed; Mississippi Department of Economic and Community Development, et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224–200725.

Title: Mississippi Department of Economic and Community Development/Mississippi State Port Authority at Gulfport/Dole Fresh Fruit Company Lease Agreement.

Parties: The Mississippi Department of Economic and Community Development ("MD of Econ. & Comm. Develop."). The Mississippi State Port Authority at Gulfport ("MSPA"). Dole Fresh Fruit Company ("Dole").

Synopsis: The Agreement provides for Dole to lease from MD of Econ. & Comm. Develop. and MSPA an area of approximately 2063 acres at the Banana Terminal located at the North Base of East Pier and Shed No. 53 located on East Pier for the purpose of operating a cargo terminal. The term of the lease is for ten years.

Agreement No.: 202–010776–073.

Title: Asia North America Eastbound Rate Agreement.

Parties: American President Lines, Ltd., Kawasaki Kisen Kaisha, Ltd., A.P. Moller-Maersk Line, Mitsui O.S.K. Lines. Ltd., Neptune Orient Lines, Ltd., Nippon Yusen Kaisha Line, Orient Overseas Container Line, Ltd., Sea-Land Service, Inc.

Synopsis: The proposed amendment modifies the agreement authority to permit the parties to agree upon the rates, terms and conditions of their arrangements with non-Agreement transportation providers with respect to cargoes originating in the People's Republic of China.

By Order of the Federal Maritime Commission.

Dated: January 6, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 93–573 Filed 1–11–93; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

The Bank of Montreal, Bankmont Financial Corp., and Harris Bankcorp, Inc.; Application to Engage in Nonbanking Activities

The Bank of Montreal, Montreal, Quebec, Canada, Bankmont Financial Corp., New York, New York, and Harris Bankcorp, Inc., Chicago, Illinois (collectively, Applicants), have applied pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) (BHC Act) and § 225.23(a)(3) of the Board's Regulation Y (12 CFR 225.23(a)(3)) to engage *de novo* through

a wholly owned subsidiary, Harris Futures Corporation, Chicago, Illinois (Company), a futures commission merchant registered under the Commodity Exchange Act (7 U.S.C. § 1 *et seq.*), in clearing only, and in clearing and executing, as agent for institutional customers, including managed commodity pools, futures contracts and options on futures contracts in the following commodities on the following exchanges: No. 2 Heating Oil and Light Sweet Crude Oil on the New York Mercantile Exchange; Corn, Wheat and Soybeans on the Chicago Board of Trade; and Live Cattle, Feeder Cattle and Live Hogs on the Chicago Mercantile Exchange. Applicants propose to conduct these activities throughout the United States and the world.

Section 4(c)(8) of the BHC Act provides that a bank holding company may, with Board approval, engage in any activity which the Board, after due notice and opportunity for hearing, has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be a proper incident thereto. This statutory test requires that two separate tests be met for an activity to be permissible for a bank holding company. First, the Board must determine that the activity is, as a general matter, closely related to banking. Second, the Board must find in a particular case that the performance of the activity by the applicant bank holding company may reasonably be expected to produce public benefits that outweigh possible adverse effects.

A particular activity may be found to meet the "closely related to banking" test if it is demonstrated that banks have generally provided the proposed activity; that banks generally provide services that are operationally or functionally similar to the proposed activity so as to equip them particularly well to provide the proposed activity; or that banks generally provide services that are so integrally related to the proposed activity as to require their provision in a specialized form. *National Courier Ass'n v. Board of Governors*, 516 F.2d 1229, 1237 (DC Cir. 1975). In addition, the Board may consider any other basis that may demonstrate that the activity has a reasonable or close relationship to banking or managing or controlling banks. Board Statement Regarding Regulation Y, 49 Federal Register 806 (1984).

Applicants believe that the proposed activities are closely related to banking or managing or controlling banks. The Board has previously approved, by regulation and order, acting as a futures commission merchant in the execution and clearance on major commodity exchanges of futures contracts and options on futures contracts in financial commodities, such as gold and silver bullion and coins, foreign exchange, government securities, certificates of deposit and money market instruments that banks may buy and sell for their own accounts, and stock and bond indices, as well as providing related investment advice. *See* 12 CFR 225.25(b)(18), (19); *Republic New York Corporation*, 63 Federal Reserve Bulletin 951 (1977); *The Sanwa Bank, Limited*, 74 Federal Reserve Bulletin 578 (1988); *The Long-Term Credit Bank of Japan, Limited*, 74 Federal Reserve Bulletin 573 (1988). The Board has also previously approved, by order, the provision of investment advice with respect to trading futures and options on futures in non-financial commodities, such as agricultural and energy commodities. *See* Swiss Bank Corporation, 77 Federal Reserve Bulletin 126 (1991).

The Board has not previously approved the proposed activities with respect to futures and options on futures in non-financial commodities. Applicants assert that the proposed activities are essentially identical to the those activities previously approved by the Board. In this regard, Applicants believe that the execution and clearance of futures and options on futures in financial and non-financial commodities is functionally indistinguishable. Furthermore, Applicants state that the volatility of non-financial futures and options is no greater than that for financial futures and options. Applicants also believe that Company's extensive experience in trading futures and options on futures in financial commodities makes it particularly well suited to engage in the proposed activities in non-financial commodities.

In order to satisfy the proper incident to banking test, section 4(c)(8) of the BHC Act requires the Board to find that the performance of the activities by Company can reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices. Applicants believe that the proposed activities will benefit the public by promoting competition. Applicants also believe that approval of this application will allow Company to provide a wider range of services and added convenience to its customers, and to offer its customers securities not otherwise available for purchase in the United States. Applicants believe that the proposed activities will not result in any unsound banking practices or other adverse effects.

In publishing the proposal for comment, the Board does not take a position on issues raised by the proposal. Notice of the proposal is published solely in order to seek the views of interested persons on the issues presented by the application and does not represent a determination by the Board that the proposal meets, or is likely to meet, the standards of the BHC Act.

Any comments or requests for hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551, not later than February 10, 1993. Any request for a hearing on this application must, as required by § 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accompanied by a statement of the reasons why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of Chicago.

Board of Governors of the Federal Reserve System, January 6, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–634 Filed 1–11–93; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Ambulatory and Hospital Care Statistics: Meeting

Pursuant to Public Law 92–463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following meeting.

Name: NCVHS Subcommittee on Ambulatory and Hospital Care Statistics.

Time and Date: 9:30 a.m.–5 p.m., January 28, 1993.

Place: Room 5051, Cohen Building, 330 Independence Avenue, SW., Washington, DC 20201.

Status: Open.

Purpose: The subcommittee will consider responses to its proposed revision of the Uniform Hospital Discharge Data Set (UHDDS), review the status of the Interagency Task Force on the UHDDS, and consider other issues included in its charge.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: January 6, 1993.

Robert L. Foster,

Assistant Director, Office of Program Support, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–586 Filed 1–11–93; 8:45 am]

BILLING CODE 4160–18–M

National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Medical Classification Systems: Meeting

Pursuant to Public Law 92–463, the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following meeting.

Name: NCVHS Subcommittee on Medical Classification Systems.

Time and date: 9 a.m.–5 p.m., January 27, 1993.

Place: Room 703A–729A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Status: Open.

Purpose: The subcommittee will hold a morning working session to review the feasibility of a single procedure classification system. The afternoon session will include briefings on the International Classification of Impairments, Disabilities, and Handicaps (ICIDH) and a Health Care Financing Administration project concerning revisions to the International Classification of Diseases 9th Revision, Clinical Modification (ICD–9–CM) V57 codes (care involving use of rehabilitation procedures).

CONTACT PERSON FOR MORE INFORMATION: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050.

Dated: January 6, 1993.

Robert L. Foster,

Assistant Director, Office of Program Support, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–587 Filed 1–11–93; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 92D–0380]

Draft Guidance to Manufacturers of In Vitro Analytical Test Systems for Preparation of Premarket Submissions Implementing the Clinical Laboratory Improvement Amendments of 1988; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is making available for public comment a draft document which provides guidance to manufacturers of in vitro diagnostic devices and biologics on when and how to obtain complexity categorizations and FDA clearance of quality control (QC) instructions for use by clinical laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578). In addition, as set forth in the draft guidance document, FDA is announcing that it will be considering QC validation when it conducts its premarket review of new in vitro diagnostic products, effective upon issuance of a final guidance.

DATES: Submit written comments by March 15, 1993.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Division of Small Manufacturers Assistance (DSMA) (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 or 1–800–638–2041. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. In addition, DSMA will mail a copy to each manufacturer whose establishment is registered with FDA.

FOR FURTHER INFORMATION CONTACT: Jan Ohrmundt, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1005.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 28, 1992 (57 FR 7002), the Department of Health and Human Services (DHHS) issued the laboratory standards regulations under CLIA. These regulations require that all laboratories in the United States and its territories that examine human specimens meet specific laboratory standards based on the complexity of tests which the laboratories perform. Among these standards is one for QC of testing. (See 42 CFR part 493, subpart K).

In response to comments on the proposed laboratory standards regulations of May 21, 1990 (55 FR 20896), DHHS integrated FDA's premarket review responsibilities for in vitro diagnostic devices and biologics under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321–394) and the Public Health Service Act (the PHS Act) (42 U.S.C. 351) into CLIA's regulatory scheme for laboratories by providing that manufacturers can request clearance of validated QC instructions from FDA (57 FR 7002 at 7057 and 7058). If the QC instructions are cleared by FDA, clinical laboratories can then use the manufacturer's QC instructions to satisfy a significant portion of the QC requirements of the laboratory standards rule (42 CFR 493.1203). (FDA clearance is signified by appearance of the statement set out in 42 CFR 493.1201 (CLIA statement) in the device labeling). In addition, the final rule provides that FDA will be making the complexity categorization decisions for new in vitro diagnostic products (42 CFR 493.17(c)).

II. FDA Implementation

As indicated in the preamble to the final laboratory standards regulation (57 FR 7002 at 7057 and 7058), FDA is administering these QC review and clearance functions by incorporating them into its existing premarket evaluation processes for in vitro diagnostic devices and biologics. In addition, for new products, FDA is announcing that, if CLIA clearance is not requested by the manufacturer (see

section II.A. of this document), the agency will be conducting a QC review as part of its review of premarket notification submissions and premarket approval applications (PMA's) for devices under sections 510(k) (21 U.S.C. 360(k)) and 515 of the act (21 U.S.C. 360e) and its review of product license applications (PLA) under section 351 of the PHS Act (42 U.S.C. 262) (hereinafter collectively referred to as premarket review). In brief, the draft guidance identifies: (1) Generally, what products (devices and biologics) will be subject to QC review and clearance, (2) the procedures for obtaining a CLIA QC review and clearance, (3) when FDA will otherwise perform a QC review, (4) what data should be gathered to adequately validate QC and how those data should be presented to the agency, and (5) when and how to obtain a complexity categorization or recategorization.

A. QC Review

1. Products subject to QC review

As set out above and in the draft guidance, FDA will be conducting QC reviews as part of its premarket review responsibilities for devices and biologics.

Accordingly, FDA has determined that it will not conduct QC reviews for those in vitro diagnostic devices that are exempt from section 510(k) of the act by a regulation under section 510(g) of the act. Further, FDA will not perform a QC review for "investigational" products (i.e., devices or biologics being distributed under the research or investigational exemptions in 21 CFR 809.10(c), the investigational device exemptions in 21 CFR part 812, or the investigational new drug exemptions in 21 CFR part 312) until a full premarket submission is submitted under the act or the PHS Act. FDA does not believe it would be appropriate to review devices under CLIA and permit a manufacturer to include the CLIA statement in its labeling when FDA has not yet determined that the device or biologic is safe and effective.

In addition, because the purpose of QC is to monitor an assay that produces an analytical result in order to report the result as valid, FDA has determined that it would make little sense to perform QC reviews for products (e.g., calibrators, controls, or accessories) that do not on their own, produce an analytical result. Thus, FDA will not conduct QC reviews for devices or biologics that do not constitute analytical test systems as that term is defined in the draft guidance.

2. CLIA clearance

Due to restrictions inherent in the mechanisms being employed to fund FDA's CLIA QC and categorization functions, it is necessary for bookkeeping purposes for manufacturers to specifically request a CLIA QC clearance in their submission to FDA if they want to place the CLIA statement in their labeling. Those manufacturers that do not specifically request clearance for CLIA purposes in the manner specified in the draft guidance will not receive CLIA clearance and cannot include the CLIA statement in their labeling (even if FDA clears or approves the product under the act or approves a license application for the product under the PHS Act). To ensure that there is no confusion, FDA's action correspondence will be revised to reflect these new factors.

3. QC under the act and the PHS Act

As noted above, FDA is announcing that it will conduct a QC review as part of its premarket review for all new in vitro diagnostic devices or biologics, even when manufacturers or sponsors do not request CLIA QC clearance in their submissions to FDA. This policy will be effective beginning 90 days after the guidance document is issued in final form.

This action is consistent with the agency's recent efforts to improve the quality of the device premarket review process. FDA therefore believes that it is appropriate that a QC validation assessment occur along with the performance evaluation for the purposes of product clearance, approval, or licensure. Presently, FDA's labeling regulations require that manufacturers provide information in the labeling on QC procedures and materials for device users. (See 21 CFR parts 650, 801, and 809.) Section 502(a) and (f)(1) of the act (21 U.S.C 352(a) and (f)(1)) do prohibit manufacturers from making unsubstantiated performance claims for their products and require that manufacturers provide adequate directions for use. (See *United States* v. *An Article of Device * * * Toftness Radiation Detector*, 731 F.2d 1253 (7th Cir. 1984).) Nevertheless, FDA has concluded that it is appropriate to determine the validity of this QC information in the context of the device's performance characteristics as determined by the manufacturer because specific performance characteristics such as accuracy, precision, specificity, and sensitivity have a direct bearing on the QC instructions recommended. FDA has thus determined that assessment of the adequacy of the QC instructions and the supporting data is relevant to FDA's evaluation of analytical performance characteristics claims and, thus, should also be relevant to FDA's ultimate determination concerning substantial equivalence, approval, or licensure.

FDA notes that the submission of deficient QC validation data or the submission of QC validation data that is inconsistent with performance claims thus may result in the agency's failure to approve a PMA or PLA or a finding that the product is "not substantially equivalent" in the case of a premarket notification (510(k)), as well as misbranded under section 502(a) and (f)(1) of the act.

4. QC instructions and supporting data

The draft guidance also sets forth the kinds of information that should be included in QC instructions and the kinds of data that are appropriate for validating QC instructions. As set out in the document, the kinds of data that FDA will look for will vary depending on whether the product has already passed through one of FDA's clearance processes or whether it is a totally new product (i.e., a product that has never passed through any clearance or approval process). Generally, however, QC instructions should be validated with data gathered from laboratories using the product in conjunction with the QC instructions.

In addition, the draft guidance explains how to submit the data to FDA (e.g., PMA or PMA supplement, PLA or PLA amendment, or premarket notification (510(k))), and how to format the data.

B. Complexity

Finally, FDA will also be responsible for complexity categorization and recategorization assignments for devices. The assignments for new devices will be made as part of the premarket review processes. Thus, FDA will not assign complexity categorizations to devices being distributed under any research or investigational exemptions until the manufacturer submits the appropriate premarket submission for FDA clearance, approval, or licensure. (FDA notes that, by operation of the CLIA regulations, all products being distributed under the act's research or investigational exemptions are automatically tests of high complexity (42 CFR 493.17).)

With respect to recategorizations, these requests need not be submitted as part of a premarket notification (510(k)), PMA or PMA supplement, or PLA or PLA amendment. However, as is set out

in the CLIA regulations (42 CFR 493.17(c)(4)), such requests must be based on new information (i.e., information not previously submitted to FDA in any form), and can be submitted for a product no more than once a year.

FDA will notify manufacturers of the availability of the final guidance by notice in the **Federal Register**. This notice will also indicate when FDA will begin receiving premarket submissions for quality control validation assessment. FDA anticipates that this date will be 90 days from the date of the publication in the **Federal Register** of the notice of availability of the final guidance.

Interested persons may, on or before March 15, 1993, submit to the Dockets Management Branch (address above) written comments on the draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 6, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–635 Filed 1–11–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 92N–0489]

Taxol; Environmental Assessments and Finding of No Significant Impact

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received environmental assessments (EA's) and issued a finding of no significant impact (FONSI) relating to the approval of a new drug application (NDA) for the drug product Taxol (paclitaxel) extracted from the Pacific Yew tree (*Taxus brevifolia*). FDA is publishing this notice because Federal regulations require this information to be available to the public for inspection.

ADDRESSES: The EA's and the FONSI may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christina L. Good, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8049.

SUPPLEMENTARY INFORMATION: The National Environmental Policy Act (NEPA) requires all Federal agencies to "use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans." (See 42 U.S.C. 4331(a).) Under section 102 of the NEPA, all Federal agencies must prepare detailed statements assessing the possible environmental impact of, and alternatives to, major Federal actions significantly affecting the environment, and such statements are to be made available to the public. (See 42 U.S.C. 4332, 21 CFR 25.41(b), and 40 CFR 1506.6.)

FDA implements NEPA through its regulations at 21 CFR part 25. Under those regulations, the approval of an NDA usually constitutes an action that ordinarily requires the preparation of an EA. (See 21 CFR 25.22(a)(14).)

FDA recently approved an NDA pertaining to the drug product Taxol (paclitaxel) (NDA 20–262).

The agency has reviewed the EA's submitted for the NDA, has reviewed the draft Environmental Impact Statement (EIS) prepared by the U.S. Forest Service, in cooperation with the U.S. Bureau of Land Management and FDA, for the underlying harvest of Taxol from the Pacific Yew tree (*Taxus brevifolia*), and has prepared a FONSI for the NDA. This notice announces that the EA's, the draft EIS for the harvesting of Taxol prepared by the U.S. Forest Service, and the FONSI for this human drug product may been seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 6, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–637 Filed 1–11–93; 8:45 am]

BILLING CODE 4160–01–F

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Anti-Infective Drugs Advisory Committee

Date, time, and place. January 28, 1993, 10 a.m., Conference rm. E, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD.

Type of meeting and contact person. Open public hearing, 10 a.m. to 11 a.m., unless public participation does not last that long; closed committee deliberations, 11 a.m. to 5 p.m.; Ermona B. McGoodwin or Mary Elizabeth Donahue, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455.

General function of the committee. The committee reviews and evaluates data relating to the safety and effectiveness of marketed and investigational human drugs for use in infectious and ophthalmic disorders.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 21, 1993, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Closed committee deliberations. The committee will review trade secret and/or confidential commercial information relevant to a pending investigational new drug application. This portion of the meeting will be closed to permit discussion of this information. (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour

long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting will be available from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting will be available from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably deliberative session to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: January 6, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 93–638 Filed 1–11–93; 8:45 am]

BILLING CODE 4160–01–F

Memorandum of Understanding on Screening Tests for Animal Drug Residues in Milk Between the Food and Drug Administration and the Association of Official Analytical Chemists Research Institute

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) under which it will work with test kit manufacturers and an independent, scientifically recognized organization/laboratory to evaluate milk test kits intended to analyze animal drug residues in milk. While FDA will enter into other arrangements to evaluate milk test kits, this announcement is to advise of the signing of an MOU between FDA and the Association of Official Analytical Chemists (AOAC) Research Institute (the Institute). Test kits that are evaluated by the Institute and accepted by FDA will be recommended by FDA for use in milk monitoring programs performed under the provisions of the Pasteurized Milk Ordinance (PMO). In addition, test kits recommended for use by the kit manufacturer on milk from the individual cow will also be evaluated under this program. Kits that are acceptable to FDA will be available for use by veterinarians and milk producers to monitor milk from individual cows.

DATES: The agreement became effective October 22, 1992.

FOR FURTHER INFORMATION CONTACT: Norris E. Alderson, Food and Drug Administration, Center for Veterinary Medicine (HFV–500), 7500 Standish Pl., Rockville, MD 20855, 301–295–8702.

SUPPLEMENTARY INFORMATION: In a notice that appeared in the **Federal Register** of December 13, 1990 (55 FR 51339), in which FDA asked for information on commercially available screening tests that can be used to detect animal drug residues in milk, and announced its

intention to conduct a limited evaluation of such tests. Eleven test kit manufacturers responded to that notice, and the agency selected chloramphenicol as the first drug to evaluate available tests. The laboratory work, which was conducted entirely by FDA chemists in the Center for Veterinary Medicine's Office of Science, has been completed and a final report describing the results of this initial evaluation is being prepared.

The need for reliable animal drug residue test kits to screen milk for animal drug residues in State and Federal milk monitoring programs is recognized by regulatory agencies and the milk industry. At the 1991 National Conference on Interstate Milk Shipments (NCIMS), the Conference approved a number of changes in the PMO, the ordinance which specifies safety standards and requirements for milk including specific provisions for the monitoring of milk for animal drug residues. One of these changes required that the milk industry begin, on January 1, 1992, to screen each bulk milk pickup tanker for beta lactam residues prior to processing. In addition, under the change in the PMO, beginning July 1, 1992, State milk officials were required to audit the industry monitoring program by conducting their own monitoring; implementation of this requirement is still ongoing. The PMO changes provided that, following an interim period, only test kits that were evaluated by the AOAC and/or accepted by FDA could be used in the monitoring programs. The PMO also permits FDA to require monitoring for additional drug residues when it determines additional testing is needed.

FDA determined that the PMO changes could not be implemented expeditiously under the program announced in the December 13, 1990, **Federal Register** notice. Therefore, FDA decided to set aside that program and enter into an MOU with the Institute.

On October 22, 1992, FDA executed an MOU with the Institute, a subsidiary of AOAC International, which provides for FDA evaluation of animal drug milk test kits submitted to the Institute for review under the Institute's performance testing program. Under its program, the Institute will prescribe specific studies to be conducted and submitted by test kit manufacturers. The Institute will evaluate the submitted study results, and it will design, arrange for the conduct of, and evaluate additional testing by an independent laboratory in order to verify the data provided by kit manufacturers. Under the MOU, the Institute will provide the data from the kit manufacturer and laboratory testing to FDA. An FDA scientist will evaluate the data to determine whether the test kit is acceptable to the agency. Such kits will be recommended by the agency for use in PMO monitoring programs.

While the agency has entered into this MOU with the Institute, the agency is not precluded from entering into other arrangements for FDA evaluation of milk test kits. For example, test kit manufacturers may submit the appropriate data directly to FDA for evaluation. Test kit manufacturers are not required to submit their test kits to the Institute as a prerequisite for FDA's evaluation of the kits.

In accordance with 21 CFR 20.108(c), which states that all written agreements and memoranda of understanding between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this memorandum of understanding.

Dated: December 23, 1992.

Gary Dykstra,

Acting Associate Commissioner for Regulatory Affairs.

Memorandum of Understanding Between the AOAC Research Institute and the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Veterinary Medicine

I. Purpose

The purpose of this memorandum of understanding (MOU) is to provide for cooperation between the AOAC Research Institute (Institute) and the Center for Veterinary Medicine (CVM), Food and Drug Administration (FDA) in evaluating test kits for detecting animal drug residues in milk. Test kits provide the means for State and federal regulatory agencies and milk processors to screen economically and efficiently large quantities of milk for a wide range of drug residues. In addition, the use of test kits by the veterinarian or milk producer provides the means to preclude unsafe milk from the individual treated cow from entering the food chain. However, if the use of these test kits is to provide credible results, the tests must perform reliably and accurately.

The cooperation between the Institute and CVM/FDA specified in this MOU is designed to result in test kits that are evaluated by the Institute and acceptable to CVM/FDA. These kits that are acceptable to CVM/FDA will then be recommended by CVM/FDA to the Milk Safety Branch, Center for Food Safety and Applied Nutrition (CFSAN), FDA, for subsequent recommendation to State regulatory agencies to monitor for animal drug residues in grade A milk as specified in the Pasteurized Milk Ordinance (PMO). These kits will also be recommended for use in monitoring programs by State regulatory agencies for "manufacturing" grade milk. In addition, test kits intended for use by the kit manufacturer on milk from the individual cow will also be evaluated under this program. Kits that are acceptable to CVM/FDA will be available for use by veterinarians and milk producers in monitoring milk from individually treated cows.

II. Background

FDA's responsibilities under the Federal Food, Drug, and Cosmetic Act include the regulation of milk shipped in interstate commerce. FDA's milk safety program was initiated in 1 46 at the request of the Conference of State and Territorial Health Officers. Since that time, that organization has evolved into the National Conference on Interstate Milk Shipments (NCIMS). The NCIMS is a voluntary organization directed and controlled by the member States. In order for the milk industry to ship milk interstate, the State where the milk originates must participate in this conference and pass laws or regulations which enact the provisions of the PMO. The PMO sets out standards, requirements and procedures that must be followed to ensure the safety of milk. All fifty States and Puerto Rico have chosen to participate in the PMO. FDA collaborates with the NCIMS to provide a system of regulation in the milk industry.

The PMO includes specific provisions regarding the monitoring of milk for animal drug residues. The PMO requires that each dairy farm be represented in a sampling program and tested for drug residues at least four times in each six month period. These tests are conducted by the States. This is in addition to the requirement that the industry test each bulk milk tanker of milk for beta lactams before it is processed. Positive results from these tests result in direct regulatory action by the State against the farm involved. FDA coordinates with the NCIMS on the implementation of State monitoring programs for other drugs.

The PMO also provides for the use by the States of "methods which have been evaluated by AOAC and/or accepted by FDA" as one method for monitoring milk for animal drug residues. In this regard the PMO provides that "FDA shall review the AOAC evaluation for each test kit and make a determination as to the acceptability of the use of the method in accordance with all applicable sections of the [PMO]." A similar arrangement between the States and the United States Department of Agriculture prescribes for use of AOAC evaluated and/or FDA accepted methods for the State monitoring of "manufacturing" grade milk.

Since the PMO specifies that all milk test kits must be accepted by FDA before use in State monitoring programs, the Institute and CVM/FDA are entering into this MOU. The Institute recognizes, as does CVM/FDA, the importance of timely evaluation of milk screening tests. This timely review and final acceptance of the test kits by FDA is the impetus for the cooperation described in this MOU. This cooperation as specified in this MOU will provide for CVM/FDA to determine whether a milk test kit evaluated by the Institute is acceptable to FDA.

The AOAC Research Institute is a non-profit subsidiary of AOAC International (AOAC). The Institute has recently announced its intention to evaluate test kits through a test kit performance testing

program. The purpose of this program is to provide an independent third-party review of manufacturers' performance claims for analytical test kits including those intended to detect or measure animal drug residues in milk. This MOU applies only to evaluation of test kits for analyzing for animal drug residues in milk.

As for test kits, AOAC Research Institute is establishing a new procedure for the evaluation of test kits' performance that is separate from the official AOAC collaborative study procedure. AOAC is recognized internationally as the organization which provides the mechanism for the collaborative study, validation and publication of reliable, official methods of analysis. FDA accepts and utilizes AOAC methods for regulatory enforcement as specified in 21 CFR 2.19. The PMO also provides for the use of official AOAC methods by the States for monitoring milk for animal drug residues. The Institute's test kit evaluation program, however, will not qualify tests as AOAC Official Methods, rather the procedure will certify the performance characteristics specified by the manufacturer for the test kit.

Under the Institute's program, manufacturers who elect to participate in the program will submit data to the Institute to support the labeled performance claims on the specific test kit. The Institute will select expert scientists to evaluate those data to determine whether the kit meets specific performance criteria for the intended use. These expert scientists will be selected worldwide from academia, industry, and government based on the scientist's individual recognition in the scientific community for his/her expertise in the specific area of science. The Institute will also select independent testing laboratories to conduct tests of each test kit and provide the results to the expert reviewers for evaluation. The Institute will grant a "PERFORMANCE TESTED" status to test kits it determines meet specific performance criteria.

To integrate CVM/FDA acceptance of test kits as specified in the PMO with the Institute's evaluation of the test kits, the Institute will provide the manufacturers' data and the laboratory testing data to CVM/FDA scientists for evaluation. In addition, the Institute and CVM/FDA will jointly develop protocols for laboratory testing of the test kits. The Institute will advise manufacturers of the results of the evaluation.

CVM/FDA is particularly interested in the performance of those kits which claim to detect animal drug residues in milk. This MOU provides one means for the milk test kits to be evaluated by CVM/FDA such that they could be recommended to the states, by the Milk Safety Branch, CFSAN/FDA, for regulatory purposes. Test kits intended by the kit manufacturer to detect animal drug residues in the milk of individually treated cows which are evaluated in the Institute's program and accepted by CVM/FDA will be available to the veterinarian and milk producer.

III. Substance of the Agreement

A. AOAC Research Institute agrees to:

1. Provide data submitted to the Institute by test kit manufacturers and data resulting from laboratory testing for CVM/FDA's evaluation of the test kit to CVM/FDA scientists.
2. Provide for CVM/FDA participation in the development of test protocols.
3. Ensure that laboratory testing is conducted in accordance with CVM/FDA accepted protocols.
4. Coordinate the CVM/FDA test kit evaluations with the evaluations of the Institute expert scientists.
5. Provide for CVM/FDA participation in meetings convened of Institute expert scientists.
6. Advise test kit manufacturers of the progress and results of the CVM/FDA evaluation.

B. The CVM/FDA agrees to:

1. Appoint a scientist to represent FDA for each announced Institute test kit review under the AOAC Research Institute Test Kit Performance Testing Program. This scientist will represent the Agency in all discussions with the Institute regarding test kits for specific drug(s). In addition, this scientist will be supported by other Agency scientists in the review of data and for the development of protocols for the evaluation of test kits for monitoring drug residues in milk submitted to the AOAC Research Institute. FDA scientists will perform their reviews as part of their normal duties at their FDA work locations.
2. Provide the Institute with parameters and criteria necessary to CVM/FDA in the evaluation of test kits for monitoring drug residues in milk.
3. If requested by the Institute to provide incurred drug residues in milk or chemical analysis of milk test samples to be used for laboratory testing of test kits by AOAC Research Institute, a minimum of ninety days notice shall be required for CVM/FDA to provide such samples. The request for incurred drug reside samples in milk must include the date required, levels of residue in the milk as outlined in the protocol, number of samples of each level, and any other information which may be a part of the protocol.
4. If the label claims of a test kit are such that the test kit is not intended to meet CVM/FDA levels of residue concern, then CVM/FDA would decline to participate in the review and evaluation of that test kit. Such test kits evaluated by the Institute would not be subject to CVM/FDA review under this MOU.
5. CVM/FDA agrees to provide to AOAC Research Institute:

a. "Memorandum of Initial Review"

This memorandum is a review of kit performance claims as submitted by the manufacturer and is not a review of any data. This review is to review what the test is claimed to detect and that it does so at the tolerance or safe level set by CVM/FDA for drug residues in milk. Possible responses by CVM/FDA include "unqualified acceptance," "acceptance contingent on changes in labeling reflecting accuracy of information and adequate directions for use," "acceptance but with FDA explaining limitations to the expected user (States, milk processor, veterinarian, or milk producer)," and "non-acceptance by CVM/FDA" with reasons provided.

b. "Memorandum of Acceptance"

This memorandum would follow the complete CVM/FDA review and analysis of the application package, data submission, and Institute testing. Possible responses could be those in 5.a. above or "based on the CVM/FDA review of the labeling, directions for use, data submitted by the kit sponsor, and data from Institute testing, CVM/FDA recommends the test kit for use by the (States and milk processors) for monitoring milk for (name of drug)."

C. It is mutually agreed that:

1. This agreement is limited to the evaluation of test kits intended to detect animal drug residues in milk.
2. CVM/FDA does not take any position on any aspect of the Institute's program. The Institute decisions regarding its program are independent decisions without CVM/FDA involvement.
3. CVM/FDA is not bound by any position the Institute may take as a result of the Institute's evaluation of a test kit. CVM/FDA decisions are independent decisions with the information provided by the Institute as specified in this MOU being considered.
4. The Institute is not bound by any position CVM/FDA may take as a result of CVM/FDA's evaluation of a test kit. The Institute's decisions are independent with the CVM/FDA input being considered as specified in this MOU.
5. The Institute's granting a test kit a "PERFORMANCE TESTED" status reflects only the Institute's acceptance of the kit. CVM/FDA's acceptance of a test kit is separate and apart from the "PERFORMANCE TESTED" status granted by the Institute.
6. Either party on their own initiative may conduct additional research as it deems appropriate on drug residue test kits for milk. Following a determination that a drug residue test kit for drug residues in milk is not performing in an acceptable manner or if changes are needed in labeling, such will be communicated to the other party for any action it deems appropriate. CVM/FDA, on its own, may take any action deemed appropriate as to the status of any test kit claimed to detect drug residues in milk.

IV. Names and Addresses of Participating Agencies

A. AOAC Research Institute, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201–3301.

B. Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855.

V. Liaison Officers

A. Liaison Officer for AOAC Research Institute: Mr. Scott G. Coates, Manager, AOAC Research Institute, 2200 Wilson Blvd., Suite 400, Arlington, VA 22201–3301. Phone: 703–522–2529.

B. Liaison Officer for Center for Veterinary Medicine: Dr. Joseph A. Settepani, Center for Veterinary Medicine, Food & Drug

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Administration, Agricultural Research Center, Beltsville, MD 20705. Phone: 301–504–8500.

VI. Period of Agreement

This agreement becomes effective upon acceptance by both parties and will continue indefinitely. It may be modified by mutual written consent at any time. It may be terminated by either party upon a 30-day advance written notice to the other party at the address listed in Section IV.

Approved and Accepted for the AOAC Research Institute
By: Scott G. Coates.
Title: Manager AOAC Research Institute.
Date: October 22, 1992.

Approved and Accepted for the Food and Drug Administration
By: Ronald G. Chesemore,
Title: Associate Commissioner for Regulatory Affairs.
Date: October 22, 1992.

[FR Doc. 93–554 Filed 1–11–93; 8:45 am]
BILLING CODE 4160–01–F

[Docket No. 92N–0422]

Raju Vegesna; Proposal to Debar; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is proposing to debar Mr. Raju Vegesna under section 306(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a(a)). FDA bases this proposal on a finding that Mr. Vegesna was convicted of a felony under Federal law for conduct: relating to the development or approval, including the process for development or approval, of a drug product; and relating to the regulation of a drug product under the act. This notice also offers an opportunity for a hearing on the proposal. The agency is issuing this notice in the **Federal Register** because it is unable to serve notice by certified mail on Mr. Vegesna, a fugitive who has fled to India.

DATES: Written requests for a hearing by February 11, 1993; information in support of the hearing request due by March 15, 1993.

ADDRESSES: Submit written requests for a hearing and supporting information to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Megan L. Foster, Center for Drug Evaluation and Research (HFD–366), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8041.

SUPPLEMENTARY INFORMATION:

I. Conduct Related to Conviction

On July 30, 1990, the United States District Court for the District of Maryland accepted Mr. Vegesna's plea of guilty and entered judgment against him for two counts of Interstate Travel in Aid of Racketeering; aiding and abetting, a Federal felony offense under 18 U.S.C. 1952 and 18 U.S.C. 2. The underlying facts supporting these felony convictions are as follows:

From 1985 to 1990, Mr. Vegesna was the President, Chief Executive Officer, and a major stockholder of American Therapeutics, Inc. (ATI). ATI, a generic drug manufacturing firm in New York, regularly submitted drug applications to the Division of Generic Drugs (DGD) of FDA.

DGD was responsible for reviewing applications submitted by generic drug manufacturers seeking FDA's approval to market their products to the public. The division had four chemistry review branches that reviewed applications to determine, among other things, whether the manufacturing procedures and analytical controls described in the applications were adequate to assure the identity, strength, quality, and purity of drug products for which FDA approval was being sought. This determination is essential for product approval under the act.

During the time that Mr. Vegesna was the President of ATI, Mr. Charles Chang was the branch chief of one of DGD's chemistry review branches. Mr. Chang's branch had reviewed and approved several generic drug applications submitted by ATI. At this time, Mr. Vegesna provided Mr. Chang with various unlawful benefits.

One of these unlawful benefits provided to Mr. Chang was a free trip around the world, which occurred during the summer of 1987. Mr. Vegesna paid for Mr. Chang's airfare to and major expenses in such places as Hong Kong, Bangkok, and London.

Mr. Vegesna also purchased furniture and a computer for Mr. Chang at a cost totaling over $9,000.

In return for these benefits, Mr. Chang, who supervised the review of several of ATI's applications, unlawfully advanced and protected ATI's interests at FDA. Mr. Chang assigned ATI's drug applications in such a way as to assure their prompt reviews, and he provided Mr. Vegesna with information regarding the status of ATI's applications and those of its competitors.

On February 27, 1990, Mr. Vegesna agreed to waive indictment and to plead guilty to a criminal information charging him with two counts of interstate travel in aid of racketeering; aiding and abetting, in violation of 18 U.S.C. 1952 and 18 U.S.C. 2.

On July 30, 1990, the United States District Court for the District of Maryland convicted and sentenced Mr. Vegesna for these offenses.

II. FDA's Finding

Section 306(a)(2)(A) of the act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. FDA finds that Mr. Vegesna was convicted of a felony under Federal law for conduct relating to the development and approval of ATI's drug products. He was convicted of a felony offense under 18 U.S.C. 1952 and 18 U.S.C. 2 for causing travel in interstate commerce and for causing interstate facilities to ship furniture with the intent to carry on the unlawful activity of giving unlawful gratuities. Mr. Vegesna gave these gratuities to the chemistry review branch chief who was responsible for reviewing ATI's applications to determine whether they met certain statutory standards for approval.

Section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product. Mr. Vegesna's convictions under 18 U.S.C. 1952 and 18 U.S.C. 2 were for illegal conduct relating to the regulation of ATI's drug products. Mr. Vegesna, the President of ATI, gave illegal gratuities to Mr. Charles Chang, the chemistry review branch chief who was involved in the regulation of ATI's drug products. Under section 306(l)(2) of the act (21 U.S.C. 335a(l)(2)), debarment is mandatory for an individual convicted up to 5 years prior to this notice. Section 306(c)(2)(A)(ii) of the act (21 U.S.C. 335a(c)(2)(A)(ii)) requires that Mr. Vegesna's debarment be permanent.

III. Proposed Action and Notice of Opportunity for a Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(A) and (a)(2)(B) of the act, permanently debarring Mr. Vegesna from providing services in any capacity to a person that has an approved or pending drug product application.

In accordance with section 306 of the act and 21 CFR part 12, Mr. Vegesna is

hereby given an opportunity for a hearing to show why he should not be debarred. Although FDA ordinarily uses certified letters to issue proposals to debar with notice of opportunity for a hearing, this document is being issued in the **Federal Register** because the agency is unable to serve notice on Mr. Vegesna, whose whereabouts are unknown.

An individual who decides to seek a hearing shall file: (1) A written notice of appearance and request for a hearing on or before February 11, 1993; and (2) the information relied on to justify a hearing on or before March 15, 1993. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the act (21 U.S.C. 335a(i)).

The failure of Mr. Vegesna to file a timely written notice of appearance and request for a hearing constitutes a waiver of any right to an opportunity for a hearing concerning his debarment. Under these circumstances, the agency will not hold a hearing and will issue the debarment order as proposed in this notice.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the information and factual analyses in the request for a hearing that there is no genuine and substantial issue of fact which precludes the order of debarment, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

The facts underlying Mr. Vegesna's convictions are not at issue in this proceeding. The only material issue is whether he was convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction mandates his debarment.

Mr. Vegesna's request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. 92N–0422 and sent to the Dockets Management Branch (address above). All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 306 (21 U.S.C. 335a)) and under authority delegated to the Deputy Commissioner for Operations (21 CFR 5.20).

Dated: December 29, 1992.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–636 Filed 1–11–93; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Rural Health Outreach Grant Program

AGENCY: Health Resources and Services Administration (HRSA), PHS, HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Office of Rural Health Policy, Health Resources and Services Administration (HRSA), announces that applications are being accepted for Rural Health Outreach Demonstration Grants to expand or enhance the availability of essential health services in rural areas. Awards will be made from funds appropriated under Public Law 102–394 (HHS Appropriation Act for FY 1993). Grants for these projects are authorized under section 301 of the Public Health Service Act.

National Health Objectives for the Year 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The Rural Health Outreach program is related to the priority areas for health promotion, health protection and preventive services. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–C) or Healthy People (Summary Report: Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325 (Telephone (202) 783–3238).

Funds Available

Approximately $24.5 million is available for the Outreach Grant program in FY 1993. Of this amount, approximately $21.5 million is for noncompeting continuances and $3 million will be available to support new one-term outreach grants. With these funds, the Office of Rural Health Policy expects to make approximately 15 new awards for one year. The start date for new projects will be September 30, 1993.

Individual grant awards under this notice will be limited to a total amount of $300,000 (direct and indirect costs) per year. Applications for smaller amounts are strongly encouraged. It is expected that the average grant award will be approximately $180,000 for one year. Applicants may propose project periods for up to three years. However, applicants are advised that continued funding of grants beyond the periods supported under this announcement is subject to appropriation of funds and assessment of grantee performance.

DATES: Applications for the program must be received by the close of business on May 1, 1993. Applications must be received by the Grants Management Officer at the address shown below.

Applications shall be considered as meeting the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date and received in time for orderly processing. Applicants must obtain a legible dated receipt from a commercial carrier or the U.S. Postal Service in lieu of a postmark. Private metered postmarks will not be acceptable as proof of timely mailing. Late applications will be returned to the sender.

ADDRESS: Requests for grant application kits and additional information regarding business or fiscal issues should be directed to: Opal McCarthy, Grants Management Office, Bureau of Primary Health Care, 12100 Parklawn Drive, Rockville, Maryland 20857, (301) 443–5414. The standard application form and general instructions for completing applications (Form PHS–5161–1, OMB 0937–0189) have been approved by the Office of Management and Budget

FOR FURTHER INFORMATION CONTACT: Requests for technical or programmatic information on this announcement should be directed to Glenda Koby, Office of Rural Health Policy, room 9–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–0835.

SUPPLEMENTARY INFORMATION:

Program Objectives

The purpose of the program is to support projects that demonstrate new and innovative models of outreach and health care services delivery in rural areas that lack basic health services. Grants will be awarded either for the direct provision of health services to rural populations, especially for those

who are not currently receiving them, or to enhance access to and utilization of existing available services.

Applicants may propose projects to address the needs of a wide range of rural population groups including the poor, the elderly, the disabled, pregnant women, infants, adolescents, rural minority populations, and rural populations with special health care needs. Projects should be responsive to the special cultural and linguistic needs of specific populations. The following areas are of special interest. Applications in these areas are particularly encouraged.

1. Projects to provide ambulatory health and/or mental health or substance abuse services in Health Professions Shortage Areas and in frontier areas.

2. Projects to provide, enhance or revitalize emergency medical services in rural areas.

3. Projects to reduce high rates of infant mortality in rural areas.

4. Projects designed to reduce high rates of suicide and depression among rural adolescents through the provision of mental, social, educational and related services.

5. Projects to enhance the health and safety of farmers, farm families, and migrant and seasonal farm workers through direct services.

A central goal of the demonstration program is to develop new and innovative models for more effective integration and coordination of health services in rural areas. It is hoped that some of these models will prove significant to solving rural health problems in States, regions of the country, or throughout the country. In order to better integrate the provision of health services in rural areas, participation in the program requires the formation of consortium arrangements among three or more separate and distinct entities to carry out the demonstrations. A consortium must be composed of three or more existing health care providers, or a combination of three or more health care and social service providers. Individual members of a consortium might include such entities as hospitals, public health agencies, home health providers, mental health centers, substance abuse service providers, rural health clinics, social service agencies, health profession schools, emergency service providers, community and migrant health centers, etc. Strong consortium arrangements are required in which the roles and responsibilities of each member organization are clearly defined, where each member contributes significantly to the goals of the project, and where there is a strong management plan for operating the consortium.

The HRSA is particularly interested in consortia involving primary care providers and public health organizations.

Eligible Applicants

All public and private entities, both nonprofit and for-profit may participate as members of a consortium arrangement as described above. However, a grant award will be made to only one entity in a consortium. The grant recipient must be a nonprofit or public entity which meets one of the three requirements stated below.

(1) The applicant is located outside of a Metropolitan Statistical Area as defined by the Office of Management and Budget. A list of the cities and counties that are designated as being within a Metropolitan Statistical Area will be included with the application kit.

(2) The applicant is located in a rural census tract of one of the counties listed in Appendix I to this announcement. Although each of these counties is a Metropolitan Statistical Area, or part of one, large parts of the counties are rural. Organizations located in these rural areas are eligible for the program. Rural portions of these counties have been identified by census tract since this is the only way we have found to clearly differentiate them from urban areas in the large counties. Appendix I provides a list of these census tracts for each county. Appendix II includes the telephone numbers for regional offices of the Census Bureau. Applicants may call these offices to determine the census tract in which they are located.

(3) The applicant is an organization that is constituted exclusively to provide services to migrant and seasonal farmworkers in rural areas and is supported under section 329 of the Public Health Service Act. These organizations are eligible regardless of the urban or rural location of their administrative headquarters.

Applications from organizations that do not meet one of the three requirements described above will not be reviewed.

Review Consideration

Grant applications will be evaluated on the basis of the following criteria:

(1) The extent to which the applicant has proposed a new and innovative approach to health care in the rural area.

(2) The extent to which the applicant has justified and documented and need(s) for the project and developed measurable goals and objectives for meeting the need(s).

(3) The extent to which the applicant has clearly defined the roles and responsibilities for each member of the consortium and developed a workable plan for managing the consortium's activities.

(4) The reasonableness of the budget proposed for the project.

(5) The extent to which the proposed project would be capable of replication in rural areas with similar needs and characteristics.

(6) The level of local commitment and involvement with the project, including the extent of cost participation by the applicant and/or other organizations, and the extent to which the project will contribute to enhancing the local economy.

(7) The feasibility of plans to continue the project after federal grant support is completed.

(8) The strength of the project evaluation plan.

The HRSA hopes to expand the outreach program into geographic areas not currently served by the program. Consequently, HRSA will consider geographic coverage when deciding which approved applications to fund. We do not anticipate supporting additional projects in areas that are currently funded by this program.

Other Information

Grantees will be required to use at least 85 percent of the total amount awarded for outreach and care services as opposed to administrative costs. It is also required that more than 50 percent of the funds awarded be spent in rural areas. Grant funds may not be used for purchase, construction or renovation of real property or to support the delivery of inpatient services.

Applicants are advised that the narrative description of their program and the budget justification may not exceed 40 pages in length. Applications that exceed the 40 page limit for the program narrative and budget justification will not receive consideration. All applications must be typewritten and clearly legible with no less than ½" margin on all sides.

Public Health System Impact Statement

This program is subject to the Public Health System Reporting Requirements. Reporting requirements have been approved by the Office of Management and Budget—0937–0195. Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide

information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based non-governmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

a. A copy of the face page of the application (SF 424)

b. A summary of the project PHSIS, not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State or local health agencies.

Executive Order 12372

The Rural Health Outreach Grant Program has been determined to be a program which is subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs by appropriate health planning agencies an implemented by 45 CFR part 100. Executive Order 12372 allows States the option of setting up a system for reviewing applications from within their States for assistance under certain Federal programs. Applicants (other than federally recognized Indian tribal governments) should contact their State Single Point of Contact (SPOCs), a list of which will be included in application kit, as early as possible to alert them to the prospective applications and receive any necessary instructions on the State process. For proposed projects serving more then one State, the applicant is advised to contact the SPOC of each affected State. All SPOC recommendations should be submitted to Opal McCarthy, Grants Management Office, Bureau of Health Care Delivery and Assistance, 12100 Parklawn Drive, Rockville, Maryland 20857, (301) 443–5414. The due date for State process recommendations is 60 days after the application deadline for new and competing awards. The granting agency does not guarantee to "accommodate or explain" for State process recommendations it receives after that date. (See part 148, Intergovernmental Review of PHS Programs under Executive Order 12372 and 45 CFR part 100 for a description of the review process and requirements.

The OMB Catalog of Federal Domestic Assistance number is 93.912.

Dated: December 4, 1992.

John H. Kelso,

Acting Administrator.

Appendix I

* Census tract numbers are shown *below* each county name.

STATE

County

Tract number

ALABAMA

Baldwin	0114	0002
0101	0115	0006
0102	0116	0072.02
0106	*Mobile*	*Tuscaloosa*
0110	0059	0107

ARIZONA

Maricopa	0811	*Pima*
0101	0822.02	0044.05
0405.02	5228	0048
0507	7233	0049

CALIFORNIA

Butte	0034	0203
0024	0035	0204
0025	0036	0216
0026	0037	0217
0027	0040	0219
0028	0041	0220
0029	0042	*Riverside*
0030	0043	0421
0031	0044	0427.02
0032	0045	0427.03
0033	0046	0429
0034	0047	0430
0035	0048	0431
0036	0049	0432
El Dorado	0050	0444
0301.01	0051.01	0452.02
0301.02	0052	0453
0302	0053	0454
0303	0054	0455
0304.01	0055.01	0456.01
0304.02	0055.02	0456.02
0305.01	0056	0457.01
0305.02	0057	0457.02
0305.03	0058	0458
0306	0059	0459
0310	0060	0460
0311	0061	0461
0312	0063	0462
0313	*Los Angeles*	*San Bernardino*
0314	5990	0069.01
0315	5991	0069.02
Fresno	9001	0090.01
0040	9002	0090.02
0063	9004	0091.01
0064.01	9012.02	0091.02
0064.03	9100	0093
0065	9101	0094
0066	9108.02	0095
0067	9109	0096.01
0068	9110	0096.02
0071	9200.01	0096.03
0072	9201	0097.01
0073	9202	0097.03
0074	9203.03	0097.04
0077	9301	0098
0078	*Monterey*	0099
0079	0109	0100.01
0080	0112	0100.02
0081	0113	0102.01
0082	0114.01	0102.02
0083	0114.02	0103
0084.01	0115	0104.01
0084.02	*Placer*	0104.02
Kern	0201.01	0104.03
0033.01	0201.02	0105
0033.02	0202	0106
0107	*Santa Barbara*	0035
San Diego	0018	0036.05
0189.01	0019.03	0037
0189.02	*Santa Clara*	0038
0190	5117.04	0039.01
0191.01	5118	0039.02
0206	5125.01	*Tulare*
0209.01	5127	0002
0209.02	*Shasta*	0003
0210	0126	0004
0212.01	0127	0005
0212.02	1504	0006
0213	*Sonoma*	0007
San Joaquin	1506.04	0026
0040	1537.01	0028
0044	1541	0040
0045	1542	0043
0052.01	1543	0044
0052.02	*Stanislaus*	*Ventura*
0053.02	0001	0001
0053.03	0002.01	0002
0053.04	0032	0046
0054	0033	0075.01
0055	0034	

COLORADO

Adams	*Larimer*	0032
0084	0014	0034
0085.13	0017.02	*Weld*
0087.01	0019.02	0019.02
El Paso	0020.01	0020
0038	0022	0024
0039.01	*Pueblo*	0025.01
0046	0028.04	0025.02

FLORIDA

Collier	0403.02	0083.02
0111	0404	*Polk*
0112	0405.01	0125
0113	0405.02	0126
0114	0405.03	0127
Dade	0405.05	0142
0115	0406	0143
Marion	*Palm Beach*	0144
0002	0079.01	0152
0004	0079.02	0154
0005	0080.01	0155
0027	0080.02	0156
Osceola	0081.01	0157
0401.01	0081.02	0158
0401.02	0082.01	0159
0402.01	0082.02	0160
0402.02	0082.03	0161
0403.01	0083.01	

KANSAS

Butler	0203	0205
0201	0204	0209

LOUISIANA

Rapides	0136	0123
0106	*Terrebonne*	
0135	0122	

MINNESOTA

St. Louis	0129	0152
0105	0130	0153
0112	0131	0154
0113	0132	0155
0114	0133	*Stearns*
0121	0134	0103
0122	0135	0105
0123	0137.01	0106
0124	0137.02	0107
0125	0138	0108
0126	0139	0109
0127	0141	0110
0128	0151	0111

MONTANA

Cascade	*Yellowstone*	0016
0105	0015	0019

NEVADA		
Clark	*Washoe*	0033.02
0057	0031.04	0033.03
0058	0032	0033.04
0059	0033.01	0034
NEW MEXICO		
Dona Ana	*Santa Fe*	0103.01
0014	0101	
0019	0102	
NEW YORK		
Herkimer	0108	0111
0101	0109	0112
0105.02	0110.01	0113.01
0107	0110.02	
NORTH DAKOTA		
Burleigh	0114	*Morton*
0114	0115	0205
0115	0116	
Grand Forks	0118	
OKLAHOMA		
Osage	0105	0108
0103	0106	
0104	0107	
OREGON		
Clackamas	*Jackson*	0007.02
0235	0024	0008
0236	0027	0013
0239	*Lane*	0014
0240	0001	0015
0241	0005	0016
0243	0007.01	
PENNSYLVANIA		
Lycoming	0101	0102
SOUTH DAKOTA		
Pennington	0116	0117
TEXAS		
Bexar	0619	0631
1720	0620.01	0632
1821	0620.02	*Harris*
1916	0621	0354
Brazoria	0622	0544
0606	0623	0546
0609	0624	*Hidalgo*
0610	0625.01	0223
0611	0625.02	0224
0612	0625.03	0225
0613	0626.01	0226
0614	0626.02	0227
0615	0627	0228
0616	0628	0230
0617	0629	0231
0618	0630	0243
WASHINGTON		
Benton	*Snohomish*	0110
0116	0532	*Yakima*
0117	0536	0018
0118	0537	0019
0119	0538	0020
0120	*Spokane*	0021
Franklin	0101	0022
0208	0102	0023
King	0103.01	0024
0327	0103.02	0025
0328	0133	0026
0330	0143	
0331	*Whatcom*	
WISCONSIN		
Douglas	0017	0021
0303	0018	0022
Marathon	0020	0023
WYOMING		
Laramie	0017	
0016	0018	

Appendix II

Bureau of the Census Regional Information Service

Atlanta, GA 404–730–3957
Alabama, Florida, Georgia
Boston, MA 617–565–7078
Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, Upstate New York
Charlotte, NC 704–344–6144
Kentucky, North Carolina, South Carolina, Tennessee, Virginia
Chicago, IL 708–409–4617
Illinois, Indiana, Wisconsin
Dallas, TX 214–767–7105
Louisiana, Mississippi, Texas
Denver, CO 303–969–7750
Arizona, Colorado, Nebraska, New Mexico, North Dakota, South Dakota, Utah, Wyoming
Detroit, MI 313–354–4654
Michigan, Ohio, West Virginia
Kansas City, KS 913–236–3711
Arkansas, Iowa, Kansas, Missouri, New Mexico, Oklahoma
Los Angeles, CA 818–904–6339
California
New York, NY 212–264–4730
Brookly, Bronx, Manhattan, Queens, Staten Island, Nassau Co., Orange Co., Suffolk Co., Rockland Co., Westchester Co.
Philadelphia, PA 215–597–8318
Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania
Seattle, WA 206–728–5314
Idaho, Montana, Nevada, Oregon, Washington

[FR Doc. 93–620 Filed 1–11–93; 8:45 am]
BILLING CODE 4160–15–M

National Institutes of Health

Establishment

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92–463, 86 Stat. 770–776) and section 402(b)(6), of the Public Health Service Act, as amended (42 U.S. Code 282(b)(6), the Director, National Institutes of Health (NIH), announces the establishment of the National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

The National Institute on Deafness and Other Communication Disorders Special Emphasis Panel will advise the Director, National Institutes of Health, and the Director of the National Institute on Deafness and Other Communication Disorders regarding research grant and cooperative agreement applications and contract proposals, relating to communication sciences and disorders, such as hearing, balance, smell, taste, voice, speech and language.

Duration of this committee is continuing unless formally determined by the Director, NIH, that termination would be in the best public interest.

Dated: January 4, 1993.

Bernadine Healy,

Director, National Institutes of Health.

[FR Doc. 93–579 Filed 1–11–93; 8:45 am]
BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; Meeting: AIDS Research Advisory Committee, NIAID

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the AIDS Research Advisory Committee, National Institute of Allergy and Infectious Diseases, on February 9–10, 1993, in the Versailles Ballroom of the Holiday Inn, 8120 Wisconsin Avenue, Bethesda, Maryland 20814.

The entire meeting will be open to the public from 8 a.m. until recess on February 9 and from 8:30 a.m. until adjournment on February 10. The AIDS Research Advisory Committee (ARAC) advises and makes recommendations to the Director, National Institute of Allergy and Infectious Diseases, on all aspects of research on HIV and AIDS related to the mission of the Division of AIDS (DAIDS).

The Committee will provide advice on scientific priorities, policy, and program balance at the Division level. The Committee will specifically focus on plans for research in vaccines, opportunistic infections and antiviral treatment, and provide concept clearance for proposed research initiatives. Attendance by the public will be limited to space available.

Ms. Patricia Randall, Office of Communications, National Institute of Allergy and Infectious Diseases, Building 31, room 7A32, National Institutes of Health, Bethesda, Maryland 20892, telephone 301–496–5717, will provide a summary of the meeting and a roster of the committee members upon request.

Jean S. Noe, Executive Secretary, AIDS Research Advisory Committee, DAIDS, NIAID, NIH, Solar Building, Room 2A22, telephone 301–496–0545, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health).

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Dated: January 4, 1993.
Susan K. Feldman,
Committee Management Officer, NIH.
[FR Doc. 93–580 Filed 1–11–93; 8:45 am]
BILLING CODE 4140–01–M

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting: The National Kidney and Urologic Diseases Advisory Board

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Kidney and Urologic Diseases Advisory Board on February 22, 1993. The meeting will begin at approximately 8 a.m. and adjourn by 5 p.m. The Board will meet at the Crystal Gateway Marriott, 1700 Jefferson Davis Highway, Arlington, Virginia. The meeting, which will be open to the public, is being held to discuss the future activities of the Board. Attendance by the public will be limited to space available.

Dr. Ralph Bain, Executive Director, National Kidney and Urologic Diseases Advisory Board, 1801 Rockville Pike, suite 500, Rockville, Maryland 20852, (301) 496–6045, will provide on request an agenda and roster of the members. Summaries of the meeting may also be obtained by contacting his office.

(Catalog of Federal Domestic Assistance Program No. 93.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health.)

Dated: January 4, 1993.
Susan K. Feldman,
Committee Management Officer, NIH
[FR Doc. 93–581 Filed 1–11–93; 8:45 am]
BILLING CODE 4140–01–M

Public Health Service

Centers for Disease Control; Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HC (Centers for Disease Control) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–67776, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 57 FR 40688–40689, dated September 4, 1992) is amended to reflect the name change for the Centers for Disease Control to the Centers for Disease Control and Prevention (CDC) pursuant to the enactment of the Preventive Health Amendments of 1992. Congress also specified that the Centers for Disease Control and Prevention (CDC) would continue to be recognized by the initials CDC. This notice also revises the list of officials in the Order of Succession.

Section HC–B, Organization and Functions, is hereby amended as follows:

Change the name of the Centers for Disease Control by adding the words "and Prevention" to the title. In practice the following title will be used: "Centers for Disease Control and Prevention (CDC)". In the mission statement, change the reference to the Centers for Disease Control by adding the words "and Prevention."

Section HC–C, Order of Succession. After the first sentence, delete the listing of officials and substitute the following: (1) Deputy Director, (2) Associate Director for Management and Operations, (3) Assistant Director for Policy, Planning, and Evaluation, (4) Associate Director for Policy Coordination, (5) Associate Director for Minority Health, (6) Associate Director for International Health, (7) Associate Director for Science, (8) Associate Director for HIV/AIDS.

Dated: January 4, 1993.
Louis W. Sullivan,
Secretary.
[FR Doc. 93–616 Filed 1–11–93; 8:45 am]
BILLING CODE 4160–18–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

National Cooperative Geologic Mapping Program Advisory Committee; Establishment

This notice is published in accordance with section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), 5 U.S.C. app. (1988). Pursuant to Public Law 102–285, the Geologic Mapping Act of 1992, the United States Geological Survey (USGS) gives notice of the establishment of an Advisory Committee for the National Cooperative Geologic Mapping Program.

The Committee is established to (a) review and critique the draft implementation plan prepared by the Director; (b) review the scientific progress of the geologic mapping program; and (c) submit an annual report to the Secretary that evaluates the progress of the Federal and State mapping activities and evaluates the progress made toward fulfilling the purposes of the Geologic Mapping Act of 1992. The panel will function solely as an advisory body and in compliance with provisions of the Federal Advisory Committee Act. The Charter will be filed under the Act fifteen days from the date of publication of this notice.

Further information regarding the Advisory Committee may be obtained from the Director, U.S. Geological Survey, Department of the Interior, 12201 Sunrise Valley Drive, Reston, Virginia 22092.

Certification of establishment is published below.

Certification

I hereby certify that the establishment of the Advisory Committee for the National Cooperative Geologic Mapping Program is necessary and in the public interest in connection with performance of duties imposed on the Department of the Interior by 43 U.S.C. 31 and section 4 of Public Law 102–285 (the National Geologic Mapping Act of 1992).

Dated: December 30, 1992.
Manuel Lujan, Jr.,
Secretary of the Interior.
[FR Doc. 93–598 Filed 1–11–93; 8:45 am]
BILLING CODE 4310–31–M

Fish and Wildlife Service

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget (OMB) for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed information collection requirement and related forms and explanatory material may be obtained by contacting the Service's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Service Clearance Officer and the Office of Management and Budget, Paperwork Reduction Project (FWS–0002) Washington, DC 20503, telephone 202–395–7340.

Title: Survey to Assess the Public Knowledge of Anadromous Fish in the Klamath River Basin
OMB Approval Number: N/A
Abstract: The Kalamath River Basin Fisheries Task Force is authorized to administer the Klamath restoration program. An important part of such restoration program is to educate the public on (1) the various activities that are being funded, or acted upon by the restoration program; and (2) the life history and environmental requirements of anadromous fish. The information collection will be used to

assess the knowledge of the general public, special interest groups, and school children. Such information will be used to determine the specific educational needs of the local people of the Klamath River Basin, and to develop correctly targeted public communication and educational materials for teaching people about anadromous salmonids in the Klamath Basin.

Service Form Number: None.

Frequency: One-time survey.

Description of Respondents: Individuals and households.

Estimated Completion Time: 15 minutes per response.

Annual Responses: 1,500.

Annual Burden Hours: 375.

Service Clearance Officer: James E. Pinkerton, 703–358–1943 Mail Stop—224 Arlington Square, U.S. Fish and Wildlife Service, Washington, DC 20240.

Dated: December 4, 1992.

Gary Edwards,

Assistant Director—Fisheries.

[FR Doc. 93–557 Filed 1–11–93; 8:45 am]

BILLING CODE 4310–55–M

Bureau of Land Management

[NV–930–03–4210–05; N–55296]

Intent To Prepare a Planning Amendment to the Lahontan Resource Management Plan

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Intent to prepare a plan amendment and an Environmental Assessment (EA) and invitation for public participation.

SUMMARY: The Carson City District proposes to amend the District's Lahontan Resource Management Plan (RMP) in order to provide for a golf course and regional park complex proposed for development in the Spanish Springs Valley area of Washoe County, approximately 5 miles northeast of Sparks, Nevada. The City of Sparks has applied under the authority of the Recreation and Public Purposes Act of 1926 (43 U.S.C. 869 et seq.) for lease and eventual purchase of 449.28 acres of public land for development and operation of these facilities. The public land proposed for least and eventual purchase is described as follows:

Mount Diablo Meridian

T. 20 N., R. 21 E.,
Sec. 18, Lots 1–4, NE¼NE¼, W½E½, SE¼SE¼.

This public land is within an area currently identified in the Lahontan RMP for retention in federal ownership for multiple uses.

DATES AND ADDRESSES: For a period of 30 days from the date of publication of this notice in the **Federal Register**, interested persons may submit comments regarding the proposed plan amendment and environmental assessment to the District Manager, Carson City District Office, 1535 Hot Springs Road, suite 300, Carson City, Nevada 89706.

SUPPLEMENTARY INFORMATION: The public is invited to participate in the identification of issues related to the proposed lease and eventual purchase of the subject land to the City of Sparks for development and operation of a golf course and regional park complex. Anticipated issues include:

(1) Transfer of public land out of Federal ownership.

(2) Change in character and use of land from undeveloped open space utilized mainly for dispersed recreation activities and livestock grazing to a golf course and regional park complex.

(3) Potential impacts to livestock grazing and cultural resources.

(4) Potential impacts to adjacent landowners.

Planning documents and other pertinent materials may be examined at the Carson City District Office between 7:30 a.m. and 4:15 p.m. Monday through Friday.

Dated this 28th day of December, 1992.

Karl Kipping,

Acting District Manager.

[FR Doc. 93–556 Filed 1–11–93; 8:45 am]

BILLING CODE 4310–HC–M

National Park Service

National Register of Historic Places; Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before January 1, 1993. Pursuant to § 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, P.O. Box 37127, Washington, DC 20013–7127. Written comments should be submitted by January 27, 1993.

Carol D. Shull,

Chief of Registration, National Register

ALABAMA

Lauderdale County

Walnut Street Historic District (Boundary Increase), 415—609 N. Poplar St. (odd numbers), Florence, 92001836

Perry County

West Marion Historic District, Routhly bounded by W. Lafayette St., Washington St., Murfree Ave., College St. and Margin St., Marion, 92001844

COLORADO

Clear Creek County

Mint Saloon, 13 E. Park Ave. (US 40), Empire, 92001845

Custer County

Westcliffe Jail, 116 Second St., Westcliffe, 92001846

Douglas County

Hammar, Benjamin, House, 203 Cantril St., Castle Rock, 92001847

Jefferson County

Camp George West Historic District (Camp George West MPS), 15000 S. Golden Rd., Golden vicinity, 92001865

Mesa County

Coates Creek Schoolhouse, D S Rd. 16 mi. W of Glade Park, Glade Park vicinity, 92001839

Weld County

Milne Farm (Historic Farms and Ranches in Weld County MPS), 18457 CO 392, Lucerne vicinity, 92001840

FLORIDA

Volusia County

Barberville Central High School, 1776 Lightfoot Ln., Barberville, 92001838

ILLINOIS

Cook County

Groesbeck, Abraham, House, 1304 W. Washington Blvd., Chicago, 92001841

Greene County

White Hall Historic District (Boundary Increase), 120 S. Jacksonville St., White Hall, 92001837

Kane County

Gridley, Mrs., A.W., House, 637 N. Batavia Ave., Batavia, 92001850

Ogle County

Barber, Bryant H. and Lucie, House, 103 N. Barber Ave., Polo, 92001849

Sangamon County

Flagg, Cornelius, Farmstead, Tipton School Rd., 0.4 mi. W of I–55 Bus, and 0.4 mi. S

of Andrew Rd., Sherman vicinity, 92001848

Warren County

Colwell, E.B., and Company Department Store, 208 S. Main St. and 2111 S. A St., Monmouth, 92001851

LOUISIANA

Orleans Parish

Canal Station, 2819 Canal St., New Orleans, 92001873

St. James Parish

Laura Plantation (Louisiana's French Creole Architecture MPS), 2247 LA 18, Vacherie vicinity, 92001842

MISSOURI

Franklin County

Bethel Church, MO T 2 mi. W of Labadie, Labadie vicinity, 92001867

St. Louis County

Bassett, Dr. Samuel A., Office and Residence, 1200 S. Big Bend Blvd., Richmond Heights, 92001866

NORTH CAROLINA

Rutherford County

Rutherfordton—Spindale Central High School, Jct. of Charlotte Rd. (US 74 Bus.) and US 74, NW corner, Rutherfordton, 92001843

SOUTH DAKOTA

Aurora County

Aurora County Courthouse (County Courthouses of South Dakota MPS), Main St. between Fourth and Fifth Sts., Plankinton, 92001855

Charles Mix County

Charles Mix County Courthouse (County Courthouses of South Dakota MPS), Main St. between Fourth and Fifth Sts., Lake Andes, 92001856

Faulk County

Faulk County Courthouse (County Courthouses of South Dakota MPS), Jct. of Ninth Ave. and Court St., Faulkton, 92001857

Grant County

Grant County Courthouse (County Courthouses of South Dakota MPS), Jct. of Park Ave. and Main St., Milbank, 92001858

Hughes County

Hughes County Courthouse (County Courthouses of South Dakota MPS), Capitol Ave. between Grand and Euclid Aves., Pierre, 92001859

Jerauld County

Jerauld County Courthouse (County Courthouses of South Dakota MPS), Jct. of South Dakota Ave. and Burrett St., Wessington Springs, 92001860

Lake County

Lake County Courthouse (County Courthouses of South Dakota MPS), Center St. between Harth and Lee Aves., Madison, 92001861

McCook County

McCook County Courthouse (County Courthouses of South Dakota MPS), Essex Ave. between Nebraska and Main, Salem, 92001862

Minnehaha County

Presentation Children's Home, Address Restricted, Sioux Falls, 92001852

Sioux Falls Light and Power Hydro Electric Plant, N. Weber Ave. on E Bank of Big Sioux R., Sioux Falls, 92001854

Moody County

Moody County Courthouse (County Courthouses of South Dakota MPS), Pipestone Ave. between Crescent and Wind Sts., Flandreau, 92001863

Sully County

Goosen, Jacob D., Barn, Roughly 0.6 mi. E of Onida, Onida vicinity, 92001853

Ziebach County

Ziebach County Courthouse (County Courthouses of South Dakota MPS), Main St. between Second and Third Sts., Dupree, 92001864

TENNESSEE

Madison County

Greyhound Bus Station (Transportation-Related Properties of Jackson MPS), 407 E. Main St., Jackson, 92001871

Illinois Central Railroad Division Office (Transportation-Related Properties of Jackson MPS), 245 W. Sycamore St., Jackson, 92001869

Murphy Hotel (Transportation-Related Properties of Jackson MPS), 545 S. Royal St., Jackson, 92001872

Nashville, Chattanooga & St. Louis Passenger Depot—Jackson (Transportation-Related Properties of Jackson MPS), 590 S. Royal St., Jackson, 92001870

Southern Engine and Boiler Works (Transportation-Related Properties of Jackson MPS), 342 N. Royal St., Jackson, 92001868

[FR Doc. 93–590 Filed 1–11–93; 8:45 am]

BILLING CODE 4310–70–M

National Park Service's Systemwide Archeological Inventory Program; Announcement of the Final Program

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice on the *National Park Service's Systemwide Archeological Inventory Program*.

SUMMARY: This notice announces the availability of a new publication that describes the *National Park Service's Systemwide Archeological Inventory Program*. This program was announced by National Park Service Director James M. Ridenour on October 13, 1992. The goal of the long-term program is to conduct systematic, scientific research to locate, evaluate, and document archeological resources on National Park System lands.

DATES: Published copies of the *National Park Service's Systemwide Archeological Inventory Program* will be available in February 1993.

ADDRESSES: Single copies of the publication may be obtained at no charge by writing to the Anthropology Division, National Park Service, P.O. Box 37127, Washington, DC 20013–7127.

FOR FURTHER INFORMATION CONTACT: Ms. Michele C. Aubry at (202) 343–1879.

SUPPLEMENTARY INFORMATION: As of October 27, 1992, the National Park System consisted of 367 park units and 10 National Cemeteries covering over 80 million acres. About 53,000 land and submerged archeological sites are known at present. It is estimated that over 390,000 additional sites remain undiscovered. These sites contain valuable, unique, and irreplaceable information about the nation's prehistory and history. Many also are important for associations to contemporary society.

It is the National Park Service's (NPS) policy to ensure that archeological resources under its stewardship are conserved, protected, preserved *in situ*, and managed for long-term scientific research and for appropriate public interpretation and education. Unfortunately, information about the location, characteristics, and significance of the majority of archeological resources in park areas is lacking. This seriously impairs the ability of park managers, planners, interpreters, law enforcement officers, and other specialists to effectively carry out their responsibilities.

The *National Park Service's Systemwide Archeological Inventory Program* was developed to correct this problem. In addition, it will provide the framework for the NPS to fulfill the archeological inventory and survey requirements contained in Executive Order 11593 (*Protection and Enhancement of the Cultural Environment*) the National Historic Preservation Act, and the Archaeological Resources Protection Act.

As noted above, the goal of the long-term program is to conduct systematic, scientific research to locate, evaluate, and document archeological resources under NPS stewardship. The primary objectives are to:

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1. Determine the nature and extent of archeological resources in park areas;

2. Record and evaluate those resources, including nominating eligible properties for listing in the National Register of Historic Places; and

3. Recommend appropriate strategies for conserving, protecting, preserving *in situ*, managing, and interpreting those resources.

A Servicewide task force of archeologists developed the inventory program.[1] During January and February of 1992, a draft (Dec. 1991) of the program was circulated widely within and outside of the NPS for review and comment. Thirty-three commenters provided written comments. Without exception, all commenters were supportive of the draft program. Many of them also provided suggestions for improvement. To the degree possible, the final program approach reflects the perspectives and insights provided by the commenters.

Copies of the *National Park Service's Systemwide Archeological Inventory Program* will be distributed to the NPS Washington Office and Field Directorates; Park Superintendents; State Historic Preservation Officers; State Archeologists; Historic Preservation Officers of Federal land management agencies; Historic Preservation Officers and other officials of Indian tribes, Alaska Native villages and corporations, and Native Hawaiian organizations whose lands are near national parks or who have traditional associations with national park areas; officials who represent national Native American organizations and national professional archeological societies; and the Executive Directors of the National Conference of State Historic Preservation Officers, the Advisory Council on Historic Preservation, and the Federal Preservation Forum. Single copies also will be sent to other interested persons who request them.

Dated: January 6, 1993.

Jerry L. Rogers,

Associate Director, Cultural Resources, National Park Service.

[FR Doc. 93–591 Filed 1–11–93; 8:45 am]

BILLING CODE 4310–70–M

[1] Task force members include Ms. Michele C. Aubry (Washington Office), Mr. Dane C. Linck (Applied Archeology Center), Dr. Mark J. Lynott (Midwest Archeological Center), Mr. Robert R. Mierendorf (North Cascades National Park), and Dr. Kenneth M. Schoenberg (Alaska Regional Office).

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

Agency for International Development

Public Information Collection Requirements Submitted to OMB for Review

The Agency for International Development (A.I.D.) submitted the following public information collection requirements to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Comments regarding these information collections should be addressed to the OMB reviewer listed at the end of the entry no later than ten days after publication. Comments may also be addressed to, and copies of the submissions obtained from the Reports Management Officer, Fred D. Allen (202) 467–9367, FA/AS/ISS, Room 3726 NS, Washington, DC 20523–0042.

Date Submitted: December 30, 1992.

Submitting Agency: Agency for International Development.

OMB Number: None.

Form Number: None.

Type of Submission: New Collection.

Title: General Public and Target Audiences Survey.

Purpose: The Development Education Program (DEP) of the U.S. Agency for International Development (A.I.D.) was created to facilitate, among the American public, organizations, and leadership, widespread understanding, discussion, and analysis of the social, economic, and political conditions related to world hunger and poverty. Under the program, some $2.7 million is administered annually through competitive grants to organizations which fall under the classification of "Private Voluntary Organizations" (PVOs). A.I.D. has considered the evaluation of this program as one of its highest evaluation priorities because of the lack of evaluation and changing climate in public opinion toward international assistance caused by the end of the Cold War.

Annual Reporting Burden Respondents: 1800; annual responses: 1; average hours per response: .583; burden hours: 1,047

Reviewer: Lin Liu (202) 395–7340, Office of Management and Budget, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: December 24, 1992.

Elizabeth Baltimore,

Information Support Services Division.

[FR Doc. 93–564 Filed 1–11–93; 8:45 am]

BILLING CODE 6116–01–M

Grant Proposal Draft Guidance; Availability

Notice of Availability: The following document, "FY 1994 Public Law 480, Title II Voluntary Agency Program Plan and Section 202(e) Grant Proposal Draft Guidance," is available free of charge. If you desire a copy, please contact: Rita Hudson, Office Food for Peace, Bureau for Food and Humanitarian Assistance, Telephone: 703–351–0115.

Dated: January 5, 1993.

Robert Hechtman,

Acting Director, Office of Food for Peace, Bureau for Food and Humanitarian Assistance.

[FR Doc. 93–563 Filed 1–11–93; 8:45 am]

BILLING CODE 6116–01–M

INTERNATIONAL TRADE COMMISSION

[Investigations Nos. 731–TA–636–638 (Preliminary)]

Stainless Steel Wire Rod From Brazil, France, and India

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of preliminary antidumping investigations.

SUMMARY: The Commission hereby gives notice of the institution of preliminary antidumping investigations Nos. 731–TA–636–638 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from Brazil, France, and/or India of stainless steel wire rod, provided for in subheading 7221.00.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value.[1] The Commission must complete preliminary antidumping investigations in 45 days, or in this case by February 16, 1993.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through

[1] For purposes of these investigations, stainless steel wire rod consists of all diameters, shapes, and grades of lengths of alloy steels containing, by weight, 1.2 percent or less of carbon and 10.5 percent or more of chromium, with or without other elements, hot-rolled or hot-rolled annealed and pickled, of solid cross-section, in coils, for subsequent cold-drawing or cold rolling.

E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

EFFECTIVE DATE: December 30, 1992.

FOR FURTHER INFORMATION CONTACT: Larry Reavis (202)–205–3185), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION

Background

These investigations are being instituted in response to a petition filed on December 30, 1993, by Al Tech Specialty Steel Corp., Dunkirk, NY; Armco Stainless & Alloy Products, Inc., Baltimore, MD; Carpenter Technology Corp., Reading, PA; Republic Engineered Steels, Inc., Massilon, OH; and Talley Metals Technology, Inc., Hartsville, SC; and the United Steelworkers of America, AFL–CIO/CLC.

Participation in the Investigations and Public Service List

Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven (7) days after publication of this notice in the **Federal Register.** The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these preliminary investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made not later than seven (7) days after the publication of this notice in the **Federal Register.** A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference

The Commission's Director of Operations has scheduled a conference in connection with these investigations for 9:30 a.m. on January 22, 1993, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Larry Reavis (202–205–3185) not later than January 19, 1993, to arrange for their appearance. Parties in support of the imposition of antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written Submissions

As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before January 27, 1993, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three (3) days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to section 207.12 of the Commission's rules.

Issued: January 5, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–827 Filed 1–8–93; 4:06 pm]

BILLING CODE 7020–02–M

[Investigations Nos. 731–TA–639 and 640 (Preliminary)]

Stainless Steel Flanges From India and Taiwan

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of preliminary antidumping investigations.

SUMMARY: The Commission hereby gives notice of the institution of preliminary antidumping investigations Nos. 731–TA-639 and 640 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from India and Taiwan of stainless steel flanges, finished or unfinished, provided for in subheadings 7307.21.10 and 7307.21.50 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value. The Commission must complete preliminary antidumping investigations in 45 days, or in this case by February 16, 1993.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

EFFECTIVE DATE: December 31, 1992.

FOR FURTHER INFORMATION CONTACT: Woodley Timberlake (202–205–3188), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION:

Background

These investigations are being instituted in response to a petition filed on December 31, 1992, by Flowline Division, Markovitz Enterprises, Inc., New Castle, PA; Gerlin, Inc., Carol Stream, IL; Ideal Forging Corp., Southington, CT; and Maass Flange Corp., Houston, TX.

Participation in the Investigations and Public Service List

Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in sections 201.11 and 207.10 of the Commission's rules, not later than seven (7) days after publication of this notice in the **Federal Register**. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List

Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these preliminary investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made not later than seven (7) days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference

The Commission's Director of Operations has scheduled a conference in connection with these investigations for 9:30 a.m. on January 21, 1993, at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Woodley Timberlake (202–205–3188) not later than January 19, 1993, to arrange for their appearance. Parties in support of the imposition of antidumping duties in these investigations and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the conference.

Written Submissions

As provided in sections 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before January 26, 1993, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties may file written testimony in connection with their presentation at the conference no later than three (3) days before the conference. If briefs or written testimony contain BPI, they must conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with sections 201.16(c) and 207.3 of the rules, each document filed by a party to these investigations must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to section 207.12 of the Commission's rules.

Issued: January 5, 1993.
By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–828 Filed 1–8–93; 4:06 pm]

BILLING CODE 7020–02–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32157]

Burlington Northern Railroad Co.; Purchase and Operation Exemption; Southern Pacific Transportation Co.

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission, under 49 U.S.C. 10505, exempts, from prior approval requirements of 49 U.S.C. 11343, the purchase and operation by Burlington Northern Railroad Company of Southern Pacific Transportation Company's 13.45-mile rail line, and related property, between milepost 324.39 at South Sherman, TX and milepost 337.84 at Denison, TX. The exemption is subject to standard employee protection conditions.

DATES: This exemption will be effective on February 11, 1993. Petitions to stay must be filed by January 27, 1993. Petitions for reconsideration must be filed by February 8, 1993.

ADDRESSES: Send pleadings referring to Finance Docket No. 32157 to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

(2) Petitioner's representative: Ethel A. Allen, Burlington Northern Railroad Company, 3800 Continental Street, Forth Worth, TX 76102.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder, (202) 927–5610.

[TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTAL INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Decided: January 4, 1993.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–625 Filed 1–11–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–1 (Sub-No. 247X)]

Chicago and North Western Transportation Company—Abandonment Exemption—In Milwaukee, WI.; Notice of Exemption

Chicago and North Western Transportation Company (C&NW) has filed a verified notice under 49 CFR Part 1152 subpart F—*Exempt Abandonments* to abandon a 3.0-mile rail line between mileposts 86.13 and 89.13 in the City of Milwaukee, Milwaukee County, WI.

C&NW has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) any overhead traffic on the line can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7(b) (service of environmental report on agencies), 49 CFR 1105.8(c) (service of historic report on State Historic Preservation Officer), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (service of verified notice on governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial

revocation under 49 U.S.C. 10505(d) must be filed.

This exemption will be effective on February 11, 1993,[1] unless stayed or a formal expression of intent to file an offer of financial assistance (OFA) is filed. Petitions to stay that do not involve environmental issues[2] and formal expressions and formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2)[3] must be filed by January 22, 1993. Petitions to reopen must be filed by February 1, 1993.

C&NW indicates in its verified notice that in 1974 Milwaukee County obtained title to the right-of-way beneath the involved rail line through condemnation, subject to an easement for C&NW rail operations. C&NW asserts that the County requested this abandonment so that it could expand and extend a bicycle path that it had constructed on its right-of-way adjacent to C&NW's rail line. In a routine abandonment class exemption proceeding, provision would be made in the notice of exemption published in the **Federal Register** for filing requests for public use and trail use/rail banking conditions. Here, however, this would be a meaningless act since C&NW has only an easement interest in the right-of-way, a portion of the right-of-way is already being used for public (trail) purposes, and the proposed future use of the remainder of the right-of-way is for those purposes. Accordingly, no such requests will be entertained.

An original and 10 copies of any pleading filed with the Commission should be sent to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any pleading filed with the Commission should be sent to C&NW's representative: Robert T. Opal, Chicago and North Western Transportation Company, One North Western Center, Chicago, IL 60606–1551.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

[1] C&NW indicates in its verified notice that it proposes to consummate the abandonment on February 10, 1993. C&NW is reminded that consummation may not occur before the effective date of the exemption, here February 11, 1993.

[2] A stay will be issued routinely where an informed decision on environmental issues, whether raised by a party or by the Commission's Section of Energy and Environment (SEE), cannot be made before the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay on environmental grounds is encouraged to file promptly so that the Commission may act on the request before the effective date.

[3] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

C&NW has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. SEE will issue an environmental assessment (EA) by January 15, 1993. Interested persons may obtain a copy of the EA by writing to SEE (room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEE, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA is available to the public.

Environmental and historic preservation conditions will be imposed, where appropriate, in a subsequent decision.

Decided: January 6, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–729 Filed 1–11–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–55 (Sub-No. 438X)]

CSX Transportation, Inc.—Abandonment Exemption—In Albemarle and Louisa Counties, VA

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: Pursuant to 49 U.S.C. 10505, the Commission exempts from the prior approval requirements of 49 U.S.C. 10903–10904 the abandonment by CSX Transportation, Inc., of 1.71-miles of rail line in Albemarle and Louisa Counties, VA, between milepost CPG–0.0 and milepost CPG–1.71, subject to standard labor protective conditions.

DATES: Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on February 11, 1993. Formal expressions of intent to file an offer of financial assistance[1] under 49 CFR 1152.27(c)(2) must be filed by January 22, 1993, petitions to stay must be filed by January 27, 1993, and petitions for reconsideration must be filed by February 8, 1993. Requests for public use conditions must be filed by February 1, 1993.

ADDRESSES: Send pleadings referring to Docket No. AB–55 (Sub–No. 438X) to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423, and

[1] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

(2) Petitioner's representative: Charles M. Rosenberger, 500 Water Street—J150, Jacksonville, FL 32202.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder (202) 927–5610, [TDD number: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721.]

Decided: January 5, 1993.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–628 Filed 1–11–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–55 (Sub-No. 447X)]

CSX Transportation, Inc.—Abandonment Exemption—Summit County, OH; Notice of Exemption

CSX Transportation, Inc. (CSXT) has filed a notice of exemption under 49 CFR Part 1152 subpart F—*Exempt Abandonments* to abandon its 8.15-mile line of railroad between mileposts BJB–25.55 at Aultman and BJB–33.70 at Krumroy, in Summit County, OH.

CSXT has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; and (3) no formal complaint filed by a user of rail service on the line (or a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period. CSXT also certified that it has complied with the requirements at 49 CFR 1152.50(d)(1) (notice to government agencies).

As a condition to the use of this exemption, any employee affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expressions of intent to file an offer of financial assistance (OFA) has been received, this

exemption will be effective on February 11, 1993, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking statements under 49 CFR 1152.29 must be filed by January 22, 1993.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by February 1, 1993, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Charles M. Rosenberger; CSX Transportation, Inc., 500 Water Street J150, Jacksonville, FL 32202.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

Applicant has filed an environmental report which addresses the abandonment's effect, if any, on the environmental or historic resources.

The Section of Energy and Environment (SEE) will issue an environmental assessment (EA) by January 15, 1993. Interested persons may obtain a copy of the EA from SEE by writing to it (room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief, SEE at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: January 6, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–629 Filed 1–11–93; 8:45 am]

BILLING CODE 7035–01–M

[1] A stay will be routinely issued by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Section of Energy and Environment in its independent investigation) cannot be made prior to the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible in order to permit this Commission to review and act on the request before the effective date of this exemption.

[2] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[3] The Commission will accept a late-filed trail use statement as long as it retains jurisdiction to do so.

[Docket No. AB–290 (Sub-No. 124X)]

Norfolk and Western Railway Company—Abandonment Exemption—In Smyth and Washington Counties, VA; Notice of Exemption

Norfolk and Western Railway Company (NW), has filed a notice of exemption under 49 CFR, 1152 subpart F—*Exempt Abandonment* to abandon approximately 8.2 miles of railroad between milepost G–1.00, at Glade Spring, and milepost G–9.20, at Saltville, in Smyth and Washington Counties, VA.[1]

Applicant has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period, and (4) that the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

This exemption will be effective on February 11, 1993, unless stayed or a formal expression of intent to file an offer of financial assistance (OFA) is filed. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[3] and trail use/rail banking requests under 49 CFR 1152.29[4] must be filed by January 22, 1993. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by February 1, 1993, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any pleading filed with the Commission should be sent to applicant's representative: Richard W. Kienle, Three Commercial Place, Norfolk, VA 23510.

If the notice of exemption contains false or misleading information, the exemption is void *ab initio*.

Applicant has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. SEE will issue an environmental assessment (EA) by January 15, 1993. Interested persons may obtain a copy of the EA by writing to SEE (room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEE, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA is available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: December 18, 1992.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–630 Filed 1–11–93; 8:45 a.m.]

BILLING CODE 7035–01–M

[1] Washington County filed a comment in opposition to the abandonment. The County's comment will be treated as a petition for reconsideration and considered later.

[2] A stay will be issued routinely where an informed decision on environmental issues, whether raised by a party or by the Commission's Section of Energy and Environment (SEE), cannot be made before the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay on environmental grounds is encouraged to file promptly so that the Commission may act on the request before the effective date.

[3] See Exempt. of Rail Abandonment—Offers of Finan. Assist. 4 I.C.C.2d 164 (1987).

[4] The Commission will accept a late-filed trail use request as long as it retains jurisdiction to do so.

[Finance Docket No. 32195]

Southern Electric Railroad Co.; Construction Exemption; Effingham County, GA

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: Pursuant to 49 U.S.C. 10505, the Commission conditionally exempts Southern Electric Railroad Company from the prior approval requirements of 49 U.S.C. 10901 to construct approximately 2.5 miles of track in Effingham County, GA. The proposed line would run from Plant McIntosh owned and operated by Savannah Electric and Power Company to a main line of the Norfolk Southern Railway Company. The exemption is subject to the Commission's subsequent approval of the environmental aspects of the proposal.

DATES: The Commission's decision to exempt the proposed construction will become effective upon completion of its

environmental review process. Petitions to reopen must be filed by February 1, 1993.

ADDRESSES: Send pleadings referring to Finance Docket No. 32195 to: (1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423; and

(2) Petitioner's representatives:

John R. Molm, Esq., NationsBank Plaza, Suite 5200, 600 Peachtree Street, NE., Atlanta, GA 30308–2216, and

Leamon R. Holliday, Esq., 447 Bull Street, P.O. Box 2139, Savannah, GA 31498.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder, (202) 927–5610. [TDD for hearing impaired: (202) 927–5721.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5721].

Decided: December 30, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–626 Filed 1–11–93; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Lodging of Consent Decree Pursuant to the Clean Water Act; United States v. Alaqua et al.

In accordance with Department Policy, 28 CFR 50.7., notice is hereby given that a consent decree in *United States* v. *Alaqua et al.* was lodged with the United States District Court for the Middle District of Florida on December 10, 1992.

The proposed consent decree concerns alleged violations of section 404 of the Clean Water Act, 33 U.S.C. 1344, as a result of discharges of fill material onto portions of property located east of the Little Wekiva River in Township 20S, Range 29E, Northeast Seminole County, Florida, which are alleged to be "waters of the United States." The Consent Decree requires defendants Alaqua, Westbury Alaqua, Inc., and Westbury Development, Inc. (collectively "Alaqua") to remove any fill activity which is not permitted as a result of an after-the-fact permit application Alaqua has filed with the United States Army Corps of Engineers. In addition, the Consent Decree requires Alaqua to pay a civil penalty of three hundred thousand dollars ($300,000).

The Department of Justice will receive written comments relating to the consent decree submitted within thirty (30) days from the date of this notice. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, United States Department of Justice, Environmental and Natural Resources Division, Attention: David Dana, Attorney, Environmental Defense Section, 10th and Pennsylvania Ave., NW., Washington, DC 20530; and should refer to *United States* v. *Alaqua*, DJ reference No. 90–5–1–4–356.

The consent decree may be examined at the Clerk's Office, United States District Court, Middle District of Florida, during regular business hours; or upon written request to David A. Dana, Attorney, United States Department of Justice, Environment and Natural Resources Division, United States Department of Justice, Environmental Defense Section, 10th and Pennsylvania Ave., NW., Washington, DC 20530.

Roger Clegg,

Acting Assistant Attorney General, Environment and Natural Resources Division.

[FR Doc. 93–597 Filed 1–11–93; 8:45 am]

BILLING CODE 4410–01–M

Antitrust Division

U.S. v. Airline Tariff Publishing Co., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b) through (h), that a proposed Final Judgment, Stipulation and Competitive Impact Statement have been filed with the United States District Court for the District of Columbia in *United States* v. *Airline Tariff Publishing Company, et al.*, Civil Action No. 92 2854.

The Complaint in this case alleged that eight airline defendants, Alaska Airlines, Inc., American Airlines, Inc., Continental Airlines, Inc., Delta Air Lines, Inc., Northwest Airlines, Inc., Trans World Airlines, Inc., United Air Lines, Inc., and U.S. Air, Inc., engaged in various combinations and conspiracies with other of the airline defendants and co-conspirators to increase fares, eliminate discounted fares and set fare restrictions for tickets purchased for travel between cities in the United States. These combinations and conspiracies were reached and effectuated through the airline defendants' use of the computerized fare dissemination services of the defendant Airline Tariff Publishing Company ("ATP").

The Complaint also alleged that the airline defendants, ATP, and co-conspirators engaged in a combination and conspiracy to create, maintain, operate and participate in the ATP fare dissemination system. This fare dissemination system has been formulated and operated in a manner that unnecessarily facilitates coordinated interaction among the airline defendants and co-conspirators.

The proposed Final Judgment enjoins the settling defendants, United Air Lines, Inc. and USAir, Inc., for a period of ten years, from entering into any agreements with any other airline to fix, establish, raise, stabilize, or maintain any fare or fare restriction. Furthermore, the proposed Final Judgment prohibits United Air Lines, Inc. and USAir, Inc. from disseminating certain information that may allow them to reach agreements or to facilitate coordinated interaction among themselves and other airlines. The proposed Final Judgment also requires United Air Lines, Inc. and USAir, Inc. to establish and maintain an antitrust compliance program.

Public comment is invited within the statutory 60-day comment period. Such comments, and responses thereto, will be published in the **Federal Register** and filed with the Court. Comments should be directed to Mark C. Schechter, Chief, Transportation, Energy and Agriculture Section, Antitrust Division, Department of Justice, room 9104, 555 Fourth St., NW., Washington, DC 20001, (telephone: 202–307–6349).

Joseph H. Widmar,

Director of Operations, Antitrust Division.

Filed 12/21/92, Judge Revercomb.

Stipulation

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties thereto, and venue of this action is proper in the District of Columbia;

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. 16), and without further notice to any party or other proceedings, provided that Plaintiff has not withdrawn its consent,

which it may do at any time before the entry of the Proposed Final Judgment by serving notice thereof of Defendants and by filing that notice with the Court;

3. In the event Plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this Stipulation, this Stipulation shall be of no effect whatever, and the making of this Stipulation shall be without prejudice to any party in this or any other proceeding.

Dated: December 21, 1992.

For Plaintiff United States of America

J. Mark Gidley,

Acting Assistant Attorney General.

Joseph H. Widmar.

Mark C. Schechter.

Roger W. Fones.

Attorneys, U.S. Department of Justice.

Donna N. Kooperstein.

Mary Jean Moltenbrey.

Michael D. Billiel.

Jill Ptacek.

Bradley S. Lui.

Attorneys, U.S. Department of Justice, Antitrust Division, 555 4th Street, NW., room 9104, Washington, DC 20001, (202) 307–6388.

For Defendant United Air Lines, Inc., O'Melveny & Myers.

By: Henry C. Thuman, A Member of the Firm.

400 South Hope Street, Los Angeles, CA 90071–2899, (213) 669–6000.

For Defendant USAir, Inc.; Covington & Burling.

By: Charles F. Rule, a Member of the Firm.

1201 Pennsylvania Ave., N.W., Washington, DC 20044, (202) 662–6000.

Filed: 12/21/92, Judge Revercomb.

Final Judgment

Plaintiff, United States of America, filed its Complaint on December 21, 1992. Plaintiff and defendants, by their respective attorneys, have consented to the entry of the Final Judgment without trial or adjudication of any issue of fact or law. This Final Judgment shall not be evidence against or an admission by any party with respect to any issue of fact or law. Therefore, before the taking of any testimony and without trial or adjudication of any issue of fact or law herein, and upon consent of the parties, it is hereby

Ordered, adjudged, and decreed, as follows:

I. Jurisdiction

This Court has jurisdiction of the subject matter of this action and of each of the parties consenting hereto. The Complaint states a claim upon which relief may be granted against the defendants under Section 1 of the Sherman Act, 15 U.S.C. 1.

II. Definitions

As used herein, the term:

(A) "airline" means any scheduled air passenger carrier as defined in 49 U.S.C. 1301(3), its officers, directors, employees, agents, and any other persons acting on its behalf;

(B) "ATP" means the Airline Tariff Publishing Company;

(C) "change" means abandon, add, alter, modify, discontinue, drop, exchange, replace, substitute, switch, or transform;

(D) "coupon" means a coupon or similar voucher offering either a discount off existing fares or a special fare not otherwise available;

(E) "CRS" means computer reservation system;

(F) "defendants" means United Air Lines, Inc. and USAir, Inc.;

(G) "document" means all "writings and recordings" as that phrase is defined in Rule 1001(1) of the Federal Rules of Evidence;

(H) "fare" means the price charged for domestic passenger transportation by any airline, and any rules, restrictions, terms, or conditions governing the availability or use of any such price, but does not include any contract or other negotiated price or any coupon;

(I) "fare class" means a group of fares treated similarly for seat allocation purposes;

(J) "first ticket date" means the first date that a fare is available for sale;

(K) "footnote" means the mechanism used by ATP to store and transmit first ticket dates, last ticket dates, and other limitations on the use of a fare;

(L) "footnote designator" means an alphanumeric designator used to identify a footnote;

(M) "including" means including but not limited to;

(N) "last ticket date" means the last date that a fare is available for sale;

(O) "person" means any natural person, corporation, firm, company, sole proprietorship, partnership, association, institution, governmental unit, or other legal entity;

(P) "promotional fare" as used in Section V(C) means a new fare or group of new fares that, in conjunction with it first being offered for sale, is advertised as being available for purchase for a specified and limited period of time, provided that, where a group of fares is being so advertised, it shall be sufficient to provide a general description of included city or airport pairs and fare levels without specifically identifying each city or airport pair and fare level;

(Q) "relate to" means discuss, refer to, reflect, evidence, concern, or pertain to, in whole or in part;

(R) "tag" means a code used by an airline solely to identify a group of fares for similar processing by ATP; and

(S) "travel date" means a date that limits when a passenger may travel on a fare.

III. Applicability

(A) This Final Judgment applies to the defendants and to each of their successors, assigns, and to all other persons in active concert or participation with any of them who shall have received actual notice of the Final Judgment by personal service or otherwise.

(B) Nothing herein contained shall suggest that any portion of this Final Judgment is or has been created for the benefit of any third party and nothing herein shall be construed to provide any rights to any third party.

IV. Prohibited Conduct

Each of the defendants is enjoined and restrained from:

(A) Agreeing with any other airline to fix, establish, raise, stabilize, or maintain any fare;

(B) Disseminating any first ticket dates, last ticket dates, or any other information concerning the defendant's planned or contemplated fares or changes to fares;

(C) Making visible or disseminating its own tags or any other similar designating mechanism to any other airline;

(D) Making visible or disseminating to any other airline any fare that is intended solely to communicate a defendant's planned or contemplated fares or changes to fares;

(E) Making visible or disseminating two or more footnote designators that identify footnotes that contain identical information, or making visible or disseminating any footnote designator that identifies a footnote that contains no information; and

(F) Using fare codes that convey information other than fare class or terms and conditions of sale or travel.

V. Limiting Conditions

(A) Nothing in this Final Judgment shall prohibit any defendant from submitting its fare changes to ATP for processing, or disseminating to CRSs or other reservations systems rules that do not contain or describe any first ticket date, last ticket date, or planned or contemplated fare level.

(B) Nothing in this Final Judgment shall prohibit any defendant from engaging in communications with another airline when such communications are reasonably necessary to establish, implement, or modify a joint, code share, commuter, or other interline fare with that airline.

(C) Nothing in this Final Judgment shall prohibit any defendant from

advertising that a promotional fare will cease to be available for purchase on a specified date or after a specified period of time, provided that such advertising occurs (i) in conjunction with the promotional fare first being offered for sale, (ii) in media of general circulation or through mass mailings, and (iii) in a manner designed to directly reach a meaningful number of potential consumers likely to purchase the promotional fare. In the event such advertising occurs, nothing in this Final Judgment shall prohibit the advertising defendant from otherwise disseminating information that such fare will cease to be available for purchase on the specified date or after the specified period of time.

After any airline disseminates a promotional fare with a last ticket date in any city or airport pair, nothing in this Final Judgment shall prohibit a defendant from promptly thereafter disseminating, without advertising, a new fare with the same fare level and restrictions and same last ticket date, in the same city or airport pair as that promotional fare, and from thereafter otherwise disseminating such information.

(D) Nothing in this Final Judgment shall prohibit any defendant from disseminating public statements regarding contemplated changes in fares, provided such statements describe neither effective dates nor the particular amounts or rules relating to particular city or airport pairs or sets of city or airport pairs.

(E) Nothing in this Final Judgment shall prohibit any defendant from advocating or discussing, in accordance with the doctrine established in *Eastern Railroad Presidents Conference* v. *Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and its progeny, legislative, judicial or regulatory actions, or governmental policies or actions.

(F) The dissemination of travel dates, in and of itself, does not constitute a violation of this Final Judgment.

(G) Nothing in this Final Judgment shall be construed to prohibit any defendant, in unilaterally determining its own fares, from considering all publicly available information relating to the fares of other airlines.

(H) Regardless of what fares any airline offers in any city or airport pair, offering any fare in the same or any other city or airport pair, in and of itself, does not constitute a violation of this Final Judgment.

VI. Compliance Program

(A) Each defendant is ordered to maintain an antitrust compliance program which shall include designating, within 30 days of entry of this Final Judgment, an Antitrust Compliance Officer with responsibility for accomplishing the antitrust compliance program and with the purpose of achieving compliance with this Final Judgment. The Antitrust Compliance Officer shall, on a continuing basis, supervise the review of the current and proposed activities of his or her defendant company to ensure that it complies with this Final Judgment. The Antitrust Compliance Officer shall be responsible for accomplishing the following activities:

(1) Distributing, within 60 days from the entry of this Final Judgment, a copy of this Final Judgment to all officers and to employees who have any responsibility for approving, disapproving, analyzing, monitoring, studying, recommending, or implementing any fares, or disseminating any fares to ATP, CRSs or any airlines;

(2) Distributing in a timely manner a copy of this Final Judgment to any officer or employee who succeeds to a position described in section VI(A)(1);

(3) Briefing annually those persons designated in section VI(A)(1) on the meaning and requirements of this Final Judgment and the antitrust laws and advising them that the defendant's legal advisors are available to confer with them regarding compliance with the Final Judgment and the antitrust laws;

(4) Obtaining from each officer or employee designated in section VI(A)(1) an annual written certification that he or she: (1) has read, understands, and agrees to abide by the terms of this Final Judgment; and (2) has been advised and understands that his or her failure to comply with this Final Judgment may result in conviction for criminal contempt of court; and

(5) Maintaining a record of recipients to whom the Final Judgment has been distributed and from whom the certification in section VI(A)(4) has been obtained.

(B) At any time, if a defendant's Antitrust Compliance Officer learns of any past or future violations of Section IV of this Final Judgment, that defendant shall, within 45 days after such knowledge is obtained, take appropriate action to terminate or modify the activity so as to comply with this Final Judgment.

(C) For each last ticket date placed in ATP or a CRS pursuant to Section V(C), each defendant shall retain (1) a record of the dates that such last ticket date was disseminated in the system and the specific fares and city or airport pairs to which the last ticket date was attached, and (2) either a representative copy or transcript of the advertisement that was used in conjunction with any such last ticket date and a record of the use of such advertising, or a representative copy or transcript of the advertisement of the promotional fare to which the defendant was responding. Such records and representative copies or transcripts shall be maintained in a manner that facilitates prompt retrieval and review of the documentation required by this section. These documents shall be retained for a period of three years from the first date any such advertising appeared or the first date any such last ticket date appeared in ATP or a CRS.

VII. Certification

(A) Within 75 days after the entry of this Final Judgment, each defendant shall certify to the plaintiff whether it has designated an Antitrust Compliance officer and has distributed the Final Judgment in accordance with Section VI above.

(B) For 10 years after the entry of this Final Judgment, each defendant shall certify to the plaintiff whether it has designated an Antitrust Compliance Officer and has distributed the Final Judgment in accordance with Section VI above.

(B) For 10 years after the entry of this Final Judgment, on or before its anniversary date, each defendant shall file with the plaintiff a statement as to the fact and manner of its compliance with the provisions of section VI.

VIII. Plaintiff Access

(A) To determine or secure compliance with this Final Judgment and for no other purpose, duly authorized representatives of the plaintiff shall, upon written request of the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to any defendant made to its principal office, be permitted, subject to any legally recognized privilege:

(1) Access during such defendant's office hours to inspect and copy all documents in the possession or under the control of such defendant, who may have counsel present, relating to any matters contained in this Final Judgment; and

(2) Subject to the reasonable convenience of such defendant and without restraint or interference from it, to interview officers, employees or agents of such defendant, who may have counsel present, regarding such matters.

(B) Upon the written request of the Assistant Attorney General in charge of the Antitrust Division made to any defendant's principal office, such defendant shall submit such written

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reports, under oath if requested, relating to any matters contained in this Final Judgment as may be reasonably requested, subject to any legally recognized privilege.

(C) No information or documents obtained by the means provided in section VIII shall be divulged by the plaintiff to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

(D) If at the time information or documents are furnished by any defendant to plaintiff, such defendant represents and identifies in writing the material in any such information or documents to which a claim of protection may be asserted under Rule 26(c)(7) of the Federal Rules of Civil Procedure, and such defendant marks each pertinent page of such material, "Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then 10 days notice shall be given by plaintiff to such defendant prior to divulging such material in any legal proceeding (other than a grand jury proceeding) to which that defendant is not a party.

IX. Further Elements of the Final Judgment

(A) This Final Judgment shall expire ten years from the date of its entry.

(B) If, subsequent to the entry of this Final Judgment, a stipulated final judgment in this matter is filed with respect to another airline, or if this Final Judgment or a subsequently filed stipulated final judgment in this matter is modified in any respect, any defendant, in its sole discretion, may move this Court, and the Court shall grant such a motion, to substitute such a stipulated final judgment or modified stipulated final judgment for this Final Judgment.

(C) Jurisdiction is retained by this Court for the purpose of enabling any of the parties to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish violations of its provisions.

(D) Entry of this Final Judgment is in the public interest.

Dated: _____.

_____

United States District Judge

Filed: 12/21/92, Judge Revercomb.

Competitive Impact Statement

Pursuant to section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16 (b)–(h), the United States submits this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry with the consent of United Air Lines, Inc., and USAir, Inc., in this civil antitrust proceeding.

I. Nature and Purpose of the Proceeding

On December 21, 1992, the United States filed a civil antitrust complaint alleging that Alaska Airlines, American Airlines, Continental Airlines, Delta Air Lines, Northwest Airlines, Trans World Airlines, United Air Lines, and USAir ("airline defendants"), Airline Tariff Publishing Company ("ATP"), and co-conspirators conspired unreasonably to restrain competition among themselves in violation of section 1 of the Sherman Act, 15 U.S.C. 1. The Complaint alleges two causes of action.

The first cause of action alleged in the Complaint is that, during the period beginning at least as early as April 1988 and continuing through at least May 1990, each of the airline defendants and co-conspirators engaged in various combinations and conspiracies with other of the airline defendants and co-conspirators, consisting of agreements, understandings, and concerted actions to fix prices by increasing fares, eliminating discounted fares, and setting fare restrictions for tickets purchased for travel between cities in the United States. These agreements, understandings, and concerted actions were reached and effectuated through each of the airline defendant's use of the computerized fare dissemination services of ATP to (1) exchange proposals and negotiate fare changes; (2) trade fare changes in certain markets in exchange for fare changes in other markets; and (3) exchange mutual assurances concerning the level, scope, and timing of fare changes. The combinations and conspiracies alleged in the first cause of action had the effect of depriving consumers of scheduled air passenger transportation services of the benefits of free and open competition in the sale of such services.

The second cause of action alleged in the Complaint is that, during the period beginning at least as early as April 1988 and continuing through to the date of the Complaint, the airline defendants, ATP, and co-conspirators engaged in a combination and conspiracy, consisting of an agreement, understanding, and concert of action to create, maintain, operate, and participate in the ATP fare dissemination system. This fare dissemination system has been formulated and operated in a manner that unnecessarily facilitates coordinated interaction among the airline defendants and co-conspirators, enabling them to: (1) Communicate more effectively with one another about future increases to fares, future changes to fare restrictions, and future elimination of discounted fares; (2) establish links between proposed fare changes in one or more city-pair markets and proposed changes in other city-pair markets; (3) monitor each other's changes, including changes in fares that are not available for sale; and (4) lessen uncertainty concerning each other's pricing intentions. The combination and conspiracy alleged in the second cause of action has made coordinated interaction among the airline defendants and co-conspirators more likely, successful, and complete, and has deprived consumers of air passenger transportation services of the benefits of free and open competition in the sale of such services.

The Complaint seeks relief that will prevent the defendants from continuing or renewing the alleged conspiracies, or engaging in any other conspiracy or adopting any other practice having a similar purpose or effect.

On December 21, 1992, the United States, United and USAir filed a Stipulation in which they consented to the entry of the proposed Final Judgment containing prohibitions on the conduct of United and USAir (the settling defendants) that provides the relief the United States seeks in the Complaint. Under the proposed Final Judgment, the settling defendants will be required to institute a compliance program to ensure that they do not continue or renew the alleged conspiracies or engage in any other conspiracy or practice having a similar purpose or effect. Additionally, the proposed Final Judgment requires that United and USAir file annual reports with the Government certifying that each has complied with section VI of the Final Judgment.

The United States and the settling defendants have stipulated that the Court may enter the proposed Final Judgment after compliance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), provided the United States has not withdrawn its consent. The proposed Final Judgment provides that its entry does not constitute any evidence against or admission by any party with respect to any issue of fact or law.

Entry of the proposed Final Judgment will terminate the action against United and USAir, except that the Court will

retain jurisdiction over the matter of further proceedings that may be required to interpret, enforce, or modify the Final Judgment, or to punish violations of any of its provisions.

II. Description of the Practices Involved in the Alleged Violations

A. Industry Background

The domestic passenger airline industry generates annual sales in the tens of billions of dollars. Each of the airline defendants is a significant competitor, providing scheduled nonstop, one-stop, and multi-stop domestic air passenger services between a large number of origin and destination cities (city pairs).

Through hub and spoke route systems, the airlines are able to consolidate passengers from many points at a single location (the hub) and then transport them, along with passengers originating at the hub, to a common destination. The hub system generally permits an airline to serve many more city pairs than it otherwise would be able to serve with nonstop service alone.

Although each of the airline defendants operates an extensive network of city-pair routes, the networks are not identical. All airlines do not serve all city pairs, and the service offered by airlines on the same city pair may vary as to the type of service offered (nonstop versus one or more stops). In addition, the times and frequencies of service offered may vary considerably among airlines. As a consequence of service variations and differences in passenger mixes and cost structures, airlines may have varying preferences as to the prices that should be charged passengers for travel on a particular city pair.

For each of the thousands of city pairs served by each airline, numerous fares are offered to customers. Many of these fares carry different types of restrictions that are designed to segment the market for air travel into groups with varying sensitivities to price and time of travel. For example, fares designed to appeal to leisure travelers may carry longer advance purchase requirements than fares designed for business travelers.

Airlines constantly alter fares in response to changes in costs, both industrywide and airline-specific, and to changes in consumer demand, both for travel generally and travel on particular city pairs. Moreover, the availability to consumers of a seat on a particular flight at a particular fare is controlled by each airline's continuous adjustment, based upon projected and actual demand, of the inventory of seats available at that fare.

ATP is the central source for the collection, organization, and dissemination of fare information for virtually every domestic airline. (ATP does not receive seat allocation information.) Each of the airline defendants owns and participates in the ATP fare dissemination system through which information is exchanged about fares. ATP also provides this information to computer reservation systems ("CRSs") and other subscribers.

Each airline supplies ATP with basic information about its fares. This information includes: fare codes (which indicate the names of the fares—*e.g.*, "F" is first class; "Y" is full coach), fare amounts, rules, and routings. Rules contain restrictions that limit or condition the use of the fare, including advance purchase requirements and penalties for itinerary changes. Routings are used to limit fares to travelers using a particular itinerary, for example, connecting flights over a particular hub.

An airline also can attach up to two footnotes to any fare in the ATP date base. Footnotes are identified by alphanumeric codes ("footnote designators"), such as "A" or "32." Footnotes are used by airlines to identify, among other things, the relevant ticketing and travel dates.

A first ticket date indicates a future date at which a fare is currently scheduled to become available for purchase by consumers. The dissemination of a fare with a first ticket date does not mean that the fare will ever be offered for sale; the airlines often change the first ticket date to an earlier or later time than originally announced, or withdraw the fare altogether before the first ticket date arrives.

A last ticket date indicates a future date at which a fare currently offered for sale may no longer be available for sale. Again, no obligation is implied by the dissemination of a last ticket date, and the airlines often change the last ticket date to an earlier or later time than originally announced, or withdraw the fare before its last ticket date.

The travel dates contained in footnotes indicate when a consumer can travel using a particular fare. A first travel date indicates the first date upon which travel on a particular fare may commence. A last travel date indicates the last date upon which travel may commence.

At least once every weekday, each airline defendant submits its fare changes to ATP. Fare changes include changes in existing fares, both those available and unavailable for sale, as well as the addition of new fares, which may be either available or unavailable for sale. Many of the airline defendants' changes to existing fares involve changes in footnotes that add, change or remove the first or last ticket dates. To indicate that fare changes in different markets are connected, airlines can use a common footnote designator for each set of changes.

Once ATP receives the fare changes, it processes the changes and then disseminates those fare changes at least once each weekday to the airline defendants and other ATP subscribers, including CRSs. The information disseminated by ATP includes, among other things, the fare codes, dollar amounts, and rules involved in each airline defendant's pricing actions. ATP also disseminates the footnotes used by each airline defendant on each fare, including the footnote designators and the ticketing and travel dates contained in the footnotes.

The information disseminated by ATP is used differently by the CRSs and the airline defendants. The airline defendants, either directly or by contract with third parties, employ sophisticated computer programs that process and sort the fare and fare change information received from ATP to produce detailed daily reports. These reports display the fare changes in a variety of ways that allow the airline defendants to monitor and analyze all of each other's fares and contemplated changes to fares and to discern patterns or links among fare changes in various markets.

In contrast, CRSs load the information into their data bases, which travel agents use to make reservations and price tickets on fares that are available for sale. Travel agents using a CRS can obtain fare information for only one market at a time, most often for a specific flight on a given day, and they do not have access to any airline's footnote designators. Thus, travel agents cannot readily determine all of the airlines' contemplated changes to fares. Nor can they easily determine relationships between fares (including proposed fare increases and proposed elimination of discounted fares) in one or more city pairs and fares in other city pairs.

B. Illegal Agreements to Fix Prices by Increasing Fares, Eliminating Discounted Fares, and Setting Fare Restrictions in Various City-Pair Markets

The first cause of action is based on an alleged series of Sherman Act section 1 *per se* illegal price fixing agreements that were reached beginning as early as

April 1988 and continuing through at least May 1990. Using the ATP fare dissemination system, the airline defendants participated in a complex, iterative, and essentially private exchange of future fare information with the purpose and effect of reaching agreements on price. Using, among other things, first and last ticket dates and footnote designators, they exchanged clear and concise messages setting forth the fare changes that each preferred, and they engaged in an electronic dialogue to work out their differences. The airline defendants conducted complex negotiations, offered explanations, traded concessions with one another, took actions against their independent self-interests, punished recalcitrant airlines that discounted fares, and exchanged commitments and assurances—all to the end of reaching agreements to increase fares, eliminate discounts, and set fare restrictions.

There is evidence of two types of price fixing agreements and each of the airline defendants was a party to such agreements. These price fixing agreements occurred frequently, were of significant duration, and involved many city-pair markets, including some of the most heavily traveled in the United States.

In the first type of agreement, the airline defendants rely primarily on fares with first ticket dates in the future, (that is, fares that are not available for purchase by consumers), in conjunction with footnote designators and other devices, to communicate proposals, counterproposals, and commitments to increase fares. For example, Carrier A initially proposes to increase a set of fares in a number of markets by filing these changes in ATP with a first ticket date two weeks in the future (and attaching a last ticket date to the corresponding existing fares that are to be replaced). The increase may involve raising the level of a particular fare or making the rules for a particular fare more restrictive. Other airlines than respond to Carrier A's proposal by filing similar fares with future first ticket dates, filing different fares with future first ticket dates, or expanding the set of fares with future first ticket dates to include different markets or fare types. Fares in thousands of markets may be involved. Typically, each airline links the markets and far types involved by using the same footnote designator on all of the fares that it proposes to increase.

The process of negotiation through fare proposals may go through several iterations during which the fare level originally proposed may be modified and different types of fares or sets of markets may be added or subtracted from the proposal, as the airlines bargain and make trades with each other. (Airline A, for instance, may go along with increases that it did not prefer in markets X and Y in exchange for Airline B going along with increases that it did not prefer in markets R and S.) The first ticket date (and corresponding last ticket dates) may be repeatedly postponed into the future to ensure that the fares do not go into effect until all significant competitors have committed to them. This complex negotiation ends when all airlines have indicated their commitment to the fare increases by filing the same fares in the same markets with the same first ticket date. The increases take effect on that future date and then, and only then, are the lower fares withdrawn and the new and higher fares sold in their place.

In the second type of agreement, the airlines rely primarily on last ticket dates, in conjunction with footnotes designators and other devices, to communicate proposals, counterproposals and commitments to eliminate discounted fares which are currently being sold to consumers. The negotiation process may mirror that described above except that the airlines communicate by placing last ticket dates on the particular fares that each proposes to eliminate. The negotiation ends when all of the airlines have placed the same last ticket date on the same fares. On that date, the particular discounted fares expire.

In certain instances, an airline may create a basis for an agreement to eliminate particular discounted fares at a particular time. For example, Airline A independently concludes that it is in its best interest to file a discounted fare in a market important to Airline B. Airline B, however, finds the discounted fare objectionable. Airline B may create a basis for a trade by placing a low fare in one of Airline A's more profitable markets. It then attaches to that fare a last ticket date that is only a few days in the future. Airline B may use a unique footnote designator for the fare, that is, a designator that is different from that used for any other fare with the same last ticket date, thus highlighting its action. To ensure that Airline A understands the link between the new "tradeable" discount fare and the targeted discount fare, Airline B may also use a fare basis code and dollar amount for the new fare similar to that of the targeted fare. In some cases, Airline B may also file in its own market a fare that matches Airline A's original discount fare but that has the same last ticket date and footnote designator as its new tradeable discount fare in Airline A's market, thus linking Airline A's original discount fare and Airline B's new fare even more clearly.

In these ways, Airline B conveys an offer to Airline A: "I'll remove my discount from your market on the indicated last ticket date if you remove your discount from my market on that date." Airline A then accepts the offer by placing a short last ticket date on its original discount fare, often matching Airline B's last ticket date. Airlines A and B then allow the original discounted fare and the new discounted fare to expire on the agreed upon last ticket date, and higher prices are re-established and maintained in both markets.

C. Illegal Agreement to Operate A Fare Dissemination System that Unreasonably Facilitates Fare Coordination

The second cause of action is based on alleged joint activities that began as early as April 1988 and continued until the date of the Complaint and that are illegal under a Sherman Act Section 1 "rule of reason" analysis. The core of the second cause of action is that the airline defendants agreed to exchange fare information (including information on fares that were not available for sale to consumers) with one another through ATP in a manner that unnecessarily and unreasonably allowed them to coordinate fares.

ATP is a joint venture in which all of the airline defendants are co-owners. Airlines, including a number of the airline defendants, serve on its board of directors. ATP maintains its fare data base on behalf of the airline defendants.

ATP provides the airlines with a number of communication devices that allow them to coordinate better across markets and within each market on fares and fare changes. The principal ATP communication devices are first ticket dates, last ticket dates, and footnote designators. They enabled the defendants on many occasions to reach overt price-fixing agreements of the type described in the first cause of action. These same devices also facilitate pervasive coordination of airline fares short of price fixing—coordination that would not occur simply by virtue of the structure of the airline industry.

The likelihood of successful coordination among horizontal competitors is substantially enhanced when firms are able to identify mutually beneficial terms of coordination, detect deviations (or "cheating") from the coordinated outcome, and punish or credibly threaten to punish those deviations (that is, make the deviation

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less profitable than adhering to the coordinated price).

The airline industry has a number of characteristics that make it susceptible to successful coordination among firms. Many airline city-pair markets are highly concentrated. All current fares (those available for sale to consumers) and fare restrictions are necessarily widely distributed and easily monitored by the competing airlines. In addition, using CRSs, the airlines can monitor whether a competitor is making seats available at a discount fare at any given time. (The ability to cheat by increasing the amount of discount seats sold is also limited by restrictions that make discount fares unattractive or unavailable to large numbers of customers.) Each of these factors tends to make coordination among competitors easier and more likely to occur, even in the absence of communication through ATP.

On the other hand, other inherent characteristics of the airline industry tend to make anticompetitive coordination more difficult. Airlines' costs of serving particular city-pair markets vary widely, as do consumers' preferences or demand for different airlines' services in different city-pair markets. This is particularly true when one airline offers nonstop service in a city pair where it has a hub at one endpoint, while its competitors offer one-stop or connecting service. These differences result in the various airlines serving a city-pair market often having quite different preferred prices, making it difficult for them to identify a mutually beneficial coordinated price. The large number of city-pair markets and fare changes also makes coordination a difficult task. Finally, coordination is discouraged by the difficulty of distinguishing fare changes that are intended to punish a competitor for cheating from fare changes that are themselves deviations from the coordinated price; misconstruing a competitor's intentions could precipitate additional fare cutting.

The ATP communication devices enable the airlines to substantially overcome many of these impediments to better coordination. Without these tools (or some other substitute mechanism), each airline is more likely to act independently, charging low prices in certain city pairs, such as those in which it is the low cost carrier, or matching low prices in other markets where it would have preferred a higher price. With these devices, the airlines can coordinate and achieve fare levels above those that otherwise would have prevailed.

1. ATP Facilitates the Identification of Mutually Beneficial Terms for Coordination

By filing fares with a first ticket date in the future, or extending a first ticket date further into the future as the original first ticket date approaches, the airlines are able to exchange information about fares that are in essence mere proposals rather than offers to sell tickets to consumers. The airlines can then change and modify these unavailable fares through an iterative process of multiple proposals, counterproposals, and other messages. The airlines can also use footnote designators to indicate which markets are involved in their proposals. The use of such fare proposals allows airlines to see how competitors will react to a proposed increase, consider alternative proposals, and identify a mutually acceptable fare increase, without the risk of losing sales during the process to a competitor with lower fares. Ultimately, each airline can increase its fares with greater certainty of its competitors' likely fare actions.

Similarly, by placing a last ticket date on discounted fares, airlines can communicate their desires to eliminate those fares and determine their competitors' willingness to do likewise, without risking any loss of traffic. Through a process of repeated filing and changing last ticket dates, often in conjunction with the use of footnote designators to link markets, the airlines can develop at virtually no cost a consensus on whether and when a discounted fare should be removed. Consequently, airlines can remove discount fares with greater certainty of their competitors' likely actions.

Last ticket dates, first ticket dates, and footnote designators also facilitate trades among the airlines during the negotiation process. Increased prices desired by some airlines are exchanged for increases desired by others in different markets. Often such trades involve hubs. Each airline tends to prefer higher fares on routes to or from its hub cities, where it tends to have high market shares and generate the highest profits. Thus, an airline may be willing to raise fares above its most preferred fare on others' hub routes in order to ensure that those airlines charge the higher fares it desires on its own hub routes. By using first and last ticket dates and footnote designators to link the markets involved in the trade, the airlines can more precisely communicate the terms of such multimarket trades at very low cost.

2. ATP Makes Punishing Deviations More Effective and Less Costly

When coordinated prices are above the competitive level, an airline will have an incentive to deviate from the coordinated price, that is, to lower its price. The greater the incentive to deviate, the less likely it is that firms will attempt to coordinate prices in the first place, and the less effective will be any coordination. However, if deviations from coordinated fare levels can be detected quickly and made unprofitable ("punished") by other airlines, effective coordination becomes more likely.

The broad and rapid dissemination of fares in the airline industry ensures that any airline's fare changes can be detected easily and rapidly by other airlines. Because of the large number of markets and the frequency of fare changes, however, determining whether fare changes are deviations from coordinated fare levels is more difficult. Punishment is unlikely to be effective if a deviating airline cannot determine which fare changes are intended as punishment, or which of its fare actions elicited the punishment. Moreover, the risk of other airlines misinterpreting fare changes intended to be punishment as deviations, which themselves should be punished, raises the cost of punishment.

ATP makes punishment easier and less costly. The airlines use footnote designators or last ticket dates to link city-pair markets together, communicating to both the cheater and its other competitors that a fare action is intended as punishment for another airline's fare action, not itself a deviation that should be punished. In this way, ATP facilitates the successful elimination of many discounts and discourages competitive pricing in the first place.

While first and last ticket dates and footnote designators are of immeasurable value to the airlines in facilitating pricing coordination, they provide little benefit to consumers. Because the airlines change the ticket dates often as they react to each other's messages and attempt to reach a consensus, the ticket dates for a particular fare do not provide travel agents or consumers with reliable information on when the fare will be increased or discontinued. Consumers cannot rely on the presence or absence of a last ticket date on a fare as assurance that the fare will be available for a certain period of time—the airlines may withdraw the fare or may stop making seats available at the fare without prior notice. Determining whether fare changes will actually be

implemented requires the ability to sort fare change data to reveal patterns and connections between fares. This requires information and analytical tools not readily available to travel agents through CRSs. The airlines, on the other hand, have the incentive and ability to sort the fare change data to make maximum use of the communicative value of first and last ticket dates and footnote designators and to predict, with some certainty, each other's fare actions.

III. Explanation of the Proposed Final Judgment

The proposed Final Judgment is intended to ensure that United and USAir do not continue to use the ATP fare dissemination system or any similar mechanism in a manner that unnecessarily facilitates fare coordination or that enables them to reach specific price-fixing agreements. It prohibits the settling defendants from disseminating first ticket dates or using designating mechanisms, and substantially restricts their use of last ticket dates. It does not, however, prevent United and USAir from instituting programs to protect passengers from unanticipated fare changes, such as guaranteeing fares at the time a reservation is made. The proposed Final Judgment also prohibits other conduct that would allow the settling defendants to communicate costlessly their pricing intentions or signal competitors that fare actions in different markets are linked. The proposed Final Judgment, however, does not prevent the settling defendants from disseminating their currently available fares through ATP to CRSs for consumer booking and ticketing, from advertising current fare information to consumers, or from offering for sale fares for which travel can only begin in the future, for example, offering fares in the summer that apply to winter travel to Florida. Finally, nothing in the Final Judgment regulates the independent pricing decisions of United and USAir, whether or not their prices respond to or evoke a response from other airlines.

A. Prohibited Conduct

Section IV of the proposed Final Judgment contains six categories of prohibited conduct. Certain exceptions to these prohibitions are contained in the limiting conditions in section V.

Section IV(A) contains general prohibitions on agreements between airlines "to fix, establish, raise, stabilize, or maintain any fare." This provision prohibits the settling defendants from any further price fixing whether by the means alleged in the Complaint or by other means violative of the Sherman Act.

Section IV(B) contains one of the key provisions of the proposed Final Judgment. It prohibits the settling defendants from "disseminating any first ticket dates, last ticket dates, or any other information concerning the defendant airline's planned or contemplated fares or changes to fares." This provision bars, with limited exceptions discussed below, the settling defendants' use of first and last ticket dates, as well as any alternative means of communicating their future pricing intentions. For example, it prevents the settling defendants from, with any precision, negotiating fare increases through press releases. Similarly, it prevents the settling defendants from beginning to use travel dates to coordinate fare changes rather than to communicate meaningful information to consumers on the relevant travel periods for particular fares. This provision will prevent United and USAir from participating in the extensive and costless negotiation over the amount, scope and timing of fare changes.

The ban on the settling defendants' use of first ticket dates is absolute. All of the settling defendants' fares, whether in ATP, a CRS or elsewhere, must be currently available for sale to consumers.

The settling defendants may continue to use last ticket dates, but only in very limited circumstances. Section V(C) of the Final Judgment permits the settling defendants, through advertising in media of general circulation or through mass mailings, and in a manner designed to directly reach a meaningful number of likely potential consumers, to state that a promotional fare (a new fare) will end on a particular date. Once having included the last ticket date in such advertising, the settling defendants may indicate the promotional fares' last ticket dates in a CRS and elsewhere. Once another airline has disseminated a last ticket date for a promotional fare in accordance with this section, the settling defendants may disseminate a last ticket date in a CRS or elsewhere on an identical new fare in one or more of the same city pairs without advertising. These restrictions apply only when a settling defendant chooses to use a last ticket date. The settling defendants remain free to advertise and market their services and fares in any other manner they choose, including any marketing or advertising that a fare will be available only for a short period of time.

The restrictions on the dissemination of last ticket dates contained in section V(C) increase the likelihood that last ticket dates will not be used by the settling defendants to coordinate fare changes but rather to generate whatever additional consumer demand may be created by advertising that a fare ends on a precisely defined date. The requirement that the fare be a new fare, and that the last ticket date be disseminated at the time the fare is first offered for sale, will help to ensure that last ticket dates are not used to engage in an iterative negotiation process to eliminate existing discount fares or to facilitate trades across markets. However, the restrictions are flexible enough to allow the settling defendants to tailor their advertising programs that employ last ticket dates to particular promotions and to allow the settling defendants to take advantage of changes in the nature of mass communication. The restrictions do not require that advertising that uses last ticket dates be national in scope, nor do they prescribe the advertising medium that must be used to justify use of a last ticket date. Thus, for a nationwide promotion, the settling defendants might need to broadly advertise to reach a meaningful number of potential consumers, while for a local or regional promotion, local or regional advertising would be sufficient. Similarly, as new methods of advertising become more prevalent and widely used by consumers, those methods may satisfy the requirement that the last ticket date be advertised in media of general circulation.

Section V(D) provides a limited exception to the prohibition on disseminating information relating to planned or contemplated fare changes. It will allow the settling defendants to continue to give consumers general information on impending fare changes For example, the settling defendants may make general public statements that because of increases in costs they expect fares to increase, or may advertise that certain low fares are for a limited time only. Because the information is general, it is unlikely that the settling defendants could use it to coordinate fares.

Section IV(C) prohibits the settling defendants from "making visible or disseminating its own tags or any other similar designating mechanism to any other airline." This provision prohibits the settling defendants from using any device to link markets and coordinate fare changes in the way that they currently use footnote designators. It would, for example, prevent the settling defendants from attaching arbitrary but unique travel complete dates to fares in different markets in order to

communicate a connection or link between those fares.

Section IV(D) prohibits the settling defendants from "making visible or disseminating to any other airline any fare that is intended solely to communicate a defendant airline's planned or contemplated fare or contemplated changes to fares." This provision would proscribe fares that, although technically available currently for sale, will not, as a practical matter, be considered by consumers. For example, section IV(D) would preclude a settling defendant from communicating its intention to increase fares by filing fares that are higher but otherwise identical to existing fares, and then waiting for other airlines to file identical higher fares before withdrawing its lower fares. Because no rational consumer would purchase the higher fares as long as the lower existing were available, the higher fares would be "intended solely to communicate" a settling defendant's contemplated changes to fares.

Section IV(E) prohibits the settling defendants from "disseminating two or more footnote designators that identify footnotes that contain identical information." This provision will prevent the settling defendants from continuing to use multiple footnotes, each with different designators, that contain the same ticketing and travel date information. In addition, section IV(E) prohibits the settling defendants from disseminating any footnote designator that identifies an "empty" footnote, that is, one that has no travel days, last ticket date or other information. In both cases, the footnote designator serves no purpose other than to communicate connections between fares or to call competitors' attention to particular fares.

Section IV(F) prohibits the settling defendants from "using fare codes that convey information other than fare class or terms and conditions of sale or travel." Certain standard fare codes are used throughout the industry to identify the class, as well as the restrictions associated with a fare, such as advance purchase requirements. This provision is intended to prevent the settling defendants from using codes not related to either the fare class or the terms and conditions of sale or travel to send messages and link markets. For example, Section IV(F) prevents a settling defendant from sending a message to another airline by placing letters that identify that airline in the settling defendant's fare code.

B. Compliance Program and Certification

In addition to the prohibitions contained in sections IV and V, each settling defendant would be obligated to implement an antitrust compliance program. This program would require each settling defendant to designate an Antitrust Compliance Officer within 30 days of entry of the Final Judgment. The Antitrust Compliance Officer for each settling defendant would be responsible for distributing copies of the Final Judgment to all officers of that defendant and to employees of that defendant who have any responsibility for fares. These persons would be required annually to certify that they understand and agree to abide by the terms of the Final Judgment. Each settling defendant must, within 45 days after the Antitrust Compliance Officer learns of any violations of the Final Judgment, take appropriate action to terminate or modify the activity so as to comply with the Final Judgment. Finally, the settling defendants must maintain records relating to their use of last ticket dates under the limited exception provided in section V(C).

C. Effect of the Proposed Final Judgment on Competition

The relief in the proposed Final Judgment is designed to remove, as to United and USAir, the artificial restraints that have been imposed by all defendants on competition. The proposed Final Judgment effectively will remove United and USAir as participants in the coordination of fares through ATP. The Department of Justice believes that the proposed Final Judgment contains sufficient provisions to prevent further violations by United and USAir of the type alleged in the Complaint and remedy the effects of the alleged conspiracy as to these defendants.

IV. Remedies Available to Potential Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages suffered, as well as costs and reasonable attorney's fees. Entry of the proposed Final Judgment will neither impair nor assist the bringing of such actions. Under the provisions of section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the Judgment has no *prima facie* effect in any subsequent lawsuits that may be brought against any defendant in this matter.

V. Procedures Available for Modification of the Proposed Final Judgment

As provided by the Antitrust Procedures and Penalties Act, any person believing that the proposed Final Judgment should be modified may submit written comments to Mark C. Schechter, Chief, Transportation, Energy and Agriculture Section, U.S. Department of Justice, Antitrust Division, 555 Fourth Street, NW., room 9104, Washington, DC 20001, within the 60-day period provided by the Act. These comments, and the Department's responses, will be filed with the Court and published in the **Federal Register**. All comments will be given due consideration by the Department of Justice, which remains free to withdraw its consent to the proposed Judgment at any time prior to entry.

VI. Alternative to the Proposed Final Judgment

The alternative to the proposed Final Judgment would be a full trial of the case against United and USAir. In the view of the Department of Justice, such a trial would involve substantial cost to the United States and is not warranted because the proposed Final Judgment provides relief that will remedy the violations of the Sherman Act alleged in the United States' Complaint.

VII. Determinative Materials and Documents

No materials and documents of the type described in section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b), were used in formulating the proposed Final Judgment.

Dated: December 21, 1992.

Respectfully submitted,

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[FR Doc. 93-608 Filed 1-11-93; 8:45 am]
BILLING CODE 4410-01-M

Notice Pursuant to the National Cooperative Research Act of 1984; CAD Framework Initiative, Inc.

Notice is hereby given that, on October 27, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), CAD Framework Initiative, Inc. ("CFI") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing certain changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the purpose of this additional notification is to disclose the following information: (1) The addition of the following Corporate Members: Data General Corporation, Westboro, MA; Philips Semiconductors, Eindhoven, The Netherlands; Vantage Analysis Systems, Inc., Fremont, CA; (2) the addition of the following Associate Members: Canadian Microelectronics Corp., Kingston, Ontario, Canada; Massachusetts Institute of Technology, Cambridge, MA; Teradyne, Inc., Boston, MA; John Hardin, San Diego, CA; Wolfgang Herden, Stuttgart, Germany; Hitoshi Nishimura, Tokyo, Japan; (3) Intel Corporation, Santa Clara, CA, has changed its CFI membership from Associate to Corporate.

On December 30, 1988, CFI filed its original notification pursuant to section 6(a) of the Act. That filing was amended on February 7, 1989. The Department of Justice published a notice concerning the amended filing in the **Federal Register** pursuant to section 6(b) of the Act on March 13, 1989 (54 FR 10456). A correction notice was published on April 20, 1989 (54 FR 16013).

The last notification was filed with the Department on July 27, 1992. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on November 5, 1992 (57 FR 52796).

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–607 Filed 1–11–93; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research Act of 1984; International Business Machines Corp.

Notice is hereby given that, on September 15, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), International Business Machines ("IBM") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties are International Business Machines ("IBM"), Armonk, NY; Siemens Aktiengesellschaft ("Siemens"), Munich, Germany; and Toshiba Corporation ("Toshiba"), Tokyo, Japan. Effective on July 9, 1992, IBM, Siemens and Toshiba entered into an agreement to undertake cooperative research, experimentation and development activities in the field of fabrication processes suitable for future generations of semiconductors, including a prototype 256 megabit dynamic random access memory (256M DRAM). The parties' activities will include, but are not limited to: Formulating and developing processes for fabricating 0.25 micron semiconductor features; formulating and developing the design of a 256M DRAM; and fabricating prototypes for the experimental demonstration of such process technology and 256M DRAM design.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–603 Filed 1–11–93; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research Act of 1984; Open Software Foundation, Inc.

Notice is hereby given that, on November 17, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Open Software Foundation, Inc. ("OSF") filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The additional notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the identities of the new, non-voting members of OSF are as follows: Aluminum Company of America, Pittsburgh, PA; Guardian Royal Exchange Assurance, Lancashire, England; Dalhousie University, Halifax, Nova Scotia, Canada; SIP, Rome, Italy; Indiana University, Bloomington, IN; Auspex Systems, Inc., Santa Clara, CA; Bureau of the Census/Casic Staff, Washington, DC; Australian Computer & Communication Institute, Carlton, Victoria, Australia; Technical University of Budapest, Budapest, Hungary; MAXM Systems Corporation, Vienna, VA; Peregrine Systems, Inc., Carlsbad, CA; Protek, Berkshire, England; Hughes Aircraft Company, Los Angeles, CA; Walker Interactive Systems, San Francisco, CA; McDonald's Corporation, Oak Brook, IL; KAPSCH Aktiengesellschaft, Vienna, Austria; The Computing Center, Academia Sinica, Taipei, Taiwan; University of Cape Town, Rondebosch, South Africa. No new voting members have been added as of this filing.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OSF intends to file additional written notifications disclosing all changes in membership.

On August 8, 1988, OSF and the Open Software Foundation Institute, Inc. (the "Institute") filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on September 7, 1988 (53 FR. 34594).

The last notification was filed with the Department on July 29, 1992. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on October 6, 1992 (57 FR 46047).

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–604 Filed 1–11–93; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research Act of 1984; Petroleum Environmental Research Forum

Notice is hereby given that, on December 4, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301, *et seq.* ("the Act"), the participants in the Petroleum Environmental Research Forum ("PERF") Project No. 91–14, titled "Reducing Desalter Environmental Impact," have filed written notifications simultaneously with the Attorney General and with the Federal Trade Commission disclosing (1) the identities of the parties participating in PERF Project No. 91–14 and (2) the nature and objectives of the venture. The notification was filed for the purpose of invoking the Act's provisions limited the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties participating in PERF

Project No. 91–14, together with the nature of objectives of the research program, are Amoco Oil Company, Naperville, IL; Atlantic Richfield Company, Plano, TX; BP America, Inc., Warrensville Hts., OH; Chevron Research & Technology Co., Richmond, CA; Exxon Research & Engineering Company, Florham Park, NJ; Mobil Research and Development Corporation, Princeton, NJ; Petro-Canada, Alberta, Canada; Phillips Petroleum Company, Bartlesville, OK; and Texaco Inc., Port Arthur, TX.

Research and development work required in furtherance of PERF Project No. 91–14 is to be carried out by BP Research, a division of BP America, Inc., under contract with the above participants. The nature and objectives of the research program to be carried out in accordance with this Project is to investigate practical methods for reducing environmental impact of the crude oil desalting process.

Participation in this Project will remain open to interested persons and organizations until issuance of the final Project Report, which is presently expected to occur approximately fourteen (14) months after the Project commences. The Participants intend to file additional written notifications disclosing all changes in membership of parties involved in this Project.

Information regarding participation in the Project may be obtained from R.D. Andrew, Engineering Department, Mobil Research and Development Corporation, P.O. Box 1026, Princeton, NJ 08543.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–605 Filed 1–11–93; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research Act of 1984; Sumitomo Light Metal Industries, Ltd., and Reynolds Metals Co.

Notice is hereby given that, on November 25, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Sumitomo Light Metal Industries, Ltd., and Reynolds Metals Company have filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties are Sumitomo Light Metal Industries, Ltd., Tokyo, Japan; and Reynolds Metals Company, Richmond, VA. The objectives of the venture, and the general areas of planned activity, are joint development of aluminum sheet for automobiles, heavy and light trucks, vans, buses, trains, railroad cars, high speed trains and trailers and the joint development of processes for producing such sheet.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–606 Filed 1–11–93; 8:45 am]

BILLING CODE 4410–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Networking and Communications Research and Infrastructure; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Special Emphasis Panel in Networking and Communications Research and Infrastructure

Date and Time: January 25, 1993; 8:30 a.m. to 5 p.m.

Place: Sprint, 13221 Woodland Park Road, Herndon, VA 22071

Type of Meeting: Closed

Contact Person: Mr. Steven Goldstein, Networking and Communications Research and Infrastructure, National Science Foundation, room 416, Washington, DC 20550 (202–357–9717)

Purpose of Meeting: To review and evaluate the performance of International Connections Manager for NSFNET at Sprint.

Agenca: Site visit to review and evaluate the performance of International Connections Manager for NSFNET and Sprint.

Reason for Closing: The project being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries, and personal information concerning individuals associated with the proposals.

These matters are exempt under 5 U.S.C. 552 b. (c) (4) and (6) of the Government in the Sunshine Act.

Dated: January 6, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–572 Filed 1–11–93; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements: Office of Management and Budget (OMB) Review

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of the Office of Management and Budget Review of Information Collection.

SUMMARY: The NRC has recently submitted to the Office of Management and Budget (OMB) for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. Type of submission: Revision.

2. Title of the information collection: "Proposed Amendments to 10 CFR parts 30, 40, 50, 70, and 72 to Allow Self-Guarantee as an Additional Financial Assurance Mechanism".

3. The form number if applicable: None.

4. How often is the collection required: Annually for most information; on occasion for some.

5. Who will be asked to report: Large non-electric utility licensees who desire to use self-guarantee as a financial assurance mechanism.

6. An estimate of the number of responses: One report per year from 20 licensees.

7. An estimate of the total number of hours needed to complete the requirements or requests: 380 hours annually including reporting and recordkeeping.

8. The average burden per response: 19 hours per year.

9. An indication of whether section 3504(h), Public Law 96–511 applies: applicable.

10. Abstract: In response to a petition for rulemaking submitted by licensees, NRC is proposing to allow certain non-electric utility licensees who meet stringent financial standards to use self-guarantee as a financial assurance mechanism for discomissioning funding. The use of self-guarantee would reduce licensee costs because licensees qualifying to use self-guarantee would not have to purchase third-party financial assurance (e.g., letters of credit, surety bonds). However, use of self-guarantee is strictly optional; licensees do not have to use this method of providing financial assurance. Therefore, any information requested by NRC in this proposed rule is only required if licensees choose to use self-guarantee in place of one of the already

allowed financial assurance mechanisms. The proposed rule would amend the financial assurance sections of parts 30, 40, 50, 70, and 72.

The information collection is needed to permit NRC to review the financial status of licensees using self-guarantee. A financial test, focusing on tangible net worth, bond rating, and the ratio of tangible net worth to decomissioning cost estimates, is required. In addition, the proposed rule has provisions for timely updating of information regarding a licensee's financial condition. For example, copies of current reports filed with the Securities and Exchange Commission must be submitted to NRC.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC.

Comments and questions should be directed to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs, (3150–0017, –0020, –0011, –0009, and 0132), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments can also be communicated by telephone to (202) 395–3084. NRC Clearance Officer is Brenda Jo Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 31st day of December, 1992.

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resource Management.

[FR Doc. 93–471 Filed 1–11–93; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Nuclear Waste; Meeting

The Advisory Committee on Nuclear Waste (ACNW) will hold its 50th meeting on Wednesday and Thursday, January 27 and 28, 1993, 8:30 a.m. until 6 p.m., room P–110, 7920 Norfolk Avenue, Bethesda, MD. Notice of this meeting was published in the **Federal Register** on Wednesday, December 23, 1992 (57 FR 61104).

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

A. Review and comment on the NRC staff's analysis of the issues that the National Academy of Sciences will be addressing as a result of the Energy Policy Act of 1992 and the impacts this Act will have on NRC's high-level waste program.

B. Review the activities of the Center for Nuclear Waste Regulatory Analyses, specifically the use of natural analogues.

C. Explore the creation of a performance indicator or event reporting system that would monitor the current status of the management and disposal of low-level radioactive waste.

D. Prepare the next four-month plan of ACNW activities for the period February–May 1993.

E. Discuss anticipated and proposed Committee activities, future meeting agenda, administrative, and organizational matters, as appropriate. Also, discuss matters and specific issues that were not completed during previous meetings as time and availability of information permit.

Procedures for the conduct of and participation in ACNW meetings were published in the **Federal Register** on June 6, 1988 (53 FR 20699). In accordance with these procedures, oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Committee, its consultants, and staff. Use of still, motion picture, and television cameras during this meeting may be limited to selected portions of the meeting as determined by the ACNW Chairman. The office of the ACRS is providing staff support for the ACNW. Persons desiring to make oral statements should notify the Executive Director of the Office of the ACNW/ACRS as far in advance as practical so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements. Information regarding the time to be set aside for this purpose may be obtained by a prepaid telephone call to the Executive Director of the Office of the ACNW/ACRS (telephone 301/492–4516), prior to the meeting. In view of the possibility that the schedule for ACNW meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with the ACNW/ACRS Executive Director or call the recording (301/492–4600) for the current schedule if such rescheduling would result in major inconvenience.

Dated: January 6, 1993.

John C. Hoyle,

Advisory Committee Management Officer

[FR Doc. 93–612 Filed 1–11–93; 8:45 am]

BILLING CODE 7590–01–M

Westinghouse Electric Corp., Receipt of Application for Design Certification

Notice is hereby given that the Nuclear Regulatory Commission (the Commission) has received an application from Westinghouse Electric Corporation dated June 26, 1992, filed pursuant to section 103 of the Atomic Energy Act and 10 CFR part 52, for the standard design certification of the AP600 Standard Plant Design. On December 15, 1992, the application was supplemented with information identified as missing or incomplete during the NRC staff's acceptance review of the June 26, 1992, submittal. The application is now considered sufficiently complete to be accepted formally as a docketed petition for design certification. A notice relating to the rulemaking pursuant to 10 CFR 52.51 for design certification, including provisions for participation of the public and other parties, will be published in the future.

The AP600 design is a 600 MWe pressurized water reactor plant design in which passive safety systems are used for the ultimate safety protection of the plant. All of the safety systems are designed to be passive, where natural forces, such as gravity, natural circulation, and stored energy (in the form of pressurized accumulators and batteries), are used as the motive forces of these systems. The AP600 has a number of unique features that distinguish it from both the current generation of light water reactors and the evolutionary advanced light water reactors. The AP600 application includes the entire power generation complex, except those elements and features considered site-specific, and is not a modular design in which major components are shared.

A copy of the application is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC. Previous correspondence on this application is filed under Project Number 676. The docket established for this application is 52–003.

Dated at Rockville, Maryland this 31st day of December 1992.

For the Nuclear Regulatory Commission.

Robert C. Pierson,

Director, Standardization Project Directorate, Associate Directorate for Advanced Reactors and License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 93–611 Filed 1–11–93; 8:45 am]

BILLING CODE 7590–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2618]

Connecticut (And Contiguous Counties in New York); Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on December 17, 1992, I find that the Counties of Fairfield, New Haven and Middlesex in the State of Connecticut constitute a disaster area as a result of damages caused by a winter storm and coastal flooding which occurred December 10–13, 1992. Applications for loans for physical damage may be filed until the close of business on February 15, 1993, and for loans for economic injury until the close of business on September 17, 1993 at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd., South, 3rd Fl., Niagara Falls, NY 14303, or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the contiguous counties of Hartford, Litchfield, and New London in the State of Connecticut and Dutchess County in the State of New York may be filed until the specified date at the above location.

Any counties contiguous to the above-named primary counties and not listed herein are covered under a separate declaration for their own state for the same occurrence.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Other (including non-profit organizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 261811 and for economic injury the numbers are 781900 for Connecticut and 782000 for Dutchess County, New York.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 28, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 93–671 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2586]

Declaration of Disaster Loan Area; Florida, Amendment #2

The above-numbered Declaration is hereby amended in accordance with an amendment dated December 10, 1992, to the President's major disaster declaration of August 24, to extend the deadline for filing applications for physical damage. The new deadline is January 20, 1993.

The termination date for filing applications for economic injury remains the close of business on May 24, 1993.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: December 15, 1992.

Bernard Kulik,

Assistant Administrator for Disease Assistance.

[FR Doc. 93–667 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2614]

Declaration of Disaster Loan Area; Georgia, Amendment #1

The above-numbered Declaration is hereby amended in accordance with an amendment dated December 11, 1992, to the President's major disaster declaration of December 1, to establish the incident period for this disaster as beginning on November 22, 1992 and continuing through December 7, 1992.

All other information remains the same; i.e., the termination date for filing applications for physical damage is February 1, 1993, and September 1, 1993 for economic injury.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: December 15, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 93–668 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2614]

Georgia (and Contiguous Counties in Alabama and Tennessee); Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on December 1, 1992, and an amendment thereto on December 4, I find that the Counties of Carroll, Cherokee, Cobb, Dade, Greene, Putnam, and Talbot in the State of Georgia constitute a disaster area as a result of damages caused by tornadoes, high winds, and heavy rains which occurred on November 22, 1992 and continuing. Applications for loans for physical damage may be filed until the close of business on February 1, 1993 and for loans for economic injury until the close of business on September 1, 1993, at the address listed below: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, suite 300, Atlanta, Georgia 30308 or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the contiguous Counties of Baldwin, Bartow, Chattahoochee, Coweta, Dawson, Douglas, Forsyth, Fulton, Gordon, Hancock, Haralson, Harris, Heard, Jasper, Jones, Marion, Meriwether, Morgan, Muscogee, Oconee, Oglethorpe, Paulding, Pickens, Taliaferro, Taylor, Upson, and Walker in the State of Georgia; Cleburne, DeKalb, Jackson, and Randolph Counties in the State of Alabama; Hamilton and Marion Counties in Tennessee may be filed until the specified date at the above location.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 261412 and for economic injury the numbers are 777700 for Georgia; 777800 for Alabama; and 780200 for Tennessee.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: December 10, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistant.

[FR Doc. 93–669 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

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[Declaration of Disaster Loan Area #2616]

Territory of Guam; Declaration of Disaster Loan Area

The Territory of Guam constitutes a disaster area as a result of damages caused by Typhoon Gay which occurred on November 23, 1992. Applications for loans for physical damage may be filed until the close of business on February 11, 1993 and for economic injury until the close of business on September 13, 1993 at the address listed below: U.S. Small Business Administration, Disaster Area 4 Office, P.O. Box 13795, Sacramento, CA 95853–4795; or other locally announced locations.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 261606 and for economic injury the number is 780000.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 11, 1992.

Patricia Saiki,

Administrator.

[FR Doc. 93–670 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2617]

Republic of the Marshall Islands; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on December 16, 1992, I find the Ailuk, Aur, Bikini, Enewetak, Likiep, Utirik, Wotho, Wotje, Maloelap, and Ujelang Atolls and Mejit Island in the Republic of the Marshall Islands constitute a disaster area as a result of damages caused by Typhoon Gay which occurred on November 17–18, 1992. Applications for loans for physical damage may be filed until the close of business on February 16, 1993, and for loans for economic injury until the close of business on September 17, 1993, at the address listed below: Disaster Area 4 Office, Small Business Administration, P.O. Box 13795, Sacramento, CA 95853–4795, or other locally announced locations.

The interest rules are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit orgunizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000%

The number assigned to this disaster for physical damage is 261706 and for economic injury the number is 781800.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 28, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 93–674 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2606]

Declaration of Disaster Loan Area; Mississippi (and Contiguous Counties in Alabama and Louisiana)

As a result of the President's major disaster declaration on November 25, 1992, and an amendment thereto on December 2, I find that the Counties of Amite, Attala, Chickasaw, Choctaw, Copiah, Covington, Jasper, Jefferson Davis, Kemper, Lauderdale, Leake, Lincoln, Neshoba, Newton, Noxubee, Rankin, Scott, Simpson, Smith, Webster, and Wilkinson in the State of Mississippi constitute a disaster area as a result of damages caused by tornadoes, high winds, and severe storms which occurred on November 21–22, 1992. Applications for loans for physical damage may be filed until the close of business on January 23, 1993, and for loans for economic injury until the close of business on August 25, 1993, at the address listed below: U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, suite 300, Atlanta, Georgia 30308, or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the contiguous Counties of Adams, Calhoun, Carroll, Claiborne, Clarke, Clay, Forrest, Franklin, Grenada, Hinds, Holmes, Jefferson, Jones, Lamar, Lawrence, Lee, Lowndes, Madison, Marion, Monroe, Montgomery, Oktibeha, Pike, Pontotoc, Walthall, Wayne, Winston, and Yazoo in the State of Mississippi; Choctaw, Pickens, and Sumpter Counties in the State of Alabama; and Concordia, East Feliciana, St. Helena, Tangipahoa, and West Feliciana Parishes in Louisiana may be filed until the specified date at the above location.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 260612 and for economic injury the numbers are 776800 for Mississippi; 776900 for Alabama; and 780100 for Louisiana.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: December 10, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 93–666 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2619]

New Jersey; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on December 18, 1992, and amendments thereto on December 18 and 22, I find that the Counties of Atlantic, Bergen, Cape May, Cumberland, Essex, Hudson, Middlesex, Monmouth, Ocean, Somerset, and Union in the State of New Jersey constitute a disaster area as a result of damages caused by a severe coastal storm, unusual high tides, heady rain and riverine flooding beginning on December 10, 1992. Applications for loans for physical damage may be filed

until the close of business on February 16, 1993, and for loans for economic injury until the close of business on September 20, 1993, at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd., South, 3rd Fl., Niagara Falls, NY 14303, or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the contiguous counties of Burlington, Camden, Gloucester, Hunterdon, Mercer, Morris, Passaic, and Salem in the State of New Jersey may be filed until the specified date at the above location.

Any counties contiguous to the above-named primary counties and not listed herein are covered under a separate declaration for their own state for the same occurrence.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 261911 and for economic injury the number is 782100.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 28, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 93–673 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2620]

New York; Declaration of Disaster Loan Area

As a result of the President's major disaster declaration on December 21, 1992, and an amendment thereto on December 22, I find that Nassau, Rockland, Suffolk, and Westchester Counties and New York City (all five boroughs) in the State of New York constitute a disaster area as a result of damages caused by a coastal storm, high tides, heavy rains and riverine flooding beginning on December 10, 1992. Applications for loans for physical damage may be filed until the close of business on February 19, 1993, and for loans for economic injury until the close of business on September 21, 1993, at the address listed below: U.S. Small Business Administration, Disaster Area 1 Office, 360 Rainbow Blvd., South, 3rd Fl., Niagara Falls, NY 14303, or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the contiguous counties of Orange and Putnam in the State of New York may be filed until the specified date at the above location.

Any counties contiguous to the above-named primary counties and not listed herein are covered under a separate declaration for their own state for the same occurrence.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 262011 and for economic injury the number is 782200.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 28, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 93–672 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2615]

Declaration of Disaster Loan Area; Texas

As a result of the President's major disaster declaration on December 4, 1992, I find that Harris County in the State of Texas constitutes a disaster area as a result of damages caused by thunderstorms and tornadoes which occurred on November 21, 1992. Applications for loans for physical damage may be filed until the close of business on February 2, 1993, and for loans for economic injury until the close of business on September 7, 1993, at the address listed below: U.S. Small Business Administration, Disaster Area 3 Office, 4400 Amon Carter Blvd., suite 102, Ft. Worth, TX 76155, or other locally announced locations. In addition, applications for economic injury loans from small businesses located in the contiguous Counties of Brazoria, Chambers, Fort Bend, Galveston, Liberty, Montgomery, and Waller in the State of Texas may be filed until the specified date at the above location.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	7.625
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage is 261512 and for economic injury the number is 779900.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: December 10, 1992.

Bernard Kulik,

Assistant Administrator for Disaster Assistance.

[FR Doc. 93–665 Filed 1–11–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Aviation Proceedings; Agreements Filed During the Week Ended January 1, 1993

The following agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. 412 and 414. Answers may be filed within 21 days of date of filing.

Docket Number: 48577
Date filed: December 29, 1992.
Parties: Members of the International Air Transport Association
Subject: Comp Mail vote 608, Fare Increase from Bulgaria.
Proposed Effective Date: January 1, 1993
Docket Number: 48578.

Date filed: December 29, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC 31 Reso/P 0970 dated December 1, 1992, North America-Southwest Pacific Resos, Tables—TC31 Fares 0137 dated December 22, 1992, Minutes—TC31 Meet/P 0211 dated December 11, 1992.
Proposed Effective Date: April 1, 1993
Docket Number: 48579.
Date filed: December 29, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC12 Reso/P 1444 dated October 16, 1992, North Atlantic-Middle East (except Israel).
Proposed Effective Date: April 1, 1993.
Docket Number: 48584
Date filed: December 31, 1992
Parties: Members of the International Air Transport Association
Subject: TC3 Reso/P 0489 dated September 11, 1992, Within Southeast Asia Resos r-1 to r-9, TC3 Reso/P 0486 dated September 11, 1992, TC3 Areawide Resos r-10 to r-12, TC3Reso/P 0491 dated September 11, 1992, Within Southwest Pacific r-13 to r-17, TC3 Reso/P 0493 dated September 11, 1992, SEast Asia-South Asian Subc. r-18 to r-21, TC3 Reso/P 0496 dated September 11, 1992, SEast Asia-SWPacific Resos r-22 to r-26, TC3 Reso/P 0500 dated September 11, 1992, Japan/Korea-SEast Asia r-27 to r-37.
Proposed Effective Date: April 1, 1993.
Docket Number: 48585.
Date filed: December 31, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC23 Reso/P 0553 dated October 20, 1992, Europe-Southwest Pacific Resos r–1 to r–20.
Proposed Effective Date: April 1, 1993.
Docket Number: 48586.
Date filed: December 31, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC23 Reso/P 0549 dated October 16, 1992, Middle East-TC3 Resos r–1 to r–26.
Proposed Effective Date: April 1, 1993.
Docket Number: 48587.
Date filed: December 31, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC23 Reso/P 0540 dated October 2, 1992, Europe-Japan/Korea Resos r–1 to r–36.
Proposed Effective Date: March 31/April 1, 1993.
Docket Number: 48589.
Date filed: December 31, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC3 Reso/P 0487 dated September 11, 1992, Within South Asian Subc. r–1 to r–7, TC3 Reso/P 0488 dated September 11, 1992, Within Southeast Asia r–8 to r–16, TC3 Reso/P 0490 dated September 11, 1992, Within Southwest Pacific r–17 to r–21, TC3 Reso/P 0492 dated September 11, 1992, SEast Asia-South Asian Subc. r–22 to r–29, TC3 Reso/P 0494 dated September 11, 1992, S.Asian Subc-SWPacific r–30 to r–37, TC3 Reso/P 0495 dated September 11, 1992, SEAsia-SWPacific r–38 to r–42, TC3 Reso/P 0497 dated September 11, 1992, Japan-Korea r–43 to r–53, TC3 Reso/P0498 dated September 11, 1992, Japan/Korea-S.Asian Subc. r–54 to r–64, TC3 Reso/P 0499 dated September 11, 1992, Japan/Korea-SEast Asia r–65 to r–80.
Proposed Effective Date: April 1, 1993.
Docket Number: 48588.
Date filed: December 31, 1992.
Parties: Members of the International Air Transport Association.
Subject: TC12 Reso/P 1432 dated June 19, 1992, Mid Atlantic-Africa Resos r–1 to r–6.
Proposed Effective Date: April 1, 1993.

Phyllis T. Kaylor,
Chief, Documentary Services Division.
[FR Doc. 93–566 Filed 1–11–93; 8:45 am]
BILLING CODE 4910–62–M

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week of January 1, 1993

The following applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: 48580.
Date filed: December 30, 1992.
Due Date for Answers, Conforming Applications, or Motion to Modify Scope: January 27, 1993.
Description: Application of United Air Lines, Inc., pursuant to section 401 of the Act and subpart Q of the Regulations applies for a certificate of public convenience and necessity to authorize United to engage in the scheduled foreign air transportation of persons, property and mail between Saipan, Commonwealth of the Northern Mariana Islands; and Osaka, Japan.

Phyllis T. Kaylor,
Chief, Documentary Services Division.
[FR Doc. 93–565 Filed 1–11–93; 8:45 am]
BILLING CODE 4910–62–M

Federal Aviation Administration

Receipt of Noise Compatibility Program Revision No. 3 and Request for Review; Hartsfield Atlanta International Airport, Atlanta, GA

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces that it is reviewing a proposed revision to the noise compatibility program that was submitted for Hartsfield Atlanta International Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96–193) (hereinafter referred to as "the Act") and 14 CFR part 150 by the City of Atlanta. This revised program was submitted subsequent to a determination by FAA that associated noise exposure maps submitted under 14 CFR part 150 for Hartsfield Atlanta International Airport were in compliance with applicable requirements effective October 16, 1984.

Upon acceptance of the Noise Exposure Maps, the FAA received the initial noise compatibility program on October 16, 1984. It was approved on April 10, 1985. The FAA has since approved two changes to the program. Revision No. 1 was approved on June 25, 1985, and revision No. 2 was approved on October 24, 1988. The proposed revision No. 3 to the noise compatibility program will be approved or disapproved on or before June 16, 1993.

EFFECTIVE DATE: The effective date of the start of FAA's review of the revised noise compatibility program is December 18, 1992. The public comment period ends January 21, 1993.

FOR FURTHER INFORMATION CONTACT: Lolita M. Kyker, Program Manager, Atlanta Airports Districts Office, Suite 101, 1680 Phoenix Boulevard, Atlanta, Georgia 30349, Telephone (404) 994–5306. Comments on the revised noise compatibility program should also be submitted to the above office.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA is reviewing a proposed noise compatibility program revision for Hartsfield Atlanta International Airport which will be approved or disapproved on or before June 16, 1993. This notice also announces availability of this program for public review and comment.

This revision will add acoustical treatment for multi-family residences and churches within the 70 Ldn and 75 Ldn noise exposure curves.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150 promulgated pursuant to title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The FAA has formally reviewed the noise compatibility program for Hartsfield Atlanta International Airport, effective on December 18, 1992. It was requested that the FAA review this material and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility program, but that further review will be necessary prior to approval or disapproval of the program. This formal review period, limited by law to a maximum of 180 days, will be completed on or before June 16, 1993.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Atlanta Airports District Office, Suite 101, 1680 Phoenix Boulevard, Atlanta, Georgia 30349.

Airport Commissioners Office, Hartsfield Atlanta International Airport, Atlanta, Georgia 30320.

Questions may be directed to the individual above under the heading, "**FOR FURTHER INFORMATION CONTACT.**"

Issued in Atlanta, Georgia December 18, 1992.

Samuel F. Austin,

Manager, Atlanta Airports District Office.

[FR Doc. 93–624 Filed 1–11–93; 8:45 am]

BILLING CODE 4910–13–M

Federal Highway Administration

Environmental Impact Statement: Beaufort-Pitt Counties, North Carolina

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Intent.

SUMMARY: The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in Beaufort and Pitt Counties, North Carolina.

FOR FURTHER INFORMATION CONTACT: Mr. Roy C. Shelton, Operations Engineer, Federal Highway Administration, 310 New Bern Avenue, suite 410, Raleigh, North Carolina 27601, Telephone (919) 856–4350.

SUPPLEMENTARY INFORMATION: The FHWA, in cooperation with the North Carolina Department of Transportation (NCDOT), will prepare an environmental impact statement (EIS) for the proposed U.S. 17 Washington Bypass in Beaufort and Pitt Counties. The proposed action would involve construction of a multi-lane freeway extending approximately 14 miles from the intersection of US 17 and SR 1152 northwest to the intersection of US 17 and NC 121. Access would be fully controlled and interchanges would be provided at locations with major traffic movements. This facility is needed to relieve traffic congestion on existing US 17.

Alternatives under consideration include the No-Build or Do-Nothing Alternative, the Transportation Systems Management Alternative, the Mass Transit Alternative, and the Build Alternative. The Build Alternative involves consideration of a corridor for constructing the proposed improvements entirely on new location, an upgrade of the existing US 17 facility, and a combination of both new location and upgrading the existing facility.

A formal scoping meeting will be held to solicit comments on the proposed action. Appropriate Federal, State and local agencies will be notified by mail of the meeting time and place. A complete public involvement program has been developed for the project to include: The distribution of newsletters to interested parties, along with public meetings and public hearing to be held in the study area. Information regarding the time and place of the public meetings and the public hearing will be provided in the local news media. The draft EIS will be available for public and agency review and comment prior to the public hearing.

To assure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions are invited from all interested parties. Comments or questions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: January 4, 1993.

Roy C. Shelton,

Operations Engineer, Raleigh, North Carolina.

[FR Doc. 93–555 Filed 1–11–93; 8:45 am]

BILLING CODE 4910–22–M

Research and Special Programs Administration

Office of Pipeline Safety; Risk Based Prioritization Planning

AGENCY: Research and Special Programs Administration, DOT.

ACTION: Notice of public meeting.

SUMMARY: The Research and Special Programs Administration (RSPA) invites representatives of industry, government, special interest groups, environmental organizations and the public to an open meeting on the subject of risk assessment as the basis for developing and prioritizing an action plan for the Office of Pipeline Safety (OPS).

DATES: The meeting will be held on February 2, 1993 from 12:30 to 3:30 p.m.

ADDRESSES: The meeting will be held at the J. W. Marriott Hotel, 5150 Westheimer Road, Houston, Texas 77056. There will be no formal recorded transcript of the meeting. OPS will

prepare and maintain a record of the meeting, and make the record available to those requesting it.

FOR FURTHER INFORMATION CONTACT: G. Joseph Wolf, Office of Pipeline Safety (DPS–13), Research and Special Programs Administration, 400 Seventh Street, SW., Washington, DC 20590, 202–366–4560.

SUPPLEMENTARY INFORMATION: RSPA, through its Office of Pipeline Safety, regulates the transportation of gas and hazardous liquids by pipeline and regulates liquefied natural gas facilities. OPS frequently must allocate its resources to address safety issues, many identified by authorities outside of the agency, including Congress, the National Transportation Safety Board, and the General Accounting Office. Issues should be addressed with the benefit of comparing the relative significance of the reduction in risk, the costs to implement, and the apportioned benefits achievable using any regulatory approach. Therefore, OPS needs a comprehensive analytical approach to support the development and implementation of its own agenda. Given the limited resources available, OPS believes that risk-based analysis and prioritization leads to optimal use of pipeline safety resources.

As a result of a thorough assessment of its operation conducted in 1991, OPS adopted in 1992 a set of values, goals, and specific actions necessary to enable OPS to respond most effectively to increasing pipeline safety concerns. The key goal is to develop an achievable agenda and allocate OPS resources to tasks with greatest potential to improve public safety and the protection of the environment without undue burden to industry. Toward that goal, OPS is developing a Risk Based Prioritization Planning (RBPP) program to provide a sound basis for identifying and ranking pipeline safety risks and their potential solutions. The principles used in planning would consider the effect of a solution on the probability and consequence of accident occurrence and the economic impact of implementation on both industry and government.

OPS expects that the number of practicable solutions to pipeline safety risks identified would be so large as to far exceed the capacity of OPS resources to implement all solutions. OPS recognizes that no organization has the resources in staff or funding to eliminate or minimize all risks. OPS also recognizes that some solutions may be so cost prohibitive as to preclude implementation. Considering the intent to use RBPP to rank potential pipeline safety risks so that the resources of OPS are assigned to those actions having the greatest probability of protecting public safety and the environment, OPS is seeking input from industry and the public through participation in this open meeting and other opportunities for comment and participation. The location and time of the meeting has been selected to maximize industry and public attendance and comment since many interested parties will be assembled at the same location for the 2½ days after the OPS meeting to attend an international seminar on pipeline rehabilitation.

The objective of the meeting will be to present to industry and the public the RBPP concept and sufficient details of the concept to permit comments either at the meeting or by mail after the meeting. A representative of OPS will present the concept in illustrated lecture format. Handouts describing RBPP will be available at the conclusion of the presentation. Following the presentation, there will be an opportunity for questions and discussion. OPS is seeking constructive comment to consider in maximizing the validity and effectiveness of RBPP.

In essence, the RBPP process would identify risks and solutions by polling panels of selected experts for their individual opinions and not to obtain consensus advice. The groundwork for polling would be a diagram of regulator and operator functions relevant to pipeline safety and the protection of the environment. The results of the polls would be analyzed and a list of solutions prepared. OPS would prepare an economic impact estimate for each solution. Again, OPS would poll a panel of selected experts who would rate, using simple methodology, each solution in terms of the effect of the solution on the probability and consequence of accident occurrence, and the economic impact of the solution. OPS has not decided on the make-up of the panels or the polling processes at the time of preparation of this notice.

A mathematical analysis of probability, consequence, and economic impact resulting from polling will generate a prioritized list for consideration by OPS management who then would allocate available resources to the highest priority solutions for implementation. Certain solutions, e.g., those mandated in statute, would receive special consideration. The assignments for implementation would constitute the annual OPS action plan. While the process would be executed on an annual basis, it would be adaptable to evaluation of risks and solutions at any time using the same methods.

Procedures for conducting the meeting will be announced at the meeting. Every effort will be made to hear all who wish to comment within the time available. Comments by mail are also invited, and should be submitted promptly because OPS intends to develop and implement RBPP at a rapid pace. Comments should be mailed to G. Joseph Wolf at the address shown above.

Issued in Washington, DC on January 6, 1993.

George W. Tenley, Jr.,

Associate Administrator for Pipeline Safety.

[FR Doc. 93–621 Filed 1–11–93; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

January 6, 1993.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Financial Management Service

OMB Number: 1510–0057.

Form Number: None.

Type of Review: Extension.

Title: Annual Letter—Certification of Authority.

Description: The letter is sent to insurance companies that provide surety bonds to protect the Federal Government. These companies then provide information necessary for the renewal of their Treasury Certification and the determination of their underwriting limit. Summary information about the company is then published in Circular 570 for use by Federal bond approving officers.

Respondents: Businesses or other for-profit.

Estimated Number of Respondents: 305.

Estimated Burden Hours Per Response: 62 hours, 30 minutes.

Frequency of Response: Quarterly and Annually.

Estimated Total Reporting Burden: 19,063 hours.

Clearance Officer: Jacqueline R. Perry (301) 344–8577, Financial Management Service, 3361–L 75th Avenue, Landover, MD 20785.

OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–639 Filed 1–11–93; 8:45 am]

BILLING CODE 4810–35–M

Debt Management Advisory Committee; Meeting

Notice is hereby given, pursuant to section 10 of Public Law 92–463, that a meeting will be held at the U.S. Treasury Department in Washington, DC on February 2 and 3, 1993, of the following debt management advisory committee: Public Securities Association, Treasury Borrowing Advisory Committee.

The agenda for the Public Securities Association Treasury Borrowing Advisory Committee meeting provides for a working session on February 2 and the preparation of a written report to the Secretary of the Treasury on February 3, 1993.

Pursuant to the authority placed in Heads of Departments by section 10(d) of Public Law 92–463, and vested in me by Treasury Department Order 101–05, I hereby determine that this meeting is concerned with information exempt from disclosure under subsection 552b(c)(9)(A) of title 5 of the United States Code, and that the public interest requires that such meetings be closed to the public.

My reasons for this determination are as follows. The Treasury Department requires frank and full advice from representatives of the financial community prior to making its final decision on major financing operations. Historically, this advice has been offered by debt management advisory committees established by the several major segments of the financial community, which committees have been utilized by the Department at meetings called by representatives of the Secretary. When so utilized, such a committee is recognized to be an advisory committee under Public Law 92–463.

Although the Treasury's final announcement of financing plans may not reflect the recommendations provided in reports of an advisory committee, premature disclosure of these reports would lead to significant financial speculation in the securities market. Thus, these meetings fall within the exemption covered by subsection 552b(c)(9)(A) of title 5 of the United States Code.

The Assistant Secretary (Domestic Finance) shall be responsible for maintaining records of debt management advisory committee meetings and for providing annual reports setting forth a summary of committee activities and such other matters as may be informative to the public consistent with the policy of section 552b of title 5 of the United States Code.

Dated: January 6, 1993.

John C. Dugan,

Assistant Secretary (Domestic Finance).

[FR Doc. 93–583 Filed 1–11–93; 8:45 am]

BILLING CODE 4810–35–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 7
Tuesday, January 12, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: Commission Meeting, Thursday, January 14, 1993, 10:00 a.m.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Maryland.

STATUS: Closed to the Public.

MATTERS TO BE CONSIDERED:

Compliance Status Report

The staff will brief the Commission on the status of various compliance matters.

FOR A RECORDED MESSAGE CONTAINING THE LATEST AGENDA INFORMATION, CALL: (301) 504-0709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207 (301) 504-0800.

Dated: January 7, 1993.

Sheldon D. Butts,

Deputy Secretary.

[FR Doc. 93-785 Filed 1-8-93; 2:23 pm]

BILLING CODE 6355-01-M

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Published December 28, 1992, 57 FR 61610.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 5:30 p.m., January 12, 1993.

PLACE: The Boulder Broker Inn, The Ballroom, 555-30th Street, Boulder, Colorado 80303.

STATUS: Open.

CHANGE IN THE MEETING: The meeting date and place have been changed. The new date is February 2, 1993. The new place is Building 1 Auditorium, Department of Commerce, 325 Broadway, Boulder, CO. The time remains as previously announced, 5:30 p.m.

MATTERS TO BE CONSIDERED: The open public meeting and hearing will address the Department of Energy's Operational Readiness Review and other matters related to the resumption of plutonium operations in Building 707 at the Rocky Flats Plant. The Department of Energy will take appropriate measures to safeguard any classified or controlled nuclear information it presents at this meeting. The public hearing portion is independently authorized by 42 U.S.C. 2286b.

FOR MORE INFORMATION CONTACT: Kenneth M. Pusateri, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW., Suite 700, Washington, DC 20004, (202) 208-6400. This is not a toll free number.

SUPPLEMENTARY INFORMATION: The Board had already received a number of requests to speak at the meeting originally scheduled for January 12, 1993. Those commentators who were scheduled to speak at the January 12 meeting should confirm with the Board their intention to speak on February 2, 1993. The order in which the original requests to speak were received will be maintained so long as the public commentators contact the Board prior to close of business on January 28, 1993. So that everyone who wishes to speak will have an opportunity, speakers will be limited to five minutes each. Additional requests to speak at the hearing may be submitted in writing or by telephone. We ask that commentators describe the nature and scope of the oral presentation. Those who contact the Board prior to close of business on January 28, 1993, will be scheduled for time slots, beginning at approximately 8:00 p.m. The Board will post a schedule for those speakers who have contacted the Board before the hearing. The posting will be made at the entrance to the Building 1 Auditorium, Department of Commerce, 325 Broadway, Boulder, CO, at the start of the 5:30 p.m. meeting.

Anyone who wishes to comment, provide technical information or data may do so in writing, either in lieu of, or in addition to making an oral presentation. The Board members may question presenters to the extent deemed appropriate. The Board will hold the record open until February 12, 1993, for the receipt of materials. A transcript of the meeting will be made available by the Board for inspection by the public at the Defense Nuclear Facilities Safety Board's Washington office and at the DOE's public reading room at DOE's Front Range Community College, 3645 West 112 Avenue, Westminster, CO 80030.

After the close of the record, and before resumption of plutonium operations, the Board may conduct further deliberations pursuant to Section 3133(a) of the National Defense Authorization Act, P.L. 102-190, Dec. 5, 1991, to determine if the Secretary's response to select Board recommendations adequately protects public health and safety with respect to the operation of Building 707.

The Board specifically reserves its right to further schedule and otherwise regulate the course of the meeting and hearing, to recess, reconvene, postpone or adjourn the meeting, conduct further reviews, and otherwise exercise its power under the Atomic Energy Act of 1954, as amended.

Dated: January 27, 1993.

Kenneth M. Pusateri,

General Manager.

[FR Doc. 93-728 Filed 1-8-93; 2:28 pm]

BILLING CODE 6820-KD-M

FEDERAL COMMUNICATIONS COMMISSION

The Federal Communications Commission will hold an Open Meeting on the subjects listed below on Thursday, January 14, 1993, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, NW., Washington, DC.

Item No., Bureau, and Subject

1—Common Carrier—Title: Amendment of the Commission's Rules Regarding Safeguards to improve the Administration of the Interstate Access Tariff and Revenue Distribution Processes (RM-7736). Summary: The Commission will consider adoption of a *Notice of Proposed Rulemaking* concerning the administration of the interstate access tariff and revenue distribution processes by the National Exchange Carrier Association, Inc. (NECA). Title: Audit Costs of the National Exchange Carrier Association, Inc. Billed to Subset I Companies. Summary: The Commission will consider adoption of a *Memorandum Opinion and Order* concerning Southwestern Bell Telephone Company's and Pacific Bell's "Joint Petition for Waiver or in the Alternative Motion to Modify" the Commission's November 9, 1990 Letter to NECA. Title: Letter to the National Exchange Carrier Association, Inc. Summary: The Commission will consider adoption of a *Letter* to NECA regarding the *Safeguards* and *Adjustments Audits* ordered in the Commission's November 9, 1990 Letter.

2—Common Carrier—Title: Amendment of the Commission's Rules to Establish Rules and Policies Pertaining to a Non-Voice, Non-Geostationary Mobile-Satellite Service (CC Docket No. 92-76). Summary: The Commission will consider adoption of a *Notice of Proposed Rulemaking* on the

technical and service rules for a new mobile-satellite service in the frequency bands below 1 GHz.

3—Office of Engineering and Technology—Title: Amendment of Section 2.106 of the Commission's Rules to Allocate Spectrum to the Fixed-Satellite Service and the Mobile-Satellite Service for Low-Earth Orbit Satellites (ET Docket No. 91–280, RMs–7334, 7399, 7612, PPs–1, 2, & 3). Summary: The Commission will consider adoption of a *Report and Order* addressing allocation of the 137–138, 148–150.05, 399.9–400.05, and 400.15–401 MHz bands for low-Earth orbit satellite services.

4—Office of Engineering and Technology—Title: Amendment of the Commission's Rules Regarding Compatibility Between Cable Systems and Consumer Electronics Equipment. Summary: The Commission will consider adoption of a *Notice of Inquiry* regarding issues pertaining to regulations for assuring compatibility between cable systems and consumer electronics equipment.

5—Private Radio and Managing Director—Title: Amendment of Parts 1, 2 and 21 of the Commission's Rules Governing Use of the Frequencies in the 2.1 and 2.5 GHz Bands (PR Docket No. 92–80). Summary: The Commission will consider adoption of a *Report and Order* amending its rules in a manner designed to expedite the processing of applications for stations in the Multipoint Distribution Service (MDS) and to streamline the MDS regulatory scheme.

6—Private Radio—Title: Amendment of Part 90 of the Commission's Rules to Create the Emergency Medical Radio Service (PR Docket No. 91–72, RM–7336). Summary: The Commission will consider adoption of a *Report and Order* concerning the creation of the Emergency Medical Radio Service.

7—Private Radio—Title: Amendment of Part 13 of the Commission's Rules to Privatize the Administration of Examinations for Commercial Operator Licenses and to Clarify Certain Rules (FO Docket No. 92–206). Summary: The Commission will consider adoption of a *Report and Order* privatizing the administration of commercial radio operator examinations.

8—Private Radio—Title: Amendment of Parts 2 and 90 of the Commission's Rules to Provide for the Use of 200 Channels Outside the Designated Filing Areas in the 896–901 MHz and 935–940 MHz Bands Allocated to the Specialized Mobile Radio Service (PR Docket No. 89–553, RMs–6724 and 6579). Summary: The Commission will consider adoption of a *First Report and Order and Further Notice of Proposed Rulemaking* concerning the licensing of the 200 channels in the 900 MHz band allocated for use in the Specialized Mobile Radio Service.

9—Mass Media—Title: Amendment of the Commission's Rules Regarding Implementation of the Cable Television Consumer Protection and competition Act of 1992—Carriage of Home Shopping Stations. Summary: The Commission will consider adoption of a *Notice of Proposed Rulemaking* that seeks comment on implementation of the provision of the Cable Television Consumer Protection and Competition Act of 1992 relating to the carriage of broadcast television stations that are predominantly utilized for the transmission of sales presentations or program length commercials ("home shopping stations").

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Steve Svab, Office of Public Affairs, telephone number (202) 632–5050.

Issued: January 8, 1993.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–743 Filed 1–8–93; 12:05 am]

BILLING CODE 6712–01–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

January 7, 1993.

TIME AND DATE: 10:00 a.m., Thursday, January 14, 1993.

PLACE: Room 600, 1730 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *Island Creek Coal Company*, Docket No. VA 91–47–R, etc. (Issues include whether the judge erred in vacating two imminent danger orders of withdrawal issued to Island Creek by the Secretary of Labor, pursuant to 30 U.S.C. § 817(a), alleging that the south gob at its mine contained an explosive level of methane and that Island Creek violated 30 CFR § 75.316)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR § 2706.150(a)(3) and § 2706.160(e).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5629/(202) 708–9300 for TDD Relay/1–800–877–8339 for toll free.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 93–786 Filed 1–8–93; 2:24 pm]

BILLING CODE 6735–01–M

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

TIME AND DATE: 10:00 a.m., January 19, 1993.

PLACE: 4th Floor, Conference Room, 1250 H Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of the minutes of the last meeting.
2. Thrift Savings Plan activity report by the Executive Director.
3. Review of audit reports:
   - "Executive Summary of Fiscal Year 1991 Federal Agency Fiduciary Compliance Reviews."
   - "Pension and Welfare Benefits Administration Review of the Thrift Savings Plan Annuity Operations at the Metropolitan Life Insurance Company and the Federal Retirement Thrift Investment Board."
   - "Pension and Welfare Benefits Administration Review of ADP Operations Management of the Thrift Savings Plan at the United States Department of Agriculture, Office of Finance and Management, National Finance Center."

CONTACT PERSON FOR MORE INFORMATION: Tom Trabucco, Director, Office of External Affairs, (202) 942–1640.

Dated: January 8, 1993.

Francis X. Cavanaugh,

Executive Director, Federal Retirement Thrift Investment Board.

[FR Doc. 93–824 Filed 1–8–93; 8:45 am]

BILLING CODE 6760–01–M

SECURITIES AND EXCHANGE COMMISSION

Agency Meetings

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of January 11, 1993.

Closed meetings will be held on Wednesday, January 13, 1993, at 2:30 p.m. and on Friday, January 15, 1993 following the 11:00 a.m. open meeting. An open meeting will be held on Friday, January 15, 1993 at 11:00 a.m., in Room 1C20.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meetings. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at closed meetings.

Commissioner Roberts, as duty officer, voted to consider the items listed for the closed meetings in closed session.

The subject matter of the closed meeting scheduled for Wednesday, January 13, 1993, at 2:30 p.m., will be:

Institution of administrative proceedings of an enforcement nature.

Settlement of administrative proceedings of an enforcement nature.
Institution of injunctive action.
Settlement of injunctive action.
Opinion.

The subject matter of the open meeting scheduled for Friday, January 15, 1993, at 11:00 a.m., will be:

Oral argument on an appeal from an administrative law judge's initial decision by V.F. Minton Securities, Inc., a registered broker-dealer, and Vernon F. Minton, the firm's President. The firm and Minton have appealed from findings that they violated antifraud and registration provisions of the securities laws. For further information, please contact George J. Zornada at (202) 272–2435.

The subject matter of the closed meeting scheduled for Friday, January 15, 1993, following the 11:00 a.m. open meeting will be:

Post oral argument discussion.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Steve Luparello at (202) 272–2100.

Dated: January 6, 1993.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–711 Filed 1–7–93; 4:49 pm]

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Federal Register

Tuesday
January 12, 1993

Part II

Environmental Protection Agency

40 CFR Part 86

Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines; Regulations for Light-Duty Vehicle and Light-Duty Truck 1994, 1995 and 1996; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 86

[FRL–4550–2]

RIN 2060–AD 36

Control of Air Pollution from New Motor Vehicles and New Motor Vehicle Engines; Regulations for Light-Duty Vehicle and Light-Duty Truck 1994, 1995, and 1996 Model Year Durability Testing Procedures, and 1994 and Later Model Year Allowable Maintenance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action revises durability procedures and allowable maintenance provisions in the Federal motor vehicle emission certification regulations. The durability program revisions apply to model year 1994, 1995, and 1996 light-duty vehicles (LDVs) and light-duty trucks (LDTs). The rule includes durability procedures for the certification of vehicles subject to the Tier 1 emission standards promulgated on June 5, 1991. The revised durability procedures are in large part consistent with those adopted by the State of California.

The allowable maintenance provisions apply to model year 1994 and later LDVs and LDTs. The new regulations generally extend maintenance intervals for LDVs in response to the longer Tier 1 definition of LDV useful life and update the provisions applicable to LDTs.

EFFECTIVE DATE: January 12, 1993. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 12, 1993.

ADDRESSES: Materials relevant to this final rule are contained in the EPA Air Docket, Attention Docket No. A–90–24, located at the Air Docket Section, USEPA, room M–1500, 401 M Street SW., Washington, DC 20460; telephone (202) 260–7548. The docket may be inspected between the hours of 8:30 am to 12 noon and from 1:30 to 3:30 pm. Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: James A. McCargar, Certification Division, U.S. Environmental Protection Agency, National Vehicle and Fuel Emissions Laboratory, 2565 Plymouth Road, Ann Arbor, Michigan, 48105. Telephone (313) 668–4244.

SUPPLEMENTARY INFORMATION:

I. Introduction

The Agency published a Notice of Proposed Rulemaking (NPRM) for this rulemaking on April 30, 1992.[1] The preamble to that proposed rule contains substantial information relevant to the matters discussed throughout this Notice. The reader is referred to that document for additional background information as well as for discussion of the various issues raised during the rulemaking. The NPRM preamble also includes a discussion of the important role durability procedures play in the Federal motor vehicle certification process.[2]

The Clean Air Act Amendments of 1990 (hereafter referred to as the Amendments) mandated new, more stringent motor vehicle emission standards and modified the definitions of motor vehicle useful life.[3] The Environmental Protection Agency (EPA) published regulations setting forth certain of these new requirements, referred to as the Tier 1 light-duty emission standards and useful life levels, on June 5, 1991.[4]

Lengthening of useful life mileages mandated by the Amendments for light-duty vehicles (LDVs) and light-duty trucks (LDTs) subject to the Tier 1 standards made some sections of the current durability regulations obsolete, prompting EPA to make changes for model year 1994 (MY94), the first year Tier 1 standards take effect.[5] Prior to the Amendments, the Agency had been considering broad improvements to various aspects of the certification durability procedures, due to input from the General Accounting Office, the vehicle manufacturers, and the Agency's own assessments of the program. Given the effect of the Amendments on the useful life mileages, EPA determined there was insufficient time to resolve all the key technical issues involved with a broad durability program revision before vehicle makers had to certify MY94 vehicles.

Consequently, the Agency's NPRM proposed revisions to establish interim durability procedures for MY94 and MY95 LDVs and LDTs; light-duty durability procedures for the 1996 and later model years would be proposed in a separate notice to address technical and procedural improvements to the durability program undergoing evaluation by the Agency.[6] The two rulemakings have been referred to as Revised Durability Program I and II (RDP–I and RDP–II).

Previous EPA regulations have specified that before a manufacturer performs maintenance on vehicles or components used to determine deterioration factors (DFs), it must demonstrate that the maintenance is "technologically necessary to assure in-use compliance with emission standards."[7] The Agency has promulgated a list of emission-related components and systems together with the shortest "allowable maintenance intervals" considered technologically necessary. These intervals are also the shortest periods of time in which a manufacturer can require owners to perform emission-related maintenance as a condition of continued Federal emission warranty coverage.

In the RDP–I NPRM, the Agency proposed increasing LDV allowable maintenance intervals based on the adoption of a 100,000-mile useful life for Tier 1 LDVs. The Agency also proposed limited adjustments to the LDT allowable maintenance intervals and additions to the list of maintained components. The Agency based the proposed changes to these intervals on its technical analysis of what interval was technologically necessary, the current LDT requirements, intervals used in manufacturers' current maintenance manuals, and current California Air Resources Board (CARB) requirements.

A public hearing was held on May 15, 1992, in Ann Arbor, Michigan, at which the Agency took comment on the RDP–I NPRM. The comment period remained open until June 15, 1992. The next two sections of this preamble provide a description of this final rule action and the consideration of public comment that led to changes from the NPRM. The final sections of the preamble describe the economic, environmental, and cost-benefit impacts of the rule and address certain administrative requirements.

II. Description of the Action

A. Revisions to Durability Procedures

With this rule the Agency is modifying the current durability procedures for use in certifying MY94 through MY96 LDVs and LDTs. The addition of MY96 to the applicability of the interim durability program is in response to public comment and in

[1] 57 FR 18544 (April 30, 1992).

[2] 57 FR 18544, 18545 (April 30, 1992).

[3] Pub. L. No. 101–549, 104 Stat. 2399.

[4] 56 FR 25724, June 5, 1991.

[5] The Amendments added a "full" useful life of 10 years/100,000 miles for LDVs, a 50,000 mile "intermediate" useful life for LDTs, and truncated the full useful life of the lighter LDTs at 10 years/100,000 miles.

[6] 57 FR 18544, April 30, 1992.

[7] See 40 CFR 86.090–25(b)(2).

recognition of the short leadtimes remaining before manufacturers must know with some certainty their durability program options for that model year.

As proposed in the NPRM, much of the structure of the current LDV durability program remains intact. The standard LDV durability program still calculates DFs on the basis of data from preproduction durability data vehicles (DDVs). The Automobile Manufacturers Association (AMA) cycle is carried forward in its historical form as the standard EPA-defined procedure for LDV mileage accumulation. For Tier 0 LDVs, the duration of AMA mileage accumulation remains at 50,000 miles.[8] Manufacturers may still petition the Administrator for the use of modified versions of the AMA (substitute AMA option) and to apply for an alternative durability program based in large part on data from production DDVs (Production AMA Durability Program option).

Much of the current HDT durability program is also maintained. Manufacturers may continue to develop and submit DFs under a Standard Self-Approval Durability Program based on their own service accumulation and vehicle/component selection methodologies, if the program design is consistent with good engineering practice. However, as proposed in the NPRM, the Production AMA Durability Program option based on production DDVs has been deleted for LDTs. As noted in the proposal, the 1985 promulgation of the self-approval program for LDTs made this earlier alternative essentially moot.

Several important new durability program elements will apply for MY94 through MY96. First, the duration of AMA mileage accumulation for Tier 1 LDVs certified under the Standard AMA Durability Program is set at 100,000 miles. Manufacturers may request approval to terminate DDV mileage accumulation and emission testing on Tier 1 LDVs at any point beyond 75,000 miles and to calculate 100,000-mile DFs based on extrapolations from those test data. The manufacturer's request for approval to extrapolate must include information demonstrating the durability of the vehicle's emission control components and systems at or beyond the full useful life. The Agency will approve such requests based primarily on evaluations of the linear correlation of the test data, the impact of outlier data, the maintenance history of the DDV, and the supplemental data provided by the manufacturer to substantiate satisfactory 100,000-mile component durability. Other information may also be considered. These provisions have been adopted without change from the proposal. Further discussion of the Agency's rationale for these provisions may be found in the NPRM.

Second, the Agency is adding the new Alternative Service Accumulation Durability Program (ASADP) option that was proposed in the NPRM for LDVs and LDTs.[9] Under this option, the manufacturer submits for the Administrator's approval an ASADP using preproduction vehicles and including the following elements: (1) An alternative service accumulation procedure; (2) a selection method for vehicles and components; (3) procedures for determining the DF, including a demonstration that the alternative procedures would generate DFs that are representative of actual in-use deterioration; (4) an in-use verification program (the "reality check"); and (5) data showing that all emission-related components are designed to operate properly for the entire useful life of vehicles in actual use (or for the minimum intervals specified in the allowable scheduled maintenance regulations).

The service accumulation procedure may consist of whole-vehicle mileage accumulation, bench cycling techniques that simulate in-use aging and operating environments, or a combination of the two. For the in-use verification program, the manufacturer agrees to recruit and test in-use vehicles in subsequent years to determine whether the alternative procedures accurately predict the deterioration of the vehicle's emissions in actual use for the applicable useful life. The manufacturer's proposal for the in-use reality check should include the method for selecting the vehicle sample, the criteria to be used in evaluating the results of the vehicle testing, and the remedies for failure to satisfy those criteria.

The Agency believes the ASADP will lead to increased flexibility in the durability process of motor vehicle certification, resulting in manufacturers developing more accurate durability programs that cost less than current procedures. The Agency structured the ASADP rules to meet this goal, allowing EPA to restrict its approval to those alternative programs that it believes are an improvement over current durability procedures. Approval is limited to programs where EPA is confident the ASADP will generate DFs that are representative of actual in-use deterioration and confident of the full-life durability of emission-related components. In addition, the ASADP approach includes an important feedback mechanism or reality check not present under EPA's current durability procedures. The Agency therefore believes the resulting durability programs will lead to more accurate DFs. Based on CARB's experience to date with a similar program, along with the interest expressed by various manufacturers in using the ASADP approach, the Agency believes the increased flexibility allowed under these rules will also lead to cost savings for manufacturers.

If the Administrator approves the manufacturer's proposed ASADP, all necessary aspects of the program will be included in a written agreement between the manufacturer and EPA. Any certificate of conformity issued by EPA based on such an alternative durability program will be conditioned on full compliance by the manufacturer with the terms of the in-use verification component of the written agreement.[10] If the manufacturer fails to fully execute the in-use verification program, then the manufacturer will be viewed as failing to comply with the terms and conditions upon which the certificate has been issued. As a result, the vehicles or trucks originally covered by the certificate will instead not be covered by the certificate, and the manufacturer may be subject, at the Agency's enforcement discretion, to the imposition of civil penalties violating section 203(a)(1) of the Act.

The Agency recognizes that manufacturers may develop ongoing improvements to their in-use verification testing programs. Therefore, the manufacturer and EPA may agree to amend the in-use verification portion of the initial agreement, if the

[8] In compliance with the Amendments, the Tier 1 regulations established new vehicle emission standards starting with MY94 and providing a phase-in for the manufacturers. For LDVs, for example, 40 percent of a manufacturer's MY94 vehicles must meet the new tighter standards, increasing to 80 percent in MY95, and finally, 100 percent in MY96. Tier 0 refers to those vehicles that, during the phase-in years, continue to be certified to the older, less stringent standards.

[9] The "service accumulation method" is the method used in a durability program to simulate the accumulation of actual in-use age and mileage on a vehicle; "mileage accumulation cycles" are the subset of service accumulation methods that employ whole-vehicle mileage accumulation. The Agency chose the name Alternative Service Accumulation Durability Program to distinguish it from EPA's historical Alternative Durability Program and to make clear the availability of both whole-vehicle and bench-aging options under the new option.

[10] Manufacturers must comply with all other terms of the written agreement prior to issuance of the certificate of conformity.

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manufacturer demonstrates and the Agency determines that the amended agreement will improve the in-use verification portion of the agreement.

Another change included in the interim procedures for MY94 through MY96 is a provision for a manufacturer to request alternative mileage intervals between test points for DDVs. This is expected to facilitate common testing with the California Air Resources Board (CARB).

For the convenience of readers, EPA is summarizing many of the durability requirements in a single section, 40 CFR 86.094–13, "Light Duty Exhaust Durability Programs." Finally, the term "durability useful life" has been added to the definitions of section 86.094–2. The durability useful life is the highest useful life mileage of all the useful life mileages that apply to a particular vehicle. More than one useful life may apply to a vehicle because emission standards for a given pollutant may exist at more than one mileage point and because the definition of full useful life may be different for different pollutants. In these cases, the new term simplifies the regulatory language for determination of the duration of service accumulation on a given durability data vehicle.

B. Revisions to Allowable Maintenance Intervals

The Agency is also adopting revisions to the allowable maintenance regulations, applicable to MY94 and later LDVs and LDTs, exactly as proposed in the NPRM and for the reasons discussed in the NPRM. No adverse comment was received on these changes. For all LDTs, two modifications are included: the maintenance interval for exhaust gas recirculation systems increases from 50,000 miles to 100,000 miles, and a new supercharger interval is established at 100,000 miles. For diesel cycle LDTs, the fuel injector tip cleaning interval is extended from 50,000 miles to 100,000 miles; because a 100,000-mile interval already existed in the regulations for other diesel-cycle LDT fuel injector maintenance, this change is accomplished by simply deleting the separate tip cleaning interval that existed in earlier regulations. The maintenance intervals for all LDVs are proposed to match the complete list of LDT intervals, as revised.

III. Public Participation

This section summarizes significant comments received from the public and EPA's response to those comments. Submissions were received from a total of seven commenters, including four motor vehicle manufacturers, one State government agency, and a joint submission from two professional associations. Copies of the comments in their entirety can be obtained from the docket for this rule (see "ADDRESSES"). The docket also includes a Response to Comments document for this rule, which provides greater detail on the comments received and EPA's response.

A. Model Year Applicability

Model Years of the Interim Program

One commenter recommended that EPA amend the interim durability program in RDP–I to cover certification of MY94 through MY97, which would be more orderly and economical, and would permit it to learn more about the new ASADP process and to perfect ASADP procedures. Another manufacturer commented that its leadtime requirements made it desirable to have the RDP–II rule completed by the end of calendar year 1992.

Based on the current status of the long-term durability program (RDP–II) rulemaking and the above comments, EPA has chosen to finalize the RDP–I regulations with a period of applicability for the interim durability program of MY94 through MY96. In EPA's judgment, the addition of MY96 to the interim program should provide sufficient time for promulgation of the RDP–II rule effective in MY97, while providing manufacturers with three model years to experiment with the ASADP option for Federal certification. The Agency believes this duration is an appropriate response to the issues raised by the commenter; in addition, the issue will, by its nature, again be considered in the RDP–II rulemaking.

Carryover and Carryacross to Future Model Years[11]

One manufacturer commented that EPA regulations should allow case-by-case carryover of data derived from AMA durability programs or Standard Self Approval durability programs to MY98, presuming EPA accepted the manufacturer's recommended duration for the interim durability program (through MY97). Another encouraged EPA to provide greater assurance that durability data from MY94 and MY95 durability demonstrations could be carried over to MY96 and beyond.

As noted in the response to the previous issue, EPA has chosen to extend the applicability for the interim durability program to the period from model years 1994 through 1996. The issue of carryover to model years beyond the interim period is outside the scope of the RDP–I rulemaking and will be addressed by EPA as part of the RDP–II rulemaking.

B. Linecrossing

The RDP–I NPRM did not propose changes to the current regulations defining linecrossing policy.[12] One manufacturer commented that Federal linecrossing criteria are too stringent. The commenter apparently does not question the basic policy that, if the DDV is a surrogate for the eventual calibration, linecrossing data provides clear evidence of potential in-use emission problems. Rather, it appears to be addressing the more narrow issue of consistency between EPA and CARB linecrossing policy.

The Agency's understanding is that CARB permits use of linecrossing durability data in only two limited circumstances. In the first, a manufacturer may conditionally carry over durability data gathered from a Federal Tier 0 durability data vehicle to a California Tier 1 certification, in order to save the expense of running a second DDV solely for California certification. However, CARB prohibits this option if the Federal certification had been denied on the basis that the original 50,000-mile durability data linecrossed the Federal standards, and this situation is largely mooted by promulgation of the Federal Tier 1 standards.

In the second circumstance, a manufacturer might seek to carry across durability data between two vehicles that have essentially identical engine and emission control systems, but that fall in different vehicle classes. The manufacturer cited a hypothetical example of this case where it uses an essentially identical system in two different trucks, and the weights of the two trucks fall on either side of the boundary between the LDT1 and LDT2 subclasses, which have different Tier 1 emission standards; the manufacturer wishes to avoid running one DDV for each system. The commenter states that California permits the conditional use of the LDT2 durability data for

[11] Under 40 CFR 86.094–24(f), manufacturers may use data generated by one test vehicle to represent data in a different engine family, if certain design similarities exist. This is generally termed "carryover" when applying data from one model year to the next, or "carryacross" when applying data from one engine family to another within the same model year.

[12] Data from the DDV is used to develop a straight-line graph reflecting emissions versus mileage. Linecrossing occurs when the emissions from the first official test point, the interpolated intermediate useful life mile point, or the interpolated full useful life mile point on this line exceed the applicable low-altitude emission standards.

certification of the LDT1, even if the data linecross at the tighter LDT1 standards, by calculating DFs from a revised deterioration line drawn parallel to the LDT2 deterioration line and intersecting the applicable CARB LDT1 emission standard. The commenter then states that the EPA linecrossing policy in the NPRM would prohibit the additional step of carrying across the durability data to a Tier 1 LDV certification, where California would permit the carryacross.

As noted above, the linecrossing language in the NPRM was not a new proposal; it was carried forward intact from current regulations. For trucks, manufacturers self-approve their durability programs, and may self-approve the kind of carryover from LDT2s to LDT1s cited in the comment. For LDVs, however, all durability program options other than the standard (AMA) program require specific EPA approval. Thus, the policy would preclude the additional step in the commenter's example where LDT carryacross data were linecrossing at the LDV standards. The commenter provided no data to support a reversal of the Agency's policy. The consequence that a new DDV must be run to replace the linecrossing data has always been present, and in the Agency's view, appropriate. Without new information with which to justify a change in the long-established policies for LDVs, the Agency has chosen in the final rule to continue the present policy.

C. Restrictions on Multiple-Standard Engine Families

A manufacturer commented that requiring separate engine families for vehicles certified to different standards increases the number of DDVs. This comment was apparently in response to the requirements of 40 CFR 86.094–30, which states that only one certificate be issued per engine family and that each certificate must certify compliance with no more than one set of in-use and certification emission standards. The effect of these requirements is to prohibit certification of multiple-standard engine families.

These provisions are part of existing regulations and were neither modified nor raised for comment in the RDP–I proposal. The commenter also failed to detail sufficient reason to modify this provision, therefore EPA has not changed the RDP–I final rule in response to this comment.

D. Fuels

Durability Programs for Alternative-Fuel Vehicles

One respondent expressed concern about the applicability of the proposed durability revisions to gaseous-fueled vehicles such as compressed natural gas and liquid petroleum gas (LPG) vehicles. The commenter requested that the Agency insert language specifically restricting the durability regulations to certification of vehicles fueled by gasoline, diesel fuel, and methanol.

The Agency believes that the durability regulations as proposed can appropriately be applied to all motor vehicles currently subject to emission standards promulgated under the Act, notwithstanding the fuel for which the vehicle was designed. While the Agency has not yet promulgated sandards and procedures applicable to gaseous-fueled vehicles, a proposal for such a rulemaking is in preparation. The Agency expects to propose these revised durability procedures for new natural gas and LPG vehicles in the context of that separate rulemaking. This is consistent with the "level playing field" approach the Agency has applied and continues to apply to its treatment of alternative fueled vehicles.

Service Accumulation Fuels

Two commenters jointly sought careful consideration by EPA of the potential impact of in-use fuels on emission durability. The organizations requested that the Agency clarify several aspects of current policy on service accumulation fuels and any changes that might be implied by the RDP–I proposal.

The RDP–I NPRM did not propose any amendments to the service accumulation fuel regulations for current LDV and LDT durability programs. While a careful re-evaluation of these regulations was impossible in this rulemaking to establish the interim durability program, EPA may propose revisions to the service accumulation fuel requirements as part of the RDP–II rulemaking, including aspects such as the sulfur content of the fuel.

For manufacturers seeking to use the new ASADP option, the elements of the in-use verification, including any consideration of customer fuel usage as a criterion in the recruitment process, are a subject for proposal by the manufacturer and approval by the Agency as part of the manufacturer's ASADP plan. The Agency would consider all elements of the in-use verification, including vehicle recruitment plans and fuels, in determining whether the ASADP strategy overall is likely to generate DFs that reflect in-use deterioration. However, because ASADP plans will be manufacturer specific and potentially quite different from one another, the Agency believes it is inappropriate to define specific fuels criteria for the in-use verification. At the same time, in its case-by-case review of in-use verifications, EPA would not expect to approve an in-use verification program that would reject a candidate test vehicle solely on the basis of customer fuel use, if the fuel was reasonably commercially available and lawful. EPA takes this position to be consistent with the goal of predicting in-use deterioration. If EPA obtains information that differences among legal in-use fuels or manufacturer targeting of recruitment on the basis of likely customer fuel usage may be affecting the results of the in-use verification, then EPA may consider adoption of fuels criteria in the future, and in the meantime, it would apply that knowledge to its case-by-case evaluations.

E. Approval Mechanisms for the Extrapolation Option

One manufacturer commented that, without advance approval to extrapolate a durability vehicle from three-quarters of the applicable durability useful life to the full useful life prior to starting mileage accumulation, it is required to start on a time schedule that assumes a full 100,000 miles may be required. For related reasons, a second manufacturer suggested that EPA delegate the authority for making an extrapolation determination to the manufacturer under the Abbreviated Certification Protocol. The first commenter also expressed the opinion that the extrapolation criteria should require only that the extrapolated data comply with the applicable emission standards.

The Agency believes it should only approve extrapolation if the data are reasonably expected to generate DFs that are equivalent to those that would have resulted from full-useful-life mileage accumulation. The Agency sees no basis for legitimately presuming that extrapolation from data not yet gathered will be acceptable. This is based on the need to consider factors such as unscheduled maintenance, as well as linearity and scatter of the data in determining whether extrapolation is appropriate. Even with minimal leadtime benefits, however, manufacturers that successfully complete three-quarter-life mileage accumulation and obtain Agency approval to extrapolate the data will accrue significant savings from the

foregone mileage accumulation. In addition, a manufacturer may verify with EPA in advance the sample size, outlier procedure, and linearity evaluation it seeks to apply; approval to extrapolate would then be expedited, assuming verification that the actual data meet the agreed-upon criteria.

Because of the sensitivity of linear regressions to data at the extremes on the abscissa, EPA believes it cannot justify accepting extrapolated data which merely projects that the line falls below applicable emission standards. In such cases, the manufacturer must demonstrate through an increase in the sample size or tighter data fit that the extrapolated data represent no loss in predictive power caused by loss of the high-mileage data.

The Abbreviated Certification Protocol relies on a significant amount of prior certification experience being gained before manufacturers are allowed to make determinations on individual items. As the Agency gains experience with the extrapolation decision process, allowing manufacturers to determine whether 75,000-mile extrapolation is appropriate in a given case may also be considered. In the meantime, EPA will seek to minimize delays in a manufacturer's durability time schedule. Manufacturers can speed this approval process as well by ensuring completeness of their responses to the regression line fit criteria and documentation of emission system component durability.

F. General Provisions of the Alternative Service Accumulation Durability Programs (ASADP)

Use of Additive Deterioration Factors

Two commenters acknowledged that the proposal allowed for use of additive DFs for LDVs under an approved ASADP and requested changes in the final regulations to allow the same provision for LDTs. A third manufacturer commented that it made sense from both a practical and mathematical standpoint to use additive DFs irrespective of the type of certification durability program. The commenter supported this position with the statement that positive prediction bias occurred for multiplicative DFs calculated for vehicles under the tighter Tier 1 emission levels.[13]

As indicated at the May 15, 1992, public hearing, EPA intends to allow a manufacturer to request an additive DF as an option when certifying with an ASADP for LDTs as well as LDVs.

[13] Positive prediction bias is the tendency of the data to produce DFs that err on the high side.

Omission of this option in the proposal was an oversight.

The Agency continues to believe that a multiplicative DF most accurately reflects the deterioration characteristics of actual emission control systems. Catalysts, which will continue to be the dominant emission control technology for the foreseeable future, are best characterized by their conversion efficiency, and the loss of conversion efficiency over time in the presence of stable engine-out emissions is a phenomenon that may be directly modeled as multiplicative deterioration. The Agency will continue to analyze this position as data become available from new systems designed to meet more stringent emission control standards.

Nevertheless, EPA does not wish to exclude the possibility that additive DFs may represent a more appropriate model for durability options that are tailored to a particular manufacturer's fleet. For this reason, EPA may accept alternative DF calculation methodologies for manufacturers choosing the ASADP option. In such cases, the in-use verification requirement provides necessary additional safeguards against additive DFs that would be poor predictors of actual deterioration.

Costs of In-Use Verification

One manufacturer commented that it was not apparent whether EPA included the cost estimates for conducting in-use verification testing in the economic impact analysis and calculation of reporting burden.

The calculations cited in the Economic Impact section in this preamble include in-use verification testing for ASADPs. The Information Collection Request (ICR) for this rule provides additional details.

The Agency projected respondent burden for the in-use verification portion of an ASADP at 750 hours per engine family for recruitment, testing, data reporting, and record storage. This constitutes about 37 percent of the total burden of running an ASADP for one engine family. The costs of running the verification are approximately $45,000 out of the total $122,000 cost per ASADP engine family. This is equivalent to approximately $3,000 per vehicle test, which is consistent with the current EPA average cost for surveillance and confirmatory testing.

Substitute AMA Option

Four vehicle manufacturers have approached the Agency with questions related to, or draft proposals for, the use of substitute AMA cycles that would be substantially dissimilar to the AMA procedure. These manufacturers have sought to clarify their prospects for approval of the substitute cycles for MY94 certification and to assess their options for carryacross of data from California to Federal durability programs. The Agency considers these inquiries as requests to allow substitute AMA cycles that are substantially dissimilar to the AMA.

The RDP–I proposal did not propose amendments to substantively change current EPA regulations on substitute AMA cycles. Historically, the Agency has approved numerous requests for minor variations in the AMA procedure in order, for example, to accommodate differences between the length of a manufacturer's test track and the length of one standard AMA circuit. On the other hand, EPA has not approved any request by a manufacturer to employ a mileage accumulation cycle that includes major revisions to the AMA. In each case, EPA has concluded that the justifications for the proposed substitutes were not sufficient to ensure a substantial improvement in the accuracy of the resulting DFs.

These more recent inquiries by manufacturers indicate a renewed interest in the substitute AMA option by initiating or resurrecting work on a spectrum of potential cycles. These include not only cycles based on full-life mileage accumulation, but also cycles that attempt to simulate full-life mileage accumulation through very high-speed, abbreviated-mileage operation, an approach not anticipated by EPA in the RDP–I NPRM.

After evaluating these most recent inquiries, EPA believes that the up-front justifications provided by the manufacturers are insufficient to demonstrate likely, substantial improvement in the resulting DFs and, further, the Agency remains reluctant to ignore the risk of degradation in the quality of the durability program. The Agency acknowledges that the current policy has proven to be a difficult hurdle. Since there is insufficient time to initiate new test programs in support of a request for a substantially dissimilar substitute AMA for use in certification in the model years 1994 through 1996, manufacturers must necessarily rely on available historical data to justify their request. Approval of requests based on such data bears inherent risks because historical data will not be recent enough to reflect adequately on new designs being certified. Moreover, testing programs performed for other purposes and then used in a substitute AMA petition do not necessarily provide adequate coverage of each manufacturer's fleet.

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Based on the above considerations, no change is made in the finalized RDP–I regulations; they continue to permit Administrator approval of substitute AMA cycles. Manufacturers may continue to seek approval of substitute cycles that incorporate either minor or major deviations from the AMA schedule. However, for cycles that bear little resemblance to the AMA, EPA is convinced that it will be unable to establish preapproval acceptance criteria for these cycles. The Agency is not optimistic that it will be possible to conclude that such cycles are indeed substantially more effective in predicting in-use emission deterioration.

On the other hand, EPA believes that the ASADP option may provide a more fruitful avenue, and the final regulations permit manufacturers to seek approval of programs based on substantially different substitute mileage accumulation cycles under that option. As with other ASADPs, manufacturers requesting this option must include an in-use verification in their agreement. This policy will permit manufacturer innovation while addressing the Agency's concern over the quality of the DFs they generate.

G. In-Use Verification

Range of Configurations Subject to Recruitment

The preamble to the NPRM stated that the vehicles recruited under an ASADP in-use verification must represent the range of vehicle configurations in each engine family certified using the ASADP. Three manufacturers commented that this requirement would reduce the reliability of any comparison between the in-use data and the certification DF, which by implication suggest that ASADPs would be limited in their ability to accurately reflect in-use deterioration. Commenters speculated on the additional test costs that might be required to compensate for increased scatter in the data, an added burden that would be inconsistent with the objectives of the rule.

Two manufacturers sought consistency with CARB policy, which permits manufacturers to restrict recruitment to the DDV configuration. A third manufacturer supported recruitment across a "reasonably representative mix" of vehicles in the family, achieved by proportional recruitment across the configurations in a family, with exceptions allowed for small sales families, small sales powertrains, and others.

The Agency has always acknowledged that differences between configurations in the same engine family would mean that the broader the sampling across the family, the greater the scatter in the resulting data. Conversely, if the sampling is narrowly confined to a few configurations, the general applicability of the results across the engine family is less secure. Based on these comments and considerations, EPA has concluded that requiring either single-configuration sampling or sampling across all configurations would cement the manufacturers' options at the extremes of this tradeoff, when the most effective choice may vary based on other considerations in the ASADP. The Agency is therefore deleting the requirement that in-use verification must in each case include vehicles from each engine system combination certified under the program. Instead, the regulations will require testing of in-use vehicles certified under the program, with the range of vehicle testing to be determined on a case by case basis. The Agency believes that manufacturers can propose options that will adequately address the issue of the reliability of their data but will not require a proliferation of testing. For example, the Agency would consider foregoing some engine-family-specific comparisons where scatter would weaken the conclusions in favor of cross-family analyses of data aggregated from several ASADP engine families.

This final rule places only one explicit restriction on the recruitment method for the in-use verification, applicable only to those manufacturers seeking to use the additive DF option. The risk of the additive DF arises where the DDV configuration is calibrated lower than other configurations in the family; in this case, certain vehicle configurations may show passing certification values with an additive DF when certification values calculated with a multiplicative DF would fail. If in-use vehicles actually behave according to the multiplicative model, and manufacturers calibrate their configurations sufficiently above the DDV, vehicles with additive DFs may be inappropriately certified. Consequently, EPA will not accept in-use verification programs relying on single-configuration recruitment schemes if the manufacturer employs an additive DF. EPA maintains that if a manufacturer has no other program element explicitly designed to verify use of the additive DF and the DDV configuration alone is sampled, the testing will be unable to verify whether employing an additive DF was appropriate.

Basis for Determining Pass/Fail

One manufacturer commented that the variability of in-use data would make comparisons between in-use DFs and certification DFs inappropriate. It argued that a manufacturer should not be required to modify its ASADP as long as the in-use data complies with the emission standards.

The basis for determining pass/fail during the in-use verification will depend on the quality of the data, which in turn will depend on factors like the sample size, recruitment methods, and deterioration model (e.g., additive or multiplicative DF) employed in the ASADP. With today's rule, each of these program elements is proposed by the manufacturer; consequently, EPA has not specified an algorithm for evaluating the in-use data against the certification DFs.

The Agency does not wish to restrict manufacturer initiative in choosing from among the many statistical measures and the tolerances that may be applied to those measures when comparing in-use and certification results. Therefore, EPA finds it inappropriate to reject the possibility of a direct comparison between DFs derived from in-use data and DFs derived from certification. Similarly, EPA believes that restricting the pass/fail decision to a simple test of whether the in-use vehicles pass emission standards ignores the purpose of the check, which is to verify the adequacy of the manufacturer-designed elements of the ASADP in predicting the deterioration of the vehicle's emissions over its useful life.

Certification emission values almost never fall directly on the emission standard. The suggestion by the commenter to use only an in-use pass/fail criteria would therefore permit the manufacturer to perpetuate an ASADP that erroneously and consistently underpredicted deterioration. If the flawed ASADP were subsequently applied to an engine family with higher emission levels, an improper certification of this engine family would not be detected until surveillance testing (or a subsequent in-use verification) occurred some years later. This is precisely one of the problems that EPA is trying to address in revising the durability program.

The Agency believes that this rule, by not restricting the options a manufacturer may propose to use, provides an appropriate middle ground. Through flexibility in the regulations, EPA neither mandates criteria that may be unnecessarily burdensome nor settles for criteria that may be ineffective due to oversimplicity.

H. Condition on the Certificates

The Agency proposed that completion of the in-use verification would be a condition on the certificate because of the importance of the in-use reality check. If a manufacturer failed to satisfy this condition, then all or some of the motor vehicles in that engine family would not be covered by the certificate, potentially subjecting the manufacturer to civil penalties for introduction of new motor vehicles into commerce that are not covered by a certificate of conformity. The Agency made it clear that it would exercise all appropriate enforcement discretion in evaluating any such situations.

Two manufacturers objected to this provision. They maintained that the Act did not authorize a retrospective determination that vehicles previously sold in good faith under a certificate could later be considered not sold under a valid certificate. This essentially amounted to voiding the certificate ab initio and was not authorized under the Act. They argued that the Agency's Selective Enforcement Audit (SEA) assembly line testing under section 206(b)(2)(A) was an appropriate analogy to the in-use verification. That provision authorizes EPA to suspend or revoke an engine family's certificate of conformity based on a failure of such audit, but limits it to vehicles still in the hands of the manufacturer or yet to be manufactured. According to the commenters, EPA therefore does not have the authority to condition a certificate of conformity as proposed.

The commenters also argued that the proposed use of a condition on the certificate was unnecessary, as section 208 of the Act authorized EPA to require the in-use testing involved in the reality check. Failure to comply with a valid test order under section 208 would potentially subject a manufacturer to civil penalties of $25,000 per day. In the commenters' opinion, this was an adequate and lawful mechanism for EPA to ensure completion of the in-use verification.

The Agency notes that the Act authorizes the use of conditions or terms on the certificate of conformity. Specifically, section 206(a)(1) of the Act authorizes issuance of a certificate of conformity "upon such terms as * * * [the Administrator] may prescribe." This broadly phrased grant includes authority to prescribe appropriate conditions or terms that must be met, whether prior or subsequent to introduction of the motor vehicles into commerce. Section 206(b)(2)(A) does not limit this authority. That provision is not applicable; it establishes separate EPA authority to suspend or revoke a certificate in those situations where SEA testing produces evidence of noncompliance. It does not address the scope of "terms" that EPA may prescribe under section 206(a)(1).

Violation of the condition on the certificate does not amount to voiding of the certificate ab initio. While EPA believes it could adopt such an enforcement posture, EPA instead proposed a condition on certificates such that all or some of the vehicle configurations in the engine family would lose certificate coverage if the manufacturer failed to comply with conditions on the certificate.[14] Determination of the number of vehicles subject to loss of coverage under a certificate would be based on the specific facts involved in a failure to comply with the in-use verification conditions. For example, the scope of testing conducted compared to the scope required would be an important factor in determining whether all or some of the vehicles in an engine family are covered under the certificate. The Agency recently adopted a similar enforcement approach in rulemakings involving a phase-in over time of certain new motor vehicle standards.[15 16]

Notwithstanding existing authority under section 208 of the Act to require manufacturers to perform emission testing, EPA believes it is appropriate to condition certificates as proposed. Rather than issuing requests to test under section 208 to each individual manufacturer participating in the alternative durability program, the Agency has decided to take advantage of the opportunity provided by this rulemaking to establish this condition beforehand for all manufacturers opting to use the ASADP programs. In the interest of ensuring the integrity of this new program, EPA wants to make manufacturer responsibilities and liabilities very clear. The Agency also believes that the importance of the in-use verification requirement warrants the potentially larger civil penalties associated with failing to comply with conditions on the certificate.

As stated in the NPRM, the Agency plans to exercise enforcement discretion to determine whether civil penalties are appropriate. The EPA recognizes that circumstances may arise in which it becomes reasonable to terminate the in-use reality check before all agreed-upon testing would have been completed (e.g., if initial testing were to clearly demonstrate that the deterioration factor applied is unacceptable). The EPA also recognizes that a manufacturer, notwithstanding its best efforts, may fail to perform the required in-use reality check due to circumstances beyond its control. Thus, the Agency will consider all relevant factors when determining whether a manufacturer has complied with the reality check condition on the certificate.

I. Sunsetting

One manufacturer recommended that the Administrator have the authority to waive reality check testing for a manufacturer if that manufacturer demonstrates its projections are consistently accurate.

The Agency distinguishes between curtailing an in-use verification that is already in progress and sunsetting the requirement proposed in 40 CFR 86.094–13(e)(5) that new ASADPs must include an in-use verification. The Agency believes the proposed regulations explicitly provided the authority in section 86.094–13(e)(5) for the former, and this language is retained in the final rule. At this time, however, EPA does not believe it appropriate to accept an ASADP that does not contain in-use verification, even if a manufacturer demonstrates the ability of prior ASADPs to consistently develop accurate DFs. Manufacturers are likely to propose ASADPs for a wide variety of engine families and model years, and the in-use verification provides a constant incentive for the development of accurate DFs. In the three years of the interim durability program, EPA does not believe it is feasible to develop the historical data needed to substitute for this necessary incentive. Thus, the final RDP–I regulation does not provide for sunsetting of 40 CFR 86.094–13(e)(5). However, EPA will revisit this issue in the RDP–II rulemaking, which will address ASADPs for 1997 and subsequent model years.

IV. Economic, Environmental, and Cost-Benefit Impacts

A. Economic Impacts

As noted in the preamble to the proposal, the costs of this rulemaking are almost exclusively those incurred by the manufacturers in running the durability program itself a reporting the results to EPA. These costs are considered to be costs of information collection, and details on EPA's cost projections were therefore included in the proposed ICR prepared in conjunction with the proposal. This

[14] EPA employs this provision in other enforcement mechanisms under Title II of the Act, such as remedies for banking, trading and averaging programs and for violations of the recordkeeping and reporting requirements under these programs.

[15] 56 FR 25734, June 5, 1991.

[16] 57 FR 31888, July 17, 1992.

proposed ICR was an amendment to the larger ICR covering the certification program as a whole.

Due to changes incorporated in the final rule (primarily the extension by one model year of the interim durability program), the Agency has revised the ICR and the impact projections. The methodology in the revision is the same: total annual costs are projected by calculating the unit cost of running a DDV and applying that unit cost to the number of DDVs projected for a given model year. The incremental burden attributable to the rule was determined by comparing the results of the mean year from the durability program to the base year of the current certification ICR.

In the revised ICR, EPA again derived the projections for the number of engine families and DDVs from the Tier 1 regulation. Essentially all manufacturers employing Standard AMA Durability Program are presumed to utilize the extrapolation option. As in the proposal, EPA examined a matrix of possible outcomes based on the percentage of carryover from California data and the percentage penetration of the ASADP option.

Table 1 projects EPA's revised estimate for the final rule for the change in the mean annual cost of the interim light-duty durability program under several of these scenarios. The carryover and ASADP penetrations in Table 1 were selected to bracket the most extreme cases that might occur. The Agency believes that manufacturers will seek as much California carryover as possible and will actually achieve on the order of 90 percent. Based on indications from the manufacturers of their intent to implement ASADPs, the likely penetration rate will average between 40 percent and 60 percent over the three years the program will be effective. On this basis, Table 1 shows that EPA projects the rule to generate a net annual savings to manufacturers of approximately $8.6 million.

Allowing the use of alternative durability programs federally is expected to promote their use in California and ultimately to result in cost savings of an additional $2.5 million per year for the California durability program.

TABLE 1.—MEAN ANNUAL REDUCTION IN TOTAL COST OF THE LIGHT-DUTY DURABILITY PROGRAM

[In Millions of Dollars ($M)]

California carryover (percent)	Alternative durability program use			
	0%	25%	50%	75%
50	($0.3)	($1.0)	($1.8)	($2.5)
80	(6.2)	(6.6)	(6.8)	(7.1)
90	(8.3)	(8.4)	(8.6)	(8.7)
100	(10.2)	(10.2)	(10.2)	(10.2)

Estimates of the per-vehicle impact of the durability regulations may then be obtained by spreading the total cost of a given scenario across the projected MY96 Tier 1 new-vehicle fleet size (derived in the Tier 1 Regulatory Impact Analysis) of 15.25 million vehicles. The range of impacts thus obtained is a decrease of 2.0 cents per vehicle for the highest-cost scenario (50 percent carryover; no alternative durability programs) to a decrease of 67 cents per vehicle for the lowest-cost scenario (full California carryover, with 75 percent alternative durability program penetration). The $8.6 million cost savings for EPA's projected most likely scenario corresponds to approximately 56 cents per vehicle.

As noted in the proposal, the cost savings of the durability rule is attributable primarily to the use of California carryover durability data and secondarily to the use of alternative durability programs.

The Agency has not inserted any increase or decrease in costs associated with the revised allowable maintenance intervals adopted through this regulation. As noted in the proposal, the Agency believes that no incremental costs will accrue to manufacturers, over and above any redesign costs that have already been addressed in the Tier 1 rulemaking. No comments were received from the public on the issue of costs from the changed allowable maintenance intervals.

B. Environmental and Cost-Benefit Impacts

The current proposal provides revisions to the testing and administrative procedures that are necessary to determine compliance with the Tier 1 rules promulgated in June 1991. The emission benefits of the Tier 1 standards and the revised useful life definitions were analyzed in conjunction with the Tier 1 rule. No environmental benefit is claimed for this revision to the durability procedures, beyond that already accounted for in the Tier 1 rule.

V. Administrative Requirements

A. Administrative Designation

Under Executive Order 12291, EPA must judge whether a regulation is a "major" rule and, therefore, subject to the requirement that a Regulatory Impact Analysis (RIA) be prepared. Since EPA has determined that this regulation is not major, an RIA has not been prepared.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to those comments are in the public docket for this rulemaking.

B. Reporting and Recordkeeping Requirement

The information collection requirements in this final rule have been approved by the Office of Management and Budget (OMB) under the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* An Information Collection Request document has been prepared by EPA (ICR No. 2060–0104) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC 20460 or by calling (202) 260–2740.

Public reporting burden for this collection of information is estimated to be a reduction of 5740 hours per response annually for the 25 affected respondents. However, the estimate decreases to a reduction of 1670 hours per response when distributed across all 86 respondents to which the entire program applies. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information.

C. Impact on Small Entities

The Regulatory Flexibility Act of 1980 requires federal agencies to identify potentially adverse impacts of federal

regulations upon small entities. In instances where significant impacts are possible on a substantial number of these entities, agencies are required to perform a Regulatory Flexibility Analysis (RFA).

EPA has determined that the regulations adopted today will not have a significant impact on a substantial number of small entities. This regulation will affect only manufacturers of motor vehicles, a group which does not contain a substantial number of small entities.

Therefore, as required under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, I certify that this regulation does not have a significant impact on a substantial number of small entities.

VI. Statutory Authority

The promulgation of these regulations is authorized by sections 202, 203, 205, 206, 207, 208, 215, 216, and 301(a) of the Clean Air Act as amended by the Clean Air Act Amendments of 1990 (42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7549, 7550, and 7601(a)).

VII. Judicial Review

Under section 307(b)(1) of the Act, EPA hereby finds that these regulations are of national applicability. Accordingly, judicial review of this action is available only by filing of a petition for review in the United States Court of Appeals for the District of Columbia Circuit within 60 days of publication. Under section 307(b)(2) of the Act, the requirements which are the subject of today's Notice may not be challenged later in judicial proceedings brought by EPA to enforce these requirements.

List of Subjects in 40 CFR Part 86

Administrative practice and procedure, Air pollution control, Confidential business information, Environmental protection, Gasoline, Imports, Incorporation by reference, Labeling, Motor vehicles, Motor vehicle pollution, Reporting and recordkeeping requirements.

Dated: December 19, 1992.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, part 86 of title 40 of the Code of Federal Regulations is amended as follows:

PART 86—CONTROL OF AIR POLLUTION FROM NEW AND IN-USE MOTOR VEHICLES AND NEW AND IN-USE MOTOR VEHICLE ENGINES: CERTIFICATION AND TEST PROCEDURES

1. The authority citation for part 86 is revised to read as follows:

Authority: Secs. 202, 203, 205, 206, 207, 208, 215, 216, 217, and 301(a), Clean Air Act as amended (42 U.S.C. 7521, 7522, 7524, 7525, 7541, 7542, 7549, 7550, 7552, and 7601(a))

Subpart A—[Amended]

2. Section 86.094–1 is added to read as follows:

§ 86.094–1 General applicability.

(a) The provisions of this subpart generally apply to 1994 and later model year new Otto-cycle and diesel-cycle light-duty vehicles, 1994 and later model year new Otto-cycle and diesel-cycle light-duty trucks, and 1994 and later model year new Otto-cycle and diesel-cycle heavy-duty engines. In cases where a provision applies only to a certain vehicle group based on its model year, vehicle class, motor fuel, engine type, or other distinguishing characteristics, the limited applicability is cited in the appropriate section or paragraph.

(b) *Optional applicability.* A manufacturer may request to certify any heavy-duty vehicle of 10,000 pounds Gross Vehicle Weight Rating or less in accordance with the light-duty truck provisions. Heavy-duty engine or vehicle provisions do not apply to such a vehicle.

(c) [Reserved]

(d) [Reserved]

(e) *Small volume manufacturers.* Special certification procedures are available for any manufacturer whose projected combined U.S. sales of light-duty vehicles, light-duty trucks, heavy-duty vehicles, and heavy-duty engines in its product line (including all vehicles and engines imported under the provisions of §§ 85.1505 and 85.1509 of this chapter are fewer than 10,000 units for the model year in which the manufacturer seeks certification. To certify its product line under these optional procedures, the small-volume manufacturer must first obtain the Administrator's approval. The manufacturer must meet the eligibility criteria specified in § 86.092–14(b) before the Administrator's approval will be granted. The small-volume manufacturer's certification procedures are described in § 86.092–14.

(f) *Optional procedures for determining exhaust opacity.* (1) The provisions of subpart I of this part apply to tests which are performed by the Administrator, and optionally, by the manufacturer.

(2) Measurement procedures, other than that described in subpart I of this part, may be used by the manufacturer provided the manufacturer satisfies the requirements of § 86.091–23(f).

(3) When a manufacturer chooses to use an alternative measurement procedure it has the responsibility to determine whether the results obtained by the procedure will correlate with the results which would be obtained from the measurement procedure in subpart I of this part. Consequently, the Administrator will not routinely approve or disapprove any alternative opacity measurement procedure or any associated correlation data which the manufacturer elects to use to satisfy the data requirements for subpart I of this part.

(4) If a confirmatory test(s) is performed and the results indicate there is a systematic problem suggesting that the data generated under an optional alternative measurement procedure do not adequately correlate with data obtained in accordance with the procedures described in subpart I of this part, EPA may require that all certificates of conformity not already issued be based on data obtained from procedures described in subpart I of this part.

3. Section 86.094–2 is amended by adding in alphabetical order the definition for "Durability useful life":

§ 86.094–2 Definitions.

* * * * *

Durability useful life means the highest useful life mileage out of the set of all useful life mileages that apply to a given vehicle. The durability useful life determines the duration of service accumulation on a durability data vehicle. The determination of durability useful life shall reflect any alternative useful life mileages approved by the Administrator under § 86.094–21(f). The determination of durability useful life shall exclude any standard and related useful life mileage for which the manufacturer has obtained a waiver of emission data submission requirements under § 86.094–23(c)

* * * * *

4. Section 86.094–13 is added to read as follows:

§ 86.094–13 Light-duty exhaust durability programs.

(a) (1) This section describes the various durability programs available to

manufacturers for determining exhaust deterioration factors (DFs) for the certification of 1994, 1995, and 1996 model year light-duty vehicles and light-duty trucks. While this section describes many of the important elements of these durability programs, it is not intended as an exhaustive list of all requirements applicable either to these programs or to the certification process.

(2) The durability programs consist of various elements, such as a statement of applicability, a service accumulation method, vehicle/component selection methods, durability data vehicle compliance requirements, in-use verification requirements, optional elements, data reporting requirements, and additional requirements. Cross references to other sections in this subpart are indicated where appropriate.

(b) The following table summarizes the durability programs available to all manufacturers of light-duty vehicles and light-duty trucks. The Tier 1 and Tier 0 standards cited in the table are those specified in § 86.094–8 (for light-duty vehicles) and § 86.094–9 (for light-duty trucks) . The durability programs described in this section are separate and distinct alternatives, such that determination of an exhaust deterioration factor under one program does not require compliance with the requirements of a different durability program.

Class	Standards	Durability program name	Optional elements
Light-duty Vehicles	Tier 1	Standard AMA	Carryover. Extrapolation. Substitute AMA.
		Production AMA	Carryover. Extrapolation. Substitute AMA.
		Alternative Service Accumulation	Carryover.
	Tier 0	Standard AMA	Carryover. Substitute AMA.
		Production AMA	Carryover. Substitute AMA.
		Alternative Service Accumulation	Carryover.
Light-duty Trucks	Tier 1 & Tier 0	Standard Self-Approval	Carryover.
		Alternative Service Accumulation	Carryover.

(c) *Standard AMA durability program*—(1) *Applicability.* The standard AMA durability program is applicable to light-duty vehicles in model years 1994, 1995, and 1996.

(2) *Service accumulation method.* The method shall be mileage accumulation performed on whole durability data vehicles, using the Durability Driving Schedule (commonly referred to as the AMA schedule) specified in Appendix IV to this part. The provisions of § 86.094–26(a), which include vehicle weight requirements, the duration of mileage accumulation, and the specification of emission tests to be performed during the mileage accumulation, shall apply. Scheduled and unscheduled maintenance may be performed on the vehicle in accordance with the provisions of § 86.094–25.

(3) *Vehicle/component selection method.* Durability data vehicles shall be selected by the Administrator as required in § 86.090–22(a) and in accordance with the provisions of § 86.094–24(c)(1). Typically, the Administrator selects one durability data vehicle to represent each engine-system combination. The selection of durability data vehicles is also governed by § 86.091–7(a)(2)(i)(A), which generally requires that vehicles used for certification must be representative of production vehicles.

(4) *Durability data vehicle compliance requirements.* Durability data vehicle compliance requirements for the Standard AMA Durability Program are contained in § 86.094–28(a). These include the method of calculating deterioration factors, line crossing criteria, and related requirements.

(5) *In-use verification.* Manufacturer testing of in-use vehicles subsequent to certification is not a requirement of the Standard AMA Durability Program.

(6) *Optional elements—(i) Extrapolation.* Manufacturers selecting the Standard AMA Durability Program may petition the Administrator for the use of extrapolated mileage accumulation data according to the provisions of § 86.094–26(a)(4) for use in certifying light-duty vehicles to the Tier 1 standards of § 86.094–8. If use of extrapolated data is approved, deterioration factors are determined by the method of linear extrapolation described in § 86.094–28(a)(4)(i).

(ii) *Substitute AMA.* Manufacturers selecting the Standard AMA Durability Program may petition the Administrator under § 86.094–26(a)(2)(ii) to substitute a different whole-vehicle mileage accumulation schedule for the Durability Driving Schedule (standard AMA) specified in Appendix IV to this part.

(iii) *Carryover and carryacross.* Manufacturers selecting the Standard AMA Durability Program may petition. the Administrator for the use of carryover or carryacross mileage accumulation data according to the provisions of § 86.094–24(f). If use of carryover or carryacross data is approved, deterioration factors are determined by the method of linear extrapolation described in § 86.094–28(a)(4)(i).

(7) *Data reporting requirements.* Data reporting requirements for the Standard AMA Durability Program are contained in § 86.094–21, § 86.094–23(b)(1)(i), and § 86.094–26 (a)(6)(ii) and (a)(7).

(d) *Production AMA durability program*—(1) *Applicability.* The production AMA durability program is applicable to light-duty vehicles in model years 1994, 1995, and 1996.

(2) *Service accumulation method.* The method shall be mileage accumulation performed on whole durability data vehicles, using the Durability Driving Schedule (commonly referred to as the AMA schedule) specified in Appendix IV to this part. The provisions of § 86.094–26(a), which include vehicle weight requirements, the duration of mileage accumulation, and the specification of emission tests to be performed during the mileage accumulation, shall apply. Scheduled and unscheduled maintenance may be performed on the vehicle in accordance with the provisions of § 86.094–25.

(3) *Vehicle/component selection method.* Durability data vehicles shall be selected by the Administrator as required in § 86.090–22(a) and in accordance with the provisions of § 86.094–24(h) . Typically, the Administrator selects several random production durability data vehicles, up to a maximum of three vehicles per engine family group.

(4) *Durability data vehicle compliance requirements.* Durability data vehicle compliance requirements for the Production AMA Durability Program are contained in § 86.094–28(a)(7) . These include the method of calculating deterioration factors, line crossing criteria, and related requirements.

(5) *In-use verification.* The Production AMA Durability Program includes no requirement for manufacturer testing of in-use vehicles subsequent to certification.

(6) *Optional elements*—(i) *Extrapolation.* Manufacturers selecting the Production AMA Durability Program may petition the Administrator for the use of extrapolated mileage accumulation data according to the provisions of § 86.094–26(a)(4) for use in certifying light-duty vehicles to the Tier I standards of § 86.094–8. If use of extrapolated data is approved, deterioration factors are determined by the method of linear extrapolation described in § 86.094–28(a)(7)(ii)(B).

(ii) *Substitute AMA.* Manufacturers selecting the Production AMA Durability Program may petition the Administrator under § 86.094–26(a)(2)(ii) to substitute a different whole-vehicle mileage accumulation schedule for the Durability Driving Schedule (standard AMA) specified in Appendix IV to this part.

(iii) *Carryover and carryacross.* Manufacturers selecting the Production AMA Durability Program may petition the Administrator for the use of carryover or carryacross mileage accumulation data according to the provisions of § 86.094–24(h)(1)(v) . If use of carryover or carryacross data is approved, deterioration factors are determined by the method of linear extrapolation described in § 86.094–28(a)(7)(ii)(B).

(7) Data reporting requirements for the Production AMA Durability Program are contained in § 86.094–21, § 86.094–23(b)(1)(i), and § 86.094–26 (a)(6)(ii) and (a)(7).

(8) *Additional requirements.* (i) For engine families subject to the procedures of the Production AMA Durability Program, the manufacturer shall submit deterioration factors to the Administrator for approval to use them for certification. The Administrator shall approve the use of deterioration factors that:

(A) The manufacturer attests are representative of the durability performance of its vehicles in actual field use when maintained according to the manufacturer's maintenance instructions (as limited under § 86.094–25(a)); and

(B) Are equal to or greater than the deterioration factors that EPA determines under paragraph (d)(8)(ii) of this section.

(ii) EPA shall determine minimum deterioration factors for engine families subject to the Production AMA Durability Program. This determination shall be based on a procedure of grouping engine families (see § 86.094–24(a)) in order to use historical certification data to determine deterioration factors for each engine family group. The historical data shall be updated yearly through the testing of production durability data vehicles. Test vehicle requirements under these procedures are contained in § 86.094–24 (h) and compliance requirements are contained in § 86.094–28(a)(7).

(iii) *Request procedures.* (A) A manufacturer wishing to participate in the Production AMA Durability Program must submit to the Administrator, for each model year, a written request describing the engine families that the manufacturer elects to be included in the program.

(B) The Administrator may declare ineligible any engine family for which the Administrator determines there is unreasonable risk in determining a deterioration factor using the methods of the Production AMA Durability Program. Furthermore, the Administrator may limit the number of engine families within the manufacturer's product line that are eligible for the Production AMA Durability Program.

(C) Upon approval of the manufacturer's request to participate, the Administrator and the manufacturer may enter into a written agreement prescribing the terms and conditions of the program. This agreement shall be equitable as compared to agreements entered into with other manufacturers. The agreement shall specify:

(*1*) The engine families to be included in the program and the engine family groups that have been established by the provisions of § 86.094–24(a) (8) and (9);

(*2*) The procedures for the selection of production durability data vehicles specified under the provisions of § 86.094–24(h); and

(*3*) The procedures for the determination of minimum exhaust emission deterioration factors for each engine family group.

(iv) *Withdrawal from Production AMA Durability Program.* (A) Subject to the conditions of paragraphs (d)(8)(iv) (B) through (F) of this section, a manufacturer may, at any time, withdraw all of its product line or separate engine family groups from this program. Only entire engine family groups may be withdrawn.

(B) Once any engine family in an engine family group is certified using deterioration factors determined in the Production AMA Durability Program, the manufacturer shall operate and test the production durability data vehicles specified in § 86.094–24(h) in accordance with the procedures of this part.

(C) The Administrator shall notify the manufacturer if a nonconformity of a category of vehicles within the engine family group is indicated by the production durability data. For the purpose of this paragraph, a nonconformity is determined to exist if:

(*1*) Any emission data vehicle within an engine family of the model year most recently certified under the production AMA Durability Program is projected to exceed an emission standard by applying deterioration factors generated by a production durability data vehicle within the same engine family; or

(*2*) Any of the most recent model year's production durability data vehicle configurations tested under paragraph (d)(8)(iv)(B) of this section line crosses as defined in § 86.094–28(a)(7)(ii)(C). For the purpose of this paragraph, data from identical vehicles will be averaged as under § 86.094–28(a)(4)(i) (A) and (B)

(D) If the Administrator notifies a manufacturer of such a nonconformity, the manufacturer shall submit, by a date specified by the Administrator, a plan to remedy the nonconformity which is acceptable to the Director, Office of Mobile Sources. For the purpose of this paragraph, the term "remedy the nonconformity" will have the same meaning as it does when it appears in section 207(c)(1) of the Clean Air Act (42 U.S.C. 7541(c)(1)).

(E) The manufacturer shall comply with the terms of the remedial plan approved by the Director, Office of Mobile Sources.

(F) If a manufacturer does not comply with the requirements of paragraph (d)(8)(iv) (B), (D), or (E) of this section, the Administrator may deem the certificate of conformity for the affected engine families void ab initio.

(e) *Alternative Service Accumulation Durability Program*—(1) *Applicability.* The Alternative Service Accumulation Durability Program is applicable to light-duty vehicles and light-duty trucks in model years 1994, 1995, and 1996.

(2) *Service accumulation method.* (i) The manufacturer shall propose a service accumulation method for the Alternative Service Accumulation Durability Program, for advance approval by the Administrator. The

method shall be consistent with good engineering practice and be designed to accurately predict the deterioration of the vehicle's emissions in actual use over its full useful life.

(ii) Manufacturers may propose service accumulation methods based upon whole-vehicle mileage accumulation, bench aging of individual components or systems, or a combination of the two approaches. Bench procedures should simulate the aging of components or systems over the applicable durability useful life as defined in § 86.094–2 and should simulate cycles and environments found in actual use. For this purpose, manufacturers may remove the emission-related components, in whole or in part, from the durability vehicle itself and deteriorate them independently. Vehicle testing for the purpose of determining deterioration factors may include the testing of durability vehicles that incorporate such bench-aged components.

(iii) Service accumulation shall be according to the method approved in advance by the Administrator.

(3) *Vehicle/component selection method.* The manufacturer shall propose a vehicle/component selection method for the Alternative Service Accumulation Durability Program for advance approval by the Administrator. The vehicle/component selection shall be according to the method approved in advance by the Administrator. The selection of durability data vehicles and components is also governed by § 86.091–7(a)(2)(i)(A), which generally requires that vehicles and components used for certification must be representative of production vehicles and components.

(4) *Durability data vehicle compliance requirements.* The manufacturer shall propose procedures for the calculation of deterioration factors and for the determination of vehicle compliance for advance approval by the Administrator. The Administrator may approve the use of such procedures if the manufacturer demonstrates that the resulting deterioration factors are likely to be representative of the in-use performance of the vehicles. The calculation of deterioration factors and the determination of vehicle compliance shall be according to the procedures approved in advance by the Administrator.

(5) *In-use verification.* Manufacturers selecting the Alternative Service Accumulation Durability Program shall agree to perform an in-use verification program, which shall include testing on in-use vehicles certified under the program in the years subsequent to certification. The purpose of the in-use verification program is to confirm the adequacy of the manufacturer-designed components of the Alternative Service Accumulation Durability program. The manufacturer shall propose sample sizes, recruitment procedures, testing procedures, optional provisions for the cessation of testing in the event the in-use testing confirms the adequacy of elements of the Alternative Service Accumulation Durability Program, and remedies in the event the in-use testing fails to confirm the adequacy of elements of the Alternative Service Accumulation Durability program. These and other elements of in-use verification are subject to advance approval by the Administrator.

(6) *Optional element: Carryover and carryacross.* Manufacturers selecting the Alternative Service Accumulation Durability Program may petition the Administrator for the conditional use of carryover or carryacross mileage accumulation data according to the provisions of § 86.094–24(f). If use of carryover or carryacross data is approved, deterioration factors are determined by the method described in paragraph (e)(4) of this section.

(7) *Data reporting requirements.* (i) Data reporting requirements for the Alternative Service Accumulation Durability Program are contained in §§ 86.094–21, 86.094–23(b)(1)(i), and 86.094–26(a)(6)(ii) and (a)(7).

(ii) In addition to the reporting of deterioration factors determined under paragraph (e)(4) of this section, the manufacturer shall provide reliability data that shows to the Administrator's satisfaction that all emission-related components are designed to operate properly for the durability useful life of the vehicles in actual use (or such shorter intervals as permitted in section § 86.094–25).

(8) *Additional requirements.* (i) The manufacturer shall consolidate the approved versions for each of the required elements of the Alternative Service Accumulation Durability Program into a written agreement that documents the details of the program and the manufacturer's responsibilities. The manufacturer shall submit this agreement for approval by the Administrator as part of the application for certification.

(ii) The manufacturer may amend the written agreement entered into pursuant to paragraph (e)(8)(i) of this section so long as the manufacturer demonstrates to the satisfaction of the Administrator that the proposed amendments to the agreement improve upon the in-use verification portion of the existing agreement. Such amendment to the Alternative Service Accumulation Durability Program agreement is subject to the prior approval of the Administrator.

(iii) The certification requirements described in § 86.094–30(a)(14) are applicable.

(f) *Standard Self-Approval Durability Program*—(1) *Applicability.* The Standard Self-Approval Durability Program is applicable to light-duty trucks in the 1994, 1995, and 1996 model years.

(2) *Service accumulation method.* The manufacturer shall determine the form and extent of service accumulation used in the Standard Self-Approval Durability Program, according to the provisions of § 86.094–26(b)(2). The method shall be consistent with good engineering practice and be designed to evaluate the mechanisms that are expected to cause deterioration of the vehicle's emissions over its full useful life.

(3) *Vehicle/component selection method.* The manufacturer shall determine the vehicle/component selection method for use in the Standard Self-Approval Durability Program according to the provisions of § 86.094–24(c)(2). Manufacturers shall select the vehicles, engines, subsystems, or components for each engine-system so that their emissions deterioration characteristics may be expected to represent those of in-use vehicles, based on good engineering judgment. The selection of durability data vehicles or components is also governed by § 86.091–7(a)(2)(A), which generally requires that vehicles and components used for certification must be representative of production vehicles and components.

(4) *Durability data vehicle compliance requirements.* Durability data vehicle compliance requirements for the Standard Self-approval Durability Program are contained in § 86.094–28(b). These include the method of calculating deterioration factors and related requirements.

(5) *In-use verification.* The Standard Self-Approval Durability Program includes no requirement for manufacturer testing of in-use vehicles subsequent to certification.

(6) *Data reporting requirements.* Data reporting requirements for the Standard Self-Approval Durability Program are contained in § 86.094–21, § 86.094–23(b)(1)(ii), and § 86.094–26(d).

(7) *Additional requirement.* The Administrator does not approve the test procedures for establishing exhaust emission deterioration factors. The manufacturer shall submit these

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procedures and determinations as required in § 86.094–21(b)(5)(i)(A).

(g) *Assigned deterioration factor durability program*—(1) *Applicability*—(i) *Small volume manufacturers.* The Assigned Deterioration Factor Durability Program is applicable to light-duty vehicles and light-duty trucks certified under the small volume manufacturer provisions of §§ 86.094–1(e) and 86.094–14(b).

(ii) *Small volume engine families.* The Assigned Deterioration Factor Durability Program is available to light-duty vehicles and light-duty trucks certified under the small volume engine family provisions of § 86.094–24(e)(2).

(2) *Determination of deterioration factors.* No service accumulation method or vehicle/component selection method is required. Deterioration factors are proposed by the manufacturer or assigned by the Administrator based on the provisions of § 86.094–14(c)(7)(i)(C).

(3) *In-use verification.* The Assigned Deterioration Factor Durability Program includes no requirement for manufacturer testing of in-use vehicles subsequent to certification.

(4) *Data reporting requirements.* Data reporting requirements for the Assigned Deterioration Factor Durability Program are contained in § 86.094–14 (c)(4), (c)(6), and (c)(11)(ii).

5. Section 86.094–14 is added to read as follows:

§ 86.094–14 Small-volume manufacturers certification procedures.

(a) The small-volume manufacturers certification procedures described in paragraphs (b) and (c) of this section are optional. Small-volume manufacturers may use these optional procedures to demonstrate compliance with the general standards and specific emission requirements contained in this subpart.

(b)(1) The optional small-volume manufacturers certification procedures apply to light-duty vehicles, light-duty trucks, heavy-duty vehicles, and heavy-duty engines produced by manufacturers with U.S. sales, including all vehicles and engines imported under the provisions of §§ 85.1505 and 85.1509 of this chapter (for the model year in which certification is sought) of fewer than 10,000 units (Light-Duty Vehicles, Light-Duty Trucks, Heavy-Duty Vehicles and Heavy-Duty Engines combined).

(2) For the purpose of determining the applicability of paragraph (b)(1) of this section, the sales the Administrator shall use shall be the aggregate of the projected or actual sales of those vehicles and/or engines in any of these groupings:

(i) Vehicles and/or engines produced by two or more firms, one of which is 10 percent or greater part owned by another;

(ii) Vehicles and/or engines produced by any two or more firms if a third party has equity ownership of 10 percent or more in each of the firms;

(iii) Vehicles and/or engines produced by two or more firms having a common corporate officer(s) who is (are) responsible for the overall direction of the companies;

(iv) Vehicles and/or engines imported or distributed by all firms where the vehicles and/or engines are manufactured by the same entity and the importer or distributor is an authorized agent of the entity.

(3) If the aggregated sales, as determined in paragraph (b)(2) of this section are less than 301 units, the manufacturers in the aggregated relationship may certify under the provisions in this section that apply to manufacturers with sales of less than 301 units.

(4) If the aggregated sales, as determined in paragraph (b)(2) of this section are greater than 300 but fewer than 10,000 units, the manufacturers in the aggregated relationship may certify under the provisions in this section that apply to manufacturers with sales from and including 301 through 9,999 motor vehicles and motor vehicles engines per year.

(5) If the aggregated sales, as determined in paragraph (b)(2) of this section are equal to or greater than 10,000 units, then the manufacturers involved in the aggregated relationship will be allowed to certify a number of units under the small-volume engine family certification procedures (reference § 86.094–24(e)) in accordance with the criteria identified in paragraphs (b)(5) (i) through (iii) of this section.

(i) If a manufacturer purchases less than 50 percent of another manufacturer, each manufacturer retains its right to certify 9,999 units using the small-volume engine family certification procedures.

(ii) If a manufacturer purchases 50 percent or more of another manufacturer, the manufacturer with the over 50 percent interest must share, with the manufacturer it purchased, its 9,999 units under the small-volume engine family certification procedures.

(iii) In a joint venture arrangement (50/50 ownership) between two manufacturers, each manufacturer retains its eligibility for 9,999 units under the small-volume engine family certification procedures, but the joint venture must draw its maximum 9,999 units from the units allocated to its parent manufacturers.

(c) Small-volume manufacturers shall demonstrate compliance with the applicable sections of this subpart. The appropriate model year of the applicable sections detailed in paragraphs (c) (1) through (15) of this section shall be determined in accordance with § 86.084–4.

(1) Sections 86.094–1, 86.094–2, 86.094–3, 86.084–4, 86.090–5, 86.078–6, 86.094–7, 86.094–8, 86.094–9, and 86.094–11 are applicable.

(2) Section 86.080–12 is not applicable.

(3) Sections 86.094–13, 86.094–14, 86.084–15, and 86.085–20 are applicable.

(4) Small-volume manufacturers shall include in their records all of the information that EPA requires in § 86.094–21. This information will be considered part of the manufacturer's application for certification. However, the manufacturer is not required to submit the information to the Administrator unless the Administrator requests it.

(5) Section 86.094–22 is applicable except as noted in paragraph (c)(5)(i) of this section.

(i) Small-volume light-duty vehicle and light-duty truck manufacturers may satisfy the requirements of § 86.094–22(e) by including a statement of compliance on adjustable parameters in the application for certification. In the statement of compliance the manufacturer shall state that the limits, stops, seals, or other means used to inhibit adjustment have been designed to accomplish their intended purpose based on good engineering practice and past experience. If the vehicle parameter is adjustable the vehicle must meet emission standards with the parameter set any place within the adjustable range (reference § 86.094–21).

(ii) [Reserved]

(6) Section 86.094–23 is applicable.

(7) Section 86.094–24 is applicable except as noted in paragraphs (c)(7) (i) through (ii) of this section.

(i) Small-volume manufacturers may satisfy the requirements of § 86.094–24 (b) and (c) in accordance with paragraphs (c)(7)(i) (A) through (C) of this section.

(A) *Emission data.* Selecting one emission data test vehicle (engine) per engine family by the worst-case emissions criteria in accordance with paragraph (c)(7)(i)(A) (*1*), (*2*), or (*3*) of this section.

(*1*) *Light-duty vehicles and light-duty trucks.* The manufacturer shall select the vehicle with the heaviest equivalent test weight (including options) within

the engine family. Then within that vehicle the manufacturer shall select, in the order listed, the highest road load power, largest displacement, the transmission with the highest numerical final gear ratio (including overdrive), the highest numerical axle ratio offered in the engine family, and the maximum fuel flow calibration.

(*2*) *Heavy-duty Otto-cycle engines.* The manufacturer shall select one emission data engine first based on the largest displacement within the engine family. Then within the largest displacement the manufacturer shall select, in the order listed, highest fuel flow at the speed of maximum rated torque, the engine with the most advanced spark timing, no EGR or lowest EGR flow, and no air pump or lowest actual flow air pump.

(*3*) *Heavy-duty diesel engines.* The manufacturer shall select one emission data engine based on the highest fuel feed per stroke, primarily at the speed of maximum rated torque and secondarily at rated speed.

(B) Testing light-duty vehicles or light-duty truck emission data vehicles at any service accumulation distance of at least 2,000 miles (3,219 kilometers) or, catalyst equipped heavy-duty emission data engines at any service accumulation time of at least 62 hours, or non-catalyst equipped heavy-duty engine emission data engines at any service accumulation time determined by the manufacturer to result in stabilized emissions. The emission performance of the emission data vehicle or engine must be stabilized prior to emission testing.

(C) *Durability data.* Satisfying the durability data requirements by complying with the applicable procedures described in paragraphs (c)(7)(i)(C)(*1*) through (*4*) of this section.

(*1*) Manufacturers with aggregated sales of less than 301 motor vehicles and motor vehicle engines per year may use assigned deterioration factors that the Administrator determines and prescribes. The factors will be the Administrator's estimate, periodically updated and published in an advisory letter or advisory circular, of the 70th percentile deterioration factors calculated using the industry-wide data base of previously completed durability data vehicles or engines used for certification. However, the manufacturer may, at its option, accumulate miles (hours) on a durability data vehicle (engine) and complete emission tests for the purpose of establishing its own deterioration factors.

(*2*)(*i*) Manufacturers with aggregated sales from and including 301 through 9,999 motor vehicles and motor vehicle engines per year certifying light-duty vehicle exhaust emissions from vehicles equipped with proven emission control systems shall use assigned deterioration factors that the manufacturer determines based on its good engineering judgment. However, the manufacturer may not use deterioration factors less than either the average or 70th percentile of all of that manufacturer's deterioration factor data, whichever is less. These minimum deterioration factors shall be calculated according to procedures in paragraph (c)(7)(i)(C)(*2*)(*ii*), of this section. If the manufacturer does not have at least two data points to calculate these manufacturer specific average deterioration factors, then the deterioration factors shall be no less than the EPA supplied industry-wide deterioration factors. However, the manufacturer may, at its option, accumulate miles on a durability data vehicle and complete emission tests for the purpose of establishing its own deterioration factors.

(*ii*) The manufacturer's minimum deterioration factors shall be calculated using the deterioration factors from all engine families, within the same vehicle/engine-fuel usage category (e.g., gasoline-fueled light-duty vehicle, etc.) previously certified to the same emission standards. The manufacturer shall use only deterioration factors from engine families previously certified by the manufacturer and the deterioration factors shall not be included in the calculation more than once. The deterioration factors for each pollutant shall be calculated separately. The manufacturer may, at its option, limit the deterioration factors used in the calculation of the manufacturer's minimum deterioration factors to those from all similar systems to the system being certified if sufficient data (i.e., from at least two certified systems) exists. All data eligible to be grouped as similar system data shall be used in calculating similar system deterioration factors. Any deterioration factors used in calculating similar system deterioration factors shall not be included in calculating the manufacturer's minimum deterioration factors used to certify any of the manufacturer's remaining vehicle systems.

(*3*) Manufacturers with aggregated sales from 301 through 9,999 motor vehicles and motor vehicle engines and certifying light-duty vehicle exhaust emissions from vehicles equipped with unproven emission control systems shall use deterioration factors that the manufacturer determines from official certification durability data generated by vehicles from engine families representing a minimum of 25 percent of the manufacturer's sales equipped with unproven emission control systems. The sales projections are to be based on total sales projected for each engine/system combination. The durability programs applicable to such manufacturers for this purpose shall be the Standard AMA, the Production AMA and the Alternative Service Accumulation Durability Programs of § 86.094–13. The durability data vehicle (engine) mileage accumulation and emission tests are to be conducted in accordance with § 86.094–13. The manufacturer must develop deterioration factors by generating durability data in accordance with § 86.094–13 on a minimum of 25 percent of the manufacturer's projected sales (by engine/system combination) that is equipped with unproven emission control systems. The manufacturer must complete the 25 percent durability requirement before the remainder of the manufacturer's sales equipped with unproven emission control systems is certified using manufacturer-determined assigned deterioration factors. Alternatively, any of these manufacturers may, at their option, accumulate miles on durability data vehicles and complete emission tests for the purpose of establishing their own deterioration factors on the remaining sales.

(*4*) For light-duty vehicle, light-duty truck, and heavy-duty vehicle evaporative emissions and for light-duty truck, and heavy-duty engine exhaust emissions, deterioration factors shall be determined in accordance with § 86.094–24.

(ii) Section 86.094–24(d) and (e) are not applicable.

(8) Section 86.094–25 is applicable to maintenance performed on durability data light-duty vehicles, light-duty trucks, heavy-duty vehicles, and heavy-duty engines when the manufacturer completes durability data vehicles or engines; § 86.087–38 is applicable to the recommended maintenance the manufacturer includes in the maintenance instructions furnished the purchasers of new motor vehicles and new motor vehicle engines under § 86.087–38.

(9)(i) Section 86.094–26 is applicable if the manufacturer completes durability data vehicles or engines.

(ii) Section 86.090–27 is applicable.

(10) Sections 86.094–28 and 86.091–29 are applicable.

(11)(i) Section 86.094–30 is applicable, except for § 86.094–30 (a)(2) and (b). In the place of § 86.094–30 (a)(2) and (b), small-volume manufacturers shall comply with

paragraphs (c)(11) (ii) through (v) of this section.

(ii) Small-volume manufacturers shall submit an application for certification containing the elements contained in paragraphs (c)(11)(ii) (A) through (E) of this section.

(A) The names, addresses, and telephone numbers of the persons the manufacturer authorizes to communicate with us.

(B) A brief description of the vehicles (or engines) covered by the certificate (the manufacturers' sales data book or advertising, including specifications, may satisfy this requirement for most manufacturers). The description shall include, as a minimum, the items listed in paragraphs (c)(11)(ii)(B)(*1*) through (*18*) of this section as applicable.

(*1*) Engine evaporative family names and vehicle (or engine) configurations.

(*2*) Vehicle carlines or engine models to be listed on the certificate of conformity.

(*3*) The test weight and horsepower setting for each vehicle or engine configuration.

(*4*) Projected sales.

(*5*) Combustion cycle.

(*6*) Cooling mechanism.

(*7*) Number of cylinders.

(*8*) Displacement.

(*9*) Fuel system type.

(*10*) Number of catalytic converters, type, volume, composition, surface area, and total precious metal loading.

(*11*) Method of air aspiration.

(*12*) Thermal reactor characteristics.

(*13*) Suppliers' and/or manufacturers' name and model number of any emission related items of the above, if purchased from a supplier who uses the items in its own certified vehicles(s) or engine(s).

(*14*) A list of emission component part numbers.

(*15*) Drawings, calibration curves, and descriptions of emission related components, including those components regulated under § 86.085–22(e), and schematics of hoses and other devices connecting these components.

(*16*) Vehicle adjustments or modifications necessary for light-duty trucks to assure that they conform to high-altitude standards.

(*17*) A description of the light-duty vehicles and light-duty trucks which are exempted from the high-altitude emission standards.

(*18*) Proof that the manufacturer has obtained or entered an agreement to purchase, when applicable, the insurance policy, required by § 85.1510(b) of this chapter. The manufacturer may submit a copy of the insurance policy or purchase agreement as proof that the manufacturer has obtained or entered an agreement to purchase the insurance policy.

(C) The results of all emission tests the manufacturer performs to demonstrate compliance with the applicable standards.

(D)(*1*) The following statement signed by the authorized representative of the manufacturer: "The vehicles (or engines) described herein have been tested in accordance with (list of the applicable subparts A, B, D, I, M, N, or P) of part 86, title 40, Code of Federal Regulations, and on the basis of those tests are in conformance with that subpart. All of the data and records required by that subpart are on file and are available for inspection by the EPA Administrator. We project the total U.S. sales of vehicles (engines) subject to this subpart (including all vehicles and engines imported under the provisions of §§ 85.1505 and 85.1509 of this chapter to be fewer than 10,000 units."

(*2*) A statement as required by and contained in paragraph (c)(5) of this section signed by the authorized representative of the manufacturer.

(*3*) A statement that the vehicles or engines described in the manufacturer's application for certification are not equipped with auxiliary emission control devices which can be classified as a defeat device as defined in § 86.094–2.

(*4*) A statement of compliance with section 206(a)(3) of the Clean Air Act (42 U.S.C. 7525(a)(3)).

(*5*) A statement that, based on the manufacturer's engineering evaluation and/or emission testing, the light-duty vehicles comply with emission standards at high altitude unless exempt under § 86.094–8(h).

(*6*) A statement that, based on the manufacturer's engineering evaluation and/or emission testing, the light-duty trucks sold for principle use at designated high-altitude locations comply with the high-altitude emission requirements and that all other light-duty trucks are at least capable of being modified to meet high-altitude standards unless exempt under § 86.094–9(g)(2).

(*7*) A statement affirming that the manufacturer will provide a list of emission and emission-related service parts, including part number designations and sources of parts, to the vehicle purchaser for all emission and emission-related parts which might affect vehicle emission performance throughout the useful life of the vehicle. Secondly, it must state that qualified service facilities and emission-related repair parts will be conveniently available to serve its vehicles. In addition, if service facilities are not available at the point of sale or distribution, the manufacturer must indicate that the vehicle purchaser will be provided information identifying the closest authorized service facility to the point of sale, if in the United States, or the closest authorized service facility to the point of distribution to the ultimate purchaser if the vehicle was purchased outside of the United States by the ultimate purchaser. Such information should also be made available to the Administrator upon request.

(E) Manufacturers utilizing deterioration factors determined by the manufacturer based on its good engineering judgment (reference paragraph (c)(*7*)(i)(C)(*2*) of this section) shall provide a description of the method(s) used by the manufacturer to determine the deterioration factors.

(iii) If the manufacturer meets the requirements of this subpart, the Administrator will issue a certificate of conformity for the vehicles or engines described in the application for certification.

(iv) The certificate will be issued for such a period not to exceed one model year as the Administrator may determine and upon such terms as he may deem necessary to assure that any vehicle or engine covered by the certificate will meet the requirements of the Act and of this subpart.

(v)(A) If, after a review of the statements and descriptions submitted by the manufacturer, the Administrator determines that the manufacturer has not met the applicable requirements, the Administrator shall notify the manufacturer in writing of his intention to deny certification, setting forth the basis for his determination. The manufacturer may request a hearing on the Administrator's determination.

(B) If the manufacturer does not request a hearing or present the required information, the Administrator will deny certification.

(12) Sections 86.079–31 and 86.079–32 are not applicable.

(13) Under § 86.079–33, small-volume manufacturers are covered by paragraphs (c)(13) (i) and (ii) of this section.

(i) Small-volume manufacturers may make production changes (running changes) without receiving the Administrator's prior approval. The manufacturer shall assure (by conducting emission tests as it deems necessary) that the affected vehicles (engines) remain in compliance with the requirements of this part.

(ii) The manufacturer shall notify the Administrator within seven days after implementing any production related change (running change) that would

affect vehicle emissions. This notification shall include any changes to the information required under paragraph (c)(11)(ii) of this section. The manufacturer shall also amend as necessary its records required under paragraph (c)(4) of this section to confirm with the production design change.

(14) Section 86.082–34 is not applicable.

(15) Sections 86.094–35, 86.079–36, 86.085–37, 86.087–38 and 86.079–39 are applicable.

(Approved by the Office of Management and Budget under control number 2060–0104)

6. Section 86.094–21 is revised to read as follows:

§ 86.094–21 Application for certification.

(a) A separate application for a certificate of conformity shall be made for each set of standards (or family emission limits, as appropriate) and each class of new motor vehicles or new motor vehicle engines. Such application shall be made to the Administrator by the manufacturer and shall be updated and corrected by amendment.

(b) The application shall be in writing, signed by an authorized representative of the manufacturer, and shall include the following:

(1)(i) Identification and description of the vehicles (or engines) covered by the application and a description of their engine (vehicles only), emission control system, and fuel system components. This description will include:

(A) A detailed description of each Auxiliary Emission Control Device (AECD) to be installed in or on any vehicle (or engine) covered by the application;

(B) A detailed justification of each AECD (described in (b)(1)(i)(A) of this section) which results in a reduction in effectiveness of the emission control system. Such a justification may be disapproved by consideration of currently available technology, whereupon the application for certification may be disapproved under § 86.094–22(b) for the incorporation of a defeat device;

(C) The manufacturer must submit a Statement of Compliance in the application for certification which attests to the fact that they have assured themselves that the engine family is designed to be within the intermediate temperature cold testing defeat device guidance as described in § 86.094–16.

(1) This Statement of Compliance will be supported by a brief description of the vehicle's technological method of controlling CO emissions at intermediate temperatures.

(2) The manufacturer will determine a method (e.g., a test program, an engineering evaluation) which is adequate to support their Statement of Compliance. The manufacturer will support this Statement with a brief summary of the chosen method. Further details must be made available upon the Administrator's request.

(ii)(A) The manufacturer shall provide to the Administrator in the application for certification:

(1) A list of those parameters which are physically capable of being adjusted (including those adjustable parameters for which access is difficult) and that, if adjusted to settings other than the manufacturer's recommended setting, may affect emissions;

(2) A specification of the manufacturer's intended physically adjustable range of each such parameter, and the production tolerances of the limits or stops used to establish the physically adjustable range;

(3) A description of the limits or stops used to establish the manufacturer's intended physically adjustable range of each adjustable parameter, or any other means used to inhibit adjustment;

(4) The nominal or recommended setting, and the associated production tolerances, for each such parameter.

(B) The manufacturer may provide, in the application for certification, information relating to why certain parameters are not expected to be adjusted in actual use and to why the physical limits or stops used to establish the physically adjustable range of each parameter, or any other means used to inhibit adjustment, are effective in preventing adjustment of parameters on in-use vehicles to settings outside the manufacturer's intended physically adjustable ranges. This may include results of any tests to determine the difficulty of gaining access to an adjustment or exceeding a limit as intended or recommended by the manufacturer.

(C) The Administrator may require to be provided detailed drawings and descriptions of the various emission related components, and/or hardware samples of such components, for the purpose of making his determination of which vehicle or engine parameter will be subject to adjustment for new certification and Selective Enforcement Audit testing and of the physically adjustable range for each such vehicle or engine parameter.

(2) Projected U.S. sales data sufficient to enable the Administrator to select a test fleet representative of the vehicles (or engines) for which certification is requested, and, for model year 1994 through 1995 light-duty vehicles and light light-duty trucks and model year 1996 heavy light-duty trucks, data sufficient to determine projected compliance with the Tier 1 standards implementation schedules of §§ 86.094–8 and 86.094–9. The data shall also include the altitude of intended sale for model year 1994 light-duty trucks certified to the Tier 0 standards of § 86.094–9. Volume projected to be produced for U.S. sale may be used in lieu of projected U.S. sales.

(3) A description of the test equipment and fuel proposed to be used.

(4)(i) For light-duty vehicles and light-duty trucks, a description of the test procedures to be used to establish the evaporative emission deterioration factors required to be determined and supplied in § 86.094–23(b)(2).

(ii) For heavy-duty vehicles equipped with gasoline-fueled or methanol-fueled engines, the Administrator does not assume that each evaporative emission family-evaporative emission control system combination will deteriorate in a unique manner during the useful life of the vehicle. The manufacturer shall therefore identify those evaporative emission deterioration factors which shall be applied to the various evaporative emission family-evaporative emission control system combinations which are expected to exhibit similar deterioration characteristics during the useful life of the vehicle.

(5)(i)(A) A description of the test procedures to be used to establish the durability data or the exhaust emission deterioration factors required to be determined and supplied in § 86.094–23(b)(1).

(B) For each light-duty truck engine family provided an optional useful life period under the provisions of paragraph (f) of this section, and for each heavy-duty engine family, a statement of the useful life.

(C) For engine families provided an alternative useful-life period under paragraph (f) of this section, a statement of that alternative period and a brief synopsis of the justification.

(ii) For heavy-duty diesel engine families, a statement of the primary intended service class (light, medium, or heavy) and an explanation as to why that service class was selected. Each diesel engine family shall be certified under one primary intended service class only. After reviewing the guidance in § 86.090–2, the class shall be determined on the basis of which class best represents the majority of the sales of that engine family.

(iii)(A) For each light-duty vehicle engine family, each light-duty truck engine family, and each heavy-duty

engine family, a statement of recommended maintenance and procedures necessary to assure that the vehicles (or engines) covered by a certificate of conformity in operation conform to the regulations, and a description of the program for training of personnel for such maintenance, and the equipment required.

(B) A description of vehicle adjustments or modifications necessary, if any, to assure that light-duty vehicles and light-duty trucks covered by a certificate of conformity conform to the regulations while being operated at any altitude locations, and a statement of the altitude at which the adjustments or modifications apply.

(iv) At the option of the manufacturer, the proposed composition of the emission data test fleet or (where applicable) the durability data test fleet.

(6) *Participation in averaging programs*—(i) *Particulate averaging.* (A) If the manufacturer elects to participate in the particulate averaging program for diesel light-duty vehicles and/or diesel light-duty trucks or the particulate averaging program for heavy-duty diesel engines, the application must list the family particulate emission limit and the projected U.S. production volume of the family for the model year.

(B) The manufacturer shall choose the level of the family particulate emission limits, accurate to hundredth of a gram per mile or hundredth of a gram per brake horsepowerhour for heavy-duty engines.

(C) The manufacturer may at any time during production elect to change the level of any family particulate emission limit(s) by submitting the new limit(s) to the Administrator and by demonstrating compliance with the limit(s) as described in §§ 86.090–2 and 86.094–28(b)(5)(i).

(ii) *NO_x averaging.* (A) If the manufacturer elects to participate in the NO_x averaging program for light-duty trucks or the NO_x averaging program for heavy-duty engines, the application must list the family NO_x emission limit and the projected U.S. production volume of the family for the model year.

(B) The manufacturer shall choose the level of the family NO_x emission limits, accurate to one-tenth of a gram per mile or to one-tenth of a gram per brake horsepower-hour for heavy-duty engines.

(C) The manufacturer may at any time during production elect to change the level of any family NO_x emission limit(s) by submitting the new limits to the Administrator and by demonstrating compliance with the limit(s) as described in §§ 86.088–2 and 86.094–28(b)(5)(ii).

(7)(i) For Otto-cycle heavy-duty engines, the application must state whether the engine family is being certified for use in all vehicles regardless of their Gross Vehicle Weight Rating (see § 86.091–10 (a)(1)(i) and (a)(3)(i)), or only for use in vehicles with a Gross Vehicle Weight Rating greater than 14,000 pounds.

(ii) If the engine family is being certified for use in all vehicles and is being certified to the emission standards applicable to Otto-cycle engines for use only in vehicles with a Gross Vehicle Weight Rating over 14,000 pounds under the provisions of § 86.091–10(a)(3), then the application must also attest that the engine family, together with all other engine families being certified under the provisions of § 86.091–10(a)(3), represent no more than 5 percent of model year sales of the manufacturer of all Otto-cycle heavy-duty engines for use in vehicles with Gross Vehicle Weight Ratings of up to 14,000 pounds.

(8) For each light-duty vehicle or light-duty truck engine family, the exhaust emission standards (or family emission limits, if applicable) to which the engine family is to be certified, and the corresponding exhaust emission standards (or family emission limits, if applicable) which the engine family must meet in-use.

(c) Complete copies of the application and of any amendments thereto, and all notifications under §§ 86.079–32, 86.079–33, and 86.082–34 shall be submitted in such multiple copies as the Administrator may require.

(d) Incomplete light-duty trucks shall have a maximum completed curb weight and maximum completed frontal area specified by the manufacturer.

(e) For vehicles equipped with gasoline-fueled or methanol-fueled heavy-duty engines, the manufacturer shall specify a maximum nominal fuel tank capacity for each evaporative emission family-evaporative emission control system combination.

(f) Light-duty truck and heavy-duty engine manufacturers who believe that the useful life periods of § 86.094–2 are significantly unrepresentative for one or more engine families (either too long or too short), may petition the Administrator to provide an alternative useful-life period. This petition must include the full rationale behind the request together with any supporting data and other evidence. Based on this or other information the Administrator may assign an alternative useful-life period. Any petition should be submitted in a timely manner, to allow adequate time for a thorough evaluation. For model year 1994 and later light-duty trucks not subject to the Tier 0 standards of § 86.094–9, alternative useful life periods will be granted only for THC, OMHCE, and idle CO requirements.

(g) The manufacturer shall identify those families which will not comply with cold temperature carbon monoxide standards.

(Approved by the Office of Management and Budget under control number 2060–0104)

7. Section 86.094–22 is revised to read as follows:

§ 86.094–22 Approval of application for certification; test fleet selections; determinations of parameters subject to adjustment for certification and Selective Enforcement Audit, adequacy of limits, and physically adjustable ranges.

(a) After a review of the application for certification and any other information which the Administrator may require, the Administrator may approve the application and select a test fleet in accordance with § 86.094–24.

(b) *Disapproval of application.* (1) The Administrator may disapprove in whole or in part an application for certification for reasons including incompleteness, inaccuracy, inappropriate proposed mileage (or service) accumulation procedures, test equipment, or fuel; or incorporation of defeat devices in vehicles (or on engines) described by the application.

(2) The issuance of a certificate of conformity does not exempt the covered vehicles from further evaluation or testing for defeat device purposes as described in § 86.094–16.

(c) Where any part of an application is rejected, the Administrator shall notify the manufacturer in writing and set forth the reasons for such rejection. Within 30 days following receipt of such notification, the manufacturer may request a hearing on the Administrator's determination. The request shall be in writing, signed by an authorized representative of the manufacturer and shall include a statement specifying the manufacturer's objections to the Administrator's determinations, and data in support of such objections. If, after the review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, he shall provide the manufacturer a hearing in accordance with § 86.078–6 with respect to such issue.

(d) *Approval of test procedures.* (1) The Administrator does not approve the test procedures for establishing the evaporative emission deterioration factors for light-duty vehicles and light-duty trucks. The manufacturer shall submit the procedures as required in

§ 86.094–21(b)(4)(i) prior to the Administrator's selection of the test fleet under § 86.094–24(b)(1), and if such procedures will involve testing of durability data vehicles selected by the Administrator or elected by the manufacturer under § 86.094–24(c)(1), prior to initiation of such testing.

(2) *Light-duty trucks using the Standard Self-Approval durability Program and heavy-duty engines only.* The Administrator does not approve the test procedures for establishing exhaust emission deterioration factors for light-duty trucks using the Standard Self-Approval Durability Program described in § 86.094–13(f) nor for heavy-duty engines. The manufacturer shall submit these procedures and determinations as required in § 86.094–21(b)(5)(i) prior to determining the deterioration factors.

(3) Heavy-duty vehicles equipped with gasoline-fueled or methanol-fueled engines only. The Administrator does not approve the test procedures for establishing the evaporative emission deterioration factors. The test procedure will conform to the requirements in § 86.094–23(b)(3).

(e) *Parameter adjustment requirements.* When the Administrator selects emission data vehicles for the test fleet, he will at the same time determine those vehicle or engine parameters which will be subject to adjustment for certification, Selective Enforcement Audit and Production Compliance Audit testing, the adequacy of the limits, stops, seals, or other means used to inhibit adjustment, and the resulting physically adjustable ranges for each such parameter and will then notify the manufacturer of his determinations.

(1) *Determining parameters subject to adjustment.* (i) Except as noted in paragraph (e)(1)(iv) of this section, the Administrator may determine to be subject to adjustment the idle fuel-air mixture parameter on Otto-cycle vehicles (or engines) (carbureted or fuel-injected); the choke valve action parameter(s) on carbureted, Otto-cycle vehicles (or engines); or any parameter on any vehicle (or engine) (Otto-cycle or diesel) which is physically capable of being adjusted, may significantly affect emissions, and was not present on the manufacturer's vehicles (or engines) in the previous model year in the same form and function.

(ii) The Administrator may, in addition, determine to be subject to adjustment any other parameters on any vehicle or engine which is physically capable of being adjusted and which may significantly affect emissions. However, the Administrator may do so only if he has previously notified the manufacturer that he might do so and has found, at the time he gave this notice, that the intervening period would be adequate to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period. In no event will this notification be given later than September 1 of the calendar year two years prior to the model year.

(iii) In determining the parameters subject to adjustment, the Administrator will consider the likelihood that, for each of the parameters listed in paragraphs (e)(1) (i) and (ii) of this section, settings other than the manufacturer's recommended setting will occur on in-use vehicles (or engines). In determining likelihood, the Administrator may consider such factors as, but not limited to, information contained in the preliminary application, surveillance information from similar in-use vehicles (or engines), the difficulty and cost of gaining access to an adjustment, damage to the vehicle (or engine) if an attempt is made to gain such access and the need to replace parts following such attempt, and the effect of settings other than the manufacturer's recommended setting on vehicle (or engine) performance characteristics including emission characteristics.

(iv) Manual chokes of heavy-duty engines only will not be considered a parameter subject to adjustment under the parameter adjustment requirements.

(2)(i) The Administrator shall determine a parameter to be adequately inaccessible or sealed if:

(A) In the case of an idle mixture screw, the screw is recessed within the carburetor casting and sealed with lead, thermosetting plastic, or an inverted elliptical spacer or sheared off after adjustment at the factory, and the inaccessibility is such that the screw cannot be accessed and/or adjusted with simple tools in one-half hour or for $20 (1978 dollars) or less;

(B) In the case of a choke bimetal spring, the plate covering the bimetal spring is riveted or welded in place, or held in place with nonreversible screws;

(C) In the case of a parameter which may be adjusted by elongating or bending adjustable members (e.g., the choke vacuum break), the elongation of the adjustable member is limited by design or, in the case of a bendable member, the member is constructed of a material which when bent would return to its original shape after the force is removed (plastic or spring steel materials);

(D) In the case of any parameter, the manufacturer demonstrates that adjusting the parameter to settings other than the manufacturer's recommended setting takes more than one-half hour or costs more than $20 (1978 dollars).

(ii) The Administrator shall determine a physical limit or stop to be an adequate restraint on adjustability if:

(A) In the case of a threaded adjustment, the threads are terminated, pinned, or crimped so as to prevent additional travel without breakage or need for repairs which take more than one-half hour or cost more than $20 (1978 dollars);

(B) The adjustment is ineffective at the end of the limits of travel regardless of additional forces or torques applied to the adjustment;

(C) The manufacturer demonstrates that travel or rotation limits cannot be exceeded with the use of simple and inexpensive tools (screwdriver, pliers, open-end or box wrenches, etc.) without incurring significant and costly damage to the vehicle (or engine) or control system or without taking more than one-half hour or costing more than $20 (1978 dollars).

(iii) If manufacturer service manuals or bulletins describe routine procedures for gaining access to a parameter or for removing or exceeding a physical limit, stop, seal or other means used to inhibit adjustment, or if surveillance data indicate that gaining access, removing, or exceeding is likely, paragraphs (e)(2)(i) and (ii) of this section shall not apply for that parameter.

(iv) In determining the adequacy of a physical limit, stop, seal, or other means used to inhibit adjustment of a parameter not covered by paragraph (e)(2)(i) or (ii) of this section, the Administrator will consider the likelihood that it will be circumvented, removed, or exceeded on in-use vehicles. In determining likelihood, the Administrator may consider such factors as, but not limited to, information contained in the preliminary application; surveillance information from similar in-use vehicles (or engines); the difficulty and cost of circumventing, removing, or exceeding the limit, stop, seal, or other means; damage to the vehicle (or engine) if an attempt is made to circumvent, remove, or exceed it and the need to replace parts following such attempt; and the effect of settings beyond the limit, stop, seal, or other means on vehicle (or engine) performance characteristics other than emission characteristics.

(3) The Administrator shall determine two physically adjustable ranges for each parameter subject to adjustment:

(i)(A) In the case of a parameter determined to be adequately inaccessible or sealed, the

Administrator may include within the physically adjustable range applicable to testing under this subpart (certification testing) all settings within the production tolerance associated with the nominal setting for that parameter, as specified by the manufacturer in the preliminary application for certification; or

(B) In the case of other parameters, the Administrator shall include within this range all settings within physical limits or stops determined to be adequate restraints on adjustability. The Administrator may also include the production tolerances on the location of these limits or stops when determining the physically adjustable range.

(ii)(A) In the case of a parameter determined to be adequately inaccessible or sealed, the Administrator shall include within the physically adjustable range applicable to testing under subparts G or K (Selective Enforcement Audit and Production Compliance Audit) only the actual settings to which the parameter is adjusted during production; or

(B) In the case of other parameters, the Administrator shall include within this range all settings within physical limits or stops determined to be adequate restraints on adjustability, as they are actually located on the test vehicle (or engine).

(f) *Submittal of advance information.* (1) If the manufacturer submits the information specified in § 86.094–21(b)(1)(ii) in advance of its full preliminary application for certification, the Administrator shall review the information and make the determinations required in paragraph (e) of this section within 90 days of the manufacturer's submittal.

(2) The 90-day decision period is exclusive of the elapsed time during which EPA may request additional information from manufacturers regarding an adjustable parameter and the receipt of the manufacturers' response(s).

(g) Within 30 days following receipt of notification of the Administrator's determinations made under paragraph (e) of this section, the manufacturer may request a hearing on the Administrator's determinations. The request shall be in writing, signed by an authorized representative of the manufacturer, and shall include a statement specifying the manufacturer's objections to the Administrator's determinations, and data in support of such objections. If, after review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, he shall provide the manufacturer a hearing in accordance with § 86.078–6 with respect to such issue.

8. Section 86.094–23 is revised to read as follows:

§ 86.094–23 Required data.

(a) The manufacturer shall perform the tests required by the applicable test procedures and submit to the Administrator the information described in paragraphs (b) through (l) of this section, provided, however, that if requested by the manufacturer, the Administrator may waive any requirement of this section for testing of vehicle (or engine) for which emission data are available or will be made available under the provisions of § 86.091–29.

(b) *Durability data.* (1)(i) The manufacturer shall submit exhaust emission durability data on such light-duty vehicles tested in accordance with applicable test procedures and in such numbers as specified, which will show the performance of the systems installed on or incorporated in the vehicle for extended mileage, as well as a record of all pertinent maintenance performed on the test vehicles.

(ii) The manufacturer shall submit exhaust emission deterioration factors for light-duty trucks and heavy-duty engines and all test data that are derived from the testing described under § 86.094–21(b)(5)(i)(A), as well as a record of all pertinent maintenance. Such testing shall be designed and conducted in accordance with good engineering practice to assure that the engines covered by a certificate issued under § 86.094–30 will meet each emission standard (or family emission limit, as appropriate) in § 86.094–8, § 86.091–10, or § 86.094–11 as appropriate, in actual use for the useful life applicable to that standard.

(2) For light-duty vehicles and light-duty trucks, the manufacturer shall submit evaporative emission deterioration factors for each evaporative emission family-evaporative emission control system combination and all test data that are derived from testing described under § 86.094–21(b)(4)(i) designed and conducted in accordance with good engineering practice to assure that the vehicles covered by a certificate issued under § 86.094–30 will meet the evaporative emission standards in § 86.094–8 or § 86.094–9, as appropriate, for the useful life of the vehicle.

(3) For heavy-duty vehicles equipped with gasoline-fueled or methanol-fueled engines, the manufacturer shall submit evaporative emission deterioration factors for each evaporative emission family-evaporative emission control system combination identified in accordance with § 86.094–21(b)(4)(ii). Furthermore, a statement that the test procedure(s) used to derive the deterioration factors includes, but need not be limited to, a consideration of the ambient effects of ozone and temperature fluctuations, and the service accumulation effects of vibration, time, and vapor saturation and purge cycling. The deterioration factor test procedure shall be designed and conducted in accordance with good engineering practice to assure that the vehicles covered by a certificate issued under § 86.094–30 will meet the evaporative emission standards in §§ 86.091–10 and 86.094–11 in actual use for the useful life of the engine. Furthermore, a statement that a description of the test procedure, as well as all data, analyses, and evaluations, is available to the Administrator upon request.

(4)(i) For heavy-duty vehicles with a Gross Vehicle Weight Rating of up to 26,000 lbs and equipped with gasoline-fueled or methanol-fueled engines, the manufacturer shall submit a written statement to the Administrator certifying that the manufacturer's vehicles meet the standards of § 86.091–10 or § 86.094–11 (as applicable) as determined by the provisions of § 86.094–28. Furthermore, the manufacturer shall submit a written statement to the Administrator that all data, analyses, test procedures, evaluations, and other documents, on which the requested statement is based, are available to the Administrator upon request.

(ii) For heavy-duty vehicles with a Gross Vehicle Weight Rating of greater than 26,000 lbs and equipped with gasoline-fueled or methanol-fueled engines, the manufacturer shall submit a written statement to the Administrator certifying that the manufacturer's evaporative emission control systems are designed, using good engineering practice, to meet the standards of § 86.091–10 or § 86.094–11 (as applicable) as determined by the provisions of § 86.094–28. Furthermore, the manufacturer shall submit a written statement to the Administrator that all data, analyses, test procedures, evaluations, and other documents, on which the requested statement is based, are available to the Administrator upon request.

(c) *Emission data*—(1) *Certification vehicles.* The manufacturer shall submit emission data, including, in the case of methanol fuel, methanol, formaldehyde, and organic material hydrocarbon equivalent, on such vehicles tested in accordance with applicable test

procedures and in such numbers as specified. These data shall include zero-mile data, if generated, and emission data generated for certification as required under § 86.094–26(a)(3) (i) or (ii). In lieu of providing emission data the Administrator may, on request of the manufacturer, allow the manufacturer to demonstrate (on the basis of previous emission tests, development tests, or other information) that the engine will conform with certain applicable emission standards of § 86.094–8 or § 86.094–9. Standards eligible for such manufacturer requests are those for idle CO emissions, smoke emissions, or particulate emissions from methanol-fueled diesel-cycle certification vehicles, and those for particulate emissions from model year 1994 and later gasoline-fueled or methanol-fueled Otto-cycle certification vehicles that are not certified to the Tier 0 standards of § 86.094–9(a)(1) (i), (ii), or § 86.094–8(a)(1)(i). Also eligible for such requests are standards for total hydrocarbon emissions from model year 1994 and later certification vehicles that are not certified to the Tier 0 standards of § 86.094–9(a)(1)(i), (ii), or § 86.094–8(a)(1)(i). By separate request, including appropriate supporting test data, the manufacturer may request that the Administrator also waive the requirement to measure particulate emissions when conducting Selective Enforcement Audit testing of Ottocycle vehicles.

(2) *Certification engines.* (i) The manufacturer shall submit emission data on such engines tested in accordance with applicable emission test procedures of this subpart and in such numbers as specified. These data shall include zero-hour data, if generated, and emission data generated for certification as required under § 86.094–26(c)(4). In lieu of providing emission data on idle CO emissions or particulate emissions from methanol-fueled diesel-cycle certification engines, or on CO emissions from petroleum-fueled or methanol-fueled diesel certification engines the Administrator may, on request of the manufacturer, allow the manufacturer to demonstrate (on the basis of previous emission tests, development tests, or other information) that the engine will conform with the applicable emission standards of § 86.094–11.

(ii) For heavy-duty diesel engines, a manufacturer may submit hot-start data only, in accordance with subpart N of this part, when making application for certification. However, for conformity Selective Enforcement Audit and recall testing by the Agency, both the cold-start and hot-start test data, as specified in subpart N of this part, will be included in the official results.

(d) The manufacturer shall submit a statement that the vehicles (or engines) for which certification is requested conform to the requirements in § 86.084–5(b), and that the descriptions of tests performed to ascertain compliance with the general standards in § 86.084–5(b), and that the data derived from such tests are available to the Administrator upon request.

(e)(1) The manufacturer shall submit a statement that the test vehicles (or test engines) for which data are submitted to demonstrate compliance with the applicable standards (or family emission limits, as appropriate) of this subpart are in all material respects as described in the manufacturer's application for certification, that they have been tested in accordance with the applicable test procedures utilizing the fuels and equipment described in the application for certification, and that on the basis of such tests the vehicles (or engines) conform to the requirements of this part. If such statements cannot be made with respect to any vehicle (or engine) tested, the vehicle (or engine) shall be identified, and all pertinent data relating thereto shall be supplied to the Administrator. If, on the basis of the data supplied and any additional data as required by the Administrator, the Administrator determines that the test vehicles (or test engine) was not as described in the application for certification or was not tested in accordance with the applicable test procedures utilizing the fuels and equipment as described in the application for certification, the Administrator may make the determination that the vehicle (or engine) does not meet the applicable standards (or family emission limits, as appropriate). The provisions of § 86.094–30(b) shall then be followed.

(2) For evaporative emission durability, or light-duty truck or heavy-duty engine exhaust emission durability, the manufacturer shall submit a statement of compliance with paragraph (b)(1)(ii), (b)(2), or (b)(3) of this section, as applicable.

(f) Additionally, manufacturers participating in the particulate averaging program for diesel light-duty vehicles and diesel light-duty trucks shall submit:

(1) In the application for certification, a statement that the vehicles for which certification is requested will not, to the best of the manufacturer's belief, when included in the manufacturer's production-weighted average emission level, cause the applicable particulate standard(s) to be exceeded; and

(2) No longer than 90 days after the end of a given model year of production of engine families included in one of the diesel particulate averaging programs, the number of vehicles produced in each engine family at each certified particulate FEL, along with the resulting production-weighted average particulate emission level.

(g) Additionally, manufacturers participating in the NO_x averaging program for light-duty trucks shall submit:

(1) In the application for certification, a statement that the vehicles for which certification is required will not, to the best of the manufacturer's belief, when included in the manufacturer's production-weighted average emission level, cause the applicable NO_x standard(s) to be exceeded; and

(2) No longer than 90 days after the end of a given model year of production of engine families included in the NO_x averaging program, the number of vehicles produced in each engine family at each certified NO_x emission level.

(h) Additionally, manufacturers participating in any of the NO_x and/or particulate averaging, trading, or banking programs for heavy-duty engines shall submit for each participating family the items listed in paragraphs (h)(1) through (3) of this section.

(1) *Application for certification.* (i) The application for certification will include a statement that the engines for which certification is requested will not, to the best of the manufacturer's belief, when included in any of the averaging, trading, or banking programs cause the applicable NO_x or particulate standard(s) to be exceeded.

(ii) The application for certification will also include the type (NO_x or particulate) and the projected number of credits generated/needed for this family, the applicable averaging set, the projected U.S. (49-state) production volumes, by quarter, NCPs in use on a similar family and the values required to calculate credits as given in § 86.094–15. Manufacturers shall also submit how and where credit surpluses are to be dispersed and how and through what means credit deficits are to be met, as explained in § 86.094–15. The application must project that each engine family will be in compliance with the applicable NO_x and/or particulate emission standards based on the engine mass emissions, and credits from averaging, trading and banking.

(2) [Reserved]

(3) *End-of-year report.* The manufacturer shall submit end-of-year reports for each engine family participating in any of the averaging,

trading, or banking programs, as described in paragraphs (h)(3) (i) through (iv) of this section.

(i) These reports shall be submitted within 90 days of the end of the model year to: Director, Manufacturers Operations Division (EN–340F), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

(ii) These reports shall indicate the engine family, the averaging set, the actual U.S. (49-state) production volume, the values required to calculate credits as given in § 86.094–15, the resulting type (NO_x or particulate) and number of credits generated/required, and the NCPs in use on a similar NCP family. Manufacturers shall also submit how and where credit surpluses were dispersed (or are to be banked) and how and through what means credit deficits were met. Copies of contracts related to credit trading must also be included or supplied by the broker if applicable. The report shall also include a calculation of credit balances to show that net mass emissions balances are within those allowed by the emission standards (equal to or greater than a zero credit balance). The credit discount factor described in § 86.094–15 must be included as required.

(iii) The 49-state production counts for end-of-year reports shall be based on the location of the first point of retail sale (e.g., customer, dealer, secondary manufacturer) by the manufacturer.

(iv) Errors discovered by EPA or the manufacturer in the end-of-year report, including errors in credit calculation, may be corrected up to 90 days subsequent to submission of the end-of-year report. Errors discovered by EPA after 90 days shall be corrected if credits are reduced. Errors in the manufacturer's favor will not be corrected if discovered after the 90 day correction period allowed.

(i) Failure by a manufacturer participating in the averaging, trading, or banking programs to submit any quarterly or end-of-year report (as applicable) in the specified time for all vehicles and engines that are part of an averaging set is a violation of section 203(a)(1) of the Clean Air Act (42 U.S.C. 7522(a)(1)) for each such vehicle and engine.

(j) Failure by a manufacturer generating credits for deposit only-in either the HDE NO_x or particulate banking programs to submit their end-of-year reports in the applicable specified time period (i.e., 90 days after the end of the model year) shall result in the credits not being available for use until such reports are received and reviewed by EPA. Use of projected credits pending EPA review will not be permitted in these circumstances.

(k) Engine families certified using NCPs are not required to meet the requirements outlined in paragraphs (f) through (j) of this section.

(l) Additionally, manufacturers certifying vehicles shall submit for each model year 1994 through 1997 light-duty vehicle and light light-duty truck engine family and each model year 1996 through 1998 heavy light-duty truck engine family the information listed in paragraphs (l) (1) and (2) of this section.

(1) *Application for certification.* In the application for certification, the manufacturer shall submit the projected sales volume of engine families certifying to the respective standards, and the in-use standards that each engine family will meet. Volume projected to be produced for U.S. sale may be used in lieu of projected U.S. sales.

(2) *End-of-year reports for each engine family.* (i) These end-of-year reports shall be submitted within 90 days of the end of the model year to: Director, Manufacturers Operations Division (EN–340F), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

(ii) These reports shall indicate the model year, engine family, and the actual U.S. sales volume. The manufacturer may petition the Administrator to allow volume produced for U.S.. sale to be used in lieu of U.S. sales. Such petition shall be submitted within 30 days of the end of the model year to the Manufacturers Operations Division. For the petition to be granted, the manufacturer must establish to the satisfaction of the Administrator that production volume is functionally equivalent to sales volume.

(iii) The U.S. sales volume for end-of-year reports shall be based on the location of the point of sale to a dealer, distributor, fleet operator, broker, or any other entity which comprises the point of first sale.

(iv) Failure by a manufacturer to submit the end-of-year report within the specified time may result in certificate(s) for the engine family(ies) certified to Tier 0 certification standards being voided ab initio plus any applicable civil penalties for failure to submit the required information to the Agency.

(v) These reports shall include the information required under § 86.094–7(h)(1). The information shall be organized in such a way as to allow the Administrator to determine compliance with the Tier 1 standards implementation schedules of §§ 86.094–8 and 86.094–9, and the Tier 1 and Tier 1_f implementation schedules of §§ 86.708–94 and 86.709–94.

(Approved by the Office of Management and Budget under control number 2060–0104)

9. Section 86.094–24 is revised to read as follows:

§ 86.094–24 Test vehicles and engines.

(a) *General.* Paragraph (a) of this section applies to the grouping of vehicles or engines into families.

(1) The vehicles or engines covered by an application for certification will be divided into groupings of engines which are expected to have similar emission characteristics throughout their useful life. Each group of engines with similar emission characteristics shall be defined as a separate engine family.

(2) To be classed in the same engine family, engines must be identical in all the respects listed in paragraphs (a)(2) (i) through (x) of this section.

(i) The cylinder bore center-to-center dimensions.

(ii)–(iii) [Reserved]

(iv) The cylinder block configuration (air-cooled or water-cooled: L–6, 90 deg., V–8, etc.).

(v) The location of the intake and exhaust valves (or ports).

(vi) The method of air aspiration.

(vii) The combustion cycle.

(viii) Catalytic converter characteristics.

(ix) Thermal reactor characteristics.

(x) Type of air inlet cooler (e.g., intercoolers and after-coolers) for diesel heavy-duty engines.

(3)(i) Engines identical in all the respects listed in paragraph (a)(2) of this section may be further divided into different engine families if the Administrator determines that they may be expected to have different emission characteristics. This determination will be based upon a consideration of the features of each engine listed in paragraphs (a)(3)(i) (A) through (G) of this section.

(A) The bore and stroke.

(B) The surface-to-volume ratio of the nominally dimensioned cylinder at the top dead center positions.

(C) The intake manifold induction port sizes and configuration.

(D) The exhaust manifold port size and configuration.

(E) The intake and exhaust valve sizes.

(F) The fuel system.

(G) The camshaft timing and ignition or injection timing characteristics.

(ii) Light-duty trucks and heavy-duty engines produced in different model years and distinguishable in the respects listed in paragraph (a)(2) of this section

shall be treated as belonging to a single engine family if the Administrator requires it, after determining that the engines may be expected to have similar emission deterioration characteristics.

(4) Where engines are of a type which cannot be divided into engine families based upon the criteria listed in paragraphs (a) (2) and (3) of this section, the Administrator will establish families for those engines based upon those features most related to their emission characteristics. Engines that are eligible to be included in the same engine family based on the criteria in paragraphs (a)(2) and (a)(3)(i) of this section may be further divided into different engine families if the manufacturer determines that they may be expected to have different emission characteristics. This determination will be based upon a consideration of the features of each engine listed in paragraphs (a)(4) (i) through (iii) of this section.

(i) The dimension from the center line of the crankshaft to the center line of the camshaft.

(ii) The dimension from the center line of the crankshaft to the top of the cylinder block head face.

(iii) The size of the intake and exhaust valves (or ports).

(5) The gasoline-fueled and methanol-fueled light-duty vehicles and light-duty trucks covered by an application for certification will be divided into groupings which are expected to have similar evaporative emission characteristics throughout their useful life. Each group of vehicles with similar evaporative emission characteristics shall be defined as a separate evaporative emission family.

(6) For gasoline-fueled or methanol-fueled light-duty vehicles and light-duty trucks to be classed in the same evaporative emission family, vehicles must be similar with respect to the items listed in paragraphs (a)(6) (i) through (iii) of this section.

(i) Type of vapor storage device (e.g., canister, air cleaner, crankcase).

(ii) Basic canister design.

(iii) Fuel system.

(7) Where vehicles are of a type which cannot be divided into evaporative emission families based on the criteria listed in paragraph (a)(2) of this section, the Administrator will establish families for those vehicles based upon the features most related to their evaporative emission characteristics.

(8)(i) If the manufacturer elects to participate in the Production AMA Durability Program, the engine families covered by an application for certification shall be grouped based upon similar engine design and emission control system characteristics. Each of these groups shall constitute a separate engine family group.

(ii) To be classed in the same engine family group, engine families must contain engines identical in all of the respects listed in paragraphs (a)(8)(ii) (A) through (D) of this section.

(A) The combustion cycle.

(B) The cylinder block configuration (air-cooled or water-cooled: L–6, V–8, rotary, etc.).

(C) Displacement (engines of different displacement within 50 cubic inches or 15 percent of the largest displacement and contained within a multidisplacement engine family will be included in the same engine family group).

(D) Catalytic converter usage and basic type (noncatalyst, oxidation catalyst only, three-way catalyst equipped).

(9) Engine families identical in all respects listed in paragraph (a)(8) of this section may be further divided into different engine family groups if the Administrator determines that they are expected to have significantly different exhaust emission control system deterioration characteristics.

(10) A manufacturer may request the Administrator to include in an engine family group engine families in addition to those grouped under the provisions of paragraph (a)(8) of this section. This request must be accompanied by information the manufacturer believes supports the inclusion of these additional engine families.

(11) A manufacturer may combine into a single engine family group those light-duty vehicle and light-duty truck engine families which otherwise meet the requirements of paragraphs (a) (8) through (10) of this section.

(12) Those vehicles covered by an application for certification which are equipped with gasoline-fueled or methanol-fueled heavy-duty engines will be divided into groupings of vehicles on the basis of physical features which are expected to affect evaporative emissions. Each group of vehicles with similar features shall be defined as a separate evaporative emission family.

(13) For gasoline-fueled or methanol-fueled heavy-duty vehicles to be classified in the same evaporative emission family, vehicles must be identical with respect to:

(i) Method of fuel/air metering (i.e., carburetion versus fuel injection); and

(ii) Carburetor bowl fuel volume, within a 10 cc range.

(14) For vehicles equipped with gasoline-fueled or methanol-fueled heavy-duty engines to be classified in the same evaporative emission control system, vehicles must be identical with respect to the items listed in paragraphs (a)(14) (i) through (ix) of this section.

(i) Method of vapor storage.

(ii) Method of carburetor sealing.

(iii) Method of air cleaner sealing.

(iv) Vapor storage working capacity, within a 20g range.

(v) Number of storage devices.

(vi) Method of purging stored vapors.

(vii) Method of venting the carburetor during both engine off and engine operation.

(viii) Liquid fuel hose material.

(ix) Vapor storage material.

(15) Where vehicles equipped with gasoline-fueled or methanol-fueled heavy-duty engines are types which cannot be divided into evaporative emission family-control system combinations based on the criteria listed above, the Administrator will establish evaporative emission family-control system combinations for those vehicles based on features most related to their evaporative emission characteristics.

(b) *Emission data*—(1) *Light-duty vehicles and light-duty trucks.* Paragraph (b)(1) of this section applies to light-duty vehicle and light-duty truck emission data vehicles.

(i) Vehicles will be chosen to be operated and tested for emission data based upon engine family groupings. Within each engine family, one test vehicle will be selected based on the criterion that the Administrator shall select the vehicle with the heaviest equivalent test weight (including options) within the family. If more than one vehicle meets this criterion, then within that vehicle grouping the Administrator shall select, in the order listed, the highest road-load power, largest displacement, the transmission with the highest numerical final gear ratio (including overdrive), the highest numerical axle ratio offered in that engine family, and the maximum fuel flow calibration

(ii) The Administrator shall select one additional test vehicle from within each engine family. The additional vehicle selected shall be the vehicle expected to exhibit the highest emissions of those vehicles remaining in the engine family. If all vehicles within the engine family are similar the Administrator may waive the requirements of this paragraph.

(iii) Within an engine family and exhaust emission control system, the manufacturer may alter any emission data vehicle (or other vehicles such as current or previous model year emission data vehicles, fuel economy data vehicles, and development vehicles provided they meet emission data vehicles' protocol) to represent more

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than one selection under paragraph (b)(1) (i), (ii), (iv), or (vii) of this section.

(iv) If the vehicles selected in accordance with paragraphs (b)(1) (i) and (ii) of this section do not represent each engine-system combination, then one vehicle of each engine-system combination not represented will be selected by the Administrator. The vehicle selected shall be the vehicle expected to exhibit the highest emissions of those vehicles remaining in the engine family.

(v) For high-altitude exhaust emission compliance for each engine family, the manufacturer shall follow one of the procedures described in paragraphs (b)(1)(v) (A) and (B) of this section.

(A) The manufacturer will select for testing under high-altitude conditions the vehicle expected to exhibit the highest emissions from the nonexempt vehicles selected in accordance with paragraphs (b)(1) (ii), (iii), and (iv) of this section; or

(B) In lieu of testing vehicles according to paragraph (b)(1)(v)(A) of this section, a manufacturer may provide a statement in its application for certification, based on the manufacturer's engineering evaluation of such high altitude emission testing as the manufacturer deems appropriate,

(*1*) That all light-duty vehicles not exempt under § 86.094–8(h) comply with the emission standards at high altitude; and

(*2*) That light-duty trucks sold for principal use at designated high-altitude locations comply with the high-altitude emission requirements and that all light-duty trucks sold at low altitude, which are not exempt under § 86.094–9(h), are capable of being modified to meet high-altitude standards.

(vi) If 90 percent or more of the engine family sales will be in California, a manufacturer may substitute emission data vehicles selected by the California Air Resources Board criteria for the selections specified in paragraphs (b)(1) (i), (ii), and (iv) of this section.

(vii) Vehicles will be chosen to be operated and tested for evaporative emission data based upon evaporative emission family groupings as defined in paragraphs (a) (12) through (15) of this section.

(A) Vehicles of each evaporative emission family will be divided into evaporative emission control systems.

(B) The Administrator will select the vehicle expected to exhibit the highest evaporative emissions from within each evaporative family to be certified. This vehicle is selected from among the vehicles represented by the exhaust emission data selections for the engine family, unless evaporative testing has already been completed for the vehicle expected to exhibit the highest evaporative emissions for the evaporative family as part of another engine family's testing.

(C) If the vehicles selected in accordance with paragraph (b)(1)(vii)(B) of this section do not represent each evaporative emission control system then the Administrator will select the highest expected evaporative emission vehicle from within the unrepresented evaporative system.

(viii) For high-altitude evaporative emission compliance for each evaporative emission family, the manufacturer shall follow one of the procedures described in paragraphs (b)(1)(viii) (A) and (B) of this section.

(A) The manufacturer will select for testing under high-altitude conditions the one nonexempt vehicle previously selected under paragraph (b)(1)(vii) (B) or (C) of this section which is expected to have the highest level of evaporative emissions when operated at high altitude; or

(B) In lieu of testing vehicles according to paragraph (b)(1)(viii)(A) of this section, a manufacturer may provide a statement in its application for certification, based on the manufacturer's engineering evaluation of such high-altitude emission testing as the manufacturer deems appropriate,

(*1*) That all light-duty vehicles not exempt under § 86.094–8(h) comply with the emission standards at high altitude; and

(*2*) That light-duty trucks sold for principal use at designated high-altitude locations comply with the high-altitude emission requirements and that all light-duty trucks sold at low-altitude, which are not exempt under § 86.094–9(h), are capable of being modified to meet high-altitude standards.

(ix) Vehicles selected for high altitude exhaust emission testing under paragraph (b)(1)(v)(A) of this section may be used to satisfy the evaporative emission testing requirements of paragraph (b)(1) (viii) (A) of this section.

(x) *Light-duty trucks only.* (A) The manufacturer may reconfigure any of the low-altitude emission data vehicles to represent the vehicle configuration required to be tested at high altitude.

(B) The manufacturer is not required to test the reconfigured vehicle at low altitude.

(xi) For cold temperature CO exhaust emission compliance for each engine family, the Administrator will select for testing the vehicle expected to emit the highest emissions from the vehicles selected in accordance with paragraphs (b)(1) (i), (ii), (iii), and (iv) of this section. This vehicle shall be tested by the manufacturer in accordance with the test procedures in subpart C of this part or with alternative procedures requested by the manufacturer and approved in advance by the Administrator.

(2) *Otto-cycle heavy-duty emission data engines.* Paragraph (b)(2) of this section applies to Otto-cycle heavy-duty engines.

(i)–(ii) [Reserved]

(iii) The Administrator shall select a maximum of two engines within each engine family based upon features indicating that they may have the highest emission levels of the engines in the engine family in accordance with the criteria described in paragraphs (b)(2)(iii) (A) and (B) of this section.

(A) The Administrator shall select one emission data engine first based on the largest displacement within the engine family. Then from those within the largest displacement the Administrator shall select, in the order listed, highest fuel flow at the speed of maximum rated torque, the engine with the most advanced spark timing, no EGR or lowest EGR flow, and no air pump or lowest actual flow air pump.

(B) The Administrator shall select one additional engine, from within each engine family. The engine selected shall be the engine expected to exhibit the highest emissions of those engines remaining in the engine family. If all engines within the engine family are similar the Administrator may waive the requirements of this paragraph.

(iv) If the engines selected in accordance with paragraphs (b)(2) (ii) and (iii) of this section do not represent each engine displacement-exhaust emission control system combination, then one engine of each engine displacement-exhaust emission control system combination not represented shall be selected by the Administrator.

(v) Within an engine family/displacement/control system combination, the manufacturer may alter any emission data engine (or other engine including current or previous model year emission data engines and development engines provided they meet the emission data engines' protocol) to represent more than one selection under paragraph (b)(2)(iii) of this section.

(3) *Diesel heavy-duty emission data engines.* Paragraph (b)(3) of this section applies to diesel heavy-duty emission data vehicles.

(i) Engines will be chosen to be run for emission data based upon engine family groupings. Within each engine family, the requirements of paragraphs (b)(3) (i) through (iv) of this section must be met.

(ii) Engines of each engine family will be divided into groups based upon their exhaust emission control systems. One engine of each engine system combination shall be run for smoke emission data (diesel engines only) and gaseous emission data. Either the complete gaseous emission test or the complete smoke test may be conducted first. Within each combination, the engine that features the highest fuel feed per stroke, primarily at the speed of maximum rated torque and secondarily at rated speed, will usually be selected. If there are military engines with higher fuel rates than other engines in the same engine system combinations, then one military engine shall also be selected. The engine with the highest fuel feed per stroke will usually be selected.

(iii) The Administrator may select a maximum of one additional engine within each engine-system combination based upon features indicating that it may have the highest emission levels of the engines of that combination. In selecting this engine, the Administrator will consider such features as the injection system, fuel system, compression ratio, rated speed, rated horsepower, peak torque speed, and peak torque.

(iv) Within an engine family control system combination, the manufacturer may alter any emission data engine (or other engine including current or previous model year emission data engines and development engines provided they meet the emission data engines' protocol) to represent more than one selection under paragraphs (b)(3) (ii) and (iii) of this section.

(c) *Durability data*—(1) *Light-duty vehicle durability data vehicles.* Paragraph (c)(1) of this section applies to light-duty vehicle durability data vehicles.

(i) A durability data vehicle will be selected by the Administrator to represent each engine-system combination. The vehicle selected shall be of the engine displacement with the largest projected sales volume of vehicles with that control-system combination in that engine family and will be designated by the Administrator as to transmission type, fuel system, inertia weight class, and test weight.

(ii) A manufacturer may elect to operate and test additional vehicles to represent any engine-system combination. The additional vehicles must be of the same engine displacement, transmission type, fuel system and inertia weight class as the vehicle selected for that engine-system combination in accordance with the provisions of paragraph (c)(1)(i) of this section. Notice of an intent to operate and test additional vehicles shall be given to the Administrator no later than 30 days following notification of the test fleet selection.

(2) *Light-duty trucks.* Paragraph (c)(2) of this section applies to vehicles, engines, subsystems, or components used to establish exhaust emission deterioration factors for light-duty trucks.

(i) The manufacturer shall select the vehicles, engines, subsystems, or components to be used to determine exhaust emission deterioration factors for each engine-family control system combination. Whether vehicles, engines, subsystems, or components are used, they shall be selected so that their emissions deterioration characteristics may be expected to represent those of in-use vehicles, based on good engineering judgment.

(ii) [Reserved]

(3) *Heavy-duty engines.* Paragraph (c)(3) of this section applies to engines, subsystems, or components used to establish exhaust emission deterioration factors for heavy-duty engines.

(i) The manufacturer shall select the engines, subsystems, or components to be used to determine exhaust emission deterioration factors for each engine-family control system combination. Whether engines, subsystems, or components are used, they shall be selected so that their emissions deterioration characteristics may be expected to represent those of in-use engines, based on good engineering judgment.

(ii) [Reserved]

(d) For purposes of testing under § 86.094–26(a)(9) or (b)(11), the Administrator may require additional emission data vehicles (or emission data engines) and durability data vehicles (light-duty vehicles only) identical in all material respects to vehicles (or engines) selected in accordance with paragraphs (b) and (c) of this section, provided that the number of vehicles (or engines) selected shall not increase the size of either the emission data fleet or the durability data fleet by more than 20 percent or one vehicle (or engine), whichever is greater.

(e)(1) [Reserved]

(2) Any manufacturer may request to certify engine families with combined total sales of fewer than 10,000 light-duty vehicles, light-duty trucks, heavy-duty vehicles, and heavy-duty engines utilizing the procedures contained in § 86.094–14 for emission data vehicle selection and determination of deterioration factors. The deterioration factors shall be applied only to entire engine families.

(f) *Carryover and carryacross of durability and emission data.* In lieu of testing an emission data or durability data vehicle (or engine) selected under paragraph (b) or (c) of this section, and submitting data therefore, a manufacturer may, with the prior written approval of the Administrator, submit exhaust emission data and/or evaporative emission data, as applicable on a similar vehicle (or engine) for which certification has previously been obtained or for which all applicable data required under § 86.094–23 has previously been submitted.

(g)(1) Paragraph (g) of this section applies to light-duty vehicles and light-duty trucks, but does not apply to the production vehicles selected under paragraph (h) of this section.

(2)(i) Where it is expected that more than 33 percent of a carline, within an engine-system combination, shall be equipped with an item (whether that item is standard equipment or an option), the full estimated weight of that item shall be included in the curb weight computation for each vehicle available with that item in that carline, within that engine-system combination.

(ii) Where it is expected that 33 percent or less of the carline, within an engine-system combination, will be equipped with an item (whether that item is standard equipment or an option), no weight for that item will be added in computing the curb weight for any vehicle in that carline, within that engine-system combination, unless that item is standard equipment on the vehicle.

(iii) In the case of mutually exclusive options, only the weight of the heavier option will be added in computing the curb weight.

(iv) Optional equipment weighing less than three pounds per item need not be considered.

(3)(i) Where it is expected that more than 33 percent of a carline, within an engine-system combination, will be equipped with an item (whether that item is standard equipment or an option) that can reasonably be expected to influence emissions, then such items shall actually be installed (unless excluded under paragraph (g)(3)(ii) of this section) on all emission data and durability data vehicles of that carline, within that engine-system combination, on which the items are intended to be offered in production. Items that can reasonably be expected to influence emissions are: air conditioning, power steering, power brakes, and other items determined by the Administrator.

(ii) If the manufacturer determines by test data or engineering evaluation that the actual installation of the optional

equipment required by paragraph (g)(3)(i) of this section does not affect the emissions or fuel economy values, the optional equipment need not be installed on the test vehicle.

(iii) The weight of the options shall be included in the design curb weight and also be represented in the weight of the test vehicles.

(iv) The engineering evaluation, including any test data, used to support the deletion of optional equipment from test vehicles, shall be maintained by the manufacturer and shall be made available to the Administrator upon request.

(4) Where it is expected that 33 percent or less of a carline, within an engine-system combination, will be equipped with an item (whether that item is standard equipment or an option) that can reasonably be expected to influence emissions, that item shall not be installed on any emission data vehicle or durability data vehicle of that carline, within that engine-system combination, unless that item is standard equipment on that vehicle or specifically required by the Administrator.

(h) *Production AMA Durability Program durability data vehicles.* Paragraph (h) of this section applies to light-duty vehicle durability data vehicles selected under the Production AMA Durability Program described in § 86.094–13.

(1) In order to update the durability data to be used to determine a deterioration factor for each engine family group, the Administrator will select durability data vehicles from the manufacturer's production line. Production vehicles will be selected from each model year's production for those vehicles certified using the Production AMA Durability Program procedures.

(i) The Administrator shall select the production durability data vehicle designs from the designs that the manufacturer offers for sale. For each model year and for each engine family group, the Administrator may select production durability data vehicle designs of equal number to the number of engine families within the engine family group, up to a maximum of three vehicles.

(ii) The production durability data vehicles representing the designs selected in paragraph (h)(1)(i) of this section will be randomly selected from the manufacturer's production. The Administrator will make these random selections unless the manufacturer (with prior approval of the Administrator) elects to make the random selections.

(iii) The manufacturer may select additional production durability data vehicle designs from within the engine family group. The production durability data vehicles representing these designs shall be randomly selected from the manufacturer's production in accordance with paragraph (h)(1)(ii) of this section.

(iv) For each production on durability data vehicle selected under paragraph (h)(1) of this section, the manufacturer shall provide to the Administrator (before the vehicle is tested or begins service accumulation) the vehicle identification number. Before the vehicle begins service accumulation the manufacturer shall also provide the Administrator with a description of the durability data vehicle as specified by the Administrator.

(v) In lieu of testing a production durability data vehicle selected under paragraph (h)(1) of this section, and submitting data therefrom, a manufacturer may, with the prior written approval of the Administrator, submit exhaust emission data from a production vehicle of the same configuration for which all applicable data has previously been submitted.

(2) If, within an existing engine family group, a manufacturer requests to certify vehicles of a new design, engine family, emission control system, or with any other durability-related design difference, the Administrator will determine if the existing engine family group deterioration factor is appropriate for the new design. If the Administrator cannot make this determination or deems the deterioration factor not appropriate, the Administrator shall select preproduction durability data vehicles under the provisions of paragraph (c) of this section. If vehicles are then certified using the new design, the Administrator may select production vehicles with the new design under the provisions of paragraph (h)(1) of this section.

(3) If a manufacturer requests to certify vehicles of a new design that the Administrator determines are a new engine family group, the Administrator shall select preproduction durability data vehicles under the provisions of paragraph (c) of this section. If vehicles are then certified using the new design, the Administrator may select production vehicles of that design under the provisions of paragraph (h)(1) of this section.

(Approved by the Office of Management and Budget under control number 2060–0104)

10. A new § 86.094–25 is added to subpart A to read as follows:

§ 86.094–25 Maintenance.

(a)(1) *Applicability.* This section applies to light-duty vehicles, light-duty trucks, and heavy-duty engines.

(2) Maintenance performed on vehicles, engines, subsystems, or components used to determine exhaust or evaporative emission deterioration factors is classified as either emission-related or non-emission-related and each of these can be classified as either scheduled or unscheduled. Further, some emission-related maintenance is also classified as critical emission-related maintenance.

(b) This section specifies emission-related scheduled maintenance for purposes of obtaining durability data and for inclusion in maintenance instructions furnished to purchasers of new motor vehicles and new motor vehicles engines under § 86.087–38.

(1) All emission-related scheduled maintenance for purposes of obtaining durability data must occur at the same mileage intervals (or equivalent intervals if engines, subsystems, or components are used) that will be specified in the manufacturer's maintenance instructions furnished to the ultimate purchaser of the motor vehicle or engine under § 86.094–35. This maintenance schedule may be updated as necessary throughout the testing of the vehicle/engine, provided that no maintenance operation is deleted from the maintenance schedule after the operation has been performed on the test vehicle or engine.

(2) Any emission-related maintenance which is performed on vehicles, engines, subsystems, or components must be technologically necessary to assure in-use compliance with the emission standards. The manufacturer must submit data which demonstrate to the Administrator that all of the emission-related scheduled maintenance which is to be performed is technologically necessary. Scheduled maintenance must be approved by the Administrator prior to being performed or being included in the maintenance instructions provided to purchasers under § 86.087–38. The Administrator has determined that emission-related maintenance at shorter intervals than those outlined in paragraphs (b) (3) and (4) of this section is not technologically necessary to ensure in-use compliance. However, the Administrator may determine that maintenance even more restrictive (e.g., longer intervals) than that listed in paragraphs (b) (3) and (4) of this section is also not technologically necessary.

(3) For Otto-cycle light-duty vehicles, light-duty trucks and heavy duty engines, emission-related maintenance

in addition to, or at shorter intervals than, that listed in paragraphs (b)(3) (i) through (vii) of this section will not be accepted as technologically necessary, except as provided in paragraph (b)(7) of this section.

(i)(A) The cleaning or replacement of light-duty vehicle or light-duty truck spark plugs shall occur at 30,000 miles of use and at 30,000-mile intervals thereafter.

(B) The cleaning or replacement of Otto-cycle heavy duty engine spark plugs shall occur at 25,000 miles (or 750 hours) of use and at 25,000-mile (or 750-hour) intervals thereafter, for engines certified for use with unleaded fuel only.

(ii) For light-duty vehicles and light-duty trucks, the adjustment, cleaning, repair, or replacement of the items listed in paragraphs (b)(3)(ii) (A) through (D) of this section shall occur at 50,000 miles of use and at 50,000-mile intervals thereafter.

(A) Positive crankcase ventilation valve.

(B) Emission-related hoses and tubes.

(C) Ignition wires.

(D) Idle mixture.

(iii) For heavy-duty engines, the adjustment, cleaning, repair, or replacement of the items listed in paragraphs (b)(3)(iii) (A) through (D) of this section shall occur at 50,000 miles (or 1,500 hours) of use and at 50,000-mile (or 1,500-hour) intervals thereafter.

(A) Positive crankcase ventilation valve.

(B) Emission-related hoses and tubes.

(C) Ignition wires.

(D) Idle mixture.

(iv) For light-duty vehicles, light-duty trucks and heavy-duty engines, the adjustment, cleaning, repair, or replacement of the oxygen sensor shall occur at 80,000 miles (or 2,400 hours) of use and at 80,000-mile (or 2,400-hour) intervals thereafter.

(v) For heavy-duty engines, the adjustment, cleaning, repair, or replacement of the items listed in paragraphs (b)(3)(v) (A) through (G) of this section shall occur at 100,000 miles (or 3,000 hours) of use and at 100,000-mile (or 3,000-hour) intervals thereafter.

(A) Catalytic converter.

(B) Air injection system components.

(C) Fuel injectors.

(D) Electronic engine control unit and its associated sensors (except oxygen sensor) and actuators.

(E) Evaporative emission canister.

(F) Turbochargers.

(G) Carburetors.

(vi) For light-duty vehicles and light-duty trucks, the adjustment, cleaning, repair, or replacement of the items listed in paragraphs (b)(3)(vi) (A) through (I) of this section shall occur at 100,000 miles of use and at 100,000-mile intervals thereafter.

(A) Catalytic converter.

(B) Air injection system components.

(C) Fuel injectors.

(D) Electronic engine control unit and its associated sensors (except oxygen sensor) and actuators.

(E) Evaporative emission canister.

(F) Turbochargers.

(G) Carburetors.

(H) Superchargers.

(I) EGR System including all related filters and control valves.

(vii) For heavy-duty engines certified for use with unleaded fuel only, the adjustment, cleaning, repair, or replacement of the EGR system (including all related filters and control valves) shall occur at 50,000 miles (or 1,500 hours) of use and at 50,000-mile (or 1,500-hour) intervals thereafter.

(4) For diesel-cycle light-duty vehicles, light-duty trucks, and heavy-duty engines, emission-related maintenance in addition to, or at shorter intervals than that listed in paragraphs (b)(4) (i) through (iv) of this section will not be accepted as technologically necessary, except as provided in paragraph (b)(7) of this section.

(i) For heavy-duty engines, the adjustment, cleaning, repair, or replacement of the items listed in paragraphs (b)(4)(i) (A) through (C) of this section shall occur at 50,000 miles (or 1,500 hours) of use and at 50,000-mile (or 1,500-hour) intervals thereafter.

(A) Exhaust gas recirculation system including all related filters and control valves.

(B) Positive crankcase ventilation valve.

(C) Fuel injector tips (cleaning only).

(ii) For light-duty vehicles and light-duty trucks, the adjustment, cleaning, repair, or replacement of the positive crankcase ventilation valve shall occur at 50,000 miles of use and at 50,000-mile intervals thereafter.

(iii) The adjustment, cleaning, repair, or replacement of items listed in paragraphs (b)(4)(iii) (A) through (D) of this section shall occur at 100,000 miles (or 3,000 hours) of use and at 100,000-mile (or 3,000-hour) intervals thereafter for light heavy-duty engines, or, at 150,000 miles (or 4,500 hours) intervals thereafter for medium and heavy-duty engines.

(A) Fuel injectors.

(B) Turbocharger.

(C) Electronic engine control unit and its associated sensors and actuators.

(D) Particulate trap or trap-oxidizer system (including related components).

(iv) For light-duty vehicles and light-duty trucks, the adjustment, cleaning, repair, or replacement shall occur at 100,000 miles of use and at 100,000-mile intervals thereafter of the items listed in paragraphs (b)(4)(iv) (A) through (G) of this section.

(A) Fuel injectors.

(B) Turbocharger.

(C) Electronic engine control unit and its associated sensors and actuators.

(D) Particulate trap or trap-oxidizer system (including related components).

(E) Exhaust gas recirculation system including all related filters and control valves.

(F) Catalytic converter.

(G) Superchargers.

(5) [Reserved]

(6) (i) The components listed in paragraphs (b)(6)(i) (A) through (G) of this section are currently defined as critical emission-related components.

(A) Catalytic converter.

(B) Air injection system components.

(C) Electronic engine control unit and its associated sensors (including oxygen sensor if installed) and actuators.

(D) Exhaust gas recirculation system (including all related filters and control valves).

(E) Positive crankcase ventilation valve.

(F) Evaporative emission control system components (excluding canister air filter).

(G) Particulate trap or trap-oxidizer system.

(ii) All critical emission-related scheduled maintenance must have a reasonable likelihood of being performed in-use. The manufacturer shall be required to show the reasonable likelihood of such maintenance being performed in-use, and such showing shall be made prior to the performance of the maintenance on the durability data vehicle. Critical emission-related scheduled maintenance items which satisfy one of the conditions defined in paragraphs (b)(6)(ii) (A) through (F) of this section will be accepted as having a reasonable likelihood of the maintenance item being performed in-use.

(A) Data are presented which establish for the Administrator a connection between emissions and vehicle performance such that as emissions increase due to lack of maintenance, vehicle performance will simultaneously deteriorate to a point unacceptable for typical driving.

(B) Survey data are submitted which adequately demonstrate to the Administrator that, at an 80 percent confidence level, 80 percent of such engines already have this critical maintenance item performed in-use at the recommended interval(s)

(C) A clearly displayed visible signal system approved by the Administrator

is installed to alert the vehicle driver that maintenance is due. A signal bearing the message "maintenance needed" or "check engine,", or a similar message approved by the Administrator, shall be actuated at the appropriate mileage point or by component failure. This signal must be continuous while the engine is in operation and not be easily eliminated without performance of the required maintenance. Resetting the signal shall be a required step in the maintenance operation. The method for resetting the signal system shall be approved by the Administrator.

(D) A manufacturer may desire to demonstrate through a survey that a critical maintenance item is likely to be performed without a visible signal on a maintenance item for which there is no prior in-use experience without the signal. To that end, the manufacturer may in a given model year market up to 200 randomly selected vehicles per critical emission-related maintenance item without such visible signals, and monitor the performance of the critical maintenance item by the owners to show compliance with paragraph (b)(6)(ii)(B) of this section. This option is restricted to two consecutive model years and may not be repeated until any previous survey has been completed. If the critical maintenance involves more than one engine family, the sample will be sales weighted to ensure that it is representative of all the families in question.

(E) The manufacturer provides the maintenance free of charge, and clearly informs the customer that the maintenance is free in the instructions provided under § 86.087–38.

(F) Any other method which the Administrator approves as establishing a reasonable likelihood that the critical maintenance will be performed in-use.

(iii) Visible signal systems used under paragraph (b)(6)(ii)(C) of this section are considered an element of design of the emission control system. Therefore, disabling, resetting, or otherwise rendering such signals inoperative without also performing the indicated maintenance procedure is a prohibited act under section 203(a)(3) of the Clean Air Act (42 U.S.C. 7522(a) (3)).

(7) *Changes to scheduled maintenance.* (i) For maintenance practices that existed prior to the 1980 model year, only the maintenance items listed in paragraphs (b) (3) and (4) of this section are currently considered by EPA to be emission-related. The Administrator may, however, determine additional scheduled maintenance items that existed prior to the 1980 model year to be emission-related by announcement in a **Federal Register** Notice. In no event may this notification occur later than September 1 of the calendar year two years prior to the affected model year.

(ii) In the case of any new scheduled maintenance, the manufacturer must submit a request for approval to the Administrator for any maintenance that it wishes to recommend to purchasers and perform during durability determination. New scheduled maintenance is that maintenance which did not exist prior to the 1980 model year, including that which is a direct result of the implementation of new technology not found in production prior to the 1980 model year. The manufacturer must also include its recommendations as to the category (i.e., emission-related or non-emission-related, critical or non-critical) of the subject maintenance and, for suggested emission-related maintenance, the maximum feasible maintenance interval. Such requests must include detailed evidence supporting the need for the maintenance requested, and supporting data or other substantiation for the recommended maintenance category and for the interval suggested for emission-related maintenance. Requests for new scheduled maintenance must be approved prior to the introduction of the new maintenance. The Administrator will then designate the maintenance as emission-related or non-emission-related. For maintenance items established as emission-related, the Administrator will further designate the maintenance as critical if the component which receives the maintenance is a critical component under paragraph (b)(6) of this section. For each maintenance item designated as emission-related, the Administrator will also establish a technologically necessary maintenance interval, based on industry data and any other information available to EPA. Designations of emission-related maintenance items, along with their identification as critical or non-critical, and establishment of technologically necessary maintenance intervals, will be announced in the **Federal Register.**

(iii) Any manufacturer may request a hearing on the Administrator's determinations in paragraph (b)(7) of this section. The request shall be in writing and shall include a statement specifying the manufacturer's objections to the Administrator's determinations, and data in support of such objections. If, after review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, he shall provide the manufacturer a hearing in accordance with § 86.078–6 with respect to such issue.

(c) *Non-emission-related scheduled maintenance* which is reasonable and technologically necessary (e.g., oil change, oil filter change, fuel filter change, air filter change, cooling system maintenance, adjustment of idle speed, governor, engine bolt torque, valve lash, injector lash, timing, adjustment of air pump drive belt tension, lubrication of the exhaust manifold heat control valve, lubrication of carburetor choke linkage, retorqueing carburetor mounting bolts, etc.) may be performed on durability data vehicles at the least frequent intervals recommended by the manufacturer to the ultimate purchaser, (e.g., not at the intervals recommended for severe service).

(d) *Unscheduled maintenance on light-duty durability data vehicles.* (1) Unscheduled maintenance may be performed during the testing used to determine deterioration factors, except as provided in paragraphs (d) (2) and (3) of this section, only under the following provisions defined in paragraphs (d)(1) (i) through (iii) of this section.

(i) A fuel injector or spark plug may be changed if a persistent misfire is detected.

(ii) Readjustment of an Otto-cycle vehicle cold-start enrichment system may be performed if there is a problem of stalling.

(iii) Readjustment of the engine idle speed (curb idle and fast idle) may be performed in addition to that performed as scheduled maintenance under paragraph (c) of this section if the idle speed exceeds the manufacturer's recommended idle speed by 300 rpm or more, or if there is a problem of stalling.

(2) Any other unscheduled vehicle, emission control system, or fuel system adjustment, repair, removal, disassembly, cleaning, or replacement during testing to determine deterioration factors shall be performed only with the advance approval of the Administrator. Such approval will be given if the Administrator:

(i) Has made a preliminary determination that the part failure or system malfunction, or the repair of such failure or malfunction, does not render the vehicle or engine unrepresentative of vehicles or engines in-use and does not require direct access to the combustion chamber, except for spark plug, fuel injection component, or removable prechamber removal or replacement; and

(ii) Has made a determination that the need for maintenance or repairs is indicated by an overt indication of malfunction such as persistent misfiring, engine stalling, overheating,

fluid leakage, loss of oil pressure, excessive fuel consumption, or excessive power loss. The Administrator shall be given the opportunity to verify the existence of an overt indication of part failure and/or vehicle/engine malfunction (e.g., misfiring, stalling, black smoke), or an activation of an audible and/or visible signal, prior to the performance of any maintenance to which such overt indication or signal is relevant under the provisions of this section.

(3) Emission measurement may not be used as a means of determining the need for unscheduled maintenance under paragraph (d)(2) of this section, except under the conditions defined in paragraphs (d)(3) (i) through (ii) of this section.

(i) The Administrator may approve unscheduled maintenance on durability data vehicles based upon a significant change in emission levels that indicates a vehicle or engine malfunction. In these cases the Administrator may first approve specific diagnostic procedures to identify the source of the problem. The Administrator may further approve of specific corrections to the problem after the problem has been identified. The Administrator may only approve the corrective action after it is determined that:

(A) The malfunction was caused by nonproduction build practices or by a previously undetected design problem;

(B) The malfunction will not occur in production vehicles or engines in-use; and

(C) The deterioration factor generated by the durability data vehicle or engine will remain unaffected by the malfunction or by the corrective action (e.g., the malfunction was present for only a short period of time before detection, replacement parts are functionally representative of the proper mileage or hours, etc.).

(ii) Following any unscheduled maintenance approved under paragraph (d)(3)(i) of this section, the manufacturer shall perform an after-maintenance emission test. If the Administrator determines that the after-maintenance emission levels for any pollutant indicates that the deterioration factor is no longer representative of production, the Administrator may disqualify the durability data vehicle or engine.

(4) If the Administrator determines that part failure or system malfunction occurrence and/or repair rendered the vehicle/engine unrepresentative of vehicles in-use, the vehicle/engine shall not be used for determining deterioration factors.

(5) Repairs to vehicle components of a durability data vehicle other than the engine, emission control system, or fuel system, shall be performed only as a result of part failure, vehicle system malfunction, or with the advance approval of the Administrator.

(e) *Maintenance on emission data vehicles and engines.* (1) Adjustment of engine idle speed on emission data vehicles may be performed once before the low-mileage/low-hour emission test point. Any other engine, emission control system, or fuel system adjustment, repair, removal, disassembly, cleaning, or replacement on emission data vehicles shall be performed only with the advance approval of the Administrator.

(2) [Reserved]

(3) [Reserved]

(4) Repairs to vehicle components of an emission data vehicle other than the engine, emission control system, or fuel system, shall be performed only as a result of part failure, vehicle system malfunction, or with the advance approval of the Administrator.

(f) Equipment, instruments, or tools may not be used to identify malfunctioning, maladjusted, or defective engine components unless the same or equivalent equipment, instruments, or tools will be available to dealerships and other service outlets and:

(1) Are used in conjunction with scheduled maintenance on such components; or

(2) Are used subsequent to the identification of a vehicle or engine malfunction, as provided in paragraph (d)(2) of this section for durability data vehicles or in paragraph (e)(1) of this section for emission data vehicles; or

(3) Unless specifically authorized by the Administrator.

(g)(1) Paragraph (g) of this section applies to light-duty vehicles.

(2) Complete emission tests (see §§ 86.106 through 86.145) are required, unless waived by the Administrator, before and after scheduled maintenance approved for durability data vehicles. The manufacturer may perform emission tests before unscheduled maintenance. Complete emission tests are required after unscheduled maintenance which may reasonably be expected to affect emissions. The Administrator may waive the requirement to test after unscheduled maintenance. These test data may be submitted weekly to the Administrator, but shall be air posted or delivered within 7 days after completion of the tests, along with a complete record of all pertinent maintenance, including a preliminary engineering report of any malfunction diagnosis and the corrective action taken. A complete engineering report shall be delivered to the Administrator concurrently with the manufacturer's application for certification.

(h) All test data, maintenance reports, and required engineering reports shall be compiled and provided to the Administrator in accordance with § 86.090–23.

11. A new § 86.094–26 is added to subpart A to read as follows:

§ 86.094–26 Mileage and service accumulation; emission requirements.

(a)(1) Paragraph (a) of this section applies to light-duty vehicles. It prescribes mileage and service accumulation requirements for durability data vehicles run under either the Standard AMA Durability Program of § 86.094–13(c) or the Production AMA Durability Program of § 86.094–13(d), and for emission data vehicles regardless of the durability program employed. Service accumulation requirements for durability data vehicles run under the Alternative Service Accumulation Program may be found in § 86.094–13(e).

(2) The standard method of whole-vehicle service accumulation for durability data vehicles and for emission data vehicles in model years 1994, 1995, and 1996 shall be mileage accumulation using the Durability Driving Schedule as specified in appendix IV to this part. A modified procedure may also be used if approved in advance by the Administrator. Except with the advance approval of the Administrator, all vehicles will accumulate mileage at a measured curb weight which is within 100 pounds of the estimated curb weight. If the loaded vehicle weight is within 100 pounds of being included in the next higher inertia weight class as specified in § 86.129, the manufacturer may elect to conduct the respective emission tests at higher loaded vehicle weight.

(3) *Emission data vehicles.* Unless otherwise provided for in § 86.094–23(a), emission data vehicles shall be operated and tested as described in paragraphs (a)(3) (i) and (ii) of this section.

(i) *Otto-cycle.* (A) The manufacturer shall determine, for each engine family, the mileage at which the engine-system combination is stabilized for emission data testing. The manufacturer shall maintain, and provide to the Administrator if requested, a record of the rationale used in making this determination. The manufacturer may elect to accumulate 4,000 miles on each test vehicle within an engine family without making a determination. The manufacturer must accumulate a

minimum of 2,000 miles (3,219 kilometers) on each test vehicle within an engine family. All test vehicle mileage must be accurately determined, recorded, and reported to the Administrator. Any vehicle used to represent emission data vehicle selections under § 86.094–24(b)(1) shall be equipped with an engine and emission control system that has accumulated the mileage the manufacturer chose to accumulate on the test vehicle. Fuel economy data generated from certification vehicles selected in accordance with § 86.094–24(b)(1) with engine-system combinations that have accumulated more than 10,000 kilometers (6,200 miles) shall be factored in accordance with § 600.006(c) of this chapter. Complete exhaust and evaporative (if required) emission tests shall be conducted for each emission data vehicle selection under § 86.094–24(b)(1) . The Administrator may determine under § 86.094–24(f) that no testing is required.

(B) Emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1) (v) or (viii) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing under high-altitude conditions.

(C) Exhaust and evaporative emissions tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1) (i), (ii), (iii), (iv), or (vii)(B) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing under low-altitude conditions.

(D) For each engine family, the manufacturer will either select one vehicle previously selected under § 86.094–24(b)(1) (i) through (iv) to be tested under high-altitude conditions or provide a statement in accordance with § 86.094–24(b)(1)(v). Vehicles shall meet emission standards under both low- and high-altitude conditions without manual adjustments or modifications. In addition, any emission control device used to conform with the emission standards under high-altitude conditions shall initially actuate (automatically) no higher than 4,000 feet above sea level.

(ii) *Diesel-cycle.* (A) The manufacturer shall determine, for each engine family, the mileage at which the engine-system combination is stabilized for emission data testing. The manufacturer shall maintain, and provide to the Administrator if requested, a record of the rationale used in making this determination. The manufacturer may elect to accumulate 4,000 miles on each test vehicle within an engine family without making a determination. The manufacturer must accumulate a minimum of 2,000 miles (3,219 kilometers) on each test vehicle within an engine family. All test vehicle mileage must be accurately determined, recorded, and reported to the Administrator. Any vehicle used to represent emission data vehicle selections under § 86.094–24(b)(1) shall be equipped with an engine and emission control system that has accumulated the mileage the manufacturer chose to accumulate on the test vehicle. Fuel economy data generated from certification vehicles selected in accordance with § 86.094–24(b)(1) with engine-system combinations that have accumulated more than 10,000 kilometers (6,200 miles) shall be factored in accordance with § 600.006 of this chapter. Complete exhaust emission tests shall be conducted for each emission data vehicle selection under § 86.094–24(b)(1). The Administrator may determine under § 86.094–24(f) that no testing is required.

(B) Emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1)(v) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing under high-altitude conditions.

(C) Exhaust and evaporative emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1) (i), (ii), (iii), (iv), or (vii)(B) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing under low-altitude conditions.

(D) For each engine family, the manufacturer will either select one vehicle previously selected under § 86.094–24(b)(1) (i) through (iv) to be tested under high-altitude conditions or provide a statement in accordance with § 86.094–24(b)(1)(v). Vehicles shall meet emission standards under both low- and high-altitude conditions without manual adjustments or modifications. In addition, any emission control device used to conform with the emission standards under high-altitude conditions shall initially actuate (automatically) no higher than 4,000 feet above sea level.

(4) (i) *Durability data vehicles.* (A) Unless otherwise provided for in § 86.094–13(e) or § 86.094–23(a) or in paragraph (a)(4)(i)(B) of this section, each durability data vehicle shall be driven on the whole-vehicle mileage accumulation cycle specified in paragraph (a)(2) of this section, with all emission control systems installed and operating, up to a mileage endpoint corresponding to the vehicle's durability useful life as defined in § 86.094–2.

(B) *Extrapolation of durability data and changes to the mileage accumulation cycle.* (*1*) Once a durability vehicle has reached the greater of 75,000 miles or three-quarters of the applicable durability useful life, the manufacturer may petition the Administrator to extrapolate the durability data obtained up to that point out to the durability useful life or to replace the mileage accumulation cycle with an alternative that meets the criteria of paragraph (a)(2) of this section. In the petition, the manufacturer shall supplement the durability vehicle data with other information demonstrating the durability of the vehicle's emission control components and systems at or beyond the durability useful life.

(*2*) Factors the Administrator will consider in evaluating petitions for extrapolation of durability data or for changes to the mileage accumulation cycle include, but are not limited to, any unusual scheduled maintenance, unscheduled maintenance, the general linearity and scatter of the actual data, reasonable explanations for all outlier data, the technical validity of any substitute mileage accumulation cycle, and evidence supplied by the vehicle manufacturer of component and system durability.

(*3*) If a petition for extrapolation of durability data is approved, the endpoint for whole-vehicle mileage accumulation of the durability data vehicle shall be the mileage attained by the vehicle as reflected in the petition.

(*4*) Discontinuation of a durability data vehicle shall be allowed only with the consent of the Administrator.

(C) Complete exhaust emission tests shall be made at nominal test point mileage intervals that the manufacturer determines. At a minimum, two complete exhaust emission tests shall be made. The first test shall be made at a distance not greater than 6,250 miles. The last shall be made at the mileage accumulation endpoint determined in paragraph (a)(4)(i) (A) or (B) of this section, whichever is applicable.

(D) Except with advance approval of the Administrator, the mileage interval between nominal test points must be of equal length except for the interval between zero miles and the first test, and any interval before or after testing conducted in conjunction with vehicle maintenance as specified in § 86.094–25(g)(2).

(ii) The manufacturer may, at its option, alter the durability data vehicle at the selected nominal test point to

represent emission data vehicle(s) within the same engine-system combination and perform emission tests on the altered vehicle. Upon completion of emission testing, the manufacturer may return the test vehicle to the durability data vehicle configuration and continue mileage accumulation.

(5)(i) All tests required by this subpart on emission data vehicles shall be conducted at a mileage equal to or greater than the mileage the manufacturer determines under paragraph (a)(3) of this section.

(ii) All tests required by this subpart on durability data vehicles shall be conducted within 250 miles of each of the nominal test points. This ±250 mile test point mileage tolerance may be modified with the advance approval of the Administrator if the basis for the written request is to prevent an interruption of durability mileage accumulation due to test scheduling conflicts for weekends, holidays, and other similar circumstances.

(6)(i)(A) The manufacturer may conduct multiple tests at any test point at which the data are intended to be used in the deterioration factor. At each test point where multiple tests are conducted, the test results from all valid tests shall be averaged to determine the data point to be used in the deterioration factor calculation, except under paragraph (a)(6)(i)(B) of this section. The test results from emission tests performed before maintenance affecting emissions shall not be averaged with test results after the maintenance.

(B) The manufacturer is not required to average multiple tests if the manufacturer conducts no more than three tests at each test point and if the number of tests at each test point is equal. All test points must be treated the same for all exhaust pollutants.

(ii) The results of all emission testing shall be supplied to the Administrator. The manufacturer shall furnish to the Administrator explanation for voiding any test. The Administrator will determine if voiding the test was appropriate based upon the explanation given by the manufacturer for the voided test. Tests between test points may be conducted as required by the Administrator. Data from all tests (including voided tests) may be submitted weekly to the Administrator, but shall be air posted or delivered to the Administrator within 7 days after completion of the test. In addition, all test data shall be compiled and provided to the Administrator in accordance with § 86.091–23. Where the Administrator conducts a test on a durability data vehicle at a prescribed test point, the results of that test will be used in the calculation of the deterioration factor.

(iii) The results of all emission tests shall be rounded to the number of places to the right of the decimal point indicated by expressing the applicable emission standard of this subpart to one additional significant figure, in accordance with the rounding off method specified in ASTM E 29–67 (reapproved 1980) ("Standard recommended practice for indicating which places of figures are to be considered significant in specified limiting values," American Society for Testing and Materials). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103. Copies may be inspected at the U.S. Environmental Protection Agency, Air Docket Section, room M–1500, 401 M Street SW., Washington, DC 20460 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington DC.

(7) Whenever a manufacturer intends to operate and test a vehicle which may be used for emission or durability data, the manufacturer shall retain in its records all information concerning all emissions tests and maintenance, including vehicle alterations to represent other vehicle selections. For emission data vehicles, this information shall be submitted, including the vehicle description and specification information required by the Administrator, to the Administrator following the emission data test. For durability data vehicles, this information shall be submitted following the 5,000-mile test.

(8) The data from emission data vehicles and durability data vehicles obtained pursuant to the provisions of this section will be used in the calculations under § 86.094–28.

(9) (i) The Administrator may elect to operate and test any test vehicle during all or any part of the mileage accumulation and testing procedure. In such cases, the manufacturer shall provide the vehicle(s) to the Administrator with all information necessary to conduct this testing.

(ii) The test procedures in §§ 86.108 through 86.145 will be followed by the Administrator. The Administrator will test the vehicles at each test point. Maintenance may be performed by the manufacturer under such conditions as the Administrator may prescribe.

(iii) The data developed by the Administrator for the engine-system combination shall be combined with any applicable data supplied by the manufacturer on other vehicles of that combination to determine the applicable deterioration factors for the combination. In the case of a significant discrepancy between data developed by the Administrator and that submitted by the manufacturer, the Administrator's data shall be used in the determination of deterioration factors.

(10) Emission testing of any type with respect to any certification vehicle other than that specified in this part is not allowed except as such testing may be specifically authorized by the Administrator.

(11) This section does not apply to testing conducted to meet the requirements of § 86.091–23(b)(2).

(b) (1) Paragraph (b) of this section applies to light-duty trucks.

(2) Four types of mileage or service accumulation are applicable to light-duty trucks, as described in paragraphs (b)(2) (i) through (iv) of this section.

(i) Paragraph (b)(2)(i) of this section applies to service accumulation conducted under the Standard Self-Approval Durability Program of § 86.094–13(f) . This type of service accumulation is applicable for model years 1994, 1995, and 1996 only. The manufacturer determines the form and extent of this service accumulation, consistent with good engineering practice, and describes it in the application for certification. Service accumulation under the Standard Self-Approval Durability Program is conducted on vehicles, engines, subsystems, or components selected by the manufacturer under § 86.094–24(c)(2)(i).

(ii) Paragraph (b)(2)(ii) of this section applies to service accumulation conducted under the Alternative Service Accumulation Durability Program of § 86.094–13(e) . This type of service accumulation is applicable for model years 1994, 1995, and 1996 only. The service accumulation method is developed by the manufacturer to be consistent with good engineering practice and to accurately predict the deterioration of the vehicle's emissions in actual use over its full useful life. The method is subject to advance approval by the Administrator and to verification by an in-use verification program conducted by the manufacturer under § 86.094–13(e)(5).

(iii) Paragraph (b)(2)(iii) of this section applies to mileage accumulation of the duration selected by the manufacturer on emission data vehicles selected under § 86.094–24(b)(1). The procedure

for mileage accumulation will be the Durability Driving Schedule as specified in Appendix IV to this part. A modified procedure may also be used if approved in advance by the Administrator. Except with the advance approval of the Administrator, all vehicles will accumulate mileage at a measured curb weight which is within 100 pounds of the estimated curb weight. If the loaded vehicle weight is within 100 pounds of being included in the next higher inertia weight class as specified in § 86.129, the manufacturer may elect to conduct the respective emission tests at higher loaded vehicle weight.

(iv) Service or mileage accumulation may also be part of the test procedures used by the manufacturer to establish evaporative emission deterioration factors.

(3) Exhaust emission deterioration factors will be determined on the basis of the mileage or service accumulation described in paragraph (b)(2) (i) or (ii) of this section and related testing, according to the manufacturer's procedures.

(4) Each emission data vehicle shall be operated and tested as follows:

(i) *Otto-cycle.* (A) The manufacturer shall determine, for each engine family, the mileage at which the engine-system combination is stabilized for emission data testing. The manufacturer shall maintain, and provide to the Administrator if requested, a record of the rationale used in making this determination. The manufacturer may elect to accumulate 4,000 miles on each test vehicle within an engine family without making a determination. The manufacturer must accumulate a minimum of 2,000 miles (3,219 kilometers) on each test vehicle within an engine family. All test vehicle mileage must be accurately determined, recorded, and reported to the Administrator. Any vehicle used to represent emission data vehicle selections under § 86.094–24(b)(1) shall be equipped with an engine and emission control system that has accumulated the mileage the manufacturer chose to accumulate on the test vehicle. Fuel economy data generated from certification vehicles selected in accordance with § 86.094–24(b)(1) with engine-system combinations that have accumulated more than 10,000 kilometers (6,200 miles) shall be factored in accordance with § 600.006 of this chapter. Complete exhaust emission tests shall be conducted for each emission data vehicle selection under § 86.094–24(b)(1). The Administrator may determine under § 86.094–24(f) that no testing is required.

(B) Emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1) (v) or (viii) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing or at 6,436 kilometers (4,000 miles) under high-altitude conditions.

(C) Exhaust and evaporative emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1) (ii), (iii), (iv)(A), or (vii)(B) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing or at 6,436 kilometer (4,000 mile) test point under low-altitude conditions.

(D) If the manufacturer recommends adjustments or modifications in order to conform to emission standards at high altitude, such adjustments or modifications shall be made to the test vehicle selected under § 86.094–24(b)(1) (v) and (viii) (in accordance with the instructions to be provided to the ultimate purchaser) before being tested under high-altitude conditions.

(ii) *Diesel-cycle.* (A) The manufacturer shall determine, for each engine family, the mileage at which the engine-system combination is stabilized for emission data testing. The manufacturer shall maintain, and provide to the Administrator if requested, a record of the rationale used in making this determination. The manufacturer may elect to accumulate 4,000 miles on each test vehicle within an engine family without making a determination. The manufacturer must accumulate a minimum of 2,000 miles (3,219 kilometers) on each test vehicle within an engine family. All test vehicle mileage must be accurately determined, recorded, and reported to the Administrator. Any vehicle used to represent emission data vehicle selections under § 86.094–24(b)(1) shall be equipped with an engine and emission control system that has accumulated the mileage the manufacturer chose to accumulate on the test vehicle. Fuel economy data generated from certification vehicles selected in accordance with § 86.094–24(b)(1) with engine-system combinations that have accumulated more than 10,000 kilometers (6,200 miles) shall be factored in accordance with § 600.006(c) of this chapter. Complete exhaust emission tests shall be conducted for each emission data vehicle selection under § 86.094–24(b)(1). The administrator may determine under § 86.094–24(f) that no testing is required.

(B) Emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1)(v) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing or at the 6,436 kilometer (4,000 mile) test point under high-altitude conditions.

(C) Exhaust and evaporative emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1) (ii), (iii), and (iv) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing or at the 6,436 kilometer (4,000 mile) test point under low-altitude conditions.

(D) If the manufacturer recommends adjustments or modifications in order to conform to emission standards at high-altitude, such adjustments or modifications shall be made to the test vehicle selected under § 86.094–24(b)(1) (v) and (viii) (in accordance with the instructions to be provided to the ultimate purchaser) before being tested under high-altitude conditions.

(iii) [Reserved]

(iv) All tests required by this subpart on emission data vehicles shall be conducted at a mileage equal to or greater than the mileage the manufacturer determines under paragraph (b)(4) of this section.

(c)(1) Paragraph (c) of this section applies to heavy-duty engines.

(2) Two types of service accumulation are applicable to heavy-duty engines, as described in paragraphs (c)(2) (i) and (ii) of this section.

(i) Service accumulation on engines, subsystems, or components selected by the manufacturer under § 86.094–24(c)(3)(i). The manufacturer determines the form and extent of this service accumulation, consistent with good engineering practice, and describes it in the application for certification.

(ii) Dynamometer service accumulation on emission data engines selected under § 86.094–24(b) (2) or (3). The manufacturer determines the engine operating schedule to be used for dynamometer service accumulation, consistent with good engineering practice. A single engine operating schedule shall be used for all engines in an engine family-control system combination. Operating schedules may be different for different combinations.

(3) Exhaust emission deterioration factors will be determined on the basis of the service accumulation described in paragraph (b)(2)(i) of this section and related testing, according to the manufacturer's procedures.

(4) The manufacturer shall determine, for each engine family, the number of hours at which the engine system combination is stabilized (no less than 62 hours for catalyst equipped) for

emission data testing. The manufacturer shall maintain, and provide to the Administrator if requested, a record of the rationale used in making this determination. The manufacturer may elect to accumulate 125 hours on each test engine within an engine family without making a determination. Any engine used to represent emission data engine selections under § 86.094–24(b)(2) shall be equipped with an engine system combination that has accumulated at least the number of hours determined under this paragraph. Complete exhaust emission tests shall be conducted for each emission data engine selection under § 86.094–24(b)(2). Evaporative emission controls need not be connected provided normal operating conditions are maintained in the engine induction system. The Administrator may determine under § 86.094–24(f) that no testing is required.

(d)(1) Paragraph (d) of this section applies to both light-duty trucks and heavy-duty engines.

(2)(i) The results of all emission testing shall be supplied to the Administrator. The manufacturer shall furnish to the Administrator explanation for voiding any test. The Administrator will determine if voiding the test was appropriate based upon the explanation given by the manufacturer for the voided test. Tests between test points may be conducted as required by the Administrator. Data from all tests (including voided tests) may be submitted weekly to the Administrator, but shall be air posted or delivered to the Administrator within 7 days after completion of the test. In addition, all test data shall be compiled and provided to the Administrator in accordance with § 86.094–23. Where the Administrator conducts a test on a durability data vehicle at a prescribed test point, the results of that test will be used in the calculation of the deterioration factor.

(ii) The results of all emission tests shall be recorded and reported to the Administrator. These test results shall be rounded, in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(6)(iii) of this section), to the number of decimal places contained in the applicable emission standard expressed to one additional significant figure.

(3) Whenever a manufacturer intends to operate and test a vehicle (or engine) which may be used for emission data, the manufacturer shall retain in its records all information concerning all emissions tests and maintenance, including vehicle (or engine) alterations to represent other vehicle (or engine) selections. This information shall be submitted, including the vehicle (or engine) description and specification information required by the Administrator, to the Administrator following the emission data test.

(4)–(5) [Reserved]

(6) Emission testing of any type with respect to any certification vehicle or engine other than that specified in this subpart is not allowed except as such testing may be specifically authorized by the Administrator.

(Approved by the Office of Management and Budget under control number 2060–0104)

12. A new § 86.094–28 is added to read as follows:

§ 86.094–28 Compliance with emission standards.

(a) (1) Paragraph (a) of this section applies to lightduty vehicles.

(2) Each exhaust and evaporative emission standard (and family particulate emission limit, as appropriate) of § 86.094–8 applies to the emissions of vehicles for the appropriate useful life as defined in §§ 86.094–2 and 86.094–8.

(3) Since it is expected that emission control efficiency will change with mileage accumulation on the vehicle, the emission level of a vehicle which has accumulated mileage equal to the specified useful life will be used as the basis for determining compliance with the standard (or family particulate emission limit, as appropriate).

(4) The procedure for determining compliance of a new motor vehicle with exhaust and evaporative emission standards (or family particulate emission limit, as appropriate) is as described in paragraphs (a)(4) (i) through (v) of this section, except where specified by paragraph (a)(7) of this section for the Production AMA Durability Program.

(i) Separate emission deterioration factors shall be determined from the exhaust emission results of the durability data vehicle(s) for each engine-system combination. A separate evaporative emission deterioration factor shall be determined for each evaporative emission family-evaporative emission control system combination from the testing conducted by the manufacturer (gasoline-fueled and methanol-fueled vehicles only).

(A) The applicable results to be used, unless excluded by paragraph (a)(4)(i)(A)(*4*) of this section, in determining the exhaust emission deterioration factors for each engine-system combination shall be those described in paragraphs (a)(4)(i)(A) (*1*) through (*3*) of this section.

(*1*) All valid exhaust emission data from the tests required under § 86.094–26(a)(4) except the zero-mile tests. This shall include the official test results, as determined in § 86.094–29 for all tests conducted on all durability data vehicles of the combination selected under § 86.094–24(c) (including all vehicles elected to be operated by the manufacturer under § 86.094–24(c)(1)(ii)).

(*2*) All exhaust emission data from the tests conducted before and after the scheduled maintenance provided in § 86.094–25.

(*3*) All exhaust emission data from tests required by maintenance approved under § 86.094–25, in those cases where the Administrator conditioned his approval for the performance of such maintenance on the inclusion of such data in the deterioration factor calculation.

(*4*) The manufacturer has the option of applying an outlier test point procedure to completed durability data within its certification testing program for a given model year. The outlier procedure will be specified by the Administrator. For any pollutant, durability data test points that are identified as outliers shall not be included in the determination of deterioration factors if the manufacturer has elected this option. The manufacturer shall specify to the Administrator before the certification of the first engine family for that model year, if it intends to use the outlier procedure. The manufacturer may not change procedures after the first engine family of the model year is certified. Where the manufacturer chooses to apply both the outlier procedure and averaging (as allowed under § 86.094–26(a)(6)(i)) to the same data set, the outlier procedure shall be completed prior to applying the averaging procedure.

(B)(*1*) *Line crossing.* For each exhaust constituent to which a standard in § 86.094–8 applies, all applicable exhaust emission results shall be rounded to the nearest mile and plotted as a function of the mileage on the system. The best fit straight line, fitted by the method of least squares, shall be drawn through all these data points. The data for a given exhaust constituent will be acceptable for use in the calculation of deterioration factors only if the first official test point as determined in § 86.094–26(a)(4)(i)(C), the interpolated intermediate useful life mile point, and the interpolated full useful life mile point on this line, as applicable, are each less than or equal to the respective low-altitude standards provided in § 86.094–8. An exception to this where

data are still acceptable is when a best fit straight line crosses an applicable standard but no data points exceeded the standard. This exception shall not apply when mileage accumulation has been curtailed before the durability useful life has been reached, under the provisions of § 86.094–26(a)(4)(i)(B).

(2) *Exhaust deterioration factor determination.* Multiplicative exhaust emission deterioration factors shall be calculated for each standard and for each engine-system combination from points on the regression line derived in paragraph (a)(4)(i)(B)(*1*) of this section, and in accordance with paragraphs (a)(4)(i)(B)(2) (*i*) and (*ii*) of this section.

(*i*) Factor=Exhaust emissions at the useful life mileage for that standard divided by exhaust emissions at 4,000 miles.

(*ii*) These interpolated values shall be carried out to a minimum of four places to the right of the decimal point before dividing one by the other to determine the deterioration factor. The results shall be rounded to three places to the right of the decimal point in accordance with ASTM E 29–67 (reapproved 1980) ("Standard recommended practice for indicating which places of figures are to be considered significant in specified limiting values," American Society for Testing and Materials). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19103. Copies may be inspected at the U.S. Environmental Protection Agency, Air Docket Section, room M–1500, 401 M Street SW., Washington, DC 20460 or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(*iii*) When calculating intermediate and full useful life deterioration factors all data points should be included in the calculations, except that total hydrocarbon (THC) test points beyond the 50,000-mile (useful life) test point shall not be included in the calculations.

(*iv*) The calculation specified in paragraph (a)(4)(i)(B)(*2*) of this section may be modified with advance approval of the Administrator for engine-system combinations which are certified under the Alternative Service Accumulation Durability Program specified in § 86.094–13(e).

(C) *Evaporative deterioration factor determination.* An evaporative emissions deterioration factor (gasoline-fueled and methanol-fueled vehicles only) shall be determined from the testing conducted as described in § 86.094–21(b)(4)(i) and in accordance with paragraphs (a)(4)(i)(C) (*1*) and (*2*) of this section, for each evaporative emission family-evaporative emission control system combination to indicate the evaporative emission level at the applicable useful life relative to the evaporative emission level at 4,000 miles.

(*1*) Factor=Evaporative emission level at the useful life mileage for that standard minus the evaporative emission level at 4,000 miles.

(*2*) The factor shall be established to a minimum of two places to the right of the decimal.

(ii)(A)(*1*) The official exhaust emission test results for each applicable exhaust emission standard for each emission data vehicle at the selected test point shall be multiplied by the appropriate deterioration factor: *Provided,* that if a deterioration factor as computed in paragraph (a)(4)(i)(B) of this section is less than one, that deterioration factor shall be one for the purposes of this paragraph.

(*2*) The calculation specified in paragraph (a)(4)(ii)(A)(*1*) of this section may be modified with advance approval of the Administrator for engine-system combinations which are certified under the Alternative Service Accumulation Durability Program specified in § 86.094–13(e).

(B) The official evaporative emission test results (gasoline-fueled and methanol-fueled vehicles only) for each evaporative emission data vehicle at the selected test point shall be adjusted by addition of the appropriate deterioration factor, provided that if a deterioration factor as computed in paragraph (a)(4)(i)(C) of this section is less than zero, that deterioration factor shall be zero for the purposes of this paragraph.

(iii) The emissions to compare with the standard (or the family particulate emission limit, as appropriate) shall be the adjusted emissions of paragraphs (a)(4)(ii) (A) and (B) of this section for each emission data vehicle. Before any emission value is compared with the standard (or the family particulate emission limit, as appropriate) it shall be rounded, in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section), to two significant figures. The rounded emission values may not exceed the standard (or the family particulate emission limit, as appropriate).

(iv) Every test vehicle of an engine family must comply with the exhaust emission standards (or the family particulate emission limit, as appropriate), as determined in paragraph (a)(4)(iii) of this section, before any vehicle in that family may be certified.

(v) Every test vehicle of an evaporative emission family must comply with the evaporative emission standard, as determined in paragraph (a)(4)(iii) of this section, before any vehicle in that family may be certified.

(5) If a manufacturer chooses to change the level of any family particulate emission limit(s) in the particulate averaging program, compliance with the new limit(s) must be based upon existing certification data.

(6) If a manufacturer chooses to participate in the diesel particulate averaging program, the production-weighted average of the family particulate emission limits of all affected engine families must comply with the particulate standards in § 86.094–8(a)(1)(iv), or the composite particulate standard defined in § 86.094–2, as appropriate, at the end of the production year.

(7) The procedure to determine the compliance of new motor vehicles in the Production AMA Durability Program described in § 86.094–13 is the same as described in paragraphs (a)(4) (iii) through (v) of this section. For the engine families that are included in the Production AMA Durability Program, the exhaust emission deterioration factors used to determine compliance shall be those that the Administrator has approved under § 86.094–13. The evaporative emission deterioration factor for each evaporative emission family shall be determined and applied according to paragraph (a)(4) of this section. The procedures to determine the minimum exhaust emission deterioration factors required under § 86.094–13(d) are as described in paragraphs (a)(7) (i) and (ii) of this section.

(i) Separate deterioration factors shall be determined from the exhaust emission results of the durability data vehicles for each emission standard applicable under § 86.094–8, for each engine family group. The evaporative emission deterioration factor for each evaporative family will be determined and applied in accordance with paragraph (a)(4) of this section.

(ii) The deterioration factors for each engine family group shall be determined by the Administrator using historical durability data from as many as three previous model years. These data will consist of deterioration factors generated by durability data vehicles representing certified engine families and of deterioration factors from vehicles selected under § 86.094–24(h). The

Administrator shall determine how these data will be combined for each engine family group.

(A) The test result to be used in the calculation of each deterioration factor to be combined for each engine family group shall be those test results specified in paragraph (a)(4)(i)(A) of this section.

(B) For each durability data vehicle selected under § 86.094–24(h), all applicable exhaust emission results shall be plotted as a function of the mileage on the system rounded to the nearest mile, and the best fit straight lines, fitted by method of least squares, shall be drawn through all these data points. The exhaust deterioration factor for each durability data vehicle shall be calculated as specified in paragraph (a)(4)(i)(B) of this section.

(C) *Line-crossing.* The line-crossing criteria of § 86.094–28 (a)(4)(i)(B) apply.

(*1*) The Administrator will not accept for certification line-crossing data from preproduction durability data vehicles selected under § 86.094–24(c).

(*2*) The Administrator will not accept for certification line-crossing data from production durability data vehicles selected under § 86.094–24(h)(1) unless the 4,000-mile test result multiplied by the engine family group deterioration factor does not exceed the applicable emission standards. The deterioration factors used for this purpose shall be those that were used in the certification of the production vehicle. Manufacturers may calculate this product immediately after the 4,000-mile test of the vehicle. If the product exceeds the applicable standards, the manufacturer may, with the approval of the Administrator, discontinue the vehicle and substitute a new vehicle. The manufacturer may continue the original vehicle, but the data will not be acceptable if line crossing occurs.

(b)(1) Paragraph (b) of this section applies to light-duty trucks.

(2) Each exhaust and evaporative emission standard (and family particulate emission limit, as appropriate) of § 86.094–9 applies to the emissions of vehicles for the appropriate useful life as defined in §§ 86.094–2 and 86.094–9.

(3) Since emission control efficiency generally decreases with the accumulation of mileage on the vehicle, deterioration factors will be used in combination with emission data vehicle test results as the basis for determining compliance with the standards (or family emission limits, as appropriate).

(4)(i) Paragraph (b)(4) of this section describes the procedure for determining compliance of a new vehicle with exhaust emission standards (or family emission limits, as appropriate), based on deterioration factors. If the manufacturer certifies under the Standard Self-Approval Program as specified in § 86.094–13(f), the manufacturer supplies the deterioration factors. If the manufacturer certifies under the Alternative Service Accumulation Durability Program as specified in § 86.094–13(e), the applicable procedure for the determination of deterioration factors for light-duty trucks is the same as that described in paragraph (a)(4) of this section for light-duty vehicles.

(ii) Separate exhaust emission deterioration factors, determined from tests of vehicles, engines, subsystems, or components conducted by the manufacturer, shall be supplied for each standard and for each engine-system combination.

(iii) The official exhaust emission results for each applicable exhaust emission standard for each emission data vehicle at the selected test point shall be adjusted by multiplication by the appropriate deterioration factor. However, if the deterioration factor supplied by the manufacturer is less than one, it shall be one for the purposes of this paragraph.

(iv) The emission values to compare with the standards (or family emission limits, as appropriate) shall be the adjusted emission values of paragraph (b)(4)(iii) of this section rounded to two significant figures in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section) for each emission data engine.

(5)(i) Paragraphs (b)(5)(i) (A) and (B) of this section apply only to manufacturers electing to participate in the particulate averaging program.

(A) If a manufacturer chooses to change the level of any family particulate emission limit(s), compliance with the new limit(s) must be based upon existing certification data.

(B) The production-weighted average of the family particulate emission limits of all applicable engine families, rounded to two significant figures in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section), must comply with the particulate standards in § 86.094–9(a)(1)(iv) or (d)(1)(iv), or the composite particulate standard as defined in § 86.094–2, as appropriate, at the end of the product year.

(ii) Paragraphs (b)(5)(ii) (A) and (B) of this section apply only to manufacturers electing to participate in the NO_x averaging program.

(A) If a manufacturer chooses to change the level of any family NO_x emission limit(s), compliance with the new limit(s) must be based upon existing certification data.

(B) The production-weighted average of the family NO_x emission limits of all applicable engine families, rounded to two significant figures in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section), must comply with the NO_x emission standards of § 86.094–9(a)(1)(iii) (A) or (B) of § 86.094–9(d)(1)(iii) (A) or (B), or the composite NO_x standard as defined in § 86.094–2, at the end of the product year.

(6) [Reserved].

(7)(i) Paragraph (b)(7) of this section describes the procedure for determining compliance of a new vehicle with evaporative emission standards. The procedure described here shall be used for all vehicles in all model years.

(ii) The manufacturer shall determine, based on testing described in § 86.091–21(b)(4)(i), and supply an evaporative emission deterioration factor for each evaporative emission family-evaporative emission control system combination. The factor shall be calculated by subtracting the emission level at the selected test point from the emission level at the useful life point.

(iii) The official evaporative emission test results for each evaporative emission data vehicle at the selected test point shall be adjusted by the addition of the appropriate deterioration factor. However, if the deterioration factor supplied by the manufacturer is less than zero, it shall be zero for the purposes of this paragraph.

(iv) The emission value to compare with the standards shall be the adjusted emission value of paragraph (b)(7)(iii) of this section rounded to two significant figures in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section) for each evaporative emission data vehicle.

(8) Every test vehicle of an engine family must comply with all applicable standards (and family emission limits, as appropriate), as determined in paragraphs (b)(4)(iv) and (b)(7)(iv) of this section, before any vehicle in that family will be certified.

(c) (1) Paragraph (c) of this section applies to heavy-duty engines.

(2) The exhaust emission standards (or family emission limits, as appropriate) for Otto-cycle engines in § 86.094–10 or for diesel-cycle engines in § 86.094–11 apply to the emissions of engines for their useful life.

(3) Since emission control efficiency generally decreases with the accumulation of service on the engine, deterioration factors will be used in combination with emission data engine test results as the basis for determining compliance with the standards.

(4) (i) Paragraph (c)(4) of this section describes the procedure for determining compliance of an engine with emission standards (or family emission limits, as appropriate), based on deterioration factors supplied by the manufacturer.

(ii) Separate exhaust emission deterioration factors, determined from tests of engines, subsystems, or components conducted by the manufacturer, shall be supplied for each engine-system combination. For Otto-cycle engines, separate factors shall be established for transient HC (OMHCE), CO, and NO_x; and idle CO, for those engines utilizing aftertreatment technology (e.g., catalytic converters). For diesel-cycle engines, separate factors shall be established for transient HC (OMHCE), CO, NO_x, and exhaust particulate. For diesel-cycle smoke testing, separate factors shall also be established for the acceleration mode (designated as "A"), the lugging mode (designated as "B"), and peak opacity (designated as "C").

(iii)(A) Paragraphs (c)(4)(iii)(A) (*1*) and (*2*) of this section apply to Otto-cycle heavy-duty engines.

(*1*) *Otto-cycle heavy-duty engines not utilizing aftertreatment technology (e.g., catalytic converters).* For transient HC (OMHCE), CO, and NO_x, the official exhaust emission results for each emission data engine at the selected test point shall be adjusted by the addition of the appropriate deterioration factor. However, if the deterioration factor supplied by the manufacturer is less than zero, it shall be zero for the purposes of this paragraph.

(*2*) *Otto-cycle heavy-duty engines utilizing aftertreatment technology (e.g., catalytic converters).* For transient HC (OMHCE), CO, and NO_x, and for idle CO, the official exhaust emission results for each emission data engine at the selected test point shall be adjusted by multiplication by the appropriate deterioration factor. However, if the deterioration factor supplied by the manufacturer is less than one, it shall be one for the purposes of this paragraph.

(B) Paragraph (c)(4)(iii)(B) of this section applies to diesel-cycle heavy-duty engines.

(*1*) *Diesel-cycle heavy-duty engines not utilizing aftertreatment technology (e.g., particulate traps).* For transient HC (OMHCE), CO, NO_x, and exhaust particulate, the official exhaust emission results for each emission data engine at the selected test point shall be adjusted by the addition of the appropriate deterioration factor. However, if the deterioration factor supplied by the manufacturer is less than zero, it shall be zero for the purposes of this paragraph.

(*2*) *Diesel-cycle heavy-duty engines utilizing aftertreatment technology (e.g., particulate traps).* For transient HC (OMHCE), CO, NO_x, and exhaust particulate, the official exhaust emission results for each emission data engine at the selected test point shall be adjusted by multiplication by the appropriate deterioration factor. However, if the deterioration factor supplied by the manufacturer is less than one, it shall be one for the purposes of this paragraph.

(*3*) *Diesel-cycle heavy-duty engines only.* For acceleration smoke ("A"), lugging smoke ("B"), and peak smoke ("C"), the official exhaust emission results for each emission data engine at the selected test point shall be adjusted by the addition of the appropriate deterioration factor. However, if the deterioration factor supplied by the manufacturer is less than zero, it shall be zero for the purposes of this paragraph.

(iv) The emission values to compare with the standards (or family emission limits, as appropriate) shall be the adjusted emission values of paragraph (c)(4)(iii) of this section, rounded to the same number of significant figures as contained in the applicable standard in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section), for each emission data engine.

(5)–(6) [Reserved]

(7) Every test engine of an engine family must comply with all applicable standards (or family emission limits, as appropriate), as determined in paragraph (c)(4)(iv) of this section, before any engine in that family will be certified.

(d) (1) Paragraph (d) of this section applies to heavy-duty vehicles equipped with gasoline-fueled or methanol-fueled engines.

(2) The applicable evaporative emission standard in § 86.091–10 or § 86.094–11 applies to the emissions of vehicles for their useful life.

(3)(i) For vehicles with a GVWR of up to 26,000 pounds, because it is expected that emission control efficiency will change during the useful life of the vehicle, an evaporative emission deterioration factor shall be determined from the testing described in § 86.088–23(b)(3) for each evaporative emission family-evaporative emission control system combination to indicate the evaporative emission control system deterioration during the useful life of the vehicle (minimum 50,000 miles). The factor shall be established to a minimum of two places to the right of the decimal.

(ii) For vehicles with a GVWR of greater than 26,000 pounds, because it is expected that emission control efficiency will change during the useful life of the vehicle, each manufacturer's statement as required in § 86.094–23(b)(4)(ii) shall include, in accordance with good engineering practice, consideration of control system deterioration.

(4) The evaporative emission test results, if any, shall be adjusted by the addition of the appropriate deterioration factor, provided that if the deterioration factor as computed in paragraph (d)(3) of this section is less than zero, that deterioration factor shall be zero for the purposes of this paragraph.

(5) The emission level to compare with the standard shall be the adjusted emission level of paragraph (d)(4) of this section. Before any emission value is compared with the standard, it shall be rounded, in accordance with ASTM E 29–67 (reapproved 1980) (as referenced in paragraph (a)(4)(i)(B)(*2*)(*ii*) of this section), to two significant figures. The rounded emission values may not exceed the standard.

(6) Every test vehicle of an evaporative emission family must comply with the evaporative emission standard, as determined in paragraph (d)(5) of this section, before any vehicle in that family may be certified.

(Approved by the Office of Management and Budget under control number 2060–0104)

13. Section 86.094–30 is revised to read as follows:

§ 86.094–30 Certification.

(a)(1)(i) If, after a review of the test reports and data submitted by the manufacturer, data derived from any inspection carried out under § 86.091–7(c) and any other pertinent data or information, the Administrator determines that a test vehicle(s) (or test engine(s)) meets the requirements of the Act and of this subpart, he will issue a certificate of conformity with respect to such vehicle(s) (or engine(s)) except in cases covered by paragraphs (a) (1) (ii) and (c) of this section.

(ii) *Gasoline-fueled and methanol-fueled heavy-duty vehicles.* If, after a review of the statement(s) of compliance submitted by the manufacturer under § 86.094–23(b)(4) and any other pertinent data or information, the Administrator determines that the requirements of the Act and this subpart have been met, he will issue one certificate of conformity per

manufacturer with respect to the evaporative emission family(ies) covered by paragraph (c) of this section.

(2) Such certificate will be issued for such period not to exceed one model year as the Administrator may determine and upon such terms as he may deem necessary or appropriate to assure that any new motor vehicle (or new motor vehicle engine) covered by the certificate will meet the requirements of the Act and of this part.

(3)(i) One such certificate will be issued for each engine family. For gasoline-fueled and methanol-fueled light-duty vehicles and light-duty trucks, one such certificate will be issued for each engine family evaporative emission family combination.

(A) *Light-duty vehicles.* Each certificate will certify compliance with no more than one set of in-use and certification standards (or family emission limits, as appropriate).

(B) *Light-duty trucks.* Each certificate will certify compliance with no more than one set of in-use and certification standards (or family emission limits, as appropriate), except where there are both low-altitude standards and high altitude standards applicable. The certificate shall state that it covers vehicles sold or delivered to an ultimate purchaser for principal use at a designated high-altitude location only if the vehicle conforms in all material respects to the design specifications that apply to those vehicles described in the application for certification at high altitude.

(ii) For gasoline-fueled and methanol-fueled heavy-duty vehicles, one such certificate will be issued for each manufacturer and will certify compliance for those vehicles previously identified in that manufacturer's statement(s) of compliance as required in § 86.094–23(b) (4) (i) and (ii).

(iii) For diesel-cycle light-duty vehicles and light-duty trucks, or diesel-cycle heavy-duty engines, included in the applicable particulate averaging program, the manufacturer may at any time during production elect to change the level of any family particulate emission limit by demonstrating compliance with the new limit as described in §§ 86.094–28(a)(6) and 86.094–28(b)(5)(i) . New certificates issued under this paragraph will be applicable only for vehicles (or engines) produced subsequent to the date of issuance.

(iv) For light-duty trucks or heavy-duty engines included in the applicable NO_x averaging program, the manufacturer may at any time during production elect to change the level of any family NO_x emission limit by demonstrating compliance with the new limit as described in § 86.094–28(b)(5)(ii). New certificates issued under this paragraph will be applicable only for vehicles (or engines) produced subsequent to the day of issue.

(4)(i) The adjustment or modification of any light-duty truck in accordance with instructions provided by the manufacturer for the altitude where the vehicle is principally used will not be considered a violation of section 203(a)(3) of the Clean Air Act (42 U.S.C. 7522 (a)(3)).

(ii) A violation of section 203(a)(1) of the Clean Air Act (42 U.S.C. 7522(a)(1)) occurs when a manufacturer sells or delivers to an ultimate purchaser any light-duty vehicle or light-duty truck, subject to the regulations under the Act, under any of the conditions specified in the remainder of this paragraph.

(A) When a light-duty vehicle or light-duty truck is not configured to meet high-altitude requirements:

(*1*) At a designated high-altitude location, unless such manufacturer has reason to believe that such vehicle will not be sold to an ultimate purchaser for principal use at a designated high-altitude location; or

(*2*) At a location other than a designated high-altitude location, when such manufacturer has reason to believe that such motor vehicle will be sold to an ultimate purchaser for principal use at a designated high-altitude location.

(B) When a light-duty vehicle is not configured to meet low-altitude requirements, as provided in § 86.094–8(i) :

(*1*) At a designated low-altitude location, unless such manufacturer has reason to believe that such vehicle will not be sold to an ultimate purchaser for principal use at a designated low-altitude location; or

(*2*) At a location other than a designated low-altitude location, when such manufacturer has reason to believe that such motor vehicle will be sold to an ultimate purchaser for principal use at a designated low-altitude location.

(iii) A manufacturer shall be deemed to have reason to believe that a light-duty vehicle that has been exempted from compliance with emission standards at high-altitude, or a light-duty truck which is not configured to meet high-altitude requirements, will not be sold to an ultimate purchaser for principal use at a designated high-altitude location if the manufacturer has informed its dealers and field representatives about the terms of these high-altitude regulations, has not caused the improper sale itself, and has taken reasonable action which shall include, but not be limited to, either paragraph (a)(4)(iii) (A) or (B), and paragraph (a)(4)(iii)(C) of this section:

(A) Requiring dealers in designated high-altitude locations to submit written statements to the manufacturer signed by the ultimate purchaser that a vehicle which is not configured to meet high-altitude requirements will not be used principally at a designated high-altitude location; requiring dealers in counties contiguous to designated high-altitude locations to submit written statements to the manufacturer, signed by the ultimate purchaser who represents to the dealer in the normal course of business that he or she resides in a designated high-altitude location, that a vehicle which is not configured to meet high-altitude requirements will not be used principally at a designated high-altitude location; and for each sale or delivery of fleets of ten or more such vehicles in a high-altitude location or in counties contiguous to high-altitude locations, requiring either the selling dealer or the delivering dealer to submit written statements to the manufacturer, signed by the ultimate purchaser who represents to the dealer in the normal course of business that he or she resides in a designated high-altitude location, that a vehicle which is not configured to meet high-altitude requirements will not be used principally at a designated high-altitude location. In addition, the manufacturer will make available to EPA, upon reasonable written request (but not more frequently than quarterly, unless EPA has demonstrated that it has substantial reason to believe that an improperly configured vehicle has been sold), sales, warranty, or other information pertaining to sales of vehicles by the dealers described above maintained by the manufacturer in the normal course of business relating to the altitude configuration of vehicles and the locations of ultimate purchasers; or

(B) Implementing a system which monitors factory orders of low-altitude vehicles by high-altitude dealers, or through other means, identifies dealers that may have sold or delivered a vehicle not configured to meet the high-altitude requirements to an ultimate purchaser for principal use at a designated high-altitude location; and making such information available to EPA upon reasonable written request (but not more frequently than quarterly, unless EPA has demonstrated that it has substantial reason to believe that an improperly configured vehicle has been sold); and

(C) Within a reasonable time after receiving written notice from EPA or a State or local government agency that a

dealer may have improperly sold or delivered a vehicle not configured to meet the high-altitude requirements to an ultimate purchaser residing in a designated high-altitude location, or based on information obtained pursuant to paragraph (a)(4)(iii) of this section that a dealer may have improperly sold or delivered a significant number of such vehicles to ultimate purchasers so residing, reminding the dealer in writing of the requirements of these regulations, and, where appropriate, warning the dealer that sale by the dealer of vehicles not configured to meet high-altitude requirements may be contrary to the terms of its franchise agreement with the manufacturer and the dealer certification requirements of § 85.2108 of this chapter.

(iv) A manufacturer shall be deemed to have reason to believe that a light-duty vehicle which has been exempted from compliance with emission standards at low-altitude, as provided in § 86.094–8(i), will not be sold to an ultimate purchaser for principal use at a designated low-altitude location if the manufacturer has informed its dealers and field representatives about the terms of the high-altitude regulations, has not caused the improper sale itself, and has taken reasonable action which shall include, but not be limited to, either paragraph (a)(4)(iv) (A) or (B), and (a)(4)(iv)(C) of this section:

(A) Requiring dealers in designated low-altitude locations to submit written statements to the manufacturer signed by the ultimate purchaser that a vehicle which is not configured to meet low-altitude requirements will not be used principally at a designated low-altitude location; requiring dealers in counties contiguous to designated low-altitude locations to submit written statements to the manufacturer, signed by the ultimate purchaser who represents to the dealer in the normal course of business that he or she resides in a designated low-altitude location, that a vehicle which is not configured to meet low-altitude requirements will not be used principally at a designated low-altitude location; and for each sale or delivery of fleets of ten or more such vehicles in a low-altitude location or in counties contiguous to low-altitude locations, requiring either the selling dealer or the delivering dealer to submit written statements to the manufacturer, signed by the ultimate purchaser who represents to the dealer in the normal course of business that he or she resides in a designated low-altitude location, that a vehicle which is not configured to meet low-altitude requirements will not be used principally at a designated high-altitude location. In addition, the manufacturer will make available to EPA, upon reasonable written request (but not more frequently than quarterly, unless EPA has demonstrated that it has substantial reason to believe that an improperly configured vehicle has been sold), sales, warranty, or other information pertaining to sales of vehicles by the dealers described above maintained by the manufacturer in the normal course of business relating to the altitude configuration of vehicles and the locations of ultimate purchasers; or

(B) Implementing a system which monitors factory orders of high-altitude vehicles by low-altitude dealers, or through other means, identifies dealers that may have sold or delivered a vehicle not configured to meet the low-altitude requirements to an ultimate purchaser for principal use at a designated low-altitude location; and making such information available to EPA upon reasonable written request (but not more frequently than quarterly, unless EPA has demonstrated that it has substantial reason to believe that an improperly configured vehicle has been sold); and

(C) Within a reasonable time after receiving written notice from EPA or a state or local government agency that a dealer may have improperly sold or delivered a vehicle not configured to meet the low-altitude requirements to an ultimate purchaser residing in a designated low-altitude location, or based on information obtained pursuant to paragraph (a)(4)(iv) of this section that a dealer may have improperly sold or delivered a significant number of such vehicles to ultimate purchasers so residing, reminding the dealer in writing of the requirements of these regulations, and, where appropriate, warning the dealer that sale by the dealer of vehicles not configured to meet low-altitude requirements may be contrary to the terms of its franchise agreement with the manufacturer and the dealer certification requirements of § 85.2108 of this chapter.

(5)(i) For the purpose of paragraph (a) of this section, a "designated high-altitude location" is any county which has substantially all of its area located above 1,219 meters (4,000 feet) and:

(A) Requested and extension past the attainment date of December 31, 1982, for compliance with either the National Ambient Air Quality Standards for carbon monoxide or ozone, as indicated in part 52 (Approval and Promulgation of Implementation Plans) of this title; or

(B) Is in the same state as a county designated as a high-altitude location according to paragraph (a)(5)(i)(A) of this section.

(ii) The designated high-altitude locations defined in paragraph (a)(5)(i) of this section are listed below:

State of Colorado

Adams
Alamosa
Arapahoe
Archuleta
Boulder
Chaffee
Cheyenne
Clear Creek
Conejos
Costilla
Crowley
Custer
Delta
Denver
Dolores
Douglas
Eagle
Elbert
El Paso
Fremont
Garfield
Gilpin
Grand
Gunnison
Hinsdale
Huerfano
Jackson
Jefferson
Kit Carson
Lake
La Plata
Larimer
Las Animas
Lincoln
Mesa
Mineral
Moffat
Montezuma
Montrose
Morgan
Otero
Ouray
Park
Pitkin
Pueblo
Rio Blanco
Rio Grande
Routt
Saguache
San Juan
San Miguel
Summit
Teller
Washington
Weld

State of Nevada

Carson City
Douglas
Elko
Esmeralda
Eureka
Humboldt
Lander
Lincoln
Lyon
Mineral
Nye
Pershing
Storey
Washoe
White Pine

State of New

Bernalillo
Catron
Colfax
Curry
De Baca
Grant
Guadalupe
Harding
Hidalgo
Lincoln
Los Alamos
Luna
McKinley
Mora
Otero
Rio Arriba
Roosevelt
Sandoval
San Juan
San Miguel
Santa Fe
Sierra
Socorro
Taos
Torrance
Union
Valencia

State of Uta

Beaver
Box Elder
Cache
Carbon
Daggett
Davis
Duchesne
Emery
Garfield
Grand
Iron
Juab
Kane
Millard
Morgan
Piute
Rich
Salt Lake
San Juan
Sanpete
Sevier
Summit
Tooele
Uintah
Utah
Wasatch
Wayne
Weber

(iii) For
of this sect
altitude lo
has substa
below 1,21

(iv) The
locations a
in the Unit
in either p
section or

State of Ari

Apache
Cochise
Coconino
Navajo
Yavapai

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State of New Mexico

Bernalillo
Catron
Colfax
Curry
De Baca
Grant
Guadalupe
Harding
Hidalgo
Lincoln
Los Alamos
Luna
McKinley
Mora
Otero
Rio Arriba
Roosevelt
Sandoval
San Juan
San Miguel
Santa Fe
Sierra
Socorro
Taos
Torrance
Union
Valencia

State of Utah

Beaver
Box Elder
Cache
Carbon
Daggett
Davis
Duchesne
Emery
Garfield
Grand
Iron
Juab
Kane
Millard
Morgan
Piute
Rich
Salt Lake
San Juan
Sanpete
Sevier
Summit
Tooele
Uintah
Utah
Wasatch
Wayne
Weber

(iii) For the purpose of paragraph (a) of this section, a "designated low-altitude location" is any county which has substantially all of its area located below 1,219 meters (4,000 feet).

(iv) The designated low-altitude locations so defined include all counties in the United States which are not listed in either paragraph (a)(5)(ii) of this section or in the list below:

State of Arizona

Apache
Cochise
Coconino
Navajo
Yavapai

State of Idaho

Bannock
Bear Lake
Bingham
Blaine
Bonneville
Butte
Camas
Caribou
Cassia
Clark
Custer
Franklin
Fremont
Jefferson
Lemhi
Madison
Minidoka
Oneida
Power
Treton
Valley

State of Montana

Beaverhead
Deer Lodge
Gallatin
Jefferson
Judith Basin
Madison
Meagher
Park
Powell
Silver Bow
Wheatland

State of Nebraska

Banner
Cheyenne
Kimball
Sioux

State of Oregon

Harney
Klamath
Lake

State of Texas

Jeff Davis
Hudspeth
Parmer

State of Wyoming

Albany
Campbell
Carbon
Converse
Fremont
Goshen
Hot Springs
Johnson
Laramie
Lincoln
Natrona
Niobrara
Park
Platte
Sublette
Sweetwater
Teton
Uinta
Washakie
Weston

(6) Catalyst-equipped vehicles, otherwise covered by a certificate, which are driven outside the United States, Canada, and Mexico will be presumed to have been operated on leaded gasoline resulting in deactivation of the catalysts. If these vehicles are imported or offered for importation without retrofit of the catalyst, they will be considered not to be within the coverage of the certificate unless included in a catalyst control program operated by a manufacturer or a United States Government agency and approved by the Administrator.

(7) For incomplete light-duty trucks, a certificate covers only those new motor vehicles which, when completed by having the primary load-carrying device or container attached, conform to the maximum curb weight and frontal area limitations described in the application for certification as required in § 86.094–21(d).

(8) For heavy-duty engines, a certificate covers only those new motor vehicle engines installed in heavy-duty vehicles which conform to the minimum gross vehicle weight rating, curb weight, or frontal area limitations for heavyduty vehicles described in § 86.082–2.

(9) For incomplete gasoline-fueled and methanol-fueled heavy-duty vehicles a certificate covers only those new motor vehicles which, when completed, conform to the nominal maximum fuel tank capacity limitations as described in the application for certification as required in § 86.094–21(e).

(10)(i) For diesel-cycle light-duty vehicle and diesel-cycle light-duty truck families which are included in a particulate averaging program, the manufacturer's production-weighted average of the particulate emission limits of all engine families in a participating class or classes shall not exceed the applicable diesel-cycle particulate standard, or the composite particulate standard defined in § 86.090–2 as appropriate, at the end of the model year, as determined in accordance with this part. The certificate shall be void ab initio for those vehicles causing the production-weighted FEL to exceed the particulate standard.

(ii) For all heavy-duty diesel-cycle engines which are included in the particulate averaging, trading, or banking programs under § 86.094–15, the provisions of paragraphs (a)(10)(ii)(A) through (C) of this section apply.

(A) All certificates issued are conditional upon the manufacturer complying with the provisions of § 86.094–15 and the averaging, trading, and banking related provision of other applicable sections, both during and after the model year production.

(B) Failure to comply with all provisions of § 86.094–15 will be considered to be a failure to satisfy the conditions upon which the certificate was issued, and the certificate may be deemed void ab initio.

(C) The manufacturer shall bear the burden of establishing to the satisfaction of the Administrator that the conditions upon which the certificate was issued were satisfied or excused.

(11) (i) For light-duty truck families which are included in a NO_x averaging program, the manufacturer's production-weighted average of the NO_x emission limits of all such engine families shall not exceed the applicable NO_x emission standard, or the composite NO_x emission standard defined in § 86.088–2, as appropriate, at the end of the model year, as determined in accordance with this part. The certificate shall be void ab initio for those vehicles causing the production-weighted FEL to exceed the NO_x standard.

(ii) For all heavy duty engines which are included in the NO_x averaging, trading, or banking programs under § 86.091–15, the provisions of paragraphs (a)(11)(ii) (A) through (C) of this section apply.

(A) All certificates issued are conditional upon the manufacturer complying with the provisions of § 86.094–15 and the averaging, trading, and banking related provision of other applicable sections, both during and after the model year production.

(B) Failure to comply with all provisions of § 86.094–15 will be considered to be a failure to satisfy the conditions upon which the certificate was issued, and the certificate may be deemed void ab initio.

(C) The manufacturer shall bear the burden of establishing to the satisfaction of the Administrator that the "conditions upon which the certificate was issued were satisfied or excused.

(12) For all light-duty vehicles certified to standards under § 86.094–8 or to which standards under § 86.708–94 are applicable, the provisions of paragraphs (a)(12) (i) through (iii) of this section apply.

(i) All certificates issued are conditional upon the manufacturer complying with all provisions of §§ 86.094–8 and 86.708–94 both during and after model year production.

(ii) Failure to meet the required implementation schedule sales percentages as specified in §§ 86.094–8 and § 86.708–94 will be considered to be a failure to satisfy the conditions upon which the certificate(s) was issued and the vehicles sold in violation of the implementation schedule shall not be covered by the certificate.

(iii) The manufacturer shall bear the burden of establishing to the satisfaction of the Administrator that the conditions upon which the certificate was issued were satisfied.

(13) For all light-duty trucks certified to standards under § 86.094–9 and to which standards under § 86.709–94 are applicable, the provisions of paragraphs (a)(13) (i) through (iii) this section apply.

(i) All certificates issued are conditional upon the manufacturer complying with all provisions of §§ 86.094–9 and 86.709–94 both during and after model year production.

(ii) Failure to meet the required implementation schedule sales percentages as specified in §§ 86.094–9 and 86.709–94 will be considered to be a failure to satisfy the conditions upon which the certificate(s) was issued and the individual vehicles sold in violation of the implementation schedule shall not be covered by the certificate.

(iii) The manufacturer shall bear the burden of establishing to the satisfaction of the Administrator that the conditions upon which the certificate was issued were satisfied.

(14) For all light-duty vehicles and light-duty trucks certified with an Alternative Service Accumulation Durability Program under § 86.094–13(e), paragraphs (a)(14) (i) through (iii) of this section apply.

(i) All certificates issued are conditional upon the manufacturer performing the in-use verification program pursuant to the agreement described in § 86.094–13(e)(8).

(ii) Failure to fully comply with all the terms of the in-use verification program pursuant to the agreement described in § 86.094–13(e)(8) will be considered a failure to satisfy the conditions upon which the certificate was issued. A vehicle or truck will be considered to be covered by the certificate only if the manufacturer fulfills the conditions upon which the certificate is issued.

(iii) The manufacturer shall bear the burden of establishing to the satisfaction of the Administrator that the conditions upon which the certificate was issued were satisfied.

(b)(1) The Administrator will determine whether a vehicle (or engine) covered by the application complies with applicable standards (or family emission limits, as appropriate) by observing the following relationships: in paragraphs (b)(1) (i) through (iv) of this section:

(i) *Light-duty vehicles.* (A) The durability data vehicle(s) selected under § 86.094–24(c)(1)(i) shall represent all vehicles of the same engine system combination.

(B) The emission data vehicle(s) selected under § 86.094–24(b)(1) (ii) through (iv) shall represent all vehicles of the same engine-system combination as applicable.

(C) The emission data vehicle(s) selected under § 86.094–24(b)(1)(vii) (A) and (B) shall represent all vehicles of the same evaporative control system within the evaporative family.

(ii) *Light-duty trucks.* (A) The emission data vehicle(s) selected under § 86.094–24(b)(1)(ii), shall represent all vehicles of the same engine-system combination as applicable.

(B) The emission data vehicle(s) selected under § 86.094–24 (b)(I)(vii) (A) and (B) shall represent all vehicles of the same evaporative control system within the evaporative family.

(C) The emission data vehicle(s) selected under § 86 .09424(b) (1} (v) shall represent all vehicles of the same enginesystem combination as applicable.

(D) The emission data vehicle(s) selected under § 86.094–24(b)(1)(viii) shall represent all vehicles of the same evaporative control system within the evaporative emission family, as applicable.

(iii) *Heavy-duty engines.* (A) An Otto-cycle emission data test engine selected under § 86.094–24(b)(2)(iv) shall represent all engines in the same family of the same engine displacement-exhaust emission control system combination.

(8) An Otto-cycle emission data test engine selected under § 86.094–24(b)(2)(iii) shall represent all engines in the same engine family of the same engine displacement-exhaust emission control system combination.

(C) A diesel emission data test engine selected under § 86.094–24(b)(3)(ii) shall represent all engines in the same engine-system combination.

(D) A diesel emission data test engine selected under § 86.094–24(b)(3)(iii) shall represent all engines of that emission control system at the rated fuel delivery of the test engine.

(iv) Gasoline-fueled and methanol-fueled heavy-duty vehicles. A statement of compliance submitted under § 86.094–23(b)(4) (i) or (ii) shall represent all vehicles in the same evaporative emission family-evaporative emission control system combination.

(2) The Administrator will proceed as in paragraph (a) of this section with respect to the vehicles (or engines) belonging to an engine family or engine family-evaporative emission family combination (as applicable), all of

which comply with all applicable standards (or family emission limits, as appropriate).

(3) If after a review of the test reports and data submitted by the manufacturer, data derived from any additional testing conducted pursuant to § 86.091–29, data or information derived from any inspection carried out under § 86.094–7(d) or any other pertinent data or information, the Administrator determines that one or more test vehicles (or test engines) of the certification test fleet do not meet applicable standards (or family emission limits, as appropriate), he will notify the manufacturer in writing, setting forth the basis for his determination. Within 30 days following receipt of the notification, the manufacturer may request a hearing on the Administrator's determination. The request shall be in writing, signed by an authorized representative of the manufacturer and shall include a statement specifying the manufacturer's objections to the Administrator's determination and data in support of such objections. If, after a review of the request and supporting data, the Administrator finds that the request raises a substantial factual issue, he shall provide the manufacturer a hearing in accordance with § 86.078–6 with respect to such issue.

(4) For light-duty vehicles and light-duty trucks the manufacturer may, at its option, proceed with any of the following alternatives with respect to an emission data vehicle determined not in compliance with all applicable standards (or family emission limits, as appropriate) for which it was tested:

(i) Request a hearing under § 86.078–6; or

(ii) Remove the vehicle configuration (or evaporative vehicle configuration, as applicable) which failed, from his application:

(A) If the failed vehicle was tested for compliance with exhaust emission standards (or family emission limits, as appropriate) only: The Administrator may select, in place of the failed vehicle, in accordance with the selection criteria employed in selecting the failed vehicle, a new emission data vehicle to be tested for exhaust emission compliance only; or

(B) If the failed vehicle was tested for compliance with both exhaust and evaporative emission standards: The Administrator may select, in place of the failed vehicle, in accordance with the selection criteria employed in selecting the failed vehicle, a new emission data vehicle which will be tested for compliance with both exhaust and evaporative emission standards. If one vehicle cannot be selected in accordance with the selection criteria employed in selecting the failed vehicle, then two vehicles may be selected (i.e., one vehicle to satisfy the exhaust emission vehicle selection criteria and one vehicle to satisfy the evaporative emission vehicle selection criteria). The vehicle selected to satisfy the exhaust emission vehicle selection criteria will be tested for compliance with exhaust emission standards (or family emission limits, as appropriate) only. The vehicle selected to satisfy the evaporative emission vehicle selection criteria will be tested for compliance with both exhaust and evaporative emission standards; or

(iii) Remove the vehicle configuration (or evaporative vehicle configuration, as applicable) which failed from the application and add a vehicle configuration(s) (or evaporative vehicle configuration(s), as applicable) not previously listed. The Administrator may require, if applicable, that the failed vehicle be modified to the new engine code (or evaporative emission code, as applicable) and demonstrate by testing that it meets applicable standards (or family emission limits, as appropriate) for which it was originally tested. In addition, the Administrator may select, in accordance with the vehicle selection criteria given in § 86.094–24(b), a new emission data vehicle or vehicles. The vehicles selected to satisfy the exhaust emission vehicle selection criteria will be tested for compliance with exhaust emission standards (or family emission limits, as appropriate) only. The vehicles selected to satisfy the evaporative emission vehicle selection criteria will be tested for compliance with both exhaust and evaporative emission standards (or family emission limits, as appropriate); or

(iv) Correct a component or system malfunction and show that with a correctly functioning system or component the failed vehicle meets applicable standards (or family emission limits, as appropriate) for which it was originally tested. The Administrator may require a new emission data vehicle, of identical vehicle configuration (or evaporative vehicle configuration, as applicable) to the failed vehicle, to be operated and tested for compliance with the applicable standards (or family emission limits, as appropriate) for which the failed vehicle was originally tested.

(5) For heavy-duty engines the manufacturer may, at his option, proceed with any of the following alternatives with respect to any engine family represented by a test engine (s) determined not in compliance with applicable standards (or family emission limit, as appropriate):

(i) Request a hearing under § 86.078–6; or

(ii) Delete from the application for certification the engines represented by the failing test engine. (Engines so deleted may be included in a later request for certification under § 86.079–32.) The Administrator may then select in place of each failing engine an alternate engine chosen in accordance with selection criteria employed in selecting the engine that failed; or

(iii) Modify the test engine and demonstrate by testing that it meets applicable standards. Another engine which is in all material respect the same as the first engine, as modified, may then be operated and tested in accordance with applicable test procedures.

(6) If the manufacturer does not request a hearing or present the required data under paragraphs (b) (4) or (5) of this section (as applicable) of this section, the Administrator will deny certification.

(c)(1) Notwithstanding the fact that any certification vehicle(s) (or certification engine(s)) may comply with other provisions of this subpart, the Administrator may withhold or deny the issuance of a certificate of conformity (or suspend or revoke any such certificate which has been issued) with respect to any such vehicle(s) (or engine(s)) if:

(i) The manufacturer submits false or incomplete information in his application for certification thereof;

(ii) The manufacturer renders inaccurate any test data which he submits pertaining thereto or otherwise circumvents the intent of the Act, or of this part with respect to such vehicle (or engine);

(iii) Any EPA Enforcement Officer is denied access on the terms specified in § 86.091–7(d) to any facility or portion thereof which contains any of the following:

(A) The vehicle (or engine);

(B) Any components used or considered for use in its modification or buildup into a certification vehicle (or certification engine);

(C) Any production vehicle (or production engine) which is or will be claimed by the manufacturer to be covered by the certificate;

(D) Any step in the construction of a vehicle (or engine) described in paragraph (c)(iii)(C) of this section;

(E) Any records, documents, reports, or histories required by this part to be kept concerning any of the above; or

(iv) Any EPA Enforcement Officer is denied "reasonable assistance" (as

defined in § 86.091–7(d) in examining any of the items listed in paragraph (c)(1)(iii) of this section.

(2) The sanctions of withholding, denying, revoking, or suspending of a certificate may be imposed for the reasons in paragraphs (c)(1) (i), (ii), (iii), or (iv) of this section only when the infraction is substantial.

(3) In any case in which a manufacturer knowingly submits false or inaccurate information or knowingly renders inaccurate or invalid any test data or commits any other fraudulent acts and such acts contribute substantially to the Administrator's decision to issue a certificate of conformity, the Administrator may deem such certificate void ab initio.

(4) In any case in which certification of a vehicle (or engine) is proposed to be withheld, denied, revoked, or suspended under paragraph (c)(1) (iii) or (iv) of this section, and in which the Administrator has presented to the manufacturer involved reasonable evidence that a violation of § 86.091–7(d) in fact occurred, the manufacturer, if he wishes to contend that, even though the violation occurred, the vehicle (or engine) in question was not involved in the violation to a degree that would warrant withholding, denial, revocation, or suspension of certification under either paragraph (c)(1) (iii) or (iv) of this section, shall have the burden of establishing that contention to the satisfaction of the Administrator.

(5) Any revocation or suspension of certification under paragraph (c)(1) of this section shall:

(i) Be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with § 86.078–6 hereof; and

(ii) Extend no further than to forbid the introduction into commerce of vehicles (or engines) previously covered by the certification which are still in the hands of the manufacturer, except in cases of such fraud or other misconduct as makes the certification invalid ab initio.

(6) The manufacturer may request in the form and manner specified in paragraph (b)(3) of this section that any determination made by the Administrator under paragraph (c)(1) of this section to withhold or deny certification be reviewed in a hearing conducted in accordance with § 86.078–6. If the Administrator finds, after a review of the request and supporting data, that the request raises a substantial factual issue, he will grant the request with respect to such issue.

(d)(1) For light-duty vehicles. Notwithstanding the fact that any vehicle configuration or engine family may be covered by a valid outstanding certificate of conformity, the Administrator may suspend such outstanding certificate of conformity in whole or in part with respect to such vehicle configuration or engine family if:

(i) The manufacturer refuses to comply with the provisions of a test order issued by the Administrator pursuant to § 86.603; or

(ii) The manufacturer refuses to comply with any of the requirements of § 86.603; or

(iii) The manufacturer submits false or incomplete information in any report or information provided pursuant to the requirements of § 86.609; or

(iv) The manufacturer renders inaccurate any test data which he submits pursuant to § 86.609; or

(v) Any EPA Enforcement Officer is denied the opportunity to conduct activities related to entry and access as authorized in § 86.606 of this part and in a warrant or court order presented to the manufacturer or the party in charge of a facility in question; or

(vi) EPA Enforcement Officers are unable to conduct activities related to entry and access or to obtain "reasonable assistance" as authorized in § 86.606 of this part because a manufacturer has located its facility in a foreign jurisdiction where local law prohibits those activities; or

(vii) The manufacturer refuses to or in fact does not comply with § 86.604(a), § 86.605, § 86.607, § 86.608, or § 86.610.

(2) The sanction of suspending a certificate may not be imposed for the reasons in paragraph (d)(1) (i), (ii), or (vii) of this section where the refusal is caused by conditions and circumstances outside the control of the manufacturer which render it impossible to comply with those requirements.

(3) The sanction of suspending a certificate may be imposed for the reasons in paragraph (d)(1) (iii), (iv), or (v) of this section only when the infraction is substantial.

(4) In any case in which a manufacturer knowingly submitted false or inaccurate information or knowingly rendered inaccurate any test data or committed any other fraudulent acts, and such acts contributed substantially to the Administrator's original decision not to suspend or revoke a certificate of conformity in whole or in part, the Administrator may deem such certificate void from the date of such fraudulent act.

(5) In any case in which certification of a vehicle is proposed to be suspended under paragraph (d)(1)(v) of this section and in which the Administrator has presented to the manufacturer involved reasonable evidence that a violation of § 86.606 in fact occurred, if the manufacturer wishes to contend that, although the violation occurred, the vehicle configuration or engine family in question was not involved in the violation to a degree that would warrant suspension of certification under paragraph (d)(1)(v) of this section, the manufacturer shall have the burden of establishing the contention to the satisfaction of the Administrator.

(6) Any suspension of certification under paragraph (d)(1) of this section shall:

(i) Be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with § 86.614; and

(ii) Not apply to vehicles no longer in the hands of the manufacturer.

(7) Any voiding of a certificate of conformity under paragraph (d)(4) of this section will be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with § 86.614.

(8) Any voiding of the certificate under § 86.091–30(a)(10) will be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with § 86.614.

(e) *For light-duty trucks and heavy-duty engines.* (1) Notwithstanding the fact that any vehicle configuration or engine family may be covered by a valid outstanding certificate of conformity, the Administrator may suspend such outstanding certificate of conformity in whole or in part with respect to such vehicle or engine configuration or engine family if:

(i) The manufacturer refuses to comply with the provisions of a test order issued by the Administrator pursuant to § 86.1003; or

(ii) The manufacturer refuses to comply with any of the requirements of § 86.1003; or

(iii) The manufacturer submits false or incomplete information in any report or information provided pursuant to the requirements of § 86.1009; or

(iv) The manufacturer renders inaccurate any test data submitted pursuant to § 86.1009; or

(v) Any EPA Enforcement Officer is denied the opportunity to conduct activities related to entry and access as authorized in § 86.1006 of this part and in a warrant or court order presented to the manufacturer or the party in charge of a facility in question; or

(vi) EPA Enforcement Officers are unable to conduct activities related to entry and access as authorized in § 86.1006 of this part because a manufacturer has located a facility in a foreign jurisdiction where local law prohibits those activities; or

(vii) The manufacturer refuses to or in fact does not comply with the requirements of §§ 86.1004(a), 86.1005, 86.1007, 86.1008, 86.1010, 86.1011, or 86.1013.

(2) The sanction of suspending a certificate may not be imposed for the reasons in paragraph (e)(1) (i), (ii), or (vii) of this section where such refusal or denial is caused by conditions and circumstances outside the control of the manufacturer which renders it impossible to comply with those requirements. Such conditions and circumstances shall include, but are not limited to, any uncontrollable factors which result in the temporary unavailability of equipment and personnel needed to conduct the required tests, such as equipment breakdown or failure or illness of personnel, but shall not include failure of the manufacturers to adequately plan for and provide the equipment and personnel needed to conduct the tests. The manufacturer will bear the burden of establishing the presence of the conditions and circumstances required by this paragraph.

(3) The sanction of suspending a certificate may be imposed for the reasons outlined in paragraph (e)(1) (iii), (iv), or (v) of this section only when the infraction is substantial.

(4) In any case in which a manufacturer knowingly submitted false or inaccurate information or knowingly rendered inaccurate any test data or committed any other fraudulent acts, and such acts contributed substantially to the Administrator's original decision not to suspend or revoke a certificate of conformity in whole or in part, the Administrator may deem such certificate void from the date of such fraudulent act.

(5) In any case in which certification of a light-duty truck or heavy-duty engine is proposed to be suspended under paragraph (e)(1)(v) of this section and in which the Administrator has presented to the manufacturer involved reasonable evidence that a violation of § 86.1006 in fact occurred, if the manufacturer wishes to contend that, although the violation occurred, the vehicle or engine configuration or engine family in question was not involved in the violation to a degree that would warrant suspension of certification under paragraph (e)(1)(v) of this section, he shall have the burden of establishing that contention to the satisfaction of the Administrator.

(6) Any suspension of certification under paragraph (e)(1) of this section shall:

(i) Be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with § 86.1014; and

(ii) Not apply to vehicles or engines no longer in the hands of the manufacturer.

(7) Any voiding of a certificate of conformity under paragraph (e)(4) of this section shall be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with § 86.1014.

(8) Any voiding of the certificate under paragraph (a) (10) or (11) of this section will be made only after the manufacturer concerned has been offered an opportunity for a hearing conducted in accordance with § 86.1014.

(Approved by the Office of Management and Budget under control number 2060–0104)

14. Section 86.094–35 is amended by removing and reserving paragraphs (a)(2)(iii)(F) and (c)(1)(ii)(B)(*2*).

15. Section 86.095–14 is revised to read as follows:

§ 86.095–14 Small-volume manufacturers certification procedures.

Section 86.095–14 includes text that specifies requirements that differ from § 86.094–14. Where a paragraph in § 86.094–14 is identical and applicable to § 86.095–14, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.094–14." Where a corresponding paragraph of § 86.094–14 is not applicable, this is indicated by the statement "[Reserved]."

(a) through (c)(11)(ii)(B)(*15*) [Reserved]. For guidance see § 86.094–14.

(c)(11)(ii)(B)(*16*) A description of vehicle adjustments or modifications required by §§ 86.094–8(j) and 86.094–9(j), if any, to assure that light-duty vehicles and light-duty trucks covered by a certificate of conformity conform to the regulations while being operated at any altitude locations, and a statement of the altitude at which the adjustments or modifications apply.

(*17*) A description of the light-duty vehicles and light-duty trucks which are exempted from the high altitude emission standards.

(*18*) Proof that the manufacturer has obtained or entered an agreement to purchase, when applicable, the insurance policy required by the § 85.1510(b) of this chapter. The manufacturer may submit a copy of the insurance policy or purchase agreement as proof that the manufacturer has obtained or entered an agreement to purchase the insurance policy.

(C) The results of all emission tests the manufacturer performs to demonstrate compliance with the applicable standards.

(D)(*1*) The following statement signed by the authorized representative of the manufacturer: "The vehicles (or engines) described herein have been tested in accordance with (list of the applicable subparts A, B, D, I, M, N, or P) of part 86, title 40, Code of Federal Regulations, and on the basis of those tests are in conformance with that subpart. All of the data and records required by that subpart are on file and are available for inspection by the EPA Administrator. We project the total U.S. sales of vehicles (engines) subject to this subpart (including all vehicles and engines imported under the provisions of 40 CFR 85.1505 and 40 CFR 85.1509) to be fewer than 10,000 units."

(*2*) A statement as required by and contained in § 86.094–14(c)(5) signed by the authorized representative of the manufacturer.

(*3*) A statement that the vehicles or engines described in the manufacturer's application for certification are not equipped with auxiliary emission control devices which can be classified as a defeat device as defined in § 86.092–2.

(*4*) A statement of compliance with section 206(a)(3) of the Clean Air Act (42 U.S.C. 7525(a)(3)).

(*5*) A statement that, based on the manufacturer's engineering evaluation and/or emission testing, the light-duty vehicles and light-duty trucks comply with emission standards at high altitude unless exempt under § 86.094–8(h) or § 86.094–9(h).

(*6*) [Reserved]

(c)(11)(ii) (D)(*7*) through (c)(15) [Reserved] . For guidance see § 86.094–14.

(Approved by the Office of Management and Budget under control number 2060–0104)

16. Section 86.095–24 is revised to read as follows:

§ 86.095–24 Test vehicles and engines.

Section 86.095–24 includes text that specifies requirements that differ from § 86.094–24. Where a paragraph in § 86.094–24 is identical and applicable to § 86.095–24, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.094–24." Where a

corresponding paragraph of § 86.094–24 is not applicable, this is indicated by the statement "[Reserved]."

(a) through (b)(1)(v) introductory text [Reserved]. For guidance see § 86.094–24.

(b)(1)(v)(A) The manufacturer will select for testing under high-altitude conditions the vehicle expected to exhibit the highest emissions from the nonexempt vehicles selected in accordance with § 86.094–24(b)(1) (ii), (iii), and (iv); or

(B) In lieu of testing vehicles according to paragraph (b)(1)(v)(A) of this section, a manufacturer may provide a statement in its application for certification that, based on the manufacturer's engineering evaluation of such high-altitude emission testing as the manufacturer deems appropriate that all light-duty vehicles and light-duty trucks not exempt under § 86.090–8(h) or § 86.094–9(h) comply with the emission standards at high altitude.

(vi) If 90 percent or more of the engine family sales will be in California, a manufacturer may substitute emission data vehicles selected by the California Air Resources Board criteria for the selections specified in § 86.094–24(b)(1) (i), (ii), and (iv).

(vii)(A) Vehicles of each evaporative emission family will be divided into evaporative emission control systems.

(B) The Administrator will select the vehicle expected to exhibit the highest evaporative emissions, from within each evaporative family to be certified, from among the vehicles represented by the exhaust emission data selections for the engine family, unless evaporative testing has already been completed on the vehicle expected to exhibit the highest evaporative emissions for the evaporative family as part of another engine family's testing.

(C) If the vehicles selected in accordance with paragraph (b)(1)(vii)(B) of this section do not represent each evaporative emission control system then the Administrator will select the highest expected evaporative emission vehicle from within the unrepresented evaporative system.

(viii) For high-altitude evaporative emission compliance for each evaporative emission family, the manufacturer shall follow one of the following procedures:

(A) The manufacturer will select for testing under high-altitude conditions the one nonexempt vehicle previously selected under paragraph (b)(1)(vii) (B) or (C) of this section which is expected to have the highest level of evaporative emissions when operated at high altitude; or

(B) In lieu of testing vehicles according to § 86.094–24(b)(1)(viii)(A), a manufacturer may provide a statement in its application for certification that, based on the manufacturer's engineering evaluation of such high-altitude emission testing as the manufacturer deems appropriate, that all light-duty vehicles and light-duty trucks not exempt under § 86.090–8(h) or § 86.094–9(h) comply with the emission standards at high altitude.

(ix) Vehicles selected under paragraph (b)(1)(v)(A) of this section may be used to satisfy the requirements of paragraph (b)(1)(viii)(A) of this section.

(x) [Reserved].

(b)(2) through (h) [Reserved]. For guidance see § 86.094–24.

(Approved by the Office of Management and Budget under control number 2060–0104)

17. Section 86.095–26 is revised to read as follows:

§ 86.095–26 Mileage and service accumulation; emission measurements.

Section 86.095–26 includes text that specifies requirements that differ from § 86.094–26. Where a paragraph in § 86.094–26 is identical and applicable to § 86.095–26, this may be indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.094–26." Where a corresponding paragraph of § 86.094–26 is not applicable, this is indicated by the statement "[Reserved]."

(a) through (b)(4)(i)(C) [Reserved]. For guidance see § 86.094–26.

(b)(4)(i)(D) For each engine family, the manufacturer will either select one vehicle previously selected under § 86.094–24(b)(1) (i) through (iv) to be tested under high altitude conditions or provide a statement in accordance with § 86.095–24(b)(1)(v). Vehicles shall meet emission standards under both low- and high-altitude conditions without manual adjustments or modifications. In addition, any emission control device used to conform with the emission standards under high-altitude conditions shall initially actuate (automatically) no higher than 4,000 feet above sea level.

(ii) *Diesel.* (A) The manufacturer shall determine, for each engine family, the mileage at which the engine-system combination is stabilized for emission data testing. The manufacturer shall maintain, and provide to the Administrator if requested, a record of the rationale used in making this determination. The manufacturer may elect to accumulate 4,000 miles on each test vehicle within an engine family without making a determination. The manufacturer must accumulate a minimum of 2,000 miles (3,219 kilometers) on each test vehicle within an engine family. All test vehicle mileage must be accurately determined, recorded, and reported to the Administrator. Any vehicle used to represent emission data vehicle selections under § 86.094–24(b)(1) shall be equipped with an engine and emission control system that has accumulated the mileage the manufacturer chose to accumulate on the test vehicle. Fuel economy data generated from certification vehicles selected in accordance with § 86.094–24(b)(1) with engine-system combinations that have accumulated more than 10,000 kilometers (6,200 miles) shall be factored in accordance with § 600.006–87(c) of this chapter. Complete exhaust emission tests shall be conducted for each emission data vehicle selection under § 86.094–24(b)(1). The Administrator may determine under § 86.094–24(f) that no testing is required.

(B) Emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1)(v) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing or at the 6,436 kilometer (4,000 mile) test point under high-altitude conditions.

(C) Exhaust and evaporative emission tests for emission data vehicle(s) selected for testing under § 86.094–24(b)(1) (ii), (iii), and (iv) shall be conducted at the mileage (2,000 mile minimum) at which the engine-system combination is stabilized for emission testing or at the 6,436 kilometer (4,000 mile) test point under low-altitude conditions.

(D) For each engine family, the manufacturer will either select one vehicle previously selected under § 86.094–26(b)(1) (i) through (iv) to be tested under high altitude conditions or provide a statement in accordance with § 86.095–24(b)(1)(v). Vehicles shall meet emission standards under both low- and high-altitude conditions without manual adjustments or modifications. In addition, any emission control device used to conform with the emission standards under high-altitude conditions shall initially actuate (automatically) no higher than 4,000 feet above sea level.

(b)(4)(iii) through (d) [Reserved]. For guidance see § 86.094–26.

(Approved by the Office of Management and Budget under control number 2060–0104)

18. Section 86.095–30 is revised to read as follows:

§ 86.095–30 Certification.

Section 86.095–30 includes only text that specifies requirements that differ from § 86.094–30. Where a paragraph in § 86.094–30 is identical and applicable to § 86.095–30, this is indicated by specifying the corresponding paragraph and the statement "[Reserved]. For guidance see § 86.094–30." Where a corresponding paragraph of § 86.094–30 is not applicable, this is indicated by the statement "[Reserved]."

(a)(1)(i) through (a)(2) [Reserved]. For guidance see § 86.094–30.

(a)(3)(i) One such certificate will be issued for each engine family. For gasoline-fueled and methanol-fueled light-duty vehicles and light-duty trucks, one such certificate will be issued for each engine family evaporative emission family combination. Each certificate will certify compliance with no more than one set of in-use and certification standards (or family emission limits, as appropriate).

(ii) For gasoline-fueled and methanol fueled heavy-duty vehicles, one such certificate will be issued for each manufacturer and will certify compliance for those vehicles previously identified in that manufacturer's statement(s) of compliance as required in § 86.094–23(b)(4) (i) and (ii).

(iii) For diesel light-duty vehicles and light-duty trucks, or diesel heavy-duty engines, included in the applicable particulate averaging program, the manufacturer may at any time during production elect to change the level of any family particulate emission limit by demonstrating compliance with the new limit as described in §§ 86.094–28(a)(6) and 86.094–28(b)(5)(i). New certificates issued under this paragraph will be applicable only for vehicles (or engines) produced subsequent to the date of issuance.

(iv) For light-duty trucks or heavy-duty engines included in the applicable NO_x averaging program, the manufacturer may at any time during production elect to change the level of any family NO_x emission limit by demonstrating compliance with the new limit as described in § 86.094–28(b)(5)(ii). New certificates issued under this paragraph will be applicable only for vehicles (or engines) produced subsequent to the day of issue.

(4)(i) For exempt light-duty vehicles and light-duty trucks under the provisions of §§ 86.094–8(j) or 86.094–9(j), an adjustment or modification performed in accordance with instructions provided by the manufacturer for the altitude where the vehicle is principally used will not be considered a violation of section 203(a)(3) of the Clean Air Act (42 U.S.C. 7522(a)(3)).

(ii) A violation of section 203(a)(1) of the Clean Air Act (42 U.S.C. 7522(a)(1)) occurs when a manufacturer sells or delivers to an ultimate purchaser any light-duty vehicle or light-duty truck, subject to the regulations under the Act, under any of the conditions specified in paragraph (a)(4)(ii) of this section.

(A) When a light-duty vehicle or light-duty truck is exempted from meeting high-altitude requirements as provided in § 86.090–8(h) or § 86.094–9(h):

(*1*) At a designated high-altitude location, unless such manufacturer has reason to believe that such vehicle will not be sold to an ultimate purchaser for principal use at a designated high-altitude location; or

(*2*) At a location other than a designated high-altitude location, when such manufacturer has reason to believe that such motor vehicle will be sold to an ultimate purchaser for principal use at a designated high-altitude location.

(B) When a light-duty vehicle or light-duty truck is exempted from meeting low-altitude requirements as provided in § 86.094–8(i) or § 86.094–9(i):

(*1*) At a designated low-altitude location, unless such manufacturer has reason to believe that such vehicle will not be sold to an ultimate purchaser for principal use at a designated low-altitude location; or

(*2*) At a location other than a designated low-altitude location, when such manufacturer has reason to believe that such motor vehicle will be sold to an ultimate purchaser for principal use at a designated low-altitude location.

(iii) A manufacturer shall be deemed to have reason to believe that a light-duty vehicle or light-duty truck that has been exempted from compliance with emission standards at high altitude, will not be sold to an ultimate purchaser for principal use at a designated high altitude location if the manufacturer has informed its dealers and field representatives about the terms of those high altitude regulations, has not caused the improper sale itself, and has taken reasonable action which shall include, but shall not be limited to, either § 86.094–30(a)(4)(iii) (A) or (B), and § 86.094–30(a)(4)(iii)(C).

(a)(4)(iii) (A) through (C) [Reserved]. For guidance see § 86.094–30.

(a)(4)(iv) A manufacturer shall be deemed to have reason to believe that a light-duty vehicle or light-duty truck which has been exempted from compliance with emission standards at low altitude, as provided in § 86.094–8(i) or § 86.094–9(i), will not be sold to an ultimate purchaser for principal use at a designated low-altitude location if the manufacturer has informed its dealers and field representatives about the terms of the high-altitude regulations, has not caused the improper sale itself, and has taken reasonable action which shall include, but not be limited to either § 86.094–30 (a)(4)(iv) (A) or (B) and § 86.094–30(a)(4)(iv)(C):

(a)(4)(iv)(A) through (a)(12) [Reserved]. For guidance see § 86.094–30.

(a)(13) For all light-duty trucks certified to Tier 0 standards under § 86.094–9 and to which standards under § 86.709–94 are applicable:

(i) All certificates issued are conditional upon the manufacturer complying with all provisions of §§ 86.094–9 and 86.709–94 both during and after model year production.

(ii) Failure to meet the required implementation schedule sales percentages as specified in §§ 86.094–9 and 86.709–94 will be considered to be a failure to satisfy the conditions upon which the certificate(s) was issued and the individual vehicles sold in violation of the implementation schedule shall not be covered by the certificate.

(iii) The manufacturer shall bear the burden of establishing to the satisfaction of the Administrator that the conditions upon which the certificate was issued were satisfied.

(a)(14) through (e)(8) [Reserved]. For guidance see § 86.094–30.

(Approved by the Office of Management and Budget under control number 2060–0104)

19. Section 86.095–35 is amended by removing and reserving paragraphs (a)(2)(iii)(F) and (c)(1)(ii)(B)(*2*).

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Coast Guard

33 CFR Parts 155 and 156
Overfill Devices; Proposed Rule

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 155 and 156

[CGD 90-071a]

RIN 2115-AD87

Overfill Devices

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish minimum standards for overfill devices for tank vessels that carry oil as their primary cargo. The proposed regulations also would require the phased-in installation and use of overfill devices on the cargo tanks of certain tank vessels that carry oil. These regulations are required by the Oil Pollution Act of 1990. The purpose of the regulations is to reduce the likelihood of oil spills when oil is loaded as cargo.

DATES: Comments must be received by March 15, 1993.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council (G-LRA/3406) (CGD 90-071a), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001, or may be delivered to Room 3406 at the same address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267-1477. Comments on collection of information must be mailed also to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, ATTN: Desk Officer, U.S. Coast Guard.

The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of the docket and will be available for inspection and copying at room 3406, U.S. Coast Guard Headquarters.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander Michael B. Karr, Project Manager, (202) 267-6756.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify both this rulemaking (CGD 90-071a) and the specific section of the rulemaking to which each comment applies, and give the reason for the comment. Each person wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Marine Safety Council at the address listed under "ADDRESSES." If the Coast Guard determines that the opportunity for oral presentations will aid this rulemaking, it will hold a public hearing at a time and place announced by a later notice in the Federal Register.

Drafting Information

The principal persons involved in drafting this document are Lieutenant Commander Michael B. Karr, Project Manager, and Pamela M. Pelcovits, Project Counsel, Oil Pollution Act (OPA 90) Staff.

Background and Purpose

Section 4110 of the Oil Pollution Act of 1990 (Pub. L. 101-380) (OPA 90), (found as a statutory note following 46 U.S.C. 3703) contains two regulatory initiatives concerning the carriage of oil in bulk as cargo aboard vessels. The first addresses the establishment of minimum standards for overfill warning, tank level, and pressure monitoring devices. The second initiative establishes requirements concerning the use of these devices. These devices would warn of tank overfills (overfill devices) and detect the loss of cargo (tank level or pressure monitoring devices).

The Coast Guard is proposing requirements in this notice of proposed rulemaking (NPRM) that address minimum standards for overfill devices and the use of these devices. Tank level and pressure monitoring devices are being dealt with under a separate rulemaking. The Coast Guard published an advance notice of proposed rulemaking (ANPRM) addressing minimum standards for and the use of tank level or pressure monitoring devices on May 7, 1991 (56 FR 21116).

An overfill spill occurs when too much oil is piped into a cargo tank during a transfer operation (e.g., from a facility to a tank vessel or from one tank vessel to another). Human error is the most often reported cause of this type of spill. Many overfill spills are small; however, some reported spills have involved large quantities of oil. For example, 17,000 gallons of No. 2 fuel oil were accidentally discharged as the result of an overfill into Kill Van Kull, near New York City, in June 1991.

While current Coast Guard regulations (33 CFR parts 155 and 156) require vessel operators to follow pollution prevention procedures (including equipment requirements) during oil transfer operations, devices to detect and warn of impending overfills are not required presently on cargo tanks.

However, Coast Guard regulations do address procedures to follow when transfer operations include the use of a vapor control system. Vapor control involves collecting the vapors that are emitted from a cargo tank during transfers and piping them away from the transfer location for processing. Vapor control may improve air quality and can reduce occupational exposure to toxic fumes. The use of a vapor control system, though, introduces the potential for additional hazards to transfer operations on tank vessels.

In recognition of these hazards, the Coast Guard has issued regulations for the safe design, installation, and use of vapor control systems (provided in sections of 33 CFR parts 154, 155, and 156 and 46 CFR parts 30, 32 35, and 39). At least four states, New Jersey, Pennsylvania, Louisiana, and California, are implementing requirements for the use of vapor control systems for loading oil. Additional States may require the use of vapor control systems in response to the Clean Air Act amendments of 1990 (Pub. L. 101-549).

One of the primary hazards associated with vapor control equipment is overpressurization of a cargo tank caused by overfilling. Therefore, the Coast Guard's current regulations for acceptable vapor control systems include standards for overfill devices (called liquid overfill protection devices). For a tankship, the liquid overfill protection device requirements include closed gauging, a high level alarm, and an overfill alarm. For a tank barge, an alternative system is acceptable. This alternate system includes: closed gauging; a high level indicating device; and either an automatic shutdown system, spill valves, or rupture discs.

The use of overfill devices has been an accepted practice for certain liquid bulk cargos for some time. They are required for specified chemicals and gases under the International Maritime Organization (IMO) codes in order to protect personnel involved in the transfer of these cargos, the vessels, and the environment.

Discussion of Proposed Amendments

1. Location of Regulations

In section 4110(b)(2) of OPA 90, the Coast Guard is directed to establish

"* * * requirements concerning the use of * * *" overfill devices. The Coast Guard proposes placing the regulations requiring the installation and use of overfill devices in 33 CFR parts 155 and 156. These parts provide regulations for preventing pollution to the marine environment during transfer operations, including requirements for written transfer procedures.

2. Definition of Oil

The definition of oil in OPA 90 includes oil of any type or in any form, including petroleum, fuel oil, sludge, oil refuse, and oil mixed with wastes except dredged spoil. This definition includes non-petroleum oils.

Under international agreements to which the United States is a signatory, a different definition of oil, that excludes non-petroleum oils, is used for purposes of preventing pollution to the marine environment. The Coast Guard's policy is that this more limited definition of oil applied for international purposes is appropriate for this rulemaking and within the discretion permitted under section 4110(b) of OPA 90. Accordingly, the proposed regulations specifically apply the definitions of oil provided in § 151.05, which is based on Annex I to the International Convention for the Prevention of Pollution by Ships, 1973, as amended by the Protocol of 1978 (MARPOL). The NPRM also revises the language of § 155.10 and § 156.105 to reflect this approach. The Coast Guard may extend the regulations to additional oils in the future.

3. Applicability

Section 4110(b) authorizes the Coast Guard to require the use of overfill devices on all U.S. and foreign flag vessels constructed or adapted to carry, or that carry oil in bulk when either loading oil as cargo in the navigable waters of the United States or loading oil as cargo in the U.S. exclusive economic zone if the oil is destined for a port or place in the United States. The Coast Guard has broad discretion to determine which vessels will be subject to the proposed regulations. Due to the findings of the Regulatory Evaluation (RE) as discussed later, the Coast Guard is excluding secondary cargo carriers from the proposed rule based on the small amount of cargo oil spilled from these vessels. The Coast Guard is proposing that, for now, these regulations be limited to self-propelled and nonself-propelled tank vessels that carry oil as their primary cargo (oil tankers as defined in § 151.05). This will exclude ships such as offshore supply vessels, and certain fish tenders, etc., which carry limited quantities of oil as secondary cargoes.

The Coast Guard also proposes to limit the applicability of the new regulations to oil tankers with a cargo capacity of 250 barrels or more. These vessels are currently required to comply with the transfer procedure requirements of 33 CFR part 155. The proposed regulations are consistent with the Coast Guard current requirements for pollution control during transfer operations.

The Coast Guard may extend the application of the regulations to additional vessels at a later time.

4. Minimum Standards for Overfill Devices

Section 4110(a) of OPA 90 requires the establishment of minimum standards for devices warning of overfills in oil cargo tanks. As discussed previously, the Coast Guard developed standards for overfill devices (liquid overfill protection devices) through public notice and comment as part of the regulations that established standards for vapor control systems.

The Coast Guard proposes to use these standards, found at 46 CFR 39.20–7 and 39.20–9, as the basis for the minimum standards required by OPA 90. The Coast Guard expects that owners and operators affected by the overfill device requirements of OPA 90 will find this approach helpful, as it proposes standards already subjected to public review. In addition, the use of these standards eliminates a potential additional burden for those jurisdictions already requiring vapor control systems.

For tankships, the overfill devices described in these proposed regulations consist of a high level alarm and a tank overfill alarm installed in each tank. Many tankships currently utilize such alarms. The Coast Guard is aware, though, that such devices are less common on tank barges and that installation of the devices will be costly for tank barges, especially those that do not maintain an on-board source of power.

The Coast Guard recognizes that the different operating environment of tank barges necessitates adjustments and alternatives to the existing standards. Because the purpose of installing overfill devices in connection with a vapor control system is to prevent structural damage to a vessel (rather than the discharge of oil into the water), the current standards allow some components (spill valves and rupture disks) that could result in deflecting overfills onto the deck of a tank vessel. This oil could flow into the water, thereby creating an overfill spill. Accordingly, permitting the use of spill valves and rupture disks by themselves as a liquid overfill protection system (46 CFR 39.20–9) conflicts with the purpose of the proposed regulations. However, under the proposed regulations spill valves and rupture disks may continue to be used on tank barges if additional overfill devices are installed.

For tank barges, the proposed regulations require any one of the following three approaches: (1) A high level alarm and a tank overfill alarm installed in each tank; (2) an automatic shutdown system; or (3) a high level indicating device, such as a stick gauge.

The Coast Guard is interested in comments on the high level indicating device, or stick gauge. This device is described in the vapor control regulations (46 CFR 39.20–3(b)) and is currently used, in conjunction with other vapor control devices, on some tank barges to reduce the likelihood of damage to the vessel occasioned by overfills. A stick gauge installed at each cargo tank for use as an overfill warning device would be a lower cost alternative because it does not require any electrical power. While a stick gauge can provide a visual warning that a tank is filled beyond a certain limit, it must be visible from all cargo control areas on a tank barge to be effective. When stick gauges are used, a proposed amendment to the oil transfer regulations (§ 155.750(e)) requires the person in charge of the transfer operation on the barge to regularly check each high level indicating device, even after a tank has been topped off.

Stick gauges are an improvement over the current practice on many tank barges. The efficacy of the stick gauge depends on the vigilance of the person in charge.

The Coast Guard is interested in comments on the impact of implementing the standard on various kinds of tank vessels.

5. Proposed section 155.480 Overfill Devices

This section would require certain tank vessels with a cargo capacity of 250 barrels or more that carry oil in bulk as cargo or cargo residue to be equipped with overfill devices.

As previously discussed, the minimum standards for the overfill devices to be installed on a tank vessel are cross referenced, where appropriate, to the standards for liquid overfill protection devices found in the vapor control system regulations. Separate requirements are provided for tankships (self-propelled oil tankers) and tank barges (nonself-propelled oil tankers).

Finally, this section proposes that the required devices be installed on tank vessels at their next cargo tank internal examination, but no later than 5 years following the effective date of the regulations. Because the Coast Guard recognizes that installing the devices requires costly gas-freeing of cargo tanks, this provision will coordinate the installation of overfill devices with the gas-freeing of tanks for other required purposes (either under Coast Guard regulations for U.S. flag vessels or under the requirements of the flag administration for foreign flag vessels).

6. Amended Section 155.750 Contents of Transfer Procedures

The Coast Guard is proposing to add the following items to the written transfer procedures that the operator of a vessel covered by the regulation must maintain: (1) A description of the overfill devices; (2) pre-transfer inspection requirements; and (3) if a high level indicating device is used, procedures to monitor a cargo level and shut down procedures. The transfer procedures are required to be used by a tank vessel operator as part of the cargo transfer process.

7. Proposed Section 155.775 Maximum Cargo Level of Oil

This section would establish a maximum cargo level for oil. The standard conforms to the levels established for vapor control systems (46 CFR 39.30–1(e)).

8. Proposed Section 156.120 Requirements for Transfer

The Coast Guard is proposing to add a new paragraph (bb) to § 156.120 to require that overfill devices must be operating when oil is loaded as cargo.

Regulatory Evaluation

This proposal is not major under Executive Order 12291 and not significant under the Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). A draft Regulatory Evaluation (RE) is available in the docket for inspection or copying, as indicated in the "ADDRESSES" section of this preamble.

A copy of the draft RE also has been placed in a special file (CGD 91–207) established to facilitate review of the programmatic Regulatory Impact Analysis for titles IV and V of OPA 90. Any public comments received will also be placed in that file.

The Coast Guard assumes that tankship owners and operators would purchase one high quality, float-type overfill device for each cargo tank. Costs for the purchase and installation of the equipment are estimated at $2,875 per tank for tankships ($40,250 for a tankship with 14 cargo tanks).

The Coast Guard also assumes that tank barge owners and operators would purchase one high level indicating device for each cargo tank. The cost of purchasing and installing a high level indicating device is $1,650 per tank ($13,200 for a tank barge with 8 cargo tanks).

The total cost of overfill devices to the industry is developed first by estimating cost by vessel type and use for a typical size, and then by aggregating the costs for all vessels engaged in the trade. The analysis includes self-propelled and nonself-propelled oil tankers. Total costs, including annualized costs, are estimated separately by vessel type, use, flag, and route.

Assuming a 15 year life for overfill devices, the total annualized cost of compliance to oil tanker owners and operators is projected to be approximately $14.3 million to $14.8 million, distributed as follows: (1) To U.S. tank barges and tankships, $11.2 million; (2) to foreign flag tankships, $3 to $3.5 million; and (3) to U.S. government tankships and cargo vessels, $0.12 million. The net present value of the cost of compliance is $65.3 million. The proposed regulation will affect approximately 3,976 inland and coastal barges, 218 U.S. flag tankships, 500–600 foreign flag tankships, and 23 U.S. Navy and U.S. Maritime Administration (MARAD) vessels. Enforcement costs to the Federal Government are estimated at $2 million.

The analysis indicates that, if the entire cost of the implementation of the proposed regulation is passed on to consumers, the retail price of domestically consumed petroleum products would be increased approximately 3 cents per ton or one one-hundredths of a cent per gallon; and the retail price of U.S. petroleum products in export markets would rise by approximately 8.3 cents per ton or three one-hundredths of a cent per gallon.

According to Coast Guard records, approximately 73,000 gallons of oil and petroleum products were spilled in the U.S. waters from tank overflows in 1989. The Coast Guard estimates that the proposed regulation will prevent 44 percent of these oil spills or save approximately 31,944 gallons per year.

The net present value of the quantified direct benefits from the installation of overfill warning devices on tankships and tank barges is 261,248 gallons of oil not spilled, calculated for a 15 year overfill device life and at a ten percent discount rate.

The estimated cost-benefit ratio (net present value of costs/net present value of benefits) for tankships and tank barges is $250 to prevent spilling one gallon of oil.

The Coast Guard examined the costs and benefits associated with including vessels other than those tank vessels that carry oil as their primary cargo. These secondary cargo carriers include certain passenger, freight, offshore supply and fishing industry vessels carrying a limited amount of oil, in bulk, as cargo.

The Coast Guard is excluding secondary cargo carriers from the proposed rule based on the small amount of cargo oil spilled from these vessels. During 1989 only 1,300 gallons of the 73,000 gallons (1.78%) of cargo oil spilled were from these vessels. Of the 217 cargo oil spills that occurred during 1989, 19 (8.7%) were from these vessels.

Assuming a 15 year life for overfill devices, the total annualized cost of compliance for secondary cargo carrier owners and operators would have been approximately $1.12 million, affecting 600 offshore supply vessels, 177 cargo vessels and 90 MARAD vessels. The net present value of the cost of compliance is $5.9 million. The net present value of direct benefits for offshore supply and cargo vessels is estimated at 5,068 gallons of oil not spilled. The estimated cost-benefits (net present value of costs/net present value of benefits) for offshore supply and cargo vessels is $730/gallon of oil not spilled. That means it would cost $730 to prevent spilling one gallon of oil.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposal will have a significant impact on a substantial number of small entities. "Small entities" include independently owned and operated businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (5 U.S.C. 632). "Small entities" also include small not-for-profit organizations and small governmental jurisdictions. Based on the Coast Guard's analysis in the RE, it certifies under 5 U.S.C. 605(b) that this proposal, if adopted, would not have a significant economic impact on a substantial number of small entities.

If, however, you think your business qualifies as a small entity and that the proposal will have a significant economic impact on your business, you

may submit a comment (see "ADDRESSES") explaining why you think your business qualifies and in what way and to what degree the proposal will affect your business.

Collection of Information

Under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) reviews each proposed regulation that contains collection of information requirements to determine whether the practical value of the information is worth the burden imposed by its collection. Collection of information requirements include reporting, recordkeeping, notification, and other similar requirements.

This proposal contains collection of information requirements in the following sections: 155.750 (Contents of transfer procedures) and 156.150 (Declaration of inspection). While this proposed rule does not amend § 156.150, that section requires collection of information based on the requirements of § 156.120, which is amended by this proposal.

The reporting and recordkeeping requirements associated with this rule are being submitted to the OMB for approval in accordance with 44 U.S.C. chapter 35. Both of the proposed requirements would revise previously approved information collections. The following particulars apply:

DOT No: 2115; *OMB Control No: 2115–0506.*

Administration: U.S. Coast Guard.

Title: Declaration of inspection.

Need for information: As part of the Coast Guard's Port Safety and Security program this information is used in order to identify potential or actual violations of the regulations. The declaration of inspection must be continued for the U.S. to ensure compliance with specific procedures and certain conditions that prevent pollution of U.S. waters or damage to vessels and facilities. If no records were kept, there would be a significant increase in pollution and damage resulting from persons in charge either not knowing their responsibilities (in the case of foreign nationals working on foreign ships that transfer oil or hazardous materials in bulk in U.S. ports) or not following the proper procedures. It would also be far more difficult to ascertain culpability for accidents and spills.

Proposed use: The Coast Guard provides specific procedures to follow and specific conditions to maintain in order to prevent pollution of waters and damage to vessels and facilities within the U.S. A declaration of inspection alerts the person in charge of the transfer operation of his responsibilities under Federal regulations. The declaration requires him to identify himself and complete a checklist verifying he has complied with the regulations. A declaration of inspection is completed by the person in charge for each bulk transfer conducted. A copy of the declaration of inspection must be kept on board the vessel and facility for one month from the date of signature.

Overfill devices will be required where none have been required before. The information collection burden will increase because persons in charge of oil transfer procedures will have to physically verify that the dual alarm or automatic shutdown system at each tank is working prior to taking on each load of cargo.

Frequency: Each time cargo oil is loaded into a vessel with a capacity of 250 or more barrels of cargo oil.

Burden estimate: 18,000 hours/year.

Respondents: 4,500.

Average burden hours per respondent: 4 hours/year.

Recordkeepers: 4,500.

DOT No: 2115; *OMB Control No:* 2115–0120.

Administration: U.S. Coast Guard.

Title: Requirements for transfer.

Need for information: One of the methods employed by the Coast Guard to prevent the accidental discharge or spillage of oil is to require all vessels with the capacity of 250 or more barrels of oil to develop and follow oil transfer procedures that provide basic safety information for operating the transfer system. This recordkeeping requirement directs the vessel operator to maintain onboard and make available to the Coast Guard Captain of the Port, upon request, the vessel's oil transfer procedures.

Certain tank vessels will now be required to install and use overfill devices to prevent oil spills due to overfilling of tanks. The oil transfer procedures therefore must be amended to include procedures regarding overfill devices.

Proposed use: Vessel personnel are required to follow the vessel's transfer procedures each time oil or a hazardous material is transferred to or from the vessel or from tank to tank within the vessel. Vessel crews change frequently. Written procedures provide a means of ensuring that new personnel are familiar with the complex system of pumps, piping, valving, vapor control equipment, and overfill devices used to transfer oil or hazardous materials. If the information were not required to be recorded, vessel personnel might be unfamiliar with the vessel's transfer system. This might result in accidental discharge of oil or hazardous materials, fire, or explosion.

Overfill devices will be required where none were required before. A description of how the overfill device system operates and the pretransfer equipment inspection requirements will become part of the oil transfer procedures. The overfill device system description in the oil transfer procedures will be available to the person-in-charge (PIC) of a vessel. The PIC will use this information to make sure the equipment prevents the overflow of a cargo tank.

Frequency: Once.

Burden estimate: 9,064 hours.

Respondents: 824.

Average burden hours per respondent: 11 hours.

Recordkeepers: 824.

For further information contact: The Information Requirements Division, M–34, Office of the Secretary of Transportation, 400 Seventh Street, SW., Washington, DC 20503, (202) 395–7340

Federalism

The Coast Guard has analyzed this proposal in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

This NPRM proposes standards and requirements for the phased-in installation and use of overfill devices on oil cargo tanks of certain cargo tank vessels. The authority to regulate tank vessel equipment is delegated to the Coast Guard by the Secretary of Transportation, whose authority is committed by statute. Because tank vessels move between U.S. ports in the national marketplace, and between U.S. and foreign ports in the international marketplace, standards for overfill devices and their use are a matter for which regulations should be of national scope to avoid unreasonably burdensome variances. The Coast Guard intends that these regulations preempt State action addressing the same subject matter. However, the NPRM will not affect the ability of States to require the use of vapor control systems under the Clean Air Act amendments as discussed earlier in the preamble.

Environment

The Coast Guard has considered the environmental impact of this proposal under COMDTINST M16475.1B. A draft Environmental Assessment (EA) is available in the docket for copying and inspection as indicated in the

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"ADDRESSES" section of this preamble. The draft EA discusses and compares the proposed action and alternatives, subsequent expected environmental impacts, and overall need for the action.

Actual reductions in the numbers and volumes of oil spills as a result of the promulgation of the proposed regulations cannot be accurately estimated, due to interrelationships among different spill prevention and mitigation measures being implemented as a result of other proposed OPA 90 actions. Less than 1 percent of all vessel oil spills into U.S. waters come from tank overfills. Though some reduction in adverse natural resource impacts should result from issuing these regulations, overfills tend to result (with exceptions) in relatively small spills that occur either in harbors where rapid response and containment are possible and where hydrographic conditions (wave and water current regimes) favor good cleanup efficiency, or in offshore lightering zones where oil spills are less likely to have an impact on sensitive ecosystmes. As a result, when considered independently of other proposed OPA 90 actions, these regulations are not expected to result in significant impact on the quality of the human environment. Therefore, the Coast Guard expects to issue a Finding of No Significant Impact.

List of Subjects

33 CFR Part 155

Hazardous substances, Oil pollution, Reporting and recordkeeping requirements.

33 CFR Part 156

Hazardous substances, Oil pollution, Reporting and recordkeeping requirements, Water pollution control.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR parts 155 and 156 as follows:

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

1. The authority citation for 33 CFR part 155 and the note following the citation are revised to read as follows:

Authority: 33 U.S.C. 1231, 1321(j)(1)(C); sec. 2, E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp., p. 793; 49 CFR 1.46. Sections 155.100 through 155.130, 150.350 through 155.400, 155.430, 155.440, and 155.470 also issued under 33 U.S.C. 1903(b). Sections 155.480, 155.750(e), and 155.775 are issued under section 4110, Public Law 101–380, 104 Stat. 515 (46 USC 3703 note).

Note: Additional requirements for vessels carrying oil or hazardous materials are contained in 46 CFR parts 30 through 40, 150, 151, and 153.

2. Section 155.110 is revised to read as follows:

§ 155.110 Definitions.

Except as specifically stated in a section, the definitions in part 151 of this chapter, other than for the word "oil," and in part 154 of this chapter also apply to this part.

3. Section 155.480 is added to read as follows:

§ 155.480 Overfill devices.

(a) An oil tanker with a cargo capacity of 250 or more barrels of oil, loading oil as cargo, must have permanently installed on each cargo tank an overfill device that meets the requirements of this section.

(1) On a self propelled oil tanker, each cargo tank must be equipped with an overfill device that meets the requirements of 46 CFR 39.20–7(a), (b), (c), and (d).

(2) On a non-self propelled oil tanker, each cargo tank must be equipped with an overfill device that meets one of the following arrangements.

(i) 46 CFR 39.20–7(a), (b), (c), and (d), and 46 CFR 39.20–9(a);

(ii) 46 CFR 39.20–9(b); **or**

(iii) 46 CFR 39.20–3(b) (1), (2), and (3).

(b) Each cargo tank of a United States flag oil tanker subject to this section must have installed on it an overfill device meeting the requirements of this section at the first cargo tank internal examination performed on the vessel under 46 CFR 31.10–21, following [*Insert the effective date of the final rule.*] but not later than [*Insert date 5 years from the effective date of the final rule.*]

(c) Each cargo tank of a foreign flag oil tanker subject to this section must have installed on it an overfill device meeting the requirements of this section at the first survey that includes dry docking, as required by the vessel's flag administration to meet the International Convention for the Safety of Life at Sea, 1974, as amended (SOLAS) or the International Load Line Convention of 1966 following [*Insert the effective date of the final rule.*]; but not later than [*Insert date 5 years from the effective date of the final rule.*]

(d) For purposes of this section, oil has the same meaning as provided in § 151.05 of this chapter.

4. In § 155.750, paragraph (e) is added to read as follows:

§ 155.750 Contents of transfer procedures.

* * * * *

(e) If the cargo tanks of a vessel are fitted with overfill devices, the transfer procedures must contain a description of the overfill devices including—

(1) The high level alarm system, if fitted;

(2) The independent shutdown system, if fitted;

(3) The high level indicating device, if fitted, and specific procedures for the person in charge to—

(i) Monitor the level of cargo in tanks that have been topped off; and

(ii) Shut down transfer operations in time to ensure that the cargo level in each tank does not reach the maximum height permitted by § 155.775(a)(1) of this chapter.

(4) Pre-transfer equipment inspection requirements.

5. Section 144.775 is added to read as follows:

§ 155.775 Maximum cargo level of oil.

(a) A cargo tank on a tank vessel may not be filled with oil in bulk as cargo higher than—

(1) 98.5 percent of the cargo tank volume; or

(2) The level at which an overfill alarm complying with 46 CFR 39.20–7 or 46 CFR 39.20–9(b)(2) is set.

(b) For purposes of this section, oil has the same meaning as provided in § 151.05 of this chapter.

PART 156—OIL AND HAZARDOUS MATERIAL TRANSFER OPERATIONS

6. The authority citation for 33 CFR part 156 is revised to read as follows:

Authority: 33 U.S.C. 1231, 1321(j)(1) (C) and (D); 46 U.S.C. 3715; sec. 2, E.O. 11735, 38 FR 21243, 3 CFR 1971–1975 Comp., p. 793; 49 CFR 1.46. Section 156.120(bb) is issued under section 4110, Pub. L. 101–380, 104 Stat. 515 (46 U.S.C. 3703 note).

7. Section 156.105 is revised to read as follows:

§ 156.105 Definitions.

Except as specifically stated in a section, the definitions in § 154.105 of this chapter apply to this subpart.

8. In § 156.120 paragraph (bb) is added as follows:

§ 156.120 Requirements for transfer.

* * * * *

(bb) If the transfer operation involves loading oil, as defined in § 151.05 of this chapter, into a cargo tank, the overfill devices required by § 155.480 of this chapter are installed and operating properly.

Dated: January 5, 1993.

R.C. North,

Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 93–522 Filed 1–11–93 8:45 am]

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Federal Register

Tuesday
January 12, 1993

Part IV

Department of the Interior

Bureau of Indian Affairs

25 CFR Part 23
Indian Child Welfare Act; Proposed Rule

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 23

RIN 1076–AC55

Indian Child Welfare Act

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Proposed rule.

SUMMARY: The Bureau of Indian Affairs (BIA) is proposing to revise the regulations governing the Indian Child Welfare Act (ICWA) discretionary grant process and the administration of these grant programs as authorized under the Indian Child Welfare Act of 1978. Until now, the ICWA grants have been awarded competitively based on BIA review of applications from Indian tribes and Indian organizations. Under this process tribes have been unable to develop long-term plans and programs due to the uncertainty of sustained resources. The proposed regulations will provide for noncompetitive formula-based funding for all federally recognized Indian tribes above a minimum population; contain provisions for off-reservation ICWA programs to continue to be awarded competitively through a centralized review process; and establish new requirements for internal evaluation processes.

DATES: Written comments must be received on or before February 11, 1993. Comments received after this date will not be considered in the Final Rulemaking. Persons submitting written comments should allow ample time for the mail delivery service. Telephonic facsimiles (faxes) up to 10 pages will be accepted. Facsimiles exceeding the tenth page will not be considered.

ADDRESSES: Written comments must be directed to the Division of Social Services, Bureau of Indian Affairs, 1849 C Street, NW., Mailstop 310 SIB, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: David Hickman, Chief, Division of Social Services, Bureau of Indian Affairs, 1849 C Street, NW., Mailstop 310 SIB, Washington, DC 20240, telephone number: (202) 208–2721; FTS: 268–2721.

SUPPLEMENTARY INFORMATION: This proposed revision is published in exercise of the authority delegated by the Secretary of the Interior (Secretary) to the Assistant Secretary—Indian Affairs in the Departmental Manual at 209 DM 8.

This rulemaking action is to revise 25 CFR part 23, regulations governing the grant process specified in the ICWA Indian Child Welfare Act of 1978 (Pub. L. 95–608).

The revisions incorporate recommendations received from tribes and Indian organizations during recent consultation sessions held by each BIA area office. Contingent upon annual Congressional appropriations, the intended effect of these regulatory revisions is to promote long-term planning, stabilize and provide core funding for all tribal ICWA programs, enabling them to develop, coordinate, and implement comprehensive Indian child and family programs.

Changes are being made in 25 CFR part 23, §§ 23.1, Purpose; 23.2, Definitions; 23.3, Policy; 23.4, Information collection; 23.11, Notice; 23.12, Designated tribal agent for service of notice; 23.13, Payment for appointed counsel in Indian child custody proceedings in state courts; 23.21, Eligibility requirements; 23.22, Purpose of grants; 23.23, Obtaining application instructions and materials; 23.26, Submitting applications; 23.27, Technical assistance; 23.28, Area office review and certification of off-reservation programs; 23.30, Deadline for Central Office action; 23.31, Grant approval limitation; 23.32, Grant execution, administration and monitoring; 23.33, Subgrants; 23.41, Uniform grant administration requirements and applicability; 23.43, Reports and availability of information to Indians; 23.44, Matching shares and agreements; 23.45, Fair and uniform provision of services; 23.47, Grant renewal and modification; 23.48, Penalties; 23.51, Revisions or amendments of grants; 23.71, Recordkeeping and information availability; 23.81, Assistance in identifying witnesses; 23.82, Assistance in identifying interpreters; and, 23.83, Assistance in locating biological parents of Indian child after termination of adoption.

The following citations are new §§: 23.24, Noncompetitive multi-year on-reservation tribal program application contents; 23.25, Application selection criteria for competitive grants; 23.29, Centralized review and decision for off-reservation and applications; 23.42, Financial management, internal and external controls and other assurances; 23.46, Service eligibility; 23.52, Grant carry over authority; 23.53, Grant suspension; 23.54, Cancellation of grant for cause; 23.61, Appeals from decision or action by Area Director; 23.62, Appeals from decision or action by the Director, Office of Tribal Services; and 23.63, Appeals from inaction of official.

The changes reflect recommendations received from tribes and Indian organizations, current case law and changes in jurisprudence since passage of the Act, and includes mechanisms for accountability through internal evaluation processes and systematic reporting and data collection requirements.

In accordance with the Paperwork Reduction Act and 5 CFR part 1320, the information collection requirements contained in 25 CFR part 23 will be reviewed by the Office of Management and Budget (OMB) under 44 U.S.C. 3501 *et seq.* and approved before solicitation occurs.

This rulemaking will affect only a limited number of persons and will not result in an annual gross effect on the economy of one hundred million dollars or more. This rule will not have any significant effects on the economy or in costs or prices for consumers, individual industries, Federal, state or local agencies or geographical regions. The rule will not have any adverse effects on competition, employment, investment, productivity or in the export/import market.

This rulemaking action revising 25 CFR part 23 will be limited in applicability to federally recognized Indian tribes and off-reservation Indian tribal organizations applying for grant programs. BIA personnel will receive and process grant applications and monitor the grants once awarded. Indian tribes and off-reservation Indian organizations will administer and manage the day-to-day operations of the grant activities. Individual Indians and Indian families will be the recipients of services under these grant programs. Given the low level of funding which are expected to be available for small tribes, this rule will not impose a significant economic effect on a substantial number of small entities.

The Department of the Interior has determined, in accordance with Executive Order 12291, that this rule is not a major rule because only a limited number of individuals will be affected by the revisions to the regulations contained in 25 CFR part 23.

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because of the limited applicability as stated above.

The Department of the Interior has determined that this rule is not a major Federal action significantly affecting the quality of the human environment and that neither an environmental

assessment nor an environmental impact statement is required.

The primary author of this document is Betty B. Tippeconnic, Branch Chief, Branch of Child and Family Services, Division of Social Services, Office of Tribal Services.

The policy of the Department of the Interior is, whenever practical, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions or objections regarding these proposed revisions to the Division of Social Services, Bureau of Indian Affairs, 1849 C Street, NW., Mailstop 310 SIB, Washington, DC 20240.

List of Subjects in 25 CFR Part 23

Administrative practices and procedures, Child custody proceedings, Child welfare, Grant programs—Indians, Grant programs—social programs, Hearings and appeals, Indians, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, part 23 of title 25, chapter I, of the Code of Federal Regulations is proposed to be revised as set forth below.

PART 23—INDIAN CHILD WELFARE ACT

Subpart A—Purpose, Definitions, and Policy

Sec.

23.1 Purpose.
23.2 Definitions.
23.3 Policy.
23.4 Information collection.

Subpart B—Notice of Involuntary Child Custody Proceedings and Payment for Appointed Counsel in state courts

23.11 Notice.
23.12 Designated tribal agent for service of notice.
23.13 Payment for appointed counsel in Indian child custody proceedings in state courts.

Subpart C—Grants to Indian Tribes and Indian Organizations for Title II Indian Child and Family Programs

23.21 Eligibility requirements.
23.22 Purpose of grants.
23.23 Obtaining application instructions and materials.
23.24 Noncompetitive multi-year on-reservation tribal program application contents.
23.25 Application selection criteria for competitive grants.
23.26 Submitting applications.
23.27 Technical assistance.
23.28 Area office role.
23.29 Centralized review and decision for off-reservation applications.
23.30 Deadline for Central Office action.
23.31 Grant approval limitation.
23.32 Grant execution, administration and monitoring.
23.33 Subgrants.

Subpart D—General Grant Requirements

23.41 Uniform grant administration requirements and applicability.
23.42 Financial management, internal and external controls and other assurances.
23.43 Reports and availability of information to Indians.
23.44 Matching shares and agreements.
23.45 Fair and uniform provision of services.
23.46 Service eligibility.
23.47 Grant renewal and modification.
23.48 Penalties.

Subpart E—Grant Revision, Carry over Authority, Grant Suspension, or Cancellation

23.51 Revisions or amendments of grants.
23.52 Grant carry over authority.
23.53 Grant Suspension.
23.54 Cancellation.

Subpart F—Hearings and Appeals

23.61 Appeals from decision or action by Area Director.
23.62 Appeals from decision or action by the Director, Office of Tribal Services.
23.63 Appeals from inaction of official.

Subpart G—Administrative Provisions

23.71 Recordkeeping and information availability.

Subpart H—Assistance to State Courts

23.81 Assistance in identifying witnesses.
23.82 Assistance in identifying interpreters.
23.83 Assistance in locating biological parents of Indian child after termination of adoption.

Authority: 5 U.S.C. 301; 25 U.S.C. 2, 9, 1901–1952.

Subpart A—Purpose, Definitions, and Policy

§ 23.1 Purpose.

The purpose of the regulations in this part is to govern the performance of the responsibilities of the Federal Government under the Indian Child Welfare Act of 1978 (Pub. L. 95–608, 92 Stat. 3069, 25 U.S.C. 2, 9, 1901–1952).

§ 23.2 Definitions.

Act means the Indian Child Welfare Act, Pub. L. 95–608, 92 Stat. 3069. 25 U.S.C. 1901 *et seq.*

Assistant Secretary means the Assistant Secretary—Indian Affairs, the Department of the Interior.

Child custody proceeding means and includes:

(1) *Foster care placement* which shall mean any action removing an Indian child from his or her parent or Indian custodian for temporary placement in a foster home or institution or the home of a guardian or conservator where the parent or Indian custodian cannot have the child returned upon demand, but where parental rights have not been terminated;

(2) *Termination of parental rights* which shall mean any action resulting in the termination of the parent-child relationship;

(3) *Preadoptive placement* which shall mean the temporary placement of an Indian child in a foster home or institution after the termination of parental rights, but prior to or in lieu of adoptive placement; and

(4) *Adoptive placement* which shall mean the permanent placement of an Indian child for adoption, including any action resulting in a final decree of adoption.

(5) The above term or terms shall not include a placement based upon an act which, if committed by an adult, would be deemed a crime in the jurisdiction where the act occurred or upon an award, in a divorce proceeding, of custody to one of the parents. It does include status offenses, such as truancy, incorrigibility, etc.

Consortium means an association or partnership of two or more eligible applicants who enter into an agreement to administer a grant program and to provide services under the grant to resident Indians in a specific geographical area when it is administratively feasible to provide an adequate level of services to the area.

Director, Office of Tribal Services means the Director, Office of Tribal Services, Bureau of Indian Affairs, the Department of the Interior.

Extended Family Member shall be as defined by the law or custom of the Indian child's tribe or, in the absence of such law or custom, shall be a person who has reached the age of 18 and who is the Indian child's grandparent, aunt or uncle, brother or sister, brother-in-law or sister-in-law, niece or nephew, first or second cousin, or stepparent.

Grant means a written agreement between the BIA and the governing body of an Indian tribe or Indian organization where the BIA provides funds to the grantee to plan, conduct and administer specific programs, services, or activities and where the administrative and programmatic provisions are specifically delineated.

Grantee means the tribal governing body of an Indian tribe or Board of Directors of an Indian organization responsible for grant administration.

Indian means, for purposes of matters related to child custody proceedings only, any person who is a member of an Indian tribe, or who is an Alaska Native and a member of a Regional Corporation as defined in section 7 of the Alaska Native Claims Settlement Act, 43 U.S.C. 1606.

Indian child means any unmarried person who is under age 18 and is either a member of an Indian tribe, or is eligible for membership in an Indian tribe and is the biological child of a member of an Indian tribe.

Indian child's tribe means the Indian tribe in which an Indian child is a member or is eligible for membership or, in the case of an Indian child who is a member of or is eligible for membership in more than one tribe, the Indian tribe with which the Indian child has the more significant contacts.

Indian custodian means any Indian person who has legal custody of an Indian child under tribal law or custom or under State law or to whom temporary physical care, custody, and control has been transferred by the parent of such child.

Indian organization means any legally established group, association, partnership, corporation, or other legal entity which is owned, or controlled by Indians, or a majority (51 percent or more) of whose members are Indians.

Indian preference means preference and opportunities for employment and training provided to Indians in the administration of the grants in accordance with section 7(b) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450).

Indian tribe means any Indian tribe, band, nation, or other organized group or community of Indians recognized as eligible for the services provided to Indians by the Secretary because of their status as Indians, including any Alaska Native village as defined in section 3(c) of the Alaska Native Claims Settlement Act, 43 U.S.C. 1602(c), as amended.

Indirect Costs means costs incurred for a common or joint purpose benefiting more than one grant objective, or which are not readily assignable to the grant objectives specifically benefited without effort disproportionate to the results achieved.

Indirect cost rate means the rate arrived at through negotiation between an Indian tribe or tribal organization and the appropriate Federal agency.

Near-reservation means those areas or communities adjacent or contiguous to reservations which are designated by the Assistant Secretary—Indian Affairs upon recommendation of the local BIA Superintendent, which recommendation shall be based upon consultation with the tribal governing body of those reservations, as locales appropriate for the extension of BIA financial assistance and or social services under 25 CFR part 20, on the basis of such criteria as: Number of Indian people native to the reservation residing in the area; a written designation by the tribal governing body that members of their tribe and family members who are Indian residing in the area, are socially, culturally and economically affiliated with their tribe and reservation; geographical proximity of the area to the reservation; and administrative feasibility of providing an adequate level of services to the area. The Assistant Secretary shall designate each area and publish the designations in the **Federal Register**.

Parent means any biological parent or parents of an Indian child or any Indian person who has lawfully adopted an Indian child, including adoptions under tribal law or custom. It does not include the unwed father where paternity has not been acknowledged or established.

Reservation means Indian country as defined in 18 U.S.C. 1151 and any lands not covered under such section, title to which is either held by the United States in trust for the benefit of any Indian tribe or individual or held by any Indian tribe or individual subject to a restriction by the United States against alienation.

Secretary means the Secretary of the Interior.

Service area for newly recognized and/or restored Indian tribes means those service areas Congressionally established by Federal law to be the equivalent of a reservation for the purpose of determining the eligibility of a newly recognized and/or restored Indian tribe and its members for all Federal services and benefits. For purposes of grant programs under the Act, tribes with such legislatively identified service areas shall be deemed eligible to apply for on-reservation tribal programs.

State Court means any agent or agency of a state, including the District of Columbia or any territory or possession of the United States, or any political subdivision empowered by law to terminate parental rights or to make foster care placements, preadoptive placements, or adoptive placements.

Subgrant means a secondary grant which undertakes part of the obligations of the primary grant, and assumes the legal and financial responsibility for the funds awarded and for the performance of the grant supported activity.

Technical assistance means the provision of relevant information and assistance to prospective grant applicants in the development of their grant proposals. Technical assistance may include a preliminary review of the application to assist the applicant in identifying the strengths and weaknesses of its proposal, ongoing program planning, design and evaluation, and such other program specific assistance as is necessary for ongoing grants administration and management.

Tribal court means a court with jurisdiction over child custody proceedings and which is either a Court of Indian Offenses, a court established and operated under the code or custom of an Indian tribe, or any other administrative body of a tribe which is vested with authority over child custody proceedings.

Unduplicated case count means an annual consolidated statistical report listing the unduplicated number of persons associated with the unduplicated case count served during the grant year by sex of recipient within the category of service and by age grouping of the recipient.

§ 23.3 Policy.

The policy of the Act and of these regulations is to protect Indian children from arbitrary removal from their families and tribal affiliation by establishing procedures to ensure that measures to prevent the breakup of Indian families are followed in child custody proceedings. This will ensure the stability and protection of Indian tribes and protect the best interests of Indian children and Indian families. Assistance and funding provided to federally recognized Indian tribes and off-reservation Indian organizations in the operation of child and family services programs shall reflect the unique values of Indian culture and promote the stability and security of Indian families. In administering the grant authority for Indian Child and Family Programs, it shall be BIA policy to emphasize the provision of preventive and reunification services and of programs to promote the stability of Indian families.

§ 23.4 Information collection.

(a) The information collection requirement contained in §§ 23.13 and 23.71 has been approved by the OMB under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1076–0111. The information is collected in a notice from the state court in order to certify payment of appointed counsel in Indian child custody proceedings. The information will be used to determine if an individual involved in an Indian child custody proceeding is eligible for payment of appointed counsel. Response is required to obtain a benefit.

(b) The information collection requirements contained in §§ 23.11, 23.24, 23.25, 23.43 and 23.71 will be reviewed by OMB and will not be solicited until OMB approval occurs.

Subpart B—Notice of Involuntary Child Custody Proceedings and Payment for Appointed Counsel in State Courts

§ 23.11 Notice.

(a) If the identity or location of the parents, Indian custodians or the Indian child's tribe cannot be determined, notice of the pendency of any involuntary child custody proceeding involving an Indian child in a state court shall be sent by certified mail with return receipt requested to the appropriate Area Director listed in paragraph (b) of this section. In order to establish tribal identity it is necessary to provide as much information as is known on the Indian child's direct lineal descendants, including but not limited to the information delineated at paragraphs (c) (1) through (4) of this section.

(b)(1) For proceedings in Alabama, Connecticut, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, West Virginia or any territory or possession of the United States, notice should be sent to the following address: Eastern Area Director, Bureau of Indian Affairs, 3701 N. Fairfax Dr., MS–260, Virginia Square, Arlington, Virginia 22201.

(2) For proceedings in Illinois, Indiana, Iowa, Michigan, Minnesota, Ohio, or Wisconsin, notice should be sent to the following address: Minneapolis Area Director, Bureau of Indian Affairs, 331 Second Avenue South, Minneapolis, Minnesota 55401–2241.

(3) For proceedings in Nebraska, North Dakota, or South Dakota, notice should be sent to the following address: Aberdeen Area Director, Bureau of Indian Affairs, 115–4th Avenue, SE., Aberdeen, South Dakota 57401.

(4) For proceedings in Kansas, Texas, and the western Oklahoma counties of Alfalfa, Beaver, Beckman, Blaine, Caddo, Canadian, Cimarron, Cleveland, Comanche, Cotton, Custer, Dewey, Ellis, Garfield, Grant, Greer, Harmon, Harper, Jackson, Kay, Kingfisher, Kiowa, Lincoln, Logan, Major, Noble, Oklahoma, Pawnee, Payne, Pottawatomie, Roger Mills, Texas, Tillman, Washita, Woods and Woodward, notice should be sent to the following address: Anadarko Area Director, Bureau of Indian Affairs, P.O. Box 368, Anadarko, Oklahoma 73005.

(5) For proceedings in Montana or Wyoming, notice should be sent to the following address: Billings Area Director, Bureau of Indian Affairs, 316 N. 26th Street, Billings, Montana 59101.

(6) For proceedings in the Texas counties of El Paso and Hudspeth and proceedings in Colorado or New Mexico, (exclusive of those New Mexico counties listed in paragraph (b)(9) of this section), notice should be sent to the following address: Albuquerque Area Director, Bureau of Indian Affairs, 615 First St., P.O. Box 26567, Albuquerque, New Mexico 87125.

(7) For proceedings in Alaska, notice should be sent to the following address: Juneau Area Director, Bureau of Indian Affairs, 709 West 9th St., Juneau, Alaska 99802–1219.

(8) For proceedings in Arkansas, Missouri, and the eastern Oklahoma counties of Adair, Atoka, Bryan, Carter, Cherokee, Craig, Creek, Choctaw, Coal, Delaware, Garvin, Grady, Haskell, Hughes, Jefferson, Johnston, Latimer, LeFlore, Love, Mayes, McCurtain, McClain, McIntosh, Murray, Muskogee, Nowata, Okfuskee, Okmulgee, Osage, Ottawa, Pittsburgh, Pontotoc, Pushmataha, Marshall, Rogers, Seminole, Sequoyah, Wagoner, Washington, Stephens and Tulsa, notice should be sent to the following address: Muskogee Area Director, Bureau of Indian Affairs, Federal Court House Building, Muskogee, Oklahoma 74401.

(9) For proceedings in the Arizona counties of Apache, Cocoaino, and Navajo; the New Mexico counties of McKinley (except for notices to the Zuni tribe), San Juan, and Socorro; and the Utah county of San Juan, notice should be sent to the following address: Navajo Area Director, Bureau of Indian Affairs, P.O. Box 1060, Gallup, New Mexico 87301.

(10) For proceedings in Arizona (exclusive of those counties listed in paragraph (b)(9) of this section), Nevada or Utah (exclusive of San Juan county), notice should be sent to the following address: Phoenix Area Director, Bureau of Indian Affairs, 1 North First St., P.O. Box 10, Phoenix, Arizona 85001.

(11) For proceedings in Idaho, Oregon or Washington, notice should be sent to the following address: Portland Area Director, Bureau of Indian Affairs, 911 NE. 11th Avenue, Portland, Oregon 97232.

(12) For proceeding in California or Hawaii, notice should be sent to the following address: Sacramento Area Director, Bureau of Indian Affairs, Federal Office Building, 2800 Cottage Way, Sacramento, California 95825.

(c) Notice shall include the following information if known:

(1) Name of the Indian child, birthdate and the child's birthplace.

(2) Indian child's tribal affiliation.

(3) Indian child's mother's maiden name and biological father's name, names of maternal and paternal grandparents and or great grandparents or Indian custodians, including their birthdates, birthplaces, and tribal enrollment numbers if known.

(4) A copy of the petition, complaint or other document by which the proceeding was initiated.

(d) Upon receipt of the notice, the BIA shall make reasonable documented efforts to locate and notify the Indian child's tribe and the Indian child's parents or Indian custodians. Such notice may be by certified mail with return receipt requested or by personal services and shall include the information provided under paragraph (c) of this section in addition to the following:

(1) A statement of the absolute right of the biological parents, Indian custodians and the Indian tribe to intervene in the proceedings.

(2) A statement that if the parent(s) or Indian custodian(s) is unable to afford counsel, counsel will be appointed to represent them.

(3) A statement of the right of the parents, the Indian custodians and the child's tribe to be granted, upon request, up to 20 additional days to prepare for the proceedings.

(4) The location, mailing address, and telephone number of the court.

(5) A statement of the right of parents, Indian custodians and the Indian child's tribe to petition the court for transfer of the proceeding to the child's tribal court pursuant to 25 U.S.C. 1911, and the right of the parents or the tribal court to refuse to permit the case to be transferred.

(6) A statement of the potential legal consequences of the proceedings on the future custodial and parental rights of the parents or Indian custodians.

(7) A statement that, since child custody proceedings are usually conducted on a confidential basis, BIA officials shall keep confidential the information contained in the notice concerning the particular proceeding and not reveal it to anyone who does not need information in order to exercise the tribe's rights under the Act.

(e) The BIA shall have 10 days, after receipt of the notice from the persons initiating the proceedings, to notify the child's tribe and parents or Indian custodians and send a copy of the notice to the court. If within the 10 day time period the BIA is unable to verify that the child is in fact an Indian, or meets the criteria of an Indian child as defined in 25 U.S.C. 1903 of the Act, or is unable to locate the parents or Indian custodians, the BIA shall so inform the

court prior to initiation of the proceedings and state how much more time, if any, it will need to complete the search. The BIA shall complete its efforts even if those efforts cannot be completed before the child custody proceeding begins.

(f) Upon request from a potential participant in an anticipated Indian child custody proceeding, the BIA shall make a reasonable attempt to identify and locate the Indian child's tribe, parents or Indian custodians for the person making the request.

§ 23.12 Designated tribal agent for service of notice.

Any Indian tribe entitled to notice may designate by resolution, or by such other form as the tribal constitution or current practice requires, an agent for service of such notice other than the tribal chairman and send a copy of the designation to the Secretary. The Secretary shall publish the name and address of the designated agent in the **Federal Register** on an annual basis. A current listing of such agents will be available through the area offices.

§ 23.13 Payment for appointed counsel in Indian child custody proceedings in state courts.

(a) When a state court appoints counsel for an indigent Indian party in an Indian child custody proceeding, for which the appointment of counsel is not authorized under state law, the court shall send written notice of the appointment to the BIA area office designated for that state in § 23.11. The notice shall include the following:

(1) Name, address, and telephone number of attorney who has been appointed.

(2) Name and address of client for whom counsel is appointed.

(3) Relationship of client to child.

(4) Name of Indian child's tribe.

(5) Copy of the petition or complaint.

(6) Certification by the court that state law makes no provision for appointment of counsel in such proceedings.

(7) Certification by the court that the Indian client is indigent.

(b) The Area Director shall certify that the client is eligible to have his or her appointed counsel compensated by the BIA unless:

(1) The litigation does not involve a child custody proceeding as defined in 25 U.S.C 1903(1);

(2) The child who is the subject of the litigation is not an Indian child as defined in 25 U.S.C. 1903(4);

(3) The client is neither the Indian child who is the subject of the litigation, the Indian child's parent as defined in 25 U.S.C. 1903(9), or the child's Indian custodian as defined in 25 U.S.C. 1903(6);.

(4) State law provides for appointment of counsel in such proceedings;

(5) The notice to the Area Director of appointment of counsel is incomplete; or

(6) Funds are not available for the particular fiscal year.

(c) No later than 10 days after receipt of the notice of appointment of counsel, the Area Director shall notify the court, the client and the attorney in writing whether the client has been certified as eligible to have his or her attorney fees and expenses paid by the BIA. In the event that certification is denied, the notice shall include written reasons for that decision together with a statement that the Area Director's decision may be appealed to the Assistant Secretary—Indian Affairs under part 2 of this chapter.

(d) When determining attorney fees and expenses the court shall:

(1) Determine the amount of payments due appointed counsel by the same procedures and criteria it uses in determining the fees and expenses to be paid appointed counsel in the state juvenile delinquency proceedings.

(2) Submit approved vouchers to the Area Director who certified eligibility for BIA payment together with the court's certification that the amount requested is reasonable under the state standards and considering the work actually performed in light of the criteria that apply in determining fees and expenses for appointed counsel in state juvenile delinquency proceedings.

(e) The Area Director shall authorize the payment of attorney fees and expenses in the amount requested in the voucher approved by the court unless:.

(1) The amount of payment due the state appointed counsel is inconsistent with the fees and expenses as specified in § 23.13(d)(1), or

(2) The client has not been previously certified as eligible under paragraph (c) of this section; or

(3) The voucher is submitted later than 90 days after completion of the legal action involving a client certified as eligible for payment of legal fees under paragraph (b) of this section.

(f) No later than 15 days after receipt of a payment voucher the Area Director shall send written notice to the court, the client and the attorney stating the amount of payment, if any, that has been authorized. If the payment has been denied or the amount authorized is less than the amount requested in the voucher approved by the court, the notice shall include a written statement of the reasons for the decision together with a statement that the decision of the Area Director may be appealed to the Interior Board of Indian Appeals under part 2 of this chapter.

(g) Failure of the Area Director to meet the deadlines specified in paragraphs (c) and (f) of this section may be treated as a denial for purposes of appeal under paragraph (f) of this section.

(h) This provision does not extend to payment for appointed counsel in behalf of Indian tribes in state court child custody proceedings nor for Indian families involved in Indian child custody proceedings in tribal courts.

Subpart C—Grants to Indian Tribes and Indian Organizations for Title II Indian Child and Family Programs

§ 23.21 Eligibility requirements.

(a) The governing body of any Indian tribe or consortium of tribes, or any Indian organization may apply for a grant individually or as a consortium under this part.

(b) No applicant may submit more than one grant application during an application period. The application period during which grant applications will be accepted shall be published as a **Federal Register** notice.

(c) Selection for grants under this part for tribal on-reservation programs shall be limited to the governing body of the tribe(s) to be served by the grant. The governing body of the tribe may make a subgrant to another Indian tribe(s) or an Indian organization, subject to the provisions of § 23.33.

(d) Actual funding of approved grant applications shall be subject to the availability of funds. These funds will include those which are:

(1) Directly appropriated by the Congress for the implementation of this Act. Distribution of these appropriated funds will be based upon a formula designed to ensure insofar as possible that all applicants approved for funding will receive a proportionate share of the available funds. This formula will be published annually as a **Federal Register** notice.

(2) Appropriated under other statutes for BIA programs which are related to the purposes prescribed in § 23.22.

§ 23.22 Purpose of grants.

(a) The Secretary is authorized to make grants to Indian tribes for the establishment and operation of on- and near-reservation Indian child and family service programs, for the preparation and implementation of child welfare codes, and to provide non-Federal matching shares for other Federal financial assistance programs which contribute to the purpose of the Act.

(i) The objective of every Indian child and family service program shall be to prevent the breakup of Indian families and, in particular, the ensure that the permanent removal of an Indian child from the custody of his/her parent or Indian custodian shall be a last resort. Grant funds may be used for any of the following activities so long as the services provided with grant funds do not duplicate services provided by existing Federal, State, or other child and family service programs:

(i) a system for licensing or otherwise regulating Indian foster and adoptive homes, such as, establishing tribal standards for approval of on-reservation foster or adoptive homes;

(ii) the operation and maintenance of facilities for the counseling and treatment of Indian families and for the temporary custody of Indian children with the goal of strengthening Indian families and preventing parent-child separations;

(iii) Family assistance, including homemaker and home counselors, protective day care and afterschool care, recreational activities, respite care, and employment support services with the goal of strengthening Indian families and contributing toward family stability;

(iv) Home improvement programs with the primary emphasis of preventing the removal of children due to unsafe home environments by making the homes safer, but not to make extensive structural home improvements;

(v) The employment of professional and other trained personnel to assist the tribal court in the disposition of domestic relations and child welfare matters, but not to establish tribal court systems;

(vi) Education and training of Indians, including tribal court judges and staff, in skills relating to child and family assistance and service programs;

(vii) A subsidy program under which Indian adoptive children not eligible for state or BIA subsidy programs may be provided support comparable to that for which they would be eligible as foster children, taking into account the appropriate state standards of support for maintenance and medical needs; and,

(viii) Guidance, legal representation and advice to Indian families involved in tribal, state, or Federal child custody proceedings.

(2) Grants may be provided to tribes in the preparation and implementation of child welfare codes within their jurisdiction or pursuant to a tribal-state and or Indian organization agreement.

(3) Grantees may enhance their capabilities by utilizing grant funds as non-Federal matching shares in connection with funds provided under titles IV–B and XX of the Social Security Act or other Federal financial assistance programs promoting the reunification of families. The services provided through matching share grants must promote the intent and purposes of the Act through the provision of prevention or reunification services. Any grantee receiving additional funds through matching shares must indicate how these funds are to be coordinated with and not duplicate other tribal, Federal, state, and local resources available for the same purpose.

(b) The Secretary is also authorized to make grants to off-reservation Indian organizations to establish and operate off-reservation Indian child and family service programs. In accordance with policy in § 23.3 to emphasize the provision of preventive and reunification services to promote the stability of Indian families, program priorities may be established by the Assistant Secretary to be utilized when more than one application obtains the same competitive score under procedures specified in § 23.25. Grants to off-reservation Indian organizations are for the purpose of stabilizing Indian families and tribes by developing prevantive or reunification services. Provided the off-reservation programs or services are not duplicative of existing Federal, State, or other child and family service programs, grantees may provide:

(1) A system for regulating, maintaining, and supporting Indian foster and adoptive homes, including a subsidy program under which Indian adoptive children may be provided support comparable to that for which they would be eligible as Indian foster children, taking into account the appropriate state standards of support for maintenance and medical needs;

(2) The operation and maintenance of facilities and service for counseling and treatment of Indian families and Indian foster and adoptive children with the goal of strengthening and stabilizing Indian families;

(3) Family assistance (including homemaker and home counselors), protective day care and afterschool care, employment support services, recreational activities, and respite care with the goal or strengthening Indian families and contributing toward family stability; and

(4) Guidance, legal representation and advice to Indian families involved in state child custody proceedings.

§ 23.23 Obtaining application instructions and materials.

(a) Tribal application instructions and related application material may be obtained from the Superintendents or appropriate Area Director. Application instructions and related application material for off-reservation programs may be obtained from the appropriate Area Director.

(b) Prior to the beginning or during the grant year(s) in which grants for off-reservation programs will be awarded, the BIA will publish in the Federal Register an announcement of the grant application process for the year, including: priorities, if any, applicant eligibility criteria, the required application contents, the amount of available funding and evaluation criteria for off-reservation programs.

(c) Based on the announcement described in paragraph (b) of this section, an off-reservation applicant shall prepare an application in accordance with § 23.25 for the competitive review and scoring process.

§ 23.24 Noncompetitive multi-year on reservation tribal program application contents.

The Secretary shall, subject to the tribe's fulfillment of the mandatory application requirements and the availability of appropriated funds, make a grant to the tribal governing body of any Indian tribe or consortium of tribes eligible to apply for a grant under this part. An application for a grant under this part shall be submitted to the Superintendent prior to or on the announced deadline date published in the Federal Register and transmitted to the Area Director within five working days for disposition. Mandatory tribal application requirements shall include:

(a) A tribal resolution requesting the Secretary to enter into a grant by the Indian tribe(s) to be served by the grant. If a tribe is applying for a grant benefiting more than one Indian tribe (consortium), an authorizing resolution from each affected tribal governing body to be served must be obtained. The request shall be in the form of a resolution by the tribal governing body and shall include the following:

(1) The full name of the tribal governing body(s);

(2) A brief description of the specific program being requested;

(3) The results of the majority vote in support of the proposed program (the number for and against), the date the resolution was approved, and signature of a tribal official duly authorized to certify the accuracy of the information contained in the resolution.

(4) A provision stating that the resolution shall remain in effect for the duration of the program or until the resolution expires or is rescinded.

(b) A completed Application for Federal Assistance form, SF–424.

(c) Identification of the geographic area(s) to be served; based on verifiable resident Indian population statistics, an identification of actual and/or estimated number of resident Indian families and/or persons who will benefit from or receive services from the grant. The accuracy of these population statistics shall be supported by appropriate data and verified by an authorized tribal representative with concurrence by the Agency Superintendent/Tribal Operations or Area Office/Tribal Operations where applicable. Disagreements relative to these statistics shall be resolved by the Area Director.

(d) A comprehensive and developmental multi-year plan in narrative form describing the proposed program, including culturally defined approaches, the tribe(s) will administer. At a minimum, a narrative description of the program shall include a brief description of the specific community conditions and problems the project will address; an overview of how its long-range goals and objectives relate to preventing family break-ups or provide for the reunification of families; demographics of the population to be served; expected results and benefits from the program; a methodology which includes in measurable terms a work and time schedule to accomplish each goal and objective applicable to each program year and consistent with the master plan; and a discussion of internal evaluation criteria to be used to evaluate the results and success of the program in stabilizing Indian families. In order to provide comprehensive services, as well as avoid duplication, the program shall identify and complement other existing services by coordinating and carrying out its activities in concert with these services.

(e) A description of the applicant's proposed key personnel, including their qualifications, criteria for the prospective employee's knowledge of the Indian culture and a sense of cultural sensitivity, academic training, responsibilities and functions, a copy of their position descriptions, and the inclusion of Indian preference criteria for employment. All programs providing specialized, professional child welfare services shall have at least one staff member with a master of social work degree or a master's degree in an allied field of study. Professional child welfare programs that are unable to comply with this requirement shall establish a plan for regular access to professional consultation and or a formal staff training plan to achieve this standard within a reasonable specified timeframe. Regular access to professional consultation may include access via the local child protection team members, telephone case consultation, or such other system of consultation adapted to the unique needs of the tribe.

(f) The extent of an applicant's financial participation in other programs, such as title IV–B, title XX, or other non-Federal matching shares, if any, in the proposed program indicating the type of contribution, such as cash or in-kind services, loans of full or part time staff, equipment, space, materials or facilities, or other contributions for the applicable grant year(s).

(g) Proof of liability insurance coverage for the applicable grant years.

(h) Where an applicant proposes to obtain consultative services, the application shall state the qualifications and the experience of the consultant reflecting the requirements for performing the work, a schedule and description of the services to be provided, and a detailed budget for the proposed services.

(i) A detailed budget and narrative justification to be submitted on an annual basis for the amount of the grant award must specifically relate to and be clearly supported by the proposed plan and program activities. Because appropriations under this Act are intended primarily for direct services, contract support costs are not applicable to grants awarded under this part. Hence, negotiated indirect cost rates are also not applicable under this part, hence, all direct and indirect costs shall be itemized as costs to the grant.

(j) Fiscal provisions which meet 25 CFR 23.42.

(k) Program income resulting from the operation of programs under this part, such as day care operations, may be retained and shall be used for the purposes and under the conditions of the grant agreement.

(l) Continued annual funding of grants under this part shall be contingent upon the existing grant program receiving a satisfactory evaluation from the area office for the previous year of operation. A copy of this evaluation shall be included in the program's annual performance report. Minimum standards for receiving a satisfactory evaluation shall include the timely submission of all fiscal and programmatic reports, accomplishing programmatic goals and objectives within its specified timeframes and resources, as well as the implementation of corrective action measures if applicable.

§ 23.25 Application selection criteria for competitive grants.

(a) The Secretary shall, contingent upon the availability of funds, make a multi-year grant under this part for an off-reservation program when officially requested by a resolution by the governing body of the respective Indian organization, upon the applicant's fulfillment of the mandatory application requirements, and upon the applicant's successful competition in the grant process.

(b) An application for a competitive multi-year grant under this part shall be submitted to the appropriate area office prior to or on the announced deadline date published in the **Federal Register**. The area office shall certify the application contents pursuant to § 23.28 and forward the application within 15 working days to the centralized review committee composed of members designated by the Assistant Secretary/designated official for further review and disposition. Modifications and or information received after the close of the application period as announced in the **Federal Register** shall not be reviewed by the centralized review committee in the competitive process.

(c) Mandatory application requirements for Indian organizations shall include:

(1) Written assurances that the organization meets the definition of Indian organization at § 23.2;

(2) A copy of the organization's current Articles of Incorporation;

(3) Proof of the organization's nonprofit status;

(4) A copy of the organization's IRS tax exemption certificate and IRS employer identification number;

(5) Proof of liability insurance for the applicable grant years; and,

(6) Current written assurances meeting the requirements of Circular A–128 for fiscal management, accounting, and recordkeeping.

(d) The Secretary or his/her designated representative shall select those proposals which will in his/her judgment best promote the purposes of the Act. Such selection will be made through a centralized review process in which each application will be scored competitively, taking into consideration the mandatory requirements as specified above and the following selection criteria:

(1) The degree to which the application reflects an understanding of the social service problems or issues affecting the resident Indian client

population which the applicant proposes to serve.

(2) The degree to which and the methods by which the applicant intends to fulfill the intent, purpose and scope of the Act to promote the stability and security of Indian tribes and families, specifically relating its developmental multi-year plan and the long-range goals and the objectives in measurable terms to each program year and consistent with the master plan, and a discussion of internal evaluation criteria to be used to evaluate how the proposed activities will either prevent family breakups or provide for the reunification of families.

(3) Whether the applicant presents a narrative needs assessment, quantitative data, and demographics of the client Indian population to be served. Examples of such data include:

(i) The number of actual or estimated Indian child placements outside the home;

(ii) The number of actual or estimated Indian family breakups; and

(iii) The need for and type(s) of prevention program(s), including culturally defined approaches, to address the identified needs.

(4) Documentation of the relative accessibility which the Indian population to be served under a specific proposal already has to existing child and family service programs emphasizing the prevention of Indian family breakup such as mandatory state services provided through title IV–E. Factors to be considered in determining accessibility include:

(i) Cultural barriers;

(ii) Discrimination against Indians;

(iii) Inability of potential Indian clientele to pay for services;

(iv) Technical barriers created by existing public or private programs;

(v) Availability of transportation to existing programs;

(vi) Distance between the Indian community to be served under the proposal and the nearest existing programs;

(vii) Quality of service provided to Indian clientele; and

(viii) Relevance of service provided to specific needs of Indian clientele.

(5) If the proposed program duplicates existing Federal, State, or local child and family service programs emphasizing the prevention of Indian family breakups, proper and current documented evidence that repeated advocacy for services has failed.

(6) Evidence of substantial tribal and community support for the proposed program from the Indian community or communities to be served, including but not limited to:

(i) Tribal support evidenced by a tribal resolution or cooperative service agreements between the administrative bodies of the affected tribe(s) and the applicant for the duration of the grant period if more than one-half of the proposed Indian population to be served are members of one tribe. If a tribe includes in its plan under 25 U.S.C. 1931 that services will be provided to its tribal members residing in its officially designated near-reservation service area, its population will be excluded from the service area population of the off-reservation program located in the same geographic area.

(ii) Letters of support from social service organizations familiar with the applicant's past work experience.

(7) The explanation of proposed facilities and of the structure of the Indian organization, including the structure of the particular unit within the organization requesting grant funds, and the organization's annual budget.

(8) A description of the applicant's proposed key personnel, including their qualifications, criteria for the prospective employee's knowledge of the Indian culture and a sense of cultural sensitivity, academic training, responsibilities and functions, a copy of their position descriptions, and inclusion of Indian preference criteria for employment. All programs providing specialized, professional child welfare services shall have at least one staff member with a master's degree in social work or an allied field of study. Professional child welfare programs that are unable to comply with this requirement shall establish a plan for regular access to professional consultation and/or a formal staff training plan to achieve this standard.

(9) Where an applicant proposes to obtain consultative services, the application shall state the qualifications and the experience of the consultant reflecting the requirements for performing the work, a schedule and description of the services to be provided, and a detailed budget for the proposed services.

(10) The reasonableness and relevance of the estimated overall costs of the proposed program or service and its overall relation to the organization's funding base, activities, and mission. A detailed budget and narrative justification to be submitted on an annual basis for the amount of the grant request must be consistent with and clearly supported by the proposed plan and program activities. Because appropriations under this Act are intended primarily for direct services, contract support costs are not applicable to grants awarded under this part. Negotiated indirect cost rates are also not applicable under this part, hence, all direct and indirect costs shall be itemized as costs to the grant.

(e) Two or more grants receiving the same competitive score will be prioritized pursuant to § 23.22.

(f) Continued annual funding for off-reservation Indian organizations shall be contingent upon the existing grant program receiving a satisfactory evaluation from the area office for the previous year of operation. A copy of this evaluation shall be included in the application requirements under this part. Minimum standards for receiving a satisfactory evaluation shall include the timely submission of all fiscal and programmatic reports, accomplishing programmatic goals and objectives within their specified timeframes and resources, as well as the implementation of mutually determined corrective action measures if applicable. If an applicant has been a grantee during the grant cycle immediately preceding the year for which a new application is being made, a program must have received a satisfactory evaluation upon completion of the previous grant administration.

§ 23.26 Submitting applications.

(a) *Noncompetitive tribal programs.* An application for a grant under this part for an on- or near-reservation program shall be submitted to the appropriate Superintendent for review and certification as prescribed in § 23.24. Programs proposing to serve more than one agency office jurisdiction shall be submitted simultaneously to each affected agency office, and upon certification shall be transmitted to the appropriate area office. Each agency office will review and certify whether applications contain and meet all the application requirements specified at § 23.24, state whether it concurs with the accuracy of the resident Indian population statistics submitted by the tribal applicants, and transmit the application within five working days to the area office for disposition.

(b) *Competitive off-reservation programs.* An application for a grant under this part for off-reservation programs shall be submitted to the appropriate Area Director for certification and transmitted within 15 working days to the centralized review committee for disposition.

§ 23.27 Technical assistance.

(a) Tribal requests. Pre-application technical assistance in the development of a grant proposal may be requested by a tribe or consortium of tribes from the area office to which the tribes will be submitting an application under § 23.24 within 60 days of the close of the

application period but not later than 30 days prior to the application deadline.

(1) The area office shall as soon as possible but not later than 30 days after receiving a request provide the necessary technical assistance to the tribe in meeting the application requirements. Tribal applications not meeting the intent, purpose, and scope of the Act shall be returned to the tribe, with a detailed explanation of their deficiencies within 15 working days but no later than 15 days prior to the published deadline for the receipt of applications in final form. All pre-application technical assistance shall be completed 15 days prior to the published deadline for applications.

(2) Applications shall be resubmitted to the Area Director by the close of the application period as published in the **Federal Register** for the applicable grant year.

(3) If an acceptable application has not been submitted by the deadline, the tribe's proportionate share of funds shall be reallocated by Central Office to other grantees. The tribe may submit another application the next grant year.

(b) Upon request by an Indian tribe, ongoing technical assistance shall be provided by the respective area office for the purposes of program planning and design, and assistance in establishing program evaluation criteria for ongoing grant administration and management.

(c) Off-reservation requests. Upon request by an off-reservation Indian organization, pre-application and ongoing technical assistance may be provided by the respective area office for the purposes of the development of a grant proposal, program planning and design, and assistance in establishing program evaluation criteria for ongoing grant administration and management. The request for and the provision of pre-application technical assistance shall be in accordance with the established timeframes in paragraph (a) of this section.

§ 23.28 Area office role.

Upon receipt of an application for a grant by an on- or near-reservation or off-reservation program at the area office, the Area Director shall:

(a) Complete and sign the area office certification form. In completing the area certification form, the Area Director shall assess and certify whether applications contain and meet all the application requirements specified at §§ 23.24 and 23.25, respectively;

(b) Advise the applicant in writing within 10 days of the receipt of the application;

(c) Advise on- or near-reservation applicants of the disposition of their application within 10 days of the receipt of the application; and

(d) Transmit the off-reservation applications within 15 working days of receipt to the centralized review committee for further disposition.

§ 23.29 Centralized review and decision for off-reservation applications.

(a) Upon receipt of an application for an off-reservation grant under this part, requiring the approval of the Assistant Secretary, the Director, Office of Tribal Services, as the Assistant Secretary's designated official, shall:

(1) Establish a centralized review committee.

(2) Review the area office certification form required in § 23.28. Area Directors will be responsible for the completion of the area office certification form for all applications submitted to the area office by off-reservation Indian organizations.

(3) Review the application in accordance with the competitive review procedures prescribed in § 23.25. An application shall not receive approval for funding under the centralized competitive review and scoring process unless a review of the application determines that it:

(i) Contains all the information required in § 23.25, and,

(ii) Receives at least the minimum score in a competitive review under the scoring process using the selection criteria set out in § 23.25. The minimum score will be established by the Central Office prior to each application period and announced in the **Federal Register** for the applicable grant year(s).

(4) Approve or disapprove the application. Approval for funding of all grant applications under this part shall be the responsibility of the Director, Office of Tribal Services. This decision shall be appealable directly to the Interior Board of Indian Appeals under part 2 of this chapter, except as noted in the appeals section of this part.

(5) Promptly notify the applicant in writing as to the approval or disapproval of the application. If the application is disapproved, the Director, Office of Tribal Services, will include in the written notice the specific reasons therefore.

(b) Modifications of the grant application received after the close of the application period will not be considered in the review and action on the application as prescribed in § 23.25.

(c) Actual funding of approved grant applications shall be subject to the availability of funds as announced in the **Federal Register** for the applicable grant year(s). Priority consideration in the funding of grants shall be given to Indian tribes applying for grants under § 23.24 of this part.

§ 23.30 Deadline for Central Office action.

Within 60 days of the receipt of an application for a grant under § 23.29, requiring the approval of the Assistant Secretary for funding, the Director, Office of Tribal Services shall take action as prescribed in § 23.29(a). Extension of this deadline will require consultation with, and written consent of, the applicant.

§ 23.31 Grant approval limitation.

(a) *Tribal on- or near-reservation programs.* Authority for approval of a grant application under this part shall be with the Area Director when the intent, purpose and scope of the proposal pertains solely to reservations located within that Area Director's service area jurisdiction.

(b) *Off-reservation programs.* Authority for approval of a grant application under this part shall be with the Assistant Secretary, when the intent, purpose and scope of the grant proposal pertains to off-reservation Indian service populations or programs.

§ 23.32 Grant execution, administration, and monitoring.

All grants shall be executed, administered, and monitored at the area office level. The area offices shall be responsible for monitoring activities to assure compliance with the grant, applicable Federal requirements and performance goals. Grantees shall be responsible for managing the day-to-day operations of the grant activities.

§ 23.33 Subgrants.

The grantee may make subgrants under this part provided that such subgrants are for the purpose for which the grant was made and that the grantee retains administrative and financial responsibility over the activity and the funds.

Subpart D—General Grant Requirements

§ 23.41 Uniform grant administration requirements and applicability.

The general and uniform grant administration requirements identified under this subpart are applicable to all grants provided to tribal governing body(s) and Indian organizations under this part.

§ 23.42 Financial management, internal and external controls and other assurances.

A grantee's financial management system shall meet the following standards for accurate, current, and

complete disclosure of its financial activities.

(a) OMB Circular A–102 (Common Rule, 43 CFR part 12)

(b) OMB Circular A–128 (Single Audit Act),

(c) OMB Circular A–122 (Cost principles for non-profit organizations and tribal organizations where applicable), and

(d) OMB Circular A–87 (Cost principles for state and local governments and federally recognized Indian tribal governments).

(e) Internal Control. Effective control and accountability must be maintained for all grants. Grantee must adequately safeguard any property and must ensure that it is used solely for authorized purposes.

(f) Budget Control. Actual expenditures must be compared with budgeted amounts for the grant. Financial information must be related to program performance requirements.

(g) Source Documentation. Accounting records must be supported by such source documentation as cancelled checks, paid bills, payrolls, time and attendance records, grant documents, or others as required in the grantees financial management system. The Secretary may review the adequacy of the financial management system of an Indian tribe or Indian organization applying for a grant under this part.

(h) Existing grantees shall include in their annual program performance reports a copy of a satisfactory program evaluation from the area office for the previous year of operation at the expiration of each grant year.

(i) Pursuant to 25 U.S.C. et seq. (Pub. L. 101–630), title IV, The Indian Child Protection and Family Violence Prevention Act, all grantees shall conduct character and background investigations of those personnel identified in that statute.

(j) Pursuant to the Drug-Free Workplace Act of 1988, all grantees shall meet the mandatory Drug-Free Workplace Certification, a regulatory requirement for Federal grant recipients.

§ 23.43 Reports and availability of information to Indians.

(a) Any tribal governing body or Indian organization receiving a grant under this part shall make general programmatic information and reports concerning that grant available to the Indian people it serves or represents. Access to this information may be requested in writing and shall be made available within 10 days of receipt of the request. Except as required by title IV of Pub. L. 101–630, the Indian Child Protection and Family Violence Prevention Act, the grantee shall hold confidential all information obtained from persons receiving services from the grant, and shall not release such information without the individual's written consent. Information may be disclosed in a manner which does not identify particular individuals.

(b) Grantees shall submit Standard Form 269 or 269A to report the status of funds for all grants. Reports are required to be submitted on a quarterly basis and will be due 30 days after the end of each quarter. Final reports are due 90 days after the expiration or termination of each grant year.

(c) A narrative performance report will contain, for each grant, brief information the following:

(1) The actual accomplishments as related to the objectives established for the period. Where the output of the project can be quantified, a computation of the cost per unit of output may be required if that information will be useful.

(2) The reasons for not meeting established objectives.

(3) Additional pertinent information including, when appropriate, analysis and explanation of unit costs.

(d) Grantees shall submit reports in response to specific data requests for programmatic information which have been requested by the OMB, Congress, or the Secretary.

(e) Quarterly reporting requirements for all direct service programs shall include data which collect the following information:

(1) Report of all significant Title II grant activities;

(2) Data reflecting numbers of individuals referred for out-of-home placements, numbers of individuals benefiting from Title II services and types of services provided; and

(3) Information and referral activities.

(f) Events may occur between scheduled performance reporting dates which have significant impact on the grant supported activity. In such cases, the grantee must inform the awarding agency as soon as problems, delays, adverse conditions, or serious incidents giving rise to liability become known and which will materially impair the ability to meet the objective of the award.

(g) Grantees shall submit annual performance reports which shall be due 60 days after the end of each grant budget period and a final performance report shall be due 60 days after the expiration of each grant year.

(h) Grantees shall submit with their annual performance report an annual consolidated statistical report listing the unduplicated number of persons associated with the unduplicated case count served during the grant year by sex of recipient within the category of service and by age grouping of the recipient.

(i) Each grantee providing direct services shall maintain a case record on each individual and or family being served by the grant as reflected in paragraph (e) of this section. At a minimum, each case record shall contain the following information:

(1) Documentation from appropriate tribe that verifies Indian status and service eligibility as defined at 25 CFR 23.2 and 23.46.

(2) All services provided shall be documented in a case plan. A case plan must be reviewed and updated every six months.

(3) A record of all referrals made to other agencies.

(4) A record of other pertinent data, such as school records, health records, court orders, and social histories.

(5) Documentation of progress or impediments toward reaching the goal of providing preventive and reunification services to all Indian children and families being served under the grant.

§ 23.44 Matching shares and agreements.

(a) Grant funds provided to Indian tribes under 25 U.S.C. 1931 may be used as non-Federal matching shares in connection with funds provided under titles IV–B and XX of the Social Security Act or under any other Federal financial assistance programs which contribute to the purposes specified in §§ 23.3 and 23.22.

(b) Pursuant to 25 U.S.C. 1933, the Secretary may enter into agreements with the Secretary of Health and Human Services, and the latter Secretary is authorized by the Act to use funds appropriated for the Department of Health and Human Services programs similar to those funded under 25 U.S.C. 1931 and 1932, provided that authority to make payment pursuant to such agreements shall be effective only to the extend and in such amounts as may be provided in advance by appropriation Acts.

§ 23.45 Fair and uniform provision of services.

(a) Grants awarded under this part shall include provisions assuring compliance with the Indian Civil Rights Act and provisions prohibiting discriminatory distinctions among eligible Indian beneficiaries and assuring the fair and uniform provision by the grantees of the services and assistance they provide to eligible Indian beneficiaries under such grants.

(b) Indian beneficiaries of the services to be rendered under a grant shall be afforded access to tribal administrative or judicial bodies empowered to adjudicate complaints, claims, or grievances brought by such Indian beneficiaries against the grantee arising out of the performance of the grant.

§ 23.46 Service eligibility.

(a) *On- and near-reservation Indian child and family service programs.* Any person meeting the definition of Indian, Indian child, Indian custodian, or Indian parent of any unmarried person under the age of 18 as defined in § 23.2 is eligible for services provided under 25 U.S.C. 1931 of the Act. Tribal membership status shall be determined by the tribal law, ordinance, or custom. Indian tribes with officially designated near-reservation service areas as defined in § 23.2 shall serve their tribal members and those individuals eligible for membership within their tribes and are residing in these service areas. The tribe may, within available resources, extend services under this part to non-tribal Indian residents in the tribe's designated service area.

(b) *Off-reservation Indian child and family service programs and agreements with the Secretary of Health and Human Services pursuant to 25 U.S.C. 1933.* For purposes of eligibility for services provided under 25 U.S.C. 1932 and 1933 of the Act, any person meeting the definition of Indian, Indian child, Indian custodian, or Indian parent of any unmarried person under the age of 18 as defined in § 23.2, or the definition of Indian as defined in 25 U.S.C. 1603 (c), shall be eligible for services. Tribal membership status shall be determined by the tribal law, ordinance, or custom.

§ 23.47 Grant renewal and modification.

(a) *Tribal application renewal.* Following the initial application cycle, a tribal grantee may continue to submit noncompetitive applications for continued grant funding, contingent upon satisfactory program evaluations from the area for the existing grant program, under the applicable Federal Register announcement. The renewal application shall contain all applicable and updated information as required in § 23.24.

(b) *Off-reservation application renewal.* Off-reservation applicants may continue to apply for grants under the competitive process specified in § 23.25 and as announced in the Federal Register for the applicable grant period.

§ 23.48 Penalties.

If any officer, director, agent, employee of, or anyone connected with any recipient of a grant or subgrant under this part embezzles, willfully misapplies, steals, or obtains by fraud any of the funds, assets, or property which are the subject of such a grant or subgrant, he or she may be subject to penalties as provided in 18 U.S.C. 1001.

Subpart E—Grant Revision, Carry Over Authority, Grant Suspension or Cancellation

§ 23.51 Revisions or amendments of grants.

Any grantee may submit a written request for a post award grant modification covering material changes to the terms and conditions of the grant. The modification request shall include a narrative description of any significant additions, deletions, or changes to the approved program activities or budget in the form of a grant amendment proposal.

§ 23.52 Grant carry over authority.

Unless restricted by appropriation and contingent upon satisfactory program evaluations from the area for the existing program, grantees are authorized to carry over unliquidated grant funds which remain at the end of a budget period for two years beyond the initial grant funding period to be utilized only for the intent, purpose and scope of the original grant. These carry over grant funds shall not be reprogrammed into other appropriation activities or subactivities. Funds carried over into another fiscal year would be in addition to the grantee's new fiscal year grant award.

§ 23.53 Grant Suspension.

(a) When the grantee has materially failed to comply with the terms and conditions of the grant, the BIA may, after reasonable notice to the grantee and the provision of requested technical assistance, suspend the grant. The notice preceding the suspension shall include the effective date of the suspension, the corrective measures necessary for reinstatement of the grant, and, if there is no immediate threat to safety, a reasonable timeframe for corrective action prior to actual suspension.

(b) No obligation incurred by the grantee during the period of suspension shall be allowable under the suspended grant, except that the BIA may at its discretion allow necessary and proper costs which the grantee could not reasonably avoid during the period of suspension if such costs would otherwise be allowable under the applicable cost principles.

(c) Appropriate adjustments to the payments under the suspended grant will be made either by withholding the payments or by not allowing the grantee credit for disbursements which the grantee may make in liquidation of unauthorized obligations the grantee incurs during the period of suspension.

(d) Suspension shall remain in effect until the grantee has taken corrective action to the satisfaction of the BIA or given assurances satisfactory to the BIA that corrective action will be taken, or until the BIA cancels the grant.

§ 23.54 Cancellation.

(a) The BIA may cancel any grant in whole, or in part, at any time before the date of completion, whenever it is determined that the grantee has:

(1) Materially failed to comply with the terms and conditions of the grant;

(2) Violated the rights as specified in § 23.45 or endangered the health, safety, or welfare of any person; or

(3) Been grossly negligent in or has mismanaged the handling or use of funds provided under the grant.

(b) When it appears that cancellation of the grant will become necessary, the BIA shall promptly notify the grantee in writing of this possibility. This written notice shall advise the grantee of the reason for the possible cancellation and the corrective action necessary to avoid cancellation. The BIA shall also offer and provide, if requested by the grantee, any technical assistance which may be required to effect the corrective action. The grantee shall have 60 days in which to effect this corrective action before the BIA provides notice of intent to cancel the grant as provided in paragraph (c) of this section.

(c) Upon deciding to cancel for cause, the BIA shall promptly notify the grantee in writing of that decision, the reasons for the cancellation, and the effective date. The Area Director or his/her designated official shall also provide a hearing for the grantee before cancellation. However, the BIA may immediately cancel the grant, upon notice to the grantee, if the BIA determines that continuance of the grant poses an immediate threat to safety. In this event, the BIA shall provide a hearing for the grantee within 10 days of the cancellation.

(d) The hearing referred to in paragraph (c) of this section shall be conducted as follows:

(1) The grantee affected shall be notified, in writing, at least 10 days before the hearing. The notice should give the date, time, place, and purpose of the hearing.

(2) A written record of the hearing shall be made. The record shall include written statements submitted at the

hearing or within five days following the hearing.

Subpart F—Hearings and Appeals

§ 23.61 Appeals from decision or action by Area Director.

An applicant or grantee may appeal any decision made or action taken by an Area Director under this part. Such an appeal shall be made to the Assistant Secretary as provided in part 2 of this chapter.

§ 23.62 Appeals from decision or action by the Director, Office of Tribal Services.

An applicant or grantee may appeal any decision made or action taken by the Director, Office of Tribal Services, that is alleged to be in violation of the U.S. Constitution, Federal statutes, or the regulations of this part; however, an applicant may not appeal a score assigned to its application nor the amount of grant funds awarded under this part. These appeals shall be filed with the Interior Board of Indian Appeals as provided in part 2 of this chapter.

§ 23.63 Appeals from inaction of official.

A person or persons whose interests are adversely affected, or whose ability to protect such interests is impeded by the failure of an official to act on a request to the official, may make the official's inaction the subject of an appeal under part 2 of this chapter.

Subpart G—Administrative Provisions

§ 23.71 Recordkeeping and information availability.

(a)(1) Any state court entering a final decree or adoptive order for any Indian child shall provide the Secretary of the Interior within 30 days a copy of said decree or order, together with any information necessary to show:

(i) The name of the child, the birth date of the child, and the tribal affiliation of the child pursuant to 25 U.S.C. 1951.

(ii) Names and addresses of the biological parents and the adoptive parents;

(iii) Identity of any agency having relevant information relating to said adoption placement.

(2) To assure and maintain confidentiality where the biological parent(s) have by affidavit requested their identity remain confidential, a copy of such affidavit shall be provided to the Secretary. Information provided pursuant to 25 U.S.C. 1951 (a) shall not be subject to the Freedom of Information Act (5 U.S.C. 552), as amended. The Secretary shall ensure that the confidentiality of such information is maintained. The address for transmittal of information required by 25 U.S.C. 1951(a) of the Act is: Chief, Division of Social Services, Bureau of Indian Affairs, 1849 C Street, NW., Washington, DC 20245. The envelope containing all such information should be marked "Confidential." This address shall be sent to the highest court of appeal, the Attorney General and Governor of each state. In some states, a state agency has been designated to be repository for all state court adoption information. Where such a system is operative, that agency may assume reporting responsibilities for the purpose of the Act.

(b) The Division of Social Services, Bureau of Indian Affairs, is authorized to receive all information and to maintain a central file on all state Indian adoptions. This file shall be confidential and only designated persons shall have access to it. Upon the request of the adopted Indian individual over the age of 18, the adoptive or foster parents of an Indian child, or an Indian tribe, the Division of Social Services shall disclose such information as may be necessary for enrollment or determining any rights or benefits associated with membership, except the name of the biological parents where an affidavit of confidentiality has been filed, to those persons eligible to request such information under the Act. The Chief Tribal Enrollment Officer of the BIA is authorized to disclose enrollment information relating to an adopted Indian child where the biological parents have by affidavit requested anonymity. In such cases, the Chief Tribal Enrollment Officer shall certify to the child's tribe, where the information warrants, that the child's parentage and other circumstances entitle the child to enrollment consideration under the criteria established by said tribe.

Subpart H—Assistance to State Courts

§ 23.81 Assistance in identifying witnesses.

Upon the request of a party in an involuntary child custody proceeding or of a court the Secretary shall assist in identifying qualified expert witnesses. Such requests for assistance should be sent to the Area Director designated in § 23.11(b).

§ 23.82 Assistance in identifying interpreters.

Upon the request of a party in any Indian child custody proceeding or of a court the Secretary shall assist in identifying interpreters. Such requests for assistance should be sent to the Area Director designated in § 23.11(b).

§ 23.83 Assistance in locating biological parents of Indian child after termination of adoption.

Upon the request of a child placement agency, the court or an Indian tribe, the Secretary shall assist in locating the biological parents or prior Indian custodian of an Indian adopted child whose adoption has been terminated pursuant to 25 U.S.C. 1914 of the Act. Such requests for assistance should be sent to the Area Director designated in § 23.11(b).

William D. Bettenberg,

Acting Assistant Secretary—Indian Affairs.

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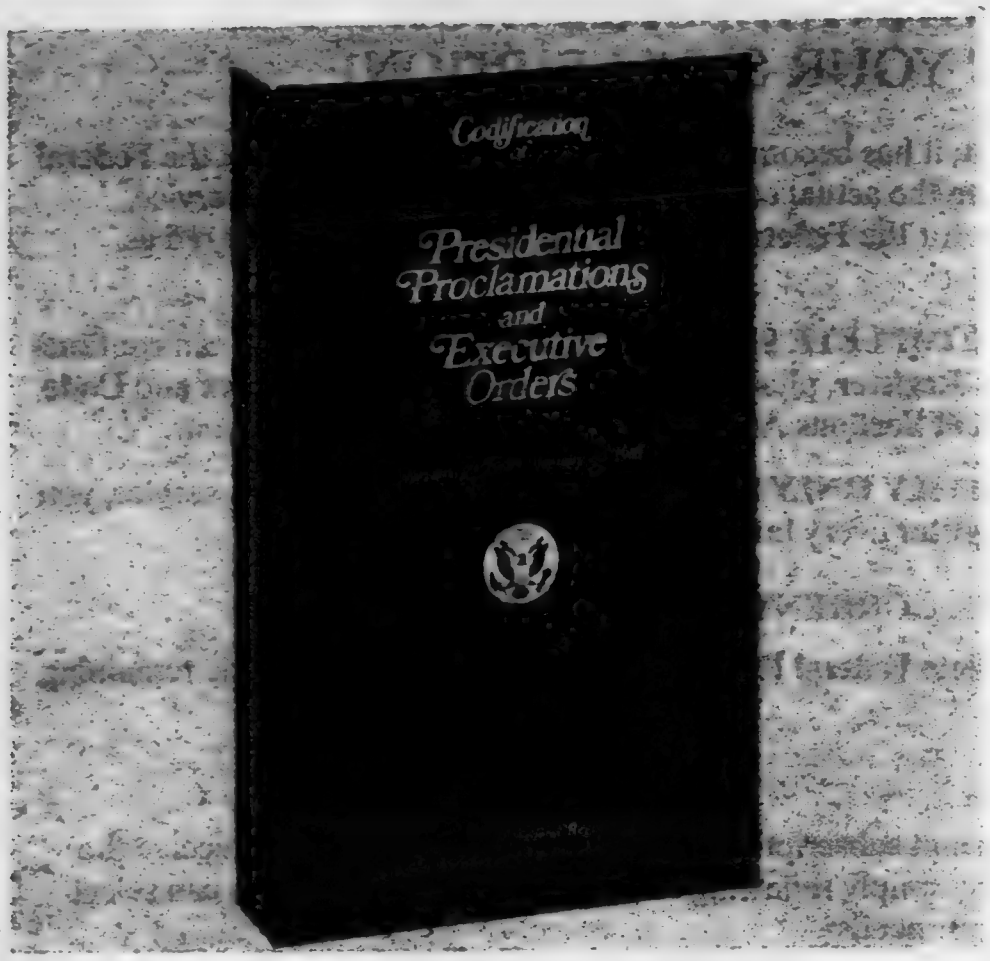

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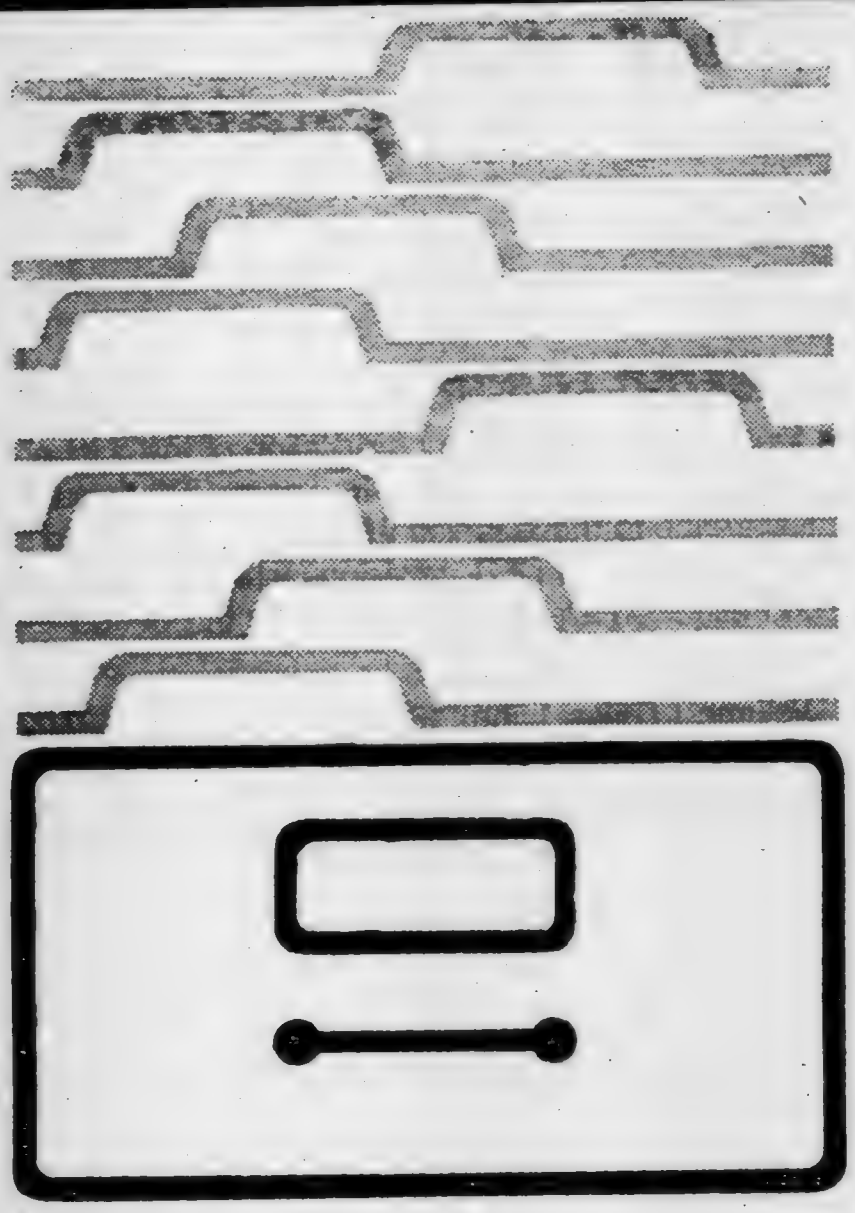

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Presidential Documents

Title 3—

The President

Presidential Determination No. 93–7 of January 5, 1993

Determination Pursuant to Public Law 101–513, the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1991, and Public Law 102–145, the Joint Resolution on Further Continuing Appropriations for October 1, 1991, through March 1992

Memorandum for the Secretary of State

Pursuant to Public Law 101–513, the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1991, as made applicable to FY 1992 by the Joint Resolution on Further Continuing Appropriations, Fiscal Year 1992 (Public Law 102–145) (the Appropriations Laws), I hereby certify that it is in the national interest to obligate funds appropriated for payment to the International Development Association during FY 1992 but previously withheld from obligation under the Appropriations Laws.

You are directed to publish this determination in the **Federal Register** and report it to the Committee on Appropriations and the Committee on Banking, Finance and Urban Affairs of the House of Representatives and the Committee on Appropriations and the Committee on Foreign Relations of the Senate.

George Bush

THE WHITE HOUSE,
Washington, January 5, 1993.

[FR Doc. 93–991
Filed 1–11–93; 3:33 pm]
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[FR Doc. 93–9
Filed 1–11–93
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Presidential Documents

Executive Order 12830 of January 9, 1993

Establishing the Military Outstanding Volunteer Service Medal

By the authority vested in me as President by the Constitution and the laws of the United States of America, and as Commander in Chief of the Armed Forces, it is hereby ordered as follows:

Section 1. There is hereby established a Military Outstanding Volunteer Service Medal, with accompanying ribbons and appurtenances, for award by the Secretary of Defense or, with respect to the Coast Guard when it is not operating as a service in the Navy, the Secretary of Transportation. Members of the Armed Forces of the United States (including Reserve components) who perform outstanding volunteer service to the civilian community of a sustained, direct, and consequential nature are eligible for the medal.

Sec. 2. The Military Outstanding Volunteer Service Medal and ribbons and appurtenances thereto shall be of appropriate design approved by the Secretary of Defense. The Secretary of Defense shall prescribe regulations to govern the award and wear of the Military Outstanding Volunteer Service Medal. The regulations shall place the Military Outstanding Volunteer Service Medal in order of precedence immediately after the Humanitarian Service Medal.

Sec. 3. No more than one award of the Military Outstanding Volunteer Service Medal may be made to any one person, but for each subsequent act justifying such an award, a suitable device may be awarded to be worn with that medal as prescribed by appropriate regulations issued by the Secretary of Defense.

Sec. 4. The Military Outstanding Volunteer Service Medal may be awarded posthumously, and when so awarded, may be presented to such representatives of the deceased as may be deemed appropriate by the Secretary of Defense or, in the case of a member of the Coast Guard when it is not operating as a service in the Navy, the Secretary of Transportation.

George Bush

THE WHITE HOUSE,
January 9, 1993.

[FR Doc. 93–947
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Rules and Regulations

Federal Register
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Wednesday, January 13, 1993

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1410

RINS 0560–AC66 and 0560–AC93

Amendments to the Conservation Reserve Program Regulations Regarding Small Wetlands and Other Statutory Requirements

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This action covers four general areas. First, the final rule adopts, with changes, the proposed rule published on June 25, 1992, at 57 FR 28468 concerning the eligibility of small farmed wetlands to be enrolled in the Conservation Reserve Program (CRP). This allows producers greater flexibility in both enrolling and achieving enhanced environmental benefits under CRP. Second, the regulations are amended to incorporate certain nondiscretionary changes regarding limited grazing and easement requirements of the CRP, as required by the Food, Agriculture, Conservation, and Trade Act Amendments of 1991 (the 1991 Act) (Pub. L. 102–237) and legislation entitled "To Amend the Food Security Act of 1985 To Remove Certain Easement Requirements Under the Conservation Reserve Program and for Other Purposes" (the 1992 Act) (Pub. L. 102–324). Third, the regulations are amended to be consistent with the Wetlands Reserve Program (WRP) provisions relative to CRP participants offering eligible wetlands for enrollment into the WRP. The WRP final rule was published on June 4, 1992 (57 FR 23908). Fourth, the regulations are amended to ensure clarity and accuracy.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: James R. McMullen, Director, Conservation and Environmental Protection Division, ASCS, USDA, P.O. Box 2415, Washington, DC 20013–2415; phone 202–720–6221.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under USDA procedures established in accordance with Executive Order 12291 and provisions of Departmental Regulation 1512–1 and has been classified as "nonmajor." It has been determined that these provisions will not result in: (1) An annual effect on the national economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, State or local agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

It has been determined by an environmental evaluation that this action will not adversely affect the environmental, historical, social, or economic resources of the Nation. Therefore, it has been determined that these actions will not require an Environmental Assessment nor an Environmental Impact Statement.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

This final rule has been reviewed in accordance with Executive Order 12778. The provisions of this final rule are not retroactive and do not preempt State laws. Before any judicial action may be taken with respect to the provisions of this final rule, administrative remedies at 7 CFR part 780 must be exhausted.

The title and number of the Federal Domestic Assistance Program, as found in the Catalog of Federal Domestic Assistance, to which this rule applies are Conservation Reserve Program—10.069.

The information and collection requirements of this final rule at 7 CFR part 1410 have been submitted to the Office of Management and Budget for review and approval in accordance with the Paperwork Reduction Act of 1980. A response from OMB regarding the information collection approval is forthcoming.

The public reporting burden for the information collections required by this final rule is estimated to be 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Current Regulations

The current regulations in 7 CFR part 1410, published as a final rule on April 19, 1991 (56 FR 15980), implemented the Environmental Conservation Acreage Reserve Program, which consists of CRP and WRP.

The intent of CRP is to permit the Commodity Credit Corporation (CCC) to enter into contracts with owners and operators of highly erodible and other environmentally sensitive cropland to assist such owners and operators in conserving and improving the Nation's soil and water resources. By entering into a contract, the owner or operator agrees to implement a conservation plan approved by the local Conservation District for converting highly erodible cropland normally devoted to the production of an agricultural commodity to a less intensive use. CCC provides (1) technical assistance by way of a conservation plan, (2) financial assistance for the costs of establishing the conservation practices required by the conservation plan, and (3) annual land rental payments to compensate the owner or operator for taking the cropland out of production.

The current regulations address the following terms and conditions of the CRP for enrollment during 1991 through 1995: (1) eligibility of land; (2) duration of contracts; (3) obligations of participants and CCC; (4) eligible practices; (5) levels of cost-share for establishing practices; (6) provisions for annual rental payments; (7) handling of violations; and (8) other program matters.

With respect to land eligibility, § 1410.103 provides that the Secretary of Agriculture (Secretary) may consider certain lands to be eligible for CRP if a useful life easement is created for the practice. Further, § 1410.103 prohibits the enrollment of farmed wetlands otherwise eligible for CRP.

Section 1410.108 permits, if approved by CCC, land subject to an existing CRP

contract to be enrolled into WRP, provided that (1) the application for transfer into WRP is made during the first or second available signup for intention period under the WRP for the State, and (2) all funds and benefits paid under the CRP contract were refunded with interest.

Section 1410.110 generally prohibits any harvesting, or grazing, or other commercial use of the forage on land subject to a CRP contract, except that the Secretary could permit fall and winter grazing of grass waterways where the grazing is incidental to the gleaning of crop residue on the fields in which the grass waterways are located for an applicable reduction in rental payment.

Statutory Changes

Title XII of the Food, Agriculture, Conservation, and Trade Act of 1990 (the 1990 Act) (Pub. L. 101–624) enacted on November 28, 1990, amended the Food Security Act of 1985 (the 1985 Act) (Pub. L. 99–198) with respect to CRP. Section 1232(a)(7) of the 1990 Act was amended on December 13, 1991, by the 1991 Act to specify that the Secretary may permit incidental grazing of CRP (1) during the 7-month period in which grazing of conserving use acreage is allowed in a State under the price support programs, or (2) after the producer harvests the grain crop of the surrounding field. In either case, the CRP rental payment must be reduced commensurate with the limited economic value of such incidental grazing.

The 1992 Act amended section 1231(b)(4)(C) and section 1235A(a)(2) of the 1985 Act, as amended, to remove certain easement requirements under CRP.

Other Changes

This rule also (1) amends the regulations in 7 CFR 1410.108 to reflect consistency with the final rule for WRP published at 7 CFR part 703 on June 4, 1992, (2) corrects a typographical error, (3) includes minor editorial changes for clarity, and (4) due to further review of statutory authority, removes the provision that payments made under part 1410 are subject to the regulations under 7 CFR part 796—Denial of Program Eligibility for Controlled Substance Violation.

CRP will continue to be implemented by CCC through the Agricultural Stabilization and Conservation Service (ASCS) using ASCS's State and county offices.

Discussion of Comments

CCC received five comments concerning the proposed rule published on June 25, 1992, at 57 FR 28468. Entities responding included a State farm organization, a national farm organization, two national wildlife organizations, and a member of Congress. The discussion of comments that follows is organized in the same sequence as the final rule.

Thus, all the changes made by this final rule are based on a combination of the public comments to the proposed rule, recent legislative changes and other statutory requirements, CCC's experience in administering CRP since inception, and the need for clear, current, and consistent regulations.

Section 1410.103 Eligible Land

Three comments supported the inclusion of small farmed wetlands as land eligible to be enrolled in CRP, stating that the proposal would not interfere with the enrollment of eligible land into WRP, and this expansion of cropland eligibility would further enhance the improvement of soil and water resources. Two additional comments supported the concept and recommended that the approved plan provide for the continued protection of the eligible small wetland areas and that these areas be contained in fields that are otherwise eligible for CRP. Although this was the intent of the proposed rule, the final rule has been clarified to ensure that the small farmed wetlands to be enrolled are (1) limited to small areas included in otherwise eligible fields, and (2) guaranteed enduring protection under the approved conservation plan.

List of Subjects in 7 CFR Part 1410

Administrative practices and procedures, Conservation plan, Contracts, Easements, Environmental indicators, Natural resources, and Technical assistance.

Accordingly, 7 CFR part 1410 is amended as follows:

PART 1410—1991–95 CONSERVATION RESERVE PROGRAM

1. The authority citation for 7 CFR part 1410 continues to read as follows:

Authority: 15 U.S.C. 714b and 714c; 16 U.S.C. 3831–3847.

§ 1410.13 [Amended]

2. Section 1410.13 is amended by removing paragraph (a) and designating paragraphs (b), (c), and (d) as paragraphs (a), (b), and (c).

3. Section 1410.103 is amended by:

A. Revising paragraphs (d)(2), (d)(3), and (d)(4); and

B. Revising paragraph (f)(2) to read as follows:

§ 1410.103 Eligible land.

* * * * *

(d) * * *

(2) Land devoted to living snowfences, windbreaks, wildlife habitat, shelterbelts or filterstrips with trees or shrubs;

(3) Land devoted to newly created permanent grass waterways or contour grass sod strips created after November 28, 1990, which are established and maintained according to an approved conservation plan;

(4) Non-irrigated or irrigated cropland which produce, as determined by the Deputy Administrator, saline seeps or which are functionally related to such saline seeps, or where a rising water table contributes to increased levels of salinity at or near the ground surface.

* * * * *

(f) * * *

(2) Farmed wetlands which may be eligible for the Wetlands Reserve Program (WRP) under 7 CFR part 703, except this restriction shall not apply to small farmed wetlands contained in, and are a part of, fields that are otherwise eligible for CRP as determined by CCC.

§ 1410.108 [Amended]

4. Section 1410.108 is amended as follows:

A. The introductory sentence is amended by removing the phrase "provided that" and all that follows to and including "prior to October 1, 1992;" and inserting in lieu thereof the following: "provided that such offer for transfer occurs during the first or second available signup for intention period under the WRP for the State and agreed to by ASCS. Transfers on offers submitted after the second available WRP signup period within a State will only be permitted if the owner agrees to refund all payments received under CRP since the close of the second available WRP signup period within the State"; and

B. Paragraph (b) is amended by removing the word "letter" and inserting the word "title" in its place.

5. Section 1410.110 is amended by revising paragraph (d) to read as follows:

§ 1410.110 Obligations of the Commodity Credit Corporation.

* * * * *

(d) Permit grazing of grassed waterways on CRP land where the grazing is incidental to the gleaning of crop residues on fields where the contracted land is located, such incidental grazing is limited to the 7-month period in which grazing of conservation use acreage is allowed, as

determined by CCC, in a State under the Agricultural Act of 1949 (7 U.S.C. 1421 *et seq.*), or after the producer harvests the grain crop of the surrounding field. Further, CCC must provide prior approval of the incidental grazing of the CRP in exchange for an applicable reduction in the annual rental payment, as determined appropriate by the Deputy Administrator.

Signed at Washington, DC on January 5, 1993.

John A. Stevenson,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 93–759 Filed 1–12–93; 8:45 am]

BILLING CODE 3410–05–M

Farmers Home Administration

7 CFR Part 1900

Reporting Authorities for Internal Processing of Appeals Cases

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations regarding designated reporting authorities for internal processing of appeals cases. This action is necessary due to Agency provisions which require certain Agency officials to make decisions for cases in the appeal process. The intended effect is to ensure correct processing of appeals.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Jennifer Barton, Community Facilities Division, Farmers Home Administration, room 6314, South Agriculture Building, Washington, DC 20250, telephone (202) 720–1504.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291. Since this action has no impact on FmHA borrowers or other members of the public, it has been determined to be exempt from those requirements because it involves only internal Agency management. It is the policy of this Department to publish, for comment, rules relating to public property, loans, grants, benefits, or contracts, notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This action, however, is not published for proposed rule making since it involves only internal Agency management and publication for comment is unnecessary. Community and Business Programs have been assigned to the Rural Development Administration (RDA), and RDA is now administering this program. RDA is utilizing FmHA regulations which makes it necessary to establish the organizational structure of RDA's reporting authorities for its Regional Office operations. Specifically, Exhibit D of subpart B of part 1900 is amended to include RDA personnel as decision makers for RDA cases involved in appeals.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." FmHA has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and, in accordance with the National Environmental Policy Act of 1969, Public Law 91–190, an Environmental Impact Statement is not required.

Intergovernmental Review

The programs administered will be listed in the Catalog of Federal Domestic Assistance and will be subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. This action affects the following programs:

10.414 Resource Conservation and Development Loans;
10.418 Water and Waste Disposal Systems for rural communities;
10.419 Watershed Protection and Flood Prevention;
10.422 Business and Industrial Loans;
10.423 Community Facilities Loans;
10.424 Rural Development Grants;
10.434 Nonprofit National Corporation;
10.436 Technical Assistance and Training Grants;
10.438 Intermediary Relending Program;
10.440 Emergency Community Water Assistance Grants.

FmHA conducts intergovernmental consultation in the manner delineated in FmHA Instruction 1940–J. Programs 10.414, 10.418, 10.419, 10.422, 10.423, and 10.438 are subject to the provisions of E.O. 12372; the remaining programs affected are not subject to this provision.

List of Subjects in 7 CFR part 1900

Appeals, Credit, Loan programs—Housing and community development.

Accordingly, part 1900 of chapter XVIII, title 7, Code of Federal Regulations is amended as follows:

PART 1900—GENERAL

1. The authority citation for part 1900 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

2. Exhibit D of subpart B is revised to read as follows:

Exhibit D of Subpart B—Hearings/Review Officer Designations

HEARING/REVIEW OFFICER DESIGNATIONS

Decisionmaker or decision	Hearing officer	Review officer
County Supervisor	National Appeals Staff Hearing Officer	State Director and/or Director, National Appeals Staff.
County Committee	National Appeals Staff Hearing Officer	State Director and/or Director, National Appeals Staff.
*District Director, *State Program Chief, *District Specialist.	National Appeals Staff Hearing Officer	**State Director and/or Director, National Appeals Staff.
*State Director, *Regional Director	As appointed by Director, National Appeals Staff	Director, National Appeals Staff.
Division Director or Assistant Administrator	As appointed by Director, National Appeals Staff	Director, National Appeals Staff.
Assistant Administrator	As appointed by Director, National Appeals Staff	Director, National Appeals Staff.
Deputy or Associate Administrator	As appointed by Director, National Appeals Staff	Director, National Appeals Staff.

*Decisionmaker for Rural Development Administration (RDA) cases for Regional Office Operations.
**Review officer will be the Regional Director and/or the Director, National Appeals Staff for RDA cases.

Notes

1. District Director also means Assistant District Director or District Loan Specialist.

2. County Supervisor also means Assistant County Supervisor with loan approval authority.

3. The Director of the National Appeals Staff may designate a staff member to conduct a hearing or review. When the hearing/review is completed,

the designee will send the complete case file, hearing notes, tape recordings, and a recommended decision to the Director for a final decision. The Director may, for individual cases, delegate final decision authority to a designee.

4. For decisions not directly covered above, advice should be sought from the Director of the National Appeals Staff.

5. An appellant may elect to have an appeal reviewed by the State Director, or the Director of the National Appeals Staff. The decision of the State Director will be subject to further review by the Director of the National Appeals Staff upon request of the appellant.

Dated: December 10, 1992.

LaVerne Ausman,

Administrator, Farmers Home Administration.

Dated: December 9, 1992.

Mary Ann Baron,

Administrator, Rural Development Administration.

[FR Doc. 93-707 Filed 1-12-93; 8:45 am]

BILLING CODE 3410-07-M

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7 CFR Part 1951

Delegation of Authority

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment to the Farmers Home Administration (FmHA) regulations is to specify that when FmHA State Directors are delegated exception authority in certain situations in accordance with § 1951.916 of 7 CFR, subpart S of part 1951, the request for the exception will not require the recommendation of the appropriate Program Assistance Administrator. This will eliminate the requirement that the request be sent to the FmHA National Office. The intended effect is to speed up the processing of exceptions in specific situations where there is an urgent need for quick action.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT:

Arthur V. Hall, Director, Loan Servicing and Property Management Division, Farmer Programs, Farmers Home Administration, USDA, room 5449, South Agriculture Building, 14th and Independence Avenue, SW., Washington, DC 20250, Telephone (202) 720-4572.

SUPPLEMENTARY INFORMATION:

Programs Affected

These changes affect the following FmHA programs as listed in the catalog of Federal Domestic Assistance:

10.404 Emergency Loans
10.406 Farm Operating Loans
10.407 Farm Ownership Loans
10.410 Low Income Housing Loans (Section 502 Rural Housing Loans)
10.416 Soil and Water Loans

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human environment, and in accordance with the National Environmental Policy Act of 1969, Public Law 91-190, an Environmental Impact Statement is not required.

Background

FmHA Farmer Program borrowers in the States of Florida and Louisiana who were in the arrears on their FmHA loan installments were notified of FmHA servicing options available to them prior to devastation of Hurricane Andrew. They had 60 days to respond to the notices. However, Hurricane Andrew knocked out utility services, disrupted mail service, destroyed homes, etc., in these areas. This made it impossible for all the notified FmHA Farmer Program borrowers to respond to the notices within the 60-day timeframe. Therefore, it was necessary to issue a temporary change in FmHA Instructions to allow the Administrator to delegate exception authority to these two State Directors to allow an exception to the 60-day response requirement for some borrowers in these designated disaster areas without a recommendation by the Program Assistant Administrator. This temporary Instruction change was immediately necessary to avoid further panic and distress to farmers whose farms were devastated by Hurricane Andrew and were unable to promptly respond to the notices for much needed assistance. To avoid the necessity of making a temporary change in FmHA Instructions in the future, FmHA is revising its regulations to provide for this internal administrative authority.

This action has been reviewed under USDA procedures established in Departmental Regulation 1512-1, which implements Executive Order 12291. It has been determined to be exempt from those requirements because it involves only internal Agency management. It is the policy of this Department to publish for comment rules relating to public property, loans, grants, benefits, or contracts, notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This action, however, is not published for proposed rulemaking since it involves only internal Agency management and publication for comment is unnecessary.

List of Subjects in 7 CFR Part 1951

Accounting servicing, Credit, Debt restructuring, Loan programs—Agriculture, Loan programs—Housing and community development, Low and moderate income housing loans—Servicing.

Accordingly, part 1951 of chapter XVIII, title 7, Code of Federal Regulations, is amended as follows:

PART 1951—SERVICING AND COLLECTIONS

1. The authority citation for part 1951 continues to read as follows:

Authority: 7 U.S.C. 1989; 41 U.S.C. 1460; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart S—Farmer Programs Account Servicing Policies

2. Section 1951.916 is revised to read as follows:

§ 1951.916 Exception authority.

The Administrator or delegate may, in individual cases, make an exception to any requirement or provision of this subpart or address any omission of this subpart which is not inconsistent with the authorizing statute or other applicable law if the Administrator determines that the Government's interest would be adversely affected. The Administrator will exercise this authority upon request of the State Director with recommendation of the appropriate Program Assistant Administrator, or upon request initiated by the appropriate Program Assistant Administrator. In certain situations such as a natural disaster, the Administrator may delegate this authority to specific State Director positions in certain states. In such cases, the State Director will exercise the delegation of authority upon the request of the County Supervisor with the recommendation of the District Director, rather than the appropriate Program Assistant Administrator. Requests for exceptions must be made in writing and supported with documentation to explain the adverse effect, propose alternative courses of action, and show how the adverse effect will be eliminated or minimized if the exception is granted.

Dated: December 11, 1992.

LaVerne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 93-708 Filed 1-12-93; 8:45 am]

BILLING CODE 3410-07-M

7 CFR Part 1965

Single Family Housing Security Servicing

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule; correction.

SUMMARY: The Farmers Home Administration (FmHA) amends its security servicing regulation for single family housing loans to clarify that whether or not the loan is subject to recapture will not be changed by virtue of a same rates and terms assumption. This has been FmHA policy since the recapture program was started in 1979. It was through oversight that this statement was erroneously omitted from the regulation as this was not proposed to be changed at the time revisions were made to this regulation effective August 24, 1988 (53 FR 27819).

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Jean F. Leavitt, Senior Loan Specialist, Single Family Housing Servicing and Property Management Division, Farmers Home Administration, USDA, South Agriculture Building, room 5309, Washington, DC 20250, telephone: (202) 720-1452.

SUPPLEMENTARY INFORMATION: This regulation is revised to add a statement that whether or not the loan is subject to recapture will not be changed by virtue of a same rates and terms assumption. This statement was included in the regulation prior to August 1988. Through oversight it was erroneously omitted at the time revisions were made to the regulation effective August 24, 1988.

List of Subjects in 7 CFR Part 1965

Administrative practice and procedure, Loan programs—Housing and community development, Low and moderate income housing—Rental, Mortgages, Rural areas.

Accordingly, chapter XVIII, title 7, Code of Federal Regulations is corrected as follows:

PART 1965—REAL PROPERTY

1. The authority citation for part 1965 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23 and 2.70.

Subpart C—Security Servicing for Single Family Rural Housing Loans

2. In § 1965.126, the introductory text of paragraph (c)(2) is revised to read as follows:

§ 1965.126 Transfer of property with assumption of indebtedness.

* * * * *

(c) * * *

(2) In the situations outlined in paragraphs (b)(12) and (c)(2)(i), (c)(2)(ii) and (c)(2)(iii) of this section only, the assuming party will execute an assumption agreement to assume the indebtedness on the existing terms; unless, due to more favorable terms available at the time, the assuming party desires to assume the loan on new terms. If the assuming party desires to assume the loan on new terms, all eligibility requirements of subpart A of part 1944 of this chapter must be met. If a same terms assumption is consummated, FmHA's accounting records will change to reflect the name and case number of the assuming party. Same terms assumptions under this paragraph are authorized without considering the assuming party's eligibility for program assistance. The interest rate, final due date, payment date, account status (current, delinquent, ahead of schedule) and whether or not the loan is subject to recapture will not be changed by virtue of the assumption. After assumption, compliance with loan conditions is required. If a same terms transfer is consummated and the account is delinquent, it may be reamortized in accordance with subpart G of part 1951 of this chapter. Eligibility for interest credit will be considered or re-evaluated at the time of assumption. Situations where these terms are authorized are:

* * * * *

Dated: November 25, 1992.

LaVerne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 93-709 Filed 1-12-93; 8:45 am]

BILLING CODE 3410-07-M

Food Safety and Inspection Service

9 CFR Parts 318 and 381

[Docket No. 86-044F]

RIN 0583-AA75

Use of Potassium Lactate and Sodium Lactate as Flavoring Agents in Various Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations to permit the use of potassium lactate and sodium lactate as flavor enhancers and flavoring agents in various meat and poultry products. The Food and Drug Administration (FDA) has affirmed these substances as generally recognized as safe (GRAS) for use as direct human food ingredients, as flavor enhancers, flavoring agents, adjuvants, humectants, and pH control agents, except in infant formulas and infant food, when used at levels sufficient for purpose in accordance with good manufacturing practices. This final rule is in response to petitions submitted by Oscar Mayer Foods Corporation and Shenandoah Products, Inc.

EFFECTIVE DATE: February 12, 1993.

FOR FURTHER INFORMATION CONTACT: Charles R. Edwards, Director, Product Assessment Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington DC 20250, Area Code (202) 205-0080.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Agency has determined that this final rule is not a major rule within the scope of Executive Order 12291. It will not result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Executive Order 12778

This final rule has been reviewed pursuant to Executive Order 12778, Civil Justice Reform. This final rule concerns the use of substances in meat and poultry products. States are precluded from imposing and marking, labeling, packaging, or ingredient requirements on federally inspected meat or poultry products that are in addition to, or different than those imposed under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 678) or Poultry Products Inspection Act (PPIA) (21 U.S.C. 467e). States may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official

establishments for the purpose of preventing the distribution of meat or poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. States that conduct meat and poultry inspection programs must impose requirements at least equal to those imposed on federally inspected products and establishments under the FMIA or PPIA. These States may, however, impose more stringent requirements on such State-inspected products and establishments.

This rule is not intended to have retroactive effect. There are no applicable administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this final rule. However, the administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an inspector relating to inspection services provided under the FMIA or PPIA. The administrative procedures specified in 9 CFR part 335 and part 381, subpart W, must be exhausted prior to any judicial challenge to the application of the provisions of this rule with respect to labeling decisions.

Effects on Small Entities

The Administrator, FSIS has determined that this final rule will not have a significant economic impact on a substantial number of small entities. This final rule provides manufacturers the option of using potassium lactate and sodium lactate as flavor enhancers and flavoring agents in various meat and poultry products. Manufacturers, both large and small, opting to use potassium lactate and sodium lactate as flavor enhancers and flavoring agents in various meat and poultry products would be required to revise the ingredients statement on product labels to show the presence of potassium lactate and sodium lactate. However, any costs associated with new label applications would be covered under existing approved paperwork burdens of FSIS's prior label approval system. Thus, the final rule imposes no new paperwork requirements on industry.

Background

The Agency has been petitioned by Oscar Mayer Food Corporation (Oscar Mayer) to amend the Federal meat and poultry products inspection regulations to allow the use of potassium lactate and sodium lactate as flavor enhancers and flavoring agents in cooked meat and poultry products. The petitioner wishes to use potassium lactate and sodium lactate to contribute to the salty taste in cooked meat and poultry products. Oscar Mayer contends that potassium lactate and sodium lactate can be used in conjunction with sodium chloride (common table salt) to achieve a salty flavor in these products. In support of this contention, the petitioner has conducted flavor studies in cooked meat and poultry products, comparing the levels for equivalent saltiness of sodium lactate and sodium chloride. Results from these studies have revealed that in roasted turkey breast, 2.1 percent sodium lactate has the equivalent saltiness equal to 0.5 percent sodium chloride; and in cured cooked beef, 2.5 percent sodium lactate equals 0.8 sodium chloride. Oscar Mayer believes that their data "clearly demonstrates the sodium lactate has the technical effect of a flavoring by contributing to the salty taste of products." The petitioner has presented no figures on the levels of use necessary to achieve saltiness equivalent of potassium lactate, but has estimated that they would be the same as for sodium lactate. The Agency agrees with the petitioner's estimate concerning potassium lactate, due to FDA's assessment sodium lactate and potassium lactate and reports on lactic acid and lactates that affirm that sodium and potassium salts of lactic acid will perform the technical effects of flavor enhancer and flavoring agency.

While the Agency was evaluating the petition and background information from Oscar Mayer Foods Corporation, a petition, supported by pertinent technical information, was also submitted by Shenandoah Products, Inc., for the use of sodium lactate up to 2.0 percent in raw poultry as a flavor enhancer. The technical information includes results of taste panel and chemical rancidity evaluations of ground turkey samples.

The data submitted by Shenandoah Products show results from taste panel evaluations of cooked ground turkey patties containing four different levels of sodium lactate. The four different levels used were 0 percent (control samples), 0.5 percent, 1.0 percent, and 2.0 percent. Samples were evaluated on their "meaty" flavor by a trained taste panel at Webb Technical Group, Inc., Raleigh, North Carolina. In each replication of the panel, ground turkey with sodium lactate was preferred over the flavor of control samples. Three of the four replication samples with 2.0 percent sodium lactate were scored higher than other samples.

FSIS believes that meat and poultry products will not become adulterated by the use of potassium lactate and sodium lactate as flavor enhancers and flavoring agents in processing at levels that do not exceed 2.0 percent. These substances were affirmed as GRAS by the FDA on April 6, 1987, for use as direct human food ingredients, as flavor enhancers, flavoring agents, adjuvants, humectants, and pH control agents, except in infant formulas and infant foods. Potassium lactate and sodium lactate were added to 21 CFR 184.1639 and 184.1768 (52 FR 10884). That regulation affirmed these substances as GRAS at levels sufficient for purpose when used in accordance with good manufacturing practices.

Proposed Rule

Based upon FDA's prior safety determinations, as evidenced by its GRAS findings, FSIS published a proposed rule on March 1, 1990 (55 FR 7339), to approve the use of potassium lactate and sodium lactate as flavor enhancers and flavoring agents in various meat and poultry products at levels not to exceed 2.0 percent in accordance with FDA regulations (21 CFR 184.1639 and 184.1768). These substances would not be permitted, however, in meat or poultry products produced for consumption by infants.

The Administrator has determined that (1) the proposed use of potassium lactate and sodium lactate would be in compliance with applicable FDA requirements, (2) their use would be functional and suitable for the products intended, (3) the substances would be used at the lowest level necessary to accomplish their intended technical effect, and (4) the use of these substances in products at levels not to exceed 2.0 percent would not render the products adulterated, misbranded, or otherwise not in accordance with the requirements of the Federal Meat Inspection Act and the Poultry Products Inspection Act.

Discussion of Comments

The Agency received 18 comments in response to the proposed rule. Eight comments were submitted by meat and poultry processors, 4 by ingredient manufacturers, 3 by trade groups, 2 by academia, and 1 by a research organization. Eleven of the 18 comments were in support of the proposed rule, while the remaining 7 opposed the proposed rule.

1. Meat Poultry Processors

The seven meat and poultry processors that supported the proposed rule in its entirety believe that the flavor enhancing properties of sodium lactate

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add significantly to the flavor of meat and poultry products. One of the supporters stated that the proposal cites that sodium lactate and potassium lactate were affirmed as GRAS by FDA for use as direct human food ingredients as flavor enhancers and flavor ingredients. The regulations affirmed these substances as GRAS at levels sufficient for purpose when used in accordance with good manufacturing practices. Therefore, the commenters proposed that the upper usage level of 2.0 percent based on formulation be deleted from the proposal and that use be permitted at levels sufficient for purpose. The one processor that opposed the proposed rule believes that the primary purpose of using lactate salts is to improve food safety by retarding growth of common spoilage bacteria. This processor stated that the secondary effects are as a flavor enhancer or flavoring agent. The processor also stated that the Department should consider a category of "lactate salts."

2. Trade Groups

One trade group supports the use of potassium lactate and sodium lactate, but also believes that the uses should be allowed at levels sufficient for purpose. Another trade group objects to the proposed use of these substances as flavor enhancers and flavoring agents in meat and poultry products and requests that the proposed regulation either be modified to recognize that lactates are being used for their preservative characteristics or be withdrawn.

The other trade association that opposed the proposed rule supports a complete representation of the uses of potassium lactate and sodium lactate in one rulemaking. It stated that the use of these ingredients in meat and poultry products has functional value for their intended technical effect and are self-limiting in terms of the amount to be used and should be permitted by regulation.

3. Academia

Two universities supported the proposed rule. One university believes that lactates provide a substantial benefit in relation to product flavor when incorporated into processed meat products. It contends that indicating lactates by their common and usual name in the ingredients statement would provide sufficient information for the consumer to satisfy the requirements of ingredient identification.

The other university gave a summary of its research that documents the flavor enhancing characteristics of sodium lactate. The data strongly suggest that the addition of sodium lactate to cooked beef products enhances the flavor of these products. Trained sensory evaluation panels reported that cooked beef ("brothy"), serum ("bloody"), and grain ("cowy") flavor notes were enhanced with the addition of sodium lactate. According to consumer sensory panel evaluations, sodium lactate-treated samples were more desirable overall in texture and flavor. Overall flavor and beef flavor were enhanced by the addition of sodium lactate.

Although treated samples were saltier, there was no difference in desirability of the salty taste. Treated roasts were more often described by consumer panelists as being more flavorful with a stronger beefy or meaty flavor, while control samples were more bland with a weak beefy flavor and not enough seasonings or salt. These research data also document the use of sodium lactate in limiting microbial growth in cooked, whole muscle beef top round roast. This university strongly supports either the incorporation of the "antimicrobial" benefits into the current ruling or the drafting of a second proposed rule which documents the use of potassium lactate and sodium lactate as a means of controlling microbial growth. Also, the university supports limiting usage of sodium lactate to a maximum of 5.0 percent in the final product for either flavor enhancement or microbial growth inhibition uses.

4. Ingredient Manufacturers

Of the four food ingredient companies commenting on the proposed rule, only one voiced its support. The major concerns of the companies opposing the proposed rule were: (1) The primary intended effect of sodium lactate is extended shelf life, even possible storage without refrigeration; (2) only one preservative would be available to industry which would add approximately 3 cents per pound cost to the product containing it, thus creating a monopoly and unfair treatment to industry; (3) this would be the first time in modern history that a preservative would be allowed in fresh and non-cured cooked meat products produced under FSIS regulations; (4) the proposed rule does not recognize the most common use of the lactates which is as an antimicrobial agent to reduce undesirable microorganism growth; (5) the proposed rule is unclear as to whether the proposed 2.0 percent maximum usage level refers to sodium lactate and potassium lactate at the 100 percent pure basis, which is not commercially available, or the 60 percent solutions in water which are the normal products of commerce; and (6) they were not aware that potassium lactate has a "salty taste" like that of sodium lactate.

5. Research Organization

A research organization supported a rulemaking that is based on complete representation of sodium lactate and potassium lactate and their functional properties.

Response to Comments

This rulemaking permits the use of potassium lactate and sodium lactate as flavor enhancers and flavoring agents in various meat and poultry products. The second rulemaking, under consideration by the Agency, proposes the use of potassium lactate and sodium lactate as secondary barriers to the growth of certain pathogenic microorganisms in refrigerated, ready-to-eat, hermetically packaged, cooked uncured and cured meat and poultry products.

Potassium lactate and sodium lactate may be considered as having "antimicrobial" properties, and the Agency already allows the use of certain substances with antimicrobial properties but classifies them by their primary functions. For example, sodium nitrate and glucono delta-lactone have antimicrobial properties but are curing agents and acidulants, respectively. With regard to the concern that only one preservative would be available to industry, both potassium lactate and sodium lactate are available to the industry, but are not proposed for use as "preservatives," nor do data support that a product containing potassium lactate and sodium lactate could be stored at room temperatures without resulting in a spoiled product. Also, potassium lactate and sodium lactate are not classified as "preservatives" by FDA.

Potassium lactate and sodium lactate usually exist as solutions of 60 percent lactate to 40 percent water. The 2.0 percent given in the proposed rule means 2.0 percent on a pure basis. Potassium lactate and sodium lactate will be listed by their common name in the ingredients statement. This will provide consumers with sufficient information. Additionally, sufficient data exist to support the flavor enhancing effects of lactates.

Final Rule

After careful consideration of the comments and other available information, FSIS is amending the chart of approved substances in 9 CFR 318.7 and 381.147 to include the use of potassium lactate and sodium lactate as flavor enhancers and flavoring agents at

levels not to exceed 2 percent for use in various meat and poultry products.

List of Subjects

9 CFR Part 318

Food additives, Meat inspection.

9 CFR Part 381

Food additives, Poultry inspection.

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

1. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

2. Section 318.7(c)(4) is amended by adding to the chart of substances, under the Class of substance "Flavoring agents; protectors and developers," the following substances at the end thereof:

§ 318.7 Approval of subsetances for use in the preparation of products.

* * * * *

(c) * * *

(4) * * *

Class of substance	Substance	Purpose	Products	Amount
•	•	•	•	•
Flavoring agents; protectors and developers.	Potassium lactate	To flavor product	Various meat and meat food products, except infant formula and infant food.[2]	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Sodium lactate	.....do	.....do	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1768.
•	•	•	•	•

[2] Information as to the specific products for which use of this substance is approved may be obtained upon inquiry addressed to the Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 450; 21 U.S.C. 451–470; 7 CFR 2.17, 2.55.

4. Section 381.147(f)(4) is amended by adding to the table of substances, under the Class of substance "Flavoring agents; protectors and developers," the following substances at the end thereof:

§ 381.147 Restrictions on the use of subsetances in poultry products.

* * * * *

(f) * * *

(4) * * *

Class of substance	Substance	Purpose	Products	Amounts
•	•	•	•	•
Flavoring agents; protectors and developers.	Potassium lactate	To flavor product	Various poultry and poultry food products, except infant formula and infant food.[3]	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1639.
	Sodium lactate	.....do.....	.....do.....	Not to exceed 2 percent of formulation; in accordance with 21 CFR 184.1768.
•	•	•	•	•

[3] Information as to the specific products for which use of this substance is approved may be obtained upon inquiry addressed to the Standards and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, U.S. Department of Agriculture, South Building, 14th Street and Independence Avenue SW., Washington, DC 20250.

Done at Washington, DC, on December 31, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

[FR Doc. 93–696 Filed 1–12–93; 8:45 am]

BILLING CODE 3410–DM–M

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 7

[Docket No. 93–01]

Messenger Services

AGENCY: Comptroller of the Currency, Treasury.

ACTION: Final rule.

SUMMARY: This action revises the Interpretive Ruling of the Office of the Comptroller of the Currency (the Office or OCC) regarding the use of messenger services by national banks and their customers to facilitate transactions between them. This action is needed to update the ruling to reflect current case law. The action is intended to provide guidance to national banks concerning the applicability to messenger services of the branching restrictions set forth in the McFadden Act.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Jerome Edelstein, Senior Counsel, Corporate Operations and Resolutions Division, (202) 874–5300; Cindy Hausch, Licensing Policy and Systems Analyst, Bank Organization and Structure, (202) 874–5060.

SUPPLEMENTARY INFORMATION:

I. Background

Interpretive Rule 7.7490, 12 CFR 7.7490, has long established the standards under which national banks and their customers may use messenger services to transport items pertaining to deposits, withdrawals and other business transactions between the bank and the homes or offices of specific customers without the need for the national bank to seek branch approval. During the past several years, however, certain issues have been raised with respect to the use of such services and the utility of this ruling has been called into question. See, e.g., *Brown* v. *Clarke*, 873 F.2d 627 (2d Cir. 1989).

Specifically, issues relate to the use by national banks of messenger services for branching and non-branching functions and about the use of messenger services owned by the bank or by third parties.

Applying the relevant statutes, case law, and OCC precedents on a case-by-case basis, the OCC has analyzed proposals to use such facilities to determine whether they are authorized under the incidental powers clause of 12 U.S.C. 24(7) and, when applicable, the McFadden Act, 12 U.S.C. 36, which governs national bank branching. The following revision to Interpretive Rule 7.7490 reflects the OCC's position on these issues.

II. Purpose of this Revision

This revision seeks to clarify the OCC's position in situations in which: (1) A national bank establishes a messenger service or uses a messenger service established by a third party for non-branching-related transactions; (2) a messenger service established by a third party is used for branching-related transactions; and (3) a national bank establishes a messenger service for branching-related transactions.

The rule establishes a safe harbor under which national banks and their customers may use third-party messenger services to engage in transactions pertaining to branching activities without the messenger service being deemed a branch. This safe harbor is not meant to be exclusive. Alternative factors, as determined on a case-by-case basis, may justify a similar conclusion.

III. Analysis

The ruling is based on case law which has placed emphasis on two primary factors in determining whether a particular facility is subject to the McFadden Act: whether the activity involved is a branching function; and whether the facility has been "established" by the national bank.

A. Messenger Services Are Considered To Be Bank Branches if They Engage in "Branching Functions" and Are "Established" by the Bank

1. Branching Functions

A national bank may undertake branching functions only at its main office or at a branch office. It is undisputed that the functions mentioned in 12 U.S.C. 36(f)—receiving deposits, making loans, and paying checks—are branching functions subject to the McFadden Act's limitations. The Supreme Court in *Clarke* v. *Securities Industry Association*, 479 U.S. 388 (1987) (Clarke), however, left open the question of whether functions other than these three functions constitute branching functions—what it referred to as "core banking functions"—subject to the branching limitations set forth in the McFadden Act. *Id.* at 409. But the Court did make it clear that not all of the activities in which a national bank engages are considered "core banking functions"—that is, not all activities are branching functions. *Id.* (discount brokerage service is not a core banking function and, thus, is not subject to the McFadden Act). A national bank may engage in such nonbranching functions without regard to the restrictions imposed by the branching laws.

The Supreme Court also held that where a national bank owns and controls a facility involved in branching functions, that facility will be considered to be a branch despite contractual arrangements regarding the relationship between the bank and the customer that would suggest otherwise. Thus, the Supreme Court held that an armored car, undeniably owned and controlled by a national bank, was a branch of that bank if it engaged in branching functions specified in 12 U.S.C. 36(f). See *First National Bank of Plant City* v. *Dickinson*, 396 U.S. 122 (1969) ("Plant City"). The Court noted that the national bank in that case employed the teller and driver-guard, operated the car under the name of the bank, directed all of its movements and routing, paid for the cost of the car's operations, and assumed complete responsibility for the deposits during transport through an insurance policy bought and paid for by the bank. *Id.* at 127–128. The Court concluded that the facility was a branch of the bank despite a contractual arrangement between each customer and the bank which specified that, in providing the service, the bank was acting as agent for the customer and transmittal of currency and cash items would not be deemed to be a deposit until delivered to a bank teller at the bank's office. *Id.*

2. "Establishment" of a Branch

Assuming a facility engages in transactions pertaining to the branching functions within the meaning of section 36(f), the next issue in determining whether that facility is a "branch" is whether the facility has been "established" by the bank. Two cases are particularly relevant to this issue.[1]

a. *The Smith and Marine Midland Cases.* In *Independent Bankers Association* v. *Smith*, 534 F.2d 921 (D.C. Cir.), *cert. denied*, 429 U.S. 862 (1976) (Smith), the court rejected the Comptroller's argument that a bank-owned CBCT, which the court found to receive deposits, was not a branch because the CBCT was indistinguishable from the mail or a telephone used to facilitate deposit taking. The court stated that facilities such as mailboxes were not bank branches because they were not "established (*i.e.*, owned or rented)" by the bank. The court concluded, however, that because the CBCT was owned by the bank, it was a branch. In accordance with this determination, the OCC incorporated the "owned or rented" standard into its regulation pertaining to the establishment by national banks of CBCTs as branches. 12 CFR 5.31. Subsequently, the Court of Appeals for the Second Circuit applied this test in determining that an automatic teller machine owned by a supermarket did not constitute a branch of a national bank the customers of which used the facility. See *Independent Bankers Association of New York State* v. *Marine Midland Bank*. 757 F.2d 453 (2d Cir. 1985), *cert. denied*, 476 U.S. 1186 (1986) (Marine Midland).

The court in Marine Midland observed that the supermarket, rather than the bank, determined where the facility was to be located, maintained the facility, decided whether to allow customers of different banks to use the facility, and identified the machine as its own. *id.* at 462. In addition, the court concluded that the transaction fees paid by the bank each time a customer used the facility did not constitute "rent" and did not render the facility a bank branch. *Id.* at 463.

The OCC believes that the establishment standard as developed in Smith and Marine Midland is directly applicable to messenger services. If, as in Smith, mailing a deposit with postage paid by the bank does not cause the Post Office to be a branch, the OCC believes that other forms of third party messenger services need not be subject to the McFadden Act's restrictions. Moreover, at least one case predating Smith and Marine Midland applied an approach similar to those cases in holding that a third party messenger service was not a branch. See *Dickinson* v. *Bay National Bank and Trust Co.*, Marianna Civil Action No. 673 (N.D. Fla. 1973).

b. *OCC Precedent.* In addition to the considerations set forth in Smith and Marine Midland, the OCC in its rule and related interpretations regarding whether messenger services are branches, has long considered the following to be relevant in determining whether a messenger service facility is

[1] The Supreme Court in *Plant City* did not have to address this issue. Under the facts, it was clear that the national bank had established the facility.

a branch: the existence of an agency agreement between the messenger service and the customer, the risk undertaken by the messenger service during transit, and the fact that items are not considered to be received by the bank until delivered to the bank's premises and are considered to be paid by the bank when they are given to the messenger. The OCC is retaining these factors as part of the safe harbor test for determining whether such facilities are branches.

IV. Explanation of the Revision

Based on the general principles set forth above, the OCC is revising its current ruling on messenger services, 12 CFR 7.7490, to provide more specific guidance to national banks with respect to the establishment of messenger services and to clarify the circumstances under which branch applications are required for such facilities. The following summarizes the revised ruling:

A. Section 7.7490(a): Definition of Messenger Service

Paragraph (a) defines a "messenger service" as any service used by a national bank and its customers to pick up from and deliver to specific customers at locations, such as their homes or offices, items relating to transactions between the customer and the bank.

B. Section 7.7490(b): Pick up and Delivery of Items Relating to Nonbranching Activities

Paragraph (b) states that, under 12 U.S.C. 24(7), messenger services involving nonbranching functions may be established by national banks or established by third parties and used by national banks and their customers. The paragraph states that because only nonbranching functions are involved, the McFadden Act is inapplicable and a national bank may establish such a service without OCC branching approval. Such functions include, among other things, securities brokerage (see Clarke at 479 U.S. 388), and activities of a loan production office (12 CFR 7.7380). The paragraph also states that, in providing or using messenger services to facilitate nonbranching activities, national banks may set terms, conditions, and limitations that they deem appropriate to assure compliance with safe and sound banking practices.

This paragraph does not apply to branching activities as defined in 12 U.S.C. 36(f), i.e., the receipt of deposits, payment of checks, or lending of money. In addition, as stated, the Supreme Court has left open the question of whether additional activities may be considered to be core banking functions and, thus, branching activities within the meaning of section 36(f). See Clark at 409. In the event that additional activities are determined to be core banking functions, proposed § 7.7490(b) would not apply to the provision of such services. Rather, the provision of such services would be addressed by § 7.7490 (c) or (d).

C. Section 7.7490(c): Pick up and Delivery of Items Pertaining to Branching Functions Where the Messenger Service Facility is Established by a Third Party

This paragraph addresses messenger services used by national banks and their customers to deliver items in connection with activities that are branching functions. The facts and circumstances of such use will determine whether the messenger service will be considered to have been established and operated by the third party and thus not be considered to be a branch.

Paragraph (c)(1) states that transport of items in connection with these branching functions may be accomplished through a messenger service, notwithstanding branching limitations, if a third party establishes and operates the service. The paragraph provides that, in acting pursuant to this ruling, the national bank may establish terms, conditions, and limitations, not inconsistent with this ruling, that it deems appropriate to assure compliance with safe and sound banking practices.

Paragraph (c)(2) provides that whether a messenger service has been established by a third party will be determined based on an evaluation of all of the circumstances. The paragraph, however, sets forth a safe harbor, based on case law and OCC precedent, under which a messenger service would be considered to be established and operated by a third party and thus would not be considered to be a branch of the bank.

If a messenger service complies with all of the requirements set forth in (c)(2), the OCC will not consider the facility to be a branch. As stated, this test is not meant to be exclusive. Undoubtedly, there could be other factors that would cause a facility not to be considered a branch because it was not "established" by the national bank. Likewise, there may be facts and circumstances under which the failure to satisfy certain of the listed factors would not cause the facility to be considered as a branch of the bank.

Paragraph (c)(3) permits a national bank to defray costs incurred by a customer in transporting items by a messenger service without causing the service to be considered as "established" by the bank. For example, the OCC and the courts have long recognized that such costs may be paid by the bank on a transaction-by-transaction basis. See Marine Midland at 463, and § 5.31(f)(4) (pertaining to payment on a transactional fee basis by a national bank for customer's transactions at a CBCT facility owned by a third party). See also OCC Interpretive Letter No. 188 of May 12, 1981, reprinted at Fed. Banking Law Rep. (CCH) para. 85,269 (payment of transactional fee by a national bank for use of third party-owned CBCT by a customer is analogous to the distribution by a bank to its customers of postage-paid envelopes for purposes of deposit-by-mail services). This paragraph also states that the bank may impose terms, conditions, and limitations with respect to the payment of such costs.

D. Section 7.7490(d): Branching Activities Where the Bank has Established the Facility

This paragraph states that, if a national bank-established messenger service is conducting a branching activity, the facility is subject to the relevant provisions of 12 CFR part 5 regarding OCC branch approvals.

Notice and Comment

The OCC has determined that notice and comment and delayed effectiveness are unnecessary under 5 U.S.C. 553 (b)(A) and (d)(2) which exempts interpretive rules from such procedures.

Regulatory Flexibility Act

It is hereby certified that this Interpretive Ruling will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. The purpose of the ruling is to clarify the authority of all national banks, regardless of size, and of their customers to use messenger services to facilitate transactions between them.

Executive Order 12291

The OCC has determined that this document is not a major regulation as defined in Executive Order 12291 and a regulatory impact analysis is not required. Overall, the Office expects the changes to benefit consumers and national banks by clarifying the authority of national banks and their customers to use messenger services to facilitate transactions between them.

List of Subjects in 12 CFR Part 7

Credit, Insurance, Investments, National banks, Reporting and recordkeeping requirements, Securities, Surety bonds.

Authority and Issuance

For the reasons set forth in the preamble, part 7 of chapter I of title 12 of the Code of Federal Regulations is amended as set forth below:

PART 7—INTERPRETIVE RULINGS

1. The authority citation for part 7 continues to read as follows:

Authority: 12 U.S.C. 1 *et seq.*; 12 U.S.C. 93a.

2. Section 7.7490 is revised to read as follows:

§ 7.7490 Messenger service.

(a) *Definition.* For purposes of this section, a "messenger service" refers to any service, such as a courier service or armored car service, that is used by a national bank and its customers to pick up from, and deliver to, specific customers at locations such as their homes or offices items relating to transactions between the bank and such customers.

(b) *Pickup and delivery of items relating to nonbranching activities.* Pursuant to 12 U.S.C. 24(7), a national bank may establish and operate a messenger service, or use, with its customers, a third party messenger service, to transport items relevant to the bank's transactions with its customers without regard to the limitations set forth in 12 U.S.C. 36, provided the service does not engage in branching functions within the meaning of 12 U.S.C. 36(f). In establishing or using such a facility, the national bank may establish terms, conditions, and limitations that it deems appropriate to assure compliance with safe and sound banking practices.

(c) *Pickup and delivery of items pertaining to branching functions by a messenger service established by a third party.* (1) Pursuant to 12 U.S.C. 24(7), a national bank and its customers may use a messenger service to pick up from, and deliver to, customers items which relate to branching functions within the meaning of 12 U.S.C. 36(f) without regard to the limitations set forth in 12 U.S.C. 36, provided the messenger service is established and operated by a third party. In using such a facility, a national bank may establish terms, conditions, and limitations, not inconsistent with this ruling, as it deems appropriate to assure compliance with safe and sound banking practices.

(2) Whether a messenger service is established by a third party is based on a case-by-case review of all of the circumstances, provided a messenger service is established by a third party if:

(i) A party other than the national bank owns the service and its facilities (or rents them from another party other than the bank) and employs the persons engaged in the provision of the service; and

(ii) The messenger service:

(A) Makes its services available to the public, including other depository institutions;

(B) Retains ultimate discretion to determine which customers and geographical areas it will serve;

(C) Maintains ultimate responsibility for scheduling, movement, and routing;

(D) Does not operate under the name of the bank, and the bank and the messenger service do not advertise, or otherwise represent, that the bank itself is providing the service, although the bank may advertise that its customers may use one or more third party messenger services to transact business with the bank;

(E) Assumes responsibility for the items during transit and maintains adequate insurance covering holdups, employee fidelity, and other in-transit losses; and

(F) Enters into contracts with customers which provide that the messenger service acts as the agent for the customer when the items are in transit between the bank and the customer and, in the case of items intended for deposit, such items shall not be deemed to have been deposited until delivered to the bank at an established bank office, and, in the case of items representing withdrawals, such items shall be deemed to be paid when the item is given to the messenger service.

(3) A national bank is permitted to defray all or a part of the costs incurred by a customer in transporting items through a messenger service. Payment of such expenses may only cover costs associated with each transaction involving the customer and the messenger service. The national bank may impose such terms, conditions, and limitations as it may deem appropriate with respect to the payment of such costs.

(d) *Pickup and delivery of items pertaining to branching activities where the messenger service is established by the national bank.* A national bank may establish and operate a messenger service to transport items relevant to the bank's transactions with its customers if such transactions involve one or more branching functions within the meaning of 12 U.S.C. 36(f), provided the bank receives approval to establish the proposed branch pursuant to the relevant provisions of 12 CFR part 5.

Dated: August 27, 1992.

Stephen R. Steinbrink,

Acting Comptroller of the Currency.

[FR Doc. 93–697 Filed 1–12–93; 8:45 am]

BILLING CODE 4810-33-M

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R-0755]

Review Criteria for Bank Holding Company Applications

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is correcting a codification error in a document published in 58 FR 471, January 6, 1993. That document amended Regulation Y to implement certain regulatory improvements contained in sections 202(d) and 210 of the Federal Deposit Insurance Corporation Improvement Act of 1991.

EFFECTIVE DATE: February 4, 1993.

FOR FURTHER INFORMATION CONTACT: Scott G. Alvarez, Associate General Counsel (202-452-3583), or Brian E.J. Lam, Attorney (202-452-2067), Legal Division, Board of Governors of the Federal Reserve System. For the hearing impaired *only*, Telecommunications Device for the Deaf (TDD), Dorothea Thompson (202-452-3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington DC 20551.

SUPPLEMENTARY INFORMATION: The final rule published in the Federal Register on January 6, 1993, revised § 225.2(k) (defining the term "person") rather than revising § 225.2(l) (defining the term "principal shareholder") of the Board's Regulation Y (12 CFR 225.2(k) and (l)). This final rule restores the pre-existing definition of the term "person" in § 225.2(k), and properly revises § 225.2(l) to define the terms "controlling shareholder" and "principal shareholder" as intended by the final rule published on January 6, 1993.

List of Subjects in 12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

For the reasons set forth in the preamble, and pursuant to the Board's

authority under section 5(b) of the Bank Holding Company Act of 1956, 12 U.S.C. 1844(b), the Board amends part 225 of Chapter II of Title 12 of the Code of Federal Regulations as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL

1. The authority citation for part 225 is revised to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818(b), 1828(o), 1831i, 1843(c)(8), 1844(b), 1972(l), 3106, 3108, 3907, 3909, 3310, 3331-3351.

2.Section 225.2 is amended by revising paragraphs (k) and (l) to read as follows:

§ 225.2 Definitions.

* * * * *

(k) *Person* includes an individual, bank, corporation, partnership, trust, association, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, or any other form of entity.

(l)(1) *Controlling shareholder* means a person that owns or controls, directly or indirectly, 25 percent or more of any class of voting securities of a bank or other company.

(2) *Principal shareholder* means a person that owns or controls, directly or indirectly, 10 percent or more of any class of voting securities of a bank or other company, or any person that the Board determines has the power, directly or indirectly, to exercise a controlling influence over the management or policies of a bank or other company.

* * * * *

By order of the Board of Governors of the Federal Reserve System, January 7, 1993.

William W. Wiles,

Secretary of the Board.

[FR Doc. 93-771 Filed 1-12-93; 8:45 am]

BILLING CODE 6210-01-F

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

Small Business Size Standards; Environmental Services

AGENCY: Small Business Administration.

ACTION: Interim final rule.

SUMMARY: The Small Business Administration (SBA) is establishing on an interim basis a size standard of $18.0 million in average annual receipts for Environmental Services, an activity which involves work identified with a number of different functions including: preliminary assessment, site inspection, testing, remedial investigation, feasibility studies, remedial design, containment, remedial action and security and site closeouts. It is SBA's determination that environmental services is an emerging industry in which firms perform tasks that depart from traditional activities in any one industry as presently defined under the Standard Industrial Classification (SIC) System; this could result in a different and distinct industry structure in which firms tend to be of a different size than firms specializing in any other industry. Until SBA is able to review the characteristics of this new "emerging" industry it is choosing to use the size standard of $18.0 million.

The reason underlying the creation of a new environmental services size standard is to clarify the present uncertainty among contracting officers in determining the SIC classification of contracts involving environmental services.

In addition, SBA is seeking information and data which would either support 18.0 million size standard for this activity or suggest the need for a different size standard. For commentors offering a different size standard, SBA is seeking data which would provide some perspective of the magnitude of differences in industry structure (e.g., average firm size in receipts and assets, size distribution of firms, the concentration of economic activity among a few firms, etc.) between firms specializing in environmental services and firms specializing in activities which are related, such as sanitary services and refuse collection and disposal, as well as any other information which supports an alternative standard. While SBA has sufficient information to justify this interim rule, this request for public comment is meant to provide SBA with complete statistical data for this activity/industry. SBA believes it is necessary to seek public input as a complement to its own research on this activity/industry since it is not yet identified as a separate industry under the SIC system and therefore data are not gathered for this activity/industry by the Federal agencies.

DATES: This interim rule is effective January 13, 1993; comments must be submitted on or before February 12, 1993.

ADDRESSES: *Send comments to:* Gary M. Jackson, Director, Size Standards Staff, U.S. Small Business Administration, 409 3rd Street, SW, Suite 8150, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Robert N. Ray, Economist, Size Standards Staff, Tel: (202) 205–6618.

SUPPLEMENTARY INFORMATION: The Small Business Administration (SBA) is establishing, on an interim basis, a size standard of $18.0 million for the activity/industry of environmental services. At present, the most closely matched classification of procurements for this activity is Sanitary Services, Not Elsewhere Classified (SIC code 4959), an industry which involves establishments performing sanitary services not identified with other sanitary service industries. A second industry which has limited applicability to some of the functions is Refuse Systems (SIC code 4953), an industry which involves establishments primarily engaged in the collection and disposal of refuse by processing or destruction in the operation of incinerators, waste treatment plants, landfills, or other sites for the disposal of such materials. Both SIC codes 4959 and 4953 have varied activities. Classifying environmental services within these SIC codes results in some activities which are usually performed by fairly small firms (e.g., collection and disposal of garbage, ashes, rubbish and sweeping services) having the same size standard as other activities in the same industry that are usually performed by much larger firms (e.g., collection and disposal of hazardous waste, radioactive waste, oil spill cleanup and operation of landfill or waste disposal sites, primarily for the Federal government). Such anomalies may occasionally occur under SBA's system in which size standards are usually associated with four-digit Standard Industrial Classification (SIC) code industries. When these anomalies occur, SBA will consider defining a separate new industry classification. SBA also will consider a separate industry based upon changes within the activities of the present SIC code suggesting that a new industry is taking shape which would have a different structure than the industries with which it is associated under its current designations. This consideration seems to apply to environmental services, an activity in which Federal procurements have expanded significantly in recent years.

The size standard for environmental services is established on an interim basis because no SIC code currently exists which encompasses the types of activities associated with environmental services. Over the past decade, restoration of contaminated sites has grown significantly into a major activity, involving new technologies and a

variety of firms from various industries. A number of different SIC codes have been designated for environmental services, as discussed later in the rule, but none fully describe the type of activity being performed by firms. SBA believes this action is in the public interest in response to the confusion experienced by contracting activities over the industry classification of environmental services and the resulting size standard. Furthermore, Federal contracting is beginning to expand with multi-year contracts ranging in sizes from $25.0 million to $100 million. Accordingly, an appropriate industry designation and size standard are needed to eliminate the uncertainty over which firms are considered small business in the activity of environmental services. Under SBA's size standards regulations, § 121.301(c), if a size standard for a new industry has not been established, SBA may issue an interim rule establishing a size standard. It is not expected that the Standard Industrial Classification System will establish a separate industry code for environmental services for many years. However, for SBA's small business set-aside and 8(a) programs, an industry designation is greatly needed to ensure an appropriate size standard exists for small businesses engaged in environmental services.

In evaluating an emerging industry for size standard purposes, the SBA must consider whether the activity under consideration for a distinct size standard is a component of a large four-digit SIC code industry or includes activities which are incorporated in several SIC industries. The latter would seem to be the case for environmental services. Other industries in addition to SIC Code 4959 and 4953 in which environmental services sometimes have been classified include: SIC code 8734 (Pollution Testing); SIC code 8711, (Engineering Services); SIC code 1629 (Heavy Construction, Not Elsewhere Classified); SIC code 1795, (Wrecking and Demolition Work); SIC code 1799 (Special Trade Contractors, Not Elsewhere Classified); and SIC code 8731 (Commercial, Physical and Biological Research). Significantly, these industries have widely varying size standards. Thus, SBA is soliciting public comments on its policy of combining activities which involve three or more activities in different industries into the single industry category of environmental services with a size standard of $18.0 million. SBA, however, also must evaluate the appropriate size standard for this industry/activity. Its standard approach for evaluating a size standard is discussed below.

In considering the appropriateness of a size standard, SBA evaluates an industry using five primary factors. The primary factors include: industry competition, average firm size, start-up costs, distribution of firms by size and the impact on SBA's programs. Preliminary information based on both established data sources and anecdotal information, using the above factors as guidelines, point to the need for a relatively high size standard for the activity of environmental services. However, SBA's information may not be sufficiently broadbased for it to support a permanent size standard. Therefore, an interim size standard is being established along with a request for public comment on this action. Information relating to any of these factors would greatly assist SBA in its evaluation of the acceptability of the interim size standard of $18.0 million in average annual receipts for environmental service. These factors are reviewed below based upon SBA's research. This information is provided to demonstrate the basis for SBA's action and to assist the public in providing additional relevant information to the SBA.

Factors Influencing the Size Standard Decision Process

As an indicator of industry competition, SBA first looks at competition within the industry as measured by the share of industry sales controlled by producers above a relatively high size. In this case, SBA would be most interested in information which would indicate industry activity for firms active in environmental services that individually exceed $25.0 million in annual sales. To the extent that economic activity is concentrated in an industry or a component of an industry by a few producers that are relatively large, SBA tends to set higher size standards to assist firms in a broader size range to compete with firms that are dominant in the industry. If this pattern occurs for environmental service activities to a greater degree than alternate industry activities (e.g., construction, sanitary services, refuse collection, testing, research and development and engineering), there would be a justification for a higher size standard for this activity.

Average firm size is the second factor considered by SBA. For equity reasons, SBA tends to set higher size standards in industries with high average firm size and low size standards in industries with low average firm size. Any information which commentors have relating to differences in the average size of firms active in environmental service activities as contrasted with average firm size for the related industries would assist SBA to evaluate the need for a separate, distinct size standard for environmental service activities.

Indexes of start-up costs are the third factor to evaluate size standards. High start-up costs affect a firm's initial size because potential entrants into an industry must have sufficient capital to start a viable business, and these capital requirements vary significantly by industry. To the extent that firms active in environmental services have greater capital expenses than firms active in related industries, the SBA would be justified in considering a higher size standard for environmental services. High average start-up costs are viewed as a justification for a relatively high size standard, while low average start-up costs are usually associated with smaller size standards.

The fourth factor—firm size distribution—relates the proportion of industry sales, employment and other economic activity accounted for by firms of different sizes within an industry to its size standard. If the preponderance of an industry's output is by smaller firms, this would tend to support a low size standard. The opposite would be the case for an industry in which firm size distribution indicates that output is concentrated among intermediate sized and/or large firms.

The fifth and final factor to be considered is the impact of the proposed size standard revision on SBA's programs. These usually involve a calculation of small business shares of Federal procurement, and often the size of Federal contracts in an industry. In general, the lower the share of Federal procurement activity by small firms in an industry, and the greater the average size of Federal contracts, the greater would be the justification for a higher size standard. Patterns of SBA lending guarantees by industry have also been used by SBA in the past to evaluate the need for a size standard revision to meet SBA's program needs. Any information which commentors may have relating to the impact of the present size standards or the interim size standard on any of SBA's major programs could affect the decision for environmental services.

Selection of $18.0 Million Size Standard

As already discussed, the primary concern of this interim rule is to standardize the classification of contracts for environmental services and

establish a size standard of $18.0 million. A preliminary evaluation of the various factors associated with firms which specialize in this activity suggests the need for a size standard which is at the highest level among SBA's dollar based size standards.

The primary source of data underlying this appraisal is Wards Business Directory, a publication which describes a firm's activities within its industry classification. It is possible from this business source to determine whether a firm is active in environmental services required for Federal services. The largest single grouping of firms which is capable of performing environmental services, are listed in SIC code 4953. Data for this industry are used in table 1. This table first portrays all firms within this SIC, many of which specialize in garbage and trash collection activities. The second part of this table separates out by size those firms within the SIC code which are involved in environmental services from the larger industry.

TABLE 1

[Size Distribution of Firms in Refuse Systems Total Industry (SIC code 4953)]

Firm	Size of less than 100 empl.	100–249 empl.	250–999 empl.	1,000–4,999 empl.	5,000+ empl.	Total
No. of Firms	44	29	19	11	5	104
No. of Empl.	2,200	3,900	8,400	21,100	136,500	174,000
Firms Specializing in Environmental Services in SIC code 4953						
No. of Firms	28	14	10	10	4	66
No. of Empl.	1,400	1,900	4,200	18,600	133,100	159,200

Source: Data derived from Wards Business Directory of U.S. Private and Public Companies—1992.

This table clearly indicates that very large firms in this industry tend to be involved in environmental services. The larger the size class of firm, the more likely that it is dominated by firms that have the ability to do environmental services. This table, therefore, suggests that the size standard for firms involved in environmental services should be significantly higher than the size standard for all of refuse systems ($6.0 million), and tends to support the decision to set the size standard for this activity at a level which is three times that of other refuse collection and disposal activities. However, this data source is somewhat limited (Wards generally gathers comprehensive information on larger firms while providing only limited information on smaller firms in an industry's distribution of firms). As such, SBA is electing to establish an interim final rule for this activity, a rule which specifically invites a response from the public as to the advisability of this decision.

The classification of this activity/industry under the industry of Facilities Support Management Services (SIC code 8744) rather than either of the two refuse collection and disposal industries (SIC code 4953—Refuse Systems; and SIC code 4959)—Sanitary Services, N.E.C.) reflects SBA's awareness that this activity/industry is comprised of activities in three or more different industries similar to Base Maintenance which is also a subcategory of Facilities Support Management Services. SBA believes that Base Maintenance is closely related in concept to environmental services in other ways as well since the great majority of environmental services will occur on Federal lands and installations similar to base maintenance, and virtually all economic activity in both industries is related to Federal procurement. Thus, both the number of activities and the dependence of both activities to Federal purchases suggest a similarity between base maintenance and environmental services.

As already discussed, SBA specifically invites comment on the appropriateness of the size standard of $18.0 million (either higher or lower) for environmental services. Comments suggesting other standards should address the questions of:

(1) The interaction of this size standard with SBA's programs;

(2) The relative levels of participation at different size standards;

(3) The effect of this proposed size standard or other alternative size standard on the businesses within the industry and;

(4) The prospect of significant new entries into these businesses in response to a change in the size standard.

Compliance With Regulatory Flexibility Act, Executive Orders 12291, 12612, 12778 and the Paperwork Reduction Act

Based on all available information, SBA believes that this interim final rule would not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. An increase from $6.0 million to $18.0 million for those firms in the refuse systems industry that are active in environmental services is estimated (from admittedly limited data) to affect nine firms with receipt levels in the $6.0 million to $18.0 million range. These nine firms are collectively estimated to generate $80 million or an amount equivalent to $8.9 million per firm. Under a size standard of $18.0 million, these nine firms could, on average, each increase revenues by $4.6 million by being awarded Federal contracts while still retaining eligibility for SBA's procurement and financial preference programs. This totals, among all nine firms, $41 million, well below the $100 million threshold required for a major rule.

The SBA also estimates that none of these newly eligible firms would be seeking assistance under SBA's business loan program. SBA's guaranteed loans are limited to $750,000, a figure much less than the level of assistance which is likely to be sought by firms involved in the heavily capital intense activity of environmental services.

Based on these estimates, SBA certifies that this rule will not be a major rule within the meaning of Executive Order 12291, because it is not expected to have an annual economic impact of $100 million or more as previously discussed. This regulation will not likely result in a major increase in costs or prices or have a significant effect on the United States economy.

SBA certifies that this rule will not impose any requirement subject to the Paperwork Reduction Act of 1980, 44 U.S.C., chapter 35. SBA certifies that this rule will not have federalism implications warranting the preparation

of a Federalism Assessment in accordance with Executive Order 12612.

For purposes of Executive Order 12778, SBA certifies that this rule is drafted, to the extent practicable, in accordance with the standards set forth in section 2 of that order.

List of Subjects in 13 CFR Part 121

Government procurement, Government property, Grant programs—business, Loan programs—business, Small business.

Accordingly, part 121 of 13 CFR is amended as follows:

PART 121—[AMENDED]

1. The authority citation for part 121 continues to read as follows:

Authority: 15 U.S.C. 632(a), and 632(b)(6), 637(a) and 644(c).

§ 121.601 [Amended]

2. In § 121.601, in the table, Major Group 87 is amended by revising SIC code 8744 to read as follows:

§ 121.601 Standard Industrial Classification codes and size standards

* * * * *

SIC (*=New SIC code in 1987, not used in 1972)	Description (N.E.C.=Not elsewhere classified)	Size standards in number of employees or millions of dollars
8744*	Facilities Support Management Services[19]	$3.5
	Base Maintenance[20]	13.5
	Environmental Services[21]	18.0

3. In § 121.601, the footnotes section following the Standard Industrial Classification Table, footnote 21 is added as follows:

[21] *SIC code 8744:* If the primary purpose of the federal procurement is for Environmental Services which consist of such activities as remedial activities to restore a contaminated environment, preliminary environmental assessment studies, remedial investigation and feasibility studies, remedial design, site inspection, remedial action and/or security and site closeouts (generally accounting for 50 percent or more of the procurement activity) the appropriate classification of the procurement would be under SIC code 8744, Environmental Services, with a size standard of $18.0 million in annual receipts.

Dated: October 21, 1992.

Patricia Saiki,

Administrator, U.S. Small Business Administration

[FR Doc. 93–675 Filed 1–12–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF COMMERCE

Bureau of the Census

15 CFR Part 50

[Docket No. 921188–2288]

RIN 0607–AA17

Fee Structure for Age Search and Citizenship Information

AGENCY: Bureau of the Census.

ACTION: Final rule.

SUMMARY: The Bureau of the Census is hereby amending title 15, Code of Federal Regulations, chapter I, part 50, § 50.5, fee structure for age search and citizenship information, to increase the fee for an age search from $25.00 to $40.00, to increase the additional fee for a full schedule transcript from $6.00 to $10.00, and to reduce the number of censuses searched per fee from two to one. This change is being made to recover the actual cost to process a request. We conducted an in-depth analysis of the costs associated with processing requests for searches of census records and have determined that the current fee structure does not allow us to recover our costs. Title 13, United States Code, requires recovery of the costs. No transcript of any record will be furnished that would violate statutes requiring that information furnished to the Bureau of the Census be held confidential and not used to the detriment of the person to whom it relates.

EFFECTIVE DATE: January 31, 1993.

FOR FURTHER INFORMATION CONTACT: Jane Woods, Bureau of the Census, 1201 E. 10th Street, Jeffersonville, IN 47132, (812) 288–3212.

SUPPLEMENTARY INFORMATION: This is not a major rule within the meaning of section 1 of Executive Order 12291. It will not result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The rulemaking provisions of the Administrative Procedure Act (APA), 5 U.S.C. section 553 are inapplicable because this rule falls within the proprietary exception of subparagraph (a)(2) of section 553. The purpose of the rule is to make a technical amendment adjusting the agency's fee structure to cover the actual cost for searching the records and furnishing information therefrom. The actual or estimated cost recovery is required by 13 U.S.C. 8(a). This cost increase is minimal, reflecting the actual costs for searching and furnishing the information, and funds for this purpose are not available from any other source. Requests for searches should be directed to the Bureau of the Census, P.O. Box 1545, Jeffersonville, IN 47131–0001.

Since notice and opportunity to comment are not required by the APA or any other law, this rule is not a "rule" within the meaning of the Regulatory Flexibility Act and neither an initial nor final regulatory flexibility analysis will be prepared.

This rule does not impose an information collection requirement for purposes of the Paperwork Reduction Act.

The legal authority is title 13, United States Code.

List of Subjects in 15 CFR Part 50

Census data.

For the reasons set forth herein, part 50 of chapter I of Title 15 of the Code of Federal Regulations is amended to read as follows:

PART 50—SPECIAL SERVICES AND STUDIES BY THE BUREAU OF THE CENSUS

1. The authority citation for 15 CFR part 50 continues to read as follows:

Authority: Sec. 3, 49 Stat. 293, as amended; 15 U.S.C. 192a.

Interprets or applies Sec. 1, 40 Stat. 1256, as amended, Sec. 1, 49 Stat. 292, Sec. 8, 60 Stat. 1013, as amended, 15 U.S.C. 192, 189a, 13 U.S.C. 8.

2. Section 50.5 is revised to read as follows:

§ 50.5 Fee structure for age search and citizenship information.

Type of service	Fee
Searches of one census for one person and one transcript	$40.00
Each additional copy of census transcript	2.00
Each full schedule requested	10.00

Note.—The $10.00 for each full schedule requested is in addition to the fee increase to $40.00

Dated: January 6, 1993.

Barbara Everitt Bryant,

Director, Bureau of the Census.

[FR Doc. 93–640 Filed 1–12–93; 8:45 am]

BILLING CODE 3510–07–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1615 and 1616

Standards for Flammability of Children's Sleepwear: Sizes 0 Through 6X and 7 Through 14; Stay of Enforcement

AGENCY: Consumer Product Safety Commission.

ACTION: Stay of enforcement.

SUMMARY: This notice announces the staff's decision to stay enforcement of sleepwear requirements against garments currently being used as sleepwear that are labeled and marketed as underwear if these garments are skin-tight or nearly skin-tight and garments that are essentially identical in design, material, and fit to such "underwear" garments.

DATES: The stay becomes effective on January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Patricia A. Fairall, Office of Compliance and Enforcement, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0400.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the **Federal Register**, the Commission is issuing an advance notice of proposed rulemaking ("ANPR") concerning the possible amendment of the Commission's flammability standards for children's sleepwear in sizes 0 through 6X and 7 through 14. The current flammability standard for children's sleepwear in sizes 0 through 6X is codified at 16 CFR part 1615 and the standard for children's sleepwear in sizes 7 through 14 is codified at 16 CFR part 1616.

While the Commission considers this possible amendment, the staff will stay enforcement of the sleepwear requirements against certain garments described below.

As stated in the ANPR which is published elsewhere in this issue of the **Federal Register**, the staff has noted that many garments currently in the marketplace and labeled as "playwear" or "underwear" are suitable for use as sleepwear and are being used as sleepwear in a substantial number of cases. Pending Commission consideration of amendments to the sleepwear standards, the Compliance staff is staying enforcement against some of these garments. The staff does not intend to enforce the sleepwear requirements against garments currently being used as sleepwear that are labeled and marketed as underwear if those garments are relatively free of ornamentation and are skin-tight or nearly skin-tight. Such garments may be either one or two piece garments and typically are manufactured of a fabric such as rib knit, interlock knit, or waffle knit. The stay will also cover garments that are essentially identical in design, material, and fit to such "underwear" garments. Examples of the type of garments covered by the stay are illustrated on pages 4 and 6 of the Supplemental CPSC Staff Guide to the Enforcement Policy Statements of the Flammability Standard for Children's Sleepwear (1989).

Although the staff will stay enforcement against these garments under its sleepwear standards, these garments must comply with the Standard for the Flammability of Clothing Textiles, 16 CFR part 1610.

Dated: January 4, 1993.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 93–777 Filed 1–12–93; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. 91N–0278]

RIN 0905–AD66

New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that issued final regulations under which the agency will accelerate approval of certain new drugs and biological products for serious or life-threatening illnesses, with provisions for any necessary continued study of the drugs' clinical benefits after approval or with restrictions on use, if necessary. The document was published in the **Federal Register** of December 11, 1992 (57 FR 58942) with an inadvertent error. This document corrects that error.

EFFECTIVE DATE: January 11, 1993.

FOR FURTHER INFORMATION CONTACT: Robin F. Thomas, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

In FR Doc. 92–30129, appearing on page 58942, in the **Federal Register** of Friday, December 11, 1992, the following correction is made: On page 58945, in the second column, the following text is added to the end of the last paragraph to read as follows: "As discussed later in this document, the decision whether to seek review under accelerated approval or traditional procedures lies with the drug's sponsor. Of course, should an applicant seek approval under the accelerated approval requirements, and FDA finds neither postmarketing studies nor restricted use is required as a basis for approval, FDA will approve the drug under its existing standard procedures."

Dated: December 31, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–692 Filed 1–12–93; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8468]

RIN 1545–AQ67

TeleFile Voice Signature test

AGENCY: Internal Revenue Service, Treasury.

ACTION: Temporary regulations.

SUMMARY: This document contains temporary regulations providing that an individual Federal income tax return completed as part of the TeleFile Voice Signature test will be treated as a return that is signed, authenticated, verified, and filed by the taxpayer as required by the Internal Revenue Code. The temporary regulations affect those taxpayers who are eligible to, and elect to, file their individual income tax returns for the 1992 calendar year by telephone under the test. The temporary regulations are needed to implement the test. The text of the temporary regulations set forth in this document also serves as the text of the proposed regulations for the notice of proposed rulemaking on this subject in the Proposed Rules section of this issue of the Federal Register.

EFFECTIVE DATE: These regulations are effective January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Celia Gabrysh (202) 622–4960 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

This regulation is being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information requirement contained in this regulation has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under control number 1545–1348. The estimated burden per respondent varies from 5 minutes to 9 minutes, depending upon individual circumstances, with an average of 7 minutes.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents may require greater or less time, depending on their particular circumstances.

For further information concerning this collection of information, and where to submit comments on this collection of information, the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-reference notice of proposed rulemaking published in the Proposed Rules section of this issue of the Federal Register.

Background

The Internal Revenue Service is actively engaged in efforts to broaden the base of the existing Electronic Filing program and to reduce the filing burden of taxpayers. Among these efforts is the TeleFile Voice Signature test. The purpose of the test is to explore the technical feasibility, public acceptance, vulnerability, and other benefits and costs of giving certain taxpayers the option of filing their individual income tax returns by telephone.

The Internal Revenue Service will notify certain individuals who live in the Cincinnati District Office geographic area that they may be eligible to participate in the TeleFile Voice Signature test. Taxpayers eligible to participate in this test (which is limited to one filing season) are individuals who (1) are eligible to file Form 1040EZ, Income Tax Return for Single Filers With No Dependents, (2) reside within the geographic boundaries of the Cincinnati District Office, and (3) will file their 1992 income tax returns from the same address from which they filed their 1991 income tax returns.

Under sections 6012, 6061, and 6065 of the Internal Revenue Code, each individual with gross income in excess of a specified amount must file an annual income tax return that (i) is signed in accordance with prescribed forms and instructions and, (ii) except as otherwise provided by the Service, contains (or is verified by) a written declaration that the return is made under penalties of perjury.

This document amends the Income Tax Regulations (26 CFR part 1) by adding temporary regulations §§ 1.6012–7T, 1.6061–2T and 1.6065–2T, which provide rules to facilitate the implementation of the TeleFile Voice Signature test. Generally, the temporary regulations provide that a taxpayer's individual income tax return will be treated as having been properly filed if the taxpayer is eligible to participate in the TeleFile Voice Signature test and, pursuant to the instructions from the TeleFile system interactive voice computer, provides the requested information and the voice signature during the telephonic filing session.

Explanation of Provisions

A participating taxpayer will be treated as having filed an individual income tax return at the time the TeleFile Voice Signature system computer states to the taxpayer that the filing is completed. The taxpayer's voice signature will be treated as a signing and verification of the individual Federal income tax return by the taxpayer. By providing a voice signature during the telephonic filing session, the taxpayer will be treated as having made the income tax return under penalties of perjury.

Special Analyses

It has been determined that these temporary rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and therefore, a final Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking for the regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on the regulations' impact on small business.

Need for Temporary Regulations

There is need for immediate guidance with respect to the provisions contained in this Treasury decision. For this reason, it is found impracticable to issue this Treasury decision with prior notice as required by section 553(b) of title 5 of the United States Code.

Drafting Information

The principal author of these temporary regulations is Celia Gabrysh of the Office of Assistant Chief Counsel (Income Tax & Accounting), Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in their development.

List of Subjects

26 CFR 1.6001–1 Through 1.6109–2

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAX; TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1953

Paragraph 1. The authority citation for part 1 is amended in part by adding the following citations to read as follows:

Authority: 26 U.S.C. 7805 * * * Section 1.6012–7T also issued under 26 U.S.C. 6012. * * * Section 1.6061–2T also issued under 26 U.S.C. 6061. * * * Section 1.6065–2T also issued under 26 U.S.C. 6065. * * *

Par. 2. Sections 1.6012–7T, 1.6061–2T and 1.6065–2T are added to read as follows:

§ 1.6012–7T Telephone return filing using voice signature (temporary).

(a) *In general.* For all purposes of the Internal Revenue Code, a return completed by an eligible taxpayer under the TeleFile Voice Signature test in accordance with the instructions provided over the telephone is an individual income tax return filed at the time the TeleFile system interactive voice computer states to the taxpayer that the filing is completed. For provisions relating to the signing and verification of the TeleFile Voice Signature test returns made under this section, see §§ 1.6061–2T and 1.6065–2T, respectively.

(b) *Manner of filing return by telephone.* An eligible taxpayer who chooses to participate in the TeleFile Voice Signature test must dial from a touch-tone telephone the telephone number provided by the Internal Revenue Service. When an eligible taxpayer dials this telephone number, the TeleFile system interactive voice computer will give the taxpayer filing instructions. The taxpayer must provide all the information and a voice signature at the time and in the manner required by those instructions.

(c) *Eligible taxpayer defined.* An eligible taxpayer is an individual who lives in the Cincinnati District Office geographic area, who is eligible to file Form 1040EZ, and whose current name and address appears on the mailing label attached to the taxpayer's tax package for 1992.

(d) *Address to which refunds are sent.* If a taxpayer who files a TeleFile return is entitled to a refund, the taxpayer's refund will be sent to the address on the mailing label attached to the taxpayer's tax package for 1992.

(e) *Effective dates.* This section is effective for returns filed by eligible taxpayers in the TeleFile Voice Signature test after January 13, 1993, and before April 16, 1993. No returns can be filed through the TeleFile Voice Signature test after April 15, 1993.

§ 1.6061–2T Signing of returns by voice signature (temporary).

(a) *In general.* An eligible taxpayer who makes an income tax return under § 1.6012–7T in the TeleFile Voice Signature test is treated, for all purposes of the Internal Revenue Code, as having signed that return by providing the voice signature at the time and in the manner required by the instructions that are provided over the telephone by the TeleFile system interactive voice computer. For provisions relating to the verification of the TeleFile returns made under § 1.6012–7T, see § 1.6065–2T.

(b) *Effective dates.* This section is effective for returns filed by eligible taxpayers in the TeleFile Voice Signature test after January 13, 1993, and before April 16, 1993.

§ 1.6065–2T Verification of returns by voice signature (temporary).

(a) *In general.* An eligible taxpayer who makes an income tax return under § 1.6012–7T in the TeleFile Voice Signature test, by providing the voice signature at the time and in the manner required by the instructions that are provided over the telephone by the TeleFile system interactive voice computer, is treated for all purposes of the Internal Revenue Code as having affirmed that the return is made under penalties of perjury and as having verified the return.

(b) *Effective dates.* This section is effective for returns filed by eligible taxpayers in the TeleFile Voice Signature test after January 13, 1993, and before April 16, 1993.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 3. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 4. Section 602.101(c) is amended by adding the following entries in the table:

§ 602.101 OMB Control Numbers.

* * * * *

(c) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.6012–7T	1545–1348.
1.6061–2T	1545–1348.
* * * * *	

Shirley D. Peterson,
Commissioner of Internal Revenue.

Approved: December 16, 1992.

Alan J. Wilensky,
Deputy Assistant Secretary of the Treasury.

[FR Doc. 93–658 Filed 1–12–93; 8:45 am]

BILLING CODE 4830–01–M

Office of Foreign Assets Control

31 CFR Part 580

Haitian Transactions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule; amendment.

SUMMARY: This rule amends the Haitian Transactions Regulations (the "Regulations"), to give general authorization for the commercial exportation from the United States to Haiti of medicine and medical supplies intended strictly for medical purposes. This rule also announces the availability of specific licenses for the exportation to Haiti of personal hygiene items, of ingredients and materials for the manufacture of medicines and of paper and school supplies. Specific licenses are also available for generators and generator parts, if they are intended for use in humanitarian projects.

EFFECTIVE DATE: January 8, 1993.

FOR FURTHER INFORMATION CONTACT: John T. Roth, Chief of Policy Planning and Program Management (tel.: 202/622–1604), Steven I. Pinter, Chief of Licensing (tel.: 202/622–2480), or William B. Hoffman, Chief Counsel (tel.: 202/622–2410), Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION: On March 31, 1992, the Department of the Treasury promulgated the Regulations (31 CFR part 580) in consultation with the Department of State to implement the President's Executive Orders of October 4, 1991, declaring a national emergency with respect to Haiti and ordering specified measures against Haiti, and of October 28, 1991, ordering a trade embargo against Haiti.

Section 580.510 is amended to give general authorization for the exportation from the United States to Haiti of medicines and medical supplies intended strictly for medical purposes, rather than requiring the specific licensing of such transactions as is presently required. No payments to the *de facto* regime in Haiti or to anyone acting on behalf of the regime are permitted in connection with such transactions. Section § 580.510 is also

amended to indicate that specific licenses are available on a case-by-case basis for the exportation of personal hygiene items and of ingredients and materials used in the manufacture of medicines.

New § 580.517 provides that specific licenses may be issued on a case-by-case basis authorizing the exportation of paper, school supplies, generators and generator parts. Generators and generator parts must be intended for use in humanitarian projects, with the nature of the humanitarian project fully described in the license application.

Because the Regulations involve a foreign affairs function, Executive Order 12291 and the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation, and delay in effective date, are inapplicable. Because no notice of proposed rulemaking is required for this rule, the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, does not apply.

List of Subjects in 31 CFR Part 580

Administrative practice and procedure, Banking and finance, Blocking of assets, Exports, Haiti, Imports, Penalties, Reporting and recordkeeping requirements, Shipping, Transfer of assets, Vessels.

For the reasons set forth in the preamble, 31 CFR part 580 is amended as follows:

PART 580—HAITIAN TRANSACTIONS REGULATIONS

1. The authority citation for part 580 continues to read as follows:

Authority: 50 U.S.C. 1701, *et seq.*; E.O. 12775, 3 CFR 1991 Comp., p. 349 (Oct. 7, 1991); E.O. 12779, 3 CFR 1991 Comp., p. 367 (Oct. 30, 1991).

Subpart E—Licenses, Authorizations and Statements of Licensing Policy

2. Section 580.510 is revised to read as follows:

§ 580.510 Exports of medicines and medical supplies.

(a) Exportation from the United States to Haiti of medicines and medical supplies is authorized. No payment to the *de facto* regime in Haiti, or to anyone acting for or on behalf of the *de facto* regime, is authorized in connection with such shipment.

(b) "Medicines" shall mean finished pharmaceutical compounds, mixtures or preparations ready for ingestion, injection or topical application. It shall not include:

(1) Ingredients or materials used in the manufacture of such items; or

(2) Personal hygiene items.

(c) Specific licenses for commercial exportation to Haiti of:

(1) Ingredients or materials used in the manufacture of medicines; and

(2) Personal hygiene items may be issued on a case-by-case basis.

3. Section 580.517 is added to read as follows:

§ 580.517 Exportation of certain products for use in humanitarian projects.

Specific licenses may be issued on a case-by-case basis authorizing the exportation from the United States to Haiti of paper and school supplies. Specific licenses may be issued on a case-by-case basis authorizing the exportation of generators and generator parts for use in humanitarian projects.

Dated: December 31, 1992.

R. Richard Newcomb,

Director, Office of Foreign Assets Control.

Approved: January 4, 1993.

Nancy L. Worthington,

Acting Assistant Secretary (Enforcement).

[FR Doc. 93–780 Filed 1–8–93; 3:54 pm]

BILLING CODE 4810–25–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Public Land Order 6953

[ID–943–02–4210–06; IDI–29616, IDI–29575]

Jurisdiction Transfer, Arkansas-Idaho Land Exchange Act of 1992; ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order transfers jurisdiction of 9,114.44 acres of public lands from the Bureau of Land Management to the Forest Service and 7,978.91 acres of National Forest System lands from the Forest Service to the Bureau of Land Management. Subsequent to the jurisdictional transfers, the 7,978.91 acres transferred to Bureau of Land Management will, in turn, be conveyed to the Potlatch Corporation. These actions are being taken pursuant to the Arkansas-Idaho Land Exchange Act of 1992 (Pub L. 102–584).

EFFECTIVE DATE: December 2, 1992.

FOR FURTHER INFORMATION CONTACT: Sally Carpenter, BLM Idaho State Office, 3380 Americana Terrace, Boise, Idaho 83706, 208–384–3163.

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714 (1988), and pursuant to the Arkansas-Idaho Land Exchange Act of 1992, Public Law 102–584, it is hereby ordered as follows:

1. Jurisdiction of the following described public lands administered by the Bureau of Land Management is hereby transferred to the Forest Service for inclusion in the National Forest System:

Boise Meridian

T. 42 N., R. 1 E.,
Sec. 6, lots 4 and 6.
T. 43 N., R. 2 E.,
Sec. 4, NW¼SE¼.
T. 44 N., R. 2 E.,
Sec. 20, SE¼NE¼;
Sec. 24, SE¼NE¼ and SE¼;
Sec. 25, N½NE¼ and SW¼NE¼;
Sec. 32, W½NW¼.
T. 46 N., R. 2 E.,
Sec. 1, N½SW¼ and S½SE¼;
Sec. 2, lots 3 and 4, SW¼NE¼, and NE¼SE¼;
Sec. 12, E½NE¼;
Sec. 13, SE¼NE¼.
T. 47 N., R. 2 E.,
Sec. 25, W½SW¼, SE¼SW¼, and SW¼SE¼;
Sec. 26, SE¼SE¼;
Sec. 27, W½NE¼, NW¼, NE¼SW¼, and W½SE¼;
Sec. 34, N½NE¼ and SE¼NE¼;
Sec. 35, N½NE¼, NW¼, and NW¼SW¼.
T. 43 N., R. 3 E.,
Sec. 11, SE¼SW¼ and S½SE¼;
Sec. 12, SW¼SW¼;
Sec. 13, W½NW¼;
Sec. 14, NE¼, NE¼NW¼, N½SE¼, SW¼SE¼, and NW¼SE¼SE¼;
Sec. 15, W½NW¼, SE¼NW¼, N½SW¼, and SE¼SW¼;
Sec. 19, E½SE¼;
Sec. 20, all;
Sec. 21, W½NE¼, W½, W½SE¼, and SE¼SE¼;
Sec. 22, W½NE¼, SE¼NE¼, NE¼NW¼, NE¼SW¼, S½SW¼, and SE¼;
Sec. 23, W½NW¼NE¼ and W½NW¼SW¼;
Sec. 27, W½NE¼ and W½;
Sec. 28, E½, NE¼NW¼, and S½SW¼;
Sec. 29, NW¼NE¼, S½SW¼, and S½SE¼;
Sec. 30, S½SE¼;
Sec. 31, E½ and SE¼SW¼;
Sec. 32, W½NE¼, W½, and S½SE¼;
Sec. 33, N½N½, SW¼NE¼, S½SW¼, and W½SE¼;
Sec. 34, NW¼NE¼, N½NW¼, and SE¼NW¼.
T. 44 N., R. 3 E.,
Sec. 3, lot 2, SW¼NE¼, and E½SW¼;
Sec. 4, S½NE¼ and NW¼SE¼;
Sec. 5, S½NW¼, NW¼SW¼, and SE¼SE¼;
Sec. 6, S½NE¼;
Sec. 8, SW¼NE¼ and NE¼SE¼;
Sec. 9, NE¼NE¼.
T. 45 N., 3 E.,
Sec. 24, N½N½;
Sec. 26, NE¼ and E½SE¼;

Sec. 32, S½NE¼ and N½SE¼;
Sec. 34, NE¼SE¼.
T. 45 N., R. 4 E.,
Sec. 2, lots 1 to 4, inclusive, W½SW¼, and E½SE¼;
Sec. 3, lots 1 to 8, inclusive, S½N½, and S½.

The areas described aggregate 9,114.44 acres in Latah and Shoshone Counties.

2. Jurisdiction of the following described National Forest System lands is hereby transferred to the Bureau of Land Management for subsequent transfer to the Potlatch Corporation. The transfer to the Potlatch Corporation will be subject to valid existing rights, which will be enumerated in the patent.

(a) The following described National Forest System lands have Weeks Law status:

Boise Meridian

T. 41 N., R. 1 E.,
Sec. 4, lot 1 and SE¼NE¼.
T. 43 N., R. 1 E.,
Sec. 22, NE¼SE¼;
Sec. 28, NW¼NE¼, NE¼NW¼, and W½SW¼;
Sec. 29, W½NE¼, NW¼, N½SW¼, and E½SE¼;
Sec. 30, lots 3 and 4, N½NE¼, SE¼NE¼, E½SW¼, and NE¼SE¼;
Sec. 31, lots 1 and 2;
Sec. 33, W½NW¼;
T. 46 N., R. 1 E.,
Sec. 23, NE¼SE¼;
Sec. 24, SE¼SW¼;
Sec. 25, N½NW¼;
Sec. 26, S½NW¼NW¼, S½S½NE¼NW¼, and SE¼NW¼;
Sec. 27, S½N½NE¼.
T. 42 N., R. 2 E.,
Sec. 1, lots 3 and 4, S½NW¼, and N½SW¼;
Sec. 2, lots 1 to 4, inclusive, S½NE¼, and N½SE¼;
Sec. 9, NE¼NW¼;
Sec. 23, NE¼SE¼.
T. 45 N., R. 2 E.,
Sec. 4, SE¼SW¼;
Sec. 5, lots 16 and 17;
Sec. 14, NW¼, W½SW¼, and NE¼SW¼.
T. 46 N., R. 2 E.,
Sec. 30, lots 3 and 4, SE¼SW¼, and SE¼SE¼, excluding .80 acre;
Sec. 32, S½NE¼, NE¼SW¼, and SE¼.
T. 45 N., R. 3 E.,
Sec. 7, lot 4 and SE¼NW¼;
Sec. 8, W½SW¼;
Sec. 9, SW¼NE¼, SE¼NW¼, and NE¼SW¼;
Sec. 10, lot 8;
Sec. 12, SW¼SW¼ less 5.9 acres south 198 ft.;
Sec. 15, SE¼NE¼, E½SW¼, and SE¼;
Sec. 17, N½NE¼ and NE¼NW¼;
Sec. 28, S½NE¼;
Sec. 29, NW¼NE¼, S½NW¼, and NW¼SE¼;
Sec. 31, W½NE¼ and NE¼NW¼.
T. 45 N., R. 4 E.,
Sec. 14, S½N½;
Sec. 16, lots 5 to 8, inclusive, and S½;
Sec. 19, lot 1, N½ of lot 2, NW¼NE¼, N½S½NE¼, NE¼NW¼; and N½SE¼NW¼;
Sec. 30, lots 2 to 4, inclusive, SE¼NW¼, and E½SW¼;
Sec. 32, N½N½, S½NE¼, SE¼NW¼, and NE¼SW¼;
Sec. 34, NW¼.
T. 42 N., R. 1 W.,
Sec. 4, lot 4 and SW¼NW¼.
T. 44 N., R. 1 W.,
Sec. 29, SW¼;
Sec. 30, SW¼NE¼ and E½SE¼;
Sec. 31, E½E½;
Sec. 32, SE¼NE¼, S½S½, and N½SE¼;
Sec. 33, E½;
Sec. 34, N½SW¼ and SW¼SW¼.
T. 45 N., R. 1 W.,
Sec. 7, lot 4.

(b) The following described National Forest System lands have reserved public domain status:

Boise Meridian

T. 43 N., R. 1 W.,
Sec. 12, S½NE¼, NW¼ and W½SW¼
T. 44 N., R. 2 W.,
Sec. 30, NW¼SE¼.
T. 43 N., R. 3 W.,
Sec. 3, lot 4, SW¼NW¼, and W½SW¼.
T. 44 N., R. 3 W.,
Sec. 26, N½NE¼, SE¼NE¼, and NW¼;
Sec. 32, lot 1, NE¼, NE¼NW¼, and S½NW¼;
Sec. 34, NE¼NE¼ and SW¼SW¼.

The areas described aggregate 7,978.91 acres in Benewah, Latah, and Shoshone Counties.

Dated: December 2, 1992.

Dave O'Neal,

Assistant Secretary of the Interior.

The following letter from the U.S. Forest Service provides their concurrence in the transfer of jurisdiction of lands identified in Public Land Order No. 6953:

Honorable Manuel Lujan, Jr.,
Secretary of the Interior, Room 6151, 1849 C Street, NW., Washington, D.C. 20240

Dear Mr. Secretary: This is to document the Department of Agriculture's concurrence with the transfer of jurisdiction of lands as identified in Public Land Order 6953, dated December 2, 1992. These lands are being transferred from the jurisdiction of the Secretary of Agriculture to the Secretary of the Interior for conveyance to the Potlatch Corporation as required by section 3(a)(2) of the Arkansas-Idaho Land Exchange Act of 1992 (Public Law 102–584).

Sincerely,

John H. Beuter,

Acting Assistant Secretary, Natural Resources and Environment.

[FR Doc. 93–602 Filed 1–12–93; 8:45 am]
BILLING CODE 4310-00-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA–7561]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the fourth column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the NFIP at: Post Office Box 457, Lanham, MD 20706, (800) 638–7418.

FOR FURTHER INFORMATION CONTACT: Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, 500 C Street, SW., room 417, Washington, DC 20472, (202) 646–2717.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map (FHBM) or Flood Insurance Rate Map (FIRM). The date of the flood map, if one has been published, is indicated in the fifth column of the table. In the communities listed where a flood map has been published, section 102 of the Flood Disaster Protection Act of 1973, as amended, 42 U.S.C. 4012(a), requires the purchase of flood insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard areas shown on the map.

The Director finds that the delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Federal Insurance Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, because the rule creates no additional burden, but lists those communities eligible for the sale of flood insurance.

Regulatory Impact Analysis

This rule is not a major rule under Executive Order 11291, Federal Regulation, February 17, 1981, 3 CFR 1981 Comp., p. 127. No regulatory impact analysis has been prepared.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*, Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR 1979 Comp., p. 376.

§ 64.6 [Amended]

2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date of authorization/cancellation of sale of flood insurance in community	Current effective map date
New Eligibles—Emergency Program			
Indiana:			
Osceola, town of, St. Joseph County	180506	Dec. 14, 1992	—
Iowa:			
Dallas County, unincorporated areas	190860	....do	Oct. 25, 1977.
Kansas:			
Marion County, unincorporated areas	200593	Dec. 29, 1992	Aug. 22, 1978.
New Eligibles—Regular Program			
Georgia:			
Spalding County, unincorporated areas	130388	Dec. 11, 1992	July 2, 1991.
Florida:			
Freeport, city of, Walton County	120319	Dec. 14, 1992	Apr. 30, 1986.
Georgia:			
Auburn, city of, Barrow County	130468	Dec. 15, 1992	May 16, 1992.
Reinstatements—Regular Program			
West Virginia:			
East Bank, town of, Kanawha County	540077	May 29, 1975, Emerg.; June 1, 1982, Reg.; Nov. 16, 1992, Susp.; Dec. 4, 1992, Rein.	June 1, 1982.
Virginia:			
Greene County, unincorporated areas	510200	Apr. 11, 1974, Emerg.; Sept. 10, 1984, Reg.; Dec. 2, 1992, Susp.; Dec. 11, 1992, Rein.	Sept. 10, 1984.
Pennsylvania:			
Sadsbury, township of, Crawford County	422396	Aug. 6, 1975, Emerg.; Aug. 19, 1991, Reg.; Aug. 19, 1991, Susp.; Dec. 11, 1992, Rein.	Aug. 19, 1991.
New York:			
Mooers, village of, Clinton County	361488	May 23, 1984, Emerg.; Jan. 17, 1986, Reg.; Nov. 4, 1992, Susp.; Dec. 22, 1992, Rein.	Jan. 17, 1986.
Saranac, town of, Clinton County	360171	May 9, 1978, Emerg.; June 5, 1985, Reg.; Nov. 4, 1992, Susp.; Dec. 22, 1992, Rein.	Mar. 3, 1992.
Angelica, village of, Allegany County	360023	June 8, 1976, Emerg.; Feb. 1, 1984, Reg.; Nov. 4, 1992, Susp.; Dec. 23, 1992, Rein.	Feb. 1, 1984.
Richburg, village of, Allegany County	360022	May 21, 1976, Emerg.; Jan. 5, 1978, Rein.; Nov. 4, 1992, Susp.; Dec. 23, 1992, Rein.	Jan. 5, 1978.
Virginia:			
Bath County, unincorporated areas	510196	Sept. 16, 1975, Emerg.; Sept. 10, 1984, Rein.; Dec. 20, 1992, Susp.; Dec. 29, 1992, Rein.	Sept. 10, 1984.
Florida:			
Minneola, city of, Lake County	120412	Jan. 24, 1977, Emerg.; Aug. 15, 1984, Rein.; Aug. 15, 1984, Susp.; Dec. 29, 1992, Rein.	Aug. 15, 1984.
REGULAR PROGRAM CONVERSIONS			
Region III			
Pennsylvania:			
Peters, township of, Franklin County	421654	Dec. 2, 1992, Suspension withdrawn	Dec. 2, 1992.

State and location	Community No.	Effective date of authorization/cancellation of sale of flood insurance in community	Current effective map date
Region VII			
Missouri:			
Cottleville, village of, St. Charles County	290898	Dec. 15, 1992, Suspension withdrawn	Dec. 15, 1992.
O'Fallon, city of, St. Charles County	290361	do	Dec. 15, 1992.
St. Charles County, unincorporated areas	290315	do	Dec. 15, 1992.
St. Peters, city of, St. Charles County	290319	do	Dec. 15, 1992.
Wentzville, city of, St. Charles County	290320	do	Dec. 15, 1992.
St. Charles, city of, St. Charles County	290318	do	Dec. 15, 1992.

Code for reading fourth column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension, Rein.—Reinstatement.

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Issued: January 7, 1993.

C.M. "Bud" Schauerte,

Administrator, Federal Insurance Administration.

[FR Doc. 93–768 Filed 1–12–93; 8:45 am]

BILLING CODE 6718–21–M

44 CFR Part 64

[Docket No. FEMA–7560]

Suspension of Community Eligibility

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. These communities are located in Dade County, Florida and are currently participating in the NFIP under the Dade County Metropolitan Government. If FEMA receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register**.

EFFECTIVE DATE: The effective date of each community's suspension is the third date ("Susp.") listed in the fourth column of the following tables.

ADDRESSES: If you wish to determine whether a particular community was suspended on the suspension date, contact the appropriate FEMA Regional Office or the NFIP servicing contractor.

FOR FURTHER INFORMATION CONTACT: Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, 500 C Street, SW., room 417, Washington, DC 20472, (202) 646–2717.

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits flood insurance coverage as authorized under the National Flood Insurance Program, 42 U.S.C. 4001 *et seq.*, unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures.

The communities listed in this document have been participating in the NFIP under the eligibility of the Dade County (Florida) Metropolitan Government. On May 4–8, 1992, FEMA conducted a comprehensive Community Assistance Visit (CAV) of the administration of the NFIP by Dade County and by the 27 incorporated municipalities within Dade County. The CAV identified a significant number of program deficiencies and potential violations in many of the municipalities and in the unincorporated areas of the county. As a result of the findings and in order to allow the county and individual municipalities an opportunity to participate in the NFIP's Community Rating System (CRS), it was determined by the Federal Insurance Administration to change the eligibility status of Dade County from one metropolitan community to 28 separate communities. To implement the change, a countywide Flood Insurance Rate Map (FIRM) has been issued. It becomes effective on January 20, 1993. The FIRM includes community boundaries and new community identification numbers (CID's). Each community is required to meet the statutory requirement for compliance with program regulations, 44 CFR part 59 *et seq.* Accordingly, the communities which do not adopt compliant ordinances will be suspended on the effective date in the fourth column. As of that date, flood insurance will no longer be available in the community. However, many of these communities may make application, adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue their eligibility for the sale of insurance. A notice withdrawing the suspension of the communities will be published in the **Federal Register.**

In addition, the Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Insurance Rate Map (FIRM). The date of the FIRM is indicated in the fifth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than one year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Administrator finds that notice and public comment under 5 U.S.C. 553(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community's Chief Executive Officer has received a 6-month, 90-day, and 30-day notifications that the community will be suspended unless the community makes application and adopts the required floodplain management measures prior to the effective suspension date. Since these notifications have been made, this final rule may take effect within less than 30 days.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Federal Insurance Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4002, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirement, and after the effective date, flood insurance will no longer be available in the communities unless they take remedial action.

Regulatory Impact Analysis

This rule is not a major rule under Executive Order 12291, Federal Regulation, February 17, 1981, 3 CFR, 1981 Comp., p. 127. No regulatory impact analysis has been prepared.

Paperwork Reduction Act

This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, October 26, 1987, 3 CFR, 1987 Comp., p. 252.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, October 25, 1991, 56 FR 55195, 3 CFR, 1991 Comp., p. 309.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 64.6 [Amended]

2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date of authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in special flood hazard areas
SUSPENSIONS				
Region IV				
Florida:				
Bay Harbour Islands, town of Dade County.	120637	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Jan. 20, 1993.
Florida City, city of Dade County.	120641	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Hialeah Gardens, city of Dade County.	120644	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Homestead, city of Dade County	120645	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Indian Creek, village of Dade County	120646	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Islandia, city of Dade County	120647	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Key Biscayne, city of Dade County.	120648	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Medley, town of Dade County	120649	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
North Bay Village, city of Dade County.	120654	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Opa-Locka, city of Dade County	120657	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Surfside, town of Dade County	120658	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	Jan. 20, 1993	Do.
Sweetwater, city of Dade County	120660	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	NSFHA[1]	Do.
West Miami, city of Dade County	120662	Aug. 14, 1970, Emerg.; Sept. 29, 1972, Reg.; Jan. 20, 1993, Susp.	NSFHA[1]	Do.

[1] No Special Flood Hazard Areas.

Code for reading fourth column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

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(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Issued: January 7, 1993.

C.M. "Bud" Schauerte,

Administrator, Federal Insurance Administration.

[FR Doc. 93–770 Filed 1–12–93; 8:45 am]

BILLING CODE 6718–21–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1832 and 1852

Addition of Coverage to NASA FAR Supplement on the Use of Milestone Billing Arrangements for Contract Financing

AGENCY: Office of Procurement, Procurement Policy Division, National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This notice amends the NASA Federal Acquisition Regulation Supplement (NFS), Chapter 18 of the Code of Federal Regulations. This rule sets forth the policies and criteria for the use of milestone billing arrangements for contract financing, as well as the cause to be included in contracts using such financing. It also sets forth the policy regarding advance payment determinations and findings for the use of milestone billing arrangements for expendable launch vehicle (ELV) services contracts.

EFFECTIVE DATE: This rule shall take effect on January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Le Cren, Procurement Analyst, Contracting Pricing and Financial Division (Code HC), Telephone: (202) 358–0444.

SUPPLEMENTARY INFORMATION:

A. Background

On July 13, 1992, a proposed rule to amend the NFS to add policies and criteria for the use of milestone billing arrangements for contract financing was published in the **Federal Register** (57 FR 30933) for comment. All comments were reviewed and, where warranted, changes have been made in the final rule.

Among the changes made are two clarifications. They involve 1832.7001, where it was made clear that milestone billing arrangements, although subject to prompt pay, are not subject to interest penalties; and 1832.7004 where it now states that milestone payments can continue for the next end item, if the time between deliveries of one major end item and the next exceeds three months and there is mutual agreement.

Several policy changes were also made. Those changes were to 1832.7004 (c) and (e). 1832.7004(c) was revised to allow for the delegation of processing milestone billing vouchers outside of NASA if specific directions are provided to the administrative contracting officer, and the contracting officer performs periodic reviews of the process. The change at 1832.7004(e) was to allow the milestone billing amounts to be changed due to economic price adjustments, if provided for in the economic price adjustment clause, and the changes to the milestone amounts occur at the same time as the contract price adjustment.

Other changes also occurred in the clause at 1852.232–83, specifically paragraphs (b), (c), (f), and (h)(3). The change at paragraph (b) is to streamline the voucher payment process by allowing for the contractor's voucher to be submitted at the same time as its certification, instead of after contracting officer verification of completion of the milestone. Paragraph (c) was revised to make it more consistent with 1832.7004(a) and also to incorporate the change made there. Paragraph (f) was changed to allow contractors to self-insure, as well as to purchase the insurance described. The final change was made at paragraph (h)(3) to allow for the payment of milestones completed out of sequence so long as the prior written consent of the contracting officer is obtained.

Impact

The Director, Office of Management and Budget (OMB), by memorandum dated December 14, 1984, exempted certain agency procurement regulations from Executive Order 12291. This proposed regulation falls in this category. NASA certifies that this regulation will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule does not impose any reporting or record keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 48 CFR Parts 1832 and 1852

Government procurement.

Don G. Bush,

Assistant Administrator for Procurement.

1. The authority citation for 48 CFR parts 1832 and 1852 continues to read as follows:

Authority: 42 U.S.C. 2473(c)(1).

PART 1832—CONTRACT FINANCING

2. Part 1832 is amended as set forth below:

a. Section 1832.402–2 is added to read as follows:

1832.402–2 Expendable launch vehicle services contracts.

Determinations and findings are not required for advance payments for contracts supporting expendable launch vehicle (ELV) services contracts (however, see 1832.70 for Milestone Billing Arrangements). Instead all advance payments clauses for ELV services contracts shall be submitted to Code HC for concurrence prior to issuance of the solicitation (see 1832.7005), and to the Assistant Administrator for Procurement (Code HC) for approval prior to award (see 1832.7006).

b. Subpart 1832.70 is added to read as follows:

Subpart 1832.70—Milestone Billing Arrangements

Sec.

1832.7001 General.
1832.7002 Policy.
1832.7003 Criteria for use.
1832.7004 Contractual implementation.
1832.7005 Concurrence prior to solicitation.
1832.7006 Approval prior to contract award.
1832.7007 Subcontracts and contract amendments.
1832.7008 Solicitation and contract clause.

Subpart 1832.70—Milestone Billing Arrangements

1832.7001 General.

As authorized at FAR 32.102(e), milestone billing arrangements may be used for contract financing. Milestone billing arrangements fall between progress payments based on costs with unusual terms and advance payments in the order of preference specified in FAR 32.106. Milestone billing arrangements are contractual provisions which provide for payments to a contractor upon successful completion of specific performance events not involving physical deliveries to the Government. As milestone arrangements are interim payments with respect to total contract performance, they are fully recoverable, in the same manner as progress payments, in the event of default. Milestone payments shall not be considered as payments for contract items delivered and accepted, incentive price revisions, or inspection and acceptance provisions of the contract. Milestone billing arrangements are contract financing payments and as such are not subject to prompt payment interest penalties.

1832.7002 Policy.

In negotiating milestone billing arrangements, contracting officers must seek to establish an overall level of contract financing that will result in the contractor maintaining an appropriate investment in contract work-in-process inventory. The level of contract financing should be based on the number, value and timing of the milestone billing events, and the manner in which milestone payments are liquidated against contract line item deliveries. Therefore, proposed milestone billing arrangements should be carefully evaluated to ensure that contract financing objectives are being met, that the proposed milestone billing arrangement will not result in an unreasonably low or negative level of contractor work-in-process inventory, or create an administrative burden (e.g., too frequent payments).

1832.7003 Criteria for use.

(a) Milestone billing arrangements are limited to fixed-price type contracts in excess of $10 million with long lead times (at least 12 months) between the initial incurrence of costs under the contract and the delivery of the first end item.

(b) The contract shall not provide for progress payments based on cost or advance payments, with the exception of expendable launch vehicle (ELV) services contracts (see 1832.7003(d)).

(c) The established milestone events will be readily determinable.

(d) Milestone billing amounts shall not exceed the Government's best estimate of the cost to perform each milestone event. For ELV services contracts, 42 U.S.C. 2459c provides authority to make advance payments in conjunction with milestone billing arrangements. Advance payments provided under such arrangements must be reasonably related to launch vehicle and related equipment, fabrication, and acquisition costs. However 42 U.S.C. 2459c provides considerable flexibility in determining what types of costs (committed, incurred, expended) may be considered in determining payment schedules for ELV services contracts. Individual milestone payments may exceed a contractor's incurred costs during performance only if the payment schedules comply with the intent of 42 U.S.C. 2459c, are considered fair and reasonable, and serve the Government's best interests.

(e) The contract milestones should represent the completion of substantial items of service or events that would normally require management visibility and attention to assure their timely accomplishment. Milestones should not be based on insignificant events, administrative functions, percentage of completion estimates, or the passage of time. The number of milestone events will be kept to a minimum.

1832.7004 Contractual implementation.

Contracts containing milestone billing arrangements will include the following requirements:

(a) Normally, milestone billings will not be submitted after deliveries of a major end item commences upon which milestone payments have been made. In the event the period between delivery of such major end item and the next end item delivery exceeds three months, milestone payments can continue to be made for the next end item as mutually agreed for appropriate events.

(b) Completion of each milestone must be certified by the contractor and verified by the contract administration office in order for payment to be made.

(c) The processing of milestone billing vouchers shall not be delegated outside NASA without specific instructions from the contracting officer, and the periodic review of payments by the contracting officer, e.g., reviews of action taken on issues that have arisen.

(d) The relationship between milestone billing events and deliverable contract line items will be clearly established in the contract. A milestone billing event should normally be associated with only one contract line item. However, a contract line item may have more than one related milestone billing event. Upon delivery and acceptance of a contract line item on which milestone payment(s) has/have been made, the amount of the related milestone payment(s) will be deducted from the amount otherwise payable for the contract line item.

(e) Milestone billing amounts will not be subject to the "Adjusting Billing Prices" paragraph of the "Incentive Price Revision-Firm Target clause (FAR 52.216–16(f)) in fixed-price incentive contracts, and will not be adjusted for actual costs incurred above or below the contract target cost. Adjustments to milestone billing amounts shall not be made unless specifically provided for in the economic price adjustment (EPA) clause of the contract. Furthermore, any adjustment to milestone amounts arising from an EPA clause shall be made at the same time as the contract price adjustment.

(f) Milestone payments are interim payments with respect to total performance, and, as such, are fully recoverable in the case of default, in the same manner as progress payments.

1832.7005 Concurrence prior to solicitation.

Prior to the issuance of a solicitation in which a milestone billing arrangement is made available, concurrence shall be requested in writing from Code HC. The request shall provide the reasons why a milestone billing arrangement is appropriate and include a copy of the milestone billing arrangement clause if it differs from the clause at 1852.232–83, Milestone Billing Arrangements.

1832.7006 Approval prior to contract award.

Subsequent to solicitation, but prior to contract award, a request for approval of the milestone billing arrangement shall be submitted to the Assistant Administrator for Procurement (Code HC). The request for approval should include the following information:

(a) The name and phone number of the contracting officer.

(b) A copy of the contractor's support for a milestone billing arrangement, including the rationale and statement of need for milestone billings.

(c) A copy of the proposed milestone billing clause.

(d) Description of the milestone billing events, with a schedule of milestone completion dates and milestone values, and the method of verifying completion.

(e) Description of the contract end items with their delivery schedule and prices.

(f) Proposed milestones and contract end items, with appropriate narrative showing how the milestone amounts were estimated and distributed to the contract end items for interim milestone payment and end item final payment purposes.

(g) Financial analysis (numeric and graphic) showing cash flow and contractor investment in the contractor work-in-process inventory, with and without milestone billings.

(h) Any other information considered relevant.

1832.7007 Subcontracts and contract amendments.

Subcontracts and amendments to prime contracts that incorporate milestone billing arrangements are also subject to the criteria, contractual implementation, concurrence and approval policies in this subpart. Requests for concurrence and approval shall be submitted to the prime contractor through the next higher tier subcontractor, if applicable, to the contracting officer.

1832.7008 Solicitation and contract clause.

(a) The contracting officer shall insert a clause substantially the same as the clause at 1852.232-83, Milestone Billing Arrangements, in solicitations and contracts when a fixed-price type contract will be awarded and a milestone billing arrangement is contemplated.

(b) The contracting officer shall include a clause substantially the same as the clause at 1852.232-84, Milestone Billing Arrangements—Subcontracts, in all solicitations and contracts when a fixed-price subcontract in excess of $10 million with a milestone billing arrangement is contemplated.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

3. Sections 1852.232-83 and 1852.232-84 are added to read as follows:

1852.232-83 Milestone Billing Arrangements.

As prescribed in 1832.7008(a), insert the following clause.

Milestone Billing Arrangements (December 1992)

(a) A payment will be made to the contractor upon completion of each milestone event specified in paragraph (g) of this clause in the amount specified for the relevant milestone event.

(b) Upon completion of each milestone billing event, the contractor shall notify the contracting officer in writing, accompanied by a voucher and certification, that the milestone event has been completed. The contractor's written notification shall contain a brief narrative of the work activity accomplished for the particular milestone event. The contracting officer shall promptly verify that successful completion of the milestone event has occurred, notify the contractor of NASA's concurrence, and forward the contractor's voucher with a copy of the verification to the designated paying office.

(c) Milestone billings, normally, will not be submitted after deliveries of major end items commence upon which milestone payments have been made. In the event the period between delivery of such major end item and the next end item delivery exceeds three months, milestone payments can continue to be made for the next item, as mutually agreed for appropriate events.

(d) All milestone payments are interim contract financing payments with respect to total contract performance. As such, they are fully recoverable in the event of default under the Default clause. Therefore, all milestone payments made with respect to contract line items that are not delivered and accepted by the Government shall, in the event of a termination for default, be paid to the Government upon demand.

(e) The contractor shall establish and record a preferred creditor's lien on behalf of the Government, i.e., a first lien paramount to all other liens, in each jurisdiction where property subject to this contract is located. The lien shall be on the contractor's work-in-process covered by the contract, except to the extent that the Government by virtue of any other terms of this contract, or otherwise, shall have valid title to the supplies, materials, or other property as against other creditors of the contractor. The property subject to the liens shall include that to be acquired under subcontracts where payments are to be made to the subcontractor prior to the acceptance of such property. The contractor shall promptly provide to the Government a copy of all lien filings.

(f) The contractor represents and warrants that it maintains (1) insurance on plant and equipment against fire and other hazards, to the extent that similar properties are usually insured by others operating plants and properties of similar character in the same general locality; (2) adequate insurance against liability on account of damage to persons or property; and (3) adequate insurance under all applicable workers' compensation laws. The contractor agrees that, until work under this contract has been completed and all payments made under the contractor have been liquidated, it will maintain this insurance and furnish any certificates with respect to its insurance that the administering office may require.

(g) Upon successful completion of a milestone event, the contractor may request milestone payments based on the following milestone data:

Milestone event	Contract line item	Amount	Estimated date of completion
(1)			
(2)			
(3) etc.			

(h)(1) A milestone event may be successfully completed in advance of the date appearing in paragraph (g) of this clause. However, payment shall not be made prior to that date without the prior written consent of the contracting officer.

(2) The contractor is not entitled to partial payment for less than successful completion of a milestone event.

(3) All preceding milestone events must be successfully completed before payment can be made for the next milestone event, unless the prior written consent of the contracting officer is obtained.

(End of clause)

1852.232-84 Milestone billing arrangements—subcontracts.

As prescribed in 1832.7008(b), insert the following clause.

Milestone Billing Arrangements—Subcontracts (December 1992)

(a) The Contractor is prohibited from using milestone billing arrangements in subcontracts except in accordance with subpart 1832.70.

(b) The Contractor shall insert the substance of this clause, including this paragraph (b), in all subcontracts in excess of $10 million.

(End of clause)

[FR Doc. 93-721 Filed 1-12-93; 8:45 am]
BILLING CODE 7510-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 217, 222, and 227

[Docket No. 921184-3004]

Sea Turtle Conservation; Restrictions Applicable to Fishery Activities

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Temporary turtle excluder device requirement for vessels in the summer flounder trawl fishery, and request for comments.

SUMMARY: NMFS requires owners and operators of vessels participating in the trawl fishery for summer flounder from Oregon Inlet to the southern border of North Carolina, to use turtle excluder devices (TEDs) in any net that is rigged for fishing, for a 30-day period starting January 7, 1993, unless exempted from doing so by NMFS. This action supersedes the action published on December 18, 1992 (57 FR 60135); the requirements herein modify and extend the requirements announced in the preceding action. As a result of this action, the size of the area where TEDs are required is reduced by moving the northern boundary from 37°05'N. latitude (Cape Charles, Virginia) to 35°48.1'N. latitude (Oregon Inlet, North Carolina). The purpose of this action is to relieve a restriction on fishermen in the summer flounder fishery while providing protection to endangered and threatened sea turtles for an extended period of time. The action is authorized by 50 CFR 227.72(e)(8).

DATES: This action is effective January 7, 1993 through February 8, 1993. Comments on this action must be received by February 8, 1993.

ADDRESSES: Requests for a copy of the environmental assessment for this action should be addressed to Dr. Michael F. Tillman, Acting Director, Office of Protected Resources, NMFS, 1335 East-West Highway, Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: Phil Williams, NMFS National Sea Turtle Coordinator (301/713-2319), Charles A. Oravetz, Chief, Protected Species Program, NMFS, Southeast Region (813/893-3366), or Colleen Coogan, Protected Species Program, NMFS, Northeast Region (508/281-9291).

SUPPLEMENTARY INFORMATION:

Background

All sea turtles that occur in U.S. waters are listed as either endangered or threatened under the Endangered Species Act of 1973, 16 U.S.C. 1531 *et seq.* (ESA). According to the National Academy of Sciences, incidental takings in shrimp trawls are by far the leading cause of human-induced mortality to sea turtles in the water; collectively, activities in non-shrimp fisheries, which include the summer flounder fishery, constitute the second largest source.

NMFS took emergency action pursuant to 50 CFR 227.72(e)(6) to require the use of TEDs in the trawl fishery for summer flounder from Cape Charles, Virginia, to the southern border of North Carolina, and to require vessels to carry an observer, if selected to do so. These requirements were initially effective November 15, 1992, through December 15, 1992 (57 FR 53603, November 12, 1992), and were extended from December 16, 1992, through January 14, 1993 (57 FR 60135, December 18, 1992). The specific requirements, their background and rationale, and summaries of pertinent biological opinions were included in the cited **Federal Register** publications and are not repeated here.

Recent Events

NMFS' continuing review of the available information regarding the temporary TED requirement under the ESA in the summer flounder bottom trawl fishery indicates that conditions continue to necessitate the use of TEDs in some of the waters off North Carolina. Sea turtles and bottom trawling continue to co-occur in these waters based on observations of turtles, both at sea and from strandings on ocean beaches.

Incomplete reports show that 99 sea turtles have stranded on ocean beaches from New Jersey through North Carolina from October 29, 1992 through January 5, 1993, coinciding with the operation of the summer flounder fishery, as well as other fisheries, in the mid-Atlantic region. However, since NMFS' December 16, 1992, action to continue requiring TED use (57 FR 60135), five sea turtle strandings have been reported on North Carolina beaches. A stranding of a loggerhead sea turtle was reported south of Cape Hatteras, North Carolina, in Drum Inlet, as recently as January 2, 1993.

Three loggerhead sea turtles have been reported captured by a summer flounder trawler equipped with a TED during this temporary TED requirement. A NMFS observer on board this trawler south of Cape Hatteras observed two turtles caught during one tow and a third turtle caught in a second tow. Each of the turtles dropped into the water, apparently unharmed, upon net retrieval as a result of clogging which caused much of the catch, including the turtles, to overflow the net.

NMFS and the U.S. Coast Guard are continuing to conduct cooperative enforcement activities in the waters off of southern Virginia and North Carolina. NMFS has determined that compliance with the TED-use requirement has been good. Boardings have shown one alleged violation of the TED requirement since November 15, 1992.

NMFS has determined, based on past interactions between sea turtles and the summer flounder fishery, that bottom trawl nets without TEDs capture and kill sea turtles at a rate comparable to that of the shrimp trawl fishery along the southern U.S. Atlantic coast, where TED use is now required at all times. Based on this information, when turtles and summer flounder bottom trawling co-occur, the use of TEDs should be a required conservation measure.

However, based on available data regarding turtle distribution, fishing activity, and the turtle conservation measures that are currently in effect, the potential threat to sea turtles within the northern boundary of the TED-use area from Cape Charles, Virginia, to Oregon Inlet, North Carolina, has diminished since the onset of the summer flounder season. While there is risk to sea turtles associated with moving the northern boundary of the TED-use area southward, NMFS has determined that this risk is acceptable and will not jeopardize the continued existence of endangered and threatened sea turtles.

The distribution of sea turtles in the waters off southern Virginia and North Carolina during the late fall and winter appears to be greatly influenced by the Gulf Stream and the relatively warm waters associated with it. During the late fall and winter, as nearshore water temperatures cool, there is a general southward migration of sea turtles out of the estuarine and nearshore waters of the Mid-Atlantic Bight. But, turtles may remain off southern Virginia and North Carolina because of the presence of relatively warm waters associated with the northward flowing Gulf Stream. This is especially true south of Cape Hatteras, North Carolina, but may occur north of Cape Hatteras as well.

However, the influence of the Gulf Stream is unpredictable owing to the impacts of strong north winds in the fall and winter. Strong north winds will push colder nearshore water south, displacing the warmer Gulf Stream waters, and any turtles in them, offshore. If the north winds subside, however, the southward-flowing, cold-water system relaxes, and turtles move with the warmer water shoreward and northward.

In addition, turtles are capable of withstanding much cooler waters than previously believed. During the 1991–1992 summer flounder fishing season, turtles were caught by trawlers in waters where surface temperatures were 10 °C and were sighted in waters where surface temperatures were as cold as 6 °C. In fact, a loggerhead turtle, equipped with a satellite transmitter, is currently being tracked off Maryland and Delaware in surface water temperatures at or below 10 °C, demonstrating that some turtles appear to behave normally in relatively cold waters. However, while 23 percent of the turtles sighted in aerial surveys off Virginia and North Carolina during the 1991–1992 fishing season were in surface water temperatures of 10 °C or less, observations or captures of turtles in waters below 10 °C were substantially reduced.

Based on observed catch rates of turtles during the 1991–1992 fishing season, the greatest risk to sea turtles occurred south of Cape Hatteras. Catch rates were substantially greater (six to eight times as great) south of Cape Hatteras throughout the fishing season, though the density of turtles sighted during aerial surveys did not differ substantially north or south of Cape Hatteras throughout the season.

In 1991, based on available information, including the relatively cooler waters observed north of Cape Hatteras, NMFS moved the northern boundary of the turtle conservation zone, where restricted tow times were required, from Cape Charles, Virginia, to Oregon Inlet, North Carolina, effective December 27, 1991 (57 FR 213, January 3, 1992). After December 18, 1991, there were no observed or reported incidental captures of sea turtles in the trawl fishery for summer flounder north of Oregon Inlet. Only five captures, including one mortality, were recorded in December 1991 north of Oregon Inlet, all of which were loggerhead turtles.

Recent sea surface temperatures acquired by satellite sensors indicate that temperature conditions north of Oregon Inlet are similar to those observed in the latter part of December 1991. Based on last year's observations, NMFS expects that nearshore water temperatures north of Oregon Inlet will decline further, and that with this decline, the probability of sea turtle captures will also decline. Accordingly, NMFS finds that it can reduce the area

off southern Virginia and North Carolina where TEDs are required and extend the TED requirement for 30 days within the newly designated restricted area without jeopardizing the continued existence of endangered and threatened sea turtles.

Based on last year's observations of fishing activity after January 1, 1992, the nearshore summer flounder bottom trawl fishery occurred south of Oregon Inlet, and the remainder moved offshore, particularly into the canyon areas. No turtles were captured on boats with observers fishing in the offshore canyon area during January and February 1992.

However, NMFS cannot predict the extent or timing of the Gulf Stream influences on turtle distribution; as shown last season, such influences can occur throughout the winter. Therefore, NMFS will continue to monitor sea surface temperatures and Gulf Stream position to determine the risk to turtles by capture from trawlers. In addition, NMFS and the North Carolina Division of Marine Fisheries will monitor fishing activity and will continue its requirement for observers on selected flounder trawlers north and south of Oregon Inlet to monitor any incidental capture of turtles. If monitoring or observer reports, or other information indicate that the level of incidental take of sea turtles authorized as a result of consultation under section 7 of the ESA is being approached or is exceeded, the TED requirement may be reinstituted north of Oregon Inlet.

Comments on the Temporary TED-Use Requirement

No comments have been received on NMFS' December 16, 1992, action.

Sea Turtle Conservation Measures

Based on the information presented and evidence indicating that the summer flounder trawl fishery takes endangered and threatened sea turtles, the Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has determined that continued action is necessary to conserve sea turtles as authorized by 50 CFR 227.72(e)(6). The Assistant Administrator has determined that incidental takings of sea turtles during summer flounder fishing are unauthorized unless those takings are consistent with the applicable biological opinions and associated incidental take statements. A biological opinion on the impacts of the summer flounder trawl fishery managed under the Fishery Management Plan for the Summer Flounder Fishery (FMP) and Amendment 2 to the FMP was issued on August 18, 1992; that incidental take statement allows for the documented lethal take of 18 sea turtles; three in any combination of Kemp's ridley, hawksbill, green, or leatherback sea turtles; and 15 loggerhead turtles.

A new biological opinion was prepared for this action. Authorization for this action differs from the August 10, 1992, authorization by including both lethal takes and takes by injury. Furthermore, while only documented takes will be calculated for vessels using TEDs, takings for vessels that are not using TEDs may be based on direct observations or estimates from other on-board observers, or from other sources, such as reported strandings of sea turtles. NMFS has authorized a take, by death or injury, of one Kemp's ridley, hawksbill, green, or leatherback sea turtle; or three loggerhead turtles, during the effectiveness period of this action. If the authorized take is met or exceeded, NMFS may re-establish the requirement to use TEDs north of Oregon Inlet, or take other necessary measures.

Requirements

This action is authorized by 50 CFR 227.72(e)(6). The definitions in 50 CFR 217.12, as revised by the final regulations (57 FR 57348, December 4, 1992), are applicable to this action, as well as all relevant provisions in 50 CFR parts 217, 222, and 227. For example, § 227.71(b)(3) provides that it is unlawful to fish for or possess fish or wildlife contrary to a restriction specified or issued under § 227.72(e) (3) or (6). Section 227.72(b)(1) states that it is unlawful to own, operate, or be onboard a vessel, unless that vessel is in compliance with all the applicable provisions of § 227.72(e).

For purposes of this action, the term "summer flounder restricted area" means all offshore waters, which are defined to include waters seaward of the COLREGS (International Regulations for Preventing Collisions at Sea, 1972) demarcation line, bounded on the north by a line along 35°46.1'N latitude (Oregon Inlet) and bounded on the south by a line along 33°35'N. latitude (North Carolina-South Carolina border).

NMFS hereby notifies owners and operators of summer flounder trawl vessels that for a 30-day period, starting January 7, 1993, they must have an approved TED (as defined in 50 CFR 217.12) installed in each net that is rigged for fishing if the vessel is in the summer flounder restricted area. For the purpose of this action and notwithstanding 50 CFR 227.72(e)(2)(i), a net is rigged for fishing if it is in the water or if it is shackled, tied, or otherwise connected to any trawl door or board.

The provisions of 50 CFR 227.72(e) (4) and (5) as revised by the final regulations (57 FR 57348, December 4, 1992), are applicable to summer flounder trawl vessels and summer flounder trawl gear as if they were shrimp trawlers or shrimp trawl gear. For purposes of this action, large-mesh webbing may be attached outside of the webbing flap to prevent chafing on downward shooting TEDs, if it does not interfere with or otherwise restrict the turtle escape opening. It is the responsibility of the owner and the operator of any summer flounder trawl vessel to ensure that any sea turtle taken by that vessel is handled and resuscitated in accordance with the requirements specified under 50 CFR 227.72(e)(1) (i) and (ii).

The Assistant Administrator may grant a written waiver of the requirement for a summer flounder trawler to have a TED in its net(s) if that vessel is conducting research operations approved under 50 CFR 227.72(e)(5)(ii) (for further information concerning waivers contact Director, Southeast Region, NMFS, 9450 Koger Boulevard, St. Petersburg, FL 33702, (813/893–3366)). In order for this waiver to be applicable, the written waiver issued by the Assistant Administrator must be carried onboard the vessel at all times that the vessel is in the summer flounder restricted area and does not have a TED installed in each of its nets that is rigged for fishing.

The Assistant Administrator may consider the use of restricted tow times instead of TEDs in the future. Any allowance for trawlers to use restricted tow times instead of TEDs may require that the vessel operators carry a NMFS-approved observer at their own expense and limit tow times to no longer than 75 minutes, measured from the time the trawl doors or boards enter the water until they are removed from the water.

NMFS hereby notifies owners and operators of summer flounder trawl vessels that they must carry a NMFS-approved observer onboard such vessel(s) if selected to do so by the Director, Southeast Region, NMFS, upon written notification sent to either the address specified for the vessel in either the NMFS or state fishing permit application, or for registration or documentation purposes, or otherwise served on the owner or operator of the vessel. A summer flounder trawl vessel must comply with the terms and conditions specified in such written notification.

A NMFS-approved observer may be required regardless of whether the

vessel is fishing within the summer flounder restricted area and regardless of whether the summer flounder trawl vessel has TEDs installed in its nets if observer information is necessary to document interactions with sea turtles or to determine the effectiveness of conservation measures.

All NMFS-approved observers will report any violation of the conservation measures required by this action, or other applicable regulations and laws; such information can be used for law enforcement purposes.

Any person who does not comply with any requirement in this document, including any term or condition in any written notification issued hereunder, is in violation of the final sea turtle conservation regulations, codified at 50 CFR 227.71(b)(3).

Additional Sea Turtle Conservation Measures

The Assistant Administrator may, at any time, modify the requirements of this action through notification in the **Federal Register**, if necessary, to ensure adequate protection of endangered and threatened sea turtles. Under this procedure, the Assistant Administrator will impose any necessary additional or more stringent measures, if he determines that summer flounder trawl vessels are having a significant adverse effect on sea turtles. Likewise, conservation measures may be modified if the incidental take for the fishery is projected to reach the incidental take level established by the biological opinion for this action issued as a result of consultation under section 7 of the ESA. Additional conservation measures are likely if one or more Kemp's ridley, hawksbill, green, or leatherback sea turtle; or three loggerhead turtles, are lethally taken or injured by summer flounder trawlers subject to this notice during the 30-day effectiveness period of this notice.

The Assistant Administrator will impose additional conservation measures on this fishery if the incidental take level is approached or exceeded, or if significant or unanticipated levels of lethal or nonlethal takings or strandings of sea turtles associated with summer flounder fishing activities occur. Such additional measures may expand the restricted area or the time during which TEDs are required or impose requirements to carry NMFS-approved observers at the expense of vessel owners or operators. The Assistant Administrator may withdraw or modify the requirement for specific conservation measures or any restriction on fishing activities if the Assistant Administrator determines that such action is warranted. Notification of any additional sea turtle conservation measures, including any extension of the 30-day requirement to use TEDs in summer flounder trawls, will be published in the **Federal Register**.

Classification

The Assistant Administrator has determined that this action is necessary in order to continue protections for threatened and endangered sea turtles in an area south of Oregon Inlet; without further action current protections under the ESA would expire on January 14, 1993, and significant numbers of sea turtles are likely to be taken in the summer flounder fishery in that area. The Assistant Administrator also has determined that this action is necessary to relieve a restriction on fishermen in the trawl fishery for summer flounder in an area north of Oregon Inlet where there is less risk of incidental takings of sea turtles. This action is consistent with the ESA and other applicable law. This action does not require a regulatory impact analysis E.O. 12291 because it is not a major rule.

Because neither section 553 of the Administrative Procedure Act (APA), nor any other law, requires that general notice of proposed rulemaking be published for this action, under section 603(b) of the Regulatory Flexibility Act, an initial regulatory flexibility analysis is not required.

The Assistant Administrator prepared an environmental assessment (EA) for this action that concludes that it will have no significant impact on the human environment. A copy of the EA is available (see **ADDRESSES**).

The Assistant Administrator finds there is good cause to take this action without full notice and opportunity for comment under section 553(b)(B) of the Administrative Procedure Act (APA). The Assistant Administrator finds that full notice and opportunity for comment is unnecessary, impracticable, and contrary to the public interest. Comments were requested on the initial emergency action (57 FR 53603, November 12, 1992) and a subsequent action (57 FR 60135, December 18, 1992). Comments received were responded to previously. Further comments on this action are invited. Providing full notice and opportunity for comment before this action becomes effective may cause unnecessary economic hardship on fishermen before January 14, 1992, and is likely to result in significant incidental takings of sea turtles after that date; such incidental takings could jeopardize the continued existence of some species of sea turtles or could result in the closure of the fishery. NMFS will continue to monitor the situation in order to insure that adequate protections are maintained for sea turtles.

In addition, the Assistant Administrator has determined that good cause exists to waive the delayed effectiveness date otherwise required by section 553(d) of the APA; such a delay would be impracticable and contrary to the public interest. With respect to the area south of Oregon Inlet, this action continues an existing requirement to use TEDs in the summer flounder fishery and additional time to prepare to comply with this requirement is unnecessary. With respect to the area north of Oregon Inlet, this action relieves a restriction (the requirement to use TEDs) that would otherwise apply to fishermen in the trawl fishery for summer flounder and that may cause an economic hardship. NMFS will continue to provide TED technology assistance to fishermen in order to facilitate compliance.

List of Subjects

50 CFR Part 217

Endangered and threatened species, Exports, Fish, Imports, Marine Mammals, Transportation.

50 CFR Part 222

Administrative practice and procedure, Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

50 CFR Part 227

Endangered and threatened species, Exports, Imports, Marine Mammals, Transportation.

Dated: January 7, 1993.

Samuel W. McKeen,

Program Management Officer.

[FR Doc. 93–683 Filed 1–7–93; 3:04 pm]

BILLING CODE 3510-22-M

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50 CFR Part 228

[Docket No. 910802–2336]

Taking of Ringed Seals Incidental to On-Ice Seismic Activity

January 6, 1993.

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Final rule.

SUMMARY: NMFS is issuing regulations that govern the taking of ringed seals incidental to oil and gas exploratory activities (seismic operations on the ice) in the Beaufort Sea from 1993 through 1997. The incidental taking of small

numbers of marine mammals is allowed under section 101(a)(5) of the Marine Mammal Protection Act (MMPA) if certain findings are made and regulations are issued that include requirements for monitoring and reporting.

EFFECTIVE DATE: This rule will be effective from February 12, 1993 through December 31, 1997.

ADDRESSES: Dr. Michael Tillman, Acting Director, Office of Protected Resources, 1335 East-West Highway, Silver Spring, MD 20910. Send comments on the collection of information burden estimate to the Office of Information and Regulatory Affairs, Project (0648–0151), Office of Management and Budget, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Margaret C. Lorenz, Office of Protected Resources, NMFS, (301) 713–2322 or Ron Morris, Western Alaska Field Office, (907) 271–5006.

SUPPLEMENTARY INFORMATION:

Background

Section 101(a)(5) of the MMPA directs the Secretary of Commerce (Secretary) to allow, on request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and regulations are issued.

Permission may be granted for periods of 5 years or less if the Secretary finds that the taking will have a negligible impact on the species or stock and will not have an unmitigable adverse impact on the availability of the species or stock for subsistence uses. Specific regulations governing a taking of ringed seals incidental to on-ice seismic activity (47 FR 21254, May 18, 1992, and 52 FR 1199, Jan., 12, 1987) expired December 31, 1991.

Summary of Request

On April 8, 1992, NMFS received a petition from BP Exploration (Alaska), Chevron U.S.A., Inc., Halliburton Geophysical Services, Inc. and Western Geophysical Company to renew the incidental take regulations in 50 CFR part 228, subpart B, that govern the taking of ringed seals incidental to seismic activities on the ice offshore Alaska for a period of 5 years.

The scope of the request is limited to pre-lease and post-lease seismic exploration activities in State waters and the Outer Continental Shelf in the Beaufort Sea offshore Alaska during the ice-covered season. Operations are usually confined from January through May. Seismic surveys are conducted using two types of energy sources: (1) Vibroseis, which uses large trucks with vibrators mounted on them, which systematically put variable frequency energy into the earth, and (2) waterguns or airguns carried by a sleigh or other vehicle. Over the next 5-year period, the petitioners expect on-ice seismic activity to cover from 1,000 to 3,000 line miles (200 to 600 miles) (322 to 965 km) in any given year.

NMFS published a notice of the request for rulemaking on May 14, 1992 (57 FR 20667), and a proposed rulemaking on September 15, 1992 (57 FR 42538).

Summary of Final Rule

The final regulations apply only to the incidental taking of ringed seals (*Phoca hispida*) by U.S. citizens engaged in seismic activities on the ice and associated activities in the Beaufort Sea from the shore outward to 45 miles (72 km) and from Point Barrow east to Demarcation Point and only from January 1 through May 31 of any calendar year.

The incidental, but not intentional, taking of ringed seals by U.S. citizens holding a Letter of Authorization is permitted during the following activities:

(1) On-ice geophysical seismic activities using two types of energy sources (i.e., vibroseis or waterguns or airguns) and

(2) Operation of transportation and camp facilities associated with seismic activities.

All activities must be conducted in a manner that minimizes adverse effects on ringed seals and their habitat. The activities must be conducted as far as practicable from any observed ringed seals or ringed seal lair. No energy source may be placed over an observed seal lair.

The requirements for monitoring and reporting include designating a qualified individual to observe and record the presence of ringed seals and ringed seal lairs along shot lines and around camps. An annual report must be submitted to NMFS within 90 days of completing the year's activities.

Comments

Comments on the proposed rulemaking were received from the Marine Mammal Commission (Commission), Unocal Corporation and two individuals. The Commission is concerned that although it seems unlikely that any one on-ice seismic, drilling, or related support activity would adversely affect the ringed seal populations in the Beaufort or Chukchi seas, it may be that the activities collectively are having or could have a significant adverse effect on the ringed seal populations and/or the dependent polar bear populations (ringed seals are a common food source for polar bears). Therefore, the Commission recommended that NMFS consult with the Minerals Management Service, the Fish and Wildlife Service, the Alaska Department of Fish and Game and relevant industry and Native groups to agree upon and, as possible, arrange for cooperative funding of a long-term program to monitor the status of the ringed seal population(s) in Alaskan waters.

Also, the Commission is concerned that the required monitoring program is not adequate to determine the number of ringed seals taken by the activities and the significance of the effects of the taking. Two marine mammal biologists also suggested that the proposed monitoring requirements would not result in monitoring as intended by the MMPA due to the winter behavior of ringed seals which prevents them or their lairs and breathing holes from being observed from the surface of the ice by humans. The Commission recommended that NMFS (a) assess whether the activity-specific monitoring program required by the proposed rule is likely to provide an accurate estimate of the number of ringed seals affected by the authorized activities, and the nature and significant of the effects and (b) identify and take into account activities, in addition to Native subsistence hunting and the planned seismic surveys and related support activities, that may affect ringed seals and their habitat in areas offshore Alaska. The biologists believe that only trained dogs are able to detect the presence of ringed seal breathing holes and lairs.

Response to Comments

In conjunction with a spring 1993 workshop to review monitoring programs required for open-water energy exploration activities in the Beaufort Sea, NMFS plans to consult with the industry and relevant Federal, State and local agencies concerning a long-term program to monitor the status of ringed seal populations in Alaskan waters.

Although the industry estimated that on-ice seismic activities might cover a maximum of 1,800 square nautical miles annually between 1987–1991, NMFS actually authorized a take of ringed seals incidental to only about 800 square nautical miles of on-ice seismic operations during the entire 5-year period. This allowed incidental take may have resulted in a displacement of

about 480 ringed seals (out of an estimated arctic Alaska population of 1 to 1.5 million) during that time. No on-ice seismic operations were conducted in 1992, and no more than 600 square nautical miles are predicted for any year during 1993–1997. Therefore, NMFS does not believe that the low level of on-ice seismic activity that has occurred in the past and that is predicted for the next 5 years warrants a more extensive monitoring program than is being required. However, at the workshop referenced above, NMFS will also consult with appropriate groups to determine whether a different or more extensive monitoring plan, as recommended, is appropriate.

Classification

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has determined that this is not a "major rule" requiring a regulatory impact analysis under E.O. 12291. The regulations are not likely to result in (1) an annual effect on the economy of $100 million or more, (2) a major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regions or (3) a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The General Counsel of the Department of Commerce has certified that this rule will not have a significant economic impact on a substantial number of small entities as described in the Regulatory Flexibility Act because members of the industry requesting the authorization are major energy exploration companies. Therefore, a regulatory flexibility analysis is not required.

This rule contains collection-of-information requirements subject to the Paperwork Reduction Act. These requirements have been approved by the Office of Management and Budget (OMB) under section 3504(b) of the Paperwork Reduction Act issued under OMB Control Number 0648–0151. Public reporting burden for this collection of information is estimated to average 27.5 hours per response including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing the burden, to NMFS and OMB (see **ADDRESSES**).

This rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

The Assistant Administrator has determined that this rule is consistent to the maximum extent practicable with the approved Coastal Zone Management Program of the State of Alaska. This determination has been submitted for review by the responsible State agency under section 3.7 of the Coastal Zone Management Act.

NMFS prepared an environmental assessment (EA) for this rulemaking and concluded that there would be no significant impact on the human environment as a result of this rule. Copies of the EA are available on request (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 228

Marine mammals, Reporting and recordkeeping requirements.

Dated: January 6, 1993.

Nancy Foster,

Acting Deputy Assistant Administrator for Fisheries.

For the reasons set forth in the preamble, 50 CFR part 228 is amended as follows:

PART 228—REGULATIONS GOVERNING SMALL TAKES OF MARINE MAMMALS INCIDENTAL TO SPECIFIED ACTIVITIES

1. The authority citation for part 228 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*

2. Section 228.11 is revised to read as follows:

§ 228.11 Specified activity and specified geographical region.

Regulations in this subpart apply only to the incidental taking of ringed seals (*Phoca hispida*) by U.S. citizens engaged in on-ice seismic exploratory and associated activities over the Outer Continental Shelf of the Beaufort Sea of Alaska, from the shore outward to 45 miles (72 km) and from Point Barrow east to Demarcation Point, from January 1 through May 31 of any calendar year.

3. Section 228.12 is revised to read as follows:

§ 228.12 Effective dates.

Regulations in this subpart are effective from February 12, 1993 through December 31, 1997.

4. In § 228.13, paragraphs (b) and (c) are revised to read as follows:

§ 228.13 Permissible methods.

* * * * *

(b) All activities identified in § 228.13(a) must be conducted in a manner that minimizes to the greatest extent practicable adverse effects on ringed seals and their habitat.

(c) All activities identified in § 228.13(a) must be conducted as far as practicable from any observed ringed seal or ringed seal lair. No energy source must be placed over an observed ringed seal lair, whether or not any seal is present.

5. In § 228.14, paragraph (b) and paragraph (c) introductory text are revised to read as follows:

§ 228.14 Requirements for monitoring and reporting.

* * * * *

(b) Holders of Letters of Authorization must designate a qualified individual or individuals to observe and record the presence of ringed seals and ringed seal lairs along shot lines and around camps, and the information required in § 228.14(c).

(c) An annual report must be submitted to the Assistant Administrator for Fisheries within 90 days after completing each year's activities and must include the following information:

* * * * *

[FR Doc. 93–718 Filed 1–12–93; 8:45 am]
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50 CFR Part 642

[Docket No. 920246–2229]

Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Trip limit reduction.

SUMMARY: NMFS reduces the trip limit to 1000 pounds (454 kg) per day for the commercial fishery for Spanish mackerel from the southern zone of the Atlantic migratory group. NMFS has determined that 80 percent of the adjusted commercial allocation of Atlantic migratory group Spanish mackerel was reached on January 7, 1993. This trip limit reduction is necessary to protect the overfished Atlantic Spanish mackerel resource.

EFFECTIVE DATE: The 1000-pound (454-kg) commercial trip limit is effective on January 8, 1993, through March 31, 1993, unless 100 percent of the adjusted commercial allocation is harvested prior to March 31, in which case the trip limit

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will be further reduced by publication of a notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mark F. Godcharles, 813–893–3161.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP), prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils, and its implementing regulations at 50 CFR part 642, under the authority of the Magnuson Fishery Conservation and Management Act.

Commercial trip limits for Atlantic migratory group Spanish mackerel for the current fishing year (April 1, 1992, through March 31, 1993) were approved under Amendment 6 to the FMP and published in the **Federal Register** on December 9, 1992 (57 FR 58151). In accordance with 50 CFR 642.27(a)(2)(iii), the commercial vessel trip limits in the southern zone are to be set at 1000 pounds (454 kg) per day when 80 percent of the adjusted allocation is taken. The southern zone extends from the Georgia/Florida boundary (30°42′45.6″N. latitude) southward to a line extending directly east from the Dade/Monroe County, Florida, boundary (25°20.4′N. latitude). The adjusted allocation for Atlantic group Spanish mackerel, as set forth at 50 CFR 642.27(b), is 3.25 million pounds (1.47 million kg), and, thus, 80 percent of the adjusted allocation is 2.60 million pounds (1.18 million kg).

As required by 50 CFR 642.27(b), NMFS announces that 80 percent of the adjusted allocation was reached on January 7, 1993. Accordingly, the commercial trip limit for Spanish mackerel in the southern zone is 1000 pounds (454 kg) per day effective January 8, through March 31, 1993, the end of the fishing year, unless 100 percent of the adjusted allocation is taken prior to that date, in which case the trip limits will be further reduced to 500 pounds (227 kg) by notice in the **Federal Register**.

Classification

This action is required by 50 CFR 642.27 (a)(2)(iii) and (b) and complies with E.O. 12291.

Authority: 16 U.S.C. 1801 *et seq.*

List of Subjects in 50 CFR Part 642

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: January 7, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–690 Filed 1–7–93; 3:27 pm]

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Farmers

7 CFR P

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AGENCY:
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Proposed Rules

Federal Register
Vol. 58, No. 8
Wednesday, January 13, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Farmers Home Administration

7 CFR Part 1956

RIN 0575–AB26

Debt Settlement—Community and Business Programs

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend its policies and procedures governing debt settlement of Community Programs Loans. These changes are necessary to comply with section 2384, title XXIII, of the Food, Agriculture, Conservation, and Trade Act of 1990 (Pub. L. 101–624). This law is to establish and implement a program that is similar to the program established under section 353 of the Consolidated Farm and Rural Development Act (7 U.S.C. 2001), except that the debt restructuring and loan servicing procedures shall apply to delinquent Community Facility hospital or health care program loans rather than Farmer Program loans. The intended effect is to keep these facilities in operation with manageable debt.

DATES: Written comments must be received on or before February 12, 1993.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Regulations Analysis and Control Branch, Farmers Home Administration, USDA, room 6348, South Agriculture Building, Washington, DC 20250. All written comments will be available for public inspection during regular working hours at the above address. The reporting requirements contained in this regulation have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980. Public reporting burden for this collection of information is estimated to vary from 30 minutes to 30 hours per response with an average of 8.15 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Agriculture, Clearance Officer, OIRM, room 404–W, Washington, DC 20250; and to the Office of Management and Budget, Attention: Desk Officer for the Farmers Home Administration, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Joyce Brooks, Loan Specialist, Community Facilities Division, Farmers Home Administration, room 6320, South Agriculture Building, Washington, DC 20250, telephone (202) 382–1506.

SUPPLEMENTARY INFORMATION:

Classification

This proposed action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291, and has been determined to be nonmajor. The proposed action is not likely to result in any of the following: (a) An annual effect on the economy of $100 million or more; (b) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of the United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This action is not expected to substantially affect budget outlay or to affect more than one agency or to be controversial The net result is expected to provide better service to rural communities.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." FmHA has determined that the proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the National Environmental Policy Act of 1969 (Pub. L. 91–190), an Environmental Impact Statement is not required.

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome and are easy from the public to understand, use or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992 memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this Notice.

Executive Order 12778

The proposed regulation had been reviewed in light of Executive Order (E.O.) 12778 and meets the applicable standards provided in sections 2(a) and (2)(b)(2) of that E.O. Provisions within this part which are inconsistent with State law are controlling. All administrative remedies pursuant to 7 CFR part 1900, subpart B, must be exhausted prior to filing suit.

Intergovernmental Review

This action affects the following FmHA programs as listed in the Catalog of Federal Domestic Assistance: No. 10.423 Community Facility Loans. This

program is subject to the provisions of E.O. 12372 which requires intergovernmental consultation with State and local officials. (7 CFR part 3015, subpart V; 48 FR 29112, June 24, 1983, 49 FR 2267, May 31, 1984, 50 FR 14088, April 10, 1985.)

Discussion

Section 2384 of the Food, Agriculture, Conservation, and Trade Act of 1990, Public Law 101–624, amended the Consolidated Farm and Rural Development Act and requires the Secretary of Agriculture to develop a debt restructuring and loan servicing program for FmHA hospital or health care facilities borrowers. This program is similar to the loan restructuring and servicing program in effect for delinquent Farmer Program loans. This proposed rule would amend current FmHA regulations to implement this program. The program is intended to facilitate the continued operation of rural hospitals and health care facilities by implementing all possible debt restructuring options available that will result in an economically viable facility.

Given the congressional intent to provide rural hospitals and health care facilities a debt restructuring option similar to that provided Farmer Program borrowers, this proposed regulation is modeled in a general sense on the Farmer Program restructuring scheme. Under the proposal, a hospital or health care borrower who is delinquent on its FmHA loan, and is unable to cure its delinquency through more traditional servicing methods, will be notified of the options available for debt restructuring. The borrower can apply for consideration by providing financial and operational information and proposing its own plan for curing the delinquency.

In order to be eligible for consideration for debt restructuring, the borrower's delinquency must have been caused by factors outside the borrower's control. In addition, the borrower must have acted in good faith with regard to the FmHA loan. FmHA will make these determinations based on the borrower's representation and the Agency's review of other documents relevant to these preliminary matters.

Once the borrower provides the financial and operational information required, FmHA will conduct a thorough analysis of the borrower's operations. This analysis will typically include contracting for an independent appraisal of the collateral securing the loan and contracting with an independent expert to prepare an "operations review." This review will provide FmHA with information regarding the facility's operations, its financial standing, and suggest alternatives that could be implemented to address the delinquency.

Using the information obtained from these sources and in consultation with the borrowers and the experts, FmHA will calculate two values as required by the statute. First, FmHA will determine the loan's "net recovery" value. This value represents the current value of the loan, if FmHA were to foreclose. Generally, the value is calculated by adding the value of assets securing the loan and subtracting the costs that would be incurred if the loan was foreclosed. Second, FmHA will determine the value of the restructured loan. This value is determined after a proposed plan is developed for the operation of the facility. That is, the operation and/or debt is modified to determined if the borrower can attain a positive cash flow and pay an adjusted debt service payment plus fund the FmHA reserve account.

After the restructured loan value and the net recovery value are calculated, FmHA can determine whether the borrower's request for debt restructuring can be approved. As required by the statute, FmHA can approve debt restructuring only if the value of the restructured loan is greater than, or equal to, the net recovery value. Once the Agency reaches this conclusion, the borrower will be notified of the results and given its options. If possible, the debt will be restructured and the facility will continue operations. If the net recovery value is greater than the value of the restructured loan, the borrower may choose to pay off the loan at the reduced net recovery value. If this option is not chosen, the loan likely will be accelerated.

Finally, if the borrower's debt is restructured or if the borrower elects to pay off the debt at the net recovery value, then the borrower will be required to execute an Appreciation Recapture Agreement. As explained in the statute, these agreements allow the Agency to recoup a part or all of the debt that is written down if the borrower's underlying collateral appreciates in value over time and if the borrower sells the collateral within 10 years.

List of Subjects in 7 CFR Part 1956

Accounting, Loan programs—Agricultural, Rural areas.

Accordingly, FmHA proposes to amend chapter XVIII, title 7, Code of Federal Regulations, as follows:

PART 1956—DEBT SETTLEMENT

1. The authority citation for Part 1956 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 31 U.S.C. 3711; 7 CFR 2.23; 7 CFR 2.70.

Subpart C—Debt Settlement—Community and Business Programs

2. Section 1956.102 is amended by redesignating the introductory text as paragraph (a), adding a title, and by adding a new paragraph (b) to read as follows:

§ 1956.102 Application of policies.

(a) *General.* * * *

(b) *For hospitals and health care facilities only.* Loan servicing and debt restructuring options according to § 1956.146 must be exhausted before the other settlement authorities of this subpart are applicable.

3. Section 1956.146 is added to read as follows:

§ 1956.146 Debt restructuring—hospitals and health care facilities.

This section pertains exclusively to delinquent Community Facility hospital and health care facilities. Those facilities which are non-program (NP) loans as defined in § 1951.203(f) of subpart E of part 1951 of this chapter are excluded. The purpose of debt restructuring is to keep the hospital or health care facility in operation with manageable debt.

(a) *Definitions.* As used in this section, the following definitions apply:

(1) *Consolidation.* The combining of two or more debt instruments into one instrument, normally accompanied by amortization.

(2) *Debt writedown.* A one-time reduction of the debt owed to FmHA including principal and interest with a limit of $300,000 per borrower. The writedown will be applied first to interest and then principal.

(3) *Delinquent borrower.* For purposes of this section, delinquency is defined as being 180 days behind schedule on the FmHA payments. That is, one full annual installment, or the equivalent for monthly, quarterly, or semiannual installments.

(4) *Delinquency due to circumstances beyond the control of the borrower.* Includes situations such as: The borrower has less money than planned due to unexpected and uncontrollable events such as unexpected loss of service area population, unforeseeable costs incurred for compliance with State or Federal regulatory requirements, or the loss of key personnel.

(5) *Eligibility.* Applicants must be delinquent due to circumstances beyond

their control and have acted in good faith by trying to fulfill the agreements with FmHA in connection with the delinquent loans.

(6) *Interest rate reduction.* Reduction of the interest rate on the restructured loan to as low as 5 percent.

(7) *Loan deferral.* The temporary delay of principal and interest payments for up to 6 months. The borrower must be able to demonstrate the ability to pay the debt, as restructured, at the end of this delay period.

(8) *Net recovery value.* A calculation of the net value of the collateral and other assets held by the borrower. This value would be determined by adding the fair market value of FmHA's interest in any real property pledged as collateral for the loan, plus the value of any other assets pledged or otherwise available for the repayment of the debt, minus the anticipated administrative and legal expenses that would be incurred in connection with the liquidation of the loan. This value of the assets should be calculated based upon the facility continuing to operate as a going concern. Therefore, the facility should be valued not merely as an empty building but as a facility continuing to offer health care services which may, or may not, be similar to that offered by the current operators.

(9) *Operations review.* A study of management and business operations of the facility by an independent expert. For example, a study of a hospital and nursing home would include such areas as: General and administrative, dietary, housekeeping, laundry, nursing, physical plant, social services, income potential, Federal, State, and insurance payments, and rate analysis. Also, recommendations and conclusions are to be included in the study which would indicate the creditworthiness of the facility and its ability to continue as a going concern. In analyzing a borrower's proposed restructuring plan, FmHA may contract for the completion of an operations review. These reviews will be developed by individuals and entitles who have demonstrated an expertise in the analysis of health care facilities from an operational and administrative standpoint. FmHA will consider the following criteria for selection: Past experience in health care facility analysis, a familiarity with the problems of rural health care facilities, a knowledge of the particular area currently served by the facility in question, and a willingness to work with both FmHA and the borrower in developing a final plan for restructuring.

(10) *Restructured loan.* A revision of the debt instruments including any combination of the following: writing down of accumulated interest charges and principal, deferral, consolidation, and adjustment of the interest rates and terms, usually followed by reamortization.

(b) *Borrower notification.* All servicing actions permitted under subpart E of Part 1951 of this chapter are to be exhausted prior to consideration for debt restructuring under this section. To this end, the servicing official must ensure that the case file clearly documents that all servicing actions under subpart E of part 1951 have been exhausted and that the borrower is at least 1 full year's debt service behind schedule for a minimum of 180 days. The borrower then should be informed of the debt restructuring available under this section by using language similar to that provided in Guide 1 of this subpart (available in any FmHA Office) as follows:

(1) An introductory paragraph:

(2) A paragraph concerning prior servicing attempts;

(3) A discussion of eligibility, as defined in this section, including the provision that the borrower acted in good faith in connection with their FmHA loan and that the delinquency was caused by circumstances beyond their control;

(4) A paragraph that explains the goal of the debt restructuring program;

(5) A paragraph stating that debt restructuring may include a combination of servicing actions listed in paragraph (a)(10) of this section; and

(6) Information that details what the borrower must do to apply for restructuring. A response must be received within 45 days of receipt of this letter to request consideration for debt restructuring and the request must include:

(i) Projected balance sheets, budgets, and cash flow statements which include and clearly identify funding of the FmHA reserve account for the next 3 years;

(ii) A discussion of FmHA's analysis and calculation process; and

(iii) A paragraph identifying the FmHA official who may be contacted for assistance.

(c) *State Director's restructuring determination.* Upon receipt of the delinquent borrower's request for debt restructuring consideration, the FmHA State Director will:

(1) Within 15 days of receipt of borrower's request if an operations review is deemed necessary, send a memorandum to the Administrator asking for program authority to contract for the review in accordance with FmHA Instructions 2024–A, Exhibit D (available in any FmHA Office). The name of the borrower involved and the projected amount of funds anticipated to be spent for the contract should also be provided. It is anticipated that an operations review will be necessary in most cases and that the only exceptions would be for smaller health care facilities or facilities that have developed a proposed plan that is comprehensive and realistic. Upon receipt of the Administrator's program contracting approval authority, a contract is to be awarded to an organization qualified to perform an operations review as defined in paragraph (a)(9) of this section. The operations review normally will be completed and delivered to FmHA within 60 days of the award date.

(2) Contract for an appraisal to be performed by an independent qualified fee appraiser. Note: To the extent possible, the appraisal should be scheduled for completion no later than the completion date of the operations review.

(3) Complete an analysis of the operations review, appraisal, and other documentation information, and make an eligibility determination.

(i) *Eligibility determination.* The State Director must conclude that the borrower is eligible for debt restructuring consideration. This conclusion will be clearly documented in the case file based on a review of the following:

(A) The borrower acted in good faith with regard to the delinquent loan. The case file must reflect the borrower's cooperation in exploring servicing alternatives. The case file should contain no evidence of fraud, waste, or conversion by the borrower, and no evidence that the borrower violated the loan agreement or FmHA regulations.

(B) The delinquency was caused by circumstances beyond the control of the borrower. This determination will be based on the borrower's narrative on this issue, which is a required part of the application for debt restructuring, and a separate review of the borrower's case file and operations.

(C) As part of the application for debt restructuring, the borrower submitted a proposed operating plan that presents feasible alternatives for addressing the delinquency.

(ii) *Borrower determined eligible.* If the borrower is determined to be eligible for debt restructuring, a determination of a net recovery value and level of debt the facility will support will be made. It is anticipated that meetings with the borrower, the contractor who performed the operations review, and others as appropriate, could be necessary to develop these values; although it should

be emphasized throughout these meetings that any calculations and conclusions reached are preliminary in nature, pending final review by the Administrator. For debt restructuring calculations, and computing a feasible cashflow projection, the following order and combinations of loan servicing actions will be followed:

(A) Loan deferral for up to 6 months.

(B) Interest rate reduction to not less than 5 percent. Interest rate reduction will be considered only in conjunction with an extension of the term of the loan to the remaining useful life of the facility or 40 years, whichever is less.

(C) Debt writedown. Other creditors of the borrower, representing a substantial portion of the total debt, are expected to participate in the development of a restructuring plan which includes debt writedown. However, failure of these creditors to agree to participate in the plan shall not preclude the use of principal and interest writedown by FmHA if it is determined that this option results in the least cost to the Federal Government.

(iii) *Borrower determined ineligible.* If the State Director concludes that the borrower is not eligible for debt restructuring consideration for any of the reasons listed in paragraph (c)(3)(i) of this section, then the borrower will be notified by letter that includes the following information:

(A) The basis for the determination;

(B) The next step in servicing the loan; possible acceleration if the delinquency is not cured; and

(C) The borrower may appeal this determination in accordance with subpart B of part 1900 of this chapter.

(iv) *State Director's recommendation.* Upon completion of the determination of net recovery value and restructured debt in accordance with paragraph (c)(3)(ii) of this section, and prior to formal presentation to the borrower, the State Director will forward a recommendation to the National Office with the following documentation:

(A) That all other servicing efforts have been exhausted as required in paragraph (b) of this section.

(B) Financial statements including balance sheets, income and expense, and cash flows for the most recent actual year and projections for the next 3 years. The amount of FmHA's restructured debt and reserve account requirements are to be clearly indicated on the projected statements. Also, operating statistics including number of beds, patient days of care, outpatient visits, occupancy percentage, etc., for the same periods of time must be included;

(C) Copies of the operations review, developed for the particular loan, and appraisal;

(D) Calculations of the net recovery value;

(E) Debt restructuring calculations including a listing of the various servicing combinations used in these calculations as contained in paragraph (c)(3)(ii) of this section. For example:

(*1*) Interest rate reduced from 6.5 percent to 5 percent on all loans; and

(*2*) Extension of the terms from 25 to 30 years.

(F) Information concerning discussions with the borrower and their agreement or disagreement with the calculations and recommendations;

(G) If debt restructuring is proposed:

(*1*) A draft of Form FmHA 451–33, "Reamortization Request," if applicable, and any other necessary comments or requirements that may be required by the Office of the General Counsel and bond counsel in § 1951.223(c) (3) and (4) of subpart E of part 1951 of this chapter.

(*2*) A draft of Form FmHA 1956–1, if applicable, Complete only Parts I, II, VI, and VIII. Part VI, "Debtors Offer and Certification," will be in a separate attachment and contain the adjusted unpaid principal amount for which FmHA approval is requested. In part VI of the form, type "see attached." (H) If the proposed restructured debt will not cash flow or is less than the net recovery value, omit the items in paragraph (c)(3)(iv)(G) of this section.

(d) *National Office processing of State Director's request.* (1) After reviewing the recommendation to either debt restructure or liquidate for the net recovery value, the Administrator, after concurring, modifying, or not concurring in the recommendation, will return the submission for further processing.

(2) If a debt writedown is used in the restructuring process, the amount will be included in the National Office transmittal memorandum. The draft Form FmHA 1956–1 will not need to be finalized and returned to the Administrator for signature. The State Director's signature on the final copy will be sufficient. However, a copy of the National Office memorandum is to be attached to the Form when completed.

(e) *Borrower notification of debt restructuring and net recovery value calculations.* The State Director will provide a copy of the basis for the debt restructuring or net recovery determination to the borrower.

(1) If the value of the restructured loan is equal to, or greater than, the recovery value, the borrower will be made an offer to accept the restructured debt by using language similar to that provided in Guide 2 of this subpart (available in any FmHA Office) and including the following paragraphs:

(i) An introductory paragraph indicating that FmHA has concluded its consideration of the borrower's request;

(ii) A paragraph indicating FmHA's approval of the debt restructuring request and that acceptance must be received by FmHA within 45 days from receipt of this letter; and

(iii) That the borrower's acceptance will require the execution of a Shared Appreciation Agreement similar to Guide 4 of this subpart (available in any FmHA Office) and possible new debt instruments accompanied by bond counsel opinions.

(2) If the debt analysis calculations indicate that a restructured debt would be less than the net recovery value of the security, a letter using language similar to that provided in Guide 3 of this subpart (available in any FmHA Office), will be sent to the borrower that includes the following paragraphs:

(i) An introductory paragraph indicating that FmHA has concluded its consideration of the borrower's request;

(ii) Paragraphs indicating that:

(A) The borrower may pay FmHA the net recovery value of the loan. The borrower will be given 30 days from receipt of this letter to inform FmHA of its intent, 90 days to finalize the payoff, and will be notified that an election to pay off FmHA would require the execution of a Net Recovery Buy Out Recapture Agreement; or

(B) If the debt is not paid of at the net recovery value, FmHA will proceed to liquidate the loan.

(f) *Borrower responses to debt restructuring and net recovery value calculations.* Responses from the borrower will be handled as follows:

(1) *Acceptance of FmHA's restructured debt offer.* When a borrower accepts the offer for debt restructuring, processing will be in accordance with § 1951.223(c) of subpart E of part 1951 of this chapter using the adjusted unpaid principal and outstanding accrued interest at the Administrator's approved interest rate and terms. The borrower will be required to execute a Shared Appreciation Agreement which will provide that should the borrower sell or transfer title to the facility within the next 10 years, FmHA is entitled to a portion of any gain realized. This agreement will include language similar to that found in Guide 4 of this subpart (available in any FmHA Office). The original of Form FmHA 1956–1, with appropriate attachments signed by the

State Director, and a copy of the shared appreciation agreement will be sent to the Finance Office. Note: All documents pertaining to this transaction will be sent to the Finance Office in one single complete package; and

(2) *Acceptance by borrower to pay off loan at the recovery value.* Processing of this transaction will be in accordance with § 1956.124 of this subpart. However, the account does not need to be accelerated. The borrower will be required to execute a Net Recovery Buy Out Recapture Agreement, similar to that found in Guide 5 of this subpart (available in any FmHa Office). The original of Form FmHA 1956–1, with appropriate attachments signed by the State Director, and a copy of the recorded Net Recovery Buy Out Recapture Agreement will be sent to the Finance Office. The Executed Net Recovery Buy Out Recapture Agreement will be recorded in the county in which the facility is located. The Finance Office will credit the accounts of borrowers who entered into Net Recovery Buy Out Recapture Agreements with the amount paid by the borrower (net recovery value). Note: All documents pertaining to this transaction will be sent to the Finance Office in one single complete package.

(g) *Collection and processing of recapture.* (1) When FmHA becomes aware of the sale or transfer of title to the facility on which there is an effective Net Recovery Buy Out Recapture Agreement or a Shared Appreciation Agreement outstanding and a determination is made that a recapture is appropriate, FmHA will notify the borrower of the following:

(i) Date and amount of recapture due; and

(ii) FmHA action to be taken if borrower does not respond within the designated timeframe with the amount of recapture due.

(2) When the recapture is received, the payment will be processed on Form FmHA 451–2, "Schedule of Remittance," as a miscellaneous collection in accordance with Subpart B of Part 1951 of this chapter. The 451–2 along with a copy of the Net Recovery Buy Out Recapture Agreement or Shared Appreciation Agreement, as appropriate, will be forwarded to the Finance Office.

(3) When the amount of the recapture has been paid and credited to the borrower's account, the borrower will be released from liability by using Form FmHA 1965–8, "Release from Personal Liability," modified, as appropriate.

(h) *No recapture due.* If FmHA determines there is no recapture due, the Net Recovery Buy Out Recapture Agreement or Shared Appreciation Agreement will be appropriately annotated, the Recapture Agreement released from the record, and the agreement returned to the borrower.

Dated: November 2, 1992.

LaVerne Ausman

Administrator, Farmers Home Administration.

Dated: November 3, 1992.

Mary Ann Baron

Administrator, Rural Development Administration.

[FR Doc. 93–719 Filed 1–12–93; 8:45 am]

BILLING CODE 3410–07–M

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 30, 40, 70, and 72

RIN 3150–AD85

Timeliness in Decommissioning of Materials Facilities

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to require timely decontamination and decommissioning by nuclear material licensees. These amendments would establish specific time periods for decommissioning unused portions of operating nuclear materials facilities and for decommissioning the entire site upon termination of operations. The NRC is also proposing to amend the regulations to require that licensees provide a description of the conditions of the site as part of the information to be submitted in support of decommissioning plans. The proposed rule is intended to reduce the potential risk to public health and the environment from radioactive material at such facilities after licensed activities have ceased.

DATES: Comment period expires March 29, 1993. Comments received after this date will be considered if it is practical to do so, but consideration can only be assured if comments are received on or before this date.

ADDRESSES: Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments between 7:45 a.m. and 4:15 p.m. on Federal workdays to: 11555 Rockville Pike, Rockville, Maryland.

Copies of the regulatory analysis, the environmental assessment and finding of no significant environmental impact, the supporting statement submitted to OMB, and comments received may be examined at: the NRC Public Document Room at 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Paul J. Kovach, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–3729.

SUPPLEMENTARY INFORMATION:

Background

Over the past several years, the Nuclear Regulatory Commission (NRC) has identified over 40 nuclear material sites that warrant special attention by the Commission. The sites have buildings, former waste disposal areas, large piles of tailings, ground water, and soil contaminated with low levels of uranium or thorium (source material) or other radionuclides. Consequently, they present varying degrees of radiological hazard, cleanup complexity, and cost. At some sites, licensees are financially and technically capable of completing cleanup in a reasonable timeframe, whereas at other sites, the licensee or responsible party is unable or unwilling to perform cleanup. In addition, the sites are currently in various stages of decommissioning. At some sites, licensees have initiated decommissioning, whereas at other sites, decommissioning has not yet been planned or initiated.

In 1990, the NRC implemented the Site Decommissioning Management Plan (SDMP) to identify and resolve issues associated with the timely cleanup of these sites. The SDMP does not include mere routine decommissioning cases. The SDMP has been effective in ensuring coordination and resolution of some of the policy and regulatory issues affecting site decommissioning. Progress on actual site remediation, however, continues to be slow. The limited progress to date prompted the Commission to direct the NRC staff to initiate actions to accelerate the cleanup of SDMP sites. The staff developed, and on April 3, 1992, the Commission approved, an Action Plan to describe NRC's case-by-case approach for accelerating remediation of sites listed in the SDMP.

These SDMP contaminated sites are symptomatic of the need for definitive NRC regulations which specify acceptable time periods for decommissioning nuclear material facilities when the licensed activities have ceased. If decommissioning is

delayed for long periods following cessation of operations, there is a risk that safety practices at the inactive facility or the inactive portion of the operating facility may become lax as key personnel relocate and management interest wanes. In addition, bankruptcy, corporate takeover, or other unforeseen changes in the company's financial status may complicate and perhaps further delay decommissioning.

The issuance of a rule to establish timeliness criteria for decommissioning nuclear materials licensee facilities would avoid future problems resulting from delayed actions on cleanup of contaminated inactive facilities, and minimize the difficulties associated with a case-by-case approach to requiring timely decontamination and decommissioning.

Discussion

The lack of definitive criteria as to when licensees shall commence and complete decommissioning their facilities has resulted in instances where the Commission has had to issue orders to establish schedules for timely decommissioning. Because timeliness in decommissioning is a generic issue, the Commission is proposing to amend its regulations to clearly delineate the licensee's responsibility for timely decommissioning. The proposed rule would provide the needed regulatory basis for compelling decommissioning in a timely manner. In addition, the proposed rule would place a limit on the time permitted to decontaminate and decommission and place the burden of proof directly on the licensee to demonstrate that a longer period of time is required for completing decommissioning.

In developing details of these proposed requirements, the NRC considered whether to impose them on all licensees, or to limit the requirements only to those licensees who, because of the size of their operations, had greater potential for needing significant cleanup before their sites could be fully decommissioned—i.e., those licensees covered by the financial assurance requirements for decommissioning in 10 CFR 30.35, 40.36, 70.25, and 72.30. Limiting the application of these requirements would affect fewer licensees (approximately 1,650 versus 24,000 NRC and Agreement State licensees), whereas applying the proposed rule to all licensees would have the advantage of ensuring that dormant areas with significant levels of contamination will be decommissioned, regardless of the size or extent of the licensee's operations. The Commission has determined that the provisions of the rule should extend to all 10 CFR Parts 30, 40, 70, and 72 licensees.

The proposed rule would establish specific requirements for: (1) Timely decommissioning of the entire site at the end of all licensed activity at the site, thereby allowing license termination and release of the site for unrestricted use (i.e., "end-of-license" decommissioning); and (2) timely decommissioning of separate buildings and outdoor areas where licensed activities have ceased while licensed activities continue to be conducted at other site locations (i.e., "end-of-use" decommissioning). Licenses would be amended to exclude decommissioned buildings or outdoor areas as authorized places of use following satisfactory completion of end-of-use decommissioning.

The proposed rule would define principal activities as those activities that are essential to achieving the purpose for which the license was issued or amended. Principal activities are commonly listed or described in the license under the Authorized Use heading. Principal activities are defined in the regulation to prevent licensees from avoiding end-of-use decommissioning requirements by using passive activities. For example, a licensee could not store licensed radioactive material in an otherwise unused building to avoid end-of-use decommissioning, unless storage was a principal activity for that building as a part of ongoing operations.

The proposed rulemaking clarifies the regulations to address license termination, expiration, revocation, denial of renewal, and their relationship to each other. In general, a license "expires" when: (1) The expiration date stated in the license is reached [unless the licensee has appropriately filed for renewal], (2) the Commission revokes the license, or (3) the Commission formally denies an application to renew the license. The current rules provide that a license continues in effect until a final Commission determination has been made on the renewal application. The current rules do not specifically address continued authority and responsibility with respect to materials possessed under the license until the license is terminated by the Commission. "Expiration" of a license, whether voluntary or involuntary, refers to the end of a licensee's authorization to perform licensed activities under the Atomic Energy Act of 1954, as amended, with the exception of a licensee's continuing authorization to perform licensed activities incident to and necessary for site decontamination and decommissioning. Licensees with expired licenses must then decommission pursuant to the time limits and other requirements stated in the regulations. The proposed rule would make clear that the decommissioning and timeliness criteria apply to all licensees for whom the authorization to perform licensed activities has expired, regardless of whether the expiration was voluntary or involuntary. When the Commission has determined that decommissioning has been completed in a satisfactory manner, the Commission will relieve the licensee of license obligations by terminating the license. All licenses remain in effect until formally terminated by the Commission.

The proposed rule would require licensees to submit notification of the existence of inactive buildings or outdoor areas but would not require them to provide notification of the existence of inactive parts of buildings, such as rooms or laboratories. To include parts of buildings in the regulation was seen as a cumbersome regulatory requirement both for licensees and the NRC without sufficient resultant benefit. In addition to notification, licensees would be required to initiate decommissioning or, within 12 months, submit a decommissioning plan for Commission approval. Decontamination or decommissioning of internal building areas is covered under the normal inspection and licensing process. If the cleanup involved routine procedures used by the licensee, they would be handled under the licensee's existing license or radiation safety program. If the cleanup involved procedures not employed routinely by the licensee, NRC could request additional information regarding the cleanup.

The time requirements for completing decommissioning consist of time periods both for initiating the decommissioning process and for subsequently completing decommissioning activities. In determining the appropriate time requirement for initiating decommissioning, the NRC staff considered the health safety benefits to be obtained by allowing short-lived isotapes to decay before beginning decommissioning operations, and also the licensee's need to make business decisions concerning future use of inactive buildings or outdoor areas. In determining the appropriate time requirements for the completion of subsequent decommissioning activities, the NRC staff considered the time needed to plan and safely carry out

decommissioning operations based on previous experience.

With regard to initiation of the decommissioning process, the background information developed for the rulemaking on general requirements for decommissioning (53 FR 24018; June 27, 1988) included an evaluation of decommissioning planning and preparation requirements for the wide variety of different sized operations licensed under 10 CFR parts 30, 40, and 70. That evaluation indicated that, in general for materials license facilities, further benefits derived from radiological decay are not likely to be gained by delaying decommissioning beyond approximately 3 years from the date that operations cease. With respect to making business decisions on further use of inactive facilities, the Commission considers a period of approximately 24 months to be reasonable. This would permit licensees sufficient time to make decisions concerning future use of an inactive facility, while accommodating periods of inactivity due to normal operations, testing, or routine business cycles.

Based on the 24-month time period considered reasonable for making business decisions, and considering that the incremental benefits due to radioactive decay between the second and third years of inactivity are small, the Commission considers a period of approximately 24 months to be a reasonable time period to permit a building or outdoor area to remain inactive without undergoing decommissioning. Therefore, the proposed rule would stipulate that licensees must notify NRC if they have buildings or outdoor areas where no principal activities have been conducted for 24 months. Notification would also be required when the license has expired or when the licensee has decided to permanently cease principal activities and begin the formal process leading to license termination. The proposed rule would allow licensees 60 days to provide notification. The proposed rule would require licensees not required to submit decommissioning plans to begin decommissioning within the 60-day period provided for notification unless the Commission has granted a delay or postponement. Licensees required to submit decommissioning plans would be required to submit final decommissioning plans within 12 months following notification to cease principal activities. The timetables for required decommissioning activities are discussed below.

The Commission recognizes that licensees may not wish to decommission the site or separate buildings or outdoor areas when submitting the notification described above; thus, the rule would permit licensees to make a request and justify delay or postponement. Licensees would be required to submit the request with justification 30 days prior to the time notification would have been required as described above. In practical terms, this would mean: (1) 30 days prior to the license expiration date, or (2) 30 days following the decision to permanently cease principal activities at the site or in separate buildings or outdoor areas, or (3) 30 days following the end of the 24-month time period of inactivity for the site or in separate buildings or outdoor areas.

With regard to subsequent completion of decommissioning activities, licensees who are not required by license condition or existing regulatory requirements to submit a decommissioning plan would be permitted a maximum of 18 months to complete decommissioning. Licensees who are required to submit a decommissioning plan would be permitted 12 months to prepare and submit the plan and a maximum of 18 months to complete decommissioning following NRC approval of the plan.

The proposed regulations will permit licensees to request the Commission to consider extending the 18-month time limit for decommissioning. The Commission will consider site-specific factors on a case-by-case basis. Factors that the Commission may consider to be appropriate include: (1) Availability of waste disposal facilities, (2) Reductions in dose or waste volume due to radioactive decay, (3) Technical feasibility of decommissioning, (4) Regulatory requirements of other government agencies, (5) Lawsuits, (6) Ground-water treatment activities, (7) Monitored natural ground-water restoration, or (8) Other factors that could result in more environmental harm than deferred clean-up or that are beyond the control of the licensee.

Based on the time periods discussed above, the NRC estimates that licensees who are not required to submit decommissioning plans should complete their decommissioning activities in approximately 44 months or less after cessation of operations (i.e., 24 months of inactivity, 60 days for notification, and 18 months to complete decommissioning). Licensees who are required to submit decommissioning plans would be expected to complete their decommissioning activities in approximately 56 months or less (i.e., 24 months of inactivity, 60 days for notification, 12 months to submit a decommissioning plan, and 18 months to complete decommissioning). Commission review and approval of decommissioning plans (estimated to be 6 months or less) would be in addition to the 56-month total.

Uranium recovery licensees consist of conventional mills, commercial and research and development in-situ facilities, ore buying stations, and heap-leach facilities. These sites may contain processing facilities and waste disposal areas. The sites, other than the waste disposal areas, will be decommissioned and released for unrestricted use. The waste disposal areas are reclaimed and, when the specific license is terminated, licensed for long-term care under the general license in § 40.28.

The current requirements for decommissioning and reclamation of these sites are contained in appendix A to 10 CFR part 40. In particular, criterion 9 of Appendix A requires that there must be a Commission-approved plan for:

(1) Decontamination and decommissioning of mill buildings and the milling site to levels which allow unrestricted use of these areas upon decommissioning, and

(2) The reclamation of tailings and waste disposal areas in accordance with technical criteria presented in section I of appendix A.

The effect of the proposed rule would be to require the uranium recovery licensees to notify the Commission within 60 days when they have permanently ceased operations or have not conducted operations for 24 months (§ 40.42(d)) and to submit a decommissioning plan within 12 months of this notification or license expiration. The provisions in the proposed § 40.42(g) on the content of a decommissioning plan are consistent with the intent of the decommissioning plan required in Criterion 9 of appendix A to 10 CFR part 40. Some uranium recovery licensees may require additional time to conduct final decommissioning and site survey in order to support the reclamation of waste disposal areas.

Because waste disposal areas are not released for unrestricted use and criterion 9 of appendix A to 10 CFR Part 40 and subpart T of 40 CFR part 61 specifically require the submittal and approval of a timely reclamation plan, the provisions in the proposed rule in § 40.42(f) for the content of a plan and § 40.42(g) for the timing of completion of the plan do not apply to the reclamation plan for the waste disposal areas at uranium recovery facilities. Section 40.42(k) presents the exemption

for the waste disposal areas at uranium recovery facilities.

To coordinate decommissioning of uranium recovery facilities and reclamation of disposal areas, the Commission may need to extend the date for completion of the decommissioning plan and final radiological survey until the reclamation of the disposal area has been completed. Typically, the reclamation of a disposal area may require several years of drying, several construction seasons, and a period of stability monitoring prior to the licensee proposing to terminate the license. Requests for delay in completion of the final aspects of the decommissioning plan can be accommodated through the provisions in proposed § 40.42(h).

The Commission recognizes the fluctuation that has occurred in the uranium industry. The proposed regulation would allow the Commission to extend the 24-month period of inactivity if the Commission determined, based on a request by the licensee, that this relief is not detrimental to the public health and safety and is otherwise in the public interest.

This proposed rule would also clarify requirements for radiological surveys performed as part of the license termination process. This proposed rule would clarify that licensees need only submit the final survey showing that the site or area is suitable for release for unrestricted use after decommissioning has been completed. The Commission has recognized that existing requirements may be construed to require two surveys. However, the Commission must be aware of the conditions of the site in order to adequately review and approve a decommissioning plan. Therefore, a new item has been added to the content of a proposed decommissioning plan which requires a description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan. This may be a preliminary radiation survey or other types of documentation which characterize the conditions of the site.

The existing regulations (72.42(b)) require that applications for renewal of ISFSI and MRS licenses be filed at least 2 years prior to expiration of the existing license. This rulemaking would require licensees to notify the Commission (at least 2 years prior to license expiration) if an application for renewal will not be filed. The notification requirement, coupled with the 12-month time period for preparation of the final decommissioning plan, is equivalent to the current requirement in § 72.54(a) for submittal of a plan 1 year before expiration of the license. The requirement also has the effect of clearly documenting the licensee's decision on the future of the site 2 years before license termination.

This proposed rule would implement the Commission's directive on metrication that was established on October 7, 1992 (57 FR 46202). Reports of radiation exposure and exposure rates, dose and dose rates are now given using SI units, with special units in parentheses.

This proposed rule does not define radiological criteria for release for unrestricted use. The NRC intends to establish these levels in an enhanced participatory rulemaking that will be noticed in the **Federal Register**. Pending promulgation of the new radiological criteria, licensees are expected to comply with current criteria and practices as described in the NRC Action Plan Ensuring Timely Decommissioning of SDMP Sites (57 FR 13389; April 16, 1992). Further information on acceptable criteria may be obtained through the NRC regional or headquarters offices.

In keeping with the Commission's April 11, 1991, directive to the NRC staff concerning cooperation with the Agreement States, the NRC staff discussed its plans for this rulemaking with the Agreement States. The discussion was held at two open meetings in Wichita, Kansas, on May 14, 1991. These meetings were held to provide information and discussion in conjunction with the annual meeting of the Conference of Radiation Control Program Directors, Inc. During the meetings, the questions and comments that were raised focused upon the following:

(1) What licensee types should be covered and whether all facilities should be covered or only those with significant (but unspecified levels at that time) contamination;

(2) The time period that should be allowed for decommissioning and the options for extending the time period; and

(3) Other procedural questions such as the need for a residual radioactivity rule, related guidance on timeliness, enforcement, etc.

The staff has considered the comments made at the meetings. The content of the proposed rule and the Discussion section of this Supplementary Information address the concerns raised at the meetings.

The NRC recommends that the rule be made a Division 2 matter of compatibility. Under this level of compatibility, the Agreement States would be expected to adopt a timeliness in decommissioning rule but would be permitted flexibility to apply more stringent requirements if deemed appropriate by the State.

Although a total of about 24,000 licensees (including both NRC and approximately 16,000 Agreement State licensees) would be affected by this rulemaking, minimal impact is expected upon the 19,700 NRC or Agreement State licensees using only sealed sources or sources with short half-lived material.

Enforcement

The Commission intends to modify Enforcement Policy in 10 CFR part 2, appendix C, supplement 6, such that failure to provide notification or decommission facilities in accordance with this proposed rule would be considered a severity level 3 violation. This may subject licensees to civil penalties, including daily civil penalties, for such violations.

Request for Comment

Comments are invited on the proposed regulatory text in 10 CFR 30.36. The paragraphs in the existing regulations that would be revised to establish these criteria and timetables are found in §§ 30.36(a)–(e), and 30.37(a); the sections in the proposed rule being added to establish these criteria and timetables are 30.36 (g), (h), (i), and (j). Sections 30.36(d) and 30.37(b) have been deleted. A definition of principal activities has been added to § 30.4.

The text in the existing regulation in §§ 30.36 (c)(2)(i)(A)–(D), (c)(2)(iii)(A), (c)(2)(iii)(C), (c)(2)(iii)(D), and 30.36(f)(1)–(3) is unchanged (although renumbered). The text of these paragraphs is included as part of the codified text for clarity, completeness of presentation, and ease of amendment. However, comments are not requested on the provisions of these paragraphs nor will such comments be considered as part of this proposed rulemaking.

Similar amendments are being made to § 40.42, § 70.38 and 72.42. Specifically, comments are invited on the proposed regulatory text for these parts. The paragraphs in the existing regulations that would be revised to establish these criteria and timetables are §§ 40.42(a)–(e), and 40.43(a). The section being added to establish these criteria and timetables are 40.42 (g), (h), (i), (j), and (k). Sections 40.42(d) and 40.43(b) have been deleted. A definition of principal activities has been added to § 40.4.

The text in §§ 40.42(c)(2)(i)(A)–(D); (c)(2)(iii)(A), (c)(2)(iii)(C), (c)(2)(iii)(D), and 40.42(f)(1)–(3) is unchanged (although renumbered). The text of these paragraphs is included as part of the codified text for clarity, completeness of presentation, and ease of amendment. However, comments are not requested on the provisions of these paragraphs nor will such comments be considered as part of this proposed rulemaking.

Similarly, with regard to a § 70.38, comments are invited on the amended regulatory text. The paragraphs that would be revised to establish these criteria and timetables are found in §§ 70.38 (a)–(e) and (f)(5). The sections being added to establish these criteria and timetables are 70.38(g), (h), (i), and (j). Sections 70.33(b) and 70.38(d) have been deleted. A definition of principal activities has been added to § 70.4.

The text in §§ 70.38(c)(2)(i)(A)–(D), 70.38(c)(iii)(A), (c)(iii)(C)–(E), and 70.38(f)(1)–(3) is unchanged (although renumbered). The text of these paragraphs is included as part of the codified text for clarity, completeness of presentation, and ease of amendment. However, comments are not requested on the provisions of these paragraphs not will such comments be considered as part of this proposed rulemaking.

Similarly, with regard to part 72, comments are invited on the amended regulatory text which establishes criteria and timetables for decommissioning of independent storage and high level waste facilities. The paragraphs that would be revised to establish these criteria and timetables are found in § 72.54(a)–(c). The sections being added to establish these criteria and timetables are 72.54(f)(1), (f)(2) and 72.54(h)–(i). The definition of principal activities would be added to § 72.3. The text in § 72.54(b)(2)–(c) is unchanged (although renumbered). The text of these paragraphs is included as part of the codified text for clarity, completeness of presentation, and ease of amendment. However, comments are not requested on the provisions of these paragraphs nor will such comments be considered as part of this proposed rulemaking.

With regard to the timetable established 10 CFR 30.36(b), 40.42(b), 70.38(b) and 72.54(a) for providing NRC with notification that facilities have been inactive for 24 months, as well as the requirement that justifications for delaying or postponing initiation of the decommissioning process be filed 23 months after cessation of operations, the Commission specifically requests comments as to whether these time periods provide an adequate balancing of reduction in exposure levels due to decay and the time needed to make business decisions regarding inactive buildings or outdoor areas as a licensee's site.

Finding of No Significant Environmental Impact: Availability

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and therefore, an environmental impact statement is not required. The proposed action would establish specific requirements for timely decommissioning of nuclear materials facilities. The proposed action is directed to improving the regulatory, licensing, inspection, and enforcement framework relating to these facilities and does not change the underlying fundamental requirement to decommission facilities to levels acceptable for unrestricted use. Thus, this proposed action will not adversely affect the quality of the human environment. The environmental assessment and finding of no significant impact on which this determination is based are available for inspection at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, D.C. Single copies may be obtained from: Mr. P.J. Kovach, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–3729.

Paperwork Reduction Act Statement

This proposed rule amends information collection requirements that are subject to the Paper Reduction Act of 1980 (44 U.S.C. 3501 et seq.) This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements

The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Information and Records Management Branch (MNBB–7714), U.S. Nuclear Regulatory Commission, Washington, DC, 20555; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–3019 (3150–0009, 3150–0017, 315–0020, 3150–0028, and 3150–0132), Office of Management and Budget, Washington, DC, 20503.

Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The draft regulatory analysis is available for inspection at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC. Single copies of the draft analysis may be obtained from Mr P. J. Kovach, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 492–3729.

The NRC requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC as indicated under the ADDRESSES heading.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The proposed rule would impose requirements for timely decommissioning of a site. Although the proposed rule would include all 24,000 licenses regulated by the NRC and the Agreement States, decommissioning efforts for licensees that possess and use only materials with short half-lives or materials only in sealed sources are simple and require only that enough time be permitted to either allow short-lived materials to decay or to enable them to properly dispose of their sealed sources. Therefore, the impact of the rule on these licenses should not be significant. The net cost to the remaining licensees, estimated to number 4300, is expected to be small based on an analysis of the costs of decommissioning, including waste disposal. The analysis indicates that in nearly all cases, the cost of decommissioning (which includes the costs of waste disposal) would increase if decommissioning is delayed. Completed details of the cost analysis are contained in Section 6.2 of the Regulatory Analysis which can be obtained in the manner noted above. At realistic discount rates, for less than 50 licensees the calculated costs of delaying decommissioning may be lower than for decommissioning in a timely manner. However, these licensees are not likely to be small entities and, in addition, there actually may be significant costs of cleanup of

secondary contamination if decommissioning is delayed.

Although the above discussion indicates that there is a not a significant impact on a substantial number of small entities, the NRC is seeking comments and suggested modifications because of the widely differing conditions under which materials licensees operate.

Any entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates the following:

(1) The licensee's size and how the proposed regulation would result in a significant economic burden upon the licensee as compared to the economic burden on a larger licensee.

(2) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities.

(3) The benefits that would accrue, or the detriments that would be avoided, if the proposed regulations were modified as suggested by the licensee.

(4) How the proposed regulation, as modified, would more closely equalize the impact of NRC regulations or create more equal access to the benefits of Federal programs as opposed to providing special advantages to any individual or group.

(5) How the proposed regulation, as modified, would still adequately protect public health and safety.

Backfit Analysis

The NRC has determined that the backfit rule, 10 CFR 50.109, does not apply to this proposed rule and, therefore, that a backfit analysis is not required for this proposed rule because these amendments do not involve any provisions which would impose backfits as defined in 10 CFR 50.109(a)(1).

List of Subjects

10 CFR Part 30

Byproduct material, Criminal penalty, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 40

Criminal penalty, Government contracts, Hazardous materials—transportation, Nuclear materials, Reporting and recordkeeping requirements, Source material, and Uranium.

10 CFR Part 70

Criminal penalty, Hazardous materials—transportation, Material control and accounting, Nuclear materials, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Scientific equipment, Security measures, Special nuclear material.

10 CFR Part 72

Independent storage of spent fuel and high level waste, Manpower training programs, Nuclear materials, Occupational safety and health, Reporting and recordkeeping requirements, Security measures, and Spent fuel.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR parts 30, 40, 70, and 72.

PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for part 30 is revised to read as follows:

Authority: Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended; sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2233, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In § 30.4 a definition of the term *principal activities* is added in alphabetical order to read as follows:

§ 30.4 Definitions.

* * * * *

Principal activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended, excluding storage during which no licensed material is accessed for use or disposal and excluding activities incidental to decontamination or decommissioning.

* * * * *

3. Section 30.36 is revised to read as follows:

§ 30.36 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a) Each specific license expires at the end of the day on the expiration date stated in the license except when a licensee has filed an application for renewal pursuant to § 30.37 not less than 30 days prior to the expiration date stated in the existing license. When an application for renewal has been filed at least 30 days prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of residual byproduct material present as contamination until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall—

(1) Limit actions involving byproduct material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 30.6, each licensee shall provide notification to the Commission in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, such that the building or outdoor area is unsuitable for release for unrestricted use, or submit within 12 months of notification a decommissioning plan, if required by paragraph (f)(1) of this section, and begin decommissioning upon approval of that plan if—

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease *principal activities*, as defined in this part, at the entire site or in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use; or

(3) No *principal activities* under the license have been conducted for a period of 24 months; or

(4) No *principal activities* have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use.

(e) The Commission may grant a request to delay or postpone initiation of the decommissioning process if the Commission determines that such relief is not detrimental to the public health and safety and is otherwise in the public interest. Such requests shall be submitted no later than 30 days prior to notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section shall not commence until the Commission has made a determination on the request.

(f)(1) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section, if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in paragraph (f)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 18 months after plan approval, the plan shall include a justification for the delay based on the criteria in paragraph (h) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(g)(1) Except as provided in paragraph (h) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 18 months following initiation of decommissioning.

(2) Except as provided in paragraph (h) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 18 months following initiation of decommissioning.

(h) The Commission may approve a request for an alternative schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 18-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 18-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(i) As the final step in decommissioning, the licensee shall—

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates that the premises are suitable for release for unrestricted use in some other manner. The licensee shall, as appropriate—

(i) Report levels of radiation in units of micro gray (microrads) per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces, and report levels of radioactivity, including alpha, in units of mega becquerels (disintegrations per minute of microcuries) per 100 square centimeters removable and fixed for surfaces, mega becquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Byproduct material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

4. Section 30.37 is revised to read as follows:

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§ 30.37 Application for renewal of licenses.

(a) Application for renewal of a specific license shall be filed on NRC Form 314 and in accordance with § 30.32.

(b) (Reserved).

PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

5. The authority citation for part 40 is revised to read as follows:

Authority: Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95–604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); sec. 275, 92 Stat. 3021, as amended by Pub. L. 97–415, 96 Stat. 2067 (42 U.S.C. 2022).

Section 40.7 also issued under Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

6. In § 40.4 a definition of the term *principal activities* is added in alphabetical order to read as follows:

§ 40.4 Definitions.

* * * * *

Principal activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended, excluding storage during which no licensed material is accessed for use or disposal and excluding activities incidental to decontamination or decommissioning.

* * * * *

7. Section 40.42 is revised to read as follows:

§ 40.42 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a) Each specific license expires at the end of the day on the expiration date stated in the license except when a licensee has filed an application for renewal pursuant to § 40.43 not less than 30 days prior to expiration of the existing license. When an application for renewal has been filed, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day of the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of residual source material present as contamination until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall—

(1) Limit actions involving source material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 40.5, each licensee shall provide notification to the Commission in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, such that the building or outdoor area is unsuitable for release for unrestricted use, or submit within 12 months of notification a decommissioning plan, if required by paragraph (f)(1) of this section, and begin decommissioning upon approval of that plan if—

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease *principal activities*, as defined in this part, at the entire site or in any separate building or outdoor area; or

(3) No *principal activities* under the license have been conducted for a period of 24 months; or

(4) No *principal activities* have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use.

(e) The Commission may grant a request to delay or postpone initiation of the decommissioning process if the Commission determines that such relief is not detrimental to the public health and safety and is otherwise in the public interest. Such requests shall be submitted no later than 30 days prior to notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section shall not commence until the Commission has made a determination on the request.

(f)(1) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section, if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in paragraph (f)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include:

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) For decommissioning plans calling for completion of decommissioning later than 18 months after plan approval, a justification for the delay based on the criteria in paragraph (h) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practicable and that the health and safety of workers and the public will be adequately protected.

(g)(1) Except as provided in paragraph (h) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 18 months following initiation of decommissioning.

(2) Except as provided in paragraph (h) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 18 months following initiation of decommissioning.

(h) The Commission may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 18-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 18-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as the regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(i) As the final step in decommissioning, the licensee shall—

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates that the premises are suitable for release for unrestricted use in some other manner. The licensee shall, as appropriate—

(i) Report levels of radiation in units of micro gray (microrads) per hour of beta and gamma radiation at on centimeter and gamma radiation at one meter from surfaces, and report levels of radioactivity, including alpha, in units of megal becquerels (disintegrations per minute or microcuries) per 100 square centimeters removable and fixed for surfaces, mega becquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Source material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

(k) Specific licenses for uranium milling are exempt from the content requirements in paragraph (f) of this section and the timing of completion requirement in paragraph (g) of this section for the reclamation plans submitted under criterion 9 of appendix A to this part.

8. Section 40.43 is revised to read as follows:

§ 40.43 Renewal of Licenses.

(a) Application for renewal of a specific license shall be filed on NRC Form 313 and in accordance with § 40.31 of this part.

(b) (Reserved).

PART 70—DOMESTIC LICENSING OF SPECIAL NUCLEAR MATERIAL

9. The authority citation for part 70 is revised to read as follows:

Authority: Secs. 51, 53, 161, 182, 183, 68 Stat. 929, 930, 948, 953, 954, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2201, 2232, 2233, 2282); secs. 201, as amended, 202, 204, 206, 88 Stat. 1242, as amended, 1244, 1245, 1246 (42 U.S.C. 5841, 5842, 5845, 5846).

Sections 70.1(c) and 70.20a(b) also issued under secs. 135, 141, Pub. L. 96–425, 96 Stat. 2232, 2241 (42 U.S.C. 10155, 10161). Section 70.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 70.21(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 70.31 also issued under sec. 57d, Pub. L. 93–377, 88 Stat. 475 (42 U.S.C. 2077). Sections 70.36 and 70.44 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 70.61 also issued under secs. 186, 187, 68 Stat. 955 (42 U.S.C. 2236, 2237). Section 70.62 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138).

10. In § 70.4 a definition of the term *principal activities is* added in alphabetical order to read as follows:

§ 70.4 Definitions.

* * * * *

Principal activities means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended, excluding storage during which no licensed material is accessed for use or disposal and excluding activities incidental to decontamination or decommissioning.

* * * * *

§ 70.33 [Amended]

11. Section 70.33 is amended by removing and reserving paragraph (b).

12. Section 70.38 is revised to read as follows:

§ 70.38 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a) Each specific license expires at the end of the day on the expiration date stated in the license except when a licensee has filed an application for renewal pursuant to § 70.33 not less than 30 days prior to expiration of the existing license. When an application for renewal has been filed, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date stated in the determination.

(b) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license, or on the expiration date stated in the determination, or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of residual special nuclear material present as contamination until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall—

(1) Limit actions involving special nuclear material to those related to decommissioning; and

(2) Continue to control entry to restricted areas until they are suitable

for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

(d) Within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 70.5, each licensee shall provide notification to the Commission in writing and either begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity, such that the building or outdoor area is unsuitable for release for unrestricted use, or submit within 12 months of notification a decommissioning plan, if required by paragraph (f)(1) of this section, and begin decommissioning upon approval of that plan if:

(1) The license has expired pursuant to paragraph (a) or (b) of this section; or

(2) The licensee has decided to permanently cease *principal activities*, as defined in this part, at the entire site or in any separate building or outdoor area; or

(3) No *principal activities* under the license have been conducted for a period of 24 months; or

(4) No *principal activities* have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use.

(e) The Commission may grant a request to delay or postpone initiation of the decommissioning process if the Commission determines that such relief is not detrimental to the public health and safety and is otherwise in the public interest. Such requests shall be submitted no later than 30 days prior to notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section shall not commence until the Commission has made a determination on the request.

(f)(1) A decommissioning plan shall be submitted if required by license condition or if the procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area have not been previously approved by the Commission and these procedures could increase potential health and safety impacts to workers or to the public, such as in any of the following cases:

(i) Procedures would involve techniques not applied routinely during cleanup or maintenance operations;

(ii) Workers would be entering areas not normally occupied where surface contamination and radiation levels are significantly higher than routinely encountered during operation;

(iii) Procedures could result in significantly greater airborne concentrations of radioactive materials than are present during operation; or

(iv) Procedures could result in significantly greater releases of radioactive material to the environment than those associated with operation.

(2) The Commission may approve an alternate schedule for submittal of a decommissioning plan required pursuant to paragraph (d) of this section, if the Commission determines that the alternative schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety and is otherwise in the public interest.

(3) Procedures such as those listed in paragraph (f)(1) of this section with potential health and safety impacts may not be carried out prior to approval of the decommissioning plan.

(4) The proposed decommissioning plan for the site or separate building or outdoor area must include—

(i) A description of the conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(ii) A description of planned decommissioning activities;

(iii) A description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning;

(iv) A description of the planned final radiation survey; and

(v) An updated detailed cost estimate for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning.

(vi) A description of the physical security plan and material control and accounting plan provisions in place during decommissioning.

(vii) For decommissioning plans calling for completion of decommissioning later than 18 months after plan approval, a justification for the delay based on the criteria in paragraph (h) of this section.

(5) The proposed decommissioning plan will be approved by the Commission if the information therein demonstrates that the decommissioning will be completed as soon as practical and that the health and safety of workers and the public will be adequately protected.

(g)(1) Except as provided in paragraph (h) of this section, licensees shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 18 months following initiation of decommissioning.

(2) Except as provided in paragraph (h) of this section, when decommissioning involves the entire site, the licensee shall request license termination as soon as practicable but no later than 18 months following initiation of decommissioning.

(h) The Commission may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 18-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 18-month period;

(3) Whether a significant volume reduction in wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as regulatory requirements of other government agencies, lawsuits, ground-water treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(i) As the final step in decommissioning, the licensee shall—

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a radiation survey of the premises where the licensed activities were carried out and submit a report of the results of this survey, unless the licensee demonstrates that the premises are suitable for release for unrestricted use in some other manner. The licensee shall, as appropriate—

(i) Report levels of radiation in units of micro gray (microrads) per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces, and report levels of radioactivity, including alpha, in units of mega becquerels (disintegrations per minute or microcuries) per 100 square centimeters removable and fixed for surfaces, mega becquerels (microcuries) per milliliter for water, and becquerels

(picocuries) per gram for solids such as soils or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(j) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that:

(1) Special nuclear material has been properly disposed;

(2) Reasonable effort has been made to eliminate residual radioactive contamination, if present; and

(3)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL AND HIGH-LEVEL RADIOACTIVE WASTE

13. The authority citation for part 72 is revised to read as follows:

Authority: Secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 68 Stat. 929, 930, 932, 933, 934, 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2232, 2233, 2234, 2236, 2237, 2238, 2282); sec. 274, Pub. L. 86–373, 73 Stat. 688, as amended (42 U.S.C. 2021); sec. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846); Pub. L. 95–601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851); sec. 102 Pub. L. 91–190, 83 Stat. 853 (42 U.S.C. 4332). Secs. 131, 132, 133, 135, 137, 141, Pub. L. 97–425, 96 Stat. 2229, 2230, 2232, 2241, sec. 148, Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10151, 10152, 10153, 10155, 10157, 10161, 10168).

Section 72.44(g) also issued under secs. 142(b) and 148(c), Pub. L. 100–203, 101 Stat. 1330–232, 1330–236 (42 U.S.C. 10162(b), 10168(c), (d)). Section 72.46 also issued under sec. 189, 68 Stat. 955 (42 U.S.C. 2239); sec. 134, Pub. L. 97–425, 96 Stat. 2230 (42 U.S.C. 10154). Section 72.96(d) also issued under sec. 145(g), Pub. L. 100–203, 101 Stat. 1330–235 (42 U.S.C. 10165(g)). Subpart J also issued under secs. 2(2), 2(15), 2(19), 117(a), 141(h), Pub. L. 97–425, 96 Stat. 2202, 2203, 2204, 2222, 2244, (42 U.S.C. 10101, 10137(a), 10161(h)). Subparts K and L are also issued under sec. 133, 98 Stat. 2230 (42 U.S.C. 10153) and Sec. 218(a) 96 Stat. 2252 (42 U.S.C. 10198).

14. In § 72.3, a definition of the term *principal activities* is added in alphabetical order to read as follows:

§ 72.3 Definitions.

* * * * *

Principal activities, as used in this part, means activities authorized by the license which are essential to achieving the purpose(s) for which the license was issued or amended, excluding activities incidental to decontamination or decommissioning.

* * * * *

15. In § 72.42, a new paragraph (d) is added to read as follows:

§ 72.42 Duration of license; renewal.

* * * * *

(d) Each licensee shall notify the Commission in writing at least 2 years prior to expiration of its existing license if an application for renewal will not be filed pursuant to this section.

16. Section 72.54 is revised to read as follows:

§ 72.54 Expiration and termination of licenses and decommissioning of sites and separate buildings or outdoor areas.

(a) Each specific license expires at the end of the day on the expiration date stated in the license except when a licensee has filed an application for renewal pursuant to § 72.42 not less than 24 months prior to expiration of the existing license. When an application for renewal has been filed at least 24 months prior to the expiration date stated in the existing license, the existing license expires at the end of the day on which the Commission makes a final determination to deny the renewal application or, if the determination states an expiration date, the expiration date stated in the determination.

(B) Each specific license revoked by the Commission expires at the end of the day on the date of the Commission's final determination to revoke the license or on the expiration date stated in the determination or as otherwise provided by Commission Order.

(c) Each specific license continues in effect, beyond the expiration date if necessary, with respect to possession of licensed material present as residual radioactivity until the Commission notifies the licensee in writing that the license is terminated. During this time, the licensee shall—

(1) Limit actions involving spent fuel or other licensed material to those related to decommissioning and

(2) Continue to control entry to restricted areas until they are suitable for release for unrestricted use and the Commission notifies the licensee in writing that the license is terminated.

(d) As required by § 72.42(d), or within 60 days of the occurrence of any of the following, consistent with the administrative directions in § 72.4, each licensee shall notify the Commission in writing, and submit within 12 months of notification, a final decommissioning plan and begin decommissioning upon approval of the plan if—

(1) The licensee has decided to permanently cease *principal activities*, as defined in this part, at the entire site or any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use; or

(2) No *principal activities* under the license have been conducted for a period of 24 months; or

(3) No *principal activities* have been conducted for a period of 24 months in any separate building or outdoor area that contains residual radioactivity such that the building or outdoor area is unsuitable for release for unrestricted use.

(e)(1) The Commission may grant a request to delay or postpone initiation of the decommissioning process if the Commission determines that such relief is not detrimental to the public health and safety and is otherwise in the public interest. Such requests shall be submitted no later than 30 days prior to notification pursuant to paragraph (d) of this section. The schedule for decommissioning set forth in paragraph (d) of this section shall not commence until the Commission has made a determination on the request.

(2) The Commission may approve an alternate schedule for submittal of the final decommissioning plan required pursuant to paragraph (d) of this section of the Commission determines that the alternate schedule is necessary to the effective conduct of decommissioning operations and presents no undue risk from radiation to the public health and safety, and is otherwise to the public interest.

(f) The proposed final decommissioning plan must include—

(1) A description of the current conditions of the site or separate building or outdoor area sufficient to evaluate the acceptability of the plan;

(2) The choice of the alternative for decommissioning with a description of the activities involved;

(3) A description of controls and limits on procedures and equipment to protect occupational and public health and safety;

(4) A description of the planned final radiation survey; and

(5) An updated detailed cost estimate for the chosen alternative for decommissioning, comparison of that estimate with present funds set aside for decommissioning, and plan for assuring the availability of adequate funds for completion of decommissioning including means for adjusting cost estimates and associated funding levels

over any storage or surveillance period; and

(6) A description of technical specifications and quality assurance provisions in place during decommissioning.

(g) For final decommissioning plans in which the major dismantlement activities are delayed by first placing the ISFSI or MRS in storage, planning for these delayed activities may be less detailed. Updated detailed plans must be submitted and approved prior to the start of such activities.

(h) If the final decommissioning plan demonstrates that the decommissioning will be completed as soon as practicable, performed in accordance with the regulations in this chapter, and will not be inimical to the common defense and security or to the health and safety of the public, and after notice to interested persons, the Commission will approve the plan subject to such conditions and limitations as it deems appropriate and necessary and issue an order authorizing decommissioning.

(i)(1) Except as providing in paragraph (j) of this section, each licensee shall complete decommissioning of the site or separate building or outdoor area as soon as practicable but no later than 18 months following approval of the final decommissioning plan by the Commission.

(2) Except as provided in paragraph (j) of this section, when decommissioning involves the entire site, each licensee shall request license termination as soon as practicable but no later than 18 months following approval of the final decommissioning plan by the Commission.

(j) The Commission may approve a request for an alternate schedule for completion of decommissioning of the site or separate building or outdoor area, and license termination if appropriate, if the Commission determines that the alternative schedule is warranted by consideration of the following:

(1) Whether it is technically feasible to complete decommissioning within the allotted 18-month period;

(2) Whether sufficient waste disposal capacity is available to allow completion of decommissioning within the allotted 18-month period;

(3) Whether a significant volume reduction is wastes requiring disposal will be achieved by allowing short-lived radionuclides to decay;

(4) Whether a significant reduction in radiation exposure to workers can be achieved by allowing short-lived radionuclides to decay; and

(5) Other site-specific factors which the Commission may consider appropriate on a case-by-case basis, such as regulatory requirements of other government agencies, lawsuits, groundwater treatment activities, monitored natural ground-water restoration, actions that could result in more environmental harm than deferred cleanup, and other factors beyond the control of the licensee.

(k) As the final step in decommissioning, the licensee shall—

(1) Certify the disposition of all licensed material, including accumulated wastes, by submitting a completed NRC Form 314 or equivalent information; and

(2) Conduct a final radiation survey of the premises where the licensed activities were conducted and submit a report of the results of this survey, unless the licensee demonstrates that the premises are suitable for release for unrestricted use in some other manner. The licensee shall, as appropriate—

(i) Report levels of radiation in units of micro gray (microrads) per hour of beta and gamma radiation at one centimeter and gamma radiation at one meter from surfaces, and report levels of radioactivity, including alpha, in units of mega becquerels (disintegrations per minute or microcuries) per 100 square centimeters removable and fixed for surfaces, mega becquerels (microcuries) per milliliter for water, and becquerels (picocuries) per gram for solids such as solid or concrete; and

(ii) Specify the survey instrument(s) used and certify that each instrument is properly calibrated and tested.

(l) Specific licenses, including expired licenses, will be terminated by written notice to the licensee when the Commission determines that—

(1) The decommissioning has been performed in accordance with the approved final decommissioning plan and the order authorizing decommissioning; and

(2)(i) A radiation survey has been performed which demonstrates that the premises are suitable for release for unrestricted use; or

(ii) Other than information submitted by the licensee is sufficient to demonstrate that the premises are suitable for release for unrestricted use.

17. In § 72.86, paragraph (b), is revised to read as follows:

§ 72.86 Criminal penalties.

* * * * *

(b) The regulations in part 72 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 72.1, 72.2, 72.3, 72.4, 72.5, 72.7, 72.8, 72.9, 72.16, 72.18, 72.20, 72.22, 72.24, 72.26, 72.28, 72.32, 72.34, 72.40, 72.46, 72.56, 72.58, 72.60, 72.62, 72.84, 72.86, 72.90, 72.96, 72.108, 72.120, 72.122, 72.124, 72.126, 72.128, 72.130, 72.182, 72.194, 72.200, 72.202, 72.204, 72.206, 72.210, 72.214, 72.220, 72.230, 72.236, 72.238, and 72.240.

Dated at Rockville, Maryland, this 7th day of January, 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93–745 Filed 1-12–93; 8:45 am]

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FEDERAL ELECTION COMMISSION

11 CFR Part 104

[Notice 1993–2]

Recordkeeping and Reporting by Political Committees; Best Efforts

AGENCY: Federal Election Commission.

ACTION: Notice of public hearing.

SUMMARY: The Federal Election Commission is considering holding a public hearing on proposed revisions to its regulations which require that treasurers of political committees exercise best efforts to obtain, maintain and report the complete identification of each contributor whose contributions exceed $200 per calendar year. Further information is provided in the supplementary information which follows.

DATES: The Commission is considering holding a hearing on March 24, 1993 at 10 a.m. if a sufficient number of persons are interested in testifying. Requests to testify must be received on or before February 26, 1993. Persons requesting to testify must also submit written comments by February 26, 1993, if they have not previously filed written comments on the proposed rules.

ADDRESSES: Requests to testify, and any accompanying comments, must be made in writing and addressed to: Ms. Susan E. Propper, Assistant General Counsel, 999 E Street, NW., Washington, DC 20463. Commission hearings are held in the Commission's ninth floor meeting room, 999 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Susan E. Propper, Assistant General Counsel, (202) 219–3690 or (800) 424–9530.

SUPPLEMENTARY INFORMATION: On September 24, 1992 (57 FR 44137) the Commission published a Notice of Proposed Rulemaking regarding possible changes to 11 CFR 104.7(b). This regulation explains the actions necessary to meet the treasurer's statutory obligation to exercise best

efforts to obtain and report the name, address, occupation and employer of all contributors who give over $200 to the political committee in a calendar year, together with the date and amount of such contributions. *See* 2 U.S.C. 434(b)(3)(A). The proposed rules would require political committees to make separate and distinct requests for the necessary information when they receive solicited or unsolicited contributions that do not contain the information needed. The proposed changes would also require treasurers to report information which is known to them, but which was not specifically provided by the contributors. The proposals would also clarify the existing requirement to amend reports upon receipt of additional contributor information.

A number of comments were received in response to the NPRM. One commentor suggested that the Commission hold a public hearing regarding these rules. The Commission is willing to hold a hearing if a sufficient number of those interested in the proposed changes to the regulations would like an opportunity to testify. In particular, testimony is sought from political committees who would be subject to the revised best efforts requirements. The Commission is interested in testimony on whether political committees expect to find the new proposals to be excessively burdensome or whether the proposed rules would provide a workable method of ensuring more complete public disclosure of contributor information. In addition, the Commission would welcome testimony on the timing of amended reports containing this information.

List of Subjects in 11 CFR Part 104

Campaign funds, Political candidates, Political committees and parties, Reporting requirements.

Dated: January 8, 1993.

Scott E. Thomas,

Chairman, Federal Election Commission.

[FR Doc. 93–725 Filed 1–12–93; 8:45 am]

BILLING CODE 6715–01–M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1615 and 1616

Standards for Flammability of Children's Sleepwear: Sizes 0 Through 6X and 7 Through 14; Advance Notice of Proposed Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Commission is considering amendment of the flammability standards for children's sleepwear in sizes 0 through 6X and 7 through 14. The amendment under consideration would exempt tight fitting garments and garments intended for infants from the existing sleepwear standards. The Commission is considering such an amendment because of changes in the marketplace and consumer preference. This notice discusses the risk of injury, the products subject to the existing regulation, and the changes the Commission is considering. The Commission invites comments concerning the risk of injury identified in this notice, the regulatory alternatives being considered, and other possible alternatives for addressing the risk. The Commission also invites submission of an existing standard or statement of intention to modify or develop a voluntary standard to address the risk of injury. Elsewhere in this issue of the **Federal Register** the staff announces its decision to stay enforcement of sleepwear requirements against garments currently being used as sleepwear that are labeled and marketed as underwear if these garments are skin-tight or nearly skin-tight and garments that are essentially identical in design, material, and fit to such "underwear" garments.

DATES: Comments and submissions are due not later than March 15, 1993.

ADDRESSES: Comments and submissions should be sent, preferably in five copies, to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207.

FOR FURTHER INFORMATION CONTACT: Terrance R. Karels, Directorate for Economic Analysis, Consumer Product Safety Commission, Washington, DC 20207; telephone (301) 504–0962.

SUPPLEMENTARY INFORMATION:

A. Background

Section 4 of the Flammable Fabrics Act ("FFA"), 15 U.S.C. 1193, sets forth procedures for issuing or amending flammability standards for products of wearing apparel made from fabrics and related materials, and fabrics and related materials used in products of wearing apparel. Standards or amendments may be issued under provisions of the FFA to protect the public from unreasonable risks of the occurrence of fire leading to death, personal injury, or significant property damage.

In 1971, the Secretary of Commerce issued a flammability standard for children's sleepwear in sizes 0 through 6X, which became effective in 1972. That standard prescribes tests for children's sleepwear garments and fabrics intended for use in children's sleepwear. The flammability standard for children's sleepwear in sizes 0 through 6X is codified at 16 CFR part 1615.

In 1973, responsibility for administration and enforcement of the FAA was transferred to the Consumer Product Safety Commission by provisions of section 30(b) of the Consumer Product Safety Act (15 U.S.C. 2079(b)). In 1974, the Commission issued a flammability standard for children's sleepwear in sizes 7 through 14, to become effective in 1975. The tests in that standard are substantially the same as those in the standard for children's sleepwear in sizes 0 through 6X. The flammability standard for children's sleepwear in sizes 7 through 14 is codified at 16 CFR part 1616.

Both standards require that test specimens must self-extinguish when exposed to a small open-flame ignition source. Self-extinguishing fabrics and garments are those that stop burning when removed from an ignition source. Both standards require manufacturers of sleepwear garments to perform prototype tests on specimens of fabric, seams, and trim with acceptable results before beginning production of sleepwear garments. Both standards also require manufacturers of sleepwear fabrics and garments to group fabrics and garments into production units and to randomly sample and test products from each production unit.

Neither standard requires that specific fabrics or flame-retardant treatments be used in the manufacture of children's sleepwear.

The standards define "children's sleepwear" to mean:

> any product of wearing apparel up to and including size 6x [or sizes 7 through 14], such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping. Diapers and underwear are excluded from this definition.

16 CFR 1615.1(a) and 1616.2(a).

The Commission has previously considered certain amendments to the children's sleepwear standards. In 1977, the Commission proposed an amendment to the standard for sizes 0 through 6X to exempt sleepwear garments smaller than size 1 from the standard. See 42 FR 4849. However, the Commission subsequently withdrew the proposal. The Commission concluded, at that time, that "the potentially higher

risk for injury to infant due to burns, exceeds the possible benefits from untreated cotton." See 43 FR 31348–49. Similarly, when the Commission considered the sleepwear standard for sizes 7–14, some comments requesting an exemption for close fitting pajamas were received. However, at that time, the Commission did not believe that such an exemption was appropriate. See 40 FR 3276, 3278 (1975); 39 FR 15210 (1974).

Now that the Commission has had more experience with the flammability standards and has had an opportunity to observe changes in the marketplace, the Commission is considering amending the standards to exempt sleepwear garments that are close-fitting or that are intended for infants under one year of age. After examining the data on ignition incidents involving such garments and considering consumers' preference for cotton sleepwear, the Commission believes that this exemption is likely to allow greater consumer preference without increasing the risk of injury.

The Commission also believes that such an exemption would alleviate the current confusion in interpreting the term "children's sleepwear." Due to frequent changes in garment design and use, the distinction between "sleepwear" and "daywear" has become increasingly blurred.

In 1984, the Commission staff developed an enforcement guideline pamphlet with guidelines to distinguish between children's sleepwear and non-sleepwear garments. Due to frequent fashion changes, the pamphlet has since been revised five times. Under its enforcement policy, 16 CFR 1615.64(c) and 1616.65(c), the staff considers three factors in determining whether a garment is sleepwear: (1) Its suitability for sleeping, (2) the distribution and promotion of the product, and (3) the likelihood that the item will be used as sleepwear. (Reference 1.)

In response to concerns about the marketing of garments similar to sleepwear that did not comply with the sleepwear standards, about difficulties with the term sleepwear, and continued demand by consumers for cotton garments, the Commission established a project to re-examine the scope of the children's sleepwear standards in November 1991.

As a result of this examination, the Commission is issuing this advance notice of proposed rulemaking ("ANPR") which could result in amendment of the children's sleepwear standards that would exempt tight fitting garments and garments intended for infants from the children's sleepwear standards. These garments would still be subject to the general wearing apparel standard codified at 16 CFR part 1610.

B. Statutory Provisions

The sleepwear standards under the FFA were issued "to protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury or significant property damage." 15 U.S.C. 1193(a). Based on current information, the Commission believes that the amendment it is considering in this notice would address recent changes in the marketplace but would not lower the level of protection of the public from the unreasonable risk of fire.

The FFA sets forth the process by which the Commission can issue or amend a flammability standard. The Commission first must issue an ANPR which: (1) Identifies the fabric or product and the nature of the risk associated with the fabric or product; (2) summarizes the regulatory alternatives under consideration; (3) provides information about existing relevant standards and reasons why the Commission does not preliminarily believe that these standards are adequate; (4) invites interested persons to submit comments concerning the identified risk of injury, regulatory alternatives being considered, and other possible alternatives; (5) invites submission of an existing standard or portion of a standard as a proposed regulation; and (6) invites submission of a statement of intention to modify or develop a voluntary standard to address the risk of injury. 15 U.S.C. 1193(g).

If, after reviewing comments and submissions responding to the ANPR, the Commission determines to continue the rulemaking proceeding, it will issue a notice of proposed rulemaking. This notice must contain the text of the proposed rule along with alternatives the Commission has considered and a preliminary regulatory analysis. 15 U.S.C. 1193(i). Before issuing a final rule, the Commission must prepare a final regulatory analysis, and it must make certain findings concerning any relevant voluntary standard, the relationship of costs and benefits of the rule, and the burden imposed by the regulation. *Id.* 1193(j). The Commission also must provide an opportunity for interested persons to make an oral presentation before the Commission issues a final rule. *Id.* 1193(d).

C. Possible Amendment

This notice initiates the rulemaking process to amend the children's sleepwear flammability standards.

1. The Products

The products of concern are children's sleepwear garments in sizes 0 through 6X and 7 through 14 that are currently subject to the Commission's flammability standards in 16 CFR parts 1615 and 1616.

Currently, untreated garments made of 100 percent cotton cannot be sold for children's sleepwear because they will not pass the tests in the children's sleepwear flammability standards without flame retardant treatment. There has been an increasing trend toward consumer preference for cotton. There have been changes in the market as a result of this demand, such as (1) more multipurpose clothing and (2) sale of so-called "long underwear" year round, that have resulted in confusion between "sleepwear" and non-sleepwear. (Reference 1.)

Presently, there is a relatively low per capita consumption of complying sleepwear. (Reference 4.) This indicates that consumers may be using other items, such as cotton long underwear, playwear, and T-shirts, for sleeping. The exemption the Commission is considering would allow certain cotton garments (close fitting or intended for infants under one year of age) to be sold as sleepwear. The availability of some tight fitting cotton garments, which appear to be safer than looser fitting garments, for sleepwear might result in a move away from use of some cotton non-sleepwear items, such as loose fitting T-shirts, as sleepwear. (Reference 5.)

At the present time, the staff estimates that there are 63 known domestic manufacturers of children's sleepwear. The estimated annual sales of children's sleepwear are approximately 105 million units. The retail value of sales is estimated at $1.1 billion. (Reference 4.)

2. The Risk of Injury

The standards are intended to eliminate the risk of personal injury or death from fire as a result of contact between children's sleepwear and an ignition source.

The staff reviewed injury data from the National Electronic Injury Surveillance System ("NEISS") involving ignition of clothing for 1980 through 1991. Children less than 15 years old, the group presumably covered by the sleepwear standards, made up about one-third of the estimated injuries. Among this group of children, nightwear accounted for only about eight percent of the estimated 11,450 injuries in those cases where the type of garment was reported. (Reference 2.)

Infants younger than one year old accounted for a very small proportion of the estimated injuries (1.3 percent) in incidents where the type of garment was reported. About 170 infants were estimated to have been treated for burn injuries involving ignition of clothing. This estimate was based on an actual sample of only three cases, one involving daywear, one involving nightwear, and one involving an unspecified type of clothing. (Reference 2.)

Although the Commission has limited data on the fit of sleepwear garments involved in ignition incidents, in a majority of incidents involving sleepwear, the garments worn were nightgowns which are loose fitting. Approximately 96 percent of the estimated 910 nightwear injuries involved females, while only 35 percent of the estimated 9,710 daywear injuries involved females. The injury reports indicate that nightgowns were the predominant kind of nightwear involved in injuries to girls. (Reference 2.)

Since issuance of these standards, several studies have been conducted concerning the influence of garment configuration on clothing ignition. A Canadian study in 1985 indicated that a loose and flowing garment style was the dominant factor in burn severity in clothing burns of Canadian children. A 1978 study of U.S. clothing fire incidents found that ignition often occurred in the loosest area of the garment. (Reference 3.)

Several studies involving mannequins have shown that garment design is an important factor in flammability. Although mannequin tests cannot simulate the movement of a victim, and therefore do not perfectly reflect reality, they do provide some useful data. Some such studies have shown that even use of a belt can slow the rate of flame spread and reduce the area of burn. An Australian study used mannequins to compare pajamas and nightgowns of the same fabric and found that for each of five fabrics the nightgowns presented greater risk. (Reference 3.)

As explained above, it appears that non-complying cotton garments are being worn as sleepwear. If the standards are changed to allow close fitting cotton garments for sleepwear, consumers may substitute such items for looser fitting cotton garments. This substitution could reduce the risk of ignition injuries. (Reference 5.)

Risk of clothing ignition may be affected by things other than the garments themselves. Research conducted in the 1970's found that common ignition sources in burns associated with wearing apparel were small open flames such as matches, lighters, and candles. Ranges, open fires, and space heaters were other frequent ignition sources. Substantial market changes have occurred with these ignition sources since that study. The decline in the number of smokers has likely had some effect on the accessibility of matches and lighters. In 1970, 50.2 percent of all males and 30.8 percent of females in the United States smoked; in 1987, 31 percent of males and 26.2 percent of females smoked. The percentage of households with gas ranges has also declined from 58 percent in 1960 to 42 percent in 1987. Additionally, gas ranges and electric space heaters have been the subject of improved voluntary standards. Also, sales of kerosene heaters have declined significantly in the past ten years. These factors may have contributed to a decreased risk of injury associated with ignition of children's sleepwear over the past 20 years. (Reference 5.)

3. Regulatory Alternatives

The Commission is considering amending its children's sleepwear standards to accommodate market changes and consumer preferences that have arisen since issuance of the flammability standards. The Commission believes that it can amend the standard to address these changes without reducing the protection of the public against the unreasonable risk of fire.

The first alternative being considered by the Commission is amendment of the children's sleepwear standards to exempt tight fitting garments and garments intended for infants. These garments would, however, continue to be subject to the requirements of the Standard for the Flammability of Clothing Textiles, codified at 15 CFR part 1610.

The Commission seeks comments concerning the group of garments it is considering exempting from the sleepwear standards. Comments addressing how the Commission should define "tight fitting garments" and what sizes or types of garments should be considered intended for infants would be helpful.

A second alternative is for the Commission to issue an enforcement policy rather than amending the flammability standards. Under this approach, the Commission would issue a notice of enforcement policy explaining that the Commission would relax its enforcement of the existing sleepwear regulations when applying them to tight fitting garments and sleepwear intended for infants. The notice would provide guidance to the regulated community on the items for which enforcement would be relaxed.

Another alternative under consideration is to maintain the existing sleepwear standards and the current enforcement policy without change.

4. Existing Relevant Standards

The provisions of both flammability standards for children's sleepwear require that specimens must self-extinguish when exposed to an open flame ignition source. The average char length must not exceed 7 inches, and no individual char length may exceed 10 inches. Both standards define "children's sleepwear" as "any product of wearing apparel (up to size 6X or sizes 7 through 14) such as nightgowns, pajamas, or similar or related items, such as robes, intended to be worn primarily for sleeping or activities related to sleeping. Diapers and underwear are excluded from this definition." 16 CFR 1615.1(a); 16 CFR 1616.2(a).

No voluntary standards addressing the flammability of children's sleepwear exist.

As part of its review of the FFA sleepwear standards, the staff examined the sleepwear standards in Canada, Australia, and New Zealand. All three standards make a distinction between sleepwear that presents a low fire hazard and those items that present a greater risk. (Reference 3.)

Canada

In 1971, Canada issued minimal flammability regulations for children's sleepwear in sizes 0 to 6X. Because burn injuries and deaths to children resulting from the ignition of sleepwear continued, further studies were conducted. These studies indicated that garment style played a major role in the flammability hazard of sleepwear, and that loose and flowing nightgowns were responsible for the most severe burns. Currently there are two regulations for flammability of children's sleepwear in Canada; one applies to sleepwear considered to be a low fire hazard and the other to sleepwear that presents a greater fire hazard.

Sleepwear in the high fire hazard category are children's nightgowns, nightshirts, dressing gowns, bathrobes, housecoats, robes, pajamas and baby doll pajamas in sizes up to and including 14X. Testing methods are similar to those of the U.S. sleepwear standards. Sleepwear considered to present a low fire hazard are sleepwear designed for hospital use in sizes 0 to 14, sleepwear designed for infants up to 7kg (15.4lb.), and polo pajamas and

sleepers in sizes 0 to 14X. Tests for these garments are similar to the Commission's general clothing flammability standard.

Australia

In Australia, research also was conducted that found fitting and clinging sleepwear garments were less likely to be involved in burn accidents than loose garments and that burns were likely to be less severe with the closer fitting garments. Australia's standard has three categories of sleepwear based on fire risk. Category 1 garments are made from low fire hazard type fabrics. They must be labeled "low fire danger." Category 2 garments are those that are styled to be form fitting and are designed to reduce fire hazard. The standard provides illustrations of acceptable styles of sleepwear. In addition to garment style, the burning behavior of the fabric is also considered. These garments must be labeled "styled to reduce fire danger." Category 3 garments are all other garments that do not fit into categories 1 or 2. These garments must be labeled "warning high fire danger keep away from fire."

New Zealand

New Zealand's requirements are similar to, but more stringent than, Australia's. They require all commercially manufactured nightwear for children from 1 to 14 years old be made from fabrics defined as "low fire risk" or be designed in a safer (i.e., closer fitting, pajama-type) style.

5. Invitations to Comment

In accordance with section 4(g) of the FFA, the Commission invites comments on this notice. Specifically, the Commission invites the following types of comments.

1. Comments concerning the risk of injury identified in this notice, the regulatory alternatives discussed above, and other alternatives to address the risk of injury;

2. An existing standard or portion of a standard as a proposed rule;

3. A statement of intention to modify or develop a voluntary standard to address the risk of injury identified in the notice along with a description of a plan to modify or develop the standard.

In addition, the Commission is interested in obtaining further information that could assist its development of an appropriate amendment. Thus, the Commission seeks comments on the following issues.

1. Guidance on defining "tight fitting garments" and "garments intended for infants."

2. The need for labeling on any tight fitting or infant garments that could be exempted from the children's sleepwear standards.

3. Potential economic effects of the alternatives discussed in this notice on manufacturers, retailers, and consumers of children's sleepwear.

4. The percentage of sales of children's sleepwear that are loose fitting garments and that are tight fitting.

5. The number of U.S. sleepwear manufacturers who sell their products in Canada.

6. Description of consumer trends toward non-traditional cotton sleepwear for children.

All comments and submissions should be addressed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, and received no later than March 15, 1993.

D. Stay of Enforcement

Elsewhere in this issue of the Federal Register the staff announces its decision to stay enforcement of sleepwear requirements against (1) garments currently being used as sleepwear that are labeled and marketed as underwear if these garments are skin-tight or nearly skin-tight and (2) garments that are essentially identical in design, material, and fit to such "underwear" garments.

Dated: January 4, 1993.

Sadye E. Dunn,

Secretary, Consumer Project Safety Commission.

References

The following documents contain information relevant to this rulemaking proceeding and are available for inspection at the Office of the Secretary, Consumer Product Safety Commission, room 420, 5401 Westbard Avenue, Bethesda, Maryland:

1. Memorandum from Liz Gomilla, Division of Regulatory Management and Eric Stone, Division of Administrative Litigation, to Terrance R. Karels, Project Manager, dated March 13, 1992, entitled Problems Associated with Enforcement of the Children's Sleepwear Standards.

2. Memorandum from Bea Harwood and Terry L. Kissinger, EPHA, to Terrance R. Karels, Project Manager, dated April 20, 1992, entitled Injury Data Related to the Sleepwear Flammability Standards and Information on Surveys of Burn Treatment Centers. ECPA, dated May 6, 1992, entitled Final Report, Children's Sleepwear Project.

3. Memorandum from Linda Fansler, ESME, to Terrance R. Karels.

4. Memorandum from Anthony C. Homan, ECPA, to Terrance R. Karels, Project Manager, dated March 25, 1992, entitled Market Sketch—Children's Sleepwear.

5. Briefing Memorandum from Terrance R. Karels to the Commission, dated November 3, 1992.

[FR Doc. 93–778 Filed 1–12–93; 8:45 am]
BILLING CODE 6355–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 4

Extension of Time Limit in Which to File Vessel Repair Documents

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Customs Regulations to extend the time limit allowed to vessel operators to file documentation submitted in connection with vessel repair entries, to include applications for relief from the assessment of duties under the vessel repair statute. It is also proposed that any shipyard cost estimates available be submitted at the time that a vessel repair entry is made.

DATES: Comments must be received on or before March 15, 1993.

ADDRESSES: Written comments (preferably in triplicate) may be addressed to the Regulations and Disclosure Law Branch, Franklin Court, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Bruce Friedman, Office of Trade Operations, 202–343–0024 (operational matters), or Larry L. Burton, 202–482–6940 (legal matters).

SUPPLEMENTARY INFORMATION:

Background

Section 1466 of title 19 of the United States Code provides that a duty of 50 per cent ad valorem shall be assessed upon the value of repairs accomplished outside of the United States on certain American-flag vessels. The statute itself, as well as numerous judicial and administrative interpretations, provides exceptions to the assessment of duty under specific circumstances.

The statutory mandate is implemented in § 4.14 of the Customs Regulations (19 CFR 4.14), which provides the necessary working guidelines for Customs as well as vessel operators. Among the matters set forth in § 4.14 are the procedures for making entry and for seeking administrative refund or remission of assessed duty. It is required that American-flag vessels submit a vessel repair entry to Customs

within 5 working days after arrival from a foreign port following any shipyard work. Depending upon whether actual shipyard invoices are available at the time an entry is submitted, the regulations provide that such entry may be denominated either a complete or incomplete submission.

The regulations currently provide that, absent the grant of an extension, in the case of incomplete entries documents providing a full and complete account of foreign shipyard costs incurred must be submitted to Customs within 60 days from the date of vessel arrival in the United States (19 CFR 4.14(b)(2)(ii)). Vessel repair liquidation units may extend this time by 30 days. Additional extensions must be approved by Customs Headquarters.

Comments have long been heard from vessel operators that the matter of final charges is frequently the subject of negotiation between themselves and foreign shipyards. It is claimed that this process often makes it impossible to meet the regulatory submission deadline without the necessity of seeking an extension from Customs. Customs has been reluctant to extend the filing period, recognizing that extending the period for the gathering of all evidence has the inevitable effect of delaying the eventual collection of the revenue. It appears, however, that such a delay already exists owing to the large number of operators seeking extensions, and that a savings to both vessel operators and Customs may be realized by not having to process numerous requests for extension. Customs is proposing, therefore, to extend the filing period from the current 60-day limit to a period of 90 days.

Customs is taking this opportunity to propose an additional amendment to the vessel repair regulations. In the case of vessel repair entries submitted as incomplete accounts, Customs requires that the best estimate of foreign repair costs must be provided pending receipt of actual final invoices. Such statements of cost are used to calculate the amount of the bond or duties estimated that must be deposited with Customs prior to departure of vessels from port.

It has been noted that, on some occasions, final invoice amounts are wildly divergent from initially estimated costs, and the revenue may be inadequately protected by small deposits or bonds. It is also known that, in many cases, estimates from foreign shipyards have been submitted to vessel operators prior to the commencement of repair operations. This is nothing more than sound business practice. Customs merely proposes to require that, when an estimate has been submitted to a vessel operator, the estimated cost filed at the time of submission of an incomplete vessel repair entry must reflect that estimate.

In addition, a cross reference to the bond provisions in part 113, not revised when that part was revised, is corrected.

Comments

Before adopting this proposal, consideration will be given to any written comments timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations and Disclosure Law Branch, U.S. Customs Service, Franklin Court, suite 4000, 1099 14th St., NW., Washington, DC.

Regulatory Flexibility Act

For the reasons set forth in the preamble and pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that, if adopted, the proposed amendments will not have a significant economic impact on a substantial number of small entities. Accordingly, they are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified in E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Drafting Information

The principal author of this document was Larry L. Burton, Carrier Rulings Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 4

Customs duties and inspection, Reporting and recordkeeping requirements, Vessels.

Proposed Amendments

Accordingly, it is proposed to amend § 4.14 Customs Regulations (19 CFR 4.14), as set forth below.

PART 4—VESSELS IN FOREIGN AND DOMESTIC TRADES

The general authority citation for part 4 and the relevant specific authority citation for § 4.14 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1624; 46 U.S.C. app. 3;

* * * * *

Section 4.14 also issued under 19 U.S.C. 1466, 1498;

* * * * *

§ 4.14 [Amended]

2. Section 4.14, paragraph (b)(1) is proposed to be amended by removing the reference "§ 113.14(m)" and adding, in its place, "§ 113.13".

§ 4.14 Foreign equipment purchases by, and repairs to, American vessels.

* * * * *

(b) * * *

(2) * * *

3. Section 4.14, paragraph (b)(2) introductory text, is proposed to be amended by adding a new fifth sentence to read as follows: * * * Estimated foreign shipyard costs in the possession of or known to the vessel operator at the time of filing the entry must be submitted with an entry marked as an incomplete account.

* * * * *

4. Section 4.14, paragraphs (b)(2)(ii), (b)(2)(ii)(B), and (d)(1)(ii), is proposed to be amended by removing the number "60" where it appears, and adding, in its place, the number "90".

Carol Hallett,

Commissioner of Customs.

Approved: January 4, 1993.

Peter K. Nunez,

Assistant Secretary of the Treasury.

[FR Doc. 93-470 Filed 1-12-93; 8:45 am]

BILLING CODE 4820-02-M

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19 CFR Part 142

Publication of Filer Codes and the Names of Individuals, Brokers or Importers Assigned the Codes

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: This document gives advance notice of a proposal to amend the Customs Regulations to provide for the publication of a list of filer codes and the identity of individuals, licensed Customs brokers or importers assigned the specific number. This publication will improve control for various components of the trade community and reduce numerous questions and problems for Customs relating to entry processing requirements, but could also provide a means to access commercial import information heretofore treated as confidential by Customs.

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DATES: Comments must be received on or before March 15, 1993.

ADDRESSES: Comments (preferably in triplicate) may be submitted to the Regulations and Disclosure Law Branch, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Deann Seckler, Entry Rulings Branch, (202) 482–7040.

SUPPLEMENTARY INFORMATION:

Background

Customs has undertaken numerous initiatives relating to the development and implementation of a comprehensive integrated Automated Commercial System (ACS). Since its inception ACS has enabled Customs and the trade community to more efficiently control the flow of imported merchandise into the United States. The ACS procedure was a significant departure from the manual processing of Customs entries. The program has evolved over the past 20 years and certain changes to procedures originally developed have been modified in response to agency and trade community needs.

T.D. 85–122 describes certain entry procedures required by the ACS, including the identification of an entry filer code, which became effective October 1, 1985. The entry filer code is a unique 3 character (alphabetic, numeric, or alphanumeric) code which is assigned to all licensed broker companies currently filing Customs entries and importers currently filing a significant number of entries on a regular basis. Entry filer codes are not assigned to intermittent importers. The entry preparer uses this code nationwide as the beginning 3 characters of the number for all Customs entries, regardless of where the entries are filed.

As a result of trade community concerns, Customs proposes to publish a list of filer codes and the identity of individuals, licensed Customs brokers or importers assigned that number. This new publication will improve control for various components of the trade community and reduce numerous questions and problems for Customs relating to entry processing requirements.

Because publication of the filer codes and the names could provide a means for the public to gain access to commercial information regarding import transactions which Customs has heretofore treated as confidential, under the Trade Secrets Act (18 U.S.C. 1905) and the Freedom of Information Act (5 U.S.C. 552(b)(4)), Customs is soliciting the views of interested parties. Specific requests for this proposal have been initiated by the National Customs Brokers and Forwarders Association of America, sureties, and others.

Comments

In order to assist Customs in determining whether to proceed with this proposal, this notice invites written comments. Consideration will be given to any written comments that are timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), section 1.4, Treasury Department Regulations (31 CFR 1.4), and section 103.11(b), Customs Regulations (19 CFR 103.11(b)), during regular business days between the hours of 9 a.m. and 4:30 p.m., at the Regulations and Disclosure Law Branch, Franklin Court, 1099 14th Street, NW., suite 4000, Washington, DC.

Carol Hallett,

Commissioner of Customs.

Approved: December 24, 1992.

John P. Simpson,

Acting Assistant Secretary of the Treasury.

[FR Doc. 93–779 Filed 1–12–93; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 92N–0382]

Gastroenterology-Urology Devices; Effective Date of Requirement for Premarket Approval of Testicular Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of product development protocol (PDP) for the testicular prosthesis, a medical device. The agency is also summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the statute's approval requirements and the benefits to the public from the use of the device. In addition, FDA is announcing an opportunity for interested persons to request that the agency change the classification of the device based on new information. This action is a followup to FDA's notice of intent published in the **Federal Register** of January 6, 1989 (54 FR 550).

DATES: Written comments by March 15, 1993; requests for a change in classification by January 28, 1993. FDA intends that if a final rule is issued, based on this proposed rule, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mark D. Kramer, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1194.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. For the sake of convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as "preamendments devices."

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved premarket approval application (PMA) until 90 days after FDA's promulgation of a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act (21 U.S.C. 360c), whichever is later. Also, a preamendments device is not required to have an approved investigational device exemption (IDE) (21 CFR part 812) contemporaneous with its commercial distribution until the date

identified by FDA in the final rule requiring the submission of a PMA for the device.

Section 515(b)(2)(A) of the act provides that a proceeding to promulgate a final rule to require premarket approval shall be initiated by publication in the Federal Register of a notice of proposed rulemaking containing: (1) The proposed rule, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity for the submission of comments on the proposed rule and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that, if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, promulgate a final rule to require premarket approval or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or a notice of completion of a PDP for any such device be filed within 90 days of the date of promulgation of the final rule or 30 months after final classification of the device under section 513 of the act, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). FDA has in the past requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for testicular prostheses.

The act does not permit an extension of the 90-day period after promulgation of a final rule within which an application or a notice is required to be filed. The House Report on the amendments states that "the thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval." (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).

A. Classification of the Testicular Prosthesis

In the Federal Register of November 23, 1983 (48 FR 53012 at 53024), FDA issued a final rule classifying the testicular prosthesis into class III (§ 876.3750 (21 CFR 876.3750)). The preamble to the proposal to classify the testicular prosthesis (46 FR 7580, January 23, 1981) included the recommendation of the Gastroenterology-Urology Devices Panel (the Panel), an FDA advisory committee, which met on September 26 and 27, 1976, regarding the classification of the device. The Panel recommended that the device be in class II, but identified certain risks to health presented by the device. FDA disagreed with the Panel's recommendation and proposed that the testicular prosthesis be classified into class III. The proposal stated that the agency believed that insufficient information existed to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device or to establish a performance standard to provide this assurance. The proposal stated that premarket approval is necessary for this device because it presents a potential unreasonable risk of injury due to: (1) Possible migration of silicone gel from the interior of the prosthesis to adjacent tissue (with or without rupture of the silicone elastomer shell); and (2) possible long-term toxic effects of the silicone polymers from which the prosthesis is fabricated. In support of its proposal to strengthen regulatory surveillance of the device, FDA cited references supporting the proposed classification.

In the Federal Register of April 7, 1981 (46 FR 20687), the agency reopened the comment period for the proposed regulation classifying this device for an additional 60 days. This additional 60-day comment period was established because the proposed classification regulation for the testicular prosthesis had stated incorrectly that the Panel recommended that the device be classified into class III, rather than class II. In the Federal Register notice of April 7, 1981, FDA announced that on April 13, 1981, a meeting of the Panel would be held. During this meeting, the Panel reviewed all comments, and again recommended that the testicular prosthesis be classified into class II. No other comments were received during the remainder of the comment period. Again, FDA disagreed with the Panel's recommendation and proposed that the testicular prosthesis be classified into class III. FDA searched the medical literature and further documented the risks to health resulting from silicone implants.

The preamble to the November 23, 1983 final rule (48 FR 53012) classifying the device advised that the earliest date by which PMA's for the device could be required was June 30, 1986, or 90 days after promulgation of a rule requiring premarket approval for the device, whichever occurs later.

In the Federal Register of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval of 31 preamendments class III devices assigned a high priority by FDA for the application of premarket approval requirements. Among other things, the notice described the factors FDA takes into account in establishing priorities for proceedings under section 515(b) of the act for promulgating final rules requiring that preamendments class III devices have approved PMA's. Using those factors, FDA has determined that the testicular prosthesis identified in § 876.3750 has a high priority for initiating a proceeding to require premarket approval. Accordingly, FDA is commencing a proceeding under section 515(b) of the act to require that the testicular prosthesis has an approved PMA.

B. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for the testicular prosthesis within 90 days after promulgation of any final rule based on this proposal. An applicant whose device was in commercial distribution before May 28, 1976, or has been found by FDA to be substantially equivalent to such a device, will be permitted to continue marketing the testicular prosthesis during FDA's review of the PMA or notice of completion of the PDP. FDA intends to complete the review of any PMA for the device within 180 days and a notice of completion of a PDP within 90 days. FDA cautions that, under section 515(d)(1)(B)(i) of the act, FDA may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that "* * * the continued availability of the device is necessary for the public health."

FDA intends that, under 21 CFR 812.2(d), the preamble to any final rule based on this proposal will state that, as of the date on which a PMA or notice of completion of a PDP is required to be filed, the exemptions in 21 CFR 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any testicular prosthesis which is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA or PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for the testicular prosthesis is not filed with FDA within 90 days after the date of promulgation of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period to avoid interrupting investigations.

C. Description of the Device

A testicular prosthesis is an implanted device that consists of a solid or gel-filled silicone rubber prosthesis that is implanted surgically to resemble a testicle.

The proposed rule to require premarket approval of testicular prostheses applies only to legally marketed testicular prostheses identified above that were commercially distributed before May 28, 1976, and to devices introduced into commercial distribution since that date that have been found to be substantially equivalent to such testicular prostheses.

D. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring the testicular prosthesis to have an approved PMA or PDP, and (2) the benefit to the public from the use of the device.

E. Degree of Risk

On April 13, 1981, the Panel met to review and consider all comments that were submitted to FDA on the proposed regulation to classify testicular implants into class III. During this meeting the panel reviewed all comments and again recommended that the testicular prosthesis be classified into class II. Again FDA disagreed with the Panel's recommendation and proposed that the testicular prosthesis be classified into class III.

Because the silicone gel-filled testicular prosthesis is similar in materials and construction to the silicone gel-filled breast prosthesis (Refs. 1 through 3), many of the risks associated with the use of the silicone gel-filled breast prosthesis may also be associated with the use of the silicone gel-filled testicular prosthesis. Additionally, several of these risks may also be associated with the use of the solid silicone rubber testicular prosthesis. FDA has now determined that the following are significant risks associated with the use of either the solid or the gel-filled silicone rubber testicular prosthesis:

1. *Extrusion/erosion of the testicular prosthesis.* Extrusion and erosion of the testicular implant through the scrotal wall are among the most common complications associated with the use of these devices. Prosthesis extrusion is usually associated with concurrent wound dehiscence in instances where the device was inserted through a scrotal incision (Refs. 1, 4 through 8). Skin erosion has been reported following implantation of the testicular prosthesis due to the presence of a Dacron suture tab (Refs. 6, 8, and 9), insertion of an oversized device (Ref. 5), or aggressive dissection of the subdartos pocket (Ref. 10), and could result in subsequent infection or device extrusion. Beer and Kay (Ref. 11) suggest that the rate of extrusion due to wound dehiscence alone is between 3 and 8 percent.

2. *Displacement of the testicular prosthesis.* Displacement or migration is another commonly reported adverse event. The prosthesis can migrate to a variety of locations within the body, including in front of or behind the contralateral testis or above the scrotum. Displacement can be caused by either inadequate scrotal distension prior to insertion or improper surgical placement/fixation (Refs. 4, 5, and 12).

3. *Fibrous capsular contracture.* Fibrous capsular contracture, the formation of a constricting fibrous layer around the prosthesis, has been associated with the presence of testicular implants (Ref. 6). Capsular contracture may result in excessive scrotal firmness, discomfort, pain, disfigurement, and displacement of the implant.

Although the etiological factors of capsular contracture have not been reported with testicular implants, several factors have been suggested with the breast implant, including hematoma, infection, and foreign body reaction. Despite these reports, no single factor has been demonstrated to be the sole cause of contracture. The etiology of contracture is not understood (Refs. 13 through 18).

4. *Infection.* Infection, a risk of any surgical implant procedure, is associated with the use of testicular implants (Refs. 4, 6, 7, 8, 11, 12, 19, and 20). As in any implantation procedure, compromised device sterility and surgical techniques may be major contributing factors to this risk. Usually, the occurrence of infection necessitates the removal of the prosthesis (Refs. 6, 7, 8, 20, and 21). It has been suggested with the silicone gel-filled breast prosthesis that infection may also contribute to the early development of capsular contracture (Refs. 14, 15, 16, 22, and 23).

5. *Human carcinogenicity.* Carcinogenesis has been widely discussed as a reputed risk secondary to implantation of any material. Evidence from the literature indicates that, in animal studies, different forms of silicone have been associated with various types of cancer (Refs. 24 through 28). Cases of several types of cancer in humans have been reported in association with various forms of

implanted silicone (Refs. 29 through 32).

6. *Human reproductive and teratogenic effects.* The effect of certain silicone compounds on the reproductive potential of the male is largely unknown. Le Vier and Jankowiak report that at least one form of organosiloxane, which is known to be present in some silicone gels, mimics estrogens in the male rat, leading to rapid testicular atrophy (Ref. 36).

Teratogenesis includes the origin or mode of production of a malformed fetus and the disturbed growth processes involved in the production of a malformed fetus. Studies using silicone fluid in animals have been minimal, and yield contradictory and inconclusive results (Refs. 33 through 35). Prolonged contact with either the solid silicone device, or the silicone gel-filled membrane and its components, presents a potential risk of teratogenicity in humans.

The risk of adverse reproductive and teratogenic effects from testicular implants exists only in the subset of patients who have a single prosthesis with a remaining functional testicle.

7. *Immune related connective tissue disorders—immunological sensitization.* Immunological sensitization may be a serious risk associated with the implantation of a testicular prosthesis. Immune related connective tissue disorders have been reported in women who have silicone gel-filled breast prostheses or who have had silicone injections in augmentation mammoplasty. There are clinical reports of several patients who have undergone augmentation mammoplasty with silicone gel-filled breast prostheses and later presented with connective tissue disease-like syndromes (Ref. 37). Because testicular prostheses consist of similar silicone elastomers and gels, further study of the potential risk of immune related connective tissue disorders in humans with these implants is warranted.

8. *Biological effects of silica.* Amorphous (fumed) silica is bound to the silicone in the elastomer of the testicular prosthesis, and may be fibrogenic and immunogenic. Fumed silica and the silicone shell each elicit cellular responses in rats (Ref. 38). The biological effects of silica, particularly the immunologic component of these reactions, present a potential risk and need to be examined.

9. *Silicone gel leakage and migration.* This potential risk pertains only to the gel-filled silicone rubber testicular prosthesis. Silicone gel leakage and migration from the silicone elastomer envelope, either from rupture of the envelope or by leaking of the gel through the envelope (gel "bleed"), are also significant risks of silicone gel-filled testicular prostheses. Rupture of the envelope with gel leakage and subsequent migration may be secondary to surgical technique or mechanical stresses, such as routine manual massage, trauma, and wear on the envelope, and necessitates removal of the prosthesis. In addition to the above, silicone gel-filled breast implants, which are similar to testicular implants in materials and construction, are reported to "bleed" micro amounts of silicone through the intact silicone elastomer shell into the surrounding tissues (Refs. 39 through 48). Although diffusion of silicone gel through the elastomer shell has not specifically been measured in the testicular prosthesis, gel bleed continues to be a possible risk with this device and needs to be evaluated. Migration of the gel into the human body presents the potential for development of adverse effects such as granulomas or lymphadenopathy (Refs. 29 and 30). The ultimate fate of migrating silicone gel within the body is currently not well understood.

10. *Degradation of polyurethane foam.* This potential risk is associated only with those testicular prostheses that are covered with polyurethane foam. The polyurethane foam material that has been used to cover some testicular prostheses is known to degrade over time with a potential breakdown product of 2,4 diaminotoluene (TDA), a known carcinogen in animals (Refs. 49 through 54). The fate of the degraded product in vivo is unknown to date, and the use of this material in testicular implants may have been discontinued (Ref. 6). Case reports of the polyurethane foam covered silicone gel-filled breast implant indicate that there is greater difficulty with the removal of this type of prosthesis due to a fragmented polyurethane shell and/or capsular tissue ingrowth (Refs. 55 through 61). Foreign body responses have been reported concurrent with the use of the polyurethane foam covered testicular prosthesis in humans (Ref. 6).

F. Benefits of the Device

The testicular prosthesis is intended to simulate the presence of a testicle within the male scrotum, and it is indicated in subjects who are missing one or both testes due to either congenital or acquired reasons. Testicular prosthesis implantation is a discretionary surgical procedure performed for psychological, rather than for other medical reasons.

Testicular prostheses are commonly used to correct congenital anomalies in young males who are born without one or both testicles (i.e., testicular agenesis or atrophy) (Refs. 6, 19, and 62 through 64). Additionally, such devices are often implanted subsequent to removal of one or both testes for one of several reasons: Malignant cancer of the prostate, testicular cancer, testicular torsion, cryptorchidism, failed orchiopexy, epididymitis/orchitis, or testicular trauma (Refs. 4, 6, 12, and 65 through 68).

Men facing orchiectomy (removal of the testicles) may experience depression that accompanies this degenerative change in body image. Such feelings of depression have been equated to the experiences of women who have undergone mastectomy or hysterectomy (Refs. 6, 8, and 19). Shame and feelings of inferiority are common, and can lead to anxiety, personality changes, changes in one's customary life style, fear of sexual rejection, and psychogenic impotence (Refs. 5 through 8, 11 and 69). It has also been reported that a visible defect in a child's genital region may result in feelings of inferiority, leading to social isolation. Such occurrences may produce psychological problems, and they may have an effect upon the child's emotional development and sexual identity (Refs. 2, 3, 5 through 8, 11, 63, and 70). Implantation of a testicular prosthesis may help to alleviate such feelings in males of all ages, thereby improving quality of life (Refs. 69, 71, and 72). The studies which have been published indicate that recipients of testicular prostheses exhibit a high degree of satisfaction with their surgery (Refs. 2, 67, and 73). However, these conclusions regarding the psychological benefit of the testicular prosthesis are neither quantitative, nor were they measured using established standardized tests.

G. Need for Information for Risk/Benefit Assessment of the Device

As the above sections indicate, there is reasonable knowledge of the risks and benefits associated with the testicular prosthesis. There is, however, insufficient valid scientific evidence to permit FDA to perform a risk/benefit analysis. Therefore, FDA is now seeking further information on the following safety and effectiveness issues associated with the testicular prosthesis:

1. Long-term effectiveness data for the device is needed. The incidence of implant failure and attendant causes, as well as the incidence of reoperations required, have not been clearly identified. Such device failures include, but are not limited to: Implant

migration, extrusion, and erosion. Also, the incidences of infection, hematoma, pain/discomfort, and penile and scrotal edema secondary to testicular prosthesis implantation are poorly understood. This information is necessary in order to perform an appropriate risk/benefit analysis.

2. The incidence of fibrous capsular contracture must be clarified. It is not clear what methods are used in the prevention and treatment of capsular contracture in patients with testicular implants, nor is it clear how these approaches may reduce the risks associated with use of this device.

3. For the gel-filled silicone rubber testicular prosthesis, the potential risks associated with silicone gel leakage and its subsequent migration need further clarification. This should include consideration of gel cohesiveness, envelope thickness/strength, diffusion of the gel through the envelope (gel "bleed"), and the role that physical, mechanical, and chemical characteristics of silicone elastomers and gels play in the immediate or long-term rupture of testicular implants.

4. Data from both long-term clinical studies and mechanical testing are needed to determine the incidence of rupture/fracture and its relationship to the physical characteristics, e.g., tensile strength and compressive cyclic fatigue strength, of the device.

5. The potential long-term adverse effects of testicular implants, such as cancer, immune related connective tissue disorders, and reproductive and teratogenic effects, are unknown. Likewise, in the polyurethane foam covered testicular prosthesis, the long-term effects of the polyurethane foam (such as mechanical integrity and carcinogenicity) are also not understood. The agency notes that neither the particles, which may be shed from the shell (Refs. 18 and 74), nor the chemical forms of silicone monomers or other additives, which may leach from the shell, have been characterized, and their metabolic fates are not known (Ref. 33). Furthermore, no satisfactory independent study has thoroughly evaluated the chronic long-term toxicology of crosslinked silicone polymers of different molecular sizes. Because young males, including infants, are the recipients of a significant percentage of these implants, information regarding the chronic toxic effects, including possible reproductive and teratogenic effects of silicone, could be of substantial importance in determining the risk to these patients.

6. The immediate post-surgical and long-term psychological benefits of the device, as compared to pre-surgical levels, need to be examined and quantified. In order to document the benefits of scrotal construction/restoration with testicular prostheses, such factors as patient satisfaction, improved self-image, and improved psychological outlook, need to be studied using well established standardized tests.

FDA believes, therefore, that the testicular prosthesis should undergo premarket approval to determine whether the risks of using the device are adequately balanced by its benefits.

II. PMA Contents

Any PMA for the device must include the information required by section 515(c)(1) of the act and the implementing provisions under 21 CFR 814.20. Such a PMA shall include a detailed discussion, accompanied by the results of applicable preclinical and clinical studies, of the above identified risks and the effectiveness of the device. In particular, the PMA shall include all known or otherwise available data and other information regarding: (1) Any risks known to the applicant that have not been identified in this document, and (2) the effectiveness of the specific testicular prosthesis that is the subject of the application (or, if adequate justification can be provided, applicable effectiveness information for other testicular prostheses). Valid scientific evidence, as defined in 21 CFR 860.7, addressing the safety and effectiveness of the device should be presented, evaluated and summarized in a section or sections of the PMA separate from known or otherwise available safety and effectiveness information that does not constitute valid scientific evidence (e.g., isolated case reports, random experiences, etc.).

A. Manufacturing Information

All manufacturing information for the device should be completely described. The information should include, but not necessarily be limited to, the chemical formulation and manufacturing procedures and processes, presented in a step-by-step manner from the starting materials to the finished product, including, but not limited to, all nonreactants and reactants (including intermediate precursors) for the outer shell, patch, internal gel, suture tab, and polyurethane foam covering (if applicable). A complete master list of the common chemical names and alternate names (manufacturer's trade name or code) for all nonreactants, reactants (including intermediate precursors) and products should be provided. Chemical characterization of the elastomer intermediates, outer shell, patch, internal gel, suture tab, and polyurethane foam covering (if applicable) sufficient to demonstrate control of the chemical processing of the device materials should be provided. This should be based on lot-to-lot comparisons of the following information: (1) The molecular weight distribution, expressed as weight average molecular weight (Mw), number average molecular weight (Mn), peak molecular weight (Mp), Z average molecular weight (Mz), polydispersity (MWD), and viscosity average molecular weight (Mv) of these precursors; (2) the results of analyses for residual levels of volatile and nonvolatile cyclic compounds; and (3) a comparison of viscosity, number average molecular weight, and percent volatiles on a single graph. Documentation establishing the extent of crosslinking in the shell material, or the silicone-hydride and vinyl content of crosslinked shell material, as well as the particle size of the silica if present in the shell, patch, or gel should be provided. The standard operating procedures for sterility and materials qualifications should be included.

B. Preclinical Data

Complete identification and quantification of all chemicals, including residual cyclics and oligomers, extractable from each of the individual structural components (outer shell, patch, internal gel, suture tab, and any other materials) as they are found in the final sterilized device should be reported. The solvents used for extraction should have varying polarities and should include, but not be limited to: ethanol, ethanol/saline (1:9), and dichloromethane. Other, more contemporary extraction techniques, such as analytical-scale supercritical fluid extraction, also may be useful, at least for exhaustive extraction of the silicone materials. Experimental evidence must be provided that exhaustive extraction is achieved with one of the selected solvents, and the percent recovery, especially for the more volatile components, reported. The molecular weight distribution of the extract should also be provided along with the number and weight average molecular weight, and polydispersity. All experimental methodology must be described, and raw data (including instrument reports) provided along with all chromatographs, spectrograms, etc. The limit of detection (2X noise level) must be provided when the analyte of interest is not detected. Laboratory test methods and animal experiments used in the characterization of the physical, chemical (other than exhaustive

extraction) and mechanical properties of the device should be applicable to the intended use of the device in humans. Information relevant to the distribution and metabolic fate of silicone and any other materials used in the manufacturing of the device should be supplied.

All physical and chemical properties of the device should be completely characterized, using a statistically valid number of samples per test. These properties should include, but not necessarily be limited to, tensile, fatigue and shear strengths, elastic modulus, and chemical properties of the sterilized finished device. These tests should include the following specific methods or their equivalent: ASTM Test Method D412 to measure ultimate elongation and total energy to rupture of the outer shells, patches, and other elastomeric components that comprise either the lumen (with the gel-filled silicone rubber testicular prosthesis) or the bulk (with the solid silicone rubber testicular prosthesis) of the finished product; ASTM Test Method D624 to determine tear resistance of all elastomeric components, including the patch material; abrasion resistance test of the outer elastomeric component(s); applied pressure at the rate of 1 Hertz in air versus number of cycles (S/N) curve, constructed on the basis of cyclical compression testing of intact sterilized devices; and ASTM Test Method F703 (section 7.2) to test integrity of adhered or fused joints. A complete report of the cohesivity testing of the gel must also be reported for the gel-filled silicone rubber devices.

For the silicone gel-filled testicular prostheses, the gel bleed performance of the shell (including patch materials in separate testing), determined from the results of measurements using a standard diffusion cell maintained slightly below body temperature (i.e., 35° C) and using stirred, physiologic saline as a receptacle medium for the bleed, must be reported. Each variation in shell thickness or design must be measured to accurately determine diffusion coefficients (with appropriate time dependencies). The chemical identification of the bleed product, including molecular weight distribution, must be reported.

Toxicological effects (e.g., cytotoxicity, mutagenicity, suppression of the immune system, allergenicity, and reproductive and developmental toxicity) should be identified. Complete mutagenicity testing of each chemical extracted from the finished, sterilized components of the device should include the following tests: Bacterial mutagenicity, mammalian mutagenicity, DNA damage, and cell transformation assay.

Acute, subchronic and chronic toxicity studies using the chemicals recovered by the above exhaustive extraction processes should be provided in the evaluation of long-term biocompatibility of the device, including dose response and time to response as well as gross and histopathological findings in tissues both surrounding implants and distal to implant sites (lymph nodes, contralateral testis, prostate, bladder, liver, kidneys, lungs, etc.). Animal studies of chronic toxicity, carcinogenicity, reproductive toxicity, teratogenicity and later effects on offspring should be performed using scientifically justified test methods. This must include animal testing of the individual compounds extracted from the final sterilized device. In particular, a subset of these studies must test the compounds extracted from the materials of the sterilized device for estrogen-like antigonadotropic activity in an appropriate animal model using scientifically valid methods. Teratology/reproductive testing of the final sterilized device and extractables should be performed in an appropriate species using validated methods.

Pharmacokinetic/biodegradation studies of all materials contained in the finished device should be reported. Of special concern are questions regarding the ultimate fate, quantities, sites/organs of deposition, routes of excretion, and potential clinical significance of silicone retention and migration.

For the polyurethane foam covered designs, FDA believes that in vivo implant studies must be performed to identify and determine the bioabsorption, distribution, and elimination of the polyurethane coating (as well as their degradation products) in experimental animals. It is also important to identify and determine the mechanism and rate of degradation, as well as the quantity of TDA generated by the breakdown of polyurethane foam covered testicular prostheses after prolonged exposure under in vivo conditions in animals. Additionally, the agency recommends that retrospective epidemiological and prospective clinical studies be designed to assess the potential of cancer and other long-term complications related to polyurethane foam covered testicular prostheses in humans. The agency suggests that these preclinical and epidemiological studies be conducted as a separate subset of testicular implant safety studies.

C. Clinical Data

Valid scientific evidence should include well-controlled clinical studies, with detailed long-term followup, in order to provide reasonable assurance of the safety and effectiveness of the testicular prosthesis. Such studies should include data on time course presentations of clinical data demonstrating the presence or absence of device migration, skin erosion, implant extrusion, rupture, fibrous capsular contracture, infection, or any other adverse health event, including any effects on the immune system (both local to the device and systemic) and the reproductive system, without regard to the device relatedness of the event. The diagnostic criteria for each type of immunological and allergic phenomenon should be defined at the beginning of the study and cases should be well documented utilizing these criteria.

A detailed protocol for the clinical trial, with explicit patient inclusion/exclusion criteria and a well-defined followup schedule, should be specified. Any deviations from the protocol should be stated and justified. Time course presentations of patient satisfaction with and psychological benefit from the implantation of this device as well as information on the anatomical effect of this device should be provided. Full patient accounting, including: Theoretical followup (the number of patients that would have been examined if all patients were examined according to their followup schedules); lost to followup, including measures taken to minimize such (with all information obtained on patients lost to followup); time course of revisions, including all explant data; and time course of deaths, should be reported. As part of this, each clinical report should clearly state the date that the database was closed to the addition of new information. Detailed patient demographic analyses and characterizations should be presented, and should show that the patients included in the study are representative of the population intended to receive the device.

A statistical demonstration, based on the number of patients who complete the required study period, should show that the sample size of the clinical study was adequate to provide accurate measures of the safety and effectiveness of this device. The statistical demonstration should identify the effect criteria; reasonable levels for Type I (alpha) and Type II (beta) errors; anticipated variances of the response variables; and provide any assumptions

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or statistical formulas with copies of any references used and all calculations made. A complete description of any patient randomization technique used, and how these techniques were employed to exclude potential sources of bias, should be provided. Statistical justifications for pooling across several variables, such as investigational site, device usage (initial implantation versus revision), type of device (solid or silicone gel-filled, polyurethane foam coated or uncoated), types of device surfaces, device placement, and incision site, should be provided.

Appropriate control/comparison groups should be included and justified and, if not, their absence must be justified. All hypotheses to be tested must be clearly stated. Appropriate statistical techniques must be employed to test these hypotheses and support claims of safety and effectiveness. A sufficient number of patients needs to be followed for a sufficient length of time to adequately support all statistical claims in any PMA submission.

For the polyurethane foam covered prosthesis, the following information also needs to be presented: (1) The kinetics of the end products generated from the degradation of the polyurethane foam (in vivo); (2) the frequency and incidence of infection and complication of retrieval of the implant by surgeons using both polyurethane foam covered and uncoated prostheses in a retrospective cohort study; and (3) the neoplasticity of the material as well as its general toxicity, including neurological, physiological, biochemical, and hematological effects, as well as pathology following prolonged and repeated exposure to polyurethane foam covered testicular prostheses.

Any epidemiological studies should contain enough subjects to detect a small but significant increase in one or more connective tissue diseases (especially scleroderma) that may be associated with the use of the device.

The agency believes that insufficient time has elapsed to permit a direct evaluation of the risks of cancer and immune related connective tissue disorders posed by the presence of silicone in the human body and that sufficient epidemiological data or experimental animal data are not available to make a reasonable and fair judgment. Therefore, the agency will require long-term postapproval followup for any testicular prosthesis permitted to continue in commercial distribution. Well-designed clinical prospective studies with long-term followup, together with experimental animal studies, will be considered as essential in the determination of safety and effectiveness of the device. Further, these clinical studies must collect long-term data on the teratogenic/reproductive effects of the device as well as later effects on offspring (from those patients with a unilateral, functional testicle).

FDA recognizes that the primary benefit of testicular prostheses is cosmetic in nature. The effectiveness of the device is probably the maintenance or enhancement of a male's psychological well-being (Refs. 6 and 7), which can be balanced against any illness or injury from the use of the device. FDA understands that evaluation of the degree of benefit involves an assessment of patient satisfaction and psychological well-being, particularly in light of the function of the device. Such evaluation includes subjective factors, relates to patient expectations, and may be transient in nature.

The evaluation parameters for this portion of the clinical study should be structured for an objective and standardized recording/measurement of the psychological benefit of the device. The primary requirements for an acceptable scientific documentation of psychological benefits of the device are the use of: (1) Prospective research designs, including pre-and post-surgical repeated measures; (2) appropriate control/comparison groups; and (3) standardized test instruments rather than informal, yet-validated questionnaires. Documentation of the psychological consequences of testicular implants shall include: (1) Pre-surgical baseline assessment of psychological status; (2) post-surgical followup of any changes in psychological status for at least 5 years, or until physical maturity of the subject (whichever occurs later); (3) statistical comparison of post-surgical psychological test scores versus pre-surgical test scores within the group of treated patients; (4) statistical comparison of psychological test scores of treated patients versus untreated control patients at all pre-surgical and post-surgical assessment intervals; and (5) correlation of the psychological data with the physical outcomes of the implant procedure. The risk/benefit assessment (as with the entire PMA) must rely on valid scientific evidence as defined in 21 CFR 860.7(c)(2) from well-controlled studies as described in 21 CFR 860.7(f) in order to provide reasonable assurance of the safety and effectiveness of the testicular prosthesis in the surgical correction, restoration, or construction of the male scrotal anatomy.

Applicants should submit any PMA in accordance with FDA's "Premarket Approval (PMA) Manual." The manual is available upon request from the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1901 Chapman Ave., Rockville, MD 20852.

III. Request for Comments With Data

FDA is providing a 60-day period for interested persons to submit to the Dockets Management Branch (address above) written comments regarding this proposal and its findings. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Those wishing to make comments are encouraged to discuss all aspects of the proposed findings regarding the: (1) Degree of risk, illness or injury associated with the use of the testicular prosthesis, (2) experimental, animal, and human studies required in a PMA of the device in order to assess its safety and effectiveness, (3) feasibility of these studies within the time permitted by the act, etc., and (4) benefits to the public from the use of the device.

The comments must discuss in detail, for example, the reasons why important new information on the safety and effectiveness of the device could not feasibly be submitted within the time permitted, or why animal studies may not be available to assess long-term effects such as connective tissue disorders, or that carefully designed epidemiological studies may not be available to evaluate the long-term silicone related illnesses, etc.

CDRH staff are available to provide guidance to manufacturers on any proposed laboratory, animal, or epidemiological studies needed in a PMA or PDP.

IV. Opportunity to Request A Change in Classification

Before requiring the filing of a PMA or PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of the testicular prosthesis is to be in the form of a reclassification petition containing the information required by § 860.123, including new information relevant to the classification of the device, and shall, under section

515(b)(2)(B) of the act, be submitted by January 28, 1993.

The agency advises that to assure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of the testicular prosthesis is submitted, the agency will, by March 15, 1993, after consultation with the appropriate PDA advisory committee and by an order published in the Federal Register, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and § 860.130 of the regulations.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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VI. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect upon the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Economic Impact

FDA has examined the economic consequences of this proposed rule in accordance with the criteria in section 1(b) of Executive Order 12291 and finds that this proposal would not be a major rule as specified in the Order. The agency believes that only a small number of firms will be affected by this proposed rule, and the agency certifies under the Regulatory Flexibility Act (Pub. L. 96–354) that the proposed rule will not have a significant economic impact on a substantial number of small entities. An assessment of the economic impact of any final rule based on this proposal has been placed on file in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Comments

Interested persons may, on or before March 15, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Interested persons may, on or before January 28, 1993, submit to the Dockets Management Branch a written request to change the classification of the testicular prosthesis. Two copies of any comments or requests are to be submitted, except that individuals may submit one copy. Comments or requests are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Comments are encouraged on all aspects of the proposed findings and the recommended PMA Contents.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

2. Section 876.3750 is amended by revising paragraph (c) to read as follows:

§ 876.3750 Testicular prosthesis.

* * * * *

(c) Date premarket approval application (PMA) is required. A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), for any testicular prosthesis that was in commercial distribution before May 28, 1976, or that has on or before (insert date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to the testicular prosthesis that was in commercial distribution before May 28, 1976. Any other

testicular prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

Dated: December 22, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-742 Filed 1-12-93; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[IA-15-92]

RIN 1545-AQ68

TeleFile Voice Signature Test

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations.

SUMMARY: In the Rules and Regulations portion of this issue of the **Federal Register**, the Internal Revenue Service is issuing temporary regulations providing that an individual Federal income tax return completed as part of the TeleFile Voice Signature test will be treated as a return that is signed, authenticated, verified, and filed by the taxpayer as required by the Internal Revenue Code. The temporary regulations affect those taxpayers who are eligible to, and elect to, file their individual income tax returns for the 1992 calendar year by telephone under the test. The temporary regulations are needed to implement the test. The text of the temporary regulations also serves as the comment document for this notice of proposed rulemaking.

DATES: Comments and requests for a public hearing must be received by March 15, 1993.

ADDRESSES: Send comments and requests for a public hearing to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attn: CC:CORP:T:R (IA-15-92), room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Celia Gabrysh (202) 622-4960 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information requirement contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collection(s) of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Office T:FP, Washington, DC 20224.

The collection of information requirement in these regulations is in §§ 1.6012-7T and 1.6061-2T. This information is required by the Internal Revenue Service to implement the TeleFile Voice Signature test. The respondents are those eligible taxpayers that choose to file their income tax returns under the test.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents may require greater or less time, depending on their particular circumstances.

Estimated total annual reporting burden: 11,667 hours.

The estimated average annual burden per respondent: 7 minutes.

Estimated number of respondents: 100,000.

Estimated annual frequency of responses: once.

Background

The temporary regulations published in the Rules and Regulations portion of this issue of the **Federal Register** add new temporary regulations §§ 1.6012-7T, 1.6061-2T and 1.6065-2T to part 1 of title 26 of the Code of Federal Regulations. The temporary regulations provide that an individual Federal income tax return completed as part of the TeleFile Voice Signature test will be treated as a return that is signed, authenticated, verified, and filed by the taxpayer as required by the Internal Revenue Code. For the text of the new temporary regulations, see T.D. 8468 published in the Rules and Regulations portion of this issue of the **Federal Register**. The preamble to the temporary regulations explains the regulations.

Special Analyses

It has been determined that these proposed regulations are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on the regulations' impact on small business.

Comments and Requests for a Public Hearing

Before the adoption of these proposed regulations, consideration will be given to an written comments that are submitted timely (preferably an original and eight copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner of Internal Revenue by any person who also submits timely written comments. If a public hearing is held, notice of the time and place will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Celia Gabrysh of the Office of Assistant Chief Counsel (Income Tax & Accounting), Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in their development.

Proposal of Regulations

The temporary regulations (T.D. 8468) published in the Rules and Regulations section of this issue of the **Federal Register**, are hereby also proposed as final regulations under sections 6012, 6061, and 6065 of the Internal Revenue Code of 1986.

Shirley D. Peterson,

Commissioner of Internal Revenue.

[FR Doc. 93-676 Filed 1-12-93; 8:45 am]

BILLING CODE 4830-01-M

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26 CFR Parts 1, 20, and 25

[PS-102-88]

RIN 1545-AM85

Income, Gift and Estate Tax; Hearing

AGENCY: Internal Revenue Service, Treasury.

ACTION: Rescheduling of the date of public hearing on proposed regulations; change of date to submit requests to speak and outlines of oral comments.

SUMMARY: This document reschedules the date of the public hearing and changes the date to submit requests to

speak and outlines of oral comments on a notice of proposed rulemaking on Income Tax Regulations relating to income tax imposed under chapter 1, the estate tax imposed under chapter 11 and the gift tax imposed under chapter 12 of the Internal Revenue Code of 1986.

DATES: The public hearing will be held on Friday, April 2, 1993, beginning at 10 a.m. Requests to speak and outlines of oral comments must be received by Friday, March 12, 1993.

ADDRESSES: The public hearing will be held in the IRS Auditorium, Seventh floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Requests to speak and outlines of oral comments should be submitted to the Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attn: CC:CORP:T:R [PS–102–88], room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit, Assistant Chief Counsel (Corporate), 202–622–7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION: A notice of public hearing appearing in the **Federal Register** on Tuesday, January 5, 1993 (58 FR 322), announced among other things, that a public hearing relating to proposed regulations relating to income tax imposed under chapter 1, the estate tax imposed under chapter 11 and the gift tax imposed under chapter 12 of the Internal Revenue Code of 1986 would be held Tuesday, March 2, 1993, beginning at 10 a.m. in the IRS Auditorium, Seventh floor, 7400 corridor, Internal Revenue Building, 1111 Constitution Ave, NW., Washington, DC, and that requests to speak and outlines of oral comments should be received by Tuesday, February 16, 1993. The proposed regulations were published in the **Federal Register** on Tuesday, January 5, 1993 (58 FR 305).

There has been a change in the date of the public hearing, and a change of date to submit requests to speak and outlines of oral comments. The hearing will be held on Friday, April 2, 1993, beginning at 10 a.m. The requests to speak and outlines or oral comments must be received by Friday, March 12, 1993. Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the persons testifying. Copies of the agenda will be available free of charge at the hearing.

By direction of the Commissioner of Internal Revenue.

Cynthia E. Grigsby,

Alternate Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 93–660 Filed 1–12–93; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF JUSTICE

Parole Commission

28 CFR Part 2

Paroling, Recommitting, and Supervising Federal Prisoners: Prisoners Transferred to the United States Under Prisoner-Exchange Treaties

AGENCY: United States Parole Commission, Justice.

ACTION: Proposed rule.

SUMMARY: The U.S. Parole Commission is proposing to add to its regulation concerning transfer treaty prisoners a comprehensive interpretation of the relevant federal statutes, with particular regard to the relationship between the "release date" to be determined by the Commission under 18 U.S.C. 4106A, and the "release date" to be determined by the Bureau of Prisons (by calculation of foreign and domestic good time credits) under 18 U.S.C. 4105(c)(1) and 18 U.S.C. 3624(a). The rule is proposed to respond to a recent upsurge of appellate litigation from transfer treaty prisoners seeking to have their good time credits deducted from the "release date" determined by the Commission under 18 U.S.C. 4106A.

DATES: Comments must be received by March 15, 1993.

ADDRESSES: Send comments to Office of General Counsel, U.S. Parole Commission, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815.

FOR FURTHER INFORMATION CONTACT: Richard Preston, Office of General Counsel, telephone (301) 492–5959.

SUPPLEMENTARY INFORMATION: The U.S. Parole Commission has jurisdiction to determine a release date, and a period of supervised release, for any prisoner transferred to the United States under a prisoner-exchange treaty, who committed a crime in the transferring country on or after November 1, 1987. 18 U.S.C. 4106A(b)(1)(A). Such determinations are based upon the treaty obligation of the United States to carry out the conviction and sentence imposed by the foreign court. Transfer treaty prisoners are additionally entitled to the benefit of any good time credits (or the equivalent) earned in the foreign country. After their transfer to the United States, they also receive the benefit of applicable good time credits under U.S. law. Under 18 U.S.C. 4105(c)(1), these combined good time credits are deducted from the foreign sentence to give the prisoner a "release date" pursuant to 18 U.S.C. 3624 (which assigns that responsibility to the U.S. Bureau of Prisons).

The release date established by the Parole Commission under 4106A is made by reference to the applicable sentencing guideline range, as if the prisoner has been convicted of a "similar offense" under U.S. law. This release date is, in some cases, earlier than the release date established by the Bureau of Prisons under 18 U.S.C. 4105(c)(1). See *Hansen* v. *U.S. Parole Commission*, 904 F.2d 306 (5th Cir. 1990). In other cases, the Parole Commission has determined that the prisoner should serve to the release date established by the Bureau of Prisons under 4105(c)(1), especially in cases where the applicable sentencing guideline range requires as much or more prison time than the foreign sentence (less good time credits) will permit. See *Thorpe* v. *Parole Commission*, 902 F.2d 291 (5th Cir. 1990). Transfer treaty prisoners have the right to appeal the Commission's release date determination to a U.S. Court of Appeals. 18 U.S.C. 4106A(b)(2)(A).

In their appellate litigation, many prisoners have asserted that good time credits required by section 4105(c)(1) should be deducted from the release date set by the Commission under 4106A(b)(1)(A). Some prisoners have also argued that 4106A(b)(1)(A) requires that a mandatory minimum term of supervised release provided for certain drug offenders under U.S. laws must also be applied by the Commission in transfer treaty determinations, resulting in a limit on the period of imprisonment which could be imposed by the Commission.

This appellate litigation is the reason for the proposed interpretative rule that appears below. This rule makes clear the Parole Commission's interpretation that Congress did not intend that good time credits should be deducted from the "release date" determined by the Commission under 4106A. Instead, the Commission's construction of the statutes at 4105 and 4106A is that Congress assigned the U.S. Bureau of Prisons its traditional role of determining a mandatory release date by deducting good time credits from the full term of the sentence, and that it assigned to the Parole Commission its

traditional role of establishing a discretionary release date, pursuant to a guideline range, at any point in the sentence up to (and including) the mandatory release date determined by the Bureau of Prisons.

Furthermore, it is the Commission's interpretation of 4106A(b)(1)(A) that Congress never intended that mandatory minimum sentencing provisions apply, in any request, to transfer treaty cases. *Molano-Garza* v. *U.S. Parole Commission*, 965 F.2d 20, 24–5 (5th Cir. 1992). Thus, guideline provisions promulgated by the U.S. Sentencing Commission solely to accommodate mandatory minimum sentencing laws may not be applied by the Commission in a transfer treaty case.

Finally, the rule makes it clear that a period of supervised release will always extend from the release date set by the Commission to the full term of the foreign sentence unless the applicable treaty permits less than full enforcement of the foreign sentence.

This interpretative rule is being published for public comment because it may be viewed as having some substantive impact upon the rights and entitlements of transfer treaty prisoners under the above statutory provisions.

Executive Order 12291 and Regulatory Flexibility Statement

The U.S. Parole Commission has determined that this proposed rule is not a major rule within the meaning of Executive Order 12291. This proposed rule, if adopted, will not have a significant economic impact upon a substantial number of small entities, within the meaning of the Regulatory Flexibility Act, 5 U.S.C. § 605(b).

List of Subjects in 28 CFR Part 2

Administrative practice and procedure, probation and parole, prisoners.

Accordingly, the U.S. Parole Commission proposes the following amendment to 28 CFR part 2.

The Proposed Amendment

(1) The authority citation for 28 CFR part 2 continues to read as follows:

Authority. 18 U.S.C. 4203(a)(1) and 4204(a)(6).

(2) 28 CFR part 2, § 2.62 is proposed to be amended by adding the following new paragraph (l):

§ 2.62 Prisoners transferred pursuant to treaty.

* * * * *

(l) Statutory interpretation. (1) It is the Commission's interpretation of 18 U.S.C. 4106A that every transfer treaty prisoner is entitled to a release date determined by the Commission in accordance with the applicable sentencing guideline range, and that upon release from imprisonment the transferee must serve a period of supervised release extending to the full term of the sentence imposed by the foreign court. However, if the applicable treaty allows the Commission to limit the period of supervised release to the maximum term specified at 18 U.S.C. 3583(b), the combined period of imprisonment and supervised release may be less than the full term of the foreign sentence.

(2) The applicable sentencing guideline range is determined by selecting the offense in the U.S. Code that is most similar to the offense for which the transfer treaty prisoner was convicted in the foreign court, and by using that U.S. Code offense as the basis for calculating a guideline range as though the prisoner has been convicted of that offense in a U.S. District Court. In so doing, the Commission considers itself required by law and treaty to respect the offense definitions contained in the foreign criminal code under which the prisoner was convicted, as well as the documentation supporting that conviction supplied by the foreign court.

(3) The release date that is determined by the Parole Commission under section 4106A(b)(1)(A) is a prison release determination and does not represent the imposition of a new "sentence" for the transfer treaty prisoner. (Nor does the Commission impose a "term of supervised release" as described in 18 U.S.C. 3583.) Because good time credits are only deducted from the prisoner's sentence under 18 U.S.C. 4105(c)(1), good time credits are not deducted from the release date set by the Commission under section 4106A. All foreign and domestic good time credits earned by the transfer treaty prisoner are deducted by the Bureau of Prisons from the full term of the sentence imposed by the foreign court, pursuant to 18 U.S.C. 4105(c)(1) and 18 U.S.C. 3624(a).

(4) If the Commission has set a release date under section 4106(b)(1)(A) that is earlier than the mandatory release date under section 4105(c)(1), then the release date set by the Commission controls. The Commission may, however, determine that the appropriate release date for the prisoner under section 4106A(b)(1)(A) is the mandatory release date earned by application of good time credits from the full term of the foreign sentence, under section 4105(c)(1), if such a decision is found warranted by analogy to U.S.S.G. 5G1.1(a). In such a case, the Commission will order "continue to expiration." If good time credits result in mandatory release date that is earlier than the release date set by the Commission under section 4106A(b)(1)(A), then the mandatory release date controls. Whether the prisoner is released on the date set by the Commission under section 4106A, or on the mandatory release date set by the Bureau under section 4105 and section 3624, the prisoner must complete the remainder of his foreign sentence on supervised release unless the Commission expressly provides otherwise.

(5) It is the Commission's interpretation of section 4106A that sentencing guideline provisions implementing U.S. Code requirements for mandatory minimum sentences and terms of supervised release do not apply in a section 4106A(b)(1)(A) release date determination. Alternatively, it is the Commission's position that there is "good cause" in every transfer treaty case for a departure from any applicable mandatory minimum sentence provision in the sentencing guidelines, including U.S.S.G. § 5G1.1(b), because Congress did not enact mandatory sentence laws with transfer treaty offenders in mind. Thus, in every transfer treaty case, the release date will be determined through an exercise of Commission discretion, according to the sentencing guideline range that is derived from a case-specific "similar offense" determination, rather than by reference to any provision concerning mandatory minimum sentences of imprisonment or terms of supervised release.

* * * * *

Dated: December 8, 1992.

Jasper R. Clay, Jr.,

Vice Chairman, U.S. Parole Commission.

[FR Doc. 93–688 Filed 1–12–93; 8:45am]

BILLING CODE 4410–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 126

[CGD 92–026]

RIN 2115–AE022

Handling of Explosives or Other Hazardous Materials Within or Contiguous to Waterfront Facilities

AGENCY: Coast Guard, DOT.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Coast Guard is considering a major revision to the regulations in 33 CFR part 126 that govern the handling of break-bulk, containerized, and dry bulk hazardous materials on waterfront facilities. Part 126 was written in the 1950's and does not necessarily take into account modern transportation methods. Comments are sought on the changes needed to update these regulations, including the extent to which current industry standards may be appropriate for incorporation.

DATES: Comments must be received on or before April 13, 1993.

ADDRESSES: Comments may be mailed to the Executive Secretary, Marine Safety Council, (G–LRA/3406) (CGD 92–026), U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593–0001, or may be delivered to room 3406 at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477.

The Executive Secretary maintains the public docket for this rulemaking. Comments will become part of this docket and will be available for inspection or copying at room 3406, U.S. Coast Guard Headquarters.

FOR FURTHER INFORMATION CONTACT: Mr. Gary W. Chappell, Office of Marine Safety, Security, and Environmental Protection (G–MPS–3), (202) 267–0491

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this early stage of rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their name and address, identify this rulemaking (CGD 92–026) and the specific section of this notice to which each comment applies, and give the reason for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period, before it acts further on this rulemaking. It may change this proposal in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Marine Safety Council at the address under **ADDRESSES**. The request should include reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Drafting Information

The principal persons involved in drafting this document are Mr. Gary W. Chappell, Project Manager, and Mr. Donald W. Faleris, Project Counsel, Office of Chief Counsel.

Background

The scope of part 126 has been the subject of two related rulemaking projects. One of those projects (CGD 86–034) has been completed and became effective on October 4, 1990. That rulemaking amended part 126 to remove its applicability to all bulk liquid hazardous materials other than 17 specified liquefied gasses. It also relocated to 33 CFR part 154 the regulations governing liquid bulk hazardous materials.

An ANPRM for the second regulatory project (CGD 88–049) was published and a NPRM is being drafted. Among other things under consideration are amendments to part 126 so that it will no longer apply to liquefied gasses in bulk. Also under consideration are amendments to delete from part 126 the requirements for liquid cargo transfer systems, currently contained in § 126.15(o). If the changes under consideration for this second regulatory project are implemented, regulations governing liquefied hazardous gasses handled in bulk will be located in 33 CFR part 127.

Purpose

The proposal set forth in this advance notice of proposed rulemaking would amend the regulations in 33 CFR part 126 which set safety precautions for the handling of explosives and other hazardous materials within or contiguous to waterfront facilities. Part 126 would prescribe specific standards and procedures pertaining to break-bulk, containerized, and dry bulk hazardous materials. Since the part 126 regulations were written in the 1950's and have not been substantially updated, they would be revised to better reflect today's transportation methods, practices, and industry standards. Appropriate industry standards would be incorporated into the regulations. Existing provisions of part 126 would also be modified to ensure consistency with new provisions. This would improve regulatory coherence and clarity.

Approach

By limiting the scope of part 126 to packaged and dry bulk hazardous materials, updating requirements, and incorporating industry standards where appropriate, this proposal would better address the hazards and precautions for these hazardous materials, particularly containerized materials.

The Coast Guard is considering different approaches for regulating the handling of packaged and dry bulk hazardous materials in and contiguous to waterfront facilities. One option would require waterfront facilities handling such hazardous materials to prepare and maintain operations manuals similar to the manuals required for waterfront facilities handling liquid bulk hazardous materials. Although these manuals need not be as comprehensive as those for bulk liquid facilities, they would serve two important functions. First, the operations manual would let the Coast Guard Captain of the Port (COTP) know where hazardous materials are being handled in the port. Currently, a waterfront facility handling only packaged and dry bulk materials is not required to notify the COTP of its intent to operate. Without knowing where hazardous materials are being handled, the COTP cannot monitor operations or plan responses to hazardous material releases. Second, the operations manual would set forth procedures for safely handling hazardous materials and for responding to fires or hazardous material releases. These procedures would protect facility employees, the public, and the environment.

Another option would require waterfront facilities handling packaged and dry bulk hazardous materials to comply with National Fire Protection Association (NFPA) Standard 307. NFPA 307 was developed by a committee representing both industry and government interests, and became effective on August 17, 1990. This standard establishes fire protection design specifications and operating procedures for piers, wharves, terminal buildings, and terminal yards on waterfront facilities. It has been adopted, and is being enforced, by many local governments. Therefore, incorporating NFPA 307 by reference into the regulations contained in part 126 would enhance the uniformity of Federal and local standards.

Regulatory Evaluation

At this early stage of the rulemaking process, the Coast Guard anticipates that any final rule will not be considered major under Executive Order 12291, or significant under the Department of Transportation's Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). Most of the new requirements

would follow industry standards and therefore should not impose a significant cost burden. Some changes, such as pier or wharf construction requirements, could have a considerable economic impact on some facilities. A few facilities may benefit from regulatory changes to the stacking height requirements, which would allow more efficient storage of cargo. However, because regulations have not yet been drafted, and alternative approaches to regulation are being considered, the exact extent of any of these impacts cannot be analyzed at this time. The Coast Guard has taken steps to prepare an economic impact study to assist in evaluating the effects of different regulatory approaches. This information will be used, together with public comments received on this proposal, to prepare a Regulatory Evaluation to assess any economic impacts under Executive Order 12291 and the Department of Transportation's Regulatory Policies and Procedures, given the regulatory approach eventually undertaken.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this proposal, if adopted, will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

At this time, the Coast Guard does not anticipate that this proposal would have more than a minimal impact on any small entity since few small entities own or operate waterfront facilities that would be affected by this rulemaking. If, however, you think that your business qualifies as a small entity and that this proposal may have a significant economic impact on your business, please submit a comment (see "ADDRESSES") explaining why you think your business qualifies and in what way and to what degree this proposal could economically affect your business.

Collection of Information

Under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) reviews each proposed rule that contains a collection of information requirement to determine whether the value of the information is worth the burden imposed by its collection. Collection of information requirements include reporting, recordkeeping, notification, and other similar requirements.

If rules are developed, this proposal may require operators of waterfront facilities to establish and maintain records and operations manuals which detail the facility's procedures and activities relative to handling packaged or dry bulk hazardous materials. However, the Coast Guard is considering a number of alternative approaches to regulation, some of which may not contain collection of information requirements. Therefore, the exact nature of those requirements, if adopted, is not known at this time. Consequently, an estimate of the potential information collection burden, if any, is not yet possible. Persons are encouraged to submit comments on the advisability and potential impact or burden which may result from requiring waterfront facilities to (1) prepare and maintain operations manuals, including policies and procedures relative to handling explosives and other hazardous materials and (2) maintain records on an ongoing basis which detail the hazardous material handling activities of the facility.

Federalism

Given the alternative approaches being considered by the Coast Guard at this time, any rules developed under this proposal are not expected to have sufficient federalism implications to warrant the preparation of a Federalism Assessment in accordance with the principles and criteria contained in Executive Order 12612. States and political subdivisions are not preempted from prescribing safety equipment requirements or safety standards with respect to structures. Thus, if regulations developed under this proposal incorporate existing NFPA or other industry standards which have been adopted and are already enforced by State or local governments, uniformity between Federal and local standards would be enhanced. If, however, you think that this proposal may have federalism implications for State and local governments, please submit a comment (see "ADDRESSES") explaining why you believe this to be so, and in what way and to what degree you think that this proposal would have significant federalism implications.

Environment

The Coast Guard expects any new requirements for packaged and dry bulk hazardous materials would not have a significant effect on the environment, although increased regulation, if undertaken, should promote safe handling of hazardous materials and better preparation of responses to hazardous materials releases, thus better protecting the environment. If rules are developed, the Coast Guard will prepare an Environmental Assessment which will address potential impacts of the rulemaking.

Questions

The Coast Guard is soliciting input from the public regarding all of the options and issues set forth in this advance notice of proposed rulemaking. Comments pertaining to regulatory impacts, such as administrative and economic burdens, paperwork burdens, federalism impacts, and environmental impacts, are encouraged. Suggestions for other possible approaches are also welcome. Specific responses to the following questions will assist in evaluating this proposal and developing a notice of proposed rulemaking:

(1) Do you see a need for updating the current regulations in 33 CFR part 126 for packaged and dry bulk cargoes? If so, what requirements should be changed?

(2) How do these regulations currently impact you or your business?

(3) Do you see a need for reducing the burden that these regulations impose on you or your business? What burdens should be reduced?

(4) Do you see a need for increased safety during the handling of packaged and dry bulk hazardous materials? What hazards need to be addressed?

In addition to the above general and specific comments on this proposal, the Coast Guard requests specific responses to the following questions to assist in evaluating this proposal and developing a notice of proposed rulemaking, if appropriate:

(1) Do waterfront facilities currently regulated under part 126 typically consist of contiguous or noncontiguous land or structures? If noncontiguous, are the noncontiguous areas enclosed by fences or other barriers? How are the noncontiguous portions separated from the contiguous portions?

(2) How far from the water is the most distant noncontiguous land or structure currently regulated under part 126?

(3) Part 126 currently contains a definition of "waterfront facility" which includes all piers, wharves, docks, and similar structures to which a vessel may be secured; areas of land, water, or land and water under and in immediate proximity to them; buildings on such structures or contiguous to them; and equipment and materials on such structures or in such buildings. It does not include facilities directly operated by the Department of Defense. Is this definition sufficiently clear to enable a person to determine whether part 126

applies to a facility? What problems, if any, have you encountered in applying or interpreting this definition? What parameters, if any, should be established under a more detailed definition of waterfront facility in order to arrive at a practical, useful definition?

(4) If the definition of waterfront facility is in need of clarification, the Coast Guard may consider establishing a definition which specifically includes noncontiguous land and structures. Such a definition may define the term "noncontiguous" (e.g., a roadway, railway, public utility right-of-way, or other natural or man-made division with certain characteristics). What factors should determine whether noncontiguous portions of land or structures are considered to be part of a waterfront facility?

(5) Are you aware of any other Federal agency asserting similar regulatory authority over all or any portion of your facility?

(6) Is NFPA Standard 307 appropriate for incorporation into regulations governing waterfront facilities that handle packaged and dry bulk hazardous materials? Do you know of other industry standards that should be incorporated, in whole or in part?

Dated: January 6, 1993.

R.C. North,

Captain, U.S. Coast Guard, Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 93–792 Filed 1–12–93; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 162

[CGD9 93–01]

Temporary Amendment to Inland Waterways Navigation Regulations Establishing Speed Limits on Connecting Waters From Lake Huron to Lake Erie

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commander, Ninth Coast Guard District, proposes to make a temporary amendment to the inland waterways navigation regulations at 33 CFR 162.138 establishing speed limits on connecting waters from Lake Huron to Lake Erie in order to allow nondisplacement power vessels less than 100 gross tons to exceed the normal speed limits, when approval for each transit is granted by the Coast Guard Captain of the Port, during the 1993 season. This temporary amendment is necessary to prevent an undue restriction on commerce, but will only be invoked by the Coast Guard Captain of the Port when he determines that no undue risk to safety will result.

DATES: Comments must be received on or before March 1, 1993.

ADDRESSES: Comments and supporting materials should be mailed or delivered to the Chief of the Ninth Coast Guard District Marine Port & Environmental Safety Branch, room 2069, 1240 East Ninth Street, Cleveland, Ohio, 44199–2060, (216) 522–3994. Please reference the name of the proposal and the docket number in the heading above. If you wish receipt of your mailed comment to be acknowledged, please include a stamped self-addressed envelope or postcard for that purpose. Comments and materials received will be available for public inspection at the above location from 9 a.m. to 3 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Captain Dennis W. Cleaveland, U.S. Coast Guard, Chief of the Ninth Coast Guard District Marine Port & Environmental Safety Branch, room 2069, 1240 East Ninth Street, Cleveland, Ohio, 44199–2060, (216) 522–3994.

SUPPLEMENTARY INFORMATION: The Coast Guard encourages interested persons to participate in this rulemaking by submitting comments which may consist of data, views, arguments, or proposals for amendments to the proposed regulations. The Coast Guard does not currently plan to have a public hearing. However, consideration will be given to holding a public hearing if it is requested. Such a request should indicate how a pubic hearing would contribute substantial information or views which cannot be received in written form. If it appears that a public hearing would substantially contribute to this rulemaking, the Coast Guard will announce such a hearing by a later notice in the **Federal Register**. The Coast Guard will consider all comments received before the closing date indicated above, and may amend or revoke this proposal in response to such comments.

Drafting Information

The drafters of these regulations are Captain Dennis W. Cleaveland, U.S. Coast Guard, project officer, Ninth Coast Guard District Marine Port & Environmental Safety Branch, and Commander M. Eric Reeves, U.S. Coast Guard, project attorney, Ninth Coast Guard District Legal Office.

Discussion of Regulations

Current regulations in 33 CFR 162.138 which apply to connecting waters from Lake Huron to Lake Erie set maximum speed for vessels 20 meters or more in length at limits ranging from 4 to 12 statute miles per hour in various areas. One of the purposes of these speed regulations is to limit wake damage, and they were not written to account for the substantially lesser wake generating characteristics of nondisplacement vessels. In fact, certain vessels designed for nondisplacement operation would generate larger wakes at these speeds because they would therefore be forced to operate in a displacement mode. Also, the current regulations were not written with consideration for the different operating characteristics of nondisplacement vessels. The Commander of the Ninth Coast Guard District proposes to temporarily amend these regulations in order to allow trial runs of nondisplacement vessels which have requested permission to operate in the area. The period for trial runs would be April through November of 1993. Because this is a new form of operation and because there are other safety considerations when a vessel is operating at a high speed, the Commander of the Ninth Coast Guard District is proposing to set an upper limit of 40 statute miles per hour and the higher speeds will only be allowed when authorized on a case by case basis, for each proposed transit of the area, by the Coast Guard Captain of the Port. Case by case approval is also necessary in order to allow for coordination with Canadian and local officials.

Federalism Implications

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. This amendment does not impose any new regulatory requirements in an area not heretofore regulated by the Federal Government, and does not impose any requirements or restrictions on State or local authorities.

Environment

The Coast Guard has considered the environmental impact of these regulations and concluded that, under section 2.B.2.c of the Coast Guard Commandant Instruction M16475.1B, they are categorically excluded from further environmental documentation.

Economic Assessment and Certification

These regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under Department of

Transportation regulatory policies and procedures (44 FR 11034 of February 26, 1979). The economic impact of these regulations is expected to be so minimal that a full regulatory evaluation is unnecessary. In fact, the Coast Guard is making this amendment in part in order to avoid causing the existing regulations to have an unintended economic impact on a new mode of commercial operation. Since the impact of this regulation is expected to the minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

Collection of Information

These regulations will impose no collection of information requirements under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

List of Subjects in 33 CFR Part 162

Marine safety, Navigation (water).

Regulations

In consideration of the foregoing, the Coast Guard proposes to amend part 162 of title 33, Code of Federal Regulations as follows:

PART 162 [AMENDED]

1. The authority citation for part 162 is temporarily amended to read as follows:

Authority: 33 U.S.C. 1231; 49 CFR 1.46, 33 CFR 162.134(d), and 33 CFR 162.138(b).

2. A temporary § T162.139 is added as follows:

§ T162.139 Nondisplacement Vessels under 100 gross tons.

(a) Notwithstanding §§ 162.134 and 162.138(a), nondisplacement vessels 20 meters or more in length but under 100 gross tons may operate in the nondisplacement mode at speeds not more than 40 miles per hour, and may overtake other vessels, when conditions otherwise safely allow and approval is granted by the Coast Guard Captain of the Port or District Commander prior to each transit of the area. Except for provisions on overtaking other vessels, the provisions in § 162.134 continue to apply.

(b) This section becomes effective on April 1, 1993 and terminates on November 30, 1993.

Dated: December 16, 1992.

G.A. Penington,

Rear Admiral, USCG, Commander, Ninth Coast Guard District.

[FR Doc. 93–790 Filed 1–12–93; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300258; FRL–4077–1]

RIN 2070–AC18

Revocation of Exemption from Requirement of a Tolerance for Certain Inert Chemicals in Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to revoke exemptions from the requirement of a tolerance for residues of seven pesticidally inert ingredients in or on raw agricultural commodities (RAC's). EPA is initiating this action because the data base for these inerts is so deficient that EPA cannot conclude that a tolerance is not necessary to protect the public health.

DATES: Written comments, identified by the document control number [OPP-300258], must be received on or before March 15, 1993.

ADDRESSES: By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1128, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1128 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Melissa L. Chun, Registration Support Branch (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 718, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, 703-305-6354.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA establishes tolerances (maximum legal residue levels) or exemptions from the requirement of a tolerance for pesticide residues in food. Pesticide products are usually made up of one or more pesticidally active ingredient(s) and one or more ingredient(s) which are not intended to be pesticidally active (such as solvents) which are known as inerts.

In the **Federal Register** of April 22, 1987 (52 FR 13305), EPA issued a notice which announced certain policies designed to reduce the potential for adverse effects from the use of pesticide products containing toxic inert ingredients. In developing this policy, the Agency has categorized inert ingredients into the following four lists according to toxicity: List 1—Inerts of toxicological concern; List 2—Potentially toxic inerts, with high priority for testing; List 3—Inerts of unknown toxicity; List 4—Inerts of minimum concern.

Based on a review of the toxicity information on chemicals used as inert ingredients in registered pesticide formulations, the Agency concluded that some inert ingredients have been shown to have significant toxicity. The criteria used to place chemicals on List 1 were carcinogenicity, adverse reproductive effects, neurotoxicity or other chronic effects, developmental toxicity (birth defects), ecological effects, or the potential for bioaccumulation.

Any registrant who retains an inert ingredient on List 1 in his or her registered product(s) must submit data to support continued use. The Agency conducted a Data Call-In in April 1988 and March 1989 to require that the registrants of List 1 inerts provide the Agency with needed data under section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. These data included chronic toxicology, product chemistry, residue, and environmental fate data and are necessary to support the continued registration of product(s) containing the above-noted inert ingredients.

Registrants who failed to respond or responded improperly were sent Notices of Intent to Suspend (NOITS) for products containing the inert ingredients.

Exemptions from tolerances currently exist for seven List 1 inerts: chloroform, epichlorohydrin, ethylene dichloride, hexane, methyl chloride, perchloroethylene, and propylene oxide. The data base for these inerts is so deficient that EPA cannot conclude that a tolerance is not necessary to protect the public health. This

document proposes to revoke exemptions for each of these inerts.

The Agency is not recommending the establishment of action levels in place of these exemptions from tolerance. In response to the Data Call-In, the registrants of several products containing chloroform, epichlorohydrin, and perchloroethylene canceled their product registrations. The remaining products were either reformulated (ethylene dichloride, hexane, perchloroethylene, propylene oxide) or the product registrations were suspended due to failure to respond to the Data Call-Ins (epichlorohydrin, hexane, methyl chloride, perchloroethylene, and propylene oxide). Since these inerts have been eliminated from products or the product registrations have been canceled or suspended, there is no legal sale or distribution in the United States. Furthermore, since sufficient time has elapsed in order for the residues to dissipate, residues should not appear in any domestically produced commodities. EPA requests that interested persons submit information pertaining to whether these inerts are used in foreign countries and may be present in commodities grown in those countries and imported to the United States.

The exemptions from tolerance, listed in 40 CFR part 180, being proposed for revocation are as follows:
§ 180.1001(c)—hexane, methyl chloride, perchloroethylene, and propylene oxide; § 180.1001(d)—chloroform, epichlorohydrin, ethylene dichloride (1,2-dichloroethane), and hexane (including isomeric hexanes);
§ 180.1001(e)—ethylene dichloride (1,2-dichloroethane), perchloroethylene, and propylene oxide.

Simultaneously with this proposal, EPA is informing the member countries of the Codex Alimentarius Commission and other countries of its proposed revocation action so that those who might be affected are afforded the opportunity to comment on the proposed action.

Within 30 days after publication of this document in the **Federal Register**, any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, which contains these inert ingredients may request that this rulemaking proposal to revoke the tolerance exemptions for these inert ingredients be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP-300258]. All written comments filed in response to this notice will be available in the Public Information Branch, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

Executive Order 12291

In order to satisfy requirements for analysis as specified by Executive Order 12291, the Agency must determine whether a proposed regulatory action is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. The Agency has determined that this proposed action is not a major regulatory action, i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

The proposed regulatory action has been reviewed by the Office of Management and Budget as required by E.O. 12291.

Regulatory Flexibility Act

This proposed regulatory action has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96-354, 94 Stat. 1164; 5 U.S.C. 601 et seq.), and it has been determined that it will not have a significant economic impact on a substantial number of small businesses, small governments, or small organizations.

This regulatory action is intended to prevent the sale of food commodities containing pesticide residues only where the subject pesticides have been used in an unregistered or illegal manner.

Since all products containing these inerts have been canceled, suspended, or reformulated without these inerts in response to Data Call-Ins in 1988 and 1989, there should be no further use of products containing these inerts. Furthermore, sufficient time has elapsed for residues of these inerts to dissipate. Therefore, the Agency does not expect any impact or costs on users or business enterprises of any size as a result of revoking these exemptions from the requirement of tolerances for these inerts.

Accordingly, I certify that this proposed regulatory action does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 29, 1992.

Victor J. Kimm,
Acting Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In § 180.1001(c), (d), and (e) tables by removing the following entries, as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *

(c) * * *

Inert ingredients	Limits	Uses
* * *	* *	* *
Hexane [Removed]	[Removed]	[Removed]
* * *	* *	* *
Methyl chloride [Removed]	[Removed]	[Removed]
* * *	* *	* *
Perchloroethylene [Removed]	[Removed]	[Removed]
* * *	* *	* *
Propylene oxide [Removed]	[Removed]	[Removed]

Inert ingredients	Limits	Uses
• • •	•	• •

(d) * * *

Inert ingredients	Limits	Uses
• • •	•	• •
Chloroform [Removed]	[Removed]	[Removed]
• • •	•	• •
Epichlorohydrin [Removed]	[Removed]	[Removed]
Ethylene dichloride (1,2-dichloroethane) [Removed]	[Removed]	[Removed]
• • •	•	• •
Hexane (including isomeric hexanes) [Removed]	[Removed]	[Removed]
• • •	•	• •

(e) * * *

Inert ingredients	Limits	Uses
• • •	•	• •
Ethylene dichloride (1,2-dichloroethane) [Removed]	[Removed]	[Removed]
• • •	•	• •
Perchloroethylene [Removed]	[Removed]	[Removed]
• • •	•	• •
Propylene oxide [Removed]	[Removed]	[Removed]
• • •	•	• •

[FR Doc. 93–376 Filed 1–12–93; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 372

[OPPTS–400068; FRL–4078–4]

Di-n-Octyl Phthalate; Toxic Chemical Release Reporting; Community Right-To-Know

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to grant a petition to delete di-n-octyl phthalate (CAS Number 117–84–0) from the list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-To-Know Act (EPCRA) of 1986. EPA believes that this chemical satisfies the statutory criterion for delisting and therefore should not be included on the list.

DATES: Written comments on this proposed rule should be submitted by March 15, 1993.

ADDRESSES: Written comments should be submitted in triplicate to: OPPT Docket Clerk, TSCA Public Docket Office (TS–793), Environmental Protection Agency, Rm. NE–G004, 401 M St., SW., Washington, DC 20460, Attn: Docket Number OPPTS–400068.

FOR FURTHER INFORMATION CONTACT: Maria J. Doa, Petitions Coordinator, Emergency Planning and Community Right-To-Know Information Hotline, Environmental Protection Agency, Mail Stop OS–120, 401 M St., SW., Washington, DC 20460, Toll free: 800–535–0202.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Statutory Authority

This proposal is issued under section 313(d) and (e)(1) of the Emergency Planning and Community Right-To-Know Act of 1986 (42 U.S.C. 11023). EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986.

B. Background

Section 313 of EPCRA requires certain facilities manufacturing, processing, or otherwise using toxic chemicals to report their environmental releases and off-site transfers of such chemicals annually. Beginning with the 1991 reporting year, such facilities also must report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the Pollution Prevention Act (42 U.S.C. 13106). EPCRA section 313 establishes an initial list of toxic chemicals that is comprised of more than 300 chemicals and 20 chemical categories. Any person may petition EPA to add chemicals to or delete chemicals from the list.

EPA issued a statement of petition policy and guidance in the **Federal Register** of February 4, 1987 (52 FR 3479), to provide guidance regarding the recommended content and format for petitions. EPCRA section 313(e) requires EPA to respond to petitions within 180 days either by initiating a rulemaking or by publishing an explanation of why the petition is denied.

II. Description of the Petition

On January 28, 1992, EPA received a petition from Vista Chemical Company of Houston, Texas, to delist di-n-octyl phthalate (DnOP; also known as n-dioctyl phthalate) from the list of toxic chemicals under section 313 of EPCRA.

The petitioner addressed the following topics: physical and chemical properties, production and use patterns, releases, and concentration levels beyond the facility; the current regulatory status of DnOP; the basis of delisting authority; and DnOP toxicity, including acute and chronic health and environmental effects. The petitioner concludes that DnOP should be deleted from the EPCRA section 313 list because it does not meet any of the criteria for inclusion in the section 313 list of toxic chemicals. The petitioner also states that DnOP is not known and cannot reasonably be anticipated to cause significant adverse effects on human health or the environment. Further, the petitioner contends that there are other equally innocuous phthalate esters of similar structure produced in larger quantities which are not on the EPCRA section 313 list, and this puts DnOP producers at an undue commercial disadvantage.

III. Regulatory Status of DnOP

DnOP is designated as a hazardous substance under section 102 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA; 42 U.S.C. 9602). The reportable quantity (RQ) for DnOP is currently set at 5,000 lbs (40 CFR 302.4). This is the maximum value defined under CERCLA for triggering release reporting to Federal, State, and local authorities. In addition, discarded products, off-specification species, container residues, and spill residues of DnOP are regulated as hazardous waste U107 under the Resource Conservation and Recovery Act (RCRA).

DnOP is on the Priority Pollutant List (PPL) of section 307 of the Clean Water Act (33 U.S.C. 1317). The other phthalate esters on the EPCRA section 313 list (butyl benzyl phthalate, di-n-butyl phthalate, di-2-ethylhexyl phthalate, dimethyl phthalate, and diethyl phthalate) are also on the PPL. Insufficient data preclude the derivation of ambient water quality criteria for DnOP by the Agency.

This petition does not request that any action be taken under any statute other than EPCRA, and today's proposal should not be inferred as a proposed action under any statute other than EPCRA. Each statute prescribes different standards for adding or deleting chemicals or pollutants from their respective list. Specifically, the deletion of DnOP from the EPCRA section 313 list does not preclude its continued regulatory status under other environmental statutes. Today's proposal is based solely on the criteria in EPCRA section 313.

IV. EPA's Review of DnOP

The technical review of the petition to delete DnOP covers the chemistry, health and environmental effects, production and use, environmental release, and environmental fate of DnOP. EPA reports prepared in support of this proposal include "Di-n-Octyl Phthalate Exposure Report for Delisting Petition" (Ref. 1), "Hazard Assessment of Di-n-Octyl Phthalate (DnOP) in Response to Delisting Petition of Vista Chemical Company" (Ref. 2), "Final Economics Report for TRI Delisting of DnOP" (Ref. 3), and "Chemistry Report on Di-n-Octyl Phthalate" (Ref. 4). These reports, which are cited in Unit VIII of this proposal, contain lists of references that were used in their preparation.

A. Chemistry

DnOP is a linear dioctyl ester of phthalic acid. It is a colorless, odorless, oily liquid with a low melting point (-25 °C), a high boiling point (estimated to be 390 to 420 °C at 760 torr based on measured boiling points at reduced pressure), and low volatility (The vapor pressure of DnOP is estimated to be 10^{-6} to 10^{-7} torr at 25 °C based on boiling points at reduced pressures).

Information on DnOP and related chemicals is often commingled and misidentified. For example, the physical data and Toxic Release Inventory (TRI) releases and transfers of DnOP's branched isomer, di-(2-ethylhexyl) phthalate (DEHP), the largest volume plasticizer commonly used in polyvinyl chloride (PVC), are often mistakenly reported as DnOP. Both DnOP and DEHP are often referred to as dioctyl phthalate (DOP) in the literature and in industry (as is diisooctyl phthalate; DIOP). Thus, DOP can be used to indicate any of the eight-carbon side-chain containing phthalates: DnOP, DEHP, or DIOP. The petition submitted by the Vista Chemical Company, and this proposed rule, address only DnOP.

DnOP has a very low water solubility, but it is highly soluble in certain organic solvents and oils. Measured values for the aqueous solubility of DnOP range from 50 milligrams per liter (mg/L) to 0.020 mg/L, with estimated values ranging as low as less than 0.001 mg/L. Considering the methodological problems in many of the water solubility studies (i.e., older methods tended to give overestimated values for the solubility of DnOP), EPA believes that the measured value of 0.020 mg/L is more likely to approximate the true solubility of DnOP than higher measured values.

Phthalate esters undergo step-wise hydrolysis to the monoester and then to the dicarboxylic acid, phthalic acid. The hydrolysis is catalyzed by acid or base. For phthalate esters, acid hydrolysis at pH 4 to 6 is generally estimated to be slower than alkaline hydrolysis at pH 8 to 10. Neutral hydrolysis is too slow to measure. Some estimated half-lives for the hydrolysis of DnOP at various pH's are shown in Table 1 below (Ref. 4):

Table 1.—Hydrolysis Half-Lives for DnOP at Various pH's (estimated)

Acid/Base Hydrolysis at 30 °C:	
pH	Half-life, days (estimated)
1	7
4	7,220
7	22,315
8	2,238
10	22

B. Toxicological Evaluation

Toxicological data on the health and environmental effects of DnOP were obtained from information submitted with the petition, from articles retrieved from the literature, and from Agency documents. These data were reviewed with respect to the statutory criteria (EPCRA section 313(d)(2)(A), (B), and (C)). Specifically, the data were reviewed for evidence indicating absorption and metabolism, acute toxicity, liver and kidney toxicity, immunotoxicity, carcinogenicity, mutagenicity, developmental and reproductive toxicity, neurotoxicity, and environmental effects (Ref. 2).

1. *Absorption and metabolism.* Phthalic acid esters are expected to be readily absorbed from the gastrointestinal tract, well absorbed (about one-third of exposure concentration) from the lung, and poorly absorbed from the skin. Based on data from other phthalate esters, DnOP is expected to be rapidly metabolized to the monoester in the intestine and the liver. The n-octyl side chain of the monoester is expected to undergo a variety of oxidations. In general, phthalic acid esters and their metabolites distribute primarily to the liver, kidneys, fat, and gastrointestinal tract, but they are not retained for long in the body. The esters and their metabolites are rapidly excreted, mainly in the urine.

2. *Acute toxicity.* DnOP exhibits very low acute toxicity to animals. The rat oral LD_{50} values are greater than 13 g/kg, and mouse acute oral LD_{50} values are greater than 6.5 g/kg. The acute dermal LD_{50} value is greater than 5 g/kg for guinea pigs. DnOP is slightly irritating to rabbit eyes but not to rabbit skin.

Data on human exposure indicate that DnOP is irritating to mucous

membranes and eyes but not to the skin. Mild contact dermatitis or hypersensitivity reactions have been reported among workers exposed dermally to phthalate ester mixtures; however, human dermal patch testing of DnOP showed no irritation or sensitization. The oral lethal dose for DnOP in humans has been reported to range from 0.5 to 15 grams per kilogram (g/kg) for a 70 kg adult.

3. *Liver toxicity.* Several subchronic studies, from 14 days to 14 weeks duration, indicate that DnOP is hepatotoxic to rats and mice at high dose levels (1.0 to 7.5 g/kg) by the oral route.

4. *Kidney toxicity.* Limited subchronic (14-week) data on the nephrotoxicity of DnOP in rodents imply that the compound may be toxic to the kidney, but only at high doses (0.3 g/kg intraperitoneally (ip) or 7.5 g/kg in the diet).

5. *Immunotoxicity.* The results of two rat studies are inadequate to evaluate the immunotoxic potential of DnOP. The methods were not presented in sufficient detail to allow comparison with standard procedures, quantitative data were not presented, there appear to be large variances associated with some of the means, and the positive control did not demonstrate all the immunosuppressant effects reported in the peer-reviewed literature. Thus, these studies provide suggestive, but not definitive, evidence of immunotoxicity in rats at high doses (0.60, 5.0, and 10.0 g/kg) by ip injection over periods of 5 days or 45 to 90 days.

6. *Carcinogenicity.* There are no epidemiological studies or long-term animal carcinogenicity assays of DnOP to permit an evaluation of the oncogenicity of the chemical to humans. Data on structure-activity relationships, chronic toxicity, and genotoxicity do not provide sufficient evidence that one may reasonably anticipate that DnOP will cause cancer in humans.

7. *Mutagenicity.* DnOP was not mutagenic in several short-term assays with or without metabolic activation.

8. *Developmental and reproductive toxicity.* The results of several studies, conducted at doses of 2 to 7.5 g/kg in mice and 3 to 10 g/kg in rats, show that DnOP has a very low potential to cause developmental or reproductive toxicity in laboratory animals. In one study, pregnant rats were dosed ip with DnOP at 5 or 10 g/kg on gestation days 5, 10, and 15. DnOP did not appear to be embryotoxic, even at 10 g/kg. Several of the resulting fetuses had gross abnormalities. Skeletal abnormalities were not observed. Thus, DnOP produced developmental effects only at extremely high doses. A reproductive toxicity study with mice fed diets containing about 2 to 7.5 g/kg DnOP per day was negative.

9. *Neurotoxicity.* Available data are inadequate to assess the neurotoxicity of DnOP fully. Two studies of workers imply that phthalate ester mixtures may be neurotoxic at workplace levels (1 to 60 milligrams per cubic meter (mg/m^3); concentration of DnOP not known). Limited animal neurotoxicity studies in the literature imply that DnOP may be neurotoxic, but at high doses (ca. 1.8 to 12 g/kg). All of these studies are severely limited and are inadequate for hazard assessment under EPCRA section 313. All suffer from a lack of complete reporting of data, and in several studies it is not clear as to which isomer, DnOP or DEHP, was present or tested. There are no additional supporting neurotoxicity data on DnOP in humans and no indication of neurotoxic effects in other available animal studies of DnOP.

10. *Environmental effects.* Based on available information, DnOP is not likely to have adverse effects on aquatic organisms at its aqueous solubility limit during acute and chronic exposures (undissolved material is not bioavailable by passive diffusion through external membranes). Effect concentrations reported in the petition are in excess of DnOP's aqueous solubility limit. When dialkyl phthalates analogous to DnOP were tested at their aqueous solubility limits, there were no toxic effects to environmental organisms.

Based on information from other dialkyl phthalates, DnOP is expected to bioconcentrate in aquatic organisms and be transported up the food chain; however, dispersion rather than biomagnification is likely to occur as the compound becomes incorporated into organisms higher up the food chain. That is, as DnOP is transported up the food chain, residues should become smaller rather than larger since organisms with more diverse and specialized metabolic pathways are more likely to metabolize the compound than are organisms lacking advanced pathways.

DnOP biodegrades under aerobic conditions. It is persistent under anaerobic conditions. Due to its persistence and hydrophobicity, DnOP is expected to accumulate in sediments. However, DnOP is not expected to be bioavailable because it strongly sorbs to sediments.

C. Production, Use, Releases, and Environmental Fate

1. *Production and use.* DnOP is manufactured as a component of mixed phthalate esters (linear chain C_6, C_8, and C_{10}) by three U.S. companies: Aristech Chemical Corporation, Teknor Apex Company, and Vista Chemical Company in a total of 14 to 15 million pounds annually. Teknor Apex Company produces a n-octyl, n-decyl phthalate ester which contains DnOP. The production volume of DnOP is roughly 5 percent of the production volume of DEHP. In general, DnOP is manufactured by heating an excess mixture of normal alcohols with phthalic anhydride in the presence of a catalyst to form a mixture of esters.

The chemical has many applications, the most important of which is its use as a plasticizer in the plastic and resin materials industry. It is a plasticizer for cellulose ester resins, polystyrene resins, and, primarily, PVC. Plasticizers are blended with the synthetic plastics and resin materials to improve the workability during fabrication, to extend or modify the natural properties of the material, and to develop new or improved properties not present in the original material. They can be present in concentrations from 5 percent to 60 percent of the total weight of the plastics and resins. DnOP can also be used as a dye carrier in plastic production (mostly PVC) and as a component in the production of adhesives, plastisols, and nitrocellulose lacquer coatings (Refs. 3 and 4).

2. *Releases.* In 1989, 99 facilities reported DnOP releases and transfers under EPCRA section 313. This number includes at least one facility (Mazda Motor USA Corporation (Mazda), the largest releaser of DnOP to air for 1989) which was confirmed to have erroneously reported releases to air of DEHP as DnOP. Additionally, this facility erroneously reported transfers to publicly owned treatment works (POTWs) and other off-site locations. Omitting the reporting by Mazda, the corrected releases and transfers of DnOP for 1989 are as follows: 112,476 pounds released to air; 1,251 pounds released to water; 1,813 pounds released to land; 66 pounds injected underground; 12,376 pounds transferred to POTWs; and 164,140 pounds transferred to other off-site locations (Ref. 3).

3. *Environmental fate.* DnOP sorbs strongly to organic matter in soils and sediments. Adsorption is likely the most important transport mechanism in surface waters.

Hydrolysis and volatilization are expected to be relatively slow processes for removal of DnOP from surface waters.

Under aerobic conditions, biodegradation of DnOP occurs with a half-life of 7 to 30 days. Under aerobic

conditions, the general biodegradation mechanism consists of enzymatic hydrolysis of the ester to soluble intermediates, presumably via a phthalic acid monoester. Anaerobic biodegradation is expected to be very slow (greater than months) (Ref. 1).

DnOP strongly absorbs ultraviolet (UV) radiation with a wavelength of 274.5 nanometers (nm) and is a candidate for photolysis (i.e., decomposition by absorption of light). However, EPA is not aware of any experimental photolysis data for phthalate esters. An estimation for the photolysis half-life of DnOP in surface waters is 144 days. Direct photolysis of DnOP in the atmosphere is not expected to occur to any significant extent; however, DnOP will be photodegraded by photochemically produced hydroxyl radicals found in the atmosphere. A half-life of 14 hours has been estimated (Refs. 1 and 4).

4. *Exposure.* Bottom sediment steady-state concentrations exceeding 10 mg of DnOP per kg of dry weight sediments are estimated downstream from manufacturing facilities, thus potentially exposing benthic organisms. However, as DnOP strongly sorbs to sediments, it is not expected to be bioavailable.

It is estimated that 80 percent of the DnOP in wastewater is removed in secondary waste water treatment systems. DnOP concentrations in surface waters (under mean flow conditions) downstream from facilities reporting releases are estimated to be between less than 1 ppb and 9 ppb. Concentration levels entering major drinking water utilities were estimated to determine potential exposures to large populations, and the levels were estimated at less than 0.5 ppb (Ref. 1).

V. Rational for Delisting

EPA is proposing to grant the petition submitted by Vista Chemical Company to delete DnOP from the section 313 list of toxic chemicals. The decision to grant this petition is based on the total weight of available evidence for all applicable toxicity endpoints.

With respect to deletions, EPCRA provides at section 313(d)(3) that "[a] chemical may be deleted if the Administrator determines there is not sufficient evidence to establish any of the criteria described in paragraph [(d)(2)(A)-(C)]." As DnOP exhibits acute toxicity only at levels that greatly exceed releases and resultant exposures, DnOP cannot reasonably be anticipated to cause ". . . significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring releases." Thus, EPA does not believe that DnOP meets the toxicity criteria for listing under EPCRA section 313(d)(2)(A).

EPA does not believe that DnOP meets the toxicity criteria of EPCRA section 313(d)(2)(B) because DnOP (1) cannot reasonably be anticipated to cause cancer, teratogenic effects, immunotoxicity, or neurotoxicity and (2) cannot reasonably be anticipated to cause liver toxicity, kidney toxicity, or reproductive and developmental toxicity, except, as discussed in Unit IV, at relatively high dose levels, such that EPA believes the section 313(d)(2)(B) criteria are not satisfied.

EPA does not believe that DnOP meets the toxicity criteria of EPCRA section 313(d)(2)(C) because adverse effects of DnOP on aquatic organisms occur only at levels that are in excess of the aqueous solubility limit of DnOP. Thus, EPA believes that any potential significant adverse effects on the aquatic environment are mitigated by DnOP's low solubility in water. Furthermore, although DnOP does bioconcentrate in aquatic organisms, it will become dispersed rather than biomagnified in higher organisms.

VI. Rulemaking Record

The record supporting this proposed rule is contained in docket number OPPTS–400068. All documents, including an index of the docket, are available in the TSCA Public Docket Office from 8 a.m. to noon and 1 p.m. to 4 p.m., Monday through Friday, excluding legal holidays. The TSCA Public Docket Office is located at EPA Headquarters, Rm. NE–G004, 401 M St., SW., Washington, DC 20460.

VII. Request for Public Comment

EPA requests public comment on this proposal to delete DnOP from the list of chemicals subject to EPCRA section 313. Comments should be submitted to the address listed under the ADDRESSES unit. All comments must be received by March 15, 1993.

VIII. References

(1) Nold, Annette. Di-n-Octyl Phthalate Exposure Report for Delisting Petition. USEPA. July 9, 1992.

(2) Randecker, Lorraine. Hazard Assessment of Di-n-Octyl Phthalate (DnOP) in Response to Delisting Petition of Vista Chemical Company. USEPA. July 15, 1992.

(3) Reid, Matt. Final Economics Report for TRI Delisting of DnOP. USEPA. July 15, 1992.

(4) Tou, Jenny. Chemistry Report on Di-n-Octyl Phthalate. USEPA. July 15, 1992.

IX. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore, requires a Regulatory Impact Analysis. EPA has determined that this is not a "major rule" because it will not have an effect on the economy of $100 million or more. This proposed rule would decrease the impact of the EPCRA section 313 reporting requirements on covered facilities and would result in cost-savings to industry, EPA, and the States. Therefore, this is a minor rule under Executive Order 12291. This proposed rule was submitted to the Office of Management and Budget (OMB) under Executive Order 12291. In 1990, the number of facilities that reported on DnOP was 82. Thus, under the proposed rule these 82 facilities would no longer report on this chemical. The estimated cost savings to industry by deleting the listing is estimated to be $1,395 per year per reporting facility that no longer is required to report. The cost saving to EPA is $72 per facility per report. The total cost savings to EPA and industry is estimated to be $120,294 per annum.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980, the Agency must conduct a small business analysis to determine whether a substantial number of small entities will be significantly affected by a proposed rule. Because the proposed rule results in cost savings to facilities, the Agency certifies that small entities will not be significantly affected by the proposed rule.

C. Paperwork Reduction Act

This proposed rule does not have any information collection requirements under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 372

Chemicals, Community right-to-know, Environmental protection, Reporting and recordkeeping requirements, Toxic chemicals.

Dated: January 6, 1993.

Linda J. Fisher,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore it is proposed that 40 CFR part 372 be amended to read as follows:

1. The authority citation for part 372 would continue to read as follows:

Authority: 42 U.S.C. 11013 and 11028.

§ 372.65 [Amended]

2. Sections 372.65(a) and (b) are amended by removing the entire entry for n-Dioctyl phthalate under paragraph (a) and removing the entire CAS No. entry for 117–84–0 under paragraph (b).

[FR Doc. 93–787 Filed 1–12–93; 8:45 am]
BILLING CODE 6560–50–F

FEDERAL MARITIME COMMISSION

46 CFR Part 514

[Docket No. 93–01]

Electronic Filing of Military Rates

AGENCY: Federal Maritime Commission.

ACTION: Proposed rule.

SUMMARY: The Federal Maritime Commission ("Commission" or "FMC"), pursuant to section 16 of the Shipping Act of 1984 ("1984 Act") and section 35 of the Shipping Act, 1916 ("1916 Act") is proposing to exempt from the filing requirements of the 1984 Act and the 1916 Act and remove from the requirements of 46 CFR part 514, on certain conditions, transportation of U.S. Department of Defense ("DOD") cargo moving under terms and conditions negotiated and approved by the Military Sealift Command ("MSC") and set forth in a rate guide or tender. In addition, the Commission proposes to allow any military rate filed in a commercial tariff of a carrier or conference to become effective upon filing.

DATES: Comments are due February 12, 1993.

ADDRESSES: Written comments (original and 15 copies) must be submitted to: Joseph C. Polking, Secretary, Federal Maritime Commission, 800 North Capitol Street, NW., Washington, DC 20573–0001.

FOR FURTHER INFORMATION CONTACT: John Robert Ewers, Deputy Managing Director, Office of the Managing Director, Federal Maritime Commission, 800 North Capitol Street, NW., Washington, DC 20573–0001.

SUPPLEMENTARY INFORMATION: MSC is responsible for arranging ocean transportation services for all components of DOD. Although MSC can utilize commercial tariff rates and service contracts for the carriage of DOD cargo, most DOD cargo moves pursuant to rates tendered to MSC in bid form *i.e.*, "tenders," which, if accepted, become special contractual arrangements which MSC enters into with the carriers. The development of such tenders, therefore, is quite different from the carrier generation of rates for commercial cargo in a tariff publication. While military tenders are required to be filed, they are subject to a continuing special permission, 46 CFR 580.1(d), which provides:

(d) The following services are subject to continuing special permission authority to deviate from the 30-day notice requirement of section 8 of the [1984] Act and the form and content requirements of this part: Transportation of U.S. Department of Defense cargo by American-flag common carriers under terms and conditions negotiated and approved by the Military Sealift Command (MSC), if all the following conditions are met:

(1) Exact copies of all common carrier quotations or tenders accepted by MSC are filed with the Commission as soon as possible after they are approved by MSC, but on not less than one day's filing notice prior to the effective date thereof;

(2) All tenders are filed in triplicate, one copy of which is signed and maintained at the Commission's Washington Office for public inspection;

(3) A letter of transmittal accompanies the filing stating that the documents are submitted in accordance with the requirements of the Shipping Act of 1984 and this section;

(4) Tenders submitted for filing are to be numbered by the respective common carriers as part of a distinct tariff series, with each common carrier's series to begin with the number "1" and run consecutively thereafter;

(5) Each tender which supersedes a prior tender must specifically cancel the prior tender by its series number; and

(6) Amendments or supplements to tenders must also be filed with the Commission upon not less than one day's filing notice and contain an appropriate reference to the original tender being amended or supplemented.

In Docket No. 90–23, Tariffs and Service Contracts, the Commission is developing rules that will govern the electronic formatting and filing of all tariff data pursuant to the Automated Tariff Filing and Information ("ATFI") system. As a part of Docket No. 90–23, the Commission carried forward the continuing special permission pertaining to military rate tenders to ATFI. The proposed continuing special permission was set forth in section 514.3(b)(4) [1] of the proposed rules and comments thereon were requested. In response to comments, the continuing special permission was modified, resulting in the following provision which appeared in the interim rule of August 12, 1992:

[514.3(b)] (4) *Department of Defense cargo in foreign commerce—certain requirements.* Transportation in foreign commerce of U.S. Department of Defense cargo by American-flag common carriers, under terms and conditions negotiated and approved by the Military Sealift Command ("MSC"), is subject to continuing special permission authority to deviate from the 30-day notice requirement of section 8 of the 1984 Act, if all of the following conditions are met:

(i) All common carrier quotations or tenders, including amendments thereto, are filed with the Commission as soon as possible after they are accepted and approved by MSC, but no later than on the effective date;

(ii) MSC tenders are filed in the carrier's foreign commodity tariff(s) covering the trade route(s) applicable to the tender(s);

(iii) MSC tenders are filed for distinct commodities or as separate TLI's within a commodity, as applicable, using the filing/amendment code "M" under section 514.9(b)(13);

(iv) The use of the filing/amendment code "M" is understood by the filer to mean that the tariff material filed is submitted in accordance with the requirements of the Shipping Act of 1984 and this part; and

(v) The terms and conditions governing the military rates, as set forth in the applicable MSC rate agreement(s), are included in Tariff Rule 32, section 514.15(b)(32), and assessorials are properly formatted and linked to the commodity description and/or TLI.

In the Supplementary Information to the August 12 interim rule, the Commission stated:

Even though MSC suggests consideration of parallel filing of tenders in paper form, the Commission does not think this is necessary or desirable. The purpose of ATFI is to do away with paper filing to the extent possible * * *. [57 FR 36259.]

Pursuant to the interim rule's invitation for further comment in Docket No. 90–23, comments on the electronic filing of military rates were filed by MSC, as well as by two ocean carriers, Farrell Lines, Inc. and Sea-Land Service, Inc. ("Carriers"). Because these comments raised issues not originally within the scope of proposed Part 514, or requested reconsideration of actions previously taken, they cannot be implemented in the interim amendments in Docket No. 90–23. Accordingly, these issues have been severed from Docket No. 90–23, and are being considered in this proceeding.[2]

The Carriers argue that § 514.3(b)(4) has "reregulated" the filing of U.S. military rates, thereby eviscerating the tariff filing exemption now found in 46 CFR 580.1(d). Under the interim rule, the Carriers point out that each filing carrier will be required to take all the rates accepted by MSC, enter them into ATFI, and draft algorithms for assessorial charges. The Carriers further

[1] *See also* the companion provisions at sections 514.9(b)(13) and 514.15(b)(32).

[2] A proposed rule and an interim (final) rule cannot be contained in the same document for Federal Register publication.

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point out that these rates are used by only one shipper, *i.e.*, MSC, and conclude that there is no interest served by filing MSC rates in ATFI format. Hence, according to the Carriers, § 514.3(b)(4) is "unwarranted and unworkable."

The comments of the Carriers appear to have merit. Accordingly, the Commission proposes to exempt the transportation of DOD cargo moving under terms and conditions negotiated and approved by MSC from the tariff filing requirements of the 1916 and 1984 Acts and remove such transportation from the rules of this part, provided a copy of the applicable military rate guide or tender is filed with the FMC. The result of this proposed rule would be, in essence, to preserve the *status quo* with respect to the treatment of rates contained in military rate guides or tenders.[3]

Section 514.15(b)(32), which requires Tariff Rule 32 to contain all terms and conditions pertaining to MSC tenders, is proposed to be deleted as unnecessary. However, § 514.9(b)(13), which prescribes the symbol "M" for military rates, is retained, but amended for situations where the military rates may be filed by the carrier itself in the carrier's commercial tariff.

The exemption proposed here will be under section 16 of the 1984 Act, 46 U.S.C. app. section 1715, and section 35 of the 1916 Act, 46 U.S.C. app. section 833a, which require findings that the exemption will not substantially impair effective regulation, be unjustly discriminatory, result in a substantial reduction in competition (1984 Act only), or be detrimental to commerce.

It appears that: 1. The exemption will not substantially impair effective regulation by the Commission. It is unnecessary for military rates to be converted to a commercial staff format in order for the Commission to carry out its regulatory responsibilities. For rate analyses, and for the purpose of investigation, surveillance and enforcement, the rate guides and tenders in their present format should be sufficient.

2. The exemption will not be unjustly discriminatory, result in substantial reduction in competition,[4] or be detrimental to commerce. In essence, the proposed exemption would preserve the *status quo* with respect to the treatment of rates contained in military rate guides or tenders.

Accordingly, the Commission believes that an exemption under section 16 of the 1984 Act and section 35 of the 1916 Act is warranted.

Although the Commission, as an independent regulatory agency, is not subject to Executive Order 12291, dated February 17, 1981, it nonetheless has reviewed the proposed rule in terms of this Order and has determined that this rule is not a "major rule" as defined in Executive Order 12291, because it will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovations, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Federal Maritime Commission certifies, pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(a), that this rule will not have a significant economic impact on a substantial number of small entities, including small businesses, small organizational units and small government jurisdictions. To the extent that rates on military cargo may be filed by a small entity, the proposed rule, if adopted, will decrease filing burdens by reverting to the status quo ante, whereby military rates will be filed by the Military Sealift Command, rather than by the small-entity carriers, as required by current part 514.

The collection of information requirements contained in 46 CFR part 514 (and Exhibit 1 to part 514) have been approved by the Office of Management and Budget (OMB) in accordance with 44 U.S.C. chapter 35 and have been assigned OMB control number 3072–0055. The proposed amendments to part 514 contained in this rulemaking contain no information collection requirements additional to those already approved.

List of Subjects in 46 CFR Part 514

Barges, Cargo, Cargo vessels, Exports, Fees and user charges, Freight, Harbors, Imports, Maritime carriers, Motor carriers, Ports, Rates and fares, Reporting and recordkeeping requirements, Surety bonds, Trucks, Water carriers, Waterfront facilities, Water transportation.

Therefore, for the reasons set forth in the preamble, and pursuant to 5 U.S.C. 552 and 553; 31 U.S.C. 9701; 46 U.S.C. app. 804, 812, 814–817(a), 820, 833a, 841a, 843, 844, 845, 845a, 845b, 847, 1702–1712, 1714–1716, 1718, 1721 and 1722; section 2(b) of Public Law 101–92, and section 502 of Public Law 102–582; part 514 of title 46, Code of Federal Regulations, is proposed to be amended as follows:

PART 514—TARIFFS AND SERVICE CONTRACTS

1. The authority citation for part 514 continues to read as follows:

Authority: 5 U.S.C. 552 AND 553; 31 U.S.C. 9701; 46 U.S.C. app. 804, 812, 814–817(a), 820, 833a, 841a, 843, 844, 845, 845a, 845b, 847, 1702–1712, 1714–1716, 1718, 1721 and 1722; and sec. 2(b) of Pub. L. 101–92, 103 Stat.601.

2. In § 514.3, paragraph (b)(4) is revised to read as follows:

§ 514.3 Exemptions and exclusions.

* * * * *

(b) * * *

(4) *Department of Defense cargo*—Transportation of U.S. Department of Defense cargo moving under terms and conditions negotiated and approved by the Military Sealift Command ("MSC") and published in a rate guide or tender is exempt from the tariff filing requirements of the 1916, 1933 and 1984 Acts and the rules of this part if an exact copy of the rate guide or tender, including any amendments thereto, is filed with the Commission prior to the effective date of the rate guide or tender.

* * * * *

3. In § 514.9, paragraph (b)(13) is revised to read as follows:

§ 514.9 Filing/amendment codes and required notice periods.

* * * * *

(b) * * *

(13) Where a rate for military cargo is incorporated as a separate TLI in the commercial tariff of a carrier or conference the filing/amendment code "M" shall be used to identify the TLI. Any such military rate shall be effective upon filing.

* * * * *

§ 514.15 [Amended]

4. In § 514.15, paragraph (b)(32) is removed and marked "Reserved."

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[3] MSC filed comments which sought to make the exemption from the 30-day filing requirement available to all carriers, not simply American-flag vessels. The exemption proposed herein is considerably broader than the exemption from the 30-day filing requirement and is available to all carriers regardless of flag.

[4] The requirement that the exemption not result in a substantial reduction in competition does not appear in section 35 of the 1916 Act. In any event, the Commission fails to see how preservation of the *status quo* with respect to military rate tenders would result in a substantial reduction in competition.

By the Commission.
Joseph C. Polking,
Secretary.
[FR Doc. 93-695 Filed 1-12-93; 8:45 am]
BILLING CODE 6730-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Chapter I

MSS Above 1 GHz Negotiated Rulemaking Committee

AGENCY: Federal Communications Commission.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, this notice advises interested persons of the second meeting of the MSS Above 1 GHz Negotiated Rulemaking Committee ("Committee"), which will be held at the Federal Communications Commission in Washington, D.C.

DATES: Thursday, January 28, 1993 at 9:30 a.m.

ADDRESSES: Federal Communications Commission, Rm. 856, 1919 M Street, NW., Washington, DC 20554.

FOR ADDITIONAL INFORMATION CONTACT: Kathleen Campbell, Administrative Assistant to the Committee, at (202) 634-1952.

SUPPLEMENTARY INFORMATION: The agenda for the second meeting of the MSS Above 1 GHz Negotiated Rulemaking Committee is as follows:

1. Opening Remarks/Comments
2. Adoption of Agenda
3. Minutes/Records of Previous Meeting
4. Introduction of Documents
5. Informal Working Group Reports—Issues
6. Acceptance/Approval of Recommended Rules
7. Acceptance/Approval of Report Text
8. Agenda for future meetings—Schedule for future meetings
9. Other Business

Members of the general public may attend this meeting. The Federal Communications Commission will attempt to accommodate as many people as possible. However, admittance will be limited to the seating available. There will be no public oral participation, but the public may submit written comments to Fern J. Jarmulnek, the Committee's Designated Federal Officer, before the meeting.

Subsequent Committee meetings are scheduled for Thursday, February 2; Monday, February 8; Thursday, February 18; Thursday, February 25; Thursday, March 4; Tuesday, March 8; Thursday, March 18; Thursday, March 25; and Friday, April 2. All meetings are scheduled to begin at 9:30 a.m. at the Federal Communications Commission, 1919 M Street NW., room 856, Washington, DC 20554.

Federal Communciations Commission.
Donna R. Searcy,
Secretary.
[FR Doc. 93-875 Filed 1-12-93; 8:45 am]
BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 90-162, FCC 92-573]

Broadcast Services; Financial Interest and Syndication Provisions

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document seeks comment with regard to how the Commission should respond to the U.S. Court of Appeals for the Seventh Circuit decision in *Schurz Communications, Inc., et al.*, v. *FCC (Schurz)* which vacated this Commission's decision relaxing and modifying its financial interest and syndication rules. The Court instructed the Commission to provide more justification for its rules, or in the alternative, to propose a new set of rules. The Notice asks commenters to submit new information in support of the rules or, in the alternative, to propose a revised set of financial interest and syndication rules.

DATES: Comments are due by February 1, 1993, and reply comments are due by February 16, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Judith Herman, Mass Media Bureau, Policy and Rules Division, (202) 632-6302.

SUPPLEMENTARY INFORMATION:

Second Further Notice of Proposed Rulemaking

Adopted: December 31, 1992; Released: December 31, 1992.

Comment Date: February 1, 1993.

Reply Comment Date: February 16, 1993.

By the Commission: Chairman Sikes issuing separate statement.

I. Introduction

1. On November 5, 1992, the U.S. Court of Appeals for the Seventh Circuit in *Schurz Communications, Inc., et al.*, v. *FCC (Schurz)*[1] vacated this Commission's decision relaxing and modifying its financial interest and syndication rules.[2] The Court invalidated the Commission's decision except insofar as the Court found it to abrogate the original (1970) financial interest and syndication rules.[3] The Court stayed its decision for 120 days, remanding the matter to the Commission for further proceedings consistent with its ruling. In this Second Further Notice of Proposed Rulemaking we seek comment with regard to how we should resolve the Court's concerns.

II. Background

2. The financial interest and syndication rules, originally adopted in 1970, were designed to limit the power of the broadcast television networks over television programming. The rules prohibited the television networks from acquiring any financial interests in the subsequent broadcast of outside produced programs (i.e., programs not solely produced by the network) other than the right to exhibit such programs on the network. The rules also prohibited the networks from actively engaging in the domestic syndication business, or from having any ongoing interest in the syndication of programs for non-network broadcast distribution. Networks were allowed, however, to syndicate outside the United States programs that they solely produced or that were produced by foreign entities.

3. In 1991, this Commission determined, after an extensive notice and comment rulemaking proceeding and an *en banc* hearing, that it should relax, but not repeal the financial interest and syndication rules. Accordingly, the 1991 rules: (1) Eliminated restrictions on network ownership and syndication of network programming as to all dayparts and all programs other than prime time entertainment programming; (2) allowed networks to retain all rights in all "in-house" productions; (3) permitted networks to fill up to, but not more than, 40 percent of their prime time entertainment schedule with "in-house" productions; (4) allowed networks to acquire all rights, including financial interests, domestic syndication rights

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[1] See *Schurz Communications, Inc., et al.* v. *Federal Communications Commission and the United States of America*, Nos. 91-2350, *et al.*, slip opinion (7th Cir., November 5, 1992), and *modified*, (December 7, 1992).

[2] Report and Order in MM Docket No. 90-162, 6 FCC Rcd 3094 (1991) 56 FR 26242, June 6, 1991 Recon. granted in part/denied in part, 7 FCC Rcd 345 (1991).

[3] The Commission had expressly advised the Court that it had no independent intention to and, in fact, had not repealed the 1970 rules in its Order. Public Notice, FCC 92-520 (released November 20, 1992) (Chairman Sikes and Commissione Quello dissenting and issuing statements).

and foreign syndication rights, in outside productions on their own or another network, subject to certain safeguards; (5) allowed networks to engage in foreign syndication of network programs without limitation; and (6) allowed limited network participation in first-run syndication. The Commission also adopted a new definition of "network" and imposed certain behavioral safeguards.[4]

III. Discussion

4. The Court supported two important aspects of the Commission's reasoning in this proceeding. First, the Court agreed with the Commission's determination that the structure of the television industry has changed significantly since the financial interest and syndication rules were adopted in 1970. *Schurz* at 4. Second, the Court agreed that the Commission has the authority to regulate the networks in accordance with the public interest, convenience, or necessity and, thus, has the authority to restrict network programming activities so as to foster a diversity of programming sources and outlets even if the networks were without any market power. *Schurz* at 8–10.

5. The Court stated, however, that while the modified rules appear plausible, the decision did not address all the objections to the Commission's approach that were raised in the record of this proceeding. The Court concluded, therefore, that the Commission's justification for the 1991 rules was inadequate. The Court remanded the decision to give the Commission an opportunity to better articulate its justification. The Court opined that such a proceeding could result in significant modifications in the rules. *Schurz* at 12.

6. The Court identified several areas warranting further explanation. It stated that the Commission did not respond to the network's objection that the 1991 rules do not increase the networks' access to the programming market and may decrease it. The Court noted, for example, that the networks state that the 40 percent limitation on the amount of prime-time entertainment they can supply from in-house production is a new restriction, having no counterpart in the original rules.[5] Schurz at 13.

7. Further, the Court opined that the 1991 rules appear to harm rather than to help outside producers as a whole, especially the smallest and least able to bear risk, by reducing their bargaining options. The Court also stated that the Commission's decision did not fully explain how the 1991 rules prevent networks from extracting financial interests or syndication rights from outside producers. In particular, it questioned whether the new safeguards (e.g., the 30-day phased negotiations) could provide meaningful protection against extraction. Schurz at 16.

8. The Court also stated that the Commission failed to respond to the argument that its rules limit competition with the established networks, thereby limiting rather than promoting diversity. Specifically, the Court noted that the 1991 rules limit Fox Broadcasting Company to supplying no more than 15 hours of programming to its affiliates if Fox is to remain exempt from the 1991 rules. Thus, the Court found these rules to weaken Fox's incentives to furnish prime-time programming to its affiliates, many of whom are traditionally weak UHF stations, which appeared contrary to the Commission's desire to strengthen such stations. Schurz at 17–18.

9. The Court also found that the Commission's Order did not adequately address the 1983 Tentative Decision and Request for Further Comments in Docket 82–345,[6] and its legal significance as a Commission precedent. The Court said that the Commission should have better explained the differences between the 1983 Tentative Decision and the 1991 Order. Finally, the court said that while the Commission's Order states that a primary purpose of the 1991 rules is to promote "diversity", the Commission did not define the term nor adequately explain how the 1991 rules promote diversity. Schurz at 19. Accordingly, we seek specific comment on whether and how the 1991 rules are likely to preserve or enhance diversity of prime time broadcast television programming services and outlets.

10. The Court conceded that the arguments raised by the Justice Department, the networks and others with respect to the effect of the rules on competition, risk-sharing and diversity may be speculative, theoretical or wrong. These arguments were, however, sufficiently persuasive, in the Court's opinion, to have placed a burden of explanation that the Commission did not meet. In remanding the matter to the Commission, the Court suggested that we could seek to "rejustify" the 1991 rules or, in the alternative, draft new rules. The Court imposed a deadline of 120 days. The Court noted that the Commission may ask the Court for a stay, but, failing that, all Commission financial interest and syndication rules would be eliminated after 120 days. In compliance with the Court's mandate, we intend to reexamine the extensive record already compiled with a view toward reconciling new or revised rules, if any, with the Court's concerns. Commenters are invited to submit new information in support of the 1991 rules or, in the alternative, to propose a revised set of financial interest and syndication rules. Comments should not merely reiterate parties' positions already on the record, but should instead respond specifically and directly to the Court's opinion and the appropriate Commission response. In addition, we will consider the impact of regulatory changes and marketplace developments that have occurred during the intervening period. For example, commenters may want to assess the impact of the Commission's modified network-cable rules,[7] or the program access and industry structural review initiatives required by the 1992 Cable Act.[8] In this regard, commenters are invited to assess the need for a revised review period or the adoption of a presumption of sunset of any future rules in light of the Court's remand. We particularly encourage parties to consolidate their pleadings whenever possible.

IV. Administrative Matters

A. Regulatory Flexibility Analysis

11. As required by section 603 of the Regulatory Flexibility Act, the FCC has prepared an initial regulatory flexibility analysis (IRFA) of the expected impact of these proposed policies and rules on small entities. The IRFA is set forth in appendix A. Written public comments are requested on the IRFA. These comments must be filed in accordance with the same filing deadlines as comments on the rest of the Second Further Notice of Proposed Rulemaking, but they must have a separate and distinct heading designating them as responses to the regulatory flexibility analysis. The Secretary shall cause a copy of this Second Further Notice of Proposed Rulemaking, including the initial regulatory flexibility analysis, to be sent to the Chief Counsel for

[4] See 47 CFR 73.658(k), 73.659–73.662, 73.3526(a)(11) (1991).

[5] We note that neither the 1970 rules nor the 1983 Tentative Decision and Request for Further Comments permitted network domestic syndication of any programming. The 1991 rules relaxed the prior syndication prohibition, but invoked a scheduling safeguard as an interim measure.

[6] 94 FCC 2d at 1063.

[7] See Report and Order in MM Docket No. 92–434, 7 FCC Rcd 6156 (1992) 57 FR 35468, August 10, 1992, reconsideration pending.

[8] See, Cable Television Consumer Protection and Competition Act of 1992, Pub. L. No. 102–385, 106 Stat. (1992).

Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, Pub. L. No. 96–354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.* (1981).

B. Ex Parte

12. This is a non-restricted notice and comment rule-making proceeding. *Ex parte* presentations are permitted, except during the Sunshine Agenda period, provided they are disclosed as provided in the Commission's rules. See generally 47 CFR 1.1202, 1.203, and 1.206(a).

C. Comment Procedures

13. Pursuant to applicable procedures set forth in §§ 1.415 and 1.419 of the Commission's Rules, 47 CFR 1.415 and 1.419, interested parties may file comments on or before February 1, 1993, and reply comments on or before February 16, 1993. To file formally in this proceeding, you must file an original plus five copies of all comments, reply comments, and supporting comments. If you want each Commissioner to receive a personal copy of your comments, you must file an original plus nine copies. You should send comments and reply comments to Office of the Secretary, Federal Communications Commission, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the FCC Reference Center, room 239, 1919 M Street, NW., Washington, DC 20554.

14. The Commission must reach a decision in an expeditious manner, in light of the 120-day deadline imposed by the Court. Thus, comments on the issues raised in this Second Further Notice of Proposed Rulemaking shall not exceed thirty double-spaced typed pages, and reply comments shall not exceed twenty double-spaced typed pages.

D. Ordering Clauses

15. Authority for this proposed Second Further Notice of Proposed Rulemaking is contained in sections 4(i) and (j), and 301, 303(i), 303(r), 313 and 314 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 301, 303(i), 303(r), 313 and 314.

16. For further information on this proceeding, contact Judith Herman, Mass Media Bureau, (202) 632–6302.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

Appendix A.—Initial Regulatory Flexibility Analysis

Pursuant to the Regulatory Flexibility Act of 1980, the Commission finds:

I. *Reason for action.* This Second Further Notice of Proposed Rulemaking is initiated to obtain comment regarding the appropriate action the Commission should take in response to the Court's remand of the Commission's decision in the Order in this proceeding.

II. *Objectives.* The Commission seeks to review and perhaps modify its 1991 financial interest and syndication rules in light of the Court's decision.

III. *Legal basis.* Action as proposed for this rulemaking is contained in sections 4(i), 4(j), 301, 303(i), 303(r), 313 and 314 of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 301, 303(i), 303(r), 313 and 314.

IV. *Reporting, recordkeeping and other compliance requirements.* None.

V. *Federal rules which overlap, duplicate or conflict with this rule.* None.

VI. *Description, potential impact and number of small entities affected.* Any rule changes in this proceeding could affect television program producers, television networks and their affiliate stations, non-network television stations, cable networks, cable television program producers, cable television networks and cable television operators. After evaluating the comments in this proceeding, the Commission will further examine the impact of any rule changes on small entities and set forth our findings in the Final Regulatory Flexibility Analysis.

VII. *Any significant alternatives minimizing impact on small entities and consistent with stated objective.* None.

Statement of FCC Chairman Alfred C. Sikes Regarding the Reassessment of the "Financial Interest and Syndication" Rule

December 31, 1992.

I continue strongly to believe that the Government should not be involved in commercial battles between television networks and the producer community in general—especially the big multinational entertainment companies.

I can hypothesize, however, sound public policy reasons why some limited Government role might be warranted if it were clearly shown there is no other means of fostering more genuine program diversity. Consequently, commenters should address—and debate should surround—the question whether the networks, if they were accorded free rein, would be more or less hospitable to prospective or nascent producers, especially those with new programming ideas. If networks are likely to be less hospitable, commenters should then recommend reasonable steps this agency might take to ensure an environment that is more conducive to allowing prospective or nascent producers to make a contribution.

It may well be that there is no good reason to assume any Government rules would be publicly beneficial—or, more accurately, work markedly better than a marketplace solution. Markets need not work better than regulation to be desirable; all markets need do is work as effectively as regulation and, as anyone exposed to the regulatory process appreciates, it is not hard to work "as effectively" as regulation. We should, however, endeavor to explore fully this one question of how best to foster a program production environment conducive to a diversity greater than we enjoy today. Comments on this point, accordingly, would be welcome.

[FR Doc. 93–613 Filed 1–12–93; 8:45 am]
BILLING CODE 6712–01–M

DEPARTMENT OF ENERGY

Office of the Secretary

48 CFR Part 970

Acquisition Regulation; Implementation of Requirements of Major Fraud Act of 1988

AGENCY: Department of Energy (DOE).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Energy (DOE) today proposes a rule which, when issued as a final rule, will amend the Department of Energy Acquisition Regulation (DEAR) and implement the requirements of the Major Fraud Act of 1988 (Pub. L. 100–700), enacted November 19, 1986, hereafter referred to as the "Act." The intended effect of this proposal is to establish, for incorporation in all of DOE's management and operating (M&O) contracts, awarded or extended after November 19, 1988, mandatory contract provisions prohibiting, in specified circumstances, the reimbursement of certain costs related to legal and other proceedings.

DATES: Written comments must be submitted no later than February 12, 1993.

ADDRESSES: Comments must be addressed to: Gwendolyn S. Cowan, Director, Business and Financial Policy Division (PR–122), Office of Procurement, Assistance and Program Management, U.S. Department of Energy, 1000 Independance Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Gwendolyn S. Cowan, Business and Financial Policy Division (PR–122), Office of Procurement, Assistance and Program Management, U.S. Department of Energy, Washington, DC 20585. (202) 586–8159.

Mary Ann Masterson, Office of the Assistant General Counsel for Procurement and Finance (GC–34),

U.S. Department of Energy, Washington, DC 20585. (202) 586–1900.

SUPPLEMENTARY INFORMATION:

I. Background
II. Procedural Requirements
A. Review Under Executive Order 12291
B. Review Under the Regulatory Flexibility Act
C. Review Under the Paperwork Reduction Act
D. Review Under the National Environmental Policy Act
E. Review Under Executive Order 12612
F. Review Under Executive Order 12778
III. Public Comments

I. Background

Under section 644 of the Department of Energy Organization Act, Public Law 95–91 (42 U.S.C. 7254), the Secretary of Energy is authorized to prescribe such procedural rules and regulations as may be deemed necessary or appropriate to accomplish the functions vested in that position. Accordingly, the DEAR was promulgated with an effective date of April 1, 1984 (49 FR 11922, March 28, 1984), 48 CFR chapter 9.

The purpose of this rule is to revise the DEAR to formally establish policies, procedures and contract provisions to apply the Act's provisions in all cases where a criminal, civil or administrative proceeding is brought by Federal, State, local or foreign government against an M&O contractor. Accordingly, the proposed DEAR amendments include provisions for determining the allowability of an M&O contractor's costs incurred in connection with a criminal, civil or administrative proceeding involving contractor violation of, or failure to comply with, a Federal, State, local or foreign statute or regulation.

All M&O contracts awarded or extended after November 19, 1988, the effective date of the Act, are subject to the Act and will be amended, as soon as possible, after the final rule is promulgated. Existing M&O contracts awarded or extended prior to the Act's effective date will be amended at that time of the next contract extension, if extended.

A brief description of the proposed DEAR amendments to part 970 follows:

Under DEAR subpart 970.31, "Contract Costs Principles and Procedures, "subsection 970.3102–20, "Defense of fraud proceedings," is replaced in its entirety by a new section titled "Costs related to legal and other proceedings." Subsection 970.3103, "Contract clauses," is revised to prescribe a new contract clause entitled "Costs related to legal and other proceedings."

Under DEAR subpart 970.52, "Contract Clauses For Management And Operating Contracts," subsection 970.5204–13, "Allowable costs and fixed-fee (management and operating contracts)," is revised, in paragraph (e)(33), to implement the Act and include a reference to the new contract clause specified at DEAR 970.5204–59; subsection 970.5204–14, "Allowable costs and fixed-fee (support contracts)," is revised, in paragraph (e)(31), to implement the Act and include a reference to the new contract clause specified at DEAR 970.5207–59; and subsection 970.5204–59, "Costs related to legal and other proceedings," to implement the Major Fraud Act Of 1988.

II. Procedural Requirements

A. Review Under Executive Order 12291

This Executive Order, entitled "Federal Regulation," requires that certain regulations be reviewed by the Office of Management and Budget (OMB) prior to their promulgation. The Director, OMB by memorandum dated December 14, 1984, exempted certain agency procurement regulations from Executive Order 12291. The exemption applies to this rule.

B. Review Under the Regulatory Flexibility Act

This proposed rule was reviewed under the Regulatory Flexibility Act of 1980, Public Law 96–354, which requires preparation of a regulatory flexibility analysis for any rule which is likely to have significant economic impact on a substantial number of small entities. DOE certifies that this rule will not have a significant economic impact on a substantial number of small entitips and, therefore, no regulatory flexibility analysis has been prepared.

C. Review Under the Paperwork Reduction Act

No information collection or reporting requirements are imposed by this proposed rulemaking. Accordingly, no OMB clearance is required by the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq).

D. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this rule would not represent a major Federal action having significant impact on the human environment under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq. (1976)), or the Council on Environmental Quality regulations (40 CFR parts 1500–1508) and the DOE guidelines (10 CFR part 1021), and, therefore, does not require an environmental impact statement or an environmental assessment pursuant to NEPA.

E. Review Under Executive Order 12612

Executive Order 12612 (52 FR 41685, October 30, 1987) requires that regulations, rules, legislation, and any other policy actions be reviewed by any substantial direct effects on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among various levels of government. If there are sufficient substantial direct effects, then the Executive Order requires preparation of a federalism assessment to be used in all decisions involved in promulgating and implementing a policy action.

Today's proposed rule, when finalized, will revise certain policy and procedural requirements. However, the Department of Energy has determined that none of the revisions will have a substantial direct effect on the institutional interests or traditional functions of States.

F. Review Under Executive Order 12778

Section 2 of Executive Order 12778 instructs each agency subject to Executive Order 12291 to adhere to certain requirements in promulgating new regulations and reviewing existing regulations. These requirements, set forth in sections 2(a) and (b)(2), include eliminating drafting errors and needless ambiguity, drafting the regulations to minimize litigation, providing clear and certain legal standards for affected conduct, and promoting simplification and burden reduction. Agencies are also instructed to make every reasonable effort to ensure that the regulation: specifies clearly any preemptive effect, effect on existing Federal law or regulation, and retroactive effect; describes any administrative proceedings to be available prior to judicial review and any provisions for the exhaustion of such administrative proceedings; and defines key terms. DOE certifies that today's proposal meets the requirements of sections 2 (a) and (b) of Executive Order 12778.

III. Public Comments

Interested persons are invited to participate by submitting data, views, or arguments with respect to the proposed DEAR amendments set forth in this notice. Three copies of written comments should be submitted to the address indicated in the ADDRESSES section of this notice. All comments received will be available for public inspection in the DOE Reading Room,

room 1E–190, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, between the hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. All written comments received by the date indicated in the DATES section of this notice will be carefully assessed and fully considered prior to publication of the proposed amendment as a final rule. Any information considered to be confidential must be so identified and submitted in writing, one copy only. DOE reserves the right to determine the confidential status of the information and to treat it according to our determination.

The Department has concluded that this proposed rule does not involve a substantial issue of fact or law and that the proposed rule should not have substantial impact on the nation's economy or a large number of individuals or businesses. Therefore, pursuant Public Law 95–91, the DOE Organization Act, and the Administrative Procedure Act (5 U.S.C. 553), the Department does not plan to hold a public hearing on this proposed rule.

List of Subjects in 48 CFR Part 970

Government procurement.

For the reasons set out in the preamble, part 970 of chapter 9 of title 48 of the Code of Federal Regulations is proposed to be amended as set forth below.

Issued in Washington, DC, on December 30, 1992.

Berton J. Roth,

Acting Director, Office of Procurement, Assistance and Program Management.

PART 970—DOE MANAGEMENT AND OPERATING CONTRACTS

1. The authority citation for part 970 continues to read as follows:

Authority: Sec. 161 of the Atomic Energy Act of 1954 (42 U.S.C. 2201); sec. 644 of the Department of Energy Organization Act, Pub. L. 95–91 (42 U.S.C. 7254); sec. 201 of the Federal Civilian Employee and Contractor Travel Expenses Act of 1985 (41 U.S.C. 420); and sec. 1534 of the Department of Defense Authorization Act,1986, Pub. L. 99–145 (42 U.S.C. 7256a), as amended.

2. Section 970.3102–20 is revised to read as follows:

970.3102–20 Cost prohibitions related to legal and other proceedings.

(a) Contractor costs incurred in connection with a criminal, civil or administrative proceeding involving contractor violation of, or failure to comply with, a Federal, State, local or foreign statute or regulation are subject to the allowable costs limitations established in section 8 of the Major Fraud Act of 1988, Public Law 100–700 (see 41 U.S.C. 256).

(b) Implementation of the Major Fraud Act's contract cost limitations is specified in the applicable cost principles clauses at 970.5204–13(e)(33) or 970.5204–14(e)(31). Definitive cost principle criteria for determining the allowability of an M&O contractor's costs incurred in connection with a criminal, civil or administrative proceeding are set forth in the contract clause at 970.5204–59. The referenced clauses are effective, retroactively, for any contract awarded or extended on or after November 19, 1988, the effective date of the Major Fraud Act, and any change made to the cost principle criteria specified therein constitutes a deviation requiring Procurement Executive approval pursuant to 970.3100–3.

3. Section 970.3103, Contract clauses, is amended by adding paragraph (c) to read:

970.3103 Contract clauses

* * * * *

(c) The clause setting forth cost prohibitions related to legal and other proceedings at 970.5204–59 shall be included in all M&O contracts.

4. Section 970.5204–13, Allowable costs and fixed-fee (management and operating contracts), is amended by revising paragraph (e)(33) to read as follows:

§ 970.5204–13 Allowable costs and fixed-fee (management and operating contracts).

* * * * *

(e) * * *

(33) Costs incurred in connection with any criminal, civil or administrative proceeding commenced by the Federal Government or a State, local or foreign government, as provided in the clause titled "Cost prohibitions related to legal and other proceedings" incorporated elsewhere in this contract.

* * * * *

5. Section 970.5204–14, Allowable costs and fixed-fee (support contracts), is amended by revising paragraph (e)(31) to read as follows:

§ 970.5204–14 Allowable costs and fixed-fee (support contracts).

* * * * *

(e) * * *

(31) Costs incurred in connection with any criminal, civil or administrative proceeding commenced by the Federal Government or State, local or foreign government, as provided in the clause titled "cost prohibitions related to legal and other proceedings" incorporated elsewhere in this contract.

* * * * *

6. Section 970.5204–59, Cost prohibitions related to legal and other proceedings, is added as follows:

§ 970.5204–59 Cost prohibitions related to legal and other proceedings.

(a) Definitions.

Conviction, as used herein, means a judgment or conviction of a criminal offense by any court of competent jurisdiction, whether entered upon a verdict or a plea, including a conviction due to a plea of nolo contendre.

Costs, include, but are not limited to, administrative and clerical expenses; the cost of legal services, whether performed by in-house or private counsel; the costs of the services of accountants, consultants, or others retained by the contractor to assist it; all elements of compensation, related costs, and expenses of employees, officers and directors; and any similar costs incurred before, during, and after commencement of a proceeding which bears a direct relationship to the proceeding.

Fraud, as used herein, means—

(1) Acts of fraud or corruption or attempts to defraud the Government or to corrupt its agents,

(2) Acts specified under 10 CFR 1035.5(a)(1) which constitute a cause for debarment or suspension (see 10 CFR 1035.5 (a) and (b)), and

(3) Acts which violate the False Claims Act, 31 U.S.C. 3729–3731, or the Anti-kickback Act, 41 U.S.C. 51 and 54.

Penalty, does not include restitution, reimbursement, or compensatory damages.

Proceeding, includes an investigation.

(b) Except as otherwise described herein, costs incurred in connection with any criminal, civil or administrative proceeding commenced by the Federal Government, or a State, local or foreign government, are not allowable if the proceeding relates to a violation of, or failure to comply with, a Federal, State, local or foreign statute or regulation by the contractor, and results in any of the following dispositions:

(1) In a criminal proceeding, conviction.

(2) In a civil or administrative proceeding involving an allegation of fraud or similar misconduct, a determination of contractor liability.

(3) In the case of any civil or administrative proceeding, the imposition of a monetary penalty.

(4) A final decision by an appropriate Federal official to debar or suspend the contractor, to rescind or void a contract, or to terminate a contract for default by reason of a violation of or failure to comply with a law or regulation.

(5) A disposition by consent or compromise, if the action could have

resulted in any of the dispositions described in paragraphs (b) (1), (2), and (3) or (4) of this section.

(6) Not covered by paragraphs (b) (1) through (5) of this section, but where the underlying alleged contractor misconduct was the same as that which led to a different proceeding whose costs are unallowable by reason of paragraphs (b) (1) through (5) of this section.

(c) If a proceeding referred to in paragraph (b) of this section is commenced by the Federal Government and is resolved by consent or compromise pursuant to an agreement entered into by the contractor and the Federal Government, then the costs incurred by the contractor in connection with such proceeding that are otherwise unallowable under paragraph (b) of this section may be allowed to the extent specifically provided in such agreement.

(d) If a proceeding referred to in paragraph (b) of this section is commenced by a State, local or foreign government, the Contracting Officer may allow the costs incurred in such proceeding, provided the Procurement Executive determines that the costs were incurred as a result of compliance with a specific term or condition of the contract, or specific written direction of the Contracting Officer.

(e) Costs incurred in connection with a proceeding described in paragraph (b) of this section, but which are not made unallowable by that paragraph, may be allowed by the Contracting Officer only to the extent that:

(1) The total costs incurred are reasonable in relation to the activities required to deal with the proceeding and the underlying cause of action;

(2) Payment of the costs incurred, as allowable and allocable contract costs, is not prohibited by any other provision(s) of this contract.

(3) The costs are not otherwise recovered from the Federal Government or a third party, either directly as a result of the proceeding or otherwise; and

(4) The amount of costs allowed does not exceed 80 percent of the total costs incurred and otherwise allowable under the contract. Such amount that may be allowed (up to the 80 percent limit) shall not exceed the percentage determined by the Contracting Officer to be appropriate, considering the complexity of procurement litigation, generally accepted principles governing the award of legal fees in civil actions involving the United States as a party, and such other factors as may be appropriate. However, where an agreement reached under paragraph (c) of this section explicitly considered this 80 percent limitation, then an amount up to the full amount of costs specifically provided in such agreement may be allowed.

(f) Contractor costs incurred in connection with the defense of suits brought by employees or ex-employees of the contractor under section 2 of the Major Fraud Act of 1988, including the cost of all relief necessary to make such employee whole, where the contractor was found liable or settled, are unallowable.

(g) Costs which may be unallowable under this clause, including directly associated costs, shall be differentiated and accounted for by the contractor so as to be separately identifiable. During the pendency of any proceeding covered by paragraphs (b) and (f) of this section, the Contracting Officer shall generally withhold payment and not authorize the use of funds advanced under the contract for the payment of such costs. However, the Contracting Officer may, in appropriate circumstances, provides for conditional payment upon provision of adequate security, or other adequate assurance, and agreements by the contractor to repay all unallowable costs, plus interest, if the costs are subsequently determined to be unallowable.

[FR Doc. 93–767 Filed 1–12–93; 8:45 am]
BILLING CODE 6450–01–M

DEPARTMENT OF THE INTERIOR

Fish And Wildlife Service

50 CFR Part 17

RIN 1018–AB

Endangered and Threatened Wildlife and Plants; Public Hearing and Reopening of Comment Period on Proposed Endangered Status for the Plant Ipomopsis sancti-spiritus

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of public hearing and reopening of comment period.

SUMMARY: The U.S. Fish and Wildlife Service (Service) gives notice that a public hearing will be held and the comment period is reopened on the proposed rule to list *Ipomopsis sancti-spiritus* (Holy Ghost ipomopsis) as an endangered species. The comment period is being reopened to allow the Service to accept oral or written comments at the hearing and for a reasonable period of time thereafter.

DATES: The public hearing will be held from 6:30 p.m. to 9 p.m. on January 27, 1993, in Santa Fe, New Mexico. The comment period for this proposal is reopened on January 13, 1993 and now closes on February 23, 1993.

ADDRESSES: The public hearing will be held at the Public Employee's Retirement Association (PERA) Building, Apodaca Hall, 1120 Paseo de Peralta, Santa Fe, New Mexico. Written comments and materials should be sent to the Field Supervisor, U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 3530 Pan American Highway, Suite D, Albuquerque, New Mexico 87107. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above Field Office address.

FOR FURTHER INFORMATION CONTACT: For information on the public hearing, contact Philip Clayton at the above Field Office address, telephone (505) 883–7877.

SUPPLEMENTARY INFORMATION:

Background

Holy Ghost ipomopsis is a member of the phlox family and is known to occur only in a limited area of the Sangre de Cristo Mountains, San Miguel County, New Mexico. Holy Ghost ipomopsis is threatened by road maintenance, wildfire and fire management policy, habitat alteration, and pesticide application. A proposed rule to list this species as endangered was published in the **Federal Register** (57 FR 43682) on September 22, 1992.

Section 4(b)(5)(E) of the Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et seq.*), requires that a public hearing be held if requested within 45 days of the publication of a proposed rule. On October 21, 1992, the Service received a written request for a public hearing from Mr. Bert Turner, President of the San Miguel/Mora County Farm and Livestock Bureau, Wagon Mound, New Mexico. The Service has scheduled this public hearing for January 27, 1993, from 6:30 p.m. to 9 p.m. in the Public Employee's Retirement Association Building, Santa Fe, New Mexico. Those parties wishing to make statements for the record should bring a copy of their statement to present to the Service at the start of the hearing. Oral statements may be limited in length, if the number of parties present at the hearing necessitates such a limitation. There are, however, no limits to the length of written comments or materials presented at the hearing or mailed to the Service.

The comment period on the proposed rule originally closed on November 23,

1992. The Service is reopening the comment period until February 23, 1993. This will allow the Service to accept oral or written comments presented at the hearing, and to accept written comments for a reasonable period of time after the hearing. Written comments should be submitted to the Service office in the ADDRESSES section.

Author

The primary author of this notice is Philip Clayton, U.S. Fish and Wildlife Service, New Mexico Ecological Services Field Office, 3530 Pan American Highway, Suite D, Albuquerque, New Mexico 87107, (505) 883–7877.

Authority: The authority for this action is the Endangered Species Act (16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Dated: January 7, 1993.

James A. Young,

Acting Regional Director.

[FR Doc. 93–727 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–55–M

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AB69

Endangered and Threatened Wildlife and Plants; Notice of Public Hearing and Reopening of Comment Period on Proposed Endangered Status for 23 Plants From the Island of Kauai, HI

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of public hearing and reopening of comment period.

SUMMARY: The U.S. Fish and Wildlife Service (Service), pursuant to the Endangered Species Act of 1973, as amended (Act), gives notice that a public hearing will be held on the proposed rule to list 23 plants from the island of Kauai, Hawaii, as endangered species, and that the comment period on the proposal is reopened. The proposal was published in the **Federal Register** on October 30, 1991 (56 FR 55862). The public hearing will be held on February 10, 1993, in Kapa'a, Hawaii. Interested parties may submit oral or written comments on the proposal to the Service at the hearing.

DATES: The comment period on the proposal is reopened on January 13, 1993. The public hearing will be held from 6 to 8 p.m. on Wednesday, February 10, 1993, in Kapa'a, Hawaii. The comment period, which originally closed on December 30, 1991, now closes on February 20, 1993.

ADDRESSES: The public hearing will be held in the auditorium of the Kapa'a Public Library, 1464 Kuhio Highway, Kapa'a, Kauai, Hawaii. Written comments and materials should be sent to Robert P. Smith, Field Supervisor, Pacific Islands Office, U.S. Fish and Wildlife Service, 300 Ala Moana Boulevard, room 6307, P.O. Box 50167, Honolulu, Hawaii 96850. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Joan E. Canfield, at the above address (telephone 808/541–2749).

SUPPLEMENTARY INFORMATION:

Background

Brighamia insignis, Cyanea asarifolia, Cyrtandra limahuliensis, Delissea rhytidosperma, Diellia laciniata, Exocarpos luteolus, Hedyotis cookiana, Hibiscus clayi, Lipochaeta fauriei, Lipochaeta micrantha, Lipochaeta waimeaensis, Lysimachia filifolia, Melicope haupuensis, Melicope knudsenii, Melicope pallida, Melicope quadrangularis, Munroidendron racemosum, Nothocestrum peltatum, Peucedanum sandwicense, Phyllostegia waimeae, Pteralyxia kauaiensis, Schiedea spergulina, and *Solanum sandwicense* are endemic to or have the majority of their populations on the island of Kauai, Hawaii. Sixteen of these species are endemic to Kauai; two additional species are now found only on that island. One of these species is now or was previously also known from Niihau, five from Oahu, two from Molokai, two from Maui, and one from the island of Hawaii.

The 23 plant species and their habitats have been variously affected or are currently threatened by one or more of the following: Habitat degradation by wild, feral, or domestic animals (goats, pigs, mule deer, cattle, and red jungle fowl); competition for space, light, water, and nutrients by naturalized, introduced vegetation; erosion of substrate produced by weathering or human- or animal-caused disturbance; recreational and agricultural activities; habitat loss from fires; and predation by animals (goats and rats). Due to the small number of existing individuals and their very narrow distributions, these species and most of their populations are subject to an increased likelihood of extinction and/or reduced reproductive vigor from stochastic events.

The proposed rule to list these plants as endangered was published on October 30, 1991 (56 FR 55862). The comment period for the proposal originally closed on December 30, 1991. In order to accommodate the hearing, the Service reopens the public comment period. Written comments may now be submitted until February 20, 1993, to the Pacific Islands Office (See ADDRESSES section).

A public hearing will be held on Wednesday, February 10, 1993, from 6 to 8 p.m., in the auditorium of the Kapa'a Public Library, 1464, Kuhio Highway, Kapa'a, Kauai, Hawaii. Those parties wishing to make statements for the record should bring a copy of their statements to present to the Service at the start of the hearing. Oral statements may be limited in length, if the number of parties present at the hearing necessitates such a limitation. There are no limits to the length of written comments or materials presented at the hearing or mailed to the Service. Written comments will be given the same weight as oral comments. Written comments may be submitted at the hearing or mailed to the Pacific Islands Office (see ADDRESSES section).

Author

The primary author of this notice is Dr. Joan E. Canfield, Fish and Wildlife Enhancement, Pacific Islands Office, U.S. Fish and Wildlife Service, P.O. Box 50167, Honolulu, Hawaii 96850 (808/541–2749).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

Dated: January 6, 1993.

Richard N. Smith,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 93–741 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–55–M

VOL 58 ISS 8 JA 13 1993 UMI

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 663

Pacific Coast Groundfish Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of availability of an amendment to a fishery management plan and request for comments.

SUMMARY: NMFS issues this notice that the Pacific Fishery Management Council has submitted Amendment 7 (amendment) to the Pacific Coast Groundfish Fishery Management Plan (FMP) for review by the Secretary of Commerce (Secretary). Amendment 7 proposes to establish a framework authority to reduce bycatch of nongroundfish species in the groundfish fishery. Written comments are invited from the public. Copies of the amendment may be obtained from the address below.

DATES: Written comments must be received on or before March 15, 1993.

ADDRESSES: Comments should be sent to Rolland A. Schmitten, Director, Northwest Region, National Marine Fisheries Service, NOAA, 7600 Sand Point Way NE., BIN C15700-Bldg. 1, Seattle, WA 98115–0070, or Dr. Gary Matlock, Acting Director, Southwest Region, National Marine Fisheries Service, 501 West Ocean Blvd., suite 4200, Long Beach, CA 90802–4213. Copies of the amendment are available upon request from Lawrence D. Six, Executive Director, Pacific Fishery Management Council, Metro Center, suite 420, 2000 SW. First Avenue, Portland, OR 97201–5344.

FOR FURTHER INFORMATION CONTACT: William L. Robinson, Fisheries Management Division, Northwest Region, NMFS, at 206–526–6140; Rodney R. McInnis, Fisheries Management Division, Southwest Region, NMFS, at 310–980–4040; or Lawrence D. Six, Pacific Fishery Management Council, at 503–221–6352.

SUPPLEMENTARY INFORMATION: The Magnuson Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* (Magnuson Act), requires that a regional fishery management council submit any amendment to a fishery management plan it has prepared to the Secretary for review and approval, disapproval, or partial disapproval. The Magnuson Act also requires that the Secretary, upon receipt of the amendment, immediately publish a notice stating that the amendment is available for public review and comment. The Secretary will consider all public comments received during the public comment period in deciding whether to approve the amendment for implementation.

Amendment 7 to the FMP would establish the authority to impose management measures on the groundfish fishery to reduce the bycatch of salmon and other non-groundfish species. The amendment would: (1) Add a new management objective under the conservation goal (i.e., prevent overfishing by managing for appropriate harvest levels, and prevent any net loss of the habitat of living marine resources) currently contained in section 2.1 of the FMP; and (2) establish a regulatory process (framework) that could be used to implement specific management measures when a conservation issue has been identified or in response to requirements of the Endangered Species Act or other applicable law. The amendment itself would not impose any management measures.

An environmental assessment (required under the National Environmental Policy Act) and a regulatory impact review (satisfying the requirements of Executive Order 12291) are incorporated in the amendment. All are available for public review as noted above.

Proposed regulations to implement this amendment are scheduled to be published within 15 days of this notice.

List of Subjects in 50 CFR Part 663

Administrative practice and procedure, Fisheries, Fishing, Reporting and recordkeeping requirements.

Authority: 16 U.S.C. 1801 *et seq.*)

Dated: January 7, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–691 Filed 1–7–93; 3:27 pm]

BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 58, No. 8
Wednesday, January 13, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Government Owned Inventions Available for Licensing

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of Government Owned Inventions Available for Licensing.

SUMMARY: The inventions listed below are owned by the U.S. Government as represented by the Department of Agriculture, and are available for licensing in accordance with 35 U.S.C. 207 and 37 CFR part 404 to achieve expeditious commercialization of results of federally funded research and development. Foreign patents are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Technial and licensing information on these inventions may be obtained by writing to: M. Ann Whitehead, Patent Coordinator, USDA, ARS, Room 403, Bldg. 005, BARC-West, Beltsville, Maryland 20705; 301–504–6786 or Fax 301–504–5060. All patent applicants may be purchased, specifying the serial number listed below, by writing NTIS, 5285 Port Royal Road, Springfield, Virginia, 22161; NTIS Sales Desk 703–487–4650. Issued patents may be obtained from the Commissioner of Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

SUPPLEMENTARY INFORMATION: The inventions available for licensing are:

6–436,541, (U.S. 4,495,207) Production of Food-Grade Corn Germ Product by Supercritical Fluid Extraction
6–445,112, (U.S. 4,474,755) Bagworm Moth Attractant and Plant Protectant
6–500,049, (U.S. 4,522,838) 2-Acetyl-1-Pyrroline and Its Use for Flavoring Foods
6–527,894, (U.S. 4,443,222) Zinc Pyrithione Process to Impart Antimicrobial Properties to Textiles
6–534,015, (U.S. 4,493,854) Production of Defatted Soybean Products by Supercritical Fluid Extraction
6–539,907, (U.S. 4,582,704) Control of Bean Rust with *Bacillus subtilis*
6–566,469, (U.S. 4,523,327) Sesbanimide and the Use Thereof in Treating Leukemic Tumors
6–635,945, (U.S. 4,737,371) Process for Stabilizing Whole Cereal Grains
6–860,351, (U.S. 4,721,727) Control of Pests with Annonaceous Acetogenins
6–922,616, (U.S. 4,826,765) Yeast Strains Genetically Engineered to Produce Wheat Gluten Proteins
7–123,411 (U.S. 4,839,450) Moisture-Shrinkable Films From Starch Graft Copolymers
7–140,470, (U.S. 4,835,818) Differential Ginning Process and Apparatus

M. Ann Whitehead,
National Patent Coordinator.

[FR Doc. 93–760 Filed 1–12–93; 8:45 am]
BILLING CODE 3410-03-M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 46–90]

Foreign-Trade Zone 72—Indianapolis, Indiana; Application for Subzone; Forklift Truck Plant; Columbus, Indiana; Amendment to Application

Notice is hereby given that the application submitted by the Indianapolis Airport Authority, grantee of FTZ 72, requesting special-purpose subzone status for the forklift truck manufacturing facility of Toyota Industrial Equipment Mfg., Inc. (TIEM) (subsidiary of Toyota Automatic Loom Works, Ltd. of Japan) in Columbus, Indiana (55 FR 49662, 11/30/90) has been amended to limit the scope of the authority requested in the application with respect to components.

The original application requested authority to use full zone procedures for a wide range of foreign-sourced components so that TIEM could choose the finished product duty rate (duty-free) for those components (duty rates to 11%). The amendment limits the request to foreign-sourced engines and transmissions (duty rates to 5.7%). All other components would be admitted in domestic or foreign privileged status.

The application remains otherwise unchanged.

The comment period is reopened until March 1, 1993.

Dated: January 6, 1993.

John J. Da Ponte, Jr.,
Executive Secretary.

[FR Doc. 93–798 Filed 1–12–93; 8:45 am]
BILLING CODE 3510-DS-M

[Docket No. 69–91]

Foreign-Trade Zone 41—Milwaukee, Wisconsin; Application for Expansion; Amendment of Application

The pending application of the Foreign-Trade Zone of Wisconsin, Ltd., grantee of FTZ 41, requesting authority to reorganize and expand its zone in Milwaukee, Wisconsin, within the Milwaukee Customs port of entry, (Docket 69–91, filed 10/29/91, 56 FR 57513, 11/12/91 and amended 10/2/92, 57 FR 45606), has been further amended to request authority for an additional site.

The initial application requested authority to add a new site (Port of Milwaukee complex, 300 acres) to the zone project and to delete three existing sites.

This amendment requests authority for an additional site (210,500 sq. ft.) located at 1925 E. Kelly Lane, Cudahy, Wisconsin. It would accommodate the activity formerly conducted at Site 1, which is being deleted. The application, as amended, would decrease the total number of sites for the FTZ 41 project to three.

The comment period is reopened until February 12, 1993.

The application and amendment material are available for public inspection at the following locations:

U.S. Department of Commerce, District Office, 517 East Wisconsin Avenue, room 606, Milwaukee, Wisconsin 53202.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, 14th and Pennsylvania Avenue, NW., room 3716, Washington, DC 20230.

Dated: January 6, 1993.

John J. Da Ponte, Jr.,
Executive Secretary.

[FR Doc. 93–799 Filed 1–12–93; 8:45 am]
BILLING CODE 3510-DS-M

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of opportunity to request administrative review of antidumping or countervailing duty order, finding, or suspended investigation.

BACKGROUND: Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspension of investigation, an interested party as defined in section 771(9) of the Tariff Act of 1930 may request, in accordance with § 353.22 or 355.22 of the Commerce Regulations, that the Department of Commerce ("the Department") conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

OPPORTUNITY TO REQUEST A REVIEW: Not later than January 31, 1993, interested parties may request administrative review of the following orders, finding, or suspension of investigations, with anniversary dates in January for the following periods:

Antidumping duty proceedings	Period
Brazil: brass sheet & strip (A–351–603).	01/01/92–12/31/92.
Canada: brass sheet & strip (A–122–601).	01/01/92–12/31/92.
Canada: color picture tubes (A–122–605).	01/01/92–12/31/92.
France: anhydrous sodium Metrasilicate (A–427–098).	01/01/92–12/31/92.
Japan: color picture tubes (A–588–609).	01/01/92–12/31/92.
Singapore: color picture tubes (A–559–601).	01/01/92–12/31/92.
Spain: potassium permanganate (A–469–007).	01/01/92–12/31/92.
South Africa: low–fuming brazing copper wire and rod (A–791–502).	01/01/92–12/31/92.
Taiwan: certain stainless steel cooking ware (A–583–603).	01/01/92–12/31/92.
The People's Republic of China: potassium permanganate (A–570–001).	01/01/92–12/31/92.
The Republic of Korea: brass sheet and strip (A–580–603).	01/01/92–12/31/92.
The Republic of Korea: color picture tubes (A–580–605).	01/01/92–12/31/92.
The Republic of Korea: stainless steel cooking ware (A–580–601).	01/01/92–12/31/92.
Suspension agreements	**Period**
Canada: potassium chloride (A–122–701).	01/01/92–12/31/92.
Colombia: miniature carnations (C–301–601).	01/01/92–12/31/92.
Costa Rica: fresh cut flowers (C–223–601).	01/01/92–12/31/92.
Hungary: truck trailer axle and brake assemblies (A–437–001).	01/01/92–12/31/92.
Countervailing duty proceedings	
Argentina: non-rubber footwear (C–357–052).	01/01/92–12/31/92.
Brazil: brass sheet and strip (C–351–604).	01/01/92–12/31/92.
Ecuador: fresh cut flowers (C–331–601).	01/01/92–12/31/92.
The Republic of Korea: stainless steel cookware (C–580–602).	01/01/92–12/31/92.
Spain: stainless steel wire rod (C–469–004).	01/01/92–12/31/92.
Taiwan: stainless steel cookware (C–583–604).	01/01/92–12/31/92.
Thailand: butt-weld pipe fittings (C–549–804).	01/01/92–12/31/92.

In accordance with §§ 353.22(a) and 355.22(a) of the Commerce regulations, an interested party may request in writing that the Secretary conduct an administrative review of specified individual producers or resellers covered by an order, if the requesting person states why the person desires the Secretary to review those particular producers or resellers. If the interested party intends for the Secretary to review sales of merchandise by a reseller (or a producer if that producer also resells merchandise from other suppliers) which was produced in more than one country of origin, and each country of origin is subject to a separate order, then the interested party must state specifically which reseller(s) and which countries of origin for each reseller the request is intended to cover.

Seven copies of the request should be submitted to the Assistant Secretary for Import Administration, International Trade Administration, room B–099, U.S. Department of Commerce, Washington, DC 20230. Further, in accordance with § 353.31 or 355.31 of the Commerce Regulations, a copy of each request must be served on every party on the Department's service list.

The Department will publish in the **Federal Register** a notice of "Initiation of Antidumping (Countervailing) Duty Administrative Review", for requests received by January 31, 1993.

If the Department does not receive, by January 31, 1993, a request for review of entries covered by an order or finding listed in this notice and for the period identified above, the Department will instruct the Customs Service to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of (or bond for) estimated antidumping or countervailing duties required on those entries at the time of entry, or withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

This notice is not required by statute, but is published as a service to the international trading community.

Dated: January 6, 1993.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 93–794 Filed 1–12–93; 8:45 am]

BILLING CODE 3510–DS–M

[A–583–009]

Color Television Receivers, Except for Video Monitors, From Taiwan; Preliminary Results of Antidumping Duty Administrative Review

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Notice of preliminary results of antidumping duty administrative review.

SUMMARY: In response to a request by Zenith Electronics Corporation, the Department of Commerce has conducted an administrative review of the antidumping duty order on color television receivers, except for video monitors, from Taiwan. This notice covers 14 manufacturers/exporters and the period April 1, 1991 through March 31, 1992. The review indicates the existence of dumping margins for certain firms during the period.

As a result of this review, we have preliminarily determined to assess antidumping duties equal to the differences between United States price and foreign market value.

Interested parties are invited to comment on these preliminary results.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: John Kugelman or Michael J. Heaney, Office of Antidumping Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 482–0649/4475.

SUPPLEMENTARY INFORMATION:

Background

On May 12, 1992, the Department of Commerce (the Department) published in the **Federal Register** (57 FR 20241) the final results of the 1990–1991 (seventh) administrative review of the antidumping duty order on color television receivers, except for video

monitors, from Taiwan (49 FR 18336, April 30, 1984). In April 1992, Zenith Electronics Corporation, a domestic interested party, requested, in accordance with § 353.22(a) of the Commerce Regulations, that we conduct an administrative review for the period April 1, 1991 through March 31, 1992. We published a notice of initiation of the antidumping duty administrative review on May 22, 1992 (57 FR 27169).

The Department initiated a review for Action Electronics Co., Ltd. (Action), AOC International (AOC), Funai Electric Co., Ltd. (Funai), Hitachi Television (Taiwan) Ltd., (Hitachi), Kuang Yuan Co., Ltd. (Kuang Yuan), Nettek Corp. Ltd. (Nettek), Paramount Electronics (Paramount), Proton Electronic Industrial Co., Ltd. (Proton), Sampo Corporation (Sampo), Sanyo Electric (Taiwan) Co., Ltd. (Sanyo), Shinlee Corporation (Shinlee), Tatung Corporation (Tatung), Teco Electric & Machinery Co., Ltd. (Teco), and Thomson Consumer Electronics, Inc./ TCE Television Taiwan Limited (Thomson) for the 1991–1992 period.

The Department has now conducted a review for this period in accordance with section 751 of the Tariff Act of 1930, as amended (the Tariff Act).

Scope of the Review

Imports covered by this review are shipments of color television receivers, except for video monitors, complete or incomplete from Taiwan. The orders covers all color television receivers regardless of tariff classification. This merchandise is classified under the Harmonized Tariff Schedule (HTS) items 8528.10.80, 8529.90.15, 8529.90.20, and 8540.11.00. HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

This review covers 14 manufacturers/ exporters of Taiwanese color television receivers, except for video monitors, and the period April 1, 1991 through March 31, 1992.

AOC, Funai, Hitachi, Kuang Yuan, Sampo, and Sanyo had no shipments of the subject merchandise, and Nettek, Paramount, Shinlee, and Teco failed to respond to our questionnaire. For those firms which had no shipments, we continued the deposit rate for each firm for the last period for which a review has been completed and during which that firm had shipments. For those firms that failed to respond to our questionnaire, we used as the best information available (BIA), the highest margin among respondent firms in the current review period, or the highest rate received by any firm in prior reviews whichever was higher. See Final results of Antidumping Duty Administrative Review, Color Television Receivers, Except for Video Monitors from Taiwan, 57 FR 20241 (May 12, 1992).

On June 22, 1992, Kuang Yuan requested revocation based upon it's sales at not less than foreign market value during the periods April 1, 1986 through March 31, 1987, and April 1, 1989 through March 31, 1991, and no shipments of the subject merchandise during the periods April 1, 1987 through March 31, 1989, and April 1, 1991 through March 31, 1992.

On March 28, 1989, the Department changed its regulations regarding revocation of antidumping duty orders. See Antidumping Duties, final rule, 54 FR 12742 (preamble). See also, 19 CFR 353.25 (1992). Under the new regulations periods of no shipments are no longer a separately listed basis upon which the Department will revoke an antidumping duty order as it pertains to a particular manufacturer/exporter. Therefore, though periods of no shipments may be considered among other factors when the Department is considering a request for revocation pursuant to 19 CFR 353.25(d), that factor alone is no longer a sufficient basis for revocation. See preamble at 12758.

Section 353.25(a)(2)(i) of our regulations states that an order may be revoked in part if one or more producers "have sold the merchandise at not less than foreign market value for a period of at least three consecutive years." Since Kuang Yuan had no shipments during the current review period, and since a period of "no shipments" is not equivalent to a period of sales "at not less than fair value", Kuang Yuan has failed to meet the revocation requirements required by § 353.25(a)(2)(i). Moreover, we do not consider periods of "no shipments" intermixed with periods of sales at not less than foreign market value to be a sufficient basis for revocation of an antidumping order pursuant to § 353.25(d)(ii). We, therefore, are denying Kuang Yuan's request for revocation.

United States Price

In calculating United States Price (U.S. price), we used purchase price or exporters sales price (ESP), both as defined in section 772 of the Tariff Act. Purchase price and ESP were based on the packed, f.o.b. prices to the first unrelated purchasers in the United States.

We made deductions, where appropriate for export promotion fees, finders' fees, foreign and U.S. brokerage fees, foreign inland freight, ocean freight, marine insurance, U.S. inland freight, U.S. Customs duties, discounts, rebates, credit expenses, commissions, warranties, royalties, advertising expenses, bank charges, and U.S. indirect selling expenses.

We accounted for any commodity taxes imposed in Taiwan, but not collected by reason of exportation to the United States, by multiplying the appropriate duty paying value (DPV) of the merchandise sold in the United States by the tax rate in Taiwan, and adding the result to the U.S. price. In Taiwan, the DPV is the ex-factory price for merchandise produced in a bonded factory; for merchandise produced in an unbonded factory, the DPV is the price to the first unrelated purchaser in the United States.

We accounted for the value added tax (VAT) imposed in Taiwan, but not collected by reason of exportation to the United States, by multiplying the U.S. invoice value by the VAT rate, and adding the result to U.S. price. Where appropriate, we also made an addition to U.S. price for import duties which were rebated, or which were not collected, by reason of the exportation of the merchandise to the United States.

No other adjustments were claimed or allowed.

Foreign Market Value

In calculating FMV, we used home market price or constructed value, as defined in section 773 of the Tariff Act, as appropriate.

Home Market price was used when sufficient quantities of such or similar merchandise were sold in the home market above the cost of production (COP) to provide a reasonable basis for comparison. We sued home market sales as the basis for FMV for Action, Proton, and Tatung.

We used constructed value for Thomson since Thomson had insufficient sales of such or similar merchandise in both the home and third-country markets. We used constructed value for Proton for those U.S. models for which we could find no contemporaneous, home-market sales of such or similar merchandise above the COP.

Home market price was based upon the packed, delivered price to unrelated purchasers in the home market. Where applicable, we made deductions for inland freight, discounts, rebates, credit, warranties, royalties, advertising, post-sale warehousing, commissions, differences in the physical characteristics of the merchandise, and differences in packing.

We also made adjustments, where applicable, for indirect selling expenses to offset commissions, and to offset U.S. selling expenses deducted in ESP calculations, but not for amounts exceeding the U.S. commissions and indirect selling expenses. For Action, we made adjustments for U.S. indirect selling expenses on purchase price sales, in amounts not exceeding home market commissions. Finally, we made circumstance of sale (COS) adjustments for commodity tax differences and VAT differences, where appropriate.

No other adjustments were claimed or allowed.

Constructed value consisted of the sum of the costs of materials, fabrication, general expenses, profit, and the cost of export packing. Because the statutory minimum of 10 percent of the cost of materials and fabrication exceeded the actual amount of general expenses, we added the statutory minimum amount. Because the statutory minimum of eight percent of the sum of the cost of materials, fabrication, and general expenses exceeded the actual profit, we added the statutory minimum. See section 773(e)(1)(B) of the Tariff Act.

Preliminary Results of the Review

As a result of our review, we preliminarily determine that the following margins exist:

Manufacturer/exporter	Review period	Margin (percent)
Action	04/01/91–03/31/92	16.11
AOC	04/01/91–03/31/92	[1]23.89
Funai	04/01/91–03/31/92	[1]23.89
Hitachi	04/01/91–03/31/92	[1]23.89
Kuang Yuan	04/01/91–03/31/92	[1]0.00
Nettek	04/01/91–03/31/92	[2]23.89
Paramount	04/01/91–03/31/92	[2]23.89
Proton	04/01/91–03/31/92	21.94
Sampo	04/01/91–03/31/92	[1]0.78
Sanyo	04/01/91–03/31/92	[1]4.66
Shinlee	04/01/91–03/31/92	[2]23.89
Tatung	04/01/91–03/31/92	18.27
Teco	04/01/91–03/31/92	[2]23.89
Thomson	04/01/91–03/31/92	.25

[1] No shipments during the period; rate is from the last review in which there were shipments.
[2] No response; we therefore used as best information available either the highest margin among respondent firms in the current review, or the highest rate received by any firm in prior reviews, whichever was higher.

Interested parties may request a disclosure within 5 days of publication of this notice and may request a hearing within 10 days of the date of publication. Any hearing, if requested, will be held 44 days after the date of publication, or the first workday thereafter. Interested parties may submit case briefs within 30 days of the date of publication. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than 37 days after the day of publication. The Department will publish a notice of the final results of this administrative review, which will include the results of its analysis of issues raised in any such case briefs.

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between U.S. Price and FMV may vary from the percentages stated above. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements will be effective for all shipments of color television receivers, other than video monitors, from Taiwan, entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(1) of the Tariff Act: (1) The cash deposit rates for reviewed firms will be those established in the final results of this review; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in previous reviews or the original less-than-fair-value investigation, the cash deposit will continue to be the rate published in the most recent final results or determination for which the manufacturer or exporter received a company specific rate; (3) if the exporter is not a firm covered in this review, earlier reviews, or the original investigation, but the manufacturer is, the cash deposit rate will be that established for the manufacturer of the merchandise in the final results of this review, earlier reviews, or the original investigation, whichever is the most recent; (4) the cash deposit rate for any future entries from all other manufacturers or exporters, who are not covered in this or prior administrative reviews and who are unrelated to the reviewed firms or any previously reviewed firm, will be the "All Others" rate established in the final results of this administrative review. This rate represents the highest rate for any firm in this administrative review (whose first shipments to the United States were reviewed), other than those firms receiving a rate entirely based on the best information available. These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with sections 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22.

Dated: January 6, 1993.

Rolf Th. Lundberg, Jr.,

Acting Assistant Secretary for Import Administration.

[FR Doc. 93–796 Filed 1–12–93; 8:45 am]

BILLING CODE 3510–DS–M

[C–357–404]

Certain Textile Mill Products From Argentina; Final Court Decision and Rescission of Revocation of Countervailing Duty Order Correction

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Correction.

On November 18, 1992, the Department of Commerce (the Department) published in the **Federal Register** (57 FR 54368) notice of the final court decision and rescission of countervailing duty order on certain textile mill products from Argentina.

On page 54369 in the second column, the first paragraph should read: "Thus, consistent with the decision of the CIT in Belton (Slip op. 92–39), and the CIT's subsequent May 7, 1992 order, Commerce hereby rescinds its August 13, 1990, revocation of the countervailing duty order on certain textile mill products from Argentina. Commerce hereby reinstates the order, effective May 18, 1992, and continues to suspend liquidation of entries of the subject merchandise. In accordance with the countervailing duty order, published at 50 FR 9846 (March 12, 1985), Commerce is directing the U.S. Customs Service to require a cash deposit in the amount of 4.53 percent *ad valorem*, the last published deposit rate, for each entry of the subject merchandise from Argentina which is entered, or withdrawn from warehouse, for consumption on or after the date of issuance of this notice, November 9, 1992."

EFFECTIVE DATE: November 18, 1992.

FOR FURTHER INFORMATION CONTACT: Lorenza Olivas or Kelly Parkhill, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; Telephone: (202) 482–2786.

Dated: January 6, 1993.

Rolf Th. Lundberg, Jr.,

Acting Assistant Secretary for Import Administration.

[FR Doc. 93–795 Filed 1–12–93; 8:45 am]

BILLING CODE 3510–DS–M

[C–201–405, C–357–404, C–549–401]

Certain Textile Mill Products From Mexico, Certain Apparel From Argentina, and Certain Apparel From Thailand

AGENCY: International Trade Administration/Import Administration, Department of Commerce.

ACTION: Certain textile mill products from Mexico, certain apparel from Argentina, and certain apparel from Thailand: Notice of amendment to the existing conversion of the scopes of these orders from the Tariff Schedules of the United States Annotated to the Harmonized Tariff Schedule.

SUMMARY: On January 1, 1989, the United States fully converted to the international harmonized system of tariff classification. On January 11, 1989, the Department of Commerce (the Department) published the Conversion to Use of the Harmonized Tariff Schedule of Classifications for Antidumping and Countervailing Duty Proceedings (54 FR 993; January 11, 1989) (1989 Conversion) for all antidumping and countervailing duty orders in effect or investigations in progress as of January 1, 1989. On September 15, 1992 (57 FR 42545) the Department published a notice of proposed amendment to the existing conversion; interested parties were invited to comment on this proposed amended conversion. Based on our analysis of the comments received, the Department is now publishing an amended conversion of the scopes of the countervailing duty orders on textile mill products from Mexico and on apparel from Argentina and Thailand.

EFFECTIVE DATE: January 1, 1989.

FOR FURTHER INFORMATION CONTACT: Christopher Beach, Dana Mermelstein, or Maria MacKay, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230, telephone (202) 482–2786.

Background

In 1985, the Department issued the following countervailing duty orders:

Certain Textile Mill Products from Mexico (C–201–405) (50 FR 10824; March 18, 1985),

Certain Apparel from Argentina (C–357–404) (50 FR 9846; March 12, 1985), and

Certain Apparel from Thailand (C–549–401) (50 FR 9818; March 12, 1985).

The scopes of these orders were originally defined solely in terms of the Tariff Schedules of the United States Annotated (TSUSA) item numbers; no narrative product description was provided. On January 1, 1989, the United States fully converted from the TSUSA to the Harmonized Tariff Schedule (HTS). Section 1211 of the Omnibus Trade and Competitiveness Act of 1988 directed the Department to "take whatever actions are necessary to conform, to the fullest extent practicable, with the tariff classification system of the Harmonized Tariff Schedule [for] all * * * orders * * *" in effect at the time of the implementation of the HTS.

Accordingly, on January 11, 1989, after reviewing comments received from the public, the Department published the 1989 Conversion for all antidumping and countervailing duty orders in effect or investigations in progress as of January 1, 1989. The notice also included the conversion of the scopes of the referenced textile and apparel orders from TSUSA to HTS item numbers. The 1989 Conversion was based on a one-to-one correspondence of the TSUSA and HTS item numbers. In the notice, the Department stated that the conversion could be amended, as warranted, at any time during the applicable proceeding as a result of the submission of comments or new factual information.

As a result of comments submitted to the Department by the importing public and advice received from the U.S. Customs Service, the Department determined that the 1989 Conversion did not accurately reflect the scopes of the referenced orders and, thus, should be amended. The Department, with the assistance of the U.S. Customs Service and the U.S. International Trade Commission (USITC), has compared the TSUSA and the HTS classification systems. Specifically, for each of the orders mentioned above, we compared the TSUSA-defined scopes and the HTS-defined scopes provided by the 1989 Conversion, and identified those HTS numbers that more reasonably correspond with the scopes of the referenced orders.

On September 15, 1992 (57 FR 42545) the Department published a notice of proposed amendment to the existing conversion. Based on our analysis of the comment received, the Department has now amended the 1989 Conversion governing the countervailing duty orders on textile mill products from Mexico and on apparel from Argentina and Thailand. The changes are reflected in the attached Appendix.

Analysis of Comments Received

We gave interested parties an opportunity to comment on our proposed amended conversion. We received a comment from Finetex Yarn Corporation ("Finetex"), a U.S. importer of certain textile mill products from Mexico.

Comment 1: Finetex states that the Department should exclude certain acrylic yarns classified under HTS subheadings 5509.31.00 and 5509.32.00 from the proposed amended scope of the order on certain textile mill products from Mexico. Finetex contends that blended yarns of acrylic/nylon, containing continuous filament nylon were not covered by the petition and are not within the scope of this order. As defined by TSUSA, blends consisting of spun acrylic and continuous filament nylon were classifiable under item number 310.6038 which was not within the scope of this order. In addition, Finetex argues that any subsidy attributable to merchandise covered by the TSUSA item number listed above was excluded from the Department's subsidy calculations in every administrative review of this order covering the periods 1985 through 1988. In the 1989/1990 review periods the Department continued this practice by basing its calculations on those subsidies attributable to the covered 100 percent acrylic yarns, excluding the acrylic/nylon blends discussed above, even though both were classified under the same HTS numbers.

Finetex contends that the Department lacks the authority to alter the scope of an order so as to expand it beyond the original intent (*Smith Corona Corp.* v. *United States*, 915 F.2d 683 (Fed. Cir.1990)). The Department must ensure that its conversion for this order provide specifically for the continued exclusion of singles and plied yarns of acrylic/nylon blends containing continuous filament nylon.

Department's position: We agree with Finetex, the singles and plied yarns of acrylic/nylon blends containing continuous filament nylon were not covered in the original scope. For this reason, the Department did not examine any subsidy attributable to this merchandise in the administrative reviews of this order for calendar years 1985 through 1990. Therefore, we have amended the conversion of the scope of the order on certain textiles from Mexico by providing an annotation to HTS items numbers 5509.31.00 (singles)

and 5509.32.00 (plied) which specifically excludes singles and plied yards of acrylic/nylon blends containing continuous filament from the scope of this order.

Instructions to Customs

The Department will instruct the Customs Service to liquidate without regard to countervailing duties all unliquidated entries of the subject merchandise not covered in the attached Appendix that were exported on or after January 1, 1989. The Department will also instruct Customs to liquidate at the appropriate rate all unliquidated entries of the subject merchandise covered in the attached appendix that were exported on or after January 1, 1989.

In addition, the suspension of liquidation for all entries of the subject merchandise not covered in the attached appendix, that are entered or withdrawn from warehouse on or after the date of publication of this notice, is terminated. The Department will also instruct the Customs Service to continue to suspend liquidation and collect the appropriate cash deposit of estimated countervailing duties for the subject merchandise listed in the attached Appendix, entered or withdrawn from warehouse on or after the date of publication of this notice.

Dated: January 6, 1993.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

Appendix

Certain Apparel Argentina C–357–404

6104.41.00,	6104.43.10,	6104.44.10,
6104.51.00,	6104.53.10,	6104.61.00,
6104.63.15,	6105.10.00,	6105.20.20,
6106.10.00,	6106.20.10,	6106.90.10,
6109.90.20,	6110.10.20,	6110.20.20,
6111.10.00,	6112.41.00,	6112.49.00,
6115.20.00,	6115.91.00,	6115.93.10,
6115.99.14,	6116.91.00,	6116.93.15,
6201.12.20,	6202.11.00,	6202.13.30,
6202.91.10,	6202.91.20,	6202.92.20,
6202.93.40,	6203.22.30,	6203.42.40,
6204.11.00,	6204.13.10,	6204.19.10,
6204.21.00,	6204.31.20,	6204.33.40,
6204.39.20,	6204.41.20,	6204.42.30,
6204.43.30,	6204.44.30,	6204.51.00,
6204.53.20,	6204.59.20,	6204.61.00,
6204.63.25,	6204.69.20,	6205.10.20,
6206.20.30,	6206.40.25,	6209.10.00,
6209.20.10,	6209.20.50,	6209.90.30,
6211.12.30,	6211.41.00,	6214.30.00,
6214.40.00.		

Certain Textile Mill Products Mexico C–201–405

4010.10.10,	5109.10.60,	5109.90.00,
5111.11.70,	5111.19.60,	5111.20.90,
5111.30.90,	5112.20.30,	5112.30.30,
5204.11.00,	5204.19.00,	5204.20.00,
5205.11.10,	5205.12.10,	5205.12.20,
5205.13.10,	5205.13.20,	5205.14.10,
5205.23.00,	5205.24.00,	5205.25.00,
5205.31.00,	5205.32.00,	5205.33.00,
5205.34.00,	5205.42.00,	5205.43.00,
5205.44.00,	5206.11.00,	5206.12.00,
5206.13.00,	5206.14.00,	5206.15.00,
5206.31.00,	5206.32.00,	5206.33.00,
5206.34.00,	5206.35.00,	5206.41.00,
5206.42.00,	5206.43.00,	5206.44.00,
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5208.41.60,	5208.41.80,	5208.42.30,
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5208.49.40,	5208.51.40,	5208.51.60,
5208.51.80,	5208.52.30,	5208.52.40,
5208.52.50,	5208.53.00,	5208.59.20,
5208.59.80,	5209.11.00,	5209.19.00,
5209.31.60,	5209.32.00,	5209.41.60,
5209.43.00,	5209.51.60,	5209.52.00,
5210.21.40,	5210.21.60,	5210.22.00,
5210.29.40,	5210.29.60,	5210.32.00,
5210.39.40,	5210.39.60,	5210.52.00,
5210.59.60,	5211.31.00,	5211.51.00,
5401.10.00,	5401.20.00,	5402.10.30,
5402.20.30,	5402.31.30,	5402.31.60,
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5402.51.00,	5402.52.00,	5402.59.00,
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5509.69.40,	5509.99.20,	5509.99.40,
5511.10.00,	5511.20.00,	5511.30.00,
5513.11.00,	5513.13.00,	5513.19.00,
5513.21.00,	5513.23.00,	5513.29.00,
5513.33.00,	5513.39.00,	5513.41.00,
5513.43.00,	5513.49.00,	5514.11.00,
5514.19.00,	5514.21.00,	5514.29.00,
5514.41.00,	5514.49.00,	5515.13.05,
5516.11.00,	5516.12.00,	5516.13.00,
5516.14.00,	5516.41.00,	5516.42.00,
5516.43.00,	5516.44.00,	5516.91.00,
5516.92.00,	5516.93.00,	5516.94.00,
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5702.32.20,	5702.41.10,	5702.41.20,
5702.42.10,	5702.42.20,	5702.51.20,
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5702.91.40,	5702.92.00,	5703.10.00,
5703.20.10,	5703.20.20,	5703.30.00,
5704.10.00,	5704.90.00,	5705.00.20,
5801.31.00,	5801.33.00,	5801.34.00,
5801.35.00,	5801.36.00,	5803.10.00,
5803.90.30,	5804.10.00,	5804.21.00,
5804.29.00,	5804.30.00,	5805.00.25,
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5911.31.00,	5911.32.00,	6001.10.20,
6001.22.00,	6001.92.00,	6002.10.80,
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6304.91.00,	6304.92.00,	6304.93.00,
6304.99.15,	6304.99.60,	7019.20.10,
9404.90.90;		

5209.32.00 Coverage limited to fabrics, not napped, of numbers 17 to 33.

5209.52.00 Coverage limited to fabrics, not napped, of numbers 17 to 33.

5402.10.30 Coverage limited to yarns provided for in subheading 5402.10.3040.

5402.20.30 Coverage limited to yarns provided for in subheading 5402.20.3040.

5402.33.30 Coverage limited to yarns, valued not over $2.20 per kilogram.

5402.41.00 Coverage limited to yarns provided for in subheading 5402.41.0040.

5402.43.00 Coverage limited to yarns provided for in subheading 5402.43.0040.

5402.49.00 Coverage limited to yarns provided for in subheadings 5402.49.0070 and 5402.49.0080.

5509.31.00 not to include single blended yarns containing a combination of noncontinuous acrylic and continuous nylon filaments.

5509.32.00 not to include plied blended yarns containing a combination of noncontinuous acrylic and continuous nylon filaments.

Certain Apparel Thailand C–549–401

6101.20.00,	6102.20.00,	6104.22.00,
6104.32.00,	6104.42.00,	6104.43.20,
6104.44.20,	6104.52.00,	6104.62.10,
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6112.11.00,	6112.20.20,	6112.31.00,
6112.39.00,	6112.41.00,	6112.49.00,
6114.20.00,	6115.19.00,	6117.10.10,
6117.10.20,	6117.20.00,	6117.90.00,
6201.12.20,	6201.92.20,	6202.11.00,
6202.13.30,	6202.19.00,	6202.91.10,
6202.91.20,	6202.92.20,	6202.93.40,
6202.93.50,	6202.99.00,	6203.11.20,
6203.12.10,	6203.19.10,	6203.22.30,
6203.32.20,	6203.42.40,	6204.11.00,
6204.12.00,	6204.13.10,	6204.13.20,
6204.19.10,	6204.19.20,	6204.19.30,
6204.21.00,	6204.22.30,	6204.23.00,
6204.31.20,	6204.33.40,	6204.39.20,
6204.39.80,	6204.41.20,	6204.42.30,
6204.43.30,	6204.43.40,	6204.44.30,
6204.44.40,	6204.49.50,	6204.51.00,
6204.53.20,	6204.59.20,	6204.59.40,
6204.61.00,	6204.62.20,	6204.62.40,
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6206.40.30,	6206.90.00,	6211.12.30,

6211.20.50, 6214.20.00, 6214.90.00, 6215.20.00, 6215.90.00.

[FR Doc. 93–797 Filed 1–12–93; 8:45 am]
BILLING CODE 3510–DR–M

[Docket No. 921115–2315]

Market Development Cooperator Program

AGENCY: International Trade Administration (ITA), Commerce.

ACTION: Notice.

SUMMARY: The mission of ITA is to promote U.S. exports and to strengthen the international trade position of the United States. The degree to which ITA can fulfill its mission is enhanced through partnerships with the private sector. To encourage such partnerships, ITA announces a pilot program, the Market Development Cooperator Program, to assist trade associations and nonprofit industry organizations working together with ITA to develop, maintain, and expand foreign markets for nonagricultural goods and services produced in the United States. For purposes of this pilot program, "nonagricultural goods and services" means goods and services other than agricultural products as defined in 7 U.S.C. 451. "Produced in the United States" means having substantial inputs of materials and labor originating in the United States, such inputs constituting at least 50 percent of the value of the good or service to be exported.

The advantage of joint private sector-ITA effort is that it permits the Government and private industry to pool expertise and funds so that each gets more mileage out of its market development resources. Partnerships of this sort also may offer a sharper focus on long-term export market development than do traditional trade promotion activities and serve as a mechanism for improving Government-industry relations.

While the Market Development Cooperator Program is sponsored, guided and funded by the Department of Commerce with a matching requirement by the recipient, applications are expected to develop, initiative and carry out market development project activities. As an active partner, ITA will provide assistance identified by the applicant as being essential to the achievement of project goals and objectives. U.S industry is best able to assess its problems and needs in the foreign marketplace and to recommend innovative solutions and programs that can be the formula to success in international trade.

Examples of activities that might be included in an applicant's project are described below. No one of these activities or any combination of these activities must be included for a proposal to receive favorable consideration. Applicants are encouraged to purpose activities that (1) would be most appropriate to the market development needs of their industry or industries and (2) display the imagination and innovation of the private sector working in partnership with the Government to obtain the maximum market development impact.

DATES: Completed applications must be submitted or be postmarked no later than February 12, 1993.

ADDRESSES: To obtain a copy of the application kit, please send a written request with a self-addressed mailing label to Mr. Jerry Morse, Director, Resource Management and Planning Staff, Trade Development/OPCRM, room 3223, HCHB, U.S. Department of Commerce, Washington, DC 20230. Application kits also may be picked up in room 3211, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC 20230. Only one application kit will be provided to each organization requesting it, but the kit may be reproduced by the requester. All forms necessary to submit an application will be included in the application kit.

Completed applications should be sent to the Office of Planning, Coordination and Resource Management Trade Development, Room 3223, HCHB 14th & Constitution Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Applicants wanting further information on this pilot program should contact Mr. Jerry Morse, Director, Resource Management and Planning Staff, Trade Development, room 3211, HCHB, Washington, DC 20230, (202) 482–1180.

SUPPLEMENTARY INFORMATION:

Program Authority: The Omnibus Trade and Competitiveness Act of 1988, Public Law No. 100–418, title II, section 2303, 102 Stat. 1342, 15 U.S.C. 4723.

Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act, 1993, Public Law No. 102–395, 106 Stat. 1828.

Program Objective: The objective of the Market Development Cooperator Program is to identify promising foreign market opportunities for U.S. exports and to introduce U.S. goods, processes and services to foreign buyers.

Funding Instrument and Project Duration: Since it is anticipated that ITA will be substantially involved in the implementation of each project for which an award is made, the funding instrument for this pilot program will be a cooperative agreement.

It is contemplated that a minimum of four (4) cooperative agreements will be concluded with eligible entities for this pilot program. Each cooperative agreement will not exceed a total of $500,000 regardless of the duration of the award. Funds may be expended over the period of time required to complete the scope of work, but not to exceed three years (3) from the date of the award.

The total amount of funds appropriated for this pilot program is $2.5 million.

Program Priorities: Applicants will be expected to supply two thirds (2/3) of total project costs, with the Federal portion to be one third (1/3). For applications targeting the Newly Independent States (NIS) that made up the former Soviet Union, the Department of Commerce recognizes that there may be extraordinary risk, difficulty and cost involved in developing these markets. Therefore, in unusual circumstances, the Department of Commerce will consider raising the Federal portion of funding for projects emphasizing the NIS up to 50 percent (50%) of proposed eligible project costs. The overall maximum of Department of Commerce funds of $500,000 per cooperative agreement still applies for NIS projects.

The Department of Commerce will support only the direct costs of each project. Each applicant will support a portion of the direct costs (to be specified in the application) and all of the indirect costs of its project. For purposes of this program, "direct costs" will be defined as personnel, fringe benefits, travel, equipment, supplies, contractual, and other (e.g., rent and furnishings for an overseas office).

A minimum of one half (½) of each applicant's support must be in the form of cash. Applicants' support of the non-Federal share may consist of cash or in-kind contributions (goods and services).

Market Development Cooperator Program funds should not be viewed as a replacement for funding from other sources, either public or private. An important goal of this program is to increase the sum of Federal and non-Federal market development activities. This goal can best be achieved by using program funds to encourage new initiatives. In addition to new initiatives, expansion of the scope of an existing project also may qualify for funding consideration. The Department of Commerce will fund such projects as if they are entirely new initiatives, not just the expansion portion of the project

Applicants may charge companies in the industry or other industry organizations reasonable fees to take part in or avail themselves of services provided as part of applicant's projects. Plans to charge fees should be described in detail in the applicant's application.

Eligibility: Trade associations and nonprofit industry organizations are eligible to apply for cooperative agreements under this pilot program.

Eligible entities may join together to submit an application as a joint venture and to share costs. For example, two trade associations representing different segments of a single industry or related industries can pool their resources and submit one application. Foreign businesses and private groups also may join with U.S. organizations to submit applications and to share the costs of proposed projects.

Applications will be accepted from eligible entities representing any industry, subsector of an industry or related industries. Some industries are represented by more than one eligible entity. Each applicant must permit all companies in the industry in question to participate, on equal terms, in all activities that are scheduled as part of a proposed project.

Applications may be targeted for any market in the world. While it is expected that proposed projects will entail an overseas presence, some activities may take place in the United States if it is necessary to the project's success.

Application Requirements: Competitive application kits will be available from the Department of Commerce starting December 1992. Standard Forms 424 (Rev. 4–88), 424A (Rev. 4–88), and 424B (Rev. 4–88), which are required as part of the application, are available from the contact person indicated above. Applicants must submit a signed original and two copies of the application and supporting materials. It is anticipated that it will take 4 weeks to process applications.

Closing Date: The closing date for applications for this pilot program is February 12, 1993.

Credentials/Documentation: Eligible entities desiring to participate in this pilot program must demonstrate the ability to provide a competent, experienced staff and other resources to assure adequate development, supervision and execution of the proposed project activities. Applicants also should describe in detail all assistance expected from the Department of Commerce or other Federal Government agencies to implement project activities successfully.

Each applicant must also provide a description of the membership of the eligible entity, the degree to which the entity represents the industry or industries in question, and the role, if any, foreign membership plays in the affairs of the eligible entity.

Applicants should summarize both the recent history of their industry or industries' competitiveness in the international marketplace and the export promotion history of the eligible entity or entities submitting the application.

Project Plans: Developing a project plan requires solid background research. Applicants should study, and applications should reflect such study of the following:

1. The market potential of the good or service to be promoted in a particular market(s),
2. The competition from host-country and third-country suppliers, and
3. The economic situation and prospects that bear upon the ability of a country to import the good or service.

Applicants also should present in their applications an assessment of industry resources that can be brought to bear for developing a market; the industry's ability to meet potential market demand expeditiously; and the industry's after-sales service capability in a particular foreign market(s).

After describing their complete basic research, applicants should develop marketing plans that set forth the overall objectives of the projects and the specific activities applicants will undertake as part of these projects. Applications should display the imagination and innovation of the private sector working in partnership with the Government to obtain the maximum market development impact.

Examples of Activities that Might Be Included in Applicant Applications: The following are examples of activities which might be included in an application. No one of these activities or any combination of these activities must be included for an application to receive favorable consideration. Applicants are encouraged to propose activities that would be most appropriate to the market development needs of their industry or industries:

(1) Opening an overseas office or offices to perform a variety of market development services for companies joining a consortium to avail themselves of such services [such an office should not duplicate the programs or services of the U.S. and Foreign Commercial Service (US&FCS) post(s) in the region];

(2) Detailing a private sector individual to a US&FCS post in accordance with 15 U.S.C. 4723(c);

(3) Entering into a contract with a bona fide market research company to conduct detailed, product-specific market research;

(4) Assigning industry specialists to work with Department of Commerce/U.S. Executive Director Procurement Liaison Offices at the Multilateral Development Banks to seek out and develop procurement opportunities;

(5) Underwriting the cost of overseas market research or participation in overseas trade exhibitions and trade missions, or covering the expenses of reverse trade missions and/or foreign buyer group travel to domestic trade shows;

(6) Overseas product demonstrations;

(7) Seminars in the United States or in the market(s) to be developed;

(8) Technical trade servicing which helps overseas buyers to choose the right U.S. good or service and to use the good for service efficiently;

(9) Joint promotions with foreign customers;

(10) Training of foreign nationals to perform after-sales service or to act as distributors;

(11) Working with organizations in the foreign marketplace responsible for setting standards and for product testing to improve market access; and

(12) Publishing an export resource guide or an export product directory for the industry or industries in question.

Evaluation Criteria: The Department of Commerce is interested in projects that demonstrate the possibility of both significant results during the project period and lasting benefits extending beyond the project period. To that end, consideration for financial assistance under the Market Development Cooperator Program will be based upon the following evaluation criteria:

(1) Anticipated increase in U.S. exports generated by the proposed expenditure of funds, including criteria for quantitative measurement and evaluation;

(2) Degree to which a project has a multiplier effect whereby industry and Government working in partnership can maximize outreach to companies capable of expanding into new markets or capable of increasing market share in present markets;

(3) Export potential of the good(s) or service(s) to be promoted;

(4) Probability of success in maintaining or increasing exports of the subject U.S. good(s) or service(s);

(5) Compatibility with U.S. trade and commercial policy;

(6) Willingness and ability of the applicant to back up promotional

activities with aggressive marketing and after-sales service;

(7) Intent and capability of the applicant to enlist the participation of small and medium size American companies in consortia and activities that are to be part of the proposed project;

(8) Size of the cash portion of the applicant's funding for the proposed project;

(9) Probability that the project can be continued on a self-sustained basis after the completion of the award;

(10) Creativity and innovation displayed by the work plan while at the same time being realistic;

(11) Institutional capacity of the applicant to carry out the work plan; and

(12) Reasonableness of the itemized budget for project activities.

Evaluation criteria 1–3 are of utmost importance in the selection process and will be worth 55 out of a possible 100 points as follows:

Criterion #1—maximum 25 points
Criterion #2—maximum 15 points
Criterion #3—maximum 15 points

Evaluation criteria 4–12 together will be worth a total of 45 points. Evaluation criteria 4–12 will be weighted equally.

Additional Requirements: All applicants are advised of the following:

1. Past Performance—Unsatisfactory performance under prior Federal awards may result in an application not being considered for funding.

2. Preaward Activities—If applicants incur any costs prior to an award being made, they do so solely at their own risk of not being reimbursed by the Government. Notwithstanding any verbal assurance that they may have received, there is no obligation on the part of the Department of Commerce to cover pre-award costs.

3. No Obligation for Future Funding—If an application is selected for funding, the Department of Commerce has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of the Department of Commerce.

4. Delinquent Federal Debts—No award of Federal funds shall be made to an applicant who has an outstanding delinquent Federal debt until either:

(A) The delinquent account is paid in full;

(B) A negotiated repayment schedule is established and at least one payment is received; or

(C) Other arrangements satisfactory to the Department of Commerce are made.

5. Intergovernmental Review—Executive Order 12372 "Intergovernmental Review of Federal Programs" does not apply to this program.

6. Name Check Review—All non-profit and for-profit applicants are subject to a name check review process. Name checks are intended to reveal if any key individuals associated with the applicant have been convicted of or are presently facing criminal charges such as fraud, theft, perjury, or other matters which significantly reflect on the applicant's management honesty or financial integrity.

7. Primary Applicant Certifications—Primary applicants must submit a completed Form CD–511, "Certifications Regarding Debarment, Suspension and Other Responsibility Matters; Drug Free Workplace Requirements and Lobbying." In addition, applicants are advised that:

A. Nonprocurement Debarment and Suspension—Prospective participants (as defined at 15 CFR part 26, section 105) are subject to 15 CFR part 26, "Nonprocurement Debarment and Suspension" and the related section of the certification form.

B. Drug Free Workplace—Grantees (as defined at 15 CFR part 26, section 605) are subject to 15 CFR part 26, subpart F, "Government-wide Requirements for Drug-Free Workplace (Grants)" and the related section of the certification form.

C. Anti-Lobbying—Persons (as defined at 15 CFR part 28, section 105) are subject to the lobbying provisions of 31 U.S.C. 1352, "Limitations on use of appropriated funds to influence certain Federal contracting and financial transactions," and the lobbying section of the certification form which applies to applications/bids for grants, cooperative agreements, and contracts for more than $100,000, and loans and loan guarantees for more than $150,000, or the single family maximum mortgage limit for affected programs, whichever is greater; and

D. Anti-Lobbying Disclosures—Any applicant that has paid or will pay for lobbying using any funds must submit an SF–LLL, "Disclosure of Lobbying Activities," as required under 15 CFR part 28, Appendix B.

8. Lower Tier Certifications—Recipients shall require applicants/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the award to submit, if applicable, a completed Form CD–512, "Certifications Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions and Lobbying" and disclosure form, SF–LLL, "Disclosure of Lobbying Activities." Form CD–512 is intended for the use of recipients and should not be transmitted to the Department of Commerce. SF–LLL submitted by any tier recipient or subrecipient should be submitted to the Department of Commerce in accordance with the instructions contained in the award document.

9. *False Statements*—A false statement on the application is grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001.

10. *Federal Policies and Procedures*—Recipients and sub recipients are subject to all applicable Federal laws and Federal and Departmental policies, regulations, and procedures applicable to Federal financial assistance awards.

Classification: This notice does not constitute a major rule within the meaning of section 1(b) of Executive Order 12291 because it is not likely to result in an annual effect on the economy of $100 million or more; a major increase in costs of prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. Accordingly, a Regulatory Impact Analysis was not required or prepared.

The requirements of section 553 of the Administrative Procedure Act (5 U.S.C. 553) including having to give notice and an opportunity for comment do not apply to this notice because the notice relates to grants, benefits or contracts. Since notice and an opportunity to comment are not required under any other statute, a Regulatory Flexibility Analysis is not required under the Regulatory Flexibility Act and was not prepared.

The Department of Commerce has determined that the Federal assistance covered by this notice not significantly affect the quality of the human environment. Therefore, no draft or final Environmental Impact Statement has been or will be prepared.

This notice does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

Dated: January 7, 1993.

Jerry Morse,

Director, Resource Management and Planning Staff, Trade Development.

[FR Doc. 93–726 Filed 1–12–93; 8:45 am]
BILLING CODE 3510–DR–M

National Oceanic and Atmospheric Administration

Threatened Marine Mammals; Steller Sea Lion; Buffer Area Exemption

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Notice of exemption determination.

SUMMARY: The Alaska Regional Office, NMFS, has received and granted a request from Dr. George L. Hunt, Jr., of the University of California, Irvine, for an exemption to allow passage into the 3-nautical-mile buffer zones around the Buldir Island, Kiska Island, Ayugadak Point, Ulak Island, and Semisopochnoi Island Steller sea lion rookeries. The request is to continue National Science Foundation-supported seabird research that cannot be accomplished without entering the buffer areas.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Steven Zimmerman, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802 (907–586–7235).

SUPPLEMENTARY INFORMATION:

Background

On November 26, 1990, NMFS published a final rule (55 FR 49204) that listed the Steller (northern) sea lion as a threatened species under the Endangered Species Act (16 U.S.C. 1531–1543). That rule contained several protective regulations codified at 50 CFR 227 12(a), including the establishment of buffer zones around 35 sea lion rookeries in the Gulf of Alaska, Bering Sea and Aleutian Islands. These buffer zones prohibit the approach of any vessel within 3 nautical miles (nm) (5.5 km) of these rookeries or the approach of any person on land not privately owned within one-half statutory mile (0.8 km) or within sight of a listed rookery site, whichever is greater.

The final rule gave the Director, Alaska Region, NMFS (Regional Director), with the concurrence of the Assistant Administrator for Fisheries, NOAA (Assistant Administrator), the authority to grant exemptions to the prohibitions of 50 CFR 227.12(a)(6). Exemptions allowing entry into buffer zones may be granted only if (1) the activity will not have a significant adverse impact on Steller sea lions; (2) the activity has been conducted historically and traditionally in the buffer zones; and (3) there is no readily available and acceptable alternative to, or site for, the activity.

In a letter dated October 28, 1992, Dr. George L. Hunt, Jr., submitted a request to the Regional Director for an exemption to allow passage into the buffer zones around the Buldir Island, Kiska Island, Ayugadak Point, Ulak Island, and Semisopochnoi Island Steller sea lion rookeries. The request is to continue National Science Foundation-supported seabird research that cannot be accomplished without entering the buffer areas. Information supplied by Dr. Hunt in his letter, and in discussions with NMFS staff, indicates that the request meets the conditions required for granting exemptions:

(1) Steller sea lions on these islands will not be disturbed by the research activity. The proposed research is to document the distribution and abundance of foraging auklets, using the R/V *Alpha Helix*. No rookery approaches from land are proposed. To ensure that Steller sea lions will not be disturbed, the research vessel will be required to remain at least 0.5 nm from the boundary of Steller sea lion rookeries at all times.

(2) The proposed research is a continuation of a long-term study, and thus, there is historical precedent for this action.

(3) There are no reasonable and feasible alternatives for the proposed activity. Auklet colonies are located on only a few of the Aleutian Islands, and these birds forage in a limited number of areas. The research cannot be relocated to an area where there are no sea lion rookeries. Also, researchers need to sample the same locations where past work was conducted to assess seasonal or annual changes in foraging patterns, and to achieve research goals.

For these reasons, the Regional Director recommended granting these exemptions and the Assistant Administrator concurs. In a letter of authorization to Dr. Hunt, the Regional Director stressed that authority is granted solely to obtain necessary observations related to this seabird research project. Research vessels must not approach within 0.5 nm of the sea lion rookeries, and are requested to stay as far away from the rookeries as possible. No disruption or disturbance of sea lions on the rookeries is authorized.

NMFS has determined that the proposed action is likely to cause only minimal disruption in normal sea lion behavior and is not likely to imperil the survival or impede the recovery of Steller sea lions. The maintenance of a 0.5-nm minimum approach within the buffer zones, in conjunction with other existing regulations, is expected to provide adequate protection for Steller sea lions.

Dated: January 7, 1993.

Nancy Foster,

Acting Deputy Assistant Administrator for Fisheries.

[FR Doc. 93–717 Filed 1–12–93; 8:45 am]

BILLING CODE 3510–22–M

DEPARTMENT OF DEFENSE

Department of the Air Force USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board (SAB) Ad Hoc Committee on GPS Integrity and Denial will meet from 8 a.m. to 5 p.m. on 9–10 February 1993 at USSPACECOM and AFSCPACECOM, Colorado Springs, Colorado.

The purpose of this meeting is to receive information briefings on GPS capabilities, threats, potential vulnerabilities and program impacts. The meeting will be closed to the public in accordance with section 552b(c) of title 5, United States Code, specifically subparagraphs (1) and (4).

For further information, contact the SAB Secretariat at (703) 697–8404.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 93–678 Filed 1–12–93; 8:45 am]

BILLING CODE 3910–01–M

Department of the Army

Armed Forces Epidemiological Board; Open Meeting

AGENCY: Armed Forces Epidemiological Board, DOD.

ACTION: Notice of open meeting.

1. In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–462) announcement is made of the following committee meeting:

NAME OF THE COMMITTEE: Armed Forces Epidemiological Board, DOD.

DATES OF THE MEETING: 25–26 February 1993.

TIME: 0800–1600.

PLACE: Ramada Renaissance, Washington/Dulles.

PROPOSED AGENDA: 25–26 February 1992—Service preventive medicine reports, HIV education, influenza vaccine for 1993–1994 influenza season.

2. This meeting will be open to the public but limited by space accommodations. Any interested person may attend, appear before or file statements with the committee at the time and in the manner permitted by the

committee. Interested persons wishing to participate should advise the Executive Secretary, AFEB, Skyline Six, 5109 Leesburg Pike, room 667, Falls Church, VA 22041–3258.

Gregory D. Showalter,

Alternate Army Federal Register Liaison Officer.

[FR Doc. 93–723 Filed 1–12–93; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF EDUCATION

Fund for the Improvement and Reform of Schools and Teaching; Board Meeting

AGENCY: Fund for the Improvement and Reform of Schools and Teaching Board, Education.

ACTION: Notice of an open meeting.

SUMMARY: This notice sets forth the schedule and agenda of an open meeting of the Fund for the Improvement and Reform of Schools and Teaching Board. This notice also describes the functions of the Board. Notice of this meeting is required under section 10(a)(2) of the Federal Advisory Committee Act. This document is intended to notify the general public of their opportunity to attend.

DATES AND TIMES: January 28, 1993, 9 a.m.–5 p.m.; January 29, 1993, 9 a.m.–12 p.m.

ADDRESSES: Hyatt Regency Washington, 400 New Jersey Avenue, NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Paula Shipp, Fund for the Improvement and Reform of Schools and Teaching, U.S. Department of Education, 555 New Jersey Avenue, NW., room 522, Washington, DC 20208–5524, (202) 219–1496.

SUPPLEMENTARY INFORMATION: The Fund for the Improvement and Reform of Schools and Teaching (FIRST) Board was established under section 3231 of the Hawkins-Stafford Elementary and Secondary School Improvement Amendments of 1988 (Pub. L. 100–297). The Board was established to advise the Secretary concerning developments in education that merit his attention; identify promising initiatives to be supported under the authorizing legislation; and advise the Secretary and the Director of FIRST on the selection of projects under consideration for support, and on planning documents, guidelines and procedures for grant competitions carried out by FIRST.

The meeting of the FIRST Board will be open to the public. On January 28, 1993, the Board will introduce its new members and approve the minutes from the September meeting. The agenda will include an update on World Class Standards and related initiatives to develop curriculum frameworks and improved assessments. Time will be allotted for Q&A's.

The Board will also discuss, and the FIRST Family School Partnership—Pre-application process, and an update on the recently funded FIRST Projects. These discussions will continue on January 29, 1993. The meeting will conclude with a discussion of the upcoming agenda for and date of the next Board meeting.

Records are kept of all Board proceedings, and are available for public inspection at the office of the Fund for the Improvement and Reform of Schools and Teaching, U.S. Department of Education, 555 New Jersey, NW., room 522, Washington, DC 20208–5524, from the hours of 8:30 a.m. to 5 p.m.

Dianne Ravitch,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 93–722 Filed 1–12–93; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ES93–17–000, et al.]

Electric Rate, Small Power Production, and Interlocking Directorate Filings; Glen Park Associates Limited Partnership, et al.

Take notice that the following filings have been made with the Commission:

1. Glen Park Associates Limited Partnership

[Docket No. ES93–17–000]

January 4, 1993.

Take notice that on December 30, 1992, Glen Park Associates Limited Partnership (Glen Park) filed an application with the Federal Energy Regulatory Commission under section 204 of the Federal Power Act requesting authorization for blanket prior approval to issue securities and to assume obligations with respect to securities. Glen Park's filing relies upon the Commission's action in Alternative Energy, Inc., Docket No. ES91–30–000, 56 FERC ¶ 61,270 (1991).

Glen Park is a New York limited partnership and owns and operates the 32.4 MW Glen Park Hydroelectric Project (FERC No. 4796) located on the Black River in Jefferson County, New York. The output of the project is sold to Niagara Mohawk Power Corporation pursuant to long term power sale contract which has previously been accepted for filing by this Commission.

Comment date: January 29, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Consolidated Edison Company of New York, Inc.

[Docket No. ES93–305–000]

January 5, 1993.

Take notice that on December 30, 1992, Consolidated Edison Company of New York, Inc. (Con Edison) tendered for filing a Supplement to Con Edison Rate Schedule FERC No. 94 for transmission service for the Long Island Lighting Company (LILCO). The Rate Schedule provides for transmission of power and energy from the New York Power Authority's Blenheim-Gilboa station. The Supplement provides for a decrease in annual revenues under the Rate Schedule by a total of $106,215. Con Edison has requested waiver of notice requirements so that the Supplement can be made effective as of July 1, 1992.

Con Edison states that a copy of this filing has been served by mail upon LILCO.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Consolidated Edison Company of New York, Inc.

[Docket No. ER93–290–000]

January 5, 1993.

Take notice that on December 21, 1992, Consolidated Edison Company of New York, Inc. (Con Edison) tendered for filing a Supplement to its Rate Schedule FERC No. 105, an agreement to provide transmission service for Orange and Rockland Utilities, Inc. (O&R). The Supplement provides for a decrease in the monthly transmission charge from $0.83 to $0.79 per kilowatt thus decreasing annual revenues under the Rate Schedule by a total of $60,000.00. Con Edison has requested waiver of notice requirements so that the decrease can be made effective as of July 1, 1992.

Con Edison states that a copy of this filing has been served by mail upon O&R.

Comment date: January 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. Enter Power, Inc.

[Docket No. ER93–291–000]

January 5, 1993.

Take notice that Entergy Power, Inc. (Entergy Power), on December 22, 1992

tendered for filing two Notices of Cancellation for two short term sales of capacity and associated energy to the Tennessee Valley Authority.

Entergy Power requests an effective date of August 3, 1992 for the Notice of Cancellation for Entergy Power Rate Schedule FERC No. 6 (including Supplement No. 1). Entergy Power requests an effective date of September 1, 1992 for the Notice of Cancellation for Entergy Power Rate Schedule FERC No. 7 (including Supplement No. 1). Entergy Power requests waiver of the Commission's notice requirements under § 35.15 of the Commission's Regulations.

Comment date: January 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Boston Edison Company

[Docket No. ER86-645-006]

January 5, 1993.

Take notice that on December 4, 1992, Boston Edison Company of Boston, Massachusetts submitted for filing additional information to supplement its June 15, 1992 filing to comply with Opinion Nos. 350 and 350-A issued on July 9, 1990 and April 14, 1992, respectively (52 FERC ¶ 61,010; 59 FERC ¶ 61,062). This submittal was made in response to a November 4, 1992 letter order of the Commission.

Boston Edison states that it has served copies of the submittal on all persons listed on the official service list in the proceeding.

Comment date: January 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

6. Baltimore Gas and Electric Co.

[Docket No. ER93-93-000]

January 6, 1993.

Take notice that on December 30, 1992, Baltimore Gas and Electric Company (BG&E) tendered for filing an Amendment to its October 30, 1992 filing of the System Energy Sales Agreement between Baltimore Gas and Electric Company (BG&E) and the Long Island Lighting Company (LILCO) in the above captioned docket. The Amendment consists of changes to section 6a of the Agreement.

BG&E has requested waiver of the Commission's notice requirements to allow an effective date of November 2, 1992 as originally requested.

Copies of the filing were served on the Maryland and New York Public Service Commission.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

7. Milford Power Limited Partnership

[Docket No. ER93-304-000]

January 6, 1993.

Take notice that Milford Power Limited Partnership (Milford), on December 30, 1992, tendered for filing proposed changes in its Rate Schedule FERC No. 1.

The proposed change to Milford's rate formulae was required to accommodate a change in the gas supply arrangements for the Milford Project. The prposed change in Milford's rate of formulae is expected to have a *de minimis* effect on Milford's revenues.

A copy of the filing was served upon New England Power Company.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. Ohio Power Co.

[Docket Nos. ER82-553-006; ER82-554-006]

January 6, 1993.

Take notice that on December 29, 1992, Ohio Power Company (OPCo) tendered for filing a proposed plan for repayment of amounts owed to OPCo by its Municipal Resale Electric Service customers and Wheeling Power Company pursuant to the Commission's Order issued in Docket No. ER82-553-004 and ER82-554-004.

Copies of the filing were served upon Wheeling Power Company, the Public Service Commission of West Virginia, the affected municipal customers, the Public Utilities Commission of Ohio and other parties of record.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

9. Northern States Power Company (Minnesota) and Northern States Power Company (Wisconsin)

[Docket No. ER93-135-000]

January 6, 1993.

Take notice that on December 30, 1992, Northern States Power Company (Minnesota) and Northern States Power Company (Wisconsin) (jointly NSP Companies) tendered for filing a certain Transmission Services Agreement entered into by the NSP Companies pursuant to the Settlement Tariff portion of the NSP Companies FERC Electric Tariff, Original Volume No. 1. This administrative filing was required under the Federal Energy Regulatory Commission's Policy Statement issued October 9, 1992, regarding filing of service agreements under tariffs of general applicability.

The NSP Companies request acceptance for filing of a standard form Transmission Services Agreement with the Wisconsin Public Power, Inc. SYSTEM (WPPI) effective November 1, 1991. The proposed Agreement supersedes the executed agreement with WPPI executed under NSP's original October 1990 Tariff, and replaces the unexecuted draft Settlement Tariff agreement contained in NSP's initial filing. The amendment also provides certain corrections and additional information supplementing the initial filing.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. Minnesota Power & Light Co.

[Docket No. ER93-289-000]

January 6, 1993.

Take notice that on December 21, 1992, Minnesota Power & Light Company (MP&L) tendered for filing an Amendment, dated November 24, 1992, to the Electric Service Agreement between MP&L and Dahlberg Light and Power Company. The Amendment provides, among other things, for a ten year extension of the Agreement, through December 31, 2004.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. Central Vermont Public Service Corp.

[Docket No. ER93-302-000]

January 6, 1993.

Take notice that on December 29, 1992, Central Vermont Public Service Corporation (Central Vermont or the Company) tendered for filing with the Federal Energy Regulatory Commission (the Commission) notification that the Company would continue to provide service pursuant to an Option Power Sales Agreement and Amended Distribution Service Agreement (the Agreement) between Central Vermont and the State of Vermont Department of Public Service which was filed and approved previously in Docket No. ER90-151-000. Central Vermont states that the Agreement expired in accordance with its terms on October 31, 1993, and requests waiver of the Commission's regulations in order to permit the notification of the customer's desire to continue to receive service thereafter in accordance with the rates, terms and conditions of the Agreement to be effective as of that date, and the Company's willingness to provide such service.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

12. Philadelphia Electric Co.

[Docket No. ER93–301–000]

January 6, 1993.

Take notice that on December 29, 1992, Philadelphia Electric Company (PE) tendered for filing under section 205 of the Federal Power Act and part 35 of the regulations issued thereunder, an Agreement between PE and Long Island Lighting Company (LILCO) dated December 22, 1992.

PE states that the Agreement sets forth the terms and conditions for the sale of system energy which it expects to have available for sale from time to time and the purchase of which will be economically advantageous to LILCO. In order to optimize the economic advantage to both PE and LILCO, PE requests that the Commission waive its customary notice period and permit the agreement to become effective on January 1, 1993.

PE states that a copy of this filing has been sent to LILCO and will be furnished to the Pennsylvania Public Utility Commission and the New York Public Service Commission.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

13. Pacific Gas and Electric Co.

[Docket No. ER93–154–000]

January 6, 1993.

Take notice that on December 31, 1992, Pacific Gas and Electric Company (PG&E) tendered for filing a request for deferment. On December 22, 1992, FERC staff requested additional information for the 31 Agreements previously filed in this docket with FERC on November 17, 1992 in response to the Commission's "Supplemental Order Rescinding Refund Obligation and Announcing Additional 30-Day Amnesty Period for the Filling of Jurisdictional Agreements Involving Contributions in Aid of Construction". In order to allow sufficient time for PG&E to gather this information, PG&E is requesting a deferment of (1) the lesser of 90 days from December 22, 1992 or (2) the end of any new amnesty period that may result from the technical conference scheduled for January 28, 1993 in Docket No. PL93–2–000.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

14. PacifiCorp

[Docket No. ER93–25–000]

January 6, 1993.

Take notice that PacifiCorp on December 30, 1992, tendered for filing in accordance with 18 CFR part 35 of the Commission's Rules and Regulations, an amended filing to this docket.

Copies of this filing were supplied to Bonneville and the Public Utility Commission of Oregon.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

15. Midwest Power Systems Inc.

[Docket No. ER93–10–003]

January 6, 1993.

Take notice that on October 28, 1992, Midwest Power Systems Inc. (Midwest) filed an application with the Federal Energy Regulatory Commission under section 204 of the Federal Power Act requesting authorization to issue not more than $750 million principal amount of General Mortgage Bonds and/or Medium-Term Notes and the guarantee of the issuance and sale of Pollution Control Revenue Bonds. Also, Midwest requested exemption from the Commission's competitive bidding regulations. The filing was noticed on November 3, 1992, with no comments or protests being filed. By letter orders dated December 2, 1992 and December 11, 1992, the Chief Accountant authorized the requests.

On January 5, 1993, Midwest filed an amendment with the Federal Energy Regulatory Commission under section 204 of the Federal Power Act requesting authorization for exemption from compliance with the negotiated placement requirements at 18 CFR 34.2(b)(2)(i)(B) of the Commission's regulations under the Federal Power Act.

Comment date: January 14, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–700 Filed 1–12–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. ER93–116–000, et al.]

Puget Sound Power & Light Co.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

December 31, 1992.

Take notice that the following filings have been made with the Commission:

1. Puget Sound Power & Light Co.

[Docket No. ER93–116–000]

Take notice that on December 24, 1992, Puget Sound Power & Light Company tendered for filing additional information concerning its earlier filing in this docket.

Comment date: January 14, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Arroyo Energy, Limited Partnership

[Docket No. QF92–179–000]

On December 28, 1992, Arroyo Energy, Limited Partnership (Applicant), tendered for filing an amendment to its filing in this docket.

The amendment provides additional information pertaining to the ownership structure of its proposed cogeneration facility. No determination has been made that the submittal constitutes a complete filing.

Comment date: January 14, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Puget Sound Power & Light Co.

[Docket No. ER93–119–000]

Take notice that on December 18, 1992, Puget Sound Power & Light Company tendered for filing additional information concerning its earlier filing in this docket of an agreement with Pacific Gas and Electric Company for seasonal exchange of capacity and associated energy.

Comment date: January 14, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. Puget Sound Power & Light Co.

[Docket No. ER93–117–000]

Take notice that on December 24, 1992, Puget Sound Power & Light Company tendered for filing additional information concerning its earlier filing in this docket.

Comment date: January 14, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-701 Filed 1-12-93; 8:45 am]

BILLING CODE 6717-01-M

Notice of Application Filed with the Commission

January 7, 1993

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. Type of Application: Request for Extension of Time to Commence Project Construction.

b. Project No.: 6641-025.

c. Date Filed: December 16, 1992.

d. Applicants: The City of Marion, Kentucky and Smithland Hydroelectric Partners.

e. Name of Project: Smithland Lock and Dam Hydro Project.

f. Location: In Livingston County, Kentucky, on the Ohio River.

g. Filed Pursuant to: Section 1701(c)(3) of the Energy Policy Act of 1992, Public Law No. 102-486.

h. Applicant Contacts: J. Pierce, Smithland Hydro Partners, 120 Calumet Court, Aiken, SC 29801, (803) 648-0276. Louis Rosenman, Attorney, c/o City of Marion, Kentucky and Smithland Hydroelectric Partners 1725 DeSales Street, NW., Suite 800, Washington, DC 20036, (202) 659-6568.

i. FERC Contact: Mr. Lynn R. Miles, (202) 219-2671.

j. Comment Date: February 5, 1993.

k. Description of the Request: Pursuant to Section 1701(c)(3) of the Energy Policy Act of 1992, Public Law No. 102-486, the licensee requests that the deadlines for the acquisition of real property and the commencement of construction on FERC Project No. 6641 be extended to June 29, 1996, and the deadline for the completion of construction be extended to June 29, 2000. The licensee states that it has diligently pursued the development of the project and has invested over $1,000,000 in this effort. The licensee further contends that the U.S. Army Corps of Engineers proposed construction and operation of a prototype Wicket Gate Test Facility at the project site conflicts with the construction of Project No. 6641, due to identical sites and overlapping construction schedules.

1. This notice also consists of the following standard paragraphs: B, C, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS," "RECOMMENDATIONS FOR TERMS AND CONDITIONS," "NOTICE OF INTENT TO FILE COMPETING APPLICATION," "COMPETING APPLICATIONS," "PROTEST" or "MOTION TO INTERVENE," as applicable, and the project number of the particular application to which the filing is in response. Any of these documents must be filed by providing the original and the number of copies required by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to: The Director, Office of Hydropower Licensing, Division of Project Compliance and Administration, Federal Energy Regulatory Commission, ATTN: HL-21, room 1148 UCP, at the above address. A notice of intent, competing application, or motion to intervene must also be served upon each representative of the applicant specified in the particular application.

D2. Agency Comments—The Commission invites federal, state, and local agencies to file comments on the described application. (Agencies may obtain a copy of the application directly from the applicant). If an agency does not file comments within the time specified for filing comments, the Commission will presume that the agency has none. One copy of an agency's comments must also be sent to the applicant's representatives.

Lois D. Cashell,

Secretary.

[FR Doc. 92-702 Filed 1-12-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP93-129-000, et al.]

Texas Eastern Transmission Corp. et al.; Natural Gas Certificate Filings

Take notice that the following filings have been made with the Commission:

1. Texas Eastern Transmission Corp.

[Docket No. CP93-129-000]

January 4, 1993.

Take notice that on December 23, 1992, Texas Eastern Transmission Corporation (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056-5310, filed in Docket No. CP93-129-000 a request pursuant to § 157.205 of the Commission's Regulations to add an existing delivery point to an existing service agreement with Libra Marketing Company (Libra) at an interconnection with Libra in San Patricio County, Texas under Texas Eastern's blanket certificate issued in Docket No. CP82-535-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Texas Eastern proposes to add existing 6-inch tap connection on its 6-inch No. 16-L in San Patricio County, Texas. Texas Eastern would add the existing delivery point to the amended service agreement dated August 31, 1992, for service to Libra under Texas Eastern's Rate Schedule IT-1. Texas Eastern states that the peak and average day deliveries at the delivery point would be 100,000 dth of natural gas. Texas Eastern states that the addition of the existing facilities would have no effect on its peak day or annual deliveries and would be accomplished without detriment or disadvantage to its other customers. Texas Eastern states that Libra would reimburse Texas Eastern for the cost of the facilities which is estimated to be $78,000. Libra would install approximately 24,000 feet of 8-inch pipeline and two single 6-inch meter runs with regulators connecting to Texas Eastern's Line No. 16-L, it is indicated.

Comment date: February 16, 1993, in accordance with Standard Paragraph G at the end of this notice.

2. Southern Natural Gas Co.

[Docket No. CP93–000]

January 4, 1993.

Take notice that on December 23, 1992, Southern Natural Gas Company (Southern), filed in Docket No. CP93–134–000, an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon a sales service provided to Florida Gas Transmission Company (Florida), effective April 30, 1992, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Southern is requesting authorization to abandon firm sales service provided to Florida under Rate Schedule OCDL–1, because Florida has already abandoned its purchase from Southern on April 30, 1992, pursuant to Order No. 490. As a result, Southern is requesting the retroactive effective date to coincide with the effective date of Florida's abandonment.

Southern states in its application that it has not sold gas to Florida since the April 30 date, the contract between the two parties has expired, and that no facilities are proposed to be abandoned with the request herein.

Comment date: January 25, 1992, in accordance with Standard Paragraph F at the end of this notice.

3. Colorado Interstate Gas Co.

[Docket No. CP93–120–000]

January 4, 1993

Take notice that on December 18, Colorado Interstate Gas Company (CIG) Post Office Box 1087, Colorado Springs, Colorado 80944, filed pursuant to section 7(c) of the Natural Gas Act (NGA), an application in Docket No. CP93–120–000 for a certificate of public convenience and necessity to construct and operate facilities necessary to increase the injection capability into the Fort Morgan Storage Field, all as more fully set forth in the application on file with the Commission and open to public inspection.

CNG indicates that the proposed new facilities are part of its restructuring proposal under Order Nos. 636 et seq. which was filed by CIG on October 1, 1992 in Docket No. RS92–4–000. CIG requests authority to: (1) Install approximately 5,800 feet of 8-inch and 6-inch pipeline and appurtenant facilities to connect six existing injection/withdrawal wells—FMU#17, FMU#19, FMU#20, FMU#21, FMU#23 and FMU#24—to the Fort Morgan high-pressure gathering system; and (2) install approximately 2,200 additional horsepower consisting of two 1,100 horsepower compressor units, and approximately 1,000 feet of 12-inch yard piping and appurtenant facilities to be housed in a separate building, located approximately 200 feet east of the existing Fort Morgan compressor building within the existing yard.

CIG indicates that these facilities are required to increase the injection capability into the Fort Morgan Storage Field from approximately 60 MMcf per day to approximately 100 MMcf per day with actual injection capability dependent on system operating conditions. CIG states that it is not requesting authority to increase the peak day or seasonal deliverability.

CIG states that the estimated cost of the proposed facilities as set forth in Exhibit K is $3,612,500 and the cost of service associated with the proposed facilities as included in Exhibit N. The cost of the proposed facilities will be financed from funds on hand and internally generated cash from operations.

Comment date: January 25, 1993, in accordance with Standard Paragraph F at the end of the notice.

4. Columbia Gas Transmission Corp.

[Docket No. CP93–89–000]

January 4, 1993

Take notice that on December 3, 1992, Columbia Gas Transmission Corporation (Columbia), 1700 MacCorkle Avenue, SE., Charleston, West Virginia 25314, filed in Docket No. CP93–89–000, as supplemented on December 14, 1992, a request pursuant to § 157.205 of the Commission's Regulations to construct and operate three points of delivery for interruptible and firm transportation service to Equitable Gas Company (Equitable) Butler, Allegheny and Beaver Counties, Pennsylvania under Columbia's blanket certificate issued in Docket No. CP83–76–000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request on file with the Commission and open to public inspection.

Columbia proposes to construct and operate (1) an 8-inch tap, 2 filter separators, 12'×16' building and an 8-inch turbine meter for the delivery of up to 10,000 dth per day of natural gas and 3,650,000 dth per year of natural gas, on an interruptible basis, to Equitable to serve Witco Chemical, an industrial customer in Butler County, Pennsylvania at an estimated cost of $406,000 which would be reimbursed by Equitable; (2) a 6-inch tap, 2 filter separators, 12'×16' building and an 8-inch turbine meter for the delivery of up to 10,000 dth per day of natural gas and 3,650,000 dth per year of natural gas, on a firm basis, to Equitable to serve Airport Corridor, a commercial customer in Allegheny County, Pennsylvania at an estimated cost of $375,000 which would be reimbursed by Equitable and; (3) a 4-inch tap, 2 filter separators, 12' x 16' building and a 4-inch turbine meter for the delivery of up to 3,000 dth per day of natural gas and 1,095,000 dth per year of natural gas, on a firm basis, to Equitable to serve McAllister Crossroad, a commercial/industrial customer in Beaver County, Pennsylvania at an estimated cost of $266,000 which would be reimbursed by Equitable. Columbia states that the three additional delivery points have been requested by Equitable for commercial and industrial service under Rate Schedule X–70 to be provided pursuant to Article IV of the Stipulation and Agreement In Settlement entered into by Kentucky West Virginia Gas Company and Columbia filed August 5, 1992, in Docket Nos. TQ89–1–46–000, *et al.*

Comment date: February 16, 1993, in accordance with Standard Paragraph F at the end of the notice.

5. Colorado Interstate Gas Co.

[Docket No. CP93–136–000]

January 4, 1993.

Take noticd that on December 28, 1992, Colorado Interstate Gas Company (CIG), Post Office Box 1087, Colorado Springs, Colorado 80944, filed in Docket CP93–136–000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon the sale of natural gas to Questar Pipeline Company (Questar), a firm sales customer, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

CIG proposes to abandon the sale of 1,500 Mcf of natural gas per day to Questar and 547,000 Mcf on an annual basis, carried out under the terms of CIG's Rate Schedule P–1. CIG requests abandonment authorization in response to a request from Questar in a letter dated November 13, 1992. It is stated that CIG requests an effective date for the abandonment of October 1, 1992, to be concurrent with the termination of the service agreement between CIG and Questar. it is asserted that no other customers of CIG would be affected by the proposed abandonment.

No facilities are proposed to be abandoned.

Comment date: January 25, 1993, in accordance with Standard Paragraph F at the end of this notice.

6. Penn-York Energy Corp.

[Docket No. CP76-492-051]

January 4, 1993.

Take notice that on December 22, 1992, Penn-York Energy Corporation (Applicant), 10 Lafayette Square, Buffalo, New York 14203, filed in Docket No. CP76-492-051 pursuant to section 7(c) of the Natural Gas Act this Petition to Amend the "Order Approving Settlement Offer with modifications and Issuing Certificate" issued February 4, 1981.[1] Applicant herein requests authority to modify the authorized capacity of its three storage fields by 2.7 Bcf, all as more fully set forth on the request, on file with the Commission and open to public inspection.

Applicant seeks authority to increase the authorized base capacity of its three storage fields by an additional 2.7 Bcf. Specifically, Applicant seeks authority to increase the base gas capacity of its Beech Hill storage field by 2.2 Bcf to 13.1 Bcf.[2] Applicant also seeks authority to increase the base gas capacity of the East Independent Field by 300,000 Mcf and the West Independent Field by 200,000 Mcf.

In 1990, Applicant indicates that the pressure in its storage fields was continuing to decline. During the withdrawal cycle in 1990-91, Applicant's withdrawal from its storage fields was 11.14 Bcf. After injecting 5.7 Bcf of additional gas, Applicant states that the volume withdrawn increased to 12.23 Bcf during the 1991-92 withdrawal cycle. Based upon the improvement in withdrawal quantities, Applicant states that the reservoir is expanding. Thus, the Applicant indicates that the additional base gas is necessary to improve the deteriorating performance of Applicant's storage fields.

Applicant states that the additional 2.7 Bcf of base gas that was provided to Applicant by its customers through the operation of the storage loss allocation provision in Section 2.4 of the SS-1 and SS-2 Rate Schedule ("FLA") has already injected. Applicant also states that it does not request any change in rates or terms of service to Applicant's customers in this application. Applicant reiterates that it only seeks authority for the increase in base gas capacity by 2.7 Bcf.

[1] *Penn-York Energy Corporation*, 38 FERC ¶61,135 (1987).

[2] Inclusive of Applicant's Petition to Amend its Certificate of Public Convenience and Necessity to increase by 3 Bcf the base gas capacity of the Beech Hill Field proposed at Docket No. CP76-492-050.

Comment date: January 25, 1993, in accordance with the first Standard Paragraph F at the end of this notice.

7. Williston Basin Interstate Pipeline Co.

[Docket No. CP93-123-000]

January 6, 1993.

Take notice that on December 21, 1992, Williston Basin Interstate Pipeline Company, (Williston Basin), 200 North Third Street, Suite 300, Bismarck, North Dakota 58501, filed an application pursuant to section 7(b) of the Natural Gas Act for an order permitting the abandonment of certain transmission and gathering facilities located in Wyoming as well as the abandonment of certain jurisdictional services all as a result of the sale of property, as more fully set forth in the application which is on file with the Commission and open to public inspection.

Williston Basin will sell the facilities to K N Energy, Inc., Wind River Gathering Company, K N Gas Gathering, Inc., and Northern Gas Company. Williston Basin describes sales prices and accounting treatment in the application. The application affects services to the town of Pavillion, Wyoming and 13 farm customers in Fremont County, Wyoming.

Comment date: January 27, 1992, in accordance with Standard Paragraph F at the end of this notice.

8. Williston Basin Interstate Pipeline Co.

[Docket No. CP93-121-000]

January 6, 1993.

Take notice that on December 21, 1992, Williston Basin Interstate Pipeline Company (Williston Basin), 200 North Third Street, Suite 300, Bismarck, North Dakota 58501, filed in Docket No. CP93-121-000, an application for a Certificate of Public Convenience and Necessity pursuant to section 7(c) of the Natural Gas Act for authorization to uprate 59.8 miles of existing 12-inch natural gas transmission pipeline from its Worland Compression Station in Washakie County, Wyoming to the Madden/Wind River Junction in Fremont County, Wyoming by increasing its maximum allowable operating pressure (MAOP) from 850 psig to 1,017 psig and to modify the discharge piping and install an additional gas cooler at the Worland Compressor Station. Williston Basin states that it will also relocate the first stage regulators presently located at the Worland and Thermopolis town border stations to their respective lateral line interconnections with the uprated main transmission line. The estimated cost of the project is approximately $577,638. Uprating is required, according to Williston Basin, because of a proposed sale of facilities in the Wind River Basin area of Wyoming to K N Energy, Inc. proposed in the abandonment application of Williston Basin in Docket No. CP93-123-000.

Comment date: January 27, 1992, in accordance with Standard Paragraph F at the end of this notice.

9. U-T Offshore System

[Docket No. CP93-113-000]

January 6, 1993.

Take notice that on December 16, 1992, U-T Offshore System, (U-TOS) P.O. Box 1396, Houston, Texas 77251, filed in Docket No. CP93-113-000 an application pursuant to section (7)(b) of the Natural Gas Act, as amended, and the Rules and Regulations of the Federal Energy Regulatory Commission (Commission), for an order permitting and approving abandonment of firm and associated interruptible overrun transportation services provided to Transcontinental Gas Pipe Line Corporation (Transco) under U-TOS' Rate Schedules T-2 and I, respectively, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Service for Transco was certified in Docket No. CP76-118 by order issued January 13, 1977. Texas Gas Transmission Corporation, et al. 57 FPC 199 (1977). Transco's currently effective contract demand under the T-2 Rate Schedule is 199,608 Mcf per day, and its overrun quantity under Rate Schedule I is 413,000 Mcf per day.

U-TOS states that it was notified by Transco by letter dated June 5, 1992 of Transco's intent to terminate the service agreement underlying the T-2 Rate Schedule at the end of the primary term thereof, *i.e.*, on June 10, 1993. Accordingly, U-TOS requests an order permitting and approving abandonment of Rate Schedule T-2 and related Rate Schedule I (interruptible overrun) service effective on June 10, 1993.

U-TOS states that it does not propose to abandon any facilities in the instant application. U-TOS states that no service to any of its customers will be affected by the abandonmnt authorization requested herein.

Comment date: January 20, 1992, in accordance with Standard Paragraph F at the end of this notice.

10. High Island Offshore System

[Docket No. CP93-118-000

January 6, 1993.

Take notice that on December 18, 1992, High Island Offshore System

(HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed an application pursuant to section (7)(b) of the Natural Gas Act, as amended, and the Rules and Regulations of the Federal Energy Regulatory Commission (Commission), for authorization to abandon transportation service (currently being rendered for Trunkline Gas Company (Trunkline).

In its application, HIOS proposes to terminate its firm transportation service which HIOS is rendering in accordance with HIOS' Rate Schedule T–12, as well as associated Interruptible Overrun Transportation Service volumes rendered in accordance with HIOS' Rate Schedule I, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

HIOS proposes to terminate these services at the end of the primary term of Rate Schedule T–12, i.e., effective June 14, 1993, in accordance with the terms of such rate schedule and in accordance with timely notice given by Trunkline to HIOS.

HIOS states that it does not propose to abandon any facilities in the instant application. HIOS states that no service to any of its other customers will be affected by the abandonment authorization requested herein.

Comment date: January 20, 1993, in accordance with Standard Paragraph F at the end of the notice.

11. K N Energy, Inc.

[Docket No. CP93–125–000]

January 6, 1993.

Take notice that on December 21, 1992, K N Energy, Inc. (KN), P.O. Box 281304, Lakewood, Colorado 80228, filed an application pursuant to section 7(c) of the Natural Gas Act, as amended, and part 157 of the Commission's Regulations thereunder for a certificate of public convenience and necessity authorizing the acquisition from Williston Basin Interstate Pipeline Company (WBI) and the ownership and operation of certain pipeline and appurtenant facilities comprising Williston Basin's Madden Lateral in Fremont County, Wyoming. The facilities to be acquired consist of approximately 10.3 miles of 8-inch transmission pipeline, gathering facilities, a field dehydration unit, and appurtenant facilities, in Fremont County, Wyoming; all as more fully described in the application on file with the Commission. K N will pay WBI the net book value of $400,535.07 for the facilities.

Comment date: January 27, 1993, in accordance with Standard Paragraph F at the end of this notice.

12. K N Energy, Inc.

[Docket No. CP93–137–000]

January 6, 1993.

Take notice that on December 30, 1992, K N Energy, Inc. (K N), P.O. Box 281304, Lakewood, Colorado, 80228, filed in Docket No. CP93–137–000 a request pursuant to § 157.205(b) 157.208 and 157.212 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205(b), 157.208 and 157.212) seeking certificate authority, under its blanket certificate issued in Docket Nos. CP83–140–000 and CP83–140–001 to jointly with Williston Basin Interstate Pipeline Company, install and own a new measuring station at the Northwest end of the Madden Lateral and to add such measuring station as a redelivery point under its Rate Schedule X–4, all as more fully set forth in the request on file with the Commission and open to public inspection. The facility will cost $300,000.

Comment date: February 16, 1993, in accordance with Standard Paragraph G at the end of this notice.

13. Williston Basin Interstate Pipeline Company

[Docket No. CP93–122–000]

January 6, 1993.

Take notice that on December 21, 1992, Williston Basin Interstate Pipeline Company (Williston Basin), 200 North Third Street, Suite 300, Bismarck, North Dakota 58501, filed a request pursuant to §§ 157.205, 157.211 and 157.212 of the Commission's Regulations, for authorization to construct a new metering station and appurtenant facilities and to add such new metering station to the interruptible transportation service rendered to K N Energy, Inc. (K N) under Rate Schedule X–3 pursuant to the prior notice procedure under Williston Basin's blanket certificate issued in Docket Nos. CP82–487–000, *et al.* and CP83–1–000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In conjunction with an application filed the same date to abandon certain facilities by sale, Williston Basin seeks authorization to construct and operate a new metering station and a receipt/delivery point to the interruptible transportation service provided to K N under Rate Schedule X–3. The proposed metering station receipt/delivery point will be located in the vicinity of the existing interconnection of the 8-inch Madden (Lost Cabin) pipeline to the 12-inch Riverton-Worland line on existing pipeline right-of-way.

Williston Basin states that the facilities to be constructed will consist of two 8-inch bi-directional flow orifice-type gas custody transfer meters, miscellaneous regulators, gauges and valves, a fence, one meter building, and one building containing instruments and SCADA telemetering equipment. The total cost of the proposed facilities is estimated to be $300,000. The cost of the proposed facilities is to be shared by Williston Basin, Wind River Gathering Company and K N. Williston Basin further states that the installation of the proposed facilities should have no significant effect on its peak day or annual requirements.

Comment date: February 16, 1993, in accordance with Standard Paragraph G at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a

protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93–703 Filed 1–12–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–124–000]

ANR Pipeline Co.; Request Under Blanket Authorization

December 31, 1992.

Take notice that on December 21, 1992, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan 48243, filed in Docket No. CP93–124–000 a request pursuant to §§ 157.205 and 157.211 of the Commission's Regulations for authorization to operate under the provisions of the Natural Gas Act (NGA) certain facilities that have been constructed pursuant to section 311 of the Natural Gas Policy Act of 1978, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

ANR proposes an extension of the temporary exemption granted by the Commission to permit ANR to continue to use the uncertificated section 311 facilities which are the subject of this application to provide converted transportation services pending certification of the facilities.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93–704 Filed 1–12–93; 8:45 am]

BILLING CODE 6717–01–M

Office of Hearing and Appeals

Cases Filed During the Week of December 18 through December 25, 1992

During the Week of December 18 through December 25, 1992, other relief listed in the appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Dated: January 6, 1993.

George B. Breznay,

Director, Office of Hearings and Appeals.

REFUND APPLICATIONS RECEIVED

[Week of December 18 to December 25, 1992]

Date received	Name of refund proceeding/name of refund application	Case No.
12/18/92 thru 12/25/92.	Texaco Oil Refund applications received.	RF321–19529 thru RF321–19538.
12/18/92 thru 12/25/92.	Gulf Oil Refund applications received.	RF300–20778 thru RF300–20803.
12/18/92 thru 12/25/92.	Atlantic Richfield applications received.	RF304–13463 thru RF304–13483.
12/18/92 thru 12/25/92.	Crude Oil Refund applications received.	RF272–94012 thru RF272–94021.
12/21/92	Armstrong and Troutwine, Inc.	RF309–1426.
12/21/92	The City of Los Angeles, CA.	RF347–3.
12/23/92	Lawtell Highway Canal.	RF346–16.
12/23/92	St. Martinville Canal	RF346–17.

[FR Doc. 93–766 Filed 1–12–93; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[AD–FRL–4554–4]

Hazardous Air Pollutants List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Denial.

SUMMARY: Under section 112(b)(3)(A) of the Clean Air Act (CAA) as amended in 1990, any person may petition the Administrator to modify the initial list of hazardous air pollutants (HAPs) in CAA section 112(b)(1) by adding or deleting a particular chemical substance, or by removing specific substances from listed categories other than coke oven emissions, mineral fibers, or polycyclic organic matter. In this notice, the U.S. Environmental Protection Agency (EPA) announces that it is denying a petition to remove five specific substances [diethylene glycol monobutyl ether (112–34–5), diethylene glycol monobutyl ether acetate (124–17–4), triethylene glycol monomethyl ether (112–35–6), triethylene glycol monoethyl ether (112–50–5), and triethylene glycol monobutyl ether (143–22–6)] from the category of glycol ethers as listed in CAA section 112(b)(1).

FOR FURTHER INFORMATION CONTACT: Dr. Nancy B. Pate, Petition Coordinator, Emission Standards Division (MD–13), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; (919) 541–5347.

SUPPLEMENTARY INFORMATION: On October 16, 1991, EPA received a petition from the Chemical Manufacturers Association (CMA) to remove diethylene glycol monobutyl ether (112–34–5), diethylene glycol monobutyl ether acetate (124–17–4), triethylene glycol monomethyl ether (112–35–6), triethylene glycol monoethyl ether (112–50–5), and triethylene glycol monobutyl ether (143–22–6) from the category of glycol ethers listed as a Hazardous Air Pollutant (HAP) in section 112(b)(1). The EPA is denying the petition because the petitioner did not provide sufficient data or analysis to enable the EPA to determine whether emissions of these substances could be reasonably anticipated to cause adverse effects to human health or the environment. In particular, the petition contained insufficient information concerning the actual or estimated exposures which would result from emissions from manufacture and use of these specific

substances. Although public information indicated that over 140 million pounds of these substances are used annually in the U.S. and that there is a general trend towards greater usage, the petitioner did not provide measurements or estimates regarding the emissions associated with such use. In the absence of such information, EPA cannot make the substantive determination contemplated by CAA Section 112(b)(3).

After determining that the CMA petition was insufficient, EPA afforded CMA an opportunity to withdraw its petition, develop further emission and exposure information, and resubmit the petition at a later time. The CMA decided not to withdraw the petition. After additional discussion, CMA agreed that any supplementary information would be submitted only in the context of a new petition. EPA then met with CMA representatives to discuss the substantive deficiencies that needed to be remedied prior to submission of a new petition.

As a general matter, when EPA determines that a petition submitted under CAA section 112(b)(3) is deficient or imcomplete, EPA intends to return the petition to the petitioner, along with a brief description of the deficiency or missing information. Rather than formally denying a petition in such circumstances, EPA will afford the petitioner an opportunity to remedy the deficiency or supply the missing information prior to formal action on the petition. However, under CAA section 112(b)(4), if a petition to delete or remove a substance was filed prior to November 15, 1991, EPA must grant or deny the petition prior to promulgating emission standards for affected source categories. In view of the decision by CMA not to withdraw its incomplete petition, EPA has decided that it must formally deny that petition rather than return it to CMA, in order to assure that EPA is not prevented in the future from issuing any emission standard applicable to sources emitting the five glycol ethers.

This denial notice constitutes final action under CAA section 112(b)(3)(A). This denial action disposes only of the CMA petition submitted on October 16, 1991, and CMA may submit without prejudice a new petition to remove the specified five glycol ethers from the HAP list. This denial action is based on a determination of nationwide scope and effect and is therefore reviewable only in the United States Court of Appeals for the District of Columbia, as provided by CAA section 307(b)(1). This action is not a rule and does not modify the list of hazardous air pollutants in CAA section 112(b)(1). It is not subject to the provisions of Executive Order 12291 or the Regulatory Flexibility Act.

Dated: January 7, 1993.

Michael Shapiro,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 93–758 Filed 1–12–93; 8:45 am]

BILLING CODE 6560-60-M

[AMS–FRL–4554–6]

Motor Vehicle-Related Air Toxics Study—Availability of Public Review Draft

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability of public review draft of motor vehicle-related air toxics study.

SUMMARY: Today's action provides notice of availability of a public review draft of the Motor Vehicle-Related Air Toxics Study. This report is required by section 202(l) (1) of the Clean Air Act as amended in 1990. A public review draft of the report is being released to provide interested parties with an opportunity to review the document and provide EPA with comments. Public comments received will be summarized in the final report, as required by section 202(l)(1).

DATES: Comments must be received by March 1, 1993.

ADDRESSES: To obtain a copy of this draft report, please send requests by fax or by mail to Penny M. Carey. Fax: (303) 668–4368. Mailing address: U.S. EPA National Vehicle and Fuel Emissions Laboratory, EPSD–TSB, 2565 Plymouth Road, Ann Arbor, MI 48105. A copy has also been placed in the public docket.

Written comments on the draft report should be sent in duplicate to Air Docket Section [LE–131], Attention: Docket No. A–91–19, U.S.. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. The Agency requests that a separate copy also be sent to Penny M. Carey, U.S. EPA National Vehicle and Fuel Emissions Laboratory, EPSD–TSB, 2565 Plymouth Road, Ann Arbor, MI, 48105.

Materials relevant to this report have been placed in Docket No. A–91–19 by EPA. The docket is located at the above address in room M–1500, Waterside Mall (ground floor), and may be inspected from 8:30 a.m. to 12 noon and from 1:30 p.m. to 3:30 p.m., Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: Penny M. Carey, U.S. EPA National Vehicle and Fuel Emissions Laboratory, EPSD–TSB, 2565 Plymouth Road, Ann Arbor, MI, 48105. Telephone: (313) 668–4355.

SUPPLEMENTARY INFORMATION: Section 202 (l) (1) of the Clean Air Act directs EPA to complete a study of the need for, and feasibility of, controlling emissions of toxic air pollutants which are unregulated under this Act and associated with motor vehicles and motor vehicle fuels. The study shall focus on those categories of emissions that pose the greatest risk to human health or about which significant uncertainties remain, including emissions of benzene, formaldehyde, and 1,3-butadiene. The proposed report shall be available for public review and comment and shall include a summary of all comments.

Section 202(l)(2) also directs that, based on the study, EPA promulgate (and from time to time revise) regulations containing reasonable requirements to control hazardous air pollutants from motor vehicles and motor vehicle fuels. The regulations shall, at a minimum, apply to emissions of benzene and formaldehyde.

This study is the result of the first directive of section 202(l). Specific pollutants or pollutant categories which are discussed in this report include benzene, formaldehyde, 1,3-butadiene, acetaldehyde, diesel particulate, gasoline particulate, gasoline vapors, as well as selected metals and motor vehicle-related pollutants identified in section 112 of the Clean Air Act. The study focuses on carcinogenic risk, which is the major impact of benzene, 1-3-butadiene, and formaldehyde, emissions specifically mentioned in section 202(l)(1). The report also discusses non-cancer effects for these and other pollutants.

With respect to benzene, formaldehyde, 1,3-butadiene, acetaldehyde, diesel particulate, gasoline particulate, and gasoline vapors, the draft report discusses the chemical and physical properties of the pollutant, formation and control technology, emissions (including other emission sources), atmospheric reactivity and residence times, exposure estimation, EPA's carcinogenicity assessment, other views of carcinogenicity assessment, recent and ongoing research, carcinogenic risk, and non-carcinogenic health effects from inhalation exposure. The draft report also describes the qualitative change in toxic pollutant levels with the use of alternative clean fuels, along with a summary of EPA's nonroad engine and vehicle study. Finally, the report discusses the costs of various existing

regulatory control programs and provides a qualitative discussion of the toxics benefits of these programs.

This report attempts to summarize what is known about motor vehicle-related air toxics and to present all significant scientific opinion on each issue.

Dated: January 7, 1993.

Michael H. Shapiro,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 93–783 Filed 1–12–93; 8:45 am]

BILLING CODE [illegible]

[AMS FRL 4554–5]

California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption; Decision

AGENCY: Environmental Protection Agency.

ACTION: Notice regarding waiver of federal preemption.

SUMMARY: EPA is granting California a waiver of Federal preemption pursuant to section 209(b) of the Clean Air Act to enforce amendments to its motor vehicle emission standards and test procedures to phase-in substantially more stringent "low-emission vehicle (LEV)" standards for light-duty vehicles. California also amended its corresponding regulations.

ADDRESSES: A copy of the above standards and procedures, the decision document containing an explanation of the Administrator's determination, and the record of those documents used in arriving at this decision, are available for public inspection during normal working hours (8:30 a.m. to 12 p.m. and 1:30 p.m. to 3:30 p.m.) at the U.S. Environmental Protection Agency, Air Docket (LE–131), (Docket A–91–71), room M–1500, Waterside Mall, 401 M Street, SW., Washington, DC 20460. Copies of the decision document can be obtained from EPA's Manufacturers Operations Division by contacting Robert Doyle or Karl Simon, as noted below.

FOR FURTHER INFORMATION CONTACT: Robert M. Doyle, Attorney/Advisor, or Karl J. Simon, Environmental Engineer, Manufacturers Operations Division (6405–J), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Telephone: (202) 233–9258 (R. Doyle), (202) 233–9299 (K. Simon).

SUPPLEMENTARY INFORMATION: I have decided to grant California a waiver of Federal preemption pursuant to section 209(b) of the Clean Air Act, as amended (Act), 42 U.S.C. 7543(b), for amendments to its exhaust emission standards and test procedures which establish new categories of light-duty vehicles based on levels of exhaust emission standards.[1] These amendments also require manufacturers to meet a "Non-Methane Organic Gas" fleet average requirement, a "Zero Emission Vehicle" production requirement, and other requirements. A comprehensive description of the California LEV program can be found in the decision document for this waiver and in materials submitted to the Docket by CARB.

Section 209(b) of the Act provides that, if certain criteria are met, the Administrator shall waive Federal preemption for California to enforce new motor vehicle emission standards and accompanying enforcement procedures. The criteria include consideration of whether California arbitrarily and capriciously determined that its standards are, in the aggregate, at least as protective of public health and welfare as the applicable Federal standards; whether California needs State standards to meet compelling and extraordinary conditions; and whether California's amendments are consistent with section 202(a) of the Act.

CARB determined that these standards and accompanying enforcement procedures do not cause California's standards, in the aggregate, to be less protective to public health and welfare than the applicable Federal standards. Information presented to me by parties opposing California's waiver request did not demonstrate that California arbitrarily or capriciously reached this protectiveness determination. Therefore, I cannot find California's determination to be arbitrary and capricious.

CARB has continually demonstrated the existence of compelling and extraordinary conditions justifying the need for its own motor vehicle population control program, which includes the subject standards and procedures. No information has been submitted to demonstrate that California no longer has a compelling and extraordinary need for its own program. Therefore, I agree that California continues to have compelling and extraordinary conditions which require its own program, and, thus, I cannot deny the waiver on the basis of the lack of compelling and extraordinary conditions.

CARB has submitted information that the requirements of its emission standards and test procedures are technologically feasible and present no inconsistency with Federal requirements and are, therefore, consistent with section 202(a) of the Act. Information presented to me by parties opposing California's waiver request did not satisfy the burden of persuading EPA that the standards are not technologically feasible within the available lead time, considering costs. In addition, California's amendments generally parallel the Federal certification test procedures, and do not establish inconsistent test procedures. Accordingly, I hereby grant the waiver requested by California.

My decision will affect not only persons in California but also the manufacturers outside the State who must comply with California's requirements in order to produce motor vehicles for sale in California. For this reason, I hereby determine and find that this is a final action of national applicability.

Under section 307(b)(1) of the Act, judicial review of this final action may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by March 15, 1993. Under section 307(b)(2) of the Act, judicial review of this final action may not be obtained in subsequent enforcement proceedings.

As with past waiver decisions, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Dated: January 7, 1993.

William K. Reilly,

Administrator.

[FR Doc. 93–784 Filed 1–12–93; 8:45 am]

BILLING CODE [illegible]

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[1] California's waiver request ("LEV waiver request") also included amendments establishing new standards for certain low-emission categories of medium-duty vehicles ("MDVs"). There is a pending waiver request from the California Air Resources Board (CARB) for other regulatory amendments pertaining to MDVs (Docket A–91–55; see 57 FR 909 (January 9, 1992)) which was submitted to ERA before the LEV waiver request. Because my action on the LEV waiver request precedes my action on Docket A–91–55, I will defer action on the portions of the LEV waiver request that add new standards and requirements for the low-emission categories of MDVs until action is taken on the MDV waiver request. Therefore, these MDV amendments should not be considered as included in the CARB regulations which are the subject of this waiver. (CARB is in agreement with this deferral.)

[OPP–66171; FRL–4182–2]

Methazole; Receipt of Request for Voluntary Cancellation; Cancellation Order

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice to cancel registrations.

SUMMARY: This notice, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), announces EPA's receipt and acceptance of a request from Sandoz Agro, Inc. to voluntarily cancel the remaining registrations of pesticide products containing methazole (2-(3,4-dichlorophenyl)-4-methyl-1,2,4-oxadiazolidine-3,5-dione). Sandoz Agro, Inc. is the sole registrant of methazole products. EPA is accepting the voluntary cancellation request based on FIFRA section 6(a)(2) data submitted by the registrant to the Agency which indicates that unreasonable worker risks may be associated with the use of methazole. This notice also announces the restriction of distribution and sale of canceled methazole products until additional toxicological data regarding the potential risks have been considered by the Agency.

DATES: The cancellations and interim restriction of distribution and sale of existing stocks are effective on January 13, 1993.

FOR FURTHER INFORMATION CONTACT: By mail: Joseph Bailey, Special Review and Reregistration Division (H7508W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Special Review Branch, Room 2G6, Crystal Station 1, 2800 Jefferson Davis Highway, Arlington, VA (703) 308–8173.

SUPPLEMENTARY INFORMATION:

I. Background

Methazole is a selective herbicide used to control several varieties of weeds in cotton. It is registered for preemergence use west of the Mississippi and directed postemergence use both east and west of the Mississippi. Its use is prohibited in the states of Arizona and California. Most of the methazole produced for cotton production is applied in Louisiana and Mississippi with some use occurring in other cotton producing states. The season for methazole use typically begins in April/May.

II. Voluntary Cancellation

Under FIFRA section 6(f)(1)(A), registrants may request at any time that EPA cancel any of their pesticide registrations. If the pesticide for which cancellation was requested is registered for any minor agricultural use, section 6(f)(1)(C) dictates that EPA publish in the **Federal Register** a notice of the receipt of the cancellation request, and allow 90 days for public comment before granting the request unless either the registrants request a waiver of the 90–day period or the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

On May 18, 1992, Sandoz Agro, Inc. requested voluntary cancellation of the remaining two registered methazole products. Prior to the submission of the voluntary cancellation request, Sandoz Agro, Inc. had submitted to the Agency, pursuant to FIFRA section 6(a)(2), preliminary results from a rat reproduction study indicating that a high percentage of the dosed generation's offspring developed cataracts. The Agency concluded from these test results that an unacceptable risk is possible to those workers exposed to methazole, particularly mixer/loaders and applicators. The products for which cancellation was requested are listed in Table 1 (section 3 registrations only) below.

On August 12, 1992, the Agency notified Sandoz Agro, Inc. that it had accepted their request for voluntary cancellation; however, due to the potential risks posed to workers exposed to methazole, the Agency waived the 90–day comment period usually afforded to such voluntary cancellations. In the Agency's notice, it was stated that a cancellation order establishing provisions for existing stock disposition would be forthcoming.

Table 1.—Methazole Section 3 (national) Registrations: Voluntary Cancellation Requests

Company Registration Number	Company Name/Address	Product Registration Number	Product Name
55947	Sandoz Agro, Inc. 1300 East Touhy Avenue Des Plaines, IL 60018	55947–22 55947–23	Technical Probe Probe 75 Wettable Powder

Methazole will no longer be considered a registered active ingredient and will be removed from List B reregistration chemicals. Once an active ingredient is canceled, any person wishing to bring the pesticide back on the market would need to apply to EPA for a "new chemical" registration. Such a registration generally would not be approved until all applicable data requirements are satisfied.

III. Existing Stocks Provision

In accordance with the Agency's June 26, 1991 Existing Stocks of Pesticide Products Statement of Policy, distribution and sale of existing stocks of canceled pesticide products that raise risk concerns will not be allowed unless it is demonstrated that such distribution and sale would not result in unreasonable adverse effects. At this time, the Agency is not granting any provisions for the distribution and sale of existing stocks of methazole products. The Agency has agreed to consider additional data to be submitted by Sandoz Agro, Inc. which may provide a more refined risk assessment for workers exposed to methazole. Methazole is no longer being produced by Sandoz Agro, Inc. and the only remaining stocks are held in the chain of distribution by sellers, distributors, and end-users. FIFRA section 12(a)(1)(A) states that it is unlawful for any person in any state to distribute or sell to any person any pesticide whose registration has been canceled unless such distribution or sale has been authorized by the Administrator. Therefore, distributors and sellers with methazole products in their possession are responsible to ensure that any existing stocks held are not distributed or sold until the Agency provides notification of a final decision on the disposition of such existing stocks. Sandoz Agro, Inc. has notified customers who may have methazole in their possession that they should not move any of the existing stocks until the Agency has reviewed the additional data and reached a final determination regarding the potential risk. Existing stocks in the hands of end-users may continue to be used until such stocks are exhausted provided that such use is in strict accordance with the product's previously-approved labeling.

Dated: December 24, 1992.
Douglas D. Campt,
Director, Office of Pesticide Programs.
[FR Doc. 93-788 Filed 1-12-93; 8:45 am]
BILLING CODE 6560-50-F

FEDERAL DEPOSIT INSURANCE CORPORATION

Information collection submitted to OMB for review

AGENCY: Federal Deposit Insurance Corporation.
ACTION: Notice of information collection submitted to OMB for review and approval under the Paperwork Reduction Act.

SUMMARY: The submission is summarized as follows:

Type of Review: Revision of a currently approved collection.
Title: Certified Statement—Semiannual Deposit Insurance Assessment.
Form Number: FDIC 6420/07, 6420/10, 6420/11.
OMB Number: 3064-0057.
Expiration Date of Current OMB Clearance: 02/28/93.
Frequency of Response: Semiannually.
Respondents: Insured depository institutions that are members of the Bank Insurance Fund (BIF) and the Savings Association Insurance Fund (SAIF).
Number of Respondents: 14,500.
Number of Responses Per Respondent: 2.
Total Annual Responses: 29,000.
Average Number of Hours Per Response: 1.
Total Annual Burden Hours: 29,000.
OMB Reviewer: Gary Waxman, (202) 395-7340, Office of Management and Budget, Paperwork Reduction Project 3064-0057, Washington, DC 20503.
FDIC Contact: Steven F. Hanft, (202) 898-3907, Office of the Executive Secretary, room F-400, Federal Deposit Insurance Corporation, 550 17th Street, NW., Washington, DC 20429.
Comments: Comments on this collection of information are welcome and should be submitted on or before March 15, 1993.

ADDRESSES: A copy of the submission may be obtained by calling or writing the FDIC contact listed above. Comments regarding the submission should be addressed to both the OMB reviewer and the FDIC contact listed above.

SUPPLEMENTARY INFORMATION: The FDIC is requesting OMB approval to extend the period of use of the forms filed by insured depository institutions that are members of the Bank Insurance Fund (BIF) and the Savings Association Insurance Fund (SAIF) certifying the semiannual assessment due under the provisions of section 7 of the Federal Deposit Insurance Act. The forms show the deposit liabilities, less authorized deductions, the computation of the assessment base and the amount of the assessment due for each semiannual assessment period involved. The FDIC is also requesting approval for minor revisions to the forms. Further, the FDIC is also requesting permission to combine OMB collection 3064-0101 (Assessment for SAIF Members) and OMB collection 3064-0057 (Assessments for BIF Members) into a single collection. The combination is an administrative convenience that will not affect the reporting requirements contained in the collections.

Dated: January 8, 1993.
Federal Deposit Insurance Corporation
Hoyle L. Robinson,
Executive Secretary.
[FR Doc. 93-776 Filed 1-12-93; 8:45 am]
BILLING CODE 6714-01-M

Coastal Barrier Improvement Act Property Availability; Chambers Tract I (735.66 acres), Chambers County, TX

AGENCY: Federal Deposit Insurance Corporation.
ACTION: Notice.

SUMMARY: Notice is hereby given that the property known as the "Chambers Tract I" located in Chambers County, Texas is affected by section 10 of the Coastal Barrier Improvement Act of 1990, as specified below.

DATES: Written Notices of Serious Interest to purchase or effect other transfer of the property may be mailed or fixed to the Federal Deposit Insurance Corporation until April 13, 1993.

ADDRESSES: Copies of detailed descriptions of the property can be obtained by contacting the following person: James Pridgen, Federal Deposit Insurance Corporation, 4440 Piedras Drive South, San Antonio, TX 78228, Telephone (210) 731-2049, Fax (210) 737-1101.

SUPPLEMENTARY INFORMATION: The 1537.79 acre property is divided into two tracts. Tract I and Tract II contain 735.66 and 802.13 acres respectively. Tract II is not covered under the Coastal Barrier Improvement Act. Tract I is located approximately one mile south of FM 1985, with frontage on the east side of the Anahuac National Wildlife Refuge road easement. The property is in the southeast quadrant of Chambers County, fronting the north boundary line of the Anahuac National Wildlife Refuge. The Tract is predominantly cleared, irrigated farm land with lower elevations along Oyster Bayou.

Written notice of serious interest to purchase the property must be received on or before April 13, 1993, by James Pridgen at the above address.

Those entities eligible to submit written notices of serious interest are:

1. Agencies or entities of the Federal government.
2. Agencies or entities of the state or local government, and
3. "Qualified organizations" pursuant to section 170(h) of the Internal Revenue Code of 1986 (26 U.S.C. 170(h)(s)).

FORM OF NOTICE: Notices of serious interest should be in the following form: Notice of Serious Interest re: Chambers Tract I Land, Chambers County, Texas.

1. Name of eligible entity.
2. Declaration of eligibility to submit notice under criteria set forth in Public Law 101-591, section 10(b)(2).
3. Brief description of proposed terms of purchase or other offer (e.g. price and method of financing).
4. Declaration by entity that it intends to use the property primarily for wildlife refuge, sanctuary, open space, recreational, historical, cultural or natural resource conservation purposes.

Dated: January 7, 1993.
Federal Deposit Insurance Corporation
Hoyle L. Robinson,
Executive Secretary.
[FR Doc. 93-699 Filed 1-12-93; 8:45 am]
BILLING CODE 6714-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed; Jacksonville/ Marine Transportation Services, et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before

communicating with the Commission regarding a pending agreement.

Agreement No. 224–200468–003.
Title: Jacksonville/Marine Transportation Services Sea Barge Group Terminal Agreement.
Parties: Jacksonville Port Authority Marine Transportation Services Sea Barge Group, Inc.
Synopsis: The amendment modifies Agreement provisions pertaining to the commencement of throughput charges and to rental and other rates specified in the Agreement.
Agreement No. 224–200713.
Title: L.A. Cruise Ship Terminals/ Holland America Terminal Agreement.
Parties: L.A. Cruise Ship Terminals, Inc. ("L.A. Cruise") Holland America Lines Westours Inc. ("Holland America").
Synopsis: The Agreement provides that L.A. Cruise will provide terminal facilities and services to Holland America in the Port of Los Angeles.
Agreement No. 207–011397.
Title: Empremar/CTE Agreement.
Parties: Empremar S.A. Compania Trasatlantica Espanola S.A.
Synopsis: The proposed Agreement permits the parties to operate a joint service in the trade between U.S. Atlantic and Gulf ports and points, and ports and points in Venezuela, Mexico, Columbia, Ecuador, Peru and Chile. It also permits the parties to agree on the number of vessels they will operate, pool profits, and establish rates, charges, rules and practices. The parties have requested a shortened review period.

Dated: January 7, 1993.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 93–705 Filed 1–12–93; 8:45 am]

BILLING CODE 6730–01–M

Agreement(s) Filed; Houston/Port-Cooper/T. Smith Stevedoring, et al.

The Federal Maritime Commission hereby gives notice that the following agreement(s) has been filed with the Commission pursuant to section 15 of the Shipping Act, 1916, and section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments and protests are found in § 560.602 and/or 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the agreement at the address shown below.

Agreement No.: 224–200715.
Title: Houston/Terminal Agreement.
Parties: Port of Houston Authority ("Port") Port-Cooper/T. Smith Stevedoring ("Cooper").
Filing Party: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas 77252–2562.
Synopsis: The Agreement permits Cooper to utilize the Port's Open & Shed Areas Number 16 through 18 for cargo handling purposes during calendar years 1993 and 1994.
Agreement No.: 224–200716.
Title: Houston/Flanagan Stevedores Terminal Agreement.
Parties: Port of Houston Authority ("Port") James J. Flanagan Stevedores ("Flanagan").
Filing Party: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas 77252–2562.
Synopsis: The Agreement permits Flanagan to utilize the Port's Open & Shed Areas Number 21 through 24 W. for cargo handling purposes during calendar years 1993 and 1994.
Agreement No.: 224–200718.
Title: Houston/Strachan Shipping Terminal Agreement.
Parties: Port of Houston Authority ("Port") Strachan Shipping Company ("Strachan").
Filing Party: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas 77252–2562.
Synopsis: The Agreement permits Strachan to utilize the Port's Barbours Cut Transit Shed Number Two Section B (West) for cargo handling purposes during calendar years 1993 and 1994.
Agreement No.: 224–200719.
Title: Houston/Ryan Walsh Terminal Agreement.
Parties: Port of Houston Authority ("Port") Ryan Walsh Incorporated ("Ryan Walsh").
Filing Party: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas 77252–2562.
Synopsis: The Agreements permits Ryan Walsh to utilize the Port's Open and Shed Areas Number 30 and 32 for cargo handling purposes during calendar years 1993 and 1994.
Agreement No.: 224–200720.
Title: Houston/Ceres Gulf Terminal Agreement.
Parties: Port of Houston Authority ("Port") Ceres Gulf Incorporated ("Ceres Gulf").
Filing Party: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas 77252–2562.
Synopsis: The Agreement permits Ceres Gulf to utilize the Port's Open and Shed and Shed Areas Number 19 and 20 for cargo handling purposes during calendar years 1993 and 1994.
Agreement No.: 224–200721.
Title: Houston/Port Houston Terminal C.E.S., Inc. Terminal Agreement.
Parties: Port of Houston Authority ("Port") Port Houston Terminal C.E.S., Inc. ("PHT, Inc.").
Filing Party: Martha T. Williams, Staff Counsel, Port of Houston, 111 East Loop North, P.O. Box 2562, Houston, Texas 77252–2562.
Synopsis: The Agreement PHT, Inc. to utilize the Port's Open and Shed Areas Number 8 and 9 for cargo handling purposes during calendar years 1993 and 1994.

Dated: January 7, 1993.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 93–706 Filed 1–12–93; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Community Bank-Corp. of Sheboygan, Inc., et al.; Acquisitions of Companies Engaged in Permissible Nonbanking Activities

The organizations listed in this notice have applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated for the application or the offices of the Board of Governors not later than February 5, 1993.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Community Bank-Corp. of Sheboygan, Inc., Sheboygan, Wisconsin; to acquire G & H Insurance Agency, Sheboygan, Wisconsin, which will become Community Insurance and Financial Services, Inc., Sheboygan, Wisconsin, and thereby engage in insurance agency activities pursuant to § 225.25(b)(8) of the Board's Regulation Y. These activities will be conducted in the State of Wisconsin.

B. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. Zions Bancorporation, Salt Lake City, Utah; to enter into a joint venture with American Bankers Insurance Group, Inc., Miami, Florida, by selling American Bankers Insurance Group, Inc., approximately $1.5 million in variable rate voting preferred stock of Zions Bancorporation's wholly-owned subsidiary, Zions Insurance Company, Salt Lake City, Utah, and to continue to engage through the letter in credit life, accident and disability insurance activities pursuant to § 225.25(b)(8) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 7, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-772 Filed 1-12-93; 8:45 am]

BILLING CODE 6210-01-F

Creditanstalt-Bankverein, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 1, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. Creditanstalt-Bankverein, Vienna, Austria; to engage *de novo* through its subsidiary, Steinberg Asset Management Company, L.P., New York, New York, in investment advisory activities pursuant to § 225.25(b)(4) of the Board's Regulation Y.

2. Internationale Nederlanden Group N.V., Amsterdam, The Netherlands; to engage *de novo* through its subsidiary, Internationale Nederlanden Capital Corporation, New York, New York, in making, servicing, and acquiring loans and other extensions of credit (including issuing letters of credit and accepting drafts), directly or indirectly, for ING's own account or the account of others, such as would be made, for example, by a consumer or commercial finance, credit card, mortgage or factoring company pursuant to § 225.25(b)(1) of the Board's Regulation Y.

3. Internationale Nederlanden Group N.V., Amsterdam, The Netherlands; to engage *de novo* through its subsidiary, Internationale Nederlanden Securities Corporation, New York, New York, in providing securities brokerage services, related securities credit activities, and incidental activities such as offering custodial services, individual retirement accounts, and cash management services solely as agent for the account of customers and providing such securities brokerage services in combination with the investment advisory services listed below; serving as an advisory company for mortgage and real estate investment trusts; serving as investment adviser to investment companies registered under the Investment Company Act of 1940, including sponsoring, organizing, and managing closed-end investment companies; providing portfolio investment advice to any other person; furnishing general economic information and advice, general economic statistical forecasting services and industry studies; providing financial advice to state and local and foreign governments, such as with respect to the issuance of their securities; providing financial and transactional advice to institutional customers with respect to restructuring, financing and negotiating mergers, acquisitions, divestitures, joint ventures, leveraged buyouts, recapitalizations, capital structurings, structuring and arranging loan syndications, financings and other corporate transactions, rendering fairness opinions, providing valuation services, and conducting feasibility studies; and providing financial and transactional advice regarding the structuring and arranging of swaps, caps, and similar transactions relating to interest rates, currency exchange rates or prices, and economic financial indices pursuant to § 225.25(b)(4) and (b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 7, 1993.
Jennifer J. Johnson,
Associate Secretary of the Board.
[FR Doc. 93-773 Filed 1-12-93; 8:45 am]
BILLING CODE 6210-01-F

First Fidelity Bancorporation, et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than February 5, 1993.

A. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. First Fidelity Bancorporation, Lawrenceville, New Jersey; to acquire 100 percent of the voting shares of Northeast Bancorp, Inc., New Haven, Connecticut, and thereby indirectly acquire Union Trust Company, Stamford, Connecticut.

B. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. Fidelity Bancorp, Inc., Pittsburgh, Pennsylvania; to become a bank holding company by acquiring 100 percent of the voting shares of Fidelity Savings Bank, Pittsburgh, Pennsylvania.

C. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. CCB Financial Corporation, Durham, North Carolina; to acquire 100 percent of the voting shares of CCB Savings Bank, Inc., SSB, Lenoir, North Carolina, the successor by conversion to Mutual Savings Bank.

2. Horizon Bancorp, Inc., Beckley, West Virginia; to merge with Alleghany Bankshares Corporation, Lewisburg, West Virginia, and thereby indirectly acquire Greenbrier Valley National Bank, Lewisburg, West Virginia, and First National Bank in Marlinton, Marlinton, West Virginia.

D. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. Century Bancorp, Inc., Milledgeville, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Century Bank and Trust, Milledgeville, Georgia.

E. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. LeRoy C. Darby, Inc., Monona, Iowa; to merge with Keystone Bancshares, Inc., Elkader, Iowa, and thereby indirectly acquire Peoples State Bank, Elkader, Iowa.

2. Midstates Bancshares, Inc., Missouri Valley, Iowa; to acquire 98.33 percent of the voting shares of Peoples National Bank, Avoca, Iowa.

F. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Community First Bankshares, Inc., Fargo, North Dakota; to merge with Citizens Bancorp, Inc., Morris, Minnesota, and thereby indirectly acquire Citizens Bank, Morris, Minnesota.

2. First National Corporation North Dakota, Grand Forks, North Dakota; to become a bank holding company by becoming the sucessor by merger with First National Corporation, Grand Forks, North Dakota, and thereby indirectly acquire First National Bank North Dakota, Grand Forks, North Dakota.

3. Mellette Holding Company, Mellette, South Dakota; to become a bank holding company by acquiring 100 percent of the voting shares of Farmers State Bank of Mellette, Mellette, South Dakota.

G. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Archer, Inc., Palmer, Nebraska, and Osceola Insurance, Inc., Osceola, Nebraska; to acquire 14.6 percent of the voting shares of Guaranty Corporation, Denver, Colorado, and thereby indirectly acquire Guaranty Bank and Trust Company, Denver, Colorado.

Board of Governors of the Federal Reserve System, January 7, 1993.
Jennifer J. Johnson,
Associate Secretary of the Board.
[FR Doc. 93-774 Filed 1-12-93; 8:45 am]
BILLING CODE 6210-01-F

Van Buren Bancorporation Employee Stock Ownership Plan, et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; and Acquisitions of Nonbanking Companies

The companies listed in this notice have applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed companies have also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The applications are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 5, 1993.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. Van Buren Bancorporation Employee Stock Ownership Plan, Keosauqua, Iowa; to become a bank holding company by acquiring 100 percent of the voting shares of Van Buren Bancorporation, Keosauqua, Iowa, and thereby indirectly acquire State Savings Bank, Cantril, Iowa, and Farmers State Bank, Keosauqua, Iowa.

In connection with this application, Applicant and Van Buren Bancorporation have applied to engage *de novo* in the making, servicing or acquisition of loans pursuant to § 225.25(b)(1) of the Board's Regulation Y.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Norwest Corporation, Minneapolis, Minnesota; to merge with Financial Concepts Bancorp, Inc., Green Bay, Wisconsin, and thereby indirectly acquire University Bank, Green Bay, Wisconsin.

In connection with this application, Applicant also proposes to acquire the mortgage servicing business of University Bank, Green Bay, Wisconsin, and thereby engage in mortgage banking activities including portfolio servicing through Norwest's subsidiary, Norwest Mortgage, Inc., pursuant to § 225.25(b)(1) of the Board's Regulation Y; and to acquire the brokerage business of University Bank, Green Bay, Wisconsin, and thereby engage in full-service brokerage, government securities, and limited underwriting activities in Green Bay, Wisconsin, through Norwest's subsidiary, Norwest Investment Services, Inc., pursuant to Board Order. *Norwest Corporation*, 76 Federal Reserve Bulletin 79 (1990). These activities will be conducted in Green Bay, Wisconsin.

C. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Green Top, Inc., Central City, Nebraska; to merge with Anmer Corporation, Neligh, Nebraska, and thereby indirectly acquire 97.19 percent of First United Bank, Neligh, Nebraska, and 64.07 percent of the voting shares of Schuyler State Bank and Trust Co., Schuyler, Nebraska; Dawson Corporation, Lexington, Nebraska, and thereby indirectly acquire 84.28 percent of The Farmers State Bank and Trust Co., Lexington, Nebraska; Heartland Bancorporation, Aurora, Nebraska, and thereby indirectly acquire 80.04 percent of The Farmers State Bank and Trust Co., Aurora, Nebraska, and 100 percent of The Crete State Bank, Crete, Nebraska; North Platte Corporation, Torrington, Wyoming, and thereby indirectly acquire 95.9 percent of The Citizens Bank & Trust Co., Torrington, Wyoming, 100 percent of The First National Bank, Worland, Wyoming, and 95.86 percent of the voting shares of Western Bank of Cody, Cody, Wyoming; Pinnacle Bancorp, Inc., Ft. Lupton, Colorado, and thereby indirectly acquire 90.53 percent of the voting shares of First Security Bank, Ft. Lupton, Colorado, 100 percent of First Security Bank, Craig, Colorado; and 100 percent of First Security Bank, Windsor, Colorado; Pinnacle Bancorp, Inc., Abilene, Kansas, and thereby indirectly acquire 98 percent of First National Bank, Abilene, Kansas; Pinnacle Bancorp, Inc., Papillion, Nebraska, and thereby indirectly acquire 96.35 percent of Bank of Papillion, Papillion, Nebraska; Pinnacle Bancorp, Inc., Newcastle, Wyoming, and thereby indirectly acquire 85.86 percent of First Security Bank, Newcastle, Wyoming; and Shelby Insurance, Inc., Shelby, Nebraska, and thereby indirectly acquire 100 percent of The First National Bank, Shelby, Nebraska.

In connection with this application, Applicant also proposes to engage *de novo* in making and servicing loans pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 7, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–775 Filed 1–12–93; 8:45 am]

BILLING CODE 6210–01–F

HARRY S. TRUMAN SCHOLARSHIP FOUNDATION

Scholarships; Closing Date for Nominations From Eligible Two-Year Institutions of Higher Education

Notice is hereby given that, pursuant to the authority contained in the Harry S. Truman Memorial Scholarship Act, Public Law 93–642 (20 U.S.C. 2001), nominations are being accepted from eligible two-year institutions of higher education for Truman Scholarships. Procedures are prescribed at 45 CFR Part 1801, and were published in the **Federal Register** on September 23, 1991 (56 FR 48076).

In order to be assured of consideration, all documentation in support of nominations must be received by The Truman Scholarship Review Committee, Recognition Programs, Operations Division, 2255 North Dubuque Road, Iowa City, Iowa 52243 no later than February 25, 1993.

Louis H. Blair,

Executive Secretary.

[FR Doc. 93–714 Filed 1–12–93; 8:45 am]

BILLING CODE 6820–AB–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Information Collection Under OMB Review

AGENCY: Office of Financial Management, Administration for Children and Families, HHS.

ACTION: Notice.

Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), we have submitted to the Office of Management and Budget (OMB) a request for approval of a reinstatement of a previously approved information collection titled: "The Annual Budget Request for Title IV–B Funds and Annual Summary of Child Welfare Services". This request is made by the Office of Financial Management of the Administration for Children and Families (ACF).

ADDRESSES: Copies of the Information Collection request may be obtained from Steve Smith of the Office of Information Systems Management, ACF, by calling (202) 401–9235.

Written comments and questions regarding the requested approval for information collection should be sent directly to: Kristina Emanuels, OMB Desk Officer for ACF, OMB Reports Management Branch, New Executive Office Building, room 3002, 725 17th Street, NW., Washington, DC 20503, (202) 395–7316.

Information on Document

Title: Annual Budget Request for Title IV–B Funds and Annual Summary of Child Welfare Services Form CWS–101

OMB No.: 0980–0047

Description: The Annual Budget Request for title IV–B Funds and the Annual Summary of Child Welfare Services are two companion information collection documents which States must submit to the Administration for Children and

Families to request grant awards under title IV–B of the Social Security Act. The purpose of title IV–B grants is to enable the Federal government to cooperate with State public welfare agencies in establishing, extending, and strengthening child welfare services. The information obtained from the use of Form CWS–101 Annual Budget Request for title IV–B Funds will enable States and Indian Tribal Organizations to request its share of the federal allotment. Without this information, no grant amounts can be determined and no grants can be made.

The form used for the collection of information for the Annual Summary of Child Welfare Services will be submitted by States to provide a summary of child welfare services for the next year by service, by source of funds, and by number of clients to be served. Indian Tribal Organizations do not need to submit the Annual Summary of Child Welfare Services.

Annual Number of Respondents: 95
Annual Frequency: 1.5
Average Burden Hours Per Response: 6
Total Burden Hours: 855

Dated: December 30, 1992.

Larry Guerrero,

Deputy Director, Office of Information Systems Management.

[FR Doc. 93–679 Filed 1–12–93; 8:45 am]

BILLING CODE 4130–01–M

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee (CLIAC) Subcommittee on Test Categorization; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC), announces the following committee meeting.

Name: CLIAC Subcommittee on Test Categorization.

Time and Date: 8 a.m.–5 p.m., January 29, 1993.

Place: CDC, Auditorium A, Building 2, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Status: Open to the public, limited only by the space available.

Purpose: The subcommittee will advise CLIAC on revisions to the list of waived tests and the categorization of tests of moderate and high complexity.

Agenda: This is the initial meeting of this subcommittee. The agenda will include a review of the criteria used and the tests currently contained on the waived test list; a review of the categorization of high-density lipoproteins (HDL) cholesterol test systems; a discussion of the Gram stain, Tzank and other test systems relative to the physician-performed microscopy category; a review of direct antigen tests for Group A Streptococcus; and other pertinent test issues.

Written comments are welcome and should be received by the contact person listed below no later than January 20, 1993. Copies of comments that are germane to the topics on the agenda will be supplied to the subcommittee members for review prior to the meeting. Public oral comments will be accepted at the discretion of the Chairman at the close of the meeting if time permits.

Agenda items are subject to change as priorities dictate.

Contact Person for Additional Information: Henry M. Colvin, Assistant Director for Program Policy, Division of Laboratory Systems, Public Health Practice Program Office, CDC, 1600 Clifton Road, NE., Mailstop G–25, Atlanta, Georgia 30333, telephone 404/639–1706.

Dated: January 7, 1993.

Robert L. Foster,

Assistant Director, Office of Program Support, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–715 Filed 1–12–93; 8:45 am]

BILLING CODE 4160–18–M

Advisory Council for the Elimination of Tuberculosis; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Time and Dates: 8:30 a.m.–4:30 p.m., January 28, 1993. 8:30 a.m.–3:30 p.m., January 29, 1993.

Place: Lanier Plaza Conference Center, Executive II and III Conference Rooms, 418 Armour Drive, NE., Atlanta, Georgia 30324.

Status: Open to the public, limited only by the space available.

Purpose: This Council advises and makes recommendations to the Secretary, Department of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Discussed: The status of antituberculosis drug distribution by CDC, and antituberculosis drug costs; criteria for a model TB program; results of the National Survey of Physicians' Knowledge and Practices Concerning Tuberculosis, and the Ethnographic Studies of Five At-Risk Groups; limitations of population-based tuberculin skin test screening; new Guidelines for Preventing Tuberculosis Transmission; Tuberculosis in Jails; global TB control efforts; Recommendations for State TB Control Laws; and surveillance case definition for tuberculosis.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Dixie E. Snider, Jr., M.D., Associate Director for Science, and Executive Secretary, ACET, National Center for Prevention Services, CDC, 1600 Clifton Road, NE., Mailstop E–07, Atlanta, Georgia 30333, telephone 404/639–2776.

Dated: January 7, 1993.

Robert L. Foster,

Assistant Director, Office of Program Support, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–716 Filed 1–12–93; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

Temporary Deferment of Activities Relating to Biologics Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Document Control Center of the Center for Biologics Evaluation and Research (CBER) will be moving from various locations in Rockville and Bethesda, MD to the Woodmont Office Center in Rockville, MD in January, 1993. During the period required for relocation of the office, the agency will temporarily defer those submissions subject to CBER review and approval, and the review period, if any, on pending submissions will be suspended. FDA is also requesting that sponsors voluntarily refrain from filing submissions during this period.

FDA estimates that the deferment period will be about 3 weeks. FDA will publish a notice providing the new

address for submissions and identifying the exact period during which action on pending submissions was temporarily deferred.

FOR FURTHER INFORMATION CONTACT: Mark A. Elengold, Center for Biologics Evaluation and Research (HFM–11), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 301–295–9000.

SUPPLEMENTARY INFORMATION: CBER is responsible for many FDA activities implementing the Federal Food, Drug, and Cosmetic Act and section 351 of the Public Health Service Act (42 U.S.C. 262), including:

(1) Developing policy and procedures governing the premarket approval, review, and evaluation of biological products;

(2) Receiving, reviewing, evaluating, and taking appropriate action on investigational new drug applications (IND's) and investigational device exemption applications (IDE's) for certain products for which CBER has been assigned responsibility;

(3) Receiving, reviewing, evaluating, and taking appropriate action on product license applications (PLA's) and establishment license applications (ELA's) submitted for biological products;

(4) Receiving, reviewing, evaluating, and taking appropriate action on new drug applications (NDA's), premarket approval applications (PMA's), and premarket notifications (510k's) for which CBER has been assigned responsibility; and

(5) Receiving, reviewing, evaluating, and taking appropriate action on recommendations concerning denial, suspension, or revocation of PLA's and ELA's.

In an effort to consolidate CBER offices, FDA is moving various CBER offices from their present locations in Bethesda and Rockville, MD to the Woodmont Office Center in Rockville, MD. This move will occur in January, 1993. Because FDA will be moving staff, equipment, and files, CBER will be unable to start work or continue work on existing submissions and reports until its new offices are ready; therefore, FDA plans to temporarily defer action on those submissions subject to CBER review and approval, including IND's, PLA's, ELA's, NDA's, 510k's, PMA's, or IDE's. FDA is also requesting that sponsors voluntarily refrain from filing submissions during this period, which began on January 2, 1993, and will continue until January 22, 1993.

FDA anticipates that this period will be about 3 weeks or less. During this period, although FDA will continue to accept mail, it will not be officially logged in nor will review of submissions begin. Any review period will not begin until the relocation is completed and CBER review functions resume. CBER will attempt to keep the mail in the order of the day received. When work resumes, it will be done according to the order that it was received. Also, the review periods on pending submissions will be suspended during the relocation period. CBER will attempt to minimize the period during which regular procedures are suspended. Following the move, FDA will publish a notice providing the new address for submissions and identifying the exact period during which action on new and existing submissions was temporarily deferred.

Persons who may be affected by this temporary deferment should call the contact person listed above or CBER's Division of Congressional and Public Affairs at 301–295–9000 with any questions regarding CBER's move to the Woodmont Office Center. Questions regarding emergency IND's and waiver of the 30-day waiting period for IND's will be directed to appropriate staff.

Dated: January 7, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–740 Filed 1–12–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 84N–0241]

1992 Revision of the National Shellfish Sanitation Program Manual of Operations, Part I "Sanitation of Shellfish Growing Areas" and Part II "Sanitation of the Harvesting, Processing, and Distribution of Shellfish;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the 1992 revision of the National Shellfish Sanitation Program (NSSP) Manual of Operations, part I, "Sanitation of Shellfish Growing Areas" and part II, "Sanitation of the Harvesting, Processing, and Distribution of Shellfish." This project was initiated in cooperation with the Interstate Shellfish Sanitation Conference (ISSC) to help assure that only safe and sanitary shellfish are offered for sale in interstate commerce.

ADDRESSES: Submit written requests for single copies of the manual (free of charge) to the Food and Drug Administration, Shellfish Sanitation Branch (HFS–407), 200 C St. SW., Washington, DC 20204. Requests should be identified with the docket number found in brackets in the heading of this document. Send two self-addressed adhesive labels to assist that office in processing your requests. The manual is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: David M. Dressel, Office of Seafood, Center for Food Safety and Applied Nutrition (HFS–407), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–3971.

SUPPLEMENTARY INFORMATION: FDA is responsible for the Federal administration of the NSSP, which is a voluntary program involving State shellfish control agencies, the shellfish industry, FDA, and other Federal agencies. Six foreign countries also actively participate in the NSSP through international bilateral agreements.

The NSSP is concerned with the sanitary control of fresh and frozen molluscan shellfish (oysters, clams, mussels, and scallops) offered for sale in interstate commerce. The program has been in existence since 1925. In the interest of assuring uniform administrative and technical controls, the NSSP has developed and maintained recommended shellfish control practices. These control practices have been published in the form of a Manual of Operations, parts I and II.

In 1982, interested State officials and members of the shellfish industry formed the ISSC. The purpose of the ISSC is to provide a formal structure wherein State regulatory authorities can establish updated guidelines for improving shellfish sanitation and safety. The ISSC has established uniform procedures for developing and adopting new guidelines. Those persons interested in obtaining additional information about the ISSC should contact Kenneth Moore, Chairman, Interstate Shellfish Sanitation Conference, c/o South Carolina Department of Health and Environmental Control, 2600 Bull St., Columbia, SC 29202.

FDA and the ISSC entered into a memorandum of understanding (MOU) that was published in the Federal Register of March 30, 1984 (49 FR 12751). This agreement states, among other things, that FDA will provide technical assistance to the ISSC, including participating in the

cooperative efforts of the Conference, to develop or revise program criteria and guidelines.

Based on the MOU, FDA developed draft revisions of the NSSP Manual of Operations, parts I and II, in cooperation with the ISSC. FDA announced the availability of the 1986 revision of part I in the **Federal Register** of June 5, 1987 (52 FR 21375). The initial working draft of part II was made available for comment in the **Federal Register** of September 11, 1985 (50 FR 37055), with a revised second draft being made available for further comment on July 11, 1986 (51 FR 25261). Based on the comments received, and in consideration of the comments and views expressed on parts I and II by State regulatory officials, industry representatives, and other interested parties at the ISSC's 1987 and 1988 annual meetings in Austin, TX, and Denver, CO, respectively, FDA announced the availability of the 1988 revision of the completed Manual of Operations in the **Federal Register** of February 17, 1989 (54 FR 7281). Subsequent revisions were announced in the **Federal Register** of April 25, 1990 (55 FR 17503) and December 13, 1990 (55 FR 51341).

Continuing with this arrangement, FDA and ISSC are now announcing the availability of the 1992 revision of the NSSP Manual of Operations, part I, "Sanitation of Shellfish Growing Areas" and part II, "Sanitation of the Harvesting, Processing, and Distribution of Shellfish." The 1992 revision contains changes and improvements to the NSSP considered and passed at the 1991 and 1992 ISSC national meetings held in Fort Lauderdale, FL, and Schaumburg, IL.

The revised manual includes: (1) A completely new section devoted to aquaculture; (2) inclusion of scallops intended for consumption in the "whole animal" or "roe-on" product forms (scallop products consisting of only the adductor muscle are not covered by the NSSP); (3) guidelines that suggest increased frequency of data analysis by State officials who monitor and classify shellfish growing waters; and (4) new inspection criteria for use by State officials when certifying shellfish processors for listing in the Interstate Certified Shellfish Shippers List. Major topics include: General administrative and laboratory procedures; growing area surveys and classification; contingency plans for the control of marine biotoxins; and the accepted sanitary procedures for the harvesting, handling, shucking, and packing of shellfish.

Dated: January 6, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93-693 Filed 1-12-93; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

[Docket No. N-93-2059; FR-2697-N-06]

Correction to Address Information in Lead-Based Paint Guidelines

AGENCY: Office of Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice; correction.

SUMMARY: This document updates and corrects the address of a public agency in Hawaii that was incorrectly set out in an appendix to the Department's April 18, 1990 published Lead-Based Paint Interim Guidelines. It has recently come to HUD's attention that the telephone number listed for the Honolulu, Hawaii agency was that of a private individual.

FOR FURTHER INFORMATION CONTACT: Janice Rattley, Director, Office of Construction, Rehabilitation and Maintenance, Office of Public and Indian Housing, room 4138, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Telephone (202) 708-1800 (TDD: (202) 708-0850). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: On April 18, 1990, the Department published its Lead-Based Paint Hazard Identification and Abatement Guidelines (55 FR 14556).

Among other matters, the Guidelines contained a state-by-state listing of agencies conducting "Childhood Lead Poisoning Prevention Programs and Activities."

On page 14624 of the April 18, 1990 Guidelines, the listing for the State of Hawaii contained an incorrect telephone number. As a result of that publishing error, Hawaii resident's private number was carried as that of the agency, and this individual has received occasional telephone calls (including calls originating from the mainland from individuals not sensitive to the time zone difference experienced in Hawaii) intended for the agency.

The purpose of this document is to republish the name and telephone number of the appropriate Hawaiian state agency to be contacted on matters pertaining to childhood lead poisoning prevention activities:

That agency is: Children with Special Needs Branch, Department of Health, 741 Sunset Avenue, Honolulu, HI 96816, telephone (808) 733-9070, Alan Taniquchi, MD, Branch Chief.

Individuals and entities making use of HUD's Lead-Based Paint Guidelines are requested to take notice of this correction contained in the Published Guidelines.

Dated: January 7, 1993.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 93-713 Filed 1-12-93; 8:45 am]

BILLING CODE 4210-32-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-050-93-7122-03-X218; AZA-054-92-2]

Arizona; Temporary Closure of Selected Public Lands in La Paz County, Arizona, During the Operation of the 1993 SCORE Parker 400 Off-Road Vehicle Race

AGENCY: Bureau of Land Management (BLM).

ACTION: Notice of temporary closure of selected public lands.

SUMMARY: The District Manager of the Yuma District announces the temporary closure of selected public lands under the District's administration. This action is being taken to provide for public safety and to prevent unnecessary environmental degradation during the officially permitted running of the 1993 SCORE Parker 400 Off-Road Vehicle Race.

DATES: January 20, 1993, through January 24, 1993.

FOR FURTHER INFORMATION CONTACT: BLM Rangers Rob Smith or Mark Harris, or Outdoor Recreation Planner Myron McCoy, Havasu Resource Area, 3189 Sweetwater Avenue, Lake Havasu City, Arizona 86403, telephone (602) 855-8017.

SUPPLEMENTARY INFORMATION: Specific restrictions and closure periods are as follows:

Designated Course

1. The portion of the course comprised of BLM lands, roads, and ways south of the Bill Williams River, east and north of Highway 72, and west of Wenden Road is closed to public vehicle use from midnight (12 a.m.) Wednesday, January 20, 1993, to noon (12 p.m.) Sunday, January 24, 1993 (Mountain Standard Time).

2. Vehicles are prohibited from the following four Wilderness Areas and one Wilderness Study Area:

a. AZ–030–12 (Gibraltar Mountain Wilderness Area)
b. AZ–050–15A (Swansea Wilderness Area)
c. AZ–050–71 (Buckskin Mountains Wilderness Area)
d. AZ–050–17 (East Cactus Plain Wilderness Area)
e. AZ–050–14A/B (Cactus Plain Wilderness Study Area)

3. The entire area encompassed by the designated course and all areas within 1 mile outside of the designated course are closed to all vehicles except authorized and emergency vehicles. Access routes leading to the course are closed to vehicles. All closed routes will be posted throughout the closure period.

4. Spectator viewing is limited to two designated spectator areas:

a. South of Shea Road (approximately 6 miles east of Parker, Arizona).

b. Bouse Road, also known as Swansea Road (about 1½ miles north of Bouse, Arizona).

Camping is allowed only in the two designated spectator areas. Vehicle travel or parking outside these designated locations is prohibited. All vehicles operated within these two locations shall be legally registered for street and highway operation. No off-highway vehicle use is permitted in the race area. Spectators should not bring their off-highway vehicles to the race as this activity is prohibited.

5. Vehicle parking or stopping along Bouse Road, Shea Road, and Swansea Road is prohibited except at the two designated spectator areas.

6. All vehicles operated within designated pit areas shall be legally registered for street and highway operation.

7. Spectators are not permitted on the race course or in any wash located within the race course, including all of Osborne Wash.

8. Cutting or collection of firewood is prohibited within the closure.

Signs and maps directing the public to the designated spectator areas will be provided by the BLM and the event sponsor.

The above restrictions do not apply to emergency vehicles and vehicles owned by the United States, the State of Arizona, or La Paz County. Vehicles under permit for operation by event participants must follow the race permit stipulations. Operators of permitted vehicles shall maintain a maxium speed limit of 35 miles per hour on all La Paz County and BLM roads and ways. This speed limit shall not apply to vehicles entered in the race during race day, Saturday, January 23, 1993.

Authority for closure of public lands is found in title 43, Code of Federal Regulations, subparts 8340 and 8341; title 43, Code of Federal Regulations, subpart 8360 and subpart 8364, § 1; and title 43, Code of Federal Regulations, subpart 8372. Persons who violate this closure order are subject to arrest and, upon conviction, may be fined not more than $100,000 and/or imprisoned for not more than 12 months.

This notice is published under the authority of title 43, Code of Federal Regulations, subpart 8364.

Dated: January 7, 1993.

Bill D. Wattenberg,

Acting Yuma District Manager.

[FR Doc. 93–719 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–32–M

Farmington District Advisory Council; Establishment

AGENCY: Bureau of Land Management, Interior.

ACTION: Farmington District Advisory Council; notice of establishment.

SUMMARY: This notice is published in accordance with section 9(a)(2) of the Federal Advisory Committee Act of 1972, 5 U.S.C. Appendix. Notice is hereby given that the Secretary of the Interior is establishing the Bureau of Land Management's (BLM) Farmington District Advisory Council, in New Mexico. The purpose of the Council will be to advise the BLM Farmington District Manager on the various citizens' interests concerning the management and use of the public land resources located within the newly created BLM Farmington District. The Council is required by the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1739.

The Council will be composed of 10 members, who will be appointed by and serve at the pleasure of the Secretary of the Interior. The initial appointments will be for staggered terms as follows: Three members will be appointed for a 1-year term, three members will be appointed for a 2-year term, and four members will be appointed for a 3-year term. Subsequent member appointments will be for 3-year terms. Members' eligibility for reappointment for additional terms may be affected by rules established by the Department of the Interior.

Council members will advise the District Manager on programs and policies concerning management of the public lands within the Farmington District. As required by the Federal Advisory Committee Act, 5 U.S.C. Appendix, membership of the Council is to be balanced in terms of points of view and functions to be performed. To achieve this balance, members will be selected from among persons who are qualified through education, training, knowledge, or experience to provide informed advice concerning eight categories of interest: Elected Official of General Purpose Government; Environmental Protection; Non-Renewable Resources; Public-at-Large Recreation; Renewable Resources; Transportation/Rights-of-Way; and Wildlife.

FOR FURTHER INFORMATION CONTACT: Committee Management Officer, Department of the Interior, 1849 C Street NW., Washington, DC 20240, telephone (202) 208–6182.

Dated: December 31, 1992.

Manuel Lujan, Jr.,

Secretary of the Interior.

[FR Doc. 93–680 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–10–M

[UT–040–02–4830–01]

Cedar City District Advisory Council; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of meeting of the Cedar City District Advisory Council.

SUMMARY: Notice is hereby given in accordance with Public Law 92–463 of a meeting of the Cedar City District Advisory Council. Agenda items will include discussion about the Dixie and Escalante/Kanab Resource Management Plans, and an update of current district activities such as Warm Springs EIS, mining claims, North Creek Reservoir proposal, landfill closures, the Elk Plan, and desert tortoise activities.

DATES: February 16, 1993. The meeting will begin at 9:30 a.m. at the Cedar City District Office, 176 East D.L. Sargent Drive, Cedar City, Utah.

FOR FURTHER INFORMATION CONTACT: District Manager Gordon R. Staker, Cedar City District, 176 East D.L. Sargent Drive, Cedar City, Utah 84720. Telephone: 801–586–2401.

SUPPLEMENTARY INFORMATION: Advisory Council Meetings are open to the public. Interested persons may make oral statements or file written statements for the Council's consideration. Anyone wishing to make a statement notify the District Manager by Friday, February 12, 1993. A time limit may be established by the District Manager.

Dated: January 5, 1993.
Gordon R. Staker,
District Manager.
[FR Doc. 93–733 Filed 1–12–93; 8:45 am]
BILLING CODE 4310–DQ–M

[CA–010–4212–13, CACA 31259]

Realty Action; Exchange of Public Land in Amador, Calaveras and Sacramento Counties, CA

AGENCY: Bureau of Land Management, Department of the Interior.

SUMMARY: The following described public land (surface and mineral estate) is being considered for exchange under section 206 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1716):

Selected Public Land

Selected Public Land

Amador County

T. 5N., R. 10E., M.D.M.
Sec. 16: NW¼SW¼
Sec. 17: N½N½SE¼, N½S½NE¼SE¼
Sec. 32: NE¼SE¼
Sec. 33: NW¼SW¼, SW¼NW¼

Calaveras County

T. 2N., R. 13N., M.D.M.
Sec. 11: lot 14
T. 3N., R. 13E., M.D.M.
Sec. 32: lots 23, 24, 25, 26, 27 and 28
T. 6N., R. 14E. M.D.M.
Sec. 7: SW¼SE¼

Sacramento County

T. 8N., R. 8E., M.D.M.
Sec. 14: SW¼NE¼ excluding lot 1
Containing 270 acres, more or less.

The selected public land described above is hereby segregated from settlement, location and entry under the public land laws and from the mining laws for a period of two years from the date of publication of this notice in the **Federal Register**.

The above land is being considered for possible transfer to a nonprofit conservation organization. In exchange, the public would receive private land located on either the North Fork or South Fork of the American River or the Merced River, or marshlands and waterfowl habitat located in the California Central Valley. This proposal is considered to be in the public interest and is consistent with current land use plans.

SUPPLEMENTARY INFORMATION: The above described Federal land would be transferred subject to a reservation to the United States for ditches and canals; also any rights-of-way of record would be identified as prior existing rights.

All necessary clearances including clearances for archaeology, and rare plants and animals would be completed prior to any conveyance of title by the U.S.

FOR ADDITIONAL INFORMATION CONTACT: Contact Mike Kelley at (916) 985–4474 or at the address listed below.

ADDRESSES: For a period of 45 days from publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, c/o Area Manager, Folsom Resource Area, 63 Natoma Street, Folsom, CA 95630.

D.K. Swickard,
Area Manager.
[FR Doc. 93–736 Filed 1–12–93; 8:45 am]
BILLING CODE 4310–40–M

[ID–943–03–4210–04; IDI–26669]

Issuance of Land Exchange Conveyance Document; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Exchange of public and private lands.

SUMMARY: The United States has issued an exchange conveyance document to American Public Land Exchange Company, Inc. under section 206 of the Federal Land Policy and Management Act. The land acquired by the United States will remain closed to the public land, mining, and mineral leasing laws.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Sally Carpenter, BLM, Idaho State Office, 3380 Americana Terrace, Boise, Idaho, (208) 384–3163.

1. In an exchange made under the provisions of section 206 of the Act of October 21, 1976, 90 Stat. 2756, 43 U.S.C. 1716, the following described lands have been conveyed from the United States:

Boise Meridian

T. 4N., R. 18 E.,
Sec. 18, block 39, lot 7, and block 40, lots 6 to 8, inclusive, including vacated alley.
Comprising 0.52 acres of public land.

2. In exchange for these lands, the United States acquired the following described land:

Boise Meridian

T. 4 N., R. 17 E.,
Sec. 12, a subdivision of Tax Lot 4807 known as lot 2 of Industrial East Subdivision; excepting therefrom, the North 71 feet.
Comprising 1.48 acres of private land.

The purpose of the exchange was to acquire non-Federal land which has high public value for administrative site purposes. The public interest was well served through completion of the exchange. The values of the Federal and private lands were equal.

3. The land acquired by the United States will remain closed to the public land, mining, and mineral leasing laws.

Dated: January 4, 1993.
William E. Ireland, Chief,
Realty Operations Section.
[FR Doc. 93–681 Filed 1–12–93; 8:45 am]
BILLING CODE 4310–GG–M

[ID–010–03–4210–04; IDI–28361]

Exchange of Public and Private Lands; Elmore County, ID

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action IDI–28361; exchange of public and private lands in Elmore County, Idaho.

SUMMARY: The following described public lands have been determined to be suitable for disposal by exchange under Section 206 of the Federal Land Policy and Management Act of October 21, 1976 (43 U.S.C. 1716):

Boise Meridian, Idaho

T. 4 S., R. 3 E.
Sec. 31: Lots 1, 2, 3,
Sec. 32: NW¼SW¼.
Containing 156 acres, more or less.

In exchange for the above described public lands, BLM will acquire the following described private lands from Jean M. Smith:

Boise Meridian, Idaho

T. 5 S., R. 3 E.
Sec. 9: Lots 2 and 3.
Containing 51.55 acres, more or less.

The purpose of this exchange is to dispose of public lands that have, for a number of years, been operated for concentrated livestock management purposes under the authority of section 4 of the Taylor Grazing Act. These public lands possess very little public resource value, are difficult and uneconomic to manage, and would better be managed in private ownership. The public lands will be exchanged for private lands lying within the boundaries of the Trueblood Wildlife Management Area that contain important raptor and raptor prey habitat, important waterfowl and upland game habitat, important recreation values, and riparian habitat along over a ½ mile stretch of the Snake River. The public interest will be well served by the completion of this exchange, as the consummation thereof will fulfill the Secretary's Fish and Wildlife 2000, Recreation 2000, and riparian management initiatives. The

exchange will be consummated on an equal value basis. An appraisal has shown the lands to be of equal value.

DATES: For a period of 45 days from the date of publication of this notice in the Federal Register, interested parties may submit comments to the District Manager, Bureau of Land Management, Boise District, 3948 Development Avenue, Boise, Idaho 83750. Objections to this proposal will be reviewed by the State Director, who may sustain, modify, or vacate this realty action. In the absence of any adverse comments, this realty action will become the final determination of the Department of the Interior.

FOR FURTHER INFORMATION CONTACT: John Sullivan, Bruneau Resource Area Realty Specialist at (208) 384–3338. The Environmental Assessment is available for review at the above address.

SUPPLEMENTARY INFORMATION: Publication of this notice in the Federal Register segregates the public lands from operation of the public land laws, except the exchange provisions of the Federal Land Policy and Management Act, and the mining laws, but not the mineral leasing laws. The segregative effect will end upon issuance of patent or two (2) years from the date of publication, whichever occurs first.

Lands to be transferred from the United States will be subject to the following reservations, terms, and conditions:

Excepting and Reserving to the United States: 1. A right-of-way thereon for ditches or canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).

Subject To: 2. Those rights for electric powerline line purposes granted to Idaho Power Company, its successors or assigns, by Right-of-Way No. BL–054697, under the Act of March 4, 1911 (43 U.S.C. 961).

3. Those rights for irrigation canal purposes granted to the Snake River Irrigation District, its successors or assigns, by Right-of-Way No. IDI–03816, under the Act of March 3, 1891 (43 U.S.C. 946–951) as amended.

4. Those rights for buried telephone cable purposes granted to Gem State Utilities Corporation, its successors or assigns, by Right-of-Way No. IDI–16430, under the Act of October 21, 1976 (43 U.S.C. 1761).

Dated: January 4, 1993.

J. David Brunner,

District Manager.

[FR Doc. 93–662 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–GG–M

[CO–942–02–4730–12]

Colorado; Filing of Plats of Survey

December 18, 1992.

The plats of survey of the following described land, will be officially filed in the Colorado State Office, Bureau of Land Management, Lakewood, Colorado, effective 10 a.m., December 18, 1992.

The plat (in three sheets) representing the dependent resurvey of portions of the Twelfth Auxiliary Guide Meridian West (east boundary), south and north boundaries, subdivisional lines, and certain claim lines, and the subdivision of certain sections, T. 2 N., R. 101 W., Sixth Principal Meridian, Colorado, Group No. 851, was accepted October 20, 1992.

The plat (in four sheets) representing the dependent resurvey of the north boundary, portions of the subdivisional lines, and certain claim lines, and the subdivision of certain sections, T. 2 N., R. 100 W., Sixth Principal Meridian, Colorado, Group No. 851, was accepted November 23, 1992.

The plat representing the dependent resurvey of a portion of certain mineral claims in section 23, T. 3 S., R. 73 W., Sixth Principal Meridian, Colorado, Group No. 1002, was accepted November 17, 1992.

These surveys were executed to meet certain administrative needs of this Bureau.

The plat representing the dependent resurvey of a portion of the Eleventh Standard Parallel North (south boundary, T. 45 N., R. 13 W.), portions of the south and west boundaries, and the subdivisional lines, the subdivision of certain sections, and the remonumentation of certain original corners, T. 44 N., R. 13 W., New Mexico Principal Meridian, Colorado, Group Nos. 449 and 937, was accepted October 29, 1992.

The plat (in two sheets) representing the dependent resurvey of portions of the subdivisional lines and Mineral Survey Numbers 20734 and 20797, and the survey of the east and west center line of section 18, T. 11 N., R. 79 W., Sixth Principal Meridian, Colorado, Group No. 870, was accepted November 23, 1992.

The plan representing the dependent resurvey of a portion of the Colorado-Wyoming State Boundary from the 113th to the 115th mile post and a portion of the subdivisional lines, and the subdivision of section 23 and 26 of Fractional T. 12 N., R. 79 W., Sixth Principal Meridian, Colorado, Group No. 870, was accepted November 23, 1992.

The plat representing the dependent resurvey of a portion of the subdivisional lines and the subdivision of sections 16 and 17, T. 8 S., R. 74 W., Sixth Principal Meridian, Colorado, Group No. 940, was accepted November 13, 1992.

The plat representing the dependent resurvey of portions of the Base Line (south boundary), subdivisional lines, and certain tracts, and the subdivision of section 26, T. 1 N., R. 82 W., Sixth Principal Meridian, Colorado, Group No. 951, was accepted November 13, 1992.

These surveys were executed to meet certain administrative needs of the U.S. Forest Service.

The plat representing the dependent resurvey of portions of the south and east boundaries, subdivisional lines, and the subdivision of certain sections, T. 34 N., R. 10 W. (South of the Ute Line), New Mexico Principal Meridian, Colorado, Group No. 993, was accepted December 1, 1992.

This survey was executed to meet certain administrative needs of the Bureau of Indian Affairs.

The plat (in two sheets) representing the dependent resurvey of portions of the Ute Base Line (south boundary, T. 1 N., R. 2 W., Ute Meridian), the subdivisional lines, and the Colorado National Monument Boundary, the subdivision of sections 21 and 27, and the metes-and-bounds survey of National Park Service Land in sections 17, 21, and 27, Fractional T. 11 S., R. 101 W., Sixth Principal Meridian, Colorado, Group No. 987, was accepted November 13, 1992.

This survey was executed to meet certain administrative needs of the National Park Service.

All inquiries about this land should be sent to the Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado, 80215.

Homer L. Gilson,

Acting Chief, Cadastral Surveyor for Colorado.

[FR Doc. 93–739 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–JB–M

[ID–943–4210–06; IDI–14542]

Proposed Continuation of Withdrawal; Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management proposes that a 2769.39 acre withdrawal for Powersite

Classification No. 435, continue for an additional twenty years. The land is still needed for waterpower purposes. These lands will remain closed to surface entry, but have been and will remain open to mineral leasing and mining.

EFFECTIVE DATE: Comments should be received within 90 days of the date of publication of this notice.

FOR FURTHER INFORMATION CONTACT: Larry R. Lievsay, Idaho State Office, BLM, 3380 Americana Terrace, Boise, Idaho 83706, (208) 384–3166.

The Bureau of Land Management proposes that the existing land withdrawal made by the U.S. Geological Survey Order dated August 16, 1955, be continued for a period of 20 years pursuant to Section 204 of the Federal Land Policy and Management Act of 1976, 90 Stat. 2751; 43 U.S.C. 1714, insofar as it affects the following described land:

Boise Meridian

T. 1 S., R. 2 W.,
Sec. 25, N½SW¼ and SW¼SE¼;
Sec. 28, lots 6 and 7;
Sec. 33, NE¼NE¼;
Sec. 34, SE¼NE¼ and NW¼NW¼.
T. 2 S., R. 1 E.,
Sec. 18, NW¼NE¼.
T. 3 S., R. 1 E.,
Sec. 34, E½NE¼.
T. 3 S., R. 2 E.,
Sec. 31, lots 2, 3 and 6.
T. 4 S., R. 2 E.,
Sec. 4, S½SW¼;
Sec. 5, lots 4 and 8 and SE¼SE¼;
Sec. 6, lots 2, 5 and 8;
Sec. 8, lots 1, 2 and 4;
Sec. 9, lots 1 to 8 inclusive;
Sec. 10, lots 3, 4, 7 and 8;
Sec. 28, lot 5.
T. 4 S., R. 3 E.,
Sec. 31, SE¼NE¼.
T. 5 S., R. 3 E.,
Sec. 9, lots 1 and 4.
T. 5 S., R. 8 E.,
Sec. 32, lot 1;
Sec. 33, lot 1 and SE¼SW¼.
T. 6 S., R. 8 E.,
Sec. 1, lots 10 and 11;
Sec. 2, lot 7;
Sec. 4, lots 4, 5, 8 and 9;
Sec. 5, lot 1;
Sec. 14 NW¼.
T. 5 S., R. 9 E.,
Sec. 26, lots 2 to 4 inclusive; sec. 27, NE¼SE¼;
Sec. 31, SE¼NW¼;
Sec. 32, lot 6;
Sec. 33, lots 2 to 8 inclusive;
Sec. 34, lots 3 and 4.
T. 5 S., R. 10 E.,
Sec. 21, lots 2 and 3;
Sec. 22, lot 10.
T. 6 S., R. 10 E.,
Sec. 6, lots 1 and 2.

The areas described aggregate 2769.39 acres in Ada, Elmore and Owyhee Counties.

The withdrawal is essential for protection of potential waterpower development. The existing withdrawal closes the described land to surface entry but not to mineral leasing and mining. No change in the segregative effect or use of the land is proposed by this action.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments in connection with the proposed withdrawal continuation may present their views in writing to the Idaho State Director at the above address.

The authorized officer of the Bureau of Land Management will undertake such investigations as necessary to determine the existing and potential demand for the land and its resources. A report will also be prepared for consideration by the Secretary of the Interior, the President and Congress, who will determine whether or not the withdrawal will be continued; and if so, for how long. The final determination of the withdrawal will be published in the **Federal Register**. The existing withdrawal will continue until such determination is made.

Dated: January 5, 1993.

William E. Ireland,

Chief, Realty Operations Section.

[FR Doc. 93–684 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–84–M

Bureau of Reclamation

River Maintenance Program for the Rio Grande, NM

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability of draft supplement to the final environmental impact statement (Draft Supplement): DES–93–02.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, the Bureau of Reclamation (Reclamation) has prepared a draft supplement to the 1977 final environmental impact statement on a reformulated river maintenance program within the Rio Grande floodway. The proposed maintenance program consists of 6 broadbased alternatives for river channel maintenance, based on 10 distinctive morphological reaches of the Rio Grande.

DATES: A 60-day public review period begins with the publication of this notice. Written comments on the Draft Supplement may be submitted within the 60-day review period (by March 15, 1993) to the Regional Director or Projects Manager at the addresses below.

ADDRESSES: Single copies of the Draft Supplement may be requested from Reclamation's offices at the addresses below.

Copies of the Draft Supplement are available for inspection at the following locations:

Regional Director, Bureau of Reclamation, Attention: UC–700, Federal Building, 125 South State Street, Salt Lake City UT 84138; telephone: (801) 524–5517.
Bureau of Reclamation, Denver Office Library, Denver Federal Center, 6th and Kipling, Building 67, room 167, Denver CO 80225; telephone: (303) 236–6963
Projects Manager, Bureau of Reclamation, Attention: ALB–150, 505 Marquette NW, Suite 1313, Albuquerque NM 87102–2162; telephone: (505) 766–1753
Bureau of Reclamation, Technical Liaison Division, U.S. Department of the Interior, 1849 C Streets NW., Washington DC 20240; telephone: (202) 343–4662
Middle Rio Grande Conservancy District, 193 Second Street SW., Albuquerque NM 87130; telephone: (505) 247–0234

Libraries

Albuquerque city libraries:
Main Library, 501 Copper Avenue NW.
Erna Ferguson, 3700 San Mateo Boulevard NE.
Ernie Pyle, 900 Girard Boulevard SE.
Esperanza, 5600 Esperanza Drive NW.
Juan Tabo, 3407 Juan Tabo Boulevard NE.
Lomas and Tramway, 908 Eastridge Drive NE.
Los Griegos, 1000 Griegos Road NW.
San Pedro, 5600 Trumbull Avenue SE.
South Valley, Bernalillo County, 3908 Isleta Boulevard SW.
Taylor Ranch, 5700 Bogart Street NW.
University of New Mexico Library, Albuquerque, New Mexico
New Mexico State University, Las Cruces, New Mexico

FOR FURTHER INFORMATION CONTACT: Mr. William E. Burleigh (Activity Manager, Albuquerque Projects Office), telephone: (505) 766–2518.

SUPPLEMENTARY INFORMATION: Under the reformulated river maintenance program, river channel maintenance will be designed and constructed based on the hydrologic characteristics of the Rio Grande and take into account the environmental values associated with each reach. Future mitigation measures will be addressed on a site-specific basis based on "best management practices."

Dated: December 10, 1992.

Kathy E. Gerdon,

Deputy Assistant Commissioner Administration.

[FR Doc. 93–782 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–00–M

National Park Service

National Register of Historic Places; NHL Boundaries

January 4, 1993.

The National Park Service has been working to establish boundaries for all National Historic Landmarks for which no specific boundary was identified at the time of designation and therefore are without a clear delineation of the amount of property involved. The results of such designation make it important that we define specific boundaries for each landmark.

In accordance with the National Historic Landmark program regulations 36 CFR part 65, the National Park Service notifies owners, public officials and other interested parties and provides them with an opportunity to make comments on the proposed boundaries.

The 60-day comment period on the attached National Historic Landmark has ended, and the boundaries have been established. Copies of the documentation of the landmark and its boundaries, including maps, may be obtained from Jerry L. Rogers, Associate Director, Cultural Resources, and Keeper of the National Register of Historic Places, National Park Service, P.O. Box 37127, Washington, DC 20013–7127, Attention: Chief of Registration (Phone: 202–343–9536).

Carol D. Shull,

Chief of Registration, National Register of Historic Places, Interagency Resources Division.

Boundaries established for: Chilkoot Trail and Dyea National Historic Landmark, Taiya River Valley, Alaska; designated a Landmark on June 16, 1978.

Beginning at Bench Mark "Lame" in T28S R59E, Cooper River Meridian (CRM), thence in a northerly direction along a line one-half mile east of the center of the Taiya River to a point on the U.S. Canadian Border one-half mile southeast of Monument 120 in T25S, R60E, CRM, thence northwest along the U.S.-Canadian border for a distance of one mile, thence in a southerly direction along a line one-half mile west of the center of the Taiya River to a point due west of Bench Mark "Lame," thence due east to Bench Mark "Lame." Where the Taiya River has more than one channel running side-by-side, the "center" of the river is the center of the easternmost channel for purposes of the eastern boundary line of this description and the "center" of the river is the center of the westernmost channel for purposes of the western boundary line of this description.

[FR Doc. 93–724 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–70–M

Little Bighorn National Monument Advisory Committee

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice.

SUMMARY: The Secretary of the Interior is soliciting nominations to serve on the Little Bighorn National Monument Advisory Committee. Pursuant to Public Law 102–201, the purpose of the Committee is to advise the Secretary on matters pertaining to a memorial honoring the Indian participants at the Battle of the Little Bighorn.

DATES: All nominations should be submitted on or before February 12, 1993.

ADDRESSES: Nominations should be sent to: Victoria E. Barrios, Director, Boards and Commissions, U.S. Department of the Interior, 18th and C Streets, NW., Washington, DC 20240. All nominations should be accompanied by complete biographical and professional information, and include home and business addresses and telephone numbers.

FOR FURTHER INFORMATION CONTACT: Bernard Fagan, National Park Service, U.S. Department of the Interior, 18th and C Streets, Washington, DC. A copy of the charter for this Committee is available upon request.

SUPPLEMENTARY INFORMATION: Pursuant to Public Law 102–201, the Secretary of the Interior will design, construct, and maintain a memorial at the Little Bighorn Battlefield National Monument to honor the Indian participants in the battle. Also pursuant to Public Law 102–201, the Secretary has established the Little Bighorn Battlefield National Monument Advisory Committee. The purpose of the Committee is to provide advice to the Secretary to ensure that the memorial is appropriate to the Monument, its resources and landscape; sensitive to the history being portrayed; and artistically commendable. Also, the Secretary will consult with the Committee on the selection of the site for the memorial and on a national design competition to select the design of the memorial.

Public Law 102–201 stipulates that the Committee shall be composed of 11 members appointed by the Secretary: 6 individuals representing Native American tribes who participated in the Battle of the Little Bighorn or who now reside in the area, 2 individuals who are nationally recognized artists, and 3 individuals knowledgeable in history, historic preservation, and landscape architecture. Through this notice, the Secretary is soliciting nominations for any of the appointments from interested organizations or individuals.

Manuel Lujan, Jr.,

Secretary of the Interior.

[FR Doc. 93–747 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–70–M

Grand Canyon National Park; Colorado River Running Services

SUMMARY: The National Park Service is seeking parties interested in applying for contracts to operate river running services for park visitors on the Colorado River within Grand Canyon National Park. Existing contracts are expiring. Eighteen separate contracts are to be awarded.

SUPPLEMENTAL INFORMATION: It is expected that within sixty (60) days the National Park Service will issue a Prospectus describing the terms and conditions that will apply to applicants for the above contracts. Parties interested in making such applications should contact Ms. Teresa Jackson, Division of Concession Program Management, Western Regional Office, (415) 744–3981 (fax telephone number (415) 744–3951) to place themselves on the mailing list for the Prospectus.

Dated: November 23, 1992.

Lewis Albert,

Acting Regional Director, Western Region.

[FR Doc. 93–746 Filed 1–12–93; 8:45 am]

BILLING CODE 4310–70–M

INTERNATIONAL TRADE COMMISSION

Certain Cutting Tools for Flexible Plastic Conduit and Components Thereof; Notice of Designation of Additional Commission Investigative Attorney

[Investigation No. 337–TA–344]

Notice is hereby given that, as of this date, Alesia M. Woodworth, Esq. and Gabrielle Siman, Esq. of the Office of Unfair Import Investigations are designated as the Commission investigative attorneys in the above-

cited investigation instead of Gabrielle Siman, Esq.

The Secretary is requested to publish this Notice in the Federal Register.

Dated: January 6, 1993.

Lynn I. Levine,

Director, Office of Unfair Import Investigations.

[FR Doc. 93–753 Filed 1–12–93; 8:45 am]

BILLING CODE 7020–02–M

[Investigations Nos. 701–TA–314 through 317 (Final) and Investigations Nos. 731–TA–552 through 555 (Final)]

Certain Hot-Rolled Lead and Bismuth Carbon Steel Products From Brazil, France, Germany, and the United Kingdom

AGENCY: United States International Trade Commission.

ACTION: Revised schedule for the subject investigations.

EFFECTIVE DATE: December 30, 1992.

FOR FURTHER INFORMATION CONTACT: Jim McClure (202–205–3191), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION: On November 2, 1992, and November 13, 1992, respectively, the Commission instituted the subject investigations and established a schedule for their conduct (57 FR 54607, Nov. 19, 1992 and 57 FR 58220, Dec. 9, 1992). Subsequently, on December 28, 1992, the Department of Commerce advised the Commission it was extending the date for its final determinations in the investigations concerning France, Germany, and the United Kingdom from January 11, 1993 to January 19, 1993.[1] The Commission, therefore, is revising its schedule in the investigations to conform with Commerce's new schedule.

The Commission's new schedule for the investigations is as follows: requests to appear at the hearing must be filed with the Secretary to the Commission not later than January 19, 1993; the prehearing conference will be held at the U.S. International Trade Commission Building at 9:30 a.m. on January 22, 1993; the prehearing staff report will be placed in the nonpublic record on January 15, 1993; the deadline for filing prehearing briefs is January 26, 1993; the hearing will be held at the U.S. International Trade Commission Building at 9:30 a.m. on February 2, 1993; and the deadline for filing posthearing briefs is February 10, 1993.

For further information concerning these investigations see the Commission's notice of investigation cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: These investigations are being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.20 of the Commission's rules.

Issued: January 7, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–756 Filed 1–12–93; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–337]

Certain Integrated Circuit Telecommunication Chips and Products Containing Same, Including Dialing Apparatus; Notice of Commission Determination Not To Review an Initial Determination Finding a Respondent in Default

AGENCY: U.S. International Trade Commission

ACTION: Notice

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's initial determination (ID) in the above-captioned investigation finding respondent Kingtel Telecommunication Corp. ("Kingtel") in default, and that Kingtel has thereby waived its right to appear, to be served with documents, and to contest the allegations in issue in this investigation.

FOR FURTHER INFORMATION CONTACT: Matthew T. Bailey, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–205–3108.

SUPPLEMENTARY INFORMATION: On September 22, 1992, the presiding administrative law judge (ALJ) issued an order (Order No. 70) giving Kingtel until October 1, 1992, to show cause why it should not be found to be in default. Kingtel failed to respond to that order. On December 10, 1992, the ALJ issued an ID finding Kingtel to be in default and to have waived its right to appear, to be served with documents, and to contest the allegations in issue in this investigation.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, and § 210.53 of the Commission's Interim Rules of Practice and Procedure, 19 CFR 210.53.

Copies of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–3000. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

Issued: January 7, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–755 Filed 1–12–93; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–341]

Certain Static Random Access Memories, Components Thereof, and Products Containing Same; Commission Determination not to Review an Initial Determination Finding a Respondent in Default

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (ALJ's) initial determination (ID) in the above-captioned investigation finding respondent Micro-Comp Industries ("Micro-Comp") in default, and that Micro-Comp has thereby waived its right to appear and to contest the allegations in issue in the investigation.

FOR FURTHER INFORMATION CONTACT: Matthew T. Bailey, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–205–3108.

SUPPLEMENTARY INFORMATION: On November 19, 1992, the ALJ issued an order (Order No. 1) giving Micro-Comp until December 1, 1992, to show cause why it should not be held in default. Micro-Comp did not respond to that order. On December 3, 1992, the ALJ

[1] Commerce is scheduled to make its final determinations in the investigations concerning Brazil by January 25, 1993.

issued an ID (Order No. 3) finding Micro-Comp in default. In doing so, the ALJ found that Micro-Comp had waived its right to appear and to contest the allegations at issue in the investigation.

This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, and § 210.53 of the Commission's Interim Rules of Practices and Procedure, 19 CFR 210.53.

Copies of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–205–3000. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

Issued: January 6, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–754 Filed 1–12–93; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32207]

Albany Bridge Co., Inc.; Acquisition and Operation Exemption, South Carolina Central Railroad Co., Inc., d/b/a/ Georgia Great Southern Division

Albany Bridge Company, Inc. (ABC), A non-carrier, has filed a verified notice under 49 CFR part 1150 subpart D—Exempt Transactions to acquire and operate a railroad bridge and related track from South Carolina Central Railroad Company, Inc., d/b/a/ Georgia Great Southern Division (GGS). The railroad bridge (about 3470 feet in length) and related track are located between the point of switch at track chaining station 5473+20 and track chaining station 543+50 of GGS' mainline track in Albany, Dougherty County, GA. These rail properties are currently used by GGS to enter the rail yard of Gulf and Ohio Railways, Inc., d/b/a/ Atlantic & Gulf Railroad (A&GA), to interchange with A&GR. The exemption became effective December 22, 1992, and the parties expect to consummate the transaction on or after that date.[1]

As part of the agreement between the parties, GGS will retain a perpetual right to use the property to continue interchanging traffic with A&GR. In addition, CSX Transportation, Inc., currently has trackage rights over the GGS segment to be acquired by ABC. GGS will assign the trackage rights agreement to ABC when the transaction is consummated.

This proceeding is related to Finance Docket No. 32208, H. Peter Claussen and Linda C. Claussen—Continuance in Control Exemption—Albany Bridge Company, Inc., wherein H. Peter Claussen and Linda C. Claussen, noncarrier individuals, concurrently have filed a petition for exemption to continue to control ABC and three other rail carriers on ABC's becoming a carrier.[2]

Also concurrently filed, in Finance Docket No. 32222, Gulf and Ohio Railways d/b/a/ Atlantic & Gulf Railroad—Operation Exemption—Albany Bridge Company, Inc., is a verified notice wherein A&GR seeks an exemption to operate the involved rail properties on behalf of ABC.[3] ABC will retain a residual common carrier obligation to provide service over the line.

Any comments must be filed with the Commission and served on Adam M. Mycyk, Weiner, Brodsky, Sidman & Kider, P.C., Suite 800, 1350 New York Avenue, NW., Washington, DC 20005–4797.

If the verified notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the exemption's effectiveness.

Decided: January 7, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–734 Filed 1–12–93; 8:45 am]

BILLING CODE 7035-01-M

[1] The parties indicate in the verified notice that they expect to consummate the transaction "on or about" December 22, 1992. Since it is unclear what is meant by "about", the parties are reminded that consummation may not occur before the exemption's effective date.

[2] The Claussens now control through stock ownership three other rail common carriers: Gulf and Ohio Railways; Wiregrass Central Railroad Company; and H & S Railroad Company. Although the Claussens will own all of the outstanding stock of ABC, they have placed this stock in an irrevocable voting trust with an independent voting trustee pending Commission action on the petition filed in Finance Docket No. 32208.

[3] Commission action in the operation exemption proceeding will be deferred until the Commission acts on the continuance in control petition in Finance Docket No. 32208.

[Finance Docket No. 32228]

The Atchison, Topeka and Santa Fe Railway Co.; Trackage Rights Exemption; Trinidad Railway, Inc.

Trinidad Railway, Inc., has agreed to grant trackage rights to The Atchison, Topeka and Santa Fe Railway Company over approximately 29.6 miles of rail line between milepost 0.0 at Jansen, CO, and milepost 29.6 at Stonewall, CO. The trackage rights were to become effective on December 30, 1992.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Michael A. Smith, The Atchison, Topeka and Santa Fe Railway Company, 1700 E. Golf Road, Schaumburg, IL 60173.

As a condition to the use of this exemption, any employees affected by the trackage rights will be protected pursuant to Norfolk and Western Ry. Co.—Trackage Rights—BN, 354 I.C.C. 605 (1978), as modified in Mendocino Coast Ry., Inc.—Lease and Operate, 360 I.C.C. 653 (1980).

Dated: January 7, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–731 Filed 1–12–93; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 32210]

Exemption; Grand Truck Corp.; Continuance in Control; Grand Trunk Western Railroad, Inc.

Grand Trunk Corporation (GT), has filed a verified notice of exemption for continuance in control of Grand Trunk Western Railroad, Inc. (GTW II), upon GTW II's becoming a carrier.

GTW II, a noncarrier, has filed concurrently a verified notice of exemption in Finance Docket No. 32209, Grand Trunk Western Railroad, Inc.—Acquisition Exemption—Grand Trunk Western Railroad Company, to acquire all of Grand Trunk Western Railroad Company's (GTW I) property, assets and liabilities with the exception of GTW's 100 percent ownership interest in Domestic Three Leasing Corp. and its stock interest in Belt Railway Company of Chicago. GTW II will assume all obligations and agreements to which GTW I is currently a party. The parties planned to

consummate the transaction on or about December 31, 1992.

GTW I and GTW II are wholly owned by GT which in turn is owned by the Canadian National Railway Company (CN). CN also owns St. Clair Tunnel Company. These transactions are among a series of transactions relating to the relocation of an existing railroad tunnel under the St. Clair River, between Sarnia, Ontario and Port Houron, MI.[1] According to GT, GTW II's acquisition of GTW I's operating assets and liabilities is intended to help facilitate the financing of the tunnel.

This is a transaction within a corporate family of the type specifically exempted from prior approval under 49 CFR 1180.2(d)(3). The parties indicate that the continuance in control by GT of GTW II will not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family.

As a condition to the use of this exemption, any employees affected by the transaction will be protected by the conditions set forth in New York Dock Ry.—Control—Brooklyn Eastern Dist., 360 I.C.C. 60 (1979).

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Pleadings must be filed with the Commission and served on: Charles A. Spitulnik, Hopkins & Sutter, 888 16th Street, NW., suite 700, Washington, DC 20006.

Decided: January 6, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–737 Filed 1–12–93; 8:45 am]

BILLING CODE 7035–01–M

[1] Notices of exemption were served on August 4, 1992, in: Finance Docket No. 32115, Grand Trunk Western Railroad Company—Trackage Rights Exemption—St. Clair Tunnel Company; Finance Docket No. 32116, St. Chair Tunnel Company—Acquisition Exemption—Grand Trunk Western Railroad Company; and Finance Docket No. 32117, Canadian National Railway Company—Continuance in Control Exemption—St. Clair Tunnel Company. Notices of exemption were served on December 10, 1992, in: Finance Docket No. 32196, St. Clair Tunnel Company—Acquisition Exemption—Canadian National Railway Company; and Finance Docket No. 32197, Canadian National Railway Company—Trackage Rights Exemption—St. Clair Tunnel Company.

[Finance Docket No. 32209]

Grand Trunk Western Railroad, Inc.; Acquisition Exemption; Grand Trunk Western Railroad Co.

Grand Trunk Western Railroad, Inc. (GTW II), a noncarrier, has filed a notice of exemption: (1) To acquire approximately 834 miles of rail line owned by the Grand Trunk Western Railroad Company (GWT I) in the States of Michigan, Ohio, and Indiana;[1] and (2) to acquire approximately 40 miles of incidental trackage rights over four rail lines in the States of Michigan, Ohio, and Indiana. Additionally, GTW II will acquire all of GTW I's property, assets and liabilities except GTW I's 100 percent ownership interest in Domestic Three Leasing Corp. and its stock interest in Belt Railway Company of Chicago. GTW II will also acquire all obligations and agreements to which GTW I is currently a party.

The rail line being acquired consists of 14 subdivisions described as follows:

(1) *South Bend Subdivision* between milepost 4.90 in Chicago, IL, and milepost 178.6 in Battle Creek, MI;

(2) *Flint Subdivision* between milepost 178.6 in Battle Creek, MI, and milepost 335.9 in Port Huron, MI, and *Flint Subdivision* (old main line) between milepost 272.3 and milepost 273.8, and between milepost 269.98 and milepost 263.73, all in Flint, MI;

(3) *Kalamazoo Subdivision* between milepost 0.00 in Pavilion Township, MI, and milepost 9.22 in Kalamazoo, MI;

(4) *Holly Subdivision* between milepost 0.3 in Detroit, MI, and milepost 67.0 in Durand, MI, and *Holly Subdivision* (Pontiac Belt Line) between milepost 0.0, and milepost 2.5 in Pontiac, MI;

(5) *Grand Rapids Subdivision* between milepost 67.0 and milepost 69.17 in Durand, MI;

(6) *Shoreline Subdivision* between milepost 0.0 in Toledo, OH, and milepost 54.8 in Detroit, MI;

(7) *Mount Clemens Subdivision* between milepost 4.6 in Detroit, MI, and milepost 59.89 in Port Huron, MI;

(8) *Romeo Subdivision* between milepost 38.5 in Pontiac, MI, and milepost 0.0 in Richmond, MI;

(9) *Jackson Subdivision* between milepost 35.3 and milepost 38.4 in Pontiac, MI;

(10) *Cass City Subdivision* between milepost 0.0 in Pontiac, MI, and milepost 8.01 in Orion Township, MI;

(11) *Dearborn Subdivision* between milepost 0.0 in Flat Rock, MI, and milepost 13.64 in Dearborn, MI;

(12) *River Subdivision* between milepost 1.7 in Ecorse, MI, and milepost 17.2 in Flat Rock, MI;

(13) *Flat Rock Subdivision* between milepost 17.2 in Flat Rock, MI, and milepost 200.50 in Springfield, OH; and

(14) *Springfield Subdivision* between milepost 200.50 and milepost 202.70 in Springfield, OH.

The incidental trackage rights that GW II will acquire as part of the transaction will be over the following lines:

(1) Consolidated Rail Corporation's line between milepost 99.60 and milepost 100.94 in South Bend, IN;

(2) Norfolk Southern's line between milepost 46.8 and milepost 50.2 in Detroit, MI;

(3) St. Clair Tunnel Company's line between milepost 40.5 in Richmond, MI, and milepost 55.6 in Port Huron, MI; and

(4) CSX Transportation, Inc.'s line between milepost 107.3 in Leipsic, OH, and milepost 128.3 in Lima, OH.

The parties planned to consummate the transaction on or about December 31, 1992. Upon consummation of the transaction, GTW II will become a class I carrier.

This transaction is related to a notice of exemption filed concurrently in Finance Docket No. 32210, Grand Truck Corporation—Continuance in Control Exemption—Grand Truck Western Railroad, Inc., for GT's continuance in control of GTW II when GTW II becomes a carrier upon consummation of the transaction described in this notice. These transactions are also related to a series of transactions involving the relocation of the existing railroad tunnel which crosses under the St. Clair River between Sarnia, Ontario and Port Huron, MI.[2]

[1] GTW I and GTW II are wholly owned subsidiaries of Grand Trunk Corporation (GT) which in turn is owned by the Canadian National Railway Company (CN). CN also owns the St. Clair Tunnel Company.

[2] Notice of exemption were published in the Federal Register and served on August 4, 1992, in: Finance Docket No. 32115, Grand Truck Western Railroad Company—Trackage Rights Exemption—St. Clair Tunnel Company, for GTW I's acquisition of trackage rights from St. Clair Tunnel Company (SCTC) over 16.4 miles of rail line between Port Huron, MI and Richmond, MI; Finance Docket No. 32116, St. Clair Tunnel Company—Acquisition Exemption—Grand Trunk Western Railroad Company, for SCTC's acquisition of the 16.4 miles of rail lines set forth above from GTW I; and Finance Docket No. 32117, Canadian National Railway—Continuance in Control Exemption—St. Clair Tunnel Company, for CN's continuance in control of SCTC upon SCTC becoming a carrier. Additionally, notices of exemption were published in the Federal Register and served on December 10, 1992, in: Finance Docket No. 32196, St. Clair Tunnel Company—Acquisition Exemption—Canadian National Railway Company, for SCTC's acquisition of CN's St. Clair Subdivision; and

Continued

Any comments must be filed with the Commission and served on: Charles A. Spitulnik, Hopkins & Sutter, 888 16th Street, NW., suite 700, Washington, DC 20006.

The notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: January 6, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93-738 Filed 1-12-93; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 32217]

Morris H. Kulmer, Kern W. Schumacher, Troy W. Schumacher, and Michael J. Van Wagenen; Continuance in Control Exemption; Tulare Valley Railroad Co.

Morris H. Kulmer, Kern W. Schumacher, Troy W. Schumacher, and Michael J. Van Wagenen (applicants) have filed a notice of exemption to continue in control of Tulare Valley Railroad Company (Tulare) upon the latter's becoming a carrier. Tulare, a noncarrier, has concurrently filed a notice of exemption in Finance Docket No. 32215, Tulare Valley Railroad Company—Acquisition and Operation Exemption—The Atchison, Topeka & Santa Fe Railway Company, to: (1) Acquire, by purchase or lease, and to operate approximately 158 miles of rail lines owned by The Atchison, Topeka & Santa Fe Railway Company (ATSF); and (2) acquire incidental trackage rights over lines of Southern Pacific Transportation Company (SP) and ATSF in the State of California. Tulare expected the transaction to be consummated on or about December 21, 1992.

Applicants also control T and P Railroad, Inc. (T&P), which is a class III rail carrier operating in the State of Kansas, and SF & LR Railway, Inc. (SF&LR), which was expected to become a carrier upon consummation on or about December 22, 1992, of a transaction subject to the proceeding in Docket No. AB-3 (Sub-No. 101X) involving the acquisition of an 18.23-mile line in Texas. Applicants indicate that: (1) The rail lines of T&P, SF&LR, and Tulare will not connect with each other; (2) the transactions are not part of a series of anticipated transactions that would connect the railroads with each other or any railroad in their corporate family; and (3) the transaction does not involve a class I carrier. The transaction therefore is exempt from the prior approval requirements of 49 U.S.C. 11343. See 49 CFR 1180.2(d)(2).

As a condition to the use of this exemption, any employees affected by the transaction will be protected by the conditions set forth in New York Dock Ry.—Control—Brooklyn Eastern Dist., 360 I.C.C. 60 (1979).

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction. Pleadings must be filed with the Commission and served on: Adam M. Mycyk, Weiner, Brodsky, Sidman & Kider, P.C., Suite 800, 1350 New York Avenue, NW., Washington, DC 20005-4797.

Decided: January 7, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93-735 Filed 1-12-93; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 32215]

Tulare Valley Railroad Co.; Acquisition and Operation Exemption; The Atchison, Topeka & Santa Fe Railway Co.

Tulare Valley Railroad Company (Tulare), a noncarrier, has filed a verified notice of exemption: (1) To acquire, by purchase or lease, and to operate approximately 158 miles of lines of railroad owned by The Atchison, Topeka & Santa Fe Railway Company (ATSF) in the State of California; and (2) to acquire incidental trackage rights over one line segment of Southern Pacific Transportation Company (SP) and three line segments of ATSF in the State of California. Tulare will become a class III rail carrier. The transaction was to be consummated on or about December 21, 1991.[1]

The rail lines involved in the acquisition, by purchase or lease, consist of nine branch and spur lines, which are described below. Lines to be purchased include: (1) ATSF's undivided 50 percent interest in the Arvin branch line between milepost 316 + 4092 feet at Magunden, CA, and milepost 333 + 4400 feet at Arvin, CA;[2] (2) ATSF's undivided 50 percent interest in the Oil City branch line between milepost 308 + 477 feet at Oil Junction, CA, and milepost 312 + 2902 feet at Maltha, CA;[3] (3) the Porterville branch line between milepost 71 + 2969.2 feet at Ducor, CA, and milepost 19 at Cutler, CA; (4) the Porterville branch line between milepost 111 + 4029 feet and milepost 111 + 383 feet, both near Oil Junction, CA; (5) the Visalia branch line between milepost 1 + 290 feet at Corcoran, CA, and milepost 67 at Calwa, CA; (6) the Cameo spur line between milepost 0 + 160 feet at Fresno, CA, and milepost 6 near Fresno, CA; (7) the Orange Cove spur line between milepost 20.6 at Wyeth, CA, and milepost 11 + 1126.5 feet at Orange Cove, CA; and (8) ATSF's rights-of-way between milepost 11 + 1126.5 feet at Orange Cove, CA, and milepost 0 + 2936 feet at Minkler, CA, and between milepost 19 + 2930 feet at Minkler, CA, and milepost 6 near Fresno, CA. The following line will be leased: The Landco spur line between the Porterville Subdivision milepost 111 + 4029 feet near Oil Junction, CA, and milepost 113 + 3717 feet at or near Bakersfield, CA. The initial term of the lease will be for 5 years and renewable for consecutive 5-year terms.

The incidental trackage rights that Tulare will acquire as part of the proposed transaction will be over the following ATSF lines: (1) The Visalia Subdivision line between milepost 1 + 290 feet east of the Corcoran yard and milepost 951 + 200 feet and milepost 951 + 2600 feet near the southwestern end of the Visalia Subdivision; (2) the Visalia Subdivision line between milepost 67 east of the Calwa Yard and the Cameo spur line (Stockton Subdivision) milepost 0 + 160 feet; and (3) the Bakersfield Yard between the Porterville Subdivision milepost 113 + 3717 feet west of the Bakersfield Yard and the Bakersfield Subdivision milespost 885 + 931 feet east of the Bakersfield Yard. Tulare will also acquire trackage rights, by assignment from ATSF, over SP's line between Oil Junction, CA (SP milepost 308.6—ATSF

Finance Docket No. 32197, Canadian National Railway Company—Trackage Rights Exemption—St. Clair Tunnel Company, whereby SCTC granted trackage rights back to CN over the St. Clair Subdivision.

[1] This proceeding is related to Finance Docket No. 32217, Morris H. Kulmer, et al.—Continuance in Control Exemption—Tulare Valley Railroad Company, wherein Morris H. Kulmer and others have concurrently filed a verified notice of exemption to continue in control of Tulare when it becomes a carrier upon consummation of the transaction described in this notice.

[2] SP owns the other undivided 50 percent interest.

[3] SP owns the other undivided 50 percent interest.

Porterville Subdivision milepost 110.7) and Ducor, CA (SP milepost 287.1—ATSF Porterville Subdivision milepost 71.9).

Tulare indicates that some of the involved lines have marginal traffic densities and that, if any of the acquired properties cannot be operated profitably on a long-term basis, it will seek Commission authority to abandon such segments.

Any comments must be filed with the Commission and served on: Adam M. Mycyk, Weiner, Brodsky, Sidman & Kider, P.C., Suite 800, 1350 New York Avenue, NW., Washington, DC 20005-4797.

This notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: January 7, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–732 Filed 1–12–93; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research Act of 1984; Cable Television Laboratories, Inc.

Notice is hereby given that, on October 8, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Cable Televivion Laboratories, Inc. ("CableLabs") and Com21, Inc. ("Com21") filed a written notification simultaneously with the Attorney General and the Federal Trade Commission diclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notification was filed for the purpose of involving the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties are CableLabs, Boulder, CO; and Com21, Atherton, CA.

The area of planned activity is cooperation in the exchange of information about and development of interface concepts between storage devices, Asynchronous Tranfer Mode ("ATM") systems and cable system networks, including the functions, operation and architecture of ATM systems and cooperation in the conduct of laboratory and field tests of such interface concepts.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–685 Filed 1–12–93; 8:45 am]

BILLING CODE 4410–01–M

Antitrust Division

Notice Pursuant to the National Cooperative Research Act of 1984; "Hybrid Superconducting Digital Systems"

Notice is hereby given that, on November 16, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 et. seq. ("the Act"), Conductus has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties, and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties and its general areas of planned activities are given below.

The parties to the venture are Conductus, Sunnyvale, CA; TRW, Redondo Beach, CA; Hewlett-Packard, Palo Alto, CA; Stanford University, Palo Alto, CA; and University of California, Berkeley, Berkeley, CA. The parties entered into a collaborative research agreement on November 9, 1992, to create significant advances in technology for electronic measurement.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–686 Filed 1–12–93; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research Act of 1984; Spectra Diode Laboratories, Inc. and Xerox Corp.

Notice is hereby given that, on December 2, 1992, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Spectra Diode Laboratories, Inc. and Xerox Corporation have filed written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Pursuant to section 6(b) of the Act, the identities of the parties to the venture are Spectra Diode Laboratories, San Jose, CA; and Xerox Corporation, Stamford, CT. Stanford University, Palo Alto, CA, will be a subcontractor under the agreement. The objective of the venture is to develop a full monolithic approach to the development of a multi-wavelength addressable laser diode array where the lasers are spaced on 10 um centers and operate independently at predetermined wavelengths ranging from 430 nm to 1.1 um.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 93–687 Filed 1–12–93; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Employment and Training Administration

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period of December 1992.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–27,931; Thiokol Corp., Ordnance Operations, Marshall, TX

TA–W–27,878; Douglas Pacific Veneer, Inc., Bandon, OR

In the following cases, the investigation revealed that the criteria for eligibility has not been met for the reasons specified.

TA–W–27,869; Monessen, Inc., Monessen, PA

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–27,920; Bell Helicopter, Fort Worth, TX

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–27,945; Santa Fe Drilling Co., Houston, TX

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–27,932; D & H Manufacturers, Inc., Muskegon, MI

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–27,963; Dresser Industries, Security Div., Eunice, LA

U.S. imports of oil and gas field machinery were negligible in 1991 and in January-July 1992.

TA–W–27,462E; Transco Gas Pipe Line Corp., Houston, TX

The investigation revealed that criterion (2) has not been met. Sales or production did not decline during the relevant period as required for certification.

TA–W–27,366; Forest Oil Corp., Lafayette, LA

The investigation revealed that criterion (2) and criterion (3) have not been met. Sales or production did not decline during the relevant period as required for certification. Increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have not contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Affirmative Determinations

TA–W–27,959; Pennzoil Sulphur Co., Pecos, TX

A certification was issued covering all workers separated on or after October 26, 1992.

TA–W–27,960; Pennzoil Sulphur Co., Galveston, TX

A certification was issued covering all workers separated on or after October 26, 1992.

TA–W–27,462A; Transco Exploration & Production Co., Headquartered in Houston, TX and Operating at Various Locations in The Following States: B; CO, C; LA, D; TX

A certification was issued covering all workers engaged in the production of exploration and production of crude oil and natural gas who became totally or partially separated on or after November 28, 1992.

TA–W–27,461; Transco Energy Corp., Aviation Dept., Houston, TX

A certification was issued covering all workers engaged in the production of exploration and production of crude oil and natural gas who became totally or partially separated on or after June 8, 1991.

TA–W–27,462; Transco Energy Corp., Administration, Houston, TX

A certification was issued covering all workers engaged in support for the exploration and production of crude oil and natural gas who became totally or partially separated on or after June 8, 1991

TA–W–27,902; Dana Fashions, Inc., Brent, AL

A certification was issued covering all workers separated on or after September 28, 1991.

TA–W–27,977; Exxon Co., USA Corporate Headquarters Staff, Located Throughtout Houston, TX

A certification was issued covering all workers separated on or after August 13, 1991.

TA–W–27,975; Charles Komar & Sons Seamprufe Corp., McAlester, OK

A certification was issued covering all workers separated on or after October 29, 1991.

TA–W–27,966; Frontier Processing Co., Littleton, CO

A certification was issued covering all workers separated on or after October 28, 1991.

TA–W–27,924; Leakesville Manufacturing, Inc., Leakesville, MS

A certification was issued covering all workers separated on or after October 14, 1991.

TA–W–27,914; Grace Energy Corp., Dallas, TX

A certification was issued covering all workers separated on or after October 7, 1991.

TA–W–27,788; Paper Converting Machine Co., Green Bay, WI

A certification was issued covering all workers separated on or after January 1, 1992.

TA–W–27,956; Oil Technology Service, Inc., Houston, TX

A certification was issued covering all workers separated on or after October 23, 1991.

TA–W–28,013; Amoco Corp., Information Technology Dept., Houston Westlake Office and Houston Data Center, Houston, TX

A certification was issued covering all workers separated on or after October 30, 1991.

TA–W–27,840; American Standard, Inc., Louisville, KY

A certification was issued covering all workers separated on or after October 1, 1992.

I hereby certify that the aforementioned determinations were issued during the month of December 1992. Copies of these determinations are available for inspection in room C–4318, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons to write to the above address.

Dated: January 4, 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93–751 Filed 1–12–93; 8:45 am]

BILLING CODE 4510-30-M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitiions have been filed with the Secretary of Labor under Section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the

determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 25, 1993.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than January 25, 1993.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 28th day of December 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers/firm—	Location	Date received	Date of petition	Petition No.	Articles produced
Thumb Plastics-McAllen, Inc (Wkrs)	Traverse City, MI	12/28/92	12/17/92	28,143	Injection molded plastics.
Lucas Aerospace Power Transmission (Wkrs)	Utica, NY	12/28/92	12/18/92	28,144	Industrial couplings.
Fleck, Inc (Wkrs)	Biloxi, MS	12/28/92	12/14/92	28,145	Wire harnesses.
Siemens Nixdorf (Wkrs)	Burlington, MA	12/28/92	11/11/92	28,146	Engineering development.
Midland Southwest Div/MA Hanna Co (Wkrs)	Midland, TX	12/28/92	12/16/92	28,147	Oil and gas.
T-Bar Div/Data Switch (Wkrs)	Milford, CT	12/28/92	12/18/92	28,148	Mainframe computer component.
Deeville Blouse Co (ILGWU)	Danielsville, PA	12/28/92	12/18/92	28,149	Blouses and skirts.
Deeville Cutting (ILGWU)	Slatington, PA	12/28/92	12/18/92	28,150	Blouses and skirts.
Martech Int. (Wkrs)	Broussard, LA	12/28/92	12/15/92	28,151	Marine services.
Coil Coating (USWA)	Warren, OH	12/28/92	12/18/92	28,152	Coil coating for steel industry.
Coltec Industries, Inc (Wkrs)	Pittsburgh, PA	12/28/92	12/18/92	28,153	Stainless and alloy steel products.
M/A- Com, Anzac Div. (Wkrs)	Bangor, ME	12/28/92	12/08/92	28,154	Integrated circuits.
Ramco Oil and Gas, Inc (Wkrs)	Tulsa, OK	12/28/92	12/03/92	28,155	Oil and gas.
Fireye, Inc (Wkrs)	Derry, NH	12/28/92	12/16/92	28,156	Sensing products.
Oglebay Norton Company (Wkrs)	Cleveland, OH	12/28/92	12/16/92	28,157	Transports bulk raw materials.
Northrop Corp (Wkrs)	Norwood, MA	12/28/92	12/03/92	28,158	Electromagnetic components.
Coalinga Corp (Co)	Lafayette, LA	12/28/92	12/17/92	28,159	Oil and gas production.
Coalinga Corp (Co)	Los Angeles, CA	12/28/92	12/17/92	28,160	Oil and gas production.

[FR Doc. 93–749 Filed 1–12–93; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–27,742, TA–W–27,742A, and TA–W–27,742B

Timco Services, Inc., et al., Lafayette, LA; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on October 21, 1992, applicable to all workers of Timco Services, Inc., and Timco-TMS, Inc., both of Lafayette, Louisiana. The certification notice was published in the Federal Register on November 3, 1992 (57 FR 49721).

At the request of the State Agency, the Department reviewed the certification for workers of the subject firms. The investigation findings show that the claimants' wages for both Timco Services, Inc., and Timco-TMS, Inc., are being reported under Southcoast Services, Inc., Lafayette, Louisiana, the parent firm.

Accordingly, the Department is amending the certification to properly reflect the correct worker groups.

The intent of the Department's certification is to include all workers of Timco Services, Inc., Timco-TMS, Inc., and Southcoast Services, Inc., Lafayette, Louisiana irrespective to which account their unemployment insurance (UI) taxes are paid.

The amended notice applicable to TA–W–27,742 is hereby published as follows:

"All workers of Timco Services, Inc., Lafayette, Louisiana, Timco-TMS, Inc., Lafayette, Louisiana a/k/a/ Southcoast Services, Inc., Lafayette, Louisiana who became totally or partially separated from employment on or after August 17, 1991, are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974."

Signed at Washington, DC this December 31, 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93–750 Filed 1–12–93; 8:45 am]

BILLING CODE 4510–30–M

[TA–W–27,705]

UNOCAL Corp., Lafayette, LA; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18 an application for administrative reconsideration was filed with the Director of the Office of Trade Adjustment Assistance for workers at UNOCAL Corporation, Lafayette, Louisiana. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA–W–27,705; UNOCAL Corporation
Lafayette, Louisiana (December 31, 1992)

Signed at Washington, DC this 31st day of December, 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93–748 Filed 1–12–93; 8:45 am]

BILLING CODE 4510–30–M

NATIONAL CREDIT UNION ADMINISTRATION

Public Information Collection Requirement Submitted to OMB for Review

Dated: January 4, 1993.

The National Credit Union Administration has submitted the following public information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submissions may be obtained by calling the NCUA Clearance Officer listed. Comments regarding

information collections should be addressed to the OMB reviewer listed and to the NCUA Clearance Officer, NCUA, Administrative Office, room 7344, 1776 G Street, Washington, DC 20456.

National Credit Union Administration

OMB Number: 3133–
Form Number: None.
Type of Review: New collection.
Title: Written Investment Policies, Recording Credit Decision, Documenting Investment in Certain Securities.
Description: To ensure that federal credit unions make safe investments, the rule requires that they establish written investment policies and review them annually, record credit decisions regarding deposits in certain financial institutions, and document analyses of certain securities purchased to reduce interest rate risk.
Respondents: Federal credit unions.
Estimated Number of Respondents: 8,075.
Estimated Burden Hours Per Response: 6 hours.
Frequency of Response: On occasion.
Estimated Total Reporting Burden: 48,450.

OMB Number: 3133–
Form Number: NCUA 10603.
Type of Review: Review of new collection.
Title: Survey Nonmember Accounts.
Description: NCUA intends to revise rules and regulations and operating procedures dealing with nonmember deposit and/or accounts in certain federal credit unions. The information obtained in the survey will be helpful in the decision making process.
Estimated Number of Respondents: 37.
Estimated Burden Hours Per Response: 40 minutes.
Frequency of Response: One time collection.
Estimated Total Reporting Burden: 24.7 hours.

OMB Number: 3133–0011
Form Number: NCUA 9600.
Type of Review: Reinstatement of a previously approved collection for which approval has expired.
Title: Application for Insurance of Accounts State-chartered Credit Unions.
Description: The Federal Credit Union Act and NCUA regulations require that federal credit unions convert to state charters and desiring to maintain federal insurance must reapply for insurance. All state-chartered credit unions desiring federal insurance must apply as well.
Respondents: Federal and state-chartered credit unions.
Estimated Number of Respondents: 123.
Estimated Burden Hours per Response: 307.5 hours.
Frequency of Response: One time.
Estimated Total Reporting Burden: 369.

OMB Number: 3133–0024
Form Number: 4302 through 4310.
Type of Review: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.
Title: 12 CFR part 708, subpart A, Mergers of Federally Insured Credit Unions.
Description: 12 CFR part 708, subpart A, provides merger procedures for credit union where at least one of the credit unions involved is federally insured. This subpart, although issued as part of a NPRM, is substantively the same as existing part 708.
Estimated Number of Respondents: 380.
Estimated Burden Hours per Response: 3.30 hours.
Frequency of Response: On occasion.
Estimated Total Reporting Burden: 1,254.

OMB Number: 3133–0035.
Form Number: None.
Type of Review: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.
Title: Trustees and Custodians of Pension Plans.
Description: A federal credit union acting as trustee or custodian of a Keogh Plan or individual retirement account must maintain individual records for each member/participant showing all transactions in detail.
Respondents: Federal credit unions.
Estimated Number of Respondents: 3,968.
Estimated Burden Hours per Response: 50 hours.
Frequency of Response: On occasion.
Estimated Total Reporting Burden: 198,400.

OMB Number: 3133–0052.
Form Number: None.
Type of Review: Reinstatement of a previously approved collection for which approval has expired.
Title: Federal Credit Union Membership.
Description: Federal Credit Unions.
Estimated Number of Respondents: 1,997.
Estimated Burden Hours per Response: 1 hour.
Frequency of Response: On Occasion.
Estimated Total Reporting Burden: 1,997.
OMB Number: 3133–0058.
Form Number: None.
Type of Review: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.
Title: Credit Committee Records Article IX, section 3 and 4 of the Federal Credit Union Bylaws.
Description. Record keeping requirement, not collection of data. Credit unions must maintain records of the actions they take regarding approval/disapproval of loans.
Respondents: Federal credit unions.
Estimated Number of Respondents: 7,989.
Estimated Burden Hours per Response: 8 hour.
Frequency of Response: Monthly.
Estimated Total Reporting Burden: 63,912.

OMB Number: 3133–0064.
Form Number: NCUA 7000–A, 7001, 7002, 7003, and 7004.
Type of Review: Reinstatement of a previously approved collection for which approval has expired.
Title: Request for Funds—CLF.
Description: Forms used by each borrower requesting a loan from the Central Liquidity Facility.
Respondents: Federally insured credit unions.
Estimated Number of Respondents: 25.
Estimated Burden Hours per Response: 1 hour.
Frequency of Response: Only when borrowing.
Estimated Total Reporting Burden: 26.

OMB Number: 3133–0080.
Form Number: None.
Type of Review: Extension of the expiration date of a currently approved collection without any change in substance or in the method of collection.
Title: Special Meetings of Federal Credit Union (FCU) Board.
Description: This section of the Federal Credit Union Bylaws requires that the credit union president call a special meeting of the board of directors upon receipt of a written request to do so signed by a majority of the directors.
Respondents: Federal credit unions.
Estimated Number of Respondents: 799
Estimated Burden Hours per Response: 0.4 hours.
Frequency of Response: On occasion.
Estimated Total Reporting Burden: 320.

OMB Number: 3133–0117.
Form Number: None.
Type of Review: Reinstatement of a previously approved collection for which approval has expired.
Title: Designation of Low Income Status.

Description: Credit unions serving predominantly low-income members, as defined in § 701.32 must receive a low-income designation from the NCUA before accepting nonmember deposits other than credit union and public deposits.

Respondents: Federally insured credit unions.

Estimated Number of Respondents: 15.

Estimated Burden Hours per Response: 15 hours.

Frequency of Response: One time.

Estimated Total Reporting Burden: 225.

OMB Number: 3133–0118.

Form Number: NCUA 8023.

Type of Review: Extension of the expiration date of a currently approved collection without any change in the substance or in the method of collection.

Title: Requirements for An Outside Audit; Requirements for Insurance.

Description: The rule prescribes the regulatory requirement for an outside, independent audit of any federally insured credit union by a certified public accountant under certain specified conditions. The rule was added to reflect applicable provisions of Public Law 101–73, the Federal Financial Institutions, Reform, Recovery, and Enforcement Act of 1989.

Estimated Number of Respondents: 634.

Estimated Burden Hours per Response: 160 hours.

Frequency of Response: Reporting only required if noncompliance with existing regulations.

Estimated Total Reporting Burden: 101,440.

Clearance Officer: Wilmer A. Theard or Patricia Slye, (202) 682–9700, National Credit Union Administration, room 7344, 1776 G Street, NW., Washington, DC 20456.

OMB Reviewer: Gary Waxman (202) 395–7340, Office of Management and Budget, room 3208, New Executive Office Building, Washington, DC 20503.

Becky Baker,

Secretary of the NCUA Board.

[FR Doc. 93–689 Filed 1–12–93; 8:45 am]

BILLING CODE 7535–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–31885; File No. SR–NASD–92–48]

January 6, 1993.

Self-Regulatory Organizations; Proposed Rule Change by National Association of Securities Dealers, Inc., Relating to Establishment of Requirements for Real-Time Reporting of Members' Over-The-Counter Transactions in Certain Equity Securities

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1) ("Act"), notice is hereby given that on November 24, 1992, the National Association of Securities Dealers, Inc. ("NASD") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD hereby files this proposed rule change, pursuant to section 19(b)(1) of the Act and Rule 19b–4 thereunder, to establish requirements for real-time trade reporting of members' over-the-counter transactions in equity securities that are not currently reportable on a real-time basis. Securities affected by this proposal are those for which members now submit, on a daily basis, their aggregate volume data and price ranges pursuant to Schedule H to the NASD By-Laws. The proposed reporting requirements are patterned after those established for Nasdaq listed securities (i.e., Parts XII and XIII of Schedule D to the NASD By-Laws). (New language is italicized while deleted language is bracketed.)

Part XIV—Reporting Transactions in Over-the-Counter Equity Securities

This Part has been adopted pursuant to Article VII of the Corporation's By-Laws and sets forth the trade reporting requirements applicable to members' transactions in equity securities for which real-time trade reporting is not otherwise required (hereinafter referred to as "OTC Equity Securities"). Members shall utilize the Automated Confirmation Transaction Service ("Act") for trade reporting in OTC Equity Securities.

Section 1—Definitions

(a) Terms used in this Part shall have the same meaning as those defined in the Association's By-Laws and Rules of Fair Practice unless otherwise specified herein.

(b) "OTC Equity Security" means any equity security not classified as a "designated security", for purposes of Parts XII and XIII of Schedule D to the Corporation's By-Laws. This term also includes certain exchange-listed securities that do not otherwise qualify for real-time trade reporting because they are not "eligible securities" as defined by section 1(d) of Schedule G to the NASD By-Laws. The term "OTC Equity Security" shall not include "restricted securities," as defined by Rule 144(a)(3) under the Securities Act of 1933, nor any securities designated in the PORTAL Market[SM]*.*

(c) "Automated Confirmation Transaction Service" or ACT is the service that, among other things, accommodates reporting and dissemination of last sale reports in OTC Equity Securities. Regarding those OTC Equity Securities that are not eligible for clearance and settlement through the facilities of the National Securities Clearing Corporation, the ACT comparison function will not be available. However, ACT will support the entry and dissemination of last sale data on such securities.

(d) "OTC Market Maker" means a member of the Association that holds itself out as a market maker by entering proprietary quotations or indications of interest for a particular OTC Equity Security in any inter-dealer quotation system, including any system that the Securities and Exchange Commission has qualified pursuant to section 17B of the Securities Exchange Act of 1934. A member is an OTC Market Maker only in those OTC Equity Securities in which it displays market making interest via an inter-dealer quotation system.

(e) "Non-Market Maker" means a member of the Association that is not an OTC Market Maker with respect to a particular OTC Equity Security.

Section 2—Transaction Reporting

(a) When and How Transactions Are Reported

(1) OTC Market Makers shall, within 90 seconds after execution, transmit through ACT last sale reports of transactions in OTC Equity Securities executed during normal market hours. Transactions not reported within 90 seconds after execution shall be designated as late.

(2) Non-Market Makers shall, within 90 seconds after execution, transmit

through ACT or the ACT service desk (if qualified pursuant to Part IX of Schedule D to the By-Laws), or if ACT is unavailable due to system or transmission failure, by telephone to the Market Operations Department in New York City, last sale reports of transactions in OTC Equity Securities executed during normal market hours. Transactions not reported within 90 seconds after execution shall be designated as late.

(3) Last sale reports of transactions in OTC Equity Securities executed between 9 a.m. and 9:30 a.m. Eastern Time shall be transmitted through ACT within 90 seconds after execution and shall be designated as ".T" trades to denote their execution outside normal market hours. Last sale reports of transactions in OTC Equity Securities between the hours of 4 p.m. and 5:15 p.m. Eastern Time shall also be transmitted through ACT within 90 seconds after execution; trades executed and reported after 4 p.m. Eastern Time shall be designated as ".T" to denote their execution outside normal market hours.

(4) All members shall report weekly to the Market Operations Department in New York City, on a form designated by the Board of Governors, last sale reports of transactions in OTC Equity Securities that are executed outside the hours of 9 a.m. and 5:15 p.m. Eastern Time.

(5) A pattern or practice of late reporting without exceptional circumstances may be considered conduct inconsistent with high standards of commercial honor and just and equitable principles of trade, in violation of Article III, Section 1 of the Rules of Fair Practice.

(b) Which Party Reports Transaction

(1) In transactions between two OTC Market Makers, only the member representing the sell side shall report.

(2) In transactions between an OTC Market Maker and a Non-Market Maker, only the OTC Market Maker shall report.

(3) In transactions between two Non-Market Makers, only the member representing the sell side shall report.

(4) In transactions between a member and a customer, the member shall report.

(c) Information To Be Reported

Each last sale report shall contain the following information:

(1) Symbol of the OTC Equity Security;

(2) Number of shares;

(3) Price of the transaction as required by paragraph (d) below; and

(4) A symbol indicating whether the transaction is a buy, sell, or cross.

(d) Procedures for Reporting Price and Volume

Members that are required to report pursuant to paragraph (b) above shall transmit last sale reports for all purchases and sales in OTC Equity Securities in the following manner:

(1) For agency transactions, report the number of shares and the price excluding the commission charged.

(2) For dual agency tranactions, report the number of shares only once, and report the price excluding the commission charged.

(3) For principal transactions, except as provided below, report each purchase and sale transaction separately and report the number of shares and the price. For principal transactions that are executed at a price which includes a mark-up, mark-down or service charge, the price reported shall exclude the mark-up, mark-down or service charge. Such reported price shall be reasonably related to the prevailing market, taking into consideration all relevant circumstances including, but not limited to, market conditions with respect to the OTC Equity Security, the number of shares involved in the transaction, the published bids and offers with size displayed in any inter-dealer quotation system at the time of the execution (including the reporting firm's own quotation), the cost of execution, and the expenses involved in clearing the transaction.

Exception: A "riskless" principal transaction in which a Non-Market Maker, after having received from a customer an order to buy, purchases the security as principal from another member or customer to satisfy the order to buy or, after receiving from a customer an order to sell, sells the security as principal to another member or customer to satisfy the order to sell, shall be reported as one transaction in the same manner as an agency transaction, excluding the mark-up or mark-down.

(e) Transactions Not Required To Be Reported

The following types of transactions shall not be reported:

(1) Transactions which are part of a primary distribution by an issuer, a registered secondary distribution (other than "shelf distributions"), or of an unregistered secondary distribution;

(2) Transactions made in reliance on section 4(2) of the Securities Act of 1933;

(3) Transactions where the buyer and seller have agreed to trade at a price substantially unrelated to the current market for the security.

(4) Purchases or sales of securities effected upon the exercise of an option pursuant to the terms thereof, or the exercise of any other right to acquire securities at a pre-established consideration unrelated to the current market.

Interpretation of the Board of Governors

The Corporation seeks to emphasize the obligations of members to report transactions in OTC Equity Securities within 90 seconds after execution. All transactions in OTC Equity Securities not reported within 90 seconds after execution shall be reported as late, and the Corporation routinely monitors members' compliance with the 90 second requirement. If the Corporation finds a pattern or practice of unexcused late reporting, that is, repeated reports of executions in OTC Equity Securities after 90 seconds without reasonable justification or exceptional circumstances, the member may be found to be in violation of Article III, Section 1 of the Corporation's Rules of Fair Practice. Exceptional circumstances will be determined on a case-by-case basis and may include conditions such as extreme volatility in an OTC Equity Security, or in the market as a whole. Timely reporting of all transactions in OTC Equity Securities is necessary and appropriate for the fair and orderly operation of the marketplace, and to ensure the collection of adequate information for surveillance purposes; the Corporation will, therefore, view noncompliance as a rule violation.

Part [XIV] XV—Mutual Fund Quotation Program

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the NASD included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Through the instant filing, the NASD is seeking the SEC's approval of a rule

package that would extend real-time transaction reporting to NASD members' transactions in equity securities that are not subject to real-time reporting under existing provisions of the NASD rules.[1] The universe of securities affected by this rule proposal is the same universe for which members now submit aggregate volume and price range data at the end of each business day pursuant to Section 2 of Schedule H to the NASD By-Laws.[2] Since the adoption of Schedule H in 1988, the NASD has collected Schedule H data solely for regulatory purposes and has not disseminated such information via the Nasdaq network or the networks of commercial vendors.

Under this proposal, the NASD will capture trade-by-trade information—on a real-time basis within 90 seconds of execution—for OTC Equity Securities by means of members' entries into the Automated Confirmation Transaction Service ("ACT"). The data elements comprising a transaction report would be the same as those now required for transaction reports in Nasdaq and exchange-listed securities reported through ACT. Implementation of the proposed reporting rules will enable the NASD to capture sufficient trade details to construct a transaction audit trail reflecting members' daily trading in OTC Equity Securities. This development will materially enhance the NASD's regulatory database and permit the use of automated surveillance techniques comparable to those utilized for the Nasdaq Stock Market. Moreover, the collection of transactional data through ACT will allow the NASD to phase out Schedule H price/volume reporting for OTC Equity Securities.[3] Assuming Commission approval, the proposed reporting rules will result in consistent trade reporting and audit trail requirements across all market segments for which the NASD has primary self-regulatory responsibility. The proposed reporting requirements would be put into effect no later than mid-August of 1993, which corresponds to the target date for completing the associated system changes.

The instant proposal is also intended to cause the OTC Bulletin Board service ("OTCBB") to meet the requirements of section 17B of the Act, which was added to the statute by the Securities Enforcement Remedies and Penny Stock Reform Act of 1990. This section requires the Commission to facilitate the establishment of one or more automated quotation systems (under the auspices of a self-regulatory organization) for the entry and display of dealers' quotations in "penny stocks" (as now defined by Rule 3a51–1 under the Act). Section 17B(b)(2) specifies the characteristics required of such systems. With the addition of facilities for collecting, processing, and disseminating last sale information on OTC Equity Securities, the NASD believes that the OTCBB will satisfy those minimum statutory requirements. The Commission has designated the OTCBB, on an interim basis, as a Qualifying Electronic Quotation System for purposes of certain penny stock disclosure rules adopted under section 15(g) of the Act.[4]

In defining members' reporting obligations under the instant proposal, the term "OTC Market Maker" encompasses only those firms that hold themselves out as market makers in some inter-dealer system, including a system qualified by the Commission under Section 17B of the Act. This status attaches on a security-by-security basis. A firm's status as a Non-Market Maker is similarly determined on a security-by-security basis. Basically, a Non-Market Maker incurs the obligation to report a transaction in an OTC Equity Security (within 90 seconds of execution) only when the contra party is not an OTC Market Maker in the subject security. This approach is consistent with the reporting obligations already established for the Nasdaq Stock Market. Hence, the proposed reporting rules are equally comprehensive in their application.

The NASD recognizes that the market structure reforms of section 17B were directed at penny stocks and that the universe of OTC Equity Securities is broader. Nonetheless, the NASD proposes to collect and disseminate transactional information real-time, on all domestic OTC Equity Securities, regardless of whether they are quoted in the OTCBB. This last sale information will be made available through customary vendor channels as well as the NASD's communications network. Finally, last sale information input by member firms on the subset of OTC Equity Securities consisting of foreign and ADR issues will be collected and used exclusively for regulatory purposes without real-time dissemination. This limitation is believed appropriate because, at the Commission's request, OTCBB dealers in such securities may only update their quotes twice daily, and are therefore precluded from entering firm quotations into the OTCBB for such issues. The NASD will not publish trade reports on these securities in order to avoid any reconsideration of the present exemption from registration pursuant to Rule 12g3-2(b) under the Act.

The NASD believes that the proposed rule change is consistent with sections 11A(a)(1), 15A(b)(6) and 17B of the Act. Section 11A(a)(1) sets forth the Congressional findings and policy goals respecting operational enhancements to the securities markets. Basically the Congress found that new data processing and communications techniques should be applied to improve the efficiency of market operations, broaden the distribution of market information, enhance the ability of investors to monitor the quality of executions received, and foster competition among market participants. Section 15A(b)(6) requires, *inter alia*, that the NASD's rules be designed to prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, and facilitate transactions in securities. Finally, section 17B contains Congressional findings and directives respecting the collection and distribution of quotation and last sale information on certain low-priced equity securities (classified as "penny stocks" pursuant to Rule 3a51-1 under the Act) that are neither Nasdaq nor exchange-listed.

B. Self-Regulatory Organization's Statement on Burden on Competition

The NASD believes that the rule change will not result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments were neither solicited nor received.

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[1] See Parts XII and XIII of Schedule D and Schedule G to the NASD By-Laws, CCH NASD Manual, ¶¶1865, 1867A, and 1917.

[2] Currently, the requirement to report price/volume data pursuant to Schedule H to the NASD By-Laws extends to members' activity in "Non-Nasdaq Securities." Paragraph (a) of Schedule H Defines that term to mean any equity security that is neither included in the Nasdaq System nor traded on any national securities exchange. Paragraph (a) also extends Schedule H reporting to over-the-counter transactions in exchange-listed securities that do not qualify for real-time trade reporting because they are not "eligible securities," as defined in section 1(d) of Schedule G to the NASD By-Laws. The term "OTC Equity Security", as used in this rule proposal, would encompass this limited group of exchange-listed equity securities as well as those equities that are neither Nasdaq or exchange-listed.

[3] This phase out will be accomplished through a subsequent Rule 19b–4 filing by the NASD.

[4] Letter from Margaret H. McFarland, Deputy Secretary, SEC, to Richard Ketchum, Executive Vice President, NASD, dated December 30, 1992.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. In addition, the Commission specifically solicits comment on whether the OTCBB should be considered an automated quotation system for penny stocks within the meaning of section 17B of the Exchange Act, upon the incorporation of last sale reporting capability.

Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. Copies of the submissions, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by February 3, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12)

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–752 Filed 1–12–93; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–19205; No. 811–3308]

American General Fixed-Income Accumulation Fund, Inc.; Application for an Order

January 4, 1993

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for an order under the Investment Company Act of 1940 (the "1940 Act").

APPLICANT: American General Fixed-Income Accumulation Fund, Inc. (the "Applicant").

RELEVANT 1940 ACT SECTION: Order requested under section 8(f) of the 1940 Act.

SUMMARY OF APPLICATION: The Applicant seeks an order declaring that it has ceased to be an investment company as defined by the 1940 Act.

FILING DATE: The application was filed on November 12, 1992, and amended and restated on December 8, 1992 and December 24, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving the Applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on January 29, 1993, and should be accompanied by proof of service on the Applicant in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the requester's interest, the reason for the request and the issues contested. Persons may request notification of a hearing by writing to the Secretary of the SEC.

ADDRESSES: Secretary, SEC, 450 5th Street NW., Washington, DC 20549.

APPLICANT: American General Fixed-Income Accumulation Fund, Inc., 2800 Post Oak Boulevard, Houston, Texas 77056.

FOR FURTHER INFORMATION CONTACT: Yvonne M. Hunold, Senior Attorney, at (202) 272–2676, or Wendell Faria, Deputy Chief, at (202) 272–2060, Office of Insurance Products (Division of Investment Management).

SUPPLEMENTARY INFORMATION: Following is a summary of the application; the complete application is available for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. The Applicant was organized as a corporation on October 20, 1981, under the laws of Maryland. The Applicant remains in existence and in good standing in Maryland.

2. On November 2, 1981, the Applicant filed a Notification of Registration as an open-end investment company on Form N–8A, and its initial registration statement on Form N–1 under the 1940 Act and under the Securities Act of 1933 (File No. 2–74664). Five hundred million (500,000,000) shares of common stock, all of one class, $0.01 par value per share ("Common Stock"), were registered at that time. Applicant's registration statement became effective on January 4, 1982, and the initial public offering commenced on January 28, 1992.

3. On July 24, 1991, the Applicant's Board of Directors ("Board") authorized the Applicant to join in the filing of an Application ("Application") for: (i) An Order under section 26(b) of the 1940 Act approving the substitution of shares of American General Series Portfolio Company ("AGSPC") and American Capital Life Investment Trust ("LIT") for shares of the Applicant, and (ii) an Order under section 17(b) or, alternatively, section 6(c), of the 1940 Act exempting the Applicant from sections 17(a)(1) and 17(a)(2) of the 1940 Act to the extent necessary to permit certain purchase and sale transactions between affiliates in connection with the substitution. On September 20, 1991, the Commission issued an order granting the Application (Investment Co. Act Rel. No. 18326).

4. On September 12, 1991, the Board authorized the dissolution of Applicant. No vote of Applicant's securityholders was required by law, and none was sought. No proxy materials were distributed to Applicant's securityholders.

5. On September 30, 1991, the Applicant had 3,036,781 shares of Common Stock outstanding, for an aggregate net asset value of $19,066,039, or $6.28 per share.

6. Effective September 30, 1991, the Applicant transferred securities valued at $7,109,211.22 and $194,645.13 in cash to LIT, and securities valued at $11,250,410.27, $351,219.87 in cash and $160,476.25 in accrued interest to AGSPC, on behalf of its securityholders in satisfaction of redemption requests made by such securityholders in connection with the substitution. In addition, $76.26 in cash was paid to American Capital Companies Shareholder Services, Inc., the transfer agent, in redemption of shares held in an audit account.

7. The Applicant bore all expenses it incurred in connection with carrying out its part of the substitution. These

expenses consisted of legal fees, printing, postage/shipping and filing fees. The Applicant, in turn, allocated its expenses to its investment adviser, American Capital Asset Management, Inc.

8. Applicant has transferred all of its portfolio securities and other assets to its securityholders.

9. Applicant has no securityholders to whom distributions to complete liquidation have not been made. The Applicant has no securityholders, assets, debts or other liabilities outstanding.

10. The Applicant has not, within the last 18 months, for any reason, transferred any of its assets to a separate trust, the beneficiaries of which were Applicant's securityholders.

11. Applicant is not a party to any litigation or administrative proceeding.

12. Applicant is not engaged, nor does it propose to engage, in any business activities other than those necessary to wind up its affairs.

13. As of the date of filing of the Application, the Applicant was current in all filing required to be made under the 1940 Act, including Form N–SAR.

14. The Applicant will file Articles of Dissolution in accordance with Maryland law after receipt of an order of the Commission declaring that the Applicant is no longer an investment company under the 1940 Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–694 Filed 1–12–93; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of Reporting Requirements Submitted for Review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Comments should be submitted within 30 days of this publication in the **Federal Register**. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (S.F. 83), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Cleo Verbillis, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416, Telephone: (202) 205–6629

OMB Reviewer: Gary Waxman, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

Title: U.S. Small Business Administration's Applicant Survey

SBA Form No.: SBA Form 1843

Frequency: Quarterly and Annually

Description of Respondents: Individuals seeking employment

Annual Responses: 7,500

Burden: 1,275

Dated: January 8, 1993.

Calvin Jenkins,

Director, Office of Administrative Services.

[FR Doc. 93–781 Filed 1–12–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

[CGD–91–224]

Extension of Certification of Alternative Advisory Group in Lieu of a Council

AGENCY: Coast Guard, DOT.

ACTION: Notice.

SUMMARY: On December 17, 1992, the Coast Guard extended for six months the certification of the Prince William Sound Regional Citizens' Advisory Council as an alternative voluntary advisory group pursuant to the Oil Pollution Act of 1990. The certification has been extended through June 30, 1992 to allow the group to use guidelines recently finalized by the Coast Guard in the group's next request for annual certification.

FOR FURTHER INFORMATION CONTACT: Ms. Janice Jackson, Project Manager, Marine Environmental Protection Division, (G–MEP–3), (202) 267–0500, U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001.

SUPPLEMENTARY INFORMATION: Congress passed the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990, 33 U.S.C. 2732 (the Act), to foster the long-term partnership among industry, government, and local communities in overseeing compliance with environmental concerns in the operation of crude oil terminals and tankers.

Paragraph (o) of the Act (33 U.S.C. 2732(o)) permits an alternative voluntary advisory group to represent the communities and interests in the vicinity of the oil terminal facilities in Prince William Sound in lieu of a council of the type specified in 33 U.S.C. 2732(d), if certain conditions are met. The Act requires that the group enter into a contract to ensure annual funding and receive annual certification by the President that it fosters the general goals and purposes of the Act and is broadly representative of the community and interests in the vicinity of the terminal facilities. Accordingly, in 1991, the President granted certification to the Prince William Sound Regional Citizens' Advisory Council.

The authority to certify alternative advisory groups was subsequently delegated to the Commandant of the Coast Guard, and redelegated to the Chief, Office of Marine Safety, Security and Environmental Protection. The Coast Guard recertified the Prince William Sound Regional Citizens' Advisory Council as an alternative voluntary advisory group in 1992 (57 FR 14440). At that time the Coast Guard advised alternative voluntary advisory groups that guidelines would be issued to assist them in the annual recertification process. Because the guidelines for recertification will not be available before its current certification expires, the Coast Guard has extended the certification of Prince William Sound Regional Citizens' Advisory Council.

Extension of Certification

By letter dated December 17, 1992, the Chief, Office of Marine Safety, Security, and Environmental Protection extended, through June 30, 1993, the certification for the Prince William Sound Regional Citizens' Advisory Council to act as an alternative voluntary advisory group under the provisions of 33 U.S.C. 2732(o).

Issued on: January 6, 1993.

R.C. North,

Captain, U.S. Coast Guard Acting Chief, Office of Marine Safety, Security and Environmental Protection.

[FR Doc. 92–793 Filed 1–12–92; 8:45 am]

BILLING CODE 4910–14–M

[CGD 92-078]

Discontinuance of Coast Guard Medium Frequency (MF) Morse Radiotelegraphy Services

AGENCY: Coast Guard, DOT.

ACTION: Notice of intent.

SUMMARY: The United States Coast Guard intends to discontinue watchkeeping on the distress frequency 500 kHz at all of its Communication Stations and cutters, and cease all Morse Code services in the medium frequency radiotelegraphy band effective August 1, 1993.

FOR FURTHER INFORMATION CONTACT: LCDR Frank Irr, Telecommunications Operations Division (G-TTO), Office of Command, Control and Communications, U.S. Coast Guard, 2100 Second Street SW., Washington, DC 20593-0001, telephone (202) 267-1348, telefax (202) 267-4662, or telex 892427 (COASTGUARD WASH). Normal office hours are between 7 a.m. and 3:30 p.m. Monday through Friday, except holidays.

SUPPLEMENTARY INFORMATION: Morse radiotelegraphy was first used to save lives at sea in 1899. In 1914, after the sinking of the TITANIC, the first International Convention for the Safety of Life at Sea (SOLAS) was adopted, requiring certain ships to maintain a continuous Morse radiotelegraphy listening watch to ensure that calls from a ship in distress would be received. Coast stations had similar requirements to maintain a continuous listening watch during their hours of service. This maritime radio distress system was originally developed as a ship-to-ship alerting system, but slowly evolved into a ship-to-shore alerting system as radio performance improved and shore-based rescue coordination centers were created. Use of Morse telegraphy as the primary international distress and calling system for ships at sea has remained relatively unchanged for almost 100 years.

The Global Maritime Distress and Safety System (GMDSS) amendments to the SOLAS Convention were adopted in 1988. This system is more efficient and provides the mariner with options for initiating or relaying distress alerts, and passing and receiving maritime safety information. Options now available in the United States include Inmarsat satellite, radio telex, MF/HF single sideband, VHF radiotelephone, and satellite emergency position indicating radiobeacons (EPIRBs) for distress alerts and telecommunications; and Inmarsat SafetyNET, Navtex and HF Navtex for maritime safety information broadcasts. The SOLAS Convention requires that ships install Navtex equipment and satellite EPIRBs by August 1, 1993.

Navtex broadcasts include the same notices to mariners, weather, search and rescue and fixed fishing gear location products that have been provided by United States MF Morse broadcasts. Distress and other calls to any U.S. Coast Guard Communication Station can also be made on any of the following HF single sideband radiotelephone channels: 424 (4134 kHz), 601 (6200 kHz), 816 (8240 kHz), 1205 (12242 kHz).

The Coast Guard believes that the above options are sufficient to ensure that adequate distress and safety communication capabilities are available. Therefore, effective August 1, 1993, the Coast Guard will cease all medium frequency Morse radiotelegraphy services.

D.E. Ciancaglini,

Rear Admiral, U.S. Coast Guard, Chief, Office of Command, Control and Communications.

[FR Doc. 93-791 Filed 1-12-93; 8:45 am]

BILLING CODE 4910-14-M

[CGD2-93-01]

Second Coast Guard District Industry Day

AGENCY: Coast Guard, DOT.

ACTION: Notice of meeting.

DISCUSSION OF NOTICE: On 18 March 1993, the Commander, Second Coast Guard District will sponsor an Industry Day program to provide an open exchange of information, ideas, and opinions on matters of mutual interest or concern to the inland marine community and the Coast Guard. Industry Day activities will be held at the Henry VIII Hotel, 4690 North Lindbergh, St. Louis, Missouri as follows:

Wednesday, 17 March

5-7 p.m. Registration for early arrivals.

Thursday, 18 March

7:30 a.m.—Registration continues.
8:30 a.m.—General Session: Opening comments-Selected Presentations.
10 a.m.—Panel Discussions: Three separate small group panels focusing on Towing Industry, Shoreside Facilities, and Small Passenger Vessel Industry.
12 p.m.—Banquet-style luncheon.
1:30 p.m.—Panel Discussions continue.
4:30 p.m.—Industry Day concludes.

Advance registration and payment of the $24.00 conference fee is required. The fee includes the luncheon and refreshments. Registration forms or additional information on the Industry Day activities and events scheduled by other groups to coincide with Industry Day may be obtained from one of the officers named below. Written recommendations for agenda discussion topics are encouraged and should be mailed directly to one of the officers named below. Registration forms and fees should be mailed directly to the Henry VIII Hotel, Attn: Reservations, c/o Amelia Koncki, 4690 N. Lindbergh, St. Louis, Missouri 63044 and must be received by March 15, 1993.

FOR FURTHER INFORMATION CONTACT: Commander Jonathan S. Glantz or Lieutenant Charles L. McAllister, Commander (mpb), Second Coast Guard District, 1222 Spruce Street, room 2.102G, St. Louis, Missouri 63103-2832. The telephone number is: (314) 539-2655.

Dated: December 29, 1992.

Norman T. Saunders,

Rear Admiral (Lower Half), United States Coast Guard; Commander, Second Coast Guard District.

[FR Doc. 93-789 Filed 1-12-93; 8:45 am]

BILLING CODE 4910-14-M

Federal Transit Administration

FTA Sections 3 and 9 Grant Obligations

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice.

SUMMARY: The Department of Transportation and Related Agencies Appropriations Act, 1993, Public Law 102-338, signed into law by President George Bush on October 6, 1992, contains a provision requiring the Federal Transit Administration (FTA) to publish an announcement in the Federal Register every 30 days of grants obligated pursuant to sections 3 and 9 of the Federal Transit Act, as amended. The statute requires that the announcement include the grant number, the grant amount, and the transit property receiving each grant. This notice provides the information as required by statute.

FOR FURTHER INFORMATION CONTACT: Janet Lynn Sahaj, Chief, Resource Management and State Programs Division, Office of Capital and Formula Assistance, Department of Transportation, Federal Transit Administration, Office of Grants Management, 400 Seventh Street, SW., room 9305, Washington, DC 20590, (202) 366-2053.

SUPPLEMENTARY INFORMATION: The section 3 program provides capital assistance to eligible recipients in three categories: Fixed guideway modernization, construction of new fixed guideway systems and extensions, and bus purchases and construction of bus related facilities. The section 9 program apportions funds on a formula basis to provide capital and operating assistance in urbanized areas. Section 9 grants reported may include flexible funds transferred from the Federal Highway Administration to the FTA for use in transit projects in urbanized areas. These flexible funds are authorized under the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA) to be used for highway or transit purposes. Pursuant to the statute FTA reports the following grant information.

SECTION 3 GRANTS

Transit property	Grant No.	Grant amount	Obligation date
Port Authority of Allegheny County, Pittsburgh, PA	PA-03-0227-00	$13,200,000	10/29/92
Michigan Department of Transportation, Michigan	MI-01-0128-00	9,675,000	11/02/92
Bi-State Development Agency, St. Louis, MO-IL	MO-03-0027-04	39,303,000	11/16/92
City of Tucson, Tucson, AZ	AZ-03-0016-00	3,254,316	12/28/92
San Francisco Bay Area Rapid Transit District, San Francisco-Oakland, CA	CA-03-0384-00	12,800,000	12/22/92
Metropolitan Dade Transit Agency, Miami-Hialeah, FL	FL-03-0131-00	7,250,000	12/08/92
State of Hawaii, Kauai, Hawaii	HI-03-0016-00	2,000,000	12/22/92
Des Moines Metropolitan Transit Authority, Des Moines, IA	IA-03-0068-00	80,000	12/22/92
City of Detroit Department of Transportation, Detroit, MI	MI-03-0120-01	2,415,850	12/07/92
City of Minneapolis—Office of City Coordinator, Minneapolis-St. Paul, MN	MN-03-0045-06	8,000,000	12/07/92
New Jersey Transit Corporation, New York, NY—Northeastern, NJ	NJ-03-0094-00	21,000,000	12/09/92
Rhode Island Department of Transportation, Providence-Pawtucket, RI-MA	RI-03-0016-00	3,312,000	12/29/92

SECTION 9 GRANTS

Transit property	Grant No.	Grant amount	Obligation date
Gary Public Transportation Corporation, Chicago, IL—Northwestern IN	IN-90-X174-00	$2,576,211	10/30/92
Transit Authority of River City, Louisville, KY-IN	KY-90-X040-01	56,445	10/30/92
Dallas Area Rapid Transit, Dallas-Ft. Worth, TX	TX-90-X248-00	19,834,000	10/01/92
City of Waco, Waco, TX	TX-90-X260-00	1,663,270	10/21/92
City of Phoenix, Phoenix, AZ	AZ-90-X030-00	12,127,534	11/05/92
City of Phoenix, Phoenix, AZ	AZ-90-X031-00	535,598	11/05/92
City of Phoenix, Phoenix, AZ	AZ-90-X033-00	5,700,000	11/05/92
Kalamazoo Metro Transit, Kalamazoo, MI	MI-90-X157-01	169,056	11/30/92
Municipality of Anchorage, Anchorage, AK	AK-90-X010-00	761,428	12/28/92
City of Tucson, Tucson, AZ	AZ-90-X034-00	4,607,418	12/28/92
City of Modesto, Modesto, CA	CA-90-X482-00	1,293,056	12/22/92
City of Lompoc, Lompoc, CA	CA-90-X507-00	161,832	12/22/92
San Diego Association of Governments, San Diego, CA	CA-90-X521-00	909,000	12/21/92
Sunline Transit Agency, Palm Springs, CA	CA-90-X522-00	1,081,842	12/21/92
City of Pueblo, Pueblo, CO	CO-90-X071-00	1,474,585	12/28/92
Mesa County, Grand Junction, CO	CO-90-X072-00	284,920	12/28/92
Connecticut Department of Transportation, Connecticut	CT-90-X213-00	11,445,960	12/24/92
Connecticut Department of Transportation, Connecticut	CT-90-X214-00	4,454,000	12/29/92
Greater Hartford Transit District, Hartford-Middletown, CT	CT-90-X215-00	1,675,800	12/29/92
Connecticut Department of Transportation, Connecticut	CT-90-X216-00	484,817	12/29/92
Milford Transit District, Bridgeport-Milford, CT	CT-90-X217-00	75,000	12/29/92
East Volusia County—East Volusia Transportation Authority, Daytona Beach, FL	FL-90-X198-00	1,112,147	12/21/92
Broward Co Bd of Co Commissioners—Broward Co Mass Transit Division, Ft. Lauderdale-Hollywood-Pompano Bch, FL	FL-90-X199-00	7,220,544	12/21/92
Sarasota County Transportation Authority, Sarasota-Bradenton, FL	FL-90-X207-00	2,000,000	12/21/92
Panama City Metropolitan Planning Organization, Panama City, FL	FL-90-X212-00	179,680	12/21/92
City of Tallahassee—Tallahassee Transit Authority, Tallahassee, FL	FL-90-X213-00	797,600	12/21/92
City of New Smyrna Beach—Smyrna Transit System, Daytona Beach, FL	FL-90-X214-00	195,809	12/21/92
Cedar Rapids Transit Department, Cedar Rapids, IA	IA-90-X139-00	1,026,926	12/18/92
Keyline Bus System, Dubuque, IA-IL	IA-90-X140-00	394,226	12/23/92
City of Sioux City, Sioux City, IA-NE-SD	IA-90-X145-00	571,429	12/23/92
Greater Lafayette Public Transportation Corporation, Lafayette-West Lafayette, IN	IN-90-X172-00	848,435	12/18/92
City of Kokomo, Indiana, Kokomo, IN	IN-90-X173-00	303,378	12/18/92
Evansville Urban Transit Study, Evansville, IN-KY	IN-90-X174-00	1,505,454	12/18/92
Fort Wayne Public Transportation Corp., Fort Wayne, IN	IN-90-X175-00	1,148,827	12/18/92
Indianapolis Public Transportation Corporation, Indianapolis, IN	IN-90-X177-00	3,391,900	12/18/92
Johnson County Transit, Kansas City, KS-MO	KS-90-X056-00	295,319	12/23/92
Jefferson Parish, New Orleans, LA	LA-90-X138-00	2,340,000	12/22/92
City of Baton Rouge, Baton Rouge, LA	LA-90-X139-00	1,743,077	12/22/92
Berkshire County Regional Planning Commission, Pittsfield, MA	MA-90-X144-00	20,000	12/29/92
Greater Attleboro-Taunton Regional Transit Authority, Taunton, MA	MA-90-X145-00	1,123,983	12/29/92
Southeastern Regional Transit Authority, New Bedford, MA	MA-90-X146-00	1,863,503	12/29/92
Worcester Regional Transit Authority, Worcester, MA-CT	MA-90-X148-00	2,466,150	12/29/92
Merrimack Valley Regional Transit Authority, Lawrence-Haverhill, MA-NH	MA-90-X150-00	4,385,875	12/29/92
Cape Ann Transportation Authority, Boston, MA	MA-90-X153-00	75,000	12/29/92
Greater Portland Transit District, Portland, ME	ME-90-X064-00	401,020	12/29/92
Suburban Mobility Authority for Regional Transportation, Detroit, MI	MI-90-X150-01	2,174,978	12/09/92
Grand Rapids Area Transit Authority, Grand Rapids, MI	MI-90-X164-00	1,530,723	12/18/92
Twin Cities Area Transportation Authority, Benton Harbor, MI	MI-90-X165-00	404,139	12/18/92
City of Moorhead, Fargo-Moorhead, ND-MN	MN-90-X063-06	259,896	12/28/92
City of Springfield City Utilities, Springfield, MO	MO-90-X079-00	815,000	12/16/92

SECTION 9 GRANTS—Continued

Transit property	Grant No.	Grant amount	Obligation date
Bi-State Development Agency, St. Louis, MO–IL	MO–90–X067–00	9,958,709	12/23/92
Kansas City Area Transportation Authority, Kansas City, MO–KS	MO–90–X068–00	4,451,011	12/28/92
City of Hattiesburg—Planning & Community Development, Hattiesburg, MS	MS–90–X044–00	238,095	12/21/92
City of Durham, Durham, NC	NC–90–X139–01	649,869	12/21/92
City of Asheville, Asheville, NC	NC–90–X147–00	702,641	12/21/92
City of Raleigh, Raleigh, NC	NC–90–X148–00	2,130,373	12/21/92
Town of Chapel Hill, Durham, NC	NC–90–X149–00	1,016,999	12/21/92
City of Bismarck, Bismarck, ND	ND–90–X028–00	344,792	12/28/92
Cooperative Alliance for Seacoast Transportation, Portsmouth-Dover-Rochester, NH–ME	NH–90–X035–00	2,674	12/29/92
New Jersey Transit Corporation, New York, NY—Northeastern NJ	NJ–90–X035–00	30,000,000	12/23/92
New Jersey Transit Corporation, New York, NY—Northeastern NJ	NJ–90–X036–00	4,000,000	12/22/92
Regional Transportation Commission of Clark County, Las Vegas, NV	NV–90–X018–01	1,728,036	12/28/92
Regional Transportation Commission of Washoe County, Reno, NV	NV–90–X019–00	1,686,986	12/28/92
Niagara Frontier Transportation Authority, Buffalo-Niagara Falls, NY	NY–90–X233–00	4,000,000	12/23/92
Dutchess County, Poughkeepsie, NY	NY–90–X236–00	796,400	12/23/92
New York Metropolitan Transportation Authority, New York, NY—Northeastern NJ	NY–90–X237–01	50,000,000	12/23/92
New York Metropolitan Transportation Authority, New York, NY—Northeastern NJ	NY–90–X239–00	93,726,964	12/16/92
Niagara Frontier Transportation Authority, Buffalo-Niagara Falls, NY	NY–90–X243–00	492,000	12/28/92
Utica Transit Authority, Utica-Rome, NY	NY–90–X248–00	472,089	12/24/92
Saratoga County Planning Board, Albany-Schenectady-Troy, NY	NY–90–X249–00	1,048,000	12/23/92
Greater Glens Falls Transit System, Glen Falls, NY	NY–90–X250–00	302,638	12/28/92
Niagara Frontier Transportation Authority, Buffalo-Niagara Falls, NY	NY–90–X251–00	7,394,347	12/28/92
Canton Regional Transit Authority, Canton, OH	OH–90–X173–00	1,089,091	12/18/92
Portage Area Regional Transportation Authority, Akron, OH	OH–90–X177–00	253,901	12/23/92
Greater Cleveland Regional Transit Authority, Cleveland, OH	OH–90–X179–00	13,446,720	12/18/92
Metropolitan Tulsa Transit Authority, Tulsa, OK	OK–90–X042–00	2,092,493	12/22/92
Rogue Valley Transportation District, Medford, OR	OR–90–X042–01	111,419	12/28/92
Cumberland-Dauphin-Harrisburg Transit Authority, Harrisburg, PA	PA–90–X241–01	1,117,403	12/21/92
City of Sharon, Sharon, PA–OH	PA–90–X243–00	266,864	12/24/92
Southeastern Pennsylvania Transportation Authority, Philadelphia, PA–NJ	PA–90–X246–00	54,662,198	12/16/92
Commonwealth of Puerto Rico—Department of Transp. and Public Works, San Juan, PR	PR–90–X011–08	1,600,000	12/28/92
Municipality of Manati, Vega Baja-Manati, PR	PR–90–X066–01	592,000	12/21/92
Metropolitan Bus Authority, San Juan, PR	PR–90–X072–00	7,251,519	12/21/92
Municipality of Manati, Vega Baja-Manati, PR	PR–90–X073–00	440,000	12/21/92
Rhode Island Department of Transportation, Providence-Pawtucket, RI–MA	RI–90–X021–00	5,654,349	12/29/92
City of Rapid City, Rapid City, SD	SD–90–X021–00	443,756	12/28/92
City of Sioux Falls, Sioux Falls, SD	SD–90–X022–00	741,032	12/28/92
City of Knoxville, Knoxville, TN	TN–90–X106–00	1,484,640	12/21/92
City of San Angelo, San Angelo, TX	TX–90–X257–00	564,990	12/22/92
City of Galveston, Galveston, TX	TX–90–X258–00	819,600	12/22/92
City of Plano, Dallas-Ft. Worth, TX	TX–90–X262–00	13,000	12/22/92
City of Beaumont, Beaumont, TX	TX–90–X263–00	836,431	12/22/92
City of Amarillo, Amarillo, TX	TX–90–X264–00	1,090,833	12/22/92
Corpus Christi Regional Transit Authority, Corpus Christi, TX	TX–90–X265–00	2,309,844	12/22/92
Peninsula Transportation District Commission, Newport News-Hampton, VA	VA–90–X095–01	1,956,195	12/22/92
City of Charlottesville, Charlottesville, VA	VA–90–X104–00	525,524	12/18/92
Snohomish County Transportation Authority, Seattle, WA	WA–90–X138–00	300,000	12/22/92

Issued on: January 8, 1993.

Brian W. Clymer,

Administrator.

[FR Doc. 93–763 Filed 1–12–93; 8:45 am]

BILLING CODE 4910–57–M

National Highway Traffic Safety Administration

[Docket No. 92–54; Notice 2]

Determination that Nonconforming 1986 BMW 316 Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of determination by NHTSA that nonconforming 1986 BMW 316 passenger cars are eligible for importation.

SUMMARY: This notice announces the determination by NHTSA that 1986 BMW 316 passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because they are substantially similar to a vehicle originally manufactured for importation into and sale in the United States and certified by its manufacturer as complying with the safety standards (the 1986 GMW 325), and they are capable of being readily modified to conform to the standards.

DATE: The determination is effective January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Ted Bayler, Office of Vehicle Safety Compliance, NHTSA (202–366–5306).

SUPPLEMENTARY INFORMATION:

Background

Under section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act), 15 U.S.C. 1397(c)(3)(A)(i), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States on and after January 31, 1990, unless NHTSA has determined that

> (I) the motor vehicle is * * * substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under section 114 [of the Act], and of the same model year * * * as the model of the motor vehicle to be compared, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards * * *

Petitions for eligibility determinations may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment

period, NHTSA determines, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this determination in the **Federal Register**.

Wallace Environmental Testing Laboratories, Inc. of Houston, Texas [Registered Importer R–90–005] petitioned NHTSA to determine whether 1986 BMW 316 passenger cars are eligible for importation into the United States. NHTSA published notice of the petition on October 7, 1992 (57 FR 46236) to afford an opportunity for public comment. The reader is referred to that notice for a thorough description of the petition. No comments were received in response to the notice. Based on its review of the information submitted by the petitioner, NHTSA has determined to grant the petition.

Vehicle Eligibility Number for Subject Vehicles

The importer of a vehicle admissible under any final determination must indicate on the form HS–7 accompanying entry the appropriate vehicle eligibility number indicating that the vehicle is eligible for entry. VSP #25 is the vehicle eligibility number assigned to vehicles admissible under this notice of final determination.

Final Determination

Accordingly, on the basis of the foregoing, NHTSA hereby determines that a 1986 BMW 316 is substantially similar to a 1986 BMW 325 originally manufactured for importation into and sale in the United States and certified under section 114 of the National Traffic and Motor Vehicle Safety Act, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Authority: 15 U.S.C. 1397(c)(3)(A)(i)(I) and (C)(ii); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: January 7, 1993.

William A. Boehly,

Associate Administrator for Enforcement.

[FR Doc. 93–765 Filed 1–12–93; 8:45 am]

BILLING CODE 4910–59–M

[Docket No. 92–47; Notice 2]

Transportation Manufacturing Corp.; Grant of Petition for Determination of Inconsequential Noncompliance

This notice grants the petition of the Transportation Manufacturing Corporation (TMC) of Roswell, New Mexico, to be exempted from the notification and remedy requirements of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1381 *et seq.*) on the basis that its noncompliance with Federal Motor Vehicle Safety Standard No. 106, "Brake Hoses," is inconsequential as it related to motor vehicle safety.

Notice of receipt of the petition was published on September 11, 1992, and an opportunity afforded for comment (57 FR 41804).

Paragraph S7.3.7 of Standard No. 106 specifies that, "[e]xcept for hose reinforced by wire, an air brake hose shall withstand a tensile force of 8 pounds per inch of length before separation of adjacent layers."

TMC was notified by Dana Corporation (the manufacturer of this hose) of a potential cover adhesion noncompliance involving its H33806 hose which TMC used for air brake applications on buses manufactured at Roswell, New Mexico. Some of the subject hoses do not comply with the adhesion requirements of FMVSS No. 106, "Brake Hoses."

TMC supports its petition for inconsequential noncompliance with the following.

TMC states that the subject hoses are used in two applications. In the first, the hose operates at 85 pounds per square inch (psi) air pressure and the only function is to keep the parking brake off. If the hose were to fail completely in this application, the parking brake would immediately engage. The service brake would remain functional, but air pressure would rapidly be lost in the system. In the second, the hose operates at 100 psi air pressure and it functions as part of the backup brake system. In this application, a hose failure would not affect the operation of a properly functioning main service brake system.

Due to the length of time the subject hoses have been on the buses, differentiating the possibly noncompliant hoses from the compliant ones would be difficult, if not impossible, due to wear and tear from typical use. TMC estimates that less than eight percent of the installed hoses are of the potentially noncompliant type, but over 4,500 hoses would be required to be repalced if a recall were required. TMC believes that the potential safety problems would be greater if all 4,500 hoses were replaced without factory quality control, than if the existing hoses continue to be used.

In summary, based on TMC's warranty history and the function of the hoses, TMC believes that the noncompliance will not affect the safety of their vehicles and, therefore, is inconsequential as it relates to motor vehicle safety.

No comments were received on the petition.

A petition by Navistar International relating to adhesion failures in hoses manufactured by Dana was granted on October 11, 1991 (56 FR 51440), on the basis of the following arguments:

1. The end use of the hoses is such that they are subject to pressure, not vacuum applications.

2. If the hoses are used in vacuum applications, their crimped end fittings make it unlikely that air would become trapped between the layers of the hose.

3. If there is any permeation of air from the inner tube, the hoses are designed to release it through the pin-pricked outer layer.

The hoses used by the petitioner are Dana Weatherhead hoses and they are used in pressure applications. The outer layer of the hoses is pin-pricked. The hoses are equipped with the same crimped end fittings as the Weatherhead hoses. Thus, the same factors exist in this case as the previous petition which was granted.

Accordingly, petitioner has met its burden of persuasion that the noncompliance herein described is inconsequential as it relates to motor vehicle safety, and its petition is granted.

(15 U.S.C. 1417; delegations of authority at 49 CFR 1.50 and 49 CFR 501.8)

Issued on: January 7, 1993.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 93–698 Filed 1–12–93; 8:45 am]

BILLING CODE 4910–59–M

Research and Special Programs Administration

[Notice No. 93–2]

Metric Conversion Policy

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of proposed policy and request for comments.

SUMMARY: This document solicits comments on a proposed policy that would promote an orderly conversion to the metric system for all RSPA programs which are affected by the statutory mandates of Section 5164 of the Omnibus Trade and Competitiveness Act, Public Law 100–418. This Act makes it the policy of the United States to designate the metric system of measurement as the preferred system of weights and measures for United States trade and commerce. The Act requires Federal agencies to use the metric system in procurements, grants, and

other business-related activities to the extent economically feasible by the end of 1992. RSPA will comply with the policy established by the Department of Commerce, the agency leading this effort, and by the Department of Transportation.

DATES: Written Comments must be received on or before February 22, 1993.

ADDRESSES: Submit written, signed comments to the number assigned to this notice, Research and Special Programs Administration, Volpe National Transportation Systems Center, Management Systems Office, room 1127, 55 Broadway, Cambridge, MA 02142. All comments received will be available for examination.

FOR FURTHER INFORMATION CONTACT: David M. Daley, Management Systems Office, at the above address or telephone (617) 494–2419.

SUPPLEMENTARY INFORMATION:

I. Background

Federal agencies are required to use the metric system of measurement in procurement, grants and other business-related activities, except to the extent that such use is impractical or is likely to cause significant inefficiencies or loss of markets to the United States firms, such as when foreign competitors are producing competing products in non-metric units. (Omnibus Trade and Competitiveness Act Pub. L. 100–418, section 5164.) The U.S. Department of Commerce published its guidance for Federal agencies, which requires these agencies to: (1) Establish metric conversion plans and dates for use of the metric system to procurement, grants, and other business-related activities; (2) coordinate with other Federal agencies, State and local governments and the private sector; (3) assist in the removal of barriers to metric system transition; and (4) provide for full public involvement and timely information about significant metrification policies, programs and actions.

The Department of Commerce further requires that Federal agencies shall give due consideration to known effects of their actions on State and local governments and the private sector as well as publications or agency statements of general applicability and future effect designed to implement, interpret, or prescribe law or policy or describe the paying business particular attention to effect on small business. (Omnibus Trade and Competitiveness Act Pub. L. 100–418, section 5164.)

The Department of Transportation has issued implementing guidance under DOT Order 1020.1C. The Order states that the Department of Commerce interprets the 1992 deadline for metric conversion to mean that plans scheduling such conversion should be in place by then, with some conversion underway and other conversions scheduled, as appropriate, for later dates. For purposes of these guidelines such scheduled conversions should be completed where possible by 1997, and where necessary go beyond that year.

II. Purpose

The purpose of this notice is to solicit comments on the action and the proposed timetable for conversion to the metric system for all RSPA programs.

Metric conversion for RSPA is not voluntary; it is now mandatory for RSPA's procurement, grants, and other business-related activities, except to the extent that such use is impractical or is likely to cause significant inefficiencies or loss of markets to United States firms.

A. Definitions

Metric system means the international System of Units (SI) established by the General Conference of Weights and Measures in 1960, as interpreted or modified from time to time for the United States by the Secretary of Commerce under the authority of the Metric Conversion Act of 1975.

Other business-related activities means measurement-sensitive commercial or business-directed transactions or programs, i.e., standard or specification development, procedure or practice requirements of an agency.

Measurement-sensitive means that the choice of a measurement unit is a critical component of the activity; i.e., an agency rule/regulation to collect samples or measure something at specific distances or to specific depths, or specifications, requiring intake or discharge of a product to certain volumes or flow rates; guidelines for clearances between objects for safety, security or environmental purposes, etc.

B. General Policy

RSPA will promote an orderly transition to the metric system for all programs in accordance with the statutory requirements, Department of Commerce policy guidance and Department of Transportation guidance.

The Federal Acquisition Regulations issued by the General Services Administration (GSA), in addition to other GSA and DOT regulations and policies, will govern metric conversion of RSPA's procurement policies. RSPA will determine the training needs of personnel most closely associated with implementation of the metric conversion plan. Requests for conversion tables and staff training will provide minimal impact on budgetary planning for most programs.

Training activities will be coordinated through the DOT's Metric Coordinating Committee. RSPA will establish a working committee with representatives from each program area to coordinate the implementation of its metric conversion plan. RSPA timetable for total metric conversion is FY 1997.

C. Program Exclusions

Metric usage shall not be required to the extent such use is impractical or is likely to cause significant inefficiencies or loss of markets to United States firms. (Omnibus Trade and Competitiveness Act Pub. L. 100–418, section 5164).

Issued on: January 7, 1993.

Douglas Ham,

Acting Administrator.

[FR Doc. 93–764 Filed 1–12–93; 8:45 am]

BILLING CODE 4910-60-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Dated: January 7, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Financial Management Service

OMB Number: 1510–0035
Form Number: None
Type of Review: Extension
Title: Assignment Form
Description: This form is used when awardholders wish to assign or transfer all or a portion of their award to another person. In doing so, awardholder forfeits all future rights to the portion assigned.
Respondents: Individuals or households
Estimated Number of Respondents: 150
Estimated Burden Hours Per Response: 30 minutes
Frequency of Response: Other (as needed)
Estimated Total Reporting Burden: 75 hours

Clearance Officer: Jacqueline R. Perry, (301) 344–8577, Financial Management Service, 3361–L 75th Avenue, Landover, MD 20785.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports, Management Officer.
[FR Doc. 93–762 Filed 1–12–93; 8:45 am]
BILLING CODE 4810–35–M

Public Information Collection Requirements Submitted to OMB for Review

Dated: January 7, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–0633
Form Number: IRS Notices 437, 438, 466
Type of Review: Extension
Title: Notice of Intention to Disclose
Description: Notice is required by 26 U.S.C. 6110(f). A reply is necessary if recipient disagrees with the Service's proposed deletions. The Service uses the reply to consider propriety of making additional deletions to public inspection version of written determinations or related background file documents.
Respondents: Individuals or households, State or local governments, Farms, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations
Estimated Number of Respondents: 5,000
Estimated Burden Hours Per Respondent: 30 minutes
Frequency of Response: On occasion
Estimated Total Reporting Burden: 2,500 hours.
OMB Number: 1545–0806
Regulation ID Number: EE–12–78 Final
Type of Review: Extension
Title: Nonbank Trustees of Pension and Profit-Sharing Trusts Benefiting Owner-Employees
Description: IRS section 408(a)(2) permits a person other than a bank to be the trustee of an IRA. To do so, application needs to be filed and various qualifications need to be met. IRS uses the information to determine whether a person qualifies to be a non-bank trustees.
Respondents: Businesses or other for-profit, Small businesses or organizations
Estimated Number of Respondents/ Recordkeepers: 340
Estimated Burden Hours Per Respondent/Recordkeeper: 46 minutes
Frequency of Response: On occasion
Estimated Total Reporting/ Recordkeeping Burden: 260.
OMB Number: 1545–0881
Form Number: IRS Form 8271
Type of Review: Extension
Title: Investor Reporting of Tax Shelter Registration Number
Description: All persons who are claiming a deduction, loss, credit, or other tax benefit, or reporting any income on their returns from a tax shelter required to be registered (under IRC 6111) must report the tax shelter registration number on that return. Form 8271 is used for this. We use the information to associate claimed benefits with the tax shelter and to determine if any compliance actions are needed.
Respondents: Individuals or households, State or local governments, Farms, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations
Estimated Number of Respondents/ Recordkeepers: 297,500
Estimated Burden Hours Per Respondent/Recordkeeper:

Recordkeeping	7 minutes
Learning about the law or the form	15 minutes
Preparing the form	17 minutes
Copying, assembling, and sending the form to the IRS	14 minutes

Frequency of Response: Annually
Estimated Total Reporting/ Recordkeeping Burden: 258,825 hours
Clearance Officer: Garrick Shear, (202) 622–3869, Internal Revenue Service, Room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,
Departmental Reports, Management Officer.
[FR Doc. 93–761 Filed 1–12–93; 8:45 am]
BILLING CODE 4830–01–M

DEPARTMENT OF VETERANS AFFAIRS

Information Collection Under OMB Review

AGENCY: Department of Veterans Affairs.
ACTION: Notice.

The Department of Veterans Affairs has submitted to OMB the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). This document lists the following information: (1) The title of the information collection, and the Department from number(s), if applicable; (2) a description of the need and its use; (3) who will be required or asked to respond; (4) an estimate of the total annual reporting hours, and recordkeeping burden, if applicable; (5) the estimated average burden hours per respondent; (6) the frequency of response; and (7) an estimated number of respondents.

ADDRESSES: Copies of the proposed information collection and supporting documents may be obtained from Patti Viers, Records Management Service (723), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420 (202) 233–3172.

Comments and questions about the items on the list should be directed to VA's OMB Desk Officer, Joseph Lackey, NEOB, room 3002, Washington, DC 20503, (202) 395–7316. Do not send requests for benefits to this address.

DATES: Comments on the information collection should be directed to the OMD Desk Officer on or before February 12, 1993.

Dated: January 6, 1993.
By direction of the Secretary:

Frank E. Lalley,
Associate Deputy Assistant Secretary for Information Resources Policies and Oversight.

Extension

1. 38 CFR 1.519 Lists of Names and Addresses.

2. The information is used to determine whether an applicant for a list of VA beneficiary names and addresses is a nonprofit organization and intends to use the list for a proper purpose.

3. State or local Governments—Non-profit institutions.
4. 106 hours.
5. 60 minutes.
6. On occasion.
7. 106 respondents.

[FR Doc. 93-769 Filed 1-12-93; 8:45 am]

BILLING CODE 6820-01-M

VOL 58 ISS 8 JA 13 1993 UMI

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COMMODITY "FEDERAL PREVIOUS PREVIOUSL MEETING: 1 4, 1993.

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CONTACT P Jean A. W Jean A. We *Secretary o*

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DEFENSE N BOARD:

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PLACE: Fe 825 Jadwi 99352.

STATUS: C the Sunsh the sched a meeting that an op case furth underlyin the Board

MATTERS public me held so as latest and of current the Hanfo members

Sunshine Act Meetings

Federal Register
Vol. 58, No. 8
Wednesday, January 13, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 375.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:30 a.m., Thursday, January 4, 1993.

CHANGES IN THE MEETINGS: The Commodity Futures Trading Commission has cancelled the meeting previously announced to discuss Enforcement Matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, 254–6314.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 93–882 Filed 1–11–93; 2:26 pm]

BILLING CODE 6351–01–M

DEFENSE NUCLEAR FACILITIES SAFETY BOARD:

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given of the Board's meeting described below. The Board will also conduct a public hearing pursuant to 42 U.S.C. 2286b and invites any interested persons or groups to present any comments, technical information, or data concerning current health or safety questions at the Hanford Site.

TIME AND DATE: 5:30 p.m. February 11, 1993—Department of Energy presentations; 8:00 p.m.—Opportunity for interested persons to present oral comments concerning the matters to be considered.

PLACE: Federal Building Auditorium, 825 Jadwin Avenue, Richland, WA 99352.

STATUS: Open. While the Government in the Sunshine Act does not require that the scheduled briefing be conducted in a meeting, the Board has determined that an open meeting in this specific case furthers the public interests underlying both the Sunshine Act and the Board's enabling legislation.

MATTERS TO BE CONSIDERED: The open public meeting and hearing are being held so as to provide the Board with the latest and best information on a number of current health and safety questions at the Hanford Site, and to receive from members of the public any pertinent comments they wish to make on these or other Hanford-related health and safety issues. The Department of Energy will take appropriate measures to safeguard any classified or controlled nuclear information it presents at this meeting. The public hearing portion is independently authorized by 42 U.S.C. 2286b.

FOR FURTHER INFORMATION CONTACT: Kenneth M. Pusateri, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue, NW, Suite 700, Washington, DC 20004, (202) 208–6400. This is not a toll free number.

SUPPLEMENTARY INFORMATION: Requests to speak at the hearing may be submitted in writing or by telephone. We ask that commentators describe the nature and scope of the oral presentation. Those who contact the Board prior to close of business on February 8, 1993, will be scheduled for time slots, beginning at approximately 8:00 p.m. The Board will post a schedule for those speakers who have contacted the Board before the hearing. The posting will be made at the entrance to the Federal Building Auditorium at the start of the 5:30 p.m. meeting.

Anyone who wishes to comment, provide technical information or data may do so in writing, either in lieu of, or in addition to making an oral presentation. The Board members may question presenters to the extent deemed appropriate. The Board will hold the record open until February 22, 1993, for the receipt of materials. A transcript of the meeting will be made available by the Board for inspection by the public at the Defense Nuclear Facilities Safety Board's Washington office and at the DOE's public reading room at DOE's Richland Field Office, Federal Building, Room 157 (A1–65), 825 Jadwin Avenue, Richland, WA 99352.

The Board specifically reserves its right to further schedule and otherwise regulate the course of the meeting and hearing, to recess, reconvene, postpone or adjourn the meeting, conduct further reviews, and otherwise exercise its power under the Atomic Energy Act of 1954, as amended.

Dated: January 11, 1993.

Robert M. Andersen,

General Counsel.

[FR Doc. 93–949 Filed 1–11–93; 2:29 pm]

BILLING CODE 6820–KD–M

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 57 FR 61965, Tuesday, December 29, 1992.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:00 a.m. (Eastern Time), Tuesday, January 12, 1993.

CHANGE IN THE MEETING: The meeting has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: Frances M. Hart, Executive Officer, on (202) 663–4070.

Dated: January 11, 1993.

Frances M. Hart,

Executive Officer, Executive Secretariat.

[FR Doc. 93–959 Filed 1–11–93; 2:46 pm]

BILLING CODE 6750–06–M

FARM CREDIT ADMINISTRATION

Farm Credit Administration Board; Regular Meeting

SUMMARY: Notice is hereby given, pursuant to the Government in the Sunshine Act (5 U.S.C. 552b(e)(3)), of the forthcoming regular meeting of the Farm Credit Administration Board (Board).

DATE AND TIME: The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on January 14, 1993, from 10:00 a.m. until such time as the Board concludes its business.

FOR FURTHER INFORMATION CONTACT: Curtis M. Anderson, Secretary to the Farm Credit Administration Board, (703) 883–4003, TDD (703) 883–4444.

ADDRESSES: Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102–5090.

SUPPLEMENTARY INFORMATION: Parts of this meeting of the Board will be open to the public (limited space available), and parts of this meeting will be closed to the public. The matters to be considered at the meeting are:

Open Session

VOL 58 ISS 8 JA 13 1993 UMI

A. Approval of Minutes

B. Reports

1. Collateral Evaluation Regulations

C. Unfinished Business

1. Privacy Act Notice for Investigative Files of the Office of Inspector General

D. New Business

1. Regulations

a. Employee Responsibilities and Conduct; 12 CFR Part 601 (Final).

2. Rules for Transaction of Business

Closed Session*

A. New Business

1. Enforcement Actions

*Session closed to the public—exempt pursuant to 5 U.S.C. 552b(c)(8) and (9).

Dated: January 11, 1993.

Curtis M. Anderson,

Secretary, Farm Credit Administration Board.

[FR Doc. 93-900 Filed 1-11-93; 8:45 am]

BILLING CODE 6705-01-M

FEDERAL HOUSING FINANCE BOARD

TIME AND DATE: 9:00 A.M., THURSDAY, JANUARY 21, 1993, 9:00 A.M., FRIDAY, JANUARY 22, 1993

PLACE: 2000 W. Westcourt Way, Tempe, Arizona.

STATUS: This entire meeting will be closed to the public.

MATTERS TO BE CONSIDERED:

PORTIONS CLOSED TO THE PUBLIC: The Board will consider the following:

1. GSE Studies.
2. System 2000
3. Agency's 1993 Priorities
4. Board Management Issues.

The above matters are exempt under one or more of sections 552b(c) (2) and (9) (A) and (B) of title 5 of the United States Code.

CONTACT PERSONS FOR MORE INFORMATION: Elaine L. Baker, Executive Secretary to the Board, (202) 408-2837.

Philip L. Conover,

Managing Director.

[FR Doc. 93-943 Filed 1-11-93; 2:28 pm]

BILLING CODE 6725-01-M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATES: 11:00 a.m., Tuesday, January 19, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposals regarding a Federal Reserve Bank's renovation project.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204. You may call (202) 452-3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: January 11, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-994 Filed 1-11-93; 3:49 pm]

BILLING CODE 6210-01-M

Corre

This section contains edit published Pr and Notice d prepared by Register. Ag issued as sig the appropria elsewhere in

DEPARTM

Mine Safet

Petitions f

Correction

In notice beginning Wednesday the followi

1. On pa under the Resources, "Corbonda "Carbonda

2. On the column, u Westmorel No. should

BILLING CODE

Corrections

Federal Register
Vol. 58, No. 8
Wednesday, January 13, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

Correction

In notice document 92–31578 beginning on page 62390 in the issue of Wednesday, December 30, 1992, make the following corrections:

1. On page 62391, in the first column, under the heading **"5. Mid-Continent Resources, Inc."**, in the third line, "Corbondale" should read "Carbondale".

2. On the same page, in the second column, under the heading **"10. Westmoreland Coal Co."**, the Docket No. should read "M–92–181–C".

BILLING CODE 1505–01–D

PENSION BENEFIT GUARANTY CORPORTATION

29 CFR Parts 2616 and 2617

RIN 1212–AA41 and RIN 1212–AA47

Distress Terminations of Single-Employer Plans; Standard Terminations of Single-Employer Plans

Correction

In rule document 92–30057 beginning on page 59206 in the issue of Monday, December 14, 1992, make the following corrections:

1. On page 59208, in the third column, the first two headings should read:

"Standard Termination Time Line"

"420 Days or Approximately 14 Months"

2. On page 59215, in the 2d column, in the 16th and 18th lines, "i.e.," should read "*i.e.,*" each time it appears.

3. On page 59216, in the second column, in the ninth line from the bottom, "(e.g.," should read "(*e.g.,*".

4. On the same page, in the third column, in the last line, after "not" insert "impossible, and the PBGC has therefore added paragraph (e).)"

§ 2616.1 [Corrected]

5. On page 59218, in the second column, in § 2616.1(b), in the last line, "January 28, 1992." should read "January 28, 1993."

§ 2617.24 [Corrected]

6. On page 59230, in the third column, in § 2617.24(b), the parenthetical "(i)" and "(ii)" should read "(1)"and "(2)" respectively.

7. On page 59231, in the first column, in § 2617.24(d)(4), in the seventh line, "e.g.," should read "*e.g.,*.

8. On the same page, in the same column, in § 2617.24(e), the first and second lines should read "(e) *Benefits of participants not in pay status but form and starting date known.*"

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National Institutes of Health

Privacy Act of 1974; Annual Publication of Notices of Systems of Records

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Privacy Act of 1974; Annual Publication of Notices of Systems of Records

AGENCY: Public Health Service, DHHS.

ACTION: Privacy Act: Annual republication of notices of revised systems of records.

SUMMARY: The National Institutes of Health (NIH) has conducted a comprehensive review of all Privacy Act systems of records and is publishing the resulting revisions. None of the revisions meet the OMB criteria for a new or altered system of records requiring an advance period for public comment. These changes are in compliance with circular A–130, appendix 1. The notices republished below are complete and accurate as of December 14, 1992.

SUPPLEMENTARY INFORMATION: The following information summarizes the current status of systems of records which had minor modifications during 1992 and lists all systems maintained by NIH:

A. System name. The following systems have been updated to reflect a change in the name of the system:

09–25–0036, Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement/ Chartered Advisory Committee, HHS/NIH/ DRG and HHS/NIH/CMO.

09–25–0075, Institutions Submitting Assurances for Protection from Research Risks and Animal Welfare, HHS/NIH/OD/ OER.

09–25–0087, Administration: Senior Staff, HHS/NIH/NIAID.

09–25–0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/ OSR.

09–25–0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/ NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09–25–0201, Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH.

09–25–0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

B. System location. The following systems have been updated to reflect a change in the system locations. These changes do not affect the access by the individual to the individual's records.

09–25–0005, Administration: Library Operations and User I.D. File, HHS/NIH/OD.

09–25–0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.

09–25–0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.

09–25–0069, NIH Clinical Center: Admissions of the National Cancer Institute, HHS/NIH/NCI.

09–25–0087, Administration: Senior Staff, HHS/NIH/NIAID.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.

09–25–0126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI.

09–25–0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/ OSR.

09–25–0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/ NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09–25–0165, National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD.

09–25–0201, Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH.

09–25–0202, Patient Records on PHS Beneficiaries (1935–1974) and Civilly Committed Drug Abusers (1967–1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/ NIDA.

09–25–0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.

09–25–0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/ NIDA and HHS/NIH/NIMH.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

09–25–0210, Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/NIH/ NIDA.

C. Categories of individuals covered by the system. The following systems have been updated to reflect a change in the categories covered by the system. This change does not alter the character or purpose of the system.

09–25–0124, Administration: Pharmacology Research Associates, HHS/ NIH/NIGMS.

09–25–0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/ NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09–25–0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

D. Categories of records. The following systems have been updated to reflect a change in the categories of records in the system. This change does not alter the character or purpose of the system.

09–25–0124, Administration: Pharmacology Research Associates, HHS/ NIH/NIGMS.

09–25–0206, Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA.

09–25–0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/NIH/NIDA.

E. Authority. The following systems have been updated to reflect a change in the authority. This change does not alter the character or purpose of the system.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

09–25–0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/ NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09–25–0158, Administration: Records of Applicants and Awardees of the NIH Intramural Research Training Awards Program, HHS/NIH/OD.

09–25–0204, Records of Contracts Awarded to Individuals, HHS/NIH/NIDA, HHS/NIH/NIAAA, and HHS/NIH/NIMH.

09–25–0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/ NIDA and HHS/NIH/NIMH.

09–25–0206, Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA.

09–25–0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/NIH/NIDA.

09–25–0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

09–25–0210, Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/NIH/ NIDA.

F. Storage. There are no changes in this category.

G. Retrieval. There are no changes in this category.

H. Safeguards. The following systems have been updated to reflect a change in the safeguards:

09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

09–25–0202, Patient Records on PHS Beneficiaries (1935–1974) and Civilly Committed Drug Abusers (1967–1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/ NIDA.

09–25–0206, Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

I. **Retention and disposal.** The following systems have been updated to reflect a change in retention and disposal:

09–25–0165, National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD.

09–25–0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/NIH/NIDA.

J. **System manager(s) and address(es).** The following systems have been updated to reflect a change in the system manager or the address of the system manager. These changes do not affect the access by the individual to the individual's records.

09–25–0005, Administration: Library Operations and User I.D. File, HHS/NIH/OD.

09–25–0028, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.

09–25–0036, Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement/ Chartered Advisory Committee Information), HHS/NIH/DRG and HHS/NIH/CMO.

09–25–0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.

09–25–0087, Administration: Senior Staff, HHS/NIH/NIAID.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.

09–25–0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.

09–25–0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID.

09–25–0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/OSR.

09–25–0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR.

09–25–0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD.

09–25–0156, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institutes of Health, HHS/NIH/OD.

09–25–0161, Administration: NIH Consultant File, HHS/NIH/DRG.

09–25–0202, Patient Records on PHS Beneficiaries (1935–1974) and Civilly Committed Drug Abusers (1967–1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/NIDA.

09–25–0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.

09–25–0204, Records of Contracts Awarded to Individuals, HHS/NIH/NIDA, HHS/NIH/NIAAA, and HHS/NIH/NIMH.

09–25–0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH.

09–25–0206, Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA.

09–25–0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/NIH/NIDA.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

09–25–0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

K. **Record access.** The following system has been updated to reflect a change in the record access procedures.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

L. **Notification procedures.** The following systems have been updated to reflect a change in the office, official, and/or address to write to in order to determine whether or not the system contains a record about the individual.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

09–25–0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD.

09–25–0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09–25–0165, National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD.

09–25–0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

M. **The following systems have been changed for clarity and editing purposes.** In addition, the language in the sections on Safeguards, Record Access Procedures, and Contesting Record Procedures for the systems listed in the Table of Contents has been edited to improve the clarity and specificity of the system notice and/or to incorporate standardized language to achieve uniformity.

09–25–0005, Administration: Library Operations and User I.D. File, HHS/NIH/OD

09–25–0036, Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement/ Chartered Advisory Committee Information), HHS/NIH/DRG and HHS/NIH/CMO.

09–25–0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.

09–25–0124, Administration: Pharmacology Research Associates, HHS/NIH/NIGMS.

09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

09–25–0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.

09–25–0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID.

09–25–0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09–25–0161, Administration: NIH Consultant File, HHS/NIH/DRG.

09–25–0201, Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH.

09–25–0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.

09–25–0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH.

09–25–0206, Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA.

09–25–0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

09–25–0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

N. **Organization name change.** The NIH has assumed responsibility for the following systems from ADAMHA and has renamed and revised them as follows.

09–25–0201, Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH.

09–25–0202, Patient Records on PHS Beneficiaries (1935–1974) and Civilly

Committed Drug Abusers (1967–1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/NIDA.

09–25–0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.

09–25–0204, Records of Contracts Awarded to Individuals, HHS/NIH/NIDA, HHS/NIH/NIAAA, and HHS/NIH/NIMH.

09–25–0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH.

09–25–0206, Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA.

09–25–0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/NIH/NIDA.

09–25–0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

09–25–0210, Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/NIH/NIDA.

09–25–0211, Intramural Research Program Records of In- and Out-Patients With Various Types of Alcohol Abuse and Dependence, Relatives of Patients With Alcoholism, and Healthy Volunteers, HHS/NIH/NIAAA.

09–25–0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

O. Deleted systems of records. The following systems of records which appeared in the 1992 annual publication are now being deleted because:

09–25–0048, Clinical Research: Serology-Epidemiology Parasite Research, HHS/NIH/NIAID. The study has been completed and the records destroyed.

09–25–0096, Contracts: NCI Contract Management System Principal Investigators, Project Officers and Contract Specialists. The system no longer contains personal information on individuals.

The following is a list of active systems of records maintained by NIH.

Table of Contents

09–25–0001, Clinical Research: Patient Records, HHS/NIH/NHLBI, published Federal Register, Vol. 55, Number 101, May 24, 1990.

09–25–0005, Administration: Library Operations and User I.D. File, HHS/NIH/OD, published Federal Register, Vol. 56, No. 79, April 24, 1991, p. 18830.

09–25–0007, Administration: NIH Safety Glasses Issuance Program, HHS/NIH/ORS, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0010, Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0011, Clinical Research: Blood Donor Records, HHS/NIH/CC, published Federal Register, Vol. 55, Number 101, May 24, 1990.

09–25–0012, Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0014, Clinical Research: Student Records, HHS/NIH/CC, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0015, Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINDS, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0016, Clinical Research: Collaborative Perinatal Project HHS/NIH/NINDS, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0025, Clinical Research: Nervous System Studies, HHS/NIH/NINDS, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0026, Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0031, Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINDS, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0033, International Activities: Fellowships Awarded by Foreign Organizations, HHS/NIH/FIC, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0034, International Activities: Scholars-in-Residence Program, HHS/NIH/FIC, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0035 International Activities: Health Scientist Exchange Programs, HHS/NIH/FIC, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0036, Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement/Chartered Advisory Committee, HHS/NIH/DRG and HHS/NIH/CMO, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0037, Clinical Research: The Baltimore Longitudinal Study of Aging, HHS/NIH/NIA, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0038, Clinical Research: Patient Data, HHS/NIH/NIDDK, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0039, Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIDDK, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0040, Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIDDK, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0041, Research Resources: Scientists Requesting Hormone Distribution, HHS/NIH/NIDDK, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0044, Clinical Research: Sensory Testing Research Program, HHS/NIH/NIDR, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0046, Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0053, Clinical Research: Vision Studies, HHS/NIH/NEI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0054, Administration: Property Accounting, HHS/NIH/ORS, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0057, Clinical Research: Burkitt's Lymphoma Registry, HHS/NIH/NCI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0067, Clinical Research: National Cancer Incidence Surveys, HHS/NIH/NCI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0069, NIH Clinical Center: Admissions of the National Cancer Institute, HHS/NIH/NCI, published Federal Register, Vol. 55, No. 101, May 24, 1990.

09–25–0074, Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0075, Institutions Submitting Assurances for Protection from Research Risks and Animal Welfare, HHS/NIH/OD/OER, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0077, Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0078, Administration: Consultant File, HHS/NIH/NHLBI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0087, Administration: Senior Staff, HHS/NIH/NIAID, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0091, Administration: General Files on Employees, Donors and Correspondents, HHS/NIH/NEI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0093, Administration: Administration Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0099, Clinical Research: Patient Medical Records, HHS/NIH/CC, published Federal Register, Vol. 55, Number 101, May 24, 1990.

09–25–0100, Clinical Research: Neuropharmacology Studies, HHS/NIH/NINDS, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0102, Administration: Grants Associates Program Working Files, HHS/NIH/DRG, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0105, Administration: Health Records of Employees, Visiting Scientists, Fellows, Contractors and Relatives of Inpatients, HHS/NIH/OD, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0106, Administration: Executive Secretariat Correspondence Records, HHS/NIH/OD, published Federal Register, Vol. 56, No. 8, January 11, 1991.

09–25–0108, Personnel: Guest Researchers/Student Scientists/Special Volunteers/Scientists Emeriti, HHS/NIH/DPM, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0112, Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0118, Contracts: Professional Services Contractors, HHS/NIH/NCI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0121, International Activities: Senior International Fellowships Program, HHS/NIH/FIC, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0124, Administration: Pharmacology Research Associates, HHS/NIH/NIGMS, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0128, Clinical Research: Neural Prosthesis and Biomedical Engineering Studies, HHS/NIH/NINDS, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0129, Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NIDCD, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0130, Clinical Research: Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI, published **Federal Register**, Vol. \$6, No. 8, January 11, 1991.

09–25–0134, Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0140, International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0145, Clinical Trials and Epidemiological Studies Dealing with Visual Disease and Disorders in the National Eye Institute, HHS/NIH/NEI, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological Disorders and Stroke and the National Institute on Deafness and Other Communication Disorders, HHS/NIH/NINDS and HHS/NIH/NIDCD, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0151, Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/OSR, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0154, Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

09–25–0156, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institutes of Health, HHS/NIH/OD, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0158, Administration: Records of Applicants and Awardees of the NIH Intramural Research Training Awards Program, HHS/NIH/OD, published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0160, United States Renal Data System (USRDS), HHS/NIH/NIDDK published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0161, Administration: NIH Consultant File, HHS/NIH/DRG published **Federal Register**, Vol. 56, No. 8, January 11, 1991.

09–25–0165, National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD, published **Federal Register**, August 5, 1991, Vol. 56, No. 150, p. 37223.

09–25–0166, Administration: Radiation Safety Information, HHS/NIH/ORS, published **Federal Register**, September 26, 1991, Vol. 56, No. 187, p. 48806.

09–25–0167, National Institutes of Health (NIH) Transhare Program, HHS/NIH/OD, published **Federal Register**, September 2, 1992, Vol.57, No.171, p. 40194.

09–25–0201, Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH, published **Federal Register**, November 24, 1986, Vol. 51, No. 226, p. 42376.

09–25–0202, Patient Records on PHS Beneficiaries (1935–1974) and Civilly Committed Drug Abusers (1967–1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/NIDA, published **Federal Register**, January 11, 1991, Vol. 56, No. 8, p. 1235.

09–25–0203, National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA published **Federal Register**, January 11, 1991, Vol. 56, No. 8, p. 1235.

09–25–0204, Records of Contracts Awarded to Individuals, HHS/NIH/NIDA, HHS/NIH/NIAAA, and HHS/NIH/NIMH, published **Federal Register**, January 11, 1991, Vol. 56, No. 8, p. 1235.

09–25–0205, Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH, published **Federal Register**, December 24, 1991, Vol. 56, No. 247, p. 66675.

09–25–0206, Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA, published **Federal Register**, November 24, 1986, Vol. 51, No. 226, p. 42388.

09–25–0207, Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/NIH/NIDA published **Federal Register**, November 24, 1986, Vol. 51, No. 226, p. 42390.

09–25–0208, Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA, published **Federal Register**, December 24, 1991, Vol. 56, No. 247, p. 66675.

09–25–0209, Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA, published **Federal Register**, November 24, 1991, Vol. 51, No. 226, p. 42392.

09–25–0210, Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/NIH/NIDA, published **Federal Register**, January 11, 1991, Vol. 56, No. 8, p. 1237.

09–25–0211, Intramural Research Program Records of In- and Out-Patients With Various Types of Alcohol Abuse and Dependence, Relatives of Patients With Alcoholism, and Healthy Volunteers, HHS/NIH/NIAAA, published **Federal Register**, November 24, 1986, Vol. 51, No. 226, p. 42376.

09–25–0212, Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH, published **Federal Register**, June 14, 1988, Vol. 53, No. 114, p. 23850.

Dated: December 22, 1992.

Bernadine Healy,

Director, National Institutes of Health.

09–25–0005

SYSTEM NAME:

Administration: Library Operations and User I.D. File, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located in National Institutes of Health (NIH) facilities in Bethesda, Maryland, or facilities of contractors of the NIH. Write to the appropriate system manager listed below for a list of current contractor locations.

National Institutes of Health, Building 10, Room 1L07, 9000 Rockville Pike, Bethesda, MD 20892 and

National Institutes of Health, Building 12A, Room 3018, 9000 Rockville Pike, Bethesda, MD 20892 and
National Institutes of Health, Building 38, Room 1S33, 8600 Rockville Pike, Bethesda, MD 20894 and
National Institutes of Health, Building 38, Room B1E23, 8600 Rockville Pike, Bethesda, MD 20894 and
National Institutes of Health, Building 38A, Room 4N419, 8600 Rockville Pike, Bethesda, MD 20894 and
National Technical Information Service, Accounting Department, 8001 Forbes Place, Room 208P, Springfield, Virginia 22151

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Users of Library Services.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, organization, address, phone number, user code and identification number; and when applicable, credit card number and billing information.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301 of the Public Health Service Act, describing the general powers and duties of the Public Health Service relating to research and investigation (42 U.S.C. 241).

PURPOSE OF THE SYSTEM:

(1) To monitor library material, services, and circulation control; (2) to provide user documentation; (3) to provide copying services (duplication of library materials); and (4) to manage invoice and billing transactions for library services.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to contractors and staff to monitor library material, services, circulation control; to provide user documentation; and to process or refine the records. Recipients are required to maintain Privacy Act safeguards with respect to those records.

4. Disclosure may be made for billing purposes to: (a) Contractors providing copying services; and (b) NTIS for MEDLARS Services.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on computer tape and disc, microfiche, paper and file cards.

RETRIEVABILITY:

Records are retrieved by name, user code and/or identification number.

SAFEGUARDS:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to Library staff members who need to verify that Library identification cards have been issued to those Library users requesting services such as MEDLINE and other computer online bibliographic searches, translations and interlibrary loans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. The contractor maintains a list of personnel having authority to access records to perform their duties.

2. *Physical Safeguards:* The offices housing the cabinets and file drawers for storage of records are locked during all library off-duty hours. During all duty hours offices are attended by employees who maintain the files. The contractor has secured records storage areas which are not left unattended during the working hours and file cabinets which are locked after hours.

3. *Procedural Safeguards:* Access to the file is strictly controlled by employees who maintain the files. Records may be removed from files only at the request of the system manager or other authorized employees. Access to computerized records is controlled by the use of security codes known only to authorized users. Contractor personnel receive instruction concerning the significance of safeguards under the Privacy Act.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 8000–D–2, which allows records to be kept until superseded or for a maximum period of 6 years. Refer to the NIH Manual Chapter for specific conditions on disposal.

SYSTEM MANAGER AND ADDRESS:

The Policy Coordinating Official for this system is the Management Analyst, Office of Administration, National Library of Medicine, Building 38, Room 2N21, 8600 Rockville Pike, Bethesda, MD 20894.

Chief, Reference and Bibliographic Services Section, Library Branch, National Center for Research Resources, National Institutes of Health, Building 10, Room 1L21, 9000 Rockville Pike, Bethesda, MD 20892 and
Librarian, Division of Computer Research and Technology, National Institutes of Health, Building 12A, Room 3018, 9000 Rockville Pike, Bethesda, MD 20892 and
Supervisory Librarian, Preservation Section, Public Services Division, Library Operations, National Library of Medicine, National Institutes of Health, Building 38, Room B1E23, 8600 Rockville Pike, Bethesda, MD 20894 and
Chief, Public Services Division, Library Operations, National Library of Medicine, National Institutes of Health, Building 38, Room 1S33, 8600 Rockville Pike, Bethesda, MD 20894 and
Chief, Medlars Management Section, Bibliographic Services Division, Library Operations, National Institutes of Health, National Library of Medicine, Building 38A, Room 4N419, 8600 Rockville Pike, Bethesda, MD 20894

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individual, NIH Library ID card data.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0028

SYSTEM NAME:

Clinical Research: Patient Medical Histories, HHS/NIH/NINDS and HHS/NIH/NIDCD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Building 10, Building 31, and Building 36, NIH, 9000 Rockville Pike, Bethesda, MD 20892.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Past and present patients of the National Institute of Neurological Disorders and Stroke (NINDS) and the National Institute on Deafness and Other Communication Disorders (NIDCD), and individuals being referred for admission to the NIH Clinical Center.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical histories and diagnoses.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

Clinical research on various diseases of the nervous system and hearing, hearing loss, and communication disorders by HHS scientists and their authorized collaborators, with the specific aim of improving patient care and treatment by evaluating therapeutic procedures.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Clinical research data are made available to approved or collaborating researchers, including HHS contractors and grantees. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

2. Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant access only to HHS researchers and their authorized collaborators.

2. *Physical Safeguards:* Records are kept locked in a file cabinet when not in use and in a location which is locked during non-working hours.

3. *Procedural Safeguards:* Records are returned to the files at the close of each working day and are used only in the system location or in a designated work area.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1 — "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director of Intramural Research, NINDS Building 10, Room 5N214, NIH, 9000 Rockville Pike, Bethesda, MD 20892
and
Director of Intramural Research, NIDCD, Building 31, Room 3C25, NIH, 9000 Rockville Pike, Bethesda, MD 20892

NOTIFICATION PROCEDURE:

To determine if a record exists, contact:

Chief, Administrative Services Branch, NINDS, Building 31, Room 8A49, NIH, 9000 Rockville Pike, Bethesda, MD 20892 or
Chief, Administrative Management Branch, NIDCD, Building 31, Room 3C21, NIH, 9000 Rockville Pike, Bethesda, MD 20892

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

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RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought, and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Referring and attending physicians, hospital records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0036

SYSTEM NAME:

Extramural Awards and Chartered Advisory Committees: IMPAC (Grant/Contract/Cooperative Agreement Information/Chartered Advisory Committee Information), HHS/NIH/DRG and HHS/NIH/CMO.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892 and Building 12, NIH Computer Center, 9000 Rockville Pike, Bethesda, MD 20892

For information pertaining to the chartered advisory committees of the National Institutes of Health: Building 31, Room 3B-55, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicant and Principal Investigators; Program Directors; NRSA Trainees and Fellows; Research Career Awardees; and Chartered Advisory Committees.

CATEGORIES OF RECORDS IN THE SYSTEM:

Applications, awards, associated records, trainee appointments, and current and historical information pertaining to chartered advisory committees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241c, 58 Stat. 691c & d repealed.

PURPOSE OF THE SYSTEM:

(1) To support centralized grant programs of the Public Health Service. Services are provided in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting. The data base is used to provide complete, accurate, and up-to-date reports to all levels of management. (2) To maintain communication with former fellows and trainees who have incurred a payback obligation through the National Research Service Award Program. (3) To maintain current and historical information pertaining to the establishment of chartered advisory committees of the National Institutes of Health and the appointment or designation of their members.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to the National Technical Information Service (NTIS), Department of Commerce, for dissemination of scientific and fiscal information on funded awards (abstract of research projects and relevant administrative and financial data).

2. Disclosure may be made to the cognizant audit agency for auditing.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department Regulations for opinions as a part of the application review process.

5. Disclosure may be made to a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision in the matter.

6. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

7. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to such records.

8. Disclosure may be made to the grantee institution in connection with performance or administration under the conditions of the award.

9. Disclosure may be made to the Department of Justice, or to a court or other tribunal, from this system of records when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on discs and magnetic tapes.

RETRIEVABILITY:

Records are retrieved by name, application, grant or contract ID number.

SAFEGUARDS:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to PHS extramural staff. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical Safeguards:* Physical access to DRG work areas is restricted to DRG employees.

3. *Procedural Safeguards:* Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, etc. The computer system maintains an audit record of all attempted and successful requests for access.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 4000–A–2, which allows records to be destroyed when no longer needed for administrative purposes. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGERS AND ADDRESSES:

Chief, Information Systems Branch, Division of Research Grants, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892.

For information pertaining to the chartered advisory committees of the National Institutes of Health: NIH Committee Management Officer, Building 31, Room 3B–55, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists write to:

Privacy Act Coordinator, Division of Research Grants, Westwood Building, Room 449, 5333 Westbard Avenue, Bethesda, MD 20892.

For information pertaining to the chartered advisory committees of the National Institutes of Health: NIH Committee Management Officer, Building 31, Room 3B–55, 9000 Rockville Pike, Bethesda, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individual, individual's educational institution and references.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0060

SYSTEM NAME:

Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, 8601 Old Georgetown Road, Bethesda, MD 20892 and
Frederick Cancer Research and Development Center, Building 426, Frederick, MD 21701 and
National Cancer Institute, Biological Response Modifiers Program (BRMP), 501 W. 7th Street, Suite No. 3, Frederick, MD 21701 and
National Cancer Institute, Navy Hospital, Building 8, Room 3146, Bethesda, MD 21814 and
National Cancer Institute, Division of Cancer Treatment, Cancer Therapy Evaluation Program, Executive Plaza North, Room 707, Bethesda, MD 20892, and at hospitals and clinics, educational and research institutions, Federal, State or local government agencies, and private facilities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All patients who have been hospitalized or seen in outpatient clinics on treatment research protocols in the National Cancer Institute.

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 241, 281, 282.

PURPOSE(S) OF THE SYSTEM:

(1) Patient care and treatment. (2) Clinical and epidemiological research.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. Disclosure may be made to a contractor when the Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to

directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on magnetic tapes, microcomputer disks, index cards, microfiche, and manual paper records.

RETRIEVABILITY:

Records are retrieved by patient name or number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the National Cancer Institute, or its contractors, whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical Safeguards:* Records are kept in a limited access area. Offices are locked during off-duty hours. Input data for computer files is coded to avoid individual identification.

3. *Procedural Safeguards:* Access to manual files is strictly controlled by files staff. Files may be accessed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users. Access codes are changed frequently.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESSES:

Head, Biostatistics and Data Management Section, National Institutes of Health, 8601 Old Georgetown Road, Bethesda, MD 20892 and

Chief, Clinical Research Branch, Biological Response Modifiers Program, Frederick Cancer Research and Development Center, 501 W. 7th Street, Suite #3, Frederick, MD 21701 and

Navy Hospital, Deputy Branch Chief, NCI—Naval Medical Oncology Branch, Building 8, Room 5101, Bethesda, MD 20814 and

Head, Drug Management and Authorization Section, Cancer Therapy Evaluation Program, Division of Cancer Treatment, National Cancer Institute, Executive Plaza North, Room 707, Bethesda, MD 20892 and

Director, Extramural Clinical Studies, BRB, BRMP, Division of Cancer Treatment, National Cancer Institute, Frederick Cancer Research and Development Center, Fort Detrick, Frederick, MD 21701

NOTIFICATION PROCEDURE:

Write to the system manager for the appropriate location to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Hospital medical records, referring physician, referring hospitals, clinical laboratories, patient contact, and Central Tumor Registries.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0069

SYSTEM NAME:

NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Chief, Family Studies, Section, DCE, Executive Plaza North, Rooms 400 and 439, 6130 Executive Blvd., Bethesda, MD 20892 and

National Institutes of Health, Division of Computer Research and Technology, Building 12A, 9000 Rockville Pike, Bethesda, MD 20892 and

WESTAT, Inc., Manugistics Building, Suite 402, 2115 E. Jefferson Street, Rockville, MD 20852 and

Survey Research Associates, Inc., Executive Office Center, Suite 201, 2101 E. Jefferson Street, Rockville, MD 20852

Write to the System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former cancer patients and their family members admitted to the NIH Clinical Center or the National Cancer Institute (NCI).

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical histories, reports and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 285a.

PURPOSE OF THE SYSTEM:

National Cancer Institute physicians and supporting staff are involved in research on the cause and diagnosis of disease and the treatment of patients, requiring the maintenance of working files to chart progress, responses to treatment, etc.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with respect to these records.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

3. Disclosure may be made to a contractor when the Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

5. (a) PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and on computer files.

RETRIEVABILITY:

Records are retrieved by identification number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to physicians, scientists and support staff of the National Cancer Institute and the Clinical Center whose duties require the use of such information. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical Safeguards:* Records are kept in limited access areas. Offices are locked during off-duty hours. Input data for computer files is coded to avoid individual identification.

3. *Procedural Safeguards:* Access to manual files is strictly controlled by files staff. Files may be accessed only at the request of the system manager or other authorized employee. Access to computer files is controlled through security codes known only to authorized users. Access codes are changed frequently.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESSES:

National Cancer Institute, NIH, Division of Cancer Etiology, Epidemiology and Biostatistics Program, Chief, Family Studies Section, EEB, Executive Plaza North, Suite 439, Bethesda, MD 20892
and
Chief, Clinical Genetics Section, Clinical Epidemiology Branch, Executive Plaza North, Suite 400, Bethesda, MD 20892

NOTIFICATION PROCEDURE:

Write to system manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a

record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Patients' personal physicians, NIH staff treating the patients or performing tests, requested outside records, and patients themselves.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0075

SYSTEM NAME:

Administration: Institutions Submitting Assurances for Protection From Research Risks and Animal Welfare, HHS/NIH/OD/OER.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 31, Room 5B59, 9000 Rockville Pike, Bethesda, MD 20892.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons submitting research proposals to the National Institutes of Health involving risks to subjects or matters pertaining to the protection of the rights and welfare of human research subjects.

CATEGORIES OF RECORDS IN THE SYSTEM:

Research protocol, identification of Principal Investigator, institution.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241(c)(g).

PURPOSE OF THE SYSTEM:

Monitoring of research proposals that may involve undue risks to subjects or ethical considerations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored on card file.

RETRIEVABILITY:

Records are retrieved by name of Principal Investigator.

SAFEGUARDS:

1. Authorized Users: Members of the professional staff of the Office for Protection from Research Risks (OPRR) may use information from the file in connection with follow-up procedures of research proposals identified as involving potential risk to the protection of the rights and welfare of human research subjects.

2. Physical Safeguards: Records are maintained in offices which are monitored during business hours and are locked during off-duty hours.

3. Procedural Safeguards: Requests for information from the file are made to the Compliance Coordinator who supervises and is responsible for the file. Computer files are password protected.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 7000-A-1, which allows records to be destroyed after a maximum period of 6 years after the file is closed. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director, OPRR, National Institutes of Health, Building 31, Room 5B59, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

Write to System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Proposals submitted by individuals, but identified by employees or consultants of HHS as possibly involving undue hazards.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0087

SYSTEM NAME:

Administration: Senior Staff, HHS/NIH/NIAID.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Building 31, Room 7A34, 9000 Rockville Pike, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former key professional employees of the Institute and consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Press releases, curriculum vitae, nominations for awards and photographs.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241(d) 289a.

PURPOSE OF THE SYSTEM:

For background records to provide public announcements on National Institute of Allergy and Infectious Diseases (NIAID) research.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored in file folders.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to staff whose duties require the use of such information. Authorized users are located in the Office of the Director, NIAID. Other one time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical Safeguards:* Records in this system are stored in file folders which are kept in locked cabinets. The room is locked during off-duty hours.

3. *Procedural Safeguards:* Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–G. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS

Director, Office of Communications, National Institutes of Health, Building 31, room 7A50, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: National Institutes of Health, Privacy Act Coordinator, NIAID, Solar Bldg., room 4C–01, 6003 Executive Blvd., Rockville, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as record notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the System Manager at the address above, and reasonably identify the record and specify the information to be contested, and state the corrective action sought and the reasons for the correction, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individuals and newspaper clippings.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0112

SYSTEM NAME:

Grants and Cooperative Agreements: Research, Research Training, Fellowship and Construction Applications and Related Awards, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

See Appendix I.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Grant applicants and Principal Investigators; Program Directors; Institutional and Individual Fellows; Research Career Awardees; and other employees of Applicant and/or grantee institutions.

CATEGORIES OF RECORDS IN THE SYSTEM:

Grant and cooperative agreement applications and review history, awards, financial records, progress reports, payback records, and related correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Research and Investigation," "Appointment and Authority of the Directors of the National Research Institutes," "National Institute of Mental Health," "National Institute on Drug Abuse," "National Institute on Alcohol Abuse and Alcoholism," "National Cancer Institute," "National Heart, Lung and Blood Institute," "National Institute of Diabetes, and Digestive and Kidney Diseases," "National Institute of Arthritis and Musculoskeletal and Skin Diseases," "National Institute on Aging," "National Institute on Allergy and Infectious Diseases," "National Institute of Child Health and Human Development," "National Institute of Dental Research," "National Eye Institute," "National Institute of Neurological Disorders and Stroke," National Institute of General Medical Sciences," "National Institute of Environmental Health Sciences," "National Institute on Deafness and Other Communication Disorders," and the "National Library of Medicine," of the Public Health Service Act. (42 U.S.C. 241, 284, 285, 285(b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), 286b–286b–7.

PURPOSE(S) OF THE SYSTEM:

(1) Information provided is used by NIH staff for review, award, and administration of grant programs.

(2) Information is also used to maintain communication with former fellows who have incurred an obligation

through the National Research Service Award Program.

(3) Staff may also use curriculum vitae to identify candidates who may serve as ad hoc consultants or committee and council members in the grant peer review process.

(4) As a part of the cost analysis of a proposed grant, a budget review is conducted of the percentage of time and effort listed under personnel category, equipment and supply categories, and other items listed under "other" category.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made of assignments of research investigators and project monitors to specific research projects to the National Technical Information Service (NTIS), Department of Commerce, to contribute to the Smithsonian Science Information Exchange, Inc.

2. Disclosure may be made to the cognizant audit agency for auditing.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

5. Disclosure may be made to qualified experts not within the definition of Department employees as prescribed in Department Regulations, 45 CFR 56.2, for opinions as a part of the application review and award administration processes.

6. Disclosure may be made to a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

7. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected; or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

8. Disclosure may be made to a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in a system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records;

9. Disclosure may be made to the grantee institution in connection with the review of an application or performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made on a grant proposal.

10. Disclosure may be made to the profit institution's president or official responsible for signing the grant application in connection with the review or award of a grant application and in connection with the administration and performance of a grant under the terms and conditions of the awards.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

DISCLOSURES PURSUANT TO 5 U.S.C. 552a(b)(12):

Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

The Department may disclose to consumer reporting agencies information on individuals who have failed to meet payback obligations incurred under awards made under authority of the National Research Service Awards Program (41 U.S.C. 289l–1). Information disclosed includes data identifying the individual, the amount, status and history of the obligation, and that the obligation arose from an award made under the National Research Service Awards Program.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored in file folders, on computer tapes and discs, cards and in notebooks.

RETRIEVABILITY:

Retrieved by name and grant number.

SAFEGUARDS:

A variety of physical and procedural safeguards are implemented, as appropriate, at the various locations of this system:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to officials whose duties require use of the information. These officials include review groups, grants management staff, other extramural program staff, health scientist administrators, data processing and analysis staff and management officials with oversight responsibilities for extramural programs. Other one-time and special access is granted on an individual basis as specifically authorized by the system manager. Authorization for access to computerized files is controlled by the system manager or designated official and is granted on a need-to-know basis. Lists of authorized users are maintained.

2. *Physical Safeguards:* Secured facilities, locked rooms, locked cabinets, personnel screening; records stored in order of grant numbers which are randomly assigned.

3. *Procedural Safeguards:* Access to file rooms and files is strictly controlled by files staff or other designated officials; charge-out cards identifying

users are required for each file used; inactive records are transferred to controlled storage in Federal Records Center in a timely fashion; retrieval of records from inactive storage is controlled by the system manager or designated official and by the NIH Records Management Officer; computer files are password protected and access is actively monitored by the Computer Center to prevent abuse. Employees are given specialized training in the requirements of the Privacy Act as applied to the grants program.

These particular safeguards are developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), items: 4000–B–1; 4000–B–4; 4000–C–1 and, 4600–D–1. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

See Appendix II.

NOTIFICATION PROCEDURE:

Write to official at the address specified in Appendix II to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Write to the official at the address specified in Appendix IV to obtain access to a record, and provide the same information as is required under the Notification Procedures above. Requesters should also reasonably specify the record contents being sought.

Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified in Appendix II, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information submitted by applicant; supplemented by outside reviewers and internal staff.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I—System Location

National Cancer Institute, Executive Plaza South, Suite T–42, 6120 Executive Boulevard, Bethesda, MD 20892
National Heart, Lung, and Blood Institute, Westwood Building, Room 4A09, 5333 Westbard Avenue, Bethesda, MD 20892
National Library of Medicine, Building 38A, Room 5N509, 8600 Rockville Pike, Bethesda, MD 20894
National Institute of Allergy and Infectious Diseases, Chief, Grants Management Branch, DEA, Solar Bldg., Room 4B–21, 6003 Executive Blvd., Rockville, MD 20892
National Institute of Allergy and Infectious Diseases, Chief, Management Information Systems Section, FMISB, OAM, Westwood Building, Room 733, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Diabetes and Digestive and Kidney Diseases, Westwood Building, Room 618, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Arthritis and Musculoskeletal and Skin Diseases, Westwood Building, Room 5A03, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Child Health and Human Development, 6100 Executive Blvd., Room 7A07, Bethesda, MD 20892
National Institute on Aging, Gateway Building, Room 2N–212, 7201 Wisconsin Avenue, Bethesda, MD 20892
National Institute of Dental Research, Grants Management Officer, Westwood Building, Room 518, Bethesda, MD 20892
National Institute of Environmental Health Sciences, Grants Management Officer, Building 2, Room 204, 104 Alexander Drive, Research Triangle Park, NC 27709
National Institute of General Medical Sciences, Grants Management Officer, Westwood Building, Room 953, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Neurological Disorders and Stroke, Federal Building, Room 10A12, 7550 Wisconsin Avenue, Bethesda, MD 20892
National Institute on Deafness and Other Communication Disorders, Executive Plaza South, Room 400B, 6120 Executive Boulevard, Rockville, MD 20892
National Eye Institute, Building 31, Room 6A47, 9000 Rockville Pike, Bethesda, MD 20892
National Center for Research Resources, Westwood Building, Room 853, 5333 Westbard Avenue, Bethesda, MD 20892
National Center for Nursing Research, Building 31, Room 5B06, 9000 Rockville Pike, Bethesda, MD 20892
Fogarty International Center, Building 31, Room B2C32, 9000 Rockville Pike, Bethesda, MD 20892
Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409
National Institute on Drug Abuse, Grants Management Branch, Room 8A–54, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
National Institute on Alcohol Abuse and Alcoholism, Grants Management Branch, Room 16–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
National Institute of Mental Health, Grants Management Branch, ORM, Room 7C–15, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

Appendix II—System Manager and Address

National Cancer Institute, Grants Management Analyst, Executive Plaza South, Suite 234, 6120 Executive Boulevard, Bethesda, MD 20892
National Heart, Lung, and Blood Institute, Chief, Grants Operations Branch, Division of Extramural Affairs, Westwood Building, Room 4A10, 5333 Westbard Avenue, Bethesda, MD 20892
National Heart, Lung, and Blood Institute, Administrative Officer, Division of Extramural Affairs, Westwood Building, Room 7A11, Bethesda, MD 20892
National Library of Medicine, Associate Director for Extramural Programs, Building 38A, Room 5N505, 8600 Rockville Pike, Bethesda, MD 20894
National Institute of Allergy and Infectious Diseases, Chief, Grants Management Branch, DEA, Solar Bldg., Room 4B–21, 6003 Executive Blvd., Rockville, MD 20892
National Institute of Allergy and Infectious Diseases, Chief, Management Information Systems Section, FMISB, OAM, Westwood Building, Room 733, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Arthritis and Musculoskeletal and Skin Diseases, Grants Management Officer, Westwood Building, Room 407, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Diabetes and Digestive and Kidney Disease, Grants Management Officer, Room 637, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Child Health and Human Development, Chief, Office of Grants & Contracts, 6100 Executive Blvd., Room 8A01, Bethesda, MD 20892
National Institute on Aging, Grants Management Officer, Gateway Building, Room 2N–212, 7201 Wisconsin Avenue, Bethesda, MD 20892
National Institute of Dental Research, Grants Management Officer, NIDR, Westwood

Building, Room 518, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Environmental Health Sciences, Grants Management Officer, Building 2, Room 204, 104 Alexander Drive, Research Triangle Park, NC 27709
National Institute of General Medical Sciences, Grants Management Officer, NIGMS, Westwood Building, Room 953, Bethesda, MD 20892
National Institute of Neurological Disorders and Stroke, Grants Management Officer, Federal Building, Room 1004A, Bethesda, MD 20892
National Institute on Deafness and Other Communication Disorders, Grants Management Officer, Executive Plaza South, Room 400B, 6120 Executive Boulevard, Rockville, MD 20852
National Center for Nursing Research, Grants Management Officer, Building 31, Room 5B06, 9000 Rockville Pike, Bethesda, MD 20892
National Eye Institute, Grants Management Officer, Building 31, Room 6A48, 9000 Rockville Pike, Bethesda, MD 20892
National Center for Research Resources, Director, Office of Grants and Contracts Management, Westwood Building, Room 853, 5333 Westbard Avenue, Bethesda, MD 20892
Fogarty International Center, Scientific Review Administrator, International Studies Branch, Building 31, Room B2C32, 9000 Rockville Pike, Bethesda, MD 20892
National Institute on Drug Abuse, Chief, Grants Management Branch, Room 8A–54, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
National Institute on Alcohol Abuse and Alcoholism, Chief, Grants Management Branch, Room 16–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
National Institute of Mental Health, Grants Management Officer, ORM, Room 7C–15, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

Appendix III—Notification Procedures

National Cancer Institute. See Appendix II.
National Heart, Lung, and Blood Institute, Privacy Act Coordinator, Building 31, Room 5A08, Bethesda, MD 20892
National Library of Medicine. See Appendix II.
National Institute of Allergy and Infectious Diseases. See Appendix II.
National Institute of Diabetes and Digestive and Kidney Diseases, Administrative Officer, Building 31, Room 9A46, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Child Health and Human Development. See Appendix II.
National Institute of Aging. See Appendix II.
National Institute of Dental Research, NIDR Privacy Act Coordinator, Building 31, Room 2C–35, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Environmental Health Sciences. See Appendix II.
National Institute of General Medical Sciences. See Appendix II.
National Institute of Neurological Disorders and Stroke. See Appendix II.
National Institute on Deafness and Other Communication Disorders. See Appendix II.
National Eye Institute. See Appendix II.
National Center for Nursing Research. See Appendix II.
National Center for Research Resources. See Appendix II.
Fogarty International Center. See Appendix II.
National Institute on Drug Abuse. See Appendix II.
National Institute on Alcohol Abuse and Alcoholism. See Appendix II.
National Institute of Mental Health, Privacy Act Coordinator, Room 15–81, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

Appendix IV—Records Access Procedures

National Cancer Institute, Privacy Act Coordinator, Building 31, Room 10A30, 9000 Rockville Pike, Bethesda, MD 20892
National Heart, Lung, and Blood Institute. See Appendix III.
National Library of Medicine. See Appendix II.
National Institute of Allergy and Infectious Diseases, Privacy Act Coordinator, Solar Bldg., Room 4C–01, Rockville, MD 20892
National Institute of Diabetes and Digestive and Kidney Diseases. See Appendix II.
National Institute of Child Health and Human Development. See Appendix II.
National Institute on Aging. See Appendix II.
National Institute of Dental Research, Grants Management Officer, Westwood Building, Room 518, 5333 Westbard Avenue, Bethesda, MD 20892
National Institute of Environmental Health Sciences. See Appendix II.
National Institute of General Medical Sciences, Privacy Act Coordinator, Westwood Building, Room 722, Bethesda, MD 20892
National Institute of Neurological Disorders and Stroke, Chief, Administrative Services Branch, Building 31, Room 8A49, 9000 Rockville Pike, Bethesda, MD 20892
National Institute on Deafness and Other Communication Disorders, Chief, Administrative Management Branch, Building 31, Room 3C02, 9000 Rockville Pike, Bethesda, MD 20892
National Eye Institute, Administrative Officer, Building 31, Room 6A17, 9000 Rockville Pike, Bethesda, MD 20892
National Center for Research Resources, Privacy Act Coordinator, Westwood Building, Room 10A15, 5333 Westbard Avenue, Bethesda, MD 20892
Fogarty International Center. See Appendix II.
National Institute on Drug Abuse. See Appendix II.
National Institute on Alcohol Abuse and Alcoholism. See Appendix II.
National Institute of Mental Health. See Appendix II.

09–25–0115

SYSTEM NAME:

Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Solar Bldg., Room 3A01, 6003 Executive Blvd., Bethesda, MD 20892

and

Ogden BioServices Corporation, 621A Lofstrand Lane, Rockville, MD 20850

Write to the System Manager at the address below for the address of the Federal Records Center where records are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Consultants and Clinical Investigators under National Institute of Allergy and Infectious Diseases (NIAID) Investigational New Drug Applications.

CATEGORIES OF RECORDS IN THE SYSTEM:

Curriculum vitae.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a.

PURPOSE OF THE SYSTEM:

(1) To maintain a record of the investigators under Investigational New Drug (IND) applications, and

(2) To appoint consultants to the NIAID Institutional Review Board (IRB).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored in books.

RETRIEVABILITY:

Retrieved by name.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. *Authorized Users:* Employees who maintain records in this system are instructed to grant regular access only to NIAID staff whose duties require the use of such information. Authorized users are located in the Clinical and Regulatory Affairs Branch, Division of Microbiology and Infectious Diseases, NIAID. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical Safeguards:* Building is locked during off-duty hours.

3. *Procedural Safeguards:* Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–G. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Acting Chief, Clinical and Regulatory Affairs Branch, DMID, NIAID Solar Bldg., Room 3A–01, 6003 Executive Blvd., Rockville, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: NIAID Privacy Act Coordinator, Control Data Bldg., Room 4C–01, 6003 Executive Blvd., Rockville, MD 20892.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as record notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Individuals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0124

SYSTEM NAME:

Administration: Pharmacology Research Associates, HHS/NIH/NIGMS

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Westwood Building, Room 919, 5333 Westbard Avenue, Bethesda, MD 20892.

Write to System Manager at the address below for the address of the Federal Records Center where records are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for positions as Pharmacology Research Associates with the National Institute of General Medical Sciences (NIGMS) and current and former Pharmacology Research Associates.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual application forms, addresses, telephone numbers, lists of awards received, research keywords, preceptor and institute during time of fellowship for former fellows, academic transcripts, reprints and references, curriculum vitae and salary adjustment memorandum for fellows.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 209.

PURPOSE(S) OF THE SYSTEM:

For review, award and administration of the Pharmacology Research Associate Program (PRAT).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders.

RETRIEVABILITY:

By name of applicant.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical, and procedural safeguards such as the following:

1. *Authorized Users:* Employees who maintain the system are instructed to grant access only to authorized personnel (System Manager and staff assigned to the program).

2. *Physical Safeguards:* The records are maintained in locked file cabinets when not in use and system location is locked during nonworking hours.

3. *Procedural Safeguards:* Access to files is strictly controlled by responsible

individuals who heve been instructed in the Privacy Act requirements. Records are returned to the locked cabinets when not in use.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–320–2(a). Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Director, PRAT Program,
Pharmacological Sciences, NIGMS,
Westwood Building Room 919,
Bethesda, MD 20892

NOTIFICATION PROCEDURE:

To determine if a record exists, write to System Manager and provide the following information: applicant's name and date of application.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official at the address specified under notification procedures above, and reasonably identify the record and specify the information to be contested, the corrective action sought. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information obtained from applicants, university registrars, and persons supplying recommendations through the PRAT Program. Salary adjustment memos from preceptors. Information on former fellows obtained from former fellows.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0126

SYSTEM NAME:

Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records included in this system are located in hospitals, universities, research centers, research foundations, and coordinating centers under contract with the National Heart, Lung, and Blood Institute, and in NHLBI facilities in Bethesda, Maryland. Write to the system manager at the address below for a list of locations, including the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Participants in these studies include (1) individuals who have been or who are presently being treated by the National Heart, Lung, and Blood Institute, for diseases or conditions of the heart, lung, blood vessels and blood; (2) individuals whose physical, genetic, social, economic, environmental, behavioral or nutritional conditions or habits are being studied in relation to the incidence of heart, lung, blood vessel and blood diseases among human beings; and (3) normal volunteers who have agreed to provide control data germane to these studies.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of a variety of clinical, medical, and statistical information resulting from or contained in research findings, medical histories, vital statistics, personal interviews, questionnaires, or direct observation. The system also includes records of current addresses of study participants, photographs, fingerprints, and correspondence from or about participants in these studies.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sec. 412, 413 of the Public Health Service Act (42 U.S.C. 287a, 287b).

PURPOSE(S) OF THE SYSTEM:

(1) Summaries of data resulting from these studies are used by the National Heart, Lung, and Blood Institute to monitor and evaluate the incidence of the diseases or the conditions under investigation and the relationship of various factors to the occurrence of these diseases. (2) The summaries are also used for program planning and evaluation purposes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Referrals may be made of assignments of research investigators and project monitors to specific research projects to the Smithsonian Institution to contribute to the Smithsonian Science Information Exchange, Inc.

3. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosures may be made to the Department of Justice for the purpose of obtaining its advice.

4. Where the appropriate official of the Department, pursuant to the Department's Freedom of Information Regulation determines that it is in the public interest to disclose a record which is otherwise exempt from mandatory disclosure, disclosure may be made from this system of records.

5. The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

7. Disclosure may be made to organizations deemed qualified by the

Secretary to carry out quality assessments, medical audits or utilization review.

8. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

9. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, magnetic tapes or discs, punched cards, bound note books.

RETRIEVABILITY:

Name and/or participant identification number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to authorized researchers, physicians and their assistants whose duties require the use of such information.

2. *Physical safeguards:* Records are kept in locked file cabinets and in some instances in locked offices or guarded buildings. Locations are locked during non-working hours, and are attended at all times during working hours.

3. *Procedural safeguards:* Access to the data is controlled by the System Manager and the Project Officer. Data stored in computers is accessed through the use of key words known only to principal investigators or authorized personnel.

The particular safeguards implemented at each site are developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Associate Director for Epidemiology and Biometry, National Heart, Lung, and Blood Institute, Federal Building, 2C–08, 7550 Wisconsin Avenue, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, contact: NHLBI Privacy Coordinator, Building 31, Room 5A–08, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Requesters must provide the following information in writing: (1) Full name; (2) Name and location of research study; and (3) Approximate dates of enrollment.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to System Manager as indicated above. The contestor must reasonably specify in writing the record contents at issue and state the corrective action sought and the reasons for the correction. The right to contest with supporting justification. The record is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants and from medical and clinical research observations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0140

SYSTEM NAME:

International Activities: International Scientific Researchers in Intramural Laboratories at the National Institutes of Health, HHS/NIH/FIC.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Fogarty International Center, Building 16A, Room 101, 9000 Rockville Pike, Bethesda, MD 20892

and

Division of Computer Research and Technology, Building 12A, Room 3061, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892

Ancillary records are located in the Office of the Associate Director for Intramural Affairs, laboratories, administrative and personnel offices where participants are assigned. Write to System Manager at the address below for the address of the Federal Records Center where records are stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Health scientists at all levels of their postdoctoral or equivalent research careers who are invited to the National Institutes of Health for further training or to conduct research in their biomedical specialties under the auspices of FIC's administration of International Activities. Most of these scientists are foreign, however some may be resident aliens or U.S. citizens.

Individuals in these categories include Visiting Associates, Visiting Scientists, Foreign Special Experts who are employees and Visiting Fellows, Guest Researchers, Exchange Scientists, International Research Fellows, Fogarty Scholars, Special Volunteers, Adjunct Scientists and Residents who are not employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

History of fellowship, employment and/or stay at NIH; education, immigration data and references. For payroll purposes, social security numbers are requested of all applicants accepted into the program.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 2421 and section 307 of the Public Health Service Act.

PURPOSE OF THE SYSTEM:

To document the individual's presence at the NIH, to record immigration history of the individual in order to verify continued eligibility in existing programs, and to meet requirements in the Code of Federal Regulations (8 CFR, "Aliens and Nationality," and 22 CFR, "Foreign Relations").

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Information is made available to authorized employees and agents of the U.S. Government including, but not limited to, the General Accounting Office, the Internal Revenue Service, and the FBI and Immigration and Naturalization Service, Department of Justice, for purposes of investigations, inspections and audits.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has any interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and on file cards, computer tapes, computer disks and microfilm.

RETRIEVABILITY:

By name, country of citizenship, institution, fellowship number, social security number, visa and immigration status, program category, dates of stay at NIH, NIH component, and home address.

SAFEGUARDS:

A variety of safeguards is implemented for the various sets of records included under this system according to the sensitivity of the data they contain.

1. *Authorized users:* NIH administrative and personnel staff screened by FIC staff to access information on a need-to-know basis. Only FIC staff are authorized to add, change, or delete data. Access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

2. *Physical safeguards:* The records are maintained in file cabinets in offices that are locked during off-duty hours.

3. *Procedural safeguards:* Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employees. For computerized records, access is controlled by the use of security codes known only to authorized users; access codes are changed periodically. The computer system maintains an audit record of all requests for access.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–320, which allows records to be destroyed after a maximum period of 6 years after the close of a case. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, International Services and Communications Branch, Building 16A, Room 101, Fogarty International Center, National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Same as notification procedure. Requesters should also reasonably

specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official listed under notification procedure above, and reasonably identify the record, and specify the information to be contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individuals and other Federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0142

SYSTEM NAME:

Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records included in this system will be located in hospitals and clinics, research centers and research foundations, and in facilities of the National Institute on Aging (NIA) in Bethesda, MD. They may be stored at Federal Records Centers. A list of locations is available upon request from the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Participants in these studies will include: (1) individuals whose physical, genetic, social, psychological, cultural, economic, environmental, behavioral, pharmacological, or nutritional conditions or habits are studied in relationship to the normal aging process and/or diseases and other normal or abnormal physical or psychological conditions of the aged, and (2) normal volunteers who are participants in such studies.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system will consist of a variety of health, demographic, and statistical information resulting from or contained in research findings, medical histories, vital statistics, personal interviews, questionnaires, or direct observations. The system will also include records of current addresses of study participants, and correspondence from or about participants in the studies. When supplied on a voluntary basis, Social Security numbers will also be included.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority is provided by Sections 301, Research Contracting, and 463–4, Health Research Extension Act of 1985, Pub. L. 99–158.

PURPOSE(S) OF THE SYSTEM:

The National Institute on Aging will use the data collected; (1) In research projects on (a) the health status of individuals and changes in health status over time, (b) the incidence and prevalence of certain diseases and problems of the aged in certain populations, and (c) the changes that take place as individuals age; (2) and for program planning and evaluation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Records may be disclosed to HHS contractors, collaborating researchers and their staffs in order to accomplish the basic research purpose of this system. The recipients will be required to maintain Privacy Act safeguards with respect to such records.

2. Data may be disclosed to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosure may be made to the Department of Justice for the purpose of obtaining its advice.

5. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

6. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, magnetic tapes or discs, punched cards, or bound notebooks. Stored data may include textual, photographic, X-ray, or other material.

RETRIEVABILITY:

Information will be retrieved by personal identifiers such as name, code number and/or Social Security number, when this is supplied on a voluntary basis.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel,

physical and procedural safeguards such as the following:

1. *Authorized users:* Access will be limited to principal investigators, collaborating researchers and necessary support staff.

2. *Physical safeguards:* Hard copy data will be maintained in locked file cabinets. Information stored in computer systems will be accessible only through proper sequencing of signal commands and access codes specifically assigned to the Project Officer or contractor.

3. *Procedural safeguards:* Access to the information will be controlled directly by the Project Officer or his or her representative at remote locations, and by the system manager at NIA locations. Contractors and collaborating researchers will be notified that they are subject to the provisions of the Privacy Act, and will be required to make formal agreements to comply with these provisions.

The particular safeguards implemented in each project are developed in accordance with Chapter 45–13 and supplementing Chapter PHS hf: 45–13 of the HHS General Administration Manual and Part 6, ADP Systems Security, of the HHS Information Resources Management Manual, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Associate Director, Epidemiology, Demography and Biometry Program, National Institute on Aging, Gateway Building, Suite 3C309, 7201 Wisconsin Avenue, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the above address and provide the foliowing information in writing:

1. Full name at time of participation in the study,
2. Date of birth,
3. Home address at the time of study,
4. The facility where the examination was given or where information was collected,
5. Approximate date or dates of participation,
6. Name of study, if known,
7. Current name, address and telephone number.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical or dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Contact the system manager at the above address and provide the same information as outlined under the notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the System Manager at the above address. The contestor must reasonably identify the record, specify in writing the information being contested, and state the corrective action sought and the reasons for the correction. The right to contest records is limited to information which is incomplete, irrelevant, incorrect or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information will be obtained directly from individual participants and from medical and clinical research observations, or indirectly from existing source documents such as disease registries.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0143

SYSTEM NAME:

Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

At National Institutes of Health facilities in Bethesda, Maryland, and at hospitals, medical schools, universities, research institutions, commercial organizations, state agencies, and collaborating Federal agencies. Inactive records may be retired to Federal Records Centers. A list of locations is available upon request from the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Patients with infectious diseases, immunologic diseases involving adverse reactions of the body (e.g., allergic reactions) and related diseases (e.g. Acquired Immunodeficiency Disease Syndrome/AIDS), normal healthy volunteers who serve as controls for comparison with patients, relatives of patients and other individuals whose characteristics or conditions are being studied for possible connections with the occurrence of the diseases under investigation.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of a variety of clinical, medical, and epidemiological information resulting from or contained in direct observations, medical records and other histories, vital statistics reports, records on biological specimens (e.g., blood, urine, etc.), personal interviews, questionnaires, progress reports, correspondence or research findings.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 U.S.C. 241, 289a, 289c.

PURPOSE OF THE SYSTEM:

This system will be used to support: (1) Epidemiologic, clinical and biometric investigations into the causes, nature (morbidity and mortality), outcome, therapy and cost of infectious, immunologic and related diseases; and (2) Review and evaluation of the progress of these research projects, and identification of and planning for improvements or for additional research.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to protect such records from improper disclosure.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality

assessments, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unanthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. In the event the Department deems it desirable or necessary, in determining whether particular records are required to be disclosed under the Freedom of Information Act, disclosures may be made to the Department of Justice for the purpose of obtaining its advice.

5. The Department contemplates that it may contract with one or more private firms for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to such records.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice or other appropriate Federal agency to enable that agency to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

7. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, computer-accessible forms (e.g. tapes or discs), punched cards, bound notebooks, microfilm, charts, graphs, and X-rays.

RETRIEVABILITY:

Information is retrieved by name and/or participant identification number.

SAFEGUARDS:

1. *Authorized users:* Access to or disclosure of information is limited to collaborating researchers, contractors and NIAID employees who are involved in the conduct, support or review and evaluation of the research activities supported by this system.

2. *Physical safeguards:* Data are kept in secured areas (e.g. rooms which are locked when not in regular use, buildings with controlled access). Data stored in computer-accessible form is accessed through the use of key words known only to principal investigators or authorized personnel; all other information is stored in locked files.

3. *Procedural safeguards:* Contractors and collaborating researchers are required to comply with the provisions of the Privacy Act and with Department regulations.

These and other appropriate safeguards are implemented in each project in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Epidemiology and Biometry Branch, DMID, National Institute of Allergy and Infectious Diseases, Solar Building, Room 3A24, Bethesda, Maryland 20892, and Chief, Epidemiology Branch, DAIDS, Room 240P, Solar Building, 6003 Executive Blvd., Rockville, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: NIAID Privacy Act Coordinator, Solar Bldg., Room 4C–01, 6003 Executive Blvd., Rockville, MD 20892, and provide the following information:

1. System name,
2. Complete name and home address at the time of the study,
3. Birth date,
4. Facility conducting study,
5. Disease type (if known),
6. Approximate dates of enrollment in the research study.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, other health professional, or other responsible individual, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record

shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants, from physicians, research investigators and other collaborating persons and from medical records and clinical research observations at hospitals, HHS agencies, universities, medical schools, research institutions, commercial institutions, state agencies, collaborating Federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0151

SYSTEM NAME:

Administration: Public Health Service ALERT Records Concerning Individuals Under Investigation for Possible Misconduct in Science or Subject to Sanctions for Such Misconduct, HHS/PHS/OSR.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of Science Research, Public Health Service (PHS), 5515 Security Lane, Suite 700, Rockville, MD 20852.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Subjects may include (1) researchers currently or formerly employed by the Federal Government; (2) individuals being considered for appointment to Public Health Service (PHS) advisory committees; (3) investigators on research grants, fellowships, cooperative agreements, or contracts awarded by any PHS agency, ("Investigators" may include principal investigators, co-investigators, program directors, trainees, recipients of career awards or fellowships, or other individuals who conduct or are responsible for research or research training funded by PHS.); (4) research investigators, such as guest workers, not employed by PHS but who conduct research in PHS facilities or are closely associated with research conducted by PHS; (5) other individuals, such as subgrantees, subcontractors or assistants on research or research training grants, contracts or cooperative agreements, who by training, experience, occupation or other qualifications are potential candidates for research or research training grants, contracts, cooperative agreements or other benefits.

Such individuals would be subjects of records in this system if they fall within either of the following two categories: (1) Subjects of formal investigations for scientific misconduct or serious misappropriation of Federal research funds, if the PHS Agency-level/Staff Office Misconduct Policy Officer has determined that the alleged misconduct is serious enough, or that the investigation has produced sufficient information, to warrant attention when a PHS agency considers awarding research or research training funds or other benefits to such individuals; (2) Subjects of sanctions imposed as a result of determinations that scientific misconduct or serious misappropriation of Federal research funds has occurred. Such sanctions include (a) actions affecting eligibility for research and training awards, such as special conditions for receipt of an award, suspension or termination of an award, or debarment of an individual; (b) actions affecting eligibility for appointment to a committee which advises PHS; (c) special restrictions on regulated research, such as disqualification from eligibility to use investigational drugs or special conditions for protection of human research subjects; and (d) termination of employment or other disciplinary action against an employee of PHS.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system contains records relating to investigations or findings of misconduct in science and to actions that PHS has taken in connection with such investigations or findings. Misconduct in science is defined as (1) the serious deviation, such as fabrication, falsification, or plagiarism, from accepted practices in proposing, conducting and reporting the results of research; or (2) the material failure to comply with Federal requirements affecting specific aspects of the conduct of research, e.g., the protection of human subjects and the welfare of laboratory animals.

In addition to records relating to misconduct in science, the system includes records relating to investigations or findings of serious misappropriation of Federal research funds—e.g., diversion of such funds to personal use. It does not include records documenting normal business transactions between a PHS agency and an awardee institution, except to the extent that such records are directly relevant to consideration of the fitness of an individual to receive a PHS award or other benefit.

The system consists of two subsystems which contain the following types of records: (1) Records on pending or ongoing investigations identifying the alleged misconduct; the individual and/or institution under investigation; any present, past or pending research, and/or research training awards; PHS agencies or offices involved, and the organization responsible for the investigation; (2) Records summarizing sanctions imposed because of a finding of misconduct, which adversely affect the individual's eligibility for research or research training awards or other benefits for a specified period of time. Either subsystem may contain responses from subject individuals.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system comes from the legislation which authorizes PHS to make awards for biomedical research and research training, and from PHS's concomitant responsibility to assure both that funds disbursed under awards are spent for authorized purposes and that recipients of such funds conform to all appropriate laws and regulations. (Public Health Service Act: 42 U.S.C. 241, 242b, 242c, 242l, 242m, 247c, 281–289h, 290aa–9, 290bb, 290bb–1, 290cc, 300a–2, 300b–1–b–3, 300c–12, 300z–7, as these provisions relate to awards for biomedical research and research training; Occupational Safety and Health Act: 29 U.S.C. 669).

PURPOSE OF THE SYSTEM:

This system of records enables PHS agencies to discharge effectively their responsibilities in the award and administration of research and training grants, cooperative agreements and contracts, while protecting the privacy

and other rights of individuals under investigation or sanction for scientific misconduct or misappropriation of funds. The ALERT system is used to collect, control and disseminate to PHS agency officials on a need-to-know basis information that an individual (1) is under investigation for possible misconduct in science or misappropriation of funds, or a decision has been made to undertake such an investigation; or (2) has been subjected to a sanction at the conclusion of an investigation for misconduct or misappropriation of funds.

Specifically, (1) PHS records the existence of such sanctions in the system so that PHS agencies can track and implement the sanctions, for example by refusing to accept an application or proposal from a debarred person. In addition, PHS informs members of technical merit review groups of actions taken if the disclosure bears directly on the scientific merit of an application or proposal under consideration or the fiscal integrity of the investigator or applicant, or if necessary to ensure an unbiased review by providing an accurate account of the case, for example, when information concerning the conduct investigated has been disclosed by other sources, such as the press or other communications media. PHS does not use this system to make decisions on imposition of sanctions. (2) When investigative findings fail to confirm an instance of misconduct or show that any misconduct was not of sufficient importance to warrant imposing sanctions, leading to a decision not to impose any sanctions, (a) the individual's name is removed from the ALERT system of records and the individual is notified in writing; (b) responsible PHS agency officials are notified of the outcome; (c) if any interim administrative sanctions had been imposed, they are lifted; and (d) if a competing application or proposal from the individual is pending or anticipated in the near future, the Misconduct Policy Officer of the relevant agency consults with officials responsible for review of the application or proposal to identify and resolve any concerns that might affect the objectivity of the review. For example, technical merit review groups would be informed of the outcome of the investigation if there were reason to believe that reviewers had received incomplete or misleading information about the case. (3) PHS agencies use ALERT system records on pending or ongoing investigations to make informed decisions on appropriate actions regarding awards of research, research training and related activities or other benefits to individuals under investigation as follows: (a) PHS agency officials responsible for the award of research funds, in consultation with the PHS agency-level Misconduct Policy Officer, weigh information on investigations in deciding whether to take interim administrative action, such as delaying, restricting or denying award of research funds. Any interim action is taken with a view towards protecting the rights of all parties involved and minimizing disruption to an ongoing project, the awardee institution, and the activities of those involved in the project. (b) To obtain independent advice on appropriate actions with respect to potential competing awards to individuals or organizations under investigation, these officials or their designees inform the members of the appropriate National Advisory Council or Board, advisory bodies legally established to advise PHS on funding of research projects, of the existence and status of an investigation. Such disclosure is made in closed session when the Council or Board is considering the funding of research by the individual or institution. To avoid influencing Technical Reviews, PHS will not inform members of scientific review groups about instances of possible misconduct or ongoing investigations. However, if a given case has received such extensive publicity that review of an application or proposal may be compromised, the responsible PHS agency official may defer the review or inform the reviewers of the status of PHS's activities with respect to the possible misconduct. (4) The PHS Committee on Misconduct in Science, and individual PHS Agency/Staff Office Misconduct Policy Officers, review ALERT records in order to inform appropriate officials within their organizations who are responsible for deciding on the actions described in other items of this section. (5) PHS Committee Management Officers may review records in the system concerning candidates for appointment to advisory committees in order to make informed decisions about making, delaying or denying appointments. (6) Upon request, the system manager may disclose information to PHS agency officials who are considering hiring a subject individual. (7) When a research activity within PHS (i.e., intramural research activity) is the subject of an investigation by a PHS regulatory agency, information on that investigation in this system may be communicated to the PHS intramural officials responsible for the research activity.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. PHS may notify responsible officials of awardee institutions or organizations when, in connection with an investigation or finding of misconduct by an individual employed by or affiliated with the institution or organization, a PHS agency takes an action affecting research and research training awards to the institution or organization. Information disclosed will be limited to the name of the subject individual, description of the action and the reasons for it.

2. Information may be disclosed to qualified experts not within the definition of Department employees as prescribed in Department Regulations to the extent the information is pertinent to the review of applications by those experts.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. Disclosure may be made from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) HHS employee in his or her individual capacity or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name of the individual under investigation or subject to sanction.

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SAFEGUARDS:

1. *Authorized users:* Records are available only to the system manager, PHS Agency-level/Staff Office Misconduct Policy Officers, the Deputy Director for Extramural Research and Training, NIH, and other responsible PHS agency officials considering the award of funds for research, research training or related activities or other benefits to a subject individual or institution, the appointment of a subject individual to an advisory committee, the hiring of a subject individual, or the management of a PHS agency research activity under investigation. Any disclosure to other individuals must be authorized by the system manager.

2. *Procedural safeguards:* Access to records is strictly controlled by the system manager and the officials specified under "Authorized Users." Individuals who receive disclosures from this system are informed that the information is confidential. They are instructed to address all questions and inquiries from any party either to the system manager or to the appropriate Misconduct Policy Officer for reply. Disclosures to Boards, Councils or review groups are made in sessions which are closed to the public. In addition, PHS staff and others not directly responsible for a potential award may be barred when a Board or Council considers an ALERT case, if they would not have been informed about the case otherwise. Only the PHS Committee on Misconduct in Science or individual PHS agency-level Misconduct Policy Officers, acting on the advice of the system manager, may authorize additions, alterations or deletion of records in this system.

3. *Physical safeguards:* Records are kept in locked file cabinets in offices which are locked when not attended. Special measures, commensurate with the sensitivity of the records, are taken to prevent unauthorized copying or disclosure of records.

These practices are in compliance with the standards of chapter 45–13 of the HHS General Administration Manual and supplementary chapter PHS hf: 45–13.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 4000–E–3, which allows records on an investigation in progress to be retained until the investigation is completed. If the investigation results in a determination that no misconduct occurred, or that any misconduct was not significant enough to warrant official sanction, the record relating to that investigation is destroyed. If an investigation results in official sanction, a record of such sanction is maintained for the duration of the sanction and is then destroyed. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Deputy Director, Office of Science Research, Public Health Service, 5515 Security Lane, Suite 700, Rockville, MD 20852.

NOTIFICATION PROCEDURE:

Individuals are routinely notified in writing when they become the subject of a record in this system, unless a law enforcement agency has instructed PHS not to do so. Subject individuals are also informed routinely when their records are deleted from the system. Individuals may request notification by writing to the system manager at the address above; provide your full name and state that the inquiry concerns Privacy Act system of records number 09–25–0151. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a fine of not more than five thousand dollars.

RECORD ACCESS PROCEDURE:

Individuals may write to the system manager at the address above and provide the same information as required for notification. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the system manager and reasonably identify the record and the information being contested; and state your reasons for requesting the change, along with supporting information to show that the record is untimely, incomplete, irrelevant or inaccurate. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information in these records is obtained from subject individuals, awardee institutions or organizations, PHS agencies and organizations responsible for investigations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0152

SYSTEM NAME:

Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records included in this system are collected by contractors and are located in hospitals and clinics; research centers; educational institutions; commercial; local, State and Federal government agencies; and in National Institute of Dental Research (NIDR) facilities. Inactive records may be stored at Federal Records Centers. A list of locations and contracts is available upon request from the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary participants in epidemiological and biometric studies sponsored by NIDR, including adults and minors, both males and females, with known or suspected diseases or disorders of the teeth and supporting structures, as well as normal or non-suspect individuals in control or study groups for purposes of comparison.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of medical and dental records and information resulting from personal interviews, questionnaires, or direct observation. The system may also include current addresses of study participants, radiographs, records on biological specimens (e.g., teeth, plaque, etc.), study models, computerized epidemiological data and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Sections 301, 401, 405 and 453 of the Public Health Service Act (42 U.S.C. 241, 281, 284, 285h). These sections establish the National Institute of Dental Research and authorize the conduct and support of dental and oral research and related activities.

PURPOSE(S) OF THE SYSTEM:

This system is used to; (1) Support research on diseases and disorders of the oral cavity (teeth and their supporting structures); their causes and

treatment; the incidence and prevalence of these diseases and disorders; and familial, demographic and behavioral factors related to their causes and treatment; (2) Provide data for program review, evaluation, planning, and administrative accountability.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff for the purpose of analyzing data and preparing scientific reports and articles in order to accomplish the research purpose for which the records are collected. The recipients are required to maintain Privacy Act safeguards with regards to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose, (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect records.

5. Disclosure may be made to a congressional office from the record to an individual in response to an inquiry from the congressional office made at the request of the individual.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, magnetic tapes or disks, punched cards, or bound notebooks.

RETRIEVABILITY:

Information is retrieved by name and/or a participant identification number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in these systems are instructed to grant regular access only to contractor personnel; consultants to the contractor; the NIDR project officer; and NIDR employees whose duties require the use of such information. Access to the data controlled by the Project Director, the NIDR Project Officer, and/or the System Manager.

2. *Physical safeguards:* Records are stored in locked files or secured areas. Computer terminals are in secured areas.

3. *Procedural safeguards:* Names and other identifying particulars are deleted when data from original records is encoded for analysis. Encoded data is indexed by code numbers. Tables linking these code numbers with actual identifiers are maintained separately. Code numbers and identifiers are linked only if there is a specific need. Data stored in computers is accessed through the use of keywords known only to the principal investigators or authorized personnel. These keywords are changed frequently.

The particular safeguards implemented in each project will be developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–4, which does not allow records to be destroyed. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESSES:

Chief, Contract Management Section, Extramural Program, National Institute of Dental Research, Westwood Building, Room 533, 5333 Westbard Avenue, Bethesda, MD 20892

NOTIFICATION PROCEDURE:

Write to: Privacy Act Coordinator, National Institute of Dental Research, 9000 Rockville Pike, Building 31, Room 2C–35, Bethesda, MD 20892.

and provide the following information in writing:

1. Full name at time of participation in the study.
2. Name and description of the study.
3. Location and approximate dates of participation.

The requester must also verify his or her identity by providing either a notarization of the request or a written

certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of, or access to, a medical or dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, the medical record of a child or incompetent person shall designate a family physician or other health professional (other than a family member) to whom the records, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Same as notification. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Contact the System Manager at the address above. The contestor must reasonably identify the record, specify in writing the information being contested, and state the corrective action sought, and the reason(s) for the corrective action, with supporting justification. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants and from medical/dental and clinical research observations.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0153

SYSTEM NAME:

Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records included in this system are located in hospitals and clinics, research centers, educational institutions, commercial organizations, local and State agencies, and other Executive Branch agencies of the Federal Government under contract to the National Institute of Child Health and Human Development (NICHD), and in NICHD facilities in Bethesda, Maryland. Inactive records may be stored at Federal Records Centers. A list of specific locations and contractors is available upon request from the System Manager, whose address is listed below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Participants in these studies include adults and children (a) who are presently or have been treated by the NICHD, (b) whose physical, genetic, social, economic, environmental, behavioral or nutritional conditions or habits are being studied by the NICHD, or (c) normal volunteers who have agreed to provide control data for purposes of comparison.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of a variety of clinical, medical, and statistical information collected in biomedical and behavioral research studies, such as medical histories, vital statistics, personal interviews, questionnaires, current addresses of study participants, radiographs, records on biological specimens, study models, and correspondence from or about participants in these studies.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301, Research and Investigation, and Section 441, National Institute of Child Health and Human Development, of the Public Health Service Act as amended (42 U.S.C. 241, 298d).

PURPOSE(S) OF THE SYSTEM:

This system is used: (1) For program review, evaluation, planning, and administrative management for research on child health and human development; (2) to monitor the incidence, prevalence or development of the disease, condition, behavior, or health status under investigation; (3) to determine the relation of various factors (e.g., social, economic, environmental, physical, and medical) to the occurrence of the disease, condition, development, behavior, or health status under investigation; (4) to identify abnormal disease, condition, or health status and inform the Centers for Disease Control (CDC) or the Food and Drug Administration (FDA) of the existence of such conditions. CDC uses this information in fulfilling its congressionally mandated responsibility for the monitoring of disease and prevention of epidemics. FDA uses this information in carrying out its congressional mandate for controlling certain potentially harmful products.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff for the purpose of analyzing data and preparing scientific reports and articles in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

4. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

5. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information,

and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

6. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

7. In the event of litigation where the defendant is: (a) The Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee; for example, in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, microfilm, magnetic tapes or disks, punched cards, or bound notebooks.

RETRIEVABILITY:

Information is retrieved by name and/or a participant identification number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* Employees who maintain records in this system are instructed to grant regular access only to contractor personnel; consultants to the contractor; the NICHD project officer; and NICHD employees whose duties require the use of such information. One time and special access to the data is controlled by the System Manager, the NICHD Project Officer, and the Contract and/or Project Director.

2. *Physical safeguards:* Records are stored in locked files or secured areas. Computer terminals are in secured areas.

3. *Procedural safeguards:* Names and other identifying particulars are deleted when data from original records is encoded for analysis. Encoded data is indexed by code numbers. Tables linking these code numbers with actual identifiers are maintained separately. Code numbers and identifiers are linked only if there is a specific need, such as alerting the volunteer subjects to any findings in the study that might affect their health. Data stored in computers is accessed through the use of passwords/keywords known only to the principal investigators or authorized personnel. These passwords/keywords are changed frequently.

The particular safeguards implemented in each project will be developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS hf: 45–13; Part 6, "ADP Systems Security," of the HHS ADP Systems Manual, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Chief, Contracts Management Branch, NICHD, Executive Plaza North, Room 7A07, 6100 Executive Blvd., North Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to: NICHD Privacy Act Coordinator, Executive Plaza North, Room 4A01B, 6100 Executive Blvd., North Bethesda, MD 20892 and provide the following information in writing:

1. Full name and address at time of participation in the study.

2. Name or description of the study.

3. Location and approximate dates of participation.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, the medical record of a child or incompetent person shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify his or her relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Same as notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants, medical and clinical research observations, and other Federal agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0154

SYSTEM NAME:

Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative (WHI) Studies, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, Executive Plaza North, room 343K, 6130 Executive Blvd., Bethesda, MD 20892,

and

National Institutes of Health, Building 12, 9000 Rockville Pike, Bethesda, MD 20892,

and

National Institutes of Health, Building 1, room 260, 9000 Rockville Pike, Bethesda, MD 20892,

and at hospitals, medical schools, universities, research institutions, commercial organizations, collaborating State and Federal Government agencies, and Federal Records Centers. Write to system manager at the address below for the address of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NCI: Adults and children in the following categories: Patients with cancer; persons for whom cancer risk can potentially be lowered; and persons without signs or symptoms who may be identified through screening and detection methods as having cancer or being at increased risk of developing cancer. For certain types of epidemiologic studies, e.g., case-control studies, NCI may also collect, for purposes of comparison, records on other persons. These comparison groups could include normal individuals (e.g., family members or neighborhood controls), or other patient groups (e.g., hospital controls) who do not have cancer or are not at a particularly high risk of developing cancer. WHI: Women for whom risk of cancer and/or other chronic disease may potentially be lowered. Women without signs or symptoms of chronic disease who may be identified through screening and detection methods as being at risk for serious chronic ailments. WHI may also collect, for purposes of comparison, longitudinal records on other women for whom no added disease risk has been identified.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information identifying participants (such as name, address, Social Security Number), medical records, progress reports, correspondence, epidemiological data, and records on biological specimens (e.g., blood, tumors, urine, etc).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

NCI: Sections 301, Research and Investigation, 405, Appointment and Authority of the Directors of the National Research Institutes, and Title IV, Part C, Subpart 1—National Cancer Institute, of the Public Health Service (PHS) Act (42 U.S.C. 241, 284 and 285–285a–5). WHI: 42 U.S.C. 241 and Section 402, Appointment and Authority of Director of NIH, of the PHS (42 U.S.C. 282).

PURPOSE(S) OF THE SYSTEM:

Records in this system will be used, (1) to evaluate cancer and other chronic disease control programs, including prevention, screening, detection, diagnosis, treatment, rehabilitation, and continuing care; (2) to identify characteristics of persons who may be particularly susceptible to environmental or occupational factors for substances which cause or prevent cancer and/or other chronic diseases; (3) to determine risk factors or substances which cause or prevent cancer and/or other chronic diseases, and the ways in which they do so; (4) to evaluate statistical and epidemiological methodologies for risk factor assessment, clinical trials, cancer control studies, and the study of the natural history of cancers and/or other chronic diseases; (5) to plan for, administer, and review research activities as described in the above purposes; (6) information from this system may be reported to the Food and Drug Administration (FDA) as a condition for approval of clinical investigations of new drugs, or to report adverse effects of drugs so that FDA can make informed decisions on authorizing use of such drugs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purposes for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

4. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

5. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the

Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, microfilm, charts, graphs, computer tapes, disks, and punch cards.

RETRIEVABILITY:

By name, Social Security Number when supplied voluntarily or contained in existing records used in projects under this system, or other identifying number.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for each location and for the particular records maintained in each project. Each site implements personnel, physical and procedural safeguards such as the following:

1. *Authorized users:* NCI and WHI employees who maintain records in this system are instructed to grant regular access only to physicians, scientists, and support staff of the National Cancer Institute and Women's Health Initiative, respectively, or their contractors, grantees or collaborators who need such information in order to contribute to the research or administrative purposes of the system. The system managers specifically authorize one-time and special access by others on a need-to-know basis consistent with the purposes and routine uses of the system.

2. *Physical safeguards:* Records are kept in limited access areas. Offices and records storage locations are locked during off-duty hours. Input data for computer files is coded to avoid individual identification. Where possible, information on individual identities is kept separate from data used for analysis.

3. *Procedural safeguards:* Access to manual files is granted only to authorized personnel, as described above. Access to computer files is controlled through security codes known only to authorized users. Names and other details necessary to identify individuals are not included in data files used for analysis. These files are indexed by code numbers. Code numbers and complete identifiers are linked only if there is a specific need, such as for data verification.

Contractors, grantees or collaborators who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager and permitted by the Privacy Act. Privacy Act requirements are specifically included in contracts and in agreements with grantees or collaborators participating in research activities supported by this system. HHS project director, contract officers and project officers oversee compliance with these requirements.

The particular safeguards implemented at each site are developed in accordance with Chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary Chapter PHS.hf: 45–13, and Part 6, "ADP Systems Security", of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESS:

Associate Director, Surveillance Program, DCPC, National Cancer Institute, Executive Plaza North, Room 343K, 6130 Executive Blvd., Bethesda, MD 20892

and

Director, Women's Health Initiative, Office of the Director, National Institutes of Health, Building 1, Room 260, 9000 Rockville Pike, Bethesda, MD 20892

NOTIFICATION PROCEDURE:

To determine if a file exists, write to the appropriate system manager and provide the following information:

a. System name: "Biomedical Research Records of Subjects: (1) Cancer Studies of the Division of Cancer Prevention and Control, HHS/NIH/NCI; and (2) Women's Health Initiative Studies, HHS/NIH/OD."

b. Complete name at time of participation;

c. Facility and home address at the time of participation;

d. In some cases, where records are retrieved by an identifying number, such as the Social Security Number or Hospital Identification Number, it may be necessary to provide that number. In some cases, to ensure proper identification it may be necessary to provide date(s) of participation (if known), birth date, disease type (if known), and study name and location (if known).

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a maximum fine of five thousand dollars.

Individuals seeking notification of or access to medical records should designate a representative (including address) who may be a physician, other health professional, or other responsible individual, who would be willing to review the record and inform the subject individual of its contents, at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Write to the appropriate system manager and provide the same information as requested under the notification procedure above. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the appropriate system manager, identify the record, and specify the information contested. State the corrective action sought and your reasons for requesting the correction,

and provide supporting information to show that the record is inaccurate, incomplete, irrelevant, untimely, or unnecessary. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

HHS agencies, institutions under contract to the U.S. Government, such as universities, medical schools, hospitals, research institutions, commercial institutions, state agencies, other U.S. Government agencies, patients and normal volunteers, physicians, research investigators and other collaborating personnel.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0156

SYSTEM NAME:

Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institutes of Health, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located either in the organizations responsible for conducting evaluations or at the sites of programs or activities under evaluation. Locations include National Institutes of Health (NIH) facilities in Bethesda, Maryland, or facilities of contractors of the NIH. Write to the appropriate System Manager below for a list of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system are those who provide information or opinions that are useful in evaluating programs or activities of the NIH, other persons who have participated in or benefitted from NIH programs or activities; or other persons included in evaluation studies for purposes of comparison. Such individuals may include (1) participants in research studies; (2) applicants for and recipients of grants, fellowships, traineeships or other awards; (3) employees, experts and consultants; (4) members of advisory committees; (5) other researchers, health care professionals, or individuals who have or are at risk of developing diseases or conditions studied by NIH; (6) persons who provide feedback about the value or usefulness of information they receive about NIH programs, activities or research results; (7) persons who have received Doctorate level degrees from U.S. institutions; (8) persons who have worked or studied at U.S. institutions that receive(d) institutional support from NIH.

CATEGORIES OF RECORDS IN THE SYSTEM:

This umbrella system of records covers a varying number of separate sets of records used in different evaluation studies. The categories of records in each set depend on the type of program being evaluated and the specific purpose of the evaluation. In general, the records contain two types of information: (1) Information identifying subject individuals, and (2) information which enables NIH to evaluate its programs and services.

(1) Identifying information usually consists of a name and address, but it might also include a patient identification number, grant number, Social Security Number, or other identifying number as appropriate to the particular group included in an evaluation study.

(2) Information used for evaluation varies according to the program evaluated. Categories of evaluative information include personal data and medical data on participants in clinical and research programs; personal data, publications, professional achievements and career history of researchers; and opinions and other information received directly from individuals in evaluation surveys and studies of NIH programs.

The system does not include any master list, index or other central means of identifying all individuals whose records are included in the various sets of records covered by the system.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Authority for this system comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 2891-1 and 44 U.S.C. 3101).

PURPOSE OF THE SYSTEM:

This system supports evaluation of the policies, programs, organization, methods, materials, activities or services used by NIH in fulfilling its legislated mandate for (1) conduct and support of biomedical research into the causes, prevention and cure of diseases; (2) support for training of research investigators; (3) communication of biomedical information.

This system is not used to make any determination affecting the rights, benefits or privileges of any individual.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to HHS contractors and collaborating researchers, organizations, and State and local officials for the purpose of conducting evaluation studies or collecting, aggregating, processing or analyzing records used in evaluation studies. The recipients are required to protect the confidentiality of such records.

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessments, medical audits or utilization review.

3. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

4. The Department may disclose information from this system of records to the Department of Justice, to court or other tribunal, or to another party before such tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the tribunal, or the other party is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders, bound notebooks, or computer-accessible media (e.g., magnetic tapes or discs).

RETRIEVABILITY:

Information is retrieved by name and/or participant identification number within each evaluation study. There is no central collection of records in this system, and no central means of

identifying individuals whose records are included in the separate sets of records that are maintained for particular evaluation studies.

SAFEGUARDS:

A variety of safeguards are implemented for the various sets of records in this system according to the sensitivity of the data each set contains. Information already in the public domain, such as titles and dates of publications, is not restricted. However, sensitive information, such as personal or medical history or individually identified opinions, is protected according to its level of sensitivity. Records derived from other systems of records will be safeguarded at a level at least as stringent as that required in the original systems. Minimal safeguards for the protection of information which is not available to the general public include the following:

1. *Authorized users:* Regular access to information in a given set of records is limited to NIH or to contractor employees who are conducting, reviewing or contributing to a specific evaluation study. Other access is granted only on a case-by-case basis, consistent with the restrictions required by the Privacy Act (e.g., when disclosure is required by the Freedom of Information Act), as authorized by the system manager or designated responsible official.

2. *Physical safeguards:* Records are stored in closed or locked containers, in areas which are not accessible to unauthorized users, and in facilities which are locked when not in use. Records collected in each evaluation project are maintained separately from those of other projects. Sensitive records are not left exposed to unauthorized persons at any time. Sensitive data in machine-readable form may be encrypted.

3. *Procedural safeguards:* Access to records is controlled by responsible employees and is granted only to authorized individuals whose identities are properly verified. Data stored in mainframe computers is accessed only through the use of keywords known only to authorized personnel. When personal computers are used, magnetic media (e.g. diskettes) are protected as under Physical Safeguards. When data is stored within a personal computer (i.e., on a "hard disk"), the machine itself is treated as though it were a record, or records, under Physical Safeguards. Contracts for operation of this system of records require protection of the records in accordance with these safeguards; NIH project and contracting officers monitor contractor compliance.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–C–2. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGERS AND ADDRESSES:

See Appendix 1.

Policy coordination for this system is provided by: Director, Division of Planning and Evaluation, Office of Science Policy and Legislation, National Institutes of Health, Building 31, Room 4B25, 9000 Rockville Pike, Bethesda, MD 20892.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the official of the organization responsible for the evaluation, as listed in Appendix 2. If you are not certain which component of NIH was responsible for the evaluation study, or if you believe there are records about you in several components of NIH, write to: NIH Privacy Act Coordinator, Building 31, Room 3B07, 9000 Rockville Pike, Bethesda, MD 20892.

Requesters must provide the following information:

1. Full name, and name(s) used while studying or employed;
2. Name and location of the evaluation study or other NIH program in which the requester participated or the institution at which the requester was a student or employee, if applicable;
3. Approximate dates of participation, matriculation or employment, if applicable.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, other health professional, or other responsible individual, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURES:

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Information contained in these records is obtained directly from individual participants; from systems of records 09–25–0036, "Grants: IMPAC (Grants/Contract Information), HHS/NIH/DRG;" 09–25–0112, "Grants: Research, Research Training, Fellowship and Construction Applications and Awards, HHS/NIH/OD"; NSF–6, "Doctorate Record File", NSF–43, "Doctorate Work History File" (previously entitled "NSF–43, "Roster and Survey of Doctorate Holders in The United States" and other records maintained by the operating programs of NIH; the National Academy of Sciences, professional associations such as the AAMC and ADA, and other contractors; grantees or collaborating researchers; or publicly available sources such as bibliographies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix 1—System Managers

National Institutes Health, Office of the Director, Director, Division of Planning and Evaluation, Office of Science Policy and Legislation, Building 31, Room 4B25, 9000 Rockville Pike, Bethesda, MD 20892

National Institutes Health, Office of the Director, Director, Division of Personnel Management, Building 1, Room B1–60, 9000 Rockville Pike, Bethesda, MD 20892

National Heart, Lung, and Blood Institute (NHLBI), Director, Office of Program Planning & Evaluation, Building 31, Room 5A03, Bethesda, MD 20892

National Library of Medicine (NLM), Assistant Director for Planning and Evaluation, Building 38, Room 2S18, Bethesda, MD 20894

National Eye Institute (NEI), Associate Director, Office of Science Policy and Legislation, Building 31, Room 6A27, Bethesda, MD 20892

National Cancer Institute (NCI), Public Health Educator, OCC, NCI, National Institutes of Health, Building 31, Room 4B43, Bethesda, MD 20892

National Institute on Aging (NIA), Chief, Office of Planning, Analysis, Technical Information and Evaluation, Federal Building, Room 6A09, 7550 Wisconsin Avenue, Bethesda, MD 20892

National Institute of Allergy and Infectious Diseases (NIAID), Chief, Evaluation and Reporting Section, Policy Analysis and Legislation Branch, Office of Administration Management, Building 31, Room 7A52, Bethesda, MD 20892

National Institute of Child Health and Human Development (NICHD), Chief, Office of Science Policy and Analysis, Building 31, Room 2A10, Bethesda, MD 20892

National Institute on Deafness and Other Communication Disorders, Chief, Program Planning and Health Reports Branch, Building 31, Room 3C35, 9000 Rockville Pike, Bethesda, MD 20892

National Institute of Dental Research (NIDR), Chief, Office of Planning Evaluation, and Communications, Building 31, Room 2C36, Bethesda, MD 20892

National Institute of Environmental Health Sciences (NIEHS) Program Analyst, Office of Program Planning and Evaluation, P.O. Box 12233, Research Triangle Park, N.C. 27709

National Institute of General Medical Sciences (NIGMS), Chief, Office of Program Analysis, Westwood Building, Room 934, 5333 Westbard Avenue, Bethesda, MD 20892

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892

Division of Research Grants (DRG), Assistant Director for Special Projects, Westwood Building, Room 457, 5333 Westbard Avenue, Bethesda, MD 20892

National Center for Research Resources (NCRR), Evaluation Officer, Office of Science Policy, Westwood Building, Room 8A03, Bethesda, MD 20892

National Center for Nursing Research (NCNR), Chief, Office of Planning, Analysis and Evaluation, Building 31, Room 5B13, Bethesda, MD 20892

National Institute of Mental Health, Associate Director, Office of Program Planning and Science Policy, Parklawn Building, Room 7C–06, 5600 Fishers Lane, Rockville, MD 20857

Appendix 2—Notification and Access Officials

NIH, Office of the Director, Associate Director for Science, Policy and Legislation, Building 1, Room 137, 9000 Rockville Pike, Bethesda, MD 20892

National Institutes Health, Office of the Director, Director, Division of Personnel Management, Building 1, Room B1–60, 9000 Rockville Pike, Bethesda, MD 20892

National Heart, Lung, and Blood Institute (NHLBI), Privacy Act Coordinator, Building 31, Room 5A29, Bethesda, MD 20892

National Library of Medicine (NLM), Assistant Director for Planning and Evaluation, Building 38, Room 2S18, Bethesda, MD 20894

National Eye Institute (NEI), Executive Officer, Building 31, Room 6A25, Bethesda, MD 20892

Fogarty International Center (FIC), National Institutes of Health, Assistant Director for Planning, Evaluation and Public Affairs, Building 31, Room B2C32, Bethesda, MD 20892

Division of Research Grants (DRG), Assistant Director for Special Projects, Westwood Building, Room 457, 5333 Westbard Avenue, Bethesda, MD 20892

National Center for Research Resources (NCRR), Evaluation Officer, Office of Science Policy, NIH, Westwood Building, Room 8A03, Bethesda, MD 20892

National Cancer Institute, Privacy Act Coordinator, National Institutes of Health, Building 31, Room 10A30, Bethesda, MD 20892

National Institute of Mental Health, Privacy Act Coordinator, Parklawn Building, Room 15–81, 5600 Fishers Lane, Rockville, MD 20857

09–25–0158

SYSTEM NAME:

Administration: Records of Applicants and Awardees of the NIH Intramural Research Training Awards Program, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of the Associate Director for Intramural Affairs, National Institutes of Health, Building 1, Room 140, 9000 Rockville Pike, Bethesda, MD 20892

and

Office of Education, Building 10, Room 1C125, 9000 Rockville Pike, Bethesda, MD 20892,

and at locations in each of the intramural offices and laboratories Here the Intramural Research Training Awards (IRTA) Fellow is located and assigned, including the respective Scientific Director's office, the administrative and personnel offices, and in Division of Personnel Management branches responsible for administering the IRTA Program.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Applicants for IRTA Fellowships, current IRTA Fellows, and former IRTA Fellows.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records contain information relating to education and training, employment history, scientific publications; research goals; letters of reference; and personal information such as name, date of birth, Social Security number, home address and citizenship; and information related to fellowship awards such as stipend levels, training assignments, training expenses and travel allowances.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

42 USC 284(b)(1)(C), 286b–3, and 287c–1 authorizes PHS to make awards for biomedical research and research training.

PURPOSE(S) OF THE SYSTEM:

Records in this system are used to determine individuals' eligibility and evaluate their qualifications for IRTA Fellowships; to document the basis for management actions relating to Fellowships that are awarded; and to provide data for program evaluation.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. Disclosure may be made to the Office of Personnel Management for evaluation of NIH Personnel programs.

2. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the written request of that individual.

3. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any

of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

4. Disclosure may be made to a Federal, State or local agency maintaining civil, criminal or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the selection or retention of a fellow.

5. Disclosure may be made to a Federal agency, in response to its request, in connection with hiring or retention of an employee, the issuance of a security clearance, an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders, and on magnetic tapes and disks.

RETRIEVABILITY:

Records are retrieved by name, Social Security number, or institute list number.

SAFEGUARDS:

1. *Authorized users:* Access is granted only to NIH scientists, administrative office staff, personnel staff and financial management staff directly involved in the administration of the IRTA Program.

2. *Physical safeguards:* File folders are kept in locked drawers or locked rooms when system personnel are not present.

3. *Procedural safeguards:* Access to file folders is controlled by system personnel. Records may be removed from the files only with the approval of the system manager or other authorized employees. Data stored in the automated system is accessed through the use of keywords known only to authorized personnel.

These practices are in compliance with the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and Part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 4000–E–3. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER AND ADDRESSES:

Associate Director for Intramural Affairs, NIH, Building I, Room 103, 9000 Rockville Pike, Bethesda, Maryland 20892

NOTIFICATION PROCEDURE:

Write to the System Manager to determine if a record exists. The requestor must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORDS ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Write to the official specified under the notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is untimely, incomplete, irrelevant or inaccurate. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Applicants, persons and institutions supplying references.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0161

SYSTEM NAME:

Administration: NIH Consultant File, HHS/NIH/DRG.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

This system of records is an umbrella system comprising separate sets of records located in each of the NIH organizational components or facilities of contractors of the NIH.

Division of Computer Research and Technology, Data Management Branch, Building 12A, Room 4041B, National Institutes of Health, Bethesda, Maryland 20892

Write to the appropriate system manager listed in Appendix I for a list of current locations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Consultants who provide the evaluation of extramural grants and cooperative agreement applications and research contract proposals, including the NIH Reviewers' Reserve.

CATEGORIES OF RECORDS IN THE SYSTEM:

Names, addresses, Social Security numbers, resumes, curriculum vitae (C.V.s), areas of expertise, publications, travel records, and payment records for consultants.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 301 of the Public Health Service Act, describing the general powers and duties of the Public Health Service relating to research and investigation, and section 402 of the Public Health Service Act, describing the appointment and authority of the Director of the National Institutes of Health (42 USC 241, 282 and 290aa).

PURPOSE OF THE SYSTEM:

This umbrella system comprises separate sets of records located in each of the NIH organizational components or facilities of contractors of the NIH. These records are used: (1) To identify and select experts and consultants for program reviews and evaluations; (2) To identify and select experts and consultants for the review of special grant and cooperative agreement applications and research contract proposals; and (3) To pay consultants and provide necessary reports related to payment to the Internal Revenue Service.

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ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. Disclosure may be made to contractors to process or refine the records. Contracted services may include transcription, collation, computer input, and other records processing.

4. Information in this system of records is used routinely to prepare W–2 and 1099 Forms to submit to the Internal Revenue Service and applicable State and local governments those items to be included as income to an individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored in file folders, computer tapes and disks, microfiche, and microfilm.

RETRIEVABILITY:

Records are retrieved by name, address, or expertise.

SAFEGUARDS:

1. *Authorized users:* Data on computer files is accessed by keyword known only to authorized users who are NIH or contractor employees involved in managing a review or program advisory committee, conducting a review of extramural grant applications, cooperative agreement applications, or research contract proposals, performing an evaluation study or managing the consultant file. Access to information is thus limited to those with a need to know.

2. *Physical safeguards:* Rooms where records are stored locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel.

3. *Procedural safeguards:* Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through the use of keywords known only to authorized users. Contractors who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager and permitted by the Privacy Act.

This system of records will be protected according to the standards of Chapter 45–13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, and part 6, "ADP Systems Security," of the HHS Information Resources Management Manual and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 1100–G. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER(S) AND ADDRESS:

The policy coordinator for this system is also the system manager listed for the Division of Research Grants.

Chief, Physiological Sciences Review Section, Referral and Review Branch, Division of Research Grants, Westwood Building, Room 203A, 5333 Westbard Avenue, Bethesda, Maryland 20892
and
See Appendix I

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate system manager as listed in Appendix I.

The requestor must also verify his or her identity by providing either a notarization of the request or a written certification that the requestor is whom he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requestors should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures that have been made of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the official under notification procedures above, reasonably identify the record, specify the information to be contested, and state the corrective action sought with supporting information. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I—System Managers

Office of the Director (OD), Extramural Programs Management Officer, Building 1, Room 328, Bethesda, MD 20892
National Center for Research Resources (NCRR), Director, Office of Review, Westwood Building, Room 5A16, Bethesda, MD 20892
National Cancer Institute (NCI), Chief, Review Logistics Branch, Westwood Building, Room 850, Bethesda, MD 20892
National Eye Institute (NEI), Review and Special Projects Officer, Building 31, Room 6A06, Bethesda, MD 20892
National Heart, Lung, and Blood Institute (NHLBI), Associate Director for Review, Westwood Building, Room 557A, Bethesda, MD 20892
National Institute on Aging (NIA), Chief, Scientific Review Office, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892
National Institute of Allergy and Infectious Diseases (NIAID), Deputy Director, Division of Extramural Activities, Solar Bldg., Room 4C–03, 6003 Executive Blvd., Rockville, MD 20892.
National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Chief, Grants Review Branch, Westwood Building, Room 406, Bethesda, MD 20892
National Institute of Child Health and Human Development (NICHD), Director, Division of Scientific Review, Executive Plaza North, Room 520, Bethesda, MD 20892
National Institute on Deafness and Other Communication Disorders (NIDCD), Chief, Scientific Review Branch, Executive Plaza South, Room 400B, 620 Executive Boulevard, Rockville, MD 20852
National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Chief, Review Branch, Westwood Building, Room 603, Bethesda, MD 20892
National Institute of Dental Research (NIDR), Chief, Scientific Review Section, POB, Westwood Building, Room 519, Bethesda, MD 20892
National Institute of Environmental Health Sciences (NIEHS), Deputy Director,

Division of E
Training, P.O
Triangle Park
National Institu
Sciences (NIG
Activities, W
9A18, Bethes
National Institu
and Stroke (N
Review Bran
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Review, Buil
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Building, Ro
Rockville, M
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OPRM, Park
5600 Fishers

09–25–0165

SYSTEM NAME:

National I
Immunodefi
Research Lo
HHS/NIH/O

SECURITY CLAS

None:

SYSTEM LOCAT

Office of AID
National I
31, Room
Bethesda,
and
Division of C
Technolog
Institutes
Room 403
Bethesda,
and
Operations A
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National I
31, Room
Bethesda,
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NIH offices
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Center wher
may be stor

Division of Extramural Research and Training, P.O. Box 12233, Research Triangle Park, NC 27709

National Institute of General Medical Sciences (NIGMS), Chief, Office of Review Activities, Westwood Building, Room 9A18, Bethesda, MD 20892

National Institute of Neurological Disorders and Stroke (NINDS), Chief, Scientific Review Branch, Federal Building, Room 9C10A, Bethesda, MD 20892

National Center for Nursing Research (NCNR), Executive Secretary, NRRC and NACNR, Building 31, Room 5B19, Bethesda, MD 20892

National Library of Medicine (NLM), Chief, Biomedical Information Support Branch, Building 38A, Room 5S522, Bethesda, MD 20894

National Center for Human Genome Research (NCHGR), Chief, Office of Scientific Review, Building 38A, Room 606, Bethesda, MD 20892

National Institute of Mental Health, Contract Officer, Contracts Management Branch, ORM, Parklawn Building, Room 7C18, 5600 Fishers Lane, Rockville, MD 20857

National Institute on Alcohol Abuse and Alcoholism, Contract Officer, Contracts Management Branch, OPRM, Parklawn Building, Room 14C06, 5600 Fishers Lane, Rockville, MD 20857

National Institute of Drug Abuse, Contract Officer, Contracts Management Branch, OPRM, Parklawn Building, Room 10–49, 5600 Fishers Lane, Rockville, MD 20857

09–25–0165

SYSTEM NAME:

National Institutes of Health Acquired Immunodeficiency Syndrome (AIDS) Research Loan Repayment Program, HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Office of AIDS Research (OAR), National Institutes of Health, Building 31, Room 5C12, 9000 Rockville Pike, Bethesda, Maryland 20892

and

Division of Computer Research and Technology (DCRT), National Institutes of Health, Building 12A, Room 4037, 9000 Rockville Pike, Bethesda, Maryland 20892

and

Operations Accounting Branch, Division of Financial Management (DFM), National Institutes of Health, Building 31, Room B1B55, 9000 Rockville Pike, Bethesda, Maryland 20892.

See Appendix I for a listing of other NIH offices responsible for administration of the AIDS Research Loan Repayment Program. Write to the System Manager at the address below for the address of any Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who have applied for, who have been approved to receive, who are receiving, and who have received funds under the NIH AIDS Research LRP; and individuals who are interested in participation in the NIH AIDS Research LRP.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, address, Social Security number; service pay-back obligations, standard school budgets, educational loan data including deferment and repayment/delinquent/default status information; employment data; professional and credentialing history of licensed health professionals including schools of attendance; personal, professional, and demographic background information; employment status verification (which includes certifications and verifications of continuing participation in AIDS research); Federal, State and local tax information, including copies of tax returns.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 487A (42 USC 288–1) of the PHS Act, as amended, directing the NIH to establish and implement a program of educational loan repayment for qualified health professionals who agree to conduct, as employees of NIH, AIDS research. The provisions of section 338B of the PHS Act (42 USC 2541–1), as amended, governing the NHSC loan repayment program, are incorporated except as inconsistent. The Internal Revenue Code at 26 USC 6109 requires the provision of the SSN for the receipt of loan repayment funds under the NIH AIDS Research LRP.

PURPOSE(S) OF THE SYSTEM:

(1) To identify and select applicants for the NIH AIDS Research LRP; (2) To monitor loan repayment activities, such as payment tracking, deferment of service obligation, and default; and (3) To assist NIH officials in the collection of overdue debts owed under the NIH AIDS Research LRP. Records may be transferred to system No. 09–15–0045, "Health Resources and Services Administration Loan Repayment/Debt Management Records System, HHS/HRSA/OA," for debt collection purposes when NIH officials are unable to collect overdue debts owed under the NIH AIDS Research LRP.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

2. Disclosure may be made to the Department of Justice or to a court or other tribunal from this system of records, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity: or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States of any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided, however, that in each case HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, or local, charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

4. NIH may disclose records to Department contractors and subcontractors for the purpose of collecting, compiling, aggregating, analyzing, or refining records in the system. Contractors maintain, and are also required to ensure that subcontractors maintain, Privacy Act safeguards with respect to such records.

5. NIH may disclose information from this system of records to private parties such as present and former employers, references listed on applications and associated forms, other references and educational institutions. The purpose of such disclosures is to evaluate an individual's professional accomplishments, performance, and educational background, and to determine if an applicant is suitable for participation in the NIH AIDS Research LRP.

6. NIH may disclose information from this system of records to a consumer reporting agency (credit bureau) to obtain a commercial credit report to

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assess and verify the ability of an individual to repay debts owed to the Federal Government. Disclosures are limited to the individual's name, address, Social Security number and other information necessary to identify him/her; the funding being sought or amount and status of the debt; and the program under which the applicant or claim is being processed.

7. NIH may disclose from this system of records a delinquent debtor's or a defaulting participant's name, address, Social Security number, and other information necessary to identify him/her; the amount, status, and history of the claim, and the agency or program under which the claim arose, as follows:

a. To another Federal agency so that agency can effect a salary offset for debts owed by Federal employees; if the claim arose under the Social Security Act, the employee must have agreed in writing to the salary offset.

b. To another Federal agency so that agency can effect an unauthorized administrative offset; i.e., withhold money, other than federal salaries, payable to or held on behalf of the individual.

c. To the Treasury Department, Internal Revenue Service (IRS), to request an individual's current mailing address to locate him/her for purposes of either collecting or compromising a debt, or to have a commercial credit report prepared.

8. NIH may disclose information from this system of records to another agency that has asked the Department to effect a salary or administrative offset to help collect a debt owed to the United States. Disclosure is limited to the individual's name, address, Social Security number, and other information necessary to identify the individual to information about the money payable to or held for the individual, and other information concerning the offset.

9. NIH may disclose to the Treasury Department, Internal Revenue Service (IRS), information about an individual applying for loan repayment under any loan repayment program authorized by the Public Health Service Act to find out whether the applicant has a delinquent tax account. This disclosure is for the sole purpose of determining the applicant's creditworthiness and is limited to the individual's name, address, Social Security number, other information necessary to identify him/her, and the program for which the information is being obtained.

10. NIH may report to the Treasury Department, Internal Revenue Service (IRS), as taxable income, the written-off amount of a debt owed by an individual to the Federal Government when a debt becomes partly or wholly uncollectible, either because the time period for collection under the statute of limitations has expired, or because the Government agrees with the individual to forgive or compromise the debt.

11. NIH may disclose to debt collection agents, other Federal agencies, and other third parties who are authorized to collect a Federal debt, information necessary to identify a delinquent debtor or a defaulting participant. Disclosure will be limited to the individual's name, address, Social Security number, and other information necessary to identify him/her; the amount, status, and history of the claim, and the agency or program under which the claim arose.

12. NIH may disclose information from this system of records to any third party that may have information about a delinquent debtor's or a defaulting participant's current address, such as a U.S. post office, a State motor vehicle administration, a professional organization, an alumni association, etc., for the purpose of obtaining the individual's current address. This disclosure will be strictly limited to information necessary to identify the individual, without any reference to the reason for the agency's need for obtaining the current address.

13. NIH may disclose information from this system of records to other Federal agencies that also provide loan repayment at the request of these Federal agencies in conjunction with a matching program conducted by these Federal agencies to detect or curtail fraud and abuse in Federal loan repayment programs, and to collect delinquent loans or benefit payments owed to the Federal Government.

14. NIH may disclose from this system of records to the Department of Treasury, Internal Revenue Service (IRS): (1) A delinquent debtor's or a defaulting participant's name, address, Social Security number, and other information necessary to identify the individual; (2) the amount of the debt; and (3) the program under which the debt arose, so that IRS can offset against the debt any income tax refunds which may be due to the individual.

15. NIH may disclose information provided by a lender to other Federal agencies, debt collection agents, and other third parties who are authorized to collect a Federal debt. The purpose of this disclosure is to identify an individual who is delinquent in loan or benefit payments owed to the Federal Government.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 U.S.C. 552a(b)(12): Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of these disclosures are: (1) To provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable NIH to improve the quality of loan repayment decisions by taking into account the financial reliability of applicants, including obtaining a commercial credit report to assess and verify the ability of an individual to repay debts owed to the Federal Government. Disclosure of records will be limited to the individual's name, Social Security number, and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in file folders, computer tape, discs, and file cards.

RETRIEVABILITY:

Records are retrieved by name, Social Security number, or other identifying numbers.

SAFEGUARDS:

1. *Authorized users:* Data on computer files is accessed by keyword known only to authorized users who are NIH employees responsible for implementing the NIH AIDS Research LRP. Access to information is thus limited to those with a need to know.

2. *Physical safeguards:* Rooms where records are stored and locked when not in use. During regular business hours rooms are unlocked but are controlled by on-site personnel. Security guards perform random checks on the physical security of the data.

3. *Procedural and technical safeguards:* A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information from public view and from unauthorized personnel entering an unsupervised office.

These practices are in compliance with the standards of Chapter 45–13 of

the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45–13, the Department's Automated Information System Security Handbook, and the National Institute of Standards and Technology Federal Information Processing Standards (FIPS Pub. 41 and FIPS Pub. 31).

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B–361), item 2300–537–1. Participant case files are transferred to a Federal Records Center one year after closeout and destroyed five years later. Closeout is the process by which it is determined that all applicable administrative actions and loan repayments have been completed by the LRP and service obligations have been completed by the participant. Applicant case files are destroyed three years after disapproval or withdrawal of their application. Official appeal and litigation case files are destroyed six years after the calendar year in which the case is closed. Other copies of these files are destroyed two years after the calendar year in which the case is closed.

SYSTEM MANAGER AND ADDRESS:

Director, NIH AIDS Research Loan Repayment Program, Office of AIDS Research, National Institutes of Health, Building 31, room 5C12, 9000 Rockville Pike, Bethesda, Maryland 20892.

NOTIFICATION PROCEDURES:

To determine if a record exists, write to the System Manager listed above. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be. The request should include: (a) Full name, and (b) appropriate dates of participation. The requester must also understand that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine. Requesters appearing in person must provide a valid driver's license or passport, including photo, and at least one other form of identification.

RECORD ACCESS PROCEDURES:

Write to the System Manager specified above to attain access to records and provide the same information as is required under the Notification Procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosure of their records, if any.

CONTESTING RECORD PROCEDURES:

Contact the System Manager specified above and reasonably identify the record, specify the information to be contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual; participating lending institutions; educational institutions attended; other Federal agencies; consumer reporting agencies/credit bureaus; and third parties that provide references concerning the subject individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I—System Locations

Office of AIDS Research, National Institutes of Health, Building 31, Room 5C12, 9000 Rockville Pike, Bethesda, Maryland 20892
Division of Computer Research and Technology, National Institutes of Health, Building 12A, Room 4037, 9000 Rockville Pike, Bethesda, Maryland 20892
Operations Accounting Branch, Division of Financial Management, National Institutes of Health, Building 31, Room B1B55, 9000 Rockville Pike, Bethesda, Maryland 20892
Division of Cancer Treatment, National Cancer Institute, National Institutes of Health, Building 31, Room 3A44, 9000 Rockville Pike, Bethesda, MD 20892
Division of Cancer Etiology, National Cancer Institute, National Institutes of Health, Building 41, Room A208, 9000 Rockville Pike, Bethesda, MD 20892
Division of Cancer Biology, Diagnosis, and Centers, National Cancer Institute, National Institutes of Health, Building 31, Room 3A05, 9000 Rockville Pike, Bethesda, MD 20892
National Heart, Lung, and Blood Institute, National Institutes of Health, Building 10, Room 7N218, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Dental Research, National Institutes of Health, Building 31, Room 2C23, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Building 10, Room 9N222, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Neurological Disorders and Stroke, National Institutes of Health, Building 10, Room 5N220, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Allergy and Infectious Diseases, National Institutes of Health, Building 31, Room 7A05, 9000 Rockville Pike, Bethesda, MD 20892
Pharmacological Sciences Program, National Institute of General Medical Sciences, National Institutes of Health, 5333 Westbard Avenue, Room 919, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Child Health and Human Development, National Institutes of Health, Building 31, Room 2A25, 9000 Rockville Pike, Bethesda, MD 20892
National Eye Institute, National Institutes of Health, Building 10, Room 10N202, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Environmental Health Sciences, National Institutes of Health, P.O. Box 12233, Research Triangle Park, NC 27709
Gerontology Research Center, National Institute on Aging, National Institutes of Health, 4940 Eastern Avenue, Baltimore, MD 21224
National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health, Building 31, Room 4C13, 9000 Rockville Pike, Bethesda, MD 20892
National Institute of Deafness and Communication Disorders, National Institutes of Health, Building 31, Room 3C02, 9000 Rockville Pike, Bethesda, MD 20892
National Center for Research Resources, National Institutes of Health, Building 31, Room 3B36, 9000 Rockville Pike, Bethesda, MD 20892
National Center for Nursing Research, National Institutes of Health, Building 31, Room 5B06, 9000 Rockville Pike, Bethesda, MD 20892
Critical Care Medicine Department, Clinical Center, National Institutes of Health, Building 10, Room 7D43, 9000 Rockville Pike, Bethesda, MD 20892
National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, Parkiawn Building, Room 16C05, 5600 Fishers Lane, Rockville, MD 20857
National Institute on Drug Abuse, National Institutes of Health, Parklawn Building, Room 10A38, 5600 Fishers Lane, Rockville, MD 20857.
National Institute of Mental Health, National Institutes of Health, Parklawn Building, Room 1599, 5600 Fishers Lane, Rockville, MD 20857.

09–25–0201

SYSTEM NAME:

Clinical Research: National Institute of Mental Health Patient Records, HHS/NIH/NIMH.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20205.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

In- and out-patients with emotional, psychiatric, and neurophysiological disability, normal subjects, and research subjects.

CATEGORIES OF RECORDS IN THE SYSTEM:

Research data of wide variety including biochemical measures, psychophysiological and psychological tests, questionnaires, clinical and behavioral observations and interviews, physical examinations, and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301, 302, and 303 (42 U.S.C. 241, 242, 242a).

PURPOSE(S) OF THE SYSTEM:

These records are used for diagnosis and treatment of patients with neuropsychiatric illnesses; behavioral research relating to the causes, diagnoses, and treatment of neuropsychiatric disorders; and basic research on behavioral processes and personality development.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USE:

1. A record may be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

3. In the event of litigation where the defendant is (a) the Department, and component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

In original state; files, indexes, magnetic and other tapes.

RETRIEVABILITY:

Retrieved by name (coded).

SAFEGUARDS:

1. *Authorized users:* Only authorized medical and research staff have access to these records.

2. *Physical safeguards:* Magnetic tapes, files, indexes, and other tapes that contain individually identifiable data are stored in a locked cabinet in a limited access area.

3. *Procedural safeguards:* Magnetic data are further protected by special account numbers and passwords.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual, and Part 6, "ADP System Security" in the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the NIH Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Intramural Research Program, National Institute of Mental Health, Building 10, Room 4N–224, 9000 Rockville Pike, Bethesda, Maryland 20205.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. Provide notarized signature as proof of identity. The request should include as much of the following information as possible: (a) Full name; (b) nature of illness (if any); (c) ward or laboratory; (d) title of study; (e) name of researcher conducting study. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of child's/incompetent person's record shall at the time the request is made designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The designate will receive the record in all cases and upon review will determine whether the record should be made available to the parent or guardian.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Information gathered from individuals under study, either patient or normal subject, contract surveys, hospital records, medical and nursing staff notes.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0202

SYSTEM NAME:

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Drug Abuser
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SECURITY CLAS

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09–25–0202

SYSTEM NAME:

Patient Records on PHS Beneficiaries (1935–1974) and Civilly Committed Drug Abusers (1967–1976) Treated at the PHS Hospitals in Fort Worth, Texas, or Lexington, Kentucky, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Addiction Research Center, National Institute on Drug Abuse, Francis Scott Key Medical Center, PO Box 5180, Baltimore, Maryland 21224.
Federal Records Center, 1557 St. Joseph Avenue, East Point, Georgia 30344.
Washington National Records Center, 4205 Suitland Road, Washington, DC 20409.
National Business Activities, 8200 Preston Court, Suite One, Jessup, Maryland 20794.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Civilly committed narcotic addicts (1967–1976) and adult PHS beneficiaries (1935–1974) treated at either the PHS hospital in Fort Worth, Texas, or Lexington, Kentucky.

CATEGORIES OF RECORDS IN THE SYSTEM:

Administrative records, such as treatment admission and release dates, name and address, and other demographic data; medical records, such as, but not limited to, medical history information, drug abuse/use data as well as treatment information, any laboratory tests, etc.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Narcotic Addict Rehabilitation Act of 1966, and Narcotic Addict Rehabilitation Amendments of 1971, Titles I and III (42 U.S.C. 3411 et seq. and 28 U.S.C. 2901 et seq.), and Public Health Service Act, sections 321–326, 341 (a) and (c) (42 U.S.C. 248–253, 257 (a) and (c)).

PURPOSE(S) OF THE SYSTEM:

The records were collected originally to monitor the individual's progress while being treated at either of two PHS hospitals and to ensure continuity of that care. These systems are now inactive. The records are used to respond to requests from subject individuals (or his/her designated representative) to (1) establish eligibility for certain Federal benefits for the individual or his/her dependent(s), and (2) provide information to subsequent health care providers at the request of the individual regarding medical treatment received to ensure continuity of care.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

None.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records at National Institute on Drug Abuse (NIDA) are on microfilm and contain only part of the admission and discharge information. The microfilm is stored in a file cabinet in a locked room. Records sent to Federal Records Center are stored in GSA-approved storage containers.

RETRIEVABILITY:

The administrative records and microfilm are filed by patient name. The medical records are filed either by patient name or by patient's hospital number with a cross-reference list at NIDA matching number to name.

SAFEGUARDS:

1. *Authorized users:* Only the System Manager and designated staff.

2. *Physical safeguards:* The microfilm is in a room which has limited access, or stored at a security coded warehouse. The room is located in a building with a 24-hour security patrol/television surveillance system. Sign in and out procedures are used at all times. The warehouse has security access, records can only be retrieved by the System Manager or designated staff using a confidential code number. The warehouse is patrolled on a 24-hour basis with television surveillance.

3. *Procedural safeguards:* Only the System Manager and his/her staff have access to the microfilm information and have been trained in accordance with the Privacy Act.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual.

RETENTION AND DISPOSAL:

All administrative and medical records have been retired to a Federal Records Center. The records collected under the Narcotic Addict Rehabilitation Act of 1966 will be destroyed when they are 25 years old, which will be in 2001 because the last patient was released from treatment in 1976. The PHS beneficiaries' records will be destroyed at the same time. The records will be shredded in 2003 upon written request from the System Manager.

SYSTEM MANAGER(S) AND ADDRESSES:

Clinical Director, Addiction Research Center, National Institute on Drug Abuse, Francis Scott Key Medical Center, Box 5180, Baltimore, Maryland 21224.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself or herself upon written request with a notarized signature. The request should include, if known: Patient hospital record number, full name or any alias used, patient's address during treatment, birth date, veteran status (if applicable) and approximate dates in treatment, and Social Security Number.

An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the individual of its content at the representative's discretion.

RECORD ACCESS PROCEDURES:

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Patients; patients' drug treatment program counselors; court records; hospital personnel.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0203

SYSTEM NAME:

National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Research Files, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Addiction Research Center, Francis Scott Key Medical Center—Building C, P.O. Box 5150, Baltimore, Maryland 21224

Maryland Medical Laboratories, Inc., Pathology Building, 1901 Silver Spring Road, Baltimore, Maryland 21227
Federal Records Center, 1557 St. Joseph Avenue, East Point, Georgia 30344
Washington National Records Center, 4205 Suitland Road, Washington, DC 20409
NOVA, Francis Scott Key Medical Center—Building C, 4940 Eastern Avenue, Baltimore, Maryland 21224
National Business Activities, 6200 Preston Court, Suite One, Jessup, Maryland 20794

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Volunteers, adult males (from 1968 to present), adult females (beginning in 1985) and adolescents (ages 13–18, beginning in 1983) and children (neonate to 12 beginning in 1989). Clinical research projects conducted at the Addiction Research Center (ARC). This system also includes records on adult Federal prisoners involved in research projects at ARC when located at Lexington, Kentucky, from 1968–1976, and some records from system 09–30–0020 to be used for statistical research only.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories of records involved are administrative, medical and research records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, section 301(a) (42 U.S.C. 241(a)); sections 341(a) and 344(d) (42 U.S.C. 257(a) and 260(d)); sections 503 and 515 (42 U.S.C 290aa-2 and 290cc). These sections authorize the conduct of research in all areas of drug abuse.

PURPOSE(S) OF THE SYSTEM:

(1) To collect and maintain a data base for research activities at ARC, and (2) to enable Federal drug abuse researchers to evaluate and monitor the subjects' health during participation in a research project. The areas of research include, but are not limited to, biomedical, clinical, behavioral, pharmacological, psychiatric, psychosocial, epidemiological, etiological, statistical, treatment and prevention of narcotic addiction and drug abuse.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. The National Institute on Drug Abuse (NIDA) uses a contractor to recruit volunteers and to screen these individuals for their acceptability to participate in specific research projects, and limits the contractor's access to the records to these procedures. NIDA also uses a contractor to perform routine medical laboratory tests on blood and urine samples. These routine tests verify that the subject is in good health. Both contractors disclose records from this system only to NIDA and are required to maintain Privacy Act safeguards with respect to such records.

2. (a) PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

(b) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has, notified such sexual or needle-sharing partner(s).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Data may be stored in file folders or on computer disks or magnetic tapes.

RETRIEVABILITY:

Administrative and medical records are indexed and retrieved by the subject's name. Research records are indexed and retrieved by the subject's name and an identification code.

SAFEGUARDS:

1. *Authorized areas:* Only authorized ARC staff (Principal Investigator and his/her research team) are allowed access to these files. The contractor staff has access to the files during the recruitment/screening process.

2. *Physical safeguards:* Files and file rooms are locked after business hours. Building has electronic controlled entry at all times with a 24-hour guard/television surveillance system. The computer terminals are in a further secured area.

3. *Procedural safeguards:* All users of personal information in connection with the performance of their jobs protect information from unauthorized personnel. Access codes to the research records are available only to the Principal Investigator and his/her research team. Access to the records is strictly limited to those staff members trained in accordance with the Privacy Act. The contractor staff members are required to secure the information in accordance with the Privacy Act. ARC Project Officer and contracting officials will monitor contractor compliance.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual; and Chapter 6–05, "Risk Management," under Part 6 in the Department's ADP Systems Security Manual.

In addition, because much of the data collected in these research projects are sensitive and confidential, special safeguards have been established. Certificates of confidentiality have been issued under Protection of Identity—Research Subjects Regulations (42 CFR part 2a) to those projects initiated since February 1980. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding their names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding to identify such individuals. In addition, these records are subject to 42 CFR part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been disclosed pursuant to these regulations for the purpose of conducting scientific research * * * information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State."

RETENTION AND DISPOSAL:

Records will be disposed of in accordance with the NIH Records Control Schedule, i.e., when the records are 10 years old or no longer required for administrative or research purposes. The records on individuals who do not qualify for a specific research project are

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kept for one year by the contractor who then destroys them by shredding.

SYSTEM MANAGER(S) AND ADDRESS:

Clinical Director, NIDA, Addiction Research Center, Francis Scott Key Medical Center—Building C, P.O. Box 5150, Baltimore, Maryland 21224.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. Provide a notarized signature as proof of identity. This can be waived if the request is made through official federal, state, or local channels. The request should include the patient's register number and/or the number of years of incarceration (for prisoner subjects), full name at time of participation in the research project, date(s) of research participation, and title of research project or name of drug being studied. An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or legal guardian who requests notification of an adolescent's record shall designate a family physician or other health professional (other than a family member) of the Addiction Research Center staff to whom the record, if any, will be sent. The parent or legal guardian must verify in writing the relationship to the adolescent as well as his/her own identity.

RECORD ACCESS PROCEDURES:

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures that have been made of his/her records, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought and reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

The individual; observations and medical recordings (such as blood pressure, dosage of compound administered, etc.) made by the Principal Investigator and his/her research team; system of records number 09–30–0020; drug treatment programs; Bureau of Prisons; case workers; psychiatrists; research laboratories; and pharmacies and hospitals. Many of these records are confidential and privileged communication is guaranteed under section 344(d) of the PHS Act.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0204

SYSTEM NAME:

Records of Contracts Awarded to Individuals, HHS/NIH/NIDA, HHS/NIH/NIAAA, and HHS/NIH/NIMH.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institute on Drug Abuse, Contracts Management Branch, Room 10–49, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

National Institute on Alcohol Abuse and Alcoholism, Contracts Management Branch, Room 14C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

National Institute of Mental Health, Contracts Management Branch, ORM, Room 7C–18, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Washington National Records Center, 4205 Suitland Road, Washington, DC 20409

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

An individual who receives a contract as well as individuals who apply or compete for an award but do not receive the award and their consultants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Curriculum vitae, salary information, evaluations of proposals by contract review committees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301, 503, 502 and 504 (42 U.S.C. 241, 290aa–2, 290aa–1, and 290–aa3).

PURPOSE(S) OF THE SYSTEM:

To document the history of each contract procurement action and award made within NIH to an individual. The records are also used by contract review committee members when evaluating a proposal submitted by an individual.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

3. A record from this system may be disclosed to the following entities in order to help collect a debt owed the United States: (a) To another Federal agency so that agency can effect a salary offset; (b) to another Federal agency so that agency can effect an administrative offset under common law or under 31 U.S.C. 3716 (withholding from money payable to, or held on behalf of, the individual); (c) to the Treasury Department to request his/her mailing address under I.R.C. 6103(m)(2) in order to locate him/her or in order to have a credit report prepared; (d) to agents of the Department and to other third parties to help locate him/her in order to help collect or compromise a debt; (e) to debt collection agents under 31 U.S.C. 3718 or under common law to help collect a debt; and (f) to the Justice Department for litigation or further administrative action. Disclosure under part (d) of this routine use is limited to the individual's name, address, Social Security number, and other information necessary to identify him/her. Disclosure under parts (a)–(c) and (e) is limited to those items; the amount, status, and history of the claim; and the agency or program under which the claim arose. An address obtained from IRS may be disclosed to a credit

reporting agency under part (d) only for purposes of preparing a commercial credit report on the individual. Part (a) applies to claims or debts arising or payable under the Social Security Act if and only if the employee consents in writing to the offset.

4. NIH may disclose information from its records in this system to consumer reporting agencies in order to obtain credit reports to verify credit worthiness of contract applicants. Permissible disclosures include name, address, Social Security number or other information necessary to identify the individual; the funding being sought; and the program for which the information is being obtained.

5. When a debt becomes partly or wholly uncollectible, either because the time period for collection under the statute of limitations has expired or because the Government agrees with the individual to forgive or compromise the debt, a record from this system of records may be disclosed to the Internal Revenue Service to report the written-off amount as taxable income to the individual.

6. A record from this system may be disclosed to another Federal agency that has asked the Department to effect an administrative offset under common law or under 31 U.S.C. 3716 to help collect a debt owed the United States. Disclosure under this routine use is limited to: name, address, Social Security number, and other information necessary to identify the individual, information about the money payable to or held for the individual, and other information concerning the administrative offset.

7. NIH may disclose from this system of records to the Department of Treasury, Internal Revenue Service (IRS): (1) A delinquent debtor's name, address, Social Security number, and other information necessary to identify the debtor; (2) the amount of the debt; and (3) the program under which the debt arose, so that IRS can offset against the debt any income tax refunds which may be due to the debtor.

DISCLOSURES TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to 5 U.S.C. 522a(b)(12). Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681 (F)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purpose of such disclosures is to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records. Information disclosed will be limited to name, Social Security number, address, other information necessary to establish the identity of the individual, and amount, status, and history of the claim, and the agency or program under which the claim arose. Such disclosures will be made only after the procedural requirements of 31 U.S.C. 3711(f) have been met.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Documents filed in folders in enclosed and/or locked file cabinets.

RETRIEVABILITY:

By contract number and cross indexed by individual's name.

SAFEGUARDS:

1. *Authorized users:* Federal contract and support personnel, Federal contract review staff and outside consultants acting as peer reviewers of the project.

2. *Physical safeguards:* All folders are in file cabinets in a room that is locked after business hours in a building with controlled entry (picture identification). Files are withdrawn from cabinet for Federal staff who have a need to know by a sign in and out procedure.

3. *Procedural safeguards:* Access to records is strictly limited to those staff members trained in accordance with the Privacy Act.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual.

RETENTION AND DISPOSAL:

Records are retired to a Federal Records Center and subsequently disposed of in accordance with the NIH Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

SYSTEM MANAGER(S) AND ADDRESSES:

National Institute on Drug Abuse, Chief, Contracts Management Branch, OPRM, Room 10–49, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

National Institute on Alcohol Abuse and Alcoholism, Chief, Contracts Management Branch, Room 14C–06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

National Institute of Mental Health, Chief, Contracts Management Branch, Room 7C–18, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate System Manager at the address above. An individual may learn if a record exists about himself/herself upon written request with notarized signature. The request should include, if known, contractor's name, contract number, and approximate date contract was awarded. An individual may also request accounting of disclosures that have been made of his/her record, if any.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Contract proposals and supporting contract documents, contract review committees, site visitors.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0205

SYSTEM NAME:

Alcohol, Drug Abuse, and Mental Health Epidemiologic and Biometric Research Data, HHS/NIH/NIAAA, HHS/NIH/NIDA and HHS/NIH/NIMH.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at the research facilities which collect or provide research data for this system under contract to the agency. Contractors may include, but are not limited to, research centers, clinics, hospitals, universities, research foundations, national associations, and coordinating centers. Records may also be located at the research facilities of the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA); and the National Institute of Mental Health (NIMH). A current list of sites is available by writing to the appropriate System Manager at the address below.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are the subjects of research in epidemiologic, clinical, methodologic, and longitudinal research studies and surveys of mental health and alcohol and drug use/abuse and mental, alcohol, and/or drug abuse disorders. These individuals are selected as representative of the general adult and/or child population or of special groups. Special groups include, but are not limited to, normal individuals serving as controls; clients referred for or receiving medical, mental health, and alcohol and/or drug abuse related treatment and prevention services; providers of services; demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to hypothesized risks, such as relatives of individuals who have experienced mental health and/or alcohol, and/or drug abuse disorders, life stresses, or have previous history of mental, alcohol, and/or drug abuse related illness.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about the individual as relevant to a particular research study. Examples include, but are not limited to, items about the health/mental health and/or alcohol or drug consumption patterns of the individual; demographic data; social security numbers (voluntary); past and present life experiences; personality characteristics; social functioning; utilization of health/mental health, alcohol, and/or drug abuse services; family history; physiological measures; and characteristics and activities of health/mental health; alcohol abuse, and/or drug abuse care providers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301 and 405 (42 U.S.C. 241, and 284, General Research and Investigation Authorities); Public Health Service Act, sections 301, 302, 303 and title V, parts A and B (42 U.S.C. 241, 242, 242(a)).

PURPOSE(S) OF THE SYSTEM:

The purpose of the system of records is to collect and maintain databases for research activities. Analyses of these data involve groups of individuals with given characteristics and do not refer to special individuals. The generation of information and statistical analyses will ultimately lead to a better description and understanding of mental, alcohol, and/or drug abuse disorders, their diagnosis, treatment and prevention, and the promotion of good physical and mental health.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (a) As determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 290 (dd–3), 42 U.S.C. 241 and 405, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 242a and 42 CFR part 2a; (b) as determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; and (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from a congressional office made at the written request of that individual.

3. In the event of litigation, where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee; the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., disclosure may be made to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of the individual's participation in activities of a Federal Government supported research project).

4. The Department contemplates that it will contract with a private firm for the purpose of collecting, analyzing, aggregating, or otherwise refining records in this system. Relevant records will be disclosed to such contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored on index cards, file folders, computer tapes and disks, microfiche, microfilm, and audio and video tapes. Normally, the factual data, with study code numbers, are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper files.

RETRIEVABILITY:

During data collection stages and followup, if any, retrieval by personal identifier (e.g., name, social security number) (in some studies), or medical record number, is necessary. During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. *Authorized users:* Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research

studies, e.g., interviewers and interviewer supervisors; project managers; statisticians involved in designing sampling plans.

2. *Physical safeguards:* Records are stored in locked rooms, locked file cabinets, and/or secured computer facilities. Personal identifiers and link files are separated as much as possible and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. *Procedural safeguards:* Collection and maintenance of data is consistent with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When an Institute Division or a contractor provides anonymous data to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The HHS project directors, contract officers, and project officers oversee compliance with these requirements.

4. *Implementation guidelines:* DHHS Chapter 45—and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual and Part 6, "ADP System Security" of the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:

Personal identifiers are retained only as long as they are needed for the purposes of the current research project, and for followup studies generated by the present study. Removal or disposal of identifiers is done according to the storage medium (e.g., erase computer tape, shred or burn index cards, etc.). A staff person designated by the System Manager will oversee and will describe and confirm the disposal in writing.

SYSTEM MANAGER(S) AND ADDRESSES:

Director, Division of Epidemiology and Services Research, National Institute of Mental Health, Room 10–105, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Clinical and Treatment Research, National Institute of Mental Health, Room 18C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Neuroscience and Behavioral Research, National Institute of Mental Health, Room 11–103, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Office of AIDS Programs, National Institute of Mental Health, Room 15–99, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Biometry and Epidemiology, National Institute on Alcohol Abuse and Alcoholism, Room 14C–26, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Clinical and Prevention Research, National Institute on Alcohol Abuse and Alcoholism, Room 14C–10, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Clinical Research, National Institute on Drug Abuse, Room 10A–38, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Division of Epidemiology and Prevention Research, National Institute on Drug Abuse, Room 9A–55, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Director, Medications Development Division, National Institute on Drug Abuse, Room 11A–55, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate System Manager at the address above. Provide individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and a notarized statement by two witnesses attesting to the individual's identity.

RECORD ACCESS PROCEDURE:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

An individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

CONTESTING RECORD PROCEDURE:

Contact the appropriate official at the address specified under System Manager(s) above and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), by written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, such as health, mental health, alcohol, and/or drug abuse care providers; relatives; guardians; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0206

SYSTEM NAME:

Psychotherapy of Opiate-Dependent Individual, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Drug Dependence Treatment and Research Center, Philadelphia Veterans Administration Hospital (116D), University of Pennsylvania, 39th Street and Woodland Avenue, Philadelphia, Pennsylvania 19104.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Research subjects are adult clients admitted to a participating drug abuse treatment program of psychotherapy and drug counseling offered by and located in the Philadelphia Veterans Administration Hospital, between September 30, 1977, and September 29, 1981.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name and address of study subjects and their responses to interview

instruments and tests in the following areas: Sociodemographic characteristics; and psychiatric diagnosis; symptom, social functioning, and personality measures. Information on the drug abuse treatment and psychotherapy provided, including audiotapes of therapy sessions and therapists' evaluations, are also included.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Drug Abuse Prevention, Treatment and Rehabilitation Act (1972), section 410 (21 U.S.C. 1177); Public Health Act, sections 301 and 405 (42 U.S.C. 241 and 284).

PURPOSE(S) OF THE SYSTEM:

The system was created to provide a data base to be used by NIDA for research leading to a better knowledge and understanding of the psychiatric status of opiate-dependent individuals and to determine the efficacy of psychotherapy as part of a treatment program for such individuals. We do not anticipate any disclosure of individually identifiable information to other persons or organizations within the Department of Health and Human Services. Should a request for disclosure occur within the Department, such as provided by section 3(b) of the Privacy Act, disclosure would not be permitted except in accordance with confidentiality regulations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except: (A) In emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on interview forms, audiotapes, keypunch cards, magnetic tapes, and disks.

RETRIEVABILITY:

Research records and locational information for followup are maintained in numerical order by assigned client number. A list is also maintained by name and assigned client number for cross reference.

SAFEGUARDS:

1. *Authorized users:* Federal Project Officer and contract staff designated on the negotiated contract to work as part of the contract staff. These persons could be, but not limited to, Project Director, and his/her assistants and secretary. All contract staff are required to maintain all Privacy Act safeguards requirements.

2. *Physical safeguards:* Records are stored in files that are locked in a room that is locked after hours. The building has controlled entry (i.e., picture identification and/or sign in and out procedures). The computerized information is password protected.

3. *Procedural safeguards:* An authorization under section 303(a) of the Public Health Service Act as amended (42 U.S.C. 242a(a), implemented by confidentiality regulations (42 CFR part 2a), has been issued to the contractor to assure that the contractor may not be compelled in any legal proceeding to identify the research subjects. In addition, these records are subject to the protective restrictions of the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56).

Project documentation, including cross-reference list, completed interview forms, audiotapes, and computerized data files, is maintained under strict controls in a secure room at the contractors' facilities to ensure data integrity and confidentiality. The list, interview forms and audiotapes are stored in a locked and secure work space until data is entered on magnetic media and verified. The forms and cross-reference list are destroyed by burning or shredding, and audiotapes are erased when the connection to the individual is no longer necessary in the analysis of the data. The original analysis has been completed, but reanalyses are done periodically and are expected to be completed in approximately 5 years (1997). After study source documents are disposed of, no connection can be made between computer file data and the individual. Magnetic tapes and disks are kept in a vault area. During all stages of processing and storage, senior project personnel control access to and removal and replacement of all documents from specified working and storage areas. Access is permitted only upon the written authority of the Principal Investigator or Co-Principal Investigators. The contractor has developed an extensive computer facilities security system which is used by programmers to protect computer account codes and data from access by unauthorized users.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual, and Part 6, "ADP System Security" in the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:

After reanalysis of the data is completed (which is anticipated to be no more than 5 years from current time (1992), the NIDA project officer will authorize, in writing, the destruction of the personal identifiers and source documents unless the information is needed for research purposes.

SYSTEM MANAGER(S) AND ADDRESS:

Branch Chief, Treatment Research Branch, Division of Clinical Research, National Institute on Drug Abuse, Room 10A–30, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself or herself upon written request with notarized signature. The request should include, if known: Name of the researcher, name of the study, location of the research site, approximate date of data collection, any alias used by individual, and assigned client number.

An individual who requests notification of, or access to, a medical record, shall, at the time the request is

made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURES:

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Research subjects, drug treatment programs, clinical evaluators, counselors, psychiatrists, psychotherapists, family members, research assistants, pharmacies, hospitals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0207

SYSTEM NAME:

Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Department of Psychiatry, School of Medicine, University of North Carolina, Chapel Hill, North Carolina 27514

Research Triangle Institute, Life Sciences Division, Research Triangle Park, North Carolina 27154

University of California, San Francisco, Langley Porter Psychiatric Institute, San Francisco, California 94143

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Normal, healthy adults who voluntarily participate in studies on the pharmacokinetics of drugs of abuse, at the University of North Carolina, during the period November 1979 through September 1984, and at the Research Triangle Institute and Langley Porter Psychiatric Institute, during the period September 1987 through September 1993.

CATEGORIES OF RECORDS IN THE SYSTEM:

Research records on each subject-participant contain the following information: Name; clinician's records including medical history, laboratory test results, physical examinations, psychological profile, and drug use profile; drug study data including records of drugs administered, exposures to radioactivity, and drug reactions; and date of study in which the subject participated.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301(a), 503 and 405 (42 U.S.C. 241 and 284).

PURPOSE(S) OF THE SYSTEM:

The primary purpose of this system is to support research on the pharmacokinetics of drugs of abuse. The term "pharmacokinetics" refers to the manner in which the human body processes a drug.

The clinical investigator used data of a medical nature that is contained in the system to make determinations regarding drug dosages and/or radiochemical exposures appropriate to the individual human subject-participants, in order to preserve and protect the health of each. The system also provides baseline data for studying the drug effects.

The Food and Drug Administration (FDA) also may use the records in routine inspections FDA conducts in accordance with its responsibilities to develop standards on the composition, quality, safety, and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. We may disclose to a congressional office the record of an individual in response to a verified inquiry from the congressional office made at the written request of the individual.

2. NIH contractors, use the records in this system to accomplish the research purpose for which the records are collected. The contractors are required to maintain Privacy Act safeguards with respect to such records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The contractor maintains the records on paper in file folders.

RETRIEVABILITY:

The contractor indexes and retrieves the records by the subject-participant's name.

SAFEGUARDS:

1. *Authorized users:* Only the contract Project Director and his/her research team and the Federal Project Officer and his/her support staff have access to these records.

2. *Physical safeguards:* The contractor keeps all records in a locked metal file cabinet in premises with limited accessibility. Only the clinical investigator (Project Director) has the key to the locked files.

3. *Procedural safeguards:* Only the contract staff have access to the files. Persons other than subject participants who request individually identifiable data from a record, must provide written consent from the subject participant permitting the requested disclosure. The only exception would be for disclosure to persons or organizations permitted by the Privacy Act, section 3(B) to obtain personally identifiable data.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual. In addition, the contract staff complies with contractor's (School of Medicine of the University of North Carolina) standard procedures for safeguarding data.

RETENTION AND DISPOSAL:

The records will be kept no later than September 1998 (5 years after the anticipated completion of the studies). At that time, the NIDA project officer will authorize in writing the clinical investigators to destroy the records by shredding or burning.

SYSTEM MANAGER(S) AND ADDRESS:

Project Officer, Pharmacokinetic Studies on Drugs of Abuse, Division of Basic Research, National Institute on Drug Abuse, National Institutes of Health, Room 10A–19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the system manager listed above. Provide the following information: Subject-participant's full name and a letter of request (or permission, if the requester is not the subject-participant) with notarized signature of the individual who is the subject of the record, approximate date(s) of experiment(s) in which the individual participated, and drug name (if known). In addition, an individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its content at the representative's discretion.

RECORD ACCESS PROCEDURES:

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURES:

Contact the System Manager at the address above and reasonably identify the record, specify the information to be contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

The subject-participants and the contractor personnel conducting the research studies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0208

SYSTEM NAME:

Drug Abuse Treatment Outcome Study (DATOS), HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

For records collected between 1979 through 1986: National Institute on Drug Abuse, Division of Clinical Research, 5600 Fishers Lane, Rockville, Maryland 20857.

New Records collected between 1991 hrough 1995 will be located with Research Triangle Institute, Life Sciences Division, Research Triangle Park, N.C. 27709, an NIH contractor.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary adult clients of federally funded treatment programs, including Treatment Alternative Street Crime (TASC) Programs of the Department of Justice, who requested to be included in TOPS from 1979 through 1986. New data collected from voluntary adults and young adult clients of public and private funded-treatment programs beginning in 1991 and will continue through 1995.

CATEGORIES OF RECORDS IN THE SYSTEM:

The categories are: Demographic data, treatment outcome data, treatment process data, client locator information, and personal identifiers (name and assigned numerical identifier).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301 and 405 (42 U.S.C. 241 and 284).

PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to compile information on drug abusers in drug abuse treatment programs in order to derive information on the treatment environments and abusers' behaviors and characteristics subsequent to treatment. Researchers and drug abuse service providers may use the aggregate data to address issues and generate hypotheses to understand better the interactions among the client and community.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Within the restrictions set forth in HHS regulations concerning the confidentiality of drug abuse patient records (42 CFR 2.56), we may disclose a record for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except: (A) In emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to, abide by these provisions.

2. The Research Triangle Institute, an NIH contractor, uses the records in this system to accomplish the research purpose for which the records are collected. In the event of followup studies or continuation studies because the contract has been terminated for convenience by the Government, we may disclose records in this system to a subsequent NIH contractor. We would require the new contractor to maintain Privacy Act safeguards with respect to such records.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Interview forms, magnetic tapes, and disks.

RETRIEVABILITY:

Records are indexed and retrieved by unique alpha numerical identifier. In order to relate the data collected to specific individuals, one must use the link file discussed under Safeguards.

SAFEGUARDS:

1. *Authorized users:* Contractor personnel, the agency project officer, and agency employees whose duties require the use of the information in the system.

2. *Physical safeguards:* The data management task leader, the project leader, or the project director provide technical supervision of all data collection and processing activities. Individually identified forms are stored in a secure, vault-like room provided for this purpose. Authorized personnel have access to the room by one locked door with controlled entry, i.e., only on the written authority of the professional staff member in charge. Computerized records are kept in a vault area with limited accession.

3. *Procedural safeguards:* Because some of the data collected in this study, such as data on drug use, are sensitive and confidential, special safeguards have been established. A Certificate of Confidentiality has been issued under 42 CFR part 2a. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding the names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. In addition, these records are subject to 42 CFR part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been

disclosed pursuant to (these regulations) for the purpose of conducting scientific research * * * information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State."

Another safeguard is that the forms containing subject identification information for client followup and data matching purposes do not include any reference to the purpose of the study. Identification and location information is kept separate from any information that would suggest that the respondent has been in a drug treatment program.

Information on completed forms is entered immediately on the computer. Completed forms and computerized data are released only to authorized persons. Only aggregate data are provided and used in the preparation of necessary and appropriate reports.

A link file system is used. This system has three components: (1) Personal information, (2) data base information, and (3) the link file, which contains identifying number pairs which can be used to match data with individuals. The advantage of this system is that the data base can be used directly for report generation, etc., without the use of decrypting subroutines or access to the personal information or matching link files.

In addition, the computer center being utilized has developed an extensive security system to protect computer account codes and data. This system is described in a publication that is available from the System Manager upon request.

We do not anticipate any disclosure of individually identifiable information to other persons or organizations within the Department of Health and Human Services. Nor does the contractor provide individually identification information to the Department of Justice, with which NIDA has a cooperative agreement for this study.

4. *Implementation guidelines:* We used the National Bureau of Standards guidelines and Part 6, HHS ADP Systems Security Manual, "ADP System Security" in developing the computer safeguard procedures. Safeguards for nonautomated records are in accordance with DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual. In addition, project staff complies with the contractor's (Research Triangle Institute) standard procedures for safeguarding data.

The contractor provides only aggregate information to NIDA.

RETENTION AND DISPOSAL:

The contractor destroys interview forms by shredding or burning immediately after contractor staff have completed and verified direct entry on magnetic tape or disk storage. The contractor will destroy individual identification and location data by shredding or burning, under the explicit written authorization of the System Manager, which is anticipated to be no longer than 5 years after the termination of the study unless the information is needed for research purposes. We will retain aggregate data tapes for research purposes. These tapes will not have any individually identifiable information. In accordance with the NIH Records Control Schedule, these tapes will be retained for 5 years after completion of the project (approximately 2000). At that time, the tapes will be retired to the Federal Records Center and destroyed when they are 10 years old or when they are no longer needed for research purposes.

SYSTEM MANAGER(S) AND ADDRESS:

Drug Abuse Treatment Outcome Study (DATOS), Project Officer, Treatment Research Branch, Division of Clinical Research, National Institute on Drug Abuse, National Institutes of Health, Room 10A–30, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself/herself upon written request, with notarized signature. The request should include, if known, name of the researcher, location of the research site, approximate date of data collection, any alias used, and subject identification number.

An individual who requests notification of a medical record shall, at the time the request in made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or legal guardian who requests notification of an adolescent's record shall designate a family physician or other health professional (other than a family member) of the Division of Clinical Research staff to whom the record, if any, will be sent. The parent or legal guardian must verify in writing the relationship to the adolescent as well as his/her own identity.

RECORD ACCESS PROCEDURES:

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

Persons other than subject individuals, who request individually identifiable data from a record must provide written consent from the subject individual permitting the requested disclosure. The only exception (if not in conflict with confidentiality regulations) would be for disclosure to persons or organizations permitted by the Privacy Act, section 3(b), to obtain personally identifiable data.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Research subjects, and staff in participating drug abuse treatment programs, written clinical evaluations, counselors, psychiatrists, psychotherapists, family members, research assistants, hospitals.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0209

SYSTEM NAME:

Subject-Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Veterans Administration Hospital, Cooperative Studies Program, Department of Veterans Medical Center, Perry Point, MD 21902

Dixon and Williams Pharmaceutical, 5775 Hyde Park Circle, Jacksonville, Florida 32210

Medications Development Division, Room 11A–55, and Division of Clinical Research, Room 10A–38, Parklawn Building, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Voluntary adult clients of federally funded and other drug abuse treatment programs who have requested to receive

investigational new or marketed drugs, such as but not limited to, naltrexone, levo-alpha acetylmethadol (LAAM), or Buprenorphine as part of their treatment. Data collection for the earlier LAAM studies began in 1975 and continued through September 1979; additional LAAM studies began in 1992 and will continue through September 1997, naltrexone studies began in 1977 and continued through June 1984; and studies for other investigational new compounds (buprenorphine, gepirone, etc,) began in 1992 and will continue through September 1997.

CATEGORIES OF RECORDS IN THE SYSTEM:

Demographic data, treatment outcome data, treatment process data, client locator information, and personal identifiers (name and assigned numerical identifier).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301, 464p, and 405 (42 U.S.C. 241, and 284).

PURPOSE(S) OF THE SYSTEM:

1. To maintain information on the effectiveness of drugs with abuse potential in various treatment environments and modalities and changes in the behavior and characteristics of drug abusers who received these substances as part of their treatment regimen.

2. To provide data required by the Food and Drug Administration (FDA) to support new drug applications for various drugs with abuse potential. A new drug application is a notice to FDA that a pharmaceutical company believes they have enough data to demonstrate the safety and efficacy of a substance to satisfy FDA for marketing the substance. FDA may also use the records in routine inspections. FDA conducts in accordance with its responsibilities to develop standards on the composition, quality, safety and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. NIH contractor(s) use the records in the system in order to accomplish the research and development purposes for which the records were collected. In the event of a followup study or continuation study, the responsible project officer may disclose records in this system to a subsequent ADAMHA contractor(s). Any new contractor(s) is and would be required to maintain Privacy Act safeguards with respect to such records and to comply with the confidentiality restrictions of 42 CFR part 2.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Interview forms, magnetic tapes, disks and microfiche in boxes in closed cabinets in a locked room with limited accessibility.

RETRIEVABILITY:

The records are indexed and retrieved by subject-participant's name and unique numerical identifier. In order to relate the data collected to specific individuals, however, one must use the link file discussed under safeguards.

SAFEGUARDS:

1. *Authorized users:* For the naltrexone study, the System Manager or Federal Project Officer and only authorized contract staff have access to the records (computerized and hard copy files) in the system. The contractor provides only aggregate data in reports to NIDA, FDA, or the public. Only the NIDA personnel mentioned previously and selected authorized contract staff have access to the stored LAAM records.

A certificate of confidentiality has been issued to researchers conducting the naltrexone study under 42 CFR, part 2, Protection of Identity—Research Subjects. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding the names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. The earlier LAAM study (from 1975 through 1979) was not conducted under a certificate of confidentiality. The 1992 LAAM studies are being conducted under the protection afforded by a confidentiality certificate. These regulations do not prohibit voluntary disclosure by the researcher. However, the records of both studies also are subject to 42 CFR part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: "Where the content of patient records has been disclosed. Pursuant to (these regulations) for the purpose of conducting scientific research * * * information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily of in response to any legal process whether Federal or State."

The contractor's institutional review board reviewed and approved the safeguards described above in accordance with 45 CFR part 46 on the Protection of Human Subjects.

2. *Physical safeguards:* For the naltrexone records, the contractor(s) stored individually identified forms in a locked room with controlled entry, i.e., only on written authority of the professional staff member in charge of data handling and processing). The contractor staff entered the collected information onto computer tape or disks as soon after contact with the subject-participant as possible, and stores the computerized records in a secured area with access limited as above.

For the LAAM records, NIDA stores the individually identified forms in a lockable cabinet in a secure room. Only authorized NIDA personnel, i.e., Division of Clinical Research and Medications Development professional staff (research psychologist or medical officer) and their support staff (program assistant, clerk-typist, or secretary) have access to the room with controlled entry. The room is in a building which has a 24-hour guard/television surveillance system and has controlled entry (picture identification sign in and out procedures) before and after normal working hours.

Another safeguard for both studies is that the forms containing subject identification information do not include any reference to the purpose of the study. The identification information is separate from any information that would suggest that the respondent is or has been in a drug abuse treatment program. In addition, the computer center being utilized for naltrexone has developed an extensive security system to protect computer account codes and data.

3. *Procedural safeguards:* Access to the computerized records of the naltrexone study is protected by a computerized password routine which is changed periodically. In addition, the project staff complies with the contractor's standard procedures for safeguarding data. The link file system that identifies individuals with personal data has three components: (1) Identification information, (2) data base information, and (3) the link file, which contains identifying number pairs which match data with individuals. The advantage of this system is that one may use the baseline data directly for report generation, etc., without using the subroutines or accessing the personal information or link files.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual and Part 6, "ADP System Security" in the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:

The naltrexone staff will destroy identifiable information by shredding or burning when it is no longer needed for analysis or research purposes; then the tapes will be erased. NIDA will destroy individual identification and match-up information by shredding or burning 5 years after FDA completes the review and approves the new drug applications.

NIDA will retain the aggregate data tapes from both studies for research purposes. These tapes will not have any individually identifiable information. In accordance with the FDA regulations governing new drug applications, the aggregate tapes will be retained for 5 years after FDA approves the new drug applications. At that time, the tapes will be retired to the Federal Records Center and destroyed when they are 5 years old or when they are no longer needed for research purposes.

SYSTEM MANAGER(S) AND ADDRESS:

Project Officer, Naltrexone Study, Division of Clinical Research, Room 10A–30, Parklawn Building, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857

Project Officer, LAAM and Other Compound Records, Medications Development Division, Room 11A–55, Parklawn Building, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, MD 20857

NOTIFICATION PROCEDURE:

An individual may determine if a record exists about himself/herself upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, to the appropriate system manager at the address above. The following information should be included, if known: subject-participant's full name and a letter of request with notarized signature of the subject-participant of the record, any alias used, subject-participant's identification number, name of the researcher, name of clinic or research center, name of substance, and approximate date of study participation.

An individual who requests notification of a medical record must, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Research subject-participants, staff in the participating drug abuse treatment programs, written clinical evaluations, private physicians, counselors, psychiatrists, psychotherapists, family members, research assistants, and hospital records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0210

SYSTEM NAME:

Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/NIH/NIDA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Research Technology Branch, Division of Basic Research, National Institute on Drug Abuse, Room 10A–13, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857

Research Triangle Institute, Research Triangle Park, North Carolina 27709

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individual researchers and organizations who are registered with the Drug Enforcement Administration (DEA), Department of Justice (DOJ), some since 1966, and who have voluntarily submitted documentation to the National Institute on Drug Abuse (NIDA) in order to obtain, through the NIDA Drug Supply Program (DSP), drugs of abuse for use in a research project.

CATEGORIES OF RECORDS IN THE SYSTEM:

While the records in this system are research project-related, they support the eligibility of individual researchers to receive drugs of abuse. Types of information contained in the records are: Researcher's name, curriculum vitae, research protocol, DEA and (if applicable) Nuclear Regulatory Commission registration numbers (when a radiolabeled compound is requested and shipped), business address (location of research project) and telephone number, summary of research project(s), requests for substance(s), name and amount of each compound requested and shipped, dates material is shipped and received, shipment numbers, and order form numbers.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, sections 301, and 405 (42 U.S.C. 241 and 284); Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.); Atomic Energy Act of 1954, as amended, section 81 (42 U.S.C 2111); and Energy Reorganization Act of 1974, section 201 (42 U.S.C. 5841). Energy Reorganization Act of 1974, section 201 (42 U.S.C. 5841).

PURPOSE(S) OF THE SYSTEM:

To facilitate operation of DSP which is a centralized research support service through which the United States Government supplies to the national and international scientific community for research purposes, most Schedule I and many Schedule II–V controlled and noncontrolled substances as specified in the Controlled Substances Act (CSA) of 1970 (21 U.S.C. 801 et seq.). Controlled substances are chemicals and other substances, and their immediate precursors, that the Attorney General has determined to have such potential for abuse as to warrant regulation under the CSA. Some of these substances are radiolabeled materials. Radiolabeled materials are substances to which a small amount of radioactivity is added for use in various studies, such as drug metabolism and mechanisms of drug actions.

This system of records was established to facilitate DSP by enabling NIDA:

1. To verify that requests for drugs of abuse, some of which are radiolabeled, are from authorized individuals/organizations for use in a research project;

2. To verify that the amounts of the materials requested by researchers for animal, in vivo, and in vitro research are justified and available;

3. To supply controlled substances in amounts approved by the Food and Drug Administration (FDA) to researchers conducting research with human subjects;

4. To ship these materials securely in accordance with CSA and the Atomic Energy Act; and

5. To maintain records of these transactions.

FDA also may use the records in routine inspections in accordance with FDA's responsibilities to develop standards on the composition, safety, and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. We may disclose the record of an individual to a congressional office in response to a verified inquiry from the congressional office made at the written request of the individual.

2. We may disclose information to DEA, DOJ, to enable DEA to carry out its responsibilities as described in the Controlled Substances Act of 1970.

3. An NIH contractor routinely uses the records in this system to ship controlled substances to authorized recipients. Such contractor is required to maintain Privacy Act safeguards with respect to these records.

4. An NIH contractor may have access to the records in this system in the performance of its software modification/correction tasks specified in its contract. Such contractor is required to maintain Privacy Act safeguards with respect to these records.

5. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice, or to a court or other tribunal, when (a) HHS, or any component thereof; or (b) any HHS employee in his or her official capacity; or (c) any HHS employee in his or her individual capacity where the Department of Justice (or HHS, where it is authorized to do so) has agreed to represent the employee; or (d) the United States or any agency thereof where HHS determines that the litigation is likely to affect HHS or any of its components, is a party to litigation or has an interest in such litigation, and HHS determines that the use of such records by the Department of Justice, the court or other tribunal is relevant and necessary to the litigation and would help in the effective representation of the governmental party, provided however, that in each case, HHS determines that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

NIDA maintains "hard copy" records in file folders and automated records on computer disk.

RETRIEVABILITY:

Authorized NIDA and contractor personnel index and retrieve the computerized records by a researcher code number assigned by a computer program at the time a new record is established. Authorized NIDA personnel index and retrieve "hard copy" records by researcher's name. NIDA maintains a computerized, alphabetical cross-reference list that matches names and numbers.

SAFEGUARDS:

1. *Authorized users:* The Chief, Research Technology Branch and his or her support staff, program assistant and clerk-typist, and the contracts' project directors and their support staffs have access to the records.

2. *Physical safeguards:* The "hard copy" records and main computer are physically located at the Parklawn Building, Rockville, Maryland. The computerized records are kept in a room with limited admittance. The room is locked after working hours. The "hard copy" records are stored in locked file cabinets in a room with very limited admittance. This room is also locked after working hours. The Parklawn Building has a 24-hour guard patrol service.

3. *Procedural safeguards:* The terminals are housed in a secured work area with limited admittance. Contract personnel use a password identification system to obtain access; NIDA changes the passwords periodically.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual, and Part 6, "ADP System Security," in the HHS ADP Systems Security Manual.

RETENTION AND DISPOSAL:

NIDA maintains an individual's record for 5 years after the researcher's last request for, or shipment of, a drug of abuse. We consider the record inactive after that, and erase it from the computer disk by a delete routine. The delete routine automatically deletes the computerized cross-reference as well. We destroy the "hard copy" record by shredding. The system is checked once a year for inactive records.

SYSTEM MANAGER(S) AND ADDRESS:

Project Director, Drug Supply Program, Research Technology Branch, Division of Preclinical Research, Room 10A–13, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself or herself upon written request. The request should include the researcher's name and business address at the time of last shipment. The request must be signed in ink by the individual researcher. Verifiable proof of identity is required.

RECORD ACCESS PROCEDURES:

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Initial source is the individual researcher. Some of the DEA registration information provided by a researcher is verified through a DEA computer check. FDA provides information concerning type and amount of controlled substance(s) to be shipped to an individual researcher for research projects involving human subjects.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09–25–0211

SYSTEM NAME:

Intramural Research Program Records of In- and Out-Patients With Various Types of Alcohol Abuse and Dependence, Relatives of Patients With Alcoholism, and Healthy Volunteers, HHS/NIH/NIAAA.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892.

A list of specific project sites is available from the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

In- and out-patients with alcohol abuse and dependence, alcohol-induced organic brain syndromes; their relatives; and healthy volunteers.

CATEGORIES OF RECORDS IN THE SYSTEM:

Research data of wide variety including biochemical measures, psychophysiological and psychological tests, questionnaires, clinical and behavioral observations and interviews, physical examinations, and correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Public Health Service Act, as amended, sections 301 (42 U.S.C. 241) and 510 (42 U.S.C. 290bb). These sections authorize the conduct of general health research and research into alcoholism and alcohol abuse.

PURPOSE(S) OF THE SYSTEM:

These records are used for diagnosis and treatment of patients with alcohol abuse and dependence and related conditions; behavioral research relating to the causes, diagnoses, and treatment of addictions; and basic research on behavioral and biological processes.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records in this system are covered by section 527 of the Public Health Service Act (42 U.S C. 290ee–3) and 42 CFR, chapter I, subchapter A, part 2, on confidentiality of alcohol and drug abuse patient records. In accordance with these regulations, the records are confidential and may only be disclosed with the written consent of the patient with specific restrictions, and without the patient's consent in the following instances: (1) To medical personnel to the extent necessary to meet a bona fide emergency; (2) to qualified personnel for the purpose of conducting scientific research; or (3) if authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor, after certain considerations, and with appropriate safeguards. Routine uses of information in this system are limited to the following:

1. A record may be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office at the written request of that individual, in accordance with 42 CFR, chapter I, subchapter A, part 2.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored in file folders, on index cards, computer tapes and disks, microfiche, microfilm and audio and video tapes. Normally the factual data, with study code numbers, are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper files.

RETRIEVABILITY:

During data collection stages and followup, retrieval by personal identifier (e.g., name or medical record number) is necessary. During the data analysis stage, data are normally retrieved by variables of interest, e.g., age, diagnosis, etc.

SAFEGUARDS:

Measures to prevent unauthorized disclosures are implemented as appropriate for the particular records maintained in each project. Depending on the sensitivity of the project, additional safeguards may be added.

1. *Authorized users:* Only NIAAA medical and research staff have access to these records, as authorized by the system manager.

2. *Physical safeguards:* Records are stored in locked rooms, locked file cabinets, and/or secured computer facilities. Personal identifiers and link codes are separated as much as possible and stored in locked files.

3. *Procedural safeguards:* Collection and maintenance of data are consistent with legislation and regulations for protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients. Computer data access is limited through the use of key words, a series of account numbers, and passwords which are changed frequently and known only to authorized personnel.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General Administration Manual, and Part 6, "ADP System Security" in the HHS Information Resource Management Manual.

RETENTION AND DISPOSAL:

Records are held for 5 years after completion of the project, retired to a Federal Records Center, and subsequently disposed of after 10 years.

SYSTEM MANAGER(S) AND ADDRESS:

Clinical Director, Laboratory of Clinical Studies, Division of Intramural Clinical and Biological Research, National Institutes of Health, Building 10, Room 3B–19, 9000 Rockville Pike, Bethesda, Maryland 20892

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the address above. Provide notarized signature as proof of identity. The request should include as much of the following information as possible: (a) Full name; (b) nature of illness (if any); (c) title of study; (d) name of researcher conducting study. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of child's/incompetent person's record shall at the time the request is made designate a family physician or other health professional (other than a family member) to whom the record, if any,

will be sent. The designee will receive the record in all cases and upon review will determine whether the record should be made available to the parent or guardian.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosures of their records, if any.

CONTESTING RECORD PROCEDURES:

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

Information gathered from individuals under study, either patient or normal subject, contract surveys, hospital records, medical and nursing staff notes, and from Privacy Act system of records 90–25–0099, "Clinical Research: Patient Medical Records, HHS/NIH/CC."

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

9–25–0212

SYSTEM NAME:

Clinical Research: Neuroscience Research Center Patient Medical Records, HHS/NIH/NIMH.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Neuroscience Research Center at Saint Elizabeths Hospital, William A. White Building, Room 144, 2700 Martin Luther King, Jr. Avenue, SE., Washington, DC 20032, and at private organizations under contract. A list of specific sites is available from the System Manager.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Registered clinical research patients and some individuals not registered as patients but seen for diagnostic tests.

CATEGORIES OF RECORDS IN THE SYSTEM:

Inpatient and outpatient medical clinical records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Public Health Service Act, section 301 (42 U.S.C. 241), "Research and Investigation," and section 321 (42 U.S.C. 248), "Hospital."

PURPOSE(S) OF THE SYSTEM:

(1) To provide a continuous history of the treatment afforded individual patients in the National Institute of Mental Health Clinical Research Program at the William A. White Building.

(2) To provide a data base for the clinical research conducted at the William A. White Research program.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. Social work staff may give pertinent information to community agencies to assist patients for their families.

3. Referring physicians receive medical information for continuing patient care after discharge.

4. Information regarding diagnostic problems, or having unusual scientific value may be disclosed to appropriate medical research organizations or consultants in connection with treatment of patient or in order to accomplish the research purposes of this system. For example, tissue specimens may be sent to the Armed Forces Institute of Pathology; x-rays may be sent for the opinion of a radiologist with extensive experience in a particular kind of diagnostic radiology. The recipients are required to maintain Privacy Act safeguards with respect to these records.

5. Records may be disclosed to representatives of the Joint Commission on Accreditation of Hospitals conducting inspections to ensure that the quality of the William A. White Clinical Research Program medical recordkeeping meets established standards.

6. Certain infectious diseases are reported to government jurisdictions as required by law.

7. Medical information may be disclosed to tumor registries for maintenance of health statistics.

8. The Department contemplates that it may contract with a private firm for transcribing, updating, copying, or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to comply with the requirements of the Privacy Act with respect to such records.

9. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending a claim against the Public Health Service based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, disclosure may be made to the Department of Justice to enable that Department to present an effective defense, provided that such disclosure is compatible with the purpose for which the records were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders and/or on microfiche, and on computer tapes. Files are stored in locked file cabinets or locked rooms.

RETRIEVABILITY:

The records are retrieved by unit number and patient name.

SAFEGUARDS:

1. *Authorized users:* Employees maintaining records in this system are instructed to grant regular access only to physicians and dentists and other health care professionals officially participating in patient care and to contractors or to NIMH researchers specifically authorized by the system manager.

2. *Physical safeguards:* All record facilities are locked when system personnel are not present.

3. *Procedural safeguards:* Access to files is strictly controlled by the system manager. Records may be removed only by system personnel following receipt of a request signed by authorized user. Access to computerized records is controlled by the use of security codes known only to the authorizer user. Codes are user- and function-specific. Contractor compliance is assured through inclusion of Privacy Act requirements in contract clauses, and through monitoring by contract and project officers. Contractors who maintain records in this system are instructed to make no disclosure of the records except as authorized by the system manager.

4. *Implementation guidelines:* DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 of the General

Administration Manual, and Part 6, "ADP System Security" in the HHS Information Resource Management Manual.

RETENTION AND DISPOSAL:

Records are retained for 5 years after last discharge or upon death of a patient and then transferred to the Washington National Records Center, where they are retained until 30 years after discharge or death.

SYSTEM MANAGER(S) AND ADDRESS:

Clinical Director, Neuroscience Research Center, Division of Intramural Research Programs, National Institute of Mental Health, Saint Elizabeths Hospital, Room 133, William A. White Building, 2700 Martin Luther King Jr., Avenue, SE., Washington, DC 20032.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System manager at the address above. An individual or a legally authorized representative may learn if a record exists about that individual upon written request with notarized signature. The request should include: (a) Full name or any alias used, (b) social security number, and (c) approximate time of participation in the hospital/project.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing a family physician or health professional (other than a family member) to whom the record will be released. The representative must verify relationship to the individual as well as his/her own identity.

A parent or guardian who requests notification of, or access to, a child's/incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Individuals may also request an accounting of disclosures of their records, if any.

CONTESTING RECORD PROCEDURES:

Contact the System Manager at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought and the reasons for correcting the information, along with supporting justification to show how the record is inaccurate, incomplete, or irrelevant.

RECORD SOURCE CATEGORIES:

Referring physicians, other medical facilities (with patient's consent), patients, relatives of patients.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

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Part III

Department of Housing and Urban Development

Office of the Secretary

24 CFR Part 770 et al.
Determination of Undue Concentration of Poverty-Level Population; Conforming Amendments; Rule

VOL 58 ISS 8 JA 13 1993 UMI

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Parts 770, 882, 889, 890, 941

[Docket No. R-93-1627; FR-3256-I-01]

RIN 2501-AB37

Determination of Areas of Undue Concentration of Poverty-Level Population; and Conforming Amendments

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule with request for comments.

SUMMARY: This rule amends HUD's regulations to create a new regulatory part, which establishes objective, quantitative criteria for determining whether a proposed site for HUD-assisted housing contains an undue concentration of persons living in poverty (poverty-level population). The "undue concentration" determination is one of the site and neighborhood standards currently applied to the selection of sites for HUD-assisted housing. These site and neighborhood standards are codified in HUD's regulations governing programs that involve construction, rehabilitation and acquisition of HUD-assisted housing. The existing undue concentration standard, however, does not set out the criteria by which a determination of undue concentration is to be made.

Accordingly, this rule creates a new regulatory part, which prescribes uniform and objective criteria for making an undue concentration determination. This rule also makes conforming amendments to other regulations to reference the standards set forth in new part 770. The purpose of this rule is to ensure that proposed sites for HUD-assisted housing are evaluated under the undue concentration standard in a uniform and consistent manner.

DATES: *Effective Date:* February 12, 1993.

Comment Due Date: March 15, 1993.

ADDRESSES: Interested persons are invited to submit comments regarding this rule to the Office of General Counsel, Rules Docket Clerk, room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying on weekdays between 7:30 a.m. and 5:30 p.m. at the above address.

FOR FURTHER INFORMATION CONTACT: David E. Shenk, Director of the Division of Economic and Market Analysis, Office of Policy Development and Research, Department of Housing and Urban Development, room 8222, 451 Seventh Street, SW., Washington, DC 20410-5000, telephone (202) 708-0577 or (202) 708-0770 (TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

Background

HUD's approval of a proposed location, or site, for HUD-assisted housing is conditioned upon the site meeting certain standards. These standards, referred to as "site and neighborhood standards," assess the suitability of the proposed site, and the area surrounding the site, to accommodate and sustain assisted housing. The site and neighborhood standards address such issues as the area's need for subsidized housing, the environmental impact on the area of additional multifamily housing, the area's concentration of minority residents, and the area's concentration of low-income persons. These standards are codified in HUD's regulations governing programs that involve construction, rehabilitation and acquisition of HUD-assisted housing. (See, *e.g.*, 24 CFR 882.404, 882.708, 941.202.)

The standard for assessing the concentration of low-income persons has been codified, to date, as follows—"the site must promote greater choice of housing opportunities and avoid undue concentration of assisted persons in areas containing a high proportion of lower income persons." (See 24 CFR 880.206, 881.206, 882.404, 882.708, 883.309, 941.202.) This language appropriately reflects the policy intended to be served by this standard (the undue concentration standard)—promoting the provision of assisted housing in a variety of locations by avoiding significant concentrations of low-income families in any one section of a metropolitan area. However, the language fails to explain the methodology to be used to ensure that this policy is served. To date, HUD has not provided any detailed guidance, in regulation or handbook, concerning how a determination is to be made that the proportion of lower income persons residing in the area of a proposed site for HUD-assisted housing is sufficiently high that approval of additional assisted housing for that area would result in an undue concentration of assisted persons.[1]

Before issuance of this rule, HUD had refrained from requiring use of quantitative, objective criteria in making an undue concentration determination on the premise that a proper undue concentration determination requires HUD's Regional and Field Offices (who have responsibility for making undue concentration determinations) to assess a wide variety of subjective, non-quantitative local factors. HUD was concerned that prescribing quantitative criteria, applicable to all sites, would interfere unfairly with the flexibility needed at the local level to consider local factors and conditions. However, a recent study of undue concentration reviews performed throughout the HUD Regions disclosed that there was less reliance and decision-making based on local subjective factors, and greater reliance on locally-developed quantitative, objective criteria.

The study revealed that all the Regions applied distinct percentage thresholds (although varied, from Region to Region) to determine whether an area under consideration for HUD-assisted housing contained an undue concentration of lower-income persons or assisted persons, or both, and several Regions used a percentage threshold as a rigid benchmark for determining undue concentration. The study also revealed that several Regions used census tracts to define the geographical boundaries of the area under consideration, and relied primarily on the most recent decennial census data. The study on undue concentration reviews also included interviews with the HUD Regional and Field officials responsible for undue concentration determinations. The study disclosed that the majority of these officials supported uniform guidance for arriving at undue concentration determinations.

On the basis of this study, HUD has concluded that a better and preferred approach to an undue concentration determination would be one that applies uniform, objective factors. The substantial reliance by the Regions on objective criteria, rather than on subjective criteria, indicates to HUD that, contrary to its initial assumption, determining the concentration of lower income persons is a determination that

[1] The "undue concentration" determination should not be confused with HUD's determination of whether a proposed location for HUD-assisted housing is in an area with a concentration of minority residents. Although related, the undue concentration and minority concentration determinations are two separate and distinct determinations. This rule only addresses the undue concentration requirement.

is made more easily, and perhaps more accurately, by applying objective criteria.

HUD also has concluded on the basis of its study that if objective criteria are to applied, then the same objective criteria should be applied throughout all the Regions to reduce disparity in undue concentration determinations. HUD noted that although the Regions applied different percentage thresholds to determine undue concentration, the differences were not extreme, but nevertheless produced varying results for sites with almost identical characteristics. The Regions' use of similar, if not identical, percentage thresholds indicates that use of uniform, quantitative criteria in the undue concentration process would not unfairly interfere with local assessments of undue concentration.

Additionally, HUD has concluded, following its review of local undue concentration determinations, that the fundamental goal of the undue concentration standard (and indeed of all the site and neighborhood standards) is not so much to identify the most suitable site for assisted housing, because a site can be approvable under HUD's site and neighborhood standards without being the most ideally suited site for a HUD-assisted housing development. Rather, the fundamental goal of the undue concentration standard is to exclude sites in those areas that are clearly unsuitable for assisted housing—those areas, which because of social and economic conditions, are unable to accommodate and sustain assisted housing. HUD has determined that this fundamental goal can be achieved by application of the undue concentration standard in a uniform and objective manner. Accordingly, new part 770 establishes uniform, numerical criteria for making an undue concentration determination.

Changes to Undue Concentration Standard

In revising the undue concentration standard, HUD has not only introduced numerical criteria by which a determination of undue concentration is to be made, but has made certain significant changes to the undue concentration concept.

First, the revised undue concentration standard shifts the focus from the number of assisted persons and the number of lower-income persons in the area of the proposed site to a single group—the number of persons living at or below the poverty level (hereafter, "poverty-level population"). The poverty income thresholds were developed by the Federal Government for administrative uses, for example, as a criterion for determining eligibility for some low-income assistance programs, such as the Community Services Block Grant program and the Head Start program. The U.S. Bureau of the Census uses these thresholds to determine the poverty status of persons based on income data obtained from the decennial census. HUD is adopting the poverty income standard for using in making undue concentration determinations because research sponsored by HUD found a significant relationship between high levels of poverty and undesirable neighborhood living conditions.

The primary research on this issue is described in an article published by the National Research Council in a book entitled Inner-City Poverty in the United States (L. Lynn, Jr., and M. McGeary eds. 1990). In this article, the authors concluded that the neighborhoods with high rates of poverty population exhibited most of the social and physical environmental problems that would make them undesirable places to live. The researchers chose the 40 percent poverty population standard after mapping census tract statistics and visiting a number of the cities. Their observations led them to conclude that tracts exceeding this threshold are typically characterized as having undesirable living conditions. The research included analysis showing that these neighborhoods generally had the highest levels of unemployment, incidence of crime, single parent families receiving assistance, and percentage of population with less than a high school education. A longitudinal study of 1970 and 1980 data also revealed that most of these neighborhoods had experienced an out-migration of residents who were not poor. City and local Census Bureau officials consulted by the researchers concurred in this assessment.

It should be noted that HUD does not use the poverty income standard to determine eligibility for HUD-assisted housing. The applicable statutes governing HUD's assisted housing programs require HUD to develop income limit schedules which are based on metropolitan area or nonmetropolitan county median incomes. These income limits are separate and distinct from the poverty standard. In particular, the income limits used for HUD assisted housing are locally based and have adjustments for housing costs.

The poverty income standard also differs from the criteria that are used by local jurisdictions to define areas of low-income concentration for purposes of a Comprehensive Housing Affordability Strategy (CHAS). (See 24 CFR part 91) HUD provides these jurisdictions with information from the decennial census on households in the low-income categories below 80 percent, 50 percent and 30 percent of the local median family income. The undue concentration standard based on poverty income differs from the CHAS low-income standard in that the poverty income standard is intended to identify a subset of low-income census tracts that also have significant social problems. As such, the areas identified as having reached the poverty income threshold are more distressed and troubled than areas that are categorized in the CHAS as low-income.

On the basis of its research, HUD has determined that the income level with which the undue concentration standard should be concerned is poverty-level, and that "concentration" should be measured without regard to whether the poverty-level population resides in assisted housing. The areas where social and economic conditions are undesirable for potential residents and untenable for sustaining assisting housing are those areas that contain a significant concentration of persons below the poverty level. HUD believes that by focusing solely on the proportion of poverty-level population, the undue concentration standard will provide a more accurate assessment of areas that are socially and economically troubled and, therefore, unsuitable for additional assisted housing.

Second, the revised undue concentration standard combines the "high proportion" and "undue concentration" aspects of the former undue concentration standard. With the focus of the standard now solely on the poverty-level population, the standard no longer requires two measurement components—one to assess the concentration (undue concentration) of assisted housing, and one to assess the concentration (high proportion) of lower income persons. HUD believes that the concentration of poverty level population more accurately describes what is considered acceptable or unacceptable in the area in which HUD-assisted housing is proposed to be located. HUD will exclude from consideration as sites for HUD-assisted housing those sites located in areas that contain an unacceptably high proportion (an undue concentration) of poverty-level population. (The percentage of poverty-level population that identifies an area as being an area of undue concentration is discussed later in this preamble.)

Third, the undue concentration standard has been revised to promote a single objective. As noted earlier, the undue concentration standard has, to date, been set forth in regulation as follows: "the site must promote greater choice of housing opportunities *and* avoid undue concentration of assisted persons in areas containing a high proportion of lower income persons." (Emphasis *added*.) The revised undue concentration standard establishes its objective as promoting a greater choice of housing opportunities by avoiding the location of HUD-assisted housing in areas with significant concentrations of persons living below the poverty level.

The following overview presents a summary of the principal provisions of new part 770, and discusses the additional changes that have been made to the undue concentration standard.

Overview of Interim Rule

Purpose

The interim rule sets forth the purpose of the undue concentration standard, which is to promote a greater choice of housing opportunities by avoiding the location of assisted housing developments in areas containing an undue concentration of poverty level population. These areas, because of their high poverty rate, have been determined to be socially and economically untenable for sustaining assisted housing. (As discussed later in this preamble, under the "Applicability" section, these "areas" do not include nonmetropolitan areas.)

As discussed previously, the undue concentration standard implements an important HUD policy—promoting the provision of assisted housing in a variety of locations by avoiding areas with significant concentrations of poverty-level populations. This policy is consistent with objectives set forth in various statutes under which HUD administers its programs. These statutes include: The Housing Act of 1949 (42 U.S.C. 1441–1490h) and its objective of eliminating substandard and other inadequate housing through the clearance of slums and blighted areas; and title I of the Housing and Community Development Act of 1974 (42 U.S.C. 5301–5320) and its objective of reducing the isolation of income groups within communities and geographic areas.

The interim rule also provides that the purpose of new part 770 is to establish objective and quantitative criteria for making an undue concentration determination, and thus, to ensure that applications submitted in connection with the construction, rehabilitation or acquisition of HUD-assisted housing are evaluated fairly and uniformly with respect to the undue concentration site standard.

Applicability

The interim rule sets forth which HUD programs are subject to the revised undue concentration standard (covered program). HUD programs not listed in the interim rule are not covered by the revised undue concentration standard. This section of the preamble lists the HUD programs subject to the revised undue concentration standard. This section of the preamble also discusses why certain HUD programs, which involve construction, acquisition or rehabilitation of housing, are not subject to the revised undue concentration standard.

Covered HUD Programs

The revised undue concentration standard is applicable to the following HUD programs:

—Section 8 Housing Assistance Payments Program—Existing Housing; Special Procedures for Moderate Rehabilitation, 24 part 882, subpart D;
—Section 8 Housing Assistance Payments Program—Existing Housing; Section 8 Certificate Program Attached to Units (Project-Based Certificate Assistance) 24 part 882, subpart G;
—Supportive Housing for the Elderly, 24 CFR part 889;
—Supportive Housing for Persons with Disabilities, 24 CFR part 890;
—Public Housing Development, 24 CFR part 941.

Coverage of "Acquisition" of Housing

To date, the undue concentration standard has not been expressly applicable to the "acquisition" of housing assisted by HUD. The undue concentration has been applied to rehabilitation, which may involve acquisition. Two new programs—Supportive Housing for the Elderly (24 CFR part 889), and Supportive Housing for Persons with Disabilities (24 CFR part 890) have expressly made their site and neighborhood standards applicable to the acquisition of housing. In amending the site and neighborhood standards of these programs to include the undue concentration standard, the revised undue concentration standard is made applicable to the acquisition of housing.

Site and neighborhood standards for HUD's public housing development program (24 CFR part 941) currently are not applicable to the acquisition of public housing. However, HUD is developing a rule which would make comprehensive amendments to part 941 to update the regulations of this part to conform to recent statutory amendments applicable to public housing.[2] This rule would make the prescribed site and neighborhood standards (including the undue concentration standard), expressly applicable to the acquisition of public housing.

HUD Programs Not Covered

The revised undue concentration standard is not applicable to the following programs:

—Section 8 Housing Assistance Payments Program for New Construction (24 CFR part 880);
—Section 8 Housing Assistance Payments Program for Substantial Rehabilitation (24 CFR part 881);
—Section 8 Housing Assistance Payments Program for State Housing Agencies (24 CFR part 883).

The previous undue concentration standard was applicable to the above three programs. However, the new funding authority for these three programs has been repealed for nine years, and the regulations governing these programs have been retained only for their management content. The interim rule therefore does not amend these regulations to incorporate the revised undue concentration standard.

In addition to the above three programs, the revised undue concentration standard is not applicable to the following Homeless Housing Assistance Programs of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11301–11404c), which include:

—Emergency Shelter Grants (24 CFR part 576);
—Transitional Housing (24 CFR part 577);
—Permanent Housing for Handicapped Homeless Persons (24 CFR part 578);
—Single Room Occupancy Housing (24 CFR part 882, subpart H); and
—Shelter Plus Care (24 CFR subtitle A, appendix D).

The undue concentration standard also is not applicable to the Housing Opportunities Program for Persons with Aids (24 CFR part 574).

The Homeless Housing Assistance Programs and the Housing Opportunities Program for Persons with AIDS are not subject to the revised undue concentration standard because these programs are intended to provide assisted housing with supportive

[2] See Department of Housing and Urban Development Semiannual Regulatory Agenda, published in the **Federal Register** on November 3, 1992 (57 FR 51392); see, especially, sequence number 1501 at 57 FR 51436, titled "Public Housing Development—Program Amendments."

services for special needs population (e.g., persons with disabilities, the homeless, the terminally ill) for the purpose of (1) improving living conditions for special needs populations already living in low-income areas, or (2) providing assisted housing to complement existing neighborhood supportive services for special needs populations. Application for the undue concentration standard to these programs would interfere with the objectives of these programs.

Additionally, the undue concentration standard is not applicable to HUD's homeownership programs: The HOPE Programs (HOPE is an acronym for "Homeownership and Opportunity for People Everywhere"), including the HOPE for Public and Indian Housing Homeownership Program, HOPE for Homeownership of Multifamily Units Program, and HOPE for Homeownership of Single Family Housing Programs (these programs are codified as appendix A to subtitle A of 24 CFR); the Low Rent Housing Homeownership Opportunities Program (24 CFR part 904); and the section 5(h) Homeownership Program (24 CFR part 906). These programs are not subject to the undue concentration standard because their purpose is not the establishment of additional HUD-assisted housing in certain areas. The purpose of these programs is to provide homeownership opportunities for eligible low-income families and individuals by assisting these families and individuals acquire ownership of single family homes, or units in multifamily dwellings, including public and Indian housing developments. These programs, in themselves, constitute a means for stabilizing and upgrading neighborhood conditions.

The rules does not apply to the HOME Investment Partnerships Program (24 CFR part 92) because that program is a block grant, and Congress intended to allow flexibility to local governments in making use of the funds, within the parameters established by the statute. For HUD to impose a rigid constraint on the location of assisted housing under HOME would run counter to the local discretion intended by Congress.

Exemption for Nonmetropolitan Areas

The standard is not applicable to nonmetropolitan areas. Because nonmetropolitan areas have lower population densities than metropolitan areas, the concentration of certain population groups is not a concern in these areas. Thus, application of the undue concentration standard to nonmetropolitan areas would be burdensome without serving a useful purpose.

Date of Applicability of Revised Undue Concentration Standard

The interim rule clarifies that evaluation of a site under the criteria set forth in new part 770 only would be applicable to applications for assistance submitted in response to a notice of funding availability (NOFA), published after the effective date of this interim rule, that is soliciting applications for construction, rehabilitation or acquisition of housing that is subject to HUD's site and neighborhood standards.

Responsibility for Undue Concentration Determinations

The interim rule clarifies that HUD's Regional and Field Offices have responsibility for evaluating the area in which HUD-assisted housing is proposed to be located.

The Relevant Population

As discussed earlier in this preamble, the revised undue concentration standard focuses on the poverty-level population of the area of the proposed site. HUD believes that attention solely to the percentage of poverty-level in the area of the proposed site population will provide a more accurate basis for determining areas that are socially and economically troubled, and which, therefore, should be excluded from consideration as suitable locations for assisted housing. HUD further believes that this shift in focus provides a more direct and simplified method for making an undue concentration determination.

In new part 770, "poverty-level population" refers to those persons who are living below the poverty level, as determined by the U.S. Bureau of the Census (Census Bureau). The number of persons classified as being above or below the poverty level in census tracts is based on information contained in the decennial census.

Defining the Area of the Project

The first step in making an undue concentration determination is defining the geographical boundaries of the area of the proposed site for HUD-assisted housing. New part 770 defines the area of the site or "site area" as the census tract, or census tracts if the proposed site area is located in more than one census tract or borders another tract, in which the HUD-assisted housing is proposed to be located. HUD selected the census tract as the applicable area because the census tract constitutes a predetermined geographic area for which there exists considerable social and economic data compiled by the Census Bureau. Census tract boundaries are established cooperatively by local Census Statistical Areas Committees in accordance with Census Bureau guidelines. As noted by the Census Bureau, in the technical appendices of census tract publications, census tracts "are designed to be relatively homogeneous areas with respect to population characteristics, economic status, and living conditions." (See Appendix A, "Area Classifications", in Summary Population and Housing Characteristics, 1990 CPH–1, U.S. Department of Commerce, Bureau of the Census.)

Defining Undue Concentration

New part 770 establishes a clear numerical standard for determining whether a site area contains an undue concentration of poverty-level population. Part 770 provides that if the percentage of the site area's poverty-level population is equal to or greater than 40 percent of the total population of the area, or will be equal to or greater than 40 percent of the total population if the proposed housing is approved for HUD assistance, then the site area will be determined to have an undue concentration of poverty-level population.

Use of the 40 percent threshold is based on HUD-sponsored research that related the incidence of poverty to the incidence of social problems in census tracts and neighborhoods. The research found that the 40 percent criterion provided the most distinct dividing line between neighborhoods that contain a high level of poverty, and those that, in addition to having a high level of poverty, also have significant social problems. The research involved mapping census tract statistics and conducting on-site assessments in a number of urban cities in the United States. The research revealed that census tracts and neighborhoods with a minimum of 40 percent poverty-level population experienced significantly higher levels of unemployment, higher incidence of crime, higher percentage of residents with less than a high school education, than did census tracts with a poverty-level population below the 40 percent level.

Determining Areas of Undue Concentration

To determine whether a site area contains a poverty-level population of 40 percent or more, new part 770 requires the applicable HUD office to consult the most recent decennial census data available to determine the percentage of persons in the site area who have incomes below the poverty

level. If the census data reveal that the population for the site area under review is below the 40 percent threshold, a determination must be made whether approval of HUD-assisted housing for that area would increase the poverty level population of the site area to the 40 percent threshold. To make this determination, part 770 provides that the applicable HUD office must divide the estimated total poverty-level population of the site area (estimated to include the expected poverty-level population of the proposed assisted housing development) by the estimated total population of the site area (estimated to include the total expected population of the proposed assisted housing development). This procedure is as follows:

(1) *Determining the estimated total population of the site area.* To determine the estimated total population of the site area, the number of persons residing in the site area shall be added to the estimated total population of the proposed housing development.

(a) The number of persons residing in the site area shall be determined from the most recent decennial census data available.

(b) The estimated total population of the proposed housing development is determined by multiplying (i) the average number of persons for each unit size of the development, by (ii) the total number of units of that size in the proposed housing development. The total number of persons for each unit size are then added, and the sum represents the estimated total population of the proposed housing.

Unit size is determined by the number of bedrooms in the unit. The average number of persons per unit size is as follows, based on occupancy guidelines for HUD assisted housing:

Size of unit	Average persons per unit
Efficiency (0-bedroom)	1
One bedroom	1.5
Two bedrooms	3
Three bedrooms	4.5
Four bedrooms	6

The revised undue concentration standard further provide that for units with more than four bedrooms, the average number of persons per bedroom for general occupancy units is 1.5 persons. For units in elderly and disabled housing, the averages are: One person for efficiency (0-bedroom) and one-bedroom units; and two persons for two-bedroom units.

(2) *Determining the estimated total poverty-level population of the site area.* To determine the estimated total poverty-level population of the site area, the number of poverty-level persons residing in the site area shall be added to the estimated poverty-level population of the proposed housing development.

(a) The number of poverty-level persons residing in the site area shall be determined from the most recent decennial census data available.

(b) The estimated poverty-level population of the proposed housing development shall be based on 65 percent of the estimated total population of the development, as determined under paragraph (1)(b) above. HUD has determined that, on average, 65 percent of the residents of section 8 housing and public housing have incomes below the poverty-level.

Exception to the Undue Concentration Site Standard for Revitalization of Site Area

New part 770 provides for the possibility of an exception to be granted to the undue concentration site standard on the basis of revitalization of the site area. New part 770 provides that an exception to the undue concentration standard may be granted on the basis of: (1) Revitalization of the site area initiated by the Federal Government through the designation of Federal enterprise zones; and (2) revitalization of the site area under the sponsorship or approval of the unit of general local government. These two circumstances are further discussed below.

The rule provides for an applicant seeking HUD assistance to request an exception to the undue concentration standard at the time of submission of the application for assistance. However, for this to occur, the applicant will need to know before submission of the application whether the proposed site for HUD-assisted housing constitutes an "area of undue concentration," as this term is defined in the rule. Thus, the rule provides for the applicant to request the responsible HUD office to make an undue concentration determination for the proposed site area. Where the HUD office has made such a determination, the applicant may request an exception under the revitalization of site area exception if it believes that the site qualifies under one of the two revitalization circumstances provided in the rule, and discussed below. The request for an exception must be in writing, and accompany the applicant's application for assistance. No special form for requesting an exception is required.

(1) *Federally-designated enterprise zone.* The first revitalization circumstance involves revitalization initiated by the Federal Government through the designation of Federal enterprise zones. Generally, the purpose of a Federal enterprise zone development program is to promote the revitalization of economically distressed areas, primarily by encouraging, through significant tax incentives, the formation, retention and expansion of businesses within the designated, the employment of "zone" residents, and the improvement of local services and opportunities for housing in the designated zone. (See 24 CFR part 596.) If the site area is located within the boundaries of a Federally-designated enterprise zone, an exception to the undue concentration standard will be granted automatically.

(2) *Revitalization of site area under local jurisdiction sponsorship or approval.* The second revitalization circumstance involves revitalization of the site area under the sponsorship or approval of the unit of general local government. If the site area is currently undergoing revitalization as a result of either public or private sector support (or both), and if there are firm plans for revitalization of the area that have been adopted or approved, or for which adoption or approval is pending, by the unit of general local government or another appropriate governing body, an exception to the undue concentration standard may be granted. For an exception to be granted on this basis, the responsible HUD office must verify, through a review of supporting documentation obtained by HUD with the cooperation and assistance of the applicant, that the expenditure of funds and the concentrated efforts being undertaken will result in significant improvements to the site area. If the revitalization plan is pending (for example, all planning stages are not completed, or final plan approval has not been received), any HUD approval of an assisted housing development will be conditional, and subject to the approval of the final plan by the applicable local governing body, which must occur no later than two years from the date of the assisted housing application.

Revitalization plans need not be restricted to the site area under consideration, or tailored to meet the requirements of the assisted housing application. Revitalization plans can be broader in scope, in terms of geographic area and subject matter coverage, and they can be part of city-wide redevelopment or urban renewal processes, as would be the case for a Comprehensive Housing Affordability Strategy (CHAS). However, to qualify as

an approvable exception under part 770, the revitalization activities already underway, and those proposed, must be determined to have direct physical, social and economic impact on the site area. The revitalization plans, therefore, must include the following information:

(a) A listing and evaluation of the specific projects and budget information on the amounts of State and local funds already expended, or committed for expenditure within two years, for redevelopment, revitalization and preservation efforts in the site area;

(b) A listing and evaluation of the specific projects and budget information on the amounts of Federal funds already spent or committed for Federal loan and grant programs for redevelopment, revitalization and preservation efforts in the site area;

(c) A listing of private sector investment in residential and nonresidential developments and improvements in the area, including those that are completed, under construction or are to begin construction within two years;

(d) Evidence of active steps, programs, and progress in improving social conditions and expanding services in the site area;

(e) Evidence of a continuing commitment for renewal, revitalization or preservation of the area based on the development schedule of the local revitalization plan, which shows the specific developments and activities that will have been completed or substantially underway by the time the HUD-assisted housing has been developed, and the approximate date of completion of redevelopment of the area; and

(f) If revitalization is occurring as a result of private sector support, evidence that the revitalization efforts involved will significantly improve conditions by the time the proposed HUD-assisted housing is developed.

Because a jurisdiction's housing strategy in areas of undue concentration is affected, the revitalization plan shall be referenced and made part of any Comprehensive Housing Affordability Strategy (CHAS) covering the site area.

Justification for Interim Rulemaking

It is HUD's general policy to publish a rule for notice and comment before issuing a rule for effect, in accordance with its own rule on rulemaking, codified at 24 CFR part 10. However, part 10 provides for exceptions from that general rule where the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is determined to be "impracticable, unnecessary, or contrary to the public interest." (See 24 CFR 10.1) HUD finds that good cause exists to publish this rule for effect without first soliciting public comment in that prior public procedure is contrary to the public interest.

HUD believes that it is in the interest of applicants submitting applications for assistance for construction, rehabilitation or acquisition of HUD-assisted housing which requires site approval, that HUD prescribe uniform criteria for use in the undue concentration review process. As discussed in this preamble, to date, HUD has not established specific criteria for determining whether an area would be approvable or disapprovable under the undue concentration standard. Thus, applicants have been without adequate guidance concerning whether the sites proposed for HUD-assisted housing are possibly approvable under the undue concentration standard.

The establishment of uniform criteria to be used in the undue concentration review process will reduce the possibility of disparate treatment of sites within and among the Regions containing similar characteristics, and ensure undue concentration determinations that will advance the policy of promoting a greater choice of housing opportunities by excluding those areas determined to be the least suitable to support assisted housing.

Although this rule is being published for immediate effect, HUD requests public comments on the standards prescribed in new part 770. All public comments will be considered by HUD in the development of a final rule on this subject.

Other Matters

Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Policy Act of 1969. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of the Rules Docket Clerk at the above address.

Regulatory Impact

This rule would not constitute a "major rule" as that term is defined in section 1(b) of the Executive Order on Federal Regulations issued by the President on February 17, 1981. An analysis of the rule indicates that it would not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets. Although the criteria for determining an undue concentration of poverty-level population has been quantified by this rule, HUD does not anticipate a significant difference between the number and types of housing sites approved or rejected under the previous standard, and those approved or rejected under the new standard.

Impact on Small Entities

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this rule, and in so doing certifies that this rule will not have a significant economic impact on small entities. Applicants for HUD-assistance for construction, acquisition or rehabilitation of HUD-assisted housing are subject, under HUD's existing regulations, to certain site and neighborhood standards. These standards include avoidance of areas that contain an undue concentration of persons living in poverty. This rule establishes numerical criteria by which HUD will determine whether a proposed site area contains, or will contain if the application for HUD-assisted housing is approved, an undue concentration of poverty-level population. The establishment of this criteria will ensure acceptable, consistent and uniform project site determinations within and among HUD's Regions.

Federalism Impact

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this rule would not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. This rule further implements HUD's stated policy, consistent with statutory objectives, to avoid locating assisted housing in areas that contain an undue concentration of persons living in poverty by establishing numerical criteria pursuant to which the HUD will determine whether a

proposed site area contains, or will contain if the application for assisted housing is approved, an undue concentration of poverty level population.

Impact on the Family

The General Counsel, as the Designated Official under Executive Order 12606, the Family, has determined that this rule does not have the potential for significant impact on family formation, maintenance, and general well-being, and thus, is not subject to review under the Order. The purpose of the revised undue concentration standard is to avoid locating assisted housing in neighborhoods where social and economic conditions are undesirable for potential residents, and untenable for sustaining assisted housing viability. No significant change in this policy will result from promulgation of this rule.

Semiannual Agenda of Regulations

This rule was listed as sequence number 1380 in HUD's Semiannual Agenda of Regulations published on November 3, 1992 (57 FR 51392, 51409) pursuant to Executive Order 12291 and Regulatory Flexibility Act.

List of Subjects

24 CFR Part 770

Grant programs—housing and community development, Reporting and recordkeeping.

24 CFR Part 882

Grant programs—housing and community development, Lead poisoning, Manufactured homes, Homeless, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 889

Aged, Low and moderate income housing, Capital advance programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 890

Disabled, Mental health programs, Civil rights, Low and moderate income housing, Capital advance programs—housing and community development, Rent subsidies, Reporting and recordkeeping requirements.

24 CFR Part 941

Grant programs—housing and community development, Loan programs—housing and community development, Public housing.

Accordingly, title 24 of the Code of Federal Regulations is amended by adding a new part 770, and by making conforming amendments to parts 882, 889, 890, and 941 to read as follows:

1. A new part 770 is added to read as follows:

PART 770—DETERMINATION OF AREAS OF UNDUE CONCENTRATION OF POVERTY-LEVEL POPULATION

Sec.

770.101 Purpose.
770.102 Applicability.
770.103 Definitions.
770.104 Procedures for determining areas of undue concentration.
770.105 Exception for revitalization of site area.

Authority: 42 U.S.C. 1437; 42 U.S.C. 1441; 42 U.S.C. 3608; 42 U.S.C. 5301; 42 U.S.C. 3535(d).

§ 770.101 Purpose.

The purpose of this part is to recognize the importance, in the administration of its housing programs, of promoting a greater choice of housing opportunities by avoiding the location of HUD-assisted housing in areas containing an undue concentration of persons living in poverty (poverty-level population). Accordingly, this part establishes the criteria to be used by HUD to determine whether an area in which HUD-assisted housing is located or proposed to be located contains, or would contain, if the housing were approved by HUD, an undue concentration of poverty-level population.

§ 770.102 Applicability.

(a) *Covered HUD programs.* The undue concentration site standard, as set forth in this part, is applicable to the following HUD programs:

(1) Section 8 Housing Assistance Payments Program—Existing Housing; Special Procedures for Moderate Rehabilitation (24 CFR part 882, subpart D);

(2) Section 8 Housing Assistance Payments Program—Existing Housing; Section 8 Certificate Program Attached to Units (Project-Based Certificate Assistance) (24 CFR part 882, subpart G);

(3) Supportive Housing for the Elderly (24 CFR part 889);

(4) Supportive Housing for Persons with Disabilities (24 CFR part 890);

(5) Public Housing Development (24 CFR part 941).

(b) *Exemption for nonmetropolitan areas.* The undue concentration standard is not applicable to nonmetropolitan areas.

(c) *Date of applicability.* This part is applicable to applications for assistance submitted in response to a notice of funding availability (NOFA), published after February 12, 1993, that is soliciting applications for construction, rehabilitation or acquisition of HUD-assisted housing under one of the programs set forth in paragraph (a) of this section.

§ 770.103 Definitions.

As used in this part:

Area of the site or *site area* means the census tract within a metropolitan area in which HUD-assisted housing is proposed to be located. If the assisted housing site encompasses more than one census tract, the site area is defined to include all of the affected census tracts. For assisted housing sites located on census tract boundaries, the site area means the census tract in which the assisted housing is located and the census tract(s) adjacent to the boundary on which the assisted housing development is located.

Area of undue concentration means a site area in which the HUD-assisted housing is proposed to be located, and in which the percentage of population living below the poverty-level, based on information from the most recent decennial census, is equal to or greater than 40 percent of the total population of the site area, or would be equal to or greater than 40 percent of the population of the site area, if the application for HUD-assisted housing were approved by HUD for assistance.

Census tract means the geographical area delineated by the U.S. Bureau of the Census in the most recent decennial census as a census tract. Block Numbering Areas (BNAs) are the census tract equivalents for delineating small statistical subdivisions where census tracts have not been established.

HUD or *Department* means the Department of Housing and Urban Development, including its Regional and Field Offices to which responsibility is assigned to perform functions under this part.

HUD-assisted housing means low-income housing acquired, developed (constructed) or rehabilitated with assistance provided by HUD under one or more of the programs listed in § 770.102(a).

Metropolitan area means a Metropolitan Statistical Area or Primary Metropolitan Statistical Area as established by the Office of Management and Budget.

Poverty-level population means the population of the applicable site area with incomes below the poverty level, as determined by the U.S. Bureau of the Census in the most recent decennial census.

Population means the total population of the applicable site area

based on data from the most recent decennial census.

§ 770.104 Procedures for determining areas of undue concentration.

(a) *Compliance with undue concentration standard.* Proposed sites for new construction, rehabilitation or acquisition of housing developments, for which assistance is sought under one or more of the programs listed in § 770.102(a), must promote a greater choice of housing opportunities by avoiding undue concentration of poverty-level population. To determine whether a proposed site meets this specific site and neighborhood standard, the following procedures apply.

(b) *Responsibility for determining compliance with undue concentration standard.* HUD's Regional and Field Offices have responsibility for determining whether a proposed site for HUD-assisted housing is located in an area of undue concentration, or whether the site area would become an area of undue concentration if the housing were approved for assistance.

(c) *Unacceptable site area.* Unless granted an exception to the undue concentration standard under § 770.105 of this part, or granted a waiver under HUD's general waiver authorities (24 CFR 799.101, 899.101, 999.101), a proposed site will be ineligible for approval under the undue concentration standard if the site is located in an area in which the percentage of poverty-level population is equal to or greater than 40 percent of the total population of the site area, or will become equal to or greater than 40 percent of the population of the site area, if the housing is approved for assistance.

(d) *Undue concentration determination*—(1) *Determining percentage of poverty-level population.* To determine whether a site area contains (or would contain, if proposed housing is approved for assistance) an undue concentration of poverty-level population, the applicable HUD office will consult the most recent decennial census data to determine the percentage of persons living in the site area who have incomes below the poverty level. Subject to certain exceptions set forth in § 770.105 of this part, proposed sites will be approved under the undue concentration site standard only if the percentage of poverty-level population is less than 40 percent of the population of the site area.

(2) *Determining projected increase in poverty-level population for below-threshold sites.* To determine whether a site area with a poverty-level population below the 40 percent threshold would be increased to 40 percent or greater if the site were approved by HUD, the applicable HUD office will divide the estimated total poverty-level population of the site area (estimated to include the expected poverty-level of the housing for which HUD assistance is sought) by the estimated total population of the site area (estimated to include the total expected population of the proposed housing development). The estimated total population of the site area, and the estimated total poverty-level population of the site area will be determined based on the most recent decennial census data available as follows:

(i) *Determining the estimated total population of the site area.* To determine the estimated total population of the site area, the number of persons residing in the site area shall be added to the estimated total population of the proposed housing development.

(A) The number of persons residing in the site area shall be determined from the most recent decennial census data available.

(B) The estimated total population of the proposed development is determined by multiplying the average number of persons for each unit size of the development, by the total number of units of that size in the proposed housing development. The total number of persons for each unit size are then added, and the sum represents the estimated total population of the proposed housing development.

(C) Unit size is categorized by the number of bedrooms in the unit. The average number of persons per unit size is as follows, based on occupancy guidelines for HUD assisted housing:

Size of unit	Average persons per unit
Efficiency (0-bedroom)	1
One bedroom	1.5
Two bedrooms	3
Three bedrooms	4.5
Four bedrooms	6

For units with more than four bedrooms, the average number of persons per bedroom for general occupancy units is 1.5 persons. For units in elderly and disabled housing, the averages are: One person for efficiency (0-bedroom) and one-bedroom units; and two persons for two-bedroom units.

(ii) *Determining the estimated total poverty-level population of the site area.* To determine the estimated total poverty-level population of the site area, the number of poverty-level persons residing in the site area shall be added to the estimated poverty-level population of the proposed housing development.

(A) The number of poverty-level persons residing in the site area shall be determined from the most recent decennial census data available.

(B) The estimated poverty-level population of the proposed housing development shall be 65 percent of the estimated total population of the development, as determined under paragraph (d)(2)(i) of this section.

§ 770.105 Exception for revitalization of site area.

A proposed site for HUD-assisted housing located in an area of undue concentration may be granted an exception from the undue concentration site standard on the basis that the site area is undergoing or will undergo revitalization. For an exception to be granted on this basis, the applicant seeking HUD assistance for the proposed housing development must request a determination by the responsible HUD office that the proposed site for the housing development is located in an area of undue concentration. Where the HUD office has made such a determination, the applicant may request an exception if it believes the requirements of paragraph (a) or (b) of this section are met. The request for an exception must be: In writing; accompany the applicant's application for assistance; and identify whether an exception is requested under paragraph (a) or paragraph (b) of this section. No special form for requesting an exception is required.

(a) *Federally-designated enterprise zone.* If the site area is located within the boundaries of a Federally-designated Enterprise Zone, an exception to the undue concentration standard will be granted automatically.

(b) *Revitalization of site area under local jurisdiction sponsorship or approval*—(1) *Verifiable evidence of planned revitalization.* If the site area is currently undergoing revitalization as a result of either public or private sector support (or both), and if there are firm plans for revitalization of the area that have been adopted or approved, or for which adoption or approval is pending, by the unit of general local government or another appropriate governing body, an exception to the undue concentration standard may be granted. For an exception to be granted on this basis, the responsible HUD office must verify, through a review of supporting documentation, obtained by HUD with the cooperation and assistance of the applicant, that the expenditure of funds and the concentrated efforts being

undertaken will result in significant improvements to the site area.

(2) *Conditional approval where revitalization plans are pending.* If the revitalization plan is pending (for example, all planning stages are not completed or final approval has not been received from the applicable governing body), any HUD approval of an assisted housing development will be conditional and subject to the approval of the final plan by the applicable governing body no later than two years from the date of the assisted housing application.

(3) *Form of revitalization plans.* Revitalization plans need not be restricted to the site area or tailored to meet the requirements of the assisted housing application. Revitalization plans can be broader in scope, in terms of geographic area and subject matter coverage, and they can be part of city-wide redevelopment or urban renewal processes, as would be the case for a Comprehensive Housing Affordability Strategy (CHAS). In order to qualify as an approvable exception to under this part, the revitalization activities already underway and those proposed must be determined to have direct physical, social and economic impact on the site area.

(4) *Required components of revitalization plan.* Approvable revitalization plans must include the following information:

(i) A listing and evaluation of the specific projects and budget information on the amounts of State and local funds already expended, or committed for expenditure within two years, for redevelopment, revitalization and preservation efforts in the site area;

(ii) A listing and evaluation of the specific projects and budget information on the amounts of Federal funds already spent or committed for Federal loan and grant programs for redevelopment, revitalization and preservation efforts in the site area;

(iii) A listing of private sector investment in residential and nonresidential developments and improvements in the area, including those that are completed, under construction or are to begin construction within two years;

(iv) Evidence of active steps, programs and progress in improving social conditions and expanding services in the site area;

(v) Evidence of a continuing commitment for renewal, revitalization or preservation of the area based on the development schedule of the local revitalization plan, which shows the specific developments and activities that will have been completed or substantially underway by the time the HUD-assisted housing has been developed, and the approximate date of completion of redevelopment of the area; and

(vi) If revitalization is occurring as a result of private sector support, evidence that the revitalization efforts involved will significantly improve conditions by the time the proposed HUD-assisted housing is developed.

(5) *Relationship of revitalization plan to CHAS.* Because a jurisdiction's housing strategy in areas of undue concentration is affected, the revitalization plan shall be referenced and made part of any Comprehensive Housing Affordability Strategy (CHAS) covering the site area.

PART 882—SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAM—EXISTING HOUSING

2. The authority for part 882 continues to read as follows:

Authority: 42 U.S.C. 1437a, 1437c, 1437f; 42 U.S.C. 3535(d).

3. In § 882.404, paragraph (b)(3) is revised to read as follows:

§ 882.404 Housing quality standards.

(b) * * *

(3) Promote a greater choice of housing opportunities by avoiding areas that contain (or would contain if the housing were approved for assistance) an undue concentration of poverty-level population, as determined under 24 CFR part 770.

* * * * *

4. In § 882.708, paragraph (d) is revised to read as follows:

§ 882.708 New construction: Site and neighborhood standards.

* * * * *

(d) The site must promote a greater choice of housing opportunities by avoiding areas that contain (or would contain if the housing were approved for assistance) an undue concentration of poverty-level population, as determined under 24 CFR part 770.

* * * * *

PART 889—SUPPORTIVE HOUSING FOR THE ELDERLY

5. The authority for part 889 continues to read as follows:

Authority: 12 U.S.C. 1701q; 42 U.S.C. 3535(d).

6. In § 889.230, a new paragraph (f) is added to read as follows:

§ 889.230 Site and neighborhood standards.

* * * * *

(f) The site must promote a greater choice of housing opportunities by avoiding areas that contain (or would contain if the housing were approved for assistance) an undue concentration of poverty-level population, as determined under 24 CFR part 770.

PART 890—SUPPORTIVE HOUSING FOR PERSONS WITH DISABILITIES

7. The authority for part 890 continues to read as follows:

Authority: 42 U.S.C. 8013; 42 U.S.C. 3535(d).

8. In § 890.230, a new paragraph (h) is added to read as follows:

§ 890.230 Site and neighborhood standards.

* * * * *

(h) The site must promote a greater choice of housing opportunities by avoiding areas that contain (or would contain if the housing were approved for assistance) an undue concentration of poverty-level population, as determined under 24 CFR part 770.

PART 941—PUBLIC HOUSING DEVELOPMENT

9. The authority for part 941 continues to read as follows:

Authority: 42 U.S.C. 1437b, 1437c, and 1437g; 42 U.S.C. 3535(d).

10. In § 941.202, paragraph (d) is revised to read as follows:

§ 941.202 Site and neighborhood standards.

* * * * *

(d) The site must promote a greater choice of housing opportunities by avoiding areas that contain (or would contain if the housing were approved for assistance) an undue concentration of poverty-level population, as determined under 24 CFR part 770.

* * * * *

Dated: December 24, 1992.

Jack Kemp,

Secretary.

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Department of Housing and Urban Development

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24 CFR Part 888
Section 8 Housing Assistance Payments Program; Rule

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Secretary

24 CFR Part 888

[Docket No. 93-3550; FR-3346-N-01]

Section 8 Housing Assistance Payments Program—Contract Rent Annual Adjustment Factors

AGENCY: Office of the Secretary, HUD.

ACTION: Notice of revised contract rent annual adjustment factors.

SUMMARY: The United States Housing Act of 1937 (1937 Act) requires that the assistance contracts signed by owners participating in the Department's Section 8 Housing Assistance Payments programs provide for annual or more frequent adjustment in the maximum monthly rentals for units covered by the contract to reflect changes based on fair market rents prevailing in a particular market area, or on a reasonable formula. This Notice announces revised Annual Adjustment Factors (AAFs), which are based on a formula using data on rent and utilities cost changes from the Bureau of Labor Statistics Consumer Price Index, the Bureau of the Census American Housing Surveys, and the HUD Random Digit Dialing (RDD) rent change surveys. The revised AAFs are to be used to adjust contract rents of program units in the Section 8 Housing Assistance Payment programs.

EFFECTIVE DATE: January 13, 1993.

FOR FURTHER INFORMATION CONTACT: Gerald J. Benoit, Rental Assistance Division, Office of Public and Indian Housing (202) 708–0477 (TDD: (202) 708–0850), for questions relating to the Section 8 Voucher, Certificate, and Moderate Rehabilitation programs; James Tahash, Program Planning Division, Office of Multifamily Housing Management (202) 708–3944 (TDD: (202) 708–4594), for questions relating to all other Section 8 programs; for technical information regarding the development of the schedules for specific areas or the method used for calculating the AAFs, Michael R. Allard, Economic and Market Analysis Division, Office of Policy Development and Research (202) 708–0577 (TDD: (202) 708–0770). Mailing address for above persons: Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. (Telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: Section 8(c)(2)(A) of the United States Housing Act of 1937 (42 U.S.C. 1437f(c)(2)(A)) requires the Department to provide for adjustments in the maximum monthly rents for units covered by the Section 8 Housing Assistance Payments (HAP) Contracts. Adjustments must reflect changes in the Fair Market Rents (FMRs) prevailing in particular market areas, or they must be based on a reasonable formula.

HUD has elected to establish the AAFs using the formula-based alternative. HUD regulations provide that the AAFs will be published annually in the **Federal Register** (24 CFR 888.202). These revised AAFs are applicable (subject to the limitations on applicability discussed below) for adjusting Contract Rents on or after November 8, 1992, the anniversary date for this publication.

Applicability of AAFs to Various Section 8 Programs

In general, AAFs established by this Notice are used to adjust Contract Rents for Section 8 program units. The following provides a general description of how AAFs apply under the several Section 8 Housing Assistance Payments programs. The application of the AAFs should be determined by reference to the HAP Contract and to appropriate program regulations or requirements.

In certain cases, AAFs are not used to adjust Contract Rents. AAFs are not used for the Section 8 Voucher program. In addition, AAFs are not used for Section 8 Certificate program units subject to 24 CFR 882.110(d), which applies to units in certain otherwise subsidized projects that are rented to Section 8 Certificate program families. (The housing assistance payment for such a unit is equal to the difference between the subsidized rent and the rent payable by the eligible family. Adjustments to the subsidized rents are made in accordance with rules and procedures governing the particular subsidized housing program involved.) In addition, AAFs are not used for units placed under HAP contract in recent years under the Section 202/Section 8 program. Instead, those rents are based on a HUD-approved budget for the project.

Contract Rents for many projects receiving Section 8 subsidies under the Loan Management provisions of 24 CFR part 886, subpart A, and for projects receiving Section 8 subsidies under the Property Disposition provisions of 24 CFR part 886, subpart C, are adjusted, at HUD's option, either by applying the AAFs or by adjusting rents in accordance with 24 CFR 207.19(e).

The AAFs apply to rental units of all bedroom sizes in each rent interval. Under the Section 8 Moderate Rehabilitation program, the public housing agency (PHA) should use the base rent, not the Contract Rent, to select the correct AAF to apply to the base rent.

Each AAF applies to a specified geographical area. Program participants should refer to the Table at the end of Schedule C that provides the list of states included in each of the ten HUD Regions and of the metropolitan areas with separate local CPI surveys (defined by counties of New England towns) to make certain that they are using the correct factors. Units located in metropolitan areas with separate local CPI surveys must use the corresponding AAFs for that metropolitan area. Units that are located in metropolitan areas without a local CPI survey or are located outside metropolitan areas must use the respective metropolitan or nonmetropolitan area AAFs for the HUD Region within which the state is located.

Owners of Section 8 units (other than units assisted under the Section 8 Certificate, Moderate Rehabilitation (both regular and SRO), Project-based Assistance Certificates, and FmHA programs) who have HAP Contracts with anniversary dates falling on November 8, 1992 through January 13, 1993 may request that the AAFs be applied retroactively to the anniversary date of their HAP Contracts. Retroactivity is permitted to avoid any detriment to owners because of HUD's delay in the annual publication, as required by 24 CFR 888.202, of the factors. For units assisted under the Section 8 Certificate, Moderate Rehabilitation (both regular and SRO), Project-based Assistance Certificates, and the FmHA programs, the factors are not applied retroactively; the annual adjustments, as of any anniversary date are determined using the AAFs most recently published in the **Federal Register** (see 24 CFR 882.108(a)(l)(i) and 884.109(b)(2)).

Calculation of Annual Adjustment Factors

In the September 26, 1991 **Federal Register** publication of the final FMRs for FY 1992, HUD announced that it intended to use the RDD survey technique as the method for obtaining the formula-based rent change factors. This year's AAFs initiate use on a national basis of the RDD regional survey results. The RDD survey method is based on a sampling procedure that uses computers to select a statistically random sample of rental housing, dial and keep track of the telephone calls and process the responses. This technique has been tested in areas where extensive Census data are

available and has been found to be very reliable. Starting this year, RDD surveys were conducted for the metropolitan parts (exclusive of CPI areas) and nonmetropolitan parts of the 10 HUD Regions, a total of 20 surveys. The results of these 20 surveys replace the previous AAFs which were based on CPI data for the four Census Regions that comprise the United States. The increased number of rent change factors covering the much smaller and more homogeneous HUD Regions result in a significant improvement over the current system.

AAFs are provided for the metropolitan parts (exclusive of CPI areas) and the nonmetropolitan parts of the ten HUD Regions, for the 73 metropolitan areas with local CPI surveys and for the State of Hawaii. The formula for calculating the AAFs for each area was developed as follows: (1) Changes in the shelter rent and utilities components were calculated based on the most recent CPI and RDD annual average change data; (2) the shelter rent factor was calculated by eliminating the effect of heating costs that are included in the rent of some of the units included in the CPI surveys; (3) the gross rent factors were calculated by weighing the rent and utility components of rent with the updated 1980 Census Regional and state components; and (4) the AAFs were then adjusted to reflect rent change variations by rent range determined from 1990 national AHS data.

Puerto Rico and the Virgin Islands use the HUD Region IV AAFs. All areas in Hawaii use the AAF schedule for Hawaii, which is based on the CPI survey for the Honolulu metropolitan area; the Pacific Islands use the HUD Region IX nonmetropolitan AAFS. The Anchorage metropolitan area has its own AAFs based on a local CPI survey; all other areas in Alaska use the HUD Region X nonmetropolitan area AAFs.

Section 8 Certificate Program AAFs for Manufactured Home Spaces

This Notice contains a separate set of AAFs for adjusting Contract Rents for manufactured home spaces. There is one factor for each area, which represents the change in the median rent for the area. These factors were derived by following steps one and two in the formula described above.

Other Matters

An environmental assessment is unnecessary, since revising Annual Adjustment Factors is categorically excluded from the Department's National Environmental Policy Act procedures under 24 CFR 50.20(*l*).

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies contained in this Notice do not have federalism implications and, thus, are not subject to review under the Order. The Notice merely announces the adjustment factors to be used to adjust contract rents in the Section 8 Housing Assistance Payment programs, as required by the United States Housing Act of 1937.

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has also determined that this Notice does not have potential significant impact on family formation, maintenance, and general well-being and, thus, is not subject to review under the Order. The Notice merely announces the adjustment factors to be used to adjust contract rents in the Section 8 Housing Assistance Payment programs, as required by the United States Housing Act of 1937.

The Catalog of Federal Domestic Assistance program number for Lower Income Housing Assistance programs (Section 8) is 14.156.

Accordingly, the Department publishes these Contract Rent Annual Adjustment Factors for the Section 8 Housing Assistance Payments Program as set forth in the following tables:

Dated: January 4, 1993.

Frank Keating,

Acting Secretary

BILLING CODE 4210-32-M

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
PREPARED ON 120292

HUD REGION I METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 270	1.031	1.029
$ 270 TO 319	1.029	1.027
$ 320 TO 379	1.028	1.026
$ 380 TO 429	1.026	1.022
$ 430 TO 489	1.024	1.022
$ 490 TO 539	1.023	1.017
$ 540 TO 649	1.020	1.013
$ 650 TO 759	1.017	1.011
$ 760 TO 859	1.014	1.007
$ 860 PLUS	1.011	1.007

HUD REGION II METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.040	1.038
$ 230 TO 269	1.038	1.036
$ 270 TO 319	1.036	1.034
$ 320 TO 359	1.034	1.032
$ 360 TO 409	1.032	1.023
$ 410 TO 449	1.030	1.023
$ 450 TO 539	1.026	1.020
$ 540 TO 629	1.022	1.015
$ 630 TO 719	1.018	1.012
$ 720 PLUS	1.014	1.010

HUD REGION III METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 180	1.054	1.056
$ 180 TO 219	1.051	1.050
$ 220 TO 259	1.048	1.050
$ 260 TO 289	1.046	1.047
$ 290 TO 329	1.043	1.035
$ 330 TO 359	1.040	1.035
$ 360 TO 439	1.035	1.030
$ 440 TO 509	1.030	1.023
$ 510 TO 579	1.024	1.018
$ 580 PLUS	1.019	1.018

HUD REGION IV METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 190	1.039	1.035
$ 190 TO 229	1.038	1.035
$ 230 TO 269	1.036	1.035
$ 270 TO 309	1.034	1.031
$ 310 TO 349	1.032	1.024
$ 350 TO 389	1.030	1.024
$ 390 TO 459	1.026	1.021
$ 460 TO 539	1.022	1.014
$ 540 TO 619	1.018	1.010
$ 620 PLUS	1.014	1.010

HUD REGION I NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 260	1.021	1.017
$ 260 TO 319	1.020	1.017
$ 320 TO 369	1.019	1.017
$ 370 TO 419	1.018	1.015
$ 420 TO 479	1.017	1.013
$ 480 TO 529	1.016	1.012
$ 530 TO 629	1.014	1.009
$ 630 TO 739	1.012	1.006
$ 740 TO 849	1.010	1.004
$ 850 PLUS	1.008	1.003

HUD REGION II NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 220	1.054	1.050
$ 220 TO 259	1.051	1.050
$ 260 TO 309	1.048	1.049
$ 310 TO 349	1.046	1.045
$ 350 TO 399	1.043	1.043
$ 400 TO 439	1.040	1.036
$ 440 TO 529	1.035	1.029
$ 530 TO 619	1.030	1.023
$ 620 TO 699	1.024	1.017
$ 700 PLUS	1.019	1 017

HUD REGION III NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 180	1.049	1.055
$ 180 TO 209	1.046	1.046
$ 210 TO 249	1.044	1.043
$ 250 TO 279	1.041	1.042
$ 280 TO 319	1.039	1.033
$ 320 TO 349	1.037	1.033
$ 350 TO 419	1.032	1.026
$ 420 TO 489	1.027	1.022
$ 490 TO 559	1.022	1.015
$ 560 PLUS	1.017	1.015

HUD REGION IV NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 190	1.034	1.029
$ 190 TO 229	1.033	1.029
$ 230 TO 259	1.031	1.029
$ 260 TO 299	1.029	1.025
$ 300 TO 339	1.027	1.019
$ 340 TO 379	1.026	1.019
$ 380 TO 449	1.022	1.017
$ 450 TO 529	1.019	1.008
$ 530 TO 599	1.016	1.008
$ 600 PLUS	1.012	1.008

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
PREPARED ON 120292

HUD REGION V METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 180	1.038	1.037
$ 180 TO 219	1.036	1.037
$ 220 TO 249	1.034	1.034
$ 250 TO 289	1.032	1.030
$ 290 TO 329	1.030	1.026
$ 330 TO 359	1.029	1.026
$ 360 TO 439	1.025	1.020
$ 440 TO 509	1.021	1.017
$ 510 TO 579	1.017	1.011
$ 580 PLUS	1.013	1.011

HUD REGION VI METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 180	1.043	1.042
$ 180 TO 209	1.041	1.041
$ 210 TO 249	1.038	1.039
$ 250 TO 289	1.036	1.033
$ 290 TO 319	1.034	1.030
$ 320 TO 359	1.032	1.026
$ 360 TO 429	1.028	1.023
$ 430 TO 499	1.024	1.017
$ 500 TO 569	1.019	1.011
$ 570 PLUS	1.015	1.011

HUD REGION VII METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 180	1.050	1.056
$ 180 TO 219	1.048	1.050
$ 220 TO 249	1.045	1.047
$ 250 TO 289	1.043	1.041
$ 290 TO 319	1.040	1.033
$ 320 TO 359	1.038	1.033
$ 360 TO 429	1.033	1.028
$ 430 TO 499	1.028	1.024
$ 500 TO 579	1.023	1.017
$ 580 PLUS	1.018	1.016

HUD REGION VIII METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 170	1.052	1.047
$ 170 TO 209	1.050	1.047
$ 210 TO 239	1.047	1.044
$ 240 TO 279	1.045	1.038
$ 280 TO 309	1.042	1.037
$ 310 TO 349	1.039	1.033
$ 350 TO 419	1.034	1.026
$ 420 TO 479	1.029	1.018
$ 480 TO 549	1.024	1.014
$ 550 PLUS	1.019	1.012

HUD REGION V NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 180	1.027	1.030
$ 180 TO 209	1.026	1.026
$ 210 TO 249	1.025	1.026
$ 250 TO 279	1.023	1.019
$ 280 TO 319	1.022	1.017
$ 320 TO 349	1.021	1.017
$ 350 TO 429	1.018	1.013
$ 430 TO 499	1.015	1.011
$ 500 TO 569	1.012	1.007
$ 570 PLUS	1.010	1.007

HUD REGION VI NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 170	1.025	1.027
$ 170 TO 209	1.024	1.021
$ 210 TO 239	1.022	1.018
$ 240 TO 279	1.021	1.015
$ 280 TO 309	1.020	1.014
$ 310 TO 349	1.019	1.012
$ 350 TO 419	1.016	1.010
$ 420 TO 489	1.014	1.009
$ 490 TO 559	1.011	1.004
$ 560 PLUS	1.009	1.004

HUD REGION VII NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 170	1.025	1.027
$ 170 TO 209	1.024	1.026
$ 210 TO 239	1.023	1.022
$ 240 TO 279	1.021	1.019
$ 280 TO 309	1.020	1.017
$ 310 TO 349	1.019	1.015
$ 350 TO 419	1.016	1.013
$ 420 TO 489	1.014	1.011
$ 490 TO 559	1.011	1.006
$ 560 PLUS	1.009	1.006

HUD REGION VIII NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 170	1.055	1.052
$ 170 TO 199	1.052	1.049
$ 200 TO 229	1.049	1.047
$ 230 TO 269	1.046	1.040
$ 270 TO 299	1.044	1.032
$ 300 TO 329	1.041	1.032
$ 330 TO 399	1.036	1.025
$ 400 TO 469	1.030	1.021
$ 470 TO 529	1.025	1.014
$ 530 PLUS	1.019	1.014

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS. SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
PREPARED ON 120292

HUD REGION IX METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.042	1.039
$ 230 TO 279	1.040	1.035
$ 280 TO 329	1.038	1.033
$ 330 TO 369	1.036	1.031
$ 370 TO 419	1.033	1.028
$ 420 TO 469	1.031	1.025
$ 470 TO 559	1.027	1.017
$ 560 TO 649	1.023	1.013
$ 650 TO 739	1.019	1.009
$ 740 PLUS	1.015	1.009

HUD REGION X METROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 190	1.071	1.071
$ 190 TO 229	1.068	1.067
$ 230 TO 259	1.064	1.061
$ 260 TO 299	1.060	1.057
$ 300 TO 339	1.057	1.053
$ 340 TO 379	1.053	1.044
$ 380 TO 449	1.046	1.039
$ 450 TO 529	1.039	1.029
$ 530 TO 609	1.032	1.019
$ 610 PLUS	1.025	1.019

STATE HAWAII

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 390	1.118	1.123
$ 390 TO 469	1.113	1.116
$ 470 TO 549	1.107	1.108
$ 550 TO 629	1.101	1.103
$ 630 TO 709	1.095	1.097
$ 710 TO 789	1.089	1.083
$ 790 TO 939	1.077	1.069
$ 940 TO 1099	1.065	1.056
$1100 TO 1259	1.054	1.042
$1260 PLUS	1.042	1.042

PMSA ANAHEIM-SANTA ANA, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 420	1.045	1.045
$ 420 TO 499	1.043	1.041
$ 500 TO 579	1.041	1.039
$ 580 TO 659	1.039	1.034
$ 660 TO 749	1.036	1.031
$ 750 TO 829	1.034	1.027
$ 830 TO 999	1.030	1.026
$1000 TO 1159	1.025	1.022
$1160 TO 1329	1.021	1.018
$1330 PLUS	1.016	1.013

HUD REGION IX NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.045	1.043
$ 230 TO 269	1.043	1.036
$ 270 TO 319	1.041	1 036
$ 320 TO 359	1.039	1 035
$ 360 TO 409	1.036	1.031
$ 410 TO 449	1.034	1.026
$ 450 TO 539	1.030	1.020
$ 540 TO 629	1.025	1.015
$ 630 TO 719	1 021	1.010
$ 720 PLUS	1 016	1.010

HUD REGION X NONMETROPOLITAN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 180	1.068	1.069
$ 180 TO 219	1.065	1.065
$ 220 TO 249	1.061	1.055
$ 250 TO 289	1.058	1 055
$ 290 TO 319	1.054	1.052
$ 320 TO 359	1.051	1 041
$ 360 TO 429	1.044	1.035
$ 430 TO 509	1.038	1.026
$ 510 TO 579	1.031	1 020
$ 580 PLUS	1.024	1.020

PMSA AKRON, OH

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 210	1.076	1.089
$ 210 TO 249	1.072	1.087
$ 250 TO 289	1 068	1.074
$ 290 TO 339	1.065	1.063
$ 340 TO 379	1.061	1.053
$ 380 TO 419	1.057	1.052
$ 420 TO 509	1 050	1.032
$ 510 TO 589	1.042	1.031
$ 590 TO 669	1 034	1.031
$ 670 PLUS	1 027	1.031

MSA ANCHORAGE, AK

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 310	1.114	1 131
$ 310 TO 379	1.108	1 116
$ 380 TO 439	1.103	1.102
$ 440 TO 499	1.097	1.087
$ 500 TO 559	1.091	1.087
$ 560 TO 629	1.086	1.071
$ 630 TO 749	1.074	1.057
$ 750 TO 879	1.063	1.040
$ 880 TO 999	1.052	1 040
$1000 PLUS	1.040	1 040

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
PREPARED ON 120292

PMSA ANN ARBOR, MI

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 280	1.016	1.028
$ 280 TO 339	1.015	1.023
$ 340 TO 399	1.014	1.022
$ 400 TO 449	1.014	1.019
$ 450 TO 509	1.013	1.019
$ 510 TO 569	1.012	1.017
$ 570 TO 679	1.010	1.014
$ 680 TO 789	1.009	1.012
$ 790 TO 909	1.007	1.012
$ 910 PLUS	1.006	1.012

PMSA AURORA-ELGIN, IL

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 310	1.063	1.068
$ 310 TO 369	1.060	1.065
$ 370 TO 439	1.057	1.054
$ 440 TO 499	1.053	1.045
$ 500 TO 559	1.050	1.045
$ 560 TO 619	1.047	1.037
$ 620 TO 749	1.041	1.029
$ 750 TO 869	1.035	1.021
$ 870 TO 999	1.029	1.019
$1000 PLUS	1.022	1.019

PMSA BEAVER COUNTY, PA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 190	1.054	1.040
$ 190 TO 219	1.051	1.039
$ 220 TO 259	1.049	1.033
$ 260 TO 299	1.046	1.021
$ 300 TO 329	1.043	1.013
$ 330 TO 369	1.041	1.013
$ 370 TO 449	1.035	1.000
$ 450 TO 519	1.030	1.000
$ 520 TO 599	1.025	1.000
$ 600 PLUS	1.019	1.000

PMSA BOSTON, MA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 420	1.016	1.008
$ 420 TO 499	1.015	1.007
$ 500 TO 579	1.014	1.006
$ 580 TO 669	1.014	1.005
$ 670 TO 749	1.013	1.003
$ 750 TO 829	1.012	1.000
$ 830 TO 999	1.010	1.000
$1000 TO 1169	1.009	1.000
$1170 TO 1329	1.007	1.000
$1330 PLUS	1.006	1.000

MSA ATLANTA, GA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 270	1.010	1.016
$ 270 TO 319	1.010	1.014
$ 320 TO 369	1.009	1.012
$ 370 TO 429	1.009	1.010
$ 430 TO 479	1.008	1.010
$ 480 TO 529	1.008	1.008
$ 530 TO 639	1.007	1.007
$ 640 TO 739	1.006	1.006
$ 740 TO 849	1.005	1.005
$ 850 PLUS	1.004	1.005

MSA BALTIMORE, MD

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 260	1.057	1.057
$ 260 TO 319	1.054	1.052
$ 320 TO 369	1.051	1.043
$ 370 TO 419	1.049	1.043
$ 420 TO 469	1.046	1.034
$ 470 TO 529	1.043	1.034
$ 530 TO 629	1.037	1.028
$ 630 TO 739	1.032	1.013
$ 740 TO 839	1.026	1.013
$ 840 PLUS	1.020	1.013

PMSA BERGEN-PASSAIC, NJ

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 410	1.050	1.049
$ 410 TO 499	1.047	1.048
$ 500 TO 579	1.045	1.044
$ 580 TO 659	1.042	1.040
$ 660 TO 749	1.040	1.033
$ 750 TO 829	1.037	1.033
$ 830 TO 989	1.032	1.027
$ 990 TO 1159	1.027	1.021
$1160 TO 1329	1.023	1.015
$1330 PLUS	1.018	1.015

PMSA BOULDER-LONGMONT, CO

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 270	1.045	1.041
$ 270 TO 319	1.043	1.041
$ 320 TO 379	1.041	1.034
$ 380 TO 429	1.039	1.030
$ 430 TO 479	1.036	1.026
$ 480 TO 539	1.034	1.020
$ 540 TO 649	1.030	1.013
$ 650 TO 749	1.025	1.007
$ 750 TO 859	1.021	1.007
$ 860 PLUS	1.016	1.007

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
PREPARED ON 120292

PMSA BRAZORIA, TX

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.107	1.124
$ 230 TO 269	1.101	1.116
$ 270 TO 319	1.096	1.108
$ 320 TO 359	1.091	1.088
$ 360 TO 409	1.085	1.086
$ 410 TO 449	1.080	1.072
$ 450 TO 539	1.070	1.057
$ 540 TO 629	1.059	1.044
$ 630 TO 729	1.048	1.044
$ 730 PLUS	1.038	1.044

PMSA BROCKTON, MA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 340	1.016	1.007
$ 340 TO 409	1.015	1.005
$ 410 TO 479	1.014	1.005
$ 480 TO 549	1.014	1.004
$ 550 TO 619	1.013	1.002
$ 620 TO 679	1.012	1.002
$ 680 TO 819	1.010	1.000
$ 820 TO 959	1.009	1.000
$ 960 TO 1099	1.007	1.000
$1100 PLUS	1.006	1.000

PMSA CHICAGO, IL

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 310	1.063	1.068
$ 310 TO 369	1.060	1.062
$ 370 TO 429	1.057	1.055
$ 430 TO 489	1.053	1.052
$ 490 TO 549	1.050	1.044
$ 550 TO 609	1.047	1.036
$ 610 TO 729	1.041	1.028
$ 730 TO 859	1.035	1.020
$ 860 TO 979	1.029	1.020
$ 980 PLUS	1.022	1.020

PMSA CLEVELAND, OH

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 220	1.076	1.092
$ 220 TO 269	1.072	1.082
$ 270 TO 309	1.068	1.072
$ 310 TO 349	1.065	1.064
$ 350 TO 399	1.061	1.053
$ 400 TO 439	1.057	1.052
$ 440 TO 529	1.050	1.043
$ 530 TO 619	1.042	1.031
$ 620 TO 709	1.034	1.030
$ 710 PLUS	1.027	1.030

PMSA BRIDGEPORT-MILFORD, CT

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 330	1.050	1.053
$ 330 TO 389	1.047	1.047
$ 390 TO 459	1.045	1.042
$ 460 TO 519	1.042	1.041
$ 520 TO 589	1.040	1.034
$ 590 TO 649	1.037	1.027
$ 650 TO 779	1.032	1.021
$ 780 TO 909	1.027	1.015
$ 910 TO 1039	1.023	1.015
$1040 PLUS	1.018	1.015

PMSA BUFFALO, NY

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 210	1.056	1.053
$ 210 TO 249	1.053	1.048
$ 250 TO 289	1.050	1.044
$ 290 TO 339	1.047	1.041
$ 340 TO 379	1.044	1.033
$ 380 TO 419	1.042	1.027
$ 420 TO 499	1.036	1.027
$ 500 TO 589	1.031	1.013
$ 590 TO 669	1.025	1.013
$ 670 PLUS	1.020	1.013

PMSA CINCINNATI, OH-KY-IN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 220	1.053	1.055
$ 220 TO 259	1.050	1.050
$ 260 TO 299	1.047	1.050
$ 300 TO 349	1.045	1.037
$ 350 TO 389	1.042	1.037
$ 390 TO 439	1.040	1.029
$ 440 TO 519	1.034	1.021
$ 520 TO 609	1.029	1.016
$ 610 TO 699	1.024	1.015
$ 700 PLUS	1.019	1.015

PMSA DALLAS, TX

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 250	1.069	1.067
$ 250 TO 299	1.065	1.058
$ 300 TO 349	1.062	1.052
$ 350 TO 399	1.058	1.048
$ 400 TO 449	1.055	1.040
$ 450 TO 499	1.052	1.029
$ 500 TO 599	1.045	1.020
$ 600 TO 699	1.038	1.011
$ 700 TO 799	1.031	1.011
$ 800 PLUS	1.024	1.011

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
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PMSA DANBURY, CT

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 350	1.050	1.054
$ 350 TO 419	1.047	1.047
$ 420 TO 489	1.045	1.044
$ 490 TO 559	1.042	1.040
$ 560 TO 639	1.040	1.035
$ 640 TO 709	1.037	1.027
$ 710 TO 849	1.032	1.021
$ 850 TO 989	1.027	1.014
$ 990 TO 1129	1.023	1.014
$1130 PLUS	1.018	1.014

PMSA DETROIT, MI

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 240	1.016	1.023
$ 240 TO 289	1.015	1.023
$ 290 TO 329	1.014	1.023
$ 330 TO 379	1.014	1.020
$ 380 TO 429	1.013	1.017
$ 430 TO 479	1.012	1.015
$ 480 TO 569	1.010	1.015
$ 570 TO 669	1.009	1.011
$ 670 TO 759	1.007	1.011
$ 760 PLUS	1.006	1.011

PMSA FORT WORTH-ARLINGTON, TX

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.067	1.063
$ 230 TO 279	1.064	1.063
$ 280 TO 329	1.061	1.056
$ 330 TO 379	1.057	1.054
$ 380 TO 419	1.054	1.047
$ 420 TO 469	1.051	1.040
$ 470 TO 559	1.044	1.033
$ 560 TO 659	1.037	1.025
$ 660 TO 749	1.030	1.017
$ 750 PLUS	1.024	1.017

PMSA GARY-HAMMOND, IN

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 250	1.063	1.067
$ 250 TO 299	1.060	1.062
$ 300 TO 349	1.057	1.055
$ 350 TO 399	1.053	1.045
$ 400 TO 449	1.050	1.045
$ 450 TO 499	1.047	1.038
$ 500 TO 599	1.041	1.027
$ 600 TO 699	1.035	1.020
$ 700 TO 789	1.029	1.020
$ 790 PLUS	1.022	1.020

PMSA DENVER, CO

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.045	1.044
$ 230 TO 279	1.043	1.039
$ 280 TO 329	1.041	1.033
$ 330 TO 369	1.039	1.031
$ 370 TO 419	1.036	1.023
$ 420 TO 469	1.034	1.020
$ 470 TO 559	1.030	1.014
$ 560 TO 649	1.025	1.008
$ 650 TO 749	1.021	1.007
$ 750 PLUS	1.016	1.007

PMSA FORT LAUDERDALE-HOLLYWOOD-POMPANO BEAC

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 290	1.047	1.050
$ 290 TO 349	1.044	1.047
$ 350 TO 409	1.042	1.042
$ 410 TO 459	1.040	1.039
$ 460 TO 519	1.037	1.033
$ 520 TO 579	1.035	1.033
$ 580 TO 689	1.030	1.028
$ 690 TO 809	1.026	1.021
$ 810 TO 929	1.021	1.016
$ 930 PLUS	1.017	1.016

PMSA GALVESTON-TEXAS CITY, TX

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 200	1.107	1.122
$ 200 TO 239	1.101	1.118
$ 240 TO 289	1.096	1.109
$ 290 TO 329	1.091	1.087
$ 330 TO 369	1.085	1.087
$ 370 TO 409	1.080	1.072
$ 410 TO 489	1.070	1.058
$ 490 TO 569	1.059	1.043
$ 570 TO 649	1.048	1.043
$ 650 PLUS	1.038	1.043

PMSA HAMILTON-MIDDLETOWN, OH

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 220	1.053	1.055
$ 220 TO 259	1.050	1.050
$ 260 TO 309	1.047	1.046
$ 310 TO 349	1.045	1.036
$ 350 TO 389	1.042	1.036
$ 390 TO 439	1.040	1.029
$ 440 TO 529	1.034	1.021
$ 530 TO 609	1.029	1.016
$ 610 TO 699	1.024	1.015
$ 700 PLUS	1.019	1.015

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
PREPARED ON 120292

PMSA HOUSTON, TX

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 210	1.107	1.121
$ 210 TO 249	1.101	1.117
$ 250 TO 289	1.096	1.107
$ 290 TO 339	1.091	1.086
$ 340 TO 379	1.085	1.086
$ 380 TO 419	1.080	1.072
$ 420 TO 499	1.070	1.059
$ 500 TO 589	1.059	1.044
$ 590 TO 669	1.048	1.043
$ 670 PLUS	1.038	1.042

PMSA JOLIET, IL

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 320	1.063	1.069
$ 320 TO 379	1.060	1.063
$ 380 TO 439	1.057	1.056
$ 440 TO 509	1.053	1.053
$ 510 TO 569	1.050	1.044
$ 570 TO 629	1.047	1.037
$ 630 TO 759	1.041	1.029
$ 760 TO 879	1.035	1.021
$ 880 TO 1009	1.029	1.021
$1010 PLUS	1.022	1.020

PMSA KENOSHA, WI

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 240	1.063	1.070
$ 240 TO 289	1.060	1.060
$ 290 TO 339	1.057	1.057
$ 340 TO 389	1.053	1.052
$ 390 TO 439	1.050	1.046
$ 440 TO 489	1.047	1.037
$ 490 TO 579	1.041	1.030
$ 580 TO 679	1.035	1.021
$ 680 TO 779	1.029	1.021
$ 780 PLUS	1.022	1.021

PMSA LAWRENCE-HAVERHILL, MA-NH

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 350	1.016	1.010
$ 350 TO 419	1.015	1.008
$ 420 TO 489	1.014	1.007
$ 490 TO 559	1.014	1.006
$ 560 TO 629	1.013	1.002
$ 630 TO 709	1.012	1.001
$ 710 TO 849	1.010	1.000
$ 850 TO 989	1.009	1.000
$ 990 TO 1129	1.007	1.000
$1130 PLUS	1.006	1.000

PMSA JERSEY CITY, NJ

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 290	1.050	1.054
$ 290 TO 349	1.047	1.050
$ 350 TO 409	1.045	1.045
$ 410 TO 469	1.042	1.041
$ 470 TO 529	1.040	1.032
$ 530 TO 579	1.037	1.032
$ 580 TO 699	1.032	1.028
$ 700 TO 819	1.027	1.016
$ 820 TO 929	1.023	1.015
$ 930 PLUS	1.018	1.015

MSA KANSAS CITY, MO-KS

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 210	1.051	1.058
$ 210 TO 249	1.049	1.048
$ 250 TO 289	1.046	1.048
$ 290 TO 329	1.044	1.042
$ 330 TO 369	1.041	1.031
$ 370 TO 419	1.038	1.025
$ 420 TO 499	1.033	1.017
$ 500 TO 579	1.028	1.017
$ 580 TO 669	1.023	1.017
$ 670 PLUS	1.018	1.017

PMSA LAKE COUNTY, IL

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 320	1.063	1.069
$ 320 TO 379	1.060	1.063
$ 380 TO 449	1.057	1.055
$ 450 TO 509	1.053	1.054
$ 510 TO 579	1.050	1.044
$ 580 TO 639	1.047	1.038
$ 640 TO 769	1.041	1.028
$ 770 TO 899	1.035	1.020
$ 900 TO 1029	1.029	1.020
$1030 PLUS	1.022	1.020

PMSA LORAIN-ELYRIA, OH

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 210	1.076	1.089
$ 210 TO 249	1.072	1 083
$ 250 TO 289	1.068	1 074
$ 290 TO 329	1.065	1 065
$ 330 TO 369	1.061	1 054
$ 370 TO 409	1.057	1.054
$ 410 TO 499	1.050	1 042
$ 500 TO 579	1.042	1 030
$ 580 TO 659	1.034	1 030
$ 660 PLUS	1.027	1.030

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
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PMSA LOS ANGELES-LONG BEACH, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 370	1.045	1.042
$ 370 TO 449	1.043	1.041
$ 450 TO 519	1.041	1.039
$ 520 TO 589	1.039	1.034
$ 590 TO 669	1.036	1.032
$ 670 TO 739	1.034	1.027
$ 740 TO 889	1.030	1.027
$ 890 TO 1039	1.025	1.022
$1040 TO 1189	1.021	1.018
$1190 PLUS	1.016	1.013

PMSA MIAMI-HIALEAH, FL

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 280	1.047	1.047
$ 280 TO 329	1.044	1.046
$ 330 TO 389	1.042	1.042
$ 390 TO 439	1.040	1.039
$ 440 TO 499	1.037	1.032
$ 500 TO 549	1.035	1.032
$ 550 TO 659	1.030	1.028
$ 660 TO 769	1.026	1.021
$ 770 TO 879	1.021	1.016
$ 880 PLUS	1.017	1.015

PMSA MILWAUKEE, WI

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.057	1.057
$ 230 TO 269	1.054	1.052
$ 270 TO 319	1.051	1.047
$ 320 TO 359	1.049	1.044
$ 360 TO 409	1.046	1.036
$ 410 TO 459	1.043	1.030
$ 460 TO 549	1.037	1.022
$ 550 TO 639	1.032	1.015
$ 640 TO 729	1.026	1.015
$ 730 PLUS	1.020	1.015

PMSA MONMOUTH-OCEAN, NJ

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 340	1.050	1.052
$ 340 TO 409	1.047	1.048
$ 410 TO 479	1.045	1.047
$ 480 TO 549	1.042	1.039
$ 550 TO 619	1.040	1.034
$ 620 TO 679	1.037	1.032
$ 680 TO 819	1.032	1.028
$ 820 TO 959	1.027	1.021
$ 960 TO 1099	1.023	1.016
$1100 PLUS	1.018	1.015

PMSA LOWELL, MA-NH

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 320	1.016	1.007
$ 320 TO 379	1.015	1.007
$ 380 TO 449	1.014	1.005
$ 450 TO 509	1.014	1.004
$ 510 TO 569	1.013	1.004
$ 570 TO 639	1.012	1.000
$ 640 TO 759	1.010	1.000
$ 760 TO 889	1.009	1.000
$ 890 TO 1019	1.007	1.000
$1020 PLUS	1.006	1.000

PMSA MIDDLESEX-SOMERSET-HUNTERDON, NJ

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 380	1.050	1.050
$ 380 TO 459	1.047	1.050
$ 460 TO 529	1.045	1.044
$ 530 TO 609	1.042	1.040
$ 610 TO 689	1.040	1.032
$ 690 TO 759	1.037	1.032
$ 760 TO 909	1.032	1.028
$ 910 TO 1069	1.027	1.021
$1070 TO 1219	1.023	1.015
$1220 PLUS	1.018	1.015

MSA MINNEAPOLIS-ST. PAUL, MN-WI

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 290	1.026	1.026
$ 290 TO 339	1.025	1.025
$ 340 TO 399	1.024	1.024
$ 400 TO 459	1.022	1.023
$ 460 TO 509	1.021	1.021
$ 510 TO 569	1.020	1.019
$ 570 TO 689	1.017	1.016
$ 690 TO 799	1.015	1.013
$ 800 TO 909	1.012	1.008
$ 910 PLUS	1.009	1.008

PMSA NASHUA, NH

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 350	1.016	1.010
$ 350 TO 419	1.015	1.005
$ 420 TO 489	1.014	1.004
$ 490 TO 559	1.014	1.004
$ 560 TO 629	1.013	1.002
$ 630 TO 699	1.012	1.000
$ 700 TO 839	1.010	1.000
$ 840 TO 969	1.009	1.000
$ 970 TO 1109	1.007	1.000
$1110 PLUS	1.006	1.000

SCHEDULE C CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
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PMSA NASSAU-SUFFOLK, NY

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 410	1.050	1.051
$ 410 TO 489	1.047	1.049
$ 490 TO 569	1.045	1.045
$ 570 TO 649	1.042	1.039
$ 650 TO 729	1.040	1.035
$ 730 TO 809	1.037	1.034
$ 810 TO 969	1.032	1.027
$ 970 TO 1129	1.027	1.022
$1130 TO 1299	1.023	1.016
$1300 PLUS	1.018	1.016

PMSA NEWARK, NJ

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 340	1.050	1.052
$ 340 TO 409	1.047	1.048
$ 410 TO 479	1.045	1.047
$ 480 TO 549	1.042	1.039
$ 550 TO 609	1.040	1.034
$ 610 TO 679	1.037	1.033
$ 680 TO 819	1.032	1.028
$ 820 TO 959	1.027	1.016
$ 960 TO 1089	1.023	1.016
$1090 PLUS	1.018	1.016

PMSA NORWALK, CT

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 380	1.050	1.052
$ 380 TO 449	1.047	1.046
$ 450 TO 529	1.045	1.045
$ 530 TO 599	1.042	1.041
$ 600 TO 679	1.040	1.034
$ 680 TO 749	1.037	1.028
$ 750 TO 899	1.032	1.021
$ 900 TO 1049	1.027	1.015
$1050 TO 1199	1.023	1.015
$1200 PLUS	1.018	1.015

PMSA ORANGE COUNTY, NY

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 310	1.050	1.054
$ 310 TO 369	1.047	1.050
$ 370 TO 439	1.045	1.044
$ 440 TO 499	1.042	1.040
$ 500 TO 559	1.040	1.032
$ 560 TO 619	1.037	1.032
$ 620 TO 749	1.032	1.028
$ 750 TO 869	1.027	1.022
$ 870 TO 999	1.023	1.015
$1000 PLUS	1.018	1.015

PMSA NEW YORK, NY

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 300	1.050	1.052
$ 300 TO 359	1.047	1.048
$ 360 TO 429	1.045	1.046
$ 430 TO 489	1.042	1.039
$ 490 TO 549	1.040	1.035
$ 550 TO 609	1.037	1.033
$ 610 TO 729	1.032	1.028
$ 730 TO 849	1.027	1.022
$ 850 TO 969	1.023	1.015
$ 970 PLUS	1.018	1.015

PMSA NIAGARA FALLS, NY

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 210	1.056	1.053
$ 210 TO 249	1.053	1.052
$ 250 TO 299	1.050	1.044
$ 300 TO 339	1.047	1.044
$ 340 TO 379	1.044	1.033
$ 380 TO 419	1.042	1.027
$ 420 TO 509	1.036	1.019
$ 510 TO 589	1.031	1.013
$ 590 TO 679	1.025	1.013
$ 680 PLUS	1.020	1.013

PMSA OAKLAND, CA

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 370	1.061	1.057
$ 370 TO 439	1.058	1.052
$ 440 TO 519	1.055	1.048
$ 520 TO 589	1.052	1.043
$ 590 TO 659	1.049	1.032
$ 660 TO 739	1.046	1.032
$ 740 TO 879	1.040	1.026
$ 880 TO 1029	1.034	1.019
$1030 TO 1179	1.028	1.011
$1180 PLUS	1.022	1.011

PMSA OXNARD-VENTURA, CA

	HIGHEST COST UTILITY INCLUDED	HIGHEST COST UTILITY EXCLUDED
UNDER $ 350	1.045	1.042
$ 350 TO 429	1.043	1.041
$ 430 TO 499	1.041	1.039
$ 500 TO 569	1.039	1.036
$ 570 TO 639	1.036	1.031
$ 640 TO 709	1.034	1.028
$ 710 TO 849	1.030	1.027
$ 850 TO 989	1.025	1.022
$ 990 TO 1139	1.021	1.018
$1140 PLUS	1.016	1.012

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
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PMSA PHILADELPHIA, PA-NJ

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 280	1.057	1.060
$ 280 TO 339	1.054	1.055
$ 340 TO 389	1.051	1.049
$ 390 TO 449	1.049	1.036
$ 450 TO 509	1.046	1.036
$ 510 TO 559	1.043	1.030
$ 560 TO 679	1.037	1.023
$ 680 TO 789	1.032	1.015
$ 790 TO 899	1.026	1.014
$ 900 PLUS	1.020	1.014

PMSA PORTLAND, OR

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 240	1.091	1.098
$ 240 TO 289	1.086	1.087
$ 290 TO 329	1.082	1.084
$ 330 TO 379	1.077	1.079
$ 380 TO 429	1.073	1.062
$ 430 TO 479	1.068	1.082
$ 480 TO 569	1.059	1.083
$ 570 TO 669	1.050	1.042
$ 670 TO 759	1.041	1.031
$ 760 PLUS	1.032	1.031

PMSA RIVERSIDE-SAN BERNARDINO, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 290	1.045	1.042
$ 290 TO 349	1.043	1.041
$ 350 TO 409	1.041	1.039
$ 410 TO 459	1.039	1.034
$ 460 TO 519	1.036	1.031
$ 520 TO 579	1.034	1.027
$ 580 TO 699	1.030	1.027
$ 700 TO 809	1.025	1.023
$ 810 TO 929	1.021	1.018
$ 930 PLUS	1.016	1.012

PMSA SALEM-GLOUCESTER, MA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 370	1.016	1.009
$ 370 TO 439	1.015	1.007
$ 440 TO 509	1.014	1.004
$ 510 TO 589	1.014	1.004
$ 590 TO 659	1.013	1.003
$ 660 TO 729	1.012	1.000
$ 730 TO 879	1.010	1.000
$ 880 TO 1029	1.009	1.000
$1030 TO 1169	1.007	1.000
$1170 PLUS	1.006	1.000

PMSA PITTSBURGH, PA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 200	1.054	1.039
$ 200 TO 239	1.051	1.036
$ 240 TO 279	1.049	1.031
$ 280 TO 319	1.046	1.023
$ 320 TO 359	1.043	1.015
$ 360 TO 399	1.041	1.015
$ 400 TO 489	1.035	1.000
$ 490 TO 569	1.030	1.000
$ 570 TO 649	1.025	1.000
$ 650 PLUS	1.019	1.000

PMSA RACINE, WI

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 220	1.057	1.055
$ 220 TO 259	1.054	1.054
$ 260 TO 299	1.051	1.046
$ 300 TO 339	1.049	1.044
$ 340 TO 389	1.046	1.038
$ 390 TO 429	1.043	1.029
$ 430 TO 519	1.037	1.021
$ 520 TO 599	1.032	1.014
$ 600 TO 689	1.026	1.014
$ 690 PLUS	1.020	1.014

PMSA ST. LOUIS, MO-IL

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.015	1.015
$ 230 TO 279	1.014	1.012
$ 280 TO 319	1.013	1.010
$ 320 TO 369	1.012	1.009
$ 370 TO 409	1.012	1.009
$ 410 TO 459	1.011	1.007
$ 460 TO 549	1.010	1.004
$ 550 TO 639	1.008	1.003
$ 640 TO 739	1.007	1.001
$ 740 PLUS	1.005	1.001

MSA SAN DIEGO, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 330	1.028	1.027
$ 330 TO 389	1.026	1.025
$ 390 TO 459	1.025	1.024
$ 460 TO 529	1.024	1.020
$ 530 TO 589	1.022	1.020
$ 590 TO 659	1.021	1.018
$ 660 TO 789	1.018	1.012
$ 790 TO 919	1.015	1.011
$ 920 TO 1049	1.013	1.007
$1050 PLUS	1.010	1.007

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS - BY RENT RANGE
PREPARED ON 120292

PMSA SAN FRANCISCO, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 440	1.061	1.056
$ 440 TO 529	1.058	1.049
$ 530 TO 619	1.055	1.047
$ 620 TO 709	1.052	1.044
$ 710 TO 799	1.049	1.033
$ 800 TO 889	1.046	1.033
$ 890 TO 1069	1.040	1.026
$1070 TO 1239	1.034	1.019
$1240 TO 1419	1.028	1.011
$1420 PLUS	1.022	1.011

PMSA SANTA CRUZ, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 400	1.061	1.055
$ 400 TO 469	1.058	1.051
$ 470 TO 549	1.055	1.047
$ 550 TO 629	1.052	1.044
$ 630 TO 709	1.049	1.033
$ 710 TO 789	1.046	1.033
$ 790 TO 949	1.040	1.026
$ 950 TO 1109	1.034	1.019
$1110 TO 1269	1.028	1.011
$1270 PLUS	1.022	1.011

PMSA SEATTLE, WA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 290	1.086	1.096
$ 290 TO 349	1.082	1.087
$ 350 TO 409	1.078	1.084
$ 410 TO 469	1.073	1.080
$ 470 TO 529	1.069	1.064
$ 530 TO 579	1.065	1.064
$ 580 TO 699	1.056	1.053
$ 700 TO 819	1.048	1.043
$ 820 TO 929	1.039	1.033
$ 930 PLUS	1.031	1.033

PMSA TACOMA, WA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 230	1.086	1.093
$ 230 TO 279	1.082	1.090
$ 280 TO 329	1.078	1.085
$ 330 TO 369	1.073	1.077
$ 370 TO 419	1.069	1.063
$ 420 TO 469	1.065	1.063
$ 470 TO 559	1.056	1.054
$ 560 TO 649	1.048	1.045
$ 650 TO 749	1.039	1.033
$ 750 PLUS	1.031	1.033

PMSA SAN JOSE, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 410	1.061	1.054
$ 410 TO 489	1.058	1.051
$ 490 TO 569	1.055	1.047
$ 570 TO 649	1.052	1.044
$ 650 TO 729	1.049	1.032
$ 730 TO 819	1.046	1.032
$ 820 TO 979	1.040	1.026
$ 980 TO 1139	1.034	1.019
$1140 TO 1299	1.028	1.011
$1300 PLUS	1.022	1.011

PMSA SANTA ROSA-PETALUMA, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 350	1.061	1.054
$ 350 TO 419	1.058	1.052
$ 420 TO 489	1.055	1.048
$ 490 TO 559	1.052	1.044
$ 560 TO 629	1.049	1.034
$ 630 TO 699	1.046	1.033
$ 700 TO 829	1.040	1.025
$ 830 TO 969	1.034	1.018
$ 970 TO 1109	1.028	1.011
$1110 PLUS	1.022	1.011

PMSA STAMFORD, CT

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 450	1.050	1.052
$ 450 TO 539	1.047	1.046
$ 540 TO 629	1.045	1.043
$ 630 TO 729	1.042	1.040
$ 730 TO 819	1.040	1.034
$ 820 TO 909	1.037	1.028
$ 910 TO 1089	1 032	1.022
$1090 TO 1269	1.027	1.014
$1270 TO 1449	1.023	1.014
$1450 PLUS	1.018	1.014

PMSA TRENTON, NJ

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 350	1.057	1.056
$ 350 TO 409	1.054	1.053
$ 410 TO 479	1.051	1.049
$ 480 TO 549	1.049	1.045
$ 550 TO 619	1.046	1.038
$ 620 TO 689	1.043	1.031
$ 690 TO 829	1.037	1.024
$ 830 TO 969	1.032	1.016
$ 970 TO 1109	1.026	1.016
$1110 PLUS	1.020	1.015

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS, SECTION 8 HOUSING ASSISTANCE PAYMENTS PROGRAMS BY RENT RANGE
PREPARED ON 120292

PMSA VALLEJO-FAIRFIELD-NAPA, CA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 300	1.061	1.056
$ 300 TO 359	1.058	1.052
$ 360 TO 419	1.055	1.049
$ 420 TO 489	1.052	1.044
$ 490 TO 549	1.049	1.033
$ 550 TO 609	1.046	1.033
$ 610 TO 729	1.040	1.027
$ 730 TO 849	1.034	1.019
$ 850 TO 969	1.028	1.011
$ 970 PLUS	1.022	1.011

PMSA VINELAND-MILLVILLE-BRIDGETON, NJ

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 280	1.057	1.055
$ 280 TO 329	1.054	1.052
$ 330 TO 389	1.051	1.050
$ 390 TO 439	1.049	1.046
$ 440 TO 499	1.046	1.038
$ 500 TO 549	1.043	1.030
$ 550 TO 659	1.037	1.023
$ 660 TO 769	1.032	1.015
$ 770 TO 879	1.026	1.015
$ 880 PLUS	1.020	1.015

COUNTY WESTCHESTER, NY

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 360	1.050	1.053
$ 360 TO 439	1.047	1.047
$ 440 TO 509	1.045	1.046
$ 510 TO 579	1.042	1.039
$ 580 TO 649	1.040	1.034
$ 650 TO 729	1.037	1.034
$ 730 TO 869	1.032	1.027
$ 870 TO 1019	1.027	1.021
$1020 TO 1159	1.023	1.016
$1160 PLUS	1.018	1.015

PMSA VANCOUVER, WA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 220	1.092	1.095
$ 220 TO 259	1.088	1.092
$ 260 TO 309	1.083	1.084
$ 310 TO 349	1.078	1.076
$ 350 TO 389	1.074	1.065
$ 390 TO 439	1.069	1.063
$ 440 TO 519	1.060	1.054
$ 520 TO 609	1.051	1.042
$ 610 TO 699	1.042	1.032
$ 700 PLUS	1.033	1.031

MSA WASHINGTON, DC-MD-VA

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 380	1.042	1.044
$ 380 TO 459	1.040	1.043
$ 460 TO 539	1.038	1.038
$ 540 TO 609	1.036	1.037
$ 610 TO 689	1.034	1.034
$ 690 TO 769	1.032	1.029
$ 770 TO 919	1.028	1.025
$ 920 TO 1069	1.023	1.019
$1070 TO 1229	1.019	1.015
$1230 PLUS	1.015	1.015

PMSA WILMINGTON, DE-NJ-MD

	HIGHEST COST UTILITY INCLUDED	EXCLUDED
UNDER $ 290	1.057	1.057
$ 290 TO 339	1.054	1.054
$ 340 TO 399	1.051	1.046
$ 400 TO 459	1.049	1.037
$ 460 TO 519	1.046	1.031
$ 520 TO 569	1.043	1.029
$ 570 TO 689	1.037	1.022
$ 690 TO 799	1.032	1.013
$ 800 TO 919	1.026	1.013
$ 920 PLUS	1.020	1.013

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS - - Manufactured Home Spaces

HUD Regions	Metropolitan Area AAF	Nonmetropolitan Area AAF
Region I	1.019	1.011
Region II	1.026	1.038
Region III	1.038	1.035
Region IV	1.027	1.021
Region V	1.027	1.017
Region VI	1.029	1.012
Region VII	1.037	1.015
Region VIII	1.033	1.034
Region IX	1.025	1.027
Region X	1.048	1.045

State	AAF
Hawaii	1.087

MSA/PMSA	AAF
Akron, OH PMSA	1.068
Anaheim-Santa Ana, CA PMSA	1.028
Anchorage, AK MSA	1.091
Ann Arbor, MI PMSA	1.019
Atlanta, GA MSA	1.010
Aurora-Elgin, IL PMSA	1.049
Baltimore, MD MSA	1.036
Beaver County, PA PMSA	1.026
Bergen-Passaic, NJ PMSA	1.035
Boston, MA PMSA	1.003
Boulder-Longmont, CO PMSA	1.027
Brazoria, TX PMSA	1.092
Bridgeport-Milford, CT PMSA	1.036
Brockton, MA PMSA	1.003
Buffalo, NY PMSA	1.037
Chicago, IL PMSA	1.048
Cincinnati, OH-KY-IN PMSA	1.039
Cleveland, OH PMSA	1.068
Dallas, TX PMSA	1.042
Danbury, CT PMSA	1.036
Denver, CO PMSA	1.027
Detroit, MI PMSA	1.019
Ft Lauderdale-Hollywd-Pompano Bch, FL PMSA	1.035
Fort Worth-Arlington, TX PMSA	1.043
Galveston-Texas City, TX PMSA	1.092
Gary-Hammond, IN PMSA	1.049
Hamilton-Middletown, OH PMSA	1.039
Houston, TX PMSA	1.092
Jersey City, NJ PMSA	1.036
Joliet, IL PMSA	1.048
Kansas City, MO-KS MSA	1.042
Kenosha, WI PMSA	1.048
Lake County, IL PMSA	1.048
Lawrence-Haverhill, MA-NH	1.003
Lorain-Elyria, OH PMSA	1.068
Los Angeles-Long Beach, CA PMSA	1.028
Lowell, MA-NH PMSA	1.003
Miami-Hialeah, FL PMSA	1.035
Middlesex-Somerset-Hunterdon, NJ PMSA	1.036
Milwaukee, WI PMSA	1.040

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SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS - - Manufactured Home Spaces

MSA/PMSA	AAF
Minneapolis-St. Paul, MN-WI MSA	1.019
Monmouth-Ocean, NJ PMSA	1.036
Nashua, NH PMSA	1.003
Nassau-Suffolk, NY PMSA	1.035
New York, NY PMSA	1.035
Newark, NJ PMSA	1.036
Niagara Falls, NY PMSA	1.037
Norwalk, CT PMSA	1.036
Oakland, CA PMSA	1.035
Orange County, NY PMSA	1.035
Oxnard-Ventura, CA PMSA	1.028
Philadelphia, PA-NJ PMSA	1.040
Pittsburgh, PA PMSA	1.026
Portland, OR PMSA	1.067
Racine, WI PMSA	1.040
Riverside-San Bernardino, CA PMSA	1.028
St. Louis, MO-IL PMSA	1.009
Salem-Gloucester, MA	1.003
San Diego, CA MSA	1.018
San Francisco, CA PMSA	1.035
San Jose, CA PMSA	1.035
Santa Cruz, CA PMSA	1.035
Santa Rosa-Petaluma, CA PMSA	1.035
Seattle, WA. PMSA	1.067
Stamford, CT PMSA	1.036
Tacoma, WA PMSA	1.067
Trenton, NJ PMSA	1.040
Vallejo-Fairfield-Napa, CA PMSA	1.035
Vancouver, WA PMSA	1.067
Vineland-Millville-Bridgeton, NJ PMSA	1.040
Washington, DC-MD-VA MSA	1.030
Westchester, County, NY	1.036
Wilmington, DE-NJ-MD	1.040

SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS - - AREA DEFINITIONS

STATES IN HUD REGIONS

Region I	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont
Region II	New Jersey and New York
Region III	Delaware, Maryland, Pennsylvania, Virginia and West Virginia (Washington, D.C. has a separate factor)
Region IV	Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico and the Virgin Islands
Region V	Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin
Region VI	Arkansas, Louisiana, Oklahoma, New Mexico and Texas
Region VII	Iowa, Kansas, Missouri and Nebraska
Region VIII	Colorado, Montana, North Dakota, South Dakota, Utah and Wyoming
Region IX	Arizona, California, Nevada and the Pacific Islands (Hawaii has a separate factor)
Region X	Alaska, Idaho, Oregon and Washington

MSA/PMSA	COUNTIES IN METROPOLITAN AREAS
Akron, OH PMSA	Portage and Summit
Anaheim-Santa Ana, CA PMSA	Orange
Anchorage, AK MSA	Anchorage
Ann Arbor, MI PMSA	Washtenaw
Atlanta, GA MSA	Barrow, Butts, Cherokee, Clayton, Cobb, Coweta, De Kalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, Rockdale, Spalding and Walton
Aurora-Elgin, IL PMSA	Kane and Kendall
Baltimore, MD MSA	Anne Arundel, Baltimore, Carroll, Harford, Howard, Queen Annes and Baltimore City
Beaver County, PA PMSA	Beaver
Bergen-Passaic, NJ PMSA	Bergen and Passaic
Boston, MA PMSA	Bristol County (PART): Towns of Mansfield, Norton, and Raynham Essex County (PART): Towns of Lynn, Lynnfield, Nahant and Saugus Middlesex County (PART): Towns of Acton, Arlington, Ashland, Ayer, Bedford, Belmont, Boxborough, Burlington, Cambridge, Carlisle, Concord, Everett, Framingham, Groton, Holliston, Hopkinton, Hudson, Lexington, Lincoln, Littleton, Malden, Marlborough, Maynard, Medford, Melrose, Natick, Newton, North Reading, Reading, Sherborn, Shirley, Somerville, Stoneham, Stow, Sudbury, Townsend, Wakefield, Waltham, Watertown, Wayland, Weston, Wilmington, Winchester and Woburn Norfolk County (PART): Towns of Bellingham, Braintree, Brookline, Canton, Cohasset, Dedham, Dover, Foxborough, Franklin, Holbrook, Medfield, Medway, Millis, Milton, Needham, Norfolk, Norwood, Quincy, Randolph, Sharon, Stoughton, Walpole, Wellesley, Westwood, Weymouth and Wrentham Plymouth County (PART): Towns of Carver, Duxbury, Hanover, Hanson, Hingham, Hull, Kingston, Lakeville, Marshfield, Middleboroug, Norwell, Pembroke, Plymouth, Plympton, Rockland and Scituate Suffolk County (PART): Towns of Boston, Chelsea, Revere and Winthrop Worcester County (PART): Towns of Berlin, Bolton, Harvard, Hopedale, Lancaster, Mendon, Milford, Southborough and Upton
Boulder-Longmont, CO PMSA	Boulder
Brazoria, TX PMSA	Brazoria
Bridgeport-Milford, CT PMSA	Fairfield County (PART): Towns of Bridgeport, Easton, Fairfield, Monroe, Shelton, Stratford and Trumbull New Haven County (PART): Towns of Ansonia, Beacon Falls, Derby, Milford, Oxford and Seymour
Brockton, MA PMSA	Bristol County (PART): Town of Easton Norfolk County (PART): Town of Avon Plymouth County (PART): Towns of Abington, Bridgewater, Brockton, East Bridgew, Halifax, West Bridgewater and Whitman
Buffalo, NY PMSA	Erie
Chicago, IL PMSA	Cook, Du Page and McHenry
Cincinnati, OH-KY-IN PMSA	Dearborn, IN; Boone, Campbell and Kenton, KY; Clermont, Hamilton and Warren, OH
Cleveland, OH PMSA	Cuyahoga, Geauga, Lake and Medina
Dallas, TX PMSA	Collin, Dallas, Denton, Ellis, Kaufman, and Rockwall
Danbury, CT PMSA	Fairfield County (PART): Towns of Bethel, Brookfield, Danbury, New Fairfield, Newtown, Redding, Ridgefield and Sherman Litchfield County (PART): Towns of Bridgewater, and New Milford
Denver, CO PMSA	Adams, Arapahoe, Denver, Douglas and Jefferson
Detroit, MI PMSA	Lapeer, Livingston, Macomb, Monroe, Oakland, St. Clair and Wayne
Ft Lauderdale-Hollywd-Pompano Bch, FL PMSA	Broward

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SCHEDULE C - CONTRACT RENT ANNUAL ADJUSTMENT FACTORS

MSA/PMSA	COUNTIES IN METROPOLITAN AREAS
Fort Worth-Arlington, TX PMSA	Johnson, Parker and Tarrant
Galveston-Texas City, TX PMSA	Galveston
Gary-Hammond, IN PMSA	Lake and Porter
Hamilton-Middletown, OH PMSA	Butler
Houston, TX PMSA	Fort Bend, Harris, Liberty, Montgomery and Waller
Jersey City, NJ PMSA	Hudson
Joliet, IL PMSA	Grundy and Will
Kansas City, MO-KS MSA	Johnson, Leavenworth, Miami and Wyandotte, KS; Cass, Clay, Jackson, Lafayette, Platte and Ray, MO
Kenosha, WI PMSA	Kenosha
Lake County, IL PMSA	Lake
Lawrence-Haverhill, MA-NH	Essex County, MA (PART): Towns of Amesbury, Andover, Boxford, Georgetown, Groveland, Haverhill, Laurence, Merrimac, Methuen, Newbury, Newburyport, North Andove, Salisbury and West Newbury Rockingham County, NH (PART): Towns of Atkinson, Brentwood, Danville, Derry, East Kingston, Hampstead, Kingston, Newton, Plaistow, Salem, Sandown, Seabrook and Windham
Lorain-Elyria, OH PMSA	Lorain
Los Angeles-Long Beach, CA PMSA	Los Angeles
Lowell, MA-NH PMSA	Middlesex County, MA (PART): Towns of Billerica, Chelmsford, Dracut, Dunstable, Lowell, Pepperell, Tewksbury, Tyngsborough and Westford Hillsborough County, NH (PART): Town of Pelham
Miami-Hialeah, FL PMSA	Dade
Middlesex-Somerset-Hunterdon, NJ PMSA	Hunterdon, Middlesex and Somerset
Milwaukee, WI PMSA	Milwaukee, Ozaukee, Washington and Waukesha
Minneapolis-St. Paul, MN-WI MSA	Anoka, Carver, Chisago, Dakota, Hennepin, Isanti, Ramsey, Scott, Washington and Wright, MN; St. Croix, WI
Monmouth-Ocean, NJ PMSA	Monmouth and Ocean
Nashua, NH PMSA	Hillsborough County (PART): Towns of Amherst, Brookline, Hollis, Hudson, Litchfield, Merrimack, Milford, Mont Vernon, Nashua and Wilton Rockingham County (PART): Town of Londonderry
Nassau-Suffolk, NY PMSA	Nassau and Suffolk
New York, NY PMSA	Bronx, Kings, New York, Putnam, Queens, Richmond and Rockland
Newark, NJ PMSA	Essex, Morris, Sussex and Union
Niagara Falls, NY PMSA	Niagara
Norwalk, CT PMSA	Fairfield County (PART): Towns of Norwalk, Weston, Westport and Wilton
Oakland, CA PMSA	Alameda and Contra Costa
Orange County, NY PMSA	Orange
Oxnard-Ventura, CA PMSA	Ventura
Philadelphia, PA-NJ PMSA	Burlington, Camden and Gloucester, NJ; Bucks, Chester, Delaware, Montgomery and Philadelphia, PA
Pittsburgh, PA PMSA	Alleghany, Fayette, Washington and Westmoreland
Portland, OR PMSA	Clackamas, Multnomah, Washington and Yamhill
Racine, WI PMSA	Racine
Riverside-San Bernardino, CA PMSA	Riverside and San Bernadino
St. Louis, MO-IL PMSA	Clinton, Jersey, Madison, Monroe and St. Clair, IL; Franklin, Jefferson, St. Charles, St. Louis and St. Louis City, MO
Salem-Gloucester, MA	Essex County (PART): Towns of Beverly, Danvers, Essex, Gloucester, Hamilton, Ipswich, Manchester, Marblehead, Middleton, Peabody, Rockport, Rowley, Salem, Swampscott, Topsfield and Wenham
San Diego, CA MSA	San Diego
San Francisco, CA PMSA	Marin, San Francisco and San Mateo
San Jose, CA PMSA	Santa Clara
Santa Cruz, CA PMSA	Santa Cruz
Santa Rosa-Petaluma, CA PMSA	Sonoma
Seattle, WA. PMSA	King and Snohomish
Stamford, CT PMSA	Fairfield County (PART): Towns of Darien, Greenwich, New Canaan and Stamford
Tacoma, WA PMSA	Pierce
Trenton, NJ PMSA	Mercer
Vallejo-Fairfield-Napa, CA PMSA	Napa and Solano
Vancouver, WA PMSA	Clark
Vineland-Millville-Bridgeton, NJ PMSA	Cumberland
Washington, DC-MD-VA MSA	Washington, DC; Calvert, Charles, Frederick, Montgomery and Prince Georges, MD; Arlington, Fairfax, Loudoun, Prince William, Stafford, Alexandria, Fairfax City, Falls Church, Manassas and Manassas Park, Va
Wilmington, DE-NJ-MD	New Castle, DE; Cecil, MD; and Salem, NJ

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Federal Register

Wednesday
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Part V

The President

Proclamation 6524—Martin Luther King, Jr., Federal Holiday, 1993

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Presidential Documents

Title 3—

The President

Proclamation 6524 of January 11, 1993

Martin Luther King, Jr., Federal Holiday, 1993

By the President of the United States of America

A Proclamation

By setting aside a day in honor of the late Reverend Dr. Martin Luther King, Jr., our Nation reaffirms its commitment to the noble goals for which he labored and eventually gave his life: equal opportunity and justice for all.

Throughout his quest to end racial segregation in the United States and to promote understanding and respect among all people, Martin Luther King urged America to fulfill its promise—and its potential—as a Nation dedicated to the belief "that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness."

Always mindful of those words from our Declaration of Independence, Dr. King viewed his work as a must-win struggle for the soul and future of the Nation. He knew that efforts to promote far-reaching social change, in a peaceful, nonviolent manner, would require patience, determination, and sacrifice. Yet, despite experiencing stubborn opposition, imprisonment, and even threats to his life, he also believed that the civil rights movement would prevail. "We will reach the goal of freedom in Birmingham and all over the Nation," he wrote to his followers from jail, "because the goal of America is freedom. . . . our destiny is tied up with America's destiny."

With his inspired leadership and eloquent appeals to all who would listen, Martin Luther King set in motion a ground swell of change in the United States. The Civil Rights Act of 1957, the Civil Rights Act of 1964, and the Voting Rights Act of 1965 were critical milestones in the fight for equality under the law. Although Dr. King's assassination in 1968 at the age of 39 prevented his living to see the fulfillment of his dreams for America, his legacy has continued to challenge and inspire us. Over the years the United States has continued to eliminate legal and attitudinal barriers that have, in the past, limited opportunities on the basis of race. We must go on striving to realize Dr. King's vision of an America where individuals are "not judged by the color of their skin but by the content of their character."

While government plays a critical role in the fight against discrimination through the enforcement of civil rights laws and its own hiring practices, our efforts to promote racial harmony and justice in the United States must begin at home. Martin Luther King described the family as the "main educational agency of mankind," and it is within the family that we must first teach lessons about love and fairness, decency and kindness, and the difference between right and wrong. We honor the legacy of Martin Luther King when we show our children, by word and example, what it means to lead "a committed life"—a life dedicated to excellence and to the service of one's fellowman. We equip our children for such a life when we encourage them to recognize their own self-worth, as well as the inherent rights and worth of others. "Every man is somebody," declared Dr. King, "because he is a child of God."

A minister by vocation, Martin Luther King sought righteous hearts as well as just laws. He warned that humankind suffered from "a poverty of the spirit which stands in stark contrast to our scientific and technological abundance." In this last decade of the 20th century, as we marvel at the historic achievements of the past 100 years and anticipate the many to come, let us enrich our children with a wealth of encouragement, hope, and moral guidance—and with living examples of racial comity and friendship.

By Public Law 98–144, the third Monday in January of each year has been designated as a legal public holiday.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim Monday, January 18, 1993, as the Martin Luther King, Jr., Federal Holiday.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of January, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and seventeenth.

George Bush

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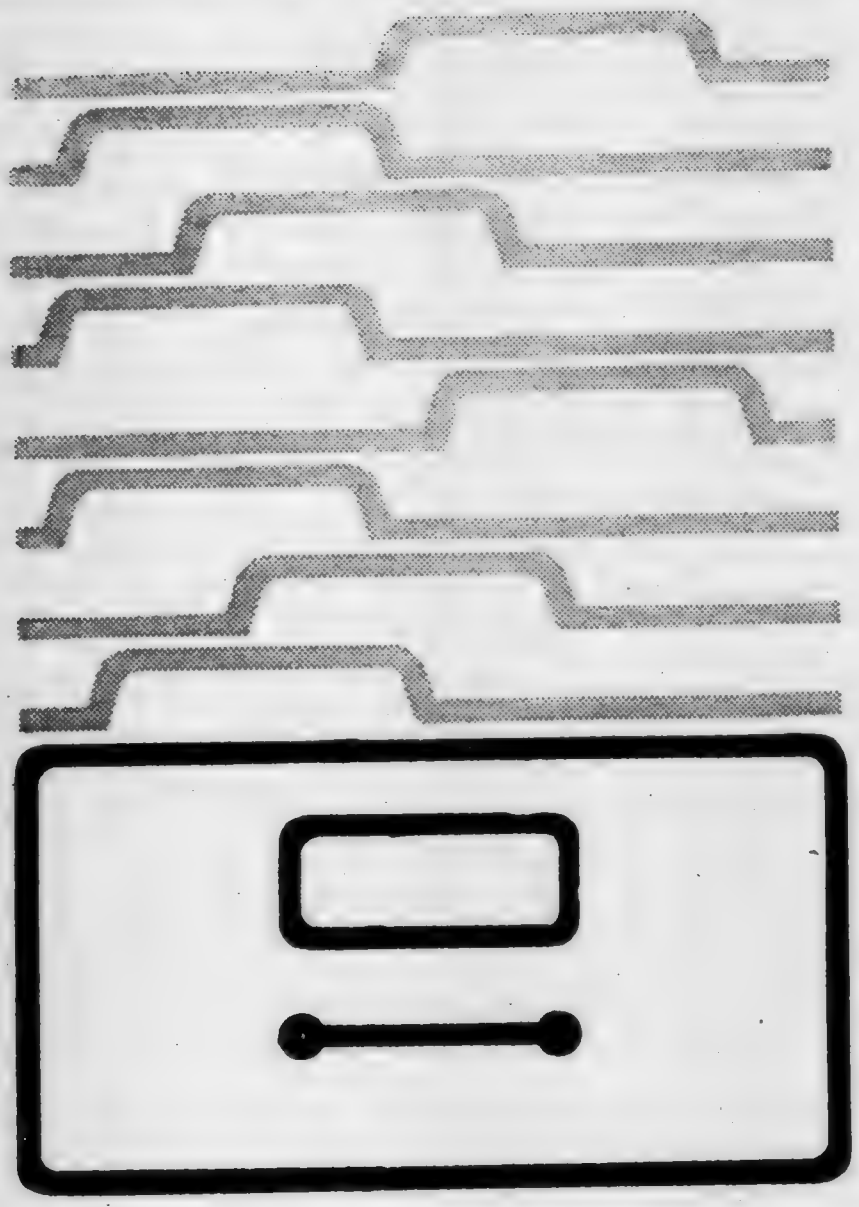

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Rules and Regulations

Federal Register
Vol. 58, No. 9
Thursday, January 14, 1993

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

ADMINISTRATIVE CONFERENCE OF THE UNITED STATES

1 CFR Part 305

Recommendations and Statements of the Administrative Conference Regarding Administrative Practice and Procedure

AGENCY: Administrative Conference of the United States.

ACTION: Recommendations and amendments; correction.

SUMMARY: The Administrative Conference of the United States is correcting an error in the title of a Conference recommendation that was published in the **Federal Register** on December 29, 1992 (57 FR 61759).

EFFECTIVE DATE: December 29, 1992.

FOR FURTHER INFORMATION CONTACT: Renee Barnow, Information Officer (202–254–7020).

SUPPLEMENTARY INFORMATION: Recommendations adopted by the Administrative Conference of the United States at its Forty-Seventh Plenary Session were published in the **Federal Register** on December 29, 1992 (57 FR 61759). At the same time, the Conference removed the texts (but not the titles) of certain recommendations and statements from the Code of Federal Regulations because they are deemed to be no longer of general interest. The title of one recommendation whose text was removed contained an error which this document corrects below.

Dated: January 6, 1993.

Michael W. Bowers,

Deputy Research Director.

The following correction is made to "Recommendations and amendments" published in the **Federal Register** on December 29, 1992 (57 FR 61759).

On page 61768, third column, the section number for Recommendation No. 79–7, Appropriate Restrictions on Participation by a Former Agency Official in Matters Involving the Agency, is changed from "§ 305.79–4" to "§ 305.79–7".

[FR Doc. 93–870 Filed 1–13–93; 8:45 am]

BILLING CODE 6110–01–M

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 52

[FV–88–202]

United States Standards for Grades of Canned Green Beans and Canned Waxed Beans

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: In compliance with the requirements for periodic review of existing regulations and in response to petitions from the National Food Processors Association (NFPA) the Agricultural Marketing Service (AMS) is revising the United States Standards for Grades of Canned Green Beans and Canned Waxed Beans. The final rule changes the U.S. grade standards for canned green beans and canned waxed beans.

EFFECTIVE DATE: February 16, 1993.

FOR FURTHER INFORMATION CONTACT: Leon R. Cary, Processed Products Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, P.O. Box 96456, room 0709, South Building, Washington, DC 20090–6456, Telephone: (202) 720–6247.

SUPPLEMENTARY INFORMATION: This action has been reviewed under Executive Order 12291 and Departmental Regulation 1512–1 and has been designated as a "nonmajor" rule. It will not result in an annual effect on the economy of $100 million or more. There will be no major increase in cost or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions. It will not result in significant effects on competition, employment, investments, productivity, innovations, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This final rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

The Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act, (5 U.S.C. 601 et seq.). The changes to the standards reflect current marketing practices. In addition, use of these standards is voluntary. A small entity may avoid incurring additional economic impact by not employing the standards.

In 1984, the Standards Subcommittee of the Fruit and Vegetable Products Technical Committee, National Food Processors Association (NFPA), requested that the United States Department of Agriculture (USDA) prepare a draft revision of the U.S. grade standards for canned green beans and canned wax beans. The draft was to incorporate a grading system where individual tolerances would be assigned to each individual defect. This system of grading, referred to as "individual attributes," would provide statistically derived acceptable quality levels (AQL's) based on the tolerances in the current grade standards.

In addition to their original request, in March 1988, NFPA asked USDA to modify the draft revised standards to reduce the recommended minimum drained weight for whole beans in No. 303 (303 x 406) containers by one-half (0.5) ounce. After studying the petition, USDA determined that to maintain consistency in the standards the minimum drained weight for whole beans in No. 300 (300 x 409) containers should also be reduced by one-half (0.5) ounce. At this time NFPA also asked for a reduction in the minimum drained weight for french style (sliced lengthwise) beans in 8 ounce Tall (211 x 304) containers by two-tenths (0.2) ounce, and in No. 303 (303 x 406) containers by forty-five hundredths (0.45) ounce. NFPA stated that virtually

none of its members packing whole or french style green or wax beans in these containers, even under optimum operating conditions, was able to meet the current recommended minimum drained weight. They explained that attempts to do so resulted in unacceptable damage to the beans and, more seriously, in false seams, knocked down flanges, and other seam defects that compromised the commercial sterility of the product.

USDA then prepared another draft incorporating the requested changes in drained weights and several other minor editorial changes. USDA staff discussed this draft with the NFPA Subcommittee on Standards in January 1989. At this meeting the Subcommittee asked USDA to revise the draft standards again to include the sample sizes, acceptable quality levels (AQL's), tolerances and acceptance numbers for lot inspection.

The proposed standards, as published in the Federal Register, incorporated these suggestions. The proposal to revise the U.S. Standards for Grades of Canned Green and Canned Wax Beans was published in the Federal Register on July 15, 1991 (56 FR 32121). In addition, the standards would incorporate USDA's policy of replacing dual grade nomenclature with single letter grade designations. Under the proposal, "U.S. Grade A" (or "U.S. Fancy"), "U.S. Grade B" (or "U.S. Extra Standard") and "U.S. Grade C" (or "U.S. Standard") would simply become "U.S. Grade A," "U.S. Grade B," and "U.S. Grade C."

The proposed revision of the voluntary grade standards would also bring the quality factors of stems, and extraneous vegetable material (EVM) in line with the Food and Drug Administration minimum quality standards and eliminate the quality factor "clearness of liquor" since this factor does not always reflect the quality of canned green and canned wax beans.

In addition to these substantive changes, the proposed standards would be modified to present them in a simple easy-to-use format. Consistent with recent revisions of other U.S. grade standards, definitions of terms and easy-to-read tables replace the textual descriptions. These changes would facilitate a better understanding and more uniform application of the grade standards.

A copy of the proposed rule was also provided to the Agricultural Research Service for help in identifying studies, monographs, data collection or other information relevant to the possible effect of pesticide use of the "cosmetic appearance elements" of the proposed rule. None was reported.

Four comments were received in response to the Notice of Proposed Rulemaking: two from industry members and two from food processing associations. One industry member commented that the proposed rule did not improve the definitions for the various defects and that the allowances for mechanical damage in cut and whole style are too restrictive for current mechanical processing methods. All comments noted that the proposed allowances for short pieces in cut style had been substantially tightened from those in the current standards and could be met only with great difficulty and considerable cost. All those commenting requested that a series of illustrations depicting various green bean defects be developed by USDA.

Also it was noted in every comment that the recommended minimum drained weights for No. 300 metal containers should be ninety percent (90%) of the recommended minimum drained weights for No. 303 metal containers.

In their comments, NFPA also petitioned for a reduction in the recommended minimum drained weights for various other styles and container sizes.

Final Rule

With respect to the comment that proposed allowances for mechanical damage in cut and whole style are too restrictive for current mechanical processing methods, USDA notes that no data was submitted to support the claim. Therefore, the allowances for mechanical damage will remain the same as published in the proposed rule.

Regarding the comments that proposed tolerances for short pieces in cut style were substantially tighter than those in the current standards and would be costly to meet, USDA reviewed data provided regarding short pieces and is in agreement with these comments. The tolerances for short pieces in cut style beans are adjusted in this final rule to be more in line with the current tolerances.

USDA agrees with the comments suggesting the development of a series of illustrations depicting various green bean defects. USDA will provide for such illustrations. These illustrations will be included in a grading manual.

USDA agrees with the comments that the recommended minimum drained weights for No. 300 metal containers should be approximately 90% of the recommended minimum drained weights for No. 303 metal containers. The recommended minimum drained weights for No. 300 metal containers will be adjusted accordingly in this final rule.

With regard to NFPA's request for reductions in the recommended minimum drained weights for various other styles and container sizes, USDA is denying this request since these changes are outside the scope of the proposed rule. USDA will, however, consider these proposed changes for future revisions based on supportive data under a separate petition.

Further, additional miscellaneous changes are made to the standards in this final rule for clarity.

Upon review of all background information and public comments collected during the rulemaking process, USDA determined that this final rule for the United States Standards for Grades of Canned Green and Canned Wax Beans appearing after this preamble should be published in the Federal Register and become effective 30 days after publication.

List of Subjects in 7 CFR Part 52

Food grades and standards, Food labeling, Frozen foods, Fruit juices, Fruits, Reporting and recordkeeping requirements, Vegetables.

For the reasons set forth in the preamble, this final rule amends 7 CFR part 52 as follows:

PART 52—[AMENDED]

1. The authority for part 52 continues to read as follows:

Authority: 7 U.S.C. 1622, 1624.

2. The Subpart—United States Standards for Grades of Canned Green Beans and Canned Wax Beans, 7 CFR 52.441–52.453 (formerly 52.441–52.456), is revised to read as follows:

Subpart—United States Standards for Grades of Canned Green Beans and Canned Wax Beans

Sec.

52.441 Product description.
52.442 Styles.
52.443 Definitions of terms.
52.444 Recommended fill of container.
52.445 Recommended minimum drained weights.
52.446 Types.
52.447 Sizes.
52.448 Kinds of pack.
52.449 Grades.
52.450 Factors of quality.
52.451 Allowances for defects.
52.452 Sample size.
52.453 Quality requirements criteria.

§ 52.441 Product description.

Canned green beans and canned wax beans are the products defined in the Food and Drug Standard of Identity for canned green beans and canned wax beans (21 CFR 155.120). For the

purposes of these standards and unless the text indicates otherwise, the terms "canned beans" or "beans" referred to in this text mean canned green beans or canned wax beans.

§ 52.442 Styles.

(a) *Whole* means canned beans that consist of whole pods, including pods which after removal of either or both ends are not less than 44 mm (1.75 in) in length or transversely cut pods not less than 70 mm (2.75 in) in length and, except for "vertical pack" or "asparagus" style, are not arranged in any definite position in the container.

(b) *Whole vertical pack* means canned beans that are "whole" and are packed parallel to the sides of the container.

(c) *Whole asparagus style* means canned beans that are "whole" and consist of pods that are cut at both ends, are of substantially equal lengths, and are packed parallel to the sides of the container.

(d) *Sliced lengthwise, Shoestring, Julienne, or French style* means canned beans consisting of pods that are sliced lengthwise.

(e) *Cut or cuts* means canned beans consisting of pods that are cut transversely into pieces less than 70 mm (2.75 in), but not less than 19 mm (0.75 in), in length, and may contain shorter end pieces which result from cutting.

(f) *Short cut or short cuts* means canned beans consisting of pieces of pods of which not less than 75 percent are less than 19 mm (0.75 in) in length and not more than 1 percent are more than 32 mm (1.25 in) in length.

(g) *Mixed or mixture means* a mixture of two or more of the following styles of canned beans: "whole;" "sliced lengthwise;" "cuts;" or "short cuts".

§ 52.443 Definitions of terms.

(a) *Acceptable Quality Level (AQL)* means the maximum percent of defective units or the maximum number of defects per hundred units of product that, for the purpose of acceptance sampling, can be considered satisfactory as a process average.

(b) *Blemish.* (1) *Minor blemished* means any unit which is affected by scars, pathological injury, insect injury or other means in which the aggregate area affected exceeds the area of a circle 3 mm (0.125 in) in diameter or the appearance or eating quality of the unit is slightly affected.

(2) *Major blemished* means any unit which is affected or damaged by discoloration or any other means to the extent that the appearance or eating quality of the unit is more than slightly affected.

(c) *Character.* (1) Round type—Green Beans.

(i) *Good character ("A")* means the pods are full fleshed; the pods are tender.

(ii) *Reasonably good character ("B")* means the pods are reasonably fleshly; the pods are tender.

(iii) *Fairly good character ("C")* means the pods have not entirely lost their fleshy structure; the pods are fairly tender.

(iv) *Poor character ("Sstd")* means the beans fail the requirements for "fairly good character."

(2) Round type—Wax Beans.

(i) *Good character ("A")* means the pods are full fleshed and may show slight breakdown of the flesh between seed cavities; the pods are tender.

(ii) *Reasonably good character ("B")* means the pods are reasonably fleshy and may show substantial breakdown of the flesh between the seed cavities; the pods are reasonably tender.

(iii) *Fairly good character ("C")* means the pods may show total breakdown of the flesh between the seed cavities with no definite seed pocket, but still retain flesh on the inside pod wall; the pods are fairly tender.

(iv) *Poor character ("Sstd")* means the beans fail the requirements for "fairly good character."

(3) Romano or Italian type.

(i) *Good character ("A")* means the pods have a full inner membrane, typical of the variety and are tender.

(ii) *Reasonably good character ("B")* means the pods have a reasonably well developed inner membrane and are reasonably tender.

(iii) *Fairly good character ("C")* means the pods may lack an inner membrane; the pods are fairly tender.

(iv) *Poor character ("Sstd")* means the beans fail the requirements for "fairly good character."

(d) *Color defective* means any unit that varies markedly from the color that is normally expected for the variety and grade.

(e) *Defect* means any nonconformance of a unit(s) of product from a specified requirement of a single quality characteristic.

(f) *Extraneous vegetable material (EVM)* means any harmless vegetable material (other than the bean pods) including, but not limited to, stalk, vine material, stem material attached to vine, leaves of the bean plant, and leaves or portions of other harmless plants.

(g) Flavor and odor. *Good flavor and odor* means the product has a good characteristic flavor and odor and is free from objectionable flavors and odors.

(h) Fiber.

(1) *Edible fiber* means fiber developed in the wall of the bean pod that is noticeable upon chewing, but may be consumed with the rest of the bean material without objection.

(2) *Inedible fiber* means fiber developed in the wall of the bean pod that is objectionable upon chewing and tends to separate from the rest of the bean material.

(i) *Mechanical damage* means any unit that is broken or split into two parts, (equal 1 defect) or has ragged edges that are greater than 5/16 inch, or is crushed or is damaged by mechanical means to such an extent that the appearance is seriously affected.

(j) *Single sample unit* means the amount of product specified (1200 grams for french style and 400 units for all other styles) to be used for unofficial inspection. It may be:

(1) The entire contents of a container;

(2) A portion of the contents of a container; or

(3) A combination of the contents of two or more containers.

(k) *Short piece* means any unit in cut style, mixed style or short cut style that is less than 13 mm (0.50 in) in length, and any unit in whole style that is less than 32 mm (1.25 in) in length, measured along the longest dimension parallel to the bean suture line.

(l) *Sloughing* means the separation of the outer surface layer of tissue from the pod.

(m) *Small pieces and odd cuts,* in french style, mean pieces of pod less than 13 mm (0.50 in) in length or pieces of pod not conforming to the normal appearance of a sliced lengthwise bean unit.

(n) *Stem* means any part or portion (loose or attached) of the hard or tough fibrous material that attaches the bean pod to the vine and is objectionable upon eating.

(o) *Tolerance* means the percentage of defective units allowed for each quality factor.

(p) *Tough strings* mean strings or pieces of strings, removed from the cooked bean pod, that will support a 227 g (½ lb) weight for not less than five (5) seconds.

(q) *Unit* means a bean pod or any individual portion thereof.

§ 52.444 Recommended fill of container.

The recommended fill of container is not incorporated in the grades of the finished product since fill of container, as such, is not a factor of quality for the purposes of these grades. It is recommended that each container of canned beans be filled with beans as full as practicable without impairment of quality and that the product and packing medium occupy not less than 90 percent of the total capacity of the container.

§ 52.445 Recommended minimum drained weights.

(a) The drained weight recommendations in Tables No. I and Ia of this section are not incorporated in the grades of the finished product since drained weight, as such, is not a factor of quality for the purposes of these grades.

(b) The drained weight of beans is determined by emptying the contents of the container upon a United States Standard No. 8 circular sieve of proper diameter containing 8 meshes to the inch (0.0937-inch ±3%, square openings) so as to distribute the product evenly, inclining the sieve slightly to facilitate drainage, and allowing to drain for 2 minutes. A sieve 8 inches in diameter is used for No. 2½ size cans (401×411) and smaller sizes, and a sieve 12 inches in diameter is used for containers larger than the No. 2½ size can.

(c) Compliance with the recommended minimum drained weights for canned beans in Table I and Table Ia of this section is determined by averaging the drained weights from all of the containers in the sample which is representative of a specific lot and such lot is considered as meeting the recommendations if the following criteria are met:

(1) The average of the drained weights from all of the containers in the sample meets the recommended minimum drained weight for the applicable style.

(2) The drained weights from the containers which do not meet the recommended minimum drained weight are not more than:

(i) 19.9 g (0.7 oz) lower than the recommended minimum average for No. 3 cylinder can size and smaller.

(ii) 56.7 g (2.0 oz) lower than the recommended minimum average for No. 10 cans.

(3) The number of containers in the sample which do not meet the requirements of paragraph (c)(2) of this section does not exceed the acceptance numbers prescribed for the sample size as outlined in 7 CFR 52.1 through 52.83.

TABLE I.—RECOMMENDED MINIMUM DRAINED WEIGHTS FOR CANNED GREEN BEANS AND WAX BEANS

[Ounces—English (Avoirdupois System)]

Container size or designation	Whole	Whole vertical pack and whole asparagus style	Short cuts and cuts less than 1½ inches	Cuts—1½ inches and longer	Mixed-cuts and short cuts	Sliced lengthwise or French style
8 oz. tall	4.0	4.6	4.5	4.1	4.5	3.9
8 oz. glass	3.9	4.5	4.4	4.0	4.4	4.0
No. 1 (picnic)	5.6	6.1	6.0	5.7	6.0	5.7
No. 300	7.2	8.6	8.3	7.8	8.3	7.4
No. 300 glass	8.2	9.2	8.5	8.2	8.5	8.2
No. 1 tall	8.5	9.5	9.2	8.7	9.2	8.7
No. 303	8.0	9.5	9.2	8.7	9.2	8.25
No. 303 glass	9.0	10.0	9.7	9.2	9.7	9.2
No. 2	10.5	11.9	11.2	11.0	11.2	11.0
No. 2½	16.0	17.0	16.4	16.2	16.4	16.2
No. 2½ glass	15.8	16.8	16.2	16.0	16.2	16.0
No. 3 cylinder	26.6	N/A	27.3	27.0	27.3	27.0
No. 10	57.5	N/A	63.0	60.0	63.0	59.0

TABLE Ia.—RECOMMENDED MINIMUM DRAINED WEIGHTS FOR CANNED GREEN BEANS AND WAX BEANS

[Grams—Metric (Systeme International)]

Container size or designation	Whole	Whole vertical pack and whole asparagus style	Short cuts and cuts less than 1½ inches	Cuts—1½ inches and longer	Mixed-cuts and short cuts	Sliced lengthwise or French style
8 oz. tall	113.4	130.4	127.6	116.2	127.6	110.6
8 oz. glass	110.6	127.6	124.7	113.4	124.7	113.4
No. 1 (picnic)	158.8	172.9	170.1	161.6	170.1	161.6
No. 300	204.1	243.8	235.3	221.1	235.3	209.8
No. 300 glass	232.5	260.8	241.0	232.5	241.0	232.5
No. 1 tall	241.0	269.3	260.8	246.6	260.8	246.6
No. 303	226.8	269.3	260.8	246.6	260.8	233.9
No. 303 glass	255.2	283.5	275.0	260.0	275.0	260.8
No. 2	297.7	337.4	317.5	311.9	317.5	311.9
No. 2½	453.6	482.0	464.9	459.3	464.9	459.3
No. 2½ glass	447.9	476.3	459.3	453.6	459.3	453.6
No. 3 cylinder	745.1	N/A	774.0	765.5	774.0	765.5
No. 10	1630.1	N/A	1786.1	1701.0	1786.1	1672.7

§ 52.446 Types.

The type of canned beans is not incorporated in the grades of finished product, since it is not a factor of quality. The types of canned beans are described as "round type" and "Romano or Italian type."

(a) *Round type* means canned beans having a width not greater than 1½ times the thickness of the beans.

(b) *Romano or Italian type* means canned beans having a width greater than 1½ times the thickness of the beans.

§ 52.447 Sizes.

The size of canned beans is not a factor of quality for the purposes of these grades. The size of a whole, cut, or short cut bean is determined by measuring the thickness at the shorter diameter of the bean transversely to the long axis at the thickest portion of the pod. The designations of the various sizes of round type and flat type (Romano or Italian) beans are shown in Tables II and IIa below.

TABLE II.—SIZES OF ROUND TYPE BEANS

Number designations	Word designation		Thickness in 1/64 inch	Thickness in millimeters
	Whole	Cut or short		
Size 1	Tiny	Small	Less than 14½	Less than 5.8.
Size 2	Small	Small	14½ but less than 18½	5.8 but less than 7.3.
Size 3	Medium	Small	18½ but less than 21	7.3 but less than 8.3.
Size 4	Medium large	Medium	21 but less than 24	8.3 but less than 9.5.
Size 5	Large	Large	24 but less than 27	9.5 but less than 10.7
Size 6	Extra large	Extra large	27 or more	10.7 or more.

TABLE IIA.—SIZES OF ROMANO OR ITALIAN TYPE BEANS

Number designations	Word designation		Thickness in 1/64 inch	Thickness in millimeters
	Whole	Cut or short		
Size 2	Small	Small	Less than 14½	Less than 5.8.
Size 3	Medium	Medium	14½ but less than 18½	5.8 but less than 7.3.
Size 4	Medium large	Medium large	18½ but less than 21	7.3 but less than 8.3.
Size 5	Large	Large	21 but less than 24	8.3 but less than 9.5.
Size 6	Extra large	Extra large	24 or more	9.5 or more.

§ 52.448 Kinds of pack.

The kind of pack of canned beans is not incorporated in the grades of finished product, since it is not a factor of quality. The kinds of pack of canned beans are described as "regular pack" and "special pack."

(a) *Regular pack* means canned beans that are packed containing single varietal characteristics.

(b) *Special pack* means canned beans that are intentionally packed containing two or more varietal characteristics (such as a mixture of green and wax beans).

§ 52.449 Grades.

(a) *U.S. Grade A* is the quality of canned green and canned wax beans that:

(1) Meets the following prerequisites in which the beans:

(i) Have similar varietal characteristics (except "special packs");

(ii) Have a good flavor and odor;

(iii) Have a good appearance;

(iv) Are not materially affected by sloughing;

(v) Are practically free from small pieces [units less than 13 mm (0.50 in) in length] and odd cut units (units not representative of the intended shape of cut) for the style of "sliced lengthwise."

(2) Is within the limits for defects as specified in Tables IIIa, IVa, Va, VIa, or VIIa in § 52.451 as applicable for the style.

(b) *U.S. Grade B* is the quality of canned green beans and canned wax beans that:

(1) Meets the following prerequisites in which the beans:

(i) Have similar varietal characteristics (except "special packs");

(ii) Have a good flavor and odor;

(iii) Have a reasonably good appearance;

(iv) Are not materially affected by sloughing;

(v) Are reasonably free from small pieces [units less than 13 mm (0.50 in) in length] and odd cut units (units not representative of the intended shape of cut) for the style of "sliced lengthwise."

(2) Is within the limits for defects as specified in Tables IIIa, IVa, Va, VIa, or VIIa in § 52.451 as applicable for the style.

(c) *U.S. Grade C* is the quality of canned green beans and canned wax beans that:

(1) Meets the following prerequisites in which the beans:

(i) Have similar varietal characteristics (except "special packs");

(ii) Have a good flavor and odor;

(iii) Have a reasonably good appearance;

(iv) Are not seriously affected by sloughing.

(2) Is within the limits for defects as specified in Tables IIIa, IVa, Va, VIa, or VIIa in § 52.451 as applicable for the style.

(d) Substandard is the quality of canned green beans and canned wax beans that fail the requirements of U.S. Grade C.

§ 52.450 Factors of quality.

The grade of canned green and canned wax beans is based on requirements for the following quality factors:

(a) Varietal characteristics (except "special packs");

(b) Flavor and odor;

(c) Sloughing;

(d) Small pieces and odd cuts (sliced lengthwise style only);

(e) Appearance;

(f) Extraneous vegetable material (EVM);

(g) Stems;

(h) Major blemished;

(i) Total blemished (includes major blemished and minor blemished);

(j) Mechanical damage;

(k) Short pieces (except sliced lengthwise style);

(l) Color;

(m) Character;

(n) Tough strings;

(o) Inedible fiber;

(p) Edible fiber.

§ 52.451 Allowances for defects.

TABLE III.—ACCEPTABLE QUALITY LEVELS (AQL'S) AND TOLERANCES FOR WHOLE STYLE CANNED GREEN BEANS AND WAX BEANS

Quality factor	Grade A		Grade B		Grade C	
	AQL	Tolerance	AQL	Tolerance	AQL	Tolerance
EVM	0.40	1.00	0.65	1.25	2.50	3.75
Stems	1.50	2.50	2.50	3.75	4.00	5.50
Blemished-major	0.65	1.25	1.50	2.50	2.50	3.75

TABLE III.—ACCEPTABLE QUALITY LEVELS (AQL'S) AND TOLERANCES FOR WHOLE STYLE CANNED GREEN BEANS AND WAX BEANS—Continued

Quality factor	Grade A		Grade B		Grade C	
	AQL	Tolerance	AQL	Tolerance	AQL	Tolerance
Blemished-total	1.50	2.50	2.50	3.75	6.50	8.50
Mechanical damage	4.00	5.50	6.50	8.50	6.50	10.75
Short pieces	20.00	23.25	N/A	N/A	N/A	N/A
Tough strings	1.00	1.75	2.50	3.75	8.50	10.75
Color defectives	4.00	5.50	8.50	10.75	15.00	17.75
Character—"B"	8.50	10.75	N/A	N/A	N/A	N/A
Character—"C"	1.00	1.75	8.50	10.75	N/A	N/A
Character—seld	0.40	1.00	1.00	1.75	8.50	10.75
Edible fiber	1.00	1.75	4.00	5.50	8.50	10.75
Inedible fiber	0.04	0.10	1.00	1.75	4.00	5.50

TABLE IIIA.—ACCEPTANCE NUMBERS FOR WHOLE STYLE CANNED GREEN BEANS AND WAX BEANS

Units of product	Grade A					Grade B					Grade C				
	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600
Extraneous vegetable material	8	15	28	43	57	12	22	43	67	89	39	73	149	234	318
Stems	25	46	92	144	195	39	73	149	234	318	59	112	232	366	499
Major blemishes	12	22	43	67	89	25	46	92	144	195	39	73	149	234	318
Total blemishes (major+minor)	25	46	92	144	195	39	73	149	234	318	92	176	368	584	799
Mechanical damage	59	112	232	366	499	92	176	368	584	799	118	227	476	758	1037
Short pieces	262	512	1067	1740	2391	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
Tough strings	18	32	64	99	134	39	73	149	234	318	118	227	476	758	1037
Edible fiber	18	32	64	99	134	39	73	149	234	318	118	227	476	758	1037
Inedible fiber	1	2	4	6	8	18	32	64	99	134	59	112	232	366	499
Color defectives	59	112	232	366	499	118	227	476	758	1037	200	388	822	1314	1803
"B" character	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
"C" character	18	32	64	99	134	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)
"Seld" character	8	15	28	43	57	18	32	64	99	134	118	227	476	758	1037

[1] No limit.

TABLE IV.—ACCEPTABLE QUALITY LEVELS (AQL'S) AND TOLERANCES FOR CUT STYLE CANNED GREEN BEANS AND WAX BEANS

Quality factor	Grade A		Grade B		Grade C	
	AQL	Tolerance	AQL	Tolerance	AQL	Tolerance
EVM	0.40	1.00	0.65	1.25	1.50	2.50
Stems	1.50	2.50	2.50	3.75	4.00	5.50
Blemished—major	0.65	1.25	1.50	2.50	2.50	3.75
Blemished—total	1.50	2.50	2.50	3.75	6.50	8.50
Mechanical damage	2.50	3.75	4.00	5.50	8.50	10.75
Short pieces	6.50	8.50	10.00	12.50	15.00	18.25
Tough strings	1.00	1.75	2.50	3.75	6.50	8.50
Color defectives	4.00	5.50	8.50	10.75	15.00	17.75
Character—"B"	8.50	10.75	N/A	N/A	N/A	N/A
Character—"C"	1.00	1.75	8.50	10.75	N/A	N/A
Character-seld	0.40	1.00	1.00	1.75	8.50	10.75
Edible fiber	1.00	1.75	2.50	3.75	6.50	8.50
Inedible fiber	0.04	0.125	0.65	1.25	2.50	3.75

TABLE IVA.—ACCEPTANCE NUMBERS FOR CUT STYLE CANNED GREEN BEANS AND WAX BEANS

Units of product	Grade A					Grade B					Grade C				
	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600
Extraneous vegetable material	8	15	28	43	57	12	22	43	67	89	25	46	92	144	195
Stems	25	46	92	144	195	39	73	149	234	318	59	112	232	366	499
Major blemishes	12	22	43	67	89	25	46	92	144	195	39	73	149	234	318
Total blemishes (major+minor)	25	46	92	144	195	39	73	149	234	318	92	176	368	584	799
Mechanical damage	39	73	149	234	318	59	112	232	366	499	118	227	476	758	1037
Short pieces	92	176	368	584	799	138	265	557	887	1216	200	388	822	1314	1803
Tough strings	18	32	64	99	134	39	73	149	234	318	92	176	368	584	799
Edible fiber	18	32	64	99	134	39	73	149	234	318	92	176	368	584	799
Inedible fiber	1	2	4	6	8	12	22	43	67	89	39	73	149	234	318
Color defectives	59	112	232	366	499	118	227	476	758	1037	200	388	822	1314	1803
"B" character	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
"C" character	18	32	64	99	134	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)
"Seld" character	8	15	28	43	57	18	32	64	99	134	118	227	476	758	1037

[1] No limit.

TABLE V.—ACCEPTABLE QUALITY LEVELS (AQL'S) AND TOLERANCES FOR SHORT CUT STYLE CANNED GREEN BEANS AND WAX BEANS

Quality factor	Grade A		Grade B		Grade C	
	AQL	Tolerance	AQL	Tolerance	AQL	Tolerance
EVM	0.15	0.50	0.40	1.00	0.65	1.25
Stems	0.65	1.25	1.00	1.75	1.50	2.50
Blemished-major	0.65	1.25	1.50	2.50	2.50	3.75
Blemished-total	1.50	2.50	2.50	3.75	6.50	8.50
Mechanical damage	12.50	15.25	15.00	17.75	20.00	23.25
Short pieces	12.50	15.25	15.00	17.75	20.00	23.25
Tough strings	1.00	1.75	2.50	3.75	2.50	3.75
Color defectives	4.00	5.50	8.50	10.75	15.00	17.75
Character-"B"	8.50	10.75	N/A	N/A	N/A	N/A
Character-"C"	1.00	1.75	8.50	10.75	N/A	N/A
Character-estd	0.40	1.00	1.00	1.75	6.50	10.75
Edible fiber	1.00	1.75	2.50	3.75	6.50	8.50
Inedible fiber	0.04	0.10	0.65	1.25	2.50	3.75

TABLE VA.—ACCEPTANCE NUMBERS FOR SHORT CUT STYLE CANNED GREEN BEANS AND WAX BEANS

Units of product	Grade A					Grade B					Grade C				
	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600
Extraneous vegetable material	4	7	12	18	24	8	15	28	43	57	12	22	43	67	89
Stems	12	22	43	67	89	18	32	64	99	134	25	46	92	144	195
Major blemishes	12	22	43	67	89	25	46	92	144	195	39	73	149	234	318
Total blemishes (major+minor)	25	46	92	144	195	39	73	149	234	318	92	176	368	584	799
Mechanical damage	169	326	689	1100	1506	200	388	822	1314	1803	262	512	1087	1740	2391
Short pieces	169	326	689	1100	1506	200	388	822	1314	1803	262	512	1087	1740	2391
Tough strings	18	32	64	99	134	39	73	149	234	318	39	73	149	234	318
Edible fiber	18	32	64	99	134	39	73	149	234	318	92	176	368	584	799
Inedible fiber	1	2	4	6	8	12	22	43	67	89	39	73	149	234	318
Color defectives	59	112	232	366	499	118	227	476	758	1037	200	388	822	1314	1803
"B" character	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
"C" character	18	32	64	99	134	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)
"Estd" character	8	15	28	43	57	18	32	64	99	134	118	227	476	758	1037

(1) No limit.

TABLE VI.—ACCEPTABLE QUALITY LEVELS (AQL'S) AND TOLERANCES FOR MIXED CUT STYLE CANNED GREEN BEANS AND WAX BEANS

Quality factor	Grade A		Grade B		Grade C	
	AQL	Tolerance	AQL	Tolerance	AQL	Tolerance
EVM	0.40	1.00	0.65	1.25	1.00	1.75
Stems	0.65	1.25	1.00	1.75	2.50	3.75
Blemished—major	0.65	1.25	1.50	2.50	2.50	3.75
Blemished—total	1.50	2.50	2.50	3.75	6.50	8.50
Mechanical damage	12.50	15.00	15.00	17.75	20.00	23.25
Short pieces	12.50	15.00	15.00	17.75	20.00	23.25
Tough strings	1.00	1.75	2.50	3.75	5.00	6.75
Color defectives	4.00	5.50	8.50	10.75	15.00	17.75
Character—"B"	8.50	10.75	N/A	N/A	N/A	N/A
Character—"C"	1.00	1.75	8.50	10.75	N/A	N/A
Character—estd	0.40	1.00	1.00	1.75	8.50	10.75
Edible fiber	1.00	1.75	2.50	3.75	6.50	8.50
Inedible fiber	0.04	0.10	0.65	1.25	2.50	3.75

TABLE VIA.—ACCEPTANCE NUMBERS FOR MIXED CUT STYLE CANNED GREEN BEANS AND WAX BEANS

Units of product	Grade A					Grade B					Grade C				
	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600
Extraneous vegetable material	8	15	28	43	57	12	22	43	67	89	18	32	64	99	134
Stems	25	46	92	144	195	39	73	149	234	318	39	73	149	234	318
Major blemishes	12	22	43	67	89	25	46	92	144	195	39	73	149	234	318
Total blemishes (major+minor)	25	46	92	144	195	39	73	149	234	318	92	176	368	584	799
Mechanical damage	169	326	689	1100	1506	200	388	822	1314	1803	262	512	1087	1740	2391
Short pieces	169	326	689	1100	1506	200	388	822	1314	1803	262	512	1087	1740	2391
Tough strings	18	32	64	99	134	39	73	149	234	318	73	138	286	453	619
Edible fiber	18	32	64	99	134	39	73	149	234	318	92	176	368	584	799
Inedible fiber	1	2	4	6	8	12	22	43	67	89	39	73	149	234	318
Color defectives	59	112	232	366	499	118	227	476	758	1037	200	388	822	1314	1803
"B" character	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)

TABLE VIA.—ACCEPTANCE NUMBERS FOR MIXED CUT STYLE CANNED GREEN BEANS AND WAX BEANS—Continued

Units of product	Grade A					Grade B					Grade C				
	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600	1200	2400	5200	8400	11600
"C" character	18	32	64	99	134	118	227	476	758	1037	(1)	(1)	(1)	(1)	(1)
"Setd" character	8	15	28	43	57	18	32	64	99	134	118	227	476	758	1037

[1] No limit.

TABLE VII.—ACCEPTABLE QUALITY LEVELS (AQL'S) AND TOLERANCES FOR FRENCH STYLE CANNED GREEN BEANS AND WAX BEANS

Quality factor	Grade A		Grade B		Grade C	
	AQL	Tolerance	AQL	Tolerance	AQL	Tolerance
EVM	0.40	1.00	0.65	1.25	2.50	3.75
Stems	1.50	2.50	2.50	3.75	4.00	5.50
Blemished-major	0.65	1.25	1.50	2.50	2.50	3.75
Blemished-total	1.50	2.50	2.50	3.75	8.50	10.75
Tough strings	1.50	2.50	4.00	5.50	8.50	10.75
Color defectives	4.00	5.50	8.50	10.75	15.00	17.75
Character—"B"	40.00	44.40	N/A	N/A	N/A	N/A
Character—"C"	5.00	8.75	20.00	23.75	N/A	N/A
Character—setd	1.00	1.75	4.00	5.50	10.00	12.50
Edible fiber	1.00	1.75	4.00	5.50	8.50	10.75
Inedible fiber	0.04	0.10	1.00	1.75	4.00	5.50

TABLE VIIa.—ACCEPTANCE NUMBERS FOR FRENCH STYLE CANNED GREEN BEANS AND WAX BEANS

Grams of product	Grade A					Grade B					Grade C				
	3600	7200	15600	25200	34800	3600	7200	15600	25200	34800	3600	7200	15600	25200	34800
Extraneous vegetable material (number of pieces)	8	15	28	43	57	12	22	43	67	89	39	73	149	234	318
Stems (number of stems)	25	46	92	144	195	39	73	149	234	318	59	112	232	366	499
Major blemishes (grams)	36	66	129	201	267	75	138	276	432	585	117	219	447	702	954
Total blemishes-maj+min (grams)	75	138	276	432	585	177	219	447	702	954	354	681	1428	2274	3111
Tough Strings (number of strings)	25	46	92	144	195	59	112	232	366	499	118	227	476	758	1037
Edible Fiber (number of pieces)	18	32	64	99	134	59	112	232	366	499	118	227	476	758	1037
Inedible Fiber (number of pieces)	1	2	4	6	8	18	32	64	99	134	59	112	232	366	499
Color Defectives (grams)	177	336	696	1098	1497	354	681	1428	2274	3111	600	1164	2466	3942	5400
"B" Character (grams)	1521	2997	6414	10299	14178	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)
"C" Character (grams)	219	414	858	1359	1857	786	1537	3261	5220	7173	(1)	(1)	(1)	(1)	(1)
"Setd" Character (grams)	54	96	192	297	402	177	336	696	1098	1497	414	795	1671	2661	3648

[1] No limit.

§ 52.452 Sample size.

The sample size used to determine whether the requirements of these standards are met shall be as specified in the sampling plans and procedures in the "Regulations Governing Inspection and Certification of Processed Fruits and Vegetables, Processed Products Thereof, and Certain Other Processed Food Products" (7 CFR 52.1 through 52.83).

§ 52.453 Quality requirements criteria.

(a) *Lot Inspection.* A lot of canned beans is considered as meeting the requirements for quality if:

(1) The prerequisite requirements specified in § 52.449 are met; and

(2) None of the allowances for the individual quality factors specified in Table IIIa, IVa, Va, VIa, or VIIa in § 52.451 as applicable for the style, are exceeded.

(b) *Single sample unit.* Each unofficial sample unit submitted for quality evaluation will be treated individually and is considered as meeting the requirements for quality if:

(1) The prerequisites requirements specified in § 52.449 are met; and

(2) The Acceptable Quality Levels in Table III, IV, V, VI, or VII in § 52.551 as applicable for the style are not exceeded.

§§ 52.454–52.456 [Removed].

(3) Sections 52.454, 52.455, and 52.456 are removed and reserved.

Dated: January 8, 1993.

Daniel Haley,

Administrator.

[FR Doc. 93–930 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–02–M

7 CFR Part 928

[Docket No. FV–92–928–1]

Papayas Grown in Hawaii; Order Directing That a Referendum be Conducted; Determination of Representative Period for Voter Eligibility; and Designation of Referendum Agents to Conduct the Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible growers of Hawaiian papayas to determine whether they favor continuance of the marketing order regulating the handling of papayas grown in the production area.

DATES: The representative production period is from July 1, 1991, through June 31, 1992. The referendum will be conducted from March 1 through March 31, 1993.

ADDRESSES: Copies of the text of the aforesaid marketing order may be obtained from the office of the referendum agent at 2202 Monterey Street, suite 102B, Fresno, California, 93721, or the Office of the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525–S, Washington, DC, 20090–6456.

FOR FURTHER INFORMATION CONTACT: Charles L. Rush, Marketing Order Administration Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, room 2522–S, P.O. Box 96456, Washington, DC 20090–6456; telephone: (202) 720–2431; or Kurt J. Kimmel, California Marketing Field Office, Marketing Order Administration Branch, Fruit and Vegetable Division, Agricultural Marketing Service, U.S. Department of Agriculture, 2202 Monterey Street, suite 102B, Fresno, California, 93721; telephone: (209) 487–5901.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 928 (17 CFR part 928), hereinafter referred to as the "order," and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (17 U.S.C. 601–674), hereinafter referred to as the "Act," it is hereby directed that a referendum be conducted within the period March 1 through March 31, 1993, among growers in the production area who, during the period July 1, 1991, through June 30, 1992, (which period is hereby determined to be a representative period for purposes of such referendum), were engaged in the production of papayas covered by the said marketing order to ascertain whether continuance of the order is favored by the growers.

The Secretary of Agriculture has determined that continuance referenda are an effective means for ascertaining whether growers favor continuation of marketing order programs. The Secretary would consider termination of the order if less than two-thirds of the growers voting in the referendum and growers of less than two-thirds of the volume of papayas represented in the referendum favor continuance. However, in evaluating the merits of continuance versus termination, the Secretary will not only consider the results of the continuance referendum, but also all other relevant information concerning the operation of the order and the relative benefits and disadvantages to growers, handlers, and consumers in order to determine whether continued operation of the order would tend to effectuate the declared policy of the Act.

In any event, section 8c(16)(B) of the Act requires the Secretary to terminate an order whenever the Secretary finds that a majority of all growers favor termination, and such majority produced for market more than 50 percent of the commodity covered under such order.

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the ballot materials that will be used in the referendum herein ordered have been submitted to and approved by the Office of Management and Budget (OMB) and have been assigned OMB No. 0581–0102. It has been estimated that it will take an average of 20 minutes for each of the approximately 120 growers of papayas to participate in the voluntary referendum balloting.

Mr. Kurt J. Kimmel, California Marketing Field Office, Fruit and Vegetable Division, Agricultural Marketing Service, USDA, is hereby designated as the referendum agent of the Secretary of Agriculture to conduct such referendum. The procedure applicable to the referendum shall be the "Procedure for the Conduct of Referenda in Connection With Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended" (7 CFR part 900.400 *et seq.*).

Ballots will be mailed to all growers and may also be obtained from the referendum agent and from his appointees at the above address.

List of Subjects in 7 CFR Part 928

Marketing agreements, Papayas, Reporting and recordkeeping requirements.

Authority: Agricultural Marketing Agreement Act of 1937, as amended, secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

Dated: January 8, 1993.

John E. Frydenlund,

Deputy Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–920 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–02–M

Commodity Credit Corporation

7 CFR Parts 1413 and 1421

RIN 0560–AC54 and 0560–AC55

1993 Feed Grain Acreage Reduction and Paid Land Diversion Programs and the 1993 Feed Grain and Oilseed Price Support Rates

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: On August 3, 1992, the Commodity Credit Corporation (CCC) issued a proposed rule with respect to the 1993 Production Adjustment Program for feed grains, which is conducted by the CCC in accordance with the Agricultural Act of 1949 (1949 Act), as amended. The 1993 feed grain Acreage Reduction Program (ARP) percentages have been determined to be 10 percent for corn, 5 percent for grain sorghum, and 0 percent for barley and oats. This final rule amends the regulations to set forth the acreage reduction percentage for the 1993 crop of feed grains. No paid land diversion (PLD) program will be implemented for the 1993 crop of feed grains. Also, this final rule amends the regulations to set forth the 1993 price support rates for feed grains and oilseeds. These actions are required by section 105B, in the case of feed grains, and section 205, in the case of oilseeds, of the 1949 Act.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Philip W. Sronce, Director, Grains Analysis Division, Agricultural Stabilization and Conservation Service, United States Department of Agriculture (USDA), P.O. Box 2415, Washington, DC 20013–2415 or call 202–720–4418.

SUPPLEMENTARY INFORMATION: The Final Regulatory Impact Analysis describing the options considered in developing this rule and the impact of the implementation of each option is available on request from the above-named individual.

This final rule has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Departmental Regulation 1512–1 and has been designated as "major." It has been determined that these program provisions will result in an annual effect on the economy of $100 million or more.

The titles and numbers of the Federal Assistance Programs, as found in the Catalog of Federal Domestic Assistance, to which this rule applies, are as follows:

Titles	Numbers
Feed Grain Production Stabilization	10.055
Commodity Loans and Purchases	10.051

It has been determined that the Regulatory Flexibility Act is applicable to this final rule because the CCC is required by section 105B(c) of the 1949 Act to publish a notice of proposed rulemaking with respect to certain provisions of this rule. A Final Regulatory Flexibility Analysis for the 1993 Feed Grain ARP was prepared as part of the Final Regulatory Impact Analysis. Copies of this analysis are available from the above-named individual.

This final rule has been reviewed in accordance with Executive Order 12778. The provisions of this final rule do not preempt State laws; are not retroactive; and do not require the exhaustion of any administrative appeal remedies.

It has been determined by an environmental evaluation that this action will not have a significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

This program/activity is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

The amendments to 7 CFR parts 1413 and 1421 set forth in this final rule do not contain information collections that require clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35).

This final rule amends 7 CFR parts 1413 and 1421 to set forth the determination of the 1993 Production Adjustment Program for feed grains and the 1993 price support rates for feed grains and oilseeds. General descriptions of the statutory basis for the 1993 Feed Grain ARP percentage determinations in this final rule were set forth at 57 FR 34087 (August 3, 1992).

The public was asked to comment on the five 1993 feed grain ARP options shown in Table 1.

TABLE 1.—1993 FEED GRAIN ARP OPTIONS

Crop	Option				
	1	2	3	4	5
	Percent				
Corn	7.5	0	5	7.5	12.5
Grain sorghum	7.5	0	5	0	7.5
Barley	7.5	0	5	0	7.5
Oats	0	0	0	0	0

Comments received during the specified comment period are summarized as follows:

A total of 1,944 respondents commented, including 171 from an open letter from the Iowa American Corn Growers Association and 1,556 from a producer survey collected by the Nebraska Corn Development, Utilization and Marketing Board at Harvest Husker Days. One thousand nine hundred and seventeen of the respondents commented on the corn ARP, 128 of the respondents commented on the grain sorghum ARP, and 145 of the respondents commented on the barley ARP. Table 2 shows a breakdown of the comments received by type of respondent.

TABLE 2.—SUMMARY OF COMMENTS ON ARP LEVELS, BY COMMODITY AND RESPONDENT TYPE

Item	ARP percentage					
	0%	5%	7.5%	10%	12.5%	>12.5%
Corn:						
Farm Organizations	0	1	0	6	5	0
Agri-businesses	5	2	0	1	0	2
Others	3	1	1	3	2	0
Producers	98	160	158	966	386	108
Total	106	164	159	976	402	110
Grain Sorghum:						
Farm Organizations	1	1	0	3	4	0
Agri-businesses	4	2	0	1	6	1
Others	3	1	0	3	2	0
Producers	3	4	2	17	71	15
Total	11	8	2	24	83	16
Barley:						
Farm Organizations	10	1	0	2	4	0
Agri-businesses	4	2	0	0	6	1
Others	4	1	0	2	2	0
Producers	4	4	2	17	65	14
Total	22	8	2	21	77	15

Respondents favoring the lower ARP's noted that the U.S. needs to produce more to take advantage of export opportunities. Many confirmed USDA's analysis that lower ARP's result in higher producer incomes. Advocates for a 0-percent barley ARP indicated the need for adequate supplies to aggressively implement the Export Enhancement Program for barley.

Respondents favoring the higher ARP's noted that feed grain prices would be higher and Government costs would be lower with higher ARP levels. Many producers wanted higher ARP's, which would increase prices and improve the profitability of their farms.

After considering these comments, the Secretary of Agriculture (Secretary) made an initial announcement on September 29, 1992, of an ARP of 10 percent for corn, 5 percent for grain sorghum, and 0 percent for barley and oats. The Secretary is authorized to make adjustments in the 1993 program no later than November 15.

On November 16, 1992, the Secretary announced that the initially announced ARP levels would not be changed. A change was not warranted because feed grain supplies had increased only 5 percent since September.

The Secretary determined that the ARP percentages announced on September 29 would maintain U.S. competitiveness in world markets while balancing the risks of excessive supplies and possible shortages.

The announced corn ARP level of 10 percent is 2.5 percentage points below

the statutory maximum of 12.5 percent. The 1949 Act provides that an ARP of 0 to 12.5 percent may be implemented if the corn ending stocks-to-use (S/U) ratio for the previous marketing year is equal to or less than 25 percent. When the 1993 ARP levels were initially announced, the S/U for the 1992/93 marketing year was estimated to be 22.7 percent. In the case of grain sorghum and barley, the 1949 Act provides for ARP percentages from 0 to 20 percent. Section 1104 of the Agricultural Reconciliation Act of 1990 provides for a minimum 7.5 percent ARP for the 1992 through 1995 crops under certain conditions. However, section 1302(b) of that Act also authorizes the Secretary to waive any ARP requirement if an agreement relating to the General Agreement on Tariffs and Trade negotiations was not entered into by June 30, 1992. Since such negotiations had not produced such an agreement, these minimum requirements could be waived.

A 10-percent ARP for corn reflects the prospects for a large 1992 crop. At the same time, a 5-percent ARP for grain sorghum and a zero-percent barley ARP signal to competitors that the U.S. will maintain its commitment to remain competitive in world markets and also signal to domestic and foreign customers that the U.S. will be a reliable supplier.

Tables 3 through 5 show the estimated impacts of three different 1993 ARP options based on September 1992 estimates, the month in which the initial 1993 ARP decisions were made.

Two barley ARP options of 0 percent are included to show the cross-commodity impacts of different ARP levels for corn and grain sorghum.

TABLE 3.—CORN SUPPLY AND DEMAND ESTIMATES

Item	1993 program options		
	1	2	3
	Percent		
ARP	10	7.5	12.5
Participation	80	80	78
	Million acres		
Planted acreage	74.0	75.1	73.8
	Million bushels		
Production	8,095	8,215	7,980
Domestic use	6,845	6,675	6,815
Exports	1,540	1,550	1,530
Ending stocks 8/31	1,746	1,826	1,671
	Dollars per bushel		
Average market price	2.10	2.05	2.15
	Million dollars		
Deficiency payments	3,595	3,830	3,195
Net income to corn producers	9,799	9,855	9,675

TABLE 4.—GRAIN SORGHUM SUPPLY AND DEMAND ESTIMATES

Item	1993 program options		
	1	2	3
	Percent		
ARP	5	0	7.5
Participation	77	85	75
	Million acres		
Planted acreage	12.1	12.4	11.9
	Million bushels		
Production	715	735	705
Domestic use	455	460	450
Exports	275	280	275
Ending stocks 8/31	125	135	120
	Dollars per bushel		
Average market price	1.96	1.92	2.01
	Million dollars		
Deficiency payments	329	402	288
Net income to Sorghum producers	894	962	890

TABLE 5.—BARELY SUPPLY AND DEMAND ESTIMATES

Item	1993 program options		
	1	2	3
	Percent		
ARP	0	0	7.5
Participation	77	77	75
	Million acres		
Planted acreage	8.6	8.6	8.2
	Million bushels		
Production	445	445	425
Domestic use	350	350	360
Exports	110	110	105
Ending stocks 5/31	134	134	119
	Dollars per bushel		
Average market price	2.10	2.07	2.18
	Million dollars		
Deficiency payments	138	144	104
Net income to Barley producers	631	625	612

Acreage Reduction

In accordance with section 105B(a)(1) of the 1949 Act, the ARP has been established with respect to the 1993 crop of corn at 10 percent, grain sorghum at 5 percent, and barley and oats at 0 percent. Accordingly, producers will be required to reduce their 1993 acreage of corn and grain sorghum for harvest from the crop acreage base established for feed grains for a farm by at least this established percentage in order to be eligible for price support loans, purchase, and payments for the respective feed grains.

Paid Land Diversion

In accordance with section 105B(e)(5) of the 1949 Act, a paid land diversion program will not be implemented for the 1993 crop of feed grains.

Price Support Rates

In accordance with sections 105B(a) and 205 of the 1949 Act, the price support rates have been established with respect to the 1993 crop of corn at $1.72 per bushel, grain sorghum at $1.63 per bushel, barley at $1.40 per bushel, oats at $0.88 per bushel, and the price support rates have been established with respect to the 1993 crop of rye at $1.46 per bushel. In accordance with section 205 of the 1949 Act, the price support rates have been established with respect to the 1993 crops of soybeans at $5.02 per bushel, and canola, flaxseed, mustard seed, rapeseed, safflower, and sunflower seed at $0.089 per pound.

List of Subjects

7 CFR Part 1413

Acreage allotments, Cotton, Disaster assistance, Feed grains, Price support programs, Reporting and recordkeeping requirements, Rice, Soil conservation, Wheat.

7 CFR Part 1421

Grains, Loan programs/agriculture, Oilseeds, Peanuts, Price support programs, Reporting and recordkeeping requirements, Soybeans, Surety bonds, Warehouses.

Accordingly, 7 CFR parts 1413 and 1421 are amended as follows:

PART 1413—FEED GRAIN, RICE, UPLAND AND EXTRA LONG STAPLE COTTON, WHEAT AND RELATED PROGRAMS

1. The authority citation for 7 CFR part 1413 continues to read as follows:

Authority: 7 U.S.C. 1308, 1308a, 1309, 1441–2, 1444–2, 1444f, 1445b–3a, 1461–1469; 15 U.S.C. 714b and 714c.

2. In § 1413.54, paragraphs (a)(2) and (d) are revised to read as follows:

§ 1413.54 Acreage reduction program provisions.

(a) * * *

(2)(i) For the 1991 crop:
(A) Corn, grain sorghum, and barley, 7.5 percent, and
(B) Oats, 0 percent;
(ii) For the 1992 crop:
(A) Corn, grain sorghum, and barley, 5.0 percent, and
(B) Oats, 0 percent; and
(iii) For the 1993 crop:
(A) Corn, 10 percent,
(B) Grain sorghum, 5 percent, and
(C) Barley and oats, 0 percent.

* * * * *

(d) Paid land diversion program payments:
(1) For the 1991 crop:
(i) Shall not be made available to producers of wheat,
(ii) Shall not be made available to producers of feed grains,
(iii) Shall not be made available to producers of upland cotton,
(iv) Shall not be made available to producers of ELS cotton, and
(v) Shall not be made available to producers of rice; and
(2) For the 1992 crop:
(i) Shall not be made available to producers of wheat,
(ii) Shall not be made available to producers of feed grains,
(iii) Shall not be made available to producers of upland cotton,
(iv) Shall not be made available to producers of ELS cotton, and
(v) Shall not be made available to producers of rice; and
(3) For the 1993 crop:
(i) Shall not be made available to producers of wheat, and
(ii) Shall not be made available to producers of feed grains.

* * * * *

PART 1421—GRAINS AND SIMILARLY HANDLED COMMODITIES

3. The authority citation for 7 CFR part 1421 continues to read as follows:

Authority: 7 U.S.C. 1421, 1423, 1425, 1441z, 1444f–1, 1445b–3a, 1445b–3a, 1444c–3, 1445e, and 1446f; 15 U.S.C. 714b and 714c.

4. In § 1421.7, paragraphs (c)(2) through (6) and (c)(9) and (10) are revised to read as follows:

§ 1421.7 Adjustment of basic support rates.

* * * * *

(c) * * *
(2)(i) 1991 Corn—$1.62 per bushel;
(ii) 1992 Corn—$1.72 per bushel;
(iii) 1993 Corn—$1.72 per bushel;
(3)(i) 1991 Barley—$1.32 per bushel;
(ii) 1992 Barley—$1.40 per bushel;
(iii) 1993 Barley—$1.40 per bushel;
(4)(i) 1991 Oats—$0.83 per bushel;
(ii) 1992 Oats—$0.88 per bushel;
(iii) 1993 Oats—$0.88 per bushel;
(5)(i) 1991 Grain sorghum—$1.54 per bushel;
(ii) 1992 Grain sorghum—$1.63 per bushel;
(iii) 1993 Grain sorghum—$1.63 per bushel;
(6)(i) 1991 Rye—$1.38 per bushel;
(ii) 1992 Rye—$1.46 per bushel;
(iii) 1993 Rye—$1.46 per bushel;

* * * * *

(9)(i) 1991 Soybeans—$5.02 per bushel;
(ii) 1992 Soybeans—$5.02 per bushel;
(iii) 1993 Soybeans—$5.02 per bushel;
(10)(i) 1991 Canola, flaxseed, mustard seed, rapeseed, safflower, and sunflower seed—$0.089 per pound;
(ii) 1992 Canola, flaxseed, mustard seed, rapeseed, safflower, and sunflower seed—$0.089 per pound;
(iii) 1993 Canola, flaxseed, mustard seed, rapeseed, safflower, and sunflower seed—$0.089 per pound.

* * * * *

Signed on January 8, 1993 at Washington, DC.

John A. Stevenson,
Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 93–922 Filed 1–13–93; 8:45 am]
BILLING CODE 3410–05–M

Animal and Plant Health Inspection Service

9 CFR Part 94

[Docket No. 92–141–2]

Importation of Animal Products and Byproducts From Countries Where BSE Exists; Removal of Denmark

AGENCY: Animal and Plant Health Inspection Service, USDA.
ACTION: Interim rule and request for comments.

SUMMARY: We are amending our regulations by removing Denmark from the list of countries where bovine spongiform encephalopathy (BSE) exists. Denmark was added to the list in September 1992 after the disease was diagnosed in a cow in that country. We are taking this action because epidemiological investigations reveal that the disease occurred in only one animal imported into Denmark from Great Britain, and that animal and the herd into which it was imported have been destroyed. The effect of this action is to relieve certain prohibitions or restrictions on the importation of certain fresh, chilled, and frozen meat, and certain other animal products and animal byproducts from ruminants which have been in Denmark, without presenting a significant risk of introducing BSE into the United States.

DATES: This interim rule is effective January 14, 1993. Consideration will be given only to comments received on or before March 15, 1993.
ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–141–2. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.
FOR FURTHER INFORMATION CONTACT: Dr. John Gray, Senior Staff Veterinarian, Import-Export Products Staff, VS, APHIS, USDA, room 756, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7885.
SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR parts 94 and 95 (referred to below as the regulations) govern the importation of meat, animal products, animal byproducts, hay, and straw into the United States in order to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE). Sections 94.18 and 95.4 of the regulations prohibit and restrict the importation of certain meat, animal products, and animal byproducts from ruminants which have been in countries in which BSE exists. These countries are listed in § 94.18 of the regulations.

Bovine spongiform encephalopathy is a neurological disease of bovine animals and other ruminants. The disease is not known to be contagious. The major means of spread of BSE appears to be through the use of ruminant feed containing protein and other products from ruminants infected with BSE. Therefore, BSE could become established in the United States if materials carrying the BSE agent, such as certain meat, animal products, and animal byproducts from ruminants in countries in which BSE exists, are imported into the United States and are fed to ruminants in the United States. At the present time, BSE is not known to exist in the United States. However, it is known to exist in France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland.

In an interim rule published in the **Federal Register** and effective on September 22, 1992 (57 FR 43606–43607, Docket No. 92–141–1), we amended the regulations by adding Denmark to the list of countries where

BSE exists, after the disease was diagnosed in a cow in that country. Comments were required to be received on or before November 23, 1992. We received two comments prior to this closing date, both submitted by representatives of foreign governments. These comments opposed the interim rule and explained how this situation occurred. There are no reports of any additional animals in Denmark being affected with BSE. Base on results of our continuing study of the situation described in the interim rule of September 22, and on the comments received, we are removing Denmark from the list of countries where BSE is known to exist. The list of countries appears in § 94.18 of the regulations.

An earlier report, by the Chief Veterinary Officer of the Danish Ministry of Agriculture, stated that BSE had been detected in one cow and suspected in another cow imported into Denmark from Great Britain. This led to our adding Denmark to the list of countries where BSE is known to exist. This action was taken in order to reduce the risk of introducing BSE into the United States. Epidemiological investigations have since revealed that there was only one infected cow, a Highland cow born in Scotland in June 1987 and imported into Denmark in June 1988. Two concentrates which were fed to the herd of origin during the winter of 1987/88 have been identified, and these two concentrates have been associated with other cases of BSE in the northeastern part of Scotland. The Danish Veterinary Service required the affected cow and the entire herd into which it was imported to be killed and the premises thoroughly cleaned and disinfected.

Further investigations by the Danish Government established that meat and bone meal have not been imported into Denmark from Great Britain for many years, and the Danish Government has imposed an official ban on the importation of such materials. Additionally, Danish farmers and veterinarians have been thoroughly informed of the symptoms of BSE, especially in relation to imported animals, and notification of a detection of symptoms of BSE is required. Finally, all Danish rendering plants are supervised and inspected daily for hygiene and processing. Diagnostic capabilities for BSE are available at the National Veterinary Laboratory in Copenhagen. Therefore, we are removing Denmark from the list of countries where BSE is known to exist.

Immediate Action

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this rule without prior opportunity for public comment.

Prompt implementation is needed to relieve unnecessary restrictions on the importation of certain fresh, chilled, and frozen meat, and certain other animal products and animal byproducts from ruminants which have been in Denmark. With these restrictions lifted, U.S. importers will be able to resume their importation of the animal products and animal byproducts described above. Danish producers and exporters, denied these U.S. markets by our September interim rule, will be able to resume their business with the United States.

Since prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest under these conditions, there is good cause under 5 U.S.C. 553 for making it effective upon publication in the **Federal Register**. We will consider comments that are received within 60 days of publication of this interim rule in the **Federal Register** After the comment period closes, we will publish another document in the **Federal Register**. It will include discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

The provisions of this rule will not have a significant economic impact. Placing Denmark on the list of countries in which BSE exists restricted or prohibited the importation of certain meat, animal products, and animal byproducts from ruminants that have been in Denmark. These restrictions and prohibitions had a minor negative economic impact on U.S. importers. Denmark is not a major export source of ruminant meat. It exported 123,000 metric tons in 1991, less than 3 percent of the world total. The United States imported only 180 tons, or $345,000 worth, of ruminant meat from Denmark in 1991, representing less than three-hundredths of one percent of the total amount of ruminant meat imported into the United States. There does not appear to be a significant amount of ruminant products or byproducts, other than meat, imported from Denmark.

At present, there are 14 U.S. importers who import ruminant meat from Denmark. Thirteen of these would be considered small entities. Relieving these restrictions would restore their ability to import ruminant meat from Denmark. The proportion of ruminant meat imported from Denmark is so small that there would be very little or no impact on U.S. producers and consumers. Additionally, price and competition in the United States would not be affected.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws, regulations, and policies that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This interim rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, the regulations in 9 CFR part 94 are amended as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), VELOGENIC VISCEROTROPIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 continues to read as follows:

Authority: 7 U.S.C. 147a, 150ee, 161, 162, and 450; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f; 31 U.S.C. 9701; 42 U.S.C. 4331, 4332; 7 CFR 2.17, 2.51, and 371.2(d).

2. In § 94.18, paragraph (a) is revised to read as follows:

§ 94.18 Ruminant meat and edible products from ruminants that have been in countries where bovine spongiform encephalopathy exists.

(a) Bovine spongiform encephalopathy exists in the following countries: France, Great Britain, Northern Ireland, the Republic of Ireland, Oman, and Switzerland.

* * * * *

Done in Washington, DC, this 8th day of January 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–923 Filed 1–13–93; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Parts 506, 509, 516, 528, 541, 543, 545, 552, 556, 558, 559, 561, 563, 563b, 563e, 567, 571, 579 and 580

[No. 92–503]

RIN 1550–AA60

Regulatory Review

AGENCY: Office of Thrift Supervision, Treasury.

ACTION: Final rule.

SUMMARY: The President announced on January 28, 1992, a review of all Federal regulations and policies for the purpose of eliminating over-burdensome regulations that discourage economic growth. The Office of Thrift Supervision (OTS) reviewed its regulations and policies, considered public comments and testimony and issued a notice of proposed rulemaking on September 3, 1992, listing recommended changes and deletions. Today, the OTS is issuing its final regulation implementing the modifications to its regulations consistent with the President's program.

DATES: February 16, 1993.

FOR FURTHER INFORMATION CONTACT: Deborah Kennedy, Project Manager, (202) 906–7324, Policy; Jennifer Lowe, Program Analyst, (202) 906–5633, Specialized Programs; Mary H. Gottlieb, Paralegal Supervisor, (202) 906–7135, Deborah Dakin, Assistant Chief Counsel, (202) 906–6445, or Karen Solomon, Deputy Chief Council, (202) 906–7240, Regulations and Legislation Division, Chief Counsel's Office, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION:

A. Background

On January 28, 1992, the President announced a Regulatory Review Program for all Federal government agencies. The agencies were asked to "weed out unnecessary and burdensome government regulations, which impede economic growth." We solicited public comments and received 58 comment letters and heard testimony from 19 savings associations, law firms and trade associations. The staff considered these comments in its review and identified a number of rules to delete or modify that fall within the guidelines of the President's program. Proposed modifications were published on September 3, 1992. 57 FR 40350 (Sept. 3, 1992).

The changes implemented today balance the benefits of promoting growth and reducing regulatory burden against the need to ensure a safe and sound thrift industry. While the changes implemented in this rulemaking touch almost every facet of our regulations, they are consistent with maintaining safe and sound operations at OTS-regulated savings associations. None of the changes alone will have a major impact on the industry, but taken together they will significantly reduce regulatory burden and clarify OTS regulatory requirements.

B. Comment Summary

We received ten comment letters in response to the notice of proposed rulemaking on Regulatory Review, all generally supporting our review initiative. The commenters were eight savings associations and two trade associations. Most commenters raised additional areas for review with specific suggestions for changes.

1. Regulations Restating Statutes or Listing Powers

Three commenters considered the general question of whether we should delete regulations that merely repeat statutory requirements or replace individual regulations setting forth savings association powers with a more general authorizing regulation. Two concluded that a large number of regulations is, in this case, warranted to ensure enforceability and to simplify tracking OTS requirements for savings associations. Eliminating specific regulations could increase uncertainty as to what savings associations may be authorized to do, or create further burdensome applications or notices. One commenter noted that OTS regulations afford federal thrifts the ability to argue preemption of state regulation and a general rule might weaken the preemption case. In view of the concerns raised by these commenters, we have decided not to modify our regulations that track statutory powers and set forth specific savings association powers at this time.

2. Affiliates Transactions

Two commenters approved of the use of "insider" rather than "affiliated person" as a further step to harmonize our transactions with affiliates rules with those of the other banking agencies. Another considered the term "insider" to have negative implications and urged another choice. We believe that no other term readily maintains the similarity of our rule "Loans to Executive Officers, Directors and Principal Shareholders of Savings Associations", 57 FR 45977 (October 6, 1992), with those of the other banking agencies. In order to ensure adequate opportunity to consider the implications of any changes to our "affiliated person" rules, however, we are undertaking a review of all of our "affiliated person" regulations in a separate rulemaking and will make appropriate proposals for revisions to terminology therein.

In response to our request for comments on all portions of the regulations, a commenter suggested deleting § 563.33(b), dealing with activities undertaken for affiliates. The section limits the circumstances under which an employee of a savings association may work for an affiliated person. Upon review, we have concluded that this provision is unnecessary because it is subsumed within the restrictions applicable to savings associations pursuant to section 23B of the Federal Reserve Act, 12 U.S.C. 371c–1. It will be deleted in this rule.

One commenter asked that we incorporate section 23A of the Federal Reserve Act, 12 U.S.C. 371c, by reference, instead of incorporating much of the text of that statute into our regulations. Because savings

associations continue to be subject to several unique statutory provisions governing their transactions with affiliates, consolidating all the applicable standards in the regulation helps to clarify how the various provisions apply to savings associations. Thus, we have determined not to change § 563.41 at this time.

3 Compliance

a. Home Mortgage Disclosure

Three commenters wrote favoring elimination of the nondiscrimination disclosure requirements at § 528.6 as duplicative of the requirements set forth in 12 CFR part 203, which are made applicable to savings associations pursuant to the Home Mortgage Disclosure Act (HMDA), 12 U.S.C. 2801 *et seq.* One commenter asserted that the current requirement of § 528.6 requiring savings associations to continue reporting the "reason for denial" on their HMDA Loan Application Registers is unnecessary as long as other published OTS guidance contains the requirement.

We agree that § 528.6 is largely duplicative of part 203 and we are therefore deleting all redundant provisions. We disagree, however, that the "reason for denial" is unnecessary. The "reason for denial" provides us with useful information that assists the examination process. We believe that retaining the regulatory requirement assures that this important data field is completed by all OTS-regulated filers, including any majority-owned savings association service corporations or affiliates. Therefore, we are amending § 528.6 to clarify that savings associations and other OTS-regulated filers that are required to keep HMDA Loan Application Registers pursuant to part 203 must enter the reason for denial for all loan denials. Because of the changes in § 528.6, we are deleting the definitions in §§ 528.1(d), (e), (f), and (g) as unnecessary

b. Truth in Savings

One commenter suggested the elimination of § 563.7, "Fixed-term accounts (certificate accounts)," and § 563.27, "Advertising," because they duplicate requirements found in Regulation DD of the Federal Reserve Board, 12 CFR part 230. The Truth in Savings Act (12 U.S.C. 4301 *et seq.*, contained in the Federal Deposit Insurance Corporation Improvement Act of 1991 (FDICIA), Pub. L. No. 102–242, 105 Stat. 2236) directed the Federal Reserve Board to issue final implementing regulations by September 1992. Regulation DD was published by the Board on September 21, 1992 and is applicable to all savings associations.

In light of the publication of Regulation DD, which covers the field of savings disclosures and advertising, we agree that certain portions of § 563.7 and 563.27 are no longer necessary and should be removed. In particular, we are amending § 563.7 to delete paragraph (d), which contains contract provisions required in certificate accounts. This paragraph is not necessary given the extensive disclosure requirements contained in Regulation DD specifying that clear, written disclosures must be provided to consumers in a form they may keep. See 12 CFR 230.3–230.6. In addition, because Regulation DD contains newly adopted advertising requirements in 12 CFR 230.8, § 563.27(a) has been superseded and, therefore, is removed. Section 563.27(b)(2) is also removed because restrictions on name and corporate title advertising are no longer necessary for consumer protection. We do, however, retain in § 563.27 the prohibition against misrepresentation of an association's services, contracts, investments, and financial condition. Regulation DD prohibits misleading advertising of an institution's deposit contracts, but the OTS's prohibition section is broader We intend to continue monitoring compliance with this section.

In addition to those sections mentioned by the commenter, we have reviewed OTS regulations and determined that paragraphs (b), (c), (d), (e), and (g) of § 561.16 should be removed in light of the new provisions in Regulation DD covering bonuses paid on accounts, 12 CFR 230.4(b)(7), 230.8(d), and the removal of identical provisions from the Federal Reserve System's Regulation Q, as amended in conjunction with its adoption of Regulation DD. Section 545.12 is amended to remove reference to the paragraphs of § 561.16 that are being deleted.

c. Community Development

Section 5(c)(3)(B) of the Home Owners' Loan Act (HOLA) authorizes federal savings associations to invest up to two percent of their assets in real property and loans located in "a geographic area or neighborhood receiving concentrated development assistance by a local government under title I of the Housing and Community Development Act of 1974." 42 U.S.C. 5301 *et seq.* OTS's implementing regulation, 12 CFR 545.41, originally promulgated in 1974, was drafted to be consistent with how the Department of Housing and Urban Development (HUD) was then administering its Title I programs. Since then, HUD has made numerous changes in its Title I programs. As a result, OTS's regulation is outdated and contains obsolete standards and criteria.

In the proposed rule, we solicited comments on how to update 12 CFR 545.41. In particular, the agency requested comments on meaningful ways to identify areas or neighborhoods receiving concentrated Title I assistance. We received no comments.

We are amending our community development regulation to eliminate the outdated criteria contained in 12 CFR 545.41(a) and to substitute a simple restatement of the authorization set forth in section 5(c)(3)(B) of the HOLA. This amendment will avoid the need to update the regulation each time modifications are made to Title I programs. Savings associations that have questions about whether particular investments will qualify under section 5(c)(3)(B) of the HOLA may contact the OTS.

We will also pursue an amendment to HOLA section 5(c)(3)(B) to eliminate its outdated references to HUD criteria that no longer exist.

4. Lending Requirements

One commenter urged us to further explore ways to authorize "untroubled associations" to use salvage powers to exceed Loans to One Borrower (LTOB) limits in "selected circumstances." We believe the concept has merit, and is feasible under 12 U.S.C. 1464(u) and 12 CFR 563.93 in certain circumstances. We plan to issue guidance soon that would allow, with prior OTS approval, greater use of salvage powers. Expanded salvage powers generally will be available for well-capitalized, well-managed institutions, but will be closely controlled for other institutions.

Another commenter recommended that we remove the regulations governing loans in §§ 545.32 through 545.45 because they are likely to change as a result of OTS adoption of interagency uniform real estate lending standards. Changes to these regulations will be made as a part of the rulemaking process for real estate lending standards.

Another commenter urged us to drop the requirement to maintain reports of the status of tax payments in loan files (§ 563.170(c)(1)(xi)). We are considering changing this provision as part of our implementation of section 132 of FDICIA, which requires the OTS and the other banking agencies to establish loan documentation requirements.

One commenter suggested that we modify our Appraisal regulation (part 564) to allow for the use of the Departure Provision of the Uniform

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Standards of Professional Appraisal Practice. This provision allows limited exceptions to industry appraisal standards. We believe this proposal has merit and will, on an interagency basis, pursue this recommendation.

The same commenter requested that we not delete two sections—571.1, "Appraisal of real estate securing assets of savings associations" and 563.90, "Appraisals on loans outside lending area." We believe that both sections can be deleted without compromising safety and soundness. Section 571.1 is a statement of policy that does not establish any specific regulatory requirements. The section generally lists the authority of the OTS to require appraisals and, even with its deletion, the OTS retains such authority. Section 563.90 requires institutions to obtain appraisals on loans outside their lending areas. Even with the deletion of this section, institutions continue to be required to obtain appraisals in accordance with part 564.

The commenter also requested that we mandate appraisals for all real estate-related loans, even those that fall at or below the $100,000 threshold established by our appraisal rule. As discussed more fully in the preamble to the final regulation that established the $100,000 threshold level, we believe it is unnecessary for the regulation to require an appraisal for loans at or below that level due to the low risk of loss generally associated with such loans.

The same commenter also opposed use of the term "evaluation" (rather than "appraisal") for loans that do not require the services of a licensed or certified appraiser under the appraisal regulation (part 564). Another commenter asked for clarification of the differences between evaluations and appraisals for real estate. We believe that the differences between the terms "evaluations" and "appraisals" are important to maintain. Thrift Bulletin 55 (TB–55) Real Estate Appraisal and Evaluation Guidelines, issued on October 13, 1992, explains each type of valuation and its use.

5. Other Comments

A commenter suggested that we repeal Thrift Bulletin 13 (TB–13) when an interest rate risk element is incorporated into the capital requirements. In the supplemental notice of proposed rulemaking for incorporating the interest rate component into the risk-based capital rule, we proposed replacing TB–13 with a new § 571.3 that sets forth the responsibilities of directors and management in managing interest rate risk exposure. See 57 FR 40524 (Sept. 3, 1992).

Another commenter recommended that we delete the liquidity requirements at § 566.2. These are statutorily mandated by 12 U.S.C. 1465, thus, we can not eliminate them as part of this rulemaking. They are being considered, however, as part of the interagency study of regulatory burden that will contain recommendations for legislative changes.

A commenter asked us to consider raising the reporting thresholds for criminal referrals in § 563.180(d). The commenter explained that law enforcement officials do not take action on many claims that fall within our reporting requirements because they are too small. We are currently working to revise this regulation and will issue changes to it in a separate rulemaking.

One commenter noted that § 563.96, limiting investments in accounts of commercial banks and thrift institutions and debt securities hedged with forward commitments, is difficult to understand. We agree that the provision needs to be revised and that these requirements could be covered in other areas of our regulations. We plan to revise the rule in the near future, possibly in conjunction with the interagency project on Interbank Liabilities.

Commenters mentioned several proposed changes that they highly approved. Among these were deletion of the "giveaway" rules (§ 545.21), obsolete gold regulations (§§ 545.79, 571.10 and 571.17), certain redundant lending disclosures (§ 563.99(d)), restrictions on prepayment penalties on ARM loans (§ 545.34), and certain restrictions on corporate names and titles. They also approved deleting Form AR filings (§ 563.45) and the outdated liability growth rule (§ 563.131). Commenters also favored the proposed changes to rules on the numbers of directors for savings associations (§ 552.6–1) and the removal of certain restrictions on advisory boards (§ 545.123). Except as discussed above, we received no other comments on the proposed rules.

C. Changes in the Proposed Rules

Besides those changes discussed above, the modifications to our rules and regulations listed in this final rule are materially unchanged from those listed in the proposal. Some minor changes have been made, however, to our Local Rules of Practice and Procedure in Adjudicatory Proceedings ("Local Rules")[1].

Changes to § 509.104 of the Local Rules from those listed in the proposal including the following:

Minor revisions to paragraphs (b), (f), (g), and (h) have been made to clarify the additional filing procedures. The term "Secretary," which refers to the Secretary to the Office, who receives adjudicatory filings, will replace the term "Corporate Secretary," which refers to the person who receives applications and other corporate filings. The proposed amendment to paragraph (d) has been withdrawn as redundant; there is no change to existing paragraph (d).

Paperwork Reduction Act

The collection of information requirement contained in this final regulation has been submitted to and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507). The collection of information is contained in 12 CFR 516.1(c).

Section 516.1 contains OTS application processing guidelines and procedures. Applications are labelled to ensure that all appropriate OTS offices receive copies. To expedite processing, OTS is now requiring the filing of two additional copies of all applications/notices that raise significant issues for concurrent review by Washington and Regional offices.

The information collection under OMB Control Number 1550–0056 entitled "Requirements for Filings" was amended to include this new collection.

The following summarizes the estimated additional burden of the information collection in § 516.1(c):

Number of hours per response	.05
Number of annual responses	630
Total number of hours yearly	31.5
Average cost per hour	$20.00
Total yearly cost	$630.00

The following summarizes the estimated total burden for the amended package under control number 1550–0056:

Number of hours per response	.055
Number of annual responses	6,300
Total number of hours yearly	346.5
Average cost per hour	$20.00
Total yearly cost	$6,930.00

Comments concerning the accuracy of these estimates and suggestions for reducing this burden should be directed to Office of Management and Budget, Paperwork Reduction Project (1550), Washington, DC 20503.

[1] The Local Rules apply to OTS administrative enforcement proceedings commenced on or subsequent to August 12, 1991. See 56 FR 38,302, 38,305, 38,317 (Aug. 12, 1991) (codified at 12 CFR 509.100–509.104).

Executive Order 12291

The OTS has determined that this regulation does not constitute a "major rule" and, therefore, does not require the preparation of a final regulatory impact analysis.

Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act, it is certified that this regulation will not have a significant economic impact on a substantial number of smaller entities. Accordingly, a Regulatory Flexibility Act Analysis is not required.

List of Subjects

12 CFR Part 506

Reporting and recordkeeping requirements.

12 CFR Part 509

Administrative practice and procedures, Penalties.

12 CFR Part 516

Applications, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 528

Advertising, Civil rights, Credit, Fair housing, Mortgages, Reporting and recordkeeping requirements, Savings associations, Signs and symbols.

12 CFR Parts 541, 543, 556, 558, 559, 561, 579 and 580

Savings associations.

12 CFR Part 545

Accounting, Consumer protection, Credit, Electronic funds transfers, Investments, Manufactured homes, Mortgages, Reporting and recordkeeping requirements, Savings associations.

12 CFR Parts 552 and 563b

Reporting and recordkeeping requirements, Savings associations, Securities.

12 CFR Part 563

Accounting, Advertising, Crime, Currency, Flood insurance, Investments, Reporting and recordkeeping requirements, Savings associations, Securities, Surety bonds.

12 CFR Part 563e

Community development, Credit, Investments, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 567

Capital, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 571

Accounting, Conflicts of interest, Gold, Investments, Reporting and recordkeeping requirements, Savings associations.

Accordingly, the Office of Thrift Supervision amends chapter V, title 12, Code of Federal Regulations, as set forth below.

SUBCHAPTER A—ORGANIZATION AND PROCEDURES

PART 506—INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT

1. The authority citation for part 506 continues to read as follows:

Authority: 44 U.S.C. 3501 *et seq.*

1a. Section 506.1 is amended by adding four new entries to the table in paragraph (b) in numerical order to read as follows:

§ 506.1 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * * *

(b) *Display*

12 CFR part or section where identified and described	Current OMB control No.
* * * *	*
516.1(b)	1550–0056
* * * *	*
563.99–563.101 (Subpart D), Appendix A	1550–0078
563.100	1550–0078
563.101	1550–0078
* * * *	*

PART 509 RULES OF PRACTICE AND PROCEDURE IN ADJUDICATORY PROCEEDINGS

1b. The authority citation for part 509 continues to read as follows:

Authority: 5 U.S.C. 556; 12 U.S.C. 1464, 1467, 1467a, 1813; 15 U.S.C. 781.

2. Section 509.104 is amended by revising paragraphs (b) and (f), by redesignating paragraph (g) as paragraph (i), and by adding new paragraphs (g) and (h) to read as follows:

§ 509.104 Additional procedures.

* * * * *

(b) *Motions.* All motions shall be filed with the administrative law judge and an additional copy shall be filed with the Secretary to the Office, who receives adjudicatory filings, ("Secretary"); provided, however, that once the administrative law judge has certified the record to the Director pursuant to § 509.38 of this part, all motions must be filed with the Director, to the attention of the Secretary, within the 10 day period following the filing of exceptions allowed for the filing of replies to exceptions. Responses to such motions filed in a timely manner with the Director, other than motions for oral argument before the Director, shall be allowed pursuant to the procedures at § 509.23(d) of this part. No response is required for the Director to make a determination on a motion for oral argument.

* * * * *

(f) *Service upon the Office.* Service of any document upon the Office shall be made by filing with the Secretary, in addition to the individuals and/or offices designated by the Office in its Notice issued pursuant to § 509.18 of this part, or such other means reasonably suited to provide notice of the person and/or office designated to receive filings.

(g) *Filings with the Director.* An additional copy of all materials required or permitted to be filed with or referred to the administrative law judge pursuant to subpart A and B of this part shall be filed with the Secretary. This rule shall not apply to the transcript of testimony and exhibits adduced at the hearing or to proposed exhibits submitted in advance of the hearing pursuant to an order of the administrative law judge under § 509.32 of this part. Materials required or permitted to be filed with or referred to the Director pursuant to suparts A and B of this part shall be filed with the Director, to the attention of the Secretary.

(h) *Filing and certification of record.* At the same time the administrative law judge files with and certifies to the Director for final determination the record of the proceeding, the administrative law judge shall furnish to the Director a certified index of the entire record of the proceeding. The certified index shall include, at a minimum, an entry for each paper, document or motion filed with the administrative law judge in the proceeding, the date of the filing and the identity of the filer. The certified index shall also include an exhibit index containing, at a minimum, an entry consisting of exhibit number and title or description for: Each exhibit introduced and admitted into evidence at the hearing; each exhibit introduced but not admitted into evidence at the hearing; each exhibit introduced and admitted into evidence after the completion of the hearing; and each exhibit introduced but not admitted into evidence after the completion of the hearing.

* * * * *

PART 516—APPLICATION PROCESSING GUIDELINES AND PROCEDURES

3. The authority citation for part 516 is revised to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1462a, 1463, 1464.

4 Section 516.1 is amended by adding a sentence to precede the last sentence of paragraph (c) introductory text to read as follows:

§ 516.1 Offices of the Office of Thrift Supervision; information and submittals.

* * * * *

(c) *Filings.* * * * Two additional conformed copies shall be filed with the Applications Filing Room, Office of Thrift Supervision, 1700 G Street, NW., Washington, DC, 20552 of any application, notice or other filing that raises a significant issue of law or policy, as defined by OTS order or other OTS guidance. * * *

* * * * *

SUBCHAPTER B—CONSUMER-RELATED REGULATIONS

PART 528—NONDISCRIMINATION REQUIREMENTS

5. The authority citation for part 528 is revised to read as follows:

Authority: 12 U.S.C. 1464, 2810 *et seq.*, 2901 *et seq.*, 15 U.S.C. 1691, 42 U.S.C. 1981, 1982, 3601–3619.

§ 528.1 [Amended]

6. Section 528.1 is amended by removing paragraphs (d) through (g).

7 Section 528.6 is revised to read as follows:

§ 528.6 Loan application register.

Savings associations and other lenders required to file Home Mortgage Disclosure Act Loan Application Registers with the Office of Thrift Supervision in accordance with 12 CFR part 203 must enter the reason for denial, using the codes provided in 12 CFR part 203, with respect to all loan denials.

SUBCHAPTER C—REGULATIONS FOR FEDERAL SAVINGS ASSOCIATIONS

PART 541—DEFINITIONS

8. The authority citation for part 541 is revised to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464.

§ 541.9 [Removed]

9 Section 541 9 is removed.

§ 541.12 [Removed]

10 Section 541.12 is removed.

§ 541.24 [Removed]

11 Section 541.24 is removed.

PART 543—INCORPORATION, ORGANIZATION, AND CONVERSION OF FEDERAL MUTUAL ASSOCIATIONS

12. The authority citation for part 543 is revised to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 2901 *et seq.*

§ 543.1 [Amended]

13. Section 543.1 is amended by removing the first sentence of paragraph (a).

PART 545—OPERATIONS

14. The authority citation for part 545 continues to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1828.

15. Section 545.12 is amended by revising paragraph (b) to read as follows:

§ 545.12 Demand deposit accounts.

* * * * *

(b) A Federal savings association shall not pay interest on a demand deposit; however, finders' fees offered in accordance with § 561.16(b) of this chapter are not payments of interest.

* * * * *

§ 545.21 [Removed]

16. Section 545.21 is removed.

17. Section 545.34 is amended by revising the second sentence of paragraph (b) and the second sentence of paragraph (c) to read as follows, and by removing the last sentence of paragraph (c):

§ 545.34 Limitations for home loans secured by borrower-occupied property.

* * * * *

(b) * * * With respect to any loan made after July 31, 1976, on the security of a home occupied or to be occupied by the borrower, no late charge, regardless of form, shall be assessed or collected by a Federal savings association, unless any monthly billing, coupon, or notice the Federal savings association may provide regarding installment payments due on the loan discloses the date after which the charge may be assessed. * * *

(c) * * * A Federal savings association may impose a penalty on the prepayment of a loan as provided in the loan contract.

§ 545.36 [Amended]

18. Section 545.36 is amended by removing the second and third sentences in paragraph (d).

19. Section 545.41 is amended by revising paragraph (a) to read as follows

§ 545.41 Community development loans and investments.

(a) *General.* Federal savings associations have the authority to make investments pursuant to section 5(c)(3)(B) of the Act.

* * * * *

§ 545.75 [Amended]

20. Section 545.75 is amended by removing and reserving paragraph (b)(5).

§ 545.79 [Removed]

21. Section 545.79 is removed.

§ 545.93 [Removed]

22. Section 545.93 is removed.

§ 545.123 [Removed]

23. Section 545.123 is removed.

PART 552—INCORPORATION, ORGANIZATION, AND CONVERSION OF FEDERAL STOCK ASSOCIATIONS

24. The authority citation for part 552 is revised to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a.

25. Section 552.6–1 is amended by revising the first sentence of paragraph (b) to read as follows:

§ 552.6–1 Board of directors.

* * * * *

(b) *Number and term.* The board of directors shall consist of not fewer than five nor more than fifteen as prescribed in the bylaws. * * *

* * * * *

§ 552.7 [Removed]

26. Section 552.7 is removed.

§ 552.8 [Amended]

27. Section 552.8 is amended by removing and reserving paragraph (b).

PART 556—STATEMENTS OF POLICY

28. The authority citation for part 556 is revised to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1464, 1701j–3; 15 U.S.C. 1693–1693r

§ 556.7 [Removed]

29. Section 556.7 is removed.

30. Part 558 is revised to read as follows:

PART 558—POSSESSION BY CONSERVATORS AND RECEIVERS FOR FEDERAL AND STATE SAVINGS ASSOCIATIONS

Sec.
558.1 Procedure upon taking possession.
558.2 Notice of appointment.

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a.

§ 558.1 Procedure upon taking possession.

(a) The conservator or receiver for a Federal or state savings association shall take possession of the savings association by taking possession of the principal office of the Federal or state savings association and in accordance with the terms of the Director's appointment.

(b) Upon taking possession, the conservator or receiver shall immediately:

(1) Give notice of the appointment to any officer or employee in the principal office who appears to be in charge of that office.

(2) Serve a copy of the order of appointment upon the savings association or upon its conservator or receiver by:

(i) Leaving a certified copy of the order of appointment at the principal office of the savings association; or

(ii) Handing a certified copy of the order of appointment to the previous conservator, receiver or other legal custodian of the savings association, or to the officer or employee of the savings association or of the previous conservator, receiver or other legal custodian in the principal office of the savings association who appears to be in charge.

(3) Take possession of the savings association's books, records and assets.

(4) Notify in writing, served personally or by registered mail or telegraph, all persons and entities that the conservator or receiver knows to be holding or in possession of assets of the savings association, that the conservator or receiver has succeeded to all rights, titles, powers and privileges of the savings associations.

(5) File with the Corporate Secretary a statement that possession was taken, including the time of the taking, which statement shall be conclusive evidence thereof.

(6) Post a notice on the door of the principal and other offices of the savings association in substantially the following form:

(i) For the appointment of a conservator:

The (name of Federal/state savings association) is in the hands of (name) as Conservator under appointment by the Director of the Office of Thrift Supervision.
Conservator _____.
Date _____.

(ii) For the appointment of a Receiver:

(A) During the period beginning on December 31, 1988 and ending on October 1, 1993:

The (name of savings association) is in the hands of the Resolution Trust Corporation as Receiver under appointment by the Director of the Office of Thrift Supervision.
Receiver _____.
Date _____.

(B) After October 1, 1993:

The (name of savings association) is in the hands of the Federal Deposit Insurance Corporation as Receiver under appointment by the Director of the Office of Thrift Supervision.
Receivor _____.
Date _____.

(7) By operation of law and without any conveyance or other instrument, act or deed, succeed to the rights, titles, powers and privileges of the savings association, and to the rights, powers, and privileges of its stockholders, members, accountholders, depositors, officers, and directors. No stockholder, member, accountholder, depositor, officer or director shall thereafter have or exercise any right, power, or privilege, or act in connection with any of the savings association's assets or property.

§ 558.2 Notice of appointment.

If the Director of the OTS appoints a conservator or receiver under this part, the Corporate Secretary shall mail a certified copy of the OTS's appointment to the savings association's address as it appears in the OTS's records, and notice of the appointment shall be filed immediately for publication in the Federal Register.

PART 559—[REMOVED]

31. Part 559 is removed.

SUBCHAPTER D—REGULATIONS APPLICABLE TO ALL SAVINGS ASSOCIATIONS

PART 561—DEFINITIONS

32. The authority citation for part 561 is revised to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a.

§ 561.5 [Removed]

33. Section 561.5 is removed.

§ 561.16 [Amended]

34. Section 561.16 is amended by removing paragraphs (b) through (e), and (g), and by redesignating paragraph (f) as paragraph (b).

§ 561.17 [Removed]

35. Section 561.17 is removed.

§ 561.22 [Removed]

36. Section 561.22 is removed.

§ 561.46 [Removed]

37. Section 561.46 is removed.

PART 563—OPERATIONS

38. The authority citation for part 563 continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a, 1468, 1817, 1828, 3806; 42 U.S.C. 4106; Pub. L. 102–242, sec. 306, 105 Stat. 2236, 2355 (1991).

§ 563.7 [Amended]

39. Section 563.7 is amended by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

§ 563.24 [Removed]

40. Section 563.24 is removed.

§ 563.27 [Amended]

41. Section 563.27 is amended by removing paragraphs (a) and (b)(2), and by removing the heading of paragraph (b) and the paragraph designations (b) and (b)(1).

§ 563.29 [Removed]

42. Section 563.29 is removed.

§ 563.32 [Removed]

43. Section 563.32 is removed.

§ 563.33 [Amended]

44. Section 563.33 is amended by removing and reserving paragraph (b).

§ 563.34 [Removed]

45. Section 563.34 is removed.

§ 563.45 [Removed]

46. Section 563.45, including Form AR, is removed.

§ 563.48 [Amended]

47. Section 563.48 is amended by removing from the first sentence of paragraph (e) the phrase "(including purchasing)" and by adding in lieu thereof the phrase "(but not including purchasing)".

§ 563.90 [Removed]

48. Section 563.90 is removed.

§ 563.93 [Amended]

49. Section 563.93 is amended by removing the phrase "as defined in paragraph (b)(13) of this section" from paragraphs (b)(6)(i) and (d)(3)(ii), and by adding in lieu thereof the phrase "as defined in paragraph (b)(11) of this section."

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§ 563.99 [Amended]

50. Section 563.99 is amended by removing and reserving paragraph (d).

§ 563.131 [Removed]

51. Section 563.131 is removed.

52. Section 563.132 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 563.132 Securities issued through subsidiaries.

(a) * * *

(1) * * *

(ii) An operating subsidiary (as defined in § 545.81(b) of this chapter), a service corporation (as defined in § 561.45 of this subchapter), or any other subsidiary of a state-chartered savings association not organized in compliance with § 545.82 of this chapter, if any proceeds of such securities are remitted to a parent savings association (unless such a subsidiary demonstrates to the OTS that the purpose for such an issuance was totally for the subsidiary's reasonable corporate needs based on reasonable written projections of its financing requirements).

* * * * *

§ 563.192 [Removed]

53. Section 563.192 is removed.

PART 563b—CONVERSIONS FROM MUTUAL TO STOCK FORM

54. The authority citation for part 563b continues to read as follows:

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a; 15 U.S.C. 78c, 781, 78m, 78n, 78w

55. Section 563b.3 is amended by adding a new paragraph (i)(4)(vi) to read as follows:

§ 563b.3 General principles for conversions.

* * * * *

(i) *Acquisition of the securities of converting and converted savings associations)*—* * *

(4) *Exceptions.* * * *

(vi) No application under paragraph (i)(3)(i) of this section generally shall be required for any proposed acquisition that requires prior approval of, or clearance by, the OTS under 12 CFR part 574 *provided* that the application required to be filed pursuant to part 574 of this chapter addresses in specific detail how the proposed transaction will comply with the criteria for approval under paragraph (i)(5) of this section, and the proposed acquisition is not opposed by the recently converted association subject to paragraph (i)(3)(i) of this section Where, pursuant to this paragraph (i)(4)(vi), no separate application under paragraph (i)(3)(i) of this section is required, the prohibition on offers to acquire equity securities contained in paragraph (i)(3)(i) of this section shall not apply.

* * * * *

PART 563e—COMMUNITY REINVESTMENT

56. The authority citation for part 563e is revised to read as follows:

Authority: 12 U.S.C. 1462a, 1463, 1464, 1467a, 2901 *et seq.*

§ 563e.6 [Amended]

57. Section 563e.6 is amended by removing the phrase "District Director" from the third, fifth, and sixth paragraphs in the sample notice, and adding in lieu thereof the phrase "Regional Director".

PART 567—CAPITAL

58. The authority citation for part 567 is revised to read as follows

Authority: 12 U.S.C. 1462, 1462a, 1463, 1464, 1467a.

§ 567.20 [Removed]

59 Section 567.20 is removed.

PART 571—STATEMENTS OF POLICY

60. The authority citation for part 571 is revised to read as follows:

Authority: 5 U.S.C. 552, 559; 12 U.S.C. 1462a, 1463, 1464.

§ 571.1 [Removed]

61 Section 571.1 is removed.

§ 571.3 [Removed]

62. Section 571.3 is removed.

§ 571.10 [Removed]

63. Section 571 10 is removed.

§ 571.16 [Removed]

64. Section 571.16 is removed.

§ 571.17 [Removed]

65. Section 571.17 is removed.

§ 571.25 [Removed]

66. Section 571.25 is removed.

§ 571.26 [Removed]

67. Section 571.26 is removed.

SUBCHAPTER E—[RESERVED]

PARTS 579 AND 580—[REMOVED]

68. Parts 579 and 580 are removed and subchapter E is removed and reserved.

Dated: December 2, 1992.

By the Office of Thrift Supervision.

Timothy Ryan,

Director

[FR Doc. 93–720 Filed 1–13–93; 8:45 am]

BILLING CODE 6720–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 91–AEA–25]

Change of Operating Hours of Control Zone; Chincoteague (Wallops Island), VA

AGENCY: Federal Aviation Administration (FAA), DOT

ACTION: Final rule; correction.

SUMMARY: This document contains a correction to the final rule published in the **Federal Register** on August 25, 1992. The final rule amended the name and operating hours of the Chincoteague (Wallops Island), VA, Control Zone. This correction adds to the description the ceiling height that was inadvertently omitted.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Curtis L. Brewington, Designated Airspace Specialist, System Management Branch, AEA–530, F.A.A. Eastern Region, Fitzgerald Federal Building #111, John F. Kennedy International Airport, Jamaica, New York 11430; telephone: (718) 553–0857.

SUPPLEMENTARY INFORMATION:

History

Federal Register Document 92–20347, Airspace Docket No. 91–AEA–25, published on August 25, 1992 (57 FR 38435), revised the name and changed the operating hours of the Chincoteague (Wallops Island), VA, Control Zone. The height of the Wallops Island, VA, Control Zone was inadvertently omitted from the description. This action corrects that error.

Correction to Final Rule

Accordingly, pursuant to the authority delegated to me, the publication on August 25, 1992 (Federal Register Document 92–20347) and the description in FAA Order 7400.7A which is incorporated by reference in 14 CFR 71.1, are corrected as follows:

§ 71.1 [Corrected]

1. On page 38435, columns 2 and 3, the description for Wallops Island, VA, Control Zone is corrected to read as follows:

Section 71.171 Designation

* * * * *

AEA VA CZ Chincoteague, VA [Removed]

* * * * *

AEA VA CZ Wallops Island, VA [Added]

NASA Wallops Flight Facility, Wallops Island, VA (lat. 37°56'30"N., long. 75°27'44"W.)

Snow Hill VORTAC (lat. 38°03'24"N., long. 75°27'50"W.)

That airspace extending upward from the surface to 2,500 feet MSL within a 4.4-mile radius of NASA Wallops Flight Facility and within 1.8 miles each side of the Snow Hill, MD, VORTAC 181° radial, extending from the 4.4-mile radius to 2.2 miles south of the VOR. This control zone shall be effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Issued in Jamaica, New York, on December 22, 1992.

Gary W. Tucker,

Manager, Air Traffic Division.

[FR Doc. 93-810 Filed 1-13-93; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 92-AWP-16]

Enlargement of the Riverside, CA 700 Foot Mean Sea Level (MSL) and Above Transition Area

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action enlarges the Riverside, CA 700 foot MSL and above transition area. This enlargement will provide controlled airspace for aircraft executing a missed approach for the Very High Frequency Omnidirectional Range-B (VOR-B) Standard Instrument Approach Procedure (SIAP) to the Riverside Municipal Airport, CA.

EFFECTIVE DATE: 0901 UTC, April 1, 1993.

FOR FURTHER INFORMATION CONTACT: Gene Enstad, Airspace Specialist, System Management Branch, AWP-530, Air Traffic Division, Western-Pacific Region, Federal Aviation Administration, 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 297-0010.

SUPPLEMENTARY INFORMATION:

History

On September 29, 1992, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to enlarge the Riverside, CA 700 foot MSL and above transition area (57 FR 44712). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. The coordinates in the proposal were North American Datum 27; however, these coordinates have been updated to North American Datum 83. Transition areas are published in section 71.181 of FAA Order 7400.7A, dated November 2, 1992, and effective November 27, 1992, which is incorporated by reference in 14 CFR 71.1. The transition areas listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations enlarges the Riverside, CA transition area. This transition area will provide controlled airspace for aircraft executing a missed approach for the VOR-B SIAP to the Riverside Municipal Airport, CA. The additional 700 foot MSL and above transition area encompasses about five square miles. In addition, a minor latitude and longitude typographical error in defining the Riverside, CA 700 foot and above transition area was made in the Notice of Proposed Rulemaking and is corrected in this final rule.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, Incorporation by reference, Transition areas.

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS, JET ROUTES, AND AREA HIGH ROUTES

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.7A, Compilation of Regulations, dated November 2, 1992, and effective November 27, 1992, is amended as follows:

Section 71.181 Designation of Transition Areas

* * * * *

AWP CA TA Riverside CA [Revised]

That airspace extending upward from 700 feet above the surface bounded by a line beginning at lat. 34°10'00"N, long. 117°59'03"W; to lat. 34°10'00"N, long. 117°01'03"W; to lat. 33°50'00"N, long. 117°01'03"W; to lat. 33°42'30"N, long. 116°56'33"W; to lat. 33°38'00"N, long. 117°09'03"W; to lat. 33°43'00"N, long. 117°15'03"W; to lat. 33°43'00"N, long. 117°20'03"W; to lat. 33°42'00"N, long. 117°20'03"W; to lat. 33°42'00"N, long. 117°25'03"W; to lat. 33°39'00"N, long. 117°25'03"W; to lat. 33°39'00"N, long. 117°30'03"W; to lat. 33°46'00"N, long. 117°45'03"W; to lat. 33°56'00"N, long. 117°53'03"W; to lat. 33°56'00"N, long. 117°59'03"W, thence to the point of beginning. That airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 34°30'00"N, long. 117°43'03"W; thence east along lat. 34°30'00"N, to the southeast boundary of V-21, thence along the southeast boundary of V-21 to long. 116°30'03"W, thence direct to lat. 34°40'30"N, long. 116°29'43"W; to lat. 34°30'00"N, long. 116°26'23"W; to lat. 34°16'00"N, long. 116°18'03"W; to lat. 33°30'00"N, long. 116°18'03"W; thence westerly along lat. 33°30'00"N, to long. 117°30'03"W; to lat. 33°39'00"N, long. 117°30'03"W; to lat. 33°46'00"N, long. 117°45'03"W; to lat. 33°56'00"N, long. 117°53'03"W; to lat. 33°56'00"N, long. 117°59'03"W; to lat. 34°10'00"N, long. 117°59'03"W; to lat. 34°10'00"N, long. 117°43'03"W, thence to the point of beginning.

* * * * *

Issued in Los Angeles, California, on December 11, 1992.

Richard R. Lien,

Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 93-885 Filed 1-13-93; 8:45 am]

BILLING CODE 4910-13-M

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Agri Beef Co. to Elanco Animal Health, A Division of Eli Lilly and Co.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Benjamin Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8646.

SUPPLEMENTARY INFORMATION: Agri Beef Co., 2201 North 20th St., P. O. Box 47, Nampa, ID 83653, has informed FDA that it has transferred ownership of, and all rights and interests in, approved NADA 140–939 for Monensin/Tylosin liquid B feed to Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285. Accordingly, the agency is amending the regulations in 21 CFR 558.355(f)(3)(ix) to reflect the change of sponsor. Also, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing Agri Beef Co. because the firm is no longer the sponsor of any approved NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry "Agri Beef Co." and in the table in paragraph (c)(2) by removing the entry "022941".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.355 [Amended]

4. Section 558.355 *Monensin* is amended in paragraph (f)(3)(ix) by removing the number "022941" and adding in its place "000986".

Dated: January 7, 1993.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 93–803 Filed 1–13–92; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Cathinone and 2,5-Dimethoxy-4-ethylamphetamine into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places cathinone and 2,5-dimethoxy-4-ethylamphetamine (DOET) into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.). As a result of this rule, the regulatory controls and criminal sanctions of a Schedule I substance under the CSA will be applicable to the manufacture, distribution, and possession of cathinone and DOET. This action is taken to enable the United States to meet its obligations under the Convention on Psychotropic Substances.

EFFECTIVE DATE: February 16, 1993.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: Cathinone and DOET are psychoactive substances which are regulated under Schedule I of the United Nations Convention on Psychotropic Substances, 1971. The United States is a signatory to that Convention. The CSA requires the Secretary of the Department of Health and Human Services (DHHS), should he concur with the scheduling decision of the United Nations Commission on Narcotic Drugs and should he determine that control measures under the CSA are not adequate to meet the requirements of the Convention, to recommend to the Attorney General that he initiate proceedings for scheduling the substance [see 21 U.S.C. 811(d)(3)(B)]. By letter dated July 2, 1987, the Assistant Secretary for Health, acting on behalf of the Secretary, recommended to the Administrator of the DEA that he initiate scheduling actions under the CSA to assure compliance with the international requirements. The Administrator proposed placing cathinone and DOET into Schedule I of the CSA in a notice which was published in the **Federal Register** (52 FR 41736, October 30, 1987). In response to the proposal, an individual requested a hearing if the placement of cathinone and DOET into Schedule I would affect his religious use of a number of psychoactive substances. Because the comment was not filed in a timely manner and the request for a hearing was not made in accordance with the procedures set forth in 21 CFR 1308.45, the request was denied.

The Administrator, by letter of December 13, 1988, requested a scientific and medical evaluation of the Assistant Secretary for Health [see 21 U.S.C. 811(b)]. The Assistant Secretary responded by letter of November 5, 1992 and recommended that cathinone and DOET be placed into Schedule I. Enclosed with the letter were documents which were entitled "Basis for the Recommendation for Control of Cathinone into Schedule I of the Controlled Substances Act" and "Basis for the Recommendation for Control of 2,5-Dimethoxy-4-ethylamphetamine (DOET) into Schedule I of the Controlled Substances Act". Each document presented an evaluation and scheduling recommendation which were based on a review of the factors which the CSA requires the Attorney General and the Secretary to consider [see 21 U.S.C. 811(c)]. The Assistant Secretary found that because cathinone's abuse potential is similar to those of the stimulants, amphetamine and methamphetamine, both of which have high potentials for abuse and are

controlled in Schedule II of the CSA, and because cathinone has not been accepted for medical use in treatment in the United States, cathinone should be controlled in Schedule I. In relation to DOET, the Assistant Secretary found that because its abuse potential is similar to that of the hallucinogens, mescaline, 2,5-dimethoxy-4-methylamphetamine and 2,5-dimethoxyamphetamine all of which are controlled in Schedule I of the CSA, 2,5-dimethoxy-4-ethylamphetamine (DOET) should be controlled similarly in Schedule I.

Cathinone is the major psychoactive component of the plant *Catha edulis* (khat). The young leaves of khat are chewed for a stimulant effect. Enactment of this rule results in the placement of any material which contains cathinone into Schedule I. When khat contains cathinone, khat is a Schedule I substance. During either the maturation or the decomposition of the plant material, cathinone is converted to cathine, a Schedule IV substance. In a previously published final rule, the Administrator stated that khat will be subject to the same Schedule IV controls as cathine, (see 53 FR 17459, May 17, 1988). When khat does not contain cathinone, but does contain cathine, khat is a Schedule IV substance.

While the clandestine synthesis of cathinone has not been encountered by the DEA, the illicit synthesis of the methyl analog, methcathinone, has been encountered at twelve clandestine laboratories. Methcathinone was placed into Schedule I on May 1, 1992 pursuant to 21 U.S.C. 811(h) (see 57 FR 18825, May 1, 1992). In January 1992, the DEA encountered a clandestine laboratory which had manufactured DOET.

Based on the information gathered and reviewed by the DEA, DHHS and the recommendation of the Assistant Secretary for Health, the Administrator of the DEA, pursuant to the provisions of 21 U.S.C. 811(a), finds that:

(A) Cathinone and DOET each have a high potential for abuse.

(B) Cathinone and DOET have no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of cathinone or DOET under medical supervision.

The above findings are consistent with placement of cathinone and DOET into Schedule I of the CSA.

Regulations that are effective on and after February 16, 1993, and imposed on cathinone and DOET are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports cathinone or DOET or who engages in research or conducts instructional activities with respect to these substances, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with parts 1301 and 1311 of title 21 of the Code of Federal Regulations.

2. *Security.* Cathinone and DOET must be manufactured, distributed and stored in accordance with §§ 1301.71–1301.76 of title 21 of the Code of Federal Regulations.

3 *Labeling and packaging.* All labels and labeling for commercial containers of cathinone and DOET must comply with the requirements of §§ 1302.03–1302.05, 1302.07 and 1302.08 of title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for cathinone or DOET shall submit applications pursuant to §§ 1303.12 and 1303.22 of title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of cathinone or DOET shall take an inventory pursuant to §§ 1304.11–1304.19 of title 21 of the Code of Federal Regulations of all stocks of these substances on hand.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21–1304.27 of title 21 of the Code of Federal Regulations shall maintain such records on cathinone and DOET.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.34–1304.37 of title 21 of the Code of Federal Regulations shall do so regarding cathinone and DOET.

8. *Order Forms.* All registrants involved in the distribution of cathinone or DOET must comply with the order form requirements of §§ 1305.01–1305.16.

9. *Importation and Exportation.* All importation and exportation of cathinone or DOET shall be in compliance with part 1312 of title 21 of the Code of Federal Regulations.

10. *Criminal Liability.* Any activity with respect to cathinone or DOET not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to 5 U.S.C. 605(b), the Administrator certifies that the placement of cathinone and DOET into Schedule I will have no impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96–354). This drug control action relates to the control of substances that have no legitimate use or manufacturer in the United States.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that this matter does not have sufficient federalism implications to require the preparation of a Federalism Assessment.

In accordance with the provisions of 21 U.S.C. 811(d), this scheduling action is a formal rulemaking that is required by United States obligations under an international convention, namely the Convention on Psychotropic Substances, 1971. Such formal proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirements of Executive Order 12291 (46 FR 13193). Accordingly, this action is not subject to those provisions of E.O. 12778 which are contingent upon review by OMB. Nevertheless, the Administrator has determined that this is not a "major rule," as that term is used in E.O. 12291, and that it would otherwise meet the applicable standards of sections 2(a) and 2(b)(2) of E.O. 12778.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Based upon the notification of the Secretary-General of the United Nations and in accordance with the recommendations of the Assistant Secretary for Health of the Department of Health and Human Services and under the authority vested in the Attorney General by 21 U.S.C. 811(a) and delegated to the Administrator by the regulations of the Department of Justice (28 CFR 0.100), the Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

2. Section 1308.11 is amended by redesignating existing paragraphs (d)(3) through (d)(28) as (d)(4) through (d)(29) and adding new paragraph (d)(3) to read as follows:

* * * * *

§ 1308.11 Schedule I.

(d) * * *

(3) 2,5-dimethoxy-4-ethylamphetamine.....7399

Some trade or other names: DOET

* * * * *

3. Section 1308.11 is amended by redesignating paragraphs (f)(1) through (f)(4) as (f)(2) through (f)(5) and adding paragraph (f)(1) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(f) * * *

(1) cathinone..... 1235

Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone.

* * * * *

Dated: January 7, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93-877 Filed 1-13-93; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Public and Indian Housing

24 CFR Part 990

[Docket No. N-93-3560; FR 3088-N-04]

Low-Income Public Housing—Project-Based Accounting

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Request for comment on estimated reporting and recordkeeping burden.

SUMMARY: This request for public comment is related to the final rule on project-based accounting for low-income public housing that was published on December 23, 1992. It deals with the subject of the burden of information collections contained in that rule. The Department has not changed the burden estimate, but it is inviting further comment from the public.

DATES: Comments are now being accepted by OMB and HUD.

ADDRESSES: Interested persons are invited to respond to this notice by sending comments on the reporting and recordkeeping burden of the project-based accounting requirement, in accordance with 24 CFR part 990, subpart C, to both of the following persons: HUD Rules Docket Clerk, room 10276, Office of General Counsel, Department of Housing and Development, 451 Seventh Street SW., Washington, DC 20410-0500; and HUD Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, 725 Seventeenth Street NW., Washington, DC 20503. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for inspection and copying during regular business hours (7:30 a.m.-5:30 p.m. Eastern Time) at the Seventh Street address.

FOR FURTHER INFORMATION CONTACT: Mr. John T. Comerford, Director, Financial Management Division, Office of Management Operations, Public and Indian Housing, room 4212, U.S. Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410, telephone (202) 708-1872 (voice) or (202) 708-0850 (TDD). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: In the final rule, published on December 23, 1992 (57 FR 61226), adding a subpart C to 24 CFR part 990, the Department mentioned that the estimated reporting and recordkeeping burden had been challenged by commenters. This Notice explains why the Department has not changed the burden estimate, while inviting further comment from the public.

Numerous objections were raised by commenters in response to the estimated reporting and recordkeeping burden of 1¼ hours per PHA for providing year-end information by project. Commenters argued that project-based accounting (PBA) would increase staff hours tremendously, require computer hardware and software redesign, staff training time, additional staff for handling accounting and reporting detail, increase accounting and auditing fees, and require the hiring of consultants.

The respondents who raised objections to the estimate of burden hours, in HUD's view, have misinterpreted the extent of the intended impact of project-based accounting on the PHA accounting system. For example, respondents assumed that the PBA requirement imposed a mandatory framework of accounting or reporting that would require extensive revision of their existing accounting systems; that separate operating budgets and/or HUD reporting forms would have to be prepared and submitted by project; that separate General Ledgers would have to be maintained by project; that PBA meant the assignment of specific staff to individual projects which would either require the hiring of additional staff or result in idle time for existing staff; that operating subsidy and operating reserves would have to be calculated and maintained by project.

On the other hand, the estimate of burden hours was based on the assumption by the Department that many PHAs, particularly larger PHAs, have existing systems in place that provide for the accumulation and allocation of resources by management area; that little, if any, modification of existing systems would be required in order to further identify consolidated income/expense categories by project or cost center; that the only continuing additional time would be in the preparation of the required year-end information reports for the Board. The elimination in the final rule of the requirement to allocate indirect income/expense among projects/cost centers further ensures that the impact on existing accounting systems will be minimal, even for smaller PHAs. Therefore, the Department did not change the number of estimated burden hours because we believe that, on the average, the ongoing additional time required by the PHA will be limited to preparing the annual project/cost center reports for distribution to the Board.

The Office of Management and Budget is currently reviewing the reporting and recordkeeping burden imposed by the rule and would welcome additional comments concerning the new requirements by housing authorities, and entities that work with them, that have had experience with these new requirements. HUD plans to re-examine the burden estimates after the new PBA requirement is operational, and, therefore, also welcomes comments concerning the burden experienced by housing authorities, especially specific descriptions of the steps taken by the housing authorities, the type of staff or consultant employed for the task, and the time actually taken by each type of staff member to implement the requirements for each project or cost center.

Dated: January 5, 1993.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 93-945 Filed 1-13-93; 8:45 am]

BILLING CODE 4210-33-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 2602

Ethical Conduct of Employees

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation ("PBGC") is repealing provisions of its regulations on the ethical conduct of employees (part 2602, subpart A). Most of the repealed provisions are superseded by Office of Government Ethics ("OGE") rules establishing uniform standards of conduct and financial disclosure requirements for executive branch employees. PBGC, in accordance with OGE guidance, is not repealing provisions of the regulations concerning clearance to engage in certain outside activities.

EFFECTIVE DATE: The removal of § 2602.20 through 2602.32 is effective October 5, 1992. All other amendments are effective February 3, 1993.

FOR FURTHER INFORMATION CONTACT: Holli Beckerman Jaffe, Attorney, Office of the General Counsel (Code 22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; 202–778–8864 (202–778–1958 for TTY and TDD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: In 1977, the Pension Benefit Guaranty Corporation ("PBGC") issued part 2602 of the regulations (29 CFR part 2602, 42 FR 43066), now designated as Subpart A (57 FR 45713, October 5, 1992), primarily pursuant to Executive Order 11222 (30 FR 6469) and regulations issued by the Civil Service Commission (5 CFR 735.104, 33 FR 12487). Executive Order 12674 (April 12, 1989), as modified by Executive Order 12731 (October 17, 1990), revoked Executive Order 11222 (section 501(a)) and directed the Office of Government Ethics ("OGE") to "establish a single, comprehensive, and clear set of executive-branch standards of conduct that shall be objective, reasonable, and enforceable" (section 201).

OGE has now issued 5 CFR part 2635, Standards of Ethical Conduct for Employees of the Executive Branch (57 FR 35006, August 7, 1992). These standards of conduct, when they become effective on February 3, 1993, supersede agency regulations promulgated pursuant to 5 CFR part 735 and authorize agencies to issue (jointly with OGE) "supplemental agency regulations which the agency determines are necessary and appropriate, in view of its programs and operations, to fulfill the purposes" of part 2635 (§ 2635.105(a), 57 FR 35043). Part 2635 does not supersede and its requirements for supplemental agency regulations do not apply to regulations that an agency has authority, independent of part 2635, to issue (§ 2635.105(c)(3), 57 FR 35044).

The PBGC is amending part 2602 by repealing provisions of subpart A that will be superseded when OGE's regulations take effect (February 3, 1993) (removal of §§ 2602.3(c) (2) and (3), 2602.4 through 2602.7, 2602.8 (a) through (c), 2602.9 (a)(2) through (c), 2602.10 through 2602.13, and 2602.17 through 2602.19 of the regulations). The PBGC is considering regulations that will supplement subpart H of part 2635 (Outside Activities) (57 FR 35061–66) by requiring employees to obtain prior approval of certain outside activities. Hence, it is not removing paragraphs (d) and (e) of § 2602.8 (Outside employment and other activity) of the regulations. As permitted by § 2635.803 (Prior approval for outside employment and activities) (57 FR 35062), the above-listed paragraphs of the PBGC's regulation will remain in effect for one year after the effective date of OGE's final rule (February 3, 1993) or until the issuance of PBGC supplemental agency regulations, whichever occurs first. The PBGC is removing paragraph (a)(1) of § 2602.9 (Financial interests) of the regulations. However, the PBGC will be considering whether to issue supplemental agency regulations addressing the holding and acquiring of specific financial interests, as provided in paragraph (a) of § 2635.403 (Prohibited financial interests) of OGE's regulations (57 FR 35053). The PBGC will issue any supplemental regulations with OGE in a separate rulemaking.

In addition, although part 2635 does not supersede all provisions of § 2602.3 (Counseling service) of the regulations, the PBGC is removing the entire section as unnecessary because the information and instructions contained therein regarding the ethnics counseling service will be distributed to its employees pursuant to OGE's final rule establishing new subpart G of 5 CFR part 2638, Executive Agency Ethics Training Programs (57 FR 11886, April 7, 1992). Section 2602.3 will therefore be superfluous.

The PBGC also is removing § 2602.16 of the regulations as unnecessary. This section addresses political activities that are permitted and prohibited under federal law, summarizing applicable requirements that appear in federal statutes and regulations. The PBGC has not prohibited or limited employee participation in any activity that is permitted under 5 CFR 733.111(a), the Office of Personnel Management's ("OPM's") regulation on permissible activities (*e.g.*, displaying a political picture, sticker, badge, or button).

OGE also has issued 5 CFR part 2634, Financial Disclosure, Qualified Trusts, and Certificates of Divestiture For Executive Branch Employees (57 FR 11800, April 7, 1992). Effective October 5, 1992, these regulations superseded the current executive branch confidential reporting regulation at 5 CFR part 735, subpart D and § 735.106 and agencies' implementing regulations. Therefore, the PBGC is further amending part 2602 by removing §§ 2602.20 through 2602.32 (Statement of Employment and Financial Interests) of the regulations and appendix A (Identification of Positions the Incumbents of Which File Financial Statements) thereto.

The PBGC has concluded that with the removal of the provisions discussed above, §§ 2602.1 (Purpose and scope) and 2602.2 (Definitions) of the regulations no longer are necessary. Therefore, it also is removing these sections.

Sections 2602.14 (Gambling, betting, and lotteries) 2602.15 (General conduct prejudicial to the Government) of the regulations are not superseded by part 2635 or any other OGE regulation. However, pursuant to Executive Order 12674, OPM has issued a final rule to complement part 2635 by establishing executive branch-wide standards in these areas that will be enforceable by the employing agency (57 FR 57433, November 30, 1992). Accordingly, the PBGC is removing §§ 2602.14 and 2602.15.

This rule relates to agency management and personnel (5 U.S.C. 553(a)(2)). As such, the notice of proposed rulemaking and delayed effective date requirements of the Administrative Procedure Act do not apply (5 U.S.C. 553 (b) and (d)).

List of Subjects in 29 CFR Part 2602

Conflict of interests, Government employees, Penalties, Political activities (Government employees), Production and disclosure of information, Testimony.

For the reasons set forth above, 29 CFR part 2602 is amended as follows:

PART 2602—[AMENDED]

1. The authority citation for Part 2602 is revised to read as follows:

Authority: 29 U.S.C. 1302(b); E.O. 11222, 30 FR 6469; 5 CFR 735.104.

Subpart A of Part 2602—[Amended]

2. Subpart A of part 2602 is amended by removing the undesignated center heading "General", §§ 2602.1 through 2602.5, the undesignated center heading "Standards of Conduct", §§ 2602.6 and 2602.7, paragraphs (a) through (c) of § 2602.8, and §§ 2602.9 through 2602.19.

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3. Subpart A of part 2602 is further amended by removing the undesignated center heading "Statements of Employment and Financial Interests", §§ 2602.20 through 2602.32 and appendix A.

Issued in Washington, DC this 8th day of January, 1993.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 93–730 Filed 1–13–93; 8:45 am]

BILLING CODE 7708–01–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

Illinois Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of a proposed amendment to the Illinois Abandoned Mine Land Reclamation Plan (hereinafter referred to as the Illinois AMLR Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Public Law 95–87, 30 U.S.C. 1231 *et seq.*, as amended.

The amendment pertains to changes to SMCRA made by the Abandoned Mine Land (AML) Reclamation Act of 1990, Public Law 101–508, which was enacted November 5, 1990. The amendment is intended to revise the Illinois AMLR Plan to address the changes to SMCRA.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Fulton, Director, Office of Surface Mining Reclamation and Enforcement, Springfield Field Office, 511 West Capitol, suite 202, Springfield, Illinois 62704, Telephone (217) 492–4495.

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision.
VI. Procedural Determinations.

I. Background on the Illinois Program

Title IV of SMCRA established an Abandoned Mine Land Reclamation (AMLR) program for the purposes of reclaiming and restoring lands and water resources adversely affected by past mining. This program is funded by a reclamation fee imposed upon the production of coal. As enacted in 1977, lands and waters eligible for reclamation were those that were mined or affected by mining and abandoned or left in an inadequate reclamation status prior to August 3, 1977, and for which there was no continuing reclamation responsibility under State or Federal law. The AML Reclamation Act of 1990, (Pub. L. 101–508, title IV, subtitle A, Nov. 5, 1990, enacted Nov. 5, 1990) amended SMCRA, 30 U.S.C. 1231 *et seq.*, to provide changes in the eligibility of project sites for AML expenditures. Title IV of SMCRA now provides for reclamation of certain mine sites where the mining occurred after August 3, 1977. These include interim program sites where bond forfeiture proceeds were insufficient for adequate reclamation and sites affected any time between August 4, 1977, and November 5, 1990, for which there were insufficient funds for adequate reclamation due to the insolvency of the bond surety. Title IV provides that a state with an approved AMLR program has the responsibility and primary authority to implement the program.

The Secretary of the Interior approved the Illinois AMLR Plan on June 1, 1982. Information pertinent to the general background of the Illinois AMLR Plan submission, as well as the Secretary's findings and the disposition of comments can be found in the June 1, 1982, **Federal Register** (47 FR 23886). Subsequent actions concerning plan amendments are identified at 30 CFR 913.25.

The Secretary adopted regulations at 30 CFR part 884 that specify the content requirements of a State reclamation plan and the criteria for plan approval. The regulations provide that a State may submit to the Director proposed amendments or revisions to the approved reclamation plan. If the amendments or revisions change the scope followed by the State in the conduct of its reclamation program, the Director must follow the procedure set forth in 30 CFR 884.14 in approving or disapproving an amendment or revision.

II. Submission of Amendment

By letter dated August 13, 1992 (Administrative Record No. IL–400–AML), the Illinois Abandoned Mined Lands Reclamation Council (Council) submitted to OSM a proposed amendment to the Illinois AMLR Plan on its own initiative, as provided for by 30 CFR 884.15. The proposed amendment consists of revisions to the Illinois Abandoned Mined Lands and Water Reclamation Act (State Act), Ill. Rev. Stat. ch. 96½, par. 8001.01–8003.08. The proposed revisions will be enacted through Illinois House Bill 3773, which passed both chambers of the Illinois General Assembly and was signed into law by the Governor of Illinois on September 1, 1992. Specifically, the State Act is revised by changing section 1.03—Definitions, and adding new section 2.13—Interim Program and Insolvent Surety Sites.

OSM announced receipt of the proposed amendment in the October 28, 1992, **Federal Register** (57 FR 48757) and in the same notice opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period ended on November 27, 1992.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR part 884, are the Director's findings concerning the proposed amendment to the Illinois plan. Any minor revisions not specifically discussed below are found to be no less stringent than SMCRA and no less effective than the Federal regulations.

The legal opinion of the chief legal officer of the Council submitted by letter dated October 19, 1992, states that the proposed amendment provides the State with all necessary legal power and authority to accomplish reclamation of insolvent surety and/or interim program sites in accordance with title IV of SMCRA (Administrative Record No. IL–412–AML). Therefore, the Director finds in accordance with 30 CFR 884.14(a)(3) that Illinois has the necessary legal authority to carry out the provisions of this proposed amendment.

1. Section 1.03—Definitions

Illinois is revising section 1.03 of the State Act to add the following language to the definition of "abandoned lands":

"Abandoned lands also means, in the appropriate context, lands and waters eligible for reclamation under section 2.11 (Non-coal Reclamation) and section 2.13 (Interim Program and Insolvent Surety Sites) of this Act." The general Federal counterpart to Illinois' definition of "abandoned lands" is section 404 of SMCRA. The Director finds the proposed revision at section 1.03(1) to be consistent with the amendments to SMCRA added as a result of the AML Reclamation Act of 1990.

2. Section 2.13—Interim Program and Insolvent Surety Sites

Illinois is adding section 2.13 to the State Act to include those post-1977 abandoned mine lands and waters made eligible for reclamation by title IV of SMCRA as amended by the AML Reclamation Act of 1990. The new section authorizes and empowers the Council to enter and perform reclamation or drainage abatement on the eligible lands and waters within unreclaimed sites that were mined for coal or were affected by such mining, wastebanks, coal processing, or other coal mining processes and left in an inadequate reclamation status after August 3, 1977, if: (1) The surface coal mining operation occurred during the period beginning August 4, 1977, and ending on June 1, 1982, and any funds for reclamation or abatement which are available from any source are not sufficient to provide for adequate reclamation or abatement; or (2) the surface coal mining operation occurred during the period beginning on August 4, 1977, and ending on November 5, 1990, and the surety of the mine operator became insolvent during that period and as of November 5, 1990, funds immediately available from any source are not sufficient to provide for adequate reclamation or abatement.

Section 402(g)(4)(B) of SMCRA provides for the expenditure of funds for the reclamation or drainage abatement of sites if the surface coal mining operation occurred during the period beginning on August 4, 1977, and either: (a) Ending on or before the date of approval of the State program and any funds for reclamation or abatement are not sufficient to provide for adequate reclamation or abatement, or (b) ending on or before November 5, 1990, and during which period the surety of the mine operator became insolvent. The Director finds the proposed amendment at section 2.13(a) no less stringent than the requirements of section 402(g)(4)(B) of SMCRA.

Section 2.13 also requires the Council to follow the priorities specified in section 2.03(a) (1) and (2) when determining which site to reclaim. Priority (1) is the protection of public health, safety, general welfare, and property from extreme danger of adverse effects of coal mining practices. Priority (2) is the protection of public health, safety, and general welfare from adverse effects of coal mining practices. The Council is also required to ensure that the reclamation priority of sites reclaimed is the same or more urgent than the reclamation priority for eligible lands and waters that were abandoned or left in an inadequate reclamation status before August 3, 1977. In section 2.03 of the current State Act, the Council is authorized to establish additional criteria including but not limited to the proximity of abandoned lands to municipalities, residential areas, and public facilities such as water supplies, parks and recreational areas. Section 2501.13(c) of Illinois' AML regulations also establishes criteria for sites identified as containing significant problem conditions, including, but not limited to, the proximity of the site to populated or public use areas.

Section 403(a)(1) of SMCRA defines a Priority I site as one where reclamation is needed to protect the public health, safety, general welfare, and property from extreme danger of adverse effects of coal mining practices. Section 403(a)(2) defines Priority II the same as Priority I except that it refers only to adverse effects of coal mining practices without the element of extreme danger. Section 402(g)(4)(C) of SMCRA requires that priority be given to those sites which are in the immediate vicinity of a residential area or which have an adverse economic impact upon a local community. The Director finds the proposed amendment at section 2.13(b), when read in conjunction with section 2.03 of the current State Act and section 2501.13(c) of the Illinois AML regulations, to be no less stringent than the requirements of sections 403(a) and 402(g) of SMCRA.

3. Section 2501—Eligible Lands and Waters

During a review of Illinois' AML regulations, it was determined that 62 IAC 2501.10 (Eligible Lands and Water) limits eligibility for reclamation activities with Federal funds to coal lands and water disturbed prior to August 3, 1977. While the existing regulations do not preclude the designation of additional eligible sites as defined by title IV of SMCRA, as amended, and the State Act, there is some ambiguity between the statute and existing regulations. Therefore, Illinois will be advised that upon final approval of the Federal Regulations required by the enactment of Public Law 101–508 for sites where the original surface coal mining operations occurred after August 3, 1977, the Illinois' AML regulation at 62 IAC 2501.10 may need to be amended to provide for the reclamation of interim program sites and of permanent program sites where the sureties are insolvent.

IV. Summary and Disposition of Comments

Public Comments

The public comment period and opportunity to request a public hearing announced in the October 28, 1992, **Federal Register** (57 FR 48757) ended on November 27, 1992. No comments were received and the scheduled public hearing was not held as no one requested an opportunity to provide testimony.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Illinois program. No comments were received.

V. Director's Decision

Based on the above findings, the Director is approving the program amendment to the Illinois AMLR Plan submitted by Illinois on August 13, 1992.

The Federal rules at 30 CFR part 913 codifying decisions concerning the Illinois program are being amended to implement this decision. This amendment to the Federal rules is being made effective immediately to expedite the State program amendment process and to encourage states to bring their programs in conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a state program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no such provisions and the EPA commented that the proposed amendment is unlikely to impact any of its program areas.

Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any alteration of an approved State program be submitted to OSM review as a program amendment. Thus, any changes to a State program are not enforceable

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until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved programs. In his oversight of the Illinois program, the Director will recognize only the statutes, regulations, and other materials approved by him together with any consistent implementing policies, directives and other materials, and will require the enforcement by Illinois of only such provisions.

VI. Procedural Determinations

Executive Order 12291

On March 30, 1992, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or disapproval of State and Tribal abandoned mine land reclamation plans and revisions thereof. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State and Tribal abandoned mine land reclamation plans and revisions thereof since each such plan is drafted and adopted by a specific State or Tribe, not by OSM. Decisions on proposed State and Tribal abandoned mine land reclamation plans and revisions thereof submitted by a State or Tribe are based on a determination of whether the submittal meets the requirements of title IV of SMCRA (30 U.S.C. 1231–1243) and the Federal regulations at 30 CFR Parts 884 and 888.

National Environmental Policy Act

No environmental impact statement is required for this rule since agency decisions on proposed State and Tribal abandoned mine land reclamation plans and revisions thereof are categorically excluded from compliance with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements established by SMCRA or previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions in the analyses for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 913

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 2, 1992.

David G. Simpson,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 913—ILLINOIS

1. The authority citation for part 913 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In § 913.25, a new paragraph (d) is added to read as follows:

§ 913.25 Approval of abandoned mine land reclamation plan amendments.

* * * * *

(d) The Illinois Abandoned Mine Land Reclamation Plan amendment submitted on August 13, 1992, is approved effective January 14, 1993.

[FR Doc. 93–861 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-05-M

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30 CFR Part 914

Indiana Regulatory Program Amendment

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of proposed amendments to the Indiana permanent regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment (Program Amendment Number 92–6) consists of revisions to Indiana's Surface Coal Mining and Reclamation Statute (IC 13–4.1) made during the second regular session of the Indiana General Assembly (1992) under House Enrolled Act (HEA) No. 1298. The revisions concern a newly enacted State reclamation fee, and changes to the Small Operators Assistance Program raising the qualifying annual tonnage from 100,000 tons to 300,000 tons. The proposed changes are intended to incorporate the additional flexibility afforded by the revised Federal regulations.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, room 301, Indianapolis, IN 46204, Telephone (317) 226–6166.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program.
II. Submission of the Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision.
VI. Procedural Determinations.

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982 **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.10, 914.15, and 914.16.

II. Submission of the Amendment

By letter dated July 16, 1992 (Administrative Record No. IND–1106), the Indiana Department of Natural Resources (IDNR) submitted proposed Program Amendment Number 92–6 to the Indiana program at Indiana Code (IC) 13–4.1. The proposed amendment is part of Indiana's 1992 House Enrolled Act No. 1298. The amendment: (1) Adds a new section IC 13–4.1–3–2(c)

concerning a reclamation fee for operators of underground coal mining operations with no support facilities located within Indiana but producing coal in Indiana; (2) changes IC 13–4.1–3–3(c) and IC 13–4.1–3–3.5(a)(1) and (a)(5) concerning Indiana's Small Operators Assistance Program (SOAP) provisions; and (3) repeals IC 13–4.1–1–1.

HEA 1298 contains other provision changes which are not submitted as State program amendments. The changes at IC 13–4.1–6–9(e) and IC 13–4.1–15–1(b) merely clarify existing Indiana program provisions and procedures and the new language does not constitute a change which needs to be submitted as a State program amendment (IND–1072 and IND–1145). The changes at IC 13–7–8.6–5.3, IC 13–7–16.5–9, IC 13–8–5–9, and IC 13–8–10–16 do not pertain to the Indiana program.

OSM announced receipt of the proposed amendment in the October 28, 1992, **Federal Register** (57 FR 48761), and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on November 27, 1992. The scheduled public hearing was not held as no one requested an opportunity to provide testimony.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Indiana program. Revisions which are not discussed below concern nonsubstantive wording changes, or revise paragraph notations to reflect organizational changes resulting from this amendment.

1 IC 13–4.1–3–2(c) Reclamation Fee

This new provision is added to provide that until July 1, 1995, all operators of underground coal mining operations with no support facilities located within Indiana, but producing coal from reserves located within Indiana shall pay to the Indiana Department of Natural Resources (IDNR) a reclamation fee. The proposed reclamation fee shall be one cent per ton of coal produced from Indiana, and the fee shall be deposited in the natural resources reclamation division fund. The natural resources reclamation division fund was previously established to receive money appropriated to administer the Indiana program.

SMCRA at section 507(a) and the Federal regulations at 30 CFR 777.17 provide that an application for a surface coal mining and reclamation permit shall be accompanied by a fee determined by the regulatory authority. Such fee may be less than, but shall not exceed, the actual or anticipated cost of reviewing, administering, and enforcing the permit. The Federal provisions also provide that the regulatory authority may develop procedures to allow the fee to be paid over the term of the permit. The Director finds that the proposed fee is consistent with and no less stringent than SMCRA at section 507(a) and no less effective than the Federal regulations at 30 CFR 777.17.

2. IC 13–4.1–3–3(c) Small Operators Assistance Program (SOAP)

Indiana proposes to amend IC 13–4.1–3–3(c) consistent with the change made to section 507(c) of SMCRA by section 6011 of the Federal Omnibus Budget Reconciliation Act of 1990. Section 6011 of the Federal Omnibus Budget Reconciliation Act revises section 507(c) of SMCRA, effective October 1, 1991, to increase from 100,000 tons to 300,000 tons the maximum annual coal production under which a mine operator is eligible for participation in the SOAP program. Indiana is proposing to make a corresponding change in the SOAP eligibility tonnage figures in the Indiana regulations. Indiana proposes to substitute the 300,000 ton eligibility limit for the existing 100,000 ton eligibility limit.

While the State's proposed amendment is in accordance with section 507(c) of SMCRA, as amended by the Federal Omnibus Budget Reconciliation Act of 1990, the Federal regulations at 30 CFR 795.6(a)(2) still provide for a production level of 100,000 tons with respect to operator eligibility under the SOAP program. Thus, there appears to be an inconsistency between the Indiana regulation and the Federal regulation. However, section 507(c) of SMCRA, as amended by the 1990 Act, supersedes in part 30 CFR 795.6(a)(2) to the extent that SOAP applicants may receive grants if their probable total and actual production from all locations during any 12 month period does not exceed 300,000 tons.

Therefore, the Director finds the State's proposal to be no less effective than 30 CFR 795.6(a)(2) as superseded in part by amended section 507(c) of SMCRA.

3. IC 13–4.1–3–3.5(a) (1) and (5) SOAP

Indiana proposes to amend subsections (a) (1) and (5) by changing the cited production levels of 100,000 tons to 300,000 tons with respect to the production limits that must be observed in order for the applicant and/or the applicant's successor to avoid liability for reimbursing the IDNR for costs of laboratory services performed pursuant to IC 13–4.1–3–3(c). The proposed amendment is in accordance with the revision made by Section 6011 of the Federal Omnibus Budget Reconciliation Act of 1990 to section 507(c) of SMCRA in increasing the production level which the operator must meet to be eligible to participate in SOAP. However, in determining applicant liability, the Indiana proposal does not consider those applicants whose eligibility was determined under the 100,000-ton production level.

The Federal regulations at 30 CFR 795.12(a)(2) still provide for a 100,000-ton production level in determining an operator's liability. OSM is proposing to amend its regulations regarding applicant liability at 30 CFR 795.12(a)(2) by deleting reference to the 100,000-ton provision and adding language which refers to the coal tonnage governing SOAP eligibility in effect at the time assistance was approved, thereby defining a transition phase keyed to the time an operator is approved for assistance. In its proposed rule, OSM has indicated its willingness to consider comments on alternatives other than its proposal.

In order not to unduly delay the State's implementation of the new production levels for SOAP eligibility, the Director is approving the State's proposed amendment to the regulations with the understanding that reference to the 300,000-ton production level in determining applicant liability refers to those applicants whose eligibility for SOAP assistance is determined under the 300,000-ton production level effective with the publication of this final rule, and the liability of those applicants whose eligibility was determined under the 100,000-ton production level will continue to be based on 100,000 tons. The Director's approval is further based on the understanding that further amendment to the State's regulations may be required when OSM issues a final notice regarding its changes to 30 CFR part 795.

4. IC 13–4.1–1–1 Legislative Findings

Indiana proposes to delete IC 13–4.1–1–1 in its entirety. The deleted provisions are legislative findings which were incorporated in the Indiana program at its inception, and which are now considered to be outdated (Administrative Record Number IND–

1144). There are no Federal counterparts to the deleted legislative findings. However, the Director finds that the deletion of IC 13–4.1–1–1 does not render the Indiana program less stringent than SMCRA nor less effective than the Federal regulations.

IV. Summary and Disposition of Comments

Agency Comments

Pursuant to section 503(b) of SMCRA and 30 CFR 732.17(h)(11)(i), comments were solicited from various interested Federal agencies. No comments were received concerning the proposed amendments to the Indiana program.

Public Comments

The public comment period and opportunity to request a public hearing was announced in the October 28, 1992, **Federal Register** (57 FR 48761). The comment period closed on November 27, 1992. No comments were received during the comment period, and no one requested an opportunity to testify at the scheduled public hearing so no hearing was held.

V. Director's Decision

Based on the findings above, the Director is approving Indiana's program amendment number 92–6 as submitted by Indiana on July 16, 1992. However, as discussed in Finding 3 above, the approved program amendment does not apply to existing SOAP grantees who were qualified under the 100,000 ton criterion. The Federal regulations at 30 CFR part 914 codifying decisions concerning the Indiana program are being amended to implement this decision. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no provisions in these categories and that EPA's concurrence is not required. However, by letter dated September 29, 1992 (Administrative Record Number IND–1154), EPA concurred without comment.

VI. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.13 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(c) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 9, 1992.

David G. Simpson,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 914—INDIANA

1. The authority citation for part 914 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In § 914.15, paragraph (rr) is added to read as follows:

§ 914.15 Approval of regulatory program amendments.

* * * * *

(rr) The following amendment (Program Amendment Number 92–6) to the Indiana program as submitted to OSM on July 16, 1992, is approved, effective January 14, 1993: IC 13–4.1–3–2(c) concerning a one cent reclamation fee; IC 13–4.1–3–3(c) and IC 13–4.1–3–3.5(a) (1) and (5) which concern the maximum annual coal production under which a mine operator is eligible for participation in the Small Operators Assistance Program (SOAP); and the deletion of IC 13–4.1–1–1 concerning legislative findings.

[FR Doc. 93–863 Filed 1–13–93; 8:45 am]
BILLING CODE 4310–05–M

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30 CFR Part 935

Ohio Regulatory Program; Revision of Administrative Rule

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval of proposed Revised Program Amendment Number 57 to the Ohio permanent regulatory program (hereinafter referred to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment was initiated by Ohio and is intended to revise one rule in the Ohio Administrative Code to change the locations at which applicants must file copies of permit applications, revisions, and renewals in order to allow public inspection of those documents.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Richard J. Seibel, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, 2242 South Hamilton Road, room 202, Columbus, Ohio 43232; (614) 866–0578.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V Director's Decision.
VI. Procedural Determinations.

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the general background of the Ohio program submission, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program, can be found in the August 10, 1982, **Federal Register** (47 FR 34688). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Submission of Amendment

By letter dated May 12, 1992 (Administrative Record Number OH–1698), Ohio submitted proposed Program Amendment Number 57 to revise the Ohio program at Ohio Administrative Code (OAC) 1501:13–5–01(A)(4)(a). In this amendment, Ohio proposed to change the locations at which applicants must file copies of permit applications, revisions, and renewals in order to allow public inspection of those documents.

OSM announced receipt of the proposed amendment in the July 14, 1992, **Federal Register** (57 FR 31163), and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on August 13, 1992. The public hearing scheduled for August 10, 1992, was not held as no one requested an opportunity to testify.

In response to a comment made by the Soil Conservation Service of the United States Department of Agriculture (Administrative Record No. OH–1711), Ohio revised Program Amendment Number 57 and resubmitted the amendment by letter dated July 22, 1992 (Administrative Record No. OH–1760). In this revised amendment, Ohio proposed to change the priority order in which the three filing locations were listed at OAC 1501:13–5–01 paragraph (A)(4)(a) in the May 12, 1992, submittal.

OSM announced receipt of proposed Revised Program Amendment Number 57 in the September 23, 1992, **Federal Register** (57 FR 43954), and, in the same notice, opened the public comment period and provided for a public hearing on the adequacy of the proposed amendment. The comment period closed on October 8, 1992. The public hearing scheduled for October 5, 1992, was not held as no one requested an opportunity to testify.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Ohio program.

Ohio is revising Ohio Administrative Code (OAC) 1501:13–5–01 paragraph (A)(4)(a) to read:

(a) The applicant shall make a full copy of the complete application for a permit, a significant permit revision, or a permit renewal available for the public to inspect and copy. This shall be done by filing copy of the application submitted to the Chief at the Division of Reclamation district office responsible for inspection of the proposed operation, or if no such office is maintained in the county where the mining is proposed to occur, the applicant shall file a copy of the application with the county recorder of than county or at the office of the Soil Conservation Service of the United States Department of Agriculture (SCS) located in the county where the mining is proposed to occur.

The current rule at OAC 1501:13–5–01(A)(4)(a) requires that coal mining permit applications, permit revisions and permit renewals be filed for public access with the county recorder where the mining is proposed, or if approved by the Chief, at the Division of Reclamation District office responsible for inspection of the proposed operation if it is determined that that office will be more accessible to local residents than the county courthouse. The proposed rule would make permit applications, revisions, and renewals available for public inspection at the Division of Reclamation office, county courthouse, or the SCS office. The proposed rule, therefore, adds an alternative filing location for accessibility by the public and changes the priority order of these public offices.

The counterpart Federal rule at 30 CFR 773.13(a)(2) states that the applicant shall file a full copy of the application for a permit, significant revision, or renewal of a permit with the recorder at the courthouse of the county where the mining is proposed to occur, or an accessible public office approved by the regulatory authority. The intent behind the local filing requirement is the accessibility to the local residents.

The proposed rule is similar to its Federal counterpart except that it adds the SCS as an alternative filing location. The SCS maintains an office in every county in Ohio thereby satisfying the accessibility requirement and fulfilling the intent of the Federal regulations. Therefore, the Director finds that the proposed rule is no less effective than the Federal regulations at 30 CFR 773.13(a)(2).

IV. Summary and Disposition of Comments

Public Comments

The public comment period and opportunity to request a public hearing announced in the July 14, 1992, **Federal Register** (57 FR 31163) closed on August 13, 1992. The public comment period was reopened again in the September 23, 1992, **Federal Register** (57 FR 43954) until October 8, 1992. Comments were received from the Ohio Historic Preservation Office (OHPO). The OHPO did not object to the proposed amendment. The scheduled public hearings were not held as no one requested an opportunity to provide testimony.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Ohio Program. The U.S. Army Corps of Engineers and the U.S. Department of Labor, Mine Safety and Health Administration, responded that they had no comments on the proposed amendment.

The SCS accepted the proposed amendment as written (Administrative

Record No. OH–1711 and OH–1770). However, the SCS recommended that the Soil and Water Conservation District office (SWCD) be identified as the location in which to file permit applications rather than the SCS. The SCS maintained that this would be appropriate since SCS programs and activities in Ohio are carried out through the local SWCD office. Ohio has considered SCS's comment, but has decided to use SCS as a filing location (Administrative Record No. OH–1797). The SWCD offices are jointly funded by the State of Ohio and individual counties. Since funding of these offices could vary from county to county, there is the possibility that certain offices could be eliminated or understaffed thereby reducing public accessibility to permit applications, revisions, and renewals. Ohio, therefore, has chosen the SCS rather than the SWCD as a filing location. As discussed above, the Director has determined that Ohio's selection of the SCS as an alternative filing location is no less effective than the Federal regulations.

V. Director's Decision

Based on the above findings, the Director is approving Ohio Revised Program Amendment Number 57, as submitted by Ohio on May 12, 1992, and revised and resubmitted by letter dated July 22, 1992.

The Federal regulations at 30 CFR part 935 codifying decisions concerning the Ohio program are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to conform their programs with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no such provisions and that EPA concurrence is, therefore, unnecessary. However, by letters dated July 24, 1992 (Administrative Record No. OH–1751) and September 29, 1992 (Administrative Record No. OH–1784), EPA submitted its concurrence without comment.

VI. Procedural Determinations

Executive Order No. 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA [30 U.S.C. 1292(d)] provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 21, 1992.

Alfred Whitehouse,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 935—OHIO

1. The authority citation for part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In § 935.15, a new paragraph (kkk) is added to read as follows:

§ 935.15 Approval of regulatory program amendments.

* * * * *

(kkk) The following amendment to the Ohio regulatory program, as submitted to OSM on May 12, 1992, and revised and resubmitted on July 22, 1992, is approved, effective January 14, 1992. Revised Amendment Number 57 which consists of revisions to the Ohio Administrative Code (OAC) at 1501:13–5–01(A)(4) paragraph (a) concerning where applicants must file copies of permit applications, revisions, and renewals in order to allow public inspection of those documents.

[FR Doc. 93–868 Filed 1–13–93; 8:45 am]
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30 CFR Part 935

Ohio Permanent Regulatory Program; Evaluation of Revegetation Success

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing the approval, with one exception, of

Revised Program Amendment No. 25 to the Ohio permanent regulatory program (hereinafter referred to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment consists of a revision to the Ohio Administrative Code (OAC) at 1501:13–9–15(J)(1) and documents which describe Ohio's proposed ocular inspection method. The proposed amendment will determine how the areal extent of vegetative ground cover will be evaluated when making performance bond release decisions on surface coal mined lands.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. Richard J. Seibel, Director, Columbus Field Office, Office of Surface Mining Reclamation and Enforcement, 2242 South Hamilton Road, room 202, Columbus, Ohio 43232; (614) 866–0578.

SUPPLEMENTARY INFORMATION:

I. Background on the Ohio Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision.
VI. Procedural Determinations.

I. Background on the Ohio Program

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the general background of the Ohio program submission, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program, can be found in the August 10, 1982, **Federal Register** (47 FR 34688). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Submission of Amendment

Pursuant to 30 CFR 732.17(f)(1), OSM sent Ohio a letter on November 6, 1985, notifying the State that certain sections of Ohio's regulations were less effective than or inconsistent with the Federal requirements for surface coal mining and reclamation operations (Administrative Record No. OH–0679). One of these rules which was determined by the Director to be deficient was OAC 1501:13–9–15(E) which concerned the method of measuring revegetation success. Ohio responded on May 16, 1986, by submitting proposed Program Amendment No. 25 to the Ohio regulatory program. In his decision on this proposed amendment, the Director found that Ohio's proposed method of evaluating revegetation as set forth in OAC 1501:13–9–15 was less effective than the Federal rules at 30 CFR 816.116. The Director reached this decision because the Ohio program did not include a statistically valid sampling technique for the evaluation of revegetation and because the existing method of using ocular inspections had not been justified to show that it has the equivalent of a 90 percent confidence level or is no less effective than the Federal standard. Therefore, pursuant to 30 CFR 732.17, the Director promulgated 30 CFR 935.16(f), which required Ohio to amend its program to include a statistically valid technique for the evaluation of revegetation to augment its existing method to be as effective as the Federal rules at 30 CFR 816.116(a) (July 17, 1987; 52 FR 26959).

Ohio responded on November 3, 1987, by submitting administrative record information pertaining to 30 CFR 935.16(f). At Ohio's request, OSM agreed to conduct a study of the Ohio method of evaluating revegetation success and to defer action until this study was completed. The study was completed and OSM announced the findings in the December 15, 1989, **Federal Register** (54 FR 51395). The Director found that the administrative record information submitted by Ohio and the study, which was conducted jointly by OSM and Ohio, had not demonstrated that Ohio's existing method of evaluating the success of revegetation was no less effective than the Federal rules at 30 CFR 816.116(a).

By letter dated December 12, 1989 (Administrative Record No. OH–1245), Ohio proposed a continuation of Revised Program Amendment No. 25. In this continuation, Ohio proposed to revise section 1501:13–9–15 of the OAC to include a statistically valid method of evaluating revegetation success in order to satisfy the OSM requirement at 30 CFR 935.16(f). This method would be used on "questionable" areas. The ocular method would be retained as the primary means of ground cover evaluation.

On January 8, 1990 (Administration Record No. OH–1259), OSM published a notice in the **Federal Register** (55 FR 649) announcing receipt of Ohio's proposed continuation of Revised Program Amendment No. 25 and inviting public comment on its adequacy. The public comment period ended on February 7, 1990.

By letter dated March 23, 1990 (Administrative Record No. OH–1292), OSM notified Ohio that the proposed revisions to OAC section 1501:13–9–15 were less effective than the Federal regulations at 30 CFR 816.116(a) because Ohio proposed to use statistically valid sampling methods only on "questionable" areas and that the Federal regulations required "statistically valid sampling techniques in all situations regardless of the outcome of any prior or accompanying ocular evaluation."

By letter dated July 24, 1990 (Ohio Administrative Record No. OH–1343), Ohio submitted further proposed revisions to OAC section 1501:13–9–15 which were intended to respond to OSM's comments of March 23, 1990. Ohio proposed to revise paragraph (I)(1) to specify that success of revegetation shall be measured using a statistically valid sampling technique with a ninety percent statistical confidence interval (i.e. one-sided test with 0.10 alpha error). Ohio also proposed to revise paragraph (I)(3)(c)(iv) to delete the requirement that, for Phase III bond release, species planted must meet the standard that no single areas with less than thirty percent cover shall exceed the lesser of three thousand square feet or 0.3 percent of the land affected.

On August 10, 1990, OSM published a notice in the **Federal Register** (55 FR 32643) announcing receipt of Ohio's additional revisions to the continuation of Revised Program Amendment No. 25 and inviting public comment on its adequacy. The public comment period ended on September 10, 1990.

By letter dated October 24, 1990 (Administrative Record No. OH–1398), OSM provided Ohio with its questions and comments about the additional revisions submitted on July 24, 1990. OSM requested that Ohio provide the details of Ohio's statistically valid sampling method for OSM's review and approval. OSM also requested that Ohio provide a justification for the proposed deletion of the vegetation standard limiting the size of areas with less than thirty percent vegetative cover (barren area standard). On December 19, 1990, OSM agreed to a time extension for Ohio to respond to the October 24, 1990, letter and provided further clarification of the issues involved (Administrative Record No. OH–1418).

By letter dated March 1, 1991 (Administrative Record No. OH–1471), Ohio submitted administrative record information in support of the revisions proposed on July 24, 1990, and responded to OSM's comments of October 24, 1990. In its response, Ohio provided information on its proposed method of sampling revegetation success and rationale for deleting the proposed barren area standard. OSM reopened the public comment period in the March 27, 1991, **Federal Register** (56 FR 12691). The comment period closed on April 26, 1991.

By letter dated March 21, 1991 (Administrative Record No. OH–1489), Ohio withdrew its March 1, 1991, submission and its July 24, 1990, proposed revisions to OAC 1501:13–9–15 paragraphs (I)(1) and (I)(3)(c)(iv). OSM announced Ohio's withdrawal in the May 7, 1991, **Federal Register** (56 FR 21113).

By letter dated June 18, 1991, Ohio submitted an informal version of Revised Program Amendment No. 25 for preliminary review by OSM. This informal submission proposed that Ohio will use two visual estimates of revegetation success followed by statistical verification of those visual estimates. In this informal submission, Ohio proposed to retain the revegetation standard limiting the size of areas with less than thirty percent vegetative cover.

By letter dated August 9, 1991 (Administrative Record No. OH–1556), Ohio withdrew the informal submission of June 18, 1991, and resubmitted a formal version of Revised Program Amendment No. 25. In this formal amendment submission, Ohio proposed revisions to OAC section 1501:13–9–15 to delete paragraph (I)(3)(c)(i)(d) limiting the size of areas with less than thirty percent vegetative cover and to add new paragraph (I)(3)(c)(ii) stating that "Success of the ground-cover (for phase III bond release for herbaceous species only) shall be measured using a statistically valid sampling technique with a ninety per cent statistical confidence interval (i.e. one-sided test with 0.10 alpha error)."

As part of its August 9, 1991, resubmission, Ohio also reinstated the March 1, 1991, Administrative Record information which provided the details of Ohio's proposed use of the Rennie-Farmer Stick Method of sampling ground cover. The March 1, 1991, Administrative Record information also provided Ohio's reasons for proposing the deletion of its barren area standard.

On August 27, 1991, OSM published a notice in the **Federal Register** (56 FR 42299) announcing receipt of Ohio's August 9, 1991, submission of Revised Program Amendment No. 25 and inviting public comment on its adequacy. The public comment period ended on September 26, 1991.

By letter dated January 3, 1992 (Administrative Record No. OH–1623), OSM provided Ohio with its questions and comments about the August 9, 1991, submission of the amendment. OSM requested that Ohio provide the details of Ohio's procedure for statistical testing of the sampling results. OSM also requested that Ohio provide a justification that Ohio's proposed standard of 70 percent ground cover is comparable to unmined sites in the State. Finally, OSM requested that Ohio further revise the rule to require statistically valid sampling for ground cover, production, and stocking. OSM found that Ohio's current system was not compatible with statistical sampling and that Ohio had inadvertently mixed two sampling methods together.

By letter dated February 10, 1992 (Administrative Record No. OH–1647), Ohio requested a meeting between Ohio, OSM, and Ohio Agricultural Research and Development Center (OARDC) personnel to clarify the issues and concerns expressed in OSM's January 3, 1992, letter. On March 31, 1992, representatives of Ohio, OSM, and the OARDC met at OARDC to discuss those issues (Administrative Record OH–1672 and OH–1683).

By letter dated June 22, 1992 (Administrative Record No. OH–1725), Ohio submitted a new version of Revised Program Amendment No. 25 and withdrew its August 9, 1991, submission. The new submission is intended to address the issues in OSM's January 3, 1992, letter. The June 22, 1992, submission proposes to revise OAC 1501:13–9–05 paragraph (J)(1) to incorporate additional language previously proposed in Ohio's July 24, 1990, submission of paragraph (I)(1) and in Ohio's August 9, 1991, submission of paragraph (I)(3)(c)(ii). Accompanying this proposed rule change, Ohio submitted four documents. These documents discuss the statistical validity of a 100-percent population census, describe Ohio's ocular method of ground cover evaluation, and discuss how inspectors will be trained to implement the Ohio method.

On August 18, 1992, OSM published a notice in the **Federal Register** (57 FR 37136) announcing receipt of Ohio's June 22, 1992, submission of Revised Program Amendment No. 25 and invited public comment on its adequacy. The public comment period ended on September 17, 1992.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment to the Ohio program.

The proposed amendment consists of two parts: a proposed one-sentence addition to Ohio's rules at OAC 1501:13–9–15(J)(1) and documents pertaining to a proposed ocular inspection method for evaluating vegetative ground cover when making performance bond release decisions. The proposed regulatory language reads as follows: "Success of revegetation shall be measured using a statistically valid sampling technique with a ninety percent statistical confidence interval (i.e. one-sided test with 0.10 alpha error)." The proposed language is substantively identical to the last sentence in 30 CFR 816.116(a)(2). The Director, therefore, finds that the rule language is no less effective than the Federal rules.

The second part of the amendment consists of documents describing Ohio's proposed ocular method of ground cover evaluation plus supporting statements concerning the method's statistical validity and the training which Ohio inspectors will undergo prior to using the method. This submission was in response to 30 CFR 935.16(f) which required that by May 31, 1990, Ohio shall amend its program to include a statistically valid technique for the evaluation of revegetation success to augment or replace its current method to be as effective as 30 CFR 816.116(a). This Federal rule requires that statistically valid sampling techniques for measuring success shall be selected by the State regulatory authority and included in an approved regulatory program.

The second part of Ohio's June 22, 1992, submission is substantively identical to previous State submissions which the Director reviewed in the July 17, 1987, **Federal Register** (52 FR 26966) and in the December 15, 1989, **Federal Register** (54 FR 51397). Ohio described its June 22, 1992, proposal to OSM as follows:

> Ohio's four-tiered vegetative cover standard requires that, at a minimum, at least 89 percent of the area being evaluated for bond release has at least 75 percent cover, no more than 10 percent of the area has between 30 and 75 percent cover (i.e. sparse), no more than one percent of the area has less than 30 percent cover (i.e. barren), and that there exists no single tract greater than either 3,000 square feet or 0.3 percent cover of the total area with less than 30 percent cover (i.e. single barren area). This system of standards entails visual estimation of the areal extent of vegetation falling within a range of values for ground cover, rather than estimation of the overall percentage of cover.
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> Prior to the bond release inspection, the inspector reviews the planting plan contained in the permit file and the portion of the permit application map representing the area for which the bond release has been requested. The inspector calculates the total square footage of the bond release area and determines the maximum square footage of sparse (i.e. 10 percent of the release area), barren area (i.e. one percent of the release area), and the maximum extent of single barren area (0.3 percent of the release area or 3,000 square feet, whichever is less) within

which the vegetative cover would be determined to be successful.

The inspector assigned to the permit is accompanied by another inspector or the district office supervisor at the time of the actual bond release inspection. Upon arrival at the bond release site, the inspectors determine the most efficient route over the bond release area to ensure that the entire area can be visually evaluated. As the inspectors walk the route, any portion of the area which is observed to have less than 75 percent ground cover is visually segregated and measured by tape measure or pacing, and the results are recorded on the inspection form. Further measurements are taken within the segregated area if it is determined by visual observation that barren portions (less than 30 percent cover) are interspersed with sparse (between 30 and 75 percent cover). If any single barren exceeds the lesser of 3,000 square feet or 0.3 percent of the total bond release area, the inspector terminates the inspection and the bond release is immediately denied.

Upon completion of the inspection, if no single barren area larger than the acceptable limit exists, the inspector tallies the total square footage of sparse and barren area. If both categories fall within the acceptable limits calculated prior to the inspection, and if no other conditions exist for which bond release would be denied in accordance with Chapter 1513 of the Ohio Revised Code and administrative rules, the bond release request is approved.

Ohio has argued that the above ocular method is a 100-percent sampling of the vegetative cover on sites considered for bond release and that such sampling is just a special case of simple random sampling (Administrative Record No. OH–1725). OSM rejects this argument. The Ohio method is an ocular estimate of percent cover by category; it is not a measurement since no discrete points are sampled and the distance from the observer to the point observed is not fixed. A 100-percent census requires measurement of 100 percent of the area which the Ohio technique does not accomplish (Administrative Record No. OH–1795). Furthermore, there is no estimate of the mean and variance, both of which are necessary to implement the proposed language at OAC 1501:13–9–15(J)(1). The proposed ocular method of evaluating ground cover does not implement the proposed rule at OAC 1501:13–9–15(J)(1). The proposed rule language and the ocular inspection method submitted by Ohio are not consistent with each other. To perform a statistical test, a sample must be taken and a mean and variance calculated. This is not possible given Ohio's proposed ocular method. The State recognized this in its previous proposal when it stated that "Ohio has not need [sic] to conform to a 90 percent statistical confidence interval because it does not utilize a sampling technique" (July 17, 1987; 52 FR at 26967).

In the Fall of 1988, OSM and Ohio jointly conducted a study of randomly selected mining sites upon which Ohio had approved bond release (Administrative Record No. OH–1196). The purpose of the study was to compare the results of Ohio's proposed ocular method of evaluating vegetative ground cover with those obtained by using a statistically valid method. The study, which was reported in the December 15, 1989, **Federal Register** (54 FR 51395) concluded that Ohio's ocular method, which is the same method proposed on June 22, 1992, was not as effective as a statistically valid method. Accordingly, the Director found that Ohio had not demonstrated that its method of evaluating the success of revegetation is no less effective than the Federal rules at 30 CFR 816.116(a). No new field studies have been submitted by Ohio to refute these findings and conclusions. Furthermore, the Director is unaware of any studies sponsored by universities, government agencies, or other parties which demonstrate that ocular estimation of the areal extent of ground cover is no less effective than the sampling methods approvable under 30 CFR 816.116(a).

In developing the Federal rules at 30 CFR 816.116(a), OSM considered the use of ocular methods but rejected them in the final rulemaking. OSM made this decision because the ocular method whereby an inspector visually inspects the site and determines whether success has been achieved, is highly dependent upon the training, experience and objectivity of the inspector. Ocular methods were believed to provide results that were too variable for bond release decision making (March 23, 1982; 47 FR at 12599). This belief is supported by others who have studied the subject of ground cover measurement. In 1982, Raelson and McKee, two agronomists at Pennsylvania State University, studied the measurement of plant cover to evaluate revegetation success on surface coal mines (Administrative Record No. OH–1796). They surveyed the literature on the methods available for measuring ground cover such as the quadrat sampling method, line-intercept method, point-frequency method and the visual estimation method. They arrived at the following conclusions concerning the visual estimation method:

> The visual estimate method is fast. It was designed to provide initial survey information on the vegetation of large areas for which detailed measurements are not possible. It is, however, highly inaccurate. Results of many studies have shown that even well trained field observers can differ by twenty-five or more percent or more in their assessment of the cover of the same area. Greig Smith (1964) pointed out that the accuracy of the method decreases through the day as observers become tired and less alert. In addition, cover estimates, even by the same observer, can vary throughout the day and from day to day. The visual estimate of cover method requires an objective standard to calibrate the observer's 'eye.' The visual estimation method, while often used, is not well suited for purposes of enforcing legal reclamation standards.

A field exercise by the authors on a reclaimed surface mine which compared visual, quadrat, and point frequency methods of ground cover estimation supported the statement that visual estimates are inherently subjective.

Ohio's proposed ocular method is a refinement of the visual method studied by Raelson and McKee. It involves the estimation of three cover classes instead of a single visual estimate and observers receive training in making such estimates. Nevertheless, the Director believes that it involves greater subjectivity than other methods acceptable under 30 CFR 816.116(a)(1).

In summary, the Director finds that Ohio has not demonstrated that its proposed ocular method is no less effective than statistically valid sampling techniques required under 30 CFR 816.116(a)(1). He rejects Ohio's argument that the proposed ocular method is a 100-percent sample and that it qualifies as a statistically valid sampling technique acceptable for making performance bond release decisions. Furthermore, its use as proposed by Ohio would result in an inconsistency between proposed rule language at OAC 1501:13–9–15(J)(1) and actual practice during inspections.

This decision is consistent with decisions on other proposed State program amendments, where the Director has not approved ocular estimation of revegetation success. See, "[D]etermination of percent moisture content and dry forage production based on representative subsamples of ocularly estimated stratified samples is not consistent with the Federal requirements." 56 FR 6559, 6561 (February 19, 1991)—Kansas; "[O]cular estimation of species cover, vegetative cover and total ground cover" is less effective. 51 FR 42209, 42212 (November 24, 1986)—Wyoming; "[T]he Secretary finds that the portion of the State's Technical Handbook which allows the use of the ocular method for determining success is less effective than 30 CFR 816.116 and 817.116 which only allow valid statistical sampling

techniques for this purpose." 50 FR 28324, 28332 (July 11, 1985)—West Virginia.

IV. Summary and Disposition of Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(11)(i), comments were solicited from various Federal agencies with an actual or potential interest in the Ohio program. The U.S. Department of Agriculture, Soil Conservation Service; the U.S. Army Corps of Engineers and the U.S. Department of Labor, Mine Safety and Health Administration responded but did not have any substantive comments.

No public comments were received for the June 22, 1992, submission. However, in response to an earlier program amendment submission, there was a comment by the Ohio Mining and Reclamation Association (the "OMRA"). The OMRA disagreed with OSM's determination that Ohio's current method for measuring revegetation was not statistically valid. The OMRA argued that Ohio's method is statistically valid because the inspectors review the entire permit area. It also argued Ohio's current system hasn't posed a problem and that to change this system would not improve the method of evaluating revegetation.

The Director disagrees with the OMRA. As discussed in the Director's Findings, Ohio's ocular method for evaluating revegetation success is not statistically valid and does not meet the 90 percent statistical confidence interval. As discussed in the Findings, Ohio's current system has posed a problem. That is, the system is based on the subjective judgment of each inspector, so that the results of each inspection cannot be repeated with any degree of certainty. This is demonstrated by the joint study conducted by OSM and Ohio, the results of which was reported in the December 15, 1989, **Federal Register** (54 FR 51397). In that study, OSM determined that there was a wide confidence interval between the three observers, which is not allowed under the Federal rules at 30 CFR 816.116(a). "[S]tatistically valid techniques and a nationwide standard of statistical confidence are necessary to insure objective, standardized and equitable evaluations of revegetation success." 51 FR 4485, 4493 (February 5, 1986).

V. Director's Decision

Based on the above findings, the Director is approving, with one exception, Revised Program Amendment No. 25, as submitted by Ohio on June 22, 1992. The Director has determined that the proposed revision to OAC 1501:13–9–15(J)(1) is no less effective than the Federal rules at 30 CFR 816.116(a)(2). However, the proposed ocular method for evaluating ground cover which was submitted as part of the June 22, 1992, amendment has been determined by the Director to be not as effective as 30 CFR 816.116(a)(1) which requires that statistically valid sampling techniques for measuring success be included as part of approved State regulatory programs. Therefore, the amendment requirement for the Ohio program at 30 CFR 935.16(f) has not been fully satisfied and remains outstanding. Specifically, Ohio must amend its program to include a statistically valid sampling technique for evaluating the areal extent of ground cover.

The Federal regulations at 30 CFR part 935 codifying decisions concerning the Ohio program are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to conform their programs with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). The Director has determined that this amendment contains no such provisions and that EPA concurrence is therefore, unnecessary. However, by letter dated September 22, 1992 (Administrative Record No. OH–1775), EPA submitted its concurrence without comment.

Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any alteration of an approved State program be submitted to OSM for review as a program amendment. Thus, any changes to a State program are not enforceable until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved programs. In the oversight of the Ohio program, the Director will recognize only the approved program, together with any consistent implementing policies, directives and other materials, and will require the enforcement by Ohio of such provisions.

VI. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.13 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(c) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 24, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

For the reasons set out in the preamble, title 30 Chapter VII, subchapter T of the Code of Federal regulations is amended as set forth below:

PART 935—OHIO

1. The authority citation for part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. In § 935.15, a new paragraph (jjj) is added to read as follows:

§ 935.15 Approval of regulatory program amendments.

* * * * *

(jjj) The following amendment to the Ohio regulatory program, as submitted to OSM on June 22, 1992, with one exception, is approved, effective January 14, 1993: The approved amendment consists of a revision to the Ohio Administrative Code at 1501:13–9–15(J)(1) which pertains to standards for measuring success of revegetation. OSM is not approving Ohio's proposed ocular method of ground cover evaluation.

3. In § 935.16(f) is revised to read as follows:

§ 935.16 Required regulatory program amendments.

* * * * *

(f) By May 14, 1993, Ohio shall amend its program to include a statistically valid technique for the evaluation of revegetation success to augment or replace its current method to be as effective as 30 CFR 816.116(a).

[FR Doc. 93–873 Filed 1–13–93; 8:45 am]
BILLING CODE 4310–05–M

30 CFR Part 938

Pennsylvania Regulatory Program; Regulatory Reform

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule.

SUMMARY: OSM is announcing the approval of a proposed amendment to the Pennsylvania permanent regulatory program (hereinafter referred to as the Pennsylvania program) approved under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment defines the term "historical resource," requires that permitting decisions take into account the effect of the proposal coal mining on properties listed on or eligible for listing on the National Register of Historic Places (NRHP), and describes permit application informational requirements pertaining to archaeological, cultural and historical resources listed on or eligible for listing on the NRHP within the permit and adjacent areas including identification of the steps to be taken to protect the historic resources.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Robert J. Biggi, Director, Harrisburg Field Office, Office of Surface Mining Reclamation and Enforcement, Harrisburg Transportation Center, Third Floor, suite 3C, 4th and Market Streets, Harrisburg, Pennsylvania 17101. Telephone (717) 782–4036.

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program.
II. Submission of Amendment.
III. Director's Findings.
IV. Summary and Disposition of Comments.
V. Director's Decision
VI. Procedural Determinations.

I. Background on the Pennsylvania Program

The Secretary of the Interior conditionally approved the Pennsylvania program on July 31, 1982. Information on the background of the Pennsylvania program including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Pennsylvania program can be found in the July 30, 1982, **Federal Register** (47 FR 33050). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 938.11, 938.12, 938.15 and 938.16.

II. Submission of Amendment

By letter dated December 18, 1991 (Administrative Record Number PA 803.00), Pennsylvania submitted a State program amendment to address four outstanding part 732 Notifications, listed below:

1. *Historic Properties,* June 9, 1987, Administrative Record Number PA 651
2. *Regulatory Reform Review II,* December 16, 1988, Administrative Record Number PA 723.
3. *Ownership and Control,* May 11, 1989, Administrative Record Number PA 773.
4. *Regulatory Reform Review III,* January 2, 1990, Administrative Record Number PA 787.03.

Other revisions are contained in the proposed amendment package to address provisions necessary for Pennsylvania to implement amendments to the Pennsylvania Surface Mining Conservation and Reclamation Act (Pub. L. No. 1570, Act 171 of December 12, 1986) and changes to clarify existing regulations.

OSM announced receipt of the proposed amendment in the April 13, 1992, **Federal Register** (57 FR 12785), and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on May 13, 1992. At the request of the Pennsylvania Coal Association, a public meeting was held on June 30, 1992.

To simplify the processing of the large amendment package, OSM separated the package into smaller amendments, according to subject matter, which then would be handled in individual final rules. This final rule addresses all the revisions proposed by Pennsylvania in response to the June 9, 1987, part 732 Notification (Administrative Record No. PA–651) concerning cultural and historical resources and other related State initiated changes to bring the Pennsylvania program into compliance with the Federal program.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.17, are the Director's findings concerning the proposed amendment to the Pennsylvania program. Nonsubstantive changes, which are proposed throughout these rules, to make grammatical corrections and to correct subsection letter notations are not specifically discussed.

1. Section 86.1 Definitions—Historical Resources

Pennsylvania proposes to add a definition of "historic resource" to section 86.1. Under the proposed rules "historic resource" means:

"A building, structure, object, district, place, site or area significant in the history, architecture, maritime heritage, archaeology or culture of this Commonwealth, its communities or the nation. The term 'historic resource' includes the terms 'cultural resource,' 'archaeological resource,' 'historic place,' 'historic property,' 'archaeological site' and 'archaeological property' as used in Chapters 86–90 of this Title."

Although the Federal regulations do not define "historic resource," the proposed definition is not inconsistent with the use of the term in the Federal regulations in reference to the NRHP. Therefore, the Director finds the proposed definition of "historic resources" will not render Pennsylvania's rules less effective than the counterpart Federal regulations.

2 Section 86.37(a)(6) Criteria for Permit Approval or Denial

Pennsylvania proposes to revise this rule to include language to require that the regulatory authority, as part of the written findings for permit application approval, take into account the effects of the proposed coal mining activities on properties listed or eligible for listing on the NRHP. In addition, the proposal further revises the rule to provide that such a finding may be supported in part by inclusion of appropriate permit conditions or operational plan changes to protect historic resources, or a documented decision that no additional protective measures are necessary.

Since the proposed revision to section 86.37(a)(6) is substantively identical to the Federal counterpart regulation at § 773.15(c)(11), the Director finds that the proposed rules are no less effective than that Federal regulation.

3. Section 86.102 Areas Where Mining is Prohibited or Limited

Pennsylvania proposes to revise section 86.102 to add language to extend the restriction on surface mining activities which will affect a publicly-owned park or a place included on the NRHP to include such places "eligible for inclusion on" the NRHP. The counterpart Federal regulation at 30 CFR 761.11(c) is similar, except that it does not include publicly-owned parks or places "eligible for inclusion" on the NRHP. Since the proposed rules would extend the protection of publicly-owned parks or places eligible for listing, the Director finds that the added language would not render the State rules less effective than the counterpart Federal regulations.

4. Sections 87.42(2), 88.22(2), 88.491(a)(1)(ii), 89.38(a), and 90.11(a)(3) General Environmental Resource Information

Pennsylvania proposes to revise its rules concerning the informational requirements of coal mining permit applications to include the nature of archaeological, as well as cultural and historic resources within the permit or adjacent areas which are listed on or eligible for listing on the NRHP. In addition, the rules provide that the regulatory authority may require the applicant to evaluate the identified historic resources through collection of additional information, field investigations or other appropriate analysis. In its issue letter to Pennsylvania (Administrative Record No. PA–803.12), OSM noted that section 88.491(a)(1)(ii) did not require information on historic resources located within the areas adjacent to the proposed permit area. Pennsylvania, in its response (Administrative Record No. PA–803.14) resolved OSM's concern by clarifying that the requirement for information on historic resources within areas adjacent to the permit for all anthracite mining activities is contained in 88.22(2).

Therefore, the Director finds that Pennsylvania's proposed rules are substantively identical and no less effective than the Federal counterpart regulations at 30 CFR 779.12(b) and 783.12(b).

5. Sections 87.54(a)(9), 88.31(a)(9), 88.491(i)(7), and 90.21(a)(9) Maps, Cross Sections, and Related Information

Pennsylvania proposes to revise its rules concerning the requirement to submit, as part of a coal mining permit application, maps and plans showing the boundaries of any public park and location of cultural or historical resource listed on the NRHP. The proposed rule extends this requirement to those sites which are eligible for listing on the NRHP. Since the proposed rules are substantively identical to the respective Federal regulations at 30 CFR 779.24(i) and 783.24(i), the Director finds them to be no less effective than these Federal regulations.

6. Sections 87.77, 88.56, 88.381(c)(9), 88.492(f), 89.38 (b) & (c), and 90.40 Protection of Public Parks and Historic Places

Pennsylvania is proposing to revise its rules to require that each permit application describe the measures that will be used to protect or minimize adverse impacts of the proposed coal mining operations on public parks and historic places. Since the measures proposed by the State are substantively identical to the corresponding Federal regulations at 30 CFR 780.31 and 784.17, the Director finds that they are no less effective than the Federal rules.

IV. Summary and Disposition of Comments

Public Comment

The public comment period and opportunity to request a public hearing announced in the April 13, 1992, **Federal Register** ended on May 13, 1992. Written comments and a request for a public meeting were received from the Pennsylvania Coal Association (PCA). None of the comments pertained to the cultural and historical provisions contained in the amendment package. The public meeting was held on June 30, 1992, and comments presented by the PCA (Administrative Record No. PA–803.15). However, these comments did not pertain to any of the issues contained in this final rule and are, therefore, not discussed in this final rule.

Agency Comments

Pursuant to section 503(b) of SMCRA and the implementing regulations at 30 CFR 732.17(h)(ii)(i), comments were solicited from various Federal and State agencies with an actual or potential interest in the Pennsylvania program, including the Pennsylvania Historical Museum Commission and the Pennsylvania Advisory Council on Historical Preservation. Responses were received from the Department of Labor, Mine Safety and Health Administration, Districts 1 and 2; the Department of Interior, Bureau of Mines; and the Department of Agriculture, Soil Conservation Service. The responses did not contain any comments concerning revision to the State's cultural and historical rules.

V. Director's Decision

Based on the findings discussed above, the Director is approving Pennsylvania's program amendment pertaining to cultural and historical protection provisions of its rules as submitted on December 18, 1991.

Effect of the Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any alteration of an approved State program be submitted to OSM for review as a program amendment. Thus any changes

to the State program are not enforceable until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved State programs. In the oversight of the Pennsylvania program, the Director will recognize only the statutes, regulations and other materials approved by him, together with any consistent implementing policies, directives and other materials, and will require the enforcement by Pennsylvania of only such provisions.

EPA Concurrence

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the Environmental Protection Agency (EPA) with respect to any provisions of a State program amendment which relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 et seq.) or the Clean Air Act (42 U.S.C. 7401 et seq.). The Director has determined that this amendment contains no such provisions and that EPA concurrence is, therefore, unnecessary.

VI. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the OSM an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 4, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

For the reasons set forth in the preamble, title 30, chapter VII, subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 938—PENNSYLVANIA

1. The authority citation for part 938 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 938.15, is amended by adding a new paragraph (x) to read as follows:

§ 938.15 Approval of regulatory program amendments.

* * * * *

(x) The following amendments to the Pennsylvania regulatory program were approved effective January 14, 1993.

86.1 Definitions: "historic resource."
86.37(a)(6) Criteria for permit approval or denial.
86.102 Areas where mining is prohibited or limited.
87.42(2): General environmental resource information.
87.54(a)(9) Maps, cross sections, and related information.
87.77 Protection of public parks and historic places.
88.22(2) General environmental resource information.
88.31(a)(9) Maps and plans.
88.56 Protection of public parks and historic places.
88.381(c)(9) General requirements; protection of public parks and historic places.
88.491(a)(1)(ii) Minimal requirements for information on environmental resources.
88.491(i)(7) Maps and cross sections.
88.492(f) Protection of public parks and historic places.
89.38(a) Archaeological and historical resources and public parks.
89.38(b)&(c) Archaeological and historical resources and public parks.
90.11(a)(3) General; nature of archaeological, cultural and historic resources.
90.21(a)(9) Maps and cross sections.
90.40 Protection of public parks and historic places.

[FR Doc. 93–860 Filed 1–13–93; 8:45 am]
BILLING CODE 4310–05–M

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS JOHN PAUL JONES (DDG 53) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a naval destroyer. The intended effect of this rule is to warn

mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: December 8, 1992.

FOR FURTHER INFORMATION CONTACT: Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS JOHN PAUL JONES (DDG 53) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS: Annex I, section 3(a) pertaining to the location of the forward masthead light in the forward quarter of the vessel, the placement of the after masthead light, and the horizontal distance between the forward and after masthead lights; Annex I, section 2(f)(i) pertaining to placement of the masthead light or lights above and clear of all other lights and obstructions; and, Annex I, section 3(c) pertaining to placement of task lights not less than 2 meters from the fore and aft centerline of the ship in the athwartship direction; without interfering with its special function as a Navy ship. The Judge Advocate General has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for 32 CFR part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table Four of § 706.2 is amended by:

a. Adding the following vessel to Paragraph 15:

Vessel	Number	Horizontal distance from the fore and aft centerline of the vessel in the athwartship direction
USS JOHN PAUL JONES.	DDG 53	1.89 meters.

b. Adding the following vessel to Paragraph 16:

Vessel	Number	Obstruction angle relative ship's headings
USS JOHN PAUL JONES.	DDG 53	89.47 thru 106.39 degrees.

3. Table Five of § 706.2 is amended by adding the following vessel:

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I sec. 3(a)	After masthead light less than ½ ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained.
USS JOHN PAUL JONES	DDG 53	X	X	X	12.5

Dated: December 8, 1992.

Approved:

W.L. Schachte, Jr.,

Rear Admiral, JAGC, U.S. Navy Acting Judge Advocate General.

[FR Doc. 93–906 Filed 1–13–93; 8:45 am]

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32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972; Amendment

AGENCY: Department of the Navy, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Navy is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Judge Advocate General of the Navy has determined that USS KEARSARGE (LHD 3) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with certain provisions of the 72 COLREGS without interfering with its special functions as a naval amphibious assault ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

EFFECTIVE DATE: December 22, 1992.

FOR FURTHER INFORMATION CONTACT: Captain R.R. Rossi, JAGC, U.S. Navy, Admiralty Counsel, Office of the Judge Advocate General, Navy Department, 200 Stovall Street, Alexandria, VA 22332–2400, Telephone number: (703) 325–9744.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Judge Advocate General of the Navy, under authority delegated by the Secretary of the Navy, has certified that USS KEARSARGE (LHD 3) is a vessel of the Navy which, due to its special construction and purpose, cannot comply fully with 72 COLREGS: Rule 21(a), pertaining to the location of the masthead lights over the fore and aft centerline of the ship; Annex 1, section 2(g), pertaining to the distance of the sidelights above the hull; Annex I, section 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship; the placement of the after masthead light and the horizontal distance between the forward and after masthead lights; and Annex I, section 3(b), pertaining to the positioning of the sidelights in relationship to the forward masthead light, without interfering with its special functions as a Navy ship. The Judge Advocate General of the Navy has also certified that the aforementioned lights are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and

contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), and Vessels.

PART 706—[AMENDED]

Accordingly, 32 CFR part 706 is amended as follows:

1. The authority citation for 32 CFR part 706 continues to read:

Authority: 33 U.S.C. 1605.

§ 706.2 [Amended]

2. Table II of § 706.2 is amended by adding the following vessel:

TABLE TWO

Vessel number	Masthead lights distance to sted of keel in meters; rule 21 (a)	Forward anchor light distance below flight deck in meters; 2(K), annex I	Forward anchor light, number of rule 30(a)(I)	Aft anchor light, distance below flight deck in meters; rule 21(e) rule 30(a) (II)	Aft anchor light number of rule 30(a) (II)	Side lights distance below flight deck in meters 2(g), annex I	Side lights distance forward of forward masthead light in meters; 3(b) annex I	Side lights distance inboard of ship's sides in meters 3(b) annex I
USS KEARSARGE (LHD 3)	8.9	.....	.....	.....	.....	3.0	91	.....

3. Table Five of § 706.2 is amended by adding the following vessel:

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstructions. Annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship. Annex I sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light. Annex I, sec. 3(a)	Percentage horizontal separation attained.
USS Kearsage	LHD 3	.....	X	X	30.5

Dated: December 22, 1992.

Approved:

W.L. Schachte, Jr.,

Rear Admiral, JAGC, U.S. Navy Acting Judge Advocate General.

[FR Doc. 93–951 Filed 1–13–93; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 1 and 10

[Docket No. 920539–2313]

RIN 0651–AA51

Revision of Patent Cooperation Treaty Provisions

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (Office) is amending the rules of practice relating to applications filed under the Patent Cooperation Treaty (PCT): (1) To amend the rules in accordance with revised regulations under the PCT; (2) to bring the rules regarding applications entering the national stage under 35 U.S.C. 371 more in line with existing regulations applicable to national applications filed under 35 U.S.C. 111; and (3) to clarify existing practice under the PCT. The changes will result in more streamlined and simplified procedures for filing and prosecuting international and national stage applications under the PCT.

EFFECTIVE DATE: May 1, 1993.

FOR FURTHER INFORMATION CONTACT: Vincent Turner by telephone at (703) 305–9384 or by mail addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231 and marked to the attention of Vincent Turner (Crystal Park 2, room 919).

SUPPLEMENTARY INFORMATION: The Office published a notice of proposed rulemaking relating to revision of the Patent Cooperation Treaty provisions, in the **Federal Register**, 57 FR 29248 (July 1, 1992) and in the Official Gazette, 1140 Off. Gaz. Pat. Office 27 (July 14, 1992). No oral hearing was held. Eight individuals or organizations submitted written comments in response to the notice of proposed rulemaking. The eight written comments are available for public inspection in the Office of the Assistant Commissioner for Patents, room 919, Crystal Park II, 2121 Crystal Drive, Arlington, VA.

Familiarity with the notice of proposed rulemaking is assumed. Changes in the text of the rules published for comment in the notice of proposed rulemaking are discussed. Comments received in writing in response to the notice of proposed rulemaking are discussed.

This rule change will improve filing and processing procedures for applicants both in the filing of international applications and in the filing of national stage applications under 35 U.S.C. 371.

Background

During the first 14 years under the PCT, the annual volume of international patent applications filed in the U.S. Receiving Office has increased from just under 100 to almost 10,000 in fiscal year 1991. The volume of U.S. national stage applications has shown similar growth to the point that the U.S. is now designated more than 10,000 times each year by applicants filing international applications under the PCT. Historically, approximately 60% of those applicants that designate the U.S. enter the national stage in the United States.

On July 8 to 12, 1991, representatives of the patent offices of the member countries, in a series of meetings held in Geneva, Switzerland, agreed upon several changes to the PCT regulations which are designed to make the PCT more user-friendly. These adopted changes require corresponding changes in Title 37, CFR.

The practice under the revised PCT regulations will permit an applicant to

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provide, in addition to at least one specified designation, a precautionary designation of all other PCT member countries and regions so that any intended designation which may have been overlooked on filing can be corrected within 15 months of the priority date by confirmation of the designation. Applicants are cautioned, however, that in order for the confirmation of a designation of the U.S. to be valid, the inventor must have been named in the application papers as filed, 37 CFR 1.421(b).

International applications are searched and published prior to the 20-month deadline for entry into the national stage. If a demand for preliminary examination is filed before expiration of 19 months from the priority date, the time for entry into the national stage is extended to 30 months from the priority date and the international application will be subject to preliminary examination under chapter II of the PCT. The practice under the revised PCT regulations permits an applicant to indicate in the demand that preliminary examination is to be based on an accompanying PCT article 34 amendment and, if the amendment is not received with the demand, the applicant will be notified and given a time period within which to file the missing amendment. This new procedure will ensure that examination will go forward based on the desired PCT Article 34 amendment.

Also, the Office is aware that certain applicants have had difficulty in properly filing national stage applications due to the different requirements in the rules for PCT and U.S. national applications. Some differences cannot be avoided due to different procedures required under the PCT from U.S. national practice. It is desirable, however, to minimize these differences and to simplify national stage filing procedures.

International applications have become abandoned for failure to timely provide an oath or declaration, a filing fee and/or an accurate translation. In national practice under 35 U.S.C. 111, if any of these items was not presented at the time of filing, a notice would be mailed to the applicant setting a period of time to provide the missing item(s) and to pay a fee. The amendments to the rules governing entering the national stage will establish a greater degree of uniformity of practice and requirements for filing an application under 35 U.S.C. 111 and entering the national stage in an international application under 35 U.S.C. 371.

Amending § 1.494 and 1.495 results in regulations much like the present § 1.53. The major exception is that a notification of any missing parts in § 1.494 and 1.495 will only be mailed in those instances where the applicant has paid the basic national fee within 20 or 30 months from the priority date depending on whether election of the U.S. under chapter II of the PCT has been made prior to 19 months. Applicants can no longer pay the basic national fee with a surcharge after the 20/30 months deadline. Failure to pay the basic national fee within 20/30 months from the priority date will result in abandonment of the application. Paying the fee gives a clear indication to the Office that the applicant desires to enter the national stage. If the required oath, declaration or translation has not been filed within 20/30 months from the priority date, as appropriate, the Office will send applicant a notice and provide a period of time to supply the deficiency. Upon paying the basic national fee within 20/30 months from the priority date, the applicant will have the opportunity to inform the Office of a U.S. correspondence address, if any. Thus, the Office will avoid unnecessary handling of approximately 40% of those applications that designate the U.S. but do not enter the national stage, and will be able to send a notice to a U.S. correspondence address in most cases.

Often at 20 or 30 months from the priority date, the only communication which has been received by the Office is a copy of the international application from the International Bureau with the address of the foreign attorney or agent who represented the applicant in the international stage. The foreign attorney or agent may not be conversant in English or knowledgeable about U.S. practice, factors which often contribute to complicating the processing of applications. Thus, the new practice, which requires payment of the basic national fee on or before 20 or 30 months from the priority date, has several advantages: (1) It will enable the applicant to identify the U.S. attorney or agent for correspondence from the Office; (2) the Office, after a check of the national stage papers at 20 or 30 months, will mail a notice identifying any deficiencies and affording applicant a period for correction of those deficiencies; and (3) as in national practice under § 1.53, it will enable applicants to extend the period of time under § 1.136 for submission of a proper oath, declaration or translation.

The changes to §§ 1.494 and 1.495 address the problems which have been most frequently encountered in entering the national stage in the United States. The new practice of notifying applicants of the omission of a proper oath, declaration or translation and setting an extendable period of time for correction will allow applicants greater flexibility in the time for submission of these documents, thus avoiding the consequence of abandonment and potential loss of rights in the United States.

Implementation

The rule changes which reflect corresponding amendments in the PCT regulations were implemented on 01 July 1992 when the amendments became effective. The remaining rule changes will be effective on 01 May 1993. Setting a date for the rules to take effect several months in the future will allow time for applicants to change their procedures to conform to these rules.

Those international applications entering the national stage under § 1.494 where 20 months from the priority date expires on, or before, 30 April 1993 are under the old rule (§ 1.494 effective 01 July 1987) and those international applications entering the national stage under § 1.495 where 30 months from the priority date expires on, or before, 30 April 1993 are under the old rule (§ 1.495 effective 01 July 1987). Those international applications entering the national stage under section 1.494 where 20 months from the priority date expires on, or after, 01 May 1993 are under the new rule (§ 1.494 effective 01 May 1993) and those international applications entering the national stage under § 1.495 where 30 months from the priority date expires on, or after, 01 May 1993 are under the new rule (§ 1.495 effective 01 May 1993). For example:

(1) If a copy of an international application (which designates the U.S.) that has a priority date of 30 August 1991 is filed in the Office by 30 April 1993 (within 20 months from the priority date), applicant may enter the national stage under 37 CFR 1.494 by submitting any required English translation, the basic national fee and the oath or declaration not later than 30 June 1993. Of course, the payment of the surcharge and processing fee (37 CFR 1.492(e) and (f)) would also be due.

(2) If a copy of an international application (which elected the U.S. before expiration of 19 months from the priority date) that has a priority date of 30 October 1990 is filed in the Office by 30 April 1993 (within 30 months from the priority date), applicant may enter the national stage by submitting any required English translation, the basic national fee and the oath or declaration not later than 30 June 1993. Of course, the payment of the surcharge and processing fee (37 CFR 1.492(e) and (f)) would also be due.

(3) If a copy of an international application (which designates the U.S.) that has a priority date of 01 September 1991 is filed in the Office by 03 May 1993 (within 20 months from the priority date—01–02 May 1993 being a Saturday and Sunday, respectively), then applicant must pay the basic national fee by 03 May 1993 to avoid abandonment of the application. If the basic national fee is timely paid, a notice will then be sent to applicant giving a time period within which to file the oath or declaration and any required translation (new § 1.494(c)).

(4) Any international application having a priority date of 01 September 1991, or later, is under the new rule. Thus, if applicant files papers for the national stage indicated to be under the procedure of the old rule (§ 1.494) in the Office before 01 May 1993 (i.e., before expiration of 20 months from the priority date) but omits the basic national fee, the application will, nonetheless, become abandoned at midnight on 03 May 1993 (after 20 months from the priority date—01–02 May 1993 being a Saturday and Sunday, respectively) because applications where the 20-month deadline expires on or after 01 May 1993 come under the new practice. In accordance with new § 1.494 (i) a copy of the international application must be furnished to the Office, and (ii) the basic national fee must be paid before expiration of 20 months from the priority date.

Response to Comments on the Rules

Eight written comments were received in response to the notice of proposed rulemaking. All of the comments were considered in adopting the changes set forth herein. The comments and responses to the comments follow.

Comment 1. One comment stated that "The proposed addition to § 1.431(b)(1) of 'and the papers filed at the time of receipt of the international application [so] indicate' goes beyond the requirements set forth in the PCT and is contrary to PCT Administrative Instructions, section 329." Two other similar comments were received and urged, in effect, that § 1.431(b)(1) be revised to adopt the procedure set forth in section 329 of the PCT Administrative Instructions.

Response: The suggestion has not been adopted. The provisions adopted in § 1.431(b)(1) are consistent with, and required by, article 11 of the PCT as interpreted by the Office. Section 329 of the PCT Administrative Instructions was issued by the International Bureau after the Bureau was advised that the Office believed new section 329 to be inconsistent with requirements of Article 11 of the Treaty and inconsistent with over 13 years of practice in the United States. In the opinion of the Office, PCT Administrative Instruction 329 is inconsistent with PCT Article 11 and Rule 20.4(a), which require the Office to promptly determine whether the applicant does not obviously lack, by reasons of residence or nationality, the right to file an international application. In accordance with PCT Rule 89.1(b), "The Administrative Instructions shall not be in conflict with the provisions of the Treaty, these regulations, * * *." The United States will not follow Administrative Instruction 329.

Comment 2. One comment stated that in § 1.431(c), the reference to "PCT Rule 15.2" should be to "PCT Rule 15" because PCT Rule 15.1 is also relevant, and the reference to "§ 1.445" should be changed to refer to "PCT Rules 14 and 16.1 because § 1.445 does not cover the European Patent Office (EPO) search fee which is also paid to the USPTO."

Response: The suggestion has not been adopted. The references to Rule 15.2 and § 1.445 are considered proper in the context in which they are used. The references to Rule 15.2 and § 1.445 are not new and have worked well in directing applicants regarding international application requirements. The EPO search fee is not mentioned in § 1.431, but is published in each issue of the Official Gazette for applicant's information.

Comment 3. One comment stated that in § 1.431(d), the words "one designation fee' should be deleted since this is covered by § 1.432(b) and that "timely made" in line 5 be changed to "paid within the one-month period" for clarity.

Response: The first suggestion in the comment is not adopted. The reference to "one designation fee" in § 1.431(d) is repeated in § 1.432(b) to add clarity on this important point. The second suggestion in the comment is not adopted since it would introduce error into § 1.431(d). Indeed, all the fees must be paid timely, and need not be paid within the one-month period set pursuant to § 1.431(c), e.g., some fee(s) may be paid prior to the one-month period. Presumably the one-month period mentioned in the comment refers to a period set pursuant to § 1.431(c) which may not need to be set in every case.

Comment 4. One comment indicated that (in the fourth paragraph of the Supplementary Information section) the discussion of new § 1.432 includes a reference to a "generic" designation of all countries which, instead, should refer to a precautionary designation of all countries except the required specified designation(s).

Response: The appropriate change has been made to the discussion of § 1.432 to clarify that an applicant may provide, in addition to at least one specified designation, a precautionary designation of all other PCT member countries and regions so that any intended designation which may have been overlooked on filing can be corrected within 15 months of the priority date.

Comment 5. One comment stated that in § 1.432(a) and (b) the word "request" should be capitalized in view of § 1.401(d). A corresponding comment was made with respect to § 1.451(a).

Response: This suggestion is adopted since PCT Rule 4.10 requires the designations to appear on the Request (form RO/101) and § 1.432 continues to require that the designation(s) be indicated in the Request on filing. Similarly, with respect to § 1.451(a), the suggestion is adopted.

Comment 6. One comment stated that in § 1.432(a) "or regions" should be changed to "for the purpose of obtaining national or regional patents".

Response: The suggestion is adopted to the extent that § 1.432(a) has been changed by replacing "or regions" with "including an indication that applicant wishes to obtain a regional patent, where applicable." The adopted wording is preferable since it is the same as the wording of PCT Rule 4.9(a)(ii).

Comment 7. One comment objected to the requirement contained in § 1.432(a) that designations in the international application shall be stated as provided in PCT Rule 4.9(a) and section 115 of the Administrative Instructions Under the PCT. Also, the comment urged that the PCT Administrative Instructions should be reproduced in §§ 1.432 and 1.451 so that applicants have access to them.

Response: Section 115 of the PCT Administrative Instructions makes reference to the names and abbreviations of all countries. Inclusion of such a long list would unnecessarily encumber § 1.432(a). The Administrative Instructions are readily available, and a list of countries is provided in the Manual of Patent Examining Procedure (chapter 200). Applicants using a current Request form will inherently comply with PCT Rule 4.9(a) and sections 110 and 115 of the PCT Administrative Instructions.

Comment 8. One comment asked "If an applicant does not pay the fee(s) set out in § 1.432(c)(2) or (3), will he/she be given an additional month to pay the fees described in § 1.432(b)(1) and (2)?"

Response: No extension of time is available to the 15-month deadline of § 1.432(c). The time period set under § 1.432(b) does not apply to section § 1.432(c). If payment for the designations to be confirmed under § 1.432(c) is not received by 15 months from the priority date, those precautionary designations are considered to be withdrawn, PCT Rule 4.9(b).

Comment 9. One comment suggested adding references to PCT Rule 4.9(a) and (b) in various locations in § 1.432.

Response: The suggestion is adopted by adding appropriate references to PCT Rule 4.9(a) and (b).

Comment 10. One comment suggested that the last sentence in § 1.432(b) be moved to become the second sentence of § 1.432(b) and the third sentence be moved to become the last sentence of § 1.432(b).

Response: These suggestions are not adopted since they would not constitute an improvement to § 1.432(b).

Comment 11. One comment suggested that, in § 1.432(c)(3) unconfirmed designations indicated to be "considered withdrawn" should be changed to "regarded as withdrawn by the applicant".

Response: This suggestion has not been adopted because it does not further clarify § 1.432(c)(3). Unconfirmed designations are considered to be withdrawn by the applicant under PCT Rule 4.9(b)(ii) and are also considered to be withdrawn by the Office.

Comment 12. One comment suggested that § 1.446(d) should be expanded to indicate that a refund of the search fee will be given even after the search copy has been transmitted just so long as the withdrawal is effective before start of the international search.

Response: This suggestion has not been adopted since refunds may or may not be appropriate in the noted instance. For example, if the EPO acting as an international searching authority begins the search after withdrawal but before receipt of the withdrawal from the U.S. receiving office, a refund may not be made.

Comment 13. On comment suggested that in § 1.446(e) "demand" should be capitalized in view of § 1.401(g).

Response: This suggestion is adopted.

Comment 14. One comment suggested that the reference in § 1.451(a) to section "201" of the Administrative Instructions should be changed to "115"

Response: This suggestion is adopted since section "201" of the Administrative Instructions has been changed effective July 1, 1992, and is now section "115".

Comment 15. One comment noted that the proposed change in § 1.455(a) does not reflect that a common representative need not be "appointed".

Response: A new sentence has been inserted into § 1.455(a) to address the situation where no common representative or agent has been appointed. Where no common representative or agent has been appointed, the first mentioned applicant who is entitled to file in the U.S. receiving office is considered to be the common representative, PCT Rules 2.2bis and 90.2(b).

Comment 16. One comment noted that the proposed change in § 1.455(a) does not reflect that if a new common representative is appointed, the previous common representative is automatically revoked.

Response: The last sentence of § 1.455(a) has been changed to reflect that the later appointment of an attorney, agent or common representative revokes any earlier appointment unless otherwise indicated.

Comment 17. One comment suggested that "In §§ 1.475(a), 1.488(a) and 1.499(e) reference should be added to PCT Rule 13, Administrative Instructions, section 206, and possibly to Annex B of the Administrative Instructions."

Response: The suggestion is not adopted because it gives no reasons for the proposed change and it is not evident that the change is needed.

Comment 18. One comment stated that in the Supplementary Information discussion of § 1.475(b), the explanation of "specially adapted" was different from the explanation in Annex B, part I of the Administrative Instructions.

Response: The discussion of § 1.475(b) has been revised to conform to Annex B, Part I of the Administrative Instructions.

Comment 19. One comment stated that in § 1.484(b) no need is seen for adding the last two sentences because "The provision relates only to International Searching Authority practice and is set forth in more detail by the PCT Rules."

Response: Section 1.484(b) is directed to conduct of the International Preliminary Examining Authority rather than the International Searching Authority. The explanation in § 1.484(b) is retained because, although it parallels PCT Rule 69.1(e), it informs applicants that delay in submission of an amendment will delay the start of examination. Applicants should be aware that, since the time for issuance of the final report is fixed by PCT Rule 69.2 and may not change, any delay in the start of examination may work to applicants' disadvantage. For example, the minimum time may have to be set for response to any opinions, there may be time for only one opinion and/or there may be less time for interviews.

Comment 20. On comment suggested that § 1.485 should be amended to take into account that amendments are permitted under PCT Rule 66.4bis even after the time period set by the International Preliminary Examining Authority.

Response: This suggestion is not adopted. Section 1.485 sets forth when an amendment may be filed so that it will be considered. Amendments filed at other times may not be considered.

Comment 21. One comment suggested that the beginning of section 1.492 should be changed to reflect that, in view of H.R. 3531, the national stage fees are under 35 U.S.C. 41(a) rather than under 35 U.S.C. 376.

Response: H.R. 3531 was enacted into law (Public Law 102–204). Accordingly, the suggestion in the comment has been adopted by revising the introductory language in § 1.492 to remove the reference to 35 U.S.C. 376.

Comment 22. One comment urged that in the Discussion of Specific Rules for §§ 1.494(b) and 1.495(b), the discussion should be modified to clarify that the applicant need only check "his or her" files to be sure that the Bureau's notice regarding transmittal of a copy of the international application has been received.

Response: The language has been revised to eliminate any ambiguity.

Comment 23. One comment suggested that "as filed" in § 1.494(c) should be set off by commas as in § 1.495(c).

Response: Section 1.494(c) has been changed as suggested.

Comment 24. One comment questioned the phrases "accurate translation" and "proper translation" as used in the Supplementary Information discussion and stated that these phrases do not further explain the word "translation" as used in the statute. Another comment suggested that the rule should provide for correction of errors in the translation without penalty of abandonment or surcharge.

Response: The statute (35 U.S.C. 371(c)(2)) requires that applicant file a translation of the international application to avoid abandonment (35 U.S.C. 371(d)). The Office has received purported translations which include amendments to the text of the international application and other inconsistencies with the text of the non-English language document. It is helpful to explain that a translation must be accurate and a proper translation. The

Office does not inspect a purported translation for all errors, it only inspects for errors which are apparent on the face of the document. For example, where the non-English language international application has 6 claims and the purported translation has 8 claims, obviously the requirement for a proper translation has not been met. Submission of inaccurate translations require additional processing by the Office, thus the requirement for a processing fee is appropriate.

Comment 25. One comment stated that in the Supplementary Information discussion of §§ 1.494 and 1.495 the reference to the U.S. correspondence address should be modified to add "if any" since none is required.

Response: The suggestion has been adopted.

Comment 26. One comment stated that in the preamble of § 1.495(e) there appears to be a contradiction in that the first sentence suggests a translation of the annex may be filed within the time period set under 1.495(c) whereas the second sentence suggests the translation of the annex must be filed by 30 months or "be considered cancelled."

Response: The sentences are compatible. The first sentence applies to the case where the translation, oath or declaration have not been submitted by 30 months. In such case, they (and any annex) may be submitted within the time period of paragraph (c). The second sentence applies to the case where the translation and oath or declaration have been submitted by 30 months, whereupon no additional time is set under paragraph (c). Thus, in the first instance, if applicants are given additional time to submit the translation or oath or declaration, they may also submit the annex in that same additional time. But where the translation and oath or declaration have been submitted by 30 months, an additional time period will not be provided simply for submitting a translation of the annex. Of course, applicant may submit a preliminary amendment under 37 CFR 1.121 including the subject matter of the annex.

Comment 27. One comment suggested that §§ 1.494(b)(3) and 1.495(b)(3) should be amended to permit an extension of time for the basic national fee so that it may be submitted, like the declaration and translation, after 20 and 30 months.

Response: The suggestion is not adopted. Submission of the basic national fee gives the Office a clear indication that applicant intends to enter the national stage. This helps the Office to avoid processing of those 40% of the international applications which designate the U.S. but do not enter the national stage. Also, filing of the basic national fee by 20 or 30 months will ordinarily provide the Office with the correspondence address of the person prosecuting the national stage application. Without this correspondence address, the Office would send any notice of missing parts to the correspondence address in the international application (e.g., the person who prosecuted the international stage and who may not be qualified to prosecute the U.S. national stage). The rules as amended address the greatest hurdle for entry into the national stage which has been submission of the oath or declaration by the 22 or 32-month deadline.

Comment 28. One comment suggested that §§ 1.494(d) and 1.495(d) should indicate that the PCT Article 19 amendments (which have not been received) are not only considered to be cancelled, but are also "disregarded under PCT Rule 49.5(c-bis)."

Response: The suggestion is not adopted because this additional reference to PCT Rule 49.5(c-bis) is not helpful. The indication that the PCT Article 19 amendments are cancelled is in accordance with 35 U.S.C. 371(d). It is standard practice in the examination of a patent application in the United States to disregard amendments that have been cancelled.

Comment 29. One comment suggested that, with respect to § 1.494, "The proposed rules do not make clear the relationship between paragraphs (c) and (g) as to the time period set for later furnishing of the translation into English."

Response: Paragraph (c) provides that applicant will be provided a period of time to file the translation (if the requirements of paragraph (b) have been met) and paragraph (g) provides that the application becomes abandoned if any required translation is not filed within the time period set in paragraph (c). Thus, where the other requirements have been met but the translation has not been provided, paragraph (c) provides a time period for submission of the translation and paragraph (g) provides the sanction (abandonment) for failing to comply within the set period.

Comment 30. One comment questioned whether the time period for translation of any PCT Article 19 amendments should be extendable with any extension for translation of the international application. A corresponding comment was made with respect to § 1.495.

Response: An extension of time for submission of the translation of any PCT Article 19 amendment is not possible in view of the provisions of 35 U.S.C. 371(d).

Comment 31. One comment suggested that §§ 1.494(g) and 1.495(h) should be modified by replacing "the translation" with "any required translation."

Response: The suggestion is adopted. Translations are not required where the international application was filed in English.

Comment 32. One comment suggested that at the beginning of § 1.495(c) after "paragraph (b)" the word "of" should be added.

Response: The suggestion is adopted.

Comment 33. One comment suggested that § 1.495(d) could be deleted since under PCT Rules 70.16 and 74.1 relevant amendments under PCT Article 19 must be annexed to the international preliminary examining report and therefore must be translated under § 1.495(e). It was further noted that superseded PCT Article 19 amendments need not be translated.

Response: The suggestion is not adopted. Section 1.495(d) covers the situation where the PCT Article 19 amendment is not annexed. For example, where applicant enters the national stage in the U.S. and withdraws the international application before issuance of the final report. In this instance, translation of the PCT Article 19 amendments would have to be submitted by the date of commencement of the national stage (which cannot be later than 30 months) or be considered cancelled.

Comment 34. One comment observed that under § 1.495(e) if there is no time period to be set for submission of the translation of the international application and/or the oath or declaration, there is no possibility for extra time (after the 30-month deadline) for submission of a translation of the annex. It was suggested that section 1.495(e) be reworded to permit extra time (after the 30-month deadline) for submission of a translation of the annex even where the translation of the international application and/or oath or declaration had been submitted by 30 months.

Response: The suggestion is not adopted. Where the translation of the international application and/or the oath or declaration have been submitted by 30 months, it is appropriate to promptly forward the application for examination rather than delay examination for a translation of the annex (especially since often it appears that applicant does not wish to proceed on the basis of the annex). Some applicants prefer to submit preliminary amendments under § 1.121 (which may

be done even after 30 months) rather than to submit a translation of the annex.

Comment 35. One comment urged that § 1.495(e) is inconsistent in that it states that the 30-month time limit may not be extended, and then states that if the translation of the international application is not filed within 30 months from the priority date additional time may be set under paragraph (c) of this section.

Response: The two statements are not contradictory. The time period for submission of the translation and oath or declaration is a new time period and is not an extension of the 30-month time limit. The fixed time limit for submission of the basic national fee is 30 months for the priority date. If the basic national fee is not paid by this 30-month deadline, the application is abandoned. If, on the other hand, the basic national fee is paid by 30 months from the priority date, the pendency of the international application continues past 30 months. If the translation or oath or declaration have not been filed by the 30-month deadline (but the basic national fee has been paid), the application is not abandoned and a time period is set for submission of the missing translation and oath or declaration.

Comment 36. One comment asked "Is it the intention of the Patent and Trademark Office to affect, in any way, the current practice of assigning a date on which the section 371(c)(4) requirement (oath or declaration) will be deemed to have been met, if an applicant submits an oath or declaration in response to a Notice of Missing Parts, thereby ultimately affecting the section 102(e) date to which the eventually granted U.S. patent will be entitled?"

Response: Nothing in the new rule will affect the 35 U.S.C. 102(e) date which will continue to be the date that the last of the 35 U.S.C. 371(c) (1), (2) and (4) requirements are fulfilled.

Comment 37. One comment suggested that section 1.821 be clarified to reflect that the notice requiring compliance with paragraphs (b) through (f) is sent by the international searching authority.

Response: The suggestion is not adopted. Section 1.821 does not specify who will send the notice and there is no need to do so in the rule.

Comment 38. One comment questioned as to section 10.9 whether a pro se applicant from Brazil, who is either an individual or a company, would have the right to practice before the U.S. as an international searching or international preliminary examining authority.

Response: Section 10.9 has been amended to clarify that it is not directed to pro se applicants.

Discussion of Specific Rules

The following is a table correlating PCT Rule changes with the new 37 CFR changes. Sections 1.431(b)(1), 1.431(b)(3)(ii), 1.451(a), 1.482(a)(2)(i), 1.492(e), 1.494 and 1.495, which are also amended, are not shown in the table because they are changes that are not required by PCT Rule changes.

RULE CORRELATION TABLE

37 CFR change	PCT rule change
1.431(c)–(e)	16bis, 27.1.
1.432(a)	4.1(b)(iv), 4.9.
1.432(b)	5.5, 16bis.
1.432(c)	15.5
1.434(a)	3.1.
1.445(a)(4)	15.5.
1.446(d)	15.6, 16.2.
1.446(e)	57.6
1.455(a)	90, 2.2bis.
1.475	13.
1.476(a)	13.
1.480(b)	53.1.
1.482(b)	57.5.
1.484(b)	60.1(g), 66, 69.1.
1.485	60.1(g).
1.487	13.
1.488(a)	13.
1.499	13.
1.821(h)	13ter.1(c).
10.9(c)	90.

Section 1.431(b)(1) is amended to clarify that an international filing date will be accorded to an International application filed in the United States where at least one applicant is indicated to be a resident or national of the United States in the papers as filed. If the papers, as filed, indicate a residence or nationality for at least one applicant, the United States Receiving Office can promptly determine whether, as required by PCT Article 11, "the applicant does not obviously lack" the requisite residence or nationality to file an international application in the United States Patent and Trademark Office.

Section 1.431(b)(3)(ii) is amended to add a cross-reference to § 1.432 which sets forth the requirements regarding designations.

Section 1.431(c) is amended to reflect that the United States Receiving Office, rather than the International Bureau, will be responsible for collecting fees not paid in full at the time of filing the international application or within one month thereafter. The change reflects the procedural change under the new PCT Regulations that the Receiving Office, rather than the International Bureau, will be responsible for communicating deficiency notices to the applicant and collecting the necessary fees. Under the procedure in paragraph (c), a notice of any fee deficiency will be mailed by the Receiving Office setting a time period of one month for payment of the fee deficiency and a late payment fee equal to the greater of (1) 50% of the amount of the deficient fees up to a maximum amount equal to the basic fee, or (2) an amount equal to the transmittal fee. The time period of one month for response to this notice cannot be extended.

Section 1.431(d) is eliminated as unnecessary since the United States Receiving Office will take over the responsibility for collecting fees in place of the International Bureau.

Section 1.431(e) is redesignated as 1.431(d) and clarifies that the failure to timely pay the fees pursuant to paragraph (c) will result in the withdrawal of the international application.

Section 1.432(a) is amended to clarify that the applicant must specify, on filing, at least one national or regional designation in order to be granted a filing date for the international application. This specific designation is required whether or not all designations are indicated pursuant to paragraph (c) of this section. The reference to section 201 of the Administrative Instructions has been changed to section 115 to correspond to the change in the Administrative Instructions.

Section 1.432(b) is amended to establish a procedure for the late payment of fees for designations that were specified on filing an international application, and a procedure, pursuant to PCT Rule 16bis.1(c), in accordance with section 321 of the PCT Administrative Instructions for allocating fees, where the amount paid is insufficient to cover all the fees. The payment of the designation fees with a late payment fee (previously termed a "surcharge") is not new. Under the revised PCT regulations, however, the Receiving Office, rather than the International Bureau, will be responsible for communicating deficiency notices to the applicant. The designation fees may be paid, without necessity for a late payment fee, within one year from the priority date or within one month from the date of receipt of the international application if that month expires after the expiration of one year from the priority date. The applicant will be notified and given one month within which to pay any deficient designation fees plus a late payment fee. The amount of the late payment fee is equal to 50% of the deficient fees, but will not be less than the amount of the transmittal fee (currently $200) and will not exceed the amount of the basic fee (currently $525).

The one-month time limit for payment of the deficient designation fees and late payment fee may not be extended. If, after expiration of the one-month time period, at least one designation fee has not been paid (with any late payment fee which is due), the international application will be withdrawn. If, after expiration of the one-month time period, at least one designation fee has been paid (with any late payment fee which is due) but the amount paid is not sufficient to cover the late payment fee and all the designation fees, the amount paid will be allocated, pursuant to PCT Rule 16bis.1(c), in accordance with section 321 of the Administrative Instructions. Section 321 of the Administrative Instructions provides that the amount will be allocated in accordance with any instructions received from the applicant or, if no instructions have been received, in the order in which the designations appear in the request part of the international application. Designations for which no designation fee is timely filed will be withdrawn. In § 1.432(b), the reference to parenthetical numbers (1) and (2) used to describe the late payment fee as proposed has been deleted in the final rule to improve clarity.

New § 1.432(c) establishes a procedure wherein, in addition to the designation(s) under paragraph (a), the applicant could indicate, on filing, all designations permitted under the Treaty and confirm desired designations of countries or regions up to 15 months from the priority date. Section 1.432(c) as promulgated requires that applicant's indication of all designations permitted under the Treaty in addition to the designation(s) under paragraph (a) be made in the Request in accordance with PCT Rule 4.9(b). The confirmation must include both a written notice of the countries or regions being confirmed, the appropriate designation fees and a confirmation fee based on the number of countries or regions being confirmed. If the amount of the fees is insufficient, the Receiving Office will allocate the amount paid in accordance with any priority of designations specified by the applicant or, if no priority is specified, in accordance with section 321 of the Administrative Instructions. A notice reminding applicant of the 15-month deadline will not be provided. Unconfirmed designations will be considered withdrawn.

Section 1.434 is amended to allow applicants to develop their own computer-generated Request form so long as the forms comply with the requirements of sections 102 (h) and (i) of the Administrative Instructions. Printed Request forms will continue to be available from the United States Patent and Trademark Office.

New § 1.445(a)(4) defines the amount of the confirmation fee required for the designations confirmed under § 1.432(c). The confirmation fee is equal to 50% of the sum of the designation fees for the designations being confirmed. For example, a confirmation of four additional designations (at $127 per designation, or $508) would require a $254 confirmation fee. The total amount of the fees due would be $762, which is the sum of $508 and $254.

Section 1.446(d) is amended to clarify that the international (basic and designation, PCT Rule 15.1) and search fees may be refunded under certain circumstances linked to whether the record copy or search copy has been transmitted to the International Bureau or International Searching Authority, respectively. The transmittal fee and any late payment fees will not be refunded, but will be retained to cover Office processing costs. If the record copy or search copy has been transmitted, the Receiving Office cannot refund or authorize the refund of the international or search fees. Any request for a refund filed after the record copy or search copy has been transmitted should be directed to the International Bureau (for the international fee) or the International Searching Authority (for the international search fee) for consideration of whether a refund should be made.

New § 1.446(e) indicates that a refund of the handling fee by the International Preliminary Examining Authority is permitted only in the situations where the demand is considered not to have been submitted or upon withdrawal of the demand before the demand has been sent to the International Bureau. If the demand has been sent to the International Bureau, requests for refund of the handling fee should be directed to the International Bureau.

Section 1.451(a) is amended to clarify that the applicant must specify, on filing, the priority of a previously filed application in order to be granted priority in the international application. The right to priority is not necessarily lost if the claim is not on the Request form, but will be lost if the claim does not appear in the papers presented on filing of the application.

Section 1.455(a) is amended to clarify that the term "common representative" means an applicant appointed by the other applicants or considered to be the representative of the other applicants. Further, since attorneys and agents are registered to practice before the Office rather than licensed, § 1.455(a) has been amended by replacing the word "licensed" with "registered." The paragraph also clarifies who can represent applicants in an international application before the U.S. International Searching Authority or the U.S. International Preliminary Examining Authority, e.g., (1) An attorney or agent registered to practice before the Office, and (2) an attorney or agent not registered to practice before the Office, but authorized to practice before the national office with which the international application was filed and for which the United States is an International Searching Authority or International Preliminary Examining Authority. In the latter case, representation is restricted to practicing before the U.S. International Searching Authority and/or the U.S. International Preliminary Examining Authority. For example, if an international application is filed in the Brazilian Patent Office, an agent authorized to practice before the Brazilian Patent Office may prosecute that application before the U.S. International Searching Authority or the U.S. International Preliminary Examining Authority. Paragraph (a) also provides that, unless otherwise indicated, the appointment of an attorney, agent or common representative revokes any earlier appointment as specified in PCT Rule 90.6(b).

Section 1.475 is amended to adopt the unity of invention principles of PCT Rule 13, as amended. Section 1.475 is further amended to reflect that the same unity of invention principles are applied by the international searching and preliminary examining authorities and during the national stage. Duplicative provisions in §§ 1.487 and 1.499 are deleted.

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basis principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

Section 1.475(a) is amended to contain both the definition of the requirement for unity of invention, and the unity of invention criteria that must be satisfied, where a group of inventions is claimed, in order to have a right to include multiple inventions in a single application. A group of inventions is linked to form a single general inventive

concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression "special technical features" is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a compound is the common technical feature in an application claiming: (1) The compound per se, (2) a method of making the compound and (3) a method of using the compound. A corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key.

Section 1.475(b) is amended to define several combinations of different categories of claims which always fulfill the unity of invention requirements of § 1.475(a) where the same or corresponding special technical feature is claimed. There may be other combinations of different categories of claims which fulfill the requirement for unity of invention, but the determination of unity must be made under § 1.475(a), not § 1.475(b).

In § 1.475(b), a process is "specially adopted" for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship defined in § 1.475(a) being present between the claimed process and the claimed product. The expression "specially adapted" as used in this section does not imply that the product could not also be manufactured by a different process.

In § 1.475(b), an apparatus or means is "specifically designed" for carrying out the process when the apparatus or means is suitable for carrying out the process with the technical relationship defined in § 1.475(a) being present between the claimed apparatus or means and the claimed process. The expression "specifically designed" does not imply that the apparatus or means could not be used for carrying out another process, nor does it imply that the process could not be carried out using an alternative apparatus or means.

Section 1.475(c) is amended to require that unity of invention might not be present if a combination of categories of invention different from those described in § 1.475(b) are presented in an application. The requirements of § 1.475(a) are always met by the combinations described in § 1.475(b) where the same or corresponding special technical feature is claimed. All other combination must be tested against the unity of invention standard of § 1.475(a).

Section 1.475(d) is amended by deleting reference to the different combinations of categories of invention that always meet the unity of invention standard (now set forth in § 1.475(b)), and to make reference to the determination of the main invention where multiple products, processes of manufacture or uses are claimed. The significance of determining the main invention is set forth in § 1.476(c).

Section 1.475(e) is amended to require that the determination regarding unity of invention be made without regard to whether a group of inventions is claimed in separate claims or as alternatives within a single claim. The basic criteria for unity of invention are the same, regardless of the manner in which applicant chooses to draft a claim or claims.

Section 1.475(f) is deleted since PCT Rule 13 has been amended and the basic principles of unity of invention are incorporated into other portions of § 1.475.

Section 1.476(a) is amended to delete the reference to § 1.475(f) (which is deleted) and PCT Rule 13.

Section 1.480(b) is amended to allow applicants to develop their own computer-generated Demand form so long as the limitations in sections 102 (h) and (i) of the Administrative Instructions are met. Printed Demand forms will continue to be available from the Office.

Section 1.482(a)(2)(i) is amended to clarify that an additional preliminary examination fee may be charged for lack of unity in Chapter II irrespective of whether there was a similar charge in Chapter I. Normally there will be a charge for lack of unity both in Chapter I and in Chapter II. In some instances, although a charge for the search of an additional invention is justified in Chapter I, the examiner chooses to proceed without charging for the search of the additional invention(s). However, circumstances may change (e.g., an amendment submitted with the Demand expanding the claims to the additional invention(s)) in Chapter II so as to warrant the examiner's requirement for an additional fee for examination of examiner's requirement for an additional fee for examination of the additional invention(s).

Section 1.482(b) is amended to remove the reference to the supplement to the handling fee which had been collected for the benefit of the International Bureau and which has been deleted from the PCT regulations. At present, applicants must pay as many supplements to the handling fee as there are languages into which the elected Offices require translations of the international preliminary examination report. Under the new PCT regulations, all countries will accept an English translation of the international preliminary examination report, thus limiting the International Bureau's translation costs. Accordingly, only one handling fee will need to be paid by the applicant, without any supplement, irrespective of the need for a translation of the report.

Section 1.484(b) is amended to permit an applicant to indicate in the demand that international preliminary examination is to begin based on the application as amended rather than on the application as filed. If a PCT Article 19 amendment is not received by the Office by 20 months from the priority date, preliminary examination will proceed. Where the demand indicates examination is to be based on an accompanying PCT Article 34 amendment, but the PCT Article 34 amendment has not been provided to the Office with the demand, the applicant will be notified and given a time period to submit the amendment. Thus, if the applicant wishes preliminary examination based on an amended version of the international application, the demand must so indicate and the amendment (PCT Article 19 or 34) must (1) accompany the demand; or (2) in the case of a PCT Article 19 amendment, be received by 20 months from the priority date; or (3) in the case of the PCT Article 34 amendment, be submitted within the nonextendable time period set by the Office.

Section 1.485 is amended to be consistent with § 1.484 and provides for amendments to be filed with the demand or within a time period set by the International Preliminary Examining Authority.

Section 1.487 is removed as unnecessary because the amendments to § 1.475 address the unity of invention principles to be applied by the International Preliminary Examining Authority.

Section 1.488(a) is amended to replace the reference to § 1.487, which is removed, with a reference to § 1.475.

Section 1.492 is amended to revise the introductory clause to eliminate the reference to 35 U.S.C. 376.

Section 1.492(e) is amended to eliminate the surcharge for filing the basic national fee after 20 or 30 months from the priority date. In accordance with the new practice under §§ 1.494 and 1.495, the basic national fee must be filed no later than 20 months, or 30 months if a timely election was filed,

from the priority date in order to avoid abandonment of the application.

Sections 1.494 and 1.495 is amended to modify the practice for entering the national stage as a designated or elected office by more closely aligning it with national application practice under § 1.53.

Section 1.494(a) is amended to clarify that absence of a Demand form is no longer the controlling event, but rather failure to elect the United States within 19 months of the priority date will trigger the time periods set forth in paragraphs (b) and (c) of this section.

Section 1.494(b) is amended to require that the basic national fee and a copy of the international application must be filed with the Office by 20 months from the priority date to avoid abandonment. The 22-month period for filing the basic national fee with a surcharge in previous rule 1.494(c) has been eliminated. The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time, the International Bureau notifies the applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage and applicant has received the notice from the International Bureau, applicant need only pay the basic national fee by 20 months from the priority date. The 20-month time limit for submission of the basic national fee and a copy of the international application is not extendable.

Section 1.494(c) is amended to provide that applicants who have provided the basic national fee and a copy of the international application by 20 months from the priority date but who omit a proper translation, oath or declaration will receive a notification setting a time period for submission of the omitted requirements. The time period set in the notice can be extended pursuant to § 1.136. Filing of the oath or declaration later than 20 months will require the payment of the surcharge set forth in § 1.492(e). Filing of the translation later than 20 months will require the payment of the processing fee set forth in § 1.492(f).

Section 1.494(d) is amended to clarify the existing practice that PCT Article 19 amendments must be submitted by 20 months from the priority date, which time may not be extended. Of course, the failure to do so does not result in loss of the subject matter of the PCT Article 19 amendments. The applicant may submit that subject matter in a preliminary amendment filed under § 1.121. In many cases, filing an amendment under § 1.121 is preferable since grammatical or idiomatic errors may be corrected.

Section 1.494(g) is removed in view of the amendments to sections (b), (c) and (d).

Section 1.494(h) is redesignated as 1.494(g) and is amended to specify when an application that fails to enter the national stage becomes abandoned. Abandonment occurs at 20 months from the priority date if the basic national fee and a copy of the international application have not been provided to the Office. If they have been provided to the Office within 20 months and the translation and/or oath or declaration are not filed timely, abandonment occurs upon expiration of the time limit set in the notification pursuant to paragraph (c). Thus, in the latter situation, abandonment would occur at the expiration of the time period set in the notice to file the missing translation, and/or oath or declaration. The phrase "where the United States has been designated but not elected *prior to* 19 months from the priority date" (emphasis added) has been changed to "where the United States has been designated but not elected *by the expiration of* 19 months from the priority date" (emphasis added) for clarity. A corresponding change has been made in § 1.495(h).

Section 1.495(a) is amended to clarify that the election of the U.S. need not be made in the Demand, but can be made subsequently if filed before expiration of 19 months from the priority date to start the time periods set forth in paragraphs (b) and (c) of this section.

Section 1.495(b) is amended to require that the basic national fee and a copy of the international application must be filed with the Office by 30 months from the priority date to avoid abandonment. The 32-month period for filing the basic national fee with a surcharge in previous rule 1.495(c) has been eliminated. The International Bureau normally provides the copy of the international application to the Office in accordance with PCT Article 20. At the same time the International Bureau notifies applicant of the communication to the Office. In accordance with PCT Rule 47.1, that notice shall be accepted by all designated offices as conclusive evidence that the communication has duly taken place. Thus, if the applicant desires to enter the national stage, the applicant normally need only check to be sure that notice from the International Bureau has been received and then pay the basic national fee by 30 months from the priority date. The 30-month time limit for submission of the basic national fee and a copy of the international application is not extendable.

Section 1.495(c) is amended to provide that applicants who have provided the basic national fee and a copy of the international application by 30 months from the priority date, but who omit a proper translation, oath or declaration, will receive a notification setting a time period for submission of the omitted requirements. The time period set in the notice can be extended pursuant to § 1.136. Filing of the oath or declaration later than 30 months will require the payment of the surcharge set forth in § 1.492(e). Filing of the translation later than 30 months will require the payment of the processing fee set forth in § 1.492(f).

Section 1.495(d) is amended to clarify the existing and continuing practice that the PCT Article 19 amendments must be submitted by 30 months from the priority date. The deadline for submitting PCT Article 19 amendments may not be extended. The failure to do so will not result in loss of the subject matter of the PCT Article 19 amendments. Applicant may submit that subject matter in a preliminary amendment filed under § 1.121. In many cases, filing an amendment under § 1.121 is preferable since grammatical or idiomatic errors may be corrected.

Section 1.495(e) is amended to specify that a translation into English of any annexes to the international preliminary examining report which are not received by 30 months from the priority date may only be submitted within the time period set in paragraph (c) for submission of any omitted translation of the international application, or oath or declaration. If any required translation of the international application and oath or declaration have been provided to the Office by 30 months, a notice under paragraph (c) will not be sent, and if the translation of annexes is not submitted within 30 months, the annexes will be considered cancelled.

Section 1.495(h) is removed in view of the amendments to sections (b), (c), (d) and (e).

Section 1.495(i) is redesignated as 1.495(h) and specifies when an application that fails to enter the national stage becomes abandoned if the United States was elected prior to 19 months from the priority date. Abandonment occurs at 30 months from the priority date if the basic national fee and a copy of the international application have not been provided to the Office. If they have been provided to

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the Office within 30 months and the translation and/or oath or declaration are not filed timely, abandonment occurs upon expiration of the time limit set in the notification pursuant to paragraph (c). Thus, in the latter situation, abandonment would occur at the expiration of the time period set in the notice to file the missing translation, and/or oath or declaration.

Section 1.499 is amended by removing paragraphs (a) through (e) because the amendments to § 1.475 address the unity of invention principles to be applied in the national stage. The reference to the official action being called a requirement for restriction has been eliminated as unnecessary.

Section 1.821(h) is amended to provide that if applicant fails to timely provide the required computer-readable form, the United States International Searching Authority shall search only to the extent that a meaningful search can be carried out.

Section 10.9 is amended to add a new paragraph (c) to be consistent with section 1.455, clarifying that an attorney or agent having the right to act before the national office with which the international application is filed may represent the applicant before the U.S. International Searching Authority or the U.S. International Preliminary Examining Authority. An individual who has the right to practice before the national office with which an international application is filed, and who is not registered under § 10.6, may not prosecute patent applications in the national stage in the Office.

Other Considerations

The rule changes are in conformity with the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., Executive Orders 12291 and 12612, and the Paperwork Reduction Act of 1980, 44 U.S.C. 3501, et seq.

The General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that the rule changes will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)), because the rules provide more streamlined and simplified procedures for filing and prosecuting international and national stage applications under the PCT.

The Patent and Trademark Office has determined that these rule changes are not a major rule under Executive Order 12291. The annual effect on the economy will be less than $100 million. There will be no major increase in costs or prices for customers; individual industries; Federal, state or local government agencies; or geographic regions. There will be no significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Patent and Trademark Office has also determined that this notice has no federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

These rule changes will not impose any additional burden under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501, et seq. The paperwork burden imposed by adherence to the PCT is currently approved by the Office of Management and Budget under control number 0651–0021.

Notice is hereby given that pursuant to the authority granted to the Commissioner of Patents and Trademarks by 35 U.S.C. 6, the Patent and Trademark Office amends title 37 of the Code of Federal Regulations as set forth below.

List of Subjects.

37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions, and patents, Reporting and record keeping requirements, Small businesses.

37 CFR Part 10

Administrative practice and procedure, Inventions and patents, Lawyers, Reporting and record keeping requirements, Trademarks.

For the reasons set forth in the preamble, 37 CFR parts 1 and 10 are amended as follows:

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 6 unless otherwise noted.

2. Section 1.431 is amended by removing paragraph (e) and revising paragraphs (b)(1) through (b)(3)(ii), (c) and (d) to read as follows:

§ 1.431 International application requirements.

* * * * *

(b) An international filing date will be accorded by the United States Receiving Office, at the time to receipt of the international application, provided that:

(1) At least one applicant (§ 1.421) is a United States resident or national and the papers filed at the time of receipt of the international application so indicate (35 U.S.C. 361(a), PCT Art. 11(1)(i)).

(2) The international application is in the English language (35 U.S.C. 361(c), PCT Art. 11(1)(ii)).

(3) The international application contains at least the following elements (PCT Art. 11(1)(iii)):

(i) An indication that it is intended as an international application (PCT Rule 4.2);

(ii) The designation of at least one Contracting State of the International Patent Cooperation Union (§ 1.432);

* * * * *

(c) Payment of the basic portion of the international fee (PCT Rule 15.2) and the transmittal and search fees (§ 1.445) may be made in full at the time the international application papers required by paragraph (b) of this section are deposited or within one month thereafter. If the basic transmittal and search fees are not paid within one month from the date of receipt of the international application, applicant will be notified and given one month within which to pay the deficient fees plus a late payment fee equal to the greater of:

(1) 50% of the amount of the deficient fees up to a maximum amount equal to the basic fee, or

(2) an amount equal to the transmittal fee (PCT Rule 16bis).

The one-month time limit set in the notice to pay deficient fees may not be extended.

(d) If the payment needed to cover the transmittal fee, the basic fee, the search fee, one designation fee and the late payment fee pursuant to paragraph (c) of this section is not timely made, the Receiving Office will declare the international application withdrawn under PCT Article 14(3)(a).

3. Section 1.432 is revised to read as follows:

§ 1.432 Designation of States and payment of designation fees.

(a) The designation of States including an indication that applicant wishes to obtain a regional patent, where applicable, shall appear in the Request upon filing and must be indicated as set forth in PCT Rule 4.9 and section 115 of the Administrative Instructions. Applicant must specify at least one national or regional designation on filing of the international application for a filing date to be granted.

(b) If the fees necessary to cover all the national and regional designations specified in the Request are not paid by the applicant within one year from the priority date or within one month from the date of receipt of the international

application if that month expires after the expiration of one year from the priority date, applicant will be notified and given one month within which to pay the deficient designation fees plus a late payment fee equal to the greater of 50% of the amount of the deficient fees up to a maximum amount equal to the basic fee, or an amount equal to the transmittal fee (PCT Rule 16bis). The one-month time limit set in the notification of deficient designation fees may not be extended. Failure to timely pay at least one designation fee will result in the withdrawal of the international application. The one designation fee may be paid:

(1) Within one year from the priority date,

(2) within one month from the date of receipt of the international application if that month expires after the expiration of one year from the priority date, or

(3) with the late payment fee defined in this paragraph within the time set in the notification of the deficient designation fees. If after a notification of deficient designation fees the applicant makes timely payment, but the amount paid is not sufficient to cover the late payment fee and all designation fees, the Receiving Office will, after allocating payment for the basic, search, transmittal and late payment fees, allocate the amount paid in accordance with PCT Rule 16bis.1(c) and withdraw the unpaid designations. The notification of deficient designation fees pursuant to this paragraph may be made simultaneously with any notification pursuant to § 1.431(c).

(c) On filing the international application, in addition to specifying at least one national or regional designation under PCT Rule 4.9(a), applicant may also indicate under PCT Rule 4.9(b) that all other designations permitted under the Treaty are made. The latter indication under PCT Rule 4.9(b) must be made in a statement on the Request that any designation made under this paragraph is subject to confirmation (PCT Rule 4.9(c)) not later than the expiration of 15 months from the priority date by:

(1) Filing a written notice with the United States Receiving Office specifying the national and/or regional designations being confirmed;

(2) Paying the designation fee for each designation being confirmed; and

(3) Paying the confirmation fee specified in § 1.445(a)(4).

Unconfirmed designations will be considered withdrawn. If the amount submitted is not sufficient to cover the designation fee and the confirmation fee for each designation being confirmed, the Receiving Office will allocate the amount paid in accordance with any priority of designations specified by applicant. If applicant does not specify and priority of designations, the allocation of the amount paid will be made in accordance with PCT Rule 16bis.1(c).

4. Section 1.434 is amended by revising paragraph (a) to read as follows:

§ 1.434 The request.

(a) The request shall be made on a standardized form (PCT Rules 3 and 4). Copies of printed Request forms are available from the Patent and Trademark Office. Letters requesting printed forms should be marked "Box PCT."

* * * * *

5. Section 1.445 is amended by adding new paragraph (a)(4) to read as follows:

§ 1.445 International application filing, processing and search fees.

(a) * * *

(4) A confirmation fee (PCT Rule 96) equal to 50% of the sum of designation fees for the national and regional designations being confirmed (§ 1.432(c)).

* * * * *

6. Section 1.446 is amended by revising paragraph (d) and adding paragraph (e) to read as follows:

§ 1.446 Refund of international application filing and processing fees.

* * * * *

(d) The international and search fees will be refunded if no international filing date is accorded or if the application is withdrawn before transmittal of the record copy to the International Bureau (PCT Rules 15.6 and 16.2). The search fee will be refunded if the application is withdrawn before transmittal of the search copy to the International Searching Authority. The transmittal fee will not be refunded.

(e) The handling fee (§ 1.482(b)) will be refunded (PCT Rule 57.6) only if:

(1) The Demand is withdrawn before the Demand has been sent by the International Preliminary Examining Authority to the International Bureau, or

(2) The Demand is considered not to have been submitted (PCT Rule 54.4(a)).

7. Section 1.451 is amended by revising paragraph (a) to read as follows:

§ 1.451 The priority claim and priority document in an international application.

(a) The claim for priority must be made on the Request (PCT Rule 4.10) in a manner complying with sections 110 and 115 of the Administrative Instructions.

* * * * *

8. Section 1.455 is amended by revising paragraph (a) to read as follows:

§ 1.455 Representation in international applications.

(a) Applicants of international applications may be represented by attorneys or agents registered to practice before the Patent and Trademark Office or by an applicant appointed as a common representative (PCT Art. 49, Rules 4.8 and 90 and § 10.10). If applicants have not appointed an attorney or agent or one of the applicants to represent them, and there is more than one applicant, the applicant first named in the request and who is entitled to file in the U.S. Receiving Office shall be considered to be the common representative of all the applicants. An attorney or agent having the right to practice before a national office with which an international application is filed and for which the United States is an International Searching Authority or International Preliminary Examining Authority may be appointed to represent the applicants in the international application before that authority. An attorney or agent may appoint an associate attorney or agent who shall also then be of record (PCT Rule 90.1(d)). The appointment of an attorney or agent, or of a common representative, revokes any earlier appointment unless otherwise indicated (PCT Rule 90.6 (b) and (c)).

* * * * *

9. Section 1.475 is revised to read as follows:

§ 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

10. Section 1.476 is amended by revising paragraph (a) to read as follows:

§ 1.476 Determination of unity of invention before the International Searching Authority.

(a) Before establishing the international search report, the International Searching Authority will determine whether the international application complies with the requirement of unity of invention as set forth in § 1.475.

* * * * *

11. Section 1.480 is amended by revising paragraph (b) to read as follows:

§ 1.480 Demand for international preliminary examination.

* * * * *

(b) The Demand shall be made on a standardized form. Copies of printed Demand forms are available from the Patent and Trademark Office. Letters requesting printed Demand forms should be marked "Box PCT".

* * * * *

12. Section 1.482 is amended by revising paragraphs (a)(2)(i) and (b) to read as follows:

§ 1.482 International preliminary examination fees.

(a) * * *

(2) An additional preliminary examination fee when required, per additional invention:

(i) Where the International Searching Authority for the international application was the United States Patent and Trademark Office.....$140.00

* * * * *

(b) The handling fee is due on filing the Demand.

13. Section 1.484 is amended by revising paragraph (b) to read as follows:

§ 1.484 Conduct of international preliminary examination.

* * * * *

(b) International preliminary examination will begin promptly upon receipt of a Demand which requests examination based on the application as filed, or as amended by an amendment which has been received by the United States International Preliminary Examining Authority. Where a Demand requests examination based on a PCT Article 19 amendment which has not been received, examination may begin at 20 months without receipt of a PCT Article 19 amendment. Where a Demand requests examination based on a PCT Article 34 amendment which has not been received, applicant will be notified and given a time period within which to submit the amendment. Examination will begin after the earliest of:

(1) Receipt of the amendment;

(2) Receipt of applicant's statement that no amendment will be made; or

(3) Expiration of the time period set in the notification.

No international preliminary examination report will be established prior to issuance of an international search report.

* * * * *

14. Section 1.485 is revised to read as follows:

§ 1.485 Amendments by applicant during international preliminary examination.

(a) The applicant may make amendments at the time of filing of the Demand and within the time limit set by the International Preliminary Examining Authority for response to any notification under § 1.484(b) or to any written opinion. Any such amendments must:

(1) Be made by submitting a replacement sheet for every sheet of the application which differs from the sheet it replaces unless an entire sheet is cancelled, and

(2) Include a description of how the replacement sheet differs from the replaced sheet.

(b) If an amendment cancels an entire sheet of the international application, that amendment shall be communicated in a letter.

§ 1.487 [Removed]

15. Section 1.487 is removed.

16. Section 1.488 is amended by revising paragraph (a) to read as follows:

§ 1.488 Determination of unity of invention before the International Preliminary Examining Authority.

(a) Before establishing any written opinion or the international preliminary examination report, the International Preliminary Examining Authority will determine whether the international application complies with the requirement of unity of invention as set forth in § 1.475.

* * * * *

17. Section 1.492 is amended by revising the introductory clause and paragraph (e) to read as follows:

§ 1.492 National stage fees.

The following fees and charges are established for international applications entering the national stage under 35 U.S.C. 371:

* * * * *

(e) Surcharge for filing the oath or declaration later than 20 months from the priority date pursuant to § 1.494(c) or later than 30 months from the priority date pursuant to § 1.495(c):

By a small entity (§ 1.9(f)).....$65.00
By other than a small entity.....$130.00

* * * * *

18. Section 1.494 is amended by removing paragraph (h) and by revising paragraphs (a), (b), (c), (d) and (g) to read as follows:

§ 1.494 Entering the national stage in the United States of America as a Designated Office.

(a) Where the United States of America has not been elected by the expiration of 19 months from the priority date (see § 1.495), the applicant must fulfill the requirements of PCT Article 22 and 35 U.S.C. 371 within the time periods set forth in paragraphs (b) and (c) of this section in order to prevent the abandonment of the international application as to the United States of America. International applications for which those requirements are timely fulfilled will enter the national stage and obtain an examination as to the patentability of the invention in the United States of America.

(b) To avoid abandonment of the application, the applicant shall furnish

to the United States Patent and Trademark Office not later than the expiration of 20 months from the priority date:

(1) A copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the United States Patent and Trademark Office; and

(2) The basic national fee (see § 1.492(a)). The 20-month time limit may not be extended.

(c) If applicant complies with paragraph (b) of this section before expiration of 20 months from the priority date but omits:

(1) a translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)) and/or

(2) the oath or declaration of the inventor (35 U.S.C. 371(c)(4); see § 1.497), applicant will be so notified and given a period of time within which to file the translation and/or oath or declaration in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of 20 months after the priority date. The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of 20 months after the priority date. A copy of the notification mailed to applicant should accompany any response thereto submitted to the Office.

(d) A copy of any amendments to the claims made under PCT Article 19, and a translation of those amendments into English, if they were made in another language, must be furnished not later than the expiration of 20 months from the priority date. Amendments under PCT Article 19 which are not received by the expiration of 20 months from the priority date will be considered to be cancelled. The 20-month time limit may not be extended.

* * * * *

(g) An international application becomes abandoned as to the United States 20 months from the priority date if the requirements of paragraph (b) of this section have not been complied with within 20 months from the priority date where the United States has been designated but not elected by the expiration of 19 months from the priority date. If the requirements of paragraph (b) of this section are complied with within 20 months from the priority date but any required translation of the international application as filed and/or the oath or declaration are not timely filed, an international application will become abandoned as to the United States upon expiration of the time period set pursuant to paragraph (c) of this section.

19. Section 1.495 is amended by removing paragraph (i) and by revising paragraphs (a), (b), (c), (d), (e) and (h) to read as follows:

§ 1.495 Entering the national stage in the United States of America as an Elected Office.

(a) Where the United States of America has been elected by the expiration of 19 months from the priority date, the applicant must fulfill the requirements of 35 U.S.C. 371 within the time periods set forth in paragraphs (b) and (c) of this section in order to prevent the abandonment of the international application as to the United States of America. International applications for which those requirements are timely fulfilled will enter the national stage and obtain an examination as to the patentability of the invention in the United States of America.

(b) To avoid abandonment of the application the applicant shall furnish to the United States Patent and Trademark Office not later than the expiration of 30 months from the priority date:

(1) A copy of the international application, unless it has been previously communicated by the International Bureau or unless it was originally filed in the United States Patent and Trademark Office; and

(2) The basic national fee (see § 1.492(a)). The 30-month time limit may not be extended.

(c) If applicant complies with paragraph (b) of this section before expiration of 30 months from the priority date but omits:

(1) A translation of the international application, as filed, into the English language, if it was originally filed in another language (35 U.S.C. 371(c)(2)) and/or

(2) The oath or declaration of the inventor (35 U.S.C. 371(c)(4); see § 1.497), applicant will be so notified and given a period of time within which to file the translation and/or oath or declaration in order to prevent abandonment of the application. The payment of the processing fee set forth in § 1.492(f) is required for acceptance of an English translation later than the expiration of 30 months after the priority date. The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of 30 months after the priority date. A copy of the notification mailed to applicant should accompany any response thereto submitted to the Office.

(d) A copy of any amendments to the claims made under PCT Article 19, and a translation of those amendments into English, if they were made in another language, must be furnished not later than the expiration of 30 months from the priority date. Amendments under PCT Article 19 which are not received by the expiration of 30 months from the priority date will be considered to be cancelled. The 30-month time limit may not be extended.

(e) A translation into English of any annexes to the international preliminary examination report, if the annexes were made in another language, must be furnished not later than the expiration of 30 months from the priority date. Translations of the annexes which are not received by the expiration of 30 months from the priority date may be submitted within any period set pursuant to paragraph (c) of this section accompanied by the processing fee set forth in § 1.492(f). Annexes for which translations are not timely received will be considered cancelled. The 30-month time limit may not be extended.

* * * * *

(h) An international application becomes abandoned as to the United States 30 months from the priority date if the requirements of paragraph (b) of this section have not been complied with within 30 months from the priority date and the United States has been elected by the expiration of 19 months from the priority date. If the requirements of paragraph (b) of this section are complied with within 30 months from the priority date but any required translation of the international application as filed and/or the oath or declaration are not timely filed, an international application will become abandoned as to the United States upon expiration of the time period set pursuant to paragraph (c) of this section.

20. Section 1.499 is revised to read as follows:

§ 1.499 Unity of invention during the national stage.

If the examiner find that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the

discretion of the examiner. Review of any such requirement is provided under §§ 1.143 and 1.144.

21. Section 1.821 is amended by revising paragraph (h) to read as follows:

§ 1.821 Nucleotide and/or amino acid sequence disclosures in patent applications.

* * * * *

(h) If any of the requirements of paragraphs (b) through (f) of this section are not satisfied at the time of filing, in the United States Receiving Office, an international application under the Patent Cooperation Treaty (PCT), applicant has one month from the date of a notice which will be sent requiring compliance with the requirements, or such other time as may be set by the Commissioner, in which to comply. Any submission in response to a requirement under this paragraph must be accompanied by a statement that the submission does not include new matter or go beyond the disclosure in the international application as filed. Such a statement must be a verified statement if made by a person not registered to practice before the Office. If applicant fails to timely provide the required computer readable form, the United States International Searching Authority shall search only to the extent that a meaningful search can be performed.

* * * * *

PART 10—[AMENDED]

22. The authority citation for 37 CFR part 10 will continue to read as follows:

Authority: 5 U.S.C. 500; 15 U.S.C. 1123; 35 U.S.C. 6, 31, 32, 41.

23. Section 10.9 is amended by adding new paragraph (c) to read as follows:

§ 10.9 Limited recognition in patent cases.

* * * * *

(c) An individual not registered under § 10.6 may, if appointed by applicant to do so, prosecute an international application only before the U.S. International Searching Authority and the U.S. International Preliminary Examining Authority, provided: the individual has the right to practice before the national office with which the international application is filed (PCT Art. 49, Rule 90 and § 1.455).

Dated: January 7, 1993.

Douglas B. Comer,

Acting Assistant Secretary and Acting Commissioner of Patents and Trademarks.

[FR Doc. 93-823 Filed 1-13-93; 8:45 am]

BILLING CODE 3510-16-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[FRL-4552-4]

Designation of Areas for Air Quality Planning Purposes; Wyoming; Redesignation of Particulate Matter Attainment Areas

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: In this action EPA is approving a February 11, 1992 request from the Governor of Wyoming to redesignate the Powder River Basin in portions of Campbell and Converse Counties as a separate particulate matter attainment area under Section 107 of the Clean Air Act, as amended (CAA). In addition, EPA is redesignating two additional particulate matter attainment areas within the Powder River Basin which represent the baseline areas of two major sources that had submitted complete prevention of significant (PSD) applications after the major source baseline date. EPA is approving the State's redesignation request because the State has adequately followed the applicable federal requirements and policy. Approval of the section 107 redesignation eliminates the minor source baseline date for particulate matter which previously applied in the Powder River Basin attainment area. According to the State regulations, the minor source baseline date will not be triggered until the submittal of the first complete PSD permit application for a major stationary source or major modification locating in or significantly impacting the Powder River Basin particulate matter attainment area, or January 1, 1996, whichever occurs first. Thus, only after the new minor source baseline date is established will changes in emissions at minor sources affect the increment.

EFFECTIVE DATE: This action will become effective on March 15, 1993 unless notice is received by February 16, 1993 that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the **Federal Register.**

ADDRESSES: Copies of the revisions are available for public inspection between 8 a.m. and 4 p.m. Monday through Friday at the following offices:

Environmental Protection Agency, Region VIII, Air Programs Branch, 999 18th Street, suite 500, Denver, CO 80202-2466.

Air Quality Division, Department of Environmental Quality, 122 West 25th Street, Herschler Building, Cheyenne, Wyoming 82002.

FOR FURTHER INFORMATION CONTACT:

Vicki Stamper, Environmental Protection Agency, Region VIII, Air Programs Branch, suite 500, Denver, CO 80202-2466, (303) 293-1765.

SUPPLEMENTARY INFORMATION:

I. Background of Redesignation Request

The State's regulations had previously established August 7, 1977 as the baseline date for total suspended particulate (TSP), and the entire State was defined as the baseline area. This meant that all major, as well as minor, sources constructed anywhere in the State after August 7, 1977 would consume the available TSP increment. The establishment of a statewide baseline date and baseline area was more stringent than required by the federal PSD regulations. Under the federal regulations, the minor source baseline date for TSP is defined as the earliest date after August 7, 1977 on which the first complete PSD application was submitted by a major stationary source or a major modification (see 40 CFR 52.21(a)(14)(iii)). In addition, the federal definition for "baseline area" provides states with the option of establishing numerous baseline areas under Section 107(d) of the CAA, as long as the baseline areas did not intersect or were not smaller than the area of 1 $\mu g/m^3$ ambient impact of any major stationary source or major modification which established the minor source baseline date or which was subject to PSD permitting requirements (see 40 CFR 52.21(a)(15)).

On September 5, 1990, the State adopted revisions to its regulations, providing definitions for "minor source baseline date" and "baseline area" consistent with the federal definitions and, thus, allowing for the establishment of the Powder River Basin as a separate baseline area with a new minor source baseline date. The regulatory revisions were submitted for approval in the State Implementation Plan (SIP) on November 20, 1990. Because the revisions were consistent with federal requirements, EPA promulgated approval of the revisions on May 24, 1991 (56 FR 23811).

Subsequent to EPA's approval of the regulatory revisions, on February 11, 1992, the State requested formal redesignation of the Powder River Basin as a separate Section 107 particulate matter attainment area, measured in terms of TSP.

II. Technical Adequacy Review of Request

EPA has specific policy governing the redesignation of baseline areas, as discussed in the August 7, 1980 **Federal Register** in which the current federal PSD regulations were adopted (see 45 FR 52676). That notice provides for redefining baseline areas through area redesignations pursuant to Section 107 of the CAA, "as long as no PSD source has located in, or significantly impacted on a clean area being considered for redesignation, the area can be redesignated as a new attainment or unclassifiable area, even if the area [was] previously part of a larger clean area in which the baseline date had been set" (see 45 FR 52716). Under this redesignation policy, an ambient air quality impact greater than or equal to 1 $\mu g/m^3$ is considered to be a significant impact (see 45 FR 52716). EPA's policy was reaffirmed in EPA's October, 1990 draft New Source Review Workshop Manual (see page C.9).

The State's February 11, 1992 submittal consisted of the following: (1) A description of the boundary of the proposed revisions to the Section 107 particulate matter attainment area; (2) a description of the PSD permitting history of the area, which indicated that two major sources in the Powder River Basin, Pacific Power and Light and Hampshire Energy, had submitted complete PSD permit applications after the major source baseline date; (3) a description of the boundaries of the 1 $\mu g/m^3$ significant impact areas for the two major sources in the Powder River Basin; (4) maps of the 1 $\mu g/m^3$ significant impact area of the two major sources; and (5) supporting modeling results which were used to define the 1 $\mu g/m^3$ significant impact areas of the major sources. Basically, the area which the State was requesting redesignation was defined as the area encompassing the Powder River Basin excluding the significant impact areas of the two major sources which had submitted complete PSD permit applications.

EPA's review of the modeled 1 $\mu g/m^3$ impact areas for the two major sources identified deficiencies in the type of model used to estimate the impact areas. EPA's concerns were that the State may have underestimated the impact areas of the two major sources because they did not take into account the effects of complex terrain, as required by EPA's Guideline on Air Quality Models. These deficiencies were discussed with the State in a May 14, 1992 meeting, and it was agreed that EPA would run the required models using the State's data for the major sources and meteorological conditions.

EPA subsequently completed the modeling analysis for the two major sources in the Powder River Basin following the procedures outlined in the Guideline on Air Quality Models. In accordance with the intermediate terrain policy, the highest predicted ambient concentration from the modeling results was used in determining the extent of the 1 $\mu g/m^3$ impact area in elevated terrain areas. The modeling resulted in an increased impact area for the Hampshire Energy site. Specifically, the impact area of the Hampshire Energy site was extended approximately one-half mile both to the east and south of the original modeled boundary. The modeled impact area of Pacific Power and Light remained unchanged. In a July 24, 1992 letter to the State, EPA provided the results of its modeling analyses and the revised boundaries of the 1 $\mu g/m^3$ impact area for the Hampshire Energy site.

The State responded to EPA's modeling results in a September 18, 1992 letter, in which a revised boundary description for the 1 ug/m^3 significant impact area of the Hampshire Energy site consistent with EPA's modeled results was submitted. In that letter, the State requested that the described changes be made part of the Powder River Basin redesignation request submitted to EPA on February 11, 1992, and the EPA proceed with approval of the request.

The State has followed the terms of EPA's redesignation policy in its February 11, 1992 and September 18, 1992 requests to establish the Powder River Basin as a separate Section 107 particulate matter attainment area. Authority for the State's action is provided for in Section 107(d)(3)(D) of the CAA, which states: "the Governor of any State may, on the Governor's own motion, submit to the Administrator a revised designation of any area or portion thereof within the State [and EPA] shall approve such redesignation." Therefore, EPA is approving the State's request to redesignate the Powder River Basin as a Section 107 particulate matter attainment area. In addition, EPA is redesignating the areas which represent the baseline areas for Hampshire Energy and Pacific Power and Light as separate particulate matter attainment areas.

This approval eliminates the minor source baseline date for particulate matter that was previously established in the Powder River Basin attainment area. According to the revised State regulations, the minor source baseline date for the Powder River Basin attainment area will not be triggered until the submittal of the first complete PSD permit application for a major stationary source or major modification locating in or significantly impacting the Powder River Basin particulate matter attainment area, or January 1, 1996, whichever occurs first. Thus, minor source emissions that exist on the Powder River Basin attainment area until the time that the minor source baseline date is triggered will become part of background emissions for the area. Once the minor source baseline date is triggered, all new growth from minor sources will begin consuming increment. The minor source baseline dates for the Hampshire Energy and Pacific and Light particulate matter attainment area are the dates that their respective PSD applications were deemed complete.

Final Action: EPA is approving the State of Wyoming's request to redesignate the Powder River Basin as a Section 107 particulate matter attainment area. The Powder River Basin particulate matter attainment area is defined as follows: That area bounded by Township 40 through 52 North, and Ranges 69 through 73 West, inclusive of the Sixth Principal Meridian, Campbell and Converse Counties, excluding the Pacific Power and Light particulate matter attainment area and the Hampshire Energy particulate matter attainment area. The Pacific Power and Light particulate matter attainment area is defined as follows: NW¼ of Section 27, T50N, R71W, Campbell County, Wyoming. The Hampshire Energy particulate matter attainment area is defined as follows: Section 6 excluding the SW¼; E½ Section 7; Section 17 excluding the SW¼; Section 14 excluding the SE¼; Sections 2, 3, 4, 5, 8, 9, 10, 11, 15, 16 of T48N, R70W and Section 26 excluding the NE¼; SW¼ Section 23; Sections 19, 20, 21, 22, 27, 28, 29, 30, 31, 32, 33, 34, 35 of T49N, R70W.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any SIP. Each request for revision to the SIP shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under 5 U.S.C. Section 605(b), the Administrator has certified that redesignations do not have a significant economic impact on a substantial number of small entities (See 46 FR 8709).

This action has been classified as a Table 3 action by the Regional Administrator under the procedures published in the **Federal Register** on

January 19, 1989 (54 FR 2214–2225). On January 6, 1989, the Office of Management and Budget (OMB) waived Table 2 and 3 SIP revisions (54 FR 2222) from the requirements of Section 3 of Executive Order 12291 for a period of two years. EPA has submitted a request for a permanent waiver for Table 2 and 3 SIP revisions. OMB has agreed to continue the temporary waiver until such time as it rules on EPA's request.

Under section 307(b)(1) of the CAA, petitions for judicial review of this section must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from the date of publication). Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review must be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see Section 307(b)(2)).

List of Subjects in 40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

Dated: December 23, 1992.

Jack W. McGraw,

Acting Regional Administrator.

40 CFR Part 81 is amended as follows:

PART 81—[AMENDED]

1. The authority citation for Part 81 is revised to read as follows:

Authority: 42 U.S.C. 7401–7671q.

2. Section 81.351 is amended by revising the Wyoming TSP table to read as follows:

§ 81.351 Wyoming.

WYOMING—TSP

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
Trona Industrial Area (Sweetwater County)		X		
Powder River Basin				X
Campbell County (part)				
Converse County (part)				
That area bounded by Township 40 through 52 North, and Ranges 69 through 73 West, inclusive of the Sixth Principal Meridian, Campbell and Converse Counties, excluding the areas defined as the Pacific Power and Light attainment area and the Hampshire Energy attainment area				X
Pacific Power and Light Area				
Campbell County (part)				
That area bounded by NW¼ of Section 27, T50N, R71W, Campbell County, Wyoming				X
Hampshire Energy Area				
Campbell County (part)				
That area bounded by Section 6 excluding that SW¼; E½ Section 7; Section 17 excluding the SW¼; Section 14 excluding the SE¼; Sections 2, 3, 4, 5, 8, 9, 10, 11, 15, 16 of T48N, R70W and Section 26 excluding the NE¼; SW¼ Section 23; Sections 19, 20, 21, 22, 27, 28, 29, 30, 31, 32, 33, 34, 35 of T49N, R70W				X
Rest of State				

* * * * *

[FR Doc. 93–934 Filed 1–13–93; 8:45 am]
BILLING CODE 6560–50–M

COMMISSION OF CIVIL RIGHTS

45 CFR Part 708

Regulations for Collection by Salary Offset From Indebted Current or Former Employees

AGENCY: United States Commission on Civil Rights .

ACTION: Final regulation.

SUMMARY: This regulation implements the collection procedures of the Debt Collection Act of 1982, Public Law 97–365, codified in 5 U.S.C. 5514. Without the Debt Collection Act of 1982, the U.S. government would be unable to administratively deduct from an employee's current salary any amount to satisfy a debt without the employee's consent. The only exception to this would be the collection of taxes (26 U.S.C. 6331). This regulation permits the Commission to set off an employee's current salary to satisfy a debt to another agency of the United States or to the Commission, and to request another agency to offset a debt to the Commission from the salary of one of their current employees. This authority is necessary since involuntary wage garnishment is not a collection tool available to the Federal government. At the same time, the due process rights of the U.S. employees are protected.

EFFECTIVE DATE: This regulation shall become effective March 15, 1993.

ADDRESSES: Solicitor's Unit, United States Commission on Civil Rights, 624 9th Street, NW., Washington, DC 20425.

Copies of this notice are available on tape for those with impaired visions or other physical handicap. They may be obtained at the above address.

FOR FURTHER INFORMATION CONTACT: Emma Monroig, Solicitor, (202) 376–8351, TDD (202) 376–2683.

Background: Under the Debt Collection Act of 1982, when the head of a Federal agency determines that an employee of an agency is indebted to the United States or is notified by the head of another Federal agency that an agency employee is indebted to the United States, the employee's debt may be offset against his/her salary. Certain due process rights must be afforded to an employee before salary offset deductions begin.

As required by the Debt Collection Act of 1982, this regulation is consistent with salary offset regulations issued by the Office of Personnel Management on July 3, 1984, 49 FR 27472, codified in 5 CFR part 550 subpart K.

PAPERWORK REDUCTION ACT: Under section 3518 of the Paperwork Reduction Act of 1980, 5 CFR 1320.3(c) the information collection provisions contained in this regulation are not subject to review and approval by the Office of Management and Budget.

Executive Order 12291

This rule has been reviewed and determined not to be a "major rule" as defined by Executive Order 12291, dated February 17, 1981 because it will not result in (1) An annual effect on the economy of more than $100 million or more; (2) a major increase in costs and

prices for consumers, individuals, industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

This rule applies only to individual Federal employees. It will have no "significant economic impact upon a substantial number of small entities" within the meaning of section 3(a) of the Regulatory Flexibility Act, Public Law 96–354, 5 U.S.C. 605(b). Accordingly, no regulatory flexibility analysis is required.

List of Subjects in 45 CFR Part 708

Administrative offset, Administrative practice, Claims, Debt collection, Government employee, Wages.

For the reasons set out in the preamble, part 708 of title 45 of the Code of Federal Regulations is added to read as follows:

PART 708—COLLECTION BY SALARY OFFSET FROM INDEBTED CURRENT AND FORMER EMPLOYEES

Sec.

708.1 Purpose and scope.
708.2 Policy.
708.3 Definitions.
708.4 Applicability.
708.5 Notice.
708.6 Petitions for hearing.
708.7 Hearing procedures.
708.8 Written decision.
708.9 Coordinating offset with another Federal agency.
708.10 Procedures for salary offset.
708.11 Refunds.
708.12 Statute of limitations.
708.13 Non-waiver of rights by payments.
708.14 Interest, penalties, and administrative costs.

Authority: 5 U.S.C. 5514; sec. 8(1) of E.O. 11609; redesignated in sec. 2–1 of E.O. 12107.

§ 708.1 Purpose and scope.

(a) These regulations provide the procedure pursuant to 5 U.S.C. 5514 and 5 CFR part 550 subpart K for the collection by administrative offset of a Federal employee's salary without his/her consent to satisfy certain debts owed to the Federal government. This procedure applies to all Federal employees who owe debts to the U.S. Commission on Civil Rights ("the Commission"). This provision does not apply when the employee consents to recovery from his/her current pay account.

(b) This procedure does not apply to debts or claims arising under:

(1) The Internal Revenue Code of 1954, as amended (26 U.S.C. 1 et seq.);

(2) The Social Security Act (42 U.S.C. 301 et seq.);

(3) The tariff laws of the United States; or

(4) To any case where collection of a debt by salary offset is explicitly provided for or prohibited by another statute (e.g., travel advances in 5 U.S.C. 5705 and employee training expenses in 5 U.S.C. 4108).

(c) The Commission shall except from salary offset provisions any adjustments to pay arising out of an employee's election of coverage or a change in coverage under a Federal benefits programs requiring periodic payroll deductions from pay, if the amount to be recovered was accumulated over four pay periods or less.

(d) These procedures do not preclude an employee or former employee from requesting a waiver of a salary overpayment under 5 U.S.C. 5584, 10 U.S.C. 2774, or 32 U.S.C. 716 or in any way questioning the amount or validity of the debt by submitting a subsequent claim to the General Accounting Office (GAO) in accordance with procedures prescribed by the GAO. In addition, this procedure does not preclude an employee from requesting a waiver pursuant to other statutory provisions applicable to the particular debt being collected.

§ 708.2 Policy.

It is the policy of the Commission to apply the procedures(s) in these regulations uniformly and consistently in the collection of internal debts from its current and former employees.

§ 708.3 Definitions.

For the purposes of these regulations the following definitions apply:

(a) *Agency* means (1) an Executive agency as defined in section 105 of title 5 United States Code, including the U.S. Postal Service and the U.S. Postal Rate Commission;

(2) A military department as defined in section 102 of title 5, United States Code;

(3) An agency or court in the judicial branch, including a court as defined in section 610 of title 28, United States Code, the District Court for the Northern Mariana Islands, and the Judicial panel on Multidistrict Litigation;

(4) An agency of the legislative branch, including the U.S. Senate and the U.S. House of Representatives; and

(5) Other independent establishments that are entities of the Federal Government.

(b) *Creditor* agency means the agency to which the debt is owed.

(c) *Debt* means an amount owed to the United States from sources which include loans insured or guaranteed by the United States, and amounts due the United States from fees, leases, rents, royalties, services, sales of real or personal property, overpayments, penalties, damages, interest, fines and forfeitures (except those arising under the Uniform Code of Military Justice), and all other similar sources.

(d) *Assistant Staff Director for Management* means the Assistant Staff Director for Management of the U.S. Commission on Civil rights or his/her absence, or in the event of a vacancy in the position or its elimination, the Personnel Officer.

(e) *Disposable pay* means that part of current basic pay, special pay, incentive pay, retired pay, retainer pay, or in the case of an employee not entitled to basic pay, other authorized pay remaining from an employee's Federal pay after required deductions for social security, Federal, state or local income tax, health insurance premiums, retirement contributions, life insurance premiums, Federal employment taxes, and any other deductions that are required to be withheld by law.

(f) *Employee* means a current employee of an agency, including a current member of the Armed Forces or a Reserve of the Armed Forces (Reserves).

(g) *Former employee* means an employee who is no longer employed with the Commission but is currently employed with another Federal agency.

(h) *FCCS* means the Federal Claims Collection Standards jointly published by the Department of Justice and the General Accounting Office at 4 CFR 101.1 et seq.

(i) *Hearing official* means an individual responsible for conducting any hearing with respect to the existence or amount of a debt claimed, and who renders a decision on the basis of such hearing. A hearing official may not be under the supervision or control of the Assistant Staff Director for Management of the U.S. Commission on Civil Rights.

(j) *Paying agency* means the agency employing the individual who owes the debt and is responsible for authorizing the payment of his or her current pay.

(k) *Pay interval* will normally be the biweekly pay period but may be some regularly recurring period of time in which pay is received.

(l) *Retainer Pay* means the pay above the maximum rate of an employee's grade which he/she is allowed to keep in special situations rather than having

the employee's rate of basic pay reduced.

(m) *Salary offset* means an administrative offset to collect a debt under 5 U.S.C. 5514 by deduction(s) at one or more officially established pay intervals from the current pay account of an employee without his or her consent.

(n) *Waiver* means the cancellation, remission, forgiveness, or non-recovery of a debt allegedly owed by an employee to an agency as permitted or required by 5 U.S.C. 5584, 10 U.S.C. 2774, or 32 U.S.C. 716, 5 U.S.C. 8346(b) or any other law.

§ 708.4 Applicability.

These regulations are to be followed when:

(a) The U.S. Commission on Civil Rights is owed a debt by an individual who is a current employee of the Commission; or

(b) The U.S. Commission on Civil Rights is owed a debt by an individual currently employed by another Federal agency; or

(c) The Commission employs an individual who owes a debt to another Federal agency.

§ 708.5 Notice.

(a) Deductions shall not be made unless the employee who owes the debt has been provided with written notice signed by the Assistant Staff Director for Management (ASDM) or in his/her absence, or in the event of a vacancy in that position or its elimination the Personnel Officer (or the U.S. Department of Agriculture, National Finance Center acting on behalf of the Commission) of the debt at least 30 days before salary offset commences.

(b) The written notice from the ASDM, acting on behalf of the Commission, as the creditor agency, shall contain:

(1) A statement that the debt is owed and an explanation of its origin, nature, and amount;

(2) The agency's intention to collect the debt by deducting from the employee's current disposable pay account;

(3) The amount, frequency, proposed beginning date, and duration of the intended deduction(s);

(4) An explanation of the requirements concerning the current interest rate, penalties, and administrative costs, including a statement that such charges will be assessed unless excused in accordance with the Federal Claims Collections Standards (4 CFR 101.1 et seq.);

(5) The employee's right to inspect, request, or receive a copy of the government records relating to the debt;

(6) The employee's right to enter into a written repayment schedule for the voluntary repayment of the debt in lieu of offset;

(7) The right to a hearing conducted by an impartial hearing official (either an administrative law judge or an official who is not under the control of the Commission);

(8) The method and time period for petitioning for a hearing;

(9) A statement that the timely filing (i.e., within 15 calendar days) of a petition for a hearing will stay the commencement of collection proceedings;

(10) A statement that a final decision on the hearing (if one is requested) will be issued at the earliest practical date but not later than 60 days after the filing of the petition requesting the hearing unless the employee requests and the hearing official grants a delay in the proceedings.

(11) A statement that an employee knowingly submitting false or frivolous statements (5 CFR part 550.1101), representations, or evidence may subject the employee to disciplinary procedures under 5 U.S.C. chapter 75 and 5 CFR part 752; penalties under the False Claims Act, 31 U.S.C. 3729–3731; or criminal penalties under 18 U.S.C. 286, 287, 1001, and 1002;

(12) A statement of other rights and remedies available to the employee under statutes or regulations governing the program for which the collection is being made;

(13) A statement that an employee will be promptly refunded any amount paid or deducted for a debt which is later waived or found not valid unless there are applicable contractual or statutory provisions to the contrary; and

(14) The name, address, and phone number of an official who can be contacted concerning the indebtedness.

§ 708.6 Petitions for hearing.

(a) Except as provided in paragraph (d) of this section, an employee who wants a hearing must file a written petition for a hearing to be received by the Assistant Staff Director for Management not later than 15 calendar days from the date of receipt of the Notice of Offset. The petition must state why the employee believes the determination of the Commission concerning the existence or amount of the debt is in error.

(b) The petition must be signed by the employee and should identify and explain with reasonable specificity and brevity the facts, evidence, and witnesses which the employee believes support his/her position.

(c) If the employee objects to the percentage of disposable pay to be deducted from each check, the petition should state the objection and the reasons for it.

(d) If the employee files a petition for a hearing later than the 15 calendar days from the date of receipt of the Notice of Offset, as described in paragraph (a) of this section, the hearing official may accept the request if the employee can show that there was good cause (such as due to circumstances beyond his/her control or because he/she was not informed or aware of the time limit) for failing to meet the deadline date.

(e) An employee will not be granted a hearing and will have his/her disposable pay offset in accordance with the ASDM's offset schedule if he/she fails to show good cause why he/she failed to file the petition for a hearing within the stated time limits.

§ 708.7 Hearing procedures.

(a) If an employee timely files a petition for a hearing under the above procedures, the Assistant Staff Director for Management shall select the time, date, and location for the hearing.

(b) The hearing shall be conducted by an impartial hearing official.

(c) The hearing shall conform to procedures contained in the Federal Claims Collection Standards, 4 CFR 102.3(c).

(d) The Commission, as the creditor agency, will have the burden of proving the existence of the debt.

(e) The employee requesting the hearing shall have the burden of proof to demonstrate that the existence or amount of the debt is in error.

§ 708.8 Written decision.

(a) The hearing official shall issue a written opinion no later than sixty (60) days after the filing of the petition for hearing; or no longer than sixty (60) days from the proceedings if an extension has been granted pursuant to § 708.5(b)(10).

(b) The written opinion will include: A statement of the facts presented to demonstrate the nature and origin of the alleged debt; the hearing official's analysis, findings, and conclusions; the amount and validity of the debt; and if applicable, the repayment schedule.

§ 708.9 Coordinating offset with another Federal agency.

(a) The Commission is the creditor agency when the Assistant Staff Director for Management determines that an employee of another Federal agency owes a delinquent debt to the Commission. The Assistant Staff Director for Management shall, as appropriate:

(1) Arrange for a hearing upon the proper petitioning by the employee;

(2) Certify in writing that the employee of the paying agency owes the debt, the amount, and basis of the debt, the date on which payment is due, the date the Government's right to collect the debt first accrued, and that the Commission's regulations for salary offset have been approved by the Office of Personnel Management;

(3) If the collection must be made in installments, the Commission, as the creditor agency, will advise the paying agency of the amount or percentage of disposable pay to be collected in each installment and the number and the commencement date of the installments;

(4) Advise the paying agency of the actions taken under 5 U.S.C. 5514(a) and provide the dates on which action was taken, unless the employee has consented to salary offset in writing or signed a statement acknowledging receipt of procedures required by law. The written consent or acknowledgement must be sent to the paying agency;

(5) If the employee is in the process of separating, the Commission will submit its debt claim to the paying agency as provided in this part. The paying agency must certify any amounts already collected, notify the employee, and send a copy of the certification of the monies already collected and notice of the employee's separation to the Commission. If the paying agency is aware that the employee is entitled to Civil Service or Foreign Service Retirement and Disability Fund or similar payments, it must provide written notification to the agency responsible for making such payments stating the amount of the debt and indicating that the provisions of this part have been followed; and

(6) If the employee has already separated and all payments due from the paying agency have been paid, the Assistant Staff Director for Management may request, unless otherwise prohibited, that money payable to the employee from the Civil Service Retirement and Disability Fund or other similar funds be collected by administrative offset. The Commission will provide the agency responsible for these payments with a properly certified claim.

(b) The Commission is the paying agency when an employee of this agency owes a debt to another Federal agency which is the creditor agency.

(1) Upon receipt of a properly certified debt claim from a creditor agency, deductions will be scheduled to begin at the next established pay interval.

(2) The Commission must give the employee written notice that it has received a certified debt claim from a creditor agency (including the amount), and the date that deductions will be scheduled to begin and the amount of the deduction.

(3) The Commission shall not review the merits of the creditor agency's determination of the amount of the certified claim or of its validity.

(4) If the employee transfers to another paying agency after the creditor agency has submitted its debt claim but before the debt is collected completely, the Commission must certify the total amount collected to the creditor agency with notice of the employee's transfer. One copy of this certification must be furnished to the employee. The creditor agency will submit a properly certified claim to the new paying agency before collection can be resumed.

(5) When the Commission, as a paying agency, receives an incomplete debt claim from a creditor agency, it must return the debt claim with a notice that procedures under 5 U.S.C. 5514 and this subpart must be provided and a properly certified debt claim received before action will be taken to collect from the employee's current pay account.

§ 708.10 Procedures for salary offset.

(a) Deductions to liquidate an employee's debt will be by the method and in the amount stated in the Assistant Staff Director for Management's written notice of intent to collect from the employee's current pay, unless alternative arrangements for repayment are made.

(b) If the employee filed a petition for a hearing with the Assistant Staff Director for Management before the expiration of the period provided, then deductions will begin after the hearing official has provided the employee with a hearing, and a final written decision has been rendered in favor of the Commission.

(c) A debt will be collected in a lump-sum if possible.

(d) If an employee is financially unable to pay in one lump sum or the amount of the debt exceeds 15 percent of disposable pay for an officially established pay interval, collection must be made in installments. The size of the installment deduction(s) will bear a reasonable relationship to the size of the debt and the deduction will be established for a period not greater than the anticipated period of employment. The deduction for the pay intervals for any period must not exceed 15% of disposable pay unless the employee has agreed in writing to a deduction of a greater amount. If possible, the installment payment will be sufficient in size and frequency to liquidate the debt in no more than three years.

(e) Installment payments may be less than 15 percent of disposable pay if the Assistant Staff Director for Management determines that the 15 percent deduction would create an extreme financial hardship.

(f) Installment payments of less than $25.00 per pay period or $50.00 per month, will only be accepted in the most unusual circumstances.

(g) Unliquidated debts may be offset by the paying agency under 31 U.S.C. 3716 against any financial payment due to a separating employee including but not limited to final salary payment, retired pay, or lump sum leave, etc. as of the date of separation to the extent necessary to liquidate the debt.

(h) If the debt cannot be liquidated by offset from any final payment due a separated employee it may be recovered by the offset in accordance with 31 U.S.C. 3716 from any later payments due the former employee from the United States.

§ 708.11 Refunds.

(a) The Commission will refund promptly any amounts deducted to satisfy debts owned to the Commission when the debt is waived, found not owed to the Commission, or when directed by an administrative or judicial order; or

(b) The creditor agency will promptly return any amounts deducted and forwarded by the Commission to satisfy debts owed to the creditor agency when the debt is waived, found not owed, or when directed by an administrative or judicial order;

(c) Upon receipt of monies returned in accordance with paragraph (b) of this section, the Commission will refund the amount to the current or former employee.

(d) Unless required by law, refunds under this subsection shall not bear interest nor shall liability be conferred to the Commission for debt or refunds owed by other creditor agencies.

§ 708.12 Statute of limitations.

If a debt has been outstanding for more than 10 years after the agency's right to collect the debt first accrued, the agency may not collect by salary offset unless facts material to the government's right to collect were not known and could not reasonably have been known by the official or officials who were charged with the responsibility for discovery and collection of such debts.

§ 708.13 Non-waiver of rights by payments.

An employee's involuntary payment of all or any part of a debt collected under these regulations will not be construed as a waiver of any rights that employee may have under 5 U.S.C. 5514 or any other provision of contract or law unless there are statutory or contractual provisions to the contrary.

§ 708.14 Interest, penalties, and administrative costs.

Charges may be assessed for interest, penalties, and administrative costs in accordance with the Federal Claims Collection Standards, 4 CFR 102.13.

Dated: December 18, 1992.

Emma Monroig,

Solicitor.

[FR Doc. 93-800 Filed 1-13-93; 8:45 am]

BILLING CODE 6325-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 90-337, FCC 92-516]

International Accounting Rates

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: On November 17, 1992, the Commission adopted an Order on Reconsideration denying MCI Telecommunications Corporation's (MCI) request that the Commission only approve accounting rate reductions implemented simultaneously among all competing U.S. carriers and US Sprint Communications Company Limited Partnership's (Sprint) request that the notification and streamlined waiver procedures adopted in Regulation of International Accounting Rates, Phase I, Report and Order (Phase I Report and Order) not be applied to telex and packet switched traffic. The Order on Reconsideration also amends the reporting requirements found in § 64.1001(g) of the Commission's Rules, 47 CFR 64.1001(g) to require that a U.S. common carrier submitting a waiver or notification pursuant to the ISP certify that it has informed the relevant foreign administration that U.S. policy requires that competing U.S. carriers have access to accounting rates negotiated by the filing carrier with the foreign administration on a nondiscriminatory basis.

EFFECTIVE DATE: April 14, 1993.

FOR FURTHER INFORMATION CONTACT: Adam Kupetsky, Attorney, Common Carrier Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration adopted on November 17, 1992 and released on November 27, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M St., NW., Washington, DC. The complete text of this decision also may be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452-1422, 1990 M St., NW., Washington, DC 20036.

Summary of Order on Reconsideration

1. The Order on Reconsideration denies MCI's and Sprint's petitions for reconsideration of the Commission's Phase I Report and Order.

2. MCI requested that the Commission approve only those accounting rate reductions with a particular foreign administration that are implemented simultaneously among all competing U.S. common carriers. While disagreeing with MCI's specific proposal, the Commission affirmed that Commission policy should be to detect and take steps to eliminate discriminatory treatment of U.S. carriers. As an initial step, the Commission changed its rules to require a U.S. carrier submitting an ISP waiver or notification to certify that it made clear to the foreign administration that FCC policy requires that competing U.S. carriers have access to accounting rates negotiated by the U.S. carrier with a particular foreign administration on a nondiscriminatory basis. The Commission also outlined further measures it may be willing to take should discrimination continue, and noted its authority to establish an accounting rate for a particular service with a particular country.

3. Sprint petitioned for reconsideration of the application of the ISP notification and streamlined waiver procedure to telex and packet services. In denying Sprint's petition, the Commission found that adoption of Sprint's proposal would unnecessarily delay the attainment of lower, more cost-based international accounting rates.

Paperwork Reduction

4. Public reporting burden for this collection of information is estimated to average 2.18 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collections of information. Send comments regarding this burden estimate or any other aspect of the collection of information, including suggestions for reducing the burden, to the Federal Communications Commission, Records Management Division, room 416, Paperwork Reduction Project (3060-0454), Washington, DC 20554 and to the Office of Management and Budget, Paperwork Reduction Project (3060-0454), Washington, DC 20503.

Ordering Clauses

5. Accordingly, *it is therefore ordered* that the petitions for reconsideration filed by Sprint and MCI are denied.

6. *It is further ordered* that pursuant to authority contained in sections 1, 4, 201-205, 211, 218-220, 303 and 405 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154, 201-205, 211, 218-220, 303 and 405, part 64 of the Commission's Rules, 47 CFR part 64, IS AMENDED as set forth below.

7. *It is further ordered* that this Order on Reconsideration and the amendment to the rules set forth in Appendix A shall become effective ninety days after publication in the **Federal Register**.

List of Subjects in 47 CFR Part 64

Communications common carriers; Reporting and recordkeeping requirements; Telegraph; Telephone.

Amendatory Text

PART 64—MISCELLANEOUS RULES RELATING TO COMMON CARRIERS

1. The authority citation for part 64 continues to read as follows:

Authority: Section 4, 48 Stat. 1066, as amended; 47 U.S.C. 154, unless otherwise noted. Interpret or apply secs. 201, 218, 225, 48 Stat. 1070, as amended, 1077; 47 U.S.C. 201, 218, 225 unless otherwise noted.

2. Paragraph (g) of § 64.1001 is revised to read as follows:

§ 64.1001 International settlements policy and waivers.

* * * * *

(g) Notification letters and waiver requests must contain notarized statements that the filing carrier:

(1) Has not bargained for, nor has knowledge of, exclusive availability of the new accounting rate;

(2) Has not bargained for, nor has any indication that it will receive, more than its proportionate share of return traffic; and

(3) Has informed the foreign administration that U.S. policy requires that competing U.S. carriers have access to accounting rates negotiated by the filing carrier with the foreign

administration on a nondiscriminatory basis.

* * * * *

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–805 Filed 1–13–93; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 73

[MM Docket No. 92–211; RM–8061]

Radio Broadcasting Services; Lumberton, MS

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 237C1 for Channel 237C2 at Lumberton, Mississippi, in response to a petition filed by Stone-Lamar Broadcast Services Corporation, and modifies the license for Station WLUN to specify operation on Channel 237C1 in accordance with § 1.420(g) of the Commission's Rules. See 57 FR 44549, September 28, 1992. The coordinates for Channel 237C1 are 30–39–34 and 89–09–59. With this action, this proceeding is terminated.

EFFECTIVE DATE: February 22, 1993.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 92–211, adopted December 7, 1992, and released January 8, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, Downtown Copy Center, 1990 M Street, NW., Suite 640, Washington, DC 20036, (202) 452–1422.

List of Subjects in 47 CFR Part 73

Radio Broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Mississippi, is amended by removing Channel 237C2 and adding Channel 237C1 at Lumberton.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93–890 Filed 1–13–93; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 73

[MM Docket No. 92–219; RM–8039]

Radio Broadcasting Services; Tarkio, MO

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document substitutes Channel 228C3 for Channel 228A at Tarkio, Missouri, and modifies the license for Station KTRX(FM) to specify operation on Channel 228C3, in response to a petition filed by KANZA, Inc. See 57 FR 46369, October 8, 1992. The coordinates for Channel 228C3 at Tarkio are 40–33–50 and 95–15–00. With this action, this proceeding is terminated.

EFFECTIVE DATE: February 22, 1993.

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Report and Order, MM Docket No. 92–219, adopted December 11, 1992, and released January 8, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, Downtown Copy Center, 1990 M Street, NW., suite 640, Washington, DC 20036, (202) 452–1422.

List of Subjects in 47 CFR Part 73

Radio Broadcasting.

PART 73—[AMENDED]

1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 73.202 [Amended]

2. Section 73.202(b), the Table of FM Allotments under Missouri, is amended by removing Channel 228A and adding Channel 228C3 at Tarkio.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93–886 Filed 1–13–93; 8:45 am]

BILLING CODE 6712–01–M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1039

[Ex Parte No. 345 (Sub-No. 27)]

Rail General Exemption Authority; Transportation Equipment

AGENCY: Interstate Commerce Commission.

ACTION: Final rule.

SUMMARY: The Commission is exempting from its regulation the rail transportation of motor vehicles (STCC 37–11) and motor vehicle parts or accessories (STCC 37–14).[1] The Commission has concluded that regulation of the rail transportation of these commodities is not necessary to carry out the rail transportation policy, and that such regulation is not needed to protect shippers from an abuse of market power. Accordingly, these commodities are being added to the list of exempt commodities in our regulations, as set forth below.

EFFECTIVE DATE: This action is effective on February 13, 1993.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar (202) 927–5660. [TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: In a decision served July 9, 1992, 57 FR 30709 (July 10, 1992), we instituted a proceeding to consider whether to exempt from the provisions of 49 U.S.C. subtitle IV the rail transportation of Transportation Equipment (STCC 37). Our analysis of the proposed exemption focused on two Transportation Equipment subcategories, motor vehicles (STCC 37–11) and motor vehicle parts or accessories (STCC 37–14), that, taken together, account for approximately 96 percent of STCC 37 revenue. We concluded, preliminarily, that exemption of the rail transportation of STCCs 37–11 and 37–14 would be consistent with the 49 U.S.C. 10505(a) exemption criteria.

In a decision served August 20, 1992, 57 FR 37763 (August 20, 1992), we narrowed the scope of the proposed exemption to motor vehicles (STCC 37–11) and motor vehicle parts or accessories (STCC 37–14). This had the effect of harmonizing the scope of the proposed exemption and the rationale that we had asserted in support thereof.[2]

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[1] STCC is the acronym for the Standard Transportation Commodity Code.

[2] In the decision served July 9, 1992, we had also proposed, as an ancillary measure, the elimination of the 49 CFR 1039.16 exemption applicable to the rail transportation of otherwise regulated new

Continued

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Comments have been filed by the Association of American Railroads (AAR) on behalf of itself and its member railroads, the Motor Vehicle Manufacturers Association of the United States, Inc. (MVMA), and Patrick W. Simmons (on behalf of the United Transportation Union, Illinois Legislative Board).

The AAR and the MVMA support the proposed exemption, essentially for the reasons provided in the decision served July 9, 1992.[3]

Mr. Simmons opposes the proposed exemption. He contends that rail carrier employees are injured by reckless competition between rail carriers, because such competition results in pressure by management for employee concessions.

The rail carrier exemption provision, 49 U.S.C. 10505(a), requires us to exempt "a person, class of persons, or a transaction or service" when we find:

(1) That regulation is not necessary to carry out the 49 U.S.C. 10101a rail transportation policy (RTP); and

(2) Either (a) that the transaction or service is of limited scope, or (b) that regulation is not needed to protect shippers from an abuse of market power.

We think that the proposed exemption of motor vehicles and motor vehicle parts or accessories satisfies the section 10505(a) exemption criteria. We are convinced that regulation is not necessary to carry out the RTP. An exemption should not bring about any public health or safety concerns, discourage fair wages or safe and suitable working conditions, result in predatory pricing or practices, or discourage energy conservation. On the contrary, an exemption should result in positive benefits that will promote the RTP. Exemption will relieve administrative and paperwork burdens associated with tariff filing and contract summary filing. It will insulate this traffic from frivolous but potentially burdensome regulatory proceedings. It will allow quick and unhindered rate and service adjustments when changed market conditions mandate them. The proposed exemption should generally: Allow, to the maximum extent possible, competition to establish reasonable rates; minimize the need for Federal regulatory control; and ensure the continuation of a sound rail transportation system.

Mr. Simmons fears that any increase in competition will have an adverse impact on rail labor, in that the increased competitive posture of the railroads will prompt rail management to pressure rail labor for additional concessions. All section 10505 exemptions that increase competition, and indeed all Commission actions that increase competition, would be subject to attack on this basis. Given the several provisions in the RTP that favor competition,[4] we will not find a proposed exemption to be inconsistent with the RTP merely because it tends to increase competition.

We are also convinced that regulation of the rail transportation of STCCs 37–11 and 37–14 is not needed to protect shippers from an abuse of market power. On account of motor carrier competition, geographic competition generally, and various shipper options and powers, there is, overall, effective competition for the rail transportation of motor vehicles and motor vehicles parts and accessories.

We are therefore exempting the rail transportation of motor vehicles (STCC 37–11) and motor vehicle parts or accessories (STCC 37–14) from the provisions of 49 U.S.C. subtitle IV.

Environmental and Energy Considerations

We conclude that this action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Regulatory Flexibility Analysis

We conclude that this action will not have a significant impact on a substantial number of small entities. The shippers of motor vehicles and motor vehicle parts and accessories are, by and large, major corporations.

List of Subjects in 49 CFR Part 1039

Agricultural commodities, Intermodal transportation, Manufactured commodities, Railroads.

Decided: December 30, 1992.

By the Commission, Chairman Philbin, Vice Chairman McDonald, Commissioners Simmons and Phillips. Commissioner Simmons commented with a separate expression.

Sidney L. Strickland, Jr.,

Secretary.

For the reasons set forth in the preamble, title 49, chapter X, part 1039 of the Code of Federal Regulations is amended as follows:

highway trailers or containers. This ancillary proposal, designed only to minimize redundancy in our regulations, did not survive the narrowing of the scope of the proposed exemption to STCCs 37–11 and 37–14.

[3] The AAR also supports a similar exemption for used motor vehicles (STCC 41–118). We will consider that matter separately, in Ex Parte No. 346 (Sub-No. 27A), Rail General Exemption Authority—Used Motor Vehicles.

[4] See 49 U.S.C. 10101a(1), (4), and (5).

PART 1039—EXEMPTIONS

1. The authority citation for part 1039 continues to read as follows:

Authority: 49 U.S.C. 10321, 10505, 10708, 10761, 10762, 11105, 11902, 11903, and 11904; and 5 U.S.C. 553

2. In § 1039.11, the material in the chart in paragraph (a), following STCC No. 36, is revised to read as follows:

§ 1039.11 Miscellaneous commodities exemptions.

(a) * * *

STCC No.	STCC tariff	Commodity
*	*	*
37 11 ...	6001–T, eff. 1–1–92.	Motor vehicles.
37 14 ...	.....do	Motor vehicle parts or accessories.
38	6001–Q, eff. 1–14–90.	Instruments, photographic goods, optical goods, watches or clocks.
39	.....do	Miscellaneous products of manufacturing.
*	*	*

[FR Doc. 93–881 Filed 1–13–93; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AB65

Endangered and Threatened Wildlife and Plants; Endangered Status for Three Foreign Butterflies

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The Service determines endangered status for the Homerus, Corsican, and Luzon peacock swallowtail butterflies, which are found, respectively, in Jamaica, Corsica (France) and Sardinia (Italy) and the Philippines. All occupy restricted ranges and are jeopardized by human habitat disruption and collection. This rule will implement the protection of the Endangered Species Act of 1973 for these three butterflies.

EFFECTIVE DATE: February 16, 1993.

ADDRESSES: The complete file for this rule is available for public inspection, by appointment, from 8 a.m. to 4 p.m., Monday through Friday, in room 750, 4401 Fairfax Drive, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Dr. Charles W. Dane, Chief, Office of

Scientific Authority; Mail Stop: Arlington Square, room 725; U.S. Fish and Wildlife Service; Washington, DC 20240 (phone 703–358–1708 or FTS 921–1708; FAX 703–358–2202).

SUPPLEMENTARY INFORMATION:

Background

The swallowtail butterflies of the insect family Papilionidae occur mainly in tropical parts of the world. They are generally large and colorful, and thus of special attraction to people, but also are particularly susceptible to excessive collection and environmental disruption. Four species have been placed on appendix I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (Convention). One of these, Queen Alexandra's birdwing (*Troides alexandrae*) was added to the U.S. List of Endangered and Threatened Wildlife in the **Federal Register** of September 21, 1989 (54 FR 38950–38951). The other three—the Homerus, Corsican, and Luzon peacock swallowtail butterflies—are now classified as endangered by the International Union for Conservation of Nature (IUCN). The Homerus was selected by the IUCN Species Survival Commission as one of 12 critically endangered species that "highlight the serious and often still deteriorating world situation for species" (Fitter 1988). Partly in conjunction with an effort to establish closer alignment between the IUCN classifications, the Convention appendices, and the U.S. Lists of Endangered and Threatened Species, when warranted, the Service, in the **Federal Register** of September 10, 1991 (56 FR 46145–46148), proposed endangered status for the three butterflies described below.

The Homerus swallowtail butterfly (*Papilio homerus*) is the largest member of the family in the Western Hemisphere. It has a wingspan of about 6 inches (150 millimeters). The wings are black or dark brown, the upper surfaces having broad yellow bands and the lower surfaces having narrower yellow bands and blue spots. The species is known only from Jamaica in the West Indies.

The Corsican swallowtail (*Papilio hospiton*) is a short-tailed, black and yellow butterfly, with blue and red markings. Its wingspan is about 3 inches (72–76 millimeters). It is found only on the islands of Corsica (France) and Sardinia (Italy).

The Luzon peacock swallowtail (*Papilio chikae*) is a beautiful green-black, red and purple, long-tailed butterfly. Its forewing length is about 2 inches (55 millimeters).

Summary of Comments and Recommendations

In the proposed rule of September 10, 1991, and associated notifications, all interested parties were requested to submit information that might contribute to development of a final rule. Cables were sent to United States embassies in countries within the ranges of the subject species, requesting new data and the comments of the governments of those countries. Four comments were received. Dr. Tim R. New, Chairman of the IUCN Species Survival Commission Lepidoptera Group, supported the listing of all three butterflies. The Science Office of the U.S. Embassy in Rome collected data supporting the listing of *P. hospiton*. However, both Rudi Mattoni, editor of the Journal of Research on the Lepidoptera, and Professor H. Descimon of the University of Provence in France submitted comments suggesting that *P. hospiton* might not be endangered. Both observed that suitable habitat for this species is still widespread and that overcollecting is not a major problem. Nonetheless, they also indicated that the species is rare and at least potentially jeopardized by habitat destruction. In addition, Professor Descimon pointed out other possible problems, including hybridization, heavy parasitism, and difficulty in enforcing protective laws. These factors, together with information available from other sources, have led the Service to conclude that classification of *P. hospiton* as endangered is appropriate.

Summary of Factors Affecting the Species

After a thorough review and consideration of all information available, the Service has determined that the three butterflies named above should be classified as endangered. Section 4(a)(1) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act were followed. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to the Homerus, Corsican, and Luzon peacock swallowtail butterflies are as follows (information largely from Collins and Morris (1985) and from proposals to add the three species to appendix I of the Convention).

A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range

Habitat destruction is the main factor in the decline of at least two of these species. The Homerus swallowtail originally was recorded from most parts of Jamaica, but now is restricted to two disjunct areas of virgin forest, each comprising only a few square kilometers. Both populations are continuing to decline, largely because of logging and agricultural activity.

The Corsican swallowtail has declined dramatically on both Corsica and Sardinia. On each island, the food plants of the butterfly are believed by the local people to be poisonous to sheep, and are therefore being destroyed by fires. In addition, developments such as ski resorts have destroyed habitat on Corsica. Populations of the butterfly are now extremely localized.

The Luzon peacock swallowtail is found in a mountainous area, part of which is a popular summer tourist resort. New roads and other developments are reducing available habitat for the butterfly.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Excessive collection by butterfly enthusiasts and commercial interests is a problem for all three species, and is the main factor jeopardizing the Luzon peacock swallowtail. The latter is among the most beautiful and desirable members of the family, and its habitat is becoming easily accessible through road construction. It is readily captured, as its flight is very slow and it is attracted by decoys. Commercial collecting has been intensive and prices on the international market have been remarkably high for this species. In 1983 specimens were being sold in Japan for the equivalent of U.S. $150. In 1986 a dealer in the Philippines reportedly was purchasing pairs from local collectors at high volume and for the equivalent of U.S. $40.

The Corsican swallowtail also has suffered through excessive taking by both local and foreign collectors, who are aware of its rarity. Collecting of the Homerus swallowtail is difficult in its mountainous habitat, but may be a problem since it does command a high price and there are no effective protective measures in place. In 1984 a female was advertised in the United States for $2,800 and a male for $1,575.

C. Disease or Predation

Not now known to be immediate problems, but of potential concern in

any case of a species reduced to very limited numbers or habitat. As noted above, parasitism may be a threat to *P. hospiton*.

D. The Inadequacy of Existing Regulatory Mechanisms

The Homerus swallowtail is not covered by any specific conservation measures. The Corsican swallowtail is protected from direct taking on Corsica under French law, but the Sardinian population is not protected. There are no regulatory measures on either island to prevent habitat destruction, which is the main problem. The Luzon peacock swallowtail and its habitat are completely unprotected. Being on Appendix I of the Convention helps to control international trade in these species, but does not affect environmental disruption or local collecting.

E. Other Natural or Manmade Factors Affecting its Continued Existence

None now known.

The decision to determine endangered status for the Homerus, Corsican, and Luzon peacock swallowtail butterflies was based on an assessment of the best available scientific information, and of past, present, and probable future threats to these insects. All three have suffered substantial losses in habitat and/or numbers in recent years and are vulnerable to human exploitation and disturbance. If conservation measures are not implemented, further declines are likely to occur, increasing the danger of extinction for these butterflies. Critical habitat is not being determined, as such designation is not applicable to foreign species.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened pursuant to the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing encourages conservation measures by Federal, international, and private agencies, groups, and individuals.

Section 7(a) of the Act, as amended, and as implemented by regulations at 50 CFR part 402, requires Federal agencies to evaluate their actions that are to be conducted within the United States or on the high seas, with respect to any species that is proposed or listed as endangered or threatened and with respect to its proposed or designated critical habitat (if any). Section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of a listed species or to destroy or adversely modify its critical habitat. If a proposed Federal action may affect a listed species, the responsible Federal agency must enter into formal consultation with the Service. No such activities are currently known with respect to the species covered by this rule.

Section 8(a) of the Act authorizes the provision of limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered species in foreign countries. Sections 8(b) and 8(c) of the Act authorize the Secretary to encourage conservation programs for foreign endangered species, and to provide assistance for such programs, in the form of personnel and the training of personnel.

Section 9 of the Act, and implementing regulations found at 50 CFR 17.21 set forth a series of general prohibitions and exceptions that apply to all endangered wildlife. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take, import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any endangered wildlife. It also is illegal to possess, sell, deliver, transport, or ship any such wildlife that has been taken in violation of the Act. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered wildlife under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22. Such permits are available for scientific purposes, to enhance propagation or survival, or for incidental take in connection with otherwise lawful activities. All such permits also must be consistent with the purposes and policies of the Act, as required by section 10(d). In some instances, permits may be issued during a specified period of time to relieve undue economic hardship that would be suffered if such relief were not available.

The Service will review these species to determine whether any of them should be placed on the Annex of the Convention on Nature Protection and Wildlife Preservation in the Western Hemisphere, which is implemented through section 8A(e) of the Act, and whether they should be considered for other appropriate international agreements, including the Cartagena Convention's Protocol for Specially Protected Areas and Wildlife.

National Environmental Policy Act

The Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** of October 25, 1983 (48 FR 49244).

Literature Cited

Collins, N.M., and M.G. Morris. 1985. Threatened swallowtail butterflies of the world. The IUCN red data book. International Union for Conservation of Nature, Gland, Switzerland, 401 pp.

Fitter, M. 1988. Twelve critically endangered species. Species (Newsletter of the International Union for Conservation of Nature Species Survival Commission) 10:22–24.

Author

The primary author of this rule is Ronald M. Nowak, Office of Scientific Authority, U.S. Fish and Wildlife Service, Washington, DC 20240 (phone 703–358–1708 or FTS 921–1708).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Regulations Promulgation

Accordingly, part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, is hereby amended as set forth below:

Part 17—[Amended]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.11(h) by adding the following, in alphabetical order under INSECTS, to the List of Endangered and Threatened Wildlife:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(c) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
INSECTS							
•	•	•	•	•	•	•	
Butterfly, Corsican swallowtail.	*Papilio hospiton*	Corsica, Sardinia	Entire	E	486	NA	NA
•	•	•	•	•	•	•	
Butterfly, Homerus swallowtail.	*Papilio homerus*	Jamaica	Entire	E	486	NA	NA
•	•	•	•	•	•	•	
Butterfly, Luzon peacock swallowtail.	*Papilio chikae*	Philippines	Entire	E	486	NA	NA
•	•	•	•	•	•	•	

Dated: October 1, 1992.

Bruce Blanchard,

Acting Director.

[FR Doc. 93–856 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-55-M

VOL 58 ISS 9 JA 14 1993 UMI

Proposed Rules

Federal Register
Vol. 58, No. 9
Thursday, January 14, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 92-140-1]

Brucellosis in Cattle; State and Area Classifications

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule.

SUMMARY: We are amending the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Oregon from Class A to Class Free. We have determined that Oregon now meets the standards for Class Free status. This action relieves certain restrictions on the interstate movement of cattle from Oregon.

DATES: Interim rule effective January 14, 1993. Consideration will be given only to comments received on or before March 15, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92-140-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT:

Dr. John D. Kopec, Senior Staff Veterinarian, Cattle Diseases and Surveillance Staff, VS, APHIS, USDA, room 729, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-6188.

SUPPLEMENTARY INFORMATION:

Background

Brucellosis is a contagious disease affecting animals and man, caused by bacteria of the genus *Brucella*.

The brucellosis regulations contained in 9 CFR part 78 (referred to below as the regulations) provide a system for classifying States or portions of States according to the rate of *Brucella* infection present, and the general effectiveness of a brucellosis control and eradication program. The classifications are Class Free, Class A, Class B, and Class C. States or areas that do not meet the minimum standards for Class C are required to be placed under Federal quarantine.

The brucellosis Class Free classification is based on a finding of no known brucellosis in cattle for the 12 months preceding classification as Class Free. The Class C classification is for States or areas with the highest rate of brucellosis. Class B and Class A fall between these two extremes. Restrictions on moving cattle interstate become less stringent as a State approaches or achieves Class Free status.

The standards for the different classifications of States or areas entail maintaining (1) a cattle herd infection rate not to exceed a stated level during 12 consecutive months; (2) a rate of infection in the cattle population (based on the percentage of brucellosis reactors found in the Market Cattle Identification (MCI) program—a program of testing at stockyards, farms, ranches, and slaughter establishments) not to exceed a stated level; (3) a surveillance system that includes testing of dairy herds, participation of all recognized slaughtering establishments in the MCI program, identification and monitoring of herds at high risk of infection (including herds adjacent to infected herds and herds from which infected animals have been sold or received), and having an individual herd plan in effect within a stated number of days after the herd owner is notified of the finding of brucellosis in a herd he or she owns; and (4) minimum procedural standards for administering the program.

Before the effective date of this interim rule, Oregon was classified as a Class A State because of its herd infection rate and its MCI reactor prevalence rate.

To attain and maintain Class Free status, a State or area must (1) remain free from field strain *Brucella abortus* infection for 12 consecutive months or longer; (2) maintain for 12 consecutive months an MCI reactor prevalence rate not to exceed one reactor per 2,000 cattle tested (0.050 percent); and (3) have a specified surveillance system, as described above, including an approved individual herd plan in effect within 15 days of locating the source herd or recipient herd.

After reviewing the brucellosis program records for Oregon, we have concluded that the State meets the standards for Class Free status. Therefore, we are removing Oregon from the list of Class A States in § 78.41(b) and adding it to the list of Class Free States in § 78.41(a). This action relieves certain restrictions on moving cattle interstate from Oregon.

Immediate Action

Robert Melland, Administrator of the Animal and Plant Health Inspection Service, has determined that there is good cause to publish this interim rule without prior opportunity for public comment. Immediate action is warranted to remove unnecessary restrictions on the interstate movement of cattle from Oregon.

Since prior notice and other public procedures with respect to this interim rule are impracticable and contrary to the public interest under these conditions, there is good cause under 5 U.S.C. 553 to make it effective upon publication. We will consider comments that are received within 60 days of publication of this interim rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. It will include discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual

industries, Federal, State or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the brucellosis status of Oregon from Class A to Class Free will promote economic growth by reducing certain testing and other requirements governing the interstate movement of cattle from the State. Testing requirements for cattle moved interstate for immediate slaughter or to quarantined feedlots are not affected by this change. Cattle from certified brucellosis-free herds moving interstate are not affected by this change.

The groups affected by this action will be herd owners in Oregon, as well as buyers and importers of cattle from the State.

There are an estimated 23,000 herds in Oregon, 98 percent of which are owned by small entities that would be affected by this rule. Most of these herds are not certified-free. Test-eligible cattle offered for sale from other than certified-free herds must have a negative test under present Class A status regulations, but not under regulations concerning Class Free status. In 1991, Oregon tested 25,081 cattle under the Class A status regulations for change-of-ownership. This testing costs approximately $3.25 per head, or $81,513.00. If such testing were distributed equally among all herds affected by this rule, Class Free status would have less than $5.00 per herd.

Therefore, we believe that changing the brucellosis status for Oregon would not have a significant economic on the small entities affected by this interim rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12778

This interim rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 78 is amended as follows:

PART 78—BRUCELLOSIS

1. The authority citation for part 78 continues to read as follows:

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

§ 78.41 [Amended]

2. Section 78.41, paragraph (a), is amended by adding "Oregon," immediately after "Ohio,".

3. Section 78.41, paragraph (b), is amended by removing "Oregon,".

Done in Washington, DC, this 8th day of January 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–948 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–34–M

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9 CFR Part 92

[Docket 92–167–1]

Limited Ports; Baudette, MN

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the animal importation regulations by adding Baudette, MN, to the list of limited ports of entry for ruminants and swine and ruminant and swine products (such as test specimens of ruminants and swine) that do not appear to require restraint and holding inspection facilities. We have determined that inspection facilities and Animal and Plant Health Inspection Service personnel are available to provide inspection service for this location. This proposed action would provide importers with an alternative port through which to import certain ruminants and swine and ruminant and swine products.

DATES: Consideration will be given only to comments received on or before March 15, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, ALPHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. please state that your comments refer to Docket No. 92–167–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue, SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Joyce Bowling, Staff Veterinarian, Import-Export Animals Staff, VS, APHIS, USDA, room 766, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782 (301) 436–8170.

SUPPLEMENTARY INFORMATION:

Background

The animal importation regulations (contained in 9 CFR part 92 and referred to below as the regulations), among other things, list ports that have inspection or quarantine facilities for ruminants and ruminant products and for swine and swine products offered for entry into the United States. Section 92.403(e) designates limited ports for the importation of ruminants and ruminant products (such as ruminant test specimens) that do not appear to require restraint and holding inspection facilities. Section 92.503(e) designates limited ports having inspection facilities for the entry of swine and swine products (such as swine test specimens) that do not appear to require restraint and holding inspection facilities.

Beaudette, MN does not have the facilities to hold large animals or to restrain animals that need to be individually inspected before entering the United States. However, Animal and Plant Health Inspection Service personnel are available to provide inspection services at Baudette, MN. Therefore, we are proposing to amend §§ 92.403(e) and 92.503(e) of the regulations by adding Baudette, MN, as a limited port. This action would provide importers an alternative limited port of entry in Minnesota for certain ruminants and swine and ruminant and swine products.

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Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule would have an effect on the economy of less than $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We anticipate that the addition of Baudette, MN, to the list of limited ports for the importation of ruminants and swine and ruminant and swine products would not cause a substantial change in the number of these animals or products entering the United States or in the number of persons importing them.

The entities affected by this proposed rule would be those importers who would wish to use the new ports. We believe that most of these entities would be considered small entities, but we do not know how many of them would opt to use a new limited port if one were to become available. Minnesota already has a limited port for the entry of ruminants and ruminant products and swine and swine products. The addition of a limited port at Baudette would provide importers with an alternate and, in some cases, a more conveniently located limited port, thereby making importations easier. We do not anticipate that there will be a significant economic impact on any small entities as a result of this proposed rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted:

(1) All State and local laws and regulations that are in conflict with this rule will be preempted;

(2) No retroactive effect will be given to this rule; and

(3) Administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Regulatory Reform: Less Burdensome of More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 9 CFR Part 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, 9 CFR part 92 would be amended as follows:

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

1. The authority citation for part 92 would continue to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 134a, 134b, 134c, 134d, 134f, and 135; 31 U.S.C. 9701; 7 CFR 2.17, 2.51, and 371.2(d).

§ 92.403 [Amended]

2. Paragraph (e) of § 92.403 would be amended by adding "Baudette and" immediately before "Minneapolis".

§ 92.503 [Amended]

3. Paragraph (e) of § 92.503 would be amended by adding "Beaudette and" immediately before "Minneapolis".

Done in Washington, DC, this 8th day of January 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–925 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–34–M

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9 CFR Part 92

[Docket No. 92–103–1]

Ports Designated for Importation of Birds and Poultry; Port Canaveral, FL

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the regulations concerning the importation of animals and animal products by adding Port Canaveral, FL, to the list of ports designated for the importation of pet birds, performing or theatrical birds, performing or theatrical poultry, and certain other poultry and poultry products, such as poultry test specimens, or hatching eggs and day old chicks, which do not appear to require restraint and holding facilities. This action would provide an alternative port of entry for these birds and poultry, and poultry products, thereby facilitating their importation into the United States.

DATES: Consideration will be given only to comments received on or before February 16, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 92–103–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Keith Hand, Senior Staff Veterinarian, Import-Export Animals Staff, VS, APHIS, USDA, room 768, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–5097.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 92 (referred to below as the regulations) contain, among other things, provisions concerning the importation of birds and poultry into the United States. These provisions are designed to prevent the introduction of exotic Newcastle disease and other communicable diseases of poultry into the United States.

Section 92.102(a) lists special ports designated for the importation of pet birds imported under the provisions of § 92.101(c)(3). Section 92.203(d) designates limited ports available for the entry of poultry and poultry products, such as poultry test specimens, or hatching eggs and day old chicks, which do not appear to require restraint and holding facilities. In accordance with § 92.101(f), performing or theatrical birds may be imported at the ports of entry listed in § 92.102(a) or § 92.203(d). And, in accordance with § 92.201(c), performing or theatrical poultry may be imported at the ports listed in § 92.203(d).

Pet birds, performing or theatrical birds, and performing or theatrical poultry are generally imported in small numbers and in carrying cases or cages, and do not require restraint and holding facilities. It appears that Port Canaveral, FL, could be used for the importation of these birds and poultry, and for certain other poultry and poultry products that do not require restraint and holding facilities. Therefore, we propose to add Port Canaveral, FL, to the list of ports in §§ 92.102(a) and 92.203(d).

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this proposed rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this proposed rule would have an effect on the economy of less than $100 million; would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and would not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed rule, if adopted, would affect owners of pet birds, performing or theatrical birds, performing or theatrical poultry and certain other poultry and poultry products, imported into the United States. This proposed rule would benefit them by providing an alternative port of entry. The convenience this alternative port would provide would not result in any significant economic benefit. Further, we do not expect that this proposed rule, if adopted, would result in any increase in the number of these birds and poultry, and poultry products, imported into the United States.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12778

This proposed rule has been reviewed under Executive Order 12778, Civil Justice Reform. If this proposed rule is adopted:

(1) All State and local laws and regulations that are inconsistent with this rule will be preempted;

(2) No retroactive effect will be given to this rule; and

(3) Administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C., 3051 *et seq.*).

Regulatory Reform: Less Burdensome or More Efficient Alternatives

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the full extent possible, consistent with law.

The Department has developed and reviewed this regulatory proposal in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable to ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in the proposal. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this notice.

List of Subjects in 9 CFR Part 92

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, 9 CFR Part 92 would be amended as follows:

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

1. The authority citation for part 92 would continue to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 134a, 134b, 134c, 134d, 134f and 135; 31 U.S.C. 9701; 7 CFR 2.17, 2.51 and 371.2(d).

§ 92.102 [Amended]

2. In § 92.102, paragraph (a) would be amended by adding "and Port Canaveral" immediately after "Miami".

§ 92.203 [Amended]

3. In § 92.203, paragraph (d) would be amended by adding "Port Canaveral," immediately after "Jacksonville,".

Done in Washington, DC, this 8th day of January 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–924 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–34–M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

Radiological Criteria for Decommissioning of NRC-licensed Facilities; Workshop

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of workshop.

SUMMARY: The Nuclear Regulatory Commission (NRC) is preparing to initiate an enhanced participatory rulemaking on establishing the

radiological criteria for the decommissioning of NRC-licensed facilities. The Commission intends to enhance the participation of affected interests in the rulemaking by soliciting commentary from these interests on the rulemaking issues before the staff develops the draft proposed rule. The Commission plans to conduct a series of workshops to solicit commentary from affected interests on the fundamental approaches and issues that must be addressed in establishing the radiological criteria for decommissioning. The first workshop will be held in Chicago, Illinois on January 27 and 28, 1993 and will be open to the public.

DATES: January 27, 1993 for 9 a.m. to 6 p.m.; January 28, 1993 from 8:30 a.m. to 4:30 p.m.

As discussed later in this notice, the workshop discussions will focus on the issues and approaches identified in a Rulemaking Issues Paper prepared by the NRC staff. The Commission will accept written comments on the Rulemaking Issues Paper from the public, as well as from workshop participants. Written comments should be submitted by May 28, 1993.

ADDRESSES: The workshop will be held at the Park Hyatt Hotel, 800 North Michigan Avenue, Chicago, Illinois.

Send written comments on the Rulemaking Issues Paper to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland between 7:45 a.m. and 4:15 p.m. on Federal workdays. The Rulemaking Issues Paper is available from Francis X. Cameron (See FOR FURTHER INFORMATION CONTACT).

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Special Counsel for Public Liaison and Waste Management, Office of the General Counsel, Washington, DC 20555, Telephone: 301–504–1642.

SUPPLEMENTARY INFORMATION:

Background

The NRC has the statutory responsibility for protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act. The NRC believes that one portion of this responsibility is to ensure the safe and timely decommissioning of nuclear facilities which it licenses and to provide guidance to licensees on how to plan for and prepare their sites for decommissioning. Once licensed activities have ceased, licensees are required to decommission their facilities so that their licenses may be terminated. This requires that the radioactivity in land, groundwater, buildings, and equipment resulting from the licensed operation be reduced to levels that allow the property to be released for unrestricted use. Licensees must then demonstrate that all facilities have been properly decontaminated and that radioactive material has been transferred to authorized recipients. Confirmatory surveys are conducted by NRC, where appropriate, to verify that sites meet NRC radiological criteria for decommissioning.

The types of nuclear fuel cycle facilities that will require decommissioning include nuclear power plants; non-power (research and test) reactors; fuel fabrication plants, uranium hexafluoride production plants, and independent spent fuel storage installations. In addition there are currently about 24,000 materials licensees. About one third of these are NRC licensees, while the remainder are licensed by Agreement States acting under the authority of the Atomic Energy Act, section 274.

These Licensees include universities, medical institutions, radioactive source manufacturers, and companies that use radioisotopes for industrial purposes. About 50% of NRC's 7,500 materials licensees use either sealed radioactive sources or small amounts of short-lived radioactive materials. Decommissioning of these facilities should be relatively simple because there is usually little or no residual radioactive contamination. Of the remaining 50%, a small number (e.g. radioactive source manufacturers, radiopharmaceutical producers, and radioactive ore processors) conduct operations that could produce substantial radioactive contamination in portions of the facility. These facilities, like the fuel cycle facilities identified above, must be decontaminated before they can be safely released for unrestricted use.

Several hundred NRC and Agreement State licenses are terminated each year. The majority of these licenses involve limited operations, produce little or no radioactive contamination, and do not present complex decommissioning problems or potential risks to public health or the environment from residual contamination. However, as the nuclear industry matures, it is expected that more and more of the larger nuclear facilities that have been operating for a number of years will reach the end of their useful lives and be decommissioned. Therefore, both the number and complexity of facilities that will require decommissioning is expected to increase.

The Commission believes that there is a need to incorporate into its regulations radiological criteria for termination of licenses and release of land and structures for unrestricted use. The intent of this action would be to provide a clear and consistent regulatory basis for determining the extent to which lands and structures must be decontaminated before a site can be decommissioned. The Commission believes that inclusion of criteria in the regulations would result in more efficient and consistent licensing actions related to the numerous and frequently complex site decontamination and decommissioning activities anticipated in the future. A rulemaking effort would also provide an opportunity to reassess the basis for the residual contamination levels contained in existing guidance in light of changes in basic radiation protection standards and decommissioning experience obtained during the past 15 years.

The new criteria would apply to the decommissioning of power reactors, non-power reactors, fuel reprocessing plants, fuel fabrication plants, uranium hexafluoride production plants, independent spent fuel storage installations, and materials licenses. The criteria would apply to nuclear facilities that operate through their normal lifetime, as well as to those that may be shut down prematurely. The proposed criteria would not apply to uranium (other than source material) mines and mill tailings, high-level waste repositories, or low-level waste disposal facilities.

Until the new criteria are in place, the Commission intends to proceed with the decommissioning of nuclear facilities on a site-specific basis as the need arises considering existing criteria. Case and activity-specific risk decisions will continue to be made as necessary during the pendency of this process.

The Enhanced Participatory Rulemaking

The Commission believes it is desirable to provide for early and comprehensive input from affected interests on important public health and safety issues, such as the development of radiological criteria for decommissioning. Accordingly, the Commission is initiating an enhancing participatory rulemaking to establish these criteria. The objective of the rulemaking is to enhance the participation of affected interests in the rulemaking by soliciting commentary from these interests on the rulemaking issues before the NRC staff develops the draft proposed rule. The NRC staff will consider this commentary in the

development of the draft proposed rule, as well as document how these comments were considered in arriving at a regulatory approach. The Commission believes that this will be an effective method for illuminating the decision making process on complex and controversial public health and safety issues. This approach will ensure that the important issues have been identified; will assist in identifying potential information gaps or implementation problems; and will facilitate the development of potential solutions to address the concerns that affected interests may have in regard to the rulemaking.

The early involvement of affected interests in the development of the draft proposed rule will be accomplished through a series of workshops. A workshop format was selected because it will provide representatives of the affected interests with an opportunity to discuss the rulemaking issues with one another and to question one another about their respective positions and concerns. Although the workshops are intended to foster a clearer understanding of the positions and concerns of the affected interests, as well as to identify areas of agreement and disagreement, it is not the intent of the workshop process to attempt to develop a consensus agreement on the rulemaking issues. In addition to the commentary from the workshop participants, the workshops will be open to the public and the public will be provided with the opportunity to comment on the rulemaking issues and the workshop discussions at discrete intervals during the workshops.

The normal process for conducting Commission rulemakings is NRC staff development of a draft proposed rule for Commission review and approval, publication of the proposed rule for public comment, consideration of the comment by the NRC staff, and preparation of a draft final rule for Commission approval. In the enhanced participatory rulemaking, not only will comments be solicited before the NRC staff prepares a draft proposed rule, but the mechanism for soliciting there early comments will also provide an opportunity for the affected interests and the NRC staff to discuss the issues with each other, rather than relying on the traditional one-to-one written correspondence with the NRC staff. After Commission review and approval of the draft proposed rule that is developed using the workshop commentary, the general process of issuing the proposed rule for public comment, NRC staff evaluation of comments, and preparation of a draft final rule for Commission approval, will occur.

Participants

In order to have a manageable discussion among the workshop participants, the number of participants in each workshop must be limited. Based on discussions with experts on workshop facilitation, the NRC staff believes that the optimum size of the workshop group is fifteen to twenty participants. Due to differing levels of interest in each region, the actual number of participants in any one workshop, as well as the number of participants that represent a particular interest in any one workshop, may vary. Invitations to attend the workshops will be extended by the NRC staff using several selection criteria. First, to ensure that the Commission has the benefit of the spectrum of viewpoints on the issues, the NRC staff is attempting to achieve the participation of the full range of interests that may be affected by the rulemaking. The NRC staff has identified several general interests that will be used to select specific workshop participants—State governments, local governments, tribal governments, Federal agencies, citizens groups, nuclear utilities, fuel cycle facilities, and non-fuel cycle facilities. In addition to these interests, the staff also plans to invite representatives from the contracting industry that performs decommissioning work and representatives from professional societies, such as the Health Physics Society and the American Nuclear Society. The NRC anticipates that most of the participants will be representatives of organizations. However, it is also possible that there may be a few participants who, because of their expertise and influence, will participate without any organizational affiliation.

The second selection criterion is the ability of the participant to knowledgeably discuss the full range of the rulemaking issues. The NRC staff wishes to ensure that the workshops will elicit informed discussions of options and approaches, and the rationale for those options and approaches, rather than simple statements of opinion. The NRC staff's identification of potential participants has been based on an evaluation of such factors as the extent of a potential participant's experience with a broad range of radiation protection issues and types of nuclear facilities, specific experience with the decommissioning issue, and the extent of a potential participant's substantive comment and participation on previous Commission regulatory or licensing actions.

The third criterion emphasizes participation from organizations within the region encompassed by the workshop. As much as practicable, those organizations that primarily operate within the region, as opposed to regional units of national organizations, will have priority in terms of participating in the corresponding regional workshops. Organizations with a national standing will be part of the "national" workshop to be held in Washington, DC.

Workshop Format

To assure that each workshop addresses the issues in a consistent manner, the workshops will have a common pre-defined scope and agenda focused on the Rulemaking Issues Paper discussed below. However, the workshop format will be sufficiently flexible to allow for the introduction of any additional issues that the participants may want to raise. At each workshop, the NRC staff will begin each discussion period with a brief overview of the workshop will be devoted to a discussion of the issues by the participants. The workshop commentary will be transcribed and made available to participants and to the public.

Personnel from The Keystone Center, a nonprofit organization located in Keystone, Colorado, will serve as neutral facilitators for each workshop. The facilitators will chair the workshop sessions and ensure that participants are given an opportunity to express their viewpoints, assist participants in articulating their interests, ensure that participants are given the opportunity to question each other about their respective viewpoints, and assist in keeping the discussion moving at a pace that will allow all major issue areas to be addressed.

Rulemaking Issues Paper

The NRC staff has prepared a Rulemaking Issues Paper to be used as a focal point for the workshop discussions. This paper, which will be distributed to participants in advance of the workshops, sets forth in neutral terms the issues that must be addressed in the rulemaking, as well as background information on the nature and extent of the problem to be addressed. In framing the issues and approaches discussed in the Rulemaking Issues Paper, the NRC staff has attempted to anticipate the variety of views that exist on these approaches and issues. The paper will provide assistance to the participants as they prepare for the workshops, suggest the

workshop agenda, and establish the level of technical discussion that can be expected at the workshops. The workshop discussions are intended to be used by the staff in developing the draft proposed rule. Prior to the workshops no staff positions will be taken on the rulemaking approaches and issues identified in the Rulemaking Issues Paper. As noted earlier, to the extent that the Rulemaking Issues Paper fails to identify a pertinent issue, this may be corrected at the workshop sessions.

The discussion of issues is divided into two parts. First are two primary issues dealing with: (1) The objectives for developing radiological criteria; and (2) application of practicality considerations. The objectives constitute the fundamental approach to the establishment of the radiological criteria, and the NRC staff has identified four distinct possibilities including:

(1) Risk Limits, which is the establishment of limiting values above which the risks to the public are deemed unacceptable, but allows for criteria to be set below the limit using practicality considerations;

(2) Risk Goals, where a goal is selected and practicality considerations are used to establish criteria as close to the goal as practical;

(3) Best Effort, where the technology for decontamination considered to be the best available is applied; and

(4) Return to Preexisting Background, where the decontamination would continue until the radiological conditions were the same as existed prior to the licensed activities.

Following the primary issues are several secondary issues that are related to the discussions of the primary issues, but which the NRC staff believe warrant separate presentations and discussions. These secondary issues include the time frame for dose calculation, the individuals or groups to be protected, the use of separate criteria for specific exposure pathways such as groundwater, the treatment of radon, and the treatment of previously buried materials.

The Rulemaking Issues Paper will be provided to each potential workshop participant. Additional copies will be available to members of the public in attendance at the workshop. Copies will also be available from the NRC staff contact identified above. In addition to the comments on the Rulemaking Issues Paper provided at the workshops, the Commission is also receptive to the submittal of written comments on the rulemaking issues, as noted under the heading DATES.

Dated at Rockville, MD this 9th day of January, 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93-850 Filed 1-13-93; 8:45 am]

BILLING CODE 7590-01M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92-CE-20-AD]

Airworthiness Directives; Avions Mudry & Cie Model CAP 10B Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to supersede Airworthiness Directive (AD) 80-24-51, which currently requires inspecting both the center wing lower skin and main spar upper flange at the wing root areas for cracks on certain Avions Mudry & Cie Model CAP 10B airplanes, and repairing any cracked part. An accident investigation has revealed cracking and failure of the wing main spar in the vicinity of a bolt hole at the wing root area on one of the affected airplanes that was in compliance with the existing AD. The proposed action would require installing an inspection opening in the wing, repetitively inspecting the upper and lower wing spar caps for cracks, and repairing any cracks. The actions specified by the proposed AD are intended to prevent fatigue failure of the wing spar, which could lead to loss of control of the airplane.

DATES: Comments must be received on or before March 26, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 92-CE-20-AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that is discussed in the proposed AD may be obtained from Avions Mudry & Cie, B.P. 214, 27300 Bernay, France; Telephone (33) 32 43 47 34; Facsimile (33) 32 43 47 90. This information may also be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond A. Stoer, Program Officer, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B-1000 Brussels, Belgium; Telephone (322) 513.38.30 ext. 2710; Facsimile (322) 230.68.99; or Mr. William Timberlake, Project Officer, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106; Telephone (816) 426-6932; Facsimile (816) 426-2169.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 92-CE-20-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 92-CE-20-AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

AD 80-24-51, Amendment 39-4119, currently requires inspecting both the center wing lower skin and main spar upper flange in the wing root areas for cracks on certain Avions Mudry & Cie Model CAP 10B airplanes, and repairing any cracked part.

An accident investigation of a recent in-flight failure of one of the referenced airplanes has revealed cracking and failure of the wing main spar in the vicinity of a bolt hole at the wing root. In addition, two other Avions Mudry & Cie Model CAP 10B airplanes have developed cracks in the same general areas, which were detected during inspections conducted after the referenced accident. All three of the referenced airplanes were in compliance with AD 80–24–51.

Avions Mudry & Cie has issued Service Bulletin (SB) CAP10B No. 15 (ATA 57–003) and SB CAP10B No. 16 (ATA 57–004), both dated April 14, 1992. These service bulletins specify procedures for installing an inspection opening in the wing, and inspecting the upper and lower wing spar caps.

The affected airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. The Direction Generale De L'Aviation Civile (DGAC), which is the airworthiness authority for France, recently issued similar AD action in order to assure the continued airworthiness of these airplanes in France. After examining the circumstances and reviewing all available information related to the accident and incidents described above, the FAA has determined that AD action should be proposed for products of this type design that are operated in the United States.

Since an unsafe condition has been identified that is likely to exist or develop in other Avions Mudry & Cie Model CAP 10B airplanes of the same type design, the proposed AD would supersede AD 80–24–51 with a new AD that would require installing an inspection opening in the wing, repetitively inspecting the upper and lower wing spar caps for cracks, and repairing any cracks. The proposed actions would be accomplished in accordance with the service bulletins referenced above.

The FAA estimates that 24 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 25 hours per airplane to accomplish the proposed action, and that the average labor rate is approximately $55 an hour. Parts are fabricated from commonly available spruce or plywood. The cost of the spruce or plywood would vary, but $50 is used for the purpose of this proposed AD. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $34,200.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13—[AMENDED]

2. Section 39.13 is amended by removing AD 80–24–51, Amendment 39–4119, and by adding the following new airworthiness directive:

Avions Mudry & Cie: Docket No. 92–CE–20–AD. Supersedes AD 80–24–51, Amendment 39–4119. Applicability: Model CAP 10B airplanes (all serial numbers), certificated in any category. Compliance: Required as indicated, unless already accomplished.

To prevent fatigue failure of the wing spar, which could lead to loss of control of the airplane, accomplish the following:

(a) For airplanes having a serial number of 263 or lower, within the next 100 hours TIS, install a permanent inspection opening in the wing in accordance with the Technical Instructions section of Avions Mudry & Cie Service Bulletin (SB) CAP10B No. 16 (ATA 57–004), dated April 27, 1992.

Note 1: The installation specified in paragraph (a) of this AD is incorporated during production for airplanes having a serial number of 264 or higher.

(b) For all serial number airplanes, within the next 100 hours TIS and thereafter at intervals not to exceed 1,000 hours TIS, inspect the upper and lower wing spar caps for cracks in accordance with the Technical Instructions section of Avions Mudry & Cie SB CAP10B No. 15 (ATA 57–003), dated April 14, 1992. If cracks are found, prior to further flight, obtain a repair scheme from the manufacturer through the Manager, Brussels Aircraft Certification Office, at the address specified in paragraph (d) of this AD, and incorporate this repair scheme.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Brussels Aircraft Certification Office.

(d) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Brussels Aircraft Certification Office.

(e) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Avions Mudry & Cie, B.P. 214, 27300 Bernay, France; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(f) This amendment supersedes AD 80–24–51, Amendment 39–4119.

Issued in Kansas City, Missouri, on January 8, 1993.

Gerald W. Pierce,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–840 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 39

[Docket No. 92–NM–132–AD]

Airworthiness Directives; McDonnell Douglas Model DC–6 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness

directive (AD) that is applicable to certain McDonnell Douglas Model DC–6 series airplanes. This proposal would require the implementation of a supplemental structural inspection program either by the accomplishment of specific inspections or by the revision of the FAA-approved maintenance program to include such a program. This proposal is prompted by a structural reevaluation, which has identified certain significant structural components to inspect for fatigue cracks as these airplanes approach and exceed the manufacturer's original design life. Fatigue cracks in these areas, if not detected and corrected in a timely manner, could compromise the structural integrity of these airplanes.

DATES: Comments must be received by March 11, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 92–NM–132–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from McDonnell Douglas Corporation, P.O. Box 1771, Long Beach, California 90846–0001, Attention: Business Unit Manager, Technical Publications—Technical Administrative Support, C1–L5B. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office (ACO), 3229 East Spring Street, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Wahib Mina, Aerospace Engineer, Los Angeles Aircraft Certification Office, ANM–120L, FAA, Transport Airplane Directorate, 3229 East Spring Street, Long Beach, California 90806–2425; telephone (310) 988–5324; fax (310) 988–5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92–NM–132–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 92–NM–132–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

A significant number of transport category airplanes are approaching their design life goal. It is expected that these airplanes will continue to be operated beyond this point. The incidence of fatigue cracking on these airplanes is expected to increase as airplanes reach and exceed this goal. In order to evaluate the impact of increased fatigue cracking with respect to maintaining the safe design of the McDonnell Douglas Model DC–6 airplane structure, the manufacturer has conducted a structural reassessment of these airplanes using engineering evaluation techniques. The criteria for this reassessment are contained in FAA Advisory Circular (AC) 91–60, "Continued Airworthiness of Older Airplanes."

In response to AC–91–60, McDonnell Douglas Corporation initiated the development of a Supplemental Inspection Document (SID) for Models DC–6, DC–6A, DC–6B, C–118A, and R6D–1 series airplanes, (hereinafter referred to as "Model DC–6"). McDonnell Douglas Corporation coordinated its efforts with the operators of Model DC–6 series airplanes. To make maximum use of service experience and existing maintenance programs, Model DC–6 operators have participated with the manufacturer and the FAA in generating the Model DC–6 SID.

McDonnell Douglas Corporation developed criteria and guidelines for: (1) Selecting the major areas of the structure, identified as Principal Structural Elements (PSE), which are candidates for supplemental inspection by using the latest engineering analysis techniques; and (2) analyzing existing inspection programs. This supplemental inspection program evaluates the adequacy of current normal maintenance inspection programs to detect fatigue damage, and provides detailed non-destructive inspection procedures to supplement the operators' existing inspection programs, as necessary.

The program was established upon the evaluation of each PSE selected. A PSE is defined as "that structure whose failure, if it remained undetected, could lead to the loss of the aircraft." Selection of a PSE is influenced by the susceptibility of a structural area, part, or element to fatigue, corrosion, stress corrosion, or accidental damage.

The FAA has reviewed and approved McDonnell Douglas Corporation SID Report No. L26–014, dated January 1992, which describes the structural supplemental inspection procedures of all Model DC–6 series airplanes.

The DC–6 SID, Chapters I, II, III, and IV, addresses five basic issues:

1. Identification of the selected PSE's;
2. When to accomplish inspection;
3. Frequency of inspection;
4. Number of inspections required; and
5. Non-destructive inspection (NDI) procedures for detecting cracks.

The SID inspection program is based on Model DC–6 current usage, durability assessment of the structure using current analysis techniques, and selection of the current non-destructive inspection methods. In order to implement the SID inspection program, each operator must compare its current structural maintenance program to the SID requirements for each PSE. If the current inspections equal or exceed the SID requirements for a given PSE, no supplemental inspections would be required for that PSE under the SID program. However, if the opposite is true, supplemental inspections in the form of more frequent inspections or more sensitive NDI methods, or both, would be necessary in addition to the operator's normal maintenance program.

Since the emphasis of the SID program is on aging aircraft, the inspection program emphasis is on the high time aircraft of each PSE population. The date and flight hours (or landings) at which modification or replacement of a PSE is made, would be required to be reported by the operator

to the manufacturer for each applicable airplane by fuselage number and/or factory serial number and PSE number. That particular configuration is then evaluated by McDonnell Douglas Corporation. The inspection threshold and interval will be established, and a change, if needed, will be published in the next revision of the SID.

Inspection Program

The expected fatigue life of each PSE is determined by a demonstrated life, either by service experience or by analysis. The time when the supplemental inspections are to begin or be completed is determined from the expected fatigue life and crack propagation characteristics of each PSE. All inspections are to be accomplished before the airplane exceeds the fatigue life threshold.

The results of the supplemental inspections are to be reported to the manufacturer on a form provided in the SID. This information will be presented in the periodic revisions for the SID.

Effects of Existing Maintenance Programs

In developing the SID, the manufacturer, operators, and the FAA reviewed the operation and maintenance practices of existing maintenance programs with respect to the basic requirements of the SID program. As a result, the McDonnell Douglas DC–6 SID allows affected operators to take credit for maintenance already being performed, and gives the operators flexibility in revising their maintenance programs to incorporate this supplemental program for their airplanes.

Proposed Requirements of this AD Action

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require the implementation of a supplemental structural inspection program, and the repair or replacement of any cracked structure detected during the inspections. Operators would have the option to implement the program either by the accomplishment of specific inspections or by revising the FAA-approved maintenance program to include such a program. Paragraph (a) of the proposal provides for accomplishment of the specific inspections described in the referenced SID; the intent of this paragraph is to address those operators that are not operating under an FAA-approved maintenance/inspection program. Paragraph (b) provides an alternative method of compliance to those operators that operate under such a program; this alternative procedure allows these operators to revise their FAA-approved maintenance/inspection programs to include a schedule for the supplemental structural inspections.

Economic Impact

There are approximately 75 McDonnell Douglas Model DC–6 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 57 airplanes of U.S. registry would be affected by this proposed AD. Of these 57 airplanes, 13 are operated pressurized and 44 are operated non-pressurized.

For the 13 pressurized airplanes, the FAA estimates that it would take approximately 330 work hours per airplane to accomplish the proposed inspection actions, at an average labor rate of $55 per work hour. Based on these figures, the total cost impact on U.S. operators of pressurized Model DC–6 series airplanes of $235,950, or $18,150 per airplane.

For the 44 non-pressurized airplanes, the FAA estimates that it would take approximately 210 work hours per airplane to accomplish the proposed inspection actions, at an average labor rate of $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators of non-pressurized Model DC–6 series airplanes of $508,200, or $11,550 per airplane.

Based on the figures discussed above, the total cost impact of this proposed AD on U.S. operators is estimated to be $744,150. This total cost figure assumes that no operator has yet accomplished the requirements of this proposed AD action.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

McDonnell Douglas: Docket 92–NM–132–AD.

Applicability: All Model DC–6, DC–6A, DC–6B, C–118A, and R6D–1 series airplanes; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To ensure the continuing structural integrity of these airplanes, accomplish the following:

(a) Except as provided by paragraph (b) of this AD, inspect each Principal Structural Element (PSE) defined in Chapter 1, Section 6, and Chapter III, of McDonnell Douglas Corporation Report No. L26–014, DC–6 Supplemental Inspection Document (SID), dated January 1992 (hereafter referred to as "the SID"), in accordance with the non-destructive inspection methods set forth in Chapter II of the SID, and in accordance with the schedule specified in paragraphs (a)(1) and (a)(2) of this AD:

(1) Complete the initial inspection of each PSE specified in Chapter I, Section 6, and Chapter III of the SID as follows:

(i) For PSE's that have not yet reached their inspection threshold as of one year after the effective date of this AD, the initial inspection must be accomplished no later that the threshold specified.

(ii) For PSE's that have exceeded their inspection threshold as of one year after the effective date of this AD, the initial inspection must be accomplished within on repeat (R) interval for the PSE, measured from a date one year after the effective date of this AD.

(2) Subsequent inspections must be accomplished at intervals not to exceed the

intervals specified in Chapter III, Section 1, of the SID for the specific NDI sequence code used at the previous inspection.

(b) As an alternative to the requirements of paragraph (a) of this AD: Within one year after the effective date of this AD, incorporate a revision into the FAA-approved maintenance inspection program which provides for inspection of the PSE's defined in Chapter I, Section 6, and Chapter III of the SID. The non-destructive inspection techniques set forth in the SID provide acceptable methods for accomplishing the inspections required by this AD.

(c) Discrepant structure detected during the inspections required by this AD must be replaced or repaired prior to further flight, in accordance with the McDonnell Douglas DC–6 Structural Repair Manual; or in accordance with data approved by the Manager, Los Angeles Aircraft Certification Office, FAA, Transport Airplane Directorate.

(d) All inspection results (positive or negative) must be reported to the McDonnell Douglas Corporation in accordance with the instructions in the SID. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Certification Office (ACO), FAA Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

(f) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on January 8, 1993.

N. B. Martenson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–837 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–13–U

Research and Special Programs Administration

14 CFR Part 234

[Docket No. 48524; Notice 93–1]

RIN 2137–AB94

Amendments to the On-Time Disclosure Rule; Extension of Comment Period

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On December 11, 1992, RSPA published a notice of proposed rulemaking (NPRM) in the **Federal Register** to amend the on-time flight reporting requirements. The NPRM provided a 30-day comment period, ending January 11, 1993. The Air Transport Association of America (ATA) requested that the comment period be extended for one month. ATA stated that the NPRM raises significant operational and cost issues for the affected carriers, and the holiday season will impede ATA's efforts to prepare a consolidated industry response to the NPRM. RSPA is extending the comment period for an additional 30 days to allow industry time to evaluate the proposal and facilitate the submission of comments.

DATES: The comment period is extended from January 11, 1993, to February 11, 1993.

ADDRESSES: Comments to this docket should be directed to the Docket Clerk, Docket 48524, room 4107, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Comments should identify the docket number and be submitted in duplicate to the above address. Receipt of comments will be acknowledged if the commenter includes a stamped, self-addressed postcard on which the following statement is made: Comments on Docket 48524. The Docket Clerk will time- and date-stamp the postcard and return it to the commenter. All comments will be available for examination in the Rules Docket both before and after the closing date for comments.

FOR FURTHER INFORMATION CONTACT:

Bernard Stankus, Office of Airline Statistics, DAI–10, Research and Special Programs Administration, Department of Transportation, at the address above. Telephone: (202) 366–4387.

Issued in Washington, DC, on January 8, 1993.

Alan I. Roberts,

Acting Administrator, Research and Special Programs Administration.

[FR Doc. 93–894 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–62–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

Schedules of Controlled Substances Temporary Placement of Alpha-ethyltryptamine into Schedule I

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of intent.

SUMMARY: The Administrator of the Drug Enforcement Administration (DEA) is issuing this notice of intent to temporarily place alpha-ethyltryptamine into Schedule I of the Controlled Substances Act (CSA) pursuant to the temporary scheduling provisions of the CSA (21 U.S.C. 811(h)). This intended action is based on the finding by the DEA Administrator that the placement of alpha-ethyltryptamine in Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Finalization of this action will impose the criminal sanctions and regulatory controls of Schedule I on the manufacture, distribution, and possession of alpha-ethyltryptamine.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr. Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington; DC 20537, Telephone: (202) 307–7183.

SUPPLEMENTARY INFORMATION: The Comprehensive Crime Control Act of 1984 (Pub. L. 98–473), which was signed into law on October 12, 1984, amended section 201 of the Controlled Substances Act (CSA) (21 U.S.C. 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA if he finds that such action is necessary to avoid an imminent hazard to the public safety. A substance may be temporarily scheduled under the emergency provision of the CSA if that substance is not listed in any other schedule under section 202 of the CSA (21 U.S.C. 812) or if there is no approval or exemption in effect under 21 U.S.C. 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. 811 to the Administrator of DEA (28 CFR 0.100). In making a finding that placing a substance temporarily in Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA (21 U.S.C. 811(c)). These factors are as follows: (4) History and current pattern of abuse; (5) The scope, duration and

significance of abuse; and (6) What, if any, risk there is to the public health.

Alpha-ethyltryptamine has been classified as a central nervous system (CNS) stimulant as well as a tryptamine hallucinogen. Chemically it is α-ethyl-1H-indole-3-ethanamine or 3-(2-aminobutyl)indole. It is structurally similar to N,N–dimethyltryptamine (DMT) and N,N–diethyltryptamine (DET) both of which are hallucinogens controlled in Schedule I of the CSA. Available data indicates that alpha-ethyltryptamine produces some pharmacological effects qualitatively similar to those of other Schedule I hallucinogens.

DEA first encountered alpha-ethyltryptamine in 1986 at a clandestine laboratory in Nevada. Several exhibits of alpha-ethyltryptamine have been analyzed by DEA and state forensic laboratories since 1989. Individuals in Colorado and Arizona have purchased several kilograms of this substance as the acetate salt from chemical supply companies and have distributed and sold quantities to individuals for the purpose of human consumption. Touted as an MDMA (3, 4-methylenedioxymethamphetamine)-like substance, it has been trafficked as "TRIP" or "ET". Distribution and use has been primarily among high school and college-aged individuals. In Arizona, the death of a 19 year old female was attributed to acute alpha-ethyltryptamine toxicity. Illicit use has been documented in both Germany and Spain where two deaths have resulted from alpha-ethyltryptamine overdose.

Alpha-ethyltryptamine acetate was marketed by the Upjohn Company in 1961 as an antidepressant under the trade name of Monase. After less than one year of marketing, Upjohn withdrew its New Drug Application when it became apparent that Monase administration was associated with the development of agranulocytosis. Recent scientific data would also suggest that this substance may produce neurotoxicity similar to the neuro-toxic effects produced by MDMA and PCA (para-chloroamphetamine).

The continued uncontrolled availability of alpha-ethyltryptamine, its CNS stimulatory and hallucinogenic properties similar to those of DMT, DET and MDMA, its association with agranulocytosis and possible neurotoxicity, pose an imminent hazard to public safety. DEA is not aware of any therapeutic use of this substance in the United States.

In accordance with the provisions of section 201(h) of the CSA (21 U.S.C. 811(h)) and 28 CFR 0.100 the Administrator has considered the three factors required for a determination of whether temporarily scheduling alpha-ethyltryptamine under the CSA is necessary to avoid an imminent hazard to the public safety. Based on a consideration of these factors and other relevant information, the Administrator finds that placement of alpha-ethyltryptamine into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety.

As required by section 201(h)(4) of the CSA (21 U.S.C. 811(h)(4)), the Administrator has notified the Assistant Secretary for Health, delegate of the Secretary of Health and Human Services, of his intention to temporarily place alpha-ethyltryptamine into Schedule I of the CSA. Comments submitted by the Assistant Secretary for Health in response to this notification including whether there is an exemption or approval in effect for alpha-ethyltryptamine under the Federal Food, Drug and Cosmetic Act, shall be taken into consideration before a final order is published. Because the Administrator finds that it is necessary to temporarily place alpha-ethyltryptamine into Schedule I to avoid an imminent hazard to the public safety, the final order, if issued, will be effective on the date of publication of the **Federal Register**. Further, it is the intention of the Administrator to issue such a final order as soon as possible after the expiration of thirty days from the date of publication of this notice and the date that notification was transmitted to the Assistant Secretary for Health.

The Administrator of the Drug Enforcement Administration hereby certifies that this notice of intent to temporarily place alpha-ethyltryptamine into Schedule I of the CSA will have no significant impact upon entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 801 *et seq.*

The temporary scheduling of alpha-ethyltryptamine is not a major rule for the purposes of Executive Order (E.O.) 12291 of February 17, 1981. It has been determined that drug scheduling matters are not subject to review by the Office of Management and Budget (OMB) pursuant to the provisions of E.O. 12291. Accordingly, this proposed emergency scheduling action is not subject to provisions of E.O. 12778 which are contingent upon review by OMB. This regulation both responds to an emergency situation posing an imminent danger to the public safety, and is essential to a criminal law enforcement function of the United States. Accordingly, it is not subject to a moratorium on regulations ordered by the President of the United States in his memorandum of January 28, 1992, as amended.

This action has been analyzed in accordance with the principles and criteria in E.O. 12291, and it has been determined that the temporary placement of alpha-ethyltryptamine into Schedule I of the CSA does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs, Reporting and record keeping requirements.

Under the authority vested in the Attorney General by section 201(h) of the CSA (21 U.S.C. 811(h)), and delegated to the Administrator of the DEA by Department of Justice regulations (28 CFR 0.100), the Administrator hereby intends to order that 21 CFR part 1308 be amended as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871b, unless otherwise noted.

2. Section 1308.11 is amended by adding paragraph (g)(5) to read as follows:

§ 1308.11 Schedule I

* * * * *

(g) * * *

(1) N-[1-benzyl-4-piperidyl]-N-phenylpropanamide (benzylfentanyl), its optical isomers, salts and salts of isomers	9818
(2) N-[1-(2-thienyl)methyl-4-piperidyl]-N-phenylpropanamide (thenylfentanyl), its optical isomers, salts and salts of isomers	9834
(5) alpha-ethyltryptamine, its optical isomers, salts and salts of isomers	7249

Some other names: etryptamine; α-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole.

Date: January 8, 1993.

Robert C. Bonner,

Administrator of Drug Enforcement.

[FR Doc. 93–878 Filed 1–13–93; 8:45 am]

BILLING CODE 4410-09-M

VOL 58 ISS 9 JA 14 1993 UMI

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 26 and 301

[PS-73-88; PS-32-90]

RIN 1545-AL75; 1545-AO89

Generation-Skipping Transfer Tax; Hearing

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of a public hearing on proposed Income Tax Regulations relating to the generation-skipping transfer tax imposed under chapter 13 of the Internal Revenue Code.

DATES: The public hearing will be held on Wednesday, April 21, 1993, beginning at 10 a.m. Requests to speak and outlines of oral comments must be received by Wednesday, March 31, 1993.

ADDRESSES: The public hearing will be held in the IRS Commissioner's Conference Room, room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Requests to speak and outlines of oral comments should be submitted to the Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Attn: CC:CORP:T:R [PS-73-88; PS-32-90], room 5228, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulation Unit, Assistant Chief Counsel (Corporate), 202-622-7190 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations that would apply additions to the Generation-Skipping Transfer Regulations (26 CFR part 26) under sections 2601 through 2663 of the Internal Revenue Code (Code). The proposed regulations were published in the **Federal Register** for Thursday, December 24, 1992 (57 FR 61356 and 61353).

The preamble of the proposed regulations inadvertently made reference to the public hearing being held on February 18, 1993, and the outline of oral comments being due on February 1, 1993. Those dates are inaccurate. The public hearing is scheduled for April 21, 1993, and the outline of oral comments is due on March 31, 1993.

The rules of § 601.601(a)(3) of the "Statement of Procedural Rules" (26 CFR part 601) shall apply with respect to the public hearing. Persons who have submitted written comments within the time prescribed in the notice of proposed rulemaking and who also desire to present oral comments at the hearing on the proposed regulations should submit not later than Wednesday, March 31, 1993, an outline of the oral comments/testimony to be presented at the hearing and the time they wish to devote to each subject.

Each speaker (or groups of speakers representing a single entity) will be limited to 10 minutes for an oral presentation exclusive of the time consumed by the questions from the panel for the government and answers to these questions.

Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the persons testifying. Copies of the agenda will be available free of charge at the hearing.

By direction of the Commissioner of Internal Revenue.

Cynthia E. Grigsby,

Alternate Federal Register Liaison Officer, Assistant Chief Counsel (Corporate).

[FR Doc. 93-661 Filed 1-13-93; 8:45 am]

BILLING CODE 4830-01-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

Indiana Regulatory Program Amendment

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing receipt of a proposed amendment submitted by Indiana as a modification to the State's regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA)

The amendment (Program Amendment 92-7) submitted consists of proposed changes to the Indiana Surface Mining Rules concerning subsidence liability. This amendment is intended to revise the permitting requirements and the performance standards for subsidence control applicable to underground coal mining operations.

This document sets forth the times and locations that the Indiana program and the proposed amendment to that program will be available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed for a public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on February 16, 1993; if requested, a public hearing on the proposed amendment is scheduled for 1 p.m. on February 8, 1993; and, requests to present oral testimony at the hearing must be received on or before 4 p.m. on January 29, 1993.

ADDRESSES: Written comments and requests to testify at the hearing should be directed to Mr. Roger W. Calhoun, Director, Indianapolis Field Office, at the address listed below. If a hearing is requested, it will be held at the same address.

Copies of the Indiana program, the amendment, a listing of any scheduled public meetings, and all written comments received in response to this document will be available for public review at the following locations, during normal business hours, Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Indianapolis Field Office, Minton-Capehart Federal Building, 575 North Pennsylvania Street, room 301, Indianapolis, IN 46204. Telephone: (317) 226-6166.

Indiana Department of Natural Resources, 402 West Washington Street, room 295, Indianapolis, IN 46204. Telephone: (317) 232-1547.

Each requester may receive, free of charge, one copy of the proposed amendment by contacting the OSM Indianapolis Field Office.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, telephone (317) 226-6166.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982, **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.10, 914.15, and 914.16.

II. Discussion of the Proposed Amendment

By letter dated December 2, 1992, (Administrative Record No. IND–1175), the Indiana Department of Natural Resources (IDNR) submitted a proposed amendment to the Indiana program at 310 Indiana Administrative Code (IAC) 12–3–87.1, 12–3–130.1 and 12–3–131.1.

The proposed amendment consists of the addition of the following Indiana rules:

1. 310 IAC 12–3–87.1 Underground Mining Permit Applications; Reclamation Plan; Subsidence Control Plan.

This provision would require the identification in the permit application of existing structures and renewable resource lands in the proposed permit area and whether any subsidence would cause damage or diminution of value. If damage or diminution of value could occur, a subsidence control plan is required which contains: A description of the mining method; a map of underground workings, planned subsidence areas, and areas where prevention or minimization measures will be taken; a description of physical conditions which would affect subsidence and related damage; subsidence monitoring; a description of subsidence control measures; a description of anticipated effects of any planned subsidence; a description of subsidence mitigation and remedial measures; and other information specified by the director of IDNR.

2. 310 IAC 12–5–130.1 Underground Mining; Subsidence Control; General Requirements.

This provision would require a permittee to either adopt measures which prevent subsidence from causing material damage, maximize mine stability, and maintain the value and use of lands; or adopt mining technology which provides for planned subsidence in a predictable and controlled manner. The permittee shall comply with the approved subsidence control plan. The permittee shall correct material damage caused to surface lands, and, to the extent required under Indiana law, correct damage to structures or facilities by repair or compensation. The rule identifies structures where mining shall not be conducted beneath or adjacent to unless the subsidence control plan demonstrates that subsidence will not cause material damage to, or reduce the reasonably foreseeable use of such structures. The rule identifies when the director of IDNR may or must limit or suspend coal extraction. This provision also requires the submittal of a detailed report of the underground workings including: Maps, descriptions of workings, and confidentiality request.

3. 310 IAC 12–5–131.1 Underground Mining; Subsidence Control; Public Notice.

This provision requires notification of proposed underground mining to owners and occupants of surface property and structures and pipeline operators. The provision also specifies the availability and contents of the notices.

The full text of the proposed program amendment submitted by Indiana is available for public inspection at the addresses listed above. The Director now seeks public comment on whether the proposed amendment is no less effective than the Federal regulations. If approved, the amendment will become part of the Indiana program.

III. Public Comment Procedures

In accordance with provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by Indiana satisfies the requirements of 30 CFR 732.15 for the approval of State program amendments. If the amendment is deemed adequate, it will become part of the Indiana program.

Written Comments

Written comments should be specific, pertain only to issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Indianapolis Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by the close of business on January 29, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons who desire to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the Indianapolis Field Office by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed above under **ADDRESSES**. A summary of the meeting will be included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.13 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(c) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 24, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director Eastern Support Center

[FR Doc. 93–871 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–05–M

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30 CFR Part 914

Indiana Abandoned Mine Land Reclamation Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the Indiana Abandoned Mine Land Reclamation (AMLR) Program (hereinafter referred to as the Indiana Program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1201 *et seq.*, as amended. The proposed amendment is intended to provide the policies and procedures with which Indiana would conduct the Abandoned Mine Land Reclamation emergency program on behalf of OSM.

This notice sets forth the times and locations that the Indiana program and the proposed amendment to that program will be available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on February 16, 1993. If requested, a public hearing on the proposed amendments will be held at 1 p.m. on February 8, 1993. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on January 29, 1993.

ADDRESSES: Written comments and requests to testify at the hearing should be mailed or hand-delivered to Mr. Roger W. Calhoun, Director, Indianapolis Field Office, at the address listed below. If a hearing is requested, it will be held at the same address.

Copies of the Indiana program, the proposed amendment, a listing of any scheduled public meetings and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays:

Office of Surface Mining Reclamation and Enforcement, Indianapolis Field Office, Minton-Capehart Federal Building, 575 N. Pennsylvania Street, room 301, Indianapolis, IN 46204, Telephone: (317) 226–6166

Indiana Department of Natural Resources, 402 West Washington Street, room 295, Indianapolis, IN 46204, Telephone: (317) 232–1547

Each requester may receive, free of charge, one copy of the proposed amendment by contacting the OSM Indianapolis Field Office.

FOR FURTHER INFORMATION CONTACT: Mr. Roger W. Calhoun, Director, Indianapolis Field Office, (317) 226–6700.

SUPPLEMENTARY INFORMATION:

I. Background on the Indiana Program

On July 29, 1982, the Indiana program was made effective by approval of the Secretary of the Interior. Information pertinent to the general background on Indiana's program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982, Federal Register (47 FR 32110). Subsequent actions concerning the conditions of approval and AMLR program amendments are identified at 30 CFR 914.20 and 914.25.

Section 410 of SMCRA authorizes the Secretary to use funds under the AMLR program to abate or control emergency situations in which adverse effects of past coal mining pose an immediate danger to the public health, safety, or general welfare. On September 29, 1982 (47 FR 42729), OSM invited States to amend their AMLR Plans for the purpose of undertaking emergency reclamation programs on behalf of OSM. States would have to demonstrate that they have the statutory authority to undertake emergencies, the technical capability to design and supervise the emergency work, and the administrative mechanisms to quickly respond to emergencies either directly or through contractors.

Under the provisions of 30 CFR 884.15, any State may submit proposed amendments to its approved AMLR Plan. If the proposed amendments change the scope of major policies followed by the State in the conduct of its AMLR program, the Director must follow the procedures set out in 30 CFR 884.14 in reviewing and approving or disapproving the proposed amendments.

The proposed assumption of the AMLR emergency program on behalf of OSM is a major addition to the Indiana AMLR program. To assure the emergency program, Indiana must revise the Indiana Plan to include conducting the AML emergency program. This amendment proposed changes to the Indiana Plan to authorize Indiana to conduct the AMLR emergency program on behalf of OSM. This proposed rule begins OSM's review process on Indiana's Program Amendment.

II. Discussion of the Proposed Amendment

By letter received November 17, 1992 (Administrative Record No. IND–1171), the Indiana Department of Natural Resources (IDNR), Division of Reclamation, submitted a proposed Program Amendment to the Indiana Program. This amendment is intended to demonstrate Indiana's capability to effectively perform the AMLR emergency program on behalf of OSM. In support of the proposed amendment, Indiana also submitted responses to

OSM's September 29, 1982, guidelines for State proposals to assume the emergency program (47 FR 42729).

Indiana's proposed revisions to the Indiana Program are briefly summarized below:

1. The proposed amendment would allow Indiana to assume the administration of the AMLR emergency program on behalf of OSM. The following information is contained in Indiana's formal submission to OSM:

A. The agency designated by the Governor as authorized to receive grants and administer an emergency program.

B. A legal opinion from the chief legal officer that the designated agency has the authority under State law to conduct the emergency program in accordance with the requirements of section 410 of title IV of the Act.

C. A description of the policies and procedures to be followed by the designated agency in conducting the reclamation program including:

(1) The purpose of the emergency reclamation program.

(2) The coordination of emergency reclamation work between the State, OSM and any Indian Tribe reclamation program located within the State.

(3) Policies and procedures regarding land acquisition on emergency projects in connection with 30 CFR 879.11(b)(2).

(4) Policies and procedures regarding emergency reclamation on private land under 30 CFR part 882, and on public lands.

(5) Policies and procedures regarding emergency project rights-of-entry under 30 CFR 877.14 and other realty functions.

(6) Public participation and involvement in the preparation of the State emergency program.

D. A description of the administrative and managerial structure to be used in conducting the emergency reclamation program including:

(1) The organization of the designated agency's emergency program.

(2) A description of the adequacy of staff numbers and technical skills to be committed to the emergency program.

(3) Administrative procedures for (a) investigating and reporting emergency complaints; (b) determining eligibility; (c) rights-of-entry and necessary appraisals; (d) project supervision; and (e) final project inspection and preparation and submission of final project reports.

(4) The purchasing and procurement systems to be used by the agency which will quickly respond to emergency situations.

(5) The accounting system to be used by the agency.

(6) Technical capability to design and supervise the emergency work.

E. A general description, derived from available data, of emergency reclamation activities to be conducted, including known or suspected geographical areas within the State, including:

(1) A map locator showing the general location of known or suspected emergencies.

(2) A description of the problems causing these emergencies.

F. Narrative description which supports the State's position that the procedures, personnel and other proposed aspects of its program give evidence of its abilities to promptly and effectively mitigate the full range of anticipated emergency conditions.

2. After assuming the emergency program Indiana would conduct potential emergency site investigations, and following OSM concurrence that an emergency situation exists, perform remedial reclamation.

3. Minor wording changes may occur in other sections of the plan, but do not substantively change the plan.

The full text of proposed program amendment submitted by Indiana is available for public inspection at the addresses listed above. The Director now seeks public comment on whether the proposed amendment is no less effective than the Federal regulations. If approved, the amendment will become part of the Indiana program.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 884.15, OSM is now seeking comment on whether the amendment proposed by Indiana satisfies the applicable requirements for the approval of State AMLR program amendments. If the amendment is deemed adequate, it will become part of the Indiana program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Indianapolis Field office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by close of business on January 29, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons who desire to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendments may request a meeting at the Indianapolis Field Office by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of the meetings will be posted in advance at the locations listed above under **ADDRESSES**. A summary of meeting will be included in the Administrative Record.

Executive Order 12291

On March 30, 1992, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or disapproval of State and Tribal abandoned mine land reclamation plans and revisions thereof. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State and Tribal abandoned mine land reclamation plans and revisions thereof since each such plan is drafted and adopted by a specific State or Tribe, not by OSM. Decisions on proposed State and Tribal abandoned mine land reclamation plans and revisions thereof submitted by a State or Tribe are based on a determination of

whether the submittal meets the requirements of title IV of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1231–1243) and the Federal regulations at 30 CFR parts 884 and 888.

National Environmental Policy Act

No environmental impact statement is required for this rule since agency decisions on proposed State and Tribal abandoned mine land reclamation plans and revisions thereof are categorically excluded from compliance with the National Environmental Policy Act (42 U.S.C. 4332) by the Manual of the Department of the Interior (516 DM 6, appendix 8, paragraph 8.4B(29)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State (or Tribal) submittal which is the subject of this rule is based upon Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements established by SMCRA or previously promulgated by OSM will be implemented by the State (or Tribe). In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions in the analyses for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 16, 1992.

Jeffrey Jarrett,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 93–866 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-05-M

30 CFR Part 915

Iowa Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the Iowa permanent regulatory program (the "Iowa program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of changes to provisions of the Iowa regulations pertaining to permanent regulatory program, exemption for coal extraction incidental to the extraction of other minerals, restriction of financial interests of State employees, exemption for coal extraction incident to government-financed highway or other construction, protection of employees, initial regulatory program, areas unsuitable for mining, permits for operations and exploration, small operator assistance, bonding and insurance, permanent program performance standards, inspection and enforcement, blaster certification, and contested cases and public hearings. The amendment is intended to revise the State program to be consistent with the corresponding Federal standards, clarify ambiguities, and improve operational efficiency.

This notice sets forth the times and locations that the Iowa program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4 p.m., c.s.t. on February 16, 1993. If requested, a public hearing on the proposed amendment will be held on February 8, 1993. Requests to present oral testimony at the hearing must be received by 4 p.m., c.s.t. on January 29, 1993.

ADDRESSES: Written comments should be mailed or hand delivered to Jerry R. Ennis at the address listed below.

Copies of the Iowa program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Kansas City Field Office.

Jerry R. Ennis, Director, Kansas City Field Office, Office of Surface Mining Reclamation and Enforcement, 934 Wyandotte, Room 500, Kansas City, MO 64105; Telephone: (816) 374–6405.

Department of Agriculture and Land Stewardship, Division of Soil Conservation, Wallace State Office Building, East 9th and Grand Streets, Des Moines, Iowa 50319; Telephone: (515) 281–6147.

FOR FURTHER INFORMATION CONTACT: Jerry R. Ennis, Telephone: (816) 374–6405.

SUPPLEMENTARY INFORMATION:

I. Background on the Iowa Program

On January 21, 1981, the Secretary of Interior conditionally approved the Iowa Program. General background information on the Iowa program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Iowa program can be found in the January 21, 1981, **Federal Register** (46 FR 5885). Subsequent actions concerning Iowa's program and program amendments can be found at 30 CFR 915.15 and 915.16.

II. Discussion of Proposed Amendment

From October 1, 1983, to December 20, 1989, a number of changes were made to Federal regulations concerning surface coal mining and reclamation operations. During this time period, pursuant to Federal regulations at 30 CFR 732.17, OSM notified Iowa in four separate 732 letters, listed below, that the State rules must be amended to be consistent with the revised Federal regulations.

1. Regulatory Reform Review II, December 12, 1988, Administrative Record Number IA–336.

2. Ownership and Control, May 11, 1989, Administrative Record Number IA–340.

3. Regulatory Reform Review III, November 28, 1989, Administrative Record Number IA–347.

4. Incidental Coal Extraction, February 7, 1990, Administrative Record Number IA–349.

By letter dated November 23, 1992 (Administrative Record No. IA–372), Iowa submitted a proposed amendment to its program pursuant to SMCRA. Iowa submitted the proposed amendment with the intent of satisfying the outstanding 732 letters from OSM and the required program amendments at 30 CFR 915.16(a) (56 FR 56578). The amendment also contains nonsubstantive revisions to eliminate editorial and typographical errors.

The substantive changes proposed by Iowa are discussed briefly below:

(1) IAC 27–40.1 (3) and (4) Professional Land Surveyor

Iowa proposes to delete the provisions that authorize land surveyors to prepare and certify cross-sections, maps, and plans anywhere in the Iowa program.

(2) IAC 27–40.1(5) Registered Professional Engineer

Iowa proposes to require, throughout the Iowa program, that professional engineers performing design or certification work in conjunction with the program be registered in Iowa.

(3) IAC 27–40.3(83) General

Iowa proposes to replace the incorporation by reference of 30 CFR part 700 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(4) IAC 27–40.4(83) Permanent Regulatory Program and Exemption for Coal Extraction Incidental to the Extraction of Other Minerals.

Iowa proposes to replace the Incorporation by reference of 30 CFR part 701 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992. Iowa also proposes to adopt by reference the Federal rules concerning exemption for coal extraction incidental to the extraction of other minerals at 30 CFR part 702, as in effect on July 1, 1992.

(5) IAC 27–40.4(7) Administrative Review

Iowa proposes to delete the Federal rule at 30 CFR 702.11(f) and replace it with a similar provision that includes State specific regulatory citations.

(6) IAC 27–40.4(8) Revocation and Enforcement

Iowa proposes to delete the Federal rules at 30 CFR 702.17(c) (2) and (3) and replace them with similar provisions that include State specific regulatory citations.

(7) IAC 27–40.4(9) Previously Mined Area

Iowa proposes to delete its incorporation of the Federal definition of "previously mined area" at 30 CFR 701.5 and replace it with a definition that would mean land previously mined on which there were no surface coal mining operations subject to the standards of the SMCRA; all highwalls created after August 3, 1977, and all fully reclaimed sites would be excluded from the definition.

(8) IAC 27–40.4(10) Full Water Year

Iowa proposes to add at its incorporation of 30 CFR 701.5 a definition of "full water year," to mean at a minimum the 9 month period from March through November.

(9) IAC 27–40.5(83) Restrictions on Financial Interests of State Employees

Iowa proposes to replace the incorporation by reference of 30 CFR part 705 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(10) IAC 27–40.6(83) Exemptions for Coal Extraction Incident to Government-Financed Highway or Other Construction

Iowa proposes to replace the incorporation by reference of 30 CFR part 707 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(11) IAC 27–40.7(83) Protection of Employees

Iowa proposes to replace the incorporation by reference of 30 CFR part 865 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(12) IAC 27–40.11(83) Initial Program

Iowa proposes to replace the incorporation by reference of 30 CFR part 710 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(13) IAC 27–40.12(83) General Performance Standards—Initial Program

Iowa proposes to replace the incorporation by reference of 30 CFR part 715 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(14) IAC 27–40.13(83) Special Performance Standards—Initial Program

Iowa proposes to replace the incorporation by reference of 30 CFR part 716 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(15) IAC 27–40.21(83) Areas Designated by an Act of Congress

Iowa proposes to replace the incorporation by reference of 30 CFR part 761 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(16) IAC 27–40.21(5) Procedures

Iowa proposes to delete the requirement at 30 CFR 761.12(c) that where the proposed operation would include Federal lands within the boundaries of any national forest, and the applicant seeks a determination that mining is permissible under 30 CFR 761.11(B), the applicant shall submit a permit application to the Director for processing under subchapter D of this chapter. The provision proposed for deletion also requires that before acting on the permit application, the Director shall ensure that the Secretary's determination has been received and the findings required by section 522(e)(2) of the Act have been made.

(17) IAC 27–40.22(83) Criteria for designating areas as unsuitable for surface coal mining operations.

Iowa proposes to replace the incorporation by reference of 30 CFR part 762 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(18) IAC 27–40.23(83) State Procedures for Designating Areas Unsuitable for Surface Coal Mining Operations

Iowa proposes to replace the incorporation by reference of 30 CFR part 764 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(19) IAC 27–40.30(83) Requirements for Coal Exploration

Iowa proposes to replace the incorporation by reference of 30 CFR part 772 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(20) IAC 27–40.31(83) Requirements for Permits and Permit Processing

Iowa proposes to replace the incorporation by reference of 30 CFR part 773 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(21) IAC 27–40.31(2) Public Participation in Permit Processing

Iowa proposes to add a requirement to 30 CFR 773.13(a)(1)(ii) that the newspaper advertisement include the following information. The legal description would have to include popular township, county, township, range, section, and the United States Geological Survey map identification by property owners. Section lines would be marked, and the sections would be identified on the map. The measure of the proposed permit area would be given to the nearest acre.

(22) IAC 27–40.31(12) Comments and Objections on Permit Applications

Iowa proposes to revise 30 CFR 773.13(b)(1) by defining the time allowed for submission of comments on permit applications to be within 60 days of notification.

(23) IAC 27–40.31(13) Review of Permit Applications

Iowa proposes to revise 30 CFR 773.15(a)(2) by adding a provision allowing the Division to require the applicant to re-apply for the same area, if a case of willful suppressing or falsifying of any facts or data is identified.

(24) IAC 27–40.31(14) Improvidently Issued Permits: Rescission Procedures

Iowa proposes to delete the Federal rule at 30 CFR 773.21(c) and replace it with a similar provision that includes State specific regulatory citations.

(25) IAC 27–40.32(83) Revision; Renewal; and Transfer, Assignment, or Sale of Permit Rights

Iowa proposes to replace the incorporation by reference of 30 CFR part 774 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(26) IAC 27–40.32(1) Definitions

Iowa proposes to revise the definitions of terms within 30 CFR part 774 with a clarification that the rules utilize the term "revision" to describe a change to a permit that constitutes a significant departure from the original permit; any change to an Iowa permit that does not constitute a significant departure from the original permit would be called an "amendment" to the permit in the context of these rules.

Iowa would further clarify these requirements with a requirement that the notice, public participation, and notice of decision requirements of 30 CFR 773.13, 773.19(b), and 728.21 apply to all revisions or "significant revisions" as they are described in the Federal regulations.

Iowa would further clarify the distinction between revisions and amendments by noting that significant departures would be treated as revisions, and would include any change in permit area, mining method, or reclamation procedure, which would, in the opinion of the regulatory authority, significantly change the effect that mining operations would have on either those persons impacted by the permitted operation or on the environment; changes which would not constitute a significant departure from the original permit would be processed as an amendment to the permit.

(27) IAC 27–40.32(3) Request to Change Permit Boundary

Iowa proposes to add a clarification that an incidental boundary revision would be considered, on demonstration by the operator, for an area in which the coal seam to be mined is contiguous to that proposed in the approved permit.

(28) IAC 27–40.32(6) Permit Revisions—General

Iowa proposes to add a requirement to 30 CFR 774.13(a) that the term "revision" would apply to a significant departure in mining and reclamation operations defined at subrule IAC 27–40.32(1)(b)(2)(a), and would require a public notice. The Division would use the term "amendment" for an insignificant revision, which would not require a public notice.

(29) IAC 27–40.32(8) Permit Renewal—General

Iowa proposes to add at 30 CFR 774.15(a) a requirement that permit renewal would not be required if the Division determines that the phase II bond was released over the entire permit area before the expiration of the permit term.

(30) IAC 27–40.32(9) Permit Renewal—Application Requirements

Iowa proposes to add to the application information required at 30 CFR 774.15(b)(2 a requirement that the renewal application include the current status of the mine plan, other details, and the time table of the remaining phases of the operation and reclamation plans, if different from the previously approved time table.

(31) IAC 27–40.32(83) General Content—Requirements for Permit Applications

Iowa proposes to replace the incorporation by reference of 30 CFR part 777 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(32) IAC 27–40.32(83) Permit Application—Minimum Requirements for Legal, Financial, Compliance, and Related Information

Iowa proposes to replace the incorporation by reference of 30 CFR part 778 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(33) IAC 27–40.32(83) Surface Mining Permit Applications—Minimum Requirements for Information on Environmental Resources

Iowa proposes to replace the incorporation by reference of 30 CFR part 779 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(34) IAC 27–40.35(2) Vegetation Information

Iowa proposes to replace the regulation at 30 CFR 779.19(b) to require that the specified vegetation map (at a scale of 1:2400 or larger), or the aerial photo, must include sufficient adjacent areas to allow evaluation of vegetation as important habitat for fish and wildlife for those species of fish and wildlife identified under 30 CFR 780.16.

(35) IAC 27–40.35(3) Land Use Information

Iowa proposes to require that the land use information required at 30 CFR 779.22(a)(1) include a map at a scale of 1:2400 or larger or an aerial photo, and a supporting narrative of the uses of the land existing at the time of the filing of the application.

(36) IAC 27–40.35 (9), (10), and (11) Climatological Information

Iowa proposes to make the information required at 30 CFR 779.18(a) mandatory for all applications.

Iowa also proposes to add a requirement that the locations of rain gauges nearest to the permit area, preferably in the same watershed as the permit itself, be marked on a map; and these rain gauges would be described in the text as well, along with the period of available record for those gauges.

Additionally, Iowa proposes to add a requirement that a brief description be provided about the impact of the climatological factors on operation and reclamation plans, specifically about what parts of the year would be more conducive to various mining and reclamation operations.

(37) IAC 27–40.35 (12), (13), and (14) Maps: General Requirements

Iowa proposes to define at 30 CFR 779.24(g) the "hydrologic area" as being the area that consists of the permit area and the adjacent area.

Iowa also proposes to add a requirement at 30 CFR 779.24(h) that maps include each public road (and its identification) located in or within 100 feet of the proposed permit area.

Iowa additionally proposes to add a requirement at 30 CFR 779.24(l) that maps include section lines and section identification.

(38) IAC 27–40.36(83) and 40.38(83) Surface and Underground Mining Permit Applications—Minimum Requirements for Reclamation and Operation Plan

Iowa proposes to replace the incorporation by reference of 30 CFR part 780 and 784 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(39) IAC 27–40.36(3) and 40.38(8) Probable Hydrologic Consequence

Iowa proposes to require that determinations of Probable Hydrologic Consequence (PHC) address all proposed mining activities associated with the permit area for which authorization is sought, as opposed to addressing only those activities expected to occur during the term of the permit.

(40) IAC 27–40.36 (5) and (6) Hydrologic Information

Iowa proposes at 30 CFR 780.21(a) to add a requirement that the methodology for measurement of the quantity of both surface water and groundwater also be described.

Iowa also proposes to make mandatory for all permit applications the modeling of surface and groundwater information at 30 CFR 780.21(d).

(41) IAC 27–40.39(83) Requirements for Permits for Special Categories of Mining

Iowa proposes to replace the incorporation by reference of 30 CFR part 785 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(42) IAC 27–40.39(1) Permits Incorporating Variances From Approximate Original Contour (AOC) Restoration Requirements for Steep Slope Mining

Iowa proposes to add by incorporation the Federal regulations at 30 CFR 785.16, to allow permit variances from AOC in conjunction with steep slope mining.

(43) IAC 27–40.39(8) Coal Preparation Plants Not Located Within the Permit Area of a Mine

Iowa proposes to add to 30 CFR 785.21(a) a requirement that off-site processing plants operated in connection with a mine but off the mine site would be regulated without regard to its proximity to the mine.

(44) IAC 27–40.41(83) Small Operator Assistance

Iowa proposes to replace the incorporation by reference of 30 CFR part 795 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(45) IAC 27–40.51(83) Bond and Insurance Requirements for Surface Coal Mining and Reclamation Operations Under Regulatory Programs

Iowa proposes to replace the incorporation by reference of 30 CFR part 800 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(46) IAC 27–40.51(5) Requirements to Release Performance Bonds

Iowa proposes to reinstate the requirement at 30 CFR 800.40(c)(2) that phase II reclamation bond not be released until the requirements for prime farmland reclamation at 30 CFR part 823 are fulfilled.

(47) IAC 27–40.51(7) Bond Release Application

Iowa proposes to revise this regulation, incorporating 30 CFR 800.40(a)(2), to require that after the application for bond release is deemed complete by the Division, an advertisement must be placed by the permittee within 30 days of the date of notification of completeness; further, the permittee would have to submit a copy of the advertisement to the Division within 30 days of the last publication.

(48) IAC 27–40.61(83) Permanent Program Performance Standards—General Provisions

Iowa proposes to replace the incorporation by reference of 30 CFR part 810 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(49) IAC 27–40.61(1) Responsibility

Iowa proposes to eliminate the requirement that the Iowa program be at least as stringent as the Federal program at 30 CFR 819.4(b), which states that State regulatory authorities shall ensure that performance standards and design requirements at least as stringent as the standards in 30 CFR parts 810–828 are implemented and enforced under every State program.

Iowa proposes to eliminate the requirement that the Iowa program be at least as stringent as the Federal program at 30 CFR 810.4(c), which states that each person conducting coal exploration or surface coal mining and reclamation operations is responsible for complying with performance standards and design requirements which are at least as stringent as the standards in 30 CFR parts 810–828 and the applicable regulatory program.

(50) IAC 27–40.61(83) Permanent Program Performance Standards—Coal Exploration

Iowa proposes to replace the incorporation by reference of 30 CFR part 815 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(51) IAC 27–40.63(83) and 40.64(83) Permanent Program Performance Standards—Surface and Underground Mining Activities

Iowa proposes to replace the incorporation by reference of 30 CFR part 816 and 817 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(52) IAC 27–40.63(7) Backfilling and Grading: Thin Overburden

Iowa proposes to delete the incorporation of 30 CFR 816.104, but rather require that any permit application shall address overburden (and the applicable performance standards) as "thick overburden" in accordance with the definition established at 30 CFR 816.105.

(53) IAC 27–40.63(9) Impoundments

Iowa proposes to add at the end of 30 CFR 816.49(a)(10)(i) a requirement that yearly inspections of impoundments be done in the second quarter of each calendar year; further, the inspection report would be submitted to the Division with the second quarter water monitoring report.

(54) IAC 27–40.63(12) Disposal of Noncoal Mine Wastes

Iowa proposes to delete the requirements of 30 CFR 816.89 and replace them as follows. Noncoal mine wastes including (but not limited to) grease, garbage, abandoned mining machinery, lumber, and other combustible materials generated during mining activities must be placed and stored in a controlled manner in a landfill permitted by the Iowa Department of Natural Resources pursuant to Iowa Administrative Code Chapters 101, 102, and 103. Lubricants, paints, and flammable liquids would not be allowed to be buried in the State of Iowa; but they, and other toxic wastes, must be disposed of in the legally prescribed manner. Final disposal of noncoal mine wastes would have to be in a designated, State-approved solid waste disposal site

permitted by the Iowa Department of Natural Resources pursuant to Iowa Administrative Code Chapters 101, 102, and 103. But notwithstanding any other provision in this chapter, any noncoal mine waste defined as "hazardous" under section 3001 of the Resource Conservation and Recovery Act (RCRA) (Pub. L. 94–580 as amended) and 40 CFR part 261 would have to be handled in accordance with the requirements of Subtitle C of RCRA and any implementing regulations.

(55) IAC 27–40.65(83) Special Permanent Program Performance Standards—Auger Mining

Iowa proposes to replace the incorporation by reference of 30 CFR part 819 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(56) IAC 27–40.66(83) Special Permanent Program Performance Standards—Operations on Prime Farmland

Iowa proposes to replace the incorporation by reference of 30 CFR part 823 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

Iowa also proposes to delete its incorporation of 30 CFR 823.11(a), which establishes a variance to the applicability of these regulations. That incorporated Federal rule exempts from the requirements of 30 CFR part 823 those coal preparation plants, support facilities, and roads of surface and underground mines that are actively used over extended periods of time and where such uses affect a minimal amount of land; the Federal rule requires, rather, that such uses meet the requirements of 30 CFR part 816 or part 817 as applicable.

(57) IAC 27–40.67(83) Permanent Program Performance Standards—Coal Preparation Plants Not Located Within the Permit Area of a Mine

Iowa proposes to replace the incorporation by reference of 30 CFR part 827 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(58) IAC 27–40.67(2) Interim Performance Standards

Iowa proposes to delete its incorporation of 30 CFR 827.13(a) and replace it with a requirement that persons operating or who have operated coal preparation plants after April 10, 1981, must comply with the applicable interim or permanent program performance standards for the Iowa program.

(59) IAC 27–40.68(83) Special Permanent Program Performance Standards—In Situ Processing

Iowa proposes to replace the incorporation by reference of 30 CFR part 828 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(60) IAC 27–40.71(83) State Regulatory Authority—Inspection and Enforcement

Iowa proposes to replace the incorporation by reference of 30 CFR part 840 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(61) IAC 27–40.73(2)g. Cessation Orders

Iowa proposes to add a requirement that, within 60 days after the issuance of a cessation order, the Division must notify in writing any person who has been identified (under 27–40.31(83) (30 CFR 773.17(i)) and 27–40.34(83) (30 CFR 778.13(c) and (d))) as owning or controlling the permit, that the cessation order was issued and that the person has been identified as an owner or controller.

(62) IAC 27–40.74(83) Civil Penalties

Iowa proposes to replace the incorporation by reference of 30 CFR 845 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(63) IAC 27–40.74(5) Procedures for Assessment Conference

Iowa proposes to delete the procedures for assessment conference requirements at 30 CFR 845.18 and replace them with similar requirements that include State specific language and citations.

(64) IAC 27–40.74(6) Request for a Hearing

Iowa proposes to delete the request for a hearing requirements at 30 CFR 845.19 and replace them with similar requirements that include State specific language and citations.

(65) IAC 27–40.74(7) Final Assessment and Payment of Penalty

Iowa proposes to delete the final assessment and payment of penalty requirements at 30 CFR 845.20 and replace them with similar requirements that include State specific language and citations.

(66) IAC 27–40.74(8) Use of Civil Penalties for Reclamation

Iowa proposes to add a provision allowing the Division (in accordance with Iowa Code section 83.10(6)) to expend funds collected from civil penalties to perform reclamation work on sites where the bond has been forfeited and additional funds are needed to complete the reclamation of the site.

(67) IAC 27–40.75(83) Individual Civil Penalties

Iowa proposes to adopt by reference 30 CFR part 846 as in effect on "July 1, 1991 [sic]," concerning individual civil penalties.

(68) IAC 27–40.75(2) Definitions

Iowa proposes to delete the definitions of "violation, failure, or refusal" at 30 CFR 846.5 and replace them with similar requirements that include State specific language and citations.

(69) IAC 27–40.75(3) Final Order and Opportunity for Review

Iowa proposes to delete the requirements of 30 CFR 846.17(b)(1) and replace them with similar requirements that include State specific language and citations.

(70) IAC 27–40.75(4) Service

Iowa proposes to delete the requirements of 30 CFR 846.17(c) and replace them with similar requirements that include State specific language and citations.

(71) IAC 27–40.81(83) Standards for Certification of Blasters

Iowa proposes to replace the incorporation by reference of 30 CFR part 850 as in effect on July 1, 1987, with the Federal rules as in effect on July 1, 1992.

(72) IAC 27–40.82(83) Certification of Blasters

Iowa proposes to replace the incorporation by reference of 30 CFR part 955 as in effect on July 1, 1987, with the rules as in effect on July 1, 1992.

III. Public Comment Procedures

In accordance with the provision of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Iowa program.

Written Comments

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commenter's recommendations.

Comments received after the time indicated under "DATES" or at locations other than the Kansas City Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., c.s.t. January 29, 1993. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment having been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the OSM office listed under **FOR FURTHER INFORMATION CONTACT.** All such meetings will be open to the public and, if possible, notices of meetings will be posted at the location listed under **ADDRESSES.** A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

Compliance With the National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA [30 U.S.C. 1292(d)] provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Compliance With Executive Order No. 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 (Reduction of Regulatory Burden) for actions related to approval or conditional approval of State regulatory programs, actions, and program amendments. Therefore, preparation of a Regulatory Impact Analysis is not necessary and OMB regulatory review is not required.

Compliance With the Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Compliance With Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR Parts 730, 731, and 732 have been met.

Compliance With the Paperwork Reduction Act

This rules does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

List of Subjects in 30 CFR Part 915

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 7, 1992.

Raymond L. Lowrie,

Assistant Director, Western Support Center.

[FR Doc. 93–862 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–05–M

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30 CFR Part 916

Kansas Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: OSM is reopening the public comment period and announcing the receipt of revisions to a previously submitted amendment to the Kansas permanent regulatory program (hereinafter, the "Kansas program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revised amendment proposes further changes to provisions of the Kansas regulations pertaining to meaning of terms, permit applications, administrative hearing procedure, permit renewal, permit transfers, assignments, and sales, coal exploration, bonding procedure, performance standards, underground mining, small operator assistance program, lands unsuitable for surface mining, training and certification of blasters, employee financial interests, and inspection and enforcement. The amendment is intended to revise the State program to be consistent with the corresponding Federal standards, clarify ambiguities, and improve operational efficiency.

This document sets forth the times and locations that the Kansas program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4:00 p.m., c.s.t., January 29, 1993.

ADDRESSES: Written comments should be mailed or hand delivered to Jerry R. Ennis at the address listed below.

Copies of the Kansas program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Kansas City Field Office.

Jerry R. Ennis, Director, Kansas City Field Office, Office of Surface Mining Reclamation and Enforcement, 934 Wyandotte, room 500, Kansas City, MO 64105 Telephone: (816) 374–6405

Kansas Department of Health and Environment, Bureau of Environmental Remediation, Surface Mining Section, 1501 S. Joplin, P.O. Box 1418, Pittsburg, KS 66762 Telephone: (316) 231–8615.

FOR FURTHER INFORMATION CONTACT: Jerry R. Ennis, telephone: (816) 374–6405.

SUPPLEMENTARY INFORMATION:

I. Background on the Kansas Program

On January 21, 1981, the Secretary of Interior conditionally approved the Kansas program. General background information on the Kansas program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Kansas program can be found in the January 21, 1981, **Federal Register** (46 FR 5892). Subsequent actions concerning Kansas' program and program amendments can be found at 30 CFR 916.12, 916.15, and 916.16.

II. Discussion of Proposed Amendment

By letter dated July 10, 1992, (Administrative Record No. KS–511) Kansas submitted a proposed amendment to its program pursuant to SMCRA. Kansas submitted the proposed amendment with the intent of satisfying the required program amendments at 30 CFR 916.16(b) and at the State's own initiative to improve its program.

OSM announced receipt of the proposed amendment in the August 18, 1992, **Federal Register** (57 FR 37132) and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period ended on September 18, 1992. The public hearing scheduled for September 14, 1992, was not held because no one requested an opportunity to testify.

By letter dated October 22, 1992 (Administrative Record No. KS–540), OSM provided Kansas with its questions and comments about the July 10, 1992, amendment submission. In response to OSM's letter, Kansas submitted a revised amendment by letter dated December 23, 1992 (Administrative Record No. KS–545). This new amendment submission contains further revisions to Articles 2 through 4 and 6 through 15 of the Kansas Administrative Regulations (K.A.R.). The amendment proposes numerous changes to the format and nonsubstantive wording changes to clarify the regulations. The substantive changes proposed by Kansas are discussed briefly below:

(1) Complete and Accurate Application

K.A.R. 47–2–14: Kansas proposes to delete its definition of complete and accurate application.

(2) Meaning of Terms

K.A.R. 47–2–75: Kansas proposes to update its regulations concerning definition of terms by changing its adoption by reference of 30 CFR 700.5, 701.5, 705.5, 773.5, and 846.5 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(3) Permit Application

a. K.A.R. 47–3–2: Kansas proposes to update its regulations concerning application for mining permit by changing its adoption by reference of 30 CFR 777.11, 777.13, 777.14, and 777.15 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

b. K.A.R. 47–3–42: Kansas proposes to update its regulations concerning application for mining permit by changing its adoption by reference of reference of 30 CFR 778.13, 778.14, 778.15, 778.16, 778.17(a), 778.18, 778.21, 778.22, 779.4, 779.11, 779.12, 779.18, 779.19, 779.21, 779.22, 779.24, 779.25, 780.4, 780.11, 780.12, 780.13, 780.14, 780.15, 780.16, 780.18, 780.21, 780.22, 780.23, 780.25, 780.27, 780.29, 780.31, 780.33, 780.35, 780.37, 780.38, 785.13, 785.17, 785.18, 785.20, 785.21, 785.22, 773.13, 773.15, 773.19, 773.20, 773.21, 701.11(e), and 773.12 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(4) Rules of Procedure

K.A.R. 47–4–14a(c)(1): Kansas proposes that hearings shall be held in the location designated by the presiding officer * * * except as otherwise provided by the State Act, K.A.R. 47–2–64.

(5) Formal Hearings

K.A.R. 47–4–14a(d)(2)(D): Kansas proposes that in the event the presiding officer fails to grant a petition for disqualification, the petitioning party may file an affidavit of personal bias or disqualification with substantiating facts, and the secretary of the Kansas department of health and environment shall determine the matter of disqualification.

(6) Orders, Initial and Final

K.A.R. 47–4–14a(d)(13)(F): Kansas proposes that the presiding officer shall allow the parties to a proceeding an opportunity to submit proposed findings of fact and conclusions of law together with a supporting brief at a time designated by the presiding officer.

(7) Permit Renewals

K.A.R. 47–6–3: Kansas proposes to update its regulations concerning permit renewals by changing its adoption by reference of 30 CFR 774.15 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(8) Permit Transfers, Assignments, and Sales

K.A.R. 47–6–4: Kansas proposes to update its regulations concerning permit renewals by changing its adoption by reference of 30 CFR 774.17, from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(9) Permit Conditions

K.A.R. 47–6–6: Kansas proposes to update its regulations concerning permit conditions by changing its adoption by reference of 30 CFR 773.17, from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(10) Termination of Jurisdiction

K.A.R. 47–6–8: Kansas proposes to update its regulations concerning termination of jurisdiction by changing its adoption by reference of 30 CFR 700.11, from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(11) Exemption for Coal Extraction Incident to Government Financed Highway or Other Construction

K.A.R. 47–6–9: Kansas proposes to update its regulations concerning exemption for coal extraction incident to government financed highway or other construction by changing its adoption by reference of 30 CFR 707.4, 707.5, 701.11, and 707.12 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(12) Exemption of Coal Extraction Incidental to the Extraction of Other Minerals

K.A.R. 47–6–10: Kansas proposes to update its regulations concerning exemption for coal extraction incidental to the extraction of other minerals by changing its adoption by reference of 30 CFR 702.1, 702.5, 702.10, 702.11, 702.12, 702.13, 702.15, 702.16, 702.17, and 702.18 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(13) Coal Exploration

K.A.R. 47–7–2: Kansas proposes to update its regulations concerning coal exploration by changing its adoption by reference of 30 CFR 772.11, 772.12, 772.13, 772.14, and 772.15 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(14) Bonding Procedures

K.A.R. 47–8–6: Kansas proposes to update its regulations concerning bonding procedures by changing its adoption by reference of 30 CFR 800.4, 800.5, 800.11, 800.12, 800.13, 800.14, 800.15, 800.16, 800.17, 800.20, 800.21, 800.30, 800.40, 800.50, and 800.60 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(15) Self Bond

K.A.R. 47–8–9, incorporating by reference 30 CFR 800.12(c): Kansas proposes to delete the provision at 30 CFR 800.12(c) that would allow Kansas to use a self bond for the performance bond.

(16) Performance Standards

K.A.R. 47–9–1: Kansas proposes to update its regulations concerning performance standards by changing its adoption by reference of 30 CFR parts 810, 815, 816, 817, 819, 823, 827, and 828 from those that existed on July 1, 1990 to those that existed on July 1, 1992.

(17) Backfilling and Grading: Time and Distance Requirements

K.A.R. 47–9–1(c), incorporating by reference 30 CFR 816.101 and 816.102: Kansas proposes to delete its requirements at 30 CFR 816.102 that absent an approved schedule, backfilling and grading will be completed within 180 days following coal removal and shall not be more than four spoil ridges behind the pit being worked, the spoil from the active pit being considered the first ridge. Kansas that adds the requirements of 30 CFR 816.101 concerning time and distance requirements for backfilling and grading.

(18) Underground Mining

K.A.R. 47–10–1: Kansas proposes to update its regulations concerning underground mining by changing its adoption by reference of 30 CFR parts 783 and 784 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(19) Small Operator Assistance Program

K.A.R. 47–11–8: Kansas proposes to update its regulations concerning the small operator assistance program by changing its adoption by reference of 30 CFR 795.3, 795,6, 795.7, 795.8, 795.9, 795.10, 795.11, and 795.12 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(20) Lands Unsuitable for Surface Mining

K.A.R. 47–12–4: Kansas proposes to update its regulations concerning lands unsuitable for surface mining by changing its adoption by reference of 30 CFR 761.5, 761.11, 761.12, 762.5, 762.11, 762.13, 762.14, 764.13, 764.15, 764.17, 764.19, 764.21, 764.23, and 764.25 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(21) Training and Certification of Blasters

K.A.R. 47–13–4: Kansas proposes to update its regulations concerning training and certification of blasters by changing its adoption by reference of 30 CFR part 850 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(22) Employee Financial Interest

K.A.R. 47–14–4: Kansas proposes to update its regulations concerning employee financial interest by changing its adoption by reference of 30 CFR 705.4 (a) and (c), 705.6(b), 705.11 (a), (b), (c) and (d), 705.13, 705.15, 705.17, 705.18, 705.19(a), and 705.21 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

(23) Inspection and Enforcement

K.A.R. 47–15–1a: Kansas proposes to update its regulations concerning inspection and enforcement by changing its adoption by reference of 30 CFR 840.11, 840.14, 843.5, 840.12, 842.14, 842.15, 843.11, 843.12, 843.13, 843.15, 843.16, 843.20, and 840.16 from those that existed on July 1, 1990, to those that existed on July 1, 1992.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Kansas program.

Written Comments

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Kansas City Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., c.s.t. January 29, 1993. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment having been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the OSM office listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

Compliance With the National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA [30 U.S.C. 1292(d)] provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Compliance With Executive Order No. 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions, and program amendments. Therefore, preparation of a Regulatory Impact Analysis is not necessary and OMB regulatory review is not required.

Compliance With the Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Compliance With Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsection (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR parts 730, 731, and 732 have been met.

Compliance With the Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

List of Subjects in 30 CFR Part 916

Intergovernmental relations, Surface mining, Underground mining.

Dated: January 5, 1993.

Raymond L. Lowrie,

Assistant Director, Western Support Center.

[FR Doc. 93–872 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-05-M

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30 CFR Part 917

Kentucky Permanent Regulatory Program; Hearings

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening and extension of comment period on proposed amendment.

SUMMARY: OSM is announcing the receipt of revisions to a previously prepared amendment to the Kentucky permanent regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). By letter of December 10, 1992 (Administrative Record No. KY–1202), Kentucky resubmitted a proposed program amendment that revises and completes their proposed hearing regulations as amended during the Kentucky regulation promulgation process under Kentucky Revised Statutes (KRS) chapter 350. The proposed amendment includes the final promulgation of regulation changes to Kentucky Administrative Regulations (KAR) at 405 KAR 7:001, 405 KAR 7:091, 405 KAR 7:092, 405 KAR 8:001, and 405 KAR 12:020 that relate to hearings. This proposed amendment supplements two earlier proposed program amendments (Administrative Record No. KY–1170, submitted July 28, 1992 and KY–1180, submitted September 18, 1992).

This document sets forth the times and locations that the Kentucky program and the proposed amendment are available for public inspection, the comment period which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding a public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on January 29, 1993. If requested, a public hearing on the proposed amendment will be held at 10 a.m. on January 25, 1993. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on January 19, 1993.

ADDRESSES: Written comments and requests for a hearing should be mailed or hand delivered to: William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 40503–2922. Copies of the Kentucky program, the proposed amendment, and all written comments received in response to this document will be available for review at the addresses listed below, Monday through Friday, 9 a.m. to 4 p.m., excluding holidays. Each requestor may receive, free of charge, one copy of the proposed amendment by contacting OSM's Lexington Field Office.

Office of Surface Mining Reclamation and Enforcement, Lexington Field Office, Regency Road, Lexington, Kentucky 40503–2922, Telephone: (606) 233–2896.

Office of Surface Mining Reclamation and Enforcement, Eastern Support Center, Ten Parkway Center, Pittsburgh, Pennsylvania 15220, Telephone: (412) 937–2828.

Department for Surface Mining Reclamation and Enforcement, No. 2 Hudson Hollow Complex, Frankfort, Kentucky 40601, Telephone: (502) 564–6940.

If a public hearing is held, its location will be: The Harley Hotel, 2143 North Broadway, Lexington, Kentucky 40505.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, Telephone (606) 233–2896.

SUPPLEMENTARY INFORMATION:

I. Background

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Information pertinent to the general background, revisions, modifications, and

amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404–21435). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 917.11, 917.15, 917.16, and 917.17.

II. Discussion of Amendment

By letter of December 10, 1992, (Administrative Record No. KY–1202) Kentucky resubmitted a proposed program amendment that revises and completes their proposed hearing regulations as amended during the Kentucky regulation promulgation process under Kentucky Revised Statutes (KRS) chapter 350. The proposed amendment includes the final promulgation of regulation changes to Kentucky Administrative Regulations (KAR) at 405 KAR 7:001, 405 KAR 7:091, 405 KAR 7:092, 405 KAR 8:001, and 405 KAR 12:020 that relate to hearings. This proposed amendment supplements two earlier proposed program amendments (Administrative Record No. KY–1170, submitted July 28, 1992 and KY–1180, submitted September 18, 1992). This resubmission is the same as the proposed amendment KY–1170 as modified and submitted in the proposed program amendment KY–1180 except for the following final changes made during the State regulation promulgation process. The changes are as follows:

1. 405 KAR 7:001 section 1(63) amended the definition of "person."

2. 405 KAR 7:091 section 5(a) amended the section by clarifying a cross reference to the subsection on service.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by Kentucky satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Kentucky program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commentor's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Lexington Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m. on January 25, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held. Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendments may request a meeting at the OSM, Lexington Field Office listed under **ADDRESSES** by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12278

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA [30 U.S.C. 1292(d)] provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval of the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

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Dated: December 29, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 93–864 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–05–M

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30 CFR Part 917

Kentucky Permanent Regulatory Program; Termination and Reassertion of Jurisdiction

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening and extension of comment period on proposed amendment.

SUMMARY: OSM is announcing the receipt of revisions to a previously prepared amendment to the Kentucky permanent regulatory program (hereinafter referred to as the Kentucky program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). By letter of December 9, 1992 (Administrative Record No. KY–1199) Kentucky resubmitted a proposed program amendment which was originally submitted on July 21, 1992 (Administrative Record Number KY–1199) Kentucky resubmitted a proposed program amendment which was originally submitted on July 21, 1992 (Administrative Record Number KY–1165). The resubmission incorporates revisions made during the Kentucky promulgation process under Kentucky Revised Statutes (KRS) Chapter 13A. The amendment consists of proposed modifications to Kentucky Administrative Regulations (KAR) at 405 KAR 7:030, 1:007 and 3:007 that relate to termination and reassertion of jurisdiction.

This document sets forth the times and locations that the Kentucky program and the proposed amendment are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding a public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on January 29, 1993. If requested, a public hearing on the proposed amendment will be held at 10 a.m. on January 25, 1993. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on January 19, 1993.

ADDRESSES: Written comments and requests for a hearing should be mailed or hand delivered to: William J. Kovacic, Director, Lexington Field Office, Office of Surface Mining Reclamation and Enforcement, 2675 Regency Road, Lexington, Kentucky 4053. Copies of the Kentucky program, the proposed amendment, and all written comments received in response to this notice will be available for review at the address listed below, Monday through Friday, 9 a.m. to 4 p.m., excluding holidays. Each requestor may receive, free of charge, one copy of the proposed amendment by contacting OSM's Lexington Field office.

Office of Surface Mining Reclamation and Enforcement, Lexington Field Office, 2675 Regency Road, Lexington, Kentucky 40503, Telephone: (606) 233–2896

Office of Surface Mining Reclamation and Enforcement, Eastern Support Center, Ten Parkway Center, Pittsburgh, Pennsylvania 15220, Telephone: (412) 937–2828

Department for Surface Mining Reclamation and Enforcement, No. 2 Hudson Hollow Complex, Frankfort, Kentucky 40601, Telephone: (502) 564–6940

If a public hearing is held, its location will be: The Harley Hotel, 2143 North Broadway, Lexington, Kentucky 40505.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, Telephone (606) 233–2896.

SUPPLEMENTARY INFORMATION:

I. Background

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Information pertinent to the general background, revisions, modifications, and amendments to the proposed permanent program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404–21435). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 917.11, 917.15, 917.16, and 917.17.

II. Discussion of Amendment

By letter of December 9, 1992, (Administrative Record No. KY–1199) Kentucky resubmitted a proposed program amendment which was originally submitted on July 21, 1992 (Administrative Record Number KY–1165). The resubmission incorporates revisions made during the Kentucky promulgation process under Kentucky Revised Statutes (KRS) Chapter 13A. The amendment consists of proposed modifications to Kentucky Administrative Regulations (KAR) at 405 KAR 7:030, 1:007 and 3:007 that relate to the termination and reassertion of jurisdiction.

This resubmission is the same as the July 21, 1992, submittal except for the following changes made during the State regulation promulgation process. The changes are as follows:

The regulations at 405 KAR 1:007 and 3:007 were changed to cover the possibility that termination of jurisdiction could occur after November 1, 1992 on sites that were subject to interim program standards but for which no bond was posted, in which case the termination of jurisdiction must be based upon a written determination that applicable requirements have been met, rather than upon a bond release determination.

Also included in the proposed program amendment is the Statement of Consideration that explains the public comments received by Kentucky during the State promulgation process.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendment proposed by Kentucky satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Kentucky program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commentor's recommendations. Comments received after the time indicated under "**DATES**" or at locations other than the Lexington Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m. on January 25, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held. Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who

wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet the OSM representatives to discuss the proposed amendments may request a meeting at the OSM, Lexington Field Office listed under "ADDRESSES" by contacting the person listed under FOR FURTHER INFORMATION CONTACT. All such meetings will be open to the public and, if possible, notices of meetings will be posted in advance at the locations listed under ADDRESSES. A written summary of each meeting will be made a part of the Administrative Record.

Executive Order No. 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the review required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731 and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 917

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 18, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 93–865 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–05–M

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30 CFR Part 924

Mississippi Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing the receipt of proposed amendments to the Mississippi regulatory program (hereinafter referred to as the Mississippi program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). By letter dated December 15, 1992, Mississippi submitted a proposed amendment which covers a wide variety of topics. This submittal constitutes a complete rewrite of the Mississippi regulations making them consistent with current Federal regulations.

This document sets forth the times and locations that the Mississippi program and proposed amendments to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendments, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on February 16, 1993. If requested, a public hearing on the proposed amendments will be held at 1 p.m. on February 8, 1993. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on January 29, 1993.

ADDRESSES: Written comments should be mailed or hand delivered to Mr. Jesse Jackson, Jr., Director, Birmingham Field Office, at the address listed below. Copies of the Mississippi program, the proposed amendments, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive, free of charge, one copy of the proposed amendments by contacting OSM's Birmingham Field Office.

Office of Surface Mining Reclamation and Enforcement, Birmingham Field Office, 135 Gemini Circle, suite 215, Homewood, Alabama 35209, telephone: (205) 290–7282.

Mississippi Department of Environmental Quality, The Office of Geology, Mining and Reclamation, 2380 Highway 80 West, Jackson, Mississippi 39209, telephone: (601) 961–5500.

FOR FURTHER INFORMATION CONTACT: Mr. Jesse Jackson, Jr., Director, Birmingham Field Office (205) 290–7282.

SUPPLEMENTARY INFORMATION:

I. Background

On September 4, 1980, the Secretary of the Interior unconditionally approved the Mississippi program. Information pertinent to the general background on the Mississippi program, including the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval can be found in the September 4, 1980, **Federal Register** (45 FR 58520). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 924.10 and 924.16.

II. Discussion of Amendments

Since the time of approval of the Mississippi program in 1980, there have been no changes to the program based on the fact that no mining was occurring in the State. However, in October 1988, due to some renewed interest in mining activity, Mississippi commenced to rewrite its regulations to conform with current Federal regulations. Since that time, Mississippi has made several informal submittals of the rewritten regulation package to OSM. The December 15, 1992, formal submittal constitutes a complete rewrite of the Mississippi regulations. While the submittal is in amendment to the Mississippi program, there are changes to literally every section of the regulations. Due to the extensive nature of the rewrite, no attempt will be made to identify changes made to each individual regulation. The sections proposed to be amended are parts 100 through 265 of the Rules and Regulations for the Surface Mining of Coal in Mississippi.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comments on whether the amendments proposed by Mississippi satisfy the applicable program approval criteria of 30 CFR 732.15. If the amendments are deemed adequate, they will become part of the Mississippi program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Birmingham Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m. on January 29, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber.

Submission on written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendments may request a meeting at the OSM office listed under **ADDRESSES** by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted the Office of Surface Mining Reclamation and Enforcement (OSM) an exemption from sections 3, 4, 7 and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of the Surface Mining Control and Reclamation Act (SMCRA) (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.13 and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(c) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(c).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by the Office of Management and Budget under the Paperwork Reduction Act, 44 U.S.C. 3507 *et seq*.

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 924

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 24, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 93–869 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-05-M

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30 CFR Part 935

Ohio Permanent Regulatory Program; Revision of Administrative Rule

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule.

SUMMARY: OSM is announcing the receipt of Revised Program Amendment Number 58 to the Ohio permanent regulatory program (hereinafter referred

to as the Ohio program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment was initiated by Ohio and is intended to revise one rule in the Ohio Administrative Code. The proposed rule revisions would phase in, over a two-year period, the requirement for two years of ground cover and productivity evaluation for final bond release on pasture land.

This document sets forth the times and locations that the Ohio program and proposed amendments to that program will be available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendments, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received on or before 4 p.m. on February 16, 1993. If requested, a public hearing on the proposed amendments will be held at 1 p.m. on February 8, 1993. Requests to present oral testimony at the hearing must be received on or before 4 p.m. on January 29, 1993.

ADDRESSES: Written comments and requests to testify at the hearing should be mailed or hand-delivered to Mr. Richard J. Seibel, Director, Columbus Field Office, at the address listed below. Copies of the Ohio program, the proposed amendments, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive, free of charge, one copy of the proposed amendments by contacting OSM's Columbus Field Office.

Office of Surface Mining Reclamation and Enforcement, Columbus Field Office, 2242 South Hamilton Road, room 202, Columbus, Ohio 43232, telephone: (614) 866–0578.

Ohio Department of Natural Resources, Division of Reclamation, 1855 Fountain Square Court, Building H–3, Columbus, Ohio 43224, telephone: (614) 265–6675.

FOR FURTHER INFORMATION CONTACT: Mr. Richard J. Seibel, Director, Columbus Field Office, (614) 866–0578.

SUPPLEMENTARY INFORMATION:

I. Background

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Information on the general background of the Ohio program submission, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Ohio program, can be found in the August 10, 1982 **Federal Register** (47 FR 34688). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 935.11, 935.12, 935.15, and 935.16.

II. Discussion of the Proposed Amendments

In response to an OSM requirement, Ohio submitted proposed Program Amendment No. 43 by letter dated January 16, 1990 (Administrative Record No. OH–1265). In part, this amendment proposed to revise Ohio Administrative Code (OAC) section 1501:13–9–15(I)(3)(c) to add the requirement that, for phase III bond release, revegetated areas must meet ground cover and production standards for any two years of the five-year period of extended responsibility, except the first year. The Director of OSM approved this proposed rule revision on July 27, 1992 (57 FR 33122).

By letter dated May 12, 1992 (Administrative Record No. OH–1699), Ohio submitted proposed Program Amendment Number 58. This amendment proposed to add new paragraphs (D) (1) and (2) at OAC section 1501:13–1–01 concerning the termination and possible reassertion of regulatory jurisdiction over all or part of a reclaimed coal mine following the release of performance bond. The Director of OSM approved these proposed additions on September 11, 1992 (57 FR 41690).

On October 14, 1992, Ohio held a public hearing on the final filing of the rule revision to OAC section 1501:13–9–15(I)(3)(c) as approved by OSM in Program Amendment Number 43. At that hearing, Ohio received comments recommending a two-year period to phase in the new requirements for final bond release. Ohio decided to adopt this suggestion by revising OAC section 1501:13–1–01 which establishes the effective date and applicability of the Ohio rules over mining and reclamation operations.

As discussed above, OSM recently approved Program Amendment Number 58 which revises OAC section 1501:13–1–01. Because Ohio has not yet promulgated Program Amendment Number 58, Ohio has decided to resubmit proposed Revised Program Amendment Number 58 to further revise OAC section 1501:13–1–01 to incorporate the two-year phase-in period suggested at its public hearing. Ohio resubmitted Revised Program Amendment Number 58 on December 9, 1992 (Administrative Record No. OH–1798). In this revised amendment, Ohio is proposing to add the following sentence to OAC section 1501:13–1–01(B):

> Each area for which there has been no phase III bond release and which is planted with a permanent cover of herbaceous species shall not be required to meet the requirements of paragraph (I)(3)(C) of rule 1501:13–9–15 of the Administrative Code for two years of the extended responsibility period until after January 1, 1994.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the amendments proposed by Ohio satisfy the applicable program approval criteria of 30 CFR 732.15. If the amendments are deemed adequate, they will become part of the Ohio program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Columbus Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m. on January 29, 1993. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment and who wish to do so will be heard following those scheduled. The hearing will end after all persons scheduled to comment and persons present in the audience who wish to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendments may request a meeting at the Columbus Field Office by contacting the person listed

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under FOR FURTHER INFORMATION CONTACT. All such meetings shall be open to the public, and, if possible, notices of the meetings will be posted at the locations listed under ADDRESSES. A written summary of each public meeting will be made a part of the Administrative Record.

IV. Procedural Determinations

Executive Order No. 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions directly related to approval or conditional approval of State regulatory programs, actions, and program amendments. Therefore, preparation of a Regulatory Impact Analysis is not necessary and OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act, 42 U.S.C. 4332(2)(C).

Paperwork Reduction Act

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3507 *et seq.*

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Hence, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 18, 1992.

Jeffrey D. Jarrett,

Acting Assistant Director, Eastern Support Center.

[FR Doc. 93-867 Filed 1-13-93; 8:45 am]

BILLING CODE 4310-05-M

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30 CFR Part 944

Utah Permanent Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: OSM is announcing the receipt of a proposed amendment to the Utah permanent regulatory program (hereinafter, the "Utah program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of changes to one provision of Utah's Coal Mining Rules, which provides for Utah's reassertion of jurisdiction over coal mining and reclamation operations in cases of fraud, collusion, or misrepresentation. The amendment is intended to revise the Utah program to be consistent with the corresponding Federal regulations.

This document sets forth the times and locations that the Utah program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4 p.m., m.s.t. February 16, 1993. If requested, a public hearing on the proposed amendment will be held on February 8, 1993. Requests to present oral testimony at the hearing must be received by 4 p.m., m.s.t. on January 29, 1993.

ADDRESSES: Written comments should be mailed or hand delivered to Robert H. Hagen at the address listed below.

Copies of the Utah program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Albuquerque Field Office.

Robert H. Hagen, Director, Albuquerque Field Office, Office of Surface Mining Reclamation and Enforcement, 505 Marquette Avenue, NW., suite 1200, Albuquerque, NM 87102, Telephone: (505) 766-1486.

Utah Division of Oil, Gas and Mining, 355 West North Temple, 3 Triad Center, suite 350, Salt Lake City, UT 84180-1203, Telephone: (801) 538-5340.

FOR FURTHER INFORMATION CONTACT: Robert H. Hagen, Telephone: (505) 766-1486.

SUPPLEMENTARY INFORMATION:

I. Background on the Utah Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Utah program. General background information on the Utah program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Utah program can be found in the January 21, 1981, **Federal Register** (46 FR 5899). Subsequent actions concerning Utah's program and program amendments can be found at 30 CFR 944.15, 944.16, and 944.30.

II. Proposed Amendment

By letter dated November 5, 1992, Utah submitted a proposed amendment to its program pursuant to SMCRA (administrative record No. UT-601). Utah submitted the proposed amendment in response to a required amendment, which OSM codified at 30 CFR 944.16(p) in the September 11, 1992, **Federal Register** (57 FR 41692). The provision of the Utah Coal Mining

Rules that Utah proposes to amend is Utah Admin. R. 645–100–452.

Existing Utah Admin. R. 645–100–452 provides that, following a termination under Utah Admin. R. 645–100–451, the Division will reassert jurisdiction under the regulatory program over a site if it is demonstrated that the bond release or written determination referred to under Utah Admin. R. 645–100–451 was based upon fraud, collusion, or misrepresentation of a material fact by the permittee. Utah proposes to delete the phrase "by the permittee" from Utah Admin. R. 645–100–452.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Utah program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Albuquerque Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4 p.m., m.s.t. on January 29, 1993. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to testify have been heard. Persons in the audience who have not been schedule to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the administrative record.

IV. Procedural Determinations

Executive Order 12291

On July 12, 1984, the Office of Management and Budget (OMB) granted OSM an exemption from sections 3, 4, 7, and 8 of Executive Order 12291 for actions related to approval or conditional approval of State regulatory programs, actions, and program amendments. Therefore, preparation of a regulatory impact analysis is not necessary, and the OMB regulatory review is not required.

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 12550) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 944

Intergovernmental relations, Surface mining, Underground mining.

Dated: December 7, 1992.

Raymond L. Lowrie,

Assistant Director, Western Support Center.

[FR Doc. 93–859 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–05–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter 1

[FRL–4552–5]

Open Meeting on Proposed Wood Furniture Rules and/or Control Techniques Guidelines

AGENCY: Environmental Protection Agency.

ACTION: Notice of public exploratory meeting.

SUMMARY: As part of EPA's effort to determine the desirability of regulatory negotiation or some other consensus-based approach to develop proposed rules regulating hazardous air pollutant emissions and/or a Control Techniques Guideline covering volatile organic compound emissions associated with wood furniture manufacturing, this meeting will discuss possible scope and issues.

DATES: The meeting will take place on January 26–27. On January 26, it will start at 9 a.m. and end at 5 p.m. On January 27, it will start at 9 a.m. and end at 3 p.m.

ADDRESSES: The meeting will take place at the Mission Valley Inn, 2110 Avent Ferry Road, Raleigh, NC 27606, (919) 828–3173.

FOR FURTHER INFORMATION CONTACT: For additional information on substantive aspects of the meeting, please contact Ellen Ducey of EPA's Office of Air Quality Planning and Standards, (919) 541–5408. For additional information on procedural or administrative matters please contact Susan Wildau or John Lingelbach, EPA's co-convenors, at (303) 442–7367.

Dated: January 11, 1993.

Chris Kirtz,

Director, Consensus and Dispute Resolution Program.

[FR Doc. 93–935 Filed 1–13–93; 8:45 am]

BILLING CODE [illegible]

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40 CFR Chapter 1

[FR–4552–7]

Public Meeting on Small Non-Road Engines Regulation

AGENCY: Environmental Protection Agency.

ACTION: Public meeting.

SUMMARY: We are giving notice of a public meeting concerning the status and potential use of a consensus based process to develop data and regulations for the control of emissions from small non-road engines under the Clean Air Act Amendments.

The EPA has decided that this particular regulatory process will focus on gasoline engines from 0–25 horsepower. Small diesel engine (0–50 hp) regulations will be developed on a separate but parallel track and discussion of diesel issues will not be included in the discussion of 0–25 horsepower gasoline issues.

The agenda will include: The scope of the regulation, design of a consensus based process, potential participants in the regulatory process, regulation development schedule and exchange of information on available new data. The meeting is open to the public without advance registration.

DATES: The meeting will be held on January 28, 1993 from 1 p.m. to 5 p.m. and on January 29, 1993 from 8:30 a.m. to 3 p.m.

ADDRESSES: The location of the meeting will be the Sheraton Inn, 3200 Boardwalk, Ann Arbor, Michigan 48108.

FOR FURTHER INFORMATION CONTACT: Persons needing further information on the technical and substantive issues related to the rule should contact Clare Ryan, National Vehicle and Fuel Emissions Laboratory, Environmental Protection Agency, 2656 Flymouth Rd., Ann Arbor, Michigan 48105; phone (313) 668–4577. Persons needing further information on procedural matters should call Deborah Dalton, Consensus and Dispute Resolution Program, Environmental Protection Agency, Washington, DC 20460; phone (202) 260–5495.

Dated: January 11, 1993.

Deborah Dalton,

Deputy Director, Consensus and Dispute Resolution Program, Office of Policy, Planning and Evaluation.

[FR Doc. 93–936 Filed 1–13–93; 8:45 am]

BILLING CODE [illegible]

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 92–301, RM–8135]

Radio Broadcasting Services; Henderson, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission requests comments on a petition filed by Dean Broadcasting, Inc., licensee of Station KGRI-FM, Channel 260A, Henderson, Texas, proposing the substitution of Channel 260C3 for Channel 260A at Henderson and modification of Station KGRI-FM's license to specify operation on the higher powered channel. Channel 260C3 can be allotted to Henderson in compliance with the Commission's minimum distance separation requirements with a site restriction of 16.3 kilometers (10.2 miles) southwest in order to avoid a short-spacing to vacant but applied for Channel 259C2, Shreveport, Louisiana. The coordinates for Channel 260C3 at Henderson are North Latitude 32–01–20 and West Longitude 94–52–58. In accordance with § 1.420(g) of the Commission's Rules, we will not accept competing expressions of interest for use of Channel 260C3 at Henderson or require the petitioner to demonstrate the availability of an additional equivalent class channel for use by such parties.

DATES: Comments must be filed on or before March 1, 1993, and reply comments on or before March 16, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Donald E. Martin, Esq., 2000 L Street, NW., suite 200, Washington, DC 20036 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Pamela Blumenthal, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 92–301, adopted December 9, 1992, and released January 8, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor, Downtown Copy Center, (202) 452–1422, 1990 M Street, NW., suite 640 Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93–887 Filed 1–13–93; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 73

[MM Docket No. 92–300, RM–8138]

Radio Broadcasting Services; Ketchum, ID

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by Idaho Broadcasting Consortium, Inc., requesting the substitution of Channel 284C for Channel 284A at Ketchum,

Idaho, and the modification of Station KYAA(FM)'s construction permit to specify operation on Channel 284C. The proposed coordinates for Channel 284C at Ketchum are North Latitude 43–38–36 and West Longitude 114–23–49.

DATES: Comments must be filed on or before March 1, 1993, and reply comments on or before March 16, 1993.

ADDRESSES: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Lee W. Shubert, Dawn M. Sciarrino, Haley, Bader & Potts, 4350 North Fairfax Drive, suite 900, Arlington, VA 22203–1633 (Attorneys for Idaho Broadcasting Consortium, Inc.).

FOR FURTHER INFORMATION CONTACT: Nancy J. Walls, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 92–300, adopted December 9, 1992, and released January 8, 1992. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW, Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, Downtown Copy Center, (202) 452–1422, 1990 M Street, NW., suite 640, Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93–888 Filed 1–13–93; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 73

[MM Docket No. 92–298, RM–8046]

Television Broadcasting Services; Appleton, New London and Suring, Wisconsin

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comment on a petition filed by Wisconsin Voice of Christian Youth, Inc., licensee of Station WSCO(TV), Channel 14, Suring, Wisconsin, requesting the reallotment of Channel 14 from Suring to Appleton, Wisconsin, or from Suring to New London, Wisconsin and the modification of its license accordingly, pursuant to Commission Rule 1.420(i). The petitioner is requested to provide additional information regarding public interest benefits in support of its proposal. Proposed coordinates for Channel 14 in Appleton are North Latitude 44–29–00 and West Longitude 88–22–30. Proposed coordinates for Channel 14 in New London are North Latitude 44–22–10 and West Longitude 88–37–40. Canadian concurrence has been requested for the proposed coordinates at Appleton and New London. Either proposal also requires a change in the offset for vacant Channel 14, Joliet, Illinois, from a minus to a plus offset. The reference coordinates for vacant Channel 14, Joliet, would remain North Latitude 41–31–40 and West Longitude 88–04–55.

DATES: Comments must be filed on or before March 1, 1993, and reply comments on or before March 16, 1993.

ADDRESSES: Federal Commuunications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested persons should serve the petitioner, or its counsel or consultant, as follows: James R. Bayes, Esq. and Wayne D. Johnsen, Esq., Wiley, Rein & Fielding, 1776 K Street, NW., Washington, DC 20006 (Counsel to Wisconsin Voice of Christian Youth, Inc.)

FOR FURTHER INFORMATION CONTACT: Arthur D. Scrutchins, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Notice of Proposed Rule Making, MM Docket No. 92–299, adopted December 8, 1992, and released January 8, 1993. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractor's Downtown Copy Center, (202) 452–1422, 1990 M Street, NW., suite 640, Washington, DC 20036.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 2.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

Michael C. Ruger,

Chief, Allocations Branch Policy and Rules Division, Mass Media Bureau.

[FR Doc. 93–889 Filed 1–13–93; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

49 CFR Part 41

[Docket No. 48599; Notice 93–2]

RIN 2105–AB79

Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction

AGENCY: Office of the Secretary, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The U.S. Department of Transportation proposes to implement the provisions of Executive Order (E.O.) 12699, "Seismic Safety of Federal and Federally-Assisted or Regulated New Building Construction." Under the Executive Order each affected Federal agency is given the responsibility for developing and implementing its own mission-appropriate and cost-effective regulations governing seismic safety. For DOT, this includes the design and construction of any of its new buildings for use of ownership, as well as the need for seismic safety recognition in all grant and safety programs affecting federally leased, assisted or regulated buildings. The purpose is to reduce the risk of death or injury to building occupants, improve the capabilities of essential buildings to function during or

after an earthquake, and to reduce earthquake losses of public buildings and investments. The rules proposed in this document may be further implemented by rulemaking actions of the DOT Operating Administrations.

DATES: Comments must be received on or before March 1, 1993.

ADDRESSES: Comments should be sent to Docket Clerk, Docket No. 48599, Department of Transportation, 400 7th Street, SW., room 4107, Washington, DC 20590. Commenters are requested to provide an original and four copies of their comments. Commenters wishing to have their comments acknowledged should enclose a stamped, self-addressed postcard with their comment. The docket clerk will time and date stamp the card and return it to the commenter.

FOR FURTHER INFORMATION CONTACT: Paul B. Larsen, Office of the Assistant General Counsel for Environmental, Civil Rights and General Law, (202) 366–9161, or Donald R. Trilling, Director, Office of Transportation Regulatory Affairs, (202) 366–4220, U.S. Department of Transportation, 400 7th St., SW., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Introduction

Seismic hazards pose a serious threat throughout much of the United States. It is therefore important in most parts of the nation to design structures according to appropriate seismic standards in order to mitigate losses from earthquakes. The Federal Government, through the Earthquake Hazards Reduction Act of 1977, has developed the National Earthquake Hazards Reduction Program (NEHRP), to reduce the risks to life and property from future earthquakes. Through work of the NEHRP, the President has issued Executive Order 12699, "Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction," which calls for Federal agencies to use appropriate seismic design and construction standards in design and construction of Federally owned, leased, assisted, and regulated new buildings. To support the implementation of this order, the Interagency Committee on Seismic Safety in Construction (ICSSC) recommends the use of seismic codes and standards that are substantially equivalent to the NEHRP Recommended Provisions for the Development of Seismic Regulations for New Buildings (Provisions and Commentary). This document offers guidelines (including maps defining the seismic groundshaking hazard nationwide) which represent the state-of-the-art in seismic design, have been widely reviewed, and are currently being incorporated into national standards and codes for adoption by state and local building codes.

Seismic Hazard

An earthquake is the oscillatory, sometimes violent movement of the Earth's surface that follows a release of energy in the Earth's crust. This energy can be generated by a sudden dislocation of segments of the crust, by volcanic eruption, and even by manmade explosions. Seismic hazards that may be induced by earthquakes include ground shaking, surface faulting, liquefaction, landslides, lateral spreading, seiches, and tsunami. Seismic risk is a measure of potential losses due to the expected seismic hazards in a given area. Therefore, an unpopulated area has a lower seismic risk than an urban area exposed to the same seismic hazards. Similarly, poorly constructed buildings are exposed to greater seismic risk than well constructed ones in the same location.

Although in the United States most earthquakes occur in areas bordering the Pacific Ocean, history shows that other areas across the U.S. are susceptible to seismic hazard. On August 31, 1886 an earthquake estimated at 7.5 on the Richter scale shook Charleston, South Carolina, causing extensive damage and killing an estimated 60 to 100 people. On the basis of geologic and geophysical studies, it appears that quakes of this magnitude are possible at geologically similar locations along the eastern seaboard. In the winter of 1811–1812, the New Madrid seismic zone, located in the Central U.S., produced three of the largest earthquakes known to have occurred in North America. This area is regarded by seismologists as the most hazardous zone east of the Rocky Mountains and it remains seismically active. The Loma Prieta earthquake that hit the San Francisco/Oakland area on October 17, 1989 measured 7.1 on the Richter scale and killed 64 people. The shock caused an estimated $7.1 billion in damage, and caused failure in key transportation links including the San Francisco-Oakland Bay Bridge and a 1½ mile long section of Interstate 880 in Oakland.

On the West Coast of the U.S. most people have experienced earthquakes, and recognize that major earthquakes will occur. The absence of large-magnitude earthquakes in the Central and Eastern U.S. since the Charleston earthquake in 1886 has resulted in a lack of awareness on the part of the general public of the existence of an earthquake threat in these areas. Nevertheless, the examples above illustrate why seismic hazard is more than a West Coast issue. Forty-six states as well as many U.S. territories and possessions are at risk from earthquakes.

Ground shaking is the seismic hazard that affects all buildings in an area impacted by an earthquake. (Liquefaction, landslides, and other seismic hazards are generally localized disturbances.) Because of the universal effect of ground shaking, it is the hazard that is addressed in greatest detail by building codes.

The ground shaking hazard is generally represented on maps. The United States Geological Survey (USGS) has developed national maps of ground shaking hazard that present equal levels of expected horizontal acceleration due to ground shaking. These maps are published in the Commentary to the 1991 NEHRP Recommended Provisions. On these maps, the plotted acceleration at any location represents a 90 percent probability that it will not be exceeded in 50 years. These maps have become the basis for the hazard maps included in up-to-date seismic design guidelines and codes. Similar maps are being developed for select areas at a larger scale that portray other seismic hazards. These illustrate the significant variation that can be expected due to multiple seismic hazards within a local region.

The derivation of the ground shaking maps considered, for each location, a number of factors. These included historical seismicity, proximity to known faults, and results of geological investigations. Because of the complexity of these factors, the development of the maps required a great deal of professional judgement and expertise.

The ground shaking maps described above quantify the significant variation in the expected hazard nationwide. The maps are the basis which allow a single building code to be applicable nationwide: the design, detailing, and construction requirements are varied according to the expected hazard as presented in the maps. Thus, a single design provision results in stringent requirements in a high hazard area and less stringent requirements in a low hazard area.

Seismic Design

Unlike hurricanes, large earthquakes cannot be predicted; they strike without warning with great destructive force. Most casualties occur from the ground shaking that can cause buildings and other structures to collapse and objects to fall. Related ground failure hazards also can cause serious losses in local areas. For these reasons, buildings and

other structures need to be designed to resist earthquake forces.

The importance of using sound engineering and construction practices in design and construction is evident when the effects of two very similar earthquakes are compared: the 1971 San Fernando, California earthquake and the 1972 Managua, Nicaragua earthquake, with magnitudes of 6.6 and 6.2 respectively. Both earthquakes occurred at times of day when most people were at home, and both affected a population of approximately 1 million. The San Fernando earthquake affected an area with much new construction that had been designed under a building code that included earthquake requirements. This quake caused 58 deaths and $550 million in economic losses. The Managua quake affected a city where few buildings had been designed using modern requirements. This event caused over 5,000 deaths and an economic loss comparable to the annual gross national product of the entire country. Studies of structural performance in earthquakes indicate that severe damages and collapses of buildings almost always are the consequence of inadequate design or construction. The successful performance of buildings designed and constructed in accord with modern seismic standards show that effects of severe earthquakes can be resisted economically.

In California, where the perception of earthquake hazards has been high, up-to-date seismic preparedness and mitigating practices are regularly adopted and enforced, particularly in the form of seismic design and construction provisions in building codes. However, in the Central and Eastern United States recognition of earthquake hazards is more recent. In the past, the model building codes used in the Central and Eastern United States have tended to lag behind the West Coast in adoption of modern seismic design and construction provisions. However, in 1991 these model code organizations incorporated the NEHRP Recommended Provisions into their 1992 editions, bringing the seismic requirements of their model codes up to date with the most current information available. State and local regulatory authorities may adopt, modify, and enforce these model code provisions to achieve seismic safety in new building construction in their jurisdictions.

The impact of an earthquake includes not only immediate destruction of life and property, but also potential dangers to critical facilities and services, including hospitals, fire stations, police stations and emergency operating centers. Functions of these critical facilities may be crippled leading to further losses from lack of these services in a time of great need. Modern seismic standards require a higher level of seismic design and safety for these facilities in order to support their functionality following an earthquake.

Federal Action

The Earthquake Hazards Reduction Act of 1977 (42 U.S.C. 7701 *et seq.*) was enacted by Congress to reduce risks to life and property from future earthquakes in the U.S. through establishment and maintenance of an effective earthquake hazards reduction program. The Act states that "Earthquakes have caused, and can cause in the future, enormous loss of life, injury, destruction of property, and economic and social disruption. With respect to future earthquakes, such loss, destruction, and disruption can be substantially reduced through the development and implementation of earthquake hazards reduction measures including improved design and construction methods and practices * * *. The Act also directs the President "to establish and maintain an effective earthquake hazards reduction program." To implement such a program, the President was to develop a plan, which specified "the roles for Federal agencies and recommended appropriate roles for State and local units of government, individuals, and private organizations." The National Earthquake Hazards Reduction Program (NEHRP) was established in response to this legislation on June 22, 1978, when it was transmitted by the President to Congress.

The objectives of the NEHRP include the development of technologically and economically feasible design and construction methods to make structures, both new and existing, earthquake resistant; the development and promotion of model codes; the development of improved understanding and capability with respect to defining and reducing seismic risk; the education of the public regarding earthquake phenomena; and research in other earthquake related areas.

The NEHRP joint memorandum to the heads of agencies transmitting the National Earthquake Hazards Reduction Program, June 22, 1978, page C–2, states that "The Federal government should set a strong example in the construction and safety of its facilities and develop guidelines and standards for Federally-assisted or licensed critical facilities. The evolutionary improvement of local building codes, which are the bases for all private construction, including Federally-assisted, non-critical construction, must be accomplished by encouragement and persuasion, particularly through working with State and local officials and professional organizations." In order to assist the Federal departments and agencies involved in construction to develop and incorporate earthquake hazards reduction measures in their ongoing programs, the Interagency Committee for Seismic Safety in Construction (ICSSC) was established. The ICSSC is composed of members representing 30 Federal departments and independent agencies involved with construction or responsible for governmental assistance for construction. Executive Order 12699, "Seismic Safety of Federal and Federally Assisted or Regulated New Building Construction" was prepared by the ICSSC to implement certain provisions of the Earthquake Hazards Reduction Act. It was signed by the President on January 5, 1990.

Executive Order 12699

The Executive Order requires all Federal agencies to ensure that new Federal buildings are designed and constructed in accord with appropriate seismic design and construction standards. The Order pertains to any new building which is federally owned, leased, assisted, or regulated. A building is defined as any structure, fully or partially enclosed, used or intended for sheltering persons or property.

Seismic safety requirements for new Federal buildings are intended to "reduce the risks to the lives of occupants of buildings owned by the Federal government and to persons who would be affected by the failure of Federal buildings in earthquakes, to improve the capability of essential Federal buildings to function during or after an earthquake, and to reduce earthquake losses of public buildings." Any new Federal building that entered the detailed design stage after January 5, 1990 must be designed and constructed in accordance with appropriate seismic standards.

Similar requirements are stated for Federally leased, assisted, or regulated buildings in order to reduce risks to the lives of persons who would be affected by earthquake failures of these buildings and to protect public investments.

For space constructed and leased for Federal occupancy, the Executive Order applies to agreements executed after January 5, 1990. For assistance, grants, and regulatory programs, the Executive Order (the Earthquake Hazard Reduction Act, 42 U.S.C. 7701 *et seq.*) requires agencies to plan and initiate

within three years (i.e., by February 1, 1993) measures to assure appropriate consideration of seismic safety. This NPRM responds to that requirement.

The Executive Order requires the use of nationally recognized private sector standards and practices, unless none is adequate. This is in accordance with OMB Circular A–119. Local building codes which are determined by the cognizant agency or by the ICSSC to provide adequately for seismic safety may be used as well. Special seismic standards and practices required by unique agency mission needs also may be used.

Each agency is responsible for issuing or amending its regulations or procedures, planning for implementation through its own budget process, and regularly reviewing its regulations and procedures. The Federal Emergency Management Agency (FEMA) is responsible for requesting an annual status report from each agency and reporting annually to the President and Congress on the execution of the Executive Order.

Section 4(a) of the Executive Order charges the ICSSC with recommending appropriate and cost-effective seismic design and construction standards and practices. In its official recommendation to FEMA, "Recommendation of Design and Construction Practices in Implementation of Executive Order 12699," the ICSSC recommends, as the minimum standard for all Federal agencies, the use of standards and practices which are substantially equivalent to or exceed the most recent or the immediately preceding edition of the NEHRP Recommended Provisions for the Development of Seismic Regulations for New Buildings.

An assessment prepared by the Council of American Building Officials and reviewed by the ICSSC compared the seismic provisions of major model building codes with the provisions of the 1988 NEHRP recommended provisions. Each of the following model codes was found to provide a level of seismic safety substantially equivalent to that provided by the 1988 NEHRP recommended provisions: 1991 ICBO Uniform Building Code, 1992 Supplement to the BOCA National Building Code, and the 1992 Amendments to the SBCC Standard Building Code. The ICSSC recommendation supports the use of these editions of the model codes as appropriate for use in implementing the Executive Order. In addition, the recommendation states that "state, county, local or other jurisdictional building ordinances adopting and enforcing these model codes in their entirety, without significant revisions or changes in the direction of less seismic safety, are also deemed adequate for implementing the Order."

The recommendation goes on to state that any other ordinances must be determined by the responsible cognizant agency to be substantially equivalent to the NEHRP recommended provisions before they can be considered to be appropriate for implementing the Order. A copy of the recommendation can be found in ICSSC RP 2.1–A, "Guidelines and Procedures for Implementation of the Executive Order on Seismic Safety of New Building Construction," which includes additional ICSSC consensus guidance for implementation. ICSSC RP 2.1–A is available from the U.S. Department of Commerce, National Institute of Standards and Technology, Building and Fire Research Laboratory, Gaithersburg, MD 20899.

The NEHRP recommended provisions are not a standard or model code, but constitute a resource document that may be used to develop effective seismic standards and building codes. The primary function of the NEHRP recommended provisions is to provide the minimum criteria considered prudent and economically justified for life safety and the protection of property as it impacts life safety in buildings subject to earthquakes at any location in the United States. The provisions were developed as a NEHRP project funded by FEMA. They are reviewed, updated, and published by the Building Seismic Safety Council (BSSC), a private sector organization representing nearly 60 organizations concerned with seismic safety. The Provisions have been extensively reviewed and balloted by the building community to provide a key source for the development of seismic provisions for national standards, model building codes, and building regulations for state and local governments in seismic areas. An updated version of the NEHRP recommended provisions is prepared every three years by the BSSC. The most recent edition available is 1991. A non-technical explanation of the background, objective, and methods related to the NEHRP recommended provisions is available from FEMA.

In late 1989, the Building Officials and Code Administrators International (BOCA) appointed an ad hoc committee to review the 1988 Edition of the NEHRP recommended provisions with the purpose of developing a comprehensive and consistent position on code requirements for earthquake loads that will reflect technology, design practices and national codes and standards. The Southern Building Code Congress (SBCC) participated in a similar cooperative effort. As a result of these efforts, the 1992 versions of the BOCA National Building Code and the SBCC Standard Building Code have incorporated the NEHRP recommended provisions into their seismic requirements. The NEHRP Recommended Provisions are also being considered by the American Society of Civil Engineers (ASCE) for adoption into the National Standard ASCE 7–88, "Minimum Design Loads for Buildings and Other Structures."

Section 3(a) of the Order requires implementation actions to "consider the seismic hazards in various areas of the country to be as shown in the most recent edition of the American National Standards Institute Standard A58, Minimum Design Loads for Buildings and Other Structures, or subsequent maps adopted for Federal use in accord with this order." The cited standard map is now available as ASCE 7. This map is based on the nationwide maps of horizontal ground acceleration developed by the USGS that also serve as the base for the design maps included with the NEHRP Recommended Provisions.

The ICSSC has recommended the use of standards and codes equivalent to the NEHRP Recommended Provisions. Therefore, the NEHRP maps are considered appropriate for Federal use in implementing the Executive Order.

Versions of the NEHRP maps have been adopted along with the NEHRP Recommended Provisions into the BOCA National and SBCC Standard building codes. The seismic zone map in the 1991 International Conference of Building Officials (ICBO) Uniform Building Code is also based on one of the USGS maps of horizontal ground acceleration. The ICBO map should be used with the ICBO code. It is not appropriate to use the NEHRP maps with the ICBO Uniform Building Code, because the design requirements of building codes are keyed to the numerical values of the map they reference.

The proposed rules apply only to new construction. All buildings owned, leased, constructed, assisted through such methods as loans, grants or guarantees of loans, or regulated by DOT must conform to the requirements of the new rules. Under the Earthquake Hazard Reduction Act, 49 U.S.C. 7701 *et seq.*, the Department of Transportation is independently responsible for ensuring that appropriate seismic design and construction standards are applied to new construction under its purview. In the Department of Transportation the DOT Operating Administrations will

further implement this rule, where necessary.

Section 41.110 states the general purpose of the rule. The rule applies to buildings. A building means any structure, fully or partially enclosed, used or intended for sheltering persons and property. "New building" is not defined. However, it is commonly accepted construction practice in this country, as expressed in the model codes, to treat additions as new buildings. Therefore, this rule should be interpreted to apply to additions to existing buildings as well as to new buildings.

Section 41.115 states that the rule applies to buildings leased for DOT occupancy. The 1988 NEHRP Recommended Provisions required that the entire building meet the most stringent requirements of any use that occupies 15 percent or more of the total building area. It is therefore reasonable to require that seismic safety provisions apply to buildings in which 15 percent or more of the total space will be leased for DOT use.

Section 41.117 provides that any buildings constructed with DOT financial assistance must be designed and constructed in accordance with approved seismic standards.

Section 41.119 provides that buildings regulated by DOT are subject to the rule.

Section 41.120 identifies the acceptable model codes. Emergency work or assistance in compliance with the Stafford Act, 42 U.S.C. 5170a, 5170b, 5174, 5178, 5192 and 5193 is not required to meet the requirements of a seismic safety program.

Finally, § 41.125 provides that nothing in this rule is intended to create any right or benefit against DOT, its Operating Administrations, its officers or any person.

Preliminary Regulatory Evaluation (PRE)

Executive Order 12291, dated February 17, 1981, directs Federal agencies to promulgate new regulations or modify existing regulations only if potential benefits to society for each regulatory change outweigh potential costs. E.O. 12291 also requires the preparation of a Regulatory Impact Analysis of all "major" rules except those responding to emergency situations or other narrowly defined exigencies. A major rule is one that is likely to result in an annual effect on the economy of $100 million or more, a major increase in consumer costs, or a significant adverse effect on competition. The Department of Transportation has determined that this rule is not "major" as defined in Executive Order 12291.

The Department has prepared a Preliminary Regulatory Evaluation (PRE), which assesses the overall costs and benefits of the rule, and demonstrates that it has reasonable justification.

The NEHRP recommended provisions represent a set of carefully evaluated construction practices. This approach recognizes that the provision of seismic design is in large measure an economic issue: The extent of seismic measures mandated by a code must be gauged by their probable benefit in saving lives as well as their cost to owners and ultimate occupants.

Cost—Determining the effect of requiring the use of modern seismic provisions on the initial cost of a building is enormously complex. It is possible to arrive at many different answers depending upon the role in society of the person answering the cost question, whether or not the building is required to remain functional after a major earthquake, whether a special effort is made to reduce property losses, and whether or not some seismic design requirements are already in effect.

The major factors influencing the cost of complying with seismic design requirements are:

1. The complexity of the shape and structural framing system for the building. (It is much easier to provide seismic resistance in a building with a simple shape and framing plan.)

2. The cost of the structural system (plus other items subject to special seismic design requirements) in relation to the total cost of the building. (In many buildings, the cost of providing the structural system may be only 25 percent of the total cost of the project.)

3. The stage in design at which the provision of seismic resistance is first considered. (The cost can be inflated greatly if no attention is given to seismic resistance until after the configuration of the building, the structural framing plan, and the materials of construction have already been chosen.)

The approximate construction cost impacts resulting from implementation of an earlier version of the NEHRP recommended provisions were determined by Stephen F. Weber during a BSSC study of the societal implications of using improved seismic provisions. These case studies were developed on the basis of a 1983–84 BSSC trial design program conducted to evaluate the usability, technical validity, and cost impact of the application of an amended version of Applied Technology Council (ATC) "Tentative Provisions for the Development of Seismic Regulations for Buildings", which was the precursor of the NEHRP Recommended Provisions.

Weber's study was based on the results of 52 case studies that compared the costs of constructing the structural components of a wide variety of buildings designed according to two distinct criteria: The prevailing local building code and the proposed set of improved seismic safety provisions. For each of the 52 designs included, a set of building requirements or general specifications was developed and provided to the responsible design engineering firm, but the designers were given latitude to ensure that building design parameters were compatible with local construction practice. Each building was designed once according to the amended Tentative Provisions and again according to the prevailing local code for the particular location of the design. Some of the case studies also compared the structural engineering design time required for the two design criteria. The case studies included multifamily residential, office, industrial, and commercial building designs in nine cities that cover the range of seismic hazard levels found in the United States (Los Angeles, Seattle, Memphis, Phoenix, New York, Chicago, Ft. Worth, Charleston, and St. Louis).

In summary, Weber's study of the results of the BSSC trial design program provides some idea of the approximate cost impacts expected from application of the NEHRP recommended provisions. For the 29 trial designs conducted in the 5 cities (Chicago, Ft. Worth, Memphis, New York, and St. Louis) whose local building codes had no seismic design provisions at the time of the study, the average projected increase in total building construction costs was 2.1 percent. For the 23 trial designs conducted in the 4 cities (Charleston, Los Angeles, Phoenix, and Seattle) whose local building codes did have seismic design provisions at that time, the average projected increase in total building construction costs was 0.9 percent. The average increase in cost for all 9 cities combined was 1.6 percent. Although no analyses of the cost effect of the 1985, 1988, and 1991 Editions of the NEHRP Recommended Provisions have been conducted, it is anticipated that the modifications made to the earlier version studied would have little effect on costs in cities subject to high seismic risk and would reduce the cost increase in cities subject to less risk.

Benefits—There are three forms of benefits that fall under the analysis: The benefit expected in any year from avoiding the loss of the value of the building itself, because it has been built

to new higher standards; the benefit of the lives saved in the building because the building has withstood the ground shaking; and the benefit of the function preserved, because the building is able to protect the mission it houses.

In the PRE, these benefits have been evaluated, using a statistical analysis which will not be repeated here. The benefits in this case are limited to the savings (in life, property and maintenance of function) that come about because a future building will be built to a new tougher standard under this rule, rather than the standard that would have been in effect earlier if no new rule were in place.

To enlarge on this, under the proposed rule, a building would be built to survive the high level of shock and/or accelerations portrayed on the NEHRP contour maps, which have a 90 percent probability of non-exceedance in 50 years. In the absence of the rule, the building would be built to a lesser standard, which would have allowed for the survivability of the building only under lesser shocks or accelerations.

The benefits counted are only those for instances where the shocks or accelerations were so high they would have destroyed a building built to the earlier lower standard, but buildings built to the new standard would survive. Similarly, the costs counted are those that are added because the building is being built to the new, higher standard, rather than the earlier lower standard.

It should be kept in mind that there is a ten percent probability that shocks or accelerations stronger than those portrayed on the NEHRP maps will be experienced, and even the buildings constructed to the new standard cannot be expected to survive shocks of that magnitude. These instance are not counted in either costs or benefits.

When the benefits are aggregated for the lives saved, the preservation of the building, and the continued functioning of the transportation mission housed in that building, the rule is cost beneficial.

For locations where there have been no provisions for earthquake protection, as exemplified by the 29 building group in the Weber study, the cost benefit ratio is 2.2, using a 10 percent discount rate. For locations where there have been some provisions for earthquake protection, as exemplified by the 23 building group in the Weber study, the cost benefit ratio is 5.1, using a 10 percent discount rate.

Incorporation by Reference

The following material would be incorporated by reference in newly established 49 CFR part 41. Each of the following model codes has been found to provide a level of seismic safety substantially equivalent to that provided by use of the 1988 NEHRP Recommended Provisions: The 1991 International Conference of Building Officials (ICBO) Uniform Building Code; the 1992 Supplement to the Building Officials and Code Administrators International (BOCA) National Building Code; and the 1992 Amendment to the Southern Building Code Congress (SBCC) Standard Building Code. Revisions of these model codes that are substantially equivalent to or exceed the then current or immediately preceding edition of the NEHRP Recommended Provisions, as it is updated, can be approved by a DOT Operating Administration to meet the requirements of this part.

Regulatory Evaluation

The proposed rule is not considered to be major under Executive Order 12291, but is significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11040), February 26, 1979. Therefore, DOT has determined that a Regulatory Impact Analysis under Executive Order 12291 is not required. Furthermore, DOT expects the regulatory impact of this proposal to be minimal. Reference is made to the discussion of cost of seismic protection below. Study indicates that the average projected increase in building construction costs for nine major U.S. cities would be 1.6%, which should not have a significant impact on initial building construction costs.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) the Department must consider whether this proposal will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632). Because, as discussed above, the Department expects the impact of this proposed rule to be minimal, the Department certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposed rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*)

Federalism

The Department has analyzed this proposed rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this proposed rule has minimal federalism implications which are insufficient to warrant the preparation of a Federalism Assessment.

Environment

The Department considered the environmental impact of this proposed rule and concluded that this rule is categorically excluded from further environmental documentation. This action solely relates to the seismic safety of buildings and clearly has no environmental impact.

List of Subjects in 49 CFR Part 41

Buildings, Seismic safety construction standards.

For reasons set out in the preamble, the Department of Transportation proposes to establish a new 49 CFR part 41 as follows:

PART 41—SEISMIC SAFETY

Sec.

41.100 Purpose and Applicability.
41.105 Definitions.
41.110 New DOT owned buildings and additions to buildings.
41.115 New buildings to be leased for DOT occupancy.
41.117 Buildings built with Federal assistance.
41.119 DOT regulated buildings.
41.120 Acceptable modal codes.
41.125 Judicial review.

Authority: 42 U.S.C. 7701 *et seq.*; 49 U.S.C. 322; Executive Order 12699, 55 FR 835, 3 CFR 1990 Comp., p. 269.

§ 41.100 Purpose and applicability.

(a) This part implements the provisions of 49 U.S.C. 7701 *et seq.* and Executive Order 12699, "Seismic Safety of Federal and Federally-Assisted or Regulated New Building Construction." Under the Executive Order the DOT is given the responsibility for developing and implementing its own mission-appropriate and cost-effective regulations governing seismic safety.

(b) This rule applies to new DOT owned buildings and to new DOT leased, assisted and regulated buildings. The purpose of the rule is to reduce risk to lives of the building occupants, improve the capabilities of essential buildings to function during or after an earthquake, and to reduce earthquake losses of public buildings and investments.

(c) This rule may be further implemented by the DOT Operating Administrations.

§ 41.105 Definitions.

As used in this chapter—

DOT means the U.S. Department of Transportation.

Operating Administration includes the Office of the Secretary.

§ 41.110 New DOT owned buildings and additions to buildings.

(a) DOT Operating Administrations responsible for the design and construction of new DOT Federally owned buildings will ensure that each building is designed and constructed in accord with the seismic design and construction standards set out in § 41.120.

(b) This requirement pertains to all building projects for which development of detailed plans and specifications is initiated after January 5, 1990. It applies to additions to existing buildings as well as to new buildings. It applies worldwide.

(c) For DOT Federally owned buildings, a certification of compliance with the seismic design and construction requirements of this part is required prior to the acceptance of the building. Such statements of compliance may include the engineer's and architect's authenticated verification of seismic design codes, standards, and practices used in the design and construction of the building, construction observation reports, local or state building department plan review documents, or other documents deemed appropriate by the DOT Operating Administration.

§ 41.115 New buildings to be leased for DOT occupancy.

(a) DOT Operating Administrations responsible for the design and construction of new buildings to be leased for DOT occupancy use will ensure that each building is designed and constructed in accord with the seismic design and construction standards set out in § 41.120.

(b) This requirement pertains to all new building projects for which the agreement covering development of detailed plans and specifications is executed after January 5, 1990.

(c) For new Federally leased buildings, a certification of compliance with the seismic design and construction requirements of this part is required prior to the acceptance of the building. Such statements of compliance may include the engineer's and architect's authenticated verification of seismic design codes, standards, and practices used in the design and construction of the building, construction observation reports, local or state building department plan review documents, or other documents deemed appropriate by the DOT Operating Administration.

§ 41.117 Buildings built with Federal assistance.

(a) Each DOT Operating Administration assisting in the financing, through Federal grants or loans, or guaranteeing the financing, through loan or mortgage insurance programs, of newly constructed buildings will ensure that any building constructed with such assistance is constructed in accord with seismic standards set out in § 41.120.

(b) This section applies to new buildings and additions to existing buildings financed in whole or in part through Federal grants or loans administered by DOT Operating Administrations, or through guaranteed financing through loan or mortgage insurance programs administered by DOT Operating Administrations.

(c) Any building constructed with Federal financial assistance, after [Insert effective date of final rule] must be designed and constructed in accord with seismic standards approved by the DOT operating Administration under § 41.120 in order to be eligible for Federal financial assistance.

(d) For buildings built with Federal assistance, a certification of compliance with the seismic design and construction requirements of this part is required prior to the furnishing of such assistance. Such statements of compliance may include the engineer's and architect's authenticated verification of seismic design codes, standards, and practices used in the design and construction of the building, construction observation reports, local or state building department plan review documents, or other documents deemed appropriate by the DOT Operating Administration.

§ 41.119 DOT regulated buildings.

(a) Each DOT Operating Administration with responsibility for regulating the structural safety of buildings and additions to existing buildings will ensure that each DOT regulated building is designed and constructed in accord with seismic design and construction standards as provided by this rule.

(b) This requirement pertains to all new building projects for which development of detailed plans and specifications begins after [Insert effective date of final rule].

(c) Any building for which a DOT Operating Administration is responsible for regulating the structural safety must comply with the seismic design and construction standards in this part.

(d) For DOT regulated buildings a certification of compliance with the seismic design and construction requirements of this part is required prior to the acceptance of the building. Such statements of compliance may include the engineer's and architect's authenticated verification of seismic design codes, standards, and practices used in the design and construction of the building, construction observation reports, local or state building department plan review documents, or other documents deemed appropriate by the DOT Operating Administration.

§ 41.120 Acceptable model codes.

(a) This section describes the standards that must be used to meet the seismic design and construction requirements of this part.

(b)(1) The following are model codes;

(i) The 1991 International Conference of Building Officials (ICBO) Uniform Building Code, published by the International Conference of Building Officials, 5360 South Workman Mill Rd., Whittier, Cal. 90601;

(ii) the 1992 Supplement to the Building Officials and Code Administrators International (BOCA) National Building Code, published by the Building Officials and Code Administrators, 4051 West Flossmoor Rd., Country Club Hills, I11. 60478–5795; and (iii) the 1992 Amendments to the Southern Building code congress (SBCC) Standard Building Code, published by the Southern Building Code Congress International, 900 Montclair Rd., Birmingham, Ala. 35213–1206.[1]

(2) Versions of the NEHRP seismic maps have been adopted along with the NEHRP Recommended Provisions into the BOCA National and SBCC Standard building codes. The seismic zone map in the ICBO Uniform Building Code is also based on one of the USGS maps of horizontal ground acceleration. However, the ICBO map should be used only with the ICBO code. Also, it is not appropriate to use the NEHRP maps with the ICBO Uniform Building Code, because the design requirements of building codes are keyed to the numerical values of the map they reference.

(c) Revisions to the model codes listed in paragraph (b) of this section that are substantially equivalent to or exceed the then current or immediately preceding

[1] These codes have been found to provide a level of seismic safety substantially equivalent to that provided by use of the 1988 National Earthquake Hazards Reduction Program (NEHRP) Recommended Provisions.

edition of the NEHRP recommended provisions, as it is updated, may be approved by a DOT Operating Administration to meet the requirements in this part.

(d) State, county, local, or other jurisdictional building ordinances adopting and enforcing the model codes, listed in paragraph (b) of this section, in their entirety, without significant revisions or changes in the direction of less seismic safety, meet the requirements in this part. For ordinances that do not adopt the model codes listed in paragraph (b) of this section, substantial equivalency of the ordinances to the seismic safety level contained in the NEHRP recommended provisions must be determined by the DOT Operating Administration before the ordinances may be used to meet the requirements of this part.

(e) DOT Operating Administrations that, as of January 5, 1990, required seismic safety levels higher than those imposed by this rule in new building construction programs will continue to maintain such levels in force.

(f) Emergencies. Nothing in this rule applies to assistance provided for emergency work or for assistance essential to save lives and protect property and public health and safety performed pursuant to section 402, 403, 502, and 503 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5170a, 5170b, 5192, and 5193, or for temporary housing assistance programs and individual and family grants performed pursuant to Sections 408 and 411 of the Stafford Act, 42 U.S.C. 7174 and 5178. However, this rule applies to other provisions of the Stafford Act after a Presidentially declared major disaster or emergency when assistance actions involve new construction or total replacement of a building.

§ 41.125 Judicial review.

Nothing in this rule is intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the DOT, its Operating Administrations, its officers, or any person.

Issued this 8th day of January, 1993 at Washington DC.

Andrew H. Card, Jr.,

Secretary of Transportation.

[FR Doc. 93–895 Filed 1–13–93; 8:45 am]

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Federal Railroad Administration

49 CFR Part 234

[FRA Docket No. RSGC–5; Notice No. 5]

RIN 2130—AA70

Timely Response to Grade Crossing Signal System Malfunctions Notice of Extension of Comment Period

AGENCY: Federal Railroad Administration (FRA), DOT.

ACTION: Notice of Proposed Rulemaking; extension of comment period.

SUMMARY: FRA is issuing notice that the period for public comment in this proceeding is being extended to February 15, 1993.

DATES: Written comments must be received no later than February 15, 1993. Comments received after that date will be considered to the extent possible without incurring additional expense or delay.

ADDRESSES: Written comments should be submitted to the Docket Clerk, Office of Chief Counsel, FRA, 400 Seventh Street SW., Washington, DC 20590. Persons desiring to be notified that their written comments have been received by FRA should submit a stamped, self-addressed postcard with their comments. The Docket Clerk will indicate on the postcard the date on which the comments were received and will return the card to the addressee. Written comments will be available for examination during regular business hours in room 8201 of the Nassif Building at the above address.

FOR FURTHER INFORMATION CONTACT: William E. Goodman, Chief, Signal and Train Control Division, Office of Safety Enforcement, FRA, 400 Seventh Street, SW., Washington, DC 20590 (telephone 202–366–0495), or Mark Tessler, Trial Attorney, Office of Chief Counsel, FRA, 400 Seventh Street, SW., Washington, DC 20590 (telephone 202–366–0628).

SUPPLEMENTARY INFORMATION: On June 29, 1992, FRA published a Notice of Proposed Rulemaking regarding timely response to grade crossing signal system malfunctions. 57 FR 28819. A public hearing was held on September 15, 1992. An open meeting was subsequently held on December 11, 1992 which included discussions of standards for safe maintenance, inspection and testing of active warning devices and as well as timely response to malfunction of such devices. At the December 11 meeting, a request was made to extend the comment closing date from January 15 to February 15, 1993. This extension would provide interested parties sufficient time to respond to information developed in the open meeting. FRA is therefore extending the comment period in this proceeding to February 15, 1993.

Issued in Washington, DC on January 8, 1993.

Gilbert E. Carmichael,

Administrator.

[FR Doc. 93–898 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–06–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AB83

Endangered and Threatened Wildlife and Plants; Correction to Proposal to List the Relict Darter and Bluemask (=Jewel) Darter as Endangered Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Correction to proposed rule.

SUMMARY: The Fish and Wildlife Service corrects the proposed rule published Friday, December 11, 1992 (57 FR 58774) that proposed to list the relict and bluemask (=jewel) darters as endangered species. An inaccurate scientific name was given for the relict darter in the table entry at 57 FR 58778. A correction is provided.

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Dr. Larry Shannon, Chief, Division of Endangered Species, U.S. Fish and Wildlife Service (452 ARLSQ), Washington, DC 20240 (703/358–2171).

SUPPLEMENTARY INFORMATION:

Background

As published, the proposed regulation provides the scientific classification of *Etheostoma* (*Doration*) sp. as a table entry for the relict darter at § 17.11(h). Since the species had been formally described as *Etheostoma chienense* at the time of publication of the proposed rule, and since this was the specific epithet used to refer to the relict darter in the preamble, the discrepancy in the table entry could cause confusion; a correction is provided below. Accordingly, the publication of December 11, 1992, of the proposed rule to amend 50 CFR 17.11(h), which was the subject of FR Doc. 92–30176, is corrected as follows:

§ 17.11 [Corrected]

At 57 FR 58778, in § 17.11(h) the table entry for the relict darter under the

"Scientific name" is corrected by changing "*Etheostoma* (*Catonotus*) sp." to read *Etheostoma chienense*".

Dated: January 7, 1993.

Richard N. Smith,

Director, Fish and Wildlife Service.

[FR Doc. 93–855 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–55–M

50 CFR Part 17

RIN 1018–AB83

Endangered and Threatened Wildlife and Plants: Proposal to Delist Echinocereus triglochidiatus var. inermis (spineless hedgehog cactus)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) proposes to remove *Echinocereus triglochidiatus* var. *inermis* (spineless hedgehog cactus) from the list of Endangered and Threatened Plants. This action is based on a review of all available data, which indicate that this plant is not a discrete and valid taxonomic entity and does not meet the definition of a species (which includes subspecies and varieties of plants) as defined by the Endangered Species Act of 1973, as amended, and therefore was listed in error. *E. t.* var. *melanacanthus* is really a sporadically occurring spineless form of *E. t.* var. *melanacanthus* is a common variety with a widespread distribution from northern Utah and Colorado south to the states of Durango and San Luis Potosi in central Mexico. If made final, this proposed rule would eliminate Federal protection of the Endangered Species Act, as amended. Comments from the public regarding this proposed rule are sought.

DATES: Comments from all interested parties must be received by March 15, 1993. Public hearing requests must be received by March 1, 1993.

ADDRESSES: Comments and materials concerning this proposal should be sent to the Colorado State Supervisor, U.S. Fish and Wildlife Service, Fish and Wildlife Enhancement, 730 Simms Street, room 290, Golden, Colorado 80401; or to the U.S. Fish and Wildlife Service, Fish and Wildlife Enhancement, Western Colorado Suboffice, 529–25½ Road, suite B–113, Grand Junction, Colorado 81505–6199. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above addresses.

FOR FURTHER INFORMATION CONTACT: Ms. Lucy Jordan, botanist, at the above Grand Junction address (Phone: 303/243–2778).

SUPPLEMENTARY INFORMATION:

Background

The spineless hedgehog cactus has been known for nearly 100 years. It was first collected in the La Sal Mountains of Utah by the German botanist Carl Albert Purpus and published by Karl Schuman in 1986 as *Echinocereus phoeniceus* Engelm var. *inermis* K. Schuman (Taylor 1985). The Purpus type collection is not available for study since it was destroyed during World War II.

Throughout its history, the spineless hedgehog cactus has generally not been recognized as taxonomically valid. For instance, in the first and only complete flora of Colorado, Harrington (1954) considered it only as a form. The current attention to the spineless hedgehog cactus began in the early 1970's when Gerald Arp conducted graduate work at the University of Colorado on the cacti of Colorado. Arp (1973) made the combination *Echinocereus triglochidiatus* Engelm. var. *inermis* (Schum.) G.K. Arp to bring the spineless hedgehog into alignment with the current taxonomic treatment of the genus. Although he recognized that the spineless hedgehog had not been considered taxonomically valid, Arp (1973) based his taxonomic recognition of it on its existence "* * * as a distinct and identifiable population." His taxonomic recognition of the spineless hedgehog cactus coincided with the passage of the Endangered Species Act (Act) of 1973 and its new provisions for the protection of endangered and threatened plants. Despite vigorous debate among Arp, Lyman Benson (a national authority on the Cactaceae), and Colorado botanists concerning the taxonomic validity of the spineless hedgehog cactus, the Fish and Wildlife Service (Service) took a conservative approach and listed it as endangered on November 7, 1979 (44 FR 64744), to provide interim protection from the primary threat of collecting. The debate was based on the taxonomic significance of the single difference of spinelessness and the existence of distinct populations in nature.

The subsequent recovery plan (U.S. Fish and Wildlife Service 1986) called for further studies to resolve this taxonomic question. In the recovery plan, a possible microsite difference in habitat between spineless plants on flat mesa tops or ridge tops and spined plants on adjacent sideslopes within a local area was noted, suggesting the possibility of populational integrity. However, these different microsties are only separated by short distances (as little as 15 m (50 ft), and the plants are essentially intermingled anyway. Subsequent inventories in the 13 years since the listing have found that, in fact, even this slight difference in microhabitat does not usually exist in nature, and both spined and spineless plants are found on either flats or slopes (James Ferguson, Bureau of Land Management, pers. comm., 1985). Also, spineless plants have been found in much more widely scattered areas.

At the time of listing, only four populations were known. Now, spineless hedgehog cacti have been found at over 20 sites, 160 km (100 mi) to the west (Heil and Porter 1989) and 40 km (25 mi) to the east and south (James Ferguson, pers. comm., 1986) of the original area. Thus, the spineless hedgehog cactus has been found to be only a form widely interspersed within the range of the spined var. *melanacanthus* in southeast Utah and southwest Colorado, over an area approximately 320 km (200 mi) by 160 km (100 mi) wide. Even in the light of the Service's listing of the spineless hedgehog cactus, subsequent taxonomic treatments have recognized it as a form only. These treatments include Benson (1982), Taylor (1985), Weber (1987), and Welsh et al. (1987). The consensus of scientific opinion thus supports its recognition as a form only, and not a taxonomic entity eligible for recognition under the Act.

In addition, attempts by cactus nurserymen to breed spineless plants from mature, 15-year-old stock have yielded a mixture of spined and spineless progeny. Thus, the spineless hedgehog plants apparently do not breed true, providing another line of evidence that they are simply forms (Steven Brack, cactus horticulturist, Belen, New Mexico, pers. comm., 1991).

The final rule stated that another reason for taxonomic recognition was that it was recognized as a distinct entity by cactus collectors. Cactus taxonomy is well-known for the notorious splitting of narrowly defined morphological variants of horticultural interest to collectors, but with no populational integrity in nature. The spineless hedgehog is one more case in point. Horticultural recognition is not necessarily the same as scientific recognition of a valid taxonomic entity in nature, and, hence, a reason for listing.

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Summary of Factors Affecting the Species

50 CFR 424.11 requires that certain factors be considered before a species can be listed, reclassified, or delisted. These factors and their application to *Echinocereus triglochidiatus* Engel. var. *inermis* (K. Schum.) G.K. Arp. (spineless hedgehog cactus) are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Echinocereus triglochidiatus var. *inermis* has been determined to be more than a spineless form of *E. t.* var. *melanacanthus* intermingled throughout the range of this variety in southeastern Utah and southwestern Colorado. *E. t.* var. *melanacanthus* is a common variety itself, extending from Utah and Colorado south into the states of Durango and San Luis Potosi in central Mexico (Benson 1982). The common *E. t.* var. *melanacanthus*, which includes *E. t.* var. *inermis*, is not significantly threatened. The final rule that designated *E. t.* var *inermis* as an endangered species identified habitat modification from pinyon-juniper chaining and mining activities. Because *E. t.* var. *inermis* is not a valid taxon and does not meet the definition of "species" as defined in the Act, and because the taxon of which it is a part is common and wide ranging, this threat has no applicability to these cacti.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

The final rule cited overcollecting by commercial and private cactus collectors as the primary threat. Here again, as stated above in Section A, this threat is not applicable to the common and wide-ranging *E. t.* var. *melanacanthus* which includes *E. t.* var. *inermis*.

C. Disease or Predation

Disease or predation is not a threat to *E. t.* var. *melanacanthus* which includes *E. t.* var *inermis*.

D. The Inadequacy of Existing Regulatory Mechanisms

Echinocereus triglochidiatus var. *melanacanthus*, as a common and wide ranging taxon, is not threatened by the inadequacy of regulatory mechanisms. All native cacti are in Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (Convention). The Convention regulates and in some cases prohibits the export and international trade in species listed in the appendices. *E. t.* var. *melanacanthus* will continue to be subject to the requirements of the Convention.

E. Other Natural and Manmade Factors Affecting Its Continued Existence

None are known.

The regulations of 50 CFR 424.11(d) state that a species may be delisted if: (1) It becomes extinct, (2) it recovers, or (3) the original classification data were in error. The Service believes current scientific information exists that demonstrates that *E. t.* var. *inermis* does not represent a valid taxonomic entity, and, therefore, does not meet the definition of "species" as defined in section 3(16) of the Act Therefore, *E. t.* var. *inermis* was listed in error.

Effects of Rule

The proposed action would result in the removal of this cactus from the List of Endangered and Threatened Plants. Federal agencies would no longer be required to consult with the Secretary of the Interior to insure that any action authorized, funded, or carried out by such agency is not likely to jeopardize the continued existence of *E. t.* var. *inermis*. There is no designated critical habitat for this cactus. Federal restrictions on taking of this species would no longer apply. There are no specific preservation or management programs for this plant that would be terminated.

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments on suggestion regarding any aspect of this proposal are hereby solicited from the public, other concerned governmental agencies, the scientific community, industry, or other interested parties. The Service particularly requests any evidence of populations of *E. triglochidiatus* whose individuals are plants referable only, or largely, to the variety *inermis*.

The Act provides for a public hearing on this proposal, if requested. Requests must be filed within 45 days of the date of the proposal. Such requests must be made in writing and addressed to the Service's State Supervisor in Golden, Colorado, or to the Western Colorado Suboffice in Grand Junction, Colorado (see **ADDRESSES** above).

National Environmental Policy Act

The Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in **Federal Register** on October 25, 1983 (49 FR 49244).

References Cited

Arp, G. 1973. Studies in the Colorado cacti-V—the spineless hedgehog. Cactus and Succulent Journal 45:132–133.

Benson, L. 1982. The cacti of the United States and Canada. Stanford University Press. Stanford, California. 1,044 pp.

Heil, K., and M.L. Porter. 1989. Endangered, threatened, rate and other plants of concern at Capitol Reef National Park. Part II Taxa of Concern. Status Report prepared for National Park Service, Capitol Reef National Park.

Harrington, H.D. 1954. Manual of the plants of Colorado. Sage Books, Denver. 666 pp.

Taylor, N.P. 1985. The genus *Echinocereus*. Timber Press, Portland, Oregon. 160 pp.

U.S. Fish and Wildlife Service. 1986. Spineless hedgehog cactus recovery plan. U.S. Fish and Wildlife Service, Denver, Colorado. 19 pp.

Weber, W.A. 1987. Colorado flora: western slope. Colorado Associated University Press, Boulder. 530 pp.

Welsh, S.L., N.D. Atwood, S. Goodrich, and L.C. Higgins. 1987. A Utah flora. Great Basin Naturalist Memoirs, No. 9, Bringham Young University Press, Provo, Utah. 894 pp.

Author

The original author of this proposed rule was John L. Anderson, botanist, U.S. Fish and Wildlife Service. The new author is Lucy Jordan, botanist (see **ADDRESSES** section above).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Proposed Regulation Promulgation

Accordingly, it is hereby proposed to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Public Law 99–625, 100 Stat. 3500, unless otherwise noted.

§ 17.12 [Amended]

2. It is proposed to amend § 17.12(h) by removing the entry "*Echinocereus triglochidiatus* var. *inermis* (spineless hedgehog cactus)" under "Cactaceae" from the List of Endangered and Threatened Plants.

Dated: Sep
Richard N.
Director, Fis
[FR Doc. 93-
BILLING CODE

Dated: September 28, 1992.

Richard N. Smith,

Director, Fish and Wildlife Service.

[FR Doc. 93–857 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–55–M

Notices

Federal Register
Vol. 58, No. 9
Thursday, January 14, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forms Under Review by Office of Management and Budget

January 8, 1993.

The Department of Agriculture has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35) since the last list was published. This list is grouped into new proposals, revisions, extension, or reinstatements. Each entry contains the following information:

(1) Agency proposing the information collection;
(2) Title of the information collection;
(3) Form number(s), if applicable;
(4) How often the information is requested; (5) Who will be required or asked to report;
(6) An estimate of the number of responses;
(7) An estimate of the total number of hours needed to provide the information;
(8) Name and telephone number of the agency contact person.

Questions about the items in the listing should be directed to the agency person named at the end of each entry. Copies of the proposed forms and supporting documents may be obtained from: Department Clearance Officer, USDA, OIRM, room 404–W Admin. Bldg., Washington, DC 20250, (202) 690–2118.

Revision

- Animal and Plant Health Inspection Service

Application for Veterinary Accreditation
Recordkeeping; Annually
State or local governments; businesses or other for-profit; Small Businesses or organizations; 49,024 responses; 49,252 hours
Julia A. Heamon (301) 436–6954

- Agricultural Stabilization and Conservation Service

7 CFR 1435—Subpart Marketing Assessments
CCC–80
Monthly
Business or other for-profit; 756 responses; 1,134 hours
John Doster (202) 703–1305

Extension

- Forest Service

Youth Conservation Corps (YCC) Application and Medical History
FS–1800–3 and FS–1800–18
On occasion
Individuals or households; 27,500 responses; 2,500 hours
Ransom Hughes (703) 235–8861

New Collection

- Forest Service

National Survey on Outdoor Recreation
On occasion
Individuals or households; 30,000 responses; 9,900 hours
Barbara McDonald (706) 546–2451

Larry K. Roberson,
Deputy Department Clearance Officer.

[FR Doc. 93–921 Filed 1–13–93; 8:45 am]
BILLING CODE 3410–01–M

Animal and Plant Health Inspection Service

[Docket No. 92–190–1]

Animal Damage Control Program; Supplement to Draft Environmental Impact Statement; Notice of Intent

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service intends to make available a supplement to the draft environmental impact statement (EIS) for the Animal Damage Control program. The draft EIS, prepared in June 1990, evaluated environmental impacts associated with wildlife damage control activities.

FOR FURTHER INFORMATION CONTACT: Mr. Richard L. Wadleigh, Staff Officer, Operational Support Staff, ADC, APHIS, USDA, room 819, Federal Building, 6505 Belcrest Road, Hyattsville, Maryland 20782, (301) 436–8281.

SUPPLEMENTARY INFORMATION:

Background

Wild animals can damage and destroy agricultural crops, grazing lands, livestock and poultry, aircraft and other transportation resources, buildings, irrigation works, or other structures, and can transmit disease. Occurrences of this nature are commonly termed "wildlife damage." The management of the problems caused by wildlife is commonly termed "wildlife damage control" and is a recognized discipline within the art and science of wildlife management.

The Federal Government's involvement in wildlife damage control began in the late 1800's. The Animal Damage Control Act of March 2, 1931 (7 U.S.C. 426–426(b)) authorized and directed government actions in wildlife damage management. In 1985, Congress transferred the Animal Damage Control (ADC) program from the U.S. Department of Interior (DOI) to the U.S. Department of Agriculture (USDA). The Animal and Plant Health Inspection Service (APHIS) of the USDA assumed the management of the ADC program, which includes the authority for identifying, demonstrating, and applying the best methods of controlling wildlife damage to protect agriculture, horticulture, natural resources, wild game animals, fur-bearing animals, and birds. The APHIS also has the authority for protecting stock and other domestic animals through the suppression of rabies and tularemia in predatory or other wild animals; and, except for urban rodent control, the authority to control nuisance mammals and birds and those mammals and bird species that are reservoirs for zoonotic diseases.

On February 21, 1986 (51 FR 6290, Docket No. 86–402), we gave notice of our intent to adopt the final environmental impact statement (EIS) that had been prepared by FWS in 1979 for the ADC program.

On November 16, 1987 (52 FR 43778–43779, Docket No. 87–151), we gave notice of our intent to prepare a new EIS evaluating the impacts on the environment of the ADC program's activities to control damage caused by wild animals. We also requested comments and gave notice of scoping meetings to allow public involvement in the first step of the EIS process.

On June 18, 1990 (55 FR 24597–24598, Docket No. 90–099), we gave

notice of the availability of the draft EIS. We also requested comments and gave notice of public meetings to further promote public involvement in the development of the EIS.

On August 31, 1990 (55 FR 35700, Docket No. 90–165), we extended the comment period for Docket No. 90–099, which advised the public that we had prepared a draft EIS. This extension was in response to requests from a sheep industry organization and an environmental organization.

On September 20, 1991 (56 FR 47734, Docket No. 91–131), we amended the notice of intent to prepare an EIS for the ADC program to include the Bureau of Land Management (BLM) of the DOI, and the Forest Service (FS) of the USDA, as cooperating agencies with APHIS.

The APHIS, in cooperation with BLM and FS, is preparing a final EIS for the ADC program. Because of the length of time that has passed since the publication of the draft EIS and the need for more detailed analysis to respond to comments received on the draft EIS, we intend to make available a supplement to the draft EIS for public review and comment. The supplement to the draft EIS will include amplified analyses, which will expand upon the following areas:

(1) The quantitative risk assessment of all chemical and nonchemical methods employed by the program;

(2) The economic analysis; and

(3) The explanation of alternatives, including an in-depth discussion of the ADC decision model.

We expect to complete the supplement to the draft EIS in January 1993. Availability of the supplement to the draft EIS and an invitation to comment on the supplement to the draft EIS will be published in a subsequent **Federal Register** notice.

Done in Washington, DC, this 8th day of January 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–927 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–34–M

[Docket No. 92–193–1]

Availability of Environmental Assessments and Findings of No Significant Impact Relative to Issuance of Permits to Field Test Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that three environmental assessments and findings of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of permits to allow the field testing of genetically engineered organisms. The environmental assessments provide a basis for our conclusion that the field testing of these genetically engineered organisms will not present a risk of introducing or disseminating a plant pest and will not have a significant impact on the quality of the human environment. Based on its findings of no significant impact, the Animal and Plant Health Inspection Service has determined that environmental impact statements need not be prepared.

ADDRESSES: Copies of the environmental assessments and findings of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Deputy Director, Biotechnology Permits, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7612. For copies of the environmental assessments and findings of no significant impact, write to Mr. Clayton Givens at the same address. Please refer to the permit number listed below when ordering documents.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 (referred to below as the regulations) regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article may be introduced into the United States. The regulations set forth the procedures for obtaining a limited permit for the importation or interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22906).

In the course of reviewing each permit application, APHIS assessed the impact on the environment that releasing the organisms under the conditions described in the permit application would have. APHIS has issued permits for the field testing of the organisms listed below after concluding that the organisms will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment. The environmental assessments and findings of no significant impact, which are based on data submitted by the applicants and on a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field tests.

Environmental assessments and findings of no significant impact have been prepared by APHIS relative to the issuance of permits to allow the field testing of the following genetically engineered organisms:

Permit No.	Permittee	Date issued	Organisms	Field test location
92–259–01, renewal of permit 92–015–02, issued on 04–30–92.	Northrup King Company .	12–04–92	Soybean plants genetically engineered to express the enzyme 5-enol-pyruvyl shikimate-3-phosphate synthase (EPSPS) and a metabolizing enzyme for tolerance to the herbicide glyphosate.	Hawaii.

Permit No.	Permittee	Date issued	Organisms	Field test location
92-265-02 renewal of permit 92-017-03, issued on 05-14-92.	Monsanto Agricultural Company.	12-04-92	Corn plants genetically engineered to express a gene from *Bacillus thuringiensis* subsp. *kurstaki* (Btk) for resistance to lepidopteran insects, and/or genes for tolerance to the herbicide glyphosate, and/or a beta-glucuron-idase (GUS) gene as a marker.	Hawaii.
92-308-01, renewal of permit 92-274-05, issued on 11-15-90.	Upjohn Company	12-07-92	Soybean plants genetically engineered to express the enzymes phosphinothricin acetyltransferase (PAT) for tolerance to the herbicide bialaphos.	Puerto Rico.

The environmental assessments and findings of no significant impact have been prepared in accordance with:

(1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*),

(2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1508),

(3) USDA Regulations Implementing NEPA (7 CFR part 1b), and

(4) APHIS Guidelines Implementing NEPA (44 FR 50381–50384, August 28, 1979, and 44 FR 51272–51274, August 31, 1979).

Done in Washington, DC, this 8th day of January 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93-928 Filed 1-13-93; 8:45 am]

BILLING CODE 3410-34-M

[Docket No. 92-194-1]

Receipt of Permit Applications for Release Into the Environment of Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that six applications for permits to release genetically engineered organisms into the environment are being reviewed by the Animal and Plant Health Inspection Service. The applications have been submitted in accordance with 7 CFR part 340, which regulates the introduction of certain genetically engineered organisms and products.

ADDRESSES: Copies of the applications referenced in this notice, with any confidential business information deleted, are available for public inspection in room 1141, South Building, U.S. Department of Agriculture, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. You may obtain copies of the documents by writing to the person listed under **FOR FURTHER INFORMATION CONTACT.**

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Deputy Director, Biotechnology Permits, Biotechnology, Biologics, and Environmental Protection, APHIS, USDA, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7612.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe Are Plant Pests," require a person to obtain a permit before introducing (importing, moving interstate, or releasing into the environment) into the United States certain genetically engineered organisms and products that are considered "regulated articles." The regulations set forth procedures for obtaining a permit for the release into the environment of a regulated article, and for obtaining a limited permit for the importation or interstate movement of a regulated article.

Pursuant to these regulations, the Animal and Plant Health Inspection Service has received and is reviewing the following applications for permits to release genetically engineered organisms into the environment:

Application No.	Applicant	Date received	Organisms	Field test location
92-337-01	Upjohn Company	12-02-92	Tomato plants and lettuce plants genetically engineered to express the nucleocapsid protein of tomato spotted wilt virus (TSWV) for resistance to TSWV.	Michigan.
92-343-01, renewal of permit 92-022-04, issued on 05-21-92.	Calgene, Incorporated	12-08-92	Tomato plants genetically engineered to express an antisense polygalacturonase (PG) gene, a cytokinin production gene, and ethylene regulation genes, all of which are involved in ripening.	California.
92-349-01, renewal of permit 91-294-02, issued on 12-04-91.	Frito-Lay Incorporated	12-14-92	Potato plants genetically engineered to over-express a metabolic enzyme to reduce cold-sensitive sweetening in potato tubers.	Wisconsin.
92-349-02, renewal of permit 91-301-01, issued on 02-03-92.	Frito-Lay, Incorporated ...	12-14-92	Potato plants genetically engineered to express metabolic enzymes in order to increase levels of dry matter in potato tubers.	Wisconsin.
92-349-03, renewal of permit 91-302-01, issued on 02-14-92.	Frito-Lay, Incorporated ...	12-14-92	Potato plants genetically engineered to express metabolic enzymes in order to inhibit accumulation of simple sugars in potato tubers.	Wisconsin.
92-349-04, renewal of permit 91-303-01, issued on 03-09-92.	Frito-Lay, Incorporated ...	12-14-92	Potato plants genetically engineered to express stress alleviating enzymes, in order to obtain higher levels of stress tolerance in potato tubers.	Wisconsin.

Done in Washington, DC, this 8th day of January 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93-929 Filed 1-13-93; 8:45 am]

BILLING CODE 3410-34-M

Forest Service

Exemption of Ally North/Fallen Haul Salvage Project From Appeal

AGENCY: USDA, Forest Service, Northern Region.

ACTION: Notification that a timber salvage project designed to recover windstorm damage timber is exempted from appeals under provisions of 36 CFR part 217.

SUMMARY: In October 1991, 160 acres of timber in the North Creek area were blown down during a severe windstorm. In 1992, the Bonners Ferry District Ranger proposed a salvage timber sale project to recover damaged sawtimber in the affected area. The District Ranger has determined, through an environmental analysis documented in the Ally North/Fallen Haul Timber Salvage Environmental Assessment (EA), that there is good cause to expedite these actions in order to rehabilitate National Forest System lands and recover damaged resources. Salvage of commercial sawtimber within the affected area must be accomplished quickly to avoid further deterioration of sawtimber and to reduce the risk of catastrophic wildfire and spruce bark beetle infestation that could damage adjacent healthy timber stands.

EFFECTIVE DATE: Effectove on January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Debbie Henderson-Norton, District Ranger, Bonners Ferry Ranger District, Idaho Panhandle National Forests, Route 4, Box 4860, Bonners Ferry, ID 83805.

SUPPLEMENTARY INFORMATION: Severe windstorms in the fall of 1991 damaged approximately 160 acres of timber in the North Creek area. The windthrown timber is located within lands designated as suitable for timber management and assigned to Management Area 2 (Idaho Panhandle Forest Plan, August 1987). In September 1992, the Bonners Ferry District Ranger, Idaho Panhandle National Forest, proposed the salvage harvest of the trees damaged by the windstorms. This proposal was designed to meet the following needs, (a) reduce potential for spruce bark beetle infestations in adjacent healthy timber stands by implementing integrated pest management prescriptions, (b) reduce wildfire hazard by reducing fuel loading, (c) rehabilitate timber stands that are understocked through site preparation for natural regeneration, and (d) salvage merchantable timber products and contribute to a continuous supply of timber by recovering sawtimber before it deteriorates in value.

An interdisciplinary team was convened, and scoping began in 1992. Four environmental issues were identified and were the basis for the environmental analysis disclosed in the EA. The interdisciplinary team utilized information and analysis disclosed in the Timber Creek and Camp Creek EA and Decision Notice (March 1981) and the East Fork Boulder Creek EA and Decision Notice (November 1979) as the basis for conducting their review. This information is incorporated by reference. Two alternatives were analyzed; no treatment (no action) and a salvage and rehabilitation proposal (proposed action). The selected alternative would salvage 160 MBF of dead and damaged timber from approximately 160 acres. All salvage areas are accessible from existing roads. No road construction or reconstruction will occur in conjunction with this action.

The salvage timber sale project is designed to accomplish the objectives as quickly as possible to minimize the risk of a spruce bark beetle epidemic, reduce the potential for catastrophic wild fire and to recover merchantable sawtimber before it deteriorates and removal becomes infeasible. To expedite implementation of this decision, procedures outlined in 36 CFR 217(a)(11) are being followed. Under this Regulation the following may be exempt from appeal:

"Decisions related to rehabilitation of National Forest System lands and recovery of Forest Resources from natural disasters or other natural phenomena, such as * * * severe wind * * * when the Regional Forester * * * determines and gives notice in the **Federal Register** that good causes exists to exempt such decisions from review under this part."

Based on the environmental analysis documented in the Ally North/Fallen Haul Timber Salvage Sale EA and the District Ranger's Decision Notice for this project, I have determined that good cause exists to exempt this decision from administrative review. Therefore, upon publication of this notice, this project will not be subject to review under 36 CFR part 217.

Dated: January 7, 1993.

John M. Hughes,

Deputy Regional Forester, Northern Region.

[FR Doc. 93-639 Filed 1-13-93; 8:45 am]

BILLING CODE 3410-11-M

Exemption of Wally Salvage Timber Sale From Appeal, Okanogan National Forest, WA

AGENCY: Forest Service, USDA.

ACTION: Notice to exempt decisions from administrative appeal.

SUMMARY: This is a notification that the decision to implement the Wally Salvage Timber Sale in the area of the Middle Fork Beaver Creek on the Okanogan National Forest is exempted from appeal. This is in conformance with provisions of 36 CFR 217.4(a)(11) as published in the **Federal Register** on January 23, 1989 (54 FR 3342).

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Allen N. Garr, District Ranger, Twisp Ranger District, P.O. Box 188, Twisp, Washington 98856, Phone (509) 997-2131.

SUPPLEMENTARY INFORMATION: During the month of June in 1992 a windstorm caused timber to be blown down in the area of Middle Fork Beaver Creek in the Okanogan National Forest. This blown-down timber is located in approximately 40 acres of land suitable for timber production. The area is located in Management Area 25 which includes intensive timber management as a goal.

In June 1992, the Twisp District Ranger proposed the salvage harvest of the blown-down timber. In July an interdisciplinary team (IDT) surveyed the affected area to assess the damage to the resources that had occurred. The IDT identified the need to salvage the timber which had blown down in as short a time as possible so the logs would remain merchantable. Merchantable timber in the area averages 12 inches in diameter at breast height with relatively little defect. The environmental analysis of this action was begun in mid-July. The IDT began with an initial scoping session on July 16, 1992. After press releases and contacts with individuals and State and other federal agencies, the following two issues were identified: (1) Whether harvest can be completed prior to the trees losing commercial value; and (2) whether harvest would create detrimental soil conditions, especially soil compaction.

Three alternatives were analyzed, including the No-Action Alternative.

This salvage sale will harvest about 150,000 board feet of mainly blown-down timber, but also includes some green-standing trees heavily infected with dwarf mistletoe. Removal of dwarf mistletoe trees is necessary to ensure establishment of a healthy, thrifty plantation, and movement toward the desired future condition. No new road construction would be necessary to implement the project. All skidding would be done by tractor; designated skid trails will limit soil compaction to forest plan standards. Harvest prescription would be seed tree followed by planting. Planting will ensure movement toward the desired future condition.

This salvage fits within category 4 of section 31.2 of Forest Service Handbook 1909.15. Therefore, this action may be categorically excluded from documentation in an environmental impact statement or an environmental assessment.

The Wally Salvage Timber Sale is designed to accomplish the objectives as quickly as possible and minimize the amount of salvage volume lost. To expedite this salvage sale and the accompanying work, this salvage sale is exempt from appeal (36 CFR part 217). Under this Regulation, the following is exempt from appeal:

> Decisions related to rehabilitation of National Forest System lands and recovery of forest resources resulting from natural disasters or other natural phenomena, such as wildfires * * * when the Regional Forester * * * determines and gives notice in the **Federal Register** that good cause exists to exempt such decisions from review under this part.

After publication of this notice in the **Federal Register**, this Decision Memo for the Wally Salvage Timber Sale may be signed by the Twisp District Ranger. Therefore, this project will not be subject to review under 36 CFR part 217.

Dated: January 5, 1993.

Richard A. Ferraro,

Deputy Regional Forester.

[FR Doc. 93–844 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–11–M

Exemption of Douglas Salvage Timber Sale From Appeal, Okanogan National Forest, WA

AGENCY: Forest Service, USDA.

ACTION: Notice to exempt decisions from administrative appeal.

SUMMARY: This is a notification that the decision to implement the Douglas Salvage Timber Sale in the area of the McFarland Creek on the Okanogan National Forest is exempted from appeal. This is in conformance with provisions of 36 CFR 217.4(a)(11) as published in the **Federal Register** on January 23, 1989 (54 FR 3342).

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Allen N. Garr, District Ranger, Twisp Ranger District, P.O. Box 188, Twisp, Washington 98856, Phone (509) 997–2131.

SUPPLEMENTARY INFORMATION: During the month of November in 1991 a windstorm caused timber to be blown down in the area of McFarland Creek on the Okanogan National Forest. This blown-down timber is located in approximately 48 acres of land suitable for timber production. The area is located in Management Area 25 which includes intensive timber management as a goal.

In June 1992, the Twisp District Ranger proposed the salvage harvest of the blown-down timber. In July an interdisciplinary team (IDT) surveyed the affected area to assess the damage to the resources that had occurred. The IDT identified the need to salvage the timber which had blown down in as short a time as possible so the logs would remain merchantable. Merchantable timber in the area averages 11 inches in diameter at breast height with relatively little defect. The environmental analysis of this action was begun in mid-July. The IDT began with an initial scoping session on July 16, 1992. After press releases and contracts with individuals and State and other federal agencies, the following three major issues here identified:

1. Whether harvest can be completed prior to the trees losing commercial value.
2. Whether harvest would change the roadless character of the inventoried Hungry Ridge roadless area, which is directly adjacent to the project area.
3. Whether harvest would result in detrimental soil conditions, especially compaction.

Three alternatives were analyzed, including the No-Action Alternative. This salvage sale will harvest about 330,000 board feet of timber. Road construction necessary to implement salvage includes .81 miles of new construction. All skidding would be done by tractor; designated skid trails will limit soil compaction to forest plan standards. Harvest prescription would be seed tree followed by planting. Planting will ensure movement of the area toward the desired future condition for Management Area 25. All units and roads are located outside of inventoried roadless areas identified in appendix C of the Final Environmental Impact Statement for the Okanogan Land and Resource management Plan.

This salvage fits within category 4 of section 31.2 of Forest Service handbook 1909.15. Therefore, this action may be categorically excluded from documentation in an environmental impact statement or an environmental assessment.

The Douglas Salvage Timber sale is designed to accomplish the objectives as quickly as possible and minimize the amount of salvage volume lost. To expedite this salvage sale and the accompanying work this salvage sale is exempt from appeal (36 CFR part 217). Under this Regulation, the following is exempt from appeal:

> Decisions related to rehabilitation of National Forest System lands and recovery of forest resources resulting from natural disasters or other natural phenomena, such as wildfires * * * when the Regional Forester * * * determines and gives notice in the **Federal Register** that good cause exists to exempt such decisions from review under this part.

After publication of this notice in the **Federal Register**, this Decision Memo for the Douglas Salvage Timber Sale may be signed by the Twisp District Ranger. Therefore, this project will not be subject to review under 36 CFR part 217.

Dated: January 5, 1993.

Richard A. Ferraro,

Deputy Regional Forester.

[FR Doc. 93–845 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–11–M

Exemption of Nicholson Salvage One and Nicholson Salvage Two Timber Sales From Appeal, Okanogan National Forest, WA

AGENCY: Forest Service, USDA.

ACTION: Notice to exempt decisions from administrative appeal.

SUMMARY: This is a notification that the decision to implement the Nicholson Salvage One and Nicholson Salvage Two Timber Sales in the headwaters of Nicholson Creek on the Okanogan National Forest is exempted from appeal. This is in conformance with provisions of 36 CFR 217.4(a)(11) as published in the **Federal Register** on January 23, 1989 (54 FR 3342).

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Elaine J. Zieroth, District Ranger, Tonasket Ranger District, P.O. Box 466, Tonasket, Washington 98855, Phone (509) 486–2186.

SUPPLEMENTARY INFORMATION: The proposed harvest units in each of these

two salvage timber sales have severe forest health problems caused by insect infestations and disease.

These units were originally part of the Nicholson Timber Sale. In recognition of the severity of the forest health problems in the area, eight units were separated from the original Nicholson Timer Sale, and split into Nicholson Salvage One and Nicholson Salvage Two Timber Sales. Splitting the salvage into two sales will facilitate treatment of all of these high priority units within a year, while the timber is still of value, and before insect and disease can spread, and will provide timber sales for small business timber sale operators in the area.

Public scoping and the environmental analysis of this project was done as part of the Nicholson Timber Sale. Subsequently, the interdisciplinary team (IDT) met and identified the eight salvage units which had high priority for treatment. The following five issues were identified:

1. Dead and dying trees would lose their merchantability within another year.

2. Dwarf mistletoe-infected overstory stands in several proposed salvage units would infect a currently manageable understory stand.

3. Trees dying from western spruce budworm activity and laminated root rot infection are increasing the fuel loading, and hence, the fire hazard on several sites.

4. Prompt salvage of timber in the Douglas-fir root rot pockets would begin the regeneration of wildlife cover. So much of the timber has already died in the diseased area that it has little or no cover value for deer or other wildlife species.

5. Livestock utilization is declining because cattle are not adequately able to utilize forage in areas with dead and down timber.

The Nicholson Salvage One Sale will produce about 891,000 board feet of dead or dying timber from three units totaling 124 acres, and requires no road construction. The Nicholson Salvage Two Sale will produce about 713,000 board feet of dead or dying timber from five units totaling 154 acres, and requires about 0.5 miles of road construction. Harvest of units in both sales will facilitate quicker movement of the area toward the desired future condition.

These salvage timber sales fit within category 4 of section 31.2 of Forest Service Handbook 1909.15. Therefore, these actions may be categorically excluded from documentation in an environmental impact statement or an environmental assessment.

The Nicholson Salvage One and Nicholson Salvage Two Timber Sales are designed to accomplish the objectives as quickly as possible and minimize the amount of salvage volume lost. To expedite these salvage sales and the accompanying work, these salvage sales are exempt from appeal (36 CFR part 217). Under this Regulation, the following is exempt from appeal:

Decisions related to rehabilitation of National Forest System lands and recovery of forest resources resulting from natural disasters or other natural phenomena, such as wildfires * * * when the Regional Forester * * * determines and gives notice in the **Federal Register** that good cause exists to exempt such decisions from review under this part.

After publication of these notices in the **Federal Register**, these Decision Memos for the Nicholson Salvage One and Nicholson Salvage Two Timber Sales may be signed by the Tonasket District Ranger. Therefore, this project will not be subject to review under 36 CFR part 217.

Dated: January 5, 1993.

Richard A. Ferraro,

Deputy Regional Forester.

[FR Doc. 93–846 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–11–M

Exemption of Boulder Salvage Units 7 and 9 From Appeal, Willamette National Forest, OR

AGENCY: Forest Service, USDA.

ACTION: Notice to exempt decisions from administrative appeal.

SUMMARY: This is a notification that the decision to implement Boulder Salvage Units 7 and 9 in the area of Boulder Creek on the Willamette National Forest is exempted from appeal. This is in conformance with provisions of 36 CFR Part 217(a)(11) as published in the **Federal Register** on January 23, 1989 (54 FR 3342).

EFFECTIVE DATE: January 14, 1993.

FOR FURTHER INFORMATION CONTACT: Darrel L. Kenops, Forest Supervisor, Willamette National Forest, P.O. Box 10607, Eugene, Oregon 97440, Phone (503) 456–6517.

SUPPLEMENTARY INFORMATION: In 1990 an intense, localized, windstorm caused extensive blow down in the Boulder Creek area. This blown-down material was included in the Boulderdash Timber Sale analysis which also included green (live), standard volume. The green non-thinning portion of Boulderdash analysis area is in Northern spotted owl habitat and therefore under injunction. A decision was made to proceed with a Decision Notice on the non-spotted owl habitat portion of the Boulderdash Timber Sale so it could be offered for sale immediately. The Decision Notice will contain two separate sales: (1) Estep Thin, which is the commercial thinning portion and (2) Boulder Salvage, which is the salvage portion (Units 7 and 9). Boulder Salvage also contains one overstory removal unit (Unit 4). Exemption from appeal of Boulder Salvage Units 7 and 9 is needed to facilitate the rapid removal of the material to reduce commercial loss of the wood products; reduce the potential for catastrophic loss from wildfire; and to help reduce the spread of insect infestation and disease.

The interdisciplinary Team (IDT) began the analysis of the impacts of this project during a meeting held December 5, 1990. After the completion of the scoping process, which included mailings of the public and contacts with individuals, State, and other Federal Agencies four significant issues were identified:

(1) Habitat diversity;
(2) Big game habitat quality;
(3) Timber supply and yield; and
(4) Hydrologic recovery.

The IDT developed four alternatives which were considered in detail, including the No-Action Alternative. The effects of these alternatives are disclosed in an environmental assessment, which was prepared for the original proposal. The Boulder Salvage Units 7 and 9 portion of the analysis (Alternative C) includes 19 acres of salvage producing 420,000 board feet of timber. Approximately .3 mile of new road will be constructed and .8 mile of existing road will be closed following harvest activities. No Pacific yew exists in the harvest units. Only Unit 9 will require replanting.

The Boulder Salvage Units 7 and 9 portion of alternative C is designed to accomplish the objectives as quickly as possible, to minimize the loss of wood value, and enhance resource protection. To expedite this salvage sale and accompanying work, this salvage sale is exempted from appeal (36 CFR part 217). Under this Regulation, the following is exempt from appeal:

Decision related to the rehabilitation of National Forest System lands and recovery of forest resources resulting from natural disasters or other natural phenomena, such as wildfires * * * when the Regional Forester * * * determines and gives notice in the **Federal Register** that good cause exists to exempt such decisions from review under this part.

After publication of this notice in the **Federal Register** this Decision Notice

for the Boulder Salvage Units 7 and 9 may be signed by the forest Supervisor. Therefore, this project will not be subject to review under 36 CFR part 217

Dated: January 5, 1993.

Richard A. Ferraro,

Acting Regional Forester.

[FR Doc. 93–843 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–11–M

Oregon Dunes National Recreation Area Management Plan, Siuslaw National Forest, Coos, Douglas, and Lane Counties, OR

AGENCY: Forest Service, USDA.

ACTION: Revision of a notice of intent to prepare environmental impact statement.

SUMMARY: The Forest Service published on June 17, 1991 a Notice of Intent (56 FR 27728) to prepare a Supplement to the 1990 Final Environmental Impact Statement (EIS) for the Siuslaw National Forest Land and Resource Management Plan, Oregon, which would consider a range of alternatives for managing the Oregon Dunes National Recreation Area (NRA). Any change in management direction for the Oregon Dunes NRA will result in amending the Forest Plan. A draft EIS was to have been available in July 1992, and the Responsible Official was to have been the Regional Forester, Pacific Northwest Region.

Following preliminary scoping and environmental analysis, it was determined that the draft proposed action is not expected to significantly alter the goals and objectives for long-term land and resource management of the Siuslaw National Forest. The proposed action is also not expected to have an important effect on the land and resources throughout a large portion of the Forest planning area or significantly alter the long-term relationship between levels of goods and services originally projected. Therefore, the amendment to the Forest Plan will be non-significant and the Responsible Official will be the Forest Supervisor of the Siuslaw National Forest.

At this time the draft EIS is scheduled to be available for public review in March 1993. The final EIS is expected to be published in September 1993.

FOR FURTHER INFORMATION CONTACT:

Questions and comments about this draft EIS should be directed to Edwin Becker, Area Ranger, Oregon Dunes National Recreation Area, 855 Highway Avenue, Reedsport, OR 97467, phone (503) 271–3611.

Dated: January 6, 1993.

Tony Vander Heide,

Strategic Planning & Analysis Staff Officer.

[FR Doc. 93–842 Filed 1–13–93; 8:45 am]

BILLING CODE 3410–11–M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Minnesota Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a planning meeting of the Minnesota Advisory Committee to the Commission will be held from 9 a.m. until 5 p.m. on Monday, February 8, 1993 at the Crown Sterling Suites, 425 S. 7th Street, Minneapolis, Minnesota. The purpose of this meeting is to review the draft report, "Stereotyping of Minorities by the Media", and to discuss other civil rights issues of interest to the Advisory Committee.

Persons desiring additional information should contact Mary E. Ryland, Committee Chairperson at (218) 727–3673 or Constance M. Davis, Regional Director of the Midwestern Regional Office, U.S. Commission on Civil Rights, at (312) 353–8311. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, January 8, 1993.

Carol Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 93–905 Filed 1–13–93; 8:45 am]

BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Export Administration.

Title: Project License Procedure.

Agency Form Number: None but requirements are found at Section 773.2(c) of the Export Administration Regulations.

OMB Approval Number: 0694–0006.

Type of Request: Extension of the expiration date of a currently approved collection.

Burden: 323 reporting/recordkeeping hours.

Number of Respondents: 107.

Avg Hours Per Response: 3 hours.

Needs and Uses: The Project License Procedure was developed to provide a single license for the export of commodities and/or technical data needed for large–scale overseas operations. It eliminates the necessity for the filing and processing of numerous individual export license applications.

Affected Public: Businesses or other for–profit institutions, small businesses or organizations.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Gary Waxman, (202) 395–7340.

Copies of the above information collection proposal can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 482–3271, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to Gary Waxman, OMB Desk Officer, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Dated: January 8, 1993

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 93–956 Filed 1–13–93; 8:45 am]

BILLING CODE 3510–CW–F

International Trade Administration

Export Trade Certificate of Review

AGENCY: International Trade Administration, Commerce.

ACTION: Notice of Initiation of Process of Revoke Export Trade Certificate of Review No. 85–00005.

SUMMARY: The Secretary of Commerce issued an export trade certificate of review to Comet Rice, Inc. Because this certificate holder has failed to file an annual report as required by law, the Department is initiating proceedings to revoke the certificate. This notice summarizes the notification letter sent to Comet Rice, Inc.

FOR FURTHER INFORMATION CONTACT:

George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration, 202/482–5131. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Title III of the Export Trading Company Act of 1982 ("the Act") (15 U.S.C. 4011–21) authorized the Secretary of Commerce to issue export trade certificates of review. The regulations implementing title III ("the Regulations") are found at 15 CFR part 325. Pursuant to this authority, a certificate of review was issued on May 24, 1985 to Comet Rice, Inc.

A certificate holder is required by law (Section 308 of the Act, 15 U.S.C. 4018) to submit to the Department of Commerce annual reports that update financial and other information relating to business activities covered by its certificate. The annual report is due within 45 days after the anniversary date of the issuance of the certificate of review (§§ 325.14(a) and (b) of the Regulations). Failure to submit a complete annual report may be the basis for revocation. (§§ 325.10(a) and 325.14(c) of the Regulations).

The Department of Commerce sent to Comet Rice, Inc. on May 14, 1992, a letter containing annual report questions with a reminder that its annual report was due on July 8, 1992. Additional reminders were sent on August 11, 1992, and on September 23, 1992. The Department has received no written response to any of these letters.

On January 11, 1993, and in accordance with § 325.10(c)(2) of the Regulations, a letter was sent by certified mail to notify Comet Rice, Inc. that the Department was formally initiating the process to revoke its certificate. The letter stated that this action is being taken for the certificate holder's failure to file an annual report.

In accordance with § 325.10(c)(2) of the Regulations, each certificate holder has thirty days from the day after its receipt of the notification letter in which to respond. The certificate holder is deemed to have received this letter as of the date on which this notice is published in the **Federal Register**. For good cause shown, the Department of Commerce can, at its discretion, grant a thirty-day extension for a response.

If the certificate holder decides to respond, it must specifically address the Department's statement in the notification letter that it has failed to file an annual report. It should state in detail why the facts, conduct, or circumstances described in the notification letter are not true, or if they are, why they do not warrant revoking the certificate. If the certificate holder does not respond within the specified period, it will be considered an admission of the statements contained in the notification letter (§ 325.10(c)(2) of the Regulations).

If the answer demonstrates that the material facts are in dispute, the Department of Commerce and the Department of Justice shall, upon request, meet informally with the certificate holder. Either Department may require the certificate holder to provide the documents or information that are necessary to support its contentions (Sec. 325.10(c)(3) of the Regulations).

The Department shall publish a notice in the **Federal Register** of the revocation or modification or a decision not to revoke or modify (§ 325.10(c)(4) of the Regulations). If there is a determination to revoke a certificate, any person aggrieved by such final decision may appeal to an appropriate U.S. district court within 30 days from the date on which the Department's final determination is published in the **Federal Register** (§§ 325.10(c)(4) and 325.11 of the Regulations).

Dated: January 11, 1993.

George Muller,

Director, Office of Export Trading Company Affairs.

[FR Doc. 93–958 Filed 1–13–93; 8:45 am]

BILLING CODE 3510–DR–M

Minority Business Development Agency

Business Development Center Applications: (Service Area) U.S. Virgin Islands

AGENCY: Minority Business Development Agency, Commerce.

ACTION: Notice.

SUMMARY: The Minority Business Development Agency (MBDA) is revising the closing date cited in the Announcement to solicit Competitive Applications under its Minority Business Development Center Program to operate a U.S. Virgin Islands MBDC for a three (3) year period, starting May 1, 1993 to April 30, 1994 in the U.S. Virgin Islands SMSA. The revised new closing date is January 22, 1993. Refer to the **Federal Register** dated December 18, 1992, 57 FR 60172.

Dated: January 6, 1993.

John F. Iglehart,

Regional Director, New York Regional Office.

[FR Doc. 93–911 Filed 1–13–93; 8:45 am]

BILLING CODE 3510–21–M

National Oceanic and Atmospheric Administration

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Pacific Fishery Management Council's Coastal Pelagic Species Plan Development Team will hold a public meeting on January 27, 1993, beginning at 10 a.m. The meeting will be held in the small conference room at the National Marine Fisheries Service, Southwest Fisheries Science Center, 8604 La Jolla Shores Drive, La Jolla, California.

The purpose of this meeting is to discuss the status of the coastal pelagic species fishery management plan.

For more information contact Patricia Wolf from the California Department of Fish and Game at (213) 590–5117 or Larry Jacobson from the National Marine Fisheries Service at (619) 546–7117.

Dated: January 8, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–832 Filed 1–13–93; 8:45 am]

BILLING CODE 3510–22–M

Pacific Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Pacific Fishery Management Council's Comprehensive Data Gathering Committee (Committee) will hold a public meeting on January 25, 1993, from 10 a.m. to 5 p.m., in the conference room of the Pacific States Marine Fisheries Commission, 2501 SW., First Avenue, suite 200, Portland, Oregon.

The Committee will review a draft report on the need for a program to gather fishery data from vessels at sea, as well as data that can be obtained when vessels return to port. The Committee will also discuss alternative approaches to potential funding sources and cost effectiveness of the approaches.

For more information contact Lawrence D. Six, Executive Director, Pacific Fishery Management Council, Metro Center, suite 420, 2000 SW.. First Avenue, Portland, Oregon 97201; telephone: (503) 326–6352.

Dated: January 8, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–833 Filed 1–13–93; 8:45 am]

BILLING CODE 3510–22–M

South Atlantic Fishery Management Council; Public Meetings/Public Hearings

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The South Atlantic Fishery Management Council (Council) and its Committees will hold public meetings on January 25–29, 1993, at the Holiday Inn-Melbourne Oceanfront, Indialantic, FL; telephone: (407) 777–4100.

Council

The Council session will begin on January 28 at 1:30 p.m., and on January 29 at 8:30 a.m. The Council will discuss reports and recommendations from the Committees. On January 28 at 1:45 p.m. the Council will hold a public hearing to solicit comments on Florida's request to change the Federal Special Non-Trap Recreational Spiny Lobster season to: (1) Coincide with the State season that falls on the last consecutive Wednesday and Thursday in July of each year; (2) limit harvest methods to diving and the use of bully nets; and (3) relax rules outside of Monroe County during the two-day period to divert fishing effort away from the Florida Keys area. A public hearing will be held at 2:30 p.m. to solicit comments on the 1993–94 Wreckfish total allowable catch (TAC). After reviewing reports and recommendations and public hearing comments, the Council is scheduled to approve the 1993–94 wreckfish TAC.

Committees

The Council's Scientific and Statistical Committee will meet on January 25 at 8:30 a.m. to review:

(1) Biological benefits of a possible closed season for rock shrimp;

(2) A stock assessment of the closed red drum fishery;

(3) A request from Florida to change the Federal two-day spiny lobster recreational season;

(4) A report for the 1993–94 wreckfish TAC; and

(5) An assessment report for the snapper-grouper fishery.

A public scoping meeting will be held on January 25 at 6 p.m. to solicit input on spearfishing and the use of powerheads, mechanically-propelled sleds and rebreathers to harvest species in the snapper-grouper management plan (including amberjacks).

The Snapper-Grouper Committee will meet jointly with its Advisory Panel (AP) on January 26 at 8:30 a.m. to discuss draft Amendment #6 to the Snapper-Grouper Fishery Management Plan (FMP). The Amendment could include possible quotas for amberjack, golden tilefish, blueline (grapy) tilefish, and snowy and yellowedge grouper, a definition of allowable gear, a requirement for Federal dealer permits, and a moratorium on commercial permits. The Committee and AP also will discuss marine fishery reserves as a management option for snapper and grouper.

The Committee will also meet with the Wreckfish AP at 1:30 p.m. to discuss setting the 1993–94 wreckfish TAC and the status of the fishery. At 3:30 p.m. and continuing at 8:30 a.m. on January 27, the Snapper-Grouper Committee will review reports and recommendations from the Snapper-Grouper Assessment Group, Advisory Panel and Scientific and Statistical Committee to develop a recommendation for the 1993–94 wreckfish TAC. The Committee also will further discuss Amendment #6 to the Snapper-Grouper FMP and will determine the next step in addressing marine fishery reserves.

The *Controlled Access Committee* will meet at 1:30 p.m. on January 27 to further review options for controlled access systems and effort controls for the deep-water snapper-grouper complex.

The *Shrimp Committee* is scheduled to meet at 8:30 a.m. on January 28 to make a decision on approval and submission of the Shrimp FMP to the Secretary of Commerce. The FMP would allow all individual states to request concurrent shrimping closures in adjacent Federal waters following severe winter mortality of white shrimp. The Committee also will discuss whether to proceed with an amendment to the FMP to address problems in the rock shrimp fishery. It will review an analysis of possible revenue increases associated with a closed season to allow small rock shrimp to reach a larger, more valuable size. Based on the outcome of this analysis, the Committee will recommend to the Council whether or not to proceed with an amendment.

A detailed agenda with specific meeting times is available to the public. For more information contact Carrie Knight, Public Information Officer, South Atlantic Fishery Management Council, One Southpark Circle, suite 306; Charleston, SC 29407–4699, telephone: (803) 571–4366.

Dated: January 7, 1993.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–834 Filed 1–13–93; 8:45 am]

BILLING CODE 3510–22–M

COMMODITY FUTURES TRADING COMMISSION

Chicago Mercantile Exchange and Intermarket Clearing Corp.; Proposals Implementing Additional Cross-Margining Programs

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of proposed contract market and clearing organization rule changes.

SUMMARY: The Chicago Mercantile Exchange ("CME") and The Intermarket Clearing Corporation ("ICC") have submitted proposals which would allow the CME and ICC to expand their cross-margining systems. Under these proposals, the ICC and CME plan on entering into an agreement with The Options Clearing Corporation ("OCC") to accommodate both "bilateral" cross-margining between CME and ICC and "trilateral" cross-margining among CME, ICC and OCC. The proposed cross-margining programs would operate in the same basic way as the existing CME–OCC program.

Acting pursuant to the authority delegated by Commission Regulation 140.96, the Director of the Division of Trading and Markets, with the concurrence of the General Counsel, has determined, on behalf of the Commission, that publication of these proposals is in the public interest and will assist the Commission in considering the views of interested persons. Accordingly, the Division, on behalf of the Commission, is publishing the proposals for public comment.

DATES: Comments must be received on or before February 16, 1993.

FOR FURTHER INFORMATION CONTACT: Elizabeth Patterson, Special Counsel, or Christopher Bowen, Attorney-Advisor, Division of Trading and Markets, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Telephone: (202) 254–8955.

SUPPLEMENTARY INFORMATION:

I. Introduction

By a letter dated September 21, 1992, ICC submitted, pursuant to section 5a(12) of the Act and Commission

Regulation 1.41(b), a proposal to enter into a cross-margining agreement with the OCC and CME to accommodate the same bilateral and trilateral cross-margining. Similarly, by letter dated December 3, 1992, the CME, pursuant to section 5a(12) of the Commodity Exchange Act ("Act") and Commission Regulation 1.41(b), submitted to the Commission a proposal to establish a bilateral cross-margining agreement with ICC and a trilateral cross-margining agreement with ICC and OCC.

In sum, the bilateral program between CME and ICC would involve the margining of ICC-cleared stock index futures and commodity options on stock-index futures and CME-cleared stock-index futures and commodity options on stock-index futures carried in proprietary and non-proprietary cross-margining accounts. The trilateral program would involve the margining of such ICC-cleared and CME-cleared contracts along with OCC-cleared stock-index options carried in proprietary and non-proprietary cross-margining accounts.

According to CME and ICC, the purpose of the proposal is to expand the universe of available hedge positions and thereby to encourage wider participation in cross-margining.

II. Request for Comments

Acting pursuant to the authority delegated by Commission Regulation 140.96, the Director of the Division of Trading and Markets, with the concurrence of the General Counsel, has determined, on behalf of the Commission, that publication of the proposals is in the public interest and will assist the Commission in considering the views of interested persons. Accordingly, the Division, on behalf of the Commission, is publishing the proposals for public comment. The Commission requests comments on any aspects of the proposals that members of the public believe may raise issues under the Act or Commission regulations.

Copies of the CME and ICC submissions are available for inspection at the Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581. Copies may also be obtained through the Office of the Secretariat at the above address or by telephoning (202) 254–6314.

Any person interested in submitting written data, views or comments on the proposals should send such comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581 by the specified date.

Issued in Washington, DC on January 11, 1993.

Alan Seifert,

Deputy Director, Division of Trading and Markets.

[FR Doc. 93–883 Filed 1–13–93; 8:45 am]

BILLING CODE 6351–01–M

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Resolution of Potential Conflict of Interest

The Defense Nuclear Facilities Safety Board (Board) has identified and resolved a potential conflict of interest situation in connection with the employment of Dr. Sol Pearlstein (Dr. Pearlstein) as Physicist in a full-time, two-year appointment. During his employment by the Board, Dr. Pearlstein will remain on a unpaid leave of absence from Brookhaven National Laboratories (BNL), where he is employed in a permanent position by Associated Universities, Inc. (AUI), the operator of BNL. Because BNL is owned by the Department of Energy (DOE), Dr. Pearlstein's continued association with BNL while he is employed by the Board might create an appearance of a conflict of interest or potential conflict of interest with respect to his indirect association with DOE. (Dr. Pearlstein has recused himself from particular matters before the Board involving AUI or BNL.)

Under the Board's Organizational and Consultant Conflict of Interest Regulations, 10 CFR part 1706 (OCI Regulations), the Board may engage National Laboratories personnel who have the expertise needed by the Board in the performance of its oversight responsibilities, where there is no conflict of interest or where the Board determines that such engagement is in the best interest of the Government and waives the conflict. The OCI Regulations require that in all cases involving National Laboratory personnel, notice of the circumstances of the contract, stating the rationale for use of the personnel, must be published in the **Federal Register**. Under the OCI Regulations, an organizational or consultant conflict of interest means, in relevant part, that because of other past, present or future planned activities or relationships, a contractor or consultant is unable, or potentially unable, to render impartial assistance or advice to the Board, or the objectivity of such contractor or consultant in performing contract work for the Board is or might be otherwise impaired. Because Dr. Pearlstein will remain an employee of BNL while employed by the Board, the Board has determined to comply with the OCI Regulations, even through Dr. Pearlstein is a Board employee and not a Board contractor or consultant.

Based on a comprehensive review of Dr. Pearlstein's situation, including the terms of his leave of absence from AUI/BNL, the work he performed at BNL, and the type of work he is likely to perform for the Board, the Board has determined that a conflict of interest between Dr. Pearlstein's employment at a DOE-owned national laboratory and his work for the Board is not likely to arise for the following reasons.

First, the work that Dr. Pearlstein was performing at BNL or is likely to do after his work for the Board is not directly related to the Board's work on defense nuclear facilities under the Board's jurisdiction, with one exception described below. The Board understands that most of the funding at BNL is provided by non-defense sources, including the Nuclear Regulatory Commission and non-defense programs in DOE, and that the DOE Office of Energy Research, which is not engaged in defense-related work, is primarily responsible for oversight at BNL. Because BNL does little or no work for the defense nuclear facilities, it is unlikely that the Board will be examining any of the programs at BNL. Dr. Pearlstein himself has not worked on projects administered by DOE-Defense Programs, nor has he worked on matters involving the defense nuclear facilities. In general, the kind of work that Dr. Pearlstein conducted at BNL consisted of preparing reference data to be used throughout the nuclear community, rather than work specifically oriented to benefit DOE only. Dr. Pearlstein's position at BNL prior to joining the Board was as Director of the National Nuclear Data Center, where he was responsible for the indexing, compilation, evaluation, distribution and international exchange of nuclear data, data benchmark calculations, management of the main-frame computer systems, and coordination of inter-laboratory data evaluation working groups. The only program Dr. Pearlstein was involved at BNL that might have fallen under the Board's jurisdiction was the Accelerator Production of Tritium project, funded by the Office of Alternative Technologies in the DOE Office of New Production Reactors, which Dr. Pearlstein worked on during the six months prior to his joining the Board's technical staff. He work on that project involved performing comparisons between theory and experiment to validate nuclear data and developing

the Annual Operating Plan. To date, the Board has not examined DOE's new production reactors programs, many of which have been terminated as a result of the Secretary of Energy's decision not to proceed with a new production reactor. If the Board does undertake oversight activities with respect to the Accelerator Production of Tritium project in the future, the Board and the Technical Director will not permit Dr. Pearlstein to participate in that work as a Board employee and will screen Dr. Pearlstein's work for the Board to ensure that he is not reviewing his own previous work at BNL or the work that BNL is doing on the project. In short, Dr. Pearlstein will not be called upon to review his own previous work while he is at the Board, and the Board does not think that a conflict of interest with Dr. Pearlstein's work for the Board will otherwise arise out of the type of work he performed at BNL.

The Board has also considered the issue of whether Dr. Pearlstein's ability to take an impartial, objective view of the activities of DOE and its contractors at the defense nuclear facilities under the Board's jurisdiction would be impaired as a result of his continuing association with AUI/BNL and thus indirectly with DOE. In evaluating this issue, the Board has considered the terms of Dr. Pearlstein's leave of absence, as well as the role DOE plays in funding Dr. Pearlstein's work at AUI/BNL. (The following evaluation of the potential for retaliatory action by AUI/BNL, DOE or others in determining whether Dr. Pearlstein's ability to give impartial advice to the Board might be impaired by his continuing relationship with AUI/BNL is part of the Board's effort to consider all possible sources of conflict of interest, but is not intended to suggest that AUI/BNL, DOE, the Secretary of Energy or any particular DOE or AUI/BNL employee would in fact act inappropriately with respect to any Board employee.) According to information received from officials at BNL, Dr. Pearlstein is effectively, if not formally, guaranteed a job at BNL, though not necessarily the same position he held previously, on return from his leave of absence, unless there is such a serious funding problem at BNL that there is no appropriate position for him in any area of BNL. Even if funding for the programs Dr. Pearlstein had worked in were cut or eliminated, the Board has been informed by BNL personnel that BNL would try to find another appropriate position for Dr. Pearlstein, such as in the area that does work for the Nuclear Regulatory Commission. The Board was further informed that it is very unusual for BNL to terminate an employee with a continuing appointment, such as Dr. Pearlstein holds, for reasons of financial exigency. Thus, in the Board's view, Dr. Pearlstein should not fear that his actions as a Board employee with respect to defense nuclear facilities would cause BNL to refuse to allow him to return. Moreover, Dr. Pearlstein apparently is already eligible for retirement from BNL and is fully vested in the defined contribution pension plan, so that his entitlement to those benefits would not be jeopardized even if he were not to return to BNL.

The Board also thinks it very unlikely that DOE might try to retaliate against Dr. Pearlstein for any criticism of DOE by not renewing the funding for the civilian programs at BNL that Dr. Pearlstein has worked on or is likely to work on, or by refusing to approve his salary at BNL after his leave of absence at the level existing prior to his Board service. The program areas of DOE that have funded most of Dr. Pearlstein work at BNL (other than the Accelerator Production of Tritium project, which he could not be involved in at the Board) should not be interested in positions he takes at the Board with respect to defense nuclear facilities. Moreover, to retaliate against Dr. Pearlstein by reducing funding for programs he might be involved in after returning to BNL, DOE would have to justify cutting funding for information collection programs it generated and has supported for years, at a facility it owns. Lastly, the credibility of Dr. Pearlstein's work at the National Nuclear Data Center at BNL, where he directed a group of scientists in evaluating and validating data obtained from other laboratories and other research and maintaining an information center with valid data, depends to a great extent on his reputation for having both knowledge of science and professional integrity. For DOE to take actions that might impugn Dr. Pearlstein's professional integrity would undermine the credibility of work at BNL that DOE itself sponsors.

At the Board, Dr. Pearlstein will also be evaluating scientific data contained in complex safety evaluations prepared by DOE and its contractors. He probably will not become heavily involved in evaluating and critiquing operations at the defense nuclear facilities, because he does not have expertise in those areas. His interactions with DOE will concern scientific and mathematical matters. Although the Board expects Dr. Pearlstein's work to be useful in advancing the Board's mission, the Board does not believe that it is the type of work that should pit Dr. Pearlstein against DOE or cause personal or institutional animosity.

Consequently, the Board does not think it warranted to question the ability of a senior scientist of Dr. Pearlstein's stature and expertise, whose ability to return to BNL is assured in all but the most dire financial circumstances, to give objective advice to the Board or to keep his professional judgment from being colored by fears of retaliation that is highly unlikely. Moreover, Dr. Pearlstein will be working directly for a Board member or under the supervision of the Technical Director and will not be taking any final actions himself, so that any question of impartiality arising in Dr. Pearlstein's case would be mitigated. It is ultimately the Board members, rather than the members of the Board's technical staff, who make significant decisions and take Federal action on behalf of the Board.

Even in a case where there is an actual or potential conflict of interest, under the Board's OCI Regulations, the Chairman has the authority to waive that conflict. The Chairman has determined in the case of Dr. Pearlstein that even if a conflict of interest or question of lack of impartiality could be said to exist, it is in the best interests of the Government to waive that conflict and permit Dr. Pearlstein's employment by the Board. There is no one else on the Board's technical staff who has a broad and extensive background in evaluating nuclear physics data, particularly in the area of nuclear applications. Dr. Pearlstein has extensive experience in looking at physics data and evaluating its integrity. Although the Board has engaged in extensive recruiting efforts, no one else with Dr. Pearlstein's kind of experience has joined the technical staff. The Board and the Technical Director for the Board are of the opinion that Dr. Pearlstein's expertise and experience are important in facilitating the accomplishment of the Board's mission, particularly in the area of reactor facilities. In the opinion of one of the Board members who has worked with Dr. Pearlstein before, Dr. Pearlstein, because of the breadth of this experience in evaluating data developed in research by other scientists, has an ability to synthesize scientific data from many sources to find solutions to complex and novel problems. The Board believes that it needs some senior technical staff members with that depth of experience and ability.

Consequently, even if there is a remote theoretical possibility that Dr. Pearlstein's continued association with BNL might create a conflict of interest, a waiver of the conflict is justified as

being in the best interests of the Government, and has been approved by the Chairman of the Board.

Dated: January 7, 1993.

Julie Kitzes Herr,

Associate General Counsel.

[FR Doc. 93–802 Filed 1–13–93; 8:45 am]

BILLING CODE 6820–KD–M

DEPARTMENT OF DEFENSE

Public Information Collection Requirement Submitted to OMB for Review

AGENCY: Department of Defense.

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Title, Applicable Form, and Applicable OMB Control Number: Tender of Service and Letter of Intent for Personal Property Household Goods and Unaccompanied Baggage Shipments; OMB Control Number 0702–0022.

Type of Request: Reinstatement.

Average Burden Hours/Minutes Per Response: 1 hr., 22 minutes.

Responses Per Respondent: 18.

Number of Respondents: 18,072.

Annual Burden Hours: 22,048.

Annual Responses: 18,072.

Needs and Uses: Since household goods move at government expense, data is needed to choose the best service at least cost. The information provided amounts to a bid for contract to transport household goods and unaccompanied baggage. The service for least cost carrier receives the contract.

Affected Public: Business of other for-profit.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Mr. Edward C. Springer.

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, room 3235, New Executive Office Building, Washington, DC 20503.

DOD Clearance Officer: Mr. William P. Pearce.

Written requests for copies of the information collecion proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, suite 1204, Arlington, Virginia 22202–4302.

Dated: January 11, 1993.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–854 Filed 1–13–93; 8:45 am]

BILLING CODE 3810–01–M

Office of the Secretary

Strategic Environmental Research and Development Program, Scientific Advisory Board

ACTION: Notice.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following Committee meeting:

DATE OF MEETING: Wednesday, January 27, 1993, and Thursday, January 28, 1993, 8 a.m. to approximately 5 p.m.

PLACE: Main Auditorium, National Guard Building, One Massachusetts Avenue, NW., Washington, DC.

MATTERS TO BE CONSIDERED: The Scientific Advisory Board will hold management sessions, will receive an overview of the six SERDP Technology thrust areas, and will review Phase III proposals that are equal to or in excess of $1M. Representatives from DoD, DOE, and EPA will provide briefings on the overviews and individual projects.

This meeting is open to the public. Any interested person may attend, appear before, or file statements with the Scientific Advisory Board at the time and in the manner permitted by the Board.

FOR FURTHER INFORMATION CONTACT: Dr. John Ingram, CERD–M, room 6213, 20 Massachusetts Avenue, NW., Washington, DC 20314–1000, 202–272–1843.

Dated: January 11, 1993.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–853 Filed 1–13–93; 8:45 am]

BILLING CODE 3810–01–M

Department of the Air Force

USAF Scientific Advisory Board; Meeting

The Boost Phase Panel of the USAF Scientific Advisory Board's Committee on Options for Theater Air Defense will meet on 11–12 February 1993, at Kirtland AFB, Albuquerque, NM from 8 a.m. to 5 p.m.

The purpose of these meetings will be to receive briefings and gather information on issues related to theater air defense.

The meeting will be closed to the public in accordance with section 552b(c) of title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the Scientific Advisory Board Secretariat at (703) 697–4811.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 93–819 Filed 1–13–93; 8:45 am]

BILLING CODE 3810–01–M

USAF Scientific Advisory Board Meeting

The Cruise Missile Panel of the USAF Scientific Advisory Board's Committee on Options for Theater Air Defense will meet on 19 February 1993, at the ANSER Corporation, 1215 Jefferson Davis Highway, Arlington, VA from 8 a.m. to 5 p.m.

The purpose of this meeting will be to receive briefings and gather information on issues related to theater air defense.

The meeting will be closed to the public in accordance with section 552b(c) of title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the Scientific Advisory Board Secretariat at (703) 697–4811.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 93–820 Filed 1–13–93; 8:45 am]

BILLING CODE 3810–01–M

USAF Scientific Advisory Board; Meeting

The Pre-Launch Panel of the USAF Scientific Advisory Board's Committee on Options for Theater Air Defense will meet on 11 February 1993, at The ANSER Corporation, 1215 Jefferson Davis Highway, Arlington, VA from 8 a.m. to 5 p.m.

The purpose of this meeting will be to gather information on issues related to theater air defense capabilities, and requirements for theater air defense through the year 2020.

The meeting will be closed to the public in accordance with section 552b(c) of title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the Scientific Advisory Board Secretariat at (703) 697–4811.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 93–821 Filed 1–13–93; 8:45 am]

BILLING CODE 3910–01–M

USAF Scientific Advisory Board; Meeting

The USAF Scientific Advisory Board's Committee on IR Countermeasures and Self Defense Against IR Missiles will meet on 16 February 1993, at The ANSER Corporation, Crystal Gateway 3, 1215 Jefferson Davis Highway, Arlington, VA from 8 a.m. to 5 p.m.

The purpose of this meeting is to receive briefings, gather information for the study.

The meeting will be closed to the public in accordance with section 552b(c) of title 5, United States Code, specifically subparagraphs (1) and (4) thereof.

For further information, contact the Scientific Advisory Board Secretariat at (703) 697–4811.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 93–822 Filed 1–13–93; 8:45 am]

BILLING CODE 3910–01–M

Department of the Army

Environmental Impact Statement (EIS) for the Reuse and Disposal of Hamilton Army Airfield, CA

AGENCY: Department of Defense, United States Army.

ACTION: Notice of intent.

SUMMARY: This Environmental Impact Statement (EIS) will evaluate alternative methods of implementing the Commission's decision to close Hamilton Army Airfield (HAAF), including alternative reuses of the disposed property. Development of the potential alternative reuses of the disposed property will be made in conjunction with the local communities and Department of Defense, Office of Economic Adjustment. As required by the National Environmental Policy Act of 1969, the Army will also analyze the "no action" alternative as a baseline for gauging the impacts of the disposal and reuse. Public Law 100–526 (BRAC I), the Defense Base Closure and Realignment Act of 1988, mandates the closure of Hamilton Army Airfield, California. The Army is required by law to analyze the environmental and socioeconomic impacts of the disposal and reuse of real property at HAAF. An EIS will be prepared to analyze and document the impacts of disposal and reuse.

Scoping: The public will be invited to participate in the scoping process, review of the draft EIS, and a public hearing. The location and time of the scoping meeting, to be scheduled during January 1993, will be announced in the local news media. Release of the draft EIS for public comment and the public meeting will also be announced in the local news media as these dates are established.

ADDRESSES: Written comments may be forwarded to: Mr. Bob Koenigs, U.S. Army Corps of Engineers, Sacramento District, CESPK–PD–R, 1325 J Street, Sacramento, California 95814–2922.

FOR FURTHER INFORMATION CONTACT: Questions regarding this action may be directed to Mr. Bob Koenigs, (916) 557–6712.

Lewis D. Walker,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health) OASA (I,L&E).

[FR Doc. 93–806 Filed 1–13–93; 8:45 am]

BILLING CODE 3710–08–M

DEPARTMENT OF ENERGY

Environment, Safety and Health Advisory Committee Reestablishment

Pursuant to section 9(a)(2) of the Federal Advisory Committee Act and in accordance with title 41 of the Code of Federal Regulations, section 101–6.1015, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Environment, Safety and Health Advisory Committee (ESHAC) has been reestablished for a 2-year period. The Committee would provide advice to the Assistant Secretary for Environment, Safety and Health.

The Committee will continue to operate in accordance with the provisions of the Federal Advisory Committee Act, the Department of Energy Organization Act (Pub. L. 95–91), and rules and regulations issued in implementation of those Acts.

Further information regarding this Committee may be obtained from Rachel Murphy at (202) 586–3279.

Issued in Washington, DC on January 8, 1993.

Howard H. Raiken,

Advisory Committee, Management Officer.

[FR Doc. 93–938 Filed 1–13–93; 8:45 am]

BILLING CODE 6450–01–M

Bonneville Power Administration

Proposed Transmission Rate Adjustment, Public Hearing, and Opportunities for Public Review and Comment

AGENCY: Bonneville Power Administration (BPA), DOE.

ACTION: Notice and Opportunities for Review and Comment. *BPA File No:* TR–93.

BPA requests that all comments and documents intended to become part of the Official Record in this process contain the file number designation TR–93.

SUMMARY: The Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act) provides that BPA must establish and periodically review and revise BPA's rates so that they are adequate to recover, in accordance with sound business principles, the costs associated with the acquisition, conservation, and transmission of electric power, and to recover the Federal investment in the Federal Columbia River Power System (FCRPS) and other costs incurred by BPA. BPA is proposing to revise its transmission rate schedules to be effective October 1, 1993, through September 30, 1995, to produce sufficient revenues for BPA to meet its statutory requirements for Fiscal Year (FY) 1994 and FY 1995.

Through its Programs in Perspective (PIP) public review process conducted during the summer of 1992, BPA and interested parties completed a thorough review of BPA's programs and program cost levels included in the budgets for FY 1994 and FY 1995. With the exception of program levels delineated in this Notice, the Administrator will not reexamine program level decisions in the rate case. The PIP process also focused on BPA's proposed 10-Year Financial Plan and its attendant financial policies. Consistent with BPA's pledge at the end of the 1991 rate case, implementation of the 10-Year Financial Plan will be addressed in this rate case.

Beginning in August 1992, BPA conducted a series of workshops on subjects relevant to BPA's ratemaking. The purpose of the workshops was to identify, simplify, and reduce the number of issues that might become part of the 1993 rate case and to reduce the amount of discovery normally required during the formal rate proceedings. Opportunity was provided to address 10-Year Financial Plan implementation issues and to understand risk analysis, revenue requirement, revenue forecast,

and ratesetting policy choices, data inputs, assumptions, and modeling. All parties to the 1991 rate case, and participants in prior workshops, were invited to attend the workshops. The workshops were well attended and provided opportunities for informal public comment on issues prior to the formal hearing process.

BPA is proposing a new transmission rate schedule, the Southern Intertie Annual Cost (AC–93) rate. The AC–93 rate will be available to parties the execute Pacific Northwest AC Intertie Capacity Ownership Agreements.

BPA is assessing the potential environmental effects of its initial rate proposal as required by the National Environmental Policy Act (NEPA). BPA intends to circulate its NEPA analysis for review and comment. Comments will be received outside the formal hearing process, but will be included in the record and considered by the Administrator in making his final decision establishing BPA's 1993 rates.

Opportunities will be available for interested persons to review BPA's proposal to adjust its 1993 rates, to participate in the rate hearing, and to submit written comments. During the development of the final rate proposal, BPA will evaluate all written and oral comments received in the rate proceeding. Consideration of comments and more current data may result in the final rate proposal differing from the rates proposed in this Notice.

Responsible Official: Mr. Sydney D. Berwager, Director, Division of Contracts and Rates, is the official responsible for the development of BPA's rates.

DATES: Persons wishing to become a formal "party" to the proceedings must notify BPA in writing of their intention to do so in accordance with requirements states in this Notice. Petitions to intervene must be received by January 25, 1993, and should be addressed as follows: Hearing Officer, c/o Kathryn Silva—APR, Hearing Clerk, Bonneville Power Administration, P.O. Box 12999, Portland, Oregon 97212. In addition, a copy of the petition must be served concurrently on BPA's Office of General Counsel—APR, c/o Kurt R. Casad, P.O. Box 3621, Portland, Oregon 97208. Persons who have been denied party status in any past BPA rate proceeding shall continue to be denied party status unless they establish a significant change of circumstances.

A prehearing conference will be held before the Hearing Officer at 9 a.m. on January 28, 1993, in the BPA Rates Hearing Room located at 2032 Lloyd Center, Portland, Oregon. Registration for the prehearing conference will begin at 8:30 a.m. BPA will profile studies and testimony at the prehearing conference. The Hearing Officer will act on all intervention petitions and oppositions to intervention petitions, rule on any motions, establish additional procedures, establish a service list, establish a procedural schedule, and consolidate parties with similar interests for purposes of filing jointly sponsored testimony and briefs and for expediting any necessary cross-examination. A notice of the dates and times of any hearings will be mailed to all parties of record. Objections to orders made by the Hearing officer at the prehearing conference must be made in person or through a representative at the prehearing conference.

BPA will be conducting public field hearings. The following are tentative dates and locations:

February 10, 1993
Federal Bldg. Auditorium, 825 Jadwin Ave., Richland, WA 99352
February 11, 1993
Shilo Inn, 780 Lindsey Blvd., Idaho Falls, ID 83402
February 16, 1993
Best Western Landmark Inn, 4300 200th St. SW., Lynnwood, WA 98036
February 17, 1993
Red Lion, 205 Coburg Rd., Eugene, OR 97401
February 18, 1993
Ridpath Hotel, West 515 Sprague Ave., Terrace Room A&B, Spokane, WA 99204

When BPA holds public field hearings, written transcripts are made and included in the official record. Dates of these hearings also will be announced through mailings and public advertising.

The following proposed schedule is provided for informational purposes. A final schedule will be established by the Hearing Officer at the prehearing conference.

January 25, 1993
Deadline for interventions to be filed with Hearing Clerk at above address.
January 28, 1993
Initial studies and testimony available at BPA's Rates Hearing Room, 2032 Lloyd Center, Portland, Oregon and BPA's Public Information Center, 905 NE. 11th, 1st Floor, Portland, Oregon.
January 28, 1993
Prehearing conference to set schedule and act on petitions to intervene.
March 2, 1993
Parties file direct cases.
March 15, 1993
Close of comments by participants.
April 5, 1993
Rebuttal testimony filed.
April 12–16, 1993
Settlement discussions.
April 26–May 12, 1993
Cross-examination.
June 25, 1993
Draft Record of Decision published.
August 2, 1991
Final Record of Decision published.

ADDRESSES: Written comments by participants must be received by March 15, 1993, to be considered in the Draft Record of Decision (ROD). Written comments should be submitted to the Public Involvement Manager—ALP, Bonneville Power Administration, P.O. Box 12999, Portland, Oregon 97212.

FOR FURTHER INFORMATION CONTACT: Ms. Shirley Price, Public Involvement Office, at the address listed above, 503–230–3478 or call toll-free 1–800–622–4519. Information may also be obtained from:

Mr. George Bell, Lower Columbia Area Manager, suite 243, 1500 Plaza Building, 1500 NE. Irving Street, Portland, Oregon 97232, 503–230–4552.

Mr. Robert N. Laffel, Eugene District Manager, room 206, 211 East Seventh Avenue, Eugene, Oregon 97401, 503–465–6952.

Mr. Wayne R. Lee, Upper Columbia Area Manager, room 561, 920 West Riverside Avenue, Spokane, Washington 99201, 509–353–2518.

Mr. George E. Eskridge, Montana District Manager, 800 Kensington, Missoula, Montana 59801, 406–329–3060.

Ms. Carol Fleischman, Spokane District Manager, room 112, U.S. Courthouse, 920 West Riverside, Spokane, Washington 99201, 509–353–3279.

Mr. Ronald K. Rodewald, Wenatchee District Manager, room 307, 301 Yakima Street, Wenatchee, Washington 98807–0741, 509–662–4377, extension 379.

Mr. Terence G. Esvelt, Puget Sound Area Manager, P.O. Box C19030, suite 400, 201 Queen Anne Avenue North, Seattle, Washington 98109, 206–553–4130.

Mr. Thomas V. Wagenhoffer, Snake River Area Manager, 101 West Poplar, Walla Walla, Washington 99362, 509–522–6226.

Ms. C. Clark Leone, Idaho Falls District Manager, 1527 Hollipark Drive, Idaho Falls, Idaho 83401, 208–523–2706.

Mr. James Normandeau, Boise District Manager, room 450, 304 N. 8th Street, Boise, Idaho 83702, 208–334–9137.

SUPPLEMENTARY INFORMATION:

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A. Transmission Rate Schedules
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I. Introduction

On December 18, 1992, in order to satisfy contractual provisions between BPA and its customers, BPA published in the **Federal Register** a notice of "Intent to Revise Transmission Rates to Become Effective October 1, 1993," 57 FR 60179. Since then, BPA has continued to study the adequacy of its current rates and has concluded that current rates must be adjusted for the FY 1994 and FY 1995 rate period.

In order to assess its current rates, BPA first determined the amount of revenues required to meet its financial obligations in FY 1994 and FY 1995. BPA has determined that the revenues BPA would expect to collect from projected sales under its current rates will not adequately recover these revenue requirements. Therefore, BPA proposes to establish revised 1993 transmission rates. BPA files its rates with the Federal Energy Regulatory Commission (FERC) for confirmation and approval.

The proposed transmission rates were prepared in accordance with BPA's statutory authority to develop rates, including the Bonneville Project Act of 1937, as amended, 16 U.S.C. 832 (1982); the Flood Control Act of 1944, 16 U.S.C. 825s (1982); the Federal Columbia River Transmission System Act (Transmission System Act), 16 U.S.C. 838 (1982); the Pacific Northwest Electric Power Planning and Conservation Act, 16 U.S.C. 839 (1982); and the Energy Policy Act of 1992, Public Law No. 102–486, 106 Stat. 2776 (1992).

The rate schedules contained in this publication were established in accordance with the Northwest Power Act, which was signed into law on December 5, 1980. The proposed rate schedules reflect many requirements contained principally in the Northwest Power Act's rate directives (section 7) and the conditions related to classes of customers and services contained in the Northwest Power Act's power sales directives (section 5).

BPA proposes that its transmission rate schedules and the General Transmission Rate Schedule Provisions (GTRSPs) associated with those schedules become effective upon interim approval or upon final confirmation and approval by FERC. BPA will request FERC approval effective October 1, 1993. Section I.A. of the GTRSPs specifies the proposed effective period for each rate.

The 1993 transmission rate schedules,and the GTRSPs associated with those rate schedules, supersede BPA's 1991 rate schedules (which became effective October 1, 1991) to the extent stated in the Availability section of each 1993 rate schedule. BPA will request extension of the TGT–1, UFT–83, and FPT–91.3 rates through September 30, 1995. BPA also proposes to extend its MT–91 rate schedule. The levels in this schedule were approved by FERC in a separate process.

Many transmission agreements were negotiated prior to the Transmission System Act and reflect conditions and policies prevalent at the time of negotiation. Provisions that differ between agreements include the types of facilities available, type of service, frequency of rate adjustments, determination of losses, and calculation of billing determinants. Some agreements, for example, specify that transmission rates may be changed annually, while other agreements limit rate adjustments to once every 3 years.

Applicable legislation requires transmission system costs to be equitably allocated between Federal and non-Federal power utilizing the system. In cases where BPA is required by contractual provisions to use a specific rate design method, such methods are used in this rate proposal.

In developing the proposed transmission rates, BPA considered many factors, including revenue requirements, ease of administration, revenue stability, rate continuity, ease of comprehension, and BPA's statutory obligations. The studies that have been prepared to support the proposed transmission rates will be available for examination on January 28, 1993, at BPA's Public Information Center, BPA Headquarters Building, 1st Floor, 905 NE. 11th, Portland, Oregon. The studies will be mailed to all parties to BPA's 1991 rate case and will be available at the prehearing conference. The studies are:

1. Loads and Resources Study and Documentation
2. Revenue Requirement Study and Documentation
3. Segmentation Study
4. Wholesale Power Rate Development Study and Documentation
5. Section 7(b)(2) Rate Test Study and Documentation
6. Transmission Rate Design Study

To request any of the studies by telephone, call BPA's document request line: (503) 230–3478 or call toll-free 1–800–622–4520. Please request the study by its above-listed title. Also state whether you require the accompanying documentation (this can be quite lengthy); otherwise the study alone will be provided. (For example, ask for the "Revenue Requirement Study and Documentation.")

II. Procedures Governing Rate Adjustments and Public Participation

Section 7(i) of the Northwest Power Act, 16 U.S.C. 839e(i), requires that BPA's rates be established according to certain procedures. These procedures include, among other things, issuance of a **Federal Register** notice announcing the proposed rates; one or more hearings; the opportunity to submit written views, supporting information, questions, and arguments; and a decision by the Administrator based on the record. This proceeding will be governed by BPA's rule for general rate proceedings, § 1010.9 of BPA's "Procedures Governing Bonneville Power Administration Rate Hearings," 51 FR 7611 (March 5, 1986). These procedures implement the statutory section 7(i) requirements. Section 1010.7 of the procedures prohibits ex parte communications. The proceeding for BPA's proposal to adjust transmission rates will be combined with the proceedings for BPA's proposal to adjust wholesale power rates.

BPA distinguishes between "participants in" and "parties to" the hearings. Apart from the formal hearing process, BPA will receive comments, views, opinions, and information from "participants," who are defined in the procedures as any person who may express views, but who does not successfully petition to intervene as a party. Participants' written comments will be made part of the official record of the case and considered by the Administrator. The participant category gives the public the opportunity to participate and have its views considered without assuming the obligations incumbent upon "parties." Participants are not entitled to participate in the prehearing conference, cross-examine parties' witnesses, seek discovery, or serve or be served with documents, and are not subject to the same procedural requirements as parties.

Written comments by participants will be included in the record if they are received by March 15, 1993. This date

follows the submission of BPA's and all other parties' direct cases. Written views, supporting information, questions, and arguments should be submitted to BPA's Public Involvement Office.

The second category of interest is that of a "party" as defined in §§ 1010.2 and 1010.4 of the "Procedures Governing Bonneville Power Administration Rate Hearings," 51 FR 7611 (March 5, 1986). Parties may participate in any aspect of the hearing process.

Persons wishing to become a formal "party" to BPA's rate proceeding must notify BPA in writing of their request. Petitions to intervene shall state the name and address of the person and the person's interests in the outcome of the hearing. Petitioners may designate no more than two representatives upon whom service of documents will be made. BPA customers and customer groups whose rates are subject to revision in the hearing will be granted intervention based on a petition filed in conformance with this section. Other petitioners must explain their interests in sufficient detail to permit the Hearings Officer to determine whether they have a relevant interest in the hearing. Intervention petitions will be available for inspection in BPA's Public Information Center, 1st Floor, 905 NE. 11th, Portland, Oregon. Any opposition to a petition to intervene must be raised at the January 28, 1993, prehearing conference. All timely applications will be ruled on by the Hearing Officer. Late interventions are strongly disfavored. Opposition to an untimely petition to intervene shall be filed and served within 2 days after service of the petition. Interventions are subject to § 1010.4 of BPA's "Procedures Governing Bonneville Power Administration Rate Hearings," 51 FR 7611 (March 5, 1986).

The record will include, among other things, the transcripts of any hearings, any written material submitted by the parties and participants, documents developed by BPA staff, BPA's environmental analysis and comments accepted on it, and other material accepted into the record by the Hearing Officer. The Hearing Officer then will review the record, will supplement it if necessary, and will certify the record to the Administrator for decision.

The Administrator will develop final proposed rates based on the entire record, including the record certified by the Hearing Officer, comments received from participants, other material and information submitted to or developed by the Administrator, and any other comments received during the rate development process. The basis for the final proposed rates will be first expressed in the Administrator's Draft ROD. Parties will have an opportunity to comment on the Draft ROD as provided in BPA's hearing procedures. The Administrator will serve copies of the Final ROD on all parties and will file the final proposed wholesale power and transmission rates together with the record with FERC for confirmation and approval.

III. Major Studies and 10-Year Financial Plan

A. Major Studies

1. Loads and Resources Study

The Loads and Resources Study presents the load and resource data necessary for developing BPA's wholesale power rates. This study incorporates results from load forecasts, resource analyses, power contracts, and BPA's Resource Program.

The load/resource balance determines BPA's obligation to serve firm loads during the test years and each corresponding 42-month critical period. It also determines the supply of surplus firm power in the region and on the Federal system in each critical period. The hydro-regulation (hydro) study incorporates system constraints such as the water budget for fish migration, the operation of thermal plants, exports and imports of power, and projected resource acquisitions. For this rate proposal, a 42-month (critical period) hydro study and a 50-year hydro study were completed. The 50-year study determines nonfirm energy availability for the region.

2. Revenue Requirement Study

The Bonneville Project Act, the Flood Control Act of 1944, the Transmission System Act, and the Northwest Power Act require BPA to design rates that are projected to collect revenues sufficient to recover the cost of acquiring, conserving, and transmitting the electric power that BPA markets, including amortization of the Federal investment in the FCRPS over a reasonable period, and to recover BPA's other costs and expenses. The Revenue Requirement Study determines whether current rates will produce enough revenues to recover all BPA costs and expenses, including BPA's repayment obligations to the U.S. Treasury. Revenue requirements are the major factor in determining the overall level of BPA's proposed power and transmission rates.

The Transmission System Act and the Northwest Power Act require that transmission rates be based on an equitable allocation of the costs of the Federal transmission system between Federal and non-Federal power using the system. In compliance with a FERC order dated January 27, 1984, 26 FERC ¶ 61,096, the Revenue Requirement Study incorporates the results of separate repayment studies for the generation and transmission components of the FCRPS. The repayment studies for generation and transmission demonstrate the adequacy of the projected revenues to recover all of the Federal investment in the FCRPS over the allowable repayment period. The adequacy of projected revenues to recover test period revenue requirements and to meet repayment period recovery of the Federal investment is tested and demonstrated separately for the generation and transmission functions.

The Revenue Requirement Study for the 1993 initial rate proposal is based on revenues and cost estimates for FY 1994 and FY 1995. BPA's Revenue Requirement Study reflects actual amortization and interest payments paid through September 30, 1992. In addition, it reflects all FCRPS obligations incurred pursuant to the Northwest Power Act, including residential exchange costs.

3. Segmentation Study

BPA operates and maintains the Federal Columbia River Transmission System (FCRTS) to provide transmission services throughout the region. Because most services do not require the use of the entire system, the FCRTS is divided into nine segments, each providing a distinct type of service. The nine segments are: integrated network; Pacific Northwest-Pacific Southwest (Southern) Intertie; Northern Intertie, Eastern Intertie, generation integration, fringe area; and delivery segments for public agency, direct service industrial (DSI), and investor-owned utility customers.

The Segmentation Study categorizes the facilities of the FCRTS according to the types of services they provide. This provides the basis for segmenting the projected transmission revenue requirements used in BPA's rate proposals. The results of the study include the historic investment and the average of the last 3 years' operations and maintenance expenses. In addition, the facilities of the integrated network are similarly divided among distinct services. This division of the FCRTS into segments provides for the equitable allocation of transmission costs between Federal and non-Federal power using the system based on the usage of the segments.

4. Wholesale Power Rate Development Study (WPRDS)

The WPRDS consists of two sections. The first section is a cost of service analysis (COSA) and the second section shows the steps in the rate design process. The COSA apportions BPA's test period revenue requirement to customer classes based on the use of specific types of service by each customer class and in accord with the rate directives of the Northwest Power Act. BPA's revenue requirement is functionalized to transmission and generation in the Revenue Requirement Study. Transmission costs are identified with segments of the transmission system in BPA's Segmentation Study. The results of these studies are used in the COSA to determine the costs of providing generation and transmission services to BPA's customers.

The COSA further identifies costs of specific types of service by classifying generation and transmission costs to the energy and capacity components of electric power, and seasonally differentiating energy costs to winter and summer periods. The final major step in the COSA is to allocate the functionalized, segmented, classified, and seasonally differentiated costs to customer classes.

The rate design steps use the allocated costs developed in the COSA and modifies them: (1) To reflect BPA's rate design objectives; (2) to conform with contractual requirements; (3) to reflect the results of other BPA studies and commitments made in other public involvement processes under section 7(i) of the Northwest Power Act; and (4) to conform with requirements of applicable legislation. BPA's rate design objectives include recovery of the revenue requirement, rate and revenue stability, practicality, fairness, and efficiency.

Rate design adjustments to the allocated costs include an excess revenue adjustment. In the initial cost allocation, BPA allocates its entire test period revenue requirement to firm power loads on the basis of resources available under critical water conditions. However, rates are set assuming that average water conditions occur and BPA will make nonfirm energy (NF) sales. Forecasted NF revenues are credited against generation and transmission costs allocated to firm loads. Similarly, revenues from nonfirm wheeling under the Energy Transmission (ET) rate schedule are credited to firm transmission loads.

Various other rate design adjustments are performed. All of the adjustments are functionalized, classified, segmented, and seasonalized where appropriate. After all adjustments are made, the final power rates are calculated.

5. Section 7(b)(2) Rate Test Study

Section 7(b)(2) of the Northwest Power Act directs BPA to assure that the wholesale power rates effective after July 1, 1985, to be charged its public body, cooperative, and Federal agency customers (the 7(b)(2) customers) for their general requirements for the rate test period plus the ensuing 4 years are no higher than the costs of power to those customers for the same time period if specified assumptions are made. The effect of the rate test is to protect the 7(b)(2) customers' wholesale firm power rates from certain costs resulting from provisions of the Northwest Power Act. The rate test can result in a reallocation of costs from the 7(b)(2) customers to other rate classes. The Section 7(b)(2) Rate Test Study describes the application and results of the section 7(b)(2) rate test implementation methodology.

6. Transmission Rate Design Study

a. *Transmission System Revenue Requirement Adjustment*—Prior to the design of transmission rates, the WPRDS-derived network wheeling revenue requirements must be adjusted to account for revenue in excess of allocated costs. The Energy Transmission (ET–93) rate is calculated first. Revenues received from the ET–93 rate and a portion of the revenue from the Nonfirm Energy (NF–93) rate are credited against the allocated transmission costs of firm power and wheeling services derived in the WPRDS. The adjustment network wheeling revenue requirement is the basis for setting the Formula Power Transmission (FPT–93) and Integration of Resources (IR–93) rates. The FPT and IR rates are based on the same costs, but the FPT rate is structured based on demand and distance factors while the IR rate is structured as a postage-stamp rate with a demand and energy charge.

b. *Proposed Transmission Rate Schedules*—(1) Formula Power Transmission (FPT)—The FPT–93 rate schedule is available for the firm wheeling of power. The form of this rate includes a distance or mileage component for transmission lines and various transformation and terminal charges. The FPT rate form is designed to reflect a wheeling formula that is prescribed by contract provisions.

In designing the FPT–93 rate, the first step is to quantify costs for the specific types of transmission facilities treated in the rate components. Estimates of the use of these facilities are determined from a simulation of the power flow of the projected peak load during the test period. The power flow study assumes certain resource and load conditions that BPA believes are reasonable for normal hydro conditions. Unit cost for the FPT rate components are derived by dividing facility cost by power flow facility use.

(2) Integration of Resources (IR)—The IR–93 rate is a flexible transmission service designed to reflect BPA's postage-stamp (independent of distance) pricing policy. The IR service does not recognize specific contract paths, but rather provides access to all FCRTS facilities contained in the definitions of Main Grid and Secondary System.

The IR–93 rate is calculated by diving the adjusted revenue requirement for the class into two equal parts to reflect a 50–50 classification of costs to capacity and energy. The quotient of these costs and the appropriate billing determinant (contract demand for capacity-related costs, total energy usage for energy) yields the rates.

As in the IR–91 rate, a short-distance discount formula is retained in the proposed IR–93 rate. Utilities have a choice of either remaining on the FPT rate schedule or accepting the IR–93 rate schedule as the only rate to apply to all of their firm wheeling needs over Main Grid and Secondary System facilities of the FCRTS, except as otherwise agreed by BPA. Utilities currently purchasing FPT may choose the rate schedule that yields the lower total charge for transmission service.

(3) Energy Transmission (ET), Intertie Transmission (IN, IE, IS), and Market Transmission (MT)—For this rate filing, rate schedules are again offered on the Northern and Southern Interties that apply to all wheeled power on these segments, whatever the characteristics of the power. The IE rate schedule applies only to nonfirm energy wheeled on the Eastern Intertie. The ET rate is limited to intra-regional FCRTS facilities excluding the Interties.

The schedule for the Energy Transmission (ET–93) class of service is not allocated costs in the WPRDS. Accordingly, it is necessary to determine the level of the rate by other means. The ET–93 rate is designed to approximate the average cost of firm wheeling on the network. It is calculated by dividing the costs allocated to FPT/IR (minus appropriate NF revenues) by all wheeling under firm wheeling contracts.

The proposed IS–93 rate consists of two parts: a nonfirm service energy-only rate, and a firm rate with separate demand and energy components.

The Northern Intertie (IN–93) rate schedule is calculated by dividing segment costs by projected wheeling energy.

The Eastern Intertie (IE–93) rate approximates the average cost of Townsend-Garrison Transmission (TGT–1). It is calculated as the ratio of TGT–1 payments from participants owning Colstrip to the projected overall wheeling of Colstrip.

BPA is continuing its Market Transmission (MT–91) rate. This rate schedule was developed for use among Western Systems Power Pool (WSPP) participants and allows for hourly, daily, weekly, and monthly charges.

(4) Southern Intertie Annual Cost (AC)—BPA is proposing the Southern Intertie Annual Cost (AC–93) rate to be applied to potential new owners of AC Intertie capacity after commercial operation of the Third AC Intertie. This new rate schedule provides for the payment by potential new owners of 21 percent of operations, maintenance, general plant, and replacements cost associated with the AC portion of the Southern Intertie. The AC–93 rate is proposed as a "bridge" rate. BPA expects to negotiate participation contracts and annual cost rate provisions in FY 1993 for AC Intertie capacity ownership. Any rate negotiated in this process is subject to provisions of section 7(i) of the Northwest Power Act. Costs recovered under the AC–93 rate schedule may be subject to adjustment based on the outcome of the negotiations and subsequent rate case.

B. 10-Year Financial Plan

At the end of the 1991 rate case, BPA committed to develop a 10-year Financial Plan jointly with customers and other interested parties before adopting long-term financial policies on a final basis that could affect the level of BPA's rates. During the latter part of 1991 and throughout 1992, BPA, its customers, and other interested parties in the region participated in development of the 10-Year Financial Plan. In April, BPA released a Staff Comment Draft of the 10-Year Financial Plan for public review and comment. BPA then developed the proposed 10-Year Financial Plan, taking into consideration the comments received on the earlier draft. In June, the Proposed 10-Year Financial Plan was released for review and comment in BPA's Programs in Perspective (PIP) process. A final version of the 10-Year Financial Plan will be released in January 1993. The financial policies included in the 10-year Financial Plan are reflected in the revenue requirement and rate levels for review and implementation in the 1993 rate case.

A primary component contained in the 10-Year Financial Plan is the agency's long-term policy choice to continue a 95 percent probability standard of meeting Treasury payments in full and on time in each rate period. The 10-Year Financial Plan identifies the target level of financial reserves necessary to achieve this standard, and outlines the individual risk mitigation components the BPA will rely on as part of its risk mitigation planning to achieve the target level of reserves. The 10-Year Financial Plan also identifies the planned sources of funding for FCRPS capital investments, and calls for use of debt to finance FCRPS capital investments, except that revenues may be used on a limited basis for certain nuclear project capital expenditures.

In implementing the long-term 95 percent probability standard of meeting Treasury payments in full and on time in each rate period, BPA is incorporating a phase-in approach for the FY 1994–1995 rate period will be established to achieve a 90 percent probability of meeting Treasury payments over the two-year period. Adoption of this phase-in approach helps to reduce the immediate rate pressures BPA faces while still achieving a significantly high probability that Treasury payments will be made in full and on time in each year of the FY 1994–1995 rate period.

To achieve this financial objective, BPA's Initial Proposal includes three primary tools for mitigating risk. These risk mitigation tools include: (1) an increment of annual Planned Net Revenues for risk that is explicitly included in revenue requirements; (2) adoption of an Interim Rate Adjustment (IRA); and (3) a cost deferral mechanism. The IRA and cost deferral mechanisms are designed to be used only under certain predetermined conditions wherein BPA's ending financial reserve level at the end of FY 1994 would reach a specified "trigger point."

To analyze the normal operating risk that BPA faces in a given rate period, BPA conducted risk analyses using the Short-Term Risk Evaluation and Analysis Model (STREAM). The STREAM provides for a systematic analytical framework for evaluating BPA's normal operating risks, including streamflows, aluminum and fuel prices, nuclear plant performance, economic conditions, and weather conditions. Alternative risk mitigation tools and the specific tool parameters were then tested using the Tool Kit model. The Tool Kit model enables an evaluation of the sufficiency of alternative combinations of tools to provide risk protection sufficient to meet the specified probability of meeting Treasury payments in full and on time in each year of a given rate period. The data, assumptions, and logic incorporated in the STREAM and Tool Kit model can significantly affect the target level of financial reserves and the level of Planned Net Revenues for risk needed to meet the Treasury payment standard.

In the 1993 rate case, BPA will propose methods for implementing various aspects of the financial policies reflected in the 10-Year Financial Plan. Consistent with the agreement reached in the settlement of the 1991 rate case, the financial policies reflected in the 10-Year Financial Plan will be subject to further review and implementation in the 1993 rate case. Such implementation issues may include: STREAM and Tool Kit assumptions, design, and logic; target level of reserves; specific IRA design issues; public process requirements for implementing the IRA; level of Planned Net Revenues for Risk; and the method of functionalizing Planned Net Revenues for risk and the Interest Credit between the generation and transmission functions.

C. Purpose and Scope of Hearing

BPA's proposal to revise its rates is needed in order to continue to recover all costs and expenses allocated to the power system, including amortization of the Federal investment in the FCRPS over a reasonable period of time, and to recover funds sufficient to achieve the goals of BPA's 10-Year Financial Plan. Inasmuch as cost recovery requirements alone necessitate substantial increases to BPA's rates, BPA seeks to avoid further disruption of its customers' needs for rate predictability and stability. Thus, alternative approaches to rate design to incorporate or modify price signals to achieve energy and resource efficiency are beyond BPA's need. Moreover, lack of reliable information on such alternatives, the substantial changes that are occurring and will occur in operating characteristics to BPA's system, and the ongoing development of the Endangered Species Act and Systems Operation Review all militate in favor of deferring alternative rate design considerations to the 1995 rate case.

At the conclusion of the 1991 rate case, BPA committed to develop a 10-Year Financial Plan through a process of public consultation. In addition, BPA pledged that to the extent the proposed goals of the 10-Year Financial Plan directly affected rate levels, it would

include the incremental rate impacts and associated rationale as part of a special or general 7(i) process.

Beginning in March 1991, BPA solicited input into the scope and content of its 10-Year Financial Plan from customers in interviews throughout the region. From October 1991 to April 1992, numerous technical and policy oriented workgroups held meetings to identify key financial issues and to develop, analyze, and evaluate risk mitigation and capital funding options that addressed the issues. BPA then released its Proposed 10-Year Financial Plan in April for review and comment in its Programs In Perspective (PIP) public involvement process.

The PIP process commenced in April in order to develop the 10-Year Financial Plan and determine program levels for FYs 1994 and 1995. Interested persons had the opportunity to solicit information from BPA, meet with Program managers to discuss program issues, and to submit oral and written comments to BPA in July and August 1992. In addition, the opportunity was extended to interested parties to meet and discuss the proposed 10-Year Financial Plan and program levels with BPA management, including the Administrator, in a series of meetings that occurred throughout the region in July. Numerous other public processes to determine BPA's program needs fed into PIP. BPA released its decision on the 10-Year Financial Plan and program levels on September 11,1992. The Final PIP version of the 10-Year Financial Plan that elaborates BPA's consideration of the regional discussions will be released in January 1993 for review and implementation in BPA's 1993 rate case.

On April 3, 1992, when the Administrator formally announced the scope and schedule for PIP to all customers and interested parties, he stated as follows concerning the intended effect of PIP:

> "In the end, the material discussed in PIP requires the kind of management judgment calls that we cannot fairly assign to our technical or legal staffs. That is why I place such importance on the personal participation during PIP itself by utility managers and policy makers on energy and the environment.
>
> After PIP and by September, it is our intent to make final determinations on all of our program budget levels for use in the rate case. These final program level decisions will be incorporated into the rate case revenue requirement study. If for some reason budget issues arise that cannot be resolved in PIP, we would provide other forums (aside from PIP and the rate case) in order to reach those decisions.
>
> After PIP, attention will then shift from these planning concerns to the more technical issues of the rate case and to the host of other contract and policy forums yet ahead of us. The rate case itself will focus on issues of cost allocation and recovery, and, if necessary, long-term financial goals. The proceedings will begin first with informal workshops through December and then move into the formal rate case itself at the beginning of 1993." (April 3, 1992, Administrator's letter to all customers and interested parties.)

This was reiterated in the Administrator's September 11, 1992, document closing out the 1992 PIP entitled "Setting the Financial Course for Fiscal Years 1993, 1994, 1995." The Administrator described Attachment B to the document as showing "final program levels," and stated, "These levels will not be revisited in the upcoming rate case, although BPA is willing to further discuss them as part of a comprehensive settlement of rate case issues.

Consistent with BPA's prior agreement, implementation of the 10-Year Financial Plan will be addressed in this rate case. Except for the limited exceptions hereafter noted, program and program level decisions will not be addressed in this rate case. Accordingly, pursuant to § 1010.3(f) of the "Procedures Governing Bonneville Power Administration Rate Hearings," 51 FR 7611 (March 5, 1986), the Administrator directs the Hearing Officer to exclude from the record any material attempted to be submitted or arguments attempted to be made in the hearing which seek to in any way visit the appropriateness or reasonableness of BPA's decisions on programs or program levels, as included in BPA's cost evaluation period of FY 1993 through FY 1995 and its test period revenue requirements for FY 1994 and FY 1995. Excepted from this direction on account of their variable nature, dependency on BPA's rate case models, or timing, are:

(1) Forecasts of residential exchange benefits;

(2) Forecasts of purchase power costs;

(3) Provision in BPA's revenue requirement for cash working capital or cash lag needs;

(4) Repayment matters, such as interest rate forecasts, scheduled amoritzation, depreciation, replacements, and interest expense; and

(5) Updates to forecasts by BPA which may occur in the Spring of 1993 and for which no other review forum has been provided.

IV. Transmission Rate Schedules and General Transmission Rate Schedule Provisions (GTRSPs)

A. Transmission Rate Schedules

Schedule FPT–93.1, Formula Power Transmission

Section I. Availability

This schedule supersedes schedule FPT–91.1 for all firm transmission agreements which provide that rates may be adjusted not more frequently than once a year. It is available for firm transmission of electric power and energy using the Main Grid and/or Secondary System of the FCRTS. This schedule is for full-year and partial-year service and for either continuous or intermittent service when firm availability of service is required. For facilities at voltages lower than the Secondary System, a different rate schedule may be specified. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

A. Full-Year Service

The monthly charge per kilowatt of billing demand shall be one-twelfth of the sum of the Main Grid Charge and the Secondary System Charge, as applicable and as specified in the Agreement.

1. Main Grid Charge

The Main Grid Charge per kilowatt of Transmission Demand shall be the sum of one or more of the following component factors as specified in the Agreement:

a. Main Grid Distance Factor: The amount computed by multiplying the Main Grid Distance by $0.0375 per mile;

b. Main Grid Interconnection Terminal Factor: $0.32

c. Main Grid Terminal Factor: $0.45

d. Main Grid Miscellaneous Facilities Factor: $1.90

2. Secondary System Charge

The Secondary System Charge per kilowatt of Transmission Demand shall be the sum of one or more of the following component factors as specified in the Agreement:

a. Secondary System Distance Factor: The amount determined by multiplying the Secondary System Distance by $0.2705 per mile;

b. Secondary System Transformation Factor: $4.01;

c. Secondary System Intermediate Terminal Factor: $1.29;

d. Secondary System Interconnection Terminal Factor: $0.70.

B. Partial-Year Service

The monthly charge per kilowatt of billing demand shall be as specified in Section II.A for all months of the year except for agreements with terms 5 years or less and which specify service for fewer than 12 months per year. The monthly charge shall be:

1. During months for which service is specified, the monthly charge defined in Section II.A, and

2. During other months, the monthly charge defined in Section II.A multiplied by 0.2.

Section III. Billing Factors

Unless otherwise stated in the Agreement, the billing demand shall be the largest of:

A. the Transmission Demand;

B. The highest hourly Scheduled Demand for the month; or

C. The Ratchet Demand.

Schedule FPT–91.3—Formula Power Transmission

Section I. Availability

This schedule continues schedule FPT–91.3 for all firm transmission agreements which provide that rates may be adjusted not more frequently than once every 3 years. It is available for firm transmission of electric power and energy using the Main Grid and/or Secondary System of the FCRTS. This schedule is for full-year and partial-year service and for either continuous or intermittent service when firm availability of service is required. For facilities at voltages lower than the Secondary System, a different rate schedule may be specified. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

A. Full-Year Service

The monthly charge per kilowatt of billing demand shall be one-twelfth of the sum of the Main Grid Charge and the Secondary System Charge, as applicable and as specified in the Agreement.

1. Main Grid Charge

The Main Grid Charge per kilowatt of Transmission Demand shall be the sum of one or more of the following component factors as specified in the Agreement:

a. Main Grid Distance Factor: The amount computed by multiplying the Main Grid Distance by $0.0281 per mile;

b. Main Grid Interconnection Terminal Factor: $0.27;

c. Main Grid Terminal Factor: $0.30;

d. Main Grid Miscellaneous Facilities Factor: $1.31.

2. Secondary System Charge

The Secondary System Charge per kilowatt of Transmission Demand shall be the sum of one or more of the following component factors as specified in the Agreement:

a. Secondary System Distance Factor: The amount determined by multiplying the Secondary System Distance by $0.1961 per mile;

b. Secondary System Transformation Factor: $2.53;

c. Secondary System Intermediate Terminal Factor: $0.84;

d. Secondary System Interconnection Terminal Factor: $0.44.

B. Partial-Year Service

The monthly charge per kilowatt of billing demand shall be as specified in Section II.A for all months of the year except for agreements with terms 5 years or less and which specify service for fewer than 12 months per year. The charge shall be:

1. During months for which service is specified, the monthly charge defined in Section II.A, and

2. During other months, the monthly charge defined in Section II.A multiplied by 0.2.

Section III. Billing Factors

Unless otherwise stated in the Agreement, the billing demand shall be the largest of:

A. The Transmission Demand;

B. The highest hourly Scheduled Demand for the month; or

C. The Ratchet Demand.

Schedule IR–93—Integration of Resources

Section I. Availability

This schedule supersedes IR–91 and is available for firm transmission service for electric power and energy using the Main Grid and/or Secondary System of the FCRTS. The definitions of Main Grid and Secondary Systems are the same as for the FPT–93.1 and FPT–91.3 rate schedules and are contained in the GTRSPs. For facilities at voltages lower than the Secondary System, a different rate schedule may be specified. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The monthly charge shall be the sum of A and B where:

A. The Demand Charge shall be:

1. $0.430 per kilowatt of billing demand; or

2. For Points of Integration (POI) specified in the Agreement as being short distance POI's, for which Main Grid and Secondary System facilities are used for a distance of less than 75 circuit miles, the following formula applies:

[0.2+(0.8/75×transmission distance)] ($0.430 per kilowatt of billing demand)

Where:

the billing demand for a short distance POI is the demand level specified in the Agreement for such POI, and the transmission distance is the circuit miles between the POI for a generating resource of the customer and a designated Point of Delivery serving load of the customer. Short distance POI's are determined by BPA after considering factors in addition to transmission distance.

B. The Energy Charge shall be:

1.07 mills per kilowatthour of billing energy.

Section III. Billing Factors

To the extent that the Agreement provides for the customer to be billed for transmission in excess of the Transmission Demand or Total Transmission Demand, as defined in the Agreement, at the nonfirm transmission rate (currently ET–93), such transmission service shall not contribute to either the Billing Demand or the Billing Energy for the IR rate provided that the customer requests such treatment and BPA approves in accordance with the prescribed provisions in the Agreement.

A. Billing Demand

The billing demand shall be the largest of:

1. the Transmission Demand, except under General Transmission Agreements where a Total Transmission Demand is defined;

2. the highest hourly Scheduled Demand for the month; or

3. the Ratchet Demand.

B. Billing Energy

The billing energy shall be the monthly sum of scheduled kilowatthours.

Schedule IS–93—Southern Intertie Transmission

Section I. Availability

This schedule supersedes IS–91 and is available for all transmission on the Southern Intertie. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

A. Nonfirm Rate

The charge for nonfirm transmission of non-Federal power shall be 2.8 mills

per kilowatthour of billing energy. This charge applies for both north-to-south and south-to-north transactions.

B. Firm Power Transmission Rate

The charge for firm transmission service granted access by BPA shall be $0.633 per kilowatt per month of billing demand and 1.43 mills per kilowatthour of billing energy. Firm transmission will only be made available to customers under this rate schedule who have executed a contract with BPA specifying use of the Firm Power Transmission rate for either north-to-south or south-to-north transactions.

Section III. Billing Factors

A. For services under Section II.A, the billing energy shall be the monthly sum of the scheduled kilowatthours, plus the monthly sum of kilowatthours allocated but not scheduled. The amount of allocated but not scheduled energy that is subject to billing may be reduced pro rata by BPA due to forced Intertie outages and other uncontrollable forces that may reduce Intertie capacity. The amount of allocated but not scheduled energy that is subject to billing also may be reduced upon mutual agreement between BPA and the customer.

B. For services under Section II.B, the billing demand shall be the Transmission Demand as defined in the Agreement. The billing energy shall be the monthly sum of scheduled kilowatthours, unless otherwise specified in the Agreement.

Schedule IN–93—Northern Intertie Transmission

Section I. Availability

This schedule supersedes IN–91 and is available for all transmission on the Northern Intertie. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The charge for transmission of non-Federal power on the Northern Intertie shall be 0.96 mills per kilowatthour.

Section III. Billing Factors

Billing Energy

The billing energy shall be the monthly sum of the scheduled kilowatthours.

Schedule IE–93—Eastern Intertie Transmission

Section I. Availability

This schedule supersedes IE–91 and is available for all nonfirm transmission on the Eastern Intertie. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The charge for transmission of nonfirm energy on the Eastern Intertie shall be 2.09 mills per kilowatthour.

Section III. Billing Factors

Billing Energy

The billing energy shall be the monthly sum of the scheduled kilowatthours.

Schedule ET–93—Energy Transmission

Section I. Availability

This schedule supersedes ET–91, unless otherwise specified in the Agreement, with respect to delivery using FCRTS facilities other than the Southern Intertie, Eastern Intertie, or the Northern Intertie, and is available for firm (of not more than 1 year duration) or nonfirm transmission between points within the Pacific Northwest. BPA may interrupt nonfirm service which is provided under this rate schedule. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The charge for transmission of non-Federal electric energy shall be 2.06 mills per kilowatthour.

Section III. Billing Factors

Billing Energy

The billing energy shall be the monthly sum of scheduled kilowatthours.

Schedule MT–91—Market Transmission

Section I. Availability

This schedule supersedes MT–89 and is available for Transmission Service for transactions using FCRTS facilities pursuant to the Western Systems Power Pool (WSPP) Agreement. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The charge shall be determined in advance by BPA. The charge shall be based on the duration of the proposed transaction and shall not exceed the following rates.

A. Hourly Rate

The maximum charge shall be 6.5 mills per kilowatthour where the total hourly revenues from a given transaction during a calendar day shall not exceed the product of the Daily rate and the maximum demand scheduled during such day.

B. Daily Rate

The maximum charge shall be $.105 per kilowattday where the total demand charge revenues in any consecutive 7-day period shall not exceed the product of the Weekly rate and the highest demand experienced on any day in the 7-day period.

C. Weekly Rate

The maximum charge shall be $.52 per kilowattweek.

D. Monthly Rate

The maximum charge shall be $2.27 per kilowattmonth.

Section III. Billing Factors

The billing factors shall be specified in advance by BPA, as to representing the Transmission Service use or reservation.

Schedule UFT–83—Use-of-Facilities Transmission

Section I. Availability

This schedule supersedes UFT–1 and UFT–2 unless otherwise provided in the Agreement, and is available for firm transmission over specified FCRTS facilities. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The monthly charge per kilowatt of Transmission Demand specified in the Agreement shall be one-twelfth of the annual cost of capacity of the specified facilities divided by the sum of Transmission Demands (in kilowatts) using such facilities. Such annual cost shall be determined in accordance with Section III.

Section III. Determination of Transmission Rate

A. From time to time, but not more often than once in each Contract Year, BPA shall determine the following data for the facilities which have been constructed or otherwise acquired by BPA and which are used to transmit electric power:

1. The annual cost of the specified FCRTS facilities, as determined from the capital cost of such facilities and annual cost ratios developed from the FCRTS financial statement, including interest and amortization, operation and maintenance, administrative and general, and general plant costs.

2. The yearly noncoincident peak demands of all users of such facilities or other reasonable measurement of the facilities' peak use.

B. The monthly charge per kilowatt of billing demand shall be one-twelfth of the sum of the annual cost of the FCRTS facilities used divided by the sum of Transmission Demands. The annual cost per kilowatt of Transmission Demand for a facility constructed or otherwise

acquired by BPA shall be determined in accordance with the following formula:

$$\frac{A}{D}$$

Where:

A=The annual cost of such facility as determined in accordance with A.1. above.

D=The sum of the yearly noncoincident demands on the facility as determined in accordance with A.2. above.

The annual cost per kilowatt of facilities listed in the Agreement which are owned by another entity, and used by BPA for making deliveries to the transferee, shall be determined from the costs specified in the Agreement between BPA and such other entity.

Section IV. Determination of Billing Demand

Unless otherwise stated in the Agreement, the factor to be used in determining the kilowatts of billing demand shall be the largest of:

A. the Transmission Demand in kilowatts specified in the Agreement;

B. the highest hourly Measured or Scheduled Demand for the month, the Measured Demand being adjusted for power factor; or

C. the Ratchet Demand.

Schedule TGT–1—Townsend-Garrison Transmission

Section I. Avilability

This schedule shall apply to all agreements which provide for the firm transmission of electric power and energy over transmission facilities of BPA's section of the Montana [Eastern] Intertie. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The monthly charge shall be one-twelfth of the sum of the annual charges listed below, as applicable and as specified in the agreements for firm transmission. The Townsend-Garrison 500–kV lines and associated terminal, line compensation, and communication facilities are a separately identified portion of the Federal Transmission System. Annual revenues plus credits for government use should equal annual costs of the facilities, but in any given year there may be either a surplus or a deficit. Such surpluses or deficits for any year shall be accounted for in the computation of annual costs for succeeding years. Revenue requirements for firm transmission use will be decreased by any revenues received from nonfirm use and credits for all government use. The general methodology for determining the firm rate is to divide the revenue requirement by the total firm capacity requirements. Therefore, the higher the total capacity requirements, the lower will be the unit rate.

If the government provides firm transmission service in its section of the Montana [Eastern] Intertie in exchange for firm transmission service in a customer's section of the Montana Intertie, the payment by the government for such transmission services provided by such customer will be made in the form of a credit in the calculation of the Intertie Charge for such customer. During an estimated 1- to 3-year period following the commercial operation of the third generating unit at the Colstrip Thermal Generating Plant at Colstrip, Montana, the capability of the Federal Transmission System west of Garrison Substation may be different from the long-term situation. It may not be possible to complete the extension of the 500-kV portion of the Federal Transmission System to Garrison by such commercial operation date. In such event, the 500/230 kV transformer will be an essential extension of the Townsend-Garrison Intertie facilities, and the annual costs of such transformer will be included in the calculation of the Intertie Charge.

However, starting 1 month after extension to Garrison of the 500-kV portion of the Federal Transmission System, the annual costs of such transformer will no longer be included in the calculation of the Intertie Charge.

A. Nonfirm Transmission Charge:

This charge will be filed as a separate rate schedule and revenues received thereunder will reduce the amount of revenue to be collected under the Intertie Charge below.

B. Intertie Charge for Firm Transmission Service:

$$\text{Intertie Charge} = \left[\left(\frac{TAC}{12} - NFR\right) \times \frac{(CR-EC)}{TCR}\right]$$

Section III. Definitions

A. TAC=Total Annual Costs of facilities associated with the Townsend-Garrison 500-kV Transmission line including terminals, and prior to extension of the 500-kV portion of the Federal Transmission System to Garrison, the 500/230 kV transformer at Garrison. Such annual costs are the total of:

(1) Interest and amortization of associated Federal investment and the appropriate allocation of general plant costs;

(2) Operation and maintenance costs;

(3) Allowance for BPA's general administrative costs which are appropriately allocable to such facilities, and

(4) Payments made pursuant to section 7(m) of Public Law 96–501 with respect to these facilities. Total Annual Costs shall be adjusted to reflect reductions to unpaid total costs as a result of any amounts received, under agreements for firm transmission service over the Montana Intertie, by the government on account of any reduction in Transmission Demand, termination or partial termination of any such agreement or otherwise to compensate BPA for the unamortized investment, annual cost, removal, salvage, or other cost related to such facilities.

B. NFR=Nonfirm Revenues, which are equal to:

(1) The product of the Nonfirm Transmission Charge described in II(A) above, and the total nonfirm energy transmitted over the Townsend-Garrison line segment under such charge for such month;

Plus (2) the product of the Nonfirm Transmission Charge and the total nonfirm energy transmitted in either direction by the Government over the Townsend-Garrison line segment for such month.

C. CR=Capacity Requirement of a customer on the Townsend-Garrison 500-kV transmission facilities as specified in its firm transmission agreement.

D. TCR=Total Capacity Requirement on the Townsend-Garrison 500-kV transmission facilities as calculated by adding (1) the sum of all Capacity Requirements (CR) specified in transmission agreements described in section I; and (2) the Government's firm capacity requirement. The Government's firm capacity requirement shall be no less than the total of the amounts, if any, specified in firm transmission agreements for use of the Montana Intertie.

E. EC=Exchange Credit for each customer which is the product of (1) the ratio of investment in the Townsend-Broadview 500-kV transmission line to the investment in the Townsend-Garrison 500-kV transmission line; and (2) the capacity which the Government obtains in the Townsend-Broadview 500-kV transmission line through exchange with such customer. If no exchange is in effect with a customer, the value of EC for such customer shall be zero.

Schedule AC–93—Southern Intertie Annual Cost

Section I. Availability

This schedule is applicable to all parties (New Owners) that execute PNW AC Intertie Capacity Ownership Agreements (Agreements) will be effective on the date of commercial operation of the facilities described in the Agreement. Service under this schedule is subject to BPA's GTRSPs.

Section II. Rate

The rate charges reflect the terms of the Memorandum of Understanding (MOU), signed in the Fall of 1991, between BPA and potential New Owners. The MOU provides for the payment by New Owners of:

(1) 21 percent of BPA's annual operations, maintenance, and general plant expense (including applicable overheads) properly chargeable to the AC Intertie facilities; and (2) 21 percent of BPA's share of capitalized replacements on the AC intertie. The monthly charge shall be the sum of the charges specified in sections II.A and II.B.

A. Maintenance and General Plant

The monthly charge shall equal $328 per megawatt of billing demand.

B. Replacement

The monthly charge shall equal $0 per megawatt of billing demand.

Section III. Adjustment to Replacements Rate

A. Determination of Billing Adjustment

New Owners will receive a billing adjustment for the difference between actual AC Intertie replacement cost and the amount paid under section II.B. The Replacement Rate Adjustment equals:

$$\frac{\text{AC Intertie work orders (\$000)} * .21}{\text{725 MW} * \text{\# months}} - \text{Replacements Rate (Section II.B) (\$/MWmo)}$$

where "# months" equals: (1) The number of months that this rate schedule is in effect during the fiscal year for the Initial Replacement Rate Adjustment; or (2) the number of months in the rate period for the Final Replacement Rate Adjustment.

B. Initial Replacements Rate Adjustment

New Owners will receive a billing adjustment for each fiscal year that the actual AC Intertie replacement cost differs from the amount paid under section II.B. At the end of each year, the cost associated with AC Intertie work orders that have closed during the fiscal year will be determined. The unit rate that would result using these closed work orders is compared to the Replacements rate in section II.B to determine the Initial Replacements Rate Adjustment.

1. Notice Provisions

Following each fiscal year, BPA shall notify all New Owners by December 15 of the proposed Replacements Rate Adjustment. BPA will provide the calculation of the adjustment and a short description of the work performed and the associated cost used as the basis for the billing adjustment. In addition to written notification, BPA may, but is not obligated to, hold a public meeting to clarify its determinations.

Written comments on the Initial Replacements Rate Adjustment will be accepted through the end of January. Consideration of comments submitted by the New Owners may result in the billing adjustment differing from the initially proposed adjustment. BPA shall notify all New Owners of the Initial Replacements Rate Adjustment by February 28.

2. Adjustment of Monthly Bills

An adjustment will be made on the New Owner's monthly bill prepared during March. The Initial Replacements Rate adjustment will be multiplied by the sum of the monthly billing factors from the relevant fiscal year (or the New Onwer's share in megawatts of BPA's PNW AC Intertie Rated Transfer Capability multiplied by the number of months that this rate schedule is effective during the fiscal year). If the Initial Replacements Rate Adjustment is positive, an adjustment on the monthly bill prepared during March will be made as an additional charge to the New Owner. If the result is negative, an adjustment on the monthly bill prepared during April will be made to credit the New Owner.

C. Final Replacements Rate Adjustment

The actual cost associated with the AC Intertie work orders that occur during the rate period may change after BPA performs its final analysis of the work orders. BPA shall compare the unit rate for the rate period using the results of the final work order analysis to the average of the unit rates from the Initial Replacements Rate Adjustments.

1. Notice Provisions

BPA shall notify all New Owners in May 1998 of the results of the calculations, an explanation of work order change(s), and any resulting billing adjustment. Written comments from New Owners will be accepted through the end of June. BPA shall notify all New Owners of the Final Replacements Rate Adjustment by July 31. Consideration of comments submitted by the New Owners may result in the Final Replacements Rate Adjustment differing from the initially proposed adjustment.

2. Adjustment of Monthly Bills

If the absolute value of the Final Replacements Rate Adjustment is greater than or equal to $1 per megawatt per month, an adjustment will be made on the New Owner's monthly bill prepared during July. For each New Owner, the Final Replacements Rate Adjustment will be multiplied by the sum of the monthly billing factors from the relevant fiscal year (or the New Owner's share in megawatts of BPA's PNW AC Intertie Rated Transfer Capability multiplied by the number of months that this rate schedule is effective during the fiscal year). If the Final Replacements Rate Adjustment is positive, an adjustment on the monthly bill prepared during July will be made as an additional charge to the New Owner. If the result is negative, an adjustment on the monthly bill prepared during July will be made to credit the New Owner. Interest will be included in any adjustment.

Section IV. Billing Factor

The billing demand shall be the New Owner's capacity ownership share in megawatts of BPA's PNW AC Inertie Rated Transfer Capability as specified in the Agreement.

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B. General Transmission Rate Schedule Provisions

Section I. Adoption of Revised Transmission Rate Schedules and General Transmission Rate Schedule Provisions

A. Approval of Rates

These rate schedules and GTRSP shall become effective upon interim approval or upon final confirmation and approval by FERC. BPA will request FERC approval effective October 1, 1993 through September 30, 1995.

B. General Provisions

These 1993 Transmission Rate Schedules and associated GTRSPs are virtually identical to and supersede BPA's 1991 Transmission Rate Schedules and GTRSPs (which became effective October 1, 1991) but do not supersede prior rate schedules required by agreement to remain in force.

Transmission service provided shall be subject to the following Acts, as amended: the Bonneville Project Act, the Regional Preference Act (Pub. L. 88–552), the Federal Columbia River Transmission System Act, and the Pacific Northwest Electric Power Planning and Conservation Act, and the Energy Policy Act of 1992, Pub. L. 102–486, 106 Stat. 2776 (1992).

The meaning of terms used in the transmission rate schedules shall be as defined in agreements or provisions which are attached to the Agreement or as in any of the above Acts.

Section II. Billing Factor Definitions and Billing Adjustments

A. Billing Factors

1. Scheduled Demand

The largest of hourly amounts wheeled which are scheduled by the customer during the time period specified in the rate schedules.

2. Metered Demand

The Metered Demand in kilowatts shall be the largest of the 60-minute clock-hour integrated demands measured by meters installed at each POD during each time period specified in the applicable rate schedule. Such measurements shall be made as specified in the Agreement. BPA, in determining the Metered Demand, will exclude any abnormal readings due to or resulting from: (a) emergencies or breakdowns on, or maintenance or, the FCRTS; or (b) emergencies on the customer's facilities, provided that such facilities have been adequately maintained and prudently operated as determined by BPA. If more than one class of power is delivered to any POD, the portion of the metered quantities assigned to any class of power shall be as agreed to by the parties. The amount so assigned shall constitute the Metered Demand for such class of power.

3. Transmission Demand

The demand as defined in the Agreement.

4. Total Transmission Demand

The sum of the transmission demands as defined in the Agreement.

5. Ratchet Demand

The maximum demand established during the previous 11 billing months. Exception: If a Transmission demand or Total Transmission Demand has been decreased pursuant to the terms of the Agreement during the previous 11 billing months, such decrease will be reflected in determining the Ratchet Demand.

B. Billing Adjustments

Average Power Factor

The adjustment for average power factor, when specified in a transmission rate schedule or in the Agreement, shall be made in accordance with the average power factor section of the General Wheeling Provisions.

To maintain acceptable operating conditions on the Federal system, BPA may restrict deliveries of power at any time that the average leading power factor or average lagging power factor for all classes of power delivered to such point or to such system is below 85 percent.

Section III. Other Definitions

Definitions of the terms below shall be applied to these provisions and the Transmission Rate Schedules, unless otherwise defined in the Agreement.

A. Agreement

An agreement between BPA and a customer to which these rate schedules and provisions may be applied.

B. Eastern Intertie

The segment of the FCRTS for which the transmission facilities consist of the Townsend-Garrison double-circuit 500 kV transmission line segment including related terminals at Garrison.

C. Electric Power

Electric peaking capacity (kW) and/or electric energy (kWh).

D. FCRTS

The transmission facilities of the Federal Columbia River Power System, which include all transmission facilities owned by the government and operated by BPA, and other facilities over which BPA has obtained transmission rights.

E. Firm Transmission Service

Transmission service which BPA provides for any non-Federal power except for transmission service which is scheduled as nonfirm. If the firm service is provided pursuant to the Agreement, the terms of the Agreement may further define the service.

F. Integrated Network

The segment of the FCRTS for which the transmission facilities provide the bulk of transmission of electric power within the Pacific Northwest, excluding facilities not segmented to the network as shown in the Wholesale Power Rate Development Study used in BPA's rate development.

G. Main Grid

As used in the FPT and IR rate schedules, that portion of the Integrated Network with facilities rated 230 kV and higher.

H. Main Grid Distance

As used in the FPT rate schedules, the distance in airline miles on the Main Grid between the POI and the POD, multiplied by 1.15.

I. Main Grid Interconnection Terminal

As used in the FPT rate schedules, Main Grid terminal facilities that interconnect the FCRTS with non-BPA facilities.

J. Main Grid Miscellaneous Facilities

As used in the FPT rate schedules, switching, transformation, and other facilities of the Main Grid not included in other components.

K. Main Grid Terminal

As used in the FPT rate schedules, the Main Grid terminal facilities located at the sending and/or receiving end of a line exclusive of the Interconnection terminals.

L. Nonfirm Transmission Service

Interruptible transmission service which BPA may provide for non-BPA power.

M. Northern Intertie

The segment of the FCRTS for which the transmission facilities consist of two 500 kV lines between Custer Substation and the United States-Canadian border, one 500 kV line between Custer and Monroe Substations, and two 230 kV lines from Boundary Substation to the United States-Canadian border, and the associated substation facilities.

N. Point of Integration (POI)

Connection points between the FCRTS and non-BPA facilities where non-Federal power is made available to BPA for wheeling.

O. Point of Delivery (POD)

Connection points between the FCRTS and non-BPA facilities where non-Federal power is delivered to a customer by BPA.

P. Secondary System

As used in the FPT and IR rate schedules, that portion of the Integrated Network facilities with operating voltage of 115 kV or 69 KV.

Q. Secondary System Distance

As used in the FPT rate schedules, the number of circuit miles of Secondary System transmission lines between the secondary POI and the Main Grid or the secondary POD, or the Main Grid and the secondary POD.

R. Secondary System Interconnection Terminal

As used in the FPT rate schedules, the terminal facilities on the Secondary System that interconnect the FCRTS with non-BPA facilities.

S. Secondary System Intermediate Terminal

As used in the FPT rate schedules, the first and final terminal facilities in the Secondary System transmission path exclusive of the Secondary System Interconnection terminals.

T. Secondary Transformation

As used in the FPT rate schedules, transformation from Main Grid to Secondary System facilities.

U. Southern Intertie

The segment of the FCRTS for which the major transmission facilities consist of two 500 kV AC lines from John Day Substation to the Oregon-California border; a portion of the 500 kV AC line from Buckley Substation to Summer Lake Substation; when completed, the Third AC facilities, which include Captain Jack Substation and the Alvey-Meridian 500 kV AC line; one 1,000 kV DC line between the Celilo Substation and the Oregon-Nevada border; and associated substation facilities.

V. Transmission Service

As used in the MT rate schedule, Transmission Service is as defined in the WSPP Agreement.

Section IV. Billing Information

A. Payment of Bills

Bills for transmission service shall be rendered monthly by BPA. Failure to receive a bill shall not release the customer from liability for payment. Bills for amounts due of $50,000 or more must be paid by direct wire transfer; customers who expect that their average monthly bill will not exceed $50,000 and who expect special difficulties in meeting this requirement may request, and BPA may approve, an exemption from this requirement. Bills for amounts due BPA under $50,000 may be paid by direct wire transfer or mailed to the Bonneville Power Administration, P.O. Box 6040, Portland, Oregon 97228–6040, or to another location as directed by BPA. The procedures to be followed in making direct wire transfers will be provided by the Office of Financial Management and updated as necessary.

1. Computation of Bills

The transmission billing determinant is the electric power quantified by the method specified in the Agreement or Transmission Rate Schedule. Scheduled power or metered power will be used.

The transmission customer shall provide necessary information to BPA for any computation required to determine the proper charges for use of the FCRTS, and shall cooperate with BPA in the exchange of additional information which may be reasonably useful for respective operations.

Demand and energy billings for transmission service under each applicable rate schedule shall be rounded to whole dollar amounts, by eliminating any amount which is less than 50 cents and increasing any amounts from 50 cents through 99 cents to the next higher dollar.

2. Estimated Bills

At its option, BPA may elect to render an estimated bill to be followed at a subsequent billing date by a final bill. The estimated bill shall have the validity of and be subject to the same payment provisions as a final bill.

3. Billing Month

For charges based on scheduled quantities, the billing month is the calendar month. For charges based on metered quantities, the billing month is defined as the interval between scheduled meter-reading dates. The billing month will not exceed 31 days in any case. While it may be necessary to read meters on a day other than the scheduled meter-reading date, for determination of billing demand, the billing month will cease at 2400 hours on the last scheduled meter-reading date. Schedules will be predetermined. The customer must give 30 days notice to request a change to the schedule.

4. Due Date

Bills shall be due by close of business on the 20th day after the date of the bill (due date). Should the 20th day be a Saturday, Sunday, or holiday (as celebrated by the customer), the due date shall be the next following business day.

5. Late Payment

Bills not paid in full on or before close of business on the due date shall be subject to a penalty of $25. In addition, an interest charge of one-twentieth percent (0.05 percent) shall be applied each day to the sum of the unpaid amount and the penalty charge. This interest charge shall be assessed on a daily basis until such time as the unpaid amount and penalty charge are paid in full.

Remittances received by mail will be accepted without assessment of the charges referred to in the preceding paragraph provided the postmark indicates the payment was mailed on or before the due date. Whenever a power bill or a portion thereof remains unpaid subsequent to the due date and after giving 30 days' advance notice in writing, BPA may cancel the contract for service to the customer. However, such cancellation shall not affect the customer's liability for any charges accrued prior thereto under such agreement.

6. Disputed Billings

In the event of a disputed billing, full payment shall be rendered to BPA and the disputed amount noted. Disputed amounts are subject to the late payment provisions specified above. BPA shall separately account for the disputed amount. If it is determined that the customer is entitled to the disputed amount, BPA shall refund the disputed amount with interest, as determined by BPA's Office of Financial Management.

BPA retains the right to verify, in a manner satisfactory to the Administrator, all data submitted to BPA for use in the calculation of BPA's rates and corresponding rate adjustments. BPA also retains the right to deny eligibility for any BPA rate or corresponding rate adjustment until all submitted data have been accepted by BPA as complete, accurate, and appropriate for the rate or adjustment under consideration.

7. Revised Bills

As necessary, BPA may render a revised bill.

a. If the amount of the revised bill is less than or equal to the amount of the original bill, the revised bill shall replace all previous bills issued by BPA that pertain to the specified customer for the specified billing period and the revised bill shall have the same date as the replaced bill.

b. If a revision causes an additional amount to be due BPA or the *specified customer* beyond the amount of the original bill, a revised bill will be issued for the difference and the date of the revised bill shall at its date of issue.

Issued in Portland, Oregon, on January 5, 1993.

Randall W. Hardy,

Administrator.

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BILLING CODE 6450–01–M

Office of Energy Research

Basic Energy Sciences Advisory Committee; Reestablishment

Pursuant to section 9(a)(2) of the Federal Advisory Committee Act and in accordance with title 41 of the Code of Federal Regulations, § 101–6.1015, and following consultation with the Committee Management Secretariat, General Services Administration, notice is hereby given that the Basic Energy Sciences Advisory Committee has been re-established for a 2-year period beginning in December 1992. The Committee will provide advice to the Director, Office of Energy Research, on the Basic Energy Sciences program.

The re-establishment of the Basic Energy Sciences Advisory Committee has been determined to be essential to the conduct of the Department's business and to be in the public interest in connection with the performance of duties imposed upon the Department of Energy by law. The Committee will operate in accordance with the provisions of the Federal Advisory Committee Act, the Department of Energy Organization Act (Pub. L. 95–91), and rules and regulations issued in implementation of those Acts.

Further information regarding this advisory committee can be obtained from Rachel Murphy at (202) 586–3279.

Issued in Washington, DC, on January 8, 1993.

Marcia L. Morris,

Deputy Advisory Committee Management Officer.

[FR Doc. 93–963 Filed 1–13–93; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket No. ER93–263–000]

Tampa Electric Co.; Filing

January 8, 1993.

Take notice that on December 7, 1992, Tampa Electric Company (Tampa Electric) tendered for filing a Letter of Commitment providing for the sale by Tampa Electric to the Seminole Electric Cooperative, Inc. (Seminole) of available capacity and/or energy. The Letter of Commitment was tendered as a supplement to Service Schedule G (Backup/Reserve Interchange Service) under the existing contract for interchange service between Tampa Electric and Seminole.

Tampa Electric proposes an effective date of the earlier of February 5, 1993, or the date that the Letter of Commitment is accepted for filing, and therefore requests waiver of the Commission's notice requirement.

Copies of the filing have been served on Seminole and the Florida Public Service Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NW., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before January 19, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–830 Filed 1–13–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–63–000]

Transcontinental Gas Pipe Line Corporation; Tariff Filing

January 8, 1993.

Take notice that Transcontinental Gas Pipe Line Corporation (TGPL) tendered for filing on January 6, 1993 Fourth Revised Sheet No. 50 to its FERC Gas Tariff, Third Revised Volume No. 1, which tariff sheet is proposed to be effective February 1, 1993.

The revised tariff sheet is filed pursuant to Section 4 of the National Gas Act and part 154 of the Federal Energy Regulatory Commission's regulations. TGPL states that the instant filing is for the limited purpose of revising rates under TGPL's FT–NT Rate Schedule such that the cost factors and rate design methodology underlying such rates are consistent with the cost factors and rate design methods reflected in TGPL's Docket No. RP92–137 general rate filing.

Included in appendix A to the filing are schedules and supporting workpapers underlying the rates submitted therein and an explanation of the derivation of such rates.

TGPL states that copies of the instant filing were mailed to each of its Rate Schedule FT–NT shippers and interested State Commissions. In accordance with provisions of § 154.16 of the Commission's Regulations, copies of this filing are available for public inspection, during regular business hours, in a convenient form and place at TGPL's main offices at 2800 Post Oak Boulevard in Houston, Texas.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protect with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before January 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–852 Filed 1–13–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP92–165–000]

Trunkline Gas Company; Informal Settlement Conference

January 8, 1993.

Take notice that an informal settlement conference will be convened in this proceeding on Friday, January 15, 1993, at 10 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC, for the purpose of finalizing a draft

settlement document in the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined in 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Betsy Carr at (202) 208–1240 or Marc G. Denkinger at (202) 208–2215.

Lois D. Cashell,

Secretary.

[FR Doc. 93–851 Filed 1–13–93; 8:45 am]

BILLING CODE 6717–01–M

Office of Fossil Energy

[Docket No. FE C&E 92–21 & 92–22; Certification Notice—112]

Filing Certification of Compliance: Coal Capability of New Electric Powerplant and Industrial Fuel Use Act

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of filing.

SUMMARY: Eagle Point Cogeneration Partnership (C&E 92–21) and Kissimmee Utility Authority (C&E 92–22) have submitted coal capability self-certifications pursuant to section 201 of the Powerplant and Industrial Fuel Use Act of 1978, as amended.

ADDRESSES: Copies of the self-certification filings are available for public inspection upon request in the Office of Fuels Programs, Fossil Energy, room 3F–056, FE–52, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Ellen Russell at (202) 586–9624.

SUPPLEMENTARY INFORMATION: Title II of the Powerplant and Industrial Fuel Use Act of 1978 (FUA), as amended (42 U.S.C. 8301 *et seq.*), provides that no new baseload electric powerplant may be constructed or operated without the capability to use coal or another alternate fuel as a primary energy source. In order to meet the requirement of coal capability, the owner or operator of such facilities proposing to use natural gas or petroleum as its primary energy source shall certify, pursuant to FUA section 201(d), to the Secretary of Energy prior to construction, or prior to operation as a base load powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certification establishes compliance with section 201(a) on the day it is filed with the Secretary. The Secretary is required to publish a notice in the **Federal Register** that a certification has been filed. The following owners/operators of proposed new baseload powerplants have filed self-certifications in accordance with section 201(d).

Owner: Eagle Point Cogeneration Partnership, Roanoke, Virginia
Operator: Coastal Technology, Inc., Roanoke, Virginia
Location: Gloucester County, New Jersey
Plant Configuration: Combined cycle cogeneration
Capacity: 217 megawatts
Fuel: Natural gas and refinery by-product gas
Purchasing Utilities: Public Service Electric and Gas Company
Expected In-Service Date: May, 1991.
Note: On November 13, 1987, ANR Venture Management Co. filed a certification for this facility stating that the net electrical capacity was 170 MW. This latest certification has been filed to notify DOE of a change in the name of the owner of the facility and also to note an increase in net electrical capacity to 217 MW.

Owner: Kissimmee Utility Authority, Kissimmee, Florida
Operator: Kissimmee Utility Authority
Location: Osceola County, Florida
Plant Configuration: Simple cycle combustion turbine (Unit 1); Combined cycle (Unit 2)
Capacity: 40 megawatts (Unit 1); 120 megawatts (Unit 2)
Fuel: Natural gas
Purchasing Utilities: Kissimmee Utility Authority and Florida Municipal Power Agency systems.
Expected In-Service Date: March, 1994 (Unit 1); January, 1995 (Unit 2)

Issued in Washington, DC, on January 6, 1993.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 93–940 Filed 1–13–93; 8:45 am]

BILLING CODE 6450–01–M

Office of Hearings and Appeals

Proposed Implementation of Special Refund Procedures

AGENCY: Office of Hearings and Appeals, Department of Energy.

ACTION: Notice of proposed implementation of special refund procedures.

SUMMARY: The Office of Hearings and Appeals (OHA) of the Department of Energy (DOE) announces the proposed procedures for disbursement of $340,000, plus accrued interest, in alleged crude oil overcharges obtained by the DOE under the terms of a Consent Order and Settlement Agreements entered into with Walter J. Scott & Benjamin J. Agajanian Oil Producers, William J. Scott, and Walter J. Scott d/b/a Scott Oil Company, Case No. LEF–0053. The OHA has tentatively determined that the funds obtained from these three firms, plus accrued interest, will be distributed in accordance with the DOE's Modified Statement of Restitutionary Policy Concerning Crude Oil Overcharges.

DATES AND ADDRESSES: Comments must be filed in duplicate on or before February 16, 1993, and should be addressed to the Office of Hearings and Appeals, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585. All comments should display a reference to case number LEF–0053.

FOR FURTHER INFORMATION CONTACT: Thomas O. Mann, Deputy Director, Roger Klurfeld, Assistant Director, Office of Hearings and Appeals, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–2094 (Mann); 586–2383 (Klurfeld).

SUPPLEMENTARY INFORMATION: In accordance with 10 CFR 205.282(b), notice is hereby given of the issuance of the Proposed Decision and Order set out below. The Proposed Decision and Order sets forth the procedures that the DOE has tentatively formulated to distribute to eligible claimants $340,000, plus accrued interest, obtained by the DOE under the terms of Consent Order Settlement Agreements entered into with Walter J. Scott & Benjamin J. Agajanian Oil Producers, Walter J. Scott d/b/a Scott Oil Company, and William J. Scott on December 17, 1986, July 27, 1991, and December 2, 1991. The funds were paid by these three firms towards the settlements of common violations of the Federal petroleum price and allocation regulations that were in effect from August 19, 1973 through January 28, 1981.

The OHA has proposed to distribute the Scott Settlement fund in accordance with the DOE's Modified Statement of Restitutionary Policy Concerning Crude Oil Overcharges, 51 FR 27899 (August 4, 1986) (the MSRP). Under the MSRP, crude oil overcharge monies are divided between the federal government, the states, and injured purchasers of refined petroleum products. Refunds to the states would be distributed in proportion to each state's consumption of petroleum products during the price control period. Refunds to eligible

purchasers would be based on the number of gallons of petroleum products which they purchased and the degree to which they can demonstrate injury.

Any member of the public may submit written comments regarding the proposed refund procedures. Commenting parties are requested to provide two copies of their submissions. Comments must be submitted within 30 days of publication of this notice in the **Federal Register** and should be sent to the address set forth at the beginning of this notice. All comments received in this proceeding will be available for public inspection between the hours of 1 p.m. and 5 p.m., Monday through Friday, except federal holidays, in the Public Reference Room of the Office of Hearings and Appeals, located in room 1E–234,1000 Independence Avenue SW., Washington, DC 20585.

Dated: January 7, 1993.

George B. Breznay,

Director, Office of Hearings and Appeals.

January 7, 1993.

Proposed decision and Order of the Department of Energy—Implementation of Special Refund Procedures

Name of Firm: Walter J. Scott & Benjamin J. Agaianian, Oil Producers, William J. Scott, Walter J. Scott d/b/a Scott Oil Company

Date of Filing: December 11, 1992

Case Number: LEF–0053

On December 11, 1992, the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) filed a Petition for the Implementation of Special Refund Procedures with the Office of Hearings and Appeals (OHA), to distribute the funds which Walter J. Scott & Benjamin J. Agajanian Oil Producers, Walter J. Scott d/b/a Scott Oil Company, and William J. Scott remitted to the DOE pursuant to a December 17, 1986 Consent Order, a July 27, 1991 Settlement Agreement and General Agreement and a December 2, 1991 Settlement Agreement and General Release. These three firms have remitted $340,000 pursuant to their respective Consent Order and Settlement Agreements, to which $57,099 has accrued as of November 30, 1992. In accordance with the procedural regulations codified at 10 CFR part 205, subpart V (subpart V), the ERA requests in its Petition that the OHA establish special procedures to make refunds in order to remedy the effects of alleged regulatory violations which were resolved by the above mentioned Consent Order and Settlement Agreements. This Proposed Decision and Order sets forth the OHA's plan to distribute these funds.

I. Background

The ERA issued Proposed Remedial Orders (PROs) to the above mentioned firms on June 4, 1982, alleging that they had violated the DOE price regulations. In the PROs, the ERA found that the three firms had sold crude oil from various leases during the respective audit periods at prices in excess of the lower-tier ceiling price specified in 10 CFR 212.73. On March 21, 1984, the DOE issued a Remedial Order that consolidated the proposed Remedial Orders issued to the three firms for common violations of the Federal petroleum price and allocation regulations that were in effect from August 19, 1973 through January 28, 1981. The DOE and Benjamin J. Agajanian entered into a December 17, 1986 Consent Order, whereby Agajanian was directed to pay the sum of $105,000, plus interest, to the DOE. The DOJ and William J. Scott entered into a July 27, 1991 Settlement Agreement and General Agreement, whereby Scott was directed to pay the sum of $125,000, plus interest, to the DOJ to settle all claims. In addition, the DOJ and Walter J. Scott entered into a December 2, 1991 Settlement Agreement and General Release, whereby Scott was directed to pay the sum of $110,000, plus interest to the DOJ to settle all claims. The three firms in total have remitted $340,000, to which $57,099 in interest has accrued as of November 30, 1992, making available a total of $397,099 (the Scott Settlement fund) for distribution through subpart V. These funds are being held in an interest-bearing escrow account maintained at the Department of the Treasury pending a determination regarding their proper distribution.

II. Jurisdiction and Authority

The subpart V regulations set forth general guidelines which may be used by the OHA in formulating and implementing a plan of distribution of funds received as a result of an enforcement proceeding. The DOE policy is to use the subpart V process to distribute such funds. For a more detailed discussion of subpart V and the authority of OHA to fashion procedures to distribute refunds, see Petroleum Overcharge Distribution and Restitution Act of 1986, 15 U.S.C. 4501–07, Office of Enforcement, 9 DOE ¶ 82,508 (1981), and Office of Enforcement, 8 DOE ¶ 82,597 (1981) (Vickers).

We have considered the ERA's petition that we implement a subpart V proceeding with respect to the Scott Settlement fund and have determined that such a proceeding is appropriate. This Proposed Decision and Order sets forth the OHA's tentative plan to distribute this fund.

III. Proposed Refund Procedures

A. Crude Oil Refund Policy

We propose to distribute the funds obtained pursuant to the above mentioned Consent Order and Settlement Agreements in accordance with the DOE's Modified Statement of Restitutionary Policy in Crude Oil Cases, 51 FR 27899 (August 4, 1986) (the MSRP). The MSRP was issued as a result of a court-approved Settlement Agreement In re: The Department of Energy Stripper Well Exemption Litigation, 653 F. Supp. 108 (D. Kan.), 6 Fed. Energy Guidelines ¶ 90,509 (1986) (the Stripper Well Settlement Agreement). The MSRP establishes that 40 percent of the crude oil overcharge funds will be remitted to the federal government, another 40 percent to the states, and up to 20 percent may be initially reserved for the payment of claims by injured parties. The MSRP also specifies that any monies remaining after all valid claims by injured purchasers are paid be disbursed to the federal government and the states in equal amounts.

The OHA has utilized the MSRP in all subpart V proceedings involving alleged crude oil violations. See Order Implementing the MSRP, 51 FR 29689 (August 20, 1986). This Order provided a period of 30 days for the filing of comments or objections to our proposed use of the MSRP as the groundwork for evaluating claims in crude oil refund proceedings. Following this period, the OHA issued a Notice evaluating the numerous comments which it received pursuant to the Order Implementing the MSRP. This Notice was published at 52 FR 11737 (April 10, 1987) (the April 10 Notice).

The April 10 Notice contained guidance to assist potential claimants wishing to file refund applications for crude oil monies under the subpart V regulations. Generally, all claimants would be required to (1) document their purchase volumes of petroleum products during the August 19, 1973 through January 27, 1981 crude oil price control period, and (2) prove that they were injured by the alleged crude oil overcharges. We also specified that end-users of petroleum products whose businesses are unrelated to the petroleum industry will be presumed to have been injured by the alleged crude oil overcharges and need not submit any additional proof of injury beyond documentation of their purchase

volumes. See City of Columbus, Georgia, 16 DOE ¶ 85,550 (1987). Additionally, we stated that crude oil refunds would be calculated on the basis of a per gallon (or "volumetric") refund amount, which is obtained by dividing the crude oil refund pool by the total consumption of petroleum products in the United States during the crude oil price control period. The OHA has adopted the refund procedures outlined in the April 10 Notice in numerous cases. See, e.g., Shell Oil Co., 17 DOE ¶ 85,204 (1988) (Shell); Mountain Fuel Supply Co., 14 DOE ¶ 85,475 (1986) (Mountain Fuel).

B. Refund Claims

We propose to adopt the DOE's standard crude oil refund procedures to distribute the monies in the Scott Settlement fund. We have chosen to initially reserve 20 percent of the fund, plus accrued interest, for direct refunds to claimants in order to ensure that sufficient funds will be available for injured parties. This reserve figure may later be reduced if circumstances warrant.

The OHA will evaluate crude oil refund claims in a manner similar to that used in subpart V proceedings to evaluate claims based on alleged refined product overcharges. See Mountain Fuel, 14 DOE at 88,869. Under these procedures, claimants will be required to document their purchase volumes of petroleum products and prove that they were injured as a result of the alleged violations.

We will adopt a presumption that the crude oil overcharges were absorbed, rather than passed on, by applicants which were (1) end-users of petroleum products, (2) unrelated to the petroleum industry, and (3) not subject to the regulations promulgated under the Emergency Petroleum Allocation Act of 1973 (EPAA), 15 U.S.C. 751–760h. In order to receive a refund, end-user claimants need not submit any evidence of injury beyond documentation of their purchase volumes. See *Shell*, 17 DOE at 88,406.

Petroleum retailer, reseller, and refiner applicants must submit detailed evidence of injury, and they may not rely upon the injury presumptions utilized in some refined product refund cases. Id. These applicants may, however, use econometric evidence of the type found in the OHA Report on Stripper Well Overcharges, 6 Fed. Energy Guidelines ¶ 90,507 (1985). See also Petroleum Overcharge Distribution and Restitution Act section 3003(b)(2), 15 U.S.C. 4502(b)(2). If a claimant has executed and submitted a valid waiver pursuant to one of the escrows established by the Stripper Well Settlement Agreement, it has waived its rights to file an application for subpart V crude oil refund monies. *See Mid-America Dairymen* v. *Herrington*, 878 F.2d 1448 (Temp. Emer. Ct. App.), 3 Fed. Energy Guidelines ¶ 26,617 (1989); In re: Department of Energy Stripper Well Exemption Litigation, 707 F. Supp. 1267 (D. Kan.), 3 Fed. Energy Guidelines ¶ 26,613 (1987).

As has been stated in prior Decisions, a crude oil refund applicant will only be required to submit one application for its share of all available crude oil overcharge funds. See, e.g., *A. Tarricone, Inc.*, 15 DOE ¶ 85,495 (1987). A party that has already submitted a claim in any other crude oil refund proceeding implemented by the DOE need not file another claim. The prior application will be deemed to be filed in all crude oil refund proceedings finalized to date. The DOE has established June 30, 1994 as the current deadline for filing an Application for Refund from the crude oil funds. Quintana Energy Corp., 21 DOE ¶ 85,032 (1991). It is the policy of the DOE to pay all crude oil refund claims at the rate of $.0008 per gallon. While we anticipate that applicants that filed their claims before June 30, 1988 will receive a supplemental refund payment, we will decide in the future whether claimants that filed later applications should receive additional refunds. See, e.g., *Seneca Oil Co.*, 21 DOE ¶ 85,327 (1991). Notice of any additional amounts available in the future will be published in the **Federal Register**.

C. Payments to the Federal Government and the States

Under the terms of the MSRP, we propose that the remaining eighty percent of the alleged crude oil overcharge amounts subject to this Proposed Decision, plus accrued interest, should be disbursed in equal shares to the states and federal government for indirect restitution. Refunds to the states will be in proportion to the consumption of petroleum products in each state during the period of price controls. The share or ration of the funds which each state will receive is contained in Exhibit H of the Stripper Well Settlement Agreement, 6 Fed. Energy Guidelines ¶ 90,509 at 90,687. When disbursed, these funds will be subject to the same limitations and reporting requirements as all other crude oil monies received by the states under the Stripper Well Settlement Agreement.

It Is Therefore Ordered That

The refund amount remitted to the Department of Energy by Walter J. Scott & Benjamin J. Agajanian Oil Producers, William J. Scott, and Walter J. Scott d/b/a Scott Oil Company pursuant to the Consent Order and Settlement Agreements entered into on December 17, 1986, July 27, 1991, and December 2, 1991, will be distributed in accordance with the foregoing Decision.

[FR Doc. 93–961 Filed 1–13–93; 8:45 am]

BILLING CODE 6450–01–M

Pittsburgh Energy Technology Center

Unsolicited Financial Assistance Award

AGENCY: U.S. Department of Energy.

ACTION: Acceptance of an unsolicited proposal application of a grant award with the University of Arizona.

SUMMARY: The Department of Energy (DOE) announces that pursuant to 10 CFR 600.14 (D) and (E), it intends to award financial assistance (grant) through the Pittsburgh Energy Technology Center to the University of Arizona for a research effort entitled "Regeneration of FGD Waste Liquors: Production of Ammonium and Potassium Sulfate Mixed Fertilizer."

ADDRESSES: Department of Energy, Pittsburgh Energy Technology Center, Acquisition and Assistance Division, P.O. Box 10940, MS 921–118, Pittsburgh, PA 15236.

FOR FURTHER INFORMATION CONTACT: Cynthia Y. Mitchell, Contract Specialist (412) 892–4862.

SUPPLEMENTARY INFORMATION:

Grant Number: DE–FG22–93PC92582.
Title of Research Effort: "Regeneration of FGD Waste Liquors: Production of Ammonium and Potassium Sulfate Mixed Fertilizer."
Awardee: University of Arizona.
Term of Assistance Effort: Twelve (12) months.
Grant Estimated Total Value: 48,787.

Objective: Based upon the authority of 10 CFR 600.14 (D) and (E), the objective of this grant is for Arizona University to study a method for regenerating the waste FGD Liquors from the Miami Fort pilot tests and to produce an ammonia and potassium sulfate mixed fertilizer product. This process involves the precipitation of the N–S compounds followed by their hydrolysis. The proposed work is considered to be relevant to the DOE mission in that the program will provide a mechanism for communication, interaction and research between DOE and Arizona University in the continuous process for the regeneration of waste scrubber liquors from the combined SO_x–NO_x

scrubbing systems. The development of this technology would assist utilities in complying with the 1990 Clean Air Act, while still encouraging and enhancing the use of coal, which is a major goal of the DOE Flue Gas Cleanup program.

Dated: December 18, 1992.

Dale A. Siciliano,

Contracting Officer.

[FR Doc. 93–939 Filed 1–13–93; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[OPP–36188; FRL–4184–6]

Sugarcane Borer Control in Louisiana and the Ecological Risks Associated With Control of the Sugarcane Borer; Notice of Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Meeting.

SUMMARY: EPA will conduct a public meeting on February 4, 1993, to solicit public comment on sugarcane borer control in Louisiana, including risks, benefits, alternative control methods and possible risk reduction measures. EPA believes that when used in the present manner, azinphos-methyl (trade name Guthion), the primary pesticide used to control the sugarcane borer, poses a hazard to the environment. EPA notes that the other pesticides used to control sugarcane borer also pose ecological hazards.

EPA intends to take action to reduce the adverse ecological effects posed by pesticides from control of the sugarcane borer and encourages public participation to assist in its decision.

DATES: The meeting will be held on February 4, 1993. Written comments from interested parties not able to attend the meeting must be received on or before February 5, 1993. Persons who wish to speak at the public meeting are encouraged to register in advance by submitting a brief written request to EPA on or before January 29, 1993.

ADDRESSES: The meeting is open to the public and will be held in the Norman Efferson Louisiana State University Agriculture Center Building, Room 214, Louisiana State University Campus, Highland Road, Baton Rouge, LA 70894-5203. The public meeting will begin at 1:00 p.m. and will continue to 7:00 p.m. Interested parties who cannot attend the public meeting but who wish to comment may do so by submitting written comments. Comments should be addressed to the person listed under **FOR FURTHER INFORMATION CONTACT.** Comments received on or before the specified date will be considered by the Agency before a final decision is reached on the appropriate action to be taken with regard to sugarcane borer control at this use site.

FOR FURTHER INFORMATION CONTACT: By mail: Tom Moriarty, Special Review and Reregistration Division, Office of Pesticide Programs (H7508W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person: Crystal Station 3rd Floor, 2800 Jefferson-Davis Highway, Arlington, VA, (703) 308-8035 (telephone), (703) 308-8041 (fax).

SUPPLEMENTARY INFORMATION:

I. Background

Sugarcane production in Louisiana accounts for 35 percent of the total U.S. sugarcane production and the sugarcane borer is one of the pests that threaten sugarcane production. Without control of this pest, the Agency estimates that the potential yield loss in Louisiana would be significant.

Several insecticides are used for control of the sugarcane borer in Louisiana. The pesticide most often used is Guthion, which is produced by Miles Incorporated and Makhteshim Chemical Works of Israel. Guthion is an organophosphate pesticide registered for use on over 100 crops for control of over 200 pests. It is an acutely toxic pesticide and all liquid formulations with concentrations of 13.5% active ingredient or greater have been classified for "restricted use".

Laboratory data indicate that Guthion is very highly toxic to aquatic organisms. Field data on Guthion confirm the laboratory data and the Agency's ecological risk concerns for this chemical. Because Guthion is moderately mobile and water soluble, it is likely to move from where it is applied into surface water. Guthion is also persistent in the terrestrial environment with a field dissipation half-life ranging from 30 to 181 days. This means a portion of the product may remain on or near the surface of the plant for the duration of this time and will likely be present even longer.

The environmental conditions under which sugarcane is grown in Louisiana and the chemical characteristics of Guthion promote runoff of this chemical into surrounding surface water. Guthion is typically applied during a time of year when Louisiana receives frequent rain showers. In addition, the predominantly clay-rich soil in which sugarcane is grown favors runoff. This has led to direct fish mortality.

In 1991, several fish-kill incidents were reported in which the total number of dead fish was estimated to range from 400,000 to 750,000. Following the 1991 incidents, significant label changes were made for Guthion use on sugarcane to try to reduce the risk to aquatic organisms. Despite the label changes that were implemented in time for the 1992 use season, further fish-kill incidents were reported which resulted in an estimated total of 26,000 fish mortalities. Because of the characteristics of both Guthion and its use in Louisiana, the Agency believes that similar fish-kill events are likely to occur.

The primary alternative to Guthion for control of the sugarcane borer is esfenvalerate (trade name Asana). Asana, a synthetic pyrethroid manufactured by DuPont, is very highly toxic to aquatic invertebrates and is also toxic to fish. EPA's data indicate that Asana is equally as efficacious as Guthion in controlling the sugarcane borer and is slightly less expensive.

Other pesticide alternatives for control of the sugarcane borer include diazinon, flowable carbofuran, and phorate. While each of these alternatives is less toxic to fish than either Guthion or Asana, all are highly toxic to birds or mammals.

It is unclear what the exact impact on yields would be if Guthion was no longer available for use on sugarcane in Louisiana; however, it appears that Asana offers similar control at similar costs. Therefore, the Agency believes that growers would not experience any significant economic impact without the availability of Guthion.

While all of the chemical alternatives pose risks to the environment, it appears that Guthion poses a greater risk than the alternatives. Nonetheless, the Agency is interested in reducing risk posed by pesticides used to control the sugarcane borer.

II. Information Sought by EPA

EPA is required by law to ensure that pesticides do not cause unreasonable adverse effects on people or the environment. As part of its evaluation process, the Agency collects information on the risks and benefits of pesticides. The Agency is interested in soliciting public comment on means to control the sugarcane borer in Louisiana while protecting the environment. An attempt has already been made to reduce the ecological risk from Guthion (through 1991 label changes) and the Agency is unaware of any effective alternative means to control the sugarcane borer which does not also cause adverse ecological effects. Therefore, the Agency

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has decided to solicit comment from all interested parties on this issue before it decides what action it will take, if any, to mitigate risks from control of the sugarcane borer.

The Agency is specifically interested in hearing public comment, or receiving written comment on the following topics.

1. *Quantity and use of pesticides to control sugarcane borer.* This includes the number of the different pesticides used to control the sugarcane borer by farmers, sugarcane grower organizations, or the State, (including the amount of pesticides stored), and the number of acres treated with pesticides to control the sugarcane borer. In addition, the Agency is interested in how the different pesticides are used such as application rates, methods of application, frequency of applications and timing.

2. *Efficacy of the various pesticide controls of sugarcane borer.* The Agency would like information on the biological efficacy of the available pesticide control alternatives (whether growers would anticipate any yield loss from the use of Guthion alternatives taking into consideration the wet conditions under which sugarcane is grown in Louisiana). In addition, the Agency would like to know if there would be, and to what degree, a resurgence of aphids if only the Guthion alternatives were available.

3. *Pest management practices and risk reduction.* The Agency would like public input on the possibility and effectiveness of different pest management techniques to control the sugarcane borer, including non-chemical pest controls. The Agency encourages comment on, but not limited to: Restriction of application, use of buffer zones, integrated pest management techniques, different tank mixes, or reduced wing span for aerial applications. The Agency is specifically interested in possible risk mitigation measures that could be used to reduce the ecological risk from Guthion.

4. *Cost of sugarcane borer control.* The Agency would like to know what costs (gains or losses to profits) would be incurred by sugarcane growing parties if only Guthion alternatives were available. For example, cost for additional extension agent service, or increased applications, or change in application equipment. Information on sugarcane crop budget would also be helpful in the Agency's benefit analysis of this use site.

5. *Environmental and human health effects from control of the sugarcane borer.* Finally, the Agency invites public comment on any known human poisoning events or additional ecological effects (fish or bird or mammal mortalities) associated with the use of Guthion or any of the alternatives when used to control the sugarcane borer.

III. Registration to Make Comments

Persons who wish to speak at the public meeting are encouraged to register in advance by submitting a brief written request to EPA on or before January 29, 1993. However, those who do not register by January 29 may register in person, on February 4th, to make a presentation at the meeting, if time permits.

The Agency encourages parties to submit data to substantiate comments whenever possible. All comments, as well as information gathered at the public meetings will be available for public inspection from 8:00 a.m. to 4:30 p.m., Monday through Friday (except legal holidays), at the Public Response and Program Resource Branch, Field Operations Division, Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted as part of any comment may be claimed as confidential by marking any or all of that information as Confidential Business Information (CBI). Information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by the Agency without prior notice to the submitter. The Agency anticipates that most of the comments will not be classified as CBI, and prefers that all information submitted be publicly available. Any records or transcripts of the open meetings will be considered public information and cannot be declared CBI.

IV. Structure of the Meeting

EPA will open the meeting with brief introductory comments. EPA will then invite those parties who have registered by January 29 to present their comments. Those who registered the day of the meeting will be offered the opportunity to present their comments, if time permits. EPA anticipates that each speaker will be permitted about 10 minutes to make comments. After each speaker, Agency representatives may ask the presenter questions of clarification. The Agency reserves the right to adjust the time for presenters depending upon the number of speakers.

Members of the public are encouraged to submit written documentation to EPA at the meeting to ensure that their entire position goes on record in the event that time does not permit a complete oral presentation. Written comments should include the name and address of the author as well as any sources used. Any information may be delivered to Tom Moriarty at the address stated earlier in this Notice.

Dated: January 8, 1993.

Daniel M. Barolo,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 93–926 Filed 1–13–93; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50752; FRL–4178–7]

Issuance of Experimental Use Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted experimental use permits to the following applicants. These permits are in accordance with, and subject to, the provisions of 40 CFR part 172, which defines EPA procedures with respect to the use of pesticides for experimental use purposes.

FOR FURTHER INFORMATION CONTACT: By mail: Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person or by telephone: Contact the product manager at the following address at the office location or telephone number cited in each experimental use permit: 1921 Jefferson Davis Highway, Arlington, VA.

SUPPLEMENTARY INFORMATION: EPA has issued the following experimental use permits:

100–EUP–95. Issuance. Ciba-Geigy Corporation, P.O. Box 18300, Greensboro, NC 27419. This experimental use permit allows the use of 16,000 pounds of the insecticide-miticide methidathion on 4,000 acres of almonds and citrus to evaluate the control of various insects and mites. The program is authorized only in the State of California. The experimental use permit is effective from November 4, 1992 to November 4, 1993. A permanent tolerance for residues of the active ingredient in or on almonds and citrus has been established (40 CFR 180.298). (Dennis Edwards, PM 19, Rm. 207, CM #2, (703–305–6386))

264–EUP–85. Renewal. Rhone-Poulenc Ag Company, P.O. Box 12014,

2 T.W. Alexander Drive, Research Triangle Park, NC 27709. This experimental use permit allows the use of 215 pounds of the fungicide iprodione on 160,000 bushels of shelled corn to evaluate the control of storage molds (aspergillus and penicillium). The program is authorized only in the States of Iowa, Illinois, Indiana, Kansas, Minnesota, and Nebraska. The experimental use permit is effective from October 28, 1992 to December 31, 1992. A temporary tolerance for residues of the active ingredient in or on field corn has been established. (Susuan Lewis, PM 21, Rm. 227, CM #2, (703–305–6900))

Persons wishing to review these experimental use permits are referred to the designated product manager. Inquires concerning these permits should be directed to the person cited above. It is suggested that interested persons call before visiting the EPA office, so that the appropriate file may be made available for inspection purposes from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

Authority: 7 U.S.C. 136.

Dated: January 5, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 93–933 Filed 1–13–93; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–180882; FRL 4183–1]

Receipt of Application for Emergency Exemption To Use Fenoxycarb; Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Washington Department of Agriculture (hereafter referred to as the "Applicant") for use of the pesticide fenoxycarb (CAS 72490–01–8) to control pear psylla (*Cacopsylla pyricola*) on up to 16,000 acres of pears. The Applicant proposes the first food use of an active ingredient; therefore, in accordance with 40 CFR 166.24, EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before January 29, 1993.

ADDRESSES: Three copies of written comments, bearing the identification notation "OPP–180882" should be submitted by mail to: Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. In person, bring comments to: Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Information submitted in any comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information." Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain Confidential Business Information must be provided by the submitter for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments filed pursuant to this notice will be available for public inspection in Rm. 1128, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Andrea Beard, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, D.C. 20460. Office location and telephone number: Rm. 718, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, (703–305–7890).

SUPPLEMENTARY INFORMATION: Pursuant to section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), the Administrator may, at his discretion, exempt a State agency from any registration provision of FIFRA if he determines that emergency conditions exist which require such exemption. The Applicant has requested the Administrator to issue a specific exemption for the use of the insecticide, fenoxycarb, manufactured as Fenoxycarb 25 WP, by Ciba-Geigy Corporation, to control pear psylla, on up to 16,000 acres of pears. Information in accordance with 40 CFR part 166 was submitted as part of this request.

The Applicant states that pear psylla is a major, chronic pest of all Washington and Oregon pear orchards. The pear psylla causes damage by injecting a toxin into the tree during the feeding process, which, in the long run, is debilitating and reduces vigor and, ultimately, yield. The pear psylla also causes injury by the copious amounts of honeydew which are secreted by the feeding nymphs. Honeydew on the fruit causes deformed fruit and russeting, major quality problems which cause downgrading of fruit and increased cullage. In addition, the honeydew causes secondary problems with black sooty mold on the fruit. If the pest is left totally uncontrolled, it will cause eventual tree debilitation and dramatic yield decreases. Pear psylla overwinter as adults in the trees. Dormant spraying is necessary to reduce the overwintering adult population before they lay eggs. The only effective winter spray materials for some years were the synthetic pyrethroids, permethrin and fenvalerate. When widespread resistance to these materials became evident in the psylla population by 1987–88, the Applicant states that cyfluthrin was used under crisis exemptions in 1988 and 1990, and under specific exemption in 1989 and 1991 and found to be highly efficacious. The Applicant also made use of cyfluthrin in 1992 under the provisions of a specific exemption. The Applicant claims that an emergency situation now exists, in that failure of cyfluthrin has been demonstrated, indicating the development of pear psylla populations which are resistant to this previously effective material.

The Applicant is requesting the use of fenoxycarb, and claims that field trials have demonstrated that this material provides excellent control of pear psylla in pears. The Applicant wishes to treat up to 16,000 acres of pear trees using up to 4,000 pounds of active ingredient. Up to two applications would be made per growing season, at a maximum rate of 2 oz. active ingredient (8 oz. product) per acre, diluted in water to make a minimum spray volume of 50-400 gallons per acre. Application of fenoxycarb would not be allowed by air or through chemigation equipment. This is the first year that the Applicant has requested this use of fenoxycarb.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 require publication of a notice of receipt in the **Federal Register** and solicit public comment on an application for a specific exemption proposing the first food use of an active ingredient. Accordingly, interested persons may submit written views on this subject to the Field Operations Division at the address above.

The Agency, accordingly, will review and consider all comments received during the comment period in determining whether to issue the emergency exemption requested by the Washington Department of Agriculture.

Dated: December 29, 1992.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 93-932 Filed 1-13-93 8:45 am]

BILLING CODE [illegible]

FEDERAL RESERVE SYSTEM

First Bank System, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than February 8, 1993.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. First Bank System, Inc., Minneapolis, Minnesota; and Central Bancorporation, Inc., Denver, Colorado; to acquire 100 percent of the voting shares of Bank Western National Association, Denver, Colorado, a *de novo* bank.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. Cherokee County Banshares, Inc., Hulbert, Oklahoma; to become a bank holding company by acquiring 100 percent of the voting shares of First State Bank, Hulbert, Oklahoma.

C. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. First Bancorp, Inc., Denton, Texas, Texas Financial Bancorporation, Inc., Minneapolis, Minnesota, and First Delaware Bancorp, Inc., Dover, Delaware; to acquire 100 percent of the voting shares of The Terrell State Bank, Terrell, Texas.

Board of Governors of the Federal Reserve System, January 8, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-952 Filed 1-13-93; 8:45 am]

BILLING CODE 6210-01-F

UJB Financial Corp., et al.; Notice of Applications To Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 3, 1993.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. UJB Financial Corp., Princeton, New Jersey; to engage *de novo* through its subsidiary, Richard Blackman & Co., Inc., Paramus, New Jersey, in securities brokerage activities pursuant to § 225.25(b)(15); and investment and financial advisory services pursuant to § 225.25(b)(4)(iii) of the Board's Regulation Y.

B. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. Dunn County Bankshares, Inc., Menomonie, Wisconsin; to engage *de novo* in making and servicing one loan pursuant to § 225.25(b)(1) of the Board's Regulation Y. This activity will be conducted in Eau Claire, Wisconsin.

Board of Governors of the Federal Reserve System, January 8, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-953 Filed 1-13-93; 8:45 am]

BILLING CODE 6210-01-F

First Bank System, Inc. and Central Bancorporation, Inc.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; and Acquisitions of Nonbanking Companies

The companies listed in this notice have applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed companies have also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The applications are available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of

Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 8, 1993.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. First Bank System, Inc., Minneapolis, Minnesota, and Central Bancorporation, Inc., Denver, Colorado; to merge with or acquire up to 100 percent of the voting shares of Colorado National Bankshares, Inc., Denver, Colorado, and thereby indirectly acquire Colorado National Bank, Denver, Colorado; Colorado National Bank - Belmont, Pueblo, Colorado; Colorado National Bank - Pueblo, Pueblo, Colorado; Colorado National Bank - Glenwood, Glenwood Springs, Colorado; Colorado National Bank - Grand Junction, Grand Junction, Colorado; Colorado National Bank - Longmont, Longmont, Colorado; Colorado National Bank - Ft. Collins, Fort Collins, Colorado; and Colorado National Bank - Exchange, Colorado Springs, Colorado.

In connection with this application, Applicants also propose to acquire Colorado National Insurance Agency, Inc., Denver, Colorado, and thereby engage in selling credit life, and accident and disability insurance pursuant to § 225.25(b)(8)(i); and Colorado National Life Insurance Company, Inc., Denver, Colorado, and thereby engage in reinsuring credit life, and accident and disability insurance pursuant to § 225.25(b)(8)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 8, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–954 Filed 1–13–93; 8:45 am]

BILLING CODE 6210–01–F

First State BancSheres, Inc.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 8, 1993.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. First State BancShares, Inc., Scottsbluff, Nebraska; to acquire Security First Savings & Loan Association, Cheyenne, Wyoming, and thereby engage in operating a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 8, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–955 Filed 1–13–93; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–66]

Request for Nominations for Peer Reviewers

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Public Health Service (PHS), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Agency for Toxic Substances and Disease Registry (ATSDR), United States Public Health Service, Department of Health and Human Services, is seeking nominations for peer reviewers for studies and research projects conducted or sponsored by ATSDR.

FOR FURTHER INFORMATION CONTACT: John S. Andrews, Jr., M.D., Associate Administrator for Science, Mailstop E–28, ATSDR, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone (404) 639–0708. Persons interested in serving as peer reviewers should send the following information: Name, address, telephone number, FAX number, and a curriculum vitae to Dr. Andrews at the above address. Persons who have previously applied should submit a revised curriculum vitae.

SUPPLEMENTARY INFORMATION: ATSDR in carrying out the health-related authorities of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (CERCLA) (42 U.S.C. 9601 *et seq.*), conducts epidemiological studies of persons exposed to hazardous substances and toxicilogical studies of hazardous substances. Protocols and final reports of studies and results of research funded, sponsored, or conducted by ATSDR will be peer reviewed in accordance with the mandates of CERCLA, section 104(i)(13) (42 U.S.C. 9604(i)(13)), which requires that all studies and results of research conducted under this subsection (other than health assessments) shall be reported or adopted only after

appropriate peer review. Such peer review shall be completed, to the maximum extent practicable, within a period of 60 days. Such peer review shall be conducted by panels consisting of no less than three nor more than seven members, who shall be disinterested scientific experts selected for such purpose by the Administrator of ATSDR on the basis of their reputation for scientific objectivity and the lack of institutional ties with any persons involved in the conduct of the study or research under review. Peer reviewers will be asked to sign statements indicating they acknowledge compliance with the conflict-of-interest provision of CERCLA section 104(i)(13) (42 U.S.C. 9604(i)(13)).

Peer reviewers will be sent protocols and final reports of studies and results of research and asked to provide their individual written comments within an agreed-upon time frame. Peer reviewers will categorize these protocols and final reports as (1) recommended, (2) recommended with required changes, or (3) not recommended. After categorization, protocols and final reports of studies and results of research will be returned to ATSDR. Individual peer review comments will be released to principal investigators and the appropriate ATSDR Divisions and may be subject to release under the Freedom of Information Act (5 U.S.C. 552, as amended).

Experts in the following areas are needed:

Analytical Chemistry
Aquatic Toxicity/Toxicity Testing
Biostatistics
Cellular and Molecular Epidemiology
Cellular and Molecular Toxicology
Chronic Disease Epidemiology
Clinical Pathology
Communication
Community Medicine
Computer Science
Developmental Pediatrics
Demography
Environmental Chemistry
Environmental Engineering
Environmental Epidemiology
Environmental Fate and Transport of Pollutants
Environmental Health
Epidemiology
Ethics
Genetic Toxicology
Health Physics
Hydrogeology
Immunology
Internal Medicine
Laboratory Medicine
Marine Biology
Minority Health Issues
Neurobehavior
Neurobehavioral Testing
Neurotoxicity
Neurotoxicology
Occupational Medicine
Pathology
Pediatrics
Physiology
Preventive Medicine
Psychology
Public Health
Pulmonary
Reproductive Health
Reproductive Toxicology
Risk Assessment
Science Policy
Sociology
Statistics
Toxicokinetics/Pharmacokinetics
Toxicology

Reviewers will be paid a consultation fee for their reviews. In general, persons who review the protocol for a particular study or research will also be asked to review the final report for the study or research.

Dated: January 8, 1993.

Walter R. Dowdle,

Acting Administrator, Agency for Toxic Substances and Disease Registry.

[FR Doc. 93-838 Filed 1-13-93; 8:45 am]

BILLING CODE 4160-70-M

National Institutes of Health

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 57 FR 54243, November 17, 1992), is amended to: (1) Correct the standard administrative codes (SAC) for the Office of Research on Minority Health from (HNE) to HNAE), and the Office of Research on Women's Health from (HNAF) to (HNAG) at the above-mentioned citation; and (2) reflect the reorganization of the Division of Computer Research and Technology (DCRT), National Institutes of Health (NIH), to better meet the needs of the biomedical community, and the NIH community at large, in the application of advanced computing technology; and more clearly reflect its reporting relationships. The reorganization consists of: (1) The realignment of the Office of Administration Management (HNU14), and the establishment of the Office of Information Resources Management (HNU18) within the Office of the Director, DCRT; (2) the establishment of the Office of Computing Resources and Services (HNU2), and the Office of Computational Bioscience (HNU3); and (3) the realignment of DCRT's standard administrative codes (SACs).

Section HN-B, Organization and Functions, is amended as follows: (1) Under the heading Office of Research on Minority Health (HNE), replace the standard administrative code (HNE) with the standard administrative code (HNAE).

(2) Under the heading Office of Research on Women's Health (HNAF), replace the standard administrative code (HNAF) with the standard administrative code (HNAG).

(3) Under the heading Division of Computer Research and Technology (HNU), insert the following:

Office of Administrative Management (HNU14)

(1) Advises the DCRT Director on management aspects of the Division's programs, policies, and procedures; (2) provides administrative services in support of DCRT program efforts; (3) coordinates DCRT's response to NIH-wide management programs; (4) provides staff support in information sciences in support of the DCRT and NIH mission; (5) plans and carries out scientific and technical communications activities for DCRT; and (6) manages a core collection of computer and computer science-related information for NIH.

Office of Information Resources Management (HNU18)

(1) Advises the Director and Deputy Director on all aspects of Information Resources Management (IRM) activities, including DCRT IRM strategic planning, capacity management and planning, security, and coordination of the acquisition of Federal Information Processing (FIP) resources; (2) manages the DCRT IRM program activities; (3) plans and conducts user surveys and studies to assess NIH computing requirements; (4) serves as the DCRT liaison to the Office of Information Resources Management, OD/NIH, on all IRM matters; and (5) assists DCRT staff in IRM management, including procurement of major FIP resources.

Office of Computational Bioscience (HNU2)

(1) Coordinates and manages all Division activities related to the conduct and support of NIH research in the computational biosciences; (2) applies computing technology to research involving molecular structure determination and modeling, protein and DNA sequence analysis and

biomedical imaging; (3) conducts and supports research in mathematical theory and biophysical instrumentation to explain biological phenomena in terms of chemistry and physics; (4) conducts research and development in computer science and computational engineering; (5) promotes the application of high performance computing to biomedical research and represents the Division to the Federal program in High Performance Computing and Communication (HPCC); (6) evaluates the overall performance of these programs; and (7) communicates and collaborates with researchers both within and outside NIH to obtain and provide information concerning DCRT's ongoing and future research, and support for research.

Office of Computing Resources and Services (HNU3)

(1) Advises the Director and Deputy Director, DCRT, on all matters pertaining to the management of DCRT ADP service and support programs; (2) coordinates and oversees all programs related to the development and provision of networking facilities; (3) provides centralized computational and data processing facilities and professional programming services; (4) provides guidance and support for end users of distributed computing technology, including personal computers, workstations, and local area networks; (5) provides engineering design to facilitate laboratory and clinical applications of automation technology; and (6) provides central systems analysis, and design and programming resources for database projects relating to scientific, technical, management, financial and administrative data.

Dated: January 6, 1993.

Bernadine Healy,

Director, NIH.

[FR Doc. 93–835 Filed 1–13–93; 8:45 am]

BILLING CODE 4140–01–M

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Substance Abuse Prevention Conference Review Committee of the Center for Substance Abuse Prevention for January 1993.

The initial review group will be performing review of applications for Federal assistance; therefore, a portion of this meeting will be closed to the public as determined by the Acting Administrator, SAMHSA, in accordance with 5 U.S.C. 552b(c)(6) and 5 U.S.C. app. 2 10(d).

A summary of the meeting and roster of committee members may be obtained from: Ms. D. Herman, CSAP Committee Management Officer, Substance Abuse and Mental Health Services Administration, Rockwall II Building, suite 630, 5600 Fishers Lane, Rockville, MD 20857 (Telephone: 301–443–4783).

Substantive program information may be obtained from the contact whose name, room number, and telephone number is listed below.

Committee Name: Substance Abuse Prevention Conference Review Committee.

Meeting Date(s): January 25–29, 1993.

Place: Bethesda Hyatt Regency, One Bethesda Metro Center, Cartier Tiffany Room, Bethesda, Maryland 20857.

Open: January 25, 1993 8:30 a.m.–9 a.m.

Closed: Otherwise.

Contact: Substance Abuse Prevention Conference, Review Committee, Ferdinand W. Hui, Ph.D., Telephone: (301) 443–4952.

Dated: January 8, 1993.

Peggy W. Cockrill,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 93–801 Filed 1–13–93; 8:45 am]

BILLING CODE 4160–20–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*):

Applicant: John J. Jackson, III, Metairie, LA. PRT–774792.

On December 24, 1992, a notice of the proposed import of one horn, removed from a live rhinoceros in Zimbabwe, was published in the **Federal Register**. The applicant has amended his application to request import of both horns taken from one sedated black rhinoceros (*Diceros bicornis*). The applicant proposes to dart a rhinoceros with anesthesia for removal of the horns by a qualified individual. He requests that the two horns be considered sport-hunted trophies and states the proposed import would serve to enhance survival of the species in the wild.

Applicant: Hunter Schuehle, San Antonio, TX. PRT–767310.

This application was previously published on October 8 and 21, 1992. Since that time, additional information has been received from the applicant and others that merits opening the comment period on the application for an additional 30 days. The applicant requests a permit to authorize interstate and foreign commerce, export, and cull of excess male red lechwe (*Kobus leche*), dama gazelle (*Gazella dama* spp.), barasingha (*Cervus duvauceli*), Eld's brow-antlered deer (*Cervus eldi*) and Arabian oryx (*Oryx leucoryx*) from his captive herd for the purpose of continued maintenance of the herd for enhancement of survival of the species.

Applicant: John Powers, Baton Rouge, LA. PRT–774116.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus dorcas dorcas*), culled from the captive herd maintained by W.S. Murray, "Graaff Reinet", Groothoek, Cape Province, Republic of South Africa, for the purpose of enhancement of survival of the species.

Applicant: Hartwell A. Burnett, Jr., Woodinville, WA. PRT–774715.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus dorcas dorcas*), culled from the captive herd maintained by J.C.P. Van Druten, "Victoria West", Riekertsfontein, Cape Province of South Africa, for the purpose of enhancement of survival of the species.

Applicant: Duke University Primate Center, Durham, NC. PRT–679043.

On June 17, 1992, a notice of this applicant's proposed activities was published in the **Federal Register**. Since that time the applicant has clarified that, in addition to dead specimens, they propose to take blood and tissue samples from live captive animals for sale in interstate and foreign commerce for purposes of scientific research and for enhancement of propagation or survival. Dead specimens and samples would be obtained from species within the following families: Lemuridae, Indriidae, Cheirogaleidae, Daubentoniidae, Tarsiidae and Lorisidae.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, room 432, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review by any party who

submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, room 432, Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: January 11, 1993.

Susan Jacobsen,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 93–858 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–55–M

Bureau of Land Management

[CA–050–93–4333–13]

Closure Order of Public Lands in Mendocino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Closure Order of Public Lands in Mendocino County, California.

SUMMARY: Notice is hereby given related to the closure of Bureau of Land Management (BLM) administered lands to public use from the hours of 9:00 p.m. to 5:00 a.m. in accordance with regulations contained in 43 CFR subpart 8364.1(a) and known as Little Darby Environmental Education Area, located in T18N, R13W, Section 1, in Mendocino County containing 20 acres more or less. This closure shall apply only to those lands included in the parking area and picnic site located adjacent to Berry Canyon Road. The closure will not apply to the remaining 980 acres nor will it apply to any peace officers, firefighters, or any other emergency service personnel while in the performance of their duties. Exemption to this closure may be granted to groups or individuals by permit from BLM.

DATES: This Closure Order is effective January 14, 1993.

SUPPLEMENTARY INFORMATION: The entire area is covered by dense chaparral and timber and was developed for wildlife habitat in 1965. In 1979, Little Darby became an environmental education area with a parking area, interpretive trail, and picnic site. Use of the area has increased as schools begin to recognize its convenience and value for environmental education. The interpretive trail is used by members of the public, particularly school children, to observe the wide variety of plant and animal species and the diversity of habitats including old growth Douglas Fir community found within the area. The night closure of the parking and picnic areas is necessitated by the increase in vandalism and consumption of alcohol occurring in these areas during the evening. The Bureau will continue to manage this area specifically for wildlife habitat as an environmental study area where members to the public can enjoy this area for hiking and nature study. The parking area and picnic site will be posted "Day Use Only", Closed 9 p.m. to 5 a.m.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Arcata, California office at (707) 822–7648.

Lynda Roush,

Arcata Resource Area Manager.

[FR Doc. 93–912 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–40–M

[AZ–010–93–4332–02; 1784–010]

Arizona Strip District Grazing Advisory Board; Meetings

AGENCY: Bureau of Land Management, Arizona Strip District, Interior.

ACTION: Notice of meeting.

SUMMARY: The new District Manager will be introduced to the Arizona Strip District Grazing Advisory Board. Topics such as desert tortoise, incentive based grazing fee, and user maintenance will be discussed.

DATES: The meeting will be held at the District Office located at 390 North 3050 East, St. George, Utah at 8 a.m. on February 4, 1993.

FOR FURTHER INFORMATION CONTACT: Raymond D. Mapston, District Manager, Arizona Strip District, 390 North 3050 East, St. George, Utah 84770 (Phone 801/6773–3545).

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Any person who would like to comment may do so the final 30 minutes of the meeting.

Dated: January 6, 1993.

Raymond Mapston,

Arizona Strip District Manager.

[FR Doc. 93–909 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–32–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–940–03–4730–02]

Land Resource Management

AGENCY: Bureau of Land Management, Montana State Office, Interior.

ACTION: Notice of filing of plat of survey.

SUMMARY: Plats of survey for the following described land accepted December 2, 1992, will be officially filed in the Montana State Office, Billings, Montana, effective 30 days after publication.

Principal Meridian, Montana

T. 23 N., Rs. 59 and 60 E.

The plat, of the NE¼ of section 13, representing the corrective dependent resurvey of portions of the east boundary, and certain subdivision of section lines, and the survey of a portion of the present left bank meanders of the Yellowstone River, and an abandoned channel of the Yellowstone River in section 13, Township 23 North, Range 59 East, and an island in the Yellowstone River in sections 13 and 18, Township 23 North, Ranges 59 and 60 East, Principal Meridian, Montana.

T. 2 N., R. 45 E.

The plat representing the dependent resurvey of a portion of the subdivisional lines and the adjusted original meanders of the former right bank of the Tongue River, downstream through section 10, and the subdivision of section 10, the survey of the new meanders of the present right bank of the Tongue River through section 10, and a division of accretion line, Township 2 North, Range 45 East, Principal Meridian, Montana.

The triplicate original of the preceding described plats will be immediately placed in the open files and will be available to the public as a matter of information.

If a protest against this survey, as shown on the plat, is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. The protested plat of survey will not be officially filed until the day after all protests have been accepted or dismissed and become final or appeals from the dismissal affirmed.

These surveys were executed at the request of the District Manager, Miles City District Office.

EFFECTIVE DATE: December 28, 1992.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, 222 North 32nd Street, P.O. Box 36800, Billings, Montana 59107–6800.

Dated: December 31, 1992.

Robert H. Lawton,

State Director.

[FR Doc. 93–818 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–DN–M

Minerals Management Service

Outer Continental Shelf (OCS) Oil and Gas Information Program; Republication

Editorial Note: FR Doc. 93-11 was originally published at page 352 in the issue of Tuesday, January 5, 1993. In that publication some paragraphs were omitted. The correction document is republished below in its entirety. .

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of availability.

SUMMARY: Notice is hereby given that the Minerals Management Service has recently released a publication entitled "Accidents Associated with Oil and Gas Operations, Outer Continental Shelf, 1956–1990, OCS Report MMS 92–0058." This 324-page report is a compilation of descriptions of all blowouts, explosions and fires, pipeline breaks or leaks, significant pollution incidents, and major accidents that occurred on federally leased offshore lands for 1956 through 1990.

The report identifies accidents by area, block number, lease number, platform number, well number, and operator. It describes the type of accident, corrective action taken, and the amount of pollution. It provides figures on fatalities, injuries, and property and environmental damage.

ADDRESSES: This OCS REPORT, MMS 92–0058, is available for inspection at the Technical Communication Services; Document Distribution Center; Minerals Management Service, Mail Stop 4530; 381 Elden Street, room 1317; Herndon, Virginia 22070–4817, telephone (703) 787–1080. Copies of this report can be obtained from the same address.

FOR FURTHER INFORMATION CONTACT: Lloyd M. Tracey; Engineering and Standards Branch; Minerals Management Service, Mail Stop 4700; 381 Elden Street; Herndon, Virginia 22070–4817, telephone (703) 787–1600.

SUPPLEMENTARY INFORMATION: This report is published pursuant to 30 CFR part 252—OCS Oil and Gas Information Program, 44 FR 46408, August 7, 1979. An outline of the contents of the report is set forth below.

Accidents Associated with Oil and Gas Operations in the OCS.

I. Introduction

II. Gulf of Mexico (GOM) OCS Region

Table 1, Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS—GOM.

Table 2–A, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Blowouts.

Table 2–B, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Explosions and Fires.

Table 2–C, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Pipeline Breaks or Leaks.

Table 2–D, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Significant Pollution Incidents, 50 bbl (2,100 gal) or More.

Table 2–E, Accidents Associated with Oil and Gas Operations on the OCS, GOM, Major Accidents.

III. Pacific OCS Region

Table 3, Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS—Pacific.

Table 4–A, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Blowouts.

Table 4–B, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Explosions and Fires.

Table 4–C, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Pipeline Breaks or Leaks.

Table 4–D, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Significant Pollution Incidents, 50 bbl (2,100 gal) or More.

Table 4–E, Accidents Associated with Oil and Gas Operations on the OCS, Pacific, Major Accidents.

IV. Alaska OCS Region

Table 5–E, Accidents Associated with Oil and Gas Operations on the OCS, Alaska, Major Accidents.

V. Atlantic OCS Region

Table 6–E, Accidents Associated with Oil and Gas Operations on the OCS, Atlantic, Major Accidents.

VI. Summary Tables for the Entire OCS

Table 7, Summary of Crude Oil and Condensate Spill Incidents of 200 or More Barrels, OCS.

Table 8, Summary of Accidents Associated with Oil and Gas Operations on the OCS, 1956–1990.

VII. Graphs of Data Pertaining to Accidents Associated With Oil and Gas Operations on the OCS

Figure 1, Crude & Condensate Spills≥200 bbl, OCS—GOM.

Figure 2, Crude & Condensate Spills≥200 bbl, OCS—Pacific.

Figure 3, Volume of Crude & Condensate Spilled, OCS—GOM.

Figure 4, Volume of Crude & Condensate Spilled, OCS—Pacific.

Figure 5, Crude & Condensate Spills≥200 bbl, OCS.

Figure 6, Volume of Crude & Condensate Spilled, OCS.

Figure 7, Summary of Accidents Associated with Oil and Gas Operations on the OCS.

Dated: December 23, 1992.

Thomas Gernhofer,

Associate Director for Offshore Minerals Management.

[FR Doc. 93–11 Filed 1–4–93; 8:45am]

Billing Code 1906–01–D

National Park Service

Native American Graves Protection and Repatriation Review Committee: Meeting

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of meeting of the Native American Graves Protection and Repatriation Review Committee.

Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. Appendix (1988), that the Native American Graves Protection and Repatriation Review Committee will meet on February 26 and 27, 1993, on the island of Oahu, Hawaii.

The Committee was established by Congress to monitor, review, and assist in implementation of the inventory and identification process and repatriation activities required under the Native American Graves Protection and Repatriation Act (25 U.S.C. 3001–3013).

The Committee will meet on Friday, February 26, 1993, at the Bishop Museum, 1525 Bernice Street, Honolulu, HI 96817–0916. Matters to be discussed will include a dispute between Hui Mālama I Nā Kūpuna 'O Hawai'i Nei and the P.A. Hearst Museum of Anthropology, Berkeley, CA.

The Committee will meet on Saturday, February 27, 1993, at the Turtle Bay Hilton Hotel, 57–091 Kamehameha Highway, Kahuku, HI 96731. Matters to be discussed will include: 1) progress made, and any barriers encountered, in implementing the statute in Hawaii, and 2) the Committee's 1992 report to Congress. The Committee is particularly interested in hearing from representatives of Native Hawaiian organizations, museums, and Federal agencies and from members of the public on issues related to identification of Native Hawaiian cultural items and the determination of cultural affiliation.

In the event that the meeting agenda is not completed on February 27, 1993, the Committee will reconvene Sunday, February 28, 1993, at the Turtle Bay Hilton, Kahuku, HI.

Meetings will begin each day at 8:30 a.m. and conclude not later than 5:00

p.m. Meetings will be open to the public. However, facilities and space for accommodating members of the public are limited and persons will be accommodated on a first-come, first-served basis. Any member of the public may file a written statement concerning the matters to be discussed with Dr. Francis P. McManamon, Departmental Consulting Archeologist.

Persons wishing further information concerning this meeting, or who wish to submit written statements may contact Dr. Francis P. McManamon, Departmental Consulting Archeologist, Archeological Assistance Division, National Park Service, P.O. Box 37127, Washington, D.C. 20013–7127, Telephone (202) 343–4101. Draft summary minutes of the meeting will be available for public inspection about eight weeks after the meeting at the office of the Departmental Consulting Archeologist, room 210, 800 North Capitol Street, Washington, DC.

Dated: January 7, 1993.

Francis P. McManamon,

Departmental Consulting Archeologist, Chief, Archeological Assistance Division.

[FR Doc. 93–891 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-70-M

Office of Surface Mining Reclamation and Enforcement

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information, related form and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirements should be made directly to the Bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project (1029–0039), Washington, DC 20503, telephone 202–395–7340.

Title: Underground Mining Permit Applications—Minimum Requirements for reclamation and Operation Plan—30 CFR part 784

OMB Number: 1029–0039

Abstract: Sections 507, 508 and 516 of Public Law 95–87 require underground coal mine permit applicants to submit an operations and reclamation plan and establish performance standards for the mining operation. Information submitted is used by the regulatory authority to determine if the applicant can comply with the applicable performance and environmental standards in Public Law 95–87.

Bureau Form Number: None

Frequency: On occasion

Description of Respondents: Underground Coal Mining Operators

Estimated Completion Time: 25 hours

Annual Responses: 3,017

Annual Burden Hours: 75,792

Bureau Clearance Officer: John A. Trelease, (202) 343–1475

Dated: October 16, 1992.

John P. Mocsseo,

Chief, Division of Technical Services.

[FR Doc. 93–902 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-05-M

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information, related form and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirements should be made directly to the Bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project (1029–0038), Washington, DC 20503, telephone 202–395–7340.

Title: Underground Mining Permit Applications—Minimum Requirements for Information on Environmental Resources, 30 CFR part 783

OMB Number: 1029–0038

Abstract: Applicants for underground coal mining permits are required to provide adequate descriptions of the environmental resources that may be affected by proposed underground coal mining activities.

Bureau Form Number: None.

Frequency: On occasion

Description of Respondents: Underground Coal Mining Operators

Estimated Completion Time: 21 hours

Annual Responses: 662

Annual Burden Hours: 14,092

Bureau Clearance Officer: John A. Trelease, (202) 343–1475

Dated: October 16, 1992.

John P. Mocsseo,

Chief, Division of Technical Services.

[FR Doc. 93–903 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-05-M

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related form and explanatory material may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the requirement should be made within 30 days directly to the Bureau clearance officer and to the Office of Management and Budget Paperwork Reduction Project (1029–0036), Washington, DC 20503, telephone 202–395–7340.

Title: Surface Mining Permit Applications—Minimum Requirements for Reclamation and Operation Plan—30 CFR part 780

OMB Number: 1029–0036

Abstract: Sections 507(b), 508(a) and 515(b) and (d) of Public Law 95–87 require applicants for surface mine permits to provide a description of each existing structure proposed to be used in the mining and reclamation operation and a compliance plan for structures proposed to be modified or constructed for use in the operation. This information is used by the regulatory authority in determining if the applicant can comply with the applicable performance and environmental standards.

Bureau Form Number: None

Frequency: On occasion

Description of Respondents: Surface Coal Mining Operators

Annual Responses: 7,487

Annual Burden Hours: 213,078

Average Burden Hours Per Response: 28

Bureau Clearance Officer: John A. Trelease (202) 343–1475

Dated: October 16, 1992.

John P. Mocsseo,

Chief, Division of Technical Services.

[FR Doc. 93–904 Filed 1–13–93; 8:45 am]

BILLING CODE 4310-05-M

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related form may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the bureau clearance officer and to the Office of Management and Budget, Paperwork Reduction Project (1029–0035), Washington, DC 20503, telephone 202–395–7340.

Title: Surface Mining Permit Applications—Minimum Requirements for Environmental Resources, 30 CFR part 779.
OMB approval number: 1029–0035.
Abstract: Applicants for surface coal mining permits are required to provide an adequate description of the environmental resources that may be affected by proposed surface mining activities. The information will be used by the regulatory authority to determine if the applicant can comply with environmental protection performance standards.
Bureau Form Number: None.
Frequency: On occasion.
Description of Respondents: Coal Mine Operators.
Annual Responses: 1,530.
Annual Burden Hours: 145,344.
Estimated Completion Time: 95 hours.
Bureau clearance officer: John A. Trelease 202–343–1475.

Dated: October 16, 1992.

John P. Mosesso,

Chief, Division of Technical Services.

[FR Doc. 93–908 Filed 1–13–93; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–622 (Final)]

Dry Film Photoresist From Japan

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of a final antidumping investigation.

SUMMARY: The Commission hereby gives notice of the institution of final antidumping investigation No. 731–TA–622 (Final) under section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act) to determine whether an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from Japan of dry film photoresist, provided for in subheading 3707.90.30 of the Harmonized Tariff Schedule of the United States (HTS). (Dry film photoresist may also be entering under subheading 3702.39.00, 3702.42.00, 3702.43.00, 3702.44.00, and 3702.95.00 of the HTS).

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

EFFECTIVE DATE: December 30, 1992.

FOR FURTHER INFORMATION CONTACT: Larry Reavis (202–205–3185), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

SUPPLEMENTARY INFORMATION:

Background

This investigation is being instituted as a result of an affirmative preliminary determination by the Department of Commerce that imports of dry film photoresist from Japan are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigation was requested in a petition filed on July 16, 1992, by E.I. Du Pont de Nemours & Co., Wilmington, DE; Morton International, Inc., Tustin, CA; and Hercules Incorporated, Middleton, DE.

Participation in the Investigation and Public Service List

Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, not later than twenty-one (21) days after publication of this notice in the **Federal Register**. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited Disclosure of Business Proprietary Information (BPI) Under an Administrative Protective Order (APO) and BPI Service List

Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this final investigation available to authorized applicants under the APO issued in the investigation, provided that the application is made not later than twenty-one (21) days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff Report

The prehearing staff report in this investigation will be placed in the nonpublic record on February 26, 1993, and a public version will be issued thereafter, pursuant to § 207.21 of the Commission's rules.

Hearing

The Commission will hold a hearing in connection with this investigation beginning at 9:30 a.m. on March 11, 1993, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before March 4, 1993. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on March 9, 1993, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the public hearing are governed by §§ 201.6(b)(2), 201.13(f), and 207.23(b) of the Commission's rules. Parties are strongly encouraged to submit as early in the investigation as possible any requests to present a portion of their hearing testimony *in camera*.

Written Submissions

Each party is encouraged to submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.22 of the Commission's rules; the deadline for filing is March 5, 1993. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.23(b) of the Commission's rules, and posthearing briefs, which must conform with the

provisions of § 207.24 of the Commission's rules. The deadline for filing posthearing briefs is March 19, 1993; witness testimony must be filed no later than three (3) days before the hearing. In addition, any person who has not entered at appearance as a party to the investigation may submit a written statement of information pertinent to the subject of the investigation on or before March 19, 1993. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.20 of the Commission's rules.

Issued: January 8, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary

[FR Doc. 93-825 Filed 1-13-93; 8:45 am]

BILLING CODE 7020-02-M

[Investigation Nos. 731-TA-548, 550, and 551 (Final)]

Sulfur Dyes From China, India, and the United Kingdom; Commission Determination to Conduct a Portion of the Hearing in Camera

AGENCY: U.S. International Trade Commission.

ACTION: Closure of a portion of a Commission hearing to the public.

SUMMARY: Upon request of respondents in the above-captioned final investigation, the Commission has determined to conduct a portion of its hearing scheduled for January 13, 1992, *in Camera*. See Commission rules 207.23(a), 201.13, and 201.35 through 201.39 (19 CFR 207.23(a), 201.12, and 201.35 through 201.39). The remainder of the hearing will be open to the public. The Commission also has determined that the 10-day advance notice of the change to a meeting was not possible. See Commission rules 201.35(c)(1) and 201.37(b) (19 CFR 201.35(c)(1) and 201.37(b)).

FOR FURTHER INFORMATION CONTACT: Katherine M. Jones, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202-205-3097. Hearing impaired individuals are advised that information on this matter may be obtained by contacting the Commission's TTD terminal on 202-205-1810.

SUPPLEMENTARY INFORMATION: The Commission believes that good cause exists in this investigation to hold a short portion of the hearing *in camera*. The *in camera* portion of the hearing will be for the purpose of addressing business proprietary information (BPI) as part of respondents' presentation in chief, and therefore properly the subject of an *in camera* hearing pursuant to Commission rule 201.36(b)(4) (19 CFR 201.36(d)(4)). In making this decision, the Commission nevertheless reaffirms its belief that wherever possible its business should be conducted in public.

The hearing will include public presentations by petitioner and respondents, with questions from the Commission. After respondents' public presentation, the Commission will hold an *in camera* session, during which time respondents will continue their presentation to the Commission and cover business proprietary information, followed by questioning by the Commissioners and time for rebuttal by petitioners regarding such information. For the *in camera* portion of the hearing, the room will be cleared of all persons except those who have been granted access to BPI under a Commission APO service list in this investigation. See Commission rule 201.35(b) (19 CFR 201.35(b)). All those planning to attend the *in camera* portion of the hearing would should be prepared to present proper identification.

Authority: The General Counsel has certified, pursuant to Commission Rule 201.39 (19 CFR 201.39), that in her opinion, a portion of the Commission's hearing in Sulfur Dyes from China, India, and the United Kingdom, Inv. Nos. 731-TA-548, 550 & 551 (Final), may be closed to the public to prevent disclosure of business proprietary information.

Issued: January 8, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93-826 Filed 1-13-93; 8:45 am]

BILLING CODE 7020-02-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 32226]

Central Vermont Railway, Inc.; Acquisition Exemption; Canadian National Railway Co.

Central Vermont Railway, Inc. (CV), a wholly owned subsidiary of the Canadian National Railway Company (CN), has filed a verified notice of exemption to acquire: (1) CN's Rouse Point Subdivision between milepost 1.2, at the U.S.—Canadian border, and milepost 0.0, at Rouse Point, NY, and related trackage used to interchange traffic with the Delaware and Hudson Railway Company; and (2) CN's Swanton Subdivision between milepost 15.6 at East Alburg, VT, and milepost 18.7 at Alburg Springs, VT, at the U.S.—Canadian border. The transaction was to be consummated on December 31, 1992.

This is a transaction within a corporate family of the type specifically exempted from the necessity of prior review and approval under 49 CFR 1180.2(d)(3). It will not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family.

As a condition to use of this exemption, any employees affected by the transaction will be protected by the conditions set forth in New York Dock Ry.—Control—Brooklyn Eastern Dist., 360 I.C.C. 60 (1979).

Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Robert P vom Eigen and Richard J. Arsenault, Hopkins and Sutter, 888 Sixteenth Street, NW., Suite 700, Washington, DC 20006.

Decided: January 8, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93-879 Filed 1-13-93; 8:45 am]

BILLING CODE 7035-01-M

[Directed Service Order No. 1512]

Request for Directed Service—Authorizing the Great Western Railway Company d/b/a Platt Valley Railway To Operate Lines of Denver Railway, Inc.—Denver, Colorado—as Directed Carrier

AGENCY: Interstate Commerce Commission.

ACTION: Directed service order.

SUMMARY: Pursuant to 49 U.S.C. 11125(a), the Commission is authorizing The Great Western Railway Company (GWRC/PVR) d/b/a/ the Platt Valley Railway (PVR) to operate as a "Directed Rail Carrier" (DRC)—uncompensated and without Federal subsidy under 49 U.S.C. 11125(b)(5)—over the Denver Railway, Inc. (DRI) for a period of 60 days.

This unsubsidized and uncompensated directed service order is based on the representation by DRI that the railroad's cash position does not permit the acquisition of locomotive equipment at this time, and thereby its continued operation over its lines in order to relieve the present cessation of service. To assure continued service to shippers that are affected by the discontinuance of operations, the Commission is authorizing GWRC/PVR as DRC to provide directed service over DRI's two line segments in Denver, CO for 60 days. See 49 U.S.C. 11125(a) (1) and (3).

DATES: *Effective Date:* Directed Service Order No. 1512 shall become effective at 12:01 p.m., EST, January 8, 1993. GWRC/PVR shall notify DRI and the Commission of the date on which it commences operations under this authority.

Expiration Date: Unless otherwise modified by order of the Commission, Directed Service Order No. 1512 will expire at 11:59 a.m., March 9, 1993.

FOR FURTHER INFORMATION CONTACT: Bernard Gaillard (202) 927–5500 or Melvin F. Clemens, Jr. (202) 927–5538. [FAX (202) 927–5529] [TDD for hearing impaired: (202) 927–5721]

SUPPLEMENTARY INFORMATION: On December 9, and December 28, 1992, Rocky Mountain Pipe Company/Fagan Iron & Metal, Inc./Dry Wall Products of Denver, Inc./Christian Salvesen Inc./ Power Assist Co./Crystal Packaging, Inc./Firestone Building Products Company (shippers), filed requests with the Commission for directed service and in support of an authorization for GWRC/PVR to provide directed service over the lines of the Denver Railway, Inc. (DRI) in Denver, CO, due to an inability of DRI to serve shippers on its lines since November 1992, and an absence of regular service since April 1992.

DRI operates two line segments in an industrial area of Denver, CO, the Stockyards segment of 3.2 miles, which connects with the Burlington Northern Railroad Company (BN), and the Airlawn segment of 8.03 miles, which connects with the Denver and Rio Grande Western Railroad Company (DRGW). The two line segments do not connect, and, as operated by DRI, they must be operated with separate locomotives. However, in preparation for the directed service operation, GWRC/PVR has negotiated an agreement with DRGW for the replacement of a switch that will allow operation between the two line segments by a single locomotive and crew.

Pursuant to 49 U.S.C. 11125(a), the Commission may issue a directed service order for up to 60 days when it finds that a *rail carrier cannot transport traffic offered to it because —(1) its cash position makes its continuing operation impossible; (2) transportation has been discontinued under court order; or (3) it has discontinued transportation without obtaining a required certificate under 49 U.S.C. 10903,* (emphasis added). Any Commission order under these provisions requiring a carrier to provide directed service also requires Federal compensation to the DRC for those operations. However, this provision also allows the Commission to authorize a carrier to provide uncompensated directed service if the carrier is willing to accept that responsibility under those terms.

The Commission has determined, from shipper statements and statements by the DRI, and through its Office of Compliance and Consumer Assistance (OCCA), that the DRI's operations have been sporadic at best since last April 1992 due to the absence of suitable locomotive equipment with which to provide switching service to shippers. In April, DRI service was discontinued and then resumed temporarily on the basis of negotiations between DRI, the shippers, OCCA, and the Class I connections that resulted in the lease of locomotives to DRI by the Class I connections (BN & DRGW) for its operations. However, the leasing carriers have since terminated those leases and required the return of the leased locomotives, allegedly due to DRI's failure timely to compensate the carriers for the leased locomotives. Moreover, DRI has been unsuccessful in acquiring additional or replacement locomotive equipment from other sources, or in maintaining its owned equipment in acceptable condition to meet the Federal Railroad Administration's (FRA) requirements. As a result, OCCA was again notified on December 9, 1992, that service to DRI shippers had been terminated in early November 1992. As contemplated by the statute, this cessation of service without authority meets the requisite criteria for directed service. Moreover, the GWRC/PVR has indicated that, in response to DRI shippers, it is amenable to serving as DRC for an initial period of 60 days.

Under a directed service order, a DRC may voluntarily provide directed service without any subsidy or compensation from the Federal Government or the Commission. See *St. Louis S.W. Ry. Co.—Directed Service—Chicago*, 363 I.C.C. 1 (1980), and Directed Service Order No. 1504, *The New York, Susquehanna and Western Railway Corporation—Directed Service—The Delaware and Hudson Railway Company*, (not printed) served June 22, 1988.[1]

Considering DRI's inability to maintain sufficient equipment to provide continuous rail service, and its repeated cessation of operations without providing a suitable alternative, we find that DRI's current situation meets the statutory standards of 49 U.S.C. 11125(a) (1) and (3).

In view of the urgent need for continued rail service over lines of the DRI, this decision grants the shippers' request and authorizes GWRC/PVR to provide uncompensated directed service on the grounds that the cessation of service by DRI creates sufficient circumstances to meet the statutory requirements for such an order and serves the public interest.

The emergency nature of this situation compels us to conclude that advance public notice and hearings would be impractical and contrary to the immediate public interest in assuring the resumption of essential rail transportation services. Accordingly, we exercise our authority under 49 U.S.C. 11125(a) to waive advance public notice and hearings in the present circumstances.

Section 11125 allows the Commission to direct service for an initial period of not more than 60 days, with an option to extend the directed service period for an additional 180 days, if cause exists. We believe directed service authority to be necessary here at least for an initial 60 day period. During this 60 day period, any interested person may file comments seeking extension of this order for up to 180 days.

Terms and Conditions

Effective Date. Directed Service Order No. 1512 shall become effective at 12:01 p.m., January 8, 1993. GWRC/PVR shall be authorized to commence operations on this date and shall notify the

[1] Likewise, the Commission may authorize directed rail service without provision for compensation to the carrier over which service is directed. See *Kansas City Terminal Ry. Co.—Operate—Chicago R.I.& P.*, 360 I.C.C. 259 (1979).

Commission and DRI immediately that they have done so.

Expiration Date. Unless otherwise modified by the Commission, Directed Service Order No. 1512 will expire at 11:59 a.m., March 9, 1993.

Compensation. GWRC/PVR's authority under Directed Service Order No. 1512 is expressly conditioned upon its waiver of all compensation under 49 U.S.C. 11125(b)(5).

Track Safety. In accordance with 49 U.S.C. 11125(b)(2)(a), GWRC/PVR need not operate over any DRI line segment certified by the FRA as being unsafe or that it believes is unsafe for its operations.

Cars and operating equipment. In operating DRI's line, GWRC/PVR shall use its own cars and operating equipment unless otherwise authorized in subsequent orders of the Commission.

Employees. In providing service under this directed service order GWRC/PVR shall comply with the requirements of 49 U.S.C. 11125(b)(4) with respect to DRI operating employees.

Preservation of the DRI property. During the period of its operation of the DRI lines, GWRC/PVR shall be responsible for performing that degree of maintenance necessary to avoid further deterioration of the DRI lines and related facilities.

Rates. GWRC/PVR are authorized to act on behalf of DRI in all matters of transportation. Rates and charges applicable to the line shall be those in effect at the time GWRC/PVR commences operations over the respective segments. Inasmuch as the rates charged to DRI shippers are generally for switching services and are contained in the respective BN and DRGW tariffs, GWRC/PVR may not seek changes in those rates and charges except by application to the Commission under this authority. All revenues from such charges shall accrue to the account of GWRC/PVR, based on their respective operations during the effective period of this order, and shall not constitute assets of the DRI.

Liability for expenses. Any rehabilitation, operational, or other costs related to the respective operations is authorized shall be the sole responsibility and liability of GWRC/PVR. Any such costs or expenditures shall not in any way be deemed an obligation or liability of the United States Government. GWRC/PVR shall hold the United States Government harmless from any and all claims arising out of the authorized operations. However, GWRC/PVR shall not be liable for any payments, obligations, fines, fees, or other encumbrances or obligations assessed or assessable against DRI at the time directed service operations commence or during the period of directed service, nor shall GWRC/PVR be responsible to compensate the DRI or any other party of interest for the use of DRI lines during the directed service.

Operational difficulties. Any operational difficulties associated with the authorized operations of a specific DRI line segment shall be resolved by GWRC/PVR through negotiated agreement, or failing agreement, by the commission. Any resumption of operations by DRI during the effective period of this order may occur only after notice to the Commission and thirty (30) days notice to the DRC.

We find: 1. DRI has discontinued service over its lines without authority due to the unavailability of locomotive equipment, and has been given an opportunity to establish that it has the ability to restore full operations. DRI has failed to demonstrate why the Commission should not allow GWRC/PVR temporarily to provide continued rail service over those lines in its behalf, and as requested by its shippers, as a DRC.

2. In order to prevent further transportation and economic disruptions due to DRI's cessation of operations, it is necessary for the Commission to authorize GWRC/PVR to operate DRI's lines under 49 U.S.C. 11125 with a waiver of any compensation from the Federal Government.

3. Our action in this decision will not substantially impair the ability of GWRC/PVR to serve its own patrons adequately or to meet its outstanding common carrier obligations, and will insure continued rail service to affected shippers on the DRI. *See* 49 U.S.C. 11125(b)(2)(B).

This action will not significantly affect either the quality of the human environment or energy conservation.

It is ordered: 1. Based upon its agreement to do so without any form of compensation from the Federal Government, GWRC/PVR is authorized to enter upon and operate DRI's lines at Denver, CO pursuant to this voluntary directed service order under 49 U.S.C. 11125.

(a) Entry by GWRC/PVR may occur on the date this order is effective and may continue no later than the sixtieth day after the effective date of this decision.

(b) GWRC/PVR shall immediately notify the Commission and the parties to this proceeding, in writing, of the date on which it commences operations under this order.

(c) Operations under this order shall conform to the directions and conditions prescribed above and contained herein.

2. During this 60 day period, any interested person may file comments seeking extension of this order for up to 180 days.

3. All submissions filed in this proceeding should refer to DSO No. 1512 and should be sent to the Commission's headquarters at 12th Street and Constitution Avenue, NW., Washington, DC 20423. An original and 10 copies should be submitted.

4. The provisions of this decision shall apply to intrastate, interstate, and foreign commerce.

5. The Commission retains jurisdiction to modify, supplement, or reconsider this decision at any time.

6. Notice of this decision shall be given to the general public by publication in the **Federal Register.** This decision will also be served on the Federal Railroad Administration, the Association of American Railroads, the American Short Line Railroad Association, The Railway Labor Executives' Association, the DRI, and the GWRC/PVR.

7. This decision and order shall become effective at 12:01 p.m., January 8, 1993.

8. Unless otherwise modified by the Commission, this order will expire at 11:59 a.m., March 9, 1993.

Decided: January 8, 1993.

By the Commission, Chairman Philbin, Vice Chairman Simmons, Commissioners Phillips, McDonald, and Walden. Commissioner Walden did not participate in the disposition of this proceeding.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–876 Filed 1–13–93; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Shipyard Employment Standards Advisory Committee; Meeting

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice of meeting.

SUMMARY: Notice is hereby given that the Shipyard Employment Standards Advisory Committee (SESAC), established under the provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., App. I) and section 7(b) of the Occupational Safety and Health Act, 29 U.S.C. 656(b),

will convene on February 18, 1993, at 8:30 a.m., at the Sheraton Inner Harbor Hotel, 300 South Charles Street, Baltimore, Maryland, 21201. The meeting will adjourn on February 19, 1993, at approximately 12:30 p.m. The public is encouraged to attend.

The agenda is as follows:

I. Call to Order.
II. Review of transcripts of July 7–8, 1992 and September 2–3, 1992 meetings.
III. Discussion of the following standards:
(a) 29 CFR part 1915, subpart F, General Working Conditions.
(b) 29 CFR part 1915, subpart L, Electrical.
(1). Temporary Services (Power/Wiring)
(2). Scope and Application
(c) 29 CFR part 1915, subpart U, Surface Preparation and Preservation.
IV. New Business. Discussion of the following standards, as time permits.
(a) 29 CFR part 1915, subpart J, Ships Machinery and Piping Systems.
(b) 29 CFR part 1915, subpart S, Compressed Gas and Compressed Air Equipment.
(c) 29 CFR part 1915, subpart O, Occupational Health and Environmental Control.

Public Participation: Time permitting, the Committee will consider oral presentations relating to the agenda items. Persons wishing to address the Committee should submit a written request to Mr. Thomas Hall (address below) by the close of business, February 5, 1993. The request must include the name and address of the person wishing to appear, the capacity in which the appearance will be made, a short summary of the intended presentation, and an estimate of the amount of time needed. Disabled individuals wishing to attend should contact Mr. Thomas Hall at the address listed below to obtain appropriate accommodations. Individuals or organizations wishing to submit written statements should send 5 copies to the address below.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Hall, U.S. Department of Labor, Occupational Safety and Health Administration, Office of Information and Consumer Affairs, room N–3647, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 219–8617.

Signed at Washington, DC, this 8th day of January, 1993.

Dorothy L. Strunk,

Acting Assistant Secretary of Labor.

[FR Doc. 93–816 Filed 1–13–93; 8:45 am]

BILLING CODE 4510-26-M

NATIONAL LABOR RELATIONS BOARD

Appointments of Individuals To Serve as Members of Performance Review Boards

5 U.S.C. 4314(c)(4) requires that the appointments of individuals to serve as members of performance review boards be published in the **Federal Register**. Therefore, in compliance with this requirement, notice is hereby given that the individuals whose names and position titles appear below have been appointed serve as members of performance review boards in the National Labor Relations Board for the rating year beginning October 1, 1991 and ending September 30, 1992.

Name and Title

Robert E. Allen—Associate General Counsel, Advice
Harold J. Datz—Chief Counsel to Board Member
Yvonne T. Dixon—Acting Deputy General Counsel
Frederick Freilicher—Chief Counsel to Board Member
John E. Higgins—Solicitor
Susan Holik—Chief Counsel to Board Member
Gloria Joseph—Director of Administration
Nicholas E. Karatinos—Acting Associate General Counsel, Enf. Lit.
Barry J. Kearney—Deputy Associate General Counsel, Advice
Joseph E. Moore—Deputy Executive Secretary
W. Garrett Stack—Associate General Counsel, Operations-Management
Elinor H. Stillman—Chief Counsel to the Chairman
Berton B. Subrin—Director, Office of Representation Appeals
John C. Truesdale—Executive Secretary
Melvin J. Welles—Chief Administrative Law Judge

John C. Truesdale,

Executive Secretary.

[FR Doc. 93–950 Filed 1–13–93; 8:45 am]

BILLING CODE 7545-01-M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Materials Research; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Date and time: February 8–9, 1993; 8 a.m. to 4 p.m.

Place: Florida State University, Tallahassee, FL (February 8th) Los Alamos National Laboratory, Los Alamos, NM (February 9th).

Type of Meeting: Closed.

Contact Person: Dr. Adriaan M. de Graef, Deputy Division Director, Division of Materials Research, room 408, National Science Foundation, 1800 G St. NW., Washington, DC 20550. Telephone: (202) 357–9794; FAX (202) 357–7959.

Purpose of Meeting: To provide advice and recommendations concerning the continued support for the National High Magnetic Field Laboratory (NHMFL) being established by Florida State University, the University of Florida, and Los Alamos National Laboratory.

Agenda: To review and evaluate the progress report and proposal for continued funding for the NHMFL.

Reason for Closing: The progress report being reviewed includes information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposal. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: January 11, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–847 Filed 1–13–93; 8:45 am]

BILLING CODE 7555-01-M

Special Emphasis Panel in Networking and Communications Research and Infrastructure; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Name: Special Emphasis Panel in Networking and Communications Research and Infrastructure.

Date and Time: February 1–3, 1993; 8:30 a.m. to 5 p.m.

Place: Room 536, National Science Foundation, 1800 G Street, NW., Washington, DC 20550.

Type of Meeting: Closed.

Contact Person: Dr. Aubrey Bush, Networking and Communications Research Program, National Science Foundation, room 416, Washington, DC 20550 (202 357–9717).

Purpose of Meeting: To provide advice and recommendations concerning proposals submitted to NSF for financial support.

Agenda: To review and evaluate proposals submitted to the Networking and Communications Research Program.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries, and personal information concerning individuals associated with the proposals.

These matters are exempt under 5 U.S.C. 552 b. (c) (4) and (6) of the Government in the Sunshine Act.

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Dated: January 11, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–849 Filed 1–13–93; 8:45 am]

BILLING CODE 7555–01–M

Expert Panel of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET); Committee on Education and Human Resources (CEHR); Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting.

Dates and Times: February 15, 1993, 8:15 a.m. to 6 p.m., February 16, 1993, 8:15 a.m. to 3 p.m.

Place: Washington DC. Call contact person for location.

Type of the Meeting: Open

Contact Person: Mr. James S. Dietz, Program Analyst, the Division of Research, Evaluation and Dissemination, the Directorate of Human Resources, National Science Foundation, room 1249, 1800 G Street, NW., Washington, DC 20550. Telephone: (202) 357–7425.

Minutes: May be obtained from the contact person listed above.

Purpose of the Meeting: The National Science Foundation acting through the FCCSET/CEHR established an Expert Panel to review the status of Federal Science, Mathematics, Engineering, and Technology (SMET) programs of member agencies. The Expert Panel provides advice and recommendations to FCCSET/CEHR on the status of Federal SMET education programs.

Agenda: Mission Discussion.

Panel Discussion on Data Update Mission

Subpanels Discussion for K–12 Programs, Program Evaluation and Undergraduate Programs

Discussion on Reform in Science Education and the Federal Role

Subpanel Discussion on Graduate/Public Literacy Programs Roundtable Panelists Report on Program Topics Summary Discussions and Closure

Dated: January 11, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–848 Filed 1–13–93; 8:45 am]

BILLING CODE 7555–01–M

NUCLEAR REGULATORY COMMISSION

Availability of Staff Technical Position on Geologic Repository Operations Area Underground Facility Design—Thermal Loads

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

SUMMARY: The Nuclear Regulatory Commission is announcing the availability of NUREG–1466, "Staff Technical Position (STP) on Geologic Repository Operations Area Underground Facility Design—Thermal Loads.".

ADDRESSES: Copies of NUREG–1466, including the staff disposition of comments, can be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013–7082. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy of NUREG–1466 is also available for public inspection and/or copying at the NRC Public Document Room, 2120 L Street (Lower Level), NW., Washington, DC 20555.

FOR FURTHER INFORMATION CONTACT: Anne E. Garcia, Repository Licensing and Quality Assurance Project Directorate, Division of High-Level Waste Management, Office of Nuclear Material Safety and Safeguards, Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, MD 20852. Telephone 301/504–2438.

SUPPLEMENTARY INFORMATION: The purpose of this STP is to provide the U.S. Department of Energy (DOE) with a methodology acceptable to the NRC staff for demonstrating compliance with 10 CFR 60.133(i). The Nuclear Regulatory Commission staff's position is that DOE should develop and use a defensible methodology to demonstrate the acceptability of a geologic repository operations area (GROA) underground facility design. The staff anticipates that this methodology will include evaluation and development of appropriately coupled models, to account for the thermal, mechanical, hydrological, and chemical processes that are induced by repository-generated thermal loads. With respect to 10 CFR 60.133(i), the GROA underground facility design: (1) Should satisfy design goals/criteria initially selected, by considering the performance objectives; and (2) must satisfy the performance objectives 10 CFR 60.111, 60.112, and 60.113. The methodology in this STP suggests an iterative approach suitable for the underground facility design.

On August 2, 1991, the Nuclear Regulatory Commission published, in the **Federal Register**, the "Notice of Availability" for the draft STP and solicited public comments (see 56 *FR* 33478). Approximately 50 comments were received from two different parties. On March 17, 1992, the staff conducted a technical exchange with DOE, the State of Nevada, and DOE program participants to discuss the intent of the draft STP. Following the March 1992 technical exchange, and a review of the public comments, significant changes and clarifications were incorporated into the revised STP. Staff responses to the public comments were documented separately as appendix D to NUREG–1466.

On July 29, 1992, the NRC staff briefed the Advisory Committee on Nuclear Waste (ACNW) on the revised STP and, as a result, the staff received a number of comments. The staff's responses to the ACNW's comments are documented separately, as Appendix E to NUREG–1466.

Dated at Rockville, Maryland this 8th day of November, 1992.

For the Nuclear Regulatory Commission,

Robert M. Bernero,

Director, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93–913 Filed 1–13–93; 8:45 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–31697; File No. SR–CBOE–92–05]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to the Addition of New Strike Prices for Index Options

January 7, 1993.

I. Introduction

On February 7, 1992, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") submitted to the Securities and Exchange Commission ("SEC" or "Commission"), pursuant to section 19(b) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] a proposal to enable the Exchange to list additional strike prices for Exchange-traded index options. Specifically, under the proposal the CBOE may add up to four strike prices above and below the current index price when a new options series is opened, up to five strike prices above and below the current index price when the current index price reaches an existing strike price, and up to six strike prices above and below the current index price wher unusual market conditions warrant.[3]

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b–4 (1991).

[3] The CBOE originally proposed that the Exchange may add up to four strike prices when a new series is opened, up to six strike prices when the current index price reaches an existing strike price, and up to seven strike prices when unusual

Notice of the proposed rule change was published for comment and appeared in the Federal Register on May 12, 1992.[4] Three comments were received in connection with the proposal.[5] This order approves the proposal.

II. Description of the Proposal

Under existing Interpretation .01 to CBOE Rule 24.9, three situations permit the Exchange to add additional strike prices for index options: (1) When a new series of index option contracts with a new expiration month are opened; (2) when the value of the index underlying a class of index options reaches an existing strike price; and (3) when unusual market conditions exist.[6] Currently, two strike prices above and below the current index price may be added when a new expiration month is added, and up to three strike prices above and below the current index price may be added when the index price reaches an existing strike price. In addition, up to four strike prices above and below the current index price may be added in unusual market conditions.

The CBOE proposal would permit the Exchange to increase the number of strike prices available for Exchange-trade index options in the following manner:

(1) When a new series of index option contracts with a new expiration cycle month are opened for trading, four strike prices above and below the current index price may be added;

(2) When the value of the index underlying a class of index options reaches a strike price, the Exchange may add one or more additional strike prices such that there are up to five strike prices above and five strike prices below the strike price which has been reached; and

(3) In unusual market conditions, the Exchange may add additional series of index option contracts up to six strike prices above and six strike prices below the current index price.

As described above, the CBOE proposes to increase the number of strike prices available for trading, which, the Exchange argues, will enhance liquidity, market depth and open interest. The CBOE indicates that the additional strike prices are necessitated by current market conditions and customer demand. In addition, the Exchange believes that additional strike prices for its index option contracts will provide increased flexibility for market participants, thereby, permitting options positions to be more finely tailored to achieve their intended investment objectives.

III. Discussion

The Commission finds that the CBOE proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6. Specifically, the Commission believes that the proposal is consistent with section 6(b)(5) of the Act because, by offering investors more flexibility in the trading of index options, it will protect investors and further the public interest by allowing them to establish options positions that are better tailored to meet their investment objectives.

The Commission also believes that the CBOE proposal strikes a reasonable balance between the Exchange's needs to accommodate market participants by offering a wide array of investment opportunities and the need to avoid excessive proliferation of options series. The Commission notes that the CBOE proposal permits a relatively small increase in the absolute number of index options series that may be outstanding at any one time. Specifically, the proposal permits the introduction and continued listing of only two additional strikes or options series above those currently allowed under the CBOE's rules and policies. The proposal also sets the maximum permissible number of strike prices, with the Exchange retaining discretion to list fewer strikes than allowed. Finally, CBOE rules allow the Exchange to delist an options series with no open interest. Therefore, if the CBOE lists an option series in anticipation of a large market movement that does not materialize, the CBOE would be able to delist such series if it attracts no trading interest.

In addition, based on representations from the Options Price Reporting Authority ("OPRA"), the Commission believes that OPRA will have adequate computer processing capacity to accommodate the additional strike prices. Specifically, OPRA represented that "'[t]he addition of four, six and seven OEX series as proposed in CBOE's rule filing SR-CBOE-92-05 will have no material impact on OPRA's capacity.'"[7] The CBOE also represents that its current system capacity is sufficient to meet the expected demands of the additional strike prices.[8] Nevertheless, the Commission requests that the Exchange monitor the volume of additional options series listed as a result of this rule change and the effect of these additional series on the capacity of the CBOE's, OPRA's and vendors' automated systems.[9]

Lastly, as reflected in the comment letters received in connection with the proposal, there is evidence that sufficient demand exists for index options series that are four strike prices away from the market.[10] Accordingly, we do not anticipate that the new strike prices likely will diminish the liquidity in Exchange-traded OEX index options.[11] In addition, in light of the increased short-term volatility of stock indexes due to market conditions, the Commission believes the CBOE's proposal will help to ensure that strike

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market conditions warrant. The Exchange subsequently amended the proposal as noted above. See letter from Joanne Moffic-Silver, Associate General Counsel & Chief Enforcement Attorney, CBOE, to Sharon Lawson, Assistant Director, SEC, dated October 6, 1992 ("Amendment No. 1"). Because this amendment is minor in nature it has not been separately noticed for comment.

[4] See Securities Exchange Act Release No. 30668 (May 6, 1992), 57 FR 20306.

[5] Prior to submitting the proposal to the Commission, the CBOE received three comment letters on the need to increase strike prices. The commentators focused on the need of market participants to have additional strike prices available in OEX index options, and, therefore, these commentators support the CBOE's initiatives to enhance its ability to add additional strike prices. *See* letters from Richard L. Spraker, Senior Vice President, Investments, Bateman, Eichler, Hill & Richards, to Jack Callahan, Chairman, OEX Floor Procedure Committee, CBOE, dated August 9, 1991 and December 24, 1991; and letter from Louis Briegel, Senior Vice President/Financial Consultant, Shearson Lehman Brothers, to Jack Callahan, Index Floor Procedures, CBOE, dated October 31, 1991.

[6] Interpretation .01 to CBOE Rule 24.9 provides that the strike price interval for OEX options with a strike price above 200 is $5.

[7] See Memorandum from Joseph P. Corrigan, Executive Director, OPRA, to Joanne Moffic-Silver, CBOE, dated August 20, 1992 which is enclosed in a letter from Joanne Moffic-Silver, Associate General Counsel & Chief Enforcement Attorney, CBOE, to Thomas Gira, Branch Chief, Division of Market Regulation, SEC, dated August 21, 1992 ("CBOE Letter").

[8] See Memorandum from Kruno Hultzingh, Executive Vice President, Systems Division, CBOE, to Joanne Moffic-Silver, Associate General Counsel & Chief Enforcement Attorney, CBOE, dated August 21, 1992 which is enclosed in the CBOE Letter, *supra* note 7.

[9] See note 11, *infra*.

[10] The level of the OEX Index has substantially increased from the date that the Commission originally approved the CBOE's strike price policy. See Securities Exchange Act Release No. 21794 (February 26, 1985), 50 FR 8091. In particular, the OEX Index was at 176.12 in March, 1985 and now stands at 395.75 (over a 50% increase). Accordingly, the increase in the OEX Index value supports the potential listing of additional strikes by the Exchange.

[11] We note that the CBOE has stated that it may want the Commission to consider additional increases in allowable strikes. In this regard, the CBOE has stated that it will monitor the impact of the additional strikes over the next six months and will report to the Commission the results including any adverse consequences, and the impact on the orderliness of opening rotations. The report should also specifically include any adverse impact on the liquidity of outstanding strikes in OEX index options in addition to the effects on capacity as described above.

prices reasonably related to the market and attractive to investors are available. The ability of the CBOE to add additional strike prices as market conditions dictate will enhance the flexibility of the Exchange in response to varying economic and market events.

In sum, the Commission finds the CBOE proposal should not result in a substantial increase in the number of index options series outstanding, and should help to ensure the constant availability of various stock index option that are attractive to investors. For these reasons, the Commission finds that the benefits to be derived from this proposal in accommodating market participants' investment needs and objectives outweigh the possible adverse effects on market liquidity due to the dispersion of trading interest in more options series.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[12] that the proposed rule change (SR-CBOE-92-05), is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[13]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93-831 Filed 1-13-93; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

Office of Defense Trade Controls

[Public Notice 1753]

Munitions Exports Involving Armour of America or Arthur G. Schreiber

AGENCY: Office of Defense Trade Controls, Department of State.

ACTION: Notice.

SUMMARY: Notice is hereby given that all existing licenses and other approvals, granted pursuant to section 38 of the Arms Export Control Act, that authorize the export or transfer by, for or to, Armour of America, Inc. and any of its subsidiaries or associated companies, and Arthur G. Schreiber, of defense articles or defense services are suspended. In addition, it shall be the policy of the Department of State to deny all export license applications and other requests for approval involving, directly or indirectly, the above cited entities. This action also precludes the use in connection with such entities of any exemptions from license or other approval included in the International Traffic in Arms Regulations (ITAR, 22 CFR parts 120–130).

EFFECTIVE DATE: December 31, 1992.

FOR FURTHER INFORMATION CONTACT: Clyde G. Bryant, Jr., Chief, Compliance Analysis Division, Office of Defense Trade Controls, Center for Defense Trade, Bureau of Politico-Military Affairs, Department of State (703:875-6650).

SUPPLEMENTARY INFORMATION: The Department of State has a reasonable basis to believe that Armor of America, Inc. and/or Arthur G. Schreiber, have violated section 38 of the Arms Export Control Act (AECA, 22 U.S.C. 2778) and its implementing regulations, the ITAR (22 CFR parts 120–130) by attempting to export from the United States defense articles without the requisite approval of the Department of State (22 CFR 127.1(a)) and/or by using an export control document containing a false statement or misrepresenting or omitting a material fact for the purpose of exporting defense articles (22 CFR 127.2(a)).

On December 31, 1992, the Department of State suspended all licenses and other written approvals (including manufacturing license and technical assistance agreements) concerning exports of defense articles and defense services to Armour of America, Inc., Los Angeles, California, and Arthur G. Schreiber, President and Chief Executive Office of Armour of America, Inc.

This action has been taken pursuant to sections 38 and 42 of the AECA (22 U.S.C. 2778 & 2791) and section 126.7(a)(2) of the ITAR (22 CFR 126.7(a)(2)). It will remain in force until rescinded.

Exceptions may be made to this policy on a case-by-case basis at the discretion of the Office of Defense Trade Controls. However, such an exception would be granted only after a full review of all circumstances, paying particular attention to the following factors: whether an exception is warranted by overriding foreign policy or national security interests; whether an exception would further law enforcement concerns; and whether other compelling circumstances exist which are not inconsistent with the foreign policy or national security interests of the United States, and which do not conflict with law enforcement concerns.

Dated: December 31, 1992.

William B. Robinson,

Director, Office of Defense Trade Controls, Bureau of Politico-Military Affairs, Department of State.

[FR Doc. 93-907 Filed 1-13-93; 8:45 am]

BILLING CODE 4710-25-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE-93-3]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA) (DOT).

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption (14 CFR part 11), this notice contains a summary of certain petitions seeking relief from specified requirements of the Federal Aviation Regulations (14 CFR chapter I), dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before February 2, 1993.

ADDRESSES: Send comments on any petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rule Docket (AGC-10), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-10), room 915G, FAA Headquarters Building (FOB 10A), 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-3132.

FOR FURTHER INFORMATION CONTACT: Mrs. Jeanne Trapani, Office of Rulemaking (ARM-1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-7624.

[12] 15 U.S.C. 78s(b)(2) (1982).

[13] 17 CFR 200.30-3(a)(12) (1991).

This notice is published pursuant to paragraphs (c), (e), and (g) of § 11.27 of part 11 of the Federal Aviation Regulations (14 CFR part 11).

Issued in Washington, DC, on January 6, 1993.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Petitions for Exemption

Docket No.: 26734.
Petitioner: Shannon Engineering, Inc.
Sections of the FAR Affected: 14 CFR 91.9(a) and 91.531(a)(1).
Description of Relief Sought: To extend the termination date of Exemption No. 5517, which expires September 30, 1994, and which allows a reduction in the 500 hours required as pilot in command or copilot of turbojet airplanes in exchange for turbo-powered flight time.

Dispositions of Petitions

Docket No.: 25351.
Petitioner: USAir.
Sections of the FAR Affected: 14 CFR 121.378 and 121.378(a).
Description of Relief Sought/ Disposition: To allow USAir to utilize certain foreign original equipment manufacturers and related repair facilities to perform maintenance, preventive maintenance, and alterations of the components, parts, and appliances that are produced by these foreign manufacturers and used on the British Airspace, BAC–111, BAE–146, Boeing B–737–300, B–737–400, B–757, B–767–200ER, Fokker F–28, and F–100 aircraft operated by USAir.

Grant, December 28, 1992, Exemption No. 5005C

Docket No.: 26961.
Petitioner: Regional Airline Association.
Sections of the FAR Affected: 14 CFR 91.205(b)(11).
Description of Relief Sought/ Disposition: To permit the operation of multi-engine turboprop airplanes without pyrotechnic signaling devices when operated over water beyond power-off gliding distance from shore.

Denial, December 24, 1992, Exemption No. 5581

[FR Doc. 93–804 Filed 1–13–93; 8:45 am]
BILLING CODE 4910–13–M

RTCA, Inc., Fifth Meeting of Special Committee 172; Future Air-Ground Communications in the VHF Aeronautical Band (118–137 MHZ); Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., appendix I), notice is hereby given for Special Committee 172 meeting to be held January 26–29, 1993, at the RTCA conference room, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036 commencing at 9:30 a.m.

The agenda for this meeting is as follows:
(1) Chairman's Remarks;
(2) Approval of the fourth meeting's minutes;
(3) Working Groups Reports:
(a) VHF Communications System Recommendations Working Group (WG–1); and
(b) VHF Data Radio Signal-in Space MASPS Working Group (WG–2);
(4) Technical presentations;
(5) Working Group Sessions. Review Current Draft Material;
(6) Back in plenary:
(a) Review Working Group Progress; and
(b) Task Assignment;
(7) Other Business; and
(8) Date and place of next meeting.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC 20036; (202) 833–9339. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 7, 1993.

Joyce J. Gillen,

Designated Officer.

[FR Doc. 93–808 Filed 1–13–93; 8:45 am]
BILLING CODE 4910–13–M

RTCA, Inc.; First Meeting of Special Committee 177, Testing Criteria and Guidance Relative to Portable Electronic Devices Carried on Board Aircraft; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., Appendix I), notice is hereby given for Special Committee 177 meeting to be held January 26, 1993, at the RTCA conference room, 1140 Connecticut Avenue, NW., suite 1020, Washington, DC 20036, commencing at 9:30 a.m.

The agenda for this meeting is as follows:
(1) Introductory Remarks;
(2) Develop proposed terms of reference. Review recommendation of ad hoc group;
(3) Develop initial work program and determine milestones;
(4) Nominate recommended Special Committee 177 Chairman;
(5) Assignment of tasks;
(6) Other business; and
(7) Date and place of next meeting.

Attendance is open to the interested public but limited to space available. With the approval of the Chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RCTA Secretariat, 1140 Connecticut Avenue, NW., suite 1020, Washington, DC 20036; (202) 833–9339. Any member of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on January 7, 1993.

Joyce J. Gillen,

Designated Officer.

[FR Doc. 93–809 Filed 1–13–93; 8:45 am]
BILLING CODE 4910–13–M

Intent to Rule on Application to Impose and Use the Revenue From a Passenger Facility Charge (PFC) at Chautauqua County/Jamestown Airport, Jamestown, NY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to rule on application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Chautauqua County/Jamestown Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 16, 1993.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Manager New York Airports District Office, 181 South Franklin Avenue, room 305, Valley Stream, New York, 11581. In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Kenneth B. Brentley, Manager of Airports for the County of Chautauqua, New York, at the following address: County of Chautauqua, P.O. Box 51, Falconer, New York 14733.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the County of Chautauqua, New York under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Philip Brito, Manager New York Airports District Office, 181 South Franklin Avenue, room 305, Valley Stream, New York, 11581 (718–553–1882). The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and use the revenue from a PFC at Chautauqua County/Jamestown Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On November 18, 1992, the FAA determined that the application to impose and use the revenue from a PFC submitted by the County of Chautauqua was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than March 2, 1993.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00.

Proposed charge effective date: December 1, 1992.

Proposed charge expiration date: December 30, 1996.

Total estimated PFC revenue: $447,810.

Brief description of proposed projects: The PFC funds will be utilized to fund the local share of the following proposed AIP projects.

—Terminal Building expansion and reconstruction
—Overlay commuter ramp
—Extend taxiway D
—Snow Removal Equipment
—Rebuilt entry road
—Overlay runway 7/25
—Remove obstructions (impose only)

Class or classes of air carriers which the public agency has requested not be required to collect PFCs: All air taxi/commercial operators filing form 1800–31. Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA Regional Airports office located at: Fitzgerald Federal Building, John F. Kennedy International Airport, Jamaica, New York, 11430.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Chautauqua County/Jamestown Airport.

Issued in Jamaica, New York on December 29, 1992.

Peter A. Nelson,

Assistant Manager, Airports Division, Eastern Region.

[FR Doc. 93–807 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–13–M

Federal Railroad Administration

Petition for Exemption or Waiver of Compliance; Michigan Shore Railroad et al.

In accordance with 49 CFR 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received requests for exemptions from or waivers of compliance with a requirement of its safety standards. The individual petitions are described below, including the party seeking relief, the regulatory provisions involved, and the nature of the relief being requested.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number RSGM–92–1) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. Communications received before February 22, 1993 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) in room 8201, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

The individual petitions seeking an exemption or waiver of compliance are as follows:

Michigan Shore Railroad

[Waiver Petition Docket Number RSGM–92–1]

In early 1992 the Michigan Shore Railroad (MS) was granted a waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for two locomotives under Docket Number RSGM–92–1. The MS states there have been no incidents involving glazing and have requested a waiver for one additional locomotive which is based at Muskegon, Michigan.

Mid Atlantic Railroad Company

[Waiver Petition Docket Number RSGM 92–21]

The Mid Atlantic Railroad Company (MRR) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for one passenger car. The car, which was built in 1955/56, is to be used for excursions, special events and school field trips. The MRR operates 76.5 miles of track between Mullins, South Carolina and Whiteville, North Carolina and between Chadbourn, North Carolina and Conway, South Carolina. Speed does not exceed 25 mph.

Texas Parts and Wildlife Department

[Waiver Petition Docket Number RSGM–92–24]

The Texas Parks and Wildlife Department (TPWX) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for three locomotives. The locomotives are used in road and yard service between Rusk and Palestine, Texas, a distance of approximately 25.5 miles. The railroad states that the area is sparsely populated and there has never been any vandalism. The locomotives are currently equipped with 1/4-inch shatterproof safety glass.

Pacific Rail Services

[Waiver Petition Docket Number RSGM–92–25]

Pacific Rail Services (PRSX) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for two locomotives. The locomotives are used in switching service at the South Intermodal Yard in Tacoma, Washington. PRS crosses one intersection with the remainder of the tracks being on private property.

San Francisco Belt Railroad

[Waiver Petition Docket Number RSGM–92–26]

Kyle Railways, Inc., on behalf of their subsidiary San Francisco Belt Railroad (SFBR), seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for two locomotives. The SFBR operates approximately 15 miles of track in an industrial area of San Francisco. Approximately 5 miles of the track is located in an interchange yard, 2 miles

in a storage yard and the remaining 8 miles are spur tracks running into three separate piers on San Francisco's southern waterfront. The railroad states there have been no incidents involving glazing and the expense of installing certified glazing would be an undue burden.

National Railroad Passenger Corporation

[Waiver Petition Docket Number H–92–8]

The National Railroad Passenger Corporation (Amtrak) seeks a one year test waiver of compliance from certain provisions of the Power Brake and Drawbars Regulations (49 CFR part 232). Amtrak is requesting that it be permitted to extend the clean, oil, test and stencil (COT&S) period from 36 months to 48 months on 73 Bi-Level passenger cars, 21 of which are "Cab Cars", owned by the Joint Powers Board's Peninsula Rail Commute Operation. The cars, which were built in the mid-1980's, are managed and maintained by Amtrak and operate in commuter service between San Francisco and San Jose, California.

The cars are equipped with 36–C type brake equipment and are in relatively light service. Each car travels about 40,000 miles per year at speeds up to 70 mph. The cars are captive to this service and are tested prior to each trip. Amtrak feels that the COT&S period of three years is too short for this service and proposes to extend the COT&S requirement to four years as long as the failure rate of any of the following air brake components does not exceed 5%: 26–C Service Portion; Emergency Portion; J–1 Relay Valve; No. 8 Vent Valve; E–3 Brake Application Valve; and B–3–B Conductors Valve.

Cab car equipment would continue to be maintained under 49 CFR part 229. Amtrak proposes that all records for the test cars would be maintained in San Francisco and be available for FRA review at any time.

Issued in Washington, DC, on January 8, 1993.

Phil Olekszyk,

Deputy Associate Administrator for Safety.

[FR Doc. 93–897 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–06–M

Petition for Exemption or Waiver of Compliance; Parr Terminal Railroad et al.

In accordance with 49 CFR 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received requests for exemptions from or waivers of compliance with a requirement of its safety standards. The individual petitions are described below, including the party seeking relief, the regulatory provisions involved, and the nature of the relief being requested.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Wavier Petition Docket Number RSGM–89–11) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW., Washington, DC 20690. Communications received before February 22, 1993 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) in room 8201, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

The individual petitions seeking an exemption or waiver of compliance are as follows:

Parr Terminal Railroad

[Waiver Petition Docket Number RSGM–89–11]

In 1990 the Parr Terminal Railroad (PRT) was granted a waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for locomotive PRT 1402 under Docket Number RSGM–89–11. The PRT states there have been no incidents involving glazing and has requested a waiver for two additional locomotives.

Mobil Mining and Minerals Company

[Waiver Petition Docket Number RSGM 92–5]

The Mobil Mining and Minerals Company (ZMMC) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for one locomotive. The locomotive is used between their phosphate rock mine and processing facility at Nichols, Florida.

Wisconsin Trolley Museum

[Waiver Petition Docket Number RSGM–92–16]

The Wisconsin Trolley Museum (WTMX) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for one locomotive. The electric locomotive is used to move 20 to 30 carloads of freight per year. The museum states their has been no vandalism in the 9 years they have been associated with the railroad.

Central of Tennessee Railway and Navigation Company

[Wavier Petition Docket Number RSGM–92–17]

The Central of Tennessee Railway and Navigation Company, Inc. (CTRN) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for one locomotive. The CTRN operates approximately 28 miles of track between Nashville and Ashland City, Tennessee. The locomotive was built in 1955 and rebuilt in February, 1991. The railroad states there have been no incidents or vandalism related to glazing.

Utah Central Railway Company

[Waiver Petition Docket Number RSGM–92–18]

The Utah Central Railway Company (UCRY) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for two locomotives. The locomotives operate in an industrial park at Ogden, Utah at a maximum speed of 10 mph. One locomotive is used five days per week and the other on an as needed basis. Round trip mileage each day is approximately 10 miles. The railroad reports there have been no incidents of vandalism relating to glazing.

PL&W Railroad, Inc.

[Waiver Petition Docket Number RSGM 92–19]

The PL&W Railroad, Inc. (PLWX) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for one locomotive. The previous owner of the locomotive, Youngstown and Southern Railway Company, had been granted Waiver RSGM–89–17. The primary use for the locomotive will be for tourist excursions with occasional backup for freight operations. The locomotive will operate in rural and suburban areas of western Pennsylvania and eastern Ohio.

Nicolet Badger Northern Railroad

[Waiver Petition Docket Number RSGM 92–20]

The Nicolet Badger Northern Railroad, Inc. (NBNR) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for four passenger cars which are owned by Golden State Ltd. and Great Lakes Central, Ltd. The cars will be operated in excursion service on the NBNR at a maximum speed of 30 mph. The railroad states there is potential to use the equipment on portions of the Wisconsin Central. The areas to be included are northern Wisconsin, upper Michigan and eastern Wisconsin.

St. Louis and Chain of Rocks Railroad

[Waiver Petition Docket Number RSGM–92–22]

The St. Louis and Chain of Rocks Railroad (SLCR) seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR part 223) for two locomotives, two passenger cars and two cabooses. Free excursion trains are operated on the three mile museum railroad on one Sunday per month between April and October. Maximum speed is 5 mph through the city riverfront park.

Smoky Hill Railway and Historical Society

[Waiver Petition Docket Number PB–92–2]

The Smoky Hill Railway and Historical Society (SHRX) seeks a permanent waiver of compliance with certain provisions of the Railroad Power Brakes and Drawbars Regulations, 49 CFR part 232. The SHRS seeks relief from the present requirements for clean, oil, test and stencil (COT&S) of passenger car air brake equipment as covered in § 232.17(b)(2). The majority of their cars are equipped with U–12 valves which must be cleaned every 15 months at a minimum expense of $500 per car. There is only one known source for this repair work. Newer air brake valves can be cleaned locally at less expense. The equipment operates in captive service on a museum/tourist railroad at speeds less than 20 mph. The railroad states that an initial terminal air brake test and inspection is performed on the cars each day they are in use.

National Railroad Passenger Corporation

[Waiver Petition Docket Number PB–92–3]

The National Railroad Passenger Corporation (Amtrak) seeks a permanent waiver of compliance with certain provisions of the Power Brake and Drawbars Regulations (49 CFR part 232). Amtrak plans to extend Trains 1 and 2, which presently run from Los Angeles to New Orleans, to Miami, Florida. This extends the trip by 1040 miles to a total of 3073. 1000-mile inspections are currently performed at El Paso and San Antonio, Texas. The distance from Los Angeles to El Paso is 855 miles, from El Paso to San Antonio is 605 miles and San Antonio to New Orleans is 573 miles. When the trip is extended to Miami, a 1000-mile inspection will be performed at Mew Orleans. the distance from New Orleans to Miami is 1040 miles.

Amtrak is requesting a waiver of the 1000-mile inspection requirement (49 CFR 232.12(b)) for the New Orleans to Miami segment of the trip. This will exceed the requirement by 40 miles. Amtrak feels that the three inspections will be adequate. Service is expected to begin in early spring, 1993.

Issued in Washington, DC, on January 8, 1993.

Phil Olekszyk,

Deputy Associate Administrator for Safety.

[FR Doc. 93–899 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–06–M

Petition for Waivers of Compliance; Wheeling and Lake Erie Railway Co.

In accordance with 49 CFR 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received a request for waivers of compliance with certain requirements of the Federal railroad safety laws and regulations. The individual petitions are described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested and the petitioner's argument in favor of relief.

Wheeling and Lake Erie Railway Company

[Waiver Petition Docket Numbers LI–92–6 and RSOP–92–1]

The Wheeling and Lake Erie Railway Company (W&LE) requests waivers of compliance with certain provisions of 49 CFR part 229, Locomotive Safety Standards, and 49 CFR part 218, Railroad Operating Practices. The W&LE is testing a number of prototype locomotives equipped with a remote control system manufactured by Vectron Corporation, called the VR 10 Radio Controls for Locomotives. The W&LE states that use of the VR 10 will result in reduced operating expenses without compromising the safety of the operation.

The VR 10 system contains several components, which includes a battery operated, portable transmitter, measuring 8 inches by 6 inches by 5.5 inches, weighing 6½ pounds, and is worn by the operator. The VR 10 system provides the following functions: Seven step throttle; Five step independent brake; Three speed automatic brake; Horn, bell, and sander controls; Headlight control; Tilt switch/Tilt bypass control; Electronic deadman; and other features available as options.

The system also contains two locomotive mounted electronic and pneumatic control panels, which can be installed in 8 to 10 days, according to the manufacturer. When the locomotive is being operated from the remote control transmitter, the operator may be at any location either on the train or on the ground. Positive visual conformation of the radio control commands is provided by a feedback system using two banks of four colored lights secured to the roof of the locomotive above the cab front windows. The W&LE Operator's Manual/Remote Control Locomotives fully describes the operational and feedback functions and signals of the VR 10 system.

The W&LE states that currently there are no Federal Railroad Administration regulations to govern operating locomotives from outside the [locomotive] cab. Section 229.5(b) defines "cab" as that portion of the [locomotive] superstructure designed to be occupied by the crew operating the locomotive. The railroad says that this definition is used in a number of regulations with the location within a "cab" of various controls, gauges, alarms, and cutoff devices. These requirements are complied with when the locomotive is being operated with the engineer occupying his normal position in the cab. When the locomotive is operated with a remote control from outside the "cab", the regulations are not being complied with.

It is because of this noncompliance when the VR 10 system is being used to remotely control a locomotive that the W&LE is petitioning the FRA for a waiver from the following Locomotive Safety Standards regulations:

Section 229.13 Control of locomotives.

Except when a locomotive is moved in accordance with § 229.9, whenever two or more locomotives are coupled in remote or multiple control, the propulsion system, the sanders, and the power brake system of each locomotive shall respond to control from the "cab" of the controlling locomotive. If a dynamic brake or regenerative brake system is in use, that portion of the

system in use shall respond to control from the "cab" of the controlling locomotive.

Section 229.53 Brake gauges.

All gauges used by the engineer for braking the train or locomotive shall be located so that they may be conveniently read from the engineer's usual position in the "cab". An air gauge may not be more than three pounds per square inch in error.

Section 229.93 Safety cut-off device.

The fuel line shall have a safety cut-off device that—

(a) Is located adjacent to the supply tank or in another safe location.

(b) Closes automatically when it trips and can be set without hazard; and

(c) Can be hand operated from clearly marked locations, one inside the "cab" and one on each exterior side of the locomotive.

Section 229.115 Slip/slide alarms.

(a) Except from MU locomotives, each locomotive in road service shall be equipped with a device that provides an audible or visual in the "cab" of either slipping or sliding wheels on powered axles under power. When two or more locomotives are coupled in multiple or remote control, the wheel slip/slide alarm of each locomotive shall be shown in the "cab" of the controlling locomotive.

(b) Except as provided in § 229.9, an equipped locomotive may not be dispatched in road service, or continue in road service following a daily inspection, unless the wheel ship/slide protective device of whatever type—

(1) Is functioning for each powered axle under power; and

(2) Would function on each powered axle if it were under power.

(c) Effective January 1, 1991, all new locomotives capable of being used in road service shall be equipped with a device that detects wheel slip/slide for each powered axle when it is under power. The device shall produce an audible alarm or visual alarm in the "cab".

The W&LE is also requesting a waiver, FRA Docket No. RSOP–92–1, with certain provisions of 49 CFR part 218, Railroad Operating Practices. Subpart B—Blue Signal Protection of Workmen, §§ 218.23, 218.25, 218.27, and 218.29 set forth the regulations pertaining to blue signal display. Basically the regulations require that when the rolling equipment to be protected includes one or more locomotives, a blue signal must be attached to the controlling locomotive where it is readily visible to the engineman or operator at the controls of that locomotive. The relevant portion of each of the sections for which the W&LE are seeking relief are as follows:

Section 218.25 Workmen on main track.

When workman are on, under, or between rolling equipment on a main track:

(b) If the rolling equipment to be protected includes one or more locomotives, a blue signal must be attached to the controlling locomotive at a location where it is readily visible to the engineman or operator at the controls of that locomotive.

Section 218.27 Workman on track other than main track.

When workman are on, under, or between rolling equipment on a main track:

(e) If the rolling equipment to be protected includes one or more locomotives, a blue signal must be attached to the controlling locomotive at a location where it is readily visible to the engineman or operator at the controls of that locomotive.

Section 218.29 Alternate methods of protection.

Instead of providing blue signal protection for workman in accordance with § 218.27, the following methods for blue flag protection may be used:

(a)(3) A blue signal must be attached to each controlling locomotive at a location where it is readily visible to the engineman or operator at the controls of that locomotive.

(d) When emergency repair work is to be done on, under or between a locomotive or one or more cars coupled to a locomotive, and blue signals are not available, the engineman or operator at the controls of that locomotive must be notified and effective measures must be taken to protect the workmen making the repairs.

A waiver would permit the operation of a remote controlled locomotive from outside the cab by an engineer, who then would not be at the controls to observe a readily visible blue signal.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number LI–92–6) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. Communications received before February 22, 1993 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m. to 5 p.m.) in room 8201, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

Issued in Washington, DC, on January 8, 1993.

Phil Olekszyk,

Deputy Associate Administrator for Safety.

[FR Doc. 93–896 Filed 1–13–93; 8:45 am]

BILLING CODE 4910–06–M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

January 8, 1993.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Internal Revenue Service

OMB Number: 1545–0807.

Regulation ID Number: TD 7533 and 7896 Final Regulations (LR 2013).

Type of Review: Extension.

Title: Time for Filing Returns of Corporations.

Description: Section 6072(b), (c), (d) and (e) of the Internal Revenue Code (IRC) deals with the filing dates of certain corporate returns. Regulation section 1.6072–2 provides additional information concerning these filing dates. The information is used to insure timely filing of corporate income tax returns.

Respondents: Businesses or other for-profit, non-profit institutions, small businesses or organizations.

Estimated Number of Respondents: 1.
Estimated Burden Hours Per Respondent: 1 hour.
Frequency of Response: On occasion and annually.
Estimated Total Reporting Burden: 1 hour.
Clearance Officer: Garrick Shear (202) 622–3869, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 93–892 Filed 1–13–93; 8:45 am]

BILLING CODE 4830-01-M

Public Information Collection Requirements Submitted to OMB for Review

January 8, 1993.

The Department of the Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Customs Service

OMB Number: 1515–0087.
Form Number: CF 255.
Type of Review: Extension.
Title: Declaration for Unaccompanied Articles.
Description: Customs Form 255 is completed by each arriving person for each parcel or container which is to be sent from an insular possession at a later date. It is used for claim of benefit purposes to determined a traveler's allowable exemption.
Respondents: Individuals or households, Businesses or other for-profit.
Estimated Number of Respondents: 7,500.
Estimated Burden Hours Per Respondent: 5 minutes.
Frequency of Response: On occasion.
Estimated Total Reporting Burden: 1,250 hours.
Clearance Officer: Ralph Meyer (202) 927–1552, U.S. Customs Service, Paperwork Management Branch, room 6316, 1301 Constitution Avenue, NW., Washington, DC 20229.
OMB Reviewer: Milo Sunderhauf (202) 395–6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

[FR Doc. 93–893 Filed 1–13–93; 8:45 am]

BILLING CODE 4830-01-M

UNITED STATES INFORMATION AGENCY

Recruitment for and Management of Central and Eastern European EFL Fellow Program and Russia and Ukraine Fellows

AGENCY: United States Information Agency.
ACTION: Notice—request for proposals.

SUMMARY: The U.S. Information Agency (USIA) solicits interest from U.S. not-for-profit institutions/organizations in conducting the recruitment, placement, and administration of up to 50 English as a Foreign Language (EFL) Fellows and English for Specific Purposes (EFL/ESP) Fellows for a special Eastern European EFL Fellow program to provide EFL teacher trainers for teachers of English and ESP teachers in Albania, Poland, Hungary, the Czech Republic, Slovakia, Romania, Bulgaria, Slovenia, Estonia, Latvia, Lithuania, Croatia, and Macedonia. This program is subject to the availability of funds from Support for Eastern European Democracy IV (SEED IV) funding for Fiscal Year 1993. In addition, the organization will recruit and place up to ten Fellows in Russia and Ukraine and supervise the administration of their grants. The Fellows recruited for Russia and Ukraine will be supported by special USIA funding for Newly Independent States (NIS)/Central and Eastern European (CEE) Initiatives.

DATES: Deadline for proposals: All copies must be received at the U.S. Information Agency by 5 p.m. Washington, DC time on Friday, February 12, 1993. Faxed documents will not be accepted, nor will documents postmarked on Friday, February 12, 1993 but received at a later date. It is the responsibility of each grant applicant to ensure that proposals are received by the above deadline. The grant should begin on or about 15 March 1993.

ADDRESSES: The original and 10 copies of the completed application, including required forms, should be submitted by the deadline to: U.S. Information Agency, Ref.: Recruitment for and Management of Central and Eastern European EFL Fellow Program, Office of Grant Management, E/XE, room 336, 301 4th St., SW, Washington, DC 20547.

FOR FURTHER INFORMATION CONTACT: Interested organizations/institutions should contact Richard A. Murphy at U.S. Information Agency, 301 4th St., SW, Office of Cultural Centers and Resources, English Language Programs Division, E/CE, room 304, Washington, DC 20547, Telephone (202) 619–5869 to request detailed application packets, which include award criteria additional to this announcement, all necessary forms, and guidelines for preparing proposals, including specific budget preparation information.

SUPPLEMENTARY INFORMATION: Pursuant to the Bureau's authorizing legislation, programs must maintain a non-political character and should be balanced and representative of the diversity of American political, social and cultural life.

Overview

The U.S. Information Agency (USIA) is soliciting proposals, from U.S. professional, not-for-profit institutions/organizations to recruit and place up to 50 EFL Fellows and to supervise attendant administration, including travel arrangements and payment of stipends, for a special Eastern European EFL Fellow program. The program is meant to provide teacher trainers and ESP teachers for Albania, Poland, Hungary, the Czech Republic, Slovakia, Romania, Bulgaria, Slovenia, Estonia, Latvia, Luthania, Croatia, and Macedonia. Additionally, the grantee organization will recruit, place and administer up to 10 EFL Fellows for Russia and Ukraine. Recruitment will be conducted to fill positions in accordance with the basic objective of USIA's EFL Fellow program for Central and Eastern Europe and the Baltic States, which is to promote the teaching of English as a vehicle to develop democracies throughout the region. The Eastern European EFL Fellow Program, initiated in 1991 and continued in 19i92, was a response to the dramatic increase in the demand for English caused by the political changes in Eastern Europe and the shift in intellectual input from East to West. The 1993 program, while continuing the effort to promote English teaching in Central and Eastern Europe, extends it to the former Soviet Republics of Russia and Ukraine.

As in the first two years of the Eastern European EFL Fellow Program, USIA proposes to focus its resources on two areas:

(a) in-service teacher training;
(b) English for specific purposes (ESP)

EFL Fellows will coordinate and implement the teacher training program as well as teach individual language courses in ESP.

Guidelines

Among the responsibilities of the institution/organization receiving the assistance award will be:

1. *Recruiting and placing Fellows.* This will include the following:

—Disseminate information through domestic and international mailings and other means concerning the Eastern European Fellow program.
—Place a public announcement in various professional journals, including the Chronicle of Higher Education, the Commerce Business Daily, and the TESOL Placement Bulletin.
—Respond to CVs and letters of inquiry with an "applicant package" of application materials, designed in consultation with USIA.
—Conduct all correspondence necessary to complete professional dossiers of each FEL Fellow candidate to be interviewed.
—Receive and process applications from candidates, screening for acceptable qualifications set forth above.
—Enter data from applications/CVs into an EFL applicant database, using Paradox 3.5 or higher software, sorting for degree, experience, language, and area preference.
—Arrange for and carry out interviews of all candidates having acceptable qualifications at, but not limited to, the annual TESOL convention in Atlanta, Georgia April 13–17, 1993 in collaboration with USIA's English Language Programs Division. (At least two TEFL/TESL qualified interviewers should be assigned to this task.)
—Establish and define duties expected of each EFL Fellow at the institution assigned, through correspondence with that institution in the particular country and in consultation with USIA's English Language Programs Division.
—Select up to 50 EFL Fellows for teacher training and English for Special Purposes in Eastern Europe, including up to eight coordinators. Additionally, select up to ten Fellows, including one coordinator for Russia and Ukraine. Each Fellow will receive a grant from USIA for one year—with the possibility of renewal. The recruiting/management organization will be provided with the exact mix of Fellow type after the grant is awarded. Coordinators, when selected for a country, will develop a country-wide program for the Fellows and oversee administrative matters connected with the program.
—Contact candidates in a timely fashion in priority order for acceptances based on best aggregate qualifications.
—Print and mail Terms and Conditions of the individual EFL Fellow grant.
—Provide letter of appointment, tax information, health insurance information and certificate to the nominee.
—Provide candidates with background information on visas and monitor their securing of visas.
—Secure the signed terms and conditions and the health certificate.

2. *Finances and Payments.*

—Make all financial arrangements, and process the EFL Fellow payments, distributing the first stipend check to the fellows before the Washington orientation session and the remaining checks during the course of their grant.
—Maintain detailed accounting records using IBM compatible software.

3. *Book Allowance for Fellows.*

—Process and ship EFL books ordered by Fellows from American publishers up to a total value of $700 plus shipping for each Fellow.

4. *Travel.*

—Make all travel arrangements for the Fellows to include travel from their residence to Washington for orientation, to place of assignment and return to residence, including finalizing their itineraries, booking, and mailing tickets and orientation letter to them. Oversee their departure to post.

5. *Orientation.*

—In consultation with USIA's English Language Programs Division, arrange for and implement a four-day orientation program for Fellows in Washington, D.C., utilizing both outside experts and USIA officers.
—Finalize the agenda; design, type, and print handouts; type insurance cards for Fellows.

6. *Review.*

Prepare and submit an evaluation report to USIA at mid-point and at the conclusion of the project.

Note: Proposal should include allowance for a representative from the recipient institution/organization to visit assignment sites proposed for the Fellows in order to become familiar with conditions at the host institutions.

Qualifications Required of the Responding Organization: To carry out the above tasks the institution/organization must be a not-for-profit or educational organization. It must have four years of international experience and possess a proven ability to network that provides and allows for the greatest dissemination of information to and among the profession of Teachers of English as a Second or Foreign Language. It must be able to provide knowledgeable, TEFL-qualified, experienced staff capable of interviewing candidates and evaluating their qualifications for teaching, developing materials, or conducting teacher-training in the context of English as a foreign language.

Proposed Budget

The grantee organization will be required to submit two comprehensive line item budgets: One for up to 50 Fellows for Eastern Europe and one for up to 10 Fellows for Russia and Ukraine. Specific details for these budgets are available in the application packet. Proposals requesting more than 20% of USIA funds for administrative costs will not be accepted.

Review Process

USIA will acknowledge receipt of all proposals and will review them for technical eligibility. Proposals will be deemed ineligible if they do not fully adhere to the guidelines established herein and in the application packet. Eligible proposals will be forwarded to panels of USIA officers for advisory review. All eligible proposals will also be reviewed by the appropriate geographic area office, and the budget and contracts offices. Proposals may also be reviewed by the Agency's Office of General Counsel. Funding decisions are at the discretion of the Associate Director for Educational and Cultural Affairs. Final technical authority for grant awards resides with USIA's contracting officer.

Review Criteria

Technically eligible applications will be competitively reviewed according to the following criteria:

1. *Quality of program idea:* Proposals should exhibit originality, substance, rigor, and relevance to Agency mission.
2. *Program planning:* Detailed agenda and relevant work plan should demonstrate substantive rigor and logistical capacity. Agenda and plan should adhere to the program overview and guidelines described above.
3. *Ability to achieve program objectives:* Objectives should be reasonable, feasible, and flexible. Proposals should clearly demonstrate how the institution will meet the program's objectives and plan.

4. *Multiplier effect/impact:* Proposed program should strengthen long-term mutual understanding, including maximum sharing of information and establishment of long-term institutional and individual linkages.

5. *Institutional Capacity:* Proposed personnel and institutional resources should be adequate and appropriate to achieve the program or project's goals. Proposal should present clear evidence of the ability to efficiently recruit and place suitable grantees for the Eastern European Fellow Program. This includes demonstrated ability to gain access to and network with EFL/ESL professionals and programs. The proposal should include evidence of strong administrative and managerial capabilities and project management experience. At least two persons should be assigned to the recruiting and placement of the Fellows at the 1993 TESOL convention in Atlanta, GA and afterwards.

6. *Institution's Track Record/Ability:* Proposals should demonstrate a track record of successful programs, including responsible fiscal management and full compliance with all reporting requirements for past Agency grants as determined by USIA's Office of Contracts (M/KG). The Agency will consider the past performance of prior grantees and the demonstrated potential of new applicants.

7. *Follow-on Activities:* Proposal should provide a plan for continued follow-on activity (without USIA support) which insures that USIA supported programs are not isolated events.

8. *Evaluation Plan:* Proposals should provide for a quarterly formative evaluation by the grantee institution and a summative evaluation at the conclusion of the project.

9. *Cost-effectiveness:* The overhead and administrative components of grants, as well as salaries and honoraria, should be kept as low as possible. All other items should be necessary and appropriate. Administrative costs exceeding 20% of USIA funds will not be accepted.

Notice

The terms and conditions published in this RFP are binding and may not be modified by any USIA representative. Explanatory information provided by the Agency that contradicts published language will not be binding. Issuance of the RFP does not constitute an award commitment on the part of the Government. Final award cannot be made until funds have been fully appropriated by Congress, allocated and committed through internal USIA procedures.

Notification

All applicants will be notified of the results of the review process on or about March 12, 1993. Awarded grants will be subject to periodic reporting and evaluation requirements. The successful organization may be awarded renewal grants for up to three years, depending on program performance and evaluations conducted by USIA.

Dated: January 8, 1993.

Barry Fulton,

Acting Associate Director, Bureau of Educational and Cultural Affairs.

[FR Doc. 93–817 Filed 1–13–93; 8:45 am]

BILLING CODE 8230–01–M

VOL 58 ISS 9 JA 14 1993 UMI

Sunshine Act Meetings

Federal Register
Vol. 58, No. 9
Thursday, January 14, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 58 FR 375, January 5, 1993.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11:00 a.m., Monday, January 11, 1993.

CHANGES IN THE MEETING: Addition of the following closed item(s) to the meeting:

Federal Reserve Bank and Branch director appointments.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: January 11, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-1017 Filed 1-12-93; 9:06 am]
BILLING CODE 6210-01-M

Corrections

Federal Register
Vol. 58, No. 9
Thursday, January 14, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary for Health; Statement of Organization, Functions and Delegations of Authority

Correction

In notice document 92–31894 appearing on page 107 in the issue of Monday, January 4, 1993, in the third column, in the first full paragraph, in the first line, "*Office of Women's Health (HAW)*" should read "*Office on Women's Health (HAW)*".

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Part 34

[Docket No. 92–27]

FEDERAL RESERVE SYSTEM

12 CFR Part 208

[Regulation H; Docket No. R–0765]

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 365

RIN 3064–AB05

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

12 CFR Parts 545 and 563

[Docket No. 92–484]
RIN 1550–AA56

Real Estate Lending Standards

Correction

In rule document 92–31481 beginning on page 62890 in the issue of Thursday, December 31, 1992, make the following corrections:

1. On page 62897, in the second column, the LOAN ADMINISTRATION section should read as follows:

LOAN ADMINISTRATION

The institution should also establish loan administration procedures for its real estate portfolio that address:

- Documentation, including:
  Type and frequency of financial statements, including requirements for verification of information provided by the borrower;
  Type and frequency of collateral evaluations (appraisals and other estimates of value).
- Loan closing and disbursement.
- Payment processing.
- Escrow administration.
- Collateral administration.
- Loan payoffs.
- Collections and foreclosure, including:
  Delinquency follow-up procedures;
  Foreclosure timing;
  Extensions and other forms of forbearance;
  Acceptance of deeds in lieu of foreclosure.
- Claims processing (e.g., seeking recovery on a defaulted loan covered by a government guaranty or insurance program).
- Servicing and participation agreements.

2. On page 62898, in the first column, under EXCLUDED TRANSACTIONS, in the fifth paragraph, in the second line, "within" should read "without".

3. On the same page, in the same column, under EXCLUDED TRANSACTIONS, in the ninth paragraph, in the third line, before "extension" insert "the".

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 205

RIN 1510–AA19

Rules and Procedures for Funds Transfers

Correction

In rule document 92–30757 beginning on page 60676 in the issue of Monday, December 21, 1992, make the following correction:

§ 205.18 [Corrected]

On page 60683, in the first column, in § 205.18(b)(2), in the first line, "20 days" should read "30 days".

BILLING CODE 1505–01–D

Federal Register

Thursday
January 14, 1993

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Parts 1910

Permit-Required Confined Spaces for General Industry; Final Rule

VOL 58 ISS 9 JA 14 1993 UMI

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–019]

RIN 1218–AA51

Permit-Required Confined Spaces

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration (OSHA) hereby promulgates safety requirements, including a permit system, for entry into those confined spaces, designated as permit-required confined spaces (permit spaces), which pose special dangers for entrants because their configurations hamper efforts to protect entrants from serious hazards, such as toxic, explosive or asphyxiating atmospheres. The new standard provides a comprehensive regulatory framework within which employers can effectively protect employees who work in permit spaces.

Few OSHA standards specifically address permit space hazards. These standards, in turn, provide only limited protection. OSHA has determined, based on its review of the rulemaking record, that the existing standards do not adequately protect workers in confined spaces from atmospheric, mechanical and other hazards. The Agency has also determined that the ongoing need for monitoring, testing and communication at workplaces which contain entry permit confined spaces can be satisfied only through the implementation of a comprehensive confined space entry program. OSHA anticipates that compliance with the provisions of this standard will effectively protect employees who work in permit- required confined spaces from injury or death.

EFFECTIVE DATE: This final rule will become effective on April 15, 1993.

ADDRESSES: In compliance with 28 U.S.C. 2112(a), the Agency designates for receipt of petitions for review of the standard, the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, U.S. Department of Labor, Occupational Safety and Health Administration, Office of Information and Consumer Affairs, Room N3647, Washington, DC 20210, (202) 523–8151.

SUPPLEMENTARY INFORMATION:

I. Background

Many workplaces contain spaces which are considered "confined" because their configurations hinder the activities of any employees who must enter, work in, and exit them. For example, employees who work in process vessels generally must squeeze in and out through narrow openings and perform their tasks while cramped or contorted. For the purposes of this rulemaking, OSHA is using the term "confined space" to describe such spaces. In addition, there are many instances where employees who work in confined spaces face increased risk of exposure to serious hazards. In some cases, confinement itself poses entrapment hazards. In other cases, confined space work keeps employees closer to hazards, such as asphyxiating atmospheres or the moving parts of a mixer, than they would be otherwise. For the purposes of this rulemaking, OSHA is using the term "permit-required confined space" (permit space) to describe those spaces which both meet the definition of "confined space" and pose health or safety hazards.

In its June 5, 1989 NPRM (54 FR 24080), OSHA determined, based on its review of accident data, that asphyxiation is the leading cause of death in confined spaces. The asphyxiations that have occurred in permit spaces have generally resulted from oxygen deficiency or from exposure to toxic atmospheres. In addition, there have been cases where employees who were working in water towers and bulk material hoppers slipped or fell into narrow, tapering, discharge pipes and died of asphyxiation due to compression of the torso. Also, employees working in silos have been asphyxiated as the result of engulfment in finely divided particulate matter (such as sawdust) that blocks the breathing passages.

The Agency has, in addition, documented confined space incidents in which victims were burned, ground-up by auger type conveyors, or crushed or battered by rotating or moving parts inside mixers. Failure to deenergize equipment inside the space prior to employee entry was a factor in many of those accidents. OSHA notes that the NPRM (54 FR 24080–24085) discussed the hazards which confront employees who enter permit spaces and the inadequacy of existing regulation in greater detail. Additionally, Section II of this preamble, *Hazards*, presents a detailed discussion of the hazards to which permit-space entrants have been exposed, demonstrating that this final rule is reasonably necessary to protect affected employees from significant risks.

OSHA has determined, based on its review of the rulemaking record, including investigation reports covering "permit space" fatalities (Exhibits (Ex.) 10 through 13 and 16), that many employers have not appreciated the degree to which the conditions of permit space work can compound the risks of exposure to atmospheric or other serious hazards. Further, the elements of confinement, limited access, and restricted air flow, can result in hazardous conditions which would not arise in an open workplace. For example, vapors which might otherwise be released into the open air can generate a highly toxic or otherwise harmful atmosphere within a confined space. Unfortunately, in many cases, employees have died because employers improvised or followed "traditional methods" rather than following existing OSHA standards, recognized safe industry practice, or common sense. The Agency notes that, as documented in the NPRM, many of the employees who died in permit space incidents were would-be rescuers who were not properly trained or equipped.

In addition, OSHA believes that, as noted in the NPRM (54 FR 24098), the failure to take proper precautions for permit space entry operations has resulted in fatalities, as opposed to injuries, more frequently than would be predicted using the applicable Bureau of Labor Statistics models. The Agency notes that, by their very nature and configuration, many permit spaces contain atmospheres which, unless adequate precautions are taken, are immediately dangerous to life and health (IDLH). For example, many confined spaces are poorly ventilated—a condition that is favorable to the creation of an oxygen deficient atmosphere and to the accumulation of toxic gases. Furthermore, by definition, a confined space is not designed for continuous employee occupancy; hence little consideration has been given to the preservation of human life within the confined space when employees need to enter it.

Accordingly, the Agency has determined that it is necessary to promulgate a comprehensive standard to require employers to take appropriate measures for the protection of any employee assigned to enter a permit space. OSHA believes this new standard will help eliminate confusion and misunderstanding by clearly stating employer responsibilities.

The record and determinations that are discussed in this final rule

culminate a series of efforts by OSHA, the National Institute for Occupational Safety and Health (NIOSH), the American National Standards Institute (ANSI) Z117 Committee, and others to address permit space hazards. The chronology of these efforts is set forth in the following paragraphs.

On July 24, 1975, OSHA issued an Advance Notice of Proposed Rulemaking (ANPR), "Standard for Work in Confined Spaces," for the purpose of obtaining data and information to be used in developing a confined spaces standard (40 FR 30880). This ANPR sought comments on 14 issues, including problems with existing regulations, factors involved in confined space injuries and deaths, and the steps necessary for the control of hazards in confined spaces.

On August 26, 1977, ANSI adopted ANSI Z117.1–1977, "Safety Requirements for Working in Tanks and Other Confined Spaces" (Ex. 13–5). That standard set "minimum requirements for safe entry, continued work in, and exit from tanks and other confined spaces at normal atmospheric pressure." The ANSI standard defined confined spaces as enclosures with limited means of access and egress, such as storage tanks, open-topped spaces more that four feet in depth with poor natural ventilation, and sewers. Explanatory information accompanying the standard stated that the standard addressed atmospheric hazards, physical hazards, the possibility of liquids, gases, or solids entering a space (e.g., drowning or engulfment hazard) and isolation of entrants in case of need (e.g., hazard of entrapment due to configuration). The ANSI standard set: (1) general precautions (such as testing, evaluation, ventilation and lockout) to be followed before entry, (2) procedures to be followed when confronting particular environmental hazards (such as oxygen-deficient, flammable and toxic atmospheres, noise, and radiation exposure), (3) entry procedures (including the use of permit to authorize entry and illumination of the space), and (4) special procedures for hot work (e.g., welding) or removal or application of preservative coatings or linings performed in confined spaces.

Citing both "the complexity of the issues and the period of time since the previous Advance Notice," OSHA issued another ANPR, "Entry and Work in Confined Spaces" (44 FR 60334), on October 19, 1979. The 24 questions raised in the 1979 ANPR were similar to, but more detailed than, the 14 issues raised in the 1975 ANPR.

The 1979 ANPR again requested suggestions for a definition of "confined space," as well as information regarding the appropriate procedures for addressing confined space hazards, and the cost of those procedures. OSHA received 68 comments in response to the 1979 ANPR. These comments, while similar to those received in response to the 1975 ANPR, broadened the informational base which supported OSHA regulatory action to address confined spaces hazards.

Most commenters suggested that OSHA develop a performance- oriented standard similar to OSHA's "fire protection standard" (29 CFR Part 1910, Subparts E, H, and L), which was then being revised and which was subsequently published as a final rule on September 12, 1980 (45 FR 60704). Also, many commenters suggested that defining the hazards confronted in confined spaces was more important than defining the term "confined space."

In December 1979, NIOSH issued a criteria document, "Working in Confined Spaces" (Ex. 13–9), which recommended procedures for protecting employees from the hazards of entering, working in, or exiting confined spaces. NIOSH defined the term "confined space" to mean "a space which by design has limited openings for entry and exit, unfavorable natural ventilation which could contain or produce dangerous air contaminants, and which is not intended for continuous employee occupancy." The criteria document states: "The standard is designed not only to make the confined space safe for the worker, but also to make the worker cognizant of the hazards associated with this work area and the safe work practices necessary to deal with these hazards."

The NIOSH recommended standard included provisions for permit to authorize entry, testing and monitoring, precautions (such as ventilation, purging and lockout), medical surveillance, training, labeling and posting of confined spaces, entry procedures (such as planning for entry, standby person, communications, and rescue), personal protective equipment, rescue equipment and recordkeeping. NIOSH would require employers whose confined spaces were immediately dangerous to life or health (categorized as "Class A") or dangerous (categorized as "Class B") to implement all of these measures, except that employers with Class B confined spaces would have a qualified person determine if it was necessary to conduct monitoring. Employers with confined spaces "in which the potential hazard would not require any special modification of the work procedure" (categorized as "Class C") would be required to implement a permit system, atmospheric testing, training, labeling and posting, entry procedures (except for stationing of standby person), and recordkeeping and to provide rescue equipment. Other measures would be taken if a qualified person determined that they were necessary.

On March 25, 1980, OSHA issued an ANPR (Construction ANPR) "Entry and Work in Confined Spaces" (45 FR 19266), to obtain information which could be used "to revise its existing standards in order to effectively cover hazards connected with these (confined space) activities in construction." The Agency stated its belief that "the hazards of work in confined spaces are also significant in the construction industry." The Construction ANPR posed 31 questions, similar to those presented in the 1979 General Industry ANPR, regarding the appropriate precautions and procedures for controlling confined space hazards which construction workers may confront. The Agency received 75 comments, most of which restated general industry-related concerns that were raised in response to the 1979 ANPR.

On April 4, 1980, OSHA scheduled public meetings (45 FR 22978) where interested parties could make oral presentations regarding confined space hazards in general industry and in construction. Those meetings were held during May 1980 in Houston, Texas, in Denver, Colorado, and in Washington, D.C. There were approximately 30 participants at these meetings.

In January 1986, NIOSH published an "Alert" titled "Request for Assistance in Preventing Occupational Fatalities in Confined Spaces" (Ex. 13–16). The Alert described the circumstances under which 16 workers died (14 of them due to atmospheric hazards) in confined space incidents. NIOSH focused on problems employers have in three areas: (1) recognizing confined spaces; (2) testing, evaluating, and monitoring confined space atmospheres; and (3) developing and implementing rescue procedures. It was noted, for example, that "[m]ore than 60% of confined space fatalities occur among would-be rescuers." The Alert recommended that employers protect employees who enter confined spaces by implementing measures similar to those presented in the 1979 Criteria Document.

In July 1987, NIOSH published "A Guide to Safety in Confined Spaces" (Ex. 14–145). The Guide addressed identification of confined spaces, measures to take when a confined space presents atmospheric hazards, and

incidents where "[l]ack of hazard awareness and unplanned rescue attempts led to [employee] deaths." NIOSH also described other potential confined space hazards (temperature extremes, engulfment, noise, slick or wet surfaces, and falling objects) and provided a checklist for employers to follow in evaluating confined spaces and in planning entry operations.

In addition, NIOSH's Fatal Accident Circumstances and Epidemiology (FACE) project focused much of its effort on confined space-related fatalities from 1984 to 1988 (Ex. 14–145). Personnel from NIOSH's Division of Safety Research evaluated numerous incidents and prepared reports which contained recommendations for improved employee protection. Those reports, which constituted the primary data base for the 1986 "Alert" and the 1987 "Guide", contributed significantly to OSHA's understanding of the broad range of hazards posed by confined spaces.

In May 1988, the ANSI Z117.1 Committee withdrew ANSI Z117.1–1977 because the committee had not completed action to renew or revise the standard within the 5-year period required by ANSI procedures for such action.

On June 5, 1989, OSHA issued a notice of proposed rulemaking (NPRM) (54 FR 24080) to set requirements for the protection of employees who work in or near permit-required confined spaces (permit spaces). In brief, the proposal required employers to identify any permit spaces in their workplaces, prevent unauthorized entry into such spaces, and protect authorized entrants from permit space hazards through a permit space program. As proposed, the permit space program, in turn, required employers to control hazards; properly inform, train and equip affected employees; document compliance with the program and authorize any entry operations through written permits; station an attendant to monitor entry operations; take the appropriate precautions for rescuing entrants from permit spaces; and assist any contractors hired for entry operations in complying with the program requirements by informing them of the hazards identified and any procedures developed for dealing with them. In addition, the NPRM presented 18 issues regarding which OSHA solicited comments and information. Detailed discussion of the proposed rule and issues raised during the rulemaking may be found in Section III, *Summary and Explanation of the Standard*, later in this preamble.

The NPRM set a comment period which ended on August 4, 1989. On July 21, 1989, in response to several requests, OSHA published a notice (54 FR 30557) which extended the time in which written comments and requests for hearing could be submitted through October 4, 1989.

On September 1, 1989, (54 FR 36644) the Agency promulgated a standard for "The control of hazardous energy (lockout/tagout)", 29 CFR 1910.147, to address "the *unexpected* energization or start up of machines or equipment, or release of stored energy [that] could cause injury to employees." OSHA anticipates that compliance with the lockout/tagout standard, in conjunction with the permit-space standard, will effectively protect employees who work in permit spaces from mechanical and other energy hazards. (See the discussion of issue 7 under *NPRM Issues*, later in this preamble, for further information on the relationship between the two standards.)

On October 5, 1989, the ANSI Z117 Committee approved ANSI Z117.1–1989, "Safety Requirements for Confined Spaces." The 1989 edition differs from the 1977 edition in two major respects: First, it distinguishes between confined spaces based on their potential to pose hazards. Under ANSI Z117.1–1989, employers would not need written permits to authorize work or attendants for spaces which fit the definition of permit-required confined space but have low potential to pose hazards. Second, it provides more specific guidance regarding the identification and evaluation of confined spaces, the training of personnel, and the appropriate procedures for having contractors work in confined spaces and for providing rescue and emergency services.

On October 10, 1989, OSHA issued a notice of informal public hearing (54 FR 41461), which announced that hearings would be held in Washington, D.C. and in Houston, Texas. The notice set out 15 issues regarding which the Agency solicited testimony, with supporting information. The testimony and other information received regarding those issues are discussed in Section III, *Summary and Explanation of the Standard*, later in this preamble. In addition, OSHA extended the written comment period through November 1, 1989.

On November 14, 1989, OSHA issued a notice of additional hearing site (54 FR 47498), which announced that the Agency would hold a hearing in Chicago, Illinois to facilitate participation by interested parties in the Chicago area.

On November 14–15, 1989, OSHA convened public hearings on the NPRM, with Administrative Law Judge Aaron Silverman presiding. Hearings were also held in Houston, Texas (December 5–6, 1989) and in Chicago, Illinois (January 30–February 2, 1990).

At the conclusion of the hearings, Judge Silverman set a post- hearing period for the submission of additional data (ending on April 18, 1990) and for the submission of additional briefs, arguments and summations (ending on May 3, 1990). On April 11, 1990, in response to requests from several parties, Judge Silverman extended the post-hearing comment periods, so that hearing participants had until May 18, 1990 to submit additional data and until June 4, 1990 to submit briefs, arguments or summations. On November 9, 1990, Judge Silverman closed and certified the hearing record for the rulemaking. The rulemaking record contains 137 exhibits and 2,279 pages of hearing transcript. OSHA received 227 comments on the proposal and 51 post-hearing comments.

In the course of drafting the final standard, OSHA has carefully reviewed the record for this rulemaking. In addition to comments and testimony at the public hearings, the Agency has also studied confined space regulations generated by states and other countries; materials generated by NIOSH; both editions of ANSI Z117.1; and the guidelines developed by other organizations (such as the American Petroleum Institute (Ex. 13–14) and the UAW-GM Human Resource Center (Ex. 64, 65, 66, 67)).

While the Agency has gained many valuable insights from the documents reviewed, OSHA believes that some standard-setting groups have not focused sufficiently on non-atmospheric hazards and have concentrated largely on air contaminants and oxygen-deficient atmospheres. For example, both the 1979 NIOSH Criteria Document and ANSI Z117.1–1989 require atmospheric testing before entry into a "confined space", even though those standards also recognize that some such spaces will pose mechanical and physical hazards rather than atmospheric hazards. Consequently, the OSHA permit-required confined space standard diverges from the approaches taken in the ANSI and NIOSH documents as necessary to indicate clearly that the OSHA standard is intended to protect employees from exposure to all permit space hazards.

Section 6(b)(8) of the Occupational Safety and Health Act of 1970 (the OSH Act) requires OSHA to explain "why a rule promulgated by the Secretary differs substantially from an existing

national consensus standard," by publishing " a statement of the reasons why the rule as adopted will better effectuate the purposes of the Act than the national consensus standard." In compliance with that requirement, the Agency has reviewed the standards proposed through this rulemaking with reference to the pertinent consensus standards. OSHA discusses the relationship between individual regulatory provisions and the corresponding consensus standards in Section III, *Summary and Explanation of the Standard*, later in this preamble.

The materials upon which OSHA has relied in drafting this final rule are available for review and copying in the OSHA Docket Office. Those materials include, among others, transcripts of the 1989 and 1990 informal public hearings, documents received by OSHA at the hearings and during the post- hearing comment periods, public comments on the NPRM, accident reports, existing regulatory language, responses to the 1975 and 1979 ANPRs, transcripts of the 1980 public meetings and the sources listed in the "References" sections of both the NPRM and this final rule.

II. Hazards

OSHA has determined, based upon the information presented in this section and upon the complete record developed as a result of this rulemaking, that working in permit-required confined spaces involves significant risks for employees and that this standard is necessary to alleviate or control such risks.

Incident Data and Confined Space Hazards Analysis.

The 1979 NIOSH Criteria document, "Working in Confined Spaces", cites a study by the Safety Sciences Division of WSA, Inc., San Diego, California, which was titled "Search of Fatality and Injury Records for Cases Related to Confined Spaces". The Safety Sciences study reviewed approximately 20,000 reports covering industrial accidents nationally for the period 1974– 1977. Even with this limited sample, 276 confined space accidents which resulted in 234 deaths and 193 injuries were identified. Safety Sciences conducted its study to determine if regulatory action was needed to control confined space hazards, not to identify the exact causes of death and injury. OSHA, in turn, has been unable to connect the 234 fatalities and 193 injuries to specific industry segments or work activities.

More recently, OSHA examined its records of accident investigations for fatal confined space incidents. In particular, OSHA sought to identify the specific hazards and work activities involved. OSHA concluded during this review that, where multiple deaths occurred, the majority of the victims in each event died trying to rescue the original entrant from a confined space. This determination is consistent with the finding by NIOSH in its 1986 "Alert" that "rescuers" accounted for more than 60 percent of confined space fatalities. This evidence indicates that untrained or poorly trained rescuers constitute an especially important "group at risk." This group is protected from permit space hazards under the terms of this final rule.

OSHA has also gathered incident data from a number of other sources, such as the Fatal Accidents Circumstances and Epidemiol- ogy (FACE) reports produced by NIOSH and reports produced by the states. That information has been very useful to OSHA, even though in some cases there was not enough detail for OSHA to evaluate the circumstances of the incidents.

The OSHA-investigated cases which OSHA analyzed to determine the cause of death in confined spaces have been compiled in four reports prepared by OSHA's Office of Statistical Studies and Analyses. These are: "Selected Occupational Fatalities Related to Fire and/or Explosion in Confined Work Spaces as Found in Reports of OSHA Fatality/Catastrophe Investigations" (Ex. 13–10), "Selected Occupational Fatalities Related to Lockout/Tagout Problems as Found in Reports of OSHA Fatality/Catastrophe Investigations" (Ex. 13–11), "Selected Occupational Fatalities Related to Grain Handling as Found in Reports of OSHA Fatality/ Catastrophe Investigations" (Ex. 13–12), and "Selected Occupational Fatalities Related to Toxic and Asphyxiating Atmospheres in Confined Work Spaces As Found in Reports of OSHA Fatality/ Catastrophe Investigations" (Ex. 13–15).

These four reports focused on fatalities because OSHA found that the reporting of injuries from permit space incidents was frequently incomplete. OSHA observes that injuries are most likely to be reported when they occur as part of an incident where fatalities do occur. The Agency anticipates that this rulemaking will lead to improved data collection regarding injuries because employers and employees are being clearly alerted to OSHA's concern about permit space hazards.

OSHA analyzed the studies to determine the underlying causes of the conditions which existed when confined space related accidents occurred. From this information, OSHA has developed measures that would have prevented virtually all of the accidents in the studies and has used those measures as the basis for both the proposed standard and the final rule. OSHA notes that many of the reports did not fully document the circumstances of the accidents covered. The Agency has determined, however, that the available accident data, despite its limitations, provides the necessary basis for characterizing permit space hazards and for requiring protective measures. OSHA has continued to collect accident data during the course of this rulemaking.

OSHA has determined that a variety of confined space hazards have caused deaths and injuries. The following discussion describes the hazards identified by OSHA. Where the Agency has obtained incident data subsequent to the publication of the NPRM, the circumstances of some of these incidents are summarized as "examples". The discussion also references the portions of the NPRM where pertinent incidents were described.

1. *Atmospheric Hazards.*

OSHA's review of accident data indicates that most confined space deaths and injuries are caused by atmospheric hazards. OSHA has classified those hazards into three categories: toxic; asphyxiating; and flammable or explosive atmospheres, in order to account for their differing effects.

Some chemical substances present multiple atmospheric hazards, depending on their concentration. Methane, for example, is an odorless substance that is nontoxic and is harmless at some concentrations. Methane, however, can displace all or part of the atmosphere in a confined space;[1] and the hazards presented by such displacement can vary greatly, depending on the degree of displacement. With only 10 percent displacement, methane produces an atmosphere which, while adequate for respiration, can explode violently. By contrast, with 90 percent displacement, methane will not burn or explode, but it will asphyxiate an unprotected worker within about 5 minutes.

OSHA is concerned that employees may be exposed to atmospheric hazards because the employer has not properly

[1] Methane is lighter than air when both are at the same temperature (the normal case), and the configuration of some confined spaces can trap accumulating methane at "ceiling" level. On the other hand, in the unlikely event that liquified methane is released into the atmosphere of a confined space, the methane released would be heavier than air and would displace the air from the "ground" level up.

evaluated the work operations or the conditions within the permit space. Problems can arise, for example, where an employer has not selected the necessary atmospheric test instruments or has not ensured their proper use. Problems have arisen because most of the instruments used to test the flammability of a permit space atmosphere do not identify oxygen deficient atmospheres. In fact, because some of these instruments rely on the presence of oxygen, their readings can be inaccurate in oxygen-depleted atmospheres.

For example, instruments of the hot-platinum-filament type are designed to measure flammable gases and vapors in air. The depend on oxidation for their operation, and normal quantities of oxygen in the air are necessary for their correct operation. Any reduction in oxidation caused by lack of oxygen will result in a lower flammability reading. Such test instruments would indicate the absence of an explosion hazard simply because the atmosphere did not contain sufficient oxygen for combustion but would not indicate the oxygen deficiency that posed an asphyxiation risk.

On the other hand, a test performed only to determine the oxygen level might indicate that conditions are acceptable for entry without respiratory protection, despite the presence of 10 percent methane, an explosive level, in the atmosphere. Therefore, in the final rule, OSHA is requiring that employers test and monitor their entry spaces with instruments which will detect all aspects of hazardous atmospheres that may be encountered in the spaces.

OSHA presents the following examples regarding atmospheric hazards to illustrate how a relatively uncomplicated series of events can lead to workplace deaths and injuries. In each case, OSHA believes that death and injury would have been prevented if the procedures and safeguards required in this rule had been used. OSHA notes that the hazards confronted could only have been controlled effectively through the use of mechanical ventilation. OSHA recognizes that many confined space workplaces present situations which are more complex than those described in the following discussion.

a. *Fatalities in asphyxiating atmospheres.* In its analysis of these confined space incidents, OSHA uses the term "asphyxiating atmosphere" when referring to an atmosphere which contains less than 19.5 percent oxygen. Oxygen levels under 19.5 percent are inadequate for an entrant's respiratory needs when performing physical work, even if the space contains no toxic materials.

There are many potential causes of asphyxiating atmospheres. For example, the oxygen in a space may have been absorbed by materials, such as activated charcoal, or consumed by chemical reaction, such as the rusting of a vessel or container. In another situation, the original atmosphere in the space may intentionally have been wholly or partly inerted using such gases as helium, nitrogen, argon, or carbon dioxide. Victims of asphyxiation often are unaware of their predicament until they are incapable of saving themselves or even calling for help.

Three incidents involving fatalities in asphyxiating atmospheres were discussed in the preamble of the NPRM (54 FR 24083). In addition, OSHA has received information during the rulemaking (Ex. 14–159) that further documents the hazards of exposure to asphyxiating atmospheres in permit-required confined spaces.

Example #1. A worker at a Texas steel mill was assigned the task of clearing a blockage at The No. 2 degasser vessel dust collector. He entered the vessel through an access manhole and proceeded to clear the obstruction. A coworker, assigned to assist, left the area to locate an electrical receptacle. About 10 or 15 minutes later, the coworker returned and found the worker who had entered the vessel unconscious. The coworker was able to remove the unconscious man and called for assistance. Unfortunately, the worker died. An oxygen test showed a level of 10% oxygen in the vessel. (The coworker was not injured.)

Example #2. A steel worker was asphyxiated when he entered a tank in the reagent storage building. There were no witnesses to the incident, but, since the tank had been used for the transport of nitrogen, it was assumed that the atmosphere within the tank was oxygen deficient.

b. *Fatalities in toxic atmospheres.* The term "toxic atmospheres" refers to atmospheres containing gases, vapors or fumes known to have poisonous physiological effects. The toxic effect is independent of the oxygen concentration. The most commonly encountered toxic gases are carbon monoxide and hydrogen sulfide.

Some toxic atmospheres may have severe harmful effects which may not manifest until years after exposure, while others may kill quickly. Some can produce both immediate and delayed effects. For example, while carbon disulfide at low concentrations may exhibit no immediate sign of exposure, it can cause permanent and cumulative brain damage as a result of repeated "harmless" exposures. At higher concentrations, it can kill quickly.

Two incidents involving fatalities in toxic atmospheres were discussed in the preamble of the NPRM (54 FR 24083, 24084). In addition, OSHA has received information during the rulemaking (Ex. 14–63, 14–159) that further documents the hazards of exposure to toxic atmospheres in permit-required confined spaces.

Example #1. A worker in Maryland entered a 6500 gallon tank trailer to finish cleaning the inside. He had with him a bucket containing about a gallon of a cleaning solvent (identified in the accident abstract only as "Niagara Trex 1900 Presol"). In only five to seven minutes the employee passed out and fell to the tank bottom. There was no ventilation, respirator or safety harness with lifeline provided. The outside "standby man" only checked the employee periodically (every three to five minutes). When the outside man discovered the unconscious employee, he attempted a rescue (without benefit of any protective equipment for himself) but was unsuccessful. He left the tank and called emergency personnel. The unconscious employee was rescued by emergency personnel and immediately transported to a hospital, where he was declared dead.

Example #2. An employee of a zinc refinery was working in a zinc dust condenser when he collapsed. Another employee donned a self-contained breathing apparatus (SCBA) and attempted to enter the condenser to rescue the downed employee. He was not able to fit through the portal wearing the SCBA, so he removed it, handed it to another employee and then entered the condenser. He planned to have the other employee hand the SCBA to him through the portal, re-don it and then continue with the rescue. He collapsed and fell into the condenser before he could re-don the SCBA. The first employee was declared dead at the scene; the would-be rescuer died two days later. The toxic air contaminant was later determined to be carbon monoxide.

c. *Fatalities due to flammable or explosive atmospheres.* OSHA considers an atmosphere to pose a serious fire or explosion hazard if a flammable gas or vapor is present at a concentration greater than 10 percent of its lower flammable limit or if a combustible dust is present at a concentration greater than or equal to its lower flammable limit. (See the definition of "hazardous atmosphere" in §1910.146(b) and the discussion of the definition of "hazardous atmosphere", which

appears in Section III, *Summary and Explanation of the Standard*, later in this preamble.) This category of hazardous atmospheres includes atmospheres containing gases such as methane or acetylene; vapors of solvents or fuel such as carbon disulfide, gasoline, kerosene, or toluene; or combustible dusts, such as coal or grain dusts.

An incident involving five fatalities in flammable or explosive atmospheres was discussed in the preamble of the NPRM (54 FR 24084). In addition, OSHA has received information during the rulemaking (Ex. 14–145) that further documents the hazards of exposures to flammable or explosive atmospheres in permit-required confined spaces.

Example. An employee of a trailer service company entered a 8500 gallon cargo tank to weld a leak on the interior wall of the tanker. Despite the presence of strong fumes of lacquer- thinner (the material previously carried in the tanker) the welder decided to proceed with the repairs even though the written company safety policy required the use of an explosion meter at that point. When he began welding, an explosion occurred. The employee was removed from the tank and taken to a nearby hospital, where he was declared dead by the attending physician.

2. *Other Hazards.*

Fatalities from engulfment. "Engulfment" refers to situations where a confined space entrant is trapped or enveloped, usually by dry bulk materials. The engulfed entrant is in danger of asphyxiation, either through filling of the victim's respiratory system as the engulfing material is inhaled, or through compression of the torso by the engulfing material. In some cases, the engulfing materials may be so hot or corrosive that the victims sustain fatal chemical or thermal burns, but are never buried to the extent that they cannot breathe.

Two incidents involving fatalities from engulfment were discussed in the preamble of the NPRM (54 FR 24084). In addition, OSHA has received information during the rulemaking (Ex. 14–159) that further documents the hazards of engulfment in permit-required confined spaces.

Example. Two Ohio foundry employees entered a sand bin to clear a jam. While they were working, sand which had adhered to the sides of the bin began to break loose and fall on them. One employee quickly became buried up to his chest, just below his armpits. The other employee left the bin to obtain a rope, intending to use it to pull his coworker out of the sand. He returned to the bin, tied the rope around the partially buried employee and tried to pull him free. He was unsuccessful. During his attempted rescue, additional sand fell, completely covering and suffocating the employee who had been only partially buried.

Fatalities due to mechanical hazards. OSHA has determined that accidents have resulted in confined spaces when employers failed to isolate equipment within the space from sources of mechanical or electric energy or when the equipment was improperly guarded. In each case reviewed, death resulted from mechanical force injury, such as the crushing of the victim. OSHA has determined from its review of accidents involving mechanical hazards that the correct preventive action would have been to secure the machinery or equipment so that it would not have been inadvertently activated while employees were exposed to it. This procedure is commonly called "lockout".

When servicing or maintenance work is being performed on machinery or equipment located in a confined space, OSHA's standard on the control of hazardous energy sources (lockout/tagout), §1910.147, also applies. When work inside a permit space does not involve servicing or maintenance of machinery or equipment in the permit space, OSHA's standards on machine guarding, in Subpart O of Part 1910, require the equipment to be guarded to protect employees from any mechanical hazards posed by the machine. In any event, this final rule on permit-required confined spaces, §1910.146, requires employers to evaluate any mechanical hazards found in permit spaces and to take all steps necessary to protect entrants.

An incident involving a fatality due to a mechanical hazard is discussed in the preamble of the NPRM (54 FR 24085).

Fatalities due to untrained rescuers. As noted previously, OSHA has determined that a high percentage of confined space accident victims have been untrained rescuers. Indeed, in some cases, the unsuccessful rescuers have died while the initial entrants have recovered. The likelihood that good intentions and poor preparation will lead to tragedy has led the Agency to establish criteria for rescue which will protect co-workers or volunteers from accidental injury or death.

Two incidents involving untrained rescuers were discussed in the preamble to the NPRM (54 FR 24085). In addition, OSHA has obtained information (Ex. 14–145) during the rulemaking that further documents the hazards of allowing untrained rescuers to enter permit spaces.

Example. A maintenance worker entered a sewer manhole to repair a pipe and collapsed at the bottom. A coworker, who had been observing the initial entrant, entered the manhole, lost consciousness, and fell to the bottom. A supervisor looked in the manhole, saw the would-be rescuer, and entered to attempt rescue. The supervisor became dizzy, climbed from the manhole, and passed out. When he regained consciousness, the supervisor summoned rescue and emergency services. Both the initial entrant and the first would-be rescuer died of hydrogen sulfide poisoning.

Conclusion. OSHA has determined, based upon the information presented in this section of the preamble and upon the complete record developed as a result of this rulemaking, that working in permit-required confined spaces involves significant risks for employees and that this standard is necessary to alleviate or control such risks. This conclusion is further supported in the next section of this preamble, *Summary and Explanation of the Standard.*

III. Summary and Explanation of the Standard

The following discussion, which tracks the final rule paragraph by paragraph, summarizes the significant substantive differences between this final rule and the proposed rule and explains how OSHA determined what the final rule would require. This section covers the comments, testimony, and information received regarding the proposed standard, the 18 issues raised in the NPRM, and the 15 issues raised in the hearing notice. Each issue is addressed under the appropriate provision of the final rule or, if the issue does not relate to a particular provision of the standard, in a separate discussion at the end of this section of the preamble. References in parentheses are to exhibits and transcript pages [2] in the rulemaking record. These references are not meant to be exhaustive but are examples of sources that support statements made in the preamble discussion.

As noted in Section I, *Background*, earlier in this preamble, section 6(b)(8) of the OSH Act requires OSHA to explain why a rule which deviates

[2] Chicago Tr.—Transcript pages from the hearing held in Chicago, IL, on January 30 to February 2, 1990.

Houston Tr.—Transcript pages from the hearing held in Houston, TX, on December 5–6, 1989.

Washington Tr.—Transcript pages from the hearing held in Washington, DC, on November 14–15, 1989.

substantially from a pertinent consensus standard better effectuates the purposes of the Act. In a case where the Agency has determined that ANSI language should be adopted, the Summary and Explanation so indicates. In addition, this section of the preamble addresses any case where the Agency has determined that adoption of the pertinent ANSI language would not provide appropriate requirements for employee safety.

Paragraph (a), Scope and Application.

Paragraph (a) states that §1910.146 contains requirements for practices and procedures to protect employees from the hazards of entry into permit-required confined spaces. This paragraph explicitly excludes agriculture, construction, and shipyard employment from the scope of the standard. This language simplifies and clarifies the proposed provision. The proposed rule stated that the section set requirements for permit-required confined spaces (PRCSs) in General Industry that could "be identified by an employer exercising reasonable care." Proposed paragraph (a) also would have excluded electric power generation and transmission, grain handling facilities, and onshore operations of the maritime industry from the scope of proposed §1910.146, to the extent that PRCSs in those industries were "regulated by a more specific confined space entry standard."

As discussed in the preamble of the NPRM (54 FR 24089), OSHA considered proposed §1910.146 to be a generic standard. Therefore, the proposed rule was intended to apply except where superseded, in whole or in part, by industry-specific regulations. The text of proposed paragraph (a) reflected the Agency's understanding of the relationship between proposed §1910.146 and the other OSHA standards. OSHA solicited comments on the scope of the standard in Issue 8 of the NPRM and in Issues 1 and 2 of the hearing notice.

Some rulemaking participants (Ex. 14–38, 14–41, 14–44, 14–54, 14–57, 14–61, 14–63, 14–94, 14–127, 14–148, 14–151, 14–163, 14–173, 14–208, 14–213, 14–216; Chicago Tr. 220–222) stated that OSHA should expand the proposed scope. These commenters asserted that all employees who work in "permit spaces" should be afforded the protection provided by compliance with proposed §1910.146, regardless of the classification of the industry in which they work. One commenter (Ex. 14–61) stated:

> OSHA's contention that the excluded industries are adequately covered by existing standards is wishful thinking at best. The very same hazards that are faced by general industry are found in the agriculture, construction and maritime sectors.... There are [repeated] references in the news media about confined space accidents in all three exempted industries.

Agreeing with this point of view, another commenter (Ex. 14–54) said:

> With the numerous confined spaces in agriculture, construction, maritime, electric generation and transmission industries, and grain handling facilities and the number of fatalities that occur in these areas, they should not be exempt!

Still another commenter (Ex. 14–163), bolstering his arguments with OSHA statistics, stated:

> I find it a grave error not to include construction in the proposed rulemaking. As your statistics succinctly point out, between 1974 and 1977, 276 confined space accidents claimed 234 lives and injured an additional 193 individuals. Electrical, Gas and Sanitary Services recorded the highest average annual fatalities of all industries listed in the Average Annual Fatality Table in this proposed rule making. The majority of the tasks that this industry performs falls into the construction field. Based upon these figures, why would you want to exclude construction?

Other rulemaking participants (Ex. 14–35, 14–43, 14–53, 14–101, 14–110, 14–153, 14–165, 14–180, 14–226; Washington Tr. 173, 176, 178–180, 182, 199, 209–210) stated that the proposed scope should be narrowed. These commenters believed that proposed paragraph (a) did not sufficiently take into account other OSHA standards that already adequately protected employees in certain industries from confined space hazards. For example, some suggested that OSHA exempt all maritime operations because there was already adequate regulation for that industry (Ex. 14–42, 14–58, 14–62, 14–198, 14–212, 14–220). Supporting this view, the National Fire Protection Association (NFPA, Ex. 14–212) stated:

> The NFPA feels that the present maritime industry standard addressing entry and work in confined and enclosed spaces exceeds the provisions of the generic standard and has years of practical application evidence to support this claim.

Representatives of the telecommunications industry (Ex. 14–39, 14–53, 14–104, 14–106, 14–110; Washington Tr. 146–148, 174–183, 196–199) formed a large portion of the group of commenters supporting a narrowing of the scope of §1910.146. This group insisted that confined space hazards found in telecommunications work are already adequately and properly addressed in §1910.268(o), covering work in manholes and unvented underground vaults. For example, Mr Donald Espach, testifying on behalf of GTE Service Corporation (Washington Tr. 175–182), made the case for this industry's view. He noted that GTE is a multi-national corporation that is made up of three core businesses: telecommunications, lighting products, and precision materials. He maintained that this diversity provided a unique perspective on OSHA's proposed permit-required confined space standard. With respect to the proposal's application to general industry, he stated:

> Based on our experience in Towanda and other manufacturing sites in GTE, GTE believes that procedures similar to the OSHA proposals are appropriate to the general industry. The OSHA proposal will ensure that facilities without comprehensive confined space entry program will develop it. Compliance with such programs will save lives.

He argued that applying the proposed rule to telecommunications manhole entry operations was not appropriate, as follows:

> But there are huge differences in confined spaces in chemical and manufacturing plants in telecommunication manholes. First and foremost, the inherent hazard of telecommunications manholes is significantly less. Telecommunication manholes are not designed to contain any kind of chemical or hazardous substance. They do not contain a residual hazardous atmosphere. Telecommunication manholes exist to provide access to underground telephone cables and conduits during splicing, testing, maintenance and air pressurization operations. In most cases, the atmosphere in telecommunication manholes is the same as that outside the manhole.
>
> Secondly, telecommunications manholes are located in and around public roads and rights-of-way all over the United States. GTE alone has over 70,000 telecommunications manholes and the entire industry probably has about 1,000,000. GTE has about 8,700 employees who will enter telecommunications manholes approximately 320,000 times a year.
>
> While there is no question as to the need for special procedures to protect employees who enter telecommunications manholes, to be effective in saving lives, these procedures must reflect the difficulties inherent in having such a large, widely-scattered workforce. Telecommunications manhole entries are routine, performed on a daily basis and, based on data in OSHA's current record, done safely.
>
> The third major difference is that entry into telecommunications manholes is already regulated by OSHA. Entry into telecommunications manholes and unvented cable vaults is currently regulated by Section 1910.268(o)(2). This regulation requires that telecommunications manholes and unvented cable vaults be tested for combustible gas and provided with continuous forced ventilation to assure an adequate oxygen supply and

remove any contaminants which may be present. It is an industry-specific regulation, which assures the safety of the employees of this industry.

Mr. Espach further stated that, based on GTE's experience with manhole operations, which included 4.5 million entries with no deaths or serious injuries, §1910.268(o)(2) provided adequate protection to telecommunications employees. He contended that applying §1910.146 to telecommunications manhole work would be unnecessary.

A third group of commenters (Ex. 14–42, 14–55, 14–58, 14–62, 14–198, 14–212, 14–220), mainly from the construction and maritime industries, stated that OSHA should promulgate the scope of §1910.146 as proposed, asserting that the proposed exclusions were justified by differences between the included and excluded industries. One commenter (Ex. 14–206) from the grain handling industry explained:

> We concur with the scope and application in the proposal which exempts confined spaces in grain handling facilities. OSHA has already addressed the significant confined space entry hazards in grain handling facilities through 29 CFR 1910.272(g) which has been in effect since March 30, 1988. Since employers in the grain industry are already subject to an industry-specific standard, they should not be required to implement the permit system set out in the proposed generic standard.

As noted earlier, proposed paragraph (a) stated "...this section [does not] apply to confined spaces in electric generation and transmission industries, grain handling facilities, or onshore operations of the maritime industries wherever these confined spaces are regulated by a more specific confined space entry standard." Some of those commenting on the scope of the proposal mistakenly assumed that the proposed language would exempt all confined spaces within the listed industries and no others. For example, the Tennessee Valley Authority (Ex. 14–36) indicated that it understood the language of proposed paragraph (a) to be an unqualified exclusion of electric generation and transmission from the scope of proposed §1910.146. On the other hand, the comments from the telecommunications industry clearly indicate that they believe their manhole and underground vault work would have been covered under proposed §1910.146, since a specific exclusion was not given.

The language proposed in paragraph (a) clearly indicated that the exclusion of the pertinent industries is conditioned upon the promulgation of standards which specifically address any permit spaces found in those industries. In particular, OSHA notes that the Notice of Proposed Rulemaking for Electric Power Generation, Transmission, and Distribution (54 FR 5023) stated that proposed §1910.269 addressed "enclosed spaces", which are defined to be spaces that contain no atmospheric hazards under normal conditions, rather than "permit spaces".[3] In addition, the preamble to proposed §1910.269 explicitly stated (54 FR 4984) that any spaces at electric generation or transmission facilities that met the definition of "permit space" would be regulated under proposed §1910.146.

Unfortunately, in spite of the language of the two proposals (§§1910.146 and 1910.269), a few commenters appeared to be confused by the extent of the exclusionary language in proposed §1910.146(a). Therefore, the Agency believes the best approach is not to carry forward the proposed scope language that appeared to exclude all permit spaces in industries that are or are to be covered by other sections of Part 1910. OSHA notes that §1910.5(c), *Applicability of standards*, already provides necessary guidance in the application of generic standards. In particular, existing §1910.5(c)(1), which provides for a specific standard to supersede a generic standard, states, in part:

> If a particular standard is specifically applicable to a condition, practice, means, method, operation, or process, it shall prevail over any different general standard which might otherwise be applicable to the same condition, practice, means, method, operation , or process.

In addition, existing §1910.5(c)(2), which provides for application of a generic standard, states, in part:

> On the other hand, any standard shall apply according to its terms to any employment and place of employment in any industry, even though particular standards are also prescribed for the industry, as in subpart B and subpart R of this part, to the extent that none of such particular standards applies.

Under current OSHA practice, as outlined in §1910.5(c), confined spaces that are presently regulated in other sections of Part 1910 will continue to be regulated under those sections, to the extent that permit spaces are already regulated under those sections. For example, telecommunications work in manholes and underground vaults is normally covered under §1910.268(o). Such work will continue to be covered under the telecommunications standard, and the provisions of §1910.146 would not apply as long as the provisions of §1910.268(o) protect against the hazards within the manhole.[4] Confined spaces that are not covered by any other OSHA rule will fall under §1910.146. Thus, confined spaces other than manholes and underground vaults (such as boilers and tanks) being entered by telecommunications employees would be covered by §1910.146.

Accordingly, based on the rulemaking record and on the language of existing §1910.5(c), OSHA has determined that the detailed exclusionary language in proposed §1910.146(a) is unnecessary and potentially confusing. Therefore, paragraph (a) of the final rule contains no references to industry-specific regulations in Part 1910.

With respect to the agriculture, construction, and shipyard employment industries, on the other hand, OSHA is retaining the proposed language exempting these industries from §1910.146, except for editorial changes. OSHA is aware that confined space accidents occur in agriculture, construction, and maritime and that employees in those industries do face a significant risk of death and serious injury from these accidents. (See Table 1 for a breakdown of the number of confined space accidents in the relevant industries.) However, the Agency believes that sufficient differences exist between these industries and general industry to warrant separate rulemaking activities. For example, Part 1926, OSHA's Construction Standards, contains requirements dealing with confined space hazards in underground construction and in underground electric transmission and distribution work (Subpart S and §1926.956, respectively). In fact, the data presented in Table 1 are based on accidents occurring well before the recent revision of Subpart S of Part 1926. OSHA believes that more current data would show a decline in the number of permit space injuries and deaths in the construction industry.

The Agency also believes that agriculture, construction, and shipyard

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[3] The question of whether or not all confined spaces found in electric power generation, transmission, and distribution work should be addressed in a separate standard was an issue in the rulemaking on proposed §1910.269 (54 FR 4974, January 28, 1989). The resolution of this issue will be discussed as part of the preamble to the final §1910.269.

[4] Taking the telecommunications examples further, the Agency can envision manholes that may be more appropriately covered by §1910.146. Although it is rare, manholes can become overwhelmingly contaminated with toxins or other hazardous chemicals (Washington Tr. 159, 165). If the work area could not be made safe before entry, as required by §1910.268(o)(2)(i)(B), entry would have to be performed under the provisions of §1910.146.

work are likely to pose permit-space working conditions that are unique to these industries. OSHA has a statutory mandate to consult the Advisory Committee on Construction Safety and Health and uses the Shipyard Employment Standards Advisory Committee to obtain recommendations on rules for industries within their purview. These advisory committees frequently identify working conditions that are unique and need separate treatment in the OSHA standards. Except as discussed in the following paragraphs, the Agency has not yet submitted the generic permit space standard to these committees for their review. A review of the data in this rulemaking record can enable these committees to recommend whatever action is necessary, be it rulemaking, enforcement of existing standards, or a combination of the two. Therefore, OSHA believes that confined space standards for agriculture, construction, and shipyard work should be addressed separately so that the Agency can focus on aspects of permit space safety that are specifically appropriate for these areas. Accordingly, §1910.146(a), as promulgated, retains the proposed language exempting these industries from the requirements of the generic permit space standard.

Table 1—Confined Space Accidents in Ariculture, Construction, and Maritime

	Source		
	Safety Sciences[1]	OSHA[2]	OSHA[3]
Agriculture	10		
Construc-tion.	95	13	40
Maritime	23	20	8

[1] "Search of Fatality and Injury Records For Cases Related to Confined Spaces" prepared by Safety Sciences, San Diego, CA, for NIOSH, February 1978, as recorded in Ex. 14–82.

[2] "Selcted Occupational Fatalities Related to Fire and/or Explosion in Confined Work Spaces as Found in Reports of OSHA Fatality/Catastrophe Investigations" prepared by OSHA Office of Statistical Studies and Analyses, Washington, D.C., April 1982, as recorded in Ex. 13–10.

[3] "Selcted Occupational Fatalities Related to Toxic and Asphyxiating Atmospheres in Confined Work Spaces as Found in Reports of OSHA Fatality/Catastrophe Investigations" prepared by OSHA Office of Data Analysis, Washington, D.C., July 1985, as recorded in Ex. 13–15.

Questions have also arisen regarding the proper manner in which to regulate land-based shipyard permit spaces. OSHA published proposed Subpart B of Part 1915 (53 FR 48092, November 29, 1988), Explosive and Other Dangerous Atmospheres in Vessels and Vessel Sections, to revise the requirements for safe entry and work in confined spaces on vessels. In particular, proposed Subpart B addressed atmospheric hazards (oxygen deficiency, toxic contamination, fire and explosion) that may arise in those spaces. Therefore, that proposal did not cover non-atmospheric hazards in vessels or vessel sections. In addition, that proposal did not cover any confined space hazards in land-based shipyard confined spaces.

At the time OSHA was drafting the proposed general industry permit space standard, the Agency had not yet decided how it would address the shipyard confined spaces that were not covered by proposed Subpart B. Therefore, proposed paragraph (a) explicitly excluded the workplaces covered by proposed Subpart B from the scope of proposed §1910.146 but provided that onshore shipyard "permit spaces" would be excluded from the scope only insofar as those spaces were regulated by a more specific standard. This left open the prospect that, if no action were taken to extend the coverage of proposed Subpart B to the entire shipyard, the final rule for general industry permit spaces would apply to the shipyard permit spaces not covered by proposed Subpart B. As noted earlier, some rulemaking participants supported total exclusion of shipyards from §1910.146, while others supported their coverage under that proposed rule.

On June 24, 1992, OSHA published a notice (57 FR 28152) reopening the rulemaking record for proposed Subpart B to receive the recommendations of the Shipyard Employment Standards Advisory Committee regarding shipyard confined spaces and to solicit comments regarding the appropriateness of expanding the scope of Subpart B of Part 1915 to cover the entire shipyard and of incorporating certain provisions of proposed §1910.146 into Subpart B. The comment period is scheduled to end on September 22, 1992. Once the record has been closed again, the Agency will review the rulemaking record and, based on that review, proceed to draft a final rule for Subpart B.

OSHA notes that, under the terms of proposed paragraph (a) of the general industry standard and §1910.5, the promulgation of §1910.146 before the promulgation of revised Subpart B would have resulted in the regulation of land-based shipyard permit spaces and shipyard permit spaces with non-atmospheric hazards under the general industry standard. However, given the Agency's general policy in favor of setting vertical standards for the shipyard industry and the recent efforts (for example, the reopening of the Subpart B record) to develop a basis for a Subpart B standard that could cover all shipyard confined spaces, OSHA believes that it would be inappropriate for the general industry standard to regulate any shipyard confined spaces at present.

Furthermore, the Agency believes that imposing the general industry standard on some shipyard spaces for the period OSHA needs to complete action on proposed Subpart B would generate confusion regarding what shipyard employers are required to do. The Agency also notes that it would be unreasonable to impose the costs of attaining compliance with the general industry standard on the shipyard industry when OSHA has not yet determined how closely the final rule for Subpart B will resemble §1910.146.

Therefore, OSHA is exempting shipyard confined spaces from compliance with final §1910.146. The Agency will continue its efforts to promulgate the revision of Subpart B and will determine what further action should be taken regarding the application of §1910.146 to shipyard confined spaces under the Subpart B rulemaking. To make this clear in the final rule, OSHA is specifying that §1910.146 does not apply to the "shipyard employment" industry, rather than "purely maritime" industry, as proposed. Additionally, the Agency has listed the standards, by Part number, that apply to the exempt industries.

Pending the resolution of this issue, OSHA will continue to protect employees who are exposed to "permit space" hazards in land-based shipyard confined spaces or who are exposed to non-atmospheric "permit space" hazards in any shipyard confined spaces by using the general duty clause (§5(a)(1)) of the OSH Act. The Agency believes that most shipyard employers comply with Subpart B of Part 1915 throughout the shipyard, not only in vessels and vessel sections. Also, OSHA does not consider it reasonable for these employers to enforce two different permit space standards. Therefore, in applying the general duty clause, OSHA will use the terms of Subpart B as guidelines for land-based permit spaces found in shipyard work.

Also, OSHA has not carried forward the language "which can be identified by an employer exercising reasonable care" from proposed paragraph (a), because the Agency has determined that this text, which addresses how OSHA would assess an employer's compliance with the standard, is not appropriate regulatory language. This standard indicates clearly that employers are responsible for identifying their permit spaces and for protecting their employees from the hazards of any such

spaces. Therefore, while an employer's "reasonable care" might be directly relevant to an enforcement proceeding, it is inappropriate to include "reasonable care" as a criteria in the standard itself.

Paragraph (b), Definitions.

Paragraph (b) sets forth the major terms, with definitions, used in the final rule. Where appropriate, proposed terms and definitions have been revised or deleted, and new terms and definitions have been added, for the sake of clarity and to reflect the rulemaking record. OSHA has revised the format for the proposed paragraph, by not numbering the definitions, because the Agency determined that presenting the terms in alphabetical order both provided adequate guidance and was consistent with acceptable Federal Register format and with OSHA's approach to definitions in other standards.

The term "acceptable entry conditions" means:

... the conditions that must exist in a permit space to allow entry and to ensure that employees involved with a permit-required confined space entry can safely enter into and work within the space.

The proposed standard defined the term "acceptable environmental conditions." That definition focused on the absence of "uncontrolled hazardous atmospheres." OSHA has determined that the term "acceptable entry conditions" should replace the proposed term so the final rule clearly indicates that no unreasonable permit space hazards of any kind may be present when entry is authorized. In addition, the Agency has revised the proposed definition, omitting the discussion of "uncontrolled hazardous atmospheres", so it is clear that air contaminants are not the only hazards addressed.

The term "attendant" means an individual who is stationed outside one or more permit spaces, who monitors the authorized entrants, and who performs all duties assigned to the attendant by the employer's permit program. While this definition is substantially the same as that contained in the proposed standard, it has been simplified by eliminating proposed language pertaining to training and the number of spaces and entrants to be monitored, because those substantive provisions are more properly covered in the regulatory text of the final standard.

The term "authorized entrant" means an employee who is authorized by the employer to enter a permit space. This definition, which is substantially the same as that presented in the proposed standard, has been simplified by the elimination of language that more properly appears in the standard's regulatory text.

The term "blanking or blinding" means:

... the absolute closure of a pipe, line, or duct by the fastening of a solid plate (such as a spectacle blind or a skillet blind) that completely covers the bore and that is capable of withstanding the maximum pressure of the pipe, line, or duct with no leakage beyond the plate.

The proposed definition of this term differed in that it specified "a solid plate ... which extends at least to the outer edge of the flange". The proposed definition was based on OSHA's belief that it was necessary to completely occlude the bore, and that it was necessary to have the edge of the occluding plate extend beyond the flange. The Agency expected that this approach would provide appropriate protection that could be verified without difficulty.

Testimony and comments (Ex. 14–88, 14–118, 14–170, 14–188; Houston Tr. 727–728, 772–773; Chicago Tr. 91) indicated that blanking or blinding, as defined in the proposal, would be unnecessarily costly and difficult to accomplish or verify. The rulemaking participants demonstrated that the use of skillet blinds or spectacle blinds would provide equivalent protection without imposing the costs and difficulties of the proposed definition. Additionally, the American Petroleum Institute (API) testified (Houston Tr. 727):

The definition of blanking or blinding in paragraph (b)(4) requires this device to extend to the outer edge of the flange. The standard blind used in our industry extends to the outer edge of the gasket surface and not to the outer edge of the flange. The bolts that hold the blind in place are inserted through bolt holes in the flange so that the blind must necessarily be smaller in diameter than the inner diameter of the bolt circle. Given the nature of this device, it is not possible for it to extend to the outer edge of the flange.

Currently, a typical refinery has hundreds of such blinds which would become obsolete if this provision remains and would have to be replaced. Our experience has been that this device is safe and effective so there is no valid reason to mandate a change. We hope that the proposed definition of blind was only an inadvertent technical error.

The Agency notes that blanking and blinding were not specifically required by the proposal (nor are they absolutely required by the final rule). This was just one recognized method of achieving the isolation of a permit space. In fact, the only place this term is used is in the definition of isolation. However, OSHA agrees that the use of skillet blinds and spectacle blinds will adequately protect employees and that the proposed definition was unnecessarily restrictive. Therefore, the Agency has changed the definition of "blanking or blinding" by removing the "requirement" that the solid plate extend at least to the outer edge of the flange. Additionally, spectacle blinds and skillet blinds are listed as examples of solid plates which will provide adequate blanking or blinding.

The term "confined space" means a space that:

1) Has adequate size and configuration for employee entry; and

2) Has limited means of access or egress; and

3) Is not designed for continuous employee occupancy.

In the NPRM, OSHA only defined a "permit required confined space"; "confined space" was not defined. The final rule contains definitions for "confined space", "permit-required confined space", and "non-permit confined space". The final rule's definition of "confined space" has been taken directly from the portion of the proposal's definition of "permit required confined space" that dealt with the confinement properties of the space (§1910.146(b)(23)(i) through (iii)). The remainder of the proposal's definition of "permit required confined space" addressed the other hazards that may be present within the space and has been retained in the final definition of that term. (See the discussions of the definitions of "non-permit confined space" and "permit-required confined space" later in this preamble. Issues and comments relating to proposed §1910.146(b)(23)(i) through (iii) are addressed under the discussion of the definition of "permit-required confined space.") OSHA believes that the addition of this definition will assist employers in understanding the relationship between the three types of spaces and in making a determination of what spaces, if any, in their workplaces are covered by the standard (that is, are "permit- required" spaces).

The term "double block and bleed" means the closure of a line, duct, or pipe by closing and locking or tagging two in-line valves and by opening and locking or tagging a drain or vent valve in the line between the two closed valves. The proposed definition was essentially identical, except for provision that a drain or vent valve would be "open to the atmosphere", rather than simply "open" as provided in the final rule. This change was made in response to concerns expressed by the Texas Chemical Council (Ex. 14–86), the Department of Defense (Ex. 14–219)

and the National Association of Manufacturers (Chicago Tr. 91) who pointed out that the definition as proposed could require employers to violate EPA emission standards by preventing the use of scavenger systems. OSHA's sole concern is to prevent the passage of toxic material into the permit space during occupancy. The Agency recognizes that the original wording could have been construed to prevent the use of scavenger systems. Additionally, OSHA notes that the use of scavenger systems would probably contribute to control of permit space atmospheric hazards. Therefore, OSHA has revised the proposed definition.

The definition of the term "emergency" in the final rule has been taken without substantive change from the corresponding definition in the proposed standard.

The term "engulfment" means the surrounding and effective capture of a person by a finely divided (flowable) solid substance that can be aspirated to cause death by filling or plugging the respiratory system or that exerts enough force on the body to cause death by strangulation, constriction, or crushing. The proposed definition was similar, except that it provided less information regarding what constitutes engulfment.

Some hearing witnesses (Chicago Tr. 365–366, 458–460; Houston Tr. 1060, 1088–1090) expressed concern that the proposed definition did not recognize all types of engulfment by a solid substance. For example, Mr. Richard Monczka, representing the United Automobile and Agricultural Implement Workers of America, testified that the solids covered by the definition should cover any material capable of flowing into and filling the space.

In response to these comments, OSHA has revised the language of the proposal so that the definition in the final rule reads as follows:

> Engulfment means the surrounding and effective capture of a person by a liquid or finely divided (flowable) solid substance that can be aspirated to cause death by filling or plugging the respiratory system or that can exert enough force on the body to cause death by strangulation, constriction, or crushing.

OSHA believes that this definition clearly indicates that any solid or liquid that can flow into a confined space and that can drown or suffocate an employee can be the engulfing medium.

The term "entry" refers to the act by which a person passes through an opening into a permit space and to the work performed in that space. Entry is considered to have occurred as soon as any part of the entrant's body breaks the plane of an opening into the space.

The proposed definition of this term was similar to the one in the final rule, except that it provided that entry began when the entrant's face broke the plane of a permit space opening and that it addressed only "intentional" entry. Testimony and comments (Ex. 14–62, 14–71, 14–76, 14–80; Houston Tr. 827) indicated that, under this definition, an entrant would not be considered inside a space, if he entered feet first, until the last part of his body, his face, broke the plane of the opening. Under that concept an employee could clearly be within a confined space but not have "entered", because his face had not yet entered the space. Voicing these arguments, Mr. Terry Krug of the Atchison, Topeka and Santa Fe Rail System (Houston Tr. 827) testified:

> So the entrant could get almost all the way into the space, [for] example, arms, legs, torso, and potentially come into contact with rotating parts, bare electrical wiring, fluids, corrosives, skin absorbing toxicants, spiders, snakes, biological, radiation, et cetera and by your present definition would not even have entered the space.
>
> So I would propose to change that particular wording to "any part of the person's body which breaks the plane of the space".

A commenter (Ex. 14–173) stated:

> In our opinion, this definition will limit protection of worker health and safety by defining entry too narrowly. Entry should occur when *any* part of the body breaks the plane of the opening. Reference to the face recognizes the respiratory hazards, but ignores physical and chemical hazards to other body systems. [Emphasis supplied in original.]

OSHA believes that the proposed definition, while adequate for permit spaces that present atmospheric hazards, did not take into account non-atmospheric hazards. OSHA agrees that exposure to permit space hazards such as caustic chemicals and dangerous mechanical devices can begin as soon as any part of an entrant's body breaks the plane of the entry portal and has revised the language contained in the proposed definition accordingly.

Other commenters (Ex. 14–116, 14–160) maintained that the definition of entry should include unintentional entry because the proposal should also address the hazards of accidental entry.

OSHA also agrees with these comments. Paragraphs (c)(3) and (d)(1) require the employer to take steps to prevent unauthorized entry into permit-required confined spaces. These steps are intended to include measures, such as guarding and barricading, necessary to protect employees from accidentally entering a permit space. In order to ensure that employees are adequately protected against falling into or otherwise inadvertently entering a permit space, the Agency has revised the language in the proposed definition to include unintentional as well as intentional entry.

The Agency notes that "entry" under final §1910.146 does not include entry into any confined space that does not pose a hazard to employees. Only entries into confined spaces that are permit-required confined spaces are covered.

The definition of an "entry permit" in the final rule has been changed slightly to read as follows:

> *Entry permit* (permit) means the written or printed document that is provided by the employer to allow and control entry into a permit space and that contains the information specified in paragraph (f) of this section.

Although the definition is essentially the same as proposed, it has been shortened and simplified by eliminating the list of items contained on the permit and replacing that list with a reference to paragraph (f), where the items contained on a permit are specified.

The term "entry supervisor" has been added and is defined as:

> ... the person (such as the employer, foreman, or crew chief) responsible for determining if acceptable entry conditions are present at a permit space where entry is planned, for authorizing entry and overseeing entry operations, and for terminating entry as required by this section.

The proposed rule contained no definition of the entry supervisor. However, the AFL-CIO, in its post-hearing comment (Ex. 142), requested that such a definition be added. The AFL-CIO correctly pointed out that the proposed rule outlined the duties of the entrant, the attendant, and the entry supervisor. They further noted that, of these three groups, only the entry supervisor (individual authorizing or in charge of entry) was undefined.

OSHA agrees that a definition of the entry supervisor is needed. Under the final rule, the entry supervisor:

(1) evaluates the conditions in and around any permit space that is to be entered;

(2) oversees entry operations, as necessary, to determine if the conditions are acceptable for entry;

(3) where acceptable entry conditions are present, either authorizes entry to begin or allows entry operations that are already underway to continue; and

(4) takes the necessary measures to protect personnel from permit space hazards.

Where acceptable entry conditions are not present, the entry supervisor either

prohibits entry or, if entry is already underway, orders the authorized entrants out of the permit space and cancels the entry permit.

OSHA has determined that adding the definition of "entry supervisor" will more clearly indicate the responsibilities imposed by paragraphs (e) and (j) (proposed as paragraphs (d) and (g)). In conjunction with this action, OSHA is relocating the language of proposed (g)(1)(vi), which allowed entry authorizers to serve as attendants or authorized entrants, to a parenthetical note in the new definition. The language of that proposed paragraph was informational rather than regulatory or definitional in nature, in that it simply describes something an entry supervisor is permitted to do. The Agency anticipates that there will be many entry situations, especially if an employer has only a few employees, where the entry supervisor will serve either as the attendant or as an authorized entrant. The language of the note indicates that this is acceptable as long as the entry supervisor is trained and equipped for each role he or she fills. All pertinent requirements relating to the duties of attendants and authorized entrants would still apply to the entry supervisor who serves as an attendant or an authorized entrant. The Agency notes that the responsibilities of the entry supervisor, as revised, are set out in paragraph (j) of the final rule.

OSHA recognizes that there are circumstances, such as when the entry permit's stated duration exceeds one workshift, under which more than one person may serve as entry supervisor for a particular entry operation. The final rule does not require the employer to repeat the entry authorization process when an entry supervisor is replaced, if there is continuous direct responsibility for the entry, with direct transfer from one entry supervisor to next, and if the successor has the necessary training and performs the required duties.

The term "hazardous atmosphere" means an atmosphere that may expose employees to the risk of death, incapacitation, impairment of ability to self-rescue, serious injury or acute illness due to:

(1) flammable gas, vapor, or mist in excess of 10 percent of the lower flammable limit (LFL),

(2) airborne combustible dust at a concentration that exceeds its LFL,

(3) atmospheric oxygen concentration that is less than 19.5 percent or greater than 23.5 percent,

(4) atmospheric concentration of any substance for which a dose or a permissible exposure limit is published in Subpart G or Subpart Z of Part 1910 and that could result in employee exposure above the pertinent dose limit or permissible exposure limit, and

(5) any other atmospheric condition recognized as immediately dangerous to life or health.

This definition, which is very similar to the proposed definition, reflects the wide range of atmospheric conditions that can pose permit space hazards. The language from the proposed definition has been modified in three respects. First, the phrase "impairment of ability to self-rescue (that is, escape unaided from a permit space)" has been added to the definition's introductory text, so that that text now reads:

... an atmosphere that may expose employees to the risk of death, incapacitation, impairment of ability to self-rescue (that is, escape unaided from a permit space), injury, or acute illness from one or more of the following causes:

The intent of this addition is to provide consistency between the "immediately dangerous to life or health" definition, which includes the phrase "interfere with an individual's ability to escape from a hazardous atmosphere", and the definition of "hazardous atmosphere" itself.

Subheading (1) of the definition, dealing with lower flammable limits, is identical to the equivalent proposed provision.

Some commenters (Ex. 14–134, 14–172) objected to OSHA's adoption of the 10 percent of LFL level proposed in paragraph (b)(11)(i). They argued that a 20 percent level was more appropriate. One of them (Ex. 14–134) maintained that existing "combustible gas meters are calibrated at 20% [of the lower flammable limit]".

OSHA does not agree with these comments. The 10 percent level is widely recognized as being the threshold value for a hazardous atmosphere. This value is used in ANSI Z117.1–1977 (Ex. 13–5), in the NIOSH criteria document for "Working in Confined Spaces" (Ex. 13–9), and in other OSHA standards (for example, §1926.800(j)(1)(viii)). The Agency believes that these national guidelines provide much stronger support for the 10 percent limit than existing company practice provides for those who have adopted a higher limit. Additionally, the fact that combustible gas meters are calibrated at 20 percent of the LFL is irrelevant. Meter calibration procedures are usually recommended by the manufacturer. The fact that certain meters are calibrated at 20 percent of the LFL means only that they are the most accurate at that level; it does not mean that these meters are significantly inaccurate at 10 percent of the LFL.

The second change is in subheading (2), addressing airborne combustible dusts, which, as proposed, included the phrase "[a concentration] that obscures vision at a distance of five feet (1.52 m) or less". This provision has been changed in the final rule to read:

Airborne combustible dust at a concentration that meets or exceeds its LFL;

The reference to visibility in the proposal was meant as an aide to employers and employees in approximating the LFL of the dust. OSHA believed that the proposed language would provide the best possible guidance, given that there was no reliable equipment available to provide on-site combustible dust concentration measurements. However, some commenters (Ex. 14–143, 14–161; Chicago Tr. 31) stated that the proposed language would be unsafe, as there are some dusts which are combustible at concentrations that would not obscure vision at 5 feet or less. OSHA agrees that this portion of the proposed definition was deficient and could have allowed a hazard to arise. OSHA has corrected this deficiency by changing the concentration of combustible dust to one that meets or exceeds the lower flammable limit. The "rule of thumb" criteria of obscured vision at a distance of 5 feet or less has been retained, for informational purposes only, in an explanatory note.

The 10 percent limitation applied to flammable gases, vapors, and mists has not been applied to combustible dust. This is because the Agency believes that the difficulty in measuring combustible dust concentrations make such a limit infeasible. Also, there is no evidence in the record to support lowering OSHA's proposed limit, which was equivalent to the lower flammable limit itself. The Agency believes that, because air- borne dust concentrations do not change rapidly and because the flammability hazard posed by air-borne dust can usually be judged visually, employees will be adequately protected.[5]

The third change is in subheading (3), addressing atmospheric oxygen concentration. The proposed provision (paragraph (b)(11)(iii)) stated that an atmospheric concentration of oxygen

[5] A level of 100 percent of the lower flammable limit for dusts as the lower limit of what is considered to be a hazardous atmosphere with respect to combustible dust may still appear to be high. Unfortunately, the rulemaking record does not include any information that the Agency could use to set a lower limit. The final rule, by requiring employers to take measures to control hazards, will force the employer to use procedures that ensure that the levels of combustible dust do not reach the lower flammable limit or that otherwise protect employees from the hazards of fire and explosion.

above 22 percent was hazardous. OSHA was concerned that an atmosphere with an oxygen concentration greater than 22 percent would be "oxygen enriched" and, therefore, would pose a hazard of fire and explosion. This is because excess oxygen can extend the flammable range of gases and vapors and make combustible materials ignite easily and burn rapidly.

Some of the rulemaking participants (Ex. 14–46, 14–47, 14–86, 14–103, 14–179; Washington Tr. 452–453, 577) expressed the view that the 22 percent threshold for oxygen enrichment was too low and that it excessively restricted the range of acceptable oxygen concentrations. A few of the commenters suggested values of 25 or 26 percent for the oxygen enriched atmosphere limit. For example, CECOS International (Ex. 14–46) stated:

> In proposed 29 CFR 1910.146(b)(11), the definition of a hazardous atmosphere would include an atmospheric oxygen concentration above 22 percent. This limit, which is only 0.5% above the normal ambient concentration presents a likelihood that a hazardous atmosphere might be falsely identified when normal conditions exist. CECOS suggests that an oxygen-enriched atmosphere be defined as one containing greater than 25% oxygen.

In support of this view, the NIOSH Criteria Document (Ex. 13–9) set 25 percent as the concentration at which an atmosphere was considered oxygen enriched. NIOSH reaffirmed that position in its hearing testimony (Washington Tr. 131).

Other comments (Ex. 14–57, 14–179, 14–187) received suggested that 23 or 23.5 percent would be a more appropriate number. The Motor Vehicle Manufacturers Association (Ex. 14–179) explained:

> The definition for "hazardous atmosphere" ... identifies an oxygen concentration above 22 percent as unacceptable. We recommend the unacceptable level be designated as more than 23.5 percent oxygen by volume. This is consistent with other OSHA regulations, such as 29 CFR 1910.134. If there is some other scientific or policy rationale for this deviation, OSHA should explain it and allow opportunity for comment.

Some rulemaking participants (Ex. 14–47, 14–179; Washington Tr. 452–453, 577) argued that the OSHA standard should be consistent with the 1989 ANSI standard (Z117.1) and other standards addressing safe upper limits on oxygen concentration. In particular, one commenter (Ex. 14–61) observed that the proposed 22 percent level was well within the acceptable range set by ANSI (19.5 to 23.5 percent) and stated "[oxygen sensors] could easily experience false alarm signals of oxygen enrichment due to possible combined effects of humidity, temperature or barometric pressure interference due to this small differential from the oxygen level of normal air."

OSHA agrees that the proposed threshold for oxygen enrichment was too close to the normal range of oxygen concentration. The Agency has determined, based on the rulemaking record, that setting the threshold for oxygen enrichment at 23.5 percent is appropriate to control fire and explosion hazards. OSHA has relied heavily on the expertise of the ANSI Z117 Committee in making this determination. Although a 25 percent level was recommended by NIOSH, the 23.5% figure in the ANSI standard appears to be more widely accepted. Therefore, the definition of "hazardous atmosphere" in final §1910.146(b), in conjunction with the definition of "oxygen deficient atmosphere" and "oxygen enriched atmosphere", sets the acceptable concentration of oxygen at 19.5 to 23.5 percent.

Subheading (4) has not been substantively changed from proposed paragraph (b)(11)(iv), except that a reference to Subpart G, *Occupational Health and Environmental Control*, of Part 1910 has been added because that subpart contains dose exposure limits that are pertinent to protection of employees who enter permit spaces. The proposed parenthetical text dealing with the situation in which OSHA has not determined a dose or permissible exposure limit has been titled as a "note" in the final standard to indicate clearly that the pertinent language is not part of the regulatory text. The note, which has been placed after subheading (5), gives other sources of information that can be used to determine appropriate exposure limits for substances not addressed in Subparts G and Z of the OSHA General Industry Standards. While the Agency will not be enforcing the note as it appears in the final rule, OSHA will use these other sources to assess an employer's compliance with subheading (5) of the definition of "hazardous atmosphere". Possession of Material Safety Data Sheets as required by §1910.1200 will put employers on notice of the potential for IDLH atmospheres under subheading (5), which OSHA will enforce.

OSHA has included a note after this subheading in the definition of hazardous atmosphere to clarify that an atmospheric concentration of any substance that is not capable of causing death, incapacitation, impairment of ability to self-rescue, injury, or acute illness due to its health effects is not covered by this provision. In other words, an atmosphere that contains a substance at a concentration exceeding a permissible exposure limit intended solely to prevent long-term adverse health effects is not considered to be a hazardous atmosphere on that basis alone.

Subheading (5) of the final rule's "hazardous atmosphere" definition, dealing with any atmospheric condition immediately dangerous to life or health not listed in subheadings (1) through (4), is identical to the proposed provision (paragraph (b)(11)(v)). There was no substantive objection to this provision of the proposal.

The term "hot work permit" means:

> ... the employer's written authorization to perform operations (for example, riveting, welding, cutting, burning, and heating) capable of providing a source of ignition.

The definition has not been changed substantively from that contained in the proposed standard. (It has only been reworded slightly to provide added clarity.) No significant comments were received on this provision in the proposal.

The term "immediately dangerous to life or health (IDLH)" means:

> ... any condition that poses an immediate or delayed threat to life or that would cause irreversible adverse health effects or that would interfere with an individual's ability to escape unaided from a permit space.

The final definition differs from the proposed one in that it explicitly includes delayed as well as immediate threats to life and omits any reference to eye damage or irritation. Several rulemaking participants (Ex. 14–45, 138; Chicago Tr. 93, 177; Houston Tr. 775, 814) stated that, since a definition of IDLH has already been promulgated in paragraph (b) of §1910.120 (OSHA's standard on hazardous waste operations and emergency response), the definition in the confined space final rule should be consistent with that in §1910.120 and should include delayed as well as immediate adverse health effects.

OSHA has accepted these comments and has adopted a definition of "immediately dangerous to life or health" that is consistent with §1910.120. OSHA notes that the proposed definition of "immediate severe health effects", a term used in the proposed definition of IDLH, covered exposure-related reactions manifested within 72 hours after exposure to a permit space hazard. For the sake of consistency with the standard on hazardous waste operations and emergency response, the Agency is not carrying forward the proposed definition of "immediate severe health effect" and is incorporating the concept

of delayed effects directly into the definition of IDLH. OSHA has also included a note that provides an example of a delayed health effect.

The reference to eye damage or irritation in the proposed standard was included to indicate conditions that could interfere with an individual's ability to escape from a hazardous atmosphere. Because the use of these examples seemed to cause some confusion (Ex. 14–45; Houston Tr. 774), OSHA has eliminated them from the definition. In their place, the definition explicitly includes any condition that "would interfere with an individual's ability to escape unaided from a permit space" as a criterion for the determination of whether a hazard is IDLH. This change also make the IDLH definitions in the OSHA confined space and hazardous waste standards more consistent.

The proposed term "immediate-severe health effects" has not been carried forward into the final rule, as discussed earlier in relation to the definition of "immediately dangerous to life or health".

The term "inerting" means:

> ... the displacement of the atmosphere in a permit space by a noncombustible gas (such as nitrogen) to such an extent that the resulting atmosphere is noncombustible.

The definition in the final rule replaces the proposed phrase "non-flammable, non-explosive or otherwise chemically non-reactive" with "noncombustible" and lists nitrogen as an example of a non- combustible gas. The Agency believes that these changes simplify and clarify the definition. The term "chemically non-reactive" could have been interpreted in absolute terms, rather than as OSHA intended with respect to the hazards of fire and explosion.

Some commenters (Ex. 14–94, 14–118, 14–161) suggested that the final rule note the hazards presented by inerting a space. They pointed out that, while inerting a space reduces the risk of fire and explosion, it creates an IDLH atmosphere, which must be eliminated or controlled before permit entry is allowed.

OSHA has accepted this suggestion and has incorporated their warning into a note following the definition of "inerting".

The final rule does not contain the proposed term "in-plant rescue team". In its place OSHA is using the term "rescue service", which covers both rescuers who are employees of the employer whose workplace contains the permit spaces and those who are employees of another employer. The use of this term, its definition, and issues related to rescue services are addressed under the summary and explanation of paragraph (k) of the final rule.

The term "isolation" means:

> ... the process by which a permit space is removed from service and completely protected against the release of energy and material into the space by such means as: blanking or blinding; misaligning or removing sections of lines, pipes, or ducts; a double block and bleed system; lockout or tagout of all sources of energy; or blocking or disconnecting all mechanical linkages.

The proposed definition of this term, on which no substantive comments were received, included language relating to the types of hazards for which isolation would be required ("which could be a serious hazard to permit space entrants"). The definition in the final rule does not carry forward that language, focusing instead on describing what "isolation" is.

The final rule's definition of "line breaking" is identical to that contained in the proposed rule. OSHA received no substantive comments on this definition.

The proposed term "low hazard permit space" has not been carried forward, since it is not used in this final rule. Many comments (Ex. 14–47, 14–76, 14–86, 14–118) indicated that the term only generated confusion and might lead to a false sense of security for employees entering a confined space designated as a "low hazard permit space". They argued that the term gave a misleading impression of the dangers that could be faced on entry into permit spaces. Based on its review of the rulemaking record, OSHA agrees with these comments and has carried forward neither the proposed definition nor proposed paragraph (i) into the final rule. A detailed discussion of the "low hazard" issue is contained later in the summary and explanation of paragraph (c)(5) of the final rule.

A definition for the new term "non-permit confined space" has been included in the final standard. It is defined as:

> ... a confined space that does not contain or, with respect to atmospheric hazards, have the potential to contain any hazard capable of causing death or serious physical harm.

Some commenters (Ex. 14–94, 14–150, 14–168, 14–219, 14–225) felt that the proposed definition of a permit-required confined space was not entirely clear and that misinterpretations were possible. They suggested that modifications be made to that definition. To solve this problem, OSHA has decided to define a "confined space" and "non-permit confined space", as well as a "permit-required confined space". (See the related discussions of the definitions of "confined space" and "permit-required confined space" elsewhere in this preamble.) The definition of a "non-permit confined space" makes it clear that a space must contain or, with respect to atmospheric hazards, must have the potential to contain a hazard capable of causing death or serious physical harm, in addition to having the configuration of a confined space, to be considered a permit-required confined space.

Examples of non-permit confined spaces include vented vaults, motor control cabinets, and dropped ceilings. Although they are "confined spaces", these spaces have either natural or permanent mechanical ventilation to prevent the accumulation of a hazardous atmosphere, and they do not present engulfment or other serious hazards.

The term "oxygen deficient atmosphere" in the final rule is identical to that contained in the proposal.

OSHA received one comment on this definition (Ex. 14–103). The commenter, the ANSI Z88 committee for respiratory protection, stated that the 19.5 percent concentration for oxygen deficiency should be changed to 12.5 percent. Their reasoning was based on the work of the ANSI Z88.2 subcommittee, which found that no respiratory protection was needed at 16 percent oxygen concentration, and that 12.5 percent oxygen concentration was the level that should be considered immediately dangerous to life and health (IDLH).

Rebutting the ANSI comment at the Washington hearing (Washington Tr.132–133), Mr. Theodore Pettit and Mr. Laurence Reed of the National Institute of Occupational Safety and Health (NIOSH), stated:

> MR. PETTIT: ANSI hasn't resolved the 12.5 that they are throwing around or the 16 percent, but I served on the ANSI committee on confined spaces. The 117.1 revision is coming out 19.5, which is the consensus industry and labor [standard], so 19.5 is still the standard as far as we are concerned. And 19.5 is also the safeguard, but with the 12.5 you have absolutely no safeguard.
>
> MR. REED: In the development of its [Respirator Decision Logic], the literature which I believe at that time was published in 1986 and we determined that 19.5 percent was the cut-off for oxygen sufficiency.

In Issue 15 of the NPRM (54 FR 24087), OSHA requested information on the extent to which employees would work in permit spaces which have oxygen-deficient atmospheres. OSHA also sought information on actual

oxygen levels encountered in oxygen-deficient permit spaces and on the effects on employees of entering oxygen-deficient atmospheres.

Several commenters (Ex. 14–4, 14–27, 14–57, 14–61, 14–62, 14–71, 14–94, 14–219) addressed Issue 15. None of them provided information on the number of employees who work in oxygen-deficient atmospheres. However, results of oxygen deficiency that were reported (Ex. 14–4, 14–57, 14–61, 14–94, 14–219) included dizziness, tiredness, difficulty in breathing, confusion, unconsciousness, and death. The U.S. Air Force (Ex. 14–219) sent a copy of a report addressing exposure to atmospheres containing 13 to 21 percent oxygen for long periods of time (not in confined spaces).

In Issue 16 of the NPRM (54 FR 24087), OSHA requested information, based on actual recorded atmospheric measurements, on any physical or physiological effects caused by rapid transition from breathing normal air (21% oxygen content) to breathing atmospheres with less than normal oxygen content. Only the U.S. Air Force (Ex. 14–219) commented on this issue. Their view was that, in general, the suddenness of the reduction of the oxygen level was not nearly as important as the physiological effect of the final oxygen level.

OSHA has not accepted the ANSI Z88 recommended change. The 19.5 percent oxygen level is widely recognized as being the minimum level needed to ensure an adequate supply of oxygen. The NIOSH Respirator Decision Logic (Ex. 14–145) utilizes 19.5 percent oxygen concentration as the decision level for use of a respirator, and the ANSI Z117.1 standard itself recognizes this concentration as a minimum. Considering the possible consequences of exposure to atmospheres containing too little oxygen as described in the record, the Agency believes, in the absence of compelling evidence to the contrary, that the proposed level is necessary to ensure an adequate oxygen supply for entrants. Therefore, OSHA has not changed the definition of oxygen deficient atmosphere.

The term "oxygen enriched atmosphere" means:

> ... an atmosphere containing more than 23.5 percent oxygen by volume.

As noted earlier in reference to the definition of "hazardous atmosphere", the final rule has adopted a safe upper limit on oxygen content of 23.5 percent rather than the proposal's 22 percent level. The comments received on the definition of "oxygen enriched atmosphere" have been addressed under the discussion of that term.

The term "permit-required confined space (permit space)" means a confined space that presents or has a potential to present one or more of the following:

(1) an atmospheric hazard;
(2) an engulfment hazard;
(3) a configuration hazard; or
(4) any other recognized serious hazard.

As noted in Section I, *Background*, earlier in this preamble, OSHA has determined that a clear definition for "permit-required confined space (permit space)" will provide the necessary guidance for employers to determine when they are subject to the permit space standard. The Agency has determined that there are three circumstances (mobility-limiting size and configuration, limited means of access and egress, and unsuitability for continuous employee occupancy) that are common to all confined spaces. As noted earlier, those are the elements that OSHA has included in the definition of "confined space". OSHA recognizes that the hazard element that differentiates permit spaces from confined spaces may vary in its nature, so the Agency has set out several ways in which a confined space could qualify as a permit space. Thus, a permit space is a confined space that has certain characteristics that make it hazardous for employees to enter without taking special precautions.

Section II, *Hazards* earlier in this preamble, discusses most of these characteristics. That discussion documents confined space accidents that were caused by atmospheric, engulfment, and other serious (such as mechanical) hazards.[6] Atmospheric hazards (such as oxygen deficiency, toxic atmospheres, and flammable atmospheres) are the most common cause of confined space accidents. Engulfment hazards, though not as widely recognized, also cause the deaths of many confined space entrants by suffocating or drowning the victims. Confined spaces that can wedge or otherwise pin an employee and cause his or her suffocation have also caused at least one of the deaths[7] described in the record (Ex. 14–145). These are the hazard characteristics specifically enumerated in the definition of "permit-required confined space". However, as noted earlier, the types of confined spaces posing serious hazards to employees are wide ranging. Therefore, the definition of PRCS also requires confined spaces that pose other unspecified serious hazards to be considered permit spaces, as well.

The definition proposed in §1910.146(b)(23) was similar to the definition promulgated in the final rule. OSHA has made some changes for the sake of clarity. As noted earlier, provisions corresponding to the first three subheadings under the proposed definition (paragraphs (b)(23)(i) through (iii)) have been put under the generic definition of "confined space", so that there is no need to repeat them in the definition of PRCS. Other editorial changes have also been made to the language of proposed §1910.146(b)(23)(iv), which has been incorporated into the definition of "permit-required confined space" in the final rule.

In Issue 3 of the NPRM, OSHA requested comments regarding the adequacy of the proposed definition of permit-required confined space and solicited suggestions for additional or alternative language.

Over 50 commenters responded to this issue. Most of the commenters suggested that OSHA revise the proposed definition. Several commenters (Ex. 14–61, 14–86, 14–145, 14–168, 14–219) stated that poor natural ventilation should be a component of the definition.

Poor natural ventilation is not a necessary condition for a confined space to be a permit space. (It should be noted that the presence or absence of natural ventilation is not relevant to whether a space is confined; it can only be relevant to whether a confined space is considered a permit-required confined space.) OSHA believes that the definition of hazardous atmosphere adequately addresses the safety of the atmosphere within the space without regard to whether or not the space is poorly ventilated. While natural ventilation can sometimes prevent the accumulation of a hazardous atmosphere, the Agency considers the most important distinguishing characteristic, with respect to atmospheric hazards, that can make a confined space a permit space to be the content of the air itself. Even with good ventilation in a confined space, certain areas within the space may be able to accumulate a hazardous atmosphere.

[6] Section II of the preamble also discusses accidents related to the lack of training for rescuers. The actual hazard present within the permit space in these accidents was actually an atmospheric one.

[7] Although very few of the accident descriptions in the record illustrate the hazard posed by spaces that can entrap and cause the asphyxiation of a worker, OSHA believes that it is important to specifically spell out the hazard in the definition. It is something that may easily be overlooked in the evaluation of a confined space; and, by highlighting the entrapment hazard, the final rule will best protect employees.

Another commenter (Ex. 14–191) was concerned that proposed paragraph (b)(23) was unclear with respect to which subparagraphs ((i), (ii), (iii), and (iv)) a space had to meet in order to qualify as a permit space. They recommended that a space be required to satisfy all the criteria set forth in proposed paragraphs (b)(23)(i) through (iii) plus any one of the additional criteria set forth in paragraph (b)(23)(iv) in order to be considered a confined space.

OSHA intended that, in order to qualify as a permit space, a space have all three of the first three characteristics (paragraphs (b)(23)(i) through (iii)) and at least one of the characteristics listed under paragraph (b)(23)(iv) of the NPRM's definition. In the final rule, OSHA has clarified this intent in two ways.

First, the final rule separates the PRCS definition into two components: "confined space" and "permit-required confined space". The characteristics common to all confined spaces (proposed paragraphs (b)(23)(i) through (iii)) are now contained in the definition of "confined space", which clearly indicates that all three criteria must be met in order for a space to be considered "confined". A permit space is now defined to be a "confined space" meeting one of four criteria corresponding to those listed in proposed paragraph (b)(23)(iv).

Second, OSHA has adopted language clarifying the intent of these two definitions. The word "and" has been inserted between the first and second criteria and between the second and third criteria of the definition of a "confined space" to indicate clearly that all three criteria must be met. The introductory text of the definition of "permit-required confined space" states that "one or more of the [listed] characteristics" (corresponding to those given in proposed paragraph (b)(23)(iv)) must be met before a confined space is considered a permit space.

The Agency believes that the final rule clearly states the criteria for determining what spaces qualify as permit-required confined spaces.

Proposed paragraph (b)(23)(i) stated, as the first criterion, that a space had to be "large enough and so configured that an employee can bodily enter and perform assigned work" in order to be considered a permit-required confined space. Several commenters (Ex. 14–4, 14–42, 14–94, 14–99, 14–143) stated that it was confusing for proposed paragraph (b)(23)(i) to provide that a permit space was sized and configured for bodily entry when the definition of "entry" provided that entry began when the employee's face broke the plane of the opening into the space. Some of the commenters (Ex. 14–42, 14–94) noted that the proposed definition excluded spaces which contained hazardous atmospheres and into which employees were able to insert only their heads and shoulders. For example, Mr. Martin Finkel, a Certified Marine Chemist with Marine & Environmental Testing, Inc. (Ex. 14–4) stated:

> The definition of Permit Required Confined Space, as stated, does not allow for small space[s] which permit entry of a worker[']s head, but not his/her whole body. Such a space may prove just as hazardous if it contains an IDLH atmosphere which the worker breathes. I recall seeing photos of a [fatality] on a barge where only the worker's head was in the tank—his body remained sprawled on deck—yet the worker was just as dead as if he had entered bodily. Therefore, I suggest removing [paragraph (b)](23)(i) entirely from the definition of Permit Required Confined Space.

The Agency has not adopted this suggestion. While OSHA is concerned that spaces that are too small for complete bodily entry may pose hazards for employees, the Agency did not intend to cover such spaces under the permit space standard. OSHA believes that the NPRM preamble discussion of permit space incidents and of proposed provisions clearly indicates that the proposed rule was intended to cover only spaces that were large enough for the entire body of an employee to enter. As commenters have correctly noted, the proposed definition of "permit required confined space" did not cover the "small" spaces. Such spaces do not meet the definition of "confined space", nor do they pose hazards comparable to those associated with confined spaces. Since an employee cannot totally enter such spaces, he or she should not have difficulty withdrawing from the space. In order for a space to be considered a permit-required confined space, it must first be a confined space. A space that cannot be entered is not confined; therefore, it does not pose hazards related to the difficulty of exiting the space.

OSHA realizes that an employee may still be injured or killed as a result of some atmospheric hazard within such an enclosed area; however, this standard is not intended to address all locations that pose atmospheric hazards. The Agency believes that the procedures necessary to protect workers from atmospheric hazards alone are not those required by this standard, but are required by other OSHA standards, such as Subpart Z of the General Industry Standards. The exposed employee must also have difficulty exiting the space for many the requirements of §1910.147 to apply. For example, the need for an attendant to be present is doubtful. Spaces that cannot be entered are small enough to be readily ventilated,[8] and in many cases a reaccumulation of a hazardous atmosphere is highly unlikely. Because the requirements set forth in final §1910.146 are not appropriate for application to spaces into which an employee cannot completely enter, OSHA has retained the language proposed in paragraph (b)(23)(i), which appears under the definition of "confined space" in the final rule.

OSHA notes that, as discussed previously in the preamble, "entry" as defined in the final rule begins when any part of the entrant's body breaks the plane of the entry portal. This language indicates the Agency's concern that exposure to a permit space hazard can occur before the entire body of the entrant is inside the space. The definition of "entry" is not intended to indicate that a space large enough to accommodate only part of an employee's body constitutes a permit space. Therefore, OSHA has determined that the definitions of "entry" and "permit-required confined space" are consistent.

Proposed paragraph (b)(23)(ii) stated, as the second criterion, that a space had to have "limited or restricted means for entry or exit" in order to be considered a permit-required confined space. The proposed paragraph listed tanks, vessels, silos, storage bins, hoppers, vaults, pits, and diked areas as examples of spaces with this characteristic. Some commenters (Ex. 14–69) felt that it was appropriate for the definition to cover open top spaces, such as dikes and excavations, while others (Ex. 14–185) stated that those same spaces should not be included.

OSHA listed these spaces as examples of limited or restricted entry or exit, not as examples of permit spaces, as some rulemaking participants believed. The final rule, under the definition of "confined space", adopts a slightly revised version of the language enumerating the examples to state this intent more clearly. As indicated in the preamble to the proposal (54 FR 24089), OSHA notes that doorways and other portals through which a person can

[8] Subpart Z of part 1910 would require the employer to use feasible engineering controls to maintain atmospheric contaminants below permissible exposure limits. Normally, ventilation would be used to meet the Subpart Z requirements, and the accident information contained in the rulemaking record does not indicate a need for additional regulation of spaces that cannot be entered completely.

walk are not considered to be limited means for entry or exit.

Proposed paragraph (b)(23)(iii) stated, as the third criterion, that a space had to be "not designed for continuous employee occupancy" in order to be considered a permit-required confined space. Some commenters expressed concern regarding the use of the phrase "continuous occupancy" in this proposed paragraph. Some of them (Ex. 14–94, 14–143, 14–163) argued that many spaces are not designed for continuous employee occupancy but should not be considered as confined spaces. They suggested rewording the proposed definition to "an enclosure with a primary function other than human occupancy." (The suggested language is essentially identical to language in the ANSI Z117.1–1989 definition of "confined space".)

OSHA notes that the criterion "not designed for continuous human occupancy" is but one of the necessary three criteria required for a space to be designated a confined space. Thus, there may be any number of spaces that are not designed for continuous human occupancy, but that cannot be considered to be confined spaces (or, subsequently, "permit-required confined spaces") under OSHA's definitions because they do not meet both of the other two criteria set forth in the "confined space" definition.

The Agency has determined that the suggested language from the ANSI standard is not appropriate. The ANSI language focuses on what the primary function of the space is, whereas OSHA's definition focuses on what the space is designed for. If the space is truly designed for human occupancy, then the primary function of the space is irrelevant. For example, a vented telecommunications vault is typically designed for continuous human occupancy—the ventilation for the vault ensures the presence of a normal atmosphere for an occupant to breathe, and the working dimensions of the space are large enough to allow an adult to work and move around while erect. It could be argued, however, that the primary function of the vault is to house telecommunications equipment. Although the distinction between the "primary function" and the "design" of a space may seem inconsequential, OSHA believes that the final rule's definition properly places the focus on the design of the space, which is the key to whether a human can occupy the space under normal operating conditions.

Another commenter (Ex. 14–144) stated that OSHA should eliminate "continuous" from the definition because its "Manholes and vaults—to the extent they are covered—are designed for employee entry and occupancy in order to service telephone cables."

OSHA has not accepted this recommendation. One of the characteristics of a confined space is that it is not designed for humans to enter and work for prolonged periods without any additional consideration for safety and health. With respect to manholes and unvented vaults, the Agency notes that atmospheric testing and portable mechanical ventilation are among the recognized procedures that must be undertaken (as required by §1910.268(o)) before employees can safely enter these spaces.[9] Therefore, the final rule's definition of confined space retains the proposed phrase "continuous human occupancy".

OSHA notes that the meaning of proposed paragraph (b)(23)(iii) has been a factor in general duty clause (section 5(a)(1)) enforcement actions brought by the Agency. For example, General Dynamics Land Systems Division (General Dynamics) contested a citation for a willful violation of section 5(a)(1) for failure to protect employees from confined space hazards. The employer referenced the proposed language to contend that an M-1 tank is not a (permit-required) confined space because the assembled tank is "intended" for continuous employee occupancy. The Occupational Safety and Health Review Commission (OSHRC) held in *General Dynamics Land Systems Div.* (15 OSHRC 1275, September 11, 1991) that the classification of a space would be based on its condition at the time employees would enter, not on the ultimate use of the space. The OSHRC determined that assembled tanks posed a recognized hazard (freon exposure) and that it was feasible to abate the hazard. Therefore, the OSHRC held that OSHA properly cited General Dynamics for failure to implement a permit space program when employees were assigned to enter assembled M-1 tanks in which freon was being used.

Additionally, the Agency notes that the preamble of the NPRM (54 FR at 24097) stated "Some products are considered permit spaces while they are being built, and entries by workers are required as part of the manufacturing process." This language reflects OSHA's recognition that there are spaces (such as assembled M-1 tanks) that may be permit spaces during fabrication, because hazards might be introduced at that time and because they are not designed for continuous occupancy until their manufacture has been completed. However, after they are completed and put to use, the hazards created by the manufacturing process are not present, and they are then designed and intended for continuous occupancy. Thus, they would not be permit spaces in actual use.

Proposed paragraph (b)(23)(iv) stated, as the fourth criterion, that a space had to contain one or more of a list of four specified hazards in order to be considered a permit- required confined space. The four listed hazards were:

(1) Atmospheric hazards (proposed paragraph (b)(23)(iv)(A)),

(2) Engulfment hazards (proposed paragraph (b)(23)(iv)(B)),

(3) Entrapment hazards that also pose the hazard of asphyxiation (proposed paragraph (b)(23)(iv)(C)), and

(4) Any other recognized serious safety or health hazard (proposed paragraph (b)(23)(iv)(D)).

The first three hazard characteristics provoked no controversy or substantive comment. However, some commenters (Ex. 14–84, 14–160, 14–171, 14–179) objected to proposed paragraph (b)(23)(iv)(D) arguing that the criterion set out therein was so broad and vague that its application could result in some spaces being inappropriately designated as permit spaces. For example, The National Solid Waste Management Association (Ex. 14–84) felt that:

> The definition contained in [proposed] §1910.146(b)(23)(iv) is too vague as currently written to be workable, specifically the provision in subparagraph (D).

Another commenter (Ex. 14–62) suggested that OSHA delete the proposed criterion because "Regulation of these hazards is best left to other specific OSHA standards for these hazards." Still another commenter (Ex. 14–63) stated that OSHA should require employers to document their determinations regarding this criterion "to assure that this [criteria] is properly considered in assessing the space."

OSHA does not agree with the comments regarding proposed paragraph (b)(23)(iv)(D). In particular, the Agency has determined that the provision needs to be worded in the broadest possible terms so that employers are required to protect affected employees from any serious hazards which may be confronted in a

[9] Telecommunications manholes and unvented vaults do pose confined space hazards (though they are not regulated under §1910.146). The necessary precautions for protecting employees entering these spaces from confined space hazards are prescribed by §1910.268(o). As noted earlier, work in such manholes or vaults need not comply with §1910.146 unless they contain hazards not fully addressed by §1910.268(o).

permit space. Examples of "other" serious hazards are radiation, noise, electricity, and moving parts of machinery. OSHA also believes that it is unnecessary to specify that employers document their compliance with this provision. The Agency will be able to determine, based on an inspection of a confined space, whether or not the conditions found pose hazards serious enough to warrant designating the space as a permit-required confined space. In making this determination, OSHA will use the same sources of information any knowledgeable person would: national consensus standards and government and industry guidelines.

OSHA is promulgating the definitions of "confined space", "non-permit confined space", and "permit-required confined space" as previously described. The Agency believes, based on the rulemaking record considered as a whole, that the final rule's definitions of these terms properly describe the spaces being regulated here, that these provisions will provide guidance to employees and employers for complying with §1910.146, and that this will result in the best protection for employees exposed to permit space hazards.

The term "permit-required confined space program (permit space program)" means:

> ... the employer's overall program for controlling, and, where appropriate, for protecting employees from, permit space hazards and for regulating employee entry into permit spaces.

Paragraph (c)(4) of final §1910.146 requires employers whose employees enter a permit space to develop and implement a written "permit-required confined space program". In promulgating this requirement, OSHA has used this term to stress the importance of taking a systematic approach to permit space operations. Except for editorial changes, the definition in the final rule is very similar to the proposed definition of this term. OSHA has replaced the proposed language addressing the prevention of unauthorized employee entry with language that more accurately indicates the general purpose of a permit space program, that is, "regulating employee entry into permit spaces".

The term "permit system" in this final rule replaces the proposed term "entry permit system". "Permit system" is defined as:

> ... the employer's written procedure for preparing and issuing permits for entry and for returning the permit space to service following termination of entry.

The final rule's definition is essentially the same as the proposed definition except that the language specifying that the permit system designates, by name or title, the individuals who may authorize entry has been removed. That provision is regulatory in nature rather than definitional.

The term "prohibited condition" in the final rule replaces the proposed term "not-permitted condition". "Prohibited condition" is defined as:

> ... any condition in a permit space that is not allowed by the permit during the period when entry is authorized.

"Prohibited condition" is the term used in the final standard's regulatory text. Although no substantive comments were received on the proposed term, the Agency is using "prohibited", because the term "not-permitted" is stilted. The new term certainly conveys the same meaning and improves the readability of the standard. The definition itself has been clarified to state specifically that the term "prohibited condition" applies only to the period during which entry into the permit space is authorized. OSHA notes that there is no reason for a condition, or set of conditions, to be prohibited in a permit space until employee entry is authorized. While this meaning was intended in the proposed definition, it was not stated clearly.

The term "rescue service" means:

> ... the personnel designated to rescue employees from permit spaces.

The definition of this term has been taken from the proposed definition of "in-plant rescue team". This is the term that has been adopted to apply to both in-plant as well as outside rescue services. The use of this term in place of the proposed term and the rationale behind the definition are explained under the discussion of paragraph (k) later in this preamble.

The final rule substitutes the term "retrieval system" for the proposed term "retrieval line" and defines a "retrieval system" as:

> ... the equipment (including a retrieval line, chest or full-body harness, wristlets, if appropriate, and a lifting device or anchor) used for non-entry rescue of persons from permit spaces.

The proposed definition was similar, except that it recognized the use of wristlets as an acceptable alternative to the use of a chest or body harness. A representative of the Chevron Corporation (Houston Tr. 862) has stated:

> We believe that wristlet devices interfere with effective work and expose the employee to additional injury in the (event) of a rescue.

OSHA agrees with this comment and has therefore changed the definition of "retrieval system" to make it clear that wristlets are not ordinarily acceptable for use by themselves. Wristlets may be used only in conjunction with a chest or body harness, unless the employer can demonstrate that the use of a chest or full body harness is infeasible or creates a greater hazard and that the use of wristlets is the safest and most effective alternative. (See the summary and explanation of paragraph (k)(3)(i) of the final rule.) Furthermore, OSHA will permit the use of wristlets only if such use will not interfere with the work (for example, by entangling entrants) and will not expose the employee to additional injury in case of a rescue.

The Chevron representative further stated (Houston Tr. 862):

> We also believe that continuously attached retrieval lines present entanglement problems. Therefore, we recommend that the definition read "Means a line or rope secured at one end to the worker by a chest, waist or full-body harness of the type that suspends a person in the upright position and with its other end secured to a lifting device or to an anchor point outside the entry."

Chevron had also suggested (Ex. 14–174) that the proposed definition be revised to state: "The retrieval line may be disengaged at the worker during those periods of activity that the employer identifies as creating hazards of entanglement."

While OSHA recognizes that entanglement can pose difficulties for entries performed using retrieval systems, the Agency has not made the suggested changes. First, the Agency believes that adding the suggested language "of the type that suspends a person in the upright position" would not address concerns regarding potential entanglement hazards. OSHA also believes that compliance with the requirements of paragraphs (d) and (k) of the final rule (regarding rescue equipment and procedures) will minimize entanglement hazards. Therefore, the Agency believes that concerns regarding entanglement can be addressed without revising the proposed definition. Second, OSHA believes that, considering the suddenness with which permit space hazards often manifest themselves, entrants who have disengaged from their retrieval lines are not adequately protected from permit space hazards. Therefore, the Agency expects that employers who have a reasonable basis for determining that the use of retrieval systems will pose excessive risk of entanglement will implement other rescue equipment and procedures.

Also, a hearing participant testified (Chicago Tr. 96):

> In [§1910.]146(b)(25), we do, however, recommend some different wording for retrieval line in that it appears in this section that a retrieval line is required in each and every confined space entry situation. There are situations where retrieval lines are ineffective, or inappropriate, or simply not required.

In particular, the hearing participant stated that retrieval lines are not needed for work inside the mud drum of a steam boiler because entrant's feet never enter the permit space and that "the configuration of the interior of a distillation column or more complex vessel will make a retrieval line inappropriate." OSHA notes that the proposed definition was provided simply for the guidance of those employers who choose to comply with the proposed requirement for rescue capability (proposed §1910.146(c)(8)) through the use of retrieval lines. OSHA recognizes that the use of retrieval systems is not always feasible for permit space entry. Therefore, as discussed further under the summary and explanation of paragraph (k)(3) of the final rule, the Agency is requiring the use of retrieval systems unless the system would increase the risk to authorized entrants or the system would not contribute to rescue. OSHA believes employers should have rescue personnel perform their duties from outside the permit space wherever possible, so that rescuers are not exposed to permit space hazards.

In addition, OSHA has clarified the proposed definition by specifying the means by which the retrieval system is attached to the authorized entrant and the means by which the authorized entrant is lifted from the permit space. The definition, as revised, also clearly indicates that retrieval systems are to be used only for non-entry rescues.

The term "testing" means:

> ... the process by which the hazards that may confront entrants of a permit space are identified and evaluated. Testing includes specifying the tests that are to be performed in the permit space.

This definition, which did not appear in the NPRM, was added to indicate clearly what the term "testing" means. The final rule, like the NPRM, sets testing requirements (in §1910.146(d)(2) and (d)(5), for example). The final rule also contains non-mandatory Appendix B, which contains guidance for employers who perform atmospheric testing. OSHA intends the term to cover the evaluation of permit space conditions both at the time an employer initially identifies the hazards and devises control measures and at the time entry would actually take place. Additionally, the Agency has determined that it is appropriate to specify that the testing process includes specifying the tests to be performed, so that OSHA can determine if the tests performed correspond to the identified permit space hazards. A note has been included to indicate the purpose of testing.

Paragraph (c), General Requirements.

Paragraph (c) sets forth general requirements for employers whose operations are within the scope of §1910.146. This paragraph reflects the Agency's determination, discussed earlier in this preamble, that it is necessary to establish a comprehensive regulatory framework under which employers are explicitly required to identify any permit spaces at their workplaces and to take the appropriate measures for the protection of affected employees.

Proposed paragraph (c) contained general requirements for the identification of permit spaces and for the protection of affected employees from the hazards posed by any permit spaces identified. The introductory text of proposed paragraph (c) would have required employers to identify any permit spaces in their workplaces, to determine if their employees would enter any such spaces, and to take the appropriate action (closing off the permit space, retaining a contractor, or instituting a permit space program) based on that determination. The balance of the paragraph (proposed paragraphs (c)(1) through (c)(10)) specified the elements of the permit space program to have been followed by employers who had employees (either their own or those of contractors) enter permit spaces.

The permit space program requirements from proposed paragraph (c) have, in general, been placed in paragraph (d) of final §1910.146. (For a cross-reference of the destinations of the provisions of the proposal, see the Distribution Table.) A discussion of these paragraphs can be found in the summary and explanation of paragraph (d) later in this preamble.

Redesignation Table to §1910.146

Proposed paragraph	*Final paragraph*
(a)	(a)
(b)	(b)
(c) intro text first sentence.	(c)(1)
second sentence	(c)(6)
third sentence	(c)(3)
fourth sentence	(c)(4)

Redesignation Table to §1910.146 Continued

Proposed paragraph	*Final paragraph*
(c)(1)	(d)(2)
(c)(2)	(d)(3)
(c)(3)	(d)(10)
(c)(4)	(c)(2)
(c)(5)	(d)(1)
(c)(6)	(g)
(c)(7)	(d)(4)
(c)(8)	(d)(4)(viii), (d)(9)
(c)(9)	(d)(3)(iv), (d)(4)(vi)
(c)(10)	(c)(8)
(d)(1)	(e)(1)
(d)(2)(i)	(f)(7)
(d)(2)(ii)	(f)(8)
(d)(2)(iii)	(f)(8)
(d)(2)(iv)	(f)(9)
(d)(2)(v)	(f)(13)
(d)(2)(vi)	(f)(11)
(d)(2)(vii)	(f)(13)
(d)(2)(viii)	(f)(12), (f)(13)
(d)(2)(ix)	(f)(13)
(d)(2)(x)	(f)(14)
(d)(3) intro text	Removed
(d)(3)(i)	(f)(1)
(d)(3)(ii)	(f)(2)
(d)(3)(iii)	(f)(3)
(d)(3)(iv)	(f)(4)
(d)(3)(v)	(f)(5)
(d)(3)(vi)	(f)(6)
(d)(3)(vii)	(f)(6)
(d)(4)	(f)(15)
(d)(5)	(e)(2)
(d)(6)	(e)(5)
(e) intro text	(g)
(e)(1)	(h)(1)
(e)(2)(i)	(h)(3)
(e)(2)(ii)	(h)(4)
(e)(3)	(h)(2)
(e)(4)	(h)(5)
(f) intro text	(g), (i)(4)
(f)(1)	(i)(3)
(f)(2)	(i)(1), (i)(6)
(f)(3)(i)	(i)(5)
(f)(3)(ii)	(i)(6)
(f)(3)(iii)	(i)(7)
(f)(3)(iv)	(i)(8)
(f)(4)	(i)(9)
(g) intro text	(g)
(g)(1)(i)	(j)(2)
(g)(1)(ii)	(j)(2)
(g)(1)(iii)	(j)(6)
(g)(1)(iv)	(j)(3)
(g)(1)(v)	(j)(3)
(g)(1)(vi)	Removed
(g)(2)	(j)(5)
(h) intro text	(k) intro text
(h)(1)(i)	(k)(1)(i)
(h)(1)(ii)	(k)(1)(ii)
(h)(1)(iii)	(k)(1)(iii)
(h)(1)(iv)	(k)(1)(iv)
(h)(2)	(k)(2)
(i)	(c)(5)

Paragraph (c), titled "General requirements" in this final rule, corresponds generally to the introductory text of paragraph (c) in combination with paragraphs (c)(4), (5) and (10) of the proposed rule. The introductory text of the proposed paragraph (c) (titled *Permit required confined space program (entry permit*

program)) did not pertain directly to the establishment of a permit program, but contained information and requirements leading up to the development of a permit program. OSHA has decided that the inclusion of these requirements in a separate paragraph, preceding the paragraph pertaining to the permit entry program, is logical and adds clarity to the final rule. Therefore, paragraph (c), titled *General requirements*, has been added to the final rule.

Paragraph (c)(1) of the final rule requires employers to evaluate their workplaces and to determine if they contain permit-required confined spaces. This provision corresponds to, and is essentially the same as, the first sentence of the introductory text of proposed paragraph (c). OSHA has included a note referencing Appendix A, the decision flowchart, to facilitate compliance with the final rule.

A few rulemaking participants (Ex. 14–116, 14–170, 138) stated that it was inappropriate to require an initial survey of workplaces to identify permit spaces. For example, the Chemical Manufacturers Association (CMA), in its post-hearing comment (Ex. 138), objected to proposed paragraphs (c) and (c)(1). CMA interpreted the proposal to require a "grand survey" of the workplace to identify permit-required confined spaces, followed by an analysis of the severity of the associated hazards in those spaces. Another commenter, the Monsanto Company (Ex. 14–170), stated:

> Paragraph (c)(1) could be interpreted to require an initial survey to identify all confined spaces and to assess the severity of the hazards that would be encountered by those who may enter these confined spaces at any future time. Monsanto *agrees* with the concept of identifying confined spaces and their hazards but strongly *disagrees* that an initial survey, should that be OSHA's intent, is necessary. In fact, it could be counterproductive to good hazard control. Not only do confined spaces change, as OSHA acknowledges, but the hazards involved in the confined spaces often change. The hazards could be different for the same confined space depending on the work that is planned to be done inside the space. For all of these reasons, Monsanto believes that, and has demonstrated that, employees can identify confined spaces and the hazards thereof by 1) training them to recognize confined spaces, 2) to identify the hazards and assess their severity, and 3) select and implement their protective measures just prior to executing the entry and as a part of the preparation of the entry permit. We would strongly recommend that OSHA not require an initial identification of all spaces and their severities. [Emphasis supplied in original.]

NIOSH testified (Washington Tr. 110) in favor of the proposed requirement stating: "In 37 of the 44 incidents [investigated as part of the FACE project through December 1988] failures to recognize the operations as involving a confined space was a contributing factor."

OSHA has determined that workspaces that meet the definition of permit space need to be identified at the time the final rule goes into effect rather than when the employer decides that certain workspaces will be entered. The Agency believes that the initial workplace survey is essential because, at the very least, it alerts the employer to the need for measures to prevent unauthorized entry. Also, delays in efforts to identify permit spaces could compromise the safety of entry operations undertaken to deal with emergencies or other unforeseen circumstances. If an employer has not evaluated the workplace, he or she would not even be able to provide the necessary training to employees so that they can indeed readily identify permit spaces. In any event, relying on employees as the primary source of information for identifying and controlling permit-required confined spaces would improperly place the principal burden for worker safety on the employee rather than on the employer, who is in the better position to identify hazards present in his or her own workplace.

OSHA has also determined, based on the incident data in the rulemaking record (Ex. 13–10, 13–15, 13–16, 14–159), that the failure to identify permit spaces properly has resulted in many fatalities and injuries. The Agency believes that the initial survey will facilitate employers' efforts to develop and implement appropriate measures so that a protective permit space program is in place when entry operations are initiated.

OSHA notes that the comments opposing this provision in its proposed form were more concerned that the Agency would require a detailed hazard analysis for each space identified as a possible permit-required confined space. Final §1910.146(c)(1) requires only the identification of permit spaces. The detailed evaluation and classification of hazards found within the space is addressed by paragraph (d)(2), which is discussed later in this preamble. OSHA further notes that any entry into a confined space performed in order to determine whether or not that space is a permit space must be performed as if the space were known to be a permit space.

Paragraph (c)(2), which corresponds to proposed paragraph (c)(4), addresses the employer's responsibility to inform their employees of the presence of permit-required confined spaces. This paragraph in the final rule requires employers who find permit spaces in their workplaces to inform exposed employees of the existence and location of those permit spaces.

Proposed paragraph (c)(4) would have required all permit spaces to be posted with signs indicating what hazards were present and that only authorized entrants could enter. Some respondents to the NPRM (Ex. 14–76, 14–77) objected to this paragraph of the proposal, basing their objections on the opinion that such a requirement would be prohibitively expensive and an invitation to unauthorized entries, particularly by teenagers, and to vandalism. In Issue 14 of the hearing notice (54 FR 41463), OSHA asked for further information on the proposed requirement for the posting of informational signs near permit spaces. OSHA asked, in its hearing notice, how such spaces should be identified to protect employees. The Agency also requested actual and projected costs of informing employees that a workplace contains permit spaces.

The Agency received extensive written comments addressing paragraph (c)(4) (Ex. 14–9, 14–30, 14–45, 14–52, 14–57, 14–59, 14–68, 14–76, 14–78, 14–80, 14–86, 14–88, 14–91, 14–94, 14–101, 14–111, 14–133, 14–143, 14–150, 14–153, 14–157, 14–163, 14–188, 14–170, 14–173, 14–174, 14–176, 14–178, 14–179, 14–184, 14–189, 14–191, 14–214, 14–222). There also was discussion of the issue during the public hearings (Houston Tr. 779–780, 940–942; Chicago Tr. 272–274, 447–448).

One commenter offered support for the proposed requirement to require signs at all confined spaces. The Quaker Oats Company (Ex. 14–173) stated:

> We recommend that all permit spaces be posted, notifying employees that hazards may be present and only authorized entrants [may] enter. These signs would be appropriate postings during non-entry times and during the permitted entry. All employees should be instructed as to restricted areas, and confined spaces should be secured whenever feasible with positive barriers such as locks.

An overwhelming majority of commenters, however, objected to the proposed requirement for posting signs identifying all permit-required confined spaces and the hazards contained within the spaces (Ex. 14–9, 14–76, 14–78, 14–80, 14–88, 14–94, 14–111, 14–143, 14–153, 14–170, 14–176, 14–189, 14–222, 138). The commenters who objected to the proposed requirement identified several burdens related to the proposed rule.

Some objections cited the great expense and total impracticality of posting a sign at the entrance to every confined space in the workplace. For example, S.C. Johnson & Son, Inc. (Ex.14–222) stated:

> The problem with this provision is that it would require signs to be posted at hundreds of thousands of locations. Virtually every piece of equipment, vault, or pit large enough for an employee to "stick his head in" would qualify as a potential confined space.

In a similar vein, the Eastman Kodak Company (Ex. 14–176) stated:

> In a complex chemical plant, there will be hundreds of tanks, reactors, columns, and other process vessels which qualify under the proposed definitions.

Union Carbide (Ex. 14–88) also objected to the numerous signs that would be required as follows:

> The problem with both provisions is that, as applied to a modern chemical plant, they would require identification, evaluation, and notification of hundreds or thousands (perhaps tens of thousands) of confined spaces. Virtually every piece of equipment, vault or pit large enough for an employee to enter would qualify as a confined space, and there are uncounted numbers of those.
>
> Every manhole into a sewer or electrical or telecommunications area is a confined space. Would OSHA require every manhole cover throughout the United States have a sign warning of the hazards which may be present?

OSHA also received testimony at the hearings (Chicago Tr. 272–274; Houston Tr 779–780, 940–942) regarding the number of signs that would be required. For example, Rohm & Haas (Houston Tr. 941) testified as follows:

> This aspect would require us to post up to 3000 additional signs in our plant. This type of labelling would be counter-productive and would also detract from the performance-oriented goal of the standard.
>
> Posting of signs would create over-reliance on a sign to identify a confined space. We are concerned that we may miss identifying many of these spaces during the plant-wide survey mentioned above, and as a result some spaces will not have signs posted. If an employee relies on a sign to tell him that a confined space hazard exists, he may determine that a confined space hazard is not present if a sign is not posted.

Similarly, AMOCO testified (Chicago Tr. 272) as follows:

> Paragraph (c)(4) requires the posting of signs near the entrance of confined spaces. There is no qualifier to indicate that the signs would be required only when there is a potential access to the space. A broad interpretation of this paragraph would require us to post signs at the potential entrances of confined spaces regardless of whether access to the space is physically possible.
>
> In our facilities, there are literally thousands of potential entrances to confined spaces.

Some commenters identified the impracticality of identifying such spaces as storm and sanitary sewers. For example, United Technologies (Ex. 14–178) stated:

> We know of no practical method of posting signs near, yet outside of, manholes located at grade level in roadways, parking lots, floor spaces, etc.

The City of Cincinnati (Ex. 14–9) also noted the impracticality of applying the posting requirement to manholes and sewers as follows:

> Many areas in the municipality meet the criteria of "permit required confined spaces," but do not allow for the posting of signs. All of our sewers fall into this category, both storm water and combined sewers.
>
> In a public environment, signs on every manhole in the street is impractical!

Other commenters identified the burden of listing individual hazards in a confined space on the sign. They argued that the burden of updating or replacing signs whenever the hazards within a confined space changed or whenever the sign was destroyed was unreasonable. For example, Union Carbide (Ex. 14–88) commented as follows:

> Besides the burdens associated with those requirements, Union Carbide is concerned that they may actually pose hazards to employees. The main hazard is an overreliance on lists and signs. The presence of hundreds or thousands of signs throughout a chemical plant would tend to downgrade awareness on the part of employees, who would come to assume that if a space is not on a list or lacks a sign, then it is not a permit-required confined space. Yet, the large number of such spaces creates the very real possibility that some may be overlooked, despite the most vigilant of programs. The result could be employee entry into permit-required confined spaces without taking the necessary precautions. Even if every single permit space were identified on a list and with a sign, signs fall off or are obscured, particularly in chemical plants where sign maintenance is a major undertaking. Where hazards change with changes in service, a posted sign may be outdated and hence dangerously misleading.

Organizational Resources Counselors, Inc. (ORC, Ex. 14–143) echoed this concern:

> Also, even when a sign has been posted outside a confined space, it can deteriorate, be removed, or become obscured. Where hundreds of such signs must be posted, it is even more likely that at least some of the signs will be damaged, removed, or obscured.
>
> Finally, requiring each sign to list the hazards which could be present in each confined space would be an administrative nightmare, especially where the hazards of confined spaces change frequently or are varied. For example, the hazards posed by entry into a tank or vessel will depend on the last contents. Are new signs to be posted every time a new chemical is introduced?

One hearing participant (Chicago Tr. 273) also claimed that sign maintenance would be costly, testifying as follows:

> Since most of the signs in a refinery or chemical plant are exposed to weather, their maintenance would be extremely expensive.

The Chemical Manufacturers Association (Ex. 138) maintained that signs can create a false sense of security and can lead to information overload. They contended that a large number of warning signs, which would be required in many chemical plants, would be ineffective because employees tended to ignore them.

As an alternative to posting signs, many commenters suggested the use of an effective confined space permit entry system in combination with training as an alternative to posting signs (Ex. 14–57, 14–76, 14–78, 14–86, 14–88, 14–91, 14–94, 14–111, 14–143, 14–157, 14–170, 14–176, 14–184, 138). For example, Beaumont & Associates (Ex. 14–57) stated:

> Employee training about confined spaces should be allowed in place of signs designating confined spaces.

Also, the Texas Chemical Council, (Ex. 14–86) said:

> It is critical that employees be trained, as well as, possibly reminded, depending upon the entry condition.

Union Carbide (Ex. 14–88) supported the training alternative as follows:

> In its years of experience with confined space permit programs, Union Carbide has learned that proper employee training and education to identify permit spaces and their hazards are more effective, more efficient, and safer than the overly burdensome approach proposed.

Still another commenter (Ex. 14–91) agreed with this point, stating:

> Training is a more appropriate and effective means of informing employees of permit space hazards.

One commenter (Ex. 14–68) disagreed, arguing that training was an ineffective means of preventing unauthorized entry, as follows:

> Training is *not* an effective means of preventing unauthorized entry nor is a posted sign. The use of the conjunction, "or," in the proposed standard leaves the employer a choice among providing a positive denial of entry provision such as a locked barrier, posting a warning sign or providing training. There should be no doubt that the first choice will usually be "training" such as "Don't go in there." At most, a sign may be posted to supplement the instructions. These

precautions are so inadequate as to be no precaution. [Emphasis supplied in original.]

Many of the accidents in the rulemaking record resulted when an employee failed to recognize the hazards involved in entering a permit-required confined space. Therefore, OSHA has determined that it is important to identify permit spaces and to inform employees of their presence and the hazards involved.

At the time of the proposal, OSHA believed that the posting of warning would be the most cost effective method of warning employees. In that regard, the Agency recognized that training all employees in the location of all permit spaces and in the hazards involved in each space could impose significant costs on employers. However, as brought out by the rulemaking participants, the posting requirement in the proposal did not account for existing permit space programs that have been successfully protecting employees, using a wide range of approaches to providing the necessary information to employees.

The record also indicates that some rulemaking participants interpreted proposed paragraph (c)(4) to require the specific hazards posed by the space to be listed on the sign. OSHA did not intend the sign to contain a list of all the specific hazards posed by the permit space. Rather, the proposed rule would simply have required the basic type of hazard (such as asphyxiation and engulfment) to be mentioned. In fact, in explaining this provision of the proposal (54 FR 24091), OSHA stated:

> The Agency believes that employees need this information to understand the seriousness of potential hazards in the workplace. The Agency anticipates that compliance with this requirement would ensure that employees who are not involved in permit space operations would be sufficiently informed so that they would not attempt to enter permit spaces. OSHA notes that only personnel who work with permit spaces would need to know more about the potential hazards.

In order to recognize all methods of informing employees and to clarify the intent of the rule, OSHA is adopting a performance-oriented version of proposed paragraph (c)(4) in the final standard. Paragraph (c)(2) of final §1910.146 reads as follows:

> If the workplace contains permit spaces, the employer shall inform exposed employees, by posting danger signs or by any other equally effective means, of the existence and location of and the danger posed by the permit spaces.

OSHA believes that this language will require employers to protect their employees but will also allow them to use the most cost-effective method available. For example, employers who are already providing sufficient training to protect their employees effectively need not purchase and maintain unnecessary signs. On the other hand, employers can choose to post danger signs to protect employees if they desire. Whatever method is used, the standard requires it to inform employees exposed to the hazards posed by permit-required confined spaces of the existence, location, and danger of those spaces. Additionally, the provision in the final rule makes it clear that the sign is to indicate the danger involved in permit space entry, not to list all the specific hazards that might be encountered.

In enforcing this provision, OSHA will check to ensure that methods other than warning signs are truly effective in imparting the required information to employees. General training in the OSHA standard, for example, cannot be expected to adequately inform employees of the location of permit spaces in the workplace. The final rule places the burdens of identifying the spaces and of controlling the resultant hazards on the employer not on the employee.

Some commenters suggested that OSHA adopt a limited posting rule that would recognize the posting of copies of the entry permit at the entrance to those spaces that are opened for entry or that would require signs only for permit spaces that could be entered inadvertently. For example, the Monsanto Company (Ex. 14–170) suggested:

> We recommend that, instead of this burdensome approach, the permit itself serve as the communication of the hazards since it will be posted during an actual entry. If a vessel has multiple entry points during a confined space entry then additional signs or copies of the permit could be posted at those points to serve as the hazard advisory.

The Chevron Corporation (Ex. 14–174) added:

> We believe that this section should be reworded to allow either signs *or copies of completed permits* that are posted near or at the entrance to the permit space to be used to notify employees of the hazards and that only authorized individuals may enter the permit space. The permit system is intended to provide all information about the permit space on the permit itself and it only seems reasonable that a copy of the permit should be able to serve as the written means of information about the space.

In its prehearing comment (Ex. 14–143), the Organization Resources Counselors, Inc. (ORC) stated:

> ORC believes that posting a sign at or near every identified permit space is unnecessary, costly, and inappropriate for those spaces which do not provide an opportunity for random or inadvertent entry. In an average chemical plant or refinery, there will be hundreds of vessels, columns, tanks, and other pieces of process equipment which would meet the criteria for definition as permit required confined spaces, but which offer no opportunity for casual or inadvertent entry because these spaces are closed when in service, and cannot be opened to permit entry without significant amounts of labor and tools.
>
> It is appropriate to post a sign where there is opportunity for random unauthorized, or casual or inadvertent [entry], such as an open pit. In addition, it would be appropriate to post signs near spaces that have been opened to permit entry by authorized employees to make others aware that entry into the space is prohibited to unauthorized individuals.

OSHA has not adopted any of these suggestions. Posting the entry permit would not serve to inform unauthorized employees of the danger of entry. If there is no authorized entry being conducted, there would be no permit to post. Thus, posting entry permits would not function to warn employees of spaces that were not the subject of an entry permit. Additionally, once authorized entry was underway, an attendant would be stationed to prevent unauthorized employees from gaining access to the space (final §1910.146(i)(8)).

ORC's suggested approach would seemingly allow permit spaces to be configured so that employees could enter them "casually" or "inadvertently".[10] The Agency believes that it is important to ensure that unauthorized employees cannot enter permit spaces unintentionally. Paragraphs (c)(3), (d)(1), (i)(8), and (j)(5) of the final rule specifically require employers to take measures intended to prevent such entry. Allowing permit spaces to remain unguarded to the extent that employees could "casually" or "inadvertently" enter them is prohibited by the standard altogether. For example, assuming that they are configured as permit-required confined spaces, open pits would have to be guarded in some manner to prevent access to the spaces except when an authorized entry was undertaken.

[10] ORC also suggested that it would be appropriate to post permit spaces where there is "opportunity for random unauthorized" entry. OSHA considers all unauthorized entry to be basically random in nature. Because of the nature of their comments and of their example (open pits), the Agency does not believe that ORC intended to recommend posting all permit spaces subject to unauthorized entry with signs. Therefore, OSHA has discussed their suggestion of posting permit spaces subject to "casual" or "inadvertent" entry. While it is possible that ORC and others who made similar comments intended something else, OSHA could not determine what that intent might be.

Therefore, OSHA is not adopting the ORC suggestion.

OSHA believes that ORC's concerns regarding the number and types of spaces that need to be posted are being addressed by the final rule. The final rule would not require the posting of any permit space whose only means of access necessitates the use of tools or keys, provided that the employees who are expected to gain entry into these spaces are trained to recognize the hazards involved. Restricting access to permit spaces in this manner protects employees effectively without the use of signs.

Paragraph (c)(3) of the final rule addresses employers who decide that their employees will not enter permit spaces. This provision requires such employers to take effective measures to prevent their employees from entering permit spaces. These measures could include permanently closing the space and barriers, supplemented by training employees and posting danger signs. In any event, the steps taken by the employer must be effective in preventing employee entry into permit spaces.

Paragraph (c)(3) of the final rule has been taken from the third sentence of the introductory text of proposed paragraph (c), on which OSHA received no substantive comment. The proposed introductory text simply referred to proposed paragraph (c)(10), relating to duties to other employers, as being the only requirement other than those in the introductory text that applied to employers whose employees do not enter permit-required confined spaces. In the final rule, due to the change in format of paragraph (c) discussed earlier, §1910.146(c)(3) lists all other requirements that must be met by these employers:

(1) Paragraph (c)(1) relating to identification of permit spaces in the workplace (first sentence of introductory text);

(2) Paragraph (c)(2) relating to informing employees of the presence of permit spaces (proposed paragraph (c)(4));

(3) Paragraph (c)(6) relating to changes in confined spaces (second sentence of introductory text); and

(4) Paragraph (c)(8) relating to work by contractors (proposed paragraph (c)(10)).

OSHA believes that these provisions in the final rule will protect employees in workplaces where permit space entry is prohibited.

Paragraph (c)(4) of the final rule requires that employers who decide to have employees enter permit spaces establish written permit space programs (permit programs) which comply with §1910.146. This provision is based on the fourth sentence of the introductory text of proposed paragraph (c).

OSHA notes that the final rule, unlike the proposed rule, specifies that the program must be written. A written plan is necessary so that confusion or misunderstanding regarding the program's requirements is avoided.

A written permit program was strongly supported by Mr. John Moran, an OSHA expert witnesses who testified at the Washington, D.C., public hearing. In his written testimony (Ex. 22), Mr. Moran stated his views regarding a written program:

> The preparation of an employer-specific written confined space program is essential, in my view. It serves not only as an essential reference for supervisors and operators, but forces—or should force—thoughtful consideration of employer-specific issues relevant to development and implementation of an effective confined spaces program.

The Food and Allied Service Trades (FAST) of the AFL-CIO (Ex. 14–213) also supported a written program, as follows:

> We cannot overstate the importance of a *written plan*. Having the plan maintained in this form and available for worksite inspection offers an invaluable set of protections for the workers employed at facilities where confined spaces may exist. [Emphasis supplied in original.]

Mr. Keith Mestrich of FAST testified at the Chicago public hearing (Chicago Tr. 37) concerning the benefits of a written plan:

> With a written pla[n] it provides workers and the representatives a chance to go into the plant and take a look exactly how the employer plans to fill out the permits; who he plans to allow in entry spaces; the training that's going to go on; everything that should be happening whenever a worker goes into a confined space.

Mr. Robert Hill of the Oil, Chemical and Atomic Workers International Union (Houston Tr. 1063) also felt that the permit program should be in writing:

> This standard should state that the permit required confined space entry program must be written and accessible to employees.... It is the workers who enter and perform work in the permit spaces.

The Utility Workers Union also recommended that a written permit space program be required. Mr. Michael Kenny, testifying on their behalf (Chicago Tr. 649), stated:

> Accountability rates an equal place with training for a successful confined space program. A written permit system identifying hazards in the permit space, restricting access to authorized employees, will provide accountability.

OSHA agrees with these commenters that a written program provides the very basis of any permit space entry operation, providing a reference for guidance and direction to supervisors and employees alike. A program that is in writing will also serve to place accountability for all functions related to permit space entry and will aid in avoiding mistakes and misunderstandings. Additionally, because of the flexibility and discretion which the standard provides to the employer in achieving compliance, a written plan is essential to demonstrate that all aspects of permit space entry have been taken into consideration. For these reasons, OSHA has decided to specify in the final rule that the permit space program be in writing. The requirement for a written program has also been added to the introductory text of paragraph (d) of the final rule. Additionally, OSHA is requiring employers to make the written program available for inspection by employees and their authorized representatives. The agency believes that such access is essential for the successful implementation of a permit space entry program.

Issue 3 of the hearing notice (54 FR 41462) requested comment on the subject of worker participation in the design and implementation of a permit-required confined spaces program. In particular, OSHA was interested in information about successful programs and the costs and benefits associated with employee participation.

The Agency received several comments on the subject (Ex. 14–38, 14–210, 14–215, 14–220, 14–222) and some testimony at the public hearings (Washington Tr. 225–226, 251, 386, 589–590; Houston Tr. 1063–1064; Chicago Tr. 317–318, 348–352, 356, 376, 379–380, 411, 427–428, 532–533, 612–613, 622–623). However, most of these commenters did not respond directly to the issue. The majority of the commenters expressed support for the concept of employee participation in the creation of a permit program. Some commenters (Ex. 14–38, 14–210; Washington Tr. 225–226, 251, 386, 589–590; Houston Tr. 1063–1064; Chicago Tr. 317–318, 348–352, 356, 379–380, 427–428) even felt that OSHA should promulgate a provision in the final rule requiring joint management-employee committees for the creation of such programs. Others (Ex. 14–215, 14–220, 14–222; Chicago Tr. 532–533, 613, 622–623) stated that OSHA should not interfere with what these commenters believed was primarily a labor-management issue.

The commenters who were in favor of requiring employee participation in a permit program cited the benefits of increased compliance and improved procedures. For example, Mr Eric Frumin of the Amalgamated Clothing and Textile Workers Union testified at the Washington hearing (Washington Tr. 589–590). Mr. Frumin said that:

> We don't know who is going to be responsible for designing the confined space program to comply with this standard, but the chances are quite high, it's going to be someone who does a lot of things other than just safety.
>
> Whatever you call them—employer relations, personnel, security, and that problem is not unique to one plant in Williamsburg, Virginia. All over this country company management is taking on more and more diverse responsibilities and less specialization in the area of safety.
>
> And the only effective check on whether untrained managers are implementing inadequate confined space programs will be the ability of workers to be involved in that process and to make sure that the programs are adequate.
>
> Given the extent of union participation in the chemical and other industries, absent a mandate from OSHA, that involvement will never take place until after an accident or catastrophe and maybe not even then.

The Independent Liquid Terminals Association (ILTA, Ex. 14–210) agreed, and also pointed out that employee involvement would increase compliance. They stated:

> ILTA is in favor of involving employees in the design and implementation of permit space programs. The employees can offer invaluable feedback on real dangers versus perceived ones. In addition, involving the employees will contribute to the successful implementation of the program since it will not be viewed as a program forced upon them without their input. This is not to say that every employee should be involved. In the terminal business[,] involving terminal operations personnel, i.e., superintendents, engineers etc., would be helpful.

Other commenters also agreed that employee involvement was desirable, but believed that OSHA should not dictate worker involvement. For example, one commenter (Ex. 14–215) said:

> Amoco considers employee suggestions when making decisions concerning confined space entry however we have no formal procedures for soliciting and reviewing employee input. Such a formalized system could delay decision-making regarding confined space entry. If any problems occur with the confined space entry program, the employer, not the employee representatives, will be held responsible. Therefore, we believe that the employer should have the ultimate authority for making decisions concerning confined space entry. How an employer addresses employee input should be a matter between management and labor and employee participation should not be mandated by regulation.

Another commenter (Ex. 14–222) stated the view that employee involvement was impossible to mandate if such involvement was to be effective,as follows:

> While employee participation in procedures development can have many benefits, it cannot be mandated. It must be voluntary.
>
> Effective communication is the key to assuring employee feedback and suggestions. Such communication must be voluntary; it cannot be forced/mandated. (Where poor employer/employee communications exist, there is little effective feedback.) For this reason, we suggest that OSHA endorse, but not require, that active employee participation be a part of the design/implementation of a firm's permit space program.

The Agency agrees that involvement by employees is vital to the creation of an effective permit space program and that such involvement should be encouraged. However, OSHA has determined that it would be very difficult to mandate labor-management collaboration in the development of the permit program. None of the respondents suggested language that would provide for employee input into an employer's permit space program without dictating how any disagreements would be resolved. Additionally, the standard does provide opportunity for the contribution of employees involved in permit space entry in paragraph (d)(13) on permit space program review and in paragraph (g)(2)(iv) on review of employee training upon evidence of deficiencies. Therefore the Agency, has decided not to require the creation of a formal system for employee input and review of entry procedures.

Paragraph (c)(5) of the final rule sets provisions that employers can follow in lieu of complying with paragraphs (d) through (f) and (h) through (k), if the employer can demonstrate that the permit space contains only atmospheric hazards and that continuous forced air ventilation will maintain those permit spaces safe for entry. This paragraph is based, in part, on paragraph (i) of the proposed rule.

Paragraph (i) of the proposal, *Special permits for entry into low hazard permit spaces*, would have allowed employee entry into a "low-hazard" permit-required confined space without an attendant on hand. OSHA included this provision in the proposal based on the belief that either the space posed a low level of risk or its hazards were controlled so as to reduce the level of risk. The Agency regarded these spaces as posing a low enough risk that an attendant would not have been necessary and that more limited procedures could have been used for entry. While a permit would still have been required, it could have been issued to authorize entry as often as necessary for up to a year.

In regard to proposed paragraph (i), Issue 11 of the NPRM asked the following questions:

(1) To what extent should permit requirements be differentiated based upon level of risk?

(2) What criteria should an employer use to determine if the use of a special permit is appropriate?

(3) Should OSHA limit an employer's ability to qualify for use of a special permit once he or she has had a special permit revoked?

In Issue 13 of the hearing notice (54 FR 41461), OSHA asked for comment on an issue raised by a commenter (Ex. 14–45) concerning how employers would document the decision that a certain permit space was a low hazard space. OSHA also asked several other questions related to the documentation of an employer's determination of a space as "low hazard". In addition, Issue 17 of the NPRM solicited comments regarding the existence of work areas that would not need all of the protective measures required by the proposed rule.

Many rulemaking participants addressed the question of to what extent the permit requirements should be differentiated based on the risk posed by the space. Some favored separate treatment of different levels of risk, either explicitly (Ex. 14–50, 14–81, 14–102, 14–149, 14–167, 14–182, 14–199, 14–221) or implicitly by their support of proposed paragraph (i) (Ex. 14–22, 14–27, 14–52, 14–57, 14–153, 14–170, 14–183; Washington Tr. 359; Chicago Tr. 617; Houston Tr. 943). Others (Ex. 14–28, 14–94, 14–99, 14–111, 14–178, 14–184, 14–193, 14–217, 119; Washington Tr. 383; Houston Tr. 789; Chicago Tr. 214, 235, 370, 674) argued that the requirements should be the same for all permit-required confined spaces.

Two commenters (Ex. 14–81, 14–167) supported OSHA's statement in the preamble to the proposal (54 FR 24087) that there are permit spaces that either pose such a low level of risk or have their hazards so controlled that they could be safely entered without an attendant under a permit lasting as long as a year. For example, the National Ready Mixed Concrete Association (Ex. 14–81) stated:

> As indicated in our general comments above, NRMCA strongly believes OSHA

should differentiate permit-requirements based on the level of risk involved in particular confined spaces. OSHA correctly states that there are confined spaces which, while subject to the proposed standard, either pose such a low level of risk or have had their hazards so controlled, that they could be entered without an attendant on hand under a permit, which could last as long as a year.

Other rulemaking participants (Ex. 14–22, 14–27, 14–52, 14–57, 14–153, 14–170, 14–183; Washington Tr. 359; Chicago Tr. 617; Houston Tr. 943) lent their support to this concept by advocating separate requirements for low hazard permit spaces. Mr. Donald Martin, testifying on behalf of Rohm and Haas, Texas (Houston Tr. 943), supported paragraph (i), as follows:

[P]aragraph (i) allows for special permits for entry into low hazard permit spaces without an attendant to up to a period of one year, under certain provisions. We generally support this concept because it requires us to formally address potential hazards that could exist in our motor control centers, drive-in storage trailers and diked areas around our storage tank farms.

Although we have never experienced an injury or fatality related to this type of confined space entry, we believe it should be addressed nonetheless.

In their initial comments on the proposal, Monsanto (Ex. 14–170) agreed with the reasoning behind paragraph (i), as follows:

Monsanto endorses the concept of OSHA allowing a confined space entry without an attendant in certain types of situations.

However, on the basis of the hearing testimony, Monsanto did reconsider their support and, in their post-hearing comment (Ex. 140), recommended a single level of permit space, as follows:

In continuing to reflect on this issue, we believe that the "low hazard" or ["]non-permitted" space may well turn out to be a confusing point to employers and to the compliance process in OSHA. A better approach may be to specify one level of confined space instead of two. The one level would require a permit and an attendant. Any other spaces would fall outside the scope of this standard.

Many of those supporting the concept of a "low-hazard" confined space (Ex. 14–27, 14–81, 14–95, 14–124; 14–139, 14–149, 14–150, 14–153, 14–162, 14–164, 14–169, 14–221; Washington Tr. 553; Chicago Tr. 189; Houston Tr. 943) noted its application to specific types of spaces. These rulemaking participants cited diked areas, manholes, and tanks as examples of spaces that posed an extremely low probability of having an IDLH atmosphere, resulting in a "low hazard" classification.

Other rulemaking participants (Ex. 14–28, 14–94, 14–99, 14–111, 14–178, 14–184, 14–193, 14–217, 119; Washington Tr. 383, 547; Chicago Tr. 214, 235, 370, 674; Houston Tr. 789) disagreed with the concept of treating any permit-required confined spaces in a different manner. Many of the commenters addressing this issue (Ex. 14–94, 14–111, 14–193, 14–217; Washington Tr. 547), felt that the creation of a special "low risk" category of permit spaces only increased the likelihood of confusion, misunderstanding and misplaced confidence, possibly increasing the chances of an accident. For example, Mr. Robert J. Cordes (Ex. 14–28) stated:

I do not like the idea of a special confined space permit based upon the level of risk. There should be no differentiation in permits based upon level of risk. When the employer initially makes his judgments about those spaces which will need a permit, he has done just that. A space either needs a permit or it does not. If, as an example, a below-grade pit containing a water pump is judged to be a permit required space, then a permit, including a test for oxygen, etc. is required every time the pit is entered. An attendant should be required every time a permit is required. On the other hand, if the initial analysis determined that there is no need to require a permit when the pit is entered, none is needed unless something special such as hot work is scheduled. No attendant is needed at those sites which do not require a permit. If a permit is required, then a qualified (i.e. competent) person, who could also be an attendant, should conduct all tests and complete the permit form. One form and one procedure should exist. We don't want to introduce possibilities for confusion and mistakes by having special rules apply to lower level risks...

Texaco's post-hearing submission (Ex. 119) reinforced their objection to "low hazard" permit spaces:

As stated in Texaco's testimony, we do not support the concept of "low hazard permit spaces". Texaco believes that paragraph (i) simply leads to confusion, dilutes the scope, application, and protection offered by the Standard and renders the Standard unreasonably vague. We again recommend that this section be deleted in its entirety.

OSHA has decided not to carry proposed paragraph (i) forward into the final rule. The Agency agrees with the view that a "low hazard" designation for certain permit-required confined spaces would lead to confusion and reduce the protection afforded employees under final §1910.146. While OSHA believes that different levels of risk should lead to different levels of protection, the permit space program will necessarily require the employer to implement protective measures that will address the hazards in the permit spaces adequately and appropriately. Under the final rule, employers will need to take increasingly stronger steps to ensure the safety of employees involved in entry operations in more and more hazardous permit spaces. The basic performance-oriented nature of OSHA's permit space standard forces employers to develop whatever procedures are necessary to eliminate or control hazards in permit-required confined spaces. Spaces posing the least risk (above the threshold set by the definition of permit-required confined space) will necessitate the fewest procedures to ensure safe entry. Spaces containing severe or multiple hazards will require more detailed and comprehensive procedures. Lastly, confined spaces not posing the minimum risk set by the definition of permit-required confined space require the least amount of effort to render them safe for employees; such spaces need neither attendants nor permits.[11]

On the other hand, there are some confined spaces that do not normally contain a hazardous atmosphere, but that might under certain conditions. These spaces are typically designed for employees to enter periodically, but they usually lack adequate ventilation to prevent the accumulation of a toxic or flammable atmosphere or to prevent the depletion of oxygen. Many of the "low-hazard" spaces mentioned in the record are spaces of this type. For example, diked areas, as noted by several commenters (Ex. 14–124, 14–150, 14–168, 14–184, 113, 140), do not normally pose hazards severe enough to warrant the issuance of permits or the presence of attendants. The telecommunications industry (Ex. 14–95, 14–104, 14–110, 14–139, 14–149, 14–162, 14–169, 14–188) contended that their manholes do not contain sufficient hazards to justify coverage under the permit space standard. Under industry practices currently used for entry into such spaces, these confined spaces do not have a potential to contain any hazard capable of causing death or serious physical harm, except in very rare circumstances.

OSHA believes that the practices necessary to make confined spaces that merely have the potential to contain hazardous atmospheres (as opposed to one that contains a hazardous atmosphere under normal conditions) safe are widely recognized and used throughout various industries. OSHA requirements for such spaces are contained in §§1910.268(o), for

[11] These spaces are addressed in the definition of non-permit-required confined space and in paragraphs (c)(1) and (c)(6) of the final rule. These provisions require employers to evaluate those confined spaces to ensure tha. they are not permit spaces and to re-evaluate them if their use or configuration changes in a manner that might pose hazards to entrants.

underground telecommunications manholes and unvented vaults, and 1926.956, for underground electric transmission and distribution work. The Agency included similar requirements in §1910.269(e), for "enclosed spaces" in its proposed standard for electric power generation, transmission, and distribution work (54 FR 5012), and in proposed §1910.146(i), for "low-hazard" permit spaces. The practices necessary for eliminating the potential hazardous atmosphere for these spaces as set out in these documents include checking the cover for evidence of possible hazards, placing barriers after the removal of the cover, performing atmospheric testing, and providing continuous mechanical ventilation. Atmospheric testing includes testing for oxygen content, for the presence of flammable vapors and gases, and for potential toxic air contaminants. Mechanical ventilation is provided if a hazardous atmosphere is detected.

OSHA believes that these practices can be adopted to ensure safe entry into any confined space that can be maintained safe for entry by ventilation alone. Some confined spaces are designed for employees to enter under normal operating conditions, although they do not provide sufficient natural or mechanical ventilation to ensure an adequate supply of oxygen or to disperse flammable gases and vapors and toxic air contaminants that may be introduced accidentally into the permit space environment. Testing the atmosphere within the space and providing adequate continuous ventilation can normally eliminate the hazardous atmosphere, producing the equivalent of a non- permit confined space. Other types of permit spaces with only atmospheric hazards can be isolated, purged, and ventilated from outside the space. If no entry is needed to achieve a safe atmosphere, then procedures similar to those described earlier for the telecommunications and electric utility industries can be followed to ensure the safety of entrants.

By contrast, however, for a permit space that contains a hazardous atmosphere under normal operating conditions, it is usually necessary to make an initial entry in order to control the hazards within the space. The initial entry involves the exposure of the entrant to any hazards within the space, since the purpose of the entry is to control the hazards for future entries. The measures that must be taken to control the hazards, such as cleaning the space, vary with the types of hazards present within the space. Similarly, permit spaces into which hazards (such as welding or toxic or flammable cleaning materials) are introduced during entry need the protection afforded by the complete permit space program in order to assure that all measures, in addition to ventilation, necessary for the protection of entrants are followed. In these cases, the employer's evaluation of the space before entry must take into account these additional sources of hazardous atmospheres that will be introduced into the space during entry. Pre-entry monitoring will not provide the needed assurances of safety in these situations. Accordingly, the permit system is necessary to provide protection form hazards in the permit space during these types of entries. The permit identifies the measures that must be taken to ensure that employees can safely enter the permit space, and the attendant watches for conditions not envisioned during the preparation of the permit and for other prohibited conditions. These two elements of the permit space program are essential for the safety of authorized entrants working in spaces that would contain a hazardous atmosphere under normal operating conditions.

Additionally, ANSI Z117.1–1989 (Ex. 129), Section 2, provides that a space which, by configuration, meets the definition of a confined space but which is found, after evaluation, to have little potential for the generation of hazards or to have had its hazards eliminated by engineering controls is to be considered as a non-permit confined space. The ANSI standard treats these spaces separately from permit-required confined spaces, applying only the requirements for identification of confined spaces and evaluation of their hazards and for atmospheric testing, along with special provisions for non-permit confined spaces. The ANSI standard does not apply the other requirements of the consensus standard to such spaces, but provides only that these other requirements be considered for application to the procedures used for entry.

OSHA has determined that it is not appropriate to require the entry permit program to be implemented for entries into permit spaces that contain only atmospheric hazards which the employer demonstrates can be controlled with ventilation alone. These spaces can be made safe for entry following specific procedures that are spelled out in paragraph (c)(5) of the final rule. Paragraph (c)(5) of the final rule allows employers to conduct entry operations for such spaces in accordance with these procedures without following the non-training related provisions of the permit space program (paragraphs (d) through (f) and (h) through (k) of the final rule). The procedures in paragraph (c)(5) are based on proposed paragraph (i), with modifications supported by the rulemaking record, and are explained in the following discussion.

Additionally, OSHA has determined that spaces that have had all hazards eliminated can be reclassified as non-permit spaces for as long as the hazards remain eliminated. (It should be noted that continuous forced air ventilation controls atmospheric hazards—it does not eliminate them.) For spaces posing only non-atmospheric hazards, if those hazards can be removed without entry into the space, the permit space may be reclassified as a non-permit confined space after the hazards are removed. For example, the engine for a cement mixer can be locked out, and the mixer can then be safely entered for maintenance (assuming there are no other hazards inside the mixing drum). For spaces with atmospheric hazards and for spaces with non-atmospheric hazards that can only be eliminated through entry into the space, the permit space can first be entered following all the requirements spelled out in paragraphs (d) through (k) of the final rule; and, after the employer certifies that the hazards have been eliminated, the space can be reclassified as a non-permit confined space. Requirements for the procedures to be used in reclassifying permit spaces are contained in final §1910.146(c)(7), discussed later in this section of the preamble.

OSHA believes that the approach taken in paragraphs (c)(5) and (c)(7) of the final rule is consistent with that taken in ANSI Z117.1–1989. The major difference is that the consensus standard treats all non-permit required confined spaces [12] alike, whereas the OSHA standard separates them into two categories—permit spaces with atmospheric hazards controlled by

[12] The ANSI definitions of "confined space", "permit-required confined space", and "non-permit confined space" differ somewhat from OSHA's definitions of these terms. OSHA's definition of "permit-required confined space" is basically the same as ANSI's definition of "confined space". Under the ANSI definition, all confined spaces have an actual or potential hazard, while OSHA's definition of "confined space" includes spaces with no hazards at all (which are not regulated under final §1910.146). The final rule's definition of "non-permit-required confined space" covers these hazard-free confined spaces, as well as spaces that have had their hazards eliminated under paragraph (c)(7). The ANSI definition of "non-permit-required confined space" covers confined spaces whose hazards have been eliminated by engineering controls and confined spaces that have "little potential for generation of hazards". It is the ANSI "non-permit-required confined spaces" that are regulated under paragraphs (c)(7) and (c)(5) of the final rule.

means of ventilation alone and permit spaces that have been reclassified as non-permit confined spaces because the hazards have been eliminated.

This two-pronged approach better protects employees than the ANSI standard for two basic reasons. First, by minimizing the amount of regulation that applies to spaces whose hazards have been eliminated, it encourages employers to actually remove all hazards from permit spaces, which is the best possible protection for entrants. The rules that do apply in such situations (paragraph (c)(7), discussed later in this section of the preamble) are only those necessary to ensure that the hazards have indeed been removed. Second, for permit spaces that can be maintained safe by ventilation alone, the regulation specifies exactly what is required of the employer. As noted earlier, the practices required by paragraph (c)(5) for these spaces have been demonstrated in the telecommunications and electric utility industries as being highly effective in protecting entrants from the limited hazards present in such spaces (Ex. 14–7, 14–39, 14–53, 14–80, 14–171; Washington Tr 180–181). The ANSI standard does not specifically require such protective measures as ventilation in such cases. If the employer needs additional flexibility in controlling the hazards in these permit spaces, it is available by following the full permit procedures outlined in paragraphs (d) through (k) of the final rule. These provisions, although they require additional protection in the form of attendants and permits, give the employer more flexibility in applying different controls to the hazards that are present.

Based on review of the record, OSHA has determined that there are circumstances in which employers can control atmospheric hazards without following the full permit procedures outlined in paragraphs (d) through (k) of the final rule. As noted earlier, some industries, such as telecommunications (regulated under §1910.268(o)), have successfully protected employees from atmospheric hazards in workspaces through testing and continuous ventilation, without following all the requirements proposed in §1910.146. OSHA believes that such experience indicates that ventilation and testing could protect employees throughout general industry from atmospheric hazards posed by similar types of permit spaces. Accordingly, OSHA has decided to allow employers, under certain conditions, to control atmospheric hazards within a permit space following specific procedures that are spelled out in the final rule in lieu of compliance with paragraphs (d) through (f) and (h) through (k) of the final rule. The only requirements from the full permit space program that would apply to entry following these procedures are the training provisions in paragraph (g) of the final rule. The Agency has determined that training employees in the procedures is necessary and appropriate and that paragraph (g) contains the relevant requirements for this training.

Paragraph (c)(5)(i) of the final rule sets forth the conditions that must be met before a permit space may be entered under the alternative procedures, which are specified in paragraph (c)(5)(ii).

The first condition, set out in paragraph (c)(5)(i)(A) of the final rule, is that the employer must be able to demonstrate that the only hazard posed by the permit space is an actual or potential hazardous atmosphere. The procedures required under paragraph (c)(5)(ii) are only appropriate for atmospheric hazards, and the spaces for which these procedures can be used pose only this type of hazard. If the space poses other hazards as well, either all the hazards must be eliminated, under paragraph (c)(7) of the final rule, or the space may only be entered following the full permit space procedures set out in paragraphs (d) through (k).

The second condition, set out in paragraph (c)(5)(i)(B) of the final rule, is that the employer must be able to demonstrate that ventilation alone is sufficient to maintain the permit space safe for entry. In order for the space to be considered safe, the atmosphere within the space after ventilation may not be expected to approach a hazardous atmosphere. This is necessary so that, if the ventilation shuts down for any reason (such as loss of power), the employees will have enough time to recognize the hazard and either exit the space or restore the ventilation. A guideline of 50 percent of the level of flammable or toxic substances that would constitute a "hazardous atmosphere" may be used by employers in making the determination required under paragraph (c)(5)(i)(B). [13] Additionally, the work to be performed within the space must not introduce any hazards—work with hazardous quantities of flammable or toxic substances and hot work are not permitted. This type of work would introduce hazards beyond those accounted for by the determination that the permit space can be maintained safe for entry. Paragraph (c)(5)(i)(B) indicates clearly that an employer who relies on continuous forced air ventilation to maintain spaces safe for entry must be able to establish that other measures are not needed to protect entrants.

The third condition, set out in paragraph (c)(5)(i)(C) of the final rule, is that the employer must develop monitoring and inspection data that supports the demonstrations required by paragraphs (c)(5)(i)(A) and (c)(5)(i)(B). The atmospheric monitoring data must show that ventilation will keep the air inside the permit space within the guidelines of paragraph (c)(5)(i)(B), discussed earlier. The data required by paragraph (c)(5)(i)(C) are essential for the employer and employees, as well as OSHA, to be able to determine whether or not the space can be maintained safe for entry with the use of ventilation alone.

The fourth condition, set out in paragraph (c)(5)(i)(D) of the final rule, is that, if an initial entry is performed to gather the data required under paragraph (c)(5)(i)(C), it be conducted in accordance with the full permit space program requirements given in paragraphs (d) through (k). The Agency recognizes that monitoring and inspection data may be obtained either through entry into a space, or from outside the space, as long as the data provide complete and accurate information on air contaminants throughout the confined space. In many instances, however, it will be necessary to make an initial entry into the space in order to make the necessary determination. Paragraph (c)(5)(i)(D) requires that any entry to obtain the data be performed in accordance with all the provisions of the standard, because any relief from permit space program requirements is not allowed until the process of demonstrating, inspecting, monitoring, and documenting the conditions to be expected during entry is completed.

The fifth condition, set out in paragraph (c)(5)(i)(E) of the final rule, is that the determinations and supporting

[13] Two examples may help to clarify this guideline.

(1) The LFL for methane is a concentration of 5 percent by volume. Ten percent of this value is 0.5 percent, a concentration which would be considered hazardous, by definition. Under the guideline, the measured concentration of methane should not exceed 0.25 percent after ventilation in order for the procedures specified in paragraph (c)(5)(ii) of the final rule to be acceptable.

(2) The 8-hour time weighted average PEL for chlorine, under Table Z-1, is 0.5 parts per million. This concentration of chlorine would be considered hazardous by the definition of "hazardous atmosphere". Under the guideline, the measured concentration of chlorine should not exceed 0.25 parts per million after ventilation in order for the procedures specified in paragraph (c)(5)(ii) of the final rule to be acceptable.

data required by paragraphs (c)(5)(i)(A) through (c)(5)(i)(C) be documented and made available to employees who enter the spaces under the terms of paragraph (c)(5). This documentation will enable the employer, employees, and OSHA to evaluate the determination that paragraph (c)(5) applies to a given permit space.

The sixth, and final, condition, set out in paragraph (c)(5)(i)(F) of the final rule, is that the entry be performed in accordance with the specific procedures required by paragraph (c)(5)(ii).

Paragraph (c)(5)(ii) of the final rule sets forth the procedures that must be followed for entries under paragraph (c)(5). The procedures detailed in this paragraph have been derived from several sources. Proposed paragraph (i) set out procedures that could be used for spaces that presented an extremely low probability of encountering atmospheric hazards. Proposed paragraphs (i)(1) and (i)(2) would have required testing, ventilation, and other measures necessary to ensure that the space remained safe for entry. These provisions, modified as warranted by the public record, have formed the basis of most of the requirements contained in paragraph (c)(5)(ii) of the final rule.

Section 4 of ANSI Z117.1–1989 provides requirements necessary for safe entry into non-permit confined spaces. OSHA also relied on some of these provisions, specifically the training and testing requirements contained in Sections 4.2 and 4.4, respectively, in the development of paragraph (c)(5)(ii) of the final rule.

Lastly, the Agency based some of the provisions of this paragraph of the final rule on the existing telecommunications and proposed electric power generation, transmission, and distribution standards. Paragraph (o) of §1910.268 sets forth requirements for the protection of employees performing telecommunications work. Current industry practice in compliance with these requirements has provided effective protection for employees performing work in such spaces as manholes and unvented vaults. Paragraph (e) of proposed §1910.269 set out provisions that OSHA believed were necessary (and widely used) for the protection of employees performing electric power generation, transmission, and distribution work in "enclosed spaces".[14] (This proposed paragraph was also based largely on §1910.268(o).) These proposed and existing standards provide provisions that OSHA believes are necessary and appropriate for the protection of employees in the two industries from atmospheric hazards that can be controlled through the use of ventilation alone. OSHA has determined that these standards, with appropriate modification, can also be used to protect employees in general industry from permit spaces presenting atmospheric hazards that can be maintained safe for entry by means of ventilation alone.

Paragraph (c)(5)(ii)(A) of the final rule requires that any conditions that make it unsafe to remove an entrance cover be eliminated before the cover is removed. Some conditions within a permit space, such as high temperature and high pressure, may make it hazardous to remove a cover from the space. For example, if the atmospheric hazards within the space cause high pressure to be present within the space, the cover could be blown off in the process of removing it. To protect employees from such hazards, a determination must be made as to whether or not it is safe to remove the cover. Such a determination would require the employer to examine the conditions that are expected to be in the permit space. The cover would be checked to see if it is hot; and, if it is fastened in place, it would be loosened gradually to release any residual pressure. An evaluation must also be made of whether conditions at the site could cause a hazardous atmosphere to accumulate in the space, which would make it unsafe for employees to remove the cover. The cover could not be removed until it is safe to do so.

Paragraph (c)(5)(ii)(B) of the final rule requires that openings to permit spaces be guarded to protect employees from falling into the space and to protect employees in the permit space from being injured by objects entering the space. The guard could be in the form of a railing, a temporary cover, or any other temporary barrier that provides the required protection. If the opening to the space is situated so that employees and objects cannot fall into the space, no additional guarding is necessary. This provision was taken from existing §1910.268(o)(1)(i), which sets forth an equivalent requirement for underground telecommunications work.

Paragraph (c)(5)(ii)(C) of the final rule requires the internal atmosphere of the permit space to be tested with a calibrated, direct-reading instrument before any employee enters the space. The atmosphere must be tested, in sequence, for oxygen content, for flammable gases and vapors, and for potential air contaminants. This provision, which is based on proposed paragraph (i)(1)(ii), is necessary to determine whether or not ventilation alone will be able to maintain the space safe for entry. The results of this testing must be within the expected range for the space, based on the employer's determination under paragraph (c)(5)(i)(A).

Paragraph (c)(5)(ii)(D) of the final rule prohibits employees from being in the space when a hazardous atmosphere is present. Any entry into a permit space containing a hazardous atmosphere must be conducted in accordance with the full permit space program requirements given in paragraphs (d) through (k).

Paragraph (c)(5)(ii)(E) of the final rule sets out requirements for the continuous forced air ventilation that must be used to maintain the permit space safe for entry. First, no employee may enter the space until the forced air ventilation has eliminated any hazardous atmosphere found within the space. Second, the ventilation must be directed to ventilate the immediate areas where an employee is or will be present within the space and must continue until all employees have left the space. Third, the air supply for the ventilation must be from a clean source and must not increase the hazards in the space. These provisions, which have been taken from ANSI Z117.1–1989 Sections 9.1 and 9.1.1 and from proposed §1910.269(e)(10) and (11), ensure that the atmosphere within the permit space remains safe during the entire entry operation.

Paragraph (c)(5)(ii)(F) of the final rule requires the permit space to be periodically tested as necessary during the entry to ensure that the continuous forced air ventilation is preventing the accumulation of a hazardous atmosphere. The frequency at which such testing would have to be performed is dependent on the nature of the permit space and the results of the initial testing performed under paragraph (c)(5)(ii)(C) of the final rule. For example, if the initial testing found no evidence of flammable gases or vapors and if the permit space is not normally expected to present the hazards posed by such gases and vapors, no further testing would be necessary. If a flammable gas or vapor is initially detected, frequent or continuous testing would be appropriate. The testing required by final paragraph (c)(5)(ii)(F), in combination with continuous forced air ventilation required by paragraph (c)(5)(ii)(E), ensures that entrants remain

[14] Defined in proposed §1910.269 as a working space, such as a manhole, vault, tunnel, or shaft, that has a limited means of egress or entry, that is designed for periodic employee entry under normal operating conditions, and that under normal conditions does not contain a hazardous atmosphere, but that may contain a hazardous atmosphere under abnormal conditions.

protected the entire time they are present within the permit space.

Paragraph (c)(5)(ii)(G) of the final rule requires employees to exit the permit space immediately if a hazardous atmosphere is detected. Additionally, the employer is required to evaluate the permit space to determine how the hazardous atmosphere developed and to implement measures to protect employees from the hazardous atmosphere before any subsequent entry under paragraph (c)(5) procedures is undertaken. Obviously, if a hazardous atmosphere is detected during entry, the permit space has not been maintained safe for entry. For any subsequent entries to be authorized under paragraph (c)(5), the employer must determine what went wrong, must take whatever measures are needed to prevent a recurrence, and must demonstrate that the subsequent entries can be performed safely, as required by paragraph (c)(5)(i).

Paragraph (c)(5)(ii)(H) of the final rule requires the employer to verify that the permit space is safe for entry and that the measures required by paragraph (c)(5)(ii) have been taken. The verification must be in the form of a certification that contains the date, the location of the space, and the signature of the certifying individual and that is made available to entrants. The certification documents the employer's compliance efforts. The certification, in combination with the documentation required under paragraph (c)(5)(i)(E), will maintain employer accountability for compliance with paragraph (c)(5)(ii), will enable OSHA to evaluate compliance with the standard, and, where permit space incidents have occurred, will assist OSHA in ascertaining how those incidents arose.

Paragraph (c)(6) of the final rule requires employers to reevaluate non-permit confined spaces whenever changes in the use or configuration of the space might increase hazards to entrants. If the reevaluation warrants, the space must be reclassified as a permit space.

The second sentence of the introductory text of proposed §1910.146(c), from which final paragraph (c)(6) was taken, would have required employers to reevaluate confined spaces in which changes have occurred to determine whether the space has become a permit space. This provision read as follows:

> If there are changes in a confined space which previously was not a permit space, the employer shall reevaluate that space to determine if it has become a permit space.

One commenter (Ex. 14–45) was concerned that all non-permit confined spaces would have to be reassessed for every change, however minor. In response to this comment, OSHA requested, in Issue 7 of the notice of public hearing (54 FR 41462), information on whether guidelines should be listed to indicate when work spaces would need reevaluation. The Agency also sought information on what those guidelines should be.

Most of the testimony on this issue dealt with the conditions under which a permit space should be "reevaluated" after entry. For example, Mr. Tom Lawrence, representing the Monsanto Company (Washington Tr. 520–528), testified that the atmosphere in the permit space would have to be retested if the entrants left the space unoccupied or if nearby environmental conditions were to impact the confined space adversely.

These comments are not directly relevant to the issue raised in the hearing notice, that is, under what conditions should a non-permit confined space be reevaluated. The final rule contains separate requirements intended to protect employees from hazards arising when conditions in a permit-required space change. For example, final paragraph (i) requires the employer to ensure that attendants know of and can recognize potential permit space hazards and that they monitor activities inside and outside the space to determine if it is safe for entrants to remain inside. It is the duty of the attendant to order entrants to leave when evidence of an uncontrolled hazard exists (final paragraph (i)(6)). Also, it is the duty of the entry supervisor to determine, at appropriate intervals, whether the conditions within the space remain safe for the presence of employees and to cancel the permit whenever conditions are otherwise (final paragraph (j)(6)). The Agency believes that the final rule fully addresses the hazards of changes within permit spaces during entry and that the wide ranging circumstances causing new hazards not addressed by the permit are too numerous to list in the standard.

The issues at hand, however, are: (1) whether OSHA should revise the language of the introductory text of proposed paragraph (c) to present guidelines as to what types of changes in confined spaces would necessitate reevaluation of non-permit spaces and (2) what types of changes would result in the reclassification of a non-permit space into a permit space. Only three commenters (Ex. 14–45, 14–57, 14–178) addressed these issues. S. C. Johnson and Son, Inc. (Ex. 14–45) suggested that the language be revised to indicate that reevaluation would only be necessary when the changes introduced increased hazards. The other two argued that periodic evaluation should be required as changes warrant.

OSHA believes that the language contained in the proposal was widely understood. However, the Agency is revising the text of this provision to indicate more clearly that reevaluation is required only when changes "that might increase the hazards to entrants" occur and to indicate that reclassification of a non- permit confined space to a permit-required confined space may be necessary. OSHA believes that this modification will clarify the standard and will result in a more performance-oriented final rule. OSHA does not expect employers to reevaluate spaces because trivial changes have occurred that do not affect the nature of the space or the work performed in the space.

Paragraph (c)(7) of the final rule gives procedures under which the employer may eliminate hazards within a permit space so that it may be reclassified as a non-permit confined space. OSHA believes that this paragraph will protect employees by encouraging employers to eliminate (as opposed to control) hazards within permit spaces. OSHA anticipates that some spaces will be reclassified back and forth from time to time, because of changes in their configuration or use. Accordingly, the Agency has included language in this paragraph to indicate clearly that the reclassification is valid only as long as the hazards remain eliminated.

Paragraph (c)(7) reflects the public input on Issues 11 and 17 of the NPRM and Issue 13 of the hearing notice, as discussed earlier under the summary and explanation of paragraph (c)(5). As noted in that discussion, OSHA believes that employees are fully protected from the hazards of permit space entry once all hazards within the space have been eliminated. Clearly, if there are no hazards within the permit space, an entrant is in no danger. By contrast, if the hazards are simply controlled rather than removed, the entrant could be injured upon failure of the control system. Therefore, the Agency has determined that it is appropriate to allow employers who eliminate hazards within permit spaces to reclassify those spaces as non-permit confined spaces.

Paragraph (c)(7)(i) of the final rule allows the employer to reclassify a permit space as a non-permit confined space if there are no actual or potential atmospheric hazards and if all other hazards within the space are eliminated

without entry into the space. The reclassification would be valid as long as the non- atmospheric hazards remain eliminated.

This paragraph applies only to permit spaces containing no actual or potential atmospheric hazards. OSHA expects that this provision will apply primarily to spaces containing hazardous energy sources or containing engulfment hazards. The control of hazardous energy sources is addressed by existing §1910.147, *The control of hazardous energy sources (lockout/tagout).* That standard covers the service and maintenance of machines and equipment in which the unexpected energizing or start up of the machines or equipment or release of stored energy could cause injury to employees. OSHA believes that it is possible in some cases to deenergize and lockout machinery and equipment, using the procedures specified in §1910.147,[15] so that the energy hazards are eliminated without any entry into the permit space. For spaces posing only engulfment hazards, it may be possible to remove the hazard by removing the engulfing material from the space before entry. In these cases, the Agency believes that entry into these spaces, after the hazards have been removed, is at least as safe as (if not safer than) entry in accordance with the full permit space program requirements given in paragraphs (d) through (k). Paragraph (c)(7)(i), therefore, allows the reclassification of these types of spaces after their hazards have been eliminated.

The reclassification of permit spaces allowed under paragraph (c)(7)(i) of the final rule recognizes that spaces such as mixers and material bins can have their hazards removed before entry, so that entrants are fully protected without the need for permits, attendants, or other features required by the full permit space program requirements given in paragraphs (d) through (k). Mixers can be locked out before it is entered for servicing or maintenance, removing the mechanical hazards. A material bin posing an engulfment hazard can be emptied before entry, thus removing that hazard. These are the types of spaces that can be made safe for entry following paragraph (c)(7)(i) of the final rule.

[15] If the equipment or machinery is not deenergized and locked out or tagged in accordance with §1910.147, then it must be guarded as required in other general industry standards, such as Subpart O, for machine guarding, and §1910.303(g) and (h), for the guarding of electric equipment. As long as the equipment or machinery inside the permit space remains guarded, employees within the space are not considered to be exposed to any equipment-related hazards.

Permit spaces that contain or have the potential to contain hazardous atmospheres may also be reclassified as non-permit spaces, under paragraph (c)(7)(ii) of the final rule. The Agency believes that these spaces need to be treated the same as any space that must be entered in order to eliminate hazards. After this type of space is isolated, purged, and ventilated from outside, it must be entered to test the atmosphere and inspect conditions within the space in order to ensure that the hazards have indeed been eliminated. (Once again, control of a hazardous atmosphere is not the same as its elimination.)

Paragraph (c)(7)(ii) of the final rule allows the employer to reclassify a permit space as a non-permit confined space after a permit entry is performed to eliminate hazards within the space. The permit entry with must be conducted in accordance with the full permit space program requirements given in paragraphs (d) through (k). This reclassification would also be valid only as long as the hazards remain eliminated.

As noted earlier, OSHA believes that entry into a permit space whose hazards have been removed is safe. Some spaces, however, must be entered either to remove the hazards or to verify that the hazards have been eliminated. For example, if the disconnecting means for an energy source is inside the permit space, the space must be entered in order to deenergize it and lock it out. Also, as noted previously, if the permit space poses any atmospheric hazards, it must first be entered in order to perform the testing and inspection that is necessary to determine whether the hazards have been eliminated. As long as the entry to remove the permit space hazards is conducted in accordance with the full permit space program requirements given in paragraphs (d) through (k), the space can be considered as safe and reclassified after the hazards have been removed.

The types of permit spaces that could fall under paragraph (c)(7)(ii) include such spaces as chemical tanks and boilers. Chemical tanks can frequently be made safe by draining them of their contents, purging any residual chemicals with water, and ventilating the space after purging is complete. Boilers can be made safe for entry by shutting them down, opening the access ports to allow for temperature reduction and natural ventilation, and entering the space to remove any residual hazards, such as loose buildup that could fall onto entrants. In each case, an entry, conducted in accordance with the full permit space program requirements given in paragraphs (d) through (k), must be performed in order to ensure that the hazards have been eliminated.

Paragraph (c)(7)(iii) of the final rule requires employers seeking to reclassify a permit space to document the basis for the determination that all permit space hazards have been eliminated, through a certification that contains the date, the location of the space, and the signature of the certifying individual. The certification must be made available to each employee entering the space.

This provision is basically equivalent to paragraphs (c)(5)(i)(E) and (c)(5)(ii)(H) of the final rule. In each case, the employer must substantiate all determinations that compliance with the alternate provisions is appropriate, so that employers, employees, and the Agency have the means by which to evaluate those determinations. Compliance with this provision will require careful consideration of the spaces to be reclassified. OSHA believes that this paragraph imposes a reasonable burden, considering that compliance will enable employers to have employees enter these reclassified spaces without the need to implement the full array of permit space program requirements.

If a permit space hazard arises in a space that has been reclassified under paragraph (c)(7), paragraph (c)(7)(iv) of the final rule requires employees to exit the space and requires employers to reevaluate the space to determine if the space must be reclassified again as a permit space.

This provision indicates clearly that employers retain responsibility for the safety of employees who enter spaces after the spaces have been reclassified as non-permit confined spaces. The employer must determine if it is still appropriate, under the circumstances identified through the reevaluation, to classify the space where the hazard arose as a non-permit confined space. A reevaluation aimed at reestablishing compliance with paragraph (c)(7) will encompass the demonstrations, testing, inspection, and documentation required in paragraphs (c)(7)(i) through (c)(7)(iii) of the final rule. OSHA anticipates that some employers will seek to reestablish compliance with paragraph (c)(7), while others will choose to conduct the entries in accordance with the full permit space program requirements given in paragraphs (d) through (k). The Agency's concern is that the approach chosen adequately protect employees who enter the spaces.

Paragraph (c)(8) of the final rule contains requirements pertaining to the responsibilities of host employers to employees of other employers (contractors) who are to perform permit-

required confined space entry. This provision corresponds to paragraph (c)(10) of the proposed rule. Host employers who comply with these requirements will enable their contractors to develop and implement permit space programs that satisfy §1910.146. As noted in the preamble to the proposal (54 FR 24091), a contractor who is unfamiliar with a particular workplace may experience difficulties in identifying and controlling permit space hazards, especially where the host employer assumes that the contractor knows how to operate safely in a particular permit space simply because the contractor has a particular professional expertise.

In Issue 18 of the NPRM (54 FR 24088), OSHA asked if the term "contractor" was sufficiently inclusive to ensure that all employers who have permit space operations in workplaces they do not control benefit from the provision in proposed paragraph (c)(10). OSHA also asked if there were employers who, while neither being contractors nor having control of the workplace, would have employees enter permit spaces.

Many commenters responded to the questions posed in Issue 18 (Ex. 14–61, 14–62, 14–63, 14–123, 14–132, 14–158, 14–161, 14–162, 14–170, 14–171, 14–182, 14–183, 14–185, 14–219). The majority felt that no further clarification of the term "contractor" was necessary. For example, the Department of Defense, Force Management and Personnel (Ex. 14–219) stated:

> The term "contractor" used in the proposed standard is suitably defined to ensure that all individuals that may have to work in confined spaces would be covered under the requirements.

The Duquesne Light Company (Ex. 14–182) agreed:

> The term "contractor" is sufficiently inclusive to ensure that noncompany employees are made aware of permit space hazards at the site on which they work.

Three commenters (Ex. 14–63, 14–158, 14–171) believed that the term "contractor" was not sufficiently inclusive. The comments of the American Insurance Association (Ex. 14–158) were typical of these:

> ... we believe that the term "contractor" does not accurately describe all employers whose employees may be required to enter into confined spaces at the premises of a host employer, and may in fact mischaracterize the nature of the relationship between the host and the visiting or guest employee in many instances. As an example, although insurance company personnel on occasion are called upon to make inspections or observations of the premises of their insureds for insurance and related purposes, insurers do not typically act as "contractors" for their insureds in that regard. We request that OSHA use another term such as "dispatching employer" or a similar term when referring to an employer whose employees are sent to the premises of a host employer.

The Atlantic Richfield Company (Ex. 14–123) recommended that "contractor" be changed to read "contractor/subcontractor" in the final rule, since many primary contractors subcontract out specific tasks. The State of Maryland (Ex. 14–63) recommended that the term "contractor" be expanded by adding to it "or temporary employment agency or service."

On the basis of the information submitted to the record, OSHA believes that the term "contractor", as it is used in the regulatory text, is inclusive enough to cover all employees who may be required to enter permit spaces. The Agency has continued to use the term, unchanged, in the final rule. Temporary employment agencies or subcontractors are considered to be "contractors" by OSHA. In any case, OSHA only uses the term "contractor" as an example (parenthetical) of the usual type of "personnel other than its own employees" that a host employer is likely to encounter. In this final rule, OSHA intends to cover the operations of all employers whose employees enter permit spaces.

Paragraph (c)(8) requires host employers:

(1) To inform the contractor that the workplace has permit spaces that may be entered only under a permit space program;

(2) To apprise the contractor of hazards associated with the permit space;

(3) To apprise the contractor of any permit space procedures the host employer has implemented;

(4) To coordinate entry operations with the contractor; and

(5) To debrief the contractor at the conclusion of entry operations.

This provision of the final rule is based on paragraph (c)(10) of the NPRM.

Several comments were received concerning the host employer's responsibilities to the contractor. The commenters agreed that the host employer should be required to inform contractors of the hazards present in, and the precautions the host employer has previously taken regarding, the host employer's permit spaces (Ex. 14–81, 14–86, 14–107, 14–111). However, there was some objection to the proposed requirement that the host employer provide "all available information" on permit space hazards to the contractor (Ex. 14–30, 14–157, 14–161, 14–171, 113). These commenters suggested that the requirement was too broad and recommended that the host employer provide only "pertinent" information to the contractor. For example, the American Petroleum Institute (Ex. 14–168) had this concern with paragraph (c)(10) of the NPRM:

> In many circumstances, it is absolutely vital to the safety of all workers that confined space entries in existing process facilities remain under the close control of the host company, using one common *and consistent set of procedures established for the facility*, conforming to the OSHA rule.
>
> However, the language proposed seems to preclude this approach, and instead requires that the host company provide the contractors with all the necessary information, and that the contractors then independently comply with the regulation through their own diverse programs. [Emphasis was supplied in original.]

The Hartford Steam Boiler Inspection and Insurance Company (Ex. 14–131) brought up a subject (identification of permit entry permit spaces) which was not covered in the NPRM. They stated:

> The regulation is unclear as to who would identify the entry permit spaces[,] the contractor or the host employer.

A comment from S.C. Johnson & Son, Inc. (Ex. 14–45) asked that OSHA "further clarify" the requirements concerning a host employer's duty to other employer's employees. Other commenters (Ex 14–111, 14–131, 14–150), while not disagreeing with the intent of proposed paragraph (c)(10), also asked that it be clarified or provided recommended language for amending the provision.

In response to the concerns expressed relating to proposed paragraph (c)(10), OSHA has rewritten and reorganized the standard's provisions. The final rule breaks out the different provisions in the proposed paragraph into separate requirements.

In paragraph (c)(8)(i), OSHA is requiring that the host employer inform the contractor that the workplace contains permit spaces, and that entry into those spaces is allowed only through compliance with a permit space program meeting the requirements of this standard. This very basic information would have been required to be provided to contractors in any case, under the proposed provision to provide "all available information"; but OSHA has decided, in order to eliminate any confusion or misunderstanding, to specifically require the host employer provide it to the contractor.

This is the type of approach taken throughout final paragraph (c)(8)—OSHA has provided more specific language with respect to what is

required, as opposed to the relatively open-ended general language contained in the proposal. The Agency believes that this approach is responsive to the comments received on proposed paragraph (c)(10) and that the final provisions give better guidance to employers as to what is expected in terms of compliance.

In paragraph (c)(8)(ii), OSHA is requiring the host employer to provide the contractor with the elements (the hazards posed by and the host employer's experience with the space) that indicate that the space in question is a permit space. This provision does not require a host employer to make a detailed investigation of any permit spaces, but merely to provide to the contractor whatever information the host employer used in identifying a permit space.

In paragraph (c)(8)(iii) of the final rule, OSHA is requiring the host employer to apprise the contractor of the precautions or procedures, if any, that the host employer has implemented for the protection of employees in or near permit spaces where contractor personnel will be working.

OSHA considers that the information required from the host employer, clearly set out in paragraphs (c)(8)(i) through (c)(8)(iii), is the minimum needed by a contractor to perform permit space entries at a host employer's workplace. This is the same information that the Agency would have required under proposed paragraph (c)(10), but it has been presented in a more precise manner. Except for the open-ended nature of proposed paragraph (c)(10), there was no substantive objection to the provision itself.

OSHA has included paragraphs (c)(8)(iv), (c)(8)(v), and (c)(9) in the final rule to further address the relationship between the host employer and the contractor. These provisions, which have no counterparts in the proposal, cover coordination of efforts to provide safe permit space entry operation and the exchange of information between the host and the contractor. They are also a direct outgrowth of the recognition, as reflected in the record, that coordination between host employers and contractors is essential to the safety of all employees who must enter permit spaces.

Various witnesses and commenters (Ex. 14–63, 14–111, 14–124, 14–147) recommended that additional coordination between host employer and contractor was desirable (see the previous discussion of paragraph (c)(8)). With respect to this question, some commenters (Ex. 14–63, 14–178, 14–183, 113, 138) recommended that the rule address the responsibilities of contractors in more detail. For example, the State of Maryland's Occupational Safety and Health Program (Ex. 14–63) stated: "Maryland strongly recommends that ... consideration be given to expanding Section (c)(10) to more clearly define the role of the contractor. Although (c)(10) indicates to the 'host employer' that he/she has obligations to the contractor, the obligations of the contractor are not clearly defined." The State of Maryland concluded that the contractor's obligation to comply with §1910.146, which was clearly noted in the preamble to the NPRM (54 FR 24091) should be made explicit in the standard as well.

Another commenter (Ex. 14–111) suggested that proposed paragraph (c)(10) require contractors to comply with all provisions of §1910.146 and that contractors be required to "... obtain all relevant information from the host employer regarding specific workplace hazards that could only be recognizable by the host employer." The commenter suggested that the host employer, in turn, be required to "provide the relevant information to the contractor."

Another rulemaking participant (Ex. 14–124) noted, however, the lack of information a host employer may have, as follows:

> ... OSHA should recognize that the owner/operator may not have expertise in confined space entry and may only be able to provide the contractor with a list of chemicals, their MSDSs and physical information on the confined space. The owner/operator may be hiring an experienced contractor to perform the work precisely because he recognizes that he does not have the expertise to perform the task safely. In such a situation, the owner could not be expected to advise the contractor.

This commenter recommended that OSHA revise proposed paragraph (c)(10) to require that contractors communicate and coordinate with host employers as necessary to comply with proposed paragraphs (c)(1) through (c)(9) and to provide that the host employer's failure to provide information requested by the contractor does not relieve the contractor from the requirement to comply with the standard.

OSHA has decided that the regulatory burdens placed upon host employers concerning permit space entry in paragraph (c)(8) of this final rule should also be placed upon contractors where applicable. Therefore, the Agency is including new paragraph (c)(9) in the final rule to address the duties of the contractor with respect to safe permit space entry operations. OSHA believes that these additional requirements will contribute significantly to the increased safety and health of host employer and contractor employees where such employees are involved in permit space entry operations.

Paragraph (c)(9)(i) of the final rule is the corollary of paragraph (c)(8)(ii) and requires that the contractor obtain any available information concerning permit space hazards and entry operations from the host employer. As noted earlier, this exchange of information should help the contractor to anticipate the permit space hazards that may be present during entry.

Numerous witnesses at the hearings commented about the host employer-to-contractor relationship. The opinion was virtually unanimous that coordination, including coordination of joint permit space entry operations between the two employers, was essential (Ex. 138; Washington Tr. 540; Houston Tr. 632, 724, 780; Chicago Tr. 302). These hearing participants argued that it is vital that each employer be aware of the other's tasks and work procedures.

Some who testified (Washington Tr. 418) felt strongly that contractors should be required to comply with the host employer's entry program, because they have observed cases where the contractor either had an inadequate program or no program at all. In their written comment (Ex. 14–188), the American Petroleum Institute (API) complained that proposed paragraph (c)(10) might be construed to prohibit a host employer from requiring a contractor to use the host's permit program. API recommended in its post-hearing comment (Ex. 113) that contractors, to minimize confusion and possible misunderstanding, adhere to the host employer's permit program when employees of each employer simultaneously conduct entry operations, stating:

> Often, contractors and the host employer's employees enter the same confined space to perform work activities. Confusion and misunderstanding could result if such a space is subject to two or more confined space programs. It is preferable in such a situation for a single confined space program to govern. Usually the host employer is in the best position to understand the hazards, and require a uniform plant-wide procedure for confined space entry.

Another commenter (Ex. 14–86) also expressed concern about situations in which both host employers and contractors have employees working in permit spaces. The commenter suggested that the standard allow contractors either to develop their own permit space programs or adopt the program used by the host employer. Additionally, this rulemaking

participant testified (Houston Tr. 781) that "[s]uch flexibility is needed to accommodate the wide variety of experience levels among contractors regarding confined space work and the wide variety of tasks required."

Some rulemaking participants (Ex. 14–131, 14–138, 117; Washington Tr. 359–360), representing companies who inspect boilers and pressure vessels, stated that proposed paragraph (c)(10) should require host employers to take all measures necessary to render permit spaces safe for entry and, where possible, "low-hazard" before having contractors enter those spaces. One witness stated (Washington Tr. 360), "Such a requirement would not put an additional burden on the host employer, while it would provide the most effective means of protecting the safety of our employees and those of other contractors or similar employers." The Factory Mutual Engineering Association, an organization whose employees are required to enter confined spaces owned and controlled by other employers, recommended in its post-hearing comment (Ex. 117) that host employers be given virtually all responsibility for testing and preparation of a permit space for entry by contractors, unless the host's employees never enter the permit spaces.

OSHA agrees with the testimony advocating coordination between the host employer and contractor and has included paragraphs (c)(8)(iv), (c)(9)(ii), and (d)(11) in the final rule to require such coordination. Paragraph (d)(requires employers to coordinate entry operations when employees of more than one employer are working simultaneously as authorized entrants in a permit space, so that employees of one employer do not endanger the employees of any other employer. This provision applies generally to all multi-employer permit space entry operations, so as to address the relevant hazards under the variety of conditions actually encountered. The hazards of multi-employer permit space entry operations exist whether or not one of the employers acts as a host employer.[16] Therefore, OSHA has adopted paragraph (d)(11) to cover coordination among all employers whose employees are present during entry operations. Paragraphs (c)(8)(iv) and (c)(9)(ii) direct the host employer and contractor, respectively, to the basic requirement for coordination of efforts to protect employees from permit space hazards. This coordination should include a determination of what permit program is to be used by the contractor. The final rule does not prohibit the host employer from requiring a contractor to use the host's permit program, nor does it require the contractor to use the host's program. The host employer may choose to condition its contract on the contractor's compliance with the host's program, as is often the case in the petrochemical industry.

While OSHA agrees that a specified division of responsibilities may be appropriate in some cases, it may not be so in others. The rulemaking record indicates that there is a wide range of circumstances in which contractor personnel enter permit spaces. There are circumstances in which contractors set up complete permit space programs at host employers' workplaces, and there are situations in which both contractor and host employer employees are working side-by-side in a permit space. For example, one commenter (Ex. 14–63) stated, "... the general industry employer often will leave to a contractor the job of cleaning, repairing and maintaining confined spaces, such as tanks, vaults and vessels."

Because of this, OSHA believes that flexibility is necessary and that the host and contractor should cooperate and should make arrangements to implement a permit program best suited to their particular situation. The final rule provides this flexibility.

Paragraph (c)(8)(v) of the final rule requires the host employer to debrief the contractor at the end of entry operations concerning any hazards confronted or created during entry operations. Paragraph (c)(9)(iii) of the final rule requires the contractor to inform the host employer of the permit program followed and of any hazards confronted or created in permit spaces. These provisions had no counterpart in the proposal.

During the hearings several witnesses were asked, because they had complained about poor contractor performance and lack of accountability, if they would favor a provision in the final rule requiring contractors to report back to the host employer concerning any problems encountered, and procedures used, during permit entry operations. Many witnesses (Washington Tr. 420; Houston Tr. 743–744; Chicago Tr. 158) agreed that such a provision would be desirable. For example, in its post-hearing comment (Ex. 119), Texaco stated:

> The contractor should be required to notify the host in case of a hazard development in order that steps may be taken for: protection of personnel, protection of personnel possibly in adjacent facilities, protection of equipment and adjacent equipment (that is, if a hazard develops, then not only could the contractor be affected, but the adjacent host's employees and equipment as well). The host must be informed in order to investigate and take corrective action if warranted.

The Agency agrees that the host employer needs to be informed of the permit space program the contractor is using. This information will enable the host employer to take steps to coordinate its efforts to protect employees from permit space hazards with the contractor. Additionally, it is necessary for the host employer to receive information on any hazards found or created within the space during entry operations in order to enable the host employer to deal with these hazards during the current entry and to take measures to control them in subsequent entries. Additionally, the host employer will have this information available to assist future contractors who may be called upon to perform permit space entry. OSHA has therefore added a provision, paragraph (c)(9)(iii), that requires contractors to inform host employers of the permit program followed and of any hazards confronted or created in the permit space during entry operations. To help ensure that such information is provided to the host employer, OSHA has included a requirement in the final rule, paragraph (c)(8)(v), that the host employer debrief the contractor at the conclusion of entry operations, seeking the same information that the contractor is required by paragraph (c)(9)(iii) to provide the host employer. This exchange of information is thus required by OSHA of both host employer and contractor.

Paragraph (d), Permit space entry program.

As noted previously, requirements proposed in paragraph (c) that related to the permit space program have been included in paragraph of the final rule. The Agency believes that separating general provisions from requirements pertaining only to the program will make the final standard more understandable. Accordingly, paragraph (d) sets forth requirements for the design and implementation of permit-required confined space programs. The Agency notes that, except insofar as paragraph (d)(2) allows employers to defer hazard evaluation until actual entry operations are planned, employers are expected to begin developing their permit space

[16] A manhole that is shared by two utility companies (gas and water, for example) is one case in which neither employer may be considered the host employer. If employees of both employers are present, but neither employer acts as the host, paragraph (d)(11) would still require coordination of permit space entry operations.

programs (such as arranging for designation and training of personnel to be involved in entry operations and for rescue and emergency services) when they identify permit spaces that are to be entered by their employees. The Agency observes that an employer who waits until the last minute before entry operations begin to develop an permit space program is unlikely to have properly trained and equipped personnel available. Paragraph (d) sets forth requirements for planning of entries, so that by the time entry begins all of the program elements are in place and entries are conducted safely.

The introductory text of paragraph (d) provides that, under the permit-required confined space program required by paragraph (c)(4) of final §1910.146, the employer must comply with all the rules given in the remaining paragraphs of paragraph (d). The introduction serves merely to introduce the list of duties of an employer under a permit space entry program.

Paragraph (d)(1) of the final rule requires the employer to implement measures necessary to prevent unauthorized entry. This provision corresponds to proposed paragraph (c)(5). As noted previously, OSHA believes that it is very important to prevent unauthorized access to permit spaces. The rulemaking record demonstrates that such entry is frequently fatal.

Some commenters (Ex. 14–124, 14–130, 14–163, 14–189) argued that proposed paragraph (c)(5) was unnecessary, because proposed paragraph (c)(4) covering the posting of warning signs provided sufficient protection.[17] For example, Amoco Corporation (Ex. 14–124) stated:

> We do not think that it is necessary to post signs *and* provide barriers in lieu of training to restrict unauthorized entry. The employer should have the option of using either signs or barriers depending on the conditions. Therefore, we suggest that the phrase, 'signs and barriers' should be replaced by 'signs or barriers.' [Emphasis supplied in original.]

Similarly, another commenter (Ex. 14–163) found the two proposed provisions redundant, as follows:

> I find paragraphs (c)(4) and (c)(5) to be redundant. Both of these issues could be dealt with in one paragraph. Perhaps, (c)(4) could read: "Information. shall post signs near permit spaces to notify employees what hazards may [be] present and that only authorized entrants may enter the permit spaces. Training and, as necessary, signs or barriers shall be used to prevent unauthorized entry into permit spaces."

Monsanto Company (Ex. 14–170), on the other hand, supported proposed paragraph (c)(5), stating:

> Again, an important element in a successful confined space entry program is training in the recognition of confined spaces and the potential hazards. As OSHA acknowledges in the next definition, (c)(5), training is an alternative to posting signs and barriers.
>
> Paragraph (c)(5)—Monsanto supports OSHA's proposal to use training or other forms of warning as equivalent means for preventing unauthorized entry into confined spaces.

Some commenters (Ex. 14–68, 14–173) felt that OSHA's proposal was too weak in this area. They felt that training and signs would not prevent employee entry into permit spaces. For example, the Quaker Oats Company (Ex. 14–173) argued:

> These sections address notification (with signs) to employees that hazards exist and that only authorized entrants may enter the permit space. Paragraph (c) (5) additionally requires training *or* signs and barriers as a means of preventing unauthorized entry. We feel that these paragraphs can be combined and strengthened.
>
> We recommend that all permit spaces be posted, notifying employees that hazards may be present and only authorized entrants enter. These signs would be appropriate postings during non-entry times and during the permitted entry. All employees should be instructed as to restricted areas, and confined spaces should be secured whenever feasible with positive barriers such as locks. [Emphasis was supplied in original.]

Another commenter (Ex. 14–68) also contended that the proposal would not provide effective protection, as follows:

> Training is *not* an effective means of preventing unauthorized entry nor is a posted sign. The use of the conjunction, 'or,' in the proposed standard leaves the employer a choice among providing a positive denial of entry provision such as a locked barrier, posting a warning sign or providing training. There should be no doubt that the first choice will usually be 'training,' such as, 'Don't go in there.' At most, a sign may be posted to supplement the instructions. These precautions are so inadequate as to be no precaution. [Emphasis was supplied in original.]

OSHA believes employees need to be informed of the hazards of permit spaces (paragraph (c)(2)) and need to be protected again the hazard of accidental entry into these spaces (paragraphs (c)(3) and (d)(1)). In the proposal, these two considerations were addressed in paragraph (c)(4), *Employee information*, and in paragraph (c)(5), *Prevention of unauthorized entry*, respectively, for employers whose employees would be entering permit spaces. In the final rule, these two considerations are addressed in paragraphs (c)(2) and (d)(1), respectively, for these same employers.

Normally, training and signs are methods of informing employees of the presence and hazards of permit spaces, and they do little to prevent unauthorized access. However, if the workplace is so configured as to prevent access of unauthorized entrants into areas containing permit spaces, training, alone or in combination with signs, may prevent the unauthorized access to the spaces. Otherwise, covers, guardrails, fences, or locks will be necessary. It is the employers responsibility to use whatever measures are necessary to prevent unauthorized entry.

Additionally, OSHA intends this provision to require the employer to take administrative measures to ensure that all entries into permit spaces are authorized entries. Unauthorized entrants are hazards to themselves and to other personnel, because they expose themselves to permit space hazards without the necessary equipment or training. Furthermore, they disrupt entry operations, jeopardizing the safety of personnel who are working in the space or who are sent in to rescue or remove them from the space. The Agency believes that many of the permit space accidents documented in the rulemaking record resulted from an overly casual attitude about the authorization of entry.

Paragraph (c)(5) of the proposal was designed to underscore the importance of allowing employees to enter permit spaces only after the employer has taken the measures necessary for safe entry. However, in view of the wide variety of possible permit spaces and assortment of protective techniques, the Agency is adopting a performance-oriented approach to this provision in the final rule. The examples given in proposed paragraph (c)(5) have not been carried forward, and paragraph (d)(1) in the final rule simply requires employers to take whatever steps are necessary to prevent unauthorized employee into permit spaces. This approach will provide the flexibility employers need to provide the most effective protection for their employees.

Paragraph (d)(2) of the final rule requires the employer to identify and evaluate the hazards of permit spaces that employees will enter before they actually do so.

This provision corresponds to paragraph (c)(1) of the proposal, which read as follows:

> [The employer shall i]dentify and evaluate each hazard of the permit spaces, including determination of severity;

[17] See the summary and explanation of final paragraph (c)(2) earlier for a discussion of the issues regarding informing employees about the presence and hazards of permit spaces.

Many commenters (Ex. 14–86, 14–88, 14–124, 14–143, 14–150, 14–177, 138) complained that the phrase "including determination of severity" was ambiguous and unneeded. In its comment, Organization Resources Counselors, Inc. (Ex. 14–143) stated:

> It is difficult to understand what OSHA intends that the employer do relative to making a "determination of severity". Neither the standard, nor the preamble, offer guidance on what this phrase means or what additional action or information should be secured by the employer under his permit required confined space program. The extensive definitions of hazardous atmosphere, IDLH, immediate-severe health effects, permit required confined space, low hazard permit space, etc., provide sufficient guidance in evaluating the hazards of a space without the need for this ambiguous phrase, therefore, we recommend that it be deleted.

Another commenter, API (Ex. 14–168), stated:

> API agrees in general with this item, but the requirement for 'including determination of severity' is undefined, impractical, and totally unnecessary, given the extensive definitions of hazardous atmosphere, IDLH, immediate severe health effects, permit required confined space, and low-hazard permit space. These definitions, woven into the employer's entry permit program, ensure adequate protection without the additional ambiguous burden of 'including determination of severity'. The preamble offers no guidance on interpreting this requirement. The phrase should be deleted.

OSHA agrees that the phrase is unnecessary and possibly confusing. Specifically, the Agency concurs with the Texas Chemical Council (Ex. 14–86), who stated:

> By definition a confined space entry has the potential for the most severe penalty—death. Therefore, to define determination of severity as death under hazard identification would not be productive nor necessary for industry.Therefore, the proposed phrase "including determination of severity" has not been carried forward into the final rule.

Some commenters (Ex. 14–94, 14–118, 14–157, 14–170, 14–176) expressed concern over when OSHA expected employers to identify and evaluate hazards to comply with proposed paragraph (c)(1). For example, The Department of the Navy (Ex. 14–91) stated:

> It is important to identify and evaluate the hazards of permit spaces, and this must be done prior to entry. Is the intent of this section to require an initial facilities inspection for permit spaces or to require inspection and evaluation as work occurs? If initial facilities inspections are required, how soon must they be completed?

CMA (Ex. 14–118) had a similar concern, saying:

> The Hazard Identification section, 29 C.F.R. 1910.146(c)(1), appears to require an initial grand survey of workplaces to identify confined spaces and an analysis of the severity of their hazards. CMA members believe very strongly that this approach is misguided and could contribute to the very hazard this standard is designed to reduce.
>
> OSHA's proposed approach would be reasonable in a static work environment. Today's business environment in the chemical industry and many others is a dynamic one. Manufacturing equipment and processes are designed to be flexible to adapt to rapidly changing product demands. Consequently, the confined space hazards in this dynamic environment are also in a state of flux. The most effective approach to hazard identification will take into account the dynamic nature of today's workplace.

Still another commenter (Ex. 14–176) agreed with this assessment, explaining:

> The potential hazard of each [permit space] will depend upon the last contents and this may change frequently in batch operations. The nature and severity of the potential hazard can only be determined just prior to actual entry into the confined space.

Paragraph (c)(1) of the NPRM would have applied only to employers whose employees would enter permit spaces. Those employers would have been the ones to develop and implement a permit program. Moreover, OSHA expected that the detailed hazard identification required by proposed paragraph (c)(1) need only be performed if actual entry into a permit space was contemplated. OSHA did not intend that the hazard identification required by proposed paragraph (c)(1) be performed as part of the initial determination of the presence or lack of permit spaces in the employer's workplace under the introductory text of proposed paragraph (c). (A discussion of the initial determination of whether or not the workplace contains permit spaces is contained under the discussion of final paragraph (c)(1) earlier in this section of the preamble).

The Agency notes that the identification of a permit space inherently involves the identification of a hazard (at least in broad terms). OSHA expects that the general information obtained through compliance with paragraph (c)(1) of final §1910.146 will facilitate compliance with paragraph (d)(2). Identification of the hazards (so that entry can be safely planned for and authorized) need only be undertaken before entry—when the entry permit is being prepared. In order to make this clear in the final rule, paragraph (d)(2) specifies that the hazards be identified before employees enter the permit space.

OSHA anticipates that employers will identify and evaluate permit space hazards as necessary for development of permit space programs. For example, the Agency expects that employers who conduct frequent entries into permit spaces will be identifying and evaluating permit space hazards at the same time they are identifying permit spaces. On the other hand, OSHA understands that employers may not need to identify or evaluate the hazards of permit spaces that are entered at 5- or 10-year intervals until several years after the identification of those spaces. In the interim, since there are no authorized entries into those spaces, the program would only require that unauthorized entries be prevented. The hazards in the spaces need only be evaluated in detail some time before entry (for example, when the entry permit is prepared). The final rule makes this clear—the basic identification of permit spaces required by paragraph (c)(1) of the final rule must be performed by the effective date of the final rule; the evaluation of the specific hazards posed by permit spaces identified under paragraph (d)(2) is required "before" entry.

Paragraph (d)(3) of the final rule requires the employer to establish the means, procedures, and practices necessary for safe permit space entry operations. This requirement has been taken from proposed paragraph (c)(2).

In reaction to the general nature of the language contained in proposed paragraph (c)(2), the State of Maryland Occupational Safety and Health Program (Ex. 14–63) stated "Although industries currently using permit entry may be familiar with these requirements, an employer to whom all of this is new will never know what to do without further guidance." They noted that, as indicated in the preamble to the NPRM (54 FR 24090), the identification of hazards does not protect affected employees during entry if the employer does not follow through with the necessary hazard controls. The State recommended that OSHA include a list of measures that would be required for hazard control.

The Agency agrees that the standard should provide some indication of the types of measures that employers will be required to take to control permit space hazards. Given the variety of permit space configurations and hazards, as well as the Agency's policy favoring performance-oriented standards, OSHA has added a list of control measures for use in permit space programs. The list, [18] which is not meant

[18] The list of control measures was taken from provisions in the final rule or the proposal, as identified in the brief discussion of each measure.

to be all inclusive, lists the common types of general control methods used to ensure safe permit space entry, as follows:

(1) *Specifying acceptable entry conditions.* This control measure ensures that the employer has identified the hazards that could reasonably be expected to be found in the space and has limited entry conditions to those that are safe for entry. For example, if a space could contain a flammable gas, the employer would set a limit of 10 percent of the LFL of the gas [19] as an entry condition. This would ensure that a flammable mixture is not present upon entry into the space. (See the summary and explanation of paragraph (f)(9), which requires the entry conditions to be specified on the entry permit, for a fuller discussion of acceptable entry conditions.)

(2) *Isolating the permit space.* The permit space must be isolated from serious hazards. For example, if energized parts of electric equipment are exposed, the circuit parts must be deenergized and locked out in accordance with §1910.333(b). Mechanical equipment posing a hazard within the space must be locked out or tagged in accordance with §1910.147 or guarded in accordance with Subpart O of the General Industry Standards. Chemical or gas lines that are open within the permit space must be isolated by such means as blanking or blinding, misaligning or removing section of lines, pipes, or ducts, or a double block and bleed system. (See the summary and explanation of paragraph (f)(8), which requires the isolation measures used to be specified on the entry permit, and the definition of "isolation" for a fuller discussion of isolation.)

(3) *Purging and ventilating the atmosphere of the space.* If the atmosphere of a permit space is IDLH, it must be made safe for employees to enter. This is accomplished by ventilating the atmosphere, after purging if the space is a flammable liquid container or if purging is otherwise necessary, before an employee enters the space. This cleans the air within the permit space so that it is no longer IDLH and, thus, safe for employees to breathe. (See the summary and explanation of paragraph (f)(8), which requires the hazard control measures, such as purging and ventilation of permit-required confined spaces, to be specified on the entry permit, for a fuller discussion of purging and ventilating permit spaces.)

(4) *Barriers.* Barriers must be provided around the permit space opening for two reasons: (1) to prevent unauthorized entry into the space [20] and (2) to protect employees inside the space from objects and persons outside the space. Paragraph (d)(3) requires barriers whenever they are necessary to protect employees within the permit space. If entrants face a substantial risk of injury due to unauthorized entry, due to objects falling into the space, or due to vehicular hazards during entry into and exit from the space, then barriers would be required. (See the discussion of proposed paragraph (c)(9), which would have required the use of barriers and which has not been carried forward into the final rule, later in this preamble.)

(5) *Testing and monitoring.* The employer must ensure that conditions in the permit space are acceptable for entry throughout the duration of entry operations. This is accomplished through the use of test instruments to monitor the atmosphere within the space, the use of ventilation to maintain a safe atmosphere, and the use of inspections to ensure that isolation is being maintained for the space. (See the summary and explanation of paragraphs (d)(5) and (f)(10), which relate to the testing and monitoring of permit-required confined spaces, for a fuller discussion of testing and monitoring conditions within these spaces.)

Paragraph (d)(4) of the final rule requires the employer to provide the equipment necessary for safe entry into and rescue from permit spaces at no cost to employees, to maintain that equipment properly, and to ensure its proper use by employees.

This provision has been taken from paragraph (c)(7) of the proposal, which read as follows:

> [The employer shall p]rovide, maintain and ensure the proper use of the equipment necessary for safe entry, including testing, monitoring, communication and personal protective equipment;

One commenter (Ex. 14–86) argued that the equipment listed in this proposed paragraph was not always necessary. The commenter recommended revising the rule to make this clear.

OSHA has adopted language in paragraph (d)(4) of the final rule that clarifies the intent of this provision. The rule now requires the employer to provide the equipment necessary for safe entry into and rescue from [21] permit spaces, as well as maintain it and ensure its safe use. The list of equipment contained in the proposal has been revised to indicate that these are among the types of equipment covered by the rule, with an indication of when each type of equipment would be necessary. Also, the equipment list has been expanded by adding ventilating, lighting, rescue, barriers, and ingress and egress equipment. These are the types of equipment normally expected to be used in permit entry operations.

In Issue 4 of the hearing notice (54 FR 41462), OSHA asked several questions concerning the accuracy of monitoring and testing devices, which might be affected by humidity or other factors. OSHA requested information on the reliability, or lack thereof, of test instruments under adverse conditions. OSHA also asked which types of devices cause the most problems, and which the least, as well as what the specific problems were and when they most often occur.

One commenter had expressed concern about the accuracy of test instruments prior to publication of the hearing notice (Ex. 14–70), but did not speak directly to the questions asked in Issue 4. Another commenter, the Johnson Wax Company (Ex.14–222), submitted a comment after the hearing notice had been published and which responded directly to Issue 4. Johnson Wax noted that the accuracy of oxygen meters was affected by altitude, in that the meters would give increasingly lower readings as the altitude increased. They also noted that oxygen meters must be allowed to "acclimate" in very cold or very humid situations.

Johnson Wax also stated that combustible gas meters had the same problems as oxygen meters, with the additional problem of degradation in the presence of chlorinated solvent or silicon fluid vapors. Lastly, Johnson Wax emphasized the importance of calibrating combustible gas meters using the gas expected to be present in the confined space. According to the commenter, calibration with a gas not encountered would result in an inaccurate reading.

In the Washington, D.C. public hearing, Mr Robert Gilardi of the

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For a discussion of the comments on the individual control methods, see the summary and explanation of the relevant paragraph later in this preamble.

[19] See the definition of hazardous atmosphere for the source of the 10 percent limit.

[20] Barriers for this purpose are not addressed by paragraph (d)(3), which treats entrant safety; they are addressed by paragraph (d)(1), which treats safety for unauthorized employees.

[21] Rescue equipment is mentioned in final §1910.146, though it was not in proposed paragraph (c)(7). In the proposal, this equipment was specifically addressed under paragraph (c)(8). The Agency decided that it would be clearer if all equipment associated with entry operations was addressed in a single provision. The remainder of proposed paragraph (c)(8), on rescue procedures, has been retained in paragraph (d)(9) of the final rule.

Compressed Gas Association (CGA, Washington Tr. 456) gave his opinion of the accuracy of testing and monitoring devices used by CGA:

> We feel that the accuracy of the instruments is very adequate and, in addition, they're calibrated before they're used. For example, without mentioning commercial names, there are small oxygen analyzers that are used by the commercial diving industry that are very accurate and they're a fairly low cost item.

The National Institute for Occupational Safety and Health (NIOSH) submitted a very helpful and detailed discussion of hearing Issue 4 in its post-hearing comment (Ex. 134). NIOSH discussed the effects of high relative humidity, altitude, and ambient temperatures on oxygen monitors, concluding that such monitors are significantly affected by high humidity only at levels exceeding 90% relative humidity, that most oxygen monitors automatically compensate for changes in temperature,[22] and that the effect of atmospheric pressure changes on oxygen monitors can be significant if they are not calibrated at the ambient pressure in which they will be operated.

NIOSH also tested combustible gas meters, concluding that the variations found were within acceptable limits. NIOSH did not test combustible gas meters for accuracy in varying pressure and temperature environments, but stated that such meters should not be significantly affected by these changes.

Regarding the use of specific material monitors (such as those for CO, CO_2, SO_2, and H_2O), NIOSH recommended adherence to manufacturer's instructions concerning temperature limits, relative humidity ranges, and any known chemical interferences. The NIOSH comment also contained information and recommendations concerning non-specific monitors.

NIOSH concluded its comment with recommendations concerning the care of batteries used in monitors and a strong emphasis on the proper calibration and maintenance of monitoring equipment. NIOSH also concluded that operator training and skill levels are very important factors to be considered in the monitoring of workplace atmospheres, to the extent that such monitoring cannot be effectively accomplished without a trained and skilled operator.

OSHA has concluded, based upon the information received in response to the questions asked in hearing Issue 4, that the accuracy of testing and monitoring equipment may be significantly affected under certain conditions of humidity, pressure, or temperature or by the presence of interfering chemicals. However, if the equipment is properly selected, calibrated, and maintained and if it is operated by well trained employees, the testing and monitoring needs for entry and work in permit-required confined spaces can be effectively met.

Paragraph (d)(5) of the final rule requires employers to evaluate permit space conditions when conducting entry operations. This paragraph also sets forth specific requirements for testing conditions within the space to ensure that hazards inside the space are eliminated or controlled. This entire paragraph is new, except for paragraph (d)(5)(iii), which pertains to the proper sequence for testing for atmospheric hazards and which was taken from proposed paragraph (i)(1)(ii).

The State of Maryland (Ex. 14–63) criticized proposed paragraph (c), covering the permit-required confined space program, in the following manner:

> It does not appear to require that any protective action be taken! All the employer would have to do is have a permit that covered these things.... For example, without the implementing language, for item (c)(1) all the employer would have to do is make a list. They went on to state:
>
> Actually the low hazard permit space requirements are more clearly spelled out in section (i) than high hazard requirements are in (c) (2).
>
> (c)(2) could benefit from the testing language in [(i)](1)(ii).

Several commenters (Ex. 14–68, 14–116, 14–147) stressed the importance of testing in the determination of acceptable entry conditions within a permit space before entry and during work inside the space. For example, one rulemaking participant (Ex. 14–147) stated:

> Prior to entry, atmospheric testing would have to be performed to ensure that the conditions under which the permit was originally issued had not changed. This is an essential requirement of ensuring that the confined workspace is safe to enter.

Several more commenters (Ex. 14–63, 14–123, 14–154) specifically recommended placing requirements relating to testing in the general paragraph (proposed paragraph (c)). Typical of these, Boeing Support Services (Ex. 14–154) stated:

> Specific references to instruments for testing procedures and to testing and ventilation requirements are stated only in the low-hazard portion. These references need to be given in the main text as well, which has only nonspecific references...

The proposed rule required evaluation of permit space conditions in an indirect way (as, for example, in proposed paragraph (d)(2)(v), which provided that the entry permit specify the testing and monitoring procedures to be used); but, as Maryland has stated, the proposal never specifically and directly required testing. OSHA agrees with the State's and other's criticisms in this regard and has included paragraph (d)(5) in the final rule to address this concern. Paragraph (d)(5) contains language that clearly requires the employer to evaluate permit space conditions before and during entry operations and that sets forth the elements of that evaluation.

Paragraph (d)(5)(i) of the final rule requires the employer to test conditions in the permit space to determine if acceptable entry conditions exist before entry is authorized to begin. As previously noted this testing is important to detect any hazardous atmosphere or other hazards that may be present in the permit space. However, if isolation of the space is infeasible because the space is large or is part of a continuous system, the employer must perform pre-entry testing to the extent feasible before authorizing entry and, if entry is authorized, must continuously monitor entry conditions in the areas where authorized entrants are working.

The type of testing that needs to be performed is dependent on the hazards that are present within the space. For permit spaces posing atmospheric hazards, atmospheric testing would be necessary. For other hazards, different tests will be necessary. For example, if the permit space poses thermal hazards, the temperature within the space would need to be tested. Paragraph (d)(5)(i) requires the employer to conduct whatever tests are necessary to ensure that acceptable entry conditions are present.

Because sewers and similar permit spaces are large, continuous systems, conditions encountered at the point of entry may not be indicative of conditions at distances further from the point of entry. Also, since the space usually cannot be effectively isolated, conditions at any particular point in the space may deteriorate suddenly due to the introduction of a material from another point in the system that creates a hazardous environment for the entrants. Under these conditions, pre-entry testing often will not detect such hazards, and the need for continuous atmospheric monitoring becomes paramount. Atmospheric monitoring is necessitated virtually from the time pre-entry testing is done until the last entrant leaves the permit space. Because of these conditions, the procedure for authorizing entry into sewers has

[22] For best results, NIOSH recommends calibration of oxygen monitors at the temperature at which it is to be operated.

evolved so that authorization is usually granted immediately before entry. In their testimony, the Service Employees Union indicated that their members who work in sewers do perform pre-entry testing, usually with a 12 to 18 inch or longer wand attached to the test instrument (Washington Tr. 403, 404). They also indicated that entrants wear monitoring equipment at all times (Washington Tr. 434) after they have entered and as they perform entry operations within the permit space.

Paragraph (d)(5)(ii) of the final rule requires permit spaces to be tested or monitored, as necessary, to determine if acceptable entry conditions are being maintained during the course of entry operations. This provision is derived from paragraph (d)(2)(v) of the proposed rule, which would have required that the procedures and equipment necessary for such testing or monitoring be placed on the permit. Such testing or monitoring would thus have been required by the proposal, but only in an indirect way. (See the preceding discussion of final paragraph (d).) To eliminate any possible doubt or confusion regarding this matter, appropriate testing or monitoring during the course of entry operations is specifically required by this final rule. This provision requires whatever periodic or continuous monitoring would be necessary to protect employees. For example, as noted earlier, sewer entry operations preclude complete pre-entry testing, and continuous monitoring is necessary to assure the safety of sewer workers. Paragraph (d)(5)(ii) of the final rule would require this continuous monitoring to be performed.

Paragraph (d)(5)(iii) of the final rule specifies the proper sequence to be used when permit spaces are tested for atmospheric hazards. This provision requires employers to test first for oxygen, then for combustible gases and vapors, and then for toxic gases and vapors.

This requirement has been taken from paragraph (i)(1)(ii) of the proposal. Proposed paragraph (i) only applied to entry into "low hazard" permit spaces. However, since the proper sequence for testing for atmospheric hazards should be the same regardless of the characterization of the permit space, this provision should be applied equally to all permit entries. By placing this provision in paragraph (d) of final §1910.146, which applies generally, the proper sequence of testing for atmospheric hazards is assured for all types of permit-required confined spaces. Paragraph (d)(5)(iii) reflects generally accepted safe work practice, as adopted in Section 6.1 of ANSI Z117.1 (Ex. 14–4, 14–127). As noted earlier, its general application was recommended by several commenters (Ex. 14–63, 14–123, 14–154).

A test for oxygen must be performed first because most combustible gas meters are oxygen dependent and will not provide reliable readings in an oxygen deficient atmosphere. In fact, the Johnson Wax Company (Ex. 14–222) stated that "there is [a] specific (sensor dependent) oxygen level below which the combustible gas sensor will *not* respond at all [emphasis was supplied in original]." Combustible gases are tested for next because the threat of fire or explosion is both more immediate and more life threatening, in most cases, than exposure to toxic gases.

Additionally, this provision contains a note indicating that atmospheric monitoring in accordance with non-mandatory Appendix B, supplemented by reference to non-mandatory Appendix E for permit space operations in sewers would be considered as satisfying the requirements of this paragraph. OSHA has included these non-mandatory appendices for use by any employers who might not have the resources to design their own atmospheric monitoring programs. The presence of these appendices in the final rule is not intended to restrict an employer's ability to design and implement an atmospheric monitoring program that meets the needs of a particular workplace.

Paragraph (d)(6) of the final rule requires an attendant to be stationed outside a permit space into which entry is authorized for the duration of entry operations. This paragraph has been taken from the introductory text of paragraph (f) of the proposal. OSHA has included a note in the final rule to explain that attendants may be assigned to monitor more than one space and that they may be stationed at any location outside the permit space, as long as they can effectively perform the duties set by paragraph (i) of final §1910.146.

The Agency has determined, based on its review of the rulemaking record, that stationing an attendant to monitor permit space entry is a critical element of an effective permit space program. In particular, OSHA believes that an attendant's ability to communicate with the authorized entrants and with the designated rescue and emergency services maximizes the likelihood that information on hazards arising in permit spaces will be transmitted in time for safe evacuation or rescue of entrants. Because of the importance of the role attendants play in permit space entry operations, OSHA believes that it is necessary to highlight the requirement for their presence outside permit spaces. Therefore, the Agency has placed this requirement in final §1910.146(d), which contains the basic rules on permit- required confined space programs, rather than in §1910.146(i), relating to the duties of attendants. OSHA believes that this stresses the importance of this requirement and that, as a result, employers will be more aware of the need to station attendants outside permit spaces during entry operations.

As noted in the summary and explanation of the definition of "attendant", the proposed definition of this term addressed the number of spaces or entrants an attendant could monitor, providing that an attendant could not monitor more spaces or entrants than specifically authorized by the entry permit. A number of commenters (Ex. 14–28, 14–45) objected to the proposed provision and suggested that OSHA allow the attendant to monitor only one permit space at a time. As a result of these early comments, the Agency listed their concerns as one of the issues in the notice of public hearing (54 FR 41462). In Issue 8 of the hearing notice, OSHA asked if the final rule should limit the number of entrants, entry portals, or permit spaces an employer may assign a single attendant to monitor. OSHA also asked what limits would be appropriate, what criteria should be used by employers in deciding on the number of attendants, and where, in relation to the entry portal, attendants should be stationed.

Several rulemaking participants (Ex. 14–179, 14–200, 14–208, 14–210, 14–215, 142; Washington Tr. 466, 551, 575; Houston Tr. 1057; Chicago Tr. 185, 245, 311, 364, 498, 534, 597, 615) addressed this issue. Some of the rulemaking participants (Ex. 14–210; Washington Tr. 575–576; Chicago Tr. 185–186, 310–311; Houston Tr. 1057) believed that attendants should not be allowed to monitor more than one permit space at a time because if an emergency developed in one space the attendant's attention would be fully taken for that space and the attendant would not be able to monitor other spaces adequately. For example, the Independent Liquid Terminals Association (ILTA, Ex. 14–210) said:

> ILTA still maintains that an attendant must be allowed to monitor only a single entry portal at one time.... How can an attendant monitor an entrant in more than one place? If the entrant's breathing apparatus breaks in any way while the attendant is at another location, how can the attendant respond to the entrant's predicament? In addition, how can the attendant protect the entrant from

external hazards or unauthorized entry if he/she is not present?

Others opposed to the language in the proposed definition (Ex. 14–38, 14–61, 14–63; Chicago Tr. 363) were more concerned that the attendant would be allowed, under a series of permits issued by an employer, to monitor more spaces than he or she can effectively handle. They argued that the standard should limit in some fashion the number of spaces that an attendant would be allowed to monitor. For example, the UAW (Ex. 14–38) stated:

> The statement that the "attendant may monitor not more entrants or more permit spaces than the entry permit specifically authorizes is vague.
>
> This definition could allow an attendant to monitor more spaces than should be safely monitored.

Still others (Ex. 14–200; Washington Tr. 466, 551–552; Chicago Tr. 534) were concerned that the standard retain its flexibility by not specifying a limit on the number of spaces that could be monitored by a single attendant. The Longview Fibre Company's comment (Ex. 14–200) was illustrative of these commenters, as follows:

> If the attendant's responsibility is only to monitor the entry work, and summon a rescue team, but not participate in actual entry for rescue purposes, the attendant should be allowed to monitor as many entries or entry points as is practical based on the work environment, work being performed and method of monitoring, i.e. radio, T.V. camera, handline or voice.
>
> * * * * *
>
> An example of monitoring various points of entry into a confined space would be a power or recovery boiler fire box, a continuous cooking pulp digester or paper machine dryer drums. Although the equipment may be entered simultaneously by various employees from different entry points, the monitoring of any of the crew members may be successfully accomplished by a single attendant. The rescue may be achieved from a common entry point, radio communications may allow for multiple monitoring, and the size of the vessels or confined spaces and/or scope of work may allow for visual monitoring of more than one entry at a time.

In response to the NPRM, another commenter (Ex. 14–34) suggested that OSHA specifically recognize the use of radios so that a single attendant could monitor as many as 32 entrants. Acknowledging the possibility that electronic surveillance and communication equipment could assist attendant in carrying out their duties and might allow the safe monitoring of multiple permit space entry operation by a single attendant, OSHA raised Issue 9, which related to the use of such equipment. In the hearing notice (54 FR 41463), OSHA observed that, if attendants were not permitted to enter permit spaces for rescue purposes, an attendant's chief responsibility with respect to rescue could be to summon the rescue team. In that case, the Agency recognized that the attendant's ability to detect that entrants need help and to summon the rescue team, not the attendant's proximity to the entrants, could be of critical importance. Therefore, OSHA requested information on the issue of whether or not the Agency should permit reliance on electronic surveillance and communication equipment and on how the permit-required confined space standard should treat this equipment.

OSHA received few comments and little testimony concerning this issue. The Longview Fibre Company (Ex. 14–200) had this to say about Issue 9:

> In many confined space entries actual visual contact is not possible due to the size of the particular vessel or complexity of the structure. In such cases, alternate means of communications such as radios may be the only workable alternative.

The Independent Liquid Terminals Association (Ex. 14–210) had this opinion:

> Remote radios would be useful in conjunction with visual observation of the entrant especially in extremely large or dark confined spaces. However, the radios under no circumstances should replace the attendant. Working inside a confined space often requires cumbersome personal protective equipment or other mechanical equipment. Handling a remote radio while wearing industrial rubber gloves would be difficult.

The Amoco Corporation (Ex. 14–215) also believed that electronic monitoring equipment should be permitted, stating:

> We do not believe that the entrant needs to be in direct line of sight of the attendant for effective monitoring.... In such circumstances [line of sight not possible], we use two-way radios to keep the entrants in contact with the attendants and have found this to be an effective monitoring system.... Different types of monitoring equipment will be suitable for monitoring different numbers of entrants safely. Setting an arbitrary upper limit based on the most sophisticated equipment will not be suitable for less sophisticated technologies. Likewise, setting a limit based on a less sophisticated technology will cause underutilization of more advanced technologies. Rather than set an arbitrary upper limit, we believe that the limit should be determined by the capabilities and limitations of the monitoring equipment used as well as other pertinent factors at the site. Therefore, we support a performance oriented approach with the employer making the determination of how many entrants can be safely monitored by an attendant.

In light of the comments and testimony received concerning these two issues, OSHA has decided to expand on the performance- oriented approach taken in the proposal. The final rule has adopted a rule in paragraph (d)(6), under the general provisions for permit-required confined space programs, that requires the employer to provide at least one attendant outside the permit space into which entry is authorized. As noted earlier, this requirement has been taken from the introductory text of proposed paragraph (f). To address the issue of how many spaces an attendant is allowed to monitor, OSHA is including an explanatory note following paragraph (d)(6) to indicate that an attendant can monitor as many spaces as is possible while complying with paragraph (i) of the final rule, which sets forth attendants' duties. The note also indicates that the attendant may be stationed in any position from which he or she can perform the duties required by paragraph (i).[23] The Agency notes that the attendant could be stationed in a control room that allows him or her to monitor entrants remotely. Electronic monitors, television monitors, public address systems, and barricades could be used to assist the attendant in performing duties required under paragraph (i). In addition, OSHA has adopted a provision requiring employers to adopt procedures to enable the attendant respond to emergencies without distraction from his or her responsibilities under paragraph (i). This provision appears in paragraph (d)(7 of the final rule.

In this manner, attendants may monitor no more permit space entry operations than they can safely handle. For example, if the attendant is communicating with authorized entrants by voice contact only, that attendant would not be able to monitor any other permit spaces that were not within voice contact, under paragraph (i)(5). Also, if the number of spaces and the number of authorized entrants are too much for one attendant to keep track of, as required by paragraph (i)(3), then additional attendants would be required. This protects authorized entrants from working in permit spaces that are not being adequately monitored.

On the other hand, this approach also provides the flexibility employers need to protect employees in a manner best suited to their permit space operations.

[23] These duties include keeping an accurate count of authorized entrants, communicating with these entrants, monitoring activities inside and outside the space for hazards, summoning rescue services, and keeping unauthorized persons out of the space.

The final rule allows the use of electronic surveillance and other devices as aids or augmentations to the monitoring process so that the attendant's duties described in paragraph (i) of the final rule can be effectively performed for each permit space being monitored. In most cases, the use of such a device would allow an employer to economize by increasing the number of permit spaces a single attendant could effectively and simultaneously monitor (although OSHA is not permitting the use of such devices to replace an attendant entirely). Additionally, the attendant would normally be stationed near the entry point of the permit space, but the use of an electronic monitoring device makes it possible for an attendant to effectively perform his assigned duties from a remote location. Television monitors, public address systems, and barricades can also be used to assist the attendant in monitoring activities outside the space and in warning unauthorized personnel away from the space.

Paragraph (d)(8) of the final rule requires the employer to designate the persons who are to have active roles in entry operations, to identify the duties of these employees, and to provide such employees with the training required by paragraph (g). This provision addresses such personnel as entry supervisors, authorized entrants, and attendants.

Paragraph (d)(8) in the final rule has been taken from proposed paragraph (c)(6), which would have required the employer to train entrants, attendants, and entry supervisors. Two commenters (Ex. 14–88, 14–163) argued that proposed (c)(6), in conjunction with proposed paragraphs (e) , (f), and (g), were too general in nature. These commenters believed that the regulation should be more specific as to the content of training, the evaluation of the training received, follow up training, and the qualifications of the trainers.

OSHA agrees with these commenters that the training provisions contained in the proposal were too general. Follow up training was not addressed in proposed paragraphs (c)(6), (e), (f), or (g), and the proposal was too vague in certain areas. To address these problems, the Agency has incorporated into the final rule a paragraph dedicated to training requirements—paragraph (g). All the specific training requirements spread throughout the proposed standard have been placed in this one paragraph to provide better guidance as to what is required and to emphasize the importance of training in the permit-required confined space program. (See the summary and explanation of paragraph (g) of the final rule for a detailed discussion of issues related to training.) OSHA has also revised the language proposed in paragraph (c)(6) so that the general program requirement for training to be provided references the specific training provisions in paragraph (g) of the final rule. Paragraph (d)(8) of the final rule also requires the employer to designate which employees will perform the various functions assigned by the standard and to identify their duties under the permit space program. This will enable employers, employees, and OSHA to identify which employees need to receive what training under final §1910.146.

Paragraph (d)(9) of the final rule requires the employer to establish procedures for summoning rescue and emergency services (to rescue entrants from permit spaces and to provide necessary emergency services to rescued employees) and for preventing unauthorized personnel from attempting a rescue. The Agency anticipates that employers will choose between entry and non- entry rescue as part of compliance with paragraph (d)(9) of the final rule.

This provision was taken from proposed paragraph (c)(8), which would have required that procedures and equipment necessary to rescue entrants be provided and implemented. For the reasons noted under the discussion of paragraph (d)(4) of final §1910.146, the Agency has placed the requirements relating to rescue equipment proposed in paragraph (c)(8) under final §1910.146(d)(4), which sets forth requirements relating to all types of equipment used in permit space entry operations. Additionally, although the Agency received no comments recommending the revision of the proposed language, OSHA has adopted wording for this requirement that is different from that in proposed paragraph (c)(8). The final rule clarifies that rescue procedures include procedures both for summoning rescue and emergency services and for preventing unauthorized rescue (that is, rescue by employees who are prohibited by the standard from performing this function).

Paragraph (d)(10) of the final rule requires the employer to establish a system for the preparation, issuance, use, and cancellation of entry permits as required by the standard.

This provision was taken from proposed paragraph (c)(3), on which no substantive comments were received. This requirement in the final rule is essentially the same as proposed paragraph (c)(3), except that "cancellation" has been added as a part of the system of permit use. Cancellation of a permit is required by various provisions in the final standard and is part of the permit's proper use. For further clarification, the language in the final rule replaces the proposed word "proper" (which was ambiguous) with the phrase "as required by this section". The "proper" preparation, issuance, use, and cancellation of permits is spelled out in paragraphs (e), (f), and (j) of final §1910.146.

Paragraph (d)(11) of the final rule requires employers to coordinate entry operations when employees of more than one employer are working simultaneously as authorized entrants in a permit space, so that employees of one employer do not endanger the employees of any other employer. The summary and explanation of this requirement can be found under the discussion of paragraphs (c)(8)(iv) and (c)(9)(ii), addressing the issue of coordination of efforts to protect employees during multi- employer permit space entry operations.

Paragraph (d)(12) of the final rule requires employers to establish the necessary procedures for concluding the entry once entry operations have been completed.

This provision was taken from proposed paragraph (d)(6), which would have required the individual authorizing the entry to cancel the permit after completion of work and after the exit of all entrants, and from proposed paragraph (g)(1)(v), which would have required the person authorizing the entry to take measures necessary for concluding the entry. Although the comments received on the proposal contain no specific recommendations for placing the two proposed provisions among the general requirements, the final rule reflects the Agency's determination that employers need to conduct their entry operations in a carefully planned and systematic fashion from start to finish, so that authorized entrants and other employees affected by entry operations are protected from permit space hazards. In particular, the cancellation of the permit would alert the employer to take the appropriate measures for the shut down of the space, the closing of the entry portal, and the return of the space to normal operating conditions. Without these procedures, employees would be exposed to such hazards as being locked inside the space, accidentally entering the space, and possible fire or explosion when the space is returned to its normal operating mode. OSHA has placed the proposed requirements among the general requirements applying to the overall permit space program in order to alert

employers to the need for planning these procedures before entry into the space.

Final paragraph (d)(12) is effectively identical to proposed paragraphs (d)(6) and (g)(1)(v). Proposed paragraph (d)(6) would have required the cancellation of the permit after entry operations were completed. Proposed paragraph (g)(1)(v) would have required the person in charge of the entry to take measures (such as closing off the permit space and canceling the permit) necessary for concluding the entry once the work authorized by the permit was completed. The requirement proposed by paragraphs (d)(6) and (g)(1)(v) that the entry supervisor actually cancel the permit and execute the shutdown procedures has been retained in the final rule as paragraphs (e)(5) and (j)(3), and the concerns raised by commenters in regards to the two proposed provisions are addressed under the discussion of paragraph (e)(5) of the final standard. Paragraph of final §1910.146 is couched in performance-oriented terms, because the Agency recognizes that the measures needed for compliance with final paragraph (d)(12) will vary from workplace to workplace. The Agency believes that combining and redesignating the language from the two proposed provisions into paragraph (d)(12) of the final rule will clearly indicate the importance of an orderly transition between periods when entry is authorized and periods when entry is not authorized.

While the preamble to the proposed rule (54 FR 24091, 24092) indicated that OSHA expected employers to review and revise their permit space programs in light of entry experience, the proposal did not specifically require such review. In Issue 6 of the notice of public hearing (54 FR 41462), OSHA raised a series of questions related to the issue of whether or not the rule should explicitly specify review of permit entry programs. The Agency was interested in gathering information on what conditions necessitated review, on the needed frequency of review, and on appropriate administrative measures for implementing the evaluation of programs.

Witnesses at the hearings and commenters who addressed this issue generally agreed that some form of review process was a part of successful permit entry programs (Ex. 14–184, 14–210, 109, 129; Washington Tr. 85, 466–467; Chicago Tr. 128–129, 166–167, 495, 523, 533, 614; Houston Tr. 1093). Most agreed that any requirement OSHA set for such a review should be performance oriented and should allow the employer the flexibility to review the permit space program as conditions at the workplace warrant. For example, the Independent Liquid Terminals Association (Ex. 14–210) stated:

> Permit programs should be reviewed on a site-by-site basis. The criteria for designating the review period should be the frequency with which personnel enter confined spaces. Facilities in which personnel routinely enter confined spaces should review their program annually, incorporating any newly identified hazards or procedures.

Similarly, Mr. Jack Dobson, representing the American Society of Safety Engineers, testified (Chicago Tr. 614) supported the ANSI Z117.1 performance-oriented approach, as follows:

> Issue No. 6. The ANSI Standard Z117 appropriately addresses the review process regarding confined space entry programs. Conformity to Sections 3.3 regarding hazard evaluation, 3.5 hazard reevaluation, and 15.5 regarding verification of training would greatly enhance the continuity of a confined space safety program.
>
> We do agree that the review process is an essential element of any safety and health program, however, we feel that any language relative to such a review should be performance oriented, thus allowing employers to develop a review system which would be consistent with their particular operation.

The Agency believes that employers have an ongoing responsibility to reevaluate their permit space programs periodically and to revise their programs based on changes in permit space hazards and on the employer's experience with their entry operations. In regard to periodic evaluation of permit space hazards, ANSI Z117.1–1989 (Ex. 129) Section 3.5 states:

> A qualified person(s) shall determine the need for periodic identification and re-evaluation of the hazards based on possible changes in activities in the space, or other physical or environmental conditions, or both, which could adversely affect the space. When need is determined, a qualified person(s) shall conduct the identification and re-evaluation process.

This language indicates that review and revision of permit space programs[24] are generally accepted practices to ensure the efficacy of these programs. OSHA has determined that, while many employers already review and revise their permit space programs, it is appropriate to require all employers to undertake such a review.

In response to the questions OSHA raised on the appropriate frequency of program evaluation, three rulemaking participants, the Independent Liquid Terminals Association (Ex. 14–184, 14–210), Midwest Consortium for Hazardous Waste Worker Training the (Ex. 109), and the National Safety Council (Ex. 129; Chicago Tr. 495), supported an annual evaluation. The Midwest Consortium for Hazardous Waste Worker Training supported their recommendation as follows:

> Annual evaluation should include evaluation of the total program as well as the identified confined spaces to assure that the program is being implemented fully. The requirements of the program specified in (c)(1—10) need to be reviewed. Monitoring the space is just one component of the evaluation. Changes in company policy, federal, state and local regulations, conditions and processes in the plant or advances in the field may impact this review. Prudent industrial hygiene practice generally includes annual review of standard operating procedures in order to provide adequate protection of employee safety and health.

Others argued, however, that periodic review should not be specified by the OSHA standard (Washington Tr. 466–467; Chicago Tr. 166–167). For example, the American Gas Association (AGA, Washington Tr. 466–467) stated:

> For the same reason, prescribing the type and extent of training, experience or qualifications of individuals who would evaluate spaces is extremely problematic and is better left to individual employers who are better suited to make that determination. We also agree with OSHA's statement in the preamble not to establish program review criteria when OSHA said it believes compliance with the proposed rule will necessitate on-going evaluation of program effectiveness. That statement reflects exactly what performance based language is all about and AGA support[s] such performance language.

OSHA believes that review of the permit space program by the employer is an important element of a successful confined space program. The record contains ample evidence of this: every employer representative questioned about program review responded that periodic review was conducted, normally every year. The question is how should the final rule address this matter. The Agency has concluded that a two-pronged approach is needed.

First, the employer should be required to review the permit space program any time conditions at the workplace indicate that the existing procedures provide inadequate protection. Several commenters and witnesses mentioned "near misses" as being indications of possible problems (Ex. 101; Chicago Tr. 166–167; Houston Tr. 1093). Other

[24] Although this ANSI requirement applies specifically to reevaluation of hazards for a particular permit space entry, OSHA views this section in the broader sense as compelling a reevaluation of the entire permit space program in order to meet the provision. Such an interpretation provides the best possible protection for employees.

conditions warranting review of an permit space program include: the detection of a hazard not addressed by the entry permit, the detection of a condition forbidden by the entry permit, a change in the use or configuration of the confined space, and employees complaints about the effectiveness of the program. This type of review will ensure that the program is updated as needed for continued employee protection.

Second, the employer should be required to review the permit program within one year from entry. This would result in an annual review for employers whose have at least one permit space entered each year. As noted in the post-hearing comment of the Midwest Consortium for Hazardous Waste Worker Training (Ex. 109), such factors as changes in company policy, new or revised governmental regulation, and changes in technology and design make a periodic review desirable, even in the absence of problems in actual entry. Additionally, annual review was common among employers who testified about periodic program evaluation. The Agency believes that an annual review can promote necessary changes to the permit space program before an employee is actually injured. An evaluation of the program each year will also force employers, who may become complacent about the hazards of confined space entry at their workplaces, into serious consideration of whether their permit space program are truly effective. Obviously, if no permit spaces were entered during the year, there would be no cancelled permits to review, and no review would be required in that year.

The review process is covered under final paragraphs (d)(13) and (d)(14), which had no counterparts in the proposal. Under paragraph (d)(13), the employer is required to review entry operations when the employer has reason to believe that the measures taken under the permit program may not protect employees. The employer must then revise the program, responding to problems brought out by the review, before any subsequent entry is authorized. Paragraph (d)(14) requires an employer to conduct a review of the permit space program, using canceled permit retained as required under paragraph (e)(6), within one year after each entry. An annual review process could be used to meet this provision; however, if permit spaces were entered less frequently than once per year, no review would be required until one year after an entry. Again, any inadequacies would have to be corrected. Both paragraphs include notes containing information to assist employers in complying with the requirements. OSHA believes that these provisions are reasonably necessary to protect employees who enter permit entry spaces, in order to assure that the permit program reflects the conditions currently encountered in the workplace.

Paragraph (e), Permit System.

Paragraph (e) specifies the elements of the permit system required by paragraph (d)(10) of the final rule. The single most important feature of the permit system is the creation and use of an entry permit. An employer uses the permit to authorize employees to enter permit spaces and to document the measures taken to protect authorized entrants from permit space hazards. (Requirements pertaining to the contents of an entry permit are set out in paragraph (f) of the final rule.)

OSHA has determined that the preparation of a permit will help the employer determine if conditions in a permit space are safe for employee entry. A permit will also provide a concise summary of the entry procedure that will be useful to the personnel who are conducting the entry operations and to any personnel who need to review the conduct of entry operations after entry has been completed.

The permit system set forth in paragraph (e) of the final rule also requires the involvement of a person (the entry supervisor) who authorizes the entry and has responsibility for entry operations. This involvement will ensure that a person with the qualifications to identify permit space hazards and the authority to order corrective measures for their control will oversee entry operations. It will also compel employers to take direct responsibility for the safety of employees working in permit- required confined spaces.

Proposed paragraph (d) contained requirements on permit systems and on the permit itself (although the title of this paragraph was *Permit system*). In the final rule, OSHA has separated the requirements into two distinct paragraphs—paragraph (e), *Permit system*, and paragraph (f), *Entry permit*. As discussed in Section I, *Background*, and in Section II, *Hazards*, earlier in this preamble, numerous injuries and fatalities have occurred because employers did not take the proper precautions for the safety of employees working in permit spaces. All too often, employers either did not recognize permit space hazards or they failed to follow through with the necessary measures for employee protection. The Agency has determined that employers who require their employees to enter permit spaces must systematically implement permit space programs to prevent injuries and fatalities. OSHA believes that separating the requirements for a permit system from those for the content of the permits themselves will alert employers to the need for adopting an overall system for authorizing entries into permit-required confined spaces. The Agency further believes that permit systems that comply with paragraph (e) will enable employers to maintain control over permit space entry operations throughout the entry's duration so as to ensure the protection of authorized entrants.

Paragraph (e)(1) of the final rule requires employers to document the completion of the measures necessary for safe entry operations through the preparation of an entry permit.

This paragraph in the final rule was based on proposed paragraph (d)(1). The rulemaking participants who addressed this proposed paragraph supported the need for a written permit. For example, the Marine Chemist Association Inc. (Ex. 14–55) stated that a permit is the essential ingredient of a permit space program, in that it establishes responsibility. The Monsanto Company (Ex. 14–170) also agreed with the requirement for a permit system that serves to identify hazards and the measures taken or to be taken during entry to control them. In support of the requirement for a permit system, Mr. Ray Witter, an OSHA expert witness, testified (Houston Tr. 639) as follows:

> Well, in my opinion, you need to prepare a written permit system because that is the only way that you can ensure that people have looked at the various hazards that exist and have decided what has to be done or if nothing has to be done. If you do not provide a permit, it is left to the evaluation of the individual, and all of us, as people, can forget something.

As discussed previously, OSHA has determined that it is necessary to require explicitly that the list of measures taken for protection of employees who enter permit spaces be recorded on a permit along with a notation that all these measures have been completed before entry. OSHA wishes to emphasize that the permit is considerably more than a simple checklist; it requires careful thought and planning. All measures necessary for making the particular permit space safe for entry must be listed; otherwise, it is likely that some procedures will be omitted, with serious consequences. The permit enables the entry supervisor and the other personnel involved in entry operations to keep track of the

precautions taken to protect employees. It also allows authorized entrants to verify that each protective measure has been checked by someone.[25]

Paragraph (e)(1) also contains a note indicating that non- mandatory Appendix D contains examples of permits whose elements are considered to comply with the requirements of this section. The precise elements that must be listed on a permit for a given permit space entry are dependent on the hazards within the space and, perhaps, on the operations to be performed during entry operations.

As noted above, this provision is based on proposed paragraph (d)(1), which required that employers prepare permits through which all conditions to be evaluated to ensure safe entry were identified. OSHA has determined that the proposed language, insofar as it focused on the "conditions" to be evaluated, did not clearly indicate what information was required in the permit. In particular, the Agency observes that proposed paragraphs (d)(2) and (d)(3) required information that did not relate to "conditions". Therefore, paragraph (e)(1) of the final rule (in conjunction with paragraph (f)) has been written to clearly indicate the breadth of the information required in the permit. Specifically, paragraph (e)(1) of final §1910.146 requires the permit to document the completion of measures required by §1910.146(d)(3). Additionally, OSHA is requiring the entry permit to be completed before entry is authorized.

Paragraph (e)(2) of the final rule requires the entry supervisor identified on the permit to sign the entry permit to authorize entry.

This provision was taken from proposed paragraph (d)(5), which would have required the signature of the person authorizing the permit before entry began but after safe entry conditions were established. (Paragraph (e)(1) of the final rule requires the employer to establish safe entry conditions before the permit is authorized.) The few rulemaking participants (Ex. 14–63, 14–170; Houston Tr. 1061) who addressed proposed paragraph (d)(5) advocated the provision. The State of Maryland's Occupational Safety and Health Program (Ex. 14–63) succinctly stated the purpose of this requirement in their support for a requirement that the person authorizing the permit sign it, as follows:

> [T]he signature establishes individual accountability. If a person is asked to sign the form, there is a greater chance that the items the form requires will be addressed than if no one has to sign the form.

Proposed paragraphs (d)(2) and (d)(3) set out the elements that would have been required on permits. Proposed paragraph (d)(2) listed the elements (the "checklist" portion of the permit) that had to be present on all permits, while paragraph (d)(3) listed additional elements that would also have had to be listed, unless the entry supervisor assumed direct charge of the entry operation for its duration. The items that would not have been required to be listed were:

(1) The identity of the permit space;
(2) The purpose of the entry;
(3) The date of the entry and the authorized duration;
(4) A list of the authorized entrants;
(5) A list of eligible attendants;
(6) A list of individuals eligible to be in charge of the entry; and
(7) The signature and printed name of the entry supervisor originally authorizing entry.

In issue 5 of the NPRM (54 FR 24086), OSHA asked several questions pertaining to the use of a "checklist" permit for permit-required permit space entry when the employer directly supervised entry operations. The questions were directed to whether or not a the use of a checklist permit in lieu of a full permit would be effective in protecting employees. OSHA also requested information on projected cost savings, actual workplace experience using the checklist approach, and examples of actual procedures and permits that have been used.

OSHA received many written comments and some hearing testimony concerning this issue. Several of the commenters (Ex. 14–47, 14–91, 14–94, 14–98, 14–119, 14–123, 14–161, 14–170, 14–179, 14–183, 14–193) who addressed this issue misunderstood the intent of the proposed standard, which was to allow the omission of several items from the written permit if the individual authorizing the entry was in direct control of the entry for its duration. These commenters apparently believed that OSHA was proposing that no permit at all be required when the entry authorizer is present for the duration of the entry. In a representative comment, the Monsanto Company (Ex. 14–170) stated:

> Our experience is that the confined space entry permit serves to assist in effective preparation of the space as well as communication about the space during the entry period. We may utilize direct supervision for a particularly difficult confined space entry but that would be in addition to, not in lieu of, a permit.

Other commenters (Ex. 14–86, 14–99, 14–153, 14–184; Chicago Tr. 102) did not directly answer the questions posed in Issue 5, choosing instead to address other related concerns. For instance, the Texas Chemical Council (Ex. 14–86) wondered how shift changes would affect the proposed provision:

> Often entries are worked on [a] 24 hour a day basis and no one individual can be there during that time period. The authority or responsibility for the job transfers between individuals. Therefore, it is necessary to have an extension of authority beyond the singular person.

These commenters apparently believed that the proposal would have required a single entry supervisor for the entire entry. Their concerns were unfounded since the proposed provision would have accepted transfer of responsibility between on-coming and off-going entry supervisors (although the proposal did not state this explicitly).

Several commenters (Ex. 14–27, 14–28, 14–30, 14–88, 14–99, 14–119, 14–137) were critical of the checklist system, as a form of abbreviated permit. Some of the commenters felt that inclusion of all the information (as listed in proposed (d)(3) as well as proposed (d)(2)) was necessary. For example, the Northwest Pipeline Corporation (Ex. 14–27) said:

> It is Northwest's opinion that a permit form requiring all information pertinent to the entry is necessary to ensure a safe entry into confined spaces and compliance with this proposed standard.

In a similar vein, the Union Carbide Corporation (Ex. 14–88) stated:

> It is important for all critical information to appear on the permit in writing. Union Carbide requires permits to include in writing the place, time, purpose, personnel assigned, and name of authorizing individual, among other information, even when the authorizing individual assumes direct charge of the entry for its duration. The potential risk of miscommunication where critical information is not written down significantly outweighs the incremental benefits of not using a written permit containing all necessary information.

Still other commenters (Ex. 14–81, 14–123, 14–137), while not objecting to the "checklist permit" provision, felt

[25] Although the entry permit does not provide an absolute method of verifying that entry conditions are acceptable, it does provide a ready means to check that all items listed on the permit have been accounted for. If no one remembered to take one of the listed precautions, it would not be documented on the permit—a hazard that should be caught by the entry supervisor during his or her review. The entry supervisor and other employees can also verify that the test results given on the permit are within the range allowed. The final rule makes the entry supervisor responsible for ensuring that the elements listed on the permit have been completed. The signature of the entry supervisor who originally authorized the entry signifies that these measures have been taken.

that the intended relief would be of little value to them. The National Ready Mixed Concrete Association (NRMCA, Ex. 14–81) commented that:

> While NRMCA has no objection to the exemption of permit required confined spaces for situations in which the person who authorizes entry assumes direct charge for the duration, we consider it unlikely that much benefit would accrue to the ready mixed concrete industry by virtue of such an exemption. It is unlikely that the authorizing supervisor could often be directly in charge of a confined space entry for its duration.

A few commenters (Ex. 14–57, 14–73, 14–98) favored the exemption. For example, Beaumont & Associates (Ex. 14–57) supported the exemption, as follows:

> It would be appropriate to allow an entry permit which did not specify location, time, purpose, persons allowed entry, and duration of permit, if the person authorizing the entry remained at the entry location for the duration of the entry.

OSHA believes that the proposed provision was, unfortunately, misunderstood by many commenters, causing them, in many instances, to generate responses not pertinent to the issue. OSHA also believes that some of the objections stemmed, to a large extent, from a misunderstanding of this provision.

Based upon the rulemaking record, OSHA has decided not to allow the use of an abbreviated, or "checklist" permit in the final rule. OSHA agrees with the Union Carbide Corporation that it is important that all critical information appear on the permit in writing for two reasons. First, all the pertinent information will then be available, on the permit, to the entrants who will then be better equipped to make independent judgments as to the adequacy of pre-entry preparations. Second, the inclusion of all critical information on the permit will facilitate the program reviews required under paragraphs (d)(12) and (d)(13) of the final rule. In fact, the elements that the proposal would have allowed to be omitted are essential for the identifying the permit space and for identifying employees who could provide information about problems that may have arisen. OSHA believes that the benefits of including all the permit items (as listed in paragraph (f) of the final rule) far outweigh the slight cost savings that might have accrued through the use of an abbreviated permit. (The employer may, however, use a preprinted, checklist-type permit, provided it contains all the information required under paragraph (f) of the final rule, with all entries completed and with the signature of the entry supervisor.)

Paragraph (e)(3) of the final rule requires the employer to make the completed permit available to all entrants at the time of entry, such as by posting it at the entry portal, so that the entrants can confirm that performance of all necessary pre-entry measures has been indicated on the permit.

This requirement was not contained in the proposed rule. However, several commenters (Ex. 14–4, 14–124, 14–157, 14–161, 14–170, 14–174) suggested that OSHA make posting a copy of the permit a requirement in the final rule or stated that their company required such posting and that they believed such posting of the permit was appropriate. They argued that this posting would alert employees to the presence of hazards within the space and of the measures necessary for the protection of employees.

OSHA agrees that making the permit available to all authorized entrants would provide them with information on protective measures to be taken to make the permit space safe for entry. By inspecting the permit and observing recorded test results and the tester's signature or initials, the authorized entrants could check to see if pre-entry preparations have been completed. OSHA agrees that making the completed permit available to the entrants (whose safety and health, after all, is most at stake during entry operations) is important enough to be required in this final rule. Entrants will then be able to make their own judgments as to the completeness of pre-entry preparations and to point out any deficiencies that they believe exist. A requirement that the completed permit be posted at the entry portal or otherwise be made available to the entrants at the time of entry has therefore been incorporated into this final rule.

Paragraph (e)(4) of the final rule requires that the duration of a permit not exceed the time required to complete the assigned task or job identified on the permit in accordance with paragraph (f)(2) of the final rule.

This provision has been taken from paragraph (d)(3)(iii) of the proposal, under which a permit would have been allowed to remain valid for up to 1 year, so long as all conditions required by the permit were maintained. The comments OSHA received concerning the proposed provision (Ex. 14–28, 14–57, 14–63, 14–80, 14–109, 14–116, 14–151, 14–161) objected to allowing permits to be valid for so long. These commenters said that the 1-year limit was arbitrary, because it was unreasonable to expect that entry conditions would remain acceptable for that long. They pointed out that conditions within the space would almost certainly change over that amount of time and that the hazards within the space would have to be reevaluated. For example, the International Brotherhood of Teamsters (Ex. 14–109) stated:

> In Section (d)(3)(iii), OSHA proposes to allow a confined space permit to be issued for as long as a year at a time "so long as all conditions under which the permit was issued are maintained." For OSHA to suggest that a permit could be good for a year defeats much of the purpose of having a permit system at all. It invites complacency, and invites workers and supervisors to make unwarranted assumptions about conditions that may affect the safety of the entry. For example, it would not be appropriate to rely on one long-term entry permit for a tank in a brewery that had to be entered repeatedly—but not continuously —over the course of a year. Even a much shorter term, designated rescuers may go home at the end of their shift. Additionally, issuance of a long-term permit means that the authorizing person, who likely only works about 40 hours a week, may very well be unaware and unavailable at times when conditions change that should cause the permit to be amended or revoked.
>
> For reasons such as these, we strongly favor the recommendation on p. 7 of the NIOSH Criteria Document on Working In Confined Spaces: "The permit shall be dated and carry an expiration time that will be valid for one shift only. The permit shall be updated for each shift with the same requirements."

OSHA has decided to limit entry permit duration to whatever period of time is necessary for completion of the assigned task or job, which is identified on the permit under paragraph (f)(2) of the final rule. The duration of the permit is not directly relevant to the safety of employees working in permit-required confined spaces. As long as acceptable entry conditions are present, employees can safely enter and perform work in permit spaces. The length of time entry operations take should not be a factor in whether acceptable entry conditions exist in the space, as long as the permit system conforms to the requirements of final §1910.146. If conditions within the space change so that entrants are endangered, then the following steps should fully protect these employees:

(1) The entry supervisor, when he or she assumes responsibility for a space and when he or she performs periodic checks, ensures the presence of acceptable entry conditions (paragraph (j)(6)).

(2) If the hazard being introduced is atmospheric in nature, the testing and monitoring of the space will detect it (paragraph (d)(5)(ii)).

(3) If other hazards are being introduced, the entry supervisor, the

attendant, and authorized entrants are trained to detect their presence (paragraphs (g), (h)(1), (i)(1), and (j)(1)).

(4) Entrants would vacate the permit space (paragraphs (h)(4) and (h)(5), (i)(6), and (j)(3)).

These steps fully protect entrants from hazards developing during entry operations. Limiting the duration of the permit to an arbitrary length of time would not reduce the risk of entry into permit spaces because the conditions within the space are required to be monitored periodically.[26] On the other hand, the permit should not be valid for a period longer than necessary to complete the task being performed inside the space. Otherwise, entrants could be unnecessarily exposed to the residual hazards of permit spaces. Therefore, OSHA has decided to adopt a requirement that the permit be valid for a period not to exceed that necessary to complete the task or job for which the permit was obtained in place of the proposed requirement that it be valid for no longer than 1 year.

In complying with paragraph (e)(4) of the final rule, the employer need not, but may, state a specific time period (a number of hours or days) on the permit. For instance, the permit's duration could be stated in terms of the removal and installation of a relief valve or the cleaning of the inside surfaces of a tank. OSHA's intent here is merely to place some reasonable limitation on permit validity.

Paragraph (e)(5) of the final rule covers cancellation of entry permits. It requires the entry supervisor to terminate the entry and cancel the permit when the entry operation covered by the permit has been completed or when a prohibited condition arises in or near the permit space.

This provision in the final rule is based upon proposed paragraphs (d)(6) and (g)(1)(iv). Specifically, paragraph (d)(6) of the proposed rule would have required the "individual authorizing the entry" to cancel the permit. Many commenters (Ex. 14–80, 14–86, 14–88, 14–94, 14–118, 14–123, 14–143, 14–150, 14–188) stated that the proposed provision was unduly restrictive because the individual who originally authorized entry was often not present upon completion of entry operations. For example, the Chemical Manufacturers Association (Ex. 14–118) argued as follows:

Paragraph (d)(6) requires that the individual who authorized the entry must cancel the permit. This requirement could pose unwarranted inefficiencies and hazards. In many cases, the original authorizing individual will be away from the worksite and unavailable to cancel the permit. In addition, another individual trained to authorize and cancel a permit may note a condition that warrants canceling the permit. Any individual trained to authorize entry should be able to cancel the permit.

The Agency acknowledges that there are situations where more than one entry supervisor is needed over the course of entry operations. For example, when multi-shift entry operations are conducted, more than one entry supervisor would be used for a permit space. Additionally, even for entry operations that do not extend across more than one shift, the original entry supervisor may be absent from the workplace for other reasons. Therefore, the Agency has adopted language to provide that the entry supervisor, not the person who authorized entry, will cancel the permit. As noted under the discussion of the term "entry supervisor", OSHA does not intend to restrict the position of entry supervisor to a single individual. Any individual who has been designated as the entry supervisor has the authority to terminate entry and cancel a permit. Of course, the entry supervisor on duty at the completion of the entry operation will normally be the one to terminate and cancel the permit.

Paragraph (e)(6) of the final rule requires that canceled entry permits be retained for at least 1 year to facilitate the annual review of the permit space program required under paragraph (d)(14). Paragraph (e)(6) had no counterpart in the proposed rule. Its inclusion in the final rule is based on OSHA's conclusion that the permit space program needs to be reviewed at least once per year. Canceled permits are among the materials that need to be covered by the annual review (as required by paragraph (d)(14)). OSHA believes that information on any problems that arise during entry operations should be available to the personnel who perform the review. For example, there may be information which, while not alarming when related to a single entry, may in fact turn out to be important evidence of a problem or of a trend that could lead to a problem. Indeed, Mr. Dan Glazier, representing the Motor Vehicle Manufacturers Association (Chicago Tr. 187–188), noted this very point in his testimony, as follows:

If you have an indication that the oxygen level has dropped in this confined space or that the combustible level has exceeded 5 percent of the [LFL], then certainly there is something unique about [that] confined space that is causing it to go bad.

Therefore, I would want to track that for a certain period of time and we never really outlined that. But to try to determine what is causing that confined space, what is unique about that [confined] space which is causing it to go bad. That lends some credibility to I think to keeping the permits for a certain period of time so that you can track confined spaces that I should say, "are known bad actors".

For these reasons, paragraph (e)(6) also requires the employer to annotate its permits to indicate any problems so that the appropriate revisions to the program can be made.

Paragraph (f), Entry Permit.

Paragraph (f) of the final rule specifies the information that must be included in the permit prepared under paragraph (e) of final §1910.146. As noted previously in the discussion of paragraph (e), that information sums up the employer's efforts to identify and control conditions in permit spaces. OSHA has determined that the preparation of the permit will be a central part of the employer's determination as to whether conditions in a permit space are safe for employee entry. The permit itself will provide a concise summary of the permit space program requirements for a particular entry that will be useful to the personnel who are conducting the entry operations and to any personnel who need to review the conduct of entry operations after the operations have been terminated. Additionally, OSHA believes that properly prepared entry permits will assure employees that the employer's permit space program will protect them from permit space hazards.

The remaining discussion of paragraph (f), following, provides a summary and explanation of each of the items required to be identified on a permit. The introductory language of paragraph (f) explicitly requires all the information listed in paragraphs (f)(1) through (f)(15) to be included on an entry permit.

Paragraph (f)(1) requires an identification of the space to be entered. This is effectively identical to paragraph (d)(3)(i) of the proposed standard. OSHA received no substantive comments on the proposed paragraph.

Paragraph (f)(2) requires the purpose of the entry to be listed on the permit. This is identical to paragraph (d)(3)(ii) of the proposed standard, on which no substantive comments were received.

Paragraph (f)(3) requires the date and the authorized duration of the entry permit to be entered. The duration of

[26] Since the final rule requires the entry supervisor to re-evaluate the space upon assuming responsibility for it (under paragraph (j)(6) of the final rule), entry conditions will be checked at least once per shift.

the entry permit need not be stated in terms of actual time, but may be stated in terms of the completion of the task for which permit space entry is being performed. This provision corresponds to paragraph (d)(3)(iii) of the proposed standard. (See the summary and explanation of paragraph (e)(4) of the final rule, earlier in this preamble for further discussion of the acceptable duration of a permit and for a discussion of the comments received on paragraph (d)(3)(iii)).

Paragraph (f)(4) requires a listing of the authorized entrants. The employer may place the names of authorized entrants on the permit or may choose to track them by any other effective means.

This provision corresponds to paragraph (d)(3)(iv) of the proposed standard. Many rulemaking participants objected to the proposed provision (Ex. 14–28, 14–86, 14–94, 14–111, 14–118, 14–124, 14–125, 14–143, 14–150, 14–161, 14–170, 14–176, 14–188, 119), citing concerns about the infeasibility of placing a large number of names on the entry permit itself. These rulemaking participants argued that, while it was important to track the presence of employees working within the space, maintaining an accurate list of authorized entrants for a particular permit space entry operation was unnecessary. They also contended that maintaining such a list would be nearly impossible for large entry operations involving hundreds of authorized entrants. Most of these rulemaking participants suggested using a performance- oriented approach that recognized all types of tracking means, such as rosters, having the attendant keep an accurate count of entrants, and sign-in and sign-out sheets.

In its post-hearing comment (Ex. 119), which was typical of the objections to proposed paragraph (d)(3)(iv), Texaco stated:

> The point is that there may be 50 to 60 people working in this one vessel and due to the complexity of the work, the personnel will change constantly. The contractor plans the work in advance, the operations personnel check and assure that the vessel is safe for entry and does this without the knowledge of the actual names of personnel who will be entering the vessel. The names of the personnel are assigned by the contractor(s) just prior to the start of the shift, *at the same time that the operator is checking the vessel for entry*. The problem with assigning *actual names* for vessel entry is compounded by the fact that the personnel change at the last moment due to absences, etc., and the fact that workers are constantly changing even throughout the shift.
>
> In *summation*, actual names on the permit would greatly delay the start of the work at each shift and Texaco submits that this delay is not warranted *since it provides no greater worker protection*. With the personnel inside the tower constantly changing, the listing of actual names *on the permit* would be a virtual impossibility. The point is to assure that all get out if an alarm is sounded. The Standard should contain performance oriented language that would allow an employer the flexibility to decide upon and implement *the most reasonable safety procedure for tracking personnel inside a particular permit space*. Of course in practical situations, this would include either sign in sheets, entry badges, or tag boards. [Emphasis supplied in original.]

The main purpose of the proposed requirement was to provide an accurate list of employees inside the space so that it would be possible to determine quickly and accurately whether all entrants had been rescued in an emergency. A second purpose was to provide assurance that all employees had evacuated the space at the end of entry operations. To achieve these goals, the proposal would have required the permit to list the names of all authorized entrants within the permit space.

Based on the rulemaking record, OSHA concludes that the proposed provision would have been unduly restrictive and somewhat impractical for permit space entry operations involving large numbers of entrants. However, the Agency is still concerned that, without an accurate entrant tracking system, entrants may be left inside permit spaces after the operation is complete.

The rulemaking participants (Ex. 14–34, 14–111, 14–118, 14–124, 14–170, 14–188, 119) mentioned several possible alternatives to the listing of entrants names on the permit: tag boards, entry badges, sign-in sheets, and electronic tracking systems. Many of these systems provide the attendant with enough information to keep accurate track of authorized entrants. OSHA believes that, as long as the system accurately traces who is in the permit space at any given moment and as long as the attendant has immediate access to the system, the attendant will be able to order the complete evacuation of a space as required by paragraph (i)(6) of the final rule. Additionally, the rescue and emergency service will be able to account for all employees working inside the permit space in the event of an emergency. Other systems, which only keep a count of the employees inside the permit space, would not be acceptable. A simple count of the number of authorized entrants would not be sufficient to ensure that all entrants have been rescued in case of emergency. Under such conditions, it would be easy to lose track of exactly how many employees have exited the space. Further, without a more systematic approach to tracking employees, entrants performing self-rescue might not inform the attendant of their emergence from the space. The rescue and emergency service employees would then be exposed, unnecessarily, to the hazards posed by entry into the permit space under hazardous circumstances. Unauthorized entrants, who might have gotten into the space and who might even have caused the emergency, could easily be counted as they exit the space, which would result in the attendant's losing track of some of the authorized entrants still in the space. These employees might then suffer further injury or death as a result.

For these reasons, paragraph (f)(4) of the final rule requires a system of tracking authorized entrants that will accurately trace who is in the permit space at any one time and that will enable the attendant to identify these employees quickly and accurately. Any system that meets the goal set by the performance-oriented language is acceptable.

Paragraphs (d)(3)(v) and (d)(3)(vi) of the proposed standard would have required a listing of all eligible attendants and individuals eligible to be in charge of the entry, respectively. Many commenters (Ex. 14–28, 14–80, 14–86, 14–94, 14–116, 14–118, 14–123, 14–124, 14–130, 14–143, 14–150, 14–157, 14–161, 14–170, 14–176, 14–188) also objected to these proposed provisions. The commenters noted that there could be large numbers of employees who were eligible to serve as attendants or as entry supervisors, even if the number who actually serve in such capacities was small. Again, the commenters urged OSHA to adopt a performance- oriented approach. For example, Dow Chemical USA (Ex. 14–130) stated:

> A list of those that are trained (or eligible) to perform the work involved in the confined space entry could be long. While a list of those directly involved and authorized for entry will be short and beneficial.

Several rulemaking participants (Ex. 14–80, 14–124, 14–188) argued that methods such as identifying attendants and entry supervisors by job title, by logs, or by badges could provide the required information in a much less burdensome fashion. Others (Ex. 14–88, 14–116, 14–130, 14–161) urged OSHA to require only the identification of attendants and entry supervisors that are involved in a particular entry operation. Some of those objecting to the proposed provision (Ex. 14–80, 14–94, 14–118, 14–157, 14–161, 14–170) noted that the information the Agency

would be requiring on the permit could be gleaned from other, more appropriate, sources (namely, personnel training files).

As discussed in the summary and explanation of paragraph (f)(4) earlier in this preamble, OSHA agrees that there are conditions, especially if large numbers of employees are involved in entry operations, under which it is unreasonable to list by name on the permit all individuals who might serve as attendants or entry supervisors. OSHA further agrees that there are methods of identifying attendants and entry supervisors other than naming them on the permit itself. Employees have another method of ensuring that individuals serving as authorized entrants, attendants, and entry supervisors are qualified. Under paragraph (g) (discussed later in this section of the preamble), the employer is required to certify that employees have received the requisite training. This certification is required to be available to employees and their representatives so that employees can verify that individuals have been appropriately trained. As a result, listing the names of eligible attendants and entry supervisors on the permit itself is not necessary.

The primary basis for proposing to require the names of the attendants and entry supervisors on the permit was that it is important for all affected employees to be able to know who the persons responsible for the safety of entrants are. If an employee notices a hazard developing, it is important for him or her to be able to notify a person with the responsibility and authority for abating the hazard or for evacuating the permit space. The proposal took the approach that the easiest method for the identification of these individuals was to name them on the permit. As noted by the comments on proposed paragraphs (d)(3) (v) and (vi), the proposal did not account for other equally effective means of identifying the appropriate persons.

At the same time, the proposal would not have afforded entrants the most effective protection. Unless provision was made for identifying the individuals currently acting as attendants or entry supervisors, permits that identify all persons eligible to fulfill those roles do not enable employees quickly or easily to identify and contact the persons actually having responsibility for safe permit entry operations at a given time. In an emergency, an employee could waste valuable time inquiring of all the individuals named on the permit to find the person that can take steps necessary to protect entrants. Meanwhile the employees inside the permit space would be endangered.

In the final rule, OSHA is requiring the employer to identify by name the current attendants (paragraph (f)(5)) and current entry supervisor (paragraph (f)(6)) for a permit space entry. Whenever new attendants or entry supervisors assume their roles, they are required to have their names placed on the permit. This provides a sure means of distinguishing these important individuals quickly and easily. It also provides the opportunity for these individuals to review the permit and entry conditions to ensure that entry conditions remain safe. In fact, under paragraph (j)(6), the new entry supervisor is required to undertake this review.

OSHA has determined that it is not necessary to identify all eligible attendants or entry supervisors on the permit. As indicated in the public comment, the list of eligible individuals could be lengthy and is of little actual use during the entry operation. Also, this information, if needed, is readily available in training records, as noted by the commenters. In fact, the employer is required to certify the training of these individuals and to make the certification available to employees and their representatives under paragraph (g)(4) of the final rule. The presence of this information on the permit would not contribute to employee safety and, as noted previously, might even hinder efforts to protect entrants in an emergency.

Paragraph (f)(7) requires the permit to contain a listing of the hazards of the permit-required space to be entered. This provision is essentially identical to paragraph (d)(2)(i) of the proposed standard on which OSHA received no significant comments.

Paragraph (f)(8) requires the permit to contain a list of the specific measures to be used for isolating the permit space and for eliminating or controlling permit space hazards before entry.

This provision combines language from proposed paragraphs (d)(2)(ii) and (iii), which proposed that the measures to be taken for isolating the permit space and for removing or controlling hazards be identified on the permit. Some commenters (Ex. 14–86, 14–124, 14–143, 14–150, 14–188) maintained that the standard operating procedures that would be used to take these measures were detailed and highly specific in nature. They argued that such detailed information was not needed on the permit itself and suggested that the final rule allow only a reference to these standard operating procedures.

With respect to these comments, OSHA notes that the entry permit need only identify the measures (such as the use of blanking to isolate a permit space) used to perform the specified steps in the permit space program. The final rule does not require the exact procedures used to be identified, because, as noted in the comments, including that degree of detail on the entry permit itself would not be practical. The detailed procedures for making the permit space safe for entry are required to be established, under paragraph (d)(3), and authorized entrants, attendants, and entry supervisors are required to be trained in their use, under paragraph (g). (See the summary and explanation of these two paragraphs for a discussion of the establishment and implementation of procedures for making spaces safe for entry and for a discussion of training requirements, respectively.) The permit need only refer to these procedures in sufficient detail to enable employees to determine what measures should be taken and how to perform those measures. (The detail to be provided on the permit is dependent, to some extent, on the training provided under paragraph (g).)

Paragraph (f)(9) requires the permit to contain a list of the acceptable entry conditions for the permit space.

This provision has been taken from proposed paragraph (d)(2)(iv), which would have required the "acceptable environmental conditions, quantified with regard to the hazards identified in the permit space, which must be maintained during entry". As noted earlier in this preamble, the proposed term "acceptable environmental conditions" has been replaced with "acceptable entry conditions" in the final rule. (See the summary and explanation of the term "acceptable entry conditions" for a discussion of the reasons for this change in terminology.)

One commenter (Ex. 14–123) argued that the acceptable entry conditions that were required to be listed on the permit were more appropriate as part of the hazard control procedures and practices required by proposed paragraph (c)(2) (paragraph (d)(3) of the final rule).

Measures for obtaining acceptable entry conditions are dependent upon the acceptable entry conditions for a given permit space. These measures must be listed on the permit under paragraph (f)(8). The entry conditions that must be present within the space must also be listed on the permit so that authorized entrants, attendants, and entry supervisors have this information on hand at the worksite. These conditions include such criteria as the

oxygen, flammable gas and vapor, and toxic substance levels that must be met before the permit space is safe for entry.[27] They also include the energy control considerations that apply to the permit space. Because the hazard control measures to be taken are directly related to the particular acceptable entry conditions for the permit space, employers will likely combine these two elements on the permit. In fact, the example permits presented in Appendix D list acceptable entry conditions as part of the hazard control measures to be taken.

Paragraph (f)(10) requires the recorded test results corresponding to the specified entry conditions, along with the signature or initials of the tester and an indication of when the tests were performed, to be entered on the permit. The results of initial and periodic tests performed under paragraph (d)(5) of the final rule would have to recorded.

This provision did not appear in the proposal. The proposal required the employer to set acceptable entry conditions (paragraphs (c)(2) and (d)(1)), to ensure that they were met before entry (paragraphs (d)(2) and (d)(5)), and to ensure that they were maintained during permit entry operations within the space (paragraphs (f)(2) and (g)(1)). The proposal required the permit to contain testing procedures and equipment necessary to verify the presence of acceptable entry conditions, and the Agency anticipated that the employer would test conditions within the space as necessary to meet these provisions.

In response to information received as part of the rulemaking record, OSHA has adopted specific requirements for the testing of conditions within permit spaces to verify that they are acceptable. (See the summary and explanation of paragraph (d)(5) for a discussion of these requirements.)

Several commenters (Ex 14–4, 14–116, 14–118, 14–148, 14–164) recommended that the results of testing performed under the standard be documented. They argued that this information would dictate the protective measures to be taken. Supporting the view that recording the results of testing was an important part of a permit system, Allwaste Tank Cleaning Company (Ex. 14–164) stated:

> The only required information should be the space identification and results of atmosphere testing. In an industry such as ours, these results will dictate the measures employed.

Additionally, there is some evidence in the record that documenting test results is a practice in current permit space programs. Three witnesses at the Chicago hearings (Chicago Tr. 123, 146, 209) agreed that documentation of test results was needed and testified that such documentation was a common practice in their particular operation.

As a result of this testimony and evidence, OSHA has concluded that recording the results of initial and periodic testing is a necessary feature of permit space programs. If the results of testing are entered on the permit, the entry supervisor has before him or her readily available evidence that pre-entry conditions have been checked and what the test results were. Additionally, the entrants themselves will be able to check the permit for themselves to see that the testing has been done and that safe conditions exist. Entrants and attendants can also use the test results as guidance on conditions to which they should pay close attention. For example, if the oxygen concentration is 19.6 percent, the attendant and entrants should be alert for signs of oxygen deficiency, such as increased breathing rate, dizziness, rapid heart beat, and headache. Furthermore, documentation of test results on the permit also facilitates the review of canceled permits required under paragraph (d)(14). If testing indicates that levels of hazardous substances are increasing, the increased hazard will be easy to recognize through a review of the recorded test results on the canceled permit. For these reasons, the Agency has concluded that a requirement to record, on the permit, the results of initial and periodic testing performed under paragraph (d)(5) is necessary and appropriate for the protection of employees entering permit- required confined spaces. This requirement appears in paragraph (f)(10) of the final rule.

Triodyne Environmental Engineering, Inc. (Ex. 14–50), stated:

> Requiring a checklist on an entry permit provides for a repetitive method which can recognize individual responsibility by requiring initials next to each task.

OSHA agrees with the commenter and has decided to require that the initials or name of the person who performed the test be placed on the permit. OSHA has also decided to require that an indication of when the tests were performed be placed on the permit as well. This information will enable the entry supervisor and the attendants to establish the identity of the person who performed the tests in case any questions arise. The date and time (or other indication of when the test was performed) will give a quick indication of when additional testing is needed. The Agency has concluded that this information is integral to the test data and that its presence on the permit is also necessary. Therefore, paragraph (f)(10) of the final rule also requires the permit to contain this information along with the results of the tests.

Paragraph (f)(11) requires the permit to list the rescue and emergency services that can be summoned and the means for summoning those services. The identification of the rescue and emergency services and the means for summoning them enable the attendant to summon the rescue and emergency services immediately in case of emergency. This provision corresponds to, and is substantively the same as, paragraph (d)(2)(vi) of the proposal. The comments on this paragraph of the proposal are discussed under the summary and explanation of paragraph (f)(13) of the final rule.

Paragraph (f)(12) requires the permit to contain a list of the communication procedures to be used by attendants and authorized entrants during entry. This provision corresponds to proposed paragraph (d)(2)(viii). The phrase "during the entry"[28] has been added in the final rule to ensure that it is understood that this provision applies only to communication equipment and procedures used during entry operations. Except as noted under the summary and explanation of paragraph (f)(13), OSHA received no significant comments on the provision as proposed.

Paragraph (f)(13) requires that the permit contain a list of equipment to be provided for compliance with the permit space standard. This equipment includes personal protective equipment, testing equipment, communications equipment, alarm systems, rescue equipment, and other equipment that the employer intends to provide to ensure compliance with final §1910.146.

Paragraph (f)(13) of the final rule has been taken from proposed paragraphs (d)(2) (v) through (ix). Requirements relating to equipment in these proposed paragraphs have been placed in one place in the final rule. OSHA believes that this simplifies these provisions. Paragraphs (d)(2)(v) through (d)(2)(viii) of the proposal would have required the permit to list the test equipment and procedures, the rescue and emergency

[27] An atmosphere meeting these levels must be not be a hazardous atmosphere, as defined in final §1910.146(b), except as otherwise permitted by §1910.132.

[28] "Entry." is defined to include the initial entry into and subsequent operations within the permit space.

services, the rescue equipment, and the communication equipment and procedures for the permit space, respectively. A few commenters (Ex. 14–28, 14–86, 14–123, 14–143, 14–170, 14–188) stated that these items were equipment and procedures that are more appropriately addressed in training or in the hazard control procedures provided under the permit space standard. Although each of these commenters was concerned about a different item to be listed, they all argued that the permit itself should be as simple as possible and that the details of the individual items are covered in more detail in training of employees or in operating procedures.

The Agency disagrees with these comments. OSHA has concluded that the permit needs to identify the equipment, as well as the procedures, necessary to ensure safe entry operations and to facilitate rescue. The authorized entrants and attendants need to know what equipment will be needed for a particular space so that the entrants spend as little time exposed to the hazards presented by permit space entry as possible. Without the proper equipment, these entrants might have to exit the space and reenter after the proper equipment has been obtained. As a result, they would be exposed to increased hazards unnecessarily. Therefore, paragraph (f)(13) of the final rule requires the permit to identify the necessary equipment.

Paragraph (f)(14) requires that the permit contain any other information whose inclusion is necessary, given the circumstances of the particular confined space, in order to ensure employee safety.

This provision is identical to proposed paragraph (d)(2)(x). One commenter (Ex. 14–161) considered the proposed requirement to be too open-ended.

OSHA believes that this performance-oriented requirement is necessary for the protection of employees involved in permit space entry operations. Due to the wide-ranging types of hazards found in permit-required confined spaces, there are many hazards that cannot be adequately addressed with any precision in a generic permit space standard. Therefore, the provision needs to be general in nature.

Paragraph (f)(15) requires that any additional permits, such as hot work permits, that have been issued to authorize work in the permit space, be identified on the permit. If the other permits are attached to the entry permit, they are considered to be part of it. This provision is essentially the same as proposed paragraph (d)(4), on which no significant comments were received.

Paragraph (g), Training.

The record strongly demonstrates a need for training employees in the hazards posed by permit spaces and in the procedures for controlling those hazards. Many of the accident descriptions in the record indicate that one of the major factors causing these accidents is a lack of employee awareness of the dangers involved in entry into permit spaces. Employees who entered these spaces were unaware of the possibility that the atmosphere inside could be immediately dangerous to life or health. In some cases, they also did not recognize the symptoms of exposure to certain life- threatening atmospheres. In other cases, they did not realize that sometimes there are no obvious symptoms. Employees who attempted to rescue fallen coworkers inside permit spaces were also unaware of the hazards involved and of the procedures for safe rescue. The result of this lack of training was often the deaths of these employees.

OSHA proposed in the NPRM to establish training requirements for permit space entrants (paragraph (e)), for attendants (paragraph (f)), and for persons authorizing or in charge of an entry (paragraph (g)). The training requirements were combined with provisions related to the duties to be performed by each of these classes of employees to stress that employees had to be instructed in these specific duties. It was the Agency's belief that these provisions would go far towards the goal of protecting employees from the hazards of permit space entry.

Some commenters (Ex. 14–62, 14–63, 14–151, 14–163, 14–173, 14–174, 14–208, 14–214) were concerned that this approach did not stress the need for training enough or that it omitted important elements. For example, several rulemaking participants (Ex. 14–63, 14–151, 14–163, 14–208, 14–214) suggested that the standard address follow-up training and instruction in cardiopulmonary resuscitation. Others (Ex. 14–45, 14–63, 14–86, 14–109) argued that the training provisions should be clarified in one way or another. To address their concerns, the State of Maryland Occupational Safety and Health Program (Ex. 14–63) recommended the incorporation of a special section on training, as follows:

> There should be a training section or an Appendix incorporated into the standard, which offers an outline or a lesson plan which addresses each item to be covered, such as reading instruments, monitoring, ventilation, rescue, etc.

The Agency agrees that the best way to address the valid concerns of these rulemaking participants is to adopt a separate paragraph on training. This approach will not only stress the overall importance of training in a permit-required confined space entry program, but will ensure consistency among the different elements required for each class of employees and will allow OSHA to treat additional considerations supported by the record.

OSHA has not provided specific training elements in the text of paragraph (g). Many of the elements of training are listed in paragraphs (h), (i), (j), and (k) for authorized entrants, attendants, entry supervisors, and rescue personnel, respectively. These other paragraphs succinctly state the duties of these individuals, and paragraph (g) requires them to be trained in these duties. Other sources also provide guidance in selecting elements of training for employees involved in permit space entry operations. For example, ANSI Z117.1–1989 (Ex. 129) lists specific elements for authorized entrants, attendants, entry supervisors, and personnel performing testing for entry operations. Employers can utilize these sources of information in developing programs for teaching employees about permit space entry operations and the hazards involved.

Paragraph (g)(1) of the final rule requires employers to provide training so that employees whose work is regulated by §1910.146 acquire the understanding, knowledge, and skills necessary for the safe performance of the duties assigned under that section. This provision combines the training requirements proposed under paragraph (f), (g), and (h) in one place.

The Agency proposed to establish training requirements for entrants, attendants, and persons to whom the employer would delegate authority to be in charge of an entry. OSHA did not specify the experience or training necessary for employees who would initially evaluate spaces or who would formulate the requirements and the procedures that employees must use for safe entry into permit spaces. Also, OSHA did not specify what experience or training would be necessary to qualify a person to perform pre-entry testing and verification of permit conditions.

In Issue 1 of the proposal, OSHA asked if the Agency should set experience, proficiency, or other criteria to qualify employees assigned to evaluate spaces initially or those assigned to develop appropriate entry procedures. OSHA also asked what those criteria should be, and if persons

with the training and experience equivalent of a certified safety professional (CSP), a registered professional safety engineer (PE), an industrial hygienist, or a marine chemist should qualify. OSHA also wanted to know if the Agency should specify experience and training requirements for persons who perform the pre-entry tests or who monitor conditions during entry and, if so, what these employees should need to know and understand.

OSHA received many comments on this issue (Ex. 14–11, 14–27, 14–35, 14–42, 14–43, 14–44, 14–45, 14–62, 14–88, 14–111, 14–118, 14–126, 14–137, 14–147, 14–157, 14–161, 14–178, 14–179, 14–182, 14–184, 14–185, 14–189, 14–193, 113, 138). The issue was also discussed during the public hearings (Washington Tr. 466; Houston Tr. 631, 1056–1057; Chicago Tr. 150–151, 314–315, 320, 370–371, 610–611, 636–637, 642).

All the commenters agreed that employees entering and attending confined spaces had to be properly trained or experienced in the duties they were to perform. Some of them (Ex. 14–11, 14–44, 14–45, 14–63, 14–163, 14–173, 14–288; Chicago Tr. 320, 642) suggested that the requirement contain specific criteria either in a separate list or in the rule itself. For example, Warren Industries (Ex. 14–44) suggested a performance standard with a list of major topics. They stated:

> OSHA should only specify the required training to the extent that they specify that "All persons dealing with Confined Spaces must have special training on these subjects" and then list certain major topics to be covered.

Marshall Hicks of the Utility Workers' International Union (Chicago Tr. 642) testified that OSHA should be more specific in its requirement. He stated:

> We would propose that the OSHA regulation specifically state what the training requirements are and the qualifications for persons who will be making a determination of whether a confined space is safe for entry or not. We believe that that particular individual is going to be determining whether or not the worker who enters is going to be able to exit and we think that the specific qualifications in training ought to be set forth in the regulation for that individual as well as others.

However, the majority of commenters recommended that OSHA should require training in a performance-oriented manner, without specifying the content of that training or the qualifications of the trainer (Ex. 14–27, 14–35, 14–43, 14–137, 14–147, 14–157, 14–161, 14–178, 14–179, 14–182, 113, 138; Houston Tr. 631). These rulemaking participants argued that there was no practical way for OSHA to itemize the training for employees because of the wide variety of hazards posed by the different types of permit spaces encountered throughout general industry. They maintained that experience was frequently the best qualification for persons who determine the appropriate measures for safe permit space entry operations. For example, Union Carbide (Ex. 14–88) stated:

> Union Carbide endorses the "competent person" concept adopted in the lockout/tagout proposed rule as the acceptable standard for proficiency. We have found that experience can be more valuable in this area than formal training.

United Technologies (Ex. 14–178) agreed that OSHA should not set detailed training criteria, stating:

> OSHA should not set experience, proficiency or other criteria for qualified individuals who are expected to evaluate spaces. Training should be a requirement but the level of training will vary with the responsibility of the individual and the complexity of the entries. The training should be appropriate for the hazards to be encountered. A uniform training requirement can only cover suggested topics (i.e. definitions, using test equipment etc.). Specific requirements will not be appropriate for many of the situations encountered. In some cases spaces may be of sufficient complexity as to require evaluation by a trained safety/Health professional.
>
> For basic programs with more limited hazards and types of spaces, adequate training may be as little as attending a short formalized training session. Field testers must be trained in hazard recognition, use of instrumentation and field checks to insure that instruments are functioning properly. Their training should be commensurate with their responsibilities. The Confined Space Program must stand alone and be evaluated on the needs and concerns of the location and hazards for which it is designed.

Ray Witter, one of OSHA's expert witnesses (Houston Tr. 631), testified as follows in support of these comments:

> There have been many comments suggesting that OSHA should specify the qualifications required to be a certified trainer. This is an impossible task so I recommend that OSHA should not even attempt to set such criteria. OSHA has set performance criteria for all other requirements and training should be no different. Thus the qualifications of the trainers must vary greatly depending on the situation facing the employer.

The Agency agrees that the wide-ranging hazards found and the various control measures to be used to control them makes specifying the types of material to be covered in training courses for workers involved in permit space entry a nearly impossible task. Furthermore, it is OSHA's policy, as set out in section 6(b)(5) of the OSH Act to state safety and health standards in terms of performance desired wherever possible. Therefore, paragraph (g)(1) does not specify the courses to be provided or otherwise detail the exact training to be provided employees involved in permit space entry operations; rather, the standard requires training employees so that they acquire the understanding, knowledge, and skills necessary to perform their duties, as required by final §1910.146. The Agency believes that this approach sets the desired objective of the training, that is, to train employees to comply with the standard.

Most rulemaking participants believed that OSHA should not require the use of professionally certified individuals, such as CSPs, PEs, certified industrial hygienists, and Marine Chemists (Ex. 14–27, 14–44, 14–45, 14–111, 14–147, 14–184; Chicago Tr. 34). For example, the Northwest Pipeline Corporation (Ex. 14–27) stated:

> OSHA should not specifically require certain criteria such as professional engineer or safety professional certification, in order to qualify for initial evaluation and procedure development. Specifications of this type would be contrary to the overall performance oriented language [of] which the rest of the document is composed.

Warren Industries (Ex. 14–44) noted that professional certification did not automatically qualify a person to evaluate permit space hazards, as follows:

> There should be NO requirement that ties the criteria for experience or proficiency to such people as CSPs, RPSEs, IHs [industrial hygienist], or Marine Chemists. Being in one of these categories in no way gives automatic qualifications for dealing with Confined Spaces and their unique problems. While the experience and education of these groups of people could be valuable in their learning the additional specifics of Confined Spaces, there is no reason to believe that a person with equivalent backgrounds would automatically be qualified to handle Confined Spaces.

S.C. Johnson & Son. (Ex. 14–45) also questioned the validity of automatic acceptance of professional certification, stating:

> A registration or certification as a safety professional (e.g., a registered professional safety engineer, industrial hygienist, a marine chemist) will not automatically qualify that person to evaluate spaces and to develop appropriate entry procedures. I have met many registered safety professionals and CIHs [certified industrial hygienist] who have little or no real world experience in the use of simple testing equipment (e.g., never used a detector tube, never calibrated a combustible gas/oxygen meter). Their entire "understanding" of confined space entries is theoretical in nature.

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Texaco, USA (Ex. 14–147) noted that, while registration as a safety and health professional gives a person a portion of the training needed to identify permit space hazards, additional specific training in permit spaces would be necessary. They argued:

> The fact that a person has been classified as a CSP, a registered professional engineer, an industrial hygienist, or a maritime chemist should not automatically qualify that person as having sufficient training and experience to evaluate spaces and develop appropriate entry procedures. Although it is likely that professionals with these designations have the proper academic background, they, as well as anyone else, should not be designated as qualified until training in confined space hazard evaluations and entry procedures has been received.

The Independent Liquid Terminals Association (Ex. 14–184) identified the burden that would be placed upon small businesses, if certified or registered professionals were required, as a major reason for not including this type of provision in the final permit space standard. This commenter was concerned that small employers would be forced to hire a contractor to evaluate the permit space and to develop entry procedures even though a person capable of performing those duties, but without the proper professional certification, was available.

There were other rulemaking participants, however, who supported the required use of certified or registered professionals (Ex. 14–42, 14–62), particularly in maritime industries. The National Fire Protection Association (Ex. 14–42) supported this view, stating:

> A similar application of the two-tier approach used by the marine industry would require use of a professionally qualified tester for those confined spaces containing or capable of producing a toxic atmosphere during entry or work in the confined space or which pose a risk from fire or explosion. In these instances a professionally qualified tester, like a Marine Chemist or other certified professional, with demonstrated experience and training in evaluating confined spaces should be required to perform initial inspections and tests of the confined spaces prior to any entry.
>
> Confined spaces whose only hazard is oxygen deficiency, engulfment, or other mechanical hazards may be tested and inspected by a person trained to recognize, evaluate and control these hazards.

The Shipbuilder's Council of America (Ex. 14–62) agreed with the need to specify proficiency and knowledge criteria. They argued that small employers who do not have qualified individuals should hire a contractor to evaluate the hazards in their permit spaces, as follows:

> OSHA should determine experience, proficiency and knowledge criteria similar to those in 29 CFR 1915.7 [29] for the person who is qualified to evaluate the hazards associated with entering and working in confined spaces. Small businesses which do not have such persons available should be required to contract with an outside firm to perform this work.

OSHA has determined that it is not appropriate to require professional certification for persons who evaluate the hazards of permit spaces and who determine the procedures needed to control those hazards. The Agency agrees with the commenters who maintained that professional certification is not an automatic guarantee of competence. (However, OSHA recognizes that Marine Chemists are required to have extensive experience with permit space entry hazards.) Additionally, professional certification may not always be necessary for the safety of authorized entrants. The extent of knowledge required of certified safety and health professionals may simply not apply to an employer's particular permit space hazards. In such cases, a person with knowledge of the unique aspects of the employer's permit spaces may be better able to protect authorized entrants from the relevant hazards.

[29] Section 1915.4 defines "competent person." as:

> The term "competent person." for purposes of this part means a person who is capable of recognizing and evaluating employee exposure to hazardous substances or to other unsafe conditions and is capable of specifying the necessary protection and precautions to be taken to ensure the safety of employees as required by the particular regulation under the condition to which it applies. For the purposes of Subparts B, C, and D of this part, except for 1915.35(b)(8) and 1915.36(a)(5), to which the above definition applies, the competent person must also meet the additional requirements of 1915.7.

Paragraph (b) of §1915.7 sets forth the criteria for designating "competent persons" as follows:

> (b) *Criteria.* The following criteria shall guide the employer in designating employees as competent persons:
>
> (1) Ability to understand the meaning of designations on certificates and of any qualifications relating thereto and to carry out any instructions, either written or oral, left by the National Fire Protection Association Certified Marine Chemist or person authorized by the U.S. Coast Guard referred to in 1915.14.
>
> (2) Ability to use and interpret the readings of an oxygen indicator and a combustible gas indicator. The ability to use and interpret the readings of a carbon monoxide indicator and a carbon dioxide indicator, if the operations involved such hazardous gases.
>
> (3) Familiarity with and understanding of Subparts B, C, D, and H of this part.
>
> (4) Familiarity with the structure and knowledge of the location and designation of spaces of the types of vessels on which repair work is done.
>
> (5) Capability to perform the tests and inspections required by Subparts B, C, D, and H of this part and to write the required logs.

Therefore, the final rule does not require that a CSP, PE, certified industrial hygienist, or Marine Chemist perform the permit space evaluation or develop the hazard control measures to be used during entry. Paragraph (g)(1) does require, however, that the person performing these duties have the understanding, knowledge, and skills necessary to perform this task. OSHA would recognize such safety professionals as having the generalized understanding, knowledge, and skills required; however, they would also have to have experience with the type of permit space found in the workplace. As noted earlier, Marine Chemists do have extensive experience with the types of permit spaces found in the maritime industry. Their experience and education would also be recognized in non-maritime workplaces without the need for supplemental training if the types of permit spaces in those workplaces were found to be comparable to those in the maritime industry. (As noted under the discussion of paragraph (a) earlier in this section of the preamble, OSHA is currently exploring the possibility of expanding the scope of Subpart B of Part 1915 to cover confined spaces throughout shipyards. Based on the rulemaking record on Subpart B, OSHA will determine whether there is a unique need for Marine Chemists in those workplaces.)

Many commenters addressed training for employees who perform pre-entry testing or who monitor conditions during permit space entry operations (Ex. 14–27, 14–35, 14–42, 14–43, 14–44, 14–45, 14–62, 14–88, 14–118, 14–126, 14–147, 14–161, 14–179, 14–182, 14–185). Some commenters gave specific criteria for the training of employees who test or monitor confined spaces (Ex. 14–42, 14–44, 14–45, 14–182). For example, NFPA (Ex. 14–42) suggested a more specific rule to qualify testers and monitors:

> Training for the "qualified tester" would not require the same exposure to the breadth of hazards [as Marine Chemists require], but should stress the importance of testing every space prior to entry, what to do when results are unacceptable, and link the "qualified tester" with the "professional tester" in some follow-up capacity. The "qualified tester" should also be required to complete some minimum number of confined space inspections and tests of atmospheres prior to being designated by the employer.
>
> * * * * *
>
> The emphasis should be placed upon the ability of the testers to recognize various confined spaces and the potential hazards and then evaluate those hazards with the proper techniques (testing of the atmosphere or other). The case histories continue to point

out that if spaces had been evaluated many of the fatalities would not have occurred. Testers need to demonstrate performance in the evaluation phase of the recognition, evaluation and control system.

For those employers without staff professional testers, these individuals could be hired in a consultant capacity to assist with the development of the safe work practice and identify instances requiring the more advanced level of testing capability. The consultant could then be used on an as needed basis to actually test and inspect spaces. This practice is presently followed by some segments of industry who use NFPA Certificated Marine Chemists or Certified Industrial Hygienists to inspect and test storage tanks in refineries and underground storage tanks prior to removal and disposal.

In its recommendations, NFPA presented an extensive list of subjects in which they thought testers should be knowledgeable. The subjects included in the list ranged from test instrument calibration and use to hazard controls and rescue.

S.C. Johnson & Son, Inc. (Ex. 14–45), suggested similar criteria for employees who test and monitor permit spaces. Although their list was less extensive, it also included subjects, such as inspecting for safety hazards and the use of personal protective equipment, that were not directly related to testing.

Two other commenters (Ex. 14–44, 14–182) stated that personnel performing pre-entry testing and monitoring should be trained in field calibration and response checks, in limitations of the monitoring equipment, and in interpretation of results.

Other commenters stated that OSHA should not specify the criteria for individuals who perform pre-entry tests or who perform monitoring of the permit space (Ex 14–27, 14–35, 14–43, 14–126, 14–179). These commenters supported a more performance- oriented approach to the rule. For example, Transco Energy Company (Ex. 14–35) stated:

> OSHA should not establish experience and training requirements for persons who perform pre-entry tests and monitor conditions during entry. A comment to the effect of, "An individual familiar with the manufacturers' testing and calibration equipment and trained in Company testing procedures shall conduct pre-entry and/or continuous monitoring of the space," should be specified instead. Rigid training and experience specifications cannot adequately cover variations in the myriad of testing equipment currently on the market.

The Motor Vehicle Manufacturers Association (MVMA, Ex. 14–179) also supported the use of performance language, as follows:

> In any case, MVMA believes it is inappropriate for OSHA to specify any requirements, proficiency or other criteria to qualify individuals for any of these jobs. Training will be necessary but OSHA should allow employers to identify and delegate responsibility for these assignment based on training and experience of individuals.

The proposal did not contain any requirements pertaining to the training of employees performing testing or monitoring of permit spaces, unless the employee was performing such duties in the role of attendant, authorized entrant, or entry supervisor. The response to the issue of whether or not employees performing such testing or monitoring should be trained indicated overwhelmingly that these employees need to be knowledgeable in certain areas if the results of the testing or monitoring are to be meaningful. The rulemaking record indicates that those using test instruments need to be familiar with the use and calibration of the instruments, at a minimum. If these employees are involved in determining whether acceptable entry conditions have been achieved, they also need to know about the limitations of the instruments being used and about the meaning of the results obtained. If these employees also have to select the equipment to be used, they must also be trained in the selection of the proper equipment. The need for training employees performing testing and monitoring of permit spaces is clear. Therefore, the final rule adopts language that requires the employer to provide training so that all employees regulated by the standard will have the necessary understanding, knowledge, and skills.

On the other hand, the Agency is not convinced that training requirements for employees performing the testing or monitoring, or for any other employee having duties under final §1910.146 for that matter, can be specified with any precision. It is clear from the record that employers having permit space programs in place currently require attendants, authorized entrants, and entry supervisors to perform duties that are different across the various programs. Thus, for example, one employer might have the attendant perform the testing of the atmosphere within a permit space; another might have testing done by a specially trained person without other permit space duties; and a third might have the entry supervisor perform this duty. The person conducting the testing might have different responsibilities under each of these scenarios.

For these reasons, OSHA has determined that a performance- oriented approach is necessary for setting criteria on employee training, regardless of the duties involved. As noted earlier, the duties of authorized entrants, attendants, entry supervisors, and rescue personnel are spelled out in detail in paragraphs (h), (i), (j), and (k) of the final rule. Paragraph (g)(1) requires the training to impart the understanding, knowledge, and skills necessary for the safe performance of duties assigned under those paragraphs. In this way, the Agency is requiring the employer to provide whatever training is necessary to achieve this goal. The performance language used in paragraph (g)(1) will allow the employer to develop and implement the most effective confined space training program to meet the needs of the specific workplace. At the same time, by requiring employees to be trained in the duties addressed by §1910.146 and by specifying what those duties are (in paragraphs (h) through (k), in particular, and in other paragraphs of the final rule generally), the final rule sets forth guidance as to what how the training must be directed and what its content should be.

Paragraph (g)(2) of the final rule sets out the conditions under which training would have to be provided.

This provision had no counterpart in the proposed rule. Several rulemaking participants (Ex. 14–63, 14–151, 14–163, 14–208, 14–214; Chicago Tr. 316) recommended that training be provided under certain conditions. For example, the Communications Workers of America (Ex. 14–206) stated that "retraining is a very important issue" and recommended that OSHA specifically require refresher training in the final rule because of the decreasing frequency of confined space entry, at least among members of the CWA. Other commenters (Ex. 14–151, 14–214) were concerned that the proposed rule did not specify when the initial training was to be provided. The American Federation of State, County and Municipal Employees (Ex. 14–151) suggested that the rule require that training be provided before any entry is allowed.

Because of these concerns, OSHA is adopting provisions setting forth the circumstances under which training is required. OSHA has found, where training has been addressed in its standards, that refresher or ongoing safety instruction has invariably been an important component of training programs. Requirements for ongoing or refresher training can be found in many other OSHA standards, such as §1910.120, *Hazardous waste operations and emergency response*, §1910.147, *Control of hazardous energy sources (lockout/tagout)*, §1910.1025, *Lead*, and §1928.51, *Roll-over protective structures*

(ROPS) for tractors used in agricultural operations. OSHA has therefore adopted provisions specifying the conditions under which training is required by the final rule. These provisions address initial training, training based upon changes affecting safe permit space entry operations, and refresher training. The following paragraphs describe and explain each of the conditions triggering the requirement to train employees assigned duties under §1910.146.

Paragraph (g)(2)(i) requires training before an employee is first assigned duties under this section. As noted earlier, some commenters recommended that OSHA require that employees be trained before permit space operations begin. The rulemaking record strongly indicates that lack of training is one of the major causes of deaths and injuries resulting from permit space entries. The record also demonstrates that employees who have not been trained adequately endanger fellow employees as well as themselves. Because of the danger involved in allowing untrained employees to take part in permit space entry operations, OSHA is requiring employees to be trained before first being assigned duties under final §1910.146. OSHA is not providing any additional delay for training beyond the effective date. However, employees who are currently performing duties outlined in the standard and who have previously been trained need further instruction only insofar as they are unfamiliar with the hazards involved and must change their work practices so as to conform to §1910.146. The employer must still certify the training of these individuals, as required by paragraph (g)(4). Additionally, OSHA will accept on-the-job training as long as the employee involved is under the direct supervision of a trained individual and has received sufficient instruction to enable the trainee to work safely at his or her level of training.

Paragraphs , (g)(2)(iii), and (g)(2)(iv) of the final rule address the issue of refresher training. Paragraph (g)(2)(ii) requires training before there is a change in assigned duties. Such changes could be the result of new equipment or techniques introduced into the entry operations, promotions, or simple reassignments. If an employee has been previously trained in the new duties, then additional training is not required under this paragraph, provided the employer has no reason to believe that there are inadequacies in the employee's knowledge or use of the relevant permit space procedures. (If there is reason to believe such inadequacies exist, training is required under paragraph (g)(2)(iv).)

Paragraph (g)(2)(iii) requires training before there is a change in permit space operations that presents a hazard about which an employee has not previously been trained.

Paragraph (g)(2)(iv) requires training whenever the employer has reason to believe that there are deviations from the permit space entry procedures or that there are inadequacies in the employee's knowledge or use of these procedures.

Several rulemaking participants (Ex. 14–50, 14–61, 14–63, 14–82, 14–151, 14–163, 14–214) recommended that the standard require refresher training and evaluation of employee knowledge and skills to maintain employee knowledge and skills. For example, the American Federation of State, County and Municipal Employees (AFSCME, Ex. 14–151) made the following comment:

> AFSCME further believes that all training must be completed before any entry into a confined space is allowed and that training must be repeated on an annual basis or any time the hazards associated with the entry change.

Mr. Timothy Grabenstein (Ex. 14–163) supported periodic evaluation of the effectiveness of training, as follows:

> Also periodic follow-up evaluation must be included as part of this rule making to assure competency.

OSHA acknowledges the need for refresher training. Paragraphs (g)(2)(ii), (g)(2)(iii), and (g)(2)(iv) require "refresher" or "follow-up" training whenever there is a demonstrated need for it. Changes in assigned permit space program duties or exposure to hazards for which an employee has not been trained are obvious indications of a need for additional or refresher training. Similarly, any deficiency noted in an employee's work performance that is related to the safety and health of entrants would probably be a strong indication of the need for training for that employee. If training proves to be insufficient to improve the employee's performance (eliminate the unsafe acts), the employer then might consider other means of action, such as clarification of the procedures involved or disciplinary action. However, OSHA believes that training is normally the primary corrective action to be taken. Other evidence of the need for additional training may be brought out in the review of permit space program under paragraphs (d)(13) and (d)(13) of the final rule. Certainly, incidents during entry operations that employees were nearly injured are evidence of a possible need for additional training. The Agency believes that paragraph (g)(2) of the final rule will ensure that employers provide ongoing training to their employees and evaluate their permit space programs to confirm that employees have the understanding, knowledge, and skills needed for safe permit space entry operations.

Paragraph (g)(3) of the final rule requires the training to establish employee proficiency and to introduce new or revised procedures, as necessary, to assure compliance with this final rule.

As noted earlier under this discussion of paragraph (g), OSHA has decided based on the rulemaking record to set performance- oriented requirements for permit space training. Although the Agency has concluded that it is inappropriate to set specific criteria for the areas in which training is to be provided, OSHA has determined that it is necessary to set the overall objective for the training program itself. Paragraph (g)(3) of the final rule reflects this determination by requiring the training to establish proficiency in the tasks performed under §1910.146 and to introduce new or revised procedures developed under this section.

Paragraph (g)(4) of the final rule requires the employer to certify that employee training required by paragraphs (g)(1) through (g)(3) has been accomplished. This certification must contain each employee's name, the signature or initials of the trainers, and the dates of training.

As noted under the discussion of paragraphs (f)(4), (f)(5), and (f)(6), several commenters (Ex. 14–80, 14–94, 14–118) suggested that lists of trained employees be kept with training records. Local 660 of the Service Employees International Union (Washington Tr. 383) suggested that the dates of training certification be listed on each entry permit. The State of Maryland Occupational Safety and Health Program (Ex. 14–63) suggested that training records or certifications be maintained.

On the other hand, Monsanto (Ex. 14–170) urged the Agency not to adopt a certification requirement, as follows:

> Monsanto also believes that extensive certification of training, such as is required in the recent lockout/tagout standard, is a paperwork burden that is unnecessary for safety or for compliance checking and we would strongly urge that concept not be included in this or any future standards. It adds only to the burden of compliance and has very little to do with effective training or effective hazard control.

OSHA strongly believes that certification of employee training provides a valuable record to employers, employees, and OSHA in determining whether or not required training has

been accomplished. Standards on employee training commonly incorporate requirements for the certification of training, and OSHA has not found compliance with these rules to be a problem. The employer need not fill out extensive forms or individual certificates to meet this requirement. The employer could certify the training of any number of employees on a list or roster just as effectively as through the use of individual certificates. In fact, OSHA's experience under the certification requirements of other standards indicates that employers typically use existing training records to meet these requirements.

Paragraph (h), Duties of authorized entrants.

An authorized entrant is an employee authorized by the employer to enter a permit space. This is the person who faces the greatest risk of death or injury from exposure to the hazards contained within the space. Although the permit program is intended to provide protection to authorized entrants during permit space entry operations, the entrants themselves must also perform duties to assure their own safety. The employer is responsible to ensure that authorized entrants perform these duties. This is accomplished by means of training, communication of effective work rules, and internal administration.

Paragraph (h) of the final rule, which is based, in part, on proposed paragraph (e), addresses the duties required of authorized entrants. As discussed previously, paragraph (d)(8) of the final rule requires the employer to designate the employees who will have roles (such as authorized entrants) in entry operations, to identify the duties of each such employee, and to train those employees to perform their duties. OSHA has determined that while the training required for all personnel involved in entry operations under paragraph (d)(8) can properly be covered in a single paragraph (§1910.146(g)), the duties of the three classes of employees (authorized entrants, attendants, and entry supervisors) differ sufficiently that those duties need to be addressed in separate paragraphs. Training under paragraph (g) of the final rule must focus on the duties spelled out in these paragraphs.

Paragraph (h)(1) of the final rule requires entrants: (1) to know the hazards that may be faced during entry, including information on the mode of exposure, (2) to be able to recognize the signs or symptoms of exposure, and (3) to understand the consequences of exposure to the hazards.

This provision is essentially the same as proposed paragraph (e)(1), which would have required entrants to know the hazards to which they may be exposed, including only the signs or symptoms and the consequences of exposure. The Service Employees Union (Washington Tr. 428) testified that death and injury in confined spaces can be caused by skin penetrating agents and that entrants should have an understanding of the hazardous chemicals and materials to which they may be exposed, including its mode of action, so that they can better protect themselves.

OSHA believes this is a valid point. For toxic substances, the mode of exposure could be by inhalation or by dermal absorption. Unless employees are knowledgeable about the mode of exposure, they may not fully understand the nature of the hazard involved. As noted in the preamble to the proposal (54 FR 24093), the Agency believes that authorized entrants who know the permit space hazards they may confront, who can recognize the effects of those hazards, and who can understand the consequences of exposure will be significantly more likely to detect a hazard in time for successful rescue. Therefore, OSHA has included the Service Employees Union's recommendation in the final rule.

OSHA notes that, if the employer knows what substance or material will be present in the permit space and if a Material Safety Data Sheet for that substance is required to be present at the workplace by the hazard communication standard (§1910.1200) information concerning that substance, including its mode of action, will be readily available at the worksite and accessible to all personnel involved in the permit space entry.

Another commenter (Ex. 14–62) suggested that the rule contain a provision requiring the entrant to know the characteristics of a permit space. They argued that "[o]ne of the key elements of any confined space training program is to ensure the entrants can recognize a confined space before they have to enter one."

OSHA has not made the suggested change. The Agency believes that, given the requirements in paragraphs (c)(2), (g), and (h)(1) of the final rule, such a requirement is not needed. Paragraph (c)(2) requires employers to inform their employees of the existence and location of permit spaces; paragraph (g) requires employees to be trained in the understanding, knowledge, and skills needed to perform their duties safely; and paragraph (h)(1) requires authorized entrants to be trained in the hazards of the permit space to be entered. Additionally, the particular permit space and the purpose of the entry are required to be entered on the permit under paragraph (f). OSHA believes that compliance with these provisions will adequately inform authorized entrants of what a permit space is and how to recognize one.

Paragraph (h)(2) requires that entrants properly use equipment as required by paragraph (d)(4) of the final rule. Paragraph (d)(4) requires employers to provide employees with the equipment necessary for safe entry operations at no cost to employees, to maintain that equipment, and to ensure that the equipment is used properly. The failure to provide and ensure the proper use of personal protective equipment has been a factor in many of the permit space fatalities and injuries documented in the rulemaking record. Therefore, the Agency believes a reference to the requirement for the use of protective and rescue equipment is appropriate to stress the importance of this provision. Additionally, stating the reference under paragraph (h) indicates clearly that it is one of the required duties of an authorized entrant and that it must, therefore, be the subject of training required under paragraph (g) of the final rule.

Paragraph (h)(2) of the final rule has been taken from proposed paragraph (e)(3), which would have required authorized entrants to be aware of the necessary protective equipment, be provided with this equipment, use it properly, and be aware of barriers and of their proper use. The Agency has not carried forward these more detailed provisions from the proposal because they would be redundant with paragraph (d)(4) of the final rule. OSHA believes that it is better to address these provisions in one place in the final standard so as to avoid any misinterpretation that might result from having two requirements that address the same subject matter but that are worded differently.

One commenter (Ex. 14–151) suggested that OSHA require all authorized entrants to wear monitoring devices that detect oxygen deficiency and other atmospheric hazards and that can activate an alarm if conditions within the permit space become hazardous.

OSHA has not adopted this recommendation. Some permit spaces do not pose atmospheric hazards. For example, a permit space could pose only mechanical hazards. In such cases, a monitoring device would serve no useful function. Additionally, the Agency believes that, even where

atmospheric hazards predominate, isolation of the space, testing of the atmosphere, and ventilation can be effective means of controlling those hazards. The successful permit space programs described in the record amply demonstrate this. OSHA believes that personal monitoring devices can be used to facilitate compliance with the requirement for effective communication with attendants; however, there are other effective options for protecting employees from atmospheric hazards.

Paragraph (h)(3) of the final rule requires that the entrant communicate with the attendant as necessary to enable the attendant to monitor entrant status and to enable the attendant to alert them of the need to evacuate the space. OSHA believes that the authorized entrant's communication with the attendant provides information that the attendant needs in order to determine if the entry can be allowed to continue. Depending on the types of atmospheric contaminants that might be present within a permit space, subtle behavioral changes detected in the authorized entrant's speech or deviation from set communication procedures could alert the attendant that it is necessary for the authorized entrant to evacuate the space or be rescued. Additionally, the attendant needs to be able to communicate with authorized entrants to order them to evacuate the space in an emergency.

Paragraph (h)(3) of the final rule is based on paragraph (e)(2) of the proposal. Proposed paragraph (f)(3)(i) contained a corresponding requirement that attendants maintain contact with authorized entrants. Although the two proposed provisions addressed the same topic (albeit from different perspectives), they were not worded consistently. Proposed paragraph (e)(2)(i) required authorized entrants to "[m]aintain contact with the attendant"; paragraph (f)(3)(i) required the attendant to "[m]aintain effective and continuous contact with authorized entrants during entry". Several commenters (Ex. 14–80, 14–94, 14–109, 14–118, 14–150, 14–157, 14–170, 14–188) requested clarification of the two proposed requirements. Two (Ex. 14–80, 14–109) noted the inconsistency in language between the two provisions. Some of these commenters (Ex. 14–80, 14–94, 14–150, 14–188) objected to the word "continuous" in proposed paragraph (f)(3)(i). They argued that this term was unclear, undefined, and impractical. The International Brotherhood of Teamsters suggested that both provisions use the phrase "effective and continuous" to describe the duty involved. They argued that schemes that provide, as the only means of communications, an electronic monitoring devices that transmit a signal at periods up to several minutes do not provide effective communications with the authorized entrants. On the other hand, most of those commenting on the two provisions (Ex. 14–94, 14–118, 14–157, 14–170) recommended that the final rule contain a flexible requirement that recognizes any effective means of communicating with employees in the permit space.

OSHA agrees that the language in the two paragraphs addressing communications between the attendant and the authorized entrants must be consistent. They are, after all, meant to accomplish the same objective, that is, to enable the attendant to monitor entrant status and to alert them of the need to evacuate the space. It is important for the attendant to know whether or not authorized entrants are in danger. At the first signs of impairment of function, the attendant must take steps to alert entrants to the danger involved and to evacuate them from the permit space. Conversely, it is important for the entrants to remain in contact with the attendant. If they recognize any symptoms of exposure to hazardous substances or if they are otherwise in immediate danger, they must be able to contact the attendant as quickly as possible.

To assure these common objectives, OSHA has adopted language in paragraphs (d)(4)(iii), (h)(3), and (i)(5) of the final rule that requires the establishment of communications enabling the attendant to monitor the status of authorized entrants and to alert them of the need to evacuate the space. The language of these provisions is performance oriented, allowing any effective means of accomplishing the goal set by the two paragraphs. Successful permit space programs currently in effect use such systems as two-way radios, television or other continuous electronic monitoring equipment in combination with alarms, and voice contact as effective methods of communication between attendants and authorized entrants. While these types of systems (because they were selected by the employer involved on the basis of experience) are acceptable, the exact type and extent of communication needed to meet paragraph (h)(3) of the final rule are dependent on the hazards that might arise and the operations being performed within the permit space. For example, work that must be performed in IDLH atmospheres (because engineering controls are infeasible) might necessitate the use of continuous monitoring equipment. In contrast, authorized entrants performing work in spaces that pose only mechanical hazards would need a communication system that provides only periodic monitoring.

Paragraph (h)(4) of the final rule requires authorized entrants to alert the attendant when the entrant recognizes any warning sign or symptom of exposure to a dangerous condition or when the entrant detects a prohibited condition. An authorized entrant who recognizes the signs or symptoms of a hazardous condition or who detects a prohibited condition maximizes his or her own chances of evacuating safely in the same permit space by exiting the space in accordance with paragraphs (h)(5)(ii) and (h)(5)(iii). The entrant ensures that other entrants are protected by informing the attendant of the presence of these conditions, which make the space hazardous to other entrants as well. [30]

Paragraph (h)(4) of the final rule is based on proposed paragraph (e)(2)(ii). The proposed provision required simply that the authorized entrant alert the attendant when self- initiating evacuation from a permit space. OSHA has revised the language from the proposed paragraph for consistency with paragraph (h)(5) of the final rule. Paragraphs (h)(5)(ii) and (h)(5)(iii) list the conditions under which authorized attendants are required to exit the permit space (that is, "self-rescue"). The text from these two paragraphs has simply been repeated in paragraph (h)(4) for clarity.

Several commenters (Ex. 14–118, 14–157, 14–161, 14–170) stated that OSHA should emphasize training of authorized entrants to exit permit spaces, because

[30] Alerting other authorized entrants can also improve their changes of escape as well. However, there are several reasons why OSHA is not requiring this. First, the permit space may well be so large that the entrant who detects a hazard cannot quickly or efficiently communicate with other authorized entrants. Under paragraph (i)(5) of the final rule, the attendant is required to have the means of communicating with all authorized entrants in the space. The quickest and most effective means of ordering the evacuation of the space is therefore normally through the attendant. In fact, this is required under paragraph (i)(6) of the final rule. Furthermore, the Agency does not believe that it is appropriate to require one employee to risk injury or death to warn another. While in some cases it may be reasonable for entrants to inform each other of the presence of uncontrolled hazards and in other cases an employee may voluntarily risk injury or death to warn his or her fellow employees, OSHA has determined that the final rule should only require authorized entrants to inform attendants. OSHA notes that the standard does permit entrants to alert other authorized entrants when the presence of prohibited conditions or warning signs or symptoms are detected.

the employer can train an authorized entrant to understand the consequences of exposure to permit space hazards and the need to evacuate but cannot ensure that an authorized entrant will exit a permit space when necessary.

In response, OSHA notes that training is not the only measure an employer can take to ensure that employees follow work rules. Company attitude and policy towards permit space safety can also influence employee behavior. The Agency notes that many of the permit space incidents reported to OSHA occurred because supervisors failed to see that employees complied with the employer's procedures for safe entry. OSHA has determined that it is necessary to set clear requirements which, when followed conscientiously by employers, will minimize the likelihood of permit space incidents.

Paragraph (h)(5) of the final rule requires the entrant to exit from the permit space as quickly as possible whenever the attendant or entry supervisor orders evacuation, whenever the authorized entrant recognizes any warning sign or symptom of exposure to a hazardous substance, whenever the entrant detects a prohibited condition, and whenever an evacuation alarm is activated. Given the speed with which permit space hazards can incapacitate and kill entrants, it is essential that the entrants evacuate permit spaces as soon as any one of the four conditions set out in paragraphs (h)(5)(i) through (h)(5)(iv) exists. As noted in the preamble to the proposal (54 FR 24093), OSHA believes that self-rescue will often provide the entrant's best chance of escaping a permit space when a hazard is present. Additionally, the time lost waiting for someone outside the space to commence rescue could be the difference between life and death. Also, narrowly configured openings of many permit spaces can make it very difficult for personnel outside those spaces to extricate victims of permit space hazards. Therefore, although OSHA recognizes that self-rescue may sometimes be impossible, the Agency stresses the importance of attempting self-rescue as a means of saving lives and minimizing injuries.

Paragraph (h)(5) of the final rule is based on proposed paragraph (e)(4), which would have required authorized entrants to exit the permit space, unless it was physically impossible to do so, whenever: (1) the attendant ordered evacuation; (2) an automatic alarm was activated; or (3) the authorized entrants perceived that they were in danger. OSHA has made some editorial revisions to the language of proposed paragraph (e)(4) in the course of drafting the final rule. For example, the phrase "unless it is physically impossible to do so" has been removed from the introductory text of the proposed provision. With this standard, as is the case with so many other standards, impossibility of compliance will be a factor to be evaluated in enforcement proceedings. Also, the Agency has included the phrase "entry supervisor" in paragraph (h)(5)(i) to reflect the entry supervisor's authority to terminate entry (as provided in paragraph (j)(3) of the final rule). Additionally, OSHA has replaced the word "automatic" with "evacuation" in paragraph (h)(5)(iv), in response to comments (Ex. 14–150, 14–168) noting that a workplace could contain many different automatic alarms, few of which may have anything to do with evacuation from a permit space. Those commenters suggested "evacuation" as a replacement for "automatic".

Several commenters (Ex. 14–161, 14–168, 14–178, 14–193) objected to the phrase "perceive that they are in danger" proposed in paragraph (e)(4)(iii). They stated that this language was too vague and was subject to misinterpretation and possible employee abuse. These commenters recommended that the provision be clarified.

OSHA has accepted this recommendation. Final paragraph (h)(5) sets out two separate conditions (paragraphs (h)(5)(ii) and (h)(5)(iii)) that address the need for evacuation of the permit space when hazards are recognized by authorized entrants. Paragraph (h)(5)(ii) requires authorized entrants to exit the space whenever they recognize "any warning sign or symptom of exposure to a dangerous situation", which they are required to know under paragraph (h)(1) of the final rule. Paragraph (h)(5)(iii) requires them to exit the space whenever they detect a prohibited condition, which, by definition, indicates that acceptable entry conditions are no longer present. The Agency believes that these two provisions in the final rule address the commenters' concerns about proposed paragraph (e)(4)(iii).

Paragraph (i), Duties of attendants.

One of the major problems in permit space entry operations is that, if an entrant within the space is injured or incapacitated, he or she cannot normally be seen from outside the space. For example, if an employee working inside a storage tank were to lose consciousness because of oxygen deficiency, employees working nearby might not see that the entrant is incapacitated, and the unconscious employee would probably die before anyone realized that something was wrong. In fact, many of the accident summaries in the record describe an employee who entered a permit space alone, was overcome by hazards within the space, and was not found until it was too late for rescue. Providing an attendant outside a permit space is a widely accepted method of monitoring the status of authorized entrants within the space, as well as conditions (relative to safety) within the space, and of providing for the summoning of rescue services. The need for an attendant outside permit spaces is recognized by other OSHA standards (for example, §§1910.252(b)(4)(iv), 1910.268(o), 1910.272(g)(3), and 1926.956), by various national consensus standards (for example, ANSI C2, ANSI Z49.1, and ANSI Z117.1), and by permit-required confined space programs currently in use by employers (Ex. 14–4, 14–57, 14–73, 14–88, 14–170, 14–209, 97, 104, 119, 143). As discussed earlier, paragraph (d)(6) of the final rule requires the employer to provide an attendant outside the space to monitor the status of authorized entrants and the conditions within the permit space.

Paragraph (i) of the final rule, which is based, in part, on proposed paragraph (f), sets forth the duties of the attendant. These duties include knowing and watching for the hazards that may be present within the space, monitoring the status of authorized entrants, keeping unauthorized employees out of the space, and evacuating entrants or summoning rescue services in the event of emergency. The introductory text of paragraph (i) requires the employer to ensure that these duties, as set out in paragraphs (i)(1) through (i)(10), are performed. As noted earlier, this is accomplished by means of training, communication of effective work rules, and administration.

Paragraph (i)(1) of the final rule requires the attendant to know the hazards that may be faced during entry, including information on the mode, signs or symptoms, and consequences of exposure. This provision is identical to a corresponding provision for authorized entrants in paragraph (h)(1) and is based on the first part of proposed paragraph (f)(2), which would have required the attendant to know of and to be able to recognize potential permit space hazards and on which OSHA received no substantive comment. For consistency with the corresponding provision in paragraph (h)(1), paragraph (i)(1) simply states that the attendants know the hazards that may be faced. OSHA believes that it is clear that knowing the hazards includes

being able to recognize them (except for being able to detect behavioral effects of hazards, which is addressed in paragraph (i)(2) of the final rule). The Agency has worded paragraphs (h)(1), (i)(1), and (j)(1) of the final rule identically because it is important that attendants, authorized entrants, and entry supervisors receive the same training on hazards and hazard recognition. The language from proposed paragraph (f)(2) addressing monitoring activities inside and outside the space has been placed in paragraph (i)(6) of the final rule.

Paragraph (i)(2) of the final rule requires the attendant to be aware of possible behavioral effects of hazard exposure on authorized entrants. This provision, as noted previously, is based on proposed paragraph (f)(2), which would have required attendants to be able to "recognize potential permit space hazards", and on proposed paragraph (f)(3)(ii)(B), which would have required the attendant to order the evacuation of the space when the attendant detects the behavioral effects of hazard exposure. OSHA believes that setting out the requirement for attendants to be aware of possible behavioral effects of hazard exposure will alert employers and attendants to the importance of this aspect of safe permit space entry operations. As noted earlier, subtle behavioral changes detected in the authorized entrant's speech or deviation from set communication procedures could alert the attendant that it is necessary for the authorized entrant to evacuate the space or be rescued.

Paragraph (i)(3) of the final rule requires the attendant to maintain a continuous accurate count of all authorized entrants in the permit space and to ensure that the means used to identify authorized entrants, under paragraph (f)(4) of the final rule, accurately identifies who is in the space.

This provision is equivalent to proposed paragraph (f)(1), which would have required an attendant to keep an accurate count of all persons within the space. The phrase "all persons" has been changed to "authorized entrants" in the final rule. It is important for the attendant to keep track of authorized entrants as they enter and exit the space. The count and identity of entrants will be necessary during rescue operations for the determination of whether all authorized entrants have been evacuated from the space.

In response to proposed paragraph (f)(1), some commenters (Ex. 14–63, 14–119) recommended that OSHA require some type of check- in, check-out procedure for tracking entrant entry and exit. They were concerned about improperly placing responsibility for this task on employees and about the attendant's being able to maintain an accurate count by memory only.

The employer is required to keeping track of authorized entrants within the space by listing them by name or by identifying them by some other means under paragraph (f)(4) of the final rule, discussed earlier in this section of the preamble. The system identified on the permit is required to enable the attendant to determine quickly and accurately which authorized entrants are inside the permit space. Paragraph (i)(3) of the final rule requires the attendant to ensure that this system is used to accurately identify who is in the permit space.

Paragraph (i)(4) of the final rule requires the attendant to remain outside the permit space during entry operations until he or she is relieved by another authorized attendant. This provision is substantially the same as that contained in the introductory text of proposed paragraph (f). Paragraph (i)(4) of the final rule also provides a note clarifying OSHA's intent concerning the issue of using attendants to perform rescue. It states that attendants may enter a permit space to attempt a rescue if it is allowed by the employer's permit program, if they have been properly equipped and trained, and if they have been relieved by another attendant.

Under paragraph (f)(4) of the proposal, attendants would have been forbidden to enter a permit space to attempt a rescue. The proposed language did not make clear, however, that, once relieved, the individual who had been acting as the attendant would no longer be the attendant for that particular permit space and then would not be precluded from attempting a rescue. Paragraph (f)(4) of the proposed standard mistakenly gave the impression that a person designated as an attendant could never enter a permit space to attempt a rescue.

In issue 10 of the hearing notice (54 FR 41463), OSHA requested comment on the Agency's proposed prohibition of rescue by confined space attendants. The Agency asked interested parties participating in the rulemaking if circumstances existed where OSHA should permit attendants to enter permit spaces for rescue purposes.

OSHA received considerable comment on this issue (Ex. 14–47, 14–64, 14–69, 14–72, 14–80, 14–88, 14–118, 14–125, 14–143, 14–148, 14–150, 14–151, 14–153, 14–157, 14–170, 14–171, 14–174, 14–177, 14–184, 14–193, 14–200, 14–201, 14–208, 14–210, 14–217). There was also considerable discussion of this issue in the public hearings (Washington Tr. 319, 388, 422–424, 465, 477–481, 517–518, 541–543, 552; Houston Tr. 630, 735–736, 787, 861, 865– 869, 896; Chicago Tr. 179, 191–192, 203–205, 263–264, 372–373, 432, 496, 499, 535, 565–566, 616).

Several commenters (Ex. 14–47, 14–118, 14–125, 14–151, 14–157, 14–170, 14–171) acknowledged that a safety or health hazard exists if OSHA permits untrained, poorly equipped attendants to enter a permit space for rescue. For example, the Monsanto Company (Ex. 14–170) stated:

> We recognize that there have been a number of fatalities from attendants or other would-be rescuers attempting to enter a confined space without the proper protective equipment or training.

The American National Can Company (Ex. 14–47) agreed, stating:

> The high incidence of "rescuer" death is most often from untrained, ill-prepared, emotional response on the part of by-standers, friends, etc.

During discussions about the hazards associated with untrained employees entering spaces to perform rescue (Washington Tr. 543), Mr. Thomas Lawrence, testifying on behalf of the Chemical Manufacturer's Association, stated:

> This is the same kind of thing that happens when attendants get in trouble when they go into spaces willy nilly without any backup or proper equipment or training. That's the whole data situation that we've been talking about, about what happens with attendants going inside.

The American Petroleum Institute (Washington Tr. 735) also shared OSHA's concern about fatalities that occur when unprepared and unqualified personnel attempt rescue.

All of the participants in this rulemaking agreed that entry into permit spaces by untrained, poorly equipped persons, whether they are attendants or not, for any purpose, including rescue, is hazardous and should be prohibited. OSHA agrees with this point. In fact, the major purpose of this rulemaking is to ensure that all employees who enter permit spaces are properly trained and equipped to do so and that they are otherwise protected from the hazards of permit space entry.

One commenter (Ex. 14–153) supported a total prohibition of permit space rescue by any attendant, as follows:

> As stated previously, it is The Hoif Co.'s position that attendants should not be permitted to rescue a down entrant.

However, as noted in the following discussion, many rulemaking participants recognized the need to permit some level of limited emergency response by an attendant. They suggested that some rescue response could be provided by a person stationed outside a permit space to monitor the activities of authorized entrants.

Several rulemaking participants (Ex. 14–47, 14–64, 14–69, 14–80, 14–88, 14–111, 14–118, 14–125, 14–143, 14–150, 14–151, 14–157, 14–170, 14–171, 14–184, 14–193, 14–200, 14–201, 14–208, 14–210, 14–217; Washington Tr. 465, 478) understood the importance of having a qualified, properly equipped person available and ready to begin rescue of an entrant impaired by a hazardous atmosphere. Some of the commenters (Ex. 14–47, 14–64, 14–72, 14–88, 14–111, 14–118, 14–125, 14–143, 14–150, 14–151, 14–157, 14–170, 14–171, 14–174, 14–184, 14–193, 14–200, 14–208, 14–210) identified the attendant as being the most readily available, qualified, properly equipped rescuer.

Some rulemaking participants suggested that OSHA permit attendants to perform rescue under certain limited circumstances. Several suggested that OSHA permit rescue entry by attendants once the attendant notifies outside emergency rescue personnel to respond (Ex. 14–148, 14–174, 14–177, 14–200, 14–201, 14–217; Chicago Tr. 372–373, 496, 499).

For example, the GTE Service Corporation (Ex. 14–201) stated:

> With regard to permitted duties for attendants, GTE also believes that attendants should be able to assist with a rescue if they have first summoned help and are trained in rescue procedures.

The Longview Fibre Company (Ex. 14–200) supported this view, as follows:

> Attendants should be allowed to enter permit spaces to perform a rescue under certain conditions where time is a critical factor in obtaining a successful rescue:
>
> The attendant must first be required to summon additional rescue assistance and be certain help is on the way prior to rescue entry.

Additionally, the National Safety Council (Chicago Tr. 496) testified:

> The employer could use the attendant as rescuer provided that the attendant is properly trained and equipped. Prior to becoming the rescuer, this individual should assure that an emergency notification system has been activated and calls for backup.

Under questioning by Mr. Chappell Pierce of the OSHA panel, Mr. Irvin Etter, representing the National Safety Council (Chicago Tr. 498), further clarified their testimony as follows:

> MR. PIERCE: ... one question on a clarification of Issue No. 10 regarding rescue by the attendant. You advocate that the attendant would be allowed to perform the rescue if he has the training and necessary equipment. Do you also advocate that he be allowed to enter before another attendant is in place?
>
> MR. ETTER: Yes. This is what we discussed in our deliberation.
>
> *****
>
> MR. PIERCE: Okay. I would like clarification on that one point.
>
> MR. ETTER: Our consideration on this was it's very difficult for the individual, if there's only one attendant on topside, to keep from going in and try to rescue a person and we feel that if the person is properly qualified, he can be making the rescue and possibly save the life if he has the proper equipment and the proper training before other people might be able to get there to perform the rescue.

Other rulemaking participants recommended a more limited rule for attendants attempting rescue, suggesting that OSHA permit a properly trained and equipped attendant to conduct a rescue after a second attendant has arrived and assumed the duties of attendant. Most of them (Ex. 14–88, 14–118, 14–125, 14–143, 14–148, 14–150, 14–170, 14–193; Washington Tr. 541–543, 630, 735–736) recommended that OSHA permit attendants to perform rescue entry after the employer notifies outside emergency responders and after the employer stations another attendant outside the permit space. For example, the Union Carbide Corporation (Ex. 14–88) stated:

> In proposed paragraph (f)(4)(i), the attendant would be prohibited from entering the permit space to attempt rescue of entrants. OSHA should clarify that once another attendant has arrived and been briefed by the first attendant, the first attendant may, if properly trained, change his or her status from attendant to member of rescue team.

The Monsanto Company (Ex. 14–170) agreed, stating:

> However, we recommend that the attendant be permitted to enter the confined space to start rescue so long as he/she is properly trained in rescue techniques *and a new attendant is in place*. In many instances, a properly trained and equipped attendant starting the rescue operation could cut valuable time off the amount of time that would be required to rescue personnel from the confined space if that rescue can begin only after the arrival of the rescue team. [Emphasis was supplied in original.]

Further support for this position came from Mr. Thomas Lawrence, representing the Chemical Manufacturer's Association (Washington Tr. 542), in response to a question from Mr. Thomas Seymour of the OSHA panel, as follows:

> MR. SEYMOUR: Is there really any reason or rationale whether [rescue by attendant] should be permitted?
>
> MR. LAWRENCE: Our position should be and is that—the discussions we've had is, hey, the attendant can go in and we want him to be able to go in if he has proper training, which he should have ... Number two, has the right equipment, which he should have. That's part of the preparation. And three, there's another person there to back him up, another attendant.

OSHA's expert witness, Ray E. Witter (Houston Tr. 630), also testified in support of allowing attendants to attempt rescue after being relieved, as follows:

> However, attendants should be allowed to enter confined spaces *only* when all of the following requirements have been met. First, the replacement attendant is present, and has been properly briefed. Second, the attendant is properly trained in rescue operations and third, the necessary protective personal equipment is used. [Emphasis was supplied in original.]

Additionally, the American Petroleum Institute (Houston Tr.735, 736) testified, as follows:

> However, an attendant that has been appropriately trained and qualified for entry, and properly equipped with breathing apparatus and protective equipment is an extremely valuable rescue resource. Such an attendant could undoubtedly perform a rescue much more expeditiously than any rescue team.
>
> For example, after an attendant has determined that an entrant needs assistance and a rescue call has been dispatched, the attendant would first attempt to perform a rescue without entering the permit confined space, using retrieval lines or devices. Should this prove to be ineffective, the attendant would then prepare for entry by donning the appropriate respiratory and personal protective equipment. Upon arrival of another qualified attendant, the original attendant could enter the permit confined space and attempt rescue.

Still other commenters (Ex. 14–47, 14–151, 14–171, 14–174, 14–184, 14–208, 14–210) suggested that OSHA allow attendants to perform rescue without prior notification of outside emergency responders and without assignment of a new attendant. For example, the American National Can Company (Ex. 14–47) stated:

> We believe [that] prohibiting attendant [rescue] is ill- advised. The high incidence of "rescuer" death is most often from untrained, ill-prepared, emotional response on the part of by-standers, friends, etc. The attendant may be in a position to provide the most immediate assistance, if well educated and trained to assess emergency conditions. The attendant may first communicate for assistance and possibly render aid or evaluate conditions prior to help arriving ... time is of the essence.

One commenter (Ex. 14–111) suggested that OSHA permit rescue entry by the attendant as long as the substitute attendant is "enroute" to the permit space.

Based upon the rulemaking record, OSHA has determined that it is necessary for anyone attempting rescue to be properly trained and equipped for rescue. As discussed further under the summary and explanation of paragraph (k), *Rescue and emergency services*, properly equipping a rescuer is important for him or her to enter a permit space safely and to be able to physically remove an incapacitated employee from the space. Proper training is necessary to ensure that the rescuer does not injure himself or herself or others during rescue operations. Therefore, the Agency is applying paragraph (k) to anyone who has rescue duties (indicating that he or she is part of the rescue service).

OSHA also believes that the evidence strongly supports the need for an attendant at all times during entry operations to monitor and protect all entrants. The presence of an attendant outside the permit space at all times during entry operations is important for three reasons:

(1) The attendant must keep unauthorized persons out of the space. This is particularly important in an emergency, when the atmosphere within the space might be IDLH and when bystanders unqualified in permit space entry might otherwise attempt rescue of injured entrants from the space.

(2) The attendant has a duty to other authorized entrants to remain outside the space, to remain alert for hazards, and to be able to assist in their evacuation as necessary. It is possible that an entrant may become incapacitated for reasons other than permit space hazards (for example, because of heart attack). Any other authorized entrants remaining in the space would still be dependent on the attendant for their safety.

(3) The attendant must be available outside the permit space to provide information to the rescue service. The information the attendant can supply the rescue services includes how many authorized entrants are within the space, what the hazards of the space are, and what prompted the emergency in the first place (for example, the injured employee's symptoms).

Therefore, OSHA has determined that the attendant's presence outside the permit space is vital even after an emergency has arisen. Accordingly, the final rule continues to require the presence of an attendant at all times during permit space entry operations.

However, after an attendant is relieved by someone who assumes the attendant's required duties, the original attendant, if trained and equipped as required by §1910.146(k)(1), can safely enter the permit space to begin a rescue attempt. Permission for the relieved attendant to do this is explicitly stated in a note following paragraph (i)(4). Although the language in the note makes no change to what was proposed, it does clarify the status of authorized attendants regarding rescue attempts that involve entry into the permit space.

Paragraph (i)(5) of the final rule requires the attendant to communicate with entrants as necessary to monitor entrant status and to alert authorized entrants of the need to evacuate the space under paragraph (i)(6) of the final rule. OSHA believes that the authorized entrant's communication with the attendant provides information that the attendant needs in order to determine if the entry can be allowed to continue. Subtle behavioral changes detected in the authorized entrant's speech or deviation from set communication procedures could alert the attendant that it is necessary for the authorized entrant to evacuate or be rescued from the space. Additionally, the attendant needs to be able to communicate with authorized entrants to order them to evacuate the space in an emergency. This provision is discussed under the summary and explanation of paragraph (h)(3) of the final rule, which contains a corresponding requirement for authorized entrants.

Paragraph (i)(6) of the final rule requires the attendant to monitor activities inside and outside the permit space to determine if it is safe for entrants to remain in the space. The attendant is also required to order authorized entrants to exit the permit space as quickly as possible whenever the attendant detects a prohibited condition, behavioral effects of hazard exposure in an authorized entrant, or a situation outside the space that could endanger the authorized entrants, or whenever the attendant, for any reason, can no longer perform the duties required under paragraph (i) of the final rule. Given the speed with which permit space hazards can incapacitate and kill entrants, it is essential that the entrants evacuate permit spaces as soon as any one of the four conditions set out in paragraphs (i)(6)(i) through (i)(6)(iv) exists. As noted in the preamble to the proposal (54 FR 24093) and in the summary and explanation of final paragraph (h)(5) earlier in this section of the preamble, OSHA believes that self-rescue will often provide the entrant's best chance of escaping a permit space when a hazard is present. Therefore, although OSHA recognizes that self-rescue may sometimes be impossible, the Agency stresses the importance of attempting self-rescue as a means of saving lives and minimizing injuries.

Paragraph (i)(6) of the final rule is based on proposed paragraph (f)(3)(ii), which would have required attendants to order the evacuation of a space whenever: (1) the attendant observed a condition that was not allowed in the permit, (2) the attendant detected behavioral effects of hazard exposure, (3) the attendant detected a situation outside the space that could endanger the entrants, (4) the attendant detected an uncontrolled hazard within the permit space, (5) the attendant was monitoring entry in more than one permit space and had to focus attention on the rescue of entrants from more than one space, and (6) the attendant had to leave the work station. OSHA has made some editorial revisions to the language of proposed paragraph (f)(3)(ii) in the course of drafting the final rule. For example, the Agency has replaced the phrase "condition which is not allowed in the entry permit" with "prohibited condition". ("Prohibited condition" is defined in the final rule as a condition that is not allowed by the permit.) Additionally, the condition listed in proposed paragraph (f)(3)(ii)(D) (that is, when the attendant detects an uncontrolled hazard) has not been carried forward into the final rule. Uncontrolled hazards are conditions not allowed by entry permits; thus, this condition is already included in the first condition (final paragraph (i)(6)(i)).

All of the substantive comments on proposed paragraph (f)(3)(ii) were in regard to paragraph (f)(3)(ii)(E), which addressed attendants monitoring more than one space at a time. The number of permit space entry operations that an attendant may monitor was the subject of Issue 8 of the hearing notice, which is addressed under the summary and explanation of final paragraph (d)(6) earlier in this section of the preamble. The Agency has decided to allow an attendant to monitor any number of permit space entry operations so long as the attendant continues to comply with the provisions of paragraph (i) of the final rule. Accordingly, OSHA is combining the last two conditions from the proposal (paragraph (f)(3)(ii)(E), when the attendant was monitoring more than one space and had to focus attention on the rescue of entrants from another space, and paragraph (f)(3)(ii)(F), when the attendant had to leave the work station). In accordance

with the Agency resolution of hearing issue 8, paragraph (i)(6)(iv) requires the attendant to order evacuation of the space whenever he or she can no longer perform the duties required under paragraph (i) of the final rule. This performance-oriented approach covers any circumstances in which an attendant cannot effectively monitor a permit space entry operation, such as emergency conditions that distract the attendant's attention [31] and any condition that forces an attendant to leave the work station. Obviously, if another attendant relieves the first one, the latter is no longer considered the attendant and is free to leave.

Paragraph (i)(7) of the final rule requires the attendant to summon rescue and other emergency services as soon as it is determined that an emergency exit from the permit space is necessary.

This provision has been taken from proposed paragraph (f)(3)(iii). Several commenters (Ex. 14–86, 14–143, 14–150, 14–157, 14–174, 14–178, 14–188) objected to the wording of this requirement in the proposal. They argued that the provision would require rescue services to be summoned whether or not they were needed. For example, Pennzoil Company (Ex. 14–150) stated:

> Item (f)(3)(iii) presents unnecessary constraints, since it does not allow the attendant to decide if employees will be able to effect an orderly withdrawal or a self-rescue from the space. Many times when the attendant recognizes cause to evacuate entrants from the space, the entrants can effect an orderly withdrawal or self-rescue. In most of these situations, the summoning of rescue and emergency services will be unnecessary. In order to correct this problem, we propose that item (f)(3)(iii) be revised as follows:
>
> "Summon rescue and other emergency services as soon as the attendant determines that authorized entrants may need assistance to escape from permit space hazards."

OSHA has accepted these recommendations. The Agency agrees that there may be times when authorized entrants can perform self-rescue from the permit space in an emergency. On the other hand, OSHA is believes that help must be summoned if there is any doubt as to whether it will be necessary. Therefore, paragraph (i)(7) of the final rule requires attendants to summon rescue and emergency services if they determines that assistance may be necessary. As long as the attendant is certain that self-rescue can be performed, no rescue summons would be necessary. However, if the attendant has any doubts as to whether an authorized entrant can exit the space under his or her own power, then the attendant is required to summon rescue and emergency services.

Paragraph (i)(8) of the final rule requires that the attendant take the following actions when unauthorized persons approach or enter a permit space while entry is underway:

(1) Warn the unauthorized persons that they must stay out of the permit space;

(2) Advise the unauthorized persons that they must exit immediately if they have entered the permit space; and

(3) Inform the authorized entrants and any other persons specified by the employer if unauthorized persons have entered the permit space.

This provision of the final rule has been taken from proposed paragraph (f)(3)(iv). Some commenters (Ex. 14–86, 14–150, 14–161, 14–170, 14–188) noted that some unauthorized person may have legitimate reasons for being near a permit space. As noted under the summary and explanation of paragraph (j)(5) of the final rule, OSHA agrees and has revised the language of proposed paragraph (f)(3)(iv)(A) so that unauthorized persons are warned to stay out of the space instead of being warned away from the space.

The Agency has also made some editorial changes to the language contained in the proposed paragraph, on which no other substantive comments were received. The changes are not significant, except that paragraph (i)(8)(iii) replaces the term "any other persons designated by the employer" from proposed paragraph (f)(3)(iv)(C) with "entry supervisor". As noted under the summary and explanation of the definition of "entry supervisor", this term is being used throughout the rule to identify the person responsible for overseeing permit space entry operations. This is the person who is responsible for the safety of authorized entrants and who should be informed of the presence of unauthorized persons inside the permit space. (See the summary and explanation of paragraph (j)(5) for a discussion of the duties of an entry supervisor in the event of unauthorized entry.)

Paragraph (i)(9) of the final rule requires the attendant to perform non-entry rescues as specified by the employer's rescue procedure.

This provision has been taken from proposed paragraph (f)(4)(ii), which would have required the attendant to use any rescue equipment provided for his or her use and would have required the attendant to perform any assigned rescue and emergency duties, without entering the space. The only comments addressing this proposed requirement concerned attendant rescue, which was discussed under the summary and explanation of paragraph (i)(4) earlier. As noted in that discussion, a person whose duties as attendant have been assumed by another is allowed to perform rescue entry following the provisions of paragraph (k). Paragraph (i)(9) of the final rule relates only to persons who remain on duty as attendants.

OSHA has not carried forward language from proposed paragraph (f)(4)(ii) relating to the use of equipment. This consideration is addressed in paragraph (d)(4) of the final rule.

OSHA wishes to emphasize that attendants monitoring more than one space must not perform any duties that would distract them from their responsibilities for all the spaces being monitored. The Agency does expect such attendants to be permitted to perform any type of rescue, including non-entry rescue, as long as they are still acting as attendants. As noted earlier, the employer's permit space program must establish procedures to enable the attendant to respond to an emergency affecting one or more of the permit spaces being monitored without distraction from the attendant's responsibilities under paragraph (i) of the final rule.

Paragraph (i)(10) of the final rule prohibits the attendant from performing other duties that may interfere with the attendant's primary duty to monitor and protect the safety of the authorized entrants. OSHA notes that keeping unauthorized persons out of the space protects authorized entrants and that the attendant would not be able to perform tasks that interfere with this duty. As noted previously, paragraph (d)(9) requires the employer to develop and implement procedures for summoning rescue services. These procedures should assist the attendant in complying with paragraph (i)(10) of the final rule.

This provision was not contained in the proposed standard. In Issue 6 of the NPRM, OSHA requested comments on the duties of an individual who would serve as an attendant for a permit-required confined space. Specifically, OSHA asked if the Agency should prohibit attendants from performing any duties other than monitoring the entrants. OSHA also asked if attendants should be permitted to pass tools or other materials to entrants and how much attention, if any, should an

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[31] Under paragraph (d)(7) of the final rule, if the attendant monitors more than one space at a time, the employer's permit program must adopt procedures to enable the attendant to respond to emergencies in one space without distraction from his or her responsibilities for all the spaces.

attendant be permitted to spare for other activities.

Many rulemaking participants responded to Issue 6 (Ex. 14–4, 14–27, 14–28, 14–30, 14–35, 14–43, 14–44, 14–57, 14–61, 14–62, 14–63, 14–73, 14–78, 14–81, 14–91, 14–94, 14–98, 14–99, 14–101, 14–109; Houston Tr. 629–630, 925–926; Chicago Tr. 39–42, 643). All of them agreed that it was important that the attendant not be distracted from the primary duties of monitoring and protecting authorized entrants. Some, however, held a stricter view about the types of permitted activities than others.

For example, the National Ready-Mixed Concrete Association (Ex. 14–81) took a limited view of what activities should be permitted, stating:

> Where attendants are required those attendants should not perform any other work that would take away from the attendant's ability to assist a person in trouble in a confined space.

The American Industrial Hygiene Association (Ex. 14–61) suggested that the attendant be limited to such additional tasks as observation and monitoring of the space, as follows:

> The underlying conflict over the attendant's duties stems from what is expected of the attendants, and who the attendant is. Within some organizations, the attendant may be a health and safety professional charged with directing the entry operation. In such a case, duties beyond that directly associated with observing the entrants and monitoring instrumentation may be too distracting.

Another commenter, Marine & Environmental Testing, Inc. (M&ET, Ex. 14–4) argued that the attendant should not be assigned duties that might interfere with the primary duty of watching out for the safety of workers inside of permit spaces.

During the public hearings in Chicago, the Food and Allied Service Trades Union (FAST) testified in opposition to allowing the attendant to perform other duties in responding to questions from Mr. Steve Jones, a member of the OSHA panel (Chicago Tr. 39). A portion of that interchange included the following:

> MR. JONES: In your written comment from October 31, you also express concern about possibility that attendants will be assigned other duties while they are serving as attendants. In fact, I get the impression that you would want the attendant to simply stand by the entire time, is that correct?
>
> MR. MESTRICH: Precisely.
>
> MR. JACKSON: Absolutely.
>
> MR. DONATOO: Can I give an example of that please?
>
> MR. JONES: Please do, Mr. Donatoo.
>
> MR. DONATOO: My duties [are] to be a grain mixer and many times I have been sent down with a man to clean a bin as a watchman. At this time, I may be running grain in. If I happen to get a ring off, or I am to shut the grain off, I have to leave this man. So, he is by himself in a bin for maybe a five minute period. If he would fall or something would crush him, in five minutes time it's too late.[32]

Later in the hearing (Chicago Tr. 41–42), Mr. Jones continued his questioning of the FAST workers:

> MR. JONES: We do have a separate requirement in the proposed standard which would have the attendant maintain continuous communication with the entrant. In fact, we have gotten a great deal of input that infers, that in some cases, that passing the tool or receiving the tool from an entrant is one of the best ways in which to maintain continuous contact.
>
> I guess that's where we are going and what I would be interested in, is if viewed in its totality the requirement for continuous contact and duties which do not interfere with the continuous contact so that you could accept such a provision.
>
> MR. JACKSON: Working with the individual down there in whatever form we would have no problem with; with the individual that he is actually working there with passing tools, or sending down another rope, or whatever. But working with anyone else around the area, that we would have difficulty with.

Other commenters (Ex. 14–27, 14–28, 14–73, 14–78) suggested that OSHA, in some way, permit the attendant to perform other duties. These commenters suggested that OSHA permit attendants to pass tools, machinery or other equipment to the entrant, but emphasized that the attendant must not leave the immediate area of the confined space entrance. For example, Robert J. Cordes & Associates (Ex. 14–28) stated:

> There is nothing wrong with the attendant performing duties which you mentioned (passing tools, etc.). The important thing is that the attendant stay at the opening and not go 100 feet away to get pipe for a job.

Arizona Electric Power Company (AEPCO, Ex. 14–73) agreed, stating:

> AEPCO feels if work inside the space is dangerous enough to require an attendant, that attendant needs to remain at the entrance and devote his attention to the safety of those inside. We see no problem with the attendant passing tools or supplies to those inside provided sight or voice contact remains possible during said duties.

Northwest Pipeline Corporation (NPC, Ex. 14–27) suggested that OSHA not prohibit additional duties by the attendant because other language in the proposal prohibited the attendant from leaving the permit space. NPC stated:

> Paragraph (f) seems clear enough to prohibit the attendant from leaving the permit space, particularly in light of the requirement for keeping accurate count of all entrants, determination of the suitability of the space for continued occupancy and maintenance of effective and continuous communication. Activities directly related to the entry, such as passing tools, should be allowed but the attendants' attention should not be distracted by assignment of unrelated tasks.

Some commenters (Ex. 14–28, 14–78) suggested that OSHA, by allowing the attendant to perform other activities related to attending the space involving contact with the entrants, could even increase entrant safety. For example, Pennwalt Corporation (Ex. 14–78) stated:

> As noted by OSHA, the provisions covering attendants and entrants are designed to complement each other. It is important that the entrant maintain contact with the attendant in order to determine any behavioral changes or changes in work environment. A most effective and practical method of maintaining this contact is for the attendant to pass and receive tools and materials and to discuss the progress of the job with the entrant or entrants. This provides routine contact and alerts the attendant to any change in either behavior or conditions that would require termination of the entry. This allows the attendant, when necessary, to order evacuation and summon rescue teams promptly.

Robert J. Cordes & Associates (Ex. 14–28) also took this position, arguing as follows:

> There is good derived from the attendant keeping active; he does not become as bored with his job, he is aware of the status of the job, and he knows the locations of employees inside the confined space. The attendant should also be certain the atmosphere and working conditions have not changed; he can be the person who conducts tests.

OSHA concludes that it is essential for the attendant to maintain his or her efforts to monitor and protect authorized entrants. The Agency believes that authorized entrants will be endangered if the attendant is distracted from these duties. If an attendant performs tasks that devote his or her attention to jobs that are unrelated to the safety of employees within the permit space, an emergency condition inside or outside the space could go undetected until injury or death results. Those who commented on Issue 6 of the NPRM obviously agree with this conclusion. However, OSHA also recognizes that

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[32] OSHA notes that this testimony implies that the "watchman" identified by Mr. Donatoo is considered an attendant. In this particular case, once the "watchman" entered the confined space, that employee would no longer be considered an attendant. Paragraph (i)(4) of the final rule requires an attendant to be stationed outside the permit space at all times during entry operations. Duties that would require the attendant to enter a confined space to help another employee are not permitted by the final rule. The attendant must not place any portion of his or her body into the permit space. However, tools and equipment may be passed to authorized entrants by means of handlines.

some tasks, particularly those that enhance the attendant's knowledge of conditions in the permit space, can be performed safely by the attendant. Accordingly, in order to protect authorized entrants from unnecessary hazards, OSHA has decided to allow attendants to perform only such duties as will not hinder their primary function of monitoring and protecting authorized entrants. Therefore, paragraph (i)(10) of the final rule prohibits attendants from performing duties that will interfere with this function. Passing tools to authorized entrants and monitoring the atmosphere of the permit space are among the types of duties that would be permitted, provided the attendant does not break the plane of an opening into the space. The repair of equipment, on the other hand, would distract an attendant, so that he or she could not adequately monitor or protect authorized entrants, and would be prohibited.

Paragraph (j), Duties of entry supervisors.

Many of the accidents in the rulemaking record resulted from the employer's lack of enforcement of confined space entry rules. Under the OSH Act, employers bear the primary responsibility for their employees' safety. Employers must take responsibility to ensure that acceptable entry conditions exist before entry begins and during entry operations and to enforce work practices necessary for employee safety. Too many times, a permit space entrant has been made responsible for his or her own safety, even when that employee was dependent on others to ensure the presence of acceptable entry conditions.

In order to place the burden of employee safety on employers, the final rule requires each permit space entry to have an entry supervisor, who has overall accountability for safe entry operations. The final rule requires the entry supervisor to verify the existence of acceptable entry conditions and the presence of rescue and emergency services, to authorize the entry (which is evidenced by his or her signature on the permit), to remove unauthorized persons from the space, and to terminate the entry operation when necessary. OSHA believes that these rules will compel employers to assume responsibility for safety during permit space entry operations.

Paragraph (j) of the final rule, the equivalent of the "duties" portion of paragraph (g) of the proposed rule, enumerates the duties of the entry supervisor. In proposed paragraph (g), the individual responsible for the entry was called the "individual authorizing or in charge of entry". As noted in the summary and explanation of the definition of "entry supervisor" earlier in this section of the preamble, OSHA is using this term in the final rule in place of the proposed term.

Paragraph (j)(1) of the final rule requires the entry supervisor to know the hazards which may be faced during entry.

This provision was not contained in the proposed standard. Some commenters (Ex. 14–174, 14–173) specifically recommended that entry supervisors receive the same training regarding hazard recognition as authorized entrants.

OSHA has accepted these recommendations. As noted in the summary and explanation of final paragraph (g)(1) earlier in this section of the preamble, the rulemaking participants agreed that personnel involved in permit space entry operations should have whatever training is needed to be able to perform duties under the final rule. In paragraphs (h)(1) and (i)(1) of the final rule, authorized entrants and attendants respectively are required to know what hazards may be faced during a permit space entry operation. Since the entry supervisor is responsible for all aspects of the entry operation it is only reasonable that he or she be expected to know at least as much, if not more, than authorized entrants and attendants. Therefore, OSHA has adopted a specific requirement for the entry supervisor to know the hazards which may be faced during entry.

Paragraph (j)(2) of the final rule requires the entry supervisor to verify, by checking that the appropriate entries have been made on the permit, that all tests specified on the permit have been conducted and that all procedures and equipment specified on the permit are in place, before endorsing the permit and allowing entry to begin.

This provision corresponds to proposed paragraphs (g)(1)(i) and (g)(1)(ii), on which no substantive comments were received. These two paragraphs from the proposal have been combined in the final rule to clarify that the entry supervisor is required to check that the permit has been completed and that the entry conditions meet those specified on the permit. The language from the proposal has been modified somewhat to specify precisely what the entry supervisor is require to check. For example, proposed paragraph (g)(1)(i) contained the term "requisite information", and paragraph (g)(1)(ii) contained the term "necessary procedures, practices and equipment". So that it is clear what information is required to be examined, the Agency has substituted the terms "tests specified by the permit" and "procedures and equipment specified by the permit". These clarifications to language of the proposed provisions provide consistency between paragraphs (f) and (j)(2) of the final rule.

Paragraph (j)(3) of the final rule requires the entry supervisor to terminate the entry and cancel the permit as required by paragraph (e)(5) of the final rule. This provision combines the requirements proposed in paragraphs (g)(1)(iv) and (g)(1)(v), on which no significant comments were received. The substantive portion of the proposed provisions (that, is when these actions are required) has been placed in paragraph (e)(5) of the final rule, discussed earlier.

Paragraph (j)(4) of the final rule requires the entry supervisor to verify that rescue services are available and that the means for summoning them are operable. The proposed rule did not contain a corresponding provision explicitly imposing this duty on the entry supervisor. Proposed paragraph (h), however, would have required the employer to have an in-plant rescue team or an arrangement under which an outside rescue team would respond in an emergency. Additionally, OSHA proposed (in paragraph (c)(8)) that employers implement and provide the procedures and equipment necessary to rescue entrants from permit spaces and (in paragraph (g)(1)(ii)) that the entry supervisor determine that the necessary procedures, practices, and equipment for safe entry are in effect. OSHA believes that the inclusion of paragraph (j)(4) in the final rule will emphasize the need for the entry supervisor to assure that rescue and emergency services are indeed readily available before entry. Since the employer delegates responsibility for safe permit entry to the entry supervisor, it is reasonable and consistent with the rescue provisions in the permit program to specify that the entry supervisor verify the availability of rescue services and the operability of the means for summoning them.

Paragraph (j)(5) of the final rule requires the entry supervisor to remove unauthorized individuals who enter or who attempt to enter the permit space during entry operations.

This provision is based on proposed paragraph (g)(2), which would have required the entry supervisor to remove "unauthorized personnel who are in or near entry permit spaces." This provision of the proposal was criticized by some commenters (Ex. 14–86, 14–150, 14–161, 14–170, 14–188) as being

too vague or too restrictive. They argued that the proposal would preclude the presence "near" permit spaces of employees who have legitimate duties there. Some of these commenters recommended that OSHA require the removal of unauthorized persons who enter or attempt to enter the space.

The Agency recognizes that some persons near a permit space may have legitimate reasons for being there. These persons will have been warned by the attendant (under paragraph (i)(6)(i)) to stay out of the permit space. They will know of the danger involved and, under the observation of the attendant, can safely remain near the space. Therefore, OSHA has incorporated the recommendation of these commenters in paragraph (j)(5) of the final rule.

Paragraph (j)(6) of the final requires the entry supervisor to determine, whenever responsibility for a permit space entry operation is transferred and at intervals dictated by the hazards and operations performed within the space, that entry operations remain consistent with terms of the entry permit and that acceptable entry conditions are maintained.

This provision is based on paragraph (g)(1)(iii) of the proposal, which would have required reevaluation of the conditions within the space at "appropriate intervals". As noted under the summary and explanation of final paragraph (e)(4) earlier in this section of the preamble, several commenters (Ex. 14–28, 14–57, 14–63, 14–80, 14–109, 14–116, 14–151, 14–161) pointed out that conditions within the space could change over time and that the hazards within the space would have to be reevaluated. One of them (Ex. 14–109) specifically recommended limiting the duration of the permit to the length of a work shift.

Although OSHA has not accepted this latter recommendation, the Agency agrees that the conditions within the space need to be reevaluated at regular intervals. For entries lasting more than one work shift, the original entry supervisor will normally have to be relieved at the end of his or her shift. The responsibilities of the entry supervisor will then be passed on to someone else. OSHA believes that it is important for the new entry supervisor to review the permit and to determine that acceptable entry conditions have been maintained. The Agency also believes that guidance, beyond that of transfer of responsibility, must be given as to what "appropriate intervals" might be. In order to accomplish these goals, paragraph (j)(6) final rule specifies that reevaluation of conditions within the space must occur whenever responsibility for a permit space entry operation is transferred and at intervals dictated by the hazards and operations performed within the space.

Paragraph (k), Rescue services.

Most of the requirements of the permit-required confined space standard are in place to ensure that employees can safely enter and work inside permit spaces. The hazards within the space must be eliminated or controlled before entry is allowed. Testing and monitoring must be performed in order to ensure that entry conditions are acceptable before entry and that they remain so during the entire entry operation. Authorized entrants, attendants, entry supervisors, and others with duties performed under §1910.146 must be trained to perform those duties safely and to recognize permit space hazards if they arise. Attendants must be stationed outside the space to keep unauthorized persons out of the space and to monitor the status of entrants to ensure (among other things) that hazards do not arise and that employees are evacuated quickly if they do.

Unfortunately, in spite of all these precautions, hazards may arise so quickly or unexpectedly that authorized entrants are unable to escape from the permit space without assistance. Paragraph (k) of the final rule addresses the rescue and emergency services needed in such an event.

Paragraph (k) of the final rule, which is based on proposed paragraph (h), sets requirements for the rescue and emergency services provided to comply with paragraph (d)(9) of the final rule. Compliance with these provisions will enable an employer to extricate authorized entrants from permit spaces where uncontrolled hazards have arisen and will maximize the likelihood that any extricated personnel are not killed or permanently injured by exposure to permit space hazards. The Agency recognizes that an employer whose permit space program complies with this section may never need to have authorized entrants rescued. However, there are permit space hazards that could arise in permit spaces during entry operations against which the other elements of the permit space program do not provide sufficient protection. This could occur in several ways—because of extraordinary circumstances that appear suddenly without warning or because of some deficiency in the permit space program. Accordingly, the Agency has determined that employers must include in their permit program the means to rescue authorized entrants.

In an emergency, rescue personnel would either enter a permit space to remove authorized entrants or would remain outside the permit space and pull out authorized entrants with retrieval lines attached to chest or full body harnesses worn by the entrants. OSHA requires simply that, whatever means are chosen, the employer arrange for the necessary rescue and emergency services. As noted earlier, the Agency anticipates that employers will choose between entry and non-entry rescue as part of compliance with paragraph (d)(9) of the final rule.

The introductory text of paragraph (k) requires employers to arrange for rescue and emergency services. Some employers may prefer to establish an on-site rescue service. The on-site service normally provides the fastest response in an emergency. Other employers may prefer to rely on off-site rescue services, perhaps because they believe that they do not have the resources to train employees to perform rescue or because the ready availability of an adequate off-site rescue service makes an on- site capability unnecessary. The final rule allows employers to make arrangements for either on-site or off-site services.

Paragraph (h) of the proposal was entitled "Rescue team". As noted by several rulemaking participants (Washington Tr. 68; Chicago Tr. 496, 564–566; Houston Tr. 952–953), rescue of entrants from permit spaces also involves provisions of emergency medical services after (and sometimes before) an entrant is removed from a permit space. Additionally, proposed paragraph (h)(1)(iv) addressed the emergency, as opposed to rescue, training that the in-plant rescue team was to have. To eliminate any ambiguity, paragraph (k) of the final rule explicitly covers emergency services provided after a rescue and is titled "Rescue and emergency services".

Proposed paragraph (h) set requirements for rescue services, which were called "rescue teams" in the proposal. The introductory language of the proposed paragraph would have required employers to have either an "in-plant" rescue team or an arrangement under which an "outside" rescue team would respond to a request for rescue services. Some commenters (Ex. 14–118, 14–123, 14–161, 14–168, 14–170) stated that the proposed term "in-plant rescue team" was too restrictive and possibly misleading. For example, Atlantic Richfield Company (ARCO, Ex. 14–123) stated:

> "In plant rescue" is too restrictive a term. In some cases the rescue team is not "in plant" but "on site", and in other cases, such as at remote operations it is difficult to define

the confined space entry as being in a "plant".

Also, the Service Employees Industrial Union (Ex. 14–148) stated that the term "rescue crew" should be used because "Many confined space workers do not work in a plant setting." Additionally, the American Petroleum Institute (Ex. 14–168) stated:

API requests this term be changed to "site rescue capability", since some member companies have expert employee rescue personnel available on call (not necessarily in-plant) that can provide rescue as rapidly as an independent outside rescue team.

* * * * *

In addition, the definition should be expanded to recognize that the rescue capability may comprise other workers (outside the permit space) who have been trained to perform rescues in the particular type of permit space. At issue is the best way to provide rescue capability at the small, remote installations where outside rescue teams do not exist.

OSHA agrees with these comments. Also, the term "rescue team" is a misnomer, because there could be cases, such as when non-entry rescue systems are used, in which one person will be responsible for the rescue of authorized entrants. As discussed under the summary and explanation of paragraph (k)(1) of the final rule, OSHA is treating all rescue services alike, whether they are provided by the employer whose permit space is being entered or by another employer and whether they are stationed on- site or off-site. Therefore, the Agency has adopted the term "rescue service" to refer to all rescue personnel provided to remove injured entrants from permit spaces.

The introductory language of proposed paragraph (h) treated "in-plant" and "outside" rescue teams as equally acceptable options for employers. In the prehearing comment period, OSHA received several comments (Ex. 14–41, 14–45, 14–54, 14–63, 14–94) contending that employers should take into account the response time for rescuers when choosing between the use of in-plant and outside rescue services. In particular, these commenters were concerned that authorized entrants who were not rescued from a hazardous atmosphere within 4 to 6 minutes would be incapacitated or killed. For example, one of the commenters (Ex. 14–41) stated:

The outside rescue team is a fine choice for small employers but fails to consider response times involved (the time [interval] between calling the rescue squad for help and the time they arrive on the scene.) A person can only go four to six minutes without oxygen before brain damage begins. After six minutes the [likelihood] of the victim recovering from the lack of oxygen is minimal. Therefore an outside rescue team needs to be able to arrive within four minutes in order to do the victim any good.

Another commenter (Ex. 14–54) expressed the following concerns about the response times of outside rescue services:

The fourth point is on Page 24094 as to employers who choose to use outside rescue services.

There is no mention of *Response Times*. If they cannot get there in 4 to 6 minutes, they will not be doing rescue! They will be doing body recovery!

Your Proposed Standard should read: "Employers who choose to use outside rescue services should evaluate realistic response times, and training and equipment that the outside rescue service has available." Then have the outside rescue service train and practice at various locations throughout your facility. Only then can you make a sensible decision to use an outside rescue team or form your own in-house team. [Emphasis was supplied in original.]

Still another commenter (Ex. 14–94) noted the ANSI recommendation on response times, as follows:

ANSI Z117 advises that treatment/rescue of a person suffering cardio/pulmonary arrest in a confined space should begin within four minutes for the victim to have the best chance of full recovery.

Some commenters recommended that OSHA not permit the use of outside rescue teams. For example, the Tennessee Valley Authority (Ex. 14–36) stated:

We recommend that employees should not have the option of having either an in-plant rescue team or an outside rescue team because accidents associated with confined spaces require an immediate response and rescue efforts [to] begin quickly.

The International Brotherhood of Teamsters (Ex. 14–109) argued that outside rescue services could not respond quickly enough, as follows:

Keeping in mind the risk of asphyxiation, we object to Section (h)(2) which allows the employer to use outside rescue services. In confined space emergencies, outside rescue teams will very rarely be able to respond quickly enough. As NIOSH points out on p. 40 of the *Citation Document on Working in Confined Spaces*, "Since irreversible brain damage can occur in approximately 4 minutes in an oxygen deficient atmosphere, it is essential that resuscitation attempts occur within that time." In two fatality cases involving entry into tanker trucks where we have information on response time by outside emergency responders, the time it took to retrieve the victims from the cargo tanks was more than 20 minutes, and approximately 30 minutes. (See NIOSH FACE–87–27–11, and the case file on OSHA Inspection 101314110.) [Emphasis was supplied in original.]

The Quaker Oats Company (Ex. 14–173) presented several reasons why OSHA should not allow outside rescue services to be used, as follows:

The employer has an option of either using outside rescue services or forming an in-plant rescue team. This option poses at least three problems:

1. Response time of an outside team may be quite lengthy and unpredictable.
2. Capabilities of an outside rescue team cannot be assured without extensive evaluation on a local basis.
3. Outside rescue teams will likely lack the additional preparation time needed to identify and develop entry procedures for the multitude of confined spaces to which they will be exposed?

Our recommendation would be to place primary responsibility for rescue on the employer. An in-house rescue team has a lower response time, can be better equipped, and has specific knowledge about the confined space they will be entering.

On the other hand, some of the comments argued that, if the outside rescuer's response time was reasonable, employers should be allowed to use outside rescue services in lieu of an in-house team. For example, AMOCO Corporation (Ex. 14–124) stated:

The term "in plant" implies that OSHA intends for the rescue team to be physically present in the plant during the entire time an entrant is inside of a permit required confined space. An "in plant" rescue team is not required in the proposed rule and employers may [choose] to use an outside rescue team instead. Clearly, response time is a critical factor in determining whether an off site rescue team is sufficient to protect the entrants. Certainly, the response time for an employee response team which is on call could be comparable to an outside team. Therefore, we believe that OSHA should allow the employer to decide for which conditions or spaces, the rescue team could be on call.

The American Feed Industry Association (Ex. 14–160) also supported the flexibility set out in the proposal, stating:

AFIA supports OSHA's basic approach of permitting the use of either an in-plant rescue team or an outside rescue team. This flexibility allows individual employers to adopt the approach that is best for their needs.

In response to these comments, the Agency solicited testimony and comments regarding the use of outside rescue teams in Issue 12 of the hearing notice. In the hearing notice (54 FR 41463), OSHA noted that atmospheric hazards which deprive authorized entrants of a safe air supply generally pose life- threatening situations after about five minutes, though some hazards incapacitate or kill even faster.

Some hearing participants testified against the use of outside rescue teams.

For example, Mr. Eric Frumin, representing the Amalgamated Clothing and Textile Workers Union (Washington Tr. 580–581), testified at the Washington hearing as follows:

I'd like to just make one followup comment as to what brother Walker stated regarding the question of rescue teams, outside rescue teams. He mentioned a necessity of establishing some sort of time to travel requirement and the whole notion of how far away can a rescue team legitimately be.

I went through an experience recently of trying to get fire insurance on a house in a relatively rural area. And if you have ever done that, you'll discover that if you're a certain number of miles from a fire house, you can forget getting fire insurance. And the insurance industry understands quite well what it means to establish strict criteria, quantitative criteria, to determine distance when those distances make all the difference in preserving property. And we think that OSHA should recognize the importance of reasonable and protective quantitative criteria for the acceptability of outside rescue teams regarding time to travel.

Otherwise, we are going to have a lot of outside rescue teams who are basically nothing more than an ambulance squad that take[s] people to the morgue.

Additionally, Ms. Diane Factor, representing the AFL-CIO (Chicago Tr. 318–319), testified:

The employer should be required to have an in-plant rescue team whenever possible. The team needs to be available within three minutes of an emergency to begin rescue. An outside rescue team can never be as effective as a well-trained in-plant team. Drills should be mandated as part of the standard to ensure that rescue skills are up-to-date. An outside team should only be used it is absolutely impossible to prepare an in-plant team. This option should be available to employers upon request using the variance procedure.

Mr. Corley, representing the National Association of Manufacturers (Chicago Tr. 124), testified as follows when asked what the appropriate response time would be for an outside rescue service:

I don't mean to be cute when I say this, but the only answer I can come up with is as quickly as possible. I don't know what the appropriate time is for people who don't have trained first-aiders, but who have a nearby medical facility. I don't know [what] that time is. In general, if the rescue capability takes more than five minutes it's generally too late.

On the other hand, some hearing participants recognized the problems faced by small employers in training and maintaining on- site rescue teams (Ex. 69, 106; Washington Tr. 286, 480–481; Chicago Tr. 318–319, 536). They argued that it was not always practical for such employers to train employees at the worksite in rescue techniques. For example, Dow Chemical Company (Ex. 69) discussed the problems involved, as follows:

We require the best effort possible to prevent or minimize any hazard prior to the entry of personnel. Our experience indicates that this provides the best results no rescues necessary. However, we recognize that the potential need for rescue exist[s] so we expect our locations to develop an on site rescue plan which will include where appropriate an off site rescue (fire department ... emergency response team, etc.) team. The three previous witnesses have a site rescue team at their respect[ive] locations that have special training. However, we have several locations that don't have the frequency of confined space entry or the resources to have dedicated rescue teams that would meet the criteria mentioned on issue eleven [rescue team qualifications and training] so they [coordinate] efforts with the local emergency effort, e.g. 15 person operation in Columbus, Ohio. And as previous testimony indicated even an [on-]site team can not always respond within four minutes of the first perceived problem with an entrant.

The American Society of Safety Engineers (ASSE, Chicago Tr. 617) argued that the important factor was whether or not an employee could be rescued quickly enough. On behalf of ASSE, Mr. Jack Dobson testified as follows:

Regarding Issue No. 12, the criteria to be used should be the safe removal of an entrant in time to save a life. If a life can be saved by outside rescue teams, then they should be allowed. In an immediately dangerous to life and health atmosphere or asphyxiation, time should be the parameter for decision making. The explanatory paragraph in the ANSI Standard in Section 14.1.2 addresses emergency treatment beginning within four minutes for persons with cardiopulmonary arrest.

Several witnesses (Chicago Tr. 537; Houston 869, 956, 1009) related the response times of their on-site rescue teams. Only half of these teams could always respond in under 4 minutes, and the times included only that necessary to arrive at the permit space. Additional time would be necessary to enter the space and remove the entrant. Other witnesses (Ex. 14–206; Washington Tr. 427, 480–481, 576) stated that no rescue team could adequately respond within 4 minutes.

OSHA believes that the need to respond as quickly as possible to an emergency within a permit spaces indicates a preference for on-site rescue teams wherever it is practical for the employer to provide a rescue capability. The response times of on-site rescuers will usually be much shorter than those for typical off- site rescue and emergency services. Unfortunately, the response of on-site teams is not always sufficient to ensure to rescue of entrants within the 4-minute time period acknowledged as the goal for successful rescue of entrants overcome by oxygen deficiency.[33] Additionally, the Agency realizes that some employers (small business employers in particular) will not be able to provide the type of in-house rescue expertise required by the final standard. Furthermore, because they are dedicated to responding to all types of medical emergencies, off-site rescue services are typically better equipped to treat injured employees.

In light of the fact that even the best rescue methods can barely respond to an emergency or retrieve an incapacitated employee from a permit space within 4 minutes and that many cannot respond that quickly, OSHA believes that it is simply not reasonable for the Agency to require employers to develop capability to provide rescue within 4 minutes of an emergency alert, regardless of cost or practicality. More importantly, OSHA is concerned that requiring employers to provide any set response time would encourage the attempted rescue of entrants before all precautions necessary to ensure the safety of rescue personnel were taken. The Agency believes that emergency conditions may induce rescuers (especially those who are not full time rescuers) to rush into the permit space, in spite of the training required under the final rule. Considering that the incident data in the record document that most of those killed in permit space entries are would-be rescuers, the Agency believes that the final rule should stress non-entry rescue methods and provisions for the safety of rescue personnel rather than the time for such personnel enter a permit space and to remove an entrant.

For these reasons, OSHA has taken several actions.

(1) The Agency has carried forward the proposal's acceptance of both on-site and off-site rescue services. The employer whose employees enter permit spaces must arrange for rescue and emergency services to be provided.

(2) The final rule incorporates a provision (discussed under the summary and explanation of paragraph (k)(1) later in this section of the preamble) for employers providing rescue services to equip and train the rescue personnel properly. This

[33] OSHA realizes that oxygen deficiency is not the only hazard faced by authorized entrants, though, as noted earlier, it is the leading cause of death of permit space entrants. Some hazards will require a quicker response in order to save the entrant, other hazards need not be responded to as quickly. OSHA does believe that a 4-minute time limit on removing an incapacitated entrant from a permit space should be the goal of every rescue plan.

provision applies equally to employers who provide rescue services for their own entrants and to employers who provide rescue services for other employers' authorized entrants.

(3) OSHA has incorporated a provision (discussed under the summary and explanation of paragraph (k)(3) later in this section of the preamble) requiring employers to provide retrieval systems or methods whenever an authorized entrant enters a permit space, unless the employer can demonstrate that the retrieval equipment would increase the overall risks of entry or that it would not contribute to the rescue of the entrant.

The Agency believes that these actions will help to ensure the safe and effective rescue of injured employees and will also provide flexibility for employers to choose the type of rescue service that best meets the demands of the workplace. OSHA acknowledges that the rescue provisions of the final rule will not ensure that all incapacitated entrants will be successfully rescued from permit spaces. However, OSHA believes that prevention of emergencies in permit spaces is the most effective approach to this problem. The basic thrust of this final rule is to require the employer to plan for entries into permit spaces and to provide for acceptable entry conditions, in order to minimize the chances that emergency conditions will arise during entry. OSHA further believes that when rescue is necessary, the rescue provisions of the final rule ensure the safety of employees performing rescue duties. This is particularly important in light of the accident data in Exhibit 13–16, which indicate that more would-be rescuers have been killed than entrants. (This point was noted in the preamble to the proposal, 54 FR 24082.)

Paragraph (k)(1) of the final rule, which is based on proposed paragraph (h)(1), sets requirements for rescue services. These provisions apply to any employer who has employees enter permit spaces to perform rescue duties.

Proposed paragraph (h)(1) would have applied only to in-plant rescue teams. Several rulemaking participants (Ex. 14–54, 14–61, 14–63, 14–148, 14–213; Washington Tr. 250–251; Chicago Tr. 374; Houston Tr. 880) recommended that the capabilities of outside rescue services be addressed as well. For example, the American Industrial Hygiene Association (Ex. 14–61) stated:

> Minimum qualifications for outside rescue teams should also be specified. These teams should comply with the same training requirements as the in-plant teams.

The commenters who objected to the term "in-plant rescue team" (Ex. 14–118, 14–123, 14–161, 14–168, 14–170) recommended using the term rescue capability so that the regulation would treat all rescue services alike.

Additionally, Mr. Dick Monczka of the International Union, United Automobile and Agricultural Implement Workers of America - UAW, testified (Chicago Tr. 374) as follows:

> If an outside rescue team is utilized by the plant, there must be provisions in the standard to require the outside rescue service to review all confined space at least on an annual basis. The outside team must also review on at least a bi-annual basis all previously issued confined space permits so they understand the type of work performed and the hazards encountered. In addition, a written rescue plan must be developed by the outside rescue service and made part of the company's confined space program. Practice sessions must occur at least annually.

Mr. Jerry Walker of Chevron was questioned by Mr. Thomas H. Seymour of the OSHA panel in the Houston public hearing. The discussion (Houston Tr. 880) went as follows:

> SEYMOUR: You mentioned about outside rescue teams or off-site rescue teams, and the employers are going to rely on them. What kinds of criteria do you think is appropriate that the employer should utilize if he is going to rely on such an outside unit to determine whether they, in fact, can be relied upon. What kind of questions or evaluations a prudent employer make in finally determine this part of his program to rely on those outside services?
>
> WALKER: Well, typically that should be trained to the level of what we have as a low-level emergency medical technician training which we call rescue training. And we would expect that the people that we would contract with or that we would have respond would [meet] that low-level of rescue training that we have put together.
>
> SEYMOUR: Would you think it would be appropriate for the host employer who is going to rely on this outside service would make available possibly training assistance that they can come in and actually see what kinds of space that they may be called upon to render assistance in and so on, as part of their orientation or possible training?
>
> WALKER: Yes. And we have done that.
>
> SEYMOUR: Would that be a normal practice? Should that be a normal practice?
>
> WALKER: I am not prepared to say that. I am saying that we would do that.
>
> SEYMOUR: I am speaking in the Chevron orientation, not say speaking for Shell or anybody else. From Chevron's point of view is that considered a normal practice, and they would do that if they were going to rely on outside people for assistance?
>
> WALKER: Right. Yes.

Mr. John Moran, OSHA's expert witness, noted the need for training of all rescuers (Washington Tr. 68), as follows:

> Rescue. In none of the confined space events previously analyzed was rescue planned. Where impromptu rescue efforts occurred, they were largely unsuccessful and often resulted in additional fatalities. Indeed, of the cases, 40 percent of the victims were would be rescuers. NIOSH's estimate is somewhat higher than that. Workers within confined spaces who are exposed to oxygen deficient, asphyxiating and similar atmospheres can often be saved, if rescue is prompt and appropriate emergency medical care is provided within four minutes. This argues for continuous communication, appropriate and timely removal from the space and prompt proper emergency medical care, including, at a minimum, CPR and first aid skills application. Rescue attempts resulting in the death of rescuers have been conducted by untrained on-site fellow workers and by rescue or police personnel from the local community. Where local community responders attempt rescues in confined spaces, they are in great jeopardy, unless they have had confined spaces rescue training and are aware of the hazards presented by the specific space they are entering. When such rescuers die, the tragedy of a confined space event is extended to the community as well, which is all [too] often already operating with scarce resources and marginal fire and rescue coverage.

As noted earlier, OSHA believes that it is important to protect employees who enter permit spaces to perform rescue duties regardless of who their employer is. The proposal did address the safety of rescue personnel in paragraph (h)(1); however, those requirements would have applied only to in-plant rescue teams. The proposal did not explicitly address the safety of rescuers of outside rescue providers. In the final rule, OSHA is applying provisions corresponding to proposed paragraph (h)(1) (final §1910.146(k)(1)) to all employers providing rescue services. The Agency has determined that this action is necessary to provide protection for employees of outside rescue services as well as those of in-plant rescue teams.

Paragraph (k)(1)(i) requires the employer to ensure that personnel assigned as rescuers are equipped with, and trained to use, all personal protective equipment and rescue equipment necessary to enable them to enter and perform rescue operations in the employer's permit required confined spaces. This provision is basically the same as proposed paragraph (h)(1)(i), on which no substantive comments were received. OSHA has made some editorial changes to the language contained in the proposal. For example, as noted earlier, the final rule uses the term "rescue service" in place of the proposed term "in-plant rescue team".

Paragraph (k)(1)(ii) requires the members of the rescue service to be

trained to perform their assigned rescue duties. They are also required to receive the training required of authorized entrants under paragraph (g) of the final rule. This is basically the same as proposed paragraph (h)(1)(ii), on which no substantive comments were received. OSHA made editorial changes to the language contained in the proposal in order to correct the syntax.

Paragraph (k)(1)(iii) of the final rule requires rescuers to practice making permit space rescues at least once every 12 months, by means of simulated rescue operations in which they remove dummies, manikins or actual persons from the actual permit spaces or from representative permit spaces. Representative permit spaces must, with respect to opening size, configuration, and accessibility, simulate the types of permit spaces from which rescue is to be performed.

This provision is based on proposed paragraph (h)(1)(iii). Some commenters (Ex. 14–45, 14–63) supported the proposed paragraph. They regarded rescue practice as an essential part of a successful entry system. They pointed out that the practice readies the rescue team for emergencies and highlights deficiencies in rescue procedures. For example, one commenter (Ex. 14–63) stated:

> Simulated rescue practices are strongly endorsed. The employer may find the respirators provided cannot fit through the entry/exit. Maryland employers and firefighters have had this unfortunate experience, resulting in fatalities. Such simulations should be practiced every six months.

On the other hand, ARCO (14–123) stated:

> [T]he requirement for practice rescues that would be representative of a rescue is again, not written as a performance standard. Rescue teams at some facilities may be called upon for a rescue in a very wide range of different confined space situations, and it is unclear how they could determine a confined space with representative size, configuration, and accessibility. ARCO recommends modifying this requirement to train rescue teams simply to be able to meet their goal, which is performing rescues quickly and competently.

Another commenter (Ex. 14–160) was concerned that this requirement was too burdensome and that the phrase "representative openings and portals whose size, configuration and accessibility closely approximate those of the permit spaces" could be interpreted to require different practice sessions over the course of the year if many different size openings were found at the workplace. This commenter recommended the elimination of the word "closely" from the text.

The Agency agrees that the language of the proposal did not account for the wide diversity of types of rescue services covered by the final rule. While some rescue services have ready access to the actual permit spaces or to exact replicas of the permit spaces for practice, others do not. OSHA does not believe that it is always appropriate for employers to make the actual permit spaces safe for entry simply to allow the rescue service to practice. (Of course, if the space must be made safe for entry for other reasons, practice could be scheduled as part of the entry operation.) On the other hand, OSHA has determined that rescue service personnel must develop and maintain familiarity with the types of permit spaces from which rescue may be required.

For these reasons, OSHA has revised the language of paragraph (h)(1)(iii) so that the final rule recognizes practice in actual permit spaces or in representative spaces that simulate (rather than "closely approximate") the permit spaces to be entered. In this way, the rule would not require multiple practice sessions for different permit spaces with similarly sized and configured openings. The rule anticipates that there will be variations between similar permit space openings. Additionally, the rule allows outside rescue services to practice in representative spaces that simulate the permit spaces they might have to enter. Thus, these services would not be required to visit every permit space every year, as long as practice rescue are conducted in representative spaces sometime during the year. It is important that the practice openings resemble those of the actual spaces, especially in means of access and egress. Otherwise, as noted earlier, the rescue service members may find that they have trouble getting into the space wearing personal protective equipment and carrying rescue equipment. In applying this rule, the Agency expects employers to conduct practice sessions using representations of the types of permit spaces the rescue service is expected to enter if the actual spaces are not available for entry. The final rule facilitates practice by outside rescue services by requiring the "host" employer to provide access to the permit spaces for planning and practice purposes.

OSHA disagrees with the commenter (Ex. 14–123) who stated that it was sufficient to require simply that employers train rescue teams to meet their goals. The Agency believes that the training requirements in paragraphs (k)(1)(i) and (k)(1)(ii) of the final rule do not, on their own, adequately ensure that the personnel assigned to perform rescues can function properly. OSHA believes that a periodic demonstration of the on-site rescue service's ability to extract authorized entrants from permit spaces will provide the necessary feedback regarding the adequacy of the rescue equipment, the rescue procedures and the training provided for performance of rescue from permit spaces.

The language incorporated in paragraph (k)(1)(iii) allows the satisfactory performance of one or more actual rescues during the 12-month period to substitute for a practice rescue from a given space. (Practices in other types of spaces would still be required.) OSHA has previously recognized in other standards (such as §1910.120, *Hazardous waste operations and emergency response*) that actual experience at a particular task is at least as valuable as a practice session or other type of training. It should be noted that the unsatisfactory performance of a rescue indicates the need for further training and does not substitute for a practice rescue. The intent of this exception is that if the rescuers performed their assigned tasks in a satisfactory manner, they need not perform a practice rescue for that 12-month period, regardless of the outcome of the rescue attempt. OSHA also notes that a rescue can be performed in a satisfactory manner and the entrants, through factors beyond the rescuers' control, still not survive.

Paragraph (k)(1)(iv) requires all members of a rescue service to be trained in basic first-aid and in cardiopulmonary resuscitation (CPR). In addition, at least one of the members on site during rescue operations must hold current certification in first-aid and in CPR.

This provision is based on proposed paragraph (h)(1)(iv), which would have required simply that at least one member of each rescue team hold current certification in first-aid and CPR. S. C. Johnson and Son, Inc. (Ex. 14–45), suggested that at least two members of each rescue team be trained in first aid and be CPR certified, that entry not be allowed unless the in-house rescue is at full strength, and that an in-plant rescue team "should not be credited as available" if either member trained in first aid and CPR is unavailable. Noting S. C. Johnson and Son's comment, OSHA requested information regarding the resources needed and available to comply with proposed paragraph (h)(1)(iv) in Issue 11 of the hearing notice (54 FR 41463).

The Agency also asked what criteria should be set to indicate what a rescue team must do in order to function effectively.

Many commenters called for more training of rescue personnel (Ex. 14–54, 14–61, 14–63, 14–111). For example, one of these commenters (Ex. 14–63) suggested that all members of the rescue team be trained in first-aid and CPR. Another (Ex. 14–54) suggested that the member of the rescue team designated to provide CPR and first-aid "should be First Responder and preferably EMT [emergency medical technician]," because this training is needed to extricate an injured employee from a permit space without exacerbating his or her injuries.

Several hearing participants also responded to this issue. (Washington Tr. 226, 251, 385; Chicago Tr. 383, 387, 434–435, 536; Houston Tr. 952–953). Some called for more training for rescuers (Washington Tr. 226, 251; Chicago Tr. 383, 387; Houston Tr. 952–953). For example, representatives of the Communications Workers of America (Washington Tr. 226, 251) testified that all members of the rescue team should be trained in first aid and CPR. Additionally, the UAW testified (Chicago Tr. 383, 387) in support of additional training requirements, as follows:

> We recommend extensive training in CPR, use, care and inspection of breathing and ventilation gear, emergency evacuation equipment, use of two-way radios and fire fighting equipment.
>
> * * * * *
>
> There is still a need for a more comprehensive training for rescue teams, the person in charge of the testing and, most importantly, the individuals who will enter these confined spaces. We recommend that every worker receive training and that individuals who may be participating in rescue teams receive additional training.

Mr. Jack Dobson, testifying on behalf of ASSE (Chicago Tr. 616–617), recommended the use of ANSI language dealing with training of emergency response personnel. Section 15.4 of ANSI Z117.1–1989 (Ex. 129) reads as follows:

> 15.4 *Training for Emergency Response Personnel.* Training shall include:
>
> 15.4.1 the rescue plan and procedures developed for each type of confined space they are anticipated to encounter;
>
> 15.4.2 use of emergency rescue equipment;
>
> 15.4.3 first aid and cardiopulmonary resuscitation (CPR) techniques;
>
> 15.4.4 work location and confined space configuration to minimize response time.

Rohm and Haas, Texas, testified (Houston Tr. 952–953) on the utility of having some advanced emergency responder medical training, as follows:

> All of them are what, in the State of Texas, is called ECA, their ECA minimum, Emergency Care Attendant. Minimum, which is about one or two levels below a paramedic. It is higher than first aid and CPR, however. It requires 40 hours of training and a State-administered exam.

On the other hand, some rulemaking participants questioned the need for the rescue personnel to be certified in CPR (Ex. 14–86, 14–160, 14–221; Chicago Tr. 536). They argued that the initial CPR course would suffice and that the annual refresher training required to maintain current certification would be burdensome. For example, the A. E. Staley Manufacturing Co. (Ex. 14–221) stated:

> OSHA has proposed requiring in-plant or outside rescue teams. (54 FR 24095 and 24105 as well as 54 FR 4163) Staley submits that formal rescue teams may not be necessary under many specific situations such as those covered by the low hazard classification.
>
> In situations where a hazard team is appropriate, greater flexibility in structuring the team should be given e.g. OSHA should consider changing the wording of proposed paragraph 1910.146 (h)(1)(iv) to allow greater program flexibility by not requiring one person to be trained in both first-aid and CPR. Equal or better treatment could be given by two people each trained in one of the two skills.

OSHA believes that rescue personnel need instruction in first aid and CPR. It is recognized (Ex. 14–45; Washington Tr. 226; Houston Tr. 953) that yearly recertification is needed to maintain one's proficiency. Therefore, the Agency has carried forward the requirement for at least one member to be certified in CPR. OSHA has not, however, extended the provision to require medical training more advanced than that proposed. Although other forms of medical training (such as for an emergency care attendant or an emergency responder) may be beneficial, such training is not necessary because the medical capabilities resulting from this training is very likely to be available from other emergency responders who will be treating the entrant after he or she is removed from the permit space. In fact, paragraph (d)(9) requires the employer to ensure the availability of necessary emergency services (such as paramedic services).

In light of the evidence on this issue, the Agency has concluded that a requirement for a lone person certified in first aid and CPR is not sufficient protection for injured permit space entrants. If that one rescuer were to depart after entry has begun or were to become incapacitated during rescue, there would be no one to render this all important first treatment in an emergency. For this reason, OSHA has incorporated into the final rule a requirement for all rescue team members to be trained in first aid and CPR (§1910.146(k)(1)(iv)). Only one member of the rescue service needs to have a current CPR and first aid certification, however.

Paragraph (k)(2) of the final rule, which is based on proposed paragraph (h)(2), sets requirements for employers who retain outside rescue services to enter permit spaces for rescue of entrants.

Proposed paragraph (h)(2) required that employers who retain outside rescue teams ensure that the designated rescuers are aware of the hazards they may confront when called on to perform rescues, so that the outside rescue team can equip, train, and conduct itself appropriately. Virtually all of the comments regarding proposed (h)(2) addressed the advisability of permitting the use of off-site rescuers. Those comments have already been addressed in the discussion of the introductory language to paragraph (k).

The requirement proposed in paragraph (h)(2) that employers inform outside rescue services of the hazards that may be faced during entry has been retained as paragraph (k)(2)(i). The language from the proposed rule has been modified for consistency with the terminology of the final rule.

The AFIA (Ex. 14–160) stated "In the interest of eliminating possible confusion, AFIA requests that OSHA confirm in the final rule itself that an employer has no equipment and training obligations with respect to an outside rescue team." The Agency acknowledges that an employer is not required to train or equip off-site rescuers. This does not mean, however, that the employer who retains an off-site rescue service has no responsibility for the adequacy of the rescue services provided. OSHA notes that both the proposal, through proposed paragraphs (c)(8) and (h)(2), and the final rule, through paragraphs (d)(9) and (k)(2), require the employer to take measures to enable the rescue of injured entrants.

Paragraph (k)(2)(ii) of the final rule requires an employer who retains off-site rescue services to provide the designated rescuers with access to permit spaces as necessary for those rescuers to develop an appropriate rescue plan and as necessary for the designated rescuers to practice rescue procedures in permit spaces whose features approximate those of the permit

spaces from which rescue may be necessary.

This provision had no counterpart in the proposal. As noted in the summary and explanation of paragraphs (k)(1)(iii) and (k)(1)(iv), earlier, several comments suggested that all rescuers have the training and the practice necessary for the performance of their duties. OSHA agrees with those commenters. A rescue service needs to know the location, configuration and other circumstances of a permit space in order to develop and practice effective rescue procedures. OSHA has determined that the off- site rescuer's need for information on the permit spaces and for opportunities to perform practice rescues can be satisfied only through access to permit spaces whose size, configuration, and accessibility approximate those of the permit spaces from which rescue may be required. The Agency believes that compliance with this requirement, while minimally disrupting an employer's operations, will greatly increase the effectiveness of off-site rescue services. It should be noted that this provision does not require the outside rescue service to actually use the permit spaces for practice; paragraph (k)(2)(ii) simply requires that the host employer provide access to the space. In performing practice rescues, the outside service may use any representative permit spaces that replicate those from which rescue may be performed, in accordance with paragraph (k)(1)(iii) of the final rule.

Paragraph (k)(3) of the final rule sets requirements for non- entry rescue systems. OSHA has incorporated this provision into the final rule so that employers will have guidance regarding the proper use of harnesses and retrieval lines in non-entry rescue.

The performance-oriented language of proposed paragraph (c)(7) required employers to provide, maintain and ensure the proper use of the equipment, including personal protective equipment, necessary for safe entry. OSHA notes that proposed paragraph (d)(2)(ix) included retrieval lines among the examples of the personal protective equipment required to be listed in the checklist portion of the permit. In addition, proposed paragraph (c)(8) required employers to ensure that the procedures and equipment necessary to rescue authorized entrants from permit spaces were implemented and provided, and proposed paragraph (d)(2)(vii) required listing of the rescue equipment provided in the checklist portion of the permit. In the proposal, OSHA anticipated that many employers would use retrieval lines for rescue of entrants. However, the Agency also understood that some employers might use other rescue methods, particularly when retrieval lines would pose an entanglement hazard. In Issue 12 of the NPRM (54 FR 24087), OSHA requested information on retrieval lines and other types of non-entry rescue methods.

Many rulemaking participants responded to this issue. Some of them stated that retrieval lines are the most appropriate form of rescue equipment, especially when connected to a powered winch or a device with a mechanical advantage (Ex. 14–30, 14–35, 14–43, 14–61, 14–162, 14–166, 14–182; Washington Tr. 394–395). Most advocates of retrieval lines based their support on successful experience with the devices. For example, Wisconsin Natural Gas Company (Ex. 14–185) stated it "has only used retrieval lines. Records of cost or effectiveness are not maintained. Performance history, however, indicates that our procedures are effective."

At the Chicago hearing, the AFL-CIO supplied information regarding near misses (Chicago Tr. 311–312). This information regarded employees who, while wearing retrieval lines, entered a space that used baffles. The employees were overcome, but were rescued using the retrieval lines.

The use of a full body harness was also recommended by some of these commenters (Ex. 14–61, 14–63, 14–68, 14–182).

Other rulemaking participants stated that retrieval lines are not always appropriate and that the use of retrieval lines should not be required under every circumstance (Ex. 14–28, 14–62, 14–73, 14–99, 14–153, 14–183, 14–187; Houston Tr. 730–731, 862; Chicago Tr. 96–97). Some pointed out that these lines pose an entanglement hazard in certain types of confined spaces, especially if air lines and electric cords are run into the same space. Most of these commenters supported OSHA's performance- oriented approach and suggested that retrieval lines only be required where they are appropriate. For example, Mr. Roger Corley, representing the National Association of Manufacturers (Chicago Tr. 96–97), testified:

> ... it appears in this section that a retrieval line is required in each and every confined space entry situation. There are situation[s] where retrievable lines are ineffective, or inappropriate, or simply not required. As a brief example in a large steam boiler, for example, which is a common piece of equipment, the steam drum or mud drum often are horizontal cylinders of less than 24 inches in diameter. When people enter those cylinders to inspect the inner surface and perhaps their feet never enter the steam drum - their feet are extended. But that's treated as a confined space entry that a standby person and all of those arrangements are there, but obviously a retrieval line would serve no purpose there.
>
> In other instances the configuration of the interior of a distillation column or more complex vessel will make a retrieval line inappropriate. In that case, we recommend language that would say retrieval line is a standard piece of equipment for a confined space entry unless it's somehow or other rendered ineffective or inappropriate by the configuration of the space being entered.

Frank Rapp of the UAW also testified (Chicago Tr. 439) that wristlets were sometimes used where the configuration of permit space prevented the use of body harness.

Although information on other non-entry rescue methods was requested, no commenters or witnesses identified such other methods. (OSHA did receive comments regarding the proposed definition of "retrieval line". These are addressed under the summary and explanation of paragraph (b), earlier in this preamble.)

OSHA believes that retrieval lines can be very effective in assisting in the rescue of an unconscious employee from a confined space. Their other major advantage in rescue is that it is not necessary for a rescuer to be placed at risk in entering the permit space to help remove an injured entrant. The effectiveness of retrieval lines in rescue is amply demonstrated by the experience of employers currently using this equipment for confined space entries. On the other hand, the Agency realizes that many spaces do not readily or safely accommodate the use of retrieval lines. As the rulemaking participants noted, obstructions can snag the retrieval line or the entrant, and air lines and electric cords within the space can pose entanglement hazards. In order to provide the greatest degree of safety while recognizing these problems, the final rule requires the use of retrieval systems or methods whenever an authorized entrant enters a permit space, except in situations, such as those described in the record, in which the retrieval equipment would increase the overall risk of entry or would not contribute to the rescue. This is the approach taken in ANSI Z117.1. OSHA believes that adopting the ANSI requirement will provide the most effective protection for employees, with due regard for situations in which retrieval systems should not be used.

In enforcing this provision, OSHA will inspect the permit space to determine whether or not a retrieval system would contribute to a rescue without increasing the overall risk of

entry. The Agency will use the following guidelines to make this determination:

(1) A permit space with obstructions or turns that prevent pull on the retrieval line from being transmitted to the entrant does not require the use of a retrieval system.

(2) A permit space from which an employee being rescued with the retrieval system would be injured because of forceful contact with projections in the space does not require the use of a retrieval system.

(3) A permit space that was entered by an entrant using an air supplied respirator does not require the use of a retrieval system if the retrieval line could not be controlled so as to prevent entanglement hazards with the air line.

Paragraphs (k)(3)(i) and (k)(3)(ii) set forth requirements for the proper use of retrieval systems. Paragraph (k)(3)(i) requires the authorized entrants to wear a chest or full body harness with retrieval line attached. The point of attachment of the retrieval line must be at the center of the entrant's back, near shoulder level, or above the entrant's head so that the entrant will present the smallest possible profile during removal, in case a rescue becomes necessary. The use of wristlets in place of the full body harness is recognized, if their use is appropriate (that is, if a full body harness cannot be used because of the configuration of the space).

Paragraph (k)(3)(ii) requires the outside end of the retrieval line to be attached to a fixed point or a lifting (or other retrieval) device in such a manner that rescue can begin as soon as the rescuer (in most cases the attendant) becomes aware that rescue is necessary. (As noted earlier, the attendant is only allowed to participate actively in non-entry rescue.) A mechanical device is required for vertical permit spaces more than 5 feet deep.

Some commenters (Ex. 14–62, 14–182) suggested that the retrieval line be attached to a mechanical lifting device. Another commenter (Ex. 14–63) focused on the need for mechanical systems "whenever practical" to remove entrants from permit spaces. That commenter stated:

> Securing the line to an anchor point does not afford the entrant an equal level of protection. It is difficult to move dead weight without mechanical assistance.

S.C. Johnson and Son, Inc. (Ex. 14–99) provided a summary of conclusions based on their near miss experiences. Their experiences showed that mechanical assistance, though difficult to provide, was necessary for retrieval.They stated:

> We found that using a simple pulley was not "sufficient" to lift anyone from inside a vertical entry confined space. An attendant did not, by himself, have sufficient strength to "remove" anyone from such a space.... Providing such mechanical assistance is complicated by a general lack of room to position such equipment above the entry point of such spaces and the need to keep that entryway "cleared" for the attendant to "observe" the entrants while they are working.

Additionally, some commenters addressed the advisability of using powered winches to remove authorized entrants from permit spaces. One commenter (Ex. 14–54) stated:

> Used powered winches, overhead cranes, etc. is the easiest way to impale victims, tear off limbs and retrieve pieces and parts of victims. The word "Rescue" means to remove a victim from danger to safety, not to add danger.

Also, Caterpillar, Inc. (Ex. 14–137) commented:

> Power [winches] will not be used where additional harm to employees may occur.

Another commenter (Ex. 14–166) stated:

> Powered retrieval winches should be recommended where depths exceed 50 ft and should be equipped with torque limiters of approx. 450 lbs to avoid damaging the incapacitated person.

Frank Rapp of the UAW testified (Chicago Tr. 440):

> Some plants we usually [use a] fork truck, attach the lifeline onto the fork over a pit and lift them up by fork truck. You can do an extreme amount of damage to that person as they're ricocheting off a wall coming up.

ANSI Z117.1, Section 12.2.1 requires a mechanical device to be available to retrieve personnel from vertical type permit spaces greater than 5 feet in depth (Ex. 129).

OSHA believes that there are circumstances where the attachment of a retrieval line to a fixed point would enable the attendant or other rescue personnel to safely extract an entrant without the need to enter the space. OSHA further recognizes that a mechanical device will usually be necessary to enable rescuers outside the space to lift entrants out of vertical permit spaces. Therefore, the OSHA has adopted the ANSI approach requiring a mechanical device to be available, if a retrieval system is used, during entry operations involving vertical type permit spaces more than 5 feet deep. (Any permit space whose opening is above the entrant is considered to be a "vertical- type permit space".) The mechanical device used should be appropriate for rescue service. The employer should not use any mechanical device, such as a fork lift, that could injure the entrant during rescue.

In response to a comment (Ex. 14–11), OSHA raised Issue 15 of the hearing notice (54 FR 41463). This issue requested testimony and evidence regarding the need to require that the applicable Material Safety Data Sheet (MSDS) accompany an injured employee to the hospital if the injury was caused by a hazardous substance and regarding the need to require the permit to contain the names and phone numbers of persons who would make important decisions regarding rescue operations in a permit space.

OSHA received a comment (Ex. 14–210) on this issue which indicated that an MSDS would be of limited usefulness to emergency services, and that the administrative burden associated with tracking and locating the MSDS would be excessive. This commenter wrote:

> While providing [an] MSDS to accompany an injured entrant to the hospital may help in some cases, the injury may not be related to a chemical. The administrative burden of constantly tracking which chemical or gas the entrant is exposed to during a repair would be onerous. Emergency information can be provided promptly to the hospital without specifically requiring it in the proposed regulation.

OSHA also received testimony on Issue 15 at the hearings (Washington Tr. 896–897; Houston Tr. 909–910, 981; Chicago Tr. 168–170, 368, 497, 539, 617–618).

For example, one witness (Chicago Tr. 368) testified that while an MSDS was important, its usefulness might be limited, stating:

> Hazardous chemicals go unlisted by the companies [or they] fail to research other sources of data as required by the standard, such as RTECS. Unfortunately, much of the material found in confined spaces is waste material and is not covered by 1910.1200 Hazard Communication Standard.
>
> The availability of MSDSs is an important issue and the individual who authorized entry must assure to themselves that this information is available during the evaluation. MSDSs must also be available for any necessary emergency treatment provided at the job site or at least a list of chemicals that are involved in the confined space entry.

Other commenters at the public hearings expressed the same views. A commenter (Houston Tr. 896–897) at the hearings in Houston, Texas, said:

> Issue No. 15, access to material safety data sheets and other information. We recommend that the supplying of the appropriate MSDSs to accompany an injured employee to medical attention should only be required where it is clear which substance or substances caused the injury and as long as

a timely card to obtain the MSDSs does not delay the medical attention for the injured employee.

This is an area that must be dealt with very carefully. It is highly likely that in the course of an accident, an incorrect MSDS or an incomplete set of MSDSs in the case of exposure to more than one chemical, may accompany an employee to medical attention.Should medical professionals change their diagnosis or treatment procedures based on incorrect or incomplete MSDSs, the results could be tragic.

We recommend that unless these conditions can be met, OSHA should not require that a MSDS accompany an injured [employee].

Another hearing participant (Chicago Tr. 539) also testified that methods other than providing MSDS's were available to provide medical personnel with information on chemical exposures. This witness stated:

Issue 14 [sic] regards chemical information, MSDSs, be communicated to the emergency medical treatment personnel treating an injured employee. We encourage our facilities to identify local medical treatment centers where employees may be taken or that may be impacted by local emergency responses and establish a communication method appropriate for their system, and whenever an employee—what we do is even our small sites go out and identify the hospital or medical treatment area, review with those emergency people the chemicals or hazards that our employees may be exposed to or our contractors, and then give them a list and review and provide access, and also, we have a policy that any time an employee is injured on the site, that a company representative will travel with that employee to the treatment area.

The Agency believes that the identification of, and the means to notify a responsible person during rescue operations is a necessary part of rescue planning. Compliance with paragraph (d)(9) of the final rule, which requires employers to implement proper procedures for rescuing employees from a permit space, will necessarily involve provision for proper notification of the appropriate management personnel.

In addition to the comments and testimony, OSHA notes that the Superfund Amendments and Reauthorization Act of 1986 (SARA) (Subtitle B, Section 311) requires employers who produce, use, or store hazardous chemicals (as defined in 29 CFR §1910.1200) in excess of Environmental Protection Agency (EPA) limits to provide MSDSs to the state emergency planning commission, the local emergency planning committee, and the local fire department. OSHA notes that hospitals are represented on the local emergency planning committee and therefore should be aware of the types of chemicals in the community. OSHA also recognizes that in some cases an existing procedure, not involving MSDS's, may exist which provides an equal or more effective means of providing chemical exposure data to medical personnel.

A proper analysis of the hazards in a permit space under paragraph (d)(2) of the final rule will provide a list of possible chemical exposures, which will be included on the permit. Therefore, employers should be able to determine whether an MSDS is available for any substance to which an employee is likely to be exposed.

OSHA believes that it is important to ensure that medical treatment facilities are provided with any available information concerning the substances to which entrants have been exposed. While OSHA recognizes that while such information may already be available to medical facilities from other sources (such as state emergency planning commissions), and that MSDS's or similar written information may not be available at all in some instances, the Agency believes, based upon the comment and testimony received in response to issue 15 of the hearing notice, that it would be reasonable and prudent to require an employer to provide MSDS's or other written information to a treating medical facility when such MSDS's or other similar written information is already required to be kept at the worksite. The employer would only have to provide the information under the following conditions:

(1) If the MSDS or other written information is already required to be kept at the worksite by other applicable Federal (such as §1910.1200, *Hazard communication*) or state regulation, and

(2) If there exists an MSDS or other written information for the specific substance or substances to which the entrant has been exposed.

Accordingly, OSHA has included paragraph (k)(4) in the final rule to requires that, if an injured entrant is exposed to a substance for which an MSDS or other similar written information is already required to be kept at the worksite, the MSDS or other written information be provided to the treating medical facility. Employers can comply with this provision by having that information accompany the employee to the medical facility or by providing it to the facility as soon as practicable after the employee's arrival there. *Appendices*

OSHA is including five non-mandatory appendices (Appendix A—Decision flow chart, Appendix B—Procedures for atmospheric testing, Appendix C—Examples of permit programs, Appendix D—Sample permits, and Appendix E—Recommended procedures for sewer entry) with the final standard.

In Issue 13 of the NPRM (54 FR 24087), public comment was requested on the use of an appendix to the confined space standard as a source of general guidance for employers in understanding and complying with the standard. OSHA asked for specific recommendations and suggestions of subjects, such as personal protective equipment or rescue procedures, that commenters thought should be added to such an appendix. The Agency, in Issue 14 of the proposal and Issue 5 of the hearing notice, also requested information on industries which might be unable to develop permit programs because of their size. OSHA received many comments on these issues. Many rulemaking participants submitted sample procedures or permits (Ex. 14–4, 14–49, 14–57, 14–73, 14–88, 14–170, 14–171, 14–183, 14–209, 57, 58, 97, 98, 99, 101, 104, 105, 106, 118, 119, 127, 128, 131, 132, 143).

Some commenters (Ex. 14–81, 14–95, 14–219) offered brief statements of support for the use of an appendix as a source of general guidance. For example, the American Industrial Hygiene Association (AIHA, Ex. 14–61) in its response to Issue 1 in the proposal said that:

...there should at the very least be guidance to the employer in an appendix to the standard, as how to evaluate a potential confined space. In that manner, the small employer in particular would derive much needed direction from the agency on how to protect their employees.

AIHA maintained that information was especially needed on the subjects of hazard recognition and emergency planning.

A comment from the National Fire Protection Association (Ex. 14–42) recommended the use of national consensus standards in the formulation of appendix material, as follows:

If the American National Standards Institute issues the revised ANSI Z117, reference to it may be helpful, since it contains mandatory and explanatory guidance. The regulations should include a model confined space program, with samples of permits which are being used.

Another commenter (Ex. 14–44) noted that an appendix could provide valuable information to employers who do not have experience in permit space programs, as follows:

There are a number of items which would be helpful in an appendix as a source of general guidance. Due to the broad industrial application of this document the information

will have to be rather generic in nature, but could still be helpful in guiding the uninitiated in developing a good program. This information could include: types of protective equipment; types of retrieval equipment; types of acceptable lighting and electrical equipment; types of detection equipment; types of acceptable communications; typical permits and modifications; basic entry procedure; etc.

The State of Maryland Occupational Safety and Health Program (Ex. 14–63) responded at length to the importance of using appendices, stating, in part:

As an absolute minimum, Maryland would recommend an Appendix providing guidance in each of the [following] areas[:] hazard identification procedures, the monitoring and evaluation procedures, personal protective equipment requirements, rescue equipment and procedures and training of personnel. OSHA notes, on p. 24092 of the preamble, "That employers have not been sufficiently careful about authorizing permit space entry, and believes that only a systematic approach will ensure that entrants receive the necessary protection." If this is true in industries already using permit entry, it is more important to offer guidance through a series of systematic steps to employers who will encounter these requirements for the first time and who may have little competence in this area.

* * * * *

There should be a training section or an Appendix incorporated into the standard, which offers an outline or a lesson plan which addresses each item to be covered, such as reading instruments, monitoring, ventilation, rescue, etc.

* * * * *

Since most confined space fatalities are multiple fatalities created by the attempts of rescuers, improperly trained and equipped, to bring the fallen employee out of the space, this is one of the crucial factors in the training. If an *appendix* is prepared with a training outline, this should be stressed. [Emphasis was supplied in original.]

Maryland also suggested that the appendix be used to address the requirements in proposed paragraph (d)(4) relating to hot-work permits. In their statement directed specifically at NPRM Issue 13, they remarked that the appendices should explain each individual paragraph of the standard and provide additional information on them. They also listed the following suggested subjects: Permit vs. non-permit spaces, approaches to ventilation, instrumentation, isolation, lockout and tagging, draining and flushing, testing, personal protective equipment, check in and out, attendants, rescue, and training.

In their comments addressing proposed paragraphs (d)(2)(i) through (v), relating to information to be placed on the permit, Organization Resources Counselors, Inc. (Ex. 14–143), recommended that OSHA make the standard addressing these elements as short as possible and that OSHA put the details of these provisions in the appendix. ORC specifically endorsed the use of an appendix, stating:

ORC supports the publication of non-mandatory appendices which contain information and additional guidance on compliance with the standard. Samples of specific procedures, examples of permits, etc., might be quite useful to employers who do not have permit programs now and wish to understand the type of information that they will need to evaluate and the type of program they will have to implement to be in compliance with the standard.

Other commenters (Ex. 14–170, 14–195) supported the view that the appendices could be used to assist employers in their efforts to comply with the standard. Still another commenter (Ex. 14–208) stated that additional guidance was needed concerning the content of the permit, as follows:

To further assist employers in complying with the standard, CWA District 1 recommends that OSHA require employers to adopt the sort of checklist that has been developed by NIOSH in its *Guide to Confined Spaces*. The NIOSH checklist or its equivalent could be made an additional appendix to 1910.146. [Emphasis was supplied in original.]

By contrast, Edison Electric Institute (Ex. 14–171) was concerned that the sample permits found in the proposed appendix would pose compliance problems for employers who did not follow them exactly, stating:

EEI is concerned with the use of the forms listed in the non-mandatory appendix C to the proposal. Although they are advisory in nature, failure of an employer to include all of the suggested points could be considered as evidence of a violation or negligence. Although OSHA could not base a citation on the appendix, it could be used by a claimant to establish a standard of care in a third party lawsuit initiated after an accident.

Some of the participants in the public hearings also addressed appendices. For example, Keith Mestrich, on behalf of the Food and Allied Service Trades - AFL-CIO, recommended that OSHA include sample permits in an appendix (Chicago Tr. 42). John Nicol, testifying for the Chemical Manufacturers Association, recommended that OSHA include a sample training program in the appendix (Chicago Tr. 142).

Two commenters (Ex. 14–14, 14–98) responded specifically to Issue 14 in the proposal, suggesting that the rendering industry and the wastewater industry may not have sufficient resources to develop their own permit programs.

OSHA believes that non-mandatory appendices are a valuable tool to convey helpful information to assist employers in complying with the standard. OSHA does not agree with the view that the information in these non-mandatory appendices will be used for enforcement of the standard by the Agency's compliance staff. Based on the needs of employers and employees as described in the record, OSHA has carried forward two of the proposed appendices (the decision flowchart and the sample permit), has not carried forward one (the list of references) and has incorporated three others not included in the proposal (the procedures for atmospheric testing, the examples of permit programs and the recommended procedures for sewer entry).

Appendix A, *Permit-required Confined Space Decision Flowchart*, has been updated to be consistent with the final standard's provisions. The information in the flowchart is based on the Agency's analysis of how the requirements of the final rule would be applied to any given workplace.

Appendix B, *Procedures for Atmospheric Testing*, has been included in the final rule. It contains detailed recommendations on the purpose and types of atmospheric testing. Information of this type, though vital to an employer's permit program, is too lengthy and detailed to be placed within the regulatory text. OSHA has therefore incorporated Appendix B into the final rule. The information in this appendix is based on the many actual permit space programs submitted to the record.

Appendix C, *Examples of Permit-required Confined Space Programs*, has been incorporated into the final rule. OSHA believes it would be helpful to provide sample permit programs as well as samples of permits. The information in this appendix is based on the many actual permit space programs submitted to the record.

Appendix D contains sample permits. OSHA, responding to comments concerning proposed Appendix C, which also contained sample permits, has improved and upgraded the examples from the proposal. The information in this appendix is based on the many actual permit space programs submitted to the record.

Appendix E, *Sewer System Entry*, has been included in the final rule. Sewer entry differs in several respects from most other types of permit entry. (The appendix itself discusses these differences.) OSHA believes that these differences, while not so great so as to require separate treatment in the standard's regulatory text, do dictate at least a detailed discussion in a non-mandatory appendix.

Proposed Appendix B, which contained references for further information, has not been carried forward into the final rule. OSHA believes that the inclusion of this list in the actual standard is unnecessary. Much of the information from those references is already outdated, and the remainder will likely become outdated in a few years. OSHA has, however, presented a list of references for interested parties in Section IV, *References*, later in this preamble.

Discussion of Issues

The NPRM (54 FR at 24086) set out 18 issues regarding which OSHA sought information. The hearing notice (54 FR 41461) set out 15 issues, based on the NPRM comments, on which the Agency requested testimony, evidence, and additional comments. Most of the NPRM and hearing notice issues related to particular provisions of the proposed rule. The comments, evidence, and testimony received in response to those issues are covered in the Summary and Explanation discussion for the pertinent provisions of the final rule. The rest of the issues requested information that would assist OSHA in evaluating the impact of the proposed rule. The comments and testimony received in response to those issues are discussed in the following paragraphs and in Section VI, *Summary of the Final Regulatory Impact Analysis and Regulatory Flexibility Analysis*, later in this preamble.

Issue 7 of the NPRM (54 FR 24087) noted the proposed rule's emphasis on engineering and work practice controls for atmospheric hazards and asked what provisions OSHA should add to address nipping or crushing hazards. Several commenters (Ex. 14–4, 14–30, 14–35, 14–50, 14–57, 14–62, 14–63, 14–71, 14–81, 14–88, 14–94, 14–110, 14–111, 14–118, 14–131, 14–137, 14–157, 14–161, 14–162, 14–170, 14–179, 14–182, 14–187, 14–193, 14–199, 14–219) responded to this issue. The great majority of these commenters were of the opinion that mechanical hazards, such as nipping or crushing, would be best handled by other standards, such as §1910.147, *Control of hazardous energy sources (lockout/tagout*, already in existence. For example, The Shipbuilders Council of America (Ex. 14–62) said:

> Confined space standards should address those hazards peculiar to confined spaces, and not address all of the hazards to which entrants could be exposed. SCA believes that other safety hazards, such as heights, falls, surfaces, lighting, machine guarding, tagout/lock-out, etc. should be governed by their respective standards.

Likewise, the Kerr-McGee Corporation (Ex. 14–161) expressed the view that other standards should address mechanical and physical hazards, stating:

> OSHA asks what additional provisions would be appropriate to protect employees against physical and mechanical hazards. Kerr-McGee believes that adequate protection against such hazards is already provided by other OSHA standards including, but not limited to, Subpart O and the new lockout/tagout rule, 1910.147, effective October 31, 1989. While permit entries *may* require control of hazardous energy sources (lockout/tagout), OSHA should keep the two rules separate by referencing, rather than incorporating portions of one rule in the other. [Emphasis was supplied in original.]

Some commenters (Ex. 14–4, 14–35, 14–50), while not exclusively addressing physical hazards, did provide examples of specific equipment or procedures that would be involved with hazards other than atmospheric. Some of the equipment listed in these comments were non-sparking tools and various explosion- proof devices. One commenter (Ex. 14–50) mentioned that permit spaces should be evaluated for excessive temperature and noise, in addition to proper levels of lighting.Another commenter (Ex. 14–63) believed that these hazards needed to be addressed in the final standard.

Under most conditions, the lockout/tagout standard in §1910.147 properly addresses the control of hazardous energy sources within permit spaces. In fact, employers must deenergize and lock out or tag energy sources for machinery within a permit space with §1910.147, in addition to taking other measures required by final §1910.146, whenever servicing and maintenance is performed on that equipment. However, even if servicing and maintenance is not being performed (in which case §1910.147 would not apply), §1910.146 requires the employer to isolate hazards within the space to protect employees from any mechanical or other energy sources that may be present in the permit space. This approach is not only performance oriented, but it also avoids placing unnecessary details in the Permit-Required Confined Space final rule. The Agency has addressed the hazards associated with energy sources in paragraph (d)(3)(ii), which requires the employer to take measures to isolate the space, and in paragraph (f)(8), which requires the permit to list the measures used to isolate the space. OSHA believes that these requirements will ensure that employers have considered the energy-related hazards that may be found in permit spaces and that employers have taken measures to eliminate or control those hazards before employees enter those spaces.

The proposed rule took a performance-oriented approach to regulating employee safety in permit space entry operations. In the preamble to the proposal (54 FR 24087), OSHA explained that this approach was chosen to provide employers with maximum flexibility in determining how to protect their employees and raised Issue 9 of the NPRM, in which public comment was requested on whether or not this approach was appropriate and on what proposed provisions should be revised to use specification language. Additionally, OSHA asked if there were any provisions that used specification-type language where performance-oriented language should be substituted.

A substantial number of the commenters who responded to this issue (Ex. 14–27, 14–28, 14–30, 14–35, 14–43, 14–47, 14–50, 14–57, 14–73, 14–98, 14–161, 14–170, 14–183) expressed overall agreement with the use of performance language. Many supported the use of performance language with a few brief words. For example, Transco Energy Company (Ex. 14–35) stated:

> [Performance language] is desirable and will allow employers maximum flexibility in establishing their safe work practices and procedures.

In the same vein, the American National Can Company (Ex. 14–47) stated:

> Generally, we endorse the performance-oriented style of the proposed standard and support its intent and objective. We believe it represents a professional effort to produce a constructive framework for reducing the national casualty rate associated with the entry of confined spaces.

Another commenter (Ex. 14–50) expressed his opinions, as follows:

> ... it is better to provide performance language for many of these items as opposed to specific non-flexible requirements.

Monsanto Company (Ex. 14–170) offered support for the use of performance-oriented language in OSHA standards, but recommended that the rule provide clarification with respect to what is expected of the employer in terms of compliance, as follows:

> The standard should have clarity of language supported by examples so that employers can understand the range of methods for acceptable compliance.

The GATX Terminals Corporation (Ex. 14–183) stated their reasons for supporting performance language, as follows:

I concur with your performance-oriented, systematic approach and highly recommend that the flexibility that you are trying to build into the program remains a viable part of the final rule. I [emphasize] this due to the fact that confined space 'hazards' vary from one extreme to the other and the characteristics of each are directly contingent on site-specific hardware and the individual [company's] standard operating procedures. If companies do not have the flexibility to develop what they feel to be the priorities, the 'real' hazards may continue to exist. On the same note, employees who are involved with confined space entry (CSE) are already required (and sometimes frustrated) to follow a variety of procedures. If additional procedures are required in the future and they are perceived to be redundant or unnecessary by the workforce, an attitude of non- importance may develop—which is the last thing that OSHA or industry wants to happen when addressing this subject.

The National Fire Protection Association (Ex. 14–42) also agreed that the proposal's performance approach was appropriate, stating:

The accident statistics indicate for the most part that it is the failure of management to actively identify confined spaces and hazards in their workplace and provide adequate awareness training for all employees. Accidents have not occurred because the wrong hazards are identified or because the wrong atmospheric exposure levels were applied. No, accidents have occurred because no one even bothers to identify and evaluate the hazards.

It should be the function of this regulation to provide the framework for management to use to develop individual systems for recognition, evaluation and control of hazards associated with confined spaces which their workers will enter. The system should be in the form of a written safe work practice and should include designation of testers (professional and qualified as necessary). The system should include performance evaluation of the testers and workers. The system should also address non-routine entry, such as emergency or rescue.

Another commenter (Ex. 14–28) noted the difficulty of applying specification-type standards to industries with widely varying circumstances, as follows:

The performance oriented approach is appropriate. I've been involved with two ANSI standards and find that what is fine for one industry is impractical for another. I did not note any language problems, i.e., performance versus specification.

The comment and testimony received in response to Issue 9 in the NPRM serve to confirm OSHA's belief that performance, rather than specification type standards, best serve the purpose of protecting employees from the hazards of permit space entry while allowing employers to choose the best methods and procedures available to them for carrying out their responsibilities under the permit-required confined space standard. OSHA has therefore carried forward to the final rule the approach of using performance language whenever possible.

In spite of their support for the performance-oriented language contained in the proposal, some rulemaking participants (Ex. 14–62, 14–118, 14–143, 14–150, 14–168) found certain proposed requirements to be too specification oriented. For example, the Chemical Manufacturers Association (Ex. 14–118) supported the performance-oriented approach of the proposal. However, they did object to proposed §1910.146(c)(1), stating:

... the hazard identification and employee information sections do not adhere to the performance philosophy. This departure from that approach compromises the overall effectiveness of the standard.

The Shipbuilders Council of America (Ex. 14–62) argued that proposed paragraph (i) was not sufficiently performance oriented, as follows:

OSHA should modify paragraph (i) [Special permits for entry into low-hazard permit spaces] to provide more performance-oriented language...

Organization Resources Counselors, Inc. (Ex. 14–143) offered two examples of regulatory language they believed to be too detailed and inconsistent with a performance standard approach, as follows:

Paragraph (d)(2)(iii) states that "procedures for purging, inerting, ventilating and flushing..." should be included on the permit. Further, paragraph (d)(2)(v) calls for "testing and monitoring equipment and procedures..." to be included in the permit. Procedures for these items can be extensive. They are part of the preparation for entry, and their accomplishment should be addressed by the checklist, but the procedures themselves should not be part of the permit.

The Pennzoil Company (Ex. 14–150) echoed the same concern about permit systems addressed in proposed paragraph (d)(2). They stated:

[We] believe that the specifications listed include too much detail to be consistent with a performance- oriented approach, and are not achievable in some instances. An excellent example is [paragraph (d)(2)(iii)] which requires "...procedures for purging, inerting, ventilating, and flushing..." These procedures are very extensive, and are part of the preparation, not part of the *permit*. The entry permit approval process will ensure completion of these steps. We believe that [paragraph (d)(2)(iii)] should simply state "...the measures used to remove or control potential hazards." [Emphasis was supplied in original.]

Similar concerns about permit systems as addressed in proposed §1910.146(d)(2), (d)(3) and performance language were raised by the American Petroleum Institute (Ex. 14–168). In discussing proposed paragraph (d)(2), API stated:

While agreeing in concept, the specifications listed in this section are far too detailed, inconsistent with the desired performance approach, and in some cases simply are not achievable.

OSHA has taken these and all other comments, testimony, and evidence into consideration in the promulgation of the individual requirements of the final rule. OSHA believes that the final rule is written in terms of performance to be achieved rather than in terms of how to achieve the desired performance to the greatest extent consistent with effective employee protection from the hazards of permit space entry. Comments on the individual provision of the proposal that were thought to be too detailed are discussed under the summary and explanation of the corresponding provision of the final rule.

OSHA recognizes that the hazards associated with particular permit spaces differ in nature and degree according to the type of space being entered. In the notice of proposed rulemaking, the Agency proposed to allow employers the flexibility to tailor their permit space programs so that the particular conditions encountered are taken into account. However, the preamble to the proposal noted that the relative cost effectiveness of the rule (as calculated in the preliminary regulatory analysis) varied greatly from SIC to SIC. If this analysis were correct, the rule as proposed would have been much more cost effective in some industries than in other industries.

To ensure the greatest cost effectiveness for the final rule, OSHA posed, in Issue 17 of the NPRM (54 FR 24087), a series of questions related to minimizing the burden of the rule on employers while maximizing safety for employees. Commenters were requested to identify areas where the hazards posed by the spaces involved were not as great as those anticipated by the standard and, alternatively, areas where the hazards were more serious.

Interested parties responding to this issue identified several types of spaces that they claimed were covered by proposed §1910.146(i) but that were not hazardous enough to be regulated as permit-required confined spaces. Some of these commenters identified open trenches, ditches, excavations, and diked areas as examples of such spaces (Ex. 14–35, 14–43, 14–126, 14–183, 14–184). The commenters noted the lack of full enclosure of the spaces'

atmospheres (the tops of the spaces are open) and the relative ease of egress from these areas. Because of this, they maintained that trenches, ditches, excavations, and diked areas do not pose sufficient hazards to warrant regulation as permit-required confined spaces.

OSHA agrees with these comments. The Agency believes that these areas will not normally meet the definition of "permit- required confined space" and will not, therefore, usually be subject to final §1910.146. A detailed discussion of issues related to proposed paragraph (i) is contained in the summary and explanation of paragraph (c)(5) of the final rule.

Many other commenters argued that telecommunication manholes and vaults did not warrant all the procedures required under proposed §1910.146 (Ex. 14–104, 14–106, 14–108, 14–110, 14–139, 14–142, 14–162, 14–167, 14–187, 14–194, 14–195, 14–207). They maintained that such manholes and vaults were adequately covered by existing §1910.268(o) and argued that accident experience under the telecommunication standard clearly demonstrated that employees working in these manholes and vaults were adequately protected without further regulation. These commenters also pointed out that manhole entry posed limited hazards in comparison to entry into permit-required confined spaces, especially when all the requirements of §1910.268 are followed.

OSHA also agrees with these commenters. In fact, under the final rule, employee entry into telecommunications manholes and vaults will normally be covered under §1910.268 rather than §1910.146. (This was also true under the proposal, although it may not have been clear.) For additional information regarding the application of §1910.146 to the telecommunications work, see the discussion of final §1910.146(a) earlier in this preamble.

With regard to the question of why the cost effectiveness of §1910.146 varied widely from SIC to SIC, very few commenters had concrete answers. Three respondents doubted the accuracy of the underlying data (Ex. 14–62, 14–63, 14–172). For example, the State of Maryland's Occupational Safety and Health program stated:

> MOSH would certainly question the data collection of several of the industries for which there appear to be no fatalities on the chart provided. It is hard to believe that in agriculture (silos), textile mill products (process vessels, bleaching vats), tobacco manufacturing (mixers, vats), printing and publishing (tanks for inks and solvents) that there have been no confined space fatalities, especially since MOSH recalls articles on such, although no specifics are readily available.

Most commenters argued that the best way to handle the problem of maximizing the cost effectiveness of the rule was to promulgate a performance-oriented standard that provides the employer with the flexibility to adapt his or her confined space entry program to the hazards posed by the spaces found in the workplace (Ex. 14–35, 14–43, 14–57, 14–73, 14–81, 14–137, 14–161, 14–170, 14–193). In this manner, they contended, the employer assumes the responsibility for employee safety and has the freedom to choose the least costly method for adequately protecting his or her employees. One of these commenters, Mr. Gerald Beaumont of Beaumont and Associates (Ex. 14–57), recognized that, even with the wide range of hazards posed by confined spaces, there are certain common dangers:

> It is appropriate to allow trained supervisors and safety professionals to apply their judgement in protecting employees within the structure of this proposed standard. Some industries may not have confined space fatalities listed because of limited exposure to confined spaces. However, the hazards of oxygen deficiency and naturally generated toxic gases are potentially present in all confined spaces along with the possible release of flammable or toxic materials by the work activity, and thus should be evaluated prior to authorizing entry.

OSHA agrees that a performance-oriented standard is the most cost effective approach to regulation. The Agency took this approach in proposing §1910.146 and has refined it in the final rule. The final rule permits employers to specify whatever procedures he or she believes will best protect his or her employees. However, OSHA is requiring certain precautions to be taken for all permit-required confined space entries, because, as noted by Mr. Beaumont and as conclusively demonstrated by the many accident descriptions in the record, certain hazards are common to all regulated spaces. There is no evidence in the record that spaces regulated by the final rule are safer in any one industry than in another. The Agency strongly believes that this final rule will prove to be cost effective in preventing the deaths of and injuries to employees from the hazards posed by confined spaces.

IV. References

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5. Organization Resource Counselors, Inc. "Sixth Draft of Proposed Performance Standard for Confined Spaces" Washington, DC 20006.

6. Michigan Department of Public Health, Division of Occupational Health. "Control Measures for Hazardous Atmospheres (Including Tank and Vessel Entry)", Lansing, Michigan 48909.

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13. American Petroleum Institute (API). Draft s3, "Guidelines for Working in Inert Confined Spaces in the Petroleum Industry", AOSC, 1985. Washington, DC 20005.

14. U.S. Department of Labor, Occupational Safety and Health Administration (U.S. DOL/OSHA). "Selected Occupational Fatalities Related To Toxic and Asphyxiating Atmospheres In Confined Spaces As Found In Reports of OSHA Fatality/Catastrophe Investigations", Washington, DC 20210. U.S. DOL/OSHA, 1985.

15. U.S. Department of Health and Human Services, National Institute for Occupational Safety and Health (DHHS/NIOSH). "Request for Assistance in Preventing Occupational Fatalities in Confined Spaces", Cincinnati, Ohio 45226. HHS/PHS/CDC/NIOSH, 1986.

16. State of New Jersey, Department of Labor and Industry, Bureau of Engineering and Safety. New Jersey Administrative Code Title 12, Chapter 170, "Work in Confined Spaces", April 1971. Trenton, New Jersey 08625.

17. State of Florida, Department of Commerce, Bureau of Workmen's Compensation. "Regulation Relating to Hazardous Atmospheres in Confined Spaces", 1969. Tallahassee, Florida 32301.

18. American National Standards Institute (ANSI). "Safety Requirements for working in Tanks and other Confined Spaces", ANSI Z117.1–1989. New York, New York 10018.

V. Statutory Considerations

A. Introduction.

OSHA has described the hazards confronted by employees who enter permit spaces and the measures required to protect affected employees from those hazards in Section I, *Background*, and Section III, *Summary and Explanation of the Standard*, respectively, earlier in this preamble. The Agency is providing the following discussion of the statutory mandate for OSHA rulemaking activity to explain the legal basis for its determination that the permit space standard, as promulgated, is reasonably necessary to protect affected employees from significant risks of injury and death.

Section 2(b)(3) of the Occupational Safety and Health Act authorizes "the Secretary of Labor to set mandatory *occupational safety and health standards* applicable to businesses affecting interstate commerce", and section 5(a)(2) provides that "[e]ach employer shall comply with *occupational safety and health standards* promulgated under this Act" (emphasis added). Section 3(8) of the OSH Act (29 U.S.C. § 652(8)) provides that "the term 'occupational safety and health standard' means a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment."

In two recent cases, reviewing courts have expressed concern that OSHA's interpretation of these provisions of the OSH Act, particularly of section 3(8) as it pertains to safety rulemaking, could lead to overly costly or under-protective safety standards. In *International Union, UAW v. OSHA*, 938 F.2d 1310 (D.C. Cir. 1991), the District of Columbia Circuit rejected substantive challenges to OSHA's lockout/tagout standard and denied a request that enforcement of that standard be stayed, but it also expressed concern that OSHA's interpretation of the OSH Act could lead to safety standards that are very costly and only minimally protective. In *National Grain & Feed Ass'n v. OSHA*, 866 F.2d 717 (5th Cir. 1989), the Fifth Circuit concluded that Congress gave OSHA considerable discretion in structuring the costs and benefits of safety standards but, concerned that the grain dust standard might be under-protective, directed OSHA to consider adding a provision that might further reduce significant risk of fire and explosion.

It is, of course, beyond doubt that OSHA rulemakings involve a significant degree of agency expertise and policy-making discretion to which reviewing courts must defer. (See for example, *Building & Constr. Trades Dep't, AFL-CIO v. Brock*, 838 F.2d 1258, 1266 (D.C. Cir. 1988); *Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 655 n. 62 (1980).) At the same time, the agency's technical expertise and policy-making authority must be exercised within discernable parameters. The lockout/tagout and grain handling standard decisions sought from OSHA more clarification on the agency's view of the scope of those parameters. In light of those decisions, OSHA believes it would be useful to include in the preamble to this safety standard a statement of its view of the limits of its safety rulemaking authority and to explain why it is confident that its interpretive views have in the past avoided regulatory extremes and continue to do so in this rule.

Stated briefly, the OSH Act requires that, before promulgating any occupational safety standard, OSHA demonstrate based on substantial evidence in the record as a whole that: (1) the proposed standard will substantially reduce a significant risk of material harm; (2) compliance is technologically feasible in the sense that the protective measures being required already exist, can be brought into existence with available technology, or can be created with technology that can reasonably be developed; (3) compliance is economically feasible in the sense that industry can absorb or pass on the costs without major dislocation or threat of instability; and (4) the standard is cost effective in that it employs the least expensive protective measures capable of reducing or eliminating significant risk. Additionally, proposed safety standards must be compatible with prior agency action, must be responsive to significant comment in the record, and, to the extent allowed by statute, must be consistent with applicable Executive Orders. These elements limit OSHA's regulatory discretion for safety rulemaking and provide a decision-making framework for developing a rule within their parameters.

B. Congress concluded that OSHA regulations are necessary to protect workers from occupational hazards and that employers should be required to reduce or eliminate significant workplace health and safety threats.

At section 2(a) of the OSH Act (29 U.S.C. § 651(a)), Congress announced its determination that occupational injury and illness should be eliminated as much as possible: "The Congress finds that occupational injury and illness arising out of work situations impose a substantial burden upon, and are a hindrance to, interstate commerce in terms of lost production, wage loss, medical expenses, and disability compensation payments." Congress therefore declared "it to be its purpose and policy ... to assure so far as possible every working man and woman in the Nation safe ... working conditions [29 U.S.C. § 651(b)]."

To that end, Congress instructed the Secretary of Labor to adopt existing federal and consensus standards during the first two years after the OSH Act became effective and, in the event of conflict among any such standards, to "promulgate the standard which assures the greatest protection of the safety or health of the affected employees [29 U.S.C. § 655(a)]." Congress also directed the Secretary to set mandatory occupational safety standards [29 U.S.C. § 651(b)(3)], based on a rulemaking record and substantial evidence [29 U.S.C. § 655(b)(2)], that are "reasonably necessary or appropriate to provide safe ... employment and places of employment." When promulgating permanent safety or health standards that differ from existing national consensus standards, the Secretary must explain "why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard [29 U.S.C. § 655(b)(8)]." Correspondingly, every employer must comply with OSHA standards and, in addition, "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees [29 U.S.C. § 654(a)]."

"Congress understood that the Act would create substantial costs for

employers, yet intended to impose such costs when necessary to create a safe and healthful working environment. Congress viewed the costs of health and safety as a cost of doing business.... Indeed, Congress thought that the *financial costs* of health and safety problems in the workplace were as large as or larger than the *financial costs* of eliminating these problems [*American Textile Mfrs. Inst. Inc. v. Donovan*, 452 U.S. 490, 519–522 (1981) (*ATMI*); emphasis was supplied in original]." "[T]he fundamental objective of the Act [is] to prevent occupational deaths and serious injuries [*Whirlpool Corp. v. Marshall*, 445 U.S. 1, 11 (1980)]." "We know the costs would be put into consumer goods but that is the price we should pay for the 80 million workers in America [S. Rep. No. 91–1282, 91st Cong., 2d Sess. (1970); H.R. Rep. No. 91–1291, 91st Cong., 2d Sess. (1970), *reprinted in* Senate Committee on Labor and Public Welfare, *Legislative History of the Occupational Safety and Health Act of 1970*, (Committee Print 1971) ("Leg. Hist.") at 444 (Senator Yarborough)]." "Of course, it will cost a little more per item to produce a washing machine. Those of us who use washing machines will pay for the increased cost, but it is worth it, to stop the terrible death and injury rate in this country [*Id.* at 324; see also 510-511, 517]."

[T]he vitality of the Nation's economy will be enhanced by the greater productivity realized through saved lives and useful years of labor.

When one man is injured or disabled by an industrial accident or disease, it is he and his family who suffer the most immediate and personal loss. However, that tragic loss also affects each of us. As a result of occupational accidents and disease, over $1.5 billion in wages is lost each year [1970 dollars], and the annual loss to the gross national product is estimated to be over $8 billion. Vast resources that could be available for productive use are siphoned off to pay workmen's compensation and medical expenses....

Only through a comprehensive approach can we hope to effect a significant reduction in these job death and casualty figures. [*Id.* at 518–19 (Senator Cranston)]

Congress considered uniform enforcement crucial because it would reduce or eliminate the disadvantage that a conscientious employer might experience where inter-industry or intra-industry competition is present. Moreover, "many employers—particularly smaller ones—simply cannot make the necessary investment in health and safety, and survive competitively, unless all are compelled to do so [Leg. Hist. at 144, 854, 1188, 1201]."

Thus, the statutory text and legislative history make clear that Congress conclusively determined that OSHA regulation is necessary to protect workers from occupational hazards and that employers should be required to reduce or eliminate significant workplace health and safety threats.

C. As construed by the courts and by OSHA, the OSH Act sets a threshold and a ceiling for safety rulemaking that provide clear and reasonable parameters for agency action.

OSHA has long followed the teaching that section 3(8) of the OSH Act requires that, before it promulgates "*any* permanent health or safety standard, [it must] make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices [*Industrial Union Dep't, AFL-CIO v. American Petroleum Inst.*, 448 U.S. 607, 642 (1980) (plurality) (*Benzene*); emphasis was supplied in original]." When, as frequently happens in safety rulemaking, OSHA promulgates standards that differ from existing national consensus standards, it must explain "why the rule as adopted will better effectuate the purposes of this Act than the national consensus standard [29 U.S.C. § 655(b)(8)]." Thus, national consensus and existing federal standards that Congress instructed OSHA to adopt summarily within two years of the OSH Act's inception provide reference points concerning the least an OSHA standard should achieve (29 U.S.C. §§ 655(a)).

As a result, OSHA is precluded from regulating insignificant safety risks or from issuing safety standards that do not at least lessen risk in a significant way.

The OSH Act also limits OSHA's discretion to issue overly burdensome rules, as the agency also has long recognized that "any standard that was not economically or technologically feasible would *a fortiori* not be 'reasonably necessary or appropriate' under the Act. See *Industrial Union Dep't v. Hodgson*, [499 F.2d 467, 478 (D.C. Cir. 1974)] ('Congress does not appear to have intended to protect employees by putting their employers out of business.') [*American Textile Mfrs. Inst. Inc.*, 452 U.S. at 513 n. 31 (a standard is economically feasible even if it portends 'disaster for some marginal firms,' but it is economically infeasible if it 'threaten[s] massive dislocation to, or imperil[s] the existence of,' the industry)]."

By stating the test in terms of "threat" and "peril," the Supreme Court made clear in *ATMI* that economic infeasibility begins short of industry-wide bankruptcy. OSHA itself has placed the line considerably below this level. (See for example, *ATMI*, 452 U.S. at 527 n. 50; 43 FR 27,360 (June 23, 1978). Proposed 200 μg/m3 PEL for cotton dust did not raise serious possibility of industry-wide bankruptcy, but impact on weaving sector would be severe, possibly requiring reconstruction of 90 percent of all weave rooms. OSHA concluded that the 200 μg/m3 level was not feasible for weaving and that 750 μg/m3 was all that could reasonably be required). See also 54 FR 29,245–246 (July 11, 1989); *American Iron & Steel Institute*, 939 F.2d at 1003. OSHA raised engineering control level for lead in small nonferrous foundries to avoid the possibility of bankruptcy for about half of small foundries even though the industry as a whole could have survived the loss of small firms.) Although the cotton dust and lead rulemakings involved health standards, the economic feasibility ceiling established therein applies equally to safety standards. Indeed, because feasibility is a necessary element of a "reasonably necessary or appropriate" standard, this ceiling boundary is the same for health and safety rulemaking since it comes from section 3(8), which governs all permanent OSHA standards.

All OSHA standards must also be cost-effective in the sense that the protective measures being required must be the least expensive measures capable of achieving the desired end (*ATMI*, at 514 n. 32; *Building and Constr. Trades Dep't AFL-CIO v. Brock*, 838 F.2d 1258, 1269 (D.C. Cir. 1988)). OSHA gives additional consideration to financial impact in setting the period of time that should be allowed for compliance, allowing as much as ten years for compliance phase-in. (See *United Steelworkers of Am. v. Marshall*, 647 F.2d 1189, 1278 (D.C. Cir. 1980), *cert. denied*, 453 U.S. 913 (1981).) Additionally, OSHA's enforcement policy takes account of financial hardship on an individualized basis. OSHA's Field Operations Manual provides that, based on an employer's economic situation, OSHA may extend the period within which a violation must be corrected after issuance of a citation (CPL. 2.45B, Chapter III, paragraph E6d(3)(a), Dec. 31, 1990).

To reach the necessary findings and conclusions that a safety standard substantially reduces a significant risk of harm, is both technologically and economically feasible, and is cost effective, OSHA must conduct rulemaking in accord with the requirements of section 6 of the OSH

Act. The regulatory proceeding allows it to determine the qualitative and, if possible, the quantitative nature of the risk with and without regulation, the technological feasibility of compliance, the availability of capital to the industry and the extent to which that capital is required for other purposes, the industry's profit history, the industry's ability to absorb costs or pass them on to the consumer, the impact of higher costs on demand, and the impact on competition with substitutes and imports. (See *ATMI* at 2501–2503; *American Iron & Steel Institute* generally.) Section 6(f) of the OSH Act further provides that, if the validity of a standard is challenged, OSHA must support its conclusions with "substantial evidence in the record considered as a whole," a standard that courts have determined requires fairly close scrutiny of agency action and the explanation of that action. (See *Steelworkers*, 647 F.2d at 1206–1207.)

OSHA's powers are further circumscribed by the independent Occupational Safety and Health Review Commission, which provides a neutral forum for employer contests of citations issued by OSHA for noncompliance with health and safety standards (29 U.S.C. §§ 659–661; noted as an additional constraint in *Benzene* at 652 n. 59). OSHA must also respond rationally to similarities and differences among industries or industry sectors. (See *Building and Constr. Trades Dep't, AFL-CIO v. Brock*, 838 F.2d 1258, 1272–73 (D.C. Cir. 1988).)

Finally, it is axiomatic that significant departures from prior practice must be justified (*International Union, UAW v. Pendergrass*, 878 F.2d 389, 400 (D.C. 1989)). In the twenty years since enactment of the OSH Act, OSHA has promulgated numerous safety standards—standards that provide benchmarks for judging risks, benefits, and feasibility of compliance in subsequent rulemakings. (OSHA's Hazardous Waste Operations and Emergency Response Standard, for example, required use of existing technology and well accepted safety practices to eliminate at least 32 deaths and 18,700 lost workday injuries at a cost of about $153 million per year (54 FR 9311–9312; March 6, 1989). The Excavation standard also drew on existing technology and recognized safety practices to save 74 lives and over 800 lost workday injuries annually at a cost of about $306 million. (54 FR 45,954; Oct. 31, 1989). OSHA's Grain Handling Facilities standard relied primarily on simple housekeeping measures to save 18 lives and 394 injuries annually, at a total net cost of $5.9 to $33.4 million (52 FR 49,622; Dec. 31, 1991).)

OSHA safety rulemaking is thus constrained first by the need to demonstrate that the standard will substantially reduce a significant risk of material harm, and then by the requirement that compliance is technologically capable of being done and not so expensive as to threaten economic instability or dislocation for the industry. Within these parameters, further constraints such as the need to find cost-effective measures and to respond rationally to all meaningful comment militate against regulatory extremes.

D. The Permit-Required Confined Space standard complies with the statutory criteria described above and is not subject to the additional constraints applicable to section 6(b)(5) standards.

As explained in Section I, *Background*, and Section III, *Summary and Explanation of the Standard*, earlier in this preamble, and in Section VI, *Summary of the Final Regulatory Impact Analysis and Regulatory Flexibility Analysis*, later in this preamble, OSHA has determined that permit spaces pose significant risks to employees (62 fatalities and 12,643 injuries and illnesses annually) and estimates that compliance with the Permit-Required Confined Space standard will reduce the risk of permit space hazards by 85 percent (preventing 53 fatalities and 10,746 injuries and illnesses annually). This constitutes a substantial reduction of significant risk of material harm. The Agency believes that compliance is technologically feasible because the rulemaking record indicates that the hazard control measures required by the standard have already been implemented, to some extent, at all the types of spaces covered by the standard. Additionally, OSHA believes that compliance is economically feasible, because, as documented by the Regulatory Impact Analysis, all regulated sectors can readily absorb or pass on compliance costs during the standard's first five years, and economic benefits will exceed compliance costs thereafter.

The standard's costs, benefits, and compliance requirements are reasonable, amounting to approximately $202.4 million annually, preventing 53 fatalities and 10,746 injuries and illnesses per year. These amounts are consistent with those of other OSHA safety standards. OSHA considered and responded to all substantive comments regarding the proposed rule on their merits. In particular, OSHA evaluated all suggested changes in terms of their impact on worker safety, their feasibility, their cost effectiveness, and their consonance with the OSH Act.

Further, the additional constraint found in section 6(b)(5) of the OSH Act, that standards dealing with employee exposure to "toxic materials or harmful physical agents" must also assure, "to the extent feasible ... that no employee will suffer material impairment of health or functional capacity even if [he is exposed] to the hazard dealt with by the standard for the period of his working life," does not apply to this rule. Standards subject to section 6(b)(5), which regulate insidious hazards that are frequently undetectable because they are subtle or develop slowly or after long latency periods, are frequently referred to as "health" standards, while those that regulate hazards, like explosions or electrocution, that cause immediately noticeable physical harm, are called "safety" standards. (See *National Grain & Feed Ass'n v. OSHA (NGFA II)*, 866 F.2d 717, 731, 733 (5th Cir. 1989). Section 6(b)(5) applies only to substances that take their toll over time or "whose deleterious effect is not readily apparent, such as a carcinogen or a harmful physical agent such as noise," not to "hazards such as explosives, that are every bit as lethal but whose impact is immediate").

The OSH Act and its legislative history clearly indicate that Congress intended this distinction between safety standards and health standards. For example in section 2(b)(6) of the OSH Act, Congress declared that the goal of assuring safe and healthful working conditions and preserving human resources would be achieved, in part:

> ... by exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions, and conducting other research relating to health problems, in recognition of the fact that occupational health standards present problems often different from those involved in occupational safety.

The legislative history makes this distinction even clearer:

> [The Secretary] should take into account that anyone working in toxic agents and physical agents which might be harmful may be subjected to such conditions for the rest of his working life, so that we can get at something which might not be toxic now, if he works in it a short time, but if he works in it the rest of his life might be very dangerous; and we want to make sure that such things are taken into consideration in establishing standards. [*Leg. Hist.* at 502–503 (Sen. Dominick), quoted in *Benzene* at 648–49]

Additionally, Representative Daniels distinguished between "insidious 'silent

killers' such as toxic fumes, bases, acids, and chemicals" and "violent physical injury causing immediate visible physical harm" (*Leg. Hist.* at 1003), and Representative Udall contrasted insidious hazards like carcinogens with "the more visible and well-known question of industrial accidents and on-the-job injury" (*Leg. Hist.* at 1004). (See also, for example, S.Rep. No. 1282, 91st Cong., 2d Sess 2–3 (1970), U.S. Code Cong. & Admin. News 1970, pp. 5177, 5179, reprinted in Leg. Hist. at 142–43, discussing 1967 Surgeon General study that found that 65 percent of employees in industrial plants "were potentially exposed to harmful physical agents, *such as severe noise or vibration*, or to toxic materials"; Leg. Hist at 412; *id.* at 446; *id.* at 516; *id.* at 845; *International Union, UAW* at 1315.)

Congress addressed this concern that insidious, long term hazards might not receive sufficient protection through section 6(b)(5), which requires OSHA to set "the most protective standard consistent with feasibility" (*Benzene* at 643 n. 48). As Justice Stevens observed:

> The reason that Congress drafted a special section for these substances ... was because Congress recognized that there were special problems in regulating health risks as opposed to safety risks. In the latter case, the risks are generally immediate and obvious, while in the former, the risks may not be evident until a worker has been exposed for long periods of time to particular substances. [*Benzene*, at 649 n. 54.]

The permit space standard addresses hazards, such as asphyxiation, explosion, and engulfment, that are immediately dangerous to life or health, not the longer term, less obvious hazards subject to section 6(b)(5). The definition of "immediately dangerous to life or health" in paragraph (b) of the final rule covers conditions that pose immediate or delayed threats to life, would cause irreversible adverse health effects or would interfere with an individual's ability to escape unaided from a permit space. The definition contemplates that any "delayed" health effects would arise within 72 hours of exposure to a permit space hazard. Accordingly, the mention of delayed effects simply reflects OSHA's recognition that some acute health effects may not manifest themselves at the very same time as the permit space incidents which trigger them. While some of the materials, particularly the air contaminants, that have been detected in permit spaces could also have long-term adverse effects on employees, those long-term effects are not addressed by the permit space standard.

Challenges to the grain dust and lockout/tagout standards included assertions that grain dust in explosive quantities and uncontrolled energy releases that could expose employees to crushing, cutting burning or explosion hazards were harmful physical agents so that OSHA was required to apply the criteria of section 6(b)(5) when determining how to protect employees from those hazards. Reviewing courts have uniformly rejected such assertions. For example, the Court in *International Union, UAW v. OSHA*, 938 F.2d 1310 (D.C. Cir. 1991) rejected the view that section 6(b)(5) provided the statutory criteria for regulation of uncontrolled energy, holding that such a "reading would obliterate a distinction that Congress drew between 'health' and 'safety' risks." The Court also noted that the language of the OSH Act and the legislative history supported the OSHA position (*International Union, UAW* at 1314). Additionally, the Court stated: "We accord considerable weight to an agency's construction of a statutory scheme it is entrusted to administer, rejecting it only if unreasonable" (*International Union, UAW* at 1313, citing *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 843 (1984)).

The Court reviewing the grain dust standard also deferred to OSHA's reasonable view that the Agency was not subject to the feasibility mandate of section 6(b)(5) in regulating explosive quantities of grain dust (*National Grain & Feed Association v. OSHA (NGFA II)*, 866 F.2d 717, 733 (5th Cir. 1989)). It therefore applied the criteria of section 3(8), requiring the Agency to establish that the standard is "reasonably necessary or appropriate" to protect employee safety.

OSHA has determined that the permit space standard, like other safety standards, is subject to the constraints of section 3(8) of the OSH Act, that it be "reasonably necessary or appropriate to provide safe or healthful employment and places of employment." But the standard is not subject to the section 6(b)(5) requirement that it limit significant risk "to the extent feasible."

The Agency believes that permit spaces pose significant risks and that the provisions of the final rule are reasonably necessary to protect affected employees from those risks. It has also determined that compliance with the permit space standard is technologically feasible because the rulemaking record indicates that the hazard control measures required by the standard have already been implemented, to some extent, at all the types of spaces covered by the standard. In addition, OSHA believes that compliance is economically feasible, because, as documented by the "*Final Regulatory Impact Analysis and Regulatory Flexibility Analysis of the Final Permit-Required Confined Space Standard*",[34] all regulated sectors can readily absorb or pass on compliance costs during the standard's first five years, and economic benefits will exceed compliance costs thereafter. In particular, the Agency believes that compliance with the permit space standard will result in substantial cost savings and productivity gains at manufacturing facilities that might otherwise be disrupted by permit space incidents.

As detailed in Section VI, *Summary of the Final Regulatory Impact Analysis and Regulatory Flexibility Analysis*, later in this preamble, the standard's costs, benefits, and compliance requirements are consistent with those of other OSHA safety standards. For example, the Hazardous Waste Operations and Emergency Response standard (29 CFR 1910.120) requires the use of existing technology and well accepted safety practices to eliminate at least 32 deaths and 18,700 lost workday injuries at a cost of about $153 million per year (54 FR 9311–9312; March 6, 1989). The Excavations standard (29 CFR 1926, Subpart P) also drew on existing technology and recognized safety practices to save 74 lives and over 800 lost workday injuries annually at a cost of about $306 million (54 FR 45,954; Oct. 31, 1989). Additionally, the Grain Handling Facilities standard (29 CFR 1910.272) relied primarily on simple housekeeping measures to save 18 lives and 394 injuries annually, at a total net cost of between $5.9 million and $33.4 million (52 FR 49,622; Dec. 31, 1987). Also, compliance with the planning, work practice, and training provisions of the Process Safety Management standard (29 CFR 1910.119) will reduce the risk of catastrophic fire and explosion (330 fatalities and 1917 injuries and illnesses annually) by 80 percent, at an annualized cost of $888.7 million in the first five years and at an annualized cost of $470.8 million in the following five years.

OSHA has considered and responded to all substantive comments regarding the proposed permit space standard on their merits in the Section III, *Summary and Explanation of the Standard*, earlier in this preamble. In particular, OSHA evaluated all suggested changes to the

[34] This document is available for inspection and copying in Docket S–019 in the Docket Office, Rm. N2634, U.S. Department of Labor, Occupational Safety and Health Administration, 200 Constitution Ave., NW, Washington, DC 20210; telephone: 202–219–7894.

proposed rule in terms of their impact on worker safety, their feasibility, their cost effectiveness, and their consonance with the OSH Act.

E. The permit space standard is necessary to address the significant risks of material harm posed by permit spaces.

OSHA believes that Section , *Background*, Section II, *Hazards*, and Section III, *Summary and Explanation of the Standard*, earlier in this preamble have clearly and comprehensively set out the Agency's bases for concluding that permit spaces pose significant risks and that the provisions of the final rule are reasonably necessary to protect affected employees from those risks. In particular, as detailed in Section VI, *Summary of the Final Regulatory Impact Analysis and Regulatory Flexibility Analysis*, later in this preamble, OSHA estimates that exposure to permit spaces hazards causes at least 62 fatalities and 12,643 injuries and illnesses annually and that compliance with the Permit-Required Confined Space standard will reduce the risk of permit space hazards by 85 percent (preventing 53 fatalities and 10,746 injuries and illnesses annually). This constitutes a substantial reduction of a significant risk of material harm to the exposed population of approximately 1,629,000 permit space entrants.

OSHA emphasizes that its risk assessment is based on employee exposure to the particular hazard of permit-required confined spaces, a hazard that exists in a large range of industries. Although Section VI, *Summary of the Final Regulatory Impact Analysis and Regulatory Flexibility Analysis*, later in this preamble, presents OSHA's estimate of the costs and benefits of the permit space standard in terms of the Standard Industrial Classification (SIC) codes for the industries regulated, OSHA does not believe that the risk associated with this hazard varies according to what SIC code a particular space may be found in. Thus, some of the industry categories within the scope of the final rule which will have compliance costs have had few or no documented permit space-related injuries or fatalities during the period covered by the RIA. In this case, OSHA has defined the scope of the rule to cover those situations it has determined to be hazardous. As explained more fully below, OSHA has determined that the lack of prior documented injuries and deaths in some SIC Codes does not indicate that the employees in those industries are not exposed to significant risks from permit spaces and permit space entry.

As the summary of the RIA explains in detail, OSHA has determined that it is appropriate to include those industries within the scope of the permit space standard because employees in those industries are exposed to the same kinds of hazards as employees in industries for which there are reported injuries and fatalities. For example, employers classified in SIC 391 (Jewelry, Silverware and Plated Ware) and in SIC 3949 (Sporting and Athletic Goods) have employees enter tanks, pits, and dust collectors that meet the permit space definition, but that have not caused any documented injuries or fatalities during the 5-year time period covered by the RIA tables. The Agency has found, however, that the permit spaces identified in SIC 391 and SIC 3949 are closely analogous, and in many cases virtually identical, to permit spaces in other SIC categories (such as SIC 28, Chemicals & Allied Products) where OSHA has documented injuries and fatalities.

As regards the other SICs for which injury and fatality data are not available, OSHA has set out the bases for concluding that permit spaces in those SICs pose significant risk of material harm in Table III–5 and the accompanying text of Chapter III of the "*Final Regulatory Impact Analysis and Regulatory Flexibility Analysis of the Final Permit-Required Confined Space Standard*". Even in industry sectors in which no injuries or fatalities have been reported, the Agency believes there is sufficient information for OSHA to determine that employees who enter permit spaces in those sectors face significant risks, based on analysis of the elements of the hazards identified and based on the similarity of hazard elements between industry sectors. Therefore, the Agency has determined that all employees who enter permit spaces face a significant risk of material harm and that compliance with the permit space standard is reasonably necessary to protect affected employees from that risk, regardless of the number of permit space incidents reported for the SIC code to which the employer has been assigned.

Also, because of the difficulties the Agency has experienced in compiling a database for permit space incidents, injuries or fatalities may have occurred in industries, including those for which no incidents have been documented, without being recorded. For example, as noted in Table I–7 of the "*Final Regulatory Impact Analysis and Regulatory Flexibility Analysis of the Final Permit-Required Confined Space Standard*", 7 of the 53 permit space fatalities (nearly 15 percent) OSHA believes will be prevented each year through compliance with the permit space standard could not be classified with a particular 2-digit SIC classification. The frequent use of contractors for permit space entry operations raises further questions regarding the reliability of incident data organized according to SIC code, because a fatality report will usually include the SIC code for the employer whose employee was killed but not necessarily the SIC code for the workplace where the permit space fatality occurred.

In addition, the SIC code-based organization of incident data may mask actual or potential permit space hazards because, while a business is classified for SIC purposes according to its principal activity, the workplace may also contain permit spaces, entered for "secondary" purposes, that have caused permit space-related injuries or fatalities. For example, a permit space incident in the utility room boiler at a new car dealer would be classified under the new car dealer SIC, even though the hazard and the incident had nothing to do with selling new cars. Therefore, OSHA believes, based on the limitations of the incident data and the circumstantial nature of many permit space incidents, that it is appropriate to require that employers protect affected employees from permit space hazards in all workplaces where permit spaces have been identified, rather than to characterize workplaces according to the injury or fatality experience of the SIC codes in which they have been classified.

The Agency also notes that, as discussed in the NPRM (54 FR 24082, 24086), permit space injuries and "near misses" are underreported, because the data collection system has focused on documenting fatalities and because the employees often "recover" without hospitalization or seeking medical attention. Based on these considerations, OSHA believes it is reasonable to conclude that permit space injuries and some of the unclassified permit space fatalities occurred in SIC categories that have no documented permit space injuries or fatalities.

Finally, it is well established in the OSH Act enforcement context that the lack of injuries or deaths to a particular employer's employees does not establish that the employees are not exposed to a hazard. In a frequently quoted passage, the Fifth Circuit long ago observed that "the goal of the Act is to prevent the first accident, not to

serve as a source of consolation for the first victim or his survivors" (*Mineral Industries & Heavy Construction Group v. OSHRC*, 639 F.2d 1289, 1294 (5th Cir. 1981)). This principle applies to regulatory actions as well. Once the agency determines that exposure to a particular condition constitutes a significant risk, it need not repeat that analysis for every situation or type of workplace in which the condition is found.

For all of the foregoing reasons, OSHA has determined that it is inappropriate to exclude any of the SICs merely because they have not recently had documented permit space injuries or fatalities, insofar as those SICs contain confined spaces which meet the configuration and hazard criteria to qualify as permit spaces.

VI. Summary of the Final Regulatory Impact Analysis and Regulatory Flexibility Analysis

A. Introduction

The Occupational Safety and Health Administration (OSHA) has determined that there is a significant risk to the health and safety of workers who enter certain types of confined spaces. To protect workers from the hazards encountered in these unique work environments, OSHA is issuing this final permit-required confined space standard (29 CFR §1910.146). This comprehensive standard supplements the existing OSHA standards that address permit space hazards in particular work settings.

Executive Order 12291 (46 FR 13197) requires that a regulatory analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. In addition, the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 et seq.) requires federal agencies to determine whether a regulation will have a significant economic impact on a substantial number of small entities.

Consistent with these requirements, OSHA has prepared a Regulatory Impact and Regulatory Flexibility Analysis for the standard on permit spaces, the full body of which is available in OSHA Docket S–019. This summary of the analysis includes an overview of affected industries and employees, estimated benefits, the technological feasibility of the standard, estimated compliance costs, economic and environmental impacts, and a discussion of the nonregulatory alternatives to this final standard.

B. Industries and Employees Affected by the Standard

Based on a report prepared under contract to OSHA by CONSAD Research Corporation (CONSAD) [1], OSHA estimates that the standard will have cost impacts in 34 two-digit Standard Industrial Classification industry groups. Affected industries are found in Agricultural Services, Oil and Gas Extraction, Manufacturing, Transportation and Utilities, Wholesale Trade, Retail Trade, and Miscellaneous Services.

Permit-required confined spaces (or permit spaces, for short), as defined in §1910.146(b), vary in size, configuration, process use and hazard across industries where the risks are present. In Manufacturing, permit spaces include storage vessels, furnaces, tank degreasers and other types of equipment requiring human entry for maintenance and repair. Permit space hazards can also appear during production itself, such as in the manufacture of railroad tank cars and aircraft parts. Examples of permit spaces found elsewhere in industry include manholes serviced in SIC 49, Electric, Gas, and Sanitary Services, and cooking vessels cleaned in SIC 70, Hotels, Rooming Houses, Camps, and Other Lodging Places.

Employees encounter a variety of hazards while working in permit spaces, chief among these being asphyxiation and poisoning from toxic atmospheres. Explosions and fires caused by a sudden exposure to a flammable source or by a dangerous reaction among volatile chemicals have also caused a number of fatalities and injuries. In some environments, worker engulfment by fine particulate, such as grain or sawdust, have resulted in deaths and injuries. When an employee is overcome by the atmosphere in a permit space, fellow employees sometimes enter in a rescue attempt. Often these would-be rescuers are unaware of or not equipped for the hazard and are overcome along with the original victim.

Many permit spaces are infrequently entered to inspect, clean, or repair equipment. Where products become permit spaces as they are built, entries during the manufacturing process can be frequent and routine. The risk associated with each entry in workplaces with frequently entered spaces may, however, be lower than in workplaces with infrequent entries. Degree of risk in this context depends more on atmospheric conditions in the space rather than on frequency of entry.

Table 3 presents, for each two-digit industry affected by the permit space standard, the number of establishments with permit spaces, the number of permit spaces, the number of employees and the number of scheduled entrants. Not all establishments in affected industries contain permit spaces. OSHA estimates that 238,853 establishments employing 12.2 million workers, have permit spaces. At these establishments, there are about 1.6 million workers, including contractors, who enter approximately 4.8 million permit spaces annually.

Table 3—Profile of Affected Establishments Employees

SIC	Industry	Number of Establishments with Permit Spaces	Number of Permit Spaces	Number of Employees	Number of Permit Space Entrants
07	Agricultural Services	10,864	79,821	62,990	25,748
13	Oil & Gas Extraction	10,000	12,477	155,660	11,239
20	Food and Kindred Products	10,236	142,727	805,247	99,420
21	Tobacco Products	69	776	37,845	2,007
22	Textile Mill Products	1,491	17,062	186,752	27,831
24	Wood Products (except furniture)	10,290	39,409	146,042	31,035
25	Furniture and Fixtures	5,254	26,012	224,589	35,424
26	Paper Products	4,397	95,533	475,171	46,206
27	Printing and Publishing	47	206	2,196	94
28	Chemicals & Allied Products	8,098	170,982	593,738	71,982
29	Petroleum Refining	1,844	93,700	104,704	15,560
30	Rubber Products	6,282	143,818	319,262	143,522

Table 3—Profile of Affected Establishments Employees—Continued

SIC	Industry	Number of Establishments with Permit Spaces	Number of Permit Spaces	Number of Employees	Number of Permit Space Entrants
31	Leather and Leather Products	151	514	6,395	1,055
32	Stone, Clay, Glass & Concrete	12,290	116,706	366,454	110,568
33	Primary Metals Industry	2,788	35,521	463,942	56,689
34	Fabricated Metal Products	8,441	88,507	346,800	33,959
35	Machinery, Except Electrical	4,330	34,670	437,200	116,987
36	Electric/Electronic Equipment	6,610	176,895	892,336	111,067
37	Transportation Equipment	3,302	1,065,966	1,043,403	31,706
38	Instruments & Related Products	64	901	7,296	514
39	Miscellaneous Manufacturing	885	31,267	18,926	5,744
42	Motor Freight Transportation	14,583	201,680	201,679	40,336
49	Electric, Gas, Sanitary Services	28,444	1,575,170	410,290	263,217
50	Wholesale Trade/Durables	2,753	3,965	36,485	3,359
51	Wholesale Trade/Nondurables	36,913	411,095	358,647	194,454
54	Food Stores	10,073	10,073	318,010	10,073
59	Miscellaneous Retail	7,149	26,201	57,923	10,694
65	Real Estate (Commercial)	13,582	45,190	391,923	12,442
70	Hotels and Other Lodging	5,099	77,672	163,323	80,442
72	Personal Services	3,577	24,604	198,447	7,154
76	Miscellaneous Repair Services	752	802	3,718	752
78	Motion Pictures	11	33	16,500	66
80	Health Services	8,252	71,709	3,357,391	27,308
84	Museums, Botanical Gardens, Zoos	130	1,183	7,338	781
	TOTAL	238,853	4,844,849	12,218,622	1,629,201

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis, based on CONSAD [1]
[1] Includes contractors.

C. Benefits

OSHA searched its Fatality/Catastrophe database [5] over the period 1986–1990 to identify accidents associated with permit- required confined spaces. Based on its review of OSHA accident reports and injury data from the Bureau of Labor Statistics, OSHA estimates that 63 fatalities, 5,931 lost-workday cases and 6,951 non-lost-workday cases occur annually in workplaces affected by the standard.

The final standard mandates a comprehensive approach for the control of permit space hazards. Included in the standard are provisions for entry permits, training, hazard recognition, isolation procedures, atmospheric testing, mechanical ventilation, and personal protective equipment. OSHA estimates that compliance with all requirements in the standard will result in an 85 percent reduction in baseline fatalities, injuries, and illnesses associated with permit spaces. Applying this safety effectiveness rate to the baseline accident statistics given earlier, OSHA predicts that 54 fatalities, 5,041 lost-workday cases and 5,908 non-lost-workday cases will be prevented as a result of the standard. Benefits by industry group are shown in Table 4.

Table 4—Annual Fatalities, Injuries, and Illnesses Preventable by the Permit Space Standard

SIC	Industry	Fatalities			Injuries					
					Lost-Workday			Non-Lost-Workday		
		Large	Small	Total	Large	Small	Total	Large	Small	Total
07	Agricultural Services	0.0	0.3	0.3	-[1]	18	18	-	17	17
13	Oil & Gas Extraction	3.1	3.7	6.8	73	89	163	54	66	120
20	Food and Kindred Products	2.0	0.7	2.7	303	101	404	384	128	513
21	Tobacco Products	0.3	0.0	0.3	51	-	51	64	-	64
22	Textile Mill Products	0.3	0.0	0.3	51	-	51	64	-	64
24	Wood Products (except furniture)	1.0	0.0	1.0	152	-	152	192	-	192
25	Furniture and Fixtures	0.0	0.0	0.0[2]	-	-	-	-	-	-
26	Paper Products	0.7	0.0	0.7	101	-	101	128	-	128
27	Printing and Publishing	0.0	0.0	0.0	-	-	-	-	-	-
28	Chemicals & Allied Products	3.4	0.7	4.1	506	101	607	641	128	769
29	Petroleum Refining	0.0	0.0	0.0[2]	-	-	-	-	-	-
30	Rubber Products	0.7	0.0	0.7	101	-	101	128	-	128
31	Leather and Leather Products	1.0	0.0	1.0	152	-	152	192	-	192
32	Stone, Clay, Glass & Concrete	0.7	0.0	0.7	101	-	101	128	-	128
33	Primary Metals Industry	2.0	0.0	2.0	303	-	303	384	-	384
34	Fabricated Metal Products	4.4	0.7	5.1	657	101	758	833	128	961
35	Machinery, Except Electrical	1.0	0.0	1.0	152	-	152	192	-	192
36	Electric/Electronic Equipment	0.0	0.0	0.0[2]	-	-	-[2]	-	-	-
37	Transportation Equipment	2.0	0.0	2.0	303	-	303	384	-	384

Table 4—Annual Fatalities, Injuries, and Illnesses Preventable by the Permit Space Standard—Continued

SIC	Industry	Fatalities			Injuries					
					Lost-Workday			Non-Lost-Workday		
		Large	Small	Total	Large	Small	Total	Large	Small	Total
38	Instruments & Related Products	0.3	0.0	0.3	51	-	51	64	-	64
39	Miscellaneous Manufacturing	0.3	0.0	0.3	51	-	51	64	-	64
42	Motor Freight Transportation	2.7	2.4	5.1	119	104	223	87	76	163
49	Electric, Gas, Sanitary Services	3.1	3.7	6.8	134	163	297	98	119	217
50	Wholesale Trade/Durables	0.0	0.3	0.3	-	42	42	-	48	48
51	Wholesale Trade/Nondurables	0.3	0.7	1.0	42	83	125	48	97	145
54	Food Stores	0.0	0.0	0.0[6]	-	-	-[7]	-	-	-
59	Miscellaneous Retail	0.0	0.3	0.3	-	42	42	-	48	48
65	Real Estate (Commercial)	0.0	0.0	0.0[8]	-	-	-	-	-	-
70	Hotels and Other Lodging	0.0	0.0	0.0[9]	-	-	-	-	-	-
72	Personal Services	0.0	0.0	0.0	-	-	-	-	-	-
76	Miscellaneous Repair Services	0.0	3.1	3.1	-	374	374	-	436	436
78	Motion Pictures	0.0	0.0	0.0	-	-	-	-	-	-
80	Health Services	0.0	0.3	0.3	-	42	42	-	48	48
84	Museums, Botanical, Zoos	0.0	0.0	0.0	-	-	-	-	-	-
	Host Employer Unidentified	3.1	4.1	7.1	229	151	380	265	171	436
	TOTAL[11]	32.6	21.1	53.7	3,630	1,411	5,041	4,396	1,512	5,908

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis
[1] Dashes indicate that prevented injuries could not be estimated utilizing injury/fatality factor (see Table III–3 in the Regulatory Analysis) due to the absence of reported fatalities during the investigated period.
[2] One pre-1986 fatality in SIC 25 reported by NIOSH [2], and one post-1990 fatality in SIC 25 reported by OSHA [5].
[3] Ten fatalities prior to 1986 reported for SIC 29 by OSHA [3], [4] and NIOSH [2].
[4] One fatality and three injuries prior to 1986 reported for SIC 36 by NIOSH [2].
[5] Twelve hospitalized injuries prior to 1986 reported for SIC 36 by OSHA [5].
[6] Three fatalities prior to 1986 reported for SIC 54 by NIOSH [2] and OSHA [5].
[7] Two hospitalized injuries prior to 1986 reported for SIC 54 by OSHA [5].
[8] One fatality and one injury reported prior to 1986 for SIC 65 by NIOSH [2].
[9] Three fatalities reported prior to 1986 for SIC 70 by OSHA [4] and NIOSH [2].
[10] Includes contractors and other service employers whose host employer at the time of the accident could not be identified in the OSHA abstracts.
[11] Row and column totals may not equal the sum of the data due to rounding.

For some affected sectors, there were no recorded accidents in the OSHA database for the five-year period ending in 1990. However, accidents in a number of these sectors were identified in other databases for earlier time periods (see, for example, [2], [3], [4]) and the same types of hazards related to permit space entry continue to be present in all of these industries. In addition, for those industries for which fatalities and injuries have not been recorded during the 1986–1990 period, OSHA has determined that the permit spaces in those industries have configurations and hazards that are closely analogous to those of permit spaces in industries for which fatality and injury data are available. The basis for this determination is presented in Table III–5 and in the accompanying text of Chapter III of the Regulatory Analysis. In some sectors, the absence of accident records for the reference period may also indicate, for example, that employers in those sectors have begun implementing protective measures for permit space entry. OSHA has determined that compliance with this final standard will protect employees from significant risks associated with entry into permit spaces throughout general industry.

D. Technological Feasibility

To assess the feasibility of complying with the final standard using applicable technologies and work practices, OSHA reviewed the rulemaking record and the compliance profile developed by CONSAD [1]. OSHA believes that the final standard will cause some firms to adopt technologies and work practices that are readily available but in limited use today. While not specifically mandated, the standard should also encourage technological innovation to achieve compliance, as well as to reduce the need to enter spaces. As reported by CONSAD [1], technologies such as atmospheric testing instruments, ventilation equipment, respirators and retrieval devices, are already in widespread use throughout industry.

Application of permit space technologies will vary according to configuration and circumstance. Where a particular piece of equipment may not be appropriate, alternative control devices can be employed effectively. For example, in spaces where atmospheric hazards may be present and ventilation is not practical, respirators are required. In entry situations in which the use of retrieval lines is counterproductive, the standard provides for entry rescue by properly equipped rescue personnel. In general, although some situations might limit the use of a particular technology, use of other pieces of equipment or work practices is permitted.

Therefore, on the basis of testimony in the record and OSHA's assessment of current industry practice for protecting workers in permit spaces, OSHA has determined that the final standard is technologically feasible.

E. Costs of Compliance

OSHA estimated compliance costs of the standard by combining the industry profile information summarized above with data on current compliance rates, unit costs for required equipment, and hourly compensation of labor. For each provision of the standard, OSHA estimated initial costs and ongoing costs. Initial costs represent up-front expenditures for program development and equipment; these costs were annualized over the expected life of the resource in order to show such costs on an annual basis. Other ongoing expenditures incurred annually include refresher training and equipment maintenance. OSHA summed annualized initial costs and ongoing costs to estimate total annual costs.

OSHA estimates that the annual cost of compliance for the permit spaces standard will total $202.4 million. Table

5 presents annual compliance costs by provision. The largest compliance expenditures are associated with atmospheric testing ($46.6 million), respiratory protection ($38.6 million), and the provision for attendants ($37.3).

Table 5—Summary of Annual Compliance Costs

Provision	Annual Costs
Establish Permit Entry Program/System	$10,955,165
Training	9,204,484
Inform Non-Entrants	7,968,174
Isolation Procedures	1,752,744
Mechanical Ventilation	27,541,362
Respiratory Protection	38,815,993
Atmospheric Testing	46,573,456
Vehicle/Pedestrian Barriers	128,233
Attendant	37,284,569
Retrieval Devices	3,185,000
Issue Permits	17,800,417
Rescue Teams	1,360,141
TOTAL	$202,369,752

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis

The final permit-required confined space standard strives to prescribe the appropriate level of safeguards for the level of risk encountered in a given confined space situation. As an extension of its general performance-oriented nature, the standard sets up a hierarchy in which some provisions, such as the requirement for attendants, are reserved for only situations in which an entrant may encounter a hazardous atmosphere. As shown in Table 6, the number of applicable requirements and cost of compliance per space rises with the level of hazard encountered. Most permit spaces fall under exemptions provided under paragraph (c)(5) of the standard.

Table 6—Cost of Complying With the Permit Space Standard by Type of Space

Type of Space	Provision	Cost	Number of Spaces (Millions)	Incremental Cost per Space[1]
Non-Entry Permit Spaces	Inventory Spaces	$1,095,517	1.5	$0.73
Spaces Declassifiable [(c)(7)(i)]	Inventory Spaces/Establish Program	328,656		
	Inform Non-Entrants	318,727		
	Isolation Procedures	70,110		
	Vehicle/Pedestrian Barriers	5,129		
	TOTAL	$722,621	0.2	$3.61
Tested and Ventilated [(c)(5)]	Establish Permit Entry Program/System	5,148,928		
	Training	5,259,705		
	Inform Non-Entrants	4,462,178		
	Isolation Procedures	981,537		
	Mechanical Ventilation	21,639,842		
	Respiratory Protection	2,325,535		
	Atmospheric Testing	26,613,404		
	Vehicle/Pedestrian Barriers	71,811		
	Certification of Conditions	4,450,104		
	TOTAL	$70,952,843	2.7	$26.28
Full Permit-Required Spaces	Establish Permit Entry Program/System	4,382,066		
	Training	3,944,779		
	Inform Non-Entrants	3,187,270		
	Isolation Procedures	701,098		
	Mechanical Ventilation	5,901,721		
	Respiratory Protection	36,290,459		
	Atmospheric Testing	19,960,053		
	Vehicle/Pedestrian Barriers	51,293		
	Attendant	37,284,569		
	Retrieval Devices	31,185,009		
	Issue Permits	13,350,313		
	Rescue Teams	1,360,142		
	TOTAL	$129,598,771	1.9	$68.21

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis.
[1]Figures in this column represent the annualized cost of coming into compliance with the standards, for average establishment, given current compliance.

OSHA also estimated compliance costs by industry, shown in Table 7. Electric, gas and sanitary services (SIC 49) are estimated to incur costs of $72.6 million, primarily in public water and sewer utilities. The relatively large number of permit spaces and permit space entrants in this sector contributes to the magnitude of their compliance

costs. Most affected sectors will incur compliance costs under $10 million.

Table 7—Summary of Annual Compliance Costs of the permit Space Standard by Industry

SIC	Industry	Total Annual Compliance Costs (Thousands of Dollars)
07	Agricultural Services	7,881
13	Oil & Gas Extraction	85
20	Food and Kindred Products	12,472
21	Tobacco Products	32
22	Textile Mill Products	263
24	Wood Products (except furniture)	1,740
25	Furniture and Fixtures	750
26	Paper Products	4,028
27	Printing and Publishing	—[1]
28	Chemicals & Allied Products	1,581
29	Petroleum Refining	2,418
30	Rubber Products	6,910
31	Leather and Leather Products	37
32	Stone, Clay, Glass & Concrete	12,150
33	Primary Metals Industry	5,801
34	Fabricated Metal Products	13,490
35	Machinery, Except Electrical	2,999
36	Electric/Electronic Equipment	13,354
37	Transportation Equipment	6,946
38	Instruments & Related Products	6
39	Miscellaneous Manufacturing	1,197
42	Motor Freight Transportation	12,958
49	Electric, Gas, Sanitary Services	72,636
50	Wholesale Trade/Durables	263
51	Wholesale Trade/Nondurables	15,792
54	Food Stores	244
59	Miscellaneous Retail	18
65	Real Estate (Commercial)	1,561
70	Hotels and Other Lodging	831
72	Personal Services	311
76	Miscellaneous Repair Services	6
78	Motion Pictures	—
80	Health Services	3,603
84	Museums, Botanical Gardens, Zoos	5
	TOTAL	$202,370

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis

[1] Hyphens denote compliance costs of under $1,000.

OSHA believes that direct compliance costs will be offset by a reduction in administrative costs associated with permit space accidents. These costs usually involve such activities as preparing insurance claims, completing accident reports, and hiring and training replacement workers. In addition, OSHA anticipates that improved worker productivity as a result of the standard will help to lower production costs and contribute to higher quality output. Although OSHA did not quantify these cost offsets, the Agency believes they will be substantial.

F. Economic Impact and Regulatory Flexibility Analysis

OSHA assessed the potential economic impact of the final standard on affected two-digit industry sectors and has determined that impacts on prices, profits, and sales will be modest for most industries. If affected establishments added the entire cost of compliance to the price of their final goods, OSHA estimates that the average price increase would not exceed 0.01 percent, based on the ratio of compliance cost to average establishment revenue. The maximum price increase in any industry sector would be 0.23 percent (SIC 07, Agricultural Services).

OSHA assessed the impact on firm profits (Table 8) under the assumption that costs would be fully absorbed internally and are not passed forward to consumers. Computing the ratio of costs to pre-tax profits, OSHA determined that the percentage of profits represented by compliance costs in this worst-case scenario would average 0.17 percent. In only two industry sectors are average profit impacts expected to exceed 1 percent, assuming zero cost pass-through. Therefore, on the basis of these results, OSHA concludes that the standard is economically feasible.

Table 8—Cost Impact by Industry

SIC	Industry	Number of Affected Firms	Number of Permit Spaces Total	Total Annual Compliance Costs	Average Cost of Rule		Cost As A Percent of Profit	
					Large Firms	Small Firms	Large Firms	Small Firms
07	Agricultural Services	10,864	79,821	$7,880,523	$3,102	$607	1.08%	4.99%
13	Oil & Gas Extraction	10,000	12,477	84,509	20	7	0.00%	0.01%
20	Food and Kindred Products	10,236	142,727	12,472,105	1,620	843	0.06%	0.53%
21	Tobacco Products	69	776	32,215	442	542	0.00%	0.00%
22	Textile Mill Products	1,491	17,062	262,733	195	104	0.02%	0.05%
24	Wood Products (except furniture)	10,290	39,409	1,739,695	161	175	0.04%	0.60%
25	Furniture and Fixtures	5,254	26,012	749,673	267	31	0.04%	0.07%
26	Paper Products	4,397	95,533	4,028,205	1,265	118	0.05%	0.04%
27	Printing and Publishing	47	206	618	14	11	0.00%	0.04%
28	Chemicals & Allied Products	8,098	170,982	1,581,380	399	26	0.01%	0.01%
29	Petroleum Refining	1,644	93,700	2,418,236	4,040	262	0.01%	0.02%
30	Rubber Products	6,282	143,818	6,910,246	1,411	725	0.15%	0.61%
31	Leather and Leather Products	151	514	36,948	603	3	0.13%	0.00%
32	Stone, Clay, Glass & Concrete	12,290	116,706	12,149,864	1,407	799	0.17%	1.17%
33	Primary Metals Industry	2,788	35,521	5,801,382	2,228	95	0.09%	0.02%
34	Fabricated Metal Products	8,441	88,507	13,490,158	2,942	604	0.41%	0.97%
35	Machinery, Except Electrical	4,330	34,670	2,999,427	1,182	303	0.04%	0.20%
36	Electric/Electronic Equipment	8,610	178,895	13,354,277	2,128	1,901	0.14%	2.10%
37	Transportation Equipment	3,302	1,085,966	6,945,783	5,097	153	0.05%	0.05%
38	Instruments & Related Products	64	901	6,262	268	2	0.00%	0.00%

Table 8—Cost Impact by Industry—Continued

SIC	Industry	Number of Affected Firms	Number of Permit Spaces Total	Total Annual Compliance Costs	Average Cost of Rule		Cost As A Percent of Profit	
					Large Firms	Small Firms	Large Firms	Small Firms
39	Miscellaneous Manufacturing	885	31,287	1,196,552	1,556	1,017	0.13%	2.67%
42	Motor Freight Transportation	14,583	201,680	12,958,195	1,038	839	0.30%	4.07%
49	Electric, Gas, Sanitary Services	28,444	1,575,170	72,636,019	10,250	3,043	0.06%	1.00%
50	Wholesale Trade/Durables	2,753	3,965	262,586	204	66	0.03%	0.12%
51	Wholesale Trade/Nondurables	36,913	411,095	15,792,080	627	407	0.04%	0.51%
54	Food Stores	10,073	10,073	243,950	38	13	0.01%	0.07%
59	Miscellaneous Retail	7,149	28,201	18,286	12	2	0.00%	0.01%
65	Real Estate (Commercial)	13,582	45,190	1,561,156	256	79	0.03%	0.19%
70	Hotels and Other Lodging	5,099	77,672	831,454	213	128	0.05%	0.47%
72	Personal Services	3,577	24,604	310,564	87	0	0.05%	0.00%
76	Miscellaneous Repair Services	752	802	6,173	25	7	0.02%	0.10%
78	Motion Pictures	11	33	26	2	0	0.00%	0.00%
80	Health Services	8,252	71,709	3,603,226	566	35	0.04%	0.04%
84	Museums, Botanical Gardens, Zoos	130	1,183	5,238	40	0	0.01%	0.00%
	TOTAL	238,853	4,844,849	$202,369,752	$1,272			
	$655	0.05%	0.75%					

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis

As required by the Regulatory Flexibility Act of 1980, OSHA assessed the economic burden faced by small establishments. Assuming inelastic demand and full cost pass-through, price impacts would average 0.04 percent for firms with 19 or fewer employees. Profit impacts under the opposite assumption of zero cost pass-through would average 0.75 percent. Profit impacts would be less than 5 percent for small firms in all sectors. In two sectors (agricultural services and motor freight transportation), costs will exceed 4 percent of profits, but in only three other industries will costs exceed 1 percent of profits. These profit impacts depict worst-case, perfectly elastic demand conditions. OSHA anticipates that given imperfectly elastic demand conditions found in most markets, and the negligible price increases necessary to offset cost increases, impacts on net earnings will be minimal due to the ability of firms to pass some of the costs forward to buyers. Therefore, OSHA has determined that the final standard is economically feasible for small establishments.

G. Industry-Specific Hazard Analysis

For affected industry sectors, OSHA compared the fatalities, injuries and illnesses avoided with cost of compliance, to assess the benefit-to-cost relationship. Annual benefits and costs of the standard are shown in Table 9. In general, employee benefits are correlated with compliance costs: industries with relatively higher total costs or costs per establishment are expected to experience a relatively greater reduction in permit-space fatalities, injuries, and illnesses.

Table 9—Annual Benefits and Cost of the Permit Space Standard

SIC	Industry	Fatalities Avoided Total[1]	Injuries and Illnesses Avoided		Compliance Costs (Thousands of Dollars) Total	Cost per Establ. (Dollars) Total
			Lost-Workday Total[1]	Non-Lost-Workday Total[1]		
07	Agricultural Services	0.3	18	17	$7,880.5	$752.4
13	Oil & Gas Extraction	6.8	163	120	84.5	8.5
20	Food and Kindred Products	2.7	404	513	12,472.1	1,218.5
21	Tobacco Products	0.3	51	64	32.2	487.8
22	Textile Mill Products	0.3	51	64	262.7	176.2
24	Wood Products (except furniture)	1.0	152	192	1,739.7	169.1
25	Furniture and Fixtures	0.0[2]	[3]	-	749.7	142.7
26	Paper Products	0.7	101	128	4,028.2	916.0
27	Printing and Publishing	0.0	-	-	0.6	13.2
28	Chemicals & Allied Products	4.1	607	709	1,581.4	195.3
29	Petroleum Refining	0.0[2]	-	-	2,418.2	1,470.0
30	Rubber Products	0.7	101	128	6,910.2	1,099.9
31	Leather and Leather Products	1.0	152	192	36.9	245.2
32	Stone, Clay, Glass & Concrete	0.7	101	128	12,149.8	988.6
33	Primary Metals Industry	2.0	303	384	5,801.4	2,090.8
34	Fabricated Metal Products	5.1	758	961	13,490.2	1,598.1
35	Machinery, Except Electrical	1.0	152	192	2,999.4	892.7
36	Electric/Electronic Equipment	0.0[2]	[3]	-	13,354.3	2,020.2
37	Transportation Equipment	2.0	303	384	6,945.8	2,103.8
38	Instruments & Related Products	0.3	51	64	6.3	97.8

Table 9—Annual Benefits and Cost of the Permit Space Standard—Continued

SIC	Industry	Fatalities Avoided Total[1]	Injuries and Illnesses Avoided		Compliance Costs (Thousands of Dollars) Total	Cost per Establ. (Dollars) Total
			Lost-Workday Total[1]	Non-Lost-Workday Total[1]		
39	Miscellaneous Manufacturing	0.3	51	64	1,196.6	1,351.8
42	Motor Freight Transportation	5.1	223	163	12,958.2	888.8
49	Electric, Gas, Sanitary Services	6.8	297	217	72,636.0	2,553.6
50	Wholesale Trade/Durables	0.3	42	48	262.6	95.4
51	Wholesale Trade/Nondurables	1.0	125	145	15,792.1	427.8
54	Food Stores	0.0[2]	-[3]	-	243.9	24.2
59	Miscellaneous Retail	0.3	42	48	18.3	2.6
65	Real Estate (Commercial)	0.0[2]	-	-	1,561.2	114.9
70	Hotels and Other Lodging	0.0[2]	-	-	831.5	163.0
72	Personal Services	0.0	-	-	310.6	86.8
76	Miscellaneous Repair Services	3.1	374	436	6.2	8.2
78	Motion Pictures	0.0	-	-	0.0	2.4
80	Health Services	0.3	42	48	3,603.2	436.6
84	Museums, Botanical Gardens, Zoos	0.0	-	-	5.2	40.2
	Host Employer Unidentified[4]	7.1	380	436		
	TOTAL $695.0	53.7	5,041	5,908	$202,369.8	

Source: U.S. Department of Labor, OSHA, Office of Regulatory Analysis
[1] Assumes that projected permit space incidents would be distributed in the same SICs in which incidents were reported from 1986–1990.
[2] Fatalities, injuries or illnesses were reported prior to 1986 or after 1990 by OSHA [3], [4], [5] or NIOSH [2].
[3] Dashes indicate that prevented injuries could not be estimated utilizing an injury/fatality factor (see Chapter III, Benefits, of the Regulatory Analysis, Table III–3) due to the absence of reported fatalities during the investigated period.
[4] Includes contractors and other service employers whose host employer at the time of the accident could not be identified in the OSHA abstracts.

For four industries where accidents could not be identified in either OSHA or NIOSH databases, OSHA notes that costs per establishment are significantly below the overall industry average of $695. OSHA's analysis of these affected industries in Chapter III of the Regulatory Analysis indicates that they contain the same spaces and hazards as other industries with recorded accidents.

H. International Trade

In accordance with Executive Order 12291, OSHA assessed the effects of the final standard on international trade. The standard is expected to affect a wide range of industrial and commercial enterprises, many of whom compete against foreign competitors in both foreign markets and the U.S. markets. If the OSHA regulation significantly increased the price of products and services of domestic producers, foreign producers could benefit. OSHA believes, however, that price impacts from this standard will be minor and have little effect on American trade overseas and on domestic sales.

I. Environmental Impact

The permit-required confined spaces standard has been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.), the regulations of the Council on Environmental Quality (CEQ, 40 CFR Part 1500), and DOL NEPA Procedures (29 CFR Part 11). OSHA anticipates that greater use of mechanical ventilation to reduce atmospheric hazards in permit spaces may result in additional release of hazardous substances to the air. Incremental release quantities related to the permit space standard are not determinable at present, but are expected to be minor relative to current overall releases. Releases of substances regulated under EPA's SARA Title III or EPA NESHAP standards are subject to reporting and control requirements in those rules.

J. Nonregulatory Alternatives

The primary objective of OSHA's standard for permit spaces is to reduce the number of employee fatalities and injuries associated with catastrophic releases of hazardous substances. OSHA believes the standard will eliminate to a considerable degree the worker risk experienced in the confined spaces falling within the scope of the rule.

The Agency examined the nonregulatory approaches for promoting the implementation of permit space programs, including (1) economic forces generated by the private market system, (2) incentives created by workers' compensation programs or the threat of private suits, and (3) related activities of private agencies. Following this review, OSHA determined that the need for government regulation arises from the significant risk of job-related injury or death caused by inadequate permit space safety programs. Private markets fail to provide enough safety and health resources due to the lack of information on risk, immobility of labor, and externalization of part of the social cost of worker injuries and deaths. Workers compensation systems do not offer an adequate remedy because premiums do not reflect specific workplace risk and liability claims are restricted by statutes preventing employees from suing their employers. While certain voluntary industry standards exist, as well as rules and recommended procedures in a limited number of states, their scope and approach fail to provide adequate protection for all workers. Thus, OSHA has determined that a federal standard is necessary.

K. References

1. CONSAD Research Corporation. "Development of Industry Profile Data for OSHA's Draft Proposed Standard for Permit Entry Confined Spaces", prepared for the U.S. Department of Labor, Occupational Safety and Health Administration under Contract No. J–9–F–0024. Pittsburgh, May 20, 1988 (Ex. 16).

2. U.S. Department of Health, Education, and Welfare. Public Health Service. Center for Disease Control. National Institute for Occupational Safety and Health. "Criteria for a Recommended Standard ... Working in Confined Spaces", DHEW (NIOSH) Publication No. 80–106. Cincinnati: NIOSH, December 1979 (Ex. 13–6).

3. U.S. Department of Labor. Occupational Safety and Health Administration. Directorate of Policy. "Selected Occupational Fatalities Related to Toxic and Asphyxiating Atmospheres in Confined Work Spaces as

Found in Reports of OSHA Fatality/Catastrophe Investigations", Washington, D.C., July 1985 (Ex. 13–15).

4. U.S. Department of Labor. Occupational Safety and Health Administration. Directorate of Technical Support. "Selected Occupational Fatalities Related to Fire and/or Explosion in Confined Work Spaces as Found in Reports of OSHA Fatality/Catastrophe Investigations", Washington, D.C., April 1982 (Ex. 13–10).

5. OSHA Integrated Management Information System, Fatality/Catastrophe Database. OSHA Office of Management Data Systems.

VII. Federalism

This regulation has been reviewed in accordance with Executive Order 12612 regarding Federalism. This order requires that agencies, to the extent possible, refrain from limiting state policy options and consult with states prior to taking any action. Agencies may act only when there is clear constitutional authority and the presence of a problem of national scope. The order provides for preemption of state law only if there is a clear congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act of 1970 expresses Congress' clear intent to preempt state laws relating to issues on which Federal OSHA has promulgated occupational safety and health standards. Under the OSH Act, a state can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective in providing safe and healthful employment and places of employment as Federal Standards. Where such standards are applicable to products distributed or used in interstate commerce, they may not unduly burden commerce and must be justified by compelling local conditions (See Section 18(c)(2) of the OSH Act).

This regulation is drafted so that employees in every state would be protected by general, performance-oriented standards. To the extent that there are state or regional peculiarities caused by the terrain, the climate or other factors, states would be able, under the OSH Act, to develop their own state standards to deal with any special problems. And, under the Act, if a state develops an approved state program, it could make additional requirements in its standards. Moreover, the performance nature of this standard, of and by itself, allows for flexibility by states and employers to provide as much safety as possible using varying methods consonant with conditions in each state.

In short, there is a clear national problem related to occupational safety and health concerning entry into confined spaces. Those states which elect to participate under the statute would not be preempted by this regulation and would be able to address special, local conditions within the framework provided by this performance-oriented standard.

OSHA notes that California, Kentucky, Maryland, Michigan, New Jersey, and Virginia currently have regulations dealing with confined space entry. Of these six state regulations, none would be preempted. New Jersey is not a state-plan state, but their confined space standard applies only to public (state and local government) employees. An analysis of state confined space rules and procedures is contained in Section VI, Summary of the Final Regulatory Impact Analysis and Regulatory Flexibility Analysis, earlier in this preamble.

VIII. State Plan States

The 25 states and territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within six months of the publication date of this final standard. These 25 states are: Alaska, Arizona, California, Connecticut (for state and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for state and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington and Wyoming. Until such time as a state standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate, in these states.

List of Subjects in 29 CFR Part 1910

Attendant, Confined Spaces, Entry permit system, Hazardous atmospheres, Hazardous materials, Incorporation by reference, Monitoring, Occupational safety and health, Permits, Personal protective equipment, Rescue equipment, Respiratory protection, Retrieval lines, Safety, Signs, Tags, Tools, Welding.

IX. Authority

This document was prepared under the direction of Dorothy L. Strunk, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Accordingly, pursuant to sections 6(b) and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657), Secretary of Labor's Order No. 1–90 (55 FR 9033), and 29 CFR Part 1911, Title 29, Chapter XVII, of the Code of Federal Regulations is amended as follows.

Signed at Washington, D.C., this 6th day of January, 1993.

Dorothy L. Strunk

Acting Assistant Secretary of Labor

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The authority citation for Subpart J of Part 1910 is revised to read as follows:

AUTHORITY: Secs. 4, 6, and 8, Occupational Safety and Health Act of 1970, 29 USC 653, 655, 657; Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable.

Sections 1910.141, 1910.142,1910.145, 1910.146, and 1910.147 also issued under 29 CFR Part 1911.

2. Section 1910.146 is added to read as follows:

§1910.146 Permit-required confined spaces.

(a) *Scope and application.* This section contains requirements for practices and procedures to protect employees in general industry from the hazards of entry into permit-required confined spaces. This section does not apply to agriculture, to construction, or to shipyard employment (Parts 1928, 1926, and 1915 of this chapter, respectively).

(b) *Definitions.*

Acceptable entry conditions means the conditions that must exist in a permit space to allow entry and to ensure that employees involved with a permit-required confined space entry can safely enter into and work within the space.

Attendant means an individual stationed outside one or more permit spaces who monitors the authorized entrants and who performs all attendant's duties assigned in the employer's permit space program.

Authorized entrant means an employee who is authorized by the employer to enter a permit space.

Blanking or blinding means the absolute closure of a pipe, line, or duct by the fastening of a solid plate (such as a spectacle blind or a skillet blind) that completely covers the bore and that is capable of withstanding the maximum pressure of the pipe, line, or duct with no leakage beyond the plate.

Confined space means a space that:

(1) Is large enough and so configured that an employee can bodily enter and perform assigned work; and

(2) Has limited or restricted means for entry or exit (for example, tanks, vessels, silos, storage bins, hoppers, vaults, and pits are spaces that may have limited means of entry.); and

(3) Is not designed for continuous employee occupancy.

Double block and bleed means the closure of a line, duct, or pipe by closing and locking or tagging two in-line valves and by opening and locking or tagging a drain or vent valve in the line between the two closed valves.

Emergency means any occurrence (including any failure of hazard control or monitoring equipment) or event internal or external to the permit space that could endanger entrants.

Engulfment means the surrounding and effective capture of a person by a liquid or finely divided (flowable) solid substance that can be aspirated to cause death by filling or plugging the respiratory system or that can exert enough force on the body to cause death by strangulation, constriction, or crushing.

Entry means the action by which a person passes through an opening into a permit-required confined space. Entry includes ensuing work activities in that space and is considered to have occurred as soon as any part of the entrant's body breaks the plane of an opening into the space.

Entry permit (permit) means the written or printed document that is provided by the employer to allow and control entry into a permit space and that contains the information specified in paragraph (f) of this section.

Entry supervisor means the person (such as the employer, foreman, or crew chief) responsible for determining if acceptable entry conditions are present at a permit space where entry is planned, for authorizing entry and overseeing entry operations, and for terminating entry as required by this section.

Note: An entry supervisor also may serve as an attendant or as an authorized entrant, as long as that person is trained and equipped as required by this section for each role he or she fills. Also, the duties of entry supervisor may be passed from one individual to another during the course of an entry operation.

Hazardous atmosphere means an atmosphere that may expose employees to the risk of death, incapacitation, impairment of ability to self-rescue (that is, escape unaided from a permit space), injury, or acute illness from one or more of the following causes:

(1) Flammable gas, vapor, or mist in excess of 10 percent of its lower flammable limit (LFL);

(2) Airborne combustible dust at a concentration that meets or exceeds its LFL;

Note: This concentration may be approximated as a condition in which the dust obscures vision at a distance of 5 feet (1.52 m) or less.

(3) Atmospheric oxygen concentration below 19.5 percent or above 23.5 percent;

(4) Atmospheric concentration of any substance for which a dose or a permissible exposure limit is published in Subpart G, *Occupational Health and Environmental Control*, or in Subpart Z, *Toxic and Hazardous Substances*, of this part and which could result in employee exposure in excess of its dose or permissible exposure limit;

Note: An atmospheric concentration of any substance that is not capable of causing death, incapacitation, impairment of ability to self-rescue, injury, or acute illness due to its health effects is not covered by this provision.

(5) Any other atmospheric condition that is immediately dangerous to life or health.

Note: For air contaminants for which OSHA has not determined a dose or permissible exposure limit, other sources of information, such as Material Safety Data Sheets that comply with the Hazard Communication Standard, §1910.1200 of this part, published information, and internal documents can provide guidance in establishing acceptable atmospheric conditions.

Hot work permit means the employer's written authorization to perform operations (for example, riveting, welding, cutting, burning, and heating) capable of providing a source of ignition.

Immediately dangerous to life or health (IDLH) means any condition that poses an immediate or delayed threat to life or that would cause irreversible adverse health effects or that would interfere with an individual's ability to escape unaided from a permit space.

Note: Some materials—hydrogen fluoride gas and cadmium vapor, for example—may produce immediate transient effects that, even if severe, may pass without medical attention, but are followed by sudden, possibly fatal collapse 12–72 hours after exposure. The victim "feels normal" from recovery from transient effects until collapse. Such materials in hazardous quantities are considered to be "immediately" dangerous to life or health.

Inerting means the displacement of the atmosphere in a permit space by a noncombustible gas (such as nitrogen) to such an extent that the resulting atmosphere is noncombustible.

Note: This procedure produces an IDLH oxygen-deficient atmosphere.

Isolation means the process by which a permit space is removed from service and completely protected against the release of energy and material into the space by such means as: blanking or blinding; misaligning or removing sections of lines, pipes, or ducts; a double block and bleed system; lockout or tagout of all sources of energy; or blocking or disconnecting all mechanical linkages.

Line breaking means the intentional opening of a pipe, line, or duct that is or has been carrying flammable, corrosive, or toxic material, an inert gas, or any fluid at a volume, pressure, or temperature capable of causing injury.

Non-permit confined space means a confined space that does not contain or, with respect to atmospheric hazards, have the potential to contain any hazard capable of causing death or serious physical harm.

Oxygen deficient atmosphere means an atmosphere containing less than 19.5 percent oxygen by volume.

Oxygen enriched atmosphere means an atmosphere containing more than 23.5 percent oxygen by volume.

Permit-required confined space (permit space) means a confined space that has one or more of the following characteristics:

(1) Contains or has a potential to contain a hazardous atmosphere;

(2) Contains a material that has the potential for engulfing an entrant;

(3) Has an internal configuration such that an entrant could be trapped or asphyxiated by inwardly converging walls or by a floor which slopes downward and tapers to a smaller cross-section; or

(4) Contains any other recognized serious safety or health hazard.

Permit-required confined space program (permit space program) means the employer's overall program for controlling, and, where appropriate, for protecting employees from, permit space hazards and for regulating employee entry into permit spaces.

Permit system means the employer's written procedure for preparing and issuing permits for entry and for returning the permit space to service following termination of entry.

Prohibited condition means any condition in a permit space that is not allowed by the permit during the period when entry is authorized.

Rescue service means the personnel designated to rescue employees from permit spaces.

Retrieval system means the equipment (including a retrieval line, chest or full-body harness, wristlets, if appropriate, and a lifting device or anchor) used for non-entry rescue of persons from permit spaces.

Testing means the process by which the hazards that may confront entrants of a permit space are identified and evaluated. Testing includes specifying the tests that are to be performed in the permit space.

Note: Testing enables employers both to devise and implement adequate control measures for the protection of authorized entrants and to determine if acceptable entry conditions are present immediately prior to, and during, entry.

(c) *General requirements.* (1) The employer shall evaluate the workplace to determine if any spaces are permit-required confined spaces.

Note: Proper application of the decision flow chart in Appendix A to §1910.146 would facilitate compliance with this requirement.

(2) If the workplace contains permit spaces, the employer shall inform exposed employees, by posting danger signs or by any other equally effective means, of the existence and location of and the danger posed by the permit spaces.

Note: A sign reading "DANGER—PERMIT-REQUIRED CONFINED SPACE, DO NOT ENTER" or using other similar language would satisfy the requirement for a sign.

(3) If the employer decides that its employees will not enter permit spaces, the employer shall take effective measures to prevent its employees from entering the permit spaces and shall comply with paragraphs (c)(1), (c)(2), (c)(6), and (c)(8) of this section.

(4) If the employer decides that its employees will enter permit spaces, the employer shall develop and implement a written permit space entry program that complies with this section. The written program shall be available for inspection by employees and their authorized representatives.

(5) An employer may use the alternate procedures specified in paragraph (c)(5)(ii) of this section for entering a permit space under the conditions set forth in paragraph (c)(5)(i) of this section.

(i) An employer whose employees enter a permit space need not comply with paragraphs (d) through (f) and (h) through (k) of this section, provided that:

(A) The employer can demonstrate that the only hazard posed by the permit space is an actual or potential hazardous atmosphere;

(B) The employer can demonstrate that continuous forced air ventilation alone is sufficient to maintain that permit space safe for entry;

(C) The employer develops monitoring and inspection data that supports the demonstrations required by paragraphs (c)(5)(i)(A) and (c)(5)(i)(B) of this section;

(D) If an initial entry of the permit space is necessary to obtain the data required by paragraph (c)(5)(i)(C) of this section, the entry is performed in compliance with paragraphs (d) through (k) of this section;

(E) The determinations and supporting data required by paragraphs (c)(5)(i)(A), (c)(5)(i)(B), and (c)(5)(i)(C) of this section are documented by the employer and are made available to each employee who enters the permit space under the terms of paragraph (c)(5) of this section; and

(F) Entry into the permit space under the terms of paragraph (c)(5)(i) of this section is performed in accordance with the requirements of paragraph (c)(5)(ii) of this section.

Note: See paragraph (c)(7) of this section for reclassification of a permit space after all hazards within the space have been eliminated.

(ii) The following requirements apply to entry into permit spaces that meet the conditions set forth in paragraph (c)(5)(i) of this section.

(A) Any conditions making it unsafe to remove an entrance cover shall be eliminated before the cover is removed.

(B) When entrance covers are removed, the opening shall be promptly guarded by a railing, temporary cover, or other temporary barrier that will prevent an accidental fall through the opening and that will protect each employee working in the space from foreign objects entering the space.

(C) Before an employee enters the space, the internal atmosphere shall be tested, with a calibrated direct-reading instrument, for the following conditions in the order given:

(*1*) Oxygen content,

(*2*) Flammable gases and vapors, and

(*3*) Potential toxic air contaminants.

(D) There may be no hazardous atmosphere within the space whenever any employee is inside the space.

(E) Continuous forced air ventilation shall be used, as follows:

(*1*) An employee may not enter the space until the forced air ventilation has eliminated any hazardous atmosphere;

(*2*) The forced air ventilation shall be so directed as to ventilate the immediate areas where an employee is or will be present within the space and shall continue until all employees have left the space;

(*3*) The air supply for the forced air ventilation shall be from a clean source and may not increase the hazards in the space.

(F) The atmosphere within the space shall be periodically tested as necessary to ensure that the continuous forced air ventilation is preventing the accumulation of a hazardous atmosphere.

(G) If a hazardous atmosphere is detected during entry:

(*1*) Each employee shall leave the space immediately;

(*2*) The space shall be evaluated to determine how the hazardous atmosphere developed; and

(*3*) Measures shall be implemented to protect employees from the hazardous atmosphere before any subsequent entry takes place.

(H) The employer shall verify that the space is safe for entry and that the measures required by paragraph (c)(5)(ii) of this section have been taken, through a written certification that contains the date, the location of the space, and the signature of the person providing the certification. The certification shall be made before entry and shall be made available to each employee entering the space.

(6) When there are changes in the use or configuration of a non-permit confined space that might increase the hazards to entrants, the employer shall reevaluate that space and, if necessary, reclassify it as a permit-required confined space.

(7) A space classified by the employer as a permit-required confined space may be reclassified as a non-permit confined space under the following procedures:

(i) If the permit space poses no actual or potential atmospheric hazards and if all hazards within the space are eliminated without entry into the space, the permit space may be reclassified as a non-permit confined space for as long as the non-atmospheric hazards remain eliminated.

(ii) If it is necessary to enter the permit space to eliminate hazards, such entry shall be performed under paragraphs (d) through (k) of this section. If testing and inspection during that entry demonstrate that the hazards within the permit space have been eliminated, the permit space may be reclassified as a non-permit confined space for as long as the hazards remain eliminated.

Note: Control of atmospheric hazards through forced air ventilation does not constitute elimination of the hazards. Paragraph (c)(5) covers permit space entry where the employer can demonstrate that forced air ventilation alone will control all hazards in the space.

(iii) The employer shall document the basis for determining that all hazards in a permit space have been eliminated, through a certification that contains the date, the location of the space, and the signature of the person making the determination. The certification shall be made available to each employee entering the space.

(iv) If hazards arise within a permit space that has been declassified to a non-permit space under paragraph (c)(7) of this section, each employee in the space shall exit the space. The employer shall then reevaluate the space and determine whether it must be reclassified as a permit space, in accordance with other applicable provisions of this section.

(8) When an employer (host employer) arranges to have employees of another employer (contractor) perform work that involves permit space entry, the host employer shall:

(i) Inform the contractor that the workplace contains permit spaces and that permit space entry is allowed only through compliance with an permit space program meeting the requirements of this section;

(ii) Apprise the contractor of the elements, including the hazards identified and the host employer's experience with the space, that make the space in question a permit space;

(iii) Apprise the contractor of any precautions or procedures that the host employer has implemented for the protection of employees in or near permit spaces where contractor personnel will be working;

(iv) Coordinate entry operations with the contractor, when both host employer personnel and contractor personnel will be working in or near permit spaces, as required by paragraph (d)(11) of this section; and

(v) Debrief the contractor at the conclusion of the entry operations regarding the permit space program followed and regarding any hazards confronted or created in permit spaces during entry operations.

(9) In addition to complying with the permit space requirements that apply to all employers, each contractor who is retained to perform permit space entry operations shall:

(i) Obtain any available information regarding permit space hazards and entry operations from the host employer;

(ii) Coordinate entry operations with the host employer, when both host employer personnel and contractor personnel will be working in or near permit spaces, as required by paragraph (d)(11) of this section; and

(iii) Inform the host employer of the permit space program that the contractor will follow and of any hazards confronted or created in permit spaces, either through a debriefing or during the entry operation.

(d) *Permit-required confined space program.* Under the permit-required confined space program required by paragraph (c)(4) of this section, the employer shall:

(1) Implement the measures necessary to prevent unauthorized entry;

(2) Identify and evaluate the hazards of permit spaces before employees enter them;

(3) Develop and implement the means, procedures, and practices necessary for safe permit space entry operations, including, but not limited to, the following:

(i) Specifying acceptable entry conditions;

(ii) Isolating the permit space;

(iii) Purging, inerting, flushing, or ventilating the permit space as necessary to eliminate or control atmospheric hazards;

(iv) Providing pedestrian, vehicle, or other barriers as necessary to protect entrants from external hazards; and

(v) Verifying that conditions in the permit space are acceptable for entry throughout the duration of an authorized entry.

(4) Provide the following equipment (specified in paragraphs (d)(4)(i) through (d)(4)(ix) of this section) at no cost to employees, maintain that equipment properly, and ensure that employees use that equipment properly:

(i) Testing and monitoring equipment needed to comply with paragraph (d)(5) of this section;

(ii) Ventilating equipment needed to obtain acceptable entry conditions;

(iii) Communications equipment necessary for compliance with paragraphs (h)(3) and (i)(5) of this section;

(iv) Personal protective equipment insofar as feasible engineering and work practice controls do not adequately protect employees;

(v) Lighting equipment needed to enable employees to see well enough to work safely and to exit the space quickly in an emergency;

(vi) Barriers and shields as required by paragraph (d)(3)(iv) of this section;

(vii) Equipment, such as ladders, needed for safe ingress and egress by authorized entrants;

(viii) Rescue and emergency equipment needed to comply with paragraph (d)(9) of this section, except to the extent that the equipment is provided by rescue services; and

(ix) Any other equipment necessary for safe entry into and rescue from permit spaces.

(5) Evaluate permit space conditions as follows when entry operations are conducted:

(i) Test conditions in the permit space to determine if acceptable entry conditions exist before entry is authorized to begin, except that, if isolation of the space is infeasible because the space is large or is part of a continuous system (such as a sewer), pre-entry testing shall be performed to the extent feasible before entry is authorized and, if entry is authorized, entry conditions shall be continuously monitored in the areas where authorized entrants are working;

(ii) Test or monitor the permit space as necessary to determine if acceptable entry conditions are being maintained during the course of entry operations; and

(iii) When testing for atmospheric hazards, test first for oxygen, then for combustible gases and vapors, and then for toxic gases and vapors.

Note: Atmospheric testing conducted in accordance with Appendix B to §1910.146 would be considered as satisfying the requirements of this paragraph. For permit space operations in sewers, atmospheric testing conducted in accordance with Appendix B, as supplemented by Appendix E to §1910.146, would be considered as satisfying the requirements of this paragraph.

(6) Provide at least one attendant outside the permit space into which entry is authorized for the duration of entry operations;

Note: Attendants may be assigned to monitor more than one permit space provided the duties described in paragraph (i) of this section can be effectively performed for each permit space that is monitored. Likewise, attendants may be stationed at any location outside the permit space to be monitored as long as the duties described in paragraph (i) of this section can be effectively performed for each permit space that is monitored.

(7) If multiple spaces are to be monitored by a single attendant, include in the permit program the means and procedures to enable the attendant to respond to an emergency affecting one or more of the permit spaces being monitored without distraction from the attendant's responsibilities under paragraph (i) of this section;

(8) Designate the persons who are to have active roles (as, for example, authorized entrants, attendants, entry supervisors, or persons who test or monitor the atmosphere in a permit space) in entry operations, identify the duties of each such employee, and provide each such employee with the

training required by paragraph (g) of this section;

(9) Develop and implement procedures for summoning rescue and emergency services, for rescuing entrants from permit spaces, for providing necessary emergency services to rescued employees, and for preventing unauthorized personnel from attempting a rescue;

(10) Develop and implement a system for the preparation, issuance, use, and cancellation of entry permits as required by this section;

(11) Develop and implement procedures to coordinate entry operations when employees of more than one employer are working simultaneously as authorized entrants in a permit space, so that employees of one employer do not endanger the employees of any other employer;

(12) Develop and implement procedures (such as closing off a permit space and canceling the permit) necessary for concluding the entry after entry operations have been completed;

(13) Review entry operations when the employer has reason to believe that the measures taken under the permit space program may not protect employees and revise the program to correct deficiencies found to exist before subsequent entries are authorized; and

Note: Examples of circumstances requiring the review of the permit-required confined space program are: any unauthorized entry of a permit space, the detection of a permit space hazard not covered by the permit, the detection of a condition prohibited by the permit, the occurrence of an injury or near-miss during entry, a change in the use or configuration of a permit space, and employee complaints about the effectiveness of the program.

(14) Review the permit-required confined space program, using the canceled permits retained under paragraph (e)(6) of this section within 1 year after each entry and revise the program as necessary, to ensure that employees participating in entry operations are protected from permit space hazards.

Note: Employers may perform a single annual review covering all entries performed during a 12-month period. If no entry is performed during a 12-month period, no review is necessary.

Appendix C to §1910.146 presents examples of permit entry programs that are considered to comply with the requirements of paragraph (d) of this section.

(e) *Permit system.* (1) Before entry is authorized, the employer shall document the completion of measures required by paragraph (d)(3) of this section by preparing an entry permit.

Note: Appendix D to §1910.146 presents examples of permits whose elements are considered to comply with the requirements of this section.

(2) Before entry begins, the entry supervisor identified on the permit shall sign the entry permit to authorize entry.

(3) The completed permit shall be made available at the time of entry to all authorized entrants, by posting it at the entry portal or by any other equally effective means, so that the entrants can confirm that pre-entry preparations have been completed.

(4) The duration of the permit may not exceed the time required to complete the assigned task or job identified on the permit in accordance with paragraph (f)(2) of this section.

(5) The entry supervisor shall terminate entry and cancel the entry permit when:

(i) The entry operations covered by the entry permit have been completed; or

(ii) A condition that is not allowed under the entry permit arises in or near the permit space.

(6) The employer shall retain each canceled entry permit for at least 1 year to facilitate the review of the permit-required confined space program required by paragraph (d)(14) of this section. Any problems encountered during an entry operation shall be noted on the pertinent permit so that appropriate revisions to the permit space program can be made.

(f) *Entry permit.* The entry permit that documents compliance with this section and authorizes entry to a permit space shall identify:

(1) The permit space to be entered;

(2) The purpose of the entry;

(3) The date and the authorized duration of the entry permit;

(4) The authorized entrants within the permit space, by name or by such other means (for example, through the use of rosters or tracking systems) as will enable the attendant to determine quickly and accurately, for the duration of the permit, which authorized entrants are inside the permit space;

Note: This requirement may be met by inserting a reference on the entry permit as to the means used, such as a roster or tracking system, to keep track of the authorized entrants within the permit space.

(5) The personnel, by name, currently serving as attendants;

(6) The individual, by name, currently serving as entry supervisor, with a space for the signature or initials of the entry supervisor who originally authorized entry;

(7) The hazards of the permit space to be entered;

(8) The measures used to isolate the permit space and to eliminate or control permit space hazards before entry;

Note: Those measures can include the lockout or tagging of equipment and procedures for purging, inerting, ventilating, and flushing permit spaces.

(9) The acceptable entry conditions;

(10) The results of initial and periodic tests performed under paragraph (d)(5) of this section, accompanied by the names or initials of the testers and by an indication of when the tests were performed;

(11) The rescue and emergency services that can be summoned and the means (such as the equipment to use and the numbers to call) for summoning those services;

(12) The communication procedures used by authorized entrants and attendants to maintain contact during the entry;

(13) Equipment, such as personal protective equipment, testing equipment, communications equipment, alarm systems, and rescue equipment, to be provided for compliance with this section;

(14) Any other information whose inclusion is necessary, given the circumstances of the particular confined space, in order to ensure employee safety; and

(15) Any additional permits, such as for hot work, that have been issued to authorize work in the permit space.

(g) *Training.* (1) The employer shall provide training so that all employees whose work is regulated by this section acquire the understanding, knowledge, and skills necessary for the safe performance of the duties assigned under this section.

(2) Training shall be provided to each affected employee:

(i) Before the employee is first assigned duties under this section;

(ii) Before there is a change in assigned duties;

(iii) Whenever there is a change in permit space operations that presents a hazard about which an employee has not previously been trained;

(iv) Whenever the employer has reason to believe either that there are deviations from the permit space entry procedures required by paragraph (d)(3) of this section or that there are inadequacies in the employee's knowledge or use of these procedures.

(3) The training shall establish employee proficiency in the duties required by this section and shall introduce new or revised procedures, as necessary, for compliance with this section.

(4) The employer shall certify that the training required by paragraphs (g)(1)

through (g)(3) of this section has been accomplished. The certification shall contain each employee's name, the signatures or initials of the trainers, and the dates of training. The certification shall be available for inspection by employees and their authorized representatives.

(h) *Duties of authorized entrants.* The employer shall ensure that all authorized entrants:

(1) Know the hazards that may be faced during entry, including information on the mode, signs or symptoms, and consequences of the exposure;

(2) Properly use equipment as required by paragraph (d)(4) of this section;

(3) Communicate with the attendant as necessary to enable the attendant to monitor entrant status and to enable the attendant to alert entrants of the need to evacuate the space as required by paragraph (i)(6) of this section;

(4) Alert the attendant whenever:

(i) The entrant recognizes any warning sign or symptom of exposure to a dangerous situation, or

(ii) The entrant detects a prohibited condition; and

(5) Exit from the permit space as quickly as possible whenever:

(i) An order to evacuate is given by the attendant or the entry supervisor,

(ii) The entrant recognizes any warning sign or symptom of exposure to a dangerous situation,

(iii) The entrant detects a prohibited condition, or

(iv) An evacuation alarm is activated.

(i) *Duties of attendants.* The employer shall ensure that each attendant:

(1) Knows the hazards that may be faced during entry, including information on the mode, signs or symptoms, and consequences of the exposure;

(2) Is aware of possible behavioral effects of hazard exposure in authorized entrants;

(3) Continuously maintains an accurate count of authorized entrants in the permit space and ensures that the means used to identify authorized entrants under paragraph (f)(4) of this section accurately identifies who is in the permit space;

(4) Remains outside the permit space during entry operations until relieved by another attendant;

Note: When the employer's permit entry program allows attendant entry for rescue, attendants may enter a permit space to attempt a rescue if they have been trained and equipped for rescue operations as required by paragraph (k)(1) of this section and if they have been relieved as required by paragraph (i)(4) of this section.

(5) Communicates with authorized entrants as necessary to monitor entrant status and to alert entrants of the need to evacuate the space under paragraph (i)(6) of this section;

(6) Monitors activities inside and outside the space to determine if it is safe for entrants to remain in the space and orders the authorized entrants to evacuate the permit space immediately under any of the following conditions;

(i) If the attendant detects a prohibited condition;

(ii) If the attendant detects the behavioral effects of hazard exposure in an authorized entrant;

(iii) If the attendant detects a situation outside the space that could endanger the authorized entrants; or

(iv) If the attendant cannot effectively and safely perform all the duties required under paragraph (i) of this section;

(7) Summon rescue and other emergency services as soon as the attendant determines that authorized entrants may need assistance to escape from permit space hazards;

(8) Takes the following actions when unauthorized persons approach or enter a permit space while entry is underway:

(i) Warn the unauthorized persons that they must stay away from the permit space;

(ii) Advise the unauthorized persons that they must exit immediately if they have entered the permit space; and

(iii) Inform the authorized entrants and the entry supervisor if unauthorized persons have entered the permit space;

(9) Performs non-entry rescues as specified by the employer's rescue procedure; and

(10) Performs no duties that might interfere with the attendant's primary duty to monitor and protect the authorized entrants.

(j) *Duties of entry supervisors.* The employer shall ensure that each entry supervisor:

(1) Knows the hazards that may be faced during entry, including information on the mode, signs or symptoms, and consequences of the exposure;

(2) Verifies, by checking that the appropriate entries have been made on the permit, that all tests specified by the permit have been conducted and that all procedures and equipment specified by the permit are in place before endorsing the permit and allowing entry to begin;

(3) Terminates the entry and cancels the permit as required by paragraph (e)(5) of this section;

(4) Verifies that rescue services are available and that the means for summoning them are operable;

(5) Removes unauthorized individuals who enter or who attempt to enter the permit space during entry operations; and

(6) Determines, whenever responsibility for a permit space entry operation is transferred and at intervals dictated by the hazards and operations performed within the space, that entry operations remain consistent with terms of the entry permit and that acceptable entry conditions are maintained.

(k) *Rescue and emergency services.* (1) The following requirements apply to employers who have employees enter permit spaces to perform rescue services.

(i) The employer shall ensure that each member of the rescue service is provided with, and is trained to use properly, the personal protective equipment and rescue equipment necessary for making rescues from permit spaces.

(ii) Each member of the rescue service shall be trained to perform the assigned rescue duties. Each member of the rescue service shall also receive the training required of authorized entrants under paragraph (g) of this section.

(iii) Each member of the rescue service shall practice making permit space rescues at least once every 12 months, by means of simulated rescue operations in which they remove dummies, manikins, or actual persons from the actual permit spaces or from representative permit spaces. Representative permit spaces shall, with respect to opening size, configuration, and accessibility, simulate the types of permit spaces from which rescue is to be performed.

(iv) Each member of the rescue service shall be trained in basic first-aid and in cardiopulmonary resuscitation (CPR). At least one member of the rescue service holding current certification in first aid and in CPR shall be available.

(2) When an employer (host employer) arranges to have persons other than the host employer's employees perform permit space rescue, the host employer shall:

(i) Inform the rescue service of the hazards they may confront when called on to perform rescue at the host employer's facility, and

(ii) Provide the rescue service with access to all permit spaces from which rescue may be necessary so that the rescue service can develop appropriate rescue plans and practice rescue operations.

(3) To facilitate non-entry rescue, retrieval systems or methods shall be used whenever an authorized entrant enters a permit space, unless the retrieval equipment would increase the overall risk of entry or would not contribute to the rescue of the entrant.

Retrieval systems shall meet the following requirements.

(i) Each authorized entrant shall use a chest or full body harness, with a retrieval line attached at the center of the entrant's back near shoulder level, or above the entrant's head. Wristlets may be used in lieu of the chest or full body harness if the employer can demonstrate that the use of a chest or full body harness is infeasible or creates a greater hazard and that the use of wristlets is the safest and most effective alternative.

(ii) The other end of the retrieval line shall be attached to a mechanical device or fixed point outside the permit space in such a manner that rescue can begin as soon as the rescuer becomes aware that rescue is necessary. A mechanical device shall be available to retrieve personnel from vertical type permit spaces more than 5 feet deep.

(4) If an injured entrant is exposed to a substance for which a Material Safety Data Sheet (MSDS) or other similar written information is required to be kept at the worksite, that MSDS or written information shall be made available to the medical facility treating the exposed entrant.

APPENDICES TO §1910.146—PERMIT-REQUIRED CONFINED SPACES

Note: Appendices A through E serve to provide information and non-mandatory guidelines to assist employers and employees in complying with the appropriate requirements of this section.

Appendix A to §1910.146—Permit-required Confined Space Decision Flow Chart

Appendix A

Permit-required Confined Space Decision Flow Chart

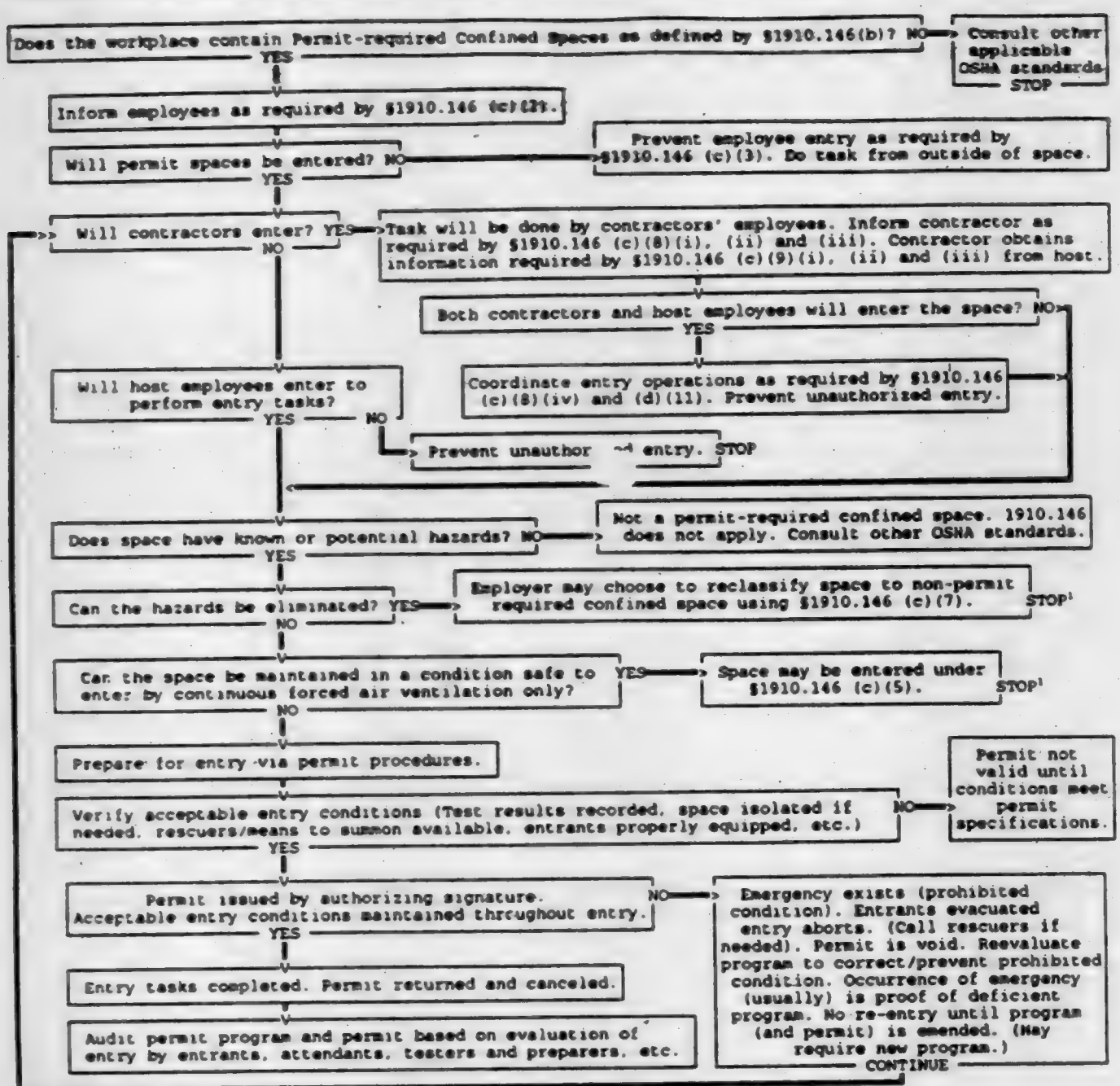

[1] Spaces may have to be evacuated and re-evaluated if hazards arise during entry

Appendix B to §1910.146—Procedures for Atmospheric Testing

Atmospheric testing is required for two distinct purposes: evaluation of the hazards of the permit space and verification that acceptable entry conditions for entry into that space exist.

(1) *Evaluation testing.* The atmosphere of a confined space should be analyzed using equipment of sufficient sensitivity and specificity to identify and evaluate any hazardous atmospheres that may exist or arise, so that appropriate permit entry procedures can be developed and acceptable entry conditions stipulated for that space. Evaluation and interpretation of these data, and development of the entry procedure, should be done by, or reviewed by, a technically qualified professional (e.g., OSHA consultation service, or certified industrial hygienist, registered safety engineer, certified safety professional, etc.) based on evaluation of all serious hazards.

(2) *Verification testing.* The atmosphere of a permit space which may contain a hazardous atmosphere should be tested for residues of all contaminants identified by evaluation testing using permit specified equipment to determine that residual concentrations at the time of testing and entry are within the range of acceptable entry conditions. Results of testing (i.e., actual concentration, etc.) should be recorded on the permit in the space provided adjacent to the stipulated acceptable entry condition.

(3) *Duration of testing.* Measurement of values for each atmospheric parameter should be made for at least the minimum response time of the test instrument specified by the manufacturer.

(4) *Testing stratified atmospheres.* When monitoring for entries involving a descent into atmospheres that may be stratified, the atmospheric envelope should be tested a distance of approximately 4 feet (1.22 m) in the direction of travel and to each side. If a sampling probe is used, the entrant's rate of progress should be slowed to accommodate the sampling speed and detector response.

Appendix C to §1910.146—Examples of Permit-required Confined Space Programs

Example 1.

Workplace. Sewer entry.

Potential hazards. The employees could be exposed to the following:

Engulfment.

Presence of toxic gases. Equal to or more than 10 ppm hydrogen sulfide. If the presence of other toxic contaminants is suspected, specific monitoring programs will be developed.

Presence of explosive/flammable gases. Equal to or greater than 10% of the lower flammable limit (LFL).

Oxygen Deficiency. A concentration of oxygen in the atmosphere equal to or less than 19.5% by volume.

A. *Entry Without Permit/Attendant Certification.* Confined spaces may be entered without the need for a written permit or attendant provided that: 1.) the space is determined *not* to be a permit required confined space, or 2.) the space can be maintained in a safe condition for entry by mechanical ventilation alone. All spaces shall be considered permit-required confined spaces until the pre-entry procedures demonstrate otherwise. Any employee required or permitted to pre-check or enter an enclosed/confined space shall have successfully completed, as a minimum, the training as required by the following sections of these procedures. *A written copy of operating and rescue procedures as required by these procedures shall be at the work site for the duration of the job.* The Confined Space Pre-Entry Check List must be completed by the LEAD WORKER before entry into a confined space. This list verifies completion of items listed below. This check list shall be kept at the job site for duration of the job. If circumstances dictate an interruption in the work, the permit space must be re-evaluated and a new check list must be completed.

Control of atmospheric and engulfment hazards.

Pumps and Lines. All pumps and lines which may reasonably cause contaminants to flow into the space shall be disconnected, blinded and locked out, or effectively isolated by other means to prevent development of dangerous air contamination or engulfment. Not all laterals to sewers or storm drains require blocking. However, where experience or knowledge of industrial use indicates there is a reasonable potential for contamination of air or engulfment into an occupied sewer, then all affected laterals shall be blocked. If blocking and/or isolation requires entry into the space the provisions for entry into a permit- required confined space must be implemented.

Surveillance. The surrounding area shall be surveyed to avoid hazards such as drifting vapors from the tanks, piping, or sewers.

Testing. The atmosphere within the space will be tested to determine whether dangerous air contamination and/or oxygen deficiency exists. An alarm only type gas monitor may be used. Testing shall be performed by the LEAD WORKER who has successfully completed the Gas Detector training for the monitor he will use. The minimum parameters to be monitored are oxygen deficiency, LFL, and hydrogen sulfide concentration. A written record of the pre-entry test results shall be made and kept at the work site for the duration of the job. The supervisor will certify in writing, based upon the results of the pre-entry testing, that all hazards have been eliminated. Affected employees shall be able to review the testing results. The most hazardous conditions shall govern when work is being performed in two adjoining, connecting spaces.

Entry Procedures. If there are no non-atmospheric hazards present and if the pre-entry tests show there is no dangerous air contamination and/or oxygen deficiency within the space and there is no reason to believe that any is likely to develop, entry into and work within may proceed. Continuous testing of the atmosphere in the immediate vicinity of the workers within the space shall be accomplished. The workers will immediately leave the permit space when any of the gas monitor alarm set points are reached as defined. Workers will not return to the area until a SUPERVISOR who has completed the gas detector training has used a direct reading gas detector to evaluate the situation and has determined that it is safe to enter.

Rescue. Arrangements for rescue services are not required where there is no attendant. See the rescue portion of section B., below, for instructions regarding rescue planning where an entry permit is required.

B. *Entry Permit Required Permits.* Confined Space Entry Permit. All spaces shall be considered permit-required confined spaces until the pre-entry procedures demonstrate otherwise. Any employee required or permitted to pre-check or enter a permit-required confined space shall have successfully completed, as a minimum, the training as required by the following sections of these procedures. *A written copy of operating and rescue procedures as required by these procedures shall be at the work site for the duration of the job.* The Confined Space Entry Permit must be completed before approval can be given to enter a permit-required confined space. This permit verifies completion of items listed below. This permit shall be kept at the job site for the duration of the job. If circumstances cause an interruption in the work or a change in the alarm conditions for which entry was approved, a new Confined Space Entry Permit must be completed.

Control of atmospheric and engulfment hazards.

Surveillance. The surrounding area shall be surveyed to avoid hazards such as drifting vapors from tanks, piping or sewers.

Testing. The confined space atmosphere shall be tested to determine whether dangerous air contamination and/or oxygen deficiency exists. A direct reading gas monitor shall be used. Testing shall be performed by the SUPERVISOR who has successfully completed the gas detector training for the monitor he will use. The minimum parameters to be monitored are oxygen deficiency, LFL and hydrogen sulfide concentration. A written record of the pre-entry test results shall be made and kept at the work site for the duration of the job. Affected employees shall be able to review the testing results. The most hazardous conditions shall govern when work is being performed in two adjoining, connected spaces.

Space Ventilation. Mechanical ventilation systems, where applicable, shall be set at 100% outside air. Where possible, open additional manholes to increase air circulation. Use portable blowers to augment natural circulation if needed. After a suitable ventilating period, repeat the testing. Entry may not begin until testing has demonstrated that the hazardous atmosphere has been eliminated.

Entry Procedures. The following procedure shall be observed under any of the following conditions: 1.) Testing demonstrates the existence of dangerous or deficient conditions and additional ventilation cannot reduce concentrations to safe levels; 2.) The atmosphere tests as safe but unsafe

conditions can reasonably be expected to develop; 3.) It is not feasible to provide for ready exit from spaces equipped with automatic fire suppression systems and it is not practical or safe to deactivate such systems; or 4.) An emergency exists and it is not feasible to wait for pre-entry procedures to take effect.

All personnel must be trained. A self contained breathing apparatus shall be worn by any person entering the space. At least one worker shall stand by the outside of the space ready to give assistance in case of emergency. The standby worker shall have a self contained breathing apparatus available for immediate use. There shall be at least one additional worker within sight or call of the standby worker. Continuous powered communications shall be maintained between the worker within the confined space and standby personnel.

If at any time there is any questionable action or non- movement by the worker inside, a verbal check will be made. If there is no response, the worker will be moved immediately. *Exception:* If the worker is disabled due to falling or impact, he/she shall not be removed from the confined space unless there is immediate danger to his/her life. Local fire department rescue personnel shall be notified immediately. The standby worker may only enter the confined space in case of an emergency (wearing the self contained breathing apparatus) and only after being relieved by another worker. Safety belt or harness with attached lifeline shall be used by all workers entering the space with the free end of the line secured outside the entry opening. The standby worker shall attempt to remove a disabled worker via his lifeline before entering the space.

When practical, these spaces shall be entered through side openings—those within 3 1/2 feet (1.07 m) of the bottom. When entry must be through a top opening, the safety belt shall be of the harness type that suspends a person upright and a hoisting device or similar apparatus shall be available for lifting workers out of the space.

In any situation where their use may endanger the worker, use of a hoisting device or safety belt and attached lifeline may be discontinued.

When dangerous air contamination is attributable to flammable and/or explosive substances, lighting and electrical equipment shall be Class 1, Division 1 rated per National Electrical Code and no ignition sources shall be introduced into the area.

Continuous gas monitoring shall be performed during all confined space operations. If alarm conditions change adversely, entry personnel shall exit the confined space and a new confined space permit issued.

Rescue. Call the fire department services for rescue. Where immediate hazards to injured personnel are present, workers at the site shall implement emergency procedures to fit the situation.

Example 2.

Workplace. Meat and poultry rendering plants.

Cookers and dryers are either batch or continuous in their operation. Multiple batch cookers are operated in parallel. When one unit of a multiple set is shut down for repairs, means are available to isolate that unit from the others which remain in operation.

Cookers and dryers are horizontal, cylindrical vessels equipped with a center, rotating shaft and agitator paddles or discs. If the inner shell is jacketed, it is usually heated with steam at pressures up to 150 psig (1034.25 kPa). The rotating shaft assembly of the continuous cooker or dryer is also steam heated.

Potential Hazards. The recognized hazards associated with cookers and dryers are the risk that employees could be:

1. Struck or caught by rotating agitator;
2. Engulfed in raw material or hot, recycled fat;
3. Burned by steam from leaks into the cooker/dryer steam jacket or the condenser duct system if steam valves are not properly closed and locked out;
4. Burned by contact with hot metal surfaces, such as the agitator shaft assembly, or inner shell of the cooker/dryer;
5. Heat stress caused by warm atmosphere inside cooker/dryer;
6. Slipping and falling on grease in the cooker/dryer;
7. Electrically shocked by faulty equipment taken into the cooker/dryer;
8. Burned or overcome by fire or products of combustion; or
9. Overcome by fumes generated by welding or cutting done on grease covered surfaces.

Permits. The supervisor in this case is always present at the cooker/dryer or other permit entry confined space when entry is made. The supervisor must follow the pre-entry isolation procedures described in the entry permit in preparing for entry, and ensure that the protective clothing, ventilating equipment and any other equipment required by the permit are at the entry site.

Control of hazards. Mechanical. Lock out main power switch to agitator motor at main power panel. Affix tag to the lock to inform others that a permit entry confined space entry is in progress.

Engulfment. Close all valves in the raw material blow line. Secure each valve in its closed position using chain and lock. Attach a tag to the valve and chain warning that a permit entry confined space entry is in progress. The same procedure shall be used for securing the fat recycle valve.

Burns and heat stress. Close steam supply valves to jacket and secure with chains and tags. Insert solid blank at flange in cooker vent line to condenser manifold duct system. Vent cooker/dryer by opening access door at discharge end and top center door to allow natural ventilation throughout the entry. If faster cooling is needed, use an portable ventilation fan to increase ventilation. Cooling water may be circulated through the jacket to reduce both outer and inner surface temperatures of cooker/dryers faster. Check air and inner surface temperatures in cooker/dryer to assure they are within acceptable limits before entering, or use proper protective clothing.

Fire and fume hazards. Careful site preparation, such as cleaning the area within 4 inches (10.16 cm) of all welding or torch cutting operations, and proper ventilation are the preferred controls. All welding and cutting operations shall be done in accordance with the requirements of 29 CFR Part 1910, Subpart Q, OSHA's welding standard. Proper ventilation may be achieved by local exhaust ventilation, or the use of portable ventilation fans, or a combination of the two practices.

Electrical shock. Electrical equipment used in cooker/dryers shall be in serviceable condition.

Slips and falls. Remove residual grease before entering cooker/dryer.

Attendant. The supervisor shall be the attendant for employees entering cooker/dryers.

Permit. The permit shall specify how isolation shall be done and any other preparations needed before making entry. This is especially important in parallel arrangements of cooker/dryers so that the entire operation need not be shut down to allow safe entry into one unit.

Rescue. When necessary, the attendant shall call the fire department as previously arranged.

Example 3.

Workplace. Workplaces where tank cars, trucks, and trailers, dry bulk tanks and trailers, railroad tank cars, and similar portable tanks are fabricated or serviced.

A. *During fabrication.* These tanks and dry-bulk carriers are entered repeatedly throughout the fabrication process. These products are not configured identically, but the manufacturing processes by which they are made are very similar.

Sources of hazards. In addition to the mechanical hazards arising from the risks that an entrant would be injured due to contact with components of the tank or the tools being used, there is also the risk that a worker could be injured by breathing fumes from welding materials or mists or vapors from materials used to coat the tank interior. In addition, many of these vapors and mists are flammable, so the failure to properly ventilate a tank could lead to a fire or explosion.

Control of hazards.

Welding. Local exhaust ventilation shall be used to remove welding fumes once the tank or carrier is completed to the point that workers may enter and exit only through a manhole. (Follow the requirements of 29 CFR 1910, Subpart Q, OSHA's welding standard, at all times.) Welding gas tanks may never be brought into a tank or carrier that is a permit entry confined space.

Application of interior coatings/linings. Atmospheric hazards shall be controlled by forced air ventilation sufficient to keep the atmospheric concentration of flammable materials below 10% of the lower flammable limit (LFL) (or lower explosive limit (LEL), whichever term is used locally). The appropriate respirators are provided and shall be used in addition to providing forced ventilation if the forced ventilation does not maintain acceptable respiratory conditions.

Permits. Because of the repetitive nature of the entries in these operations, an "Area

Entry Permit" will be issued for a 1 month period to cover those production areas where tanks are fabricated to the point that entry and exit are made using manholes.

Authorization. Only the area supervisor may authorize an employee to enter a tank within the permit area. The area supervisor must determine that conditions in the tank trailer, dry bulk trailer or truck, etc. meet permit requirements before authorizing entry.

Attendant. The area supervisor shall designate an employee to maintain communication by employer specified means with employees working in tanks to ensure their safety. The attendant may not enter any permit entry confined space to rescue an entrant or for any other reason, unless authorized by the rescue procedure and, and even then, only after calling the rescue team and being relieved by as attendant by another worker.

Communications and observation. Communications between attendant and entrant(s) shall be maintained throughout entry. Methods of communication that may be specified by the permit include voice, voice powered radio, tapping or rapping codes on tank walls, signalling tugs on a rope, and the attendant's observation that work activities such as chipping, grinding, welding, spraying, etc., which require deliberate operator control continue normally. These activities often generate so much noise that the necessary hearing protection makes communication by voice difficult.

Rescue procedures. Acceptable rescue procedures include entry by a team of employee-rescuers, use of public emergency services, and procedures for breaching the tank. The area permit specifies which procedures are available, but the area supervisor makes the final decision based on circumstances. (Certain injuries may make it necessary to breach the tank to remove a person rather than risk additional injury by removal through an existing manhole. However, the supervisor must ensure that no breaching procedure used for rescue would violate terms of the entry permit. For instance, if the tank must be breached by cutting with a torch, the tank surfaces to be cut must be free of volatile or combustible coatings within 4 inches (10.16 cm) of the cutting line and the atmosphere within the tank must be below the LFL.

Retrieval line and harnesses. The retrieval lines and harnesses generally required under this standard are usually impractical for use in tanks because the internal configuration of the tanks and their interior baffles and other structures would prevent rescuers from hauling out injured entrants. However, unless the rescue procedure calls for breaching the tank for rescue, the rescue team shall be trained in the use of retrieval lines and harnesses for removing injured employees through manholes.

B. *Repair or service of "used" tanks and bulk trailers.*

Sources of hazards. In addition to facing the potential hazards encountered in fabrication or manufacturing, tanks or trailers which have been in service may contain residues of dangerous materials, whether left over from the transportation of hazardous cargoes or generated by chemical or bacterial action on residues of non-hazardous cargoes.

Control of atmospheric hazards. A "used" tank shall be brought into areas where tank entry is authorized only after the tank has been emptied, cleansed (without employee entry) of any residues, and purged of any potential atmospheric hazards.

Welding. In addition to tank cleaning for control of atmospheric hazards, coating and surface materials shall be removed 4 inches (10.16 cm) or more from any surface area where welding or other torch work will be done and care taken that the atmosphere within the tank remains well below the LFL. (Follow the requirements of 29 CFR 1910, Subpart Q, OSHA's welding standard, at all times.)

Permits. An entry permit valid for up to 1 year shall be issued prior to authorization of entry into used tank trailers, dry bulk trailers or trucks. In addition to the pre-entry cleaning requirement, this permit shall require the employee safeguards specified for new tank fabrication or construction permit areas.

Authorization. Only the area supervisor may authorize an employee to enter a tank trailer, dry bulk trailer or truck within the permit area. The area supervisor must determine that the entry permit requirements have been met before authorizing entry.

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Appendix D to §1910.146—Sample Permits

Appendix D - 1A Sewer Entry Permit

Confined Space Pre-Entry Check List

See Safety Procedure.
A confined space either is entered through an opening other than a door (such as manhole or side port) or requires the use of a ladder or rungs to reach the working level and test results are satisfactory. This check list must be filled out whenever the job site meets this criteria.

		Yes	No
1.	Did your survey of the surrounding area show it to be free of hazards such as drifting vapors from tanks, piping or sewers?	( )	( )
2.	Does your knowledge of industrial or other discharges indicate this area is likely to remain free of dangerous air contaminants while occupied?	( )	( )
3.	Are you certified in operation of the gas monitor to be used?	( )	( )
4.	Has a gas monitor functional test (Bump Test) been performed this shift on the gas monitor to be used?	( )	( )
5.	Did you test the atmosphere of the confined space prior to entry?	( )	( )
6.	Did the atmosphere check as acceptable (no alarms given)?	( )	( )
7.	Will the atmosphere be continuously monitored while the space is occupied?	( )	( )

Contact County Centrex for personnel rescue by local fire department in the event of an emergency. If on-site at the Regional Treatment Plant, contact the Plant Control Center (PCC).

Notice: If any of the above questions are answered "no" do not enter. Contact your immediate supervisor.

Job Location_____

LEAD MAN signature_____Date_____

Appendix D - 1B

Confined Space Entry Permit (Pre-Entry/Entry Check List)

Date and Time Issued:_____

Job site:_____

Equipment to be worked on:_____

Pre-Entry (See Safety Procedure)

1. Atmospheric Checks: Time _____
   Oxygen _____%
   Explosive _____% L.F.L.
   Toxic _____PPM

2. Source isolation (No Entry):	N/A	Yes	No
Pumps or lines blinded, disconnected, or blocked	( )	( )	( )
	( )	( )	( )

3. Ventilation Modification:	N/A	Yes	No
Mechanical	( )	( )	( )
Natural Ventilation only	( )	( )	( )

4. Atmospheric check after isolation and Ventilation:

Oxygen_____%	>	19.5	%
Explosive_____% L.F.L.	<	10	%
Toxic_____PPM	<	10	PPM H_2S

Time_____

If conditions are in compliance with the above requirements and there is no reason to believe conditions may change adversely, then proceed to the Permit Space Pre-Entry Check List. Complete and post with this permit. If conditions are not in compliance with the above requirements or there is reason to believe that conditions may change adversely, proceed to the Entry Check-List portion of this permit.

Date and Time Expires:_____

Job Supervisor_____

Work to be performed: _____

Entry (See Safety Procedure)

1. Entry, standby, and back up persons:	Yes	No
Successfully completed required training?		
Is it current?	( )	( )

2. Equipment:	N/A	Yes	No
Direct reading gas monitor - tested	( )	( )	( )
Safety harnesses and lifelines for entry and standby persons	( )	( )	( )
Hoisting equipment	( )	( )	( )
Powered communications	( )	( )	( )
SCBA's for entry and standby persons	( )	( )	( )
Protective Clothing	( )	( )	( )
All electric equipment listed Class I, Division I, Group D and Non-sparking tools	( )	( )	( )

3. Rescue Procedure:

_____

_____

_____

_____

_____

_____

We have reviewed the work authorized by this permit and the information contained here-in. Written instructions and safety procedures have been received and are understood. Entry cannot be approved if any squares are marked in the "No" column. This permit is not valid unless all appropriate items are completed.

Permit and Check List Prepared By: (Supervisor)_____

Approved By: (Unit Supervisor)_____

Reviewed By (Confined Space Operations Personnel):(printed name & signature)

_____ _____

This permit to be kept at job site. Return job site copy to Safety Office following job completion.

Copies: White Original (Safety Office) Yellow (Unit Supervisor) Hard(Job site)

Appendix D - 2

ENTRY PERMIT

_____CONFINED SPACE _____HAZARDOUS AREA

PERMIT VALID FOR 8 HOURS ONLY. ALL COPIES OF PERMIT WILL REMAIN AT JOB SITE UNTIL JOB IS COMPLETED

SITE LOCATION and DESCRIPTION _____

PURPOSE OF ENTRY _____

SUPERVISOR(S) in charge of crews Type of Crew Phone #

_____

_____

*** BOLD DENOTES MINIMUM REQUIREMENTS TO BE COMPLETED AND REVIEWED PRIOR TO ENTRY***

REQUIREMENTS COMPLETED	DATE	TIME	REQUIREMENTS COMPLETED	DATE	TIME
Lock Out/De-energize/Try-out	____	____	**Full Body Harness w/"D" ring**	____	____
Line(s) Broken-Capped-Blanked	____	____	**Emergency Escape Retrieval Equip**	____	____
Purge-Flush and Vent	____	____	**Lifelines**	____	____
Ventilation	____	____	Fire Extinguishers	____	____
Secure Area (Post and Flag)	____	____	Lighting (Explosive Proof)	____	____
Breathing Apparatus	____	____	Protective Clothing	____	____
Resuscitator - Inhalator	____	____	Respirator(s) (Air Purifying)	____	____
Standby Safety Personnel	____	____	Burning and Welding Permit	____	____

Note: Items that do not apply enter N/A in the blank.

** RECORD CONTINUOUS MONITORING RESULTS EVERY 2 HOURS

CONTINUOUS MONITORING** TEST(S) TO BE TAKEN	Permissible Entry Level	_____
PERCENT OF OXYGEN	**19.5% to 23.5%**	____ ____ ____ ____ ____ ____ ____ ____
LOWER FLAMMABLE LIMIT	**Under 10%**	____ ____ ____ ____ ____ ____ ____ ____
CARBON MONOXIDE	**+35 PPM**	____ ____ ____ ____ ____ ____ ____ ____
Aromatic Hydrocarbon	+ 1 PPM * 5PPM	____ ____ ____ ____ ____ ____ ____ ____
Hydrogen Cyanide	(Skin) * 4PPM	____ ____ ____ ____ ____ ____ ____ ____
Hydrogen Sulfide	+10 PPM *15PPM	____ ____ ____ ____ ____ ____ ____ ____
Sulfur Dioxide	+ 2 PPM * 5PPM	____ ____ ____ ____ ____ ____ ____ ____
Ammonia	*35PPM	____ ____ ____ ____ ____ ____ ____ ____

* Short-term exposure limit:Employee can work in the area up to 15 minutes.

+ 8 hr. Time Weighted Avg.:Employee can work in area 8 hrs (longer with appropriate respiratory protection).

REMARKS:_____

GAS TESTER NAME & CHECK # INSTRUMENT(S) USED MODEL &/OR TYPE SERIAL &/OR UNIT #

_____ _____ _____ _____

_____ _____ _____ _____

SAFETY STANDBY PERSON IS REQUIRED FOR ALL CONFINED SPACE WORK

SAFETY STANDBY PERSON(S)	CHECK #	NAME OF SAFETY STANDBY PERSON(S)	CHECK #
_____	_____	_____	_____
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SUPERVISOR AUTHORIZING ENTRY

ALL ABOVE CONDITIONS SATISFIED_____

DEPARTMENT_____Phone_____

AMBULANCE 2800 FIRE 2900

Safety 4901 Gas Coordinator 4529/5387

Original to Department Pink Copy to Safety

Appendix E to §1910.146—Sewer System Entry

Sewer entry differs in three vital respects from other permit entries; first, there rarely exists any way to completely isolate the space (a section of a continuous system) to be entered; second, because isolation is not complete, the atmosphere may suddenly and unpredictably become lethally hazardous (toxic, flammable or explosive) from causes beyond the control of the entrant or employer, and third, experienced sewer workers are especially knowledgeable in entry and work in their permit spaces because of their frequent entries. Unlike other employments where permit space entry is a rare and exceptional event, sewer workers' usual work environment is a permit space.

(1) *Adherence to procedure.* The employer should designate as entrants only employees who are thoroughly trained in the employer's sewer entry procedures and who demonstrate that they follow these entry procedures exactly as prescribed when performing sewer entries.

(2) *Atmospheric monitoring.* Entrants should be trained in the use of, and be equipped with, atmospheric monitoring equipment which sounds an audible alarm, in addition to its visual readout, whenever one of the following conditions is encountered: oxygen concentration less than 19.5 percent; flammable gas or vapor at 10 percent or more of the lower flammable limit (LFL); or hydrogen sulfide or carbon monoxide at or above their PEL (10 ppm or 50 ppm, respectively); or, if a broad range sensor device is used, at 100 ppm as characterized by its response to toluene. Normally, the oxygen sensor/broad range sensor instrument is best suited for sewer entry. However, substance specific devices should be used whenever actual contaminants have been identified. The instrument should be carried and used by the entrant in sewer line work to monitor the atmosphere in the entrant's environment, and in advance of the entrants' direction of movement, to warn the entrant of any deterioration in atmospheric conditions. Where several entrants are working together in the same immediate location, one instrument, used by the lead entrant, is acceptable.

(3) *Surge flow and flooding.* Sewer crews should develop and maintain liaison, to the extent possible, with the local weather bureau and fire and emergency services in their area so that sewer work may be delayed or interrupted and entrants withdrawn whenever sewer lines might be suddenly flooded by rain or fire suppression activities, or whenever flammable or other hazardous materials are released into sewers during emergencies by industrial or transportation accidents.

(4) *Special Equipment.* Entry into large bore sewers may require the use of special equipment. Such equipment might include such items as atmosphere monitoring devices with automatic audible alarms, escape self-contained breathing apparatus (ESCBA) with at least 10 minute air supply (or other NIOSH approved self-rescuer), and waterproof flashlights, and may also include boats and rafts, radios and rope stand-offs for pulling around bends and corners as needed.

[FR Doc. 93–538 Filed 1–13–1993; 8:45 am]

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January 14, 1993

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Part 29

Airworthiness Standards; Turboshaft Engine Rotor Burst Protection; Proposed Rule

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 29

[Docket No. 26037; Notice No. 89-29A]

RIN 2120-AB91

Airworthiness Standards; Turboshaft Engine Rotor Burst Protection

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: This notice reopens the comment period for Notice of Proposed Rulemaking (NPRM) No. 89-29A. In that notice, the FAA proposed to require that manufacturers consider the safety implications of a failure of an engine rotor disc and to implement practical design precautions to minimize this hazard to rotorcraft. This reopening is needed because, after the original comment period closed, representatives of the Aerospace Industries Association (AIA) and the FAA met to review the AIA's comments originally made during the public comment period concerning the issues of engine rotor containment and the use of advanced composite material. This reopening of the comment period is to afford all interested persons the same opportunity as was afforded the AIA to comment on these issues. Comments are invited only on these issues.

DATES: Comments on the issues of engine rotor containment and the use of advanced composite materials must be received on or before March 15, 1993.

ADDRESSES: Comments on the issues of engine rotor containment and the use of advanced composites material should be mailed in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-10), Docket No. 26037, 800 Independence Avenue, SW., Washington, DC 20591, or delivered in triplicate to: room 915G, 800 Independence Avenue, SW., Washington, DC 20591. Comments must be marked Docket No. 26037.

Comments may be inspected in room 915G between the hours of 8:30 a.m. and 5 p.m. weekdays, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Mathias, FAA, Regulations Group (ASW-111), Rotorcraft Directorate, Aircraft Certification Service, Fort Worth, Texas 76193-0111, telephone number (817) 624-5123.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Comments relating to the environmental, energy, federalism, or economic impact that might result from adopting the proposals in this notice are also invited. Substantive comments should be accompanied by cost estimates. Commenters should identify the regulatory docket or notice number and submit comments in triplicate to the Rules Docket address specified above. All comments received on or before the closing date for comments will be considered by the FAA before taking action on the proposed rulemaking. The proposals contained in this notice may be changed in light of the comments received.

All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Commenters wishing to have the FAA acknowledge receipt of their comments submitted in response to this notice must include a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 26037." The postcard will be date/time stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of Public Affairs, Attention: Public Inquiry Center, APA-430, 800 Independence Ave., SW., Washington, DC 20591, or by calling (202) 267-3484. Communications must identify NPRM 89-29.

Persons interested in being placed on the mailing list for future NPRM's should request a copy of Advisory Circular (AC) No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

On October 10, 1989, the FAA issued Notice No. 89-29 (54 FR 42716, October 17, 1989), which proposed that design precautions be taken to minimize the hazards to rotorcraft in the event of an engine rotor failure.

To increase the safety margin when there is an engine rotor failure, changes are proposed to §§ 29.901 and 29.903. These changes would require that design precautions be taken to minimize the hazards to transport category rotocraft in the event of an engine rotor failure. The intended design precautions may include items such as separation or duplication of critical components, care in designing engine alignment, or benign component locations. Containment provisions for one or more stages of the engine are not specifically required by this proposal. Any one or more of the previously mentioned design precautions would be effective in improving the level of safety of the rotorcraft. When evaluating an applicant's proposed method of compliance, the FAA would consider the available technology and the costs required to minimize the hazards from an engine rotor failure. The guidance contained in Advisory Circular 20-128 is intended to apply to § 29.903 in the same way that it currently applies to §§ 23.903 and 25.903 for airplanes.

The FAA recognizes that a rotorcraft design may differ significantly from that of an airplane, particularly regarding an engine location and its proximity to other engines, systems, and components. Engine rotor containment features have not been found to be necessary in airplane programs. Likewise, the FAA does not believe that containment features would be required in rotorcraft in order to "minimize the hazards * * *" in the event of a rotor failure.

Section 29.901 Proposal

The FAA is proposing to change the current FAR to require that manufacturers consider the safety implications of a failure of engine rotor discs and practical design precautions to minimize this hazard to the rotorcraft. Since this proposed regulatory wording would be inconsistent with current paragraph (c)(2) which states, "The failure of engine rotor discs need not be considered," paragraph (c)(2) would be removed.

The revision to paragraph (c), which was proposed by Notice No. 89-29, is repeated here for reference purposes.

(c) For each powerplant and auxiliary power unit installation, it must be established that no single failure or malfunction or probable combination of failures will jeopardize the safe operation of the rotorcraft except that the failure of structural elements need not be considered if the probability of any such failure is extremely remote.

Section 29.903 Proposal

For turbine engine installations, the FAA is proposing to revise paragraph (f) to state explicitly that design

precautions must be taken to minimize the hazard to the rotorcraft in the event of an engine rotor failure.

The revision to paragraph (f) which was proposed by Notice No. 89–29 is repeated here for reference purposes.

(f) *Turbine engine installation.* For turbine engine installations—

(1) Design precautions must be taken to minimize the hazards to the rotorcraft in the event of an engine rotor failure; and

(2) The powerplant systems associated with engine control devices, systems, and instrumentation must be designed to give reasonable assurance that those engine operating limitations that adversely affect engine rotor structural integrity will not be exceeded in service.

Benefits-Cost Evaluation Update

The economic impact evaluation for Notice No. 89–29 compares the benefits and costs of the proposed regulation on a per-rotorcraft basis with the rotorcraft varying in size from 8 to 20 seats. Therefore, the evaluation reduces dependence on forecasts of the size and the number of new transport rotorcraft produced.

For purposes of this evaluation, it is assumed that a Category A or B transport rotorcraft with two engines will be certificated under this proposed rule. Even though some rotorcraft will minimize the hazards from engine rotor failures by design precautions that may add little additional weight, this analysis assumes the addition of design features such as the redundancy of critical component and/or duplication of cables or tubing.

Cost of Compliance

The proposed requirement could be satisfied by minimizing the hazards from an engine rotor failure by design features that add little weight, such as relocation of critical components. These types of design features assume a weight increase of 6 pounds per engine. The one-time development cost to a manufacturer of transport rotorcraft for necessary design features is estimated to be $330 per rotorcraft produced, and the estimated manufacturing cost is $480. The increase in cost of manufacturing twin-engine rotorcraft certificated under these proposed requirements would be $480 for each engine plus $330 or $1,290.

Rotorcraft operators would also experience an increase in the operating cost of transport rotorcraft as a result of the additional weight. The estimated annual cost per pound of additional weight is $37.13. Therefore, the 12-pound weight of these design features is estimated to increase the operating cost for a twin-engine transport rotorcraft by $445.56 annually. The present value of the increase in the total cost of purchasing and operating twin-engine transport rotorcraft certificated under this proposed rule, over 15 years, would be $4,254. For a more detailed explanation of the estimation of these costs, see the regulatory evaluation included in the docket.

Comments and Meetings

Several comments have been received for Notice No. 89–29. Three commenters fully supported the entire proposal; and three commenters requested that the notice be withdrawn, in large part, because of the impracticability of containing rotor failures for one or more stages of a complete engine through extensive use of advanced composites or rotorcraft airframe mounted containment rings.

The commenters were critical of the proposed change for a number of reasons. The AIA stated, "Notice 89–29 implies very strongly that 'minimize' means to eliminate the hazard through the use of rotor containment devices, integral with, or separate from the engine." The European Joint Aviation Authorities commented that FAR parts 23 and 25 require that the hazards be minimized only for airplanes and do not refer to "engine rotor burst protection." Pratt & Whitney Canada, Inc., commented that research has never produced a composite disc containment device at an acceptable size and cost which can tolerate turbine zone temperatures even external to the engine.

The comment period for Notice No. 89–29 originally closed April 16, 1990, and was extended to October 16, 1990. In February 1991, the AIA requested and was subsequently granted a meeting to discuss its comments on the implication of Notice No. 89–29 relative to engine rotor containment and the use of advanced composite materials. Representatives of the FAA met with representatives of AIA on February 20, 1991; March 1, 1991; and June 20, 1991. During these meetings, AIA representatives opposed certain requirements that they inferred from reading the preamble to the notice. A record summary of these meetings has been placed in Docket 26037 and is available for interested parties to review. It is apparent that AIA members have concluded that mandatory engine rotor containment with the use of advanced composite materials is being proposed.

It was not the intent of the proposal to require containment or the use of advanced composite materials. Since this apparently was unclear to the AIA and many other commenters, the FAA is reopening the comment period with further explanation of the proposed amendments.

Clarification

It is not correct to assume, as some commenters have, either that engine or airframe containment of rotor burst fragments or the use of advanced composites is needed to satisfy the proposed requirement. Rather, the use of airframe design features that minimize this hazard is all that would be required. These features could include separation and duplication of critical components, special engine alignment or placement, or benign location of critical components.

Reopening of Comment Period

Department of Transportation (DOT) policy encourages full public participation in the development of rules and provides all members of the public an equal opportunity to present their views. DOT policy also provides that the general public should be afforded adequate knowledge of contacts made with individual members of the public, especially after the close of a comment period. Since the AIA was afforded the opportunity to restate its previous formal comments to representatives of the FAA after the close of the public comment period, the FAA has determined that it is appropriate to reopen the comment period for Notice 89–29. This will afford all interested persons an equal opportunity to comment on the interpretation of "design precautions to minimize the hazards to the rotorcraft in the event of an engine rotor failure" as it relates to rotor containment and the use of advanced composite materials. Accordingly, the comment period for Notice 89–29 is reopened for 60 days and will close March 15, 1993.

Conclusion

This document reopens the comment period on a notice of proposed rulemaking. Therefore, the FAA has determined that this document, like Notice 89–29, is not major under Executive Order 12291 and is considered nonsignificant under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). In addition, it is certified that reopening the docket for Notice 89–29 will not have a significant economic impact, positive or negative, on a substantial number of small entities. An initial regulatory evaluation of the proposal, including a Regulatory Flexibility Determination and Trade Impact Analysis, has been placed in the docket. A copy may be obtained by contacting

the person identified under FOR FURTHER INFORMATION CONTACT.

List of Subjects in 14 CFR Part 29

Aircraft, Air transportation, Aviation safety, Rotorcraft, Safety.

Issued in Washington, DC, on January 8, 1993.

Henry A. Armstrong,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 93-884 Filed 1-13-93; 8:45 am]

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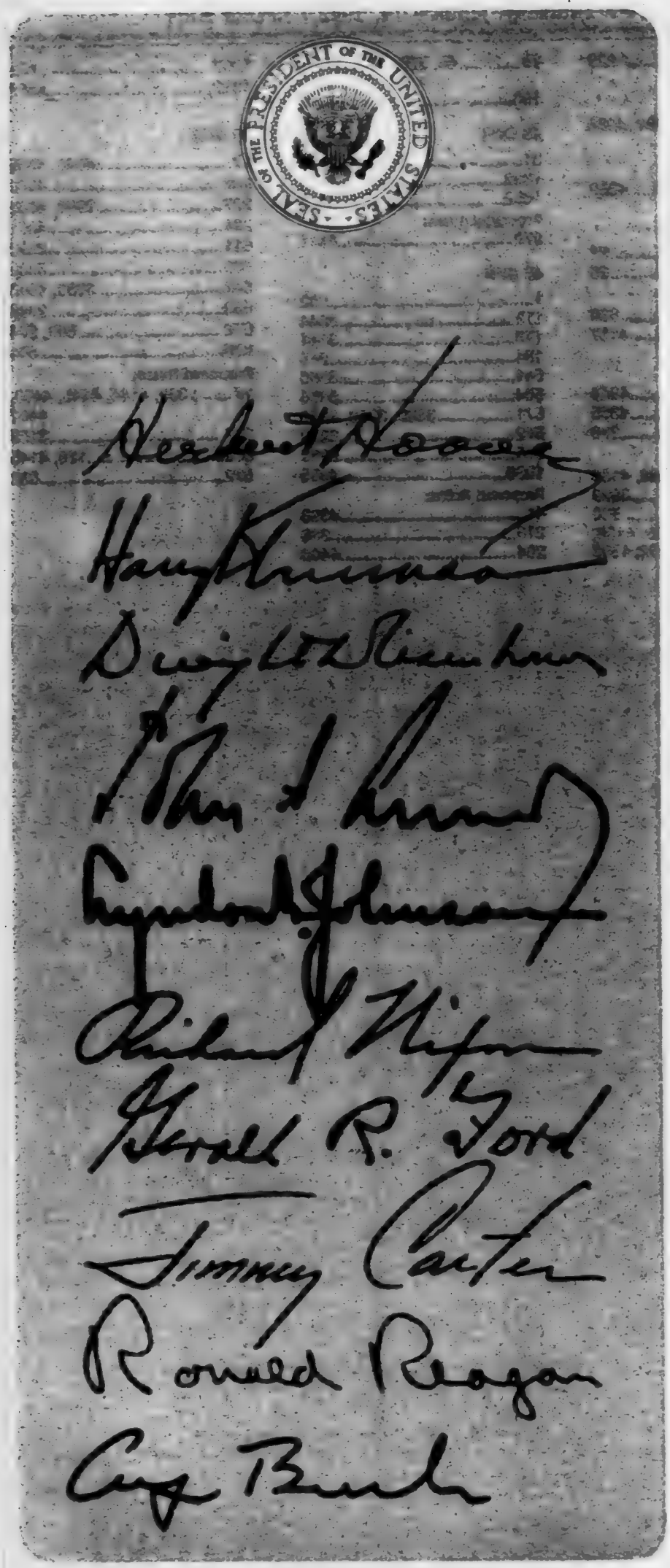

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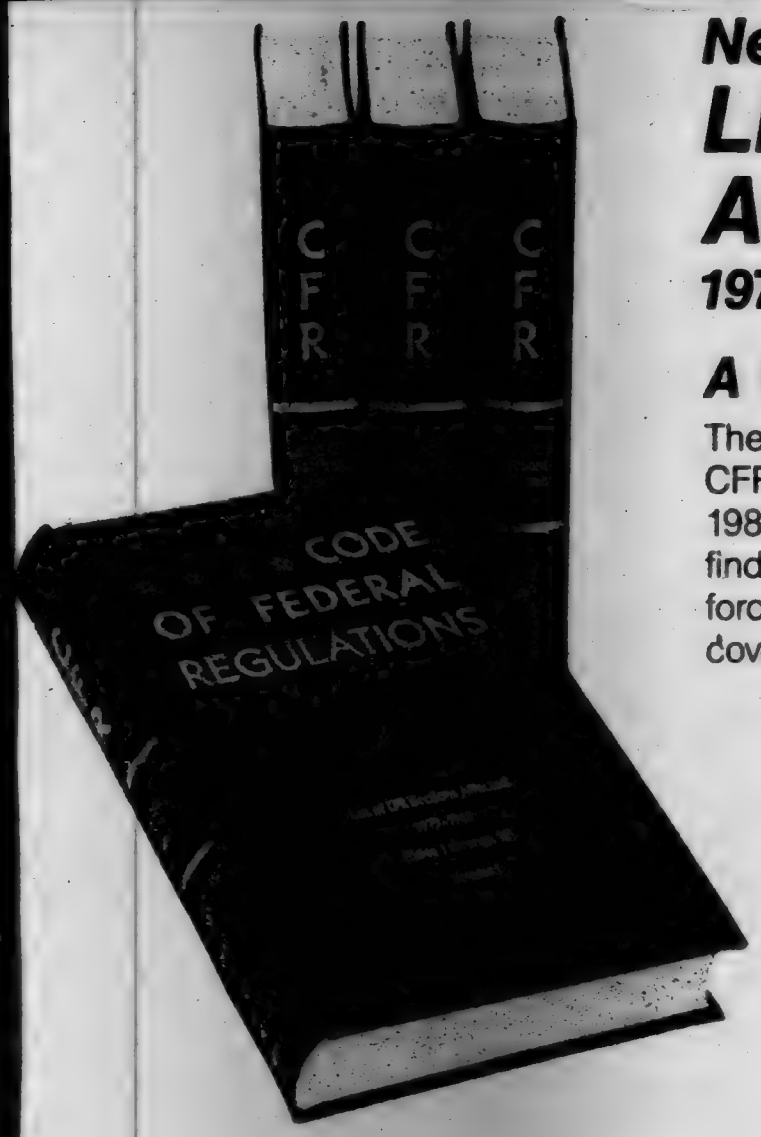

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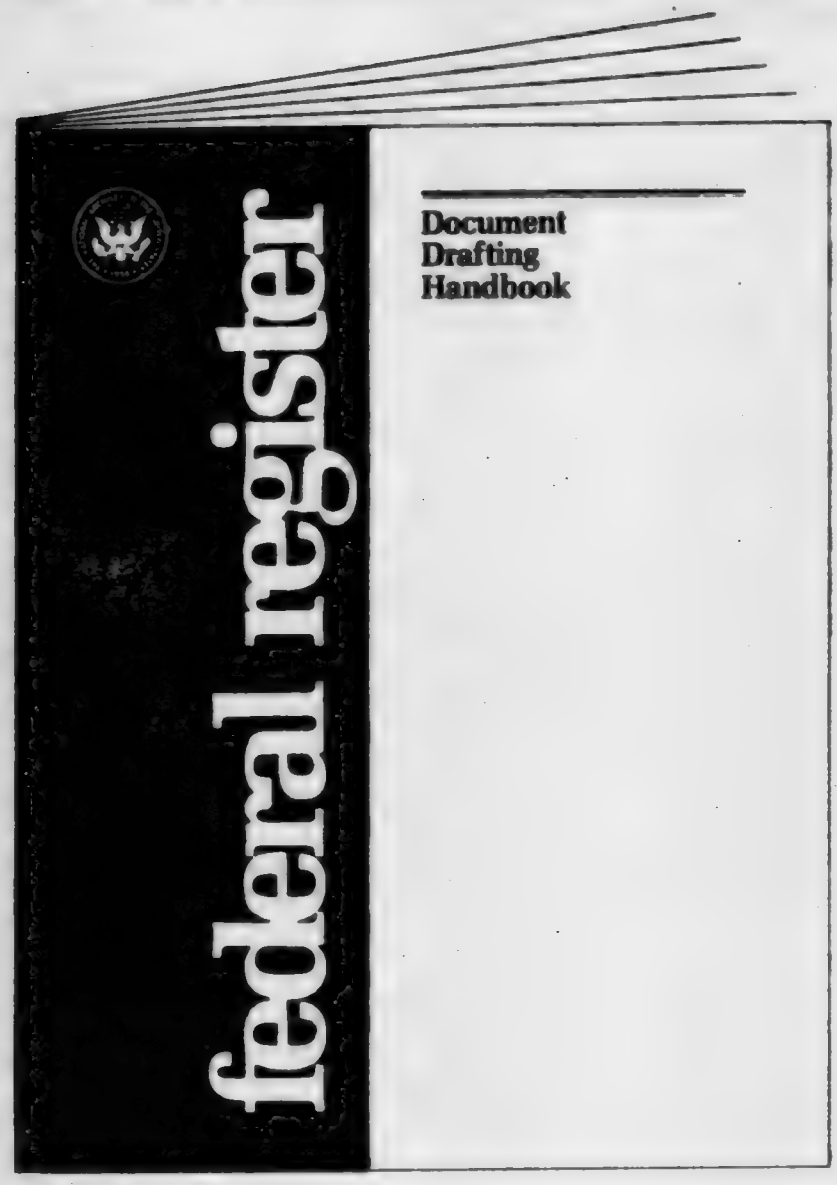

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OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 890

RIN 3206–AE90

Federal Employees Health Benefits Program: Limitation on Inpatient Hospital Charges and FEHB Program Payments

AGENCY: Office of Personnel Management.

ACTION: Interim rule; extension of comment period.

SUMMARY: The Office of Personnel Management (OPM) issued an interim regulation implementing section 7002(f) of the Omnibus Budget Reconciliation Act of 1990 (5 U.S.C. 8904(b)) in **Federal Register** Vol. 57, No. 60, on Friday, March 27, 1992. After the prior comment period closed, OPM met informally with various interested parties and discussed some aspects of the interim regulation. Included in the discussion was the option of requiring carriers to always pay the diagnostic related group (DRG) amount. The DRG amount is the amount paid by Medicare for inpatient hospital services under its prospective payment system (PPS). OPM, therefore, finds it appropriate to open the comment period to provide the opportunity for additional comments.

DATES: This interim regulation was effective January 1, 1992. Comments must be received on or before February 1, 1993.

ADDRESSES: Written comments may be sent to Andrea S. Minnicar, Assistant Director for Retirement and Insurance Policy, Retirement and Insurance Group, Office of Personnel Management, P.O. Box 57, Washington, DC 20044, or delivered to OPM, room 4351, 1900 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Abby L. Block, (202) 606–0191.

U.S. Office of Personnel Management.
Douglas A. Brook,
Acting Director.
[FR Doc. 93–857 Filed 1–14–93; 8:45 am]
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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 2

Delegations of Authority by the Secretary of Agriculture and General Officers of the Department

AGENCY: Office of the Secretary, USDA.

ACTION: Final rule.

SUMMARY: This document amends the delegations of authority from the Secretary of Agriculture to the Assistant Secretary for Economics and to the Administrations of the Economic Research Service and the National Agricultural Statistics Service to allow them to enter into cooperative arrangements with Departments of Ministries of Agriculture in other nations to conduct research, extension, and education activities, and to enter into agreements with land-grant colleges and universities and other organizations with comparable goals.

EFFECTIVE DATE: January 15, 1993.

FOR FURTHER INFORMATION CONTACT: Keith W. Anderson, Chief, Management Analysis Branch, Administrative Services Division, Economics Management Staff, United States Department of Agriculture (USDA), 14th and Independence Avenue, SW., Washington, DC 20250–3500; telephone 720–7590.

SUPPLEMENTARY INFORMATION: Section 1613 of the Food, Agriculture, Conservation, and Trade Act of 1990 amends 7 U.S.C. 3291 by expanding the authority of the Secretary of Agriculture (subject to such coordination with other Federal officials, Departments, and agencies as the President may direct) to expand the operational coordination of the Department of Agriculture with institutions and persons throughout the world that perform agricultural and related research and extension activities.

The Secretary's authorities set forth in 7 U.S.C. 3291 (a)(1) and (a)(6) are delegated to the Assistant Secretary for Economics which, in turn, are delegated to the Administrators of the Economic Research Service and the National Agricultural Statistics Service.

The delegations to the Assistant Secretary for Economics and the Adminstrators of the Economic Research Service and the National Agricultural Statistics Service have been amended to allow them to enter into cooperative arrangements with Departments of Ministries of Agriculture in other nations to conduct research, extension, and education activities and to enter into agreements with land-grant colleges and universities and other organizations with comparable goals.

This rule relates to internal agency management. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. Further, since this rule relates to internal agency management, it is exempt from the provisions of Executive Order 12291. Finally, this action is not a rule as defined by the Regulatory Flexibility Act, Public Law 96–354, and, thus, is exempt from the provisions of that Act.

List of Subjects in 7 CFR Part 2

Authority delegations (Government agencies).

Accordingly, part 2, title 7, Code of Federal Regulations, is amended as follows:

PART 2—DELEGATIONS OF AUTHORITY BY THE SECRETARY OF AGRICULTURE AND GENERAL OFFICERS OF THE DEPARTMENT

1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 301 and Reorganization Plan No. 2 of 1953.

Subpart C—Delegations of Authority to the Deputy Secretary, the Under Secretary for International Affairs and Commodity Programs, the Under Secretary for Small Community and Rural Development, and Assistant Secretaries

2. Section 2.27(a)(11) is revised to read as follows:

§ 2.27 Delegations of authority to the Assistant Secretary for Economics.

(a) *Related to economic research and statistical reporting.* * * *

* * * * *

(11) Cooperate and work with national and international institutions and other persons throughout the world in the performance of agricultural research and extension activities to promote and support the development of a viable and sustainable global and agricultural system. Such work may be carried out by:

(i) Exchanging research materials and results with the institutions or persons;

(ii) Engaging in joint or coordinated research;

(iii) Entering into cooperative arrangements with Departments and Ministries of Agriculture in other nations to conduct research, extension; and education activities (limited to arrangements either involving no exchange of funds or involving disbursements by the agency to the institutions of other nations), and then reporting these arrangements to the Secretary of Agriculture;

(iv) Stationing representatives at such institutions or organizations in foreign countries; or

(v) Entering into agreements with land-grant colleges and universities, other organizations, institutions, or individuals with comparable goals, and with the concurrence of the Office of International Cooperation and Development, USDA, international organizations (limited to agreements either involving no exchange of funds or involving disbursements by the agency to the cooperator), and then reporting these agreement to the Secretary of Agriculture (7 U.S.C. 3291(a)).

* * * * *

Subpart K—Delegations of Authority by the Assistant Secretary for Economics

3. Section 2.84(a)(6) is revised to read as follows:

§ 2.84 Administrator, Economic Research Service.

(a) *Delegations.* * * *

* * * * *

(6) Cooperate and work with national and international institutions and other persons throughout the world in the performance of agricultural research and extension activities to promote and support the development of a viable and sustainable global agricultural system. Such work may be carried out by:

(i) Exchanging research materials and results with the institutions or persons;

(ii) Engaging in joint or coordinated research;

(iii) Entering into cooperative arrangements with Departments and Ministries of Agriculture in other nations to conduct research, extension; and education activities (limited to arrangements either involving no exchange of funds or involving disbursements by the agency to the institutions of other nations), and then reporting these arrangements to the Secretary for Economics;

(iv) Stationing representatives at such institutions or organizations in foreign countries; or

(v) Entering into agreements with land-grant colleges and universities, other organizations, institutions, or individuals with comparable goals, and with the concurrence of the Office of International Cooperation and Development, USDA, international organizations (limited to agreements either involving no exchange of funds or involving disbursements by the agency to the cooperator), and then reporting these agreements to the Assistant Secretary for Economics (7 U.S.C. 3291(a)).

* * * * *

4. Section 2.85(a)(7) is revised to read as follows:

§ 2.85 Administrator, National Agriculture Statistics Service.

(a) *Delegations.* * * *

* * * * *

(7) Cooperate and work with national and international institutions and other persons throughout the world in the performance of agricultural research and extension activities to promote and support the development of a viable and sustainable global agricultural system. Such work may be carried out by:

(i) Exchanging research materials and results with the institutions or persons;

(ii) Engaging in joint or coordinated research;

(iii) Entering into cooperative arrangements with Departments and Ministries of Agriculture in other nations to conduct research, extension; and education activities (limited to arrangements either involving no exchange of funds or involving disbursements by the agency to the institutions of other nations), and then reporting these arrangements to the Secretary for Economics;

(iv) Stationing representatives at such institutions or organizations in foreign countries; or

(v) entering into agreements with land-grant colleges and universities, other organizations, institutions, or individuals with comparable goals, and, with the concurrence of the Office of International Cooperation and Development, USDA, international organizations (limited to agreements either involving no exchange of funds or involving disbursements by the agency to the cooperator), and then reporting these agreements to the Assistant Secretary for Economics (7 U.S.C. 3291(a)).

* * * * *

For Subpart C:

Dated: January 8, 1993.

Edward R. Madigan,

Secretary of Agriculture.

For Subpart K:

Dated: January 8, 1993.

Daniel A. Sumner,

Assistant Secretary for Economics.

[FR Doc. 93-1006 Filed 1-14-93; 4:17 pm]

BILLING CODE 3410-96-M

Agricultural Marketing Service

7 CFR Parts 966, 984, and 989

[Docket No. FV92-966-2FIR]

Expenses and Assessment Rates for Specified Marketing Orders

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Department is adopting as a final rule the provisions of three interim final rules (without change) authorizing expenditures and establishing assessment rates under Marketing Orders 966, 984, and 989 for the 1992–93 fiscal period. Authorization of these budgets enables the Florida Tomato Committee, the Walnut Marketing Board, and the Raisin Administrative Committee (Committees and Board) to incur expenses that are reasonable and necessary to administer the programs. Funds to administer these programs are derived from assessments on handlers.

DATES: August 1, 1992, through July 31, 1993.

FOR FURTHER INFORMATION CONTACT: John R. Toth (M.O. 966), Southeast Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, P.O. Box 2276, Winter Haven, FL 33883–2276, 813–299–4770; Richard P. Van Diest (M.O.'s 984 and 989), California Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, suite 102B, 2202 Monterey Street, Fresno, CA 93721, telephone 209–487–5901; or Martha Sue Clark, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456, telephone 202–720–9918.

SUPPLEMENTARY INFORMATION: This rule is effective under Marketing Agreement No. 125 and Order No. 966 (7 CFR part 966), both as amended, regulating the handling of tomatoes grown in Florida; Marketing Agreement and Order No. 984 (7 CFR part 984), both as amended, regulating the handling of walnuts grown in California; and Marketing Agreement and Order No. 989 (7 CFR part 989), both as amended, regulating the handling of raisins produced from grapes grown in California. The marketing agreements and orders are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

This rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the marketing order provisions now in effect, handlers of Florida tomatoes, California walnuts, and California raisins are subject to assessments. It is intended that the assessment rates as issued herein will be applicable to all assessable Florida tomatoes, California walnuts, and California raisins handled during the 1992–93 fiscal period which began August 1, 1992, through July 31, 1993. This final rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 250 producers of Florida tomatoes under Marketing Order No. 966, and approximately 50 handlers. There are approximately 5,000 producers of California walnuts under Marketing Order No. 984, and approximately 65 handlers. Also, there are approximately 5,000 producers of California raisins under Marketing Order No. 989, and approximately 25 handlers. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of the producers and handlers may be classified as small entities.

The budgets of expenses for the 1992–93 fiscal period were prepared by the Florida Tomato Committee, the Walnut Marketing Board, and the Raisin Administrative Committee, the agencies responsible for local administration of the orders, and submitted to the Department for approval. The members of these Committees and Board are producers of Florida tomatoes, and producers and handlers of California walnuts and California raisins. They are familiar with the Committees' and Board's needs and with the costs for goods and services in their local areas and are thus in a position to formulate appropriate budgets. The budgets were formulated and discussed in public meetings. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rates recommended by the Committees and Board were derived by dividing anticipated expenses by expected shipments of Florida tomatoes, expected merchantable certifications of California walnuts, and expected acquisitions of California raisins. Because these rates will be applied to actual shipments, they must be established at rates that will provide sufficient income to pay the Committees' and Board's expenses.

The Florida Tomato Committee met September 10, 1992, and unanimously recommended a 1992–93 budget of $2,686,000, which is $391,000 more than the previous year. Increases include: $5,700 for office salaries, $8,000 for employees' health insurance, $13,750 for employees' retirement program, $367,000 for education and promotion expense, and the addition of a $1,000 equipment maintenance category. These increases will be partially offset by a $4,000 decrease in research expenses.

The Committee also unanimously recommended an assessment rate of $0.04 per 25-pound container, the same as last year. This rate, when applied to anticipated shipments of 55,000,000 25-pound containers, will yield $2,200,000 in assessment income. This, along with $40,000 in interest and other income and $446,000 from the Committee's authorized reserve, will be adequate to cover budgeted expenses. Funds in the Committee's authorized reserve at the beginning of the 1992–93 fiscal period, $1,497,754, were within the maximum permitted by the order of one fiscal period's expenses.

The Walnut Marketing Board met September 11, 1992, and unanimously recommended a 1992–93 budget of $1,872,096, which is $67,980 more than the previous year. Increases include: $7,256 for administrative salaries, $807 for general insurance, $850 for audit, $3,130 for group life, retirement, and medical plan, $2,500 for office supplies, $3,000 for equipment maintenance and warranty-leases, $32,000 for domestic market research and development, $44,829 for production research, and $5,196 for production research director. These increases will be partially offset by decreases of $557 for social security taxes, $4,800 for office salaries, $14,231 for office rent, $7,000 for furniture and fixture purchases, and $5,000 for export market research and development.

The Board also unanimously recommended an assessment rate of $0.01 per kernelweight pound, $0.0015 more than the previous year. This rate, when applied to anticipated shipments of 187,209,600 kernelweight pounds of merchantable walnuts, will yield $1,872,096 in assessment income, which will be adequate to cover budgeted expenses. Unexpended funds may be used temporarily during the first five months of the subsequent marketing year, but must be made available to the handlers from whom collected within that period.

The Raisin Administrative Committee met September 25, 1992, and unanimously recommended a 1992–93 budget of $591,000, which is $3,700 less

than the previous year. Increases include: $8,800 for executive salaries, $1,500 for compliance examiners salaries, $1,000 for health insurance, $25,000 for Committee travel, $1,000 for payroll taxes, and $700 for grape survey expense. These increases will be offset by decreases of $5,000 for office supplies, $2,000 for miscellaneous expenses, $31,915 in reserve for contingencies, and an increase of $4,275 in the amount of income paid to the Committee by the California Raisin Advisory Board (Board). The Board is the administrative agency for the State marketing order under which the California raisin industry conducts its marketing promotion and paid advertising. Some of the Committee's employees also perform services for the Board. Pursuant to an agreement between the Committee and Board, the Board reimburses the Committee for the services Committee employees perform for the Board.

The Committee also unanimously recommended an assessment rate of $2.00 per ton, which is $0.10 more than last year. This rate, when applied to anticipated acquisitions of 295,500 tons, will yield $591,000 in assessment income, which will be adequate to cover budgeted expenses. Any unexpended funds from the crop year shall be credited or refunded to the handler from whom collected.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs will be offset by the benefits derived from the operation of the marketing orders. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

Interim final rules were published in the **Federal Register** on October 26, 1992, for 7 CFR part 966 (57 FR 48441), 7 CFR part 984 (57 FR 48443), and 7 CFR part 989 (57 FR 48448). Those interim final rules added § 966.230, § 984.343, and § 989.343, authorized expenses, and established assessment rates for the Committees and Board. Those rules provided that interested persons could file comments through November 25, 1992. No comments were received.

It is found that the specified expenses for the marketing orders covered in this rulemaking are reasonable and likely to be incurred and that such expenses and the specified assessment rates to cover such expenses will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because the Committees and Board need to have sufficient funds to pay their expenses which are incurred on a continuous basis. The 1992–93 fiscal periods for the programs began on August 1, 1992, and the marketing orders require that the rates of assessment for the fiscal periods apply to all assessable tomatoes, walnuts, and raisins handled during the fiscal periods. In addition, handlers are aware of these actions which were recommended by the Committees and Board at public meetings and published in the **Federal Register** as interim final rules. No comments were received concerning the three interim final rules that are adopted in this action as a final rule without change.

List of Subjects

7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

7 CFR Part 984

Marketing agreements, Nuts, Reporting and recordkeeping requirements, Walnuts.

7 CFR Part 989

Grapes, Marketing agreements, Raisins, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR parts 966, 984, and 989 are hereby amended as follows:

1. The authority citation for 7 CFR parts 966, 984, and 989 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

PART 966—TOMATOES GROWN IN FLORIDA

Note: This section will not appear in the Code of Federal Regulations.

For the reasons set forth in the preamble, the interim final rule adding § 966.230 which was published at 57 FR 48441 on October 26, 1992, is adopted as a final rule without change.

PART 984—WALNUTS GROWN IN CALIFORNIA

Note: This section will not appear in the Code of Federal Regulations.

For the reasons set forth in the preamble, the interim final rule adding § 984.343 which was published at 57 FR 48443 on October 26, 1992, is adopted as a final rule without change.

PART 989—RAISINS PRODUCED FROM GRAPES GROWN IN CALIFORNIA

Note: This section will not appear in the Code of Federal Regulations.

For the reasons set forth in the preamble, the interim final rule adding § 989.343 which was published at 57 FR 48448 on October 26, 1992, is adopted as a final rule without change.

Dated: January 11, 1993.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 93–1009 Filed 1–14–93; 8:45 am]

BILLING CODE 3410-02-M

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7 CFR Part 979

[Docket No. FV92–979–1IFR]

South Texas Melons; Increased Expenses and Establishment of Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Amended interim final rule with request for comments.

SUMMARY: This interim final rule amends a previous interim final rule which authorized administrative expenses for the South Texas Melon Committee (Committee) under M.O. No. 979. This interim final rule increases the level of authorized expenses and establishes an assessment rate to generate funds to pay those expenses. Authorization of this increased budget enables the Committee to incur expenses that are reasonable and necessary to administer the program. Funds to administer this program are derived from assessments on handlers.

DATES: Effective October 1, 1992, through September 30, 1993. Comments received by February 16, 1993 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this action. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456. Comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Belinda G. Garza, McAllen Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, 1313 East Hackberry, McAllen, TX 78501,

telephone 512–682–2833, or Martha Sue Clark, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523–S, Washington, DC 20090–6456, telephone 202–720–9918.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 156 and Order No. 979 (7 CFR part 979), regulating the handling of melons grown in South Texas. The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

The Department of Agriculture is committed to carrying out its statutory and regulatory mandates in a manner that best serves the public interest. Therefore, where legal discretion permits, the Department actively seeks to promulgate regulations that promote economic growth, create jobs, are minimally burdensome, and are easy for the public to understand, use, or comply with. In short, the Department is committed to issuing regulations that maximize net benefits to society and minimize costs imposed by those regulations. This principle is articulated in President Bush's January 28, 1992, memorandum to agency heads, and in Executive Orders 12291 and 12498. The Department applies this principle to the fullest extent possible, consistent with law.

The Department has developed and reviewed this regulatory action in accordance with these principles. Nonetheless, the Department believes that public input from all interested persons can be invaluable in ensuring that the final regulatory product is minimally burdensome and maximally efficient. Therefore, the Department specifically seeks comments and suggestions from the public regarding any less burdensome or more efficient alternative that would accomplish the purposes described in this action. Comments suggesting less burdensome or more efficient alternatives should be addressed to the agency as provided in this rule.

This rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This interim final rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the marketing order provisions now in effect, handlers of South Texas melons are subject to assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable melons handled during the 1992–93 fiscal period, which covers the period October 1, 1992, through September 30, 1993. This interim final rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing the Secretary would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 26 producers of South Texas melons under this marketing order, and approximately 30 handlers. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of South Texas melon producers and handlers may be classified as small entities.

The budget of expenses for the 1992–93 fiscal period was prepared by the South Texas Melon Committee, the agency responsible for local administration of the marketing order, and submitted to the Department of Agriculture for approval. The members of the Committee are producers and handlers of South Texas melons. They are familiar with the Committee's needs and with the costs of goods and services in their local area and are thus in a position to formulate an appropriate budget. The budget was formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of South Texas melons. Because that rate will be applied to actual shipments, it must be established at a rate that will provide sufficient income to pay the Committee's expenses.

Committee administrative expenses of $100,000 for personnel, office, and travel expenses were recommended in a mail vote completed September 10, 1992. The assessment rate and funding for the research and promotion projects were to be recommended at a later Committee meeting. The Committee administrative expenses of $100,000 were published in the **Federal Register** as an interim final rule October 26, 1992 (57 FR 48442). That interim final rule added § 979.215, authorizing expenses for the Committee, and provided that interested persons could file comments through November 25, 1992. No comments were filed.

The Committee subsequently met on November 9, 1992, and unanimously recommended slight changes in some of the administrative expense categories and recommended funding for several research and promotion projects for a total 1992–93 budget of $274,543.42. The new budget is $10,766.09 less than the budget for the previous year. Increases include: $2,000 for a new computer and computer program and $16,649.00 for production systems research. These budget increases will be offset by decreases of $1,000 for furniture and fixtures, $1,500 for contingencies, $19,387.09 in the market development program, and the elimination of variety evaluation for which $8,028 was budgeted last season.

The Committee also unanimously recommended an assessment rate of $0.05 per carton of melons, the same as last season. This rate, when applied to anticipated shipments of approximately 5,765,132 cartons, will yield $288,256.60 in assessment income, which will be adequate to cover budgeted expenses. Funds in the reserve as of October 31, 1992, $304,566, were within the maximum permitted by the order of two fiscal periods' expenses.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs will be offset by the benefits derived from the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matter presented, including the information and recommendations submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this action until 30 days after publication in the Federal Register because:

(1) The Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis;

(2) The fiscal period began on October 1, 1992, and the marketing order requires that the rate of assessment for the fiscal period apply to all assessable melons handled during the fiscal period;

(3) Handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to that taken for the 1991–92 fiscal period; and

(4) This interim final rule provides a 30-day comment period, and all comments timely received will be considered prior to finalization of this action.

List of Subjects in 7 CFR Part 979

Marketing agreements, Melons, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 979 is amended as follows:

PART 979—MELONS GROWN IN SOUTH TEXAS

1. The authority citation for 7 CFR part 979 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Section 979.215 is revised to read as follows:

Note: This section will not appear in the Code of Federal Regulations.

§ 979.215 Expenses and assessment rate.

Expenses of $274,543.42 by the South Texas Melon Committee are authorized and an assessment rate of $0.05 per carton is established for the fiscal period ending September 30, 1993. Unexpended funds may be carried over as a reserve.

Dated: January 11, 1993.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 93–1014 Filed 1–14–93; 8:45 am]

BILLING CODE 3410-02-M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2610 and 2622

Late Premium Payments and Employer Liability Underpayments and Overpayments; Interest Rate for Determining Variable Rate Premium; Amendments to Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This document notifies the public of the interest rate applicable to late premium payments and employer liability underpayments and overpayments for the calendar quarter beginning January 1, 1993. This interest rate is established quarterly by the Internal Revenue Service. This document also sets forth the interest rates for valuing unfunded vested benefits for premium purposes for plan years beginning in November 1992 through January 1993. These interest rates are established pursuant to section 4006 of the Employee Retirement Income Security Act of 1974, as amended. The effect of these amendments is to advise plan sponsors and pension practitioners of these new interest rates.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Code 22500, Pension Benefit Guaranty Corporation, 2020 K Street NW., Washington, DC 20006; telephone (202) 778–8850 ((202) 778–8859 for TTY and TTD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: As part of title IV of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), the Pension Benefit Guaranty Corporation ("PBGC") collects premiums from ongoing plans to support the single-employer and multiemployer insurance programs. Under the single-employer program, the PBGC also collects employer liability from those persons described in ERISA section 4062(a). Under ERISA section 4007 and 29 CFR 2610.7, the interest rate to be charged on unpaid premiums is the rate established under section 6601 of the Internal Revenue Code ("Code"). Similarly, under 29 CFR 2622.7, the interest rate to be credited or charged with respect to overpayments or underpayments of employer liability is the section 6601 rate. These interest rates are published by the PBGC in appendix A to the premium regulation and appendix A to the employer liability regulation.

The Internal Revenue Service has announced that for the quarter beginning January 1, 1993, the interest charged on the underpayment of taxes will be at a rate of 7 percent. Accordingly, the PBGC is amending appendix A to 29 CFR part 2610 and appendix A to 29 CFR part 2622 to set forth this rate for the January 1, 1993, through March 31, 1993, quarter.

Under ERISA section 4006(a)(3)(E)(iii)(II), in determining a single-employer plan's unfunded vested benefits for premium computation purposes, plans must use an interest rate equal to 80% of the annual yield on 30-year Treasury securities for the month preceding the beginning of the plan year for which premiums are being paid. Under § 2610.23(b)(1) of the premium regulation, this value is determined by reference to 30-year Treasury constant maturities as reported in Federal Reserve Statistical Releases G.13 and H.15. The PBGC publishes these rates in appendix B to the regulation.

The PBGC publishes these monthly interest rates in appendix B on a quarterly basis to coincide with the publication of the late payment interest rate set forth in appendix A. (The PBGC publishes the appendix A rates every quarter, regardless of whether the rate has changed.) Unlike the appendix A rate, which is determined prospectively, the appendix B rate is not known until a short time after the first of the month for which it applies. Accordingly, the PBGC is hereby amending appendix B to part 2610 to add the vested benefits valuation rates for plan years beginning in November of 1992 through January of 1993.

The appendices to 29 CFR parts 2610 and 2622 do not prescribe the interest rates under these regulations. Under both regulations, the appendix A rates are the rates determined under section 6601(a) of the Code. The interest rates in appendix B to part 2610 are

prescribed by ERISA section 4006(a)(3)(E)(iii)(II) and § 2610.23(b)(1) of the regulation. These appendices merely collect and republish the interest rates in a convenient place. Thus, the interest rates in the appendices are informational only. Accordingly, the PBGC finds that notice of and public comment on these amendments would be unnecessary and contrary to the public interest. For the above reasons, the PBGC also believes that good cause exists for making these amendments effective immediately.

The PBGC has determined that none of these amendments is a "major rule" within the meaning of Executive Order 12291, because they will not have an annual effect on the economy of $100 million or more; nor create a major increase in costs or prices for consumers, individual industries, or geographic regions, nor have significant adverse effects on competition, employment, investment, innovation or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Because no general notice of proposed rulemaking is required for these amendments, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 2610

Employee benefit plans, Penalties, Pension insurance, Pensions, and Reporting and recordkeeping requirements.

29 CFR Part 2622

Business and industry, Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements, and Small businesses.

In consideration of the foregoing, appendix A and appendix B to part 2610 and appendix A to part 2622 of chapter XXVI of title 29, Code of Federal Regulations, are hereby amended as follows:

PART 2610—PAYMENT OF PREMIUMS

1. The authority citation for part 2610 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1306, 1307 (1988 & Supp. I 1989), as amended by sec. 12021, Pub. L. 101–508, 104 Stat. 1388, 1388–573.

2. Appendix A to part 2610 is amended by adding a new entry for the quarter beginning January 1, 1993, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix A to Part 2610—Late Payment Interest Rates

The following table lists the late payment interest rates under § 2610.7(a) for the specified time periods:

From	Through	Interest rate (percent)
•	•	•
January 1, 1993	March 31, 1993	7

3. Appendix B to part 2610 is amended by adding to the table of interest rates therein new entries for premium payment years beginning in November of 1992 through January of 1993, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix B to Part 2610—Interest Rates for Valuing Vested Benefits

The following table lists the required interest rates to be used in valuing a plan's vested benefits under § 2610.23(b) and in calculating a plan's adjusted vested benefits under § 2610.23(c)(1):

For premium payment years beginning in—	Required interest rate[1]
•	•
November 1992	6.02
December 1992	6.09
January 1993	5.95

[1] The required interest rate listed above is equal to 80% of the annual yield for 30-year Treasury constant maturities, as reported in Federal Reserve Statistical Release G.13 and H.15 for the calendar month preceding the calendar month in which the premium payment year begins.

PART 2622—EMPLOYER LIABILITY FOR WITHDRAWALS FROM AND TERMINATIONS OF SINGLE-EMPLOYER PLANS

4. The authority citation for part 2622 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1362–1364, 1367–68, as amended by secs. 9312, 9313, Pub. L. 100–203, 101 Stat. 1330.

5. Appendix A to part 2622 is amended by adding a new entry for the quarter beginning January 1, 1993, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix A to Part 2622—Late Payment and Overpayment Interest Rates

The following table lists the late payment and overpayment interest rates under § 2622.7 for the specified time periods:

From	Through	Interest rate (percent)
•	•	•
January 1, 1993	March 31, 1993	7

Issued in Washington, DC, this 12th day of January 1993.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 93–1033 Filed 1–14–93; 8:45 am]

BILLING CODE 7708–01–M

29 CFR Part 2619

Valuation of Plan Benefits in Single-Employer Plans; Amendment Adopting Additional PBGC Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This amendment to the regulation on Valuation of Plan Benefits in Single-Employer Plans contains the interest rates and factors for the period beginning February 1, 1993. The use of these interest rates and factors to value benefits is mandatory for some terminating single-employer pension plans and optional for others. The Pension Benefit Guaranty Corporation adjusts the interest rates and factors periodically to reflect changes in financial and annuity markets. This amendment adopts the rates and factors applicable to plans that terminate on or after February 1, 1993, which will remain in effect until the PBGC issues new interest rates and factors.

EFFECTIVE DATE: February 1, 1993.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Code 22500, Pension Benefit Guaranty Corporation, 2020 K Street NW., Washington, DC 20006, 202–778–8850 (202–778–8859 for TTY and TDD only). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation's ("PBGC's") regulation on Valuation of Plan Benefits in Single-Employer Plans (29 CFR part 2619) sets forth the methods for valuing plan benefits of terminating single-employer plans covered under title IV of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). Under ERISA section 4041(c), all plans wishing to terminate in a distress termination must value guaranteed benefits and "benefit liabilities", i.e., all benefits provided under the plan as of the plan termination date, using the formulas set forth in part 2619, subpart C. (Plans

terminating in a standard termination may, for purposes of the Standard Termination Notice filed with PBGC, use these formulas to value benefit liabilities, although this is not required.) In addition, when the PBGC terminates an underfunded plan involuntarily pursuant to ERISA section 4042(a), it uses the subpart C formulas to determine the amount of the plan's underfunding.

Appendix B in part 2619 sets forth the interest rates and factors that are to be used in the formulas contained in the regulation. Because these rates and factors are intended to reflect current conditions in the financial and annuity markets, it is necessary to update the rates and factors periodically.

The rates and factors currently in use have been in effect since January 1, 1993. This amendment adds to appendix B a new set of interest rates and factors for valuing benefits in plans that terminate on or after February 1, 1993, which set reflects a decrease of ¼ percent in the immediate interest rate from 5¾ percent to 5½ percent.

Generally, the interest rates and factors will be in effect for at least one month. However, any published rates and factors will remain in effect until such time as the PBGC publishes another amendment changing them. Any change in the rates normally will be published in the **Federal Register** by the 15th of the month preceding the effective date of the new rates or as close to that date as circumstances permit.

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest rates and factors promptly so that the rates can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation of benefits in plans that will terminate on or after February 1, 1993, and because no adjustment by ongoing plans is required by this amendment, the PBGC finds that good cause exists for making the rates set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this is not a "major rule" under the criteria set forth in Executive Order 12291, because it will not result in an annual effect on the economy of $100 million or more, a major increase in costs for consumers or individual industries, or significant adverse effects on competition, employment, investment, productivity, or innovation.

List of Subjects in 29 CFR Part 2619

Employee benefit plans, Pension insurance, and Pensions.

In consideration of the foregoing, part 2619 of chapter XXVI, title 29, Code of Federal Regulations, is hereby amended as follows:

1. The authority citation for part 2619 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, and 1362 (1988).

2. Rate Set 102 of appendix B is revised and Rate Set 103 of appendix B is added to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix B—Interest Rates and Quantities Used to Value Immediate and Deferred Annuities

In the table that follows, the immediate annuity rate is used to value immediate annuities, to compute the quantity "Gy" for deferred annuities and to value both portions of a refund annuity. An interest rate of 5% shall be used to value death benefits other than the decreasing term insurance portion of a refund annuity. For deferred annuities, k_1, k_2, k_3, n_1, and n_2 are defined in § 2619.45.

Rate set	For plans with a valuation date		Immediate annuity rate percent	% Deferred annuities				
	On or after	Before		k_1	k_2	k_3	n_1	k_2
•	•	•	•	•	•	•	•	•
102	1–1–93	2–1–93	5.75	1.0600	1.0400	1.0400	7	8
103	2–1–93	.....	5.50	1.0475	1.0400	1.0400	7	8

Issued in Washington, DC, on this 12th day of January, 1993.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 93–1030 Filed 1–14–93; 8:45 am]

BILLING CODE 7708–01–M

29 CFR Part 2676

Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal—Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is an amendment to the Pension Benefit Guaranty Corporation's regulation on Valuation of Plan Benefits and Plan Assets Following Mass Withdrawal (29 CFR part 2676). The regulation prescribes rules for valuing benefits and certain assets of multiemployer plans under sections 4219(c)(1)(D) and 4281(b) of the Employee Retirement Income Security Act of 1974. Section 2676.15(c) of the regulation contains a table setting forth, for each calendar month, a series of interest rates to be used in any valuation performed as of a valuation date within that calendar month. On or about the fifteenth of each month, the PBGC publishes a new entry in the table for the following month, whether or not the rates are changing. This amendment adds to the table the rate series for the month of February 1993.

EFFECTIVE DATE: February 1, 1993.

FOR FURTHER INFORMATION CONTACT: Deborah C. Murphy, Attorney, Office of the General Counsel (22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; 202–778–8820 (202–778–1958 for TTY and TDD). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: The PBGC finds that notice of and public comment on this amendment would be impracticable and contrary to the public interest, and that there is good cause for making this amendment effective immediately. These findings are based on the need to have the interest rates in this amendment reflect market conditions that are as nearly current as possible and the need to issue the interest rates promptly so that they are available to the public before the beginning of the period to which they apply. (See 5 U.S.C. 553 (b) and (d)). Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply (5 U.S.C. 601(2)).

The PBGC has also determined that this amendment is not a "major rule" within the meaning of Executive Order 12291 because it will not have an annual effect on the economy of $100

million or more; or create a major increase in costs or prices for consumers, individual industries, or geographic regions; or have significant adverse effects on competition, employment, investment, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 29 CFR Part 2676

Employee benefit plans and pensions.

In consideration of the foregoing, part 2676 of subchapter H of chapter XXVI of title 29, Code of Federal Regulations, is amended as follows:

PART 2676—VALUATION OF PLAN BENEFITS AND PLAN ASSETS FOLLOWING MASS WITHDRAWAL

1. The authority citation for part 2676 continues to read as follows:

Authority: 29 U.S.C. §§ 1302(b)(3), 1399(c)(1)(D), and 1441(b)(1).

2. In § 2676.15, paragraph (c) is amended by adding to the end of the table of interest rates the new entries to read as follows:

§ 2676.15 Interest.

* * * * *

(c) *Interest Rates.*

For valuation dates occurring in the month:	The values for i_t are:															
	i_1	i_2	i_3	i_4	i_5	i_6	i_7	i_8	i_9	i_{10}	i_{11}	i_{12}	i_{13}	i_{14}	i_{15}	i_n
•	•		•		•		•		•			•				
February 1993	.0625	.06125	.06	.05875	.0575	.05625	.05625	.05625	.05625	.05625	.055	.055	.055	.055	.055	.05

Issued at Washington, DC, on this 12th day of January 1993.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 93–1031 Filed 1–14–93; 8:45 am]

BILLING CODE 7708–01–M

PENSION BENEFIT GUARANTY CORPORATION

29 CFR PART 2644

Notice and Collection of Withdrawal Liability; Adoption of New Interest Rate

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This is an amendment to the Pension Benefit Guaranty Corporation's regulation on Notice and Collection of Withdrawal Liability. That regulation incorporates certain interest rates published by another Federal agency. The effect of this amendment is to add to the appendix of that regulation a new interest rate to be effective from January 1, 1993, to March 31, 1993.

EFFECTIVE DATE: January 1, 1993.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel (22500), Pension Benefit Guaranty Corporation, 2020 K Street, NW., Washington, DC 20006; telephone 202–778–8850 (202–778–8859 or TTY and TDD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: Under section 4219(c) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"), the Pension Benefit Guaranty Corporation ("the PBGC") promulgated a final regulation on Notice and Collection of Withdrawal Liability. That regulation, codified at 29 CFR part 2644, deals with the rate of interest to be charged by multiemployer pension plans on withdrawal liability payments that are overdue or in default, or to be credited by plans on overpayments of withdrawal liability. The regulation allows plans to set rates, subject to certain restrictions. Where a plan does not set the interest rate, § 2644.3(b) of the regulation provides that the rate to be charged or credited for any calendar quarter is the average quoted prime rate on short-term commercial loans for the fifteenth day (or the next business day if the fifteenth day is not a business day) of the month preceding the beginning of the quarter, as reported by the Board of Governors of the Federal Reserve System in Statistical Release H. 15 ("Selected Interest Rates").

Because the regulation incorporates interest rates published in Statistical Release H.15, that release is the authoritative source for the rates that are to be applied under the regulation. As a convenience to persons using the regulation, however, the PGBC collects the applicable rates and republishes them in an appendix to part 2644. This amendment adds to this appendix the interest rate of 6 percent, which will be effective from January 1, 1993 through March 31, 1993. This rate represents no change from the rate in effect for the fourth quarter of 1992. This rate is based on the prime rate in effect on December 15, 1992.

The appendix to 29 CFR part 2644 does not prescribe interest rates under the regulation; the rates prescribed in the regulation are those published in Statistical Release H.15. The appendix merely collects and republishes the rates in a convenient place. Thus, the interest rates in the appendix are informational only. Accordingly, the PBGC finds that notice of and public comment on this amendment would be unnecessary and contrary to the public interest. For the above reasons the PBGC also believes that good cause exists for making this amendment effective immediately.

The PBGC has determined that this amendment is not a "major rule" within the meaning of Executive Order 12291, because it will not have an annual effect on the economy of $100 million or more; nor create a major increase in costs or prices for consumers, individual industries, or geographic regions, nor have significant adverse effects on competition, employment, investment, innovation or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 2644

Employee benefit plans, Pensions.

In consideration of the foregoing, part 2644 of subchapter F of chapter XXVI of title 29, Code of Federal Regulations, is amended as follows:

PART 2644—NOTICE AND COLLECTION OF WITHDRAWAL LIABILITY

1. The authority citation for part 2644 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3) and 1399(c)(6).

2. Appendix A to part 2644 is amended by adding to the end of the table therein a new entry as follows:

Appendix A to Part 2644—Table of Interest Rates

* * * * *

From	To	Date of quotation	Rate (percent)
* * * * *	*	*	
1/01/93	3/31/93	12/15/92	6

Issued in Washington, DC, on this 12th day of January 1993.

James B. Lockhart III,

Executive Director, Pension Benefit Guaranty Corporation.

[FR Doc. 93–1032 Filed 1–14–93; 8:45 am]

BILLING CODE 7708–01–M

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Part 250

RIN—AA29

Payment of Account of Awards of the Foreign Claims Settlement Commission of the United States

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Final rule, nomenclature changes.

SUMMARY: Treasury is revising its regulation to update the mailing address for the forwarding of forms used in connection with the payment on awards certified to the Secretary of the Treasury by the Foreign Claims Settlement Commission.

EFFECTIVE DATE: January 15, 1993.

FOR FURTHER INFORMATION CONTACT: Mia Abeya on (202) 874–8740.

SUPPLEMENTARY INFORMATION: This rule is not a major rule for the purpose of Executive Order 12291 of February 17, 1981, and a regulatory impact analysis is not required. As explained above, this revision is merely a correction of the mailing address for the forwarding of Foreign Claims forms to the Financial Management Service. As required by the Regulatory Flexibility Act, it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required.

List of Subjects in 31 CFR Part 250

Foreign claims.

Accordingly, 31 CFR part 250 is amended as follows:

1. The authority citation for part 250 continues to read as follows:

Authority: Sec. 7, 64 Stat. 16, Sec. 310, 69 Stat. 573, Sec. 413, 72 Stat. 530, Sec. 213, 76 Stat. 1111; 22 U.S.C. 1626, 1641; 16421, 50 U.S.C. App. 20171.

2. Sections 250.2, 250.3(a)(1), 250.4(f) and 250.6 are amended by removing the words "Washington, DC 20226" and inserting in their place the words "Hyattsville, MD 20782".

3. Sections 250.3(b) and 250.4(b)(1) are amended by removing the words "Investments Branch" and inserting in their place the words "Credit Accounting Branch".

Russell D. Morris,

Commissioner.

[FR Doc. 93–1043 Filed 1–14–93; 8:45 am]

BILLING CODE 4810–35–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[WA2–2–5568; FRL–4546–4]

Approval and Promulgation of State Implementation Plans: Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: By this action, EPA is approving in part, disapproving in part, and taking no action in part, on numerous revisions to the State of Washington Implementation Plan which were submitted by the Washington Department of Ecology (WDOE) on January 23, 1989 and May 14, 1991. These revisions are essentially administrative in nature and were made to improve the clarity, effectiveness, and enforceability of the state's regulations. The revisions were submitted in accordance with the requirements of section 110 of the Clean Air Act (hereinafter the Act). EPA is also taking no action on a number of provisions which are unrelated to the purposes of the implementation plan.

EFFECTIVE DATE: January 15, 1993.

ADDRESSES: Copies of the materials submitted to EPA may be examined during normal business hours at:

Air & Radiation Branch, Docket #WA2–2–5568, Environmental Protection Agency, 1200 Sixth Avenue, AT–082, Seattle, Washington 98101.

State of Washington, Department of Ecology, 4550 Third Ave. SE., Lacey, Washington 98504.

Public Information Reference Unit, Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: David C. Bray, Environmental Protection Agency, 1200 Sixth Avenue, AT–082, Seattle, Washington 98101, Telephone: (206) 553–4253.

SUPPLEMENTARY INFORMATION:

I. Background

In response to EPA's promulgation of revised ambient air quality standards for particulate matter (PM–10) on July 1, 1987, the State of Washington Department of Ecology (WDOE) amended many of its regulations. On January 23, 1989 WDOE submitted new regulations for Solid Fuel Burning Device Standards (WAC 173–433), Solid Waste Incinerator Facilities (WAC 173–434) and Ambient Air Quality Standards for Particulate Matter (WAC 173–470), as well as amendments to existing regulations for General Regulations for Air Pollution Sources (WAC 173–400), Implementation of Regulations for Air Contaminant Sources (WAC 173–403), Kraft Pulping Mills (WAC 173–405), Sulfite Pulping Mills (WAC 173–410), Primary Aluminum Plants (WAC 173–415), Open Burning (WAC 173–425), and Emergency Episode Plan (WAC 173–435).

In the spring of 1989, WDOE undertook a project to improve the overall quality, consistency, and enforceability of its regulations. On May 14, 1991 WDOE submitted amended regulations for General Regulations for Air Pollution Sources (WAC 173–400),

Kraft Pulping Mills (WAC 173–405), Sulfite Pulping Mills (WAC 173–410), Primary Aluminum Plants (WAC 173–415), Open Burning (WAC 173–425), Burning of Field and Forage and Turf Grasses Grown for Seed (WAC 173–430), Solid Fuel Burning Device Standards (WAC 173–433), Solid Waste Incinerator Facilities (WAC 173–434), Sensitive Areas (WAC 173–440), Emission Standards and Controls for Sources Emitting Volatile Compounds (WAC 173–490) and Weather Modification (WAC 173–495). In addition, the regulation for Implementation of Regulations for Air Contaminant Sources (WAC 173–403) was repealed. Many of the regulations and amendments in the January 23, 1989 submittal were superseded by the updated regulations in the May 14, 1991 submittal.

On September. 28, 1992 (57 FR 44530), EPA proposed to approve in part, disapprove in part, and take no action in part, on 12 of the 14 amended regulations submitted on January 23, 1989 and May 14, 1991. Action on the amended Emission Standards and Controls for Sources Emitting Volatile Compounds (WAC 173–490) is being proposed under separate rulemaking. The regulation for Weather Modification (WAC 173–495) is not related to the purposes of the Act and, therefore, EPA is taking no action on the submittal of this regulation. See the September 28, 1992 Notice of Proposed Rulemaking for a discussion of the amendments to each of the 12 regulations and EPA's proposed actions thereon.

II. Response to Comment

EPA received no comments on its September 28, 1992 (57 FR 44530) proposal to approve in part, disapprove in part, and take no action in part, 12 of the 14 amended regulations as revisions to Washington state implementation plan.

III. Summary of Action

EPA today is approving in part, disapproving in part, and taking no action in part, on numerous revisions to the State of Washington Implementation Plan. Specifically, EPA is approving the following as revisions to the Washington SIP:

(1) WAC 173–400 (except for –040(1)(c) and (d); –040(2); –040(4); the second paragraph of –040(6); the exception provision in –050(3); –070(7); –075; –115; –120; –131; –136; –141; and –180), as in effect on March 22, 1991.

(2) WAC 173–405 (except for –033; –035; –040(1)(b), (1)(c), (3)(b), (3)(c), and (4); –040(7), (8), and (9); and –072(2)), as in effect on March 22, 1991.

(3) WAC 173–410 (except for –035; the exception provision in –040(3); and –040(5)), as in effect on March 22, 1991.

(4) WAC 173–415 (except for –020(1) and (2); –030(1); –030(3)(b); –040; and –060(1)(a), (b), and (d)), as in effect on March 22, 1991.

(5) WAC 173–425, as in effect on October 18, 1990.

(6) WAC 173–430, as in effect on October 18, 1990.

(7) WAC 173–433, as in effect on October 18, 1990.

(8) WAC 173–434 (except for –110, –120, and –130(2)), as in effect on October 18, 1990.

(9) WAC 173–435 (except for –070(1)), as in effect on January 3, 1989.

(10) WAC 173–440, as in effect on October 18, 1990.

(11) WAC 173–470 (except for –110 and –150), as in effect on January 3, 1989. EPA is approving the repeal of WAC 173–403.

EPA is disapproving the following:

(1) WAC 173–400–040(1)(c) and (d), the second paragraph of –040(6), the exception provision in –050(3), –120, –131, –136, –141, and –180.

(2) WAC 173–405–040(7), (8), and (9).

(3) the exception provision in WAC 173–410–040(3).

(4) WAC 173–415–030(3)(b).

(5) WAC 173–435–070(1).

(6) WAC 173–470–150.

EPA is taking no action on the following:

(1) WAC 173–400–040(2), –040(4), –070(7), –075, and –115.

(2) WAC 173–405–033; –035, –040(1)(b), (1)(c), (3)(b), (3)(c), and (4); and –072(2).

(3) WAC 173–410–035 and –040(5).

(4) WAC 173–415–020(1) and (2); –030(1); –040; and –060(1)(a), (b), and (d).

(5) WAC 173–434–110, –120, and –130(2).

(6) WAC 173–470–110.

(7) WAC 173–495.

IV. Administrative Review

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 *et. seq.*, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under sections 110 and 301, and subchapter I, Part D of the CAA do not create any new requirements but simply approve requirements that the state is already imposing. Therefore, because the federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co. v. U.S.E.P.A.*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2).

EPA's disapproval of the state request under section 110 and subchapter I, Part D of the CAA does not affect any existing requirements applicable to small entities. Any pre-existing federal requirements remain in place after this disapproval. Federal disapproval of the state submittal does not affect its state-enforceability. Moreover, EPA's disapproval of the submittal does not impose any new federal requirements. Therefore, EPA certifies that this disapproval action does not have a significant impact on a substantial number of small entities because it does not remove existing requirements nor does it impose any new federal requirements.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic and environmental factors and in relation to relevant statutory and regulatory requirements.

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from date of publication). Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)) (See 42 U.S.C. 7607 (b)(2))

List of Subjects in 40 CFR Part 52

Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Note: Incorporation by reference of the Implementation Plan for the State of Washington was approved by the Director of the Office of Federal Register on July 1, 1982.

Dated: December 1, 1992.

Charles Findley,

Acting Regional Administrator.

Title 40, chapter I of part 52 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: Sections 42 U.S.C. 7401–7642.

Subpart WW—Washington

2. Section 52.2470 is amended by adding paragraph (c)(38) to read as follows:

§ 52.2470 Identification of plan.

* * * * *

(c) * * *

(38) On January 23, 1989 and May 14, 1991 the Director of the Department of Ecology submitted amended regulations as revisions to the Washington state implementation plan. EPA has approved the following as revisions to the implementation plan: WAC 173–400 (except for –040(1) (c) and (d); –040(2); –040(4); the second paragraph of –040(6); the exception provision in –050(3); –070(7); –075; –115; –120; –131; –136; –141; and –180) as in effect on March 22, 1991; the repeal of WAC 173–403 as in effect on March 22, 1991; WAC 173–405 (except for –033; –035; –040(1)(b); –040(1)(c); –040(3)(b); –040(3)(c); –040(4); –040(7); –040(8); –040(9); and –072(2)) as in effect on March 22, 1991; WAC 173–410 (except for –035; the exception provision in –040(3); and –040(5)) as in effect on March 22, 1991; WAC 173–415 (except for –020(1); –020(2); –030(1); –030(3)(b); –040; and –060(1) (a), (b), and (d)) as in effect on March 22, 1991; WAC 173–425 as in effect on October 18, 1990; WAC 173–430 as in effect on October 18, 1990; WAC 173–433 as in effect on October 18, 1990; WAC 173–434 (except for –110, –120, and –130(2)) as in effect on October 18, 1990; WAC 173–435 (except for –070(1)); as in effect on January 3, 1989; WAC 173–440 as in effect on October 18, 1990; WAC 173–470 (except for –110 and –150) as in effect on January 3, 1989.

(i) Incorporation by reference.

(A) January 23, 1989 letter from the Director of the Department of Ecology to EPA Region 10 submitting amendments to the Washington state implementation plan.

(B) May 14, 1991 letter from the Director of the Department of Ecology to EPA Region 10 submitting amendments to the Washington state implementation plan.

(C) Washington Administrative Code, Chapter 173–400 (General Regulations for Air Pollution Sources) (except for –040(1) (c) and (d), –040(2), –040(4), the second paragraph of –040(6), the exception provision in –050(3), –070(7), –075, –115, –120, –131, –136, –141, and –180) as in effect 3/22/91; Washington Administrative Code, Chapter 173–405 (Kraft Pulp Mills) (except for –033; –035; –040(1)(b), (1)(c), (3)(b), (3)(c), and (4); –040 (7), (8), and (9); and –072(2)) as in effect 3/22/91; Washington Administrative Code Chapter 173–410 (Sulfite Pulping Mills) (except for 035; the exception provision in –040(3); and –040(5)) as in effect 3/22/91; Washington Administrative Code Chapter 173–415 (Primary Aluminum Plants) (except for –020 (1) and (2); –030(1); –030(3)(b); –040; and –060(1) (a), (b), and (d)) as in effect 3/22/91; Washington Administrative Code Chapter 173–425 (Open Burning) as in effect 10/18/90; Washington Administrative Code Chapter 173–430 (Burning of Field and Forage and Turf Grasses Grown for Seed) as in effect 10/18/90; Washington Administrative Code Chapter 173–433 (Solid Fuel Burning Device Standards) as in effect 10/18/90; Washington Administrative Code Chapter 173–434 (except for –110, –120, and –130(2)) as in effect 10/18/90; Washington Administrative Code Chapter 173–435 (Emergency Episode Plan) (except for–070(1)) as in effect 1/3/89; Washington Administrative Code Chapter 173–440 (Sensitive Areas) as in effect 10/18/90; and Washington Administrative Code Chapter 173–470 (Ambient Air Quality Standards for Particulate Matter) (except for –110 and –150) as in effect 1/3/89.

3. Section 52.2479 is revised to read as follows:

§ 52.2479 Contents of the federally approved, state submitted implementation plan.

The following sections of the Washington State Implementation Plan for Compliance with Requirements of the Federal Clean Air Act (as adopted on the dates indicated) have been approved and are part of the current federally-approved, state-submitted implementation plan.

Washington State Implementation Plan for Compliance With Requirements of the Federal Clean Air Act

WAC 173–400 General Regulations for Air Pollution Sources

Section 010 Policy and purpose (3/22/91)
Section 020 Applicability (3/21/91)
Section 030 Definitions (3/21/91)
Section 040 General standards for maximum emissions (except –040(1)(c) and (d); –040(2); –040(4); and the second paragraph of –040(6)) (3/22/91)
Section 050 Emission standards for combustion and incineration units (except for the exception provision in –050(3)) (3/22/91)
Section 060 Emission standards for general process units (3/21/91)
Section 070 Emission standards for certain source categories (except –070(7)) (3/21/91)
Section 100 Registration (3/21/91)
Section 105 Records, monitoring and reporting (3/21/91)
Section 110 New source review (NSR) (3/21/91)
Section 151 Retrofit requirements for visibility protection (3/21/91)
Section 161 Compliance schedules (3/21/91)
Section 171 Public involvement (3/21/91)
Section 190 Requirements for nonattainment areas (3/21/91)
Section 200 Creditable stack height and dispersion techniques (3/21/91)
Section 205 Adjustment for atmospheric conditions (3/21/91)
Section 210 Emission requirements for prior jurisdictions (3/21/91)
Section 220 Requirements for board members (3/21/91)
Section 230 Regulatory actions (3/21/91)
Section 240 Criminal penalties (3/21/91)
Section 250 Appeals (3/21/91)
Section 260 Conflict of interest (3/21/91)

WAC 173–402 Civil Sanctions Under Washington Clean Air Act (6/24/80)

WAC 173–405 Kraft Pulp Mills

Section 012 Statement of purpose (3/21/91)
Section 021 Definitions (3/21/91)
Section 040 Emission standards (except –040(1)(b), –040(1)(c), –040(3)(b), –040(3)(c), –040(4), –040(7), –040(8), and –040(9)) (3/21/91)
Section 045 Creditable stack height and dispersion techniques (3/21/91)
Section 061 More restrictive emission standards (3/21/91)
Section 072 Monitoring requirements (except –072(2)) (3/21/91)
Section 077 Report of startup, shutdown, breakdown or upset conditions (3/21/91)
Section 078 Emission inventory (3/21/91)
Section 086 New source review (NSR) (3/21/91)
Section 087 Prevention of significant deterioration (PSD) (3/21/91)
Section 091 Special studies (3/21/91)

WAC 173–410 Sulfite Pulping Mills

Section 012 Statement of purpose (3/21/91)
Section 021 Definitions (3/21/91)
Section 040 Emission standards (except for the exception provision in –040(3) and –040(5)) (3/21/91)
Section 045 Creditable stack height and dispersion techniques (3/21/91)
Section 062 Monitoring requirements (3/21/91)
Section 067 Report of startup, shutdown, breakdown or upset conditions (3/21/91)
Section 071 Emission inventory (3/21/91)

Section 086 New source review (NSR) (3/21/91)
Section 087 Prevention of significant deterioration (PSD) (3/21/91)
Section 100 Special studies (3/21/91)

WAC 173-415 Primary Aluminum Plants

Section 010 Statement of purpose (3/21/91)
Section 020 Definitions (except -020(1) and (2)) (3/21/91)
Section 030 Emission standards (except -030(1) and -030(3)(b)) (3/21/91)
Section 045 Creditable stack height and dispersion techniques (3/21/91)
Section 050 New source review (NSR) (3/21/91)
Section 051 Prevention of significant deterioration (PSD) (3/21/91)
Section 060 Monitoring and reporting (except -060(1)(a), (b) and (d)) (3/21/91)
Section 070 Report of startup, shutdown, breakdown or upset conditions (3/21/91)
Section 080 Emission inventory (3/21/91)

WAC 173-420 State Jurisdiction Over Motor Vehicles (3/29/77)

WAC 173-422 Motor Vehicle Emission Inspection (12/31/81)

WAC 173-425 Open Burning

Section 010 Purpose (10/18/90)
Section 020 Applicability (10/18/90)
Section 030 Definitions (10/18/90)
Section 036 Curtailment during episodes or impaired air quality (10/18/90)
Section 045 Prohibited materials (10/18/90)
Section 055 Exceptions (10/18/90)
Section 065 Residential open burning (10/18/90)
Section 075 Commercial open burning (10/18/90)
Section 085 Agricultural open burning (10/18/90)
Section 095 No burn area designation (10/18/90)
Section 100 Delegation of agricultural open burning program (10/18/90)
Section 115 Land clearing project (10/18/90)
Section 120 Department of natural resources—smoke management plan (10/18/90)
Section 130 Notice of violation (10/18/90)
Section 140 Remedies (10/18/90)

WAC 173-430 Buring of Field and Forage and Turf Grasses Grown for Seed

Section 010 Purpose (10/18/90)
Section 020 Definitions (10/18/90)
Section 030 Permits, conditions and restrictions (10/18/90)
Section 040 Mobile field burners (10/18/90)
Section 050 Other approvals (10/18/90)
Section 060 Study of alternatives (10/18/90)
Section 070 Fees (10/18/90)
Section 080 Certification of alternatives (10/18/90)

WAC 173-433 Solid Fuel Burning Device Standards

Section 010 Purpose (10/18/90)
Section 020 Applicability (10/18/90)
Section 030 Definitions (10/18/90)
Section 100 Emission performance standards (10/18/90)
Section 110 Opacity standards (10/18/90)
Section 120 Prohibited fuel types (10/18/90)
Section 130 General emission standards (10/18/90)
Section 150 Curtailment (10/18/90)
Section 170 Retail sales fee (10/18/90)
Section 200 Regulatory actions and penalties (10/18/90)

WAC 173-434 Solid Waste Incinerator Facilities

Section 010 Purpose (10/18/90)
Section 020 Applicability (10/18/90)
Section 030 Definitions (10/18/90)
Section 050 New source review (NSR) (10/18/90)
Section 070 Prevention of significant deterioration (PSD) (10/18/90)
Section 090 Operation and maintenance plan (10/18/90)
Section 100 Requirement for BACT (10/18/90)
Section 130 Emission standards (except -130(2)) (10/18/90)
Section 160 Design and operation (10/18/90)
Section 170 Monitoring and reporting (10/18/90)
Section 190 Changes in operation (10/18/90)
Section 200 Emission inventory (10/18/90)
Section 210 Special studies (10/18/90)

WAC 173-435 Emergency Episode Plan

Section 010 Purpose (1/3/89)
Section 015 Significant harm levels (1/3/89)
Section 020 Definitions (1/3/89)
Section 030 Episode stage criteria (1/3/89)
Section 040 Source emission reduction plans (1/3/89)
Section 050 Action procedures (1/3/89)
Section 060 Enforcement (1/3/89)
Section 070 Sampling sites, equipment and methods (except -070(1)) (1/3/89)

WAC 173-440 Sensitive Areas

Section 010 Purpose (10/18/90)
Section 020 Applicability (10/18/90)
Section 030 Definitions (10/18/90)
Section 040 Sensitive areas designated (10/18/90)
Section 100 Standards (10/18/90)
Section 900 Appendix A—Map (10/18/90)

WAC 173-470 Ambient Air Quality Standards for Particulate Matter

Section 010 Purpose (1/3/89)
Section 020 Applicability (1/3/89)
Section 030 Definitions (1/3/89)
Section 100 Ambient air quality standards (1/3/89)
Section 160 Reporting of data (1/3/89)

WAC 173-490 Emission Standards and Controls for Sources Emitting Volatile Organic Compounds

Section 010 Purpose (8/20/80)
Section 020 Definitions (6/29/82)
Section 025 General Applicability (6/29/82)
Section 030 Registration and Reporting (8/20/80)
Section 040 Requirements (6/29/82)
Section 070 Schedule of Control Dates (8/20/80)
Section 071 Alternative Schedule of Control Dates (8/20/80)
Section 080 Exceptions (6/29/82)
Section 090 New Source Review (4/26/79)
Section 120 Compliance Schedules (4/26/79)
Section 130 Regulatory Actions (4/26/79)
Section 135 Criminal Penalties (4/26/79)
Section 140 Appeals (4/26/79)
Section 200 Petroleum Refinery Equipment Leaks (8/20/80)
Section 201 Petroleum Liquid Storage In External Floating Roof Tanks (8/20/80)
Section 202 Leaks from Gasoline Transport Tanks and Vapor Collection Systems (8/20/80)
Section 203 Perchloroethylene Dry Cleaning Systems (6/29/82)
Section 204 Graphic Arts Systems (6/29/82)
Section 205 Surface Coating of Miscellaneous Metal Parts and Products (6/29/82)
Section 207 Surface Coating of Flatwood Paneling (8/20/80)
Section 208 Aerospace Assembly and Component Coating Operations (6/29/82)

WAC 463-39 General Regulations for Air Pollution Sources

Section 010 Purpose (7/23/79)
Section 020 Applicability (7/23/79)
Section 030 Definitions (except (4), (7), (10), (24), (25), (30), (35), (36)) (7/23/79)
Section 040 General Standards for Maximum Permissible Emissions (except introductory paragraph) (7/23/79)
Section 050 Minimum Emission Standards for Combustion and Incineration Sources (7/23/79)
Section 060 Minimum Emission Standards for General Process Sources (7/23/79)
Section 080 Compliance Schedules (7/23/79)
Section 100 Registration (7/23/79)
Section 110 New Source Review (except (1), the first two sentences of (3)(b), (3)(c), (3)(d), (3)(e)) (7/23/79)
Section 120 Monitoring and Special Report (7/23/79)
Section 130 Regulatory Actions (7/23/79)
Section 135 Criminal Penalties (7/23/79)
Section 150 Variance (7/23/79)
Section 170 Conflict of Interest (7/23/79)

Puget Sound Air Pollution Control Authority—Regulation I

Article 1 Policy, Short Title & Definitions (except 1.07(s), 1.07(rr) and 1.07(xx) (12/74)
Article 1.07(s) General Definitions, "Facility" (10/11/83)
Article 1.07(rr) General Definitions, "Source" (10/11/83)
Article 1.07(xx) General Definitions, "Volatile Organic Compound" (10/11/83)
Article 3 General Provisions (12/74)
Article 6 Notices of Construction and Orders of Approval (except 6.07(b)(7) and 6.08) (12/74)
Article 6.07(b)(7) Issuance of Approval or Order (10/11/83)
Article 6.08 Special Conditions for New Air Contaminant Sources Which Will Significantly Impact A NonAttainment Area (10/11/83)
Article 9.02 Outdoor Fires (6/13/73)
Article 9.02A (6/20/74)

Article 9.03 Emission of Air Contaminant: Visual Standard (1/77)
Article 9.04 Deposition of Particulate Matter (1/77)
Article 9.05 Incinerator Burning (1/77)
Article 9.06 Refuse Burning Equipment: Time Restriction (1/77)
Article 9.07(c) Emission of Sulfur Dioxide (8/12/70)
Article 9.07(d) Emission of Sulfur Dioxide (1/77)
Article 9.07(e) Emission of Sulfur Dioxide (1/77)
Article 9.09 Emission of Particulate Meter: Weight Rate Standard (1/77)

Puget Sound Air Pollution Control Authority—Regulation II

Article 1 Purpose, Policy, Short Title and Definitions (except 1.02) (4/8/82)
Article 1, Section 1.02 Policy (12/13/84)
Article 2 Volatile Organic Compound Emission Standards Group 1 (except 2.13) (4/8/82)
Article 2, Section 2.13 Schedule of Control Dates (12/13/84)
Article 3 Volatile Organic Compound Emission Standards—Group 2 (except 3.11) (4/8/82)
Article 3, Section 3.11 Schedule of Compliance Dates (12/13/84)
Article 4 General Provisions (except 4.02) (4/8/82)
Article 4, Section 4.02 Scope, Registration, Reporting and Notice of Construction (12/13/84)

Northwest Air Pollution Authority—Regulations

Section 455.11 Particulate Matter Standard (8/9/78)

Spokane County Air Pollution Control Authority—Regulation II

Article IV, Section 4.01 Particulate Emissions—Grain Loading Restrictions (1/6/75)

[FR Doc. 93–478 Filed 1–14–93; 8:45 am]
BILLING CODE [illegible]

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 92–27; Notice 2]

RIN 2127–AE41

Federal Motor Vehicle Safety Standards; Wheel Nuts, Wheel Discs, and Hub Caps

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: In this final rule, NHTSA amends Federal Motor Vehicle Safety Standard No. 211 *Wheel Nuts, Wheel Discs, and Hub Caps* to relax the current prohibition against all wheel nuts, wheel discs, and hub caps with winged projections. As amended, the standard will permit winged wheel nuts, wheel discs, and hub caps, if, when those items are installed on a wheel rim, the projections do not extend beyond the side of the wheel rim. Pedestrian or cyclist safety will not be compromised by this change.

DATES: This final rule is effective February 16, 1993.

FOR FURTHER INFORMATION CONTACT: Ms. Margaret Gill, Office of Vehicle Safety Standards, NRM–12, room 5320, NHTSA, 400 Seventh Street, SW., Washington, DC 20590. Ms. Gill's telephone number is (202) 366–6651.

SUPPLEMENTARY INFORMATION:

Background

Standard No. 211, *Wheel Nuts, Wheel Discs, and Hub Caps* (49 CFR 571.211) was issued in 1967 (32 FR 2408) as one of the initial Federal Motor Vehicle Safety Standards. Standard No. 211 applies to motor vehicles and motor vehicle equipment. The Standard currently prohibits wheel nuts, wheel discs, and hub caps that incorporate "winged projections" (for the sake of brevity and simplicity, all three are generically referred to hereafter as "winged hub caps"). This prohibition applies to all winged hub caps, regardless of the size of the winged projections, and regardless of how far outward they jut when the hub cap is installed on any wheel rim on which it is or can be mounted.

By petition dated September 3, 1991, Consolidated International Automotive, Inc., Dayton Wheel Products, and Gorilla Automotive Products (petitioners) petitioned the agency to amend Standard No. 211. Petitioners sought an amendment that would permit the manufacture and installation of some types of hub caps. Petitioners asserted that the record contained no evidence substantiating any safety related hazards associated with the hub caps regulated by Standard No. 211. To bolster this position, petitioners enclosed the results of a survey of automotive parts wholesale and retail establishments. The survey showed no reports of injuries resulting from winged hub caps. (The results of this survey are in NHTSA Docket No. 92–27; Notice 1.) Petitioners further stated that the agency provided no guidance as to what constitutes a "winged projection," and that it is therefore difficult to discern what types of equipment are prohibited by the standard. Petitioners petitioned for Standard No. 211 to be amended so that it does not prohibit the manufacture and installation of hub caps with "winged projections" that, when installed, "do not extend beyond the outermost plane of the wheel." On December 2, 1991, NHTSA granted the petitioners' petition for rulemaking.

Notice of Proposed Rulemaking

On June 8, 1992, NHTSA implemented the grant of rulemaking by publishing in the **Federal Register** a notice of proposed rulemaking (57 FR 24207) proposing to amend Standard No. 211 to permit hub caps incorporating "winged projections" that, when installed, do not "extend beyond the plane that is tangent to the outboard edge of the wheel rim * * *". Before issuing the proposal, the agency reexamined the safety need to prohibit winged hub caps. In doing so, the agency examined available information provided by the petitioners and by other sources. This review by NHTSA was summarized in the NPRM.

In the NPRM, the agency described the accident data sources it reviewed to determine the extent of injuries involving winged hub caps. Pedestrians, motorcyclists, and bicyclists are potentially at risk from injuries resulting from contact with winged hub caps. The agency's analysis was based on a review of accident data files from the Pedestrian Injury Causation Study (PICS), the National Accident Sampling Systems (NASS), and complaints to NHTSA's Office of Defects Investigation. The data examined by NHTSA indicated that, since 1979, significant injury has not been caused to pedestrians or cyclists as a result of accidental contact with wheels or hub caps. Based on this, the agency tentatively concluded that safety would not be compromised by amending Standard No. 211 so that it permits winged hub caps if, when the winged hub caps are installed on a wheel rim, the winged projections do not extend outward beyond the plane tangent to the outside of that wheel rim.

Public Comments to the NPRM

In response to the NPRM, the agency received twenty eight public comments. The agency received separate comments from two automobile manufacturers, and a comment from counsel for the petitioners. The other comments were from automotive parts wholesale and retail establishments. All these commenters supported the proposed amendment to Standard No. 211. The majority of the commenters stated that they were not aware of any instances in which accidental contact with a winged projection on a hub cap, resulted in an injury. None of the twenty eight commenters opposed any aspect of the NPRM.

Commenters raised the following additional issues. On behalf of the petitioners, John Russell Deane III, Esq., asked whether the phrase "[A]s installed on any physically compatible combination of axle and wheel rim * * *" used in the regulatory text of the NPRM under "S4 Requirements," could be further clarified. Mr. Deane stated that the petitioners' understanding was that the language is not intended as a limitation beyond that requiring that the "knock-off" hub be used only on axle and wheel equipment where the equipment design allows for such use.

Mr. Deane's understanding is correct. The agency's intent was to prohibit winged hub caps only if, when the hub cap is installed on any wheel rim/axle combination on which the hub cap fits, the projections extend beyond the plane described in S4. NHTSA chose the language "physically compatible" instead of "designed to fit" to emphasize that manufacturers must take into consideration not only the specific wheel rim/axle combination(s) on which the hub cap was envisioned or intended to be used, but also any other combinations that the hub cap can fit.

An importer of specialty British motor vehicle equipment asked whether new replacement equipment with winged projections for pre-standard (i.e., pre-1967) vehicles are prohibited from being imported into the United States. The agency notes that this issue was addressed in the NPRM. However, since it is an important point, it will once again be addressed. Standard No. 211 has, from its issuance, been an equipment standard as well as a vehicle standard. Further, the application of the equipment requirements in Standard No. 211 is not limited to replacement equipment for vehicles manufactured on or after the effective date of the standard, January 1, 1968. Therefore, since January 1, 1968, the prohibition against winged hub caps has applied to all replacement winged hub caps manufactured on or after that date, even if they are designed to be placed on motor vehicles that were manufactured before that date.

Since none of the public comments raised concerns about a potential for pedestrian and cyclist injuries to increase if winged hub caps were permitted to extend beyond the plane tangent to the wheel rim, the agency adopts as final its tentative conclusion that safety would not be compromised by amending Standard No. 211 Based on the foregoing, the agency is adopting the proposed amendments to Standard No. 211 without change.

Effective Date

This final rule relieves a restriction in Standard No. 211. In the NPRM, the agency proposed that since the rule would relieve a restriction, the rule, if made final, would take effect 30 days after publication in the Federal Register. Only one commenter addressed the issue of the effective date. That commenter supported an effective date 30 days after publication of the final rule.

Accordingly, since this notice permits, but does not require, redesigned hub caps, the agency has concluded that the amendments made by this notice should be effective sooner than 180 days after the issuance of this rule. Therefore, the agency finds for good cause that the amendments should become effective 30 days after it is published.

This final rule would not have a retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard. Section 105 of the Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Rulemaking Analyses and Notices

1. Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The agency has analyzed the economic and other effects of this proposal and determined that they are neither "major" within the meaning of Executive Order 12291 nor "significant" within the meaning of the Department of Transportation's regulatory policies and procedures. This final rule would impose no additional requirements, but would permit manufacturers greater design flexibility by relieving a restriction. Further, any cost impacts would be so slight that they cannot be quantified. Since the effects of this final rule would be so minimal, a full regulatory evaluation is not required.

2. Regulatory Flexibility Act

In accordance with the Regulatory Flexibility Act, NHTSA has evaluated the effects of this final rule on small entities. Based on this evaluation, I certify that the final rule will not have a significant economic impact on a substantial number of small entities. The final rule will have a small beneficial effect on small manufacturers and dealers of motor vehicle equipment by relieving restrictions on the sale of certain winged hub caps. It will not affect the cost of producing or purchasing hub caps. Accordingly, a final regulatory flexibility analysis has not been prepared.

3. Executive Order 12612 (Federalism)

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612. The agency has determined that the final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

4. National Environmental Policy Act

The agency also has analyzed this rule for the purpose of the National Environmental Policy Act, and determined that it would not have any significant impact on the quality of the human environment.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles, Rubber and rubber products, Tires.

In consideration of the foregoing, 49 CFR part 571 is amended as set forth below:

PART 571—[AMENDED]

1. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

2. Section 571.211 is amended as follows:

a. Paragraph S3 is revised to read as follows:

§ 571.211 Standard No. 211; Wheel nuts, wheel discs, and hub caps.

* * * * *

S3. *Definitions.*

S3.1 *Wheel nut* means an exposed nut that is mounted at the center or hub of a wheel. It does not include any of the ordinary small hexagonal nuts that secure a wheel to an axle, and that are normally covered by a hub cap or wheel disc.

S3.2 *Winged projection* means any exposed cantilevered appendage that projects radially from a wheel nut, wheel disc or hub cap and that typically has front, edge, and/or rear surfaces which are not in contact with the wheel when the wheel nut, wheel cover or hub cap is installed on the axle. Figure 1 shows an example of a "winged projection."

f. Paragraph S4 is added after paragraph S3 to read as follows:

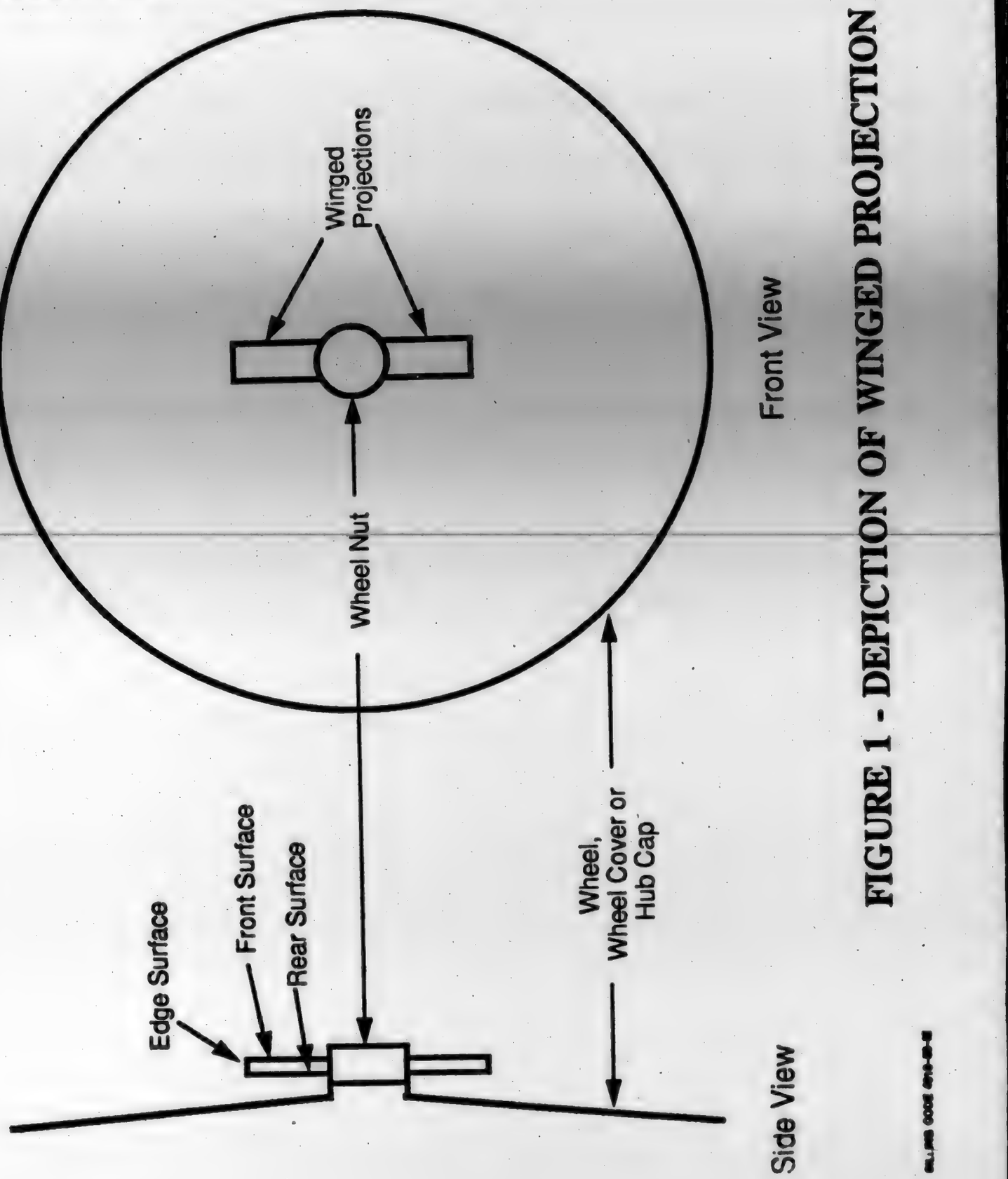

FIGURE 1 - DEPICTION OF WINGED PROJECTION

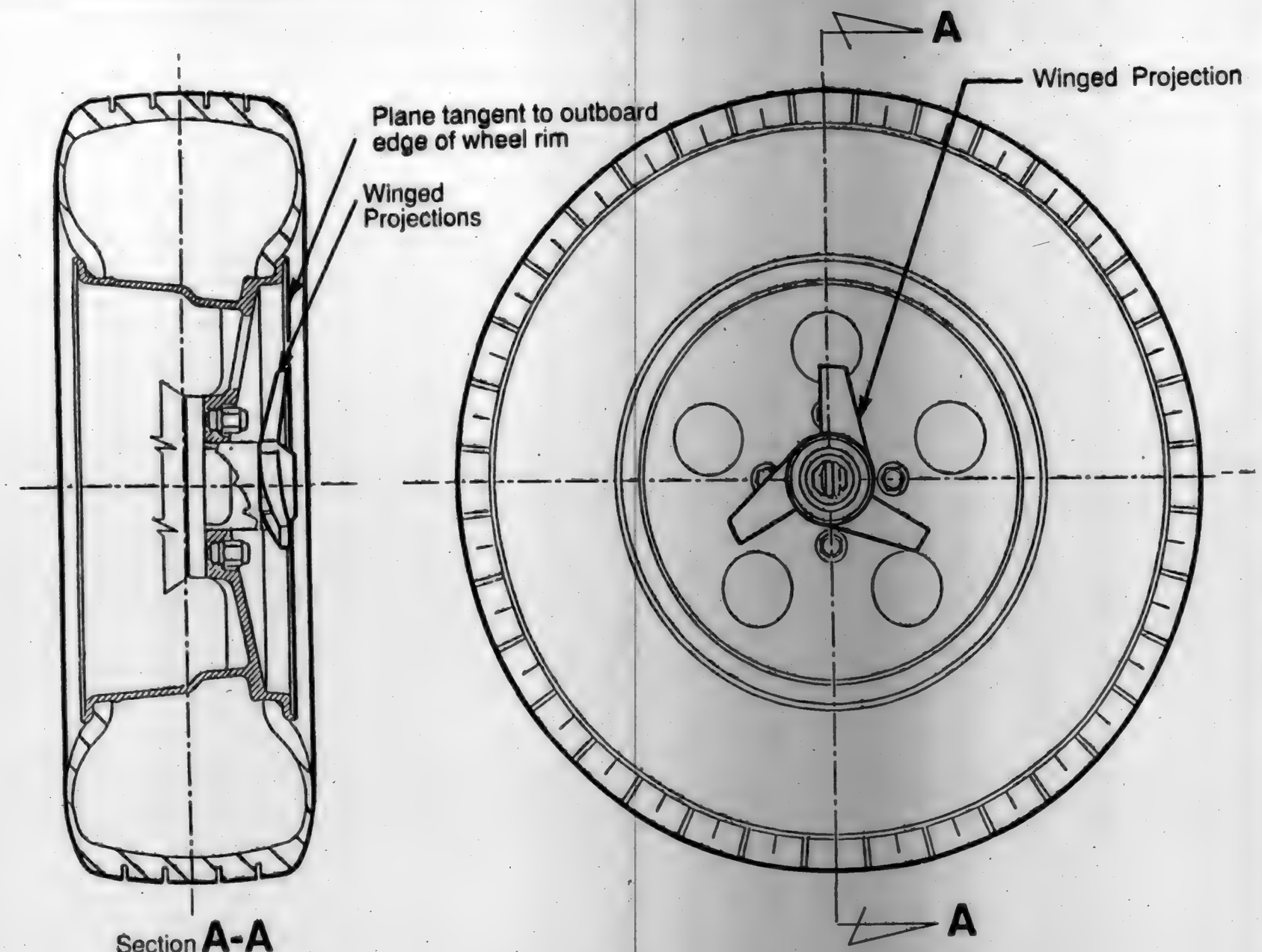

Figure 2

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S4. *Requirements.* As installed on any physically compatible combination of axle and wheel rim, wheel nuts, wheel discs, and hub caps for use on passenger cars and multipurpose passenger vehicles shall not incorporate winged projections that extend beyond the plane that is tangent to the outboard edge of the wheel rim at all points around its circumference. Figure 2 shows that plane.

c. The paragraph entitled "NOTE" at the end of Standard No. 211 is removed.

d. Figures 1 and 2 are added at the end of Standard No. 211.

Issued on January 11, 1993.

Marion C. Blakey,

Administrator.

[FR Doc. 93–1004 Filed 1–14–93; 8:45 am]

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49 CFR Part 571

[Docket No. 90–06; Notice 4]

RIN 2127–AD51

Federal Motor Vehicle Safety Standards; School Bus Passenger Seating and Crash Protection

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Final rule.

SUMMARY: This final rule amends Standard No. 222, *School Bus Passenger Seating and Crash Protection*. School buses designed (on a voluntary basis or pursuant to a legal requirement other than one issued by this agency) to transport persons in wheelchairs will be required to be equipped with wheelchair securement devices and occupant restraint systems meeting specified performance requirements. Among the performance requirements are ones regarding location and minimum strength for the anchorages of those devices and systems and ones regarding minimum strength of the devices and systems themselves.

This amendment will complement existing provisions in Standard No. 222 specifying occupant protection requirements for school bus passenger seating and restraining barriers. This amendment will provide a level of occupant protection for students in wheelchairs as comparable to that currently provided to persons able to use standard bench seats as is practicable. In addition, this amendment will prevent potential injuries to all occupants that could be caused by an inadequately secured wheelchair.

DATES: The amendments made in this rule are effective January 17, 1994. Any petitions for reconsideration must be received by NHTSA no later than February 16, 1993.

ADDRESSES: Any petitions for reconsideration should refer to the docket and notice number of this notice and be submitted to Administrator, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590. (Docket Room hours are 9:30 a.m.–4 p.m., Monday through Friday.)

FOR FURTHER INFORMATION CONTACT: Charles R. Hott, NRM–15, Office of Vehicle Safety Standards, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590. Telephone: (202) 366–0247.

SUPPLEMENTARY INFORMATION:

Background

Federal motor vehicle safety standard No. 222, *School Bus Passenger Seating and Crash Protection*, specifies occupant protection requirements for school bus passenger seating and restraining barriers. The requirements, which apply to each "school bus passenger seat," include limits on the fore and aft spacing between adjacent rows of seats in order to keep students compartmentalized or contained within their immediate seating area during a crash. The term "school bus passenger seat" is defined in S4 of the standard as "a seat in a school bus, other than the driver's seat or a seat installed to accommodate handicapped or convalescent passengers as evidenced by orientation of the seat in a direction that is more than 45 degrees to the left or right of the longitudinal centerline of the vehicle."

In July 1989, Mr. Lyle Stephens and Ms. Debra Simms filed a discrimination complaint with the U.S. Department of Transportation concerning seating for students with disabilities on school buses. They alleged that the Department had violated section 504 of the Rehabilitation Act of 1973, as amended, by failing to establish "school bus passenger seating or crash protection requirements for handicapped students who use wheelchairs or require devices other than the traditional school bus passenger seat while being transported." Since the plaintiffs indicated that the relief they sought was rulemaking, the agency treated the Stephens/Simms complaint as a petition for rulemaking and published a **Federal Register** notice granting their petition (55 FR 7346, March 1, 1990).

Shortly thereafter, the agency published a notice (55 FR 21891; May 30, 1990) announcing the availability of a study ("Wheelchair and Occupant Restraint on School Buses," DOT–HS–807–570, May 1990) on the state-of-the-art in wheelchair securement and occupant restraints on school buses. The notice requested comments on this report, as well as any other comments relating to the pending rulemaking to amend Standard No. 222 to establish requirements for school bus seating for students with disabilities.

On September 24, 1991, based upon comments received in response to the May 30 notice, NHTSA published a Notice of Proposed Rulemaking (NPRM) proposing to amend Standard No. 222 to require that school buses designed (on a voluntary basis or pursuant to a legal requirement other than one issued by this agency) to transport persons in wheelchairs have wheelchair securement devices and occupant restraint systems meeting specified performance requirements (56 FR 48140). The NPRM proposed minimum strength and location requirements for the anchorages for securement devices/restraint systems, and minimum strength requirements for the securement devices/restraint systems themselves. The NPRM also proposed that all wheelchair locations would be forward-facing.

In response to the NPRM, NHTSA received 52 comments from a variety of sources, including school districts, school bus and transportation contractors, state organizations, national and state associations, vehicle and equipment manufacturers, researchers, and private individuals. All but a few of the comments supported the concept of establishing requirements in Standard No. 222 for wheelchair securement devices/occupant protection systems. The opinions of the commenters did differ, however, on a number of the issues and questions raised in the NPRM. All of these comments were considered while formulating this final rule, and the most significant comments are addressed below. In general, the preamble uses the same organization as the NPRM's preamble, to aid the reader in comparing the two documents. Issues not discussed in the NPRM's preamble are discussed at the end of this preamble.

Issues

1. Whether To Require Each School Bus To Have a Wheelchair Securement Location

The NPRM specifically did not propose that all school buses be designed to transport at least one person in a wheelchair. The agency believed that decisions on how many school buses should be configured to carry

students in wheelchairs are most easily and accurately made by local school districts based on the particular number of children with disabilities whom they have the responsibility to transport.

No commenter objected to this position. The agency has decided to maintain the position it took in the NPRM and apply the requirements of the final rule to only those new school buses designed with one or more locations for transporting a person seated in a wheelchair.

2. System Versus Component Test Requirements

The NPRM discussed the agency's rationale for proposing static performance requirements for the various components of wheelchair securement devices/occupant restraint systems, instead of specifying full scale testing of the securement devices/restraint systems using test dummies. The NPRM also specifically asked whether there was "any existing information which indicates that conducting dynamic tests using wheelchairs and test dummies, as opposed to the proposed component tests, would result in safer wheelchair securement and occupant restraint devices?"

A number of commenters objected to the agency's tentative decision to test only the securement devices/restraint systems at the component level. These commenters believed that a dynamic test would more closely resemble real-world situations and would be a more severe test of the system than the component test proposed in the NPRM. In addition, commenters believed that agreement among the various national and international organizations that are developing dynamic test requirements would occur in the near future.

A number of other commenters believed that a dynamic test procedure was appropriate, but recognized that it may not be possible to adopt one at the current time. Accordingly, these commenters suggested that NHTSA establish a schedule for completing the work necessary to develop dynamic test requirements for wheelchair securement devices/occupant restraint systems and, in most instances, for the wheelchairs themselves. Many of these commenters recognized the ongoing national and international activities to develop standards for wheelchairs and wheelchair securement devices/occupant restraint systems.

Several commenters expressed support for static tests of wheelchair securement devices/occupant restraint systems and their anchorages. A few commenters supported the use of both static and dynamic tests.

The NRPM listed six reasons why the agency was not proposing dynamic test requirements for wheelchair securement devices and occupant restraint systems. These reasons involved the need to:

1. Develop an appropriate test dummy;
2. Identify injury tolerance levels for the disabled;
3. Establish test conditions;
4. Select a "standard" or surrogate wheelchair;
5. Establish procedures for placing the wheelchair and the test dummy in an effective test condition; and
6. Develop an appropriate test buck to represent a portion of the school bus body for securement of anchorages.

Only the University of Michigan, Transportation Research Institute (UMTRI) provided technical comments on these reasons. UMTRI believed that the "first two reasons are irrelevant and miss the point of the system dynamic test which is primarily to conduct a systems strength test using dynamic test conditions which are known to produce failures in components at much lower loads than in static tests." UMTRI stated that the purpose of the test dummy is to "generate forces that may be expected from a human occupant, rather than as an injury-sensing tool." Accordingly, it does not believe a special dummy is needed to represent a disabled person and there is no need for injury criteria. It believed dummy excursion is an acceptable measurement for potential injury. Dummy excursion is currently one of the criteria used to measure compliance with Standard No. 213, *Child Restraint Systems*.

With respect to reasons 3 through 6, UMTRI suggested "that consensus and answers to these issues are close at hand or already available." It cited the acceptance of rigid floors and anchorage points and a surrogate wheelchair by such organizations as the Society of Automotive Engineers (SAE), the International Standards Organization (ISO), and the Canadian Standards Associations (CSA), as evidence that "the implementation of a dynamic test is closer at hand than had been thought and that current standards-writing efforts could be expedited by the NHTSA's sponsorship of some needed testing and other support work."

After considering the above comments, the agency again concludes that it is not feasible to issue a Federal requirement for dynamic testing of wheelchair securement devices and occupant restraint systems at this time. The reasons given in the NPRM for not proposing dynamic tests for wheelchair securement devices and occupant restraint systems remain valid. Only one commenter, UMTRI, provided any technical information that directly addressed the reasons listed in the NPRM. The other commenters expressed their opinions, but did not provide supporting data or information. The comments of UMTRI, with respect to the technical reasons why the agency did not propose a dynamic test, note that there are still a number of issues concerning dynamic testing which have not been resolved by the national and international organizations attempting to resolve the problems. The details of the test conditions, test equipment, and performance criteria have been studied by experts for a number of years, and as noted by some of the commenters, it may take a few more years to resolve all of the issues. NHTSA does not believe it can resolve those issues before the national and international communities can reach agreement.

The Agency also notes that this final rule is intended to provide wheelchair occupants in school buses with a level of occupant protection equivalent to that which is mandated by Standard No. 222 for able-bodied students. Standard No. 222 currently provides occupant crash protection to students sitting in conventional school bus seats in school buses over 10,000 pounds GVWR through the use of strong, well-anchored, high-backed, evenly spaced seats that are subject to static tests to ensure their compliance with the standard. For school buses weighing 10,000 pounds GVWR or less, FMVSS No. 222 also requires the compartmentalized seating as well as safety belts, all of which are subjected to static tests. The agency believes that it is appropriate to specify static testing for wheelchair securement devices and occupant restraint systems since static tests are already specified for other school bus passenger seating locations.

Accordingly, the final rule includes only static test requirements for the wheelchair securement devices/occupant restraint systems and their anchorages. However, the agency intends to monitor the on-going activities of the national and international organizations interested in the transportation safety of the disabled.

3. Performance Criteria

The NPRM proposed requiring the wheelchair securement devices and occupant restraint systems to meet the requirements of Standard No. 209, *Seat belt assemblies*. The NPRM also proposed a floor strength requirement of 3,000 pounds for the anchorages (6,000 pounds if the securement devices and

restraint systems share a common anchorage), as well as specific force application angles. The NPRM also requested comment on whether there was room inside a bus to pull on the securement and restraint anchorages with forces and at the angles proposed.

No commenter objected to the proposed requirements for the securement devices and restraint systems or to the proposed anchorage strength requirements. Comments from vehicle manufacturers also indicated that there would be sufficient room in the vehicle to perform the tests. Accordingly, these requirements are adopted in the final rule.

UMTRI stated that the NPRM did not account for designs that have the restraint system anchored on or near the securement device in the static testing. For example, UMTRI stated that the NPRM requires anchorage loads over 3,000 pounds only in cases where "more than one securement device shares a common anchorage." It claimed that in cases where the restraint system is connected to a securement device, the 3,000 pound test load is not appropriate. UMTRI also stated that in a case where the restraint system is connected to the wheelchair, that the securement anchorage will be exposed to additional loads. The agency notes that proposed S5.4.3.2(e) required the loads required for each system shall be applied simultaneously when a securement device and a restraint system share a common anchorage. However, UMTRI's comments concerning the need for simultaneous testing when the restraint system is anchored to the wheelchair or the securement device are correct. NHTSA intended to require simultaneous testing of all anchorages that are used for more than one securement device and/or restraint system. Accordingly, the language of the final rule takes designs which have the restraint system anchored to the wheelchair or the securement device into account.

The only comments concerning force application angles addressed the proposed angles for the securement device anchorages. Many of these comments seemed to confuse the specification of a test angle between 40° and 50° with a requirement that the securement device be installed on a wheelchair at these angles. These test angles were not intended to limit installation angles.

Other commenters suggested that testing at a range of 30° to 60° would more accurately reflect the range of angles at which wheelchairs are installed. After reviewing these comments, NHTSA agrees that the securement anchorage strength tests should be conducted over the range of angles that represents the majority of installation angles. Therefore, the final rule adopts a requirement that securement anchorages be capable of meeting the strength requirement at any angle between 30° and 60°.

4. Wheelchair Orientation

The NPRM discussed the agency's rationale for proposing that wheelchair seating locations be forward facing and asked for information on the effect of such an orientation on the capacity of school buses.

The majority of commenters supported a requirement for forward-facing wheelchair locations on school buses. Some state/local school districts noted that they already require wheelchairs to be forward facing and that problems with lost capacity had been minimal or non-existent. To support its belief that the proposed forward-facing requirement would not affect the number of buses necessary to transport children with disabilities, the Washington Superintendent of Public Instruction (Washington State) noted that the "proposed standard applies only to new buses. When new buses are ordered, a slightly longer body length is inexpensive and readily available." It also mentioned "that buses are currently available with flat floors or raised floors with no wheel housings. These buses will provide greater flexibility when designing floor plans for walk-on passengers and wheelchair stations." However, other commenters disagreed with the forward-facing requirement based on the belief that it would cause a significant reduction in capacity.

Several commenters stated that the mandate for forward-facing orientation should allow exceptions when deemed necessary and included in a student's Individual Educational Plan (IEP).

Note: The IEP emanates from the Education of All Handicapped Children Act of 1975 (Pub. L. 94–142) and the Individuals with Disabilities Education Act (Pub. L. 101–476). These Acts provide that each child between the ages of 3 and 21 must receive free and appropriate education at public expense, including transportation to and from the educational facilities. The IEP process involves the evaluation of the educational and special needs of the child, including transportation. When the IEP is completed by the responsible state or local agency, the parent, or guardian, of the child signs the plan, which in essence is a contract between the parent and school, including the transportation.

In addressing the issue of wheelchair orientation, two commenters provided information on injuries to wheelchair occupants on school buses. The Arizona Department of Transportation (Arizona DOT) commented that it had experienced some "shoulder and neck injuries form side facing devices." It believed that the side-facing restraint was inadequate to support the mobility device during emergency maneuvers, during crashes, or during emergency stops. These injuries were all "minor bruises, broken or cracked teeth, lacerations, or whiplash." The California Department of Education mentioned that California accident data "does not support either side or forward facing positions with respect to injury reduction to the occupant."

Some commenters stated that they were already receiving requests from parents that their child be transported only in a forward-facing position. In addition, several commenters discussed the effect of having forward-facing wheelchair locations mandated in new school buses, while still having side-facing locations on some older buses, and the potential impact of parents or guardians questioning the safety of those children transported in the side-facing locations. However, other commenters stated that the problems presented would be similar to the problems experienced when there were both pre-1977 and post-1977 buses within the same district.

There was overwhelming support for forward-facing wheelchair locations from the commenters. Those that favored side-facing orientations generally based those preferences on perceived capacity and/or cost issues, not safety concerns. Based upon comments received, the agency does not believe that these capacity and cost issues are substantial enough to override safety concerns with side-facing orientations. Accordingly, the final rule mandates forward-facing wheelchair locations for the same reasons cited in the NPRM, primarily because nearly every other national and international organization studying this issue has concluded that forward-facing wheelchair locations are inherently safer, and that wheelchairs and the human body are better capable of surviving a frontal crash in a frontal orientation.

With respect to the concerns raised by some commenters that there may be certain children with medical conditions that doctors or other health professionals believe may be better transported in a side-facing direction, NHTSA notes that this final rule only mandates performance requirements for wheelchair securement devices and occupant restraint systems when they are installed in school buses. The standard does not require that the

securement devices/restraint systems be used, nor does it specify how the securement devices should be used to restrain various wheelchairs or mobile seating devices. Those types of operational issues are the responsibility of the individual state and local school districts. Thus, if a state or local school district wishes to establish a procedure, for example through the IEP process, to allow a disabled child to be transported in other than a forward-facing orientation, that is its prerogative. If a state or local school district makes such a decision, then it would be necessary to obtain equipment that would work in a side-facing direction, since it may not be possible to adapt a forward-facing securement device/restraint system to a wheelchair or other mobile seating device in a side-facing orientation. Care should be taken in making such adaptation not to violate the statutory prohibition against rendering inoperative the federally-mandated safety equipment such as the securement device/restraint system.

On the issue of the effects that mandating forward-facing wheelchair locations will have on school bus capacity, there is no clear consensus in the comments as to the extent of any capacity loss. While one commenter suggested that it was possible to get more wheelchairs in a vehicle in the forward-facing position, most commenters believed there would be a loss in capacity. However, there was a significant difference of opinion on the magnitude of the loss. A number of commenters from states or school districts that had already switched to forward-facing wheelchair locations discussed their experiences. In general, fewer problems were experienced than were anticipated. The agency believes that those commenters who have already made the change to forward-facing wheelchairs, and adapted to any difficulties, are in the best position to judge the impacts. The comments and data from Washington State on the number of conventional school bus bench seats that must be removed to accommodate forward-facing versus side-facing wheelchairs were compelling. Washington State included a chart indicating the number of both side- and forward-facing wheelchair positions that could be installed for each bench seat removed. In almost every instance, only one more side-facing seat could have been installed for each bench seat removed.

It is also important to remember that, when ordering a new school bus with one or more wheelchair locations, the state or local school district can order a slightly larger school bus to offset any loss in capacity that may occur from switching from side-facing to forward-facing wheelchair locations. Based on the information from Washington State, the loss in capacity is typically only one or two bench seats. Based on that same information, most school buses can be ordered slightly longer.

Note: Large school buses are comprised of sections. Each manufacturer offers several different sized sections, which can be put together in any combination to obtain various bus lengths. For example, Blue Bird can combine 28" and 35" sections in order to increase the length of the bus by 7" increments. It may be necessary to add one or two 7" increments to a Blue Bird bus to regain any lost capacity from forward-facing wheelchairs.

In summary, the agency does not believe there is a large loss in capacity from requiring forward-facing wheelchair locations. In those instances where there is a loss, the cost of regaining the seating capacity in a large school bus by buying a slightly larger body is relatively inexpensive. For example, if three 7" sections are added to a 66 passenger bus, with an estimated cost of $40,000, the additional cost would be $450, for an increase of 1.125% (450/40,000). However, if a school district uses only small, van-based school buses for transporting disabled students in wheelchairs, then it may have to purchase an additional vehicle. As noted in the NPRM, while there may be local cost impacts for some school districts, the agency does not believe these costs are significant on a nationwide basis.

Regarding issues concerning the operation of some vehicles with side-facing wheelchair positions and others with forward-facing positions, the agency agrees with the commenters who stated that it could be accommodated using the same type of explanation used with respect to pre-1977 and post-1977 school buses. It is also noted that every safety advance results in the newer vehicles being safer than the older ones. If the agency followed the logic of the arguments given by some commenters concerning potential problems with some school buses being considered less safe than the others, it would never change existing safety standards or issue new ones. In those instances in which parents/guardians are insistent that their children be transported in a forward-facing position, the agency agrees with the Iowa Department of Education that state and local school districts are capable of making accommodation.

5. Separate Restraint Systems for Wheelchair Securement and Occupant Restraint

The NPRM proposed a component test approach that would accommodate the various types of wheelchair securement devices and occupant restraint systems available for use in school buses. These are:

(1) Securement and restraint belts that are independently attached to the anchorage points;

(2) A main belt which secures the wheelchair and an occupant restraint system which is attached to the main belt; and

(3) A securement device that attaches to the bus and a restraint system that attaches to the wheelchair or mobile seating device.

Several commenters stated that occupant restraints should be an option, not a requirement. Some of these comments were based on concerns that these systems could make it more difficult to extricate the occupant in an emergency. Other commenters stated that lap/shoulder belts are not practical for some types of wheelchairs, such as reclining wheelchairs, or for some wheelchair occupants, as they could interfere with medical equipment such as colostomy bags, feeding tubes, or oxygen.

In response to these comments, the agency notes that this final rule will mandate only that a wheelchair securement location in a school bus have both a wheelchair securement device and an occupant restraint system. The final rule will not, indeed cannot, mandate the use of these devices/systems. These operational issues are the responsibility of the individual states and local school districts. While NHTSA recommends use of the occupant restraint system whenever feasible, a state or local school district could establish a procedure for exempting certain persons or classes of persons from use of the occupant restraint system.

In response to concerns about extrication problems due to restraint systems, the agency notes that it is unaware of any actual instances of problems. In any event, as with safety belts in other types of vehicles, the agency believes that the benefits of restraints will offset any potential extrication concerns.

Other commenters disagreed about the types of wheelchair securement devices and occupant restraint systems that should be allowed. Transportation Alternatives concurred with "NHTSA's general conclusion that * * * occupants should be secured with lap

and upper torso restraints." However, it took "strong exception to NHTSA's position" on the issue of separate securement devices and restraint systems. It did so on the assumption that the wheelchair securement devices and occupant restraint systems would be anchored to the vehicle structure (chassis). Under such conditions, it was concerned that in a major crash in which the bus body separated from, or severely shifted on, the bus chassis (as has happened in a number of crashes including the Palm Springs, California, crash in July 1991), the occupant restraint systems would have literally cut the students in half. It believed that "the wheelchair and its occupant are a single unit. This unit must be firmly secured to the vehicle, as a unit. At the same time, nothing should compromise its remaining a unit."

The Washtenaw Michigan Intermediate School District, Thomas Built Buses, the Massachusetts Department of Public Health, the American Occupational Therapy Association, and others endorsed the concept of having the wheelchair secured independently of the occupant.

Q'Straint, an equipment manufacturer, suggested that NHTSA not use the "term 'completely independently system' to refer to the lap belt attached directly to a track or the floor. Many people think that an independent system creates an independence between the wheelchair and its occupant which is totally incorrect!" It claimed that such systems actually create a number of very serious problems. First is a "phasing" problem where the chair impacts the back of the occupant. Second is the excessive "rebound after impact" resulting from greater elongation of the occupant restraint than the securement device upon impact. This allows the occupant to rebound further rearward and upward. Third, when a lap belt is not positioned properly across the pelvic area, which it believed is common with restraint systems that are attached directly to the floor, the wheelchair occupant can "submarine under the lap belt with potential internal damage resulting."

UMTRI stated that the "preferred approach is an integrated occupant restraint system which is anchored in series with the tiedown system such that the lap belt anchors to the wheelchair or the tiedown system near the wheelchair seat." Finally, the Arizona DOT supported independent securement devices and restraint systems, both those that are independently attached to a floor anchorage as well as those that use "a main belt which secures the mobility device to the floor and an occupant restraint system which has the lap belt portion attached to the main belt." However, it disagreed with securement of "the occupant restraint system to the mobility device." With respect to potential phasing problems, they believe that "phasing may be reduced through appropriate training of those personnel securing the restraints." Also, the "need for securing the mobility device and the occupant is more important than the minor injuries that may occur through phasing."

After reviewing these comments, the agency continues to believe that none of the three systems allowed by the proposed rule should be excluded. While various commenters preferred one type or another, none of the commenters submitted any data indicating that any of the three types of systems is unsafe.

On the issue concerning potential problems in crashes where the school bus body separates from the chassis, the agency notes that all of the securement and restraint anchorage devices the agency has seen attach to the body, instead of the chassis, and thus do not present an added risk to the safety of a wheelchair occupant if the body separates from the chassis. In addition, the agency does not believe that it would be practical to attach the anchorage device to the chassis instead of the body.

The NPRM also expressed the agency's concern for a "phasing" problem (i.e., the secured wheelchair's placing a load on the back of the wheelchair occupant in a crash or sudden stop) in instances in which a small child is in a heavy wheelchair. To alleviate this potential problem, the NPRM included higher belt load requirements for the securement belts than for the restraint belts, in accordance with the requirements of Standard No. 209. The NPRM requested data, particularly sled test data, on the potential "phasing" effect of a lightweight student in a heavy wheelchair. The agency also asked if the differences in elongation requirements for securement and restraint belts would affect the potential occurrence of "phasing".

None of the commenters submitted test data. However, many commenters stated that there could be a problem, depending on the type of wheelchair securement device/occupant restraint system used and the type of wheelchair. Commenters stated that this would particularly be a problem with heavyweight wheelchairs. Q'Straint commented that phasing is not a problem in designs in which the occupant restraint is either attached to the wheelchair or the wheelchair securement device, instead of the floor of the bus. This type of arrangement would be allowed under the final rule.

On the issue of belt elongation, Tie Tech, an equipment manufacturer, stated that when a securement device, with approximately one foot of webbing, is installed on a mobility aid with a tension of approximately 100 pounds of pressure, some of the elongation has already been removed from the webbing. Also, "when the lapbelt of approximately six feet in length is secured with basically no pressure, the occupant is going to move before, and more, than the mobility aid does." Other commenters stated that they were not aware of any data that would indicate that elongation would solve this problem, and that too much elongation could cause problems by permitting the occupant to move too much.

After reviewing the comments, the agency believes the potential for phasing problems is small because of the limited cases in which phasing can occur (e.g., a small child in a heavy wheelchair), the different belt load requirements for the securement and restraint belts, and the in-use differences in the belts in terms of belt length and tension. Accordingly, the final rule does not include any changes from the NPRM with respect to phasing concerns.

6. Safety Belt Implications

In response to the May 30 notice, the agency received comments suggesting that there was an inconsistency between requiring occupant restraint systems for wheelchair occupants and not requiring safety belts for other school bus passengers. The NPRM summarized the agency's reasons for not requiring safety belts on large school buses and explained why the agency did not feel the requirement for wheelchair occupant restraint systems was inconsistent. First, small school buses used to transport students in wheelchairs are required by Standard No. 222 to have lap belts at all seating positions. Second, for large school buses, wheelchair occupant restraint systems are part of the "safe environment" for passengers in wheelchairs, comparable to the "safe environment" provided for other passengers by "compartmentalization."

Many commenters nevertheless urged the agency to require safety belts for all occupants on school buses. Other commenters, however, supported the position taken by the NHTSA of not requiring safety belts on school buses.

For the reasons stated in the NPRM and because requiring safety belts at all seating positions in a school bus would be beyond the scope of this rulemaking, the agency is not adopting such a requirement. The agency continues to agree with the conclusions of the National Academy of Sciences on the issue of safety belts on school buses. These conclusions are discussed in greater detail in the NPRM.

7. Wheelchair Crashworthiness

The NPRM did not propose any requirements for the crashworthiness of wheelchairs that could be used on school buses. The agency acknowledged that some wheelchairs and other types of mobile seating devices may not withstand crash forces, but noted that identifying appropriate levels of structural integrity for wheelchairs and a means of objectively measuring that performance would take a long time.

Many commenters believed that NHTSA should do more to provide occupant crash protection to occupants of wheelchairs in school buses. They suggested that the entire system (securement device, restraint system, and the wheelchair) should be tested and evaluated. These commenters stated that requirements for wheelchair securement devices would not improve the safety of passengers in wheelchairs if their wheelchairs do not have a sufficient number of adequate securement points and the strength to withstand the forces imposed by the securement device.

Invacare, a wheelchair manufacturer, stated that "there are no wheelchairs currently on the market that have been designed to withstand the DOT crash tests [the 30-mph crash tests used to measure compliance with a variety of standards, even though those standards do not directly apply to wheelchairs], and until such time as standards are written whereby designs may be investigated and tested, we will continue to advise all of our dealers and end users to transfer to the seating surfaces of the vehicle, and use the safety belts and/or harness provided with that vehicle." It believed that "premature passing of any legislation involving transport within a vehicle and in a wheelchair would misinform the general public and cause irreparable damage as there are many thousands of wheelchairs currently in the marketplace that are unusable as transport devices within a vehicle."

The American Academy of Pediatrics, Committee on Injury and Poison Prevention, stated that "to improve wheelchair transportation on school buses * * * an effort must be made to address the safety of the entire seating system for wheelchairs, not just those components providing securement for the device and the occupant." It believed it is "imperative that NHTSA establish parameters on what types of seating devices come under the requirements relating to school bus passenger seating and crash protection." But, it noted that one of the "greatest impacts of these revised standards should be to strongly communicate that not everything on wheels can be put into a school bus and tied down."

Transportation Alternatives "concurs fully with NHTSA's position" not to regulate the crashworthiness of wheelchairs. It noted that "improve crashworthiness is not necessarily a fair trade-off for increased wheelchair weight, which would be a serious burden to wheelchair occupants during the rest of their day when they must move about in the wheelchair itself." It commented that technological improvements, e.g., composite materials, "should bring dramatic improvements in wheelchair design and construction, improvements that will make the chairs more crashworthy while at the same time improving them in other respects."

The agency agrees that some wheelchairs may not perform as well as others in a crash situation. However, after reviewing the comments, the agency remains convinced that it is inappropriate to include requirements applicable to wheelchairs and other mobile seating devices that may be used on school buses. Any attempt to do so would lead to extensive delays in this rulemaking, since there are no recognized performance requirements for such devices. Moreover, the agency does not have authority to regulate wheelchairs as such, since they are not "motor vehicle equipment" within the meaning of section 102(4) of the Safety Act. The agency has the authority to impose performance requirements on seating devices that are designed specifically for use on vehicles, as it has done with respect to certain child restraint systems (see, Standard No. 213, *Child Restraint Systems*). However, most wheelchairs are not designed for use in motor vehicles. Their use in vehicles is incidental to their primary function of providing mobility.

8. Definition of "School Bus Passenger Seat"

The NPRM proposed to delete references to other than forward-facing seating locations in the existing definition of school bus passenger seat.

While many commenters concurred with the proposed definition of "school bus passenger seat," some commenters objected to this change for the same reasons discussed above in the section on wheelchair orientation. These commenters stated that some students in wheelchairs should be transported in a side-facing position and local school districts should have this option.

The proposed change to the definition of "school bus passenger seat," by removing the exception for side-facing seats, was intended to ensure that S5.1's requirement for forward-facing orientation applies to all of the standard bench seats on school buses. None of the commenters submitted any information indicating a need for a seat (as distinguished from a wheelchair) that is side-facing. Providing occupant crash protection to school bus passengers by means of adjacent bench seats in school buses, i.e., through "compartmentalization," is premised on forward-facing seats.

Therefore, to ensure that crash protection is provided for all passengers in a school bus, the exception for side-facing seats is removed in this final rule.

9. School Bus Capacity

The NPRM discussed the Eleventh National Conference on School Transportation's standard that requires any vehicle that would have been a school bus if equipped with regular bench seats (i.e., which is intended for carrying students and has a capacity of 10 or more passengers plus a driver), to continue to be considered a school bus even if its capacity dropped to less than 10 because bench seats were removed to install wheelchair locations. The NPRM noted that the agency believes that the majority of vehicles used to transport persons in wheelchairs are vehicles which, when equipped with regular, forward-facing bench seating, have sufficient numbers of seating positions to be classified as school buses. The agency discussed its concern that if the capacity of these buses were "reduced" during manufacturing by the installation of wheelchair locations instead of bench seats, the vehicles would be classified as multipurpose passenger vehicles (MPVs). As such, the vehicle would not be subject to this final rule. The agency requested comment on the size and capacity of vehicles used to transport students in wheelchairs. The agency also requested comment on extending the wheelchair securement/occupant restraint requirements to MPVs.

Only Washington State commented on this issue. It believed that the capacity of the school bus should be based on its maximum capacity, not one that is reduced by removing seats. It noted that "(i)t makes no sense for a

vehicle manufactured with intentions to be a school bus, to not have to meet all school bus standards. * * * When seats are left out of buses (for what ever reason), the potential seating positions should be counted as the maximum number. This would insure that no school bus with a reduced capacity would be classified as an MPV and therefore not technically have to meet school bus requirements."

"School bus" is defined as a motor vehicle designed for carrying more than 10 persons for the purpose of transporting students to and from school and related events. If a final stage manufacturer or dealer reduces the passenger capacity of a new bus to less than 10 before the vehicle is sold or delivered to the owner, that manufacturer or dealer is considered an "alterer" under NHTSA regulations. By so reducing the passenger capacity, the alterer is changing the vehicle from a school bus to an MPV. Accordingly, the alterer would be required to certify that the vehicle complies with all of the Federal safety standards applicable to MPV's.

NHTSA remains concerned that, if disabled students are transported in vehicles which are large enough to be classified as a school bus if equipped with bench seats, but which are classified as MPVs due to a reduction in capacity, those students may not be receiving all the protections offered by a school bus. However, NHTSA would like to address this issue in a separate rulemaking where it will receive more focused attention. Therefore, NHTSA will issue a notice of proposed rulemaking addressing MPV's used to transport children to school in the near future.

10. Retractors on Occupant Restraint Devices

The NPRM asked about the use of retractors to keep belts clean and stored, and the impact of retractors on use.

Many commenters agreed that storage and cleanliness of the occupant restraint system was important, as people will often refuse to use the restraint if the belts are dirty. However, commenters disagreed on whether the best approach was retractable belts or a storage compartment for the belts when not in use. Commenters agreed that retractors are not practical for floor-mounted wheelchair securement systems as these could interfere with movement of the wheelchair.

Based on these comments, the agency does not believe retractors or other means of keeping any parts of a wheelchair securement device or occupant restraint system clean and stored should be mandated. However, the agency does believe that securement/restraint manufacturers should strive to devise means of keeping such systems neat and clean, while ensuring ease of use.

11. Extension to Other Vehicles

The NPRM asked for comment on the desirability of extending these requirements to non-school buses. All of the commenters who addressed this issue supported extending these requirements to other vehicles.

Despite these comments, NHTSA is not extending these requirements to vehicles other than school buses at this time. While commenters supported the idea of extending these requirements to other vehicles, none of the commenters provided information on whether these requirements are practicable for other vehicle types. The system envisioned that would meet the requirements of the final rule would require assistance to secure a wheelchair and/or occupant. Such systems may not be practicable in other vehicles where the driver may not be available for assisting in securing a wheelchair.

12. Definition of "Wheelchair Securement Device"

The MossRehab Driving School for Disabled commented that the Terminology Task Force of the SAE Adaptive Devices Committee issued a set of definitions in June 1991 that apply to adaptive devices utilized in vehicles by persons with disabilities. The purpose of the SAE definitions is "to facilitate and encourage: (a) Utilization of consistent and understandable terminology in the preparation of related standards documents, and; (b) communication between individuals from diverse backgrounds involved in this field." It asked the agency to consider the SAE's definitions for Wheelchair Tie-Down and Occupant Restraint System, Wheelchair Tie-Down, and Anchorage.

After reviewing the SAE definitions and the proposed definitions in the NPRM, the agency believes the NPRM definitions incorporate nearly all of the elements of the SAE definitions. The agency's definitions, however, are generally more specific, which is necessary to ensure that such definitions are explicit enough to be objective.

For example, the SAE defines "anchorage" as "(t)he final point of attachment for transferring seat belt assembly or wheelchair tie-down loads." The NPRM defined "wheelchair occupant restraint anchorage" and "wheelchair securement anchorage" as "the provision for transferring wheelchair occupant restraint system loads to the vehicle structure" and "the provision for transferring wheelchair securement device loads to the vehicle structure", respectively. These definitions were based on the new definition of "seat belt anchorage" in Standard No. 210, *Seat belt assembly anchorages*. See, 56 FR 63682; December 5, 1991. These definitions are intended to make it clear that, in addition to the final attachment point, any part or component that transfers loads to the vehicle structure is part of the anchorage. The definitions of "wheelchair occupant restraint anchorage" and "wheelchair securement anchorage" in the NPRM would include, but not be limited to, the securement and restraint attachment hardware, the track, and the hardware for attaching the track to the floor.

The SAE defined "Wheelchair Tie-Down" as a device "which secures the occupied wheelchair to the vehicle structure." This differs from the NPRM definition which states that a wheelchair securement device is used "for securing a wheelchair in place in a school bus." The agency believes the SAE definition more closely parallels the definition of wheelchair securement anchorage, and the final rule therefore incorporates this language.

13. Miscellaneous

For the convenience of the reader, the preamble uses U.S. units of weights and measurements since these units were used in the NPRM. However, pursuant to E.O. 12770 (56 FR 35801; July 29, 1991), the agency is in the process of converting all safety standards to metric units. Therefore, metric equivalents, rounded to the nearest whole unit, are used in the regulatory text of this notice and will be used throughout future Standard No. 222 notices.

This final rule does not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (Safety Act; 15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety standard is in effect, a state or political subdivision may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state or local requirement imposes a higher level of performance and applies only to vehicles procured for its own use. Section 105 of the Safety Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require

submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has examined the cost impacts of this rulemaking action and determined that the final rule is not major within the meaning of E.O. 12291. However, it is "significant" within the meaning of the Department of Transportation's regulatory policies and procedures because of the public interest associated with this rulemaking action. The agency has prepared a Final Regulatory Evaluation (FRE) for this final rule, and placed a copy of the FRE in the public docket for this rulemaking action. A copy of the FRE may be obtained by writing to: Docket Section, NHTSA, room 5109, 400 Seventh Street, SW., Washington, DC 20590.

NHTSA has determined that the primary consumer cost for this final rule is the cost associated with lost capacity due to the forward-facing wheelchair requirement. Many states have already mandated the forward-facing orientation, therefore, only 24 states will be affected by this requirement. NHTSA has estimated that 2,545–2,561 new school buses will be affected by this requirement, at a cost of $822–$1,035 per vehicle, for a total annual consumer cost of $2,104,820–$2,633,670.

Regulatory Flexibility Act

NHTSA has also considered the impacts of this rulemaking action under the Regulatory Flexibility Act. This analysis appears in the FRE. Based on this evaluation, I certify that the proposed amendments will not have a significant economic impact on a substantial number of small entities.

The cost of a new school bus is expected to increase only nominally because of this final rule. The anticipated cost of $822–$1,035 represents 2–3% of the weighted cost ($36,100) of a new school bus. Therefore, NHTSA does not anticipate either a negative impact on sales from this final rule, or a significant increase on the amount states currently spend on transporting students.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. No. 96–511), there are no requirements for information collection associated with this amendment.

National Environmental Policy Act

NHTSA also has analyzed this rulemaking action for the purpose of the National Environmental Policy Act. The agency has determined that implementation of this action will not have any significant impact on the quality of the human environment.

Executive Order 12612 (Federalism)

Finally, NHTSA has analyzed this final rule in accordance with the principles and criteria contained in E.O. 12612, and the agency has determined that this final rule does not have significant federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

In consideration of the foregoing, 49 CFR part 571 is amended as follows:

1. The authority citation for part 571 of title 49 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407, delegation of authority at 49 CFR 1.50.

§ 571.222 [Amended]

2. S4 of § 571.222 is amended by revising the definition of *school bus passenger seat* and adding new definitions of *wheelchair, wheelchair occupant restraint anchorage, wheelchair securement anchorage*, and *wheelchair securement device*, in alphabetical order to read as follows:

* * * * *

School bus passenger seat means a seat in a school bus, other than the driver's seat.

Wheelchair means a wheeled seat frame for the support and conveyance of a physically disabled person, comprised of at least a frame, seat, and wheels.

Wheelchair occupant restraint anchorage means the provision for transferring wheelchair occupant restraint system loads to the vehicle structure.

Wheelchair securement anchorage means the provision for transferring wheelchair securement device loads to the vehicle structure.

Wheelchair securement device means a strap, webbing or other device used for securing a wheelchair to the school bus, including all necessary buckles and other fasteners.

* * * * *

3. New sections 5.4 through S5.4.4(b) are added to § 571.222 to read as follows:

S5.4 Each school bus having one or more locations designed for carrying a person seated in a wheelchair shall comply with S5.4.1 through S5.4.4 at each such wheelchair location.

S5.4.1 *Wheelchair securement anchorages.* Each wheelchair location shall have not less than four wheelchair securement anchorages complying with S5.4.1.1 through S5.4.1.3.

S5.4.1.1 Each wheelchair securement anchorage shall have a wheelchair securement device complying with S5.4.2 attached to it.

S5.4.1.2 The wheelchair securement anchorages at each wheelchair location shall be situated so that—

(a) A wheelchair can be secured in a forward-facing position.

(b) The wheelchair can be secured by wheelchair securement devices at two locations in the front and two locations in the rear.

(c) The front wheel of a three-wheeled wheelchair can be secured.

S5.4.1.3 Each wheelchair securement anchorage shall be capable of withstanding a force of 13,344 Newtons applied as specified in paragraphs (a) through (d) of this section. When more than one securement device share a common anchorage, the anchorage shall be capable of withstanding a force of 13,344 Newtons multiplied by the number of securement devices sharing that anchorage.

(a) The initial application force shall be applied at an angle of not less than 30 degrees, but not more than 60 degrees, measured from the horizontal. (See Figure 4.)

(b) The horizontal projection of the force direction shall be within a horizontal arc of ±45 degrees relative to a longitudinal line which has its origin at the anchorage location and projects rearward for an anchorage whose wheelchair securement device is intended to secure the front of the wheelchair and forward for an anchorage whose wheelchair securement device is intended to secure the rear of the wheelchair. (See Figure 4.)

(c) The force shall be applied at the onset rate of not more than 133,440 Newtons per second.

(d) The 13,344 Newton force shall be attained in not more than 30 seconds, and shall be maintained for 10 seconds.

S5.4.2 *Wheelchair securement devices.* Each wheelchair securement device shall—

(a) If incorporating webbing or a strap—

(1) Comply with the requirements for Type 1 safety belt systems in S4.2, S4.3,

and S4.4(a) of FMVSS No. 209, *Seat Belt Assemblies*; and

(2) Provide a means of adjustment to remove slack from the device.

(b) If not incorporating webbing or a strap, limit movement of the wheelchair through either the equipment design or a means of adjustment.

S5.4.3 *Wheelchair occupant restraint anchorages.*

S5.4.3.1 Each wheelchair location shall have:

(a) Not less than one anchorage for the upper end of the upper torso restraint; and

(b) Not less than two floor anchorages for wheelchair occupant pelvic and upper torso restraint.

S5.4.3.2 Each wheelchair occupant restraint floor anchorage shall be capable of withstanding a force of 13,344 Newtons applied as specified in paragraphs (a) through (d). When more than one wheelchair occupant restraint share a common anchorage, the anchorage shall be capable of withstanding a force of 13,344 Newtons multiplied by the number of occupant restraints sharing that anchorage.

(a) The initial application force shall be applied at a angle of not less than 45 degrees, but not more than 80 degrees, measured from the horizontal. (See Figure 5.)

(b) The horizontal projection of the force direction shall be within a horizontal arc of ±45 degrees relative to a longitudinal line which has its origin at the anchorage and projects forward. (See Figure 5.)

(c) The force shall be applied at an onset rate of not more than 133,440 Newtons per second.

(d) The 13,344 Newton force shall be attained in not more than 30 seconds, and shall be maintained for 10 seconds.

(e) When a wheelchair securement device and an occupant restraint share a common anchorage, including occupant restraint designs that attach the occupant restraint to the securement device or the wheelchair, the loads specified by S5.4.1.3 and S5.4.3.2 shall be applied simultaneously, under the conditions specified in S5.4.3.2 (a) and (b). (See Figure 6.)

S5.4.3.3 Each anchorage for a wheelchair occupant upper torso restraint shall be capable of withstanding a force of 6,672 Newtons applied as specified in paragraphs (a) through (d).

(a) The initial application force shall be applied at a vertical angle of not less than zero degrees, but not more than 40 degrees, below a horizontal plane which passes through the anchorage. (See Figure 7.)

(b) The projection of the force direction onto the horizontal plane shall be within zero degrees and 45 degrees as measured from a longitudinal line with its origin at the anchorage and projecting forward. (See Figure 7.)

(c) The force shall be applied at the onset rate of not more than 66,720 Newtons per second.

(d) The 6,672 Newton force shall be attained in not more than 30 seconds, and shall be maintained for 10 seconds.

S5.4.4 *Wheelchair occupant restraints.*

(a) Each wheelchair location shall have wheelchair occupant pelvic and upper torso restraints attached to the anchorages required by S5.4.3.

(b) Each wheelchair occupant restraint shall comply with the requirements for Type 2 safety belt systems in S4.2, S4.3, and S4.4(b) of FMVSS No. 209, *Seat Belt Assemblies.*

4. New Figures 4 through 7 are added, to appear at the end of the text of § 571.222, as follows:

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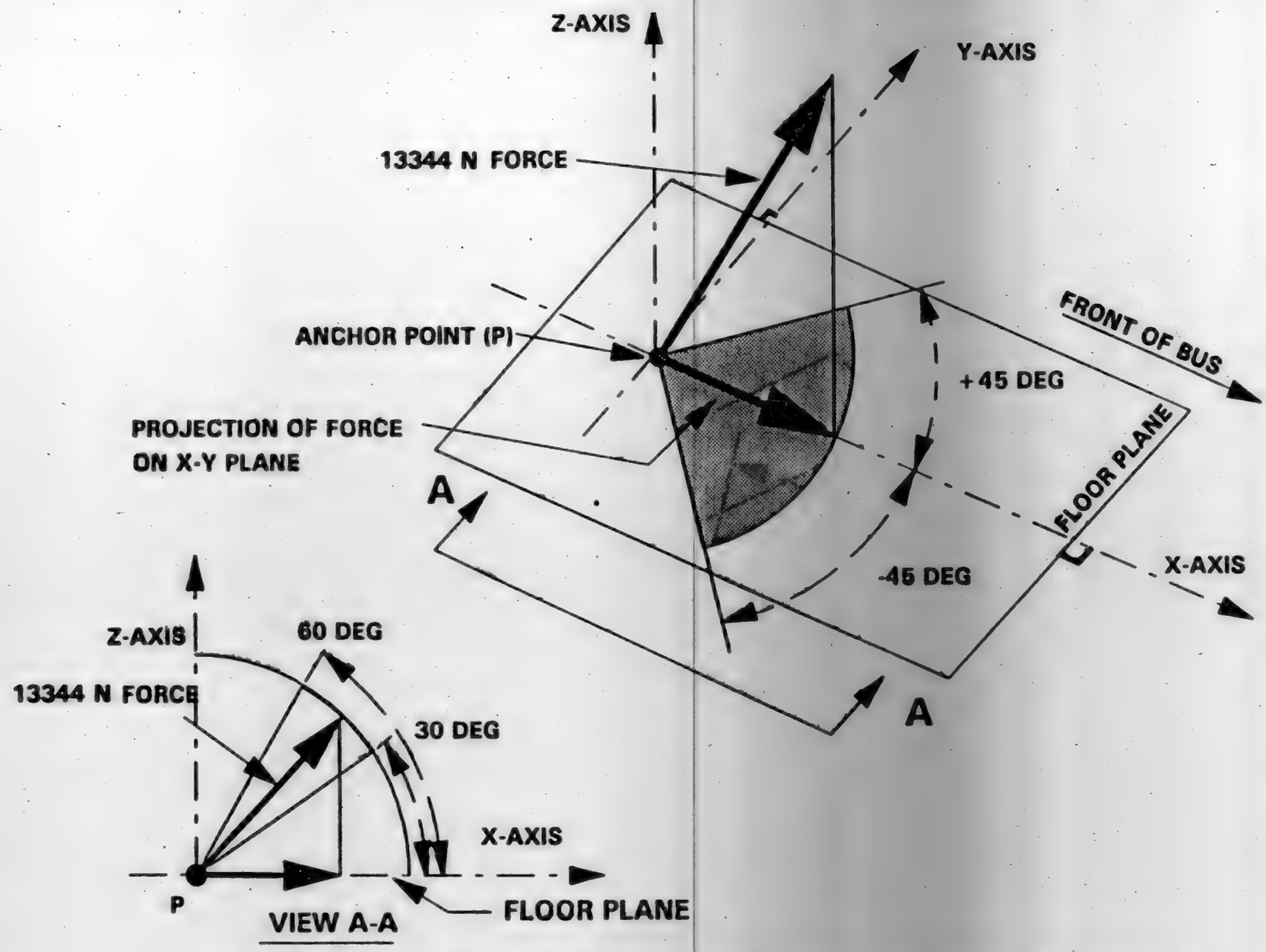

Figure 4. Wheelchair Securement Anchorage Loading Direction (Rear Anchorage Shown)

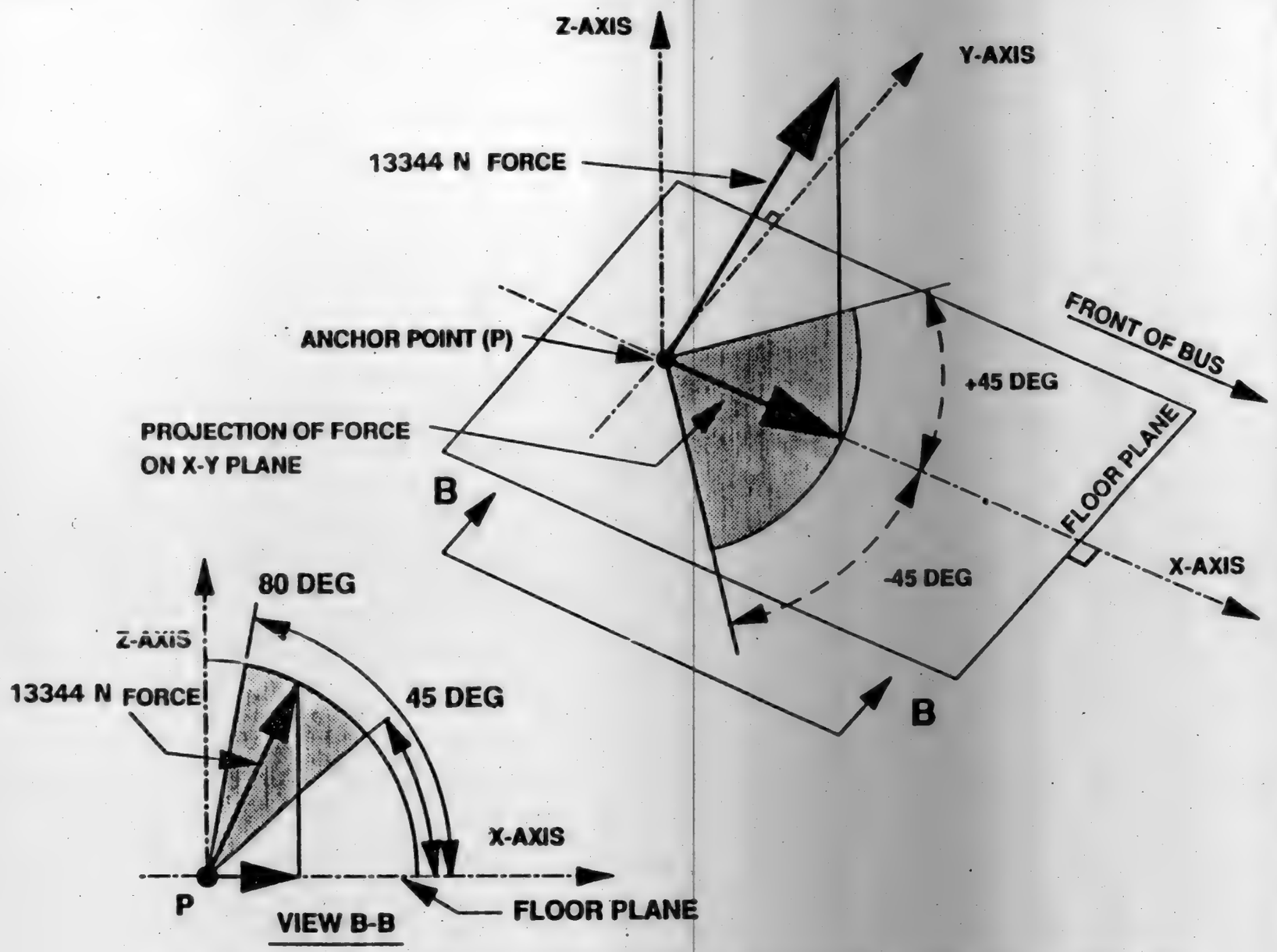

Figure 5. Pelvic Restraint Anchorage Loading Direction

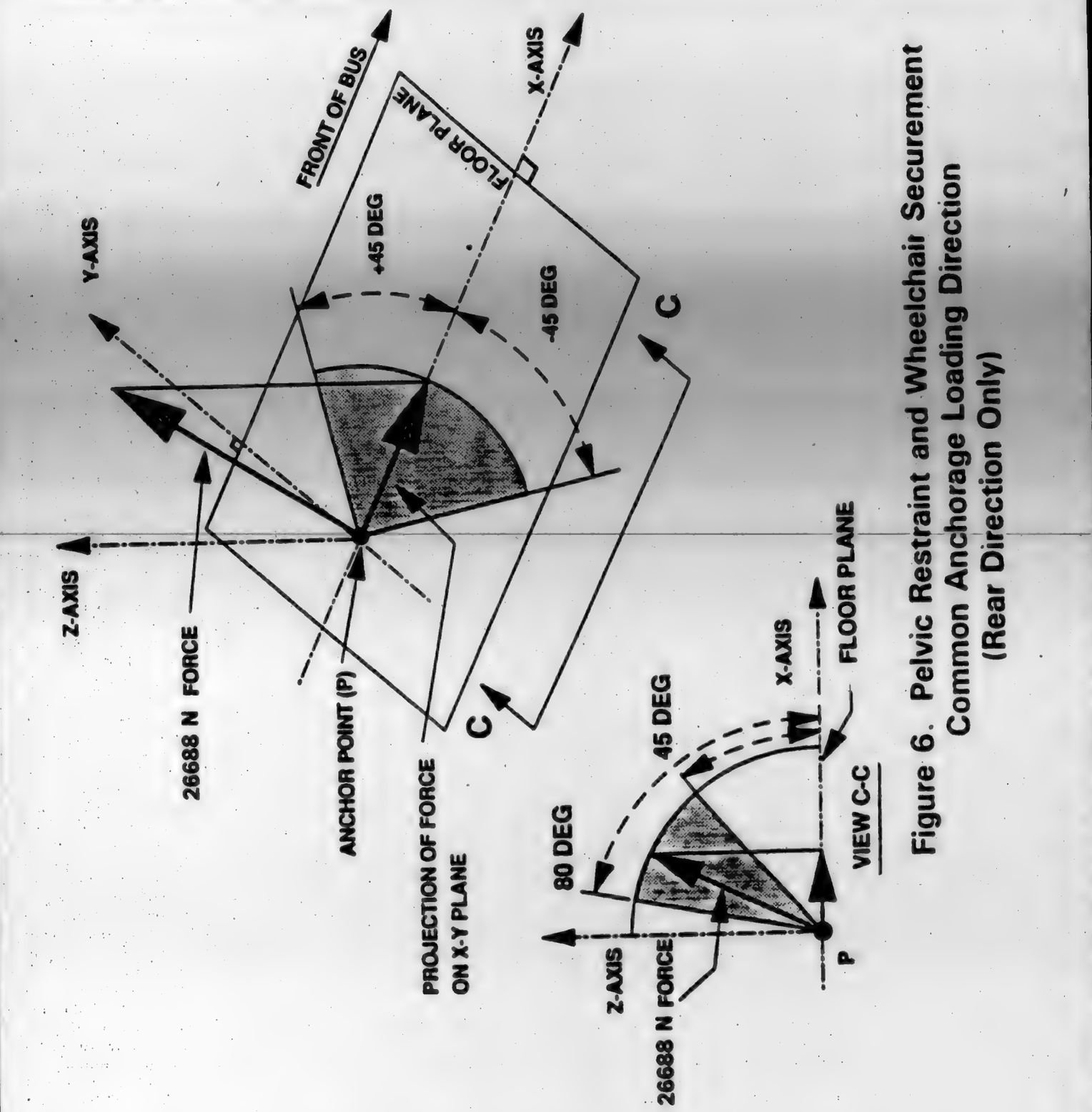

Figure 6. Pelvic Restraint and Wheelchair Securement Common Anchorage Loading Direction (Rear Direction Only)

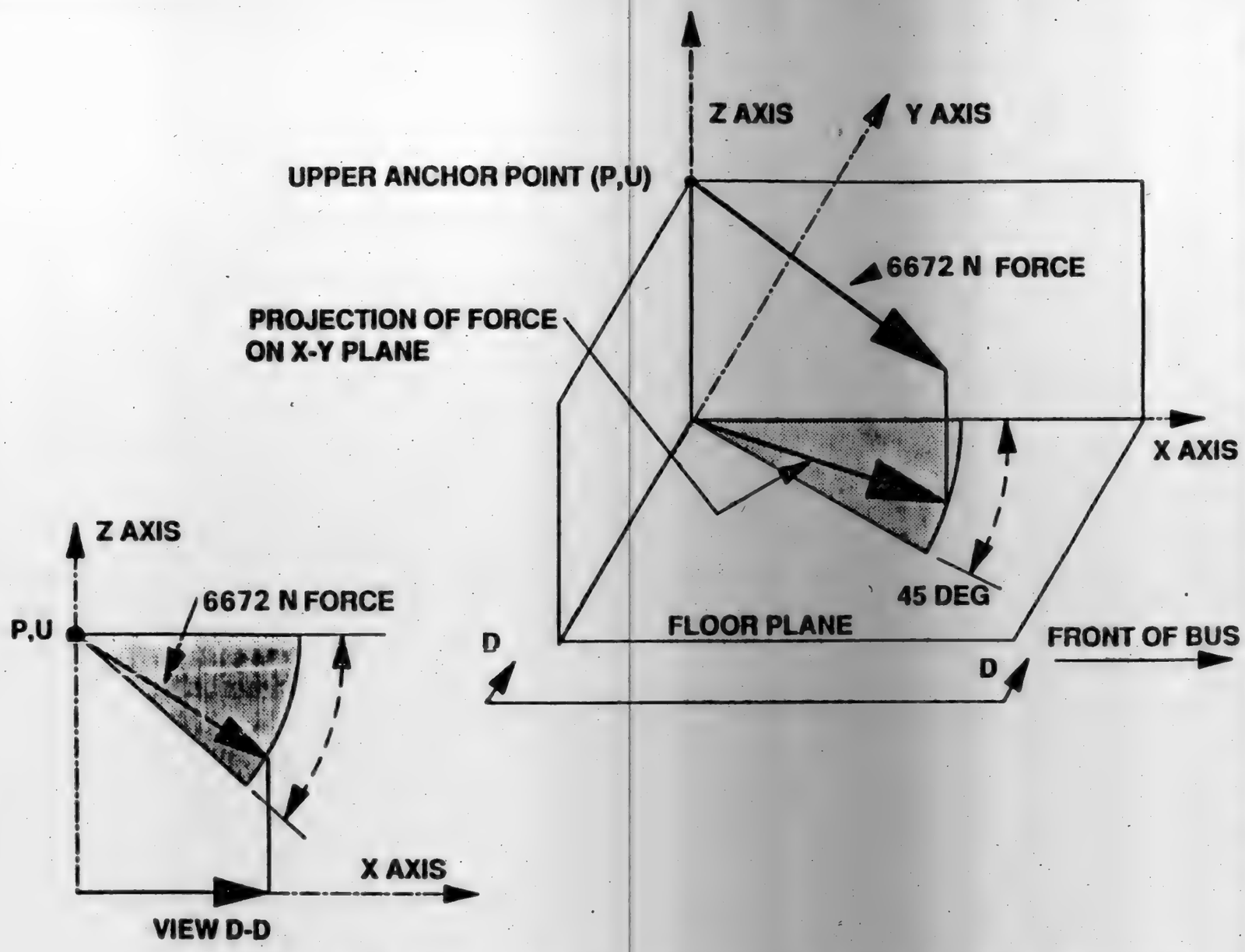

Figure 7. Upper Torso Restraint and Torso Harness Anchorage Loading Location

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Issued on January 12, 1993.

Marlen C. Blakey,

Administrator.

[FR Doc. 93–1060 Filed 1–14–93; 8:45 am]

BILLING CODE 4010-22-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 642

[Docket No. 920246–2228]

Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Closure of commercial fishery for king mackerel.

SUMMARY: NMFS closes the commercial fishery in the exclusive economic zone (EEZ) for king mackerel from the eastern zone of the Gulf migratory group. NMFS has determined that the commercial quota for Gulf group king mackerel from the eastern zone was reached on January 8, 1993. This closure is necessary to protect the overfished Gulf king mackerel resource.

EFFECTIVE DATES: Closure is effective on January 13, 1993, through June 30, 1993.

FOR FURTHER INFORMATION CONTACT: Mark F. Godcharles, 813–893–3161.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic, prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils), and its implementing regulations at 50 CFR part 642, under the authority of the Magnuson Fishery Conservation and Management Act.

Catch limits recommended by the Councils and implemented by NMFS for the Gulf of Mexico migratory group of king mackerel for the current fishing year (July 1, 1992, through June 30, 1993) set the commercial allocation at 2.50 million pounds (1.13 million kg) divided into quotas of 1.73 million pounds (0.78 million kg) for the eastern zone and 0.77 million pounds (0.35 million kg) for the western zone. The boundary between the eastern and western zones is a line directly south from the Florida/Alabama boundary (87°31′06″ W. longitude) to the outer limit of the EEZ.

Under § 642.26(a), NMFS is required to close any segment of the king mackerel commercial fishery when its allocation or quota has been reached, or is projected to be reached, by publishing a notice in the **Federal Register**. NMFS has determined that the commercial quota of 1.73 million pounds (0.78 million kg) for the eastern zone of Gulf migratory group of king mackerel was reached on January 12, 1993. Hence, the commercial fishery for Gulf group king mackerel from the eastern zone is closed effective 6:00 a.m., local time, January 13, 1993, through June 30, 1993, the end of the fishing year.

NMFS previously determined that the commercial quota of 0.77 million pounds (0.35 million kg) of king mackerel from the western zone was reached on October 17, 1992, and closed that segment of the fishery on October 18, 1992 (57 FR 47998, October 21, 1992). Thus, with the closure of the commercial fishery in the eastern zone, all commercial fisheries are closed for Gulf migratory group king mackerel in the EEZ through June 30, 1993.

Except for a person aboard a charter vessel, during the closure, no person aboard a vessel permitted to fish under a commercial allocation may fish for, retain, or have in possession in the EEZ Gulf migratory group king mackerel. A person aboard a charter vessel may continue to fish for Gulf migratory group king mackerel under the bag and possession limits set forth in § 642.24 (a)(1)(i) and (a)(2), provided the vessel is operating as a charter vessel and the vessel has an annual charter vessel permit, as specified in § 642.4(a)(2). A charter vessel with a permit to fish on a commercial allocation is operating as a charter vessel when it carries a passenger who pays a fee or when there are more than three persons aboard, including operator and crew.

During the closure, Gulf migratory group king mackerel taken in the EEZ, including those harvested under the bag limit, may not be purchased, bartered, traded, or sold or attempted to be purchased, bartered, traded, or sold. This prohibition does not apply to trade in king mackerel of the Gulf migratory group that were harvested, landed, and bartered, traded, or sold prior to the closure and held in cold storage by a dealer or processor.

Classification

This action is required by 50 CFR 642.26(a) and complies with E.O. 12291.

Authority: 16 U.S.C. 1801 *et seq.*

List of Subjects in 50 CFR Part 642

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: January 12, 1993.

Richard H. Schaefer,

Director of Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93–1072 Filed 1–12–93; 3:05 pm]

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Proposed Rules

Federal Register
Vol. 58, No. 10
Friday, January 15, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Parts 5 and 16

[Docket No. 92-22]

RIN 1557-AA65

Securities Offering Disclosure Rules

AGENCY: Office of the Comptroller of the Currency, Treasury.

ACTION: Proposed rulemaking; extension of comment period.

SUMMARY: This document extends until February 1, 1993, the Office of the Comptroller of the Currently (OCC) deadline for submission of comments on the proposal to amend its regulations governing the offer and sale of national bank securities.

DATES: Comments must be received on or before February 1, 1993.

ADDRESSES: Comments should be directed to: Communications Division, Office of the Comptroller of the Currency, Independence Square; 250 E Street, SW., Washington, DC 20219, Attention: Docket No. 92-22. Comments will be available for public inspection and photocopying at the same location.

FOR FURTHER INFORMATION CONTACT: Elizabeth Malone, Senior Attorney, Securities, Investments, and Fiduciary Practices Division, (202) 874-5210.

SUPPLEMENTARY INFORMATION: The OCC published a notice of proposed rulemaking concerning its securities regulations in 12 CFR parts 5 and 16 in the **Federal Register** on October 15, 1992 (57 FR 47280). Comments were to be received on or before December 14, 1992.

Several potential commenters have called and requested additional time to prepare and submit comments. The OCC wants to provide interested persons with adequate time to analyze the proposal and to develop meaningful comments regarding the complex issues involved Comments received will be used in developing the final rule. Therefore, the OCC is extending the comment period to February 1, 1993. The OCC urges any interested persons to file comments regarding the proposal by February 1, 1993.

Dated: December 14, 1992.

Stephen R. Steinbrink,

Acting Comptroller of the Currency.

[FR Doc. 93-1039 Filed 1-14-93; 8:45 am]

BILLING CODE 4810-33-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92-NM-136-AD]

Airworthiness Directives; Rigging Innovations, Inc., Skyhook Reserve Pilotchutes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Skyhook Reserve Pilotchutes. This proposal would require testing the pilotchutes to verify their spring tension, and modification of the pilotchutes, if necessary. This proposal is prompted by an incident of total pack closure of the reserve pilotchute. This condition, if not corrected, could result in failure of the reserve pilotchute to deploy, which would prevent safe descent of the parachutist.

DATES: Comments must be received by March 15, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM-103, Attention: Rules Docket No. 92-NM-136-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Rigging Innovations, Inc., 236 East 3rd Street, Perris, California 92570. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3229 East Spring Street, Long Beach, California.

FOR FURTHER INFORMATION CONTACT: Mr. Mauricio J. Kuttler, Aerospace Engineer Los Angeles Aircraft Certification Office, ANM-131L, FAA Transport Airplane Directorate, 3229 East Spring Street, Long Beach, California 90806-2425; telephone (310) 988-5355; fax (310) 988-5210.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92-NM-136-AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM-103, attention: Rules Docket No. 92-NM-136-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

The FAA has been advised of an incident involving a Skyhook Reserve Pilotchute in which the total pack closure of the main chute occurred. The main chute was equipped with a pull-out deployment system. Upon activating the reserve chute ripcord, the parachutist experienced a pack closure on the reserve chute. After the parachutist reached back and pulled on the container, the reserve chute deployed at approximately 400 feet above ground level. This resulted in a total inversion of the round reserve chute and caused extensive damage to its canopy. The parachutist landed safely. Subsequent to this incident, the equipment was taken to the harness/container manufacturer for examination. Testing indicated that the cause of the problem was a sub-standard spring in the pilotchute. The manufacturer has determined that spring tension less than 18 lbs. is sub-standard. This condition, if not corrected, could result in failure of the pilotchute to deploy, which would prevent safe descent of the parachutist.

The FAA has reviewed and approved Rigging Innovations Service Bulletin 1513, Revision A, dated June 22, 1992, that describes procedures for testing the pilotchutes to verify their spring tension, and modification of the pilotchutes, if necessary.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require testing the pilotchutes to verify their spring tension, and modification of the pilotchutes, if necessary. The actions would be required to be accomplished in accordance with the service bulletin described previously.

There are approximately 3,194 Skyhook Reserve Pilotchutes of the affected design worldwide. The FAA estimates that 2,750 pilotchutes in the U.S. would be affected by this proposed AD, that it would take approximately 1.5 work hours per pilotchute to accomplish the proposed actions, and that the average labor rate is $55 per work hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $226,875, or $83 per pilotchute.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Rigging Innovations, Inc: Docket 92–NM–136–AD.

Applicability: Skyhook Reserve Pilotchutes, part number 2233–( ), serial numbers 2405 through 5551, inclusive; certificated in any category.

Compliance: Required as indicated, unless accomplished previously. To ensure safe descent of the parachutist, accomplish the following:

(a) Within 120 days after the effective date of this AD, conduct a field pilotchute spring test, testing procedure TP–19P001, in accordance with Attachment A of Rigging Innovations Service Bulletin 1513, Revision A, dated June 22, 1992. The minimum spring tension allowable for passing the test is 18 lbs.

(1) If the pilotchute passes the test, mark "SB–1513A" on the cap in indelible ink, along with the date of the test. The pilotchute may then be returned to service.

(2) If the pilotchute fails the test, the pilotchute must be removed from service. Prior to any further use of the pilotchute, it must be modified according to Rigging Innovations Product Modification Procedure PMP–1213. Once it is modified, it may be returned to service.

(b) Within 10 days after completion of the test required by paragraph (a) of this AD, the operator must notify Rigging Innovations, Inc., of all test results. The following information is to be included: serial number of the Skyhook pilotchute, results of the test including the tension of the spring, date of the test, and name and qualification of the person performing the test. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Issued in Renton, Washington, on January 11, 1993.

N. B. Martenson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–1042 Filed 1–14–93; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Chapter IX

Natural Resource Damage Assessments Under the Oil Pollution Act of 1990

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Advance notice of proposed rulemaking, extension of comment period and release of contingent valuation methodology report.

SUMMARY: On March 13, 1992 (57 FR 8964), NOAA provided a status report of the proposed rulemaking concerning the natural resource damage assessment and restoration regulations required by the Oil Pollution Act of 1990 (OPA). NOAA has extended the comment period concerning nonuse values and the use of contingent valuation methodology (CVM) several times. This document further extends that comment period

from December 10, 1992, to January 15, 1993. Through this document, NOAA is also releasing the report provided by the Contingent Valuation Panel requested by NOAA to evaluate the use of CVM.

DATES: Comments concerning the calculation of nonuse values must be received no later than January 15, 1993.

ADDRESSES: Comments to Randall Luthi, Project Manager, or Linda Burlington, Assistant Project Manager, Office of General Counsel-DART, room 422, 6001 Executive Boulevard, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Randall Luthi, telephone (202) 482–1400, or Linda Burlington, Office of General Counsel-DART, NOAA, 6001 Executive Boulevard, room 422, Rockville, Maryland 20852, telephone (301) 227–6332.

SUPPLEMENTARY INFORMATION:

I. Background

The Oil Pollution Act of 1990 (OPA), 33 U.S.C. 2701 *et seq.*, provides for the prevention of, liability for, removal of and compensation for the discharge, or substantial threat of discharge, of oil into or upon the navigable waters of the United States, adjoining shorelines, or the Exclusive Economic Zone. Section 1006(e) requires the President, acting through the Under Secretary of Commerce for Oceans and Atmosphere, to develop regulations establishing procedures for natural resource trustees in the assessment of damages for injury to, destruction of, loss of, or loss of use of natural resources covered by OPA. Section 1006(b) provides for the designation of Federal, State, Indian tribal and foreign natural resource trustees to determine resource injuries, assess natural resource damages (including the reasonable costs of assessing damages), present a claim, recover damages and develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the natural resources under their trusteeship.

NOAA has published seven **Federal Register** Notices, 55 FR 53478 (December 28, 1990) 56 FR 8307 (February 28, 1991), 57 FR 8964 (March 13, 1992) and 57 FR 14524 (April 21, 1992), 57 FR 23067 June 1, 1992), 57 44347 (September 25, 1992) and 57 FR 56292 (November 27, 1992) requesting information and comments on approaches to developing damage assessment procedures. Included in this process was the establishment of a Contingent Valuation Panel (Panel) of economic experts to evaluate the use of CVM in determining nonuse values and provide comments to NOAA. The panel members are: Kenneth Arrow (co-chair), Robert Solow (co-chair), Edward Leamer, Paul Portney, Roy Randner and Howard Schuman. Through this effort, NOAA has attempted to provide an atmosphere in which an unbiased academic analysis of CVM could be conducted. The Panel received hundreds of pages of comments concerning CVM and conducted a public meeting to hear all sides of the issue. The Panel has finished its work and has submitted its report to NOAA. It is included in this document as Appendix I.

The comment period is being extended to allow only this Panel's report and the numerous comments received after the December 10, 1992, deadline through January 15, 1993, to become part of the administrative record accompanying this rulemaking process. This document does not request, nor is NOAA seeking, comments concerning the Panel's report, it is merely making the report available due to the public interest it has generated.

Later this year, NOAA will propose the natural resource damage assessment regulations. At that time, NOAA will also open the comment period on the proposed regulations and how all the comments, including this report, concerning all aspects of damage assessments have been integrated into the proposed regulations.

Authority: Sec. 1006(e), Pub. L. 101–380.

Dated: January 11, 1993.

Thomas A. Campbell,

General Counsel, National Oceanic and Atmospheric Administration.

[FR Doc. 93–1018 Filed 1–14–93; 8:45 am]

BILLING CODE 3510–12–M

Appendix I—Report of the NOAA Panel on Contingent Valuation

January 11, 1993.

I. Introduction

Under the Oil Pollution Act of 1990, the President—acting through the Under Secretary of Commerce for Oceans and Atmosphere—is required to issue regulations establishing procedures for assessing damages to or destruction of natural resources resulting from a discharge of oil covered by the Act. These procedures are to ensure the recovery of restoration costs as well as the diminution in value of the affected resources and any reasonable costs of conducting the damage assessment.

At least some of the values that might be diminished by such a discharge are relatively straightforward to measure through information revealed in market transactions. For instance, if the discharge kills fish and thereby reduces the incomes of commercial fishermen, their losses can reasonably be calculated by the reduce catch multiplied by the market price(s) of the fish (less, of course, any costs they would have incurred). Similarly, if the discharge of oil discourages tourist travel to an area, the lost incomes of those owning and/or operating motels, cottages, or other facilities can be reasonably represented by the difference in revenues between the affected period and a "normal" season. Even the losses to recreational fishermen, boaters, swimmers, hikers, and others who make active use of the areas affected by the discharge can be included in the estimate of diminished value, although these losses will generally be somewhat more difficult to value than the more obvious out-of-pocket losses.

The losses described above have come to be known as lost "use values" because they are experienced by those who, in a variety of different ways, make active use of the resources adversely affected by the discharge. But for at least the last twenty-five years, economists have recognized the possibility that individuals who make no active use of a particular beach, river, bay, or other such natural resource might, nevertheless, derive satisfaction from its mere existence, even if they never intend to make active use of it.

This concept has come to be known as "existence value" and it is the major element of what are now referred to as "non-use" or "passive-use" values (the latter term is employed in the balance of this report). In regulations promulgated by the Department of the Interior in 1986 under the Comprehensive Environmental Response, Compensation, and Liability Act—regulations that also pertained to natural resource damage assessments—passive-use values were included among the losses for which trustees could recover. The inclusion of passive-use values was recently upheld by the D.C. Court of Appeals (*State of Ohio* v. *Department of the Interior*, 880 F.2d 432 (D.C. Cir. 1989)), as long as they could be reliably measured.

This begs an interesting and important question, however. If passive-use values are to be included among the compensable losses for which trustees can make recovery under the Oil Pollution Act, how will they be estimated? Unlike losses to commercial fishermen or recreational property owners, there are no direct market transactions that can be observed to provide information on which estimates can be based. Unlike losses to boaters, swimmers, recreational fishermen and

others, there exist no indirect methods through which market data can provide at lest some clues as to lost values. In other words, there appear to be neither obvious nor even subtle behavioral trails that can provide information about lost passive-use values.

Some experts believe that there exists an approach that can provide useful information about the economic significance of the lost passive-use values individuals may suffer when oil discharges damage natural resources. Known as the contingent valuation (or CV) technique, this approach is based on the direct elicitation of these values from individuals through the use of carefully designed and administered sample surveys. Its appeal lies in its potential to inform damage assessment in an area (lost passive-use values) where there appear to be no behavioral trails to be followed.

Typically, CV studies provide respondents with information about a hypothetical government program that would reduce the likelihood of a future adverse environmental event such as an oil spill, chemical accident, or the like. Respondents are usually given some specific information about the exact nature of the damages that the program in question would prevent. And they are also confronted in the study with a question or questions that provide information about the economic sacrifice they would have to make to support the environmental program. This may take the form of an open-ended question asking what is the maximum amount they would be willing to pay for the program in question; it may involve a series of questions confronting them with different prices for the program depending on their previous answers; or it may take the form of a hypothetical referendum (like a school bond issue) in which respondents are told how much each would have to pay if the measure passed and are then asked to cast a simple "yes" or "no" vote. (The conceptually correct measure of lost passive-use value for environmental damage that has already occurred is the minimum amount of compensation that each affected individual would be willing to accept. Nevertheless, because of concern that respondents would give unrealistically high answers to such questions, virtually all previous CV studies have described scenarios in which respondents are asked to pay to prevent future occurrences of similar accidents. This is the conservative choice because willingness to accept compensation should exceed willingness to pay, if only trivially; we say more about other biases below.)

The CV technique has been used for twenty years or so to estimate passive-use values. In the last five years, however, there has been a dramatic increase in the number of academic papers and presentations related to the CV technique. This is due in part to the availability of comprehensive reference texts on the subject (Mitchell and Carson (1989), for instance), and to the growing interest both nationally and internationally in environmental problems and policies. But it is also attributable to the growing use of the CV technique in estimating lost passive-use values in litigation arising from state and federal statutes designed to protect natural resources. Since *Ohio* v. *Department of the Interior* admitted the concept of passive-use values in damage assessments, this can only give added impetus to the use of CV in such litigation.

The CV technique is the subject of great controversy. Its detractors argue that respondents give answers that are inconsistent with the tenets of rational choice, that these respondents do not understand what it is they are being asked to value (and, thus, that stated values reflect more than that which they are being asked to value), that respondents fail to take CV questions seriously because the results of the surveys are not binding and raise other objections as well. Proponents of the CV technique acknowledge that its early (and even some current) applications suffered from many of the problems critics have noted, but believe that more recent and comprehensive studies have already or soon will be able to deal with these objections.

This (sometimes acrimonious) debate has put the National Oceanic and Atmospheric Administration (NOAA) in a very difficult spot. NOAA must decide in promulgating the regulations under the Oil Pollution Act whether the CV technique is capable of providing reliable information about lost existence or other passive-use values. Toward this end, NOAA appointed the Contingent Valuation Panel to consider this question and make recommendations to it.

This report is the product of the Panel's deliberations and is organized in the following way. Following this introduction, the drawbacks to the CV technique are discussed in Section II. Section III discusses several key issues concerning the design of CV surveys, including use of the referendum format to elicit individual values, ways of addressing the so-called "embedding" problem, and the evaluation of damages that last for some period but not forever. Section IV presents guidelines to which the Panel believes any CV study should adhere if the study is to produce information useful in natural resource damage assessment. (These are elaborated upon in an Appendix.) In Section V a research agenda is described; it is the Panel's belief that future applications of the CV technique may be less time-consuming and contentious if the research described in the agenda is carried out. Section VI presents the Panel's conclusions.

II. Criticisms of the Contingent Valuation Method

The contingent valuation method has been criticized for many reasons and the Panel believes that a number of these criticisms are particularly compelling. Before identifying and discussing these problems, however, it is worth pointing out that they all take on added importance in light of the impossibility of validating externally the results of CV studies. It should be noticed, however, that this same disadvantage must inhere in any method of assessing damages from deprivation of passive-use. It is not special to the CV approach although, as suggested in Section I, there are currently no other methods capable of providing information on these values.

One way to evade this difficulty, at least partially, is to construct experiments in which an artificial opportunity is created to pay for environmental goods. The goods in question can perfectly well involve passive use. Then the results of a CV estimate of willingness to pay can be compared with the "real" results when the opportunity is made available to the same sample or an analogous sample.

A few such experiments have been attempted. The most recent, due to Seip and Strand (1992), used CV to estimate willingness to pay for membership in a Norwegian organization devoted to environmental affairs, and compared this estimate with actual responses when a number of the same respondents were presented with an opportunity actually to contribute. The finding was that self-reported willingness to pay was significantly greater than "actual" willingness to pay. A recent study by Duffield and Patterson (1991) took as the environmental amenity in question the maintenance of stream flow in two Montana rivers. The rivers in question provided spawning grounds for two rare species of fish; passive use was believed to be the main motivation for respondents. One of two parallel samples was asked about hypothetical willingness to contribute to the Montana Nature Conservancy which would then maintain stream flow; the other was offered an opportunity actually to

contribute to the same organization for the same purpose. It was found that response rates and expressed willingness to contribute were significantly higher when the contribution was hypothetical than when "expressed willingness" meant an immediate cash contribution. On the other hand, the size of contributions, hypothetical in one case and actual in the other, was not much different as between those who said they would contribute and those who did so.

These studies suggest that the CV technique is likely to overstate "real" willingness to pay. Duffield and Patterson, however, hold out hope that the differences are small enough and predictable enough that CV estimates could be discounted for possible overstatement and then used as a conservative estimate of willingness to pay. Clearly more such experiments would be useful.

A less direct test of the "reality" of CV estimates of lost passive use values is to use the technique to estimate willingness to pay for ordinary market goods and then to compare the results with actual purchases. This has been tried by Dickie, Fisher, and Gerking (1987) using the demand for strawberries. When the data were re-analyzed by Diamond, Hausman, Leonard, and Denning (1992), it was found that the CV approach tended systematically to overestimate quantity demanded at each price, sometimes by as much as 50 percent. This result has to be qualified in two ways. First, the original CV study seems to have been fairly casual by the standards now proposed by practitioners; pre-testing and improvement of the survey instrument might (perhaps) have narrowed the gap. And second, it seems to go too far to conclude from systematic over-estimation that the CV study, even as conducted, provides no information about the demand for strawberries. Much of the same could be said about a study submitted to the Panel by Cummings and Harrison (1992) comparing hypothetical and demonstrated willingness to pay for small household goods. (See also Bishop and Heberlein (1979).)

External validation of the CV method remains an important issue. A critically important contribution could come from experiments in which state-of-the-art CV studies are employed in contexts where they can in fact be compared with "real" behavioral willingness to pay for goods that can actually be bought and sold.

Of the other problems arising in CV studies, the following are of most concern to the Panel: (i) The contingent valuation method can produce results that appear to be inconsistent with assumptions of rational choice; (ii) responses to CV surveys sometimes seem implausibly large in view of the many programs for which individuals might be asked to contribute and the existence of both public and private goods that might be substitutes for the resource(s) in question; (iii) relatively few previous applications of the CV method have reminded respondents forcefully of the budget constraints under which all must operate; (iv) it is difficult in CV surveys to provide adequate information to respondents about the policy or program for which values are being elicited and to be sure they have absorbed and accepted this information as the basis for their responses; (v) in generating aggregate estimates using the CV technique, it is sometimes difficult determining the "extent of the market;" and (vi) respondents in CV surveys may actually be expressing feelings about public spiritedness or the "warm glow" of giving, rather than actual willingness to pay for the program in question. We discuss each of these briefly.

Inconsistency With Rational Choice

Some of the empirical results produced by CV studies have been alleged to be inconsistent with the assumptions of rational choice. This raises two questions: What requirements are imposed by rationality? Why are they relevant to the evaluation of the reliability of the CV method?

Rationality in its weakest form requires certain kinds of consistency among choices made by individuals. For instance, if an individual chooses some purchases at a given set of prices and income, then if some prices fall and there are no other changes, the goods that the individual would now buy would make him or her better off. Similarly, we would expect an individual's preferences over public goods (i.e., bridges, highways, air quality) to reflect the same kind of consistency.

Common notions of rationality impose other requirements which are relevant in different contexts. Usually, though not always, it is reasonable to suppose that more of something regarded as good is better so long as an individual is not satiated. This is in general translated into a willingness to pay somewhat more for more of a good, as judged by the individual. Also, if marginal or incremental willingness to pay for additional amounts does decline with the amount already available, it is usually not reasonable to assume that it declines very abruptly.

This point assumes importance in view of some empirical evidence from CV studies that willingness to pay does not increase with the good. In one study, Kahneman (1986) found that willingness to pay for the cleanup of all lakes in Ontario was only slightly more than willingness to pay for cleaning up lakes in just one region. Evidence of this kind has multiplied (see Kahneman and Knetch (1992), Desvousges, *et al.* (1992), and Diamond *et al.* (1992)). Desvousges' result is very striking; the average willingness to pay to take measures to prevent 2,000 migratory birds (not endangered species) from dying in oil-filled ponds was as great as that for preventing 20,000 or 200,000 birds from dying. Diminishing marginal willingness to pay for additional protection could be expected to result in some drop. But a drop to zero, especially when the willingness to pay for the first 2,000 birds is certainly not trivial, is hard to explain as the expression of a consistent, rational set to choices.

It has been argued on a more technical level that the studies finding such apparent inconsistencies are defective, that the choices are not presented clearly to the respondents. In the study referred to immediately above, for instance, respondents were told that 2,000 birds was "* * * much less than 1%" of the total migratory bird population while 200,000 birds was "* * * about 2%" of the total. This may have led respondents to evaluate the programs as being essentially the same. But on the face of it, the evidence certainly raises some serious questions about the rationality of the responses.

It could be asked whether rationality is indeed needed. Why not take the values found as given? There are two answers. One is that we do not know yet how to reason about values without some assumption of rationality, if indeed it is possible as all. Rationality requirements impose a constraint on the possible values, without which damage judgments would be arbitrary. A second answer is that, as discussed above, it is difficult to find objective counterparts to verify the values obtained in the response to questionnaires. Therefore, some form of internal consistency is the least we would need to feel some confidence that the verbal answers corresponded to some reality.

Implausibility of Responses

The CV method is generally used to elicit values for a specific program to prevent environmental damage, whether it be dead animals, spoilage of a pristine wilderness area, or loss of visibility in some very unusually clear area. Though

in each case, individuals often express zero willingness to pay, average willingness to pay over the whole sample is often at least a few dollars and frequently $20 to $50. With 100,000,000 households in the United States, these responses result in very large totals, frequently over $1 billion. Some have argued that these large sums are in themselves incredible and cast doubt on the CV method. The Panel is not convinced by this argument, since it is hard to have an intuition as to a reasonable total.

But there is a different problem with these answers. One can envision many possible types of environmental damage—oil spills or groundwater contamination in many different locations, visibility impairment in a variety of places, and so on. Would the average individual or household really be willing to pay $50 or even $5 to prevent each one? This seems very unlikely, since the total resulting willingness to pay for all such programs could easily become a very large fraction of one's income or perhaps even exceed it.

In other words, even if the willingness to pay responses to individual environmental insults are correct if only one program is to be considered, they may give overestimates when there are expected to be a large number of environmental problems. Similarly, if individuals fail to consider seriously the public or private goods that might be substitutes for the resources in question, their responses to questions in a CV survey may be unrealistically large.

Absence of a Meaningful Budget Constraint

Even if respondents in CV surveys take seriously the hypothetical referendum (or other type of) questions being asked them, they may respond without thinking carefully about how much disposable income they have available to allocate to all causes, public and private (see Kemp and Maxwell (1992), for instance). Specifically, respondents might reveal a willingness to pay of, say, $100 for a project that would reduce the risk of an oil spill; but if asked what current or planned expenditures they would forgo to pay for the program, they might instead re-evaluate their responses and revise them downward. This is similar to the problem identified immediately above where individuals fail to think of the possible multiplicity of environmental projects or policies they might be asked to support. To date, relatively few CV surveys have reminded respondents convincingly of the very real economic constraints within which spending decisions must be made.

Information Provision and Acceptance

If CV surveys are to elicit useful information about willingness to pay, respondents must understand exactly what it is they are being asked to value (or vote upon) and must accept the scenario in formulating their responses. Frequently, CV surveys have provided only sketchy details about the project(s) being valued and this calls into question the estimates derived therefrom.

Consider the following example. Suppose information is desired about individuals' willingness to pay to prevent a chemical leak into a river. Presumably, their responses would depend importantly on how long it would take for the chemical to degrade naturally in the river (if it would at all), what ecological and human health damage the chemical would do until it had degraded, and so on. Absent information about such matters, it is unreasonable to expect even very bright and well-informed respondents to place meaningful values on a program to prevent leaks.

Even if detailed information were supplied, there are limits on the ability of respondents to internalize and thus accept and proceed from the information given. It is one thing to tell respondents matter-of-factly that complete recovery will occur in, say, two years. It is another thing for them to accept this information completely and then incorporate it in their answers to difficult questions.

To return to the example above, respondents who take a pessimistic view of the probable consequences of a chemical leak are likely to report relatively high willingness to pay to prevent the contamination—too high, in fact if in actuality such an event had less serious effects. On the other hand, respondents with an exaggerated sense of the river's assimilative capacity or regenerative power could be expected to report a willingness to pay that understates their "true" valuation if provided with a more complete description of likely consequences.

To repeat, even when CV surveys provide detailed and accurate information about the effects of the program being valued, respondents must accept that information in making their (hypothetical) choices. If, instead, respondents rely on a set of heuristics ("these environmental accidents are seldom as bad as we're led to believe," or "authorities almost always put too good a face on these things"), in effect they will be answering a different question from that being asked; thus, the resulting values that are elicited will not reliably measure willingness to pay.

Extent of the Market

Suits for environmental damages are brought by trustees on behalf of a legally definable group. This group limits the population that is appropriate for determining damages even though individuals outside of this group may suffer loss of passive and active use. Undersampling and zero sampling of a subgroup of the relevant population may be appropriate if the subgroup has a predictably low valuation of the resource. For example, the authors of the CV study conducted in connection with the Nestucca oil spill limited their sample to households in Washington and British Columbia possibly because the individuals living elsewhere were presumed to have values too low to justify examination (or possibly because the sponsors of the study were agencies of the State of Washington and the province of British Columbia and so defined the legally appropriate population) (Rowe, Shaw, and Schulze, 1992).

"Warm Glow" Effects

Some critics of the CV technique (e.g., Diamond and Hausman (1992)) have observed that the distribution of responses to open-ended questions about willingness to pay often is characterized by a significant proportion of "zeros"—people who would pay nothing for the program—and also a number of sizable reports. This bi-modal distribution also characterizes individual giving: Most of us give nothing to most charities, but give non-trivial amounts to the ones we do support (at least $10 or $20, say). This has led these critics to conclude that individuals' responses to CV questions serve the same function as charitable contributions—not only to support the organization in question, but also to feel the "warm glow" that attends donating to worthy causes (see Andreoni (1989)). If this is so, CV responses should not be taken as reliable estimates of true willingness to pay, but rather as indicative of approval for the environmental program in question.

III. Key Issues in the Design of Contingent Valuation Instruments

In the course of its deliberations, the Panel discussed many issues surrounding the design of CV surveys. Here we provide our views on several issues that are especially important. In Section IV and in an Appendix to this report, we provide much greater detail on the characteristics of a valid application of the CV method.

The Referendum Format

Considered as a survey, a CV instrument is descriptive rather than explanatory. Description may be as simple as reporting univariate averages of one kind or another, such as the percentages of those employed, seeking work, and not seeking work in the United States, the mean number of rooms occupied by American households, or the proportion of "likely" voters favoring one or another candidate in an upcoming election. A CV study seeks to find the average willingness to pay for a specific environmental improvement. Nevertheless, as will be seen later, it is often desirable to ask respondents to specify the reasons for their reported choices.

Univariate descriptive results are meaningful mainly when the alternative responses to a question are simple and can be well specified and there is a high consensus among both respondents and investigators about the precise meaning of the questions and answers. In some cases where consensus would initially not be adequate, simple definitions can be added to a questionnaire to attain satisfactory agreement—e.g., in asking people how many rooms they have in their homes, one states whether bathrooms, basements, etc. are to be included in the count; most respondents will conform to this specification.

With questions about subjective phenomena, such as attitudes and values, treating answers as simply descriptive is seldom meaningful. Too much depends on how questions are worded, and there is neither sufficient social consensus about precise meaning, nor an external reference to facilitate such consensus. There are many examples in the survey literature of how changes in wording or context will affect results based on questions about subjective phenomena (see Schuman and Presser (1981)). For example, in national surveys close to a quarter of the population will choose the "don't know" response to most attitude questions if it is explicitly offered; yet these same people will select a substantive alternative if "don't know" is not specifically provided, even though accepted when asserted spontaneously. More puzzlingly, a question about "forbidding" a particular action tends to elicit less agreement than a question about "not allowing" the same action, although the two questions are logically equivalent. Beyond these examples, most attitude objects are simply too complex to be summarized by a single survey question, e.g., attitudes toward abortion are too dependent on the reasons for abortion and the time in pregnancy to be adequately captured by a single question; attitudes toward "gun control" vary enormously depending on the exact framing of the issue (e.g., handguns vs. all guns, registration vs. banning, and other concrete policy distinctions).

Contingent valuation studies seek descriptive information, yet call for a response similar to those elicited by questions about subjective phenomena. Thus they risk many of the same response effects and other wording difficulties that turn up regularly in attitude surveys. Minimizing these effects presents a considerable challenge to anyone wishing to elicit reliable CV estimates. The simplest way to approach the problem is to consider a CV survey as essentially a self-contained referendum in which respondents vote on whether to tax themselves or not for a particular purpose. Since real referenda are exposed to most of the response effects that occur with attitude surveys, and since we take the result of referenda as telling us something about "true" preferences, it is not necessary to claim they can be eliminated completely in a CV study.

The Panel is of the opinion that open-ended CV questions—e.g., "What is the smallest sum that would compensate you for environmental damage X?" or, "What is the largest amount you would be willing to pay to avoid (or repair) environmental damage X?"—are unlikely to provide the most reliable valuations. There are at least two reasons for this conclusion. In the first place, the scenario lacks realism since respondents are rarely asked or required in the course of their everyday lives to place a dollar value on a particular public good. There responses to such questions are therefore likely to be unduly sensitive to trivial characteristics of the scenario presented. In the second place, an open-ended request for willingness to pay or willingness to accept compensation invites strategic overstatement. The more seriously the respondent takes the question, the more likely it is that he or she will see that reporting a large response is a costless way to make a point. Both experience and logic suggest that responses to open-ended questions will be erratic and biased.

However, the referendum format, especially when cast in the willingness to pay mode—"Would you be willing to contribute (or be taxed) D dollars to cover the cost of avoiding or repairing environmental damage X?"—has many advantages. It is realistic: referenda on the provision of public goods are not uncommon in real life. There is no strategic reason for the respondent to do other than answer truthfully, although a tendency to overestimate often appears even in connection with surveys concerning routine market goods. The fact that market surveys continue to be used routinely suggests that this tendency is not a insuperable obstacle. Of course, the respondent in a CV survey understands that the referendum is hypothetical; there is no implication that the tax will actually be levied and the damage actually repaired or avoided. This suggests that considerable efforts should be made to induce respondents to take the question seriously, and that the CV instrument should contain other questions designed to detect whether the respondent has done so. Although Carson, *et al.* (1992), included a useful question to determine whether respondents believed the survey was biased in any direction, they did not sufficiently test whether the completeness of, and time period for, restoration stated in the survey were fully accepted by respondents. But, as far as strategic reasons go, a respondent who would not be willing to pay D dollars has no reason to answer "Yes," and a respondent who would be willing to pay D dollars has no reason to answer "No."

There are, however, several other reasons why one's response to a hypothetical referendum question might be the opposite of one's actual vote on a real ballot. On one hand, a respondent unwilling to pay D dollars in reality might feel pressure to give the "right" or "good" answer when responding to an in-person or telephone interviewer. This could happen if the respondent believes that the interviewer would herself favor a yes answer. On the other hand, a respondent actually willing to pay the stated amount might answer in the negative for several reasons: (i) Belief that the proposed scenarios distributed the burden unfairly; (ii) doubt of either the feasibility of the proposed action, so that any contribution would be wasted, or the ability of the relevant agency to carry out the action efficiently; or (iii) refusal to accept the hypothetical choice problem, because of either a generalized aversion to taxes or a view that someone else—the "oil industry", for example—should pay for repair or avoidance as the responsible party. The same considerations suggest that a CV instrument should include questions designed to detect the presence of these sources of bias. This is in fact often done, but we do not know how successfully.

There are two further problems that could detract from the reliability of CV responses without producing any determinate bias: (i) A feeling that one's vote will have no significant effect on the outcome of the hypothetical referendum, leading to no reply or an unconsidered one; and (ii) poor information about the damage being valued. Of course, either of these could occur in real referenda.

Here we must decide on the standard of knowledgeability of the respondents that we went to impose on a CV study. It is clear that it should be at least as high as that which the average voter brings to a real referendum on the provision of a specific public good, but should it be higher? A "conservative" CV study, i.e., one that avoids overestimating true willingness to pay, will no doubt exceed the minimum standard of information and will also lean over backwards to avoid providing information in a way that might bias the response upwards. In particular, a conservative study will provide the respondent with some perspective concerning the overall frequency and magnitude of oil spills, the amount of money currently being spent on preventing and remedying them, the overall scale of their consequences, the peculiar features of the spill in question, and similar relevant information. Placing the choice problem in a broader context helps the respondent to arrive at a realistic or even conservative valuation.

Most of the provision of public goods in this country is decided by representatives and bureaucrats rather than by direct vote of the citizens. It is presumed that these agents are more "expert" or at least draw on more knowledge than the citizens themselves. The agent's expertise, if it really exists, is about the means and cost of providing public goods, though elected officials may sometimes be presumed to "represent" judgments of ultimate value to the citizens. Nevertheless, to increase one's confidence that a CV study is conservatively reliable, one might want to compare its outcome with that provided by a panel of experts. This will help check whether respondents and those conducting the study or studies are reasonably well-informed and well-motivated. This comparison could be made on a sample of CV studies to give an idea of their reliability in general.

The above considerations suggest that a CV study based on the referendum scenario can produce more reliably conservative estimates of willingness to pay, and hence of compensation required in the aftermath of environmental impairment, provided that a concerted effort is made to motivate the respondents to take the study seriously, to inform them about the context and special circumstances of the spill or other accident, and to minimize any bias toward high or low answers originating from social pressure within the interview. This implies that, in the present state of the art, a reliably conservative CV study should be conducted with personal interviews of significant duration and will therefore be relatively costly. If follows therefore that, in order that the cost of the study not be disproportionately large compared to the amount of damages, the CV approach would likely be used only in relatively major spills, at least until further improvements in methodology can be developed and accepted. (A suggestion for doing so is offered in Section V.)

The referendum format offers one further advantage for CV. As we have argued, external validation of elicited lost passive-use values is usually impossible. There are however real-life referenda. Some of them, at least, are decisions to purchase specific public goods with defined payment mechanisms, e.g., an increase in property taxes. The analogy with willingness to pay for avoidance or repair of environmental damage is far from perfect but close enough that the ability of CV-like studies to predict the outcomes of real-world referenda would be useful evidence on the validity of the CV method in general.

The test we envision is not an election poll of the usual type. Instead, using the referendum format and providing the usual information to the respondents, a study should ask whether they are willing to pay the average amount implied by the actual referendum. The outcome of the CV-like study should be compared with that of the actual referendum. The Panel thinks that studies of this kind should be pursued as a method of validating and perhaps even calibrating applications of the CV method (see Magleby, 1984).

Addressing the Embedding Problem

Perhaps the most important internal argument against the reliability of the CV approach (as against general criticisms about vagueness, lack of information, or unreality of the scenario) is the observation of the "embedding" phenomenon (see the discussion in Section II). Different but similar samples of respondents are asked about their willingness to pay for prevention of environmental damage scenarios that are identical except for their scale: different numbers of seabirds saved, different numbers of forest tracts preserved from logging, etc. It is reported that average willingness to pay is often substantial for the smallest scenario presented but is then substantially independent of the size of the damage averted, rising slightly if at all for large changes in size.

The usual interpretation proposed by critics of the CV method is that the responses are not measuring the equivalent dollar value of the utility of the environmental assets preserved, because that would certainly be measurably larger for substantially larger programs of preservation. Instead, the fixed sum offered is the value of a feeling of having done something praiseworthy; a "warm glow" is the phrase often used.

This is potentially a very damaging criticism of the method. CV studies almost always seek to measure willingness to pay to avoid a particular incident rather then compensation that would be required for damage that has already occurred. This is because respondents are more likely to exaggerate the compensation they would require than their willingness to pay, and because the latter is expected to be less than the former and so is conservative. If reported willingness to pay accurately reflected actual willingness to pay, then, under the "warm glow" interpretation, willingness to pay might well exceed compensation required because the former contains an element of self-approbation. It might be real but not properly compensable.

Defenders of the CV approach reply to this criticism in various ways. Sometime it is argued that the evidence used to support "embedding" simply indicates diminishing marginal utility of the asset in question. In many cases, however, the constancy or near-constancy of willingness to pay does not appear consistent with the large reported amounts for the first small increment of environmental preservation.

A second defense of CV against the embedding phenomenon is that CV questions have to be posed carefully and in context. It is argued that carelessly formulated CV instruments leave respondents with the impression that they are being asked, "Would you pay $X to avert a certain small environmental harm?" In a very large population of birds, the death of 1,000 is not seen as noticeably different from the death of 100,000—and may not actually be very different—so that respondents simply answer the question just asked.

This second response leads to the obvious question: how should a CV instrument be framed to elicit an answer

that responds to the precise scenario and not to a generalized "warm glow" effect? We must reject one possible approach, that of asking each respondent to express willingness to pay to avert incidents of varying sizes; the danger is that embedding will be forcibly avoided, still without realism. This issue is best considered as part of the broader question: How much context about the incident itself and about the respondent's circumstances and choices should be included in the CV instrument?

We are recommending a high standard of richness in context to achieve a realistic background. Our proposed guidelines regarding this issue are embodied in Section IV below.

Time Dimension of Passive Use Losses

Typically, environmental damages from oil spills or similar accidents are severe for some period of time—weeks, months, or sometimes a few years—and gradually are reduced by natural forces and human efforts to a low or possibly even zero steady state level. In some circumstances, passive-use losses derive only or mostly from the steady state conditions; thus, if passive use value derives from species diversity, even a considerable loss of birds or mammals which does not endanger any species will give rise to no loss. If, on the contrary considerable passive-use value is attached to the interim state of the natural resource, then respondents have to do a very difficult present value calculation properly to compute their current willingness to pay for the difference between the fully restored state of the resource and the actual state as the level of restoration varies over time. CV surveys accordingly have to be carefully designed to allow respondents to differentiate interim from steady state passive-use loss, and, if there is interim passive-use loss, to report its present value correctly.

It is reasonable to assume that interim passive-use values are additive over time. Hence, we need a calculation of present values of the interim losses. The discounting and the estimation of the rate of recovery of the resource should be done by technical experts and not by the respondents, who are unlikely to handle these tasks adequately. Respondents should be asked only their willingness to pay to eliminate the difference between some partially restored level of the resource and the pristine state for a specific period of time, say a year, on the assumption that after that time full restoration is assured. Technical experts would estimate how the state of the resource will vary from year to year as the restoration takes place. The technical information about the state of the resource, together with the respondent's assessments of the flow valuation of the resource, can be used to construct a time series of passive-use losses which can be discounted to the present at an appropriate rate of interest to determine the present value of the damages.

IV. Survey Guidelines

In this section we try to lay down a fairly complete set of guidelines compliance with which would define an ideal CV survey. A CV survey does not have to meet each of these guidelines fully in order to qualify as a source of reliable information to a damage assessment process. Many departures from the guidelines or even a single serious deviation would, however, suggest unreliability *prima facie*. To preserve continuity, we give only a bald list of guidelines here. They are repeated together with further explanatory comments in the Appendix to this Report.

General Guidelines

- *Sample Type and Size:* Probability sampling is essential for a survey used for damage assessment.[1] The choice of sample specific design and size is a difficult, technical question that requires the guidance of a professional sampling statistician.
- *Minimize Nonresponses:* High nonresponse rates would make the survey results unreliable.
- *Personal Interview:* The Panel believes it unlikely that reliable estimates of values could be elicited with mail surveys. Face-to-face interviews are usually preferable, although telephone interviews have some advantages in terms of cost and centralized supervision.
- *Pretesting for Interviewer Effects:* An important respect in which CV surveys differ from actual referenda is the presence of an interviewer (except in the case of mail surveys). It is possible that interviewers contribute to "social desirability" bias, since preserving the environment is widely viewed as something positive. In order to test this possibility, major CV studies should incorporate experiments that assess interviewer effects.
- *Reporting:* Every report of a CV study should make clear the definition of the population sampled, the sampling frame used, the sample size, the overall sample non-response rate and its components (e.g., refusals), and item non-response on all important questions. The report should also reproduce the exact wording and sequence of the questionnaire and of other communications to respondents (e.g., advance letters). All data from the study should be archived and made available to interested parties (see Carson *et al.* (1992), for an example of good practice in inclusion of questionnaire and related details; as of this date, however, the report has not been available publicly and the data have not been archived for open use by other scholars).
- *Careful Pretesting of a CV Questionnaire:* Respondents in a CV survey are ordinarily presented with a good deal of new and often technical information, well beyond what is typical in most surveys. This requires very careful pilot work and pretesting, plus evidence from the final survey that respondents understood and accepted the main description and questioning reasonably well.

Guidelines for Value Elicitation Surveys

The following guidelines are met by the best CV surveys and need to be present in order to assure reliability and usefulness of the information that is obtained.

- *Conservative Design:* Generally, when aspects of the survey design and the analysis of the responses are ambiguous, the option that tends to underestimate willingness to pay is preferred. A conservative design increases the reliability of the estimate by eliminating extreme responses that can enlarge estimated values wildly and implausibly.
- *Elicitation Format:* The willingness to pay format should be used instead of the compensation required because the former is the conservative choice.
- *Referendum Format:* The valuation question should be posed as a vote on a referendum.
- *Accurate Description of the Program or Policy:* Adequate information must be provided to respondents about the environmental program that is offered. It must be defined in a way that is relevant to damage assessment.
- *Pretesting of Photographs:* The effects of photographs on subjects must be carefully explored.
- *Reminder of Undamaged Substitute Commodities:* Respondents must be reminded of substitute commodities,

[1] This need not preclude use of less adequate samples, including quota or even convenience samples, for preliminary testing of specific experimental variations, so long as order of magnitude differences rather than univariate results are the focus. Even then, obvious sources of bias should be avoided (e.g., college students are probably too different in age and education from the heterogeneous adult population to provide a trustworthy basis for wider generalization).

such as other comparable natural resources or the future state of the same natural resource. This reminder should be introduced forcefully and directly prior to the main valuation question to assure that respondents have the alternatives clearly in mind.

• *Adequate Time Lapse from the Accident:* The survey must be conducted at a time sufficiently distant from the date of the environmental insult that respondents regard the scenario of complete restoration as plausible. Questions should be included to determine the state of subjects' beliefs regarding restoration probabilities.

• *Temporal Averaging:* Time dependent measurement noise should be reduced by averaging across independently drawn samples taken at different points in time. A clear and substantial time trend in the responses would cast doubt on the "reliability" of the finding.

• *"No-answer" Option:* A "no-answer" option should be explicitly allowed in addition to the "yes" and "no" vote options on the main valuation (referendum) question. Respondents who choose the "no-answer" option should be asked nondirectively to explain their choice. Answers should be carefully coded to show the types of responses, for example: (i) Rough indifference between a yes and a no vote; (ii) inability to make a decision without more time or more information; (iii) preference for some other mechanism for making this decision; and (iv) bored by this survey and anxious to end it as quickly as possible.

• *Yes/no Follow-ups:* Yes and no responses should be followed up by the open-ended question: "Why did you vote yes/no?" Answers should be carefully coded to show the types of responses, for example: (i) It is (or isn't) worth it; (ii) Don't know; or (iii) The oil companies should pay.

• *Cross-tabulations:* The survey should include a variety of other questions that help to interpret the responses to the primary valuation question. The final report should include summaries of willingness to pay broken down by these categories. Among the items that would be helpful in interpreting the responses are:

Income
Prior Knowledge of the Site
Prior Interest in the Site (Visitation Rates)
Attitudes Toward the Environment
Attitudes Toward Big Business
Distance to the Site
Understanding of the Task
Belief in the Scenarios
Ability/Willingness to Perform the Task

• *Checks on Understanding and Acceptance:* The above guidelines must be satisfied without making the instrument so complex that it poses takes that are beyond the ability or interest level of many participants.

Goals for Value Elicitation Surveys

The following items are not adequately addressed by even the best CV surveys. In the opinion of the Panel, these issues will need to be convincingly dealt with in order to assure the reliability of the estimates.

• *Alternative Expenditure Possibilities:* Respondents must be reminded that their willingness to pay for the environmental program in question would reduce their expenditures for private goods or other public goods. This reminder should be more than perfunctory, but less than overwhelming. The goal is to induce respondents to keep in mind other likely expenditures, including those on other environmental goods, when evaluating the main scenario.

• *Deflection of Transaction Value:* The survey should be designed to deflect the general "warm-glow" of giving or the dislike of "big business" away from the specific environmental program that is being evaluated. It is possible that the referendum format limits the "warm glow" effect, but until this is clear the survey design should explicitly address this problem.

• *Steady State or Interim Losses:* It should be made apparent that respondents can distinguish interim from steady-state losses.

• *Present Value Calculations of Interim Losses:* It should be demonstrated that, in revealing values, respondents are adequately sensitive to the timing of the restoration process.

• *Advance Approval:* Since the design of the CV survey can have a substantial effect on the responses, it is desirable that—if possible—critical features be preapproved by both sides in a legal action, with arbitration and/or experiments used when disagreements cannot be resolved by the parties themselves.

• *Burden of Proof:* Until such time as there is a set of reliable reference surveys, the burden of proof of reliability must rest on the survey designers. They must show through pretesting or other experiments that their survey does not suffer from the problems that these guidelines are intended to avoid. Specifically, if a CV survey suffered from any of the following maladies, we would judge its findings "unreliable":

—A high nonresponse rate to the entire survey instrument or to the valuation question.
—Inadequate responsiveness to the scope of the environmental insult.
—Lack of understanding of the task by the respondents.
—Lack of belief in the full restoration scenario.
—"Yes" or "no" votes on the hypothetical referendum that are not followed up or explained by making reference to the cost and/or the value of the program.

• *Reliable Reference Surveys:* In order to alleviate this heavy burden of proof, we strongly urge the government to undertake the task of creating a set of reliable reference surveys that can be used to interpret the guidelines and also to calibrate surveys that do not fully meet the conditions.

V. Recommendations for Future Research

The Panel's major research recommendation goes toward a drastic reform of the CV procedure, extending beyond the guidelines suggestion in Section IV.

The problem of estimating the demand for highly innovative commercial products, including some that have not yet actually been produced, is much like the problem faced in CV research. It is the problem of estimating willingness to pay for a necessarily unfamiliar product. The field of market research has developed methods—"conjoint analysis," for example—that are very similar to the CV approach. (One important difference is that a new product may eventually reach the market, and projections of expected sales can be checked. Survey responses are usually found to be moderate overestimates of actual willingness to pay.) Practitioners have found that survey methods are better at estimating relative demand than absolute demand. There is an anchoring problem, even with private goods—that is, absolute willingness to pay is hard to pin down. This leads to the following suggestion.

The federal government should produce standard damage assessments for a few specific reference oil spills, either hypothetical or actual, ranging from small to large. These standard valuations could be generated by any method. One possibility would be through a jury of experts. Such a jury of experts might wish to conduct a series of CV studies, satisfying the guidelines laid out above. These CV studies would be inputs into the jury process, to be combined with other information and expert judgment. Once these

benchmarks were available, they could serve as reference points for later CV studies. When a damage assessment is required, surveys could be used to elicit answers to questions like: "Would you pay (much more, more, about the same, less, much less) to prevent this spill than you would to prevent Standard Spill A?" "Would you pay an amount to avoid this spill that is between the amounts you would pay to avoid Standard Spill B and Standard Spill C? If so, is the amount much closer to B than C, closer to B than C, halfway between B and C, closer to C than B, much closer to C than B?" These questions presumably would not be asked so schematically. Responses to such a study could then serve as one reliable source of information in the damage assessment.

We recognize that this technique would require that respondents be made familiar with the reference spills as well as the particular spill whose damage is being assessed. We expect that the additional effort would be more than offset by the greater simplicity and reliability in estimating relative willingness to pay.

This possibility suggests a slightly more radical extension of the CV method. Respondents could be asked to compare their willingness to pay to avoid a specific case of environmental damage to their willingness to pay for a range of fairly familiar private goods. It would no doubt be best if the private goods were to bear some similarity to the environmental good in question, but that is not necessary. The anchoring purpose would be served if respondents could measure their willingness to pay in units of articles of clothing or small household appliances forgone.

This latter is a suggestion for research in the CV method, not necessarily a recommendation for current practical use.

The guidelines proposed in Section IV themselves suggest areas for further research, this time within the contingent valuation community. In particular, we emphasize the urgency of studying the sensitivity of willingness to pay responses to the number and extent of budgetary substitutes mentioned in survey instruments (that is, reminders of other things on which respondents could spend their money). In such research it would be helpful if parallel studies were conducted on the sensitivity of stated intentions to buy ordinary market goods—both familiar and unfamiliar—to reminders of alternative uses of those resources. The point is to discover the extent to which the valuation of environmental public goods is intrinsically more difficult than similar exercises with respect to market goods.

A closely-related line of research is the sensitivity of responses in CV surveys to the number and extent of undamaged substitute commodities mentioned explicitly in the survey instrument (miles of nearby shoreline, miles of shoreline elsewhere, similarity for animal or bird life, alternative recreation possibilities and so on). This could be extended to variations in the way in which the budget constraint is presented to respondents. Here again, comparisons with market goods would be useful.

Finally, having urged that the availability of a no-vote option is an important component of the ability of the CV technique to mimic an actual referendum, we recommend further research into alternative ways of presenting and interpreting the no-vote option. In this respect, too, comparative studies with familiar public and private goods (local parks, school facilities, housing for the homeless, food distributions) would be enlightening. Real referenda always allow the option of not voting, in a natural way. CV studies have to achieve the same result more deliberately, so there is a need to know if the precise formulation matters very much to the result.

VI. Conclusions and Recommendations

The Panel starts from the premise that passive-use loss—interim or permanent—is a meaningful component of the total damage resulting from environmental accidents. A problem arises because passive-use losses have few or no overt behavioral consequences. The faintness of the behavioral trail means that a well-designed and adequately sensitive measuring instrument is needed to substitute for conventional observations of behavior. In particular, can the CV method provide a sufficiently reliable estimate of total loss—including passive-use loss—to play a useful role in damage assessment?

It has been argued in the literature and in comments addressed to the Panel that the results of CV studies are variable, sensitive to details of the survey instrument used, and vulnerable to upward bias. These arguments are plausible. However, some antagonists of the CV approach go so far as to suggest that there can be no useful information content to CV results. The Panel is unpersuaded by these extreme arguments.

In Section IV above, we identify a number of stringent guidelines for the conduct of CV studies. These require that respondents be carefully informed about the particular environmental damage to be valued, and about the full extent of substitutes and undamaged alternatives available. In willingness to pay scenarios, the payment vehicle must be presented fully and clearly, with the relevant budget constraint emphasized The payment scenario should be convincingly described, preferably in a referendum context, because most respondents will have had experience with referendum ballots with less-than-perfect background information. Where choices in formulating the CV instrument can be made, we urge they lean in the conservative direction, as a partial or total offset to the likely tendency to exaggerate willingness to pay.

The Panel concludes that under those conditions (and others specified above), CV studies convey useful information. We think it is fair to describe such information as reliable by the standards that seem to be implicit in similar contexts, like market analysis for new and innovative products and the assessment of other damages normally allowed in court proceedings. As in all such cases, the more closely the guidelines are followed, the more reliable the result will be. It is not necessary, however, that every single injunction be completely obeyed; inferences accepted in other contexts are not perfect either.

Thus, the Panel concludes that CV studies can produce estimates reliable enough to be the starting point of a judicial process of damage assessment, including lost passive-use values. To be acceptable for this purpose, such studies should follow the guidelines described in Section IV above. The phrase "be the starting point" is meant to emphasize that the Panel does not suggest that CV estimates can be taken as automatically defining the range of compensable damages within narrow limits. Rather, we have in mind the following considerations.

The Panel is persuaded that hypothetical markets tend to overstate willingness to pay for private as well as public goods. The same bias must be expected to occur in CV studies. To the extent that the design of CV instruments makes conservative choices when alternatives are available, as urged in Section IV, this intrinsic bias may be offset or even over-corrected. All surveys of attitudes or intentions are bound to exhibit sensitivity of response to the framing of questions and the order in which they are asked. No automatic or mechanical calibration of responses seems to be possible.

The judicial process must in each case come to a conclusion about the degree

to which respondents have been induced to consider alternative uses of funds and take the proposed payment vehicle seriously. Defendants will argue that closer attention to substitute commodities would have yielded lower valuations. Trustees will argue that they have already leaned over backwards to ensure conservative responses. Judges and juries must decide as they do in other damage cases. The Panel's conclusion is that a well-conducted CV study provides an adequately reliable benchmark to begin such arguments. It contains information that judges and juries will wish to use, in combination with other evidence, including the testimony of expert witnesses.

The Panel's second conclusion is that the appropriate federal agencies should begin to accumulate standard damage assessments for a range of oil spills, as described in Section V. That process should further improve the reliability of CV studies in damage assessment. It should thus contribute to increasing the accuracy and reducing the cost of subsequent damage assessment cases. In that sense, it can be regarded as an investment.

The proposals for further research outlined in Section V are an integral part of our recommendations. The Panel believes that the suggestions put forward there could lead to more reliable and less controversial damage assessment at reduced cost. It is not to be expected that controversy will disappear, however. There will always be controversy where intangible losses have to be evaluated in monetary terms.

Appendix—General Guidelines

• *Sample Type and Size:* Probability sampling is essential for a survey used for damage assessment.[1] The choice of sample specific design and size is a difficult, technical question that requires the guidance of a professional sampling statistician.

If a single dichotomous question of the yes-no type is used to elicit valuation responses, then a total sample size of 1000 respondents will limit sampling error to about 3% plus or minus on a single dichotomous question, assuming simple random sampling. However, this or any other sample size needs to be reconceptualized for three reasons. First, if face-to-face interviewing is used, as we suggest above, clustering and stratification must be taken into account. Second, if dichotomous valuation questions are used (e.g., hypothetical referenda), separate valuation amounts must be asked of random sub-samples and these responses must be unscrambled econometrically to estimate the underlying population mean or median. Third, in order to incorporate experiments on interviewer and wording effects, additional random sub-sampling is required. For all these reasons, it will be important to consult sampling statisticians in the design of a CV survey intended for legal or policy-making purposes.

• *Minimize Nonresponses:* High nonresponse rates would make the survey results unreliable.

To the extent that a CV study is expected to represent the adult population of the United States or a portion of it, minimizing both sample non-response and item non-response are important. The former is unlikely to be below 20% even in very high quality surveys; the latter has also been large in some CV surveys because of the difficulty of the task respondents are being asked to perform. These sources of potential bias can be partially justified on the grounds that they also occur with official referenda, in both cases with the loss especially of the least educated parts of the population. The further reduction of the final sample by elimination of "protest zeros," "unrealistic high values," and other problematic responses may lead to effective final total response rates so low as to imply that the survey population consists of interested and specially instructed quasi-experts. This consideration reinforces the desirability of combining a reasonable response rate with a high but not forbidding standard of information as discussed in Section III above.

• *Personal Interview:* The Panel believes it unlikely that reliable estimates of values could be elicited with mail surveys. Face-to-face interviews are usually preferable, although telephone interviews have some advantages in terms of cost and centralized supervision.

Assuming a CV survey is to represent a natural population, such as all adults in the United States, or those in a single urban area or a state, it is desirable that it be carried out using either face-to-face or telephone interviews. Mail surveys typically employ lists that cover too small a part of the population (e.g., samples based on telephone directories omit approximately half the U.S. population because of non-listed numbers, incorrect numbers, and non-phone households), and then miss another quarter or more of the remainder through non-response. In addition, since the content of a mail questionnaire can be reviewed by targeted respondents before deciding to return it, those most interested in a natural resource issue or in one side or the other can make their decision on that basis. It is also impossible using mail surveys to guarantee random selection within households or to confine answering to a single respondent, and it is difficult (though not impossible) to control question-order effects. Thus, mail surveys should be used only if another supplementary method can be employed to cross-validate the results on a random sub-sample of respondents.

The choice between telephone and face-to-face administration is less clear. Face-to-face surveys offer practical advantages in maintaining respondent motivation and allowing use of graphic supplements. Both coverage and response rates are also usually somewhat higher than with telephone surveys. However, telephone surveys can cut interviewing costs by between a third and a half; for CV purposes, it may be a disadvantage that most survey investigators believe telephone interviews need to be kept shorter in length than face-to-face interviews because respondent attention and cooperation are more difficult to maintain. In addition, random-digit-dial telephone surveys approximate simple random sampling. Face-to-face surveys must be based on cluster sampling and, therefore, the results provide less precise estimates than do telephone surveys of the same size.

• *Pretesting for Interviewer Effects:* An important respect in which CV surveys differ from actual referenda is the presence of an interviewer (except in the case of mail surveys). It is possible that interviewers contribute to "social desirability" bias, since preserving the environment is widely viewed as something positive. In order to test this possibility, major CV studies should incorporate experiments that assess interviewer effects.

To test for interviewer effects, two modifications might be made to a standard face-to-face CV survey. In one variant on current practice, respondents would stop when they come to the valuation question, write their "vote" on a ballot, and fold and deposit it in a sealed box. However, since this practice would not mimic the complete anonymity of the voting booth, for a subsample of respondents a second

[1] This need not preclude use of less adequate samples, including quota or even convenience samples, for preliminary testing of specific experimental variations, so long as order of magnitude differences rather than univariate results are the focus. Even then, obvious sources of bias should be avoided (e.g. college students are probably too different in age and education from the heterogeneous adult population to provide a trustworthy basis for wider generalization).

modification should be made. Respondents would be allowed to mail their "ballots" in unmarked envelopes directly to the survey organization, even though that will preclude any but the simplest analysis of responses. Tests of the effect of both these modifications of current practice will indicate whether they are needed routinely or whether at least some calibration should be introduced to compensate for interviewer effects. (The more modest of these proposed modifications—a simulated ballot box, or even voting on a portable computer—has few if any disadvantages and might be made standard if it shows any reliable departure at all from answers given orally to the interviewer.)

• *Reporting:* Every report of a CV study should make clear the definition of the population sampled, the sampling frame used, the sample size, the overall sample non-response rate and its components (e.g., refusals), and item non-response on all important questions. The report should also reproduce the exact wording and sequence of the questionnaire and of other communications to respondents (e.g., advance letters). All data from the study should be archived and made available to interested parties (see Carson *et al.* (1992)), for an example of good practice in inclusion of questionnaire and related details; as of this date, however, the report has not been available publicly and the data have not been archived for open use by other scholars).

• *Careful Pretesting of a CV Questionnaire:* Respondents in a CV survey are ordinarily presented with a good deal of new and often technical information, well beyond what is typical in most surveys. This requires very careful pilot work and pretesting, plus evidence from the final survey that respondents understood and accepted the main description and questioning reasonably well.

Parenthetically, the claim sometimes made by CV proponents that particular methods of piloting, such as focus groups, are essential should be viewed with skepticism, since these claims are unsupported by any systematic evidence. Nor is it clear that what are called "state-of-the-art" CV surveys constitute something entirely new or different from other types of serious survey investigations. Thus, although evidence that questionnaire development has been carried out carefully is certainly important, it cannot be taken as a self-sufficient basis of validity—the more so because we know that many people will answer survey questions without apparent difficulty, even when they do not understand them well. A way of reducing pressure to give answers of questionable meaningfulness would be to provide respondents an explicit "no opinion" type of alternative when a key valuation question is posed.

Guidelines for Value Elicitation Surveys

The following guidelines are met by the best CV surveys and need to be present in order to assure reliability and usefulness of the information that is obtained.

• *Conservative Design:* Generally, when aspects of the survey design and the analysis of the responses are ambiguous, the option that tends to underestimate willingness to pay is preferred. A conservative design increases the reliability of the estimate by eliminating extreme responses that can enlarge estimated values wildly and implausibly.

• *Elicitation Format:* The willingness to pay format should be used instead of compensation required because the former is the conservative choice.

In experimental settings, the gap between stated intentions to support a particular referendum and actual behavior in the voting booth can be very great (see Magleby, 1984). This gap might be treated by "calibration" if there were historical data on the relationship between such intentions and behavior. Unfortunately, we are aware of no data that is close enough to the CV context that could be used to calibrate CV responses. In the absence of historical data that can be used to calibrate the intentions reported in the CV surveys, the survey instrument has to be designed with extraordinary care so that it can stand on its own.

• *Referendum Format:* The valuation question should be posed as a vote on a referendum.

As is now generally recognized by most CV proponents, asking respondents to give a dollar valuation in response to an open-ended question presents them with an extremely difficult task. At the same time, CV proponents also recognize that presenting respondents a set of dollar amounts from which they are to choose is likely to create anchoring and other forms of bias. Thus, we recommend as the most desirable form of CV elicitation the use of a dichotomous question that asks respondents to vote for or against a particular level of taxation, as occurs with most real referenda. As already noted, such a question form also has advantage in terms of incentive compatibility. (If a double-bounded dichotomous choice or some other question form is used in order to obtain more information per respondent, experiments should be developed to investigate biases that may be introduced.)

• *Accurate Description of the Program or Policy:* Adequate information must be provided to respondents about the environmental program that is offered. It must be defined in a way that is relevant to damage assessment.

Ideally a CV survey would elicit attitudes toward three alternative (future) recovery scenarios: (A) "immediate" restoration, (b) accelerated restoration, and (c) natural restoration. Damages would be the difference between (a) and (b) on the assumption that accelerated restoration is provided by the responsible party. Unfortunately, respondents may not find "immediate" restoration very plausible and they may resist the notion that they should be expected to contribute to accelerated restoration when it is an oil company that is at fault. If respondents are unable or unwilling to deal hypothetically with the most relevant "clean-up" scenarios, alternative "prevention" scenarios will have to be used in the survey instrument. For example, respondents may be asked to vote for a referendum that offers reduced risk of another spill for a specified period of time.[2] The weaker is the linkage between the "prevention" scenarios and the "clean-up"scenarios, the more unreliable are the survey results. Rhetorically: Is a decade of prevention equal in value to the difference in value between accelerated and immediate clean-up?

• *Pretesting of Photographs:* The effects of photographs on subjects must be carefully explored.

One effective means for conveying information and holding interest in a CV interview has been the use of large and impressive photographs. However, this technique is a two-edged sword because the dramatic nature of a photograph may have much more emotional impact than the rest of the questionnaire. Thus it is important that photographs be subjected to even more careful assessment than verbal material if the goal is to avoid bias in presentation.[3]

• *Reminder of Undamaged Substitute Commodities:* Responsents must be reminded of substitute commodities, such as other comparable natural resources or the future state of the same natural resource. This reminder should

[2] As in the survey actually performed by the State of Alaska after the Valdez spill (See Carson *et al.* (1992)).

[3] Failure to test the effects of photographs on responses is one shortcoming of Carson *et al* (1992).

be introduced forcefully and directly prior to the main valuation question to assure that respondents have the alternatives clearly in mind.

• *Adequate Time Lapse from the Accident:* The survey must be conducted at a time sufficiently distant from the date of the environmental insult that respondents regard the scenario of complete restoration as plausible. Questions should be included to determine the state of subjects' beliefs regarding restoration probabilities.

Survey respondents who would not suffer interim passive-use loss may not regard full restoration as very plausible; therefore, they may report substantial passive-use loss even if told that full restoration in some reasonable amount if time is certain. Misunderstanding of the restoration probability is most acute when the accident has recently occurred and before any substantial restoration takes place. It would be ideal to assess steady state passive-use loss after natural and human restoration is complete or nearly so, since then presumably respondents would believe in the restoration. If that is not a possibility, surveys might be conducted over time until the reported willingness to pay settles down (assuming that it does), as the respondents come to believe more and more in the probable success of the restoration effort. Alternatively, respondents might be asked to value a menu of alternative possible scenarios, without being told explicitly which is applicable for the environmental insult under study. The menu should be designed to force them to consider the difference between interim and steady-state passive-use value.

• *Temporal Averaging:* Time dependent measurement noise should be reduced by averaging across independently drawn samples taken at different points in time. A clear and substantial time trend in the responses would cast doubt on the "reliability" of the finding.

• *"No-answer" Option:* A "no-answer" option should be explicitly allowed in addition to the "yes" and "no" vote options on the main valuation (referendum) question. Respondents who choose the "no-answer" option should be asked nondirectively to explain their choice. Answers should be carefully coded to show the types of responses, for example: (i) Rough indifference between a yes and a no vote; (ii) inability to make a decision without more time or more information; (iii) preference for some other mechanism for making this decision; and (iv) bored by this survey and anxious to end it as quickly as possible.

• *Yes/no Follow-ups:* Yes and no responses should be followed up by the open-ended question: "Why did you vote yes/no?" Answers should be carefully coded to show the types of responses, for example: (i) It is (or isn't) worth it; (ii) Don't know; or (iii) The oil companies should pay.

• *Cross-tabulations:* The survey should include a variety of other questions that help to interpret the responses to the primary valuation question. The final report should include summaries of willingness to pay broken down by these categories. Among the items that would be helpful in interpreting the responses are:

Income
Prior Knowledge of the Site
Prior Interest in the Site (Visitation Rates)
Attitudes Toward the Environment
Attitudes Toward Big Business
Distance to the Site
Understanding of the Task
Belief in the Scenarios
Ability/Willingness to Perform the Task

We believe that these cross tabulations will prove useful in interpreting and lending credibility to the responses and possibility also in forming adjustments that can enhance reliability.

• *Checks on Understanding and Acceptance:* The above guidelines must be satisfied without making the instrument so complex that it poses tasks that are beyond the ability or interest level of many participants.

Since CV interviews often present information that is new to respondents, the questionnaire should attempt at the end to determine the degree to which respondents accept as true the descriptions given and assertions made prior to the valuation question. Such an inquiry should be carried out in detail but non-directively, so that respondents feel free to reject any part of the information they were given at earlier points.

Goals for Value Elicitation Surveys

The following items are not adequately addressed by even the best CV surveys. In the opinion of the Panel, these issues will need to be convincingly dealt with in order to assure the reliability of the estimates.

• *Alternative Expenditure Possibilities:* Respondents must be reminded that their willingness to pay for the environmental program in question would reduce their expenditures for private goods or other public goods. This reminder should be more than perfunctory, but less than overwhelming. The goal is to induce respondents to keep in mind other likely expenditures, including those on other environmental goods, when evaluating the main scenario.

Consumers can be expected to make expenditure decisions that are adequately sensitive to other expenditure possibilities with which they are familiar. But environmental referenda of the type presented in CV surveys are unfamiliar and respondents may not be aware of the large set of other expenditure possibilities that might be offered in future CV surveys or future referenda. Unless informed otherwise, respondents may suppose that there is only one environmental scenario that will ever be offered and they may overspend on it.

It is not at all clear how exhaustive should be the list of alternative public goods that are explicitly presented. If the list is too brief, overspending can be expected. If the list is too long, respondents will be encouraged to spread expenditures to public goods for which there is not adequate total demand and which therefore cannot really be offered to them. Also, if the list gets large enough to encompass a significant fraction of income, the gap between willingness to pay and willingness to accept may widen.

It is also not clear what form the reminder should take. It does not seem enough merely to list other environmental goods since respondents would then have to guess the level of expenditure that would be necessary to pay for the alternatives.

The survey should probably include some statement about the price of alternatives, for example, the per capita expenditure that would be required to provide the items.

• *Deflection of Transaction Value:* The survey should be designed to deflect the general "warn-glow" of giving or the dislike of "big business" away from the specific environmental program that is being evaluated. It is possible that the referendum format limits the "warm glow" effect, but until this is clear the survey design should explicitly address this problem.

Economic models of consumer behavior generally are based on the assumption that value derives from the goods and services that are consumed, not from the process by which these goods are allocated. But happiness that derives from charitable giving may come mostly from the act of giving rather from the material changes that follow from the gift. To give another example, consumers may get pleasure from the act of shopping as well as from ownership of the goods they purchase. Words that might be useful to

distinguish between these utility-producing events are "consumption value" and "transaction value," the latter referring to the process or transaction that establishes ownership.

We do not question the validity of "transaction value" or differentiate it from "consumption value" as far as damage assessment is concerned. But for both forms of value, respondents need to be thinking clearly about the substitutes, since the closer are the substitutes the less the damage that is done. In the case of "transaction value," there are many close substitutes to cleaning up oil spills since there are many other charitable activities that can generate the same "warm glow" and there are many other ways to express hostility toward big business and modern technology.

• *Steady State or Interim Losses:* It should be made apparent that respondents can distinguish interim from steady-state losses.

The quality of any natural resource varies daily and seasonally around some "equilibrium" or "steady state" level. Active-use value of a resource depends on its actual state at the time of use (and at other times), not on its equilibrium. But passive-use value of a natural resource may derive only or mostly from its steady state and not from its day-to-day state. If so, full restoration at some future date eliminates or greatly reduces passive-use loss. Surveys accordingly need to be carefully designed to allow respondents to differentiate interim from steady state passive-use loss.

• *Present Value Calculations of Interim Losses:* It should be demonstrated that, in revealing values, respondents are adequately sensitive to the timing of the restoration process.

As discussed in section III above, the time profile of restoration following an accident potentially is an important determinant of active-use loss and interim passive-use loss, but respondents may have little ability to distinguish between and to evaluate different profiles.

• *Advance Approval:* Since the design of the CV survey can have a substantial effect on the responses, it is desirable that—if possible—critical features be preapproved by both sides in a legal action, with arbitration and/or experiments used when disagreements cannot be resolved by the parties themselves.

• *Burden of Proof:* Until such time as there is a set of reliable reference surveys, the burden of proof of reliability must rest on the survey designers. They must show through pretesting or other experiments that their survey does not suffer from the problems that these guidelines are intended to avoid. Specifically, if a CV survey suffered from any of the following maladies, we would judge its findings "unreliable":

—A high nonresponse rate to the entire survey instrument or to the valuation question.

—Inadequate responsiveness to the scope of the environmental insult.

—Lack of understanding of the task by the respondents.

—Lack of belief in the full restoration scenario.

—"Yes" or "no" votes on the hypothetical referendum that are not followed up or explained by making reference to the cost and/or the value of the program.

• *Reliable Reference Surveys:* In order to alleviate this heavy burden of proof, we strongly urge the government to undertake the task of creating a set of reliable reference surveys that can be used to interpret the guidelines and also to calibrate surveys that do not fully meet the conditions.

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Parts 10, 123 and 145

Elimination of Certain Documentation Requirements for Articles Entered Under Various Special Tariff Treatment Provisions and Programs

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes to amend the Customs Regulations by removing certain documentation requirements relating to the entry of articles claimed to be entitled to a partial duty exemption or duty-free treatment under various special tariff provisions or programs. These provisions and programs involve the following: (1) American goods returned; (2) U.S.-made photographic films and dry plates returned after having been exposed abroad; (3) goods exported for repairs or alterations; (4) U.S.-processed metal articles exported for further processing; (5) the Generalized System of Preferences; and (6) the Caribbean Basin Initiative. The proposed amendments will reduce regulatory procedures and paperwork and thus facilitate the entry process for both the public and Customs without affecting the ability of Customs to ensure compliance with the basic legal requirements under these provisions and programs.

DATES: Comments must be received on or before March 16, 1993.

ADDRESSES: Written comments (preferably in triplicate) may be addressed to the Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Craig Walker, Office of Regulations and Rulings, 202–482–6980.

SUPPLEMENTARY INFORMATION:

Background

Elimination of Customs Form 3311, Declaration for Free Entry of Returned American Products, for certain purposes

Subheading 9801.00.10, Harmonized Tariff Schedule of the United States (HTSUS), provides for the duty-free entry of products of the United States which are returned without having been advanced in value or improved in condition by any process of manufacture or other means while abroad. Subheading 9802.00.20, HTSUS, provides for duty-free treatment on photographic films and dry plates manufactured in the United States (except motion-picture films to be used for commercial purposes) and exposed abroad, whether developed or not. Under U.S. Notes 1 (a) and (c) to Subchapter I, Chapter 98, HTSUS, and U.S. Notes 1 (b) and (d) to Subchapter II, Chapter 98, HTSUS, subheadings 9801.00.10 and 9802.00.20, HTSUS, do not apply to any article exported either with benefit of drawback or after manufacture or production in the United States under subheading 9813.00.05, HTSUS.

Documentation requirements applicable to articles entered under subheadings 9801.00.10 and 9802.00.20, HTSUS, are set forth in § 10.1, Customs Regulations (19 CFR 10.1), and consist of the following: (1) Under paragraph (a)(1), a declaration by the foreign shipper (if the value of the returned articles exceeds $1,000); (2) under paragraph (a)(2), a declaration for free entry by the owner, importer, consignee, or agent on the top portion of Customs Form 3311; and (3) under paragraph (a)(3), a certificate of exportation on the bottom portion of Customs Form 3311 executed by the district director at the port from which the merchandise was exported. The foreign shipper's declaration as set out in § 10.1(a)(1) includes the quantity, description and value of the returned articles, the United States port of export, and the date of exportation from the United States. Customs Form 3311 similarly provides for a description of the articles and their value and also sets forth the reason for the return, whether drawback was claimed on the articles, whether the articles were previously imported under subheading 9813.00.05, HTSUS, and a signed declaration by the owner or ultimate consignee that the information provided is true and correct and that the articles meet the statutory requirements for duty-free entry. Customs Form 3311 also requires the submission of any documentation or other evidence that will substantiate a claim for duty-free status as American goods returned where the value of the articles is $10,000 or more and they are not clearly marked with the name and address of the United States manufacturer.

As a result of the significant increase in international trade in recent years and the demands which that increase has placed on Customs personnel resources, it has become increasingly impractical for Customs officers to execute the certificate of exportation on Customs Form 3311 and inspect outgoing shipments of goods to be returned under subheadings 9801.00.10 and 9802.00.20, HTSUS. It is Customs experience that the certificate is being executed or required by Customs officers less frequently both for this reason and because of a reluctance on the part of the exporter to go through the time-consuming procedure of requesting and obtaining execution of the certificate. Customs believes that requiring the certificate of exportation to be executed and subsequently filed with the entry of the returned articles should not be necessary so long as other documents or evidence are required and made available to Customs to substantiate the claim for duty-free status. Moreover, use of Customs Form 3311 at the time of entry involves a duplication of information collection because, as indicated above, some of the information to be provided by the importer on Customs Form 3311 already appears on the declaration of the foreign shipper. For the above reasons, Customs is proposing to eliminate the basic requirement in §§ 10.1(a) (2) and (3) that the owner, importer, consignee or agent file Customs Form 3311 (including the certificate of exportation) in connection with the entry of articles claimed to be duty free under subheading 9801.00.10 or 9802.00.20, HTSUS. However, some of the information and statements required on Customs Form 3311 which do not duplicate information required on the foreign shipper's declaration (such as whether drawback was previously claimed on the articles, whether the merchandise was previously imported under subheading 9813.00.05, HTSUS, and the signed declaration of the owner or ultimate consignee) are important to the processing of entries under these tariff provisions and should continue to be provided to Customs. Accordingly, it is proposed to amend § 10.1(a) further by requiring submission of a declaration by the owner, importer, consignee or agent setting forth those essential elements presently incorporated on Customs Form 3311. This new declaration, which would refer to the foreign shipper's declaration, could be either included as an addendum to that declaration or submitted separately and would have to substantially follow the format set forth in the proposed regulatory text.

Customs Form 3311 would continue to be required when used as the entry summary in the situations described in § 10.1(g) (aircraft and aircraft parts and equipment), and § 10.1(h) (nonconsumable vessel stores and equipment), or as an informal entry under § 10.1(i) (shipment the total value of which does not exceed $250), and under the circumstances described in § 10.1(j) (shipment the total value of

which does not exceed $10,000, and the goods are returned (1) for repair or alteration, or (2) after having been either rejected or returned by the foreign purchaser to the U.S. for credit). However, it is proposed to make conforming changes to paragraphs (h), (i), and (j) to reflect removal of the certificate of exportation requirement from paragraph (a).

It is also proposed to amend § 10.1 by revising paragraph (b) to provide that where the value of the returned article is $1,000 or more and it is not clearly marked with the name and address of the U.S. manufacturer, the district director may require such other documentation or evidence as may be necessary to substantiate the claim for duty-free treatment. In addition, it is proposed (1) to amend the introductory text to paragraph (a) and to revise paragraphs (d) and (f) to conform to the change regarding use of Customs Form 3311, (2) to make a similar conforming change to § 145.35 of the regulations, and (3) in § 123.4(c), to correct an inaccurate cross-reference to § 10.1(f) (which should refer to section 10.1(i)).

Customs believes that the elimination of Customs Form 3311 in the circumstances described above will eliminate an administrative burden on Customs and will provide benefits to the trade community by reducing delays at the time of exportation and by simplifying entry procedures upon return of the merchandise to the United States.

Elimination of Customs Form 4455, Certificate of Registration, for articles exported for repairs, alterations or processing

Subheading 9802.00.40, HTSUS, provides a partial duty exemption for articles of U.S. or foreign origin which are returned after having been exported for repairs or alterations made pursuant to a warranty. Subheading 9802.00.50, HTSUS, provides the same partial duty exemption for articles exported for repairs or alterations made other than pursuant to a warranty. Articles entitled to classification under either of these tariff provisions are subject to duty only upon the cost or value of the foreign repairs or alterations.

Subheading 9802.00.60, HTSUS, provides a partial duty exemption for certain metal articles, manufactured in the United States or subjected to a process of manufacture in the United States, which are exported for further processing and returned for further processing in the United States. Articles entitled to classification under this provision are subject to duty only upon the cost or value of the processing performed outside the United States.

The above three tariff provisions do not apply to any article exported with benefit of drawback or exported after manufacture or production in the United States under subheading 9813.00.05, HTSUS. See U.S. Note 1, Subchapter II, Chapter 98, HTSUS.

The special documentation requirements for articles entered under subheadings 9802.00.40 and 9802.00.50, HTSUS, are set forth in § 10.8, Customs Regulations (19 CFR 10.8), and the documentation requirements for articles entered under subheading 9802.00.60, HTSUS, are contained in § 10.9, Customs Regulations (19 CFR 10.9). The documents required for articles entered under each of these three tariff provisions are as follows: (1) Customs Form 4455, Certificate of Registration, endorsed by the Customs officer at the port of export who examined the articles prior to exportation; (2) a declaration from the person who performed the repairs or alterations or processing abroad; and (3) a declaration from the owner, importer, consignee or agent. For articles entered under subheading 9802.00.60, HTSUS, § 10.9 also requires a statement by the owner or exporter on the reverse side of Customs Form 4455, identifying the U.S. manufacturer, or the U.S. processor of the metal article and the processes performed in the United States prior to export (if the processed article was originally of foreign origin), and the U.S. company which will further process the article when returned.

Customs Form 4455 includes the quantity and a description of the articles being exported, a description of the foreign processing, the dates when, and ports where, the articles were examined by Customs and laden aboard the exporting carrier, and a signed statement by the importer that the articles were exported without benefit of drawback and are returned unchanged "except as noted". Under §§ 10.8(e) and 10.9(e), the declaration of the person who performed the repair or alteration or foreign processing shall include a description of the articles and of the repair or alteration or foreign processing, the cost or value of the repair or alteration or foreign processing, the total value of the articles after the repair or alteration or foreign processing, and a statement that only the identified repair or alteration or foreign processing was performed and that the cost or value thereof is correctly stated. Under §§ 10.8(f) and 10.9(f), the declaration of the owner, importer, consignee, or agent shall include statements that the articles being entered are the same articles covered by the Certificate of Registration and that the cost or value of the repair or alteration or foreign processing is correctly stated in the entry. With respect to subheading 9802.00.60, HTSUS, § 10.9(f) also requires that the subject declaration include a statement as to the nature of the foreign processing and the processing to be performed in the United States.

Customs is proposing in this document to revise §§ 10.8 and 10.9 in order to eliminate Customs Form 4455 as a separate required document because much of the information required to be included on the form duplicates information required in the declaration of the person who performed the repair or alteration or foreign processing and in the declaration of the owner, importer, consignee or agent. Moreover, for the same reasons stated above in regard to the certificate of exportation on Customs Form 3311, the procedure referred to in §§ 10.8 and 10.9, involving examination of the goods and endorsement of the Customs Form 4455 by a Customs officer prior to exportation, is increasingly not being followed. Customs believes that the declarations and statements and other evidence required or permitted under §§ 10.8 and 10.9 are adequate to substantiate to Customs satisfaction that the articles being returned are the same as those which were exported and that the statutory requirements are satisfied. For example, it is noted that § 10.8(k) and 10.9(i) presently provide that, where the article was exported without compliance with the registration requirements, other documentation could be submitted or required by the district director to prove actual exportation of the article, such as a foreign customs entry, a foreign customs invoice, a foreign landing certificate, bill of lading or airway bill.

The elimination of Customs Form 4455 for articles entered under subheadings 9802.00.40, 9802.00.50, and 9802.00.60, HTSUS, should save time and expense for both Customs and the importing community.

As in the case of Customs Form 3311 discussed above, some of the information which is required on Customs Form 4455 and which is not duplicated by the declarations required by §§ 10.8 and 10.9, such as the statement regarding exportation without benefit of drawback, is essential for the processing of entries under these tariff provisions and should continue to be provided to Customs. Accordingly, it is proposed to require such information as part of the declaration of the owner,

importer, consignee, or agent; this declaration would refer to the declaration of the party who performed the repair or alteration or processing abroad and could be either included as an addendum to that declaration or submitted separately. Unlike present §§ 10.8 and 10.9, the proposed revised sections would include a standard format for the declaration by the owner, importer, consignee, or agent. In addition, this proposed declaration as set forth in section 10.9 incorporates the statement by the owner or exporter presently required by § 10.9(a) to be included on the reverse side of Customs Form 4455.

Finally, as presently worded, § 10.8 only refers to subheading 9802.00.40, HTSUS, and thus does not reflect that the tariff provision was split into two subheadings so that goods under warranty could be identified separately from other repaired or altered goods. Accordingly, the proposed revision of § 10.8 set forth below includes references to subheading 9802.0050.

Elimination of the Certificate of Origin Form A Under the Generalized System of Preferences and the Caribbean Basin Initiative

The Generalized System of Preference or GSP (19 U.S.C. 2461–2466) and the Caribbean Basin Initiative or CBI (enacted as the Caribbean Basin Economic Recovery Act, 19 U.S.C. 2701–2706) are special tariff treatment programs which provide for duty-free treatment for a wide range of products from designated beneficiary developing countries (BDCs). Eligible articles which are the growth, product or manufacture of BDCs are entitled to duty-free entry under these programs if they are imported directly into the United States from the BDC and if the sum of (1) the cost or value of the materials produced in the BDC, plus (2) the direct costs of processing operations incurred in the BDC, is not less than 35 percent of the appraised value of the article at the time it is entered into the U.S. See 19 U.S.C. 2463(b) and 2703(a).

The regulations implementing the GSP are set forth in §§ 10.171–10.178, Customs Regulations (19 CFR 10.171–10.178), and the regulations relating to the CBI are contained in §§ 10.191–10.198, Customs Regulations (19 CFR 10.191–10.198). The documentation requirements for these programs are set forth in § 10.173 (GSP) and § 10.198 (CBI). Both regulations require the submission by the importer or consignee of a Certificate of Origin Form A as evidence of the country of origin of shipments covered by formal entries for which GSP or CBI treatment is claimed. The Form A must be properly completed and signed by the exporter of the merchandise in the BDC.

The Form A was originally developed under the auspices of the United Nations Conference on Trade and Development (UNCTAD) to be used on a worldwide basis in connection with GSP programs implemented by developed countries for the purpose of extending duty preferences to less developed countries, and it was subsequently determined in connection with the implementation of the CBI program that use of the Form A would be equally appropriate in that context. The Form A is not available for sale in the United States but is normally obtained from the government of the BDC. The Form A includes the following information: A description and the weight or quantity of the merchandise, the number and date of the applicable invoices, whether the merchandise is "wholly the growth, product or manufacture" of a BDC, and the percentage of the appraised value represented by the sum of the BDC materials and direct costs of processing operations (for goods not wholly produced in the BDC). The form also includes a signed declaration by the exporter that the information provided is correct and that the goods comply with the GSP or CBI origin requirements.

Where merchandise covered by a formal entry for which GSP or CBI treatment is claimed is not wholly produced in the BDC, §§ 10.173(c) and 10.198(c) provide that the exporter shall be prepared to submit to Customs, upon request, a declaration. Under the regulations, the declaration shall include the number and date of the invoices, a description and the quantity of the merchandise, a description of the processing operations in the BDC, the direct costs of processing operations incurred there, and a description of the constituent BDC-produced materials including the method of their production and their cost or value.

Customs is proposing in this document to eliminate the requirement in §§ 10.173 and 10.198 that the importer or consignee file a Certificate of Origin Form A with Customs in connection with the entry of articles for which GSP or CBI treatment is claimed. Customs believes that the information required to be provided on the Form A is of limited value in determining whether the GSP or CBI rules of origin have been met. Although the Form A requires the exporter to provide for goods not wholly produced in the BDC, a percentage showing the value attributable to the BDC for purposes of the 35 percent value-content requirement, the form does not require that the exporter indicate how that percentage was calculated. Recognizing this limited value attributable to the Form A, since 1987 Customs has administratively waived submission of the Form A except where Customs makes a specific written request for its submission.

In addition to the declaration discussed above, the GSP and CBI regulations provide that the evidence of country of origin submitted shall be subject to such verification as the district director deems necessary. The information required by the declaration and any necessary verification of that information affords Customs sufficient means to determine compliance with the GSP and CBI rules of origin.

Accordingly, Customs proposes to amend the GSP and CBI regulations as set forth below to eliminate all references to use of the Form A and, in the case of goods wholly produced in the BDC, to provide instead that this fact is to be noted on the commercial invoice and entry summary.

Comments

Before adopting the proposed amendments, consideration will be given to any written comments (preferably in triplicate) timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on normal business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Franklin Court, 1099 14th Street, NW., suite 4000, Washington, DC.

Regulatory Flexibility Act

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that, if adopted, the proposed amendments will not have a significant economic impact on a substantial number of small entities. The proposed amendments would eliminate duplicative or otherwise unnecessary paperwork requirements and thus would reduce the existing regulatory burden and consequent economic impact on those entities which file claims for tariff treatment under the subject provisions and programs. Accordingly, the proposed amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified in E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Paperwork Reduction Act

The collection of information requirements contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collection of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to Customs at the address set forth previously.

The collections of information in these proposed regulations are in §§ 10.1, 10.8, 10.9, 10.173 and 10.198. This information is used by Customs to determine whether imported merchandise meets the criteria for duty-free or reduced-duty treatment under the subject tariff provisions and programs. The likely respondents are business organizations including importers, exporters and manufacturers.

Estimated total annual reporting and/or recordkeeping burden: 450 hours.

The estimated average annual burden per respondent/recordkeeper is .6 hours.

Estimated number of respondents and/or recordkeepers: 750.

Estimated annual frequency of responses: 3.

Drafting Information

The principal author of this document was Francis W. Foote, Regulations and Disclosure Law Branch, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects

19 CFR Part 10

Customs duties and inspection, Imports.

19 CFR Part 123

Customs duties and inspection, Imports, Canada, Mexico.

19 CFR Part 145

Customs duties and inspection, Imports, Postal service.

Proposed Amendments to the Regulations

Accordingly, it is proposed to amend parts 10, 123 and 145, Customs Regulations (19 CFR parts 10, 123 and 145), as set forth below.

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The authority citation for part 10 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1202, 1481, 1484, 1498, 1508, 1623, 1624;

* * * * *

Sections 10.171 through 10.178 also issued under 19 U.S.C. 2461 *et seq.*;

Sections 10.191 through 10.198 also issued under 19 U.S.C. 2701 *et seq.*;

* * * * *

2. In § 10.1, paragraph (a)(3) is removed, and the introductory text of paragraph (a) and the introductory text of paragraph (a)(1) and paragraphs (a)(2), (b), (d), (f) and (h)(2) and the first sentence of paragraph (i) and the first sentence of paragraph (j)(2) are revised to read as follows:

§ 10.1 Domestic products; requirements on entry.

(a) Except as otherwise provided for in paragraph (g), (h), (i) or (j) of this section or elsewhere in this part or in § 145.35 of this chapter, the following documents shall be filed in connection with the entry of articles in a shipment valued over $1,000 and claimed to be free of duty under subheading 9801.00.10 or 9802.00.20, Harmonized Tariff Schedule of the Unifed States (HTSUS):

(1) A declaration by the foreign shipper in substantially the following form: * * *

(2) A declaration by the owner, importer, consignee, or agent having knowledge of the facts regarding the claim for free entry. If the owner or ultimate consignee is a corporation, such declaration may be signed by the president, vice president, secretary, or treasurer of the corporation, or may be signed by any employee or agent of the corporation who holds a power of attorney executed under the conditions outlined in subpart C, part 141 of this chapter and a certification by the corporation that such employee or other agent has or will have knowledge of the pertinent facts. This declaration shall be in substantially the following form:

I, _____, declare that the (above) (attached) declaration by the foreign shipper is true and correct to the best of my knowledge and belief, that the articles were manufactured by _____(name of manufacturer) located in _____(city and state), that the articles were not manufactured or produced in the United States under subheading 9813.00.05, HTSUS, that the articles were exported from the United States without benefit of drawback, and that the articles are being returned for the following reason:

_____

_____

(date)

(Signature)

(Address)

(Capacity)

(b) In any case in which the value of the returned articles exceeds $1,000 and the articles are not clearly marked with the name and address of the U.S. manufacturer, the district director may require, in addition to the declarations required in paragraph (a) of this section, such other documentation or evidence as may be necessary to substantiate the claim for duty-free treatment.

* * * * *

(d) If the district director is reasonably satisfied, because of the nature of the articles or production of other evidence, that the articles are imported in circumstances meeting the requirements of subheading 9801.00.10 or 9802.00.20, HTSUS, and related section and additional U.S. notes, he may waive the requirements for producing the documents specified in paragraph (a) of this section.

* * * * *

(f) In the case of photographic films and dry plates manufactured in the United States (except motion picture films to be used for commercial purposes) exposed abroad and entered under subheading 9802.00.20, HTSUS, the requirements of paragraphs (a) and (c) of this section are applicable except that the declaration by the foreign shipper provided for in paragraph (a)(1) to the effect that the articles "are returned without having been advanced in value or improved in condition by any process of manufacture or other means" shall be crossed out, and the entrant shall show on the declaration provided for in paragraph (a)(2) that the subject articles when exported were of U.S. manufacture and are returned after having been exposed, or exposed and developed, and, in the case of motion picture films, that they will not be used for commercial purposes.

* * * * *

(h) * * *

(2) The documentation described in paragraph (a) of this section shall not be required in connection with an entry for nonconsumable vessel stores and equipment on Customs Form 3311.

* * * * *

(i) When the total value of articles of claimed American origin contained in any shipment does not exceed $250 and such articles are found to be unquestionably products of the United States and do not appear to have been

advanced in value or improved in condition while abroad and no quota is involved, free entry thereof may be made under subheading 9801.00.10 on Customs Form 3311, executed by the owner, importer, consignee, or agent and filed in duplicate, without regard to the requirement of filing the documentation provided for in paragraph (a) of this section, unless the Customs officer has reason to believe that Customs drawback or exemption from internal revenue tax, or both, were probably allowed on exportation of the articles or that they are otherwise subject to duty.* * *

(j) * * *

(2) After having been either rejected or returned by the foreign purchaser to the United States for credit, free entry thereof may be made under subheading 9801.00.10, HTSUS, on Customs Form 3311 (a Customs Form 7501 must be submitted as well for such articles as provided in § 143.23(h) of this chapter), executed by the owner, importer, consignee, or agent and filed in duplicate, without regard to the requirement of filing the documentation provided for in paragraph (a) of this section, unless the Customs officer has reason to believe that Customs drawback or exemption from internal revenue tax, or both, were probably allowed on exportation of the articles or that they are otherwise subject to duty.* * *

3. Section 10.8 is revised to read as follows:

§ 10.8 Articles exported for repairs or alterations.

(a) Except as otherwise provided for in this section, the following documents shall be filed in connection with the entry of articles which are returned after having been exported for repairs or alterations and which are claimed to be subject to duty only on the value of the repairs or alterations performed abroad under subheading 9802.00.40 or 9802.00.50, Harmonized Tariff Schedule of the United States (HTSUS):

(1) A declaration from the person who performed such repairs or alterations, in substantially the following form:

I, _____, declare that the articles herein specified are the articles which, in the condition in which they were exported from the United States, were received by me (us) on _____, 19 ____, from _____(name and address of owner or exporter in the United States); that they were received by me (us) for the sole purpose of being repaired or altered; that only the repairs or alterations described below were performed by me (us); that the full cost or (when no charge is made) value of such repairs or alterations are correctly stated below; and that no substitution whatever has been made to replace any of the articles originally received by me (us) from the owner or exporter thereof mentioned above.

Marks and numbers	Description of articles and of repairs or alterations	Full cost or (when no charge is made) value of repairs or alterations (see Subchapter II, Chapter 98, HTSUS)	Total value of articles after repairs or alterations

_____
(Date)

_____
(Signature)

_____
(Address)

_____
(Capacity)

(2) A declaration by the owner, importer, consignee, or agent having knowledge of the pertinent facts in substantially the following form:

I, _____, declare that the (above) (attached) declaration by the person who performed the repairs or alterations abroad is true and correct to the best of my knowledge and belief; that the articles were not manufactured or produced in the United States under subheading 9813.00.05, HTSUS; that such articles were exported from the United States for repairs or alterations and without benefit of drawback from _____ (port) on _____, 19____; and that the articles entered in their repaired or altered condition are the same articles that were exported on the above date and that are identified in the (above) (attached) declaration.

_____
(Date)

_____
(Signature)

_____
(Address)

_____
(Capacity)

(b) The district director may require such additional documentation as is deemed necessary to prove actual exportation of the articles from the United States for repairs or alterations, such as a foreign customs entry, a foreign customs invoice, a foreign landing certificate, bill of lading, or airway bill.

(c) If the district director concerned is satisfied, because of the nature of the articles or production of other evidence, that the articles are imported under circumstances meeting the requirements of subheading 9802.00.40 or 9802.00.50, HTSUS, and related section and additional U.S. notes, he may waive submission of the declarations provided for in paragraph (a) of this section.

(d) The district director shall require at the time of entry a deposit of estimated duties based upon the full cost or value of the repairs or alterations. The cost or value of the repairs or alterations outside the United States, which is to be set forth in the invoice and entry papers as the basis for the assessment of duty under subheading 9802.00.40 or 9802.00.50, HTSUS, shall be limited to the cost or value of the repairs or alterations actually performed abroad, which will include all domestic and foreign articles furnished for the repairs or alterations but shall not include any of the expenses incurred in this country whether by way of engineering costs, preparation of plans or specifications, furnishing of tools or equipment for doing the repairs or alterations abroad, or otherwise.

4. Section 10.9 is revised to read as follows:

§ 10.9 Articles exported for processing.

(a) Except as otherwise provided for in this section, the following documents shall be filed in connection with the entry of articles which are returned after having been exported for further processing and which are claimed to be subject to duty only on the value of the processing performed abroad under subheading 9802.00.60, Harmonized Tariff Schedule of the United States (HTSUS):

(1) A declaration by the person who performed the processing abroad, in substantially the following form:

I, _____, declare that the articles herein specified are the articles which, in the condition in which they were exported from the United States, were received by me (us) on _____, 19____, from _____(name and address of owner or exporter in the United States); that they were received by me (us) for the sole purpose of being processed;

that only the processing described below was effected by me (us); that the full cost or (when no charge is made) value of such processing and the value of the articles after processing are correctly stated below; and that no substitution whatever has been made to replace any of the articles originally received by me (us) from the owner or exporter thereof mentioned above.

Marks and numbers	Description of articles and of processing	Full cost or (when no charge is made) value of processing (see Subchapter II, Chapter 98, HTSUS)	Total value of articles after processing

(Date)

(Signature)

(Address)

(Capacity)

(2) A declaration by the owner, importer, consignee, or agent having knowledge of the pertinent facts in substantially the following form:

I, _____, declare that the (above) (attached) declaration by the person who performed the processing abroad is true and correct to the best of my knowledge and belief; that the articles were manufactured in the United States by _____(name and address) or, if of foreign origin, were subjected to _____(show processes of manufacture, such as molding, casting, machining) in the United States by _____(name and address); that the articles were not manufactured or produced in the United States under subheading 9813.00.05, HTSUS; that the articles were exported for processing and without benefit of drawback from _____(port) on _____, 19____; that the articles entered in their processed condition are otherwise the same articles that were exported on the above date and that are identified in the (above) (attached) declaration; and that the returned articles will be subjected to _____ (describe processing to be performed in the United States) by _____(name and address of U.S. processor).

(Date)

(Signature)

(Address)

(Capacity)

(b) The district director may require such additional documentation as is deemed necessary to prove actual exportation of the articles from the United States for processing, such as a foreign customs entry, a foreign customs invoice, a foreign landing certificate, bill of lading, or airway bill.

(c) If the district director concerned is satisfied, because of the nature of the articles or production of other evidence, that the articles are imported under circumstances meeting the requirements of subheading 9802.00.60, HTSUS, and related section and additional U.S. notes, he may waive submission of the declarations provided for in paragraph (a) of this section.

(d) The district director shall require at the time of entry a deposit of estimated duties based upon the full cost or value of the processing. The cost or value of the processing outside the United States, which is to be set forth in the invoice and entry papers as the basis for the assessment of duty under subheading 9802.00.60, HTSUS, shall be limited to the cost or value of the processing actually performed abroad, which will include all domestic and foreign articles used in the processing but shall not include the exported United States metal article or any of the expenses incurred in this country whether by way of engineering costs, preparation of plans or specifications, furnishing of tools or equipment for doing the processing abroad, or otherwise.

§ 10.172 [Amended]

5. Section 10.172 is amended by removing the last sentence.

6. The section heading and the text of § 10.173 are revised to read as follows:

§ 10.173 Evidence of country of origin.

(a) *Shipments covered by a formal entry.*

(1) *Merchandise not wholly the growth, product, or manufacture of a beneficiary developing country.*

(i) *Declaration.* In a case involving merchandise covered by a formal entry which is not wholly the growth, product, or manufacture of a single beneficiary developing country, the exporter of the merchandise or other appropriate party having knowledge of the relevant facts shall be prepared to submit directly to the district director, upon request, a declaration setting forth all pertinent detailed information concerning the production or manufacture of the merchandise. When requested by the district director, the declaration shall be prepared in substantially the following form:

GSP Declaration

I, _____(name), hereby declare that the articles described below were produced or manufactured in _____(country) by means of processing operations performed in that country as set forth below and were also subjected to processing operations in the other country or countries which are members of the same association of countries as set forth below and incorporate materials produced in the country named above or in any other country or countries which are members of the same association of countries as set forth below:

Number and date of invoices	Description of articles and quantity	Processing operations performed on articles		Materials produced in a beneficiary developing country or members of the same association	
		Description of processing operations and country of processing	Direct costs of processing operations	Description of material, production process, and country of production	Cost or value of material

Date

Address

Signature

Title

(ii) *Retention of records and submission of declaration.* The information necessary for preparation of the declaration shall be retained in the

files of the party responsible for its preparation and submission for a period of 5 years. In the event that the district director requests submission of the declaration during the 5-year period, it shall be submitted by the appropriate party directly to the district director within 60 days of the date of the request or such additional period as the district director may allow for good cause shown. Failure to submit the declaration in a timely fashion will result in a denial of duty-free treatment.

(2) *Merchandise wholly the growth, product, or manufacturer of a beneficiary developing country.* In a case involving merchandise covered by a formal entry which is wholly the growth, product, or manufacture of a single beneficiary developing country, a statement to that effect shall be included on the commercial invoice and on the entry summary.

(b) *Shipments covered by an informal entry.* Although the filing of the declaration provided for in paragraph (a)(1)(i) of this section will not be required for a shipment covered by an informal entry, the district director may require such other evidence of country of origin as deemed necessary.

(c) *Verification of documentation.* Any evidence of country or origin submitted under this section shall be subject to such verification as the district director seems necessary. In the event that the district director is prevented from obtaining the necessary verification, the district director may treat the entry as dutiable.

7. Section 10.175 is amended by removing paragraphs (c)(3) and (c)(4), redesignating paragraph (c)(5) as (c)(3), and revising paragraph (e)(1) to read as follows:

§ 10.175 Imported directly defined.

* * * * *

(e)(1) Shipment to the U.S. from a beneficiary developing country which is a member of an association of countries treated as one country under section 502(a)(3), Trade Act of 1974, as amended (19 U.S.C. 2462(a)(3)), through the territory of a former beneficiary developing country whose designation as a member of the same association for GSP purposes was terminated by the President pursuant to section 504, Trade Act of 1974, as amended (19 U.S.C. 2464), provided the articles in the shipment did not enter into the commerce of the former beneficiary developing country except for purposes of performing one or more of the operations specified in paragraph (c)(1) of this section and except for purposes of purchase or resale, other than at retail, for export.

* * * * *

§ 10.192 [Amended]

8. Section 10.192 is amended by removing the last sentence.

9. Section 10.198 is revised to read as follows:

§ 10.198 Evidence of country of origin.

(a) *Shipments covered by a formal entry.*

(1) *Articles not wholly the growth, product, or manufacture of a beneficiary country.*

(i) *Declaration.* In a case involving an article covered by a formal entry which is not wholly the growth, product, or manufacture of a single beneficiary country, the exporter or other appropriate party having knowledge of the relevant facts in the beneficiary country where the article was produced or last processed shall be prepared to submit directly to the district director, upon request, a declaration setting forth all pertinent detailed information concerning the production or manufacture of the article. When requested by the district director, the declaration shall be prepared in substantially the following form:

CBI Declaration

I, _____(name), hereby declare that the articles described below (a) were produced or manufactured in _____ (country) by means of processing operations performed in that country as set forth below and were also subjected to processing operations in the other beneficiary country or countries (including the Commonwealth of Puerto Rico and the U.S. Virgin Islands) as set forth below and (b) incorporate materials produced in the country named above or in any other beneficiary country or countries (including the Commonwealth of Puerto Rico and the U.S. Virgin Islands) or in the customs territory of the United States (other than the Commonwealth of Puerto Rico) as set forth below:

Number and date of invoices	Description of articles and quantity	Processing operations performed on articles		Material produced in a beneficiary country or in the U.S.	
		Description of processing operations and country of processing	Direct costs of processing operations	Description of material, production process, and country of production	Cost or value of material

Date _____

Address _____

Signature _____

Title _____

(ii) *Retention of records and submission of declaration.* The information necessary for preparation of the declaration shall be retained in the files of the party responsible for its preparation and submission for a period of 5 years. In the event that the district director requests submission of the declaration during the 5-year period, it shall be submitted by the appropriate party directly to the district director within 60 days of the date of the request or such additional period as the district director may allow for good cause shown. Failure to submit the declaration in a timely fashion will result in a denial of duty-free treatment.

(iii) *Value added after final exportation.* In a case in which value is added to an article in a bonded warehouse or in a foreign-trade zone in the Commonwealth of Puerto Rico or in the U.S. after final exportation of the article from a beneficiary country, in order to ensure compliance with the value requirement under § 10.195(a), the declaration provided for in paragraph (a)(1)(i) of this section shall be filed by the importer or consignee with the entry summary as evidence of the country of origin. The declaration shall be properly completed by the party responsible for the addition of such value.

(2) *Merchandise wholly the growth, product, or manufacture of a beneficiary country.* In a case involving merchandise covered by a formal entry which is wholly the growth, product, or manufacture of a single beneficiary country, a statement to that effect shall be included on the commercial invoice and on the entry summary.

(b) *Shipments covered by an informal entry.* Although the filing of the

declaration provided for in paragraph (a)(1)(i) of this section will not be required for a shipment covered by an informal entry, the district director may require such other evidence of country of origin as deemed necessary.

(c) *Verification of documentation.* Any evidence of country of origin submitted under this section shall be subject to such verification as the district director deems necessary. In the event that the district director is prevented from obtaining the necessary verification, the district director may treat the entry as dutiable.

PART 123—CUSTOMS RELATIONS WITH MEXICO AND CANADA

1. The authority citation for part 123 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 8, Harmonized Tariff Schedule of the United States), 1624.

* * * * *

Section 123.4 also issued under 19 U.S.C. 1484, 1498;

* * * * *

2. Section 123.4(c) is amended by removing the reference "§ 10.1(f)" and adding, in its place, the reference "§ 10.1(i)."

PART 145—MAIL IMPORTATIONS

1. The authority citation for part 145 continues to read in part as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 8, Harmonized Tariff Schedule of the United States), 1624.

* * * * *

Sections 145.35 through 145.38, 145.41, also issued under 19 U.S.C. 1498;

* * * * *

§ 145.35 [Amended]

2. Section 145.35 is amended by removing the words "an importer's declaration on Customs Form 3311" and adding, in their place, the words "the declarations provided for in § 10.1(a) of this chapter".

Carol Hallett,

Commissioner of Customs.

Approved: January 8, 1993.

Peter K. Nunez,

Assistant Secretary of the Treasury.

[FR Doc. 93-1015 Filed 1-14-93; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Federal Highway Administration

23 CFR Part 1215

RIN 2127-AE50

[Docket No. 92-40 Notice 1]

Use of Safety Belts and Motorcycle Helmets—Compliance and Transfer-of-Funds Procedures

AGENCY: National Highway Traffic Safety Administration, Federal Highway Administration, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to implement the penalty provisions contained in section 153 of title 23, United States Code, as enacted by section 1031 of the Intermodal Surface Transportation Efficiency Act of 1991. Section 153 provides that a State that fails to adopt and put into effect motorcycle helmet and safety belt use laws before October 1, 1993 is subject to having the Secretary of Transportation transfer obligation authority from the State's Federal-aid highway programs to its apportionment under the section 402 safety program. This proposed rule sets forth the criteria to be used to determine a State's compliance with the Act and proposes the mechanism by which NHTSA will inform States of their compliance status.

DATES: Comments are due no later than March 1, 1993.

ADDRESSES: Written comments should refer to the docket number of this notice and should be submitted to: Docket Section, room 5109, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. (Docket hours are 9:30 am to 4 pm.)

FOR FURTHER INFORMATION CONTACT: Adele Derby, Associate Administrator for Regional Operations, room 5238, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590 (202-366-2121) or Kathleen Demeter, Office of the Chief Counsel, room 5219, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590 (202-366-1834). Also, Mila Plosky, Office of Highway Safety, room 3407, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590 (202) 366-6902 or Wilbert Baccus, Office of the Chief Counsel, room 4230, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590 (202) 366-0780.

SUPPLEMENTARY INFORMATION:

Background

Wearing safety belts and motorcycle helmets are two of the most effective actions the motoring public can take to reduce the incidence of death and serious injury from highway crashes. The best approach to increase safety belt and motorcycle helmet use is to pass effective State laws requiring motorcycle helmet and safety belt use, educate the public about the benefits of these safety devices, train law enforcement officers, and enforce use laws.

Section 1031 of the Intermodal Surface Transportation Efficiency Act of 1991 (P.L. 102-240) (the Act) adds a new section 153 to Title 23 of the United States Code which authorizes a three year incentive grant program designed to promote the passage of, and compliance with, motorcycle helmet and safety belt laws. To be eligible for funding under the Act in the first year, a State must have in effect both a law requiring all individuals on a motorcycle to wear helmets and a law requiring individuals in the front seat of passenger vehicles to wear safety belts (or be secured in child passenger safety systems).

Continued eligibility for the grants is conditioned upon meeting specific compliance rates. To be eligible in the second year a State must achieve at least 75% compliance with its motorcycle helmet law and 50% compliance with its safety belt law. For the third year, a State must achieve at least 85% compliance with its motorcycle helmet law and 70 compliance with its safety belt law.

If a State fails to adopt and put into effect motorcycle helmet and safety belt use laws before the first day of fiscal year (FY) 1994 (October 1, 1993), section 153(h) directs the Secretary of Transportation to transfer funds from the State's Federal-aid highway programs under each of subsections 104 (b)(1), (b)(2), and (b)(3) of title 23, U.S.C., to the State's highway safety program under section 402 of that title. The transfer will take place in the fiscal year succeeding the year in which the State is in non-compliance. A State not in compliance at the beginning of FY 1994 will experience transfer of 1½% of its Federal highway construction funds for FY 1995. For non-compliance in FY 1995 and beyond, the transfer will rise to 3%. Any obligation limitation applicable to the transferred construction funds prior to transfer will

apply, proportionately, to those funds after transfer.

The transferred funds may be used for approved projects in any 402 program areas. The funds shall be used without Federal earmarking of any amounts or percentages for specific program activity. The Federal share of the cost of any project carried out under section 402 with the transferred funds shall be 100%.

Proposed Compliance Criteria

To regulate the transfer process for FY 1995 and later years, the agency is proposing to apply criteria that are derived from the criteria that it employed in awarding incentive grants for FY 1992. A State that qualified for an incentive grant for FY 1992 would be considered in compliance for transfer purposes and any State not meeting those criteria on October 1, 1993, would be in non-compliance and subject to the transfer.

The law provides that, in order to avoid the funds transfer, a State must have in effect by October 1, 1993, a law which makes unlawful throughout the State the operation of a motorcycle if any individual on the motorcycle is not wearing a motorcycle helmet and a law which makes unlawful throughout the State the operation of a passenger vehicle whenever an individual in a front seat of the vehicle (other than a child who is secured in a child restrain system) does not have a safety belt properly fastened about the individual's body.

Section 153(i) contains the following definitions:

"Motorcycle" means a motor vehicle which is designed to travel on not more than 3 wheels in contact with the surface;

"Motor vehicle" means any vehicle driven or drawn by mechanical power manufactured primarily for use on public highways, except any vehicle operated exclusively on a rail or rails;

"Passenger vehicle" means a motor vehicle which is designed for transporting 10 or fewer individuals, including the driver, except that such term does not include a vehicle which is constructed on a truck chassis, a motorcycle, a trailer, or any motor vehicle which is not required on the date of the enactment of this section under a Federal Motor Vehicle Safety Standard to be equipped with a belt system;

"Safety Belt" means: (a) With respect to open-body passenger vehicles, including convertibles, an occupant restraint system consisting of a lap belt or a lap belt and a detachable shoulder belt; and (b) with respect to other passenger vehicles, an occupant restraint system consisting of integrated lap shoulder belts.

Except for children in child restraint systems, the statute does not provide for any exemptions from application. However, NHTSA recognizes that all States have exemptions written into one or both of their motorcycle helmet and safety belt laws. NHTSA believes that Congress' intent to aid States in their efforts to achieve higher safety belt and motorcycle helmet use and enact and maintain use laws would not be served by reading the statute so literally as to impose a penalty upon all States whose laws contain any exemptions. On the other hand, some exemptions are either incompatible with the language of the statute or would so undermine the safety considerations underlying the statute that States whose laws contain such exemptions should be subject to the penalties contained in the Act.

NHTSA has reviewed current State laws and proposes to permit all of the existing exemptions, except those specified below. The exemptions that the agency proposes to permit cover persons with medical excuses; postal, utility and other commercial drivers who make frequent stops in the course of their business; emergency vehicles operators and passengers; persons riding in positions not equipped with safety belts; persons in public and livery conveyances; persons riding in parade vehicles; persons in the custody of police; persons in vehicles not required to have shoulder belts in front and passengers of certain larger, heavier vehicles. NHTSA also proposes to permit exemptions from current motorcycle helmet laws, such as for riders in enclosed cabs. In NHTSA's view these exemptions apply to situations in which the risk to occupants is very low or in which there are exigent justifications. NHTSA proposes to consider the following exemptions incompatible with the statute:

1. Motorcycle helmet laws of less than universal application, such as laws which apply only to minors or novice motorcycle operators;
2. Safety belt laws which exempt vehicles equipped with air bags.

A motorcycle helmet law that exempts a significant percentage of riders from its coverage is wholly inconsistent with the statute, and would result in large numbers of riders being exposed to serious risk. A law exempting persons in vehicles equipped with air bags would leave large numbers of persons at risk in side impact and rollover crashes, crashes for which air bags provide little or no protection, and would diminish occupant protection even in frontal crashes.

NHTSA further proposes that any State considering an exemption other than those listed above should anticipate that the agency will review the exemption in accordance with these principles. An example of such an exemption would be a provision calling for secondary enforcement of a motorcycle helmet law. Under such a system the rider could not be cited for failure to wear a helmet unless stopped by a law enforcement officer for another reason. To date all motorcycle helmet use laws have been primary enforcement laws. NHTSA would consider a State helmet law with only secondary enforcement provisions non-complying because it is likely that helmet use in a jurisdiction with such a law would be significantly lower than the rate that is typical in States with primary enforcement laws. Every percentage point that is lost represents riders who will be at greater risk of fatal or serious injury.

Notification of Compliance

NHTSA proposes to notify all States of initial assessments of compliance with section 153 for FY 1994, by September 30, 1993. Each State initially found not to comply would have an opportunity to rebut this initial determination. The agency would notify all States by January 31, 1994, of its final determinations of compliance or noncompliance with section 153 for FY 1994.

For fiscal years 1995 and beyond, the agency proposes to notify States of initial assessments of compliance by September 15 of the fiscal year prior to the fiscal year for which compliance is being assessed (e.g., September 15, 1994 for compliance in FY 1995). Each State initially found not to comply would have an opportunity to rebut this initial determination. The agency would notify all States by October 10 of the fiscal year for which compliance is being assessed of its final determinations of compliance or noncompliance with section 153 for that fiscal year (e.g., October 10, 1994 for FY 1995).

Written Comments

Interested persons are invited to comment on this notice of proposed rulemaking. It is requested, but not required, that ten copies be submitted.

All comments must be limited to 15 pages in length. Necessary attachments may be appended to those submissions without regard to the 15-page limit. (49 CFR 553.21.) This limitation is intended

to encourage commenters to detail their primary arguments in a concise fashion.

Written comments to the public docket must be received by March 1, 1993. All comments received before the close of business on the comment closing date will be considered and will be available for examination in the docket at the above address before and after that date. To the extent possible, comments filed after the closing date will also be considered. However, the rulemaking action may proceed at any time after that date. Following the close of the comment period, NHTSA and FHWA will publish a final rule responding to the comments. NHTSA and FHWA will continue to file relevant material in the docket as it becomes available after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the docket should enclose, in the envelope with their comments, a self-addressed stamped postcard. Upon receiving the comments, the docket supervisor will return the postcard by mail.

Copies of all comments will be placed in Docket 92–40; Notice 1 of the NHTSA Docket Section in room 5109, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

Federalism Assessment

This rulemaking action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that it will have no federalism implication that warrants the preparation of a federalism assessment.

This proposed rule would not have any preemptive or retroactive effect. It imposes no requirements on the States, but rather encourages States to consider enacting and enforcing legislation requiring the use of safety belts and motorcycle helmets through the potential transfer of Federal-aid highway funds to the 402 program. Any transfer of funds would not take place until FY 1995, and States can avoid the transfer of funds by enacting and enforcing conforming legislation. The statute does not establish a procedure for judicial review of the final rules promulgated under its provisions. There is no requirement that individuals submit a petition for reconsideration nor is there any other administrative proceeding required before they may file suit in court.

Economic and Other Effects

NHTSA has analyzed the effect of this action and has determined that it is not "major" within the meaning of Executive Order 12291, but that it is "significant" within the meaning of Department of Transportation regulatory policies and procedures. A Preliminary Regulatory Evaluation describing in detail the expected costs and benefits from the implementation of the Act has been prepared and placed in the docket. In short, NHTSA estimates that if all of the States without safety belt or helmet use laws were to pass such laws to avoid the transfer of funds 296 lives would be saved and there would be 7539 fewer injuries, including 4041 fewer serious injuries, each year. In terms of costs to the States, the States with conforming laws will incur no costs. States penalized will accrue a loss of highway construction funds, but these monies will remain in the State to be used in the State's 402 highway safety program. For many States this will result in a doubling (or more) of the States's available 402 funding. In any event, any costs to States resulting from the fund transfer are a result of the statute, not this rule and are avoidable by passage of the requisite usage laws.

The agency has evaluated the effects of this proposed rule on small entities. Based on the evaluation, we certify that this rule will not have a significant economic impact on a substantial number of small entities. The preparation of a Regulatory Flexibility Analysis is, therefore, unnecessary.

The agency has also analyzed this action for the purpose of the National Environmental Policy Act. The agency has determined that this action will not have any effect on the human environment.

List of Subjects in 23 CFR Part 1215

Safety belts, Motorcycle helmets, Transportation, Highway safety.

In accordance with the foregoing, part 1215 of title 23 of the Code of Federal Regulations would be added as follows:

PART 1215—USE OF SAFETY BELTS AND MOTORCYCLE HELMETS—COMPLIANCE AND TRANSFER-OF-FUNDS PROCEDURES

Sec.
1215.1 Scope
1215.2 Purpose
1215.3 Definitions
1215.4 Compliance Criteria
1215.5 Notification of Compliance Status
1215.6 Transfer of Funds
1215.7 Use of Transferred Funds

Authority: 23 U.S.C. 153, delegation of authority at 49 CFR 1.50.

§ 1215.1 Scope.

This part establishes criteria, in accordance with 23 U.S.C. 153, for determining compliance with the requirement that States not having safety belt and motorcycle helmet use laws be subject to a transfer of Federal-aid highway apportionments under 23 U.S.C. 104 (b)(1), (b)(2), and (b)(3) to the highway safety program apportionment under 23 U.S.C. 402.

§ 1215.2 Purpose.

The purpose of this part is to clarify the provisions which a State must incorporate into its laws to prevent the transfer of a portion of its Federal-aid highway construction and highway safety construction funds to the section 402 highway safety program apportionment.

§ 1215.3 Definitions.

As used in this part:

Motor Vehicle means any vehicle driven or drawn by mechanical power manufactured primarily for use on public highways, except any vehicle operated exclusively on a rail or rails.

Motorcycle means a motor vehicle which is designed to travel on not more than 3 wheels in contact with the surface.

Passenger Vehicle means a motor vehicle which is designed for transporting 10 or fewer individuals, including the driver, except that such term does not include a vehicle which is constructed on a truck chassis, a motorcycle, a trailer, or any motor vehicle which is not required on the date of the enactment of this section under a Federal motor vehicle safety standard to be equipped with a belt system.

Safety Belt means: with respect to open-body passenger vehicles, including convertibles, an occupant restraint system consisting of a lap belt or a lap belt and a detachable shoulder belt; and with respect to other passenger vehicles, an occupant restraint system consisting of integrated lap shoulder belts.

§ 1215.4 Compliance criteria.

(a) In order to avoid the transfer specified in § 1215.6 a State must have a law which makes unlawful throughout the State the operation of a motorcycle if any individual on the motorcycle is not wearing a motorcycle helmet.

(b) In order to avoid the transfer specified in § 1215.6, a State must have a law which makes unlawful throughout the State the operation of a passenger vehicle whenever an individual in the front seat of the vehicle (other than a child who is secured in a child restraint system) does not have a safety belt properly fastened about the individual's body.

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(c) A State that enacts the laws specified in paragraphs (a) and (b) of this section will be determined to comply with 23 U.S.C. 153, provided that any exemptions or exceptions are consistent with the intent of paragraphs (a) and (b) of this section and apply to situations in which the risk to occupants is very low or in which there are exigent justifications.

§ 1215.5 Review and notification of compliance status.

(a) Review of each State's laws and notification of compliance status with 23 U.S.C. 153(h) for fiscal year 1994 shall occur in accordance with the following procedures:

(1) NHTSA will undertake, independently, to review appropriate State laws. NHTSA will notify States by certified mail of NHTSA's initial assessment of compliance with 23 U.S.C. 153(h) by September 30, 1993.

(2) If NHTSA initially finds that a State does not comply, the notice shall state the reasons for the noncompliance and shall inform the State that it may, within 30 calendar days of its receipt of the notice, submit documentation showing why it is in compliance. Such documentation shall be submitted to the Associate Administrator for Regional Operations, NHTSA, 400 Seventh Street, SW., Washington, DC, 20950.

(3) NHTSA will notify each State by certified mail of NHTSA's final determination of the State's compliance or non-compliance with 23 U.S.C. 153(h) by January 31, 1994.

(b) Review of each State's laws and notification of compliance status for fiscal year 1995 and beyond shall occur in accordance with the following procedures:

(1) NHTSA will undertake, independently, to review appropriate State laws. NHTSA will notify States by certified mail of NHTSA's initial assessment of compliance with 23 U.S.C. 153(h) by September 15 of the fiscal year prior to the fiscal year for which compliance is being reviewed.

(2) If NHTSA initially finds that a State does not comply, the notice shall state the reasons for the noncompliance and shall inform the state that it may, within 10 working days of its receipt of the notice, submit documentation showing why it is in compliance. Such documentation shall be submitted to the Associate Administrator for Regional Operations, NHTSA, 400 Seventh Street, SW., Washington, DC, 20950.

(3) NHTSA will notify each State by certified mail of NHTSA's final determination of the State's compliance or non-compliance with 23 U.S.C. 153(h) by October 10 of the fiscal year for which compliance is being reviewed.

§ 1215.6 Transfer of funds.

(a) If, at any time in fiscal year 1994, a State does not have in effect the laws described in § 1215.4, the Secretary shall transfer 1½ percent of the funds apportioned to the State for fiscal year 1995 under 23 U.S.C. 104 (b)(1), (b)(2) and (b)(3) to the apportionment of the State under 23 U.S.C. 402.

(b) If, at any time in a fiscal year beginning after September 30, 1994, a State does not have in effect the laws described in § 1215.4, the Secretary shall transfer 3 percent of the funds apportioned to the State for the succeeding fiscal year under 23 U.S.C. 104 (b)(1), (b)(2) and (b)(3) to the apportionment of the State under 23 U.S.C. 402.

(c) Any obligation limitation existing on the transferred construction funds prior to transfer will apply, proportionately, to those funds after transfer.

§ 1215.7 Use of transferred funds.

(a) Any funds transferred under § 1215.6 may be used for approved projects in any section 402 program area.

(b) Any funds transferred under § 1215.6 shall not be subject to Federal earmarking of any amounts or percentages for specific program activities.

(c) The Federal share of the cost of any project carried out under section 402 with the transferred funds shall be 100%.

Thomas D. Larson,

Administrator, Federal Highway Administration.

Issued on: January 11, 1993.

Marion C. Blakey,

Administrator, National Highway Traffic Safety Administration.

[FR Doc. 93–964 Filed 1–12–93; 10:44 am]

BILLING CODE 4910–59–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 52

[PS–89–91]

RIN 1545–AQ23

Exports of Chemicals That Deplete the Ozone Layer; Special Rules for Certain Medical Uses of Chemicals That Deplete the Ozone Layer

AGENCY: Internal Revenue Service, Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to taxes imposed on exports of chemicals that deplete the ozone layer, taxes imposed on ozone-depleting chemicals used as medical sterilants or propellants in metered-dose inhalers, and floor stocks taxes on ozone-depleting chemicals. The proposed regulations reflect changes to the law made by the Omnibus Budget Reconciliation Act of 1989, the Omnibus Budget Reconciliation Act of 1990, and the Energy Policy Act of 1992 and affect persons who manufacture, import, export, sell, or use chemicals that deplete the ozone layer. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written comments and requests to speak at the public hearing scheduled for Thursday, May 27, 1993, must be received by March 16, 1993. Outlines of oral comments to be presented at the hearing must be received by May 6, 1993.

ADDRESSES: Send submissions to: Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044 (Attention: CC:CORP:T:R (PS–89–91), room 5228). In the alternative, submissions may be hand delivered to: CC:CORP:T:R (PS–89–91), Internal Revenue Service, room 5228, 1111 Constitution Avenue, NW., Washington, DC 20224. The public hearing will be held in the Commissioner's Conference Room, room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Ruth Hoffman, (202) 622–3130; concerning the submissions, Carol Savage, (202) 622–8452 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collections of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, T:FP, Washington, DC 20224.

The requirements for collection of information in this proposed regulation are in §§ 52.4682–2(b) (3) and (4), 52.4682–2(d) (4) and (5), 52.4682–2(d) (1), (3) and (4), and 52.4682–2(f)(3). This information is required by the Internal Revenue Service to verify compliance with sections 4681 and 4682 of the

Internal Revenue Code. This information will be used to determine whether the amount of tax has been computed correctly. The likely respondents and/or recordkeepers are businesses and other organizations.

These estimates are an approximation of the average time expected to be necessary for a collection of information. They are based on such information as is available to the Internal Revenue Service. Individual respondents and recordkeepers may require more or less time, depending on their particular circumstances.

Estimated total annual recordkeeping burden: 141 hours.

Estimated average annual burden per recordkeeper: 0.2 hour.

Estimated number or recordkeepers: 616.

Estimated total annual reporting burden: 60 hours.

Estimated average burden per respondent: 0.1 hour.

Estimated number of respondents: 600.

Estimated frequency of responses: On occasion.

Background

This document contains proposed regulations relating to export of ozone-depleting chemicals (ODCs) under sections 4681 and 4682 of the Internal Revenue Code. Section 4682(d)(3) provides a limited exemption from tax for ODCs that are exported. Although final regulations under sections 4681 and 4682 were published in the **Federal Register** on November 4, 1991 (56 FR 56303), the section of the final regulations relating to exports of ODCs was reserved. These proposed regulations would provide the rules relating to the section 4682(d)(3) export exemption.

The Energy Policy Act of 1992 (Energy Act) increased and made uniform the base tax amounts for all ODCs and extended the floor stocks tax to calendar years after 1994. The Energy Act also amended section 4682(g) to provide a reduced rate of tax for (1) ODCs used as propellants in metered-dose inhalers (for years after 1992) and (2) ODCs used as medical sterilants and methyl chloroform (for 1993 only). These proposed regulations would amend the existing regulations to reflect and provide guidance on these changes.

Explanation of provisions

Exports of ODCs

The proposed regulations provide guidance on the limited exemption for exports that is available to manufacturers and importers of ODCs under section 4682(d)(3). Under the proposed regulations, tax is not imposed with respect to ODCs that are sold for export, to the extent that (1) the tax benefits from the sales for export do not exceed certain limits, and (2) the procedures specified in the regulations are followed. These include procedures regarding registration of persons selling and purchasing ODCs for export and documentation of actual export of the ODCs.

The proposed regulations follow the rules of section 4682(d)(3)(B) in providing for a separate limitation on tax benefits for sales for export of post-1989 ODCs and sales for export of post-1990 ODCs. The proposed regulations define these separate limits as the "post-1989 ODC exemption amount" and the "post-1990 ODC exemption amount." Under the proposed regulations, the post-1989 ODC exemption amount is the aggregate tax benefit available to a manufacturer or importer from the sale for export of post-1989 ODCs in a calendar year. The post-1990 ODC exemption amount is the aggregate tax benefit available to a manufacturer or importer from the sale for export of post-1990 ODCs in a calendar year. Tax is imposed, however, on a manufacturer's or importer's sales of ODCs, even if the ODCs are sold for export, if the tax benefits that the manufacturer or importer must take into account for the calendar year would otherwise exceed the relevant exemption amount.

The proposed regulations provide procedures for tax-free sales of ODCs by manufacturers or importers if the ODCs are to be exported. However, under the proposed regulations, tax is imposed on a sale for export unless (1) the seller and purchaser are registered with the IRS, and (2) the manufacturer or importer obtains the required certificate from the purchaser. In addition, under the proposed regulations, if a person purchases ODCs tax free for export, and the person does not export the ODCs or sell the ODCs to a second purchaser for export, the person is liable for tax under section 4681 when the ODCs are sold or used.

Under the proposed procedures, if a manufacturer or importer sells ODCs for export tax free and meets the registration and certification requirements, the manufacturer or importer need not obtain documentation of the actual export of the ODCs. However, the person who purchases ODCs for export is required to document their exportation as required by the Environmental Protection Agency.

The proposed regulations also provide procedures for manufacturers or importers of ODCs to claim a credit or refund of tax paid with respect to ODCs that are exported. To claim a credit or refund, a manufacturer or importer must obtain the documentation of export required by the Environmental Protection Agency, and meet certain other conditions. Persons other than manufacturers and importers of ODCs are not permitted to claim a credit or refund of any tax included in the purchase price of ODCs they export. Such claims may only be made by a manufacturer or importer, and are a tax benefit subject to the limitation of the manufacturer's or importer's exemption amount.

Medical Sterilants and Inhaler Propellants

Under section 4682(g)(4), ODCs used as propellants in metered-dose inhalers are subject to a reduced rate of tax in calendar years after 1992, and ODCs used as medical sterilants are subject to a reduced rate of tax in 1993 only. The proposed regulations permit sales of ODCs to purchasers for these purposes at a reduced rate of tax, if proper certification is provided to the manufacturer or importer of the ODCs. The certificates and procedures for certification are similar to those that apply to sales of ODCs for use as a feedstock or in the manufacture of rigid foam insulation.

If a purchaser bought ODCs on which the full tax was imposed and used the ODCs as medical sterilants or propellants in metered-dose inhalers, a credit or refund of tax is available to the purchaser for the excess of the full tax over the tax determined under the reduced rate. The proposed regulations provide guidance on how the credit or refund may be claimed.

Floor Stocks Taxes

Prior to its amendment by the Energy Act, section 4682(h) imposed the floor stocks tax on January 1 of calendar years 1990–1994. The Energy Act extended the floor stocks tax to apply on January 1 of calendar years after 1994. The proposed regulations amend the existing regulations to reflect this change. For example, the proposed regulations provide a de minimis rule for floor stocks tax for calendar years after 1994.

Special Analyses

It has been determined that these proposed rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility

Act (5 U.S.C. chapter 6) do not apply to these regulations and, therefore, an initial Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted, consideration will be given to any written comments that are timely submitted (preferably a signed original and eight copies) to the Internal Revenue Service. All comments will be available for public inspection and copying. A public hearing has been scheduled for Thursday, May 27, 1993, beginning at 10 a.m. Requests to speak may be submitted by anyone that timely submits written comments.

The rules of § 601.601(a)(3) of the Statement of Procedural Rules (26 CFR part 601) shall apply to the public hearing. A person wishing to make oral comments at the public hearing must file written comments and a request to speak by March 16, 1993 and submit an outline of the oral comments to be presented and the time to be devoted to each topic by May 6, 1993.

Each speaker (or group of speakers representing a single entity) will be limited to 10 minutes, exclusive of the time consumed by answering questions from the panel for the government.

An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Because of access restrictions, visitors cannot be permitted beyond the lobby of the Internal Revenue Building before 9:45 a.m.

Drafting Information

The principal author of these regulations is Ruth Hoffman, Office of Assistant Chief Counsel (Passthroughs and Special Industries). However, personnel from other offices of the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 52

Chemicals, Excise taxes, Petroleum.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 52 is proposed to be amended as follows:

PART 52—ENVIRONMENTAL TAXES

Paragraph 1. The authority citation for part 52 is amended by adding the following citation:

Authority: 26 U.S.C. 7805. * * * Section 52.4682–5 also issued under 26 U.S.C. 4662(e)(4). * * *

Par. 2. Section 52.4681–0 is amended by:

1. Adding an entry for § 52.4682–1(b)(2)(iv).
2. Revising the entries for § 52.4682–1 (f) and (g).
3. Adding entries for §§ 52.4682–1 (h) through (k) and 52.4682–2(b) (3) and (4).
4. Revising the entry for § 52.4682–2(d) heading.
5. Adding entries for § 52.4682–2(d) (4) and (5).
6. Adding entries for § 52.4682–4(b)(2) (vi) through (viii) and (d)(4).
7. Revising the entry for § 52.4682–4(e)(5).
8. Adding an entry for § 52.4682–4(e)(6).
9. Adding entries for § 52.4682–5.
10. The revisions and additions read as follows:

§ 52.4681–0 Table of contents.

* * * * *

§ 52.4682–1 Ozone-depleting chemicals.

* * * * *

(b) * * *
(2) * * *
(iv) Special rule for exports.

* * * * *

(f) Methyl chloroform; reduced rate of tax in 1993.
(g) ODCs used as medical sterilants.
(1) Phase-in of tax.
(2) Excess payments.
(3) Definition of use as a medical sterilant.
(4) Qualifying sale.
(h) ODCs used as propellants in metered-dose inhalers.
(1) Reduced rate of tax.
(2) Excess payments.
(3) Definition of metered-dose inhaler.
(4) Qualifying sale.
(i) [Reserved]
(j) Exports; cross reference.
(k) Recycling [Reserved]

§ 52.4682–2 Qualifying sales.

* * * * *

(b) * * *
(3) Use as medical sterilants.
(4) Use as propellants in metered-dose inhalers.

* * * * *

(d) *Certificate.*

* * * * *

(4) Certificate relating to ODCs used as medical sterilants.
(5) Certificate relating to ODCs used as propellants in metered-dose inhalers.

* * * * *

§ 52.4682–4 Floor stocks tax.

* * * * *

(b) * * *
(2) * * *
(vi) ODCs to be exported.
(vii) ODCs used as propellants in metered-dose inhalers; years after 1992.
(viii) ODCs used as medical sterilants; 1993.

* * * * *

(d) * * *
(4) Methyl chloroform; 1993.
(e) * * *
(5) Calendar years after 1994.
(6) Examples.

* * * * *

§ 52.4682–5 Exports.

(a) Overview.
(b) Exemption or partial exemption from tax.
(1) In general.
(2) Tax imposed if exemption amount exceeded.
(i) Post-1989 ODCs.
(ii) Post-1990 ODCs.
(iii) Allocation of tax.
(3) Mixtures.
(c) Exemption amount.
(1) Post-1989 ODC exemption amount.
(2) Post-1990 ODC exemption amount.
(3) Definitions.
(i) 1986 export percentage.
(ii) 1989 export percentage.
(d) Procedural requirements relating to tax-free sales for export.
(1) Qualifying sales.
(i) In general.
(ii) Qualifying resale.
(iii) Special rule relating to sales made before July 1, 1993.
(2) Good faith reliance.
(3) Certificate.
(i) In general.
(ii) Model certificates.
(iii) Use of Form 637 as a certificate prohibited.
(4) Documentation of export.
(e) Purchaser liable for tax.
(1) Purchaser in qualifying sale.
(2) Purchaser in qualifying resale.
(f) Credit or refund.
(1) In general.
(2) Limitation.
(3) Conditions to allowance of credit or refund.
(4) Procedural rules.
(g) Examples.
(h) Effective date.

Par. 3. Section 52.4681–1 is amended as follows:

1. Paragraph (a)(3)(ii) is revised.
2. Paragraph (c)(7)(iii)(A) is revised.
3. Paragraph (d)(3) is revised.
4. The revised provisions read as follows:

§ 52.4681–1 Taxes imposed with respect to ozone-depleting chemicals.

(a) * * *
(3) * * *
(ii) *Dates on which tax imposed.* The floor stocks tax is imposed on January 1 of each calendar year after 1989.

* * * * *

(c) * * *
(7) * * *
(iii) * * *

(A) Section 52.4682–1(b)(2)(iii) (relating to mixture elections) and (iv) (relating to mixtures for export);

* * * * *

(d) * * *

(3) Post-1989 ODCs held for sale or for use in further manufacturer by any person other than the manufacturer or importer thereof of January 1, 1990, and post-1989 and post-1990 ODCs that are so held on January 1 of each calendar year after 1990.

Par. 4. Section 52.4682–1 is amended as follows:

1. Paragraph (a) is revised.
2. The introductory text of paragraph (b)(2)(ii) is revised.
3. Paragraphs (b)(2)(iv) is added.
4. Paragraphs (f) and (g) are revised.
5. Paragraph (h) is added.
6. Paragraph (i) is added and reserved.
7. Paragraph (j) is added.
8. Paragraph (k) is added and reserved.
9. The revised, added, and reserved provisions read as follows:

§ 52.4682–1 Ozone-depleting chemicals.

(a) *Overview.* This section provides rules relating to the tax imposed on ozone-depleting chemicals (ODCs) under section 4681, including rules for identifying taxable ODCs and determining when the tax is imposed, and rules prescribing special treatment for certain ODCs. See § 52.4681–1 (a)(1) and (c) for general rules and definitions relating to the tax on ODCs.

(b) * * *

(2) * * *

(ii) *Mixtures.* Except as provided in paragraphs (b)(2) (iii) and (iv) of this section, the creation of a mixture containing two or more ingredients is treated as a use of the ODCs contained in the mixture. Thus, except as provided in paragraphs (b)(2) (iii) and (iv) of this section—

* * * * *

(iv) *Special rule for exports.* The creation of a mixture for export is not a taxable use of the ODCs contained in the mixture. See § 52.4682–5(e) for rules relating to liability of a purchaser for tax if the mixture is not exported.

* * * * *

(f) *Methyl chloroform; reduced rate of tax in 1993.* The amount of tax imposed on methyl chloroform is determined under section 4682(g)(5) if the manufacturer or importer of the methyl chloroform sells or uses it during 1993.

(g) *ODCs used as medical sterilants*—(1) *Phase-in of tax*—(i) *In general.* The amount of tax imposed on an ODC is determined under section 4682(g)(4) if the manufacturer or importer of the ODC—

(A) Uses the ODC during 1993 as a medical sterilant; or

(B) Sells the ODC in a qualifying sale (within the meaning of paragraph (g)(4) of this section) during 1993.

(ii) *Amount of tax.* Under section 4682(g)(4), ODCs described in paragraph (g)(1)(i) of this section are taxed at a reduced rate if sold or used during 1993.

(2) *Excess payments*—(1) *In general.* Under section 4682(g)(4)(B), a credit against income tax or a refund of tax is allowed to a person if—

(A) The person uses an ODC during 1993 as a medical sterilant; and

(B) The amount of any tax paid with respect to the ODC under section 4681 or 4682 exceeds the amount that would have been determined under section 4682(g)(4).

(ii) *Amount of credit or refund.* The amount of credit or refund of tax is equal to the excess of—

(A) The tax that was paid with respect to the ODCs under sections 4681 and 4682(g)(4); over

(B) The Tax that would have been imposed under section 4682(g)(4).

(iii) *Procedural rules.* (A) The amount determined under section 4682(g)(4)(B) and paragraph (g)(2)(ii) of this section is treated as credit described in section 34(a) (relating to credits for gasoline and special fuels) unless a claim for refund has been filed.

(B) See section 6402 and the regulations thereunder for procedural rules relating to claiming a credit or refund of tax.

(3) *Definition of use as a medical sterilant.* An ODC is used as a medical sterilant if it is used in the manufacture of sterilant gas.

(4) *Qualifying sale.* A sale of an ODC for use as a medical sterilant is a qualifying sale if the requirements of § 52.4682–2(b)(3) are satisfied with respect to the sale.

(h) *ODCs used as propellants in metered-dose inhalers*—(1) *Reduced rate of tax*—(i) *In general.* The amount of tax imposed on an ODC is determined under section 4682(g)(4) if the manufacturer or importer of the ODC—

(A) Uses the ODC after 1992 as a propellant in a metered-dose inhaler; or

(B) Sells the ODC in a qualifying sale (within the meaning of paragraph (h)(4) of this section) after 1992.

(ii) *Amount of tax.* Under section 4682(g)(4), ODCs described in paragraph (h)(1)(i) of this section are taxed at a reduced rate if sold or used after 1992.

(2) *Excess payments*—(i) *In general.* Under section 4682(g)(4)(B), a credit against income tax or a refund of tax is allowed to a person if—

(A) The person uses an ODC after 1992 as a propellant in a metered-dose inhaler; and

(B) The amount of any tax paid with respect to the ODC under section 4681 or 4682 exceeds the amount that would have been determined under section 4682(g)(4).

(ii) *Amount of credit or refund.* The amount of credit or refund of tax is equal to the excess of—

(A) The tax that was paid with respect to the ODCs under sections 4681 and 4682(g)(4); over

(B) The tax that would have been imposed under section 4682(g)(4).

(iii) *Procedural rules*—(A) The amount determined under section 4682(g)(4)(B) and paragraph (h)(2)(ii) of this section is treated as a credit described in section 34(a) (relating to credits for gasoline and special fuels) unless a claim for refund has been filed.

(B) See section 6402 and the regulations thereunder for procedural rules relating to claiming a credit or refund of tax.

(3) *Definition of metered-dose inhaler.* A metered-dose inhaler is an aerosol device that delivers a precisely-measured dose of a therapeutic drug directly to the lungs.

(4) *Qualifying sale.* A sale of an ODC for use a propellant for a metered-dose inhaler is a qualifying sale if the requirements of § 52.4682–2(b)(4) are satisfied with respect to the sale.

(i) [Reserved]

(j) *Exports; cross-reference.* For the treatment of exports of ODCs, see § 52.4682–5.

(k) *Recycling.* [Reserved]

Par. 5. Section 52.4682–2 is amended as follows:

1. Paragraphs (a)(1)(iii) and (iv) are added.
2. The second sentence of paragraph (a)(2) is amended by:
   a. Removing "submission of a document to" and adding "registration with" in its place.
   b. Removing "registration certificates" and adding "certificates" in its place.
3. Removing "registration" from paragraphs (b)(1)(i) and (b)(2)(i).
4. Paragraphs (b)(3) and (4) are added.
5. The heading for paragraph (d) is revised.
6. Paragraph (d)(1)(i) is revised.
7. Paragraphs (d)(4) and (5) are added.
8. The added and revised provisions read as follows:

§ 52.4682–2 Qualifying sales.

(a) * * *

(1) * * *

(iii) Under section 4682(g)(4) and § 52.4682–1(g) (relating to ODCs used as medical sterilants), ODCs sold in qualifying sales are taxed at a reduced rate in 1993.

(iv) Under section 4682(g)(4) and § 52.4682–1(h) (relating to ODCs used a

propellants in metered-dose inhalers), ODCS sold in qualifying sales are taxed at a reduced rate in years after 1992.

* * * * *

(b) * * *

(3) *Use as medical sterilants.* A sales of ODCs is a qualifying sale for purposes of § 52.4682–1(g) if the manufacturer or importer of the ODCs—

(i) Obtains a certificate in substantially the form set forth in paragraph (d)(4) of this section from the purchaser of the ODCs; and

(ii) Relies on the certificate in good faith.

(4) *Use as propellants in metered-dose inhalers.* A sale of ODCs is a qualifying sale for purposes of §§ 52.4682–1(h) and 52.4682–4(b)(2)(vii) if the manufacturer or importer of the ODCs—

(i) Obtains a certificate in substantially the form set forth in paragraph (d)(5) of this section from the purchaser of the ODCs; and

(ii) Relies on the certificate in good faith.

* * * * *

(d) *Certificate*—(1) * * * (i) *Rules relating to all certificates.* This paragraph (d) Sets forth the form of the certificates that satisfy the requirements of paragraphs (b)(1) through (4) of this section. The certificate shall consist of a statement executed and signed under penalties of perjury by a person with authority to bind the purchaser. A certificate provided under paragraph (d)(2) or (d)(5) of this section may apply to a single purchase or to multiple purchases and need not specify an expiration date. A certificate provided under paragraph (d)(3) or (d)(4) of this section may apply to a single purchase or multiple purchases, and will expire as of December 31, 1993, unless an earlier expiration date is specified in the certificate. A new certificate must be given to the supplier if any information on the current certificate changes. The certificate may be included as part of any business records normally used to document a sale.

* * * * *

(4) *Certificate relating to ODCs used as medical sterilants*—(i) *ODCs that will be resold for use by the second purchaser as medical sterilants.* If the purchaser will resell the ODCs to a second purchaser for use by such second purchaser as medical sterilants, the certificate provided by the purchaser must be in substantially the following form:

Certificate of Purchaser of Chemicals That Will Be Resold for Use by the Second Purchaser as Medical Sterilants

(To support tax-reduced sales under section 4682(g)(4) of the Internal Revenue Code.)
Effective date _____
Expiration date _____
(not after 12/31/93)

The undersigned purchaser (Purchaser) certifies the following under penalties of perjury:

The following percentage of ozone-depleting chemicals purchased from_____

(name and address of seller)
will be resold by Purchaser to persons (Second Purchasers) that certify to Purchaser that they are purchasing the ozone-depleting chemicals for use as medical sterilants (as defined in § 52.4682–1(g)(3) of the Environmental Tax Regulations).

Product	Percentage
CFC–12	_____

This certificate applies to (check and complete as applicable):

_____All shipments to Purchaser at the following location(s):

_____

_____

_____

_____All shipments to Purchaser under the following Purchaser account number(s):

_____

_____

_____

_____All shipments to Purchaser under the following purchase order(s):

_____

_____

_____

_____One or more shipments to Purchaser identified as follows:

_____

_____

_____

Purchaser will not claim a credit or refund under section 4682(g)(4) of the Internal Revenue Code for any ozone-depleting chemicals covered by this certificate.

Purchaser understands that any use by Purchaser of the ozone-depleting chemicals to which this certificate applies other than for the purpose set forth in this certificate may result in the withdrawal by the Internal Revenue Service of Purchaser's right to provide a certificate.

Purchaser will retain the business records needed to document the sales covered by this certificate and will make such records available for inspection by Government officers. Purchaser also will retain and make available for inspection by Government officers the certificates of its Second Purchasers.

Purchaser has not been notified by the Internal Revenue Service that its right to provide a certificate has been withdrawn. In addition, the Internal Revenue Service has not notified Purchaser that the right to provide a certificate has been withdrawn from any Second Purchaser who will purchase ozone-depleting chemical to which this certificate applies.

Purchaser understands that the fraudulent use of this certificate may subject Purchaser and all parties making such fraudulent use of this certificate to a fine or imprisonment, or both, together with the costs of prosecution.

_____
Signature

_____
Printed or typed name of person signing

_____
Title of person signing

_____
Name of purchaser

_____
Address

_____

_____
Taxpayer identifying number

(ii) *ODCs that will be used by the purchaser as medical sterilants.* If the purchase will use the ODCs as medical sterilants, the certificate provided by the purchaser must be in substantially the following form:

Certificate of Purchaser of Chemicals That Will Be Used by the Purchaser as Medical Sterilants

(To support tax-reduced sales under section 4682(g)(4) of the Internal Revenue Code.)
Effective date _____
Expiration date _____
(not after 12/31/93)

The undersigned purchaser (Purchase) certifies the following under penalties of perjury:

The following percentage of ozone-depleting chemicals purchased from _____

(name and address of seller)
will be used by Purchaser as medical sterilants (as defined in § 52.4682–1(g)(3) of the Environmental Tax Regulations).

Product	Percentage
CFC–12	_____

This certificate applies to (check and complete as applicable):

_____All shipments to Purchaser at the following location(s):

_____

_____

_____

_____All shipments to Purchaser under the following Purchaser account number(s):

_____

_____

_____

_____All shipments to Purchaser under the following purchase order(s):

_____

_____

_____

_____One ore more shipments to Purchaser identified as follows:

_____

_____

_____

Purchaser will not claim a credit or refund under section 4682(g)(4) of the Internal Revenue Code for any ozone-depleting chemicals covered by this certificate.

Purchaser understands that any use by Purchaser of the ozone-depleting chemicals to which this certificate applies other than as medical sterilants may result in the withdrawal by the Internal Revenue Service of Purchaser's right to provide a certificate.

Purchaser will retain the business records needed to document the use as medical sterilants of the ozone-depleting chemicals to which this certificate applies and will make such records available for inspection by Government officers.

Purchaser has not been notified by the Internal Revenue Service that its right to provide a certificate has been withdrawn.

Purchaser understands that the fraudulent use of this certificate may subject Purchaser and all parties making such fraudulent use of this certificate to a fine or imprisonment, or both, together with the costs of prosecution.

_____

Signature

_____

Printed or typed name of person signing

_____

Title of person signing

_____

Name of purchaser

_____

Address

_____

_____

Taxpayer identifying number

(5) *Certificate relating to ODCs used as propellants in metered-dose inhalers*—(i) *ODCs that will be resold for use by the second purchaser as propellants in metered-dose inhalers.* If the purchaser will resell the ODCs to a second purchaser for use by such second purchaser as propellants in metered-dose inhalers, the certificate provided by the purchaser must be in substantially the following form:

Certificate of Purchaser of Chemicals That Will Be Resold for Use by the Second Purchaser as Propellants in Metered-dose Inhalers

(To support tax-reduced sales under section 4682(g)(4) of the Internal Revenue Code.)

Date _____

The undersigned purchaser (Purchaser) certifies the following under penalties of perjury:

The following percentage of ozone-depleting chemicals purchased from _____

_____

(name and address of seller)

will be resold by Purchaser to persons (Second Purchasers) that certify to Purchaser that they are purchasing the ozone-depleting chemicals for use as propellants in metered-dose inhalers (as defined in § 52.4682–1(h)(3) of the Environmental Tax Regulations).

Product	Percentage
CFC–11	_____
CFC–12	_____
CFC–114	_____

This certificate applies to (check and complete as applicable):

_____All shipments to Purchaser at the following location(s):

_____

_____

_____

_____All shipments to Purchaser under the following Purchaser account number(s):

_____

_____

_____

_____All shipments to Purchaser under the following purchase order(s):

_____

_____

_____

_____One or more shipments to Purchaser identified as follows:

_____

_____

_____

Purchaser will not claim a credit or refund under section 4682(g)(4) of the Internal Revenue Code for any ozone-depleting chemicals covered by this certificate.

Purchaser understands that any use by Purchaser of the ozone-depleting chemicals to which this certificate applies other than for the purpose set forth in this certificate may result in the withdrawal by the Internal Revenue Service of Purchaser's right to provide a certificate.

Purchaser will retain the business records needed to document the sales covered by this certificate and will make such records available for inspection by Government officers. Purchaser also will retain and make available for inspection by Government officers the certificates of its Second Purchasers.

Purchaser has not been notified by the Internal Revenue Service that its right to provide a certificate has been withdrawn. In addition, the Internal Revenue Service has not notified Purchaser that the right to provide a certificate has been withdrawn from any Second Purchaser who will purchase ozone-depleting chemicals to which this certificate applies.

Purchaser understands that the fraudulent use of this certificate may subject Purchaser and all parties making such fraudulent use of this certificate to a fine or imprisonment, or both, together with the costs of prosecution.

_____

Signature

_____

Printed or typed name of person signing

_____

Title of person signing

_____

Name of purchaser

_____

Address

_____

_____

Taxpayer identifying number

(ii) *ODCs that will be used by the purchaser as propellants in metered-dose inhalers.* If the purchaser will use the ODCs as propellants in metered-dose inhalers, the certificate provided by the purchaser must be in substantially the following form:

Certificate of Purchaser of Chemicals That Will Be Used by the Purchaser as Propellants in Metered-dose Inhalers

(To support tax-reduced sales under section 4682(g)(4) of the Internal Revenue Code.)

Date _____

The undersigned purchaser (Purchaser) certifies the following under penalties of perjury:

The following percentage of ozone-depleting chemicals purchased from _____

_____

(name and address of seller)

will be used by Purchaser as propellants in metered-dose inhalers (as defined in § 52.4682–1(h)(3) of the Environmental Tax Regulations).

Product	Percentage
CFC–11	_____
CFC–12	_____
CFC–114	_____

This certificate applies to (check and complete as applicable):

_____All shipments to Purchaser at the following location(s):

_____

_____

_____

_____All shipments to Purchaser under the following Purchaser account number(s):

_____

_____

_____

_____All shipments to Purchaser under the following purchase order(s):

_____

_____

_____

_____One or more shipments to Purchaser identified as follows:

_____

_____

_____

Purchaser will not claim a credit or refund under section 4682(g) (4) of the Internal Revenue Code for any ozone-depleting chemicals covered by this certificate.

Purchaser understands that any use by Purchaser of the ozone-depleting chemicals to which this certificate applies other than as propellants in metered-dose inhalers may result in the withdrawal by the Internal Revenue Service of Purchaser's right to provide a certificate.

Purchaser will retain the business records needed to document the use as propellants in metered-dose inhalers of the ozone-depleting chemicals to which this certificate applies and will make such records available for inspection by Government officers.

Purchaser has not been notified by the Internal Revenue Service that its right to provide a certificate has been withdrawn.

Purchaser understands that the fraudulent use of this certificate may subject Purchaser and all parties making such fraudulent use of

this certificate to a fine or imprisonment, or both, together with the costs of prosecution.

Signature

Printed or typed name of person signing

Title of person signing

Name of Purchaser

Address

Taxpayer identifying number

Par. 6. Section 52.4682–4 is amended as follows:

1. Paragraph (b)(2) is amended by removing the introductory text.

2. Paragraph (b)(2)(i)(B)(*1*) is amended by revising the first sentence.

3. Paragraphs (b)(2)(vi) through (viii) are added.

4. Paragraph (d)(1)(i) is amended by adding a sentence at the end of the paragraph.

5. Paragraph (d)(1)(iv)(A)(*1*) is revised.

6. Paragraph (d)(4) is added.

7. Paragraph (e)(4)(i) is revised.

8. Paragraph (e)(5) is redesignated as paragraph (e)(6) and a new paragraph (e)(5) is added.

9. Newly designated paragraph (e)(6) is amended by revising *Example 5.*

10. The added and revised provisions read as follows:

§ 52.4682–4 Floor stocks tax.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(B) * * *

(*1*) *In general.* In the case of the floor stocks tax imposed on January 1 of a calendar year after 1990, the tax is not imposed on an ODC that has been mixed with any other ingredients, but only if it is established that such ingredients contribute to the accomplishment of the purpose for which the mixture will be used. * * *

* * * * *

(vi) *ODCs to be exported*—(A) *In general.* The floor stocks tax is not imposed on any ODC that was sold in a qualifying sale for export (as defined in § 52.4682–5(d)(1)).

(B) *ODCs sold before January 1, 1993.* An ODC that was sold by its manufacturer or importer before January 1, 1993, is treated, for purposes of this paragraph (b)(2)(vi), as an ODC that was sold in a qualifying sale for export for purposes of § 52.4682–5(d)(1) if the ODC will be exported.

(vii) *ODCs used as propellants in metered-dose inhalers; years after 1992*—(A) *In general.* The floor stocks tax is not imposed on January 1 of calendar years after 1992 on any ODC that was sold in a qualifying sale for use as a propellant in a metered-dose inhaler (as defined in § 52.4682–1(h)).

(B) *ODCs sold before January 1, 1993.* An ODC that was sold by its manufacturer or importer before January 1,, 1993, is treated, for purposes of this paragraph (b)(2)(vii), as an ODC that was sold in a qualifying sale for purposes of § 52.4682–1(h) if the ODC will be used as a propellant in a metered-dose inhaler (within the meaning of § 52.4682–1(h)).

(viii) *ODCs used as medical sterilants; 1993.* The floor stocks tax is not imposed in 1993 on any ODC held for use as a medical sterilant (as defined in § 52.4682–1(g)).

* * * * *

(d) * * *

(1) * * *

(i) * * * The amount of the floor stocks tax imposed on the ODCs contained in a nonexempt mixture is computed on the basis of the weight of the ODCs in that mixture.

* * * * *

(iv) * * *

(A) * * *

(*1*) The tentative tax amount is determined, except as provided in paragraph (d)(2), (3), or (4) of this section, by reference to the rate of tax prescribed in section 4681(b)(1)(B) and the ozone-depletion factors prescribed in section 4682(b).

* * * * *

(4) *Methyl chloroform; 1993.* In the case of methyl chloroform, the tentative tax amount is determined under section 4682(b)(5) for purposes for computing the floor stocks tax imposed on January 1, 1993.

(e) * * *

(4) * * *

(i) At least 400 pounds of ODCs that are not described in paragraph (d)(2) or (d)(3) of this section and are otherwise subject to tax;

* * * * *

(5) *Calendar years after 1994.* In the case of the floor stocks tax imposed on January 1 of 1995 and each following calendar year, a person is liable for the tax only if, on such date, the person holds—

(i) At least 400 pounds of ODCs that are not described in paragraph (d)(3) or (d)(4) of this section and are otherwise subject to tax;

(ii) At least 50 pounds ODCs that are described in paragraph (d)(3) of this section and are otherwise subject to tax; or

(iii) At least 1000 pounds of ODCs that are described in paragraph (d)(4) of this section and are otherwise subject to tax.

(6) * * *

Example 5. (a) On January 1, 1994, D holds for sale 300 pounds of CFC–113 (an ODC not described in paragraph (d)(2) or (d)(3) of this section) and 25 pounds of Halon-1301 (an ODC described in paragraph (d)(3) of this section). D is liable for the floor stocks tax imposed on January 1, 1994, because 25 pounds of Halon-1301 exceeds the de minimis amount specified in paragraph (e)(4)(iii) of this section. The 300 pounds of CFC–113 is less than the amount specified in paragraph (e)(4)(i) of this section. Nevertheless, tax is imposed on both the 25 pounds of Halon-1301 and the 300 pounds of CFC–113.

(b) The amount of the floor stock tax is determined separately for the 300 pounds of CFC–113 and the 25 pounds of Halon-1301 and is equal to the difference between the tentative tax amount and the amount of tax previously imposed on those ODCs. For Halon-1301, for example, the tax is determined as follows. The tentative tax amount is $1,087.50 ($4.35 (the base tax amount of 1994) x 10 (the ozone-depletion factor for Halon-1301) x 25 (the number of pounds held)). The tax previously imposed on the Halon-1301 is $6.28 ($3.35 (the base tax amount in 1993) x 10 (the ozone-depletion factor for Halon-1301) x 0.75 percent (the applicable percentage determined under section 4682(g)(2)(A)) x 25 (the number of pounds held)). Thus, the floor stocks tax imposed on the 25 pounds of Halon-1301 in 1994 is $1,081.22, the difference between $1,087.50 (the tentative tax amount) and $6.28 (the tax previously imposed).

* * * * *

Par. 7. Section 52.4682–5 is added to read as follows:

§ 52.4682–5 Exports.

(a) *Overview.* This section provides rules relating to the tax imposed under section 4681 on ozone-depleting chemicals (ODCs) that are exported. In general, tax is not imposed on ODCs that a manufacturer or importer sells for export, or for resale by the purchaser to a second purchaser for export, if the procedural requirements set forth in paragraph (d) of this section are met. The tax benefit of this exemption is limited, however, to the manufacturer's or importer's exemption amount. Thus, if the tax that would otherwise be imposed under section 4681 on ODCs that a manufacturer or importer sells for export exceeds that exemption amount, a tax equal to the excess is imposed on the ODCs. The exemption amount, which is determined separately for post-1989 ODCs and post-1990 ODCs, is calculated for each calendar year in accordance with the rules of paragraph (c) of this section. This section also provides rules under which a tax imposed under section 4681 on

exported ODCs may be credited or refunded, subject to the same limit on tax benefits, if the procedural requirements set forth in paragraph (f) of this section are met. See § 52.4681–1(c) for definitions relating to the tax on ODCs.

(b) *Exemption or partial exemption from tax*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, no tax is imposed on an ODC if the manufacturer or importer of the ODC sells the ODC in a qualifying sale for export (within the meaning of paragraph (d)(1) of this section).

(2) *Tax imposed if exemption amount exceeded*—(i) *Post-1989 ODCs.* The tax imposed on post-1989 ODCs that a manufacturer or importer sells in qualifying sales for export during a calendar year is equal to the excess (if any) of—

(A) The tax that would be imposed on the ODCs but for section 4682(d)(3) and this section; over

(B) The post-1989 ODC exemption amount for the calendar year determined under paragraph (c)(1) of this section.

(ii) *Post-1990 ODCs.* The tax imposed on post-1990 ODCs that a manufacturer or importer sells in qualifying sales for export during a calendar year is equal to the excess (if any) of—

(A) The tax that would be imposed on the ODCs but for section 4682(d)(3) and this section; over

(B) The post-1990 ODC exemption amount for the calendar year determined under paragraph (c)(2) of this section.

(iii) *Allocation of tax*—(A) *Post-1989 ODCs.* The tax (if any) determined under paragraph (b)(2)(i) of this section may be allocated among the post-1989 ODCs on which it is imposed in any manner, provided that the amount allocated to any post-1989 ODC does not exceed the tax that would be imposed on such ODC but for section 4682(d)(3) and this section.

(B) *Post-1990 ODCs.* The tax (if any) determined under paragraph (b)(2)(ii) of this section may be allocated among the post-1990 ODCs on which it is imposed in any manner, provided that the amount allocated to any post-1990 ODC does not exceed the tax that would be imposed on such ODC but for section 4682(d)(3) and this section.

(3) *Mixtures.* If a manufacturer or importer sells a mixture containing ODCs, this section applies to the ODCs contained in the mixture. For this purpose, a mixture cannot be represented by a chemical formula, and an ODC is contained in a mixture only if the chemical identity of the ODC is not changed.

(c) *Exemption amount*—(1) *Post-1989 ODC exemption amount.* A manufacturer's or importer's post-1989 ODC exemption amount for a calendar year is the sum of the following amounts—

(i) The 1986 export percentage of the aggregate tax that would (but for section 4682(d)(3), section 4682(g), and this section) be imposed under section 4681 on the maximum quantity, determined without regard to additional production allowances, of post-1989 ODCs that the person is permitted to manufacture during the calendar year under rules prescribed by the Environmental Protection Agency;

(ii) The aggregate tax that would (but for section 4682(d)(3), section 4682(g), and this section) be imposed under section 4681 on post-1989 ODCs that the person manufactures during the calendar year under any additional production allowance granted by the Environmental Protection Agency; and

(iii) The aggregate tax that would (but for section 4682(d)(3), section 4682(g), and this section) be imposed under section 4681 on post-1989 ODCs imported by the person during the calendar year.

(2) *Post-1990 ODC exemption amount.* A manufacturer's or importer's post-1990 ODC exemption amount for a calendar year is the sum of the following amounts—

(i) The 1989 export percentage of the aggregate tax that would (but for section 4682(d)(3), section 4682(g), and this section) be imposed under section 4681 on the maximum quantity, determined without regard to additional production allowances, of post-1990 ODC's the person is permitted to manufacture during the calendar year under rules prescribed by the Environmental Protection Agency;

(ii) The aggregate tax that would (but for section 4682(d)(3), section 4682(g), and this section) be imposed under section 4681 on post-1990 ODCs that the person manufactures during the calendar year under any additional production allowance granted by the Environmental Protection Agency; and

(iii) The aggregate tax that would (but for section 4682(d)(3), section 4682(g), and this section) be imposed under section 4681 on post-1990 ODCs imported by the person during the calendar year.

(3) *Definitions*—(i) *1986 export percentage.* See section 4682(d)(3)(B)(ii) for the meaning of the term *1986 export percentage.*

(ii) *1989 export percentage.* See section 4682(d)(3)(C) for the meaning of the term *1989 export percentage.*

(d) *Procedural requirements relating to tax-free sales for export*—(1) *Qualifying sales*—(i) *In general.* A sale of ODCs is a qualifying sale for export if—

(A) The seller is the manufacturer or importer of the ODCs and the purchaser is a purchaser for export or for resale to a second purchaser for export;

(B) At the time of the sale, the seller and the purchaser are registered with the Internal Revenue Service; and

(C) At the time of the sale, the seller—

(*1*) Has an unexpired certificate in substantially the form set forth in paragraph (d)(3)(ii) of this section from the purchaser; and

(*2*) Relies on the certificate in good faith.

(ii) *Qualifying resale.* A sale of ODCs is a qualifying resale for export if—

(A) The seller acquired the ODCs in a qualifying sale for export and the purchaser is a second purchaser for export;

(B) At the time of the sale, the seller and the purchaser are registered with the Internal Revenue Service; and

(C) At the time of the sale, the seller—

(*1*) Has an unexpired certificate in substantially the form set forth in paragraph (d)(3)(ii)(A) of this section from the purchaser of the ODCs; and

(*2*) Relies on the certificate in good faith.

(iii) *Special rule relating to sales made before July 1, 1993.* If a sale for export made before July 1, 1993, satisfies all the requirements of paragraph (d)(1)(i) or (ii) of this section other than those relating to registration, the sale will be treated as a qualifying sale (or resale) for export. Thus, a sale made before July 1, 1993, may be a qualifying sale (or resale) even if the parties to the sale are not registered and the required certificate does not contain statements regarding registration.

(2) *Good faith reliance.* The requirements of paragraph (d)(1) of this section are not satisfied with respect to a sale of ODCs and the sale is not a qualifying sale (or resale) if, at the time of the sale—

(i) The seller has reason to believe that the ODCs are not purchased for export; or

(ii) The Internal Revenue Service has notified the seller that the purchaser's registration has been revoked or suspended.

(3) *Certificate*—(i) *In general.* The certificate required under paragraph (d)(1) of this section consists of a statement executed and signed under penalties of perjury by a person with authority to bind the purchaser, in substantially the same form as the model certificate provided in paragraph

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(d)(3)(ii) of this section, and containing all information necessary to complete such model certificate. A new certificate must be given if any information in the current certificate changes. The certificate may be included as part of any business records normally used to document a sale. The certificate expires on the earliest of the following dates—

(A) The date one year after the effective date of the certificate;

(B) The date the purchaser provides a new certificate to the seller; or

(C) The date the seller is notified by the Internal Revenue Service or the purchaser that the purchaser's registration has been revoked or suspended.

(ii) *Model certificates*—(A) *ODCs sold for export by the purchaser.* If the purchaser will export the ODCs, the certificate must be in substantially the following form:

Certificate of Purchaser of Chemicals for Export by the Purchaser

(To support tax-free sales under section 4682(d)(3) of the Internal Revenue Code.)

Effective Date _____

Expiration Date _____
(not more than one year after effective date)

The undersigned purchaser (Purchaser) certifies the following under penalties of perjury:

Purchaser is registered with the Internal Revenue Service as a purchaser of ozone-depleting chemicals for export under registration number _____, Purchaser's registration has not been suspended or revoked by the Internal Revenue Service.

The following percentage of ozone-depleting chemicals purchased from:

_____
Name of seller

_____
Address of seller

_____
Taxpayer identifying number of seller are purchased for export by Purchaser.

Product	Percentage
CFC–11	
CFC–12	
CFC–113	
CFC–114	
CFC–115	
Halon–1211	
Halon–1301	
Halon–2402	
Carbon tetrachloride	
Methyl chloroform	
Other (specify) _____	

This certificate applies to (check and complete as applicable):

_____All shipments to Purchaser at the following location(s):

_____

_____

_____

_____All shipments to Purchaser under the following Purchaser account number(s):

_____

_____

_____

_____All shipments to Purchaser under the following purchase order(s):

_____

_____

_____

_____One or more shipments to Purchaser identified as follows:

_____

_____

_____

Purchaser understands that Purchaser will be liable for tax imposed under section 4681 if Purchaser does not export the ODCs to which this certificate applies.

Purchaser understands that any use of the ODCs to which this certificate applies other than for export may result in the revocation of Purchaser's registration.

Purchaser will retain the business records needed to document the export of the ozone-depleting chemicals to which this certificate applies and will make such records available for inspection by Government officers.

Purchaser has not been notified by the Internal Revenue Service that its registration has been revoked or suspended.

Purchaser understands that the fraudulent use of this certificate may subject Purchaser and all parties making such fraudulent use of this certificate to a fine or imprisonment, or both, together with the costs of prosecution.

_____
Signature

_____
Printed or typed name of person signing

_____
Title of person signing

_____
Name of Purchaser

_____
Address

_____

_____
Taxpayer Identifying Number

(B) *ODCs sold by the purchaser for resale for export by the second purchaser.* If the purchaser will resell the ODCs to a second purchaser for export by the second purchaser, the certificate must be in substantially the following form:

Certificate of Purchaser of Chemicals for Resale for Export by the Second Purchaser

(To support tax-free sales under section 4682(d)(3) of the Internal Revenue Code.)

Effective Date _____

Expiration Date _____
(not more than one year after effective date)

The undersigned purchaser (Purchaser) certifies the following under penalties of perjury:

Purchaser is registered with the Internal Revenue Service as a purchaser of ozone-depleting chemicals for export under registration number _____. Purchaser's registration has not been suspended or revoked by the Internal Revenue Service.

The following percentage of ozone-depleting chemicals purchased from:

_____
Name of seller

_____
Address of seller

_____
Taxpayer identifying number of seller will be resold by Purchaser to persons (Second Purchasers) that certify to Purchaser that they are (1) registered with the Internal Revenue Service as purchasers of ozone-depleting chemicals for export and (2) purchasing the ozone-depleting chemicals for export.

Product	Percentage
CFC–11	
CFC–12	
CFC–113	
CFC–114	
CFC–115	
Halon–1211	
Halon–1301	
Halon–2402	
Carbon tetrachloride	
Methyl chloroform	
Other (specify) _____	

This certificate applies to (check and complete as applicable):

_____All shipments to Purchaser at the following location(s):

_____

_____

_____

_____All shipments to Purchaser under the following Purchaser account number(s):

_____

_____

_____

_____All shipments to Purchaser under the following Purchaser account number(s):

_____

_____

_____

_____One or more shipments to Purchaser identified as follows:

_____

_____

_____

Purchaser understands that Purchaser will be liable for tax imposed under section 4681 if Purchaser does not resell the ODCs to which this certificate applies to a Second Purchaser for export and does not, itself, export those ODCs.

Purchaser understands that any use of the ODCs to which this certificate applies other than for resale to Second Purchasers for export may result in the revocation of Purchaser's registration.

Purchaser will retain the business records needed to document the sales to Second Purchasers for export covered by this certificate and will make such records available for inspection by Government officers. Purchaser also will retain and make

available for inspection by Government officers the certificates of its Second Purchasers.

Purchaser has not been notified by the Internal Revenue Service that its registration has been revoked or suspended. In addition, the Internal Revenue Service has not notified Purchaser of the revocation or suspension of the registration of any Second Purchaser who will purchase ozone-depleting chemicals to which this certificate applies.

Purchaser understands that the fraudulent use of this certificate may subject Purchaser and all parties making such fraudulent use of this certificate to a fine or imprisonment, or both, together with the costs of prosecution.

_____

Signature

_____

Printed or typed name of person signing

_____

Title of person signing

_____

Name of Purchaser

_____

Address

_____

Taxpayer Identifying Number

(iii) *Use of Form 637 as a certificate prohibited.* A Form 637, Certificate of Registry, issued by the Internal Revenue Service is not a certificate described in paragraph (d)(3)(ii) of this section.

(4) *Documentation of export.* To document the exportation of any ODCs, a person must have the evidence required by the Environmental Protection Agency as proof that the ODCs were exported.

(e) *Purchaser liable for tax*—(1) *Purchaser in qualifying sale.* The purchaser of ODCs in a qualifying sale for export is treated as the manufacturer of the ODC and is liable for any tax imposed under section 4681 (determined without regard to exemptions for qualifying sales under this section or § 52.4682–1) when it sells or uses the ODCs if that purchaser does not—

(i) Export the ODCs or does not document the exportation of the ODCs in accordance with paragraph (d)(4) of this section; or

(ii) Sell the ODCs in a qualifying resale for export.

(2) *Purchaser in qualifying resale.* The purchaser of ODCs in a qualifying resale for export is treated as the manufacturer of the ODC and is liable for any tax imposed under section 4681 (determined without regard to exemptions for qualifying sales under this section or § 52.4682–1) when it sells or uses the ODCs if that purchaser does not export the ODCs or does not document the exportation of the ODCs in accordance with paragraph (d)(4) of this section.

(f) *Credit or refund*—(1) *In general.* Except as provided in paragraph (f)(2) of this section, a manufacturer or importer that meets the conditions of paragraph (f)(3) of this section is allowed a credit or refund (without interest) of the tax it paid to the government under section 4681 on ODCs that are exported. Persons other than manufacturers and importers of ODCs cannot file claims for credit or refund of tax imposed under section 4681 on ODCs that are exported.

(2) *Limitation.* For any calendar year, the amount of credits or refunds under this paragraph (f) of tax paid on post-1989 ODCs and of tax paid on post-1990 ODCs is limited to the amount (if any) by which the exemption amount applicable to the class (i.e., post-1989 or post-1990) of ODCs exceeds the tax benefit provided to such class of ODCs under paragraph (b) of this section.

(3) *Conditions to allowance of credit or refund.* The conditions of this paragraph are met if the manufacturer or importer—

(i) Documents the exportation of the ODCs in accordance with paragraph (d)(4) of this section; and

(ii) Establishes that it has—

(A) Repaid or agreed to repay the amount of the tax to the person that exported the ODC; or

(B) Obtained the written consent of the exporter to the allowance of the credit or the making of the refund.

(4) *Procedural rules.* See section 6402 and the regulations thereunder for procedural rules relating to filing a claim for credit or refund of tax.

(g) *Examples.* The provisions of this section may be illustrated by the following examples. In each example, the sales are qualifying sales for export (within the meaning of paragraph (d)(1) of this section), all registration, certification, and documentation requirements of this section are met, and the ODCs sold for export are exported.

Example 1. (i) *Facts.* D, a corporation, manufactures CFC–11, a post-1989 ODC, and does not manufacture or import any other ODCs. In 1993, D manufactures 100,000 pounds of CFC–11, the maximum quantity D is allowed to manufacture in 1993 under EPA regulations. D has no additional production allowance from EPA for 1993. In 1993, the tax on CFC–11 is $3.35 per pound. D's 1986 export percentage for post-1989 ODCs is 50%. In 1993, D sells 80,000 pounds of CFC–11 in qualifying sales for export. The remainder of D's production is not exported.

(ii) *Components of limit on tax benefit.* Under paragraph (c)(1) of this section, D's exemption amount of 1993 is equal to the sum of—

(A) D's 1986 export percentage multiplied by the aggregate tax that would (but for section 4682(d)(3), section 4682(g), and § 52.4682–5) be imposed under section 4681 on the maximum quantity of post-1989 ODCs D is permitted to manufacture during 1993:

(B) The aggregate tax that would (but for section 4682(d)(3), section 4682(g), and § 52.4682–5) be imposed under section 4681 on post-1989 ODCs that D manufactures during 1993 under an additional production allowance; and

(C) The aggregate tax that would (but for section 4682(d)(3), section 4682(g), and § 52.4682–5) be imposed under section 4681 on post-1989 ODCs imported by D during 1993.

(iii) *Limit on tax benefit.* The amounts described in paragraphs (ii) (B) and (C) of this *Example 1* are equal to zero. Thus, D's 1993 exemption amount is $167,500 (50% of $335,000 (the tax that would otherwise be imposed on 100,000 pounds of CFC–11 in 1993)).

(iv) *Application of limit on tax benefit.* Under paragraph (b)(2) of this section, the tax imposed on the CFC–11 D sells for export is equal to the excess of the tax that would have been imposed on those ODCs but for section 4682(d)(3) and § 52.4682–5, over D's 1993 exemption amount. But for § 52.4682–5, $268,000 ($3.35×80,000) of tax would have been imposed on the CFC–11 sold for export. Thus, $100,500 ($268,000—$167,500) of tax is imposed on the CFC–11 sold for export.

Example 2. (i) *Facts.* E, a corporation, manufactures CFC–11, a post-1989 ODC, and does not manufacture or import any other ODCs. In 1993, E manufactures 100,000 pounds of CFC–11, the maximum quantity E is allowed to manufacture in 1993 under EPA regulations. E has no additional production allowance from EPA for 1993. In 1993, the tax on CFC–11 is $3.35 per pound. E's 1986 export percentage for post–1989 ODCs is 50%. In 1993, E sells 45,000 pounds of CFC–11 tax free in qualifying sales for export and pays tax under section 4681 on an additional 35,000 pounds of exported CFC–11. The remainder of E's production is not exported.

(ii) *Limit on tax benefit.* E's 1993 exemption amount is $167,500, (50% of $335,000 (the tax that would otherwise be imposed on 100,000 pounds of CFC–11 in 1993)). The credit or refund allowed to E under paragraph (f) of this section is limited under paragraph (f)(2) of this section to the amount by which E's 1993 exemption amount exceeds E's 1993 tax benefit under paragraph (b) of this section.

(iii) *Application of limit on tax benefit.* Because E sold 45,000 pounds of CFC–11 tax free in qualifying sales for export in 1993, E's 1993 tax benefit under paragraph (b) of this section is $150,750 ($3.35×45,000). Thus, the credit or refund allowed to E under paragraph (f) of this section is limited to $16,750 ($167,500–$150,750).

(h) *Effective date.* This section is effective as of January 1, 1993.

Michael P. Dolan,

Acting Commissioner of Internal Revenue.

[FR Doc. 93–814 Filed 1–14–93; 8:45 am]

BILLING CODE 4830–01–M

DEPARTMENT OF THE INTERIOR

43 CFR Part 2

RIN: 1093–AA09

Appearance of Department of the Interior Employees as Witnesses, and Production of Documents for Judicial or Administrative Proceedings

AGENCY: Department of the Interior.

ACTION: Proposed rule.

SUMMARY: The Department of the Interior is proposing to amend its regulations applicable to requests and demands for the disclosure of information, through production of official documents or employee testimony, in judicial and administrative proceedings and related matters. The amendment was necessary to provide more guidance to outside parties seeking employee testimony and official documents, and to state clearly the Department's policy in this area. The amendment requires a declaration, or, if not possible, a detailed statement to be filed with the Solicitor or his designee whenever the testimony, including the taking of affidavits, of a Department employee is sought or whenever copies of official documents are sought. The amendment prescribes what the statement must contain. The amendment also specifies the criteria to be used by the Solicitor or his designee in determining whether to grant the request or demand for testimony or records. These changes are intended to improve the procedures for dealing with requests and demands for testimony and documents and to allow for consistent treatment of outside parties by the Department.

DATES: Comments must be received by February 16, 1993.

ADDRESSES: Written comments should refer to docket number of this notice and should be submitted to Robert Moll, Assistant Solicitor, Division of General Law, MS 6531, U.S. Department of the Interior, 1849 C Street NW., Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Robert H. Moll, Assistant Solicitor, Division of General Law, Office of the Solicitor, Department of the Interior, 1849 C Street NW., Washington, DC 20240. (202) 208–4722.

SUPPLEMENTARY INFORMATION: Department of the Interior (Department) employees frequently are requested or subpoenaed to provide testimony or produce documents in litigation to which the Department is not a party. Current Department regulations do not state with specificity when Department employees are required to provide testimony in these situations. On occasion this has resulted in giving testimony that diverts employees from performing their duties and has created the appearance that the Department is an advocate for one party or the other in private litigation. This amendment is intended to address this problem by prohibiting both voluntary appearances and compliance with subpoenas except where clearly in the interest of the Department, the United States, or justice.

The current regulations provide that Department employees shall not testify or disclose official records without the prior authorization of the bureau head. These regulations are now being amended to provide additional guidelines regarding the prior authorization, and rests with the Solicitor or his designee the final authority to authorize an employee to testify. This is appropriate because the Solicitor is entrusted with the responsibility of providing legal advice to the Secretary for the Department. This responsibility includes ensuring that the Department's employees and the Department's documents are used properly in litigation only in furtherance of an official government purpose. Further, the Solicitor is in the unique position to oversee all the bureaus' employees' involvement in litigation and provide consistent decision-making.

The amendment sets forth uniform and expeditious procedures for obtaining the prescribed authorization. The amendment specifically lists the policy behind these regulations, the required details needed to be set out in the statement requesting testimony of an employee or the production of documents, and the criteria that will be used to make the decision to grant or deny authorization.

The amendment applies only to testimony or documents related to an employee's official duties. Specifically excluded from this amendment are situations where an employee is to testify on matters not related to his or her employment (i.e. divorce, custody matters, personal litigation). Further, the amendment does not apply to congressional testimony.

This rule relates to internal agency management. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity for comment is not required. However, the policy of the Department of the Interior is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments regarding the proposed rule to the location identified in the Addresses section of this Preamble.

Executive Order 12291

In compliance with Executive Order 12291 of February 1, 1981, the Department of the Interior has determined that this proposed rule is not a major rule. The amendment sets forth: 1. Uniform and expeditious procedures for obtaining authorization for Departmental testimony and the production of documents in litigation to which the Department is not a party; and 2. underlying policy considerations. This procedural amendment clearly will not result in:

(A) An annual effect on the economy of $100 million or more;

(B) A major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or

(C) Significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of the United States based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

Under this amendment the procedures for obtaining authorization for Departmental testimony and documents in litigation to which the Department is not a party are uniform and clearly set forth. The current regulations require Departmental approval for testimony or document production. Therefore, to the extent that small entities may want to obtain testimony or documents, any effect of this amendment will not be significant. The Department of the Interior certifies that this document will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Paperwork Reduction Act—This rule does not contain information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act—This regulation is of an administrative, legal and procedural nature and therefore is categorically excluded from the requirements of the National Environmental Policy Act. 516 DM 2 Appendix 1.10.

Takings Implications Assessment—This rule is not a policy that has takings implications under Executive Order 12630.

E.O. 12778

The Department certifies that it has reviewed these regulations in light of E.O. 12778 and concluded that they meet the applicable standard provided in subsection (2)(b)(2).

Drafting Information

The authors of this document are Robert H. Moll, Assistant Solicitor, and Peg Romanik, Attorney-Advisor, Branch of Administrative Law and General Legal Services, Division of General Law, Office of the Solicitor, U.S. Department of the Interior, 1849 C Street NW., Washington, DC 20240.

List of Subjects in 43 CFR Part 2

Administrative practice and procedure, records and testimony.

For the reasons set out in the Preamble, Title 43, Part 2, of the Code of Federal Regulations, is proposed to be amended as set forth below:

1. The authority citation for Part 2 continues to read as follows:

Authority: 5 U.S.C. 301, 552 and 552A; 31 U.S.C. 9701; and 43 U.S.C. 1460.

2. Subpart E to part 2 is revised to read as follows:

Subpart E—Testimony of Employees and Production of Records

Sec.

2.80 Scope and Purpose.

2.81 Department Policy.

2.82 General Rule.

2.83 Requests and subpoenas for Testimony or Documents.

2.84 Department Employees as Expert Witnesses.

2.85 Legal Proceedings between Private Litigants.

2.86 Procedures When a Department Employee Receives a Subpoena.

Subpart E—Testimony of Employees and Production of Records

§ 2.80 Scope and Purpose.

(a) This subpart sets forth procedures to be followed when a Department of the Interior employee, including a contract employee or a special government employee, is requested or subpoenaed to provide testimony or depositions or affidavits concerning information acquired in the course of performing official duties or because of the employee's official status. These procedures also apply to subpoenas *duces tecum* for any document in the possession of the Department of the Interior and to requests for certification of copies of documents.

(b) This subpart applies to: (1) All state court proceedings (including grand jury proceedings) and all state and local legislative and administrative proceedings; and

(2) All federal proceedings (including administrative proceedings), not excluded in paragraph (c) of this section.

(c) This subpart does not apply to: (1) Legal proceedings in which the Department of the Interior is a party or is representing a party;

(2) Federal criminal cases;

(3) Congressional requests or subpoenas for testimony or documents; and

(4) Legal proceedings in which a Department employee is to testify, while on leave status, as to facts or events that are in no way related to the official business of the Department.

(d) When the United States Department of Justice or a state government representing the Department's interest seeks an employee's testimony, § 2.83(g) shall apply.

(e) This subpart is intended only to provide guidance for the internal operations of the Department of the Interior, and is not intended to, and does not, and may not be relied upon to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States.

§ 2.81 Department policy.

(a) The Department's policy is that, except as provided in this part, its documents will not be voluntarily produced and Department employees will not voluntarily appear as witnesses in a legal proceeding. The reasons for this policy include:

(1) Conserving the time of Department employees for conducting official business;

(2) Minimizing the possibility of involving the Department in controversial, or other, issues that are not related to its mission;

(3) Preventing the possibility that the public will misconstrue variances between personal opinions of Department employees and Department policy;

(4) Avoiding spending time and money of the United States for private purposes;

(5) Preserving the integrity of the administrative process; and

(6) Permitting the Department to conduct its business in an impartial manner.

(b) The Department's policy is intended to ensure the orderly execution of the business of the Department and not to impede any legal proceeding and in no way affects the rights and procedures governing public access to records pursuant to the Freedom of Information Act or the Privacy Act. See, 43 CFR part 2.

§ 2.82 Testimony or production of documents; general rule.

(a) No Department employee shall give testimony concerning the official business of the Department or produce any document in the legal proceedings described above in § 2.80 without the prior authorization of the Solicitor or his designee.

(b) Requests for authenticated copies of Interior documents for purposes of admissibility under 28 U.S.C. 1733 and Rule 44 of the Federal Rules of Civil Procedure will be granted for documents that would otherwise be released pursuant to 43 CFR 2.13. For purposes of Rule 44 the "person having legal custody of the record" is the appropriate Secretary, Assistant Secretary, Bureau head, Regional Director, or his designee. Department personnel should obtain the advice of the Solicitor or his designee concerning the proper form of authentication.

§ 2.83 Requests and subpoenas for testimony or documents.

(a) A request for testimony of a Department employee shall be addressed to the Solicitor or his designee with a notification copy also mailed to the appropriate Bureau Director.

(b) A subpoena for testimony by a Department employee or for a document, shall be served in accordance with the Federal Rules of Civil or Criminal Procedure as appropriate, or applicable state procedure, and a copy of the subpoena shall be sent to the Solicitor or his designee.

(c) Every request and subpoena shall be accompanied by an affidavit or declaration under 28 U.S.C. 1746 or, if an affidavit or declaration is not feasible, a statement setting forth the title of the legal proceeding, the forum, the requesting party's interest in the legal proceeding, the reasons for the request or subpoena, any known relationship of the legal proceeding to Department programs, a showing that the desired testimony or document is not reasonably available from any other source, and if testimony is requested, a list of the specific questions to be asked of the employee, and a showing that no document could be provided and used in lieu of testimony. The purpose of this requirement is to permit the Solicitor or his designee to make an informed decision as to whether testimony or

production of documents should be authorized.

(d) Any Department employee who receives a request or is served with a subpoena should immediately notify the Solicitor or his designee.

(e) In accordance with the policy set forth in § 2.81, the Solicitor or his designee may authorize and direct a Department employee to testify concerning official business or to produce a document in a legal proceeding when: the Department has a significant interest in the legal proceeding; in the opinion of the Solicitor, production of a document or presenting testimony by a Department employee would be in the best interest of the Department or in the interest of justice; or in such other circumstances as the Solicitor may determine to be appropriate. In deciding whether it is in the interest of the Department or the interest of justice for such authorization, the Solicitor should consider that employees' official time or resources are to be used for official purposes, that the Department of the Interior's impartiality is to be maintained among private litigants, and that public funds are not to be used for private purposes. The Solicitor should also consider the potential cumulative effect of granting such requests. When production of a document is authorized by the Solicitor, fees will be assessed in accordance with 43 CFR part 2, Appendix.

(f) The Solicitor or his designee may negotiate with an attorney for a party or the party, if not represented by an attorney, to refine or limit a demand so that compliance is less burdensome, or to obtain information necessary to make the determination required by paragraph (e) of this section.

(g) When the U.S. Department of Justice or a state government representing the Department's interest seeks an employee's testimony, there shall be a presumption that it is in the best interest of the Department to allow that testimony. The Department of Justice or the state government must still request authorization from the Solicitor or his designee, along with a brief statement of the relevance of the employee's testimony. A detailed statement as described in § 2.83(c) is not necessary.

§ 2.84 Department Employees as Expert Witnesses.

(a) No Department employee may testify as an expert witness for any party other than the United States, except that in extraordinary circumstances the Solicitor or the Deputy Solicitor may approve an employee testifying for a party other than the United States where the employee is to testify in his/her capacity as an employee of the United States. A department employee must first obtain the authorization of the Solicitor or his designee before testifying as an expert witness for the United States. The Solicitor or his designee will use the criteria set out in § 2.83(e) to determine if authorization will be given.

§ 2.85 Legal Proceedings Between Private Litigants.

(a) Testimony by a Department employee and production of documents in a legal proceeding not involving the United States shall be governed by § 2.82 and § 2.83.

(b) If a Department employee is authorized to give testimony in a legal proceeding not involving the United States, the testimony, if otherwise proper, shall be limited to facts within the personal knowledge of the employee and based on his or her work product at the Department. A Department employee is prohibited from giving expert or opinion testimony, answering hypothetical or speculative questions, or giving testimony with respect to subject matter that is privileged.

§ 2.86 Procedures when a Department employee receives a subpoena.

(a) Any Department employee who receives a subpoena shall immediately forward the subpoena to the Solicitor's Office. The Solicitor, or his designee, will determine the extent to which a Department employee will comply with the subpoena in accordance with the provisions of § 2.83.

(b) If the Department employee has not yet been authorized to testify or where authority has been denied, the employee shall appear at the time and place stated in the subpoena, produce a copy of this regulation, and respectfully refuse to testify or produce any document. *United States ex rel. Touhy* v. *Ragen*, 340 U.S. 462 (1951). In the alternative, if time permits and if appropriate, the U.S. Attorney shall file a motion to quash the subpoena.

Dated: January 8, 1993.

Thomas L. Sansonetti,

Solicitor.

[FR Doc. 93–1037 Filed 1–14–93; 8:45 am]

BILLING CODE 4310–17–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 65 and 69

[Common Carrier Docket No. 92–133; FCC 92–256]

Reform the Interstate Rate of Return Represcription and Enforcement Process

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; correction.

SUMMARY: The Commission has adopted a Notice of Proposed Rulemaking and Order ("Notice") for amending parts 65 and 69 of the Commission's rules to reform the interstate rate of return represcription and enforcement process. The Notice is published at 7 FCC Rcd 4688 (1992). The Commission in the Notice certified that the Regulatory Flexibility Act of 1980 did not apply to the rulemaking. However, this certification was inadvertently not published in the **Federal Register** summary of the Notice. See 57 FR 31994 (July 20, 1992), FR Doc. 92–17051. Therefore, the commission is publishing its certification pursuant to the Regulatory Flexibility Act of 1980 in this notice.

FOR FURTHER INFORMATION CONTACT: Jennifer A. Manner, (202) 632–7500.

SUPPLEMENTARY INFORMATION: The certification by the Commission that the Regulatory Flexibility Act of 1980 does not apply to the proposals in the Notice reads as follows:

We certify that the Regulatory Flexibility Act of 1980 does not apply to this rulemaking proceeding because if the proposed rule amendments are promulgated, there will not be a significant economic impact on a substantial number of small entities, as defined by section 601(3) of the Regulatory Flexibility Act.[1] Because of the nature of local exchange and access service, the Commission has concluded that small telephone companies are dominant in their fields of operation and therefore are not "small entities" as defined by the act.[2] The Secretary shall send a copy of this Notice of Proposed Rulemaking and Order, including the certification, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with Section 603(a) of that Act.[3]

[1] 5 U.S.C. 601(3).

[2] *See* MTS and WATS Market Structure, 93 FCC 2d 241, 338–39 (1983).

[3] 5 U.S.C. § 603(a).

Federal Communications Commission.
Donna R. Searcy,
Secretary.
[FR Doc. 93-970 Filed 1-14-93; 8:45 am]
BILLING CODE 6712-01-M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

49 CFR Part 383

[FHWA Docket No. MC-92-10]

RIN: 2125-AC92

Mandatory Minimum Training Requirements for Operators of Longer Combination Vehicles (LCVs)

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Advance notice of proposed rulemaking (ANPRM); request for comments.

SUMMARY: The FHWA is requesting comments from interested parties concerning the establishment of mandatory minimum training requirements for the operators of longer combination vehicles (LCVs). This action is in response to Section 4007 of the Motor Carrier Act of 1991, which requires the Secretary of Transportation to initiate a rulemaking proceeding to establish minimum training requirements for operators of LCVs. The Congress also directed that this training include certification of an operator's proficiency by an instructor who has met the requirements established by the Secretary.

DATES: Comments must be received on or before March 16, 1993.

ADDRESSES: Submit written, signed comments to FHWA Docket No. MC-92-10, room 4232, HCC-10, Office of Chief Counsel, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Commenters may, in addition to submitting "hard copies" of their comments, submit a floppy disk in standard or high density formats containing data compatible with either WordPerfect or Wordstar for MacIntosh or DOS based systems. Commenters should clearly label submitted disk with the software used (e.g. WordPerfect 5.0 [IBM] or Microsoft Word 4.0 [Mac]). All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except legal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry L. Robin, Standards Review Division, Office of Motor Carrier Standards (202) 366-4001, or Mr. Charles Medalen, Office of Chief Counsel, (202) 366-1354, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m. e.t., Monday through Friday, except legal holidays.

SUPPLEMENTARY INFORMATION: Section 4007(b) of the Motor Carrier Act of 1991, (Title IV of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Pub. L. 102-240, 105 Stat. 1914, 2151), directs the DOT to establish Federal minimum training standards for drivers of LCVs. The Act also requires that the certification of these drivers' skills and abilities be accomplished by instructors who meet certain Federal minimum requirements to assure a certain degree of quality control and uniformity. The FHWA is responsible for the promulgation of minimum Federal regulations concerning commercial motor vehicles (CMVs), including LCVs. To date, the FHWA has not mandated minimum training standards for operators of CMVs because of the substantial progress being made by the motor carrier industry in voluntarily implementing the FHWA's "The Model Curriculum for Training Tractor-Trailer Drivers," as more fully discussed below.

Definitions

In sections 4007 and 1023 of the ISTEA, LCVs are defined as "any combination of a truck tractor and two or more trailers or semi-trailers which operate on [Interstate highways] with a gross vehicle weight greater than 80,000 pounds." Therefore, LCVs include turnpike doubles, Rocky Mountain doubles, triple-trailer combinations and unusually heavy western doubles. Turnpike doubles consist of a tractor and two trailers, each 45- to 48-feet long. A Rocky Mountain double is typically a combination with a semitrailer and a full trailer which normally operates with a long semitrailer and a shorter second trailer. Lengths for the first unit usually range from 45- to 53-feet and for the second unit 27- to 28½-feet. Triple-trailer combinations consist of one tractor hauling three 26- to 29-foot trailers. LCVs can also include usually heavy western doubles weighing in excess of 80,000 pounds.

Background

In the early 1980's the FHWA determined that a need existed for technical guidance in the area of truck driver training. Research at that time had shown that many driver training schools offered little or no structured curricula or uniform training plans.

To help correct this problem, the FHWA developed, and in 1985 issued, the "Model Curriculum for Training Tractor-Trailer Drivers" (C1985, GPO Stock No. 050-001-00293-1), which incorporated the FHWA "Proposed Minimum Standards for Training Tractor Trailer Drivers" (1984). The Model Curriculum, as it is known in the industry, is a broad set of recommendations which incorporates standardized minimum core curriculum requirements and training materials, as well as standards pertaining to vehicles, facilities, instructor hiring practices, graduation requirements, and student placement. Curriculum content includes the following areas: basic operation, safe operating practices, advanced operating practices, vehicle maintenance, and nonvehicle activities.

In 1986, the Professional Truck Driver Institute of America (PTDIA) was created by the motor carrier industry to certify acceptable training programs offered by the truck driver training schools. The Model Curriculum, although modified to meet the needs of this organization, is the fundamental base from which the PTDIA's certification criteria was derived. In mid-1988, the PTDIA began certifying driver training programs across the country. Currently, approximately 50 programs at 34 schools in operation have received the PTDIA certification.

The Model Curriculum (and hence the PTDIA program) addresses all critical aspects of entry-level truck driver training. The Curriculum is designed so that students who completed it can be expected to perform actual tractor-trailer driving skills competently and safely. However, it is geared to the education of drivers of single trailer combinations, not LCVs. A void therefore exists in the Model Curriculum in the areas of classroom and on-the-road driver training instruction specifically for the operation of LCVs.

The Commercial Motor Vehicle Safety Act of 1986 (the CMVSA) (Pub. L. 99-570, 100 Stat. 3207-170, title XII, October 27, 1986), although not directly targeted at driver training, was intended to improve highway safety. Its goal is to ensure that drivers of large trucks and buses possess the knowledge and skills to safely operate those vehicles on public highways. The CMVSA established the commercial driver's license (CDL) program and directed the FHWA to establish minimum national standards which States must meet when licensing CMV drivers. The CMVSA applies to anyone who operates a CMV

in intrastate, interstate, or foreign commerce, including most employees of Federal, State, and local governments. As defined by the implementing regulation [49 CFR 383.5, (1991)] a CMV is a motor vehicle or combination of motor vehicles used in commerce to transport passengers or property if the vehicles—

(a) Have a gross combination weight rating of 26,001 or more pounds inclusive of a towed unit with a gross vehicle weight rating of more than 10,000 pounds; or

(b) Have a gross vehicle weight rating of 26,001 or more pounds; or

(c) Are designed to transport 16 or more passengers, including the driver; or

(d) Are of any size and are used in the transportation of materials found to be hazardous for the purposes of the Hazardous Materials Transportation Act and which require the motor vehicle to be placarded under the Hazardous Materials Regulations (49 CFR part 172, subpart F).

In accordance with the CMVSA, all drivers of CMVs must possess a valid CDL by April 1, 1992, in order to be properly qualified to operate the vehicle(s) they drive. In addition to passing the CDL knowledge and skills tests required for the basic vehicle group, all persons who operate or expect to operate the following vehicles, which have special handling characteristics, must obtain endorsements: double/triple trailers, tank vehicles, passenger vehicles, or CMVs required to be placarded for hazardous materials under 49 CFR 383.93. For the passenger vehicle endorsement the driver must pass knowledge and skills tests. For all other vehicle endorsements, the driver is required to pass only a knowledge test.

The CDL standards do not require the comprehensive training proposed in the Model Curriculum since the CDL is a "licensing standard" as opposed to a "training standard." Accordingly, there are no prerequisite mandatory Federal or State training requirements to obtain a CDL.

To begin to address the void in the Model Curriculum discussed above, the FHWA awarded a contract in February 1991 to the PTDIA to develop a recommended training curriculum outline for the operation of double trailer units with lengths of up to 28- or 28½-feet each (often called "twin trailers" or "western doubles"), as permitted by the Surface Transportation Assistance Act of 1982 (Pub. L. 97–424, 96 Stat. 2097). The development of administrative guidelines necessary to evaluate an organization's implementation of the curriculum was also an integral part of this contract. This addition to the Model Curriculum will be made available to the trucking industry and hopefully be incorporated into existing training courses and programs.

In the On Guard Bulletin for March 1991, the FHWA advised the industry against making the assumption that drivers of single trailer combination units can easily switch to driving multiple trailer units with little or no specialized training. The FHWA pointed out that the controllability and maneuverability of these multiple trailer units may differ significantly from straight and even single trailer configurations. The FHWA recommended that drivers of LCVs have adequate on-the-road and classroom training to make them aware of the variables that influence the safe operation and handling of these vehicles.

Rulemaking and Questions for Comment

To fully understand the various issues relating to this topic, the FHWA is soliciting comments on the following areas, as well as any additional issues identified by respondents.

Scope

1. As used by the motor carrier industry for many years, the term LCV means any CMV with 2 trailers (either of which is over 28½ feet long) or CMV combinations with more than 2 trailers, irrespective of length. Vehicle weight plays no part in the industry use of the term. Should the definition of LCV that will be used to develop a training requirement be expanded to include vehicles not covered by the ISTEA such as multiple-trailer combinations operating with a gross weight of less than 80,000 pounds, i.e. "twin trailers" or "western doubles"? In addition, the FHWA wishes to determine whether vehicles operating under special permit at weights over 80,000 pounds and/or straight trucks pulling single or multiple trailers with overall lengths in excess of 72 feet should be included in those vehicles used to establish a LCV training requirement.

2. What difficulties would the ISTEA definition create from an enforcement standpoint, in distinguishing which vehicles meet the definition and in determining which drivers must comply with any LCV training requirements?

Program Administration

3. Once the training requirements for LCV drivers are established, what should the FHWA's role be in assuring that the training is actually carried out according to the minimum standards?

4. What standards are necessary to ensure that instructors, who will be the key to the efficiency and effectiveness of the LCV training, have been adequately and properly trained and are carrying out their training responsibilities in an acceptable manner?

5. Since LCV operations are allowed only under special State oversize/overweight permits, should the initial licensing of LCV instructors and certification of LCV drivers be accomplished by a Federal (FHWA or other) or State agency? How should this be accomplished?

6. From an enforcement perspective, what specific Federal, State or local agency should have the responsibility for assuring that the requirements of LCV training are met and what form of documentation should be established to prove to prospective employers that adequate LCV training has been successfully completed by a driver? Who should be held accountable if the training requirements are not met, the individual and/or a motor carrier-employer?

7. Should nonprofit, private organizations, such as PTDIA, be authorized to evaluate and certify the adequacy of LCV training programs?

Training and Licensing

8. What types of LCV driver training programs exist? Please provide as much detail about cost and course length as possible.

9. Should the implementation of minimum training requirements for LCV operators be "phased in" over a certain period of time? If so, what scenario do you propose and why?

10. Should LCV training be a prerequisite for a double/triple trailer endorsement on a CDL?

11. Should all LCV drivers be required to have previous experience with single trailer vehicles? If so, how much?

12. How often should LCV training be offered/repeated for both instructors and drivers?

13. Do specialized vehicle combinations such as triples or those handling special cargo require different training standards?

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action is not major within the meaning of Executive Order 12291. However, because of the public interest in

commercial motor vehicle safety, this notice is considered significant within the meaning of Department of Transportation regulatory policies and procedures. For this reason and pursuant to Executive Order 12498, this rulemaking action has been included on the Regulatory Program for significant rulemaking actions.

Due to the preliminary nature of this document and the resulting lack of necessary information on costs, the FHWA is unable to evaluate the economic impact of a regulatory requirement for mandatory training for LCV drivers. Based on the information received in response to this Notice, the FHWA intends to carefully consider the costs and benefits associated with the various alternative requirements. Comments, information and data are solicited on the economic impact of this rulemaking.

Regulatory Flexibility Act

Although the Regulatory Flexibility Act (Pub. L. 96–354; 5 U.S.C. 601 *et seq.*) does not apply to an ANPRM, the agency has evaluated the effects of this rule on small entities. Based on the evaluation, the FHWA certifies that this rule would not have a significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

National Environmental Policy Act

This agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulatory information number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center published the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 383

Commercial driver's license testing and licensing standards, Highways and roads, Motor vehicle safety.

Issued on January 8, 1993.

T.D. Larson,

Administrator.

[FR Doc. 93–876 Filed 1–14–93; 8:45 am]

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Federal Highway Administration

49 CFR Parts 383, 390, and 391

[FHWA Docket No. MC–92–13]

RIN 2125–AC83

Violations of Out-of-Service Orders by Commercial Motor Vehicle Operators; Disqualifications and Penalties

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FHWA proposes to make any violation of an out-of-service order by a driver of a commercial motor vehicle (CMV) a disqualifying offense resulting in suspension, revocation, or cancellation of the driver's commercial driver's license (CDL), or disqualification by the FHWA, for a period of time from 90 days to five years. Additional civil monetary penalties are also proposed for both drivers and their employers. This proposal implements section 4009 of the Motor Carrier Safety Act of 1991 (Title IV of Pub. L. 102–240, 105 Stat. 1914) and responds to a petition filed by the Commercial Vehicle Safety Alliance on June 22, 1990.

DATES: Comments must be received on or before March 16, 1993.

ADDRESSES: Submit written, signed comments to FHWA Docket No. MC–92–13, room 4232, HCC–10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Commenters may, in addition to submitting "hard copies" of their comments, submit a floppy disk in standard or high density formats containing data compatible with either WordPerfect or WordStar for IBM systems, or with Microsoft Word or WordPerfect for Apple Macintosh systems. Commenters should clearly label submitted disk with the software format used (e.g., WordPerfect 5.0 [IMB] or Microsoft Word 4.0 [Mac]). All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except legal holidays. Those desiring notification of receipt of comments must include a self-addressed stamped postcard

FOR FURTHER INFORMATION CONTACT: Ms. W. Teresa Doggett, Driver Standards Division, Office of Motor Carrier Standards (202) 366–4009, or Mr. David Sett, Office of the Chief Counsel, (202) 366–0834, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal holidays.

SUPPLEMENTARY INFORMATION:

Background

This rulemaking responds to Section 4009 of the Motor Carrier Act of 1991 (Title IV of the Intermodal Surface Transportation Efficiency Act of 1991 (ISTEA), Pub. L. 102–240, 105 Stat. 1914, 2156), which directs the Secretary of Transportation to establish sanctions, penalties and disqualifications relating to violations of out-of-service orders by persons operating commercial motor vehicles. The Congress mandated issuance of a rule on this subject by December 18, 1992.

The statute specifies that any operator of a CMV who is convicted of a first violation of an out-of-service order is to be disqualified for no less than 90 days; subsequent violations would lead to disqualification periods of from one to five years. The statute also sets forth civil penalties of not less than $1,000 for drivers who are convicted of a violation of an out-of-service order, and of not more than $10,000 for employers who are convicted of knowingly allowing a driver to violate an out-of-service order. Finally, the statute adds State adoption and enforcement of the penalties for out-of-service violations to the list of conditions necessary to achieve "substantial compliance" with section 12009(a) of the Commercial Motor Vehicle Safety Act of 1986, Public Law 99–570, 100 Stat. 3207–170, 3207–179, and thereby avoid a withholding of highway funds under section 12011 of that Act.

This NPRM also responds to a June 22, 1990, petition filed by the Commercial Vehicle Safety Alliance (CVSA), an association of CMV safety enforcement officials from the States, the Canadian provinces and territories, Mexico, and representatives of other interested organizations. The petition stated that the potential for operating CMVs which have been placed "out-of-service" before completion of the required repairs is a cause of great concern to CVSA members. The petitioner asserted that while the CVSA is currently developing a verification procedure to ensure that repairs have been completed and to deter violations of out-of-service orders, the enforcement program needs to be complemented by adequate sanctions. The petitioner, therefore, requested the FHWA to include violations of out-of-service orders as disqualifying offenses under the CDL requirements, since one purpose of the CDL program is to upgrade CMV safety by removing unsafe operators from the road.

Out-of-service orders are declarations issued by the Federal Highway Administration, or by an authorized enforcement officer of a State or local jurisdiction, to drivers of CMVs or motor carriers, when the driver, vehicle, or motor carrier is operating under specified unsafe conditions. The conditions for issuing out-of-service orders are specified in a number of places in the Federal Motor Carrier Safety Regulations (FMCSRs). 49 CFR Part 350 *et seq.* The FHWA is authorized generally in § 386.72(b)(1) to issue out-of-service orders with respect to drivers, vehicles, or motor carrier operations when violations of the FMCSRs are determined to present an imminent hazard. An "imminent hazard" means any condition of a vehicle, employee, or commercial motor vehicle operation which is likely to result in serious injury or death if not discontinued immediately. 49 U.S.C. 521(b)(5); 49 CFR 386.72(b)(1). Section 396.9 contains provisions for placing vehicles out of service which by reason of mechanical condition or loading would likely cause an accident or a breakdown. Sections 392.5 and 395.13 provide out-of-service conditions specific to violations of intoxicating beverage and hours of service requirements respectively.

Out-of-service orders are issued in various forms. Operations out-of-service orders result from a Safety or Compliance Review conducted by FWHA or an authorized enforcement officer of a State or local jurisdiction. Upon a finding of repeated failure to come into compliance with the FMCSRs despite enforcement actions, operations out-of-service orders direct a motor carrier to cease all or that part of the motor carrier's operations constituting an imminent hazard to safety. Additionally, hazardous materials and passenger carriers assigned unsatisfactory safety ratings are given 45 days to improve their ratings or have such operations ordered out of service. 49 CFR 385.13.

Out-of-service orders may also be issued with respect to particular drivers or vehicles, rather than the overall operations of a motor carrier. The CVSA, in cooperation with the FHWA, has established the North American Uniform Out-of-Service Criteria governing driver, vehicle, and hazardous materials out-of-service and restricted service conditions. See title 49 CFR, chapter III, subpart B, appendix G. Driver out-of-service criteria identify driver violations that render the CMV operator unqualified to drive or declared out-of-service. Vehicle out-of-service criteria identify critical vehicle inspection items and provide procedures for safety inspectors to place vehicles in an out-of-service or restricted service category. The hazardous materials out-of-service criteria delineate similar items of noncompliance, but are specifically designed to abate unsafe conditions which may be particular to carriage of hazardous materials. The States and jurisdictions which are members of the CVSA voluntarily apply these out-of-service criteria through the use of common inspection standards. See Appendix G, supra. The great majority of these inspections are conducted along the roadside. A copy of the North American Uniform Out-of-Service Criteria is available for public inspection in the docket at the above address.

A 1990 General Accounting Office (GAO) Report, "Need To Better Ensure Correction of Serious Inspection Violations" (GAO/RCED–90–202, September 1990), disclosed that five States—Idaho, Maine, Michigan, Oklahoma, and Wisconsin—participated in an FHWA-funded study to determine how often drivers continue their trips without correcting out-of-service violations. The highest noncompliance rate (53 percent) was found in Maine, where the study focused on drivers who were left unattended after the inspection facility closed. Similarly, Michigan's study found a 16 percent noncompliance rate for drivers left unattended compared to a 2 percent rate for those at open facilities. The Idaho study, based on a larger percentage of inspections at facilities staffed around the clock (where drivers were under scrutiny), indicated the lowest overall noncompliance rate (9 percent). The GAO developed a questionnaire as part of the report which showed that up to 74 percent of inspections occur at facilities not continuously staffed. The lack of staff at these inspection sites and the number of drivers left unattended provide the potential for noncompliance with out-of-service orders. The GAO report is available for public inspection in the docket at the above address.

In response to the congressional directive, the CVSA's petition, and available evidence on the potential for driver noncompliance, this rulemaking proposes disqualifications and penalties for CMV operators who drive away from safety inspection sites without correcting vehicle and/or driver out-of-service conditions or otherwise violate out-of-service orders. This rulemaking also proposes penalties for motor carriers who require or permit drivers to violate out-of-service orders.

With respect to CDL holders, States will satisfy disqualification requirements by suspending, revoking, or canceling the affected licenses under section 12009(b) of the Commercial Motor Vehicle Safety Act of 1986. In order to comply with section 12009(a), this proposal would require each State licensing agency to change existing penalty systems and related statutes, regulations and procedures by adding violations of out-of-service orders to its list of disqualifying offenses.

Certain non-CDL holders (i.e., those who are subject to the FMCSRs but not to the CDL requirements) would also be subject to this rulemaking. For those drivers, the FHWA proposes to add the same disqualification penalties which would be the responsibility of the FHWA.

Applicability

This NPRM proposes to add to 49 CFR part 383 disqualification periods and civil penalties for drivers who are convicted of violating out-of-service orders and for employers who require or permit drivers to violate out-of-service orders. Part 383 generally encompasses every driver of a motor vehicle that—

(1) Has a gross combination weight rating (GCWR) of 26,001 or more pounds, inclusive of a towed vehicle with a gross vehicle weight rating (GVWR) over 10,000 pounds; or

(2) Has a GVWR of 26,001 pounds or more; or

(3) Is designed to transport 16 or more passengers, including the driver; or

(4) Is required to be placarded for hazardous materials.

No exceptions to the applicability of CDL requirements are provided in the regulations. Pursuant to the waiver authority granted in Section 12013, however, the FHWA on September 26, 1986 (see 53 FR 37313), issued specific waiver provisions covering active-duty uniformed military personnel and, at each State's discretion, certain farmers, firefighters, and operators of emergency equipment. Similarly, on April 17, 1992 (see 57 FR 13650), the FHWA issued a notice of final disposition authorizing States to exempt certain employees of farm-related service industries from taking the CDL knowledge and skills tests in order to obtain a restricted CDL. For these groups, the FHWA found that the waivers were not contrary to the public interest and would not diminish the save operation of commercial motor vehicles.

To preserve consistency between part 383 (the CDL rules) and part 391 of the FMCSRs), the NPRM also proposes to extend the disqualifications for violations of out-of-service orders to drivers of CMVs as defined in 49 CFR 390.5. This extension would effect all vehicles with a GVWR or GCWR greater than 10,000 pounds. The scope of this rulemaking, based on FHWA's authority to establish minimum safety standards for CMVs, 49 U.S.C. 3102, 49 U.S.C. App. 2505, reflects the FHWA's belief that a smaller vehicle operating while designated as an "imminent hazard" presents the same kind of safety risk as a larger vehicle. 49 U.S.C. 3102, 49 U.S.C. App. 2505. Drivers of CMVs with a GVWR or GCWR greater than 10,000 pounds are already subject to civil penalties for violation of out-of-service orders, as described in appendix A (IV) to part 386, title 49, Code of Federal Regulations. The driver disqualification proposed in this rulemaking would serve as an additional inducement to refrain from operating an imminently hazardous vehicle or otherwise violate an out-of-service order.

Section-by-Section Analysis

Section 383.5. This section would define an "out-of-service order" as a declaration by the Federal Highway Administration, or by an authorized enforcement officer of a State or jurisdiction, that a driver, or a CMV, or a motor carrier operation is out of service under the provisions of title 49, Code of Federal Regulations, including but not limited to §§ 386.72, 392.5, 395.13, or 396.9.

Section 383.37. The proposal would prohibit an employer from using drivers and vehicles, or conducting motor carrier operations, which have been declared out-of-service until the violation has been corrected or the minimum out-of-service period has expired. This section provides a basis for the employer penalty provision proposed in § 383.53. While the FMCSR's already prohibit an employer from, and provide civil penalties for, requiring or permitting an employee to violate an out-of-service order (see §§ 395.13(c) and 386.72(b)(4)), there are no analogous regulations which cover employers subject only to part 383 and not to parts 390–399.

Section 383.51. This section would be modified by the proposal to incorporate the new offenses and the duration of the disqualification period for such offenses as mandated by Congress. As currently codified, the following structure summarizes § 383.51:

Paragraph (a): General introduction.

Paragraph (b): Long-term disqualifying offenses. (These include driving under the influence (DUI), leaving the scene of the accident, and felonies involving CMVs, and carry one-year-to-lifetime disqualifications.)

Paragraph (c): Short-term disqualifying offenses. These are "serious traffic violations" as defined in § 383.5, and carry 60- to 120-day disqualifications.

Paragraph (d): Special provisions for State compliance with blood alcohol levels.

Since the disqualification periods mandated by the Congress for violations of out-of-service orders are different from those currently included in paragraphs (b) and (c), this NPRM would place them in a new paragraph and result in the following revised structure for § 383.51:

Paragraph (a): General introduction. (Unchanged.)

Paragraph (b): Long-term disqualifying offenses. (Unchanged.)

Paragraph (c): Short-term disqualifying offenses. (Unchanged.)

Paragraph (d): Disqualifications for violation of out-of-service orders. (New paragraph.)

Paragraph (e): Special provisions for State compliance with blood alcohol levels. (Formerly paragraph (d).)

Under new paragraph (d) of § 383.51, a CMV driver who is convicted of a first violation of an out-of-service order would be disqualified for a period of not less than 90 days. For convictions of subsequent violations of an out-of-service order, the driver would be disqualified for a period of five years. Proposed §§ 383.51(d)(2)(ii) and 391.15(d)(2)(ii) would implement this provision.

The statute specifies that a "second violation of an out-of-service order" would result in a one-to-five-year disqualification. Under the discretion accorded the Secretary in the legislation, the FHWA has chosen a five-year disqualification period for all subsequent violations. Violation of an out-of-service order is a very serious offense. By definition, violation of an out-of-service order poses an "imminent hazard" to public safety or is likely to cause an accident. A five-year disqualification period is necessary to serve as a maximum deterrent to engaging in this inherently dangerous and all-too-common activity.

Section 383.53. The FHWA proposes to add civil penalties related to convictions of violations of an out-of-service order as directed by Congress. As a result, a new § 383.53(b) would be added so that a driver who is convicted of a violation of an out-of-service order would be subject to civil penalties of not less than $1,000 and any employer convicted of knowingly requiring or permitting a driver to violate an out-of-service order would be subject to civil penalties of not more than $10,000. Conviction, as defined in § 383.5, includes an administrative adjudication by either FHWA, or a State or local jurisdiction, that the driver or employer violated an out-of-service order issued by either FHWA or a law enforcement official of a State or local jurisdiction.

Civil penalties for violations of out-of-service orders by drivers who are covered by the FMCSRs already appear in part 386. (The proposed additions to § 383.53 do not duplicate part 386 because the latter is directed to the FHWA, while proposed § 383.53(b) is primarily intended for implementation by the States.) The penalties of part 386, appendix A, provisions IV (a) through (d), which would apply principally to non-CDL holders as a result of this proposal, are $1,000 maximum for employees and $10,000 maximum for employers.

Section 390.5. The definition of "out-of-service orders," as proposed for § 383.5, would also become part of § 390.5 which provides definitions of terms used in part 391.

Section 391.15. The purpose of amending § 391.15 is to apply disqualification penalties for violating out-of-service orders to non-CDL holders who operate CMVs (as defined in § 390.5) in the 10,001–26,000 pound GVWR/GCWR range. Under existing procedures, the FHWA would issue the disqualifications to these non-CDL drivers.

As currently codified, § 391.15 discloses the following structure:

Paragraph (a). General. (Consequences of disqualification on drivers and employers.)

Paragraph (b). Disqualification for loss of driving privileges.

Paragraph (c). Disqualification for criminal and other offenses (parallels § 383.51(b)).

To these existing paragraphs, which would be unaltered, this proposal would add:

Paragraph (d) (proposed): Disqualification for violation of out-of-service orders. The new paragraph (d) would duplicate the proposed § 383.51(d).

Rulemaking Analyses and Notices

Regulatory Impact

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

The FHWA has determined that this document does not contain a major rule under Executive Order 12291 or a significant regulation under the regulatory policies and procedures of the Department of Transportation. It is anticipated that the economic impact of this rulemaking will be minimal. Therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

For the above reasons and under the criteria of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 605(b)), the FHWA certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities because we believe that the overwhelming majority of carriers, including small carriers and owner-operators comply with out-of-service violations that may be issued to their drivers or vehicles. Moreover, the FHWA believes that the adoption of this rule and the attendant civil penalties and disqualification periods will serve as a deterrent for drivers who may otherwise have violated out-of-service orders. Accordingly, the FHWA believes that actual imposition of these fines and penalties will be required infrequently.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

National Environmental Policy Act

The agency has analyzed this section for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Parts 383, 390, and 391

Commercial driver's license documents, Commercial motor vehicles, Driver qualification, Highways and roads, Motor carriers licensing and testing procedures, and Motor vehicle safety.

Issued on: January 11, 1993.

T. D. Larson,

Administrator.

In consideration of the foregoing, the FHWA hereby proposes to amend title 49, Code of Federal Regulations, chapter III, subchapter B, as set forth below.

PART 383—[AMENDED]

1. The authority citation for part 383 is revised to read as follows:

Authority: 49 U.S.C. 3102; 49 U.S.C. App. 2505, 2701 *et seq.*; and 49 CFR 1.48.

2. Section 383.5 is amended by adding, in alphabetical order, the definition for *out-of-service order* as follows:

§ 383.5 Definitions.

* * * * *

Out-of-service order means a declaration by the Federal Highway Administration, or by an authorized enforcement officer of a State or local jurisdiction, that a driver, or a commercial motor vehicle, or a motor carrier operation, is out-of-service under the provisions of this title, including, but not limited to, §§ 386.72, 392.5, 395.13, or 396.9.

* * * * *

3. In § 383.37, paragraph (a) is amended by removing the last "or", paragraph (b) is amended by removing the period at the end and replacing it with "; or", and paragraph (c) is added to read as follows:

§ 383.37 Employer responsibilities.

* * * * *

(c) In which the employee, or the vehicle he/she is driving, or the motor carrier operation, is subject to an out-of-service order.

4. In § 383.51, paragraph (d) is redesignated as paragraph (e), and a new paragraph (d) is added to read as follows:

§ 383.51 Disqualification of drivers.

* * * * *

(d) *Disqualification for violation of out-of-service orders*—(1) *General rule.* A driver who is convicted of violating an out-of-service order is disqualified for the period of time specified in paragraph (d)(2) of this section. In addition, such driver is subject to special penalties as contained in § 383.53(b).

(2) *Duration of disqualification for violation of out-of-service orders:*

(i) *First violation.* A driver who is convicted of a first violation of an out-of-service order is disqualified for a period of not less than 90 days.

(ii) *Subsequent violation.* A driver who is convicted of two or more violations of out-of-service orders in separate incidents is disqualified for a period of five years.

(e) * * *

5. Section 383.53 is revised to read as follows:

§ 383.53 Penalties.

(a) *General rule.* Any person who violates the rules set forth in subparts B and C of this part may be subject to civil or criminal penalties as provided for in 49 U.S.C. 521(b).

(b) *Special penalties pertaining to violation of out-of-service orders*—(1) *Driver violations.* A driver who is convicted of violating an out-of-service order shall be subject to a civil penalty of not less than $1,000 in addition to disqualification under § 383.51(d).

(2) *Employer violations.* An employer who is convicted of a violation of § 383.37(c) shall be subject to a civil penalty of not more than $10,000.

PART 390—[AMENDED]

6. The authority citation for part 390 continues to read as follows:

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Authority: 49 U.S.C. App. 2503 and 2505; 49 U.S.C. 3102 and 3104; and 49 CFR 1.48.

7. Section 390.5 is amended by adding, in alphabetical order, the definition for *out-of-service order* as follows:

§ 390.5 Definitions.

* * * * *

Out-of-service order means a declaration by the Federal Highway Administration, or by an authorized enforcement officer of a State or local jurisdiction, that a driver, or a commercial motor vehicle, or a motor carrier operation, is out-of-service under the provisions of this title, including, but not limited to, §§ 386.72, 392.5, 395.13, or 396.9.

* * * * *

PART 391—[AMENDED]

8. The authority citation for part 391 continues to read as follows:

Authority: 49 U.S.C. App. 2505; 49 U.S.C. 504 and 3102; and 49 CFR 1.48.

9. Section 391.15 is amended to add a new paragraph (d) to read as follows:

§ 391.15 Disqualification of drivers.

* * * * *

(d) *Disqualification for violation of out-of-service orders.*

(1) *General rule.* A driver who is convicted of violating an out-of-service order is disqualified for the period of time specified in paragraph (d)(2) of this section.

(2) *Duration of disqualification for violation of out-of-service orders:*

(i) *First violation.* A driver who is convicted of a first violation of an out-of-service order is disqualified for a period of not less than 90 days.

(ii) *Subsequent violation.* A driver who is convicted of two or more violations of out-of-orders in separate incidents is disqualified for five years.

[FR Doc. 93–1083 Filed 1–14–93; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 91–49; Notice 3]

RIN 2127–AE29

Federal Motor Vehicle Safety Standards, Electric Vehicles Controls and Displays; Windshield Defrosting and Defogging Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes minor amendments of Federal Motor Vehicle Safety Standards on controls and displays, and windshield defrosting and defogging systems that would make them more appropriate for electric powered motor vehicles. The proposal is based upon comments received in response to an advance notice of proposed rulemaking (ANPRM) published in December 1991.

DATES: The comment closing date for the notice is March 1, 1993. The final rule would be effective 180 days after its publication in the Federal Register.

ADDRESSES: Comments should refer to the docket number and notice number shown above and be submitted in writing to: Docket Section, National Highway Traffic Safety Administration, room 5109, 400 Seventh Street SW., Washington, DC 20590. Docket hours are 9:30 a.m. to 4 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Chales Hott, Office of Vehicle Safety Standards, NHTSA (202–366–0247)

SUPPLEMENTARY INFORMATION:

I. Introduction

On December 27, 1991, NHTSA issued an advance notice of proposed rulemaking (ANPRM) (56 FR 67038) requesting comments on potential safety-related issues associated with the use of electric vehicles (EVs), and solicited ideas on whether the agency should, and if so how it might address those problems through possible new and amended Federal Motor Vehicle Safety Standards. The reader is referred to the ANPRM for a full discussion of these issues.

In response to the comments received on the ANPRM, this notice proposes minor amendments to two Federal Motor Vehicle Safety Standards to make them more appropriate to electric vehicles. In addition, the agency is publishing in this issue a supplemental notice of proposed rulemaking modifying the agency's proposed standard on passenger car brake systems in a manner that would accommodate electric vehicles.

The ANPRM elicited widespread public interest, and a total of 46 comments were received in response to it. A listing of the commenters in alphabetical order demonstrates the breadth of experience and viewpoints that the commenters represent. They were: Spencer E. Adler, Esq., American Tour de Sol, American Honda Motor Company, Amerigon, Battery Council International, Bay Area Rapid Transit District, Anthony R. Benedetto, Biodyne Research, Inc., BMW of North America, Chloride-RWE, Chrysler Corporation, Connecticut Department of Motor Vehicles, Cushman, Electric Power Research Institute (EPRI), Electric Transportation Association (ETA), Electric Transportation Coalition, Electric Vehicles of America, Electric Vehicle Industry Association, Electro Automotive, Ford Motor Company, General Motors Corporation, Idaho National Engineering Lab, Insurance Institute for Highway Safety, Inter City Testing & Consulting, International Auto Design, Kumn Industries, Mercedes-Benz of North America, Mitsubishi Motors Corporation, Motor Vehicle Manufacturers Association (MVMA), Nissan Research & Development (two comments), Renaissance Cars, Inc., Rubber Manufacturer's Association, SAE/Ford, Solar Electric, Solar & Electric Racing Association, Subaru of America, Suzuki Motors, Toyota Motor Corporation, TUV Rheinland of North America, Underwriters Laboratories, Inc., U.S. Department of Energy, U.S. Postal Service, Volkswagen of America, Inc., and WEC Oceanic Division.

As NHTSA noted in the ANPRM, it has twice previously reviewed the Federal Motor Vehicle Safety Standards (FMVSS) to determine their appropriateness for EVs and published the findings in response to Congressional requirements. On those occasions, which are discussed below, the agency concluded that all FMVSS are applicable to EVs although some of the crash avoidance standards might have to be revised because they contain text specifically addressing internal combustion engines or engine components. No rulemaking was initiated by the agency following those earlier reviews because the prospect of significant numbers of EVs being produced was much more uncertain than it is now.

NHTSA is issuing this notice now because it wishes to have any necessary safety standards in place as soon as possible to support the safe introduction and operation of EVs. To delay rulemaking until significant production of EVs actually begins could not only fail to prevent avoidable safety problems, but also disrupt and impede the development and commercialization of EVS.

II. Background

Public Law 94–413, the Electric and Hybrid Vehicle Research, Development, and Demonstration Act, required the Department of Transportation (DOT) to conduct a study of the current and future applicability of the FMVSS and

regulations to electric and hybrid vehicles. In response, NHTSA published a study of EV safety requirements in 1978 entitled "Applicability of Federal Motor Vehicle Safety Standards to Electric and Hybrid Vehicles." The study found that most existing FMVSS were suitable, although some containing reference to internal combustion engines or engine components would require modifications.

In 1988, the Alternative Motor Fuels Act (Public Law 100–494) was enacted. It included a requirement for a review by DOT, among other agencies, of its regulations and a report identifying those rules or standards that are barriers to introduction of EVs into commerce. DOT's report to Congress in response to Pub. L. 100–494 is titled "Federal Regulations Needing Amendment to Stimulate the Production and Introduction of Electric/Solar Vehicles." The report, published in January 1990, reviewed EVs with respect to NHTSA safety regulations and procedures. The review reached many of the same conclusions regarding the applicability of the FMVSS to EVs that were reported in 1978 in response to Pub. L. 94–413. The principal conclusions in the latter report were that existing standards for brakes, tires, and windshield defrosting and defogging would probably need to be modified so that they are suitable as they apply to EVs.

Interest in the suitability of Federal regulations as they affect EVs has increased in the last several years in response to the efforts of many major foreign and domestic automobile manufacturers to develop electrically powered passenger cars, trucks, and multi-purpose passenger vehicles (MPV). The primary impetus for the introduction of large numbers of EVs into the U.S. marketplace is a regulation of the California Air Resources Board. Similar regulations are under consideration by other States. The California regulation requires that not less than two percent of a manufacturer's sales in the State (roughly 40,000 vehicles total) must be zero emission vehicles (ZEVs), beginning in model year 1998. This requirement will increase to 10 percent or roughly 200,000 vehicles beginning in model year 2003. The definition of a ZEV is a vehicle that emits no exhaust or evaporative emission of any kind. Currently, the electric vehicle is the only vehicle which meets these requirements. The only other alternative fuel expected to meet the ZEV requirements is hydrogen fuel cells. However, this technology is still in the research and development stage.

III. Modifications to FMVSS to Improve Suitability

The FMVSS are organized into three main categories covering crash avoidance, crashworthiness, and post crash factors. Based on studies and reviews of the FMVSS's concerning their suitability for EVs, NHTSA has concluded that EVs should comply with the intent or purpose of all existing FMVSS. Several standards require modifications, however, as some aspects of them are premised on types of technology, e.g., internal combustion engines, not found in EVs. Specific comments were sought on how these standards might be modified, and whether the performance requirements of these standards should be changed for EVs, and, if so, what performance requirements would be appropriate. These issues are discussed in greater detail below.

Cash Avoidance Standards

1. FMVSS No. 101, Controls and Displays

The appropriateness of Standard No. 101 was not discussed in the ANPRM, but was the subject of comments by GM, MVMA, Chrysler Corporation, and ETA.

A. Standardization of EV-Specific Displays

ETA believes that certain displays that are unique to EVs should be standardized before EVs begin to proliferate. The displays and symbols that are candidates for standardization are a state of charge indicator, traction battery voltage, traction battery current, traction battery temperature, traction battery disconnect, and regenerative override. In the absence of any demonstrable safety need for standardization, NHTSA declines to initiate rulemaking to standardize EV-specific displays, other than for labeling the battery charge indicator and its symbol.

B. Battery Charge Indicator and Symbol

MVMA and Chrysler commented that a gauge and symbol should be required to indicate battery energy level which will provide operators with an indication of the vehicle's remaining range capability before recharging is required. GM stated that the European agencies have agreed to use the ISO battery symbol to indicate electrical power reserve and requested NHTSA's concurrence to use it.

NHTSA believes that EV manufacturers will provide a "range indicator" or "state-of-charge" indicator similar to the fuel gauge on a conventionally powered vehicle, without a regulatory requirement that they do so. The method of measuring state-of-charge should be left to the manufacturer as the accuracy of current systems varies widely at this stage of the art. However, NHTSA is proposing that the state-of-charge indicator (whether a gauge or otherwise) contain an illuminated telltale with the word "RECHARGE", and the ISO battery symbol (identical to the one presently specified to indicate "electrical charge"), which will illuminate when the electrical energy remaining in the battery system contains less than 25% of full charge. NHTSA invites specific comments as to whether a value other than 25% would be more appropriate. NHTSA also asks comments on whether use of the ISO symbol to indicate a state-of-charge warning is likely to be confusing given its present use to indicate "electrical charge" in conventionally powered vehicles, and whether an alternative symbol, such as the outline of a household electrical plug, might be desirable.

2. FMVSS No. 102, Transmission Shift Lever Sequence, Starter Interlock and Transmission Braking Effect

As NHTSA commented in the ANPRM, EVs with multi-speed transmissions that are not equipped with regenerative braking may have difficulty complying with the transmission braking provision of Standard No. 102 which requires transmission braking effects at speeds under 25 mph for automatic multi-speed transmissions.

There were two questions for which NHTSA sought comment:

(a) Should EVs be required to comply with the transmission braking effect requirements of Standard No. 102?

Although most of the 46 commenters replied in the affirmative, nine did not. Two of them noted that regenerative braking is a function of the state of the charge of the battery and will not be reliable as a safety system. Others in opposition believe that removing this requirement for EVs would permit designers a wider degree of freedom in the layout of drive trains.

The agency has decided to make no change in the standard, and notes the great support for applying Standard No. 102 to EVs with multi-speed transmissions. The purpose of the braking effect requirement is to assist the vehicle service brake system on long down-grades. Regenerative braking can perform the same function. Even though the effectiveness of the regenerative function varies with the charge in the batteries, the function of regenerative braking ought to be available in varying

degrees for most of the time in which an EV is operating.

(b) What percentage of EVs are likely to be equipped with multi-speed automatic transmissions?

At present, most EVs operate with only one forward gear ratio. In the view of the commenters, at this comparatively early stage of contemporary EV development, it is not possible to determine the percentage of EVs that ultimately may be equipped with multi-speed automatic transmissions, and NHTSA concurs with this assessment.

Because EVs with single speed transmissions are excluded from Standard No. 102, Ford commented that the standard should be modified to require the availability of a braking effect on these vehicles that can supplement the service brake. NHTSA will take this comment under advisement as a possible new regulation to address crash avoidance standards unique to EVs.

3. FMVSS No. 103, Windshield Defrosting and Defogging Systems

One provision of Standard No. 103 requires the defrosting and defogging system of a vehicle to be capable of melting a specific amount of windshield ice within a specified time period after allowing time for engine warm-up. In the past, some EVs equipped with an on-board combustion heater have used them for defrosting and defogging systems, although there is no record of an EV meeting the requirements of this portion of the standard. However, for EVs, the reference to engine warm-up is meaningless and may require revision.

There were two questions for which NHTSA sought comment:

(a) How should Standard No. 103 be modified to reflect the fact that an engine warm-up period may not be needed and a warm-up time period for a combustion heater may need to be substituted?

Generally, commenters recommended that the warm-up procedure for EVs should be the one that the manufacturer recommends for cold weather starting. NHTSA tentatively concurs, and believes that Standard No. 103 should be modified to allow the use of auxiliary defrosting/defogging systems. Thus, it is proposing that the manufacturer's cold weather warmup procedure be followed by vehicles equipped with a heating system other than a heat exchanger type that uses the engine's liquid coolant as a means to supply the heat to the heat exchanger. These changes would be made to the demonstration procedures in S4.3(a) and S4.3(b).

(b) Should the requirements of Standard No. 103 be revised for EVs? If so, what requirements for EV defrosting and defogging would be appropriate? What effect would these modifications to Standard No. 103 have on EV safety?

Most commenters believed that the performance requirements of the standard can be met with today's technology, either with a combustion heater or another device, such as resistance heating. Some noted that EV defrosting can take place while the vehicle is plugged into a recharging station, and while this is an acceptable method of maximizing the vehicle's range, there may be occasions in which the vehicle will need to be defrosted at locations where auxiliary power is not available. Therefore, NHTSA has decided not to reduce the performance requirements of Standard No. 103 for EVs.

One commenter suggested that the standard be modified to reflect the climate of the geographical area in which the EV is used. While it is true that EVs operating in Southern California may not require the defrosting/defogging capabilities of EVs used in colder climates (indeed, at one time Standard No. 103 did not apply to passenger cars manufactured for sale in Hawaii), any owner of an EV is not precluded from using it, or selling it for use, anywhere in the United States. For this reason, EVs must be subject to uniform national standards, not to standards based on local climatic considerations.

4. FMVSS No. 105, Hydraulic Brake Systems

Standard No. 105 specifies requirements for hydraulic service brakes and associated parking brake systems. One of the standard's provisions is that the vehicle be placed in neutral for some of the tests. For EVs with direct drive systems and/or regenerative braking, NHTSA considered that this test procedure may be difficult to follow.

The questions for which NHTSA sought comment were: do the test procedures of Standard No. 105 need to be modified for EVs equipped with regenerative braking and/or direct drive transmissions? If so, what should the modifications be?

Technically speaking, "regenerative braking" does not describe an application of an EV's service brake system, but the decelerative effect that results from the conversion of kinetic energy into stored electrical energy. The purpose of the regeneration system is to extend the range of the vehicle by making use of the available kinetic energy of the vehicle's velocity. NHTSA believes that an EV with regenerative braking should be tested in its normal operating state if the regeneration system is in permanent operation, and not subject to any control by the EV operator. If the regenerative effect can be switched off or the vehicle has a clutch, then the vehicle should be tested with the regenerative feature inoperative, or with the transmission in neutral.

However, most commenters believe that the portion of Standard No. 105 that addresses testing in the neutral position should be modified. NHTSA understands that EVs with direct drive transmissions have only a forward and reverse selector which reverses the rotation of the electric motor, and thus do not have a designated "neutral" position. However, the equivalent for an EV with a direct drive transmission would be the position of the selector in either forward or reverse position without any application of electromotive force (unless there is a clutch to disconnect the motor from the drive train).

GM (through Stephen Selander of its legal staff) requested interpretations of Standard No. 105 and its applicability to a vehicle braking system that consisted of front hydraulic disc (service) brakes, and rear electric (service and parking) brakes, four-wheel anti-lock braking system, and regenerative braking. NHTSA replied to Mr. Selander on April 29, 1992, that the hydraulic portion of the service brake system was cover under Standard No. 105, and should be tested in accordance with the features specified therein, and that regenerative braking should be allowed to operate normally just as engine braking occurs normally during compliance testing to Standard No. 105. GM also requested that tests be initiated with a full charge of the battery pack so that the amount of regenerative braking that would occur during the tests would be minimized, representing the "worst case" condition. NHTSA replied that the braking requirements must be met regardless of the state of charge since EVs will be driven with various states of charge. This position is consistent with GM's suggestion that compliance testing be conducted under "worst case" conditions.

GM also recommended that Standard No. 105 be amended to include electric brake systems. The performance requirements that GM viewed as appropriate for such systems were:

1. Maximum speed attainable to be determined with batteries at 90% of full charge.

2. Initiation of performance tests with battery pack charged between 95–100%.

3. External charging during test sequence permissible only if required to complete the test sequence.

4. On-board charging permissible, except where charging is disabled in the course of conducting partial failure tests.

After reviewing these comments, NHTSA has concluded that the more appropriate place for a standard for electric brake systems is proposed Standard No. 135 Passenger Car Brake Systems. This standard, proposed on July 3, 1991 (56 FR 30528), is more performance oriented and less design specific than Standard No. 105. By a separate notice, a supplemental notice of proposed rulemaking, NHTSA is amending the proposal in a manner responsive to the subject of braking systems for EVs.

Crashworthiness Standards

5. FMVSS No. 204, Steering Control Rearward Displacement

Standard No. 204 specifies the maximum rearward displacement of the steering control system during a 30 mph rigid barrier collision. It is anticipated that EVs converted from internal combustion engine (ICE) vehicles may have problems complying with Standard No. 204 and some, if not all, of the other crashworthiness standards that contain the rigid barrier crash test procedure. The converted EVs are usually at least 10 percent heavier than the ICE vehicle from which they were derived. This is potentially significant because the weight increase may result in more overall deformation of the EV during the crash test. Increased overall frontal deformation would increase the likelihood that the requirements of Standard No. 204 would not be met. For EVs having difficulty meeting the requirements of this standard, NHTSA notes that the Vehicle Safety Act provides that a manufacturer may apply for a 2-year temporary exemption for up to 2,500 vehicles per year on the basis that an exemption would facilitate the development and field evaluation of low-emission motor vehicles.

The question for which the agency sought comment was: should NHTSA consider seeking an amendment of the Vehicle Safety Act that would increase the number of vehicles that the exemption covers per year and would lengthen, from 2 years to 3 years, the maximum term allowed for exemptions granted to low-emission motor vehicles? These amendments might facilitate the production of low-emission vehicles.

The consensus among the commenters was that EVs should comply with Standard No. 204, and that the number of vehicles and the maximum term of low-emission vehicle exemptions should not be increased. In their opinion, legislative changes of this nature would contribute to a perception that EVs have a lower level of safety, and result in a delay in the introduction of roadworthy vehicles. Eight commenters, however, were in favor of increasing the exemption number or the term. After review of all relevant comments, the agency concurs with the reasoning of the consensus and will not seek to change either Standard No. 204, or the statutory provision relating to low-emission motor vehicle exemptions.

6. FMVSS No. 208, Occupant Crash Protection

Standard No. 208 places limits on the head, thorax, and leg impact responses of test dummies placed in front outboard seats during a 30 mph rigid barrier crash test. Many EVs that are designed and built as EVs (and not converted from ICE to electric propulsion) are small and light. There is concern that many such vehicles may have problems meeting the requirements of Standard No. 208 due to limited crash energy management capability. As previously stated, EVs converted from ICE vehicles may have problems complying with the standards that contain barrier crash test procedures because of the weight increase that often occurs as a result of the conversion. Previous studies of the suitability of the FMVSS for EVs have concluded that compliance with the barrier crash test standards may present problems, but it is practicable and necessary for safety. There are few crash test data available on late model EVs with which to assess objectively the ability of those existing vehicles to meet the requirements of the barrier crash test standards. For EVs needing significant modifications to meet the requirements of Standard No. 208, use of the temporary exemption procedure as an interim measure might be appropriate.

The questions for which the agency sought comment were:

(a) See the question under paragraph 5 above.

(b) If the number of exempted vehicles per year were increased for EVs, what would be the overall effect on the safety for occupants of these vehicles?

Once more, the consensus of the commenters was that Standard No. 208 should apply to EVs in the same manner as it does to other vehicles, and that amendment of the temporary exemption provisions would result in a public perception of lesser safety, inhibiting the introduction and acceptance of EVs. For these reasons, NHTSA has decided not to amend Standard No. 208 as it applies to EVs, or to seek legislative changes.

Were the number of exempted vehicles increased from the 2,500 yearly now permitted, it would have a negative effect on occupant safety. While forthcoming first-generation EVs most probably will be used in relatively short trips, most traffic accidents occur within a short distance of a vehicle's home.

Post-Crash Standards

7. FMVSS No. 301, Fuel System Integrity

Standard No. 301 specifies requirements for the integrity of motor vehicle fuel systems by limiting the maximum fuel spillage and fuel spillage rates for vehicles after rollover, frontal barrier, and rear moving barrier tests. Since many EVs may contain combustion heaters with a tank and lines, the agency concluded in its previous studies of the suitability of the FMVSS for EVs that EVs should meet the requirements of Standard No. 301. The fire and explosion hazard that results from spilled fuel may be greater for EVs because of the large number of ignition sources compared to ICE vehicles. As to battery liquids, although most electrolytes are not nearly as likely to ignite, they may be highly corrosive and toxic.

The questions for which the agency sought comment were:

(a) Should EVs comply with Standard No. 301 as it is presently written, or should it be modified for EVs? If Standard No. 301 should be amended for EVs, what should those modifications be?

Commenters universally agreed that if an EV contains combustible fuels, the vehicle should comply with Standard No. 301. Therefore, no amendment is proposed.

(b) Should requirements similar to the fuel spillage and fuel spillage rate requirements of Standard No. 301 be adopted to regulate the spillage of liquid electrolyte?

Commenters saw no present need for a requirement of this nature. Should motor vehicle safety demand rulemaking in the future, the commenters observed that the spillage rates for combustible fuels should not be adopted for liquid electrolytes, because of the variance among electrolytes, some of which are relatively benign. Some of the technologies under research for EV application are exotic and do not pose the same problems as those which may be associated with conventional lead-acid batteries.

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Proposed Effective Date

The amendments proposed by this notice would be effective 180 days after publication of the final rule in the Federal Register.

Rulemaking Analyses

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures. NHTSA has considered the impacts of this rulemaking action and has determined that it is neither major within the meaning of Executive Order 12291 "Federal Regulation", nor significant under Department of Transportation regulatory policies and procedures. The rulemaking would not have an effect upon the economy in excess of $100 million a year. It does not involve a matter of substantial public interest or controversy. Nor would it have a substantial effect on state or local government. The rulemaking action does not initiate a substantial regulatory program or constitute a change in policy. The purpose of the proposal is to clarify several existing requirements applicable to all motor vehicles so that they may, in recognition of the different characteristics of EVs, be more appropriate for EVs. Therefore, preparation of a full regulatory evaluation is not required.

Executive Order 12612 (Federalism). This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 "Federalism" and it has been determined that the notice does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

National Environmental Policy Act. The agency has determined that the notice would not have a significant effect upon the environment for the purposes of the National Environmental Policy Act. There is no environmental impact associated with the rulemaking action since it clarifies the applicability of existing FMVSS to EVs. To the extent that the rulemaking action would facilitate the production of EVs, it may result in a net positive benefit to the environment.

Regulatory Flexibility Act. The agency has also considered the effects of this rulemaking action in relation to the Regulatory Flexibility Act. I certify that this rulemaking action would not have a significant economic effect upon a substantial number of small entities.

Although some EV manufacturers may be small businesses within the meaning of the Regulatory Flexibility Act, these manufacturers are already required to comply with the FMVSS that the rulemaking action is intended to clarify. Further, small organizations and governmental jurisdictions would not be significantly affected as the price of new EVs should not be impacted. The notice clarifies some existing requirements that EVs must meet. Accordingly, no Regulatory Flexibility Analysis has been prepared.

This proposed rule would not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard. Section 105 of the Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Comments

NHTSA solicits public comments on this notice. It is requested but not required that 10 copies be submitted.

All comments must not exceed 15 pages in length, 49 CFR 553.21. Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a letter setting forth the information specified in the agency's confidential business information regulation, 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above will be considered, and will be available for examination in the docket at the above address both before and after the date. To the extent possible, comments filed after the closing date will also be considered. Comments on the notice will be available for inspection in the docket. NHTSA will continue to file relevant information as it becomes available in the docket after the closing date and it is recommended that interested persons continue to examine the docket material.

Those persons desiring to be notified upon receipt of their comments in the docket should enclose a self addressed stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

A regulatory information number (RIN) is assigned to each regulatory action listed in the United Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—FEDERAL MOTOR VEHICLE SAFETY STANDARDS

In consideration of the foregoing, it is proposed that 49 CFR part 571 be amended as follows:

1. The authority citation for part 571 would continue to read:

Authority: 15 U.S.C. 1392, 1401, 1407; delegation of authority at 49 CFR 1.50.

§ 571.101 [Amended]

Section 571.101 is amended:

2. In paragraph S5.1, "(j) Electric vehicle state-of-charge" would be added under "DISPLAYS".

3. Table 2 would be amended by adding the following: under Column 1, "Electric vehicle state-of-charge"; under Column 2, a dash to indicate no requirement; under Column 3, "Recharge"; under Column 4, the ISO battery symbol (the same symbol as presently used for "Electrical charge"); and under Column 5, a dash to indicate no requirement.

§ 571.103 [Amended]

Section 571.103 is amended:

4. Paragraphs S4.3 (a) and (b) would be revised to read:

(a) During the first 5 minutes of the test:

(1) For a passenger car equipped with a heating system other than a heat exchanger type that uses the engine's coolant as a means to supply the heat to the heat exchanger, the warm-up procedure is that specified by the vehicle's manufacturer for cold weather starting, except that connection to a power or heat source external to the vehicle is not permitted.

(2) For all other passenger cars, the warmup procedure may be that recommended by the vehicle's manufacturer for cold weather starting.

(b) During the last 35 minutes of the test period (or the entire test period if the 5–minute warmup procedure specified in paragraph (a) of this section is not used),

(1) For a passenger car equipped with a heating system other than a heat exchanger type that uses the engine's coolant as a means to supply the heat to the heat exchanger, the procedure shall be that specified by the vehicle's manufacturer for cold weather starting, except that connection to a power or heat source external to the vehicle is not permitted.

(2) For all other passenger cars, either—

(i) the engine speed shall not exceed 1,500 r.p.m. in neutral gear; or

(ii) the engine speed and load shall not exceed the speed and load at 15 m.p.h. in the manufacturer's recommended gear with road load.

* * * * *

Issued on: January 6, 1993.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 93–632 Filed 1–14–93; 8:45 am]

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49 CFR Part 571

[Docket No. 85–6; Notice 7]

RIN 2127–AA 13

Federal Motor Vehicle Safety Standards; Passenger Car Brake Systems; Electric Vehicles

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Supplemental Notice of Proposed Rulemaking (SNPRM).

SUMMARY: This notice supplements a pending notice of proposed rulemaking published in July 1991 (Notice 5) that would establish a new Standard No. 135, Passenger Car Brake Systems, to replace Standard No. 105, Hydraulic Brake Systems, as it applies to passenger cars. This SNPRM responds to an advance notice of proposed rulemaking published in December 1991 that asked for, among other things, comments on the appropriateness of Standard No. 105 to braking systems of electric vehicles. In accordance with those comments, NHTSA has tentatively concluded that any proposed changes should be made to Standard No. 135 as well as existing Standard No. 105. Hence, this notice proposes to revise Standard No. 105 and proposed Standard No. 135 to incorporate definitions, and vehicle and test conditions deemed appropriate for electric vehicles.

DATES: Comment closing date: Comments must be received not later than March 1, 1993.

Proposed effective date: The proposed addition of Standard No. 135 to the Code of Federal Regulations would become effective 30 days after publication of the final rule in the **Federal Register**. As of that date, manufacturers would have the option of complying with either Standard No. 135 or Standard No. 105. Compliance with Standard No. 135 would become mandatory on September 1st following the end of the 5-year period which would begin with the publication of the final rule in the **Federal Register**. A final rule for electric vehicles based upon this notice may be incorporated into Standards No. 105 and 135 at the time a final rule establishing Standard No. 135 is published, or may appear subsequently as amendments to Standards No. 105 and 135.

ADDRESSES: Comments should refer to Docket 85–6; Notice 7, and be submitted to: Docket Section, National Highway Traffic Safety Administration, 400 Seventh Street, SW., Washington, DC 20590. Docket hours are 9:30 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Larry Cook, Office of Vehicle Safety Standards, NHTSA (202–366–4803).

SUPPLEMENTARY INFORMATION: On December 27, 1991, NHTSA published an Advance Notice of Proposed Rulemaking (ANPRM) requesting comments to determine what existing Federal motor vehicle safety standards may need modification to meet the needs associated with the introduction of significant numbers of electric vehicles (EVs) (56 FR 67038). One of the standards for which the agency sought comments was Standard No. 105, Hydraulic Brake Systems. When the comments were evaluated, NHTSA decided that its proposed new passenger car braking standard, Standard No. 135, Passenger Car Brake Systems should incorporate the new EV requirements as well as Standard No. 105 which, according to the agency's plan, is eventually slated to be phased out.

Another notice related to the ANPRM is being published in this issue of the **Federal Register**, a notice of proposed rulemaking proposing to make minor amendments to the Federal Motor Vehicle Safety Standards No. 101, Controls and Displays, and No. 103, Windshield Defrosting and Defogging Systems.

The brake-related questions for which NHTSA sought comment in the ANPRM were whether the test procedures of Standard No. 105 need to be modified for EV's equipped with regenerative braking and/or direct drive transmissions, and, if so, the type of modifications required. For EVs with direct drive systems and/or regenerative braking, the test procedure may be difficult to follow. Technically speaking, "regenerative braking" does not describe an application of an EV's foundation brake system, but the decelerative effect that results from the conversion of kinetic energy into stored electrical energy. Regenerative braking is not designed to be the sole means of stopping a vehicle, but it does provide a portion of the stopping capability. The regeneration system's design purpose is to extend the range of the EV by making use of the available kinetic energy of the EV's velocity. The amount of deceleration is a function of the state-of-charge of the EV's propulsion batteries. However, regenerative braking may cause other features of the service brake system to operate improperly. Therefore, the agency is proposing that test procedures be modified to account for these effects.

Most commenters believed that the test condition of Standard No. 105 in which the transmission is in neutral should be modified. EVs with direct drive transmissions do not have a neutral position, only forward and reverse positions which reverse the direction of the electric motor. When such an EV does not have an electrical force field applied to its motor, the effect is similar to that which occurs when the gear selector of a conventional transmission is in the neutral position. Therefore, NHTSA has tentatively concluded that an EV whose transmission has no neutral position should be tested when there is no electromotive force applied to the motor by the vehicle operator (assuming that there is no clutch to disconnect the motor from the drive train).

On February 17, 1992, Stephen Selander of GM's legal staff requested interpretations of Standard No. 105 and its applicability to a vehicle braking system that consisted of front hydraulic disc (service) brakes, and rear electric (service and parking) brakes, four-wheel anti-lock braking system, and regenerative braking. NHTSA replied to Mr. Selander on April 29, 1992, that the hydraulic portion of the service brake system was covered under Standard No. 105, and should be tested in accordance with the features specified therein, and that regenerative braking should be allowed to operate normally (for tests

conducted in gear) just as engine braking occurs normally during compliance testing to Standard No. 105. GM also requested that tests be initiated with a full charge of the battery pack so that the amount of regenerative braking that would occur during the tests would be minimized, representing the "worst case" condition. NHTSA replied that the braking requirements must be met regardless of the state of charge since EVs will be driven with various states of charge. This position is consistent with GM's suggestion that compliance testing be conducted under "worst case" conditions.

GM also recommended that Standard No. 105 be amended to include electric brake systems. The performance requirements that GM viewed as appropriate for such systems were:

1. Maximum speed attainable to be determined with batteries at 90% of full charge.

2. Initiation of performance tests with battery pack charged between 95–100%.

3. External charging during test sequence permissible only if necessary to complete the test sequence.

4. On-board charging permissible, except where charging is disabled in the course of conducting partial failure tests.

In reviewing these comments, NHTSA came to the conclusion that any new EV braking requirements should be incorporated into the forthcoming Standard No. 135, as well as Standard No. 105, which is scheduled to be terminated for passenger cars at the end of the 5-year period during which optional compliance with Standard No. 135 is permitted.

Accordingly, this notice proposes modifications to Standard No. 105 as well as several of the provisions of Standard No. 135 as proposed on July 3, 1991 (Notice 5), that are responsive to GM's suggestions and NHTSA's concerns. A proposed definition of "Maximum Speed" should make clear that the maximum speed of an EV would be determined when the propulsion batteries are at not less than 90% charge, and in accordance with SAE Recommended Practice J227a, Electric Vehicle Test Procedure, February 1976 (and not updated since by the SAE).

A definition of "Electric Vehicle (EV)" would be added. The definition would include an internal combustion/electric hybrid as follows: "An Electric Vehicle (EV) means a vehicle which is powered by an electric motor drawing current from rechargeable storage batteries, fuel cells, or other portable sources of electrical current, and which may include a nonelectrical source of power designed to charge batteries and components thereof."

For EVs without any way of disconnecting (declutching) the power train from the drive wheels, wording would be added to the vehicle conditions section, to clarify that no electromotive force would be applied to the propulsion motors, either in a driving or retarding (regenerative) mode.

A definition of "Regenerative Braking System (RBS)" would also be added.

In the sections relating to brake system warning indicator activation, new sub-paragraphs would be added to cover vehicles with electric brake actuation, electric transmission of the brake control signal, and EVs with regenerative braking systems.

NHTSA is also concerned about EVs with electric brake systems that have as their main power source the vehicle's propulsion batteries. Therefore, NHTSA is proposing that EVs with electric brake systems also perform the specified tests (except for the burnish procedure) when the propulsion batteries are at 1 percent or less or full charge. However, NHTSA is seeking comments as the whether 1 percent is reasonable, and, if not, views on an appropriate percentage. It may be that a specific higher value will be needed if the EV is designed to automatically shut down the drive motor(s) when the propulsion batteries are depleted below a certain percentage of full charge. In this case the appropriate wording might be "when the propulsion batteries are at 1 percent or less above the actual automatic shut down value for the propulsion motor(s)."

At the beginning of the road test sequence when the brakes are burnished, the propulsion batteries must be at not less than 95% of full charge. During the burnish procedure, charging of the propulsion batteries by an external means would be permitted if necessary to complete the burnish procedure. At the beginning of the next test in the test sequence after burnish, it is proposed that the propulsion batteries be at not less than 95% of full charge and may be charged by an external means at this time. NHTSA believes that EVs will have no problem completing the road test sequence without further charging. Therefore, no further charging of the propulsion batteries would be allowed unless otherwise specified. Regenerative braking would function in its normal operating mode at all times during the tests (except the proposed new test for failed regenerative braking system), provided that it is not subject to the control of the vehicle operator. If the feature is controllable by the operator, it would be set to the minimum level of braking effect, switched off, or variable depending on the test procedure.

For the wheel lockup sequence test (S7.2) and the adhesion utilization test (torque wheel method) (S7.4) of proposed Standard No. 135, EVs that have no neutral position or means to declutch from the propulsion motor, and a driver controllable regenerative braking system (RBS), would have to pass these tests with the RBS at any point within its normal operating mode or range. RBS systems that act only on one axle may have a significant effect on the brake proportioning of the vehicle.

At this point, NHTSA is not sure that the torque wheel method (S7.4) could be applied to EVs with regenerative braking or to EVs with-electric brakes. Torque wheel calculations are based on hydraulic brake line pressures and for electric-actuated brakes there is no brake line pressure. NHTSA requests comments on the application of the torque wheel test to EVs with electric brakes and to EVs with regenerative braking systems. The effects of RBS on vehicle braking may be different from the effects of power-train/engine braking of an internal combustion engine which could have an effect on the adhesion utilization curve equation. All proposed designs for EVs known to NHTSA incorporate ABS. In this event, EVs would not be subject to torque wheel testing, so these problems may be moot. NHTSA requests comments from manufacturers of EVs whether or not the vehicle they plan will be equipped with ABS.

In paragraph S7.3 relating to ABS performance, subparagraph S7.3.2(b) specifies that the transmission position is neutral; this is being modified to cover EVs without a "transmission/power train" neutral position. In the paragraph on test procedures and performance requirements, S7.3.4, subparagraph S7.3.4.4 would be added to cover driver controlled regenerative braking systems for EVs without a "transmission/drive train" neutral position.

The "Stops with Engine Off" test (S7.7) of proposed Standard No. 135 would be modified to specify that for EV's the test is done with no power to the vehicle drive motor(s), but with brake power or brake power assist still operating, unless cutting off the drive motor(s) also disables those systems.

In the sections relating to hydraulic circuit failure, new provisions would be added to cover failed electronic transmission of brake signal between the brake pedal and the foundation brakes, regardless of whether the foundation brakes are actuated by hydraulic circuits

or by electric motors. These provisions would be equivalent to the current requirements in Standard 105 and proposed in Standard 135 for failed hydraulic brakes.

In the sections covering "Power brake unit or brake power assist unit inoperative (System depleted)", new provisions would be added to cover failure of electrically-actuated brakes (brake power unit) and failure of the regenerative braking system. Failure of electric brake power assist is already covered by Standard 105 and proposed Standard 135.

In the static parking brake test, new provisions would be added covering the method of activating the parking brakes when electric brakes are used that incorporate an ON/OFF switch/pushbutton to apply the parking brake function.

It is proposed that the dynamic parking brake test of Standard 135 would not apply to parking brake systems using electric brakes which are activated by an ON/OFF switch/pushbutton to apply the parking brake function, because there is no way to modulate these brakes. NHTSA requests comments on whether there is a safety need to have such a dynamic performance requirement for such systems.

Effective Date

Comments received in response to this notice will be considered in the development of the final version of Standard No. 135, and reflected in it when it is published, or if this is not practicable, will be issued as amendments to Standard No. 135. As NHTSA noted when it proposed Standard No. 135 on July 3, 1991, the proposed addition of Standard No. 135 to the Code of Federal Regulations would become effective 30 days after its publication in the **Federal Register**. As of that date, manufacturers would have the option of complying with either Standard No. 105 or Standard No. 135. Compliance with the new standard would become mandatory for passenger cars on September 1st following the end of the 5-year period which would begin with the publication of Standard No. 135 in the **Federal Register**. Thus, if Standard No. 135 were published on July 1, 1993, and Standard No. 105 would cease to apply to passenger cars on September 1, 1998 (Standard No. 105 will continue in effect for vehicles other than passenger cars).

Rulemaking Analyses

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures. NHTSA has considered the impacts of this rulemaking action and has determined that it is neither major within the meaning of Executive Order 12291 "Federal Regulation", nor significant under Department of Transportation regulatory policies and procedures. It does not involve a matter of substantial public interest or controversy. The rulemaking does not have a major impact upon another Federal agency, or a substantial effect upon State and local government. It does not initiate a substantial regulatory program or involve a change in policy. The rulemaking would not have an effect upon the economy in excess of $100 million a year, or have a substantial impact upon the balance of trade.

Regulatory Flexibility Act. The agency has also considered the effects of this rulemaking action in relation to the Regulatory Flexibility Act. I certify that this rulemaking action would not have a significant economic effect upon a substantial number of small entities. Motor vehicle manufactures are generally not small businesses within the meaning of the Regulatory Flexibility Act. Further, small organizations and governmental jurisdictions would not be significantly affected as the price of new motor vehicles should not be impacted (electric vehicles are already required to comply with braking requirements and the intended effect of a final rule is simply to make those requirements more appropriate for EVs). According, no Regulatory Flexibility Analysis has been prepared.

Executive Order 12612 (Federalism). This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612 on "Federalism." It has been determined that the rulemaking action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

National Environmental Policy Act. NHTSA has analyzed this rulemaking action for purposes of the National Environmental Policy Act. The rulemaking action would not have a significant effect upon the environment. There is no environmental impact associated with adaption of test procedures to make them more appropriate for vehicles already required to comply with the Federal motor vehicle safety standards. The rulemaking action would not have a direct effect. However, to the extent that this rulemaking might facilitate the introduction of EVs which are powered by an electric motor drawing current from rechargeable storage batteries, fuel cells, or other portable sources of electric current, and which may include a nonelectrical source of power designed to charge batteries and components thereof, the rulemaking would have a beneficial effect upon the environment and reduce fuel consumption because EVs emit no hydrocarbon emissions and do not depend directly upon fossil fuels to propel them.

This proposed rule would not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard. Section 105 of the Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Comments

Interested persons are invited to submit comments on the proposal. It is requested but not required that 10 copies be submitted.

All comments must not exceed 15 pages in length. (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Comments received too late for consideration in

regard to the final rule will be considered as suggestions for further rulemaking action. Comments on the proposal will be available for inspection in the docket. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with their comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—[AMENDED]

1. The authority citation for part 571 would continue to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

2. The title of Standard No. 105 would be revised to read as follows:

§ 571.105 Standard No. 105; Hydraulic and/or electric brake systems.

3. S1 of Standard No. 105 would be revised to read as follows:

S1. *Scope.* This standard specifies requirements for hydraulic and/or electric service brake and associated parking brake systems.

* * * * *

4. S3 of Standard No. 105 would be revised to read as follows:

* * * * *

S3. *Application.* This standard applies to passenger cars, multipurpose passenger vehicles, trucks, and buses with hydraulic and/or electric service brake systems.

* * * * *

5. S4 of Standard No. 105 would be amended by adding the following new definitions in alphabetical order:

* * * * *

S4. *Definitions.*

* * * * *

Electric Vehicle (EV) means a motor vehicle which is powered by an electric motor drawing current from rechargeable storage batteries, fuel cells, or other portable sources of electrical current, and which may include a non-electrical source of power designed to charge batteries and components thereof.

* * * * *

Maximum speed of an electric vehicle means the highest speed attainable by an electric vehicle as determined in accordance with SAE Recommended Practice J227a, Electric Vehicle Test Procedure, February 1976, with the propulsion batteries at not less than 90 percent charge at the beginning of the run.

* * * * *

Regenerative braking system (RBS) means an electrical energy system for recovering kinetic energy that is installed in an electric vehicle, and which uses the propulsion motor(s) as a retarder for partial braking of the vehicle in addition to the service brake system, while returning electrical energy to the propulsion batteries.

* * * * *

6. A new S5.1.2.3 would be added to Standard No. 105, to read as follows:

* * * * *

S5.1.2.3 In vehicles manufactured with a service brake system where the brake signal is transmitted electronically between the brake pedal and some or all of the foundation brakes, the vehicle shall also comply with the requirements of S5.1.2.1 of this standard with any single failure in the circuit that electronically transmits the brake signal.

* * * * *

7. A new S5.1.3.5 would be added to Standard No. 105, to read as follows:

* * * * *

S5.1.3.5 *Electric brakes.* Vehicles with electrically-activated brake systems (brake power unit) shall comply with the requirements of S5.1.3.1, S5.1.3.3, or S5.1.3.4 with any single electrical failure in the electrically-activated brake system and all other systems intact.

* * * * *

8. The introductory text of S5.3.1 would be revised and new S5.3.1 (e), (f), and (g) would be added to Standard No. 105, to read as follows:

* * * * *

S5.3.1 An indicator lamp shall be activated when the ignition (start) switch is in the "on" ("run") position and whenever any of the conditions (a), (c), (d), (e), (f), or (g) occur, or, at the option of the manufacturer, whenever any of the conditions (b), (c), (d), (e), (f), or (g) occur:

* * * * *

(e) For a vehicle with electric brake actuation, failure of the source of electric power to the brakes.

(f) For a vehicle with electric transmission of the brake control signal, failure of a brake control circuit.

(g) For an EV with a regenerative braking system, failure of the regenerative braking system.

* * * * *

9. The introductory text of S5.3.5(c)(1) would be revised to read as follows:

* * * * *

S5.3.5 * * *

(c)(1) If separate indicator lamps are used for one or more than one of the functions described in S5.3.1(a) through S5.3.1(g) of this standard, the display shall include the word "Brake" and appropriate additional labeling, except as provided in (c)(1) (A) through (D) of this section.

* * * * *

10. The introductory text of S5.4.3 would be revised to read as follows:

* * * * *

S5.4.3 *Reservoir labeling*—Each vehicle equipped with hydraulic brakes shall have a brake fluid warning statement that reads as follows, in letters at least one-eighth of an inch high: "WARNING, Clean filler cap before removing, Use only ____fluid from a sealed container." (Inserting the recommended type of brake fluid as specified in 49 CFR 571.116, e.g., "DOT 3"). The lettering shall be—

* * * * *

11. S6.2 through S6.2.6 would be added to Standard No. 105, to read as follows:

* * * * *

S6.2 *Electric vehicles.*

S6.2.1 State-of-charge of the propulsion batteries is determined in accordance with SAE Recommended Practice J227a, Electric Vehicle Test Procedure, February 1976.

S6.2.2 At the beginning of the first effectiveness test (S7.3 of this standard), the propulsion batteries are at not less than 95 percent of full charge. During each burnish procedure, the propulsion batteries may be charged by an external means if the vehicle is otherwise unable to complete the burnish procedure.

S6.2.3 After each burnish procedure and before beginning the next test in the test sequence (either S7.5, S7.7, or S7.13 of this standard), the propulsion batteries are at not less than 95 percent of full charge. At these points, the propulsion batteries may be charged by an external means. No further charging of the propulsion batteries occurs during the tests specified in S7.3, S7.5, S7.7 through S7.11, and S7.13 through S7.19 of this standard.

S6.2.4 For tests specifying "in gear," an RBS that is not subject to control by the vehicle operator functions in its normal operating mode throughout the tests, unless otherwise provided in S7. If the RBS is subject to control by the vehicle operator, it is set to produce the minimum regenerative braking effect during the test procedures.

S6.2.5 For tests specifying "in neutral," the driver of an EV with no "neutral" position (or other means such as a clutch for disconnecting the drive train from the propulsion motor(s)) does not apply any electromotive force to the propulsion motor(s). Any electromotive force that is applied to the propulsion motor(s) automatically remains in effect unless otherwise specified by the test procedure. If the RBS is subject to control by the vehicle operator, it is switched off or set to produce the minimum regenerative braking effect during the test procedures.

S6.2.6 EVs equipped with electric brakes must also perform the tests specified in S7.3, S7.5, S7.7 through S7.11, and S7.13 through S7.19 of this standard with the propulsion batteries at one percent or less of full charge. An auxiliary means may be used to accelerate the test vehicle to test speed during these tests.

* * * * *

12. S7.7.1.3 would be amended by revising the introductory test and adding a new S7.1.3(c), to read as follows:

* * * * *

S7.7.1.3 With the vehicle held stationary by means of the service brake control, apply the parking brake by a single application of the force specified in (a), (b), or (c) of this section, except that a series of applications to achieve the specified force may be made in the case of a parking brake system design that does not allow the application of the specified force in a single application:

* * * * *

(c) For vehicles using electrically activated foundation brakes initiated by an ON/OFF switch or push button to apply the parking brake function, apply the parking brake by moving the parking brake switch to the ON position.

* * * * *

13. A new S7.9.5 would be added to read as follows:

* * * * *

S7.9.5 For vehicles where the brake signal is electronically transmitted between the brake pedal and the foundation brakes, regardless of the means of activation of the foundation brakes, the tests in S7.9.1 through S7.9.3 of this standard are conducted by inducing any single failure in this electronically transmitted brake signal circuit.

* * * * *

14. S7.10 would be amended by adding new S7.10.3 and S7.10.4, to read as follows:

S7.10 * * *

S7.10.3 *Electric brakes.* For vehicles with electrically-actuated brake systems (brake power unit), the tests specified in S7.10.1 or S7.10.2 of this section are conducted with any single electrical failure in the electrically-actuated brake system and all other systems intact.

S7.10.4 *Regenerative braking systems.* For EVs with RBS, the tests specified in S7.10.1 or S7.10.2 of this section are conducted with the RBS disconnected or switched off and all other systems intact.

* * * * *

§ 571.135 Standard No. 135; Passenger Car Brake Systems

Section 571.135, as proposed at 56 FR 30528, July 3, 1991, is proposed to be amended as follows:

15. In proposed S4, the following definitions would be added in alphabetical order:

* * * * *

Electric Vehicle (EV) means a motor vehicle which is powered by an electric motor drawing current from rechargeable storage batteries, fuel cells, or other portable sources of electrical current, and which may include a non-electrical source of power designed to charge batteries and components thereof.

* * * * *

Maximum speed of an electric vehicle means the highest speed attainable by an electric vehicle as determined in accordance with SAE Recommended Practice J227a, Electric Vehicle Test Procedure, February 1976, with the propulsion batteries at not less than 90 percent charge at the beginning of the run.

* * * * *

Regenerative Braking System (RBS) means an electrical energy system for recovering kinetic energy that is installed in an electric vehicle, and which uses the propulsion motor(s) as a retarder for partial braking of the vehicle in addition to the service brake system, while returning electrical energy to the propulsion batteries.

* * * * *

16. The introductory text of proposed S5.4.3 would be revised to read as follows:

* * * * *

S5.4.3. *Reservoir labeling.* Each vehicle equipped with hydraulic brakes shall have a brake fluid warning statement that reads as follows, in letters at least 3.2-mm (⅛-inch) high: "WARNING. Clean filler cap before removing. Use only ____fluid from a sealed container." (Insert the recommended type of brake fluid as specified in 49 CFR 571.116, e.g., "DOT 3"). The lettering shall be—

* * * * *

17. Proposed S5.5.1 would be amended by revising the introductory text and adding new S5.5.1 (e), (f), and (g), to read as follows:

* * * * *

S5.5.1. *Activation.* An indicator shall be activated when the ignition (start) switch is in the "on" ("run") position and whenever any of conditions (a) through (g) occur:

* * * * *

(e) For a vehicle with electric brake actuation, failure of the source of electric power to the brakes.

(f) For a vehicle with electric transmission of the brake control signal, failure of a brake control circuit.

(g) For an EV with a regenerative braking system, failure of the RBS.

* * * * *

18. The introductory text of proposed S5.5.5(d) would be revised to read as follows:

* * * * *

S5.5.5. *Labeling.*

* * * * *

(d) If separate indicators are used for one or more than one of the functions described in S5.5.1(a) through S5.5.1(g) of this standard, the indicators shall display the following wording:

* * * * *

19. New S6.3.11 through S6.3.11.6 would be added, to read as follows:

* * * * *

S6.3.11 *Electric vehicles.*

S6.3.11.1 State-of-charge of the propulsion batteries is determined in accordance with SAE Recommended Practice J227a, Electric Vehicle Test Procedure, February 1976.

S6.3.11.2 At the beginning of the burnish procedure (S7.1 of this standard) in the test sequence, the propulsion batteries are at not less than 95 percent of full charge. During the burnish procedure, the propulsion batteries may be charged by an external means if the vehicle is otherwise unable to complete the burnish procedure.

S6.3.11.3 After the burnish procedure and before beginning of the next test in the test sequence (either S7.2 or S7.3 of this standard, depending on whether the vehicle has ABS), the propulsion batteries are at not less than 95 percent of full charge. At this point, the propulsion batteries may be charged by an external means. No further charging of the propulsion batteries occurs during the tests specified in S7.2 through S7.17.

S6.3.11.4 For tests specifying "in gear", an RBS that is not subject to

control by the vehicle operator functions in its normal operating mode throughout the tests, unless otherwise stated in S7. If the RBS is subject to control by the vehicle operator, it is set to produce the minimum regenerative braking effect during the test procedures.

S6.3.11.5 For tests specifying "in neutral", the driver of an EV with no "neutral" position (or other means such as a clutch for disconnecting the drivetrain from the propulsion motor(s)) does not apply any electromotive force to the propulsion motor(s). Any electromotive force that is applied to the propulsion motor(s) automatically remains in effect unless otherwise specified by the test procedure. If the RBS is subject to control by the vehicle operator, it is switched off or set to produce the minimum regenerative braking effect during the test procedures.

S6.3.11.6 EVs equipped with electric brakes must also perform the tests specified in S7.2 through S7.17 with the propulsion batteries at one percent or less of full charge. An auxiliary means may be used to accelerate the test vehicle to test speed during these tests.

* * * * *

20. A new S7.2.4(f) would be added to read as follows:

S7.2.4 *Performance requirements.*

* * * * *

(f) EVs with RBS subject to driver control, and which have no neutral position or means to declutch from the propulsion motor(s), shall meet the performance requirements over the entire normal operating range of the RBS.

* * * * *

21. A new S7.3.4.4 would be added to read as follows:

* * * * *

S7.3.4 *Test procedures and performance requirements.* * * *

S7.3.4.4 EVs with RBS subject to driver control, and which have no neutral position or means to declutch from the propulsion motor(s), shall meet the performance requirements over the entire normal operating range of the RBS.

* * * * *

22. A new S7.4.5.3 would be added to read as follows:

* * * * *

S7.4.5 *Performance requirements.*

* * *

S7.4.5.3 EVs with RBS subject to driver control, and which have no neutral position or means to declutch from the propulsion motor(s), shall meet the performance requirements over the entire normal operating range of the RBS.

* * * * *

23. A new S7.7.2(e) would be added to read as follows:

* * * * *

S7.7.2 *Vehicle conditions.* * * *

(e) For EVs, this test is conducted with no electromotive force applied to the vehicle propulsion motor(s), but with brake power or power assist still operating, unless cutting off the propulsion motor(s) also disables those systems.

* * * * *

24. A new S7.10.3(l) would be added to read as follows:

* * * * *

S7.10.3 *Test conditions and procedures.* * * *

(l) For vehicles where the brake signal is electronically transmitted between the brake pedal and the foundation brakes, regardless of the means of activation of the foundation brakes, this test is conducted by inducing any single failure in this electronically transmitted brake signal circuit.

* * * * *

25. New S7.11.3(m) and S7.11.3(n) would be added to read as follows:

* * * * *

S7.11.3 *Test conditions and procedures.* * * *

(m) For vehicles with electrically-actuated brake systems (brake power unit), this test is conducted with any single electrical failure in this electrically-actuated brake system and all other systems intact.

(n) For EVs with RBS, this test is conducted with the RBS disconnected or switched off and all other systems intact.

* * * * *

26. Proposed S7.12.2 would be amended by revising S7.12.2(h) and adding a new S7.12.2(o) to read as follows:

* * * * *

S7.12.2 *Test conditions and procedures.* * * *

(h) With the service brake applied sufficiently to just keep the vehicle from rolling, apply the parking brake as specified in S7.12.2(i), S7.12.2(j), or S7.12.2(o) as applicable.

* * * * *

(o) For vehicles using electrically-activated foundation brakes initiated by an ON/OFF switch or pushbutton to apply the parking brake function, apply the parking brake by turning the parking brake switch to the ON position.

* * * * *

27. New S7.13.1(d) would be added to read as follows:

* * * * *

S7.13.1 *Vehicle conditions.* * * *

(d) This test does not apply to vehicles equipped with parking brake systems using electrically-activated foundation brakes, initiated by an ON/OFF switch or pushbutton to apply the parking brake function.

* * * * *

Issued on: January 6, 1993.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 93-633 Filed 1-14-93; 8:45 am]

BILLING CODE 4910-59-M

Notices

Federal Register
Vol. 58, No. 10
Friday, January 15, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Round Valley Timber Sale, Plumas National Forest, Plumas County, CA; Environmental Impact Statement Cancellation

The Plumas National Forest is no longer involved in the preparation of an Environmental Impact Statement for the Round Valley Timber Sale.

The Notice of Intent, published in the **Federal Register** on September 21, 1990 is hereby rescinded (55 FR 38826).

For further information contact: R.C. Bennett, Environmental Coordinator, Plumas National Forest, Box 11500, Quincy, CA 95971; telephone 916–283–2050.

Dated: December 17, 1992.

H. Wayne Thornton,

Forest Supervisor.

[FR Doc. 93–917 Filed 1–14–93; 8:45 am]

BILLING CODE 3410–11–M

Feather Falls Timber Sale, Plumas National Forest, Butte County, CA; Environmental Impact Statement Cancellation

The Plumas National Forest is no longer involved in the preparation of an Environmental Impact Statement for the Feather Falls Timber Sale.

The Notice of Intent, published in the **Federal Register** on December 19, 1990 is hereby rescinded (55 FR 52603).

For further information contact: R.C. Bennett, Environmental Coordinator, Plumas National Forest, Box 11500, Quincy, CA 95971; telephone 916–283–2050.

Dated: December 17, 1992.

H. Wayne Thornton,

Forest Supervisor.

[FR Doc. 93–914 Filed 1–14–93; 8:45 am]

BILLING CODE 3410–11–M

Frenchman Timber Sale, Plumas National Forest, Plumas County, CA; Environmental Impact Statement Cancellation

The Plumas National Forest is no longer involved in the preparation of an Environmental Impact Statement for the Frenchman Timber Sale.

The Notice of Intent, published in the **Federal Register** on February 23, 1990 is hereby rescinded (55 FR 6411).

For further information contact: R.C. Bennett, Environmental Coordinator, Plumas National Forest, Box 11500, Quincy, CA 95971; telephone 916–283–2050.

Dated: December 17, 1992.

H. Wayne Thornton,

Forest Supervisor.

[FR Doc. 93–919 Filed 1–14–93; 8:45 am]

BILLING CODE 3410–11–M

Howland Flat Timber Sale, Plumas National Forest, Sierra County, CA; Environmental Impact Statement Cancellation

The Plumas National Forest is no longer involved in the preparation of an Environmental Impact Statement for the Howland Flat Timber Sale.

The Notice of Intent, published in the **Federal Register** on August 1, 1990 is hereby rescinded (55 FR 31205).

For further information contact: R.C. Bennett, Environmental Coordinator, Plumas National Forest, Box 11500, Quincy, CA 95971; telephone 916–283–2050.

Dated: December 17, 1992.

H. Wayne Thornton,

Forest Supervisor.

[FR Doc. 93–918 Filed 1–14–93; 8:45 am]

BILLING CODE 3410–11–M

Rock Creek-Cresta Dredging Project, Plumas National Forest, Plumas County, CA; Environmental Impact Statement Cancellation

The Plumas National Forest is no longer involved in the preparation of an Environmental Impact Statement for the dredging and disposal of accumulated sediments from Pacific Gas and Electric's Rock Creek and Cresta reservoirs.

The Notice of Intent, published in the **Federal Register** on April 6, 1990, is hereby rescinded (55 FR 12875).

For further information contact: R.C. Bennett, Environmental Coordinator, Plumas National Forest, Box 11500, Quincy, CA 95971; telephone 916–283–2050.

Dated: September 20, 1992.

H. Wayne Thornton,

Forest Supervisor.

[FR Doc. 93–916 Filed 1–14–93; 8:45 am]

BILLING CODE 3410–11–M

Western National Forest Livestock Grazing Fees

AGENCY: Forest Service, USDA.

ACTION: Notice of 1993 grazing fees.

SUMMARY: The fee for grazing livestock on certain specified National Forest System lands in the 16 Western States will be $1.86 per head month for the 1993 grazing year.

EFFECTIVE DATE: March 1, 1993.

FOR FURTHER INFORMATION CONTACT: Robert M. Williamson, Director of Range Management, U.S. Department of Agriculture Forest Service, P.O. Box 96090, Washington, DC 20090–6090 (202) 205–1746.

SUPPLEMENTARY INFORMATION: Grazing fees for the use and occupancy of the National Forests and Land Utilization Projects in the 16 Western States, and the Butte Valley, Crooked River and Curlew National Grasslands are established and collected annually by the Forest Service under the authority of the Organic Act of June 4, 1897, (16 U.S.C. 473–475, 477–482, 551), the Bankhead-Jones Farm Tenant Act of July 22, 1937, (7 U.S.C. 1010–1012), and Executive Order 12548 of February 14, 1986. The 16 contiguous Western States are Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Washington, and Wyoming.

The formula for establishing the annual grazing fee for these lands is set forth in regulations at 36 CFR 222.51. Fee adjustments are based on three indices—private grazing land lease rates added to the price livestock producers receive for the sale of beef cattle less the cost of livestock production. Based on the application of these combined indices to a 1966 base fair market value of $1.23 per head month, the agency will issue bills to grazing permittees in the affected States for 1993 grazing fees

at a rate of $1.86 per head month, a decrease of six cents from 1992. Fees will be lower because the costs of livestock production and the decrease in the prices received for the sale of beef cattle overshadowed the modest increase in the private grazing land lease rate.

Dated: January 8, 1993.

George M. Leonard,

Associate Chief.

[FR Doc. 93-1093 Filed 1-14-93; 8:45 am]

BILLING CODE 3410-11-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Establishment of an Import Limit for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Lebanon

January 11, 1993.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs establishing a limit.

EFFECTIVE DATE: January 21, 1993.

FOR FURTHER INFORMATION CONTACT: Jennifer Aldrich, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-5850. For information on embargoes and quota re-openings, call (202) 482-3715. For information on categories on which consultations have been requested, call (202) 482-3740.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

Inasmuch as consultations have not yet been held on a mutually satisfactory solution on Categories 338/339/638/639, the United States Government has decided to control imports in these categories for the twelve-month period beginning on October 30, 1992 and extending through October 29, 1993.

The United States remains committed to finding a solution concerning these categories. Should such a solution be reached in consultations with the Government of Lebanon, further notice will be published in the **Federal Register**.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 56 FR 60101, published on November 27, 1991; and 57 FR 54976, published on November 23, 1992). Also see 57 FR 54053, published on November 16, 1992.

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

January 11, 1993.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: Under the terms of section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended, you are directed to prohibit, effective on January 21, 1993, entry into the United States for consumption and withdrawal from warehouse for consumption of cotton and man-made fiber textile products in Categories 338/339/638/639, produced or manufactured in Lebanon and exported during the twelve-month period beginning on October 30, 1992 and extending through October 29, 1993, in excess of 298,817 dozen [1].

Textile products in Categories 338/339/638/639 which have been exported to the United States prior to October 30, 1992 shall not be subject to the limit established in this directive.

Textile products in Categories 338/339/638/639 which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1) prior to the effective date of this directive shall not be denied entry under this directive.

In carrying out the above directions, the Commissioner of Customs should construe entry into the United States for consumption to include entry for consumption into the Commonwealth of Puerto Rico.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

J. Hayden Boyd,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 93-1019 Filed 1-14-93; 8:45 am]

BILLING CODE 3510-DR-F

[1] The limit has not been adjusted to account for any imports exported after October 29, 1992.

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to Procurement List.

SUMMARY: This action adds to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: February 16, 1993.

ADDRESS: Committee for Purchase from People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202-3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603-7740.

SUPPLEMENTARY INFORMATION: On June 12 and August 28, 1992, the Committee for Purchase from People Who Are Blind or Severely Disabled published notices (57 FR 25023 and 39190) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the services, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51.2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action will not have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services proposed for addition to the Procurement List.

Accordingly, the following services are hereby added to the Procurement List:

Janitorial/Custodial, Camp LeJeune Commissary, Jacksonville, North Carolina

Janitorial/Grounds Maintenance for the following locations in Calexico, California:

Truck Inspection Building, 1 East First Street
U.S. Border Inspection Station Building, 200 First Street
Shop Building, 1 East First Street
U.S. Border Patrol Station, 8th and Andrade Street
Commercial Hazmat Office, 1 East First Street
Commercial Operations Office, 1 East First Street

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 93–1074 Filed 1–14–93; 8:45 am]

BILLING CODE 6820-33-M

Procurement List; Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to Procurement List.

SUMMARY: This action adds to the Procurement List mailing and filing tubes to be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

EFFECTIVE DATE: February 16, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: On September 25, 1992, the Committee for Purchase From People Who Are Blind or Severely Disabled published a notice (57 FR 44365) of the proposed addition of these tubes to the Procurement List. Comments were received after the close of the comment period from one of the three contractors for the mailing tubes, in response to a Committee request for information. The contractor claimed that the addition of the tubes to the Procurement List would cause severe adverse impact on the firm by depriving it of significant sales and causing unemployment of some of its unskilled minority personnel in a labor surplus area. The contractor questioned whether this work is suitable for people with severe disabilities. It claimed that removal of the tubes from competitive bidding would keep it from amortizing its capital expenditures to produce them, and proposed that part of the work be given to another nonprofit agency to which the contractor could supply tube components to lessen the impact on it of the addition of the tubes to the Procurement List.

The Committee has decided that losing the percentage of its sales which the tube contract represents, which is somewhat less than the percentage originally claimed by the contractor, would not cause severe adverse impact on the contractor. The Committee has also decided that the possibility that an uncertain number of the contractor's employees may be laid off as a result of the Committee's action is outweighed by the certain jobs for people with severe disabilities, who experience unemployment rates in excess of 65%.

The Committee is required to determine that a proposed addition to the Procurement List will generate employment for people with severe disabilities and that the nonprofit agency proposed to produce the item is capable of doing so. In making these determinations, the Committee relied on favorable capability assessments of the nonprofit agency proposed to produce the tubes which had been done by both the Government agency which buys the tubes and the central nonprofit agency which represents the nonprofit agency and on representations by the nonprofit agency and the central nonprofit agency as to the number of jobs for people with severe disabilities that will be created.

Under the competitive bidding system, no contractor is guaranteed a contract. The Committee does not consider loss of an opportunity to bid on contracts which have been added to the Procurement List to constitute severe adverse impact. Therefore, the Committee does not consider the commenting contractor's loss of the opportunity to amortize its costs on future Government contracts for the tubes to be a factor in assessing impact of the Committee's action on this contractor.

As one nonprofit agency has been found capable of producing the entire Government supply requirement for these tubes, the Committee does not consider it feasible to divide the requirement between two nonprofit agencies as the contractor proposed. However, the contractor is being afforded an opportunity to compete as a supplier of tube components to the nonprofit agency.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to produce the commodities, fair market price, and impact of the addition on the current or most recent contractors, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodities to the Government.

2. The action will not have a severe economic impact on current contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities proposed for addition to the Procurement List.

Accordingly, the following commodities are hereby added to the Procurement List:

Tube Mailing and Filing

8110–00–244–7435	8110–00–291–0347
8110–00–271–1508	8110–00–291–0348
8110–00–271–1509	8110–00–725–1471
8110–00–291–0344	8110–00–290–2048
8110–00–291–0345	8110–00–969–5406
8110–00–291–0346	

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,

Executive Director.

[FR Doc. 93–1075 Filed 1–14–93; 8:45 am]

BILLING CODE 6820-33-M

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: February 16, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, Suite 403.

1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action does not appear to have a severe adverse impact on the current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following services to the Procurement List for production by the nonprofit agency listed:

Food Service Attendant
Naval Station, Building NS 43, Charleston, South Carolina
Nonprofit Agency: Goodwill Industries of Lower South Carolina, Inc., Charleston, South Carolina
Grounds Maintenance
National Historic Site, Rt. 1, Box 85, Andersonville, Georgia
Nonprofit Agency: Macon County Mental Rehabilitation Service Center, Montezuma, Georgia
Janitorial/Custodial
Social Security Administration Operations Building (Ground Floor and Connecting Links), 6401 Security Boulevard, Baltimore, Maryland
Nonprofit Agency: The Baltimore Goodwill Industries, Inc., Baltimore, Maryland
Janitorial/Custodial
Naval Intelligence Command Building, Suitland, Maryland
Nonprofit Agency: Melwood Horticultural Training Center, Upper Marlboro, Maryland
Mailroom Operation
Army National Guard Readiness Center, 111 South George Mason Drive, Arlington, Virginia
Nonprofit Agency: Didlake, Inc. Manassas, Virginia

Beverly L. Milkman,
Executive Director.

[FR Doc. 93–1079 Filed 1–14–93; 8:45 am]
BILLING CODE 6820-33-M

DEPARTMENT OF DEFENSE

Office of the Secretary

Determination; Excess Defense Articles (Two C–130B Aircraft)

Section 517 of the Foreign Assistance Act of 1961 authorizes the transfer of excess defense articles to the military forces and local law enforcement agencies of certain major illicit drug producing or major drug-transit countries in Latin America and the Caribbean to encourage them to participate cooperatively in a comprehensive national anti-narcotics program. Section (f)(3) establishes a prerequisite to such transfer a determination by the President "that the transfer of excess defense articles will not have an adverse impact on the military readiness of the United States."

The Deputy Director, Defense Security Assistance Agency, Glenn A. Rudd, certifies that the C–130B aircraft are needed by Ecuador and determines that there will be no adverse impact on U.S. military readiness as a result of these transfers.

Dated: January 12, 1993.

L.M. Bynum,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–1029 Filed 1–14–93; 8:45 am]
BILLING CODE 3810-01-M

Defense Science Board Task Force on Aircraft Assessment; Meeting

ACTION: Notice of Change in Locations and Dates of Advisory Committee Meetings.

SUMMARY: The meeting of the Defense Science Board Task Force on Aircraft Assessment scheduled for January 12 and 13, 1993, at the Pentagon, Arlington, Virginia, as published in the **Federal Register** (Vol. 57, No. 252, page 62570, Thursday, December 31, 1992, FR Doc. 92–31779) has been relocated to the Institute for Defense Analyses, Alexandria, Virginia and rescheduled for January 21 and 22, 1993.

The meeting of the Defense Science Board Task Force on Aircraft Assessment scheduled for January 21 and 22, 1993, at the Pentagon, Arlington, Virginia, as published in the **Federal Register** (Vol. 57, No. 252, Page 62570, Thursday, December 31, 1992, FR Doc. 92–31779) has been rescheduled and relocated to the Lockheed Corporation, Marietta, Georgia, on February 4, 1993, and McDonnell Douglas Aerospace Corporation, St. Louis, Missouri, on February 5, 1993.

The meeting of the Defense Science Board Task Force on Aircraft Assessment scheduled for January 28 and 29 at the Pentagon, Arlington, Virginia, as published in the **Federal Register** (Vol. 57, No. 252, page 62570, Thursday, December 31, 1992, FR Doc. 92–31779) has been relocated to the Institute for Defense Analyses, Alexandria, Virginia and rescheduled for February 11 and 12, 1993.

Dated: January 12, 1993.

L.M. Bynum,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–1026 Filed 1–14–93; 8:45 am]
BILLING CODE 3810-01-M

Public Information Collection Requirement Submitted to OMB for Review

AGENCY: Department of Defense.
ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Title, Applicable Form, and Applicable OMB Number: Application Forms Booklet, Naval Reserve Officers Training Corps Scholarship Program; CNET 1533/74, 1533/91, 1533/87, 1533/92, 1533/88, 1533/93, 1533/89; OMB Control Number 0703–0026
Type of Request: Reinstatement
Average Burden Hours/Minutes per Response: 4 hours
Responses Per Respondent: 1
Number of Respondents: 14,000
Annual Burden Hours: 56,000
Annual Response: 14,000

Needs and Uses: To collect information to make a determination of applicant's academic and/or leadership potential and eligibility for an NROTC Scholarship.
Affected Public: Individuals or households
Frequency: On occasion
Respondent's Obligation: Required to obtain or retain a benefit
OMB Desk Officer: Mr. Edward C. Springer

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DOD, room 3235, New Executive Office Building, Washington, DC 20503.
DOD Clearance Officer: Mr. William P. Pearce

Written requests for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson David Highway, suite 1204, Arlington, VA 22202–4302.

Dated: January 12, 1993.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–1027 Filed 1–14–93; 8:45 am]

BILLING CODE 3810–01–M

Public Information Collection Requirement Submitted to OMB for Review

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).
Title, Applicable Form, and Applicable OMB Control Number: Certificate of Ecclesiastical Endorsement (Nomination of Chaplains for the Three Military Departments—Army, Navy, Air Force); DD Form 2088; 0704–0190
Type of Request: Extension
Average Burden Hours/Minutes Per Response: 1 hour
Responses Per Respondent: 1
Number of Respondents: 700
Annual Burden Hours: 700
Annual Responses: 700
Needs and Uses: This information collection certifies that the clergy applying for the chaplaincy in the Armed Forces are qualified members of a faith group recognized by DoD. It is an essential element of a chaplain's professional qualifications and provides documentation of years of professional experience for the computation of constructive credit used in determining grade, date of rank, and eligibility for promotion of appointees.
Affected Public: Non-profit institutions
Frequency: On occasion
Respondent's Obligation: Voluntary
OMB Desk Officer: Mr. Edward C. Springer

Written comments and recommendations on the proposed information collection should be sent to Mr. Springer at the Office of Management and Budget, Desk Officer for DoD, room 3235, New Executive Office Building, Washington, DC 20503.
DOD Clearance Officer: Mr. William P. Pearce

Written request for copies of the information collection proposal should be sent to Mr. Pearce, WHS/DIOR, 1215 Jefferson Davis Highway, Suite 1204, Arlington, Virginia 22202–4302.

Dated: January 12, 1993.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 93–1028 Filed 1–14–93; 8:45 am]

BILLING CODE 3810–01–M

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Board Policy on Transmittal of Trip Reports and Other Safety Information to the Secretary of Energy

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice of board adoption of policy guidance.

SUMMARY: The Defense Nuclear Facilities Safety Board has unanimously adopted a policy statement which establishes procedures that the Board will use for transmittal of trip reports and other safety information to the Secretary of Energy.

FOR FURTHER INFORMATION CONTACT: Robert M. Andersen, General Counsel, Defense Nuclear Facilities Safety Board, 625, Indiana Avenue, NW., suite 700, Washington, DC 20004, (202) 208–6387.

SUPPLEMENTARY INFORMATION: This Defense Nuclear Facilities Safety Board Policy Statement (PS–2) will guide the Board and its staff in the transmittal of trip reports and other safety information to the Secretary of Energy in those cases where (1) the information will be of assistance to the Secretary; and (2) the information does not warrant issuance of a Board recommendation.

Policy Statement (PS–2)

The Board was established as an independent agency within the Executive Branch to advise and assist the Secretary of Energy in improving public health and safety at Department of Energy (DOE) defense nuclear facilities. Most importantly, the Board's enabling statute provides that the Board shall make such recommendations to the Secretary of Energy with respect to Department of Energy defense nuclear facilities, including operation of such facilities, standards, and research needs as the Board determines are necessary to insure adequate protection of public health and safety. (42 U.S.C. § 2286a(5)). The Secretary of Energy is required to respond by transmitting to the Board in writing, a statement on whether the Secretary accepts or rejects, in whole or in part, the recommendations * * * a description of the action to be taken in response * * * and his views on such recommendations. (*Id.* at § 2286d(b)). The Board obtains information used in developing recommendations through site visits by the Board and its staff, review of documentation, formal investigations, inspections, and other fact-gathering activities.

As stated above, the Board is required to issue recommendations if the available safety information demonstrates that issuance of a formal recommendation is necessary to assure adequate protection of public health and safety. The Board and its staff often obtain valuable safety information which, while insufficient to justify issuance of a recommendation, would assist the Secretary of Energy, his staff, and site contractors in their joint pursuit of safer conditions and practices at defense nuclear facilities.

Site visits to DOE defense nuclear facilities are a major fact gathering activity of the Board and staff. During such visits briefing materials are frequently provided by DOE and contractor personnel, facilities are toured and facility operations observed. The Board's staff routinely summarizes information obtained as a result of such visits in trip reports. Information in these reports represent part of the data files that the staff accumulates on defense nuclear facilities regarding matters having public health and safety implications. The Board routinely reviews these reports and periodically requests staff briefings relative to matters of particular interest. While trip reports serve principally as internal working papers and a vehicle for facilitating Board/staff communication, the Board recognizes that information gathered pursuant to Board interest could at times prove useful to DOE.

In the past, the Board has transmitted trip reports to DOE if, in the Board's view, the reports contain safety

information which might assist the Secretary of Energy, his staff, and site contractors in their joint pursuit of safer conditions and practices at defense nuclear facilities. The Board has been most interested in conveying information that will either: (1) Simulate line management self-assessment of questionable practices or operations, (2) assist in determining the root causes of specific safety problems, or (3) aid in identifying generic problems at facilities that might benefit from cross-transfer of remedial know-how from other facilities that faced similar problems.

This practice of transmitting technical information to the Secretary for further distribution is fully consistent with the congressional intention that the Board provide assistance to the Secretary of Energy and DOE's health and safety activities, Senate Report No. 100–232, 100th Cong., 1st Sess., Nov. 20, 1987, page 10. Therefore, it will continue to be the policy of the Board to review staff-generated trip reports and other technical assessments to determine whether or not they would be of assistance to the Secretary of Energy. The Board will continue its flexible approach in determining whether or not the information should be transmitted to DOE, and in what form. In some instances, the Board will transmit trip reports, or highlights contained in those reports, to the Secretary of Energy, without further comment by the Board, for the Department of Energy's use as it sees fit. In other instances the Board, in its cover letter, may want to highlight certain safety issues and suggest ways in which the information may be used, even though a formal recommendation is not made. For example, the Board may suggest transmittal of such information directly to the relevant defense nuclear facility and the individuals who are most interested in the issues. The Board may also request that it be apprised of any action DOE takes on the information. Finally, in some instances, the Board may transmit the report to DOE for immediate use and indicate that the information contained in the report will be considered as the possible basis for a formal recommendation.

Trip reports or other documents that are provided to DOE pursuant to this policy will be placed in the DNFSB public files subsequent to any appropriate reviews, and clearance, such as for classified or unclassified controlled nuclear information.

Dated: January 11, 1993.

John T. Conway,

Chairman.

[FR Doc. 93–990 Filed 1–14–93; 8:45 am]

BILLING CODE 6820–KD–M

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Information Resources Management Service, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before February 4, 1993.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Dan Chenok: Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place, NW., room 3208, New Executive Office Building, Washington, DC 20503. Requests for copies of the proposed information collection requests should be addressed to Cary Green, Department of Education, 400 Maryland Avenue, SW., room 5624, Regional Office Building 3, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Cary Green (202) 708–5174.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Director of the Information Resources Management Service publishes this notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following:

(1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from Cary Green at the address specified above.

Dated: January 7, 1993.

Cary Green,

Director, Information Resources Management Service.

Office of Vocational and Adult Education

Type of Review: Extension
Title: Application for Adult Education Direct Grants
Frequency: Triennially
Affected Public: Non-profit institutions; small businesses or organizations
Reporting Burden:
Responses: 104
Burden Hours: 9,360
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0
Abstract: This form will be used by State Educational agencies to apply for grants under the Adult Education Program. The Department will use the information to make grant awards.

Office of Bilingual Education and Minority Languages Affairs

Type of Review: Extension
Title: Demonstration of Compliance with Terms and Conditions of the Bilingual Education Fellowship Contract
Frequency: Annually
Affected Public: Individuals or households
Reporting Burden:
Responses: 700
Burden Hours: 366
Recordkeeping Burden:
Recordkeepers: 0
Burden Hours: 0
Abstract: Regulations (34 CFR 562.47) require Fellowship Recipients to demonstrate compliance with Terms and Conditions of Assistance awarded under the Bilingual Education Fellowship Program. Recipients must either work in an approved activity or repay the financial assistance.

[FR Doc. 93–996 Filed 1–14–93; 8:45 am]

BILLING CODE 4000–01–M

[CFDA No. 84.215D]

Fund for Innovation in Education: Computer-Based Instruction Program; Notice Inviting Applications for New Awards for Fiscal Year 1993

Purpose of Program: To provide grants for projects that strengthen and expand computer-based education resources in public and private elementary and secondary schools.

Eligible Applicants: State educational agencies, local educational agencies, institutions of higher education, private schools, and other public and private agencies, organizations and institutions, or consortia of those agencies.

Deadline for Transmittal of Applications: March 29, 1993.

Deadline for Intergovernmental Review: May 26, 1993.

Applications Available: February 5, 1993.

Estimated Available Funds: $1,000,000.

Estimated Range of Awards: $50,000–$200,000.

Estimated Number of Awards: 5–8.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Budget Period: 12 months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, and 86.

SUPPLEMENTARY INFORMATION: This program and the priorities in this notice support the President's strategy for moving the Nation toward the National Education Goals. Specifically, Goal 3 states that "American students will leave grades four, eight, and twelve having demonstrated competency in challenging subject matter including English, mathematics, science, history, and geography * * *." In its report of January 24, 1992, the National Council on Education Standards and Testing (NCEST), a congressionally-mandated group, recommended the development of national standards in the core subjects as an urgently needed first step in reforming American education. The movement to develop voluntary national standards has already begun. The National Council of Teachers of Mathematics has prepared mathematics standards. Now, thousands of teachers and scholars are creating voluntary national standards in science, history, the arts, civics, geography, foreign languages, and English. By 1994–1995, the standards will be ready for use in our classrooms. Additional information is available from the contacts listed at the end of this notice.

Efforts are similarly underway for the development of State curriculum frameworks in these subject areas. The frameworks must embody coherent, non-repetitive curricula designed to ensure that all children study challenging subject material in every grade, K–12. Along with the frameworks, model guidelines for effective approaches to teacher education, certification, and recertification are being developed, all based on world-class standards.

To ensure that all students have the opportunity to reach high standards, schools will need to strengthen instruction in the core subjects. One potential way of achieving this goal is through increased subject-specific applications of computer technology.

Priorities

Under 34 CFR 75.105(c)(1), the Secretary is interested in applications that meet the following invitational priorities. However, an application that meets these invitational priorities does not receive competitive or absolute preference over other applications:

Invitational Priority 1—Projects that develop new and advanced computer software and supporting instructional materials designed specifically for teaching one or more of the following core subjects: math, science, history, the arts, civics, geography, foreign languages, and English.

Projects should include all of the following elements:

(a) Provision for collaboration among master teachers, content specialists, curriculum specialists, and private industry computer personnel in the development of materials.

(b) Provision for the testing of computer materials in a variety of school settings.

(c) Provision for the training of teachers in the uses of the new materials.

(d) Provision for the evaluation of project activities to assess effectiveness in improving instruction and student achievement.

(e) Provision for dissemination of successful results.

Applications should contain: An analysis of the instructional needs within the core subject(s) to be addressed by the proposed software and materials, and a description of the proposed new computer materials to be developed and the curricular revisions required to integrate computers into instruction.

Invitational Priority 2—Projects that develop and implement school- or system-wide teacher training to help teachers utilize and integrate available state-of-the-art computer technology in the teaching of math, science, history, the arts, civics, geography, foreign languages, and English.

Projects should include all of the following elements:

(a) Provision for the development and implementation of a strategy to train teachers in the uses of the proposed computer hardware and computer software to enhance subject-specific instruction.

(b) Provision for the involvement of personnel qualified to train teachers in the use of the proposed computer software and hardware.

(c) Provision for the evaluation of project activities to assess progress in meeting goals under paragraph (a).

(d) Provision for the dissemination of successful results.

Applications should contain a description of the goals—including measurable student outcomes—for incorporating computer education in the subject area(s), and rationale for selecting the proposed computer hardware and software designed to improve instruction in the core subjects.

Selection Criteria: In evaluating applications for grants under this competition, the Secretary uses the selection criteria in 34 CFR 75.210(b). Under 34 CFR 75.210(c), the Secretary is authorized to distribute an additional 15 points among the criteria to bring the total to a maximum of 100 points. For this competition, the Secretary distributes the additional points as follows:

Plan of Operation. (34 CFR 75.210(b)(3)). Five additional points are added to this criterion for a possible total of 20 points.

Quality of Key Personnel. (34 CFR 75.210(b)(4)). Five additional points are added to this criterion for a possible total of 12 points.

Evaluation Plan. (34 CFR 75.210(b)(6)). Five additional points are added to this criterion for a possible total of 10.

Limitation on Length of Applications: The applicant must limit the application narrative to no more than 25 double-spaced, 8½ × 11" pages (on one side only) with one-inch margins. If using a proportional computer font, use no smaller than a 12-point font. If using a nonproportional computer font or a typewriter, do not use more than 10 characters to the inch. Proposal narratives that exceed this page limit, or narratives using a smaller print size or spacing that makes the narrative exceed the equivalent of this limit, will not be considered for funding.

For Applications or Information Contact: Shirley Steele or Jaymie L. Lewis, U.S. Department of Education, 555 New Jersey Avenue, NW., room 522, Washington, DC 20208–5524. Telephone (202) 219–1496. Deaf and hearing impaired individuals may call the Federal dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

Program Authority: 20 U.S.C. 3151, 3154.

Dated: January 8, 1993.

Diane Ravitch,

Assistant Secretary for Educational Research and Improvement.

[FR Doc. 93–1005 Filed 1–14–93; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Bonneville Power Administration

Proposed Wholesale Power Rate Adjustment, Public Hearing, and Opportunities for Public Review and Comment

AGENCY: Bonneville Power Administration (BPA), DOE.

ACTION: Notice and opportunities for review and comment. BPA File No: WP–93. BPA requests that all comments and documents intended to become part of the Official Record in this process contain the file number designation WP–93.

SUMMARY: The Pacific Northwest Electric Power Planning and Conservation Act (Northwest Power Act) provides that BPA must establish and periodically review and revise its rates so that they are adequate to recover, in accordance with sound business principles, the costs associated with the acquisition, conservation, and transmission of electric power, and to recover the Federal investment in the Federal Columbia River Power System (FCRPS) and other costs incurred by BPA. BPA is proposing to revise its wholesale power rate schedules to be effective October 1, 1993, through September 30, 1995, and to produce sufficient revenues for BPA to meet its statutory requirements for Fiscal Year (FY) 1994 and FY 1995.

Through its Programs in Perspective (PIP) public review process conducted during the summer of 1992, BPA and interested parties completed a thorough review of BPA's programs and program cost levels included in the budgets for FY 1994 and FY 1995. With the exception of program levels delineated in this Notice, the Administrator will not reexamine program level decisions in the rate case. The PIP process also focused on BPA's proposed 10-Year Financial Plan and its attendant financial policies. Consistent with BPA's pledge at the end of the 1991 rate case, implementation of the 10-Year Financial Plan will be addressed in this rate case.

Beginning in August 1992, BPA conducted a series of workshops on subjects relevant to BPA's ratemaking. The purpose of the workshops was to identify, simplify, and reduce the number of issues that might become part of the 1993 rate case and to reduce the amount of discovery normally required during the formal rate proceedings. Opportunity was provided to address 10-Year Financial Plan implementation issues and to understand risk analysis, revenue requirement, revenue forecast, and ratesetting policy choices, data inputs, assumptions, and modeling. All parties to the 1991 rate case, and participants in prior workshops, were invited to attend. The workshops were well attended and provided opportunities for informal public comment on issues prior to the formal hearing process.

Consistent with BPA's 10-Year Financial Plan, BPA is proposing an Interim Rate Adjustment (IRA) that allows BPA to increase its rates for the second year of the rate period to reverse any serious, unplanned decline in financial reserves that occurs in the first year of the rate period. BPA is also proposing that a new rate schedule be included in this proposal: Power Shortage Rate (PS–93).

BPA is assessing the potential environmental effects of its initial rate proposal as required by the National Environmental Policy Act (NEPA). BPA intends to circulate its NEPA analysis for review and comment. Comments will be received outside the formal hearing process, but will be included in the record and considered by the Administrator in making his final decision establishing BPA's 1993 rates.

Opportunities will be available for interested persons to review BPA's proposal to adjust its 1993 rates, to participate in the rate hearing, and to submit written comments. During the development of the final rate proposal, BPA will evaluate all written and oral comments received in the rate proceeding. Consideration of comments and more current data may result in the final rate proposal differing from the rates proposed in this Notice.

Responsible Official: Mr. Sydney D. Berwager, Director, Division of Contracts and Rates, is the official responsible for the development of BPA's rates.

DATES: Persons wishing to become a formal "party" to the proceedings must notify BPA in writing of their intention to do so in accordance with requirements stated in this Notice. Petitions to intervene must be received by January 25, 1993, and should be addressed as follows: Hearing Officer, c/o Kathryn Silva—APR, Hearing Clerk, Bonneville Power Administration, P.O. Box 12999, Portland, Oregon 97212. In addition, a copy of the petition must be concurrently served on BPA's Office of General Counsel—APR, c/o Kurt R. Casad, P.O. Box 3621, Portland, Oregon 97208. Persons who have been denied party status in any past BPA rate proceeding shall continue to be denied party status unless they establish a significant change of circumstances.

A prehearing conference will be held before the Hearing Officer at 9 a.m. on January 28, 1993, in the BPA Rates Hearing Room located at 2032 Lloyd Center, Portland, Oregon. Registration for the prehearing conference will begin at 8:30 a.m. BPA will prefile studies and testimony at the prehearing conference. The Hearing Officer will act on all intervention petitions and oppositions to intervention petitions, rule on any motions, establish additional procedures, establish a service list, establish a procedural schedule, and consolidate parties with similar interests for purposes of filing jointly sponsored testimony and briefs and for expediting any necessary cross-examination. A notice of the dates and times of any hearings will be mailed to all parties of record. Objections to orders made by the Hearing Officer at the prehearing conference must be made in person or through a representative at the prehearing conference.

BPA will be conducting public field hearings. The following are tentative dates and locations:

February 10, 1993 Federal Bldg., Auditorium, 825 Jadwin Ave., Richland, WA 99352.

February 11, 1993 Shilo Inn, 780 Lindsey Blvd., Idaho Falls, ID 83402.

February 16, 1993 Best Western Landmark Inn, 4300 200th St., S.W., Lynnwood, WA 98036.

February 17, 1993 Red Lion, 205 Coburg Rd, Eugene, OR 97401.

February 18, 1993 Ridpath Hotel, West 515 Sprague Ave., Terrace Room A&B, Spokane, WA 99204.

When BPA holds public field hearings, written transcripts are made and included in the official record. Dates of these hearings also will be announced through mailings and public advertising.

The following proposed schedule is provided for informational purposes. A final schedule will be established by the Hearing Officer at the prehearing conference.

January 25, 1993 Deadline for interventions to be filed with Hearing Clerk at above address.

January 28, 1993 Initial studies and testimony available at BPA's Rates Hearing Room, 2032 Lloyd Center, Portland,

Oregon and BPA's Public Information Center, 905 NE. 11th, 1st Floor, Portland, Oregon.

January 28, 1993 Prehearing conference to set schedule and act on petitions to intervene.

March 2, 1993 Parties file direct cases.

March 15, 1993 Close of comments by participants.

April 5, 1993 Rebuttal testimony filed.

April 12–16, 1993 Settlement discussions.

April 26–May 12, 1993 Cross-examination.

June 25, 1993 Draft Record of Decision published.

August 2, 1993 Final Record of Decision published.

ADDRESSES: Written comments by participants must be received by March 15, 1993, to be considered in the Draft Record of Decision (ROD). Written comments should be submitted to the Public Involvement Manager—ALP, Bonneville Power Administration, P.O. Box 12999, Portland, Oregon 97212.

FOR FURTHER INFORMATION CONTACT: Ms. Shirley Price, Public Involvement Office, at the address listed above, 503–230–3478 or call toll-free 1–800–622–4519. Information may also be obtained from:

Mr. George Bell, Lower Columbia Area Manager, Suite 243, 1500 Plaza Building, 1500 NE. Irving Street, Portland, Oregon 97232, 503–230–4552.

Mr. Robert N. Laffel, Eugene District Manager, room 206, 211 East Seventh Avenue, Eugene, Oregon 97401, 503–465–6952.

Mr. Wayne R. Lee, Upper Columbia Area Manager, room 561, 920 West Riverside Avenue, Spokane, Washington 99201, 509–353–2518.

Mr. George E. Eskridge, Montana District Manager, 800 Kensington, Missoula, Montana 59801, 406–329–3060.

Ms. Carol Fleischman, Spokane District Manager, room 112, U.S. Courthouse, 920 West Riverside, Spokane, Washington 99201, 509–353–3279.

Mr. Ronald K. Rodewald, Wenatchee District Manager, room 307, 301 Yakima Street, Wenatchee, Washington 98807–0741, 509–662–4377, extension 379.

Mr. Terence G. Esvelt, Puget Sound Area Manager, P.O. Box C19030, suite 400, 201 Queen Anne Avenue North, Seattle, Washington 98109, 206–553–4130.

Mr. Thomas V. Wagenhoffer, Snake River Area Manager, 101 West Poplar, Walla Walla, Washington 99362, 509–522–6226.

Ms. C. Clark Leone, Idaho Falls District Manager, 1527 Hollipark Drive, Idaho Falls, Idaho 83401, 208–523–2706.

Mr. James Normandeau, Boise District Manager, room 450, 304 N. 8th Street, Boise, Idaho 83702, 208–334–9137.

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A. Wholesale Power Rate Schedules
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I. Introduction

On December 18, 1992, in order to satisfy contractual provisions between BPA and its customers, BPA published in the **Federal Register** a notice of "Intent to Revise Wholesale Power Rates to Become Effective October 1, 1993," 57 FR 60180. Since then, BPA has continued to study the adequacy of its current rates and has concluded that current rates must be adjusted for the FY 1994 and FY 1995 rate period.

In order to assess its current rates, BPA first determined the amount of revenues required to meet its financial obligations in FY 1994 and FY 1995. BPA has determined that the revenues BPA would expect to collect from projected sales under its current rates will not adequately cover these revenue requirements. Therefore, BPA proposes to establish revised 1993 wholesale power rates. BPA files its rates with the Federal Energy Regulatory Commission (FERC) for confirmation and approval.

The proposed wholesale power rates were prepared in accordance with BPA's statutory authority to develop rates, including the Bonneville Project Act of 1937, as amended, 16 U.S.C. 832 (1982); the Flood Control Act of 1944, 16 U.S.C. 825s (1982); the Federal Columbia River Transmission System Act (Transmission System Act), 16 U.S.C. 838 (1982); and the Pacific Northwest Electric Power Planning and Conservation Act, 16 U.S.C. 839 (1982).

The rate schedules contained in this publication were established in accordance with the Northwest Power Act, which was signed into law on December 5, 1980. The proposed rate schedules reflect many requirements contained principally in the Northwest Power Act's rate directives (section 7) and the conditions related to classes of customers and services contained in the Northwest Power Act's power sales directives (section 5).

BPA proposes that its wholesale power rate schedules and the General Rate Schedule Provisions (GRSPs) associated with these schedules become effective upon interim approval or upon final confirmation and approval by FERC. BPA will request FERC approval of its rates effective October 1, 1993. Section I.A. of the GRSPs specifies the proposed effective date for each rate.

The 1993 wholesale power rate schedules, and the GRSPs associated with those rate schedules, supersede BPA's 1991 rate schedules (which became effective October 1, 1991) to the extent stated in the Availability section of each 1993 rate schedule. These schedules and GRSPs shall be applicable to all BPA contracts, including contracts executed both prior to and subsequent to enactment of the Northwest Power Act.

In developing the proposed wholesale power rates, BPA considered many factors, including revenue requirements, ease of administration, revenue stability, rate continuity, ease of comprehension, and BPA's statutory obligations. The studies that have been prepared to support the proposed rates will be mailed to all parties to BPA's 1991 rate case and will be available for examination on January 28, 1993, at BPA's Public Information Center, BPA Headquarters Building, 1st Floor, 905 NE. 11th, Portland, Oregon. The studies also will be available at the prehearing conference. The studies are:

1. Loads and Resources Study and Documentation
2. Revenue Requirement Study and Documentation
3. Segmentation Study
4. Wholesale Power Rate Development Study and Documentation
5. Section 7(b)(2) Rate Test Study and Documentation

To request any of the above studies by telephone, call BPA's document request line: (503) 230–3478 or call toll-free 1–800–622–4520. Please request the study by its above-listed title. Also state whether you require the accompanying documentation (these can be quite lengthy); otherwise the study alone will be provided. (For example, ask for the "Revenue Requirement Study and Documentation.")

II. Procedures Governing Rate Adjustments and Public Participation

Section 7(i) of the Northwest Power Act, 16 U.S.C. 839e(i), requires that BPA's rates be established according to certain procedures. These procedures include, among other things, issuance of a **Federal Register** notice announcing the proposed rates; one or more hearings; the opportunity to submit written views, supporting information, questions, and arguments; and a decision by the Administrator based on the record. This proceeding will be governed by BPA's rule for general rate proceedings, § 1010.9 of BPA's "Procedures Governing Bonneville Power Administration Rate Hearings," 51 FR 7611 (March 5, 1986). These procedures implement the statutory section 7(i) requirements. Section 1010.7 of the procedures prohibits ex

parte communications. The proceedings for BPA's proposal to adjust wholesale power rates will be combined with the proceedings for BPA's proposal to adjust transmission rates.

BPA distinguishes between "participants in" and "parties to" the hearings. Apart from the formal hearing process, BPA will receive comments, views, opinions, and information from "participants," who are defined in the procedures as any person who may express views, but who does not successfully petition to intervene as a party. Participants' written comments will be made part of the official record of the case and considered by the Administrator. The participant category gives the public the opportunity to participate and have its views considered without assuming the obligations incumbent upon "parties." Participants are not entitled to participate in the prehearing conference, cross-examine parties' witnesses, seek discovery, or serve or be served with documents, and are not subject to the same procedural requirements as parties.

Written comments by participants will be included in the record if they are received by March 15, 1993. This date follows the submission of BPA's and all other parties' direct cases. Written views, supporting information, questions, and arguments should be submitted to BPA's Public Involvement Office.

The second category of interest is that of a "party" as defined in §§ 1010.2 and 1010.4 of BPA's "Procedures Governing Bonneville Power Administration Rate Hearings," 51 FR 7611 (March 5, 1986). Parties may participate in any aspect of the hearing process.

Persons wishing to become a formal "party" to BPA's rate proceeding must notify BPA in writing of their request. Petitions to intervene shall state the name and address of the person and the person's interests in the outcome of the hearing. Petitioners may designate no more than two representatives upon whom service of documents will be made. BPA customers and customer groups whose rates are subject to revision in the hearing will be granted intervention based on a petition filed in conformance with this section. Other petitioners must explain their interests in sufficient detail to permit the Hearing Officer to determine whether they have a relevant interest in the hearing. Intervention petitions will be available for inspection in BPA's Public Information Center, 1st Floor, 905 NE. 11th, Portland, Oregon. Any opposition to a petition to intervene must be raised at the January 28, 1993, prehearing conference. All timely applications will be ruled on by the Hearing Officer. Late interventions are strongly disfavored. Opposition to an untimely petition to intervene shall be filed and served within 2 days after service of the petition. Interventions are subject to § 1010.4 of BPA's "Procedures Governing Bonneville Power Administration Rate Hearings."

The record will include, among other things, the transcripts of any hearings, any written material submitted by the parties and participants, documents developed by BPA staff, BPA's environmental analysis and comments accepted on it, and other material accepted into the record by the Hearing Officer. The Hearing Officer then will review the record, will supplement it if necessary, and will certify the record to the Administrator for decision.

The Administrator will develop the final proposed rates based on the entire record, including the record certified by the Hearing Officer, comments received from participants, other material and information submitted to or developed by the Administrator, and any other comments received during the rate development process. The basis for the final proposed rates will be first expressed in the Administrator's Draft Record of Decision (ROD). Parties will have an opportunity to comment on the Draft ROD as provided in BPA's hearing procedures. The Administrator will serve copies of the Final ROD on all parties and will file the final proposed rates together with the record with FERC for confirmation and approval.

III. Major Studies and 10-Year Financial Plan

A. Major Studies

1. Load and Resources Study

The Loads and Resources Study presents the load and resource data necessary for developing BPA's wholesale power rates. This study incorporates results from load forecasts, resource analyses, power contracts, and BPA's Resource Program.

BPA's major customer groups are as follows:

(1) The direct-service industries (DSIs);

(2) The non- and small generating public utilities (NSGPUs);

(3) The generating public utilities (GPUs);

(4) The investor-owned utilities (IOUs);

(5) The contract Federal agencies; and

(6) The United States Bureau of Reclamation (USBR).

BPA's forecasts of regional loads by customer group are used to derive a major portion of its forecast of Federal system firm loads. The regional load forecasts are used to estimate BPA's firm DSI load, sales to other Federal agencies, current obligations to regional public agencies, and Federal transmission losses. The remaining portion of the Federal system load projections is comprised of BPA's obligations to the IOUs under their power sales contracts, and other inter- and intra-regional contractual obligations.

BPA develops forecasts of NSGPU and GPU loads using standard econometric techniques. NSGPU and GPU loads are a function of average retail electricity prices, weather-related variables, and non-agricultural employment. The IOU load forecast was produced by the staffs of BPA and the Northwest Power Planning Council. To produce utility-specific system forecasts, the IOU forecast is disaggregated by year and month based upon the utilities' forecast submittals to the Pacific Northwest Utilities Conference Committee (PNUCC) for use in the 1992 Northwest Regional Forecast.

A DSI load forecast is prepared for aluminum DSI loads by analyzing smelter production costs relative to aluminum prices, and considering other factors affecting smelter loads. A DSI load forecast for non-aluminum DSI loads is prepared by analyzing historical and technical plant information and forecasted market conditions.

BPA's resource acquisition plans are based on work by BPA and Northwest Power Planning Council staff and reflect extensive input and review by the general public and the region's utilities. The specific resource acquisitions and associated costs included in this proposal are based on BPA's 1990 and 1992 Resource Programs. Conservation savings are measured by considering several factors: economic and load growth; savings from technical conservation measures; and the assessment of the speed and degree of program implementation.

Planned resource acquisitions reflect the guidance given in the Northwest Power Planning Council's Power Plan. Besides emphasizing a diverse resource portfolio, including both conservation and generating resources, BPA is committed to moving toward a blend of acquisition methods including BPA-designed, utility-designed, and developer-initiated programs. For example, use of billing credits and competitive acquisitions is an important component of BPA's resource acquisition process. This combination of resource diversity and a variety of acquisition approaches allows BPA to

better deal with varying circumstances and uncertainties.

The load/resource balance determines BPA's obligation to serve firm loads during the test years and each corresponding 42-month critical period. It also determines the supply of surplus firm power in the region and on the Federal system in each critical period. The hydro-regulation (hydro) study incorporates system constraints such as the water budget for fish migration, the operation of thermal plants, exports and imports of power, and projected resource acquisitions. For this proposal, a 42-month (critical period) hydro study and a 50-year hydro study were completed. The time frame considered in the hydro study starts in July 1993. The 50-year study determines nonfirm energy for the region.

2. Revenue Requirement Study

The Bonneville Project Act, the Flood Control Act of 1944, the Transmission System Act, and the Northwest Power Act require BPA to design rates that are projected to collect revenues sufficient to recover the cost of acquiring, conserving, and transmitting the electric power that BPA markets, including amortization of the Federal investment in the FCRPS over a reasonable period, and to recover BPA's other costs and expenses. The Revenue Requirement Study determines whether current rates will produce enough revenues to recover all BPA costs and expenses, including BPA's repayment obligations to the U.S. Treasury. Revenue requirements are the major factor in determining the overall level of BPA's proposed power and transmission rates.

The Transmission System Act and the Northwest Power Act require that transmission rates be based on an equitable allocation of the costs of the Federal transmission system between Federal and non-Federal power using the system. In compliance with a FERC order dated January 27, 1984, 26 FERC ¶61,096, the Revenue Requirement Study incorporates the results of separate repayment studies for the generation and transmission components of the FCRPS. The repayment studies for generation and transmission demonstrate the adequacy of the projected revenues to recover all of the Federal investment in the FCRPS over the allowable repayment period. The adequacy of projected revenues to recover test period revenue requirements and to meet repayment period recovery of the Federal investment is tested and demonstrated separately for the generation and transmission functions.

The Revenue Requirement Study for the 1993 initial rate proposal is based on revenues and cost estimates for FY 1994 and FY 1995. BPA's Revenue Requirement Study reflects actual amortization and interest payments paid through September 30, 1992. In addition, it reflects all FCRPS obligations incurred pursuant to the Northwest Power Act, including residential exchange costs.

3. Segmentation Study

BPA operates and maintains the Federal Columbia River Transmission System (FCRTS) to provide transmission services throughout the region. Because most services do not require the use of the entire system, the FCRTS is divided into nine segments, each providing a distinct type of service. The nine segments are: Integrated network; Pacific Northwest-Pacific Southwest (Southern) Intertie; Northern Intertie; Eastern Intertie; generation integration; fringe area; and delivery segments for public agency, direct service industrial (DSI), and investor-owned utility customers.

The Segmentation Study categorizes the facilities of the FCRTS according to the types of services they provide. This provides the basis for segmenting the projected transmission revenue requirements used in BPA's rate proposals. The results of the Study include the historical investment and the average of the last 3 years' operations and maintenance expenses. In addition, the facilities of the integrated network are similarly divided among distinct services. This division of the FCRTS into segments provides the basis for the equitable allocation of transmission costs between Federal and non-Federal customers based on their usage of the segments.

4. Wholesale Power Rate Development Study (WPRDS)

The WPRDS consists of two sections. The first section is a cost of service analysis (COSA) and the second section shows the steps in the rate design process.

Cost of Service Analysis (COSA). The COSA apportions BPA's test year revenue requirement to customer classes based on the use of specific types of service by each customer class and in accord with the rate directives of the Northwest Power Act. BPA's revenue requirement is functionalized to transmission and generation in the Revenue Requirement Study. Transmission costs are identified with segments of the transmission system in BPA's Segmentation Study. The results of these studies are used in the COSA to determine the costs of providing generation and transmission services to BPA's customers.

Additionally, the COSA identifies resources purchased and loads served as well as costs incurred and revenues received under the Residential Exchange Program prescribed in section 5(c) of the Northwest Power Act. The COSA further identifies costs of specific types of service by performing the following steps:

Classification. BPA classifies generation and transmission costs to the energy and capacity components of electric power.

Seasonal Differentiation. BPA's costs of providing energy vary by season of the year. To reflect this variation, BPA assigns energy costs to winter and summer periods and designs rates based on this differential.

Allocation. The final major step in the COSA is to allocate the functionalized, segmented, classified, and seasonally differentiated costs to customer classes. Costs are allocated to classes of service on the basis of the relative use of services, and on the basis of priorities of service by resource pools provided in the Northwest Power Act.

The remaining steps use the allocated costs developed in the COSA and modifies them:

(1) To reflect BPA's rate design objectives;

(2) To conform with contractual requirements;

(3) To reflect the results of other BPA studies and commitments made in other public involvement processes under 7(i) of the Northwest Power Act; and

(4) To conform with requirements of applicable legislation, including the Bonneville Project Act, the Flood Control Act of 1944, the Transmission System Act, and the Northwest Project Act.

BPA's rate design objectives include recovery of BPA's revenue requirement, rate and revenue stability, practicality, fairness, and efficiency.

Rate design adjustments to the allocated COSA costs include the following:

Excess Revenue Adjustments. In the initial cost allocation, BPA allocates its entire test period revenue requirement to firm power loads on the basis of resources available under critical water conditions. However, rates are set assuming BPA recovers nonfirm sales revenues equal to the expected value of revenues under 50 years of streamflows in the historical record. Since no generation costs are allocated to NF service, forecasted NF revenues are credited against costs allocated to firm

loads. Similarly, revenues from nonfirm wheeling under the Energy Transmission (ET) Rate Schedule are credited to firm transmission loads.

DSI First Quartile Service. The DSIs are not allocated generation costs in the COSA for service to their First Quartile because BPA does not plan firm resources to serve the First Quartile. BPA serves DSI First Quartile loads with a combination of nonfirm energy, surplus firm power, hydro system shifting techniques, and economic purchases. BPA assigns a cost to First Quartile service based on an opportunity cost concept, and credits other rates through the excess revenue credit above, in the amount of the assigned First Quartile cost.

Fixed Contract Revenue Deficiencies. BPA delivers power at contractually fixed terms to two classes of customers. The Columbia Storage Power Exchange (CSPE) agreements has fixed rates, and a pre-Act capacity/energy exchange with Montana Power Company has fixed exchange ratios. In the COSA, BPA allocates costs to these customer classes. Because the contract rates and ratios cannot be adjusted, and because allocated costs exceed expected revenues, a revenue deficiency results. The revenue deficiency is allocated through an adjustment which increases rates charged to other rate classes.

Surplus Firm Power Revenue Deficiency Adjustment. BPA expects to sell any surplus firm power under long-term contracts and in the open market. Some of this surplus firm power will be sold at prices lower than the fully allocated cost, thereby causing a revenue deficiency. The difference between expected surplus firm power revenues and fully allocated costs is allocated to other customers.

Post-Act Exchange Revenue Deficiencies. BPA has entered into exchanges with out-of-region utilities that result in delayed return of energy. BPA directly allocates only transmission costs to these exchanges. Because the exchanges are noncash transactions, a revenue deficiency results. This revenue deficiency is allocated to winter users of Federal resource pools.

7(c)(2) Adjustment. The rates applicable to the DSIs are set at a level that is equitable in relation to BPA preference customers' industrial rates. The costs allocated to the DSIs are higher than revenues from the "equitable" rate. The difference is a revenue deficiency called the "7(c)(2) delta," which is allocated to other customers.

DSI Floor Rate Rounding Adjustment. The DSI rate is subject to a floor specified in section 7(c)(2) of the Northwest Power Act. If the calculated DSI rate is below the floor rate, the DSI rate is raised to the floor rate, and a rate design adjustment is necessary to credit additional revenues from the DSIs to other firm power customers. This adjustment was not necessary for this proposal. However, an adjustment is made to credit non-DSI rates to account for revenue differences between final rounded rate changes and intermediate use of unrounded VI rates.

7(b)(2) Adjustment. Section 7(b)(2) of the Northwest Power Act provides rate protection to BPA's preference customers from certain costs specified in the provisions of the Act. As discussed in greater detail below, the section 7(b)(2) rate test "triggers" in this proposal and requires the application of the 7(b)(2) adjustment.

The foregoing list of adjustments is not intended to be all-inclusive. All of the above adjustments are functionalized, classified, segmented, and seasonalized where appropriate. After all adjustments are made, the final rates are calculated.

Final rates calculated in the WPRDS are included in BPA's General Rate Schedules. These rate schedules are applied in conjunction with BPA's GRSPs, which define the applicability of the rates to the type of service provided.

5. Section 7(b)(2) Rate Test Study

Section 7(b)(2) of the Northwest Power Act directs BPA to assure that the wholesale power rates effective after July 1, 1985, to be charged its public body, cooperative, and Federal agency customers (the 7(b)(2) customers) for their general requirements for the rate test period plus the ensuing 4 years are no higher than the costs of power to those customers for the same time period if specified assumptions are made. The effect of the rate test is to protect the 7(b)(2) customers' wholesale firm power rates from certain costs resulting from provisions of the Northwest Power Act. The rate test can result in a reallocation of costs from the 7(b)(2) customers to other rate classes. The section 7(b)(2) Rate Test Study describes the application and results of the section 7(b)(2) rate test implementation methodology.

The rate projections and the actual rate test itself are performed using BPA's Supply Pricing Model (SPM). The SPM simulates BPA's rate development process, using load, resource, and cost data consistent with that used in this rate proposal. The assumptions and rate development processes such as load/resource balancing, cost allocation, and rate design are also consistent with this rate proposal. The SPM calculates two sets of wholesale power rates for BPA's preference customers:

(1) a set of rates for the test period and the ensuing 4 years, assuming that section 7(b)(2) is not in effect (program case rates); and

(2) A set for the same period considering the five assumptions listed in section 7(b)(2) (7(b)(2) case rates). Certain costs specified in section 7(g) of the Northwest Power Act (7(g) costs) are subtracted from the program case rates.

The SPM then discounts each year's rates to the test year of the relevant rate case, averages each set of discounted rates, and compares the two resulting averages rounded to the nearest tenth of a mill. If the average of the discounted program case rates, less the 7(g) costs, is larger than the average discounted 7(b)(2) case rates, the rate test triggers. If the rate test triggers, the amount of dollars to be reallocated in the test period (7(b)(2) amount) is calculated by multiplying the difference between the discounted program case and 7(b)(2) case rates by the general requirements loads of the preference customers. The 7(b)(2) amount is used as an adjustment to the allocated costs in the rate case test period. The rate test triggers in this proposal by 0.2 mills.

B. 10-Year Financial Plan

At the end of the 1991 rate case, BPA committed to develop a 10-Year Financial Plan jointly with customers and other interested parties before adopting long-term financial policies on a final basis that could affect the level of BPA's rates. During the latter part of 1991 and throughout 1992, BPA, its customers, and other interested parties in the region participated in development of the 10-Year Financial Plan. In April, BPA released a Staff Comment Draft of the 10-Year Financial Plan for public review and comment. BPA then developed the Proposed 10-Year Financial Plan, taking into consideration the comments received on the earlier draft. In June, the Proposed 10-Year Financial Plan was released for review and comment in BPA's Programs in Perspective (PIP) process. A final version of the 10-Year Financial Plan will be released in January 1993. The financial policies included in the 10-Year Financial Plan are reflected in the revenue requirement and rate levels for review and implementation in the 1993 rate case.

A primary component contained in the 10-Year Financial Plan is the agency's long-term policy choice to continue a 95 percent probability standard of meeting Treasury payments in full and on time in each rate period. The 10-Year Financial Plan identifies

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the target level of financial reserves necessary to achieve this standard, and outlines the individual risk mitigation components the BPA will rely on as part of its risk mitigation planning to achieve the target level of reserves. The 10-Year Financial Plan also identifies the planned sources of funding for FCRPS capital investments, and calls for use of debt to finance FCRPS capital investments, except that revenues may be used on a limited basis for certain nuclear project capital expenditures.

In implementing the long-term 95 percent probability standard of meeting Treasury payments in full and on time in each rate period, BPA is incorporating a phase-in approach for the FY 1994–1995 rate period. Rates during the FY 1994–95 rate period will be established to achieve a 90 percent probability of meeting Treasury payments over the two-year period. Adoption of this phase-in approach helps to reduce the immediate rate pressures BPA faces while still achieving a significantly high probability that Treasury payments will be made in full and on time in each year of the FY 1994–1995 rate period.

To achieve this financial objective, BPA's Initial Proposal includes 3 primary tools for mitigating risk. These risk mitigation tools include:

(1) An increment of annual Planned Net Revenues for risk that is explicitly included in revenue requirements;

(2) Adoption of an Interim Rate Adjustment (IRA); and

(3) A cost deferral mechanism.

The IRA and cost deferral mechanisms are designed to be used only under certain predetermined conditions wherein BPA's ending financial reserve level at the end of FY 1994 would reach a specified "trigger point."

To analyze the normal operating risk that BPA faces in a given rate period, BPA conducted risk analyses using the Short-Term Risk Evaluation and Analysis Model (STREAM). The STREAM provides for a systematic analytical framework for evaluating BPA's normal operating risks, including streamflows, aluminum and fuel prices, nuclear plant performance, economic conditions, and weather conditions. Alternative risk mitigation tools and the specific tool parameters were then tested using the Tool Kit model. The Tool Kit model enables an evaluation of the sufficiency of alternative combinations of tools to provide risk protection sufficient to meet the specified probability of meeting Treasury payments in full and on time in each year of a given rate period. The data, assumptions, and logic incorporated in the STREAM and Tool Kit model can significantly affect the target level of financial reserves and the level of Planned Net Revenues for risk needed to meet the Treasury payment standard.

In the 1993 rate case, BPA will propose methods for implementing various aspects of the financial policies reflected in the 10-Year Financial Plan. Consistent with the agreement reached in the settlement of the 1991 rate case, the financial policies reflected in the 10-Year Financial Plan will be subject to further review and implementation in the 1993 rate case. Such implementation issues may include: STREAM and Tool Kit assumptions, design, and logic; target level of reserves; specific IRA design issues; public process requirements for implementing the IRA; level of Planned Net Revenues for Risk; and the method of functionalizing Planned Net Revenues for risk and the Interest Credit between the generation and transmission functions.

C. Purpose and Scope of Hearing

BPA's proposal to revise its rates is needed in order to continue to recover all costs and expenses allocated to the power system, including amortization of the Federal investment in the Federal Columbia River Power System over a reasonable period of time, and to recover funds sufficient to achieve the goals of BPA's 10-Year Financial Plan. Inasmuch as cost recovery requirements along necessitate substantial increases to BPA's rates, BPA seeks to avoid further disruption of its customers' needs for rate predictability and stability. Thus, alternative approaches to rate design to incorporate or modify price signals to achieve energy and resource efficiency are beyond BPA's need. Moreover, lack of reliable information on such alternatives, the substantial changes that are occurring and will occur in operating characteristics of BPA's system, and the ongoing development of the Endangered Species Act and Systems Operation Review all militate in favor of deferring alternative rate design considerations to the 1995 rate case.

At the conclusion of the 1991 rate case, BPA committed to develops a 10-Year Financial Plan through a process of public consultation. In addition, BPA pledged that to the extent the proposed goals of the Plan directly affected rate levels, it would include the incremental rate impacts and associated rationale as part of a special or general 7(i) process.

Beginning in March 1991, BPA solicited input into the scope and content of its 10-Year Financial Plan from customers in interviews throughout the region. From October 1991 to April 1992, numerous technical and policy oriented workgroups held meetings to identify key financial issues and to develop, analyze, and evaluate risk mitigation and capital funding options that addressed the issues. BPA then released its Proposed 10-Year Financial Plan in April for review and comment in its Programs In Perspective (PIP) public involvement process.

The PIP process commenced in April in order to develop the 10-Year Financial Plan and determine program levels for Fiscal Years 1994 and 1995. Interested persons had the opportunity to solicit information from BPA, meet with program managers to discuss program issues, and to submit oral and written comments to BPA in July and August 1992. In addition, the opportunity was extended to interested parties to meet and discuss the proposed 10-Year Financial Plan and program levels with BPA management, including the Administrator, in a series of meetings that occurred throughout the region in July. Numerous other public processes to determine BPA's program needs fed into PIP. BPA released its decision on the 10-Year Financial Plan and program levels on September 11, 1992. The Final PIP version of the 10-Year Financial Plan that elaborates BPA's consideration of the regional discussions will be released in January 1993 for review and implementation in BPA's 1993 rate case.

On April 3, 1992, when the Administrator formally announced the scope and schedule for PIP to all customers and interested parties, he stated as follows concerning the intended effect of PIP:

> In the end, the material discussed in PIP requires the kind of management judgment calls that we cannot fairly assign to our technical or legal staffs. That is why I place such importance on the personal participation during PIP itself by utility managers and policymakers on energy and the environment.
>
> After PIP, attention will then shift from these planning concerns to the more technical issues of the rate case and to the host of other contract and policy forums yet ahead of us. The rate case itself will focus on issues of cost allocation and recovery, and, if necessary, long-term financial goals. The proceedings will begin first with informal workshops through December and then move into the formal rate case itself at the beginning of 1993. (April 3, 1992, Administrator's letter to all customers and interested parties.)

This was reiterated in the Administrator's September 11, 1992, document closing out the 1992 PIP entitled "Setting the Financial Course for Fiscal Years 1993, 1994, 1995." The

Administrator described attachment B to the document as showing "final program levels," and stated, "These levels will not be revisited in the upcoming rate case, although BPA is willing to further discuss them as part of a comprehensive settlement of rate case issues."

Consistent with BPA's prior agreement, implementation of the 10-Year Financial Plan will be addressed in this rate case. Except for the limited exceptions hereafter noted, program and program level decisions will not be addressed in this rate case. Accordingly, pursuant to section 1010.3(f) of the "Procedures Governing Bonneville Power Administration Rate Hearings," 51 FR 7611 (March 5, 1986), the Administrator directs the Hearing Officer to exclude from the record any material attempted to be submitted or arguments attempted to be made in the hearing which seek to in any way visit the appropriateness or reasonableness of BPA's decisions on programs or program levels, as included in BPA's cost evaluation period of FY 1993 through FY 1995 and its test period revenue requirement for Fiscal Years 1994 and 1995. Excepted from this direction on account of their variable nature, dependency on BPA's rate case models, or timing, are:

(1) Forecasts of residential exchange benefits;

(2) Forecasts of purchase power costs;

(3) Provision in BPA's revenue requirement for cash working capital or cash lag needs;

(4) Repayment matters, such as interest rate forecasts, scheduled amortization, depreciation, replacements, and interest expense; and

(5) Updates to forecasts by BPA which may occur in the spring of 1993 and for which no other review forum has been provided.

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A. Wholesale Power Rate Schedules

Schedule PF–93 Priority Firm Power Rate

Section I. Availability

This schedule is available for the contract purchase of firm power or capacity to be used within the Pacific Northwest. Priority Firm Power may be purchased by public bodies, cooperatives, and Federal agencies for resale to ultimate consumers for direct consumption, construction, test and startup, and station service.

Utilities participating in the exchange under section 5(c) of the Northwest Power Act may purchase Priority Firm Power pursuant to their Residential Purchase and Sale Agreements.

In addition, BPA may make power available to those parties participating in exchange agreements which use this rate schedule as the basis for determining the amount or value of power to be exchanged.

This schedule supersedes Schedule PF–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's General Rate Schedule Provisions (GRSPs).

Section II. Rate

This rate schedule includes the Preference rate and the Exchange rate. The Preference rate is available for the general requirements of public body, cooperative and Federal agency customers and includes a credit attributed to the provision of section 7(b)(2) of the Northwest Power Act. The Exchange rate is available for all purchases of residential and small farm exchange power pursuant to the Residential Purchase and Sale Agreements.

A. *Preference Rate.*

1. *Demand Charge.*

a. $4.00 per kilowattmonth of billing demand occurring during all Peak Period hours.

b. No demand charge during Offpeak Period hours.

2. *Energy Charge.*

a. 21.3 mills per kilowatthour of billing energy for the billing months September through March.

b. 16.2 mills per kilowatthour of billing energy for the billing months April through August.

B. *Exchange Rate.*

1. *Demand Charge.*

a. $4.06 per kilowattmonth of billing demand occurring during all Peak Period hours.

b. No demand charge during Offpeak Period hours.

2. *Energy Charge.*

a. 21.8 mills per kilowatthour of billing energy for the billing months September through March.

b. 16.4 mills per kiowatthour of billing energy for the billing months April through August.

Section III. Billing Factors

In this section, billing factors are listed for each of the following types of purchasers: computed requirements purchasers (section III.A), purchasers of residential exchange power pursuant to the Residential Purchase and Sale Agreements (section III.B), and metered requirements purchasers and those Priority Firm Power purchasers not covered by sections III.A and III.B (section III.C).

A. *Computed Requirements Purchasers.*

Purchasers designated by BPA as computed requirements purchasers pursuant to power sales contracts shall be billed in accordance with the provisions of this subsection.

1. *Billing Demand.*

The billing demand for actual, planned, and contracted computed requirements purchasers shall be the higher of the billing factors "a" and "b" below:

a. The lower of:

(1) The larger of the Computed Peak Requirement or the Computed Average Energy Requirement; or

(2) The Measured Demand, before adjustment for power factor.

b. The lower of:

(1) The Computed Peak Requirement; or

(2) 60 percent of the highest Computed Peak Requirement during the previous 11 billing months (Ratchet Demand).

2. *Billing Energy.*

The billing energy for actual, planned, and contracted computed requirements purchasers shall be:

a. For the months September through March, the sum of:

(1) 67 percent of the Measured Energy (excluding unauthorized increase); and

(2) 33 percent of the Computed Energy Maximum.

b. For the months April through August, the sum of:

(1) 60 percent of the Measured Energy (excluding unauthorized increase); and

(2) 40 percent of the Computed Energy Maximum.

(B). *Purchasers of Residential Exchange Power.*

Purchasers buying Priority Firm Power under the terms of a Residential Purchase and Sale Agreement shall be billed as follows:

1. *Billing Demand.*

The billing demand shall be the demand calculated by applying the load factor, determined as specified in the Residential Purchase and Sale Agreement, to the billing energy for each billing period.

2. *Billing Energy.*

The billing energy shall be the energy associated with the utility's residential load for each billing period. Residential load shall be computed in accordance with the provisions of the purchaser's Residential Purchase and Sale Agreement.

C. *Metered Requirements Purchasers, Other Purchasers Not Covered by Sections III.A and III.B, Above.*

Purchasers designated as metered requirements customers and purchasers taking or exchanging power under this rate schedule who are not otherwise covered by sections III.A and III.B shall be billed as follows:

1. *Billing Demand.*

The billing demand shall be the Measured Demand as adjusted for power factor, unless otherwise specified in the power sales contract.

2. *Billing Energy.*

The billing energy shall be the Measured Energy, unless otherwise specified in the power sales contract.

Section IV. Adjustments and Special Provisions

A. *Power Factor Adjustment.*

The adjustment for power factor, when specified in this rate schedule or in the power sales contract, shall be made in accordance with the provisions of both this section and section III.C.1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment, BPA shall increase the billing demand by 1 percentage point for each percentage point or major fraction thereof (0.5 or greater) by which the average power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

B. *Low Density Discount (LDD).*

BPA shall apply a discount to the charges for all Priority Firm Power sold to purchasers who are eligible for an LDD. Eligibility for the LDD and the amount of the discount (3, 5, or 7 percent) shall be determined pursuant to section III.C.3 of the GRSPs.

C. *Irrigation Discount.*

BPA shall apply an irrigation discount, equal to 4.9 mills per kilowatthour, to the charges for qualifying energy purchased under this rate schedule. The irrigation discount shall be applied after calculation of the LDD. The discount shall apply only to energy purchased during the billing months of April through October. Eligibility for the irrigation discount and reporting requirements shall be determined pursuant to Section III.C.4 of the GRSPs.

D. *Conservation Surcharge.*

The Northwest Power Planning Council has recommended that a conservation surcharge be imposed on those customers subject to such surcharge as determined by the Administrator in accordance with BPA's Policy to Implement the Council-Recommended Conservation Surcharge. The Conservation Surcharge shall be applied pursuant to section III.C.7 of the GRSPs and subsequent to any other rate adjustments.

E. *Outage Credit.*

Pursuant to section 7 of the General Contract Provisions, BPA shall provide an outage credit to any purchaser for those hours for which BPA is unable to deliver the full billing demand during that billing month due to an outage on the facilities used by BPA to deliver Priority Firm Power. Such credit shall not be provided if BPA is able to serve the purchaser's load through the use of alternative facilities or if the outage is for less than 30 minutes. The amount of the credit shall be calculated according to the provisions of section III.C.2 of the GRSPs.

F. *Unauthorized Increase.*

BPA shall apply the charge for Unauthorized Increase to any purchaser of Priority Firm Power taking demand and energy in excess of its contractual entitlement.

1. *Rate for Unauthorized Increase.*

100.00 mills per kilowatthour.

2. *Calculation of the Amount of Unauthorized Increase.*

Each 60-minute clock-hour integrated or scheduled demand shall be considered separately in determining the amount that may be considered an unauthorized increase. BPA first shall determine the amount of unauthorized increase related to demand and shall treat any remaining unauthorized increase as energy-related.

a. *Unauthorized Increase in Demand.*

That portion of any Measured Demand during Peak Period hours, before adjustment for power factor, which exceeds the demand that the purchaser is contractually entitled to take during the billing month and which cannot be assigned:

(1) To a class of power that BPA delivers on such hour pursuant to contracts between BPA and the purchaser; or

(2) To a type of power that the purchaser acquires from sources other than BPA and that BPA delivers during such hour, shall be billed:

(a) In accordance with the provisions of the "Relief from Overrun" exhibit to the power sales contract; or

(b) If such exhibit does not apply or is not a part of the purchaser's power sales contract, at the rate for Unauthorized Increase, based on the amount of energy associated with the excess demand.

b. *Unauthorized Increase in Energy.*

The amount of Measured Energy during a billing month which exceeds the amount of energy which the purchaser is contractually entitled to take during that month and which cannot be assigned:

(1) To a class of power which BPA delivers during such month pursuant to contracts between BPA and the purchaser; or

(2) To a type of power which the purchaser acquires from sources other than BPA and which BPA delivers during such month, shall be billed:

(a) In accordance with the provisions of the "Relief from Overrun" exhibit to the power sales contract; or

(b) As unauthorized increase if such exhibit does not apply or is not a part of the purchaser's power sales contract.

G. *Interim Rate Adjustment.*

The Interim Rate Adjustment (IRA) described in section III.C.5 of the GRSPs shall be applied uniformly to all purchases and exchanges under the PF–93 rate schedule if: (1) The balance of BPA's financial reserves falls below the IRA trigger point at the end of FY 1994; and (2) the Administrator elects, at his discretion, to implement the IRA. An increase not to exceed 10 percent shall be applied uniformly to the demand and energy charges contained in section II.A and II.B of this rate schedule. The IRA shall be applied in the following manner:

[1+(IRA%/100)] Multiplied by the demand and energy charges contained in sections II.A and II.B of this rate schedule.

An additional increment of 0.049 mills per kilowatthour shall be made to the irrigation discount for each percentage increase in the PF rates due to the IRA.

H. *Coincidental Billing Adjustment.*

Purchasers of Priority Firm Power who are billed on a coincidental basis and who have diversity charges or diversity factors specified in their power sales contracts shall have their charges

for billing demand adjusted according to the provisions of section III.C.6 of the GRSPs. Computed requirements purchasers are not subject to the Coincidental Billing Adjustment for scheduled power.

I. *Energy Return Surcharge.*

Any purchaser who preschedules in accordance with sections 2(a)(4) and 2(c)(2) of Exhibit E of the power sales contract and who returns, during a single offpeak hour, more than 60 percent of the difference between that purchaser's billing demand and computed average energy requirement for the billing month shall be subject to the following surcharge for each additional kilowatthour so returned:

1. 3.94 mills per kilowatthour for the months of April through October;
2. 1.67 mills per kilowatthour for the months of November through March.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resource categories to the PF–93 rate is 75.1 percent FBS and 24.9 percent Exchange.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule IP—93 Industrial Firm Power Rate

Section I. Availability

This schedule is available to direct service industrial (DSI) customers for both the contract purchase of Industrial Firm Power and the purchase of Auxiliary Power if requested by the DSI customer and made available by BPA. If a DSI customer purchasing power under this rate schedule requests and BPA makes available power under another applicable wholesale rate schedule, the IP–93 rate schedule is available for that portion of power purchased not covered under the alternative rate schedule. This rate schedule supersedes Schedule IP–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's General Rate Schedule Provisions (GRSPs).

Section II. Rate

The following rates shall be applied when first quartile service is provided under this rate schedule in accordance with the terms of a purchaser's Power Sales Contract dated August 25, 1981. A separate billing adjustment for the reserves provided by the purchasers of Industrial Firm Power is not contained in this rate schedule; the value of reserves credit has been included in the determination of the demand and energy charges.

Any contractual reference to the IP Premium rate shall be deemed to refer to the demand and energy charges set forth below. Any reference to the IP Standard rate shall be deemed to refer to the same demand and energy charges minus the Discount for Quality of First Quartile Service.

A. *Demand Charge.*

1. $4.94 per kilowattmouth of billing demand occurring during all Peak Period hours.
2. No demand charge during Offpeak Period hours.

B. *Energy Charge.*

1. 20.9 mills per kilowatthour of billing energy for the billing months September through March.
2. 16.8 mills per kilowatthour of billing energy for the billing months April through August.

Section III. Billing Factors

A. *Billing Demand.*

The billing demand shall be the BPA Operating Level during the Peak Period as adjusted for power factor. It there is more than one BPA Operating Level during the Peak Period within a billing month, the billing demand shall be a weighted average of the BPA Operating Levels during the Peak Period for the billing month. The BPA Operating Level is defined in section III.A.10 of the GRSPs. If BPA has agreed to serve a portion of a DSI load under an alternative rate schedule, the billing demand under the IP–93 rate schedule shall be specified in the contract initiating such arrangement.

However, if BPA has agreed, pursuant to section 4 of the DSI power sales contract, to sell Industrial Firm Power on a daily demand basis (transitional service), then BPA shall bill the purchaser in accordance with the provisions of section V.C.3 of the GRSPs.

B. *Billing Energy.*

The billing energy shall be the Measured Energy for the billing month, minus any kilowatthours on which BPA assesses the charge for unauthorized increase.

However, if BPA has agreed to serve only a portion of the DSI's load under the IP rate schedule, the billing energy for the power purchased under the IP rate shall be specified in the contract initiating such arrangement.

Section IV. Adjustments and Special Provisions

A. *Discount for quality of First Quartile Service.*

1. *Application and Amount of First Quartile Discount.*

If a purchaser requests discounted rate service, a discount of 0.7 mills per kilowatthour of billing energy shall be granted. This billing credit shall be applied to the monthly billing energy under section III.B for all power purchased under this rate schedule. No credit shall be applied to those purchases subject to unauthorized increase charges under section IV.D of this rate schedule.

2. *Eligibility Requirements for First Quartile Discount.*

To qualify for the First Quartile Discount the purchaser must request discounted rate service in writing by April 2 of each calendar year. By virtue of making such request, the Purchaser is agreeing to accept the level and quality of First Quartile service described in section 6 of the Variable Industrial rate contract. Such acceptance includes the waiver of contract rights provided in section 6.a(2)(a) of said contract.

B. *Curtailments.*

BPA shall charge the DSI for curtailments of the lower three quartiles in accordance with the provisions of section 9 of the power sales contract. BPA shall apply the demand charge in effect at the time of the curtailment in the computation of the amount of the curtailment charge. In the event that a purchaser is found to be eligible to have a portion of their load served under an alternative rate schedule, application of the curtailment charge shall be specified in the contract instituting such arrangement.

C. *Unauthorized Increase.*

1. *Rate for Unauthorized Increase.*

100.0 mills per kilowatthour.

2. *Application of the Charge.*

During any billing month, BPA may assess the unauthorized increase charge on the number of kilowatthours associated with the DSI Measured Demand in any one 60-minute clock-hour, before adjustment for power factor, that exceed the BPA Operating Level for that clock-hour, regardless of whether such Measured Demand occurs during the Peak or Offpeak Period.

D. *Power Factor Adjustment.*

The adjustment for power factor, when specified in this rate schedule or in the power sales contract, shall be made in accordance with the provisions of both this section and section III.C.1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment, BPA shall increase the billing demand by 1 percentage point for each

percentage point or major fraction thereof (0.5 or greater) by which the average leading power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

E. *Outage Credit.*

Pursuant to section 7 of the General Contract Provisions, BPA shall provide an outage credit to any DSI for those hours for which BPA is unable to deliver the full billing demand during that billing month due to an outage on the facilities used by BPA to deliver Industrial Firm Power. Such credit shall not be provided if BPA is able to serve the DSI's load through the use of alternative facilities or if the outage is for less than 30 minutes. The amount of the credit shall be calculated according to the provisions of section III.C.2 of the GRSPs.

F. *Interim Rate Adjustment.*

The Interim Rate Adjustment (IRA) described in section III.C.5 of the GRSPs shall be applied to all power purchases under the IP–93 rate schedule if the balance of BPA's financial reserves: (1) Falls below the IRA trigger point at the end of FY 1994; and (2) the Administrator elects, at his discretion, to implement the IRA. An increase not to exceed 10 percent shall be applied to the IP–93 rate schedule. Application of the IRA shall result in a uniform adjustment applied to the demand and energy charges, contained in sections II.A and II.B of this rate schedule, and the First Quartile Service Discount contained in section IV.A.1 of this rate schedule.

The IRA shall be applied in the following manner:

[1+(IRA%/100)] Multiplied by the demand and energy charges contained in sections II.A and II.B of this rate schedule, and the First Quartile service discount contained in section IV.A.1 of this rate schedule.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resource categories to the IP–93 rate is 89.2 percent Exchange and 10.8 percent New Resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule VI–91 Variable Industrial Power Rate

Section I. Availability

This schedule is available to DSI customers for purchases under the Power Sales Contract implementing the VI rate schedule (Variable Rate Contracts) of: (1) Industrial Firm Power; and (2) Auxiliary Power if requested by the DSI customer and made available by BPA. This schedule is available only for that portion of a DSI's load used in primary aluminum reduction including associated administrative facilities, if any. By virtue of incorporation of this rate schedule and associated GRSPs in the Variable Rate Contract, DSIs electing to purchase power under this rate schedule contractually agree to the terms and conditions of this rate schedule. A DSI further agrees to waive, for that portion of their load designated to purchase power at the VI rate, all rights they might otherwise have to purchase power at the Industrial Firm Power Rate Schedule for the duration of the Variable Rate Contract. Sales under this schedule are made subject to BPA's GRSPs effective October 1, 1989, and as revised in subsequent wholesale rate filings.

Section II. Term of the Rate

This rate schedule shall take effect on July 1, 1993, and shall terminate at midnight June 30, 1996.

Section III. Rate

A. *Base Rate Charges Subject to Rate Case Adjustments.*

The following base rates shall be adjusted on Rate Adjustment Dates beginning October 1, 1991, following the procedures set forth in section V. of this rate schedule, unless the Interim Rate Adjustment triggers, at which point the rates shall be adjusted following the procedures set forth in section VII. of this rate schedule. In addition, the Lower Rate Limit also will be subject to a biennial adjustment pursuant to section V, of this rate schedule. The formula to be used in the calculation of the monthly power bill is contained in section IV. A separate billing adjustment for the value of the reserves provided by purchasers of Industrial Firm Power is not contained in this rate schedule; the value of reserves credit has been included in the determination of the Plateau Energy Charge. On July 1, 1993, the base rates, as adjusted, shall be applied to purchases by DSI customers under the Variable Rate Contract. These rates shall continue to be adjusted, as described, through June 30, 1996.

1. *Base Variable Industrial Rate.*

a. *Demand Charge.*

$5.33 per kilowatt of billing demand, as adjusted, occurring during the Peak Period. (For the rate period beginning October 1, 1993, the demand charge shall be $5.87 per kilowatt of billing demand.) No demand charge is applied during Offpeak Period hours.

b. *Plateau Energy Charge.*

16.1 mills per kilowatthour of billing energy, as adjusted. (For the rate period beginning October 1, 1993, the plateau energy charge shall be 17.7 mills per kilowatthour of billing energy.)

2. *First Quartile Service Discount.*

0.5 mills per kilowatthour of billing energy. (For the rate period beginnig October 1, 1993, the First Quartile service charge shall be 0.6 mills per killowatthours of billing energy.)

3. *Lower Rate Limit.*

10.3 mills per kilowatthour of billing energy. (For the rate period beginning October 1, 1993, the lower rate limit shall be 12.9 mills per kilowatthour of billing energy.)

4. *Upper Rate Limit.*

21.9 mills per kilowatthour of billing energy. (For the rate period beginning October 1, 1993, the upper rate limit shall be 23.5 mills per kilowatthour of billing energy.)

B. *Base Rate Parameters Subject to Annual Adjustments.*

The following base rate parameters will be adjusted annually starting on July 1, 1991, and every July 1 thereafter, in accordance with the procedures contain in section V. of the GRSPs. On July 1, 1993, the base rate parameters, as adjusted, shall be used in determining power bills for DSI customers purchasing power under the Variable Rate Contracts. These parameters shall continue to be adjusted as described through June 30, 1996.

1. *Lower Pivot Aluminum Price.* 68.5 cents per pound.

2. *Upper Pivot Aluminum Price.* 79.6 cents per pound.

Section IV. Formula

The Variable Industrial Power rate is a formula rate tied to the U.S. market price of aluminum. Under this rate schedule, the monthly energy charge varies in response to changes in the average price of aluminum in U.S. markets.

A. *Demand Charge.*

1. The Demand Charge, as stated in section III.A.1.a of this rate schedule, remains constant over all aluminum prices. The demand charge is applied to billing demand occurring during all Peak Period hours for all billing months.

2. No demand charge during Offpeak Period hours.

B. *Energy Charge.*

1. *Plateau Energy Charge.*

When the monthly billing aluminum price (described in section VII.A. of the GRSPs) is between the Lower Pivot Aluminum Price and the Upper Pivot Aluminum Price inclusive (as stated in sections III.B.1 and III.B.2 of this rate schedule), the monthly energy charge shall be the Plateau Energy Charge as stated in section III.A.1.b of this rate schedule.

2. *Reductions to Plateau Energy Charge.*

When the monthly billing aluminum price is less than the Lower Pivot Aluminum Price, the monthly energy charge shall be the greater of:

a. The Plateau Energy Charge–(LP—MAP)* (LS)

where:

LP=the Lower Pivot Aluminum Price as stated in section III.B.1 of this rate schedule.

MAP=the monthly billing aluminum price in cents per pound determined pursuant to section VII.A of the GRSPs

$$LS=\text{lower slope}=\frac{\text{1 mill per kilowatthour}}{\text{1 cent per pound}}$$

or

b. The Lower Rate Limit as stated in section III.A.3 of this rate schedule.

3. *Increases to Plateau Energy Charge.*

When the monthly billing aluminum price is greater than the Upper Pivot Aluminum Price, the monthly energy charge shall be the lesser of:

a. The Plateau Energy Charge + (MAP—UP)* (US)

where:

MAP=the monthly billing aluminum price in cents per pound, as determined according to section VII.A of the GRSPs.

UP=the Upper Pivot Aluminum Price as stated in section III.B.2 of this rate schedule.

$$US=\text{upper slope}=\frac{\text{0.75 mills per kilowatthour}}{\text{1 cent per pound}}$$

or

b. The Upper Rate Limit, as stated in section III.A.4 of this rate schedule.

Section V. Billing Factors

A. *Billing Demand.*

1. *Billing Demand for Customers Whose Entire BPA Load is Served at the VI Rate.*

The billing demand for power purchased shall be the BPA Operating Level during the Peak Period as adjusted for power factor. If there is more than one BPA Operating Level during the Peak Period within a billing month, the billing demand shall be a weighted average of the BPA Operating Levels during the Peak Period for the billing month. The BPA Operating Level is defined in section III.A.10 of the GRSPs.

2. *Billing Demand or Customers When Only a Portion of Their Total BPA Load is Served at the Variable Rate.*

The Billing Demand shall be the portion of the BPA Operating Level attributable to the VI rate as determined by the method specified in the Variable Rate Contract.

3. *Billing Demand During Periods of Transitional Service.*

If BPA has agreed, pursuant to section 4 of the DSI power sales contract, to sell Industrial Firm Power on a daily demand basis (transitional service), sections V.A.1 and V.A.2 of the rate schedule shall not apply, and BPA shall bill the purchaser in accordance with the provisions of section V.C of the GRSPs.

B. *Billing Energy.*

The billing energy for power purchased shall be the Measured Energy for the billing month, minus any kilowatthours on which BPA assesses the charge for unauthorized increase.

Section VI. Other Adjustments and Special Provisions

A. *Lower and Upper Pivot Aluminum Prices.*

Effective July 1, 1991, and every July 1 thereafter, the Lower and Upper Pivot Aluminum Prices set forth in section III.B of the rate schedule shall be adjusted following the procedures set forth in section VII.B of the GRSPs. The adjusted Lower and Upper Pivot Aluminum Prices shall supersede the Lower and Upper Pivot Aluminum Prices contained in section III.B of the rate schedule. The revised Lower and Upper Pivot Aluminum Prices shall be used for billing purposes and subsequent adjustments to the Lower and Upper Pivot Aluminum Prices.

B. *Lower Rate Limit.*

On July 1, 1992, and July 1, 1994, the Lower Rate Limit as stated in section III.A.3 shall be increased by 1 mill per kilowatthour. The revised Lower Rate Limit shall supersede the Lower Rate Limit as stated in section III.A.3 of the rate schedule. This increase is in addition to rate adjustment increases in the Lower Rate Limit described in section VI.C of this rate schedule. In the event that a rate adjustment date and the annual adjustment date occur simultaneously, the Lower Rate Limit shall be adjusted first for changes in the Plateau Energy Charge pursuant to section VI.C of this rate schedule, and then increased by 1 mill per kilowatthour. The revised Lower Rate Limit shall be used for billing purposes and subsequent rate adjustments.

C. *Rate Adjustments.*

The overall rate level of this rate shall be subject to adjustment in BPA's general wholesale power rate case following the procedures and directives of the Northwest Power Act. The overall rate level consists of the Demand Charge, Plateau Energy Charge, and First Quartile Service Adjustment contained in sections III.A.1 and III.A.2; these shall be adjusted by a uniform percentage based on the percentage change in the overall rate level. The Lower and Upper Rate Limits as stated in sections III.A.3 and III.A.4 of this rate schedule shall be adjusted by an amount equal to the change, in mills per kilowatthour, in the Plateau Energy Charge. The Lower and Upper Pivot Aluminum Prices shall not be adjusted in the rate case; rather, they shall be adjusted pursuant to the procedures described in section VII.B of the GRSPs. The lower and upper slopes shall not be adjusted. The rate for unauthorized increase shall be separately determined in each rate case.

D. *Discount for Quality of First Quartile Service.*

If a purchaser requests First Quartile service with other than Surplus Firm Energy Load Carrying Capability (FELCC), a discount contained in section III.A.2 of this rate schedule shall be granted. This billing credit shall be applied to the monthly billing energy under section V.B for all power purchased under this rate schedule. No credit shall be applied to those purchases subject to unauthorized increase charges under section VI.F of this rate schedule. To qualify for the First Quartile Discount, the purchaser must request discounted rate service in writing by April 2 of each calendar year. By virtue of making such request, the Purchaser is agreeing to accept the level and quality of First Quartile service described in section 6 of the Variable Rate Contract. Such acceptance includes the waiver of contract rights provided in section 6.a(2)(a) of said contract.

E. *Curtailments.*

BPA shall charge the customer for curtailments of the lower three quartiles in accordance with the provisions of section 9 of the power sales contract and the provisions contained in the Variable Rate Contract.

F. *Unauthorized Increase.*

1. *Rate for Unauthorized Increase.*

100.0 mills per kilowatthour.

2. *Application of the Charge.* During any billing month, BPA may assess the unauthorized increase charge on the number of kilowatthours associated with the DSI Measured Demand in any

one 60-minute clock-hour, before adjustment for power factor, that exceed the BPA Operating Level for that clock-hour, regardless of whether such Measured Demand occurs during the Peak or Offpeak Period.

G. *Power Factor Adjustment.*

The adjustment for power factor, when specified in this schedule or in the power sales contract, shall be made in accordance with the provisions of both this section and section III.C.1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment, BPA shall increase the BPA Operating Level by 1 percentage point for each percentage point or major fraction thereof (0.5 or greater) by which the average leading power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

H. *Outage Credit.*

Pursuant to section 7 of the General Contract Provisions, BPA shall provide an outage credit to any DSI to whom BPA is unable to deliver the full billing demand during that billing month due to an outage on the facilities used by BPA to deliver Industrial Firm Power. Such credit shall not be provided if BPA is able to serve the DSI's load through the use of alternative facilities or if the outage is for less than 30 minutes. The amount of the credit shall be calculated according to the provisions of section III.C.2. of the GRSPs.

I. *Interim Rate Adjustment.*

The Interim Rate Adjustment (IRA) described in section III.C.5 of the GRSPs shall be applied to all power purchases under the rate schedule if the balance of BPA's financial reserves: (1) Falls below the IRA trigger point at the end of FY 1994; and (2) the Administrator elects, at his discretion, to implement the IRA. An increase not to exceed 10 percent shall be applied to the VI–91 rate schedule consistent with the procedures to adjust the Variable Industrial rate and the provisions of the Variable Rate Contract. A uniform adjustment will be made only if it causes demand and Plateau Energy charges and the First Quartile Service Discount to increase.

The Interim Rate Adjustment shall be applied in the following manner:

[1+(IRA%/100)] multiplied by the demand and Plateau energy charges contained in section III.A.1 of this rate schedule and to the First Quartile Service Discount specified in Section III.A.2 of this rate schedule.

The Lower and Upper Rate Limits stated in sections III.A.3 and III.A.4 of this rate schedule shall be adjusted by an amount equal to the change, in mills per kilowatt-hour, to the Plateau Energy charge due to application of the Interim Rate Adjustment. The adjusted rate parameters shall be used for billing purposes and supersede the rate charges subject to the adjustment contained in section III.A of this rate schedule. The adjusted rate parameters shall also be used in subsequent rate adjustments pursuant to section III.B of this rate schedule and to subsequent biennial adjustments to the lower rate limit pursuant to section VI.B of this rate schedule.

Section VII Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resource categories to the VI–91 rate is 89.2 percent Exchange and 10.8 percent New Resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule SI–93 Special Industrial Power Rate

Section I. Availability

This rate schedule is available to any DSI purchaser using raw minerals indigenous to the region as its primary resource and qualifying for this special power pursuant to the procedures established in section 7(d)(2) of the Northwest Power Act. This schedule is available for the contract purchase of this special class of industrial power and also for the purchase of Auxiliary Power if requested by the DSI and made available by BPA. Schedule SI–93 supersedes schedule SI–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's General Rate Schedule Provisions (GRSPs).

Section II. Rate

A separate billing adjustment for the value of the reserves provided by purchasers of this special class of Industrial Power is not contained in the rate schedule; the adjustment is reflected in the Special Industrial Power Rate charges.

A. *Demand Charge.*

1. $3.54 per kilowattmonth of billing demand occurring during all Peak Period hours.

2. No demand charge during Offpeak Period hours.

B. *Energy Charge.*

1. 19.5 mills per kilowatthour of billing energy for the billing months September through March;

2. 14.4 mills per kilowatthour of billing energy for the billing months April through August.

Section III. Billing Factors

A. *Billing Demand.*

The billing demand for power purchased under the Standard Special Industrial Power rate shall be the BPA Operating Level during the Peak Period as adjusted for power factor. If there is more than one BPA Operating Level during the Peak Period within a billing month, the billing demand shall be a weighted average of the Peak Period BPA Operating Levels for the billing month. The BPA Operating Level is defined in section III.A.10 of the GRSPs.

However, if BPA has agreed, pursuant to section 4 of the direct service industrial power sales contract, to sell Special Industrial Power on a daily demand basis (transitional service), BPA shall instead bill the purchaser in accordance with the provisions of section V.C of the GRSPs.

B. *Billing Energy.*

The billing energy under the Special Industrial rate shall be the Measured Energy for the billing month, minus any kilowatthours on which BPA assesses the charge for unauthorized increase.

Section IV. Adjustments and Special Provisions

A. *Curtailments.*

BPA shall charge the DSI for curtailments in accordance with the provisions of the DSI's power sales contract. Any curtailment charge levied shall be computed using the Special Industrial Power rate.

B. *Unauthorized Increase Charge.*

1. *Rate for Unauthorized Increase.* 100.0 mills per kilowatthour.

2. *Application of the Charge.* During any billing month, BPA may assess the unauthorized increase charge on the number of kilowatthours associated with the DSI Measured Demand in any one 60-minute clock-hour, before adjustment for power factor, that exceed the BPA Operating Level for that clock-hour, regardless of whether such Measured Demand occurs during the Peak or Offpeak Period.

C. *Power Factor Adjustment.*

The adjustment for power factor, when specified in this rate schedule or in the power sales contract, shall be made in accordance with the provisions of both this section and section III.C.1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which

energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment for service under the Special Industrial Power rate, BPA shall increase the billing demand by 1 percentage point for each percentage point or major fraction thereof (0.5 or greater) by which the average leading power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

D. *Outage Credit.*

Pursuant to section 7 of the General Contract Provisions, BPA shall provide an outage credit to any purchaser for those hours for which BPA is unable to deliver the full billing demand during that billing month due to an outage on the facilities used by BPA to deliver Special Industrial Power. Such credit shall not be provided if BPA is able to serve the purchaser's load through the use of alternative facilities or if the outage is for less than 30 minutes. The amount of the credit shall be calculated according to the provisions of section III.C.2 of the GRSPs.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The SI–93 rate is not based on the cost of resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule CE–93 Emergency Capacity Rate

Section I. Availability

This schedule is available for the purchase of capacity provided the purchaser requests such capacity and BPA has determined that capacity available for such purpose. This schedule is available when:

A. When an emergency exists on the purchaser's system, or

B. When the purchaser wishes to displace higher-cost firm capacity resources which are otherwise available to meet the purchaser's load.

This schedule supersedes Schedule CE–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's General Rate Schedule Provisions.

Section II. Rate

A. *Demand Charge.*

As mutually agreed by BPA and the purchase, up to $0.31 per kilowatt of demand per calendar day or portion thereof.

B. *Intertie Charge.*

The demand charge specified above shall be increased by $0.04 per kilowatt per day for capacity made available at the Oregon-California or Oregon-Nevada border for delivery over the Pacific Northwest-Pacific Southwest (Southern) Intertie.

Section III. Billing Factors

The billing demand shall be the maximum amount request by the purchaser and made available by BPA during a calendar day. If BPA is unable to meet subsequent requests by a purchaser for delivery at the demand previously established during such day, the billing demand for that day shall be the lower demand which BPA is able to supply.

Section IV. Billing Period

Bills shall be rendered monthly.

Section V. Special Provision

Energy delivered with such capacity shall be returned to BPA within 7 days of the date of delivery and shall be returned at times and rates of delivery agreed to by both the purchaser and BPA prior to delivery. BPA may agree to accept the return energy after the normal 7 day return period provided that such delay has been mutually agreed upon prior to delivery.

Section VI. Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resource categories to the CE–93 rate is 93 percent Exchange and 7 percent New Resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule NR–93 New Resource Firm Power Rate

Section I. Availability

The schedule is available for the contract purchase of firm power or capacity to be used within the Pacific Northwest. New Resource Firm Power is available to investor-owned utilities (IOUs) under net requirements contracts for resale to ultimate consumers, direct, consumption, or use in construction, test and start up, and station service. New Resource Firm Power also is available to any public body, cooperative, or Federal agency to the extent such power is needed to serve any New Large Single Load. In addition, BPA may make this rate available to those parties participating in exchange agreements that use this rate schedule as the basis for determining the amount or value of power to be exchanged. This schedule supersedes Schedule NR–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's General Rate Schedule Provisions (GRSPs).

Section II. Rate

A. *Demand Charge.*

1. $5.11 per kilowattmonth of billing demand occurring during all Peak Period hours.

2. No demand charge during Offpeak Period hours.

B. *Energy Charge.*

1. 29.3 mills per kilowatthour of billing energy for the billing months September through March.

2. 23.8 mills per kilowatthour of billing energy for the billing months April through August.

Section III. Billing Factors

In this section billing factors are listed for computed requirements purchasers (section III.A), metered requirements purchasers, and those purchasers not covered by section III.A (section III.B).

A. Computed Requirements Purchasers.

Purchasers designated by BPA as computed requirements purchasers pursuant to power sales contracts shall be billed in accordance with the provisions of this section.

1. *Billing Demand.*

The billing demand for actual, planned, and contracted computed requirements purchasers shall be the higher of the billing factors "a" and "b" below:

a. The lower of:

(1) The larger of the Computed Peak Requirement or the Computed Average Energy Requirement; or

(2) The Measured Demand, before adjustment for power factor.

b. The lower of:

(1) the Computed Peak Requirement; or

(2) 60 percent of the highest Computed Peak Requirement during the previous 11 billing months (Ratchet Demand).

2. *Billing Energy.*

The billing energy for actual, planned, and contracted computed requirements purchasers shall be:

a. For the months September through March, the sum of:

(1) 49 percent of the Measured Energy; and

(2) 51 percent of the Computed Energy Maximum

b. For the months April through August, the sum of:

(1) 41 percent of the Measured Energy; and

(2) 59 percent of the Computed Energy Maximum.

B. *Metered Requirements Purchasers and Other Purchasers Not Covered By Section III.A, Above.*

Purchasers designated as metered requirements customers and purchasers taking power under this rate schedule who are not otherwise covered by section III.A shall be billed as follows:

1. *Billing Demand.*

The billing demand shall be the Measured Demand as adjusted for power factor, unless otherwise specified in the power sales contract. However, purchasers who previously used the Firm Energy rate schedule, FE–2, either in the computation of their power bills or in the determination of the value of an exchange account, shall not be charged for demand under this rate schedule.

2. *Billing Energy.*

The billing energy shall be the Measured Energy, unless otherwise specified in the power sales contract.

Section IV. Adjustments and Special Provisions

A. *Power Factor Adjustment.*

The adjustment for power factor, when specified in this rate schedule or in the power sales contract, shall be made in accordance with the provisions of both this section and section III.C1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment, BPA shall increase the billing demand by 1 percentage point for each percentage point or major fraction thereof (0.5 or greater) by which the average leading power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

B. *Irrigation Discount.*

BPA shall apply an irrigation discount, equal to 4.9 mills per kilowatthour, to the charges for qualifying energy purchased under this rate schedule. The discount shall apply only to energy purchased during the billing months of April through October. Eligibility for the irrigation discount and reporting requirements shall be determined pursuant to section III.C.4 of the GRSPs.

C. *Conservation Surcharge.*

The Conservation Surcharge shall be applied in accordance with section III.C.7 of the GRSPs and subsequent to any other rate adjustments.

D. *Unauthorized Increase.*

BPA shall apply the charge for Unauthorized Increase to any purchaser of New Resource Firm Power taking demand and/or energy in excess of its contractual entitlement.

1. *Rate for Unauthorized Increase.*

100.0 mills per kilowatthour.

2. *Calculation of the Unauthorized Increase.*

Each 60-minute clock-hour integrated or scheduled demand shall be considered separately in determining the amount which may be considered an unauthorized increase. BPA shall first determine the amount of unauthorized increase related to demand and shall then treat any remaining unauthorized increase as energy-related.

a. *Unauthorized Increase in Demand.*

That portion of any Measured Demand during Peak Period hours, before adjustment for power factor, that exceeds the demand which the purchaser is contractually entitled to take during the billing month and that cannot be assigned:

(a) To a class of power which BPA delivers on such hour pursuant to contracts between BPA and the purchaser; or

(2) To a type of power which the purchaser acquires from sources other than BPA and which BPA delivers during such hour, shall be billed:

(a) In accordance with the provisions of the "Relief for Overrun" exhibit to the power sales contract; or

(b) If such exhibit does not apply or is not a part of the purchaser's power sales contract, at the rate for Unauthorized Increase, based on the amount of energy associated with the excess demand.

b. *Unauthorized Increase in Energy.*

The amount of Measured Energy during a billing month that exceeds the amount of energy which the purchaser is contractually entitled to take during that month and that cannot be assigned:

(1) To a class of power that BPA delivers during such month pursuant to contracts between BPA and the purchaser; or

(2) To a type of power that the purchaser acquires from sources other than BPA and that BPA delivers during such month, shall be billed:

(a) In accordance with the provisions of the "Relief from Overrun" exhibit to the power sales contract; or

(b) As unauthorized increase if such exhibit does not apply or is not a part of the purchaser's power sales contract.

E. *Coincidental Billing Adjustment.*

Purchasers of New Resource Firm Power who are billed on a coincidental basis and who have diversity charges or diversity factors specified in their power sales contracts shall have their charges for billing demand adjusted according to the provisions of section III.C.6 of the GRSPs. Computed requirements purchasers are not subject to the Coincidental Billing Adjustment for scheduled power.

F. *Outage Credit.*

Pursuant to section 7 of the General Contract Provisions, BPA shall provide an outage credit to any purchaser for those hours for which BPA is unable to deliver the full billing demand during the billing month due to an outage on the facilities used by BPA to deliver New Resource Firm Power. Such credit shall not be provided if BPA is able to serve the purchaser's load through the use of alternative facilities or if the outage is for less than 30 minutes. The amount of the credit shall be calculated according to the provisions of section III.C.2 of the GRSPs.

G. *Energy Return Surcharge.*

Any purchaser who preschedules in accordance with sections 2(a)(4) and 2(c)(2) of Exhibit E of the Power Sales contract and who returns, during a single offpeak hour, more than 60 percent of the difference between that purchaser's billing demand and estimated computed average energy requirement for the billing month shall be subject to the following surcharge for each additional kilowatthour so returned:

1. 3.94 mills per kilowatthour for the months of April through October, and

2. 1.67 mills per kilowatthour for the months of November through March.

H. *Interim Rate Adjustment.*

The Interim Rate Adjustment (IRA) described in section III.C.5 of the GRSPs shall be applied to all power purchases under the NR–93 rate schedule if the balance of BPA's financial reserves: (1) falls below the IRA trigger point at the end of FY 1994; and (2) the Administrator elects, at his discretion, to implement the IRA. An increase not to exceed 10 percent shall be applied uniformly to the demand and energy charges contained in sections II.A and II.B of this rate schedule. The IRA shall be applied in the following manner:

[1+(IRS%/100)] multiplied by the demand and energy charges contained in sections II.A and II.B of this rate schedule.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resource categories to the NR–93 rate is 89.6 percent Exchange and 10.4 percent New Resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule SP–93 Surplus Firm Power Rate

Section I. Availability

This rate schedule is available for the purchase of Surplus Firm Power for the period ending September 30, 1998, including purchases under the Western Systems Power Pool (WSPP) agreements. BPA is not obligated to make power or energy available under this rate schedule if such power or energy would displace sales under the IP–93, VI–91, PF–93, or NR–93 rate schedules. Schedule SP–93 supersedes schedule SP–91 and associated General Rate Schedule Provisions (GRSPs). Sales under this schedule are made subject to BPA's GRSPs.

Section II. Rate.

A. *Contract Rate.*

1. *Demand Charge.*

a. For contracts that specify 12 months of service per year, $61.32 per kilowatt per year of Contract Demand billed monthly at the rate of $5.11 per kilowatt of Contract Demand occurring during all Peak Period hours in each billing month.

b. For contracts that specify service for fewer than 12 months per year, the monthly demand charge shall be assessed only for the specified service months at the rate of $5.11 per kilowatt of Billing Demand occurring during the Peak Period plus:

$$\$5.11\ (12 - \text{specified service months}) \times .25$$

specified service months

c. No demand charge during Offpeak Period hours.

2. *Energy Charge.* 27.3 mills per kilowatthour of billing energy.

B. *Flexible Rate.*

Energy charges or demand and energy charges may be specified at a higher or lower average rate as mutually agreed by BPA and the purchaser. In no case shall the rate exceed 100 percent of the fixed and variable unit costs of generation and transmission of BPA's highest cost resource including exchange resources. No resource cost determination is needed for sales at less than or equal to the Contract rate.

C. *Intertie Charge.*

Rates in sections II.A and II.B that equal or exceed the Contract rate shall be increased by the following charges for transactions over the Pacific Northwest-Pacific Southwest Intertie.

1. $.63 per kilowatt per month of billing demand and

2. 1.43 mills per kilowatthour of billing energy.

Rates in section II.B having an energy-only charge that equals or exceeds 34.3 mills per kilowatthour shall be increased by 2.8 mills per kilowatthour for transactions over the Pacific Northwest-Pacific Southwest Intertie.

Section III. Billing Factors

The billing factors shall be the Measured Demand and Measured Energy, unless otherwise specified in the contract.

Section IV. Adjustments and Special Provisions

Power Factor Adjustment.

The adjustment for power factor for BPA customers that are billed for Surplus Firm Power on metered amounts, when specified in this rate schedule or in the contract, shall be made in accordance with the provisions of both this section and section III.C.1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment, BPA shall increase the billing demand or energy by 1 percentage point for each percentage point or major fraction thereof (0.5 or greater) by which the average leading power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resources categories to the SP–93 rate is 91.4 percent Exchange and 8.6 percent New Resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule NF–93 Nonfirm Energy Rate

Section I. Availability

This schedule is available for the purchase of nonfirm energy to be used both inside and outside the United States including sales under the Western Systems Power Pool (WSPP) agreements and sales to consumers. This schedule also applies to energy delivered for emergency use under the conditions set forth in section V.A of the General Rate Schedule Provisions (GRSPs). BPA is not obligated to offer nonfirm energy to any purchaser that results in displacement of firm power purchases under BPA's Power Sales Contracts. The offer of nonfirm energy under this schedule shall be determined by BPA. Schedule NF–93 supersedes Schedule NF–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's GRSPs.

Section II. Rates

The average cost of nonfirm energy is 21.9 mills per kilowatthour. The NF–93 rate schedule provides for upward and downward pricing flexibility from this average nonfirm energy cost. All rates and any subsequent adjustments contained in this rate schedule shall not exceed in total the NF Rate Cap defined in section IV.C of the GRSPs.

1. *Standard Rate.*

The Standard rate is any offered rate not to exceed 26.3 mills per kilowatthour.

B. *Market Expansion Rate.*

The Market Expansion rate is any offered rate below the Standard rate in effect. BPA may have one or more Market Expansion rates in effect simultaneously.

C. *Incremental Rate.*

The Incremental rate is the Incremental Cost of energy plus 2.0 mills per kilowatthour, where the Incremental Cost is defined as all identifiable costs (expressed in mills per kilowatthour) that BPA would have avoided had it not produced or purchased the energy being sold under this rate.

D. *Contract Rate.*

The Contract rate is 14.4 mills per kilowatthour of billing energy.

Section III. Adjustments to Rates

A. *Guaranteed Delivery Surcharge.*

A surcharge of 2.0 mills per kilowatthour of billing energy is applied to guaranteed delivery of nonfirm energy under the Standard rate and Market Expansion rate.

B. *Intertie Charge.*

The Intertie Charge, on rate offers under any of the rates specified above, for sale of nonfirm energy scheduled for delivery over Pacific Northwest-Pacific Southwest Intertie shall be:

1. Inapplicable for rate offers of less than 21.9 mills per kilowatthour;

2. At the discretion of BPA, from zero through 2.8 mills per kilowatthour, for rate offers of 21.9 mills per kilowatthour; or

3. 2.8 mills per kilowatthour, for rate offers greater than 21.9 mills per kilowatthour.

Section IV. Billing Factors

The billing energy for nonfirm energy purchased under this rate schedule shall be the Measured Energy unless otherwise specified by contract.

Section V. Application and Eligibility

Any time that BPA has nonfirm energy for sale, the Standard rate, the Market Expansion rate, the Incremental rate, the Contract rate, or a combination of these rates may be in effect.

A. *Standard Rate.*

The Standard rate:

1. is available for all purchases of nonfirm energy; and

2. applies to nonfirm energy purchased pursuant to the Relief from Overrun Exhibit to the power sales contract.

B. *Market Expansion Rate.*

1. *Application of the Market Expansion rate.*

The Market Expansion rate applies when BPA determines that all markets at the Standard rate have been satisfied and BPA offers additional nonfirm energy.

2. *Market Expansion Rate Qualification Criteria.*

In order to purchase nonfirm energy at the Market Expansion rate, a purchaser must:

a. Have a displaceable resource, displaceable purchase of electricity, or

b. Be an end-user load with a displaceable alternative fuel source.

In addition, a purchaser must demonstrate one of the following:

a. Shutdown or reduction of the output of the displaceable resource in an amount equal to the amount of Market Expansion rate energy purchased; or

b. Reduction of a displaceable purchase and the output of the resource associated with that purchase, in an amount equal to the amount of Market Expansion rate energy purchased; or

c. Shutdown or reduction of the identified output of the resource(s) indirectly in an amount equal to the amount of Market Expansion rate energy purchased (for example, the purchase may be used to run a pumped storage unit); or

d. Decrease of an end-user alternate fuel source in an amount equivalent to the amount of Market Expansion rate energy purchased.

3. *Eligibility Criteria for Market Expansion rate.*

a. When only one Market Expansion rate is offered:

Purchasers qualifying under section V.B.2 who purchased nonfirm energy directly from BPA are eligible to purchase power under the Market Expansion rate offered if the decremental cost of the qualifying resource, purchase, or qualifying alternative fuel source is lower than the Standard rate in effect plus 2.0 mills per kilowatthour.

Purchasers qualifying under section V.B.2 who purchase nonfirm energy through a third party are eligible to purchase power under the Market Expansion rate offered if the cost of the qualifying alternative fuel source is lower than the Standard rate in effect plus 4.0 mills per kilowatthour.

b. When more than one Market Expansion rate is offered:

Purchasers qualifying under section V.B.2 who purchase nonfirm energy directly from BPA are eligible to purchase power under the Market Expansion rate if the decremental cost of the qualifying resource, purchase, or qualifying alternative fuel source is lower than the Standard rate in effect plus 2.0 mills per kilowatthour. The rate applicable to a purchaser shall be the highest Market Expansion rate offered that is below the purchaser's qualifying decremental cost minus 2.0 mills per kilowatthour.

Purchasers qualifying under section V.B.2 who purchase nonfirm energy through a third party are eligible to purchase power under the Market Expansion rate if the decremental cost of the qualifying alternative fuel source is lower than the Standard rate plus 4.0 mills per kilowatthour. The rate applicable to a purchaser shall be the highest Market Expansion rate offered that is below purchaser's qualifying decremental cost minus 4.0 mills per kilowatthour.

C. *Incremental Rate.*

The Incremental rate applies to sales of energy:

1. That is produced or purchased by BPA concurrently with the nonfirm energy sale;

2. That BPA may at its option not produce or purchase; and

3. That has an Incremental Cost greater than Standard rate (plus the Intertie Charge, if applicable) less 2.0 mills mills per kilowatthour.

D. *Contract Rate.*

The Contract rate applies to contracts (except power sales contracts offered pursuant to sections 5(b), 5(c), and 5(g) of the Northwest Power Act) that refer to the Contract rate:

1. For the sale of nonfirm energy; or

2. For determining the value of energy.

E. *Western Systems Power Pool Transactions.*

BPA may make available nonfirm energy for transactions under the WSPP agreement. WSPP sales shall be subject to the terms and conditions specified in the WSPP agreement and shall be consistent with regional and public preference. The rate for transactions under the WSPP agreement is any rate within the limits specified by the Standard, Market Expansion, and Incremental rates but may not exceed the maximum rate specified in the WSPP agreement. The rate of WSPP sales may differ from the actual rate offered for non-WSPP transactions in any hour. The rate for WSPP transactions is independent of any other rate offered concurrently under this rate schedule outside that agreement.

F. *End-User Rate.*

BPA may agree to a rate or rate formula for nonfirm energy purchases by end-users. Such rate or rate formula shall be within the limits specified for the Standard and Market Expansion rates but may differ from the actual rates offered during any hour.

Section VI. Delivery

A. *Rate of Delivery.*

BPA shall determine the amount of nonfirm energy to be made available for each hour. Such determination shall be made for each applicable nonfirm energy rate.

B. *Guaranteed Delivery.*

1. *Availability.*

BPA will determine the amount and duration of nonfirm energy to be offered on a guaranteed basis. Such daily or hourly amounts may be as small as zero or as much as all the nonfirm energy that BPA plans to offer for sale on such days.

2. *Conditions.*

Scheduled amounts of guaranteed nonfirm energy may not be changed except:

a. When BPA and the purchaser mutually agree to increase or decrease the scheduled amounts; or

b. When BPA must reduce nonfirm energy deliveries in order to serve firm loads because of unexpected generation or transmission losses.

Section VII. Adjustments and Special Provisions

A. The Interim Rate Adjustments (IRA) described in section III.C.5 of the GRSPs shall be applied to the maximum standard rate under the NF–93 rate schedule if the balance of BPA's financial reserves: (1) Falls below the IRA trigger point at the end of FY 1994; and (2) the Administrator elects, at his direction, to implement the IRA. An increase not to exceed 10 percent shall be applied to the NF–93 rate schedule.

Application of the IRA shall result in a new maximum Standard rate, contained in section II.A of this rate schedule.

The IRA shall be applied in the following manner:

[1+(IRA% / 100)] multiplied by 26.3 mills per kilowatthour

Section VIII. Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resource categories to the average cost of nonfirm energy is 94.3 percent FBS and 5.7 percent New Resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule SS–93 Share-The-Savings Rate

Section I. Availability

This rate schedule is available for the contract purchase of Nonfirm Energy under an experimental rate and is limited to the term of the rate experiment. Nonfirm Energy will be made available under this rate schedule for use both inside and outside the United States for the displacement of a qualifying resource, displaceable purchase of electricity, or end-user load that can be served with alternate fuel sources. This rate schedule is only available to purchasers who execute a contract with BPA specifying use of the Share-the-Savings Rate. BPA is not obligated to offer Nonfirm Energy to any purchaser that results in displacement of firm power purchases under BPA's Power Sales Contracts. Schedule SS–93 supersedes Schedule SS–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's General Rate Schedule Provisions (GRSPs).

Section II. Rate

The rate shall be a formula rate based solely or in part on decremental cost information submitted by the purchaser. The rate formula and decremental costs, for purposes of establishing charges under this rate schedule, shall be defined in the applicable contract. The rate formula agreed upon by BPA and the purchaser shall in no event result in a rate higher than the NF Rate Cap defined in section IV.C of the GRSPs or lower than 1 mill per kilowatthour.

Section III. Billing Factors

The billing energy for Nonfirm Energy purchased under this rate schedule shall be the Measured Energy unless otherwise specified in the Share-the-Savings rate contract.

Section IV. Application and Eligibility

A. *General Requirements.*

In order to purchase Nonfirm Energy under the Share-the-Savings Rate, the purchaser must:

1. Have executed a contract specifying application of the Share-the-Savings Rate Schedule.

2. Have a displaceable resource, displaceable purchase of electricity, or be an end-user load and with a displaceable alternative fuel source. End-user loads with alternate fuel sources may not use the Decremental Cost of a displaceable purchase of electricity to qualify for this rate.

B. *BPA Service Priority.*

Offers of Nonfirm Energy under this rate schedule shall be made pursuant to the terms and conditions set forth in the Share-the-Savings rate contract. BPA will sell Nonfirm Energy under this rate schedule consistent with regional and public preference.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The SS–93 rate is not based on the cost of BPA resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule PS–93 Power Shortage Rate

Section I. Availability

This schedule is available inside the Pacific Northwest for the purchase of Shortage Power, and may include purchases made under the Share-the-Shortage agreement. This schedule is available:

A. To a utility when a shortage exists on its system and the utility requests power under this rate schedule, or when shortage power is being delivered to a utility as the result of statewide or regionwide curtailment;

B. To the direct service industrial customers for purchases made pursuant to contracts other than their Power Sales Contracts; or.

C. When BPA arranges for purchase energy at the request of a customer. BPA is not obligated to make power available under this rate schedule unless specified by contract. Sales under this schedule are made subject to BPA's General Rate Schedule provisions.

Section II. Rates

A. Power Rate.

The power rate is any offered rate not to exceed 100 mills per kilowatthour. The offered rate may be specified as an energy charge only or as demand an energy charges.

B. Brokering Rate.

The brokering rate may be up to 1 mill per kilowatthour for services provided when BPA arranges for energy purchases between a third party buyer and a third party seller.

Section III. Billing Factors

The billing factors shall be:

A. Power Purchases.

The factors to be used in determining the billings for power purchases under this rate schedule are as follows:

1. Billing Demand.

The billing demand shall be the Contract Demand as specified in the contract initiating such arrangement or as mutually agreed to by the parties. Otherwise the billing demand shall be the Measured Demand as adjusted for power factor.

2. Billing Energy.

The billing energy shall be the Contract Energy as specified in the contract initiating such arrangement or as mutually agreed to by the parties. Otherwise the billing energy shall be the Measured Energy.

B. Brokering Services.

When BPA arranges for energy purchases from a third party buyer, the purchaser shall be billed for such services based on the total amount of kilowatthours purchased.

Section IV. Adjustments and Special Provisions

A. Power Factor Adjustment.

The adjustment for power factor for BPA customers that are billed for shortage power on metered amounts, when specified in this rate schedule or in the contracts shall be made in accordance with the provisions of both this section and section III.C.1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment, BPA shall increase the billing energy by 1 percentage point for each percentage point or major fraction thereof (0.5 or greater) by which the average leading power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

B. Power Brokering.

The charge for power brokering only applies to the service provided by BPA

of finding purchased power for a third party buyer from a third party seller. BPA may agree to provide other services in addition to finding purchased power, but these services shall be billed separately at charges specified in the appropriate rate schedule(s) or agreement(s). Such services may include, but are not limited to, wheeling and load shaping.

C. Share-the-Shortage Transactions.

In the event a Share-the-Shortage type agreement, which is currently being discussed, is executed, BPA may make shortage power available to participants under such agreement. Share-the-Shortage transactions shall be subject to the terms and conditions specified in that agreement. The rate for transactions under the Share-the-Shortage agreement is any rate within the limits specified by the Power rate but may not exceed the maximum rate specified in the agreement. The rate for Share-the-Shortage transactions is independent of any rate offered under this rate schedule outside of that agreement.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The approximate cost contribution of different resource categories to the PS–93 rate is based upon the BPA's highest cost resource which currently is an FBS resource.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

Schedule RP–93 Reserve Power Rate

Section I. Availability

This schedule is available for the purchase of power:

A. In cases where a purchaser's power sales contract states that the rate for Reserve Power shall be applied;

B. For which BPA determines no other rate schedule is applicable; or

C. To serve a purchaser's firm power load in circumstances where BPA does not have a power sales contract in force with such purchaser, and BPA determines that this rate should be applied.

This rate schedule may be applied to power purchased by entities outside the United States. This rate schedule supersedes Schedule RP–91 which went into effect on October 1, 1991. Sales under this schedule are made subject to BPA's General Rate Schedule Provisions (GRSPs).

Section II. Rate

A. *Demand Charge.*

1. $3.64 per kilowatt of billing demand occurring during all Peak Period hours.

2. No demand charge during Offpeak Period hours.

B. *Energy Charge.*

25.3 mills per kilowatthour of billing energy.

Section III. Billing Factors

The factors to be used in determining the billing for power purchased under this rate schedule are as follows:

A. *Billing Demand.*

If applicable, the billing demand shall be the Contract Demand as specified in the power sales contract. Otherwise the billing demand shall be the Measured Demand as adjusted for power factor.

B. *Billing Energy.*

The billing energy shall be the Contract Demand multiplied by the number of hours in the billing month, if use of the Contract Demand for determining billing energy is specified in the power sales contract. Otherwise the billing energy for such purchasers shall be the Measured Energy.

Section IV. Power Factor Adjustment

The adjustment for power factor, when specified in this rate schedule or in the power sales contract, shall be made in accordance with the provisions of both this section and section III.C.1 of the GRSPs. The adjustment shall be made if the average leading power factor or average lagging power factor at which energy is supplied during the billing month is less than 95 percent.

To make the power factor adjustment, BPA shall increase the billing demand by 1 percentage point for each percentage point or major fraction thereof (0.5 or greater) by which the average leading power factor or average lagging power factor is below 95 percent. BPA may elect to waive the adjustment for power factor in whole or in part.

Section V. Resource Cost Contribution

BPA has made the following determinations:

A. The RP–93 rate is not based on the cost of resources.

B. The forecasted average cost of resources available to BPA under average water conditions is 19.6 mills per kilowatthour.

C. The forecasted cost of resources to meet load growth is 55.7 mills per kilowatthour.

B. *General Rate Schedule Provisions (GRSPs).*

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Section I. Adoption of Revised Rate Schedules and General Rate Schedule Provisions

A. *Approval of Rates.*

These 1993 rate schedules and General Rate Schedule revisions (GRSPs) shall become effective upon interim approval or upon final confirmation and approval by the Federal Energy Regulatory Commission (FERC). BPA will request FERC approval effective October 1, 1993. BPA proposes that the following schedules, and the GRSPs associated with these schedules, be effective for 2 years: PF–93, IP–93, SI–93, CE–93, NR–93, SS–93, NF–93, PS–93, and RP–93. BPA proposes that the SP–93 rate schedule, and the GRSPs associated with this schedule, be effective for 5 years.

B. *General Provisions.*

These 1993 rate schedules, and the GRSPs associated with these rate

schedules, supersede BPA's 1991 rate schedules (which became effective October 1, 1991) to the extent stated in the Availability section of each rate schedule. These schedules and GRSPs shall be applicable to all BPA contracts, including contracts executed both prior to and subsequent to enactment of the Northwest Power Act. All sales of power made under these rate schedules are subject to the following acts as amended: the Bonneville Project Act, the Regional Preference Act (Pub. L. 88–552), the Federal Columbia River Transmission System Act, and the Northwest Power Act.

Section II. Types of BPA Service

A. *Priority Firm Power.*

Priority Firm Power is electric power (capacity, energy, or capacity and energy) that BPA will make continuously available for resale to ultimate consumers for direct consumption, construction, test and startup, and station service by public bodies, cooperatives, and Federal agencies. (Construction, test and start-up, and station service are defined in section V.B of these GRSPs.)

Utilities participating in the exchange under section 5(c) of the Northwest Power Act may purchase Priority Firm Power pursuant to their Residential Purchase and Sale Agreements.

In addition, BPA may make Priority Firm Power available to those parties participating in exchange agreements specifying use of the Priority Firm rate for determining the amount or value of power to be exchanged.

Power purchased under the rate schedule is to be used to meet the purchaser's actual firm load within the Pacific Northwest. Such power may be restricted in accordance with the Restriction of Deliveries section of these GRSPs (section V.E). However, BPA shall not restrict Priority Firm Power until Industrial Firm Power has been restricted in accordance with the provisions of section II.C of these GRSPs.

Priority Firm Power is not available to serve New Large Single Loads.

B. *New Resource Firm Power.*

New Resource Firm Power is electric power (capacity, energy, or capacity and energy) that BPA will make continuously available:

1. For any New Large Single Load,

2. For firm power purchased by investor-owned utilities (IOUs) pursuant to power sales contracts with BPA, and

3. For construction, test and start-up, and station service for facilities owned or operated by IOUs.

New Resource Firm Power is to be used to meet the purchaser's actual firm load within the Pacific Northwest. Such power may be restricted in accordance with the Restriction of Deliveries section of these GRSPs (section V.E). However, BPA shall not restrict New Resource Firm Power until Industrial Firm Power has been restricted in accordance with the provisions of section II.C of these GRSPs.

C. *Industrial Firm Power.*

Industrial Firm Power is electric power that BPA will make continuously available to a direct service industrial (DSI) purchaser pursuant to the DSI's power sales contract and subject to:

1. The restriction applicable to deliveries of all firm power pursuant to the Uncontrollable Forces and Continuity of Service provisions of the General Contract Provisions of the power sales contract, and

2. The restrictions given in the Restriction of Deliveries section of the power sales contract.

D. *Special Industrial Power.*

Special Industrial Power is electric power which BPA will make continuously available to any DSI that qualifies for the Special Industrial Power rate pursuant to section 7(d)(2) of the Northwest Power Act. This power is similar in nature to Industrial Firm Power, but is subject to greater restriction by BPA. Special Industrial Power is made available to the qualifying DSI upon adoption of, and subject to, an amendment modifying its power sales contract.

E. *Auxiliary Power.*

Auxiliary Power is that power which a DSI requests and which BPA agrees to make available to serve that portion of the DSI's load which is in excess of the DSI's Operating Demand for Industrial Firm Power or Special Industrial Power.

F. *Shortage Power.*

Shortage Power is energy, or energy with capacity provided by BPA to a purchaser to serve such purchaser's regional load under circumstances where the purchaser's other power sources are inadequate to satisfy its load. The determination of power deficiency shall be made by the purchaser unless one or more states orders statewide load curtailment. In the event of a state ordered load curtailment, a power deficiency is deemed to exist for those purchasers whose power supply condition is in part causally related to the state initiated load curtailment.

G. *Surplus Firm Power.*

Surplus Firm Power is firm energy, firm power (firm energy with capacity), and firm capacity (capacity with energy return requirements) in excess of the amount required to meet BPA's existing contractual obligations to provide firm service. Surplus Firm Power may be used either for resale or direct consumption by purchasers both inside and outside the United States. Such power, however, may be restricted pursuant to the Restriction of Deliveries sections of these GRSPs (section V.E).

H. *Nonfirm Energy.*

Nonfirm Energy is supplied or made available by BPA to a purchaser under an arrangement that does not have the guaranteed continuous availability feature of firm power. Nonfirm energy is mostly sold under the Nonfirm Energy rate scheduled, NF–91. Nonfirm energy also may be supplied under the Share-the-Savings rate schedule, SS–91, which is available as an experimental rate for contract purchase.

In addition, BPA also can make nonfirm energy available under the Nonfirm Energy rate schedule to the Western Systems Power Pool (WSPP) subject to terms and conditions agreed upon by the members participating in the WSPP and in accordance with BPA policy for such arrangements.

However, Nonfirm Energy that has been purchased under a guarantee provision in the Nonfirm Energy rate schedule shall be provided to the purchaser in accordance with the provisions of that schedule and the power sales contract if applicable. BPA may make Nonfirm Energy available to purchasers both inside and outside the United States.

I. *Reserve Power.*

Reserve Power is firm power sold to a purchaser:

1. In cases where the purchaser's power sales contract states that the rate for Reserve Power shall be applied;

2. To provide service when no other type of power is deemed applicable; or

3. To serve the purchaser's firm power loads under circumstances where BPA does not have a power sales contract in force with the purchaser.

Sales of Reserve Power are subject to the Restriction of Deliveries section of these GRSPs (section V.E).

Section III. Billing Factors and Billing Adjustments

A. *Billing Factors for Demand.*

1. *Measured Demand.*

The purchaser's Measured Demand shall be determined in the manner described in this section. Measured Demand shall be that portion of the metered or scheduled demand that is purchased from BPA under the applicable rate schedule. For those contracts to which BPA is a party and that provide for delivery of more than one class of electric power to the purchaser at any point of delivery, the portion of each 60-minute clock-hour

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integrated demand assigned to any class of power shall be determined pursuant to the power sales contract. The portion of the total Measured Demand so assigned shall constitute the Measured Demand for each such class of power.

The Measured Demand shall be determined from the metered demand or the scheduled demand, as hereinafter defined. The Measured Demand shall be determined on either a coincidental or a noncoincidental basis, as provided in the purchaser's power sales contract.

a. *Metered Demand.* The metered demand in kilowatts shall be the largest of the 60-minute clock-hour integrated demands, adjusted as specified in the power sales contract, at which electric energy is delivered to a purchaser:

(1) At each point of delivery for which the metered demand is the basis for determination of the Measured Demand,

(2) During each time period specified in the applicable rate schedule, and

(3) During any billing period.

Such largest integrated demand shall be determined from measurements made either in the manner specified in the power sales contract or as provided in section VI.A herein. In determining the metered demand, BPA shall exclude any abnormal integrated demands due to or resulting from:

(1) Emergencies or breakdowns on, or maintenance of, the Federal system facilities; and

(2) Emergencies on the purchaser's facilities, provided that such facilities have been adequately maintained and prudently operated, as determined by BPA.

b. *Scheduled Demand.* The scheduled demand in kilowatts shall be the largest of the hourly demands at which electric energy is scheduled for delivery to a purchaser:

(1) To each system for which scheduled demand is the basis for determination of the Measured Demand;

(2) During each time period specified in the applicable rate schedule; and

(3) During any billing period.

Scheduled amounts are deemed delivered for the purpose of determining billing demand.

2. *Ratchet Demand.* The Ratchet Demand in kilowatts shall be the maximum demand established during a specified period of time either during or prior to the current billing period. The demand on which the ratchet is based is specified in the relevant rate schedule or in these GRSPs. For utilities purchasing under the PF or NR rate schedules, the Ratchet Demand is based on the highest demand during prior billing months. When the Ratchet Demand is used as a billing factor, BPA shall have specified in the appropriate schedules or GRSPs:

a. The period of time over which the ratchet shall be calculated;

b. The type of demand to be used in the calculation; and

c. The percentage (if any) of that demand which will be used to calculate the Ratchet Demand.

3. *Contract Demand.* The Contract Demand shall be the maximum number of kilowatts that the purchaser agrees to purchase and BPA agrees to make available, subject to any limitations included in the power sales contract. BPA may agree to make deliveries at a rate in excess of the Contract Demand at the request of the purchaser, but shall not be obligated to continue such excess deliveries. Any contractual or other reference to Contract Demand as expressed in kilowatthours shall be deemed, for the purpose of these GRSPs, to refer to the term "Contract Energy."

4. *Computed Peak Requirement.* For purchasers designated to purchase on the basis of computed requirements, the Computed Peak Requirement shall be determined as specified in the purchaser's power sales contract. That specification is provided in:

a. Sections 16, 17(c) and 17(f), as adjusted by other sections of the contract, for actual computed requirements purchasers;

b. Sections 16, 17(a) and 17(f), as adjusted by other sections of the contract, for planned computed requirements purchasers; and

c. Sections 16, and 17(b), as adjusted by other sections of the contract, for contracted computed requirements purchasers.

5. *Computed Average Energy Requirement.* For computed requirements purchasers, the Computed Average Energy Requirement shall be determined as specified in the purchaser's power sales contract. That specification is provided in:

a. Sections 16, 17(c) and 17(f), as adjusted by other sections of the contract, for actual computed requirements purchasers;

b. Sections 16, 17(a) and 17(f), as adjusted by other sections of the contract, for planned computed requirements purchasers; and

c. Sections 16, 17(b), as adjusted by other sections of the contract, for contracted computed requirements purchasers.

6. *Operating Demand.* The Operating Demand is that demand which is established by each DSI in accordance with section 5(b) of the DSI's power sales contract. Unless the DSI has requested, and BPA has granted, an Auxiliary Demand, the Operating Demand establishes a limit with respect to:

a. The demand which the purchaser may impose on BPA; and

b. The total amount of energy during a billing month which the DSI is entitled to purchase from BPA.

7. *Curtailed Demand.* A Curtailed Demand is the number of kilowatts of industrial power (Industrial Firm Power or Special Industrial Power) during the billing month which results from the DSI's request for such power in amounts less than the Operating Demand therefor. Each purchaser of industrial power may curtail its demand according to the terms of its power sales contract (which permits up to three levels of Curtailed Demand each month).

8. *Restricted Demand.* Restricted Demand is the number of kilowatts of industrial power (either Industrial Firm Power or Special Industrial Power) that results when BPA has restricted delivery of such power for one clock-hour or more. BPA shall make such restrictions according to the terms of the DSI's power sales contract. In a given billing month, there are as many possible levels of Restricted Demand for a DSI as there are number of restrictions.

9. *Auxiliary Demand.* Auxiliary Demand is the number of kilowatts of Auxiliary Power that a DSI requests and the BPA agrees to make available to serve a portion of the DSI's load during the period specified in the DSI's request. The DSI may request up to three levels of Auxiliary Demand during a billing month.

If BPA agrees to a request for Auxiliary Power but later becomes unable to supply such demand, the Restricted Demand for Auxiliary Power is deemed to be the Auxiliary Demand for such period of restriction. Auxiliary Power may be curtailed by the DSI according to the provisions of section 9(a) of the DSI's power sales contract.

BPA shall make Auxiliary Power available to Industrial Firm Power purchasers under the Industrial Firm Power rate schedule at the Standard Industrial rate. Auxiliary Power sales to DSIs electing to purchase under the Variable Industrial Power rate schedule (VI–91) shall be made at the rate determined pursuant to section III of the VI–91 rate schedule. Auxiliary Power sales to DSIs purchasing under the Special Industrial rate will be made only at the Standard Special Industrial Power rate.

10. *BPA Operating Level.* The BPA Operating Level is, for the purpose of these rate schedules and GRSPs, an hourly amount of industrial power (Industrial Firm Power or Special Industrial Power) for a DSI that is equal

to the lowest of the following demands during that hour.

a. Operating Demand plus Auxiliary Demand, if any;

b. Curtailed Demand; or

c. Restricted Demand.

The weighted average BPA Operating Level for each DSI can be determined by summing the hourly BPA Operating Levels and dividing by the number of hours in the billing month.

Each DSI must request service from BPA for each billing month in accordance with the terms of the power sales contract. The requested level of service will be the BPA Operating Level, provided BPA does not need to restrict the DSI and provided BPA agrees to supply and requested Auxiliary Demand. Each requested level of service may include a designation for both the Peak Period and the Offpeak Period. A DSI may request and BPA may agree to a level of service for the Offpeak Periods other than that in the Peak Period. If a DSI does not separately designate a requested level of service for the Peak and Offpeak Periods, the BPA Operating Level if the basis for determining if a DSI has incurred an unauthorized increase.

Any DSI whose Measured Demand, before adjustment for power factor, during any 1 hour exceeds the BPA Operating Level for that hour shall be subject to unauthorized increase charges for each kilowatthour of unauthorized increase associated with each overrun.

Only the BPA Operating Level applicable during the Peak Period will be used in determining the Billing Demand for power purchased under the Industrial Firm Power rate schedule, the Variable Industrial Power rate schedule, and the Standard rate under the Special Industrial rate schedule. During the Peak Period the BPA Operating Level may be no greater than the Operating Demand for the billing month unless the customer has requested, and BPA has agreed to supply, the Auxiliary Demand.

B. *Billing Factors for Energy.*

1. *Measured Energy.* Measured Energy shall be that portion of the metered or scheduled energy that is purchased from BPA under the applicable rate schedule. For those contracts to which BPA is a party and that provide for delivery of more than one class of electric power to the purchaser at any point of delivery, the portion of each 60-minute clock-hour integrated demand assigned to any class of power shall be determined pursuant to the power sales contract. The sum of the portions of the demands so assigned shall constitute the Measured Energy for each such class of power.

The Measured Energy shall be determined from the metered energy or the scheduled energy, as hereinafter defined.

a. *Metered Energy.* The metered energy for a purchaser shall be the number of kilowatthours that are recorded on the appropriate metering equipment, adjusted as specified in the power sales contract, and delivered to a purchaser:

(1) At all points of delivery for which metered energy is the basis for determination of the Measured Energy, and

(2) During any billing period.

The metered energy shall be determined from measurements made either in the manner specified in the power sales contract or as provided in section VI.A herein.

b. *Scheduled Energy.* The scheduled energy in kilowatthours shall be the sum of the hourly demands at which electric energy is scheduled for delivery to a purchaser:

(1) For each system for which scheduled energy is the basis for determination of the Measured Energy, and

2. During any billing period.

Scheduled amounts are deemed delivered for the purpose of determining billing energy.

(2) *Computed Energy Maximum.* The Computed Energy Maximum equals the product of the number of hours in the billing month and the Computed Average Energy Requirement.

3. *Contrct Energy.* The Contract Energy shall be the maximum number of kilowatthours that the purchaser agrees to purchase and BPA agrees to make available, subject to any limitations included in the power sales contract.

C. *Billing Adjustments.*

1. *Power Factor Adjustment.* The formula for determining average power factor is as follows:

$$\text{Average Power Factor} = \frac{\text{Kilowatthours}}{\sqrt{(\text{Kilowatthours})^2+(\text{Reactive kilovoltamperehours})^2}}$$

The data used in the above formula shall be obtained from meters that are ratcheted to prevent reverse registration. These data then shall be adjusted for losses, if applicable, before determination of the average power factor.

When deliveries to a purchaser at any point of delivery either:

a. Include more than one class of power; or

b. Are provided under more than one rate schedule and it is impracticable to meter the kilowatthours and reactive kilovoltamperehours for each class or rate schedule separately, the average power factor of the total deliveries for the month will be used, where applicable, as the power factor for all power delivered to such point of delivery.

To maintain acceptable operating conditions on the Federal system, BPA may, unless specifically otherwise agreed, restrict deliveries of power to a purchaser with a low power factor. Such restriction may be made to a point of delivery or to a purchaser's system at any time that the average leading power factor or average lagging power factor for all classes of power delivered to such point or to such system is below 75 percent.

2. *Outage Credit.* To the extent that BPA is unable to provide full service to a purchaser during the billing month as a result of interruptions in service due to reasons cited in the General Contract Provisions, BPA shall adjust the charges for those hours for billing demand for such purchaser to reflect BPA's inability to provide full service, provided such adjustment is mandated by the purchaser's power sales contract. The adjustment is provided on a point of delivery basis. To compute the adjustment for noncoincidentally billed systems, BPA shall determine the monthly demand charge(s) for the point(s) of delivery where the outage(s) occurred, multiply by the number of hours of outage, and divide by the total number of hours in the billing month. For coincidentally billed points of delivery, the adjustment shall apply only to those points of delivery at which BPA was unable to provide full service. For partial outages (such as an outage on one feeder in a substation with several feeders), BPA shall determine an equivalent interruption in order to arrive at the number of hours to be used in the calculation of the credit.

3. *Low Density Discount (LDD).*

a. *Basic LDD Principles.* A predetermined discount shall be applied each billing month to the charges for all power purchased under the Priority Firm Power rate schedule by eligible purchasers as defined in section b, below. The discount shall be calculated on an annual basis and shall become effective with the first billing period in the calendar year. Retroactive billing for the LDD may be required if the data are not available by the January billing date. The level of the discount shall be determined from the following ratios:

(1) The purchaser's total electric energy requirements during the previous calendar year (the purchaser's firm sales, nonfirm sales to firm retail loads, sales for resale, and associated

losses, but excluding nonfirm sales to nonfirm retail loads, such as boiler loads served under BPA's alternate fuel policy) divided by the value of the purchaser's depreciated electric plant (excluding generation plant) at the end of such year, and

(2) The average number of consumers (annual and seasonal consumers with residential, industrial, commercial, and irrigation accounts, but excluding separately billed services for water heating, electric space heating, and security lights) during the previous calendar year divided by the number of pole miles of distribution line at the end of such year. Distribution lines are defined as those that deliver electric energy from a substation or metering point, at a voltage of 34.5 kV or less, to the point of attachment to the consumer's wiring and include primary, secondary, and service facilities.

These calculations shall be based on data provided in the purchaser's annual financial and operating report. In calculating these ratios, BPA shall use data pertaining to the purchaser's entire electric utility system with the region. Results of the calculations shall not be rounded.

Customers who have not provided BPA with all four requisite pieces of annual data (see a.(1) and a.(2) above) by June 30 of each year shall be declared ineligible for the LDD effective with the June billing period for that year. BPA shall extend a customer's eligibility from the previous year through the June billing period of the following year and shall make any necessary retroactive adjustments once the new data have been processed. If no data have been received by December 31 for the previous calendar year, BPA shall assume that the utility did not qualify for an LDD for that year. LDDs issued from January 1 to June 30 shall be assumed to have been in error, and the utility shall be billed for any such discounts issued.

Revisions to the data used to calculate the amount of the LDD may be made by the purchaser for a period of up to 2 years from the first day to which the data apply. However, such revisions shall not apply to periods when the customer was ineligible for a discount due to late data submission.

b. *Eligibility Criteria.* To qualify for a discount, the purchaser must meet all six of the following eligibility criteria:

(1) The purchaser must serve as an electric utility offering power for resale;

(2) The purchaser must agree to pass the benefits of the discount through to the purchaser's consumer within the region served by BPA;

(3) The purchaser's average retail rate for the reporting year must exceed the average Priority Firm Power rate in effect for the qualifying period by 10 percent. For Calendar Year (CY) 1993, the average Priority Firm Power rate shall be the average of the PF–91 Preference rate for 9 months and the PF–93 Preference rate for 3 months. For CY 1994, the average Priority Firm Power rate shall be the PF–93 Preference rate;

(4) The purchaser's kilowatthour-to-investment ratio (Ratio 3.a.(1)) must be less than 100;

(5) The purchaser's consumers-per-mile ratio (Ratio 3.a.(2)) must be less than 12; and

(6) The purchaser must qualify for a discount based on the criteria in section c, below.

c. *Discounts.* The purchaser shall be awarded the greatest discount for which that purchaser qualifies. The discounts and the qualifying criteria for those discounts are listed below.

(1) Three percent, for any purchaser for whom:

(a) The kilowatthour-to-investment ratio is equal to or greater than 25 but less than 35; or

(b) The consumers-per-mile ratio is equal to or greater than 5 but less than 7.

(2) Five percent, for any purchaser for whom:

(a) The kilowatthour-to-investment ratio is equal to or greater than 15 but less than 25; or

(b) The consumer-per-mile ratio is equal to or greater than 3 but less than 5.

(3) Seven percent, for any purchaser for whom:

(a) The kilowatthour-to-investment ratio is less than 15; or

(b) The consumer-per-mile ratio is less than 3.

4. *Irrigation Discount.*

a. *Basic Irrigation Discount Principles.* A discount of 4.9 mills per kilowatthour shall be applied to the charges for qualifying irrigation energy purchased under the Priority Firm Power and New Resource Firm Power rate schedules, during the billing months of April through October. This discount shall be applied subsequent to calculation of the LDD, if applicable. Any energy on which the irrigation discount is claimed shall be metered separately by the Purchaser, and used exclusively for agricultural irrigation or drainage pumping.

b. *Qualifying Energy Purchases.* The qualifying irrigation energy shall be determined as follows:

(1) All irrigation energy must be used exclusively for the purpose of irrigation and drainage pumping on agricultural land and be measured at the end-use irrigation customer's meter. The discount shall apply to the measured energy sales at the end-use.

(2) Energy subject to the discount must be purchased during the billing months of April through October.

(3) Purchasers of exchange energy under the Residential Purchase and Sale Agreement (RPSA) are eligible for the irrigation discount for the portion of their irrigation sales qualifying for the exchange under the RPSA contracts. However, if the purchaser also purchases energy from BPA for general requirements, and receives an irrigation discount on those purchases, a second irrigation discount will not be applied to that energy through the RPSA exchange. Therefore, the irrigation discount will not be applied to any portion of the purchaser's irrigation sales qualifying for the RPSA exchange that receives the discount as a general requirements purchase.

(4) General requirements customers are eligible for an irrigation discount for a portion of their irrigation sales equal to the share of their total sales served by BPA firm purchases (i.e., total irrigation and drainage pumping sales multiplied by BPA billing energy for Priority Firm or New Resources firm purchases divided by the total firm utility system requirements for the billing month).

c. *Initial Reporting Requirements.* Requests for the Irrigation Discount must include the following information:

(1) To receive an irrigation discount, a purchaser must file a request for the discount with its local BPA Area or District office by April 1 each year.

(2) In the request, the purchaser must certify that the irrigation energy is sold exclusively for use in irrigation and drainage pumping on agricultural land and that the discount is passed, in its entirety, to the irrigation consumer, regardless of whether the utility has raised its rates. BPA retains the right to verify, in a manner satisfactory to the Administrator, that the discounted energy is used for the sole benefit of the purchaser's irrigation load.

d. *Annual Reporting Requirements.* Purchasers shall submit an annual irrigation report to their local BPA Area or District office in order to receive the irrigation discount. Purchasers are required to report information related to monthly irrigation energy sales. If a utility does not read its irrigation meters monthly, the utility must estimate its monthly irrigation sales. These estimates shall be reviewed by BPA area and/or district offices. Purchasers must read their meters within 3 working days of the beginning and ending of the

irrigation discount period (April-October). In order to qualify for the discount, the purchaser must submit all data to BPA by December 31 of the calendar year in which the sales occurred. Irrigation reports to BPA shall include the following monthly information for the reporting period:

(1) Utility name and period for which the report is being made;

(2) Total irrigation sales and total qualifying irrigation energy sales (in kilowatthours) by month;

(3) Total qualifying irrigation sales (in kilowatthours) by month under 400 horsepower, for exchanging utilities;

(4) Total utility firm system requirements for other than full requirement customers by month (in kilowatthours);

(5) Total energy purchased from BPA under the Priority Firm or New Resource rate by month in kilowatthours; and

(6) The Purchaser shall list each irrigation and drainage account number in its annual report and whether each irrigation consumer is billed monthly, bimonthly, or seasonally. If the Purchaser is an exchanging utility, the Purchaser shall also identify the size (in horsepower) of the connected load for each active account. A utility may submit monthly reports, if it chooses. In that case, the active list of accounts should be included in the last monthly report submitted.

5. *Interim Rate Adjustment.*

a. *Application of the Interim Rate Adjustment (IRA).* The Interim Rate Adjustment applies to the Priority Firm Power (Exchange and Preference) (PF–93), Industrial Firm Power (IP–93), Variable Industrial Power (VI–91), Nonfirm Energy (NR–93), and New Resources Firm Power (NR–93) rate schedules. A percentage adjustment, labeled as IRA%, is calculated for the 12 month period of FY 1995 and shall be applied to these rate schedules if: (1) The balance of BPA's financial reserves is projected to fall below the IRA trigger point at the end of FY 1994; and (2) the Administrator elects, at his sole discretion, to implement the IRA.

b. *Definitions.* For purposes of applying the IRA in the current 1993 rate period (FYs 1994 and 1995), the following definitions will apply:

(1) *"Financial reserves"* are defined as the sum of: (a) BPA's projected cash balance in the Bonneville Fund as of Fiscal Year End 1994; and (b) BPA's deferred borrowing balance as of Fiscal Year End 1994, representing BPA capital program expenditures temporarily financed with cash from revenues instead of through the issuance of revenue bonds or notes (borrowing) to the U.S. Treasury.

(2) *"IRA trigger point"* is defined as that point where BPA's ending FY 1994 financial reserves are projected to fall below $245 million.

(3) *"Target level of financial reserves" (TLFR)* is the level of financial reserves required to assure BPA's objectives are met and is equal to $400 million.

(4) *"Projected financial reserve balance" (PFRB)* is the end of FY 1994 projected financial reserve balance at the time of the IRA calculation.

(5) *"Interim rate adjustment maximum" (IRM)* is the maximum revenue recovery from the IRM and is equal to $290 million dollars.

c. *Adjustment Period.* The adjustment period will be for the 12 month period of FY 1995, (October 1, 1994 through September 30, 1995). The IRA may be implemented for the adjustment period if the forecasted balance of financial reserves as of September 30, 1994, is below the IRA trigger point.

d. *Formula for the Calculation of the Interim Rate Adjustment.* The IRA will be the result of a calculation based on the PFRB as of September 30, 1994, (end of Fiscal Year 1994) and the TLFR in the following manner:

(TLFR–PFRB)/IRM * 10=IRA%

If the value of the IRA% is greater than 10, then the IRA% will be reduced to 10.

e. *Interim Rate Adjustment Implementation Process.*

(1) *Calculation of FY 1994 Financial Reserves.* For purposes of implementing the IRA, the calculation of the PFRB shall be based on a compilation of actual and projected revenues, expenses, borrowings, capital expenditures, amortization payments, cash basis adjustments, and non cash expenses.

(2) *Initial Notice.* If BPA projects that the PFRB is reasonably likely to fall below the IRA trigger point at the end of FY 1994, BPA shall notify all customers, and such other parties who may request such notice, by letter on or about January 1, 1994.

(3) *Initial Calculation of FY 1994 Reserve Balance.* In the event that BPA provides the notice indicated in (e)(2) above, it shall include in its first financial Quarterly review for FY 1994, which shall be made available on or about February 15, 1994, an initial calculation to identify the preliminary PFRB. If at the time that this initial calculation is made available, BPA believes that there is a reasonable likelihood that the IRA may need to be implemented on October 1, 1994, it shall notify by letter all customers, and such other parties who may request such notice.

(4) *Second Quarter Calculation of FY 1994 Reserve Balance.*

(a) In the event that BPA provided the notice specified in (e)(2) above or in the event that BPA projects that the PFRB is reasonably likely to fall below the IRA trigger point, it shall notify all customers, and such other parties who may request such notice, of the likelihood that an IRA may need to be implemented on October 1, 1994, or if BPA's earlier forecast has changed. This notice shall be accomplished by letter sent on or about May 1, 1994.

(b) In addition, BPA shall include in its second financial Quarterly review for FY 1994 estimates of costs and revenues, together with the unaudited financial reserves balance for FY 1994. This information shall be provided to all customers, and such other parties who may so request, together with the notice specified in (e)(4)(a) above.

(5) *Third Quarter Calculation of FY 1994 Reserve Balance.*

(a) In the event that BPA provided the notice specified in (e)(2) or (e)(4)(a) above, or in the event that BPA projects that the PFRB is reasonably likely to fall below the IRA trigger point, it shall notify all customers, and such other parties who may request such notice, of the likelihood that an IRA may need to be implemented on October 1, 1994. This notice shall be accomplished by letter sent on or before August 15, 1994.

(b) In addition, BPA shall include in its third financial Quarterly review for FY 1994 its estimate of year-end FY 1994 financial reserve balances. This information shall be provided to all customers, and such other parties who may so request, together with the notice specified in (e)(5)(a) above.

(6) *Notice of IRA Calculation.* (a) If BPA determines, based on the third financial Quarterly review indicated in (e)(5)(b) above, that no rate adjustment is required, or if the Administrator should elect, at his discretion, to waive implementation of an adjustment, BPA shall state in the August 15, 1994, notice the basis for its decision and no further process shall be required.

(b) If, however, BPA determines that an adjustment is required, BPA shall state in the August 15, 1994, notice the amount of the adjustment, the calculation of the adjustment, and the resulting level of the adjustment to each applicable rate schedule. The notice shall also contain the data and assumptions prepared and relied upon by BPA, with references to additional documentation, if any, prepared and relied upon by BPA. Such documentation, if nonproprietary and/

or nonprivileged, shall be made available for review at BPA upon request. The notice shall also contain the tentative schedule for the remainder of the implementation process.

(7) *Opportunity for Review of Underlying Data.* (a) On or about August 15, 1994, BPA shall conduct a public meeting in which customers' representatives may seek off-the-record clarification of the application of the adjustment amount to specific rate schedules. For the purpose of further mailings, a list of the names and addresses of customers' representatives, and such other interested parties who may so request, will be compiled at this meeting.

(b) On or about August 22, 1994, purchasers under each applicable rate schedule may submit information requests to BPA regarding the proposed adjustment. The requests shall also be mailed to all persons on the mailing list compiled pursuant to (e)(7)(a). BPA shall respond to the requests within 5 working days of their receipt, or as soon as practicable if 5 days is insufficient time within which to respond.

(c) On or about September 5, 1994, purchasers under each applicable rate schedule, and such other interested parties who may so elect, may submit written comments to BPA regarding the adjustment. The commentor shall also mail a copy of the comments to all persons on the mailing list.

(d) On or about September 12, 1994, commentors may provide cross-comments in response to those submitted by any other commentor.

(e) On or about September 19, 1994, BPA shall conduct a public comment forum in which purchasers under each applicable rate schedule may present oral comments to BPA.

(f) On or about September 26, 1994, BPA shall notify purchasers under each applicable rate schedule of the amount of the adjustment, the calculation of the adjustment, and the resulting level of the adjustment to each applicable rate schedule. The notice shall also contain the data and assumptions prepared and relied upon by BPA, with references to additional documentation, if any, prepared any relied upon by BPA. BPA may subsequently in its sole discretion provide a written explanation for its decision on any contested issues.

(g) If there is a rate adjustment due to the IRA following the FY 1994 evaluation period, it shall be in effect from October 1, 1994, through September 30, 1995.

6. *Coincidental Billing.* Purchasers of Priority Firm Power and New Resource Firm Power shall be billed on a noncoincidental demand basis for power purchased at each point of delivery under the applicable rate schedule(s) unless the power sales contract specifically provides for coincidental demand billing among particular points of delivery. For the purpose of these rate schedules and GRSPs, the purchaser's noncoincidental demand is the sum of the highest hourly peak demands during the billing month for each of the purchaser's points of delivery. The purchaser's coincidental demand is the highest demand for the billing month calculated by summing, for each hour of every day, the purchaser's demands for power purchased under the applicable rate schedule at all coincidentally billed points of delivery. See Special Provisions Exhibits of the Power Sales Contract, GCP E 17.

7. *Conservation Surcharge.* The Conservation Surcharge shall be applied monthly and shall equal 10 percent of the customer's total monthly charge for all power purchased under each rate schedule subject to the surcharge. The PF and NR rate schedules are subject to the Conservation Surcharge. If only a portion of the customer's service area is subject to the surcharge, then the amount of the surcharge shall equal 10 percent of the total charge for all power purchases multiplied by: (a) The portion of the customer's total retail load that is subject to the surcharge, divided by (b) the customer's total retail load.

D. *Billing-Related Definitions.*

1. *Peak Period.* The Peak Period includes the hours from 7 a.m. through 10 p.m. on any day Monday through Saturday inclusive. There are no exceptions to this definition; that is, it does not matter whether the day is a normal working day or a holiday. Any charges based on Peak Period hours shall be computed starting with the 8 a.m. meter reading since this reading applies to the 7 o'clock hour (7 a.m. to 8 a.m.). The 10 p.m. meter reading (for the 9 p.m. to 10 p.m. period) is the last meter reading of the day applicable to the Peak Period.

2. *Offpeak Period.* The Offpeak Period includes all hours which do not occur during the Peak Period. Thus, the Offpeak Period consists of the hours from 10 p.m. to 7 a.m., Monday through Saturday and all hours on Sunday.

Section IV. Other Definitions

A. *Computed Requirements Purchasers.* 1. *Designation as a Computed Requirements Purchaser.* A purchaser shall be designated as a computed requirements purchaser if it is so designated pursuant to the provisions of its power sales contract.

When a purchaser operates two or more separate systems, only those systems designated by BPA will be covered by this section.

2. *Purpose of the Computed Requirements Designation.* Use of the computed requirements designation is intended to assure that each purchaser who purchases power from BPA to supplement its own firm resources will purchase amounts of firm capacity and firm energy substantially equal to that which the purchaser would otherwise have to provide on the basis of normal and prudent operations.

The amount of capacity and energy required for normal and prudent operations shall be determined pursuant to the purchaser's power sales contract.

B. *Definitions Relating to Nonfirm Energy.* Decremental Cost. Unless otherwise specified in a contractual arrangement, decremental cost as applied to Nonfirm Energy transactions shall be defined as:

1. All identifiable costs (expressed in mills per kilowatthour) associated with the use of a displaceable thermal resource or end-user load with alternate fuel source to serve a purchaser's load that the purchaser is able to avoid by purchasing power from BPA, rather than generating the power itself or using an alternate fuel source; or

2. All identifiable costs (expressed in mills per kilowatthour) to serve the load of a displaceable purchase of energy that the purchaser is able to avoid by choosing not to make the alternate energy purchase.

All identifiable costs as used in the above definition may be reduced to reflect costs of purchasing BPA energy such as transmission costs, losses, or loopflow constraints that are agreed to by BPA and the purchaser.

C. *NF Rate Cap.* 1. *Application of the NF Rate Cap.* The NF Rate Cap defines the maximum nonfirm energy price for general application. At no time shall the total price for nonfirm energy, including any applicable service charges or rate adjustment, sold under any applicable rate schedule exceed the NF Rate Cap. The level of the NF Rate Cap is based on a formula tied to BPA's system cost and California fuel costs. The NF Rate Cap applies to all sales of nonfirm energy under any applicable rate schedule for a 12-year period beginning October 1, 1987.

2. *Monthly Notification of the NF rate Cap.* Prior to the beginning of a calendar month BPA shall perform the calculations contained in section IV.C.3 of these GRSPs to determine the effective NF Rate Cap for that calendar month. BPA is obligated to provide advance notification of the NF Rate Cap

level to purchasers of nonfirm energy. BPA may waive this requirement only if BPA does not intend to offer Nonfirm Energy at prices above BPA's Average System Cost (BASC) at any time during a month. The notification will be given at least 10 calendar days prior to the first day of any calendar month in which the NF Rate Cap applies. BPA shall also maintain, on file for public review, a record of the NF Rate Cap by month throughout the period the cap is in effect.

3. *NF Rate Cap Formula.* The NF Rate Cap shall be equal to the greater of the following:

a. BASC, or
b. BASC+.30(DEC–BASC)

Where:

BASC=BPA's average system cost, determined by dividing BPA's total system costs by BPA's total system sales. For this rate period BASC has been determined to be 27.8 mills per kilowatthour.

DEC=The Decremental Fuel Cost as determined in accordance with section IV.C.5 of these GRSPs.

4. *Determination of BASC.* For purposes of determining BASC, the following definition shall apply:

a. BPA's total system costs shall be the sum of all BPA's costs forecasted in each general rate case for the applicable rate period, including total transmission costs, Federal base system costs, new resource costs, exchange resource costs, and other costs not specifically allocated to a rate pool, such as section 7(g) costs.

b. BPA's annual system sales shall be the sum of all BPA's system firm and nonfirm sales forecasted each general rate case for the applicable test period.

BASC shall be redetermined in each subsequent general rate case according to the above formula and will be in effect for the entire rate period over which the rates are in effect.

5. *Determination of Decremental Fuel Cost.* The Decremental Fuel Cost shall be determined monthly by BPA. For purposes of calculating the NF Rate Cap, a weighted average of gas and petroleum prices for California will be used for approximating decremental fuel costs. The monthly decremental fuel cost shall be:

a. The sum of: (1) The average California price for gas determined by multiplying the monthly gas use (WGU) developed pursuant to section IV.C.8.a times the monthly California gas price (MGP) determined pursuant to section IV.C.6 rounded to the nearest tenth of a mill; and

(2) The average California price for petroleum determined by multiplying the monthly petroleum use (WOU) developed pursuant to section IV.C.8.b times the monthly California petroleum price (MOP) determined pursuant to section IV.C.7 rounded to the nearest tenth of a mill.

b. Divided by the sum of the WGU and WOU developed in sections IV.C.8.a and b, respectively, rounded to the nearest tenth of a mill.

6. *California Gas Price.* The MGP for purposes of calculating the decremental cost component of the rate cap shall be based on the following formula:

$$MGP = \frac{AGP * HGP}{10}$$

Where:

AGP=the average gas price for California electric utility plants expressed in cents per million Btu as reported in the most recently monthly issue of *Electric Power Monthly* (EPM) published by the Energy Information Administration (EIA), U.S. Department of Energy. Prices shall be rounded to the nearest one-tenth of a cent.

HGP=the historical relationship between gas prices in the effective month of the NF Rate Cap (month t) and the month in which the gas prices are reported in EPM (month r) using the following procedures:

a. Summing all California gas prices, expressed in the nearest one-tenth of a cent per million Btu, reported in EPM for month t for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of the historical monthly California gas prices shall be divided by the number of years for which MGPs were reported and rounded to the nearest one-tenth of a cent;

b. Summing all California gas prices, expressed in the nearest one-tenth of a cent per million Btu, reported in EPM for month r for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of the historical monthly California gas prices shall be divided by the number of years for which MGPs were reported and rounded to the nearest one-tenth of a cent.

c. Dividing the average monthly California gas price in a above, by the average monthly California gas price in b above, and rounding to the nearest one-tenth, or three significant places.

10=the factor for converting gas prices stated in cents per million Btu to mills per kWh. The factor assumes a heat rate of 10,000 Btu per kilowatthour.

7. *California Petroleum Price.* The MOP for purposes of calculating the decremental cost component of the rate cap shall be based on the following formula:

$$MOP = \frac{AOP * HOP}{10}$$

Where:

AOP=the last available oil price for California electric utility plants expressed in cents per million Btu reported in EPM published by the EIA, U.S. Department of Energy. Prices shall be rounded to the nearest one-tenth of a cent.

HOP=the historical relationship between petroleum prices in the effective month of the NF Rate Cap (month t) and the last month in which the petroleum prices are reported in EPM (month r) using the following procedures:

a. Summing all California petroleum prices, expressed in the nearest one-tenth of a cent per million Btu, reported in EPM for month t for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of the historical monthly California petroleum prices shall be divided by the number of years for which monthly petroleum prices were reported and rounded to the nearest one-tenth of a cent;

b. Summing all California petroleum prices, expressed in the nearest one-tenth of a cent per million Btu, reported in EMP for month r for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of the historical monthly California petroleum prices shall be divided by the number of years for which monthly petroleum prices were reported and rounded to the nearest one-tenth of a cent; and

c. Dividing the average monthly California petroleum price in a. above, by the average monthly California petroleum price in b. above, and rounding to the nearest one-tenth of a percent, or three significant places.

10 = the factor for converting petroleum prices stated in cents per million Btu to mills per kWh. The factor assumes a heat rate of 10,000 Btu per kilowatthour.

8. *Weighting Factors.* For purposes of determining California fuel prices for the month, gas and petroleum prices will be weighted based on California's historical use of these two alternative fuels.

a. *Historical Gas Use in California.* The following formula shall be used to

determine the weighting factor for gas prices (WGU):

WGU = CGU * HGU

Where:

CGU = the monthly net gas-fired generation, expressed in gigawatthours, for California in the most recent monthly issue of EPM published by the EIA, U.S. Department of Energy.

HGU = the historical relationship between gas consumptions in the effective month of the NF Rate Cap (month t) and the month for which gas consumption is reported in EMP (month r) using the following procedures:

(1) Summing the reported net-gas fired generation for California, expressed in gigawatthours, from EPM from month t for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of California's historical monthly consumption shall be divided by the number of years for which gas consumption was reported and rounded to the nearest gigawatthour.

(2) Summing the reported net gas-fired generation for California, expressed in gigawatthours, from EPM for month r for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of California's historical monthly consumption shall be divided by the number of years for which gas consumption was reported and rounded to the nearest gigawatthour.

(3) Dividing the average consumption of gas in California for the month t as determined in (1) above by the average consumption of gas for the month r as determined in (2) above and rounding to the nearest one-tenth, or three significant places.

b. *Historical Petroleum Use in California.* The following formula shall be used to determine the weighting factor for petroleum prices (WOU):

WOU = COU * HOU

Where:

COU = the monthly net petroleum-fired generation, expressed in gigawatthours, in California in the most recent monthly issue of EPM published by the EIA, U.S. Department of Energy.

HOU = the historical relationship between petroleum consumptions in the effective month of the NF Rate Cap (month t) and the month for which petroleum consumption is reported in EPM (month r) using the following procedures:

(1) Summing the reported net-petroleum generation for California, expressed in gigawatthours, from EPM for month t for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of California's historical monthly consumption shall be divided by the number of years for which petroleum consumption was reported and rounded to the nearest gigawatthour;

(2) Summing the reported net-petroleum generation for California, expressed gigawatthours, from EPM for month r for the years beginning with calendar year 1982 up to and including the prior calendar year. The sum of California's historical monthly consumption shall be divided by the number of years for which petroleum consumption was reported and rounded to the nearest gigawatthour; and

(3) Dividing the average consumption of petroleum in California for the month t as determined in (1) above by the average consumption of petroleum for the month or as determined in (2) above and rounding to the nearest one-tenth, or three significant places.

D. *Determination of BPA's Average System Cost.* For purposes of determining BASC, the following definitions shall apply;

1. BPA's total system costs shall be the sum of all BPA's costs forecasted in each general rate case for the applicable rate period, including total transmission costs, Federal base system costs, new resource costs, exchange resource costs, and other costs not specifically allocated to a rate pool, such as section 7(g) costs.

2. BPA's total annual system sales shall be the sum of all BPA's system firm and nonfirm sales forecasted in each general rate case for the applicable test period.

BASC shall be redetermined in each subsequent general rate case according to the above formula and will be in effect for the entire rate period over which the rates are in effect.

Section V. Application of Rates Under Special Circumstances

A. *Energy Supplied for Emergency Use.* A purchaser taking Priority Firm or New Resource Firm Power shall pay in accordance with the Nonfirm Energy rate schedule, NF–93, and Emergency Capacity rate schedule, CE–93, for any electric energy or capacity which has been supplied:

1. For use during an emergency on the purchaser's system, or

2. Following an emergency to replace energy secured from sources other than BPA during such emergency.

Mutual emergency assistance may, however, be provided and payment therefore settled under exchange agreements.

B. *Construction, Test and Start-Up, and Station Service.* Power for the purpose of construction, test and start-up, and station service shall be made available to eligible purchasers under the Priority Firm and New Resources Firm Power Rate Schedules. Such power must be used in the manner specified below:

1. Power sold for construction is to be used in the construction of the project.

2. Power sold for test and start-up may be used prior to commercial operation both to bring the project on line and to ensure that the project is working properly.

3. Power sold for station service may be purchased at any time following commercial operation of the project. Station service power may be used for project start-up, project shut-down, normal plant operations, and operations during a plant shut-down period.

C. *Application of Rates During Initial Operation Period—Transitional Service.*

1. *Eligibility for Transitional Service.* For an initial operating period, as specified in the power sales contract, beginning with the commencement of operation of a new industrial plant, a major addition to an existing plant, or reactivation of an existing plant or important part thereof, BPA may agree to bill the purchaser in accordance with the provisions of this section. This section shall apply to both:

a. DSIs having new, additional or reactivated plant facilities, and

b. Utility purchasers serving industrial purchasers with power purchased from BPA. BPA will provide transitional service to utilities for only those industrial loads for which the demand can be separately metered by the utility and recorded on a daily basis.

2. *Calculation of the Daily Demand.* If the purchase request billing on a Daily Demand basis pursuant to its power sales contract and if BPA agrees to such billing, the billing demand for the billing month shall be the average of the Daily Demands as adjusted for power factor.

Demand for each day shall be defined as 100 percent of the Measured Demand for the day (regardless of whether such Measured Demand occurs during the Peak Period or the Offpeak Period).

3. *Billing for Transitional Service.* Utilities receiving transitional service shall provide BPA with Daily Demand information for the industrial consumer for whom transitional service is provided. To compute the power bill for the point of delivery which includes the load being served with transitional

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service, BPA shall, at its discretion, either:

a. Determine the demand for the pertinent point of delivery without the industrial load and then add the average daily demand for such industrial load; or

b. Bill the entire point of delivery on a daily demand basis. Daily demand billing shall not affect the level of any curtailment charge or energy charge assessed by BPA.

D. *Changes in a DSI's BPA Operating Level.* If a DSI requests a waiver regarding the notice requirements specified in the DSI's power sales contract for a voluntary change in its BPA Operating Level, and if BPA does not grant the waiver, or if the DSI fails to give notice of such a change and does not request a waiver, the DSI shall be billed as if no notice has been provided until such time as the number of days in the notice period have passed. If, however, BPA agrees to waive the notice requirement, the power bill shall reflect the requested changes as of the requested effective date specified in the notice or, at BPA's discretion, a date of BPA's choosing within the notice period.

E. *Restriction of Deliveries.* Deliveries of capacity or energy to any purchaser may be restricted when operation of the facilities used by BPA to serve such purchaser is:

1. Suspended,
2. Interrupted,
3. Interfered with,
4. Curtailed, or
5. Restricted by the occurrence of any condition described in the Uncontrollable Forces or Continuity of Service sections of the General Contract Provisions of the power sales contract.

Section VI. Billing Information

A. *Determination of Estimated Billing Data.* If the amounts of capacity, energy, or the 60-minute integrated demands for energy purchased from BPA must be estimated from data other than metered or scheduled quantities, historical patterns, and pertinent weather data, BPA and the purchaser will agree on billing data to be used in preparing the bill. If the parties cannot agree on estimated billing quantities, derived by any method, a determination binding on both parties shall be made in accordance with the arbitration provisions of the power sales contract.

B. *Load Shift and Outage Reports.* Load shift and outage reports must be submitted to BPA within 4 days of the corresponding load shift or outage. Reports may be made by telephone, mail, or other electronic processes where available. If customer reports are not received in a timely manner, BPA has the option to withhold load shift or outage credit.

C. *Billing for New Large Single Loads.* Any BPA customer whose actual firm load includes one or more New large Single Loads (NLSL) shall be billed for the NLSL(s) at the New Resources Firm Power Rate. The power requirements associated with the NLSL shall be established in a manner consistent with the provisions of this section.

The purchaser shall warrant to BPA that NLSLs are separately metered. The metering must include provisions for determining:

1. The NLSL demand during BPA's diurnal capacity billing periods,
2. The NLSL energy during BPA's energy billing periods, and
3. The NLSL reactive energy for the billing month.

The design for the metering equipment for the NLSL must be approved by BPA. Testing and inspections of such metering installations shall be as provided in the General Contract Provisions.

On a monthly basis, each purchaser of New Resource Firm Power shall report to BPA the quantity of power used by the NLSL during the purchaser's billing period. Data provided to BPA by the purchaser must be submitted to BPA within 2 normal working days of the date the purchaser reads the meters. BPA may elect to adjust the NLSL data for losses from the point of metering to the closest BPA point of delivery for the purchaser.

D. *Determination of Measured Demand.* 1. For point of delivery with fully operational metering under the Revenue Metering System (RMS), demand shall be measured from 0000 hours on the first day of the billing period through 2400 hours on the last day of the billing period.

2. For points of delivery that do not have RMS metering, demand shall be measured from 0000 hours on the first complete (24 hour) day of the available metering data through 2400 hours on the last complete day of the available metering data. Billing demand will be determined from the period of available metering data that most closely matches the official billing period of the customer.

E. *Determination of Measured Energy.* 1. For point of delivery with fully operational metering under RMS, energy shall be measured from 0000 hours on the first day of the billing period through 2400 hours on the last day of the billing period.

2. For points of delivery that do not have RMS metering, measured energy shall be the quantity of usage recorded on the meter between meter readings.

F. *Billing Month.* Meters normally will be read and bills computed at intervals of 1 month. A month is defined as the interval between scheduled meter-reading dates. The billing month will not exceed 31 days in any case. While it may be necessary to read meters on a day other than the scheduled meter-reading date, for determination of billing demand, the billing month will cease at 2400 hours on the last scheduled meter-reading date. Schedules will be predetermined. The customer must give 30 days notice to request a change to the schedule.

G. *Payment of Bills.* Bills for power shall be rendered monthly by BPA. Failure to receive a bill shall not release the purchaser from liability for payment. Bills for amounts due BPA of 50,000 or more must be paid by direct wire transfer, customers who expect that their average monthly bill will not exceed $50,000 and who expect special difficulties in meeting this requirement may request, and BPA may approve, an exemption from this requirement. Bills for amounts due BPA under $50,000 may be paid by direct wire transfer or mailed to the Bonneville Power Administration, P.O. Box 6040, Portland, Oregon 97228–6040, or to another location as directed by BPA. The procedures to be followed in making direct wire transfers will be provided by the Office of Financial Management and updated as necessary.

1. *Computation of Bills.* Demand and energy billings for power purchased under each rate schedule shall be rounded to whole dollar amounts, by eliminating any amount which is less than 50 cents and increasing any amount from 50 cents through 99 cents to the next higher dollar.

2. *Estimated Bills.* At its option, BPA may elect to render an estimated bill for that month to be followed at a subsequent billing date by a final bill. Such estimated bill shall have the validity of and be subject to the same payment provisions as a final bill.

3. *Due Date.* Bills shall be due by close of business on the 20th day after the date of the bill (due date). This requirement holds also for revised bills (see section 6 below). Should the 20th day be a Saturday, Sunday, or holiday (as celebrated by the purchaser), the due date shall be the next following business day.

4. *Late Payment.* Bills not paid in full on or before close of business on the due date shall be subject to a penalty charge of $25. In addition, an interest charge of one-twentieth percent (0.05 percent) shall be applied each day to the sum of

the unpaid amount and the penalty charge. This interest charge shall be assessed on a daily basis until such time as the unpaid amount and penalty charge are paid in full.

Remittances received by mail will be accepted without assessment of the charges referred to in the preceding paragraph provided the postmark indicates the payment was mailed on or before the due date. Whenever a power bill or a portion thereof remains unpaid subsequent to the due date and after giving 30 days' advance notice in writing, BPA may cancel the contract for service to the purchaser. However, such cancellation shall not affect the purchaser's liability for any charges accrued prior thereto under such contract.

5. *Disputed Billings.* In the event of a disputed billing, full payment shall be rendered to BPA and the disputed amount noted. Disputed amounts are subject to the late payment provisions specified above. BPA shall separately account for the disputed amount. If it is determined that the purchaser is entitled to the disputed amount, BPA shall refund the disputed amount with interest, as determined by BPA's Office of Financial Management.

BPA retains the right to verify, in a manner satisfactory to the Administrator, all data submitted to BPA for use in the calculation of BPA's rates and corresponding rate adjustments. BPA also retains the right to deny eligibility for any BPA rate or corresponding rate adjustment until all submitted data have been accepted by BPA as complete, accurate, and appropriate for the rate or adjustment under consideration.

6. *Revised Bills.* As necessary, BPA may render a revised bill.

a. If the amount of the revised bill is less than or equal to the amount of the original bill, the revised bill shall replace all previous bills issued by BPA that pertain to the specified customer for the specified billing period and the revised bill shall have the same date as the replaced bill.

b. If a revision causes an additional amount to be due BPA or the *specified customer* beyond the amount of the original bill, a revised bill will be issued for the difference and the date of the revised bill shall be its date of issue.

Section VII. Variable Industrial Rate Parameters and Adjustments

A. *Monthly Average Aluminum Price Determination.*

1. *Calculation of the Monthly Billing Aluminum Price.* The monthly billing aluminum price shall be determined by BPA for each billing month. For purposes of this rate schedule, the monthly billing aluminum price shall be based on the average price of aluminum in U.S. markets during the third calendar month prior to the billing month. The average price for aluminum in U.S. markets shall be defined as the average U.S. Transaction Price reported for the month by "Metals Week," in cents per pound, rounded to the nearest tenth of a cent.

2. *Notification of the Monthly Average Aluminum Price.* BPA shall provide, 45 days prior to the billing month, written notification to purchasers under this rate schedule of the monthly billing aluminum price to be used for billing purposes. Upon written request supporting documentation shall be provided.

3. *Changes in Aluminum Price Indicators.* In the event that BPA determines that factors outside its control render the monthly average U.S. Transaction Price unusable as an approximation of U.S. market prices, BPA may develop and substitute another indicator for prices in U.S. markets. BPA shall notify interested parties of its intent to do so at least 120 days prior to the billing month in which the change would become effective. In this notification, BPA shall explain the reason for the substitution and specify the replacement indicator it intends to use. BPA also shall describe the methodology to determine the monthly billing aluminum price to be used for billing purposes under this rate schedule and shall provide the necessary data to be used in the calculation. Interested persons will have until close of business 3 weeks from the date of the notification to provide comments. Consideration of comments and more current information may cause the final methodology and the substitute aluminum price index to differ from those proposed. BPA shall notify all affected parties, and those parties that submitted comments, of its final determination 90 days prior to the billing month the new indicator shall be effective.

B. *Annual Adjustments to the Lower and Upper Pivot Aluminum Prices.* On July 1, 1991, and every July 1, thereafter, the Lower and Upper Pivot Aluminum Prices, as stated in section III.B of the rate schedule, shall be subject to change for billing purposes as herein described. The term "annual adjustment date" shall refer to July 1 of each year.

1. *Implementation Procedures.* Beginning in 1991 and every year thereafter, prior to April 1 of that year, BPA shall provide the purchasers under this rate schedule preliminary written estimates of proposed adjustments to the Lower and Upper Pivot Aluminum Prices. By the last working day of the month of April, BPA shall notify interested parties in writing of BPA's revised determinations concerning changes to the Lower and Upper Pivot Aluminum Prices. BPA shall describe how the adjustments were determined and provide the data used in the calculations. In addition to written notification, BPA may, but is not obligated to, hold a public comment forum to clarify its determinations and solicit comments. Interested persons may submit comments on the determinations to BPA and other parties. Comments will be accepted until close of business on the last working Friday in May. Consideration of comments and more current information may result in the final adjustment differing from the proposed adjustment. By June 30 of each year, BPA shall notify all VI purchasers, those parties that submitted comments, and parties that requested notification, of the final determination.

2. *Annual Adjustment procedures.* a. *Annual Adjustment of the Lower Pivot Aluminum Price.* Beginning with the July 1, 1991, annual adjustment date, for each year that the Variable Industrial rate is in effect, the Lower Pivot Aluminum Price as stated in section III.B.1 of the rate schedule shall be adjusted on the July 1 annual adjustment date. The Lower Pivot Aluminum Price shall be revised by multiplying 59 cents per pound by the Cost Escalation Index described in section VII.B.3.b of these GRSPs and rounded to the nearest tenth of a cent. The revised Lower Pivot Aluminum Price shall replace the Lower Pivot Aluminum Price as stated in section III.B.1 of the rate schedule and shall be used to determine the energy rate in the subsequent 12 billing months.

b. *Annual Adjustment of the Upper Pivot Aluminum Price.* For each year that the Variable Industrial rate is in effect, the Upper Pivot Aluminum Price as stated in section III.B.2 of the rate schedule shall be adjusted on the July 1 annual adjustment date. The Upper Pivot Aluminum Price will be adjusted such that the Average Historical Aluminum Price described in section VII.B.4 of these GRSPs is the midpoint between the adjusted Upper Pivot Aluminum Price and the Average Historical Lower Pivot Aluminum Price described in section VII.B.5 below, except as limited to the greater of 65 cents per pound or the adjusted Lower Pivot Point for the year.

The Upper Pivot Aluminum Price shall equal the greater of:

(1) (2)(AAP)–ALP:

where
AAP=the Average Historical Aluminum Price described in section VII.B.4 of these GRSPs.
ALP=the Average Historical Lower Pivot Aluminum Price described in section VII.B.5 of these GRSPs.

(2) 65.0 cents per pound escalated to current dollars using the Cost Escalator for the Upper Pivot Aluminum Price described in section VII.B.3.c of these GRSPs, or

(3) The adjusted Lower Pivot Aluminum Price for the year.

The revised Upper Pivot Aluminum Price shall supersede the Upper Pivot Aluminum Price as stated in section III.B.2 of the rate schedule and shall be used to determine the energy rate in the subsequent 12 months.

3. *Cost Escalators.* a. The cost indices described below shall be used in calculating the appropriate cost escalators. Each index shall be rounded to the nearest one-tenth of a percent, or three significant places.

(1) *Electricity Cost Index.* The average VI rate in mills per kilowatthour based on the Plateau Energy Charge and the Discount for Quality of First Quartile Service in effect on the April 1 preceding the annual adjustment date and a load factor of 98.5 percent; divided by 22.8 mills per kilowatthour (the average VI–86 rate assuming the plateau energy charge and the Discount for Quality of First Quartile Service in 1986).

(2) *Labor Cost Index.* The annual average hourly earnings for the U.S. primary aluminum industry (SIC 3334) over the previous complete calendar year, from the Employment and Earnings, published by the U.S. Department of Labor, Bureau of Labor Statistics (BLS), divided by $14.20 per hour (the value of SIC 3334 earnings reported for 1985).

(3) *Alumina Cost Index.* The annual average of the monthly billing aluminum prices described in section VII.A of the GRSPs for the previous 1-year period beginning July 1 through June 30 divided by 50.8 cents per pound (the average U.S. Transaction price over the period April 1985 through March 1986).

(4) *Other Costs Index.* The annual average GNP Implicit Price Deflator for the previous complete calendar year, as published by the U.S. Department of Commerce, Bureau of Economic Analysis, divided by 1.126 (the value of the GNP Implicit Price Deflator for 1985 with 1982=1.000).

In the event the indices delineated above are discontinued or revised in a manner that BPA determines renders them unusable for calculating a consistent cost index, BPA will adjust or substitute another similar price index, following advance notification and opportunity for public comment as described in section VII.B.I of these GRSPs.

b. The Cost Escalator for the Lower Pivot Aluminum Price shall be a weighted average of the four indices contained in section VII.B.3.a above. The following weights shall be assigned each index:

Electricity Cost Index	.30
Labor Cost Index	.20
Alumina Cost Index	.20
Other Costs Index	.30

c. The Cost.Escalator for the Upper Pivot Aluminum Price shall be a weighted average of the Electricity Cost and Other Cost Escalators as stated in sections VII.B.3.a.(1) and VII.B.3.a.(4) above. The following weights shall be assigned each index:

Electricity Cost Index	.25
Other Costs Index	.75

4. *Average Historical Aluminum Price.* Prior to the July 1, 1991, annual adjustment date and every annual adjustment date thereafter, an average historical aluminum price shall be calculated for the period the VI rate has been in effect beginning August 1986. The average historical aluminum price shall be determined following the procedures set forth below:

a. Each monthly billing aluminum price determined pursuant to section VII.A of these GRSPs for the period August 1, 1986, through June 30 immediately preceding the annual adjustment date, shall be escalated to the current year dollars using the Price Deflator procedures described in section VII.B.6 below.

b. The sum of the escalated monthly billing aluminum prices shall be divided by the number of months in the period.and rounded to the nearest tenth of a cent to obtain the Average Historical Aluminum Price.

5. *Average Historical Lower Pivot Aluminum Price.* Prior to the July 1, 1991, annual adjustment date and every annual adjustment date thereafter, the average of the Lower Pivot Aluminum Prices for the period the VI rate has been in effect beginning August 1986, shall be calculated following the procedures set forth below:

a. The Lower Pivot Aluminum Price in each month for the period August 1, 1986, through June 30 of the calendar year preceding the annual adjustment date, shall be escalated to the current year's dollars using the Price Deflator procedures described in section VII.B.6 below.

b. The sum of the escalated monthly Lower Pivot Aluminum Prices shall be divided by the number of months in the period, and rounded to the nearest tenth of a cent to obtain an Average Historical Lower Pivot Aluminum Price.

6. *Price Deflator Procedures.* For purposes of converting nominal dollars to real dollars in the calculation of the Average Historical Aluminum Price and the Average Historical Lower Pivot Aluminum Price, the following Price Deflator procedures shall be used:

a. Monthly billing aluminum prices and Lower Pivot Aluminum Prices for any calendar months July through December shall be inflated by multiplying the price by the ratio of the GNP Implicit Price Deflator for the calendar year prior to the annual adjustment date divided by the Implicit Price Deflator for the calendar year in which the price occurred.

b. Monthly billing aluminum prices and Lower Pivot Aluminum Prices for any calendar months January through June shall be inflated by multiplying the price by the ratio of the Implicit Price Deflator for the calendar year prior to the annual adjustment date divided by the Implicit Price Deflator for the calendar year prior to the year in which the price occurred. Each price shall be rounded to the nearest tenth of a cent.

Issued in Portland, Oregon, on January 5, 1993.

Randall W. Hardy,
Administrator.

[FR Doc. 93–942 Filed 1–14–93; 8:45 am]
BILLING CODE 6450–01–M

Availability of the Final Environmental Impact Statement on Decommissioning of Eight Surplus Production Reactors at the Hanford Site, Richland, WA

AGENCY: U.S. Department of Energy.

ACTION: Notice of availability of the final environmental impact statement.

SUMMARY: The U.S. Department of Energy (DOE) announces the availability of the Final Environmental Impact Statement (FEIS) on "decommissioning of Eight Surplus Production Reactors at the Hanford Site Richland, Washington" (DOE/EIS–0119F). The FEIS consists of the draft Environmental Impact Statement (DEIS) and an Addendum. The FEIS provides information on the potential environmental impacts of decommissioning the eight surplus plutonium production reactors at the Hanford Site, a DOE facility located near Richland, Washington. The FEIS contains public and agency comments on the DEIS and the DOE's responses to

the comments, and identifies safe storage followed by deferred one-piece removal as DOE's preferred decommissioning alternative.

ADDRESSES: Requests for copies of the FEIS and for further information on the FEIS should be directed to Mr. Michael Talbot, Acting Director, Office of Communications, DOE Richland Field Office, U.S. Department of Energy, Richland, Washington 99352. Telephone: (509) 376–7501. For further information on the National Environmental Policy Act (NEPA) process contact Ms. Carol Borgstrom, Director, Office of NEPA Oversight, EH–25, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585.

Telephone: (202) 586–4600 or (800) 472–2756.

SUPPLEMENTARY INFORMATION: DOE published a DEIS in March 1989 on decommissioning the eight surplus plutonium production reactors located at the Hanford Site, and also published a notice of availability of the DEIS in the **Federal Register** on April 28, 1989 (54 FR 18325). During a 90-day comment period, DOE conducted four public hearings and received written comments on the DEIS. Because there were no additional alternatives identified from the public and agency review process, and because there were no additional analyses required, DOE determined that an Addendum to the DEIS could be prepared. Comment letters, public hearing transcripts, and the DOE responses to comments are printed in the Addendum. The DEIS and the Addendum constitute the FEIS under the Council on Environmental Quality (CEQ) regulations in 40 CFR 1503.4(c).

Included within the scope of the proposed action and analyses in the EIS are the reactors, their associated fuel storage basins, and the buildings that house these facilities. Not included within the scope of the EIS are reactor ancillary facilities or 100 Area cribs, burial grounds, and settling basins. These facilities are being evaluated within the scope of DOE's responsibilities under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, and the Resource Conservation and Recovery Act, as delineated in the Hanford Tri-Party Agreement.

The Agreement provides that whenever decommissioning activities result in the generation of hazardous wastes or releases of hazardous substances, the treatment, storage, or disposal of those wastes or any remediation of a release of hazardous substances shall be subject to the Tri-Party Agreement.

DOE's proposed action is to decommission the eight surplus production reactors to mitigate release of radioactive or hazardous materials in a manner protective of the public health and welfare in accordance with applicable standards. Alternatives considered in the EIS include:

1. Immediate one-piece removal (i.e., dismantlement and removal of contaminated equipment and components of the fuel storage basin and reactor buildings and one-piece removal of the reactor block assembly to the 200 West Area at Hanford for disposal);
2. Safe storage followed by deferred one-piece removal (i.e., continuation of current maintenance, monitoring, and surveillance activities for up to 75 years followed by one-piece removal);
3. Safe storage followed by deferred dismantlement (i.e., safe-storage followed by piece-by-piece dismantlement and removal of the reactor-block assembly and other contaminated equipment and components);
4. In situ decommissioning (i.e., the sealing and stabilization of the reactor facilities at their present location under an engineered protective earthen mound); and
5. No action (i.e., continuation of the present surveillance, monitoring, and maintenance activities).

Preferred Alternative: The environmental impacts of decommissioning the eight surplus production reactors do not offer a strong basis for selection among the alternatives. Based on its review of the environmental impacts, total project cost, and the results of the public hearing process, DOE identifies safe-storage, followed by deferred one-piece removal, as its preferred alternative. DOE proposes to complete this action no later than the year 2019, consistent with related activities scheduled under the Hanford Tri-Party Agreement. The shortened safe-storage period would result in cost and environmental impacts that are bounded by the immediate and the deferred one-piece removal alternatives.

Historic Preservation: DOE nominated the B Reactor for inclusion in the National Register of Historic Places in accordance with the opinion of the Washington State Historic Preservation Officer and the provisions of 36 CFR 800, "Protection of Historic and Cultural Properties." On April 3, 1992, the National Park Service entered the B Reactor in the National Register. Actions to preserve this historic resource may include extensive recordation by photographs, drawings, models, exhibits, and written histories, and may also include preservation of some portions of the B Reactor for display on or near its present location or at some other selected location.

Availability of the FEIS: Copies of the FEIS have been distributed to Federal, State, and local officials and agencies; to organizations and individuals known to be interested in decommissioning of the Hanford surplus production reactors; and to persons and agencies commenting on the DEIS. Additional copies may be obtained by contacting Mr. Talbot at the above address.

Copies of the FEIS and copies of the documents referenced in the FEIS, as well as major references used in preparing the DEIS, are available for public inspection at the following locations:

U.S. Department of Energy Public Reading Room, room 157 Federal Building, P.O. Box 800, Richland, WA 99352, (509) 376–8583.

Portland State University Library, Portland, OR 97201, (503) 725–3000.

U.S. Department of Energy Freedom of Information Reading Room, Room IE–190, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585.

Pasco Public Library, 1320 West Hopkins, Pasco, WA 99301, (509) 545–3451.

Walla Walla Public Library, 238 East Alder, Walla Walla, WA 99362, (509) 525–5353.

Kennewick Public Library, 405 South Dayton, Kennewick, WA 99336, 1–800–572–6251 or (509) 586–3156.

Richland Public Library, Swift and Northgate, Richland, WA 99352, (509) 943–9117.

Yakima Valley Main Public Library, 102 North 3rd, Yakima, WA 98901, (509) 452–8541.

Public Reference Center, Washington Department of Ecology, 5826 Pacific Avenue, Lacey, WA 98503, (206) 459–6675.

Crosby Library, Gonzaga University, East 500 Boone, Spokane, WA 99258, (509) 484–2831.

Suzzallo Library, University of Washington, Seattle, WA 98195, (206) 543–9158.

Issued in Washington, DC, on October 26, 1992.

Leo P. Duffy,

Assistant Secretary for Environmental Restoration and Waste Management.

[FR Doc. 93–645 Filed 1–14–93; 8:45 am]

BILLING CODE 6450–01–M

Office of Environmental Restoration and Waste Management

Solicitation of Comments From the Public on the Preliminary Environmental Restoration and Waste Management Five-Year Plan, Fiscal Years (FY) 1994–1998

AGENCY: Office of Environmental Restoration and Waste Management, Department of Energy (DOE).

ACTION: Notice of availability.

SUMMARY: The preliminary version of the Department of Energy's fourth Environmental Restoration and Waste Management Five-Year Plan is scheduled for release on January 15, 1993. This fourth plan, which covers Fiscal Years (FY) 1994–1998, reaffirms DOE's position that full compliance with applicable environmental requirements is an integral part of operating DOE facilities. DOE's fundamental goal is to ensure that risks to human health and the environment posed by the Department's past, present, and future operations are either eliminated or reduced to prescribed, safe levels by the year 2019.

DATES: The comment period will end on March 30, 1993. All comments received by that date will be factored into the FY 1995 planning process.

ADDRESSES: Persons requiring a single copy of the preliminary plan may submit their requests in writing to: Richard J. Aiken, Director, Five-Year Plan, Office of Environmental Restoration and Waste Management, EM–14, Department of Energy, Washington, DC 20585. A copy of the plan may also be obtained by calling the EM Hotline at (301) 903–3555 and leaving a name and address on the automatic recording device. Written comments on the preliminary Five-Year Plan should also be sent to Mr. Aiken at the above address. Multiple copies of the plan can be purchased from the Government Printing Office. Please address your requests to: Superintendent of Documents, Government Printing Office, 8610 Cherry Lane, Laurel, MD 20708. The plan will also be available in the Department of Energy's Public Reading Rooms, locations of which are:

California

US DOE-San Francisco, 1333 Broadway, Wells Fargo Building, Oakland, CA 94612, 510/273–4428

Colorado

US DOE-Grand Junction Area Office, 2597 B–3/4, P.O. Box 2567, Grand Junction, CO 81503, 303/248–6015

US DOE-Rocky Flats, Front Range Community College, 3645 W. 112 Avenue, Westminster, CO 80030, 303/469–4435

New Mexico

US DOE-Albuquerque, National Atomic Museum, Building 20358 Wyoming Blvd., P.O. Box 5400, Albuquerque, NM 87185–5400, 505/845–4378

Oklahoma

US DOE-NIPER Library, 220 N. Virginia Avenue, P.O. Box 2128, Bartlesville, OK 74003, 918/337–4372

Pennsylvania

US DOE-Philadelphia Support Office, 1421 Cherry Street, 10th Floor, Philadelphia, PA 19102, 212/597–7898

District of Columbia

US DOE-Headquarters, Room 1E–190, 1000 Independence Avenue, SW., Washington, DC 20585, 202–586–6020

Georgia

US DOE-Southeastern Power Adm., Samuel Elbert Building, Public Square, Elberton, GA 30535, 404/283–9911

Idaho

INEL Technical Library Center, 1776 Science Center Drive, P.O. Box 1625, Idaho Falls, ID 83415–1144, 208/526–1144

Illinois

US DOE-Chicago, 9800 S. Cass Avenue, Argonne, IL 60439, 312/972–2010

Massachusetts

US DOE-Chicago, Boston Support Office, 10 Causeway Street, room 1197, Boston, MA 02222–1035, 617/585–7703

Nevada

US DOE-Nevada, 2753 S. Highland Drive, P.O. Box 98518, Las Vegas, NV 89193–8518, 702/295–1128

Pennsylvania

Cochran Mill Road, Building 95, P.O. Box 10940, Pittsburgh, PA 15236–0940, 412/892–4751

Tennessee

US DOE-Oak Ridge, 200 Administration Road, P.O. Box 2001, Oak Ridge, TN 237831–8510, 615/576–1218

Texas

US DOE-Amarillo, 2201 S. Washington Street, P.O. Box 30030, Amarillo, TX 79120, 806/371–5400

US DOE-Dallas Support Office, 1440 W. Mockingbird Lane, Suite 305, Dallas, TX 75247, 214/767–7040

Washington

US DOE-Richland, 825 Jadwin Avenue, P.O. Box 1970 A1–65, Richland, WA 99352, 509/376–8583

West Virginia

US DOE-Morgantown Energy Technology Center Library, 3610 Collins Ferry Road, P.O. Box 880, Morgantown, WV 26507 304/291–4183.

FOR FURTHER INFORMATION CONTACT: Mr. Richard J. Aiken (202) 586–4373, fax (202) 586–9172.

SUPPLEMENTARY INFORMATION: The preliminary Five-Year Plan describes DOE's plans for achieving major environmental cleanup and compliance objectives over a five-year planning horizon. It includes a detailed description of major program elements (Corrective Activities and Waste Management, Environmental Restoration, Facility Transition, Technology Development, and Transportation Management) and provides summaries for all sites and facilities in the DOE complex with environmental restoration and waste management responsibilities.

This preliminary Five-Year Plan is the product of expanded predecisional involvement by external parties and the general public. The plan incorporates many of the suggestions and comments received from the public regarding the FY 1993–1997 Plan, as well as comments by the State and Tribal Government Working Group and Stakeholders' Forum participants in the predecisional version of this plan. As a result, this Five-Year Plan is more concise and is focused on crosscutting objectives, major initiatives, and progress made during the past year. As much as possible, duplication of previously published information has been avoided.

The preliminary Five-Year Plan is a document of approximately 549 pages. The first volume is approximately 300 pages and contains the first two parts of the plan. Part I includes updated mission statements, and also presents and discusses major objectives of the EM program. Part 2 is organized around the major EM programs: Corrective Activities and Waste Management, Environmental Restoration, Facility Transition and Management, Technology Development, and Transportation Management. EM's expanding mission is reflected in the decision to include a separate discussion of EM facility transfer and decontamination and decommissioning plans in this section. Both parts 1 and 2 are structured around a discussion of accomplishments, milestones, issues, and implementation strategies. Volume II provides a comprehensive overview of EM activities at each site. New this year is a strategic outlook section that presents each site's long-term strategy for achieving major assessment, cleanup, compliance, land-use, and technology development goals. The third volume of the plan, to be published in late 1992, will include detailed discussion of comments received during this public comment period.

Issued in Washington, DC, on January 15, 1993.

Leo P. Duffy,

Assistant Secretary for Environmental Restoration and Waste Management.

[FR Doc. 93–1115 Filed 1–14–93; 8:45 am]

BILLING CODE 6450–01–M

Federal Energy Regulatory Commission

[Docket Nos. ER93–307–000, et al.]

Northeast Utilities Service Co., et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Take notice that the following filings have been made with the Commission:

1. Northeast Utilities Service Co.

[Docket No. ER93–307–000]

January 7, 1993.

Take notice that on December 31, 1992, Northeast Utilities Service Company (NUSCO), on behalf of The Connecticut Light and Power Company, Western Massachusetts Electric Company, Holyoke Water Power Company, and Holyoke Power and Electric Company, tendered for filing a Unit Sales Agreement for purchase by New England Power Company (NEP).

NUSCO states that the filing is in accordance with Section 35 of the Commission's Regulations.

Comment date: January 22, 1993, in accordance with Standard Paragraph E at the end of this notice.

2. Western Massachusetts Electric Co.

[Docket No. ER92–458–001]

January 7, 1993.

Take notice that on December 11, 1992, Western Massachusetts Electric Company tendered for filing its compliance refund report pursuant to the Commission's order issued on November 12, 1992.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

3. Mississippi Power Co.

[Docket No. ER93–277–000]

January 7, 1993.

Take notice that on December 14, 1992, Mississippi Power Company (Company) tendered for filing Superseding Service Delivery Point Contracts under the Company's Electric Tariff, First Revised Volume No. 1.

The two Service Delivery Point Contracts replace existing agreement. The revised Contract for the Ansley delivery point changes the delivery pressure from 46,000 volts to 115,000 volts. The revised contract for the G.E. Plastics delivery point changes the delivery point from Logtown to G.E. Plastics. These contract revisions are necessary to accommodate changes to the facilities and/or needs of Coast's customers.

Copies of the filing were served upon Coast, Southeast Mississippi Electric Power Association, and the Mississippi Public Service Commission.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

4. Cogen Energy Technology L.P.

[Docket No. QF87–604–003]

January 7, 1993.

On December 30, 1992, Cogen Energy Technology L.P. (Applicant), filed a petition with the Federal Energy Regulatory Commission for a temporary waiver of the efficiency standard for the year 1992 pursuant to § 291.205(c) of the Commission's Regulations. No determination has been made that the submittal constitutes a complete filing.

The 62 MW topping-cycle cogeneration facility which is located in Castleton-on-Hudson, New York consists of a combustion turbine generator, and a heat recovery boiler (HRB). Steam generated in HRB will be used in processes at the Fort Orange Paper Company. The facility uses natural gas as its primary energy source. Applicant filed notices of self certifications in Dockets QF87–604–000, QF87–604–001, and QF87–604–002.

Applicant states that the temporary waiver is requested due to (1) forced outage of the facility caused by the failed steam turbine generator, and (2) the limited generation of power without concurrent use of thermal output.

Comment date: February 16, 1993, in accordance with Standard Paragraph E at the end of this notice.

5. Public Service Electric and Gas Co.

[Docket No. ER93–32–000]

January 7, 1993.

Take notice that on December 22, 1992, Public Service Electric and Gas Company (PSE&G) tendered for filing an Initial Rate Schedule to provide transmission service to American Ref-Fuel Company of Essex County ("REF–FUEL") for delivery of the power output of REF–FUEL'S independent power facility located in Newark, New Jersey to the Jersey Central Power & Light Company as well to provide for operation and maintenance of the interconnection facility. PSE&G submitted the first Supplemental Agreement and additional description and explanatory information concerning the interconnection facilities which will be used to provide service to REF–FUEL.

PSE&G proposes an effective date of the Initial Rate Schedule as of January 1, 1993, therefore, requests waiver of the Commission's notice requirements.

Copies of the filing, as amended, have been served on REF–FUEL and the New Jersey Board of Regulatory Commissioners.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

6. Green Mountain Power Corp.

[Docket No. ER92–803–000]

January 7, 1993.

Take notice that on December 22, 1992, Green Mountain Power Corporation tendered for filing unexecuted copies of an Amendment to the Sales Agreement in the above-referenced docket.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

7. Detroit Edison Co.

[Docket No. ER93–91–001]

January 7, 1993.

Take notice that on December 24, 1992, Detroit Edison Company tendered for filing its refund report in the above-referenced docket.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

8. Central Maine Power Co.

[Docket No ER91–620–002]

January 7, 1993.

Take notice that on December 22, 1992, Central Maine Power Company tendered for filing its refund report in the above-referenced docket.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

9. Southern Company Services, Inc.

[Docket No ER91–150–009]

January 7, 1993.

Take notice that on November 25, 1992, Southern Company Services, Inc. tendered for filing its compliance refund report in the above-referenced docket.

Comment date: January 20, 1993, in accordance with Standard Paragraph E at the end of this notice.

10. Northern States Power Co.

[Docket No EL91–2–002]

January 7, 1993.

Take notice that on December 28, 1992, Northern States Power Company tendered for filing revised tariff pages incorporating the modification to its fuel adjustment clauses authorized in

the Commission's order issued February 6, 1992.

Comment date: January 21, 1993, in accordance with Standard Paragraph E at the end of this notice.

11. Florida Power & Light Co.

[Docket No ER93-308-000]

January 7, 1993.

Take notice that on December 31, 1992, Florida Power & Light Company (FPL) tendered for filing Amendment Number Five to Amended Agreement to Provide Specified Transmission Service Between Florida Power & Light Company and Seminole Electric Cooperative, Inc. (Amendment No. 5). FPL requests that Amendment No. 5 be made effective January 1, 1993.

Comment date: January 22, 1993, in accordance with Standard Paragraph E at the end of this notice.

12. Black Hills Corp.

[Docket No EC93-7-000]

January 7, 1993.

Take notice that on January 4, 1993, Black Hills Corporation, which operates its electric utility under the assumed name of Black Hills Power and Light Company (BHPL), pursuant to Section 203(a) of the Federal Power Act, 16 U.S.C. 824b, tendered for filing an Application for an order authorizing BHPL to acquire two electric generating units, described as Osage Unit #3 (located in Weston County, Wyoming) and Kirk Unit #4 (located in Lawrence County, South Dakota), from Rushmore Electric Power Cooperative, Inc. (REPC), a rural electric generation and transmission cooperative. Osage Unit #4 is an 11.5 megawatt (name rating) coal-fired electric generating plant in Weston County, Wyoming and has been in service since 1952. Kirk Unit #4 is an 18.75 megawatt (name rating) coal-fired electric generating plant which has been in operation in Lawrence County, South Dakota since 1956. Both plants include step-up transformers and related transmission equipment interconnected to BHPL's integrated transmission system. BHPL has operated the two generating plants since their construction under a lease arrangement with REPC. BHPL proposes to pay REPC cash equal to REPC's actual original cost, depreciated as carried on the books of account of REPC.

BHPL generates, transmits, distributes and sells electricity to approximately 51,680 retail customers and one wholesale customer in portions of eleven counties in western South Dakota, eastern Wyoming and southeastern Montana. BHPL's retail operations are subject to regulation by the state commissions of South Dakota, Wyoming and Montana. Subject to the jurisdiction of the Federal Energy Regulatory Commission, BHPL provides partial requirements wholesale to Gillette, Wyoming and transmission service to rural electric cooperatives and purchases electricity from neighboring utilities.

REPC is a rural electric transmission and generation cooperative which purchases electricity and resells electricity to its rural electric distribution members located in western South Dakota.

BHPL believes that the acquisition of Osage Unit #3 and Kirk Unit #4 will be in the best interests of the public and its customers and shareholders and the members of REPC in that BHPL has utilized substantially all of the energy produced from the two generating plants and will continue to rely upon the two plants for an indefinite period of time, while REPC has never relied upon the energy produced from the plants and does not intend to rely thereon in the future.

BHPL has requested that further notice be waived and the application be expedited.

Comment date: January 27, 1993, in accordance with Standard Paragraph E at the end of this notice.

13. KFM Pepperell, Inc.

[Docket No EG93-10-000]

January 8, 1993.

Take notice that on December 31, 1992, KFM Pepperell, Inc. filed an application for determination of Exempt Wholesale Generator status. KFM Pepperell, Inc. states that it operates the Pepperell Power Facility, an eligible facility under the National Energy Policy Act of 1992.

Comment date: January 29, 1993, in accordance with Standard Paragraph E at the end of this notice.

14. Pepperell Power Associates Limited Partnership

[Docket No EG93-11-000]

January 8, 1993.

Take notice that on December 31, 1992, Pepperell Power Associates Limited Partnership (PPALP) filed an application for determination of Exempt Wholesale Generator status. PPALP states that it is a Massachusetts limited partnership whose principal asset is the Pepperell Power Facility, a topping cycle cogeneration facility located in Pepperell, Massachusetts.

Comment date: January 29, 1993, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-1010 Filed 1-14-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP93-139-000, et al.]

Tennessee Gas Pipeline Co., et al.; National Gas Certificate Filings

Take notice that the following filings have been made with the Commission:

1. Tennessee Gas Pipeline Co.

[Docket No. CP93-139-000]

January 7, 1993

Take notice that on December 31, 1992, Tennessee Gas Pipeline Company (Tennessee), P.O. Box 2511, Houston, Texas 77252, filed in Docket No. CP93-139-000, an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon a natural gas transportation service provided to Southern National Gas Company (Southern) under Tennessee's Rate Schedule T-173, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Tennessee states that by order issued February 20, 1985, in Docket No. CP84-133-000, Tennessee and Columbia Gulf Transmission Company (Columbia Gulf) were authorized to transport on a firm basis up to 12,000 Mcf per day each for Southern through the jointly owned South Pass 77 facilities from offshore Louisiana to Plaquemines Parish, Louisiana. Tennessee further states that by order issued November 10, 1992, in Docket No. CP92-582-000, Tennessee was authorized to partially abandon Rate Schedule T-173 by reducing Southern's maximum daily entitlement

under the Rate Schedule from 12,300 dt per day to 3,000 dt per day.[1]

Tennessee indicates that Southern no longer uses or needs the remaining 3,000 dt of transportation service currently available under Rate Schedule T–173. As a result, Tennessee states that Southern has requested a full abandonment of Rate Schedule T–173.

Tennessee requests that the abandonment of service to Southern be effective December 31, 1992, so that Southern's demand charge from Tennessee can be eliminated as of that date in accord with the parties' intent.

No facilities are proposed to be abandoned herein.

Comment date: January 28, 1992, in accordance with Standard Paragraph F at the end of this notice.

2. Frontier Gas Storage Co.

[Docket No. CP85–221–010]

January 7, 1993.

Take notice that on December 21, 1992, Frontier Gas Storage Company (Frontier), c/o Reid & Priest, Market Square, 701 Pennsylvania Ave., NW., Washington, DC 20004, in compliance with the provisions of the Commission's February 13, 1985 Order in Docket No. CP82–487–000 et al., submitted an executed Service Agreement under Rate Schedule LVS–1 providing for the possible sale of up to 1 Bcf of Frontier's gas storage inventory on an "as metered" basis to Western Gas Resources, Inc. (Western). The Service Agreement, dated December 18, 1992, contemplates the possible sale to commence January 4, 1993.

Under subpart (b) of Ordering Paragraph (F) of the Commission's February 13, 1985 Order, Frontier is "authorized to commence this sale of its inventory under such an executed service agreement fourteen days after the filing of the agreement with the Commission and may continue making such sale unless the Commission issues an order either requiring Frontier to stop selling and setting the matter for hearing or permitting the sale to continue and establishing other procedures for resolving the matter."

Comment date: January 17, 1993, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

3. High Island Offshore System

[Docket No. CP93–135–000]

January 8, 1993.

Take notice that on December 24, 1992, High Island Offshore System (HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed an application pursuant to section (7)(b) of the Natural Gas Act, as amended, and the Rules and Regulations of the Federal Energy Regulatory Commission (Commission), for authorization to abandon transportation service currently being rendered for United Gas Pipe Line Company (United).

In its application, HIOS proposes to terminate its firm transportation service which HIOS is rendering in accordance with HIOS' Rate Schedules T–5 and T–6, as well as associated Interruptible Overrun Transportation Service rendered in accordance with HIOS Rate Schedule I. HIOS proposes to terminate these services at the end of the primary term of Rate Schedules T–5 and T–6 effective March 31, 1993 and August 19, 1994, respectively, in accordance with the terms of such rate schedules and in accordance with timely notice given by United to HIOS.

HIOS requests that the abandonment be conditioned upon United remaining subject to and liable for any transition costs, exit fees, or other similar charges that are imposed as a result of HIOS' restructuring pursuant to Order Nos. 636, *et seq.*

Comment date: January 29, 1992, in accordance with Standard Paragraph F at the end of this notice.

4. High Island Offshore System

[Docket No. CP93–142–000]

January 8, 1993.

Take notice that on January 4, 1993, High Island Offshore System (HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed an application pursuant to section (7)(b) of the Natural Gas Act, as amended, and the Rules and Regulations of the Federal Energy Regulatory Commission (Commission), for authorization to abandon transportation service currently being rendered for Natural Gas Pipeline Company of America (Natural).

In its application, HIOS proposes to terminate the firm transportation service which HIOS is rendering in accordance with HIOS' Rate Schedule T–2, as well as associated Interruptible Overrun Transportation Service volumes rendered in accordance with HIOS' Rate Schedule I. HIOS proposes to terminate these services at the end of the primary term of Rate Schedule T–2, effective April 17, 1993, in accordance with the terms of such rate schedule and in accordance with timely notice given by Natural to HIOS.

HIOS requests that the abandonment be conditioned upon Natural remaining subject to and liable for any transition costs, exit fees, or other similar charges that are imposed as a result of HIOS' restructuring pursuant to Order Nos. 636, *et seq.*

Comment date: January 29, 1993, in accordance with Standard Paragraph F at the end of this notice.

5. High Island Offshore System

[Docket No. CP93–132–000]

January 8, 1993.

Take notice that on December 23, 1992, High Island Offshore System (HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed an application pursuant to section (7)(b) of the Natural Gas Act, as amended, and the Rules and Regulations of the Federal Energy Regulatory Commission (Commission), for authorization to abandon transportation service currently being rendered for El Paso Natural Company (El Paso).

In its application, HIOS proposes to terminate its firm transportation service which HIOS is rendering in accordance with HIOS' Rate Schedule T–13, as well as associated Interruptible Overrun Transportation Service rendered in accordance with HIOS' Rate Schedule I. HIOS proposes to terminate these services at the end of the primary term of Rate Schedule T–13, effective November 28, 1993, in accordance with the terms of such rate schedule and in accordance with timely notice given by El Paso to HIOS.

HIOS requests that the abandonment be conditioned upon El Paso remaining subject to and liable for any transition costs, exit fees, or other similar charges that are imposed as a result of HIOS' restructuring pursuant to Order Nos. 636, *et seq.*

Comment date: January 29, 1993, in accordance with Standard Paragraph F at the end of this notice.

6. Northern Gas Co.

[Docket No. CP93–126–000]

January 8, 1993.

Take notice that on December 21, 1992, Northern Gas Company (Northern), P.O. Box 281304, Lakewood, Colorado 80228–8304, filed a petition for a declaratory order in Docket No. CP93–126–000, requesting that the Commission declare that certain facilities to be acquired from Williston Basin Interstate Pipeline Company (Williston Basin) will not alter Northern's status as a Hinshaw pipeline exempt from the Commission's jurisdiction under section 1(c) of the Natural Gas Act (NGA), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

The facilities are approximately 30 miles of 6-inch transmission pipeline

[1] Tennessee currently measures gas in dekatherms rather than Mcf.

located in Natrona and Converse Counties, Wyoming. The pipeline will extend from Northern's existing system 30 miles to the east. The pipeline acquired is an isolated part of the Williston Basin system.

Comment date: January 29, 1992, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

7. High Island Offshore System

[Docket No. CP93-133-000]

January 8, 1993.

Take notice that on December 23, 1992, High Island Offshore System (HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed an application pursuant to Section (7)(b) of the Natural Gas Act, as amended, and the Rules and Regulations of the Federal Energy Regulatory Commission (Commission), for authorization to abandon transportation service currently being rendered for Columbia Gas Transmission Corporation (Columbia).

In its application, HIOS proposes to terminate its firm transportation service with HIOS is rendering in accordance with HIOS' Rate Schedule T-7, as well as associated Interruptible Overrun Transportation Service rendered in accordance with HIOS' Rate Schedule I. HIOS proposes to terminate these services at the end of the primary term of Rate Schedule T-7, effective June 29, 1993, in accordance with the terms of such rate schedule and in accordance with timely notice given by Columbia to HIOS.

HIOS requests that the abandonment be conditioned upon Columbia remaining subject to and liable for any transition costs, exit fees, or other similar charges that are imposed as a result of HIOS' restructuring pursuant to Order Nos. 636, *et seq.*

Comment date: January 29, 1993, in accordance with Standard Paragraph F at the end of the notice.

8. Wind River Gathering Co.

[Docket No. CP93-130-000]

January 8, 1993.

Take notice that on December 23, 1992, Wind River Gathering Company (Wind River), 12055 West 2nd Place, Lakewood, Colorado 80228-6304, filed a petition for a declaratory order in Docket No. CP93-130-000, requesting that the Commission declare that certain facilities to be acquired from Williston Basin Interstate Pipeline Company are production and gathering facilities exempt from the Commission's Regulations pursuant to section 1(b) of the Natural Gas Act (NGA), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

The facilities are pipeline facilities connecting the East Riverton Field, Riverton Dome Field, Fuller Reservoir Field, Poison Creek Field, Pavilion Field, Muddy Ridge Field, Howard Ranch Field, Bonneville Unit, Boysen Field, and Carter Draw Field in Fremont County, Wyoming. The facilities consist of 175 miles of two-inch through twelve-inch pipelines, filed separation and dehydration facilities, and a 3,030 rated up compressor station and dehydration plant in the Pavilion field.

Comment date: January 29, 1993, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

9. High Island Offshore System

[Docket No. CP93-143-000]

January 8, 1993.

Take notice that on January 4, 1993, High Island Offshore System (HIOS), 500 Renaissance Center, Detroit, Michigan 48243, filed an application pursuant to section (7)(b) of the Natural Gas Act, as amended, and the Rules and Regulations of the Federal Energy Regulatory Commission (Commission), for authorization to abandon transportation service currently being rendered for CNG Transmission Corporation (CNG).

In its application, HIOS proposes to terminate the firm transportation service with HIOS is rendering in accordance with HIOS' Rate Schedule T-8, as well as associated Interruptible Overrun Transportation Service rendered in accordance with HIOS' Rate Schedule I. HIOS proposes to terminate these services at the end of the primary term of Rate Schedule T-8, effective August 10, 1993, in accordance with the terms of such rate schedule and in accordance with timely notice given by CNG to HIOS.

HIOS requests that the abandonment be conditioned upon CNG remaining subject to and liable for any transition costs, exit fees, or other similar charges that are imposed as a result of HIOS' restructuring pursuant to Order Nos. 636, *et seq.*

Comment date: January 29, 1992, in accordance with Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

Lois D. Cashell,

Secretary.

[FR Doc. 93-1012 Filed 1-14-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP93-62-000 and CP93-92-000]

Indicated Shippers v. Arkla Energy Resources, a Division of Arkla, Inc. and Arkla Energy Resources, a Division of Arkla, Inc.; Notice of Technical Conference

January 7, 1993.

A technical conference will be held to discuss issues raised in the above-captioned proceedings on Thursday, January 28, 1993, at 10 a.m., in room 6200 at the office of the Federal Energy Regulatory Commission, 825 N. Capitol Street, NE., Washington, DC 20426.

All interested persons and Staff are permitted to attend. However, attendance does not confer party status.

For additional information, contact Timothy W. Gordon at (202) 208-2059.

Lois D. Cashell,

Secretary.

[FR Doc. 93-1011 Filed 1-14-93; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-4554-7]

Environmental Impact Statements; Notice of Availability

RESPONSIBLE AGENCY: Office of Federal Activities, General Information (202) 260–5076 OR (202) 260–5075.
Availability of Environmental Impact Statements Filed January 4, 1993 Through January 8, 1993 Pursuant to 40 CFR 1506.9.

EIS No. 930000, DRAFT EIS, AFS, MN, Superior National Forest Land and Resource Management Plan, Adoption of Boundary Waters Canoe Area (BWCA) Wilderness Management Plan, Implementation, Cook, Lake and St. Louis Counties, MN, Due: March 1, 1993, Contact: James H. Rogers (218) 720–5492.

EIS No. 930001, DRAFT EIS, COE, LA, MS, LA, West Pearl River Navigation Project, Operation and Maintenance, Portions of West Pearl River to the vicinity of Bogalusa, Implementation, Washington and St. Tammany Parishes, LA and Pearl River County, MS, Due: February 15, 1993, Contact: Marvin Cannon (601) 631–5437.

EIS No. 930002, FINAL SUPPLEMENT, COE, LA, MS, LA, North Jefferson County Wastewater Treatment Facilities, Updated Information, Construction Grant, Jefferson County, KY, Due: February 16, 1993, Contact: Heinz J. Mueller (404) 347–3776.

EIS No. 930003, FINAL EIS, COE, CA, San Rafael Canal Flood Control/Marin County Shoreline Study, Implementation, City of San Rafael, Marin County, CA, Due: February 15, 1993, Contact: Scott Miner (415) 744–3039.

EIS No. 930004, FINAL EIS, DOE, WA, Hanford Site Eight Surplus Plutonium Production Reactors Decommissioning, Implementation, Richland, WA, Due: February 15, 1993, Contact: Carol Borgstrom (202) 586–4600.

EIS No. 930005, FINAL EIS, SCS, NV, Moapa Valley Unit, Irrigation Systems, Irrigation Water Management Delivery System Improvements, Colorado River Salinity Control Program, Funding and Possible Section 404 Permit, Clark and Lincoln Counties, NV, Due: February 15, 1993, Contact: William D. Goddard (702) 784–5863.

EIS No. 930006, DRAFT EIS, USN, CA, San Diego Bay Programmatic Project, Implementation, Disposal of Dredged Material, San Diego County, CA, Due: March 1, 1993, Contact: Lowell Martin (619) 532–2991.

EIS No. 930007, DRAFT SUPPLEMENT, IBR, NM, Rio Grande-Velarde to Caballo Dam, Operation and Maintenance, Updated Information on River Maintenance Program, Rio Grande and Middle Rio Grande Project, Elephant Butte Reservoir, MN, Due: March 15, 1993, Contact: Marc Rucker (505) 766–1753.

Amended Notices

EIS No. 920447, DRAFT EIS, DOE, AK, Healy 50 Megawatt-Electric Coal Fired Power Plant Construction and Operation, Clean Coal Technologies Demonstration, Funding, NPDES and Section 404 Permits, Borough of Denali, AK, Due: January 20, 1993, Contact: Dr. Earl W. Evans (412) 892–5709. Published FR—11–20–92—Review period extended.

EIS No. 920486, FINAL SUPPLEMENT, UMC, NC, Cherry 1 Military Operating Areas (MOA), Craven, Beaufort, Hyde, Pamlico and Washington Counties and Core MOA, North Carolina Outer Banks/Cape Lookout National Seashore Establishments, Additional Mitigation Alternatives and Regional Cumulative Effects Analysis, NC, Due: January 18, 1993, Contact: Col. A. M. Lloyd (919) 466–2343. Published FR—12–18–92—Due Date Correction

EIS No. 920488, DRAFT EIS, AFS, ID, Trail Creek II Timber Sale, Implementation, Timber Harvest, Road Construction and Reconstruction, Trail, Ninemile and Packsaddle Creeks, Boise National Forest, Lowman Ranger District, Valley County, ID, Due: February 16, 1993, Contact: Dautis Pearson (208) 259–3361. Published FR—12–18–92—Review period extended.

EIS No. 920494, FINAL EIS, NOA, Atlantic Ocean Sharks Fishery Management Plan (FMP), Implementation, Possible NPDES, COE and Coast Guard Permits, Exclusive Economic Zone (EEZ) the Gulf of Mexico, Atlantic Ocean and the Caribbean Sea, Due: January 18, 1993, Contact: Richard H. Schaefer (301) 713–2334. Published FR—12–18–92—Due Date Correction

Dated: January 12, 1993.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 93–1081 Filed 1–14–93; 8:45 am]

BILLING CODE 6560–50–M

[ER-FRL-4554-8]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared December 28, 1992 Through January 4, 1993 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 10, 1992 (54 FR 12499).

Draft EISs

ERP No. D–BLM–L65143–OR

Rating EO2, Klamath Falls Resource Management Plan, Implementation, Lakeview District, Klamath County, OR.

Summary: EPA expressed environmental objections to the proposed project. EPA's objections were based on the lack of adequate safeguards to protect currently degraded watersheds; adequate riparian zone protection for first and second order streams which may cause violations of water quality standards and impacts to beneficial uses; direct health and safety effects of prescribed burning and firewood programs, and potential effects to non-attainment areas for particulates and Class I wilderness areas; potential for impacts to threatened species listed under the Endangered Species Act, including the northern spotted owl; and lack of direction regarding future environmental analysis for site-specific project proposals.

ERP No. D–BLM–L65177–OR

Rating EC2, Medford District Resource Management Plan, Implementation, Medford District, Douglas, Jackson, Coos and Curry, OR.

Summary: EPA expressed environmental concerns about the proposed project. EPA's concerns were based on the lack of adequate safeguards to protect currently degraded watersheds; adequate riparian zone protection for first and second order streams which may cause violations of water quality standards and impacts to beneficial uses; direct health and safety effects of prescribed burning and firewood programs, and potential effects to non-attainment areas for particulates and Class I wilderness areas; potential for impacts to threatened species listed under the Endangered Species Act, including the northern spotted owl; and

lack of direction regarding future environmental analysis for site-specific project proposals.

ERP No. D-BLM-L65179-OR

Rating EO2, Salem District Resource Management Plan, Implementation, Several Counties, OR.

Summary: EPA expressed environmental objections to the proposed project. EPA's objections were based on the lack of adequate safeguards to protect currently degraded watersheds; adequate riparian zone protection for first and second order streams which may cause violations of water quality standards and impacts to beneficial uses; direct health and safety effects of prescribed burning and firewood programs, and potential effects to non-attainment areas for particulates and Class I wilderness areas; potential for impacts to threatened species listed under the Endangered Species Act, including the northern spotted owl; and lack of direction regarding future environmental analysis for site-specific project proposals.

ERP No. D-COE-E30035-NC

Rating EC2, Carolina Beach and Vicinity/Area South Project, Beach Erosion Control and Hurricane Wave Protection, Implementation, New Hanover County, NC.

Summary: EPA had environmental concerns about assumptions used to characterize long-term consequences of the proposal and requested additional information.

ERP No. D-COE-K36107-CA

Rating 3, Bolsa Chica Project, Construction/Road Construction, Restoration and Flood Control Improvement, Section 10/404 Permits and Land Use Plan, City of Huntington Beach, Orange County, CA.

Summary: EPA rated the proposal inadequate because it lacked sufficient information to assess mitigation for wetland impacts, impacts to threatened and endangered species, or potential violations of federal air quality standards. EPA recommended that the Army Corps of Engineers prepare a revised DEIS to address these issues. EPA advised that a failure to resolve the issues prior to releasing the final EIS could result in referral of the project to the Council on Environmental Quality.

ERP No. D-FHW-L50005-AK

Rating EC2, Kenai River Bridge Crossing Project, Construction from Sterling Highway to Funny River Road, Funding, COE Section 10 and 404 Permits, US CGD Permit and EPA NPDES Permit, Kenai Peninsula, AK.

Summary: EPA expressed environmental concerns based on the potential for adverse water quality impacts, wetland impacts and fisheries and wildlife impacts. EPA requested additional information on these issues.

ERP No. D-UAF-E11021-NC

Rating EC2, Pope Air Force Base (AFB) Beddown of a Composite Wing under the Air Combat Command (ACC), Implementation, NC.

Summary: EPA expressed environmental concerns regarding potential noise impacts. Additional information is requested in the final document.

ERP No. DS-AFS-E65029-NC

Rating EC2, 1986—2000 Nantahala and Pisgah National Forests, Additional Information Land and Resource Management Plan, Amendment 5, Several Counties, NC.

Summary: EPA found that certain forestry activities may harm water quality especially in environmentally sensitive areas of the forests. Additional information on erosion control measures was requested.

ERP No. DS-COE-L91008-00

Rating EC2, 1992 Columbia/Snake Rivers Salmon Flow Measures, Updated Information concerning Water Management Activities, Implementation, WA, ID and OR.

Summary: EPA had concerns about water quality impacts resulting from increases in dissolved gas levels, turbidity, and resuspension of sediments, and potential reductions of wetland, riparian, and shallow water habitat.

Additional information is needed to fully assess the impacts and to evaluate the overall net (beneficial vs. adverse) effect of the flow measures on salmon survival.

Dated: January 12, 1993.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 93-1085 Filed 1-14-93; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4552-9]

Effluent Guidelines Task Force Open Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of meeting.

SUMMARY: The Effluent Guidelines Task Force, an EPA advisory committee, will hold a meeting to discuss improvements to the Agency's Effluent Guidelines Program. The meeting is open to the public.

DATES: The meeting will be held on February 9, 1993, from 8:30 a.m. to 5 p.m., and February 10, 1993, from 8:30 a.m. to 3 p.m.

ADDRESSES: The meeting will take place at the Sheraton Crystal City Hotel, South Eads Street at 18th Street, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Eric Strassler, Effluent Guidelines Task Force Staff Director, Office of Water (WH-552), 401 M Street, SW., Washington, DC 20460; telephone 202-260-7150, fax 202-260-7185.

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (Pub. L. 92-463), the Environmental Protection Agency (EPA) gives notice of a meeting of the Effluent Guidelines Task Force (EGTF). The EGTF is a subcommittee of the Technology Innovation and Economics Committee, under the National Advisory Council for Environmental Policy and Technology (NACEPT), the external policy advisory board to the Administrator of EPA.

The EGTF was established in July of 1992 to advise EPA on the Effluent Guidelines Program, which develops regulations for dischargers of industrial wastewater pursuant to title III of the Clean Water Act (33 U.S.C. 1251 *et seq.*). The Task Force consists of 22 members appointed by EPA from industry, citizen groups, state and local government, the academic and scientific communities, and EPA regional offices.

On January 31, 1992, EPA entered into a Consent Decree affecting the entire Effluent Guidelines Program (*National Resources Defense Council et al* v. *Reilly*, D.D.C. No 89-2980). The litigation leading to the Decree was brought under CWA section 304(m), which requires the Agency to publish a biennial plan for the Program. The Consent Decree required EPA to adhere to a schedule for developing regulations and to create a "Special Task Force" to assist the Agency in planning for the Effluent Guidelines Program.

The Consent Decree defines the role of the Task Force as "assist[ing] the Agency in discharging its responsibility to implement the Clean Water Act" and offering advice on the long-term strategy for the effluent guidelines program. As directed by the Decree, EPA will request the Task Force to "provide recommendations with respect to a process for expediting the promulgation of effluent guidelines," within the first year of the Task Force's establishment. The Task Force will be asked to "consider, among other pertinent matters, EPA's experience in issuing

regulations under the Clean Air Act and any other regulations subject to expedited promulgation procedures." The Agency will ask the Task Force for supplemental recommendations on expediting the rulemaking process at least annually.

The meeting agenda will include reports from Task Force work groups on specific problem areas, including: Selection criteria and methodology for preliminary industry studies, the role of non-water quality impacts and pollution prevention in effluent guidelines, and redesigning the data collection and/or rulemaking processes for effluent guidelines.

The meeting will be open to the public. Limited seating for the public is available on a first-come, first-served basis. The public may submit written comments. Comments submitted by February 1 will be considered by the Task Force at or subsequent to the meeting.

Dated: January 11, 1993.

Abby J. Pirnie,

NACEPT Designated Federal Official.

[FR Doc. 93–1051 Filed 1–14–93; 8:45 am]

BILLING CODE [illegible]

[PP 7G3526/T631; FRL 4178–7]

Iprodione; Renewal of a Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has renewed a temporary tolerance for the combined residues of the fungicide iprodione and it isomer in or on the raw agricultural commodity field corn grain at 20 parts per million (ppm).

DATES: This temporary tolerance expires December 31, 1992.

FOR FURTHER INFORMATION CONTACT: By mail: Susan T. Lewis, Product Manager (PM) 21, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW.,Washington, DC 20460. Office location and telephone number: Rm. 229, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305–6900.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the Federal Register of March 7, 1990, (55 FR 8192), stating that a temporary tolerance had been established for the combined residues of the fungicide iprodione, 3-(3,5-dichlorophenyl)-*N*-(methylethyl)-2,4-dioxo-1-imidazolidinecarboximide, and its isomer 3-(1-methylethyl)-*N*-(3,5-dichlorophenyl)-2,4-dioxo-1-imidazolidinecarboximide, expressed as iprodione equivalents in or on the raw agricultural commodity field corn grain at 20 parts per million (ppm). This tolerance is renewed in response to pesticide petition (PP) 7G3525, submitted by Rhone-Poulenc Agricultural Company, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709.

The company has requested a 1-year renewal of a temporary tolerance for residues of the fungicide to permit the continued marketing of the above raw agricultural commodity when treated in accordance with the provisions of the experimental use permit 264-EUP-85, which is being renewed under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (Pub. L. 95–396, 92 Stat. 819; 7 U.S.C. 136). The scientific data reported and other relevant material were evaluated, and it was determined that a renewal of the temporary tolerance will protect the public health. Therefore, the temporary tolerance has been renewed on the condition that the pesticide be used in accordance with the experimental use permit and with the following provisions:

1. The total amount of the active ingredient to be used must not exceed the quantity authorized by the experimental use permit.

2. Rhone-Poulenc Agricultural Co., must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The company must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This tolerance expires December 31, 1992. Residues not in excess of this amount remaining in or on the above raw agricultural commodity after this expiration date will not be considered actionable if the pesticide is legally applied during the term of, and in accordance with, the provisions of the experimental use permit and temporary tolerance. This tolerance may be revoked if the experimental use permit is revoked or if any experience with or scientific data on this pesticide indicate that such revocation is necessary to protect the public health.

The Office of Management and Budget has exempted this notice from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

Authority: 21 U.S.C. 346a(j).

Dated: January 4, 1993.

Lawrence E. Culleen,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 93–1049 Filed 1–14–93; 8:45 am]

BILLING CODE [illegible]

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

January 8, 1993.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, Downtown Copy Center, 1990 M Street, NW., suite 640, Washington, DC 20036, (202) 452–1422. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632–7513. Persons wishing to comment on this information collection should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395–4814.

OMB Number: 3060–0355.

Title: Rate of Return Report.

Form Number(s): FCC Forms 492 and 492–A.

Action: Revision of a currently approved collection.

Respondents: Businesses or other for-profit.

Frequency of Response: Quarterly, annually and Other: Price cap carriers must file correction reports within 15 months after the end of the calendar year; other carriers must file adjustments by 9/30 of the year following the enforcement period.

Estimated Annual Burden: 148 responses; 8 hours average burden per response; 1,184 hours total annual burden.

Needs and Uses: Filing of FCC Forms 492 and 492–A is required by

Sections 1.795 and 65.600 of the FCC rules and Section 219 of the Communications Act of 1934, as amended. Filing of the FCC Form 492 on a quarterly basis is required from each local exchange carrier or group of affiliated carriers which is not subject to Sections 61.41 through 61.49 of the FCC's rules and which has filed individual access tariffs during the enforcement period. Each local exchange carrier or group of affiliated carriers subject to the previously stated sections shall file the FCC Form 492–A report with the Commission for the calendar year. The forms are necessary to enable the Commission to monitor the access tariffs and to enforce maximum rate of return prescriptions and price cap earnings levels. FCC Form 492 has been slightly modified for the creation of FCC Form 492–A. This has been done so that carriers subject to price cap regulation will be able to file a simplified and more relevant set of information as required by the Commission's rules. A copy of each report must be retained in the principal office of the respondent and shall be filed in such manner as to be readily available for reference and inspection. The Commission does not specify a retention period. The data is used by FCC staff for enforcement purposes by the public in analyzing the industry. The reports are also used by the Commission staff in the tariff review process and provide both the Commission and the carriers with an early warning system if rate adjustments are necessary to correct significant targeting errors.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–969 Filed 1–14–93; 8:45 am]

BILLING CODE 6712–01–M

Advisory Committee on Advanced Television Service; Meeting

A meeting of the Advisory Committee on Advanced Television Service will be held on Wednesday, February 24, 1993, at 9:30 a.m. in room 856 of the Federal Communications Commission, 1919 M Street, NW., Washington, DC.

The purpose of this meeting is to receive reports from the Subcommittees, the Testing Laboratories, and a Special Panel, and to consider a draft Advisory Committee Report.

The agenda for the meeting is as follows:

1. Introductory Remarks by Advisory Committee Chairman Richard E. Wiley.
2. Adoption of the Minutes of the Last Meeting.
3. Remarks by FCC Chairman.
4. Reports of the Subcommittees.
5. Report of the Testing Laboratories.
6. Report of the Special Panel.
7. Draft Advisory Committee Report.
8. Future Work Plans.
9. Financial Report.
10. Other Business.
11. Adjournment.

This meeting is open to the public. Parties may submit written statements prior to or at the time of the meeting. Oral statements and discussion will be permitted under the direction of the Advisory Committee Chairman.

Any questions regarding this meeting should be directed to Richard E. Wiley at (202) 429–7010 or William H. Hassinger at (202) 632–6460.

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 93–971 Filed 1–14–93; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed; Atlantic Container Line AB et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 202–011375–003.
Title: Trans-Atlantic Agreement.
Parties: Atlantic Container Line AB, Cho Yang Shipping Co., Sea-Land Service, Inc., Nedlloyd Lijnen BV, Hapag Lloyd AG, Mediterranean Shipping Co., A.P. Moller-Maersk Line, Polish Ocean Lines, Orient Overseas Container Line (UK) Ltd., DSR-Senator Joint Service, P&O Containers Limited.
Synopsis: The proposed amendment modifies the Independent Action provisions to provide for a uniform ten days' notice period for all parties to act independently to effect a change of any tariff rate and/or service item applicable to them under this Agreement.

By Order of the Federal Maritime Commission.

Dated: January 11, 1993.

Joseph C. Polking,

Secretary.

[FR Doc. 93–993 Filed 1–14–93; 8:45 am]

BILLING CODE 6730–01–M

Agreement(s) Filed; Maryland/Ceres et al.

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC office of the Federal Maritime Commission, 800 North Capitol Street, NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the **Federal Register** in which this appears. The requirements for comments are found in section § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 224–200165–011.
Title: Maryland/Ceres Terminal Agreement.
Parties: Maryland Port Administration Ceres Corporation.
Synopsis: The amendment extends the term of the Agreement for 60 days, until March 8, 1993.
Agreement No.: 224–200332–004.
Title: The San Francisco Port Commission/Nedlloyd Lines Marine Terminal Agreement.
Parties: The San Francisco Port Commission ("Port") Nedlloyd Lines (U.S.A.) Corp.
Synopsis: The modification amends the basic Agreement to extend the term of the Agreement for three years; provides that Nedlloyd will pay dockage and wharfage rates at less than 100 percent of the rates named in the Port's tariff No. 3–C; and states that all other substantive terms and conditions remain the same.

Dated: January 12, 1993.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 93–1084 Filed 1–14–93; 8:45 am]

BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Issuance of Certificate (Performance); West Travel, Inc.

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

West Travel, Inc. (d/b/a Alaska Sightseeing/Cruise West), 4th & Battery Bldg., suite 700, Seattle, WA 98121.
Vessel: Spirit of 98.
Dated: January 11, 1993.

Joseph C. Polking,
Secretary.

[FR Doc. 93–1003 Filed 1–14–93; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Notice of Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Commodore Cruise Line Limited, 800 Douglas Road, Coral Gables, FL 33134.
Vessels: Enchanted Isle and Enchanted Seas.
Dated: January 11, 1993.

Joseph C. Polking,
Secretary.

[FR Doc. 93–999 Filed 1–14–93; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Notice of Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Public Law 89–777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Kloster Cruise Limited (d/b/a Norwegian Cruise Line), Birka Line AB and Birka Cruise Limited, 95 Merrick Way, Coral Gables, Florida 33134.
Vessel: Sunward.
Dated: January 11, 1993.

Joseph C. Polking,
Secretary.

[FR Doc. 93–998 Filed 1–14–93; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Notice of Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Public Law 89–777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Palm Beach Cruise Line Inc., Palm Beach Cruises S.A. and Grundstad Maritime Overseas, Inc.; 2790 N. Federal Highway, Boca Raton, FL 33431.
Vessel: Viking Princess.
Dated: January 11, 1993.

Joseph C. Polking,
Secretary.

[FR Doc. 93–1000 Filed 1–14–93; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Notice of Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Palm Beach Cruise Line Inc., Palm Beach Cruises S.A. and Grundstad Maritime Overseas, Inc.; 2790 N. Federal Highway, Boca Raton, FL 33431.
Vessel: Viking Princess
Dated: January 11, 1993.

Joseph C. Polking,
Secretary.

[FR Doc. 93–1001 Filed 1–14–93; 8:45 am]
BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Notice of Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Seafest Cruises, Inc. and Sabella Shipping Limited, 8751 W. Broward Blvd., suite 502, Plantation, FL 33324.
Vessel: Sapphire Seas.
Dated: January 11, 1993.

Joseph C. Polking,
Secretary.

[FR Doc. 93–1002 Filed 1–14–93; 8:45 am]
BILLING CODE 6730–01–M

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination of the waiting period provided by law and the premerger notification rules. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

TRANSACTIONS GRANTED EARLY TERMINATION BETWEEN: 12-7-92 AND 12-18-92

Name of acquiring person, name of acquired person, name of acquired entity	PMN No.	Date terminated
PolyMedica Industries, Inc., Nestle S.A., Alcon Laboratories, Inc	93-0236	12/07/92
CUC International, Leaguestar p.l.c, Leaguestar p.l.c	93-0246	12/07/92
Recovery Equity Investors, L.P., American Financial Corporation, G&H Technology, Inc	93-0274	12/07/92
Dan L. Duncan, EPC Partners, LTD, EPC Partners, LTD	93-0309	12/07/92
Dan L. Duncan, EPC Venture, Inc., EPC Venture, Inc	93-0310	12/07/92
GKH Investments, L.P., Mounger Corporation, Mounger Corporation, Pacific Trail, Inc	93-0314	12/07/92
AMR Corporation, Metro Airlines, Inc. (Debtor-in-Possession), Metroflight, Inc	93-0320	12/07/92
General Electric Company, Trammell Crow, Crow Houston Four, Ltd	93-0330	12/07/92
Den norske stats oljeselskap, Michael R. Kutsch, Catex Energy, Inc	93-0336	12/07/92
Paloma Partners L.P., Lomas Financial Corporation, Lomas Financial Corporation	93-0257	12/08/92
Georger W. Gibbs, III, ADDSCO Industries, Inc., ADDSCO Industries, Inc	93-0260	12/08/92
United Newspapers Public Limited Company, Markt & Technik Verlag Aktiengesellschaft, M&T Publishing, Inc	93-0281	12/08/92
Triveet Institutional Fund, Ltd., Norwest Corporation, NWCA, Inc	93-0326	12/08/92
GS Capital Partners, L.P., Globe Manufacturing Co., Globe Manufacturing Co	93-0193	12/09/92
Catholic Healthcare West, Valley Healthcare Corporation, Methodist Hospital of Sacramento	93-0262	12/10/92
Beusch & Lomb Incorporated, Eastman Kodak Company, Sterling Winthrop Inc	93-0271	12/10/92
PacifiCorp, Pacific Atlantic Systems Leasing, Inc., Pacific Atlantic Systems Leasing, Inc	93-0316	12/10/92
Bell Atlantic Corporation, Pacific Atlantic Systems Leasing, Inc., Pacific Atlantic Systems Leasing, Inc	93-0317	12/10/92
Anadarko Petroleum Corporation, Atlantic Richfield Company, Atlantic Richfield Company	93-0319	12/10/92
Petroleum Heat and Power Co., Inc., Agway Inc., Agway Petroleum Corporation	93-0267	12/11/92
General Electric Company, AB Volvo, Volvo Finance North America, Inc	93-0290	12/11/92
David S. Pareesky and Linda K. Pareesky, Headington Investments Limited, Thomas Cook Partnership	93-0292	12/11/92
Marvin J. Herb, Roddy Coca-Cola Bottling Company, Inc., Roddy Coca-Cola Bottling Company, Inc	93-0328	12/11/92
Southern Farm Bureau Casualty Insurance Company, Florida Farm Bureau Mutual Insurance Company, Florida Farm Bureau Mutual Insurance Company	93-0331	12/11/92
NationsBank Corporation, Chrysler Corporation, Chrysler First, Inc	93-0335	12/11/92
Keane, Inc., General Electric Company, General Electric Consulting Services Corporation	93-0342	12/11/92
Chemical Banking Corporation, Lear Siegler Holdings Corp., Lear Siegler Seymour Corp	93-0345	12/11/92
General Electric Company, E.I. du Pont de Nemours and Company, Du Pont Consumer Financing Organization	93-0346	12/11/92
Mitsui Engineering & Shipbuilding Co., Ltd., Sofec Holdings, Inc., Sofec Holdings, Inc	93-0347	12/11/92
Equilease Holding Corp., Cawsl Corp., LFC No. 25 Corp	93-0348	12/11/92
James G. Tuthill, Sr., Donald E. Hare, Coppus Engineering Corporation	93-0355	12/11/92
K-III Communications Corporation, The Edward W. Scripps Trust, United Feature Syndicate, Inc	93-0356	12/11/92
Clayton & Dubilier Private Equity Fund IV L.P., Xerox Corporation, Van Kampen Merritt Companies, Inc	93-0359	12/11/92
CIBA-GEIBY Limited, Royal Dutch Petroleum Company, Triton Diagnostic Inc	93-0367	12/11/92
Kjell Inge Rokke, Wolverine World Wide, Inc., Brooks Shoe, Inc	93-0379	12/11/92
The Berkshire Fund, A Limited Partnership, General Electric Company, Universal Brands, Inc	93-0385	12/11/92
David S. Pareesky and Linda K. Pareesky, David S. Pareesky and Linda K. Pareesky, Thomas Cook Partnership	93-0399	12/11/92
Ashland Oil, Inc., Quaker State Corporation, Great Lakes Coal & Dock Company	93-0289	12/14/92
Dominion Resources, Inc., Henry L. Hillman, Emerald Gas Company	93-0311	12/14/92
Quantum Fund N.V., Gerald A. Boelte, LLOG Exploration Company	93-0323	12/14/92
Berkshire Hathaway Inc., Morse Shoe, Inc., Lowell Shoe, Inc	93-0362	12/14/92
Ford Motor Company, LAI Acquisition Corporation, Leasing Associates, Inc.-N1	93-0368	12/14/92
Recovery Equity Investors, L.P., Recovery Equity Investors, L.P., McCain Manufacturing Corp	93-0364	12/14/92
Seagull Energy Corporation, Arkla, Inc., Arkla Exploration Company	93-0284	12/15/92
Vintage Petroleum, Inc., Atlantic Richfield Company, Atlantic Richfield Company	93-0322	12/15/92
Lincoln National Corporation, Trammell Crow Real Estate Investors, Trammell Crow Real Estate Investors	93-0353	12/15/92
WSW SF Acquisition Company, L.P., Time Warner Inc., Six Flags Entertainment Corporation	93-0358	12/15/92
Philip Morris Companies Inc., Texaco Inc., Texaco Exploration and Production Inc	93-0366	12/15/92
Charles Schusterman, Geodyne Resources, Inc., Geodyne Resources, Inc	93-0376	12/15/92
Marcam Corporation, International Business Machines Corporation, International Business Machines Corporation	93-0377	12/16/92
International Business Machines Corporation, Marcam Corporation, Marcam Corporation	93-0378	12/16/92
J. Baker, Inc., Morse Shoe, Inc., Morse Shoe, Inc	93-0306	12/17/92
Addington Resources, Inc., PacifiCorp, Vandalia Mining Corporation, Prospect Land and	93-0336	12/17/92
Oak Industries, Inc., Gilbert Engineering Acquisition Co., Inc., Gilbert Engineering Acquisition Co., Inc	93-0386	12/17/92
Spar Aerospace Limited, ComStream Corporation, ComStream Corporation	93-0270	12/18/92
William R. Zimmerman, Cooper Industries, Inc., Cooper Industries, Inc	93-0272	12/18/92
International Business Machines Corporation, McDonnell Douglas Corporation, McDonnell Douglas Aerospace Information Services	93-0296	12/18/92
Citicorp, Ronald D. Kirstien, FFFG Holding Corporation	93-0324	12/18/92
Capital Holding Corporation, Pacific Bank, National Association, Commonwealth Insurance Premium Finance Division	93-0325	12/18/92
Rochester & Pittsburgh Coal Company, Bethlehem Steel Corporation, Bethlehem Steel Corporation/BethEnergy Mines, Inc	93-0349	12/18/92
Mirage Resorts, Incorporated, Masao Nangaku, Minami (Nevada) Incorporated	93-0350	12/18/92
Philip Morris Companies Inc., Corporacion Industrial Pros S.A. de C.V., Fomento Economico Mexicano S.A. de C.V	93-0365	12/18/92
Roberts Pharmaceutical Corporation, E.I. du Pont de Nemours and Company, Du Pont Merck Pharmaceutical Company	93-0381	12/18/92
Robertson Charitable Remainder Unitrust, TVS Entertainment PLC, TVS Entertainment PLC	93-0383	12/18/92
Waremart, Inc., SUPERVALU Inc., Ohiocubco, Inc	93-0391	12/18/92
SUPERVALU Inc., Waremart, Inc., Waremart, Inc	93-0392	12/18/92
Fidelity National Financial, Inc., Harry B. Helmsley, Security Title Insurance and Guaranty Company	93-0393	12/18/92
Gerrity Oil & Gas Corporation, Martin Exploration Management Company, Martin Exploration Management Company	93-0397	12/18/92
Apogee Enterprises, Inc., Crom Corporation, Crom Corporation	93-0398	12/18/92
Globe Furniture Rentals, Inc., First Interstate Bancorp, GranTree Corporation	93-0414	12/18/92
Fund America Ventures Corporation, Global Natural Resources Inc., Global Natural Resources Corporation of Nevada	93-0417	12/18/92
Belden & Blake Corporation, Presidio Oil Company, Peake Energy, Inc. and Peake Operating Company	93-0420	12/18/92
Roberts Pharmaceutical Corporation, Merck & Co., Inc., Du Pont Merck Pharmaceutical Company	93-0426	12/18/92
U S West, Inc., U S West, Inc., Grand Forks Cellular Limited Partnership	93-0427	12/18/92

FOR FURTHER INFORMATION CONTACT: Sandra M. Peay or Renee A. Horton, Contact Representatives, Federal Trade Commission, Premerger Notification Office, Bureau of Competition, room 303, Washington, DC 20580. (202) 326–3100.

By Direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 93–1048 Filed 1–14–93; 8:45 am]

BILLING CODE 6750–01–M

GENERAL ACCOUNTING OFFICE

Federal Accounting Standards Advisory Board

AGENCY: General Accounting Office.

ACTION: January Meeting.

SUMMARY: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. No. 92–463), as amended, notice is hereby given that the monthly meeting the Federal Accounting Standards Advisory Board will be held on Wednesday, January 27 and Thursday, January 28, 1993 from 9 a.m. to 4 p.m. in room 7313 of the General Accounting Office, 441 G St., N.W., Wasington, DC.

The agenda for the meeting includes: (1) A discussion of the responses to the FASAB Exposure Draft on *Accounting for Direct Loans and Loan Guarantees,* (2) a presentation by OMB representatives of a balance sheet model for the federal government, (3) continued discussion of liabilities issues, and (4) a discussion of future projects. Other items may be added to the agenda; interested parties should contact the Staff Director for more specific information and to confirm the date of the meeting.

Any interested person may attend the meeting as an observer.

FOR FURTHER INFORMATION CONTACT: Ronald S. Young, Staff Director, 750 First St., N.E., Suite 1001, Washington, DC. 20002, or call (202) 512–7350.

Authority: Federal Advisory Committee Act. Pub. L. No. 92–463, Section 10(a/)(2), 86 Stat. 770, 774 (1972) (current version at 5 U.S.C. app. section 10(a)(2) (1988); 41 CFR 101–6.1015 (1990).

Dated: January 12, 1993.

Ronald S. Young,

Executive Director.

[FR Doc. 93–1073 Filed 1–14–93; 8:45 am]

BILLING CODE 1610–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration on Children, Youth and Families; Family and Youth Services Bureau; Agency Information Collection Under OMB Review

ACTION: Notice.

Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), we have submitted to the Office of Management and Budget (OMB) a request for approval of a new information collection, titled: "Evaluation of the Transitional Living Program (TLP) for Homeless Youth." This request is made by the Family and Youth Services Bureau within the Administration on Children, Youth and Families (ACYF) of the Administration for Children and Families (ACF).

ADDRESSES: Copies of the information collection request may be obtained from Steve Smith, Office of Information Systems Management, ACF, by calling (202) 401–9235.

Written comments and questions regarding the requested approval for information collection should be sent directly to: Kristina Emanuels, OMB Desk Officer for ACF, OMB Reports Management Branch, New Executive Office Building, room 3002, 725 17th Street, NW., Washington, DC 20503, (202) 395–7316.

Information on Document

Title: Evaluation of the Transitional Living (TLP for Homeless Youth.

OMB No.: New Request.

Description: The Transitional Living Program (TLP) for Homeless Youth is authorized under the Runaway Youth Act, title III of the Juvenile Justice and Delinquency Prevention Act (JJDPA) of 1974, as amended in 1988. A homeless youth is defined in the legislation as a youth 16 to 21 years old " * * * for whom is it not possible to live in a safe environment with a relative; and who has no other safe alternative living arrangement." The goal of the TLP program is to promote transition to self-sufficient living and to prevent long term dependency on social services. The TLP is implemented through grants to State and local governments and to private, nonprofit organizations. Funds available under TLP are to be used to enhance the capacities of youth-serving agencies to effectively address the service needs of homeless adolescents and young adults. The program is not designed to serve youth currently under the jurisdiction of a State or local welfare agency or a probation or parole program.

Title III, part D, section 361(b) of the JJDPA also requires the Secretary of the U.S. Department of Health and Human services to submit an annual report to Congress on the status and accomplishments of the TLP projects. To meet the legislative reporting requirements and to provide relevant information in its reports to Congress, ACF will conduct national evaluation of TLP. The overall goal of the evaluation is to answer the central question of the effectiveness of TLP projects. More specifically, the study will provide essential data regarding: (1) The number and characteristics of homeless youth serviced by such projects; (2) the types of activities carried out under such projects; (3) the effectiveness of such projects in alleviating the immediate problems of homeless youth; (4) the effectiveness of such projects in preparing homeless youth of self sufficiency; (5) the effectiveness of such projects in helping youth decide upon future education, employment, and independent living; and (6) the ability of such projects to strengthen family relationships, and encourage the resolutions of intra-family problems through counseling and the development of self-sufficient living skills.

Annual Number of Respondents: 1053.

Annual Frequency: 1 to 5.

Average Burden Hours per Response: .58 to 1 hr.

Total Burden Hours: 1,817.

Dated: December 22, 1992.

Larry Guerrero,

Deputy Director, Office of Information Systems Management.

[FR Doc. 93–1036 Filed 1–14–93; 8:45 am]

BILLING CODE 4130–01–M

Food and Drug Administration

[Docket No. 84F–0393]

International Flour Sales Corp.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 5A3834) proposing that the food additive regulations be amended to provide for the safe use of powdered sugar cane, with and without the naturally occurring sugar extracted, as a dietary fiber source in food.

FOR FURTHER INFORMATION CONTACT: Wesley R. Long, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9519.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 2, 1985 (50 FR 181), FDA announced that a food additive petition (FAP 5A3834) had been filed by International Flour Sales Corp., 41–540 Makakalo St., Waimanalo, HI 96795. This petition proposed that the food additive regulations be amended to provide for the safe use of powdered sugar cane, with and without the naturally occurring sugar extracted, as a dietary fiber source in food.

International Flour Sales Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: January 7, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–1046 Filed 1–14–93; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 93N–0006]

Danbury Pharmacal, Inc., et al.; Withdrawal of Approval of 24 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 24 abbreviated new drug applications (ANDA's). The holders of the ANDA's notified the agency in writing that the drug products were no longer marketed under these applications and requested that the approval of the applications be withdrawn.

EFFECTIVE DATE: February 16, 1993.

FOR FURTHER INFORMATION CONTACT: Lola E. Batson, Center for Drug Evaluation and Research (HFD–360), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8038.

SUPPLEMENTARY INFORMATION: The holders of the ANDA's listed in the table in this document have informed FDA that these drug products are no longer marketed under these applications and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing. The drugs covered by ANDA's 80–906, 84–278, and 84–630 held by Danbury Pharmacal, Inc., will be marketed over-the-counter under the agency's regulations in 21 CFR part 336.

ANDA no.	Drug	Applicant
80–906	Dimenhydrinate Tablets USP, 50 milligrams (mg)	Danbury Pharmacal, Inc., 131 West St., Danbury, CT 06810.
83–353	Isoniazid Tablets, 300 mg	Sola/Barnes Hind, 810 Kifer Rd., Sunnyvale, CA 94086–5200.
84–142	Sulfisoxazole Diolamine Ophthalmic Solution, 4%	Do.
84–143	Sulfacetamide Sodium Ophthalmic Solution 10%	Do.
84–144	Proparacaine Hydrochloride Ophthalmic Solution, 0.5%	Do.
84–145	Sulfacetamide Sodium Ophthalmic Solution, 10%	Do.
84–146	Sulfacetamide Sodium Ophthalmic Solution, 30%	Do.
84–147	Sulfacetamide Sodium Ophthalmic Solution, 30%	Do.
84–148	Sulfisoxazole Diolamine Ophthalmic Solution, 4%	Do.
84–149	Benoxinate Hydrochloride Ophthalmic Solution, 0.4%	Do.
84–150	Cyclopentolate Hydrochloride Ophthalmic Solution, 1%	Do.
84–151	Proparacaine Hydrochloride Ophthalmic Solution, 0.5%	Do.
84–168	Prednisolone Sodium Phosphate Ophthalmic Solution, 1%	Do.
84–169	Prednisolone Sodium Phosphate Ophthalmic Solution, 0.125%	Do.
84–170	Dexamethasone Sodium Phosphate Ophthalmic Solution, 0.1%	Do.
84–171	Prednisolone Sodium Phosphate Ophthalmic Solution, 0.125%	Do.
84–172	Prednisolone Sodium Phosphate Ophthalmic Solution, 1%	Do.
84–173	Dexamethasone Sodium Phosphate Ophthalmic Solution, 0.1%	Do.
84–278	Meclizine Hydrochloride Tablets, 25 mg	Danbury Pharmacal, Inc.
84–630	Meclizine Hydrochloride Tablets, 12.5 mg	Do.
84–988	Gamma Benzene Hexachloride Shampoo, 1%	Sola/Barnes Hind
84–989	Gamma Benzene Hexachloride Lotion, 1%	Do.
87–260	Azolid 100 mg Capsules	Rhone-Poulenc Rorer Pharmaceuticals Inc., 500 Arcola Rd., P.O. Box 1200, Collegeville, PA 19426–0107.
88–556	Chlorpheniramine Maleate, 4mg	Pioneer Pharmaceuticals, Inc., 269 40th St., Irvington, NJ 07111.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82), approval of the ANDA's listed above, and all amendments and supplements thereto, is hereby withdrawn, effective February 16, 1993.

Dated: January 4, 1993.

Carl C. Peck,

Director, Center for Drug Evaluation and Research.

[FR Doc. 93–1045 Filed 1–14–93; 8:45 am]

BILLING CODE 4160–01–F

Consumer Participation; Notice of Open Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following district consumer exchange meeting: Minneapolis District Office, chaired by John Feldman, District Director. The topic to be discussed is food labeling.

DATES: Thursday, January 21, 1993, 3:45 p.m. to 5 p.m.

ADDRESSES: University of Wisconsin Extension Office, 1150 Bellevue St., Green Bay, WI 54302.

FOR FURTHER INFORMATION CONTACT: Stephen A. Davis, Public Affairs Specialist, Food and Drug Administration, 517 East Wisconsin

Ave., Milwaukee, WI 53202, 414–297–3097.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's district offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: January 8, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–1047 Filed 1–14–93; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[BPO–104–PN]

Medicare Program: Uniform Hospital Billing and Payment Mechanisms

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed notice.

SUMMARY: This notice announces our intention to require hospitals to bill intermediaries electronically, to require that the payment mechanism for paying hospitals be through direct electronic deposits, and to require hospitals to receive electronic remittance advices. Although these changes represent a major step toward implementing HCFA's goal of establishing an electronic billing, payment, and remittance environment for all Medicare contractors and providers, this would not be a blanket mandate for all Medicare providers to submit claims electronically. This notice would affect only one, generally highly sophisticated, provider-type. Exceptions would be made for low volume hospitals for which a conversion to an electronic billing and payment environment would not be cost-effective to the Medicare program or the institution. This policy would result in substantial cost savings to the program and provide a foundation for establishing more efficient billing and payment environments throughout the Medicare program.

This proposal would supplement the policy announced in a final notice that we published on October 21, 1992 (57 FR 48033).

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 16, 1993.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO–104–PN, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

If you wish to submit comments on the information collection requirements contained in this proposed notice, you may submit comments to: Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: Allison Herron Eydt, HCFA Desk Officer, room 3001, New Executive Office Building, Washington, DC 20503.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments. In commenting, please refer to file code BPO–104–PN. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 245–7890).

FOR FURTHER INFORMATION CONTACT: Craig Brewer (410) 966–7541.

SUPPLEMENTARY INFORMATION:

I. Electronic Billing

A. Background

Under Medicare, HCFA, acting for the Secretary of the Department of Health and Human Services, enters into agreements with fiscal agents (intermediaries), pursuant to section 1816 of the Social Security Act, to process bills submitted by hospitals that furnish services to Medicare beneficiaries. Our regulations at 42 CFR part 424, subpart C, contain our requirements concerning claims for payment. Section 424.32 contains basic requirements for all claims and lists appropriate claims forms. All claims must be filed on a form prescribed by HCFA and in accordance with HCFA instructions. Currently, manual instructions (Section 3600 of the Medicare Intermediary Manual) provide details regarding the preparation and submission of Medicare bills.

Provider bills may be submitted electronically or in paper format. Currently there are 6,525 hospitals submitting Medicare bills. The percentage of bills submitted electronically by hospital providers to Medicare intermediaries was 92.2 percent for hospital inpatient and 89.9 percent for outpatient bills during the period October 1991–August 1992.

B. Discussion

Electronic media claims (EMC) benefit fiscal intermediaries by eliminating data entry, mailroom, microfilm and other handling costs.

Our experience has shown that when claims and remittance advices (the summaries of approved payment by HCFA) are prepared electronically the provider receives a number of benefits:

—EMC edits facilitate error identification and resolution of missing or erroneous information. Claim errors can be caught sooner; thus, the process would avoid payment delays.
—EMC claims are received the same day that they are transmitted and bypass the contractor's mailroom and the sorting functions. As a result, they enter the claims process more quickly than paper claims.
—Savings can be realized through reduced costs of paper supplies, storage and postage.
—With on-line EMC submission, there is instant electronic conformation that a claim has been received.
—An audit trail is immediately established.
—EMC eliminates the opportunity for error because contractors are not re-keying claims.
—Good software maintenance arrangements can help keep pace with change.
—Accounts receivable can be posted through electronic remittance advices, eliminating manual keying and improving the tracking system.

C. Proposed Change

In this notice, we propose to require all hospitals that have not been granted an exemption by HCFA to submit all inpatient and outpatient bills electronically using a HCFA-approved standard EMC format. Implementing this procedure would be cost effective as it would save an estimated $.50 per bill for approximately 11 million bills, or approximately $5.5 million total per year. The proposal would result in significant administrative savings but would have no effect on the amount we pay for services furnished to beneficiaries.

We propose that hospitals meet these electronic billing requirements 60 days after the final notice is published. Currently 75 percent of participating hospitals bill electronically. Although a recently conducted survey indicated that approximately 80 percent of all rural hospitals bill Medicare

electronically, we would consider temporary exemptions from this policy on a case-by-case basis for any low volume hospital that cannot implement the electronic billing requirement timely. Hospitals desiring temporary exemptions must submit their exemption requests within 30 days after the final notice is published and submit, by the end of the third month following publication of the final notice, a plan for submitting bills electronically. We will not penalize non-EMC hospitals that consistently bill a very low volume of Medicare claims (i.e., Medicare utilization rate is less than 15 percent). These hospitals may be granted an indefinite exemption from the electronic billing requirements of this notice.

We specifically solicit public comments on the timeframes proposed in this notice.

II. Electronic Payments and Remittance Notices

A. Background

Section 1815(a) of the Social Security Act provides the authority for the Secretary to pay hospitals for Medicare services at such time or times as the Secretary believes appropriate (but no less frequently than monthly). Under Medicare, HCFA, acting for the Secretary, enters into agreements with fiscal agents (intermediaries) to pay bills submitted by hospitals who furnish services to Medicare beneficiaries. Currently, manual instructions provide details regarding the preparation and issuance of hard copy checks. (Section 1412 of the Medicare Intermediary Manual.) Although there are no existing regulations that prescribe or describe details of the procedures for processing hospital requests for payment, the Medicare Act does not limit the method of making payments. In fact, sections 1816 (a)(2) and (c)(3) envision that the intermediary can make payments in a manner other than by mailing. Specifically, these sections state that payments may be "issued, mailed, or otherwise transmitted * * *". Accordingly, we conclude that we have statutory authority to require intermediates to make electronic payments.

Currently, checks are drawn on the commercial bank servicing the intermediary's Medicare account and mailed to hospitals with a remittance advice that summarizes approved payments by HCFA. HCFA underwrites the costs of postage. On the average, the hospital's bank account receives the funds three days from the date that the hard copy checks are mailed by the intermediary. We estimate the cost of mailing payment and remittance advices to providers, including the cost of the checks, to be $.35 per payment.

B. Discussion

We published a final notice, "Revised Procedures for Paying Claims from Providers of Services (BPO–93–FN)" on October 21, 1992 (57 FR 48033), which specified a uniform payment policy and procedures for paying providers of services under Medicare Parts A and B. The new procedures allow intermediaries and carriers to pay providers using electronic funds transfers (EFTs); that is, through direct deposits into providers' accounts if certain conditions are met. Additionally, the new procedures require that those providers of services that receive direct deposits accept electronic remittance advices (ERAs) in lieu of the current paper remittance advices. We indicated in the October 21st final notice that we would issue appropriate revised instructions in the Medicare Intermediary Manual and Medicare Carriers Manual, part I, Fiscal Administration.

C. Proposed Changes

In this proposed notice we also propose to implement a new uniform mechanism for making payments to hospitals for services furnished under Medicare. Limited funding for Medicare contractor operations compels us to use the most cost-effective means available to process and pay claims. The migration to electronic payment and remittance environments at most hospitals would result in greater efficiencies for the institutions and the Medicare program. Our current proposal would supplement the policy contained in the October 21st final notice in regard to hospitals. We propose to require hospitals to receive all payments and remittance advices electronically within 60 days after publication of this notice as a final notice.

At this time, we are not proposing any further changes for nonhospital providers' receipt of remittance advices or their billing methods nor are we proposing any further changes in billing, payment or remittance advices concerning services from any provider or supplier except hospitals. These providers and suppliers would continue to have the option as specified in the October 21, 1992 final notice to bill and receive payment electronically.

When these procedures are made final, we would require intermediaries to pay hospitals through direct deposits (EFTs) into the hospitals' accounts. We are also proposing to require intermediaries to furnish electronic remittance advices (ERAs) to all hospitals using a HCFA-approved format. This procedure would reduce the cost of remittance advices through reduced postage. Implementing EFT/ERA procedures for hospital payments would be cost-effective as we estimate a net savings of $.21 per payment. We estimate the total savings from the EFT/ERA requirement to be $300,000 per year. We do not expect this proposal to have any effect on benefit payments; that is, benefit payments will not be moved between fiscal years.

Consistent with current policy, hospitals would continue to receive payment as frequently as they do now without electronic funds transfers (EFTs). We propose that intermediaries make direct deposits to all hospitals that have not been granted an exemption to this policy through the electronic funds transfer method, using the Automated Clearing House function of the Federal Reserve Banking System. Intermediaries would initiate electronic funds transfers to hospitals no sooner than the 15th day following electronic receipt of the claims in accordance with current payment policy. This policy was first established under section 4031 of OBRA 1987 and has been maintained since 1989 in order to ensure a consistent flow of payments from the Medicare trust funds.

As stated earlier, we propose to require that all hospitals receive their Medicare program payments through EFTs, and also accept remittance advice information through ERAs no later than 60 days after publication of the final notice. Most fiscal intermediaries, in accordance with HCFA's Financial Core Requirements, currently have the capability of generating EFT payment files and electronic remittances. The remaining intermediaries should have EFT/ERA capability by early 1993. If a particular intermediary has not implemented EFTs or ERAs prior to publication of the final notice, we propose that each hospital served by that particular intermediary be required to accept both EFTs and ERAs within three months after the servicing intermediary begins EFT and ERA transmissions. Once this three month period has elapsed, Medicare would provide no paper checks or remittance advices to hospitals that have received no official exemption from the requirements in the final notice. Immediately following publication of the final notice, manual instructions would be distributed to all intermediaries outlining implementation details pertinent to electronic funds transfer and the use of electronic remittance advices.

Again, we propose that these general EFT/ERA requirements not be applied to hospitals with Medicare utilization rates of less than 15 percent. However, note that those hospitals with EMC capability that submit paper claims, in any instance, will be required to accept EFTs and ERAs without exception.

III. Response to Public Comments

Because of the large number of items of correspondence that we normally receive on a proposed document, we cannot acknowledge or respond to them individually. However, we will consider all comments that we receive by the date specified in the "DATE" section of this notice and respond to them in the final notice that is issued following this notice with comment period.

IV. Information Collection Requirements

This notice contains information requirements that are subject to review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980. Specifically, this notice announces our intention to require hospitals to bill intermediaries electronically, to require that the payment mechanism for paying hospitals be through electronic deposits, and to require hospitals to receive electronic remittance advices. Public reporting burden for this collection of information is estimated to be ¼ hour per hospital to arrange for direct deposit. A notice will be published in the Federal Register when approval is obtained. Other organizations and individuals desiring to submit comments regarding the burden estimate of any aspect of this collection of information, including suggestions for reducing this burden, should direct them to the Office of Information and Regulatory Affairs, Office of Management and Budget, at the address listed earlier in this document.

V. Regulatory Impact Statement

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed notice that meets one of the E.O. 12291 criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5. U.S.C. 601 through 612) unless the Secretary certifies that a proposed notice such as this would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all hospitals are considered to be small entities.

Some hospitals may incur upfront costs in order to comply with this notice. Hospitals would incur such costs if they have to modify their billing and accounting systems to accommodate electronic billing, electronic posting of remittance advices, and electronic account reconciliation. However, in most cases, hospitals will quickly recoup this investment due to the benefits and efficiencies associated with electronic billing and payment. Among other benefits, implementation of this notice will give hospitals the opportunity to receive their payments and remittances electronically, thus enabling them to perform reconciliation more efficiently. Hospitals would be assured of having monies in their accounts on the payment settlement date, thus eliminating the costs associated with controlling and depositing hard copy checks. In general, the system required by this notice should greatly improve hospitals' cash management controls.

We have concluded that this proposed notice is not a major rule under E.O. 12291 since it would not have an effect on the economy of $100 million or more and would not meet any of the other criteria, nor would it have a significant effect on a substantial number of Medicare participating hospitals.

Section 1102(b) of the Act requires the Secretary to prepare a rural impact statement if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area (MSA) and has fewer than 50 beds.

We are not preparing a rural impact statement because the Secretary certifies that this proposed notice would not have a significant economic impact on the operation of a substantial number of small rural hospitals.

(Sec. 1815(a) of the Social Security Act; 42 U.S.C. 1395g(a))

(Catalog of Federal Domestic Assistance Program No. 13.772—Medicare—Hospital Insurance)

Dated: December 8, 1992.

William Toby,

Acting Deputy Administrator, Health Care Financing Administration.

[FR Doc. 93–965 Filed 1–14–93; 8:45 am]

BILLING CODE 4120-01-M

Health Resources and Services Administration

Final Funding Preference for Grants for Health Careers Opportunity Program

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Correction.

SUMMARY: In notice document 92–31433, in the issue of Tuesday, December 29, 1992, make the following correction:

Page 61915 in the first column, Item 2, should read as follows:

2. The cohort of first-year disadvantaged students entering the health or allied health professions school in September 1992 exceeds the number of disadvantaged students enrolled in the first-year class in September 1991 by a number equal to at least 50 percent of the postbaccalaureate participants projected for enrolled in 1992.

Dated: January 11, 1993.

Robert G. Harmon,

Administrator

[FR Doc. 93–979 Filed 1–14–93; 8:45 am]

BILLING CODE 4160-15-M

Advisory Council; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of February 1993.

Name: Subcommittee on Process of the Advisory Commission on Childhood Vaccines.

Date and Time: February 4, 1993, 9:30 a.m.–5 p.m.

Place: Conference Room C, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

The meeting is open to the public.

Purpose: This Subcommittee is responsible for seeking, receiving, and analyzing systematic feedback (from interested parents' groups, petitioners' attorneys, etc.) on the implementation of the Vaccine Injury Compensation Program (VICP) and for making recommendations to the full Commission for appropriate changes in the system in order to improve the processes and

procedures used by the various parties involved in the VICP.

Agenda: The Subcommittee will examine damages process issues and awards issues.

Public comment will be permitted prior to the lunch break and at the end of the meeting. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation by January 27 to Mr. Matthew B. Barry, Vaccine Injury Compensation Program, Bureau of Health Professions, Health Resources and Services Administration, room 702, 6001 Montrose Road, Rockville, Maryland 20852, Telephone (301) 443–6593.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Vaccine Injury Compensation Program will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for presentation, but desire to make an oral statement, may sign up in Conference Rooms C before 10:00 a.m. These persons will be allocated time as time permits.

Anyone requiring information regarding the subject Commission should contact Mr. Matthew B. Barry, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Room 7–02, 6001 Montrose Road, Rockville, Maryland 20852, Telephone (301) 443–6593.

Agenda items are subject to change as priorities dictate.

Date: January 11, 1993.

Jackie E. Baum,

Advisory Committee Management Officer, HRSA.

[FR Doc. 93–978 Filed 1–14–93; 8:45 am]

BILLING CODE 4160–15–M

Public Health Service

Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Public Health Service (PHS) publishes a list of information collection requests it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The following requests have been submitted to OMB since the list was last published on Friday, January 8, 1992.

(Call PHS Reports Clearance Officer on 202–690–7100 for copies of requests)

1. HIV/AIDS Related Laboratory Training Needs—New—The purpose of this survey is to determine the training needs of laboratorians who perform tests for the HIV–1 antibody by EIA and CD4–T–cells by Floy Cytometry, as a result, training materials can be designed to fill knowledge gaps. *Respondents:* Businesses or other for-profits, Small businesses or organizations, State or local governments. *Number of Respondents:* 3,102; *Number of Responses per Respondent:* 1; *Average Burden Per Response:* 0.457 hours; *Estimated Annual Burden:* 1,419 hours.

2. Biomedical and Psychosocial Risk Factors for Tooth Loss in Older Americans—New—This study will collect primary data by telephone and clinical examination from adults at risk for tooth loss to identify sociodemographic, economic, medical status, attitudinal, and dental care utilization characteristics that place persons at increased risk for tooth loss. Data will be collected from U.S. adults, 45 years and over, and other high-risk populations, and their dental care providers. This information is expected to facilitate more cost-effective prevention of tooth loss. *Respondents:* Individuals or households, Businesses or other for-profit, Small businesses or organizations.

Title	Number of respondents	Number of responses per respondent	Average burden per response
Household Respondents	7,167	1	.11 hr.
Dental Care Providers	67	1	.5 hr.

Estimated Total Annual Burden: 834 hours.

3. OMAR Quick Launch Physician Survey, Instrument 1: Hearing Impairment in Infants—New—The Office of Medical Applications of Research (OMAR) will conduct surveys of physicians to evaluate changes in their practice behavior related to detection of childhood deafness, the subject of an upcoming Consensus Development Conference (CDC). Physicians will be surveyed twice, just before, and one year following the CDC. *Respondents:* Individuals or households, Businesses or other for-profit. *Number of Respondents:* 1,800; *Number of Responses per Respondent:* 1; *Average Burden Per Response:* .17 hours; *Estimated Annual Burden:* 306 hours.

4. A Study of Caregiving and Dementia in the Honolulu Heart Program Cohort—0925–0374—The purpose of the project is to describe predictors and outcomes of caregiver burden and the quality of life in caregivers of elderly men with dementia. Standard questionnaires will be used in an interview format to obtain information from caregivers and control group.

Respondents: Individuals or households. *Number of Respondents:* 400; *Number of Responses per Respondent:* 1.94; *Average Burden Per Response:* .5 hours; *Estimated Annual Burden:* 39 hours.

Desk Officer: Shannah Koss

Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated above at the following address: Human Resources and Housing Branch, New Executive Office Building, room 3002, Washington, DC 20503.

Dated: January 11, 1993.

James Scanlon,

Director, Division of Data Policy, Office of Health Planning and Evaluation.

[FR Doc. 93–973 Filed 1–14–93; 8:45 am]

BILLING CODE 4160–17–M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Housing

[Docket No. N–93–3563]

Submission of Proposed Information Collection to OMB

AGENCY: Office of Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: January 22, 1993.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and should be sent to: Angela Antonelli, OMB Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Kay F. Weaver, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, Southwest, Washington, DC 20410, telephone (202) 708–0050. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Ms. Weaver.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. chapter 35). It is also requesting that OMB complete its review of that form within seven days of this publication.

The Notice lists the following information:

(1) The title of the information collection proposal;

(2) The office of the agency to collect information;

(3) The description of the need for the information and its proposed use;

(4) The agency form number, if applicable;

(5) What members of the public will be affected by the proposal;

(6) How frequently information submissions will be required;

(7) An estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response;

(8) Whether the proposal is new or an extension, reinstatement or revision of an information collection requirement; and

(9) The names and telephone numbers of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

Authority: Section 3507 of the Paperwork Reduction Act, 44 U.S.C. 3507; Section 7(d) of the Department of Housing and Urban Development Act, 42 U.S.C. 3535(d).

Dated: January 6, 1993.

Arthur J. Hill,

Assistant Secretary for Housing—Federal Housing Commissioner.

Proposal: Payment Voucher for Preservation Technical Assistance.

Office: Housing.

Description of the Need for the Information and Its Proposed Use: The Notice of Funding Availability for the Preservation Technical Assistance Planning Grant Funds was published in the **Federal Register** on September 3, 1992. These funds have been made available to support resident supported-purchases of projects eligible for incentives under the Preservation Program. The first applications are in the process of being approved for grant award.

The form assists grant recipients in making requests for disbursement of funds through the automated Line of Credit Control/Voice Response System, which will expedite the disbursement of funds to the recipient. The form also allows HUD field staff to verify requests for funds.

Form Number: HUD–9738.

Respondents: Grant recipients of Preservation Technical Assistance Planning Grants.

Frequency of Submission: Periodically, as grant funds are expended and requested.

Reporting Burden:

	Number of respondents	Frequency of response	Hours per response	=	Burden hours
Information collections	120	10	.25		300

Total Estimated Burden Hours: 300.

Status: New.

Contact: Betsy Keeler, HUD, (202) 708–1142. Angela Antonelli, OMB (202) 395–6880.

Dated: January 6, 1993.

Supporting Statements, Form HUD–9738

1. Circumstances that make the collection of information necessary—legal, administrative requirements

The Notice of Funding Availability for the Preservation Technical Assistance Planning Grant Funds was published in the **Federal Register** on September 3, 1992. These funds have been made available to support resident supported-purchases of projects eligible for incentives under the Preservation Program. The form assists grant recipients in making requests for disbursement of funds through the automated Line of Credit Control/Voice Response System, which will expedite the disbursement of funds to the recipient. The form also allows HUD field staff to verify requests for funds.

2. How, by whom, and for what purpose will the information be used?

The form will be used by grantees so that they may be reimbursed for funds spent under the Preservation Technical Assistance Grant.

This information will be used by the Department to assure that grantees are vouchering for eligible activities under the grant and to monitor funds spent.

3. How might use of improved information technology affect collection?

This form was developed in conjunction with the Departments Line of Credit Control System/Voice Response System (LOCCS/VRS), an automated disbursement system accessible by the grantee through a touchtone phone. Improved technology would not affect this information collection.

4. Duplication:

There will be no duplication of information. Funds spent under this grant are not documented in any other HUD program.

5. There is no similar information already available which could be used or modified for this purpose.

6. This form and the telephone vouchering process will simplify the vouchering process for all entities including small entities.

7. This reporting requirement is necessary to efficiently disburse grant funds.

8. There are no special circumstances requiring the collection of information that is inconsistent with the guidelines in 5 CFR 1320.6.

9. The Department consulted with no outside parties on the development of this form.

10. There are no assurances of confidentiality provided to respondents.

11. The information collected contains no items of a sensitive nature.

12. Costs of the Information Collection.

Cost to respondents is estimated using the burden hours calculated in 13 below and a collar cost of $20 per hour which includes both labor and overhead. Cost to the Federal Government is also estimated using an hourly labor/overhead rate of $20.

Respondents			Burden hours	×	Cost/hour	=	Total
			300		$20		$6,000

Government	Responses	×	Hours	×	Cost/hour	=	Total
Processing	1200		.10		$20		$2,400
Total							$8,400

13. Tabulation of Burden Hours.

The amount of funds made available under the NOFA was $15 million. The Department estimates a total of 120 grants to be awarded under the NOFA. This estimate assumes all grantees receive the maximum award for all three phases of the NOFA or $125,000. The Department further estimates voucher requests for funds to be made approximately 10 times per year for each grantee. At .25 hours per form, the total annual respondent burden is 300 hours. The government processing burden is based on an estimate that verification of each request will take .10 hours.

14. This information collection is the result of the implementation of new statutory requirements.

15. The Department does not plan to use the collection of this information for any published statistical use.

BILLING CODE 4210-27-M

LOCCS/VRS
Preservation Technical Assistance Planning Grant Payment Voucher

U.S. Department of Housing and Urban Development
Office of Housing
Preservation of Affordable Housing

OMB Approval No. 2502-0000 (exp. xxxxxx)

Public reporting burden for this collection of information is estimated to average 0.25 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Reports Management Officer, Office of Information Policies and Systems, U.S. Department of Housing and Urban Development, Washington, D.C. 20410-3600 and to the Office of Management and Budget, Paperwork Reduction Project (2502-0000) Washington, D.C. 20503. Do not send this form to either of these addressees when filled-in.

1. Voucher Number: 037	2. LOCCS Pgrm. Area: PTAG	4. Type of Disbursement: ☐ 1 = Partial ☐ 2 = Final
5. Voice Response No. (5 digits, hyphen, 5 more):	6. Grantee Organization's Name:	
8. Grant No:	6a. Grantee Organization's TIN:	

DRAFT

9. Line Item no.	Type of Funds Requested	Amount:
1010	Developing of RCs and CBOs (legal, accounting, organizational costs)	.
1020	Architectural and Engineering	.
1030	Secure Financing, TPA or Mortgage documents	.
1040	Training and Technical Assistance	.
1050	Preparing Expression of Interest	.
1060	Preparing Purchase Offer	.
1070	Developing Management Capacity	.
1080	Market Studies	.
1090	(Other eligible activity):	.
		.
		.
		.
		.
		.
		.
		.
		.
10. Voucher Total:		$.

I hereby certify that all the information stated herein, as well as any information provided in any accompaniment herewith, is true and accurate. **Warning:** HUD will prosecute false claims and statements. Conviction may result in criminal and/or civil penalties. (18 U.S.C. 1001, 1010, 1012; 31 U.S.C. 3729, 3802)

11. Name & Phone Number (including area code) of the Authorized Person who completed this form:	12. Signature: X	13. Date of Request:

DRAFT

Privacy Statement: Public Law 97-255, Financial Integrity Act, 31 U.S.C. 3512, authorizes the Department of Housing and Urban Development (HUD) to collect all the information (except the Social Security Number (SSN)) which will be used by HUD to protect disbursement data from fraudulent actions. The Housing and Community Development Act of 1987, 42 U.S.C. 3543, authorizes HUD to collect the SSN. The data are used to ensure that individuals who no longer require access to Line of Credit Control System (LOCCS) have their access capability promptly deleted. Provision of the SSN is mandatory. HUD uses it as a unique identifier for safeguarding LOCCS from unauthorized access. Failure to provide the information requested may delay the processing of your approval for access to LOCCS. This information will not be otherwise disclosed or released outside of HUD, except as permitted or required by law.

form HUD-9738 (12/22/92)

Instructions for the

Preservation of Affordable Housing Program

Tecnical Assistance Planning Grant Payment Voucher:

The Planning Grant Payment Voucher form must be completed for each request of Preservation Technical Assistance funds. Prepare the Planning Grant Payment Voucher form prior to calling HUD to request funds from the Line of Credit Control System (LOCCS). Telephone the Preservation Voice Response System (VRS) at (703) 391-1400 and provide your security ID. After completing the call, keep the original of the form in the Grantee's Program file. A copy of the form, with expense documentation, must be received by the HUD Field Office within seven days after the call-in.

Instructions:

Item 1. **Voucher Number:** Provided by LOCCS / VRS at the time of call-in.

Item 2. **LOCCS Program Area:** The program code (PTAG) is preprinted in block 2.

Item 4. **Type of Disbursement:** Check "final" if this is the final disbursement for this phase of Preservation Technical Assistance Grant Award. Otherwise, check "partial."

Item 5. **Voice Response No:** Enter the 10 digit Voice Response Number assigned by HUD.

Item 6. **Grantee Organization's Name:** Enter the lead applicant identified in the grant agreement who is legally responsible for completion of the Preservation Technical Assistance Program activities.

Item 6a. **Grantee Organization's Tax Identification No:** Enter the Tax (employer) Identification Number shown in item 6 on Standard Form 424 of the Preservation Technical Assistance Application and the SF 1199A (direct deposit form).

Item 8. **Grant Number:** Enter the Grantee's grant number shown in the Grant Agreement.

Item 9. **Type of Funds Requested:** Enter the amount requested in each category (boxes 1010 through 1090) and the total funds requested under:

Item 10, Voucher Total. The voice response system (VRS) will confirm the amounts requested in each line item and the total amount requested at the end of the call-in.

Item 11. **Name & phone number** (including area code) of the authorized person who completed the call-in to VRS. The authorized person is shown on line 3 of form HUD-27054.

Item 12. Signature of the person identified in item 11.

Item 13. **Date of this Request:** Enter the date of the call-in to request funds.

[FR Doc. 93-1023 Filed 1-14-93; 8:45 am]
BILLING CODE 4210-27-C

[Docket No. N-92-3487; FR-3092-C-09]

Funds Availability: Congregate Housing Services Program NOFA for Fiscal Year 1992; Correction

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD; Office of the Commissioner, Farmers Home Administration (FmHA).

ACTION: Notice of funding availability for fiscal year 1992; correction.

SUMMARY: On December 8, 1992 (57 FR 58056), the Department published in the Federal Register, a Notice of Funding Availability (NOFA) that announced the funding of a national competition for the supportive services component of the Congregate Housing Services Program (CHSP). The purpose of this document is to insert information that was inadvertently omitted from the Application Requirements section of that NOFA.

DATES: The deadline date for submission of an application for funding under the CHSP is on or before 3 p.m., Eastern Standard Time, March 8, 1993.

RECEIPT OF APPLICATIONS: HUD will receive applications at: U.S. Department of Housing and Urban Development, Office of Procurement and Contracts (OPC), Program Support Division, ACS–KK, 451 Seventh Street, SW., room 5256, Washington, DC 20410. Upon receipt, OPC will date-stamp incoming applications to evidence (timely or late) receipt, and upon request, provide the applicant with an acknowledgement of receipt. FAXed applications are NOT acceptable. Applications will also be sent to HUD field offices or FmHA State offices, as appropriate.

FOR FURTHER INFORMATION CONTACT: For general information concerning grants under the CHSP, or limited technical assistance by telephone regarding the preparation of an application for the CHSP, potential applicants may contact HUD and FmHA headquarters as follows:

For questions regarding HUD projects, contact the Services Branch, Housing for Elderly and Handicapped People Division, Office of Elderly and Assisted Housing, Department of Housing and Urban Development. Please tell the person who answers your call the city and State the project is located in and the servicing HUD field office, if known. You will be directed to the appropriate staff person. The number is (202) 708–3291. (This is not a toll-free number.) Hearing-impaired individuals may reach the Services Branch by calling the TDD number of the Federal Relay Service, 1–800–877–TDDY, and request a transfer, or by calling (202) 708–4594.

For questions regarding FmHA projects, call the Multifamily Processing Division, Special Authorities Branch, Farmers Home Administration, Department of Agriculture. Callers may request either John Pentecost or Sue Harris. The telephone number is (202) 720–1606. (This is not a toll-free number.) Hearing-impaired individuals may reach FmHA by calling the central TDD number of (202) 245–0846, or by calling the TDD number of the Federal Relay Service, 1–800–877–TDDY and request a transfer, or by calling (202) 708–9300.

SUPPLEMENTARY INFORMATION: Accordingly, the Notice of Funding Availability (FR Doc. 92–29242), published in the **Federal Register** on December 8, 1992 (57 FR 58056), is corrected on page 58060, in the third column, in section II.B.6, by adding a new paragraph "h", to immediately follow paragraph "g", to read as follows:

II. Application Process

* * * * *

B. Application Requirements

* * * * *

6. * * *

h. For those projects proposed for CHSP funds and in which currently exists a services program(s), the following information must be submitted for project supplied services or services in the project on-site or off-site through grant, contract or third party arrangement.

(1) Documentation for current services budget including amount of dollars per service broken out by line item and numbers served for each service provide; and

(2) Justification for why additional funds are necessary under CHSP.

* * * * *

Dated: January 8, 1993.

Grady J. Norris,

Assistant General Counsel for Regulations.

[FR Doc. 93–944 Filed 1–14–93; 8:45 am]

BILLING CODE 4210-27-M

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-93-1917; FR-3350-N-14]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: January 15, 1993.

ADDRESSES: For further information, contact James Forsberg, Department of Housing and Urban Development, room 7262, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–4300; TDD number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: January 8, 1993.

Paul Roitman Bardack,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 93–874 Filed 1–14–93; 8:45 am]

BILLING CODE 4210-29-M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Exxon Valdez Oil Spill Public Advisory Group; Meetings

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of meeting.

SUMMARY: The Department of the Interior announces a public meeting of the Exxon Valdez Oil Spill Public Advisory Group to be held on February 10, 1993, at 9:30 a.m., in the first floor conference room, 645 G Street, Anchorage, Alaska.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Department of the Interior, Office of Environmental Affairs, 1689 C Street, suite 119, Anchorage, Alaska (907) 271–5011.

SUPPLEMENTARY INFORMATION: The Public Advisory Group was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991, and approved by the United States

District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska*, Civil Action No. A91–081 CV. This meeting will include:

(1) A review of restoration plan alternative themes;

(2) A review of habitat protection activities; and

(3) A review of the proposed 1994 work plan.

Dated: January 11, 1993.

Jonathan P. Deason,

Director, Office of Environmental Affairs.

[FR Doc. 93–1071 Filed 1–14–93; 8:45 am]

BILLING CODE 4310-RG-M

Bureau of Land Management

[(AK–967–4230–15), AA–10592]

Alaska Native Claims Selection

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of Sec. 14(h)(1) and 14(h)(7) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1601, 1613(h)(7), will be issued to Koniag, Inc. The lands involved are in the vicinity of Larsen Bay, Alaska.

T. 33 S., R. 28 W., Seward Meridian, Alaska

A notice of the decision will be published once a week, for four (4) consecutive weeks, in the *Kodiak Daily Mirror*. Copies of the decision may be obtained by contacting the Alaska State Office of the Bureau of Land Management, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599 ((907) 271–5960).

Any party claiming a property interest which is adversely affected by the decision, an agency of the Federal government or regional corporation, shall have until February 16, 1993, to file an appeal. However, parties receiving service by certified mail shall have 30 days form the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management at the address identified above, where the requirements for filing an appeal may be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4, subpart E, shall be deemed to have waived their rights.

Terry R. Hassett,

Chief, Branch of KCS Adjudication.

[FR Doc. 93–901 Filed 1–14–93; 8:45 am]

BILLING CODE 4310-JA-M

[CA–060–5101–10–XBHA; CA–24320]

Hidden Valley Resources Residuals Repository, San Bernardino County, CA, Draft Environmental Impact Report/Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, a Draft Environmental Impact Statement has been prepared for the proposed Hidden Valley Resources Residuals Repository for specified hazardous waste in the California Desert Conservation Area, San Bernardino County, California. The proposed action is located in the Cady Mountains, approximately 35 miles east of the City of Barstow and approximately 10 miles north of Interstate Highway 40. This document has been prepared by the Bureau of Land Management (BLM) and the County of San Bernardino as a joint Environmental Impact Report/ Environmental Impact Statement (EIR/ EIS) to meet the requirements of the National Environmental Policy Act and the California Environmental Quality Act.

Reading copies are available at: BLM, Barstow Resource Area, 150 Coolwater Lane, Barstow; BLM, California Desert District, 6221 Box Springs Blvd, Riverside; San Bernardino County Government Center, 385 N. Arrowhead Avenue, Third Floor, San Bernardino; San Bernardino County Building, 15505 Civic Drive, Victorville; Newberry Springs Community Center, 30887 Newberry Road, Newberry Springs and libraries in Victorville, Barstow, and San Bernardino.

DATES: Written comments on the draft must be delivered or postmarked no later than March 19, 1993. Oral and/or written comments may also be presented at public meetings scheduled at the following locations and dates:

Location	Date	Time
Holiday Inn, I–15 and Palmdale Road, Victorville, CA 92392.	February 23, 1993.	7–9 p.m.
Newberry Springs Community Center, 30887 Newberry Road, Newberry Springs, CA 92365.	February 24, 1993.	7–9 p.m.
San Bernardino County Government Center, Hearings Chamber, 385 N. Arrowhead Avenue, San Bernardino, CA.	February 25, 1993.	7–9 p.m.

ADDRESS: Written comments should be addressed to: County of San Bernardino, Planning Department, 385 N. Arrowhead Avenue, Third Floor, San Bernardino, CA 92415–0182, Attn: Mr. Randy Scott.

FOR FURTHER INFORMATION CONTACT: John Kalish, BLM Project Manager, 150 Coolwater Lane, Barstow, CA 92311; telephone (619) 256–3591.

SUPPLEMENTARY INFORMATION: The Draft EIR/EIS identifies and describes the probable environmental impacts that would result from the proposed construction and operation of a specified hazardous waste disposal facility. The proposed action consists of subsurface containment structures on private lands designed to accept up to 450,000 tons annually of dry, treated and stabilized hazardous waste residuals and cleanup waste over a 120 year period. A new road and rail access corridor would be placed on public lands. Administration and containment areas total 5,260 acres of private and public lands.

Issues identified through the scoping process and evaluated in the EIR/EIS include geology, soils, hydrology, noise, biological resources, cultural and paleontological resources, air quality, water supply and quality, scenic/visual resources, transportation, land use, wilderness study areas, and public health and safety.

Dated: January 8, 1993.

Karla K.H. Swanson,

Area Manager.

[FR Doc. 93–841 Filed 1–14–93; 8:45 am]

BILLING CODE 4310-40-M

[CA–060–43–7122 08 1016; CACA 27555]

Realty Action; San Bernardino County, CA

AGENCY: Bureau of Land Management, Interior.

ACTION: Amendment to the Notice of Realty Action published in the **Federal Register** June 11, 1992, Volume 57, No. 113, Pages 24809 and 24810.

SUMMARY: This amendment eliminates all of section 21, T.32 S., R.44 E., Mount Diablo Meridian, California, from the exchange and adds the following parcel containing 640 acres of offered private lands in San Bernardino County.

Mount Diablo Meridian, California

T. 31 S., R. 45 E.
Sec. 21, All;

The surface and all minerals will be conveyed to the United States.

EFFECTIVE DATE: January 15, 1993.

FOR FURTHER INFORMATION CONTACT: Additional information about this exchange is available at the Barstow Resource Area Office, 150 Coolwater Lane, Barstow, CA 92311 (619) 256–3591, and the California Desert District Office, 6221 Box Springs Blvd., Riverside, CA 92507–0714. For a period of forty-five (45) days from the date of publication of this notice in the **Federal Register** interested parties may submit comments to the District Manager, California Desert District at the above address.

Dated: January 6, 1993.

Henri R. Bisson,

District Manager.

[FR Doc. 93–1086 Filed 1–14–93; 8:45 am]

BILLING CODE 4310–40–M

[MT–0210–4210–04; MTM 80345]

Realty Action; Exchange of Public Lands and Minerals in Musselshell and Yellowstone Counties, MT; Correction

AGENCY: Bureau of Land Management, Miles City District Office, Interior.

ACTION: Correction.

SUMMARY: In notice document 92–30609 on page 60002 in the issue of Thursday, December 17, 1992, make the following correction:

In the second column, under Selected Federal Coal to be Acquired by Meridian in Musselshell County, the description was as follows: T. 6 N., R. 26 E., Section 4, all Section 12, all; Consisting of 1257.55 acres of coal. This should be changed to read T. 6 N. R. 26 E., Sections 12 and 14, all; Consisting of 1257.55 acres of coal.

SUPPLEMENTARY INFORMATION: Detailed information concerning the exchange is available at the Billings Resource Area office.

Darrel G. Pistorius,

Acting District Manager.

[FR Doc. 93–966 Filed 1–14–93; 8:45 am]

BILLING CODE 4310–DN–M

[ID–943–4210–06; IDI–29692]

Proposed Withdrawal and Opportunity for Public Meeting, Idaho

ACTION: Notice.

SUMMARY: The U.S. Forest Service, Department of Agriculture, proposes to withdraw 5.03 acres of National Forest System land for construction of the Salmon Canyon Copper Boating Site Recreation Area. This notice closes the land for up to two years from surface entry and mining. The land will remain open to mineral leasing and all other uses which may be made of National Forest System lands.

DATES: Comments and requests for a meeting should be received on or before April 15, 1993.

ADDRESSES: Comments and meeting requests should be sent to the Idaho State Director, BLM, 3380 Americana Terrace, Boise, Idaho 83706.

FOR FURTHER INFORMATION CONTACT: Larry R. Lievsay, BLM, Idaho State Office, (208) 384–3166.

SUPPLEMENTARY INFORMATION: On January 4, 1993, the U.S. Forest Service, Department of Agriculture, filed an application to withdraw the following-described National Forest System lands from settlement, sale, location or entry under the general land laws, including the mining laws, subject to valid existing rights:

Boise Meridian

T. 23 N., R. 16 E.,

A tract of land being that part of the SE¼ of unsurveyed sec. 26, more particularly described as follows:

Beginning at Salmon River Road GPS control point No. 9, a 3½ inch aluminum cap on a 1-inch aluminum drive-in rod; thence North 75°15′58″ East, 2,148.09 feet to the ordinary high water mark of the right bank of the Salmon River and AP–1, a 3½ inch aluminum cap on 1-inch aluminum drive-in rod, the *Point of Beginning*; thence North 5° 50′ 23″ West, 755.08 feet to AP–2, a 3½ inch aluminum cap on a 1-inch drive-in rod; thence North 89°54′35″ East, 640.79 feet to the ordinary high water mark of the right bank of the Salmon River and AP–3, a 3½ inch aluminum cap on a 1-inch aluminum drive-in rod; thence southwesterly along the ordinary high water line of the right bank of the Salmon River to AP–1, the *Point of Beginning*.

The area described contains 5.03 acres in Lemhi County.

Notice is hereby given that opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the Idaho State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the lands will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary uses which will be permitted during this segregative period are existing valid and authorized uses.

Dated: January 8, 1993

William E. Ireland,

Chief, Realty Operations Section.

[FR Doc. 93–1035 Filed 1–14–93; 8:45 am]

BILLING CODE 4310–GG–M

[G–910–G3–0014–4210–06; NMNM 88886]

Notice of Proposed Withdrawal and Opportunity for Public Meeting; NM

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The United States Department of Agriculture, Forest Service, has filed an application to withdraw approximately 4,887.56 acres of National Forest System lands for the East Fork River Canyon and Scenic Byway and to protect high recreation values. This notice closes the land for up to 2 years from location and entry under the United States mining laws, subject to valid existing rights. The lands will remain open to all other uses which may be made of National Forest Systems lands.

DATES: Comments and requests for a public meeting should be received on or before April 15, 1993.

ADDRESSES: Comments and meeting requests should be sent to the Albuquerque District Manager, BLM, 435 Montano Road NE, Albuquerque, New Mexico 87107.

FOR FURTHER INFORMATION CONTACT: Margie Martinez, BLM, Albuquerque District Office, (505) 761–8907.

SUPPLEMENTARY INFORMATION: On December 15, 1992, the United States Department of Agriculture filed an application to withdraw the following described National Forest System lands from location and entry under the United States mining laws, subject to valid existing rights:

New Mexico Principal Meridian

Santa Fe National Forest

T. 18 N., R. 3 E.,

Sec. 1, lots 5 to 16, inclusive, S½NE¼, and SE¼SE¼ (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306 of June 6, 1990);

Sec. 2, lot 1, S½NE¼, E½SW¼NW¼, SE¼NW¼SW¼NW¼, SW¼SW¼NW¼NW¼, SE¼NW¼, N½SW¼, E½E½SE¼SW¼, E½SE¼, N½NW¼SE¼, N½S½NW¼SE¼,

SW¼SW¼NW¼SE¼, W½W½SW¼SE¼, SE¼SW¼SW¼SE¼, and S½SE¼SW¼SE¼ (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 3, lot 8, SW¼NW¼, W½SE¼NW¼, W½SW¼, W½E½SW¼, and NE¼SE¼ (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 4, lots 3 to 6, inclusive, S½N½, SW¼, NE¼SE¼, and S½SE¼ (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 5., lots 8 to 10, inclusive, S½NE¼, and SE¼ (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 10, S½NW¼NE¼, SW¼NE¼, NW¼NE¼NW¼, S½NE¼NW¼, NW¼NW¼, S½NW¼, SW¼, SW¼NE¼NE¼SE¼, W½NE¼SE¼, W½SE¼NE¼SE¼, SE¼SE¼NE¼SE¼, W½SE¼, and SE¼SE¼ (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 12, E½;
Sec. 13, N½N½;
Sec. 14, lots 1 and 2, and N½NW¼.
T. 18 N., R. 4 E.,
Sec. 3, lots 17 and 18, and lots 22 to 24, inclusive (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 4, lots 9 to 16, inclusive, and lots 19 to 24, inclusive (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 5, lots 9 to 17, inclusive, and lots 21 to 28, inclusive (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 6, lots 7, and lots 12 to 26, inclusive (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 7, lots 2, 3, 4, 6, and 7, E½, and E½W½;
Sec. 8, SE¼SE¼NE¼NE¼, NW¼NW¼NW¼NE¼, SE¼NE¼, NE¼NE¼NE¼NW¼, S½NE¼NE¼NW¼, NW¼NW¼NE¼NW¼, E½SW¼NE¼NW¼, SE¼NE¼NW¼, W½NW¼, SE¼NW¼, N½SW¼, NE¼SE¼, and S½S½;
Sec. 9, E½, NE¼NW¼, SE¼NE¼NW¼NW¼, S½NW¼NW¼, S½NW¼, and SW¼ (excluding that portion designated as the East Fork of the Jemez Wild and Scenic River as described in Pub. L. 101–306);
Sec. 10, NW¼;
Sec. 17, N½N½;
Sec. 18, lots 1, N½NE¼ and NE¼NW¼.

The areas described aggregate approximately 4,887.56 acres in Sandoval County.

The purpose of the proposed withdrawal is to preserve the watersheds, the outdoor recreation opportunities, and the visual quality within view of the East Fork of the Jemez Wild and Scenic River and proposed East Fork National Recreation Trail and New Mexico State Highway 4 Scenic Byway.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the Albuquerque District Manager, Bureau of Land Manager.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the Albuquerque District Manager, Bureau of Land Management within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR part 2300.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the lands will be segregated as specified above unless the application is denied, canceled, or the withdrawal is approved prior to that date. The temporary uses which may be permitted during this segregative period are land uses permitted by the Forest Service under existing laws and regulations.

The temporary segregation of land in connection with this withdrawal application or proposal shall not affect the administrative jurisdiction over the land, and the segregation shall not have the effect of authorizing any use of the lands by the United States Department of Agriculture.

Dated: January 7, 1993.

Patricia E. McLean,

Acting District Manager.

[FR Doc. 93–967 Filed 1–14–93; 8:45 am]

BILLING CODE 4310-FB-M

Minerals Management Service

Availability of Outer Continental Shelf Official Protraction Diagrams

AGENCY: Minerals Management Service, Interior.

ACTION: Notice.

SUMMARY: Notice is hereby given that effective with this publication, the following revised outer continental shelf (OCS) Official Protraction Diagrams are on file and available in the Alaska OCS Region office, Anchorage, Alaska. These diagrams are based on North American Datum 1927 and were revised to reflect the recent survey results in the area of Peard Bay in the Beaufort Sea Planning Area, Alaska.

Description	Revision date
NR 4–3, Wainwright	November 20, 1992.
NR 4–4, Meade River	November 20, 1992.

ADDRESSES: Copies of these Official Protraction Diagrams may be purchased for $2 each from the Library, Minerals Management Service, Alaska OCS Region, 949 East 36th Avenue, Anchorage, Alaska 99508–4302, (907) 271–6435.

Dated: January 7, 1993.

Alan D. Powers,

Regional Director, Alaska OCS Region.

[FR Doc. 93–1034 Filed 1–14–93; 8:45 am]

BILLING CODE 4310-MR-M

National Park Service

Gateway National Recreation Area Sandy Hook Unit, NJ; Environmental Assessment for Development at Great Kills Park; Availability and Public Comment Period

In accordance with the National Environmental Policy Act (Pub. L. 91–190) the National Park Service, U.S. Department of the Interior, announces that an Environmental Assessment for Development at Gunnison and North Beaches, Sandy Hook Unit, Gateway National Recreation Area, New Jersey is available for public review and comment.

During the public review period of January 19, 1993 through February 19, 1993, interested persons may review the document and make written comments to the Superintendent, Gateway National Recreation Area, Floyd Bennett Field, Building #69, Brooklyn, New York, 11234.

Limited copies of the document are available to the public upon request by writing to the above address or calling

Paul (Skip) Cole, Site Manager, Sandy Hook Unit at (908) 872–0115.

Dated: January 8, 1993.

Steven H. Lewis,

Acting Regional Director.

[FR Doc. 93–1070 Filed 1–14–93; 8:45 am]

BILLING CODE 4310-70-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–334]

Certain Condensers, Parts Thereof and Products Containing Same, Including Air Conditioners for Automobiles

Notice is hereby given that the prehearing conference in this matter will commence at 9 a.m. on February 8, 1993, in Courtroom C (room 217), U.S. International Trade Commission Building, 500 E St. SW., Washington, DC, and the hearing will commence immediately thereafter.

The Secretary shall publish this notice in the **Federal Register.**

Issued: January 4, 1993.

Janet D. Saxon,

Administrative Law Judge.

[FR Doc. 93–977 Filed 1–14–93; 8:45 am]

BILLING CODE 7020-02-M

Report to the President on Investigation No. TA–201–63; Extruded Rubber Thread

Determination

On the basis of the information developed in the subject investigation, the Commission was equally divided on the question of whether extruded rubber thread [1] is being imported into the United States in such increased quantities as to be a substantial cause of serious injury, or the threat thereof, to the domestic industry producing an article like or directly competitive with the imported article.[2] [3] The Commission did not find that critical circumstances exist.[4]

[1] The imported article covered by this investigation is extruded rubber thread of natural rubber latex, classified under hearing 4007.00.00 of the Harmonized Tariff Schedule of the United States (HTS).

[2] Chairman Newquist and Commissioners Rohr and Nuzum voted in the affirmative. Vice Chairman Watson and Commissioners Brunsdale and Crawford voted in the negative.

[3] Section 330(d)(1) of the Tariff Act of 1930 provides that when the Commission is equally divided on the question of injury under section 201 of the Trade Act of 1974, "then the determination agreed upon by either group of Commissioners may be considered by the President as the determination of the Commission."

[4] Chairman Newquist and Commissioners Rohr and Nuzum made a negative determination with respect to the issue of critical circumstances. Vice Chairman Watson and Commissioners Brunsdale and Crawford did not reach the issue.

Finding and Recommendation on Remedy [5]

Chairman Newquist and Commissioners Rohr and Nuzum recommend that the President proclaim a tariff-rate quota on imports of such extruded rubber thread for a 5-year period:

(1) With the quota to be set at 17 million pounds for the first 2 years of the relief period and thereafter adjusted annually so as to be set at a level equal to 50 percent of domestic consumption for the prior calendar year, and

(2) With existing rates of duty to apply to within-quota imports, and with the following rates of duty, in addition to any other duties, to apply to over-quota imports: 25 percent ad valorem in the first 3 years, 15 percent ad valorem in the fourth year, and 10 percent and valorem in the fifth year.[6]

They find that this action will address the serious injury found to exist and does not exceed the amount necessary to remedy such injury, and that such action will be the most effective in facilitating the efforts of the domestic industry to make a positive adjustment to import competition. They further recommend that the continuation of this relief beyond the first 2 years be conditioned on the domestic industry's making reasonable progress in implementing the proposed adjustment plan and that such relief and industry adjustment be the subject of annual Commission review investigations under section 204 of the Trade Act of 1974 after the second year of relief for such period that relief remains in effect.

[5] Section 202(b)(6) of the Trade Act of 1974 provides that "Only those members of the Commission who agreed to the affirmative determination under subsection (b) are eligible to vote on the recommendation to be made" on remedy. The provision further states that "Members of the Commission who did not agree to the affirmative determination may submit, in the [Commission's] report * * * separate views regarding what action, if any, should be taken under section 203" by the President.

[6] Imports from Israel, Canada, and beneficiary countries under the Caribbean Basin Economic Recovery Act and the Andean Trade Preference Act are de minimis or nil. Accordingly, this recommendation does not apply to imports from Israel under the U.S.-Israel Free Trade Agreement or from beneficiary countries under the Caribbean Basin Economic Recovery Act or the Andean Trade Preference Act. With respect to imports from Canada, Chairman Newquist and Commissioners Rohr and Nuzum find that imports of extruded rubber thread from Canada are not substantial and are not contributing importantly to the serious injury to the domestic industry within the meaning of section 302(b) of the United States-Canada Free-Trade Agreement Implementation Act of 1988, and therefore recommend that any relief action not apply to such imports from Canada. Accordingly, they recommend that imports from Israel, Canada, and the CBERA and Andean Preference countries not be counted within the quota amounts.

Vice Chairman Watson and Commissioners Brunsdale and Crawford, having made a negative determination, did not participate in the vote on a remedy recommendation. However, as provided for in the statute, they are submitting views, which are included within this report, stating why they believe that the taking of a remedy action in this instance would be inappropriate.

Background

Following receipt of a petition filed on June 18, 1992,[7] by North American Rubber Thread Co., Inc., Fall River, MA, the United States International Trade Commission, effective June 23, 1992, instituted investigation No. TA–201–63 under section 202 of the Trade Act of 1974 to determine whether extruded rubber thread is being imported into the United States in such increased quantities as to be a substantial cause of serious injury, or the threat thereof, to the domestic industry producing an article like or directly competitive with the imported article. The petitioner alleged that critical circumstances exist within the meaning of section 203(b)(3)(B) of the Trade Act and sought provisional relief.

Notice of the institution of the Commission's investigation and of public hearings to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of July 15, 1992 (57 FR 31387). The hearing in connection with the injury phase of the investigation was held on September 11, 1992, and the hearing on the question of remedy was held on November 3, 1992. Both hearings were held in Washington, DC; all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on December 21, 1992. The views of the Commission are contained in USITC Publication 2563 (December 1992), entitled "Extruded Rubber Thread: Report to the President on Investigation No. TA–201–63 Under Section 202 of the Trade Act of 1974."

Issued: January 11, 1993.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–997 Filed 1–14–93; 8:45 am]

BILLING CODE 7020-02-M

[7] The petition was amended on June 23, 1992.

VOL 58 ISS 10 JA 15 1993 UMI

[Investigation No. 337–TA–333]

Certain Woodworking Accessories; Issuance of Limited Exclusion Order

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has issued a limited exclusion order in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Cynthia P. Johnson, Esq., Office of General Counsel, U.S. International Trade Commission, telephone 202–205–3098.

SUPPLEMENTARY INFORMATION: The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in § 210.58 of the Commission's Interim Rules of Practice and Procedure (19 CFR 210.58).

On November 25, 1991, Cantlin, Inc. ("Cantlin") of Lincoln, Massachusetts filed a complaint and a motion for temporary relief with the Commission pursuant to section 337. Cantlin's complaint alleged violations of section 337 in the importation and sale of certain woodworking accessories. The complaint alleged infringement of all 18 claims of Cantlin's U.S. Letters Patent 4,805,505 ("the '505 patent") by four firms: (1) Woodever Products Co. Ltd., ("Woodever") of Taiwan; (2) Taiwan Zest Industrial Co., Ltd. ("Taiwan Zest") of Taiwan; (3) Trend-Lines, Inc. ("Trendlines") of Malden, Massachusetts; and (4) An Yun Industrial Co., Ltd. ("An Yun") of Taiwan. On December 30, 1991, the Commission voted to institute an investigation of Cantlin's complaint and to provisionally accept its motion for temporary relief and refer that motion to an administrative law judge ("ALJ"). Woodever, Taiwan Zest, Trendlines, and An Yun were named respondents. A notice of investigation was published in the **Federal Register** on January 6, 1992. 57 FR 416. The motion for temporary relief was later dismissed.

Respondents Taiwan Zest and Woodever were terminated on the basis of a consent order. Respondent Trendlines was found not to be a proper party to the investigation.

On April 3, 1992, the presiding administrative law judge issued an initial determination ("ID") finding respondent An Yun in default. The Commission determined not to review that ID. 57 FR 20505 (May 13, 1992).

On October 13, 1992, Cantlin declared that pursuant to Commission interim rule 210.25(c) 19 CFR 210.25(c), it sought a limited exclusion order directed against respondent An Yun.

The Commission solicited comments from the parties, interested government agencies, and other persons concerning the issues of remedy, the public interest, and bonding. 57 FR 53337 (November 9, 1992).

Complainant and the Commission investigative attorney filed proposed remedial orders and addressed the issues of remedy, the public interest, and bonding. No comments were filed by interested government agencies or other persons.

Section 337(g)(1) of the Tariff Act of 1930 provides that the Commission shall presume the facts alleged in a complaint to be true, and upon request issue a limited exclusion order and/or cease and desist order if: (1) A complaint is filed against a person under section 337, (2) the complaint and a notice of investigation are served on the person, (3) the person fails to respond to the complaint and notice or otherwise fails to appear to answer the complaint and notice, (4) the person fails to show good cause why it should not be found in default, and (5) the complainant seeks relief limited solely to that person. Such an order shall be issued unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the Commission finds that such exclusion should not be issued.

Each of the statutory requirements for the issuance of a limited exclusion order was met with respect to defaulting respondent An Yun. The Commission further determined that the public interest factors enumerated in section 337(g)(1) did not preclude the issuance of such relief. The Commission determined that bond under the limited exclusion order during the Presidential review period shall be in the amount of one hundred (100) percent of the entered value of the imported articles.

Copies of the limited exclusion order and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone 202–205–2000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810.

Issued: January 4, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–976 Filed 1–14–93; 8:45 am]

BILLING CODE 7020–02–M

DEPARTMENT OF LABOR

Employment Standards Administration

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and

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supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., room S-3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume, State, and page number(s). Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Pennsylvania, PA91-4 p. All. (Feb 22, 1991).

Volume II

Iowa, IA91-1 (Feb 22, 1991). p. All.

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202) 783-3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, this 8th day of January 1993.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 93-815 Filed 1-14-93; 8:45 am]

BILLING CODE 4510-27-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Humanities Panel; Meeting

AGENCY: National Endowment for the Humanities

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: David C. Fisher, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone 202/606-8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on 202/606-8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; or (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated September 9, 1991, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), and (6) of section 552b of Title 5, United States Code.

1. Date: February 1, 1993
Time: 9 a.m. to 5 p.m.
Room: 315
Program: This meeting will review Reference Materials applications in Linguistics, submitted to the Division of Research Programs, for projects beginning after July 1, 1993.
2. Date: February 2, 1993
Time: 9 a.m. to 5 p.m.
Room: 415
Program: This meeting will review applications for Elementary and Secondary Education, submitted to the Division of Education Programs, for projects beginning after September 1, 1993.
3. Date: February 4, 1993
Time: 9 a.m. to 5 p.m.
Room: 315
Program: This meeting will review applications for projects in Humanities and Social Sciences in Interpretive Research, submitted to the Division of Research Programs, for projects beginning after July 1, 1993.
4. Date: February 4, 1993
Time: 9 a.m. to 5 p.m.
Room: 415
Program: This meeting will review applications in Elementary and Secondary Education, submitted to the Division of Education Programs, for projects beginning after September 1, 1993.
5. Date: February 8-9, 1993
Time: 8:30 a.m. to 5 p.m.
Room: 415
Program: This meeting will review applications submitted to the Humanities Projects in Museums and Historical Organizations, submitted by the Division of Public Programs, for projects beginning after July 1, 1993.
6. Date: February 9, 1993
Time: 9 a.m. to 5 p.m.
Room: 315
Program: This meeting will review applications for Elementary and Secondary Education, submitted to the Division of Education Programs, for projects beginning after September 1, 1993.
7. Date: February 16, 1993
Time: 9 a.m. to 5 p.m.
Room: 315
Program: This meeting will review applications for projects in American History, Politics, Science, and Technology in Interpretive Research, submitted to the Division of Research Programs, for projects beginning after July 1, 1993.
8. Date: February 18, 1993
Time: 9 a.m. to 5 p.m.
Room: 315

Program: This meeting will review applications for projects in Philosophy, Literature, and Arts in Interpretive Research, submitted to the Division of Research Programs, for projects beginning after July 1, 1993.

9. Date: February 22, 1993
Time: 9 a.m. to 5 p.m.
Room: 315
Program: This meeting will review applications for projects in World History, Politics, Science, and Technology in Interpretive Research, submitted to the Division of Research, for projects beginning after July 1, 1993.

David C. Fisher,
Advisory Committee Management Officer.
[FR Doc. 93-992 Filed 1-14-93; 8:45 am]
BILLING CODE 7536-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 40-8905]

Quivira Mining Co.; Finding of No Significant Impact

In the matter of Issuance of an Amendment to Source Material License SUA-1473 for the Quivira Mining Co., Ambrosia Lake Mill, to Incorporate Reclamation Schedules, McKinley County, NM.

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of a Finding of No Significant Impact.

1. Proposed Action

The administrative action is issuance of a license amendment to incorporate an enforceable reclamation schedule for the Ambrosia Lake Mill in McKinley County, New Mexico.

2. Reasons for Finding of No Significant Impact

The proposed amendment is administrative, incorporating reclamation milestones into the license in accordance with the Memorandum of Understanding (MOU) between the Environmental Protection Agency (EPA) and the NRC which was published in the **Federal Register** on October 25, 1991. The Notice of Intent to amend Source Material License SUA-1473 for the Ambrosia Lake Mill to incorporate reclamation schedules was published in the **Federal Register** on October 29, 1992. The NRC accepted comments on this proposed licensing action for 45 days. No comments were received. In accordance with 10 CFR 51.22(c)(11), the Commission has determined that no environmental analysis need be performed since no significant impacts will result from the proposed licensing actions.

3. Action

The Commission action is to amend Source Material License SUA-1473 upon publication of this Notice. The action is based on this Finding of No Significant Impact and no comments being received to the Notice of Intent published on October 29, 1992.

This Notice, together with the Notice of Intent to Amend Source Material License SUA-1473, are available for public inspection and copying at the Commission's Uranium Recovery Field Office at 730 Simms Street, Golden, Colorado, and at the Commission's Public Document Room at 2120 L Street, NW., Washington, DC 20555.

Dated at Denver, Colorado, this 7th day of January 1993.

For the Nuclear Regulatory Commission.
Ramon E. Hall,
Director, Uranium Recovery Field Office.
[FR Doc. 93-1020 Filed 1-14-93; 8:45 am]
BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-31707; File No. 265-18]

Market Transactions Advisory Committee; Meeting

AGENCY: Securities and Exchange Commission.

ACTION: Notice of meeting of the Securities and Exchange Commission ("Commission") Market Transactions Advisory Committee.

SUMMARY: This is to give notice that the Securities and Exchange Commission Market Transactions Advisory Committee will meet on February 10, 1993, in room 1C30 at the Commission's main offices, 450 Fifth Street NW., Washington, DC, beginning at 10 a.m. The meeting will be open to the public.

FOR FURTHER INFORMATION CONTACT: Jack Drogin, Division of Market Regulation at (202) 504-2542, or Ari Burstein, Division of Market Regulation at (202) 504-2933; Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. app 10a, the Securities and Exchange Commission Market Transactions Advisory Committee ("Committee") hereby gives notice that it will meet on February 10, 1993, in room 1C30 at the Commission's main offices, 450 Fifth Street NW., Washington, DC, beginning at 10 a.m. The meeting will be open to the public.

The Committee was formed under section 17A(f) of the Securities Exchange Act of 1934. The Committee's responsibilities include assisting the Commission in identifying State and Federal laws that may impede the safe and efficient clearance and settlement of securities transactions and in advising the Commission on the use of the Commission's authority under the Market Reform Act of 1990 to adopt uniform federal rules regarding the transfer and pledge of securities.

The purpose of the meeting will be to discuss the progress of the Committee's subgroups and to plan the continued progression of the Committee's work. In addition, the Committee will discuss the status of the project to revise Article 8 of the Uniform Commercial Code undertaken by the National Conference of Commissioners on Uniform State Laws.

Dated: January 8, 1993.
Jonathan G. Katz,
Advisory Committee Management Officer.
[FR Doc. 93-987 Filed 1-14-93; 8:45 am]
BILLING CODE 8010-01-M

[Release No. 34-31710; File No. SR-Amex-91-31]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the American Stock Exchange, Inc., Relating to the Addition of Options Series at 2½ Point Strike Price Intervals for the Major Market Index Options

January 8, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on November 27, 1991, the American Stock Exchange, Inc. ("Amex" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Amex proposes to alter its strike price policy in order to introduce near-the-money options series on the Major Market Index ("XMI" or "Index") at 2½-point strike (exercise) price intervals.[1]

[1] On December 8, 1992, the Amex amended its filing to include a memorandum from Charles H.

The text of the proposal is available at the Office of the Secretary, Amex and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In 1983, when the Exchange began trading index options, options series were introduced in 5-point strike price intervals for index values up to 200 and 10-point increments for index values above 200. Subsequently, the Exchange obtained Commission approval to list index options with 5-point strike price intervals when the value of the relevant index is above 200.[2] The Amex continues to follow this policy for all of the Exchange's index options with expirations up to one year; for longer-term index options, the Exchange may have strike price intervals as wide as 25 or 50 points.

The Amex now proposes to amend its strike price policy to allow the Exchange to list near-the-money options on the XMI at 2½-point strike price intervals. The Amex has found that the current policy of 5-point strike intervals frequently results in in-the-money options that are often "too costly" and out-of-the money options that yield too little premium to attract uncovered or covered writers. The Amex believes that the proposal to narrow strike price intervals by increasing the number of available near-the-money strike prices will enable customers to more finely tailor their options positions to achieve their intended investment objectives. In addition, the Amex believes that providing customers with greater opportunities and flexibility will further enhance the depth and liquidity of the Amex's index options markets.

The Amex also believes, in connection with the recent reduction of the XMI to one-half its previous value,[3] that the addition of 2½-point strike intervals for near-the-money options would satisfy requests by investors to maintain the pre-split "Index-to-strike price ratio" (e.g., from a 640 Index value with 5-point strike price intervals to a 320 Index value with 2½-point strike price intervals).

The Amex believes that the proposed new strike price policy will not result in a proliferation of strike prices since the 2½-point intervals will only be added to surround the XMI's current Index value. In addition, the Amex represents that listing near-the-money XMI options series at 2½-point price intervals will not adversely impact the capacity of OPRA or market information vendors. In this regard, the Amex notes that the OPRA system was upgraded in early November 1992 to accommodate up to 300 messages per second ("MPS"). The Exchange believes that this capacity is more than sufficient to accommodate the requirements of all OPRA participants, including the proposed 2½ point strike prices for the XMI, since the recent peaks in message traffic for all OPRA participants combined have been in the range of 100–125 MPS. In addition, the Amex believes that the additional options series necessitated by the proposed 2½ point strike prices for the XMI will have no impact on the ability of vendors to receive and process data. Specifically, the Exchange notes that the additional XMI strikes, which will equal 25, at most, would result in a 0.05% increase in a vendor's OPRA database.[4]

The Amex believes that the proposal is consistent with the Act, in general, and with section 6(b)(5), in particular, because it is designed to promote just and equitable principles of trade and to protect the investing public. The Amex believes that the proposed rule change will increase the flexibility accorded market participants which will, in turn, enhance the depth and liquidity of the Exchange's index options markets.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Amex believes that the proposed rule change will not impose a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reason for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by February 5, 1993.

Faurot, Amex, to Howard Baker, Amex, dated December 2, 1992, which discusses the ability of the Options Price Reporting Authority ("OPRA") and market information vendors to accommodate the additional strike prices provided for under the proposal ("OPRA Capacity Statement"). See letter from Ellen Kander, Special Counsel, Derivative Securities, Amex, to Thomas Gira, Branch Chief, Options Regulation, Division of Market Regulation, Commission, dated December 8, 1992.

[2] See Securities Exchange Act Release No. 21644 (January 9, 1985), 50 FR 2360 (order approving File No. SR-Amex-84-31).

[3] See Securities Exchange Act Release No. 29798 (October 8, 1991), 56 FR 51976 (order approving File No. SR-Amex-91-18).

[4] See OPRA Capacity Statement, *supra* note 1.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93-1058 Filed 1-14-93; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Boston Stock Exchange, Incorporated

January 8, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder for unlisted trading privileges in the following securities:

Automated Security Holdings Plc
American Depositary receipt, No Par Value (File No. 7-9929)
Brilliance China Auto Holdings, Ltd
Common Stock, $.01 Par Value (File No. 7-9930)
CMAC Investment Corp.
Common Stock, $.001 Par Value (File No. 7-9931)
MC Shipping, Inc.
Common Stock, $.01 Par Value (File No. 7-9932)
Morgan Stanley Group
Depository Shares, No Par Value (File No. 7-9933)
National Re Corp.
Common Stock, No Par Value (File No. 7-9934)
NTN Communications, Inc.
Common Stock, $.005 Par Value (File No. 7-9935)
Pilgrim Prime Rate Trust
„Shares Beneficial Interest, No Par Value (File No. 7-9936)
Ply-Gem Industries, Inc.
Common Stock, $.25 Par Value (File No. 7-9937)
Viratek, Inc.
Common Stock, $.10 Par Value (File No. 7-9938)
Americredit Corp.
Common Stock, No Par Value (File No. 7-9939)
Ameron, Inc.
Common Stock, $2.50 Par Value (File No. 7-9940)
Betz Laboratories, Inc.
Common Stock, $.10 Par Value (File No. 7-9941)
First Colony Corp.
Common Stock, No Par Value (File No. 7-9942)
General Motors
Depository Shares "PERCS", No Par Value, (Rep 1/4 sh Pfd D) (File No. 7-9943)
Maybelline, Inc.
Common Stock, $.01 Par Value (File No. 7-9944)
Revco (D.S.), Inc.
Common Stock, $1.00 Par Value (File No. 7-9945)
Value Health, Inc.
Common Stock, No Par Value (File No. 7-9946)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 1, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93-984 Filed 1-14-93; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-31709; File No. SR-CBOE-92-37]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to the Strike Price Intervals for Index Options

January 8, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on November 24, 1992, the Chicago Board Options Exchange, Inc., ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The CBOE proposes to amend Interpretation .01 to Exchange Rule 24.9, "Terms of Index Option Contracts," to codify the strike price interval of $2.50 for reduced-value, long-term index options ("LEAPS") and Russell 2000 Index ("Russell 2000") options series with a strike price below 200.[1] In addition, the CBOE proposes to amend Interpretation .03 to Exchange Rule 24.9 to delete inappropriate references to the ticker symbols for various capped-style index option contracts ("CAPS"), including Standard & Poor's ("S&P") 100 Stock Index ("S&P 100") CAPS, S&P 500 Stock Index ("S&P 500") CAPS, and Russell 2000 CAPS, and to incorporate into Interpretation .03 various provisions applicable to Russell 2000 CAPS which were approved previously by the Commission.[2]

The text of the proposed rule change is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments its received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Proposed of, and Statutory Basis for, the Proposed Rule Change

The CBOE proposes to amend Interpretation .01 to Exchange Rule 24.9, "Terms of Index Option Contracts," to codify the strike price interval of $2.50 for reduced value LEAPS and Russell 2000 options series with a strike price below 200. In addition, the CBOE proposes to amend Interpretation .03 to Exchange Rule 24.9 to delete inappropriate references to the ticker symbols for various capped-style index option contracts, including S&P 100 CAPS, S&P 500 CAPS, and Russell 2000 CAPS, and to incorporate into

[1] In its order approving the listing and trading of Russell 2000 options on the CBOE, the Commission approved strike price intervals of 2 1/2 points for Russell 2000 LEAPS when the Russell 2000 is below a level of 200.00. See Securities Exchange Act Release No. 31382 (October 30, 1992), 57 FR 52803 (order approving File No. SR-CBOE-92-02) ("Russell Approval Order").

[2] See Russell Approval Order, *supra* note 1.

Interpretation .03 various provisions applicable to Russell 2000 CAPS and S&P 100 and S&P 500 CAPS which were approved previously by the Commission.[3]

Specifically, the amendments to Interpretation .03 provide that: (i) The cap interval for S&P 100 and S&P 500 CAPS shall be $30.00 and the cap interval for Russell 2000 CAPS shall be $20.00; (ii) initially, the Exchange may list one at-the-money call and put with an expiration of up to four months into the future for S&P 100 CAPS and up to one year in the future for S&P 500 and Russell 2000 CAPS, and the Exchange may list additional at-the-money series every two months with expirations up to four months into the future for S&P 100 CAPS or up to one year in the future for S&P 500 and Russell 2000 CAPS; and (iii) the Exchange may add series to expiration months with three or more months remaining to expiration following a 20-point or greater move in the index value for the S&P 100 and the S&P 500, and a 10-point or greater move in the index value for the Russell 2000.

The CBOE notes that the Commission has already approved two tiers of strike prices for options on the Russell 2000. Specifically, the strike price interval is $2.50 if the strike price is $200.00 or less; in all other cases, the strike price interval is $5.00.[4] The CBOE proposes to amend Interpretation .01 to Exchange Rule 24.9 to formally incorporate this requirement into the Exchange's rules. In addition, the CBOE proposes to clarify Exchange Rule 24.9, Interpretation .01, by specifying that the reduced value index options referred to therein are reduced-value LEAPS, as provided in Exchange Rule 24.9, Interpretation .02.

Finally, the CBOE proposes to amend Exchange Rule 24.9, Interpretation .03, to delete inappropriate references to the ticker symbols for various index option contracts. Those symbols are descriptive of particular index options, but do not describe CAPS, for which separate ticker symbols exist. The CBOE notes that no substantive change is made by the amendments.

The CBOE believes that the proposal is consistent with section 6(b) of the Act, in general, and furthers the objectives of section 6(b)(5), in particular, in that it is designed to clarify the application of the rules of the Exchange, thereby promoting just and equitable principles of trade and protecting investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change constitutes a stated policy, practice or interpretation with respect to the administration of an existing CBOE rule. Accordingly, the proposal has become effective pursuant to section 19(b)(3)(A) of the Act and subparagraph (e) of Rule 19b–4 thereunder. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by February 8, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[5]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–1057 Filed 1–14–93; 8:45 am]

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[3] See Russell Approval Order, supra note 1, and Securities Exchange Act Release No. 29965 (October 28, 1991), 56 FR 56255 (order approving File No. SR–CBOE–91–24).

[4] See *id.*

[5] 17 CFR 200.30–3(a)(12) (1991).

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Cincinnati Stock Exchange, Incorporated

January 11, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Ohio Edison Co.
7.36% Pfd., $100.00 Par Value (File No. 7–9947)
Ohio Edison Co.
8.20% Pfd., $100.00 Par Value (File No. 7–9948)
Ohio Edison Co.
8.64% Pfd., No Par Value (File No. 7–9949)
Ohio Edison Co.
9.12% Pfd., $100.00 Par Value (File No. 7–9950)
Ohio Power Co.
8.40% Cum. Pfd., $100.00 Par Value (File No. 7–9951)
Ohio Power Co.
7.60% Cum. Pfd. B, $100.00 Par Value (File No. 7–9952)
Ohio Power Co.
7.76% Cum. Pfd., $100.00 Par Value (File No. 7–9953)
Ohio Power Co.
8.48% Cum. Pfd., $100.00 Par Value (File No. 7–9954)
Ohio Power Co.
$2.27% Cum. Pfd., $25.00 Par Value (File No. 7–9955)
Ohio Power Co.
7.60% Cum. Pfd. C, $100.00 Par Value (File No. 7–9956)
Oklahoma Gas & Electric Co.
4% Cum. Pfd., $20.00 Par Value (File No. 7–9957)
Oppenheimer Capital, L.P.
Common Stock, No Par Value (File No. 7–9958)
Orion Capital Corp.
2.125% Conv. Exch. Pfd., $100.00 Par Value (File No. 7–9959)
Orion Capital Corp.
Adj. Rte. Pfd., $1.00 Par Value (File No. 7–9960)
Orin Capital Corp.
$1.90 Conv. Exch., $1.00 Par Value (File No. 7–9961)
Pennsylvania Power & Light Co.
4.40% Cum. Pfd. A, No Par Value (File No. 7–9962)
Pennsylvania Power & Light Co.

4.50% Cum. Pfd. B, No Par Value (File No. 7–9963)
Pennsylvania Power & Light Co.
$8.60 Pfd. Ser. G, $100.00 Par Value (File No. 7–9964)
Pennsylvania Power & Light Co.
$8.40 Cum. Pfd. Ser. H, No Par Value (File No. 7–9965)
Pennsylvania Power & Light Co.
$8.00 Pfd. Ser. J, No Par Value (File No. 7–9966)
Petroleum & Resources Corp.
$1.575 Conv. Pfd., No Par Value (File No. 7–9967)
Philadelphia Electric Co.
7% Pfd. E, $100.00 Par Value (File No. 7–9968)
Philadelphia Electric Co.
3.80% Pfd. Cum. A, $100.00 Par Value (File No. 7–9969)
Philadelphia Electric Co.
4.40% Pfd. Cum. C, $100.00 Par Value (File No. 7–9970)
Philadelphia Electric Co.
4.30% Pfd. Cum B, $100.00 Par Value (File No. 7–9971)
Philadelphia Electric Co.
4.68% Pfd. D, $100.00 Par Value (File No. 7–9972)
Philadelphia Electric Co.
7.75% Pfd. Cum. I, $100.00 Par Value (File No. 7–9973)
Philadelphia Electric Co.
7.80% Pfd. Cum. J, $100.00 Par Value (File No. 7–9974)
Philadelphia Electric Co.
7.85% Pfd. H., $100.00 Par Value (File No. 7–9975)
Philadelphia Electric Co.
8.75% Pfd. G, $100.00 Par Value (File No. 7–9976)
Philadelphia Electric Co.
9.50% Pfd. Cum. K, $100.00 Par Value (File No. 7–9977)
Philadelphia Electric Co.
9.52% Pfd. Cum. L, $100.00 Par Value (File No. 7–9978)
Philadelphia Electric Co.
9.50% Pfd. 1986 Ser. K, $100.00 Par Value (File No. 7–9979)
Pioneer Financial Services, Inc.
Common Stock, $1.00 Par Value (File No. 7–9980)
Pioneer Financial Services, Inc.
$2.125 Cum. Conv. Exch. Pfd., No Par Value (File No. 7–9981)
PNC Financial Corp.
$1.60 Cum. Conv. Pfd. Ser. C, $1.00 Par Value (File No. 7–9982)
PNC Financial Corp.
$1.80 Cum. Conv. Pfd. Ser. D, $1.00 Par Value (File No. 7–9983)
PNC Financial Corp.
$2.60 Non-Vot. Pfd. Ser. E, $1.00 Par Value (File No. 7–9984)
Polygram N.V.
Common Stock, NGL 0–50 Par Value (File No. 7–9985)
Potomac Electric Co.
$2.44 Conv. Ser. of 1966 Ser. Pfd., $50.00 Par Value (File No. 7–9986)
Potomac Electric Co.
$3.37 Conv. Ser. of 1987 Ser. Pfd., $50.00 Par Value (File No. 7–9987)
Pride Companies L.P.
Conv. Pfd. Units, No Par Value (File No. 7–9988)
Proler International Corp.
Common Stock, $1.00 Par Value (File No. 7–9989)
Promus Companies, Inc.
Common Stock, $1.50 Par Value (File No. 7–9990)
Prudential Realty Trust
Income Shares, $.01 Par Value (File No. 7–9991)
PSI Energy Inc.
4.16% Cum. Pfd. B, $25.00 Par Value (File No. 7–9992)
PSI Energy Inc.
4.32% Cum. Pfd. C, $25.00 Par Value (File No. 7–9993)
PSI Energy Inc.
7.15% Cum. Pfd. D, $100.00 Par Value (File No. 7–9994)
PSI Energy Inc.
8.52% Cum. Pfd., $100.00 Par Value (File No. 7–9995)
PSI Energy Inc.
8.38% Cum. Pfd. G, $100.00 Par Value (File No. 7–9996)
PSI Energy Inc.
8.96% Cum. Pfd., $100.00 Par Value (File No. 7–9997)
Public Service Company of Colorado
7.15% Cum. Pfd., $100.00 Par Value (File No. 7–9998)
Public Service Electric & Gas Co.
4.08% Cum. Pfd. A, $100.00 Par Value (File No. 7–9999)
Public Service Electric & Gas Co.
4.30% Cum. Pfd. C, $100.00 Par Value (File No. 7–1000)
Public Service Electric & Gas Co.
4.18% Cum. Pfd., $100.00 Par Value (File No. 7–1001)
Public Service Electric & Gas Co.
5.05% Cum. Pfd. D, $100.00 Par Value (File No. 7–1002)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 3, 1993, written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–1013 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Midwest Stock Exchange, Inc.

January 8, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following securities:

CompUSA, Inc.
Common Stock, No Par Value (File No. 7–9902)
Blackrock 1999 Term Trust, Inc.
Common Stock, $.01 Par Value (File No. 7–9903)
Capital American Financial Corporation
Common Stock, N Par Value (File No. 7–9904)
Hayes Wheels Int'l, Inc.
Common Stock, $.01 Par Value (File No. 7–9905)
Nuveen Insured New York Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9906)
Nuveen Insured Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9907)
Nuveen Michigan Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9908)
Nuveen New Jersey Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9909)
Nuveen Pennsylvania Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9910)
Brandon Systems Corporation
Common Stock, $.10 Par Value (File No. 7–9911)
Carmike Cinemas, Inc.
Class A Common Stock, $.03 Par Value (File No. 7–9912)
Hadson Energy Resources Corp.
Common Stock, $.10 Par Value (File No. 7–9913)
Income Opportunities Fund 2000, Inc.
Common Stock, $.10 Par Value (File No. 7–9914)
MuniYield New York Insured Fund, III, Inc.
Common Stock, $.10 Par Value (File No. 7–9915)
Student Loan Corp.
Common Stock, $.01 Par Value (File No. 7–9916)
2002 Target Term Trust, Inc.

Common Stock, $.001 Par Value (File No. 7–9917)
Acceptance Insurance Companies, Inc.
Common Stock, $.40 Par Value (File No. 7–9918)
General Motors Corporation
Series G 9.12% Depositary Shares (each representing ¼ shares of Series G 9.12% Preferred Stock), No Par Value (File No. 7–9919)
McDonalds's Corporation
Depositary Shares (each representing 1/2,000 share of 7.72% Cumulative Preferred Stock, Series E) (File No. 7–9920)
Thermo Voltek Corp.
Common Stock, $.05 Par Value (File No. 7–9921)
Worldtex, Inc.
Common Stock, $.01 Par Value (File No. 7–9922)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 1, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such application is consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–986 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–31705; File No. SR–NASD–92–42]

Self-Regulatory Organizations; National Association of Securities Dealers, Inc.; Order Approving Proposed Rule Change Relating to Offerings of Securities by an Issuer That Majority-Owns a Member

January 8, 1993.

On October 28, 1992, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("SEC" or "Commission") a proposed rule change pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder.[2] The proposal amends Section 13 of Schedule E to the NASD By-Laws ("Section 13")[3] to provide an exemption from the NASD's Free-Riding and Withholding Interpretation ("Free-Riding Interpretation")[4] for securities of an issuer that majority-owns, but does not wholly own, the member.

Notice of the proposed rule change, together with its terms of substance, was provided by the issuance of a Commission release (Securities Exchange Act Release No. 31521, November 25, 1992) and by publication in the **Federal Register** (57 FR 57521, December 4, 1992). No comments were received on the proposal. This order approves the proposed rule change.

The rule change approved herein amends Schedule E to the NASD's By-Laws to provide that a member may sell securities to its employees and other associated persons when the securities are issued by an entity that owns at least 51% of the outstanding voting stock of the member. Currently, the NASD's Free-Riding Interpretation prohibits employees and other associated persons of NASD member firms partially owned by large holding companies from purchasing shares of their respective holding company in a public offering. The NASD believes that it is appropriate and within the origin intent of Section 13 to permit such persons to purchase the securities offered by their respective holding companies.

The Interpretation of the Board of Governors—"Free-Riding and Withholding" under Article III, Section 1 of the NASD Rules of Fair Practice ("Free-Riding Interpretation") requires NASD members to make a bona fide public distribution at the public offering price of securities of a public offering that trade at a premium in the secondary market, whenever such secondary market begins. The Free-Riding Interpretation is based on the NASD's belief that failure to make a bona fide public distribution when there is demand for an issue can be a factor in artificially raising the price at which the security trades in the secondary market. In particular, failure to make a bona fide distribution when the member may have information relating to the demand for the securities or other factors not generally known to the public is inconsistent with high standards of commercial honor and just and equitable principles of trade and leads to an impairment of public confidence in the fairness of the investment banking and securities business.[5]

Section 13 provides an exemption from the Free-Riding Interpretation to permit an NASD member to sell certain securities in a public offering that trade at a premium in the secondary market to the member's employees; to potential employees of the member resulting from a merger, acquisition, or other business combination of members that results in one public successor corporation; to persons associated with the member; and to the immediate family of such employees or associated persons. This exemption is applicable only to securities that are offered in a public offering by (1) the member; (2) a parent of a member; (3) an entity that wholly owns a member;[6] or (4) an issuer treated as a member or parent of a member pursuant to Section 9 of Schedule E.[7] The Free-Riding Interpretation exemption provided by Section 13 is based on the NASD's belief that employees of members may naturally wish to have an ownership interest in their member-employer or its parent that is a public company, and that investment by employees in their employers is beneficial to the employee-employer relationship.

On June 2, 1992, the NASD filed with the Commission a proposed rule change (SEC File No. SR–NASD–92–22) that expanded the availability of the Free-Riding exemption provided by Section 13 to situations where the issuing company is an entity that wholly owns a member.[8] The NASD had determined that it would be appropriate and within the intent of Section 13 and the Free Riding Interpretation to allow employees and other Section 13 persons associated or related to NASD members to purchase securities of entities that wholly own the member but do not meet the definition of "parent" under Schedule E. Section 2(h) of Schedule E defines the term "parent" as any entity affiliated with a member from which member the entity derives 50% or more of its gross revenues or in which it

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[1] 15 U.S.C. 78s(b)(1) (1988).

[2] 17 CFR 240.19b–4 (1992).

[3] NASD Securities Dealers Manual, Schedule E to the By-Laws, Section 13, CCH ¶ 1803.

[4] *Id.* at Article III, Section 1 of the Rules of Fair Practice, CCH ¶ 2151.06.

[5] See NASD Securities Dealers Manual, Article III, Section 1 of the Rules of Fair Practice, CCH ¶ 2151.06.

[6] This provision was recently approved in Securities Exchange Act Release No. 31279 (October 1, 1992), 57 FR 46417 (October 8, 1992).

[7] Section 9 of Schedule E provides that certain offerings that result in the issuer's affiliation with or the public ownership of the NASD member shall be subject to the provisions of Schedule E to the same extent as if the transaction had occurred prior to the filing of the offering.

[8] See Securities Exchange Act Release No. 31279, *supra* note 1.

employs 50% of more of its assets. Large, diversified holding companies often do not meet the definition of "parent" of a member due to the fact that the activities of the broker-dealer represent only a small portion of their overall business.

In the course of considering and preparing the rule change filed in SR–NASD–92–22, the NASD also considered whether to expand Section 13 to permit employees of a member to purchase the securities of an issuer that majority-owns, but does not wholly own, the member. The NASD believes that employees of members naturally desire to have an ownership interest in their employer-holding company and that investments by employees in their employer-holding company is beneficial to the employee-employer relationship.

The rule change would amend Section 13 to expand the exemption from the Free-Riding Interpretation to issuances of securities by an issuer that owns at least 51% of the outstanding voting stock of the member. There are two situations in which an issuer can meet the 51% threshold. First, the exemption would be available in connection with the purchase of securities of an issuer that alone directly owns at least 51% of the outstanding voting securities of the member. Second, the exemption would be available in connection with the purchase of securities of an issuer that, together with the ownership interest of a non-public and wholly owned subsidiary, in the aggregate owns at least 51% of the outstanding voting securities of the member. An issuer, however, may not rely on the exemption to aggregate its holdings with its holding company where the subsidiary-issuer's ownership interest does not meet the 51% threshold.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to the NASD and, in particular, the requirements of section 15A(b)(6) of the Act.[9] Section 15A(b)(6) requires that the NASD's rules be designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing and settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission believes that it is appropriate to allow employees and other Section 13 associated persons of NASD members that are majority-owned by large holding companies to purchase the securities offered by such entities even though the holding company does not come within the Schedule E definition of "parent." It is the Commission's belief that enabling such persons to purchase shares of their respective holding company in a public offering is consistent with the policy of permitting employees of members to have an ownership interest in their member-employers. The Commission believes that investment by employees in their employers is beneficial to the employee-employer relationship, and thus, is in the interest of investors, and in the public interest. For this reason, and for the reasons stated above, the Commission believes that the proposed rule change satisfies the requirements of section 15A(b)(6) of the Act.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act, that the instant rule change be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–980 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

[9] 15 U.S.C. 78o–3 (1988)

[Release No. 34–31706; File No. SR–NYSE–92–33]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the New York Stock Exchange, Inc. Relating to an Interpretation to Rule 345 ("Employees—Registration, Approval Records")

January 8, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on November 4, 1992, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. On December 23, 1992, the NYSE submitted to the Commission Amendment No. 1 to the proposal.[1] The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of an interpretation with respect to the meaning and administration of existing Exchange Rule 345 ("Employees—Registration, Approval, Records"). Rule 345 *EMPLOYEES—REGISTRATION, APPROVAL, RECORDS, /04 Compensation to Nonregistered Foreign Persons Acting as Finders.*

Members and member organizations may pay to nonregistered foreign persons transaction-related compensation based upon the business of customers they direct to members or member organizations if the following conditions are met:

(a) The member or member organization has assumed itself that the nonregistered foreign person who will receive the compensation (the "finder") is not required to register in the U.S. as a broker-dealer and has further assured itself that the compensation arrangement does not violate applicable law;

(b) The finders are foreign nationals (not U.S. citizens) domiciled abroad;

(c) The customers are foreign nationals (not U.S. citizens) or foreign entities domiciled abroad transacting business in either foreign or U.S. securities;

(d) Customers receive a descriptive document, similar to that required by Rule 206(4)–3(b) of the Investment Advisers Act of 1940, that discloses what compensation is being paid to finders;[2]

(e) Customers provide written acknowledgement to the member or member organization of the existence of the compensation arrangement;

(f) Records reflecting payments to finders are maintained on the member's or member organization's books and actual agreements between the member or member organization and persons compensated are available for inspection by the Exchange; and

(g) The confirmation of each transaction indicates that a referral or finders fee is being paid pursuant to an agreement.

[10] 17 CFR 200.30–3(a)(12)(1992).

[1] See letter from Donald van Weezel, Managing Director, Regulatory Affairs, NYSE, to Diane Luka-Hopson, Branch Chief, Exchange Regulation, Commission, dated December 23, 1992. See *infra* note 2.

[2] Amendment No. 1 to the proposed rule change changed the citation to the descriptive document in Rule 345 /04 from that required by IAA Brochure Rule 204–3(a) of the Investment Advisers Act of 1940 to that required by Rule 206(4)–3(b) of the Investment Advisers Act of 1940.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B) and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to state an interpretation concerning the meaning and administration of Exchange Rule 345 with respect to the payment of transaction-related compensation to nonregistered foreign persons (or "finders") who refer customer business to members or member organizations.

Currently, the NYSE "Interpretation Handbook" contains an interpretation under Rule 345 which limits compensation to nonregistered persons for business they direct to members and member organizations other than on an isolated basis and only to persons not routinely engaged in making such referrals. A member or member organization is prohibited from paying to nonregistered persons compensation based upon the business of customers they direct to members or member organizations if the compensation is formulated as a direct percentage of the commissions or income generated.

The existing interpretation is intended to ensure that persons who regularly solicit customer business for a member or member organization and who are paid transaction-related compensation are associated with or registered as a broker-dealer and are qualified and approved to perform the function of a registered representative.

The proposed interpretation under Rule 345 is limited in application only to compensation arrangements that involve foreign (*i.e.*, non-U.S. citizens) finders who are domiciled abroad and customers who are not U.S. citizens or U.S. institutions who are also domiciled abroad. Additionally, as one of the conditions under the proposed interpretation, customers must receive a descriptive document, describing the compensation arrangement and provide a written acknowledgement of the arrangement. If all the specified conditions of the proposed interpretation are met, members and member organizations may pay transaction-related compensation to non-registered foreign finders based on the business of non-U.S. customers that the finders refer to the member or member organization.

While the foreign finders' sole involvement would be the initial referral to a member or member organization, compensation could be made on an ongoing basis and tied to such variables as the level of business generated or assets under control. All accounts referred by such foreign finders would be carried on the books of the member organization.

The proposed interpretation will allow members and member organizations the opportunity to enhance their competitive position in foreign countries where new accounts are routinely opened on a referral basis with ongoing compensation arrangements.

2. Statutory Basis

The proposed rule change is consistent with section 6(b)(5) of the Act which requires that the rules of the Exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposal does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal office of the NYSE. All submissions should refer to File No. SR–NYSE–92–33 and should be submitted by February 5, 1993.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–1058 Filed 1–14–93; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Pacific Stock Exchange, Inc.

January 8, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Betz Laboratories, Inc.
Common Stock, $.10 Par Value (File No. 7–9923)
Citizens Utilities Co.
Class A Common Stock, $.25 Par Value (File No. 7–9924)
Citizens Utilities Co.
Class B Common Stock, $.25 Par Value (File No. 7–9925)
CompUSA, Inc.

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Common Stock, No Par Value (File No. 7–9926)
Margaretten Financial Corp.
Common Stock, $.01 Par Value (File No. 7–9927)
Old Republic International Corp.
Common Stock, $1.00 Par Value (File No. 7–9928)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 1, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Security of the Securities and Exchange Commission, 450 5th Street NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–985 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–25731]

Filings Under the Public Utility Holding Company Act of 1935 ("Act"); GPU Nuclear Corp.

January 8, 1993

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by February 1, 1993 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

GPU Nuclear Corporation

[70–8115]

GPU Nuclear Corporation ("GPUNC"), One Upper Pond Road, Parsippany, New Jersey 07054, a wholly-owned subsidiary company of General Public Utilities Corporation, a registered holding company, has filed an application under sections 9(a) and 10 of the Act.

GPUNC has submitted a proposal, together with S. Cohen & Associates ("SC&A"), a nonassociate consulting company, to provide consultation and technical support services ("Services") to the Defense Nuclear Facilities Safety Board ("Board") through January 31, 1996 on a cost plus fixed fee basis plus profits. Under the proposal, SC&A would be the prime contractor to the Board and GPUNC would serve as SC&A's subcontractor. The Services will be in the areas of nuclear chemistry and radioactive waste processing, electrical power systems, instrumentation and control, radiological confinement systems, remote handling equipment operation and design, materials and metallurgy.

GPUNC states that the provision of the Services will not interfere with its primary operation and maintenance of nuclear generating facilities on behalf of its associate companies, and that, by providing the Services, GPUNC will enhance its own ability to provide these types of services for its associate companies through the retention of professional and technological resources and capabilities. GPUNC also states that the Services will require approximately 12,500 man-hours of labor and supervision over the life of the project.

GPUNC anticipates that the total revenues to be derived from the provision of the Services will not exceed 0.25% of its total annual expenditures for the operation, maintenance and construction of the GPU system nuclear plants. In 1991, such expenditures were approximately $454 million. In addition, aggregate profits to be derived are expected not to exceed 0.025% of the total operating revenues of GPUNC on an annual basis. Any such profits would be accounted for in such a manner so as to directly benefit the ratepayers of its associate companies by offsetting the costs of services charged to its associate companies.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–1055 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Philadelphia Stock Exchange, Incorporated

January 8, 1993.

The above named national securities exchange has filed applications with the Securities and Exchange Commission ("Commission") pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f–1 thereunder for unlisted trading privileges in the following securities:

Brandon Systems Corporation
Common Stock, $.01 Par Value (File No. 7–9884)
Nuveen Michigan Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9885)
Nuveen New Jersey Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9886)
Nuveen Pennsylvania Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9887)
Nuveen Insured New York Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9888)
Nuveen Insured Premium Income Municipal Fund, Inc.
Common Stock, $.01 Par Value (File No. 7–9889)
Blackrock 1999 Term Trust, Inc.
Common Stock, $.01 Par Value (File No. 7–9890)
CompUSA, Inc.
Common Stock, No Par Value (File No. 7–9891)
Capitol American Financial Corporation
Common Stock, No Par Value (File No. 7–9892)
Hadson Corporation
Jr. Cum. Conv. Pfd. Stock, $.01 Par Value, When Issued (File No. 7–9893)
McDonalds Corporation
Depositary Shares 7.72 Cum. Pfd Stock (File No. 7–9894)
Liberte Investors
Shares of Beneficial Interest, No Par Value (File No. 7–9895)
Income Opportunities Fund 2000 Trust

Common Stock, $.01 Par Value (File No. 7–9896)
Carmike Cinemas, Inc.
Class A Common Stock, $.03 Par Value (File No. 7–9897)
Hadson Energy Resources Corporation
Common Stock, $.10 Par Value (File No. 7–9898)
Acceptance Insurance Companies, Inc.
Common Stock, $.01 Par Value (File No. 7–9899)
Student Loan Corporation
Common Stock, $.01 Par Value (File No. 7–9900)
Hayes Wheels International, Inc.
Common Stock, $.01 Par Value (File No. 7–9901)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before February 1, 1993, written data, views and arguments concerning the above-referenced application. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, 450 5th Street NW., Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the application if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 93–983 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Release No. 19209; 811–6473]

Dreyfus U.S. Government Income Fund; Notice of Application

January 8, 1993.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1940 (the "Act").

APPLICANT: Dreyfus U.S. Government Income Fund.

RELEVANT ACT SECTION: Order requested under section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on December 8, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 3, 1993, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicant, 144 Glenn Curtiss Boulevard, Uniondale, New York 11556–0144.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus, Paralegal Specialist, at (202) 272–3023, or Barry D. Miller, Senior Special Counsel, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is an open-end, diversified management investment company organized as a trust under the laws of the Commonwealth of Massachusetts. On November 14, 1991, Applicant filed a Notification of Registration on Form N–8A pursuant to section 8(a) of the Act and a registration statement on Form N–1A under section 8(b) of the Act and under the Securities Act of 1993. Applicant's registration statement was declared effective on February 4, 1992, and an initial public offering of its shares of beneficial interest commenced on March 6, 1992. However, the Applicant's sponsor and investment adviser, The Dreyfus Corporation ("Dreyfus"), has been the sole shareholder of the Applicant.

2. The Applicant's Board of Trustees determined that, because the Applicant has had only one shareholder since its inception, the Applicant should be dissolved and that the proceeds from liquidation be returned to Dreyfus as of the close of business on November 25, 1992. Accordingly, the Board of Trustees instructed Applicant to pay any of its obligations or debts, liquidate and distribute its assets, and terminate its existence in a manner which would not adversely affect its shareholder.

3. On November 24, 1992, 8,802.8 shares of beneficial interest, par value $.0001 per share, were outstanding at a net asset value of $12.52 per share. At such date, aggregate net assets of the Applicant were $110,247. All outstanding shares of the Applicant were liquidated on November 25, 1992, at the then-current net asset value per share of $12.52.

4. In connection with its liquidation, Applicant incurred expenses of approximately $2,500 consisting primarily of outside legal expenses, all of which were paid by Dreyfus. Unamortized organizational costs and initial offering expenses of the Applicant, amounting to approximately $52,000 were reimbursed to the Applicant by Dreyfus.

5. As of the date of this application, Applicant has not debts or liabilities and is not a party to any litigation or administrative proceeding. Applicant is neither engaged in, nor proposes to engage in, any business activities other than those necessary for the winding-up of its affairs.

6. Applicant is current with respect to all filings required under the Act, including all N–SAR filings.

7. Applicant intends to file all documents required to terminate its existence as a Massachusetts business trust.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–988 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

[Investment Company Act Rel. No. 19208; 811–6528]

The Jackson Fund, Inc.; Application

January 8, 1993.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of Application for Deregistration under the Investment Company Act of 1040 ("Act").

APPLICANT: The Jackson fund, Inc.

RELEVANT ACT SECTION: Order requested under section 8(f).

SUMMARY OF APPLICATION: Applicant seeks an order declaring that it has ceased to be an investment company.

FILING DATE: The application was filed on December 21, 1992.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing.

Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on February 3, 1993, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request such notification by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 Fifth Street NW., Washington, DC 20549. Applicant, 31 West 52nd Street, New York, New York 10019.

FOR FURTHER INFORMATION CONTACT: Diane L. Titus, Paralegal Specialist, at (202) 272–3023 or Barry D. Miller, Senior Special Counsel, at (202) 272–3018 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee from the SEC's Public Reference Branch.

Applicant's Representations

1. Applicant is a closed-end non-diversified management investment company that is organized as a corporation under the laws of Maryland. On January 14, 1992, applicant registered under the Act and filed a registration statement pursuant to section 8(b) of the Act. Applicant also filed a registration statement under the Securities Act of 1933 (the "Securities Act") to register 11,500 shares of applicant's common stock.

2. Applicant's registration statement under the Securities Act was not declared effective, and applicant made no initial public offering.

3. Applicant has no assists or liabilities and has never had any security holders. Applicant is not a party to any litigation or administrative proceeding. Applicant is not now engaged in, nor does it intend to engage in, any business activities other than those necessary for the winding up of its affairs.

For the SEC, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–969 Filed 1–14–93; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 35–25729]

Filings Under the Public Utility Holding Company Act of 1935 ("Act"); National Fuel Gas Co.

January 8, 1993.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by February 1, 1993 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

National Fuel Gas Company [70–8111]

Notice of Proposal To Amend Stock Incentive Plans; Order Authorizing Solicitation of Proxies

National Fuel Gas Company ("NFG"), 30 Rockefeller Plaza, New York, New York 10112, a registered holding company, has filed a declaration under sections 6(a), 7, 12(e) of the Act and Rules 50(a)(5), 62, and 65 thereunder.

NFG proposes to amend the National Fuel Gas Company 1983 Incentive Stock Option Plan ("1983 Plan") and the National Fuel Gas Company 1984 Stock Plan ("1984 Plan") (collectively, "Stock Plans") which the Commission approved on January 10, 1984 (HCAR No. 23197) and on January 16, 1985 (HCAR No. 23575), respectively. Three of the amendments are substantially similar for both Stock Plans, one amendment would affect only the 1983 Plan.

First, the Stock Plans would be amended to require shareholder approval of stock plan amendments when such amendments would materially increase the benefits available to participants, materially increase the number of shares available for issuance, or materially modify the eligibility requirements for participation. The Stock Plans presently require stockholder approval of amendments which would: (1) Increase the maximum number of common stock or restricted stock issuable or decrease the minimum purchase price of shares of common stock subject to an option; (2) extend an option's exercise term; (3) extend the Stock Plan's term; (4) change the class of employees eligible to receive options or restricted stock; (5) provide for Stock Plan administration by other than a "disinterested committee"; or (6) materially increase the cost of the Stock Plans to NFG.

Second, the Stock Plans would be amended to add entirely new change in control and change in ownership provisions. In the event of a change in control (as defined in the Stock Plans), a participant whose employment is terminated within two years of the date of such event, for a reason other than death, disability or cause (as defined in the Stock Plans), voluntary resignation for other than good reason (as defined in the Stock Plans), or retirement, would be entitled to the following treatment under the Stock Plans: (1) All of the terms and conditions in effect on any of the participant's outstanding awards would immediately lapse; (2) all of the participant's outstanding awards would automatically become one hundred percent vested; and (3) all of the participant's outstanding stock options, stock appreciation rights, and other stock-based awards would be immediately cashed out on the basis of the change in control price (as defined in the Stock Plans). Such payments would be made no later than the 90th day following such event.

Upon a change in ownership, all participants, regardless of whether their employment is terminated, would automatically receive the same treatment afforded to a terminated participant under the Stock Plans in the event of a change in control. The Stock Plans define a change in ownership as change which results in the NFG's common stock ceasing to be actively traded on the New York Stock Exchange, another national stock exchange, or the National Association of Securities Dealers Automated Quotation System.

Third, the Stock Plan's existing provisions regarding withholding taxes would be amended to allow the payment of applicable taxes by

withholding common stock otherwise issuable, or allowing a participant to remit shares of a common stock to NFG to pay applicable withholding taxes.

The final proposed amendment would effect only the 1983 Plan. It would allow the compensation committee (as defined in the 1983 Plan) within the three month period following the termination of an optionee's employment to extend the exercise period of his incentive stock options to a date not later than the date on which such options would have ceased to be exercisable absent such termination of employment. Prior to this amendment, all options issued pursuant to the 1983 Plan generally cease to be exercisable three months after termination of employment.

NFG intends to solicit proxies from its common shareholders to approve the proposed amendments to the Stock Plans at NFG's Annual Meeting of Stockholders on February 18, 1993. NFG has filed its proxy solicitation material and requests that the effectiveness of its declaration with respect to the solicitation of proxies for voting by its shareholders to approve the proposed amendments to the Stock Plans be permitted to become effective forthwith as provided in Rule 62(d).

It appearing to the Commission that NFG's declaration regarding the proposed solicitation of proxies should be permitted to become effective forthwith, pursuant to Rule 62:

It is ordered, That the declaration regarding the proposed solicitation of proxies, be, and it hereby is, permitted to become effective forthwith, under Rule 62, and subject to the terms and conditions as prescribed in Rule 24 under the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–981 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–25730]

Filings Under the Public Utility Holding Company Act of 1935 ("Act"); National Fuel Gas Co.

January 8, 1993.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by February 1, 1993 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

National Fuel Gas Company [70–8109]

Notice of Proposal to Implement Award and Option Plan; Order Authorizing Solicitation of Proxies

National Fuel Gas Company ("NFG"), 30 Rockefeller Plaza, New York, New York 10112, a registered holding company, has filed a declaration under sections 6(a), 7, 12(e) of the Act and Rules 50(a)(5), 62, and 65 thereunder.

NFG seeks Commission approval of its 1993 Award and Option Plan ("Plan"). The Plan will be administered by the Compensation Committee of the Board of Directors or another committee so designated ("Commission"). No member of the Committee is eligible to be selected to participate in the Plan. The Plan authorizes the Committee, at its discretion, to grant awards from February 18, 1993 through February 17, 2003 to key employees of NFG or any of its 80% or more owned subsidiaries. Under the Plan, 1.6 million shares of common stock of NFG are available for grant.

The NFG's Board of Directors may suspend or terminate or amend the Plan at any time but may not, without shareholder approval, adopt any amendment which would materially increase the benefits accruing to participants, materially increase the maximum number of shares which may be issued under the Plan, subject to equitable adjustment, or materially modify the Plan's eligibility requirements.

The following types of awards may be available under the Plan: (1) Stock options, including incentive stock options; (2) stock appreciation rights ("SARs"), the right to receive a payment equal to the appreciation in market value of a stated number of shares of common stock from the SARs' exercise price to the market value of the date of exercise; (3) common stock of NFG, including restricted stock; (4) common stock units; (5) performance shares; (6) performance units; and (7) any award established by the Committee which is consistent with the Plan's purpose, are as described in the Plan.

The Plan provides for the forfeiture of awards in the event of termination of employment of a reason other than death, disability, retirement, or any approved reason, unless the award provides otherwise. Forfeiture is also required if, in the Committee's opinion, the participant competes with NFG without its written consent, or if he acts in a manner inimical to NFG's best interests.

The Committee may unilaterally amend any award if, in the Committee's opinion, such amendment is not adverse to the participant. NFG may deduct from any payment under the Plan the amount of any applicable income and employment taxes, or may require the participant to pay such taxes as a condition to making such payment. The Committee may allow the participant to satisfy this obligation by withholding from any payment of common stock due, or by delivering to NFG, shares of common stock with a fair market value equal to the amount of applicable taxes.

NFG intends to solicit proxies from its common shareholders to approve the Plan at NFG's Annual Meeting of Stockholders on February 18, 1993. NFG has filed its proxy solicitation material and requests that the effectiveness of its declaration with respect to the solicitation of proxies for voting by its shareholders to approve the proposed Plan be permitted to become effective forthwith as provided in Rule 62(d).

It appearing to the Commission that NFG's declaration regarding the proposed solicitation of proxies should be permitted to become effective forthwith, pursuant to Rule 62:

It is ordered, That the declaration regarding the proposed solicitation of proxies, be, and it hereby is, permitted to become effective forthwith, under Rule 62, and subject to the terms and conditions as prescribed in Rule 24 under the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–982 Filed 1–14–93; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of reporting requirements submitted for review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Comments should be submitted on or before February 16, 1993. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (S.F. 83), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Cleo Verbillis, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416. Telephone: (202) 205–6629.

OMB Reviewer: Gary Waxman, Officer of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

Title: The Function of Failure Study.

SBA Form No.: N/A.

Frequency: One Time.

Description of Respondents: Small Business Owners.

Annual Responses: 100.

Burden: 33.

Dated: January 11, 1993.

Cleo Verbillis,

Chief, Administrative Information Branch.

[FR Doc. 93–1038 Filed 1–14–93; 8:45 am]

BILLING CODE 8025–01–M

Reporting and Recordkeeping Requirements Under OMB Review

ACTION: Notice of reporting requirements submitted for review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the Federal Register notifying the public that the agency has made such a submission.

DATES: Comments should be submitted on or before February 16, 1993. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

COPIES: Request for clearance (S.F. 83), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer. Submit comments to the Agency Clearance Officer and the OMB Reviewer.

FOR FURTHER INFORMATION CONTACT:

Agency Clearance Officer: Cleo Verbillis, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416. Telephone: (202) 205–6629.

OMB Reviewer: Gary Waxman, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503

Title: 1992 SBA Health Insurance Survey

SBA Form No.: N/A

Frequency: One-Time

Description of Respondents: Small and Large Business

Annual Responses: 989

Burden: 703

Dated: January 12, 1993.

Cleo Verbillis,

Chief, Administrative Information Branch.

[FR Doc. 93–1069 Filed 1–14–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF STATE

[Public Notice 1754]

United States Organization for the International Telegraph and Telephone Consultative Committee (CCITT) National Committee; Meetings

The Department of State announces that the U S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT) National Committee will meet on February 4 and February 23, 1993 at 9:30 a.m. in room 1107 at the Department of State, 2201 C Street, NW., Washington, DC 20520.

The agenda for the February 4 meeting will include a debrief of the CCITT Ad Hoc Group for Resolution No. 18 Meeting and its joint meeting with the CCIR Resolution No. 106 Group that will take place in Geneva, January 19–26, 1993 In addition, final preparations for the CCITT Xth Plenary Assembly (First World Telecommunications Standardization Conference) will take place during both of the open public meetings cited above.

Members of the general public may attend these meetings and join in the discussion, subject to the instructions of the Chair. Admittance of public members will be limited to the seating available. In that regard, entrance to the Department of State building is controlled and entry will be facilitated if arrangements are made in advance of the meetings. Persons who plan to attend should advise the office of Earl Barbely, Department of State, (202) 647–0201, FAX (202) 647–7407. The above includes government and non-government attendees. Public visitors will be asked to provide their date of birth and Social Security number at the time they register their intention to attend and must carry a valid photo ID with them to the meeting in order to be admitted. All attendees must use the C street entrance.

Please bring 50 copies of documents to be considered at these meetings. If the document has been mailed to the membership, bring only 10 copies.

Dated: January 11, 1993.

Earl Barbely,

Director, Telecommunications and Information Standards, Chairman, U.S. CCITT National Committee.

[FR Doc. 93–1021 Filed 1–14–93; 8:45 am]

BILLING CODE 4710–07–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Los Angeles International Airport; Los Angeles, CA; Notice of Intent to Rule

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Intent to Rule on Application to impose and impose and use the revenue from a Passenger Facility Charge (PFC) at Los Angeles International Airport, Los Angeles, California.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule

and invites public comment on the application to impose and impose and use the revenue from a PFC at Los Angeles International Airport, Los Angeles, California under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 16, 1993.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Federal Aviation Administration, Western-Pacific Region, Airports Division, AWP–600, P.O. Box 92007, WWPC, Los Angeles, CA 90009.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Clifton A. Moore, Executive Director of the Los Angeles Department of Airports at the following address: Los Angeles Department of Airports, One World Way, Los Angeles, CA 90045.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Los Angeles Department of Airports under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. John P. Milligan, Supervisor, Standards Section, AWP–621, Federal Aviation Administration, Airports Division, 15000 Aviation Blvd., Hawthorne, CA 90261, Tel (310) 297–1029. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and impose and use the revenue from a PFC at Los Angeles International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On December 29, 1992, the FAA determined that the application to impose and impose and use the revenue from a PFC at Los Angeles International Airport submitted by Los Angeles Department of Airports was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than March 30, 1993.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00

Proposed charge effective date: July 1, 1993

Proposed charge expiration date: June 30, 1998

Total estimated PFC revenue: $380.0 Million

Brief description of proposed projects: People mover system; Noise mitigation program.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs:

American Trans Air Execujet CFI, Inc.
CFI, Inc.
Chrysler Aviation
Corporation Flight, Inc.
Elliott Aviation
Geneva International
Key Air
KMR Aviation
Louisiana Pacific Corporation
Mayo Aviation, Inc.
Mcathco Enterprises, Inc.
Modesto Executive Air Charter
Morgan Equipment
Raleigh Jet Charter
Samaritan Health Services
Valko, Inc.
Windstar Aviation Corp.
Yecny Enterprises, Inc.

Any person may inspect the application in person at the FAA office listed above under "FOR FURTHER INFORMATION CONTACT" and at the FAA regional Airports office located at: Federal Building, 3rd Floor, room 3E23, 15000 Aviation Blvd., Hawthorne, CA 90261.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Los Angeles Department of Airports.

Ellsworth L. Chan,

Acting Manager, Airports Division, Western Pacific Region.

[FR Doc. 93–812 Filed 1–14–93; 8:45 am]

BILLING CODE 4910-13-M

Ontario International Airport, Ontario, CA; Notice of Intent to Rule

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of Intent to Rule on Application to impose and impose and use the revenue from a Passenger Facility Charge (PFC) at Ontario International Airport, Ontario, California.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment on the application to impose and impose and use the revenue from a PFC at Ontario International Airport, Ontario, California under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

DATES: Comments must be received on or before February 16, 1993.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Federal Aviation Administration, Western-Pacific Region, Airports Division, AWP–600, P.O. Box 92007, WWPC, Los Angeles, CA 90009.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Mr. Clifton A. Moore, Executive Director of the Los Angeles Department of Airports at the following address: Los Angeles Department of Airports, One World Way, Los Angeles, CA 90045.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Los Angeles Department of Airports under § 158.23 of part 158.

FOR FURTHER INFORMATION CONTACT: Mr. John P. Milligan, Supervisor, Standards Section, AWP–621, Federal Aviation Administration, Airports Division, 15000 Aviation Blvd., Hawthorne, CA 90261, Tel (310) 297–1029. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose and impose and use the revenue from a PFC at Ontario International Airport under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Pub. L. 101–508) and part 158 of the Federal Aviation Regulations (14 CFR part 158).

On December 29, 1992, the FAA determined that the application to impose and impose and use the revenue from a PFC submitted by Los Angeles Department of Airports was substantially complete within the requirements of § 158.25 of part 158. The FAA will approve or disapprove the application, in whole or in part, no later than March 30, 1993.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00

Proposed charge effective date: July 1, 1993

Proposed charge expiration date: June 30, 1998

Total estimated PFC revenue: $49.0 Million

Brief description of proposed projects:
Construct new airport terminal; Noise mitigation program.

Class or classes of air carriers which the public agency has requested not be required to collect PFCs:
Business Air Service South
Mayo Aviation, Inc.
Modesto Executive Air Charter
Raleigh Jet Charter
Valko, Inc.
Yecny Enterprises, Inc.

Any person may inspect the application in person at the FAA office listed above under "FOR FURTHER INFORMATION CONTACT" and at the FAA regional Airports office located at: Federal Building, 3rd Floor, room 3E23, 15000 Aviation Blvd., Hawthorne, CA 90261.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Los Angeles Department of Airports.

Ellsworth L. Chan,

Acting Manager, Airports Division, Western Pacific Region.

[FR Doc. 93-813 Filed 1-14-93; 8:45 am]

BILLING CODE 4910-13-M

Maritime Administration

[Docket No. S-806]

American President Lines, Ltd.; Application for a Waiver of Section 804(a) of the Merchant Marine Act, 1936, as Amended, To Permit Foreign-Flag Slot Charters

American President Lines, Ltd. (APL), by application dated January 6, 1993, requests waiver of the provisions of section 804 of the Merchant Marine Act, 1936, as amended (Act), for foreign-flag slot charters by APL on a vessel of Companie Maritime d'Affretement (CMA) pursuant to APL's participation in a reciprocal slot exchange and coordinated sailing agreement and in a Slot Charter Agreement, both between APL and CMA.

APL currently has section 804 waiver authority to operate two foreign-flag ships in a west coast India feeder service. APL proposes entering into the agreements cited above, to add one CMA vessel to this service, expanding the geographic coverage to the Fujayrah/Colombo range, with APL and CMA chartering space on each other's ships.

This application may be inspected in the Office of the Secretary, Maritime Administration. Any person, firm, or corporation having any interest in such request within the meaning of section 804 of the Act and desiring to submit comments concerning the application must file written comments in triplicate with the Secretary, Maritime Administration, room 7300, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. Comments must be received no later than 5 p.m. on January 25, 1993. This notice is published as a matter of discretion and publication should in no way be considered a favorable or unfavorable decision on the application, as filed or as may be amended. The Maritime Administrator will consider any comments submitted and take such action with respect thereto as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 20.804 (Operating-Differential Subsidies))

By Order of the Maritime Administrator

James E. Saari,

Secretary, Maritime Administration.

[FR Doc. 93-1066 Filed 1-14-93; 8:45 am]

BILLING CODE 4910-81-M

National Highway Traffic Safety Administration

[Docket No. 92-52; Notice 2]

Determination That Nonconforming 1989 Mercedes-Benz 500SL Passenger Cars Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice of determination by NHTSA that nonconforming 1989 Mercedes-Benz 500SL passager cars are eligible for importation.

SUMMARY: This notice announces the determination by NHTSA that 1989 Mercedes-Benz 500SL passenger cars not originally manufactured to comply with all applicable Federal motor vehicle safety standards are eligible for importation into the United States because they are substantially similar to a vehicle originally manufactured for importation into and sale in the United States and certified by its manufacturer as complying with the safety standards (the 1989 Mercedes-Benz 560SL), and they are capable of being readily modified to conform to the standards.

DATES: The determination is effective as of the date of its publication in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Ted Bayler, Office of Vehicle Safety Compliance, NHTSA (202-366-5306).

SUPPLEMENTARY INFORMATION:

Background

Under section 108(c)(3)(A)(i) of the National Traffic and Motor Vehicle Safety Act (the Act), 15 U.S.C. 1397(c)(3)(A)(i), a motor vehicle that was not originally manufactured to conform to all applicable Federal motor vehicle safety standards shall be refused admission into the United States on and after January 31, 1990, unless NHTSA has determined that

(I) the motor vehicle is * * * substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under section 114 (of the Act), and of the same model year * * * as the model of the motor vehicle to be compared, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards * * *.

Petitions for eligibility determinations may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA determines, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this determination in the **Federal Register.**

Champagne Imports Inc. of Lansdale, Pennsylvania (Registered Importer R-90-009) petitioned NHTSA to determine whether 1989 Mercedes-Benz 500SL passenger cars are eligible for importation into the United States. NHTSA published notice of the petition on October 7, 1992 (57 FR 46239) to afford an opportunity for public comment. The reader is referred to that notice for a thorough description of the petition. No comments were received in response to the notice. Based on its review of the information submitted by the petitioner, NHTSA has determined to grant the petition.

Vehicle Eligibility Number for Subject Vehicles

The importer of a vehicle admissible under any final determination must indicate on the form HS-7 accompanying entry the appropriate vehicle eligibility number indicating that the vehicle is eligible for entry. VSP #23 is the vehicle eligibility number assigned to vehicles admissible under this notice of final determination.

Final Determination

Accordingly, on the basis of the foregoing, NHTSA hereby determines that a 1989 Mercedes Benz 500SL (Model ID 129.066) is substantially similar to a 1989 Mercedes Benz 560SL (Model ID 107.048) originally

manufactured for importation into and sale in the United States and certified under section 114 of the National Traffic and Motor Vehicle Safety Act, and is capable of being readily modified to conform to all applicable Federal motor vehicle safety standards.

Authority: 15 U.S.C. 1397(c) (3) (A) (i) (I) and (C) (ii); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: January 11, 1993.

William A. Boehly,

Associate Administrator for Enforcement.

[FR Doc. 93–975 Filed 1–14–93; 8:45 am]

BILLING CODE 4910-59-M

Research and Special Programs Administration

Office of Hazardous Materials Safety; Applications for Exemptions

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of Applicants for Exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Transportation has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before February 16, 1993.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs, Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Dockets Unit, room 8426, Nassif Building, 400 7th Street SW., Washington, DC.

NEW EXEMPTIONS

Application number	Applicant	Regulation(s) affected	Nature of exemption thereof
10938–N	Westvaco Corporation, New York, NY.	49 CFR 174.67(i)	To authorize chlorine filled tank cars to remain attached during unloading without the physical presence of an unloader. (mode 2.)
10939–N	AeroTech/ISP, Las Vegas, NV	49 CFR 173, Subpart C	To authorize the shipment of model rocket motor systems (reload kits) containing certain propellant explosives and delay charge modules, classed as flammable solid, Division 4.1. (modes 1, 2, 4, 5.)
10941–N	Union Pacific Railroad Company, Omaha, NE.	49 CFR 174.83(b) (4)	To authorize a placarded flatcar to be moved in an automated, gravity actuated, freight classification yard (hump yard) over the hump and roll free into various classification tracks using a controlled reduction of momentum computer system. (mode 2.)
10942–N	Dowell Schlumberger, Inc., Houston, TX.	49 CFR 173.243(c)	To authorize the shipment of flammable liquid, corrosive n.o.s., Class 3, in DOT specification 57 portable tanks. (modes 1, 2, 3.)
10944–N	Pacific Scientific, HTL/Kin Tech Division, Duarte, CA.	49 CFR 173.304(a)(1), 175.3, 178.47.	To authorize the manufacture, mark and sale of non-DOT specification cylinders, constructed of titanium material conforming to DOT Specification 4DS for use in transporting compressed gas n.o.s., classed as nonflammable gas, Division 2.2 (modes 1, 2, 4, 5.)
10945–N	Structural Composites Industries, Pomona, CA.	49 CFR 173.302(a), 173.304(a) 175.3.	To authorize the manufacture, mark and sale of non-DOT specification fiber reinforced plastic full composite cylinders constructed of seamless 6061–T6 aluminum pressure vessel fully overwrapped with filament windings for use in transporting various material classed as flammable and non-flammable gases, Class 2. (modes 1, 2, 3, 4, 5.)
10946–N	Airco Gases of The BOC Group Inc., Murray Hill, NJ.	49 CFR 173.301(f), 173.302(a)(1) .	To authorize the transportation of compressed gas, flammable, n.o.s., Division 2.1, in DOT Specification 4l. cylinders with a service pressure of 212 psig or greater. (mode 1.)

This notice of receipt of applications for new exemptions is published in accordance with part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on January 12, 1993.

Joseph T. Herring,

Director, Office of Hazardous Materials, Exemptions and Approvals.

[FR Doc. 93–1067 Filed 1–14–93; 8:45 am]

BILLING CODE 4910-60-M

Office of Hazardous Materials Safety; Applications for Modification of Exemptions or Applications To Become a Party to an Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications for modification of exemptions or applications to become a party to an exemption.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier **Federal Register** publications, they are not repeated here. Requests for modifications of exemptions (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix "X" denote a modification request. Application numbers with the suffix "P" denote a

party to request. These applications have been separated from the new applications for exemptions to facilitate processing.

DATES: Comments must be received on or before February 1, 1993.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs, Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption number.

FOR FURTHER INFORMATION CONTACT: Copies of the applications are available for inspection in the Dockets Unit, room 8426, Nassif Building, 400 7th Street SW., Washington, DC.

Application No.	Applicant	Renewal of exemption
8006–X	Esquire Novelty Corporation, Amsterdam, NY (See Footnote 1).	8006
8990–X	Scott High Pressure Technology, Plumsteadville, PA (See Footnote 2).	8990
9775–X	Enviropack Company, Arlington, VA (See Footnote 3).	9775
9917–X	Enviropack Company, Arlington, VA (See Footnote 4).	9917
10866–X	Eco-Pak, Inc., Elizabethton, TN (See Footnote 5).	10866

(1) To renew and modify exemption to provide for rail, water and air as additional modes for transporting Class C explosives.

(2) To modify exemption to provide for flammable gas, Division 2.1, as an additional commodity for transportation in non-DOT specification cylinder.

(3) To modify exemption to provide for air and water (cargo vessel) as add modes for transporting various hazardous materials in polyethylene, removable head salvage drums.

(4) To modify exemption to provide for air as an additional mode for transporting various hazardous materials in non-DOT specification portable tanks.

(5) To reissue an exemption, originally issued on an emergency basis to authorize the manufacture, mark and sale of a UN 1A1W stainless steel drum for the shipment of certain Class 3, 8 and 9 materials and Division 4.1, 4.2, 4.3, 5.1, 5.2 and 6.1 materials.

Application No.	Applicant	Parties to exemption
4453–P	Pacific Powder Company, Olympia, WA.	4453
7052–P	Hughes Missile Systems Company, San Diego, CA.	7052
7616–P	Fox Valley & Western Ltd., Rosemont, IL.	7616
7616–P	MidSouth Corporation, Jackson, MS.	7616
8526–P	Decker Transport Co., Inc., Riverdale, NJ.	8526
8554–P	Mt. State Bit Service, Inc., Morgantown, WV.	8554
8723–P	Mt. State Bit Service, Inc., Morgantown, WV.	8723
8958–P	WASAG USA, Inc., Wilmington, DE.	8958
9015–P	Occidental Chemical Corp., Dallas, TX.	9015
9222–P	Wills Trucking, Inc., Richfield, OH (See Footnote 1).	9222
9275–P	Parfums International, Ltd., Roanoke, VA.	9275
9579–P	Pacific Powder Company, Olympia, WA.	9579
9723–P	Pollution Control Industries of Indiana, East Chicago, IN.	9723
9723–P	Bechem Transport, Inc., New Haven, CT.	9723
9750–P	Pacific Powder Company, Olympia, WA.	9750
9841–P	Stolt Tank Containers, Inc., Monrovia, Liberia.	9841
10101–P	Findley Welding Supply, Inc., Youngstown, OH.	10101

[1]To authorize party status and modify exemption to provide for solid or sludge material classed as corrosive material, Division 8 and provide for optional packaging consisting of a non-DOT specification metal container with fiberglass top and 9/10" side and bottom thickness.

This notice of receipt of applications for renewal of exemptions and party to an exemption is published in accordance with Part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on January 12, 1993.

Joseph T. Horning,

Director, Office of Hazardous Materials, Exemptions and Approvals.

[FR Doc. 93–1068 Filed 1–14–93; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF THE TREASURY

Office of the Secretary

7 Percent Treasury Bonds of 1993–98; Notice of Call for Redemption

Washington, January 15, 1993.

To Holders of 7 Percent Treasury Bonds of 1993–98, and Others Concerned:

1. Public notice is hereby given that all outstanding 7 percent Treasury Bonds of 1993–98 (CUSIP No. 912810 BP 2) dated May 15, 1973, due May 15, 1998, are hereby called for redemption at par on May 15, 1993, on which date interest on such bonds will cease.

2. Full information regarding the presentation and surrender of such bonds held in coupon and registered form for redemption under this call will be found in Department of the Treasury Circular No. 300, Revised, dated March 4, 1973. Coupon bonds must have all unmatured coupons attached to the security upon presentation for redemption at par. If any coupons for the interest payment dates of November 15, 1993, through May 15, 1998, are missing, the full face amount of the missing coupons will be deducted from the par value.

3. Such bonds held in book-entry form will be paid automatically on May 15, 1993, whether held on the books of the Federal Reserve Banks or in TREASURY DIRECT accounts.

Marcus W. Page,

Deputy Fiscal Assistant Secretary.

[FR Doc. 93–1206 Filed 1–13–93; 2:46 pm]

BILLING CODE 4810–40–M

Bureau of Alcohol, Tobacco and Firearms

[Notice No. 765]

Commerce in Explosives; List of Explosive Materials

Pursuant to the provisions of section 841(d) of title 18, United States Code, and 27 CFR 55.23, the Director, Bureau of Alcohol, Tobacco and Firearms, must publish and revise at least annually in the **Federal Register** a list of explosives determined to be within the coverage of 18 U.S.C. chapter 40, Importation, Manufacture, Distribution and Storage of Explosive Materials. This chapter covers not only explosives, but also blasting agents and detonators, all of which are defined as explosive materials in section 841(c) of title 18, United States Code. Accordingly, the following is the 1993 List of Explosive Materials subject to regulation under 18 U.S.C. chapter 40, which includes both the list of explosives (including detonators) required to be published in the **Federal Register** and blasting agents. The list is intended to also include any and all mixtures containing any of the materials in the list. Materials constituting blasting agents are marked by an asterisk. While the list is comprehensive, it is not all inclusive. The fact that an explosive material may not be on the list does not mean that it is not within the coverage of the law if it otherwise meets the statutory definitions in section 841 of title 18, Untied States Code. Explosive materials are listed alphabetically by their common names followed by chemical names and synonyms in brackets. This revised list supersedes the List of Explosive Materials dated January 9,

1992, (57 FR 950) and will be effective as of the date of publication in the Federal Register.

List of Explosive Materials

A

Acetylides of heavy metals.
Aluminum containing polymeric propellant.
Aluminum ophorite explosive.
Amatex.
Amatol.
Ammonal.
Ammonium nitrate explosive mixtures (cap sensitive).
*Ammonium nitrate explosive mixture (non cap sensitive).
Aromatic nitro-compound explosive mixtures.
Ammonium perchlorate explosive mixtures.
Ammonium perchlorate composite propellant.
Ammonium picrate [picrate of ammonia, Explosive D].
Ammonium salt lattice with isomorphously substituted inorganic salts.
*ANFO [ammonium nitrate-fuel oil].

B

Baratol.
Baronol.
BEAF [1, 2-bis (2, 2-difluoro-2-nitroacetoxyethane)].
Black powder.
Black powder based explosive mixtures.
*Blasting agents, nitro-carbo-nitrates, including non cap sensitive slurry and water-gel explosives.
Blasting caps.
Blasting gelatin.
Blasting powder.
BTNEC [bis (trinitroethyl) carbonate].
Bulk salutes.
BTNEN [bis (trinitroethyl) nitramine].
BTTN [1,2,4 butanetriol trinitrate].
Butyl tetryl.

C

Calcium nitrate explosive mixture.
Cellulose hexanitrate explosive mixture.
Chlorate explosive mixtures.
Composition A and variations.
Composition B and variations.
Composition C and variations.
Copper acetylide.
Cyanuric triazide.
Cyclotrimethylenetrinitramine [ROX].
Cyclotetramethylenetetranitramine [HMX].
Cyclonite [RDX].
Cyclotol.

D

DATB [diaminotrinitrobenzene].
DDNP [diazodinitrophenol].
DEGDN [diethyleneglycol dinitrate].
Detonating cord.
Detonators.
Dimethylol dimethyl methane dinitrate composition.
Dinitroethyleneurea.
Dinitroglycerine [glycerol dinitrate].
Dinitrophenol.
Dinitrophenolates.
Dinitrophenyl hydrazine.
Dinitroresorcinol.
Dinitrotoluene-sodium nitrate explosive mixtures.
DIPAM.
Dipicryl sulfone.
Dipicrylamine.
Display fireworks.
DNDP [dinitropentano nitrile].
DNPA [2,2-dinitropropyl acrylate].
Dynamite.

E

EDDN [ethylene diamine dinitrate].
EDNA.
Ednatol.
EDNP [ethyl 4,4-dinitropentanoate].
Erythritol tetranitrate explosives.
Esters of nitro-substituted alcohols.
EGDN [ethylene glycol dinitrate].
Ethyl-tetryl.
Explosive conitrates.
Explosive gelatins.
Explosive mixtures containing oxygen releasing inorganic salts and hydrocarbons.
Explosive mixtures containing oxygen releasing inorganic salts and nitro bodies.
Explosive mixtures containing oxygen releasing inorganic salts and water insoluble fuels.
Explosive mixtures containing oxygen releasing inorganic salts and water soluble fuels.
Explosive mixtures containing sensitized nitromethane.
Explosive mixtures containing tetranitromethane (nitroform).
Explosive nitro compounds of aromatic hydrocarbons.
Explosive organic nitrate mixtures.
Explosive liquids.
Explosive powders.

F

Flash powder.
Fulminate of mercury.
Fulminate of silver.
Fulminating gold.
Fulminating mercury.
Fulminating platinum.
Fulminating silver.

G

Gelatinized nitrocellulose.
Gem-dinitro aliphatic explosive mixtures.
Guanyl nitrosamino guanyl tetrazene.
Guanyl nitrosamino guanylidene hydrazine.
Guncotton.

H

Heavy metal azides.
Hexanite.
Hexanitrodiphenylamine.
Hexanitrostilbene.
Hexogen [RDX].
Hexogene or octogene and a nitrated N-methylaniline.
Hexolites.
HMX [cyclo-1,3,5,7-tetramethylene 2,4,6,8-tetranitramine; Octogen].
Hydrazinium nitrate/hydrazine/aluminum explosive system.
Hydrazoic acid.

I

Igniter cord.
Igniters.
Initiating tube systems.

K

KDNBF [potassium dinitrobenzo-furoxane].

L

Lead azide.
Lead mannite.
Lead mononitroresorcinate.
Lead picrate.
Lead salts, explosive.
Lead styphnate [styphnate of lead, lead trinitroresorcinate].
Liquid nitrated polyol and trimethylolethane.
Liquid oxygen explosives.

M

Magnesium ophorite explosives.
Mannitol hexanitrate.
MDNP [methyl 4,4-dinitropentanoate].
MEAN [monoethanolamine nitrate].
Mercuric fulminate.
Mercury oxalate.
Mercury tartrate.
Metriol trinitrate.
Minol–2 [40% TNT, 40% ammonium nitrate, 20% aluminum].
MMAN [monomethylamine nitrate]; methylamine nitrate.
Monoitrotoluene-nitroglycerin mixture.
Monopropellants.

N

NIBTN [nitroisobutametriol trinitrate].
Nitrate sensitized with gelled nitroparaffin.
Nitrated carbohydrate explosive.
Nitrated glucoside explosive.
Nitrated polyhydric alcohol explosives.
Nitrates of soda explosive mixtures.
Nitric acid and a nitro aromatic compound explosive.
Nitric acid and carboxylic fuel explosive.
Nitric acid explosive mixtures.
Nitro aromatic explosive mixtures.
Nitro compounds of furane explosive mixtures.
Nitrocellulose explosive.

Nitroderivative of urea explosive mixture.
Nitrogelatin explosive.
Nitrogen trichloride.
Nitrogen tri-iodide.
Nitroglycerine [NG, RNG, nitro, glyceryl trinitrate, trinitroglycerine].
Nitroglycide.
Nitroglycol (ethylene glycol, dinitrate, EGDN)
Nitroguanidine explosives.
Nitroparaffins Explosive Grade and ammonium nitrate mixtures.
Nitronium perchlorate propellant mixtures.
Nitrostarch.
Nitro-substituted carboxylic acids.
Nitroureas.

O

Octogen [HMX].
Octol [75 percent HMX, 25 percent TNT].
Organic amine nitrates.
Organic nitramines.

P

PBX [RDX and plasticizer].
Pellet powder.
Penthrinite composition.
Pentolite.
Perchlorate explosive mixtures.
Peroxide based explosive mixtures.
PETN [nitropentaerythrite, pentaerythrite tetranitrate, pentaerythritol tetranitrate].
Picramic acid and its salts.
Picramide.
Picrate of potassium explosive mixtures.
Picratol.
Picric acid (manufactured as an explosive).
Picryl chloride.
Picryl fluoride.
PLX [95% nitromethane, 5% ethylenediamine].
Polynitro aliphatic compounds.
Polyolpolynitrate-nitrocellulose explosive gels.
Potassium chlorate and lead sulfocyanate explosive.
Potassium nitrate explosive mixtures.
Potassium nitroaminotetrazole.
Pyrotechnic compositions.
PYX [2,6-bis(picrylamino)-3,5-dinitropyridine.

R

RDX [cyclonite, hexogen, T4, cyclo-1,3,5,-trimethylene-2,4,6,-trinitramine; hexahydro-1,3,5-trinitro-S-triazine].

S

Safety fuse.
Salutes (bulk).
Salts of organic amino sulfonic acid explosive mixture.
Silver acetylide.
Silver azide.
Silver fulminate.
Silver oxalate explosive mixtures.
Silver styphnate.
Silver tartrate explosive mixtures.
Silver tetrazene.
Slurried explosive mixtures of water, inorganic oxidizing salt, gelling agent, fuel and sensitizer (cap sensitive).
Smokeless powder.
Sodatol.
Sodium amatol.
Sodium azide explosive mixture.
Sodium dinitro-ortho-cresolate.
Sodium nitrate-potassium nitrate explosive mixture.
Sodium picramate.
Special fireworks.
Squibs.
Styphnic acid explosives.

T

Tacot [tetranitro-2,3,5,6-dibenzo-1,3a,4,6a tetrazapentalene].
TATB [triaminotrinitrobenzene].
TEGDN [triethylene glycol dinitrate].
Tetrazene [tetracene, tetrazine, 1(5-tetrazolyl)-4-guanyl tetrazene hydrate].
Tetranitrocarbazole.
Tetryl [2,4,6 tetranitro-N-methylaniline].
Tetrytol.
Thickened inorganic oxidizer salt slurried explosive mixture.
TMETN (trimethylolethane trinitrate).
TNEF [trinitroethyl formal].
TNEOC [trinitroethylorthocarbonate].
TNEOF [trinitroethyl orthoformate].
TNT [trinitrotoluene, trotyl, trilite, triton].
Torpex.
Tridite.
Trimethylol ethyl methane trinitrate composition.
Trimethylolthane trinitrate-nitrocellulose.
Trimonite.
Trinitroanisole.
Trinitrobenzene.
Trinitrobenzoic acid.
Trinitrocresol.
Trinitro-meta-cresol.
Trinitronaphthalene.
Trinitrophenetol.
Trinitrophloroglucinol.
Trinitroresorcinol.
Trtional.

U

Urea nitrate.

W

Water bearing explosives having salts of oxidizing acids and nitrogen bases, sulfates, or sulfamates (cap sensitive).
Water-in-oil emulsion explosive compositions.

X

Xanthamones hydrophilic colloid explosive mixture.

FOR FURTHER INFORMATION CONTACT: Linda Deel, Specialist, Firearms and Explosives Operations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226 (202–927–8310).

Approved: January 11, 1993.

Stephen E. Higgins,

Director.

[FR Doc. 93–1022 Filed 1–14–93; 8:45 am]

BILLING CODE 4810–31–M

UNITED STATES COMMISSION ON IMPROVING THE EFFECTIVENESS OF THE UNITED NATIONS

Meeting and Hearing

AGENCY: United States Commission on Improving the Effectiveness of the United Nations.

ACTION: Notice: public hearings.

SUMMARY: The purpose of these hearings is to obtain information on the subject of United Nations reform and U.S. policy toward the United Nations, and to conduct other Commission business. The meetings will be open to the public.

DATES: Los Angeles, February 1, 1993, 8:30 a.m. to 4 p.m.; San Francisco, February 2, 1993, 9 a.m. to 5 p.m.

ADDRESSES: The Los Angeles hearing will be held in the Second Floor Lounge of Ackerman Hall, University of California Los Angeles, 308 Westwood Plaza, Los Angeles, CA. The San Francisco meeting will be held in the Green Room of the War Memorial Veterans Building, 401 Van Ness Avenue, San Francisco, CA.

FOR FURTHER INFORMATION CONTACT: Kathleen O'Leary, Administrative Officer, 1825 Connecticut Avenue, Suite 1011 Washington, DC 20009; telephone: (202) 673–5012; telefax: (202) 673–5007.

Experts or representatives of interested groups wishing to present testimony should contact the Administrative Officer and submit a summary of their presentation by January 25.

Citizens interested in testifying at the Los Angeles hearing may sign up at the Second Floor Lounge of Ackerman Hall at 2 p.m. Testimony will be heard after 2:30. Witnesses are required to limit their statement to one minute. Those interested in testifying at the San Francisco hearing may sign up at the Green Room of the War Memorial Veterans Building between 9:30 a.m. and 11:30 a.m. Testimony will be heard after 3 p.m. Witnesses must limit their statements to three minutes. Citizen witnesses at either hearing will be selected on a first-come, first-served

basis. All witnesses may submit additional material for the record.

The U.S. Commission on Improving the Effectiveness of the United Nations was established by Public Law 100–204, 101 Stat. 1934 (22 U.S.C. 287 note). The Commission is charged with preparing and submitting to the President and Congress a report containing a detailed statement of its findings, conclusions and recommendations regarding reform of the United Nations system and the role of the United States in the United Nations system. The Commission is bipartisan and is privately funded.

The Commission members are: Representative James A. Leach and Charles M. Lichenstein, Co-Chairs; Thomas F. Eagleton, Edward F. Feighan, Edwin J. Feulner, Jr., Walter Hoffmann, Senator Nancy L. Kassebaum, Alan L. Keyes, Jeane J. Kirkpatrick, Peter M. Leslie, Gary E. MacDougal, Reverend Richard John Neuhaus, Senator Claiborne Pell, Jerome J. Shestack, Harris O. Schoenberg, and Jose S. Sorzano.

Dated: January 12, 1993.

Gregory Wierzynski,

Executive Director.

[FR Doc. 93–1080 Filed 1–14–93; 8:45 am]

BILLING CODE 6820–86–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 10
Friday, January 15, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

LEGAL SERVICES CORPORATION

Board of Directors Annual Meeting

TIME AND DATE: The Legal Services Corporation Board of Directors will hold its annual meeting on January 29, 1993. The meeting will commence at 9:30 a.m.

PLACE: The Legal Services Corporation, 750 1st Street, N.E., 11th Floor, The Board Room, Washington, D.C. 20002, (202) 336–8800.

STATUS OF MEEETING: *Open*, except that a portion of the meeting may be closed if a majority of the Board of Directors votes to hold an executive session. At the closed session, pursuant to receipt of the aforementioned vote, the Board will consider and vote on approval of the draft minutes of the executive session held on December 7, 1992. In addition, the Board will hear and consider the report of the General Counsel on litigation to which the Corporation is a party. Further, the Board will hear and consider its Special Counsel's report on the status of the matter *Gawler* v. *LSC, et al.* Finally, the Board will be consulted by the President regarding certain personnel-related matters. The closing will be authorized by the relevant sections of the Government in the Sunshine Act [5 U.S.C. Sections 552b(c)(2)(5), (6), and (10)], and the corresponding regulation of the Legal Services Corporation [45 C.F.R. Section 1622.5(a), (d), (e), and (h)].[1] The closing will be certified by the Corporation's General Counsel as authorized by the above-cited provisions of law. A copy of the General Counsel's certification will be posted for public inspection at the Corporation's headquarters, located at 750 First Street, N.E., Washington, D.C., 20002, in its eleventh floor reception area, and will otherwise be available upon request.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda.
2. Approval of Minutes of December 7, 1992 Meeting.
3. Election of Officers.
   a. Election of Chairperson.
   b. Election of Vice Chairperson.
4. Formation of Standard Operating Board Committees.
   a. Audit and Appropriations Committee;
   b. Office of the Inspector General Oversight Committee;
   c. Operations and Regulations Committee; and
   d. Provision for the Delivery of Legal Services Committee.
5. Formation of Special Board Committees.
   a. Special Reauthorization Committee.
   b. Other.
6. Status Report on the Competition Effort.
7. Presentation by Representatives of the American Association of Law Schools on the Continued Funding of Law School Clinical Programs.
8. Chairman's and Member's Reports.
9. Consideration of Operations and Regulations Committee Report.
   a. Consideration of Amendments to Sections 1610 and 1611 of the Corporation's Regulations.
   b. Consideration of Amendment to Section 1612 of the Corporation's Regulations.
10. Consideration of Office of the Inspector General Oversight Committee Report.
11. Consideration of Provision for the Delivery of Legal Services Committee Report.
12. Consideration of Audit and Appropriations Committee Report.
13. Consideration of Special Reauthorization Committee Report.
14. President's Report.
15. Inspector General's Report.

CLOSED SESSION:

16. Consideration of Board's Special Counsel's Report on the Matter of *Gawler* v. *LSC, et al.*
17. Consideration of the General Counsel's Report on Pending Litigation to which the Corporation is a Party.
18. Consultation with Board by President on Personnel-Related Matters.
19. Approval of Minutes of Executive Session Held on December 7, 1992.

OPEN SESSION: (Resumed)

20. Consideration of Other Business.

CONTACT PERSON FOR INFORMATION: Patricia Batie (202) 336–8800.

Upon request, meeting notices will be made available in alternate formats to accommodate individuals who are blind or have visual impairment.

Individuals who have a disability and need an accommodation to attend the meeting may notify Patricia Batie at (202) 336–8800.

Dated Issued: January 13, 1993.

Patricia D. Batie,

Corporate Secretary.

[FR Doc. 93–1229 Filed 1–13–93; 3:54 pm]

BILLING CODE 7050–01–M

[1] As to the Board's consideration and approval of the draft minutes of the executive session(s) held on the above-noted date(s), the closing is authorized as noted in the *Federal Register* notice(s) corresponding to that/those Board meeting(s).

federal register

Friday
January 15, 1993

Part II

Department of Labor

Office of the Secretary

29 CFR Part 34

Implementation of the Nondiscrimination and Equal Opportunity Requirements of the Job Training Partnership Act of 1982; Final Rule

VOL 58 ISS 10 JA 15 1993 UMI

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 34

Implementation of the Nondiscrimination and Equal Opportunity Requirements of the Job Training Partnership Act of 1982

AGENCY: Office of the Assistant Secretary for Administration and Management, Labor.

ACTION: Final rule.

SUMMARY: This rule implements the nondiscrimination and equal opportunity provisions of the Job Training Partnership Act of 1982, as amended (JTPA). Under JTPA, the Department of Labor (DOL) provides financial assistance to certain recipients, for the purposes of establishing programs to meet the job training needs of youth and adults facing serious barriers to employment. The nondiscrimination and equal opportunity provisions of JTPA prohibit discrimination on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA. The Job Training Reform Amendments of 1992 amended JTPA to impose a statutory deadline for final regulations implementing the nondiscrimination and equal opportunity provisions of JTPA. As amended, JTPA provides that such regulations be issued within 90 days of the enactment date of the Job Training Reform Amendments of 1992.

This rule clarifies the application of the nondiscrimination and equal opportunity provisions of JTPA and provides uniform procedures for implementing them. The rule applies to recipients of Federal financial assistance under JTPA. Recipients are defined as entities to which Federal financial assistance under any title of JTPA is extended directly or through the Governor or another recipient. The rule imposes general nondiscrimination and equal opportunity requirements, as well as certain affirmative obligations, such as data collection and recordkeeping requirements.

This rule does not add significantly to the responsibilities of JTPA recipients. Rather, this rule generally codifies and consolidates requirements to which JTPA recipients are subject under the nondiscrimination and equal opportunity provisions of other Federal financial assistance laws and regulations.

EFFECTIVE DATE: February 16, 1993.

ADDRESSES: Copies of this final rule are available in the following alternative formats: large print; electronic file on computer disk; and audio tape. Copies may be obtained from the Department of Labor, Directorate of Civil Rights, 200 Constitution Ave., NW., N. 4123, Washington, DC 20210 or by calling (202) 219–8927 (VOICE) or (202) 219–7090 (TDD).

FOR FURTHER INFORMATION CONTACT: Annabelle T. Lockhart, Director, Directorate of Civil Rights, (202) 219–8927 (VOICE) or (202) 219–7090 (TDD).

SUPPLEMENTARY INFORMATION:

I. Background

Section 167 of JTPA contains the nondiscrimination and equal opportunity provisions of JTPA, which prohibit discrimination on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA. As amended by the Job Training Reform Amendments of 1992, JTPA provides that final regulations implementing section 167 of JTPA be issued within 90 days of the enactment date of the Job Training Reform Amendments of 1992.

Secretary's Order 2–81, section 5a(2), authorizes the Assistant Secretary for Administration and Management (OASAM), working through the Director, Office of Civil Rights (OCR), now Directorate of Civil Rights (DCR), to establish and formulate all policies, standards and procedures, as well as to issue rules and regulations, governing the civil rights enforcement programs under grant-related nondiscrimination statutes. Secretary's Order 2–85 similarly delegates to OASAM, working through the Director, OCR, now DCR, exclusive authority for the implementation and enforcement of the nondiscrimination and equal opportunity provisions of JTPA.

Because JTPA recipients are recipients of Federal financial assistance, such recipients are subject to the requirements of 29 CFR parts 31 and 32, implementing the nondiscrimination and equal opportunity provisions of title VI of the Civil Rights Act of 1964, as amended (title VI), and section 504 of the Rehabilitation Act of 1973, as amended (section 504).

In the absence of regulations implementing section 167 of JTPA, and pursuant to authority delegated to OASAM by the Secretary, DCR has processed complaints of discrimination prohibited by JTPA under 29 CFR parts 31 and 32. Similarly, for the purposes of monitoring compliance with section 167 of JTPA, DCR has utilized the recordkeeping requirements and other affirmative obligations already imposed pursuant to 29 CFR parts 31 and 32. Thus, while this rule provides important and needed clarification, codification, and consolidation of responsibilities and procedures applicable to the enforcement of the nondiscrimination and equal opportunity provisions of JTPA, it does not generally impose substantively new obligations or call for significant changes in procedure.

II. Rulemaking History

On October 19, 1992, DOL published a notice of proposed rulemaking (NPRM), 57 FR 47690, setting forth proposed 29 CFR part 34 and soliciting public comment on the following topics: the addition of applicant information to the Standardized Program Information Record (SPIR); the nature of any costs, other than those involved in satisfying recordkeeping obligations, imposed by the rule; the proposed complaint processing procedure; additional steps that could be taken to minimize any economic burden on small businesses; and the feasibility of requesting certain information from grant applicants.

Section IV of the Supplementary Information, below, addresses comments concerning specific sections of the proposed rule. In particular, the analysis of § 34.24 discusses comments received concerning the addition of applicant information to the SPIR. Comments concerning specific costs imposed by the rule other than those related to recordkeeping are addressed in the applicable section analyses. Comments concerning the proposed complaint procedure are addressed in the analysis of § 34.42. No commenters specifically recommended steps to minimize the economic burden on small entities or addressed the feasibility of requesting certain information from grant applicants.

The comment period ended November 3, 1992. In order to have a reasonable opportunity to comply with the statutory deadline imposed by the Job Training Reform Amendments of 1992, it was necessary to limit the notice and comment period to 15 days. However, to ensure that affected parties were aware of the proposed rule and had a reasonable opportunity to comment, DCR distributed copies of the NPRM directly to Governors, JTPA and State Employment Security Agency Administrators, State Equal Opportunity Officers, and pertinent private interest groups.

In response to the NPRM, DOL received 46 comments from interested groups and individuals. In many

instances, comments were submitted by State JTPA agencies on behalf of their recipients or by Private Industry Councils on behalf of their Service Delivery Areas.

These comments have been analyzed and considered in the development of this final rule.

Copies of the written comments will remain available for public inspection during normal business hours at the Directorate of Civil Rights, U.S. Department of Labor, 200 Constitution Avenue, NW., room N–4123, Washington, DC, 20210. Persons who need assistance to review the comments will be provided with appropriate aids such as readers or print magnifiers. To schedule an appointment, call (202) 219–8927 (VOICE) or (202) 219–7090 (TDD).

III. Overview of the Rule

Subpart A—(a) provides definitions, (b) delineates statutory coverage, (c) establishes enforcement authority, and (d) sets out nondiscrimination and equal opportunity provisions applicable to recipients.

Subpart B—sets out the recordkeeping requirements and other affirmative obligations of recipients.

Subpart C—describes the Governor's supplemental responsibilities to implement the nondiscrimination and equal opportunity requirements of JTPA.

Subpart D—describes complaint handling and compliance review procedures.

Subpart E—contains the Federal procedures for effecting compliance, including: (a) actions DOL will take upon making a finding of noncompliance for which voluntary compliance cannot be achieved; (b) the rights of parties upon such a finding; and (c) hearing procedures.

IV. Section-by-Section Analysis

Subpart A—General Provisions

Section 34.1 Purpose; Application

This section describes the purpose and application of the rule.

The purpose of the rule is to implement section 167 of JTPA, which contains the nondiscrimination and equal opportunity provisions of JTPA. Section 167 of JTPA prohibits discrimination on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA. Issuance of this rule was statutorily mandated by the Job Training Reform Amendments of 1992, which amended section 167 of JTPA to require that the Department issue final regulations implementing section 167 within 90 days of the passage of the Job Training Reform Amendments of 1992.

As revised, this part applies to recipients only, as defined in § 34.2. The term recipient is defined to mean any entity to which Federal financial assistance under any title of JTPA is extended, either directly or through the Governor or through another recipient (including any successor, assignee, or transferee of a recipient), but excluding the ultimate beneficiary of the Federal assistance and the Governor. The scope of the rule has been re-defined to focus on the obligations of recipients. The NPRM contained references to entities, other than recipients, operating a program or activity. The final rule no longer contains a distinction between recipients and other entities operating a program or activity, but rather addresses the obligations of recipients only.

This change has been made for several reasons. The focus on recipient responsibilities creates a simplified rule, which more accurately reflects the actual focus of DCR's compliance activities. The revised rule also provides for greater clarity within the regulated community concerning the coverage of the rule. A number of commenters on the NPRM indicated confusion regarding the proposed rule's coverage of entities other than recipients. Some commenters also questioned the availability of practicable enforcement mechanisms to ensure compliance with the nondiscrimination and equal opportunity provisions of the rule by non-recipient entities.

As in the NPRM, subpart A of this part outlines the general nondiscrimination and equal opportunity provisions of the rule. As noted above, the application of the rule, including subpart A, is limited to recipients, as defined in § 34.2. Subpart A also addresses the particular application of the rule to the employment practices of a recipient. As in the NPRM, subparts B–D of this part contain the recordkeeping requirements and other affirmative obligations pertinent to recipients.

Recipients of Federal financial assistance under JTPA are recipients of Federal financial assistance, and therefore are subject to the applicable nondiscrimination and equal opportunity provisions of title VI of the Civil Rights Act of 1964, as amended (title VI) and section 504 of the Rehabilitation Act of 1973, as amended (section 504), and their respective implementing regulations at 29 CFR parts 31 and 32. Several commenters appeared to be unaware of the obligation of recipients of Federal financial assistance under JTPA to comply with laws and regulations pertaining to recipients of Federal financial assistance.

In order to eliminate the burden of complying with overlapping regulatory requirements, the rule provides that a recipient's compliance with this rule constitutes compliance with 29 CFR part 31 and with subparts A, D, and E of 29 CFR part 32. However, this rule does not incorporate all of the requirements contained in 29 CFR part 32. Therefore, recipients complying with this rule remain responsible for the obligations imposed by subparts B and C and Appendix A of 29 CFR part 32, which pertain to employment practices and employment-related training, program accessibility, and accommodations under section 504.

For recipients who receive any funding from the Department under JTPA, whether or not funds under JTPA constitute their sole source of funding from the Department, compliance with this part shall constitute compliance under 29 CFR part 31 and subparts A, D, and E of 29 CFR part 32.

In addition, recipients that are also public entities or public accommodations as defined by titles II and III of the ADA, should be aware of the obligations imposed pursuant to those titles.

This rule does not apply: to programs or activities exclusively funded by DOL under laws other than JTPA; to contracts of insurance and guaranty; to federally-operated Job Corps Centers; or to assistance provided to individuals who are ultimate beneficiaries. One commenter objected to these exclusions, questioning why "SDAs will be held accountable to far-reaching and expensive standards, while other entities are exempt." The rule implements the nondiscrimination and equal opportunity provisions of JTPA and, therefore, applies only to recipients of JTPA funds, as defined by this part. Federally-operated Job Corps Centers are not "exempt" from coverage under title VI or section 504; rather, they are subject to the nondiscrimination and equal opportunity regulations of the Federal department operating the Job Corps Center.

Section 34.2 Definitions

To the extent possible, the definitions contained in the rule are consistent with similar terms used in regulations implementing the nondiscrimination and equal opportunity provisions of other legislation providing Federal financial assistance. Similarly, to the extent feasible, the rule uses the terms contained in JTPA program regulations

issued by the Employment and Training Administration (ETA) within the Department. Furthermore, the rule specifically employs the definitions of applicant, eligible applicant, and participant included in the Standardized Program Information Record (SPIR). A notice concerning the data elements to be included in the SPIR was published November 12, 1992 in the **Federal Register**, 57 FR 53824. A number of commenters on the NPRM expressed dissatisfaction with apparent discrepancies between the definitions of applicant and participant contained in DCR's proposed rule and in the SPIR proposed by ETA on March 12, 1992, 57 FR 8820. The definitions of applicant, eligible applicant, and participant contained in the final rule are now substantively identical to the SPIR definitions of those terms.

Some commenters expressed disapproval of any difference in the use of certain definitions in the NPRM and in ETA regulations. Because this rule is designed for use in civil rights compliance and enforcement activities, rather than for programmatic purposes, it is not possible to use identical definitions. Therefore, the rule defines and uses certain terms as terms of art, such as JTPA-funded program or activity and recipient.

The term JTPA-funded program or activity is used as a term of art to mean a program, operated by a recipient and funded under JTPA for the provision of services, financial aid, or other benefit to individuals. One commenter expressed the view that services purchased by a participant with JTPA needs-based payments should not constitute a JTPA-funded program, now termed a JTPA-funded program or activity. A JTPA-funded program or activity, as defined in § 34.2, does not cover services purchased by a participant.

The term recipient is used as a term of art that includes any entity, public or private, that receives funding from the Department under any title of JTPA, directly or through the Governor or another recipient. The term recipient includes, but is not limited to, State-level agencies that administer JTPA-funded programs or activities, State Employment Security Agencies (SESAs), Private Industry Councils (PICs), SDA grant recipients or administrative entities, substate grantees, service providers, Job Corps Centers, and National Program recipients. The term recipient does not include federally operated Job Corps Centers.

In the final rule, the definition of recipient has been revised to exclude the Governor. This is a technical change to provide greater clarity and precision and does not represent any substantive change in the responsibilities applicable to recipients or to the Governor. As in the proposed rule, the final rule provides that the Governor has specific obligations, outlined in subpart C of this part, to ensure that recipients comply with the nondiscrimination and equal opportunity provisions of JTPA and this part.

In a related technical change, the term subrecipient has been deleted from the final rule as superfluous and confusing. As commenters indicated, the term subrecipient served no function, since the proposed rule already included subrecipients within the definition of recipient and provided that all obligations of recipients applied to subrecipients, unless otherwise provided in the rule. As in the proposed rule, the final rule exempts service providers and small recipients from certain obligations imposed by the rule.

The definitions of disability and individual with a disability have been revised for consistency with section 504 of the Rehabilitation Act of 1973, as recently amended by the Rehabilitation Act Amendments of 1992. Further, consonant with the Rehabilitation Act Amendments of 1992, the Job Training Reform Amendments of 1992 and the ADA, this part uses the term disability in place of the term handicap. The two terms are intended to have identical meanings.

One commenter criticized the definition of disability contained in the proposed rule, on the ground that it was excessively broad. However, the definition is not exclusive to this rule, but rather is substantively identical to that contained in section 504 of the Rehabilitation Act, as amended, to which recipients of Federal financial assistance, including JTPA funds, are subject. Because the rule pertains to nondiscrimination and equal opportunity on the basis of disability, rather than program eligibility, the definition of disability is necessarily different from that used for the purposes of making program determinations.

Several comments indicated a need for clarification of the term auxiliary aids and services; therefore, a definition of the term has been added to the final rule. Auxiliary aids and services pertain specifically to communications. The obligations of recipients concerning communications with individuals with disabilities are outlined in § 34.6.

Section 34.3 Discrimination Prohibited

This section sets forth a general statement of prohibited discrimination to the effect that no person, on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA, shall be excluded from participation in, denied the benefits of, or subjected to discrimination under a JTPA-funded program or activity. The suggestion of one commenter that several of these grounds be deleted from inclusion in the final rule has not been adopted, because the section implements the specific statutory prohibitions on discrimination mandated by section 167 of JTPA.

Section 34.4 Specific Discriminatory Actions Prohibited on the Ground of Race, Color, Religion, Sex, National Origin, Age, Political Affiliation or Belief, Citizenship, or Participation in JTPA

For the purposes of this section, prohibited ground is defined to mean race, color, religion, sex, national origin, age, political affiliation, citizenship, or participation in JTPA. Specific discriminatory actions that are prohibited on the ground of disability are covered in § 34.5.

This section delineates specific actions that are prohibited by the nondiscrimination and equal opportunity provisions of JTPA. In addition to the specific actions prohibited under paragraphs (a) (1)–(9) of this section, paragraph (a)(10) of the section provides that a recipient may not "otherwise limit on a prohibited ground an individual in enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving any aid, benefit, service, or training." Thus, the enumeration of specifically prohibited actions is not intended to imply the permissibility of actions not specifically enumerated. One commenter pointed out that sexual harassment was not specifically included as a prohibited action. Sexual harassment constitutes a form of discrimination on the basis of sex and is therefore prohibited under the nondiscrimination and equal opportunity provisions of JTPA and this part.

One commenter expressed the view that the list of prohibited grounds and actions contained in this section was excessive. The list of grounds on which it is prohibited to discriminate is contained in section 167 of JTPA itself; the rule implements, but does not extend, the statutory prohibitions. Further, the list of prohibited actions is essentially identical to that contained in the regulations implementing title VI. As noted in the discussion of § 34.1,

recipients of Federal financial assistance from DOL, including funds under JTPA, are already subject to these prohibitions.

One commenter requested clarification as to whether the rule's prohibition on discrimination on the ground of participation in JTPA would preclude recipients from adopting policies that would restrict the access and/or delivery of services to prior participants. The rule's prohibition on discrimination on the ground of participation in JTPA implements § 167(a)(4) of JTPA, which provides that individuals who are participants in activities supported under JTPA shall not be discriminated against solely because of their status as such participants. The Department does not consider reasonable restrictions on serving prior participants to constitute discrimination prohibited by the nondiscrimination and equal opportunity provisions of JTPA or this part.

Paragraph (d) of this section permits the exclusion of an individual because he or she is not a member of the class of beneficiaries to which participation in the program is limited by Federal statute or executive order. One commenter objected to this provision, on the ground that paragraph (d) "specifically allows illegal discrimination against persons who are not members of protected classes." This perception is incorrect; the provision does not permit "illegal discrimination," but rather is included to clarify what does and does not constitute illegal discrimination. The provision's use of the phrase "Federal statute or executive order" is intended to indicate that a Federal statute, such as the JTPA, that identifies a population which is eligible for participation in the federally-funded program and which specifically provides for the specific training needs of certain segments of that population, does not per se violate the nondiscrimination and equal opportunity provisions of JTPA or this part.

Section 34.5 Specific Discriminatory Actions Prohibited on the Ground of Disability

This section provides that a recipient shall not, directly or through contractual, licensing, or other arrangements, take certain actions with regard to individuals with disabilities. The list of actions prohibited by this section is substantially the same as contained in 29 CFR 32.4, but has been revised to reflect revisions to section 504, as amended by the Rehabilitation Act Amendments of 1992.

One commenter asked for clarification regarding the absence in the proposed rule of the term reasonable accommodation as applied to employment. As provided in § 34.1(d)(2), this rule does not affect in any way the obligation of recipients to comply with subparts B and C and appendix A of 29 CFR part 32. Thus, the rule does not purport to provide comprehensive guidance regarding employment-related obligations to provide reasonable accommodation. Such guidance is provided in 29 CFR part 32, subpart B, which covers employment practices and employment-related training and which specifically discusses the concept of reasonable accommodation, and in 29 CFR part 32, appendix A, which provides guidance and technical assistance regarding types of accommodations. Recipients that are also employers covered by titles I and II of the ADA should also be aware of obligations imposed pursuant to those titles.

For greater clarity, a subsection (e) has been added to § 34.7, Employment practices, to indicate that § 34.7 does not constitute an exhaustive list of employment-related nondiscrimination and equal opportunity obligations on the ground of disability.

Paragraph (g) of this section provides that the exclusion of an individual without a disability from the benefits of a program limited by Federal statute or Executive Order to individuals with disabilities or the exclusion of a specific class of individuals with disabilities from a program limited by Federal statute or Executive Order to a different class of individuals with disabilities is not prohibited by this part. This provision is essentially identical to the provision contained in 29 CFR 32.4.

A new paragraph (h) has been added to this section to clarify that a recipient is not required to provide to individuals with disabilities: personal devices, such as wheelchairs; individually prescribed devices, such as prescription eyeglasses or hearing aids; readers for personal use or study; or services of a personal nature including assistance with eating, toileting, or dressing. The standard imposed by this paragraph is the same as imposed pursuant to 28 CFR 35 (DOJ regulations implementing title II, subtitle A of ADA). New paragraph (h) replaces a similar provision in § 34.6(b)(2) of the NPRM.

Section 34.6 Communications With Individuals With Disabilities

This section outlines the responsibilities of recipients with regard to communications with individuals with disabilities and the provision of auxiliary aids or services.

Paragraph (a) of this section requires recipients to take appropriate steps to ensure that communications with beneficiaries, applicants, eligible applicants, participants, applicants for employment, employees and members of the public who are individuals with disabilities "are as effective as communications with others." These provisions, including the phrase "as effective as communications with others," are substantially the same as contained in the Communications provision of title II of the ADA, as implemented by 28 CFR part 35 (DOJ). Some commenters asked that the phrase "as effective" be changed to a more specific standard. The Department has not adopted this suggestion for several reasons. The use of a term other than that used in the ADA and in 28 CFR part 35 could give the erroneous impression that the Department is imposing a standard for required communications that differs from that required under the ADA. Furthermore, the type of auxiliary aid or service necessary to ensure effective communication will vary in accordance with the length and complexity of the communication involved. Factors to be considered in determining the exact type of auxiliary aid or service include, but are not limited to, the context in which the communication is taking place, the number of people involved, and the importance of the communication.

Section 34.6(c) requires that where a recipient communicates by telephone with beneficiaries, applicants, eligible applicants, participants, applicants for employment and employees, such recipient shall use TDDs or "equally effective communications systems." This requirement is substantively identical to the requirement imposed under subtitle A, title II of the ADA. One commenter interpreted paragraph (c) of this section as requiring the acquisition of TDDs and objected on the grounds that complying with such a requirement would result in prohibitive expense. However, this section does not expressly mandate the purchase of TDDs. A recipient which does not have a TDD and which needs to communicate with an individual who uses a TDD, or vice versa, may be able to use a relay service that permits communications between individuals who communicate by TDD and individuals who communicate by the telephone alone. However, TDDs should be available where services provided by telephone are a major function of the JTPA-funded program or activity.

Former paragraph (b)(2) of this section, concerning "individually prescribed devices," "readers for personal use or study," or "other devices of a personal nature," has been deleted from this section. A revised version of this provision is now contained in paragraph (h) of § 34.5.

Section 34.7 Employment Practices

This section describes the application of this part to the employment practices of a recipient. Discrimination on the ground of race, color, religion, sex, national origin, age, disability or political affiliation or belief is prohibited in the employment practices of JTPA-funded programs or activities.

As provided in §§ 34.1(d)(2) and 34.1(d)(3), this rule does not affect in any way the obligation of recipients to comply with subparts B and C and appendix A of 29 CFR part 32. However, for greater clarity, a subsection (e) has been added to emphasize that § 34.7 does not constitute an exhaustive list of employment-related nondiscrimination and equal opportunity obligations on the ground of disability. Such guidance is provided in 29 CFR part 32, subpart B, which covers employment practices and employment-related training and which specifically discusses the concept of reasonable accommodation, and in 29 CFR part 32, appendix A, which provides guidance and technical assistance regarding types of accommodations.

Recipients that are also employers covered by titles I and II of the ADA should be aware of obligations imposed pursuant to those titles and of technical assistance available from the pertinent Federal enforcement agencies.

Section 34.10 [Reserved]

The provisions contained in this section have been deleted from the final rule because they are duplicative of the provisions contained in § 34.24. Comments concerning former § 34.10 are discussed in the analysis of § 34.24.

Section 34.11 Effect of Other Obligations or Limitations

This section contains the provision that a recipient covered by this part may not exclude individuals from participation or otherwise limit their opportunity to participate in JTPA-funded training programs or activities, based on the perception that it will be unable to place such individuals in jobs after training because of their race, sex, age, disability, or other characteristic identified as a prohibited ground of discrimination. For example, a recipient may not deter a woman who is qualified for a training program in the construction trades from seeking such training, simply because such recipient believes that, after training, it will be difficult to place the woman in a construction job. One commenter objected that this provision does not "give sufficient grounds for excluding an individual from a particular training program where the program would lead to a future job which has a bona fide requirement for a specific gender, age (etc.)." The commenter did not give an example of a training program for a specific job which has such a bona fide requirement. Although Federal discrimination law provides for exceptions based on a bona fide occupational qualification, such exceptions have been interpreted extremely stringently and are generally inapplicable.

Subpart B—Recordkeeping and Other Affirmative Obligations of Recipients

Section 34.20 Assurance Required; Duration of Obligation; Covenants

One commenter asked for clarification regarding how far down the procurement chain the assurance required by this section applies. The assurance requirement applies to each application for Federal financial assistance under JTPA, as defined in § 34.2.

One commenter expressed disapproval of paragraph (c), which concerns the duration and scope of the application of the assurance specified in paragraph (a) of this section, and of paragraph (d), which provides for covenants containing such an assurance. This commenter did not think that receipt of Federal financial assistance under JTPA for the provision of, or in the form of, real property should impose on the recipient any continuing obligation not to discriminate. However, the provisions contained in paragraphs (c) and (d) of this section have been retained in the final rule. They are substantively identical to those currently applicable to recipients of Federal financial assistance pursuant to 29 CFR 31.6(a) and 32.5 (b) and (c). The language of the section has been revised and simplified for greater clarity.

Section 34.21 Equitable Services

This section requires recipients to make efforts to provide equitable services. Such efforts include, but are not limited to, conducting outreach efforts to broaden the composition of the pool of those considered for participation, to include members of both sexes, the various race/ethnicity and age groups, and individuals with disabilities. A number of commenters asked for clarification of the term "equitable services," and were concerned that the section required that services be provided to each group (e.g., individuals with disabilities) in proportion to the group's representation in the eligible population. This section is not intended to impose such a requirement; rather, it requires recipients to make outreach efforts to ensure that members of both sexes, the various race/ethnicity and age groups, and individuals with disabilities have fair access to JTPA-funded programs, activities, or services.

Section 34.22 Designation of Equal Opportunity Officer

This section requires each recipient, other than a small recipient or service provider, to designate an Equal Opportunity Officer responsible for coordinating its obligations under these regulations. This obligation includes responsibility for developing, maintaining and updating the recipient's Methods of Administration pursuant to § 34.33, as well as serving as the recipient's liaison to the Directorate. The requirement imposed by this section is consistent with existing obligations under 29 CFR 32.7, which requires recipients of Federal financial assistance to designate at least one person to coordinate the recipient's compliance efforts under section 504. A similar requirement is contained in DOJ's title VI coordinating rule at 28 CFR 42.410, which requires the assignment of title VI responsibilities to designated State personnel.

The proposed rule provided for the Equal Opportunity Officer to report directly to the recipient's Administrator, Secretary, chief elected official, governing board, Executive Director, "or other comparable body." Several commenters objected to the phrase "or other comparable body" on the grounds that it was insufficiently specific. The final rule has been revised to indicate that the Equal Opportunity Officer is to report directly to the State JTPA Director, Governor's JTPA Liaison, Job Corps Center Director, SESA Administrator, or chief executive officer of the SDA or substate grant recipient, as applicable.

This rule does not require that recipients designate a separate or additional Equal Opportunity Officer to comply with this part, but permits recipients to use their existing Equal Opportunity Officer and staff. Furthermore, this rule does not require that recipients establish a full-time position responsible solely for this part. The duties described in this section could be performed by an individual (or

individuals) who may be assigned other duties.

Paragraph (a) of this section further provides that the Director may require that the Equal Opportunity Officer and his or her staff undergo training, "the expenses of which shall be the responsibility of the recipient." The NPRM used the phrase "the expenses of which will be borne by the recipient." Several commenters objected to this provision, on the grounds that such training should be voluntary and all costs should be borne by DCR. The Department's responsibility to ensure compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part requires that the Director have authority to require necessary training. As a practical matter, however, DCR generally provides the required training free of charge; recipients are usually responsible solely for travel and accommodation costs.

Paragraph (d) of this section provides that service providers, as defined by § 34.2, are not required to designate an Equal Opportunity Officer. Rather, the duties described in this section are the responsibilities of the Governor, the SDA grant recipient or the Substate grantee, as provided in the State's Methods of Administration. A number of commenters expressed approval of this provision, as a means of lessening the burden of compliance on service providers.

Section 34.23 Dissemination of Policy

The proposed rule provided in paragraph (a) of this section that recipients take initial and continuing steps, using the notice language specified in then-paragraph (a)(1) of this section, to notify "the public, applicants, eligible applicants, participants, beneficiaries, referral sources, employees and applicants for employment, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with recipient" that it does not discriminate on any prohibited ground. The prescribed notice language included information concerning the right to file complaints and procedures applicable to complaints.

A number of commenters objected to the requirement that pamphlets and other materials ordinarily distributed to the public contain the specific notice language, particularly the information concerning the right to file complaints. These commenters expressed concern regarding the feasibility of including the full text of the notice in all recruitment and general information publications, many of which are very brief; the necessity of disseminating information concerning the right to file complaints in general materials distributed to members of the public; and the significant expense that would be involved in revising and reprinting all publications to include the full notice.

The final rule has been revised to reflect these comments. Paragraph (a) of the section now requires initial and continuing notice to be given to: applicants, eligible applicants, participants, applicants for employment, employees, and members of the public, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient. Paragraph (a)(2) of this section has been revised to clarify that the notice obligation imposed pursuant to paragraph (a)(1) of this section requires, at a minimum, that the notice specified in paragraph (a)(5) of this section be: posted prominently, in reasonable numbers and places; disseminated in internal memoranda and other written communications; included in handbooks and manuals; and made available to each participant and made a part of the participant's file. The obligation to provide notice to the public no longer requires that recipients include the full notice language in generally-distributed materials. Rather, as discussed below, new paragraph (b) provides for the inclusion of a more concise equal opportunity statement.

New paragraph (a)(3) includes the requirement contained in paragraph (a)(2) of the NPRM that recipients provide the required initial and continuing notice in appropriate formats to individuals with visual impairments. As in the NPRM, the final rule further provides that a record that such notice has been given be made a part of the individual's file. However, the final rule has been revised to indicate that a record that such notice has been given shall be made a part of the "participant's file," rather than "the eligible applicant's file." The change makes clear that the provision does not require the creation of additional "files" on eligible applicants.

In the final rule, paragraph (b) of the section clarifies the obligations of recipients with regard to the general public. Recipients are not required to include the full text of the notice prescribed in paragraph (a)(5) of this section in recruitment brochures and other materials ordinarily distributed to the public, such as pamphlets describing JTPA-funded programs or activities and/or participation requirements. However, recipients must indicate in such generally-distributed publications that the JTPA-funded program or activity is an "equal opportunity employer/program" and that "auxiliary aids and services are available upon request to individuals with disabilities." Where such materials indicate that the recipient may be reached by telephone, they must also state the telephone number of any TDD or relay service used by the recipient pursuant to § 34.6.

Paragraph (b)(2) has been revised similarly to indicate that recipients required by law or regulation to publish or broadcast program information in public media, must ensure that such publications or broadcasts state that the JTPA-funded program or activity in question is an equal opportunity employer/program (or otherwise indicate that discrimination in the JTPA-funded program or activity is prohibited by Federal law), and indicate that auxiliary aids and services are available upon request to individuals with disabilities. These requirements are substantially the same as those imposed by 29 CFR 31.5(d), 29 CFR 32.8(b), and 28 CFR 42.405(c).

The provision formerly contained in paragraph (d) of this section, concerning information in a language other than English, has been revised for greater clarity. New paragraph (c) provides that, where a significant number of the population eligible to be served, or directly affected by a JTPA-funded program or activity, requires service or information in a language other than English, recipients must take reasonable steps to provide, in appropriate languages: (1) Such information; (2) the notice required pursuant to paragraph (a) of this section; and (3) such written materials as are distributed pursuant to paragraph (b) of this section. Several commenters requested that the term "significant number" be defined more specifically. The final rule retains the term "significant number," which is used in the analogous requirement imposed under title VI by DOJ's coordinating rule at 28 CFR 42.405(d)(1). The use of a term other than that used in the DOJ rule could give the erroneous impression that the Department is requiring JTPA recipients to meet a different standard for the provision of materials in languages other than English than is generally imposed on recipients of Federal financial assistance.

Section 34.24 Data and Information Collection; Confidentiality

As indicated in the proposed rule, DCR and ETA have agreed to use, to the extent possible, a joint management

information system, now called the Standardized Program Information Record (SPIR). A notice concerning the data elements to be included in the SPIR was published in the **Federal Register** on November 12, 1992 (57 FR 53824). As the proposed rule indicated, for the purposes of complying with the nondiscrimination and equal opportunity provisions of JTPA and this part, recipients are not required to maintain a recordkeeping system that duplicates the data elements contained in the SPIR. However, at the time the NPRM was published, a proposal concerning data elements to be included in the SPIR had appeared in the **Federal Register**, but the notice had not yet been published. As a consequence, a number of commenters were concerned that the DCR and ETA recordkeeping obligations would not be consistent. These concerns are no longer applicable, since the final rule and the SPIR contain consistent requirements and definitions.

This section has been reorganized for greater clarity. New paragraph (a) of this section provides generally that recipients are not required to submit information and data pursuant to this section that the Directorate can obtain from existing sources, including those of other agencies, if the source is known and can be made available to the Director.

Paragraph (a)(1) of this section sets out the basic requirement that recipients collect and maintain such records, in accordance with procedures prescribed by the Director, as are necessary to determine compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part. Some commenters expressed concern as to the apparently open-ended nature of this provision. This provision states the Director's general authority to prescribe procedures concerning the collection and maintenance of such information as is necessary to determine compliance and thus has been retained in the final rule. New requests for the collection of information that are subject to the Paperwork Reduction Act would be submitted to OMB in accordance with that Act for approval and publication for notice and comment.

Paragraph (a)(2) of this section provides that the records required to be collected and maintained pursuant to paragraph (a)(1) of this section, shall specifically include, but are not limited to, records on the race/ethnicity, sex, age, and, where known, disability status, of each applicant, eligible applicant, participant, terminee, applicant for employment and employee. Pursuant to 29 CFR parts 31 and 32, the Department already requires that recipients maintain much of this information, including data regarding the disability status, where known, of beneficiaries and participants.

With the exception of data on employees and applicants for employment, the information specifically requested under paragraph (a)(2) of this section will be included in the SPIR for most JTPA State programs. Employers are already required to maintain information on the race/ethnicity, sex, and age of employees and applicants for employment pursuant to EEOC regulations.

The proposed rule referred to data concerning disability status "where voluntarily self-identified." In the final rule, this phrase has been changed to "where known." This change has been made for several reasons. "Where known" is the standard applicable for compliance reporting under 29 CFR part 32. For compliance purposes, it is necessary to know, not only the number of individuals who wish to identify themselves as individuals with disabilities, but also the number of individuals who are perceived by the recipient as being individuals with disabilities. Furthermore, it is only permitted to ask questions regarding disability status in certain limited circumstances, e.g., where required to determine eligibility for a federally-assisted program or otherwise required pursuant to a Federal law or regulation. If disability status has been voluntarily self-identified pursuant to such a permitted circumstance, such self-identification can provide the means by which the disability status is "known."

One commenter expressed the view that section 102 of the ADA prohibits any "pre-enrollment inquiries" regarding disability status. Section 102 of the ADA pertains to pre-employment inquiries. It is correct that pre-employment inquiries concerning an individual's disability status are generally prohibited, whether or not responses to such inquiries are voluntary. However, as noted above, this prohibition does not apply to such inquiries as are necessary to determine eligibility for federally assisted programs. Furthermore, a pre-employment inquiry about a disability is permissible if it is required or necessitated by another Federal law or regulation. Section 5.5(c) of the EEOC Technical Assistance Manual on the Employment Provisions (Title I) of the Americans with Disabilities Act, specifically provides that such inquiries as are necessary to determine eligibility for JTPA assistance or for the provision of required special services do not violate the ADA.

Paragraph (a)(1) of the proposed rule contained a provision requiring recipients to ensure that the information collected pursuant to this section be kept separate from the application or other forms and otherwise be stored to maintain confidentiality. Numerous commenters objected to the requirement that such information be kept separate, on the ground that keeping identifying data segregated from the application would require the establishment of two different recordkeeping systems. These commenters expressed full support for goal of keeping the information confidential. In addition, some commenters objected that the purpose of the "separate" requirement would be defeated by the SPIR, which is designed to produce a single record and which mandates the inclusion of such information.

The intent of the "separate" requirement contained in the proposed rule was to ensure the confidentiality of identifying information and to prevent the improper use of such information. The final rule has been revised to require recipients to safeguard the confidentiality of the required information. It does not specifically require that such information be maintained in a separate file. New paragraph (a)(2) of this section retains the requirement of old paragraph (a)(1) of this section, that the information collected pursuant to this part be used only for the purposes of recordkeeping and reporting; determining, where appropriate, eligibility for a JTPA-funded program or activity; determining the extent to which the recipient is operating its JTPA-funded program or activity in a nondiscriminatory manner; or other use authorized by the nondiscrimination and equal opportunity provisions of JTPA or this part.

Re-numbered paragraph (a)(3) of this section requires grant applicants and recipients to notify the Director of any administrative enforcement actions or lawsuits filed against a grant applicant or recipient alleging discrimination on a prohibited ground; to provide a brief description of the findings in any civil rights compliance review or complaint investigation conducted by another Federal agency where a grant applicant or recipient was found in noncompliance. Under paragraph (a)(3)(iii) of this section, each recipient is required to maintain a log containing certain information regarding complaints filed with it under this part, and to submit the information in accordance with procedures determined

by the Director. One commenter objected to the "addition" of the requirements contained in paragraph (a)(3) of this section. These requirements are essentially identical to those currently imposed by the Department pursuant to 28 CFR part 42 (DOJ coordinating regulations implementing title VI).

Paragraph (a)(4) of this section states DCR's authority to request such information and data as are necessary to investigate complaints and conduct compliance reviews concerning discrimination on prohibited grounds other than race/ethnicity, sex, age. and disability, such as national origin, religion, citizenship and political affiliation or belief. One commenter objected to this provision on the grounds that it authorizes "unnecessary 'fishing expeditions or witch hunts.'" The nondiscrimination and equal opportunity provisions contained in section 167 of JTPA are not limited to race/ethnicity, sex, age, and disability, but also include national origin, religion, political affiliation and belief, and for beneficiaries only, citizenship and participation in JTPA. Therefore in order for DCR to be able to fulfill its responsibility to ensure compliance with section 167 of JTPA, DCR must have the authority to request such information and data as are necessary to investigate complaints and conduct compliance reviews concerning discrimination on grounds covered by the JTPA.

As in the proposed rule, the final rule requires recipients to retain records, including records regarding complaints and actions taken thereunder, as well as applicant, eligible applicant, participant, employee and applicant for employment records, for a period of not less than three years. In response to a suggestion made by several commenters, paragraph (c) has been revised to clarify when the three-year retention period begins. Applicant, eligible applicant. participant, terminee, applicant for employment and employee records and such other records as are required by the Director, must be maintained for a period of not less than three years from the close of the applicable program year. Records regarding complaints and actions taken thereunder must be maintained for a period of not less than three years from the date of the resolution of the complaint.

Paragraph (b)(2) of this section provides that "asserted considerations of privacy and confidentiality" shall not be a basis for withholding information from the Directorate and shall not bar the Directorate from evaluating or seeking to enforce compliance with the nondiscrimination or equal opportunity provisions of JTPA or this part. This provision is substantively identical to that imposed by 29 CFR 32.44(c). Several commenters requested deletion of this provision, and in particular the phrase "asserted considerations of privacy and confidentiality." The final rule has not been modified. The provision is necessary to enable the Directorate to fulfill its obligation to ensure that Federal funds under JTPA are not used for discriminatory purposes.

Subpart C—Governor's Responsibilities To Implement the Nondiscrimination and Equal Opportunity Requirements of JTPA

Section 34.30 Application

This section provides that subpart C of this part is applicable to State Programs as defined in § 34.2. Section 34.32 provides that, unless the Governor has taken the steps delineated in that section, he or she shall share liability with the recipient for any finding of noncompliance. This section has been revised to clarify that the Governor's liability for any noncompliance on the part of a SESA cannot be waived. Thus. as provided in both the proposed and final rules, the provisions of 34.32 (b) and (c) do not apply to State Employment Security Agency (SESA) programs

Section 34.33 Methods of Administration

This section requires each State to develop a Methods of Administration for State programs, as defined by § 34.2 Several commenters expressed approval of this requirement, observing that it will provide a clear and uniform standard for the implementation of the nondiscrimination and equal opportunity provisions of JTPA and this part.

One commenter requested that the final rule add the words "his or her designee" to paragraph (b)(3) of this section, which provides that the Methods of Administration shall be signed by the Governor. This suggestion has not been adopted, because the definition of the term *Governor* provided in § 34.2 of this part expressly includes the Governor's designee.

This section has been revised to clarify what constitutes the "supporting documentation" required pursuant to paragraph (c)(2)(vi) of this section.

Subpart D—Compliance Procedures

Section 34.40 Compliance Reviews

Paragraph (c)(3) of this section provides that recipients shall be notified through a Letter of Findings of the preliminary findings of a post-approval review. Such Letter of Findings is to be issued within 210 days of the initiation of a post-approval review (except where a Notice to Show Cause is issued as provided in § 34.41(e)). In response to a comment, this provision has been revised to clarify that the 210 day time frame begins with the issuance of a Notification Letter pursuant to paragraph (c)(2) of this section.

Section 34.42 Adoption of Discrimination Complaint Processing Procedures

This section requires each recipient to adopt and publish procedures for processing complaints that allege a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part, regardless of the prohibited ground. Under 29 CFR part 31, individuals alleging complaints of discrimination pursuant to title VI have been required to file complaints directly with the Directorate. Under 29 CFR part 32, however, individuals alleging complaints of discrimination pursuant to section 504, have been required to exhaust local-level procedures before filing with the Directorate. Several commenters expressed approval of the NPRM's provision unifying the procedures applicable to discrimination complaints. These commenters noted that having different procedures for complaints brought under section 504 and title VI had proven confusing.

One commenter objected to the requirement that recipients be required to adopt any complaint processing procedures pursuant to the nondiscrimination and equal opportunity provisions of JTPA and this part. This commenter expressed the view that such procedures create "an unnecessary duplication of grievance processes" already provided pursuant to general JTPA requirements. As indicated above, the requirement that recipients be required to adopt procedures for responding to complaints of discrimination is not new. Furthermore, ETA's JTPA regulations at 29 CFR part 636 expressly provide that part 636 is not applicable to complaints of discrimination pursuant to section 167 of JTPA, but rather that such complaints are to be handled under 29 CFR parts 31 and 32, in accordance with other complaints of discrimination.

Section 34.45 Notice of Violation; Written Assurances; Conciliation Agreements

This section has been reorganized for greater clarity and amended to include new paragraph (c)(1), which expressly

provides that a written assurance must contain documentation that the violations listed in the Letter of Findings, Notice to Show Cause, or Initial Determination, as applicable, have been corrected.

Section 34.47 Notice of Finding of Noncompliance

This section has been reorganized for greater clarity. The final rule provides that when a compliance review or complaint investigation results in a finding of noncompliance, the Director shall so notify the Departmental granting agency and the Assistant Attorney General.

Subpart E—Federal Procedures for Effecting Compliance

Section 34.52 Decisions and Post-termination Proceedings

This section has been reorganized for greater clarity. A new paragraph (b)(1)(vi) has been added to the final rule to provide that, where exceptions to the initial decision and order of the Administrative Law Judge have not been filed, the Secretary may, on his or her own motion, serve notice on the parties that the Secretary shall review the decision.

V. Regulatory Process Matters

Interagency Coordination

The Department of Justice (DOJ), pursuant to Section 1–201 of Executive Order 12250 (45 FR 72995, November 4, 1980), is responsible for coordinating Federal enforcement of nondiscrimination laws in federally assisted programs. Executive Order 12067 (43 FR 28967, July 5, 1978) requires consultation with the Equal Employment Opportunity Commission (EEOC) regarding those provisions of regulations that involve equal employment opportunity. This rule has been reviewed and approved by both DOJ and EEOC.

Executive Order 12291

The Department has determined that this rule is not a "major rule" under Executive Order 12291. It is not likely to result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

This rule does not substantively change the existing obligation of recipients to apply a policy of nondiscrimination and equal opportunity in employment or services. This rule will not have a significant economic impact on a substantial number of small business entities. Accordingly, a regulatory flexibility analysis pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) is not required for this rulemaking.

Paperwork Reduction Act

The information collection requirements imposed pursuant to the rule have been submitted to OMB for review pursuant to the Paperwork Reduction Act. While the majority of recordkeeping obligations imposed by the rule are not new and have previously been approved by OMB, the final rule calls for DCR and ETA to use one management information system, the Standardized Program Information Record (SPIR), to the extent possible. The new paperwork submission reflects this arrangement.

List of Subjects in 29 CFR Part 34

Administrative practice and procedure, Aged, Aliens, Civil rights, Equal educational opportunity, Equal employment opportunity, Grant programs, Individuals with disabilities, Investigations, Reporting and recordkeeping requirements.

Signed at Washington, DC, this 8th day of January, 1993.

Lynn Martin,

Secretary of Labor.

Accordingly, title 29, subtitle A of the Code of Federal Regulations is amended by adding part 34 to read as set forth below:

PART 34—IMPLEMENTATION OF THE NONDISCRIMINATION AND EQUAL OPPORTUNITY REQUIREMENTS OF THE JOB TRAINING PARTNERSHIP ACT OF 1982, AS AMENDED (JTPA)

Subpart A—General Provisions

Sec.

34.1 Purpose; application.
34.2 Definitions.
34.3 Discrimination prohibited.
34.4 Specific discriminatory actions prohibited on the ground of race, color, religion, sex, national origin, age, political affiliation or belief, citizenship, or participation in JTPA.
34.5 Specific discriminatory actions prohibited on the ground of disability.
34.6 Communications with individuals with disabilities.
34.7 Employment practices.
34.8 Intimidation and retaliation prohibited.
34.9 Designation of responsible office: rulings and interpretations.
34.10 [Reserved].
34.11 Effect of other obligations or limitations.
34.12 Delegation and coordination.

Subpart B—Recordkeeping and Other Affirmative Obligations of Recipients

34.20 Assurance required; duration of obligation; covenants.
34.21 Equitable services.
34.22 Designation of Equal Opportunity Officer.
34.23 Dissemination of policy.
34.24 Data and information collection; confidentiality.

Subpart C—Governor's Responsibilities to Implement the Nondiscrimination and Equal Opportunity Requirements of JTPA

34.30 Application.
34.31 Recordkeeping.
34.32 Oversight and liability.
34.33 Methods of Administration.
34.34 Monitoring.

Subpart D—Compliance Procedures

34.40 Compliance reviews.
34.41 Notice to Show Cause.
34.42 Adoption of discrimination complaint processing procedures.
34.43 Complaints and investigations.
34.44 Corrective and remedial action.
34.45 Notice of violation; written assurances; Conciliation Agreements.
34.46 Final Determination.
34.47 Notice of finding of noncompliance.
34.48 Notification of Breach of Conciliation Agreement.

Subpart E—Federal Procedures for Effecting Compliance

34.50 General.
34.51 Hearings.
34.52 Decision and post-termination proceedings.
34.53 Suspension, termination, denial or discontinuance of Federal financial assistance under JTPA; alternate funds disbursal procedure.

Authority: 20 U.S.C. 1681; 29 U.S.C. 794, 1501, 1551, 1573, 1574, 1575, 1576, 1577, 1578, 1579; 42 U.S.C. 2000d et seq., 6101.

Subpart A—General Provisions

§ 34.1 Purpose; application.

(a) *Purpose.* The purpose of this part is to implement the nondiscrimination and equal opportunity provisions of the Job Training Partnership Act of 1982, as amended (JTPA), which are contained in section 167 of JTPA. Section 167 prohibits discrimination on the grounds of race, color, religion, sex, national origin, age, disability, political

affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA. This part clarifies the application of the nondiscrimination and equal opportunity provisions of JTPA and provides uniform procedures for implementing them.

(b) *Application of this part.* This part applies to any recipient, as defined in § 34.2. This part also applies to the employment practices of a recipient, as provided in § 34.7.

(c) *Effect of this part on other obligations.*

(1) A recipient's compliance with this part shall satisfy any obligation of the recipient to comply with 29 CFR part 31, implementing title VI of the Civil Rights Act of 1964, as amended (title VI), and with subparts A, D and E of 29 CFR part 32, implementing section 504 of the Rehabilitation Act of 1973, as amended (section 504).

(2) However, compliance with this part shall not affect any obligation of the recipient to comply with subparts B and C and appendix A of 29 CFR part 32, which pertain to employment practices and employment-related training, program accessibility, and accommodations under section 504.

(3) Recipients that are also public entities or public accommodations as defined by titles II and III of the Americans with Disabilities Act of 1991 (ADA), should be aware of obligations imposed pursuant to those titles.

(4) Compliance with this part does not affect, in any way, any obligation that a recipient may have to comply with Executive Order 11246, as amended, section 503 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 793), the affirmative action provisions of the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended (38 U.S.C. 4212), the Equal Pay Act of 1963, as amended (29 U.S.C. 206d), title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e et seq.), the Age Discrimination in Employment Act of 1967, as amended (29 U.S.C. 621), title IX of the Education Amendments of 1972, as amended (20 U.S.C. 1681), the Americans with Disabilities Act of 1990 (ADA) (42 U.S.C. 12101 et seq.) and their respective implementing regulations.

(5) This rule does not preempt consistent State and local requirements.

(6) The rule generally codifies and consolidates already existing nondiscrimination and equal opportunity requirements. However, to the extent that this rule imposes any new requirements, it is not intended to have retroactive effect.

(d) *Limitation of Application.* This part does not apply to:

(1) Programs or activities funded by the Department exclusively under laws other than JTPA;

(2) Contracts of insurance or guaranty;

(3) Federal financial assistance to a person who is the ultimate beneficiary under any program;

(4) Federal procurement contracts, with the exception of contracts to operate or provide services to Job Corps Centers; and

(5) Federally-operated Job Corps Centers. The operating Department is responsible for enforcing the nondiscrimination and equal opportunity laws to which such Centers are subject.

§ 34.2 Definitions.

As used in this part, the term:

Administrative Law Judge means a person appointed as provided in 5 U.S.C. 3105 and 5 CFR 930.203 and qualified under 5 U.S.C. 557 to preside at hearings held under the nondiscrimination and equal opportunity provisions of JTPA and this part.

Applicant means the person or persons seeking JTPA services who have filed a completed application and for whom a formal eligibility determination has been made. For State Employment Security Agency (SESA) programs, *applicant* means the person or persons who make(s) application to receive benefits or services from the State employment service agency or the State unemployment compensation agency. See also the definitions of *eligible applicant* and *participant* in this section.

Applicant for employment means the person or persons who make(s) application for employment with a recipient of Federal financial assistance under JTPA.

Application for assistance means the process by which required documentation is provided to the Governor, recipient, or Department prior to and as a condition of receiving Federal financial assistance under JTPA (including both new and continuing assistance).

Application for benefits means the process by which written information is provided by applicants or eligible applicants prior to and as a condition of receiving benefits or services from a recipient of financial assistance from the Department of Labor under JTPA.

Assistant Attorney General means the Assistant Attorney General, Civil Rights Division, United States Department of Justice.

Assistant Secretary means the Assistant Secretary for Administration and Management, United States Department of Labor.

Auxiliary aids or services includes–

(1) Qualified interpreters, notetakers, transcription services, written materials, telephone handset amplifiers, assistive listening systems, telephones compatible with hearing aids, closed caption decoders, open and closed captioning, telecommunications devices for deaf persons (TDDs), videotext displays, or other effective means of making aurally delivered materials available to individuals with hearing impairments;

(2) Qualified readers, taped texts, audio recordings, brailled materials, large print materials, or other effective means of making visually delivered materials available to individuals with visual impairments;

(3) Acquisition or modification of equipment or devices; and

(4) Other similar services and actions.

Beneficiary means the person or persons intended by Congress to receive benefits or services from a recipient of Federal financial assistance under JTPA.

Citizenship: See *Discrimination on the ground of citizenship.*

Department means the U.S. Department of Labor (DOL), including its agencies and organizational units.

Director means the Director, Directorate of Civil Rights (DCR), Office of the Assistant Secretary for Administration and Management, U.S. Department of Labor, or a designee authorized to act for the Director.

Directorate means the Directorate of Civil Rights (DCR), Office of the Assistant Secretary for Administration and Management, U.S. Department of Labor.

Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more of the major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment.

(1)(i) The phrase *physical or mental impairment* means—

(A) Any physiological disorder or condition, cosmetic disfigurement, or anatomical loss affecting one or more of the following body systems: Neurological, musculoskeletal, special sense organs, respiratory (including speech organs), cardiovascular, reproductive, digestive, genitourinary, hemic and lymphatic, skin, and endocrine;

(B) Any mental or psychological disorder such as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities.

(ii) The phrase *physical or mental impairment* includes, but is not limited to, such contagious and noncontagious diseases and conditions as orthopedic, visual, speech and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional illness, specific learning disabilities, HIV disease (whether symptomatic or asymptomatic), tuberculosis, drug addiction, and alcoholism. The term *impairment* does not include homosexuality or bisexuality.

(2) The phrase *major life activities* means functions such as caring for one's self, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning, and working.

(3) The phrase *has a record of such an impairment* means has a history of, or has been misclassified as having, a mental or physical impairment that substantially limits one or more major life activities.

(4) The phrase *is regarded as having an impairment* means—

(i) Has a physical or mental impairment that does not substantially limit major life activities but that is treated by the recipient as constituting such a limitation;

(ii) Has a physical or mental impairment that substantially limits major life activities only as a result of the attitudes of others toward such impairment; or

(iii) Has none of the impairments defined in paragraph (1) of this definition but is treated by the recipient as having such an impairment.

(5) Consistent with amendments to the Rehabilitation Act of 1973 and to the JTPA, and with the ADA, this part uses the term *disability* in place of the term *handicap*. The two terms are intended to have identical meanings.

Discrimination on the ground of citizenship means a denial of participation in programs or activities financially assisted in whole or in part under JTPA to persons on the basis of their status as citizens or nationals of the United States, lawfully admitted permanent resident aliens, lawfully admitted refugees and parolees, or other individuals authorized by the Attorney General to work in the United States.

Eligible applicant means an applicant who has been determined eligible to participate in one or more titles under JTPA.

Entity means any corporation, partnership, joint venture, unincorporated association, or State or local government, and any agency, instrumentality or subdivision of such a government.

Facility means all or any portion of buildings, structures, equipment, roads, walks, parking lots, rolling stock, or other real or personal property or interest in such property.

Federal financial assistance under JTPA means any grant, cooperative agreement, loan, contract; any subgrant made with a recipient of a grant or subcontract made pursuant to a JTPA contract; or any other arrangement by which the Department provides or otherwise makes available assistance under JTPA in the form of:

(1) Funds, including funds made available for the acquisition, construction, renovation, restoration or repair of a building or facility or any portion thereof;

(2) Services of Federal personnel; or

(3) Real or personal property or any interest in or use of such property, including:

(i) Transfers or leases of such property for less than fair market value or for reduced consideration;

(ii) Proceeds from a subsequent transfer or lease of such property if the Federal share of its fair market value is not returned to the Federal Government; or

(iii) Any other thing of value by way of grant, loan, contract, or cooperative agreement (other than a procurement contract or a contract of insurance or guaranty).

Governor means the chief elected official of any State or his or her designee.

Grant applicant means the entity which submits the required documentation to the Governor, recipient, or the Department, prior to and as a condition of receiving Federal financial assistance under JTPA.

Guideline means written informational material supplementing an agency's regulations and provided to grant applicants and recipients to provide program-specific interpretations of their responsibilities under the regulations.

Illegal use of drugs means the use of drugs, the possession or distribution of which is unlawful under the Controlled Substances Act. *Illegal use of drugs* does not include the use of a drug taken under supervision of a licensed health care professional, or other uses authorized by the Controlled Substances Act or other provisions of Federal law.

Individual with a disability means a person who has a disability, as defined in this section. The term *impairment* does not include homosexuality or bisexuality; therefore, the term *individual with a disability* does not include an individual on the basis of homosexuality or bisexuality.

(1) The term *individual with a disability* does not include an individual on the basis of:

(i) Transvestism, transsexualism, pedophilia, exhibitionism, voyeurism, gender identity disorders not resulting from physical impairments, or other sexual behavior disorders;

(ii) compulsive gambling, kleptomania, or pyromania; or

(iii) psychoactive substance use disorders resulting from current illegal use of drugs.

(2) The term *individual with a disability* also does not include an individual who is currently engaging in the illegal use of drugs, when a recipient acts on the basis of such use. This limitation should not be construed to exclude as an *individual with a disability* an individual who:

(i) Has successfully completed a supervised drug rehabilitation program and is no longer engaging in the illegal use of drugs, or has otherwise been rehabilitated successfully and is no longer engaging in such use;

(ii) Is participating in a supervised rehabilitation program and is no longer engaging in such use; or

(iii) Is erroneously regarded as engaging in such use, but is not engaging in such use, except that it shall not be a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part for a recipient to adopt or administer reasonable policies or procedures, including but not limited to drug testing, designed to ensure that an individual described in paragraph (2)(i) or (2)(ii) of this definition is no longer engaging in the illegal use of drugs.

(3) With regard to employment, the term *individual with a disability* does not include any individual who is an alcoholic whose current use of alcohol prevents such individual from performing the duties of the job in question or whose employment, by reason of such current alcohol abuse, would constitute a direct threat to property or the safety of others.

JTPA means the Job Training Partnership Act of 1982, as amended, Public Law 97–300, 96 Stat. 1322 (29 U.S.C. 1501 et seq.), including the Nontraditional Employment for Women Act of 1991, Public Law 102–235, 105 Stat. 1806 (29 U.S.C. 1501), and the Job Training Reform Amendments of 1992, Public Law 102–367, 106 Stat. 1021.

JTPA-funded program or activity means a program or activity, operated by a recipient and funded under JTPA, for the provision of services, financial aid, or other benefit to individuals (including but not limited to education or training, health, welfare, housing,

social service, rehabilitation or other services, whether provided through employees of the recipient or by others through contract or other arrangements with the recipient, and including work opportunities and cash, loan or other assistance to individuals), or for the provision of facilities for furnishing services, financial aid, or other benefits to individuals. It also includes services, financial aid, or other benefits provided in facilities constructed with the aid of Federal financial assistance under JTPA. It further includes services, financial aid, or other benefits provided with the aid of any non-JTPA funds, property, or other resources required to be expended or made available for the program to meet matching requirements or other conditions which must be met in order to receive the Federal financial assistance under JTPA.

Methods of Administration means the written document and supporting documentation developed pursuant to § 34.33.

National Programs means programs receiving Federal funds under JTPA directly from the Department. Such programs include, but are not limited to, programs funded under title IV of JTPA, such as the Migrant and Seasonal Workers Programs, Native Americans Programs, Job Corps, National Activities and such Veterans' Employment programs as are funded by the Department. *National programs* also includes programs funded under certain titles of the Nontraditional Employment for Women Act.

Noncompliance means a failure of a recipient to comply with any of the applicable requirements of the nondiscrimination and equal opportunity provisions of JTPA or this part.

Participant means an individual who has been determined to be eligible to participate in and who is receiving services (except post-termination and follow-up services) under a program authorized by JTPA. Participation shall be deemed to commence on the first day, following determination of eligibility, on which the participant began receiving subsidized employment, training, or other services provided under JTPA.

Parties to a hearing means the Department and the grant applicant(s) or recipient(s).

Prohibited ground means any basis upon which it is illegal to discriminate under the nondiscrimination and equal opportunity provisions of JTPA or this part, i.e., race, color, religion, sex, national origin, age, disability, political affiliation or belief, and, for beneficiaries only, citizenship or participation in JTPA.

Qualified individual with a disability means:

(1) With respect to employment, an individual with a disability who, with or without reasonable accommodation, is capable of performing the essential functions of the job in question;

(2) With respect to services, an individual with a disability who meets the essential eligibility requirements for the receipt of such services;

(3) With respect to employment and employment-related training programs, an individual with a disability who meets the eligibility requirements for participation in JTPA and who, with or without reasonable accommodation, is capable of performing the essential functions of the job or meets the qualifications of the training program, as applicable.

Recipient means any entity to which Federal financial assistance under any title of JTPA is extended, either directly or through the Governor or through another recipient (including any successor, assignee, or transferee of a recipient), but excluding the ultimate beneficiaries of the JTPA-funded program or activity and the Governor. *Recipient* includes, but is not limited to: Job Corps Centers and Center operators (excluding federally-operated Job Corps Centers), State Employment Security Agencies, State-level agencies that administer JTPA funds, SDA grant recipients, Substate grant recipients and service providers, as well as National Program recipients.

Respondent means the grant applicant or recipient against which a complaint has been filed pursuant to the nondiscrimination and equal opportunity provisions of JTPA or this part.

SDA grant recipient means the entity that receives JTPA funds for a service delivery area (SDA) directly from the Governor.

Secretary means the Secretary of Labor, U.S. Department of Labor, or his or her designee.

Service provider means the operator of any JTPA-funded program or activity that receives funds from or through an SDA grant recipient or a Substate grantee.

Small recipient means a recipient who serves fewer than 15 beneficiaries, and employs fewer than 15 employees at all times during a grant year.

Solicitor means the Solicitor of Labor, U.S. Department of Labor, or his or her designee.

State means the individual states of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, and Palau.

State Employment Security Agency (SESA) means the State agency which, under the State Administrator, contains both the State Employment Service agency (State agency) and the State unemployment compensation agency.

State Programs means programs funded in whole or in part under JTPA wherein the Governor and/or State receives and disburses the grant to or through SDA grant recipients or Substate grantees. Such programs include but are not limited to those programs funded in whole or in part under titles II or III of JTPA. *State programs* also includes *State Employment Security Agencies.*

Substate grantee means that agency or organization selected to administer programs pursuant to section 312(b) of JTPA. The Substate grantee is the entity that receives title III funds for a substate area directly from the Governor.

Terminee means a *participant* terminating during the applicable program year.

§ 34.3 Discrimination prohibited.

No individual in the United States shall, on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA, be excluded from participation in, denied the benefits of, subjected to discrimination under, or denied employment in the administration of or in connection with any JTPA-funded program or activity.

§ 34.4 Specific discriminatory actions prohibited on the ground of race, color, religion, sex, national origin, age, political affiliation or belief, citizenship, or participation in JTPA.

(a) For the purposes of this section, prohibited ground means race, color, religion, sex, national origin, age, political affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA. A recipient shall not, directly or through contractual, licensing, or other arrangements, on a prohibited ground:

(1) Deny an individual any service, financial aid, or benefit provided under the JTPA-funded program or activity;

(2) Provide any service, financial aid, or benefit to an individual which is different, or is provided in a different manner, from that provided to others under the JTPA-funded program or activity;

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(3) Subject an individual to segregation or separate treatment in any matter related to his or her receipt of any service, financial aid, or benefit under the JTPA-funded program or activity;

(4) Restrict an individual in any way in the enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or benefit under the JTPA-funded program or activity;

(5) Treat an individual differently from others in determining whether he or she satisfies any admission, enrollment, eligibility, membership, or other requirement or condition for any service, financial aid, function or benefit provided under the JTPA-funded program or activity;

(6) Deny or limit an individual with respect to any opportunity to participate in the JTPA-funded program or activity, or afford him or her an opportunity to do so which is different from that afforded others under the JTPA-funded program or activity;

(7) Deny an individual the opportunity to participate as a member of a planning or advisory body which is an integral part of the JTPA-funded program or activity;

(8) Aid or perpetuate discrimination by providing significant assistance to an agency, organization, or person that discriminates on a prohibited ground in providing any service, financial aid, or benefit to applicants or participants in the JTPA-funded program or activity;

(9) Refuse to accommodate a person's religious practices or beliefs, unless to do so would result in undue hardship; or

(10) Otherwise limit on a prohibited ground an individual in enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving any aid, benefit, service, or training.

(b) In determining the types of services, financial aid or other benefits or facilities that will be provided under any JTPA-funded program or activity, or the class of individuals to whom or the situations in which such services, financial aid, or other benefits or facilities will be provided, a recipient shall not use, directly or through contractual, licensing, or other arrangements, standards, procedures or criteria that have the purpose or effect of subjecting individuals to discrimination on a prohibited ground or that have the purpose or effect of defeating or substantially impairing, on a prohibited ground, accomplishment of the objectives of the JTPA-funded program or activity. This paragraph applies to the administration of JTPA-funded programs or activities providing services, financial aid, benefits or facilities in any manner, including, but not limited to, recruitment, registration, counseling, testing, guidance, selection, placement, appointment, training, referral, promotion and retention.

(c) In determining the site or location of facilities, a grant applicant or recipient may not make selections with the purpose or effect of excluding individuals from, denying them the benefits of, or subjecting them to discrimination on a prohibited ground, or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the program, or the nondiscrimination and equal opportunity provisions of JTPA or this part.

(d) The exclusion of an individual from programs or activities limited by Federal statute or Executive Order to a certain class or classes of individuals of which the individual in question is not a member is not prohibited by this part.

§ 34.5 Specific discriminatory actions prohibited on the ground of disability.

(a) In providing any aid, benefit, service or training under a JTPA-funded program or activity, a recipient shall not, directly or through contractual, licensing, or other arrangements, on the ground of disability:

(1) Deny a qualified individual with a disability the opportunity to participate in or benefit from the aid, benefit, service or training;

(2) Afford a qualified individual with a disability an opportunity to participate in or benefit from the aid, benefit, service or training that is not equal to that afforded others;

(3) Provide a qualified individual with a disability with an aid, benefit, service or training that is not as effective in affording equal opportunity to obtain the same result, to gain the same benefit, or to reach the same level of achievement as that provided to others;

(4) Provide different or separate aid, benefits, or services to individuals with disabilities or to any class of individuals with disabilities unless such action is necessary to provide qualified individuals with disabilities with aid, benefits, services or training that are as effective as those provided to others;

(5) Aid or perpetuate discrimination against a qualified individual with a disability by providing significant assistance to an agency, organization, or person that discriminates on the basis of disability in providing any aid, benefit, service or training to participants;

(6) Deny a qualified individual with a disability the opportunity to participate as a member of planning or advisory boards;

(7) Otherwise limit a qualified individual with a disability in enjoyment of any right, privilege, advantage, or opportunity enjoyed by others receiving any aid, benefit, service or training.

(b) A recipient may not deny a qualified individual with a disability the opportunity to participate in JTPA-funded programs or activities despite the existence of permissibly separate or different programs or activities.

(c) A recipient shall administer JTPA-funded programs and activities in the most integrated setting appropriate to the needs of qualified individuals with disabilities.

(d) A recipient may not, directly or through contractual or other arrangements, utilize criteria or administrative methods:

(1) That have the effect of subjecting qualified individuals with disabilities to discrimination on the ground of disability;

(2) That have the purpose or effect of defeating or substantially impairing accomplishment of the objectives of the JTPA-funded program or activity with respect to individuals with disabilities; or

(3) That perpetuate the discrimination of another entity if both entities are subject to common administrative control or are agencies of the same state.

(e) In determining the site or location of facilities, a grant applicant or recipient may not make selections with the purpose or effect of excluding individuals with disabilities from, denying them the benefits of, or otherwise subjecting them to discrimination under any JTPA-funded program or activity, or with the purpose or effect of defeating or substantially impairing the accomplishment of the objectives of the JTPA-funded program or activity or this part with respect to individuals with disabilities.

(f) As used in this section, references to the aid, benefit, service or training provided under a JTPA-funded program or activity include any aid, benefit, service or training provided in or through a facility that has been constructed, expanded, altered, leased, rented, or otherwise acquired, in whole or in part, with Federal financial assistance under JTPA.

(g) The exclusion of an individual without a disability from the benefits of a program limited by Federal statute or Executive Order to individuals with disabilities or the exclusion of a specific class of individuals with disabilities from a program limited by Federal statute or Executive Order to a different class of individuals with disabilities is not prohibited by this part.

(h) This part does not require a recipient to provide to individuals with disabilities: personal devices, such as wheelchairs; individually prescribed devices, such as prescription eyeglasses or hearing aids; readers for personal use or study; or services of a personal nature including assistance in eating, toileting, or dressing.

§ 34.6 Communications with individuals with disabilities.

(a) Recipients shall take appropriate steps to ensure that communications with beneficiaries, applicants, eligible applicants, participants, applicants for employment, employees and members of the public who are individuals with disabilities, are as effective as communications with others.

(b) A recipient shall furnish appropriate auxiliary aids or services where necessary to afford individuals with disabilities an equal opportunity to participate in, and enjoy the benefits of, the JTPA-funded program or activity. In determining what type of auxiliary aid or service is necessary, such recipient shall give primary consideration to the requests of the individual with a disability.

(c) Where a recipient communicates with beneficiaries, applicants, eligible applicants, participants, applicants for employment and employees by telephone, telecommunications devices for individuals with hearing impairments (TDDs), or equally effective communications systems shall be used.

(d) A recipient shall ensure that interested persons, including persons with visual or hearing impairments, can obtain information as to the existence and location of accessible services, activities, and facilities.

(e) A recipient shall provide signage at a primary entrance to each of its inaccessible facilities, directing users to a location at which they can obtain information about accessible facilities. The international symbol for accessibility shall be used at each primary entrance of an accessible facility.

(f) This section does not require a recipient to take any action that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens.

(1) In those circumstances where a recipient believes that the proposed action would fundamentally alter the JTPA-funded program, activity, or service, or would result in undue financial and administrative burdens, such recipient has the burden of proving that compliance with this section would result in such alteration or burdens.

(2) The decision that compliance would result in such alteration or burdens must be made by the recipient after considering all resources available for use in the funding and operation of the JTPA-funded program, activity, or service and must be accompanied by a written statement of the reasons for reaching that conclusion.

(3) If an action required to comply with this section would result in such an alteration or such burdens, the recipient shall take any other action that would not result in such an alteration or such burdens but would nevertheless ensure that, to the maximum extent possible, individuals with disabilities receive the benefits or services provided by the recipient.

§ 34.7 Employment practices.

(a) As used in this part, the term "employment practices" includes, but is not limited to, recruitment or recruitment advertising, selection, placement, layoff or termination, upgrading, demotion or transfer, training, participation in upward mobility programs, rates of pay or other forms of compensation, and use of facilities and other terms and conditions of employment.

(b) Discrimination on the ground of race, color, religion, sex, national origin, age, disability, or political affiliation or belief is prohibited in employment practices in the administration of, or in connection with, any JTPA-funded program or activity.

(c) *Employee selection procedures.* In implementing this section, a recipient shall comply with the Uniform Guidelines on Employee Selection Procedures, 41 CFR part 60–3.

(d) *Standards for employment-related investigations and reviews.* In any investigation or compliance review, the Director shall consider EEOC regulations, guidelines and appropriate case law in determining whether a recipient has engaged in an unlawful employment practice.

(e) As provided in § 34.1(c)(2) of this part, this rule does not affect in any way the obligation of recipients to comply with subparts B and C and appendix A of 29 CFR part 32, implementing the requirements of section 504 pertaining to employment practices and employment-related training, program accessibility, and accommodations. Therefore, this section should not be understood to constitute an exhaustive list of employment-related nondiscrimination and equal opportunity obligations on the ground of disability.

(f) Recipients that are also employers covered by titles I and II of the ADA should be aware of obligations imposed pursuant to those titles. See 29 CFR part 1630 and 28 CFR part 35.

(g) This rule does not preempt consistent State and local requirements.

§ 34.8 Intimidation and retaliation prohibited.

A recipient shall not discharge, intimidate, retaliate, threaten, coerce or discriminate against any person because such person has: filed a complaint; opposed a prohibited practice; furnished information; assisted or participated in any manner in an investigation, review, hearing or any other activity related to administration of, or exercise of authority under, or privilege secured by, the nondiscrimination and equal opportunity provisions of JTPA or this part; or otherwise exercised any rights and privileges under the nondiscrimination and equal opportunity provisions of JTPA or this part. The sanctions and penalties contained in section 167 of JTPA or this part may be imposed against any recipient that engages in any such proscribed activity or fails to take appropriate steps to prevent such activity.

§ 34.9 Designation of responsible office; rulings and interpretations.

(a) The Directorate of Civil Rights (DCR), in the Office of the Assistant Secretary for Administration and Management, is responsible for administering and enforcing the nondiscrimination and equal opportunity provisions of JTPA and this part and for developing and issuing policies, standards, guidelines and procedures for effecting compliance.

(b) The Director shall make any rulings under or interpretations of the nondiscrimination and equal opportunity provisions of JTPA or this part.

§ 34.10 [Reserved]

§ 34.11 Effect of other obligations or limitations.

(a) *Effect of State or local law or other requirements.* The obligation to comply with the nondiscrimination and equal opportunity provisions of JTPA or this part shall not be obviated or alleviated by any State or local law or other requirement that, on a prohibited ground, prohibits or limits an individual's eligibility to receive services, compensation or benefits, to participate in any JTPA-funded program or activity, or to be employed by any

recipient, or to practice any occupation or profession.

(b) *Effect of private organization rules.* The obligation to comply with the nondiscrimination and equal opportunity provisions of JTPA and this part shall not be obviated or alleviated by any rule or regulation of any private organization, club, league or association that, on a prohibited ground, prohibits or limits an individual's eligibility to participate in any JTPA-funded program or activity to which this part applies.

(c) *Effect of the availability of employment opportunities.* The availability of future employment opportunities, or lack thereof, in any occupation or profession for qualified individuals with disabilities or persons of a certain race, color, religion, sex, national origin, age, political affiliation or belief, or citizenship shall not be considered in recruiting, selecting or placing individuals in programs or activities.

§ 34.12 Delegation and coordination.

(a) The Secretary may from time to time assign to officials of other departments or agencies of the Government (with the consent of such department or agency) responsibilities in connection with the effectuation of the nondiscrimination and equal opportunity provisions of JTPA and this part (other than responsibility for final decisions pursuant to § 34.42), including the achievement of effective coordination and maximum uniformity within the Department and within the executive branch of the Government in the application of the nondiscrimination and equal opportunity provisions of JTPA or this part to similar programs and similar situations.

(b) Any action taken, determination made, or requirement imposed by an official of another department or agency acting pursuant to an assignment of responsibility under this subsection shall have the same effect as though such action had been taken by the Director.

(c) Whenever a compliance review or complaint investigation under this part reveals possible violation of Executive Order 11246, as amended, section 503 of the Rehabilitation Act of 1973, as amended, the affirmative action provisions of the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended (38 U.S.C. 4212), the Equal Pay Act of 1963, as amended, title VII of the Civil Rights Act of 1964, as amended, the Age Discrimination in Employment Act of 1967, as amended, the Americans With Disabilities Act, or any other Federal civil rights law, that is not also a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part, the Director shall attempt to notify the appropriate agency and provide it with all relevant documents and information.

Subpart B—Recordkeeping and Other Affirmative Obligations of Recipients

§ 34.20 Assurance required; duration of obligation; covenants.

(a) *Assurance.* (1) Each application for Federal financial assistance under JTPA, as defined in § 34.2, shall include an assurance, in the following form, with respect to the operation of the JTPA-funded program or activity and all agreements or arrangements to carry out the JTPA-funded program or activity:

> As a condition to the award of financial assistance under JTPA from the Department of Labor, the grant applicant assures, with respect to operation of the JTPA-funded program or activity and all agreements or arrangements to carry out the JTPA-funded program or activity, that it will comply fully with the nondiscrimination and equal opportunity provisions of the Job Training Partnership Act of 1982, as amended (JTPA), including the Nontraditional Employment for Women Act of 1991; title VI of the Civil Rights Act of 1964, as amended; section 504 of the Rehabilitation Act of 1973, as amended; the Age Discrimination Act of 1975, as amended; title IX of the Education Amendments of 1972, as amended; and with all applicable requirements imposed by or pursuant to regulations implementing those laws, including but not limited to 29 CFR part 34. The United States has the right to seek judicial enforcement of this assurance.

(2) The assurance shall be deemed incorporated by operation of law in the grant, cooperative agreement, contract or other arrangement whereby Federal financial assistance under JTPA is made available, whether or not it is physically incorporated in such document and whether or not there is a written agreement between the Department and the recipient, between the Department and the Governor, between the Governor and the recipient, or between recipients. The assurance may also be incorporated by reference in such grants, cooperative agreements, contracts or other arrangements.

(b) *Continuing State programs.* Each application by a State or a State agency to carry out a continuing JTPA-funded program or activity shall, as a condition to its approval and the extension of any Federal financial assistance under JTPA pursuant to the application, provide a statement that the JTPA-funded program or activity is (or, in the case of a new JTPA-funded program or activity, will be) conducted in compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part. The State shall certify that it has developed and maintains a Methods of Administration pursuant to § 34.33.

(c) *Duration and scope of obligation.* (1) Where the Federal financial assistance under JTPA is to provide or is in the form of personal property or real property or interest therein or structures thereon, the assurance shall obligate the recipient, or (in the case of a subsequent transfer) the transferee, for the period during which the property is used for a purpose for which Federal financial assistance under JTPA is extended, or for as long as the recipient retains ownership or possession of the property, whichever is longer.

(2) In all other cases, the assurance shall obligate the recipient for the period during which Federal financial assistance under JTPA is extended.

(d) *Covenants.* (1) Where Federal financial assistance under JTPA is provided in the form of a transfer of real property, structures, or improvements thereon, or interests therein, the instrument effecting or recording the transfer shall contain a covenant assuring nondiscrimination and equal opportunity for the period during which the real property is used for a purpose for which the Federal financial assistance under JTPA is extended.

(2) Where no Federal transfer of real property or interest therein from the Federal Government is involved, but real property or an interest therein is acquired or improved under a program of Federal financial assistance under JTPA, the recipient shall include such covenant described in paragraph (d)(1) of this section in the instrument effecting or recording any subsequent transfer of such property.

(3) When the property is obtained from the Federal Government, such covenant described in paragraph (d)(1) of this section may also include a condition coupled with a right of reverter to the Department in the event of a breach of the covenant.

§ 34.21 Equitable services.

Recipients shall make efforts to provide equitable services among substantial segments of the population eligible for participation in JTPA. Such efforts shall include but not be limited to outreach efforts to broaden the composition of the pool of those considered for participation, to include members of both sexes, the various race/ethnicity and age groups, and individuals with disabilities.

§ 34.22 Designation of Equal Opportunity Officer.

(a) A recipient, other than a small recipient or service provider as defined

in § 34.2, shall designate an Equal Opportunity Officer to coordinate its responsibilities under this part. Such responsibilities include, but are not limited to, serving as the recipient's liaison with the Directorate and overseeing the development and implementation of the Methods of Administration pursuant to § 34.33. The Equal Opportunity Officer shall report on equal opportunity matters directly to the State JTPA Director, Governor's JTPA Liaison, Job Corps Center Director, SESA Administrator, or chief executive officer of the SDA or substate grant recipient, as applicable. The Director may require the Equal Opportunity Officer and his or her staff to undergo training, the expenses of which shall be the responsibility of the recipient. The recipient shall make public the name, title of position, address and telephone number of the Equal Opportunity Officer.

(b) Recipients shall assign sufficient staff and resources to the Equal Opportunity Officer to ensure compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part.

(c) Small recipients shall designate an individual responsible for the adoption and publication of complaint procedures and the processing of complaints pursuant to § 34.42.

(d) Service providers as defined by § 34.2 shall not be required to designate an Equal Opportunity Officer. The responsibility for ensuring service provider compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part shall rest with the Governor, SDA grant recipient or Substate grantee, as provided in the State's Methods of Administration.

§ 34.23 Dissemination of policy.

(a) *Initial and Continuing Notice.* (1) A recipient shall provide initial and continuing notice that it does not discriminate on any prohibited ground, to: Applicants, eligible applicants, participants, applicants for employment, employees, and members of the public, including those with impaired vision or hearing, and unions or professional organizations holding collective bargaining or professional agreements with the recipient.

(2) The notice requirement imposed pursuant to paragraph (a)(1) of this section requires, at a minimum, that the notice specified in paragraph (a)(5) of this section be: posted prominently, in reasonable numbers and places; disseminated in internal memoranda and other written communications; included in handbooks or manuals; and made available to each participant and made a part of the participant's file. The required notice to the public applicable to generally-distributed publications is contained in paragraph (b) of this section.

(3) The recipient shall provide that the initial and continuing notice required by paragraph (a) of this section be provided in appropriate formats to individuals with visual impairments. Where notice has been given in an alternate format to a participant with a visual impairment, a record that such notice has been given shall be made a part of the participant's file.

(4) The notice required by paragraph (a) of this section must be provided within 90 days of the effective date of this part or of the date this part first applies to the recipient, whichever comes later.

(5) The notice required by paragraph (a) of this section shall contain the following prescribed language:

Equal Opportunity Is the Law

This recipient is prohibited from discriminating on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship or participation in programs funded under the Job Training Partnership Act, as amended (JTPA), in admission or access to, opportunity or treatment in, or employment in the administration of or in connection with, any JTPA-funded program or activity. If you think that you have been subjected to discrimination under a JTPA-funded program or activity, you may file a complaint within 180 days from the date of the alleged violation with the recipient's Equal Opportunity Officer (or the person designated for this purpose), or you may file a complaint directly with the Director, Directorate of Civil Rights (DCR), U.S. Department of Labor, 200 Constitution Avenue NW., room N–4123, Washington, DC 20210. If you elect to file your complaint with the recipient, you must wait until the recipient issues a decision or until 60 days have passed, whichever is sooner, before filing with DCR (see address above). If the recipient has not provided you with a written decision within 60 days of the filing of the complaint, you need not wait for a decision to be issued, but may file a complaint with DCR within 30 days of the expiration of the 60-day period. If you are dissatisfied with the recipient's resolution of your complaint, you may file a complaint with DCR. Such complaint must be filed within 30 days of the date you received notice of the recipient's proposed resolution.

(6) The Governor, the SDA grant recipient or the Substate grantee, as determined by the Governor in that State's Methods of Administration, shall be responsible for meeting the notice requirement of paragraph (a) of this section with respect to its service providers.

(7) Recipient's responsibility to provide notice. Whenever a recipient passes on Federal financial assistance under JTPA to another recipient, the recipient passing on such assistance shall provide the recipient receiving the assistance with the notice prescribed in paragraph (a)(5) of this section.

(b) *Publications.* (1) In recruitment brochures and other materials which are ordinarily distributed to the public to describe programs funded under JTPA or the requirements for participation by recipients and participants, recipients shall indicate that the JTPA-funded program or activity in question is an "equal opportunity employer/program" and that "auxiliary aids and services are available upon request to individuals with disabilities." Where such materials indicate that the recipient may be reached by telephone, the materials shall state the telephone number of the TDD or relay service used by the recipient, as required by § 34.6.

(2) Recipients required by law or regulation to publish or broadcast program information in the news media shall ensure that such publications and broadcasts state that the JTPA-funded program or activity in question is an equal opportunity employer/program (or otherwise indicate that discrimination in the JTPA-funded program or activity is prohibited by Federal law), and indicate that auxiliary aids and services are available upon request to individuals with disabilities.

(3) A recipient shall not use or distribute a publication of the type described in paragraph (b) of this section which suggests, by text or illustration, that such recipient treats beneficiaries, applicants, participants, employees or applicants for employment differently on any prohibited ground specified in § 34.1(a), except as such treatment is otherwise permitted under Federal law or this part.

(c) *Services or information in a language other than English.* A significant number or proportion of the population eligible to be served or likely to be directly affected by a JTPA-funded program or activity may need service or information in a language other than English in order that they be effectively informed of or able to participate in the JTPA-funded program or activity. In such circumstances, the recipient shall take reasonable steps, considering the scope of the program and the size and concentration of such population, to provide to such persons, in appropriate languages, the information needed; the initial and continuing notice required pursuant to paragraph (a) of this section; and such written materials as are

distributed pursuant to paragraph (b) of this section.

(d) *Orientation.* The recipient shall, during each presentation to orient new participants and/or new employees to its JTPA-funded program or activity, include a discussion of participants' and/or employees' rights under the nondiscrimination and equal opportunity provisions of JTPA and this part, including the right to file a complaint of discrimination with the recipient or the Director.

(e) As provided in § 34.6, the recipient shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others.

§ 34.24 Data and information collection; confidentiality.

(a) *Data and information collection.* The Director shall not require submission of data that can be obtained from existing reporting requirements or sources, including those of other agencies, if the source is known and available to the Director.

(1) Each recipient shall collect such data and maintain such records, in accordance with procedures prescribed by the Director, as the Director finds necessary to determine whether the recipient has complied or is complying with the nondiscrimination and equal opportunity provisions of JTPA or this part.

(2) Such records shall include, but are not limited to, records on applicants, eligible applicants, participants, terminees, employees and applicants for employment. Each recipient shall record the race/ethnicity, sex, age, and where known, disability status, of every applicant, eligible applicant, participant, terminee, applicant for employment and employee. Such information shall be stored in such a manner as to ensure confidentiality and shall be used only for the purposes of recordkeeping and reporting; determining eligibility, where appropriate, for JTPA-funded programs or activities; determining the extent to which the recipient is operating its JTPA-funded program or activity in a nondiscriminatory manner; or other use authorized by the nondiscrimination and equal opportunity provisions of JTPA or this part.

(3) In addition to the information which shall be collected, maintained, and upon request, submitted to the Directorate pursuant to paragraphs (a)(1) and (a)(2) of this section:

(i) Each grant applicant and recipient shall promptly notify the Director of any administrative enforcement actions or lawsuits filed against it alleging discrimination on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, and for beneficiaries only, citizenship or participation in JTPA;

(ii) Each grant applicant (as part of its application) and recipient (as part of a compliance review conducted pursuant to § 34.40 (b) or (c), or monitoring activity carried out pursuant to § 34.34) shall provide: the name of any other Federal agency that conducted a civil rights compliance review or complaint investigation during the two preceding years in which the grant applicant or recipient was found to be in noncompliance; and shall identify the parties to, the forum of, and case numbers pertaining to, any administrative enforcement actions or lawsuits filed against it during the two years prior to its application (or, with respect to recipients, its renewal application) which allege discrimination on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, citizenship or participation in JTPA;

(iii) Each recipient shall maintain a log of complaints filed with it that allege discrimination on the ground of race, color, religion, sex, national origin, age, disability, political affiliation or belief, citizenship or participation in JTPA. The log shall include: the name and address of the complainant; the ground of the complaint, i.e., race, color, religion, sex, national origin, age, disability, political affiliation or belief, citizenship or participation in JTPA; a description of the complaint; the date the complaint was filed; the disposition and date of disposition of the complaint; and other pertinent information.

(4) At the discretion of the Director, grant applicants and recipients may be required to provide such information and data as are necessary to investigate complaints and conduct compliance reviews on grounds prohibited under the nondiscrimination and equal opportunity provisions of JTPA and this part, other than race/ethnicity, sex, age, and disability.

(5) At the discretion of the Director, recipients may be required to provide such particularized information and/or to submit such periodic reports as the Director deems necessary to determine compliance with the nondiscrimination and equal opportunity provisions of JTPA or this part.

(6) At the discretion of the Director, grant applicants may be required to submit such particularized information as is necessary to determine whether or not the grant applicant, if funded, would be able to comply with the nondiscrimination and equal opportunity provisions of JTPA or this part.

(7) Service Providers. A service provider's responsibility for collecting and maintaining the information required pursuant to this section may be assumed by the Governor, SDA grant recipient or Substate grantee, as provided in the State's Methods of Administration.

(b) *Access to sources of information.* (1) Each grant applicant and recipient shall permit access by the Director during normal business hours to its premises and to its employees and participants, to the extent that such individuals are on the premises during the course of the investigation, for the purpose of conducting complaint investigations, compliance reviews, monitoring activities associated with a State's development and implementation of a Methods of Administration, and inspecting and copying such books, records, accounts and other materials as may be pertinent to ascertain compliance with and ensure enforcement of the nondiscrimination and equal opportunity provisions of JTPA or this part.

(2) Asserted considerations of privacy or confidentiality shall not be a basis for withholding information from the Directorate and shall not bar the Directorate from evaluating or seeking to enforce compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part. Information obtained pursuant to the requirements of this part shall be used only in connection with compliance and enforcement activities pertinent to the nondiscrimination and equal opportunity provisions of JTPA and this part. Whenever any information required of a grant applicant or recipient is in the exclusive possession of another agency or institution which, or person who, fails or refuses to furnish such information, the grant applicant or recipient shall provide certification to the Directorate of such refusal and the efforts it has made to obtain the information.

(c) *Record retention requirements.* (1) Each recipient shall maintain for a period of not less than three years from the close of the applicable program year, applicant, eligible applicant, participant, terminee, employee and applicant for employment records; and such other records as are required under this part or by the Director. (2) Records regarding complaints and actions taken thereunder shall be maintained for a period of not less than three years from the date of resolution of the complaint.

(d) *Confidentiality.* The identity of any person who furnishes information

relating to, or assisting in, an investigation or a compliance review shall be kept confidential to the extent possible, consistent with a fair determination of the issues. A person whose identity it is necessary to disclose shall be protected from retaliation (see § 34.8).

(e) Where designation of persons by race or ethnicity is required, the guidelines of the Office of Management and Budget shall be used.

Subpart C—Governor's Responsibilities to Implement the Nondiscrimination and Equal Opportunity Requirements of JTPA

§ 34.30 Application.

This subpart applies to State Programs as defined in § 34.2. However, the provisions of § 34.32 (b) and (c) do not apply to State Employment Security Agencies (SESAs), because the Governor's liability for any noncompliance on the part of a SESA cannot be waived.

§ 34.31 Recordkeeping.

The Governor shall ensure that recipients collect and maintain records in a manner consistent with the provisions of § 34.24 and any procedures prescribed by the Director pursuant to § 34.24(a)(1). The Governor shall further ensure that recipients are able to provide data and reports in the manner prescribed by the Director.

§ 34.32 Oversight and liability.

(a) The Governor shall be responsible for oversight of all JTPA-funded State programs. This responsibility includes ensuring compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part, and negotiating with the recipient to secure voluntary compliance when noncompliance is found under § 34.45.

(b) The Governor and the recipient shall be jointly and severally liable for all violations of the nondiscrimination and equal opportunity provisions of JTPA and this part by the recipient, unless the Governor has:

(1) Established and adhered to a Methods of Administration, pursuant to § 34.33, designed to give reasonable guarantee of the recipient's compliance with such provisions;

(2) Entered into a written contract with the recipient which clearly establishes the recipient's obligations regarding nondiscrimination and equal opportunity;

(3) Acted with due diligence to monitor the recipient's compliance with these provisions; and

(4) Taken prompt and appropriate corrective action to effect compliance.

(c) If the Director determines that the Governor has demonstrated substantial compliance with the requirements of paragraph (b) of this section, he or she may recommend to the Secretary that the imposition of sanctions against the Governor be waived and that sanctions be imposed only against the noncomplying recipient.

§ 34.33 Methods of Administration.

(a)(1) Each Governor shall establish and adhere to a Methods of Administration for State programs as defined in § 34.2. In those States in which one agency contains both SESA and JTPA programs, the Governor may develop a combined Methods of Administration.

(2) Each Methods of Administration shall be designed to give reasonable guarantee that all recipients will comply and are complying with the nondiscrimination and equal opportunity provisions of JTPA and this part.

(b) The Methods of Administration shall be:

(1) In writing;

(2) Updated periodically as required by the Director; and

(3) Signed by the Governor.

(c) The Methods of Administration shall, at a minimum:

(1) Describe how the requirements of §§ 34.20, 34.21, 34.22, 34.23, 34.24, 34.31, and 34.42 have been satisfied; and

(2) Include the following additional elements:

(i) A system for periodically monitoring the compliance of recipients with this part, including a determination as to whether the recipient is conducting its JTPA-funded program or activity in a nondiscriminatory way;

(ii) A system for reviewing the nondiscrimination and equal opportunity provisions of job training plans, contracts, assurances, and other similar agreements;

(iii) Procedures for ensuring that recipients provide accessibility to individuals with disabilities;

(iv) A system of policy communication and training to ensure that members of the recipients' staffs who have been assigned responsibilities pursuant to the nondiscrimination and equal opportunity provisions of JTPA or this part are aware of and can effectively carry out these responsibilities;

(v) Procedures for obtaining prompt corrective action or, as necessary, applying sanctions when noncompliance is found; and

(vi) Supporting documentation to show that the commitments made in the Methods of Administration have been and/or are being carried out. Supporting documentation includes, but is not limited to: policy and procedural issuances concerning required elements of the Methods of Administration; copies of monitoring instruments and instructions; evidence of the extent to which nondiscrimination and equal opportunity policies have been developed and communicated pursuant to this part; information reflecting the extent to which Equal Opportunity training, including training called for by § 34.22, is planned and/or has been carried out; as applicable, reports of monitoring reviews and reports of follow-up actions taken thereunder where violations have been found, including, where appropriate, sanctions; and copies of any notification made pursuant to § 34.23.

(d) The Governor shall, within 180 days of the effective date of this part:

(1) Develop and implement Methods of Administration consistent with the requirements of this part, and

(2) Submit a copy of the Methods of Administration to the Director.

§ 34.34 Monitoring.

(a) The Director may periodically review the adequacy of the Methods of Administration established by a Governor, as well as the adequacy of the Governor's performance under that Methods of Administration, to determine compliance with the requirements of § 34.33. The Director may review the Methods of Administration during a compliance review under § 34.40, or at another time.

(b) Nothing in this subpart shall limit or preclude the Director from monitoring directly any JTPA recipient or from investigating any matter necessary to determine a recipient's compliance with the nondiscrimination and equal opportunity provisions of JTPA or this part.

(c) The procedures contained in subpart D of this part shall apply to reviews or investigations undertaken pursuant to paragraphs (a) and (b) of this section.

Subpart D—Compliance Procedures

§ 34.40 Compliance reviews.

(a) The Director may from time to time conduct pre- and post-approval compliance reviews of grant applicants for and recipients of Federal financial assistance under JTPA to determine compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part. Techniques used in such reviews may include desk reviews, on-site reviews, and off-site analyses.

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(b) *Pre-approval reviews.* (1) As appropriate and necessary to ensure compliance with the nondiscrimination and equal opportunity provisions of JTPA or this part, the Director may review any application, or class of applications, for Federal financial assistance under JTPA prior to and as a condition of their approval. The basis for such review shall be the assurance specified in § 34.20, information and reports submitted by the grant applicant pursuant to this part or guidelines published by the Director, and any relevant records on file with the Department.

(2) Where the Director determines that the grant applicant for Federal financial assistance under JTPA, if funded, would not comply with the nondiscrimination and equal opportunity requirements of JTPA or this part, the Director shall issue a Letter of Findings. Such Letter of Findings shall advise the grant applicant, in writing, of:

(i) The preliminary findings of the review;

(ii) The proposed remedial or corrective action pursuant to § 34.44 and the time within which the remedial or corrective action should be completed;

(iii) Whether it will be necessary for the grant applicant to enter into a written Conciliation Agreement as described in § 34.45; and

(iv) The opportunity to engage in voluntary compliance negotiations.

(3) If a grant applicant has agreed to certain remedial or corrective actions in order to receive Federal financial assistance under JTPA, the Department shall ensure that the remedial or corrective actions have been taken or that a Conciliation Agreement has been entered into, prior to approving the award of further assistance under JTPA. If a grant applicant refuses or fails to take remedial or corrective actions or to enter into a Conciliation Agreement, as applicable, the Director shall follow the procedures outlined in § 34.46.

(4) The Director shall notify, in a timely manner, the departmental granting agency of the findings of the pre-approval compliance review.

(c) *Post-approval reviews.* (1) The Director may initiate a post-approval review of any recipient to determine compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part. The initiation of a review may be based on, but need not be limited to, the following: The results of routine program monitoring, the nature of or incidence of complaints, the date of the last review, and Congressional or community concerns.

(2) Such review shall be initiated by a Notification Letter, advising the recipient of:

(i) The practices to be reviewed;

(ii) The programs to be reviewed;

(iii) The data to be submitted by the recipient within 30 days of the receipt of the Notification Letter; and

(iv) The opportunity, at any time prior to receipt of the Final Determination described in § 34.46, to make a documentary or other submission which explains, validates or otherwise addresses the practices under review.

(3) Except as provided in § 34.41(e), within 210 days of issuing a Notification Letter initiating a review, the Director shall:

(i) Issue a Letter of Findings, which shall advise the recipient, in writing, of:

(A) The preliminary findings of the review;

(B) Where appropriate, the proposed remedial or corrective action to be taken, and the time by which such action should be completed, as provided in § 34.44;

(C) Whether it will be necessary for the recipient to enter into a written assurance and/or Conciliation Agreement, as provided in § 34.45; and

(D) The opportunity to engage in voluntary compliance negotiations.

(ii) Where no violation is found, the recipient shall be so informed in writing.

(4) The time limit for submitting data to the Director pursuant to paragraph (c)(2)(iii) of this section may be modified by the Director.

§ 34.41 Notice to Show Cause.

(a) The Director may issue a Notice to Show Cause to a recipient failing to comply with the requirements of this part, where such failure results in the inability of the Director to make a finding. Such a failure includes, but is not limited to, the failure or refusal to:

(1) Submit requested data within 30 days of the receipt of the Notification Letter;

(2) Submit documentation requested during a compliance review; or

(3) Provide the Directorate access to a recipient's premises or records during a compliance review.

(b) The Notice to Show Cause shall contain:

(1) A description of the violation and a citation to the pertinent nondiscrimination or equal opportunity provision(s) of JTPA and this part;

(2) The corrective action necessary to achieve compliance or, as may be appropriate, the concepts and principles of acceptable corrective or remedial action and the results anticipated; and

(3) A request for a written response to the findings, including commitments to corrective action or the presentation of opposing facts and evidence.

(c) Such Notice to Show Cause shall give the recipient 30 days to show cause why enforcement proceedings under the nondiscrimination and equal opportunity provisions of JTPA or this part should not be instituted. A recipient may make such a showing by, among other means:

(1) Correcting the violation(s) that brought about the Notice to Show Cause and entering into a written assurance and/or entering into a Conciliation Agreement, as appropriate, pursuant to § 34.45(d);

(2) Demonstrating that the Directorate does not have jurisdiction; or

(3) Demonstrating that the violation alleged by the Directorate did not occur.

(d) If the recipient fails to show cause why enforcement proceedings should not be initiated, the Director shall follow the procedures outlined in § 34.46.

(e) The 210 day requirement provided for in § 34.40(c)(3) shall be tolled during the pendency of a Notice to Show Cause.

§ 34.42 Adoption of discrimination complaint processing procedures.

(a) Each recipient shall adopt and publish procedures for processing complaints that allege a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part. The procedures shall provide for the prompt and equitable resolution of such complaints. In the case of service providers, the procedures required by this paragraph shall be adopted and published on behalf of the service provider by the Governor, the SDA grant recipient or the Substate grantee, as provided in the State's Methods of Administration.

(b) The recipient's Equal Opportunity Officer, or in the case of a small recipient, the person designated pursuant to § 34.22(c), shall be responsible for the adoption and publication of procedures pursuant to paragraph (a) of this section, and for ensuring that such procedures are followed.

(c) A recipient who processes a complaint alleging a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part shall provide the complainant with written notification of the resolution within 60 days of the filing of the complaint. Such notification shall include a statement of complainant's right to file a complaint with the Director.

§ 34.43 Complaints and investigations.

(a) *Who may file.* Any person who believes that he or she or any specific class of individuals has been or is being subjected to discrimination prohibited by the nondiscrimination and equal opportunity provisions of JTPA or this part may file a written complaint by him or herself or by a representative.

(b) *Where to file.* The complaint may be filed either with the recipient or with the Director.

(c) *Time for filing.* A complaint filed pursuant to this part must be filed within 180 days of the alleged discrimination. The Director, for good cause shown, may extend the filing time. This time period for filing is for the administrative convenience of the Directorate and does not create a defense for the respondent.

(d) *Contents of complaints.* Each complaint shall be filed in writing and shall:

(1) Be signed by the complainant or his or her authorized representative;

(2) Contain the complainant's name and address (or specify another means of contacting him or her);

(3) Identify the respondent; and

(4) Describe the complainant's allegations in sufficient detail to allow the Director or the recipient, as applicable, to determine whether:

(i) The Directorate or the recipient, as applicable, has jurisdiction over the complaint;

(ii) The complaint was timely filed; and

(iii) The complaint has apparent merit, i.e., whether the allegations, if true, would violate any of the nondiscrimination and equal opportunity provisions of JTPA or this part. The information required by this paragraph may be provided by completing and submitting the Directorate's Complaint Information and Privacy Act Consent Forms.

(e) *Right to Representation.* Each complainant and respondent has the right to be represented by an attorney or other individual of his or her own choice.

(f) *Election of recipient-level complaint processing.* Any person who elects to file his or her complaint with the recipient shall allow the recipient 60 days to process the complaint.

(1) If, during the 60-day period, the recipient offers the complainant a resolution of the complaint but the resolution offered is not satisfactory to the complainant, the complainant or his or her representative may file a complaint with the Director within 30 days after the recipient notifies the complainant of its proposed resolution.

(2) Within 60 days, the recipient shall offer a resolution of the complaint to the complainant, and shall notify the complainant of his or her right to file a complaint with the Director, and inform the complainant that this right must be exercised within 30 days.

(3) If, by the end of 60 days, the recipient has not completed its processing of the complaint or has failed to notify the complainant of the resolution, the complainant or his or her representative may, within 30 days of the expiration of the 60-day period, file a complaint with the Director.

(4) The Director may extend the 30-day time limit if the complainant is not notified as provided in paragraph (f)(2) of this section, or for other good cause shown.

(5) Notification of no jurisdiction. The recipient shall notify the complainant in writing immediately upon determining that it does not have jurisdiction over a complaint that alleges a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part. The notification shall also include the basis for such determination, as well as a statement of the complainant's right to file a written complaint with the Director within 30 days of receipt of the notification.

(g) *Complaints filed with the Director.*

(1) Notification of acceptance of complaint. The Director shall determine whether the Directorate will accept a complaint filed pursuant to this section. Where the Directorate accepts a complaint for investigation, he or she shall:

(i) Acknowledge acceptance of the complaint for investigation to the complainant and the respondent, and

(ii) Advise the complainant and respondent of the issues over which the Directorate has accepted jurisdiction.

(2) Any complainant, respondent, or the authorized representative of any complainant or respondent, may contact the Directorate for information regarding the complaint filed pursuant to this section.

(3) Where a complaint contains insufficient information, the Director shall seek the needed information from the complainant. If the complainant is unavailable after reasonable means have been used to locate him or her, or the information is not furnished within 15 days of the receipt of such request, the complaint file may be closed without prejudice upon notice sent to the complainant's last known address.

(4) The Director may issue a subpoena, as authorized by Section 163(c) of JTPA, directing the person named therein to appear and give testimony and/or produce documentary evidence, before a designated representative, relating to the complaint being investigated. Such attendance of witnesses, and the production of such documentary evidence, may be required from any place in the United States, at any designated time and place.

(5) Where the Directorate lacks jurisdiction over a complaint, he or she shall:

(i) So advise the complainant, indicating why the complaint falls outside the coverage of the nondiscrimination and equal opportunity provisions of JTPA or this part; and

(ii) Where possible, refer the complaint to an appropriate Federal, State or local authority.

(6) Where a complaint lacks apparent merit or has not been timely filed, it need not be investigated. Where a complaint will not be investigated, the Director shall so inform the complainant and indicate the basis for that determination.

(7) Where a complaint alleging discrimination based on age falls within the jurisdiction of the Age Discrimination Act of 1975, as amended, the Director shall refer the complaint in accordance with the provisions of 45 CFR 90.43(c)(3), and shall so advise the complainant and the respondent.

(8) Where a complaint solely alleges a charge of individual employment discrimination covered by the nondiscrimination and equal opportunity provisions of JTPA or this part and by title VII of the Civil Rights Act of 1964, as amended (42 U.S.C. 2000e to 2000e–17), the Equal Pay Act of 1963, as amended (29 U.S.C. 206(d)), or the Age Discrimination in Employment Act of 1976, as amended (29 U.S.C. 621, et seq.), the Director shall refer such "joint complaint" to the Equal Employment Opportunity Commission for investigation and conciliation under procedures for handling joint complaints at 29 CFR part 1691, and shall advise the complainant and the respondent of the referral.

(9) Determinations. The Director shall determine at the conclusion of the investigation of a complaint whether there is reasonable cause to believe that a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part has occurred.

(i) Upon making such a cause finding, the Director shall issue an Initial Determination. The Initial Determination shall notify the complainant and the respondent, in writing, of:

(A) The specific findings of the investigation;

(B) The proposed corrective or remedial action and the time by which the corrective or remedial action must be completed, as provided in § 34.44;

(C) Whether it will be necessary for the respondent to enter into a written agreement, as provided in § 34.45; and

(D) The opportunity to engage in voluntary compliance negotiations.

(ii) Where a no cause determination is made, the complainant and the respondent shall be so notified in writing. Such determination represents final agency action of the Department.

§ 34.44 Corrective and remedial action.

(a) A Letter of Findings, Notice to Show Cause, or Initial Determination, issued pursuant to §§ 34.40, 34.41 or 34.43 respectively, shall include the specific steps the grant applicant or recipient, as applicable, must take within a stated period of time in order to achieve voluntary compliance.

(b) Such steps shall include, but are not limited to:

(1) Actions to end and/or redress the violation of the nondiscrimination and equal opportunity provisions of JTPA or this part;

(2) Make whole relief where discrimination has been identified, including, as appropriate, back pay (which shall not accrue from a date more than 2 years prior to the filing of the complaint or the initiation of a compliance review) or other monetary relief; hire or reinstatement; retroactive seniority; promotion; benefits or other services discriminatorily denied; and

(3) Such other remedial or affirmative relief as the Director deems necessary, including but not limited to outreach, recruitment and training designed to ensure equal opportunity.

(c) Monetary relief may not be paid from Federal funds.

§ 34.45 Notice of violation; written assurances; Conciliation Agreements.

(a) *State Programs.* (1) Violations at State-office level. Where the Director has determined that a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part has occurred at the State-office level, he or she shall notify the Governor through the issuance of a Letter of Findings, Notice to Show Cause or Initial Determination, as appropriate, pursuant to §§ 34.40, 34.41 or 34.43 respectively. The Director may secure compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part through, among other means, the execution of a written assurance and/or Conciliation Agreement, pursuant to paragraph (d) of this section.

(2) Violations below State-office level. Where the Director has determined that a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part has occurred below the State-office level, the Director shall so notify the Governor and the violating recipient(s) through the issuance of a Letter of Findings, Notice to Show Cause or Initial Determination, as appropriate, pursuant to §§ 34.40, 34.41 or 34.43 respectively.

(i) Such issuance shall: (A) Direct the Governor to initiate negotiations immediately with the violating recipient(s) to secure compliance by voluntary means;

(B) Direct the Governor to complete such negotiations within 30 days of the Governor's receipt of the Notice to Show Cause or within 45 days of the Governor's receipt of the Letter of Findings or Initial Determination, as applicable. The Director reserves the right to enter into negotiations with the recipient at any time during the period. For good cause shown, the Director may approve an extension of time to secure voluntary compliance. The total time allotted to secure voluntary compliance shall not exceed 60 days.

(C) Include a determination as to whether compliance should be achieved by: Immediate correction of the violation(s) and written assurance that such violations have been corrected, pursuant to paragraph (d)(1) of this section; entering into a written Conciliation Agreement pursuant to paragraph (d)(2) of this section; or both.

(ii) If the Governor determines, at any time during the period described in paragraph (a)(2)(i)(B), that a recipient's compliance cannot be achieved by voluntary means, the Governor shall so notify the Director.

(iii) If the Governor is able to secure voluntary compliance pursuant to paragraph (a)(2)(i) of this section, he or she shall submit to the Director for approval, as applicable: written assurance that the required action has been taken, as described in paragraph (d)(1) of this section; and/or a copy of the Conciliation Agreement, as described in paragraph (d)(2) of this section.

(iv) The Director may disapprove any written assurance or Conciliation Agreement submitted for approval pursuant to paragraph (a)(2)(iii) of this section that fails to satisfy each of the applicable requirements provided in paragraph (d) of this section.

(b) *National Programs.* Where the Director has determined that a violation of the nondiscrimination and equal opportunity provisions of JTPA or this part has occurred in a National Program, he or she shall notify the National Program recipient by issuing a Letter of Findings, Notice to Show Cause or Initial Determination, as appropriate, pursuant to §§ 34.40, 34.41 or 34.43 respectively. The Director may secure compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part through, among other means, the execution of a written assurance and/or Conciliation Agreement pursuant to paragraph (d) of this section, as applicable.

(c) *Written assurance; Conciliation Agreement.* (1) Written assurance. A written assurance developed pursuant to this section must provide documentation that the violations listed in the Letter of Findings, Notice to Show Cause or Initial Determination, as applicable, have been corrected.

(2) Conciliation Agreement. A Conciliation Agreement developed pursuant to this section must:

(i) Be in writing;

(ii) Address each cited violation;

(iii) Specify the corrective or remedial action to be taken within a stated period of time to come into compliance;

(iv) Provide for periodic reporting, as determined by the Director, on the status of the corrective and remedial action;

(v) Provide that the violation(s) will not recur; and

(vi) Provide for enforcement for a breach of the agreement.

§ 34.46 Final Determination.

(a) The Director shall conclude that compliance cannot be secured through informal means when:

(1) The grant applicant or recipient fails or refuses to correct the violation(s) within the applicable time period established by the Letter of Findings, Notice to Show Cause or Initial Determination; or

(2) The Director has not approved an extension of time in which to secure voluntary compliance, pursuant to § 34.45(a)(2)(i)(B), and:

(i) Has not received notification pursuant to § 34.45(a)(2)(iii) that voluntary compliance has been achieved; or

(ii) Has disapproved a written assurance or Conciliation Agreement, pursuant to § 34.45(a)(2)(iv); or

(iii) Has received notice from the Governor, pursuant to § 34.44(a)(2)(ii), that voluntary compliance cannot be achieved.

(b) Upon so concluding, the Director may:

(1) Issue a Final Determination which shall:

(i) Specify the efforts made to achieve voluntary compliance and indicate that those efforts have been unsuccessful;

(ii) Identify those matters upon which the Directorate and the grant applicant or recipient continue to disagree;

(iii) List any modifications to the findings of fact or conclusions set forth in the Initial Determination, Notice to Show Cause or Letter of Findings;

(iv) Determine the liability of the grant applicant or recipient, as applicable, and establish the extent of the liability, as appropriate;

(v) Describe the corrective or remedial action that must be taken for the grant applicant or recipient to come into compliance;

(vi) Indicate that the failure of the grant applicant or recipient to come into compliance within 10 days of the receipt of the Final Determination may result, after opportunity for a hearing, in the termination or denial of the grant, or discontinuation of assistance, as appropriate, or in referral to the Department of Justice with a request to file suit;

(vii) Advise the grant applicant or recipient of the right to request a hearing, and reference the applicable procedures at § 34.51; and

(viii) Determine the Governor's liability, if any, in accordance with the provisions of § 34.32; or

(2) Refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted; or

(3) Take such other action as may be provided by law.

§ 34.47 Notice of finding of noncompliance.

Where a compliance review or complaint investigation results in a finding of noncompliance, the Director shall so notify: (a) the Departmental granting agency; and (b) the Assistant Attorney General.

§ 34.48 Notification of Breach of Conciliation Agreement.

(a) Where a Governor is a party to a Conciliation Agreement, the Governor shall immediately notify the Director of a recipient's breach of any such Conciliation Agreement.

(b) When it becomes known to the Director, through the Governor or by other means, that a Conciliation Agreement has been breached, the Director may issue a Notification of Breach of Conciliation Agreement.

(c) A Notification of Breach of Conciliation Agreement issued pursuant to this section shall be directed, as applicable, to the Governor and/or other party(ies) to the Conciliation Agreement.

(d) A Notification of Breach of Conciliation Agreement issued pursuant to paragraph (a) of this section shall:

(1) Specify the efforts made to achieve voluntary compliance and indicate that those efforts have been unsuccessful;

(2) Identify the specific provisions of the Conciliation Agreement violated;

(3) Determine liability for the violation and the extent of the liability, as appropriate;

(4) Indicate that failure of the violating party to come into compliance within 10 days of the receipt of the Notification of Breach of Conciliation Agreement may result, after opportunity for a hearing, in the termination or denial of the grant, or discontinuation of assistance, as appropriate, or in referral to the Department of Justice with a request from the Department to file suit;

(5) Advise the violating party of the right to request a hearing, and reference the applicable procedures at § 34.51(b); and

(6) Include a determination as to the Governor's liability, if any, in accordance with the provisions of § 34.32.

(e) Where enforcement action pursuant to a Notification of Breach of Conciliation Agreement is commenced, the Director shall so notify: the Departmental granting agency; and the Governor, recipient or grant applicant, as applicable.

Subpart E—Federal Procedures For Effecting Compliance

§ 34.50 General.

(a) *Sanctions; judicial enforcement.* If, following issuance of a Final Determination pursuant to § 34.46, or a Notification of Breach of Conciliation Agreement pursuant to § 34.48, compliance has not been achieved, the Secretary may:

(1) After opportunity for a hearing, suspend, terminate, deny or discontinue the Federal financial assistance under JTPA, in whole or in part;

(2) Refer the matter to the Attorney General with a recommendation that an appropriate civil action be instituted; or

(3) Take such action as may be provided by law.

(b) *Deferral of new grants.* When termination proceedings under § 34.51 have been initiated, the Department may defer action on applications for new financial assistance under JTPA until a Final Decision under § 34.52 has been rendered. Deferral is not appropriate when financial assistance under JTPA is due and payable under a previously approved application.

(1) New Federal financial assistance under JTPA includes all assistance for which an application or approval, including renewal or continuation of existing activities, or authorization of new activities, is required during the deferral period.

(2) New Federal financial assistance under JTPA does not include assistance approved prior to the beginning of termination proceedings or increases in funding as a result of changed computations of formula awards.

§ 34.51 Hearings.

(a) *Notice of opportunity for hearing.* As part of a Final Determination, or a Notification of Breach of a Conciliation Agreement, the Director shall include, and serve on the grant applicant or recipient (by certified mail, return receipt requested), a notice of opportunity for hearing.

(b) *Complaint; request for hearing; answer.*

(1) In the case of noncompliance which cannot be voluntarily resolved, the Final Determination or Notification of Breach of Conciliation Agreement shall be deemed the Department's formal complaint.

(2) To request a hearing, the grant applicant or recipient must file a written answer to the Final Determination or Notification of Breach of Conciliation Agreement, and a copy of the Final Determination or Notification of Breach of Conciliation Agreement, with the Office of the Administrative Law Judges.

(i) The answer must be filed within 30 days of the date of receipt of the Final Determination or Notification of Breach of Conciliation Agreement.

(ii) A request for hearing must be set forth in a separate paragraph of the answer.

(iii) The answer shall specifically admit or deny each finding of fact in the Final Determination or Notification of Breach of Conciliation Agreement. Where the grant applicant or recipient does not have knowledge or information sufficient to form a belief, the answer may so state and the statement shall have the effect of a denial. Findings of fact not denied shall be deemed admitted. The answer shall separately state and identify matters alleged as affirmative defenses and shall also set forth the matters of fact and law relied on by the grant applicant or recipient.

(3) The grant applicant or recipient must simultaneously serve a copy of its filing on the Office of the Solicitor, Civil Rights Division, Room N–2464, U.S. Department of Labor, 200 Constitution Avenue NW., Washington DC 20210.

(4)(i) The failure of a grant applicant or recipient to request a hearing under this paragraph, or to appear at a hearing for which a date has been set, is deemed

to be a waiver of the right to a hearing; and

(ii) Whenever a hearing is waived, all allegations of fact contained in the Final Determination or Notification of Breach of Conciliation Agreement shall be deemed admitted and the Final Determination or Notification of Breach of Conciliation Agreement shall be deemed the Final Decision of the Secretary as of the day following the last date by which the grant applicant or recipient was required to request a hearing or was to appear at a hearing. See § 34.52(b)(3).

(c) *Time and place of hearing.* Hearings shall be held at a time and place ordered by the Administrative Law Judge upon reasonable notice to all parties and, as appropriate, the complainant. In selecting a place for the hearing, due regard shall be given to the convenience of the parties, their counsel, if any, and witnesses.

(d) *Judicial process; evidence.*

(1) The Administrative Law Judge may use judicial process to secure the attendance of witnesses and the production of documents pursuant to Section 9 of the Federal Trade Commission Act (15 U.S.C. 49).

(2) Evidence. In any hearing or administrative review conducted pursuant to this part, evidentiary matters shall be governed by the standards and principles set forth in the Uniform Rules of Evidence issued by the Department of Labor's Office of Administrative Law Judges, 29 CFR part 18.

§ 34.52 Decision and post-termination proceedings.

(a) *Initial Decision.* After the hearing, the Administrative Law Judge shall issue an initial decision and order, containing findings and conclusions. The initial decision and order shall be served on all parties by certified mail, return receipt requested.

(b) *Exceptions; Final Decision.* (1) Final decision after a hearing. The initial decision and order shall become the Final Decision and Order of the Secretary unless exceptions are filed by a party or, in the absence of exceptions, the Secretary serves notice that the Secretary shall review the decision.

(i) A party dissatisfied with the initial decision and order may, within 45 days of receipt, file with the Secretary and serve on the other parties to the proceedings and on the Administrative Law Judge, exceptions to the initial decision and order or any part thereof.

(ii) Upon receipt of exceptions, the Administrative Law Judge shall index and forward the record and the initial decision and order to the Secretary within three days of such receipt.

(iii) A party filing exceptions must specifically identify the finding or conclusion to which exception is taken. Any exception not specifically urged shall be deemed to have been waived.

(iv) Within 45 days of the date of filing such exceptions, a reply, which shall be limited to the scope of the exceptions, may be filed and served by any other party to the proceeding.

(v) Requests for extensions for the filing of exceptions or replies thereto must be received by the Secretary no later than 3 days before the exceptions or replies are due.

(vi) If no exceptions are filed, the Secretary may, within 30 days of the expiration of the time for filing exceptions, on his or her own motion serve notice on the parties that the Secretary will review the decision.

(vii) Final Decision and Order. (A) Where exceptions have been filed, the initial decision and order of the Administrative Law Judge shall become the Final Decision and Order of the Secretary unless the Secretary, within 30 days of the expiration of the time for filing exceptions and any replies thereto, has notified the parties that the case is accepted for review. (B) Where exceptions have not been filed, the initial decision and order of the Administrative Law Judge shall become the Final Decision and Order of the Secretary unless the Secretary has served notice on the parties that the Secretary will review the decision, as provided in paragraph (b)(1)(vi) of this section.

(viii) Any case reviewed by the Secretary pursuant to this paragraph shall be decided within 180 days of the notification of such review. If the Secretary fails to issue a Final Decision and Order within the 180-day period, the initial decision and order of the Administrative Law Judge shall become the Final Decision and Order of the Secretary.

(2) Final Decision where a hearing is waived.

(i) If, after issuance of a Final Determination pursuant to § 34.46(a) or Notification of Breach of Conciliation Agreement pursuant to § 34.48, voluntary compliance has not been achieved within the time set by this part and the opportunity for a hearing has been waived as provided for in § 34.51(b)(3), the Final Determination or Notification of Breach of Conciliation Agreement shall be deemed the Final Decision of the Secretary.

(ii) When a Final Determination or Notification of Breach of Conciliation Agreement is deemed the Final Decision of the Secretary, the Secretary may, within 45 days, issue an order terminating or denying the grant or continuation of assistance or imposing other appropriate sanctions for the grant applicant or recipient's failure to comply with the required corrective and/or remedial actions, or referring the matter to the Attorney General for further enforcement action.

(3) Final agency action. A Final Decision and Order issued pursuant to § 34.52(b) constitutes final agency action.

(c) *Post-termination proceedings.* (1) A grant applicant or recipient adversely affected by a Final Decision and Order issued pursuant to paragraph (b) of this section shall be restored, where appropriate, to full eligibility to receive Federal financial assistance under JTPA if it satisfies the terms and conditions of such Final Decision and Order and brings itself into compliance with the nondiscrimination and equal opportunity provisions of JTPA and this part.

(2) A grant applicant or recipient adversely affected by a Final Decision and Order issued pursuant to paragraph (b) of this section may at any time petition the Director to restore its eligibility to receive Federal financial assistance under JTPA. A copy of the petition shall be served on the parties to the original proceeding which led to the Final Decision and Order issued pursuant to paragraph (b) of this section. Such petition shall be supported by information showing the actions taken by the grant applicant or recipient to comply with the requirements of paragraph (c)(1) of this section. The grant applicant or recipient shall have the burden of demonstrating that it has satisfied the requirements of paragraph (c)(1) of this section. Restoration to eligibility may be conditioned upon the grant applicant or recipient entering into a consent decree. While proceedings under this section are pending, sanctions imposed by the Final Decision and Order under paragraphs (b) (1) and (2) of this section shall remain in effect.

(3) The Director shall issue a written decision on the petition for restoration.

(i) If the Director determines that the requirements of paragraph (c)(1) of this section have not been satisfied, he or she shall issue a decision denying the petition.

(ii) Within 30 days of its receipt of the Director's decision, the recipient or grant applicant may file a petition for review of the decision by the Secretary, setting forth the grounds for its objection to the Director's decision.

(iii) The petition shall be served on the Director and on the Office of the Solicitor, Civil Rights Division.

(iv) The Director may file a response to the petition within 14 days.

(v) The Secretary shall issue the final agency decision denying or granting the recipient's or grant applicant's request for restoration to eligibility.

§ 34.53 Suspension, termination, denial or discontinuance of Federal financial assistance under JTPA; alternate funds disbursal procedure.

(a) Any action to suspend, terminate, deny or discontinue Federal financial assistance under JTPA shall be limited to the particular political entity, or part thereof or other recipient (or grant applicant) as to which the finding has been made and shall be limited in its effect to the particular program, or part thereof, in which the noncompliance has been found. No order suspending, terminating, denying or discontinuing Federal financial assistance under JTPA shall become effective until:

(1) The Director has issued a Final Determination pursuant to § 34.46 or Notification of Breach of Conciliation Agreement pursuant to § 34.48;

(2) There has been an express finding on the record, after opportunity for a hearing, of failure by the grant applicant or recipient to comply with a requirement imposed by or pursuant to the nondiscrimination and equal opportunity provisions of JTPA or this part;

(3) A Final Decision has been issued by the Secretary, the Administrative Law Judge's decision and order has become the Final Decision of the Secretary, or the Final Determination or Notification of Conciliation Agreement has been deemed the Final Decision of the Secretary, pursuant to § 34.52(b); and

(4) The expiration of 30 days after the Secretary has filed, with the committees of Congress having legislative jurisdiction over the program involved, a full written report of the circumstances and grounds for such action.

(b) When the Department withholds funds from a recipient or grant applicant under these regulations, the Secretary may disburse the withheld funds directly to an alternate recipient. In such case, the Secretary will require any alternate recipient to demonstrate:

(1) The ability to comply with these regulations; and

(2) The ability to achieve the goals of the nondiscrimination and equal opportunity provisions of JTPA.

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Environmental Protection Agency

40 CFR Part 82
Protection of Stratospheric Ozone; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL-4553-4]

Protection of Stratospheric Ozone

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This final rule establishes regulations to ban nonessential products releasing Class I ozone-depleting substances under section 610 of the Clean Air Act (the Act), as amended. This rulemaking prohibits the sale, distribution, or offer of sale or distribution, in interstate commerce of certain products containing or produced with CFCs after specified dates. In addition, it restricts the sale of chlorofluorocarbon-containing cleaning fluids for electronic and photographic equipment to commercial entities.

The products affected by this rulemaking use or contain chlorofluorocarbons (CFCs), the chemicals designated as Group I or Group III substances by the Clean Air Act, as amended in 1990. The products affected by this rulemaking include chlorofluorocarbon-propelled plastic party streamers and noise horns; chlorofluorocarbon-containing cleaning fluids for electronic and photographic equipment; plastic flexible and packaging foams produced with CFCs, except foam used in coaxial cable; and all aerosol products and pressurized dispensers containing chlorofluorocarbons except the following products: certain medical devices, lubricants, coatings or cleaning fluids for electrical or electronic equipment that contain CFC–11, CFC–12, or CFC–113, but no other CFCs, for nonpropellant purposes only; lubricants, coatings or cleaning fluids for aircraft maintenance that contain CFC–11 or CFC–113, but no other CFCs; mold release agents that contain CFC–11 or CFC–113, but no other CFCs, and that are used in the production of plastic and elastomeric materials; spinnerette lubricant/cleaning sprays that contain CFC–114, but no other CFCs, and that are used for synthetic fiber production; containers of CFCs used in plasma etching; document preservation sprays that contain CFC–113, but no other CFCs; and red pepper bear repellent sprays that contain CFC–113, but no other CFCs.

DATES: This final rule bans the sale, distribution, or offer of sale or distribution, in interstate commerce of the products specifically mentioned in § 82.66(a) effective on February 16, 1993. This rulemaking also bans the sale or distribution of the products specifically mentioned in § 82.66(b) effective on February 16, 1993. Finally, this rulemaking bans the sale, distribution, or offer of sale or distribution, in interstate commerce of the other products identified in this rulemaking as nonessential effective January 17, 1994.

ADDRESSES: Comments and materials supporting this rulemaking are contained in Air Docket No. A–91–39 (Docket) at: U.S. Environmental Protection Agency (LE–131), 401 M Street, SW., Washington, DC 20460. The Docket is located in room M–1500, First Floor Waterside Mall. Materials relevant to this rulemaking may be inspected from 8:30 a.m. to 12 noon and from 1:30 to 3:30 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Matthew C. Dinkel at (202) 233–9200, Stratospheric Protection Division, Office of Atmospheric Programs, Office of Air and Radiation, 6202J, 401 M Street SW., Washington, DC 20460.

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I. Background

A. Overview of the Problem

The stratospheric ozone layer protects the earth from ultraviolet (UV–B) radiation. Research conducted in the 1970s indicated that when certain industrially produced halocarbons (including chlorofluorocarbons, halons,

carbon tetrachloride and methyl chloroform) are released into the environment, they migrate into the stratosphere, where they contribute to the depletion of the ozone layer. To the extent depletion occurs, penetration of the atmosphere by UV–B radiation increases. Increased exposure to UV–B radiation produces health and environmental damage, including increased incidence of skin cancer and cataracts, suppression of the immune system, damage to crops and aquatic organisms, increased formation of ground-level ozone and increased weathering of outdoor plastics.

B. Aerosol Ban in 1978

The initial hypothesis linking chlorofluorocarbons and depletion of the stratospheric ozone layer appeared in a paper by Mario J. Molina and F.S. Rowland in 1974. Since that time, the scientific community has made remarkable advances in understanding atmospheric processes affecting stratospheric ozone and in analyzing data measuring ozone depletion, both over the polar regions and globally. In response to the initial research indicating that CFCs could cause stratospheric ozone depletion, EPA, the Consumer Product Safety Commission, and the Food and Drug Administration (FDA) acted on March 17, 1978 (43 FR 11301; 43 FR 11318) to ban the use of CFCs as aerosol propellants in all but "essential applications." During the mid-1970s, the use of CFCs as aerosol propellants constituted over 50 percent of total CFC consumption in the United States. The 1978 ban reduced the use of CFCs in aerosols in this country by approximately 95 percent, eliminating nearly half of the total U.S. consumption of these chemicals.

Some CFC aerosol products were specifically exempted from the ban based on a determination of "essentiality" (See Essential Use Determinations-Revised, 1978). Other pressurized dispensers containing CFCs were excluded from the ban because they did not fit the narrow definition of "aerosol propellant."

In the years following the aerosol ban, CFC use increased significantly in refrigeration, foam and solvent applications. By 1985, CFC use in the United States had surpassed pre-1974 levels and represented 29 percent of total global CFC consumption.

C. Montreal Protocol

Scientific research in the late 1970s and early 1980s produced additional evidence that chlorine and bromine could destroy stratospheric ozone on a global basis. In 1985, scientists discovered the existence of a substantial seasonal reduction in stratospheric ozone (an ozone "hole") over Antarctica each year. Subsequent studies linked this phenomenon to CFCs and suggested that some depletion of global stratospheric ozone levels had already occurred. In response to this research, many members of the international community began discussing the need for an international agreement to reduce global production of ozone-depleting substances. Because releases of CFCs from all areas mix in the atmosphere to affect stratospheric ozone globally, efforts to reduce emissions from specific products by only a few nations could quickly be offset by increases in emissions from other nations, leaving the risks to the ozone layer unchanged. EPA evaluated the risks of ozone depletion in Assessing the Risks of Trade Gases That Can Modify the Stratosphere (1987) and concluded that an international approach was necessary to effectively safeguard the ozone layer.

EPA participated in negotiations organized by the United Nations Environment Programme (UNEP) to achieve an international agreement to protect the ozone layer. In September 1987, the United States and 22 other countries signed the Montreal Protocol on Substances that Deplete the Ozone Layer. The 1987 Protocol called for a freeze in the production and consumption (defined as production plus imports minus exports of bulk chemicals) of CFC–11, –12, –113, –114, –115, and halon 1211, 1301 and 2402 at 1986 levels beginning in 1989, and a phased reduction of the CFCs to 50 percent of 1986 levels by 1998. Currently, 83 nations representing over 90 percent of the world's consumption are parties to the Protocol.

In its August 12, 1988 final rulemaking (53 FR 30566) EPA promulgated regulations implementing the requirements of the 1987 Protocol through a system of tradable allowances. EPA apportioned these allowances to producers and importers of these "controlled substances" based on their 1986 levels. To monitor industry's compliance with the production and consumption limits, EPA required recordkeeping and quarterly reporting and conducted periodic compliance reviews and inspections. This regulation took effect July 1, 1989.

D. Excise Tax

As part of the Omnibus Budget Reconciliation Act of 1989, the United States Congress levied an excise tax on the sale of CFCs and other chemicals which deplete the ozone layer, with specific exemptions for exports and recycling. The tax went into effect on January 1, 1990, and increases annually. By raising the cost of virgin controlled substances, the tax has created an incentive for industry to shift out of these substances and increase recycling activities, and it has encouraged the development of a market for alternative chemicals and processes. The original excise tax was amended by the Omnibus Budget Reconciliation Act of 1990 to include methyl chloroform, carbon tetrachloride and the other CFCs regulated by the amended Montreal Protocol and title VI of the Clean Air Act, as amended in 1990. The Energy Policy Act of 1992 revised and further increased the excise tax effective January 1, 1993.

E. London Amendments to the Montreal Protocol

Under the Montreal Protocol, the Parties are required to assess the science, economics and alternative technologies related to protection of the ozone layer every two years. In response to this requirement, the Parties issued their first scientific assessment in 1989 (see Environmental Effects Panel Report). In preparing the first scientific assessment required under the Protocol, scientists examined the data from the land-based monitoring stations and the total ozone measurement spectrometer (TOMS) satellite data and concluded that there had been global ozone depletion over the northern hemisphere as well. The scientific assessment reported that a three to five percent decrease in ozone levels had occurred between 1969 and 1986 in the northern hemisphere in the winter months that could not be attributed to known natural processes. In addition, further studies of the Antarctic ozone hole implicated chlorine as the main cause of ozone depletion over the Antarctic, and linked high chlorine concentrations to CFCs and other chlorinated and brominated compounds.

At the Second Meeting of the Protocol Parties, held in London on June 29, 1990, the Parties responded to this new evidence by reassessing and tightening the restrictions placed on these chemicals. The Parties to the Protocol passed amendments and adjustments which called for a full phaseout of the regulated CFCs and halons by 2000, a phaseout of carbon tetrachloride and "other CFCs" by 2000 and a phaseout of methyl chloroform by 2005. The Parties also passed a non-binding resolution regarding the use of hydrochlorofluorocarbons (HCFCs) as interim substitutes for CFCs. Partially halogenated HCFCs add much less chlorine to the stratosphere than the

fully halogenated CFCs, but still pose a significant threat to the ozone layer (See 56 FR 2420, January 22, 1991 for more information on the relative effects of different ozone-depleting substances).

F. Clean Air Act Amendments of 1990, Title VI

On November 15, 1990 the Clean Air Act Amendments of 1990 were signed into law. The Act required EPA to publish two lists of ozone-depleting substances, based on their ozone-depleting potentials (ODPs). The Act categorized CFCs, halons, carbon tetrachloride and methyl chloroform as Class I substances, substances that possess a high potential for destroying stratospheric ozone molecules. It also designated hydrochlorofluorocarbons as Class II substances, substances with a lesser, but still significant ozone depletion potential.

The other requirements in title VI of the amended Act include phaseout controls similar to those in the London Amendments, although the interim targets are more stringent and the phaseout date for methyl chloroform is earlier (2002). EPA has already promulgated regulations implementing the phaseout provisions contained in section 604 of the Act (57 FR 33754, July 30, 1992). Unlike the amended Montreal Protocol, the Clean Air Act, as amended, also restricts the uses of controlled ozone-depleting substances, including provisions to reduce emissions of controlled substances to the "lowest achievable level" in all use sectors (section 608); requires the recovery and recycling of refrigerant when servicing motor vehicle air conditioners (section 609); bans nonessential products (section 610); mandates warning labels (section 611); establishes a safe alternatives program (section 612); and requires revision of federal procurement policies to minimize government use of ozone-depleting substances (section 613). With the exception of the rulemakings implementing the phaseout (57 FR 33754, July 30, 1992) and section 609 (57 FR 31242, July 14, 1992), EPA is currently in the process of promulgating regulations pursuant to these statutory provisions.

One of the provisions of the Act which complements the nonessential products ban under section 610 is the Significant New Alternatives Policy (SNAP) program established under section 612. The SNAP program has been established to evaluate the overall effects on human health and the environment of the potential substitutes for ozone-depleting substances. The SNAP program is a powerful tool to identify substitutes that may pose unnecessary environmental hazards. Through review of substitutes, the Agency can ensure that environmentally preferable alternatives will be developed. Rules promulgated under SNAP will render it unlawful to replace on ozone-depleting substance with a substitute chemical or technology that may present adverse effects to human health and the environment if the Administrator determines that some other alternative is commercially available and that this alternative poses a lower overall threat to human health and the environment.

It is important to note that the SNAP program will promote the widest range of environmentally acceptable substitutes. The SNAP program will in no case ban all of the available substitutes. Under section 612, the SNAP program is only authorized to prohibit a particular substitute for a Class I or Class II substance when another, less environmentally harmful substitute is available. Consequently, there is no possibility that the effect of today's rulemaking and subsequent regulatory action under section 612 will be to ban the use of all available substitutes in a particular application.

G. Accelerated Phaseout

Significant scientific advances have continued since the 1989 Protocol assessments. Several reports since that time have indicated that ozone depletion is occurring more rapidly than was previously believed. The most recent Protocol Scientific Assessment was issued on December 17, 1991. The report, entitled Scientific Assessment of Ozone Depletion: 1991, analyzed information collected from ground- and satellite-based monitoring instruments. This information indicated that there had been significant decreases in total-column ozone in winter, in both the northern and southern hemispheres at middle and high latitudes. This data also indicated, for the first time, the depletion of stratospheric ozone in these latitudes in spring and summer as well. The study reported no significant depletion in the tropics. The TOMS data indicated that for the period 1979 to 1991, decreases in total ozone at 45 degrees south ranged between 4.4 percent in the fall to as much as 6.2 percent in the summer, while depletion at 45 degrees north ranged between 1.7 percent in the fall to 5.6 percent in the winter. Data from the ground-based Dobson network confirmed these losses in total column ozone during the twelve-year period, but these findings show almost twice as much depletion as the average rate measured by the ground-based network alone over a twenty-year period. Based on this new data, scientists have concluded that the ozone in the stratosphere during the 1980s disappeared at a much faster rate than experienced in the previous decade.

The recent UNEP Scientific Assessment also included new data on the estimated ozone depletion potentials (ODPs) of ozone-depleting substances. The assessment placed the ODP of methyl bromide, a chemical previously thought to have an insignificant effect on stratospheric ozone, at 0.6, with a range of uncertainty between 0.44–0.69. The Executive Summary of the Assessment stated that, "if the anthropogenic sources of methyl bromide are significant and their emissions can be reduced, then *each* ten percent reduction in methyl bromide would rapidly result in a decrease in stratospheric bromide of 1.5 pptv (parts per trillion by volume), which is equivalent to a reduction in chlorine of 0.045 to 0.18 ppbv (parts per billion by volume). This gain is comparable to that of a three-year acceleration of the scheduled phaseout of the CFCs."

Several months after the release of the Scientific Assessment, on February 3, 1992, NASA released preliminary data acquired by the ongoing Arctic Airborne Stratospheric Experiment-II (AASE–II), a series of high-altitude instrument-laden plane flights over the northern hemisphere (see Interim Findings: Second Airborne Arctic Stratospheric Expedition). Additional data were also obtained from the initial observations by NASA's Upper Atmosphere Research Satellite (UARS), launched in September 1991. The measurements showed higher levels of chlorine oxide (ClO) (the key agent responsible for stratospheric ozone depletion) over Canada and New England than were observed during any previous series of aircraft flights. These levels are only partially explainable by enhanced aerosol surface reactions due to the emissions from the Mount Pinatubo volcano. The expedition also found that the levels of hydrogen chloride (HCl), a chemical species that stores atmospheric chlorine, were observed to be low, providing new evidence for the existence of chemical processes that convert stable forms of chlorine into ozone-destroying species. The high ClO and bromide oxide (BrO) levels observed indicated that human-induced rates of ozone destruction could be as high as one to two percent per day for short periods of time beginning in late January.

In addition, the levels of nitrogen oxides (NO_x) were also observed to be

low, providing evidence of reactions that take place on the surface of aerosols that diminish the ability of the atmosphere to control the buildup of chlorine radicals. New observations of HCl and nitrogen oxide (NO) imply that chlorine and bromide are more effective in destroying ozone than previously believed.

The NASA findings indicate that in late January of 1992, the Arctic air was chemically "primed" for the potential formation of a springtime ozone "hole" similar to that formed each spring over Antarctica. These findings also are consistent with theories that ozone depletion may occur on aerosols anywhere around the globe, and not only on polar stratospheric clouds as was previously believed.

After collecting more data, NASA released an April 30, 1992 "End of Mission Statement," which indicated that while a rise in stratospheric temperatures in late January apparently prevented severe ozone depletion from occurring in the Arctic this year, observed ozone levels were nonetheless lower than had previously been recorded for this time of year. This information has further increased the Agency's concern that significant ozone loss may occur over populated regions of the earth, thus exposing humans, plants and animals to harmful levels of UV–B radiation, and adds support to the need for further efforts to limit emissions of anthropogenic chlorine and bromide.

In response to these findings, President Bush announced on February 11, 1992 that the United States would unilaterally accelerate the phaseout schedule for ozone-depleting substances, and he called upon other nations to agree to an accelerated phaseout schedule as well. At the Fourth Meeting of the Parties to the Montreal Protocol, held in Copenhagen, Denmark on November 25, 1992, the Parties adopted a more stringent phaseout schedule. Under the new agreement, CFC production will be capped at 25 percent of the 1986 baseline in 1994, and production of CFCs, carbon tetrachloride, and methyl chloroform for all but essential uses will be completely phased out by 1996. Production of halons, except for essential uses, will be phased out by 1994. EPA has begun the rulemaking process for implementing this accelerated phaseout.

The accelerated phaseout will have a significant impact upon the products affected by today's rulemaking. The combined effects of the excise tax and the original phaseout schedule have already created strong incentives for industry to find substitutes for Class I substances. In fact, current U.S. production of Class I substances is more than 40 percent below the levels set by the Montreal Protocol. The accelerated phaseout will significantly increase the incentives for Class I substance users to switch to alternatives. Consequently, even where a particular use of a Class I substance is not included in the nonessential products ban, the substance in question will rapidly become scarce and expensive, and industry will be forced to find alternative chemicals or processes.

The accelerated phaseout dramatically reduces the need for aggressive EPA action under section 610. When Congress passed the Clean Air Act Amendments of 1990, it required the phaseout of the production of Class I substances by the year 2000. Consequently, there was a period of eight years in which the Class I nonessential products ban would have had an effect on manufacturers of these products. However, the Montreal Protocol Parties' decision to end production of CFCs by January 1, 1996 means that the ban on nonessential products authorized in section 610(b)(3) will only be in effect for two years before the complete phaseout takes effect. As a result, EPA believes that other provisions of title VI provide more effective and efficient means of implementing the Act's goals of protecting the earth's stratospheric ozone layer.

The final rule reflects this belief by banning only those products specified in sections 610(b) and 610(d) that contain Class I substances. Section 610(d)(1) is self-executing and bans the sale or distribution of foam and aerosol products containing or produced with Class II substances after January 1, 1994 unless an exception is granted under paragraph 610(d)(2). The Agency believes that aerosols and plastic flexible and packaging foams containing or produced with Class I substances should also be subject to the nonessential products ban to avoid providing incentives for manufacturers to revert to CFC use when the less environmentally harmful Class II substances are banned in these applications after January 1, 1994 under section 610(d). Moreover, the Agency believes that the use of CFCs in these two sectors is nonessential; as discussed elsewhere in this preamble, a number of substitutes for CFCs have already been adopted in these sectors. The fact that the affected industries have already largely made the transition out of CFCs may have encouraged Congress to ban the use of Class II substances in aerosols and noninsulating foams under section 610(d) of the statute.

H. Requirements Under Section 610

1. Class I Products

Title VI of the Act divides ozone-depleting chemicals into two distinct classes based on their ability to destroy ozone in the stratosphere. Class I substances are those substances identified as such in section 602, as well as any substance subsequently identified that has an ozone depletion potential (ODP) of 0.2 or greater (ozone depletion potential reflects the destructiveness of an ozone-depleting substance relative to CFC–11). Class I is comprised of CFCs, halons, carbon tetrachloride and methyl chloroform. Class II substances have ODPs lower than 0.2; at this time, Class II consists exclusively of HCFCs (see listing notice, January 22, 1991; 56 FR 2420). EPA is currently evaluating other substances to determine whether they meet the criteria for Class I or Class II substances.

Section 610(b) of the Act calls on EPA to identify nonessential products that release Class I substances into the environment (including any release during manufacture, use, storage, or disposal) and to prohibit any person from selling or distributing any such product, or offering any such product for sale or distribution, in interstate commerce.

Section 610(b) (1) and (2) specifies products to be prohibited under this requirement, including "chlorofluorocarbon-propelled plastic party streamers and noise horns" and "chlorofluorocarbon-containing cleaning fluids for noncommercial electronic and photographic equipment."

Section 610(b)(3) extends the prohibition to other products determined by EPA to release Class I substances and to be nonessential. In determining whether a product is nonessential, EPA is to consider the following criteria: the purpose or intended use of the product, the technological availability of substitutes for such product and for such Class I substance, safety, health, and other relevant factors.

Section 610(a) provides that EPA is to promulgate final regulations for the Class I products ban within one year after enactment of the Clean Air Act Amendments of 1990 (November 15, 1991). Section 610(b) provides that 24 months after enactment (November 15, 1992), it shall be unlawful to sell or distribute any nonessential product to which regulations under section 610 apply. Since this rulemaking

implementing section 610(b) has been published after November 15, 1992, there were no prohibitions on nonessential products in effect. This regulation will take effect on February 16, 1993.

2. Class II Products

Section 610(d) (1) states that after January 1, 1994, it shall be unlawful for any person to sell or distribute, or offer for sale or distribution, in interstate commerce—(A) any aerosol product or other pressurized dispenser which contains a Class II substance; or (B) any plastic foam product which contains, or is manufactured with, a Class II substance. Section 610(d)(2) authorized EPA to grant exceptions to the Class II ban in certain circumstances.

EPA believes that, unlike the Class I ban, the Class II ban is self-executing and that, consequently, EPA is not required to promulgate regulations within one year of enactment under section 610 to implement the Class II ban.[1] Section 610(d) bans the sale of the specified Class II products without any reference to required regulations. EPA believes it has the authority to issue regulations as necessary to implement the Class II ban under sections 610 and 301 of the Clean Air Act, as amended, and intends to do so at a later date in order to establish a procedure for granting exceptions under section 610(d)(2). This will not, however, affect the effective date of the Class II ban. EPA is currently in the process of drafting proposed regulations for this purpose.

3. Medical Products

Section 610(e) states that nothing in this section shall apply to any medical devices as defined in section 601(8). Section 601(8) defines "medical device" as any device (as defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)) diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system—(A) if such device, product, drug, or drug delivery system utilizes a Class I or Class II substance for which no safe and effective alternative has been developed and, where necessary, approved by the Commissioner of the Food and Drug Administration (FDA); and (B) if such device, product, drug, or drug delivery system, has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator.

The FDA currently lists 12 medical devices for human use as essential uses of CFCs in 21 CFR 2.125. These devices consist of certain metered dose inhalers (MDIs), contraceptive vaginal foams, intrarectal hydrocortisone acetate, polymyxin B sulfate-bacitracin-zinc-neomycin sulfate soluble antibiotic powder without excipients for topical use, and anesthetic drugs for topical use on accessible mucous membranes where a cannula is used for application.

No medical products as defined above are banned by the provisions of today's rulemaking. Today's regulation specifically exempts medical products contained in the FDA's list of essential uses (21 CFR 2.125), as well as gauze bandage adhesives and adhesive removers, lubricants for pharmaceutical and tablet manufacture, and topical anesthetic and vapocoolant products. Regulation of medical products may be considered at a later date under the conditions in section 610(e) and section 601(8).

I. Notice of Proposed Rulemaking

On January 16, 1992, EPA published a notice,of proposed rulemaking (NPRM 57 FR 1992) addressing issues related to the prohibition required by section 610 of the Act on the sale or distribution in interstate commerce of nonessential Class I products.

In developing the proposed rule, EPA was assisted by a subcommittee of the standing Stratospheric Ozone Protection Advisory Committee (STOPAC). The STOPAC consists of members selected on the basis of their professional qualifications and diversity of perspectives and provides balanced representation from the following sectors: industry and business; academic and educational institutions; federal, state and local government agencies; and environmental groups. Since its formation, the STOPAC has provided advice and counsel to the Agency on policy and technical issues related to the protection of the stratospheric ozone layer.

In 1990, members were asked to participate in subgroups of the STOPAC to assist the Agency in developing regulations under the new requirements of title VI of the Clean Air Act, as amended in 1990. To date, the Subcommittee on Nonessential Products has met twice, reviewing two in-depth briefing packets (contained in Docket A–91–39) and offering comments and technical expertise on the January 16 proposed rule.

In its NPRM, EPA proposed definitions for the terms "chlorofluorocarbon," "commercial," "consumer," "distributor," "product," and "release." These proposed definitions would apply only to regulations under section 610. In describing these definitions, EPA discussed the legal and policy aspects of the various options considered. The NPRM also discussed at great length the criteria used to determine whether a product was nonessential under section 610(b)(3). The proposed rule listed the products identified as nonessential by the statute, as well as the products which the Agency proposed to identify as nonessential. The proposed rule called for banning the sale or distribution of the CFC-containing products specifically mentioned in the statute, and, in addition, plastic flexible or packaging foams and all aerosol products except seven uses which were specifically identified. The NPRM also explained EPA's decision to include aerosols and pressurized dispensers containing CFCs, as well as plastic flexible and packaging foams produced with CFCs in the Class I nonessential products ban. Finally, the NPRM requested comments on whether halon fire extinguishers for residential use should be banned as nonessential products.

1. Specified Class I Products

a. *CFC-propelled plastic party streamers.* EPA found only one type of product that fits the description "chlorofluorocarbon-propelled plastic party streamers" as set forth in section 601(b)(1). String confetti is a household novelty product comprised of a plastic resin, a solvent, and a propellant mixed together in a pressurized can. When the dispensing nozzle is depressed, blowing action converts the resin into plastic foam streamers and propels them a few feet. Once popular at children's parties, string confetti was commonly known by its commercial name "silly string."

String confetti was originally manufactured using CFC–12 as the blowing agent. However, EPA is unaware of any company that currently uses CFCs in this type of product. The use of CFC–12 in string confetti was not prohibited by EPA's 1978 aerosol ban because technically the CFC also served as an active ingredient in the product and not exclusively as an aerosol propellant. Manufacturers switched initially to hydrocarbon systems but, due to flammability concerns, have since moved to HCFC–22 systems. HCFC–22 is a Class II substance with an ozone depletion potential of 0.05 (one twentieth that of CFC–12) (see listing

[1] Although the legislative history of section 610 is unclear on this point, the Senate Statement of Managers specifically states that the section 608 ban on the venting of refrigerants, which like the Class II ban is an outright prohibition, is self-executing and will take effect on the stated date even if that date is in advance of EPA regulations implementing the ban. See Congressional Record, page S16948, October 27, 1990.

notice of ozone depleting substances 56 FR 2420; January 22, 1991).

EPA believes that since the excise tax and production limits on CFCs will continue to raise their cost, it is unlikely that they would again be used to propel string confetti. Nonetheless, as required by the statute, the proposed rule called for a prohibition on the sale or distribution of any CFC-propelled plastic party streamers.

b. *CFC-propelled noise horns.* A noise horn is generally regarded as a product from which the high dispensing pressure of a propellant produces a loud piercing sound that can travel long distances. EPA is aware of several products that could fit the description of "noise horns" in section 610(b)(10), including marine safety noise horns, sporting event noise horns, personal safety noise horns, wall-mounted industrial noise horns used as alarms in factories and other work areas, and intruder noise horns used as alarms in homes and cars.

In the past, many boaters used noise horns propelled by CFC–12 to meet U.S. Coast Guard regulations requiring vessels of all sizes to carry a noise-making signalling device. One of the largest manufacturers of such "marine safety" noise horns reported that all of its horn products except for the smallest canister (2.1 ounces) had either been reformulated to use HCFC–22 or dropped from its product line. According to this manufacturer, the reason that CFC–12 is still used in its smallest canister is that the Department of Transportation (DOT) has not yet approved a canister of that size to accommodate the different pressure of HCFC–22.

The use of CFC–12 in noise horns was not prohibited by the 1978 aerosol ban because the CFC served as the sole ingredient in the product and not merely as a propellant. EPA's report Alternative Formulations to Reduce CFC Use in U.S, Exempted and Excluded Aerosol Products (*Alternative Formulations*) states that as of September 1989, "several manufacturers" of noise horns had switched from CFC–12 to HCFC–22. Noise horns propelled with HCFC–22 meet or exceed all Coast Guard requirements and are available in canisters as small as 4.5 ounces. EPA believes that 4.5 ounce canisters are sufficiently small to satisfy consumer needs for all recreational, boating, automotive and home uses, and should not cost significantly more than the currently available 2.1 ounces size that uses CFC–12. Other alternative propellants for noise horns include HCFC–142b (in a mixture with HCFC–22), hydrocarbons, and hydrofluorocarbon (HFC)–134a. Hydrocarbons have not been commonly used due to flammability concerns. HFC–134a appears promising as a non-chlorinated substitute that unlike HCFC–22 poses no threat to the ozone layer. HFC–134a has recently become available in limited commercial quantities. EPA believes that the current and potential availability of effective substitutes (including either the use of a different propellant or a slightly larger canister pending DOT approval of the smallest) indicates Congressional intent to prohibit the sale and distribution of any CFC-propelled noise horns, including those which serve as safety devices.

Other products propelled with CFCs that appear to fit the description "noise horns" in section 610(b)(1) include sporting event noise horns, personal safety noise horns, wall-mounted industrial noise horns used as alarms in factories and other work areas, and intruder noise horns used as alarms in homes and cars. The availability of substitutes for these other noise horn products is similar to that of the marine safety noise horns. In fact, the same noise horn product may perform several of the uses listed above.

As with the party streamers, EPA believes that the excise tax and the limits on supply have raised the prices of CFCs so much that it may already be more economical to use substitutes in noise horns. Nevertheless, in the January 16, 1992 NPRM, EPA proposed to ban all noise horns propelled with CFCs, as required by the statute.

c. *CFC-containing cleaning fluids for noncommercial electronic and photographic equipment.* Cleaning fluids are generally used to remove oxides, contaminants, dust, dirt, oil, airborne chemicals, fingerprints, and fluxes (the waste produced during soldering) from electronic and photographic equipment. These fluids are currently comprised of CFCs, HCFCs, methyl chloroform or alcohols, either alone or in mixtures.

EPA identified several products that it considered to be CFC-containing cleaning fluids for the uses described in section 610(b)(2). These products fall into four broad categories: solvent wipes containing CFC–113 (pre-moistened cloths), liquid packaging containing CFC–113 (applied with a cloth or other applicator), solvent sprays containing CFC–113 and/or CFC–11 (sprayed from a pressurized container through a nozzle or tube), and gas sprays containing CFC–12 (pressurized fluid released as a gas to physically blow particles from a surface). These cleaning fluid products include tape and computer disk head cleaners, electronic circuit and contact cleaners, film and negative cleaners, flux removers, and camera lens and computer keyboard dusters.

EPA believes that the tax and the limits on supply are providing an ever-increasing incentive for users of noncommercial cleaning fluids to switch from products containing CFCs to alternatives. Nevertheless, the January 16, 1992 NPRM proposed to ban the noncommercial use of these products, as required by the statute.

2. Criteria

Section 610 authorizes the Administrator to identify and ban nonessential products in addition to those specifically addressed in the Act. In keeping with Congressional intent, EPA examined products that were not specifically addressed in the statute. Section 610(b)(3) provides that in examining these products, the Administrator consider the purpose or intended use of the product, the technological availability of substitutes for such product and for such Class I substance, safety, health, and other relevant factors. The statute requires EPA to consider each criterion but does not outline either a ranking or a methodology for comparing their relative importance, not does it require that any minimum standard within each criterion be met. EPA considered all of these criteria in determining whether a product was nonessential. In addition, EPA reviewed the criteria used in the development of its 1978 ban on aerosol propellant uses of CFCs under the Toxic Substances Control Act (TSCA). All of these criteria are discussed below.

a. *Criteria in the 1978 Ban.* The criteria used by EPA to determine which products should be exempted from the 1978 ban as "essential uses" were: (1) "Nonavailability" of alternative products; (2) economic significance of the product, including the economic effects of removing the product from the market; (3) environmental and health significance of the product; and (4) effects on the "quality of life" resulting from no longer having the product available or from using an alternative produce (See Essential Use Determinations—Revised, 1978). These criteria are in many ways comparable to those included in section 610.

The background document supporting the 1978 ban states that when granting "essential use" exemptions, EPA believed that no single factor was sufficient to determine that a product or particular use was essential. The lack of available substitutes alone, for example, was not sufficient for EPA to exempt a

product. The product also had to provide an important societal benefit to obtain an "essential use" exemption. If an alternative did exist, however, EPA decided that this product or use was not "essential," and that it was not necessary to make any judgements concerning the other criteria.

In other words, if EPA determined that an aerosol product had an available alternative, EPA did not need to make a determination on whether its purpose was or was not important in order to deny any petition for exemption for that product under the 1978 rule.

b. *Criteria in the Clean Air Act Amendments of 1990*—1. The Purpose of Intended Use of the Product. EPA interprets this criterion as relating to the importance of the product, specifically whether the product is sufficiently important that the benefits of its continued production outweigh the associated danger from the continued use of a Class I ozone-depleting substance in it, or alternatively, whether the product is so unimportant that even a lack of available substitutes might not prevent the product from being considered nonessential. For example, the statute seems to indicate that the purpose or intended use of medical products is important enough to preclude EPA from banning as nonessential any medical product without an "effective alternative," and that, conversely, party streamers are not important enough to warrant the continued use of CFCs regardless of the availability of substitutes.

However, the other examples of nonessential products cited by Congress for EPA to ban at a minimum do not provide as clear-cut an illustration of this criterion. Noise horns, for example, are primarily used for safety reasons. Nor is the use of cleaning fluids on noncommercial photographic and electronic equipment generally considered to be frivolous. EPA believes that these examples of nonessential products provided by Congress show that while it is critical to consider the purpose or intended use of a product along with the other specified criteria, Congress did not intend to limit EPA's authority to consideration of only the intended use.

A possible corresponding criterion from the 1978 aerosol ban is the effect on the "quality of life" of no longer having the product available or of using an alternative. As discussed above, the product had to provide an important societal benefit for EPA to grant an exemption from the 1978 ban, even if the product did not have an available alternative. Consequently, in the Class I nonessential products ban under section 610(b)(3), EPA considered the contribution to the quality of life of a product using a Class I substance, the impact of compelling a transition to a substitute chemical or process, and the impact of the product's removal from the market altogether, in evaluating this criterion.

The distinction between a "nonessential product" and a "nonessential use of Class I substances in a product" is also relevant to this criterion. While foam cushioning products for beds and furniture are not "frivolous," for example, the use of a Class I substance in the process of manufacturing foam cushioning where substitutes are readily available could be considered nonessential. EPA believes that the extent to which manufacturers of a product have already switched out of Class I substances is a relevant indicator for this criterion. For example, the Agency believes that in sectors where the grant majority of manufacturers had already shifted to substitutes, the use of a Class I substance in that product may very well be nonessential; EPA is also aware that in certain subsectors, the continued use of CFCs, despite the imposition of the excise tax and the impending production phaseout, may indicate failure to meet one or more of the criteria for nonessentiality, such as the technological availability of substitutes. Consequently, EPA carefully examined sectors in which most of the market had switched out of CFCs.

2. The Technological Availability of Substitutes. EPA interprets this criterion to mean the existence and accessibility of alternative products or alternative chemicals for use in, or in place of, products releasing Class I substances. EPA believes that the phrase "technological availability" may include both currently available substitutes (i.e., presently produced and sold in commercial quantities) and potentially available substitutes (i.e., determined to be technologically feasible, environmentally acceptable and economically viable, but not yet produced and sold in commercial quantities). However, EPA considered the current availability of substitutes more compelling than the potential availability of substitutes in determining whether a product was nonessential.

The corresponding criterion from the 1978 ban is the "nonavailability of alternative products." In its supporting documentation, EPA stated that this was the primary criterion for determining if a product has an "essential use" under the 1978 rule. EPA emphasized, however, that the absence of an available alternative did not alone disqualify a product from being banned.

The availability of substitutes is clearly a critical criterion for determining if a product is nonessential. In certain cases, a substitute that is technologically feasible, environmentally acceptable and economically viable, but not yet produced and sold in commercial quantities, may meet this criterion. EPA believes that, where substitutes are readily available, the use of controlled substances could be considered nonessential even in a product that is extremely important.

It should be noted, however, that EPA does not necessarily advocate all substitutes that are currently being used in place of CFCs in the products EPA identifies as nonessential. Some manufacturers have switched from CFCs to substitutes that may have serious health and safety concerns. EPA will be looking carefully at the relative risks and merits of different substitutes for ozone-depleting substances as it implements section 612 (SNAP). On the other hand, EPA wants to reassure the public that the section 610 and the section 612 rulemakings will not, either intentionally or inadvertently, leave manufacturers or consumers without appropriate substances for each essential use.

3. Safety and Health. EPA interprets these two criteria to mean the effects on human health and the environment of the products releasing Class I substances or their substitutes. In evaluating these criteria, EPA considered the direct and indirect effects of product use, and the direct and indirect effects of alternatives, such as ozone-depletion potential, flammability, toxicity, corrosiveness, energy efficiency, ground level air hazards, and other environmental factors.

If any safety or health issues prevented a substitute from being used in a given product, EPA then considered that substitute to be "unavailable" at this time for that specific product or use. As new information becomes available on the health and safety effects of possible substitutes, EPA may re-evaluate determinations made regarding the nonessentiality of products not covered in today's rulemaking or, as stated above, the Agency may take action under section 612.

4. Other Relevant Factors. Section 610(b)(3) does not specify that EPA must consider the economic impact of banning a product, as in the 1978 ban, but the Agency did consider the economic impact of such an action as an "other relevant factor." EPA believes that it has the authority under section

610(b)(3) to consider any relevant factors, including costs, in determining whether products are nonessential.

In considering the immediate economic impact of banning the use of a Class I substance in a product, EPA attempted to compare the cost of the possible substitutes and the cost of the Class I substance, including the effects of the excise tax and the limits on production and importation under the Clean Air Act, when this information was available. EPA believes that in many cases the tax and supply limits have already provided a compelling incentive for manufacturers using Class I substances to switch to substitutes. EPA also considered the available information on manufacturing costs associated with using substitutes or switching to alternative market lines. Finally, EPA attempted to assess the societal costs of eliminating the product altogether where appropriate.

Another relevant factor that EPA considered was the impact of state or local laws prohibiting the use of certain substances commonly used as substitutes for ozone-depleting chemicals. For example, Massachusetts, New Jersey and California all specifically limit the use of methylene chloride, which is used as a CFC-substitute for some flexible foam products. Other areas have limits on the general emissions of volatile organic compounds (VOCs). If the only available substitute for the use of a Class I substance in a product—including both alternative chemicals and product substitutes—was a chemical whose use was prohibited in certain areas, EPA considered substitutes to be unavailable for that product in those areas. As stated above, however, the lack of available substitutes did not automatically disqualify a product from being prohibited as nonessential.

Finally, after publication of the proposed rule, EPA received comments on a number of products not specifically covered in the proposed rule. A number of these products, such as tobacco expanded with CFCs and closed cell polyurethane foam used as a flotation foam, may meet the criteria for designation as nonessential products subject to the Class I nonessential products ban. EPA believes, however, that it would be inappropriate to include new product categories in the ban which were not considered by the proposed rule. Consequently, today's rulemaking covers only products included in the January 16, 1992 proposed rule. EPA has the authority to consider designating as nonessential other products which release ozone-depleting substances in future rulemakings, however, and the Agency may consider such action if at a later date EPA determines that these products satisfy the criteria for nonessentiality.

In evaluating products for inclusion in the Class I nonessential products ban, EPA considered all of the criteria described above. Any one of the criteria outlined above could be the deciding factor in relation to all other factors in determining whether a product was, or was not, covered under the ban.

3. Other Products

In determining which products to prohibit under section 610(b)(3), the Agency considered every major use sector (although not each individual product or brand) of each Class I substance (CFCs, halons, carbon tetrachloride and methyl chloroform), including refrigeration and air conditioning, solvent use, fire extinguishing, foam blowing, and aerosol uses. Based on this review, the Agency identified three broadly defined products for further preliminary evaluation: aerosol products and pressurized dispensers containing CFCs, plastic flexible and packaging foams, and halon fire extinguishers for residential use. EPA then analyzed these three sectors in more detail before preparing the January 16, 1992 NPRM.

EPA had reason to believe that in each of these sectors two important conditions existed: substitutes were already available for the product or the Class I substance used or contained in that product; and, either the affected industry had, for the most part, moved out of the Class I substances or the market share of products using or containing Class I substances was small and shrinking.

In addition, in the case of aerosols and plastic flexible and packaging foams, section 610(d) imposes a self-effectuating ban on the sale or distribution of such products containing or produced with Class II substances after January 1, 1994. The Agency was concerned that failure to ban nonessential products containing or produced with Class I substances in these use sectors would provide an incentive for the affected industries to switch back to the use of Class I substances after that date, resulting in increased damage to the environment.

In the January 16, 1992 NPRM, EPA proposed to ban the sale or distribution of aerosols and pressurized dispensers containing CFCs and plastic flexible and packaging foams manufactured with CFCs. In addition, it requested public comment on the advantages and disadvantages of including residential home fire extinguishers in the ban, but it did not propose including these products in this rulemaking. The reasoning behind EPA's decision is described in greater detail below.

Refrigeration and air-conditioning, including mobile air-conditioning, represent the largest total use of Class I substances in the United States (31.8 percent weighted by ozone-depletion potential in 1987). Substances are available for some refrigeration and air-conditioning products. EPA believes that substitutes for some uses, like refrigerant in motor vehicle air conditioners, are already available, and that the affected industries are switching to these alternatives (the major automobile companies, for example, are introducing new models which use HFC–134a rather than CFC–12 in their air conditioning systems). However, potential substitutes for other refrigeration and air-conditioning uses are still being evaluated. For example, HCFC–123 has been proposed as a replacement for CFC–11, but toxicity testing of HCFC–123 has only recently been completed.

EPA did not include prohibitions on the use of Class I substances in refrigeration or air conditioning in the proposed rule because conclusions on the appropriate substitutes were not anticipated to be available within the time-frame of this rulemaking. Accordingly, EPA could not conclude that any refrigeration or air conditioning uses were nonessential at the time of proposal. The industry continues to investigate chemical substitutes for CFCs in deep freeze applications, as well as substitutes for CFC–114 and CFC–115. EPA plans to specifically address refrigeration and air-conditioning uses of Class I substances under its upcoming section 608 regulations to require the recovery and reuse of refrigerants in these applications.

Solvent uses of Class I substances, including commercial electronics defluxing, precision cleaning, metal cleaning and dry cleaning, also represent a significant use in the U.S. (21.7 percent weighted by ODP in 1987). Industry has identified potentially available substitutes for nearly all of the thousands of products currently manufactured with Class I solvents, and many companies have already phased out the use of CFCs in certain products.

EPA did not address solvent use in the proposed regulations because the sheer number of products and the range of potential substitutes (each with specific technical and health and safety issues) made it impossible for EPA to conclude that substitutes are currently available for any of these specific uses,

and thus that such uses were nonessential, within the short statutory time-frame of this rulemaking. However, the Agency recognizes that the solvent industry is also making significant progress toward the elimination of ozone-depleting chemicals as solvents.

EPA considered the use of Class I substances in fire extinguishing applications in its initial review as well. Halons are widely used in fire extinguishing systems today. These fire extinguishing systems include both total flooding systems (such as stationary fire suppression systems in large computer facilities) and streaming systems (such as hand-held fire extinguishers). In evaluating possible nonessential uses of halons in fire fighting, the Agency divided the fire protection sector into six broad end uses: (1) Residential/ Consumer Streaming Agents, (2) Commercial/Industrial Streaming Agents, (3) Military Streaming Agents, (4) Total Flooding Agents for Occupied Areas, (5) Total Flooding Agents for Unoccupied Areas, and (6) Explosion Inertion.

Although halons are extremely effective at fighting fires, they have extremely high ODPs. In fact, although total halon production (measured in metric tons) comprised just 2 percent of the total production of Class I substances in 1986, halons represented 23 percent of the total estimated ozone depletion potential of CFCs and halons combined. Consequently, halons in fire extinguishing equipment represent a significant use sector in terms of ozone depleting potential, and the Agency has worked closely with industry and the military to minimize halon emissions and encourage a rapid transition to acceptable substitutes. Halon recycling and banking is instrumental in reducing halon emissions and will extend the availability of these chemicals past the phaseout.

The fire protection community has made considerable progress in adopting alternatives to halons in fire protection applications. Most recent efforts to develop substitutes for halon have focused primarily on halocarbon chemicals, but several "alternative" agents such as water, carbon dioxide, foam, and dry chemical are already in widespread use as fire extinguishants and can be expected to find use as substitutes for halons in many applications.

Substitutes for halons, whether other halocarbons or alternatives such as water, should meet four general criteria to provide a basis for determining that the use of halon in residential fire extinguishers is nonessential. They must be effective fire protection agents, they must have an acceptable environmental impact, they must have a low toxicity, and they must be relatively clean or volatile. In addition, they must be commercially available as a halon replacement in the near future.

The excise tax on halons is scheduled to rise from $0.25 per pound to $13.05 per pound for halon 1211 and $43.50 per pound for halon 1301 in 1994. EPA anticipates that this dramatic increase in the price of halons will provide a significant economic incentive for consumers to shift from halons to available substitutes, and for producers to develop halon substitutes and substitute products.

After its initial review of this use sector, EPA concluded that while satisfactory substitutes were not yet available in most commercial and military applications within the short statutory time-frame of this rulemaking, certain substitutes were already commercially available for hand-held halon fire extinguishers in residential settings. Consequently, the Agency decided to evaluate this application more closely in order to determine whether residential fire extinguishers containing halon should be designated nonessential products, or whether the continued use of halons, despite the imposition of the excise tax and the impending production phaseout, indicated that this application did not meet the criteria for nonessentiality. With this end in mind, the proposed rule requested comments on whether these products met the criteria for nonessentiality as well as whether, due to the excise tax on ozone-depleting substances, banning these products would be unnecessary in order to effectuate the statutory goal of removing such products from interstate commerce.

EPA considered aerosols and pressurized dispensers likely candidates for designation as nonessential products because a great deal of information on substitutes for CFCs in these applications already existed. Research on substitutes for CFCs in aerosol applications began in the 1970s in response to the early studies on stratospheric ozone depletion and the 1978 ban on the use of CFCs as aerosol propellants. Consequently, extensive data already existed on possible substitutes for most remaining aerosol uses. EPA's evaluation concentrated on products which had been exempted or excluded from the 1978 ban on CFC propellants because these products were the only remaining legal applications of CFCs in this use sector.

The 1978 aerosol ban prohibited the manufacture of aerosol products using CFCs as propellants. Other uses of CFCs in aerosols (such as solvents, active ingredients, or sole ingredients) were not included in the ban. In addition, certain "essential uses" of CFCs as aerosol propellants were exempted from the ban because no adequate substitutes were available at the time. Consequently, although the use of CFCs in aerosols was reduced dramatically by the 1978 ban, the production of a number of specific aerosol products containing CFCs is still legal. These products include: metered dose inhalant drugs; contraceptive vaginal foam; lubricants for the production of pharmaceutical tablets; medical solvents such as bandage adhesives and adhesive removers; skin chillers for medical purposes; aerosol tire inflators; mold release agents; lubricants, coatings, and cleaning fluids for industrial/ institutional applications to electronic or electrical equipment; special-use pesticides; aerosols for the maintenance and operation of aircraft; aerosols necessary for the military preparedness of the United States of America; diamond grit spray; single-ingredient dusters and freeze sprays; noise horns; mercaptan stench warning devices; pressurized drain openers; aerosol polyurethane foam dispensers; and whipped topping stabilizers. After examining the available information (see Background Document on Identification of Nonessential Products that Release Class I Substances and Alternative Formulations in Docket), EPA concluded that satisfactory substitutes were available for most uses of CFCs in aerosols and pressurized dispensers. As a result, the Agency proposed banning all uses of CFCs in aerosols and pressurized dispensers except for certain products, such as medical devices, that it specifically exempted.

EPA examined the use of Class I substances in foam products, relying heavily on the research conducted for the 1991 United Nations Environment Programme (UNEP) technical options report on foams (see Technical Options Report). The UNEP report divided polyurethane foam into three major categories: rigid foam, flexible foam, and integral skin foam. It further subdivided rigid polyurethane foams into functional categories: open cell packaging foam and closed cell insulating foam. EPA used the same categories in the section 610 rulemaking. Based on this research, the Agency proposed prohibiting the use of CFCs in flexible and packaging foams in the NPRM. The Agency focused on these foam sectors due to the clear availability of substitutes such as

water-blown foam, reformulated foams, and alternative chemicals such as HCFC–22 and methylene chloride. EPA did not propose to prohibit the use of CFCs in insulating foam, expanded polystyrene foam, polyvinyl chloride foam, or integral skin foam. The reasons for this decision are described below.

EPA did not propose the inclusion of insulating foams manufactured with CFCs in the Class I nonessential products ban. Although flexible and packaging foams have currently available substitutes, the UNEP technical options report estimated that the elimination of CFCs in insulating foams would not be technical feasible until 1995 in developed countries. Rigid insulating foams using CFCs were exempt from the excise tax in 1990, and they are subject to a reduced tax until 1994. The required ban on the use of Class II substances in foam products in section 610(d) also specifically exempts insulating foams. As a result, EPA proposed banning only flexible and packaging foams in the NPRM. The Agency intends to address insulating foams under the section 612 rulemaking.

While polyvinyl chloride foam and expanded polystyrene foam could be considered flexible and packaging foams, EPA did not propose banning products made with expanded polystyrene foam or polyvinyl chloride foam in the NPRM because the 1991 UNEP report indicates that CFCs were never used in the production of either expanded polystyrene or polyvinyl chloride foams. As a result, EPA believes that it is unnecessary to formally prohibit the use of CFCs in these products, and the Agency did not include them in the proposed Class I nonessential products ban. However, EPA reserves the right to take action in the future under this section to prohibit as nonessential the use of CFCs in these products should it appear appropriate.

EPA also considered including integral skin foam in the Class I nonessential products ban. The UNEP report treated polyurethane integral skin foam as a separate category distinct from rigid insulating, rigid packaging, and flexible foams. In preparing the proposed rule, EPA utilized the same categories as the 1991 UNEP technical options report on foams. Consequently, EPA does not consider integral skin foam to be a "flexible or packaging foam." Integral skin foam is used in a number of applications, including motor vehicle safety applications, as suggested by section 610(d)(3)(B). EPA was not able to conclusively determine in the time available that adequate substitutes for integral skin foam, or for the use of CFCs in the production of integral skin foam, were available. As a result, EPA did not include them in the proposed Class I nonessential products ban. However, EPA must address integral skin foams in its rulemaking for the Class II nonessential products ban. Section 610(d)(2)(B) exempts integral skin, rigid, or semi-rigid foam utilized to provide for motor vehicle safety in accordance with Federal Motor Vehicle Safety Standards where no adequate substitute substance (other than a Class I or Class II substance) is practicable for effectively meeting such Standards from the nonessential products ban on foams containing, or manufactured with, Class II substances. The Agency reserves the right to take action under section 610 to prohibit the use of CFCs in integral skin foams at that time, or some other future time, if necessary.

EPA did not propose banning any products releasing the other Class I substances (halons, carbon tetrachloride and methyl chloroform) in the NPRM, although it requested comments on the need to ban halon fire extinguishers for residential use (for a discussion of halons, see the preceding discussion in this section, as well as section III.B.5. in today's preamble). EPA estimates that in the United States today, most carbon tetrachloride is consumed in the production of CFCs. The nonessential products ban is directed at specific end uses, not feedstocks, and therefore, the Agency has decided not to take action on this chemical under section 610. Methyl chloroform, also a Class I chemical, is widely used as a solvent for metal cleaning, in adhesives and coatings, and in aerosols. Methyl chloroform is used in thousands of different products. EPA believes that substitutes are available for many of the current uses of methyl chloroform, but these substitutes could not be thoroughly evaluated within the time constraints established in the Act. Consequently, EPA could not conclude that any such uses were nonessential. Thus, EPA's proposed rule did not cover many use sectors or products which use methyl chloroform. Nevertheless, EPA has reason to believe that substitutes exist for a number of these applications, and many of these uses of methyl chloroform may be addressed in the Agency's section 612 rulemaking.

EPA will further analyze the sectors described above on which it has insufficient information at this time and may take further regulatory action to ban uses in such sectors as appropriate once the agency obtains sufficient data.

EPA selected the product sectors identified in today's notice for the following reasons. First, EPA believes that they all clearly fit the criteria specified by section 610(b)(3) based upon information and analysis the Agency already had or could obtain within the tight regulatory time-frame required by the statute. In fact, all the identified products are relatively well-defined, have commercially available alternatives, and have been the subject of prior federal or state-level rulemakings or voluntary agreements to limit the use of ozone-depleting substances.

EPA also took into consideration the prohibition required by section 610(d) on certain products releasing Class II substances, which goes into effect in 1994. EPA is concerned that banning the use of Class II substances in certain products in 1994, while permitting the use of the more harmful Class I substances in the same products, could provide an environmentally harmful incentive that encourages the use of Class I substances over Class II substances. Thus, the statutory prohibition in section 610(d) provided further direction in choosing products on which to focus at this time under section 610.

As a result of this process, the NPRM proposed prohibiting the sale and distribution of flexible and packaging foam using CFCs and aerosols and other pressurized dispensers containing CFCs. Below, EPA defines these product categories and then presents an overview of how each one meets the criteria specified by section 610(b)(3) and discussed above in section I.1.1. More detailed analyses of the "other" products to be prohibited are provided in the background documents accompanying this rulemaking (see Docket A–91–39).

a. Flexible and packaging foam using CFCs. CFCs have been widely used in the production of a variety of foam plastics. CFC–11, –12, –113, and –114 have all been used as blowing agents in the manufacture of foam products such as building and appliance insulation, cushioning products, packaging materials, and flotation devices. According to the 1991 UNEP Flexible and Rigid Foams Technical Options Report, the foam plastics industry used approximately 174,000 metric tons of CFCs worldwide in 1990, a 35 percent drop from the industry's estimated CFC consumption in 1986. The UNEP report also estimates that, of the CFCs consumed by the foam plastics industry, approximately 80 percent were used in building and appliance insulation while the remaining 20 percent found use as blowing agents in applications such as packaging, cushioning and flotation. In the United States, CFC use in many

foam types has decreased dramatically since 1986. In some applications, especially in flexible and packaging foams, most manufacturers have already phased out the use of CFCs completely.

CFCs have been widely used as blowing agents in the manufacturing process of many foam products because they possess suitable boiling points and vapor pressures, low toxicity, and very low thermal conductivity; in addition, they are non-flammable, non-reactive, and, until the introduction of the excise tax and production limits, cost-effective. The excise tax levied by Congress in 1989 significantly raised the price of CFCs (except for use in the manufacture of rigid insulating foam, which was exempt from the tax in 1990 and is subject to a greatly reduced tax of approximately $0.25 per pound until 1994), and as a result, foam manufacturers have switched to non-CFC substitutes in many areas.

Even before the tax went into effect, several groups of foam manufacturers, including the Foodservice and Packaging Industry and the Polyurethane Foam Association, made significant voluntary efforts in cooperation with the Agency and several environmental groups to eliminate or reduce the use of CFCs in their products ahead of the required phaseout timetable. In addition, one industry group has worked with the Agency to develop and make available an in-depth description of technical options to achieve these reductions (see Handbook for Eliminating and Reducing Chlorofluorocarbons in Flexible Foams). Among the many commonly used substitutes for CFCs in flexible and packaging foam are HCFCs, hydrocarbons and methylene chloride (See below for further discussion of these substitutes).

The 1991 UNEP technical options report provides information on potential substitutes for the entire foam industry by foam type. Each type of foam has a distinct set of product and process application needs; for example, an important distinction exists between foam plastics where the cells are closed, trapping the blowing agent inside, and those with open cells which release the blowing agent during the manufacturing process.

For the purposes of today's rulemaking, EPA identifies the following categories as "flexible and packaging foam:" Polyurethane flexible slabstock and molded foams, open cell rigid polyurethane packaging foam, polyethylene foam, polypropylene foam, and extruded polystyrene sheet foams. The included polyurethane foams are open cell thermosetting foams, where the blowing agent is mixed with chemicals which react to form the plastic. The other included foams are closed cell thermoplastic foams, where the blowing agent is injected into a molten plastic resin which hardens upon cooling.

EPA first suggested the possibility of banning flexible and packaging foams in its December 14, 1987 Proposed Rule (52 FR 47489) and again in its August 12, 1988 Advanced Notice of Proposed Rulemaking (53 FR 30604). Of the foam types identified as "flexible and packaging," EPA believes that the producers of polyurethane flexible molded foam, open cell rigid polyurethane poured foam, polyethylene foam, polypropylene foam and extruded polystyrene sheet foam have already eliminated the use of CFCs. EPA also believes that CFC emissions from the manufacture of flexible polyurethane slabstock foam can be reduced to zero because manufacturers have largely converted from CFCs to readily available substitutes and are currently exploring alternative technologies.

EPA proposed prohibiting the sale and distribution of flexible and packaging foams using CFCs in the January 16, 1992 NPRM primarily because CFC use has already largely stopped in these foam types following voluntary efforts and the imposition of the excise tax. In addition, the Agency believes that if CFCs are not prohibited in flexible and packaging foams, the self-effectuating 1994 ban on noninsulating foam products made with or containing Class II substances could set up an environmentally harmful incentive for foam manufacturers who have not switched out of CFCs to continue to use them, or for those using HCFCs to switch back to CFCs.

In making its determination that flexible and packaging foams are nonessential, EPA examined their purpose and intended use. Flexible and packaging foams are used in furniture and upholstery, transport and protective packaging, cushioning, protective wrap, food containers, and flotation devices. EPA does no consider the purposes of flexible and packaging foams "frivolous."

EPA determined, however, that adequate substitutes for CFCs in the production of flexible and packaging foams were indeed available. Substitute options currently being used in flexible and packaging foams vary depending on the foam type in question. Options for flexible polyurethane slabstock foam production include increased foam density or the use of more water in the production process, as well as the substitution of acetone, HCFCs, methyl chloroform, and methylene chloride. Other near-term alternatives available to eliminate CFCs in flexible polyurethane slabstock foam include new polyol technology which increases softness with little or no CFC use and "AB" technology which uses formic acid to double the quantity of gas generated in the reaction of isocyanate with water. Alternatives for the production of other flexible and packaging foams include hydrocarbons, carbon dioxide, or HCFCs. EPA believes that the fact that the great majority of manufacturers of these products have already switched our of CFCs to commercially available substitutes indicates that the use of CFCs in this product area is nonessential.

There are a number of safety and health issues associated with the possible substitutes for CFCs in the production of plastic flexible and packaging foams; however, EPA believes that with the proper precautions, each of these alternatives can be used safely.

Methylene chloride is classified by EPA as a B2 (probable human) carcinogen with an Occupational Safety and Health Administration Permissible Exposure Limit (OSHA PEL) of 25 parts per million. Appropriate worker health and safety practices must be followed by flexible foam manufactures in those states that allow the use of this chemical.

Hydrocarbons and acetone are flammable. Manufacturers must take special safety precautions, including appropriate ventilation, when using these substances. Hydrocarbons and acetone are also volatile organic compounds (VOCs) which can contribute to the formation of ground-level air pollution. States must consider VOC emissions in meeting requirements of State Implementation Plans (SIPs) to attain the ground-level ozone National Ambient Air Quality Standards (NAAQS).

HCFCs (particularly-141b) and methyl chloroform, although they have much less effect on stratospheric ozone than do CFCs, have measurable ozone-depletion potentials (see listing notice 56 FR 2420; January 22, 1991). In addition, these substances may be regulated elsewhere in title VI (sections 604, 605, 606, 608, 609, 611, 612, and 613).

The formic acid used in AB technology creates carbon monoxide and has a Ph of 3, so it too requires special care in handling.

EPA believes that none of the health and safety issues described above should preclude the prohibition of CFC use in flexible and packaging foams

under section 610. Each technology presents its own associated set of hazards, including the use of CFCs. The Agency believes, however, that if the proper precautionary steps are taken, these alternatives can be used safely. EPA does not necessarily endorse all of the substitutes currently being used by manufacturers in place of CFCs and intends to carefully examine the issue of safe alternatives under section 612.

In making its determination to classify flexible and packaging foams as nonessential, EPA also considered several other relevant factors. As noted earlier, the majority of flexible and packaging foam manufacturers have already phased out the use of CFCs. The excise tax and the phaseout of CFR production provide significant incentives for those manufacturers still using CFCs to switch to substitutes. In addition, the accelerated phaseout should provide manufacturers with an additional incentive to move out of the use of Class I substances as rapidly as possible. As a result, EPA anticipates that the future economic impact from today's rulemaking will be minimal, even for small businesses (see Background Document).

Finally, EPA recognizes that some states limit the use of methylene chloride. Flexible foam manufacturers still using CFCs in these areas would be unable to use this particular substitute in the production of super-soft and low-density flexible foams. EPA recognizes, however, that several substitute options apart from methylene chloride (e.g., modified polyols and water-blown foam) are currently in use or will be available in the near future as substitutes for these foam types (production of flexible slabstock foam is discussed in greater detail in section III.B.2.b.). Therefore, EPA proposed banning the use of CFCs in areas where methylene chloride use is restricted, as well as in areas where it is not.

b. *Aerosols and other pressurized dispensers containing CFCs.* In the past, CFCs have been used extensively in aerosol products worldwide, mainly as propellants, but also as solvents and diluents, and as the active ingredients in some products. In the mid-1970s the use of CFC–11 and –12 in aerosols accounted for 60 percent of the total use of these chemicals worldwide. Due to mandatory and voluntary reduction programs in several countries, including the 1978 ban in the United States, this use has been significantly reduced. However, in 1986, aerosol use was still substantial, accounting for 300,000 metric tons, representing 27 percent of the global use of CFCs. In the United States, 9870 metric tons were used in aerosols exempted or excluded from the 1978 ban, representing approximately 2.5 percent of all Class I substances (weighted by ozone-depletion potential) in 1988.

In the January 16, 1992 NPRM, EPA defined "aerosols and other pressurized dispensers containing CFCs" to include both propellant and non-propellant uses of CFCs. Propellant uses of CFCs were banned by EPA in 1978, except for essential uses. Non-propellant uses of CFCs, such as solvent use, were excluded from the 1978 ban. EPA has re-examined all of the products excluded from the 1978 ban, as well as those specifically exempted from the 1978 ban. EPA has also examined products identified by commenters to the proposed rule. As EPA stated in its August 12, 1988 Advanced Notice of Proposed Rulemaking (53 FR 30604), several alternative propellants and delivery systems have been developed since the original aerosol exemptions were granted. In addition, many previously exempted or excluded products no longer use CFCs (see Alternative Formulations).

EPA proposed banning CFCs in aerosols and other pressurized dispensers primarily because a variety of substitutes for CFCs are now widely available and currently in use. In addition, the Agency believes that it is important to ban the use of CFCs in aerosols and pressurized dispensers due to the ban on the use of Class II substances in such products under section 610(d).

Section 610(d) bans the sale, distribution, or offer of sale or distribution in interstate commerce of aerosols or pressurized dispensers containing a Class II substance effective January 1, 1994. EPA believes that if the aerosols and other pressurized dispensers containing CFCs are not included in the Class I nonessential products ban, the ban on aerosols and pressurized dispensers containing Class II substances in 1994 could set up an environmentally harmful incentive for manufacturers who have not switched out of CFCs to continue to use them, or for those using HCFCs to switch back to CFCs. Because the ozone depletion potentials of CFCs are so much greater than those of HCFCs, the continued use of CFCs in this application would have a significant adverse impact on the environment.

In making its determination that the use of CFCs in aerosols and pressurized containers was nonessential, EPA looked at the purpose or intended use of these products. CFCs have been used in aerosol products and other pressurized dispenser products as propellants, solvents, diluents, and active ingredients. Those uses exempted or excluded from the 1978 ban included: metered dose inhalant drugs; contraceptive vaginal foam; lubricants for the production of pharmaceutical tablets; medical solvents such as bandage adhesives and adhesive removers; skin chillers for medical purposes; aerosol tire inflators; mold release agents; lubricants, coatings, and cleaning fluids for industrial/institutional applications to electronic or electrical equipment; special-use pesticides; aerosols for the maintenance and operation of aircraft; aerosols necessary for the military preparedness of the United States of America (primarily pesticides, aircraft and electronics maintenance products, and specialty lubricants); diamond grit spray; single ingredient dusters and freeze sprays; noise horns; mercaptan stench warning devices; pressurized drain openers; aerosol polyurethane foam dispensers; and whipped topping stabilizers. EPA believes that the purposes of these aerosols and pressurized dispensers are generally not "frivolous."

However, EPA determined that adequate substitutes for CFCs in the production of most aerosol products and pressurized dispensers were indeed available. EPA believes that the fact that the great majority of manufacturers of these products have switched out of CFCs (see Background Document) indicates that the use of CFCs in this product area is nonessential.

Currently available substitutes for aerosols and other pressurized dispensers include: hydrocarbons (predominantly propane and butane); other higher priced/special use flammable gases (dimethyl ether, HCFC–142b, and HFC–152a); nonflammable compressed gases (such as carbon dioxide, nitrogen oxide, and HCFC–22, alone or in mixtures); solvent substitutes (methylene chloride and dimethyl ether/water mixtures); non-aerosol spray dispensers (finger pumps, trigger pumps, and mechanical pressure dispensers); and non-spray dispensers (solid sticks, roll-ons, brushes, pads, shakers, and powders). Potentially available substitutes for propellant and solvent uses of CFCs in aerosols and other pressurized dispensers include HCFCs–123, –124, –141b, 142b, and HFC–134a.

In evaluating possible substitutes for CFCs in aerosols and other pressurized dispensers, EPA relied heavily on existing Agency research due to the short statutory timeframe for this rulemaking, especially its 1989 report Alternative Formulations to Reduce CFC

Use in U.S. Exempted and Excluded Aerosol Products. The UNEP Technical Options Committee report on aerosols, sterilants and miscellaneous uses of CFCs also provided valuable information on possible substitutes for CFCs in these applications (see Aerosols). In addition, many commenters requesting exemptions for specific products provided information on possible substitutes, as did several commenters opposed to exemptions for specific products.

EPA believes that manufacturers have been working to identify substitutes for CFCs in all of their product areas. However, there are several products for which EPA has not identified satisfactory substitutes, and which, in its January 16, 1992 NPRM, EPA proposed to exclude from the ban on aerosols and other pressurized dispensers containing CFCs. These products are: contraceptive vaginal foams; lubricants for pharmaceutical and tablet manufacture; metered dose inhalation devices; gauze bandage adhesives and adhesive removers; commercial products using CFC–11 or CFC–113, but no other CFCs, as lubricants, coatings and cleaners for electrical or electronic equipment; commercial products using CFC–11 or CFC–113, but no other CFCs, as lubricants, coatings and cleaners for aircraft maintenance uses; and commercial products using CFC–11 and CFC–113 as release agents for molds used in the production of plastic and elastomeric materials. In addition, EPA received information during the public comment period about the lack of available substitutes for certain products of which the Agency had previously been unaware, such as red pepper safety sprays and document preservation sprays. EPA considered requests for exemptions for these products while preparing the final rule, and on the basis of this information excluded certain additional aerospace applications of CFCs from coverage in today's rulemaking (for additional information on the products mentioned above, see Alternative Formulations and Background Document).

There are a number of safety and health issues associated with the possible substitutes for CFCs in the production of aerosol products and other pressurized dispensers; however, EPA believes that with the proper precautions these alternatives can be used safely.

Hydrocarbons are flammable. Manufacturers and consumers must take special safety precautions, including appropriate ventilation, when using these substances. Hydrocarbons are also volatile organic compounds (VOC)s which can contribute to the formation of ground-level air pollution. States must consider VOC emissions in meeting the requirements of State Implementation Plans to attain the ground-level ozone National Ambient Air Quality Standards.

HCFCs (particularly -141b) and methyl chloroform, although they have much less effect on stratospheric ozone than CFCs, do have measurable ozone-depletion potentials (see listing notice 56 FR 2420; January 22, 1991). In addition, these substances may be regulated elsewhere in title VI (sections 604, 605, 606, 608, 609, 611, 612, and 613).

Methylene chloride is classified by EPA as a B2 (probable human) carcinogen, with an Occupational Safety and Health Administration Permissible Exposure Limit (OSHA PEL) of 25 parts per million. Appropriate worker health and safety practices must be followed by aerosol and pressurized dispenser manufacturers in those states that allow the use of this chemical.

EPA believes that none of the health and safety issues described above are persuasive enough to preclude the identification of CFC-use in aerosols and other pressurized dispensers as a nonessential product under the requirements of section 610. However, EPA does not necessarily advocate all substitutes currently being used by manufacturers in place of CFCs. EPA intends to carefully examine the issue of safe alternatives under regulations to implement section 612.

In making its determination to classify aerosols and other pressurized dispensers as nonessential, EPA also considered several other relevant factors. First, most propellant uses of CFCs have been banned already under the Toxic Substances Control Act (TSCA) since 1978. Today, aerosols and pressurized dispensers containing CFCs make up only a small percentage of existing aerosol products; consequently, EPA estimates that the economic impact of banning CFC use in these applications will be minimal (see Background Document). Second, the excise tax provides an ever-increasing economic incentive for manufacturers of aerosol and pressurized dispenser products which were exempted or excluded from the 1978 ban to switch to substitutes. In addition, the accelerated phaseout of CFC production will force most manufacturers to convert to substitutes as quickly as possible. As a result, EPA anticipates minimal future economic impact from banning aerosols and other pressurized dispensers containing CFCs under section 610.

4. Recordkeeping Requirements

In the NPRM, EPA proposed recordkeeping requirements to monitor compliance with the ban on the sale or distribution of chlorofluorocarbon-containing cleaning fluids for noncommercial electronic and photographic equipment. Recordkeeping was one of four options considered by EPA for restricting the sale of these products to commercial users. These options were described in the January 16, 1992 NPRM.

The first option would have required that CFC-containing cleaning fluids be sold in bulk. However, EPA recognized that some commercial users needed only small quantities of these products, and that the bulk sales requirement would impose a significant burden on such entities. Moreover, this restriction would raise the cost of these products for noncommercial users, but it would not prevent noncommercial users from purchasing them.

The second option EPA proposed was to prohibit the sale of CFC-containing cleaning fluids by outlets which primarily serve noncommercial users. However, as with the first option, this restriction would not prevent noncommercial users from purchasing these products. In addition, it would be a burden on commercial users who purchase these products at retail outlets. Moreover, it would be difficult to adequately define retail stores that are predominantly oriented to noncommercial users.

The third option EPA proposed would have required that stores post notices stating that the sale of these products to noncommercial users was prohibited; alternatively, EPA considered requiring warning labels on containers of these cleaning fluids indicating that they were intended for commercial use only. EPA did not include either of these provisions in the proposed regulatory language because neither of these alternatives by itself would have promoted effective EPA enforcement of the ban on the sale of these cleaning fluids to noncommercial users. In addition, the EPA was concerned that the labeling requirement would be costly and unnecessarily burdensome, given that such products are already also subject to section 611 of the Act. Section 611 requires warning labels on containers of Class I or Class II substances and products containing or manufactured with Class I substances. Consequently, in its NPRM, EPA opted for the fourth, more restrictive option presented, which proposed recordkeeping requirements, because this was the only option considered

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which EPA believed would allow the Agency to effectively enforce the prohibition on the sale of these products to noncommercial users.

The NPRM discussed two potential recordkeeping regimes, one requiring annual records of sales to commercial users and one which was transaction-specific. In each case, sellers would require purchasers to provide identifying information, as well as a commercial identification number, in order to verify that the products were being purchased for commercial use; consumers without commercial identification numbers would be unable to purchase CFC-containing cleaning fluids. Commercial identification numbers were defined in the proposed rule as federal employer identification numbers, state sales tax exemption numbers, or local business license numbers. In a transaction-specific system, distributors would be required to record the purchaser's identifying information, transaction dates, and the quantities of cleaning fluids which were purchased; in addition, distributors would be required to maintain records of their own purchases of these products. In this way, EPA could compare distributors' sales and purchases of these products to ensure compliance. Under an annual recordkeeping system, distributors would be required to maintain records of commercial purchasers but not of individual transactions. As a result, EPA would be unable to verify through annual recordkeeping that a distributor had sold these products exclusively to commercial users. EPA proposed a transaction-specific recordkeeping requirement in the proposed rule, but it requested comment on the advantages and disadvantages of annual and transaction-specific recordkeeping requirements in the preamble.

In connection with the exemptions from the 1978 ban, EPA imposed reporting requirements under 40 CFR 712.4 for those products which used a CFC propellant. These reporting requirements expired in 1982. Since that time, the 1978 ban has functioned effectively without specific reporting requirements concerning the commercial uses of these substances. EPA believes that, as a result of the 1978 ban, noncommercial use of CFC-containing aerosol lubricants, coatings, aircraft maintenance products and mold release agents is currently negligible. Therefore, EPA did not propose recordkeeping requirements in these areas.

II. Summary of Comments

A public hearing on the proposed rule was held on January 31, 1992. Six groups presented oral comments on the proposed requirements, and five of them submitted written comments to the Agency as well. A transcript of the hearing is contained in the public docket (see Docket).

The Agency received a total of 190 comments on the proposed rule (see Docket). Many commenters expressed support for the proposed rule, and some suggested expanding the types of products covered. Other commenters criticized the scope of the rule, the criteria for determining whether products are nonessential, and the citation of section 608 as additional authority for restricting the use of Class I substances. A number of commenters made suggestions regarding record-keeping requirements, and several requested clarification of the definition of "interstate commerce." Finally, a number of commenters objected to the possible inclusion of a number of products in the ban, such as self-pressurized containers, medical devices, and residential halon fire extinguishers.

III. Responses to Major Public Comments

A document summarizing the public comments to this rulemaking and responding fully to all significant comments is available in the public docket for this final rule (see Response to Comments for Proposed Rule on Nonessential Products Made with Class I Substances). The major issues raised by the commenters and the Agency's responses to them are described below.

A. Scope and Specific Provisions of Nonessential Rule

1. Support for the Proposed Rule

A number of commenters expressed their support for the proposed rule. One commenter, an industry group, supported the proposed rule in its treatment of available substitutes, consideration of other relevant factors, and the selection of other products. Another industry group supported the Agency's general approach and actions in proposing to ban the products listed in the NPRM. Many commenters wrote to urge EPA to ban the sale or distribution of all nonessential Class I and Class II substances as soon as possible.

2. Scope of Regulation

Several commenters expressed the opinion that the scope of the proposed rule was too great. In several sections of the regulations, EPA used the language "including but not limited to" in describing the products subject to the nonessential products ban. See sections 82.66 (a), (b), (c), and (d). Several commenters indicated that this language was not sufficiently specific to describe the products subject to the ban, especially in light of detailed descriptions of certain subcategories that followed such language in those sections. These commenters suggested that the phrase be deleted and that only specifically listed product subtypes be subject to the ban.

EPA believes that it is appropriate to use the phrase "including but not limited to" in describing the products subject to the ban. Section 610 clearly gives EPA the authority to ban all products within a certain category, such as cleaning fluids for electronic and photographic equipment. EPA could have simply listed the overall product categories in the rule. It is true that the rules must clearly identify those products subject to the ban, and that the descriptions cannot be overly vague. However, EPA does not believe that there is anything vague about the descriptions used in the rule. EPA believes that they are all terms with clear meaning in the industries affected and that any manufacturers or distributors will know if they are handling a product that falls within the ban.

The fact that EPA specifically listed certain subcategories of the larger product categories subject to the ban does not in any way render the overall product category descriptions vague or unclear. EPA concluded that it would be helpful to manufacturers and distributors to specifically list as many product subcategories as the Agency could identify in the rule to aid the public in identifying products subject to the ban. EPA attempted to be comprehensive in this listing, but could not be sure that it had identified all product subtypes within the overall product categories. The "including but not limited to" language is included in the final rule to clarify that all products within the stated product categories are subject to the ban on sale of nonessential products.

Several commenters stated that the Agency does not have the authority under the Act to ban the use of CFCs in aerosols. However, it is clear from the language of section 610 that EPA is authorized to examine all products which result in the release of Class I substances into the atmosphere for the purpose of determining whether they are nonessential. Under section 610(b)(3), the Administrator has the authority to restrict the use of Class I

substances in products that Congress did not specifically cite. Congress provided the Agency with criteria to determine whether a Class I product should be banned (discussed at length in section III.A.3.), and EPA has acted within these parameters in considering products for their eligibility for the nonessential products ban. The fact that CFC use in aerosols is regulated by the 1978 ban does not affect EPA's authority to regulate any aerosol uses exempted or excluded from that ban under section 610.

One commenter felt that the broadening of section 610 was not justified in light of the President's plan to accelerate the phaseout of ozone-depleting chemicals. The commenter observed that the accelerated phaseout would eliminate the production of CFCs by the end of 1995, only a short time after the nonessential products ban takes effect. The commenter questioned whether the environmental benefits of the ban during the period would justify the burden associated with expanding its scope. As stated in section I.G. of this preamble, EPA agrees with the commenter for the most part. Consequently, EPA has limited the scope of today's rule to the product categories affected by the Class II ban and those CFC-containing products specifically listed in the statute. While EPA believes that accelerated phaseout dates will do much to protect the stratospheric ozone layer, the Agency is still required to promulgate regulations to ban those uses of ozone-depleting chemicals it determines are nonessential. EPA believes that there is still a compelling argument for banning the use of CFCs in aerosol products and plastic flexible and packaging foams (see section I.G. of today's preamble). The primary reason for prohibiting the use of CFCs in these sectors is to force them to move to alternatives other than CFCs and HCFCs prior to January 1, 1994, when the Class II nonessential products ban takes effect.

One commenter suggested that the scope of the proposed rule was too narrow, and that other use sectors, such as solvents and methyl chloroform, should be included. This commenter cited examples in which manufacturers had phased out the Class I substances in various use sectors to justify expanding the scope of the rule. EPA is aware that substitutes exist for certain solvent applications of CFCs and particular uses of methyl chloroform. However, EPA could not properly evaluate the tremendous number of products manufactured with methyl chloroform within the short statutory time-frame of this rulemaking. The Agency also felt that it could not address CFC solvent uses adequately in this section 610 rulemaking, since they also find use in large numbers of applications. The Agency believes that the Class I substances and use sectors not addressed in this rulemaking can be addressed more effectively under sections 608 or 612. Finally, given the number of applications to be considered, and given EPA's preferred approach of addressing products and applications by use category rather than individually, the Agency feels it would be impractical and inconsistent to ban products based exclusively on the example of individual users.

One commenter was concerned that there may be some confusion over the use of nonessential products and the sales prohibition. The commenter suggested that EPA confirm that nonessential products purchased before the effective date may still be used, and that the Agency is not regulating the use of nonessential products, merely their sale and distribution. The Agency agrees with the commenter that section 610 of the Act does not address the use of products which are determined to be nonessential. The use of nonessential products purchased prior to the effective dates for the nonessential products ban is not subject to any restriction in this regulation, although other laws and regulations regarding the release of ozone-depleting substances may apply to such use.

3. President's Moratorium on Regulation

Two commenters questioned whether the nonessential products rule would be subject to President Bush's rulemaking moratorium. The President's directive does not allow for certain categories of regulations to be promulgated without delay. Specifically, government agencies have been directed not to postpone any regulation that is subject to a statutory or judicial deadline which falls during the period of the moratorium. Since section 610 contains a statutory deadline for the publication of the final rule, as well as an effective date of November 15, 1992, the nonessential rule is exempt from the regulatory moratorium.

4. Section 608 and EPA Authority

One commenter objected to the citation of the Lowest Achievable Emission Level (LAEL) standards in section 608 as a basis for restricting the emissions of ozone depleting substances. According to the commenter, Congress clearly intended to confine product restrictions to section 610. In particular, the commenter suggested that the LAEL standards were exclusively intended to cover emissions from the appliance and industrial process refrigeration market. The commenter cited the legislative history behind the creation of section 608 to support its interpretation of section 608.

The EPA disagrees with the commenter's suggestion that reliance on section 608 as additional authority for its actions is unwarranted. EPA considers section 608 to be a multiple phase emission control program. The Agency believes that the authority granted under section 608 (National Emission Reduction Program) may be applied to today's rulemaking, and that LAEL standards may, in certain circumstances, have the same practical effect as the nonessential products ban authorized in section 610.

It is clear from the statute that section 608(a)(1) of the National Recycling and Emission Reduction Program initially affects only appliances and industrial process refrigeration, and the Agency is addressing the recycling of refrigerant in the appliance and industrial process refrigeration sector in the section 608 proposal published in the Federal Register on December 10, 1992 (57 FR 58644). EPA believes, however, that the commenter is incorrect in suggesting that the section 608 LAEL standards apply only to appliances and industrial process refrigeration. Section 608(a)(2) requires EPA to promulgate regulations establishing standards and requirements regarding use and disposal of Class I and II substances not covered by paragraph (1) and section 608(a)(3) requires the reduction of the use and emission of such substances to the lowest achievable level. EPA believes that this statutory language gives the Agency the authority to apply the LAEL standards to all sectors using Class I and Class II substances.

Where adequate substitutes for Class I or Class II substances are available, EPA may make a determination that the lowest achievable level is zero. To implement the LAEL standards, the Agency may issue regulations requiring emission controls, work practices, the use of alternative substances, or simply setting a performance standard. A zero level performance standard under section 608 would amount to an effective ban on the use of Class I or Class II substances in that product category. EPA similarly believes that it has authority under section 608 to require the use of alternatives to certain ozone-depleting substances in specific uses. Consequently, the Agency believes that the requirements of sections 608 and 610 may overlap in some instances, and that reference to the section 608

LAEL standards in this rulemaking is appropriate.

5. Criteria for Determining Nonessentiality

Several commenters felt that Congress only banned frivolous products or products which "when used by nonprofessionals would result in large unwarranted releases of CFCs when measured against the expected beneficial results of the product's use," and that EPA in the proposed rule had overstepped its authority by attempting to ban products that are considered extremely important. EPA believes that the specific products selected by Congress reflect broader criteria for determining a product's status under section 610 than utility alone. Congress specifically cited noise horns as products in which the use of Class I substances is nonessential. Noise horns are primarily used in the area of marine safety; noise horns provide warning and maneuvering signals in case of an emergency. In addition, the noncommercial use of cleaning fluids for photographic and electronic equipment is generally not reviewed as a frivolous end use. Nevertheless, these products were specifically cited in the statute as examples of nonessential uses. Finally, Congress also prohibited the sale or distribution of aerosols and certain foam products containing Class II substances after January 1, 1994 in the nonessential products ban. The products banned in section 610(d) are clearly not all frivolous, and yet Congress banned them as nonessential products. These examples indicate that Congress relied on broader criteria than the utility of the product alone in determining a product's status under section 610, and section 610(b) specifically identified criteria other than the utility of the product for EPA to consider in determining nonessentiality for the purposes of the Class I nonessential products ban. Consequently, EPA disagrees with the commenter's contention.

One commenter who questioned the application of the ban to any product other than frivolous products cited the legal doctrine of *ejusdem generis*. Under this doctrine of statutory interpretation, where general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words. The commenter concluded that under this doctrine EPA's authority to ban other products is limited to frivolous products because the specifically enumerated products identified in sections 610(b) (1) and (2) are all frivolous products.

EPA believes that the doctrine of *ejusdem generis* is inapplicable here because the premise underlying the commenter's conclusion is false. The products specifically listed in sections 610(b) (1) and (2) are not all frivolous products. Only the first product listed in 610(b)(1), plastic party streamers, can be considered frivolous. For the reasons given above, EPA believes that the other product categories listed in 610(b) (1) and (2) clearly include products which are not frivolous. As a result, EPA believes that the specific enumerations in 610(1) and (2) do not limit the Agency's authority to identify nonessential products under 610(b)(3) that are frivolous. Rather, EPA is required by 610(b) to consider a number of factors in determining whether a product is nonessential, including the purpose or intended use of a product, the technological availability of substitutes, safety, health, and other relevant factors.

One commenter suggested that even if substitutes for Class I substances were available, EPA had no authority to ban the sale or distribution of "extremely important" products under section 610 unless substitutes were available for both the product and the Class I substance used in its manufacture. As discussed above and in the proposed rule, EPA believes that the section 610 statutory ban on noise horns, CFC-containing cleaning fluids for noncommercial electronic and photographic equipment, as well as aerosols, pressurized dispensers, and plastic foam products containing Class II substances, clearly indicates congressional intent to include important "nonfrivolous" uses of ozone-depleting substances and products produced with ozone-depleting substances in the nonessential products ban. Moreover, the statute directed EPA to consider the "technological availability of substitutes for such product and for such Class I substance," as well as the purpose or intended use of the product, in determining whether a product was nonessential. However, the statute does not specifically require EPA to determine that substitutes are available for both the product and the Class I substance used in its production. Consequently, EPA believes that the statute authorizes the Agency to ban a product containing or manufactured with Class I substances if, when EPA evaluates such a product against the five criteria mentioned in section 610(b)(3), it determines that adequate substitutes are available for either the product or the use of Class I substances in its manufacture. EPA believes that in cases where such substitutes exist, the Administrator has the authority to determine that products manufactured with Class I substances are nonessential regardless of the importance of these products. In each case, however, EPA must consider all five of the criteria in making its determination.

6. Definition of the Term "Product"

The January 16, 1992 proposed rule discussed EPA's definition of the term "product" at great length. EPA reiterates its belief that the use of the term "product" in section 610 of the statute indicates that Congress intended to apply this term to any type or category of merchandise or commodity offered for sale, as well as any use of a Class I substance in the manufacture or packaging of any such merchandise or commodity.

A number of commenters disputed EPA's definition of the term "product" Several commenters criticized EPA for banning entire categories of products rather than individual products. EPA believes that such an approach is appropriate, and that it is justified by the criteria listed in section 610(b), the statutory treatment of certain groups of products manufactured with or containing Class II substances in section 610(d), and by the tight statutory deadline for promulgation of this regulation.

In determining whether a product is nonessential, section 610(b) of the statute directs the Administrator to "consider the purpose or intended use of the product, the technological availability of substitutes for such product and for such Class I substance, safety, health, and other relevant factors". EPA reiterates its belief articulated in the proposed rule that the statutory mandate to consider the technological availability of substitutes "for such product and for such Class I substance" clearly indicates Congressional intent to focus on the use of Class I substances in broad categories of products as well as in individual products (see NPRM for greater discussion of this issue).

In addition, Congress banned entire categories of products in section 610(d)(2) when it banned aerosols, pressurized dispensers, and plastic foam products containing Class II substances. EPA believes that the statutory language of section 610(d)(2) indicates Congressional intent to address products and the use of ozone-depleting substances by broad use categories, provided that some mechanism exists for addressing particular applications within those categories for which no

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suitable substitutes exist, or for which other important concerns might justify an exemption. EPA employed such a mechanism in its section 610 rulemaking for the Class I nonessential products ban. In its NPRM, EPA proposed banning the use of CFCs in two product categories, aerosol products and flexible and packaging foams, but it also exempted products for which it had reason to believe that no satisfactory substitutes were currently available. EPA then carefully considered requests for exemptions received during the public comment period in order to address additional products within these sectors for which no suitable substitutes exist, or for which other concerns might justify an exemption. As a result of this procedure, the final rule includes exemptions from the nonessential ban for several additional products (see sections III.B and IV.E. of today's preamble).

Finally, there are hundreds of thousands of diverse end uses for Class I substances, and EPA clearly could not address the multitude of products and end uses for these substances individually given the tight statutory time-frame for promulgating this regulation. Consequently, EPA adopted the approach taken by Congress in section 610(d)(2) and proposed banning broad categories of products and end uses in the NPRM. EPA then considered any comments requesting exemptions for particular applications within these broad categories and carefully evaluated the information provided by the commenters as to why these particular applications should not be covered by the Class I nonessential products ban. EPA believes that this approach is equitable, comprehensive, and that it represents the most effective use of the Agency's resources.

7. Definition of Interstate Commerce and Grandfathering of Existing Product Inventories

Many commenters addressed the impact of the ban on existing inventories. The primary concern of all these commenters was the treatment of existing inventories of nonessential products after the effective date of the regulation. One commenter, one of the largest producers of CFCs, stated that the November 15th compliance date could affect a large number of products containing up to 50,000 pounds of CFCs.

The commenters expressed concern that banning the sale of these existing inventories would impose significant economic burdens on the affected businesses. Moreover, several commenters observed that recovery and recycling of CFCs from small aerosol containers is difficult and expensive, and that much of the ozone depleting chemical used to produce flexible and packaging foams is released in the foam-blowing process. Consequently, the recall of such products would result in little environmental benefit.

Commenters suggested changing the treatment of existing inventories in the final rule. One commenter, a major manufacturing association, felt that the November 15th compliance date should not apply to the sale of products to the ultimate consumer. Many other commenters proposed grandfathering existing inventories of products that had not been sold by November 15, 1992.

EPA agrees with these commenters that banning the sale of existing inventories after November 15, 1992, would adversely affect a number of businesses without providing any appreciable environmental benefit. The Agency is well aware that redesigning and modifying production facilities cannot be accomplished overnight. EPA is also aware that some of the affected products, such as spare parts for automobiles, which are packaged with foam, have unusually long shelf lives. Moreover, EPA recognizes that the statute contemplated that businesses would have one year to liquidate existing stocks of nonessential products, and that the late publication of the final rule allows manufacturers, distributors, and retailers insufficient time to liquidate existing inventories and revise manufacturing processes. Congress clearly intended to give these individuals a year's notice prior to banning these products. Given the late publication date of the rule, adhering to the November 15, 1992 date for all nonessential products would actually contradict Congressional intent in this regard. However, as of November 15, 1992, the statute clearly prohibits the sale, distribution, or offer of sale or distribution, in interstate commerce of nonessential products identified in EPA regulations (after the effective date of such regulations) one year after promulgation of the Class I nonessential products ban rule.

The affected industries could not have known for certain whether such products would be banned until final promulgation. Consequently, to provide some measure of relief for certain industries, with respect to any such products which Congress anticipated would be banned, EPA has decided to make January 17, 1994 the effective date for the ban on products determined to be nonessential under section 610(b)(3). This action will allow manufacturers, distributors, and retail establishments additional time to liquidate existing inventories of Class I nonessential products, and to phase out of CFC use in these applications in an efficient manner.

EPA believes, however, that the manufacturers, distributors, and retailers of products specifically mentioned in sections 610(b)(1) and 610(b)(2) of the Act have received sufficient prior notice of this action, having been on notice that such products would be banned since enactment of the statute. Consequently, chlorofluorocarbon-propelled plastic party streamers and noise horns may not be sold, distributed, or offered for sale or distribution in interstate commerce as of February 16, 1993, the effective date of this rule. Similarly, cleaning fluids for electronic and photographic equipment which contain chlorofluorocarbons may only be sold, distributed, or offered for sale or distribution, in interstate commerce to commercial purchasers effective on February 16, 1993.

EPA believes that sufficient precedent exists for this decision. The United States District Court for the District of Columbia Circuit has established a four-part test to judge the appropriateness of Agency grandfathering (*see Sierra Club v. EPA, 719 F.2d 436 (D.C. Cir. 1983)*). This test involves balancing the results of four analyses, including whether the new rule represents an abrupt departure from previously established practice, the extent to which a party relied on the previous rule, the degree of burden that application of the new rule would impose on the party, and the statutory interest in applying the new rule immediately.

For the reasons stated above, EPA believes that banning the sale, distribution, or offer of sale or distribution in interstate commerce of existing inventories of products first designated as nonessential products in this rulemaking after November 15, 1992 would constitute an abrupt departure from previously established practice and would impose an unreasonable burden on a number of affected parties without providing any significant environmental benefits that might justify an immediate ban. Prior to the publication of today's rulemaking, individuals selling or distributing these products faced no restrictions on their sale or distribution; moreover, until today, these individuals could not know for certain that the products affected under the discretionary authority of section 610(b)(3) of the Act would be identified and banned as nonessential products.

Today's rulemaking does not provide manufacturers, distributors, or retailers of products specifically mentioned in section 610(b)(1) addition time to phase out these nonessential products; however, because EPA believes that their listing in the statute provided sufficient advance notice, publication of the final rule does not in their case constitute an abrupt departure from previously established practice.

In addition, today's rule maintains the proposed rule's ban on the sale of chlorofluorocarbon-containing cleaning fluids for electronic and photographic equipment to noncommercial purchasers effective on February 16, 1993. Since existing inventories of CFC-containing cleaning fluid products not otherwise affected by this rulemaking may still be sold to commercial purchasers, on February 16, 1993 effective date will not impose any significant economic burden on the affected businesses. Manufacturers, distributors and retailers of aerosol chlorofluorocarbon-containing cleaning fluids banned under section 610(b)(3) will not be able to sell, distribute, or offer to sell or distribute, these products in interstate commerce to any user, commercial or noncommercial, after January 17, 1994, the effective date of the ban on products identified under section 610(b)(3). As described above, as with the other nonessential products banned under section 610(b)(3), the affected businesses will thus have an additional year to liquidate their existing inventories of these products after promulgation of these regulations.

One commenter requested that EPA clarify its interpretation of interstate commerce with regard to sale, distribution, or offer of sale or distribution, of nonessential products within the boundaries of a single state. EPA agrees with the commenter that the Act does not ban the sale, distribution, or offer of sale or distribution, of a product otherwise affected by this rulemaking that is manufactured, distributed, and sold without ever crossing state lines. However, the Agency wishes to clearly state its position that to avoid coverage by this rulemaking, an affected party must provide adequate documentation that not only was the product manufactured, distributed, and/or sold exclusively within a particular state, but that all of the components, equipment, and labor that went into manufacturing, distributing, selling, and/or offering to sell or distribute such a product originated within that state as well.

Finally, EPA wishes to clarify its interpretation of sale, distribution, or offer of sale or distribution, in interstate commerce with regard to the resale of used products. The Agency recognizes that more than one consumer often derives utility from owning and using certain durable goods affected by this rulemaking, such as automobiles, boats, or furniture. Many of these products contain components manufactured out of flexible and packaging foam, most notably seat cushions. Restricting the resale of such used durable goods before the end of their productive lifetimes would provide little, if any, environmental benefit because the CFCs used to blow foam for these products were, for the most part, released during their manufacture. Because restricting the resale of such used durable goods would impose significant economic hardship on a great many consumers without providing any associated environmental benefits, EPA does not feel that Congress intended to ban their resale. Consequently, while EPA's interpretation of "interstate commerce" is such that interstate commerce includes the entire chain of sale and distribution from the manufacturer of a new product to its ultimate consumer, the Agency recognizes that in the case of durable consumer goods such as boats, cars, and furniture, resale of the product to additional consumers may occur after the sale of the new product to the ultimate consumer. In such cases, EPA does not consider the resale of these nonessential products to constitute sale, distribution, or offer of sale or distribution, in interstate commerce for the purposes of this rulemaking.

8. Verification, Recordkeeping and Public Notice Requirements

Over 60 commenters considered the recordkeeping provisions contained in the proposed rule to be burdensome and unnecessary. The Agency considered the need for recordkeeping requirements at great length as a result of these comments. EPA was concerned by the suggestion that the burden imposed by these requirements far outweighed any health and environmental benefits associated with them.

The total volume of CFCs used in the U.S. in 1988 for both commercial and noncommercial cleaning fluids for electronic and photographic equipment was approximately 3000 metric tons, or less than 0.8 percent of the total use of Class I substances (weighted for ozone-depletion potential). EPA estimates that noncommercial sales represented a small but not insignificant fraction of this total 1988 use estimate and that total sales have dropped since 1988, due to the tax and the scarcity of CFCs caused by the phaseout regulations. EPA believes that the excise tax on CFCs and the limits on production and imports have already raised the price of CFCs sufficiently so that it may no longer be economical to use them as cleaning fluids for noncommercial equipment. As a result, the current sales of cleaning fluids for electronic and photographic equipment to noncommercial users are likely to be substantially lower than the 1988 level. Nevertheless, the statute specifically requires EPA to ban the sale of these products for noncommercial use. Consequently, the Agency sought to devise a means to meet the statutory requirements without imposing an undue burden on the public.

EPA has decided to eliminate the specific recordkeeping requirements proposed in the NPRM. The Agency agrees with the commenters that these requirements are too burdensome when compared to the associated environmental benefits. Instead of requiring distributors to maintain records of transactions involving CFC-containing cleaning fluids, today's final rule merely requires sellers and distributors to post signs stating that sale, distribution, or offer of sale or distribution, in interstate commerce of these products to noncommercial users is prohibited and that purchasers of these products must provide verification that they are commercial users. In addition, sellers and distributors are required to verify that purchasers of these products are commercial users. In order to purchase these products, commercial users would have to prove that they are indeed commercial entities. EPA anticipates that purchasers could fulfill this requirement by presenting any number of documents, including but not limited to invoices, purchase orders, or official correspondence, containing a commercial identification number. Sellers and distributors would have to have a reasonable basis for believing that the information presented by the purchaser is accurate and thus that the purchaser is in fact a commercial user.

EPA believes that this approach minimizes the burden of implementing the Congressionally-mandated ban on the sale of CFC-containing cleaning fluids for noncommercial electronic and photographic equipment. The Agency feels that some form of verification is necessary to ensure that these products are not sold to noncommercial users. Requiring purchasers to present, and sellers and distributors to verify, some proof of their commercial status is certainly less burdensome than the recordkeeping requirements discussed in the proposed rule. EPA could not conceive of requirements less

burdensome than these that would nonetheless meet the statutory requirement to prevent noncommercial users from purchasing CFC-containing cleaning fluids.

One commenter recommended that EPA include government contract numbers as an acceptable identification option in the sale of cleaning fluids for electronic and photographic uses to government clients who would not have a commercial identification number. The Agency believes the use of a government contract number in verification of commercial status to be a sound option which would not compromise the sales restriction to noncommercial sources.

One commenter suggested that the definition of distributor should be revised to reflect resale of CFC-containing cleaning fluids to other distributors rather than sale to the ultimate consumer. EPA believes that the commenter has raised a valid point. A number of companies that sell these products to consumers also use the products themselves (for example, many computer retailers also perform service on customers' computer equipment which requires the use of cleaning fluids). Given the nature of this industry, it may be difficult for any person who sells or distributes these products to determine whether the purchaser intends to use them or resell them; the purchaser himself may not be certain at the time of purchase whether he intends to use or resell these products. Consequently, EPA has revised the definition of distributor to include resale of CFC-containing cleaning fluids to other distributors. The Agency would like to point out, however, that due to its decision to eliminate recordkeeping requirements, this change will not require any additional recordkeeping. The Agency believes that the burden involved in verifying that a distributor who purchases these products is a commercial entity will be minimal.

9. Imports and Exports

Two commenters requested clarification on whether the import of products made with CFCs would be prohibited under the ban. EPA believes that both the import of any product for sale or distribution within the United States, or the initial sale or distribution of any product intended for ultimate export from the point of manufacture to the point of export, are acts of interstate commerce for the purposes of section 610 and would, accordingly, be affected by this regulation. The import or export of products affected by today's rulemaking will be subject to the same restrictions as the sale, distribution, or offer of sale or distribution, in the United States (for a discussion of EPA's interpretation of "interstate commerce," see section III.A.7. of today's preamble). EPA will work in close cooperation with the U.S. Customs Service to enforce this restriction. Because today's rulemaking prohibits the sale, distribution, or offer of sale or distribution, in interstate commerce of products banned pursuant to section 610(b)(3) effective on January 17, 1994, these products may continue to be imported, or sold or distributed for export, until January 17, 1994.

10. Future Regulation

Several commenters criticized EPA for limiting the scope of today's rulemaking primarily to plastic flexible and packaging foams and aerosols and pressurized dispensers that release CFCs. In addition, several commenters discussed a number of products not covered by the proposed rule. Several of these products or processes, such as tobacco expansion, aerosol insulating foam, and the use of closed-cell polyurethane foam as a flotation foam, may meet the criteria for nonessentiality; nevertheless, as discussed elsewhere in today's rulemaking, EPA believes that it would be inappropriate to ban them in today's final rule because the Agency did not propose banning these products in the NPRM.

The status of methyl chloroform under the nonessential products regulation was raised by four commenters, and at the public hearing, one commenter criticized EPA for not covering methyl chloroform in the Class I nonessential rule. This commenter cited a major corporation's policy of phasing out the use of methyl chloroform by the end of 1992 to support the inclusion of methyl chloroform in the Class I nonessential products ban. The Agency encourages and applauds companies that have phased out the use of ozone depleting chemicals as quickly as possible, and it reiterates its belief that substitutes are available for many of the current uses of methyl chloroform. Methyl chloroform is a chemical with many extremely diverse end uses, however, and insufficient time was available for the Agency to analyze the uses of methyl chloroform systematically given the short statutory time-frame mandated for this rulemaking. The Agency will continue to collect information on the uses of methyl chloroform.

The Agency is aware that the potential exists for eliminating other nonessential uses of ozone-depleting substances. In that regard, EPA wishes to emphasize that, in general, other sections of the Act provide sufficient controls for reducing emissions of ozone-depleting substances. The use sectors and product categories addressed by the commenters have already been affected by the section 604 phaseout of the production of ozone-depleting substances and the excise tax on ozone-depleting substances. In addition, it is possible that they may also be specifically addressed in a number of other provisions of title VI. For example, the Agency is currently developing regulations to implement section 608, concerning emission limitations, and section 612, concerning safe substitutes, as well as the accelerated phaseout required by the recent modifications to the Montreal Protocol. The products and use sectors discussed in the Class I nonessential products ban will be affected by these regulations as well.

EPA will continue to collect information on the use of CFCs and acceptable substitutes. EPA has the authority to revise the list of products banned under sections 610(a) and 610(b), and, although the Agency does not at this time anticipate the need to add other products to the list of banned Class I products, it reserves the right to undertake additional rulemaking in the future regarding products that release Class I substances into the environment as necessary and appropriate.

11. Regulatory Impact Analysis

One commenter suggested that banning the use of CFCs in plasma etching would increase the costs associated with this regulation to over $100 million. Executive Order 12291 requires agencies to conduct a Regulatory Impact Analysis for regulations with economic impacts which exceed this level. Consequently, the commenter requested that EPA conduct a regulatory impact analysis (RIA) for the Class I nonessential products rulemaking if the use of CFCs in plasma etching was banned. EPA believes that the commenter is correct in observing that prohibiting the use of Class I substances in plasma etching would significantly increase the economic costs associated with the Class I nonessential products ban. However, as discussed elsewhere in today's rulemaking, EPA does not intend to ban the use of Class I substances in plasma etching. Consequently, the Agency believes that the cost and benefits chapter of the background document adequately addresses the regulatory impact of section 610, since it is considered to be only a minor rulemaking (see

Background Document). EPA believes that preparing an RIA is not required by the Executive Order for the Class I nonessential products ban rulemaking, and that consequently, preparing such a document would be redundant and inappropriate.

B. Specific End Uses

1. Statutorily Mandated Products

Section 610 listed three specific products to which the Class I nonessential products ban applies: Chlorofluorocarbon-propelled plastic party streamers, chlorofluorocarbon-propelled noise horns, and chlorofluorocarbon-containing cleaning fluids for noncommercial electronic and photographic equipment.

The statute left EPA little discretion with regard to the treatment of these products under the nonessential products ban, and no significant comments were received regarding them, with the exception of comments on the treatment of existing inventories. As mentioned in section II.A.6. of today's preamble, the final rule bans the sale, distribution, or offer of sale or distribution, in interstate commerce of these products effective on February 16, 1993.

2. Foams

a. *Distinciton between insulation foams and flexible and packaging foams.* One commenter suggested that the distinction between thermal insulation foams (which are excluded from the Class I nonessential products ban) and flexible and packaging foams (which are covered by the Class I ban) should not be reapplied for the Class II ban. According to the commenter, the legislative history indicates that the definition of insulation foams to be exempted from the Class II ban should be expanded beyond thermal insulation and include foam cushioning for other uses such as medical and electronic supplies. However, the commenter did not question EPA's decision to exempt thermal insulation foams produced with CFCs from the Class I nonessential products ban. EPA will consider the commenter's recommendations on the definition of "foam insulation product" in preparing the proposed rule for the Class II ban.

b. *Flexible polyurethane slabstock foam.* In the January 16, 1992 NPRM, EPA proposed to ban the use of CFCs in flexible polyurethane slabstock foam. The Agency also requested comment on the potential impacts of individual states' limits on the use of methylene chloride (MeCl) as a blowing agent in flexible polyurethane slabstock foams. EPA received two comments arguing that state and regional restrictions on the use of MeCl are unlikely to impose significant economic burdens on flexible foam manufacturers because acceptable alternative technologies are currently available. The Agency also received a third comment arguing that a ban on the use of CFC–11 in flexible polyurethane slabstock foam production, in conjunction with the impending 1994 Class II nonessential products ban on the use of HCFCs in the production of certain foams and the possible future restriction on methyl chloroform use as well, would cause production of super-soft and low-density foams to cease in those states that limit the use of MeCl. The commenter also urged EPA to allow limited exceptions to the ban until January 1, 1994 for those companies likely to be adversely affected by it. EPA carefully considered these comments in developing the provisions of the final rule that affected the production of flexible polyurethane slabstock foam.

In making its determination, EPA examined the purpose and intended use of flexible polyurethane slabstock foam. Flexible polyurethane slabstock foam finds use in cushioning applications for furniture, carpet underlay, bedding, automobile upholstery, and packaging, among others. EPA does not consider the purposes for which flexible slabstock is employed to be "frivolous."

EPA determined, however, that adequate substitutes for CFCs in the production of flexible polyurethane slabstock foam were indeed available. According to the 1991 UNEP Flexible and Rigid Foams Technical Options Report, CFC–11 use represents only a small fraction of total auxiliary blowing agent use in flexible slabstock foams. Because the vast majority of flexible slabstock producers have converted from CFC–11 to alternative blowing agents and processes, EPA believes that substitutes for CFCs are readily available in this area and that the use of CFCs in flexible polyurethane foam is therefore nonessential. At present, there are a number of alternatives to the use of CFCs in flexible polyurethane slabstock foam. MeCl represents the most widely used and widely available alternative. In areas that restrict the use of MeCl, manufacturers have turned to alternative blowing agents such as acetone, HCFCs, and methyl chloroform. Other near-term alternatives are also available. For example, modifications in polyol technology and the use of softening additives can reduce or even eliminate the need for certain auxiliary blowing agents. "AB" technology, which uses formic acid to double the quantity of gas produced during the isocyanate reaction, may offer a viable alternative to CFCs in those areas where other substitutes are infeasible. Finally, an increase in the density of foam produced can dramatically reduce the need for auxiliary blowing agents.

There are a number of safety and health issues associated with the possible substitutes for CFCs in the production of flexible polyurethane slabstock foam; however, EPA believes that with the proper precautions these alternatives can be used safely. EPA has classified MeCl as a probable human carcinogen with an Occupational Safety and Health Administration Permissible Exposure Limit (OSHA PEL) of 25 parts per million. Flexible foam manufacturers that use MeCl must follow appropriate worker health and safety practices. Acetone is extremely flammable, and manufacturers must ensure that ventilation is adequate, and they may need to take other safety precautions as well. Moreover, acetone is a volatile organic compound (VOC) that can contribute to the formation of ground-level ozone (smog). States have the primary responsibility for enforcing the National Ambient Air Quality Standards (NAAQS) that relate to ground-level ozone, and the use of acetone could be subject to restrictions in those regions classified as ozone nonattainment areas. HCFCs and methyl chloroform, although they have much lower potential to deplete stratospheric ozone than CFCs, have measurable ozone-depletion potentials; consequently, other sections of title VI place restrictions on HCFCs and methyl chloroform. Finally, the formic acid used in the "AB" process has a low Ph and requires special handling. In addition, the carbon monoxide produced by the reaction between the isocyanate and the formic acid can prove harmful without proper ventilation. While each of these alternatives presents some degree of risk to human health and the environment, EPA believes that with the proper precautions, each can be considered a possible substitute for CFC–11 in the production of super-soft and low-density flexible polyurethane slabstock foam. Consequently, the Agency believes that substitutes are available for this use of CFC–11, and that flexible polyurethane slabstock foam produced with CFC–11 is a nonessential product.

In making its determination to classify CFC use in flexible and packaging foams as nonessential, EPA also considered several other relevant factors. EPA believes that the excise tax on CFC–11 will provide a continuing incentive for manufacturers to convert to less costly

alternatives. Moreover, in those areas where MeCl use is restricted, the wide range of near-term alternatives for CFC–11 should provide flexible slabstock manufacturers with sufficient opportunity to find an acceptable substitute. As a result, EPA expects the economic impacts associated with a ban on CFC use in flexible slabstock foams to be minimal.

Based on consideration of the above criteria, EPA believes that the use of CFCs in flexible polyurethane slabstock foam is nonessential. Therefore, today's final rule bans the use of CFCs in flexible polyurethane slabstock foam. In response to the commenter's request for a limited exemption, EPA seriously considered allowing companies with foam production facilities located in NAAQS nonattainment areas for ground-level ozone in states that prohibit the use of methylene chloride to petition the EPA for a limited exemption to the ban until January 1, 1994. For EPA to grant such an exemption, petitioners would have had to satisfactorily document the reasons why these particular facilities could not modify their production processes without undue hardship. However, the effective date in today's rulemaking for the ban on production of flexible and packaging foams with CFCs is January 17, 1993. Since the effective date of the ban on CFC use in flexible slabstock foams roughly coincides with the date requested in the comment for the termination of the limited exemption, such an exemption appears unnecessary.

c. *Integral skin foam.* Two commenters addressed the use of polyurethane integral skin foam in automobiles. Polyurethane integral skin foam is used for flexible molded foam steering wheels and pads. One commenter was concerned that integral skin foam may be covered by the Class I rulemaking due to the broad regulatory language under the plastic flexible foam and packaging foam categories, and requested an exemption for the use of CFC–11 in the production of integral skin foam until January 1, 1994. The other commenter asserted that it had developed a process for producing integral skin foam using water as the blowing agent. EPA wishes to clarify the status of integral skin foam under the Class I nonessential products rulemaking. The Agency does not consider integral skin foam to be a plastic flexible or packaging foam product (see section I.I.3. of today's preamble), and EPA has not included integral skin foam in the Class I nonessential products ban. Consequently, there was no need to consider the commenter's request for an exemption for the use of CFC–11 in the production of integral skin foam. However, the phaseout of the production of CFCs by 1996 required under the newly-modified Montreal Protocol will force manufacturers to adopt alternatives to CFCs within a relatively short period of time regardless of the nonessential products ban. In addition, the Agency must consider the production of integral skin foam during the rulemaking for the Class II nonessential products ban. Consequently, EPA was pleased to learn from the public comments that the automobile industry expects to completely phase out the use of CFCs, as well as HCFCs, in the production of integral skin foam by January 1, 1994.

d. *Closed cell polyurethane foam used as flotation form.* EPA provided several illustrative examples of "noninsulating uses" for flexible and packaging foams in its preamble to the proposed rule, including flotation foam. Since publication of the proposed rule, EPA has become aware that closed cell polyurethane foam, which EPA does not consider a flexible or packaging foam, is used as a flotation foam in the manufacture of certain boats. At least one manufacturer uses a CFC-blown foam as both structural and flotation material in the manufacture of its boats. Consequently, in drafting today's rulemaking, EPA considered whether it should include this application in the Class I nonessential products ban.

In evaluating this application of closed cell polyurethane foam, EPA examined the purpose and intended use of flotation foam. Flotation foam serves as an important safety feature of many small watercraft. In addition, in at least one product line, closed cell polyurethane foam serves as a structural element as well. Consequently, EPA does not believe that the purpose of closed cell polyurethane flotation foam is "frivolous."

The use of CFCs in this product, which EPA does not consider a flexible or packaging foam, may not be nonessential at the present time. One manufacturer of closed cell polyurethane flotation foam has indicated its intention to convert from CFCs to HCFCs in the near future. However, EPA has not verified that all uses of closed cell polyurethane flotation foam have available non-CFC alternatives at this time.

Flotation foam serves an important safety function in the design and operation of boats, and EPA does not want to take action that would jeopardize the continued manufacture of this type of foam. However, EPA is concerned about the risks to human health and the environment posed by continued use of Class I substances in the manufacture of closed cell polyurethane flotation foam as well. As a result, the Agency intends to continue examining the need to prohibit such use.

EPA also considered several other relevant factors. EPA believes that the excise tax on CFCs will provide a continuing incentive for manufacturers to move away from the use of CFC–11 where possible. In addition, the accelerated phaseout will force manufacturers to adopt alternatives within a relatively short period of time regardless of the nonessential products ban.

Finally, EPA believes that it would be inappropriate to include new product categories in the ban that were not considered by the proposed rule. EPA believes that the Administrative Procedure Act and section 307(d) of the Clean Air Act require EPA to propose rulemaking and take comment before proceeding to final rulemaking. In preparing the proposed rule, EPA relied heavily upon the research conducted for the 1991 UNEP Flexible and Rigid Foams Technical Options Report. EPA participated in the development of the definitions of product categories utilized in the UNEP technical options reports, and the Agency routinely employs these categories in its own reports, internal documents, and rulemakings. The UNEP report categorizes closed cell polyurethane foam as an insulating foam rather than a flexible or packaging foam. EPA, too, categorizes closed cell polyurethane foam as an insulating foam, not a flexible and packaging foam. Because EPA was unaware that closed cell polyurethane foam was used as a flotation foam at the time the NPRM was published, it did not include the use of closed cell polyurethane foam as a flotation foam in the proposed Class I nonessential products ban.

Today's rulemaking covers only products proposed in the January 16, 1992 proposed rule. Consequently, closed cell polyurethane flotation foam is not included in the nonessential products ban implemented by today's rulemaking. However, EPA research indicates that the use of CFC-blown closed cell polyurethane foam as flotation foam may indeed meet the criteria for nonessentiality. The Agency is also aware that the self-effectuating 1994 ban on HCFC use in noninsulating foams could encourage movement away from HCFCs and back to CFCs. Because the Agency intends to avoid promoting such environmentally harmful activity,

it will continue to examine the need to prohibit CFC use in closed cell polyurethane flotation foams. EPA has the authority to consider designating as nonessential other products which release ozone-depleting substances in future rulemakings, and the Agency may consider such action if at a later date EPA determines that these products satisfy the criteria for nonessentiality.

e. *Coaxial cable.* EPA did not address the issue of coaxial cable in the preamble to the proposed rule. At the time that EPA promulgated the proposed rule, the Agency was unaware that CFCs are used in the production coaxial cable. Moreover, the Agency received no formal comments regarding CFC use in coaxial cable. However, since promulgation of the proposed rule, manufacturers of coaxial cable have informed EPA that such use exists.

Coaxial cable is widely used as a transmitter of telephone and television signals. It consists of two conductors (e.g., steel and aluminum) separated by a dielectric (nonconducting) material. Manufacturers claim that acceptable dielectric material must generate a specific wave pattern to ensure against problems such as "signal dropout." As a result, the foam within coaxial cable must confirm to stringent performance standards.

At least one cable manufacturer currently employs an extruded polyethylene foam blown with CFC–12 as the dielectric material in its coaxial cable. The same manufacturer is in the process of converting to a non-ODP blowing agent to replace its use of CFC–12; however, it is unclear whether other manufacturers of coaxial cable could take advantage of this process.

In evaluating this product, EPA examined the purpose and intended use of coaxial cable. EPA recognizes that the purposes served by coaxial cable are not "frivolous."

EPA has not been able to determine that adequate substitutes for CFCs in the production of coaxial cable are available. Therefore, the use of CFCs in this area may not be nonessential at the present time. It appears that the largest manufacturer of coaxial cable does not use CFCs in the manufacture of its product. In addition, another manufacturer of coaxial cable has indicated its intention to convert to a non-ODP blowing agent in the manufacture of its product. However, EPA knows very little about these substitutes at this time, and the Agency has been unable to confirm that substitutes for CFCs are currently available for most coaxial cable manufacturers.

EPA is also concerned about the tradeoff between the risks to human health and the environment posed by continued use of Class I substances in the manufacture of coaxial cable and the risks to human health and the environment posed by the use of particular substitutes. As a result, EPA intends to continue collecting information on possible CFC substitutes for this application.

EPA also considered several other relevant factors. A ban on CFC use in the manufacture of coaxial cable could prove harmful to some coaxial cable manufacturers. Moreover, EPA believes that the excise tax on CFCs will provide a continuing incentive for coaxial cable manufacturers to move away from the use of CFC–12 where possible. In addition, the accelerated phaseout will force manufacturers to adopt alternatives within a relatively short period of time regardless of the nonessential products ban.

Consequently, EPA does not intend to ban the use of CFCs in coaxial cable at this time. However, the Agency will continue to examine the need to take action in the future to prohibit the use of CFCs in the manufacture of coaxial cable.

f. *Aerosol polyurethane foam.* Aerosol polyurethane foam, also known as one component foam, is used by both the building industry and by do-it-yourselfers in a variety of applications. These include draft-proofing around pipes, cable runs, doors and windows; sealing doors and window frames; and joining together insulating panels, roofing boards, and pipe insulation.

CFC–12 has traditionally been the blowing agent of choice for aerosol foams because of its relatively low boiling point. CFC–12 acts both as a propellant and as a blowing agent yielding "frothed foam" that does not flow away from the site of its application. In recent years, there has been widespread conversion away from CFC–12 and toward alternatives such as HCFC–22 and hydrocarbons.

EPA did not address aerosol foams directly in the preamble to the proposed rule. However, the Agency wishes to clarify that, for the purposes of this rulemaking, aerosol foams will be treated as foams and not as aerosols. EPA believes that this approach is consistent with regulations published by the Internal Revenue Service (52 FR 56303) that treat spray foam as an insulating foam product for tax purposes. Despite this determination, EPA did evaluate this product against the criteria in section 610(b)(3).

EPA does not believe that either the purpose or intended use of aerosol polyurethane foam is "frivolous." Moreover, because substitutes for CFCs in aerosol polyurethane foam may not be available for all applications, EPA did not determine that the use of CFCs in this product is nonessential at this time.

While many manufacturers have converted from CFCs to alternatives such as HCFCs and hydrocarbons, it is not clear that non-CFC substitutes are adequate for all applications at the present time. Hydrocarbons may pose flammability risks both at the point of manufacture and at the point of use. In addition, both hydrocarbons and HCFCs lack the thermal insulating capabilities of CFC–12.

Hydrocarbons, because of their flammability, may pose significant risks to safety and health when used as propellants and blowing agents in aerosol foams. However, EPA is also concerned about the risks to human health and the environment posed by continued use of Class I substances in aerosol foams. As a result, the Agency intends to continue examining the need to prohibit such use.

In evaluating aerosol polyurethane foam, EPA also considered several other relevant factors. Certain manufacturers may be unable to convert to non-CFC alternatives at this time due to considerations of safety, energy efficiency, or technological viability. As a result, a ban on the use of CFCs in aerosol foams may be undesirable. Moreover, EPA believes that the excise tax on CFCs will provide a continuing incentive for manufacturers to move away from the use of CFC–12 where possible. In addition, the accelerated phaseout will force manufacturers to adopt alternatives within a relatively short period of time regardless of the nonessential products ban.

Finally, EPA believes that it would be inappropriate to include new product categories in the ban that were not considered by the proposed rule. EPA considers aerosol polyurethane foam to be an insulating foam, not a flexible and packaging foam. Consequently, this product was not included in the proposed Class I nonessential products ban. Today's rulemaking covers only products proposed in the January 16, 1992 proposed rule; consequently, aerosol polyurethane foam is not included in the nonessential products ban implemented by today's rulemaking. However, preliminary EPA research indicates that the use of CFCs in aerosol polyurethane foam may indeed meet the criteria for nonessentiality. EPA has the authority to consider designating as nonessential other products that release ozone-

depleting substances in future rulemakings, and the Agency may consider such action if at a later date EPA determines that these products satisfy the criteria for nonessentiality.

3. Aerosols

a. *Impact of 1994 Class II nonessential products ban.* Several commenters argued that the proposed rulemaking's inclusion of aerosol products was unwarranted. They felt that EPA's concern that some manufacturers would switch from the use of Class II substances to Class I substances in certain products after January 1, 1994, was unjustified. The commenters stated that market forces would prevent Class I substances from being used in place of Class II substances after 1994. In response, the Agency wishes to emphasize that it is encouraged by steady movement of the aerosol market into non-ozone depleting compounds. EPA believes that the use of Class I substances in place of Class II substances in most aerosol products after January 1, 1994 is unlikely. However, without a regulatory restriction on the use of CFCs in aerosols, there are possible scenarios under which the use of CFCs may be attractive in 1994, when the ban on the use of HCFCs in aerosols takes effect. Consequently, EPA reiterates the view expressed in the proposed rule that the Class I ban on aerosols is necessary to prevent federal policy from actually encouraging additional destruction of the stratospheric ozone layer.

One commenter was concerned that by banning the use of CFCs in aerosol products, EPA was closing the provisions made in the Act for granting exceptions for the use of Class II substances. EPA notes that the commenter is correct in observing that today's rulemaking may impact the Class II ban on aerosol products. However, this does not render the exceptions in the statute irrelevant. The Act permits the continued use of Class II compounds only if the Administrator determines that the aerosol product or pressurized dispenser is essential as a result of flammability or worker safety concerns and that the only available substitute is a legally available Class I substance. While today's rulemaking does restrict the use of Class I substances in aerosol products, this is not contrary to Congressional intent. EPA is not banning all uses of Class I substances in aerosols; consequently, while today's action reduces the number of possible candidates for exceptions to the Class II ban on aerosol products, it does not preclude future action to except uses of Class II substances in aerosols or pressurized dispensers.

The restrictions on the use of Class I substances in aerosols and other pressurized dispensers under today's regulations are rooted in the fact that for many aerosol uses, which were exempted under the 1978 aerosol ban, substitutes have since been developed. EPA has shown considerable flexibility in granting exceptions for Class I compounds where a substitute is unavailable (MDIs and mold release agents, for example). In addition, the exception for the use of Class II compounds due to flammability and worker safety concerns presents another opportunity for the Agency to grant limited exceptions for the use of Class II substances.

b. *Clarification of "aerosols and other pressurized dispensers".* One commenter requested that EPA examine the use of the phrase "other pressurized dispensers" in the language for the aerosol restrictions. According to the commenter, "other pressurized dispensers" could be interpreted as applying to pressurized containers ("bulk containers") used to distribute materials for use in other products because these materials generally are self-pressurized when so contained. The commenter proposed that EPA exclude any pressurized vessel being used as the containment vessel for distribution purposes when the material therein contained is self-pressurized. EPA agrees with the commenter that further clarification of the definition of pressurized containers is necessary. The use of the phrase "other pressurized dispensers" was meant to include non-aerosol products such as CFC–12 dusters and freeze sprays. EPA does not believe that the term "other pressurized dispensers" applies to pressurized containment vessels such as small containers of motor vehicle refrigerant or containment vessels for recycled, recovered or reclaimed refrigerant. Such an interpretation would have a devastating and unintended impact on the air conditioning and refrigeration industry.

As a result of this comment, EPA wishes to clarify that the phrase "aerosol product or other pressurized dispenser" does not include containers which are used for the transportation or storage of Class I substances or mixtures (bulk containers are described in 40 CFR 82.3(i) and the July 30, 1992 final rule implementing section 604 and related provisions of sections 603, 607, and 616 of the Act (57 FR 33754)). Such a bulk container is not part of a use system; rather, as specified in 40 CFR 82.3(i), the "substance or mixture must first be transferred from a bulk container to another container, vessel, or piece of equipment in order to realize its intended use." An example of an ambiguous situation affected by this clarification is the use of a 12-ounce container of CFC–12 used to recharge a motor vehicle air-conditioner. The CFC–12, while it is in the container, is not acting and will not act as a refrigerant. The CFC must be charged into the motor vehicle air conditioning system before it can serve as a refrigerant. Once the refrigerant is charged into the air-conditioner, the container is discarded and serves no purpose in the operation of the air-conditioner. Since the container only serves to transport and store the chemical, EPA considers it to be a bulk container, and not subject to the Class I nonessential products ban.

c. *Dusters and freeze sprays.* One commenter requested an exemption for the use of CFC–12 in freeze sprays used on electronic equipment. Another commenter expressed its belief that the Act specifically prohibited the sale or distribution of Class II substances such as HCFC–22 in aerosols after January 1, 1994, but allowed the continued sale or distribution of CFC–12 dusters. The commenter felt that the use of CFC–12 in aerosol dusters was an unacceptable loophole. EPA wishes to clarify that while the Act does not specifically ban the use of Class I substances in aerosol dusters, it requires EPA to identify and ban nonessential products containing Class I substances. Consequently, the final rule addresses a number of Class I use sectors not specifically identified in the statute, including aerosols and plastic flexible and packaging foams.

Dusters and freeze sprays (also referred to as freezants) typically contain a pressurized fluid, such as CFC–12, which is released as a gas (duster) or as a liquid (freezant). Dusters and freeze sprays contain only one ingredient and are used for both commercial and noncommercial applications. The noncommercial use of dusters was addressed earlier in the preamble (see section I.I.1.c.). EPA considers gas sprays containing CFCs to be among the products described as CFC-containing cleaning fluids for noncommercial electronic and photographic equipment in section 610(b)(2). Consequently, the sale of gas sprays to noncommercial purchasers is banned by today's rulemaking, as required by the statue.

Dusters are primarily used in the electronic and photographic industries to blow fine dirt materials and dust away from products which need to be kept dust-free and which cannot be wiped clean. Freeze sprays can be used

for a variety of purposes including shrink fitting small metal products, testing for faults in electronic equipment, some medical applications, and the removal of chewing gum and other waxy or gummed substances from various surfaces.

Based on information in a recent report to EPA's Office of Research and Development and information provided by commenters, EPA evaluated dusters and freeze sprays against the criteria for nonessentiality and determined that the use of CFCs in these aerosol products, i.e. as propellant or sole ingredient, does not warrant an exemption and, therefore, should be banned as nonessential.

Dusters and freeze sprays serve an important and nonfrivolous purpose for the electronics industry as well as other users. EPA has not determined that the purpose and intended use of these products is nonessential. However, because there are commercially available substitutes, EPA believes that the use of CFC–12 in dusters and freeze sprays is nonessential.

Several substitute formulations for the use of CFC–12 in dusters and freeze sprays have been identified, including HCFCs, hydrocarbons, and inert gases (e.g., carbon dioxide and nitrogen oxide). Non-aerosol alternatives are also available. EPA believes, therefore, that adequate substitutes are readily available for CFC–12 as the sole ingredient in dusters and freeze sprays.

EPA is aware that, to ensure the safety of workers in the electronics industry, alternative formulations for aerosol products used on electronic or electrical equipment must be nontoxic and, in most applications, nonflammable. EPA believes, however, that effective and safe non-CFC propellants are readily available.

In making its determination regarding these products, EPA also considered the economic impact of banning these products. EPA acknowledges that any manufacturers still producing CFC dusters or freeze sprays would suffer some economic impact as a result of this rule. EPA believes, however, that given a 12-month period before the ban on these products takes effect, these manufacturers will have sufficient opportunity to liquidate existing inventories and reformulate their products with a substitute for CFC–12. In any case, manufacturers will have to convert to a non-CFC substitute soon, given the phaseout of CFC production by January 1, 1996 under the modified Montreal Protocol.

In conclusion, EPA has determined that the use of Class I substances such as CFC–12 as the sole ingredients in dusters or freeze sprays is nonessential and, therefore, dusters and freeze sprays are included in the ban on nonessential products promulgated in today's rulemaking. Consequently, the loophole which concerned the second commenter will not exist.

d. *Lubricants, coatings, and cleaning fluids for electrical or electronic equipment.* In the proposed rule, EPA proposed to ban the use of CFCs in all aerosol products and pressurized dispensers with a number of exemptions, including the use of CFC–11 or CFC–113 in lubricants, coatings, and cleaners for commercial electrical and electronic uses. EPA received one comment requesting that the exemption for commercial electrical and electronic uses be expanded to include CFC–12.

Lubricants and coatings typically contain an active ingredient (the lubricating or coating material), a solvent or diluent, and a propellant. Cleaning fluids can include solvent sprays and gas sprays (gas sprays are discussed in the preceding section on dusters and freeze sprays). The solvent sprays typically contain a solvent and a propellant and are dispensed as a liquid. Lubricants, coatings and cleaning fluids can contain CFCs as either solvents or as propellants. CFC–11 and CFC–113 are the most common CFCs used as solvents, although a commenter claimed that CFC–12 is also used as a solvent in certain applications. CFC–12, however, is most commonly used as a propellant. EPA believes that the use of CFC–12 as a solvent rather than a propellant is very small.

Based on information in a recent report by EPA's Office of Research and Development and information provided by commenters, EPA evaluated lubricants, coatings, and cleaning fluids for electrical and electronic equipment against the criteria for nonessentiality and determined that: (1) Use of CFCs as solvents or diluents in these aerosol products should not be banned, but that (2) use of CFCs as propellants in these aerosol products does not warrant an exemption and, therefore, should be banned.

Lubricants, coatings and cleaners for electronic and electrical equipment serve an important and nonfrivolous purpose for the electronics industry. EPA has not determined that the purpose and intended use of these products is nonessential.

EPA research indicates that adequate substitutes for the use of CFCs as solvents or diluents in these applications may not yet be available. In November 1989, EPA's Office of Research and Development (ORD) published an evaluation of the need for continued use of CFCs in both exempted and excluded uses of CFCs in aerosols (see Alternative Formulations). The ORD report concluded that adequate substitutes did not yet exist for lubricants, coatings and cleaners using CFC–11 or CFC–113 for commercial electrical and electronic equipment. EPA believes that adequate substitutes have still not been found for CFCs used as solvents or diluents in these aerosol products. In addition, according to a commenter, CFC–12 is occasionally used as a solvent in these products. EPA believes that the use of CFC–12 as a solvent is similar to that of CFC–11 and CFC–113 and that substitutes may not be available for this application either.

However, several substitute formulations for the use of CFC–12 as a propellant have been identified, including HCFCs, hydrocarbons, and inert gases (e.g., carbon dioxide and nitrogen oxide). These substitute propellants are suitable for use as propellants in products that contain other ingredients, such as solvent sprays, lubricants, and coatings. Non-aerosol alternatives are also available. EPA believes, therefore, that adequate substitutes are available for CFC–12 as a propellant in lubricants, coatings, and cleaners for commercial electrical and electronic equipment.

EPA is aware that, to ensure the safety of workers in the electronics industry, alternative formulations for aerosol products used on electronic or electrical equipment must be nontoxic and, in most applications, nonflammable. EPA believes that, while effective and safe non-CFC propellants are readily available, non-CFC solvents may not be available.

In making its determination regarding these products, EPA also considered the economic impact of banning these products. Since substitutes for CFC solvents in aerosol lubricants, coatings, and cleaners for electronic equipment are not readily available, banning these products could have a significant economic impact on the electronics industry.

In conclusion, EPA will permit the continued use of CFC–11, CFC–12, and CFC–113 in aerosol lubricants, coatings and cleaners for electronic and electrical equipment if the CFCs are used as solvents or diluents. EPA has, however, determined that the use of CFC–12 as a propellant is nonessential and, therefore, its use is banned. As noted above, EPA believes that the use of CFC–12 as a solvent rather than as a propellant is very limited. EPA, therefore, expects that CFC–12 will be used in very few aerosol products and only in situations where the

manufacturer can clearly demonstrate that CFC–12 is not used as a propellant. EPA will continue to examine the need to take action in the future regarding the remaining uses of CFCs in lubricants, coatings, and cleaning fluids.

In addition, one commenter suggested that the treatment of lubricants, coatings and cleaning fluids for electrical or electronic equipment in the proposed rule was ambiguous. The commenter requested clarification about the effect that the phrase "other than those specified above" in § 82.66(d) had on the treatment of these products.

In drafting the proposed rule, EPA intended to prohibit all aerosol uses of CFCs in lubricants, coatings, and cleaning fluids for electrical or electronic equipment except for the use of CFC–11 and CFC–113 for nonpropellant purposes in such products. The preamble to the January 16, 1992 NPRM clearly expressed this intent (as mentioned above, EPA has subsequently decided to include the use of CFC–12 for nonpropellant purposes in this exception). EPA acknowledges, however, that the use of the phrase "other than those specified above" in § 82.66(d) of the proposed rule did not clearly express this intent, because it could have been interpreted as excluding additional commercial uses of such cleaning fluids in certain electronic applications from coverage under the Class I ban. This was not EPA's intent. Consequently, in response to the commenter's request for clarification, the phrase "other than those specified above" has been changed to "other than those banned in § 82.64(a) or § 82.64(b)" in today's rulemaking.

e. *Spinnerette lubricant/cleaning spray.* In the proposed rule, EPA exempted several solvent applications of CFCs in certain aerosol products due to a lack of available substitutes. One exempted product category consisted of release agents for molds using CFC–11 or CFC–113 in the production of plastic and elastomeric materials. EPA received one comment requesting that a class of somewhat similar products, spinnerette lubricant/cleaning sprays used for synthetic fiber production, be exempted from the ban on aerosols and pressurized dispensers containing CFCs.

During the production of certain synthetic fibers such as acrylic, a silicone product is sprayed onto spinning blocks called spinnerettes. In certain applications, this aerosol product, containing CFC–114 as the solvent and silicone as the active ingredient, is used to both clean and lubricate the spinnerettes in order to remove unwanted residue which otherwise builds up on them. The formulation acts both as a lubricant and as a cleaning agent. Spinnerette lubricant/cleaning sprays currently contain CFCs, both as solvents and as propellants. CFC–114 is preferred as a solvent because it is nonflammable, nontoxic, and provides adequate dispersion of the active ingredient. CFC–12 is used as the propellant. The commenter estimates that its annual usage of CFC–114 is roughly 9,000 pounds per year.

Based on the information provided by the commenter, EPA evaluated spinnerette cleaning lubricant sprays against the criteria for nonessentiality and determined that: (1) Use of CFCs as solvents in these aerosol products should not be banned as nonessential products at this time, but that (2) use of CFCs as propellants do not warrant an exemption and, therefore, should be banned as nonessential products.

In making its determination, EPA examined the purpose and intended use of spinnerette lubricant/cleaning sprays. EPA acknowledges the importance of this product for the production of certain synthetic fibers and does not consider the use of spinnerette lubricant/cleaning sprays to be nonessential.

The commenter indicated that although research on alternatives is currently underway, no solvent substitute which is as safe and effective as the CFC–114 formulation for spinnerette lubricant/cleaning sprays is available at this time. However, several substitute formulations for the use of CFC–12 as a propellant have been identified including HCFCs and inert gases (e.g., carbon dioxide and nitrogen oxide). EPA believes, therefore, that adequate substitutes are available for CFC–12 as a propellant in spinnerette cleaning lubricants used for fiber production.

To ensure worker safety, spinnerette cleaning lubricants should be nonflammable and nontoxic. EPA believes that, while safe and effective non-CFC propellants are readily available, non-CFC solvent alternatives for CFC–114 may not be available for all applications at this time.

In making its determination, EPA also considered the economic impact of banning the use of CFC–114 in spinnerette lubricant/cleaning sprays. Since substitutes for the CFC–114 solvent in aerosol spinnerette lubricant/cleaning sprays are not readily available, banning these products could have a significant economic impact on the fiber-producing industries using this production method.

The excise tax on ozone-depleting compounds and the accelerated phaseout will force manufacturers to adopt alternatives within a relatively short period of time regardless of the nonessential products ban. The industry is currently conducting research on such substitutes.

EPA has, therefore, decided to exempt the use of CFC–114 as a solvent in spinnerette lubricant/cleaning sprays from the ban on aerosol products and pressurized dispensers containing CFCs at this time. However, the use of CFC–12 as a propellant in this product is nonessential and, therefore, such use is banned.

f. *Plasma etching.* EPA received several comments requesting that EPA exempt the use of CFCs for plasma etching from the ban on aerosol products and pressurized dispensers containing CFCs.

One step in the manufacturing process of semiconductors and other microcomputer components requires the sub-micron etching of circuit lines on thin sheets of silicon crystal. This technology process, referred to as plasma or dry etching, uses various chlorine- and fluorine-containing chemicals as halide sources to create a plasma which is used to etch the silicon wafers within a sealed chamber. The chemicals used vary depending on the process and include CFCs, halons, carbon tetrachloride, and methyl chloroform. These ozone depleting substances are transformed into chemicals with no ozone depleting potential in the plasma etching process.

The chemicals used for this process are usually contained in stainless steel cylinders. Containers of low pressure substances, such as CFC–11 and methyl chloroform, are pressurized with nitrogen or carbon dioxide; containers of high pressure substances are self pressurized. Typically, hoses and other dispensing mechanisms are attached to the containers or cylinders prior to their use for plasma etching to allow the chemical to flow into the sealed chambers at carefully regulated rates.

Based on information provided by the commenters and after conducting further research into this process, EPA evaluated pressurized dispensers for plasma etching against the criteria for nonessentiality and determined that they should not be banned as nonessential products.

In making its determination, EPA examined the purpose and intended use of plasma etching. Pressurized dispensers containing CFCs for plasma etching provide an important function for the computer industry in the

manufacture of semiconductors and are not nonessential.

EPA also evaluated the availability of substitutes for the CFCs used in plasma etching. The Agency is aware that manufacturers are in the process of developing substitutes for the Class I substances currently used for plasma etching. The excise tax on ozone-depleting compounds and the accelerated phaseout will force manufacturers to adopt alternatives within a relatively short period of time regardless of the nonessential products ban. However, no such substitutes are currently available for immediate use at economical prices. The cost of converting away from CFCs over a one-year period, as would be required if such uses were included in the ban on nonessential products—even if that conversion is technologically feasible—is economically prohibitive. Industry estimates suggest that costs would approach several million dollars per facility. Therefore, EPA does not consider that substitutes are available within the time frame of the nonessential products rule.

EPA is not aware of any safety or health considerations associated with the alternatives for CFCs in plasma etching. However, EPA is also aware that, since virtually all of the CFCs used for plasma etching are transformed, the ozone depleting potential of the CFCs used in making these products is destroyed in the plasma etching process. Consequently banning the use of CFCs in the plasma etching process would have an immeasurably small environmental benefit.

Due to the lack of available substitutes at this time, EPA has decided to include the use of CFCs for plasma etching in the list of products exempted from the ban on aerosol products and pressurized dispensers. The accelerated phaseout will force manufacturers to adopt alternatives within a relatively short period of time regardless of the nonessential products ban. EPA encourages the industry to make a swift and efficient transition to these alternatives.

g. *Red pepper bear repellent spray.* EPA received one comment requesting that red pepper defensive spray used as a bear repellent be exempted from the ban on nonessential aerosol products containing CFCs. The commenter argued that its product did not meet EPA's criteria for nonessentiality and, thus, should not be banned.

Red pepper sprays are aerosol products used to temporarily disable an attacker. They contain an active ingredient (the essence of red pepper) that causes temporary blindness, breathing difficulties, and severe skin discomfort to animals or humans that come into contact with it. Red pepper sprays are used by individuals and law enforcement agencies for a variety of purposes ranging from personal protection to crowd control. In addition, bear repellent spray containing red pepper is used by campers, hikers, and park and forest service officials, most typically against charging grizzly bears. EPA is aware that CFC–113 is used as a solvent in at least one defensive spray. EPA is not aware of any other safety sprays containing CFCs as propellants.

CFC–113 is used as a solvent in at least one defensive spray. This product, developed as a bear repellent spray, uses CFC–113 to propel the active ingredient some distance and produce a large cloud of repellent fog that remains in the air long enough to affect a charging bear. The commenter argued that no available substitute could produce the necessary cloud of repellent at sufficient distance. The commenter also uses CFC–113 because it is nonflammable, nontoxic, and compatible with the active ingredient.

Based on information provided by the commenter and after conducting further research into this product, EPA evaluated red pepper sprays against the criteria for nonessentiality and determined that: (1) Use of CFCs as solvents in red pepper sprays used as bear repellent should not be banned; but that (2) use of CFCs as solvents in other safety sprays, including red pepper sprays, is nonessential; and (3) use of CFCs as propellants in all safety sprays is nonessential and, therefore, should be banned under this rule. An exemption to the ban is warranted only for the use of CFC–113 as a solvent in bear repellent sprays.

In making its determination, EPA examined the purpose and intended use of red pepper spray. EPA acknowledges that red pepper sprays serve an important nonfrivolous use and has not concluded that the use of red pepper sprays is nonessential. However, EPA has determined that the use of CFCs in red pepper sprays is, in most cases, unnecessary and is, therefore, nonessential.

EPA determined that adequate substitutes for CFCs in the production of red pepper spray were indeed available for all applications, with the possible exception of bear repellents. Several manufacturers produce non-CFC aerosol formulations of red pepper and other personal safety sprays for protection against humans. Solvents in these formulations include methyl chloroform, HCFC–141b, dimethyl ether, and water-based compounds. As a result, EPA has concluded that effective substitutes are available for the CFC solvent in red pepper and other safety sprays used against humans, and that use of CFCs in these red pepper sprays is nonessential. However, no manufacturer has formulated a non-CFC bear repellent spray that has been proven to be effective. The solvent use of CFCs in these products is necessary to allow the spray to travel long distances and produce adequate dispersion to stop a charging bear. Therefore, the Agency believes that substitutes may not be available for application against bears.

There are a number of safety and health issues associated with the possible substitutes for CFCs in the production of red pepper spray. EPA understands that, because of potential dangers posed to both the user and the intended target, formulations (including solvents) should be nontoxic and nonflammable. EPA believes that non-CFC formulations currently exist for most defensive sprays that are both effective and safe to use. However, since proven substitutes for CFC–113 in bear repellent have not been tested yet, EPA concluded that a safe and effective non-CFC formulation for bear repellent may not be available.

EPA acknowledges that the manufacturer producing the CFC formulation would suffer some economic impact as a result of this rulemaking (the company markets this product for use against humans as well). EPA believes, however, that given a 12-month period before the ban takes effect, the manufacturer will have sufficient opportunity to reformulate its product for use against humans with a substitute for the CFC solvent. However, since substitutes for CFC solvents in red pepper sprays used as bear repellent are not readily available at this time, banning these products could cause more significant economic injury for the manufacturer of this product. In any case, the manufacturer will have to convert to a non-CFC substitute soon, given the phaseout of CFC production by January 1, 1996 under the modified Montreal Protocol.

In conclusion, EPA will permit the continued use of CFC–113 as a solvent in red pepper sprays used as bear repellent. EPA believes, however, that it is not necessary to exempt other safety sprays, including red pepper sprays, for use against humans from the ban on nonessential products. Therefore, aerosol or pressurized dispensers of red pepper sprays containing CFCs which are not sold as bear repellent will be included in the ban. EPA has also determined that the use of CFC–12 as a

propellant in safety sprays is nonessential and, therefore, such use is banned. EPA will continue to examine the need to take action in the future to prohibit the remaining uses of CFCs in red pepper safety sprays as appropriate.

h. *Document preservation.* EPA received one comment requesting that processes and products used for the preservation of books and archival documents be exempted from the ban on aerosols and pressurized dispensers containing CFCs. Further research conducted by EPA determined that at least two manufacturers in the U.S. produce aerosol products which are used for document preservation.

Books, documents, and works of art on paper can be preserved through the application of a nonaqueous deacidification treatment which neutralizes existing acids in paper and increases its expected life for several hundred years. There are several application methods for this technology, including a dipping method, a liquified gas process conducted in an enclosed chamber, and an aerosol spray method. Most of the existing methods that have proven to be both safe and effective use CFC solvents (primarily CFC–113) to dissolve the preserving and alkalizing chemicals and/or act as carriers to transport them to the paper. CFC–113 is preferred because it is nonflammable, nontoxic, evaporates quickly, is nonreactive with the document material, and displays little or no tendency to dissolve inks, dyes, or bindings. EPA estimates that the production of aerosol document preservation sprays uses less than 10,000 pounds of CFCs per year.

Most documents at large institutions are preserved through a non-aerosol mass deacidification process. This method does not necessarily require the use of CFCs but is not generally available to outside users. However, the aerosol method, which involves spraying the preserving chemicals directly onto documents through an aerosol can or pressurized dispenser, is the only method that is appropriate and affordable for extremely delicate or valuable documents or for occasional and small volume users such as librarians, conservators, and archivists. Due to the risk of loss or irreparable damage, transportation of documents to centralized deacidification facilities may often not be possible.

Based on the information provided by the commenter and by other manufacturers of this product, EPA evaluated document preservation sprays against the criteria for nonessentiality and determined that the products should not be banned as nonessential products at this time.

In making its determination, EPA examined the purpose and intended use of document preservation sprays. EPA acknowledges the importance of this product for preserving valuable and historic documents and does not consider the use of document preservation sprays to be nonessential.

Manufacturers have indicated that no substitute which is as safe and effective as the CFC formulation for aerosol document preservation sprays is available at this time. The excise tax on ozone-depleting compounds and the accelerated phaseout will force manufacturers to adopt alternatives within a relatively short period of time regardless of the nonessential products ban. EPA is aware that at least one manufacturer is currently in the process of developing a non-CFC formulation for its aerosol deacidification product. Development of this formulation is, however, in the early stages, and the technology has not yet been demonstrated to be effective in the field. EPA believes, therefore, that safe and effective solvent substitutes have not yet been found.

To protect the safety of both the user and the document to be preserved, document preservation sprays should be nonflammable and nontoxic. EPA believes that safe and effective alternatives for CFC–113 in document preservation sprays are not available at this time.

In making its determination, EPA also considered the impact on society of banning this product. Since non-CFC substitutes for CFC–113 in document preservation sprays are not readily available, banning this use of CFC–113 would eliminate a product which may be the only preservation technology available to occasional and small volume users. EPA acknowledges that, if these preservation sprays were banned, many valuable documents might not be preserved. The deterioration of many of these documents would result in a loss to society that, although difficult to measure, would be significant.

EPA has, therefore, decided to exempt the use of CFC–113 in document preservation sprays from the ban on aerosol products and pressurized dispensers containing CFCs. EPA does not believe that this product is a nonessential product under the criteria specified in Section 610. EPA will, however, continue to examine the need to take action in the future to prohibit the use of CFCs in document preservation sprays should substitutes be developed.

4. Medical Products

The proposed rule exempted certain medical products from the ban, but it requested comments on the need for continued CFC use in medical products.

The Agency received many comments regarding the omission from the regulatory language of certain products that have been declared essential uses of CFCs by the Food and Drug Administration (FDA). One commenter recommended that all products listed as essential by the FDA should be exempted from the ban. The EPA wants to clarify that it is indeed the Agency's intent to exempt all products listed as essential by the FDA in 21 CFR 2.125. With that end in mind, the final rule was re-written to reference 21 CFR 2.125 rather than to list specific uses. Today's final rule exempts the sale or distribution of CFCs in the medical products listed in 21 CFR 2.125. EPA will continue to work in close cooperation with the FDA to monitor the relevant developments in technology and to evaluate the need for CFCs in various medical applications. If, at some point in the future, the FDA removes a category of medical device from its list of essential uses of chlorofluorocarbons, that product will meet the criteria for nonessentially and be subject to the Class I ban. Other comments addressed the specific products described below.

Prior to the public comment period, EPA believed that the industry had phased out the use of CFCs for administering intrarectal hydrocortisone acetate and in anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for the application. As a result, it did not list these uses as exempt from the ban. The extensive information provided by two commenters sufficiently demonstrated the continued use of CFCs in these applications. These applications are still considered essential uses of CFCs by the FDA, and are so listed in 21 CFR 2.125. The final rule specifically excludes products listed in 21 CFR 2.125 from the nonessential products ban on Class I substances; consequently, these products are exempt from the nonessential products ban at this time.

Another commenter filed extensive comments regarding CFC use in metered dose inhalers (MDIs). EPA appreciates the detailed nature of the information presented on MDIs and is encouraged by research on alternative chemicals for use in MDIs. However, at this time, no alternative propellant has been approved by the FDA, and MDIs are still listed in 21 CFR 2.125 as essential uses

of CFCs. Consequently, under the final rule, metered dose inhalers are exempt from the nonessential products ban at this time.

One commenter applied for an exemption from the nonessential products ban for its topical anesthetic and vapocoolant products. Since the 1978 aerosol ban restricted only CFCs used as propellants, the use of CFCs as active ingredients in topical anesthetic and vapocoolants was not subject to the 1978 ban; however, in explaining the status of such products, the preamble to the 1978 ban expressed the FDA's intent to address topical anesthetic and vapocoolant products at a future date.

According to the commenter, its topical anesthetic and vapocoolant products fit the definition of medical devices under the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 321). The commenter alleged that when its topical anesthetic product is applied to human skin, it acts as a counter-irritant to block pain associated with muscle spasms.

The commenter also disputed the findings of the 1989 EPA report on alternative formulations for products which were exempted or excluded from the 1978 ban on the use of CFCs in aerosols products (see *Alternative Formulations*). The commenter claimed that the proposed replacement formula (HCFC–142b, HCFC–22 and ethanol), when applied to human skin, would produce temperatures in the range of −26 °C to −30 °C, resulting in frostbite. The commenter noted that the temperature of the proposed reformulation could be raised by increasing the proportion of HCFC–142b in the formulation, but that this change would increase the flammability risk significantly.

Finally, the commenter noted that FDA approval is necessary for the use of any alternative reformulation in medical devices, and that the FDA has not yet approved an alternative.

The EPA believes that the definition of medical device in section 601(8) of the Act applies to topical anesthetic and vapocoolant products. Consequently, the continued use of CFCs in this application is permitted by EPA until FDA takes further action with regard to such products. If and when FDA approves a safe and effective alternative formula for topical anesthetics, this product will no longer meet the statutory definition of medical device in section 601(8); at that time, EPA will consult the FDA and consider promulgating regulations to prohibit the sale, distribution, or offer of sale or distribution, in interstate commerce of topical anesthetic and vapocoolant products containing any ozone-depleting substance. EPA is encouraged to learn that the commenter is in the process of applying for FDA approval of a reformulation which does not require the use of either CFCs or HCFCs. EPA will continue to monitor these developments, and it may consider regulation of these products at a later date.

5. Residential Halon Fire Extinguishers

The Agency's request for comments on banning halon fire extinguishers for residential use produced a number of responses. Many commenters supported a ban on the sale and distribution of residential halon fire extinguishers, and a number of commenters encouraged EPA to take immediate action to remove halon fire extinguishers from store shelves; some commenters even urged EPA to ban the use of all fire extinguishers containing halons. Despite their differences, all of these commenters argued that substitutes were currently available for residential halon fire extinguishers, and that the need to reduce emissions of ozone-depleting chemicals was sufficient to justify banning these products.

Several other commenters opposed a ban on residential halon fire extinguishers, arguing that currently available alternatives were inadequate and that the threat posed to the environment by residential fire extinguishers was minimal. In addition, these commenters argued that including these products in the ban would have a significant adverse impact on manufacturers of halon fire extinguishers.

Based on the available information (see Background Document and various comments in Docket), EPA evaluated residential halon fire extinguishers against the criteria for nonessentiality and determined that they should not be currently considered nonessential products. Consequently, EPA has decided not to ban residential halon fire extinguishers at this time.

In making its determination, EPA examined the purpose and intended use of residential halon fire extinguishers. Fire extinguishers for residential use are critical home safety products. These products are clearly not frivolous.

Although there are alternatives to halon fire extinguishers commercially available for residential use, the commenters raised legitimate concerns about the suitability of these substitutes for all situations. EPA felt that the important safety function served by handheld residential fire extinguishers obligated the Agency to carefully evaluate the safety concerns associated with a ban on the sale and distribution of halon fire extinguishers for residential use. As a result of its research, however, EPA determined that adequate substitutes for halon fire extinguishers in most situations were indeed available. In fact, some of these substitutes are more effective than halons for certain types of fires, such as deep-seated fires (see Background Document). The Agency recognizes, however, that the continued use of these products suggests that in certain noncommercial applications, halon fire extinguishers do not meet the criteria for nonessentiality.

The health and safety issues associated with the possible substitutes for halon in residential fire extinguishers include the toxicity of the various chemicals and the health effects associated with the product's impact on stratospheric ozone depletion. EPA believes that excluding the effects of stratospheric ozone depletion, currently available substitutes provide an equivalent level of fire safety protection without posing any offsetting threat to safety or human health. When the health and environmental effects of stratospheric ozone depletion are considered as well, EPA believes that there is a compelling case to be made for phasing out halon fire extinguishers for residential use.

However, in making its determination to exclude halon fire extinguishers from the Class I nonessential products ban, EPA considered several other relevant factors as well. While the EPA believes that adequate substitutes for residential halon fire extinguishers currently exist for many uses, the Agency also believes that given the effective date of today's rulemaking, the scheduled increase in the excise tax on halons, and the imminent cessation of halon production under the accelerated phaseout, little environmental benefit would result from including residential halon fire extinguishers in the Class I nonessential products ban.

The dramatic increase in the tax on halons which takes effect January 1, 1994 should act as a strong incentive for manufacturers to expedite the phaseout of halons. EPA anticipates that the tax alone will significantly reduce sales of halon fire extinguishers for residential use. Moreover, halon fire extinguishers for residential use represent only a small fraction of total annual ODS emissions (far less than one percent of annual global ODP-weighted emissions).

At the time the NPRM was published, EPA believed that sufficient time remained to promulgate its final rule well before the November 15, 1992 effective date specified in the statute. Consequently, in developing the January

16, 1992 NPRM, the Agency believed that the practical effect of including residential halon fire extinguishers in the Class I nonessential products ban would be to accelerate the phaseout of these products by 14 months. One of the concerns expressed by EPA in the proposed rule was whether such an action would be worthwhile, considering the relatively short period of time during which the ban would have any impact. Since the NPRM was published, Congress has increased the tax on halons, and the Parties to the Montreal Protocol have agreed to phase out the production of halon in member countries, except for essential uses, by January 1, 1994. Given that the effective date of the ban for products identified under section 610(b)(3) in today's rulemaking nearly coincides with the January 1, 1994 increase in the excise tax and the ban on halon production under the Montreal Protocol, this concern is even more pertinent.

EPA believes that the combined effect of the excise tax and the accelerated phaseout will be to end the sale and distribution of halon fire extinguishers for residential use. Consequently, although EPA believes that adequate substitutes exist for halon in residential fire extinguishers in many situations, the Agency believes that the use of halon in these products will be addressed more effectively through the excise tax and the accelerated phaseout, and, thus, that regulation under section 610 is unnecessary. As a result, residential halon fire extinguishers are not included in the Class I nonessential products ban.

6. Other Uses

EPA received one comment requesting that expanded tobacco produced using CFC–11 as an expansion agent be included in the rule as a nonessential product.

The CFC–11 tobacco expansion process is a patented, physical process that uses CFC–11 to restore cured, aged tobacco to its original field volume. In this process, cured tobacco is impregnated with CFC–11. The impregnated tobacco is then brought in contact with hot air that causes the CFC–11 to vaporize and the tobacco to expand. The CFC–11 is then recovered by cooling and compressing. EPA is aware that other tobacco expansion methods used by tobacco companies include process using carbon dioxide, steam, and nitrogen. Carbon dioxide appears to be the most promising of these substitutes, as it can achieve the same expansion levels as the CFC–11 process. Additional information provided to EPA suggests that tobacco processors are currently engaged in converting from the CFC–11 process to the carbon dioxide process.

EPA investigated the possibility of banning the use of CFC–11 for tobacco expansion as a nonessential product due to the availability of substitutes. The Agency believes that, due to the commercial availability of substitutes for CFC–11 in this process, the use of CFC–11 in tobacco expansion is nonessential. However, as stated in section III.A.5., EPA believes it is inappropriate to ban products through this final rule that were not included in the proposed rule. Consequently, the use of CFCs in tobacco expansion is not banned as a nonessential product in today's rulemaking. Given that CFC production will end by January 1, 1996, EPA believes that there is a strong incentive for companies to convert all production processes to non-CFC methods. However, EPA will continue to examine the need to take action in the future to prohibit the use of CFC's for tobacco expansion.

IV. Summary of Today's Final Rule

This section briefly describes the provisions of today's final rule. Any changes made to the rule language as a result of the public comments are described. Various minor changes to the final rule that have been made for purposes of clarification are not described herein.

A. Authority

The authority citation remains the same as in the proposed rule.

B. Purpose (Section 82.60)

This section states that these rules implement sections 608 and 610 of the Clean Air Act Amendments of 1990 regarding emission reductions and the Class I nonessential products ban. There were no changes in this section based on public comment. Minor editing changes were made to improve clarity and consistency.

C. Definitions (Section 82.62)

This section contains the definitions of the terms "chlorofluorocarbon," "commercial," "consumer," "distributor," "product," and "release."

No major changes were made in this section of the rule since proposal, although the definitions of "distributor" and "commercial" were revised to reflect the changes made in section 82.68 in response to public comments regarding recordkeeping, verification of commercial status, and commercial identification numbers.

The definition of "chlorofluorocarbon" describes the Class I substances affected by this rule. The definition of "consumer" is intended to distinguish the ultimate purchaser, recipient or user of a product from a manufacturer, seller, or distributor. The definition of "product" is intended to describe an item or category of items affected by today's rulemaking. The definition of "release" is intended to identify products that are affected by today's rulemaking.

The definition of "commercial" is intended to identify purchasers who are not prohibited by the statute from buying cleaning fluids for electronic and electrical equipment. The definition of "distributor" is intended to identify individuals who have responsibilities in restricting the sale of CFC-containing cleaning fluids for electronic and photographic equipment to commercial users. The definitions of "distributor" and "commercial" were revised in response to public comment to include the sale of a product to another distributor. In addition, the definition of "commercial" was changed to include a government contract number as a commercial identification number in response to public comment. Other minor editing changes were made to improve clarity and consistency.

D. Prohibitions (Section 82.64)

The proposed rule contained one prohibition which, effective November 15, 1992, prohibited any person from selling, distributing, or offering to sell or distribute, in interstate commerce any product identified as being nonessential in § 82.66. The final rule differs from the proposed rule in that it implements the nonessential products ban with three prohibitions rather than one.

The first prohibition states that effective on February 16, 1993, no person may sell, distribute, or offer for sale or distribution, in interstate commerce any plastic party streamer or any noise horn which is propelled by a chlorofluorocarbon. This prohibition bans the sale, distribution, or offer of sale or distribution, of the products specifically mentioned in section 610(b)(1) of the Act. The effective date has been revised to reflect the actual publication date of today's rulemaking.

The second prohibition states that effective on February 16, 1993, no person may sell, distribute, or offer for sale or distribution, in interstate commerce any cleaning fluid for electronic and photographic equipment which contains a chlorofluorocarbon to anyone who does not provide proof that he or she is a commercial purchaser, as defined under section 82.62. This prohibition makes the sale, distribution, or offer of sale or distribution, in

interstate commerce of the products specifically mentioned in section 610(b)(2) of the Act to noncommercial purchasers unlawful, as required by the statute. The effective date has been revised to reflect the actual publication date of today's rulemaking.

The third prohibition states that effective on January 17, 1994, no person may sell, distribute, or offer for sale or distribution, in interstate commerce any product listed as nonessential in § 82.66(c) and § 82.66(d). This prohibition makes it unlawful to sell, distribute, or offer for sale or distribution, in interstate commerce any of the products determined by the Administrator under section 610(b)(3) of the Act to be nonessential. The effective date has been revised to reflect the actual publication date of today's rulemaking, to facilitate the liquidation of existing inventories, and to allow manufacturers sufficient time to redesign and modify their production facilities and manufacturing processes, consistent with congressional intent.

E. Nonessential Products and Exceptions (Section 82.66)

The list of nonessential products in the final rule differs from the proposed rule with regard to exclusions for one foam product and several aerosol products or pressurized dispensers. In its January 16, 1992 NPRM, EPA specifically excluded several products from the proposed ban on aerosols and other pressurized dispensers containing CFCs. These products were: contraceptive vaginal foams; lubricants for pharmaceutical and tablet manufacture; metered dose inhalation devices; gauze bandage adhesives and adhesive removers; products using CFC–11 or CFC–113 as lubricants, coatings and cleaners for electrical or electronic equipment; products using CFC–11 or CFC–113 as lubricants, coatings and cleaners for aircraft maintenance uses; and products using CFC–11 and CFC–113 as release agents for molds used in the production of plastic and elastomeric materials (for additional information on these products, see Alternative Formulations and Background Document).

Today's rulemaking differs from the proposed rule in that the exclusions for contraceptive vaginal foams and metered dose inhalation devices, which were originally listed separately, have been replaced by a more general exclusion for all medical devices listed in 21 CFR 2.125(e); these products are included on that list. Intrarectal hydrocortisone acetate, anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for the application, and polymyxin B sulfate-bacitracin-zinc-neomycin sulfate soluble antibiotic powder without excipients for topical use on humans are also medical devices listed as essential uses of CFCs in 21 CFR 2.125(e) and are therefore excluded from the nonessential products ban at this time. In response to comments, topical anesthetic and vapocoolant products have also been excluded from the nonessential products ban, as have products using CFC–12 for nonpropellant purposes in lubricants, coatings or cleaning fluids for electrical or electronic equipment. Spinnerette lubricant/cleaning sprays that contain CFC–114 and are used in the production of synthetic fibers have also been excluded from the nonessential products ban, as have products using CFC–113 in document preservation sprays and bear repellent sprays, and the use of CFCs in plasma etching. In addition, in response to public comment, the Agency has excluded the use of flexible and packaging foam in the manufacture of coaxial cable from the Class I products ban at this time. Other minor editing changes were made to improve clarity and consistency.

F. Verification, Public Notice, and Recordkeeping Requirements (Section 82.68)

The January 16, 1992 NPRM presented four options for restricting the sale of these products to commercial users, and proposed transaction-specific recordkeeping requirements to help ensure compliance with the prohibition on the sale of cleaning fluids for noncommercial electronic and photographic equipment.

The final rule differs from the proposed rule in that recordkeeping requirements for distributors of CFC-containing cleaning fluids for electronic and photographic equipment have been eliminated. Distributors need not maintain records of transactions involving these products; instead, distributors must verify that purchasers are commercial users, and they must post a sign stating that the sale of these products for noncommercial use is prohibited.

V. Effective Dates

The effective date for the proposed rule was November 15, 1992. This final rule differs from the proposed rule in that it makes it unlawful to sell, distribute, or offer to sell or distribute, in interstate commerce the products specifically mentioned in 40 CFR section 82.66(a) effective on February 16, 1993. This rule also restricts the sale, distribution, or offer of sale or distribution, in interstate commerce of the products specifically mentioned in 40 CFR section 82.66(b) effective on February 16, 1993, and it bans the sale, distribution, or offer of sale or distribution, in interstate commerce of the products identified in 40 CFR 82.66(c) and 82.66(d) as nonessential effective on January 17, 1994.

VI. Judicial Review

Under section 307(b)(1) of the Clean Air Act, EPA hereby finds that these regulations are of national applicability. Accordingly, judicial review of this action is available only by the filing of a petition for review in the United States Circuit Court of Appeals for the District of Columbia Circuit within 60 days of publication. Under section 307(b)(2) of the Act, the requirements that are the subject of today's rule may not be challenged later in judicial proceedings brought to enforce these requirements.

VII. Summary of Supporting Analyses

A. Executive Order 12291

Executive Order (E.O.) 12291 requires the preparation of a regulatory impact analysis for major rules, defined by the order as those likely to result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, federal, state or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

EPA has determined that this proposed regulation does not meet the definition of a major rule under E.O. 12291 and has therefore not prepared a formal regulatory impact analysis. EPA has instead prepared a background document (see Background Document), which includes a qualitative study of the economic impact of this proposed regulation for each product identified as nonessential and prohibited from sale or distribution.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601–612, requires that Federal agencies examine the impacts of their regulations on small entities. Under 5 U.S.C. 604(a), whenever an agency is required to publish a general notice of proposed rulemaking, it must prepare and make available for public comment an initial regulatory flexibility analysis

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(RFA). Such an analysis is not required if the head of an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, pursuant to 5 U.S.C. 605(b).

The Administrator believes that the regulation will not have a significant impact on a substantial number of small entities and has therefore concluded that a formal RFA is unnecessary. A qualitative treatment of potential impacts on small entities is included in EPA's background document accompanying this regulation.

EPA believes that most companies in the industries affected by this regulation have already ceased using CFCs in the affected products. In addition, EPA believes that the rising excise tax and the scarcity resulting from the required incremental reductions of these substances will provide a continually increasing incentive to switch to substitutes for those companies that have not already done so. EPA also believes that the prohibition of sales to noncommercial users in the case of the products identified in section 82.66(b) of today's rulemaking (CFC-containing cleaning fluids for electronic and photographic equipment) allows manufacturers, distributors, and retailers to continue to market those products to commercial users with little or no impact. Moreover, EPA would like to point out that the phaseout in the year 2000 of the production and import of Class I substances provides a *de facto* ban on all products using these substances. Regardless of the nonessential products ban, the phaseout will force manufacturers to adopt non-CFC alternatives in the near future. Since the publication of the proposed rule, the Parties to the Montreal Protocol have agreed to phase out production of Class I substances by January 1, 1996, and the President has announced plans to accelerate the phaseout under section 606 of the Clean Air Act, as amended (see section I.G. of today's preamble); such action will reduce the impact of today's rulemaking even more. EPA will consider the economic impact of the accelerated phaseout in its rulemaking to carry out its obligations under the Montreal Protocol. Consequently, EPA anticipates that the economic impact of today's rulemaking will be minimal.

For the purposes of this regulation, EPA believes that identifying companies by Standard Industrial Classification (SIC) code is inappropriate, because most of the affected products represent only a small fraction of the products within each SIC code. In addition, since most manufacturers have already ceased using Class I substances, only a few companies within each classification currently manufacture products containing CFCs. Due to the small number of potentially affected companies within each industry, the definition of companies as large or small is based for the most part on the characterization of manufacturing process by industry contacts, rather than on a standardized measure such as number of employees.

C. Paperwork Reduction Act

There are no information collection requirements in this rule. The proposed rule contained recordkeeping requirements associated with the sale of chlorofluorcarbon-containing cleaning fluids for electronic and photographic equipment, but these requirements have been eliminated in the final rule in favor of a public disclosure requirement. No Information Collection Request (ICR) is required for a public disclosure requirement. The Information Collection Request document prepared by EPA under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, for the proposed rule (ICR No. 1592.01) is contained in the Docket for this rulemaking. A copy may be obtained by writing to the Information Policy Branch, U.S. Environmental Protection Agency, 401 M Street, SW. PM–223Y; Washington, DC 20460 or by calling (202) 260–2740.

VIII. References

United Nations Environment Programme. Aerosols, Sterilants and Miscellaneous Uses of CFCs: Report by the Technical Options Committee (June 30, 1989).

United Nations Environment Programme. Environmental Effects Panel Report (1989).

United Nations Environment Programme. Final Report of the Halons Technical Options Committee (August 11, 1989).

United Nations Environment Programme. Flexible and Rigid Foams Technical Options Report (June 30, 1989).

United States Environmental Protection Agency. Alternative Formulations to Reduce CFC Use in U.S. Exempted and Excluded Aerosol Products (November 1989).

United States Environmental Protection Agency. Background Document on Identification of Nonessential Products that Release Class I Substances (July 1, 1991).

United States Environmental Protection Agency. Essential Use Determination—Revised: Support Document Fully Halogenated Chlorofluoroalkanes (March 17, 1978).

United States Environmental Protection Agency. Handbook for Reducing and Eliminating Chlorofluorocarbons in Flexible Polyurethane Foams (April 1991).

United States Environmental Protection Agency. Response to Comments for Proposed Rule on Nonessential Products Made with Class I Substances (October 30, 1992).

List of Subjects in 40 CFR Part 82

Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Clean Air Act Amendments of 1990, Exports, Imports, Nonessential products, Recordkeeping and reporting requirements, Stratospheric ozone layer.

Dated: December 31, 1992.

William K. Reilly,

Administrator.

Title 40, Code of Federal Regulations, part 82, is amended to read as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671(q).

2. A new subpart C is added to read as follows:

Subpart C—Ban on Nonessential Products Containing Class I Substances

Sec.

82.60 Purpose.
82.62 Definitions.
82.64 Prohibitions.
82.66 Nonessential products and exceptions.
82.68 Verification and public notice requirements.

§ 82.60 Purpose.

The purpose of this subpart is to implement the requirements of sections 608 and 610 of the Clean Air Act Amendments of 1990 on emission reductions and nonessential products.

§ 82.62 Definitions.

For purposes of this subpart:

(a) *Chlorofluorocarbon* means any substance listed as Class I group I or Class I group III part 82, appendix A to subpart A.

(b) *Commercial*, when used to describe the purchaser of a product, means a person that has one of the following identification numbers:

(1) A federal employer identification number;

(2) A state sales tax exemption number;

(3) A local business license number; and

(4) A government contract number and that uses the product in the purchaser's business or sells it to another person.

(c) *Consumer*, when used to describe a person taking action with regard to a product, means the ultimate purchaser, recipient or user of a product.

(d) *Distributor*, when used to describe a person taking action with regard to a product;

(1) Means the seller of a product or another distributor; or

(2) A person who sells or distributes that product in commerce for export from the United States.

(e) *Product* means an item or category of items manufactured from raw or recycled materials which is used to perform a function or task.

(f) *Release* means to emit into the environment during the manufacture, use, storage or disposal of a product.

§ 82.64 Prohibitions.

(a) Effective on February 16, 1993, no person may sell or distribute, or offer to sell or distribute, in interstate commerce any of the products identified as being nonessential in § 82.66(a).

Effective on February 16, 1993, no person may sell or distribute, or offer to sell or distribute, in interstate commerce any of the products specified in § 82.66(b) to a person who does not provide proof of being a commercial purchaser, as defined under § 82.62.

(c) Effective on January 17, 1994, no person may sell or distribute, or offer to sell or distribute, in interstate commerce any of the products identified as being nonessential in § 82.66(c) or § 82.66(d).

§ 82.66 Nonessential products and exceptions.

The following products which release a Class I substance (as defined in part 82, appendix A to subpart A) are identified as being nonessential, and subject to the prohibitions specified under § 82.64:

(a) Any plastic party streamer or noise horn which is propelled by a chlorofluorocarbon, including but not limited to:

(1) String confetti;

(2) Marine safety horns;

(3) Sporting event horns;

(4) Personal safety horns;

(5) Wall-mounted alarms used in factories or other work areas; and

(6) Intruder alarms used in homes or cars.

(b) Any cleaning fluid for electronic and photographic equipment which contains a chlorofluorocarbon:

(1) Including but not limited to liquid packaging, solvent wipes, solvent sprays, and gas sprays; and

(2) Except for those sold or distributed to a commercial purchaser.

(c) Any plastic flexible or packaging foam product which is manufactured with or contains a chlorofluorocarbon;

(1) Including but not limited to:

(i) Open cell polyurethane flexible slabstock foam;

(ii) Open cell polyurethane flexible molded foam;

(iii) Open cell rigid polyurethane poured foam;

(iv) Closed cell extruded polystyrene sheet foam;

(v) Closed cell polyethylene foam; and

(vi) Closed cell polypropylene foam.

(2) Except—flexible or packaging foam used in coaxial cable.

(d) Any aerosol product or other pressurized dispenser, other than those banned in § 82.64(a) or § 82.64(b), which contains a chlorofluorocarbon;

(1) Including but not limited to household, industrial, automotive and pesticide uses;

(2) Except—(i) Medical devices listed in 21 CFR 2.125(e);

(ii) Lubricants for pharmaceutical and tablet manufacture;

(iii) Gauze bandage adhesives and adhesive removers;

(iv) Topical anesthetic and vapocoolant products;

(v) Lubricants, coatings or cleaning fluids for electrical or electronic equipment, which contain CFC–11, CFC–12, or CFC–113 for solvent purposes, but which contain no other CFCs;

(vi) Lubricants, coatings or cleaning fluids used for aircraft maintenance, which contain CFC–11 or CFC–113, but which contain no other CFCs;

(vii) Mold release agents used in the production of plastic and elastomeric materials, which contain CFC–11 or CFC–113, but which contain no other CFCs;

(viii) Spinnerette lubricant/cleaning sprays used in the production of synthetic fibers, which contain CFC–114, but which contain no other CFCs;

(ix) Containers of CFCs used as halogen ion sources in plasma etching;

(x) Document preservation sprays which contain CFC–113, but which contain no other CFCs; and

(xi) Red pepper bear repellent sprays which contain CFC–113, but which contain no other CFCs.

§ 82.68 Verification and public notice requirements for distributors of certain products intended exclusively for commercial use.

(a) Effective on February 16, 1993, any person who sells or distributes any cleaning fluid for electronic and photographic equipment which contains a chlorofluorocarbon must verify that the purchaser is a commercial entity as defined in § 82.62. In order to verify that the purchaser is a commercial entity, the person who sells or distributes this product must be presented with documentation that proves the purchaser's commercial status by containing one or more of the commercial identification numbers specified in § 82.62. The seller or distributor must have a reasonable basis for believing that the information presented by the purchaser is accurate.

(b) Effective on February 16, 1993, any person who sells or distributes any cleaning fluid for electronic and photographic equipment which contains a chlorofluorocarbon must prominently display a sign where sales of such product occur which states: "It is a violation of federal law to sell, distribute, or offer to sell or distribute, any chlorofluorocarbon-containing cleaning fluid for electronic and photographic equipment to anyone who is not a commercial user of this product. The penalty for violating this prohibition can be up to $25,000 per sale. Individuals purchasing such products must present proof of their commercial status in accordance with 40 CFR 82.68(a)."

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Part IV

Environmental Protection Agency

Environmental Leadership Program; Proposed Establishment; Notice

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-4552-6]

Environmental Leadership Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of intention to develop an environmental leadership program and request for comments.

SUMMARY: This notice solicits comment on the creation of a national voluntary program to encourage and publicly recognize environmental leadership and promote pollution prevention in the manufacturing section. A possible structure for this program, set forth in this notice, includes two components: a Corporate Statement of Environmental Principles, and a Model Facility Program. A pilot test of the Environmental Leadership Program in one or more states is planned to determine the feasibility of making the Program national in scope. EPA is seeking responses to specific questions as well as general comments.

DATES: A comment period of 90 days will begin with the publication of this notice, closing on April 15,1993. At least one working public meeting will be held at the conclusion of the comment period under the auspices of the National Advisory Council for Environmental Policy and Technology. Additional public forums for dialogue are likely to be provided, perhaps during the 90 day comment period. The date and location of any such meetings will be published in the **Federal Register** at a future date.

ADDRESSES: Comments on this proposal should be mailed to: EPA/OPPTS/TIMB(TS793), Public Document Office, room G004, Northeast Mall, 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Linda Glass-Rimer, United States Environmental Protection Agency (1102), Pollution Prevention Policy Staff, 401 M Street SW., Washington, DC 20460, telephone: (202) 260–8616.

SUPPLEMENTARY INFORMATION:

I. Introduction

The objective of this **Federal Register** notice is to stimulate public discussion and comment on a potential new dimension to the Environmental Protection Agency's environmental program. This notice proposes the creation of a new Environmental Leadership Program providing special recognition to companies and facilities that reflect a CEO-level commitment to prevention-oriented environmental management that goes beyond mere compliance with regulations. Qualifying companies would be expected to demonstrate true national leadership through a statement of corporate commitment, openness to public scrutiny, model compliance records, and measurable reductions of the environmental impacts of their production processes or products.

A program of this type has exciting potential for several reasons. First, American businesses—often applying principles of Total Quality Management—see competitive and other advantages in moving beyond compliance to reduce pollution at the source, and in using energy and other resources more efficiently. The extensive and dramatic participation of companies in EPA's targeted voluntary toxics reduction ("33/50") and energy efficiency programs (Green Lights, Energy Star Computers, and others) is a sign of how much environmental improvement can result when progressive companies push the state of the art without waiting for regulations. With positive recognition and appropriate incentives from the Federal Government, these companies may decide to accelerate their development of breakthrough approaches to environmentally sound production and management.

Second, if ultimate success in achieving sustainable development depends on providing for environmental concerns in the *design* stage of strategies and projects, then it is critical to encourage marketplace innovations and leadership from our business community. James Gustave Speth, while President of the World Resources Institute, made that point quite clearly in the Foreword to Beyond Compliance: A New Industry View of the Environment, WRI's study of the voluntary efforts of progressive companies:

> "Important as pressure from environmentalists and governmental direction are to stimulating change, in the end only the corporate community can efficiently provide the necessary organization, technology, and financial resources needed to design and implement change on the scale required. Companies that are trying to be leaders on a new path to a sustainable future merit our encouragement and support, just as the inevitable backsliders deserve a vigorous shove onto the trail."[1]

EPA can advance pollution prevention by encouraging—but not dictating—superior environmental management systems that lead companies to design and develop their own innovative ideas and breakthrough improvements. Encouraging a CEO-level focus through a comprehensive national program that emphasizes risk reduction priorities and measurable results can help set the pace for these voluntary efforts.

In this notice, EPA has endeavored to envision what national environmental leadership should entail and to present a variety of ideas as candidate criteria for recognizing a company or facility as an environmental leaders. These concepts are designed to stimulate discussion—through written comments and in public forums—on what should constitute corporate environmental leadership today. We hope and expect that the state of the art will continue to advance. The Malcolm Baldridge Award for management excellence can serve as a good model in this regard. The Program must have objective criteria, but EPA welcomes comment on which of the criteria presented here do not ask enough, or ask too much, given today's realities. We also invite comment on the range of positive incentives for participation which are both consistent with EPA's mission and programs, and which appropriately recognize this level of corporate commitment.

Broad public discussion of this proposal will have a major impact on the shape of the Environmental Leadership Program. It is hoped that the cluster of concepts presented here will help EPA develop the information needed to determine more specifically the role that a national voluntary program might play in promoting sustainable development as we move toward the 21st century. EPA hopes that interested parties will take the time to comment, and to provide the Agency with the data it needs to develop an Environmental Leadership Program that inspires the private sector to greater efforts, and enjoys broad public support.

The proposal is organized in the following way:

I. Introduction
II. Public Review Process
III. Fundamental Assumptions Underlying EPA's Proposal
IV. Program Scope and Application Process
V. Criteria for Participation
VI. Compliance Screening for Model Facilities
VII. Incentives for Participation
VIII. Summary of Questions

II. Public Review Process

The United States Environmental Protection Agency (EPA) is seeking comment on a proposal to establish a new Environmental Leadership Program

[1] Smart, B., *Beyond Compliance: A New Industry View of the Environment* (1992: World Resources Institute, Washington, DC), at x.

to recognize and reward a long-term commitment to sustainable development by corporations and manufacturing facilities. The Program would encourage companies to go beyond compliance with the law by incorporating pollution prevention into the full range operations, including, for example, purchasing, product design, manufacturing, marketing and distribution.

This proposal is based in part on discussions held over the past nine months with a variety of groups and individuals representing states, trade associations, environmentalists, and industry. The Agency wishes to emphasize, however, that the proposal is in the early stages of development, and that public comment will be critical to shaping its final outcome. What follows for public review and reaction is a series of concepts rather than a finished proposal. Following public comment, EPA may choose to accept, reject, or modify one or more of these concepts, as well as incorporate new ideas not reflected in the text published today. To assist EPA in organizing and responding to public comment, reviewers are encouraged to refer to the questions listed at the end of this document. (See section VIII.)

This **Federal Register** notice is one step in an ongoing process of obtaining advice from EPA's consitituents—states, environmentalists, industry, and other interested parties. A working public meeting will be conducted at the conclusion of the comment period, under the auspices of the National Advisory Council for Environmental Policy and Technology (NACEPT). Additional public forums for dialogue are likely to be provided, perhaps during the 90 day comment period.

Finally, the Agency plans to pilot test the Program in one or more states. A thorough evaluation of these pilots will be undertaken prior to any decision to make the Program national in scope. EPA expects to solicit proposals in the spring of 1993 from states interested in these pilot projects.

Please See Section VIII. Questions 1–6

III. Fundamental Assumptions Underlying EPA's Proposal

This section summarizes the fundamental assumptions on which the Program would be based. The specific criteria for participation, outlined in sections V and VI, have been developed to reflect these basic concepts. EPA welcomes comments on each of these concepts, as well as suggestions regarding additional threshold issues that EPA should consider.

A. Recognize and Reward the Best

EPA believes the Environmental Leadership Program should be stringent enough to recognize only the very best companies; otherwise, the Program is not likely to be credible with the general public. At the same time, the criteria should be practical enough to motivate many companies to apply for participation, so that the Program will result in widespread improvements in management practices. As discussed in section IV B(2), EPA is seeking comment on whether to include one or more additional categories of participation to recognize companies that are striving to meet the Program's stringent requirements but have not yet attained them.

B. Compliance: A Threshold Requirement

EPA believes that compliance with applicable environmental laws and regulations should be the threshold criterion for Environmental Leadership, with the Program's benefits reserved for those companies that go *beyond* compliance. Accordingly, EPA will expect excellent compliance records from facilities that apply to the Program, and will expect those records to be maintained, if not improved, during participation.

C. Pollution Prevention and Sustainability

EPA believes that pollution prevention and sustainable development should be key components of the Environmental Leadership Program. "Pollution prevention", as defined by EPA, means "source reduction and other practices that reduce or eliminate the creation of pollutants through:

—increased efficiency in the use of raw materials, energy, water, or other resources, or

—protection of natural resources by conservation".[2] The Pollution Prevention Act defines "source reduction" as "any practice which—

(i) reduces the amount of any hazardous substance, pollutant, or contaminant entering any waste stream or otherwise released into the environment (including fugitive emissions) prior to recycling, treatment, or disposal; and

(ii) reduces the hazards to public health and the environment associated with the release of such substances, pollutants, or contaminants."[3]

Congress, in the Pollution Prevention Act, has also declared that pollution prevention is the highest tier in a hierarchy of acceptable practices, followed in descending order by recycling, treatment, and disposal of pollutants.[4] EPA would not expect companies participating in this voluntary program to rely exclusively on prevention to achieve results. Rather, each participant would be asked to pursue pollution prevention options aggressively before proceeding down the other steps of the hierarchy.

In its 1987 report, Our Common Future, the World Commission on Environment and Development defined "sustainable development" as development that meets the needs of the present without compromising the ability of future generations to meet their own needs. What constitutes sustainable development must be fleshed out with concrete examples which industry is often in the best position to provide. The EPA Science Advisory Board's 1990 report, Reducing Risk (SAB–EC–90–021), recommended that EPA emphasize pollution prevention as the preferred option for achieving the environmentally sound economic growth that is the key to sustainable development.

D. Emphasize Goals and Results

The Environmental Leadership Program should encourage companies to embrace policies that promote pollution prevention within the context of sustainable development. However, EPA wishes to avoid duplicating the efforts of private sector organizations, such as the Global Environmental Management Initiative (GEMI) and the Responsible Care Program of the Chemical Manufacturers Association, which are dedicated to advancing the state of the art with respect to environmental management.

EPA will look for corporate adherence to certain management principles, such as operating prevention-oriented systems, setting goals, and measuring progress, but will try to avoid prescriptive judgments about the most effective management methods. Instead, the Agency would prefer to emphasize *results* by measuring actual performance with respect to compliance, pollution prevention, and reduction of releases to the environment.

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[2] *See* Memorandum from EPA Deputy Administrator F. Henry Habicht II, dated May 28, 1992. Copies available from Pollution Prevention Policy Staff at (202) 260–6621.

[3] 42 U.S.C. § 13102(5)(A).

[4] *Id.* § 13103(b).

E. Partnership With States

EPA shares jurisdiction over environmental regulation with the fifty states, all of which have assumed substantial responsibility for writing and issuing permits, conducting inspections, and taking enforcement actions under federal and state law. Local agencies also participate in environmental regulation in many locations. Approximately 20 states have enacted planning laws that either require or encourage facilities to identify and invest in pollution prevention measures. Finally, several states have established or are considering creating voluntary programs to promote pollution prevention.

EPA believes that a national program should add to, rather than duplicate or compete with, those initiatives that have placed some states on the cutting edge of pollution prevention. In particular, EPA questions whether actions taken to comply with state law (such as pollution prevention planning) should be recognized or rewarded as voluntary behavior in a Federal program. The proposed pilot projects (discussed above) will provide opportunities to further explore the interaction between a national Environment Leadership initiative and state programs.

F. Public Accountability

Ultimately, both industry and government must be accountable to the general public for the success or failure of voluntary initiatives. The Environmental Leadership Program should include measures of accountability that allow the public to track progress toward meeting any goals established under the Program. EPA recognizes the need to protect trade secrets within the arena of public accountability. This issue is discussed further in section V.B.

G. Minimize Red Tape

While providing flexibility for innovation, EPA also wants to develop criteria for participation (*e.g.*, consistent measurement standards) that provide applicants with fair and objective standards and minimize the time needed to review and process applications. The criteria should be clearly communicated at the outset in order to establish expectations for all parties, and should be publicly verifiable to the extent possible. In the absence of consistent standards, EPA would be forced to rely on subjective evaluations of potentially hundreds of different applications. Such practices would be resource-intensive and could subject both the Agency and industry applicants to charges of "second-guessing" program requirements.

Please See Section VIII, Questions 1–6

IV. Program Scope and Application Process

This section presents EPA's views regarding the possible scope of the Environmental Leadership Program. The Agency seeks comments on the specific elements proposed below, as well as any recommendations for changes in scope.

At a minimum, the Environmental Leadership Program should recognize individual manufacturing plants that reflect state-of-the-art investments in environmental management and pollution prevention technologies. Yet the EPA Science Advisory Board's 1990 report, cited previously, found that sustainable development also requires fundamental changes in the design and marketing of products and the purchase and use of raw materials. Such actions may be beyond the control of individual plant managers and require commitments at the highest levels of the company.

EPA proposes balancing these considerations through a two-part program: a Corporate Statement of Environmental Principles, and a Model Facility Program. The basic elements of each component are described immediately below, followed by a brief discussion and request for comments.

A. Proposed Scope of Program

1. Corporate Statement of Environmental Principles

EPA is proposing to create a Corporate Statement of Environmental Principles, the elements of which would be developed or outlined by the Agency. EPA is seeking comments on a Statement which would have several distinctive features:

- The Principles would apply broadly to the way corporations design, manufacture, market and distribute their products.
- Companies would publicly subscribe to conducting their operations in accordance with the Principles. The Program would provide that companies commit to specific goals, and be publicly accountable for their progress. EPA would not evaluate or certify that companies were meeting the specific requirements; instead EPA is considering incorporating into the Principles several elements that would allow the public to monitor a company's progress.
- Companies would be asked to submit letters to EPA signaling their intention to abide by the Principles. These would be maintained in a public docket to allow interested parties to examine their contents. EPA would periodically publish the names of participating companies.
- Finally, companies wishing to have individual plants designated as "Model Facilities" would first be required to subscribe to the Statement of Environmental Principles.

EPA is aware that similar initiatives, such as the Global Environmental Management Initiative (GEMI) and the Responsible Care Program described above, have been developed in the private sector and by non-governmental groups, and would be interested in public comment regarding the success of these efforts in motivating changes in corporate behavior. EPA also seeks comment on the degree to which public scrutiny would or would not be sufficient to ensure accountability.

2. Model Facility Program

EPA is also proposing a program to publicly designate individual plants that meet stringent environmental criteria as "Model Facilities." Participation in the Model Facility Program would differ from subscribing to the Statement of Environmental Principles in several important ways:

- Companies would submit applications for EPA review on behalf of individual facilities, based on criteria presented in Sections V and VI.
- Because EPA would be certifying that these plants met high standards, the Agency would need to establish a verification process, including screening for environmental compliance. (In contrast, no application or verification would be required of a company that wished to subscribe to the corporate-wide Statement of Environmental Principles.)
- As discussed above, the company owning the facility would be required to subscribe to the Statement of Environmental Principles before an individual facility could qualify. This requirement is intended to avoid rewarding a "showcase" facility managed by a company without a strong overall environmental record.
- The application could be reviewed either by an independent "Blue Ribbon" panel of experts from government, industry, and public interest groups; by the Agency; or by a combination of both. EPA is interested in comment regarding which approach would be the most appropriate.
- EPA is proposing that states play a role in reviewing the applications. A state's disapproval would result in denial of Model Facility status. EPA is also considering allowing the states to assume some or all of the responsibility

for administering the Program in accordance with the national criteria.

- Upon approval of its application, the applicant facility would be recognized as a Model Facility for a period of several years (*e.g.*, two or three years), after which it would be required to apply for renewal.
- If an application is rejected, the applicant would, subject to needs for confidentiality regarding pending investigations, be advised confidentially of the basis for its rejection, but would not be provided with the opportunity for a hearing or appeal of the decision.
- EPA's review of a participant's status at the time of reapplication would follow the same basic process as for the initial application: information would be collected from the applicant and from various EPA and state offices and data bases. The independent panel, if used for initial application review, would not necessarily be involved in reviewing re-applications.

For recertification, a facility would be required to show progress toward the goals described in its initial application. The Agency seeks comments on the best process to assure that the facility is making adequate progress toward those goals.

B. Alternatives for Scope of Program

EPA seeks comment on the following options for expanding the scope or changing the application process for the Environmental Leadership Program. In each case, commenters are asked to balance the benefits of the option against likely EPA and industry resource limitations and the potential for additional administrative complexity.

1. Third Party Review of Application

EPA is interested in the role that independent third parties might play in the Environmental Leadership Program. For example, as noted above, EPA might establish a panel to review applications for Model Facility status, with the authority to recommend approval to the EPA Administrator. Independent auditors might play a valuable role in assessing the compliance status of facilities as part of this process. Finally, a national advisory board could be established to provide continuing advice regarding implementation of the Program.

2. Multiple Tiers for Participation

As currently envisioned, the Environmental Leadership Program would establish stringent criteria for public recognition of "state of the art" environmental management of industrial facilities. Because EPA wants to encourage many companies to move toward this ambitious level of achievement, it would be appropriate to identify ways to encourage companies to strive for interim milestones. EPA seeks comment on whether one or more preliminary tiers should be added to encourage participation from those companies which are striving toward environmental leadership and need some assistance in meeting the Program's stringent requirements.

3. Consideration for Small Business

EPA seeks comment on whether special provisions should be included in the Program to encourage participation by small businesses. The Agency is particularly interested in whether the Program should include different standards for small businesses, and whether certain types of outreach or technical assistance might be needed to accommodate this addition to the Program.

4. Multi-Sector Participation

The Environmental Leadership Program, as proposed here, is designed primarily for the manufacturing sector. EPA seeks comment on whether the Program should be expanded to include other sectors, *e.g.*, Federal facilities, energy, transportation, services, and municipalities.

Please See Section VIII, Questions 7–16

V. Criteria for Participation

EPA is seeking comment on the following six categories of criteria for both the Corporate Statement of Environmental Principles and the Model Facility Program:

A. Risk Reduction Goals
B. Measures and Public Accountability
C. Planning
D. Environmentally Sound Business Practices
E. Community and Employee Involvement
F. Compliance

For each category, a general descriptive statement is presented below, followed by an explanation of how the criterion would be applied in the Corporate Statement of Environmental Principles and in the Model Facility Program. EPA is interested in comments both on the proposed criteria and on other criteria that might be included. Readers are encouraged to address the questions outlined in Section VIII when responding.

A. Risk Reduction Goals

EPA is considering establishing a set of national risk reduction goals for the Environmental Leadership Program. Companies would need to include a plan for achieving these goals when signing on to the Corporate Statement of Environmental Principles and applying for Model Facility status (see discussion on planning, Section C). EPA does not propose specific goals in this **Federal Register** notice; rather, the Agency asks whether national goals should be established for Environmental Leadership and, if so, what these might be.

National environmental goals offer the advantage of setting clear expectations for Program participants, so that companies are not "second-guessed" by EPA during the application process or on subsequent review. The goals also would provide a basis for the public to evaluate the progress of this new voluntary program.

EPA is considering establishing national goals for pollution prevention, as that term has been defined by the Agency.[5] EPA believes these goals would provide clear incentives to focus on reducing waste at the source through, for example, process changes and raw material substitutions. The Agency seeks comment on how the Program could allow for the cost-effective use of other waste management options such as recycling and treatment.

The Toxics Release Inventory (TRI)[6] and the Pollution Prevention Act[7] provide a basis for setting national goals and measuring progress in reducing waste at its source. If EPA establishes goals for pollutants and sources not covered by TRI, or measures of energy efficiency and natural resource conservation, then additional data would be needed.

The pollutants most likely to be targeted for prevention or reduction are those which present potentially high risk to the environment and/or that are difficult to control exclusively through conventional regulatory approaches. As an example of the application of these criteria, EPA might decide to target heavy metals and other toxics with a tendency to bioaccumulate in the environment, and potential carcinogens found in the home or work place.

Goals need not be limited to toxic pollutants; for example, the Program might also include national energy efficiency goals. Additional emphasis could be placed on the voluntary reduction of greenhouse gas emissions, allowing companies the latitude to

[5] See Memorandum from EPA Deputy Administrator F. Henry Habicht II, dated May 28, 1992. Copies available from Pollution Prevention Policy Staff at (202) 260–8621.

[6] 42 U.S.C. § 11023.

[7] 42 U.S.C. § 13106.

determine how these reductions might be achieved. The Science Advisory Board's 1990 report, *Reducing Risk*, offers a useful starting point for the selection of risk reduction priorities.

EPA is inquiring whether such national risk reduction goals should include a target for achieving a nationwide reduction in specific waste streams or pollutants, and, if so, whether establishing a deadline for these reductions would be appropriate. The Agency recognizes that fixed percentage reduction goals may discriminate against companies that have already made substantial progress in reducing pollution, and seeks comment on how this issue should be addressed if that approach were to be adopted. EPA is also interested in whether, and if so, how, to establish more qualitative goals such as addressing opportunities to protect wetlands and other natural habitats.

B. Measures and Public Accountability

EPA believes that public confidence in corporate voluntary environmental programs can be assured through clear and consistent measures of environmental performance that can be verified by the public. As with national goals, measurement can help establish fair and objective expectations for applicants to the Environmental Leadership Program, reduce the time needed to review applications, and provide a mechanism for public involvement in assessing the progress of voluntary efforts. Experience with the TRI system shows that effective measurement and reporting systems also help companies determine where source reduction is most feasible.

As discussed above, TRI and the Pollution Prevention Act provide a starting point for measuring both pollution prevention and pollution reduction through other means. First, TRI is widely accepted by the general public as a data base, and second, many companies are already using TRI to track their own progress. TRI still has significant variations in the quality of the reported data, however, and currently does not cover all significant pollutants or sources. EPA is therefore proposing several additional means for gathering pertinent information through the Corporate Statement of Environmental Principles and the Model Facility Program (see below). The Agency seeks comment on these proposals, as well as on options for measuring progress in areas less susceptible to quantification (*e.g.*, conservation and habitat protection).

1. Corporate Statement of Environmental Principles

EPA's proposed Corporate Statement of Environmental Principles would invite participating companies to observe common measurement and reporting principles designed to ensure public accountability at all of their facilities. This information could be included in annual TRI data submissions or provided in a separate annual environmental report. EPA seeks public input on both the costs and the benefits of calling for additional categories of data.

EPA seeks comment on whether a company subscribing to the Statement of Environmental Principles should be asked to take the following actions beyond those currently required under TRI:

- Disclose factors responsible for significant changes in the level of TRI emissions at any of its facilities, and the amount of change associated with each factor. The potential benefit of such disclosure was documented in a recent survey of 1,200 facilities required to report under TRI. In this survey, EPA found that the respondents collectively attributed more than half of their aggregate emission reductions for 1989–90 to factors other than pollution prevention, such as declining levels of production, the use of different measurement or reporting methods, and the impact of a proposed delisting action. Companies could help the public interpret such data by providing a concrete explanation for any apparent trends at their facilities.
- Furnish TRI-equivalent emissions data for facilities located outside the United States that are owned by the company or its subsidiaries. With increasing integration of the global economy and environment, companies aspiring to environmental leadership should move toward applying comparable standards of public disclosure to their foreign and domestic operations, opening the door to expanded international cooperation in protecting the environment. Already, some multinational companies have voluntarily disclosed emissions data for their overseas facilities, and developed plans to reduce high levels of toxics released from certain plants.

2. Model Facility Program

EPA is considering requesting model facilities to provide more complete information on their environmental performance than is required under federal law or embodied in the Statement of Environmental Principles. One way to approach this would be to ask participating plants to provide comprehensive data with respect to all activities which relate to the national risk reduction goals or have a potentially significant impact on the surrounding environment. For example, a Model Facility could be asked to provide aggregate waste and emissions data for major toxic and hazardous pollutants from significant sources within the plant, including pollutants and sources not covered by current Toxic Release Inventory and Pollution Prevention Act reporting requirements. Voluntary disclosure of key non-TRI releases would give the public a more complete picture of the facility's progress in reducing emissions.

In addition, Model Facilities could be asked to publish data regarding the consumption of energy, water, and other raw materials, as well as the generation of nonhazardous solid waste. Such information would allow the company, EPA, and the public to evaluate the facility's progress toward more efficient use of natural resources. The Agency seeks comment regarding how such information could be made public without compromising confidential business information or trade secrets.

C. Planning

Experience shows that commitment and support from the highest levels of management are crucial for environmental leadership, whether in a large, multi-facility corporation or in a small business. Accordingly, participants in the Environmental Leadership Program should submit a plan for achieving any relevant national goals established under the Program, and for measuring progress.

The Corporate Statement of Environmental Principles could call for subscribing companies to develop a general plan for achieving the national goals on a company-wide basis. This plan would be included in the company's letter of commitment pledging to abide by the Statement of Environmental Principles. As stated earlier, the plan would be maintained in a public docket, but not subject to approval by EPA. More specific plans would be required as part of the application for Model Facility status, and would be evaluated by EPA. As this is a voluntary program, neither the company-wide nor the facility-specific plans would be legally enforceable.

A more specific discussion of possible elements of company and facility plans follows. EPA seeks comment on the plan elements identified below, and is particularly interested in their relationship to those of existing programs, like Responsible Care and the

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Global Environmental Management Initiative (GEMI), and state planning requirements.

1. Corporate Statement of Environmental Principles

As evidence of senior management support, EPA is considering asking participating companies to publish a plan for pollution prevention that has been endorsed by the Chief Executive Officer. Such a plan would describe how the company intends to contribute to the national goals discussed above by following the environmental hierarchy outlined in the Pollution Prevention Act. In this hierarchy, source reduction is identified as the preferred means for reducing discharges to the environment, followed in descending order by recycling, treatment, and disposal.[8]

The Agency invites comment on other elements that should be included in the plan. Examples might include: (a) Making explicit that the company's priority is to eliminate waste at the source, and to enhance efficiency through reduced use of energy, water and other natural resources; (b) establishing public goals for reducing both hazardous and nonhazardous waste releases to all media, and specifying the role that source reduction would play in meeting those goals; (c) describing the company's efforts to promote high quality environmental management practices by engaging purchasing, production, and environmental staff at all levels in developing and carrying out the plan; and (d) reaffirming the company's commitment to the other program criteria outlined in Section V.

2. Model Facility Program

Each Model Facility would develop a plan for achieving the national goals. The plan would emphasize pollution prevention measures that reduce waste through appropriate approaches that might include product design or process changes, reducing the use of toxic chemicals or materials, and implementing water and energy conservation practices that reduce nonessential uses of natural resources. The plan could also include a general statement regarding other methods (*e.g.*, recycling or treatment) that could also be used to meet national goals. It might include target dates for implementing the proposed actions, and numerical measures of performance consistent with the criteria to be established for the Program. (See Section V.B.) EPA is also interested in comment regarding measures that take into account past progress.

The success of voluntary programs such as EPA's 33/50 Program suggests that many companies may welcome the opportunity to take the initiative in setting broader and more far-reaching elective goals that make environmental and economic sense for particular facilities. As in the Statement of Environmental Principles, facilities would be encouraged to develop additional objectives beyond those EPA may identify as national goals.

EPA recognizes that many states have already established pollution prevention planning requirements for various categories of industrial facilities. The Agency wishes to avoid duplication of state requirements in developing proposed planning criteria for this program, and is specifically seeking comment on this issue. The Agency also wants to design this program in a way that minimizes paperwork requirements related to the planning process.

D. Environmentally Sound Business Practices

Environmental leadership in today's world is not simply a matter of how companies manage their facilities. To demonstrate leadership, companies must show that they are making environmental considerations a more integral and salient feature of the development and implementation of their business plans. A leading company will consider environmental factors in deciding what products it will manufacture, what materials it will use, what industrial processes it will adopt, and even how it will approach financial practices (*e.g.*, cost accounting) and institutional culture (*e.g.*, employee incentives).

An increasing number of companies are beginning to formalize their commitment to the environment by incorporating a Design for Environment (DfE) ethic into their business operations. The Design for Environment concept is analogous to other design improvement initiatives recently undertaken by companies that seek to improve the quality of the products they make, the processes they use, and other aspects of their operations. A company committed to Design for Environment will seek every available opportunity to produce safer products, use less polluting materials, implement production processes that minimize health and environmental impacts, and devise institutional systems that encourage environmental stewardship. The Environmental Leadership Program should recognize but not dictate these actions, acknowledge the industry pacesetters, and encourage others to follow their lead, thus advancing the state of the art.

The Agency is seeking advice on how to incorporate into the proposed program clear encouragement of environmentally conscious product design, marketing, and raw material use, without being either prescriptive or administratively burdensome. EPA is interested in general principles that allow ample flexibility to accommodate the wide variety in the design, manufacture, and use of products.

What follows is a description of several efforts under development at EPA to allow for accurate measurement of environmental costs and benefits, and identification of alternatives, throughout a company's business operations. The Agency invites public comment on how these concepts or alternatives might be applied in the Environmental Leadership Program. EPA is not offering at this time specific proposals for how these environmentally sound business practices could relate to the Corporate Statement of Environmental Principles or the Model Facility Program. The concepts seem most relevant to the Corporate Statement of Environmental Principles, but EPA welcomes any suggestions regarding their potential use in the Model Facility Program.

1. Life Cycle Assessment

"Life cycle assessment" refers to a collection of concepts and methods used to assess and minimize environmental impacts that result from a product, process, or activity. Impacts from all stages of a life cycle are considered, including raw materials acquisition, manufacture, use and final disposition, taking into account how these activities affect all media at all endpoints. A life cycle assessment (LCA) comprises three stages: an inventory of resource inputs and emission outputs, an analysis of the impacts that result from inputs and outputs, and an analysis of ways to minimize impacts. This tool can be used to identify design, materials, production, use, or disposal changes that have the potential to result in a net reduction in potential environmental impacts. Moreover, it can help to better insure that actions which reduce environmental impacts at one stage of the life cycle do not create more significant adverse impacts elsewhere in the life cycle.

An EPA multi-office task force led by the Office of Air and Radiation, with representation from the Offices of Solid Waste, Pollution Prevention and Toxics, and Research and Development, has recently published a technical report on

[8] 42 U.S.C. § 13101(b).

voluntary LCA inventory guidelines and principles. The Agency is proceeding to test the existing guidelines and to develop guidelines addressing impact analysis and data quality. These guidelines are being developed through a consensus-based process in coordination with the Society for Environmental Toxicology and Chemistry (SETAC).

While LCAs have been used to support business decisionmaking for more than 20 years, the development of EPA guidance is expected to significantly improve the quality of life cycle assessment results. Because information developed for one LCA can often be used in others, the resources necessary to undertake LCAs are expected to decrease as more organizations complete these studies.

For further information, please contact Tim Ream, MD–13, Research Triangle Park, North Carolina 27711.

2. Environmental Cost Accounting

"Full Cost Accounting" and "Total Cost Assessment" refer to accounting and capital budgeting practices that improve the ability of a company to assess (and reduce) the "true" costs of its polluting activities. Such methods include explicit consideration of regulatory compliance costs and liability costs and proper allocation of environmental costs to the processes or product lines that produce them. In addition, increased revenue from improved product quality and such intangibles as enhanced company and product image are factors to be considered in environmental cost accounting.

A recent study by the nonprofit organization INFORM, *Environmental Dividends: Cutting More Chemical Waste* (1992), shows that those companies achieving the greatest benefits from adopting pollution prevention approaches had instituted full cost accounting practices that allowed them to identify where their pollution and compliance costs were originating, and act to reduce them. Companies that are environmental leaders should strive to integrate environmental considerations throughout their accounting and capital budgeting systems. The concept of environmental cost accounting is evolving and is explained more fully in the EPA publication, "Total Cost Assessment: Accelerating Industrial Pollution Prevention through Innovative Project Financial Analysis" (EPA/741/R–92/002). This document can be obtained by calling the EPA Pollution Prevention Information Clearinghouse at (703) 821–4800. For further information, contact Martin Spitzer at (202) 260–4342.

3. Other Examples of Integrating the Environment Into Business Decisions

Companies are beginning to reflect their commitment to the environment by adopting other practices that promote environmental stewardship, such as implementing company-wide recycling programs and procuring materials that minimize environmental damage.

EPA has established a new Design for Environment initiative, whose objective is to assist companies in developing their own Design for Environment programs. Administered by EPA's Office of Pollution Prevention and Toxics, this program promotes the use of the above tools and practices as well as a methodology to analyze chemicals and processes to identify potential substitutes for commonly used toxics. For further information, contact Libby Parker at (202) 260–1670.

E. Community and Employee Involvement

EPA strongly supports the participation of workers in identifying, implementing, and evaluating pollution prevention practices. The Voluntary Protection Program (VPP) developed and managed by the Occupational Safety and Health Administration (OSHA) has a ten year history which suggests that worker participation has significant benefits. (For further information on OSHA's VPP Program, please contact Cathy Oliver at (202) 219–7266.) In addition, the 1992 report by the nonprofit group INFORM, *Environmental Dividends: Cutting More Chemical Waste*, showed that worker participation was a major factor in determining which companies were leaders in identifying and implementing pollution prevention practices. EPA also believes that employees can play a major role in companies' compliance activities.

Although community involvement and community interests are relatively new concerns for corporate managers, evidence suggests that these concerns are perceived as increasingly important by corporate environmental leaders.

1. Corporate Statement of Environmental Principles

The Hazard Communication Standard, administered by the Occupational Safety and Health Administration, requires communication between a company and its employees on issues related to health and safety.[9] The Emergency Planning and Community Right to Know Act (42 U.S.C. § 11001 *et seq.*), administered by the Environmental Protection Agency, requires communication between a company and its neighbors on issues related to toxics manufacture, storage, and use within a facility.

The Statement of Environmental Principles might require companies to go beyond these basic requirements for information transfer between a company and its workers and neighbors. Employees and community residents could be viewed as "stakeholders" of the company, with an interest in information related to environmental concerns and decisionmaking related to those concerns. At the same time, EPA is reluctant to prescribe specific worker training or community relations programs, given the diversity of the industrial community and the likelihood that a variety of approaches may be successful. EPA seeks comment on whether the Environmental Leadership Program should contain elements aimed at empowering communities and/or workers, and, if so, how the Program could achieve that goal without being unduly prescriptive.

2. Model Facility Program

EPA is particularly interested in public comment on possible aspects of community and worker involvement in the Model Facility Program.

EPA is considering such elements as:

- active worker involvement in training and education related to pollution prevention and source reduction opportunities within the facility, and to maintaining compliance;
- routine facility outreach to community residents to both share and gather information on issues related to environmental health and safety;
- documentation of the effectiveness of worker and community participation with significant outcome measures (such as process or policy changes that occurred as a consequence) rather than public relations metrics (such as the number of newsletters published or community focus group meetings held).

F. Compliance

EPA intends to design a program in which a systematic commitment to compliance, as measured against actual performance, is a fundamental criterion for program participation. EPA believes this commitment to compliance can best be translated into performance through the participant's adoption of a comprehensive approach to

[9] 29 CFR § 1910.1200, 1915.99, 1917.28, 1918.90, 1926.59, 1928.21 (1992).

environmental management, focusing on the anticipation and avoidance of compliance problems as well as the swift correction of problems that occur.

1. Corporate Statement of Environmental Principles

A company subscribing to the Statement of Environmental Principles might be asked to pledge to institute a company-wide environmental compliance management system, for promoting and monitoring compliance at all of its facilities. The system should include a self-auditing component. The auditing function could be performed either in-house or by an independent third party. Those conducting audits should be accountable to top corporate management.

Participating companies could also be asked to pledge to make available to the public an annual summary of governmental and citizen environmental enforcement actions including penalties and fines paid, involving their facilities. This information might be provided in an annual environmental report that included TRI-related emissions data and other measures for public accountability, as discussed above.

2. Model Facility Program

An applicant facility might be required to have established a comprehensive environmental compliance management system at least two years prior to acceptance into the Model Facility Program. This system should include a demonstrably effective self-evaluation program for finding and correcting compliance problems. In addition, EPA would review the applicant's compliance record in accordance with the criteria and process proposed in section VI below.

EPA welcomes comment on suitable criteria for the environmental compliance management systems and auditing programs called for under both the Corporate Statement of Environmental Principles and the Model Facility Program. Such systems should include the components listed in the Appendix to EPA's 1986 Auditing Policy Statement, 51 Fed. Reg. 25004, 25009 (July 9, 1986), and the factors set out in the Justice Department's 1991 policy, "Factors in Decisions on Criminal Prosecutions for Environmental Violations in the Context of Significant Voluntary Compliance or Disclosure Efforts by the Violator, "U.S. Department of Justice, July 1, 1991. EPA also anticipates that voluntary industry standards under development by several nongovernmental bodies will, when finalized, help guide the Agency in defining compliance management system criteria for this Program.

EPA recognizes that issues related to environmental auditing continue to generate significant debate. Commenters are advised that this Program is not intended to represent a comprehensive response to the myriad issues that have been raised with respect to environmental auditing. Rather, EPA anticipates that the Program will serve as a laboratory for the Agency to gain a better understanding of the issues and concerns related to self-evaluation and compliance, as the Agency's Office of Enforcement continues its broader efforts to address these issues.

Please See Section VIII, Questions 17–35

VI. Compliance Screening for Model Facilities

The Environmental Leadership Program's credibility will suffer if EPA erroneously recognizes facilities with poor compliance records. To guard against this risk, EPA proposes to include a rigorous compliance screening component in its process for reviewing Model Facility Program applications. Such a compliance screen should consist of criteria that define the compliance history expected of an "environmental leader". EPA is interested in fashioning criteria that can be applied fairly across the many different types of facilities that may seek participation in this Program.

In reviewing the following proposed compliance screening criteria and process, commenters should keep in mind that EPA welcomes comments on all aspects of this proposal, not just on those points for which a specific question has been posed in order to elicit more focused comment. Ultimately, EPA wants to encourage environmental management systems that eliminate significant non-compliance entirely. The compliance portion of the Environmental Leadership Program will be designed with an eye to what constitutes the "best" under current realities. But even today, a strong compliance record would be a prerequisite for participation in the Model Facility Program, since the Program's goal is to recognize those facilities that have gone *beyond* compliance. Accordingly, while the specific elements set forth below are open to discussion and comment, the Agency's ultimate decisions regarding compliance screening will be made in light of the need for an objectively strong record.

In the proposal set forth below, EPA would screen applicants for an acceptable compliance status through a review of their recent compliance history (Subsection A below) and an evaluation of their compliance status at the time of application to the Program (Subsection B below). A similar review would occur upon renewal of the application every few years (Subsection C below). In addition, during participation in the Program, facilities would be expected to maintain their excellent compliance records.

A. Past Compliance History

1. Criteria

Applicant facilities should have superior compliance records. Because EPA recognizes that facilities with past environmental compliance problems can turn around to become the most diligent at finding and correcting their problems, EPA's review of an applicant's record would be limited to the recent past. EPA is considering limiting its review to a five-year period preceding application.[10] EPA proposes to evaluate an applicant facility's past compliance record according to whether a federal or state criminal, civil judicial, or major administrative enforcement action, had been filed against it.[11] Using the filing of an enforcement action provides several advantages. For example, it assures that EPA would not award Model Facility status to a facility about to be adjudged guilty of environmental crimes or liable for violation of civil statutes. It also gives potential applicants an incentive to resolve ongoing enforcement actions expeditiously, and protects public confidence in the integrity of the Program, which could be compromised if a facility were admitted into the Program while several enforcement actions were pending against it.

Citizen suits can also reflect on the quality of an applicant's compliance record, and EPA solicits comment on how citizen suits should be weighed in evaluating an applicant's eligibility for the Program.

2. Process

EPA is proposing to evaluate an applicant's past compliance history by reference to the occurrence of federal or state civil judicial, criminal, and major administrative enforcement actions and, perhaps, citizen suits.

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[10] EPA is considering a five-year timeframe in order to mirror the typical statute of limitations governing environmental enforcement actions. *See* 28 U.S.C. § 2462.

[11] This would not include any civil, criminal, or major administrative enforcement action or citizen suit in which a judgment was entered in favor of the defendant or which found no violations or liability on the part of the defendant.

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EPA would conduct a review of the applicant's prior enforcement history through a review of the Agency docket and computer data bases, and through coordinated information sharing among the Office of Enforcement, Regional Offices, Headquarters Program Offices, and state and local enforcement personnel. The applicant would also provide, as part of its application materials, a list of any federal or state enforcement actions and citizen suits initiated against the facility in the last five years.

B. Compliance Status at Time of Application

Applicants to this voluntary program will be held to a high standard of compliance at the time of entry into the Program. EPA would expect applicant facilities to have conducted a diligent search for environmental compliance problems and to have addressed any known outstanding problems (including those not known to, nor subjected to enforcement by, the government) before submitting an application to the Model Facility Program.

1. Criteria

EPA proposes several criteria for determining whether an applicant's compliance status at the time of entry into the Program is acceptable. These criteria are intended to reflect the high standard consistent with the title of "environmental leader." Most of the proposed criteria are straightforward, objective measures of performance whose satisfaction an applicant should be able to ascertain easily for itself before submitting an application. These criteria include the following:

- at the time of application to the Program, the applicant facility has no significant violations of environmental laws or regulations administered by EPA or delegated to the states. EPA proposes that the existing definitions of "significant violation" that it has developed and currently employs would apply for purposes of the Program.[12] (More minor violations could be given less weight in light of the Program's expected contribution to overall compliance through its promotion of the development of effective compliance management systems.);
- the applicant facility is not the subject of an unresolved [13] ongoing state or federal administrative or judicial enforcement action under any environmental statute administered by EPA or by the state.[14] An applicant facility that is subject to an ongoing long term compliance schedule under a consent decree must have corrected the violations that were the subject of the original action, and must be in compliance with the law with the terms of the consent decree.
- the applicant facility is in compliance with all orders issued by EPA, or the state piloting the Program, related to environmental conditions or violations;
- the applicant facility is not the target of an ongoing criminal investigation or prosecution for environmental violations [15]; and
- the applicant facility is in compliance with relevant environmental laws administered by other federal agencies. These laws include, but would not necessarily be limited to, the Oil Pollution Act, the Hazardous Materials Transportation Act, the Surface Mining Control and Reclamation Act, the Endangered Species Act; and the Migratory Bird Treaty Act.

EPA is also considering evaluating two other aspects of an applicant's environmental compliance record to determine the applicant's qualifications for this Program. EPA welcomes comment on the two following criteria, and any additional criteria that might be useful in evaluating a facility's compliance record:

- the company owning the applicant facility does not have a pattern of major violations, evidenced by multiple civil or criminal enforcement actions, at its other facilities; and
- the applicant facility does not have a persistent pattern of minor violations.

2. Process

EPA proposes the following process for determining whether an applicant facility has met the proposed criteria listed above. The determination would be based on input from numerous sources: the applicant facility, EPA, the relevant states, employees of the applicant, and the community surrounding the applicant facility.

The information submitted by the applicant facility regarding its current compliance status would include two components:

First, EPA proposes that the facility would provide a good faith self-certification, signed under oath by a senior company official, which attests to the current compliance status of the facility. The certification would include a statement of all compliance problems detected at the facility through an environmental compliance audit conducted within three months prior to submitting the application.[16] EPA proposes that the audit may be conducted by either the company's own auditors or by an independent auditor. EPA would determine, using objective criteria, whether the problems detected are "significant" violations that should preclude the facility from being accepted into the Program.

The applicant would be required to describe its auditing system in its application and certify that the system includes the general elements set out in the Appendix to the Agency's 1986 Auditing Policy Statement, which remains in force.[17] The applicant's auditing system will also be evaluated in terms of the factors set out in the Justice Department's policy on voluntary compliance and disclosures.[18]

Second, the applicant facility would be required to submit additional information pertaining to its compliance status, such as a list of all pending enforcement actions against the facility and all compliance schedules to which it is subject under any consent decrees.

In addition to the information received from the applicant, EPA would

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[12] *See, e.g.*, Guidance on the "Timely and Appropriate Enforcement Response to Significant Air Pollution Violators," February 7, 1992 (lists type of violations that qualify sources as Significant Violators under the Clean Air Act); Revised Enforcement Response Policy, December 21, 1987 (defines Class I violations under the Resource Conservation and Recovery Act). EPA solicits comment, especially from States, on other appropriate guidance regarding what constitutes a "significant" violation that would preclude admission into this Program.

[13] An "unresolved" judicial enforcement action is an action in which: a settlement has not been entered in court, a judgment has not been issued, an appeal of a judgment is pending in an appellate court, or penalties or fines levied against the defendant facility remain unpaid, in violation of a consent decree or court order. An "unresolved" administrative action is an action in which a consent order has not been executed, a final order has not been issued by an administrative law judge or hearing officer, or an order is on appeal to the EPA Environmental Appeals Board, or penalties levied against the defendant facility remain unpaid, in violation of a consent decree or court order.

[14] This criterion would apply only to enforcement actions filed prior to the proposed five year period during which no enforcement actions may have been filed against the facility because any actions filed within five years of the application would independently be disqualifying under the enforcement history criteria proposed above.

[15] As noted above, an advantage of making the commencement of a criminal investigation or prosecution an eligibility factor is the protection it provides against awarding Model Facility status to a facility that is about to be indicated or adjudged guilty of environmental crimes.

[16] Self-certifications by applicant facilities as to their compliance status at time of application to the Program is intended to parallel the approach taken under existing Federal laws, *e.g.*, the Government.

[17] 51 Fed. Reg. 25004, 25009 (July 9, 1986).

[18] *See* "Factors in Decisions on Criminal Prosecutions for Environmental Violations in the Context of Significant Voluntary Compliance or Disclosure Efforts by the Violator," U.S. Department of Justice, July 1, 1991.

gather its own information independently on the compliance status of the applicant facility. This exercise would include review of the docket and computer data bases for referrals and enforcement actions, review of recent inspection records, and consultation with the states. Special inspections would not automatically be conducted in connection with applications to the Program, but EPA and the states would retain all existing rights to conduct such inspections.

If EPA determined that the compliance criteria set out above were met by the facility applicant, the "screened" application would then be reviewed in light of all other admission criteria. EPA is considering whether to utilize an independent "Blue Ribbon" panel of outside experts to review screened applications.

Employees of an applicant facility and members of the community surrounding the facility would be able to provide information to EPA or the panel that bears on whether the applicant facility should be recognized as an environmental leader. EPA welcomes comment on how such information should be gathered and utilized.

After reviewing an application, the panel, if used, would make a recommendation to the EPA Administrator, who would ultimately determine whether an applicant is accepted into the Program.

C. Ongoing Compliance Expectations for Participating Facilities

1. Compliance Evaluations

Given that the participant's self-evaluation system is a major element under consideration for Program participation, it is important that EPA and the public be assured of that system's ongoing effectiveness. Accordingly, EPA is considering how to monitor participants' compliance status while in this Program. For example, participants might be asked to provide the Agency, in the years between application and renewal, with self-certification statements reporting on the effectiveness of the self-evaluation system and the facility's compliance status. EPA solicits comment on other appropriate means of assuring participants' ongoing compliance status.

EPA recognizes that a program premised on compliance evaluations and self-certifications could place Program applicants and participants in the position of notifying the government of self-discovered compliance problems, the disclosure of which may not otherwise have been legally required. EPA has long recognized that a self-discovered, self-reported compliance problem that has been promptly corrected may warrant an enforcement response that differs from the Agency's response to other types of violations. The major environmental statutes' penalty assessment criteria and EPA's current civil penalty policies, for instance, provide that "good faith efforts to comply" is a mitigating factor in determining a penalty.[19] In addition, the Department of Justice's policy on voluntary compliance and disclosure identifies comprehensive environmental compliance programs and prompt self-correction of self-reported violations as factors to be weighed favorably in the exercise of criminal enforcement discretion.[20]

In keeping with this policy backdrop, and in light of the unusual and experimental character of this Program and its substantial anticipated environmental benefits, EPA invites comment on how the government should respond to violations which are identified solely as a result of participation in the Program and which are promptly self-corrected by Program participants.

2. Removal from the Program

As a general matter, a participant's continuing suitability for the Program would be evaluated at the time the application comes up for renewal (discussed below). EPA believes that certain types of events, however, should lead to suspension or immediate removal from the Program. Such events could include:

- The participating facility is the subject of a criminal indictment, conviction, or guilty plea for an environmental violation.
- The company's top corporate officers are the subject of an indictment, conviction, or guilty plea for an environmental violation, based on their personal actions at a facility under their control.
- A federal or state civil judicial enforcement action, or a major administrative action, is initiated against the facility.
- The facility is in violation of any federal or state order or decree (*e.g.*, consent order, emergency order), or is delinquent in payment of any adjudicated penalties, where the government has moved to enforce the order, decree, or penalty judgment.
- Violation of any federal statute, including nonenvironmental statutes, that led to listing or debarment of the facility from government contracts.

EPA welcomes comment on the appropriateness of these removal standards and on possible additions to this list. EPA is specifically interested in receiving comments on whether the initiation of an enforcement action, the issuance of an indictment, or evidence of significant noncompliance should trigger removal from the Program, as opposed to allowing participants to continue in the Program until an enforcement action is settled or adjudicated to completion. EPA also seeks comment on whether it would be appropriate to provide for temporary suspension of some or all of the Program's benefits pending resolution of an enforcement proceeding.

D. Renewal of Application

1. Criteria

Compliance-related criteria for readmission to the Program every few years generally would be equivalent to the initial entrance criteria. EPA is interested in comment on the appropriateness of this approach, and whether other considerations should be brought to bear at the time of reapplication.

2. Process

EPA's review of a participant's compliance status at the time of reapplication would follow the same basic process as for the initial application: information would be collected from the applicant; from various EPA, state, and local offices and information sources; and from the public. The independent panel, if used for initial application review, would not necessarily be involved in reviewing application renewals.

Please See Section VIII, Questions 36–53

VII. Incentives for Participation

The evidence suggests that public recognition, in particular, will provide a powerful incentive for joining the Environmental Leadership Program. When presented with a series of alternative incentives, participants at an OSHA Voluntary Protection Program (VPP) conference in August, 1992 placed the highest value on public recognition. Additionally, public recognition has helped to attract over 1,000 participants in 33/50 and Green Lights, EPA's most successful voluntary initiatives to date.

[19] *See, e.g.*, Clean Air Act Section 113(e)(1), 42 U.S.C. § 7413(e)(1); U.S. Environmental Protection Agency, "RCRA Civil Penalty Policy", October 1990, at 33–34.

[20] "Factors in Decisions on Criminal Prosecutions for Environmental Violations in the Context of Significant Voluntary Compliance or Disclosure Efforts by the Violator," U.S. Department of Justice, July 1, 1991, at 4–6.

As stated previously, EPA will offer recognition to model industrial facilities that meet applicable criteria. The Agency expects to learn from OSHA's experience with the VPP, but also seeks comment on how to provide appropriate public recognition to qualifying facilities. EPA anticipates publicly announcing the newly designated Model Facilities at a biannual conference, and providing qualifying facilities with a flag and/or seal bearing the Program's logo. While EPA would not offer the same recognition to companies subscribing to the Statement of Environmental Principles (due to lack of resources for evaluation), the Agency proposes to maintain a public list of companies that have provided EPA with a letter of commitment. EPA is interested in other suggestions for an appropriate public recognition program.

EPA welcomes comment on the extent to which incentives in addition to public recognition would encourage participation and on what these incentives might be. When considering additional incentives, commenters should keep the following points in mind:

- The Environmental Leadership Program must find the right balance between far-reaching objectives that go beyond a company's obligation to comply with the law, and incentives needed to elicit those ambitious commitments. It would be most helpful for commenters to identify which specific incentives would be needed to achieve the goals of the Environmental Leadership Program, as outlined above, and to explain why.
- The Agency is not at this time proposing any changes in statutory obligations as part of this Program. Rather, EPA is interested in incentives that can be offered under existing law using administrative authority, and that lie clearly within EPA's jurisdiction. Efforts to change statutory deadlines or amend environmental standards, or that require actions by other agencies, lie beyond the scope of this proposal.
- The Agency is particularly interested in reactions from the states, with which it shares jurisdiction over such matters.
- Finally, it is critically important for EPA to have a sense of the relative importance commenters place on the various types of incentives that they wish the Agency to consider. Accordingly, commenters who would seek additional incentives are asked to select the three most important categories of incentives from the list below. The results of this exercise will help guide the Agency in setting priorities for further review.

Please select any three of the following:

- *Public Recognition:* Company's facility recognized by EPA as meeting "state of the art" standards for environmental leadership.
- *Faster Permitting:* Accelerated review of permit applications and modifications.
- *Faster Registration:* Accelerated review of product registration.
- *Green Product/Labeling:* Public recognition that product meets environmental leadership criteria.
- *Compliance Credit:* Environmental leadership status taken into account in enforcement actions.
- *Reduced Monitoring/Reporting Requirements:* Reduced scope and/or frequency of monitoring and reporting requirements.
- *Multimedia Permits:* Requirements consolidated into one permit, providing facility with greater flexibility in meeting statutory goals.
- *"Ombudsman":* Access to Agency representative who will assist in cutting agency red tape.
- *Regulatory Credit:* Companies allowed to offset voluntary actions against future regulatory requirements.

The results of this informal survey will not, of course, be binding on the Agency. Rather, they may be used to help focus discussion in public meetings and to identify specific issues for analysis should the Agency decide to consider additional incentives for participation. Commenters are, of course, free to expand upon their selection or suggest substitute incentives.

EPA expects the public recognition program planned for Model Facilities to require a significant resource commitment from the Agency. Requests for additional incentives will need to be evaluated in light of resource and administrative constraints and the impact on the Program's credibility, weighed against the expected effectiveness of those incentives.

Please See Section VIII, Questions 51–53

VIII. Summary of Key Questions

The following section summarizes specific questions to which commenters are encouraged to respond. Questions are grouped to correspond with individual sections of this notice.

Introduction and Overview (Sections I–III)

(1) Should EPA consider establishing a national voluntary program to publicly recognize environmental leadership? Why or why not?

(2) Do the assumptions identified in this notice provide an appropriate foundation for the development of a national voluntary program? Should the assumptions be modified, or additional ones considered?

(3) Should EPA establish objective and consistent criteria to guide this Program? If not, what is the appropriate basis for fairly evaluating applications?

(4) How can EPA minimize administrative complexity and reduce transaction time involved in reviewing applications, while protecting the credibility of the Program?

(5) What is the appropriate role for the public in a national voluntary program?

(6) What is the appropriate relationship between EPA's proposed Program and existing private sector initiatives such as the Global Environmental Management Initiative and Responsible Care Program? Do these efforts currently establish environmental goals and measures of progress? Do they have sufficient credibility with the general public?

Scope of the Proposed Program (Section IV)

(7) Is the two-part structure proposed by EPA (Corporate Statement of Environmental Principles and Model Facility Program) a sound design to achieve the Program's goals?

(8) Given resource limitations, should EPA be expected to verify whether a company is acting in accordance with the Statement of Environmental Principles? Will public scrutiny be sufficient to ensure accountability for companies subscribing to the Statement of Environmental Principles?

(9) Is it reasonable to make a company's adoption of the Statement of Environmental Principles a prerequisite to that company's facilities' participation in the Model Facility Program? If not, how can EPA assure that it is not conferring environmental leadership status on "showcase" facilities managed by companies lacking strong environmental records?

(10) Should the application process for the Model Facility Program be administered by a Blue Ribbon panel, by EPA, or by a combination of both? What role, if any, should independent auditors play?

(11) Should state concurrence be a condition for the award of Model Facility status? Should EPA delegate this Program to the states?

(12) At what intervals should Model Facilities be required to apply for renewal? What measures, if any, should EPA take to monitor continuing adherence to Program criteria?

(13) Is there benefit to creating one or more "tiers" to accommodate companies that have set a goal of

becoming environmental leaders, but that need time and assistance to reach that goal? If EPA establishes multiple tiers, should participating companies be asked to support the Program through a fee?

(14) Should EPA build special provisions into this Program to accommodate small businesses?

(15) Should the Program be expanded beyond the manufacturing sector to include other sectors such as transportation, energy, agriculture, services, or municipalities?

(16) Is it practical to expect EPA to launch a comprehensive national voluntary program that covers multiple sectors, includes more than one tier, and offers special provisions for small businesses? Or should EPA incorporate these or other additional elements over time?

Criteria for Participation (Section V)

Risk Reduction Goals

(17) Should EPA establish national risk reduction priorities to help guide this Program? If so, what specific criteria should be used in selecting these priorities, and which classes of pollutants clearly meet these criteria? If not, what other alternatives exist for providing Program participants with clear expectations, and the Agency with a basis for evaluating potential applicants?

(18) How might risk reduction priorities be translated into goals for the Corporate Statement of Environmental Principles? For the Model Facility Program?

(19) Should EPA establish goals based specifically on pollution prevention or source reduction, or more general goals for reducing overall releases to the environment? If the latter, how can EPA place primary emphasis on pollution prevention or source reduction?

(20) Should the public goals for the Program include quantitative reduction targets, or should they be addressed in purely qualitative terms? Should goals be national in scope, with companies asked to document their contribution on a company-wide and facility-specific basis?

(21) How can EPA avoid discriminating against companies that have already made significant progress in preventing pollution? Should EPA consider asking companies to establish goals based on reducing waste per unit of product? Should numerical goals be national, or applicable on a company-wide or facility-specific basis?

Measurement

(22) What is the best way to establish clear measures of progress for the Corporate Statement of Environmental Principles? For the Model Facility Program?

(23) How can EPA best measure progress toward more efficient use of energy and other natural resources on a company-wide basis? At the facility level?

(24) Does the information currently collected under the Toxics Release Inventory (TRI) and the Pollution Prevention Act provide a sufficient basis for measuring pollution prevention and source reduction in the Environmental Leadership Program?

(25) If not, how can the Program build on the information currently reported to (a) insure that it is accurate and reflects environmental improvement rather than changes in measurement techniques; and/or (b) addresses major contaminants and sources of pollution not currently covered?

(26) Should the Environmental Leadership Program provide public access to Program participants' measurements of progress toward Program goals? Would public access to measurements of progress affect the Program's credibility?

(27) How can facility-specific information be expressed in a standardized form without risking disclosure of legitimate trade secrets?

(28) Should EPA review a Model Facility's reporting practices to provide assurance that they are sound? Should this review include an objective verification of actual data reported by the facility?

Planning

(29) What are the most appropriate planning criteria for the company-wide Statement of Environmental Principles? For the Model Facility Program?

(30) What is the appropriate relationship between planning requirements for the Environmental Leadership Program, and state pollution prevention planning laws?

Environmentally Sound Business Practices

(31) How can EPA best encourage environmentally sound business practices that extent to design and marketing of products, as well as manufacturing? How can these concepts be promoted through a Corporate Statement of Environmental Principles? Could such concepts be usefully applied in a Model Facility Program?

(32) How can EPA's current efforts with respect to life cycle analysis, full cost accounting, and Design for the Environment be applied to the Environmental Leadership Program?

Employee and Community Involvement

(33) What is an appropriate and meaningful role for insuring the involvement of employees and local communities in company environmental practices, as defined in the Corporate Statement of Environmental Principles? In the Model Facility Program?

(34) What types of measures can be used to evaluate the effects of employee and community participation in environmental leadership activities?

(35) What should be the criteria for an acceptable comprehensive environmental self management system and auditing program?

Compliance Screening for Model Facilities (Section VI)

(36) What is the appropriate date, prior to application, by which an applicant's comprehensive environmental compliance management system should be in operation, in order to allow evaluation of the system's effectiveness? (EPA has proposed two years.)

(37) How should a facility's prior enforcement history be evaluated? Should the focus be on the filing of enforcement actions, or on other evidence of past compliance?

(38) Should the seriousness of the violations be a factor in evaluating the relevance of judicial enforcement actions to the applicant's eligibility for the Program?

(39) Should EPA require applicants to have resolved outstanding enforcement actions by some date preceding application (*e.g.*, 2 years before applying)?

(40) How should EPA evaluate an applicant's past compliance history, and measure the effectiveness of an applicant's environmental compliance management system, if no EPA or state inspection of the facility has been conducted for several years prior to application? For example, should EPA conduct multimedia inspections of such applicants, require the applicants to hire independent auditors to conduct compliance audits, or require them to submit additional information?

(41) Should EPA consider the occurrence of accidental releases at an applicant facility to be relevant to the facility's compliance record, regardless of whether an enforcement action was taken in response to the release?

(42) How should citizen suits be weighed in evaluating a facility's eligibility for this Program? EPA is particularly interested in whether it should consider only the issuance of an adverse judgment or a settlement in a

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citizen suit, as opposed to the filing of a citizen suit. EPA also seeks comment on whether only certain types of citizen suits (*e.g.*, suits brought for EPA-defined "significant violations") should disqualify a facility from participating in the Program.

(43) Is it appropriate to disregard a facility's prior violations that were not the subject of enforcement actions in evaluating an applicant's eligibility for the Program?

(44) EPA seeks comment on how to define "major administrative enforcement action" for purposes of determining whether an administrative action is of sufficient gravity to preclude a facility from participating in the Program, including whether the definition of "major administrative enforcement action" should be based on the type of violation, size of penalty, or nature of the administrative measures taken. EPA specifically solicits comment from states on this question.

(45) What constitutes an unacceptable "pattern" of major violations at a company's facilities other than the applicant facility, and what constitutes an unacceptable "pattern" of minor violations at the applicant facility?

(46) How should a facility's status as a Superfund site or CERCLA Potentially Responsible Party affect its eligibility for the Model Facility Program? In the event that certain Superfund sites and PRPs could be eligible for the Program, how should the following factors be weighed: the degree of cooperation in cleanup activities, compliance with state and EPA orders, recalcitrance, failure to reimburse the government for response costs, good faith efforts to resolve liability, and the stage of cleanup activities?

(47) Should compliance self-certifications be employed to determine the current compliance status of applicant facilities and participants in the Program, or should other methods of gathering compliance information be used, such as self-certifications coupled with inspections?

(48) If a self-certification process is employed to determine the compliance status of applicant facilities and participants in the Program, what company officer should be required to sign compliance certifications (*e.g.*, the chief executive officer or the facility manager)?

(49) If a self-certification process is employed to determine the compliance status of applicant facilities and participants in the Program, should audits conducted as a condition of program admission be performed by independent third party auditors?

(50) What role should employees and the community surrounding a facility play in the application review process?

(51) How should the government respond to violations which are identified as a result of participation in the Program and which are promptly self-corrected by Program participants?

(52) What events should lead to a facility's removal from the Program? Should a form of temporary suspension be available for certain situations?

(53) What should be the compliance-related criteria for readmission into the Program every few years?

Incentives for Participation (Section VII)

(54) Is public recognition a sufficient incentive for participation?

(55) What form of public recognition should be offered to companies that subscribe to the Corporate Statement of Environmental Principles? To Model Facilities?

(56) Should additional incentives be offered? If so, what should they be? Please identify priorities, as discussed in Section VII.

Dated: January 10, 1993.

William K. Reilly,

Administrator.

F. Henry Habicht II,

Deputy Administrator.

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Part V

Environmental Protection Agency

40 CFR Part 310

Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases; Final Rule

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 310

[FRL–4102–8]

RIN 2050–AC11

Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is issuing a final rule to provide reimbursement to local governments for costs of temporary emergency measures taken to prevent or mitigate injury to human health or the environment. This reimbursement program is authorized under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. This regulation should help to alleviate significant financial burden on local governments for costs incurred in responding to releases or threatened releases of hazardous substances or pollutants or contaminants. CERCLA requires, however, that reimbursement must not supplant local funds normally provided for response.

EPA believes that this final rule is both consistent with the intent of Congress and appropriate for effective emergency response at the local level.

EFFECTIVE DATE: This regulation is effective October 14, 1992. The incorporation by reference of certain publications listed in this regulation is approved by the Director of the Federal Register as of January 15, 1993.

FOR FURTHER INFORMATION CONTACT: For information on specific aspects of this final rule for reimbursement to local governments contact: Elizabeth Zeller, (703) 603–8780, Local Governments Reimbursement (LGR) Project Officer, Emergency Response Division (5202–G), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

SUPPLEMENTARY INFORMATION:

Electronic Availability: This document is available as an electronic file on the *Federal Bulletin Board* at 9:00 a.m. on the date of publication in the **Federal Register**. By modem dial (202) 512–1387. This file is also available in Postscript, Wordperfect and ASCII.

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   c. Final rule.
3. Section 310.12 Penalties
   a. Interim final rule.
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B. Subpart B—Reimbursement

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   a. Interim final rule.
   b. Response to comments and clarifications.
   c. Final rule.
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   a. Interim final rule.
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VII. Regulatory Analyses

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I. Statutory Authority

Section 123 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) directs the EPA

Administrator to develop a regulation containing procedures for reimbursing local governments for expenses incurred in carrying out temporary emergency measures in response to hazardous substance threats. These measures must be necessary to prevent or mitigate injury to human health or the environment from a release or threatened release of a hazardous substance or a pollutant or contaminant. Temporary emergency measures may include such activities as erecting security fencing to limit access, responding to fires and explosions and other measures that require immediate response at the local level. CERCLA specifically limits reimbursement to $25,000 per single response and requires that reimbursement not supplant local funds normally provided for response. Any general purpose unit of local government that incurs costs in response to a release or threatened release at a facility within its jurisdiction may apply for reimbursement. Section 111 of CERCLA specifies that not more than 0.1 percent of the total amount appropriated from the Fund may be used for local governments reimbursement. Approximately, $5.1 million is authorized for the three year period beginning October 1, 1991.

The responsibility for promulgating today's final rule rests with the president, who has delegated it to the Administrator for EPA. The authority to receive, evaluate, and make determinations regarding requests for reimbursement and to issue payments to qualified applicants was delegated to the Assistant Administrator (AA) for the Office of Sold Waste and Emergency Response (OSWER). The AA for OSWER redelegated local governments reimbursement authority to the Director of the Emergency Response Division within the office of Emergency and Remedial Response. Today's rulemaking responds to public comments, discusses issues arising from three years of administering the interim final rule (IFR), and clarifies how the reimbursement program works.

II. Background

A. Overview of the Superfund Program

CERCLA was originally enacted in 1980 and established the authority to tax the chemical and petroleum industries to finance a $1.6 billion response trust fund (the Superfund or Fund). CERCLA provides broad Federal authority to respond directly to releases or threatened releases of hazardous substances and pollutants or contaminants that may endanger public health or welfare or the environment. EPA is primarily responsible for implementing the Superfund program. On October 17, 1986, the President signed into law the Superfund Amendments and Reauthorization Act of 1986. These Amendments added $8.5 billion to the Superfund Trust Fund and broaden the Federal Government's response authority. Congress has extended that authority through September 1995, with funding of $5.1 billion through September 1994.

Under the Superfund program, EPA may take legal action to force those responsible for hazardous substance releases to clean them up or to reimburse EPA for the costs of cleanup. EPA also can pay for the cleanup of hazardous waste releases when those responsible for such releases cannot be found or are unwilling or unable to conduct a cleanup themselves.

Response actions may be taken to address such incidents as illegal disposal of hazardous substances, improper handling or disposal of hazardous substances at landfills or industrial areas, spills of hazardous substances when a truck or train overturns, or discharges of hazardous substances into the air or water during a fire or other accident. Response actions may include, but are not limited to: removing hazardous substances from the release site to an EPA-approved, licensed hazardous waste facility for treatment, containment or destruction; constructing fences, posting warning signs or taking other security precautions necessary to control access; providing a temporary alternate water supply to local residents; temporarily relocating affected residents; or containing the hazardous substance on site so that it can safely remain there and present no further problem.

CERCLA responses usually are joint efforts by Federal, State and local agencies. As State and local public safety and health organizations are normally the first government representatives at the scene of a hazardous substance release, they play a critical role in providing temporary emergency measures. These temporary emergency measures may include security, control of the release source, containment of the substances released, control of contaminated runoff and similar activities that must be performed immediately to prevent or mitigate injury to human health or the environment. The National Oil and Hazardous Substances Pollution Contingency Plan (National Contingency Plan or NCP, found at 40 CFR part 300), the main Federal regulation that guides the Superfund program, outlines the roles and responsibilities of each Federal agency involved in responding to releases of hazardous substances, and describes State and local participation in hazardous substance releases. In addition, the NCP establishes procedures that are to be followed in conducting appropriate response actions.

B. Congressional Intent

The original Superfund law did not provide reimbursement to local governments for costs incurred in conducting temporary emergency measures. The Superfund Amendments and Reauthorization Act of 1986 (SARA) added a new section to the law that specifically allows such reimbursement, although the Conference Report makes it clear that "reimbursement under this provision shall not include reimbursement for normal expenditures that are incurred in the course of providing what are traditionally local services and responsibilities, such as routine emergency firefighting." With the specific requirement in section 123 that reimbursement not supplant local funds normally provided for response, Congress intends that local governments continue to bear some share of expenses for providing temporary emergency measures. However, Congress recognized that in the past, conducting such response activities has placed a significant financial burden on some local governments. Reimbursement under section 123 can provide some financial relief (limited to $25,000 per single response) to local governments most seriously affected by costs above and beyond those incurred routinely and traditionally. This $25,000 cap on individual responses plus the limited availability of funds for the program may not allow EPA to reimburse local governments for all responses that may qualify.

III. Approach to This Rulemaking

On October 21, 1987, EPA published an interim final rule in the **Federal Register** (40 CFR part 310) for reimbursing local governments for temporary emergency measures taken in response to hazardous substance releases or threats of releases. This rule was promulgated in interim final form to allow the Agency to implement the reimbursement program immediately. This approach made reimbursement money available quickly and afforded EPA the benefit of implementation experience before finalizing the rule. Public comments on the interim final rule were accepted for 60 days after its publication date.

Thirteen commenters provided comments on the interim final rule. These commenters represented six local governments in four States, three agencies in two States, two Federal agencies and two private firms. Public comments were separated into four major categories: (1) clarification of the financial burden formula; (2) effective date for reimbursable responses; (3) State role in application evaluation; and (4) clarification of eligible costs. In considering these comments, the Agency determined that some of the specific requirements of the interim final rule needed clarification. Consequently, EPA's approach to preparing this final rule is to expand and clarify in the preamble explanations of reimbursement application requirements and Agency policy regarding the reimbursement process. The preamble to today's final rule also contains an overview of the local governments reimbursement program. This overview presents information on the intent of the reimbursement program, basis of reimbursement decisions, State role, and the reimbursement process. The purpose of including this information in the preamble to the final rule is to provide a comprehensive understanding of the local governments reimbursement program and a context for reviewing the changes presented in today's rule.

The section-by-section analysis in the preamble of today's final rule is organized into four subsections: content of interim final rule; response to comments; areas of clarification, as applicable; and content of final rule. The majority of public comments on the interim final rule and procedural areas requiring clarification are addressed in this preamble. Only minor changes have been made to the regulatory text of the interim final rule.

Since the promulgation of the interim final rule, EPA has received 90 applications for reimbursement. These requests have come from local governments in 28 States. EPA has approved a total of $449,443 in reimbursements to 36 eligible applicants.

IV. Overview of the Local Governments Reimbursement Program

A. Intent of the Reimbursement Regulation

The overall purpose of the reimbursement program is to provide some financial relief to local governments in conducting temporary emergency measures in response to releases or threats of releases of hazardous substances, pollutants, or contaminants. This response may be conducted entirely by a local government or may be a response involving State or Federal assistance. The intent of today's final rule is to alleviate financial burden on a local government. EPA believes that this approach achieves the intent of section 123 of CERCLA to channel the small pool of reimbursement monies to the most deserving applicants; therefore, local governments must demonstrate that a response has created expenses that exceed the funds normally available for temporary emergency response activities. This approach also is consistent with the overall policies and goals of the Superfund program. The Agency wishes to emphasize, however, that reimbursement under section 123 does not eliminate the requirement to try to identify potentially responsible parties (PRPs) and attempt cost recovery, but is available as a measure of financial relief when PRP search and cost recovery actions have not proven successful.

B. Basis of Reimbursement Decisions

As discussed above, EPA has determined that reimbursement money should be distributed to applicants who demonstrate the greatest financial burden from conducting emergency response actions that adhere to the overall policies and goals of the Superfund program. However, due to the limited funds available for the reimbursement program (a maximum of 0.1 percent of the total amount appropriated for the Superfund, or approximately $5.1 million for the three-year period beginning October 1, 1991), not all applicants may actually receive reimbursement monies. For this reason, the Agency needs criteria for determining which requests to reimburse.

EPA has written today's final rule so that reimbursement decisions are based primarily on the ratio of eligible response costs to the applicant locality's per capita annual income adjusted for population with consideration given to other relevant financial information provided at the applicant's discretion. (For example, such information might include cost data for other hazardous substance responses if the locality has conducted numerous responses over a short period of time.) The intention of this approach is to ensure that communities with limited resources will receive priority in the reimbursement program. Basing reimbursement decisions primarily on per capita income statistics provides an objective method for deciding among requests. Allowing special consideration of other relevant data, such as frequency of recent emergency responses, recent local economic changes or other financially catastrophic events, provides flexibility.

Per capita income statistics are readily available through the Bureau of Census. EPA uses the Current Population Reports, Local Population Estimates, Series P–26, "1988 Population and 1987 Per Capita Income Estimates for Counties and Incorporated Places," published in June 1990 by the U.S. Department of Commerce, Bureau of the Census. This series will be used for the reimbursement program unless and until superseded by more recent data. Additional financial information provided by the applicant should provide the opportunity to consider economic factors that may not be represented accurately in the available income statistics. For example, if significant population shifts have occurred since the last census, the applicant may wish to supply relevant financial data demonstrating the economic effects of that shift upon the community.

C. State Role

Section 123 authorizes reimbursement to local governments for costs incurred in conducting temporary emergency measures related to hazardous substances or pollutants or contaminants. The law does not authorize reimbursement to States. Today's rule precludes States from requesting reimbursement under section 310.20(b) either for themselves or on behalf of political subdivisions within the State. EPA believes this approach helps eliminate the potential for two parties to request reimbursement for the same response.

D. Reimbursement Process

The reimbursement process comprises six steps; each is described below. The roles and responsibilities of EPA and the local government in the process are discussed as well.

1. Response to Release

The reimbursement process begins with a local government's response to a release or threatened release of hazardous substances or pollutants or contaminants. (Unlike responses to hazardous substances, which cover threats both to human health and to the environment, responses to releases of pollutants or contaminants must specifically address the imminent and substantial threats to human health or welfare in order to qualify for possible reimbursement [see CERCLA section 104(a)(1)]). This response may be

conducted by the local government solely or in conjunction with State or Federal responders. To be eligible for reimbursement, the response must be consistent with CERCLA, the National Contingency Plan and, if applicable, the local emergency plan prepared under section 303 of the Emergency Planning and Community Right-to-Know Act of 1986, title III of Public Law 99–499.

The Agency believes that reimbursement may be appropriate for activities such as security, control of the release source, containment of the substances released, control of runoff that would contaminate drinking water sources and similar activities that must be performed within minutes or hours of the release to prevent or mitigate injury to human health or the environment.

EPA also believes that actions such as ground-water decontamination, ongoing sampling and analysis programs, construction of water treatment facilities or installation of new water lines are outside the scope of the reimbursement program because they do not constitute temporary emergency measures. EPA wishes to make clear that costs of such projects are not reimbursable under this program. Instead, the local government may want to contact the EPA Regional office or the State to determine whether a Cooperative Agreement with the Agency would be appropriate for preforming long-term response projects. EPA does not intend that reimbursement monies be used for emergency response activities that are eligible for funding from other sources.

In addition, the Agency believes that PRPs should be identified and costs of temporary emergency response measures recovered from them, whenever possible. This program expressly requires that local governments demonstrate efforts to recover costs prior to submitting the request for reimbursement. Reimbursement is intended only as a last resort when funds are not available from other sources.

2. Contact With the Federal Government

Contact with a Federal response authority is a necessary condition for reimbursement under today's final rule. The purpose of this contact requirement is to give EPA or the U.S. Coast Guard (USCG) an opportunity to ascertain if Federal response action is appropriate in this instance. For this reason, contact is required as soon as possible, but not later than 24 hours after response initiation.

Contact must be made in one of two ways. The local government can use normal response communication channels to alert EPA or the USCG to the release. Normal channels include notification to the National Response Center (NRC) or established Regional networks that link local agencies with State agencies and ultimately with EPA and/or the USCG. Notification of the release through normal response communication networks satisfies the contact requirement in this rule.

Alternatively, if the locality is not part of an established communication network, the local government can contact the EPA Regional office or the NRC directly for purposes of satisfying this requirement. (Appendix I of today's rule identifies the EPA Regional office for each State and Territory and notes their and the NRC telephone numbers.) Contact must be made by telephone or radio as soon as possible, but not more than 24 hours after response initiation, to meet the Federal contact requirement for reimbursement.

3. Decision to Pursue Reimbursement

If the response has imposed significant financial burden on the community and appears to meet the basic requirements for reimbursement, as specified in § 310.30 of today's final rule, the local government may choose to seek reimbursement and proceed to the next step.

4. Reimbursement Request

The local government should obtain a reimbursement application package by calling the RCRA/CERCLA Hotline at 1–800–424–9346 (toll free) or, in the Washington, DC, metropolitan area, at 202–382–3000. The package contains the forms and detailed instructions for preparing and submitting reimbursement requests. Local governments are encouraged to obtain complete application packages rather than using photocopied forms to ensure that applications are filled out properly. Application packages will be mailed to the locality upon request. The completed application must be returned to the U.S. Environmental Protection Agency, Emergency Response Division, Attn: LGR Project Officer, (5202–G), 401 M Street, SW., Washington, DC, 20460, within one year of completion of the response. Local governments are encouraged to complete the application for reimbursement promptly to facilitate complete and accurate documentation of costs and cost recovery efforts and to expedite processing of the application by EPA. PRP search and contact activities should begin as soon as possible. Cost recovery efforts should begin no later than the date of response completion. Local governments should allow at least 60 days for PRP response prior to submitting the Local Governments Reimbursement application.

Only one request for reimbursement will be accepted for response to any single incident. When more than one local government (e.g., a city and county) has participated in such a response, those governments must determine which one of them will submit the application on behalf of them all. If more than one request is received for a single incident, all will be returned with appropriate written explanation and instructions for resubmitting a single, coordinated application.

5. Preliminary Screening

Initially, EPA will screen the request to make sure that it meets three preliminary screening criteria: (1) the request meets basic reimbursement criteria, as stated in today's final rule; (2) it complies with the procedures for filing, as defined in this rule; and (3) it is complete. A request that does not meet the requirements for reimbursement stipulated in § 310.30 will be returned to the local government with a written explanation of why the application has been rejected.

An application that meets the basic criteria but that has not compiled with the filing procedures specified in § 310.50 or that is incomplete will be returned to the local government with an explanation of its deficiencies. If the application has missed the filing deadline, an explanation for lateness must accompany the application. EPA will determine the eligibility of late applications on a case-by-case basis. Other filing or completeness deficiencies may be corrected and resubmitted to EPA within 60 days.

If all reimbursement criteria and filing requirements have been met, and the application is complete, EPA will notify the local government in writing that the request meets the preliminary screening criteria and will be considered for reimbursement. Such a notice in no way implies that reimbursement is assured. It means only that EPA will consider this request along with all other requests that also have satisfied this initial screening.

6. Evaluation of Requests

All requests for reimbursement will be evaluated on their own merits and with respect to the other requests concurrently under review. Because reimbursement monies are limited to 0.1 percent of the Superfund appropriation (or a maximum of $1.7 million for each fiscal year beginning October 1, 1986), the Agency will rank the requests and

distribute the monies accordingly until available funds are disbursed. The Agency will rank requests on the basis of significant financial burden incurred by the locality in performing the single response for which reimbursement is being sought.

The financial burden for the individual applicant is defined as the ratio of the project cost to a locality's aggregate income and is computed as follows:

$$B = \frac{C}{Y \times P}$$

Where: B=burden on applicant
C=total eligible response costs minus reimbursement from responsible parties, States, or other sources
Y=per capita annual income for the locality
P=population of locality

The Agency will use U.S. Census Bureau "Local Population Estimates" Series P–26 in conjunction with response cost data supplied by the applicant to compute financial burden on the locality. Responses with higher costs proportionate to local aggregate income (i.e., the larger fraction resulting from the financial burden calculation) will be ranked higher than responses with proportionately lower costs.

In general, EPA expects that financial burden will be computed on the basis of the single response for which reimbursement is requested. In exceptional cases, however, the Agency may consider other financial data demonstrating financial hardship incurred by the community in responding to hazardous substance threats. For example, a small community with limited resources that has had to respond to numerous hazardous substance emergencies over a short period of time may choose to supply additional information demonstrating the cost impacts of those multiple responses. As another example, a community in a declared disaster area may want to supply economic impact data associated with the disaster along with the financial information for the hazardous substance response.

Any requests not reimbursed because of limited availability of funds will be considered for up to one year, at EPA's discretion, after the initial approval of the LGR Review Panel. After that time, an unreimbursed request will no longer be considered and the applicant will be notified that the request will not be reimbursed.

V. Summary of Changes to the Interim Final Rule

Changes have been made in the following sections of the interim final rule to address public comments or reflect program experience: (1) Section 310.40(a)(10) has been added to include containerization, transport, and disposal of hazardous wastes as allowable costs; (2) Section 310.50(a) has been modified to clarify that only one LGR applicant is allowed per incident; (3) Section 310.50(d) has been changed to extend the deadline for filing an application from six months to one year from the date of response completion; and (4) Section 310.50(e) has been changed to clarify the application signature authority.

VI. Section-by-Section Analysis

A. Subpart A—General

Subpart A discusses the purpose, scope and applicability of the local government reimbursement final rule. It also provides definitions necessary for the proper interpretation and implementation of the rule and outlines penalties applicable to false statements or claims made as part of an application for reimbursement under section 123 of CERCLA.

1. Section 310.05 Purpose, Scope and Applicability

a. Interim Final Rule

The purpose of the local government reimbursement program is to alleviate significant financial burden imposed on a local government as a result of conducting temporary emergency measures to prevent or mitigate injury to human health or the environment, as authorized under section 123 of CERCLA. This purpose is consistent with the statutory requirement that reimbursement not supplant funds normally provided for response. Reimbursement only applies to local governments (e.g., a county, parish, city, municipality, township, Federally-recognized Indian tribe or other general purpose unit of local government). States are not eligible for this program.

In keeping with the statutory limits on the use of the Superfund set forth in sections 111 and 123 of CERCLA, the maximum possible reimbursement award is limited to $25,000 per single response and the amount of money available to the overall reimbursement program is restricted to 0.1 percent of the total amount appropriated from the Superfund. Due to the limited amount of money authorized for reimbursement, some requests for reimbursement may never be paid even though they meet all the requirements of this rule.

b. Response to Comments and Clarifications

One commenter suggested that the maximum reimbursement be placed on a sliding scale based on population because larger cities typically have more frequent and more expensive hazardous substance emergencies. Because unpredictability is the nature of hazardous substance releases, the Agency believes it would be inappropriate to limit the maximum reimbursement for small locales to less than the $25,000 per response authorized by CERCLA. Large scale hazardous substance releases can occur anywhere, and the intent of this regulation is to alleviate significant financial burden on local governments with limited resources for funding emergency response to such releases.

c. Final Rule

No change in section 310.05 of the interim final rule.

2. Section 310.10 Abbreviations and Section 310.11 Definitions

a. Interim Final Rule

Section 310.10 explains the acronyms used in this rule. Section 310.11 defines key terms used in the rule. In an effort to be consistent with the requirements and objectives of the overall Superfund program, most of the definitions contained in section 310.11 of this rule are taken from CERCLA and the NCP either verbatim or with minor wording changes. EPA developed the definitions of "General Purpose Unit of Local Government," "Single Response" and "Date of Completion" specifically for this rule.

b. Response to Comments and Clarifications

Several commenters requested more precise definitions of terms such as "traditionally local services and responsibilities" and "temporary emergency measures." This regulation offers guidelines and examples of the meanings of such terms but does not attempt to include exhaustive lists that might limit the Agency in determining the eligibility of highly variable response activities.

(1) *Clarification of Federally-permitted releases.* One commenter requested clarification of whether costs associated with responding to a federally permitted release were eligible for reimbursement. Releases of CERCLA hazardous substances that are federally permitted, as defined in CERCLA section 101(10), are exempt from

CERCLA reporting requirements under section 103 and from CERCLA liability under section 107. Nevertheless, a Federally permitted release may be subject to a response action undertaken pursuant to sections 104, 106, or 122. Thus, a local government may obtain reimbursement for temporary emergency measures taken at the site of a Federally permitted release during either Federal-lead or non-Federal-lead responses, if the requirements included in today's regulation are met. However, CERCLA section 107(j) indicates that recovery for response costs and damages resulting from a Federally permitted release must be sought under laws other than CERCLA. Thus, for emergency response measures taken at the site of a Federally permitted release, efforts to obtain reimbursement from all known PRPs must rely on laws other than CERCLA.

The commenter expressed the concern that a local community may believe that a substantial threat of release of a pollutant or contaminant exists at the site of a Federally permitted release, and so the community may respond to that threat and seek reimbursement from the Superfund. To avoid this situation, the commenter suggests deleting "substantial threat of release" from the definition of release and excluding Federally permitted releases from the same definition. The commenter's concern appears to reflect some confusion regarding certain CERCLA definitions and the scope of this regulation. Under CERCLA section 104, the Federal government may respond to a release or substantial threat of release into the environment of a hazardous substance or pollutant or contaminant. What is considered a "pollutant or contaminant" is defined in CERCLA section 101(33); this regulation simply incorporates that definition. The definition of release contained in this regulation is also taken from CERCLA (section 101(22)), with the addition of the final sentence indicating that release also means substantial threat of release. This addition is consistent with the definition included in the recent revisions to the National Contingency Plan (NCP) (40 CFR part 300). It also might be noted that section 104 limits response in the case of pollutants or contaminants to situations that may present an imminent and substantial danger to the public health or welfare.

These definitions thus extend to this regulation the full scope of situations where CERCLA response activities may be undertaken. However, under today's rule, local communities may seek reimbursement for temporary emergency measures only, and reimbursement may not exceed $25,000 per single response. Further, local actions must be consistent with CERCLA and the NCP. Local governments are not eligible under this regulation for reimbursement for all CERCLA-eligible response costs incurred, which appears to be the scenario suggested by this comment.

The final issue raised by this commenter is the relationship of this rule to Federally permitted releases. As clarified in the preamble to this final rule, Federally permitted releases may be the subject of a response action under CERCLA, thus a local community may seek reimbursement under this regulation for temporary emergency measures taken during Federally-lead or non-Federal-lead responses at the site of such releases.

(2) *Clarification of criteria for emergency response to hazardous substance releases.* Clarification was requested in public comment regarding the conditions under which a hazardous substance release constitutes an emergency response situation. Under CERCLA section 104, an emergency situation exists whenever immediate response is required to prevent or mitigate injury to human health or the environment.

c. Final Rule

No change in § 310.05 of the interim final rule.

3. *Section 310.12 Penalties*

a. Interim Final Rule

Section 310.12 imposes penalties for any person who knowingly gives or causes to be given any false statement or claim as part of any application for reimbursement under section 123 of CERCLA. EPA has included these penalties, under the authority of the False Statement Act, 18 U.S.C. 1001, and False Claims Act, 31 U.S.C. 3729, to prevent fraudulent or abusive use of the Fund. Failure to abide by the requirements found in these two laws when filing a reimbursement application may result in fines and/or imprisonment.

b. Response to Comments and Clarifications

The Agency received no comments on this section of the interim final rule.

c. Final Rule

No change in § 310.12 of the interim final rule.

B. Subpart B—Reimbursement

Subpart B of this rule establishes conditions that must be met for reimbursement under CERCLA section 123. Three types of conditions are set forth: Eligibility of the applicant to receive reimbursement, requirement for reimbursement, and allowable and unallowable costs. These conditions are included to ensure that (1) the intent of Congress is carried out in reimbursing local governments; (2) reimbursement is consistent with, and complementary to, the rest of the Superfund program; and (3) expenditures from the Superfund are warranted and appropriate.

1. Section 310.20 Eligibility for Reimbursement

a. Interim Final Rule

This section limits eligibility for reimbursement to general purpose units of local government. These may include cities, counties, municipalities, parishes, townships, or other official political subdivisions designated by a particular State, or Federally-recognized Indian tribes. This restriction is consistent with section 123(a) of CERCLA, which limits applicability to "(a)ny general purpose unit of local government for a political subdivision which is affected by a release or threatened release . . ."

Section 123 of CERCLA specifically designates local governments as recipients of reimbursement monies and does not indicate that this provision applies in any way to States. Therefore, State governments are not eligible for reimbursement under § 310.20(b). States also are precluded from requesting reimbursement on behalf of political subdivisions within the State. This restriction is designed to avoid any question of eligibility when reimbursement requests are reviewed by EPA.

b. Response to Comments and Clarifications

The Agency received no comments on this section of the interim final rule.

c. Final Rule

No change in § 310.20 of the interim final rule.

2. Section 310.30 Requirements for Requesting Reimbursement

The purpose of § 310.30 is to ensure consistency with the requirements, policies and practices of the Superfund program, to lend support to related initiatives, and to encourage the use of established procedures in conducting responses. EPA has established requirements to ensure an equitable distribution of funds to the most deserving applicants.

a. Effective Date for Response

(1) *Interim final rule.* Section 310.30(a) restricts reimbursement to responses initiated on or after the effective date of the interim final rule, October 21, 1987. In order to qualify for reimbursement a local government must meet the requirements of CERCLA, the NCP, and the Emergency Planning and Community Right-to-Know Act (EPCRA or Title III), and, in addition, contact the Federal government within 24 hours after response initiation to ensure that these requirements are understood and can be met. This notice requirement is discussed in greater detail in subsection 2(b) below.

(2) *Response to comments and clarifications.* The majority of commenters that addressed this issue concurred that the October 21, 1987, effective date for eligible responses is an appropriate means of ensuring fair evaluation of all applications. One commenter maintained that the effective date should be retroactive to SARA.

EPA is aware that limiting reimbursement to responses occurring after promulgation of the interim final rule precludes reimbursement of some otherwise valid and deserving requests. However, the Agency believes that the mission of the Superfund program, and specifically the local government reimbursement program, is best served if all requests are subject to the same requirements, thereby helping to ensure uniform management of limited reimbursement funds.

(3) *Final Rule.*

No change in interim final rule. October 21, 1987 remains the effective date for eligible responses.

b. Federal Contact Requirement

(1) *Interim final rule.* Section 310.30(b) requires the local government to contact EPA or the National Response Center (NRC) as a condition of reimbursement. Contact for purposes of reimbursement is to be made as soon as possible, but not more than 24 hours after response initiation, unless EPA or the USCG has been informed of the response through a release notification to the NRC or other established response communication channels.

Because EPA seeks to ensure safe and appropriate responses and appropriate use of the Fund, the Agency believes that it is appropriate for EPA or the USCG to be aware of a response for which a local government seeks reimbursement. Timely contact is useful in several respects. First, it can help EPA or the USCG assess local response capabilities relative to this response, ascertain the effectiveness of local actions, and determine whether Federal technical assistance or action is appropriate or necessary. Second, it allows EPA or the USCG to make sure the local responder understands EPA criteria and requirements, such as that response actions must be consistent with the NCP. Finally, it provides an opportunity to determine whether a response might be a candidate for reimbursement. This can prevent a locality from preparing an application for a response that is not eligible for reimbursement (e.g., an oil spill).

(2) *Response to comments and clarifications.* The majority of commenters supported the 24-hour contact requirement. One commenter on the interim final rule, however, suggested including notification of State and local agencies, as promoted under EPCRA (Title III of SARA), as a requirement for reimbursement. Title III emergency notification (section 304) requirements are not germane to this rule and exist independently of it, although they also may be triggered by the release. The LGR regulation concerns a federally administered program for providing reimbursement to local governments for extraordinary expenses incurred by providing emergency response to a hazardous substance threat. While this rule requires that local governments be a part of the Title III Local Emergency Planning Committee (LEPC) and respond to emergencies accordingly, no specific State or local agency notification if necessary for its proper administration. However, the appropriate Federal authority (EPA, USCG, or NRC) must be notified within the required 24-hours to insure that LGR requirements are being met and to determine if other Federal response is needed.

(3) *Final rule.* No change in § 310.30(b) of the interim final rule.

c. Consistency Requirement

(1) *Interim final rule.* Section 310.30(c) of this rule stipulates that response actions for which reimbursement is sought must not be inconsistent with CERCLA, the NCP, and, if applicable, the local emergency response plan required under section 303(a) of the EPCRA. Responses must comply with the provisions of CERCLA even to be eligible for this use of the Fund. In addition, section 104(a)(1) of CERCLA calls for "response measure(s) consistent with the National Contingency Plan * * *."

The NCP provides for efficient, coordinated and effective responses to actual or threatened releases of hazardous substances or pollutants or contaminants. Local government should consult the NCP for specific procedures to follow in conducting temporary emergency measures to satisfy this consistency requirement. The NCP also specifies the division of responsibility among the Federal, State and local governments during response actions and appropriate roles for private entities (NCP § 300.21 through § 300.25). Because the NCP stipulates the basic requirements for CERCLA-funded responses, a response for which reimbursement is requested must conform to the NCP. Likewise, because the Title III local emergency response plan outlines methods and procedures for responders that are specific to the community, EPA expects local agencies to comply with that plan.

(2) *Responses to comments and clarifications.* The Agency received no comments on this section of the interim final rule.

(3) *Final rule.* The final rule changed "are not inconsistent" to "are consistent" in § 310.30(c) of the interim final rule. This change was made to make the final rule language uniform and consistent.

d. Restriction on Supplanting Local Funds

(1) *Interim final rule.* Section 310.30(d) specifies that reimbursement monies may not supplant non-Federal funds normally provided for emergency response programs. As required by section 123(b)(2) of CERCLA, local governments may be reimbursed for the costs of temporary emergency measures only if reimbursement would supplement, not supplant, non-Federal (State and local) funds that would otherwise be made available. Compliance with this requirement entails certification and demonstration that reimbursement does not supplant local funds normally provided for response. (This certification is stipulated in § 310.50(c)(3) of this rule). In addition, EPA may request reimbursement applicants to submit line-item budgets for the fiscal year in which the incident for which reimbursement is requested occurred as well as response cost information. Since only limited funds are available for this program, EPA expects that the possibility of being reimbursed will not provide adequate incantive for local governments to intentionally decrease non-Federal funding for response programs.

(2) *Response to comments and clarifications.* The Agency received no comments on this section of the interim final rule.

(3) *Final rule.* No change in § 310.30(d) of the interim final rule.

e. Attempt to Recover Costs

(1) *Interim final rule.* Section 310.30(e) of this rule requires applicants to seek other funding sources before requesting reimbursement from the Fund. Local governments must make a good faith effort to recover costs from PRPs. This section also requires that local authorities pursue all other sources of funds, such as insurance or State reimbursement monies, before seeking reimbursement from the Superfund under section 123 of CERCLA.

(2) *Response to comments and clarifications.* The Agency received no comments on this section of the interim final rule.

(a) *Clarification of cost recovery requirements.* EPA recognizes that PRP searches can become extensive and costly; therefore, the Agency will be satisfied with evidence of a reasonable attempt at recovering costs. Such evidence might include documents such as copies of return-receipt letters requesting payment, with certification that payment has not been received, or copies of letters from PRPs stating refusal to pay or sworn statements from local officials that no PRP has been or can be identified, see Subpart C.1. on "Cost Recovery." These documents constitute sufficient evidence of good faith efforts to recover costs from PRPs. The evidence of attempt to recover costs must indicate that, where a PRP was identified, the PRP was given at least 60 days to satisfy the demand for cost recovery. This certification is discussed in VI.C.1. of this preamble and stipulated in § 310.50 of the rule.

In general, EPA expects documentation of cost recovery efforts described above to accompany all applications for reimbursement. The inclusion of such documentation will speed the reimbursement process by eliminating the need for repeated Agency contact with the applicant to verify that costs could not be recovered from other sources. Furthermore, including documentation of the attempt to identify a PRP ensures that the applicant is not responsible for the hazardous substance threat.

EPA has denied at least one request for reimbursement on the grounds that the local government was responsible for the release. The eligibility of other applications is in question until applicants can demonstrate that no department or agency of local government was responsible for the release. Local governments should note that a signed application certifies, in good faith, that applicants have met the requirement to pursue all other sources of cost recovery to the best of their ability. EPA will generally accept this certification at face value, provided that it is clear that the applicant is not the responsible party, but the Agency may request appropriate documentation of these efforts.

The cost recovery requirement is achieving its goal. Two local governments that submitted applications for reimbursement under the interim final rule have recovered costs from the liable parties as a result of cost recovery efforts undertaken in accordance with the reimbursement application requirements. These cost recovery successes have preserved funds available for this program and provide excellent examples of the way that CERCLA and the local government reimbursement program are intended to function.

(3) *Final rule.* No change in § 310.30(e) of the interim final rule.

f. Emergency Planning

(1) *Interim final rule.* Section 310.30(f) of this rule requires that after October 17, 1988, the applicant's jurisdiction be included in the comprehensive emergency response plan completed by the LEPC, as stipulated by section 303(a) in Title III of SARA. Because establishment of an LEPC is the responsibility of the State government, EPA will waive this requirement for localities where the State emergency response commission has not yet established a committee responsible for the geographic area in which the applicant is located.

(2) *Response to comments and clarifications.* The Agency received no comments on this section of the interim final rule.

(a) *Clarification of LEPC participation.* Under Title III of SARA, local governments are required to participate in State-established emergency response committees. To be eligible for reimbursement, a local government must be included in the comprehensive emergency response plan and participate in the LEPC responsible for the geographic area in which the local government is located, if the State has established a LEPC. To date, EPA has denied one reimbursement request for failure of the local government to participate in the State-established emergency response committee. If an applicant was denied reimbursement due to nonparticipation, the applicant may reapply after satisfying this requirement.

(3) *Final rule.* No change in § 310.30(f) of the interim final rule.

3. Section 310.40 Allowable and Unallowable Costs

a. Interim Final Rule

To be allowable for reimbursement, all costs for temporary emergency measures for which reimbursement is being sought must be consistent with Section 111 of CERCLA ("Uses of Fund") and with the Federal cost principles outlined in the Office of Management and Budget (OMB) Circular A–87, "Cost Principles for State and Local Governments." These standard requirements apply to all Superfund programs involving State and/or local governments where monies from the Trust Fund are spent. In making its cost determinations, EPA also considered the types of temporary emergency measures typically undertaken during a response, with special consideration given to the limited funds available for the reimbursement program relative to the number of potential applicants.

b. Response to Comments and Clarifications

One commenter raised a question regarding whether general revenues used for temporary emergency responses to hazardous substance releases, in the absence of funds budgeted specifically for such situations, are allowable for reimbursement.

This regulation stipulates that reimbursement will not supplant funds normally provided for response. Because many localities do not budget funds specifically for emergency responses to hazardous substance threats, general revenues expended for temporary emergency response measures are eligible for reimbursement. These expenditures must meet allowable cost requirements, and the application should state that the local government has no hazardous substance emergencies budget. In addition, costs associated with the prevention of a hazardous substance release in a non-emergency situation (i.e., when immediate response is not required to prevent or mitigate injury to human health or the environment) are not eligible for reimbursement. These costs would supplant funds normally provided for prevention and maintenance in such activities as fixing roads or storage facilities.

Several commenters also requested more specific guidelines as to when a cost is allowable. For example, one commenter suggested that costs to containerize, transport, and dispose of hazardous wastes be included as allowable costs. The Agency provided

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general examples and guidelines for determining the eligibility of costs to maintain flexibility in considering the circumstances of each response, see § 310.40 of the rule. The allowable cost list provided in the rule is not inclusive and does not disallow such costs. Since packaging and disposing of hazardous wastes is not one of the "traditionally local services and responsibilities" for which local governments are expected to budget funds, this cost would most likely be eligible for reimbursement despite the fact that it was not specifically stated to be an allowable cost.

In addition one commenter suggested allowing medical costs "where adequate coverage does not exist." The Agency maintains that reimbursing medical expenses would supplant funds normally provided by employee health insurance and Workmen's Compensation benefits.

(1) *Clarification of equipment replacement.* In developing the interim final rule, the Agency addressed the issue of replacement of equipment, because the potential for abuse is significant and because reimbursement monies are limited. EPA determined that there are potential response situations where such costs should be considered for reimbursement. For example, the loss of breathing apparatus and hoses due to irreversible contamination and contamination of other essential response equipment represents a considerable loss to local governments. EPA will allow replacement costs for equipment contaminated beyond reuse or repair, if the applicant can demonstrate that the equipment was a total loss and that the loss occurred during the response for which reimbursement is being sought. It should be noted that since the maximum reimbursement amount is limited to $25,000, it is likely that large-scale equipment replacement will not be reimbursed in full. Purchase and routine maintenance of equipment for response, however, are not allowable costs. EPA views these as costs for which local funds are normally provided.

(2) *Clarification of evacuation costs.* Costs associated with the services, supplies and equipment procured for a specific evacuation are included as allowable costs. EPA considers evacuation to be a temporary emergency measure and evacuation costs incurred that exceed services and costs normally provided by the local government may be eligible for reimbursement.

(3) *Clarification of unallowable cost.* Certain costs are unallowable for purposes of the reimbursement program. Disposable materials and supplies already owned by a local government, but consumed during response, constitute items normally provided for response by the local governments and, therefore, are not allowable costs. Employee fringe benefits, administrative costs for filing reimbursement applications, employee out-of-pocket expenses normally provided for in the applicant's operating budget, and legal expenses that may be incurred as a result of response activities are additional unallowable costs. EPA has determined that fringe benefits, certain employee out-of-pocket expenses, and legal expenses are costs normally provided for in a local government's operating budget. EPA considers administrative costs associated with filing a request for reimbursement not allowable, since it is the responsibility of the local government to determine whether or not to pursue reimbursement under this program.

(4) *Clarification of medical expense.* EPA has not included medical expenses as an allowable cost because reimbursement for such costs normally should be covered by insurance or Workmen's Compensation. Determination of what constitutes adequate medical coverage is outside the scope of EPA and of this program. Therefore, in keeping with the Congressional intent for this regulation, medical costs are considered unallowable because reimbursement for such costs normally should be covered by insurance or Worker's Compensation.

c. Final Rule

Section 310.40(a)(10) has been amended to include "containerization or packaging cost including transportation and disposal of hazardous wastes."

C. Subpart C—Procedures for Filing and Processing Reimbursement Requests

Subpart C establishes the procedures for preparing and processing reimbursement applications. The purpose of defining these procedures is to give applicants a clear understanding of what information EPA needs in considering an application, to provide a consistent basis on which to evaluate reimbursement requests, and to improve processing efficiency by making all forms and procedures standard.

1. Section 310.50 Filing Procedures

a. Interim Final Rule

(1) *Number of requests.* Section 310.50(a) of this rule limits local governments to filing only one request for reimbursement for a given response to a release even though multiple agencies (and possibly jurisdictions) may have participated. This requirement is needed to ensure that the statutory maximum of $25,000 per single response is not exceeded and that payments are not duplicated. EPA expects that local officials will work together to determine total response costs, the relative share borne by each local agency and jurisdiction, and the appropriate official who will assume responsibility for preparing the application.

(2) *Standard form.* Under § 310.50(b) of this rule, applicants must use the standard application form illustrated in Appendix II of the rule for filing their requests for reimbursement. EPA has decided to use a standard form because it reduces confusion about what information is to be supplied, helps ensure that all applicants are evaluated on the basis of comparable information and enables reviewers to check applications for completeness and consistency quickly. The form requests five basic pieces of information: (1) identification of the local government requesting reimbursement; (2) information about the incident; (3) information about the response, including the specific temporary emergency measures for which reimbursement is being sought; (4) cost data; and (5) certifications and signature of the authorized representative who is the highest ranking official of the local government. Detailed instructions for completing the form and examples are included in the application package provided by EPA to potential requesters.

(3) *Temporary emergency measures.* Section 310.50(b)(1) requires that the applicant demonstrate that costs were incurred for temporary emergency measures necessary to protect human health and the environment. The Agency has not attempted to explicitly define "temporary emergency measures," owing to the unpredictability and variability of hazardous substance releases, but actions that may qualify include security, source control, release containment, control of contaminated runoff and similar steps to protect human health and the environment from imminent threats.

Costs must be identified with specific actions, as indicated in Table 1 of the application form. The applicant should briefly state the specific temporary emergency measure for which reimbursement is being sought and indicate which local agency (e.g., fire department, sheriff's office) incurred the cost for performing this measure. Each cost element for performing this measure should be specified in detail

(e.g., overtime, decontamination services, equipment rental) and matched to the specific amount expended. Estimated amounts will not be considered for reimbursement.

(4) *Cost recovery.* Section 310.50(b)(2) requires the applicant to demonstrate that a reasonable effort has been made to obtain reimbursement from sources other than the Superfund. This filing requirement is intended to document the effort to recover costs (see § 310.30(e) of this rule). Acceptable demonstrations that cost recovery has been attempted include copies of letters from PRPs stating their inability or refusal to pay, or copies of dated letters (with return-receipt requested) from the local government to the PRP requesting payment, with a statement certifying that the PRP has failed to respond to such letters within at least 60 days. A summary of the cost recovery information must be included in Table 2 of the application. Sworn statements attesting to the fact that no PRP could be found and that insurance monies or State funds are not available to cover the costs for those temporary emergency measures also will suffice.

(5) *Certification.* Section 310.50(c) requires the applicant to certify that: (1) costs were incurred specifically for this response and are accurate; (2) the contact requirement in § 310.30(b) was met; (3) this reimbursement does not supplant local funds normally required for response; (4) PRP cannot be identified or is unwilling or unable to pay; and (5) it is understood that if the local government later recovers costs from responsible parties, States or insurance after those costs have been reimbursed from the Superfund, the local government is required to return the reimbursement monies to the Fund in the amount of the recovery up to the amount of the reimbursement. All five certification requirements are necessary to ensure that the Superfund is used appropriately and that the provisions of section 123(b)(2) of CERCLA are met.

(6) *Filing deadline.* Section 310.50(d) stipulates that the local government's request for reimbursement must be received by EPA within one year of the date of completion. For purposes of this rule, "date of completion" is defined as the date when all field work has been completed and all project deliverables have been received by the local government for the specific response.

(7) *Signature authority.* Section 310.50(e) stipulates that the application be signed by the authorized representative who is the highest ranking local government official (e.g., chief executive officer, mayor, town supervisor, chairperson of county board, city manager, etc.) or his or her delegate. A letter of delegation must accompany the application if authority has been delegated. The highest ranking official (or delegate) of the local government, by signing the application, is certifying that information contained in the request for reimbursement is complete and accurate to the best of his or her knowledge.

b. Response to Comments and Clarifications

The Agency received no comments on this section of the interim final rule.

(1) *Change in filing deadline.* The application deadline has been extended from 6 months to one year from the date of response completion to encourage applicants to complete cost recovery efforts and assemble all the required supporting documentation prior to submitting a request for reimbursement. Most applications received to date have seriously inadequate cost recovery documentation. The extension in the deadline should ensure that applications are complete when initially submitted.

(2) *Change to signature requirement.* It is particularly important that applicants for reimbursement pay close attention to the signature requirements when preparing applications for reimbursement. The interim final rule required applications to be signed by the chief executive officer. In the final rule, EPA has changed "chief executive officer" to "highest ranking local government official" to ensure that the appropriate governmental entity is certifying the application. More than half of the applications received by EPA since the promulgation of the interim final rule have been returned because the signature was not appropriate (e.g., fire chief, hazardous materials specialist). Although these applications were not considered ineligible, and applicants were given the opportunity to comply with filing procedures, application processing time has been substantially lengthened due to this application inadequacy. The certification requirement (i.e., signature of the highest ranking local government official) protects the local government from unauthorized or improper attempts to obtain reimbursement that might later preclude a legitimate request. It also provides EPA with assurance that the request is legitimate, and thus an appropriate use of the Superfund, and can be considered for reimbursement.

(3) *Clarificaton of application package.* Potential applicants are advised to obtain the entire application package rather than using photocopied forms without accompanying instructions. Applicants also may find it helpful to review this regulation in preparation for completing the application form to ensure that all requirements and filing procedures are met. Proper completion of the form expedites application processing and reimbursement.

(4) *Clarification of temporary emergency measures.* The application form includes a section for explaining exactly what temporary emergency measures were taken and why they were necessary. For example, an acceptable demonstration might be: "Erected berms to prevent migration of pesticides leaking from ruptured drums into East River, the drinking water source for the City of Middletown." By contrast, an assertion along the lines of "source control needed to protect human health" would not constitute an acceptable demonstration.

c. Final Rule

Section 310.50(d) has been amended to extend the filing deadline from 6 months to one year from the date of response completion and § 310.50(e) has been amended to change "chief executive officer" to "highest ranking official of the local government" as the signature requirement.

2. Section 310.60 Verification and Reimbursement

a. Interim Final Rule

Section 310.60 specifies the verification and reimbursement procedures EPA follows in evaluating and processing requests for reimbursement. The verification procedures are intended to ensure that all requests are complete and adequately documented. Thus, § 310.60(a) allows EPA to return an incomplete request to the applicant with written notice of the deficiencies and § 310.60(b) gives the applicant 60 days in which to respond. Under § 310.60(c), EPA notifies the applicant when the Agency has determined that the request meets all requirements for reimbursement and complies with all filing procedures. At that point, the request is considered complete and can be evaluated for reimbursement. Under § 310.60(d), if documentation is not adequate to demonstrate the reasonableness of the costs claimed, EPA can make adjustments accordingly, including asking for additional information.

Reimbursement procedures are specified in § 310.60 (e), (f) and (g). Upon reviewing a completed request, EPA will compute the financial burden borne by the community in conducting the response and rank the request relative to the financial burden

associated with other requests. Financial burden will be computed as B = C/(Y × P), where B = financial burden on applicant, C = total eligible response costs minus reimbursement from responsible parties, States or other sources, Y = per capita annual income for the locality, and P = population of the locality. Depending upon the ranking of the request and the funds available for reimbursement, EPA will either reimburse the request, deny it, or hold it for reconsideration. Section 310.60(f) limits EPA to reimbursing local governments only for (1) costs that are allowable, reasonable and necessary, and (2) the extent that the temporary emergency measures conform to the hazardous substance response criteria set forth in CERCLA, the NCP and the local emergency response plan. EPA will notify the applicant, in writing, of the Agency's decision.

b. Response to Comments and Clarifications

Commenters on the interim final rule suggested that applications be directed to the State Emergency Response Commission (SERC) under SARA Title III for preliminary evaluation before submission to EPA to ensure that responses have met the requirement for consistency with the local emergency response plan. Further, some States have expressed an interest in receiving copies of reimbursement requests in order to identify local areas in need of financial assistance.

In the interest of streamlining and expediting the application review process, EPA will continue the present system of Agency review of applications. Local officials and most State officials who offered comments to EPA in developing the interim final rule believed that there should be no administrative role for States in the reimbursement process. Some local officials, however, indicated that States might assist EPA in evaluating reimbursement requests since they may be familiar with the hazardous substance incident and local government response. EPA routinely notifies the appropriate SERCs of applications for local government reimbursement to request information regarding the applicant's participation in and consistency with a local emergency response plan.

As a result of SERC response, the agency has denied one request for reimbursement due to noncompliance with this program requirement. EPA believes that, in keeping with the expressed intent of this regulation, the primary burden of proof of response eligibility and the degree of financial burden resulting from the response rests with the local government. The reimbursement application was designed so that sufficient information for a fair evaluation by the Agency is available in a properly completed application. For these reasons, the State maintains no formal or routine role in the administration of this reimbursement program. However, EPA does not intend for this rule to preclude or interfere with existing State and local response procedures.

The Agency received several comments which suggested that aggregate income (i.e., per capita income multiplied by population) is not a reliable indicator of the size of a local government's budget. The population factor is included in the denominator of that formula to ensure that, when a large locale and a small locale with similar per capita incomes are being considered for reimbursement concurrently, priority will be given to the applicant with a smaller budget proportionate to the eligible costs of the response.

The Agency believes that the Congressional intent of the rule is to favor small local governments. However, relevant financial data and other factors are considered when making reimbursement decisions. In combination with additional financial data provided by applicants, EPA will use the present ranking to distribute reimbursements first to local governments with the most limited resources. It should be noted that the Agency's expectation that some applications may not be reimbursed due to the limited availability of funds has not been realized. In two years of implementing the local government reimbursement program, no applicant has been denied reimbursement because of the lack of available funds. This is due, in part, to the fact that many applications have documented allowable costs totalling considerably less than the $25,000 per response limit.

Comments on the interim final rule also suggested considering reimbursing on the basis of a local government's total annual response expenditures. The Agency considered this approach carefully during development of the interim final rule and maintains its position. Experience with screening reimbursement requests has shown that many applicants have difficulty documenting the costs associated with a single response that occurred recently. Information on annual expenditures would have to be for the previous year so that applicants could meet the filing deadline for the specific response for which reimbursement is requested. The Agency believes that requiring local governments to compile and document expenditures for hazardous substance responses occurring over the entire previous year would be inordinately burdensome and would discourage them from submitting applications. Furthermore, not all responses occurring in a year are eligible for reimbursement under this program. It would not be consistent with the intent of this regulation to consider the costs of ineligible responses. Information on the frequency and magnitude of previous responses is the kind of additional supporting data that EPA currently considers in determining reimbursement priority.

c. Final Rule

Section 310.60(e) has been amended to clarify that larger burden formula fractions represent a greater burden than smaller fractions.

3. Section 310.70 Records Retention

a. Interim Final Rule

This section stipulates that an applicant receiving a reimbursement must maintain cost documentation and other relevant records, and must provide EPA access to these materials for ten years from the date of reimbursement. This requirement ensures the availability of pertinent information if EPA pursues cost recovery for this response. Once the ten years has expired, the applicant must notify EPA of any intention to destroy these records. If EPA chooses not to take possession of them, the local authority may dispose of the materials. The requirements of this section do not apply to requests that have been denied and are not being disputed under § 310.90.

b. Response to Comments and Clarifications

The Agency received no comments on this section of the interim final rule.

c. Final Rule

No change in § 310.70 of the interim final rule.

4. Section 310.80 Payment of Approved Reimbursement Requests

a. Interim Final Rule

This section stipulates that reimbursement payments can be made only when an appropriation in the Superfund is available and that payments will be in the order in which approved requests are ranked, according to financial burden on the applicant. This provision is consistent with Section 111(e)(1) of CERCLA, which restricts payment of claims against the

Superfund "in excess of the total money in the Fund."

b. Response to Comments and Clarifications

The Agency received no comments on this section of the interim final rule.

c. Final Rule

No change in § 310.80 of the interim final rule.

5. Section 310.90 Disputes Resolution

a. Interim Final Rule

This section specifies EPA's procedures for reviews of a denial of reimbursement and reviews of the amount of reimbursement, either of which the requester may choose to dispute. The applicant has 60 days from the date of the reimbursement decision to request a review, otherwise that decision constitutes a final Agency action. The request for review includes a discussion of the issue involved and a statement of the applicant's objection. After filing for review, the applicant is entitled to an informal conference with the EPA disputes decision official. The requester may be represented by counsel and submit evidence for inclusion in a written record. The Agency will provide the requester with a written decision specifying the outcome of the review. This decision constitutes final EPA action on the matter.

b. Response to Comments and Clarifications

One commenter noted that the dispute resolution process may be inadequate because it considers disputed requests after all other requests have been received. Dispute decisions, therefore, might be made on the basis of availability of funds rather than merit.

As soon as the Agency receives a request for review, funds in the amount of the total reimbursement requested may be set aside until a final determination is made. The Agency intends to process disputes expeditiously and thus does not anticipate that a set aside of funds will ordinarily be necessary.

c. Final Rule

No change in § 310.90 of interim final rule.

VII. Regulatory Analyses

A. Executive Order No. 12291

Under Executive Order No. 12291, the Agency must judge whether a regulation is "major" and thus subject to the requirement of a Regulatory Impact Analysis. The notice published today is not major because the rule will not result in an effect on the economy of $100 million or more, will not result in increased costs or prices, will not have significant adverse effects on competition, employment, investment, productivity and innovation and will not significantly disrupt domestic or export markets. Therefore, the Agency has not prepared a Regulatory Impact Analysis under the Executive Order. This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order No. 12291.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 requires that a Regulatory Flexibility Analysis be performed for all rules that are likely to have "significant economic impact on a substantial number of small entities." This regulation involves reimbursement of the costs of local governments for responding to a hazardous substance release. This is a benefit authorized by CERCLA, and does not adversely affect the private sector economy or small entities, which may include local governments, and in fact provides a benefit to local governments in the form of reimbursement to offset financial hardship incurred from responses to hazardous substances and pollutants or contaminants. EPA, therefore, certifies that this regulation will not have a significant impact on a substantial number of small entities.

C. Paperwork Reduction Act

The information collection requirements contained in this rule have been approved by the Office of Management and Budget (OMB) under the provisions of the *Paperwork Reduction Act*, 44 U.S.C. 3501 *et seq.* and have been assigned OMB control number 2050–0077.

Public reporting burden for this collection of information is estimated to average 18.25 hours per response, including time for reviewing instructions, searching existing data soruces, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM–223y, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 310

Administrative practice and procedure, Hazardous substances, Incorporation by reference, Intergovernmental relations, Local governments, Reporting and recordkeeping requirements, Superfund.

Dated: October 14, 1992.

William K. Reilly,

Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is amended by revising Part 310 to read as follows:

PART 310—REIMBURSEMENT TO LOCAL GOVERNMENTS FOR EMERGENCY RESPONSE TO HAZARDOUS SUBSTANCE RELEASES

Subpart A—General

Sec.
310.05 Purpose, scope and applicability.
310.10 Abbreviations.
310.11 Definitions.
310.12 Penalties.

Subpart B—Reimbursement

310.20 Eligibility for reimbursement.
310.30 Requirements for requesting reimbursement.
310.40 Allowable and unallowable costs.

Subpart C—Procedures for Filing and Processing Reimbursement Requests

310.50 Filing procedures.
310.60 Verification and reimbursement.
310.70 Records retention.
310.80 Payment of approved reimbursement requests.
310.90 Disputes resolution.

Appendix I to Part 310—EPA Regions and NRC Telephone Lines

Appendix II to Part 310—Application for Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases Under CERCLA Section 123

Authority: 42 U.S.C. 9611(c)(11), 9623.

Subpart A—General

§ 310.05 Purpose, scope, and applicability.

(a) *Purpose.* Through this part, the Environmental Protection Agency (EPA) is establishing the procedures for reimbursing local governments for temporary emergency measures to prevent or mitigate injury to human health or the environment, as authorized under section 123 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA). This program is intended to alleviate significant financial burden on local governments for response to releases or

threatened releases of hazardous substances or pollutants or contaminants and will not supplant local funds normally provided for response. Reimbursement does not apply to expenditures incurred in the course of providing what are traditionally local services and responsibilities, such as routine firefighting.

(b) *Scope.* Applications for reimbursement for temporary emergency measures may be submitted only through the procedures established in this part. Any general purpose unit of local government for a political subdivision may request reimbursement. States are not eligible for this program. Under this part, local governments may apply for reimbursement for temporary emergency measures performed subsequent to October 21, 1987. Reimbursement may be made for temporary emergency measures conducted during either Federal-lead or non-Federal-lead responses.

(c) *Applicability.* Reimbursement to local governments for temporary emergency measures may not exceed $25,000 per single response, nor may reimbursement supplant local funds normally provided for response. Because CERCLA specifies that no more than 0.1% of the amount appropriated from the Hazardous Substance Superfund (Superfund or the Fund) may be allocated to the reimbursement program for the five fiscal years beginning October 1, 1986, some requests may not ever be reimbursed even though they meet all requirements of this part.

§ 310.10 Abbreviations.

CERCLA—The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Pub. L. 96–510, 42 U.S.C. 9601–75), as amended by the Superfund Amendments and Reauthorization Act of 1986, also known as Superfund.

EPA or the Agency—Environmental Protection Agency

NCP—National Oil and Hazardous Substances Pollution Contingency Plan also known as the National Contingency Plan.

OMB—Office of Management and Budget.

SARA—The Superfund Amendments and Reauthorization Act of 1986 (Pub. L. 99–499, 42 U.S.C. 9601).

USCG—U.S. Coast Guard.

§ 310.11 Definitions.

For purposes of this part except when otherwise specified:

(a) *Date of completion* means the date when all field work has been completed and all deliverables (e.g., lab results, technical expert reports) have been received by the local government;

(b) *Emergency Planning and Community Right-To-Know Act of 1986* means Title III—Emergency Planning and Community Right-To-Know Act of the Superfund Amendments and Reauthorization Act of 1986 (EPCRA) (Pub. L. 99–499, 42 U.S.C. 960);

(c) *General purpose unit of local government* means the governing body of a county, parish, municipality, city, town, township, Federally-recognized Indian tribe or similar governing body;

(d) *Hazardous substance,* as defined by section 101(14) of CERCLA, means:

(1) Any substance designated pursuant to section 311(b)(2)(A) of the Federal Water Pollution Control Act;

(2) Any element, compound, mixture, solution, or substance designated pursuant to section 102 of CERCLA;

(3) Any hazardous waste having the characteristics identified under or listed pursuant to section 3001 of the Solid Waste Disposal Act (but not including any waste the regulation of which under the Solid Waste Disposal Act has been suspended by Act of Congress);

(4) Any toxic pollutant listed under section 307(a) of the Federal Water Pollution Control Act;

(5) Any hazardous air pollutant listed under section 112 of the Clean Air Act; and

(6) Any imminently hazardous chemical substance or mixture with respect to which the Administrator has taken action pursuant to section 7 of the Toxic Substances Control Act.

The term does not include petroleum, including crude oil or any fraction thereof that is not otherwise specifically listed or designated as a hazardous substance under paragraphs (d)(1) through (d)(6) of this section, and the term does not include natural gas, natural gas liquids, liquefied natural gas, or synthetic gas usable for fuel (or mixtures of natural gas and such synthetic gas);

(e) *Local emergency response plan* means the emergency plan prepared by the Local Emergency Planning Committee (LEPC) as required by section 303 of the Emergency Planning and Community Right-To-Know Act of 1986 (SARA Title III) (EPCRA);

(f) *National Contingency Plan* means the National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR part 300);

(g) *National Response Center* means the national communications center located in Washington, DC, that receives and relays notice of oil discharge or releases of hazardous substances to appropriate Federal officials;

(h) *Pollutant or contaminant,* as defined by section 104(a)(2) of CERCLA, includes, but is not limited to, any element, substance, compound, or mixture, including disease-causing agents, which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations, in such organisms or their offspring. The term does not include petroleum, including crude oil and any fraction thereof that is not otherwise specifically listed or designated as a hazardous substance under section 101(14) (A) through (F) of CERCLA, nor does it include natural gas, liquefied natural gas, or synthetic gas of pipeline quality (or mixtures of natural gas and such synthetic gas);

(i) *Release,* as defined by section 101(22) of CERCLA, means any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injection, escaping, leaching, dumping, or disposing into the environment, but excludes: any release that results in exposure to persons solely within a workplace, with respect to a claim that such persons may assert against the employer of such persons; emissions from the engine exhaust of a motor vehicle, rolling stock, aircraft, vessel, or pipeline pumping station engine; release of source, by-product or special nuclear material from a nuclear incident, as those terms are defined in the Atomic Energy Act of 1954, if such release is subject to requirements with respect to financial protection established by the Nuclear Regulatory Commission under section 170 of such act, or, for the purpose of section 104 of CERCLA or any other response action, any release of source, by-product, or special nuclear material from any processing site designated under section 122(a)(1) or 302(a) of the Uranium Mill Tailings Radiation Control Act of 1978; and the normal application of fertilizer. For the purposes of this part, release also means threat of release;

(j) *Single response* means all of the concerted activities conducted in response to a single episode, incident or threat causing or contributing to a release or threatened release of hazardous substances of pollutants or contaminants.

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§ 310.12 Penalties.

Any person who knowingly gives or causes to be given any false statement or claim as part of any application for reimbursement under section 123 of CERCLA, upon conviction, may be fined or imprisoned subject to the False Statement Act (Pub. L. 97–398, 18 U.S.C. 1001) and the False Claims Act (Pub. L. 99–562, 31 U.S.C. 3729).

Subpart B—Reimbursement

§ 310.20 Eligibility for reimbursement.

(a) Any general purpose unit of local government may request reimbursement for temporary emergency measures if all requirements under § 310.30 are met.

(b) States are not eligible for reimbursement for temporary emergency measures and no State may request reimbursement on its own behalf or on the behalf of political subdivisions within the State.

§ 310.30 Requirements for requesting reimbursement.

(a) Response must have been initiated on or after October 21, 1987, the effective date of the interim final rule which governed the reimbursement process prior to the effective date of this part.

(b) The local government must inform EPA or the National Response Center (NRC) of the response as soon as possible, but not later than 24 hours after the start of a response, unless EPA or the USCG has been contacted via the NRC or other established response communication channel. EPA Regional offices and NRC telephone numbers are listed in Appendix I of this part.

(c) Requests for reimbursement must demonstrate that response actions are consistent with CERCLA, the NCP and, where applicable, the local comprehensive emergency response plan completed under the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA).

(d) Requests for reimbursement must provide assurance that reimbursement for costs incurred for temporary emergency measures does not supplant local funds normally provided for response.

(e) Applicants for reimbursement must first present requests for payment of incurred costs to all known potentially responsible parties (PRPs) and permit at least 60 days for payment or for expression of intent to pay or willingness to negotiate prior to submitting a reimbursement request to the Agency. Local governments also must pursue all other sources of reimbursemen: (e.g., insurance, reimbursement from the State) before seeking reimbursement from EPA under this part.

(f) After October 17, 1988, the applicant's jurisdiction must be included in the comprehensive emergency response plan completed by the Local Emergency Planning Committee (LEPC) as required by section 303(a) of EPCRA. This requirement does not apply if the State Emergency Response Commission (SERC) has not established an LEPC responsible for the emergency planning district(s) encompassing the applicant's geographic boundaries.

(Approved by the Office of Management and Budget under control number 2050–0077)

§ 310.40 Allowable and unallowable costs.

To be allowable, costs for which reimbursement is sought must be consistent with CERCLA and with Federal cost principles outlined in the OMB Circular A–87, "Cost Principles for State and Local Governments." The local government may also seek assistance from the EPA Regional Office in determining which costs may be allowable. Final determination of the reasonableness of the costs for which reimbursement is sought will be made by EPA.

(a) *Allowable cost.* In general, allowable costs are those project costs are eligible, reasonable, necessary and allocable to the project. Costs allowable for reimbursement may include, but are not limited to:

(1) "Disposable materials and supplies" acquired, consumed, and expended specifically for the purpose of the response for which reimbursement is being requested (hereafter referred to as "the response");

(2) Compensation for unbudgeted wages of employees for the time and efforts devoted specifically to the response that are not otherwise provided for in the applicant's operating budget (e.g., overtime pay for permanent full-time and other than full-time employees);

(3) Rental or leasing of equipment used specifically for the response (e.g., protective equipment or clothing, scientific and technical equipment) (Note: reimbursement for these costs will not exceed the duration of the response);

(4) Replacement costs for equipment owned by the applicant that is contaminated beyond reuse or repair, if the applicant can demonstrate that the equipment was a total loss and that the loss occurred during the response (e.g., self-contained breathing apparatus irretrievably contaminated during the response);

(5) Decontamination of equipment contaminated during the response;

(6) Special technical services specifically required for the response (e.g., costs associated with the time and efforts of technical experts/specialists not otherwise provided for by the local government);

(7) Other special services specifically required for the response (e.g., utilities);

(8) Laboratory costs for purposes of analyzing samples taken during the response;

(9) Evacuation costs associated with the services, supplies, and equipment procured for a specific evacuation; and

(10) Containerization or packaging cost including transportation and disposal of hazardous wastes.

(b) *Unallowable costs.* Unallowable costs for reimbursement include, but are not limited to:

(1) Purchase or routine maintenance of equipment of a durable nature that is expected to have a period of service of one year or more after being put into use without material impairment of its physical condition, except as provided in paragraphs (a)(4) and (a)(5) of this section;

(2) Materials and supplies not purchased specifically for the response;

(3) Employee fringe benefits;

(4) Administrative costs for filing reimbursement applications;

(5) Employee out-of-pocket expenses normally provided for in the applicant's operating budget (e.g., meals, fuel);

(6) Legal expenses that may be incurred as a result of response activities, including efforts to recover costs for potentially responsible parties; and

(7) Medical expenses incurred as a result of response activities.

(c) *Detailed cost documentation.* Detailed cost documentation must be provided by the local government and ensure that costs incurred are substantiated and that cost documentation is adequate for an Agency audit. Documentation of response costs must include at a minimum.

(1) Specification of the temporary emergency measures for which reimbursement is requested;

(2) Specification of the local agency incurring the cost;

(3) Detailed breakdown of actual costs, by cost element such as overtime, equipment rental;

(4) Supporting documents such as invoices, sales receipts, rental or leasing agreements; and

(5) Generally accepted accounting practices consistently applied.

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Subpart C—Procedures for Filing and Processing Reimbursement Requests

§ 310.30 Filing procedures.

(a) Only one request for reimbursement will be accepted for each hazardous substance emergency requiring immediate response at the local level. When more than one local agency or government has participated in such a response, those agencies and governments must determine which single entity will submit the request on behalf of them all.

(b) A request for reimbursement must be submitted on EPA form 9310–1, illustrated in Appendix II of this part, and must demonstrate that:

(1) Costs for which reimbursement is sought were incurred for temporary emergency measures taken by the local government to protect human health and the environment from releases or threatened releases of hazardous substances, pollutants or contaminants; temporary emergency measures may include security, source control, release containment, neutralization or other treatment methods, contaminated runoff control and similar activities mitigating immediate threats to human health and the environment;

(2) Reasonable effort has been made to recover costs from the responsible party and from any other available source and that such effort has been unsuccessful; and

(3) Response actions were not inconsistent with CERCLA, the NCP and, if applicable, the local emergency response plan required under Title III of SARA.

(c) Applicants must certify that:

(1) All costs are accurate and were incurred specifically for the response for which reimbursement is being requested:

(2) The local government complied with the requirement to inform EPA or the USCG of the response, as specified in § 310.30(b);

(3) Reimbursement for costs incurred for response activities does not supplant local funds normally provided for response;

(4) The Potentially Responsible Party (PRP) cannot be identified or is unwilling or unable to pay; and

(5) If costs subsequently are recovered from responsible parties or other sources after the local government has received reimbursement from the Superfund, the local government agrees to return to EPA the reimbursement monies for which costs have been recovered.

(d) Reimbursement requests must be received by EPA within one year of the date of completion of the response for which reimbursement is being requested. Late applications must include an explanation of the delay and will be considered on a case-by-case basis.

(e) A request for reimbursement must be signed by the authorized representative who is the highest ranking official of the local government or his or her delegate.

(f) Completed application and supporting data should be mailed to the LGR Project Officer, Emergency Response Division (5202–G), Environmental Protection Agency, 401 M Street SW., Washington, DC 20460.

(Approved by the Office of Management and Budget under control number 2050–0077)

§ 310.60 Verification and reimbursement.

(a) Upon receipt of a reimbursement request, EPA will verify that it complies with all requirements. Where the request is incomplete or has significant defects, EPA will return the request to the applicant with written notification of its deficiencies.

(b) A request returned to the applicant for correction of deficiencies must be resubmitted to EPA within 60 days.

(c) For purposes of this part, a reimbursement request is deemed complete when EPA determines that the request complies fully with all requirements for reimbursement and with all filing procedures. When the request is complete, a notice will be provided to the applicant of EPA's receipt and acceptance for evaluation.

(d) If EPA determines that it cannot complete its evaluation of a request because the records, documents and other evidence were not maintained in accordance with generally accepted accounting principles and practices consistently applied, or were for any reason inadequate to demonstrate the reasonableness of the costs claimed, EPA may reject the request or make adjustments, if possible. Further consideration of such amounts will depend on the adequacy of subsequent documentation. Any additional information requested by EPA must be submitted within 60 days unless specifically extended by EPA. The failure of the applicant to provide in a timely manner the requested information without reasonable cause may be cause for denial of the reimbursement request.

(e) When the reimbursement request is completed, EPA will rank the request on the basis of financial burden. Financial burden will be based on the ratio of eligible response costs to the applicant locality's annual per capita income adjusted for population, with larger fractions representing greater burden than smaller fractions. Per capita income and population statistics used to calculate financial burden shall be those published by the U.S. Department of Commerce, Bureau of the Census, in Current Population Reports, Local Population Estimates, Series P–26, "1988 Population and 1987 Per Capita Income Estimates for Counties and Incorporated Places," Vols. 88–S–SC, 88–ENC–SC, 88–NE–SC, 88–W–SC, 88–WNC–SC, March 1990. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR Part 51. Copies are available from the Bureau of the Census, Office of Public Affairs, Department of Commerce, Constitution Avenue, NE, Washington, DC 20230 (1–202–763–4040). Copies may be inspected at the . U.S. Environmental Protection Agency 401 M Street, SW, Washington, DC, or at the Office of the Federal Register, 800 N. Capitol Street NW., 7th Floor, suite 700, Washington, DC. In ranking requests on the basis of financial burden, EPA also will give consideration to other relevant financial information supplied by the applicant. Once the request is ranked, EPA will:

(1) Reimburse the request or;

(2) Decline to reimburse the request; or

(3) Hold the request for reconsideration if funding for the current review period has been exceeded.

(f) Reimbursement will be made:

(1) Only for costs that are allowable, reasonable and necessary; and

(2) Only to the extent that the temporary emergency measures conformed to response criteria established by CERCLA, the NCP and the local emergency response plan, if applicable.

(g) The EPA reimbursement official will provide the requester with a written final decision. Payment of approved requests will be made according to § 310.80.

(h) Requests that are not reimbursed after initial consideration remain open for reconsideration, at the EPA reimbursement official's discretion, for one year. EPA will notify the requester in writing if the request is held for later review. After that time, an unreimbursed request will no longer be considered and EPA will notify the requester in writing that the request has been denied.

§ 310.70 Records retention.

An applicant receiving a reimbursement from the Superfund is required to maintain all cost documentation and any other records

relating to the reimbursement request and to provide EPA with access to such records. If, after ten years from the date of the reimbursement from the Superfund, EPA has not initiated a cost recovery action, the applicant need retain the records no longer. The applicant must provide EPA with a 60 day notice on its intent to destroy the records. This notification will allow EPA the opportunity to take possession of these records before they are destroyed.

§ 310.80 Payment of approved reimbursement requests.

A reimbursement from the Superfund can be paid only when Superfund monies are available. An approved request in excess of Superfund appropriations available to EPA may be paid only when additional money is appropriated. As appropriations in the Superfund become available, reimbursements will be made in the order in which approved requests are ranked, according to relative financial burden.

§ 310.90 Disputes resolution.

The procedures in this section apply to reviews of denial of reimbursement and reviews of amount of reimbursement.

(a) The EPA reimbursement official's decision constitutes final Agency action unless the requester files a request for review by registered mail within 60 calendar days of the date of decision to the address given in § 310.50(f).

(b) The request for review of the EPA reimbursement official's final written decision must be filed with the disputes decision official identified in the final written decision.

(c) The request for review must include:

(1) A copy of the EPA reimbursement official's final decision;

(2) A statement of the amount in dispute;

(3) A description of the issues involved; and

(4) A concise statement of the requester's objection to the final decision.

(d) After filing for review, the requester:

(1) Is entitled to an informal conference with the EPA disputes decision official;

(2) May be represented by counsel and may submit documentary evidence and briefs for inclusion in a written record; and

(3) Is entitled to a written decision by the disputes decision official within 45 days from receipt of the request.

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3. Summary of Response Actions
j. Temporary Measures for Which Reimbursement is Sought
k. Demonstration that Costs Claimed Do Not Supplant Local Funds Normally Provided for Response and Exceed Resources Committed in Local Emergency Response Plan
l. Attach any additional material pertinent to the response

4. Cost Information

a. Total Response Cost	b. Total Reimbursement Requested
$	$

c. Complete and Attach Table 1, "Detailed Cost Breakdown"

d. Complete and Attach Table 2, "Cost Recovery Summary"

e. Attach Other Pertinent Financial Information (See Instructions)

5. Certification and Authorization (To be completed by highest ranking official of applying local government.)

I hereby certify that:

(1) All costs are accurate and were incurred specifically for the response for which reimbursement is being requested;
(2) The requirement to inform EPA or the NRC of the response has been met;
(3) Reimbursement for costs incurred for response activities does not supplant local funds normally provided for response;
(4) Cost recovery was pursued as presented in the attached Table 2; and
(5) Reimbursement funds for which costs are later recovered will be returned to EPA.

I further certify that I am authorized to request this reimbursement and to receive funds from the Federal Government.

Printed or Typed Name of Highest Ranking Local Government Official or Authorized Representative	Signature of Highest Ranking Local Government Official or Authorized Representative *
Title	Date

EPA Form 9310-1 (Rev 9-92) Reverse

BILLING CODE 6560-50-C

* Form 9310-1 is not considered complete unless it is signed by the highest ranking official of the local government requesting reimbursement, or signed by the authorized representative indicated in an enclosed letter delegating signature authority for the application process.

APPENDIX I TO PART 310.—EPA REGIONS AND NRC TELEPHONE LINES

EPA Regional Office	Telephone	States in Region
I—Boston	(617) 223–7265	ME, NH, VT, MA, RI, CT
II—New York	(908) 548–8730	NJ, NY, PR, VI
III—Philadelphia	(215) 597–9898	PA, DE, MD, DC, VA, WV
IV—Atlanta	(404) 347–4062	NC, SC, TN, MS, AL, GA, FL, KY
V—Chicago	(312) 353-2318	OH, IN, IL, WI, MN, MI
VI—Dallas	(214) 655–2222	AR, LA, TX, OK, NM
VII—Kansas City	(913) 236–3778	IA, MO, KS, NE
VIII—Denver	(303) 293–1788	CO, UT, WY, MT, ND, SD
IX—San Francisco	(415) 744–2000	AZ, CA, NV, AS, HI, GU, TT
X—Seattle	(206) 553–1263	ID, OR, WA, AK
National Response Center:		
1–800–424–8802 (National—toll free)		
202–267–2675 (Washington, DC)		

BILLING CODE 6560-50-M

Appendix II – Application for reimbursement to local governments for emergency response to hazardous substance releases under CERCLA Section 123

Please type or print all information

EPA

United States Environmental Protection Agency
Washington, D.C. 20460

Application for Reimbursement to Local Governments for Emergency Response to Hazardous Substance Releases Under CERCLA Sec. 123

Form Approved
OMB No. 2050-0077
Approval expires 7-31-94

1. Local Government Identification

a. Name of Local Government

b. Contact Name and Telephone Number

c. Official Address

d. Date of Application

2. Release Description

a. Date and Time of Occurrence or Discovery

b. Location

c. Source or Cause of Release

d. Hazardous Substances Released and Quantity (Petroleum, crude oil, or any unspecified fractions thereof are excluded. See §310.11(d) of the regulation for substances excluded from this program)

e. Threats to Human Health and Environment

f. Attach any additional material pertinent to the release

3. Response Description

a. Date and Time of HazMat Response Initiation

b. Contact Made With (Check one) You must ensure that EPA or the NRC is contacted within 24 hours of the response initiation in order to be eligible for reimbursement.

☐ EPA ☐ National Response Center

c. EPA Region

d. Date and Time Contact Made With EPA or NRC

e. Date of Response Completion (Local government has received all data, reports, and charges for response)

f. Jurisdiction in Which Response Occurred

g. Is your local government a participant in the Title III Emergency Response Plan? (You must participate to be eligible for reimbursement. See §310.30 of the regulation for possible waiver of this requirement.)

(Check one) ☐ Yes ☐ No

h. Responding Agencies and Jurisdictions

EPA Form 5310-1 (Rev 9-92)

• • • Follow instructions given in "Application Package" • • •

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Table 1
Detailed Cost Breakdcwn

Temporary Emergency Measure	Cost Incurred By	Cost Element (See Attachment 1)	Amount

ATTACHEMENT 1.—COST ELEMENT CODES AND COMMENTS

Code	Cost category	Cost element	Comments
PC	Personnel Compensation.	PC1: Overtime—for services in excess of the local agency's standard work day or work week.	Compensation of overtime costs incurred specifically for a response will be considered only if overtime is not otherwise provided for in the applicant's operating budget.
		PC2: Experts and consultants—for services rendered on a per diem or fee basis or for services of an intermittent, advisory nature.	
TR	Transportation	TR1: Passenger vehicle rental—for transportation of persons during evacuation.	Passenger and nonpassenger vehicle rental costs will be considered for private vehicles not owned or operated by the applicant or other unit of local government.
		TR2: Nonpassenger vehicle rental—for transportation of equipment or supplies.	
RC	Utilities	RC1: Utilities—for power, water, electricity and other services exclusive of transportation and communications.	Utility costs will be considered for private utilities not owned or operated by the applicant or other unit of local government.
OS	Other Contractual Services.	OS1: Contracts for technical or scientific analysis—for tasks requiring specialized hazardous substance response expertise.	May include such items as specialized laboratory analyses and sampling.
		OS2: Decontamination services—for specialized cleaning or decontamination procedures and supplies to restore clothing, equipment or other serviceable gear to normal functioning.	
SM	Supplies and Materials.	SM1: Commodities—for protective gear and clothing, cleanup tools and supplies and similar materials purchased specifically for, and expended during, the response.	May include such items as chemical foam to suppress a fire; food purchased specifically for an evacuation; air purifying canisters for breathing appartus; disposable, protective suits and gloves; and sampling supplies.
EQ	Equipment	EQ1: Replacement—for durable equipment declared a total loss as a result of contamination during the response.	Equipment replacement costs will be considered if applicant can demonstrate total loss and proper disposal of contaminated equipment.
		EQ2: Rents—for use of equipment owned by others	Equipment rental costs will be considered for privately owned equipment not owned or operated by the applicant or other unit of local government.

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Table 2
Cost Recovery Summary

Note: This "Cost Recovery Summary" must accompany each request for reimbursement.
You Must Fill Out Each Section Of This Form.

Name and Title of Source Contacted	Date(s) Contacted	Brief Summary of Response	Details Attached *
Attempts to Recover Costs from Potentially Responsible Parties (including PRP insurance)			
Attempts to Recover Costs from State Funding Sources			
Attempts to Recover Costs from Local Government Insurance			

EPA Form 9310-1 (Rev'9-92)

*Attach copies of letters, response documents, records, logs, etc.

[FR Doc. 93-995 Filed 1-14-93; 8:45 am]
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Part VI

Office of Management and Budget

Budget Rescissions and Deferrals; Cumulative Report; Notice

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OFFICE OF MANAGEMENT AND BUDGET

Cumulative Report on Rescissions and Deferrals

January 1, 1993.

This report is submitted in fulfillment of the requirement of section 1014(e) of the Congressional Budget and Impoundment Control Act of 1974 (Public Law 93–344). Section 1014(e) requires a monthly report listing all budget authority for this fiscal year for which, as of the first day of the month, a special message has been transmitted to Congress.

This report gives the status of nine deferrals contained in two special messages for FY 1993. These messages were transmitted to Congress on October 1, and December 30, 1992.

Rescissions

As of the date of this report, no rescission proposals are pending before the Congress.

Deferrals (Attachments A and B)

Attachment A provides the status of the $3,760.0 million in budget authority being deferred from obligation as of January 1, 1993. Attachment B provides the status of each deferral reported during FY 1993.

Information from Special Messages

The special messages containing information on the deferrals that are covered by this cumulative report are printed in the **Federal Registers** cited below: 57 FR 46730, Friday, October 9, 1992.

[The second special message for FY 1993 had not been printed in the **Federal Register** as of the date of this report.]

Richard Darman,

Director.

Atachments

BILLING CODE 3110-01-M

STATUS OF FY 1993 DEFERRALS

	Amounts (In millions of dollars)
Deferrals proposed by the President.....	4,113.4
Routine Executive releases through January 1, 1993.	-353.4
Overturned by the Congress.....	---
Currently before the Congress.....	3,760.0

ATTACHMENT B
Status of FY 1993 Deferrals – As of January 1, 1993
(Amounts in thousands of dollars)

Agency/Bureau/Account	Deferral Number	Amounts Transmitted: Original Request	Amounts Transmitted: Subsequent Change (+)	Date of Message	Releases(–): Cumulative OMB/ Agency	Releases(–): Congressionally Required	Congressional Action	Cumulative Adjustments (+)	Amount Deferred as of 1–1–93
FUNDS APPROPRIATED TO THE PRESIDENT									
International Security Assistance									
Economic support fund	D93–1	492,736		10–1–92					
	D93–1A		1,492,774	12–30–92	214,428				1,771,083
Foreign military financing grants	D93–8	1,487,000		12–30–92					1,487,000
Foreign military financing program	D93–9	149,200		12–30–92	138,997				10,203
Agency for International Development									
Demobilization and transition fund	D93–2	13,750		10–1–92					13,750
DEPARTMENT OF AGRICULTURE									
Forest Service									
Cooperative work	D93–3	364,582		10–1–92					364,582
Expenses, brush disposal	D93–4	40,241		10–1–92					
	D93–4A		5,835	12–30–92					46,076
DEPARTMENT OF DEFENSE – CIVIL									
Wildlife Conservation, Military Reservations									
Wildlife conservation, Defense	D93–5	2,175		10–1–92					2,175
DEPARTMENT OF HEALTH AND HUMAN SERVICES									
Social Security Administration									
Limitation on administrative expenses	D93–6	7,267		10–1–92					7,267

ATTACHMENT B
Status of FY 1993 Deferrals – As of January 1, 1993
(Amounts in thousands of dollars)

Agency/Bureau/Account	Deferral Number	Amounts Transmitted: Original Request	Amounts Transmitted: Subsequent Change (+)	Date of Message	Releases(–): Cumulative OMB/ Agency	Releases(–): Congressionally Required	Congressional Action	Cumulative Adjustments (+)	Amount Deferred as of 1–1–93
DEPARTMENT OF STATE									
Bureau for Refugee Programs									
United States emergency refugee and migration assistance fund	D93–7	10,123		10–1–92					
	D93–7A		47,761	12–30–92					57,884
TOTAL, DEFERRALS		2,567,075	1,546,371		353,425	0		0	3,760,021

[FR Doc. 93–1016 Filed 1–14–93; 8:45 am]
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Part VII

Department of Commerce

National Telecommunications and Information Administration

Comprehensive Examination of U.S. Regulation of International Telecommunications Services; Notice

VOL 58 ISS 10 JA 15 1993 UMI

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[Docket No. 921251-2351]

Comprehensive Examination of U.S. Regulation of International Telecommunications Services

AGENCY: National Telecommunications and Information Administration (NTIA), Commerce.

ACTION: Notice of inquiry; request for comments.

SUMMARY: NTIA is undertaking a comprehensive study to examine the economic, technological, regulatory, and policy factors affecting the provision of U.S. international telecommunications services (hereinafter identified as ITS), and evaluate, in light of those factors, alternative regulatory policy approaches. Public comment is requested on the issues identified in the Notice. After analyzing such comments, NTIA will issue, as appropriate, a report, which may recommend substantive and procedural changes in the existing U.S. regulatory approach to ITS.

DATES: Comments must be filed on or before April 20, 1993, and reply comments must be filed on or before May 28, 1993, to receive full consideration.

ADDRESSES: Comments (ten copies) should be sent to: Office of International Affairs, NTIA, U.S. Department of Commerce, 14th St. and Constitution Ave., NW., room 4701, Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Jean M. Prewitt, (202) 482-1304 or Suzanne R. Settle, (202) 482-1866, Office of International Affairs.

Authority: The Telecommunications Authorization Act of 1992, Pub. L. No. 102-538, 106 Stat. 3533 (1922).

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1. Introduction

1. Under the National Telecommunications and Information Administration (NTIA) Organization Act,[1] NTIA serves as the President's principal adviser on domestic and international telecommunications policy. Accordingly, NTIA conducts inquiries and develops recommendations regarding telecommunications issues and presents such recommendations to the public, the Congress, the Federal Communications Commission (hereinafter referred to as the Commission), foreign governments, and others.

2. This Notice of Inquiry (Notice) reviews U.S. regulation of international telecommunications services (ITS), which, for purposes of this Notice, include all types of telecommunications services (i.e., basic and enhanced, voice and non-voice) provided between the United States and other countries.[2] To the extent that ITS is regulated, such regulation is primarily the responsibility of the Commission, which is charged by the Communications Act of 1934 with "regulating interstate and foreign commerce in communication by wire and radio so as to make available, so far as possible, to all the people of the United States a rapid, efficient, Nation-wide, and world-wide wire and radio communication service with adequate facilities at reasonable charges, * * *."[3] The Notice also examines the relationship between the Commission's regulation of ITS (which extends only to ITS within its specific Title II or Title III authority under the Communications Act) and the Executive Branch's efforts in the trade and diplomatic arenas[4] to open foreign markets to U.S. service providers and encourage, on a worldwide basis, regulatory liberalization (through, *inter alia*, the adoption of pro-competitive policies and the elimination of unnecessary government restrictions) and the privatization of government-owned service providers.

3. In shaping its regulatory approach to ITS over the past decade, the Commission has drawn on its experience in successfully developing pro-competitive, deregulatory policies for domestic telecommunications services. It does not regulate international enhanced services and private carriage, and has opened the door to competition in international basic voice and data common carrier services. In contrast, there has been far less pro-competitive regulatory change in most foreign markets. As a result, an asymmetrical international regulatory environment for ITS has developed. Competing U.S. carriers in the liberalized U.S. market are still interacting primarily with foreign monopoly carriers in highly restricted foreign markets. In dealing with this regulatory asymmetry, the Commission has focused primarily on protecting U.S. ratepayers from anticompetitive activity by foreign monopoly carriers, although also expressing concern about the opening and liberalization of foreign markets.

4. U.S. Government officials and telecommunications industry participants and observers have increasingly shown interest in the policy questions raised by foreign participation in the U.S. ITS market.[5]

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[1] The NTIA Organization Act became law as part of the Telecommunications Authorization Act of 1992, Pub. L. No. 102-538, 106 Stat. 3533 (1992). This Act codifies the authority previously delegated to NTIA by the President and the Secretary of Commerce.

[2] While we use a broad definition for ITS, we believe the most economically significant market segment is basic common carrier telephony service (*i.e.*, international message telephone service, or IMTS) and that this is the market segment of greatest relevance to the issues raised in this Notice. IMTS is the term used in the international services context to describe the basic services carried over public switched networks, other than international telegraph and international telex services.

[3] 47 U.S.C. 151 (1988).

[4] The Notice is not intended to evaluate the underlying bases of these trade and diplomatic efforts. Rather, it focuses on the implications of the interaction between these efforts and the Commission's related, but not always perfectly congruent, regulatory approach to ITS.

[5] *See e.g.*, Letter from Carla A. Hills, U.S. Trade Representative, to Alfred Sikes, Chairman, Federal Communications Commission (April 17, 1992); Letter from John C. Danforth and Bob Packwood, U.S. Senators, to Alfred Sikes, Chairman, Federal Communications Commission (July 28, 1992); Letter from John Dingell, U.S. Representative to Alfred

Some parties have suggested that the Commission's regulatory approach should take into account a broader range of factors, including the trade and international competitiveness concerns that the Executive Branch has pursued in multilateral and bilateral fora. According to these parties, a new regulatory approach is needed because of major economic and technological changes in the international marketplace and the slow response of foreign countries to existing Executive Branch market-opening and liberalization initiatives. These parties argue that the noticeable disconnect between what the United States has been seeking and what it has been able to achieve in international fora requires more aggressive use of domestic regulatory authority as a tool to open, and liberalize the regulation of, foreign markets.

5. Alternatively, other parties assert that the Commission, as an independent agency charged with the development of specific regulations through transparent public proceedings, should remain focused on regulatory objectives clearly within its statutory mandate (*e.g.*, control of monopoly pricing, prevention of anticompetitive conduct by firms with market power, and removal of barriers to competition) and should not try to pursue trade, competitiveness, or other national goals that arguably go beyond that mandate. According to these parties, increased competition in the U.S. ITS market (through both domestic and foreign carriers) has produced substantial benefits for U.S. business and non-business consumers, which should not be unnecessarily jeopardized. Furthermore, they assert, the success of the U.S. model exerts continual pressure on other nations to likewise open and liberalize their telecommunications markets. These parties ultimately argue that proposals to pursue a broader range of national goals through the Commission's regulatory process, even though well-intentioned, are fundamentally misguided: such approaches not only are legally dubious and institutionally inappropriate, but also would ultimately prove counterproductive in effect.

6. NTIA believes it is necessary and timely to examine the following issues: (a) The underlying premises and specific provisions of the current U.S. regulatory regime; (b) the underlying causes of asymmetries between U.S. and foreign regulatory regimes and markets; (c) the interaction between U.S. regulation and the broader trade and competitiveness goals that the United States has pursued in international fora; (d) consumer benefits from continued application of pro-competitive U.S. regulatory policies; (e) comparative competitive opportunities for U.S. firms from opening and liberalizing foreign markets; (f) the impact of changes (*i.e.*, regulatory, economic, and technological) in the ITS marketplace on U.S. public policy; and (g) the types of changes, if any, needed in the U.S. regulatory approach to ITS to advance broader national goals and/or to achieve a higher level of integration and consistency in U.S. policy-making.

7. Through this Notice, NTIA also hopes to develop a strong factual record on ITS market conditions and a sound analytical framework for assessing the impact of U.S. regulation of ITS on the ability of U.S. users to reap the benefits of pro-competitive policies and the ability of U.S. firms to compete in the global marketplace. NTIA further hopes that this factual record and analytical framework will provide the basis for policy insights and recommendations that will help the Commission, the Executive Branch, and the Congress in dealing with ITS issues over the next decade.

8. In the following four sections, this Notice: (a) Describes the evolution of U.S. ITS regulation; (b) Reviews changes in the structure of the U.S. and foreign telecommunications markets, which are creating new challenges for U.S. ITS policy-making; (c) describes Executive Branch efforts to achieve parity for U.S. carriers in foreign markets; and (d) sets forth a series of questions that need to be addressed. Parties are asked to specifically address these questions, found in Section V, in their comments.

II. Evolution of U.S. Regulatory Environment for ITS

A. Introduction

9. International telecommunications services, in contrast to domestic services, are generally provided as a cooperative venture between national carriers or telecommunications entities in different countries, irrespective of market or regulatory structures in each nation. Historically, especially in the earlier part of this century, fairly stable national market structures existed for ITS. Following the theory of "natural monopoly," most markets were patterned on the traditional model of a regulated, often government-owned or controlled, monopoly service provider. Typically, a government-owned Post, Telegraph, and Telephone (PTT) operator[6] held exclusive rights for all domestic and international facilities, including the underlying network, as well as for services provided over the network and equipment attached to the network. Foreign monopoly carriers and their sovereign national governments thus controlled the foreign end of transmission facilities and networks to which privately owned U.S.-based carriers connected in order to provide ITS from the United States to foreign points.

10. In the United States, privately-owned entities provided government-regulated ITS to the public. However, U.S. regulatory policies distinguished between voice services, where American Telephone and Telegraph (AT&T) held a monopoly, and record services (telegraph, telex, and data), where competition existed.[7] The Commission's jurisdiction over ITS, like that of its foreign counterparts, was limited to the end within its own country.[8]

11. Certain legal and regulatory provisions adopted in this historical context continue to have an impact on the provision of ITS today. These provisions address concerns related to national security, foreign ownership, and facilities construction and use for the provision of ITS. While the United States has generally kept its market open to participation by foreign-owned entities, based on a longstanding policy of national treatment in investment,[9] Congress has dealt with foreign ownership issues affecting ITS in a few specific contexts. Over time, the Commission has also considered foreign ownership in certain specific instances, in acting on its public interest mandate under the Communications Act.

12. For example, in 1921, the Congress enacted the Submarine Cable Landing License Act.[10] The Act requires prior authorization from the U.S. government to land a cable and permits withholding of such authorization, or revocation of existing authorization, if U.S. nationals are not granted reciprocal landing rights in a foreign applicant's

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Sikes, Chairman, Federal Communications Commission (August 5, 1992); and Letter from Robert Allen, Chairman, AT&T, to Alfred Sikes, Chairman, Federal Communications Commission (September 30, 1992).

[6] As a result of restructuring, many PTTs are now identified as "Telecommunications Administrations"; both terms are used in this Notice.

[7] Record services were provided by regulated "international record carriers" (IRCs), the largest of which were Western Union International, RCA Global Communications, and ITT Worldcom. *See infra* note 31.

[8] This contrasts with interstate domestic services, where the Commission's jurisdiction extends from end to end. 47 U.S.C. 151–152 (1988).

[9] *See e.g.*, Letter from Charles H. Dallara, Assistant Secretary, International Affairs, Department of the Treasury, to Donna R. Searcy, Secretary, Federal Communications Commission (Jan. 29, 1991).

[10] 47 U.S.C. 34–39 (1988).

home country.[11] While the Act was adopted at a time when transoceanic cables between the U.S. and foreign points were owned entirely by one entity, it also applies when there is joint provision, as is the case today.[12]

13. Similarly, in 1934, the Congress addressed national security concerns in the Communications Act. Section 310 prohibits alien or foreign corporations, and certain corporations partially owned or controlled by an alien or foreign entity, from obtaining a "broadcast or common carrier or aeronautical en route or aeronautical fixed radio station license."[13] This prohibition, which is still in force today, does not apply to the resale of telecommunications services, so foreign entities may, through certain resale activities, enter markets otherwise covered by the prohibition.

14. In the 1930s, in the record (or non-voice) market, the Commission recognized that asymmetric regulation of foreign monopolies and competitive U.S. record carriers could produce anticompetitive effects through monopoly leveraging at the foreign end. The Commission therefore adopted a "uniform settlements policy" for dividing revenues between U.S. record carriers and their foreign counterparts.[14] The purpose was to prevent foreign monopolies from engaging in "whipsawing," *i.e.*, using their monopoly power to play one U.S. carrier against another to gain concessions and benefits, ultimately harming U.S. ratepayers.[15] The uniformity policy required that agreements concluded between U.S. carriers and foreign correspondents for the provision of service contain uniform terms and conditions, including uniform accounting rates,[16] uniform settlement rates,[17] and a 50–50 division of the accounting rate.[18]

15. With regard to international facilities, the development of satellite technology in the 1960s created opportunities to enhance significantly the range and quality of ITS.[19] In 1964, at the initiative of the United States, the International Telecommunications Satellite Organization (Intelsat) was created as a single global telecommunications satellite system to provide expanded services to all areas of the world.[20] Intelsat owns and operates the space segment (the satellites and the tracking, telemetry, command, control, monitoring and related facilities and equipment), while the earth stations handling actual traffic are typically owned and operated by operating entities (called "Signatories") in each of the member countries.[21] The U.S. Signatory, the Communications Satellite Corporation (Comsat), a Congressionally-chartered, private corporation, is regulated as a common carrier by the Commission.[22]

16. The Commission also instituted guidelines, on a region-by-region basis, requiring U.S. carriers to distribute circuits used to provide U.S.-foreign telephone service through "balanced loading" of satellite and submarine cable facilities.[23] The "balanced loading" method sought to place, to the maximum extent possible, an equal number of circuits on each type of facility used to provide service between the United States and a given country.[24] This method purported to maintain the viability of the global satellite system by requiring substantial use of Intelsat's facilities by U.S. carriers that served end users directly and also held investment interests in submarine cables.[25]

B. Opening the U.S. ITS Market to Competition

17. Prior to the 1970s, ITS represented a very small portion of U.S. telecommunications traffic. Then, a combination of improved facilities (such as high capacity submarine cables, satellites, and greater availability of private leased circuits) and pent-up demand stimulated an expansion in ITS traffic.[26] In this environment, the

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[11] *Id.* By requiring such reciprocal treatment, the Act protects "the interests of the United States and its citizens in foreign countries in connection with the issuance of cable landing rights." For a discussion of the history of this statute, see *Tel-Optik Ltd.*, Memorandum Opinion and Order, 100 FCC 2d 1033, 1042–44, paras. 21–22 (1985).

[12] *See generally Tel-Optik Ltd., supra* note 11, 100 FCC 2d at p. 1043, para. 22.

[13] 47 U.S.C. 310(b) (1988). The restriction applies to aliens and their representatives; corporations organized under the laws of foreign governments; corporations with any alien officers or directors, or with more than one-fifth stock ownership by aliens or foreign governments or their representatives; and corporations directly or indirectly controlled by other corporations of which any officer or more than one-fourth of the directors are aliens, or of which more than one-fourth of the stock is owned or voted by aliens, their representatives, or by any foreign government, if the Commission finds that the public interest will be served by the refusing or revoking of a license.

[14] The settlements process governs the amount a carrier in one country pays a carrier in another country to complete calls.

[15] *Mackay Radio and Tel. Co., Inc.*, 2 FCC 592 (1936), *aff'd, Mackay Radio and Tel. Co., Inc.* v. *FCC*, 97 F.2d 641 (1938). Without the uniformity policy, foreign monopolies could negotiate a more advantageous settlement from a U.S. carrier seeking to enter the market or increase its market share, possibly leading to higher costs for the U.S. carrier and thus higher rates for U.S. ratepayers.

[16] An "accounting rate" is a negotiated rate of reimbursement for service that is recovered by the initiating and terminating entities. *Regulation of Int'l Accounting Rates*, Second Report and Order and Second Further Notice of Proposed Rulemaking, CC Docket No. 90–337, Phase II, FCC 92–498, n.3 (released Nov. 27, 1992).

[17] A "settlement rate" is the rate of exchange by which an accounting rate is converted from one currency to another. More recently, this term also has been used to refer to each correspondent's portion of the accounting rate, generally one-half. *Id.*

[18] Most operating agreements provide that the two correspondents split the accounting rate 50–50. *Id.*

[19] Satellite policies are briefly discussed as background information in this Notice because of their relevance to competitive developments in the ITS facilities market. This Notice does not seek comment on competition in international satellite services *per se* in light of the Executive Branch's recent major review of its separate satellite systems policy. Discussed *infra* at para. 20.

[20] The 1964 provisional agreement creating Intelsat was finalized in 1973 in the Agreement Relating to the International Telecommunications Satellite Organization, Aug. 20, 1971, 23 U.S.T. 3813, T.I.A.S. No. 7532 (*Entered into Force*, Feb. 12, 1973).

[21] The Intelsat consortium has grown to include 125 countries and now operates a worldwide system of nineteen satellites. Similarly, the United States is one of 67 member-nations of the International Maritime Satellite Organization (INMARSAT), which operates a global maritime satellite telecommunications system. Comsat is the U.S. Signatory and markets a variety of maritime, land mobile, and aeronautical services. 47 U.S.C. 751–757 (1988). *See also* Convention on the Int'l Maritime Satellite Organization, Sept. 3, 1970, *revised* London, July 16, 1979, T.I.A.S. No. 9605, 31 U.S.T. 1.

[22] 47 U.S.C. 721 (1988).

[23] The Commission initially addressed the question of circuit distribution when considering an application for authority to construct a submarine cable filed after the advent of satellite communications. *ITT Cable and Radio, Inc.—Puerto Rico, et al.*, Memorandum Opinion and Order, 5 FCC 2d 823 (1966) (policy statement) and *AT&T*, Memorandum Opinion, Order, and Authorization, 7 FCC 2d 950 (1967). The Commission's circuit distribution policies then evolved over time in different regions as part of facilities planning proceedings or as part of individual transmission system authorizations. For additional background on development of this policy, see *Policy for the Distribution of U.S. Int'l Carrier Circuits Among Available Facilities During the Post-1988 Period*, Notice of Proposed Rulemaking, 2 FCC Rcd 2109, 2109–21, paras. 4–16 (1987).

[24] *See, e.g., Inquiry into the Policies to be Followed in the Authorization of Common Carrier Facilities to Meet North Atlantic Telecommunications Needs During the 1985–1995 Period*, Second Report and Order, 101 FCC 2d 1259, 1261, para. 3, n.5 (1985).

[25] *Policy for the Distribution of U.S. Int'l Carrier Circuits Among Available Facilities During the Post-1988 Period*, Report and Order, 3 FCC Rcd 2156, 2160, para. 27 (1988). The Commission's involvement in circuit distribution arose due to its 1966 policy limiting Comsat's role primarily to that of a "carrier's carrier," providing satellite circuits to other carriers for their use in furnishing international common carrier services to end users, under all but exceptional circumstances. Comsat consequently relied on AT&T and the international record carriers for nearly all of its traffic. The Commission was concerned that AT&T and the international record carriers, which held interests in submarine cables, might not use the global system developed under the Satellite Act unless required to do so. *Id.* at 2160, para. 27, n.11.

[26] *See generally Overseas Communications Services*, Report and Order, 92 FCC 2d 641, 654–57, paras. 32–39 (1982); Nat'l Telecommunications and Information Admin., U.S. Dep't of Commerce,

Commission's policies favoring competition in domestic telecommunication services increasingly influenced its development of policies governing ITS.

18. Over the past 20 years, the Commission has advocated competition in domestic services and equipment to encourage increased innovation, greater efficiency, additional service options, and reduced rates for users. The Commission first permitted service competition in the provision of interstate private lines and gradually extended this policy (with some prodding from the courts) to interstate switched services.[27] The AT&T consent decree also fostered competition by divesting the Bell Companies from AT&T and according all interstate long distance providers the same quality of interconnection to the local exchange afforded AT&T.[28] Furthermore, the deregulation of the customer premises equipment and enhanced, or value-added, services markets resulted in competition and a wide array of new choices for consumers.[29] Finally, as a complement to promoting competition among common carriers, the Commission also permitted users to build their own private networks and non-carriers to provide private telecommunications services as alternatives to common carrier offerings.[30]

19. The Commission began to apply these procompetitive policies to ITS through a series of decisions in the 1980s. With Congressional support, the regulatory distinction between voice and record services was eliminated.[31] The Commission further ruled that enhanced services (including international value-added services) were not subject to traditional common carrier regulation under Title II of the Communications Act;[32] and permitted Comsat, which provided satellite transmission facilities, to serve both carrier and non-carrier entities.[33] As in the domestic arena, these steps were taken to encourage the ITS market structure to develop in a manner that would increase efficiency in the use of services and facilities, expand consumer choice, create more diverse service offerings, and lower rates in the ITS market.[34]

20. The Commission also promoted competition in the facilities used to provide ITS.[35] Until 1984, when the United States adopted a policy to allow satellite competition, Intelsat existed as a virtual monopoly supplier of international satellite services. In 1984, the Executive Branch determined that separate international satellite systems were required in the national interest[36] and set forth criteria to establish competitive satellite systems, while minimizing the adverse impact on Intelsat.[37] The Commission established the regulatory framework for the authorization of separate systems,[38] which was recently revised pursuant to further Executive Branch guidance,[39] to allow for a greater range of services and the eventual elimination of restrictions on competition.[40]

21. In 1988, the Commission terminated its circuit distribution guidelines.[41] It found they were no longer needed to provide a firm basis for Intelsat's operations, due to Intelsat's growth and a clear commitment by AT&T to make substantial use of the Intelsat system, as evidenced by an agreement between AT&T and Comsat. In addition, the Commission determined that guaranteeing such traffic to Intelsat created disincentives for it to adapt to an increasingly competitive environment. Furthermore, the Commission preferred that both carriers and users be permitted to make decisions regarding facilities and services free from unnecessary regulatory interference.[42]

NTIA Special Pub. No. 88–21, *NTIA Telecom 2000: Charting the Course for a New Century* ch. 1 (1988).

[27] After instituting an open entry policy for private line carriers, the Commission authorized unlimited sharing and resale of private line services, eventually allowing competitive multiple entry into all interstate switched services. *See Specialized Common Carrier Services*, First Report and Order, 29 FCC 2d 870 (1971), *recon. denied*, 44 FCC 2d 467 (1973), *aff'd sub nom. Washington Utilities & Transportation Comm'n v. FCC*, 513 F.2d 1142 (9th Cir. 1975), *cert. denied, Nat'l Assoc. of Regulatory Utility Comm'rs.*, 423 U.S. 836 (1975); *Resale and Shared Use of Common Carrier Services*, Report and Order, 60 FCC 2d 261 (1976), recon. 62 FCC 2d 588 (1977), *aff'd sub nom. AT&T v. FCC*, 572 F.2d 17 (2d Cir.) *cert. denied*, 439 U.S. 875 (1978).

[28] Modification of Final Judgment, *United States v. AT&T*, 552 F.Supp. 131 (D.D.C. 1982), *aff'd sub nom. Maryland v. United States*, 460 U.S. 1001 (1983). A 1982 antitrust consent decree, effective in 1984 divested AT&T of its local telephone companies, now known as Bell Operating Companies (BOCs). The BOCs, which provide local telephone service to about 80 percent of the U.S. population, were precluded from several lines of business under the decree, including the provision of ITS to and from the United States.

[29] *See* Nat'l Telecommunications and Information Admin., U.S. Dep't of Commerce, NTIA Special Pub. No. 91–26, *The NTIA Infrastructure Report: Telecommunications in the Age of Information* 204–208 (1991). *See also Second Computer Inquiry*, Final Decision, 77 FCC 2d 384, recon. 84 FCC 2d 50 (1980) (*Computer II*), *further recon.*, 88 FCC 2d 512 (1981), *aff'd sub nom. Computer and Communications Indus. Ass'n. v. FCC*, 693 F.2d 198 (D.C. Cir. 1982), *cert. denied*, 461 U.S. 938 (1983).

[30] *See generally Domestic Fixed-Satellite Transponder Sales*, Memorandum Opinion, Order and Authorization, 90 FCC 2d 1238, 1246, para. 21 (1982), *aff'd, Wold Communications, Inc. v. FCC*, 735 F.2d 1465 (D.C. Cir. 1984).

[31] *See AT&T*, Memorandum Opinion, Order and Authorization, 75 FCC 2d 682 (1980) (*Dataphone*); *Western Union Int'l, Inc.*, Memorandum Opinion, Order and Authorization, 76 FCC 2d 166 (1980) (*Datel*) aff'd. *Western Union Int'l, Inc. v. FCC*, 673 F.2d 539 (D.C. Cir. 1982). With these orders, the Commission partially removed the dichotomy between voice and record services, allowing AT&T to offer data services and record carriers to offer voice services under limited conditions. Congress subsequently abolished this dichotomy completely in 1981, *see* 47 U.S.C. 222 (1988), and the Commission then implemented this statutory change. *See, e.g., Int'l Record Carriers*, Policy Statement and Order, 76 FCC 2d 115 (1980) and *Customer Use of Telex Serv.*, Report, Order and Further Notice of Proposed Rulemaking, 76 FCC 2d 61 (1980); both *aff'd sub nom. Western Union Tel. Co. v. FCC*, 665 F.2d 1126 (D.C. Cir. 1981).

[32] *Computer II*, *supra* note 29.

[33] *See Proposed Modifications of the Commission's Authorized User Policy Concerning Access to Int'l Satellite Services of Comsat*, Report and Order, 90 FCC 2d 1394 (1982) (*Authorized User I*), *revising Authorized Entities and Users*, 4 FCC 2d 421 (1966); *Authorized User Policy*, Second Report and Order, Memorandum Opinion and Order, 100 FCC 2d 177 (1985) (*Authorized User II*); *Authorized User Policy*, 50 Rad. Reg. (P&F) 213 (1985), aff'd *Western Union Int'l, Inc.*, 61 Rad. Reg. 2d (P&F) 984 (D.C. Cir. 1986).

[34] *See, e.g., Dataphone*, 75 FCC 2d at 695–96, para. 43; *Datel*, 76 FCC 2d at 161–62, paras. 48–49; *Computer II*, 77 FCC 2d at 427–28, paras. 111–112.

[35] *Policy for the Distribution of United States Int'l Carrier Circuits Among Available Facilities During the Post-1988 Period*, Report and Order, 3 FCC Rcd 2156, 2160, paras. 26–27 (1988) (*Int'l Carrier Circuits*).

[36] Presidential Determination No. 85–2, 49 Fed. Reg. 46,987 (1984). By 1984, six U.S. companies had filed applications with the Commission proposing to build, launch, and operate private international separate satellite systems to compete with Intelsat. These applications prompted the U.S. government to convene an Executive Branch Senior Interagency Group on International Communications and Information Policy to address the need for a new U.S. government policy, which eventually led to the 1984 Presidential Determination.

[37] Letter from George P. Shultz, Secretary of State and Malcolm Baldrige, Secretary of Commerce, to Mark S. Fowler, Chairman, Federal Communications Commission (Nov. 28, 1984).

[38] *Establishment of Satellite Systems Providing Int'l Communications (Separate Systems Order)*, Report and Order, 101 FCC 2d 1046 (1985), recon. 61 Rad. Reg. 2d (P&F) 649, *further recon.* 1 FCC Rcd 439 (1986). The Commission found that separate systems were beneficial to users but it prohibited their interconnection with the public switched network, a restriction it considered "reasonable and workable." *Id.* at 1050, 1062, 1096, paras. 8, 36, 105, respectively.

[39] Letter from James A. Baker, III, Secretary of State and Robert Mosbacher, Secretary of Commerce, to Alfred Sikes, Chairman, Federal Communications Commission (Nov. 27, 1991).

[40] *Permissible Services of U.S. Licensed Int'l Communications Satellite Systems Separate from the Int'l Telecommunications Satellite Org. (INTELSAT)*, Order, 7 FCC Rcd 2313, 2313–14, paras. 3–6 (1992) (providing for the elimination of the restriction on interconnection to the public switched network by January 1, 1997).

[41] *See generally Int'l Carrier Circuits*, *supra* note 35.

[42] *Id.* at 2160, paras. 26–27.

C. Regulatory Approach Governing ITS

22. Having established competition as a fundamental premise in its approach to ITS, the Commission has sought to apply this principle to specific areas where it is required to take regulatory action. We discuss below a number of these specific areas, including: (1) the international accounting and settlements process; (2) rules pertaining to international resale; (3) U.S. regulatory treatment of carriers providing ITS; and (4) specific requests for authorization to provide international facilities or services.

1. International Settlements Between Carriers and the Impact on Customers' Calling Rates

23. The potential for anticompetitive leveraging by foreign monopolies through "whipsawing", earlier addressed by the Commission, remained a concern in the 1980s. In reexamining the uniform settlements policy, the Commission found its continued application to parallel routes to be in the public interest, although it announced that it would consider waivers on a case-by-case basis, and that increased competition could be a factor supporting grant of a waiver.[43]

24. In the mid-1980s, the Commission reaffirmed the application of its uniform settlements policy (renamed "international settlements policy") to record carriers and determined that the policy should also extend to basic voice services, as burgeoning domestic competition for such services had enabled foreign PTTs to engage in whipsawing.[44] The Commission further modified its rules in order to prevent foreign monopolies from obtaining advantages through indirect transit routes for telecommunications traffic, although it sought to retain some flexibility for carriers in making route arrangements.[45]

25. In a 1990 rulemaking, the Commission for the first time turned its attention to the increasing U.S. net settlements deficit and to the obstacles to further reductions in U.S. accounting rates and collection charges for international services.[46] This inquiry necessarily focused attention on the actual accounting rates and collection charges of foreign Telecommunications Administrations. The Commission found that, by 1988, following the introduction of competition in the U.S. ITS market, U.S. collection charges had decreased. However, due both to the greater number of outbound telephone calls from the United States and to the continuing reluctance of foreign Telecommunications Administrations to reduce accounting rates, the United States experienced a net settlements deficit of $2 billion.[47] The Commission estimated that at least $1 billion of that deficit was a direct underwriting by U.S. carriers and ratepayers of foreign Telecommunications Administrations.[48]

26. In response to these findings, the Commission adopted procedural reforms to its international settlements policy.[49] In addition, the Commission directed U.S. carriers to negotiate cost-based accounting rates with their foreign correspondents. It also recommended that U.S. delegations to international bodies, such as the International Telecommunication Union (ITU), advocate cost-based accounting rates;[50] these efforts are discussed infra at paragraphs 75 and 76.

27. With respect to collection charges, the Commission found that while rates charged to customers in the United States for calls to foreign countries were lower (in many cases, much lower) than for calls from such foreign countries, U.S. international rates were nonetheless significantly higher than U.S. domestic rates. The Commission expressed concern that above-cost accounting rates inhibited further reductions in U.S. calling prices which, in turn, put pressure on the U.S. structure of universal service, reduced economic efficiency, and created incentives to bypass the international public switched telephone network.[51]

28. The Commission also found that wide disparities existed in accounting rates between regions and concluded that such disparities had no legitimate cost justification.[52] Accordingly, the Commission established benchmark accounting rates for Europe, Asia, and other regions, where wide disparities in accounting rates existed (*e.g.*, intra-European rates are substantially lower than U.S.-European rates).[53] In order to encourage the establishment of rates within the benchmark ranges and encourage further accounting rate reductions, the Commission required the five largest U.S. facilities-based international carriers for IMTS[54] to file progress reports regarding their success in reducing settlements rates in Europe and Asia.[55] The carriers were directed to include in the progress reports specific information about impediments in countries where their success in negotiating lower accounting rates has been limited.[56]

2. International Resale of Private Lines

29. In 1976, the Commission required carriers to permit unlimited resale and sharing of private line services and facilities for domestic interstate services, but did not apply that policy to ITS.[57] In 1980, the Commission commenced a rulemaking[58] to consider extending this procompetitive policy to

[43] *Uniform Settlement Rates on Parallel Int'l Communications Routes*, Memorandum Opinion and Order, 84 FCC 2d 121, 123, para. 5 (1980).

[44] *Implementation and Scope of the Uniform Settlements Policy for Parallel Int'l Communications Routes*, 59 Rad. Reg.2d (P&F) 982 (1986) (*Uniform Settlements Policy*). Specifically, as the number of U.S. carriers competing for voice traffic increased, foreign monopolies were better able to play off individual carriers against each other. The Commission also considered applying the international settlements policy to enhanced services, but ultimately decided against that course. *Implementation and Scope of the Int'l Settlements Policy for Parallel Int'l Communications Routes*, Further Reconsideration, 3 FCC Rcd 1614 (1988).

[45] *Uniform Settlements Policy*, *supra* note 44, 59 Rad. Reg. 2d (P&F), at 986–96, paras. 28–31.

[46] *Regulation of Int'l Accounting Rates*, Notice of Proposed Rulemaking, 5 FCC Rcd 4948 (1990).

[47] *Id.* at 4948, para. 1. In 1991, the net settlements deficit increased to an estimated $3.4 billion. *Chairman Alfred C. Sikes Commends International Telephone Rates Agreement*, FCC News (released Oct. 13, 1992).

[48] *Regulation of Int'l Accounting Rates*, *supra* note 45, 5 FCC Rcd 4948, para. 1.

[49] *Regulation of Int'l Accounting Rates*, Report and Order, 6 FCC Rcd 3552 (1991). The procedural reforms included two mechanisms for carriers to seek deviations from the uniform accounting rate: (1) a notification option for reporting simple reductions in the accounting rate; and (2) a streamlined waiver process for seeking permission to vary the rate, based on Commission guidelines established in this rulemaking.

[50] CCITT Study Group III was identified as the relevant body for such work, which involved the drafting of a revised CCITT Recommendation on international accounting rates. *Id.* at 3555, para. 23.

[51] *Regulation of Int'l Accounting Rates*, Notice of Proposed Rulemaking, 5 FCC Rcd 4948, 4949, para. 7 (1990) (footnotes omitted).

[52] The Commission noted a disparity as high as 316 percent between intra-Latin American accounting rates and U.S.-Latin American accounting rates; a disparity of approximately 500 percent between intra-African accounting rates and U.S.-African accounting rates; and a disparity of approximately 500 percent between intra-Asian accounting rates and U.S.-Asian accounting rates. *Regulation of Int'l Accounting Rates*, Second Report & Order and Second Further Notice of Proposed Rulemaking, CC Docket No. 90–337, Phase II, FCC 92–496 (released Nov. 27, 1992).

[53] *Id.* at paras. 4, 10, 15.

[54] These five carriers are AT&T, MCI International, US Sprint, TRT/FTC Communications, Inc., and GTE-Hawaiian. *Id.* at para. 22, n. 48.

[55] *Id.* at paras. 1, 4.

[56] *Id.* at para. 25. While the Commission indicated it would continue to require proportionate return traffic and equal division of tolls, it declined, at that time, to attach conditions on Section 214 authorizations filed by foreign-owned carriers at that time. *Id.* at paras. 30, 32.

[57] *Regulatory Policies Concerning Resale and Shared Use of Common Carrier Services and Facilities*, Report and Order, 60 FCC 2d 261 (1976), *recon.* 62 FCC 2d 588, 593, para. 10 (1977), *aff'd sub nom. American Telephone and Telegraph Co. v. FCC*, 572 F.2d 17 (2d Cir.), *cert. denied*, 439 U.S. 875 (1978).

[58] *Regulatory Policies Concerning Resale and Shared Use of Common Carrier Int'l Communications Services*, Notice of Proposed Rulemaking, 77 FCC 2d 831, 832, paras. 2, 7 (1980).

ITS, but this rulemaking was never concluded, and, because of its stale record, was ultimately terminated in the Commission's 1990 docket on international settlements, in which issues pertaining to resale were raised.[59]

30. In this proceeding, the Commission found that international resale would result in increased customer demand and reduced prices for most telecommunications services, while also driving international accounting rates closer to costs.[60] The Commission thus required U.S. carriers to permit resale of private line services for connection to the public switched network,[61] but only for service to those countries that provide "equivalent resale opportunities" for service to the United States.[62] To effectuate this policy, the Commission required that a Section 214 application for private line resale include a showing of "equivalent resale opportunities" in the destination country.[63]

31. The Commission's primary goal in this proceeding was to advance the benefits of two-way resale—including competitive pressures to reduce above-cost accounting rates—while avoiding the negative consequences of one-way resale into the United States. The Commission was concerned that without the equivalent resale policy, traffic diverted from U.S. carriers would decrease the number of minutes foreign entities would report under the international settlements policy, while U.S. carriers' outbound traffic volumes would remain the same. The U.S. net settlements deficit would thus increase, which could ultimately burden U.S. ratepayers with higher rates.[64]

3. International Competitive Carrier Policies

32. The Commission's interstate domestic competitive carrier decisions in the early 1980s served as a model for its 1985 international competitive carrier decision.[65] The Commission believed that relying on market forces and reducing regulatory burdens would allow carriers to operate more efficiently and to better respond to customers' needs. As U.S. carriers expanded their overseas operations and offered new, innovative services on a global basis, the Commission in the 1985 decision reduced the regulatory requirements for those international common carriers that faced effective marketplace competition and did not have market power, treating them as "non-dominant."[66]

33. After analyzing the service offerings of international common carriers in terms of product and geographic markets, the Commission determined that AT&T was dominant for IMTS and that Comsat, as the sole provider of some services, was dominant in its provision of those services.[67] All other U.S.-owned international carriers were classified as non-dominant. The Commission also concluded that the most efficient way to encourage the granting of operating agreements and to discourage market distortions was to classify all foreign-owned[68] carriers as dominant in their provision of all international common carrier services to all foreign points. Dominant carriers were subject to greater regulatory requirements than non-dominant international carriers, which could take advantage of streamlined tariffing and facilities authorization procedures.[69] The Commission also planned to monitor operating practices of foreign-owned carriers, to consider conditioning Section 214 authorizations on the granting of operating agreements (*i.e.*, reciprocal entry), and to require filing of specific traffic and revenue data.[70]

34. In 1992, the Commission reexamined its 1985 policy. Rather than imposing dominant classification on all foreign-owned carriers for all international services and routes, the Commission decided to apply that classification on the basis of a route-by-route analysis. Thus, an international carrier, whether U.S. or foreign-owned, would be considered dominant only on those routes where a foreign affiliate of the carrier had the ability to discriminate in its favor in the provision of services or facilities used to terminate U.S. international traffic.[71]

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[59] *Regulation of Int'l Accounting Rates*, Further Notice of Proposed Rulemaking, 6 FCC Rcd 3434, 3436–37, para. 17 (1991). The Commission concluded that it must take additional steps to achieve cost-based accounting and collection rates for service to and from the United States, including consideration of international resale. *Id.* at 3434, para. 1.

[60] The term "resale" was defined by the Commission as "an activity wherein one entity subscribes to the communication services and facilities of another entity and then reoffers communications services and facilities to the public (with or without 'adding value') for profit". *Regulation of Int'l Accounting Rates*, First Report and Order, 7 FCC Rcd 559, para. 5 n.7 (1991) (footnote omitted). *See also Id.* at 560, para. 11.

[61] Upon reconsideration, the Commission clarified that the equivalency requirement does not apply to the resale of international private lines for private line services. *Regulation of Int'l Accounting Rates*, Order on Reconsideration and Third Further Notice of Proposed Rulemaking, CC Docket No. 90–337, Phase II, FCC 92–517, paras. 7–8 (released Nov. 27, 1992).

[62] The Commission denied a request by AT&T to clarify that separate satellites and private cables were subject to the same regulatory requirements under the December 1991 resale order as U.S. common carriers because this issue was outside the scope of the proceeding. *Id.* at para. 18.

[63] *Regulation of Int'l Accounting Rates*, First Report and Order, 7 FCC Rcd 559, 560, paras. 9–10 (1991). Section 214 applicants bear the burden of proving that "equivalent opportunities" exist, by including either a statement that the Commission has publicly determined that "equivalent resale opportunities" exist, or evidence of open entry including terms, conditions, and prices similar to those accorded foreign competitors. For example, the Commission recently determined that "equivalent opportunities" exist in Canada, because of Canada's open entry and nondiscriminatory treatment toward U.S. carriers. It therefore granted the first international resale application using the "equivalent opportunities" test. *FONOROLA Corp. and EMI Communications Corp.*, Memorandum Opinion, Order and Certification, 7 FCC Rcd 7312 (1992), *recon. pending*.

[64] *Regulation of Int'l Accounting Rates*, *supra*, 7 FCC Rcd at 561, para. 19.

[65] *Int'l Competitive Carrier Policies*, Report and Order, 102 FCC 2d 812, 814, para. 2 (footnote omitted) (1985), *recon. denied*, 60 Rad. Reg.2d (P&F) 1435 (1986). For domestic interstate services, the Commission determined that only AT&T was dominant and therefore subject to full Title II regulation, while competitors such as MCI and Sprint were non-dominant and thereafter subject to forbearance from full Title II regulation. *Policy and Rules Concerning Rates for Competitive Carrier Services and Facilities Authorizations Therefor*, First Report and Order, 85 FCC 2d 1 (1980); Second Report and Order, 91 FCC 2d 59 (1982); Third Report and Order, 48 Fed. Reg. 46791 (Oct. 14, 1983); Fourth Report and Order, 95 FCC 2d 554 (1983); Fifth Report and Order, 98 FCC 2d 1191 (1984); Sixth Report and Order, 99 FCC 2d 1020 (1985); *aff'd and remanded sub nom. MCI Telecommunications Corp. v. FCC*, 765 F.2d 1186 (D.C. Cir. 1985). As part of its forbearance policy for domestic services, the Commission held that non-dominant carriers were not required to file tariffs for their services. This "permissive detariffing" policy was recently overturned by a Federal Court of Appeals panel on the ground that it was inconsistent with the requirements of the Communications Act. *AT&T v. FCC*, 978 F.2d 727 (D.C. Cir. 1992). The decision did not directly address international services, which are subject to streamlined regulation rather than forbearance (*See, e.g., Regulation of Int'l Common Carrier Services*, Notice of Proposed Rulemaking, 7 FCC Rcd 577, 578, n.10 (1992)). However, the decision requires examination in the international context.

[66] *Int'l Competitive Carrier Policies*, Report and Order, 102 FCC 2d 812, 821, para. 22 (1985), *recon. denied*, 60 Rad. Reg.2d (P&F) 1435 (1986).

[67] *Id.* at 821, 836–842, paras. 22, 63–72.

[68] A carrier that was over 15% directly or indirectly owned by a foreign telecommunications entity, or on whose board of directors a representative of such a foreign entity sits, was considered "foreign-owned." *Id.* at 842, para. 72, n.74.

[69] In brief, non-dominant international carriers were subject to a general streamlining of regulatory burdens (not forbearance from filing as applicable to non-dominant domestic carriers). For example, dominant carriers were required to obtain new Section 214 certification for any additional circuits, while non-dominant carriers were only required to obtain initial Section 214 authority. *Id.* at 844, para. 78. Dominant carriers were also required to comply with a longer notice period and to cost-support their tariffs with data, while tariffs of non-dominant carriers were presumed lawful. *Id.* at 843–844, paras. 76–77.

[70] *Id.* at 842, paras. 72–74.

[71] *Regulation of Int'l Common Carrier Services*, Report and Order, 7 FCC Rcd 7331, 7332, para. 4 (1992). The Commission specifically did not modify the present dominant status of AT&T and Comsat

Continued

35. An international carrier affiliated with a monopoly carrier in the destination market is presumptively classified as dominant, and an international carrier with no affiliation with a foreign carrier in the destination market is presumptively classified non-dominant.[72] If a U.S.-international carrier is affiliated with a foreign carrier that is not a monopoly in the destination market, the Commission will scrutinize the situation more closely to determine whether the foreign carrier possesses the ability to discriminate against other U.S.-international carriers.[73]

36. In addition, a presumption of non-dominance applies to U.S.-international carriers, regardless of any foreign affiliation, if they provide service on a particular route solely through the resale of an unrelated facilities-based U.S.-international carrier's switched services.[74] Finally, each foreign-affiliated U.S.-international carrier is required to certify in its section 214 application that it has not agreed to accept special concessions from any foreign carrier or government on any international route. This requirement discourages such a carrier from attempting to gain an unfair competitive advantage on unaffiliated routes.[75]

37. In developing the new policy, the Commission noted that U.S. carriers had been increasingly successful in obtaining operating agreements for IMTS service and that carriers such as MCI and Sprint were competing with AT&T in 19 of top 20 foreign markets.[76] The Commission also noted that foreign Administrations were making increased efforts to privatize, to open their markets to new providers, and to take other steps to make their markets more competitive for the provision of telecommunications services.[77] Accordingly, the Commission sought to redirect regulation to those instances where a relationship between a U.S.-international carrier and a foreign carrier presented some substantial risk of anticompetitive conduct.[78] This new policy addressed the degree to which regulatory burdens should be imposed on U.S.-international carriers regardless of ownership, but not the broader issue of whether or under what circumstances foreign-owned carriers should be permitted entry into the U.S. market.[79]

4. The Facilities and Services Authorization Process

a. *Section 214 authorizations.* 38. The Commission regulates entry into the U.S. market for international common carrier services through its section 214 process. Under this Section, common carriers seeking to provide international services must obtain authorization from the Commission to build facilities, acquire capacity on existing facilities, and provide service.[80] The governing standard is whether grant of the authorization would serve the "present or future public convenience and necessity."[81]

39. Guided by this broad public interest standard, the Commission's determinations are made on a case-by-case basis, according to the specifics of each section 214 application. This process is the primary mechanism whereby the Commission confronts issues related to foreign ownership, affiliations with foreign monopolies, and the impact on U.S.-owned carriers and consumers of permitting certain service offerings by such carriers. Increasingly, that examination has invited discussion of complex ownership schemes, the demonstrable benefits of broad open entry into the U.S. market, and the role of Commission action in the long term development of the ITS marketplace.

40. The Commission has attempted to deal with these questions by granting the authorizations so that the service in question can be provided for the benefit of U.S. consumers, while imposing specific conditions to ensure that these benefits will not be undermined by anticompetitive behavior in the international arena. For example, in 1991, the Commission considered a section 214 application to lease and operate facilities to provide international switched services.[82] Even though the applicant, Atlantic Tele-Network, Inc. (ATN), is a 100 percent U.S.-owned corporation, the Commission was concerned that ATN, with a controlling share (80 percent) of the sole provider of local services in Guyana, could exclude new U.S. entrants into the U.S.-Guyana market or provide unequal interconnection for competing U.S. carriers.[83] Therefore, the Commission conditioned its approval: It required ATN to seek authorization for additional circuits or private-line services; submit quarterly revenue and traffic reports; file any operating agreements; file a tariff pursuant to section 203 of the Communications Act; and accept only its proportionate share of return traffic.[84] Moreover, ATN was forbidden from handling or interchanging any traffic denied to other U.S. carriers.[85]

41. Recently, Cable & Wireless Communications, Inc. (CWCI) received only a conditional grant to resell, pursuant to contract, international switched voice and data communication services of TRT/FTC International, Inc. (TRT/FTC).[86] The conditions were premised on the Commission's concern regarding the potential for preferential treatment among the parties, and consequently, discrimination against competing U.S. carriers. Accordingly, CWCI's application was granted subject to the requirement that the contract, or summary of the contract, between CWCI and TRT/FTC be publicly filed in accordance with section 203 of the Communications Act. Furthermore, a condition was imposed that the services must be generally available to similarly situated customers on the same terms and conditions.[87]

b. *Authorizations for submarine cable landing licenses.* 42. In reviewing its submarine cable licensing policies in the mid-1980s, the Commission again looked to domestic pro-competitive policy. From the domestic arena, it borrowed the concept of permitting the development of private, non-carrier facilities. The Commission determined that alternative "private cable" systems, in which bulk capacity would be sold or leased on a non-common carrier basis, would introduce more meaningful competition in the provision of transmission facilities. It reasoned that this increased competition would

for certain international services. *Id.* at 7331, n.2. The Commission otherwise declined to make any specific rulings on the regulatory status of particular carriers on any given route, but provided that they could petition the Commission for a change in status from dominant to non-dominant, based on the criteria set forth in the order. *Id.* at 7337.

[72] *Id.* at 7334, para. 19.

[73] *Id.*

[74] *Id.* at 7335, para. 31.

[75] *Id.* at 7335, para. 27.

[76] *Regulation of Int'l Common Carrier Services*, Notice of Proposed Rulemaking, 7 FCC Rcd 577, 580, para. 23 (1992).

[77] *Id.* at 580, paras. 23–25.

[78] *Id.*

[79] *See Regulation of Int'l Common Carrier Services*, 7 FCC Rcd 7331, 7332, para. 4 n.9 (1992).

[80] 47 U.S.C. 214(a) (1988).

[81] *Id.*

[82] *Atlantic Tele-Network, Inc.*, Order, Authorization and Certificate, 6 FCC Rcd 6529 (Chief, Common Carrier Bureau 1991).

[83] *Id.* at 6529–6531, paras. 6, 21, 22.

[84] *Id.* at 6532, paras. 23–24.

[85] *Id.* at para. 24.

[86] *Cable & Wireless Communications, Inc.*, Order, Authorization and Certificate, 7 FCC Rcd 6653 (Chief, Common Carrier Bureau 1992). This order was premised on the Commission's treatment of CWCI as a dominant carrier under its 1985 policy. While there are new rules that would potentially alter the filing requirements of certain foreign-owned carriers, these carriers must first petition the Commission for a change of status from dominant to non-dominant. *Regulation of Int'l Common Carrier Services*, Report and Order, 7 FCC Rcd 7331, 7337, paras. 47–48 (1992).

[87] *Cable and Wireless Communications, Inc.*, *supra*, 7 FCC Rcd 6653, paras. 5, 7.

provide many of the same user benefits that were offered by the private sale of domestic satellite transponders, including stimulating technology and service development.[88] The Commission ruled, however, that a private cable operator must obtain a landing license from the Commission before connecting a submarine cable to the United States. Thus, privately owned cables used on a non-common carrier basis require a landing license, but not section 214 authority, while cables used for common carrier purposes need both.[89]

43. The Commission's continuing concerns about maintaining control of the U.S. end of submarine cables and ensuring U.S. participation in the manufacturing, installation, and maintenance of cables, is reflected in its imposition of licensing conditions on some foreign entities. For example, in one case, the Commission imposed conditions to encourage participation by U.S. interests in the construction of the cable and to ensure majority U.S. ownership and control of the cable at the U.S. end.[90] In another case, the Commission allowed the transfer of cable landing rights and section 214 authorizations from a U.S. to a foreign-owned company, with the condition that the transfer comply with the Commission's regulatory filing requirements for international dominant carriers.[91] Recently, the Commission approved the proposed sale of assets of a domestic corporation to an entity with seventy-nine percent indirect ownership by Spain's government-controlled monopoly telephone company. The Commission imposed a number of conditions to prevent discrimination against competing U.S. carriers, including a prohibition against routing traffic to or from third countries without first seeking section 214 authorization.[92]

D. Limits of U.S. ITS Regulation

44. The Commission's efforts over the past 12 years have successfully advanced competition in the U.S. ITS market and represent a clear effort to ensure that regulation is responsive to changing market conditions. Nevertheless, there are a number of ITS issues, particularly those related to trade and international competitiveness, that are not addressed by the Commission's regulatory efforts.

45. Prior to raising specific questions regarding that gap, it is important to examine other factors affecting the environment for ITS. Accordingly, the following two sections describe (a) technological changes and market structure affecting overall ITS policy-making and (b) efforts by the Executive Branch to address trade and international competitiveness issues through non-regulatory mechanisms.

III. Changing Market Environment

46. The market environment for ITS in the United States and foreign markets has been shaped by evolving regulatory regimes (discussed above), changing telecommunications technologies, and related user demands. By way of background, the following section outlines some key developments in technology and ITS markets.

A. Developments in Technology

47. Advances in telecommunications technology have significantly expanded the range of telecommunications services available, blurring the traditional distinctions between voice and data, and between mobile and fixed communications. The availability of new services has, in turn, stimulated demand for further technological innovation, putting further pressure on government policy-makers. The development of these new advanced-technology capabilities has been prompted, in large part, by the increasingly global economy and the corresponding telecommunications needs of global businesses operating in that economy with its worldwide production and distribution networks. The ability to communicate rapidly, reliably, and inexpensively can be a source of significant competitive advantage for manufacturing or service companies with multinational operations. Among U.S. companies competing globally, the importance of telecommunications to their operations creates strong demand for the same high quality and efficiency (including cost) of services internationally that they currently enjoy domestically.

48. In the last decade, broadband services, which make possible a wide variety of business applications ranging from voice to high speed data to video teleconferencing, have emerged in the international services marketplace. Smaller satellite earth stations, combined with more powerful and sophisticated satellites, have made advanced telecommunications services available where no service existed previously. Integrated Services Digital Network (ISDN) technology is emerging with the capability of providing a wide range of services, from narrowband to broadband, on an as-needed basis. In addition, the now widespread availability of high quality, digital private leased lines has offered users further control over service availability and network design.

49. Technological advances have also dramatically increased the capacity of facilities. In the case of submarine cables, the introduction of fiber optic technology has made available hundreds of thousands of additional circuits, capable of handling diverse demands (*e.g.*, voice, bulk data transfer, video conferencing, realtime computer interlinks).[93] Relatively low-cost branching points can be used to connect multiple countries directly to international cable trunks. Low-cost, repeater-less fiber optic cables have been developed for short-distance applications, and laser pump technology will massively expand the capacity of inter-continental cables. Such increases in capacity have altered the economies of scale of services and service areas.

50. In the case of satellite systems, technological improvements such as digital compression have increased the independent voice channel capacity of one 64 kilobit/s bearer channel. Depending upon frequency reuse techniques, satellite transponder configuration, and other technical characteristics, a modern communications satellite may support as many as 90,000 circuits.[94]

51. New forms of mobile satellite communications have been proposed to make "global" communications a

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[88] *Tel-Optik Ltd.*, Memorandum Opinion and Order, 100 FCC 2d 1033, 1040–41, para. 18 (1985).

[89] *See id.* at 1046–48, paras. 27–31.

[90] *Pacific Telecom Cable, Inc.*, Cable Landing License, 4 FCC Rcd 8061, 8069 (1989).

[91] *Western Union Corp. and World Communications, Inc.*, Memorandum Opinion and Order, 4 FCC Rcd 2219, 2221, paras. 14–15 (Chief, Common Carrier Bureau 1989).

[92] *Commission Approves Assignment of Authorizations of Telefonica Distancia De Puerto Rico*, Memorandum Opinion, Order, Authorization and Certificate, FCC 92–553 (released Dec. 18, 1992). The Commission noted that anticompetitive conduct is unlikely because the assets include only a limited number of circuits, and traffic originates only from Puerto Rico and the U.S. Virgin Islands to overseas points, with no interconnected international private line service.

[93] U.S. Dep't of Commerce, NTIA Pub. No. NTIA-CR–91–42, *1990 World's Submarine Telephone Cable Systems* 43 (1991) (compendium prepared by Herbert H. Schenck & Leo Waldick of Undersea Cable Engineers, Inc. for the Nat'l Telecommunications and Information Admin.).

[94] Despite the rapid growth in the deployment of international fiber optic cables, satellites continue to play a critical role in the provision of ITS. Global beams allow the provision of service to large, lightly populated area where running fiber or other terrestrial facilities is impractical. Spot beams concentrate communications capabilities on smaller, more discrete areas with larger amounts of traffic. Also, satellite point-to-multipoint connectivity provides practical efficiencies over other technologies for services such as video distribution. Finally, satellites provide a valuable back-up for traffic carried over cable facilities, which are subject to interruptions in service from physical damage to the cables caused by a number of sources, including fishing boats and sharks.

reality. For example, several U.S. companies have proposed Low-Earth Orbit (LEO) satellite systems to serve portable terminals with a combination of voice, data, and positioning services on a global basis. Most of these proposals would use a dual-purpose handset that would seek first to utilize terrestrial cellular systems and use the LEO satellite systems only when terrestrial cellular service was not available.

52. In turn, service providers are seeking to apply advanced technologies to meet this growing demand for global telecommunications services. Advanced undersea cable and satellite facilities are being interconnected to create global networks, multiple service providers from different countries are forming strategic alliances to provide services on a global basis, and new entrants are tapping the growing demand for lower-cost ITS.[95]

53. The pace of technological change is clearly affected by differences in the regulatory structures of different countries. Nonetheless, in the developing global economy, rapid changes in technology, together with associated changes in customer demand and commercial organization, also have an increasingly serious impact on the effectiveness of those regulatory structures. Service providers and their major customers are adopting a strategy of maximizing available technological and commercial opportunities in the most liberal markets in order to secure the ITS capabilities they need to compete in the global economy. Government policy-makers, particularly regulatory policy-makers, ignore this trend at the peril of their country's international competitiveness.

B. U.S. Market Structure for ITS

54. Over the past 12 years, pro-competitive regulatory initiatives have produced significant positive changes in the U.S. ITS market. New service providers have entered the market, offering business and residential consumers alternatives to the traditional carriers. Estimated total U.S. international revenues have increased from $2.25 billion in 1980 to $9.3 billion in 1991, nearly $10.5 billion in 1992, and are expected to increase to $11.9 billion in 1993.[96] These figures reflect significant growth in non-basic as well as basic market segments. For example, a variety of enhanced service providers (*e.g.*, IBM, EDS, and GEIS) have pursued an international business strategy in response to growing user demands for international services. And many large business users (*e.g.*, banks, insurance companies, and major manufacturers) have greatly expanded their private international networks to facilitate the increasingly global nature of their commercial activities.

55. According to the U.S. Department of Commerce 1992 Industrial Outlook, there are approximately 350[97] ITS providers in the United States, of which some seventy-one companies (including some wholly or partially foreign-owned firms) provide international basic voice telephone service, either on a facilities or resale basis.[98] In international basic service, for example, MCI and Sprint actively compete with AT&T for traffic to virtually all major points around the globe.[99] Rates for IMTS declined from $2.25 per minute in 1975 to $1.20 per minute in 1990,[100] and leased lines rates decreased substantially. IMTS revenues increased, as a result of increased demand and new service offerings, from $500 million in 1975 to $4.3 billion in 1990, representing an annual compound growth rate of 14.2 percent.[101]

56. Increasingly, foreign companies are looking to competitive opportunities in the United States. What follows are some examples of foreign companies that participate in the U.S. ITS market.[102] British Telecom offers private line and private carriage services, as well as international value-added network services.[103] British-owned Cable and Wireless (C&W), among the top seven U.S. long distance carriers,[104] currently provides international service on a resale basis and is seeking to expand its international services operations.[105] C&W also holds twenty percent ownership interest in the U.S. end of a private Pacific submarine cable.[106] TRT/FTC International, created as a result of a 1990 merger, is 14.9% owned by France Telecom and offers international services on both a facilities and resale basis.[107] WorldCom, a Swiss-owned company, was authorized to provide international facilities-based services in 1989[108] and has recently been acquired by IDB. In addition, there have been recent submarine cable landing license applications involving foreign ownership interests.[109]

57. Significant restrictions on domestic and international services competition remain in the United States. For example, local exchange telephone services, representing about two-thirds of the U.S. basic services market, are, in nearly all cases, provided by carriers with government-sanctioned monopolies or at least some degree of government protection from full competition. Economic and technological changes in the marketplace and regulatory reforms at both the state and the federal level, however, are paving the way for competition in the local exchange.[110]

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[95] While the provision of basic ITS has generally been a joint undertaking between national carriers in the originating and terminating countries, a newer trend is for carriers to form strategic alliances or joint ventures on a multi-country basis to provide such services as, for example, "one-stop shopping", which permits customers to deal with only one carrier for their services needs and related billing. Examples of such arrangements include the Dutch-Swedish Unisource, the multi-carrier Infonet, the BT-proposed Syncordia, and the German-French Eunetcom.

[96] These figures include IMTS, telex, and telegraph services, as well as specialized services such as private line, ISDN, virtual networks, and international value-added network services. Int'l Trade Admin., U.S. Dep't of Commerce, *U.S. Industrial Outlook '93: Business Forecasts for 350 Industries* 28–1 (1993).

[97] Int'l Trade Admin., U.S. Dep't of Commerce, *U.S. Industrial Outlook '93: Business Forecasts for 350 Industries* 28–3 (1992) (*1992 U.S. Industrial Outlook*).

[98] Information obtained from the Commission's Common Carrier Bureau, based on its traffic database for 1991.

[99] In addition, MCI and Sprint both acquired data networking firms (Infonet and Telenet), which provide both national and international services.

[100] *See Trends in the International Communications Industry, 1975–1990*, Common Carrier Bureau, Industry Analysis Division, FCC (Oct. 4, 1991).

[101] *Id.* at 2.

[102] This is intended as an illustrative overview, rather than an exhaustive listing, of foreign participation in the U.S. ITS market. Parties are requested to provide more detailed data regarding the services and facilities provided by foreign-owned entities operating in the U.S. ITS market.

[103] BT held 16 percent of the U.S. public data networking market in 1991 through its ownership of Tymnet. *1992 U.S. Industrial Outlook*, *supra* note 97, at 28–6.

[104] *Id.* at 28–6.

[105] Cable and Wireless Communications, Inc., Applications for Authority, *in* File Nos. ITC–92–065, ITC–92–066 before the Federal Communications Commission (filed Oct. 23, 1991).

[106] The Northern Pacific Cable was authorized in 1988. *Pacific Telecom Cable, Inc.*, *supra*, 4 FCC Rcd 8061.

[107] *FTC Communications, Inc.*, 2 FCC Rcd.7513, 7513 para. 3 n.8 (1987).

[108] *Western Union Corp. and World Communications, Inc.*, Memorandum Opinion and Order, 4 FCC Rcd 2210 (Chief, Common Carrier Bureau 1989).

[109] *See, e.g.*, *supra*, note 92; OPTEL Communications, Inc., Application for Authority, *in* File No. S-C-L-92-004, before the Federal Communications Commission (filed May 8, 1992).

[110] While not the focus of this Notice, cable television has heretofore generally also been offered on a franchised monopoly basis in this country. The recently enacted Cable Television Consumer Protection and Competition Act of 1992 prohibits local franchise authorities from granting exclusive franchises to cable companies or unreasonably refusing to grant additional competitive franchises to cable systems. Cable Television Consumer Protection and Competition Act of 1992, Pub. L. No. 102–385, § 7(a)(1), 106 Stat. 1460, 1463 (to be codified in the Communications Act of 1934, as amended, 47 U.S.C. § 541(a)(1) (1992)). The 1992 Act did not repeal the 1984 Cable Act's prohibition on telephone companies offering cable service. See

With respect to foreign participation in the overall U.S. telecommunications market, the restrictions of section 310(b) of the Communications Act remain in place, limiting foreign investment in companies holding certain U.S. radio-based licenses.[111] These restrictions apply not only to traditional radio-based common carrier facilities, such as microwave links, but also to rapidly growing wireless communications services, such as cellular radio (if they are classified as common carrier services).[112] Moreover, firms with foreign affiliations participating in some segments of the U.S. ITS market are still more heavily scrutinized throughout the licensing process and may be subject to different regulatory treatment, including, under certain circumstances, regulation as a "dominant" carrier or the imposition of operating and/or reporting conditions on cable landing licenses or section 214 authorizations.[113]

58. Nevertheless, the U.S. telecommunications market is, overall, increasingly open and competitive. In particular, the presence of a significant number of foreign firms attests to the openness of the U.S. ITS markets. Those firms operate under a regulatory regime requiring efficient, non-discriminatory access and interconnection to local networks (including cost-based rates, unbundling of tariffs, network information disclosure, separate cost accounting, and other safeguards against improper cross-subsidization). This pro-competitive regulatory regime is generally not duplicated throughout the rest of the world.

C. Foreign Market Structures for Domestic and International Telecommunications Services

59. The pro-competitive restructuring of the U.S. domestic and ITS markets was not immediately matched by comparable liberalization in foreign markets. Foreign PTTs and their governments initially resisted the "export" of U.S. pro-competitive deregulatory policies. With respect to ITS, many PTTs were reluctant to enter into operating agreements with new U.S. carriers, often preferring to maintain long-established relationships. In addition, most PTTs maintained restrictive policies regarding the use of international leased circuits, out of concern that use of these circuits would "bypass" their facilities and service monopolies, resulting in "creamskimming" of revenues.

60. By the mid-1980s, however, as telecommunications began to be recognized as a critical element in overall economic growth, more foreign governments began to focus attention on the benefits to be gained from injecting some competition, even on a limited basis, into their domestic and international telecommunications sectors. Business users in foreign markets became more vocal about their need for advanced telecommunications services as a way of enhancing their competitiveness. Increasingly, foreign countries began to introduce some liberalizing reforms to their telecommunications regimes, although restrictions on competition in domestic and international basic services were generally retained.

61. For example, in a series of actions between 1981 and 1987, the United Kingdom (UK) created a duopoly for the provision of telecommunications services by authorizing a second provider, Mercury (owned by Cable and Wireless), to compete with the incumbent monopolist, British Telecom. The UK also liberalized the provision of terminal equipment and value-added networks and services, established an independent regulatory body, began licensing cable television companies and permitted them to provide non-cable telecommunications services within their franchise areas, and issued licenses to two cellular radio companies.

62. In Japan, the government in 1985 abolished its domestic and international telecommunications service monopolies and sought to encourage new market entrants by creating a regulatory dichotomy based on ownership versus leasing of facilities. By 1989, there were three facilities-based (Type I) carriers providing international telephone and leased circuit services, and by 1991, there were 25 companies (Special Type II) offering value-added services over circuits leased from Type I carriers.[114] In addition, the provision of terminal equipment and value-added services were liberalized.

63. Canada and the European Community (EC) initiated telecommunications liberalization in the terminal equipment and value-added services market segments. Canada permitted the resale and sharing of leased circuits in 1984 for the provision of enhanced services and opened the terminal equipment market to competition. In 1987, the EC issued a "blueprint" for competition in telecommunications equipment and services,[115] which subsequently took operational shape in the form of specific Directives to be implemented over the next several years by the twelve EC member states.[116] In addition to introducing competition in several market segments, the EC Commission has sought to harmonize network infrastructures among the twelve member states (e.g., the Open Network Provision concept). More recently, the EC Commission has targeted satellite communications for further liberalization.[117]

64. Pro-competitive regulatory liberalization in foreign markets, albeit in many different forms, was a clearly identifiable trend by the late 1980s. This trend was complemented by new institutional distinctions between the regulatory and operational functions of telecommunications administrations and, in a few cases, with the application of new forms of pro-competitive regulatory safeguards (such as separate cost accounting and tariff unbundling, for example). Moreover, "privatization"—that is, the conversion of the telephone operating entity from a state-owned to a privately-owned enterprise—was a major factor in some countries. The UK and Japan have privatized substantial portions of their government-owned telephone companies, with plans to convert 100% to private ownership in the future,[118] while Germany is in the midst of

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Cable Communications Policy Act of 1984, Pub. L. No. 98–549, § 2(b), 98 Stat. 2779, 2785 (codified in the Communications Act of 1934, as amended, 47 U.S.C. § 533(b) (1988)).

[111] 47 U.S.C. 310(b) (1988).

[112] See supra para. 13 for a discussion of Section 310.

[113] See supra Section II.

[114] Ministry of Posts and Telecommunications, Japan, White Paper on Communications in Japan 11 (1992).

[115] *See, e.g.*, Green Paper on the Development of the Common Market for Telecommunications Services and Equipment (COM(87)290, 30.06.87), *noted in* Status Report on EC Telecommunications Policy, Commission of the European Communities, XIII/50–EN(92), 5 (Brussels, Jan. 1992).

[116] In a continuing process, the EC Commission has issued Directives on competition in terminal equipment, mutual recognition of type approval of terminal equipment, telecommunications services, a framework for open network provision (ONP), and a separate ONP directive on leased lines. ONP is also intended to apply to packet-switched data services, voice telephony, and ISDN.

[117] *See, e.g.*, Green Paper on a Common Approach in the Field of Satellite Communications in the European Community (COM(90) 490, 20.11.90), *noted in* Status Report on EC Telecommunications Policy, Commission of the European Communities, XIII/50–EN(92), 17 (Brussels, Jan. 1992).

[118] In the UK, for example, the government began selling its shares in BT in 1984 and the sale of its remaining 22 percent is under consideration. Japan began privatizing the Nippon Telegraph and Telephone Company (NTT) in 1985, although the government maintains over 50 percent ownership and NTT retains the predominant share of the domestic services market. In 1992, Japan passed laws to allow up to one-fifth foreign investment in NTT and the international carrier, KDD.

government review of privatization possibilities.[119]

65. While these trends were initially limited to a handful of large countries, this is no longer the case. Indeed, there have been significant developments recently in smaller and less economically developed countries. For example, some Latin American, newly independent Eastern European nations, and smaller or less developed Asian nations have begun to consider privatization and other means of attracting foreign investment (such as opening certain market segments to competition) in order to upgrade their public network infrastructure and improve their overall national economic performance.[120]

66. The mobile services market was another market segment in which movement toward liberalization occurred. For example, a small number of countries began to make regulatory changes to introduce further competition in market segments such as cellular radio services.[121]

67. Basic voice telephone services—still the largest and most profitable market segment in most countries—typically remain subject to restrictions on both competition and foreign investment. Although a few countries, including the UK, Sweden, Australia, Japan, Canada, and New Zealand, have begun to apply pro-competitive policies to basic telephone services,[122] monopoly provision and restrictions on participation by foreign firms in this market segment nevertheless remain the rule, and competition the exception.

IV. Market Access Initiatives of the Executive Branch

68. From the mid-1980s to the present, the United States Government (USG) has engaged in a variety of bilateral and multilateral consultations, discussions, and negotiations aimed at obtaining access for U.S. companies to foreign telecommunications markets and to this end, encouraging a more liberal and pro-competitive telecommunications regulatory structure worldwide. Specifically, in the services area, USG goals include: Increased competition in basic services, on both a facilities and resale basis; competition in the provision of enhanced (or value-added) services; access to underlying network transport facilities in order to provide enhanced and other telecommunications-dependent services (*e.g.*, banking, travel, and tourism); transparency in regulatory development and implementation; and the right to invest in telecommunications ventures in foreign markets.

A. Trade Negotiations

69. The broadest USG trade effort to seek access to foreign telecommunications services markets has occurred in the General Agreement on Tariffs and Trade (GATT) Uruguay Round negotiations. Through GATT, the USG has developed a multilateral trade regime for trade in services, including telecommunications. Three separate sets of negotiations related to telecommunications are underway: (1) GATT Parties (now 108) have negotiated a Services Framework agreement to govern international trade in services; (2) the "request/offer" negotiations discussed below; and (3) because of the dual nature of telecommunications as both a service in itself and a means to provide other services (*e.g.*, financial transactions, travel reservations), the Parties have also negotiated a Telecommunications Services Annex to the Services Framework Agreement, which seeks to secure non-discriminatory access to and use of telecommunications network facilities and services for those services a Party has included in its schedule of commitments.

70. Both the Framework and the Annex have been under intense negotiation for the past three years. In the "request/offer" phase of negotiations now underway, Parties negotiate bilaterally to obtain commitments from other Parties to allow access to their markets for specific categories of services consistent with the principles of national treatment (*i.e.*, receiving the best treatment offered to domestic firms) and Most-Favored Nation (MFN) treatment (*i.e.*, treating all Parties in the same manner). Under the Telecommunications Services Annex provisions, Parties must then provide access to and use of basic network facilities for all such scheduled services (*e.g.*, banking, tourism).

71. With respect to telecommunications services, Parties to date have generally offered commitments related solely to enhanced, or value-added, services. The USG, however, has "offered" to negotiate a binding commitment with respect to its long-distance basic services market,[123] if a significant number of Parties with major telecommunications markets do likewise. If this offer is pursued by other Parties, these negotiations would likely take place on an extended two-year timetable, to be completed no later than January 1, 1995, during which time the Commission's current regulatory authority over these services would be unaffected.

72. Bilateral telecommunications trade negotiations have been undertaken in accordance with the provisions of the Telecommunications Trade Act of 1988.[124] The Trade Act sets forth national policy goals for greater telecommunications market access within specific market segments (*e.g.*, basic and value-added services, customer premises equipment) in foreign markets. The Trade Act also addresses specific trade barriers (*e.g.*, high equipment tariffs, non-transparent standards-setting processes, lack of right of establishment for U.S. companies) that should be remedied within any identified markets.

73. These Trade Act negotiations have produced some success in individual markets. Bilateral negotiations were

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[119] Consensus has been reached within the government on the need for privatization, but the form is still under discussion (*i.e.*, public holding company versus a share holding corporation).

[120] For example, Chile, Venezuela, Argentina and Mexico have privatized their carriers, which nonetheless retain monopoly status for basic services. Pakistan is in the midst of privatizing its monopoly carrier and Singapore will begin privatizing in 1993, but will also retain a monopoly carrier structure. Indonesia allows private companies to assist the now-duopolistic national basic services carriers (both will remain state-owned) through revenue-sharing schemes for infrastructure construction, and India has announced plans to privatize its national carrier, but will maintain a national monopoly.

[121] In Asia and Latin America especially, the mobile services market may be the only area where competition is allowed for voice services. Often mobile services act as a substitute, not a complement, to basic voice services carried over a national wireline infrastructure. In Asia (*e.g.*, Japan, Indonesia, Hong Kong, Malaysia, Taiwan, New Zealand, Australia, Thailand, Korea, India, and Pakistan) and in Latin America (*e.g.*, Venezuela, Argentina, Mexico, Chile, and Peru), many countries have introduced or are in the process of introducing various forms of mobile services competition. Among U.S. companies, Motorola, the Regional Bell Operating Companies, Millicom, McCaw, and GTE are all playing leading roles in the Asian and Latin American cellular market developments.

[122] For example, the UK has permitted local and domestic long distance competition and, under certain conditions, international resale. Australia created a domestic duopoly for network facilities and allows full domestic and international resale. Resale and some long distance competition is now permitted in Canada. Japan allows limited competition in domestic, long distance, and international services, but maintains foreign ownership restrictions and prohibitions on the resale of basic voice telephony services. Sweden and New Zealand have affirmatively opened all market segments, including international switched services, to competition. Hong Kong announced full competition in non-voice basic services in July 1992 (voice to be added in 1995).

[123] As previously noted, this market is currently open to competition. However, there is no treaty commitment to maintain that status. It is that commitment which is at issue in the GATT process.

[124] Telecommunications Trade Act of 1988, Public Law 100–418, 102 Stat. 1216 (1988), *reprinted in* 19 U.S.C. 3101 *et seq.* (1988).

held with Korea and the EC between 1989 and 1992. As a result, a comprehensive agreement was reached with Korea in February, 1992, while telecommunications services issues with the EC were subsumed under the GATT Services negotiations, and some telecommunications equipment issues remain outstanding.

74. Other major negotiations include the North American Free Trade Agreement (NAFTA). In October 1992, the United States, Mexico and Canada concluded the NAFTA negotiations, which contain an entire chapter liberalizing investment in and regulation of enhanced, as opposed to basic, telecommunications services. There have also been a number of bilateral negotiations with select countries on the provision of International Value-added Network Services (IVANs). Such negotiations focus on the regulatory provisions affecting the use of international leased circuits by business users and IVANs providers in the United States and foreign countries. Beginning with the United Kingdom in 1986, the USG has successfully concluded IVANs negotiations with several countries, including Japan, Hong Kong, Korea, the Netherlands, and Germany. Consultations in progress with Sweden and Australia are expected to lead to IVANs arrangements in the near future, and other countries are under consideration for an IVANs arrangement.

B. Telecommunications Policy Consultations

75. Multilaterally, the USG has advanced telecommunications policy reform through the preeminent international organization dealing with telecommunications, the International Telecommunication Union (ITU).[125] Primarily oriented towards the development of international standards, facilities harmonization, spectrum use coordination, and infrastructure development issues, the ITU also addresses a number of tariffing and policy questions which are related to the International Telecommunications and International Radio Regulations. Over the past ten years, the United States has forcefully advocated regulatory liberalization in such key areas as: reducing the scope of international telecommunications regulations; liberalizing the terms and conditions for use of international leased circuits; reorienting the international accounting and settlements process toward the principles of cost-based pricing, transparency, and non-discrimination; and implementing technological innovations.

76. Some specific examples of success in these areas include: Acceptance of more liberal, rather than restrictive, new international telecommunications regulations through the World Administrative Telegraph and Telephone Conference (WATTC);[126] and the revision of CCITT D.1 Recommendation on international leased circuits to permit more liberal use of such circuits among like-minded countries, which is critical to the provision and use of IVANs. More recently, a revised CCITT D.140 Recommendation has been approved, advocating the application of the principles of transparency, non-discrimination, and cost-oriented pricing to international accounting rates.[127]

77. In addition, the USG has engaged in periodic bilateral policy discussions with a number of European countries, Japan, Canada, Mexico, Brazil, and other countries in Latin America, in which issues related to telecommunications liberalization are discussed. In addition to these formal sessions, USG officials conduct a large number of less formal discussions with Ministers of Communication and other telecommunications policy officials from foreign countries to exchange views on the pace and direction of telecommunications liberalization.

C. Summary

78. Since the mid-1980s, while the scope of competition, including foreign entry, in the U.S. ITS market has been progressively expanded, the USG has engaged in a continual process of seeking further opening and liberalization of telecommunications markets in foreign countries. USG trade and telecommunications policy efforts have achieved some measure of success—*e.g.*, more regulatory transparency, lower equipment tariffs, improved access to network facilities to provide enhanced services, resolution of market-specific trade barriers. Some of these successes were hard won and signified fairly dramatic negotiating achievements in the face of considerable resistance by the foreign telecommunications policy-makers. Other changes were made, in large part, in response to internal pressure in foreign countries— from users who wanted to enjoy the benefits of competition and from policy-makers who wished to use competition to stimulate development in their telecommunications sectors.

79. However, USG efforts have not yet achieved the degree of openness and liberalization that the United States ultimately desires in the international telecommunications marketplace. For example, the provision of long-distance services, which is fully open to competition in the United States, is substantially restricted in most countries. The concept of private carriage, which permits providers to offer services on a non-common carrier basis in the U.S. market virtually free of regulatory restrictions, is not an option in the vast majority of other countries. Moreover, competition in the provision of international basic services is substantially limited except in a few instances.

80. USG efforts to secure greater access for U.S. companies to foreign telecommunications markets have moved forward while the Commission has been reshaping the U.S. ITS regulatory regime. The increasing complexities of the international telecommunications environment have heightened interactions, and the potential for conflict, between the trade and diplomatic initiatives of the Executive Branch and the Commission's regulatory efforts. For example, the timing and direction of a Commission decision in any given regulatory docket may have important implications (negative or positive) for the goals and strategies being pursued by the Executive Branch.[128] These tensions are explored in the form of questions in Section V below.

V. Policy Debate/Specific Questions

81. The combination of factors noted above—in particular, the persistent regulatory and market asymmetries between the U.S. and foreign countries—suggest that U.S. ITS regulation and U.S. international telecommunications policy more broadly are at a crossroads.

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[125] Comparable efforts toward regulatory reform by the Executive Branch are directed toward the work of the Organization for Economic Cooperation and Development (OECD), the Asia Pacific Economic Cooperation (APEC) Working Group on Telecommunications, the Organization for American States Conference on Inter-American Telecommunications (CITEL), Inmarsat, and Intelsat.

[126] *International Telecommunication Regulations: Final Acts of the World Administrative Telegraph and Telephone Conference, Melbourne 1988*, International Telecommunication Union, Geneva, 1989.

[127] *See* para. 26, *supra*.

[128] *See, e.g.*, Letter from Carla A. Hills, U.S. Trade Representative, to Alfred Sikes, Chairman, Federal Communications Commission (Apr. 17, 1992); Letter from John C. Danforth and Bob Packwood, U.S. Senators, to Alfred Sikes, Chairman, Federal Communications Commission (July 28, 1992).

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82. As discussed earlier, there is now substantial debate about the scope and purpose of U.S. regulation—whether action in discrete regulatory dockets in isolation does or does not constitute an adequate response to the array of ITS-related issues confronting the United States.[129] On one hand, U.S. regulation is under increasing pressure to take the new global dynamic into account. On the other hand, the limits of regulation are becoming more evident.

83. NTIA has identified the following broad, interrelated categories of issues for comment through this Notice. These include: (1) A factual record of the ITS market in the U.S. and abroad; (2) application of specific regulatory policies to ITS; (3) the role of the Commission; and (4) potential actions to institute changes in regulation, including improved coordination with Executive Branch policy goals.

84. Parties are also invited to identify and address other issues that they believe are relevant to the concerns and themes discussed in this Notice. Parties are strongly urged, however, to focus their comments with some specificity. Factual assertions should be supported with data and legal/regulatory assertions with citations to available sources. Assertions about particular concerns, *e.g.*, potential anticompetitive (or other improper) behavior in U.S. markets by affiliates of foreign carriers with protected positions in their home markets, should be described precisely, with the concern and the proposed policy response, as well as the link between the two, identified clearly. Where possible, general observations should be illustrated by specific examples. In this way, we hope that a strong record will be compiled through this Notice, which we believe is necessary for both government policy makers and industry participants to adequately address the complex issues raised in this area.

A. Market Structures

85. Based on the factors discussed above, it appears that the degree of procompetitive deregulation in the U.S. ITS market has not yet been matched by a general opening and liberalization of foreign markets. It is true that several countries have undertaken significant transformations in their regulatory environments, and, in a few cases, have arguably gone beyond even the United States in certain market segments. Nevertheless, most countries have introduced only limited forms of competition into the basic services market. Even the trend toward privatization and foreign investment in some countries has not diminished government control or led to the introduction of competition in basic services. This is particularly true in the international basic services market, where restrictions on foreign participation and competition are, by far, the rule rather than the exception.

86. What impact this "glass half-full/glass half-empty" situation with respect to telecommunications liberalization in foreign countries should have on U.S. regulatory policy is a major issue we hope to address in this Inquiry. Should U.S. policy-makers take this situation into account in reaching regulatory decisions and, if so, how? Should U.S. policy-makers seek to influence this situation through their regulatory decisions and, if so, how?

87. In this Notice, we have provided a brief description of changes in the U.S. market structure and in foreign market structures, as well as some of the technological developments pushing these changes, over the past ten years. We ask parties to address current and, more importantly, future developments in market structures and technology that will affect ITS.

a. What is the size of the IMTS market, in terms of revenues, number and identity of participants? What is the significance, in financial as opposed to regulatory terms, of this market segment compared to the overall ITS market?

b. What is the current state of play in telecommunications liberalization? Which national markets (or market segments) are open or closed? Is there sufficient information to document trends toward increased competition in foreign markets? What is the best means of obtaining and updating this information?

c. What are the appropriate indicators of liberalization in foreign markets? What weight, for U.S. regulatory purposes, should be given to partial or sectoral liberalization (for example, liberalization limited to the value-added services market segment)? What weight should be given to the presence of U.S. firms in foreign markets, even if U.S. investment and market presence is in market segments other than basic voice telephony (and/or carries with it only the rights of an investor, rather than those of an operator)? Does the factual record of marketplace conditions warrant further deregulation of ITS in the United States?

d. If national identity of carriers or other telecommunications service providers remains relevant for U.S. policy-makers, how should it be defined? In particular, how should multinational firms, consortia, joint ventures, and/or strategic alliances among competing carriers be treated? How should U.S. policy-makers deal with the ongoing transition from closed, tightly regulated foreign markets to greater openness and liberalization?

e. What new services will technology make possible? What services will users demand? And what effect will these developments have on (1) market structure (*e.g.*, is the apparent trend toward "globalization" through multinational consortia or joint ventures likely to increase or decrease in the future); and (2) regulatory and other telecommunications-related policies both in the United States and in foreign countries?

f. What are the major factors underlying the recent rapid growth in the U.S. net settlements deficit? What accounts for the significant disparities between outbound and inbound calling volumes for U.S. international traffic? Are there factors other than differences in collection rates at play?

g. What impact do so-called "country direct services" have on the settlements deficit?[130] How many minutes of traffic are now placed through such plans and what percentage of the total volume of international traffic do they represent? What are the motivations of foreign Administrations in agreeing to permit such plans to operate in their countries? To what extent does use of such plans substitute for other types of calling that conceivably could worsen the overall U.S. balance of payments?[131] What other forms of nontraditional calling currently exist (*e.g.*, "dial back")? What impact do such other non-traditional service arrangements have on the settlements deficit? How should such arrangements be addressed in the international regulatory context?

[129] *See* paras. 4–5, *supra*.

[130] With country direct calling, a customer in a foreign country places a call directly with a U.S. carrier and the call is handled and billed as a U.S.-originated call (*e.g.*, USA Direct, MCI CALL USA and Sprint Express).

[131] For example, consider a U.S. traveller in a foreign country who places two calls to the U.S. from a hotel room. The calls are identical in all respects (duration, time-of-day, etc.), except that the first call is placed through the hotel switchboard and costs $50 (including hotel surcharges) and the second is placed through one of the direct-calling plans of a U.S. carrier and costs $20. The first call would improve, and the second call would worsen, the U.S. net settlements deficit with that country. However, the relative impact of the two calls on the overall U.S. balance of payments with that country is less clear. How would the various payments involved in the two types of calls (among the customer, the hotel, the U.S. carrier, and the foreign Administration) be factored into the overall U.S. balance of payments?

B. Application of Existing Regulatory Policies to ITS

88. It is not clear that existing regulation can meet the demands of the evolving global environment for ITS. In the current debate over the direction of U.S. regulation, some have argued that particular policies (*e.g.*, open entry for all service providers, including those affiliated with foreign carriers with protected positions in their home markets) that have been successful in the U.S. domestic market are not directly transferrable to ITS and, indeed, are increasingly out of step with emerging global market realities.

89. Others have identified some gaps or inconsistencies in existing regulation: For example, while there is a new "entry standard" for private line resale when connected to the public switched network (*i.e.*, "equivalent opportunities"), there is no articulated entry standard for facilities-based services. In addition, existing U.S. regulation appears to provide foreign companies with opportunities in the United States unavailable to U.S. companies in foreign markets (*e.g.*, private cables, private carriage). Further, there is currently no well-defined distinction between privately owned foreign entities and government-owned entities seeking authorization in the U.S. to provide ITS.

90. In this section, we ask parties to address specific regulatory policies affecting ITS.

a. How should the U.S. policy goals of increased competition and reduced regulation, so successful in the domestic area, be advanced in the international context? Does U.S. regulation address fully the possibilities of anticompetitive leveraging by affiliates of foreign firms with market power in their home countries?

b. What are the principal differences between U.S. and foreign regulation of ITS? Are existing U.S. regulatory policies responsive to new issues presented by the combination of increased foreign participation in the U.S. market and lack of comparable foreign market opportunities for U.S. firms?

c. Recognizing that the Executive Branch, as well as the Commission, is involved in determinations under the Submarine Cable Landing Act, what factors should be weighed in determining whether a foreign market meets the "reciprocity" test of the statute? Is it, as has been suggested, a test that should encompass market access issues beyond the simple question of cable landing rights? If so, which branch of government should make such determinations?

d. Will the implementation of international simple resale in the current international regulatory environment yield reductions in above-cost accounting rates? Is the "equivalent opportunities" test developed for international resale an appropriate standard? How should "equivalent opportunities" be defined and the facts substantiated in the Commission's process? Is there a connection between the private line resale "equivalent opportunities" standard and the "reciprocity" standard in the Submarine Cable Landing License Act?

e. Should an "equivalent opportunities" or similar test be used in considering Commission authorization of other services? In the global telecommunications context (and particularly in view of multinational consortia), how would such a test be defined and applied as a standard? Should the definition and resulting procedure for applying the standard involve Executive Branch coordination and/or approval?

f. What are the implications of "dominant" versus "non-dominant" carrier status, in terms of promoting further competition in the U.S. ITS market—or in terms of promoting the international competitiveness of the U.S. telecommunications industry? Does the recent Court of Appeals decision, overturning the Commission's decision on forbearance (or permissive detariffing), have any impact on the Commission's international competitive carrier policy? [132]

g. Is the Commission's current approach to international accounting and settlements an appropriate one? Has the Commission gone as far as it can in developing a response to above-cost accounting rates and the increasing U.S. net settlements deficit, or are there other mechanisms which should be considered? Has an adequate factual record been created to guide these determinations (*e.g.*, how should the impact of country direct service be factored into the Commission's decision-making process)?

h. In the context of the changing market structures for ITS, should the Commission's approach to private carriage, private cables, etc.—which involves less regulatory oversight than common carriage—be re-evaluated?

i. Are there trade-offs between the greater competition and market flexibility that these U.S. regulatory policies have promoted and the possibilities of anticompetitive or other undesirable behavior when they are applied to affiliates of foreign telecommunications monopolies?

j. What effect do current U.S. regulatory restrictions on foreign participation in the market have on the ability of foreign firms to enter the U.S. market and compete fairly and effectively with U.S. firms? How do these restrictions compare as "burdens" with restrictions on U.S. firms in foreign countries? Should the U.S. liberalize its own rules further? If so, should such action be taken unilaterally or only in response to comparable liberalization in foreign countries?

C. Role of the Commission: Institutional/Legal Issues

91. The continuing imbalance between the structures of the U.S. and foreign markets has prompted concerns about the best approach for achieving the U.S. policy goals of promoting competition in the U.S. market for ITS; preventing the leveraging of monopoly power of foreign carriers to the disadvantage of U.S. carriers and ratepayers; and encouraging foreign countries to open their markets and liberalize their regulatory regimes through the adoption of pro-competitive and non-discriminatory regulatory policies.

92. However, the current debate regarding the use of U.S. regulatory policy as a tool to promote increased competition, not only in the U.S. market, but in foreign markets as well (*e.g.*, by conditioning access to the U.S. market for foreign firms on comparable access for U.S. firms in foreign countries) has to be considered in light of the Commission's statutory authority. The responsibilities of the Commission as an independent regulatory body are established in the Communications Act of 1934, which, in relation to ITS, broadly include: The development of rules and regulations; approval for the construction and operation of telecommunications facilities and the offering of services; review of tariffs, including rates charged and other terms and conditions; and assignments of radio frequencies to non-Federal Government users.[133]

93. The Commission has been successful, for the most part, in exercising these specific regulatory responsibilities, as well as in furthering two of its principal underlying policy goals of the last two decades—that is, increasing competition in telecommunications markets and, where competitive conditions warrant,

[132] See *supra* note 65.

[133] The Commission also regulates the common carrier activities of Comsat.

reducing or eliminating unnecessary regulation.

94. The Communications Act does not generally distinguish between domestic and international common carrier facilities and services, and the broad "public interest" standard contained in the Act applies to all facilities and services. As a result, there is no explicit requirement for the Commission to take into account such considerations as the foreign policy, trade, or international competitiveness aspects of ITS regulation. In fact, when the Commission in the past has sought to address these larger concerns, particularly the impact of restrictive foreign telecommunications practices, there was considerable opposition from a number of parties, including the Executive Branch, to the initiation of regulatory action by the Commission on trade or foreign policy grounds.[134] To explore these issues further, we ask parties to address the following questions:

a. How should the "public interest" be defined by the Commission in the changing global environment for ITS? How should developments in foreign markets, including entry by U.S. firms in those markets, be factored into "public interest" determinations by the Commission? How much flexibility does the Commission have in defining the "public interest" standard of the Communications Act in order to achieve desired goals in regulating ITS? What factors are within the scope of the Commission's authority to weigh in making such determinations?

b. Can U.S. regulation be used effectively to modify the behavior of foreign carriers and/or governments? Is it appropriate to use regulatory policy as a tool to attempt to open foreign markets? If so, what policy would be most effective for this purpose and who decides when and how it should be used? What are the costs of attempting to use U.S. regulatory policy in this fashion, for example, in terms of the development and implementation of U.S. trade or foreign policy—or in terms of the reaction of foreign governments?

c. To what extent can the Commission, under its statutory authority and independently of the Executive Branch, evaluate the state of competition, or other factors, in overseas markets? For example, while the Commission is not empowered to make foreign policy or trade determinations, should it take any such determinations regarding foreign countries by other USG agencies into account in either instituting or implementing regulatory action under the Communications Act, and if so, to what extent?

d. How can the Commission best approach the regulation of ITS to avoid a piecemeal or case-by-case approach while providing industry with greater certainty and transparency regarding the state of Commission regulation?

D. Relationship Between Regulatory and Other Telecommunications Policy Goals

95. The relationship between Commission-developed regulatory policy and other international telecommunications policies advanced in different venues by the Executive Branch is an important issue in the ITS debate. For the most part, the policy goals of the Commission and the Executive Branch are complementary. In addition, there is a great deal of informal coordination between the FCC and the Executive Branch in advancing these goals.[135]

96. Notwithstanding the generally complementary nature of the policy goals pursued by the Commission and the Executive Branch, there are some significant differences in policy execution (*e.g.*, regulatory proceedings versus international negotiations, advocacy, and agreements) and the scope of various policy goals (*e.g.*, ensuring "rapid, efficient, * * * service with adequate facilities at reasonable charges * * *"[136] versus enhancing trade opportunities, international competitiveness, or foreign policy goals).

97. Some argue that these differences are increasingly significant in terms of the substance, procedures, timing, and results of overall U.S. ITS policy. In addition, they point out that there is no affirmative coordination mechanism for balancing Executive Branch and Commission actions in pursuit of overall U.S. international telecommunications policy goals. As NTIA observed in 1988, while there are a number of channels of communication between the Executive Branch and the Commission, "in almost all instances the FCC is neither legally required to accept the Executive Branch's point of view, nor obligated to accord it particular weight or deference."[137] To assist our consideration of these issues, we ask parties to address the following questions.

a. Are there specific examples of cases where the above-noted differences have in fact yielded inconsistent Commission and Executive Branch policies? If so, what effect have such inconsistencies had on U.S. policies and U.S. users and services providers?

b. Is there a need for a more comprehensive "framework" for telecommunications policy? What should a more comprehensive framework include? How would such a framework be developed and administered?

c. Should there be greater coordination (through consultation or some other means) between the Executive Branch and the Commission in the development and implementation of policies affecting ITS? For example, there is currently a statutory requirement for the Commission to obtain Executive Branch views, coordinated by the Department of State, before issuing submarine cable landing licenses—should this requirement be extended to other facilities and services authorizations? In 1988, NTIA recommended that the Executive Branch be given greater authority to establish policy (which the Commission could then implement) or to "disapprove FCC action, at least in matters of overriding national security, foreign policy, international trade, or economic policy."[138] Parties are invited to address this approach as well.

d. Does the current regulatory and other telecommunications policy-making structure in the United States provide sufficient support for U.S. companies seeking more competitive opportunities abroad? Should it? Would consumers benefit from such an approach?

e. Is legislative action needed to improve the ability of the Commission or the Executive Branch to carry out their respective statutory mandates as to ITS? Or to increase intra-governmental coordination?

VI. Conclusion

98. NTIA requests that comments be filed in response to the questions set forth in this Notice on or before April 20, 1993. Reply comments should be filed on or before May 28, 1993.

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[134] *See Regulatory Policies and Int'l Telecommunications*, 4 FCC Rcd 7387, 7389 at para. 2 (1988).

[135] Most U.S. delegations to international conferences and bilateral consultations, as well as to bilateral and multilateral trade negotiations, include representatives from all the relevant branches of the USG—including the Department of State, the U.S. Trade Representative, the Commission, and the Department of Commerce.

[136] 47 U.S.C. 151 (1988).

[137] Nat'l Telecommunications and Information Admin., U.S. Dep't of Commerce, NTIA Spec. Pub. No. 88-21 *NTIA Telecom 2000: Charting the Course for a New Century* 182 (1988).

[138] *Id.* at 184.

Dated: January 8, 1993.

Gregory F. Chapados,

Assistant Secretary of Commerce for Communications and Information.

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Part VIII

Department of Education

Research in Education of Individuals With Disabilities; Final Priorities for Fiscal Years 1993 and 1994; Applications for New Awards, Fiscal Year 1993; Notices

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DEPARTMENT OF EDUCATION

Research in Education of Individuals With Disabilities Program

AGENCY: Department of Education.

ACTION: Notice of final priorities for Fiscal Years 1993 and 1994.

SUMMARY: The Secretary announces final funding priorities for the Research in Education of Individuals with Disabilities Program. The Secretary announces these priorities to ensure effective use of program funds and to direct funds to areas of identified need during fiscal years 1993 and 1994.

EFFECTIVE DATE: These priorities take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these priorities call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT: Linda Glidewell, U.S. Department of Education, 400 Maryland Avenue SW., room 3095, Switzer Building, Washington, DC 20202–2640. Telephone: (202) 205–9099. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION: The Research in Education of Individuals with Disabilities Program, authorized by part E of the Individuals with Disabilities Education Act (20 U.S.C. 1441–1443), provides support to advance and improve the knowledge base and improve the practice of professionals, parents, and others providing early intervention, special education, and related services, including professionals in regular education environments, to provide children with disabilities effective instruction and enable them to successfully learn; and for research and related purposes, surveys, or demonstrations relating to physical education or recreation, including therapeutic recreation, for infants, toddlers, children, and youth with disabilities.

On September 8, 1992, the Secretary published a notice of proposed priorities for this program in the **Federal Register** (57 FR 40994–40996).

These priorities support AMERICA 2000, the President's strategy for moving the Nation toward the National Education Goals, by improving understanding and practice and thereby enabling children and youth with disabilities to reach the high levels of academic achievement called for by the National Education Goals.

The publication of these final funding priorities does not obligate the Department of Education to fund projects in any or all of these areas. Funding of particular projects depends on the availability of funds and the quality of the application received. The publication of these priorities does not preclude the Secretary from proposing additional priorities, nor does it limit the Secretary to funding only these priorities, subject to meeting applicable rulemaking requirements.

Note: This notice of final funding priorities does not solicit applications. A notice inviting applications under these competitions is published in a separate notice in this issue of the **Federal Register**.

Analysis of Comments and Changes

In response to the Secretary's invitation in the notice of proposed priorities, five parties submitted comments. An analysis of the comments and of the changes in the proposed priorities follows. Technical and other minor changes, as well as suggested changes the Secretary is not legally authorized to make under the applicable statutory authority, are not addressed.

Comments on Priority 1: Interventions to Support Junior High School Aged Students Who Are at Risk of Dropping Out of School

Comment: One commenter noted that the requirement under "site selection" to locate the project sites in schools with a significantly higher drop-out rate for students with disabilities may not be helpful since most schools will find a higher drop-out rate for the special education students. The commenter further stated that the Department may wish to incorporate other standards of scrutiny, such as consumer, parent, student, or community involvement.

Discussion: The Secretary has included the "site selection" requirement to ensure that potential applicants choose sites where the drop-out rate for students with disabilities is significantly higher than for students who do not have disabilities. Also, the Secretary notes that the types of activities recommended by the commenter regarding consumer, parent, student, or community involvement are included as part of the outcomes in the priority under the "project planning" section and should not be a prerequisite to funding.

Changes: None.

Comments on Priority 2: Increasing Participation in General Education Development Programs (GED) Among Youth With Disabilities

Comment: One commenter expressed concern that the GED may not be an appropriate option for special education youth because (1) the GED has evolved into a fairly difficult test that most special education students could not pass, regardless of the type of intervention proposed; (2) many schools would be attracted to "drop" students into the type of programs being sought, thus absolving the school of any responsibility to educate those students; (3) most GED preparation programs are short term in nature and are not likely to be able to close the knowledge and skill gap between drop-outs and non-drop-outs; and (4) the GED is not a high school diploma, nor is it viewed as its equal.

Discussion: As written, the focus of the priority is on research projects that study the implications of programs designed to assist students in completing high school graduation requirements, not the relative merits of the GED as opposed to a high school diploma. The Secretary also believes that the concerns raised by the commenter will be addressed by projects as part of the evaluation process.

Changes: None.

Comments on Priority 3: Enhancing Language Acquisition Among Students Who Are Deaf or Hard of Hearing

Comment: Four commenters requested that cued speech be specified as one of the comparison means of communication. One of the four commenters stated that any comparative study of English language acquisition in children who are deaf or hard of hearing is incomplete unless it includes cued speech.

Discussion: The Secretary concurs that cued speech should be specified as one of the comparison means of communication.

Changes: The priority has been clarified to include cued speech as a mode of communication that could be used to evaluate the relative effectiveness of American Sign Language (ASL) in improving achievement in reading and writing for children, 5–18 years of age, who are deaf or hard of hearing.

Priorities

Under 34 CFR 75.105(c)(3) the Secretary gives an absolute preference to applications that meet the following priorities. The Secretary funds under

these competitions only applications that meet one of these priorities.

Priority 1—Interventions to Support Junior High School Aged Students Who Are at Risk of Dropping Out of School (CFDA 84.023G)

Background

One of the National Education Goals is to increase the high school graduation rate to at least 90 percent by the year 2000. The current graduation rate for children with disabilities, forty-one percent, falls substantially below the average for all children and well below the national goal of ninety percent (National Longitudinal Study, 1991). The findings of recent research and the consistently very poor rates of high school completion reported by States for children with disabilities support the need for research to develop and implement interventions that will increase student engagement in school during the year that they become at the greatest risk of dropping out and to evaluate the effectiveness of these interventions on progress towards graduation.

Priority

This priority will support research projects to develop, implement, and evaluate the effectiveness of interventions that increase student engagement in school. Projects must focus on students with learning disabilities and those with serious emotional disturbance.

Site Selection. Project sites must be in schools whose the drop-out rate for students with disabilities is significantly higher than for children who are not disabled. Sites must encourage the implementation of school-based interventions within general education settings.

Project Planning. Projects may dedicate up to 12 months to plan for and develop the implementation of interventions with special and general educators, administrators, related service staff, parents, community agencies and groups, and others as appropriate. The plan must include activities that develop and maintain ongoing school, community, and family commitment to implement the interventions. Planning activities must include (1) the identification of school, home, and community variables that are related to student engagement in learning and the development of interventions related to these variables; (2) the specification of the procedures and participants required to implement the interventions; and (3) procedures for evaluating the implementation and impact of the interventions and the project. Variables of student engagement must be developed through a consensual process and must include school, home, and community variables that have a significant predictive relationship with student drop-out rates.

Implementation of Interventions. Projects must implement their interventions over a three-year period. Projects must select a cohort of students with learning disabilities and serious emotional disturbance who are enrolled at the seventh through tenth grade level (the "study group"). Interventions must be implemented for these students for three successive years.

Studying Effects and Implementation of the Project. During the first two years of implementation, project effects must be described with respect to the variables of student engagement. Information must be reported longitudinally on a control group of students with learning disabilities and serious emotional disturbance within the school district ("the control group") who do not receive the interventions. Data collection and analyses must permit the statement of findings for student subgroups reflecting each disability group included in the sample.

Information must also be provided regarding the process and levels of implementation of the project and a description of community, school, and student characteristics.

Collaboration. Projects must work with the other projects funded under this priority and with related projects and must budget for two annual meetings: one with the other grantees under this priority and one of all project directors.

Priority 2—Increasing Participation in General Education Development Programs (GED) Among Youth With Disabilities (CFDA 84.023P)

Background

One of the National Education Goals is to increase the high school graduation rate to at least 90 percent by the year 2000. Forty-one percent of all youth with disabilities drop out of school without completing high school graduation requirements (National Longitudinal Study, 1991). Nationally, most students who do not complete high school in the traditional fashion eventually obtain a high school diploma through the General Education Development (GED) program. This compares sharply with students with disabilities who have dropped out or withdrawn from school, less than five percent of whom ever receive a diploma.

Having a high school diploma represents one of the most important credentials a young adult must possess to access many of the adult opportunities associated with successful, independent adult outcomes, including for example, access to higher education and competitive employment. The National Longitudinal Study (1991) has provided compelling evidence that there is a consistent gap between students with disabilities who drop out as compared to those who complete high school graduation requirements with respect to several outcomes, and that the discrepancy increases over time.

Priority

This priority will support research projects to develop, implement, and evaluate interventions that will increase the participation in and successful completion of GED programs for students with disabilities who have either withdrawn from or dropped out of school. Projects must focus on students with learning disabilities and those with serious emotional disturbance.

Activities

Site Selection. Project sites must be in schools in communities where the drop-out rate for students with disabilities is significantly higher than for children who are not disabled. Sites must encourage the implementation of school-based interventions within general education settings.

Project Planning. Grantees may dedicate up to 12 months to plan for and develop the implementation of interventions that will increase the successful participation of students with disabilities in GED programs. The plan must be prepared by a group that includes those knowledgeable regarding the needs of students who have withdrawn or dropped out. The plan must include activities that ensure the involvement of GED program staff and others to implement the interventions. The plan must include (1) a site-based, descriptive study of the factors and barriers associated with the decision by young adults with disabilities to seek a GED diploma, and a synthesis describing factors (student, administrative, financial, etc.) related to the successful completion of GED programs by students with disabilities; (2) the new or adapted interventions to be studied; (3) the procedures and participants required to implement the interventions, including how students will be identified and recruited; (4) a description of how a GED program that effectively accommodates the special

learning needs and circumstances of youth with disabilities will be developed; and (5) procedures for evaluating the impact of the interventions.

Implementation of Interventions. Projects must implement their interventions and operational plan over a three-year period. Projects must annually select a cohort of youth with disabilities (three cohorts, total) that is participating in the GED program and is 6 months past the compulsory minimum age for exiting from school, as determined by State law or regulations. Information is also to be reported for a control group of students with disabilities within the community, but who are not participating in the GED program.

Studying Effects and Implementation of the Project. During the first two years of implementation, projects must study project effects and the process of implementation of the project. Data collection and analyses must include the statement of findings for student subgroups reflecting each disability area included in the sample. Information describing community, school, and student characteristics must be included.

Collaboration. Projects must work with the other projects funded under this priority and with related projects and must budget for two annual meetings: one with the other grantees under this priority and one of all project directors.

Priority 3—Enhancing Language Acquisition Among Students Who Are Deaf or Hard of Hearing (CFDA 84.023T)

Background

As reported by the Commission on Education of the Deaf (COED), in its 1988 report, Towards Equality, "the educational system has not been successful in assisting the majority of students who are deaf or hard of hearing to achieve reading skills commensurate with those of their hearing peers." Competence in understanding and using vocal, visual, and written language represents an especially critical and difficult accomplishment for children who are deaf or hard of hearing. As the COED report notes, "[a] child without a strong language and communication base faces significant barriers." The findings of this and other recent research and policy studies document the need to enhance the levels of language acquisition for individuals who are deaf or hard of hearing so as to improve levels of achievement and other outcomes.

Priority

This priority will support research projects to evaluate the effectiveness of American Sign Language (ASL) relative to other modes of communication such as signed English or cued speech in improving achievement in reading and writing for children, 5–18 years of age, who are deaf or hard of hearing.

Activities

Projects must examine achievement in reading and writing, other relevant variables, e.g., other relevant child outcomes (including social and behavioral variables), and the satisfaction of service providers. Project participants must include elementary and secondary-aged students. Projects designs must produce information on ASL relative to other modes of communication to which it is being compared by age and achievement level.

Projects must study the effectiveness of using ASL relative to other modes of communication to which it is being compared in relation the severity of hearing loss, who provides (service provider) the interventions, and where the interventions are provided (setting). Projects must also study and relate the effectiveness of using ASL and the other interventions to the age of the child at the onset of deafness and time of first intervention, respectively, and the nature and scope of family and community supports. Projects must examine the effectiveness of ASL relative to other modes of communication to which it is being compared in academic and nonacademic settings and in integrated and nonintegrated settings. Service providers may include, for example, parents, hearing or nonhearing peers, and special and regulator educators. Projects must report information describing special accommodations, if relevant, associated with using ASL relative to the other modes of communication to which it is being compared in various settings, e.g., within the home or in school environments with normally-hearing children. Projects must also report information describing the appropriate alternative reading and writing assessment systems and procedures that are best suited to document the reading and writing acquisition skills.

Dissemination. Projects must report and exchange their information and findings in formats useable to the research community and to service providers.

Collaboration. Projects must work with the other projects funded under this priority and other related projects and must budget for two annual meetings: one with the other grantees under this priority and one of all project directors.

Applicable Program Regulations: 34 CFR part 324 (1992).

Program Authority: 20 U.S.C. 1441–1443.

(Catalog of Federal Domestic Assistance Number 84.023, Research in Education of Individuals with Disabilities Program)

Dated: December 30, 1992.

Lamar Alexander,

Secretary of Education.

[FR Doc. 93–1008 Filed 1–14–93; 8:45 am]

BILLING CODE 4000-01-M

[CFDA No.: 84.023]

Research in Education of Individuals With Disabilities Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 1993

Purpose of Program: To advance and improve the knowledge base and improve the practice of professionals, parents, and others providing early intervention, special education, and related services, including professionals in regular education environments, to provide children with disabilities effective instruction and enable them to successfully learn.

These priorities support AMERICA 2000, the President's strategy for achieving the National Education Goals, by improving our understanding of how to enable children and youth with disabilities to reach the high levels of academic achievement called for by the goals.

Eligible Applicants: Eligible applicants are State and local educational agencies, institutions of higher education, and other public agencies and nonprofit private organizations.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 80, 81, 82, 85, and 86; and (b) The regulations for this program in 34 CFR part 324.

Applications Available: February 22, 1993.

Priorities

The priorities in the notice of final priorities for this program, as published elsewhere in this issue of the **Federal Register**, apply to these competitions.

RESEARCH IN EDUCATION OF INDIVIDUALS WITH DISABILITIES PROGRAM

[Application notices for fiscal year 1993]

Title and CFDA No.	Deadline for transmittal of applications	Available funds	Estimated size of awards	Estimated number of awards	Project period in months
Increasing participation in general education development programs (GED) among youth with disabilities (CFDA 84.023P).	04/19/93	$1,000,000	$2,000,000 per year[1]	5	Up to 48.
Enhancing language acquisition among students who are deaf or hard of hearing (CFDA 84.23T).	04/19/93	450,000	150,000 per year[1]	3	Up to 36.

[1] Amounts listed are the estimated funding levels for the first 12 months of the projects. Multi-year projects are likely to be level funded unless there are increases in costs attributable to significant changes in activity level.

NOTE: The Department of Education is not bound by any estimates in this notice.

FOR APPLICATIONS CONTACT: Darlene Crumblin. Telephone: (202) 205–9864. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

FOR FURTHER INFORMATION CONTACT: For information on the Increasing Participation in General Education Development Programs (GED) Among Youth with Disabilities competition please contact Dr. Helen Thornton, U.S. Department of Education, 400 Maryland Avenue SW., room 3529, Switzer Building, Washington, DC 20202–2640. Telephone: (202) 205–5910. For information on Enhancing Language Acquisition Among Students Who Are Deaf or Hard of Hearing competition please contact Judith Fein, U.S. Department of Education, 400 Maryland Avenue SW., room 3524, Switzer Building, Washington, DC 20202–2640. Telephone: (202) 205–8116. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

Program Authority: 20 U.S.C. 1441–1443.

Dated: January 11, 1993.

Robert R. Davila,

Assistant Secretary, Office of Special Education and Rehabilitative Services.

[FR Doc. 93–1007 Filed 1–14–93; 8:45 am]

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Part IX

Department of Housing and Urban Development

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 248

Preservation of Multifamily Low Income Housing; Interim Rule

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

24 CFR Part 248

[Docket No. R-93-1622; FR-3377-I-02]

Preservation of Multifamily Low Income Housing

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Interim rule.

SUMMARY: This interim rule implements section 302 of the Housing and Community Development Act of 1992 by amending part 248 of title 24 of the Code of Federal Regulations which sets forth the policies and procedures of the Department of Housing and Urban Development for preserving eligible low income multifamily housing projects. In brief, this amendment requires appraisers, when appraising eligible low income housing under title VI of the Cranston-Gonzalez National Affordable Housing Act, the Low Income Housing Preservation and Resident Homeownership Act of 1990, to assume that all Federal rental assistance terminates upon a mortgage repayment.

DATES: Effective date: January 15, 1993. Comment due date: March 16, 1993.

ADDRESSES: Submit written comments to the Office of the General Counsel, Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Communications should refer to the above docket number and title. A copy of each communication submitted will be available for public inspection and copying during regular business hours (7:30 a.m.–5:30 p.m. Eastern Standard Time) at the above address.

FOR FURTHER INFORMATION CONTACT: Kevin J. East, Office of Multifamily Housing Preservation and Property Disposition, Department of Housing and Urban Development, 451 7th Street, SW., Washington, DC 20410. Telephone, voice (202) 708–2300; TDD, (202) 708–4594. (These are not toll-free telephone numbers).

SUPPLEMENTARY INFORMATION: Subtitle A of title III of the Housing and Community Development Act of 1992 (Pub. L. 102–550 (106 Stat. 3672), approved October 28, 1992) ("title III") amends title VI of the Cranston-Gonzalez National Affordable Housing Act, the Low Income Housing Preservation and Resident Homeownership Act of 1990 (Pub. L. 101–625; 12 U.S.C. 4102 *et seq.* ("LIHPRHA"), the successor to title II of the Housing and Community Development Act of 1987, the Emergency Low Income Housing Preservation Act of 1987 (Pub. L. 100–242; 12 U.S.C. 1715*l* note) ("ELIHPA"), governing the preservation of privately-owned multifamily low income housing. The history of the preservation programs is set forth in an interim rule implementing LIHPRHA which was published on April 8, 1992 at 57 FR 11992, (the "April 1992 interim rule") and will not be repeated here.

This interim rule implements section 302 of title III by amending section 248.111 of the Department's regulations, as addressed in the following discussion. This amendment was intended to be included in the interim rule amending part 248 of title 24 of the CFR, published by the Department on December 3, 1992 at 57 FR 54312, however, it was inadvertently omitted from the final published version of that rule. The Department expects to implement the remaining provisions of title III in another interim rule which will be published shortly.

Section 248.111 (Appraisal and Preservation Value of Eligible Low Income Housing)

Section 302 of Title III amends section 213(c) of LIHPRHA which requires the Department to establish written appraisal guidelines requiring appraisers to make certain assumptions when calculating preservation value. Section 213(c) of LIHPRHA requires that the appraisal guidelines assume repayment of the existing federally-assisted mortgage, termination of the existing low-income affordability restrictions and costs of compliance with any State or local laws of general applicability. Final appraisal guidelines complying with Section 213(c) were published on May 8, 1992 at 57 FR 19970 in a notice entitled "Appraisals of Preservation Value Under the Low-Income Housing Preservation and Resident Homeownership Act of 1990" (the "Appraisal Guidelines").

In addition to the assumptions required under section 213(c) of LIHPRHA, the Appraisal Guidelines also require appraisers to assume that any Federal rental assistance, such as Section 8 project-based assistance, which, by the terms of its contract, is not coterminous with the mortgage, would remain in effect until the contract terminates. Where a Federal rental assistance contract would extend past the date of repayment of the mortgage, the cost (or benefit) of the rental assistance contract would be deemed a conversion cost for purposes of determining preservation value. However, section 302 of title III amends section 213(c) of LIHPRHA to require appraisers to make the opposite assumption; that there is simultaneous termination of any Federal rental assistance.

The Appraisal Guidelines have been amended to reflect this statutory change. Although the Department originally published the Appraisal Guidelines in the **Federal Register**, future copies of the Guidelines will be provided to owners and appraisers in up-to-date, amended form upon an owner's submission of a notice of intent under LIHPRHA. Affected persons, therefore, will have actual notice of any future amendment to the Appraisal Guidelines. Amendments to the Guidelines will be published in the **Federal Register**, and public comments will be solicited, only in instances where the changes to be made present substantive issues meriting prior notice and comment before their effectiveness.

Section 248.111 of the April 1992 interim rule, which governs appraisals, is silent as to the effect of Federal rental assistance on preservation value. However, paragraph (d) of section 248.111 lists the assumptions of section 213(c) of LIHPRHA and provides for the inclusion of conversion costs in determining value. This rule amends section 248.111(d) to include the language added to section 213(c) of LIHPRHA by section 302 of title III.

The Department began processing under LIHPRHA on May 8, 1992, the effective date of the April 1992 interim rule. Since that date, owners have been conducting appraisals on their property and as of the effective date of this rule many will not yet have completed the appraisal process. Section 248.111, as amended, and the revised Appraisal Guidelines will apply to all owners who have not received, as of January 15, 1993, the information from the Secretary under § 248.131(b). Where an owner and HUD have not exchanged appraisals under § 248.111(i), both the owner's appraiser and HUD's appraiser will be directed to comply with the revised Appraisal Guidelines. Where an owner has already completed its appraisal, but HUD has not, HUD's appraiser will comply with the revised Appraisal Guidelines and the owner may rely on HUD's appraisal or adjust its appraisal. Where HUD has completed its appraisal, but the owner has not, both the owner's appraiser and HUD's appraiser will comply with the revised Appraisal Guidelines. If both appraisals have been

completed, but the information under § 248.131(b) has not been received by the owner, HUD and the owner will adjust the appraisals during the negotiation process under § 248.111(j). If HUD and the owner cannot reconcile the differences between the two appraisals using the revised Appraisal Guidelines, a third appraisal will be conducted using the revised Appraisal Guidelines and will be binding on both parties, in accordance with § 248.111(j).

Findings and Other Matters

A. Regulatory Impact

This rule does not constitute a "major rule" as that term is defined in section 1(d) of Executive Order 12291 on Federal Regulations issued by the President on February 17, 1981. An analysis of the rule indicates that it does not (1) have an annual effect on the economy of $100 million or more; (2) cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) have a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

B. Environmental Impact

A Finding of No Significant Impact with respect to the environment has been made in accordance with HUD regulations in 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332. The Finding of No Significant Impact is available for public inspection during regular business hours in the Office of General Counsel, Rules Docket Clerk, room 10276, 451 Seventh Street, SW., Washington, DC 20410.

C. Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that the policies contained in this rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. As a result, the rule is not subject to review under the Order.

D. Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, *The Family*, has determined that some of the policies in this rule will have a significant impact on the formation, maintenance and general well-being of the family. Achievement of homeownership by low income families under the regulation can be expected to support family values, by helping families to achieve security and independence, by enabling them to live in decent, safe and sanitary housing, and by giving them the skills and means to live independently in mainstream American society. Since the impact on the family is beneficial, no further review is necessary.

E. Regulatory Flexibility Act

Under section 605 of the Regulatory Flexibility Act (5 U.S.C. 601), HUD certifies that this rule does not have a significant economic impact on a substantial number of small entities, because it carries out statutorily-mandated limitations on prepayment of the affected mortgages. Any economic impact is a direct consequence of the statute and is not separately imposed by this rule.

F. Regulatory Agenda

This rule was not listed in the Department's Semiannual Agenda of Regulations published on November 3, 1992 (57 FR 51392) in accordance with Executive Order 12291 and the Regulatory Flexibility Act.

The Catalog of Federal Domestic Assistance program number is 14.137 (Mortgage Insurance—Rental and Cooperative Housing for Low and Moderate Income Families).

List of Subjects in 24 CFR Part 248

Intergovernmental relations, Loan programs—housing and community development, Low and moderate income housing, Mortgage insurance, Reporting and recordkeeping requirements.

Accordingly, the Department amends title 24, part 248 of the Code of Federal Regulations as follows:

PART 248—PRESERVATION OF MULTIFAMILY LOW INCOME HOUSING

1. The authority citation for part 248 continues to read as follows:

Authority: 12 U.S.C. 1715*l* note; 12 U.S.C. 4101, *et seq.*; 42 U.S.C. 3535(d).

2. In § 248.111, paragraph (d) is revised to read as follows:

§ 248.111 Appraisal and preservation value of eligible low income housing.

* * * * *

(d) *Guidelines.* The Commissioner shall provide to the owner and the appraiser retained by the Commissioner guidelines for conducting the appraisal. The guidelines established by the Commissioner shall be consistent with customary appraisal standards. The guidelines shall assume repayment of the existing federally-assisted mortgage(s), termination of the existing Federal low income affordability restrictions, simultaneous termination of any Federal rental assistance, and costs of compliance with any State or local laws of general applicability. The guidelines may permit reliance upon assessments of rehabilitation needs and other conversion costs determined by an appropriate State agency, as determined by the Commissioner.

* * * * *

Dated: January 5, 1993.

James E. Schoenberger,

Associate General Deputy, Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 93–1024 Filed 1–14–93; 8:45 am]

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Part X

Federal Trade Commission

16 CFR Part 307

Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986; Final Rule, Proposed Rule and Notice

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FEDERAL TRADE COMMISSION

16 CFR Part 307

Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986

AGENCY: Federal Trade Commission.

ACTION: Amendment to final rule.

SUMMARY: The Commission is amending the regulations on smokeless tobacco advertising that deal with the rotation of health warnings on point-of-sale and non-point-of-sale promotional materials ("promotional materials"). The existing provisions on rotation, which were issued in 1991, are revoked and replaced by the provisions that were originally issued in 1986. The Commission is taking this action because it believes that it did not received adequate public comment on the 1991 amendments.

EFFECTIVE DATE: January 15, 1993.

FOR FURTHER INFORMATION CONTACT: Phillip Priesman, (202) 326–2484 or Judith P. Wilkenfeld, (202) 326–3150, Division of Advertising Practices, Federal Trade Commission, 6th & Pennsylvania Ave., NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Commission has decided to amend the portion of § 307.12(b) of 16 CFR part 307 (1992) that deals with the rotation of health warnings on point-of-sale and non-point-of-sale promotional materials ("promotional materials") because it believes that it did not receive adequate public comment on the 1991 amendments. Prior to March 1991, § 307.11(b) provided that rotation plans could be based either on the dates when promotional materials were disseminated or on the dates when the materials were ordered. 51 FR 40015 (Nov. 4, 1986). The 1991 amendment replaced § 3.11(b) with a new § 307.12(b), which required that rotational plans be based solely on the date of dissemination, 56 FR 11653 (Mar. 20, 1991). The Commission is now amending § 307.12(b) to delete the amended language and revert to the requirements originally applied to promotional materials (while keeping intact the portion of the 1991 amendments that dealt with utilitarian objects). Thus, rotational plans based on either dates of dissemination or dates of order will again be permissible for promotional materials. The Commission believes that it is unnecessary to invite public comment on this amendment because: (a) No public interest would be served by soliciting comment on the adequacy of the comments previously received, and (b) all interested parties will have the opportunity to comment in a separate rulemaking proceeding on the merits of various approaches to rotation of warnings for promotional materials. See the Notice of Proposed Rulemaking published elsewhere in this issue of the **Federal Register**.

List of Subjects in 16 CFR Part 307

Health warnings, Smokeless tobacco, Trade practices.

Accordingly, part 307 of 16 CFR is amended as follows:

PART 307—REGULATIONS UNDER THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986

1. The authority for part 307 continues to read as follows:

Authority: 15 U.S.C. 4401 et. seq.

2. Section 307.12(b) is amended by removing the last three sentences and adding the following four sentences:

§ 307.12 Rotation, display, and dissemination of warning statements in smokeless tobacco advertising.

* * * * *

(b) * * * A satisfactory plan for point-of-sale and non-point-of-sale promotional materials such as leaflets, pamphlets, coupons, direct mail circulars, paperback book inserts, or non-print items could provide for rotation according to the time that the material is scheduled to be disseminated or the order date for the material. A satisfactory plan for utilitarian objects shall provide for rotation according to the date the objects are disseminated. Because the Commission recognizes that the rotation requirement for utilitarian objects may produce hardship for companies that cannot foresee at the time of ordering what their distribution schedule will be, the Commission will consider in compliance with this provision a plan under which the objects comprising each order display all three warnings in equal proportion, and are disseminated either:

(1) In groups displaying a single warning in sequence per four-month period over a total dissemination period of three or more such four-month periods, or

(2) At random, if dissemination is to occur in fewer than three such periods.

The plan may specify that items having a useful life of significantly more than 4 months, such as clocks, electric signs, and durable dispensers may be rotated less frequently.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 93–1076 Filed 1–14–93; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

16 CFR Part 307

Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission has decided to consider for repromulgation, subject to a 30-day notice and comment period, the portion of § 307.12(b) removed by the rule amendment published elsewhere in this issue of the **Federal Register**. The language proposed for repromulgation was originally issued in March 1991. It concerns the rotation of health warnings for point-of-sale and non-point-of-sale promotional materials ("promotional materials") for smokeless tobacco products. The Commission is taking this action because it believes that it did not receive adequate public comment in 1991 respecting these materials. All persons are hereby given notice of the opportunity to submit written data, views, and arguments concerning the merits of the proposed rulemaking.

DATES: Written comments will be accepted on or before February 16, 1993.

ADDRESSES: Send comments to the Secretary, Federal Trade Commission, 6th & Pennsylvania Ave. NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Phillip Priesman, (202) 326–2484, or Judith P. Wilkenfeld, (202) 326–3150, Division of Advertising Practices, Federal Trade Commission, 6th & Pennsylvania Ave., NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Section A—Background

On March 20, 1991, the Federal Trade Commission ("the Commission") issued final regulations (56 FR 11653 (1991)) amending 16 CFR part 307, the Commission's regulations implementing the Comprehensive Smokeless Tobacco Health Education Act of 1986. The amendments added utilitarian objects to the items covered by the regulations and required that the rotation of health warnings for both utilitarian objects and promotional materials be based on the dates when these items are disseminated (16 CFR 307.12(b)). Prior to March 1991, § 307.11(b) provided that rotation plans for promotional materials could be based either on the dates when the materials were disseminated or on the dates when the materials were ordered. 51 FR 40015 (Nov. 4, 1986). The 1991 amendment replaced § 3.11(b) with a new § 307.12(b), which required that rotational plans be based solely on the date of dissemination. 56 FR 11653 (March 20, 1991). The Commission has concluded that inadequate public comment was received on the 1991 amendments affecting rotation of warnings on promotional materials. Therefore, the Commission has deleted those rotation requirements and reverted to the rotation requirements that applied previously. [See the notice of Amendment to Final Rule published elsewhere in this issue of the **Federal Register**]. The Commission is now seeking comment on the merits of the rotation plan language issued in 1991.

Section B—Questions

Although the proposed method for rotation of warning labels is identical to that mandated by the Commission in March 1991, the Commission has not determined whether adoption of the proposed method at this time is desirable. The Commission seeks a full range of comments respecting this issue, and particularly solicits information on the following questions:

Question 1. What is the likely effect of the proposed requirements for the rotation of health warnings on promotional materials on the costs, profitability, competitiveness, and employment of small business entities?

Question 2. The Smokeless Tobacco Act requires smokeless tobacco companies to submit plans to the Commission that specify the method they will use to rotate, display and distribute the required health warning statements on their packaging and advertising. The original requirement for the submission of plans by marketers of smokeless tobacco products was submitted to, and approved by, the Office of Management and Budget. OMB Control No. 3084–0082. The Commission is seeking additional OMB clearance for the information collection requirements contained in the proposed amendments to the regulations implementing the Smokeless Tobacco Act.[1]

By changing the requirements for the rotation of the health warnings on promotional materials, the proposed amendments may require some smokeless tobacco companies to revise their rotational plans for such materials to provide for rotation according to the method outlined in 16 CFR 307.12(b) excerpted above. What are the possible paperwork burdens that the promotional materials amendment to 16 CFR 307.12 may impose?

Question 3. What are the possible regulatory alternatives that would reduce the economic impact of the proposed rotational requirements for warning labels on promotional materials, yet fully implement the regulatory mandate of the Smokeless Tobacco Act?

Section C—Regulatory Flexibility Act

When the Smokeless Tobacco Regulations were first proposed, the FTC certified that the Regulatory Flexibility Act requirement for regulatory analysis was not applicable because the regulations did not appear to have a significant economic impact on a substantial number of small entities. 51 FR 24378 (1986). The Commission has re-examined this issue with respect to the proposed amendment for promotional materials, and has preliminarily determined that the proposed amendment does not affect the earlier determination. The amendment merely requires manufacturers of smokeless tobacco to modify slightly an already existing schedule by which they rotate the three required warnings on promotional materials. In order to ensure, however, that no substantial economic impact is being overlooked, the Commission is requesting public comment on the effect of the proposed regulations on costs, profitability, competitiveness, and employment in small entities. Subsequent to the receipt of public comments, the Commission will determine whether the preparation of a final regulatory flexibility analysis is warranted.

In light of the above, the Commission certifies that the proposed amendments will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b) (1982).

List of Subjects in 16 CFR Part 307

Health warnings, Smokeless tobacco, Trade practices.

Accordingly, it is proposed that part 307 of 16 CFR be amended as follows:

PART 307—REGULATIONS UNDER THE COMPREHENSIVE SMOKELESS TOBACCO HEALTH EDUCATION ACT OF 1986

1. The authority for part 307 continues to read as follows:

Authority: 15 U.S.C. 4401 et. seq.

2. Section 307.12(b) is amended by removing the last four sentences (see the version set forth in the notice of the Amendment to Final Rule published elsewhere in this issue of the **Federal**

[1] See Notice of application to OMB under the Paperwork Reduction Act, which may also be found elsewhere in this issue of the **Federal Register**.

Register) and adding the following three sentences:

§ 307.12 Rotation, display, and dissemination of warning statements in smokeless tobacco advertising.

* * * * *

(b) * * * A satisfactory plan for point-of-sale and non-point-of-sale promotional materials such as leaflets, pamphlets, coupons, direct mail circulars, paperback book inserts, or non-print items or for utilitarian objects shall provide for rotation according to the date the materials or objects are disseminated. Because the Commission recognizes that the rotation requirement for promotional materials and utilitarian objects may produce hardship for companies that cannot foresee at the time of ordering what their distribution schedule will be, the Commission will consider in compliance with this provision a plan under which the materials or objects comprising each order display all three warnings in equal proportion, and are disseminated either:

(1) In groups displaying a single warning in sequence per four-month period over a total dissemination period of three or more such four-month periods, or

(2) At random, if dissemination is to occur in fewer than three such periods.

The plan may specify that items having a useful life of significantly more than 4 months, such as clocks, electric signs, and durable dispensers may be rotated less frequently.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 93–1077 Filed 1–14–93; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

Request for OMB Clearance of Information Collection Requirements; Regulations Under the Comprehensive Smokeless Tobacco Health Education Act of 1986

AGENCY: Federal Trade Commission.

ACTION: Notice of application to OMB under the Paperwork Reduction Act (44 U.S.C. 3501–35180) for clearance of information collection requirements contained in proposed amendments to regulations under the Comprehensive Smokeless Tobacco Health Education Act of 1986.

SUMMARY: The FTC is seeking OMB clearance for information collection requirements contained in proposed amendments to the regulations implementing the Smokeless Tobacco Health Education Act, 15 U.S.C. 4401 (Smokeless Tobacco Act), 16 CFR part 307.

The Smokeless Tobacco Act requires, among other things, that manufacturers, packagers, and importers of smokeless tobacco products include health warnings on packages and in advertisements. The Act also requires each manufacturer, packager, and importer of a smokeless tobacco product to submit a plan to the Commission that specifies the method used to rotate, display, and distribute the warning statements required to appear in advertising and labeling. Section 3(d) directs the Commission to approve plans that provide for the rotation, display, and distribution of the warning statements in accordance with the regulations. The proposed amendment would require affected firms to submit new plans for Commission approval in connection with promotional materials.

The Supporting Statement submitted with the Request for OMB Review includes an estimate that the total annual paperwork burden for the rule is 2,000 hours. The basis for this estimate is described in more detail in the Supporting Statement.

The amendment of previously submitted plans to incorporate rotational plans for promotional materials should require less time than was devoted to the original submissions. Because we have no substantial basis for calculating the proportion of the 1986 burden estimate that will be attributable to the amendment process, we propose to retain the existing burden estimate.

DATES: Comments on this application must be submitted on or before February 16, 1993.

ADDRESSES: Send comments to Mr. Don Arbuckle, FTC Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, room 3228, Washington, DC 20503. Copies of the application may be obtained from the Public Reference Section, room 130, Federal Trade Commission, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Elaine W. Crockett, Attorney, Office of the General Counsel, Federal Trade Commission, Washington, DC 20580 (202) 326–2453.

Donald S. Clark,

Secretary.

[FR Doc. 93–1078 Filed 1–14–93; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 630

[Docket No. 90–B]

RIN 2132–AA36

Uniform System of Accounts and Records and Reporting System

AGENCY: Federal Transit Administration, DOT.

ACTION: Final rule.

SUMMARY: This document implements a number of changes to the structure and content of the Uniform System of Accounts and Records and Reporting System (the "Section 15 system"). These changes are the result of an extensive evaluation completed by the Federal Transit Administration (FTA) of the future direction of the Section 15 system, and reflect recommendations from the public transit industry. These changes reduce the burden of reporting information to the FTA and improve the value of the reported data for analysis.

EFFECTIVE DATE: The regulation is effective on February 16, 1993, and applies to all Section 15 reporting years beginning with 1992. The 1992 reporting year covers local transit agencies' fiscal years ending on or between January 1, 1992 and December 31, 1992.

FOR FURTHER INFORMATION CONTACT: Marvin Futrell, Chief, Audit Review and Analysis Division, Office of Capital and Formula Assistance, Federal Transit Administration, TGM–13, (202) 366–1610.

SUPPLEMENTARY INFORMATION:

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I. Background

A. The Rulemaking Process

This final rule implements comprehensive changes to the structure, content, and operations of the Section 15 Uniform System of Accounts and Records and Reporting System (the Section 15 system), and represents a major stage in the fourteen year evolution of the Section 15 system. After the production of thirteen annual data bases, the FTA began a major evaluation of the fundamental objectives of the Section 15 system, including its strengths and weaknesses.

The evaluation employed the rulemaking process to solicit public comments on structural and procedural proposals to modify the systems, and related issues. The changes to the Section 15 system implemented in this final rule are the result of this rulemaking process. These changes should result in a less complex structure for the systems, less burdensome reporting requirements, and a more accurate and useful data base.

The FTA began this evaluation with a consideration of the fundamental purpose of Section 15 system, to determine whether the systems should continue or be modified. In identifying changes to improve the system, the FTA considered both the interests of reporting agencies, generally supporting a simpler structure with a less detailed data base, as well as the interests of current and potential data users, supporting a more detailed and comprehensive data base. The overall goal was to improve the balance between the benefits of the data collected against the costs and burden of reporting, and the FTA data base production costs.

As part of this review to determine the future direction for the section 15 system, prior to initiation of this rulemaking, the FTA received comments and recommendations from experts representing transit operators; other Federal, state, and local public agencies; the private sector; academia; and other constituencies of the public transit industry. The FTA received detailed recommendations and proposals from the FTA Section 15 Reporting System Advisory Committee, the American Public Transit Association (APTA) Section 15 Committee, and the Transportation Research Board.

This final rule is the result of a rulemaking process that began with an Advance Notice of Proposed Rulemaking (ANPRM) published in the **Federal Register** (55 FR 33078) on August 13, 1990. In the ANPRM, the FTA requested public comments concerning: the future direction of the Section 15 system; a broad range of proposals to change the structure and content of the Section 15 systems; and various related issues.

On August 12, 1991, the FTA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (56 FR 38256) which proposed a comprehensive revision of the regulation. The FTA developed the proposals in the NPRM based on an evaluation of 59 comments on the ANPRM from the public, transit operators, state departments of transportation, the private sector, and other industry representatives. In addition to publication of the NPRM in the **Federal Register**, the FTA sent the NPRM to every section 15 reporting agency. The FTA discussed and responded to the ANPRM comments in the NPRM.

This final rule is based on the 26 public comments made in response to the proposals in the NPRM, and includes summaries and responses to those comments. References to comments in this final rule refer to those received in response to the NPRM. The comments were submitted by 21 public transit authorities, three regional planning organizations, one public transit trade organization, and one public accountants trade organization. Most commenters supported some proposals, but raised concerns with or offered alternatives to other proposals. The comments were carefully considered by the FTA in formulating this final rule.

The FTA will continue to make required annual improvements to the system, which will be formally announced in either the annual Reporting Manual or regulatory amendments. Any reference documents issued by the FTA, including the Reporting Manual, are only procedural. Changes made in the Reporting Manual involve clarification of definitions and modified reporting procedures.

Substantive changes to the Section 15 systems, such as the addition or elimination of categories of data or reporting forms, or restructuring of the systems, will be made through the rulemaking process. These changes will be announced in the Federal Register, with an opportunity for public comment.

System and structural changes described in the rule are effective for the 1992 report year, unless otherwise indicated, and apply to all section 15 reporting years beginning with 1992. The 1992 reporting year covers local transit agencies' fiscal years ending on or between January 1, 1992 and December 31, 1992. Report due dates follow reporting agencies' fiscal year end dates, and range from October 28, 1992 to April 30, 1993 for the 1992 report year.

B. The Uniform System of Accounts and Records and Reporting System

The Uniform System of Accounts and Records and Reporting System were authorized in 1974 under section 15 of the Federal Transit Act, as amended, and prescribed in January 1977, as called for in the Act. Section 15 requires the FTA Administrator (as delegated by the Secretary of Transportation) to establish a uniform system of accounts and records and a reporting system to collect and disseminate public mass transportation financial and operating data. The section 15 system is used by over 500 public transit agencies to record summary information in annual reports filed with the FTA. The FTA then applies quality checks to the reported data, works with reporting agencies to correct errors, and distributes data in published reports and on computer media.

Section 15 information is used for management and planning by transit systems, and policy analysis and investment decisions at all levels of government. This information provides a resource for consultants, researchers, and industry suppliers. Additionally, the section 9 formula grant program apportions approximately $1.7 billion in FTA grant funds annually based on a statutory formula which uses section 15 data. No grant can be issued under section 9 unless the applicant and any person or organization to receive benefits directly from that grant are each subject to both the Reporting System and the Uniform System of Accounts and Records prescribed by section 15. Section 15 of the Federal Transit Act, as amended, requires applicants and direct beneficiaries of grants under section 9 of the Federal Transit Act to maintain and report uniform financial and operating information.

II. Overview of the Final Rule

This rule implements two types of changes to 49 CFR part 630, the Uniform System of Accounts and Records and Reporting System (the "Section 15 system").

(1) The text of part 630, which prescribes the Section 15 procedural requirements, has been shortened and simplified. However, the actual procedural requirements and findings remains essentially the same. As with the previous rule, Part 630 will continue to define the procedural requirements for compliance with the Section 15 system, for example, procedures for filing auditor statements or requesting extensions on due dates. Part 630 summarizes the purposes and methodology of the Section 15 system, but does not describe the structure and content of the Section 15 system in detail. Reporting agencies, data users, and others are referred to the current reference documents (the Uniform System of Accounts and Records and the Reporting Manual) for complete descriptions of details, for example, the required number of operating expense details.

(2) This rule also implements major changes to the structure and content of the Section 15 system. These changes, which will substantially reduce the burden on reporting agencies, are summarized in the next section.

III. Overview of the Major Changes to the Section 15 System

This rule implements a number of changes to 49 CFR Part 630 (Uniform System of Accounts and Records and Reporting System), Appendix which affect the structure and content of the Uniform System of Accounts and Records and Reporting System (the "Section 15 system"). These changes reduce the burden of reporting while improving the analytical value of the data. All changes are the result of an extensive evaluation completed by the Federal Transit Administration (FTA) to determine the future direction of the Section 15 system.

The evaluation balanced trade-offs between the usefulness of the data base against the burden of reporting. In this evaluation, the FTA considered public comments received in response to an Advanced Notice of Proposed Rulemaking (ANPRM) published in the Federal Register (55 FR 33078) and the subsequent Notice of Proposed Rulemaking (NPRM) published in the Federal Register (56 FR 38256) requesting comments on the direction of the Section 15 system and proposals to change the structure and content of the Uniform System of Accounts and Records and Reporting System. All comments are available for public inspection in room 9316 of the DOT, Departmental Headquarters, Nassif Building, 400 7th St., SW., Washington, DC 20590.

Predicated on the results of this evaluation, the FTA implemented the following major changes:

(1) Simplification of the basic reporting structure. Three voluntary and one required report level were replaced with a single required reporting level. In addition, reporting agencies have the option to report a smaller set of additional financial and operational details.

(2) Reduction of the details used to report operating expenses (the most complex component of the systems) by 95% for the reporting agencies choosing to provide optional details.

(3) Increasing the number of purchased transportation contracts that can be reported using a sub-set of required information. The threshold for complete reports on service provided under a purchased transportation contract is raised from the previous 50 or more vehicles operated in maximum service to 100 or more vehicles. Formerly, reporting agencies contracting for service provided with less than 50 vehicles operated in maximum service were able to provide a reduced amount of information for that service. This exception to a complete report has been extended to contracted service provided with less than 100 vehicles operated in maximum service.

(4) Transferring security and ticketing costs from the administration to the operations grouping. These changes respond to industry concerns that the systems exaggerated administrative costs. The disadvantage from this more logical alignment is a reduction in the historical continuity of summary expenses for most reporting agencies.

(5) Revision of capital reporting by the addition of sources and uses of capital in place of the balance sheet. This change overcomes a major weakness in the application of section 15 data. The absence of capital costs had encouraged an over-emphasis on operating rather than capital costs, thereby distorting comparisons between modes or transit operators with different labor or capital intensity.

(6) Elimination of employee contributions on the fringe benefits schedule. This revision simplifies reporting with an insignificant loss of data.

(7) Simplification and redefinition of employee labor categories. To improve consistency, labor is measured in hours worked instead of labor years, which had been defined by using a single standard that was inapplicable to all transit operators. The FTA reduced the number of labor categories from ten to seven to parallel reduced operating expense details.

(8) Consolidation of fleet inventory information from three different forms onto a single form.

(9) Restructuring and simplification of reports of transit operators' work time. This change reduces the reporting burden with only a minor loss of data.

(10) Addition of an option to indicate paid hours by part-time employees, including revenue vehicle operators. These valuable data enhance assessments of the effect of part-time labor on performance.

(11) Elimination of required reporting of all service supplied (vehicle miles and hours) and consumed (unlinked trips) measures by peak and other time-of-day periods. Time-of-day reporting for these measures is optional; vehicles in operation by time period is required. This change reduces the reporting burden while adequately indicating peaking characteristics of transit supply and demand.

(12) Complete allocation of joint expenses. Reporting agencies must allocate all joint expenses by function and object class. This change increases the value of data for analysis of modal costs, which offsets any additional efforts required of reporters to perform additional cost allocations.

(13) Elimination of two required reporting forms because their reporting burden negates the analytical value of the reported data.

(i) *Pension plans.* Inapplicable to many agencies, difficult to compile, and seldom used in analysis.

(ii) *Balance sheet.* These object classes are inconsistently reported and of minimal value to analysts.

IV. Summary of Changes and Comments

As part of its review, the FTA considered the fundamental purpose of the Section 15 system, and whether the system should continue or be significantly modified. To focus and encourage comments, the FTA framed the questions and identified the issues in the ANPRM and NPRM. The evaluation considered all concerns related to the systems. Additional issues and changes related to the specific forms referred to in this section are discussed in section IV.

A. General Issues and Changes

(1) Does the Section 15 system satisfy legislative intent? How successfully does the system serve the requirements of a broad range of current and potential data users?

As stated in section 15 of the Act, the Uniform system of Accounts and Records and the Reporting System were to be designed to provide information on which to base planning for public transportation services and public sector investment decisions at all levels of government. General comments received suggest that this legislative intent has been satisfied.

The FTA asked how effectively the Section 15 system provides information for the overall transit industry, including Federal, state, and regional policy-makers. The FTA also considered the difficulty of satisfying all the needs of all the data users, while limiting the costs and burdens of the reporting requirements. Industry comments found Section 15 to have a broad range of applications, including: a source of standardized definitions; a resource for academic research; and a tool for local management.

The FTA posited several modifications to the structure, format, and content to present a compromise among competing interests. The FTA implemented several operational improvements to ease the reporting burden, while retaining valuable data for analysis.

(2) What should be the direction of the Section 15 system? Should it continue?

All comments from the transit industry and public supported continuing the Section 15 system. There was strong support for the overall revised structure, as proposed in the NPRM. Of the 26 NPRM responses, nineteen either endorsed the entire NPRM, or endorsed it with limited comments. Two NPRM comments suggested that the FTA develop a routine process to review planned changes to the Section 15 system with industry representatives.

The FTA also received numerous comments requesting a reduction in the level of required data, particularly for smaller agencies, and operational improvements to streamline reporting and improve data access.

Actions. In response to these comments, the FTA implemented the following measures:

(1) Development of automated reporting procedures. The FTA developed software for the 1992 report year to permit interested reporting agencies to perform basic validation before their Section 15 report is filed with the FTA. The reporting agencies may file Section 15 reports in a form that can be read directly by computer. This capability was supported in nine NPRM comments.

(2) Reduction in efforts required to report contract service. The requirement for a full Section 15 report for contract service has been raised from 50 to 100 vehicles in maximum service. This is a substantial reduction in the burden for reporting information on the growing number of contract services. Additional details are provided in section IV.A of this preamble.

(3) Reduction of the reporting burden for small systems. The FTA will continue to waive specific reporting requirements that are particularly burdensome for small reporters. Reporting agencies with 25 or fewer revenue vehicles operated in maximum service (the peak period when the greatest number of vehicles are operating in revenue service) are currently not required to provide data on operators wages (Form 321), fringe benefits (Form 331), and pension plans (Form 332). In addition, sampling or other procedures that meet prescribed precision and confidence levels need only be applied every third year by reporting agencies: (a) That serve urbanized areas of less than 500,000 population; (b) that directly operate fewer than 100 revenue vehicles for all modes in maximum; or (c) that purchase transportation services (use private or public carriers to provide transit service under contract to a public agency). Purchased service contractors that submit separate Section 15 reports are not included.

(4) Improvement of data access and applications. The majority of changes in this rule simplify and rationalize the content and structure of the systems. The combination of streamlined reporting procedures, coupled with these changes, should improve the quality of the data base and provide the foundation for the next stage in the evolution of the Section 15 system, which will emphasize improved data applications by all industry groups. To increase the usefulness of the data base, the FTA is developing improved computerized access, new reports, and training and user guides to encourage data applications.

B. Structural Issues and Changes

This section focuses on changes to fundamental aspects of the structure of the Section 15 systems. These modifications and related issues cut across several components of the systems or address areas identified in

the comments as major weaknesses. Modifications of specific components of the systems, including data reported on many of the forms mentioned in this section, are elaborated upon in section IV.

(1) The number of voluntary or required reporting levels.

Before changes in this rule, a major characteristic of the Reporting System structure was the use of different reporting formats. The required (R) level applied to all agencies and specified the minimum data that must be reported by all beneficiaries of FTA section 9 funds. Agencies had the option of reporting additional details at any of three voluntary (A,B, or C) levels. In order of detail, the A level required the most information, followed by B, C, and R levels.

The only difference between the required and voluntary levels of reporting was the amount of detail provided for operating expenses and revenues. All other information was required of all reporting agencies and was filed on the same forms. Voluntary levels of expense and revenues had the same basic structure as the required level, but expanded into greater detail. There was no difference in the underlying Uniform System of Accounts and Records.

Although the FTA suggested that agencies with certain fleet sizes report at specific voluntary levels, this was not a requirement. Several of the largest agencies reported at the required level, while some small agencies reported at the more detailed voluntary levels. Agencies that received FTA grants for Management Information Systems (MIS) were obligated to report at voluntary levels. Beginning with the 1991 report year, reporting agencies that received MIS grants were able to report at either the required or voluntary levels (see section IV.D).

The FTA considered whether to continue voluntary reporting, considering the usefulness of a data base that provides different levels of financial details for different agencies. The FTA was interested in whether a subset of the national data base with more detailed information was of value for important analysis, or if it encouraged biased results. The FTA solicited comments on whether the system was unnecessarily burdensome or excessively detailed; on how many levels to provide; and on whether selection of level should be required or voluntary.

Few of the 26 NPRM commenters addressed reporting levels, either in general or in detail. Of the three comments that opposed the simplified NPRM approach of one required and one optional level, two supported a single required level, and a third supported having all reporting agencies provide the same required information, using one or two levels, with no optional information. Fifteen commenters either explicitly supported the proposed approach to reporting levels, or supported the overall NPRM structure, and did not directly refer to reporting levels, the major proposed structural change.

The FTA reached the following conclusions in its evaluation of proposals to change the approach to reporting expenses and revenues:

(a) The previous structure was unnecessarily complex; the value of a large number of voluntary expense and revenue details to analysts was insufficient to justify their continued reporting.

(b) The previous required level alone did not provide enough details on costs and revenues to meet Section 15 system objectives of providing data to support management, policy, and investment analysis.

(c) Financial reporting requirements could not be increased for the large number of agencies reporting at the previous required level who would have increased requirements under any proposals for two or more required levels.

(d) Most large agencies have internal accounting systems, based on the Section 15 Accounting System, with a greater level of detail than the previous required level.

(e) Forms or data cells that are inapplicable to most agencies do not create a reporting burden for those agencies. For example, the existence of expense details on maintenance of roadway and track or communications systems do not create a burden to the majority of agencies who can ignore these costs items.

(f) Data reported for some but not all agencies can have valid and important applications. Valuable and undistorted analysis can be performed using an incomplete data set, if sources are identified and no universal conclusions are attempted without statistically valid methods. For example, optional costs such as fare collection, maintenance of roadway and track and passenger stations, and security could be useful in deriving unit costs for analysis of investments in alternative modes, even if reported by some but not all agencies.

The following modifications are based on the above conclusions.

Action: The FTA has reduced reporting levels from three voluntary and one required to a single basic level, based on the previous required (R) level, to be reported by all reporting agencies. In addition, reporting agencies have the option of providing a limited number of additional details using the same basic level expense, revenue, and operations forms. Such details as modal fares are of value to a broad range of industry analysts, but are not universally collected by reporting agencies.

For the reporting agencies choosing to provide all optional details, the new single basic level reduces the number of expense details previously reported at the most detailed voluntary level by 95%. The reporting levels are described in the current edition of the Reporting Manual.

Action: The FTA will provide all data in accessible microcomputer formats to encourage large agencies and others that have the optional details available to contribute to the national data base. Improved access, combined with improved data quality, will provide the foundation for the next stage in the evolution of the Section 15 system, which is an emphasis on improved data applications by all industry groups.

(2) Reporting frequency.

There were no comments in response to the proposal to continue annual reporting.

Action: The FTA will continue annual reporting. The burden of annual reporting was mitigated by the overall reduction in required forms.

(3) Reports for overall operations of a transit system or separation of some details by mode.

From its original design, the Section 15 system has required that reporting agencies submit some data by mode and other data based on the overall operations of the transit system. For example, reporting agencies are currently required to submit operators' wages, labor years, ridership data, and service statistics by mode. Operating expenses by function (operations, vehicle and non-vehicle maintenance, and administration) were also reported by mode. However, reporting agencies submitting operating expenses by object class (for example, wages, contracts, and fuel) have not been required to report these data separately by mode; typically, there was a residual category of joint expenses that were not allocated to mode. No commenters on the NPRM opposed the continuation of modal reporting for some operating and service statistics.

Action: The FTA has maintained the current structure of modal separation for operating statistics. In addition to previous modal separations, the FTA has added allocation of all operating expenses to modes, with no residual

joint expenses. This change, which will improve the description of modal costs, is discussed in detail in section IV.

(4) Revision or expansion of demographic data.

At the time of the ANPRM, each reporting agency was required to submit a statement from the local Metropolitan Planning Organization (MPO) stating the agency's service area and population, and describing the planning methods used to determine that service area.

The FTA assigns a single Census-defined urbanized area code (UZA), with population and surface area, to each reporting agency. This code, which is used to apportion section 9 funds, can be an inexact measure of service area and population.

Action: Consistent with the general objectives of increasing accuracy and simplifying reporting, the FTA eliminated the requirement for a summary from the MPO stating the operating agency's service area and population. However, because the Census data provide an inexact measure of service area and population, the FTA has added service area and population to the transit system identification form. There were no comments on the NPRM proposal to continue reporting demographic data.

(5) Modification of the current method of access to the data base.

All data submitted to the FTA by section 15 reporting agencies are stored on magnetic tapes available for public use. A subset of the complete data base, containing some, but not all, required level data, is published in the Annual Report and distributed on diskettes for use on microcomputers. For example, much of the revenue and financial details provided by voluntary level reporting agencies are available only on tape for use with mainframe computers. Some required level details, including vehicle operators' time and fleet inventories, are also only available on tape.

The FTA received comments that analysts find access to the tapes to be very difficult. Commenters requested better automated access to the data base through new computer formats or on-line access.

Action: The FTA is improving access to the data base. The entire data base described in this rule will be accessible to the public for use on microcomputers running standard spreadsheet and data base software. Beginning with the 1990 data base, all operating expense and revenue data, including that which has in the past only been available on tape, will be available for microcomputer applications. Beginning with the 1992 report year, the FTA improved the ease of access to and application of important data by developing three new products: (1) Summary reports for individual reporting agencies, with key data items, performance measures, and graphic displays; (2) a new annual report of national transportation trends; and (3) an analysis data base of key information for use with standard data base management software.

V. Modifications to the Detailed Structure of the Section 15 Systems, With Related Issues

Section III.B focused on proposals to change fundamental characteristics of the systems, such as reporting by mode. In contrast, this section presents modifications to more specific components of the system and formulates related issues.

General comments on reducing voluntary level details: In restructuring and simplifying the number of voluntarily reported expense and revenue details, the FTA intended to carefully balance reporting burdens against any losses of valuable detail for analysis and historical continuity. The FTA used the following criteria to consolidate the number of required and optional details.

(a) Consolidate minor cost items (in terms of dollars and reporting agencies providing that item);

(b) Report major types of costs as separate details;

(c) Retain easy-to-collect items;

(d) Avoid irrelevant or analytically meaningless items;

(e) Retain items that are key decision variables;

(f) Avoid realignments from one category to another in the interest of preserving the continuity of twelve years of historical data.

A. Basic Information

Purchased Transportation Services

Transportation service provided under contract is described on several reporting forms. Form 002 describes contractual relationships. Costs of contracts are reported as expenses on the 300-series forms. Complete reports had to be filed for or by contractors providing over 50 revenue vehicles. A public agency contracting for under 50 revenue vehicles also described contract service on separate Forms 004 and 408 for vehicles operated, 403 for transit way mileage, and 406/407 for service supplied and ridership.

The FTA proposed that the information on service provided under purchased service contracts to public agencies be decreased by changing the fleet size level at which a complete Section 15 report must be filed. This change would be consistent with the FTA's objective of easing the reporting burden for small transit agencies. No commenters opposed this proposal.

Action: The threshold level for submission of a separate Section 15 report by a purchased transportation provider has been raised from 50 to 100 vehicles in maximum service (the peak period when the greatest number of vehicles are operating in revenue service). This change is consistent with the FTA's objective of easing the reporting burden for small transit agencies.

B. Capital Expenses

The Reporting System previously collected a limited amount of information on capital expenses relative to the detail provided on operating expenses. Capital expense information included a balance sheet (Form 101) with basic financial information on assets, liabilities, and capital at the end of the financial year. Rolling stock, facilities, and equipment were combined into a single category. Unlike operating expenses, which are structured to allow modal separation of costs, reporting agencies did not separate capital accounts by mode.

In addition, a single depreciation figure for all modes combined is reported on the expense forms (300 series) with no separations to identify depreciation of vehicles or other asset categories or assets by mode. The Accounting System does not provide or recommend standardized approaches to depreciation or require reporting agencies to identify the approaches they use. The amount and source of public assistance funds dedicated to capital are also identified for all modes.

It is likely that the previous lack of capital cost data encouraged over-emphasis on operating costs in analyses of performance and alternative investments, and limited thorough evaluation of total expenses, revenues, and outputs. Capital expenses data can include purchases and depreciation of capital assets, including rolling stock, plant, or other equipment. They were no NPRM comments on the proposed sources and uses of the capital data form.

Action: The capital data form has been revised to report sources and uses of capital. The revised form combined previously reported information on private and public sources of revenues for capital with new information on uses of capital, including purchases of rolling stock and facilities. This new information will provide some valuable information for analysis without adding

to the reporting burden. All major categories for use of capital are identified by mode.

To compensate for the new informational requirement to report uses of capital, the FTA eliminated the balance sheet. There is support in the industry to retain the balance sheet, but the FTA suggests that this information does not provide a useful description of capital expenses; it is often inconsistent, and is of limited value for analysis. In the interest of limiting the information in the national data base to that which is most useful for analysis, the FTA believes that sources and uses of capital should replace the balance sheet.

C. Revenues

Information on revenues is reported in several different categories. The required level Form 201 contains information on fares, other earnings, and Federal, state, and local grants, with identification of total subsidies for handicapped, senior, or student passengers combined. Form 202, formerly used by all voluntary level reporting agencies, expanded the Form 201 structure into greater detail. For example, Form 202 expanded the single fare total on 201 into seven categories. Forms 201 and 202 identified revenues for publicly operated but not contracted service. Multi-mode agencies only provided system-wide totals on Forms 201 and 202, although all reporting agencies had the option of separating fares by mode. The Annual Report and the Section 15 diskettes contain voluntary revenue details consolidated to the required level. Complete revenue information was previously available only on computer tape.

The previous Forms 103 and 203 described revenues by governmental source (Federal, state, and local) and by means used to collect revenues (sales, income, and gasoline taxes and tolls) for operating and capital assistance.

Action: Consistent with the proposed approach to reporting optional details described in section III.B.1, the FTA eliminated Form 202 and added a limited number of optional details to Form 201, which is completed by all reporting agencies. Optional items include fares by mode and type (adult, senior, and student), and other revenues (investment income). The new structure, which is detailed in the current edition of the Reporting Manual, was the result of applying the criteria described in the introduction to section IV.

Voluntary or required level reporting agencies have had the option of allocating fares by mode since the 1984 report, but few did so even though most agencies collect this information for their own use. Although analysts are interested in modal fares, few use this information because of the effort required to extract data from the computer tapes.

Action: The FTA encourages reporting of modal fares by highlighting this option in the Reporting Manual and improving access to modal fares through published reports and microcomputer files. The FTA recognizes the high level of interest by analysts in modal splits of fares, which would allow Section 15 data to be used to analyze a broad range of important modal performance measures, including farebox recovery rates, and average fares and subsidies per rider. The FTA decided not to require modal fares because of the difficulty this presents for agencies with large numbers of transfers and monthly or other passes.

D. Operating Expenses

Transit systems use the 300-series Forms to report operating expenses in function (operations, vehicle and non-vehicle maintenance, and general administration) and object class (wages, fringe benefits, and other) categories. Before the changes in this rule, reporting agencies at the required level used the basic four functions and fourteen object classes. These details expanded for agencies at any of the three voluntary levels up to 44 functions and 47 object classes at the most detailed A level. Voluntary expense details were consolidated to the required level in the Annual Report and on the Section 15 diskettes. Complete expense information was available only on computer tape.

Functions and object classes could be cross-classified, allowing, for example, fringe benefits paid to vehicle operators to be identified. There was, however, only a limited ability to separate modal costs for multi-mode agencies. Modal costs could be separated by function (for example, light rail vehicle maintenance), but usually not by object class (for example, light rail wages) or by function and object class (for example, light rail operators' wages). Reporting agencies with more than one mode typically did not allocate all object code costs by mode, and instead retained a category of unallocated or residual "joint expenses." Joint costs limited the ability to evaluate some important costs by mode.

In the NPRM, the FTA proposed two reporting levels; the required level would be maintained, and the previous three voluntary levels would be simplified into a single voluntary level with 21 functions and 26 object classes. No NPRM comments were received in support of the existing system of one required and three voluntary operating expense levels. The consensus was that the expense structure should be simplified. Seven comments supported the NPRM proposed structure or a further reduction in detail. Of these, one supported a single required level for all reporting agencies, one endorsed either one or two required levels, and one supported the NPRM proposal.

Action: In response to the absence of public comments in support of the original system of four detailed reporting levels, and broad support for simplified reporting, the FTA has streamlined the operating expense reporting structure. The previous required level is the foundation for a new basic level to be reported by all reporting agencies; a small set of additional expense details are optional. All reporting agencies will use a single form. The FTA has eliminated all other forms.

The new financial reporting structure has the following characteristics:

(1) The four R and C level expense functions (Vehicle Operations, Vehicle and Non-Vehicle Maintenance, and General Administration) are maintained.

(2) All reporting agencies will use the same set of fourteen object class expenses. This is a reduction of 70% from the maximum of 47 expense details reported by voluntary-level reporting agencies.

(3) Reporting agencies have the option of providing a limited set of optional functions, which are components of the four basic functions, using the same basic level operating expense form. These optional details are: Administration and Support, Revenue Vehicle Operations, Ticketing and Fare Collection, and System Security for Vehicle Operations. Although these details are of value to a broad range of industry analysts, they are not collected by all reporting agencies, particularly smaller agencies.

(4) The FTA has realigned two previous A level functions—Ticketing & Fare Collection (151) and System Security (161)—from the General Administration to the Vehicle Operations category, in response to an industry proposal. These functions were the fourth and fifth largest of the 44 A level cost functions previously reported. The logic of moving these items into operations outweighs the disruption to the continuity of fourteen years of historical costs caused by the realignment. The definitions and value of Vehicle Operations and General Administration will change. Historical continuity is assured for reporting agencies identifying optional costs for

Ticketing and Fare Collection, and Security; historical continuity will not be possible for other reporting agencies. There were two NPRM comments in support of the realignment, and no comments in opposition.

(5) Reporting agencies must now allocate joint expenses by function and object class for each mode. Previously, allocations were only required by function. This change increases the value of data for analysis by eliminating residual joint expenses that limited the ability to evaluate object class expenses by mode for multi-modal agencies. Additional efforts required for direct allocation of all joint expenses are offset by a simplified reporting structure and the improved usefulness of data for analysis of modal costs.

These revisions to the Uniform System of Accounts and Records and Reporting System reduce the number of expense details at the most detailed voluntary level by over 95% for the reporting agencies choosing to provide the optional details. The new structure is detailed in the current edition of the Reporting Manual.

E. Other Financial Data

Operators Wages and Hours Schedule

The Operators Wages and Hours Schedule on Form 321 provided a detailed breakdown of the hours and wages paid to revenue vehicle operators, including major categories of wages and hours for operating and non-operating paid work. In the NPRM, the FTA proposed to simplify reporting operators wages and hours by consolidating categories. There were no comments opposing this proposed consolidation.

Action: The FTA simplified the Operators Wages and Hours Schedule by consolidating details to less than half the previous number of time classifications. The new structure is detailed in the current edition of the Reporting Manual.

Fringe Benefit Contributions

Fringe benefit contributions of both employers and employees are reported on Form 331. The FTA proposed elimination of employee contributions to fringe benefits in the NPRM to simplify reporting. Two commenters agreed with the FTA's proposal to eliminate Form 331 because of questionable value of data. There were no comments opposing this proposal.

Action: The FTA eliminated reports of employee contributions to fringe benefits. This change is consistent with specific comments on fringe benefits and general support for simplifying reporting.

Pension Plans

Information on the cost components of the various pension plans that reporting agencies provide for their employees were reported on Form 332. Pension plan data were not published in the Annual Report.

No commenters supported the collection of this data. Employee contributions to fringe benefits were proposed to be eliminated because employee contributions come out of wages, which are already reported by the agencies. Consequently, the inclusion of employee contributions would result in double-counting. In addition, pension plan data are of limited value for analysis because the data involve plan-specific details.

Action: The FTA has eliminated Form 332, Pension Plan Questionnaire. This change is consistent with the comments on the minimal value of pension data and general support for simplifying reporting and reducing the number of forms. The total cost of pension plans will continue to be included within the costs of fringe benefits.

F. Non-Financial Operating Data

The Reporting System uses several forms to collect information on a broad range of non-financial characteristics of transit service, including maintenance of vehicles, fleet inventories, infrastructure, labor resources, safety, service supplied, and ridership.

Fleet Inventory

Prior to the changes in this rule, the Reporting System recorded several types of fleet information on several different forms. Forms 003 and 004 contained the number and type of vehicles required and available to meet peak or maximum several requirements measured at the time of year when maximum service occurs. Forms 406 and 407 recorded the number of vehicles in operation during average daily time periods. Form 408 measured all vehicles in the total fleet, including vehicles that are active, stored, and awaiting sale. In the NPRM, the FTA proposed a reduction in the number of reporting forms by consolidating the forms used to report fleet inventory data. Two NPRM comments encouraged the FTA to eliminate Forms 003 and 004. These comments agreed with the FTA's proposal to consolidate the information on these forms with Form 406, 407, and 408. The FTA received no comments opposing the proposal.

Action: Consistent with numerous NPRM responses requesting general simplification of reporting and reduction in the number of forms, the FTA eliminated Forms 003 and 004 by incorporating the information from those forms into Forms 406 and 407.

Service Periods

Time periods of transit service for each mode, including a.m. and p.m. peaks, midday and hours of service for weekdays, Saturdays, and Sundays were reported on Form 401. These data were not published in the Annual Report. In the NPRM, the FTA proposed to eliminate Form 401 and incorporate this information on Forms 406 and 407. The FTA received no comments opposing this proposal as published.

Action. To simplify reporting and to reduce the number of forms, the FTA eliminated Form 401. Information on service period schedules is incorporated onto Forms 406 and 407.

Service Reliability—Roadcalls

Data on roadcalls for mechanical failure and other reasons are reported on Form 402.

The FTA considered if reports of roadcalls are of value, if definitions should be revised to make the data more useful, or if alternative data items should be substituted to measure reliability.

Commentators expressed dissatisfaction with the approach to reporting roadcalls—Two commenters proposed elimination of roadcall information from Section 15 reporting, and two suggested either elimination of roadcalls or development of standard definitions.

Action: Since roadcalls are a crucial aspect of performance, the FTA has retained the definition of roadcalls. The FTA will work with the transit industry to develop an improved measure of reliability for future inclusion in Section 15.

Transit System Employee Counts

Prior to this rule, system-wide hours worked were categorized by different functions on Form 404. For simplicity, these hours were divided by 2080 and reported as full-time equivalents; there were no distinctions between labor of full-and part-time employees. The proposal in the NPRM to report annual work hours instead of annual equivalents was supported in one comment and opposed in another. The NPRM also proposed adding a check-off box to indicate use of part-time operators, and, on a trial basis, providing the option of indicating the percentage paid hours for revenue vehicle operations provided by part-time operators. The only comment on the proposed additional information on

part-time employees was one opposing required reporting of this information.

Action. The FTA has modified The Transit System Employee Count Schedule to report work hour instead of equivalent work years. This change avoids the arbitrariness of the previous definition of full-time equivalent employees.

Action: The FTA has added a check-off box to Form 404 to indicate use of part-time employees in revenue vehicle operators and other categories. In addition, all reporting agencies have the option of indicating the paid hours for part-time employees for all labor classifications. The reporting agency must summarize the local definition of part-time on Form 005. The FTA believes that these data are of value in assessments of the effect of part-time labor on performance, including on costs, service, and safety.

Action: The FTA reduced the number of labor categories from ten to seven to parallel reduced operating expenses details and simplify reporting.

Service Supplied and Consumed

Service supplied (vehicle miles and vehicle hours) and service consumed (ridership) information is reported on Form 406 for non-rail modes and on Form 407 for rail modes. Information includes measures of the quantity of service supplied, including vehicle miles and hours, actual and scheduled vehicle revenue miles, and capacity miles; and unlinked passenger trips and passenger miles. Some items on these forms were reported by time-of-day (peak and base, and day of week averages).

On the seven NPRM commenters supporting simplified service consumed and supplied reporting, two were particularly concerned with the complexity of time-of-day reporting.

Three NPRM commenters supported eliminating capacity miles, which are determined by multiplying seating and standing capacity by vehicle revenue miles. Capacity miles can be a useful measure of service supplied in comparisons between agencies with different size vehicles operating the same or different modes. One NPRM commenter supported development of new measures of service quality.

Action: To reduce the reporting burden, the FTA eliminated required reporting of the five service consumed and supplied measures by peak and other time-of-day periods. Reporting agencies are only required to provide vehicles in operation by time period, but are able to continue reporting the time-of-day statistics as an option. The FTA believes that this reduced level of information adequately indicates the peaking characteristics of transit supply and demand for a broad range of analyses, including for regional analysis of transit and automobile use in regions with congestion or air quality problems.

Action: Although the FTA has not added measures of service quality, it has improved access to reports of actual and scheduled vehicle revenue miles, which were reported prior to this rule. Scheduled vehicle revenue miles were previously available only on tape. Comparisons of actual and scheduled vehicle revenue miles can provide a measure of one aspect of service reliability.

Action: The FTA eliminated the reporting of capacity miles. This can be a valuable measure of service supplied, but inconsistencies in local policies on seating and standing, and different seat configurations created inconsistencies between reporting agencies and encouraged biased comparisons.

VI. Bibliography

Reference documents for the Uniform System of Accounts and Records and Reporting System are as follows:

Reporting Manual For the 1992 Section 15 Report Year, Federal Transit Administration April 1992.

Urban Mass Transportation Industry Uniform System of Accounts and Records, (current edition), Federal Transit Administration.

Circular 2710.1A, Sampling Procedures for Obtaining Fixed Route Bus Operating Data Required Under the Section 15 Reporting System, July 1988.

Circular 2710.2A, Sampling Procedures for Obtaining Demand Responsive Bus System Operating Data Required Under the Section 15 Reporting System, July 1988.

Circular 2710.4A, Revenue Based Sampling Procedures for Obtaining Fixed Route Bus Operating Data Required Under the Section 15 Reporting System, July 1988.

Transit Profiles—The Thirty Largest Agencies for the 1990 Section 15 Report Year, Federal Transit Administration, November 1991.

Transit Profiles—Agencies in Urbanized Areas Exceeding 200,000 Population for the 1990 Section 15 Report Year, Federal Transit Administration, November 1991.

Transit Profiles—Agencies in Urbanized Areas with a Population of Less Than 200,000 for the 1990 Section 15 Report Year, Federal Transit Administration, November 1991.

Data Tables for the 1990 Section 15 Report Year, Federal Transit Administration, December 1991.

Data User's Guide to the FTA Section 15 Reporting System, Research and Special Programs Administration/John A. Volpe National Transportation Systems Center, June 1, 1989.

VII. Appendix

Attached to Part 630 is Appendix A, which explains the overall structure of the Section 15 Uniform System of Accounts and Records and Reporting System. This Appendix provides a general overview of the Systems. It is important to emphasize that in the actual preparation of a report, reporting agencies must use part 630, the Reporting Manual, and any other materials provided by the FTA. The Appendix describes the level of reporting and recordkeeping used in the Reporting and the Accounts and Records Systems, and the use and structure of the Systems.

VIII. Regulatory Analyses and Notices

A. Executive Order 12291

This action has been reviewed under Executive Order 12291, and it has been determined that it is not a major rule. It will not result in an annual effect on the economy of $100 million or more. This regulation is not significant under the Department's Regulatory Policies and Procedures. The FTA finds that the economic impact of this regulation is so minimal that a full regulatory evaluation is not required.

B. Regulatory Flexibility Act

In accordance with 5 U.S.C. 605(b), as added by the Regulatory Flexibility Act, Pub. L. 96–354, the FTA certifies that this rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Act. To the extent the new regulation will be more easily understood and will more clearly state the basic reporting procedures, it may save small entities time in determining their rights and responsibilities.

C. Environmental Impacts

This final regulation would not adversely affect the environment.

D. Paperwork Reduction Act

The collection of information requirements in the present rule are subject to the Paperwork Reduction Act, Public Law 96–511, 44 U.S.C. chapter 35, and have been approved by the Office of Management and Budget as number 2132–0008.

List of Subjects in 49 CFR Part 630

Mass transportation, Reporting and recordkeeping requirements, Uniform System of Accounts.

Accordingly, for the reasons stated above, the FTA revises 49 CFR part 630 as follows:

PART 630—UNIFORM SYSTEM OF ACCOUNTS AND RECORDS AND REPORTING SYSTEM

Sec.
630.1 Purpose.
630.2 Scope.
630.3 Definitions.
630.4 Requirements.
630.5 Failure to report data.
630.6 Late and incomplete reports.
630.7 Failure to respond to questions.
630.8 Questionable data items.
630.9 Notice of FTA Action.
630.10 Waiver of reporting requirements.
630.11 Data adjustments.
630.12 Display of OMB control numbers.

Appendix to Part 630—Overview and Explanation of the Urban Mass Transportation Industry Uniform System of Accounts and Records and Reporting System

Authority: Sec. 111, Pub. L. 93–503, 88 Stat. 1573 (49 U.S.C. 1611); Secs. 303(a) and 304(c), Public Law 97–424, 96 Stat. 2141 (49 U.S.C. 1607); and 49 CFR 1.51.

§ 630.1 Purpose.

The purpose of this part is to prescribe requirements and procedures necessary for compliance with the Uniform System of Accounts and Records and Reporting System mandated by section 15 of the Federal Transit Act, as amended, 49 U.S.C. 1611, and to set forth the procedures for addressing a reporting agency's failure to comply with these requirements.

§ 630.2 Scope.

This part applies to all applicants and beneficiaries of Federal financial assistance under section 9 of the Federal Transit Act, as amended (49 U.S.C. 1607a).

§ 630.3 Definitions.

(a) Except as otherwise provided, terms defined in the Federal Transit Act, as amended (49 U.S.C. 1601 et seq.), are used in this part as so defined.

(b) Terms defined in the current editions of the Urban Mass Transportation Industry Uniform System of Accounts and Records and the annual Reporting Manual, are used in this part as so defined.

(c) For purposes of this part:

Administrator means the Federal Transit Administrator or the Administrator's designee.

Applicant means an applicant for assistance under section 9 of the Federal Transit Act, as amended.

Assistance means Federal financial assistance for the acquisition, construction, or operation of public mass transportation services.

Beneficiary means any organization operating and delivering urban transit services that directly receives benefits from assistance under section 9 of the Federal Transit Act, as amended.

Chief Executive Officer (CEO) means the principal executive in charge of and responsible for the reporting agency.

Current edition of the Urban Mass Transportation Industry Uniform System of Accounts and Records and the Reporting Manual means the most recently issued edition of the reference documents.

Days mean calendar days.

The Federal Transit Act means the Federal Transit Act, as amended (49 U.S.C. 1601a et seq.)

Mass Transportation Agency or transit agency means an agency authorized to transport people by bus, rail, or other conveyance, either publicly or privately owned, and which provides to the public general or special service (but not including school, charter, or sightseeing service) on a regular and continuing, scheduled or unscheduled, basis. Transit agencies are classified according to the mode of transit service operated. A multi-mode transit agency operates two or more modes, which are defined in the current editions of the Urban Mass Transportation Industry Uniform System of Accounts and Records and the Reporting Manual.

Reference Document(s) means the current editions of the Urban Mass Transportation Industry Uniform System of Accounts and Records, and the Reporting Manual. These documents are subject to periodic revision. Beneficiaries and applicants are responsible for using the current editions of the reference documents.

Reporting agency means the agency required to submit a report under section 15.

§ 630.4 Requirements.

(a) *Uniform system of accounts and records.* Each applicant for and direct beneficiary of Federal financial assistance under section 9 of the Federal Transit Act must comply with the applicable requirements of the section 15 Uniform System of Accounts and Records, as set forth in the current edition of the "Urban Mass Transportation Industry Uniform System of Accounts and Records"; the "Reporting Manual"; Circulars; and other reference documentation.

(b) *Reporting system.* Each applicant for, and direct beneficiary of, Federal financial assistance under section 9 of the Federal Transit Act must comply with the applicable requirements of the section 15 Reporting System, as set forth in the current edition of the "Urban Mass Transportation Industry Uniform System of Accounts and Records"; the "Reporting Manual"; Circulars; and other reference documentation.

(c) *Copies.* Copies of these referenced documents are available from the Federal Transit Administration, Office of Grants Management, Audit Review and Analysis Division, P.O. Box 61126, Washington, DC 20039–1126. These reference documents are subject to periodic revision. Revisions of these documents will be mailed to all persons required to comply and a notice of any significant changes in these reference documents will be published in Federal Register.

§ 630.5 Failure to Report Data.

Failure to report data in accordance with this part will result in the reporting agency being ineligible to receive any section 9 grants directly or indirectly (e.g., a public agency receiving The FTA funds through another public agency rather than directly from the FTA). This ineligibility applies to all reporting agencies without regard to the size of the urbanized area served by the reporting agency.

§ 630.6 Late and Incomplete Reports.

(a) *Late reports.* Each reporting agency shall ensure that its report is received by the FTA on due dates prescribed in the annual Reporting Manual. A reporting agency may request an extension of 30 days after the due date. The FTA will treat a failure to submit the required report by the due date as failure to report data under § 630.05.

(b) *Incomplete reports.* The FTA will treat any report or submission which does not contain all the necessary reporting forms, data, or certifications for services directly operated by the reporting agency in substantial conformance with the definitions, procedures, and format requirements set out in the section 15 Uniform System of Accounts and Records and Reporting System as failure to report data under § 630.05. The FTA will treat the submission of a report with incomplete data or missing forms for services provided under contract to the reporting agency by private or public carriers as failure to report data under § 630.05 provided that the reporting agency has exhausted all possibilities for obtaining this information.

§ 630.7 Failure to Respond to Questions.

The FTA will review each section 15 report to verify the reasonableness of the data submitted. If any of the data do not appear reasonable, the FTA will notify the reporting agency of this fact and request written justification to document the accuracy of the questioned data. Failure of a reporting

agency to make a good faith written response to this request will be treated under § 630.5 as failure to report data.

§ 630.9 Questionable data items.

The FTA may enter a zero or adjust any questionable data item(s) in a reporting agency's section 15 report used in computing the section 9 apportionment. These adjustments may be made if any data appear inaccurate or have not been collected and reported in accordance with the FTA's definitions and/or confidence and precision levels, or if there is lack of adequate documentation or a reliable recordkeeping system.

§ 630.8 Notice of FTA Action.

Before taking final action under § 630.5, § 630.6, § 630.7 or § 630.8, the FTA will transmit a written request to the reporting agencies to provide the necessary information within a specified reasonable period of time. The FTA will advise the reporting agency of its final decision in this regard.

§ 630.10 Waiver of Reporting Requirements.

Waivers of one or more sections of the reporting requirements may be granted at the discretion of the Administrator on a written showing that the party seeking the waiver cannot furnish the required data without unreasonable expense and inconvenience. Each waiver will be for a specified period of time.

§ 630.11 Data Adjustments.

Errors in the data used in making the apportionment may be discovered after any particular year's apportionment is completed. If so, the FTA shall make adjustments to correct these errors in a subsequent year's apportionment to the extent feasible.

§ 630.12 Display of OMB Control Numbers.

All of the information collection requests in this part have been approved by the Office of Management and Budget under control number 2132–0008.

Appendix A to Part 630—Overview and Explanation of the Urban Mass Transportation Industry Uniform System of Accounts and Records and Reporting System

A. Introduction

Section 15 of the Federal Transit Act, as amended, provides for establishment of two information-gathering analytic systems: A Uniform System of Accounts and Records, and a Reporting System for the collection and dissemination of public mass transportation financial and operating data by uniform categories. The purpose of these two Systems is to provide information on which to base public transportation planning and public sector investment decisions. The section 15 system is administered by the Federal Transit Administration (FTA).

The Uniform System of Accounts and Records consists of:

- Various categories of accounts and records for classifying financial and operating data;
- Precise definitions as to what data elements are to be included in these categories; and
- Definitions of practices for systematic collection and recording of such information.
- While a specific accounting system is recommended for this recordkeeping, it is possible to make a translation from most existing accounting systems to comply with the *Section 15 Reporting System*, which consists of forms and procedures:
- For transmitting data from transit agencies to the FTA;
- For editing and storing the data; and
- For the FTA to report information to various groups.

Under the terms of section 15 of the Federal Transit Act, as amended, all applicants for, and beneficiaries of, Federal assistance under section 9 of the Act (under the formula grant programs) must comply with the Reporting System and the Uniform System of Accounts and Records in order to be eligible for Federal grants. It should be noted that separate and complete Section 15 reports must be submitted by or for each purchased transportation service provider that operates 100 or more revenue vehicles for the purchased service during the maximum service period.

B. Purpose of This Appendix

This appendix presents a general introduction to the structure and operation of the two Systems. It is not a detailed set of instructions for completion of a Section 15 report or establishment of a System of Accounts and Records. Persons in need of more information should refer to the current editions of the Urban Mass Transportation Industry Uniform System of Accounts and Records and the Reporting Manual, available from: Federal Transit Administration, Audit Review and Analysis Division, Office of Capital and Formula Assistance, P.O. Box 61126, Washington, DC 20039–1126.

The FTA periodically updates these reference documents or supplements them to revise or clarify section 15 definitions, reporting forms and instructions. Section 630.4 makes clear that reporting agencies must use the most recent edition of reference documents and reporting forms to comply with the section 15 requirements. The FTA therefore encourages local officials to check with the FTA before completing a Section 15 report to avoid unnecessary efforts and delays.

C. Special (Reduced) Reporting Requirements

Certain information collection and recording requirements were tailored to accommodate the unique characteristics of certain transportation modes. Reduced requirements were permitted during limited time periods to ease transition to complete reporting for these modes. Reduced reporting requirements for commuter rail systems and vanpool services ended in the 1987 report year. In addition, the reduced reporting requirements for private subscription and private noncontract conventional bus service is eliminated for the 1992 report year.

D. A Single Required Level of Section 15 Reporting and Recordkeeping

The FTA has developed a single required reporting format for use by all transit agencies. The single required level accommodates variations in size, local laws, and modes of transport.

The Uniform Systems also contain a limited amount of additional more detailed financial and operational data that can be submitted at the reporting agency's option. Because the optional subcategories of data can be aggregated to the required level, these subcategories define the more aggregated data. The definitions for data reported at the required level are consistent with, and summarized from, those for the more detailed optional data.

E. The Uniform System of Accounts and Records

The Uniform System of Accounts and Records (USOA) consists of a financial accounting and operational recordkeeping system designed for mass transportation managers and planners. Its uniformity permits more thorough and accurate comparisons and analyses of different transit agencies' operating costs and efficiencies than if each had a unique recordkeeping and accounting system. The System establishes various categories of accounts and records for classifying mass transportation operating and financial data, and includes precise definitions of transportation terminology to ensure that all users share a common understanding of how to use and interpret the collected data.

(1) Use of the Accounts and Records System

Beneficiaries of, and applicants for, Federal assistance are not required to use the Uniform System of Accounts and Records in keeping their own records. If an applicant or beneficiary chooses not to use the System, however, it must nevertheless be able to translate its accounts and records system to the accounts prescribed in the System. The accounting system that the reporting agency uses must permit preparation of financial and operating data that conform to the Uniform System directly from its records at the end of the fiscal year, and must be consistent with the following:

(i) The data must have been developed using the accrual method of accounting. Those transit systems that use cash-basis accounting, in whole or in part, must make work sheet adjustments in their account books to record the data on the accrual basis.

(ii) Reporting agencies must follow or be able to directly translate their system to the accounting treatment specified in the publication "Uniform System of Accounts and Records."

(iii) The reporting agency's accounting categories (chart of accounts) must be correctly related, using a clear audit trail, to the accounting categories prescribed in the Uniform System of Accounts and Records.

(2) General Structure of Uniform System of Accounts and Records

In the Section 15 Uniform System of Accounts and Records, operating expenses incurred by the transit system are classified by transit mode. The FTA developed expense classifications in two dimensions for uniformity and to enhance the usefulness of the data collected under section 15. The classifications are typical of those of most transit accounting systems. The two dimensions are:

(i) The type of expenditure (expense object class); and

(ii) The function or activity performed.

Operating expenses can be identified either in function or object class categories, or cross-classified, allowing identification using both categories. The Uniform System also categorizes expenditures by four basic functions submitted by all reporting agencies. A limited number of additional details are optional. All reporting agencies are required to use a single set of object class categories.

The Uniform System has a single set of revenue object classes to be used by all reporting agencies, and provides a limited number of additional details that are optional.

The Uniform System provides a classification for sources and uses of capital to be submitted by all reporting agencies. These classifications replace capital information previously required on the balance sheet and capital subsidiary schedule.

The Uniform System of Accounts and Records also includes collecting and recording of certain operating data elements.

Details and definitions of the expense object classes, functions, revenue object classes, sources and uses of capital, and operating data elements are contained in the current edition of the "Reporting Manual," which is updated annually, and the USOA reference documents.

F. The Reporting System

(1) The Section 15 Reporting System consists of forms and procedures for transmitting data from transit agencies to the FTA. All beneficiaries of Federal financial assistance must submit the required forms and information in order to allow the FTA to: (1) Store and generate information on the Nation's mass transportation systems; and (2) calculate apportionment allocations for the section 9 formula grant program (for urbanized areas of 200,000 or more inhabitants). Agencies submitting Section 15 reports may only submit data for transit services which they directly operate and purchase under contract from public agencies and/or private carriers.

Separate and complete Section 15 reports must be submitted by or for each purchased transportation service provider that operates 100 or more revenue vehicles for the purchased service during the maximum service period. The reporting requirements include the following major segments, which are based on information assembled through the Uniform System of Accounts and Records:

1. Capital report.
2. Revenue report.
3. Expense report.
4. Nonfinancial operating data reports.
5. Miscellaneous auxiliary questionnaires and subsidiary schedules.
6. Data declarations.

(2) The Section 15 Reporting System includes two data declarations.

(a) The Chief Executive Officer (CEO) Certification.

The CEO of each reporting agency is required to submit a certification with each annual Section 15 report. The certification must attest:

- To the accuracy of all data contained in the Section 15 report;
- That all data submitted in the Section 15 report are in accord with Section 15 definitions;
- If applicable, that the reporting agency's accounting system used to derive all data submitted in the Section 15 report is the section 15 Uniform System of Accounts and Records and that a Section 15 report using this system was certified by an independent auditor in a previous report year;
- If applicable, the fact that the reporting agency's internal accounting system is other than the Uniform System of Accounts and Records, and that its: (i) accounting system uses the accrual basis of accounting, (ii) accounting system is directly translated, using a clear audit trail, to the accounting treatment and categories specified by the section 15 Uniform System of Accounts and Records, and (iii) accounting system and direct translation to the Uniform System of Accounts and Records are the same as those certified by an independent auditor in a previous reporting year; and
- That a 100% count of passenger mile data was conducted or that the sampling method used to collect passenger mile data for each mode/type of service meets the FTA requirements.

(b) Auditor Statement on Section 15 Financial Data Reporting Forms and Section 9 Data.

Reporting agencies must submit with their Section 15 report a statement signed by an independent public accountant or other responsible independent entity such as a state audit agency. This statement must express an opinion on whether the financial data reporting forms in the Section 15 report present fairly, in all material respects, the information required to be set forth therein in accordance with the Uniform System of Accounts and Records. The statement shall also indicate whether any of the reporting forms or data elements do not conform to the section 15 requirements, and describe the discrepancies. The statement must consider both required and optional data entries.

Each agency is required to file an Auditor Statement unless it received a written waiver from the FTA. The criteria in either Condition I or Condition II for granting a financial data waiver are:

Condition I. The reporting agency (1) has adopted the Industry Uniform System of Accounts and Records (USOA) and (2) has previously submitted a Section 15 report that was compiled using the USOA and was reviewed by an independent auditor; or

Condition II. The reporting agency (1) uses an internal accounting system other than the accounting system prescribed by the USOA, (2) uses the accrual basis of accounting, (3) directly translates the system and accounting categories, using a clear audit trail, to the accounting treatment and categories specified by the USOA, and (4) has previously submitted a Section 15 report that was compiled using the same internal accounting system and translation to the USOA and was reviewed by an independent auditor.

For agencies that have received a waiver, the CEO annual Certification must verify that the financial data meet one of the above two conditions.

Additionally, all reporting agencies that are in or serve urbanized areas with populations of 200,000 or more and whose report covers 100 or more vehicles in annual maximum service across all modes and types of service must have an independent auditor review all section 15 data used in the section 9 formula allocation. The statement should discuss, by mode and type of service: directional route miles, vehicle revenue miles, passenger miles, and operating cost, and include both directly operated and purchased service. The independent, certified public accountant shall perform the verification in accordance with the "Statements on Standards for Attestation Engagements" issued by the American Institute of Certified Public Accountants. The specific procedures to be reviewed are described in the most recent Section 15 Reporting Manual.

Issued on: January 12, 1993.

Roland J. Mroes,

Deputy Administrator.

[FR Doc. 93–1061 Filed 1–14–93; 8:45 am]

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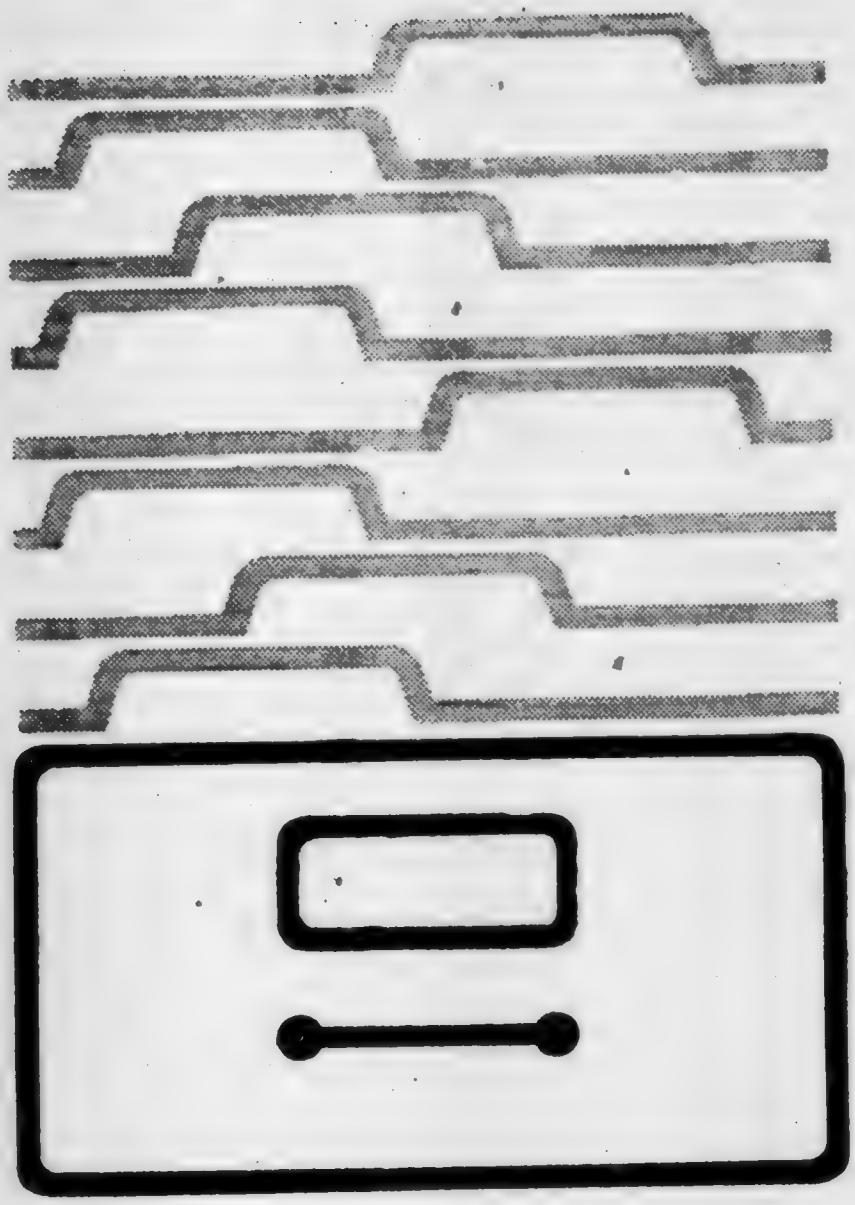

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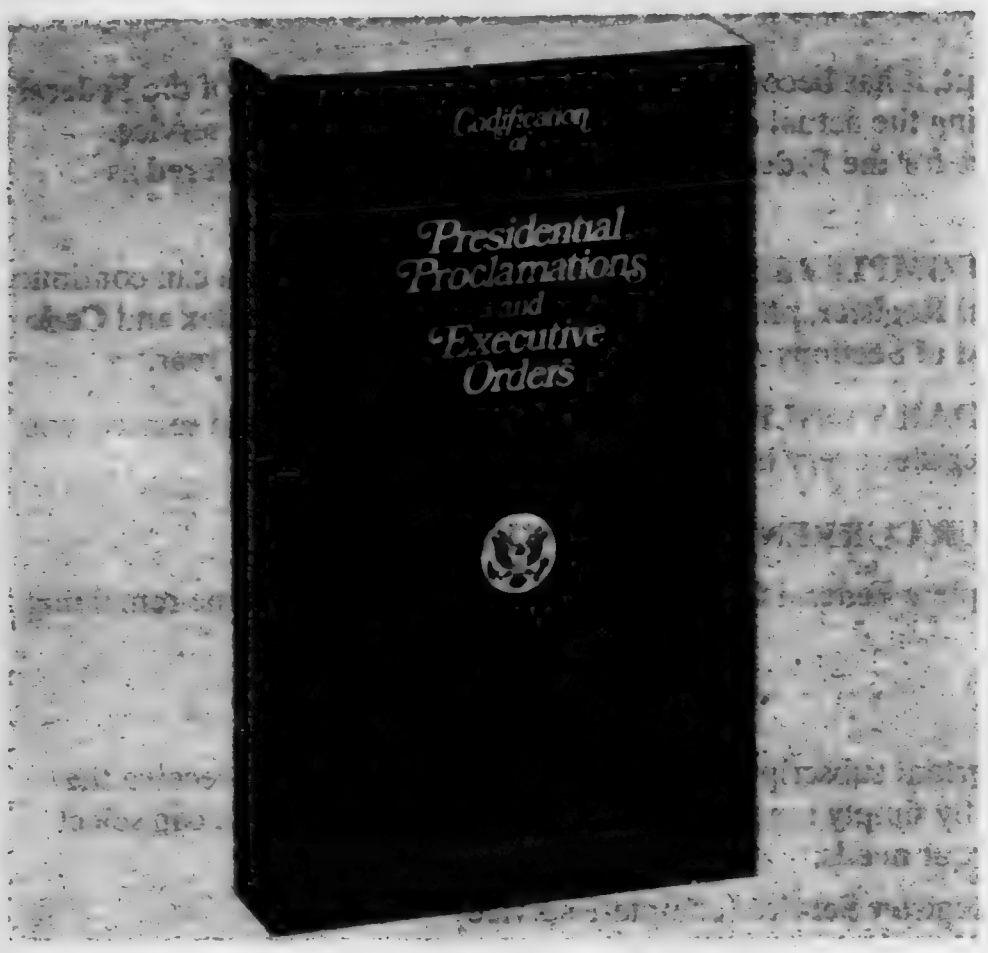

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